

CARDIAC RHYTHM HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2015

Second Edition – Issue 73

Medtronic

CRHF Product Performance Report

2015

Second Edition
Issue 72

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Cutoff date for this edition is 31 July 2015 for Lead Study data and 2 November 2015 for all other data, unless otherwise stated.

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
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Medtronic Cardiac Rhythm Heart Failure
Medtronic, Inc.

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Outside the United States:

Your Medtronic representative or international technical center at the number above.

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EnTrust MRI	Sensing Assurance	
GEM®	Sigma	
InSync®		
InSync Marquis™		
InSync II Marquis™		
InSync III Marquis™		

Introduction

For 32 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.

This Product Performance Report (PPR) presents device survival estimates, advisory summaries, performance notes, and other information pertinent to assessing the performance of Medtronic implantable pulse generators (IPGs), implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implantable pacing and defibrillation leads.

This Product Performance Report has been prepared in accordance with International Standard ISO 5841- 2:2000(E).

The survival estimates provided in this report are considered to be representative of worldwide performance.

Survival Estimates

Medtronic, like other companies, monitors CRT, ICD, and IPG device performance using returned product analysis. We also monitor CRT, ICD, and IPG device performance using an active multicenter clinical study.

Returned product analysis is a passive approach to assessing product performance. This approach provides a suitable measure of product performance only when a significant number of explanted products are returned to the manufacturer. Returned product analysis provides a measure of hardware performance, but not necessarily the total clinical performance (e.g., the incidence of complications such as infection, erosion, muscle stimulation, etc. are not estimated).

The survival estimates provided in this report for CRT, ICD, and IPG devices are based on returned product analysis. This approach is suitable because a significant number of explanted generators are returned for analysis.

Lead performance is monitored differently. In contrast to CRT, ICD, and IPG devices, a very small percentage of leads are returned to the manufacturer due to the difficulty of explanting them. For leads, an active clinical study provides more accurate survival estimates compared to estimates based solely on returned product analysis.

Survival estimates for leads are based on clinical observations recorded via Medtronic'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 PAN registry.

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.

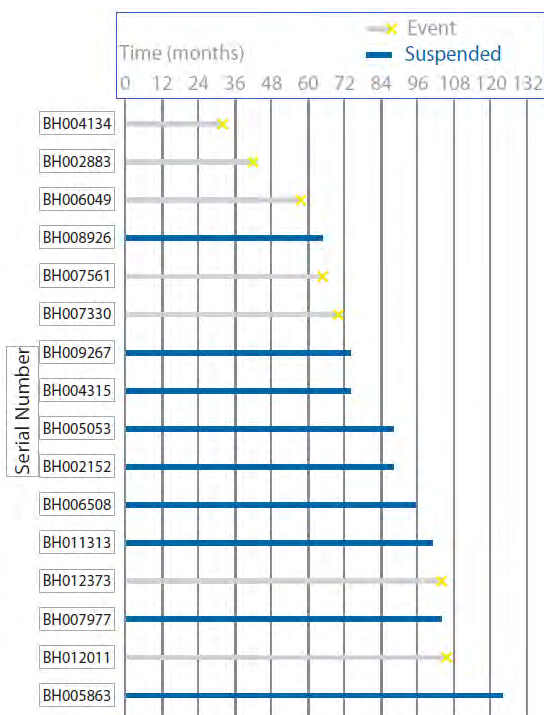


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

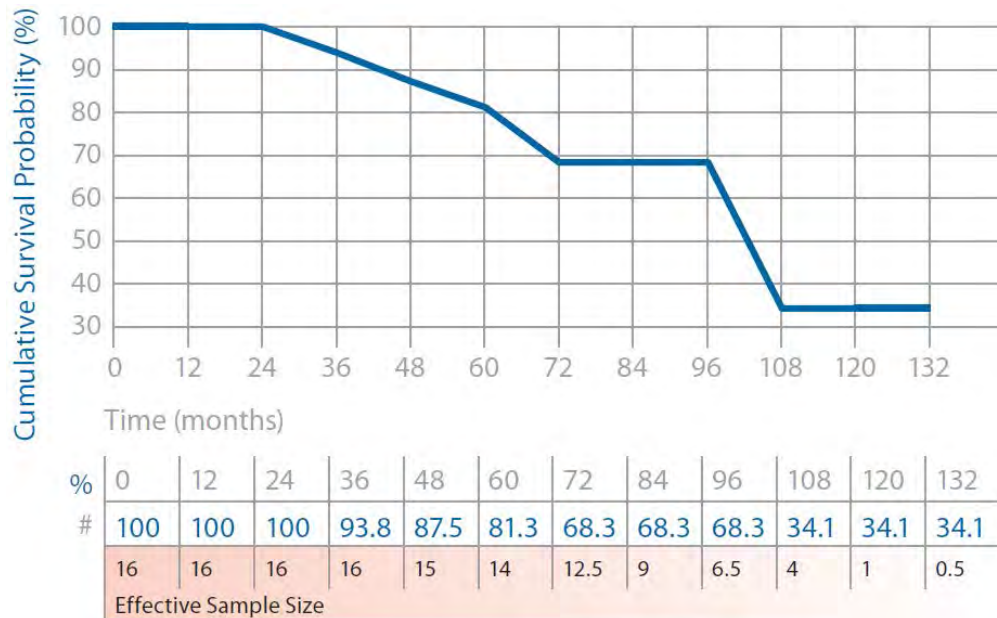
Definitions:

A	B	C	D	E	F	G
Number Entered	Number Suspended	Number of Events	Effective Sample Size	Proportion with Event	Interval Survival Probability	Cumulative Survival Probability
Number of devices active at the start of the interval	Number of devices removed from service for reasons other than an event	Number of units removed from service due to an event	Number of units with full opportunity to experience a qualifying event in the interval. Computed by subtracting one half the Number Suspended from the Number Entered.	Proportion of devices that had an event in the interval. Computed by dividing the Number of Events by the Effective Sample Size.	The probability of surviving to the end of the interval, assuming the device was working at the beginning of the interval. Computed as 1 minus the Proportion With Event.	The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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



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 method¹ 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.

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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.

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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.

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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.

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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 8-Apr-05

CE Market Approval Date

Registered US Implants 31,168

Estimated Active US Implants 1,281

Normal Battery Depletions (US) 9,923

NBG Code VVE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 179

Therapy Not Compromised Malfunctions 169

Battery Malfunction 0

Electrical Component 19

Electrical Interconnect 0

Other Malfunction 1

Poss Early Battery Depltn 147

Software Malfunction 2

Therapy Compromised Malfunctions 10

Battery Malfunction 0

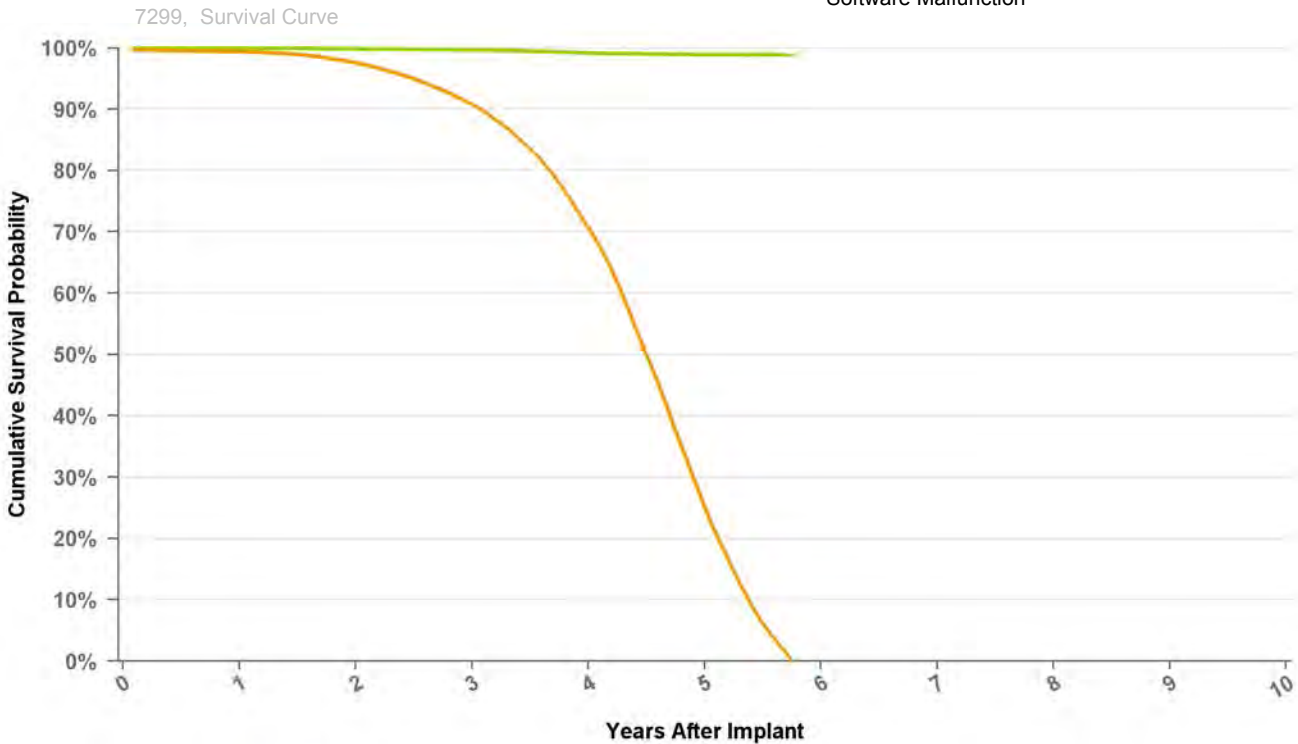
Electrical Component 10

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.7%	99.2%	98.9%	98.8%
Including NBD	99.4%	97.6%	90.8%	70.8%	25.2%	0.2%
Effective Sample Size	26216	22991	18607	12345	3885	145

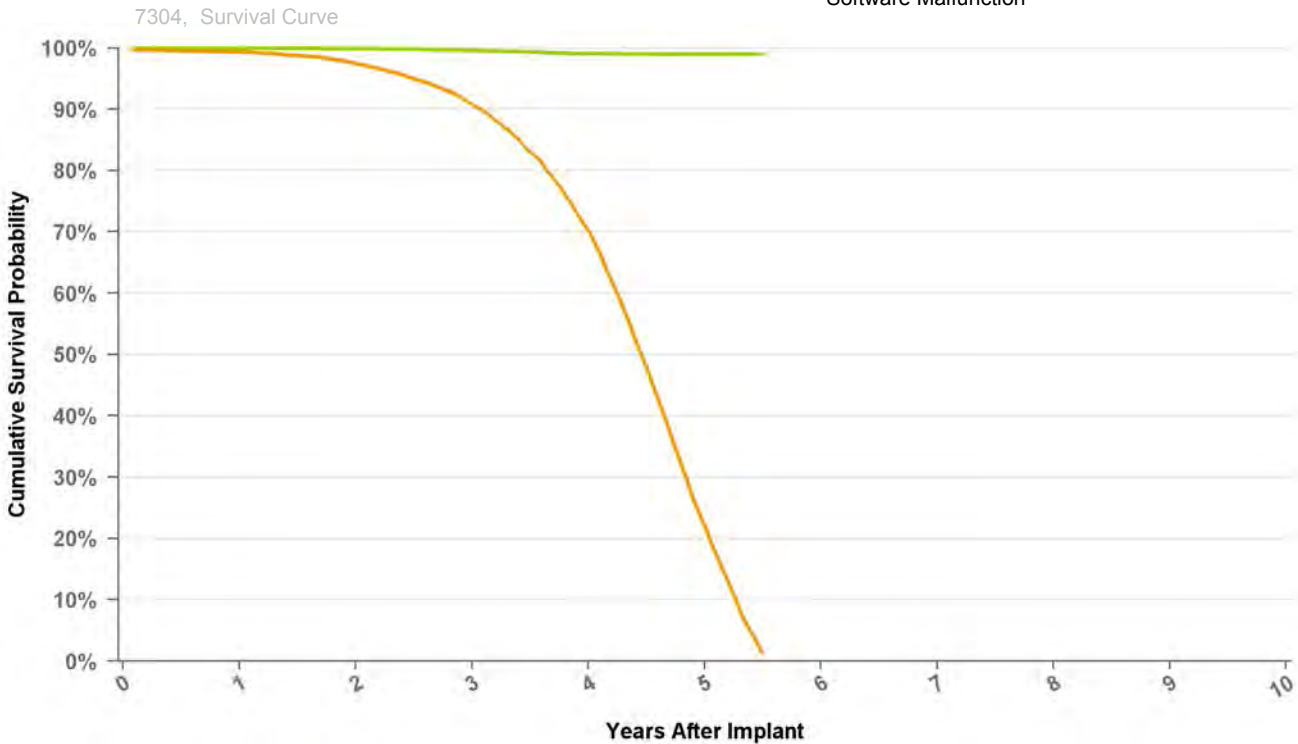
Cardiac Resynchronization Therapy

7304

InSync Maximo

US Market Release Date	8-Apr-05
CE Market Approval Date	14-Jan-05
Registered US Implants	18,962
Estimated Active US Implants	920
Normal Battery Depletions (US)	5,579
NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	113
Therapy Not Compromised Malfunctions	108
Battery Malfunction	1
Electrical Component	16
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	90
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

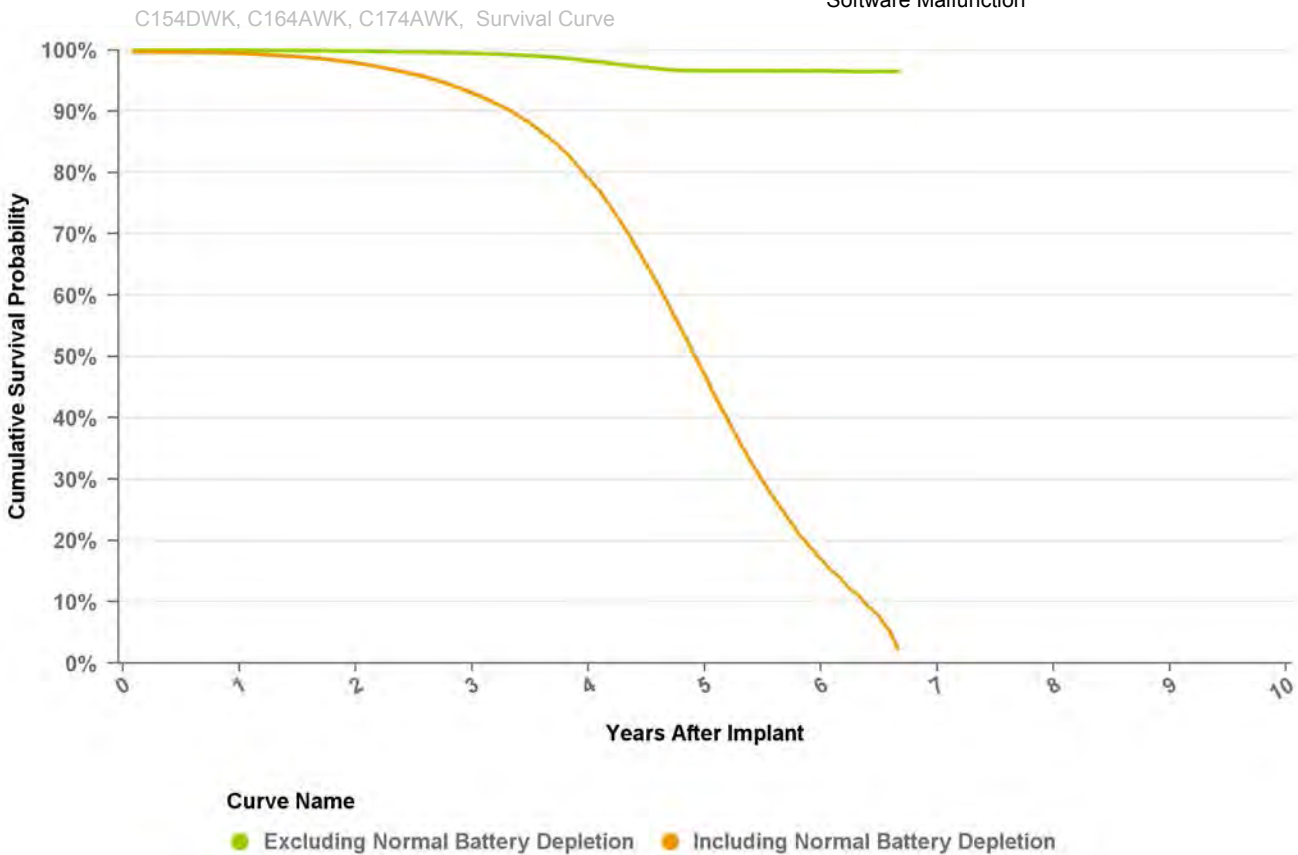
Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.9%	99.6%	99.1%	99.0%	99.0%
Including NBD	99.3%	97.4%	90.7%	70.3%	22.1%	1.3%
Effective Sample Size	15966	13937	11258	7400	1902	186

Cardiac Resynchronization Therapy

C154DWK Concerto CRT-D

US Market Release Date	12-May-06
CE Market Approval Date	
Registered US Implants	81,226
Estimated Active US Implants	8,510
Normal Battery Depletions (US)	24,001
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,426
Therapy Not Compromised Malfunctions	1,378
Battery Malfunction	0
Electrical Component	720
Electrical Interconnect	2
Other Malfunction	3
Poss Early Battery Depltn	649
Software Malfunction	4
Therapy Compromised Malfunctions	48
Battery Malfunction	0
Electrical Component	46
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.8%	99.5%	98.2%	96.6%	96.6%	96.5%
Including NBD	99.4%	97.9%	92.9%	79.1%	47.1%	17.0%	2.3%
Effective Sample Size	68101	59870	50658	38642	19933	5842	275

Cardiac Resynchronization Therapy

C164AWK Concerto CRT-D

US Market Release Date 17-Apr-07

CE Market Approval Date

Registered US Implants 178

Estimated Active US Implants 4

Normal Battery Depletions (US) 72

NBG Code DDE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 4

Therapy Not Compromised Malfunctions 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

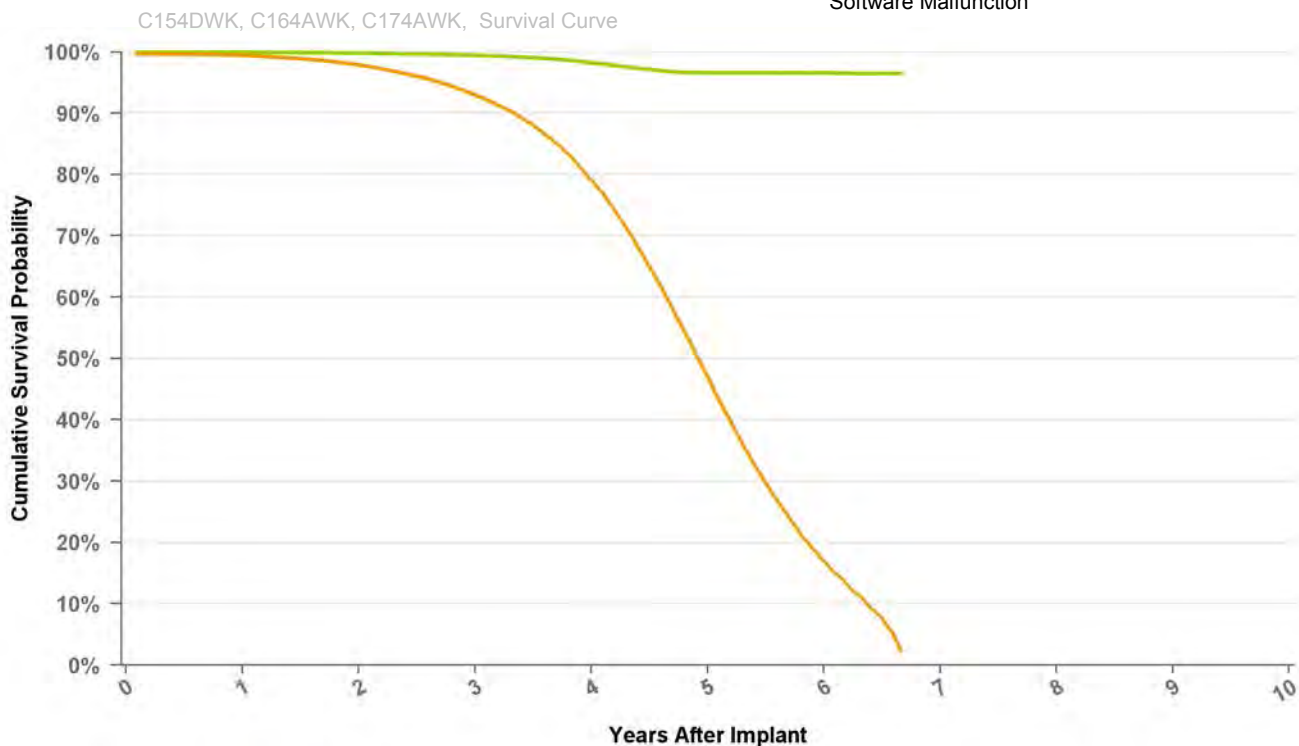
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.8%	99.5%	98.2%	96.6%	96.6%	96.5%
Including NBD	99.4%	97.9%	92.9%	79.1%	47.1%	17.0%	2.3%
Effective Sample Size	68101	59870	50658	38642	19933	5842	275

Cardiac Resynchronization Therapy

C174AWK Concerto CRT-D

US Market Release Date

CE Market Approval Date 7-Mar-06

Registered US Implants 6

Estimated Active US Implants 3

Normal Battery Depletions (US) 1

NBG Code DDE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

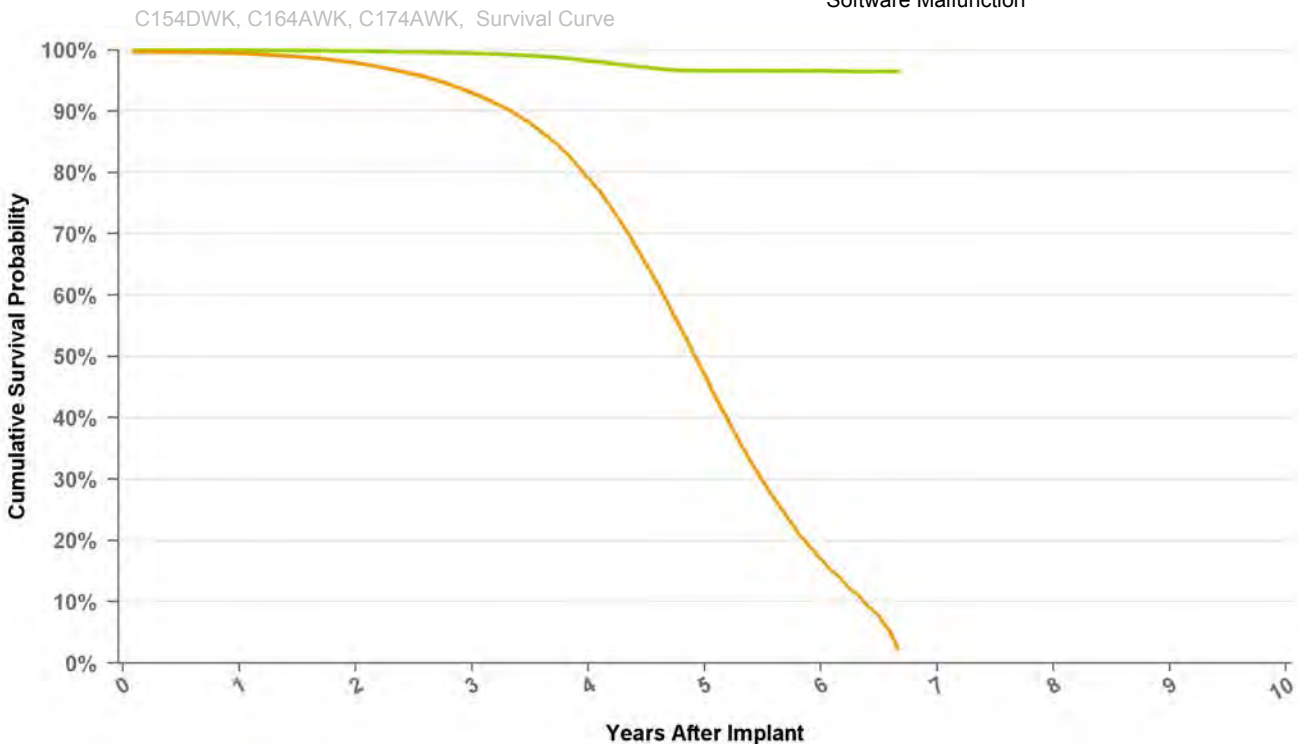
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

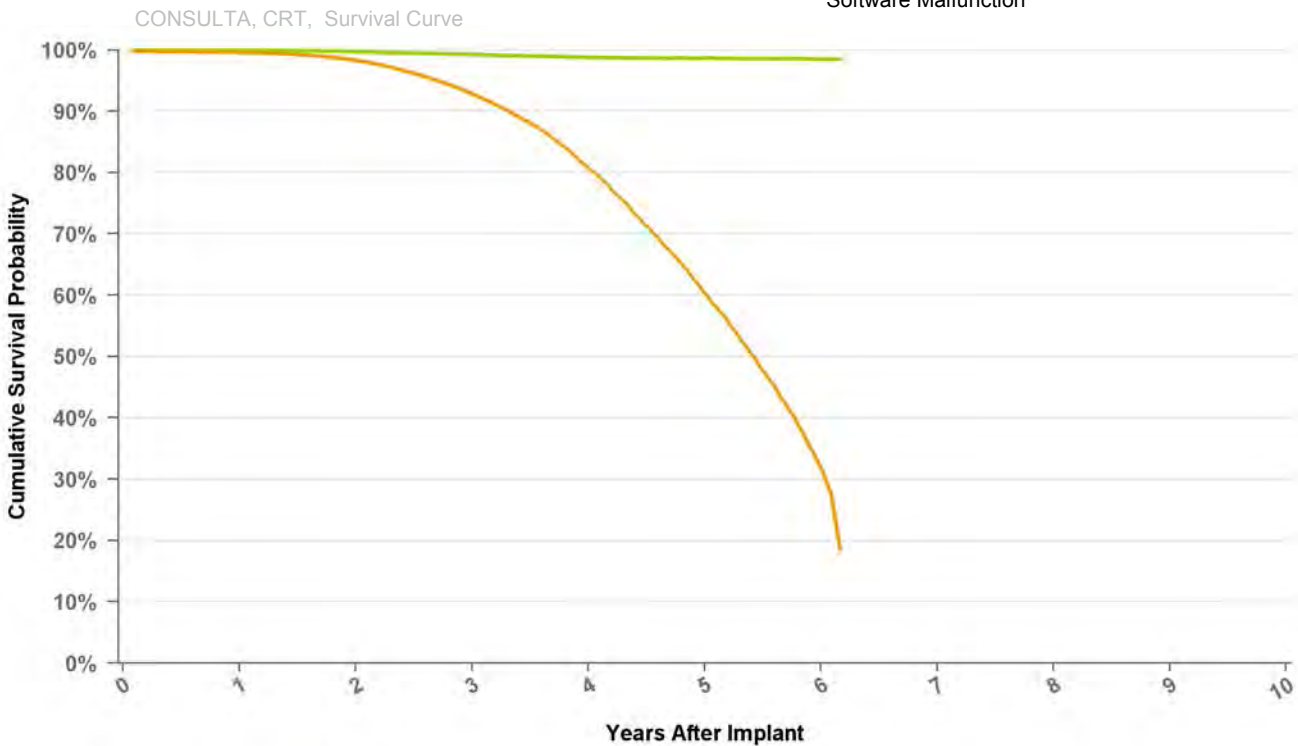
Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.8%	99.5%	98.2%	96.6%	96.6%	96.5%
Including NBD	99.4%	97.9%	92.9%	79.1%	47.1%	17.0%	2.3%
Effective Sample Size	68101	59870	50658	38642	19933	5842	275

Cardiac Resynchronization Therapy

D204TRM Consulta CRT-D

US Market Release Date	9-Jan-12
CE Market Approval Date	
Registered US Implants	2,081
Estimated Active US Implants	1,716
Normal Battery Depletions (US)	24
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

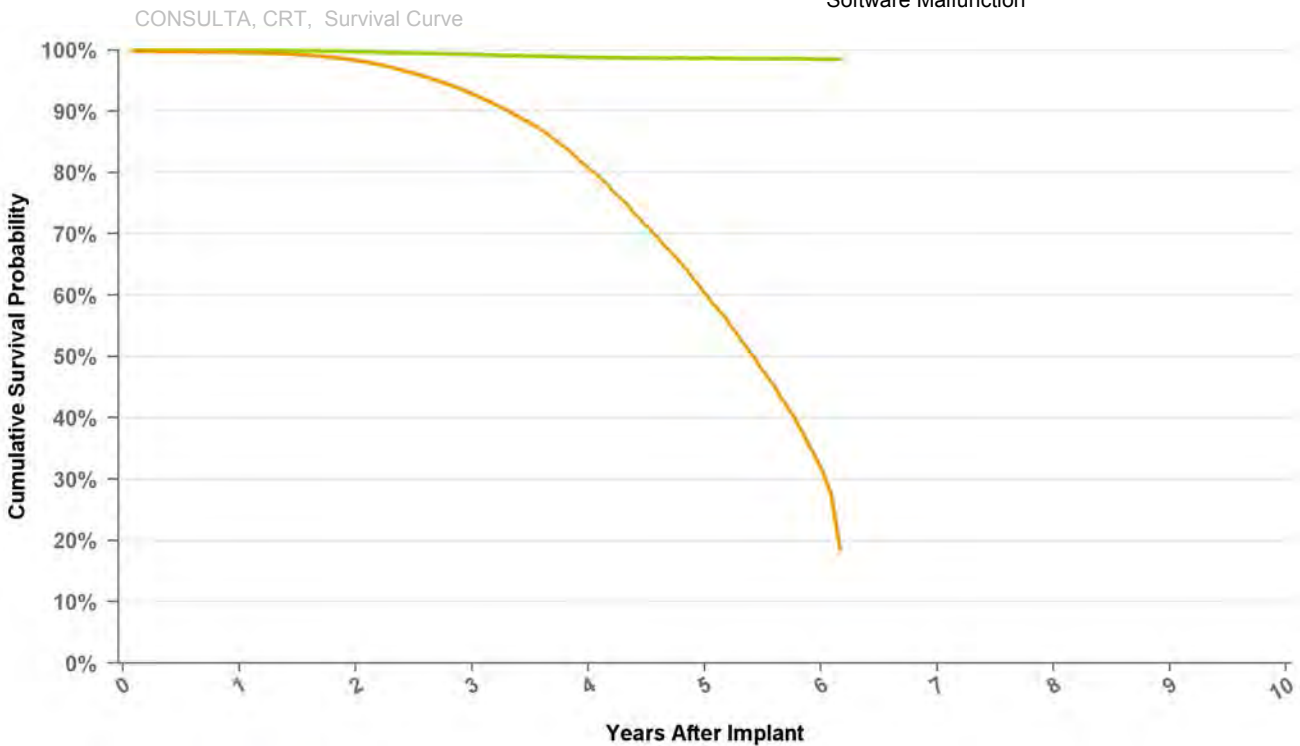
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.5%
Including NBD	99.6%	98.3%	92.8%	80.7%	60.4%	31.9%	18.6%
Effective Sample Size	57528	51958	42528	30282	12359	883	113

Cardiac Resynchronization Therapy

D214TRM Consulta CRT-D

US Market Release Date	
CE Market Approval Date	22-Jul-10
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 Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

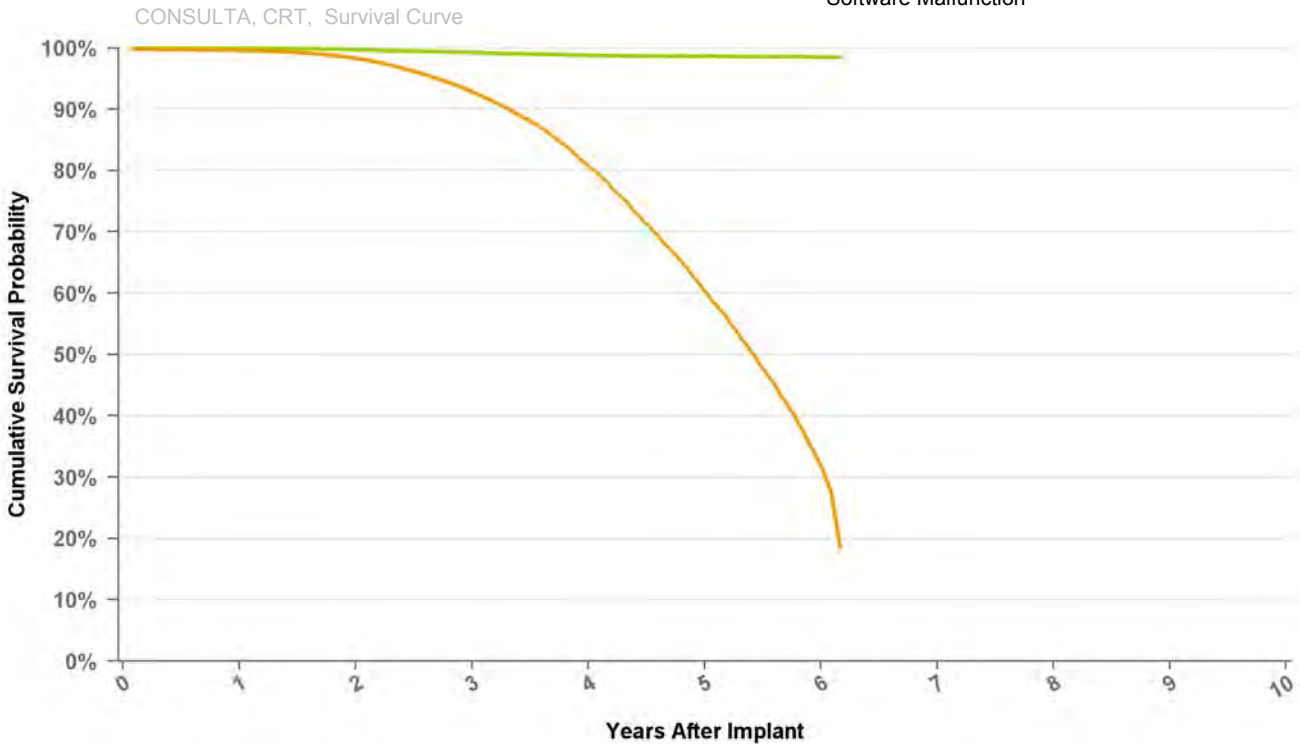
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.5%
Including NBD	99.6%	98.3%	92.8%	80.7%	60.4%	31.9%	18.6%
Effective Sample Size	57528	51958	42528	30282	12359	883	113

Cardiac Resynchronization Therapy

D224TRK Consulta CRT-D

US Market Release Date	15-Sep-08
CE Market Approval Date	
Registered US Implants	65,775
Estimated Active US Implants	24,521
Normal Battery Depletions (US)	11,235
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	590
Therapy Not Compromised Malfunctions	566
Battery Malfunction	2
Electrical Component	60
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	496
Software Malfunction	6
Therapy Compromised Malfunctions	24
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

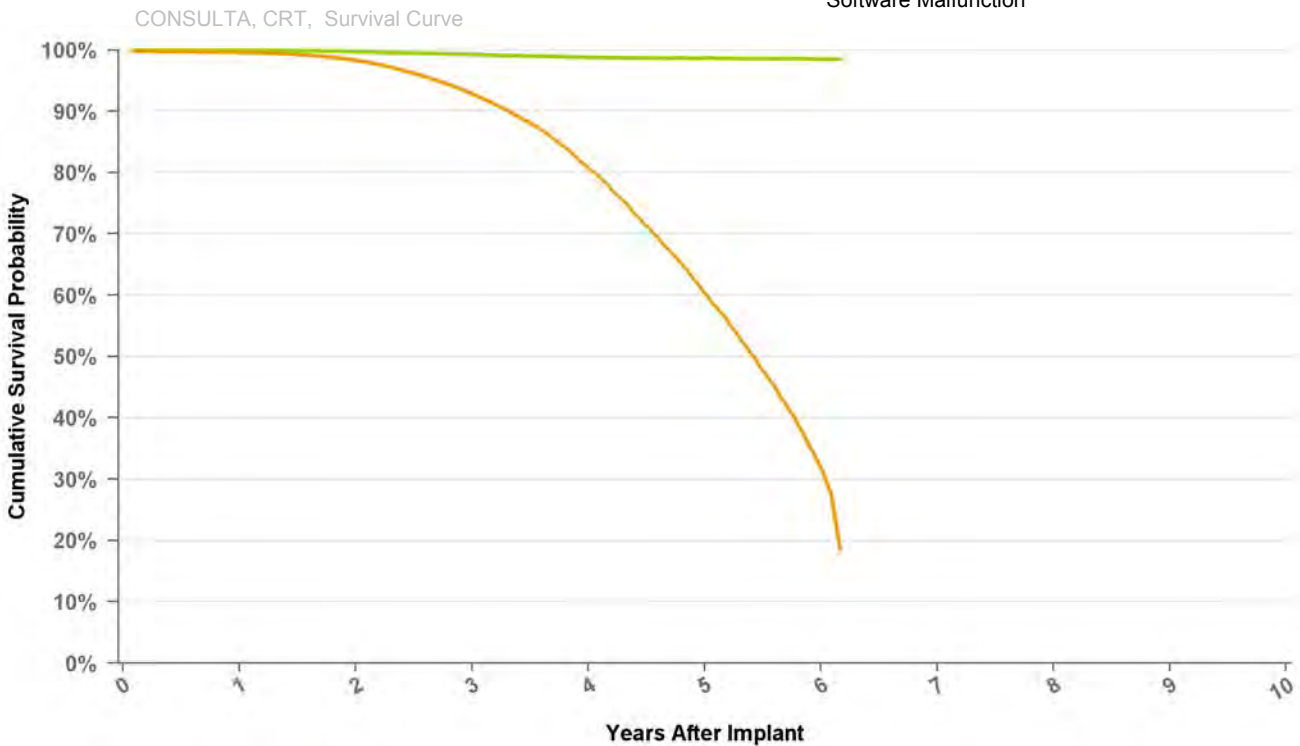
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.5%
Including NBD	99.6%	98.3%	92.8%	80.7%	60.4%	31.9%	18.6%
Effective Sample Size	57528	51958	42528	30282	12359	883	113

Cardiac Resynchronization Therapy

D234TRK Consulta CRT-D

US Market Release Date	
CE Market Approval Date	14-Mar-08
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 Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

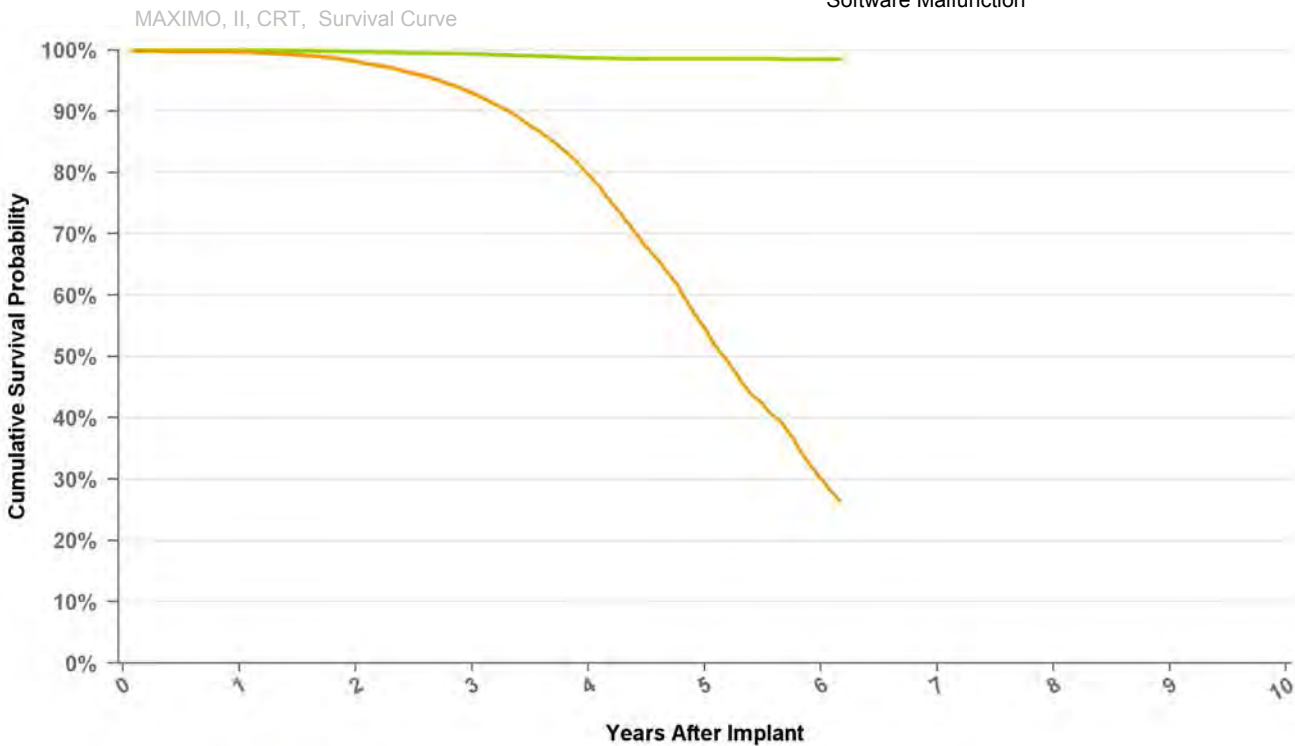
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.5%
Including NBD	99.6%	98.3%	92.8%	80.7%	60.4%	31.9%	18.6%
Effective Sample Size	57528	51958	42528	30282	12359	883	113

Cardiac Resynchronization Therapy

D264TRM Maximo II CRT-D

US Market Release Date	9-Jan-12
CE Market Approval Date	22-Jul-10
Registered US Implants	15
Estimated Active US Implants	12
Normal Battery Depletions (US)	0
NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

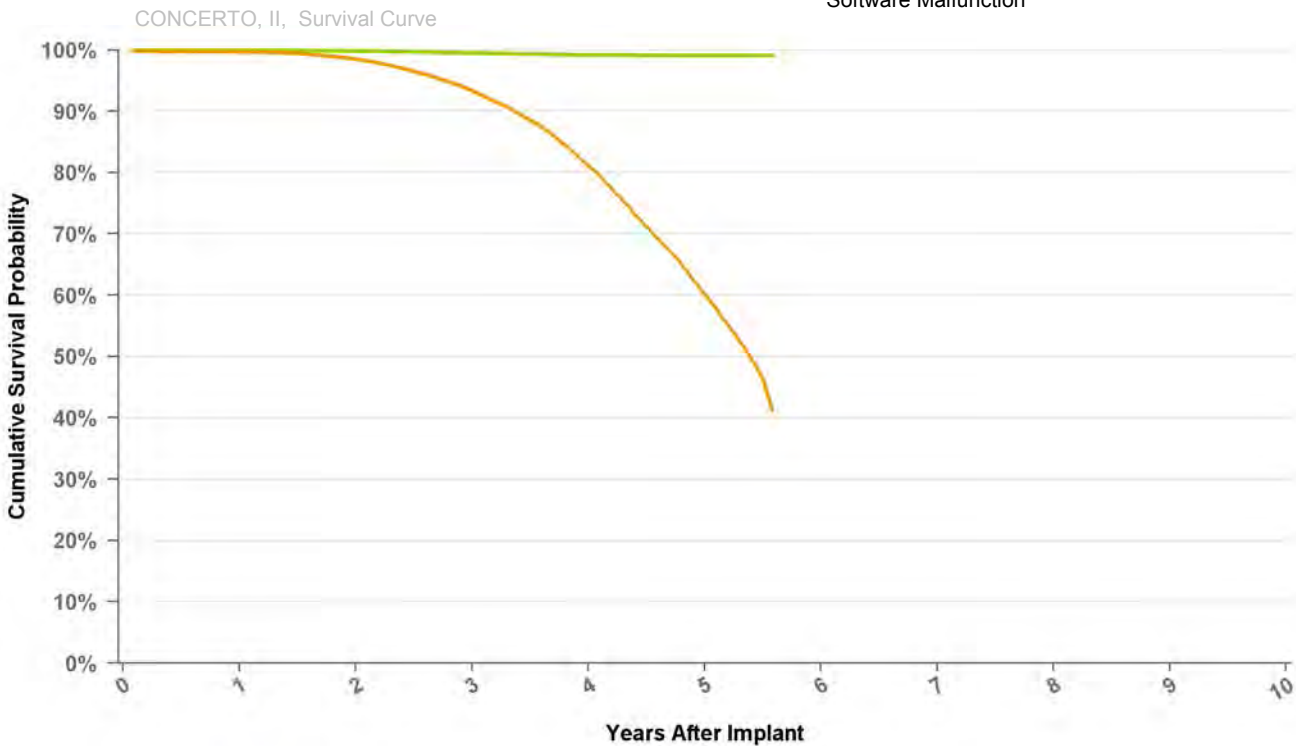
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.6%	98.5%	98.5%
Including NBD	99.7%	98.2%	92.9%	79.8%	54.7%	30.2%	26.4%
Effective Sample Size	12761	11425	9375	6445	2578	295	115

Cardiac Resynchronization Therapy

D274TRK Concerto II CRT-D

US Market Release Date	15-Aug-09
CE Market Approval Date	
Registered US Implants	30,164
Estimated Active US Implants	11,427
Normal Battery Depletions (US)	4,847
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	180
Therapy Not Compromised Malfunctions	173
Battery Malfunction	1
Electrical Component	20
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	151
Software Malfunction	1
Therapy Compromised Malfunctions	7
Battery Malfunction	1
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

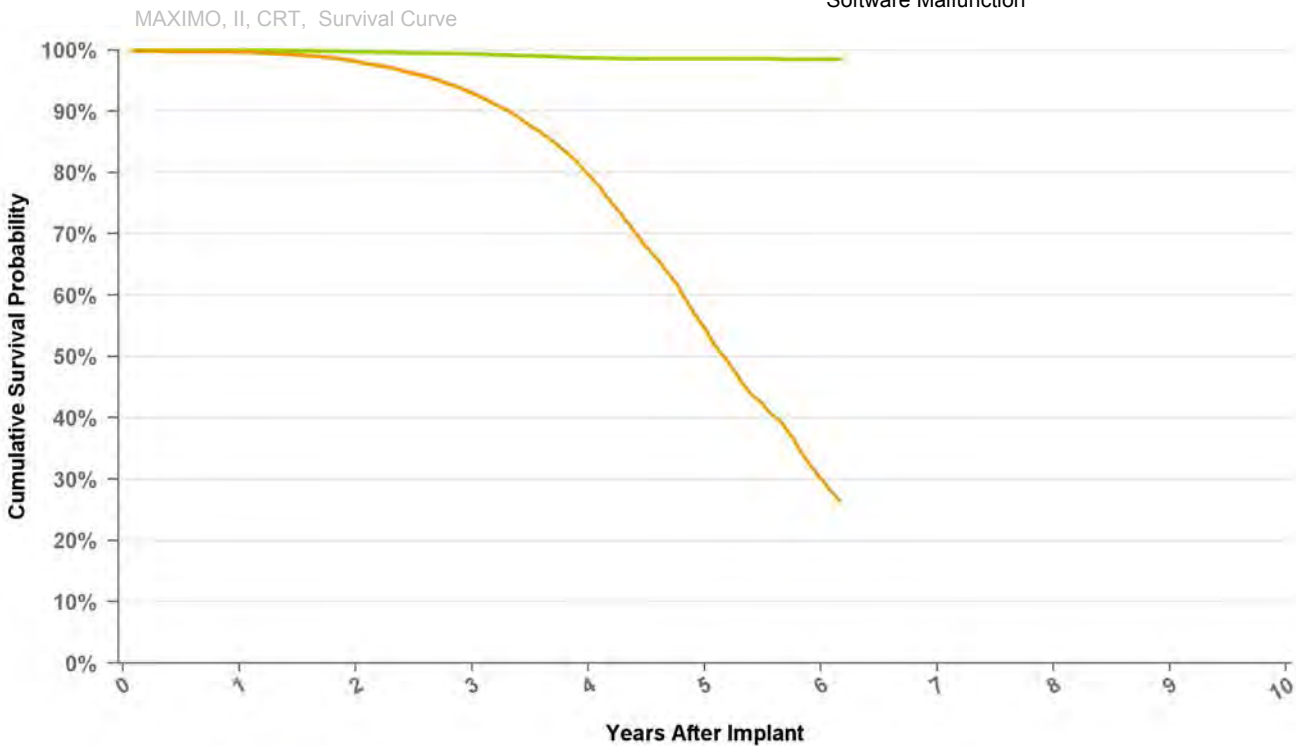
Years	1	2	3	4	5	at 67 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%
Including NBD	99.7%	98.5%	93.4%	81.1%	60.3%	41.2%
Effective Sample Size	25329	23157	20180	15117	4969	394

Cardiac Resynchronization Therapy

D284TRK Maximo II CRT-D

US Market Release Date	17-Sep-08
CE Market Approval Date	14-Mar-08
Registered US Implants	15,131
Estimated Active US Implants	5,520
Normal Battery Depletions (US)	2,772
NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	135
Therapy Not Compromised Malfunctions	130
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	124
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

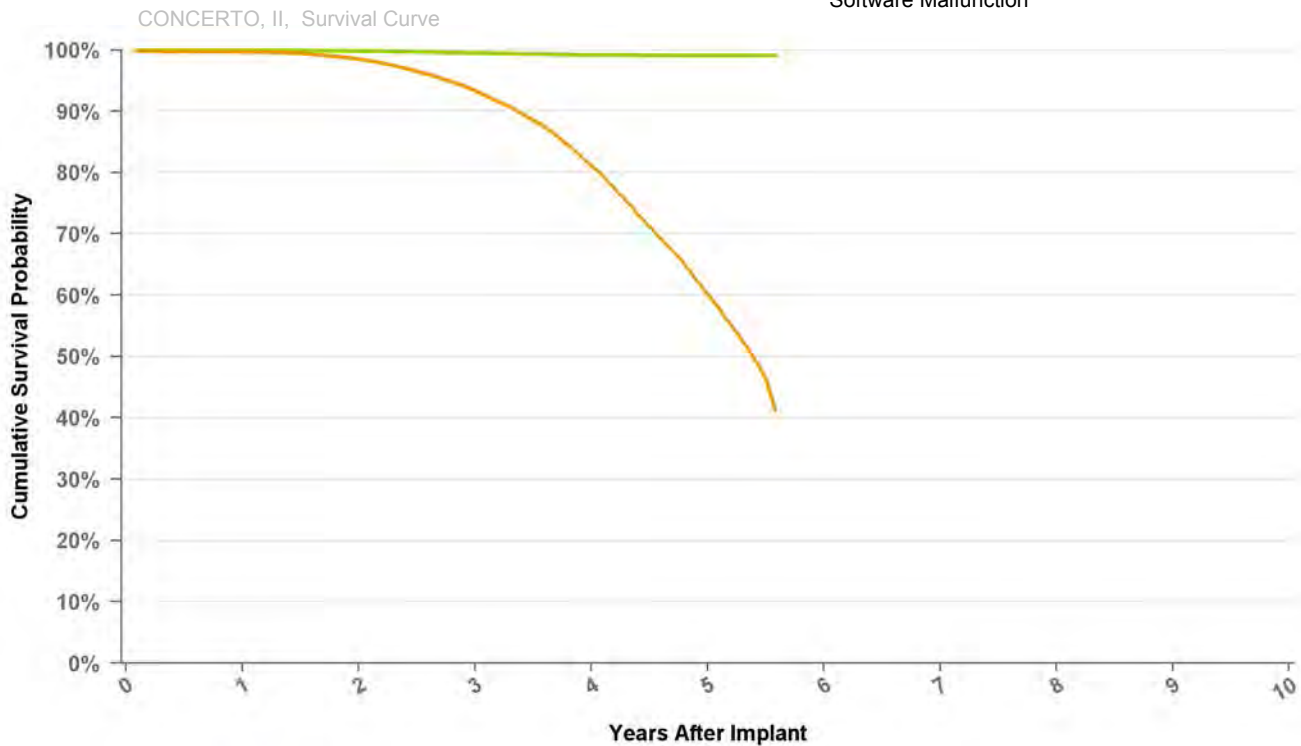
Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.6%	98.5%	98.5%
Including NBD	99.7%	98.2%	92.9%	79.8%	54.7%	30.2%	26.4%
Effective Sample Size	12761	11425	9375	6445	2578	295	115

Cardiac Resynchronization Therapy

D294TRK Concerto II CRT-D

US Market Release Date	
CE Market Approval Date	20-Aug-08
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 Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

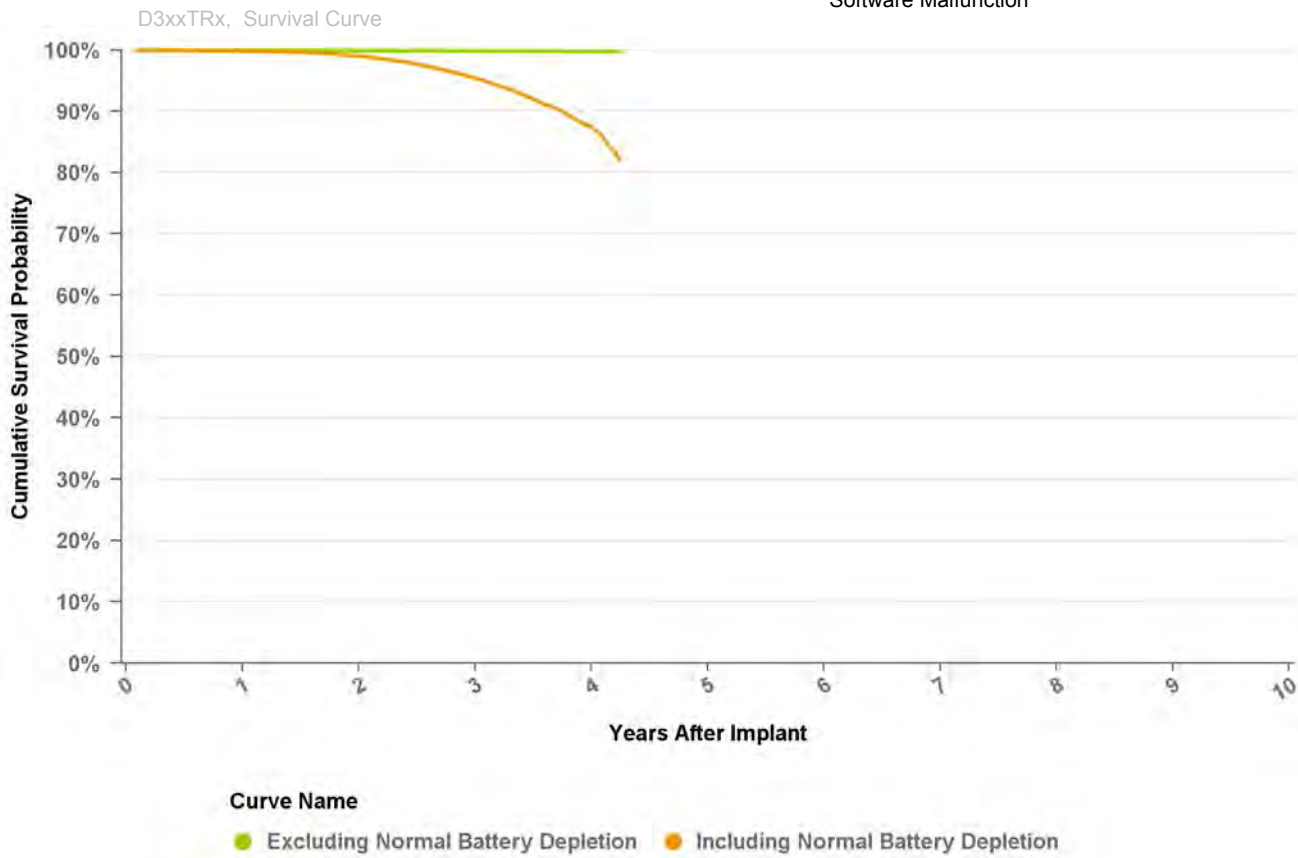
Years	1	2	3	4	5	at 67 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%
Including NBD	99.7%	98.5%	93.4%	81.1%	60.3%	41.2%
Effective Sample Size	25329	23157	20180	15117	4969	394

Cardiac Resynchronization Therapy

D314TRG Protecta XT CRT-D

US Market Release Date	25-Mar-11
CE Market Approval Date	
Registered US Implants	42,063
Estimated Active US Implants	31,101
Normal Battery Depletions (US)	1,698
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	64
Therapy Not Compromised Malfunctions	60
Battery Malfunction	0
Electrical Component	25
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	34
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



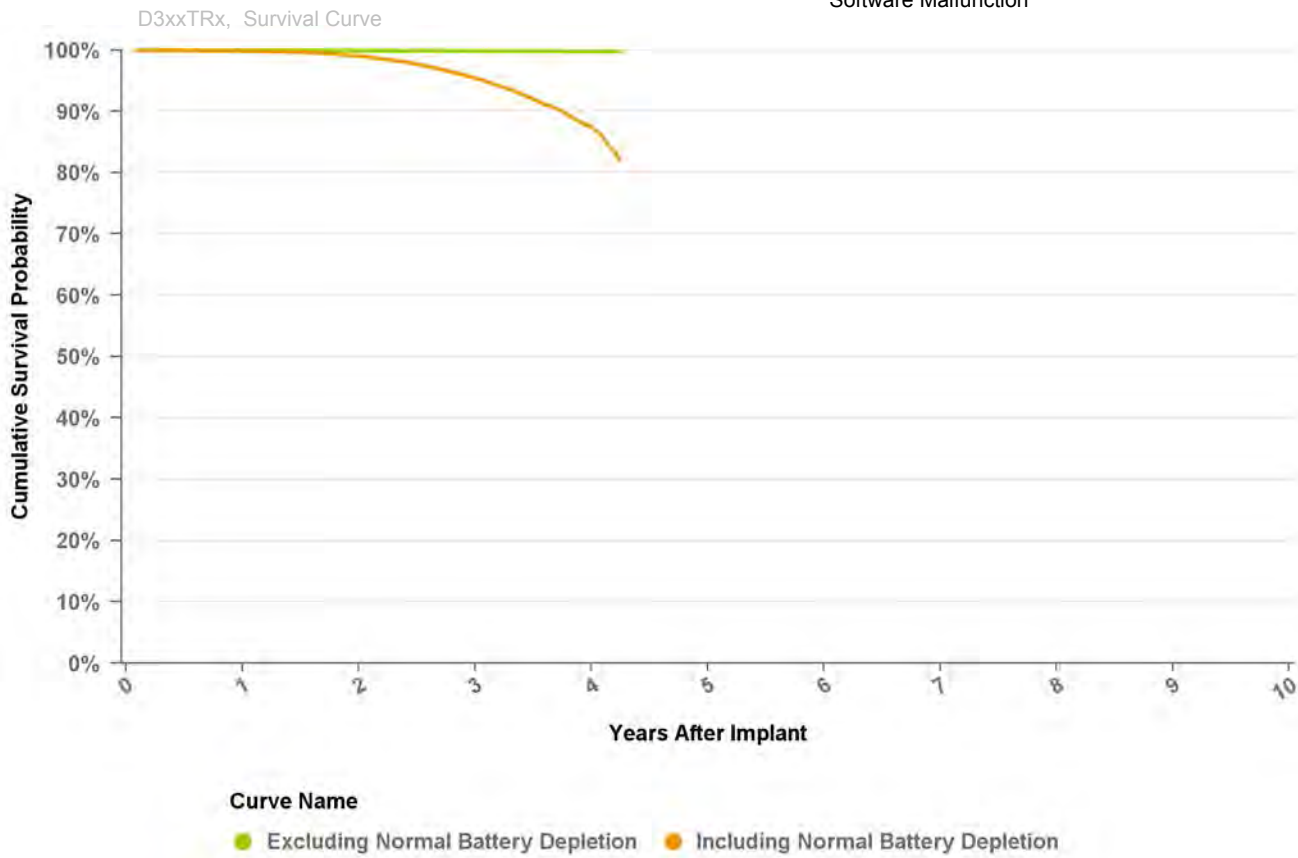
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D314TRM Protecta XT CRT-D

US Market Release Date	9-Nov-11
CE Market Approval Date	
Registered US Implants	12,227
Estimated Active US Implants	10,302
Normal Battery Depletions (US)	162
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

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



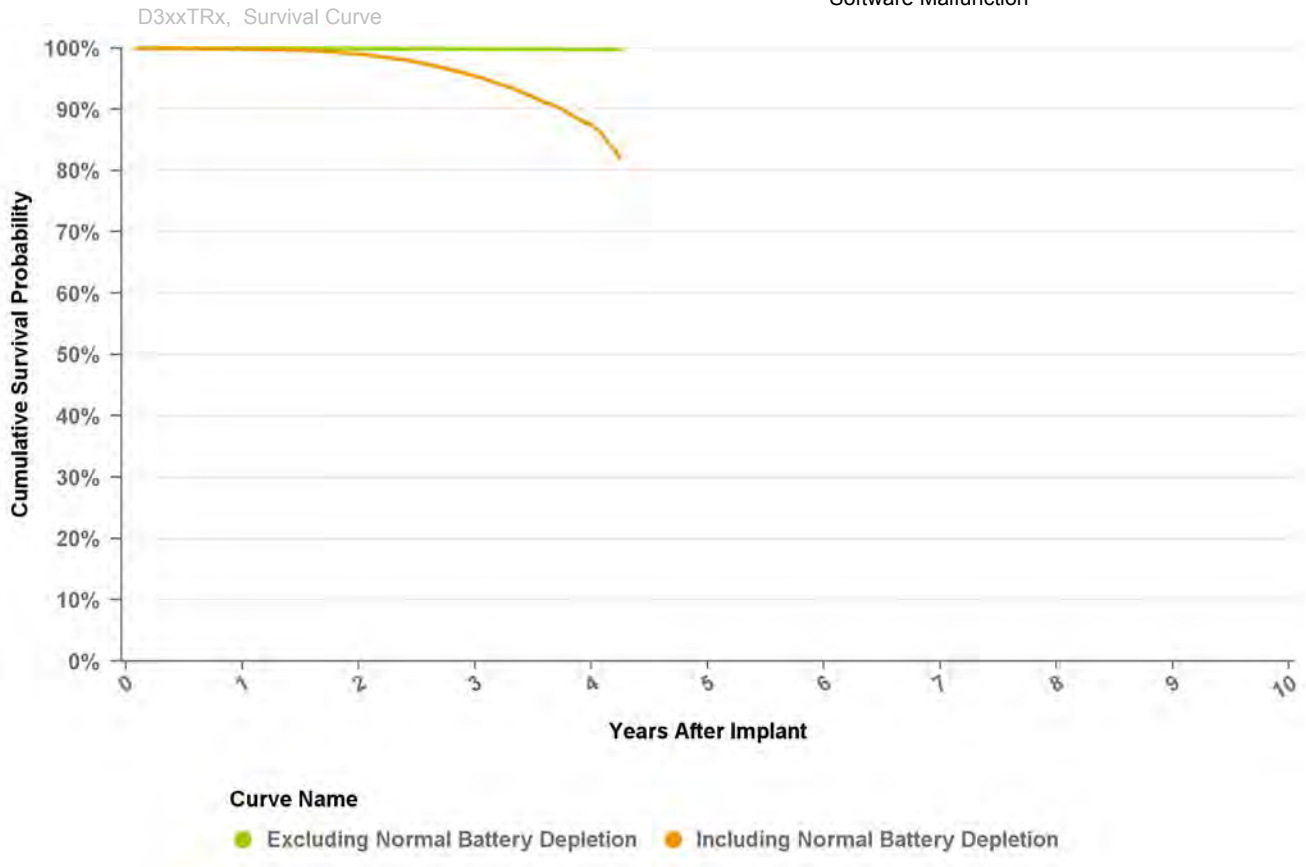
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D334TRG Protecta CRT-D

US Market Release Date	25-Mar-11
CE Market Approval Date	
Registered US Implants	8,041
Estimated Active US Implants	6,174
Normal Battery Depletions (US)	252
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



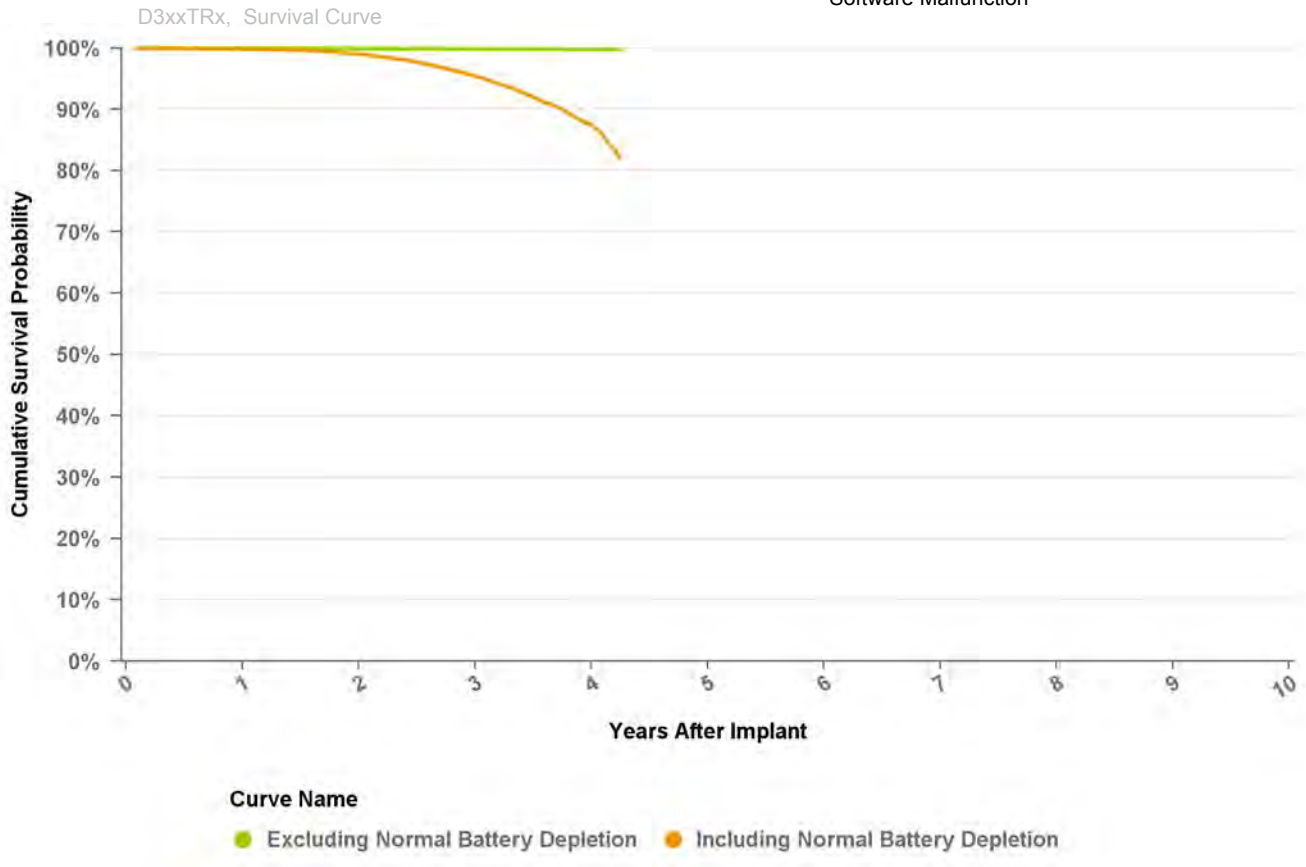
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D334TRM Protecta CRT-D

US Market Release Date	9-Nov-11
CE Market Approval Date	
Registered US Implants	1,763
Estimated Active US Implants	1,493
Normal Battery Depletions (US)	22
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
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	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D354TRG Protecta XT CRT-D

US Market Release Date

CE Market Approval Date 25-Mar-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

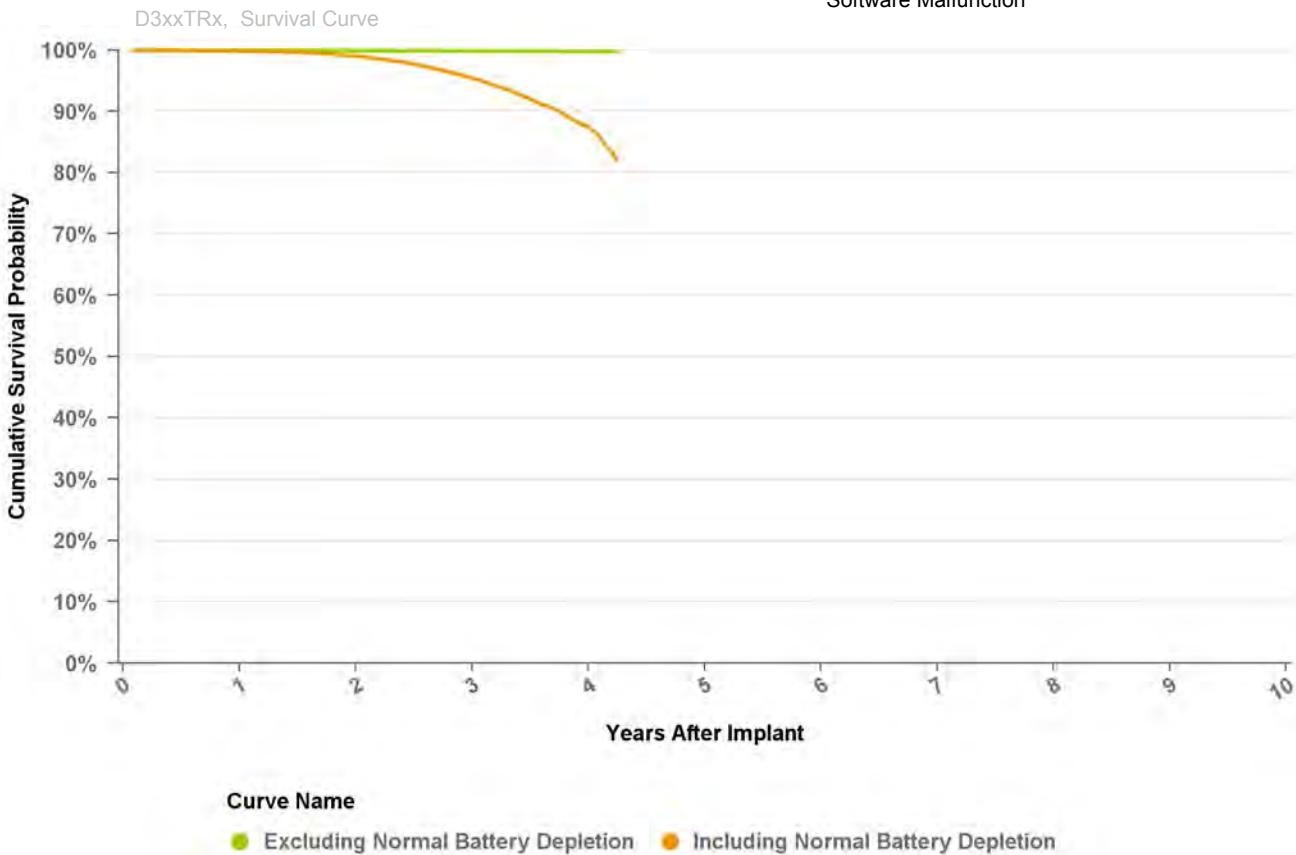
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D354TRM Protecta XT CRT-D

US Market Release Date

CE Market Approval Date 15-Jul-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

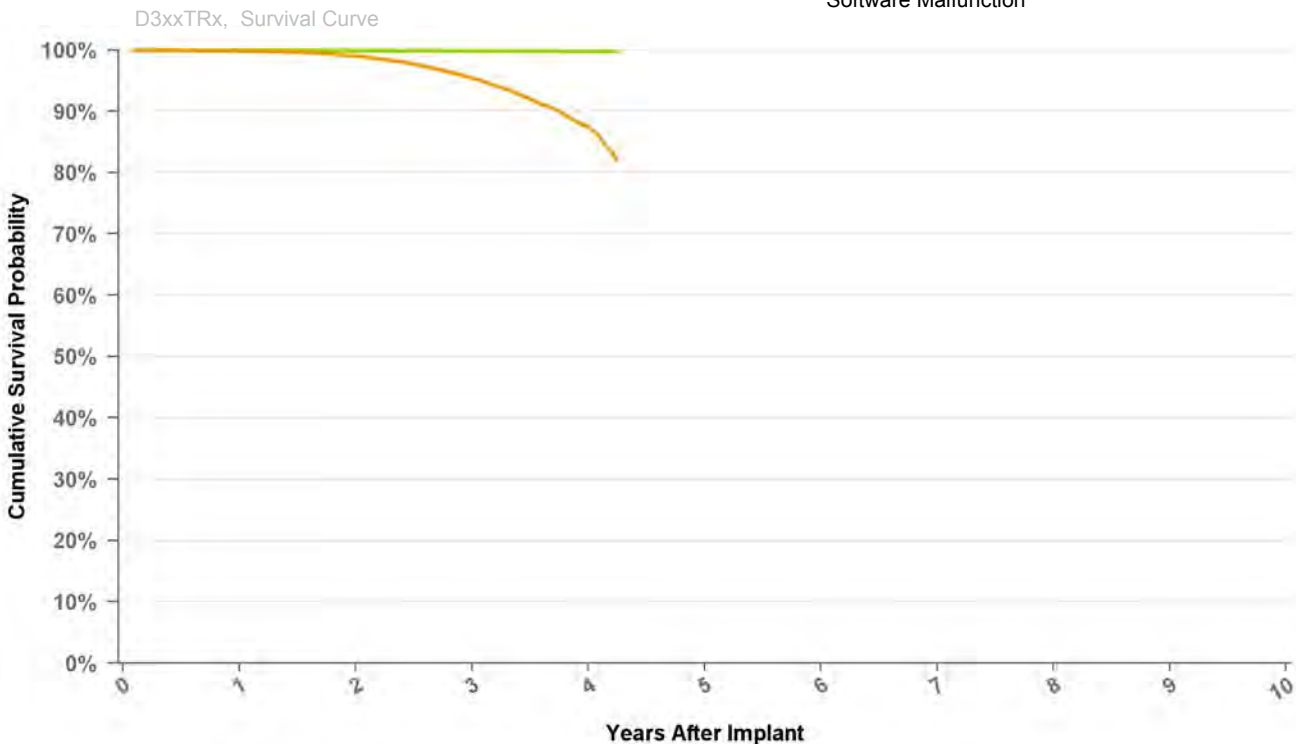
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

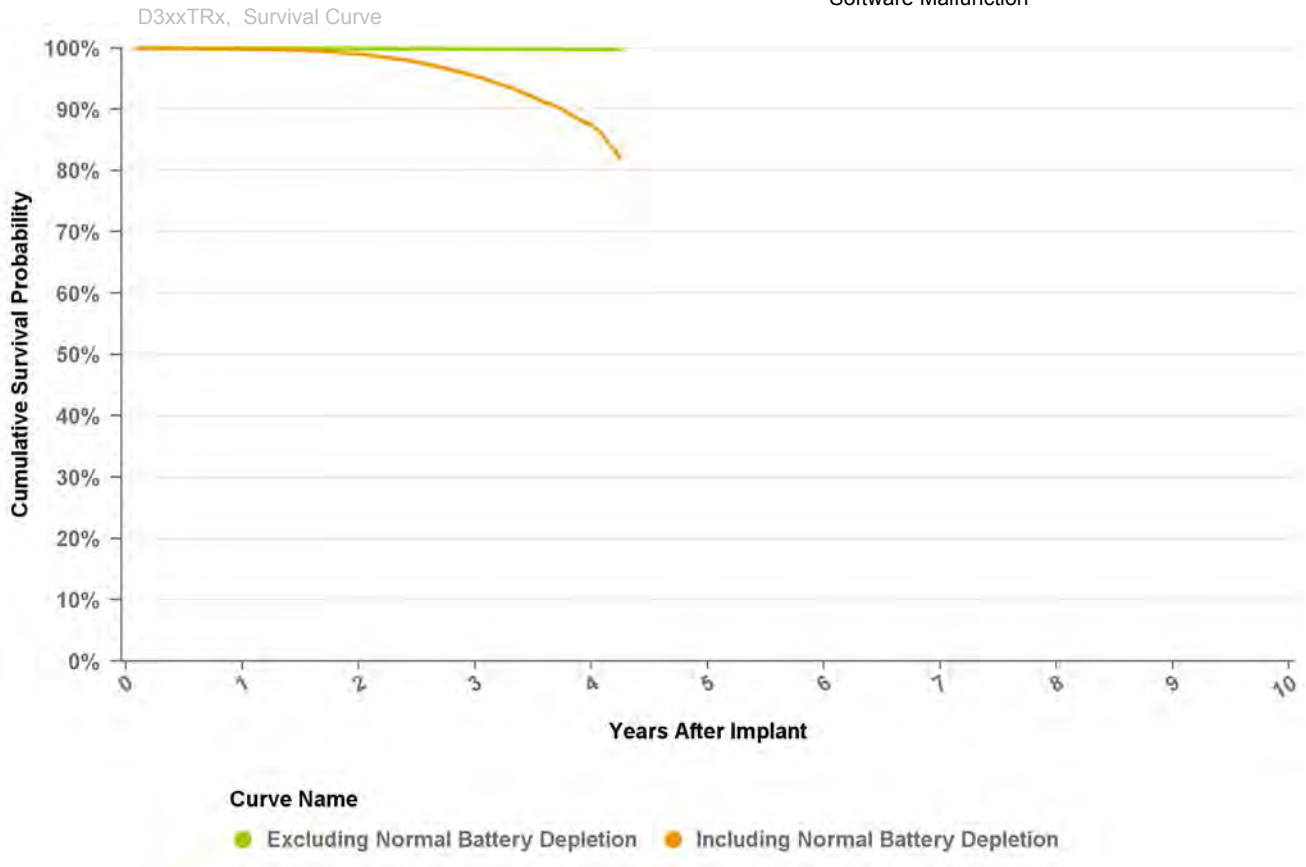
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D364TRG Protecta CRT-D

US Market Release Date	
CE Market Approval Date	25-Mar-10
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 Malfunctions	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 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D364TRM Protecta CRT-D

US Market Release Date

CE Market Approval Date 15-Jul-10

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 Malfunctions 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

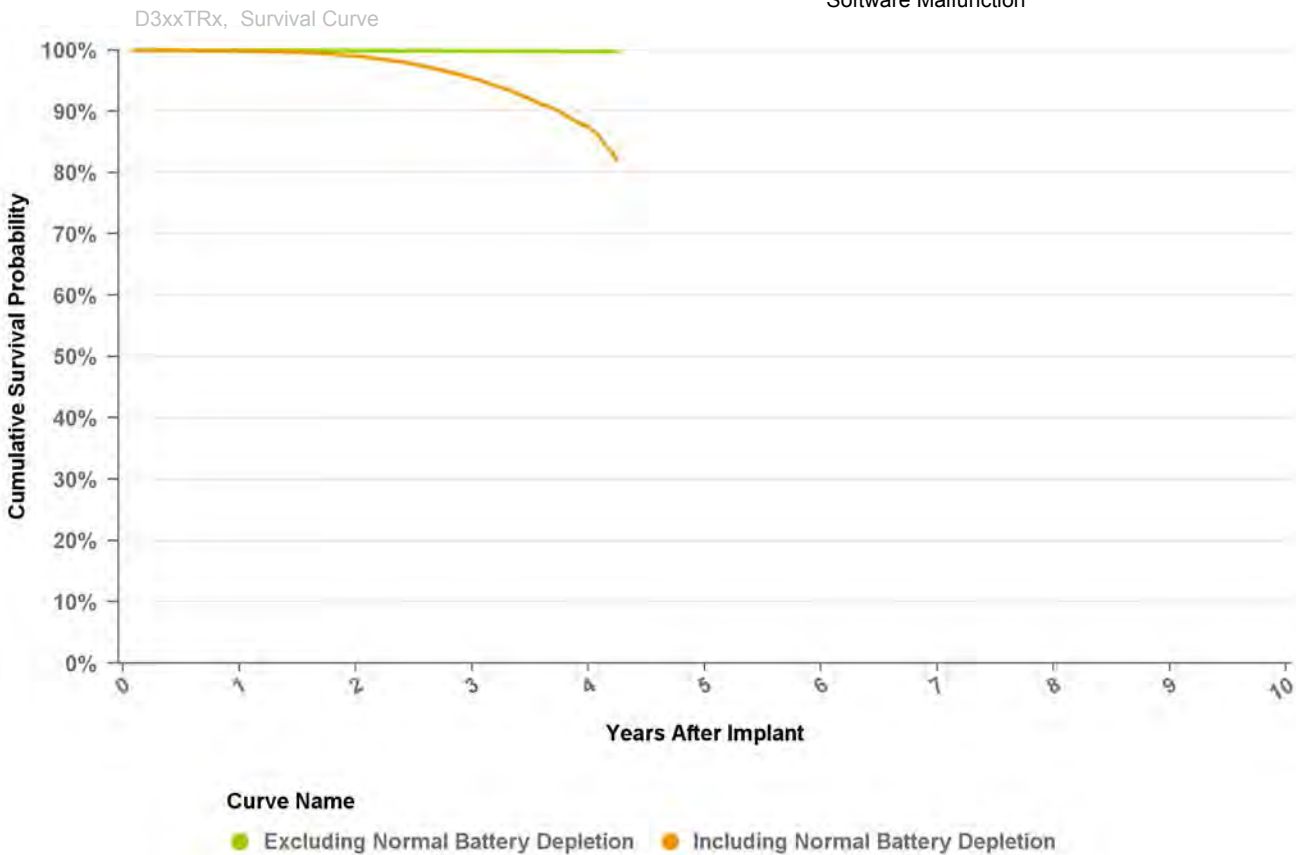
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



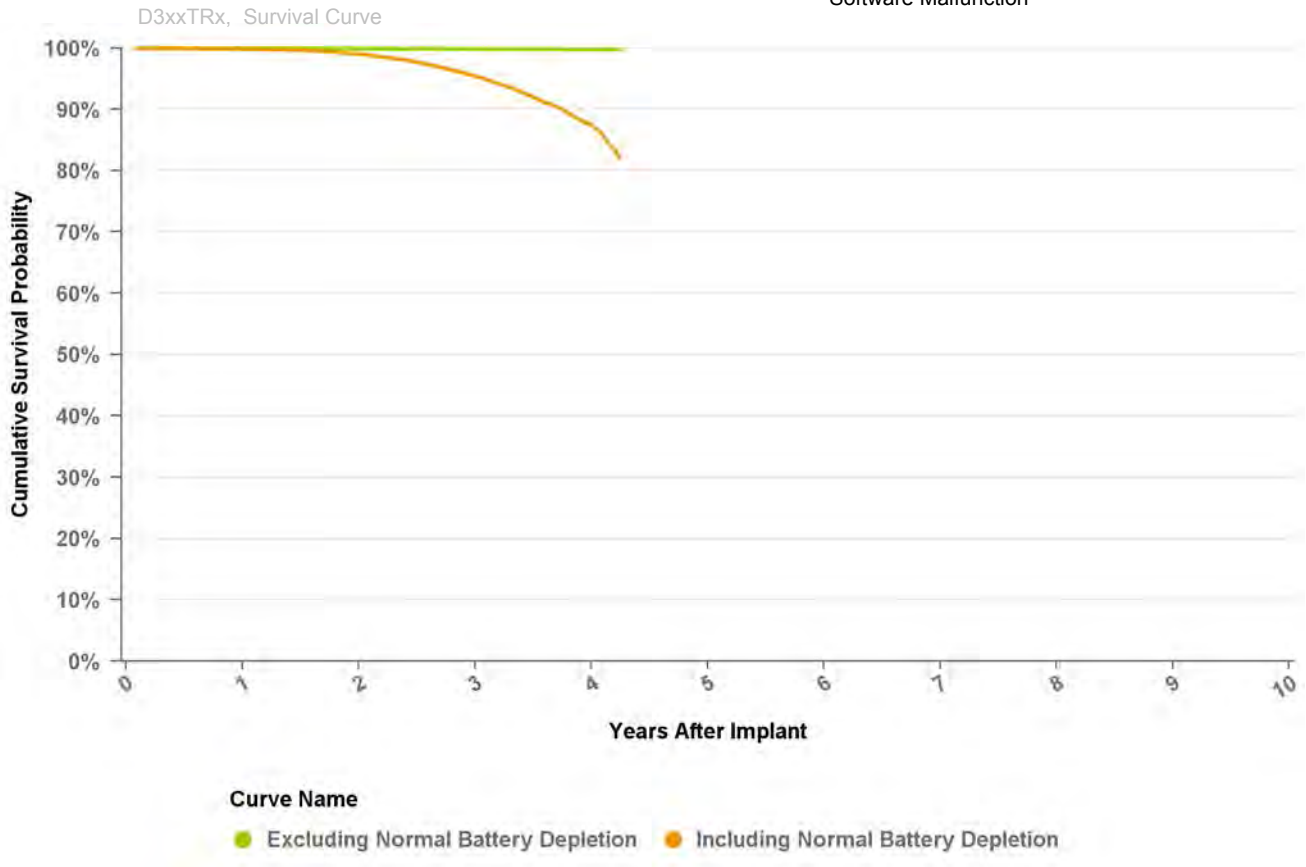
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D384TRG Cardia CRT-D

US Market Release Date	
CE Market Approval Date	12-Jan-11
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 Malfunctions	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 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

D394TRG Egida CRT-D

US Market Release Date

CE Market Approval Date 12-Jan-11

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 Malfunctions 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

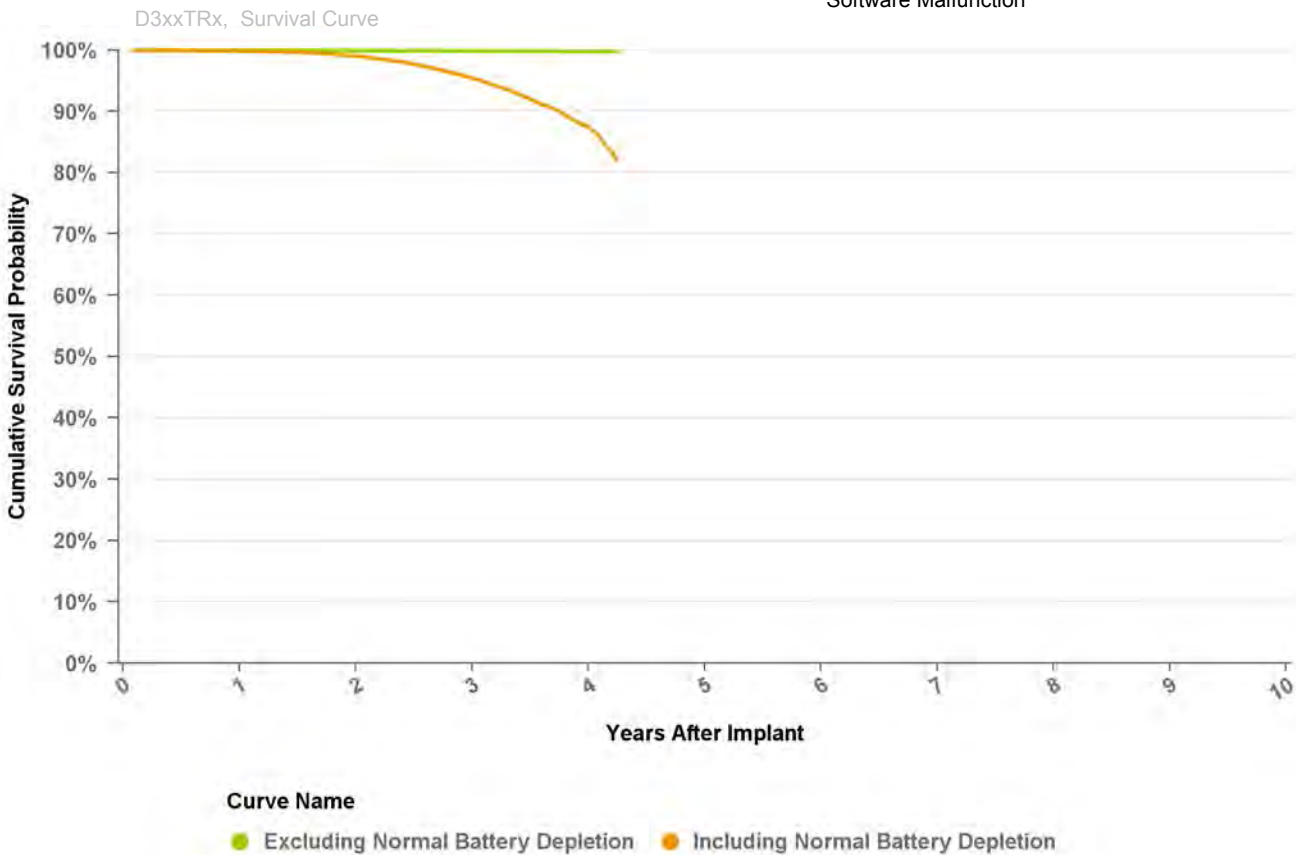
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



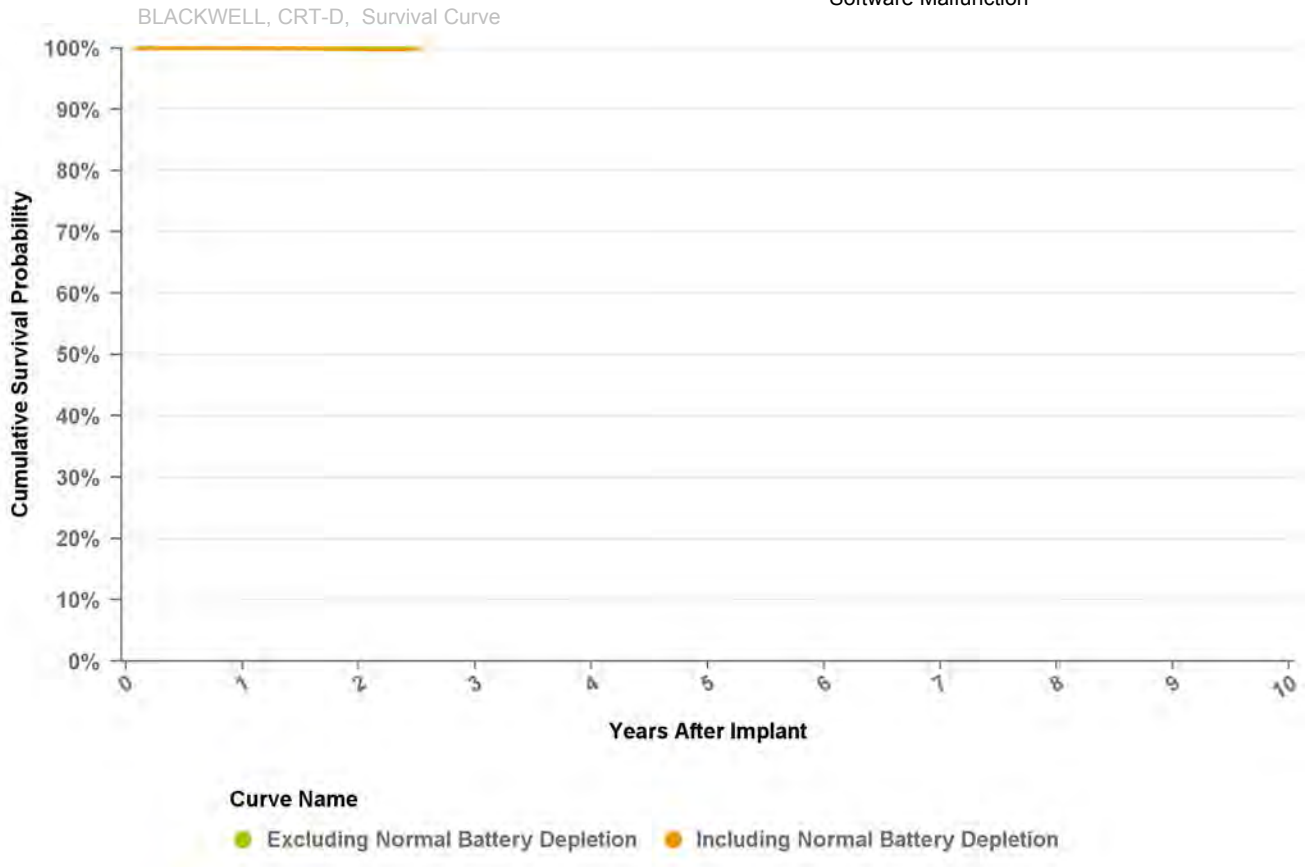
Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.0%	95.4%	87.5%	82.1%
Effective Sample Size	55392	49055	26938	4127	760

Cardiac Resynchronization Therapy

DTBA1D1 Viva XT

US Market Release Date	29-Jan-13
CE Market Approval Date	
Registered US Implants	32,733
Estimated Active US Implants	30,692
Normal Battery Depletions (US)	6
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



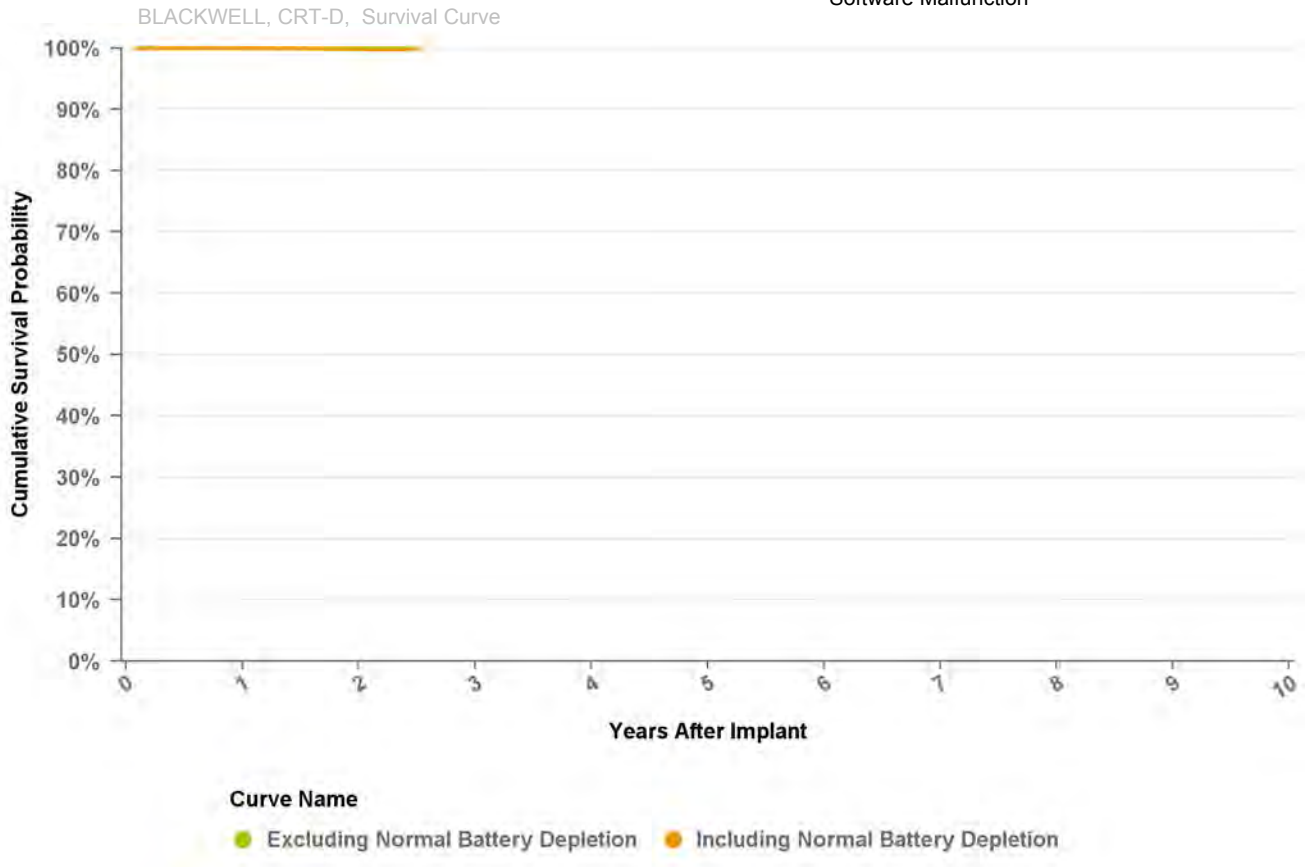
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA1D4 Viva XT

US Market Release Date	29-Jan-13
CE Market Approval Date	
Registered US Implants	14,165
Estimated Active US Implants	13,205
Normal Battery Depletions (US)	7
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	6
Therapy Not Compromised Malfunctions	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



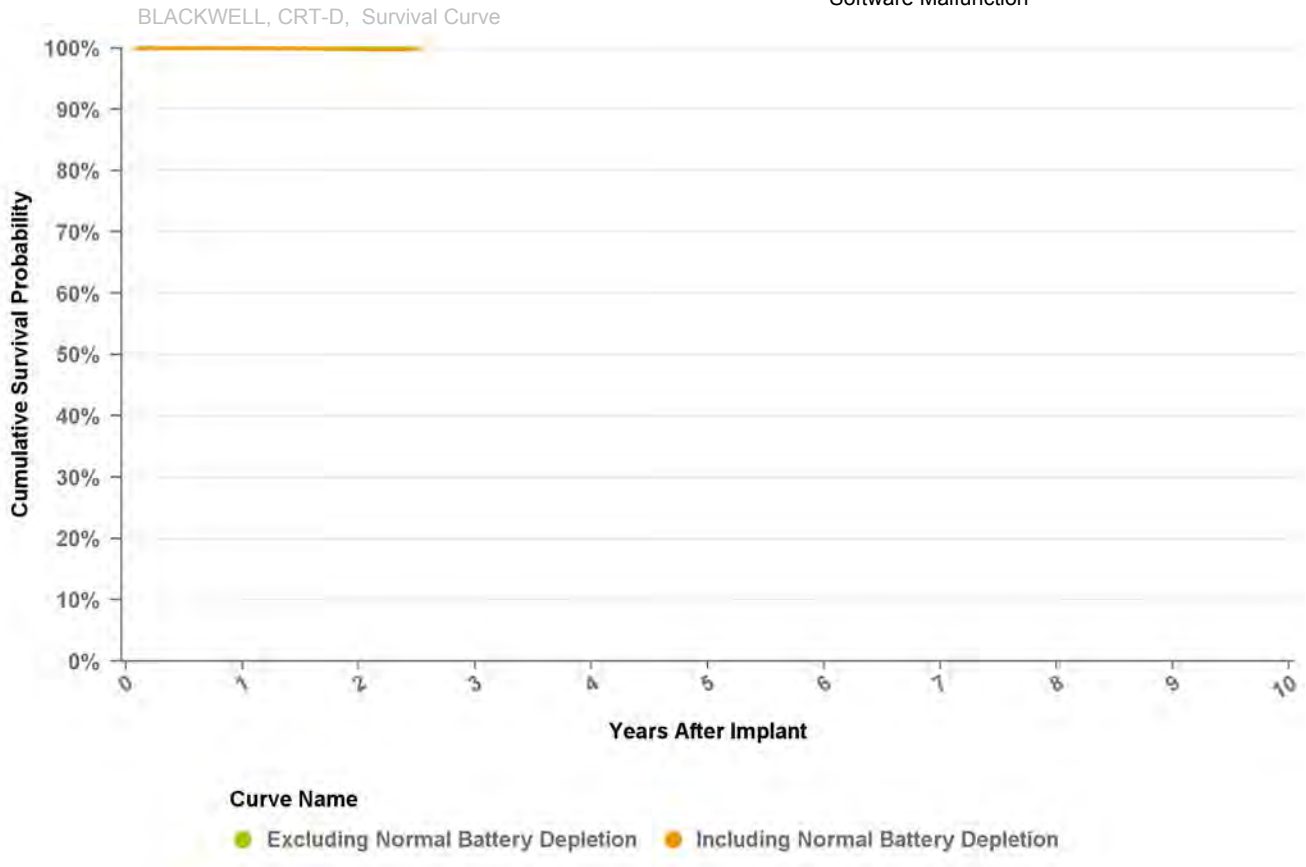
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA1Q1 Viva Quad XT

US Market Release Date	3-Jul-14
CE Market Approval Date	
Registered US Implants	4,944
Estimated Active US Implants	4,772
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



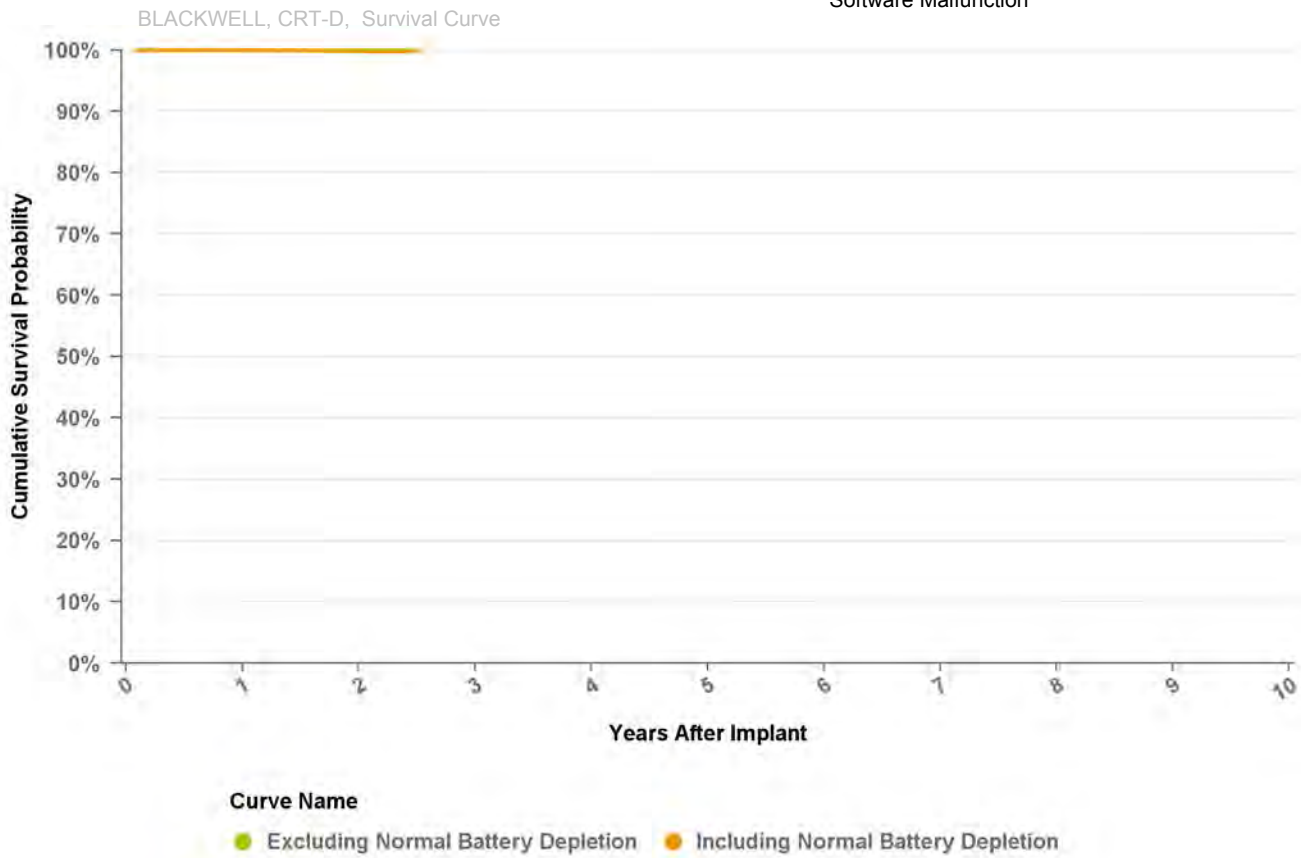
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA1QQ Viva Quad XT

US Market Release Date	3-Jul-14
CE Market Approval Date	
Registered US Implants	14,279
Estimated Active US Implants	14,027
Normal Battery Depletions (US)	2
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



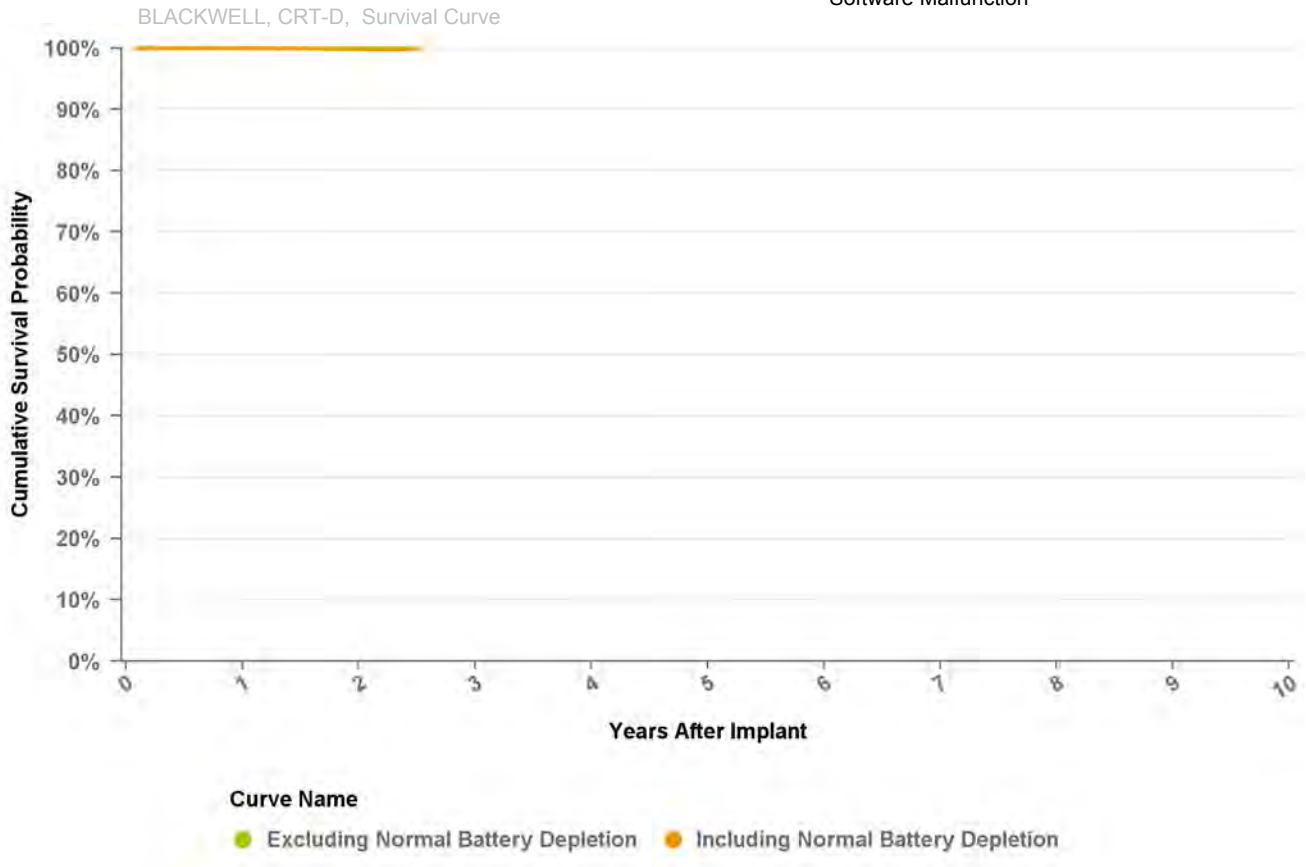
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA2D1 Viva XT

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



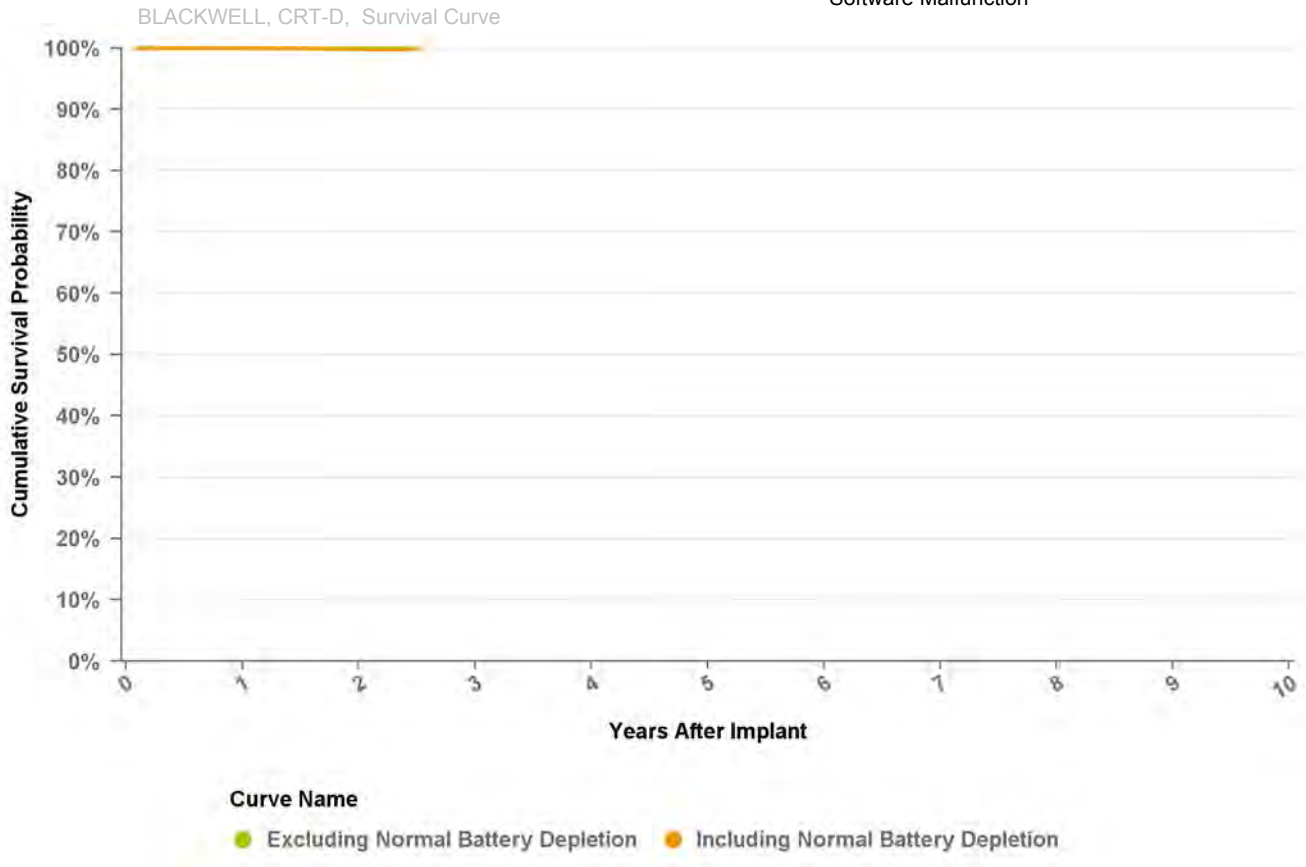
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA2D4 Viva XT

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



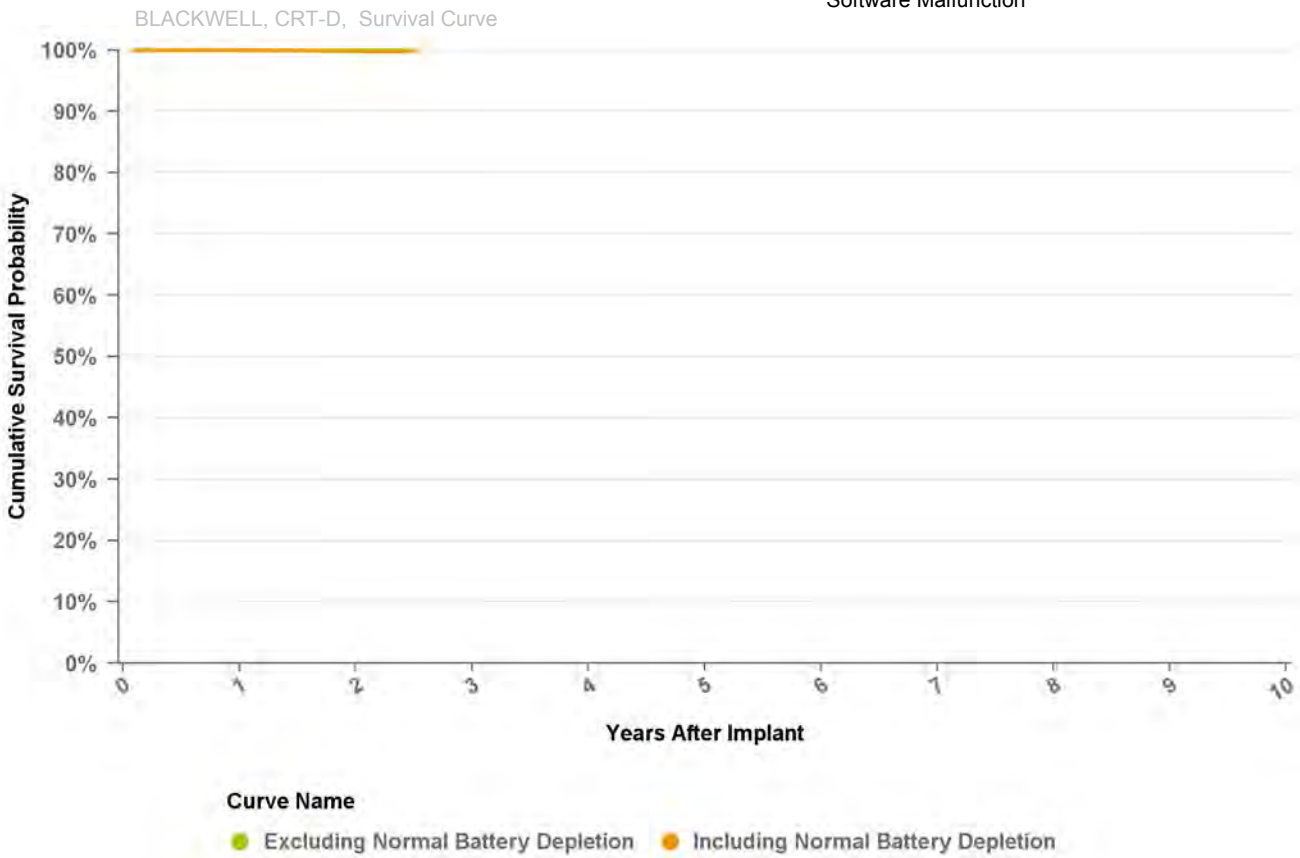
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA2Q1 Viva Quad XT

US Market Release Date	
CE Market Approval Date	13-Sep-13
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



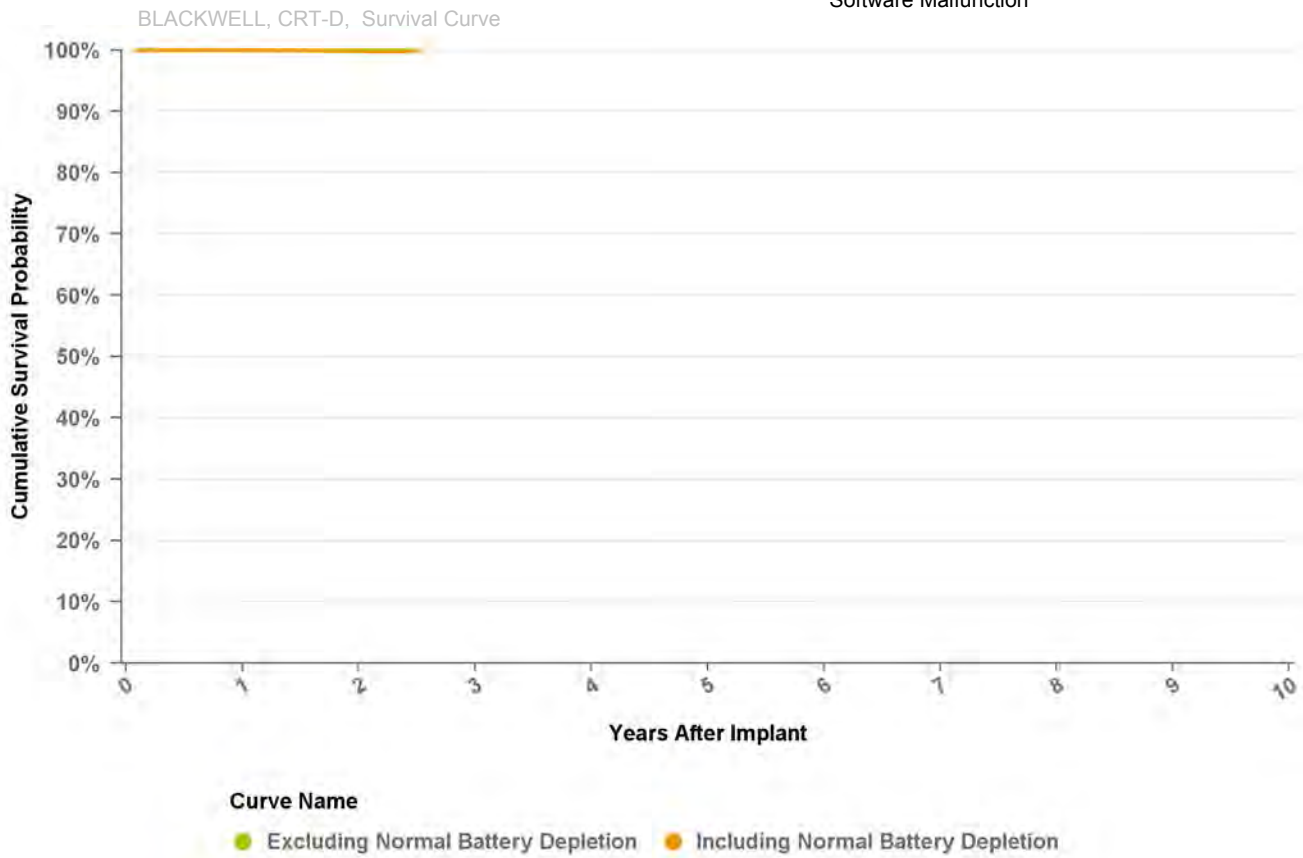
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBA2QQ Viva Quad XT

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB1D1 Viva S

US Market Release Date 29-Jan-13

CE Market Approval Date

Registered US Implants 8,864

Estimated Active US Implants 8,202

Normal Battery Depletions (US) 5

NBG Code DDE-DDDR

Max Delivered Energy 36 J

Total Malfunctions (US) 1

Therapy Not Compromised Malfunctions 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

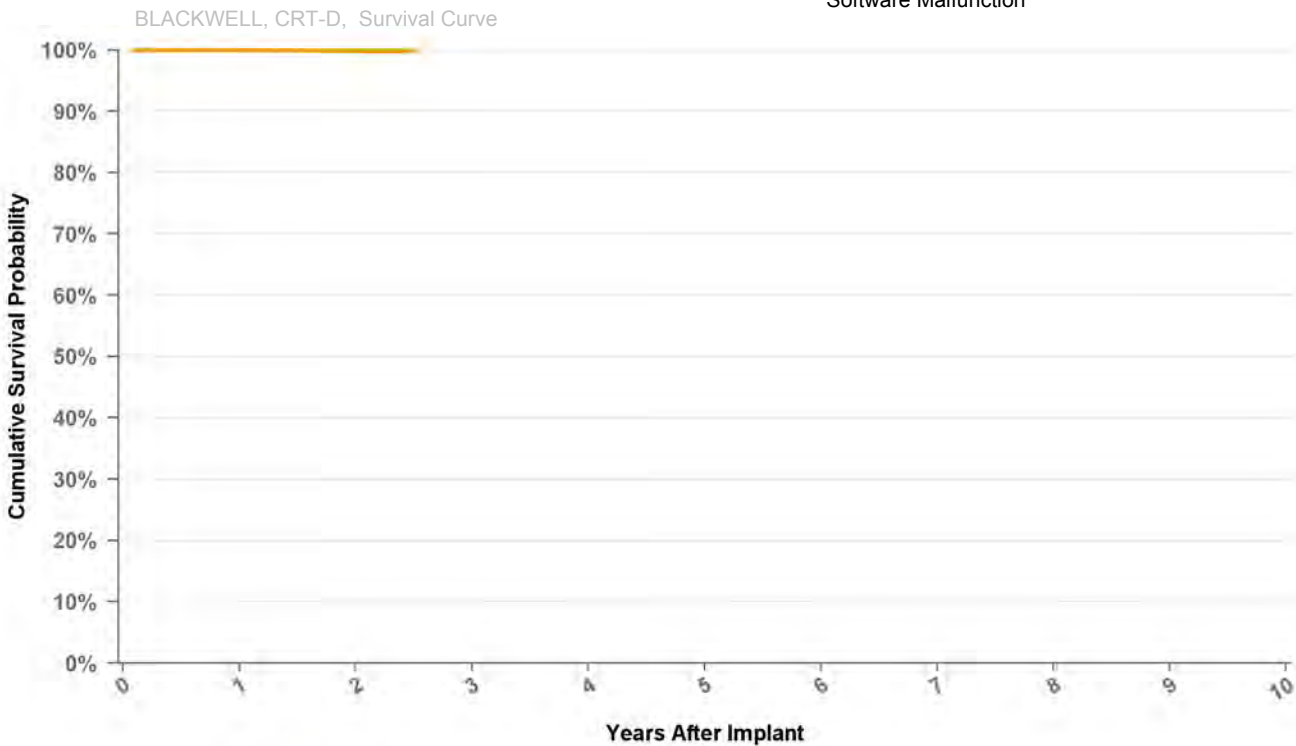
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

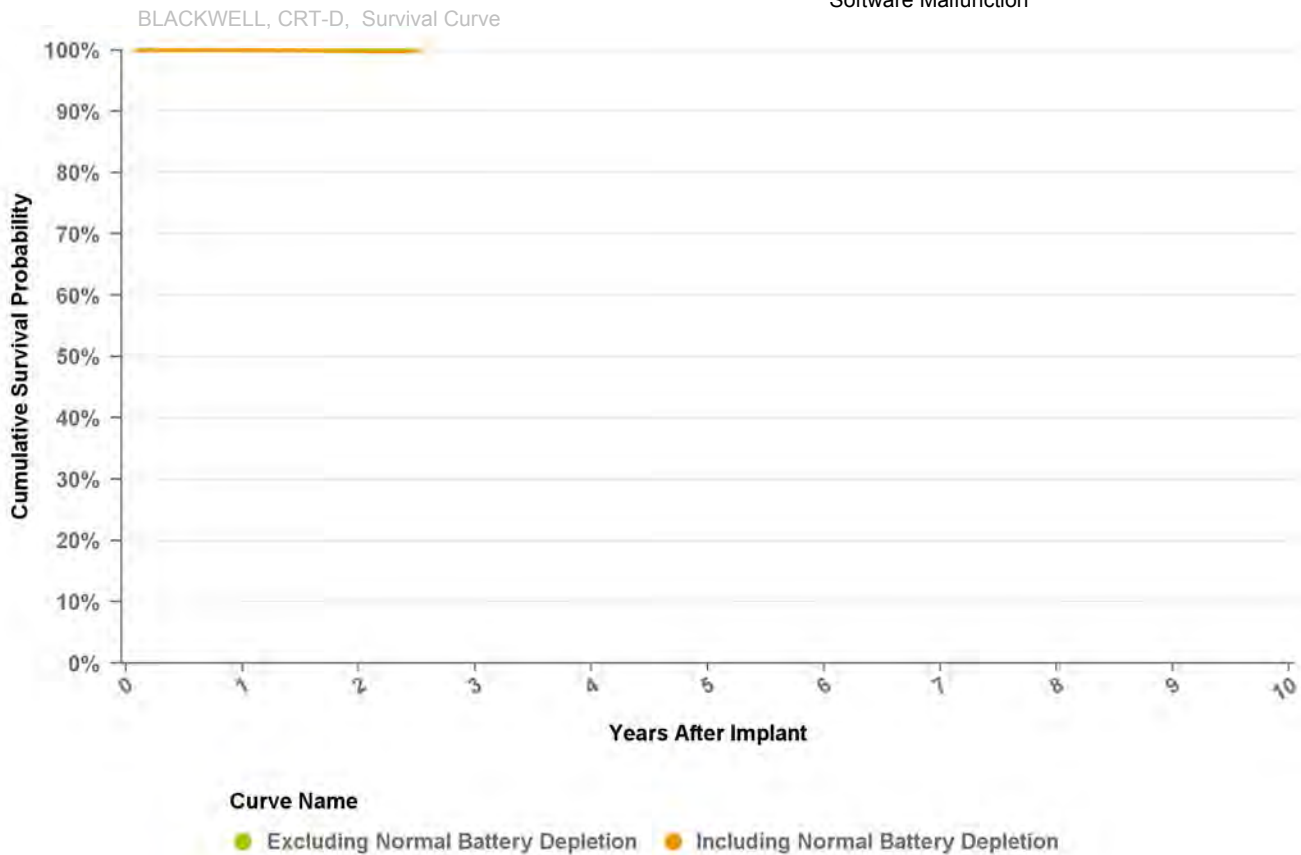
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB1D4 Viva S

US Market Release Date	29-Jan-13
CE Market Approval Date	
Registered US Implants	3,180
Estimated Active US Implants	3,001
Normal Battery Depletions (US)	2
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



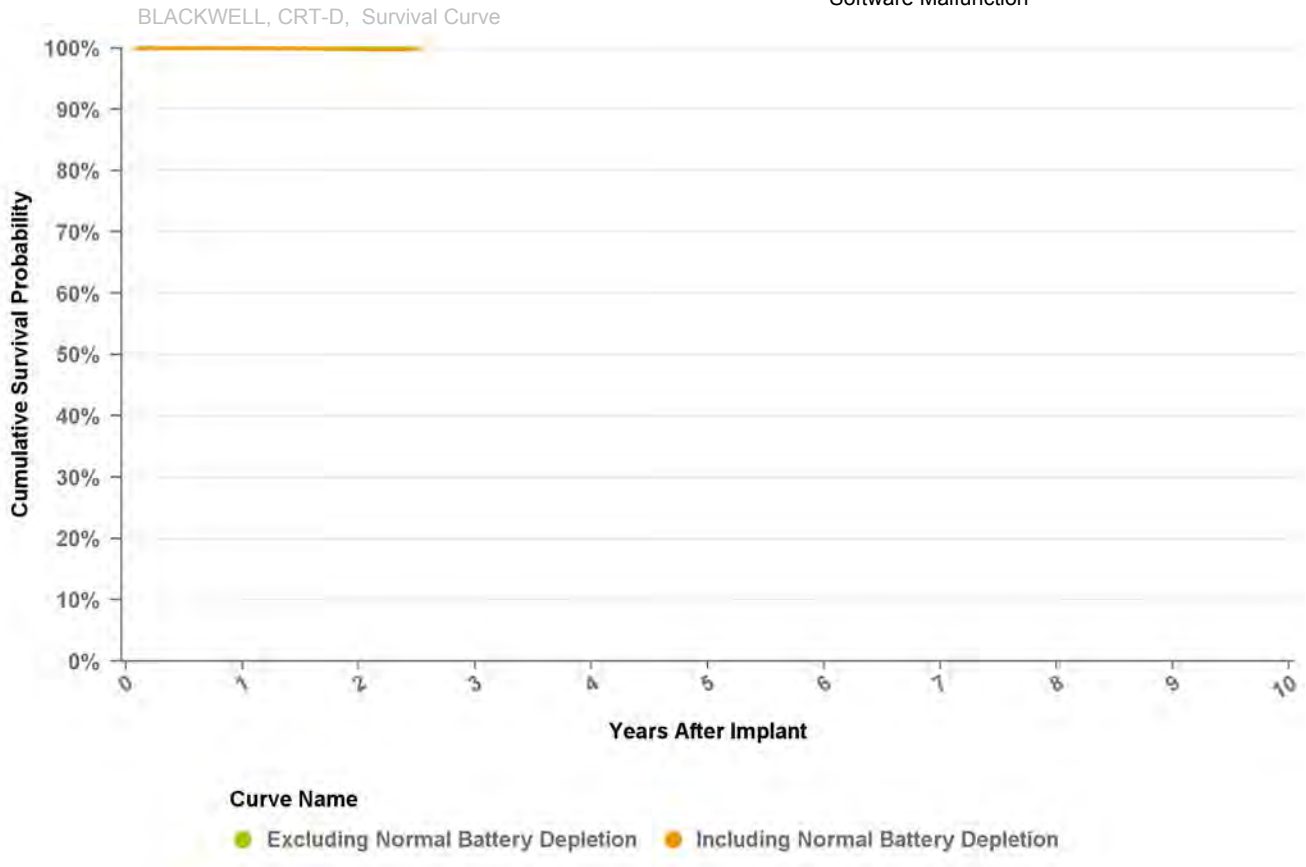
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB1Q1 Viva Quad S

US Market Release Date	3-Jul-14
CE Market Approval Date	
Registered US Implants	817
Estimated Active US Implants	790
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



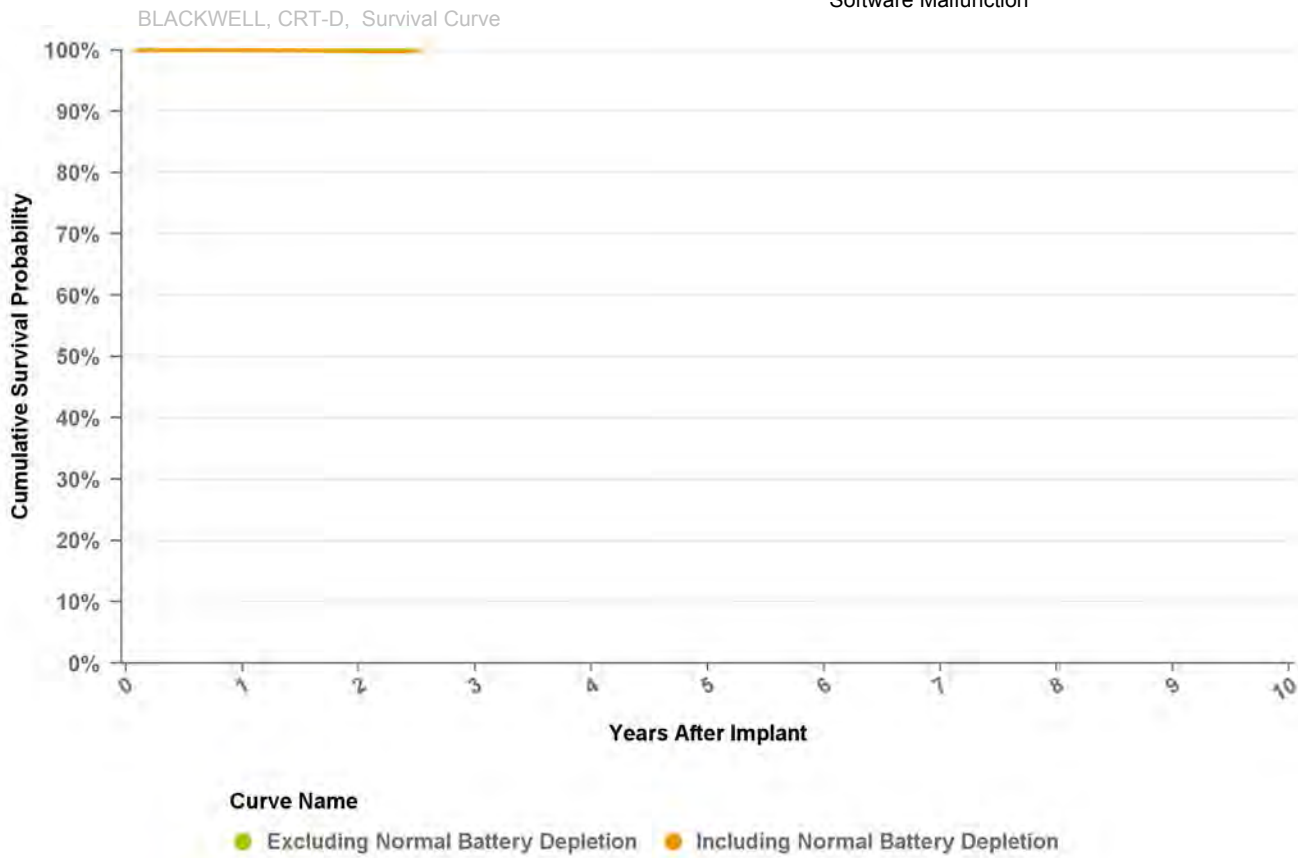
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB1QQ Viva Quad S

US Market Release Date	3-Jul-14
CE Market Approval Date	
Registered US Implants	2,199
Estimated Active US Implants	2,158
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



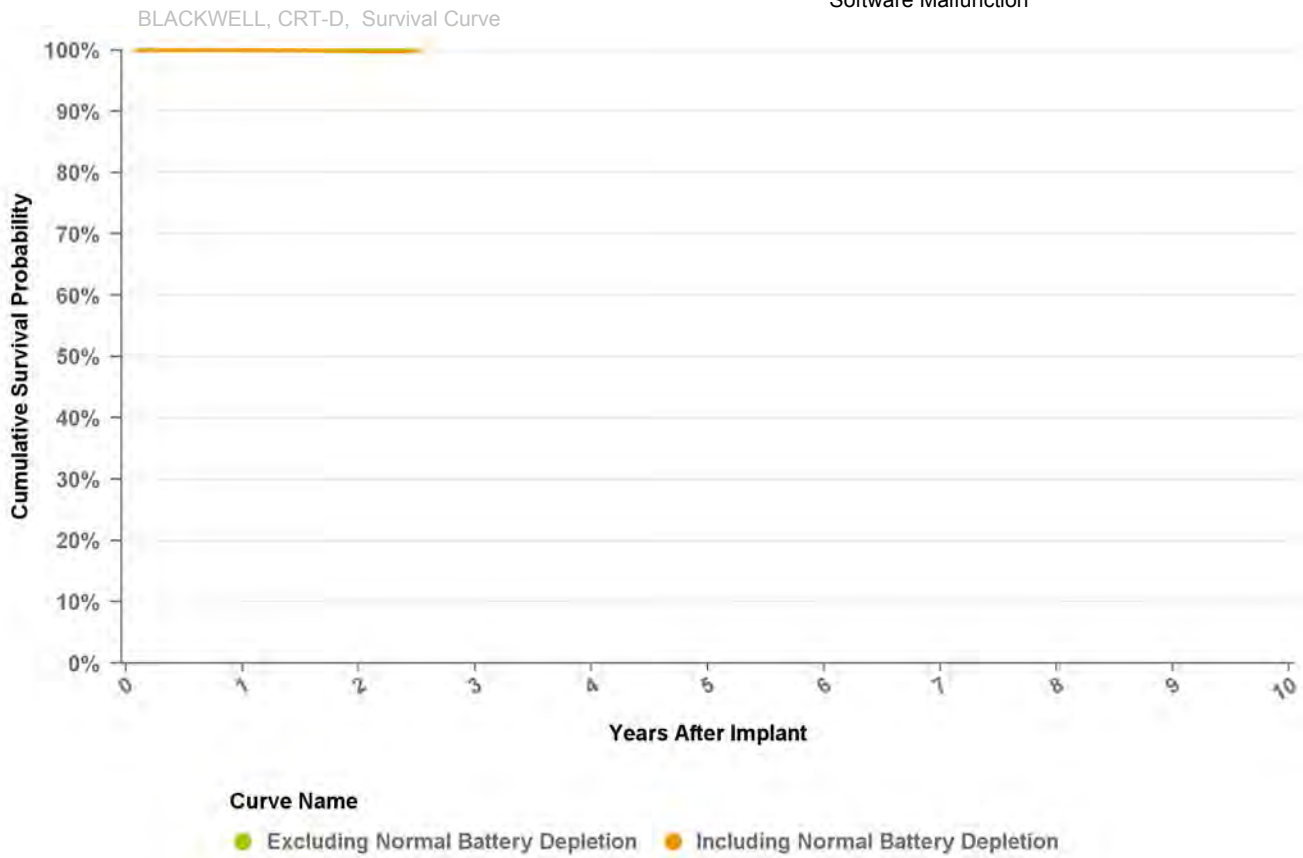
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB2D1 Viva S

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



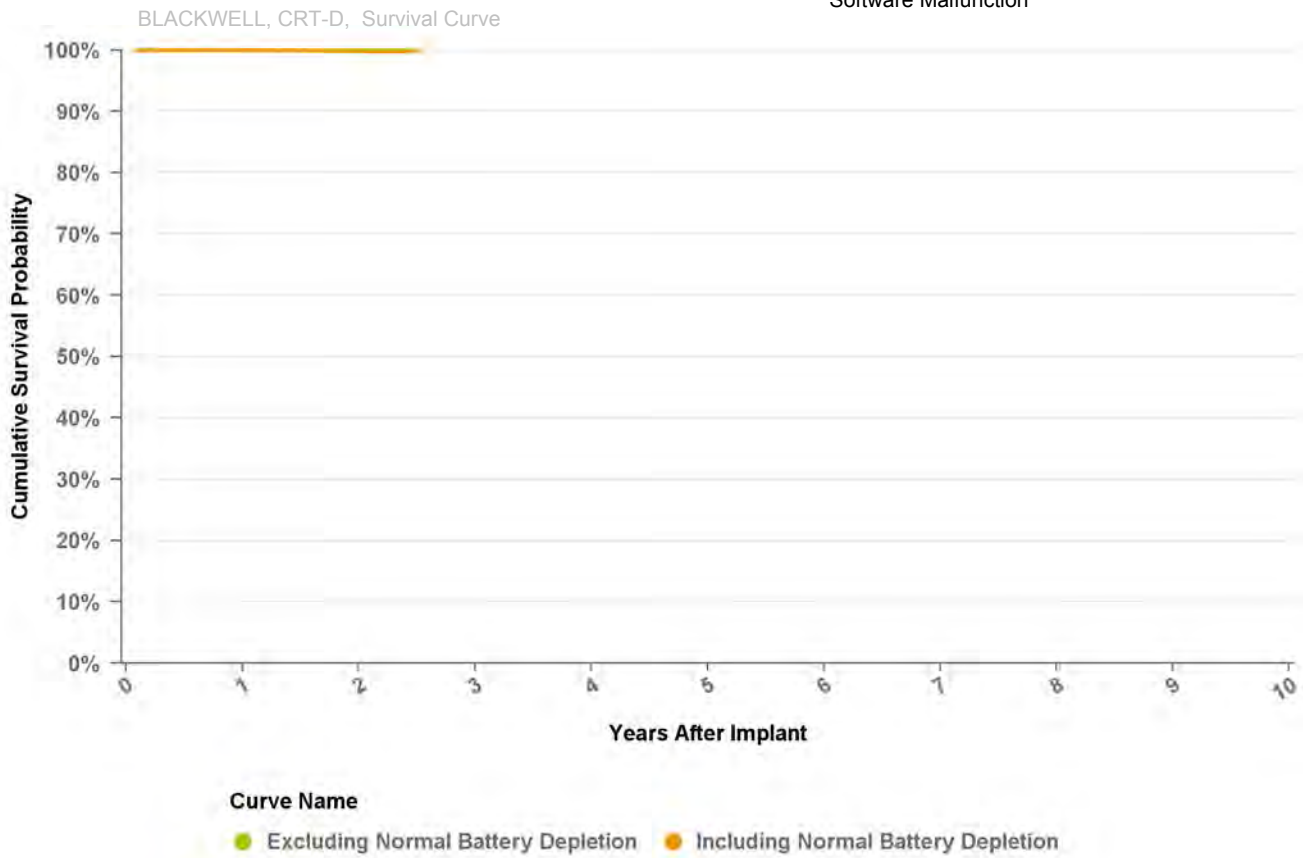
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB2D4 Viva S

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



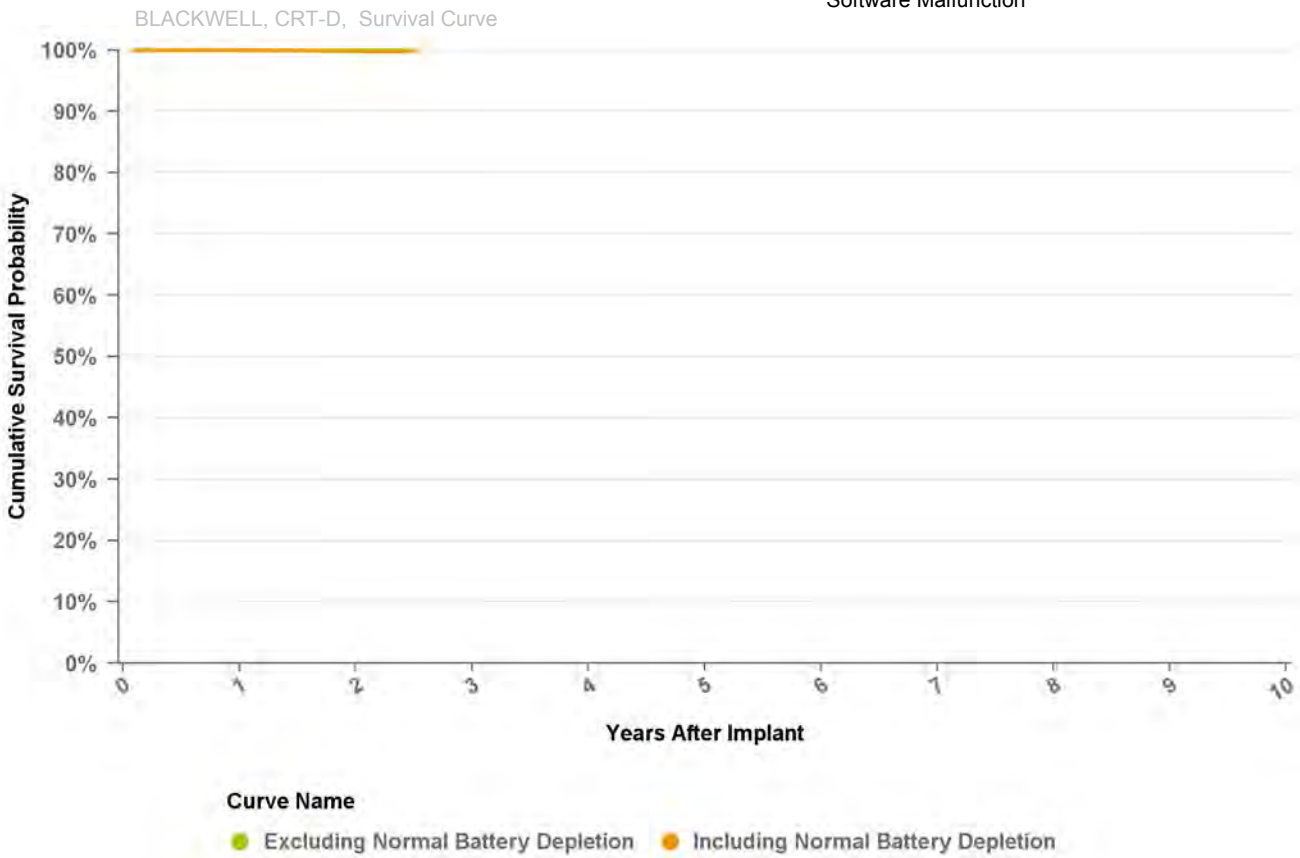
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBB2QQ Viva Quad S

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



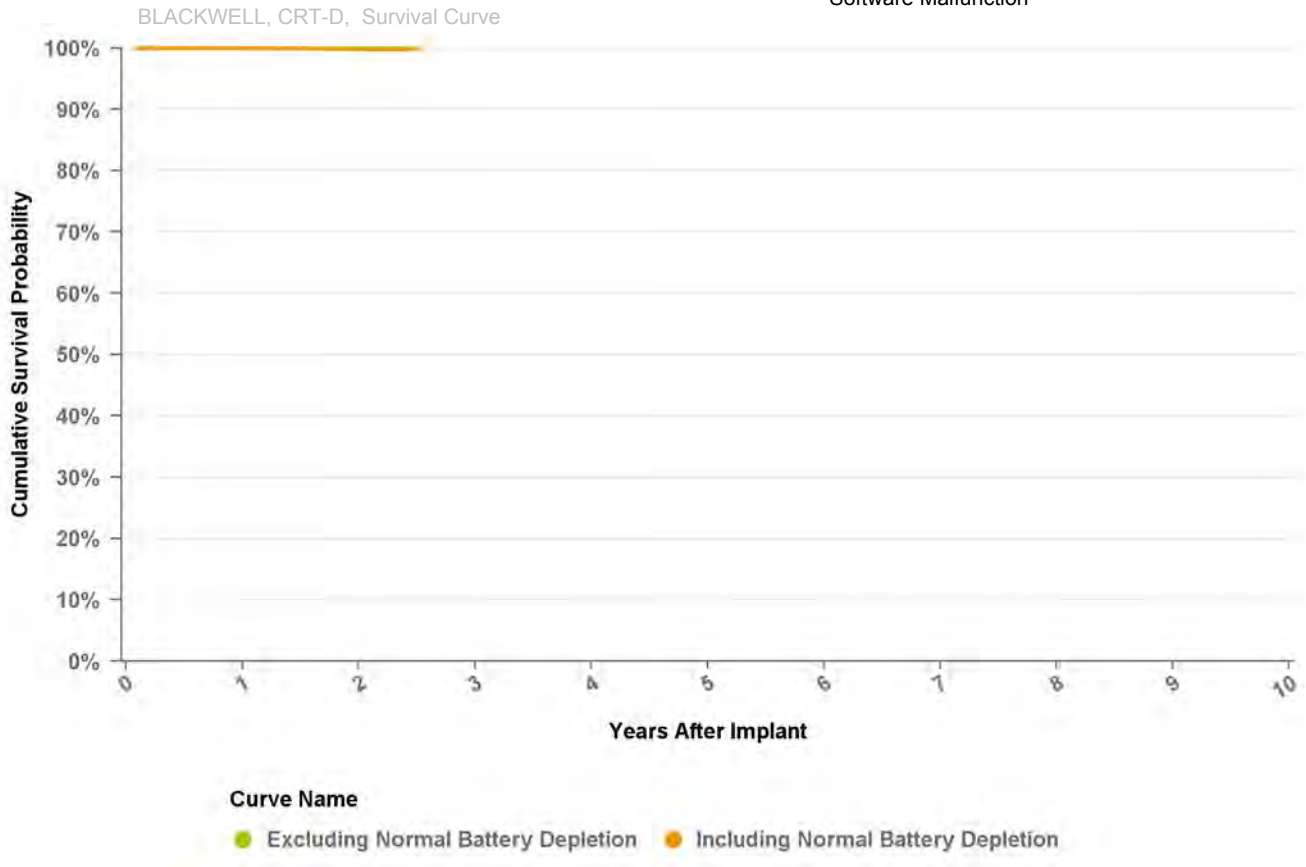
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBC2D1 Brava

US Market Release Date	
CE Market Approval Date	10-Aug-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBC2D4 Brava

US Market Release Date

CE Market Approval Date 10-Aug-12

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

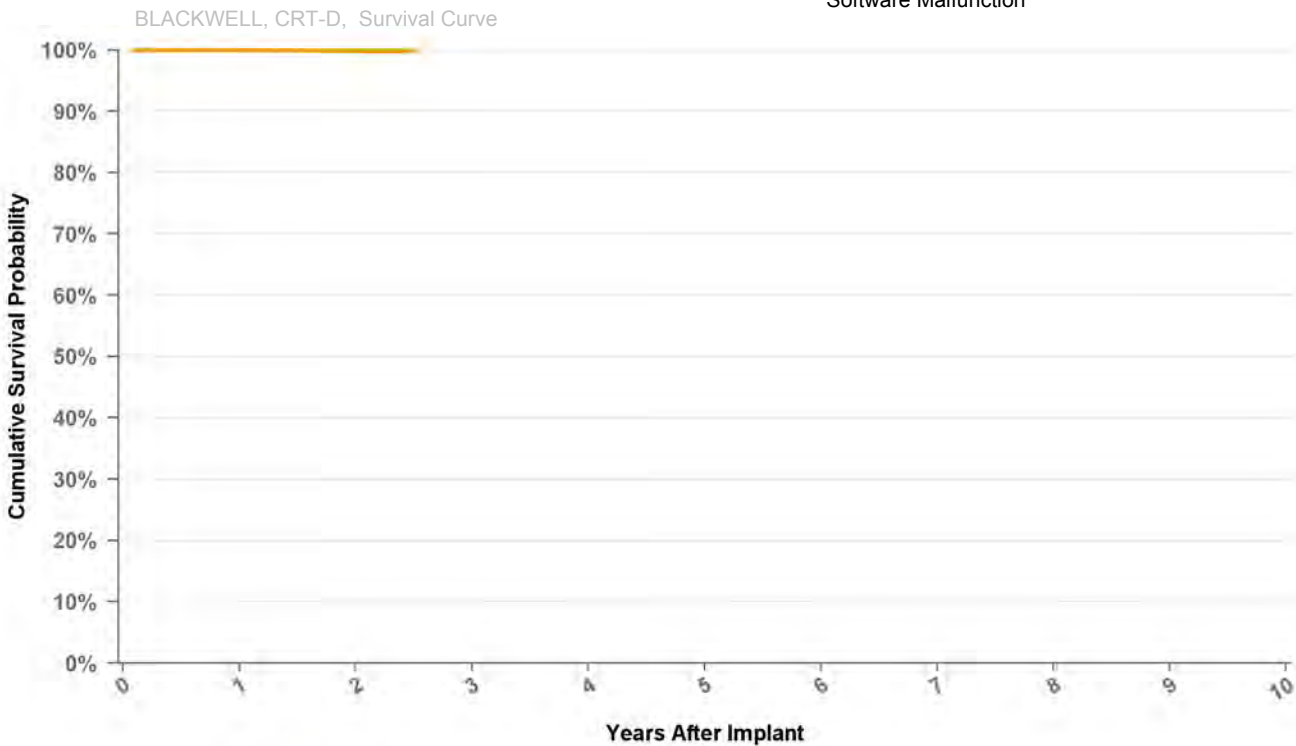
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

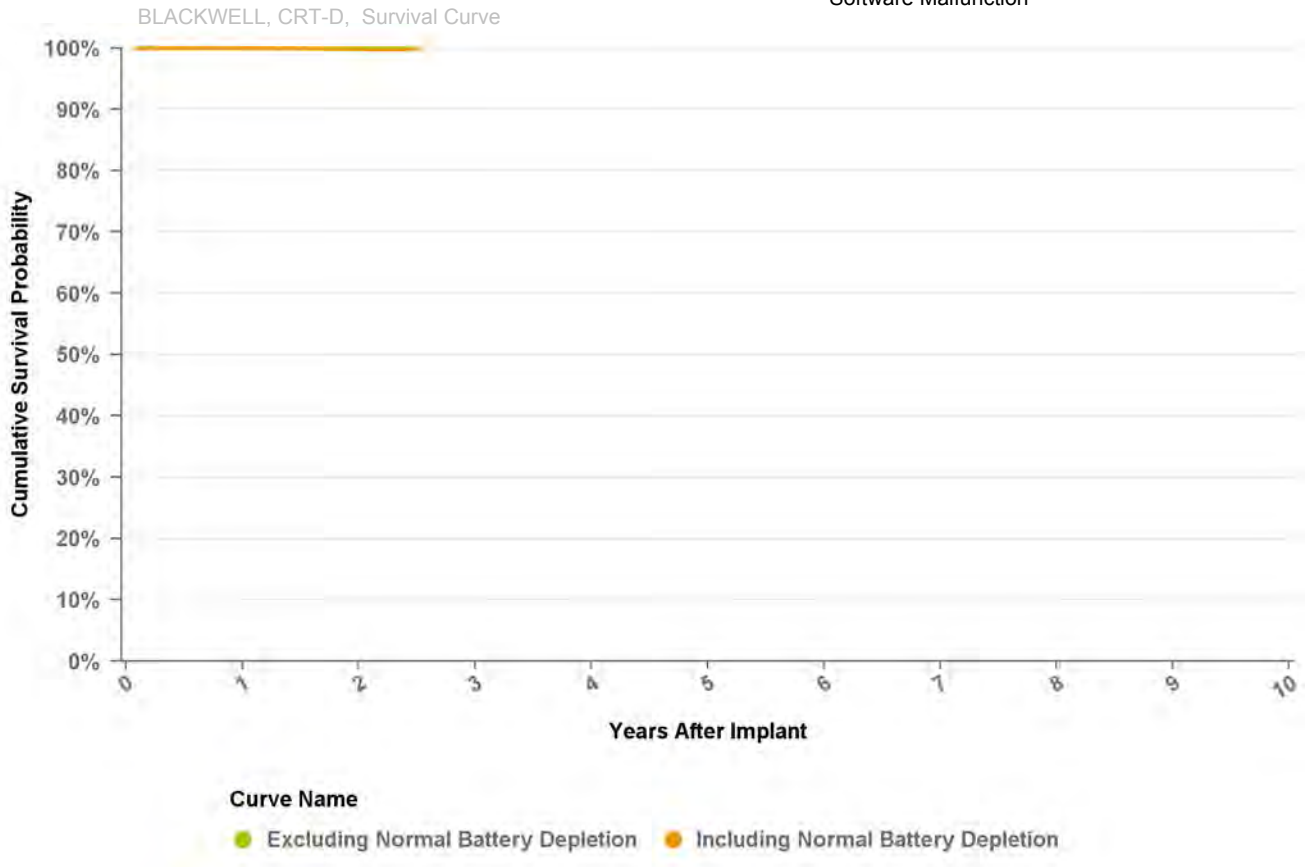
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBC2Q1 Brava Quad

US Market Release Date	
CE Market Approval Date	13-Sep-13
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBC2QQ Brava Quad

US Market Release Date

CE Market Approval Date 10-Aug-12

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 Malfunctions 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

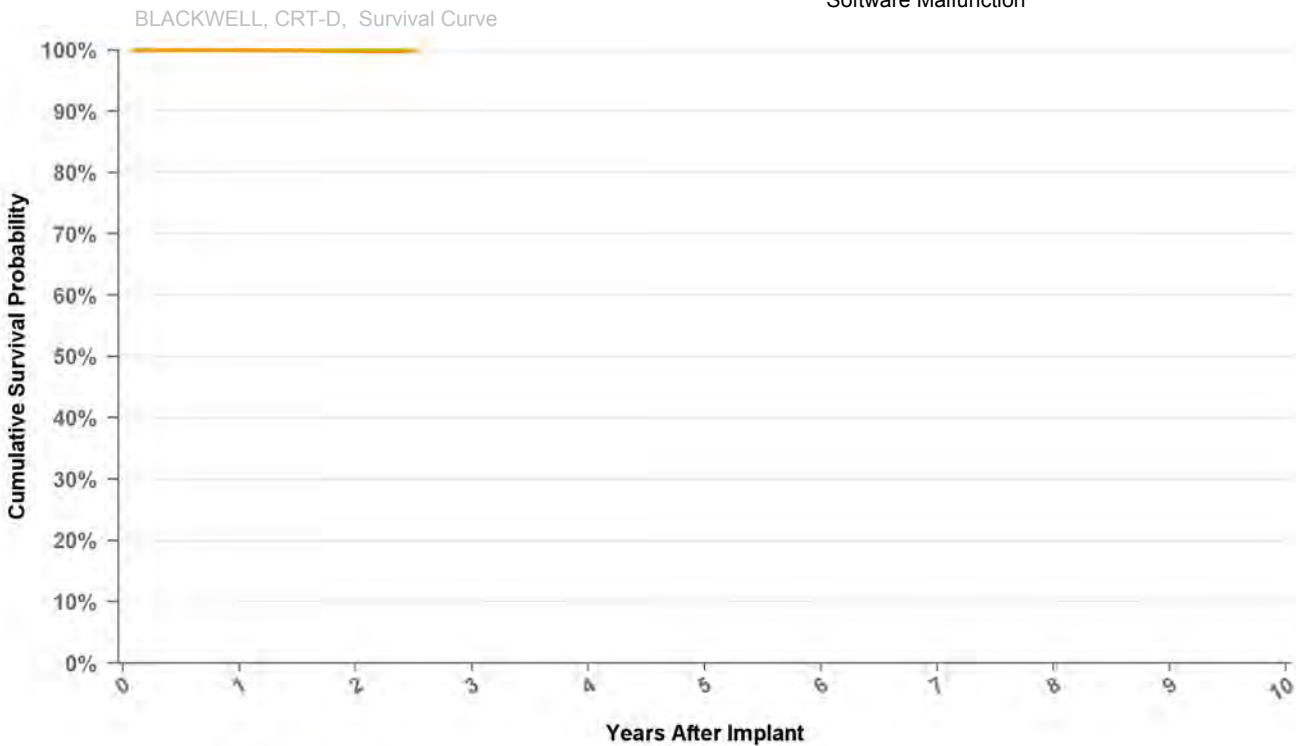
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

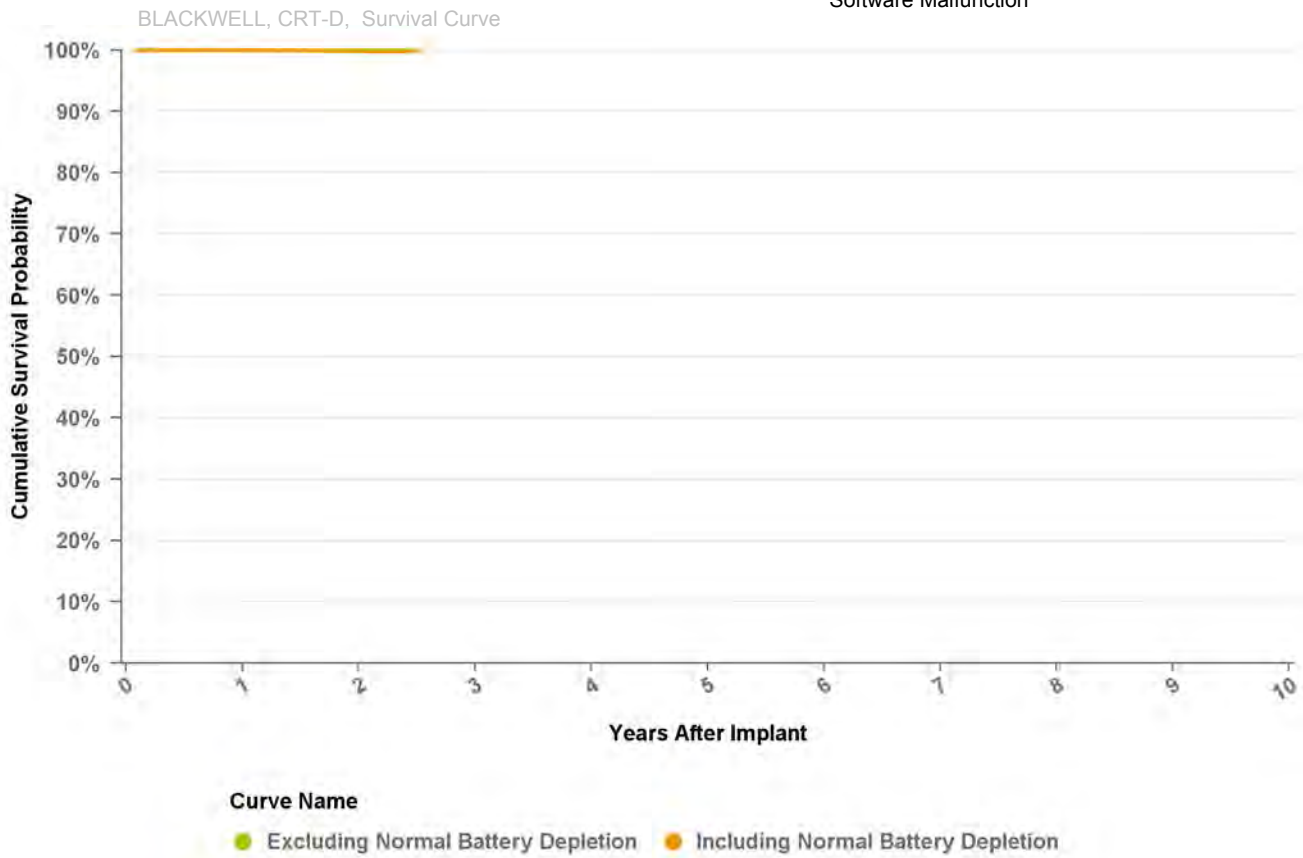
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBX1QQ Viva Quad C

US Market Release Date	3-Jul-14
CE Market Approval Date	
Registered US Implants	638
Estimated Active US Implants	593
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



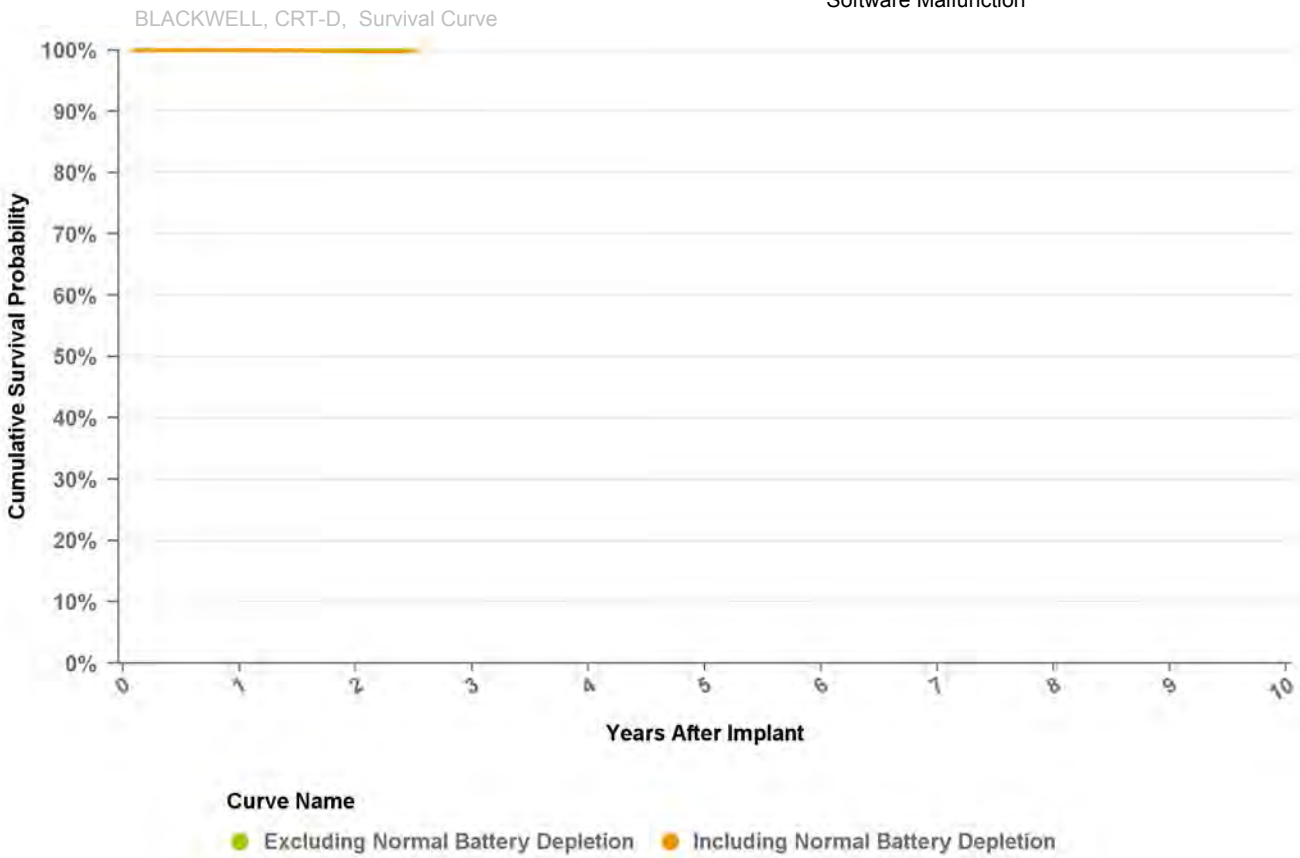
Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

Cardiac Resynchronization Therapy

DTBX2QQ Viva Quad C

US Market Release Date	
CE Market Approval Date	28-Jun-11
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%
Effective Sample Size	40149	8598	135

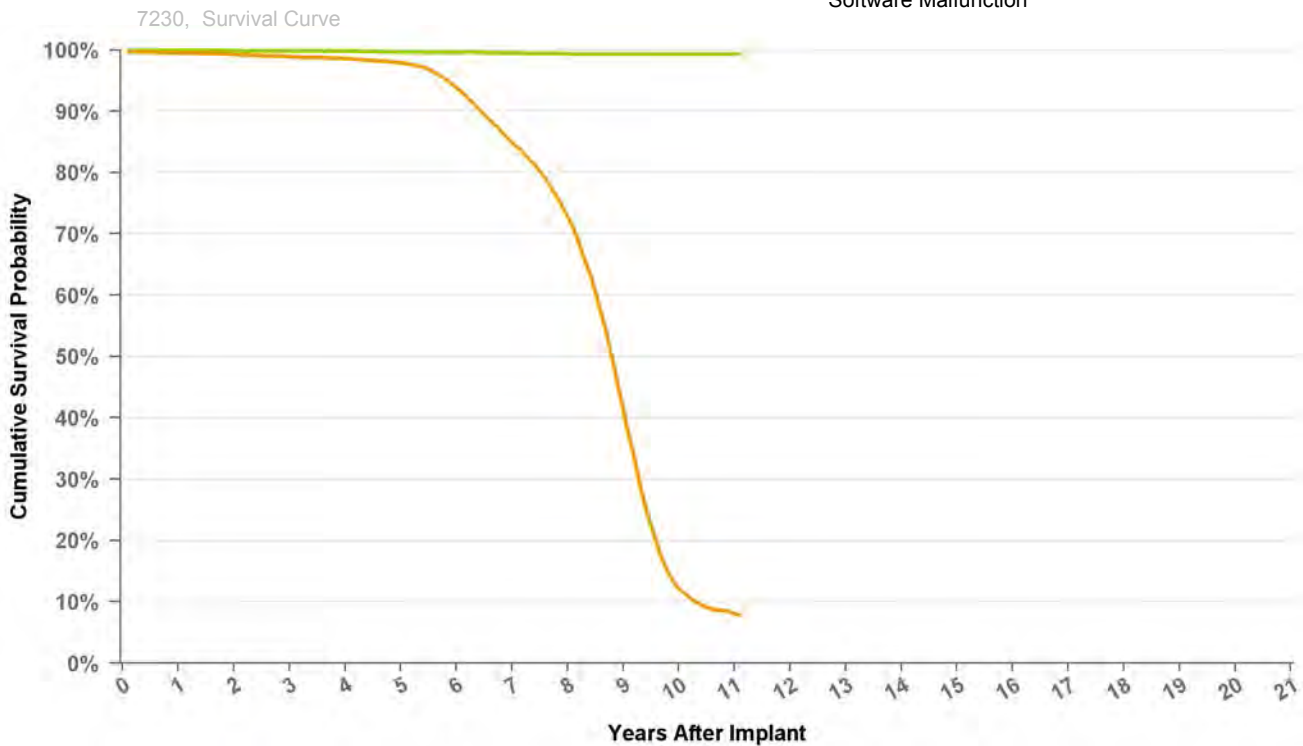
Implantable Cardioverter Defibrillator

7230B

Marquis VR

US Market Release Date	17-Dec-02
CE Market Approval Date	21-Aug-02
Registered US Implants	237
Estimated Active US Implants	14
Normal Battery Depletions (US)	26
NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	at 133 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.5%	99.3%	98.9%	98.6%	97.9%	93.8%	84.9%	72.9%	41.5%	12.2%	8.0%	7.8%
Effective Sample Size	16372	12670	10512	9395	8373	7289	6057	4821	2563	584	143	104

Implantable Cardioverter Defibrillator

7230Cx

Marquis VR

US Market Release Date 17-Dec-02

CE Market Approval Date 10-Apr-02

Registered US Implants 18,520

Estimated Active US Implants 1,316

Normal Battery Depletions (US) 3,388

NBG Code VVE-VVIR

Max Delivered Energy 30J

Total Malfunctions (US) 57

Therapy Not Compromised Malfunctions 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

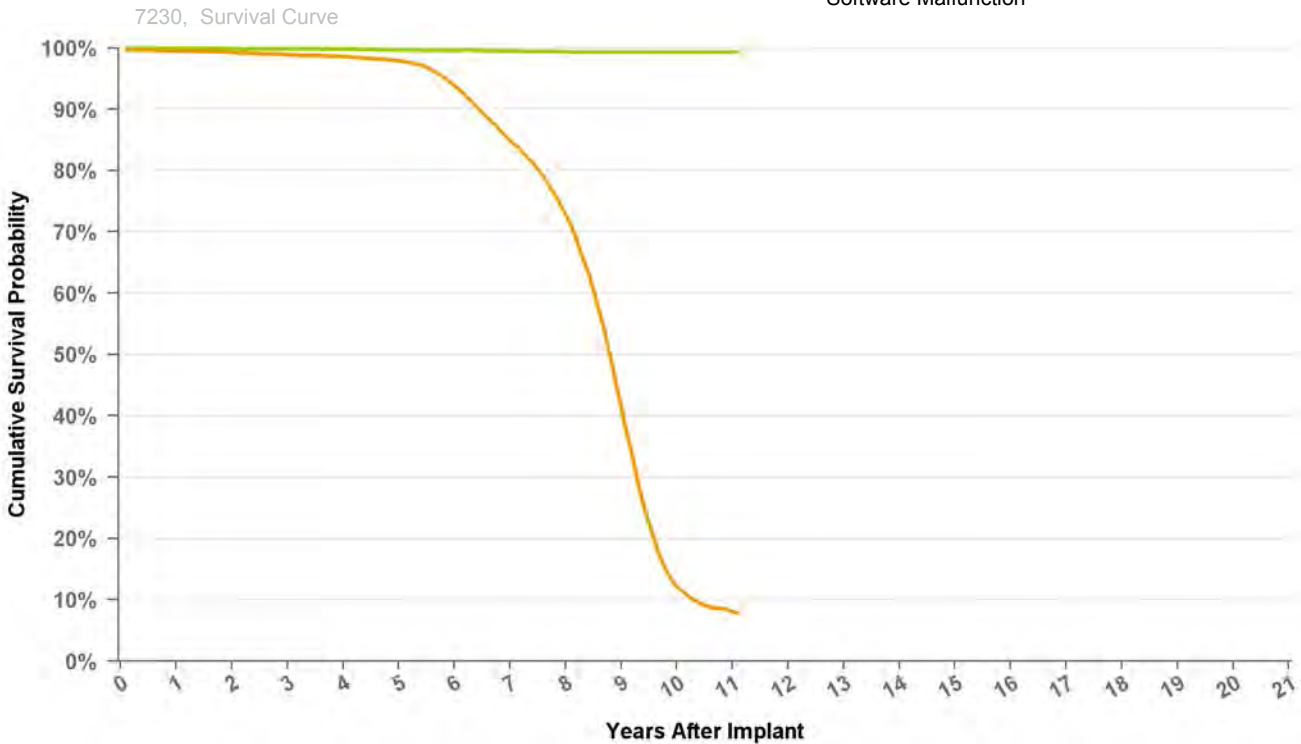
Electrical Component 9

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	at 133 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.5%	99.3%	98.9%	98.6%	97.9%	93.8%	84.9%	72.9%	41.5%	12.2%	8.0%	7.8%
Effective Sample Size	16372	12670	10512	9395	8373	7289	6057	4821	2563	584	143	104

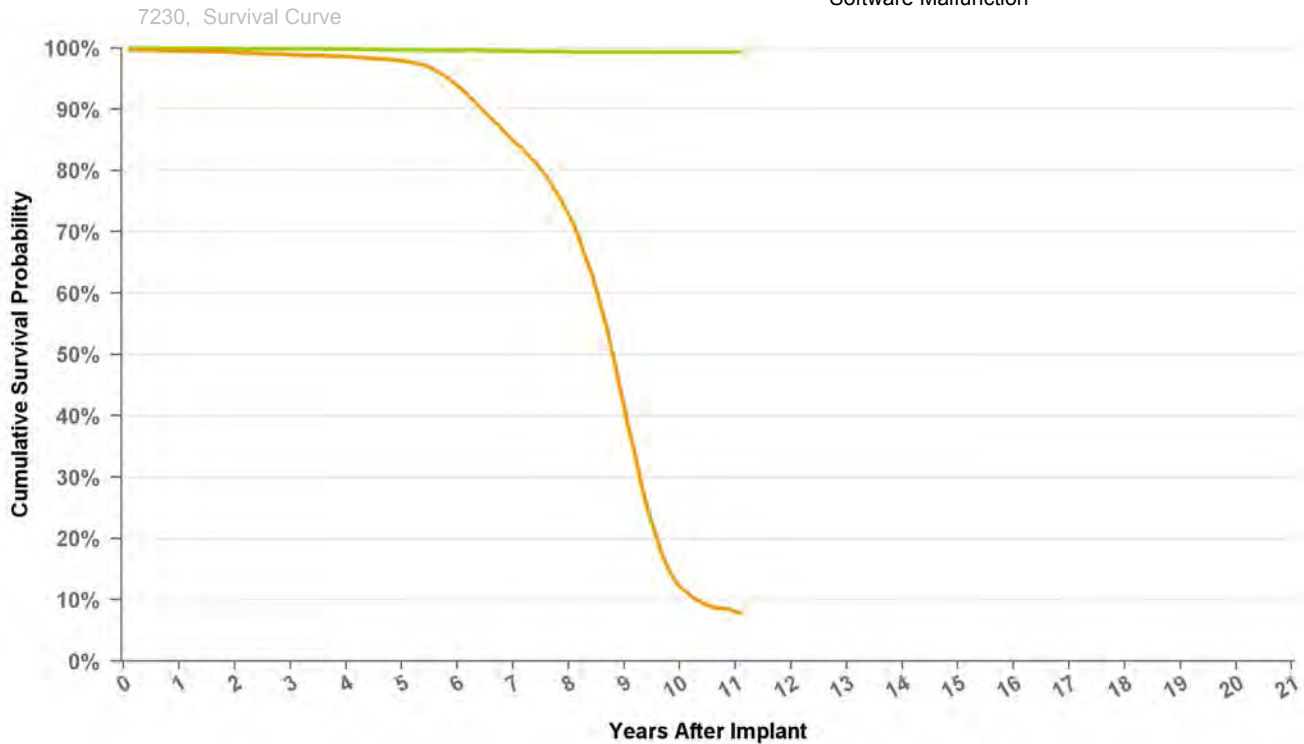
Implantable Cardioverter Defibrillator

7230E

Marquis VR

US Market Release Date	17-Dec-02
CE Market Approval Date	21-Aug-02
Registered US Implants	633
Estimated Active US Implants	43
Normal Battery Depletions (US)	78
NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	at 133 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.5%	99.3%	98.9%	98.6%	97.9%	93.8%	84.9%	72.9%	41.5%	12.2%	8.0%	7.8%
Effective Sample Size	16372	12670	10512	9395	8373	7289	6057	4821	2563	584	143	104

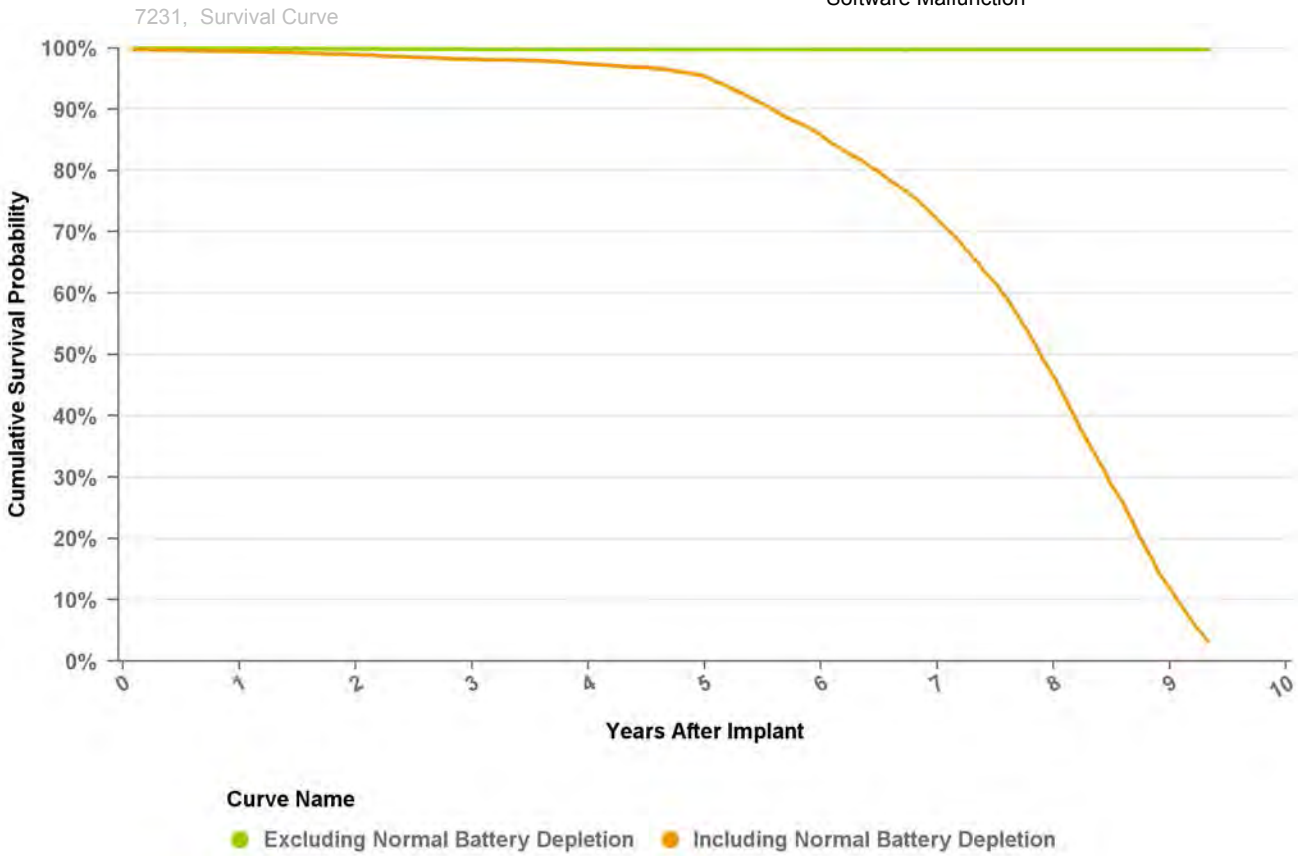
Implantable Cardioverter Defibrillator

7231Cx

GEM III VR

US Market Release Date	12-Dec-00
CE Market Approval Date	8-Dec-00
Registered US Implants	17,492
Estimated Active US Implants	1,043
Normal Battery Depletions (US)	3,966
NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	35
Therapy Not Compromised Malfunctions	25
Battery Malfunction	1
Electrical Component	20
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



Years	1	2	3	4	5	6	7	8	9	at 112 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	99.4%	98.9%	98.2%	97.4%	95.4%	85.7%	72.1%	46.5%	11.9%	3.2%
Effective Sample Size	14722	13120	11561	10125	8765	7182	5500	3181	680	180

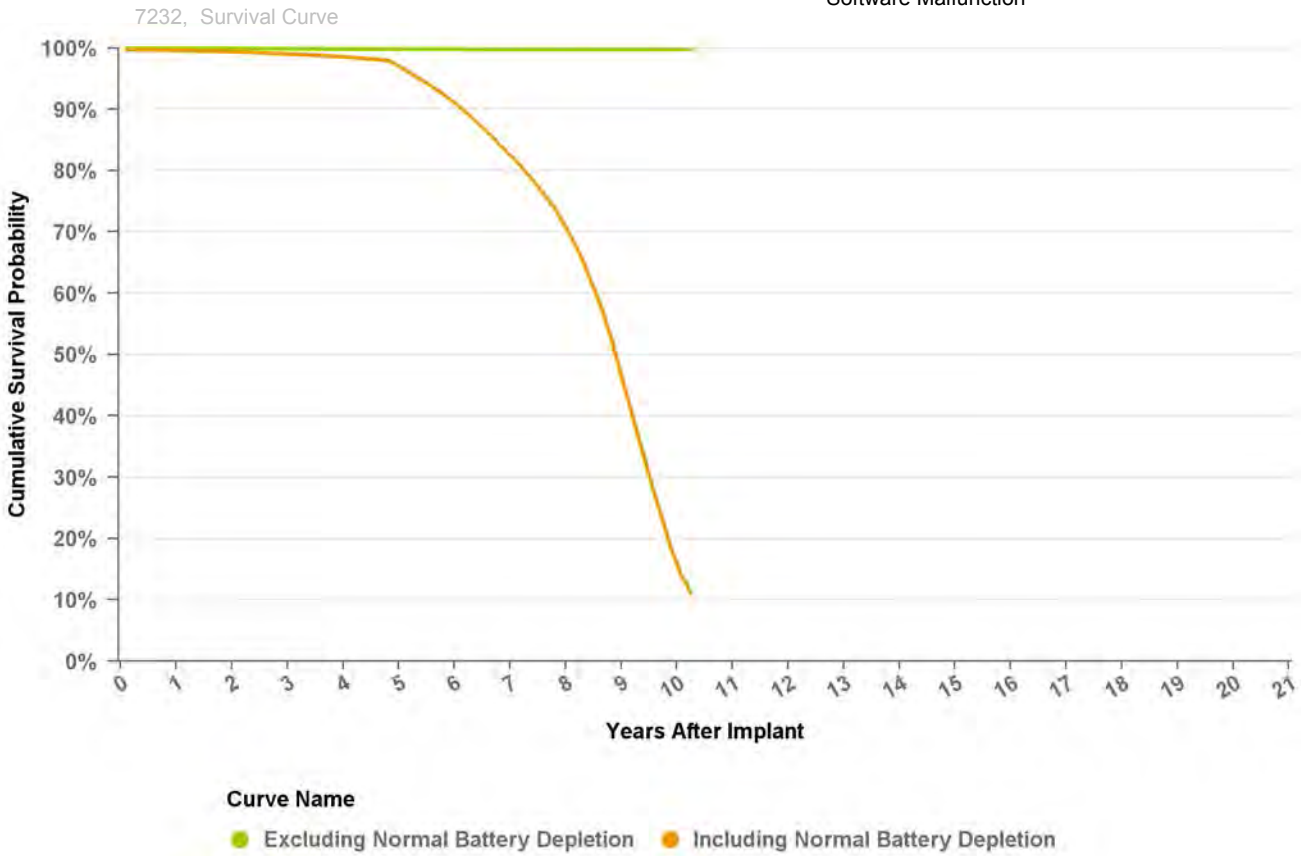
Implantable Cardioverter Defibrillator

7232B

Maximo VR

US Market Release Date	6-Oct-03
CE Market Approval Date	22-Oct-04
Registered US Implants	170
Estimated Active US Implants	46
Normal Battery Depletions (US)	25
NBG Code	VVE-VVIR
Max Delivered Energy	35J

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



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.6%	99.4%	99.0%	98.6%	97.1%	91.1%	82.6%	70.8%	46.7%	16.1%	11.1%
Effective Sample Size	37959	34054	30437	26878	23672	20488	17151	13245	7407	1241	327

Implantable Cardioverter Defibrillator

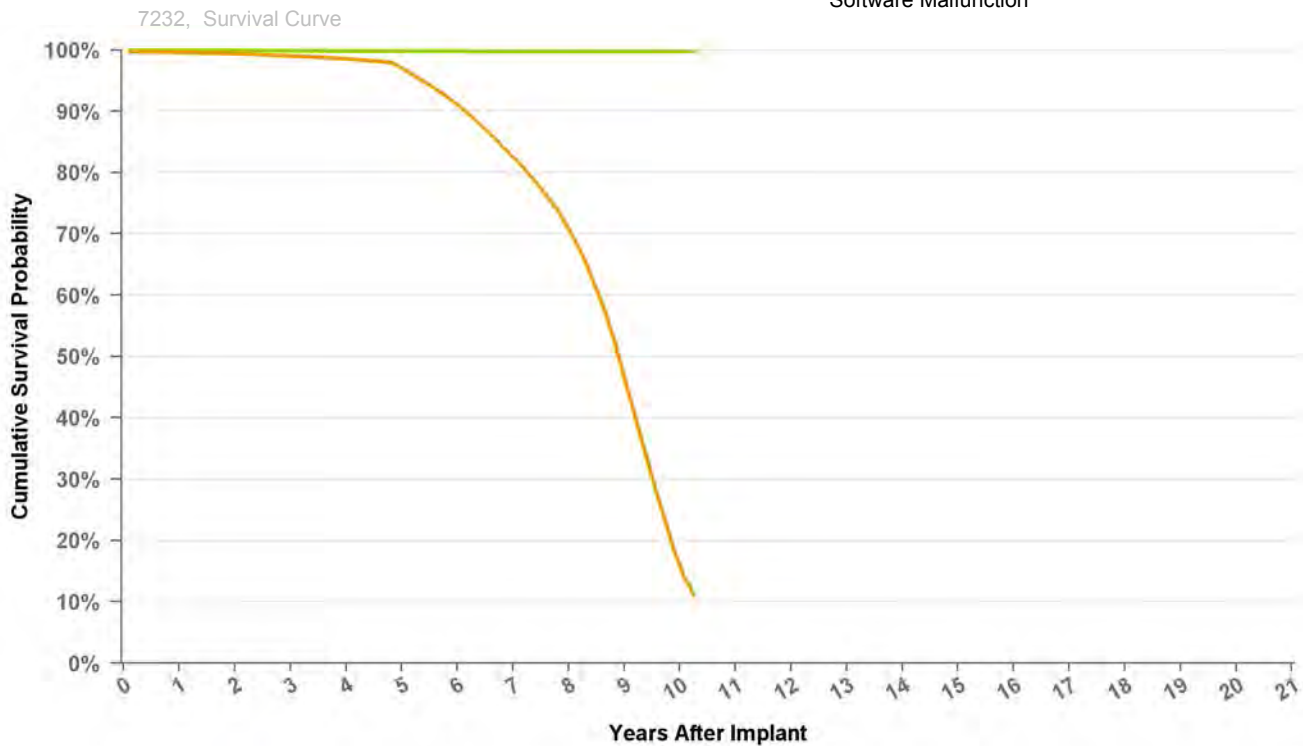
7232Cx

Maximo VR

US Market Release Date	6-Oct-03
CE Market Approval Date	28-Oct-03
Registered US Implants	43,670
Estimated Active US Implants	7,157
Normal Battery Depletions (US)	9,298

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	76
Therapy Not Compromised Malfunctions	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



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%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.6%	99.4%	99.0%	98.6%	97.1%	91.1%	82.6%	70.8%	46.7%	16.1%	11.1%
Effective Sample Size	37959	34054	30437	26878	23672	20488	17151	13245	7407	1241	327

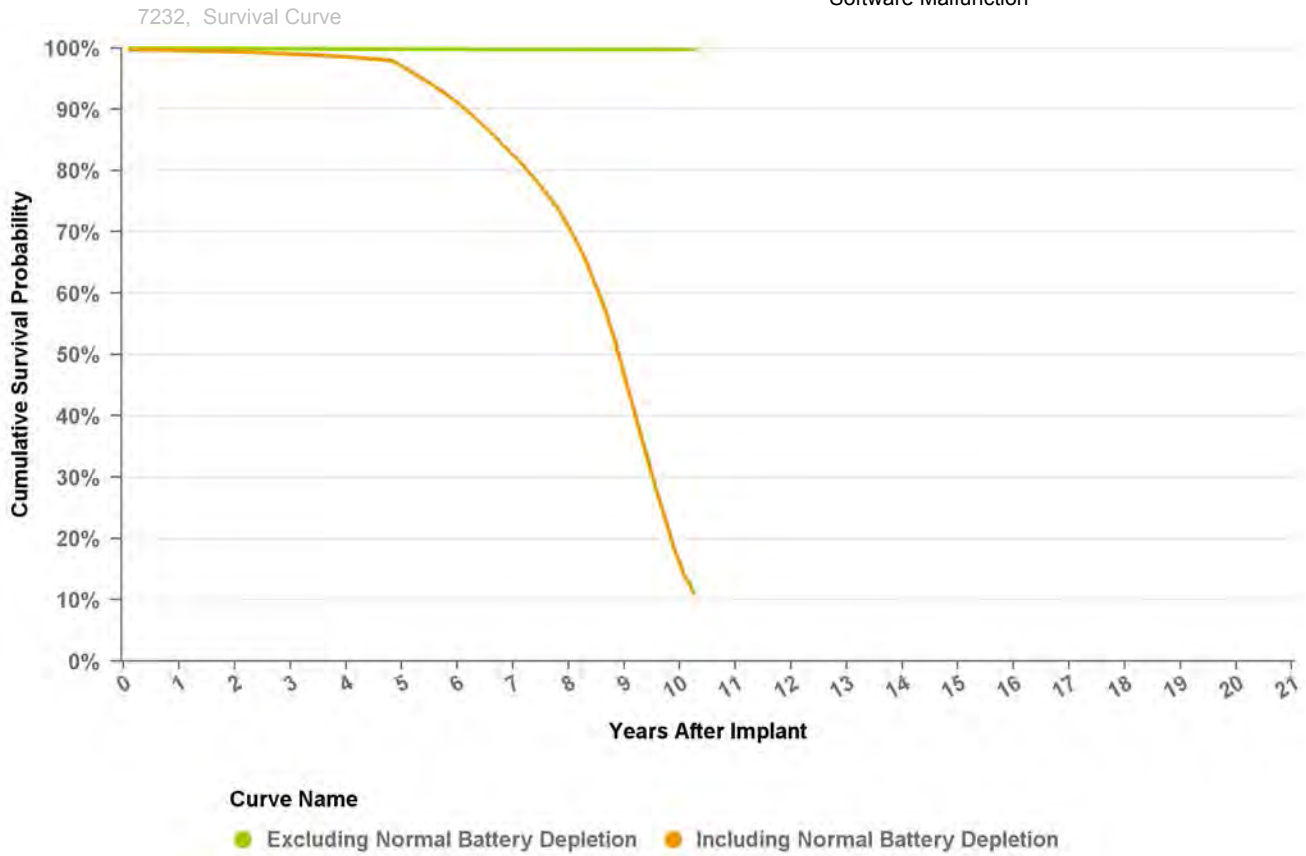
Implantable Cardioverter Defibrillator

7232E

Maximo VR

US Market Release Date	6-Oct-03
CE Market Approval Date	22-Oct-04
Registered US Implants	491
Estimated Active US Implants	120
Normal Battery Depletions (US)	57
NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.6%	99.4%	99.0%	98.6%	97.1%	91.1%	82.6%	70.8%	46.7%	16.1%	11.1%
Effective Sample Size	37959	34054	30437	26878	23672	20488	17151	13245	7407	1241	327

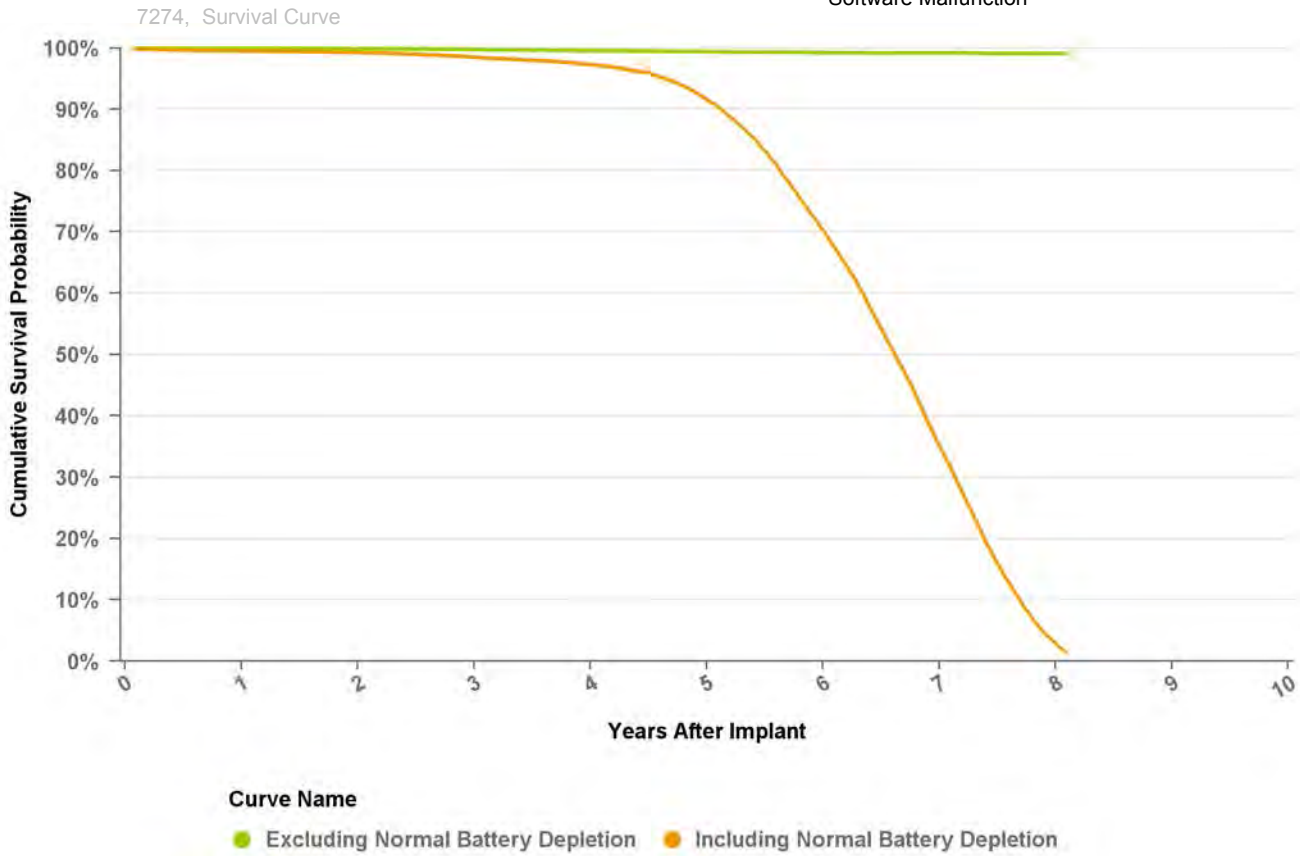
Implantable Cardioverter Defibrillator

7274

Marquis DR

US Market Release Date	1-Mar-02
CE Market Approval Date	25-Feb-02
Registered US Implants	48,251
Estimated Active US Implants	1,911
Normal Battery Depletions (US)	9,091
NBG Code	VVE-DDDR
Max Delivered Energy	30J

Total Malfunctions (US)	196
Therapy Not Compromised Malfunctions	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



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.2%	99.2%	99.1%	99.1%
Including NBD	99.5%	99.3%	98.5%	97.3%	91.6%	70.4%	35.2%	2.9%	1.4%
Effective Sample Size	41305	33095	25308	21431	17718	12020	5286	366	217

Implantable Cardioverter Defibrillator

7278

Maximo DR

Total Malfunctions (US)	72
Therapy Not Compromised Malfunctions	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

US Market Release Date 6-Oct-03

CE Market Approval Date 28-Oct-03

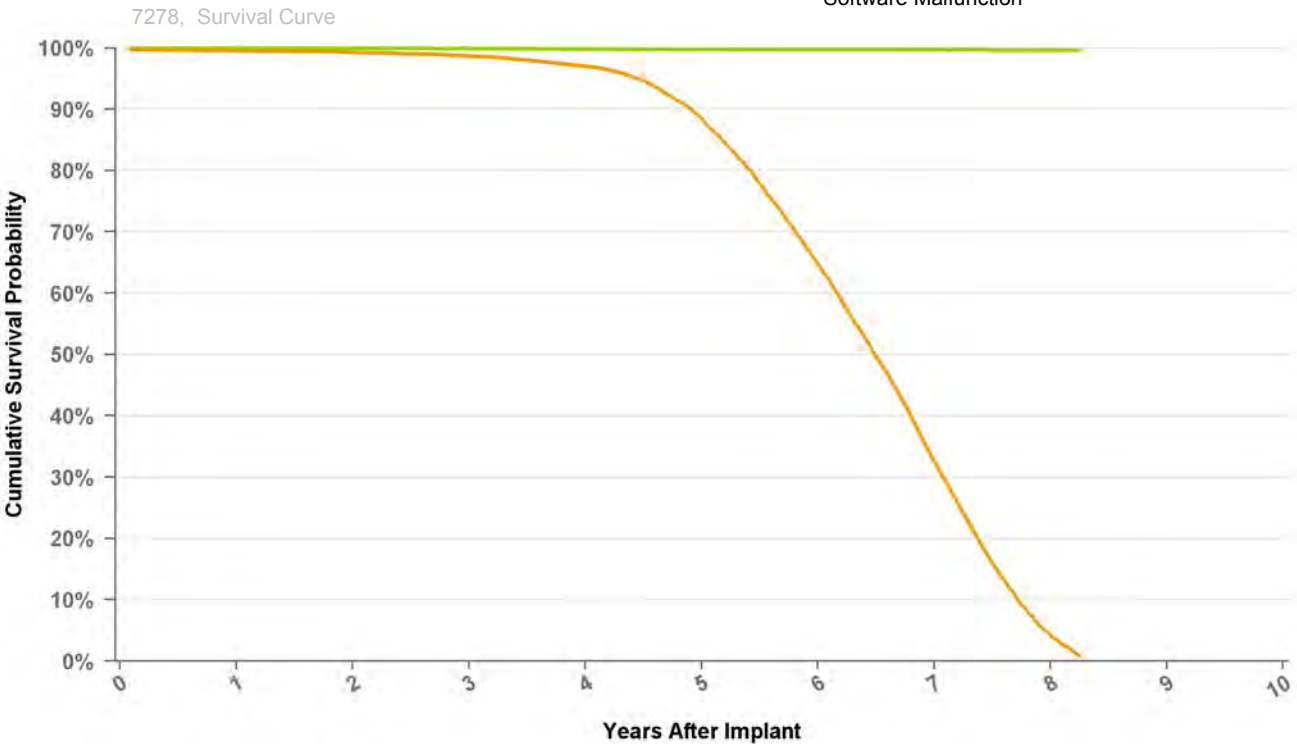
Registered US Implants 37,648

Estimated Active US Implants 2,949

Normal Battery Depletions (US) 10,683

NBG Code VVE-DDDR

Max Delivered Energy 35J



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%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.6%	99.3%	98.7%	97.0%	88.5%	64.8%	32.6%	4.1%	0.8%
Effective Sample Size	32551	29089	26049	22890	18893	12515	5559	562	131

Implantable Cardioverter Defibrillator

7288

Intrinsic

Total Malfunctions (US)

72

Therapy Not Compromised Malfunctions

65

Battery Malfunction 2

Electrical Component 28

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

US Market Release Date 21-Jun-04

CE Market Approval Date 4-May-04

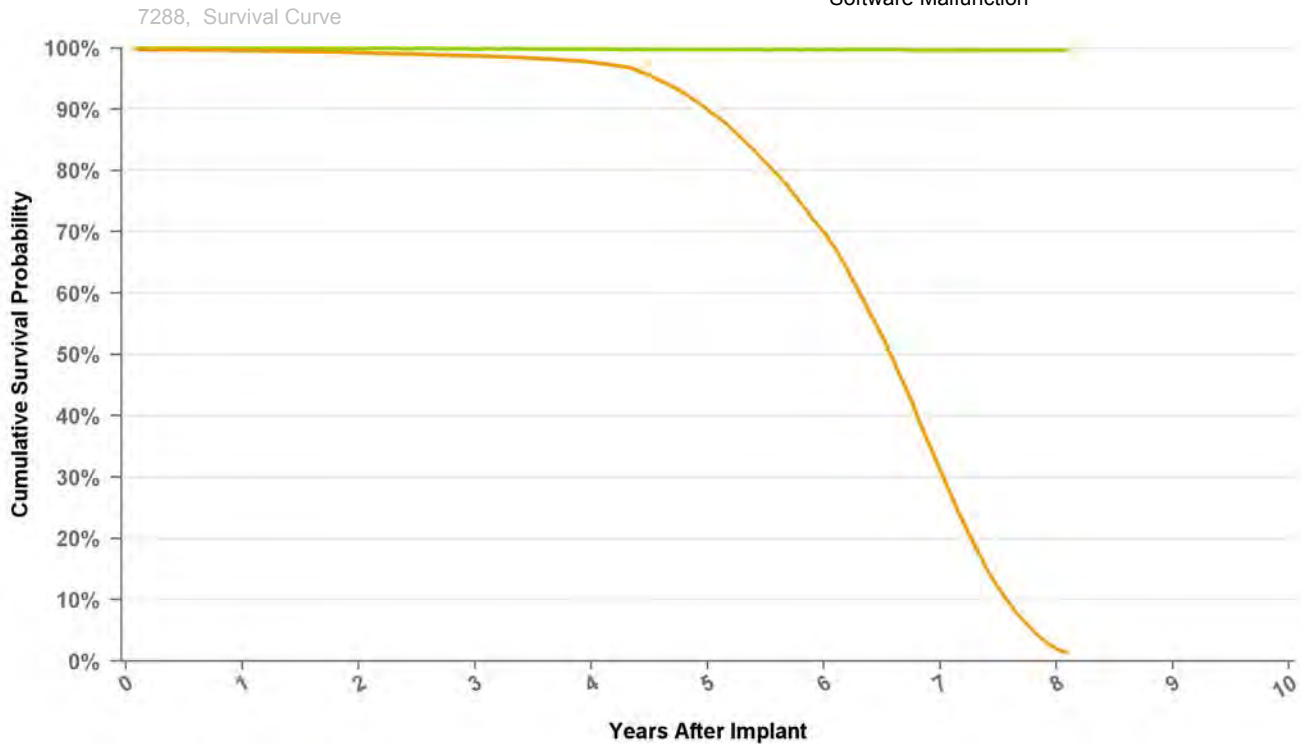
Registered US Implants 30,652

Estimated Active US Implants 2,105

Normal Battery Depletions (US) 10,080

NBG Code VVE-DDDR

Max Delivered Energy 35J



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

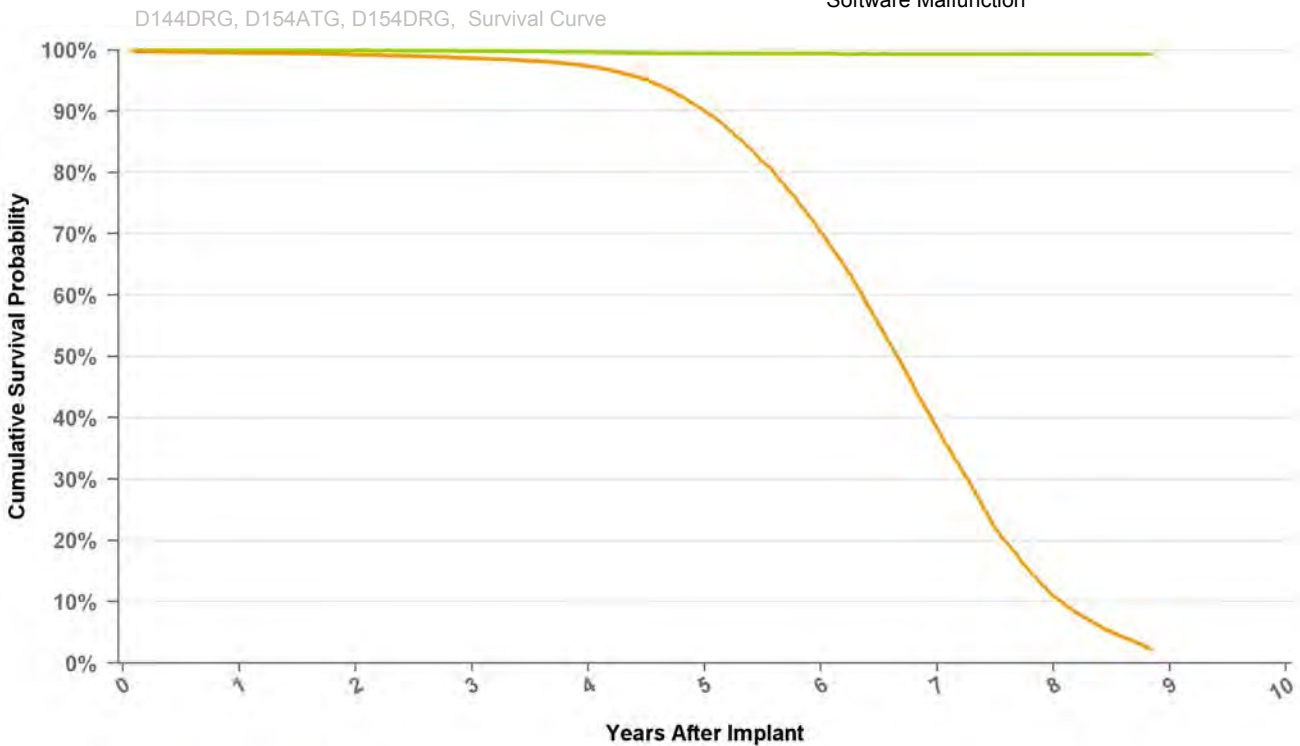
Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%
Including NBD	99.6%	99.2%	98.7%	97.7%	89.9%	70.0%	31.2%	1.9%	1.4%
Effective Sample Size	27051	24804	22342	19697	16553	11775	4934	268	154

Implantable Cardioverter Defibrillator

D144DRG Entrust Escudo

US Market Release Date	
CE Market Approval Date	5-Jun-08
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 Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

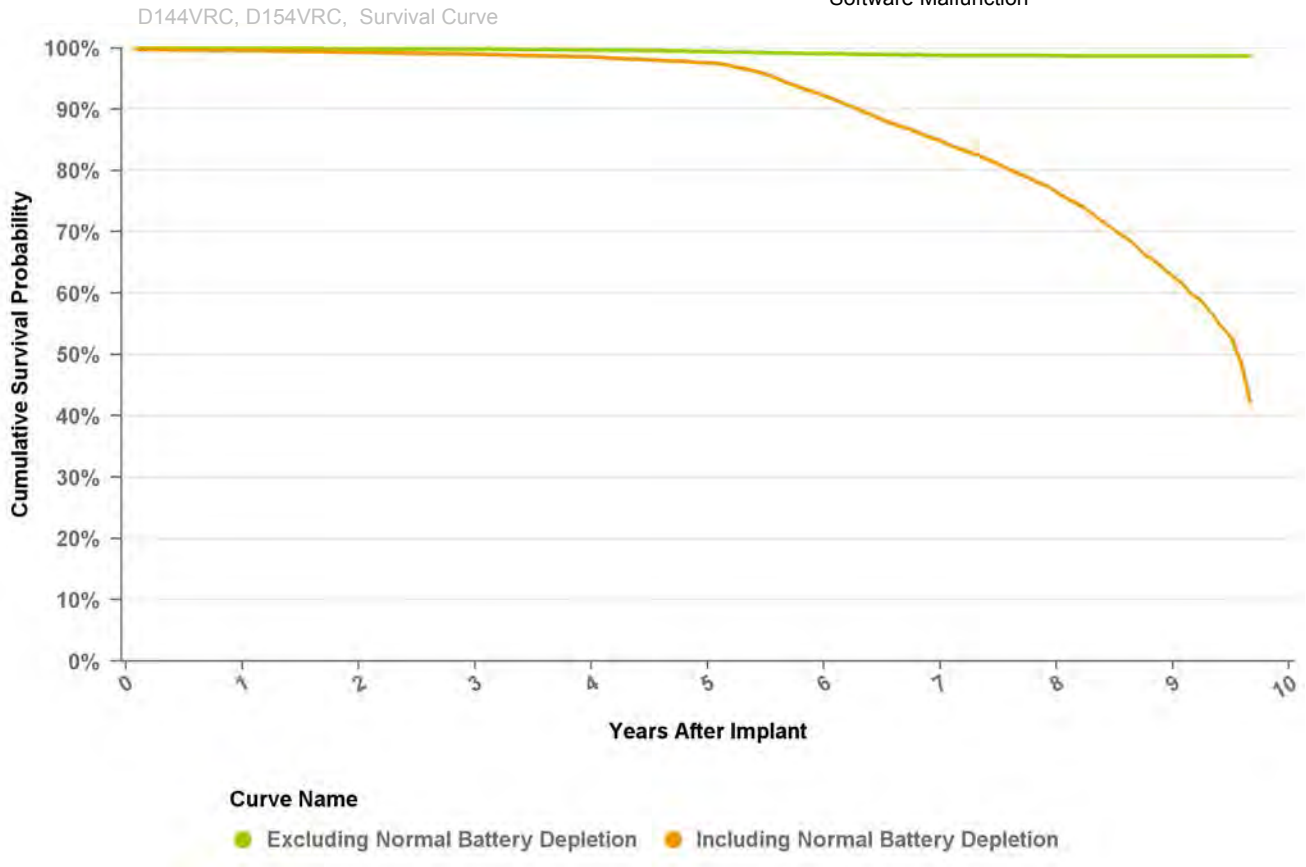
Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%
Including NBD	99.5%	99.2%	98.7%	97.3%	90.1%	70.4%	38.3%	10.9%	2.2%
Effective Sample Size	24747	22634	20338	17951	14881	10827	5377	1231	102

Implantable Cardioverter Defibrillator

D144VRC Entrust Escudo

US Market Release Date	
CE Market Approval Date	5-Jun-08
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



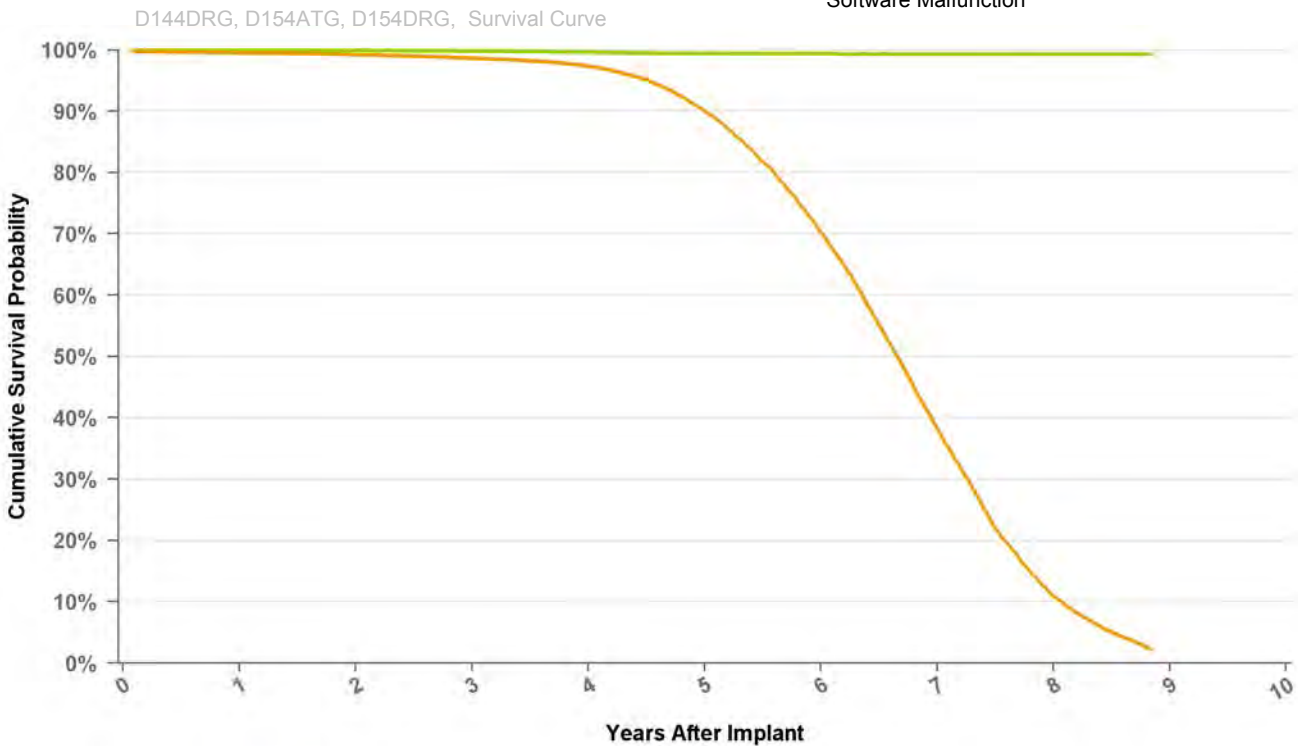
Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.6%	99.3%	99.0%	98.6%	97.6%	92.2%	84.9%	76.4%	62.8%	42.4%
Effective Sample Size	12560	11419	10212	9025	7960	6966	5977	4709	2766	296

Implantable Cardioverter Defibrillator

D154ATG Entrust AT

US Market Release Date	30-Jun-05
CE Market Approval Date	4-Feb-05
Registered US Implants	28,154
Estimated Active US Implants	2,626
Normal Battery Depletions (US)	8,844
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	125
Therapy Not Compromised Malfunctions	109
Battery Malfunction	0
Electrical Component	30
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	74
Software Malfunction	3
Therapy Compromised Malfunctions	16
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

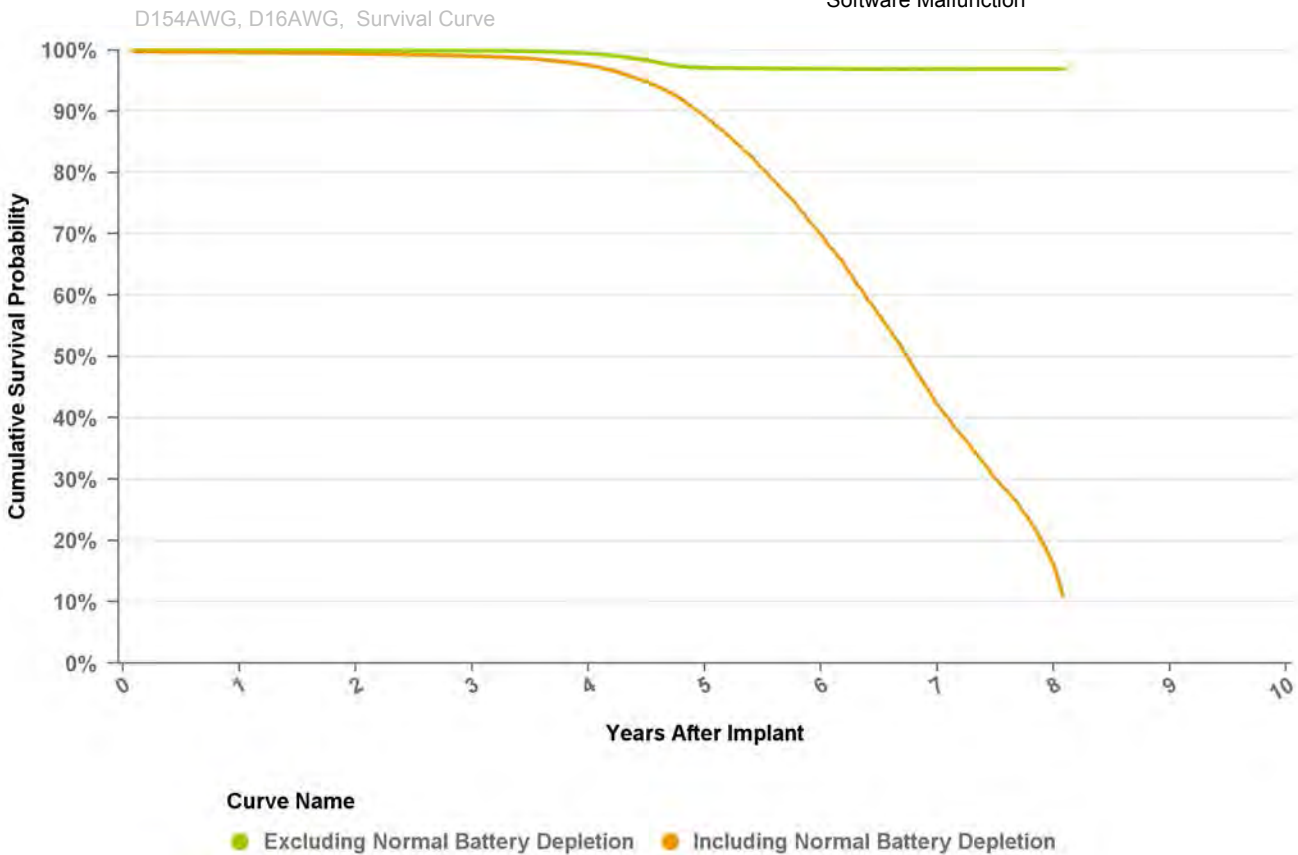
Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%
Including NBD	99.5%	99.2%	98.7%	97.3%	90.1%	70.4%	38.3%	10.9%	2.2%
Effective Sample Size	24747	22634	20338	17951	14881	10827	5377	1231	102

Implantable Cardioverter Defibrillator

D154AWG Virtuoso DR

US Market Release Date	12-May-06
CE Market Approval Date	
Registered US Implants	72,679
Estimated Active US Implants	17,961
Normal Battery Depletions (US)	17,132
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,455
Therapy Not Compromised Malfunctions	1,426
Battery Malfunction	6
Electrical Component	1,278
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	132
Software Malfunction	4
Therapy Compromised Malfunctions	29
Battery Malfunction	0
Electrical Component	26
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	1
Software Malfunction	0



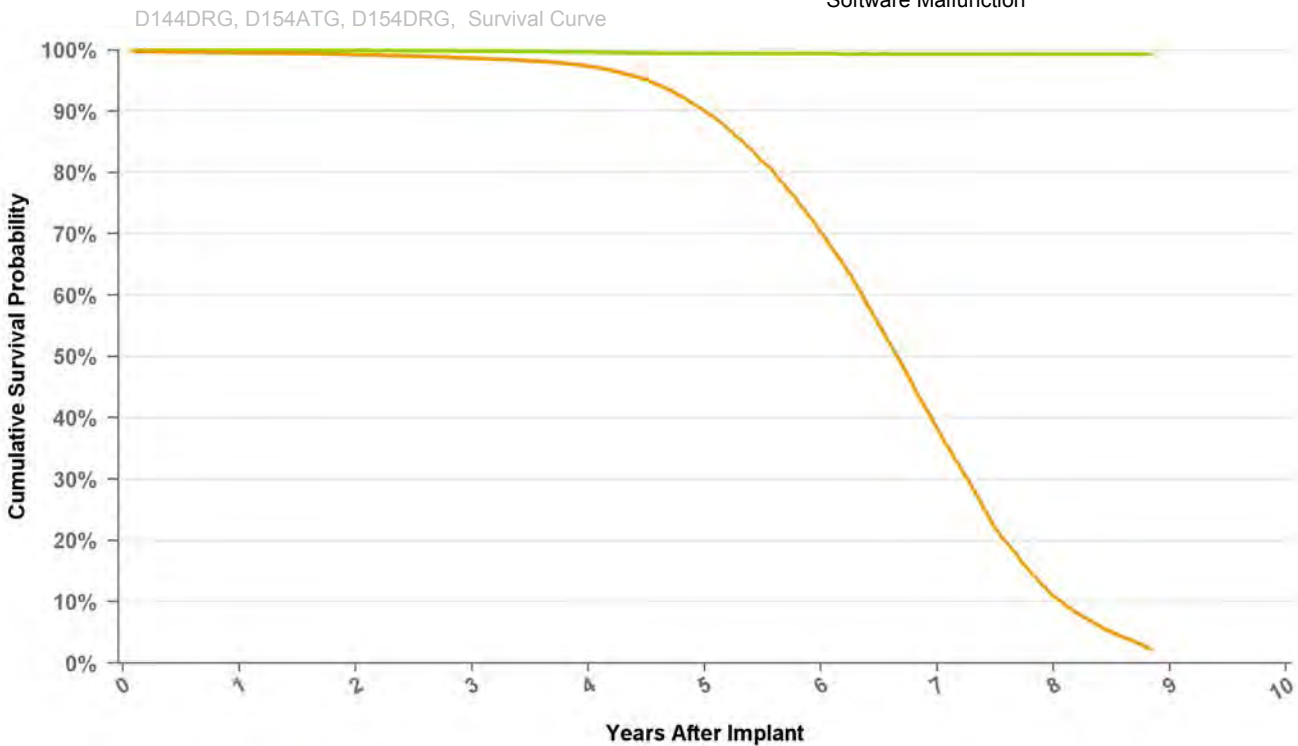
Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.9%
Including NBD	99.6%	99.4%	99.0%	97.5%	89.2%	69.9%	42.2%	16.2%	11.0%
Effective Sample Size	63042	57891	52794	47982	40761	29506	12222	1008	398

Implantable Cardioverter Defibrillator

D154DRG Entrust DR

US Market Release Date	14-Jun-05
CE Market Approval Date	4-Feb-05
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 Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

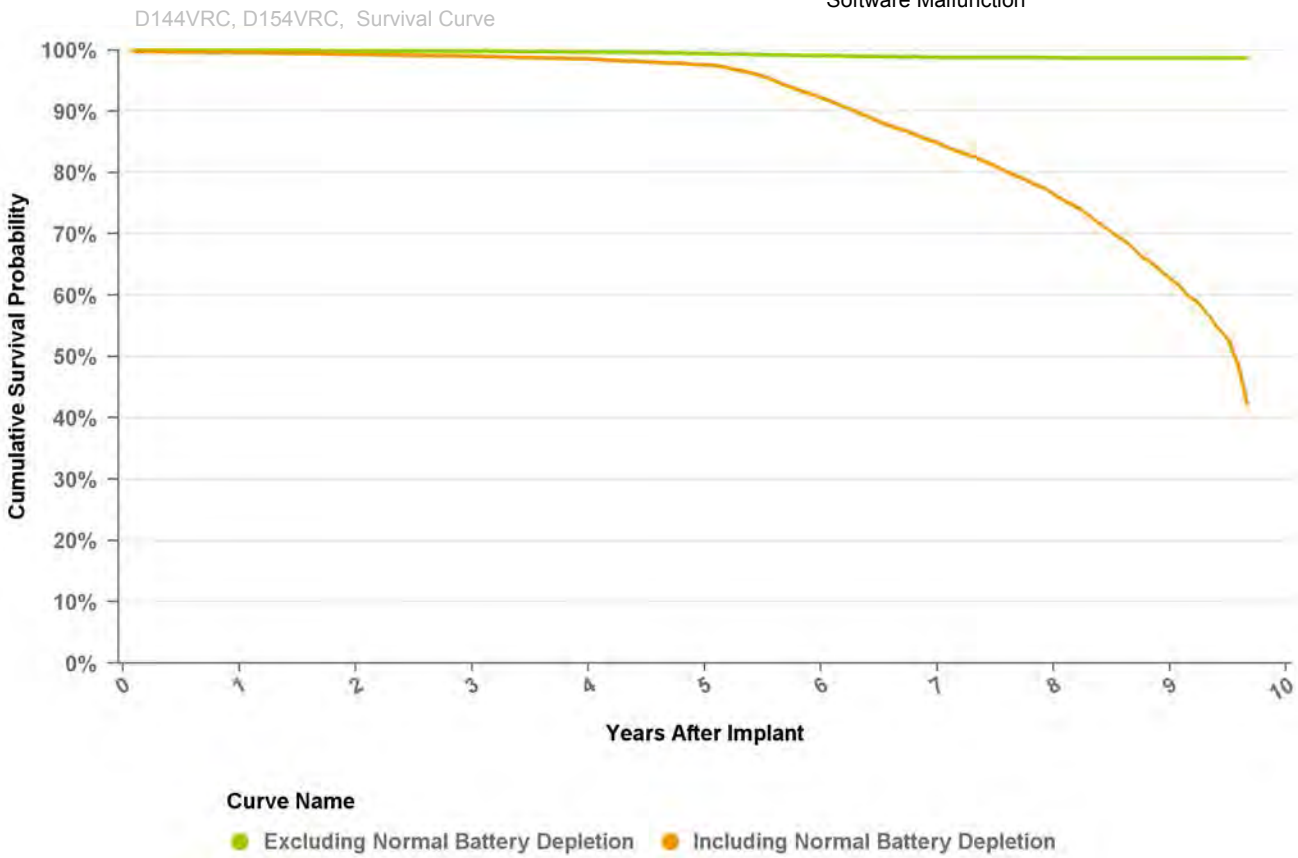
Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%
Including NBD	99.5%	99.2%	98.7%	97.3%	90.1%	70.4%	38.3%	10.9%	2.2%
Effective Sample Size	24747	22634	20338	17951	14881	10827	5377	1231	102

Implantable Cardioverter Defibrillator

D154VRC Entrust VR

US Market Release Date	30-Jun-05
CE Market Approval Date	4-Feb-05
Registered US Implants	14,463
Estimated Active US Implants	4,498
Normal Battery Depletions (US)	1,805
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	111
Therapy Not Compromised Malfunctions	89
Battery Malfunction	11
Electrical Component	44
Electrical Interconnect	0
Other Malfunction	10
Poss Early Battery Depltn	24
Software Malfunction	0
Therapy Compromised Malfunctions	22
Battery Malfunction	1
Electrical Component	20
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



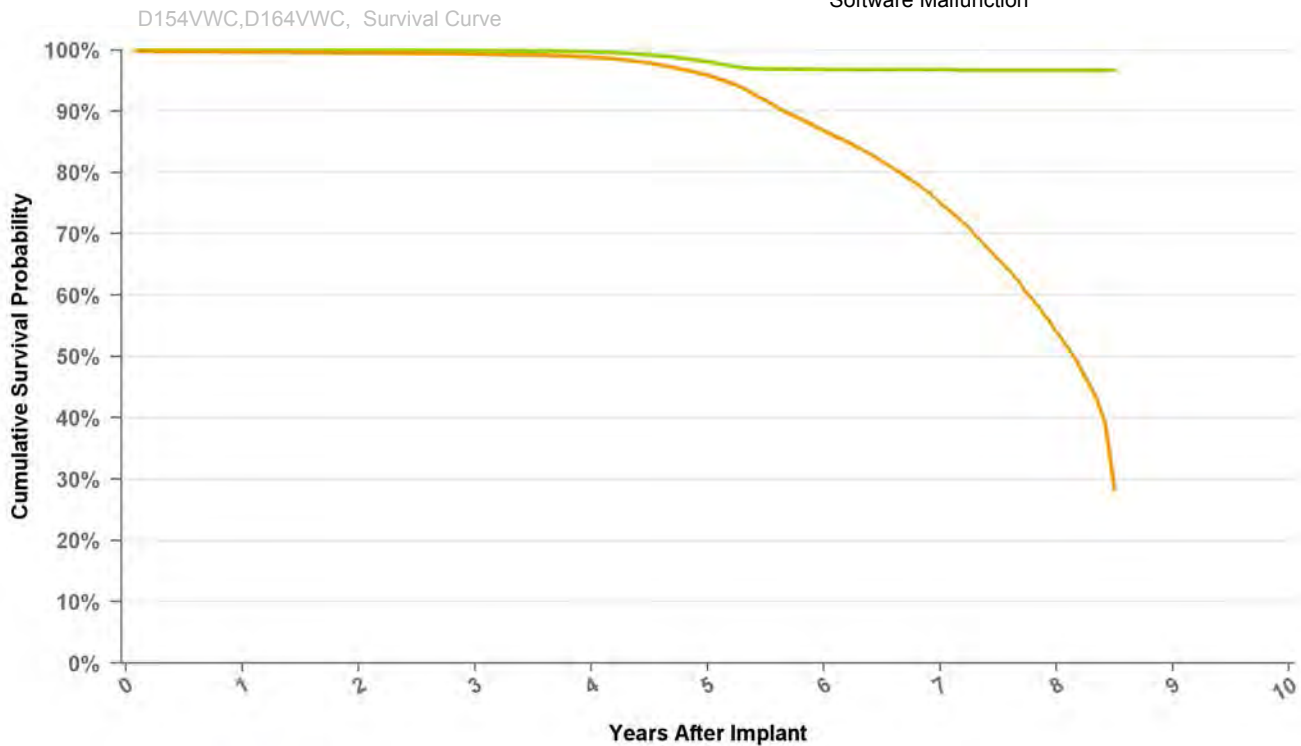
Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.6%	99.3%	99.0%	98.6%	97.6%	92.2%	84.9%	76.4%	62.8%	42.4%
Effective Sample Size	12560	11419	10212	9025	7960	6966	5977	4709	2766	296

Implantable Cardioverter Defibrillator

D154VWC Virtuoso VR

US Market Release Date	12-May-06
CE Market Approval Date	
Registered US Implants	33,128
Estimated Active US Implants	12,855
Normal Battery Depletions (US)	3,871
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	670
Therapy Not Compromised Malfunctions	654
Battery Malfunction	5
Electrical Component	629
Electrical Interconnect	1
Other Malfunction	4
Poss Early Battery Depltn	15
Software Malfunction	0
Therapy Compromised Malfunctions	16
Battery Malfunction	1
Electrical Component	15
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



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%	99.7%	98.1%	96.8%	96.8%	96.8%	96.8%
Including NBD	99.7%	99.5%	99.3%	98.8%	95.9%	86.8%	74.9%	54.0%	28.4%
Effective Sample Size	28453	25966	23673	21661	19242	16018	10331	2862	125

Implantable Cardioverter Defibrillator

D164AWG Virtuoso DR

US Market Release Date

CE Market Approval Date 7-Mar-06

Registered US Implants 11

Estimated Active US Implants 4

Normal Battery Depletions (US) 3

NBG Code DDE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

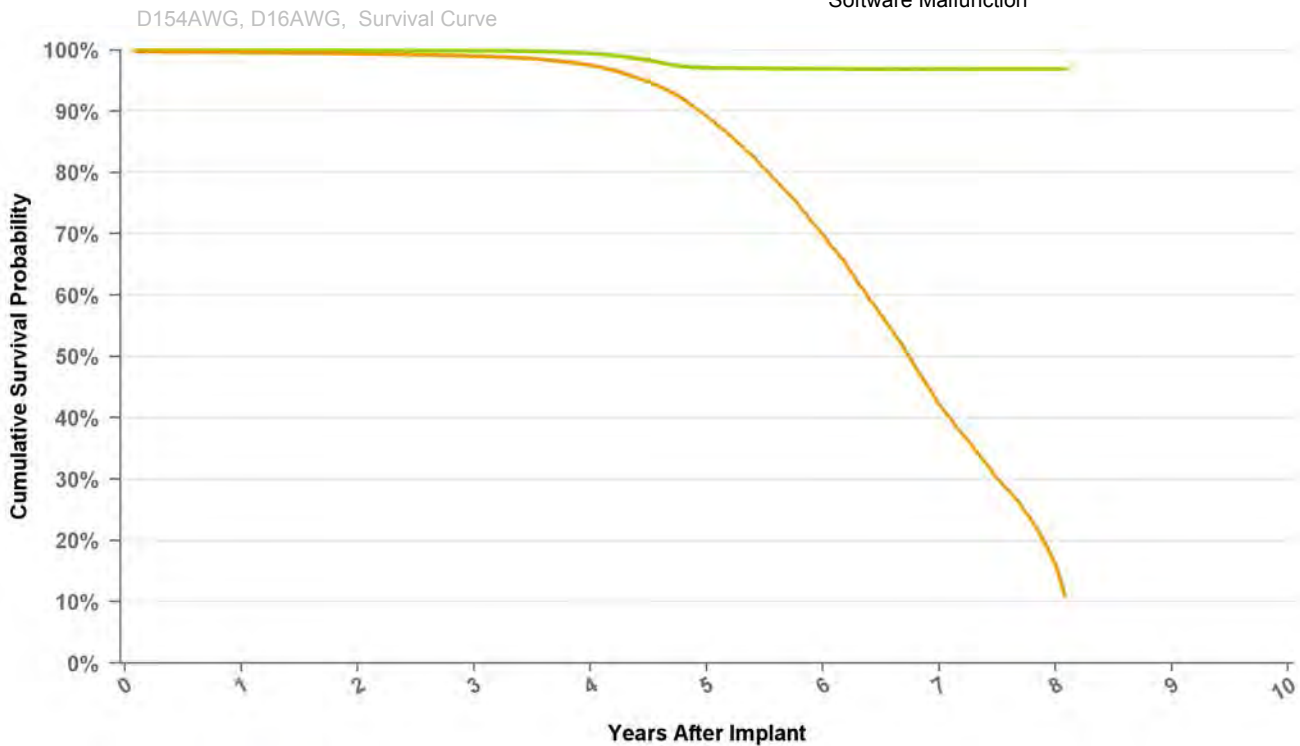
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

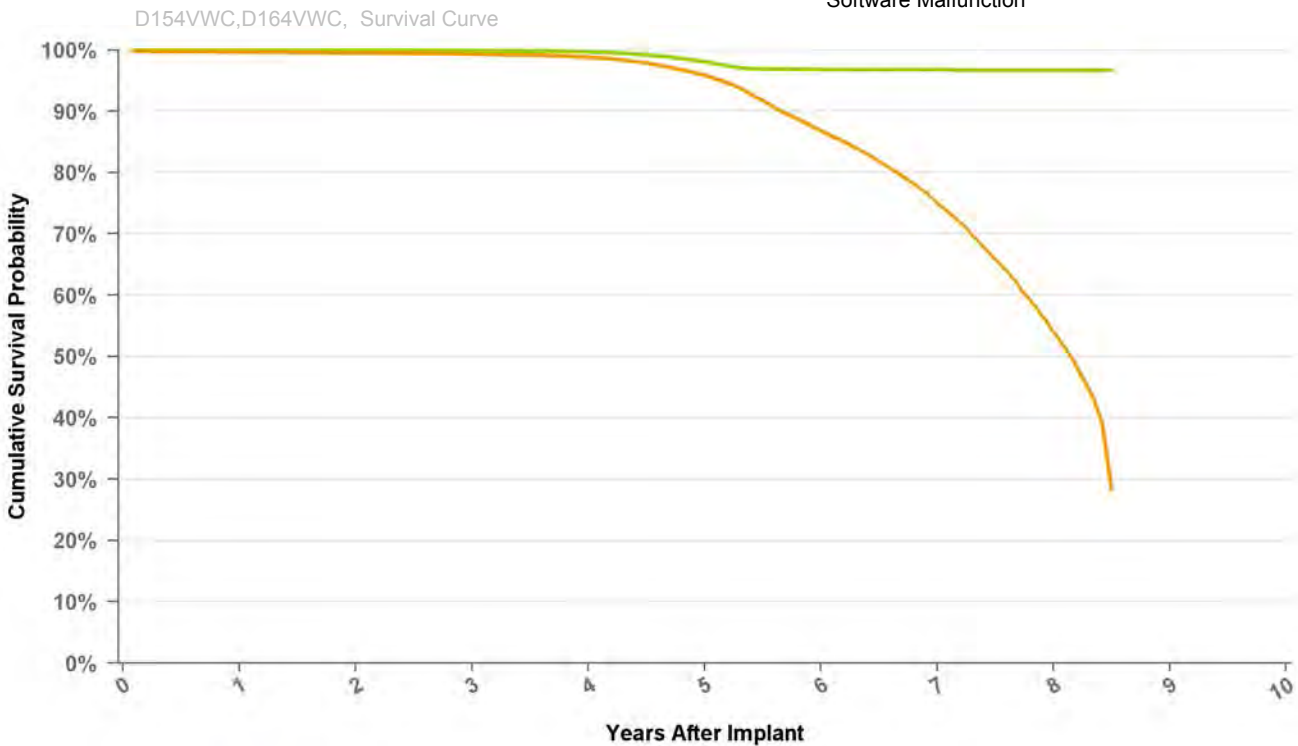
Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.9%
Including NBD	99.6%	99.4%	99.0%	97.5%	89.2%	69.9%	42.2%	16.2%	11.0%
Effective Sample Size	63042	57891	52794	47982	40761	29506	12222	1008	398

Implantable Cardioverter Defibrillator

D164VWC Virtuoso VR

US Market Release Date	
CE Market Approval Date	7-Mar-06
Registered US Implants	6
Estimated Active US Implants	3
Normal Battery Depletions (US)	0
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

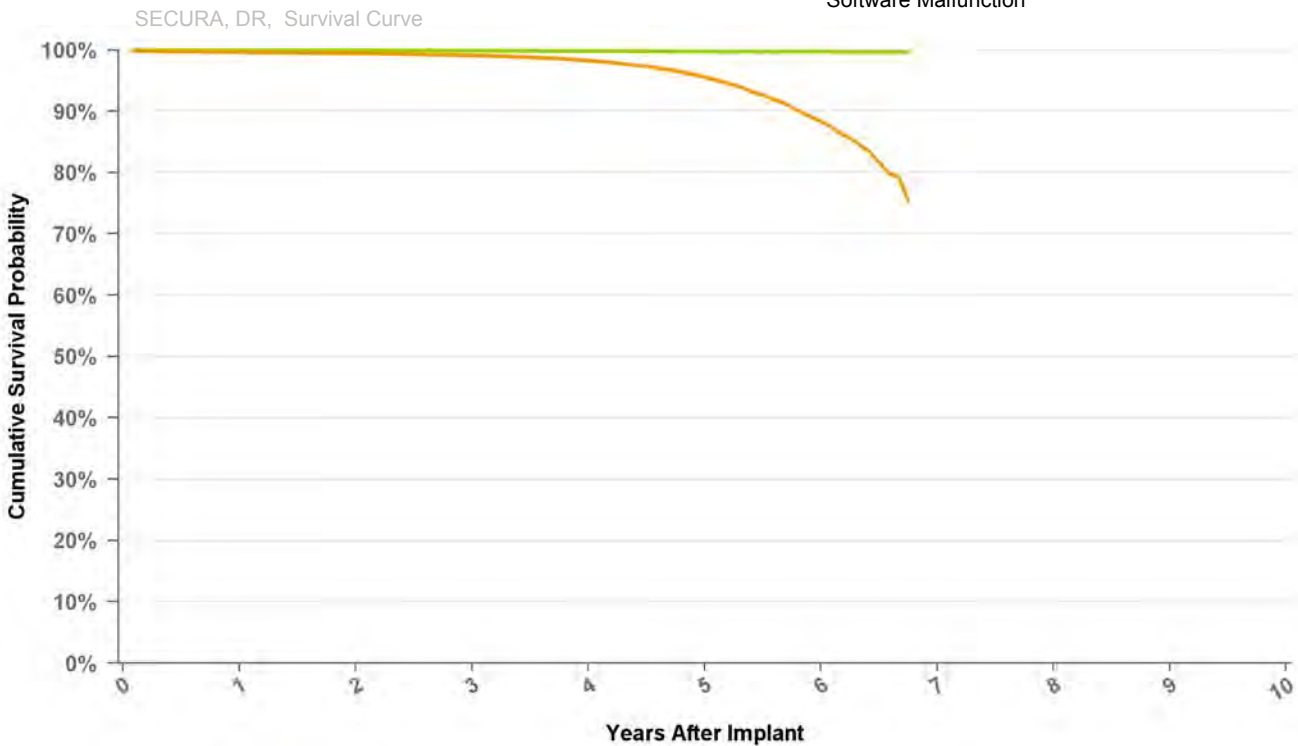
Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.8%	96.8%	96.8%	96.8%
Including NBD	99.7%	99.5%	99.3%	98.8%	95.9%	86.8%	74.9%	54.0%	28.4%
Effective Sample Size	28453	25966	23673	21661	19242	16018	10331	2862	125

Implantable Cardioverter Defibrillator

D204DRM Secura DR

US Market Release Date	9-Jan-12
CE Market Approval Date	
Registered US Implants	1,878
Estimated Active US Implants	1,642
Normal Battery Depletions (US)	2
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.4%	99.1%	98.3%	95.6%	88.3%	75.5%
Effective Sample Size	45095	41844	37236	31811	19947	6648	403

Implantable Cardioverter Defibrillator

D204VRM Secura VR

US Market Release Date 2-May-12

CE Market Approval Date

Registered US Implants 1,173

Estimated Active US Implants 1,032

Normal Battery Depletions (US) 0

NBG Code VVE-VVIR

Max Delivered Energy 35 J

Total Malfunctions (US) 1

Therapy Not Compromised Malfunctions 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

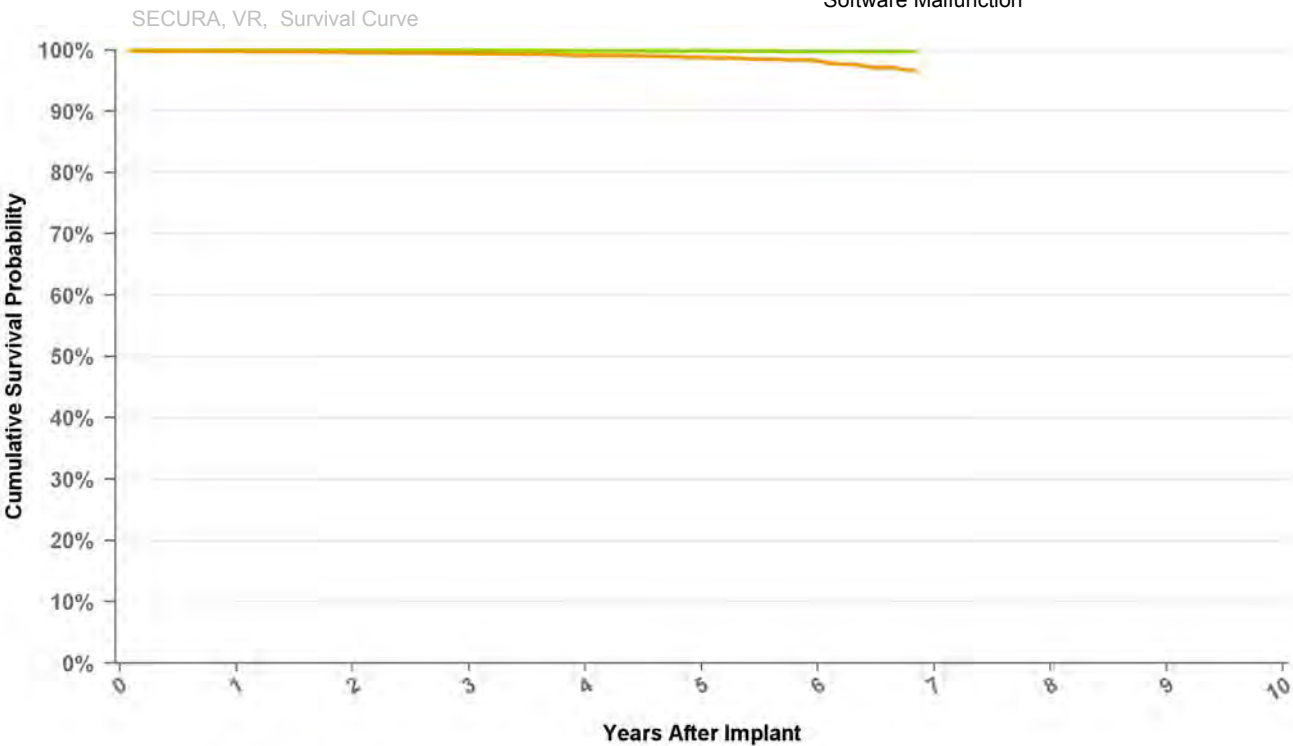
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.2%	96.7%
Effective Sample Size	18133	16724	14412	11961	7768	3164	208

Implantable Cardioverter Defibrillator

D214DRM Secura DR

US Market Release Date

CE Market Approval Date 22-Jul-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

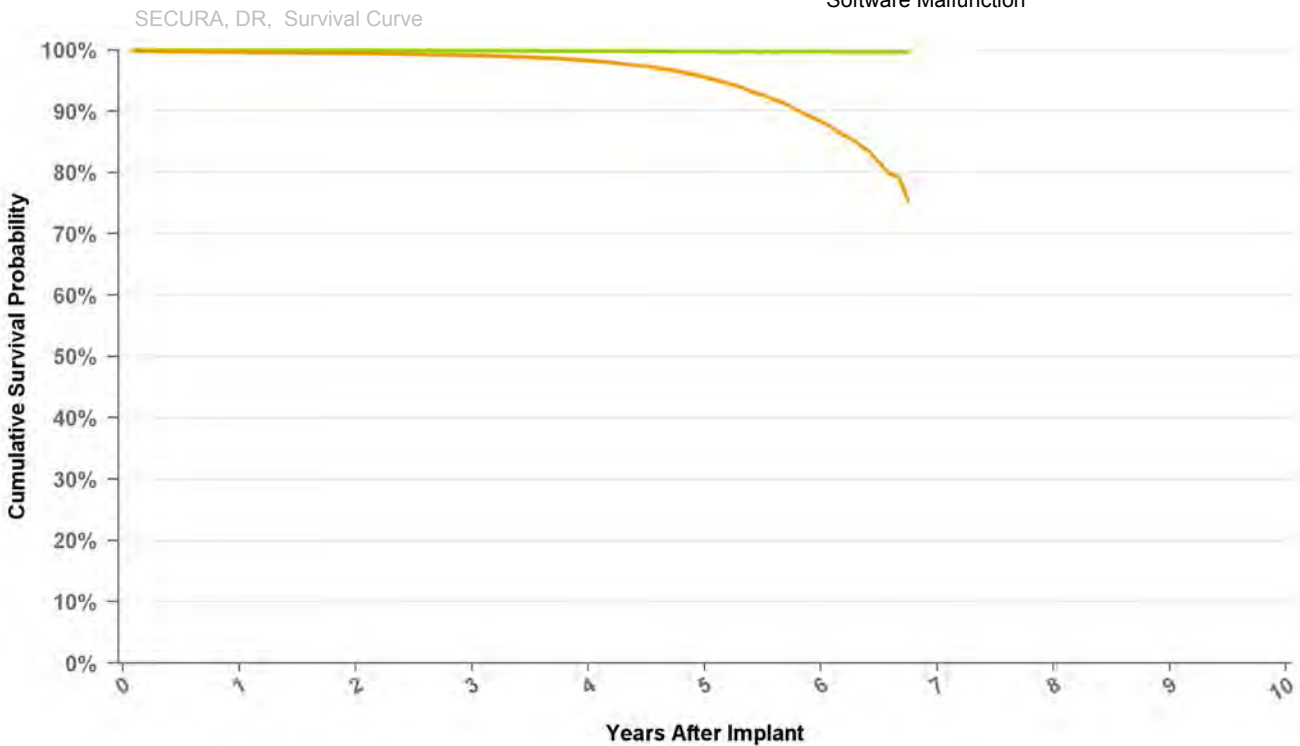
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

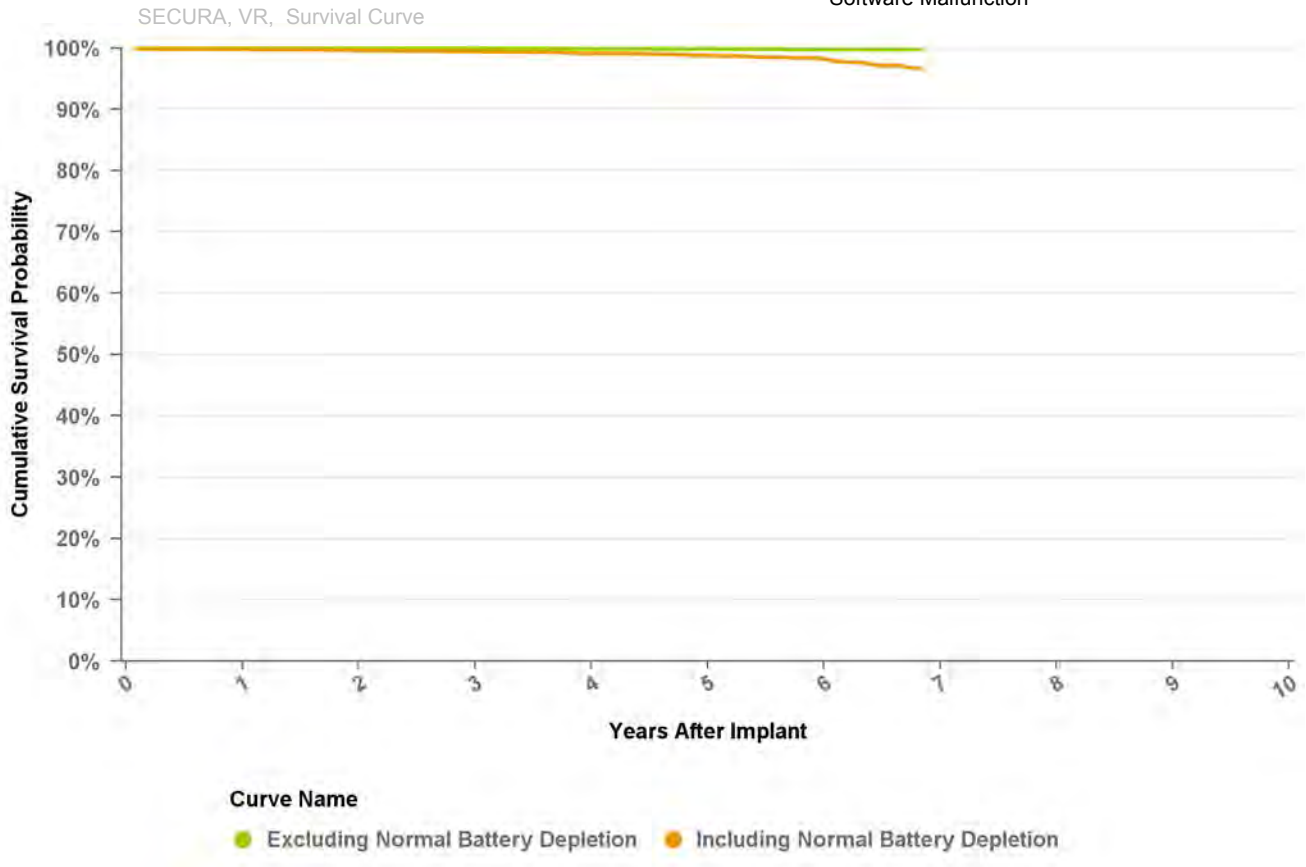
Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.4%	99.1%	98.3%	95.6%	88.3%	75.5%
Effective Sample Size	45095	41844	37236	31811	19947	6648	403

Implantable Cardioverter Defibrillator

D214VRM Secura VR

US Market Release Date	
CE Market Approval Date	17-Dec-10
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 Malfunctions	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



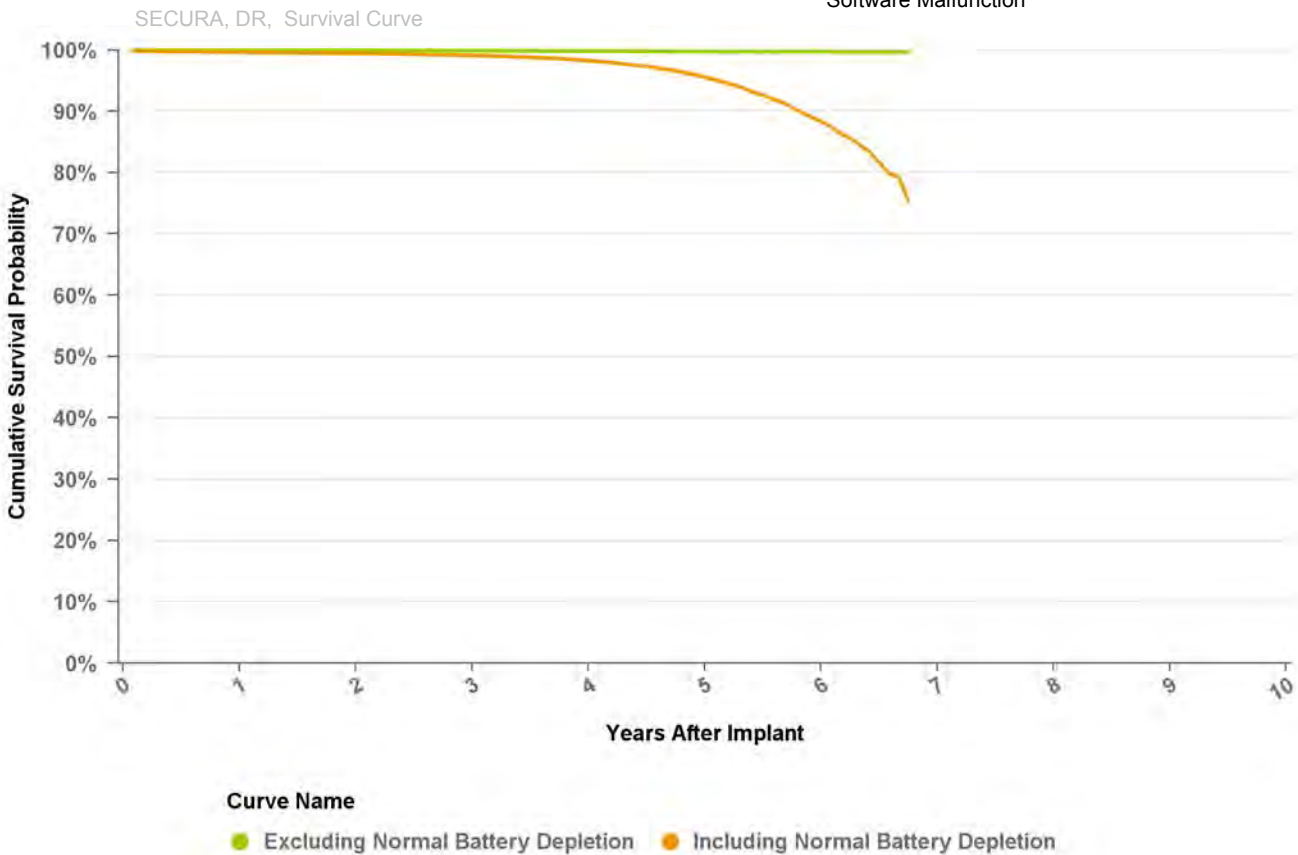
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.2%	96.7%
Effective Sample Size	18133	16724	14412	11961	7768	3164	208

Implantable Cardioverter Defibrillator

D224DRG Secura DR

US Market Release Date	15-Sep-08
CE Market Approval Date	
Registered US Implants	49,862
Estimated Active US Implants	32,352
Normal Battery Depletions (US)	1,610
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	103
Therapy Not Compromised Malfunctions	87
Battery Malfunction	2
Electrical Component	26
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	49
Software Malfunction	9
Therapy Compromised Malfunctions	16
Battery Malfunction	1
Electrical Component	13
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.4%	99.1%	98.3%	95.6%	88.3%	75.5%
Effective Sample Size	45095	41844	37236	31811	19947	6648	403

Implantable Cardioverter Defibrillator

D224VRC Secura VR

US Market Release Date 15-Sep-08

CE Market Approval Date

Registered US Implants 19,944

Estimated Active US Implants 14,032

Normal Battery Depletions (US) 105

NBG Code VVE-VVIR

Max Delivered Energy 35 J

Total Malfunctions (US) 28

Therapy Not Compromised Malfunctions 22

Battery Malfunction 5

Electrical Component 6

Electrical Interconnect 0

Other Malfunction 1

Poss Early Battery Depltn 8

Software Malfunction 2

Therapy Compromised Malfunctions 6

Battery Malfunction 0

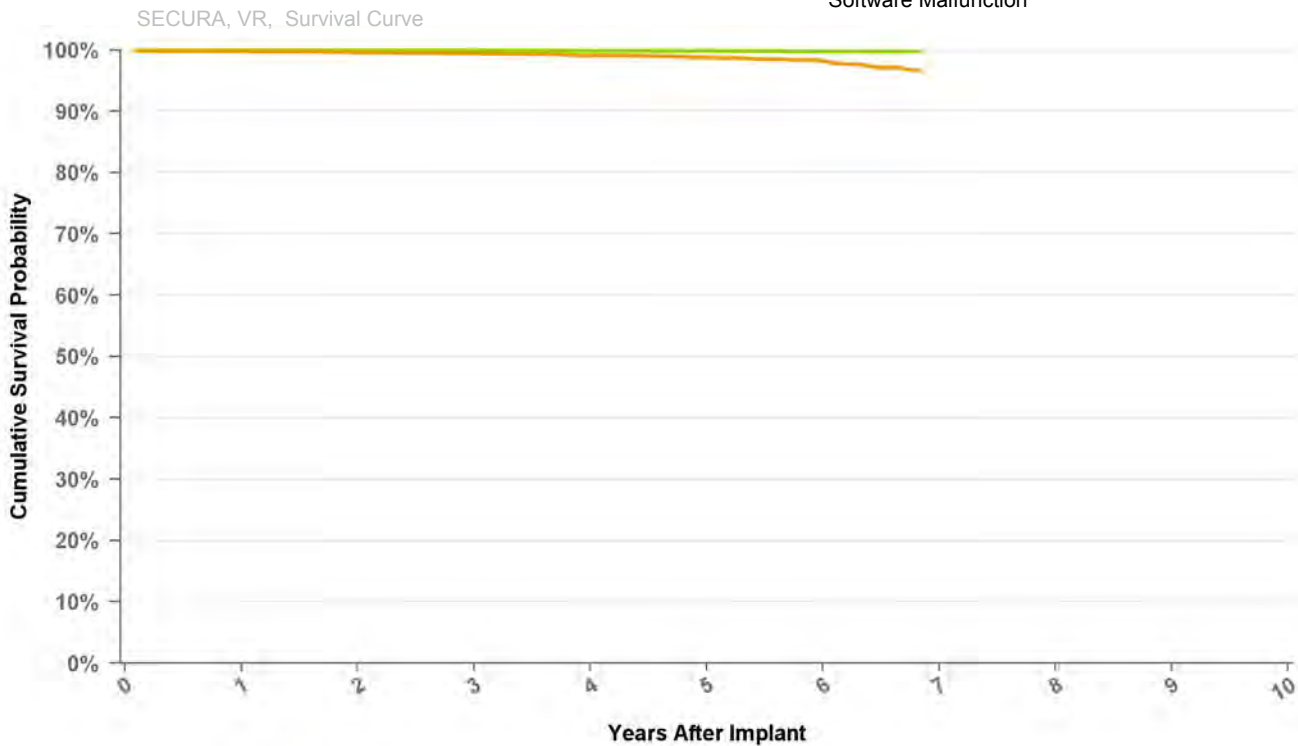
Electrical Component 5

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 1



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

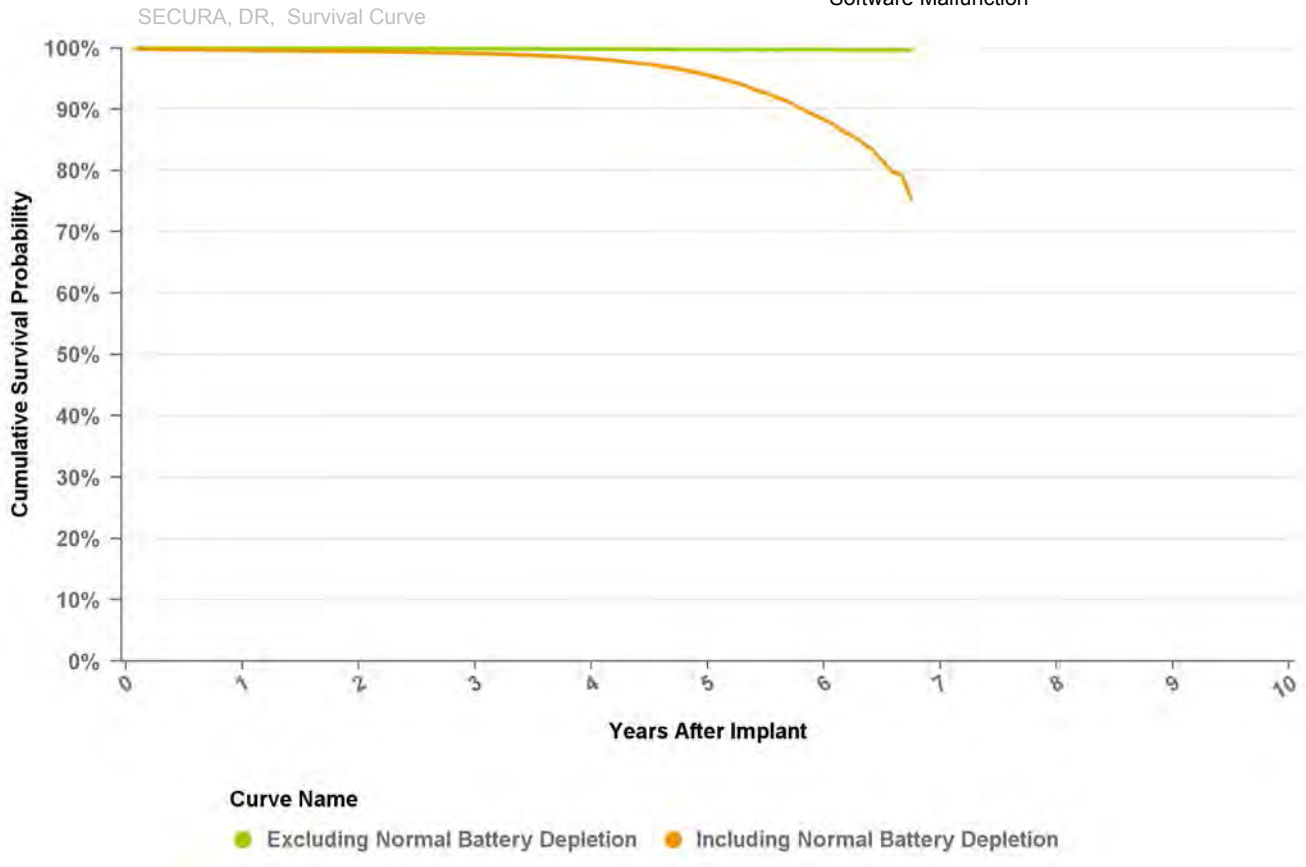
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.2%	96.7%
Effective Sample Size	18133	16724	14412	11961	7768	3164	208

Implantable Cardioverter Defibrillator

D234DRG Secura DR

US Market Release Date	
CE Market Approval Date	14-Mar-08
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 Malfunctions	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



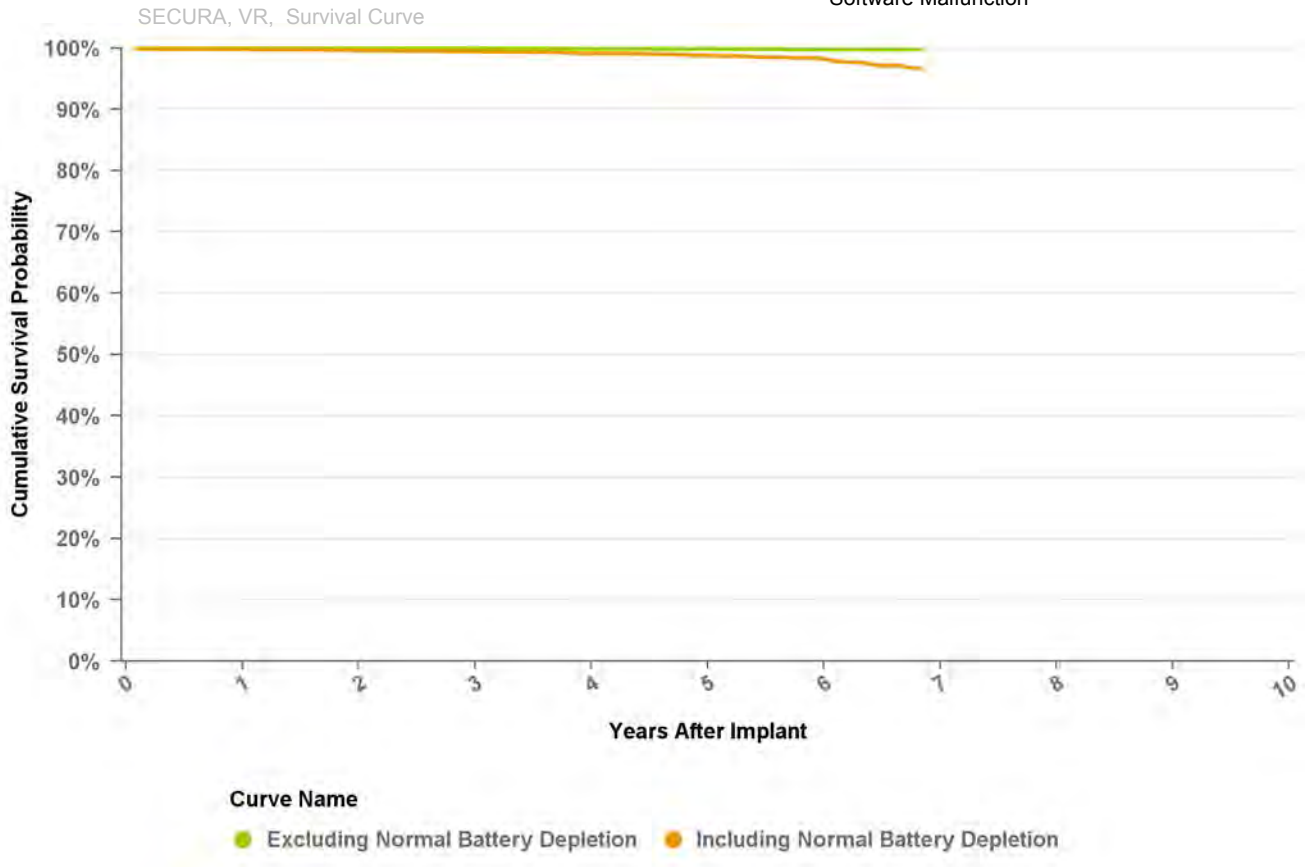
Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.7%	99.4%	99.1%	98.3%	95.6%	88.3%	75.5%
Effective Sample Size	45095	41844	37236	31811	19947	6648	403

Implantable Cardioverter Defibrillator

D234VRC Secura VR

US Market Release Date	
CE Market Approval Date	14-Mar-08
Registered US Implants	2
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 Malfunctions	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



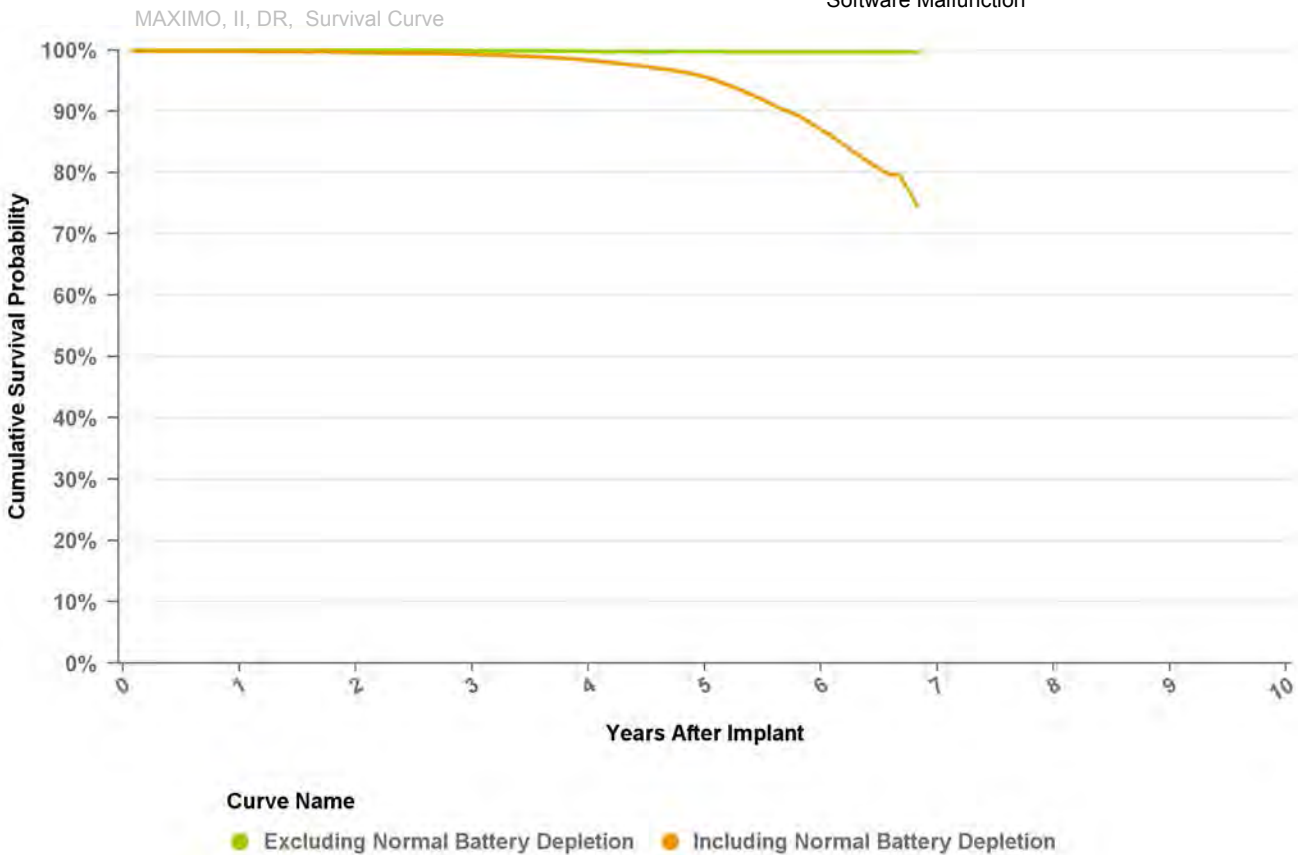
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.2%	96.7%
Effective Sample Size	18133	16724	14412	11961	7768	3164	208

Implantable Cardioverter Defibrillator

D264DRM Maximo II DR

US Market Release Date	9-Jan-12
CE Market Approval Date	22-Jul-10
Registered US Implants	6
Estimated Active US Implants	5
Normal Battery Depletions (US)	0
NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



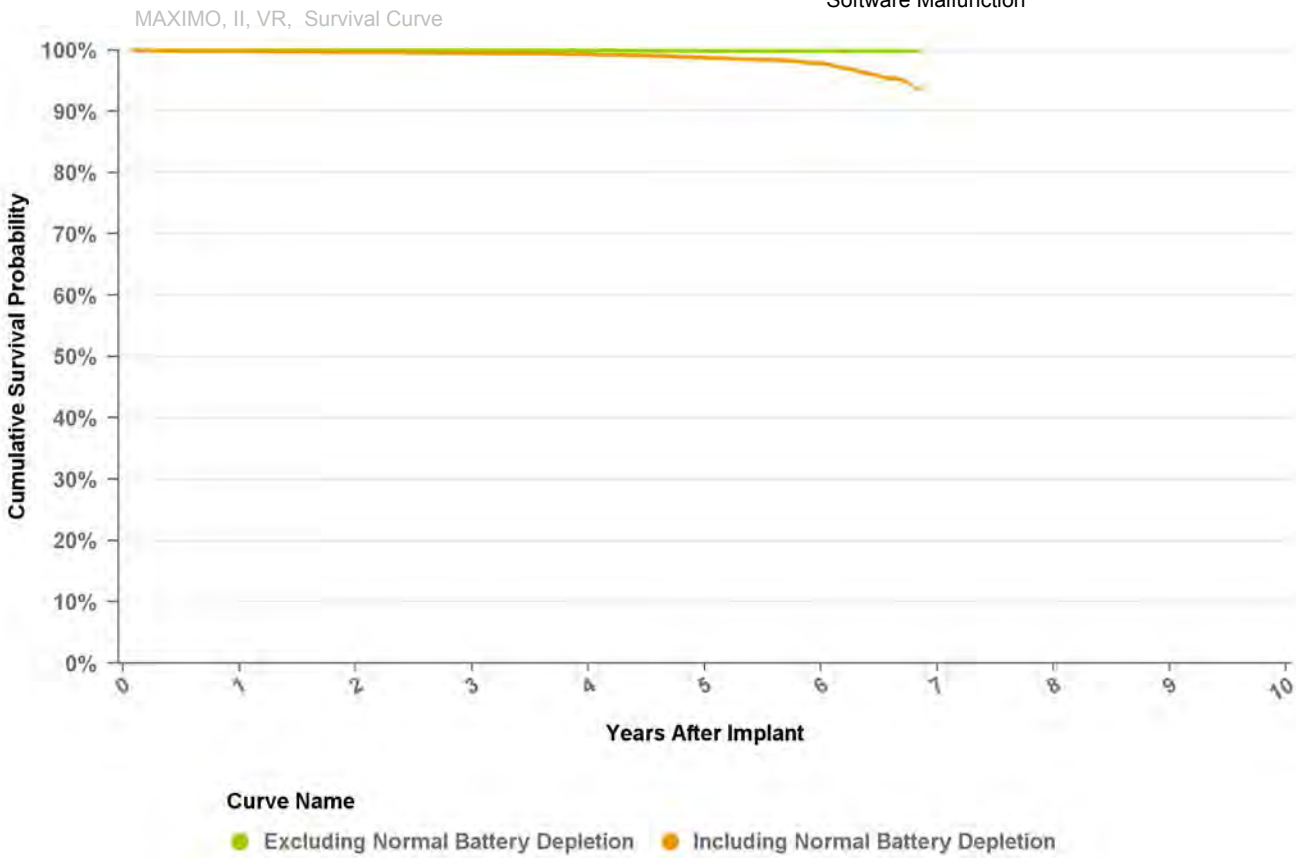
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.3%	95.7%	87.0%	74.4%
Effective Sample Size	17475	16173	14311	11881	7969	3287	210

Implantable Cardioverter Defibrillator

D264VRM Maximo II VR

US Market Release Date	2-May-12
CE Market Approval Date	17-Dec-10
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 Malfunctions	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



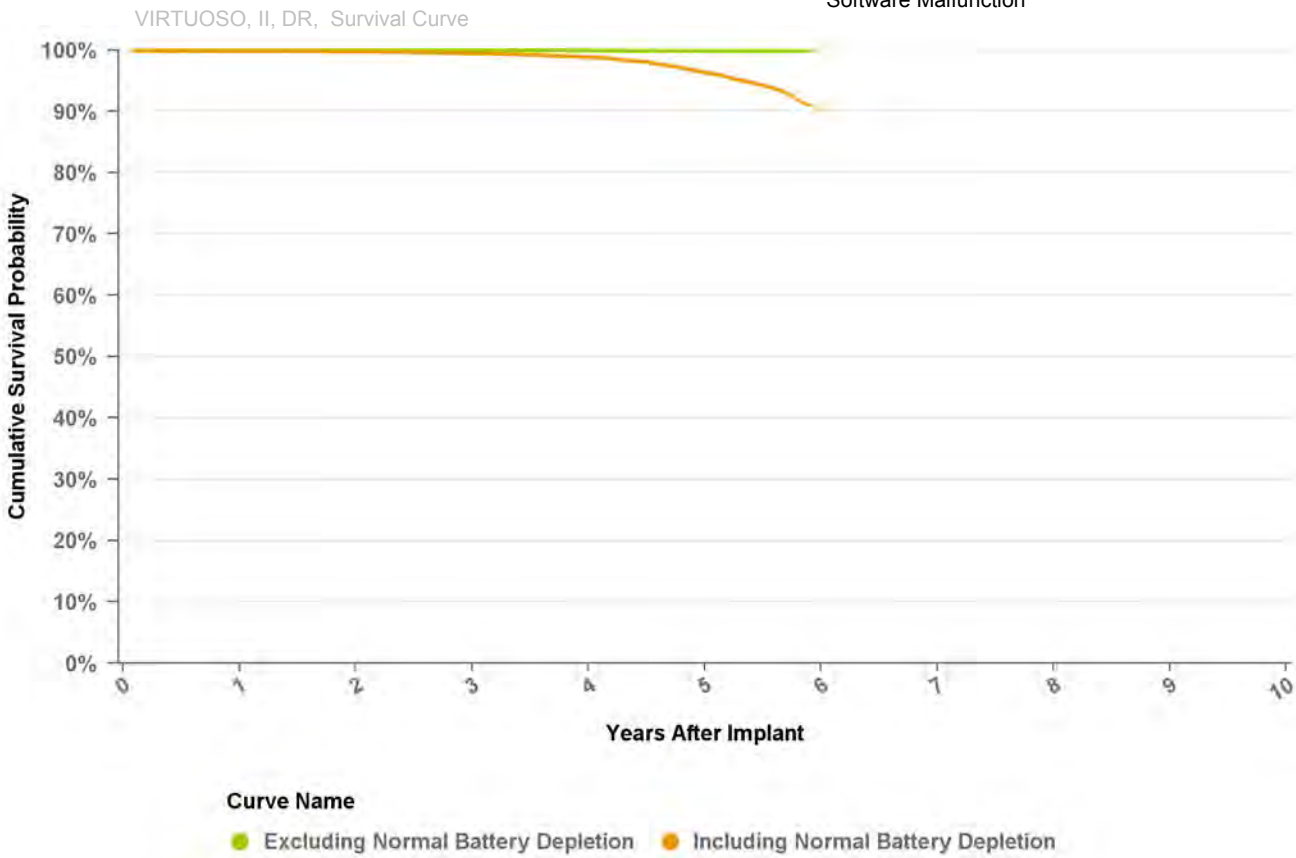
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.5%	99.3%	98.8%	97.9%	93.4%
Effective Sample Size	11139	10321	9032	7358	4931	2177	143

Implantable Cardioverter Defibrillator

D274DRG Virtuoso II DR

US Market Release Date	15-Aug-09
CE Market Approval Date	
Registered US Implants	22,234
Estimated Active US Implants	15,116
Normal Battery Depletions (US)	392
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	24
Therapy Not Compromised Malfunctions	21
Battery Malfunction	4
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	7
Software Malfunction	1
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



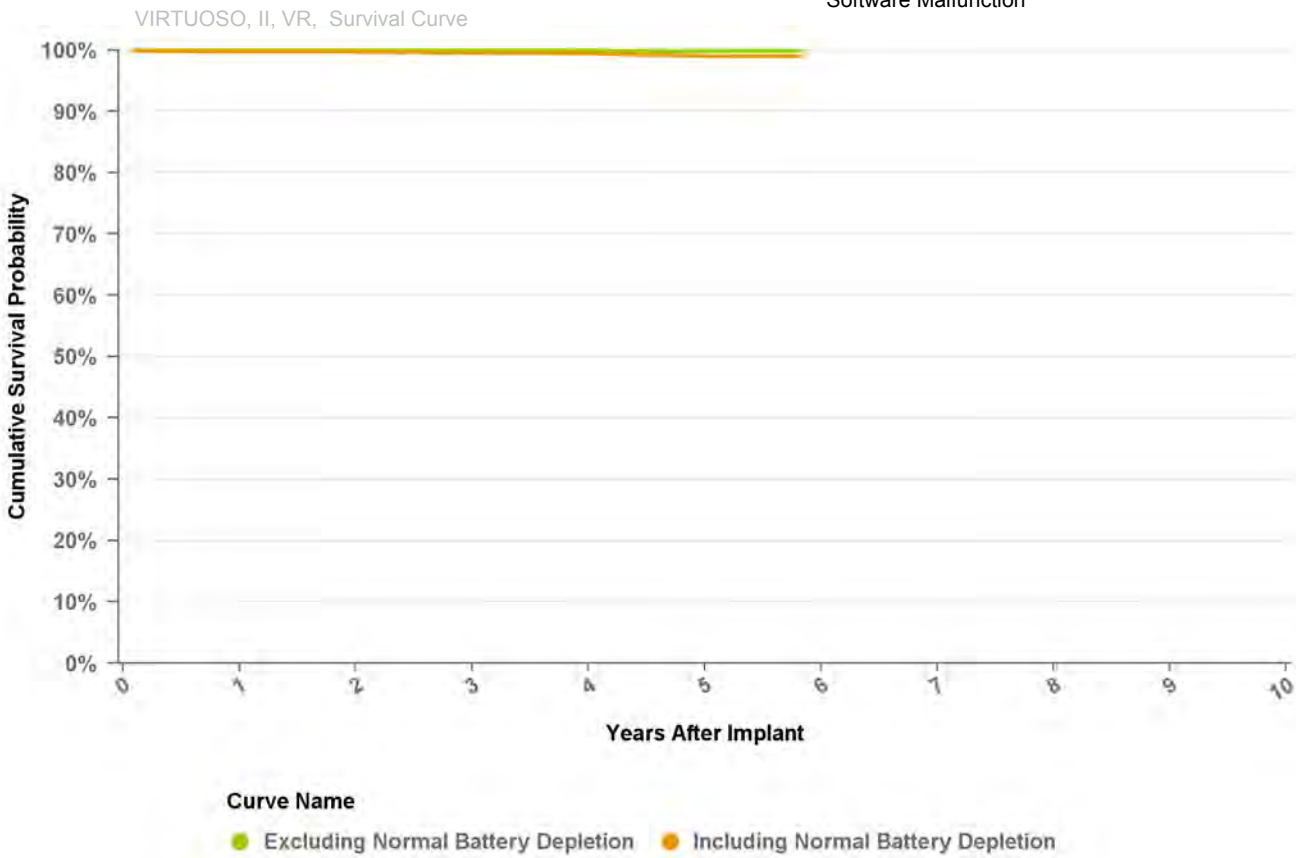
Years	1	2	3	4	5	at 71 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.8%	99.7%	99.4%	98.8%	96.3%	90.9%
Effective Sample Size	19261	18088	17029	15227	8206	434

Implantable Cardioverter Defibrillator

D274VRC Virtuoso II VR

US Market Release Date	15-Aug-09
CE Market Approval Date	
Registered US Implants	9,117
Estimated Active US Implants	6,610
Normal Battery Depletions (US)	31
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	8
Therapy Not Compromised Malfunctions	8
Battery Malfunction	3
Electrical Component	2
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	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.1%	99.1%
Effective Sample Size	7760	7290	6879	6083	3221	301

Implantable Cardioverter Defibrillator

D284DRG Maximo II DR

US Market Release Date 17-Sep-08

CE Market Approval Date 14-Mar-08

Registered US Implants 20,043

Estimated Active US Implants 12,834

Normal Battery Depletions (US) 791

NBG Code VVE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 44

Therapy Not Compromised Malfunctions 38

Battery Malfunction 0

Electrical Component 10

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 28

Software Malfunction 0

Therapy Compromised Malfunctions 6

Battery Malfunction 0

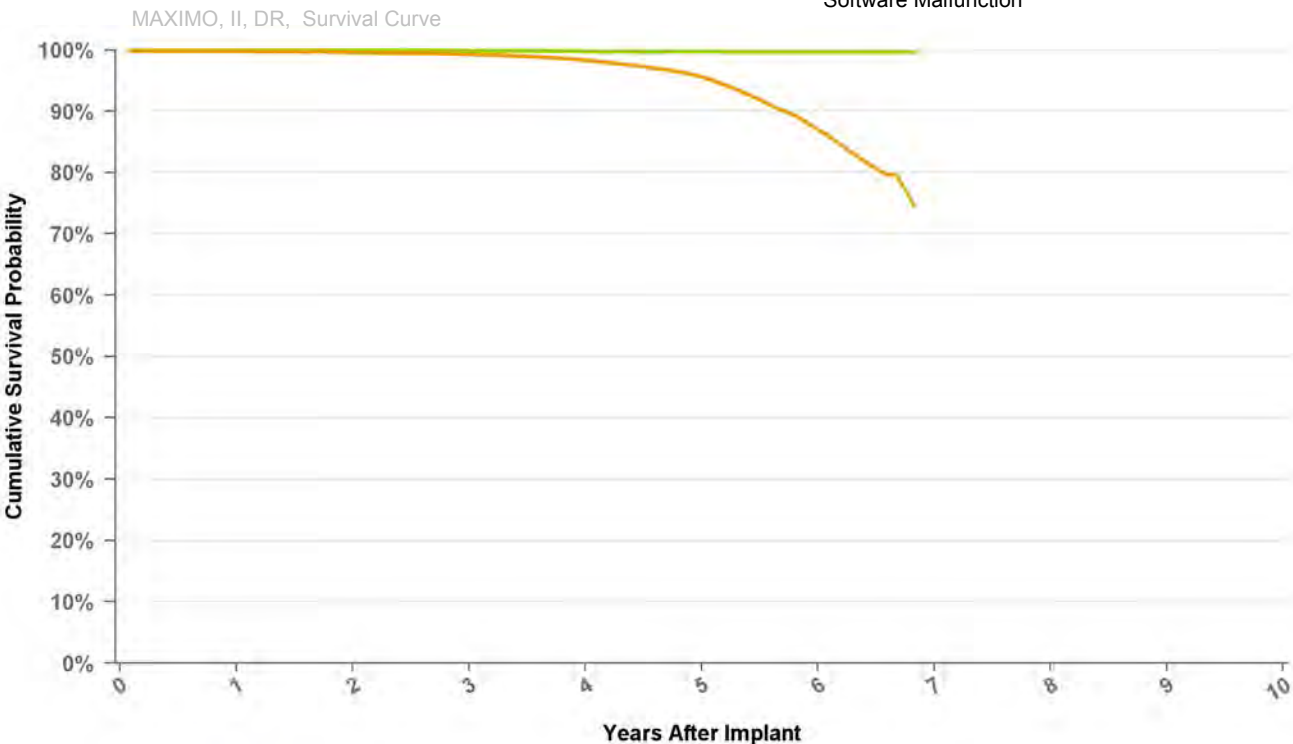
Electrical Component 5

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 1

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

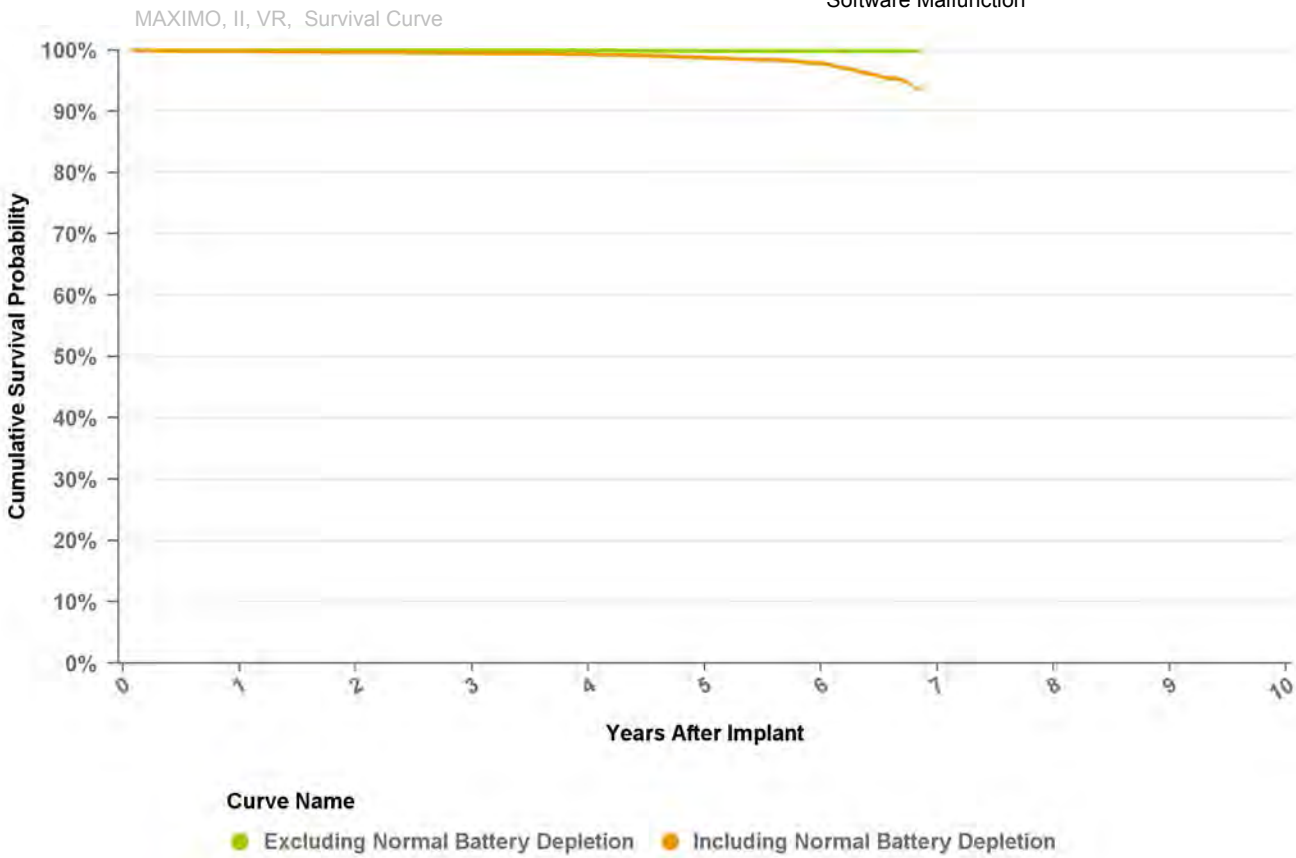
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.3%	95.7%	87.0%	74.4%
Effective Sample Size	17475	16173	14311	11881	7969	3287	210

Implantable Cardioverter Defibrillator

D284VRC Maximo II VR

US Market Release Date	17-Sep-08
CE Market Approval Date	14-Mar-08
Registered US Implants	12,957
Estimated Active US Implants	9,297
Normal Battery Depletions (US)	101
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	16
Therapy Not Compromised Malfunctions	12
Battery Malfunction	2
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	3
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



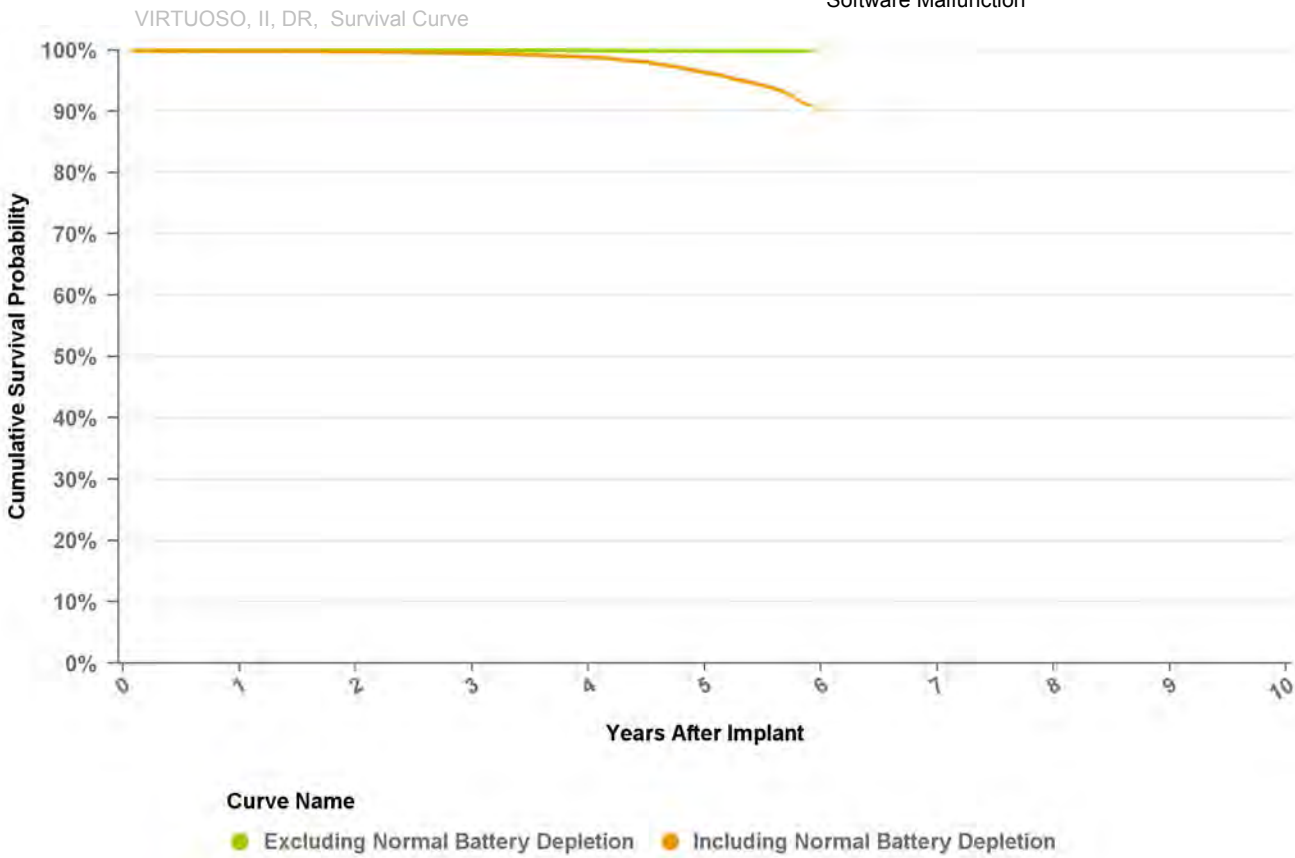
Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.5%	99.3%	98.8%	97.9%	93.4%
Effective Sample Size	11139	10321	9032	7358	4931	2177	143

Implantable Cardioverter Defibrillator

D294DRG Virtuoso II DR

US Market Release Date	
CE Market Approval Date	20-Aug-08
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 Malfunctions	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 71 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.8%	99.7%	99.4%	98.8%	96.3%	90.9%
Effective Sample Size	19261	18088	17029	15227	8206	434

Implantable Cardioverter Defibrillator

D294VRC Virtuoso II VR

US Market Release Date

CE Market Approval Date 20-Aug-08

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

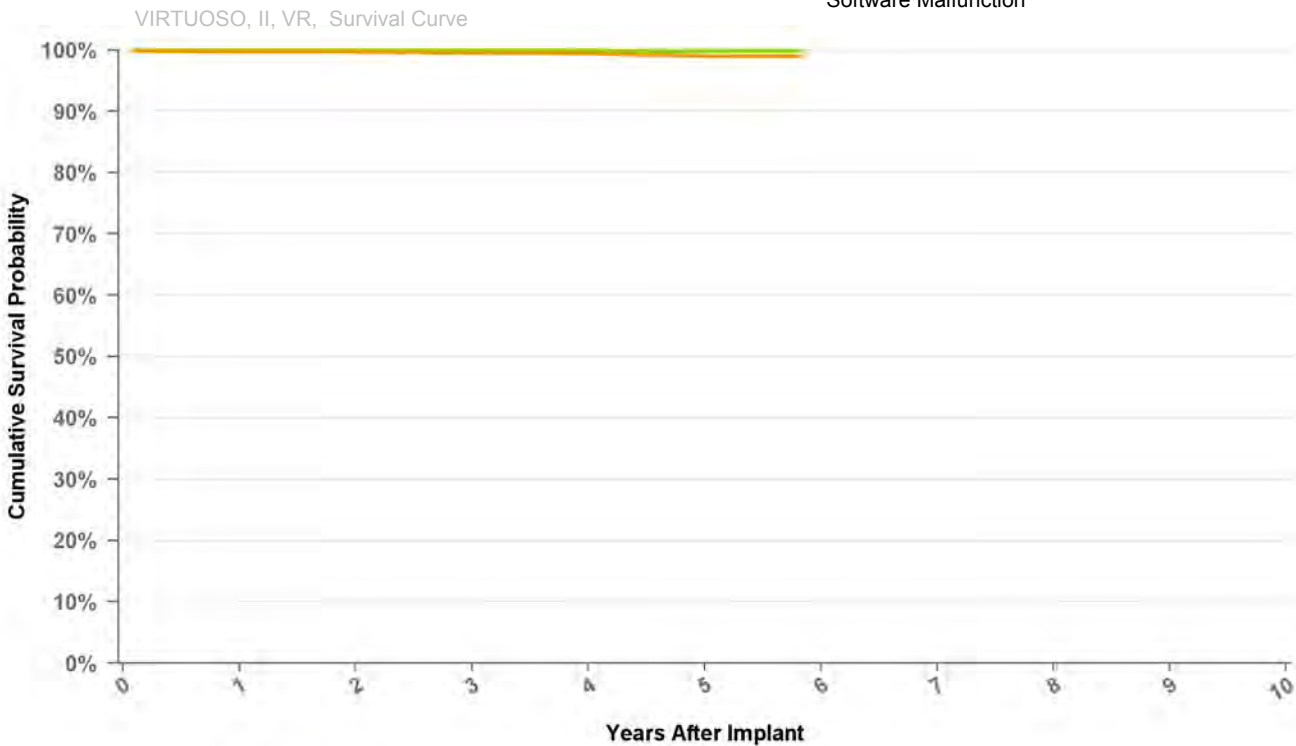
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

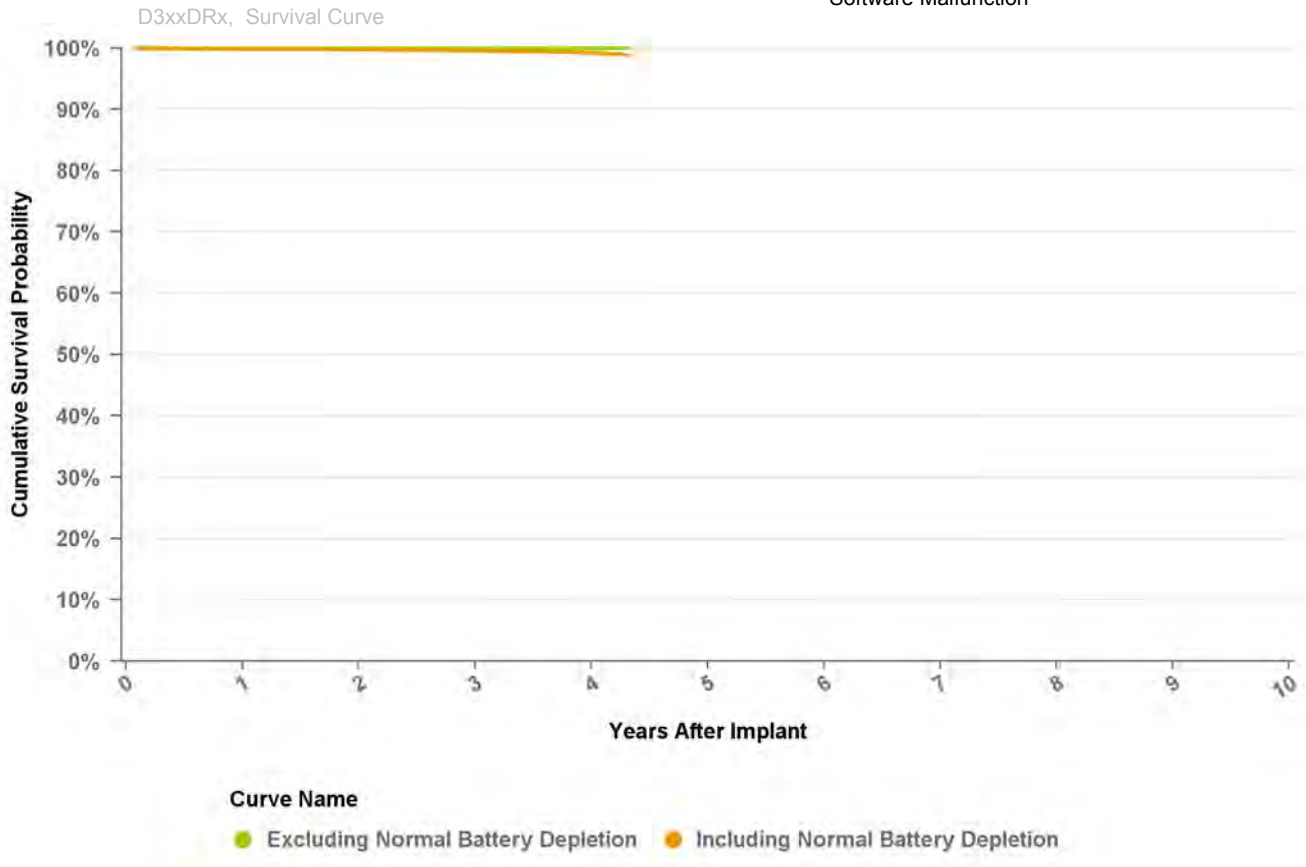
Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.1%	99.1%
Effective Sample Size	7760	7290	6879	6083	3221	301

Implantable Cardioverter Defibrillator

D314DRG Protecta XT DR

US Market Release Date	25-Mar-11
CE Market Approval Date	
Registered US Implants	34,602
Estimated Active US Implants	28,936
Normal Battery Depletions (US)	88
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	24
Therapy Not Compromised Malfunctions	18
Battery Malfunction	1
Electrical Component	15
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



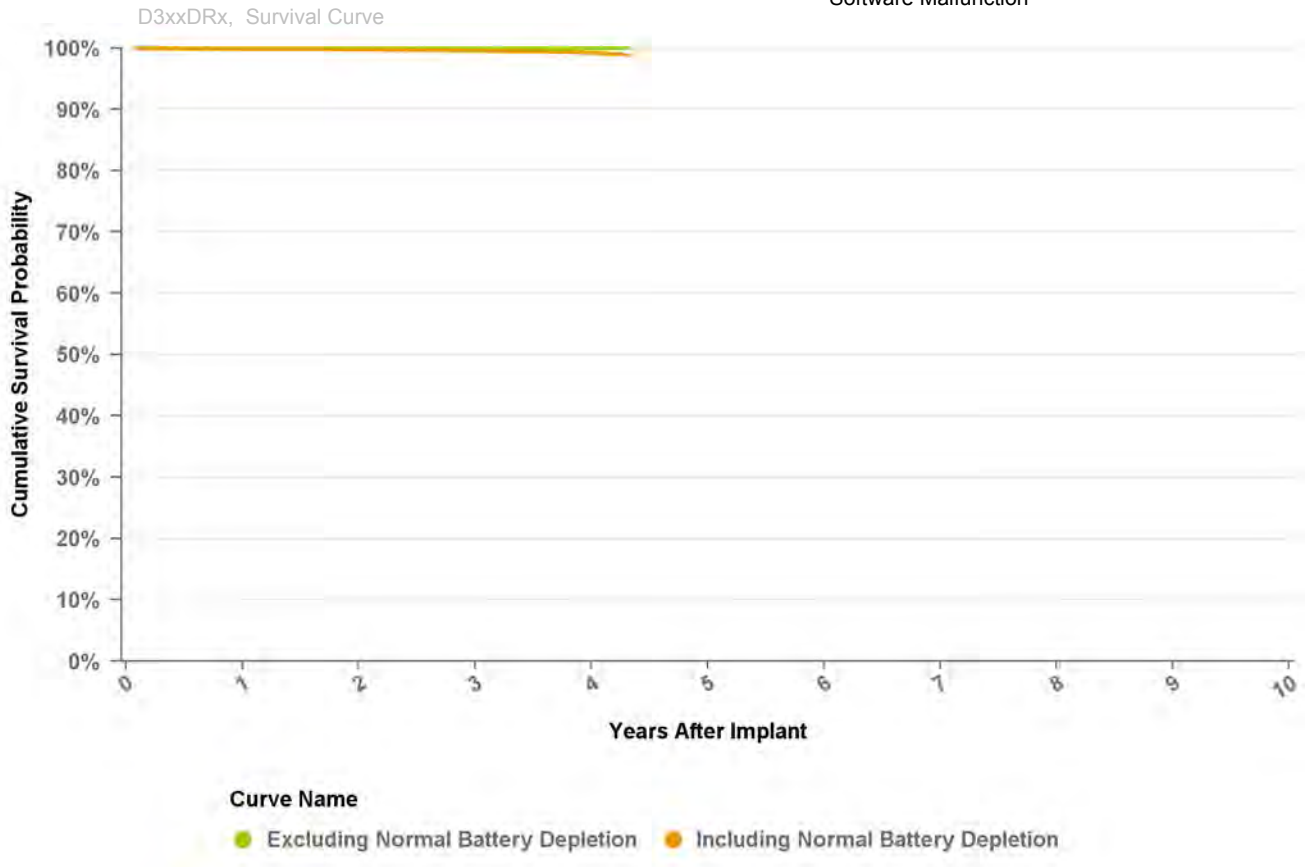
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D314DRM Protecta XT DR

US Market Release Date	9-Nov-11
CE Market Approval Date	
Registered US Implants	13,828
Estimated Active US Implants	12,167
Normal Battery Depletions (US)	18
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

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



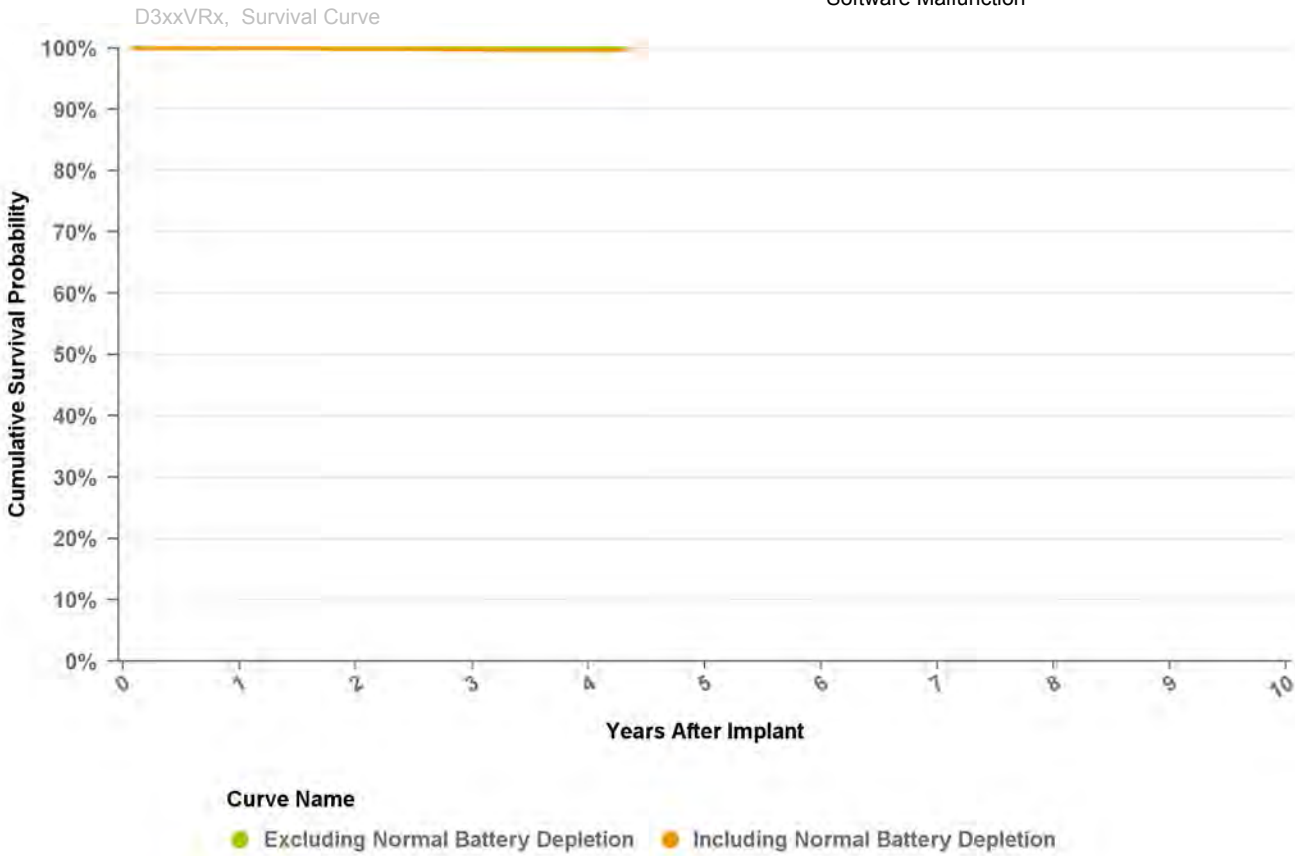
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D314VRG Protecta XT VR

US Market Release Date	25-Mar-11
CE Market Approval Date	
Registered US Implants	14,092
Estimated Active US Implants	11,900
Normal Battery Depletions (US)	19
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	7
Therapy Not Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
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



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D314VRM Protecta XT VR

US Market Release Date 2-May-12

CE Market Approval Date

Registered US Implants 7,324

Estimated Active US Implants 6,435

Normal Battery Depletions (US) 3

NBG Code VVE-VVIR

Max Delivered Energy 35 J

Total Malfunctions (US) 1

Therapy Not Compromised Malfunctions 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

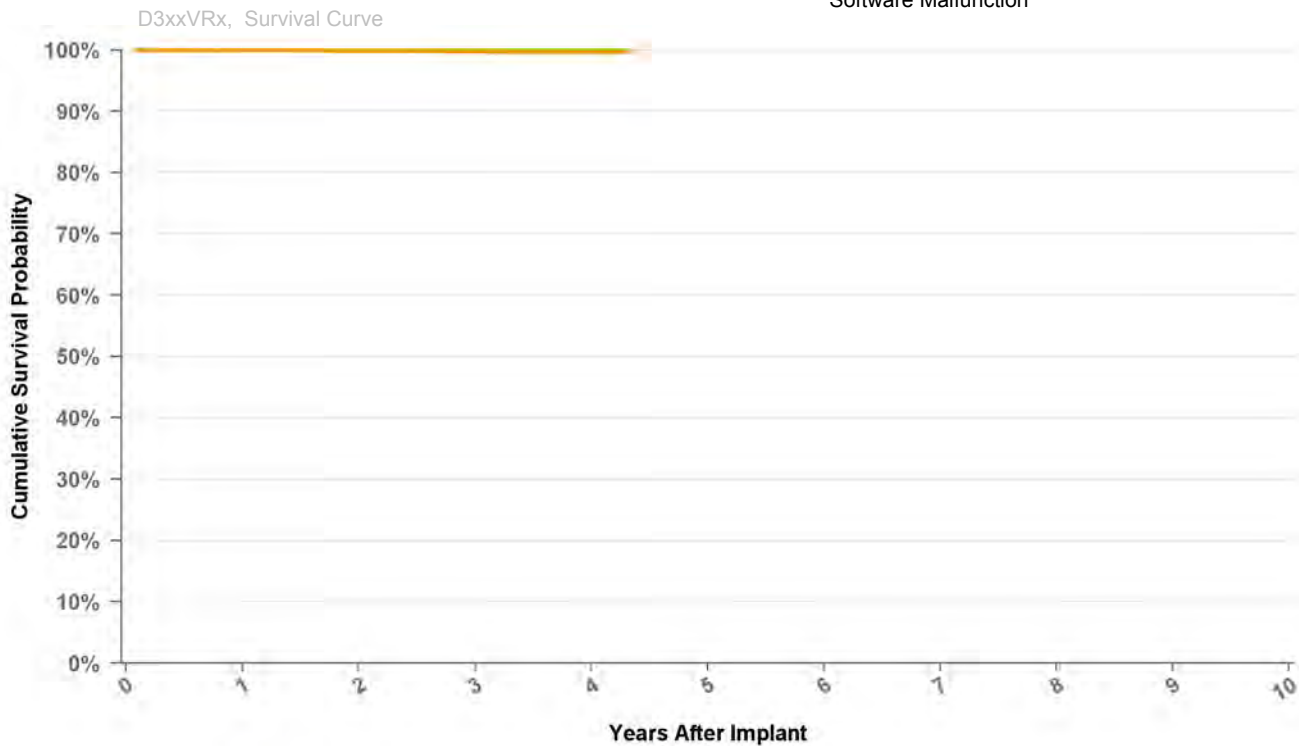
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D334DRG Protecta DR

US Market Release Date 25-Mar-11

CE Market Approval Date

Registered US Implants 10,601

Estimated Active US Implants 9,024

Normal Battery Depletions (US) 25

NBG Code DDE-DDDR

Max Delivered Energy 35 J

Total Malfunctions (US) 8

Therapy Not Compromised Malfunctions 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

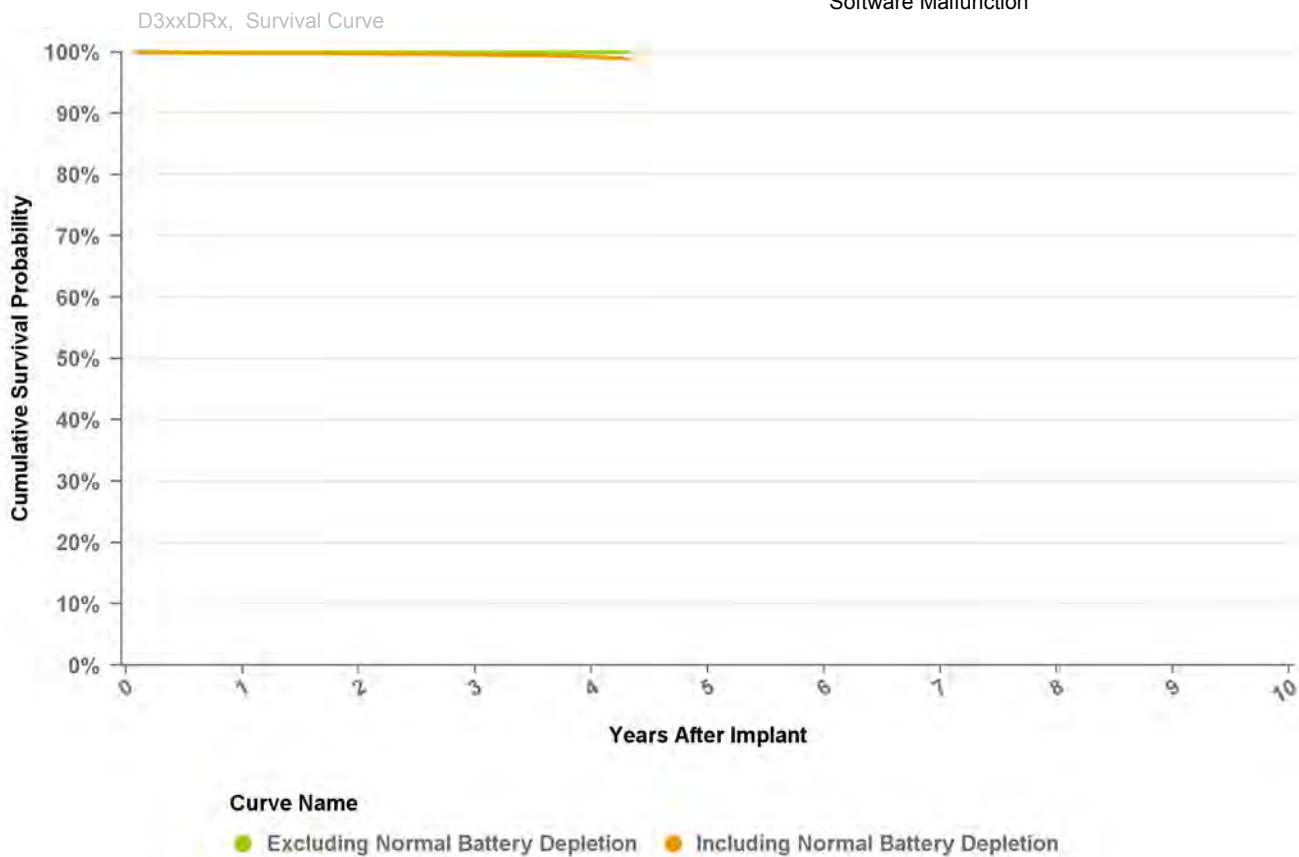
Electrical Component 2

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



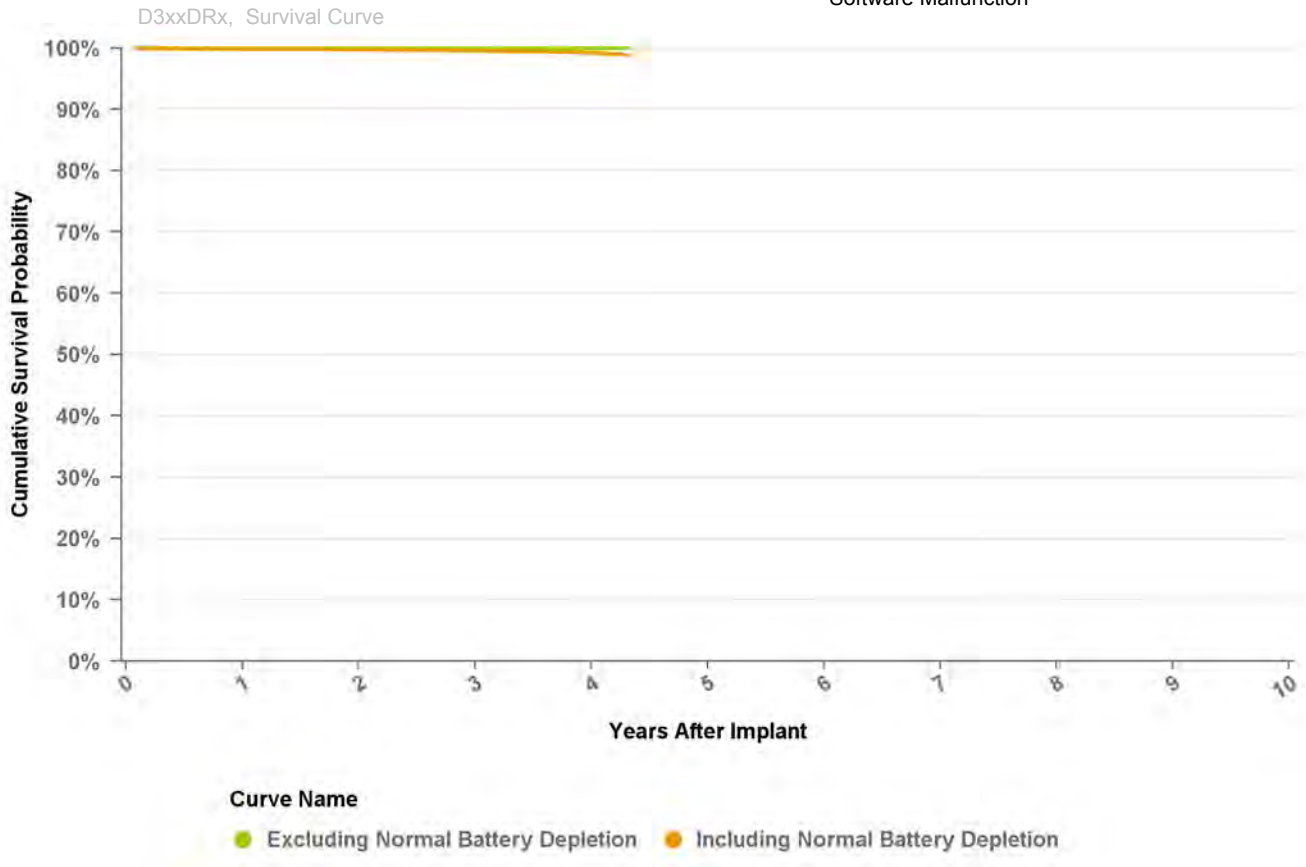
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D334DRM Protecta DR

US Market Release Date	9-Nov-11
CE Market Approval Date	
Registered US Implants	2,949
Estimated Active US Implants	2,644
Normal Battery Depletions (US)	5
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



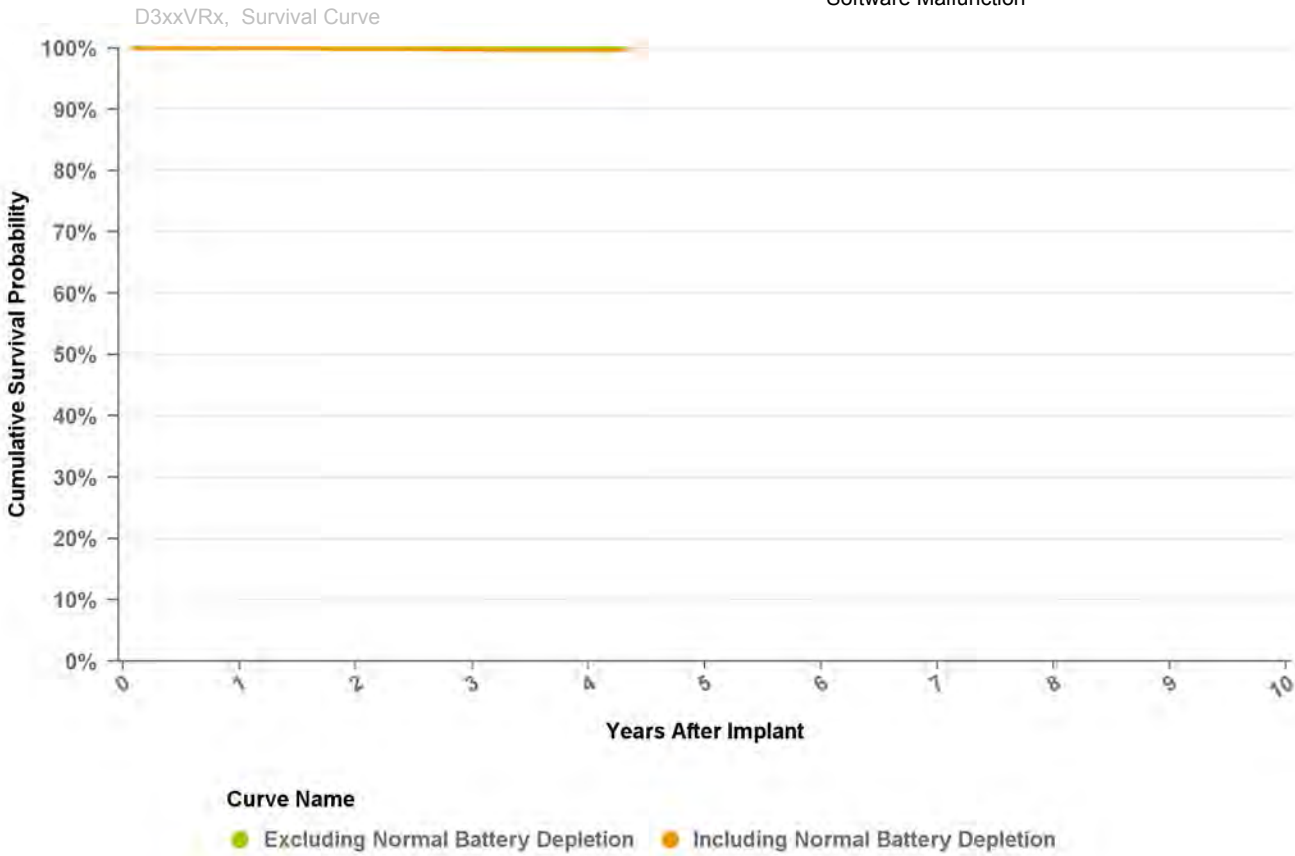
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D334VRG Protecta VR

US Market Release Date	25-Mar-11
CE Market Approval Date	
Registered US Implants	6,400
Estimated Active US Implants	5,500
Normal Battery Depletions (US)	6
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

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



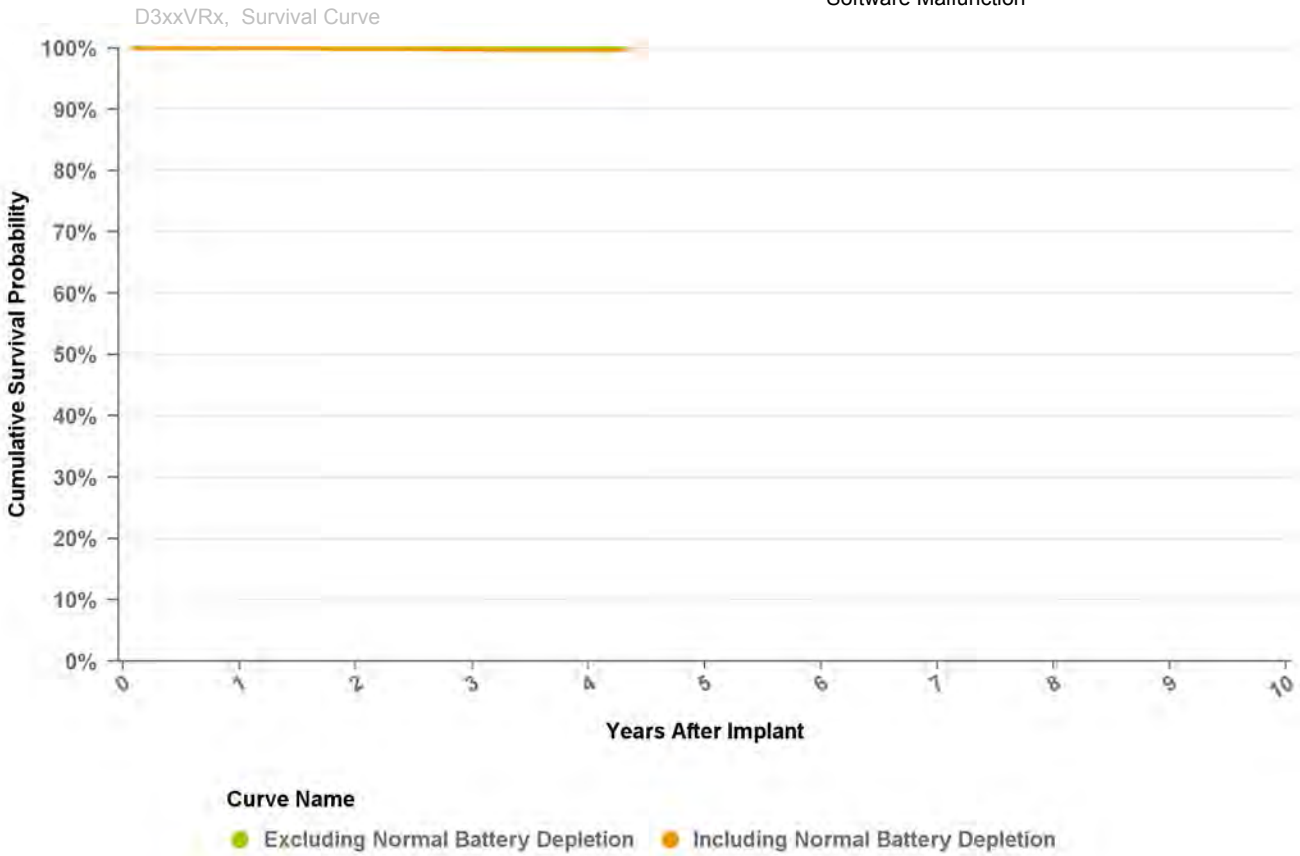
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D334VRM Protecta VR

US Market Release Date	2-May-12
CE Market Approval Date	
Registered US Implants	2,150
Estimated Active US Implants	1,919
Normal Battery Depletions (US)	0
NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D354DRG Protecta XT DR

US Market Release Date

CE Market Approval Date 25-Mar-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

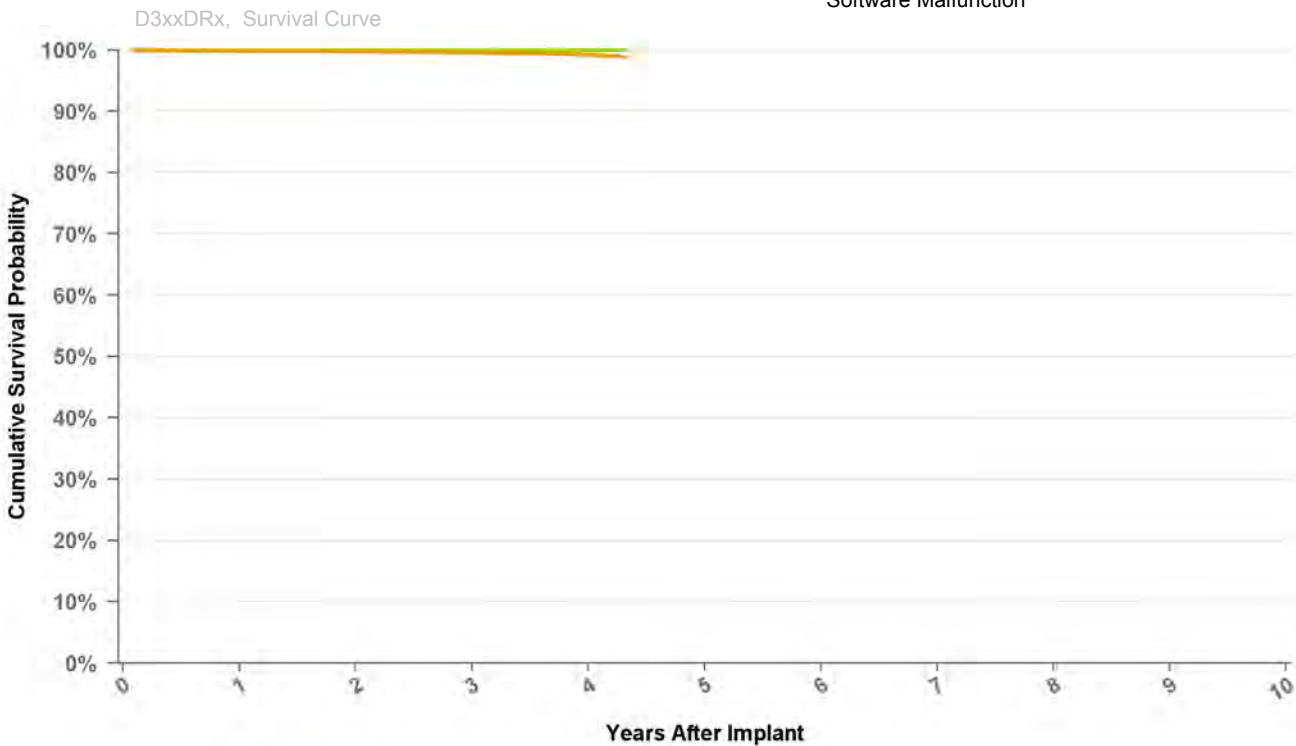
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D354DRM Protecta XT DR

US Market Release Date

CE Market Approval Date 15-Jul-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

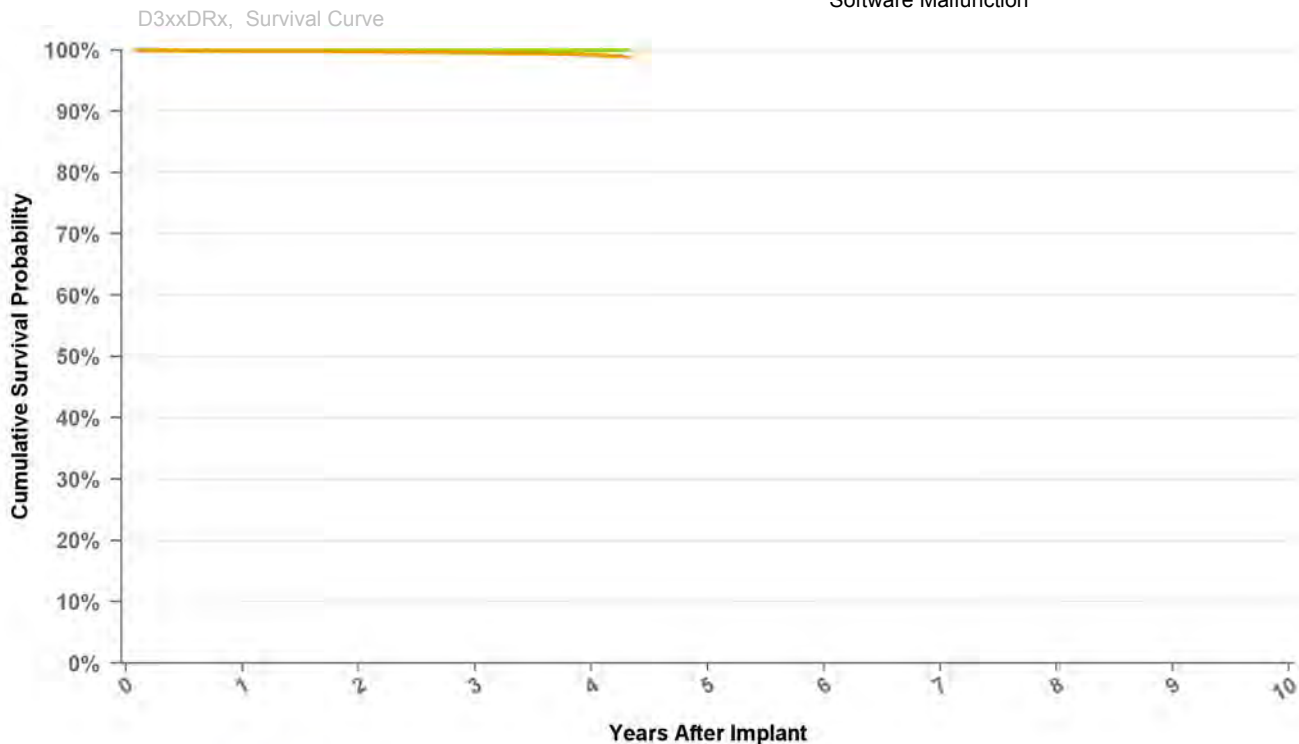
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

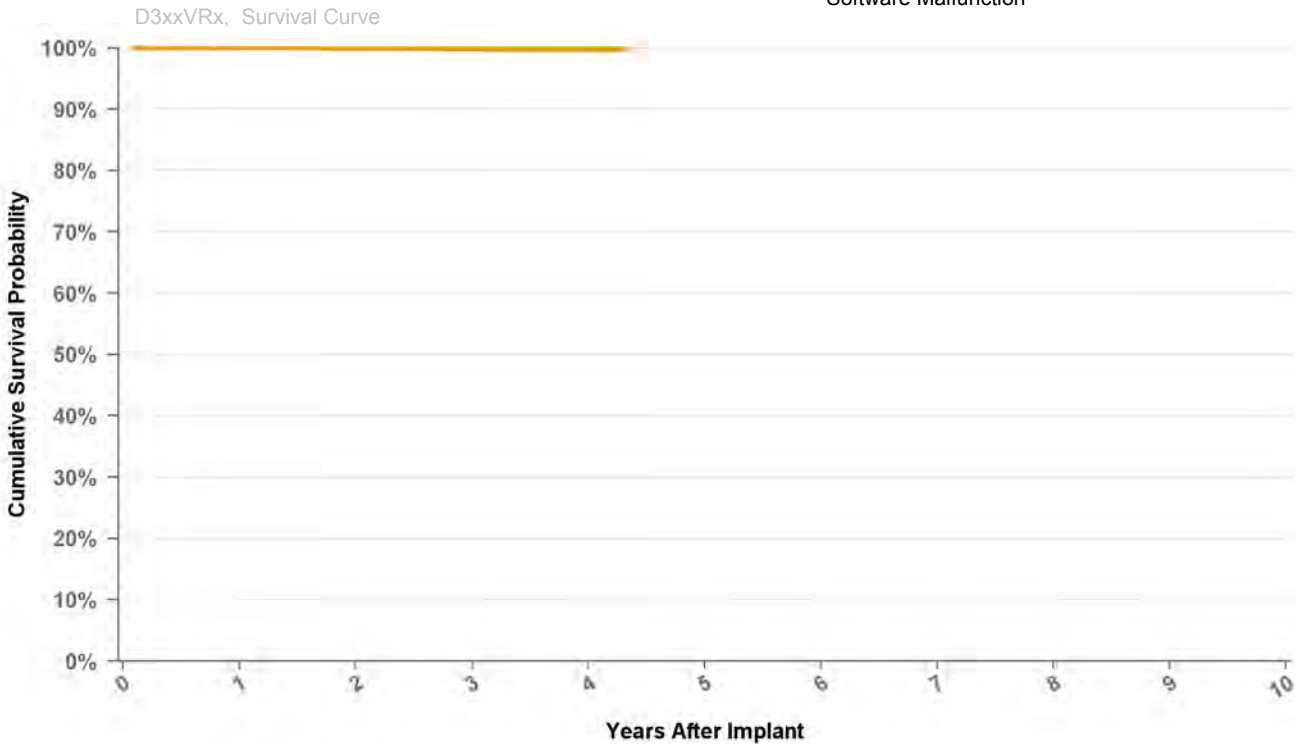
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D354VRG Protecta XT VR

US Market Release Date	
CE Market Approval Date	25-Mar-10
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 Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

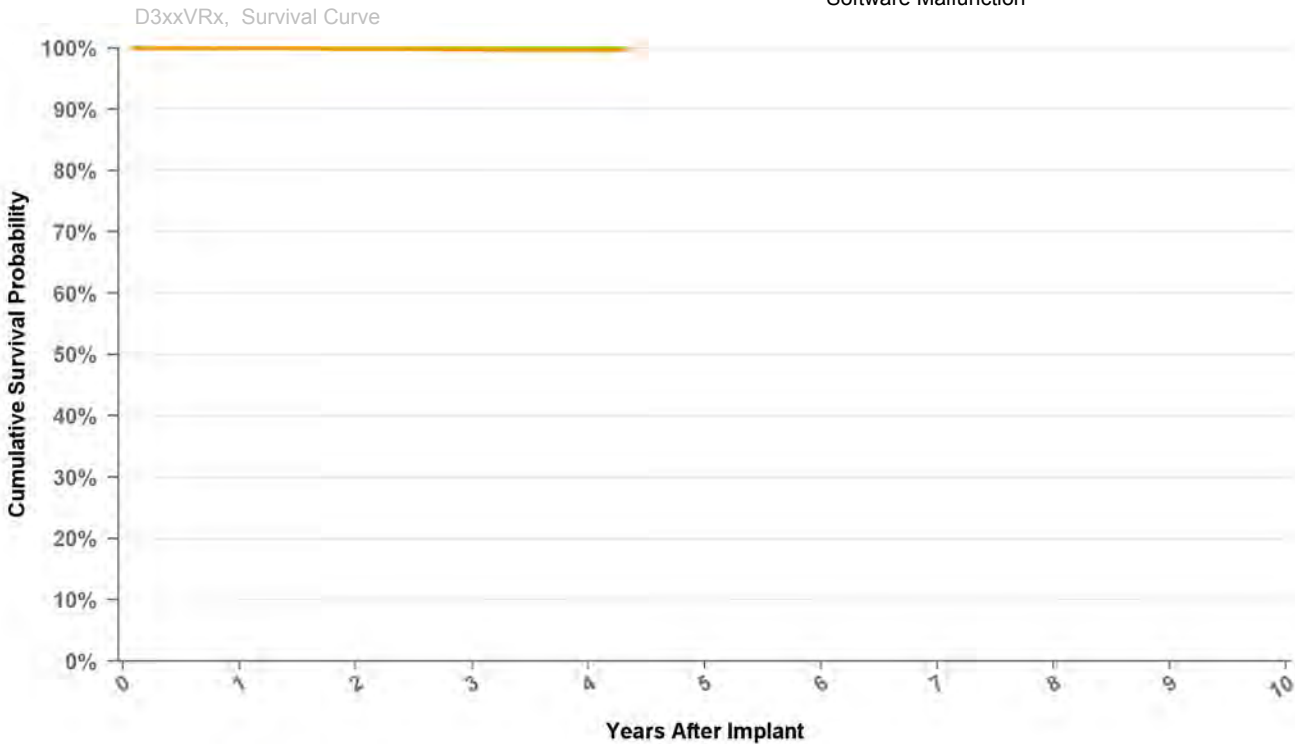
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D354VRM Protecta XT VR

US Market Release Date	
CE Market Approval Date	17-Dec-10
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 Malfunctions	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



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%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D364DRG Protecta DR

US Market Release Date

CE Market Approval Date 25-Mar-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

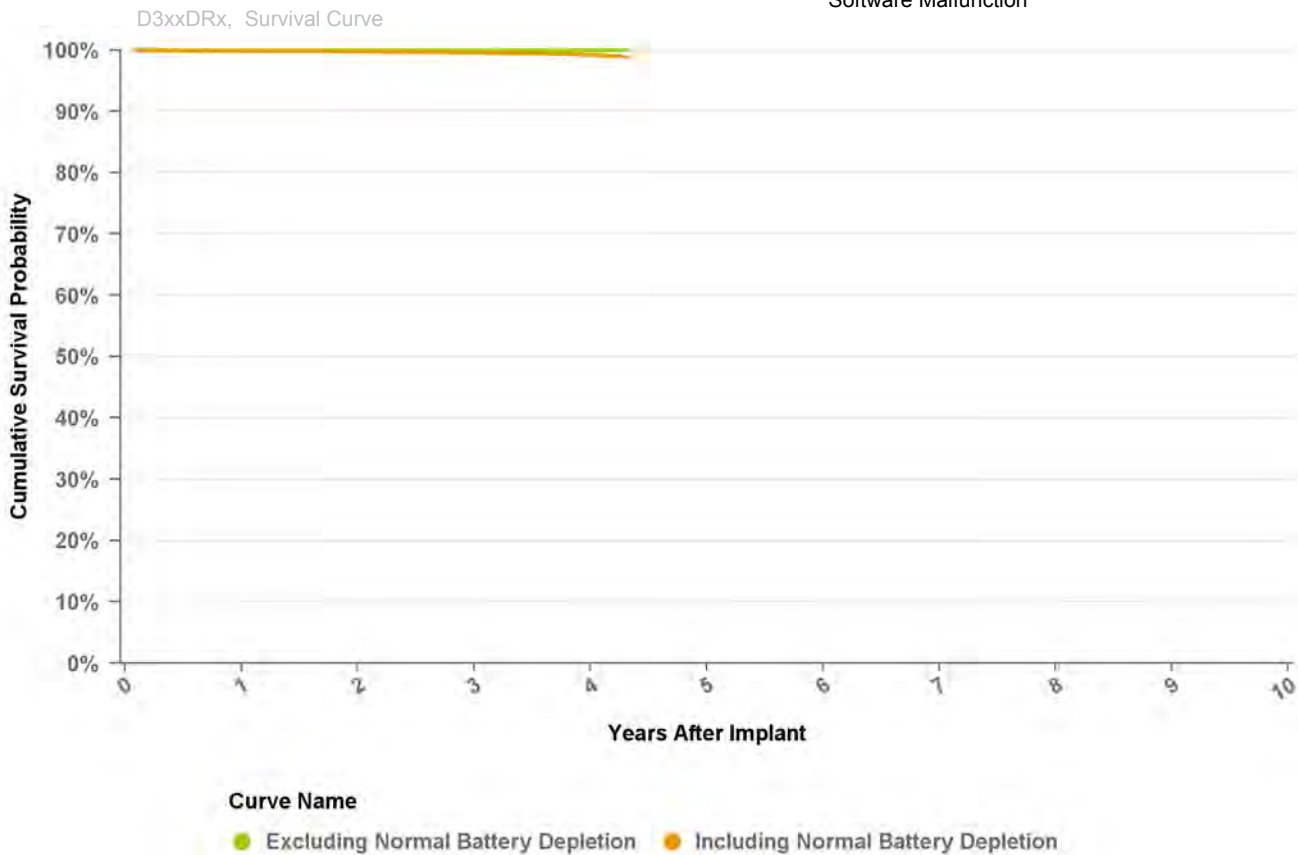
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



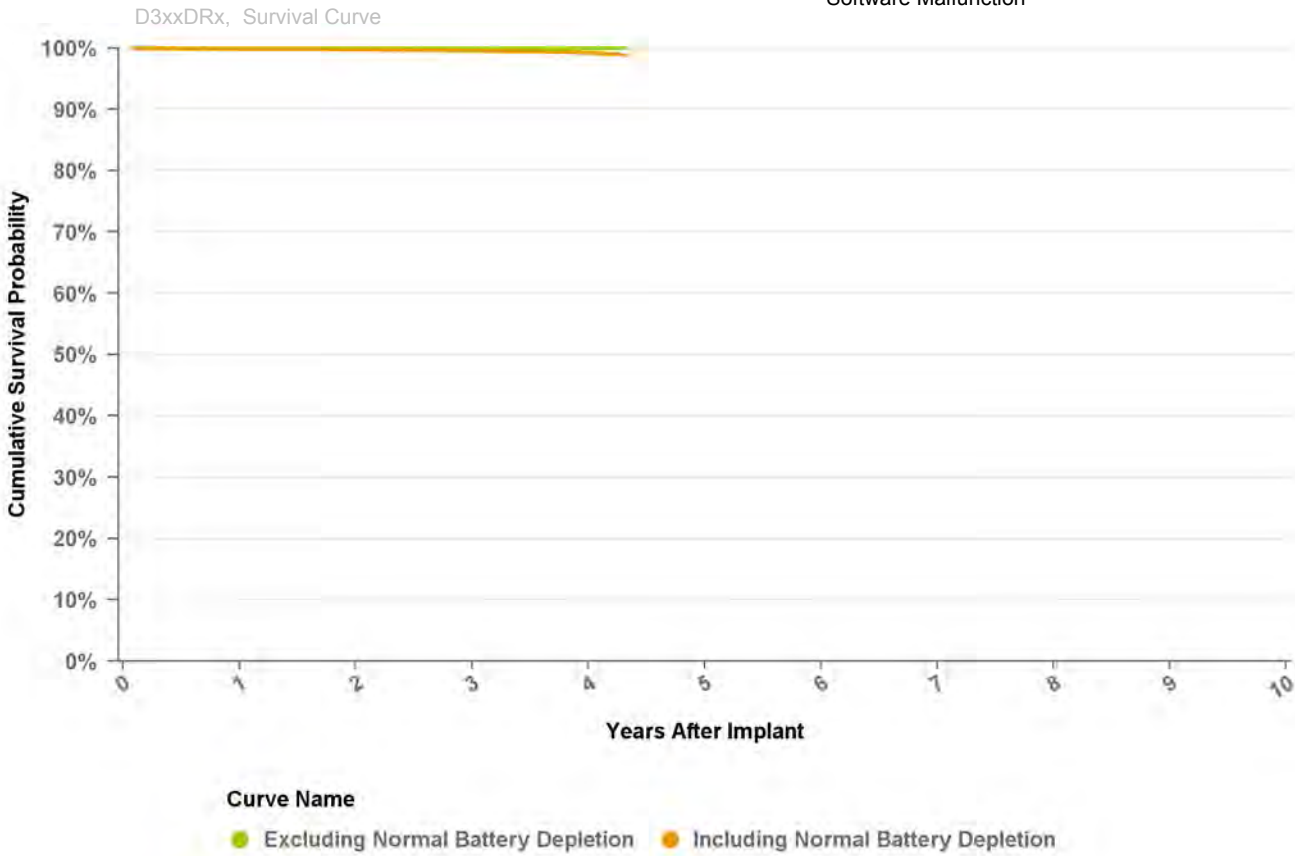
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D364DRM Protecta DR

US Market Release Date	
CE Market Approval Date	15-Jul-10
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 Malfunctions	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 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D364VRG Protecta VR

US Market Release Date

CE Market Approval Date 25-Mar-10

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

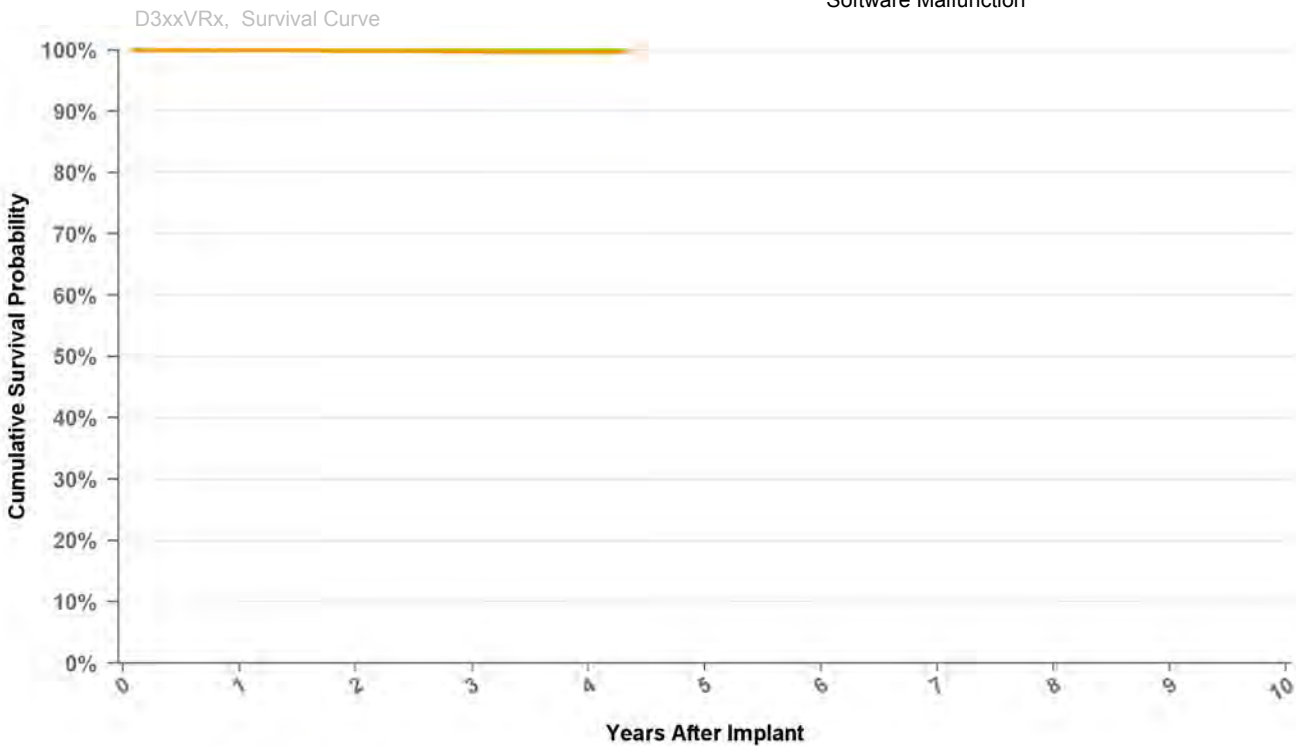
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D364VRM Protecta VR

US Market Release Date

CE Market Approval Date 17-Dec-10

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 Malfunctions 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

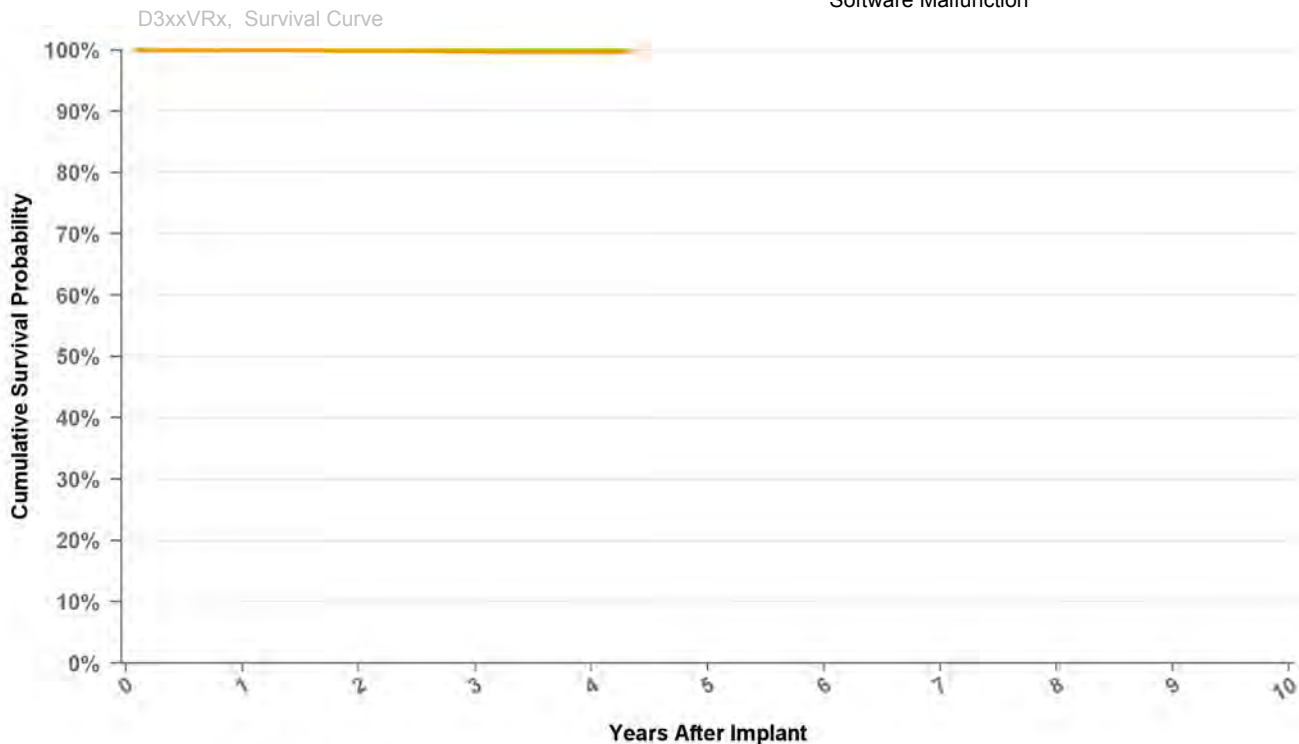
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D384DRG Cardia DR

US Market Release Date

CE Market Approval Date 12-Jan-11

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

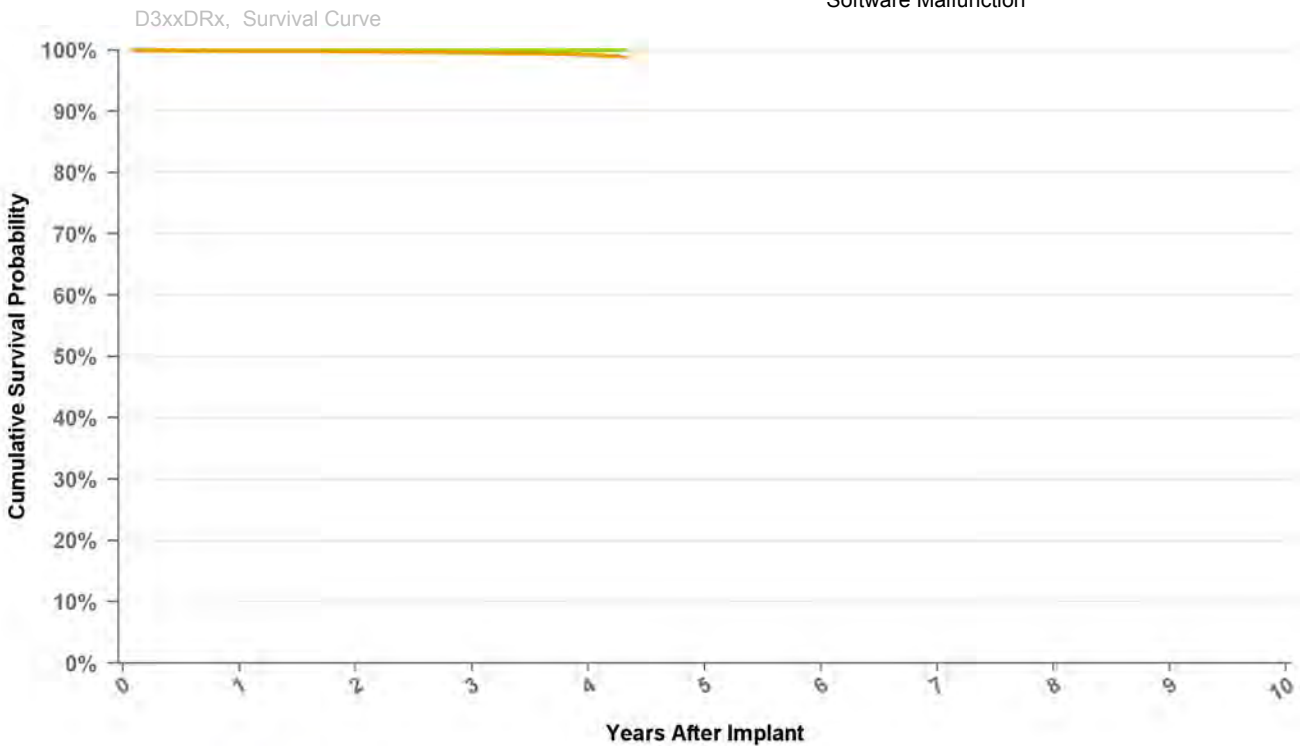
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

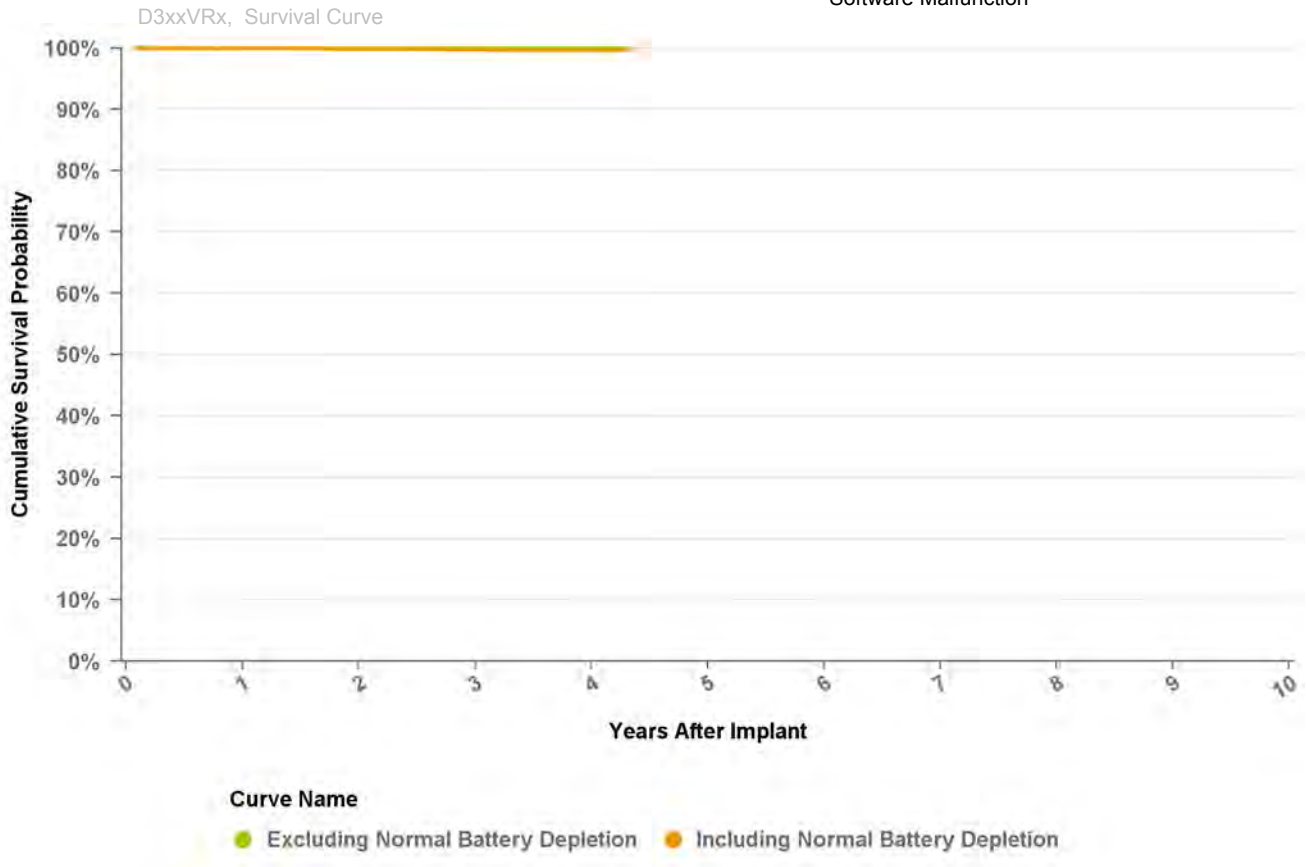
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D384VRG Cardia VR

US Market Release Date	
CE Market Approval Date	12-Jan-11
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 Malfunctions	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



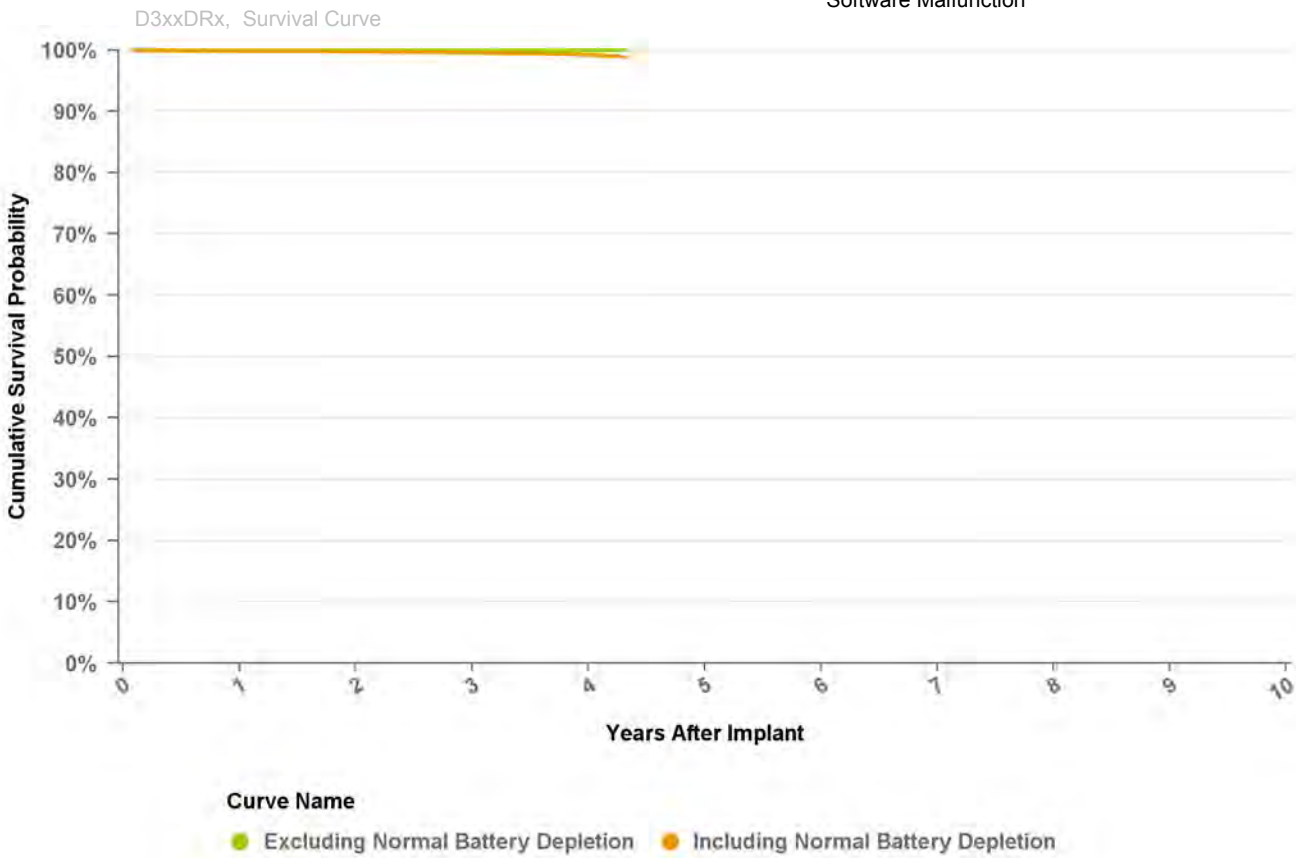
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

D394DRG Egida DR

US Market Release Date	
CE Market Approval Date	12-Jan-11
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 Malfunctions	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



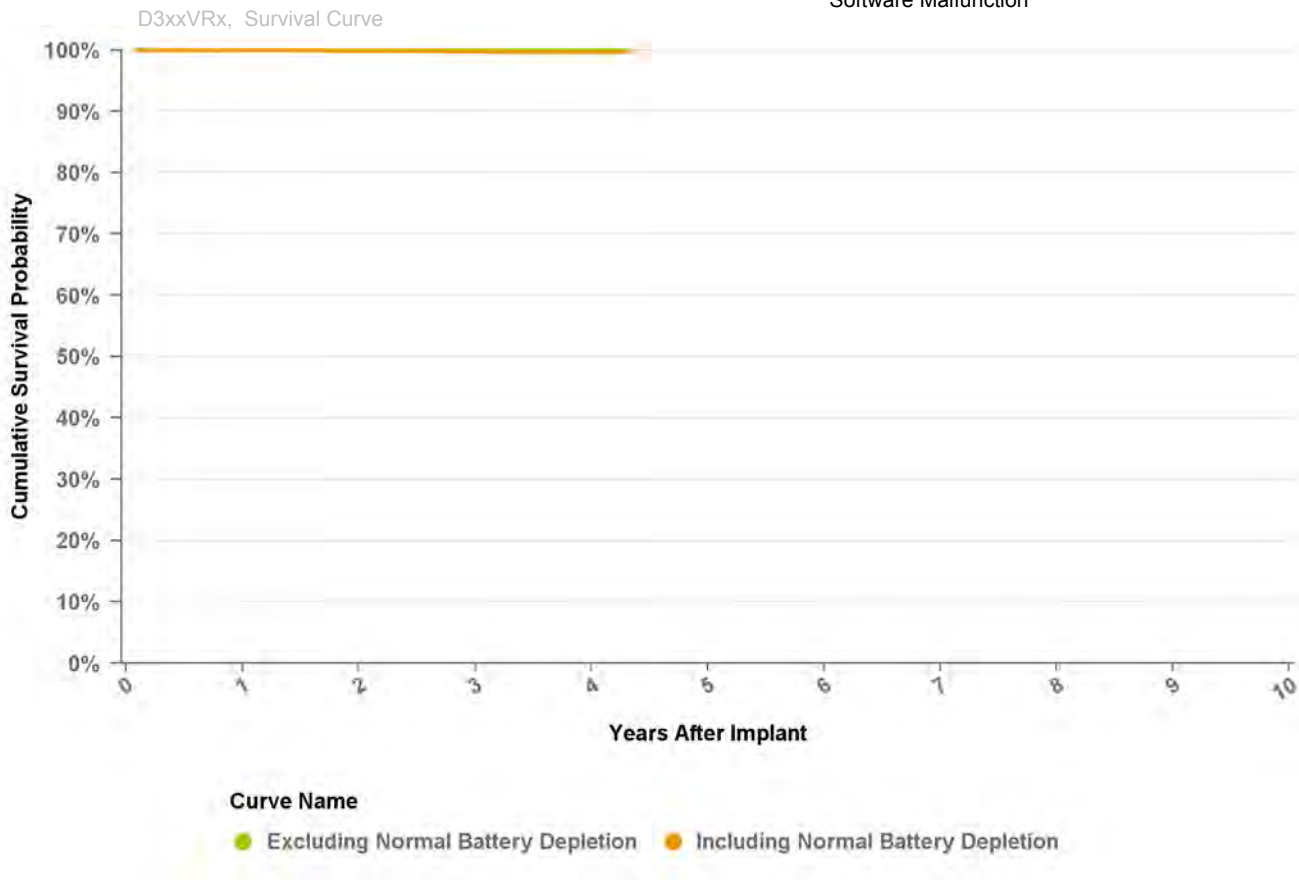
Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.8%
Effective Sample Size	55136	49446	28264	5392	813

Implantable Cardioverter Defibrillator

D394VRG Egida VR

US Market Release Date	
CE Market Approval Date	12-Jan-11
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 Malfunctions	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 52 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.6%
Effective Sample Size	26300	22961	12301	2131	166

Implantable Cardioverter Defibrillator

DDBB1D1 Evera XT

US Market Release Date 3-Apr-13

CE Market Approval Date

Registered US Implants 22,899

Estimated Active US Implants 21,737

Normal Battery Depletions (US) 3

NBG Code DDE-DDDR

Max Delivered Energy 36 J

Total Malfunctions (US) 3

Therapy Not Compromised Malfunctions 2

Battery Malfunction 0

Electrical Component 2

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 1

Battery Malfunction 0

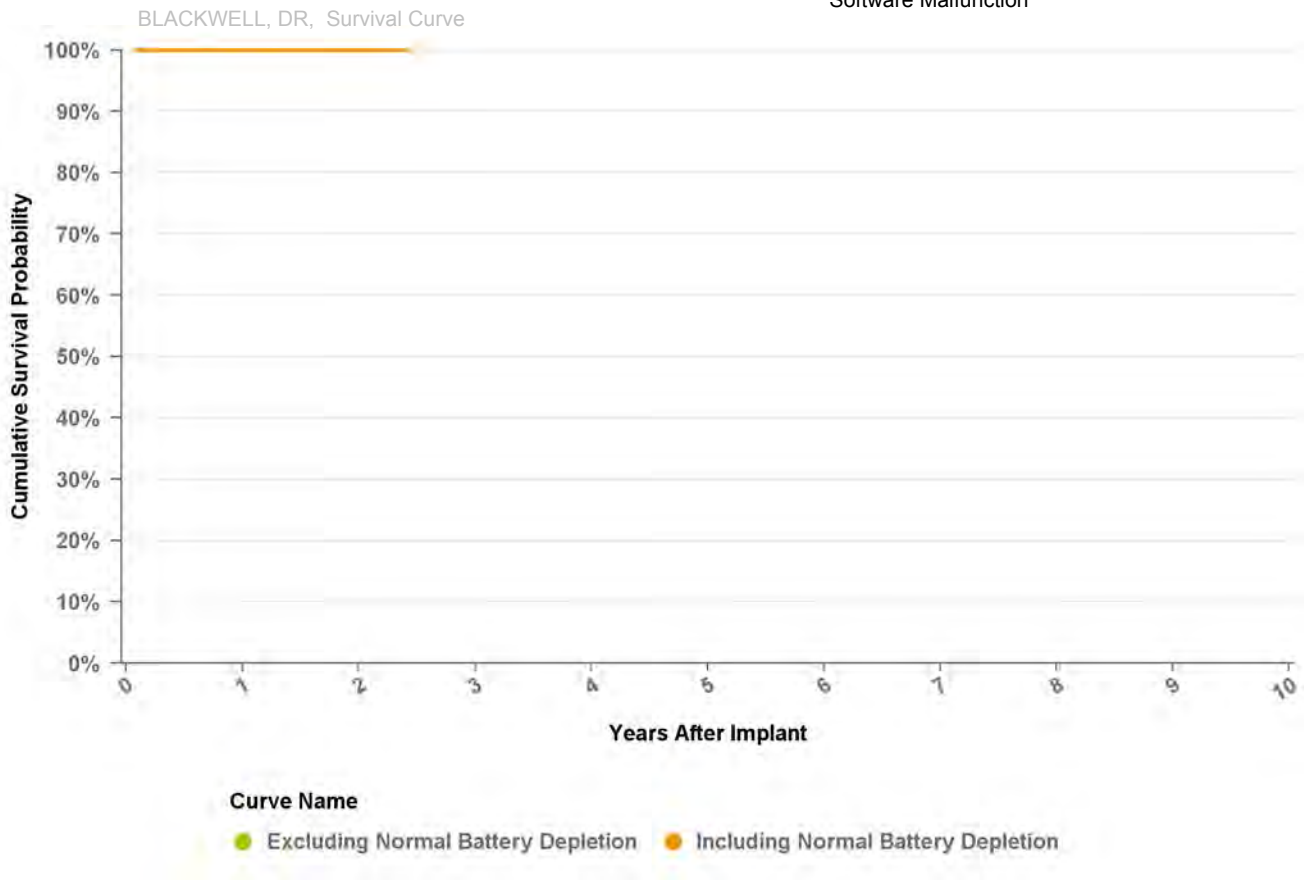
Electrical Component 1

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDBB1D4 Evera XT

US Market Release Date 3-Apr-13

CE Market Approval Date

Registered US Implants 24,748

Estimated Active US Implants 23,746

Normal Battery Depletions (US) 3

NBG Code DDE-DDDR

Max Delivered Energy 36 J

Total Malfunctions (US) 2

Therapy Not Compromised Malfunctions 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

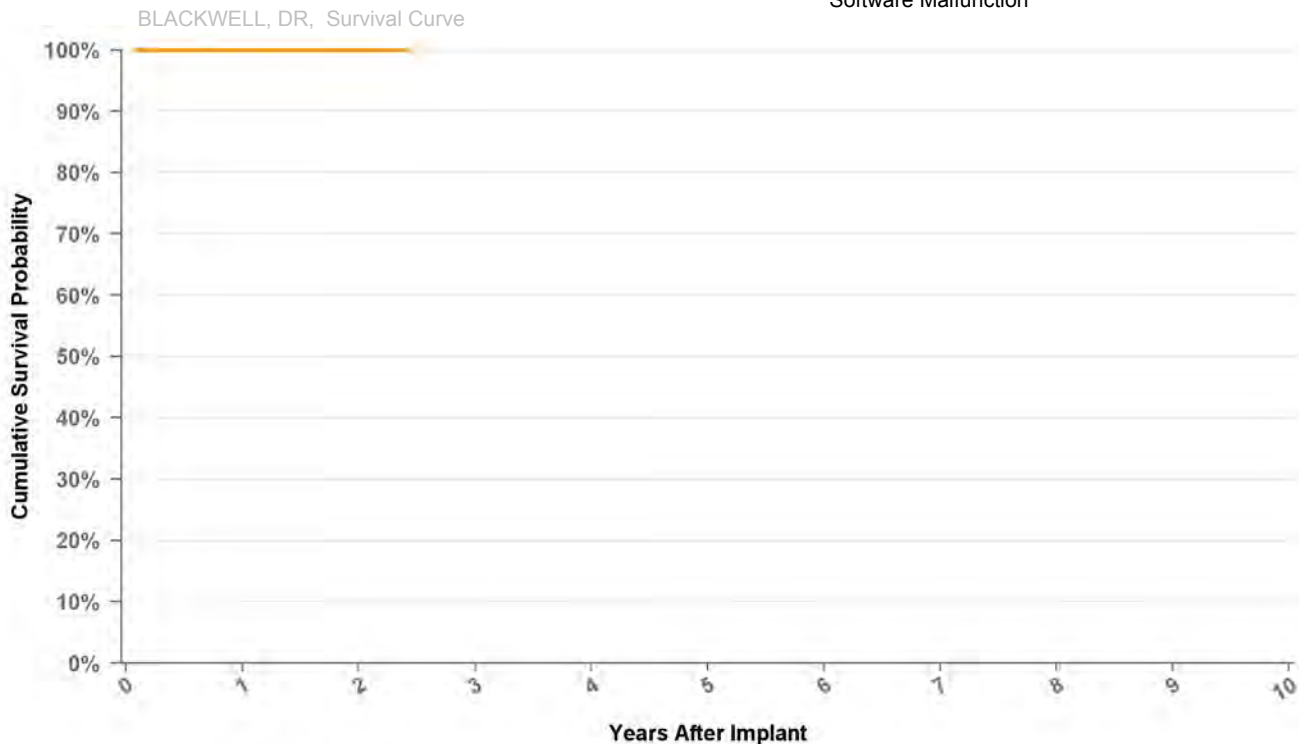
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

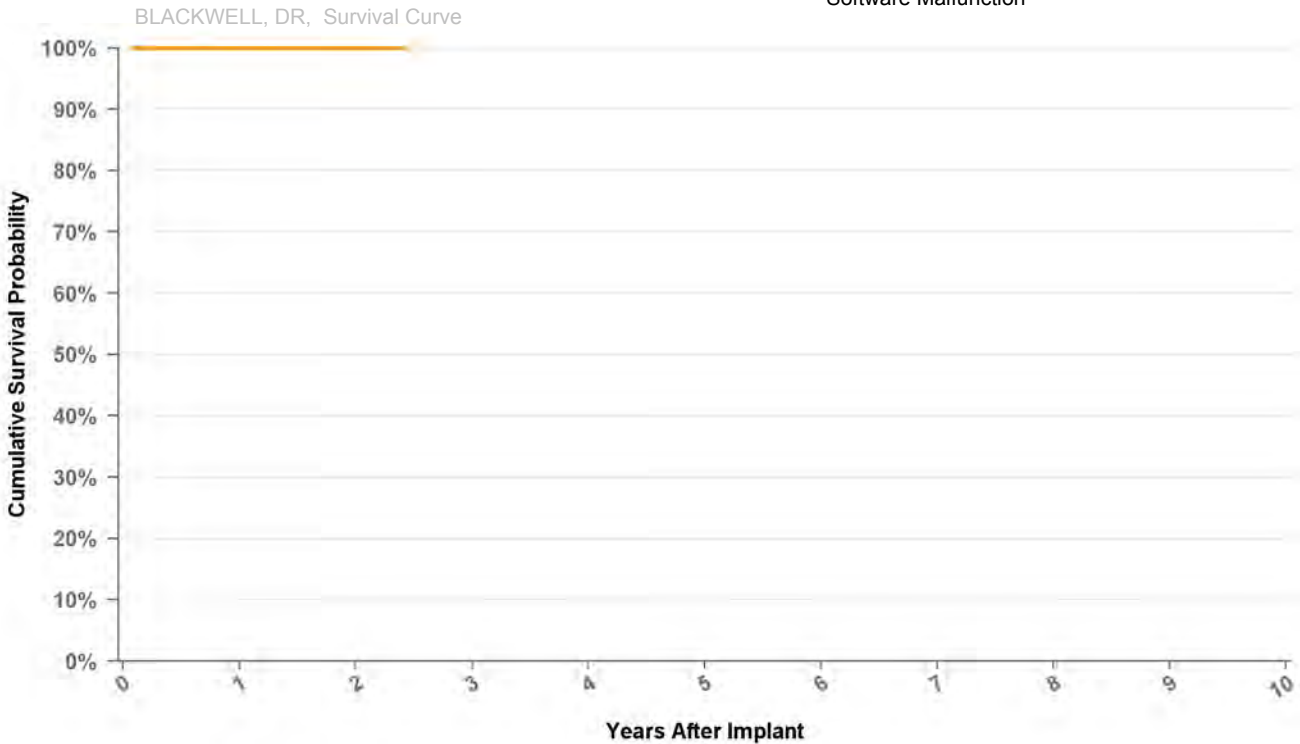
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDBB2D1 Evera XT

US Market Release Date	
CE Market Approval Date	17-Dec-12
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 Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDBB2D4 Evera XT

US Market Release Date

CE Market Approval Date 17-Dec-12

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

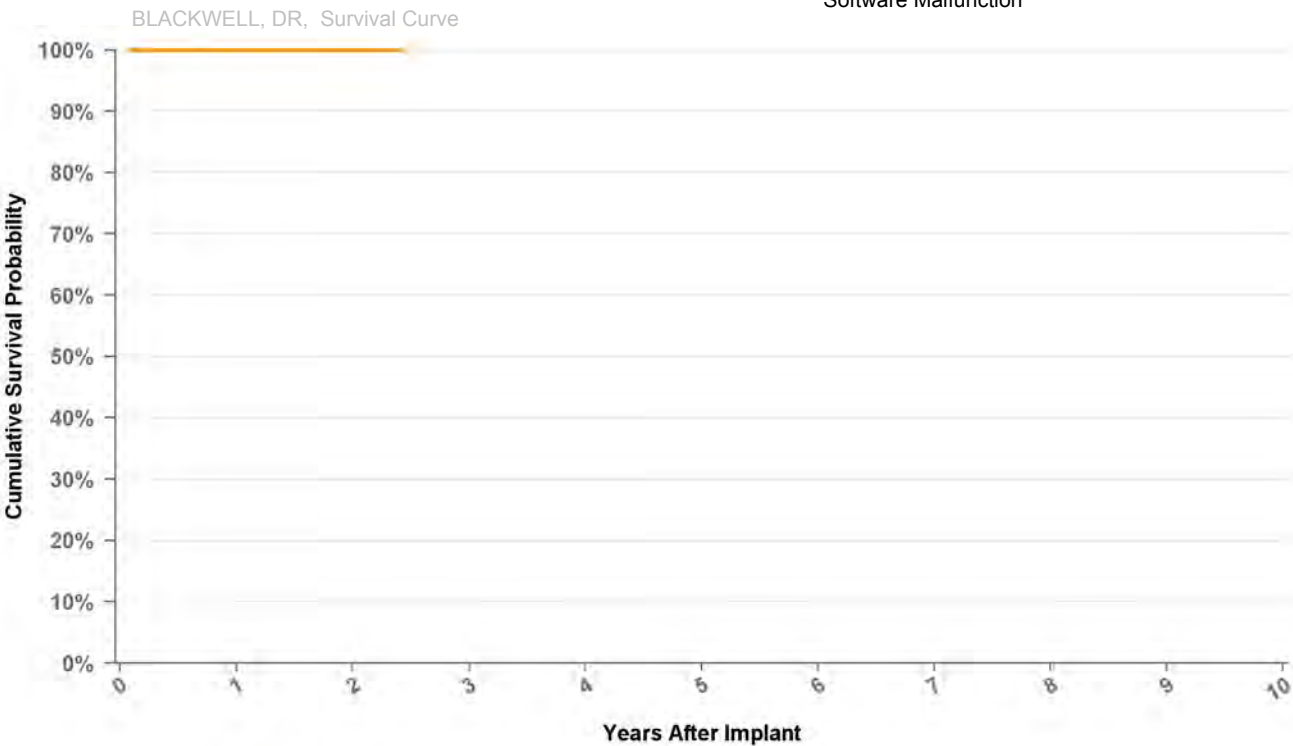
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

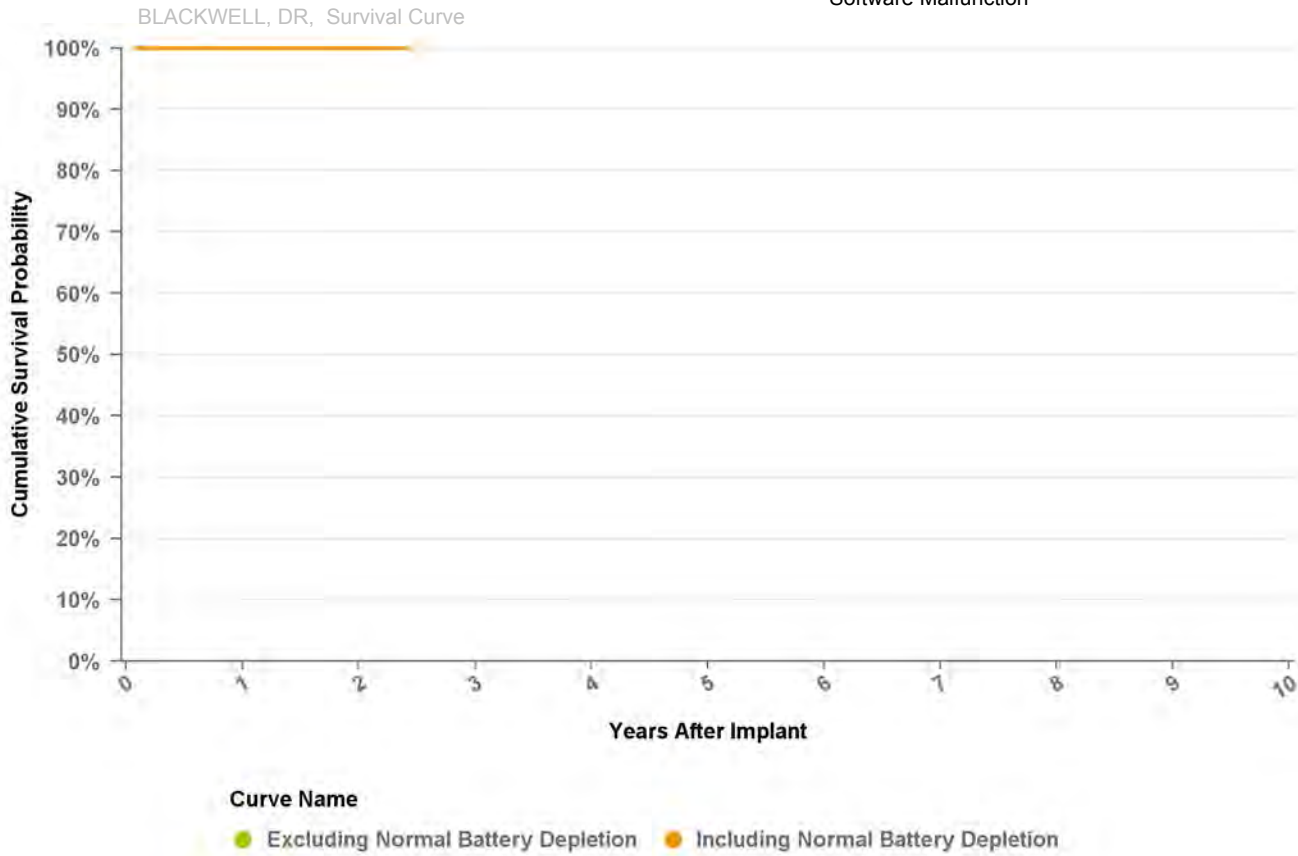
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDBC3D1 Evera S

US Market Release Date	3-Apr-13
CE Market Approval Date	17-Dec-12
Registered US Implants	4,773
Estimated Active US Implants	4,499
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



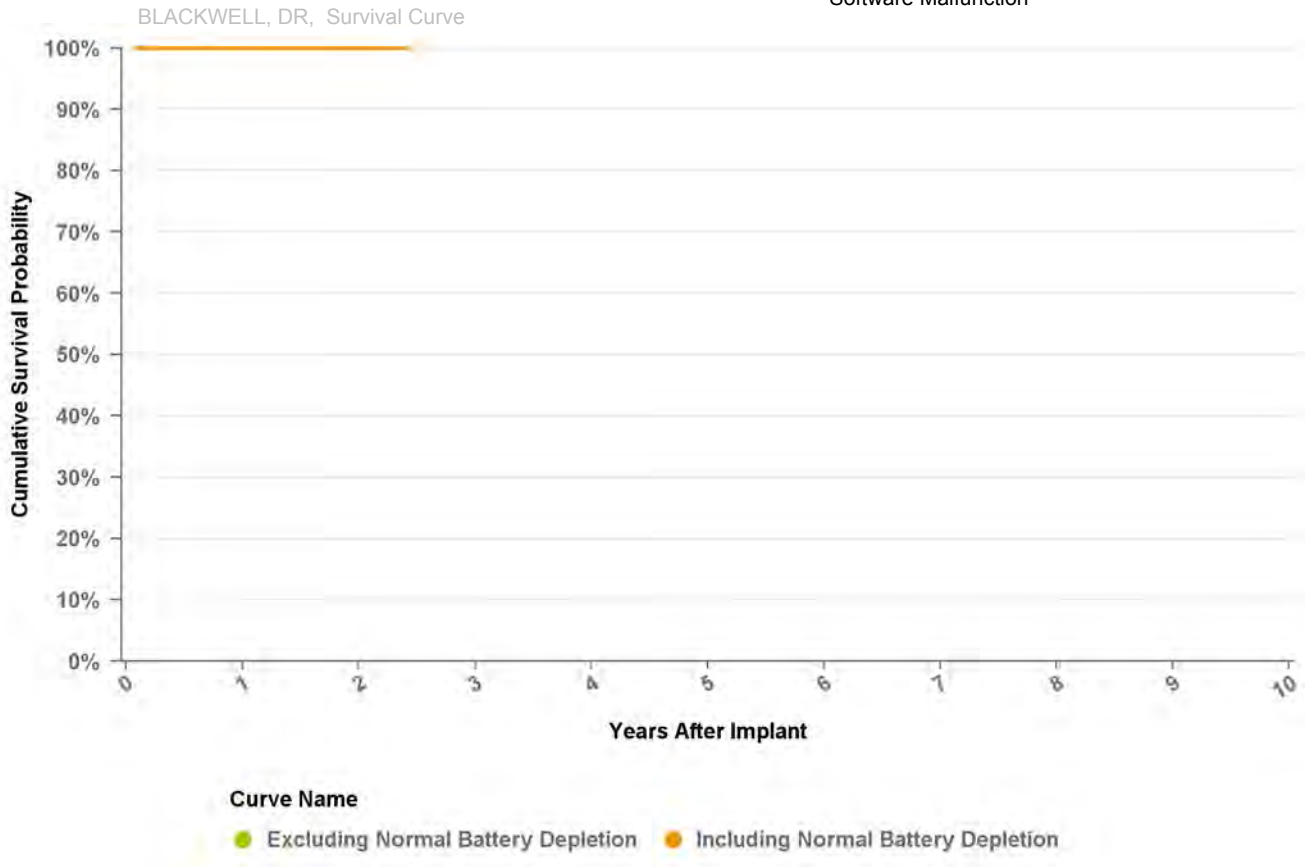
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDBC3D4 Evera S

US Market Release Date	3-Apr-13
CE Market Approval Date	17-Dec-13
Registered US Implants	4,316
Estimated Active US Implants	4,110
Normal Battery Depletions (US)	1
NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



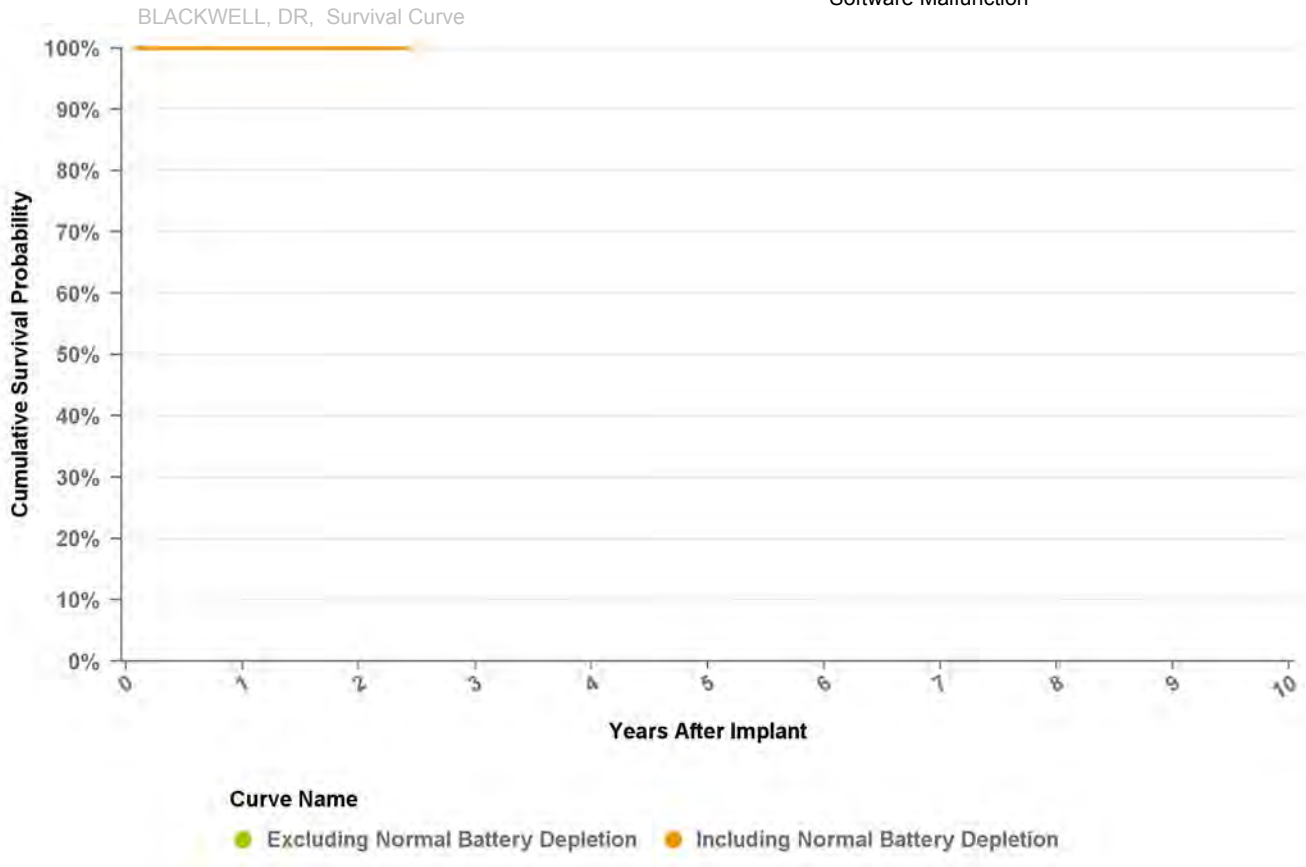
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDMB1D4 Evera MRI XT

US Market Release Date	11-Sep-15
CE Market Approval Date	
Registered US Implants	762
Estimated Active US Implants	759
Normal Battery Depletions (US)	0
NBG Code	
Max Delivered Energy	

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



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDMB2D4 Evera MRI XT

US Market Release Date

CE Market Approval Date 31-Mar-14

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

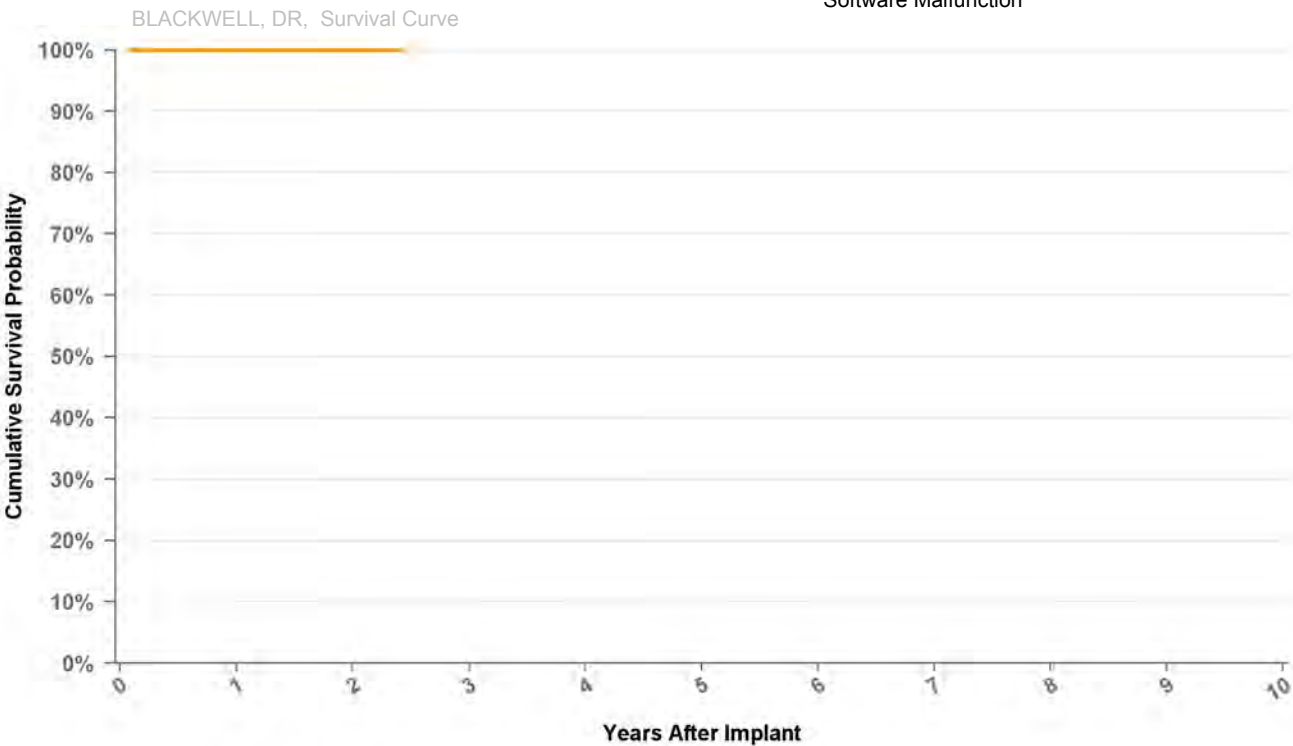
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

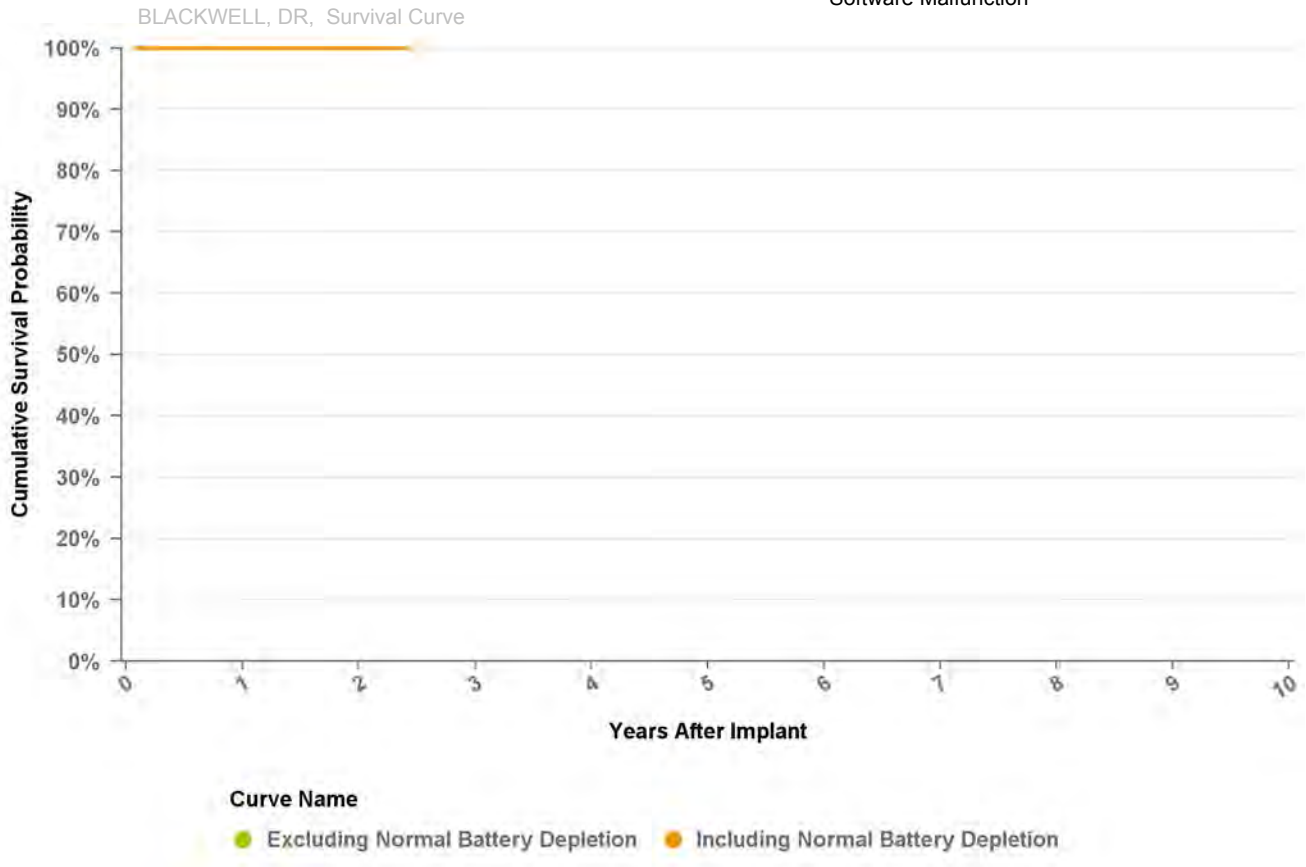
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DDMC3D4 Evera MRI

US Market Release Date	
CE Market Approval Date	31-Mar-14
Registered US Implants	42
Estimated Active US Implants	42
Normal Battery Depletions (US)	0
NBG Code	DDE-DDDR
Max Delivered Energy	35 J

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



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	30821	6910	175

Implantable Cardioverter Defibrillator

DVBB1D1 Evera XT

US Market Release Date	3-Apr-13
CE Market Approval Date	
Registered US Implants	11,370
Estimated Active US Implants	10,859
Normal Battery Depletions (US)	1
NBG Code	VVE-VVIR
Max Delivered Energy	36 J

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



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVBB1D4 Evera XT

US Market Release Date 3-Apr-13

CE Market Approval Date

Registered US Implants 19,329

Estimated Active US Implants 18,548

Normal Battery Depletions (US) 4

NBG Code VVE-VVIR

Max Delivered Energy 36 J

Total Malfunctions (US) 2

Therapy Not Compromised Malfunctions 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

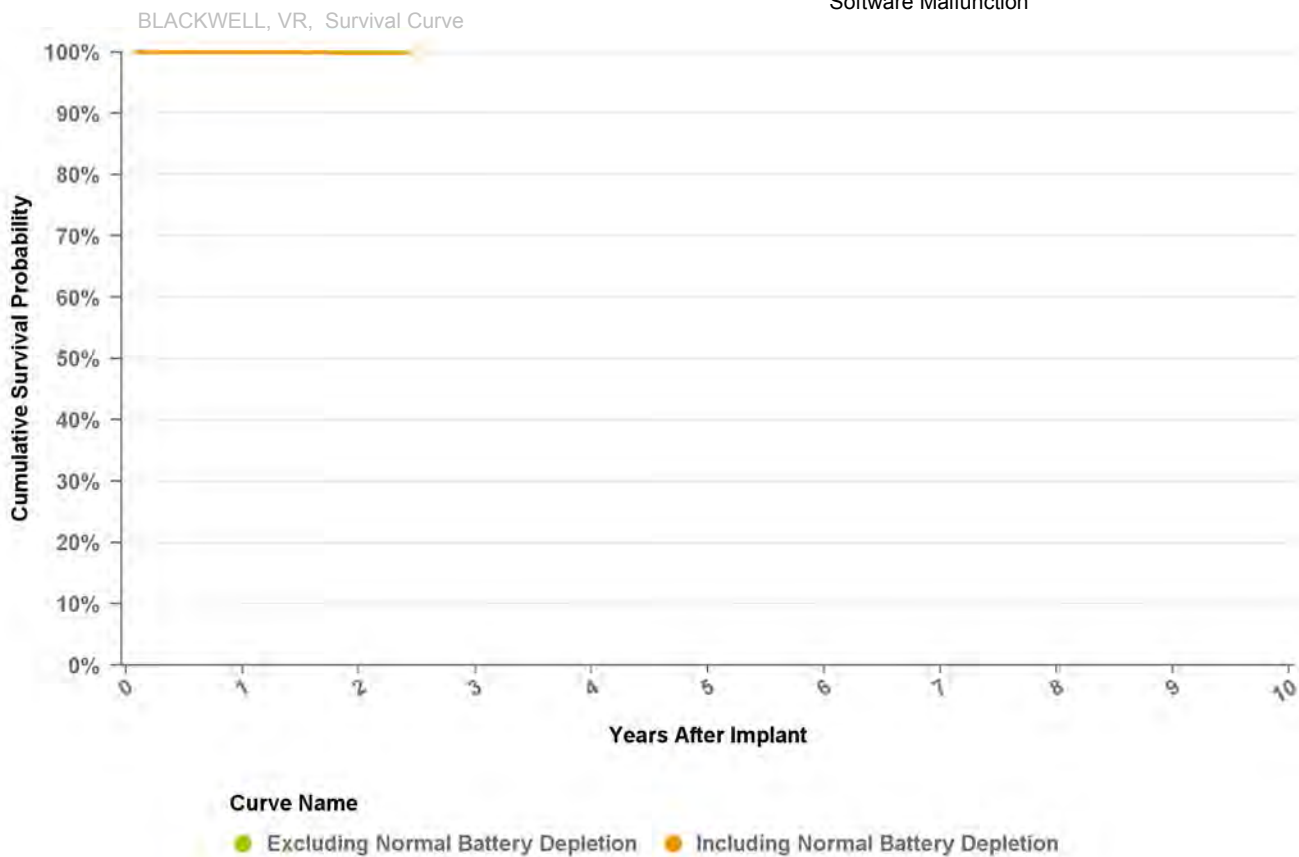
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



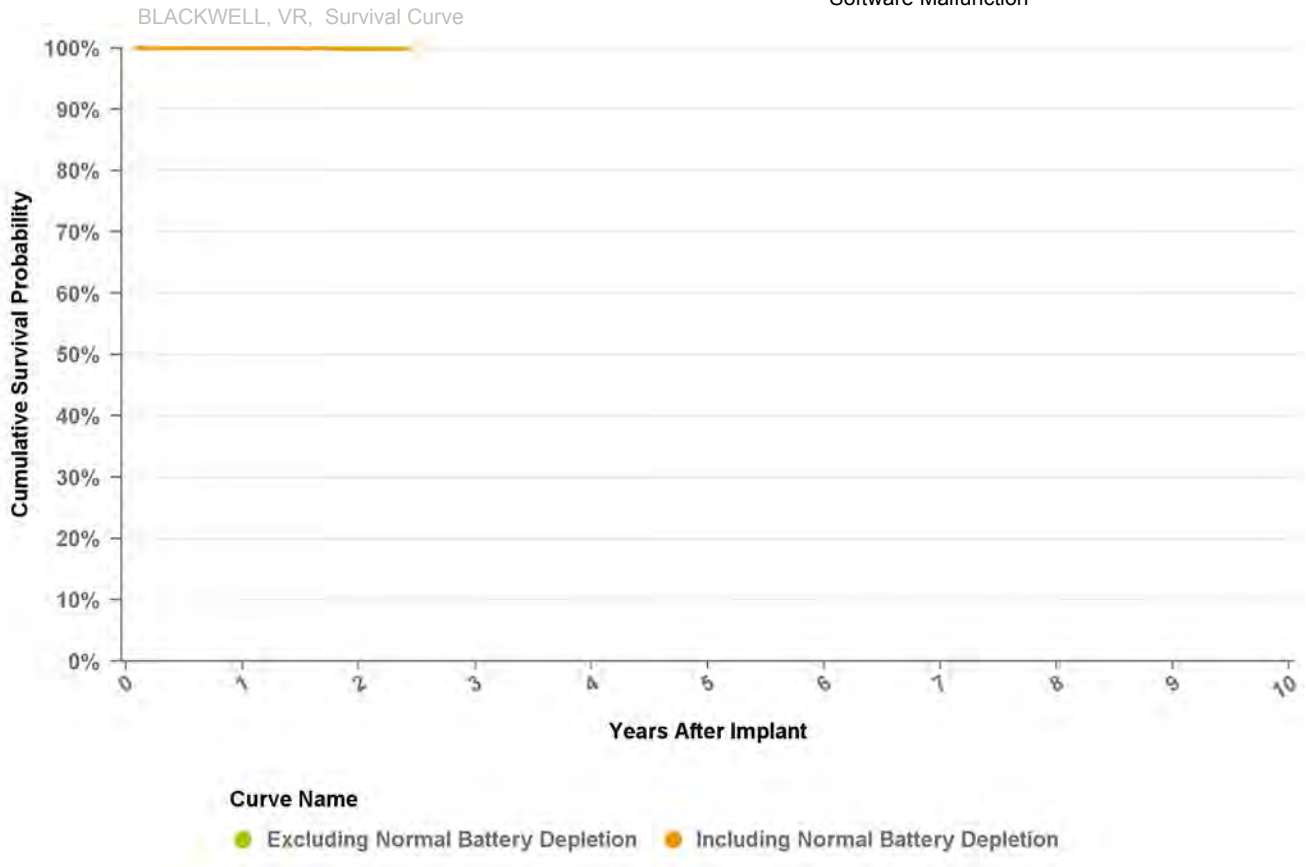
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVBB2D1 Evera XT

US Market Release Date	
CE Market Approval Date	17-Dec-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



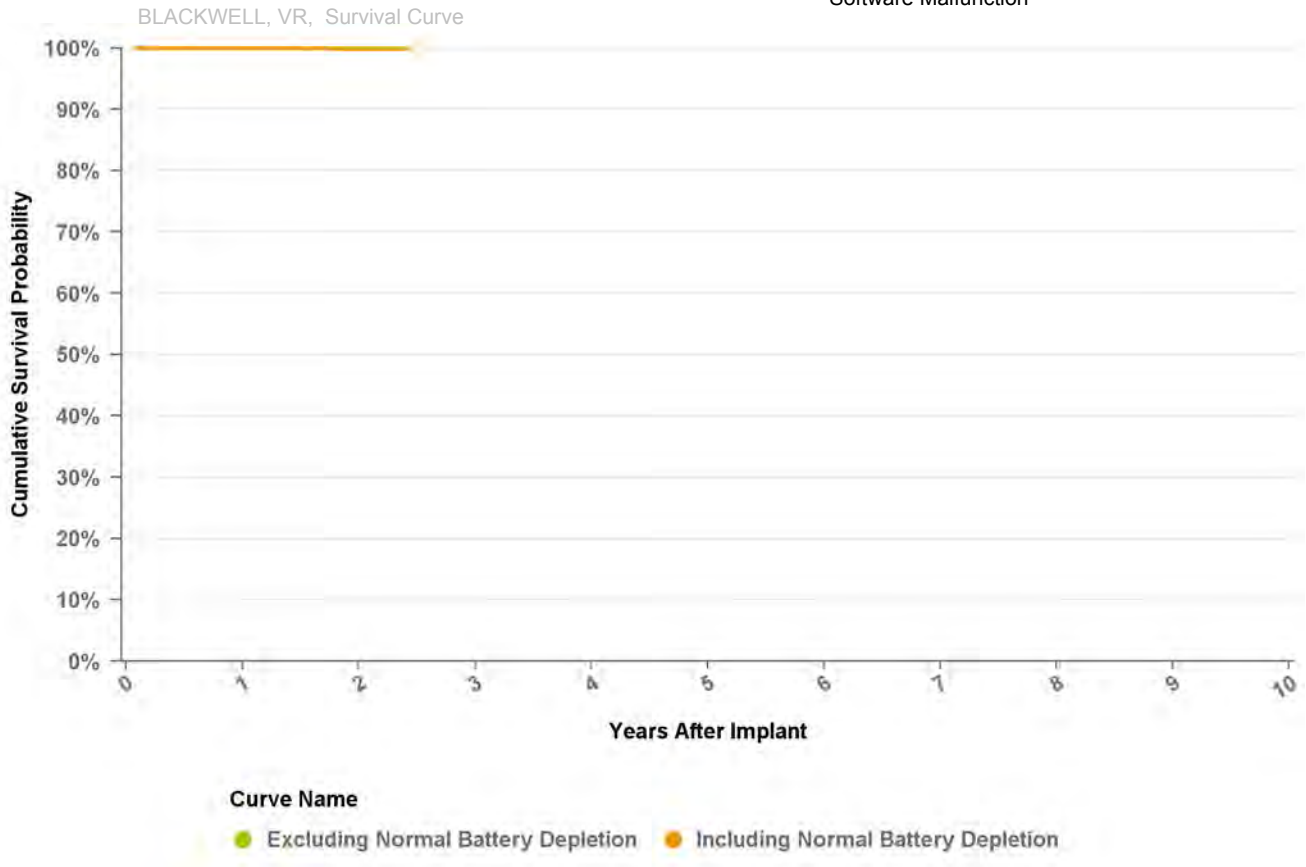
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVBB2D4 Evera XT

US Market Release Date	
CE Market Approval Date	17-Dec-12
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



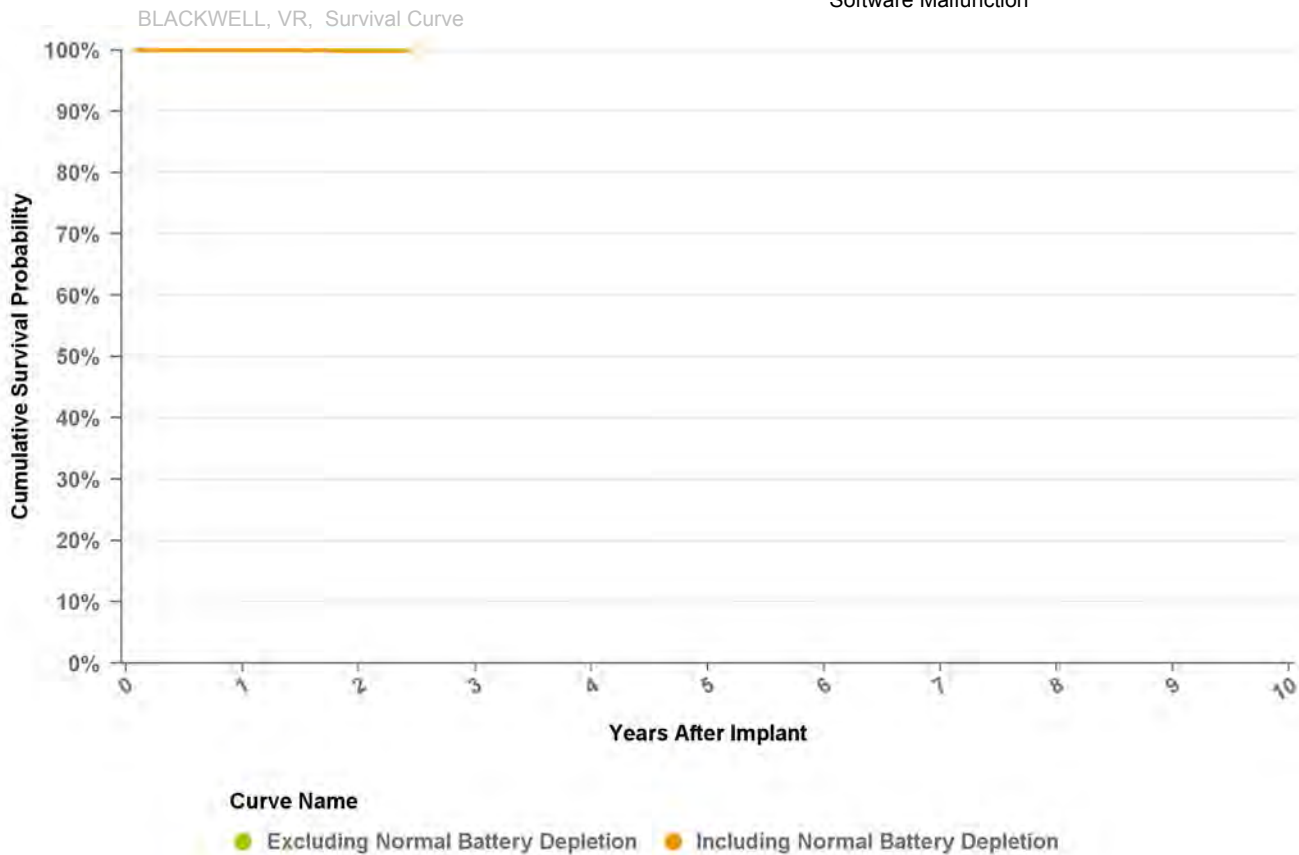
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVBC3D1 Evera S

US Market Release Date	3-Apr-13
CE Market Approval Date	17-Dec-12
Registered US Implants	2,876
Estimated Active US Implants	2,748
Normal Battery Depletions (US)	0
NBG Code	VVE-VVIR
Max Delivered Energy	36 J

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



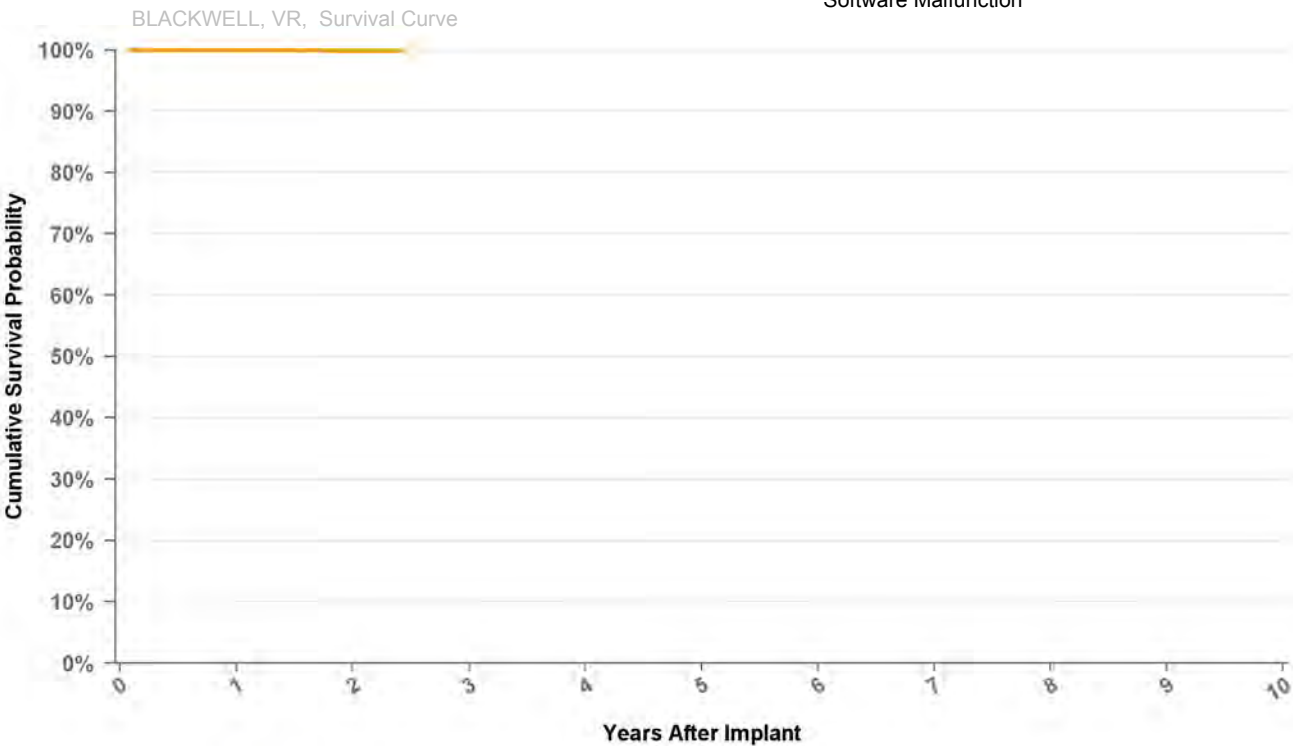
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVBC3D4 Evera S

US Market Release Date	3-Apr-13
CE Market Approval Date	17-Dec-12
Registered US Implants	4,127
Estimated Active US Implants	3,944
Normal Battery Depletions (US)	0
NBG Code	VVE-VVIR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVMB1D4 Evera MRI XT

US Market Release Date 11-Sep-15

CE Market Approval Date

Registered US Implants 625

Estimated Active US Implants 619

Normal Battery Depletions (US) 0

NBG Code VVE-VVIR

Max Delivered Energy 35 J

Total Malfunctions (US) 1

Therapy Not Compromised Malfunctions 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

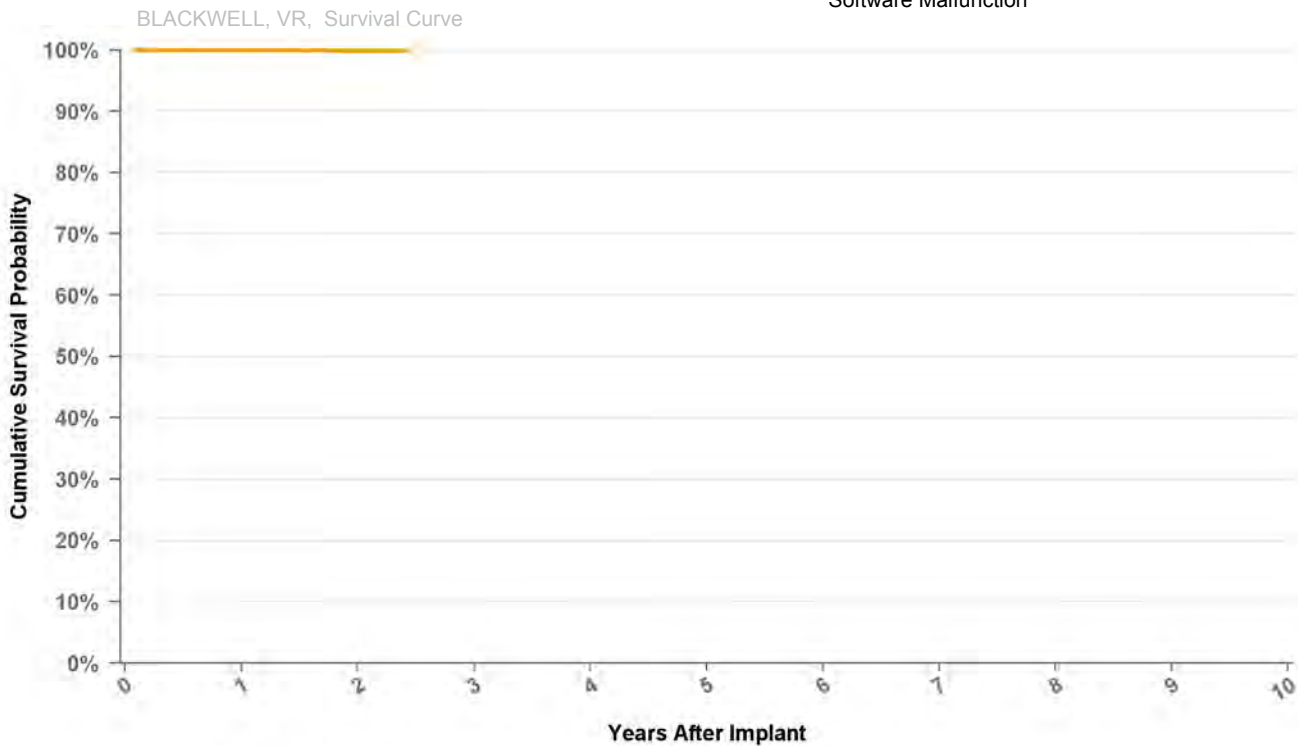
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

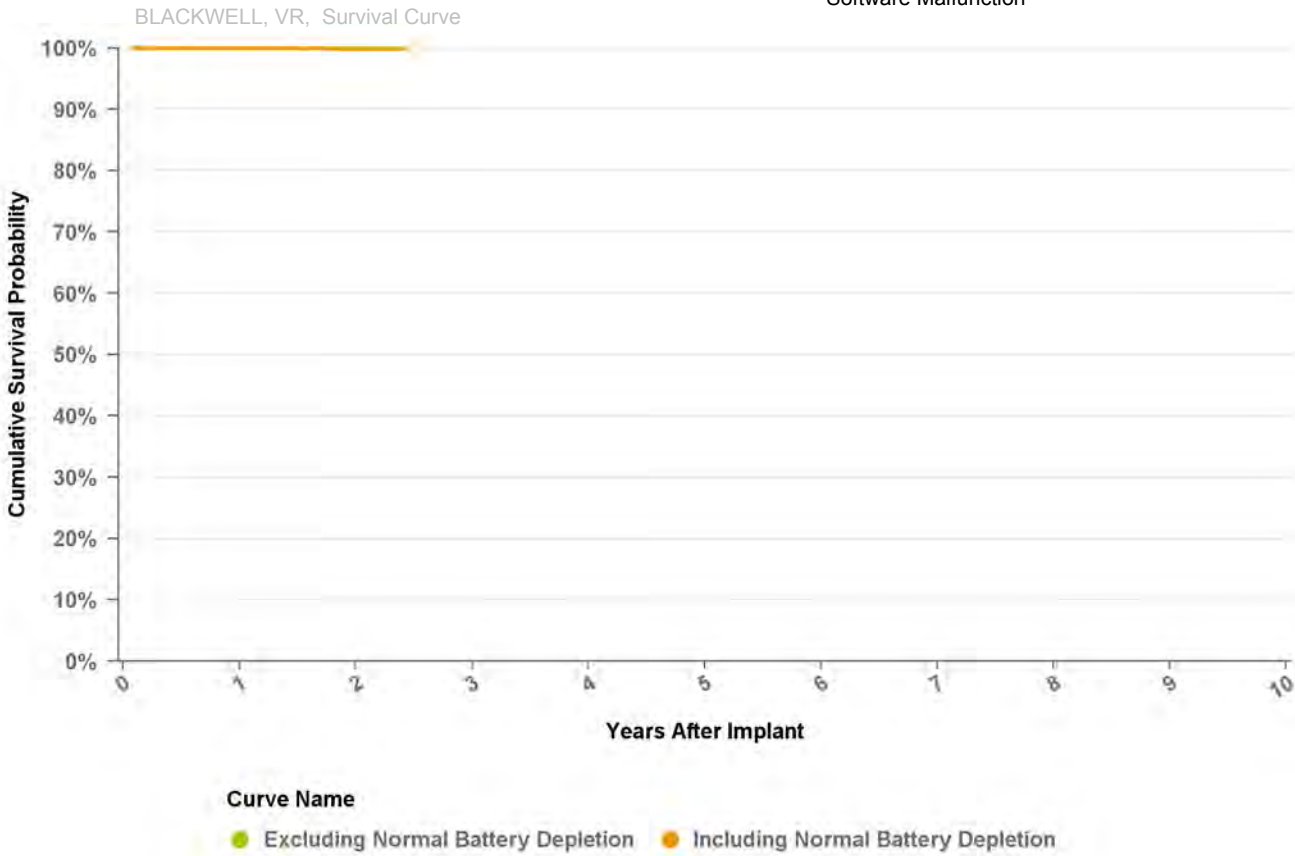
Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVMB2D4 Evera MRI XT

US Market Release Date	
CE Market Approval Date	31-Mar-14
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 Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

Implantable Cardioverter Defibrillator

DVMC3D4 Evera MRI S

US Market Release Date

CE Market Approval Date 31-Mar-14

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 Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

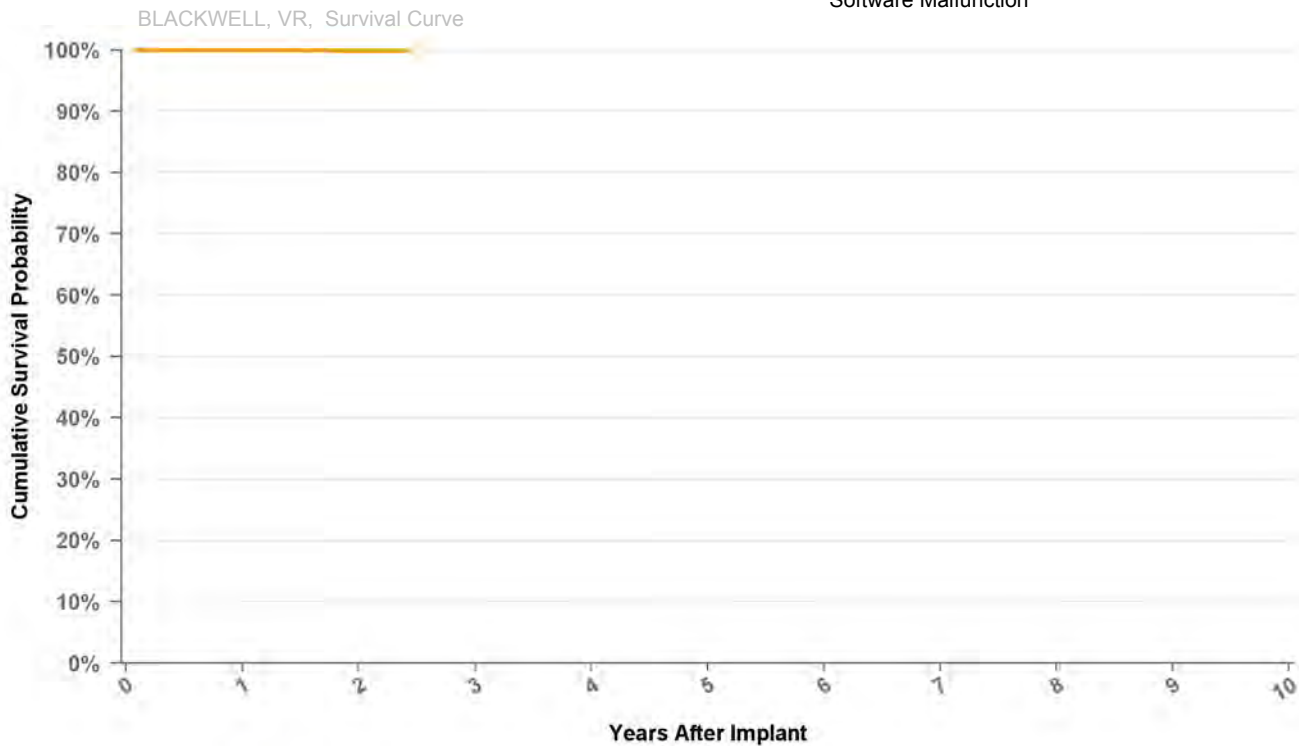
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	19101	3751	111

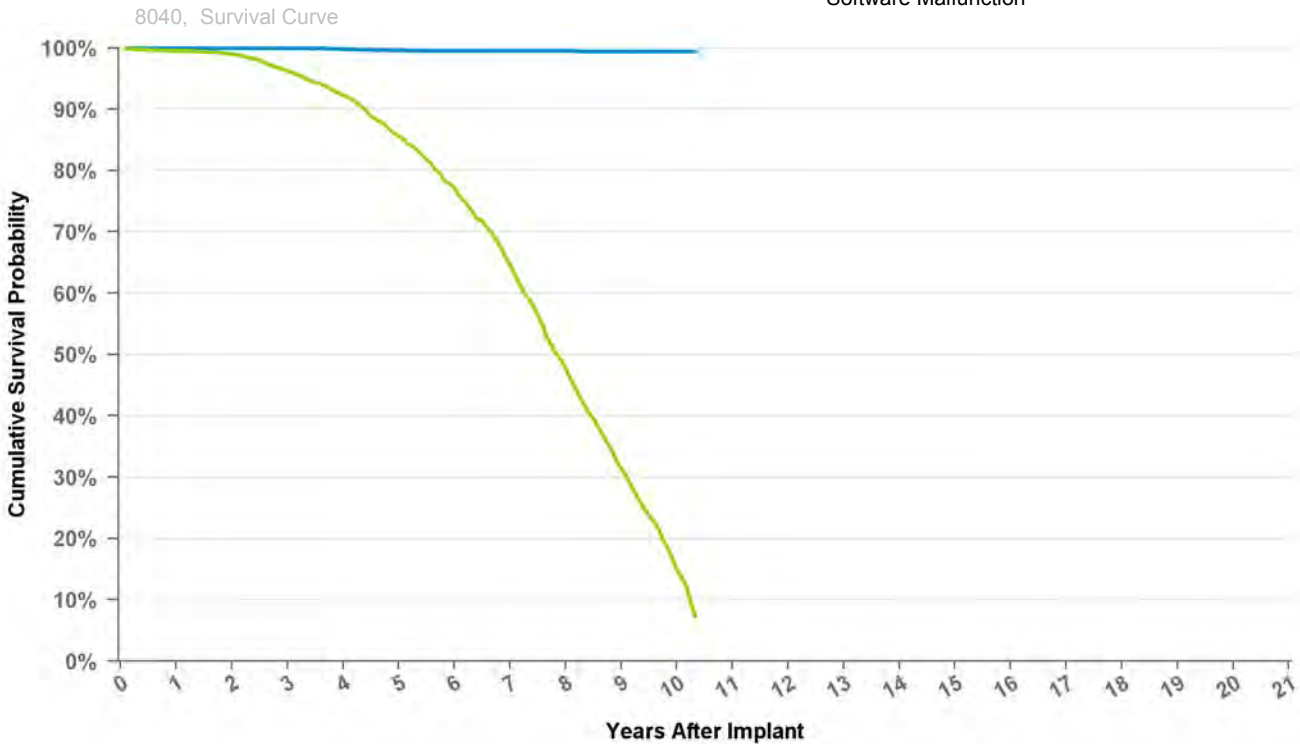
Cardiac Resynchronization Therapy

8040

InSync

US Market Release Date	28-Aug-01
CE Market Approval Date	
Registered US Implants	15,333
Estimated Active US Implants	749
Normal Battery Depletions (US)	1,532
NBG Code	DDDR

Total Malfunctions (US)	34
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.6%	99.5%	99.5%	99.5%	99.5%	99.4%	99.4%
Including NBD	99.6%	99.0%	96.3%	92.3%	85.6%	77.2%	64.7%	47.8%	31.4%	15.0%	7.3%
Effective Sample Size	11559	9457	7469	5719	4368	3208	2187	1283	659	233	109

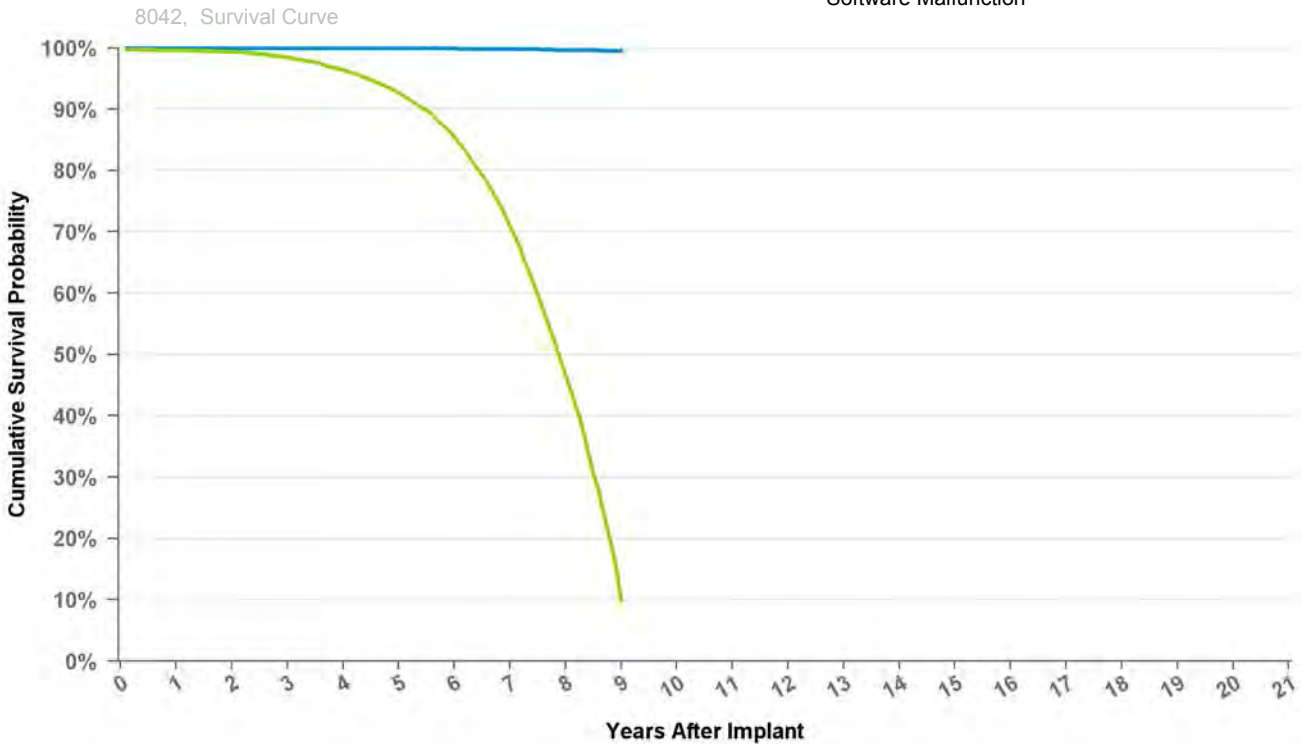
Cardiac Resynchronization Therapy

8042

InSync III

US Market Release Date	25-Feb-03
CE Market Approval Date	7-Feb-01
Registered US Implants	39,433
Estimated Active US Implants	8,945
Normal Battery Depletions (US)	3,887
NBG Code	DDDR

Total Malfunctions (US)	42
Therapy Not Compromised Malfunctions	24
Battery Malfunction	10
Electrical Component	2
Electrical Interconnect	3
Other Malfunction	7
Poss Early Battery Depltn	2
Software Malfunction	0
Therapy Compromised Malfunctions	18
Battery Malfunction	7
Electrical Component	0
Electrical Interconnect	11
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

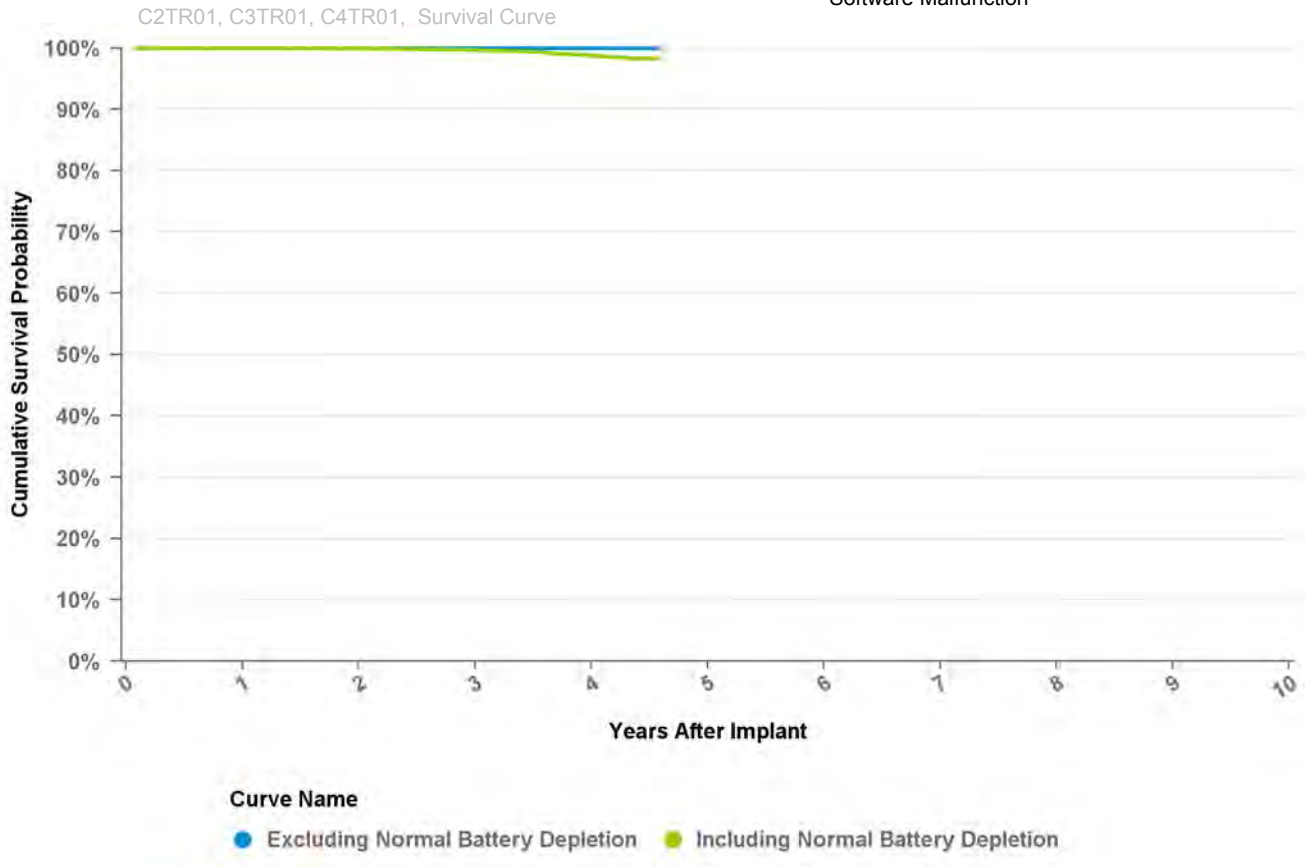
Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.5%
Including NBD	99.6%	99.4%	98.5%	96.4%	92.7%	85.5%	71.0%	46.7%	9.8%
Effective Sample Size	30224	25989	22390	19161	15767	9969	5559	2338	195

Cardiac Resynchronization Therapy

C2TR01 Syncra CRT-P

US Market Release Date	22-Mar-11
CE Market Approval Date	11-May-10
Registered US Implants	8,896
Estimated Active US Implants	7,084
Normal Battery Depletions (US)	20
NBG Code	OOE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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 55 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.8%	98.3%
Effective Sample Size	20939	13997	7886	2690	165

Cardiac Resynchronization Therapy

C3TR01

Consulta CRT-P

US Market Release Date

CE Market Approval Date 11-May-10

Registered US Implants 1

Estimated Active US Implants 1

Normal Battery Depletions (US) 0

NBG Code OAE-DDDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

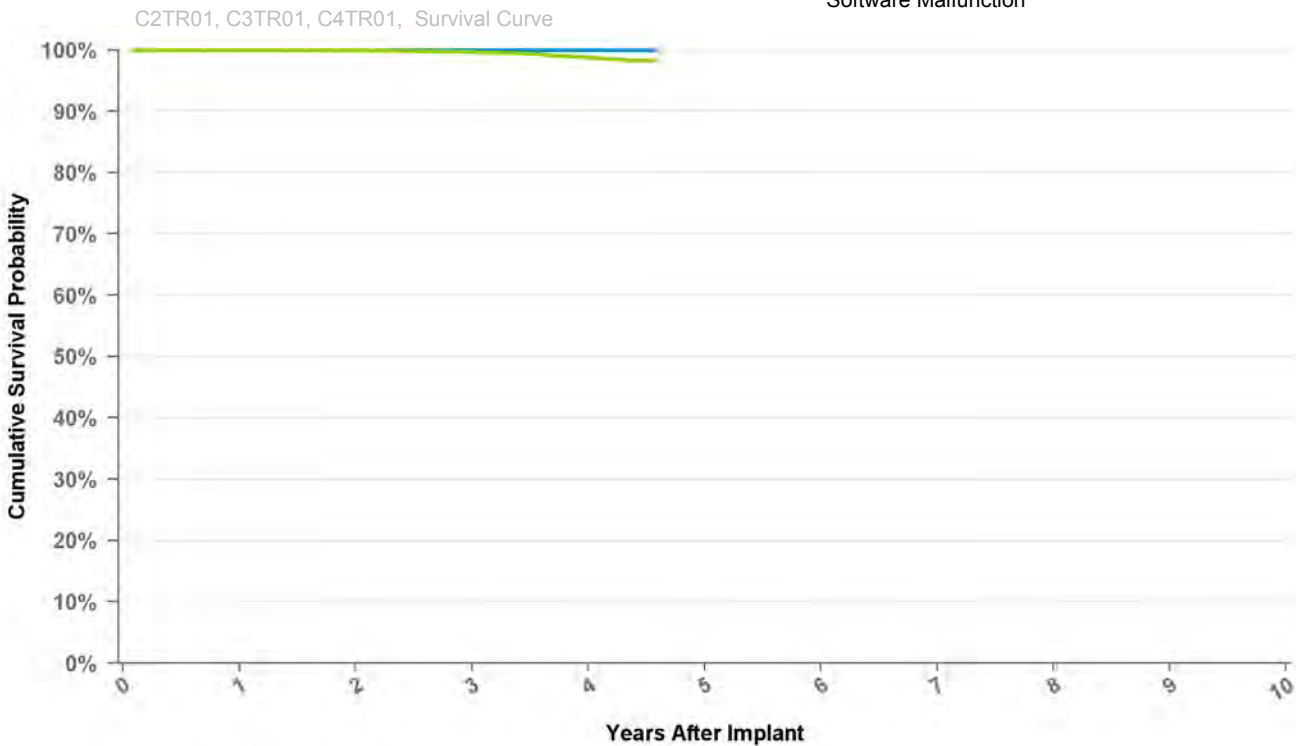
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

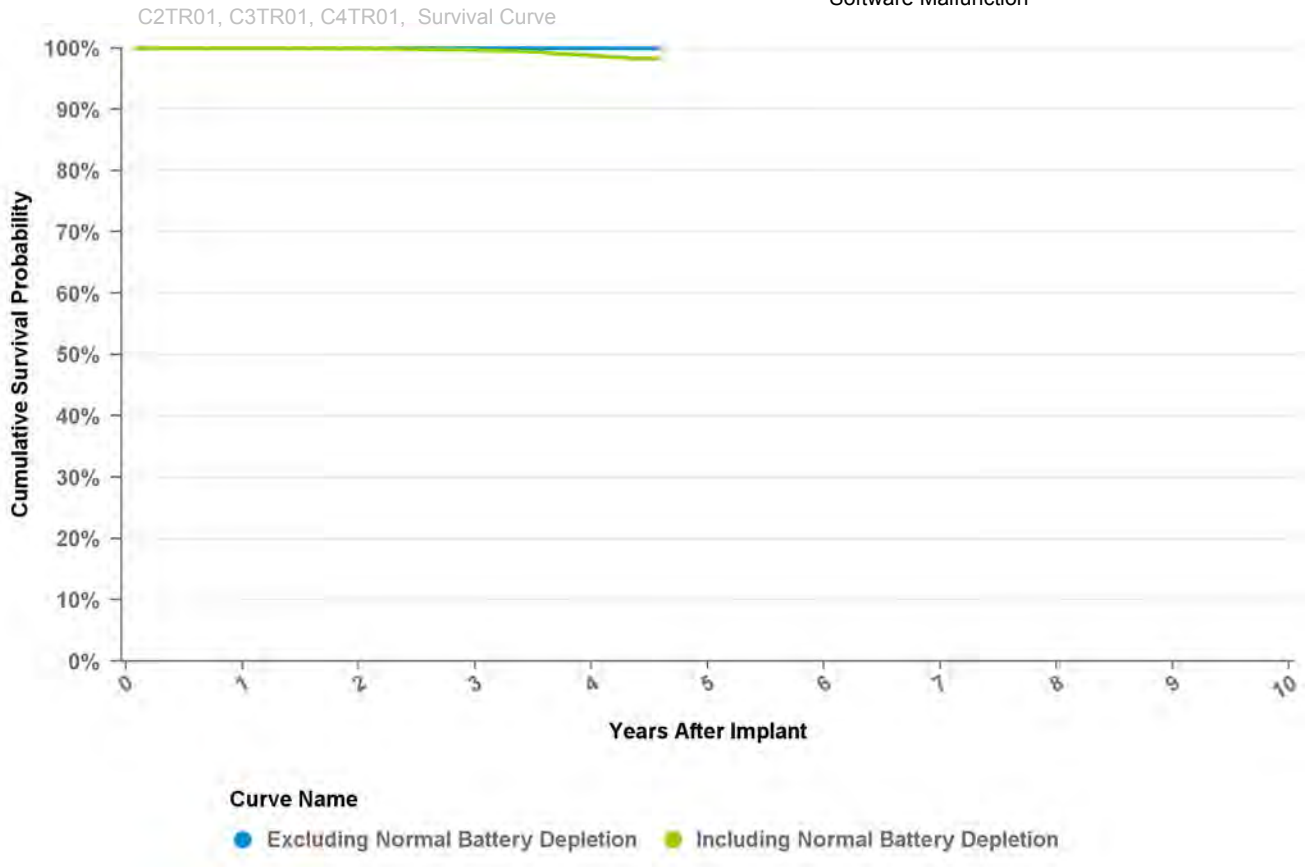
Years	1	2	3	4	at 55 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.8%	98.3%
Effective Sample Size	20939	13997	7886	2690	165

Cardiac Resynchronization Therapy

C4TR01 Consulta CRT-P

US Market Release Date	22-Mar-11
CE Market Approval Date	
Registered US Implants	19,309
Estimated Active US Implants	16,477
Normal Battery Depletions (US)	31
NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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 55 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.8%	98.3%
Effective Sample Size	20939	13997	7886	2690	165

Cardiac Resynchronization Therapy

C5TR01 Viva CRT-P

US Market Release Date	
CE Market Approval Date	4-Apr-14
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



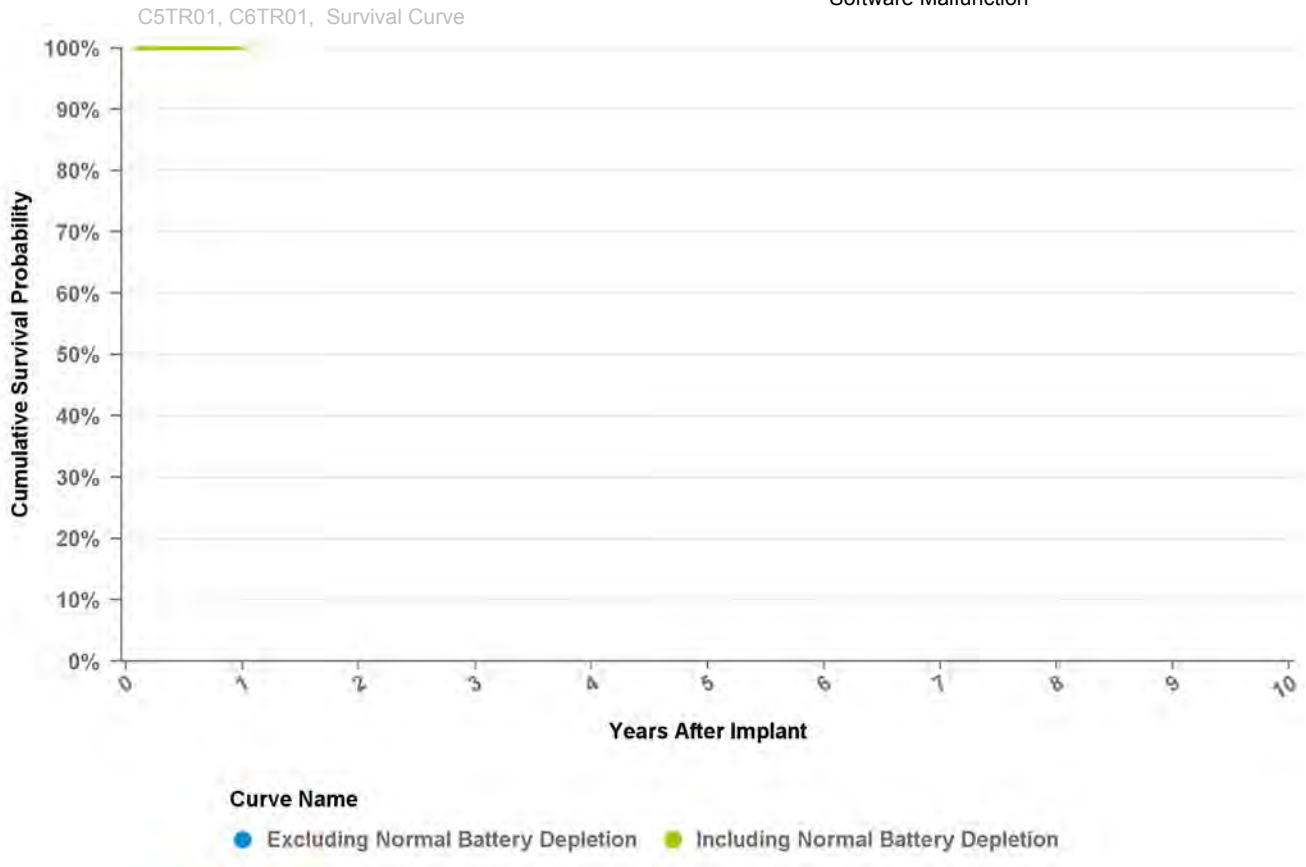
Years	at 12 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	115

Cardiac Resynchronization Therapy

C6TR01 Viva CRT-P

US Market Release Date	9-Jul-14
CE Market Approval Date	
Registered US Implants	2,158
Estimated Active US Implants	2,117
Normal Battery Depletions (US)	0
NBG Code	OAE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



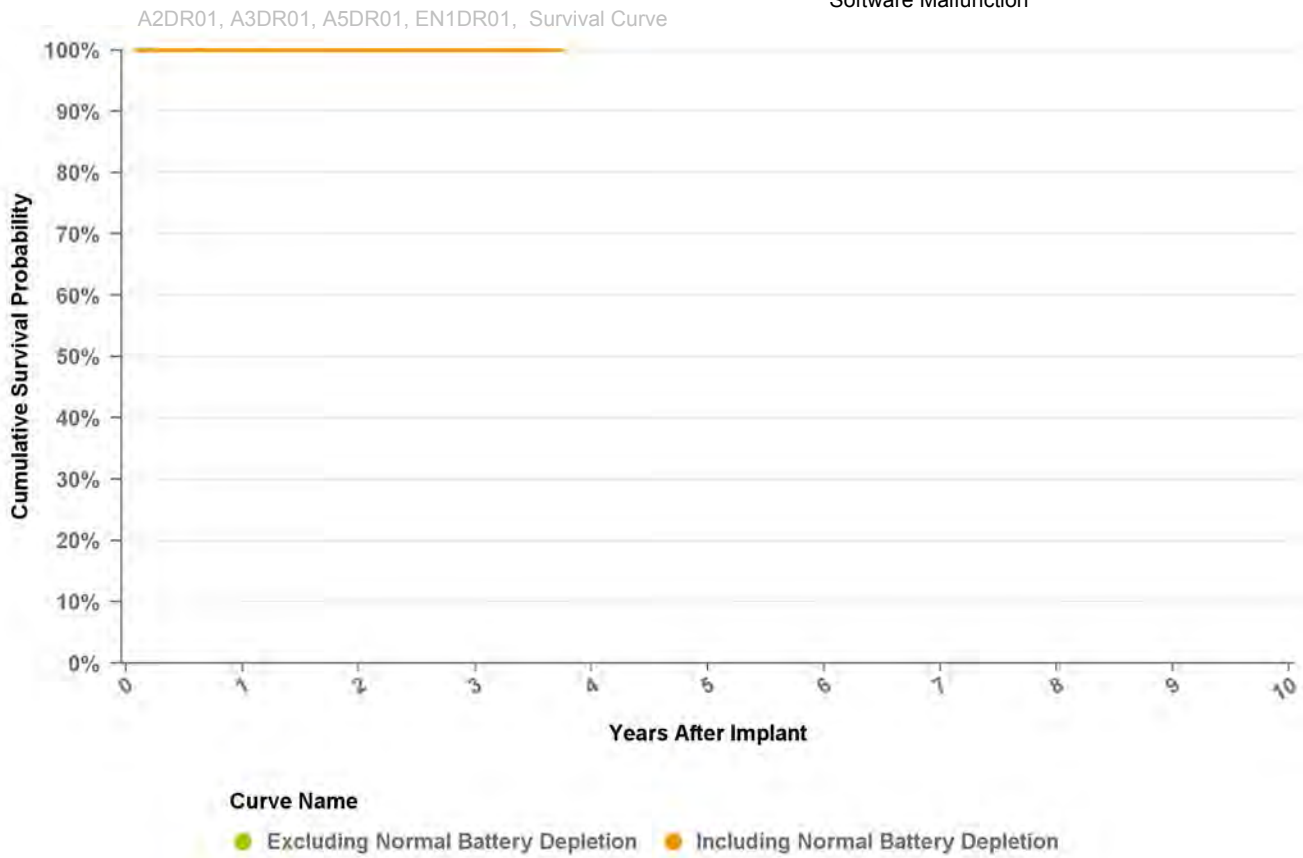
Years	at 12 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	115

Implantable Pulse Generator

A2DR01 Advisa DR MRI

US Market Release Date	15-Jan-13
CE Market Approval Date	
Registered US Implants	124,321
Estimated Active US Implants	120,428
Normal Battery Depletions (US)	4
NBG Code	OAE-DDDR

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



Years	1	2	3	at 45 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	55527	15601	703	125

Implantable Pulse Generator

A3DR01 Advisa DR MRI

US Market Release Date

CE Market Approval Date 2-Jun-09

Registered US Implants 1

Estimated Active US Implants 1

Normal Battery Depletions (US) 0

NBG Code OAE-DDDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

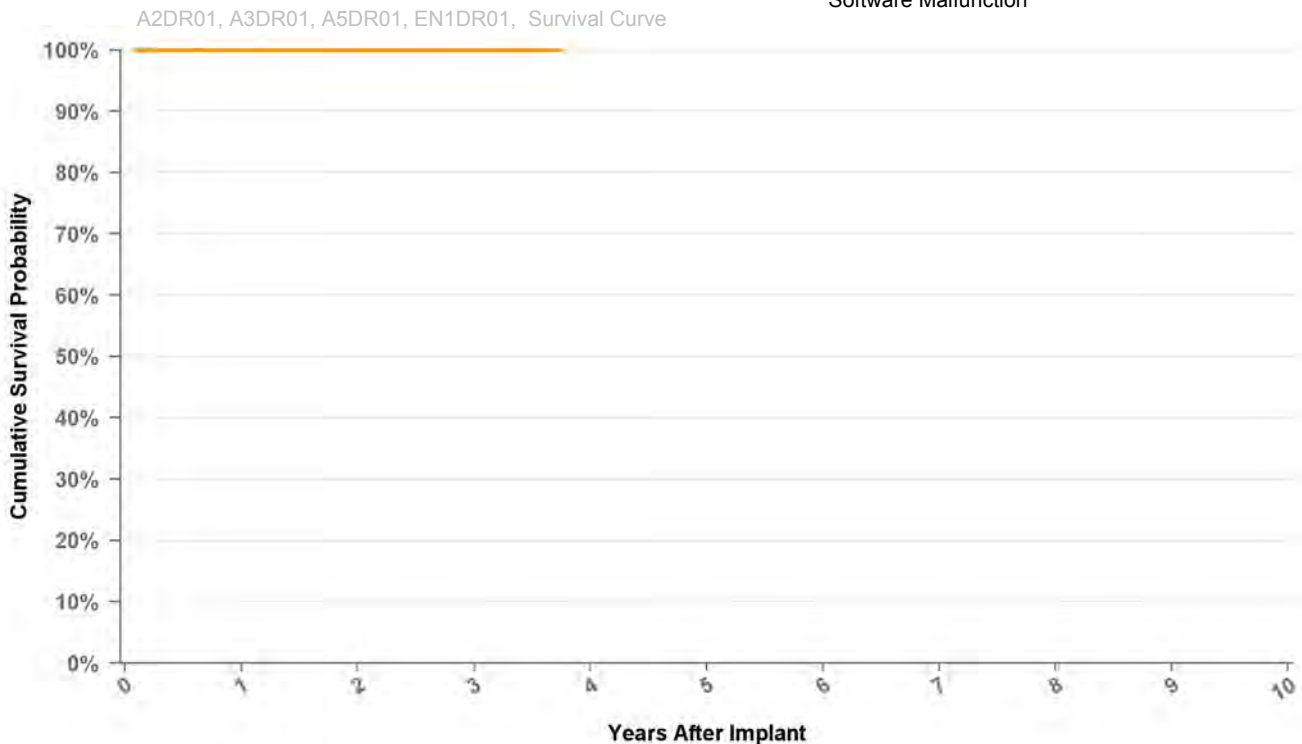
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

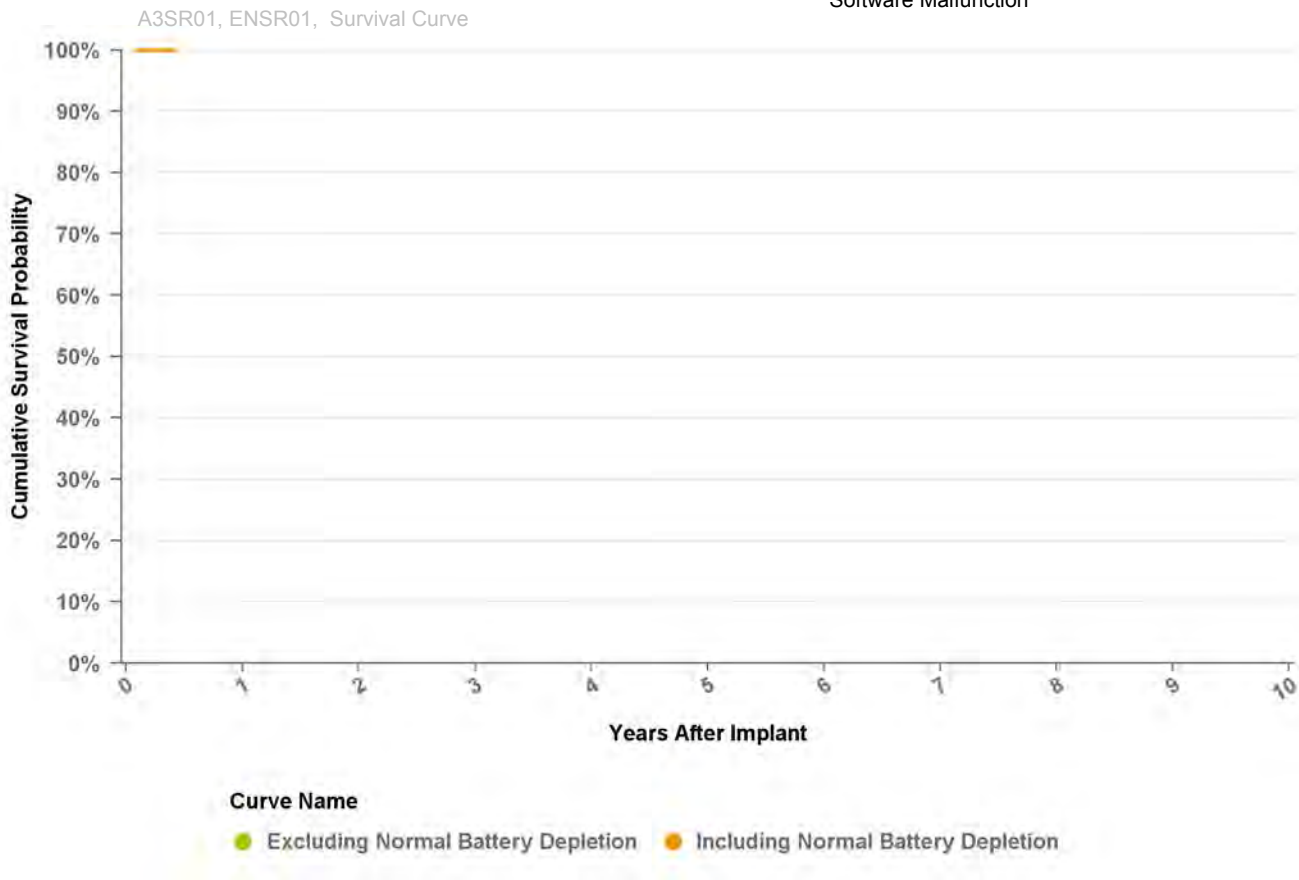
Years	1	2	3	at 45 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	55527	15601	703	125

Implantable Pulse Generator

A3SR01 Advisa SR

US Market Release Date	19-Mar-15
CE Market Approval Date	24-Apr-14
Registered US Implants	2,176
Estimated Active US Implants	2,159
Normal Battery Depletions (US)	0
NBG Code	VVIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	197

Implantable Pulse Generator

A4DR01 Advisa DR

US Market Release Date 4-Apr-11

CE Market Approval Date

Registered US Implants 1,535

Estimated Active US Implants 1,371

Normal Battery Depletions (US) 0

NBG Code OAE-DDDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

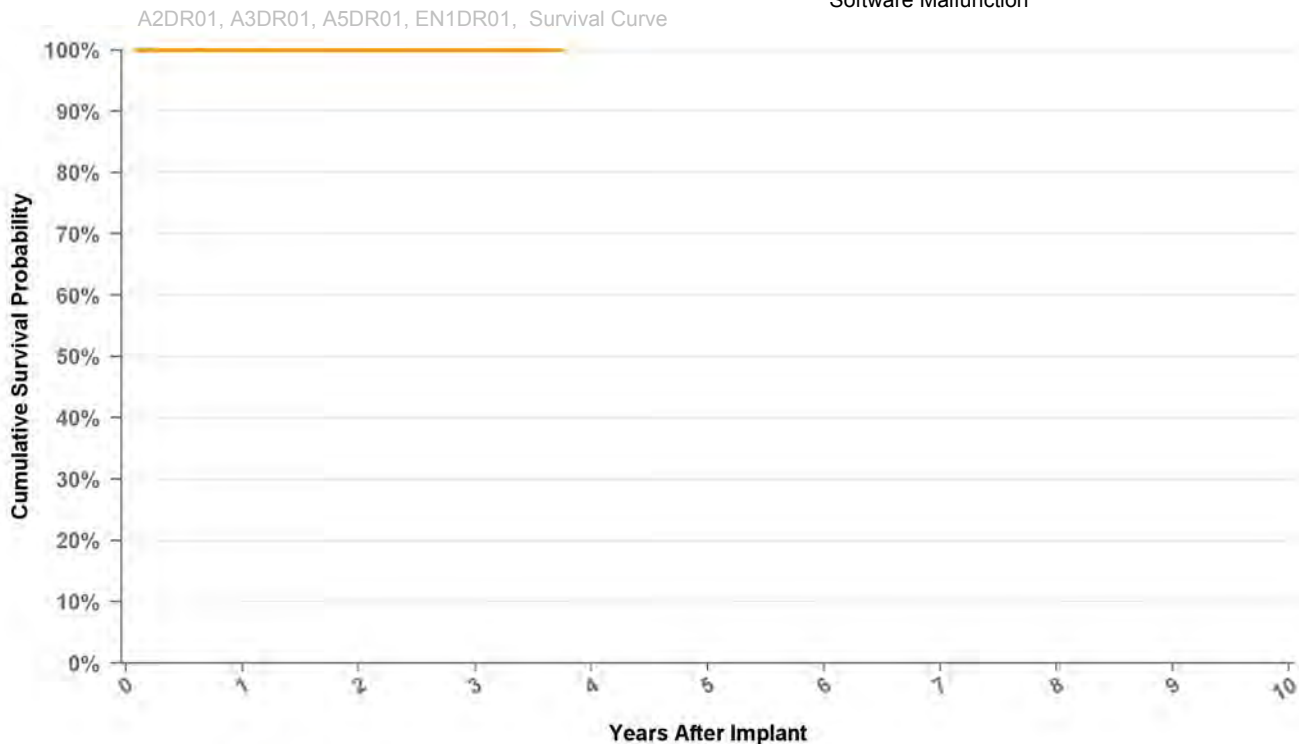
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	at 45 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	55527	15601	703	125

Implantable Pulse Generator

A5DR01 Advisa DR

US Market Release Date

CE Market Approval Date 2-Jun-09

Registered US Implants 1

Estimated Active US Implants 1

Normal Battery Depletions (US) 0

NBG Code OAE-DDDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

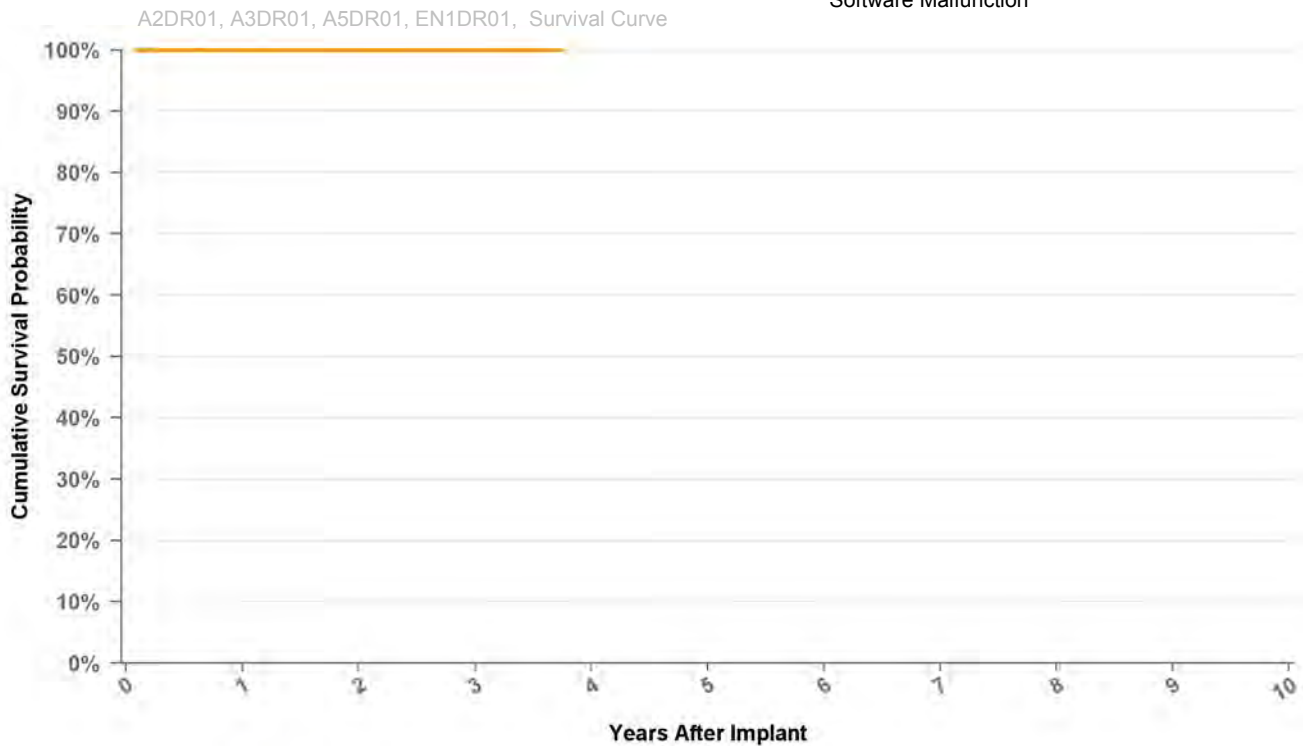
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	at 45 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	55527	15601	703	125

Implantable Pulse Generator

ADD01

Adapta D

US Market Release Date 17-Jul-06

CE Market Approval Date 20-Sep-05

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code DDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

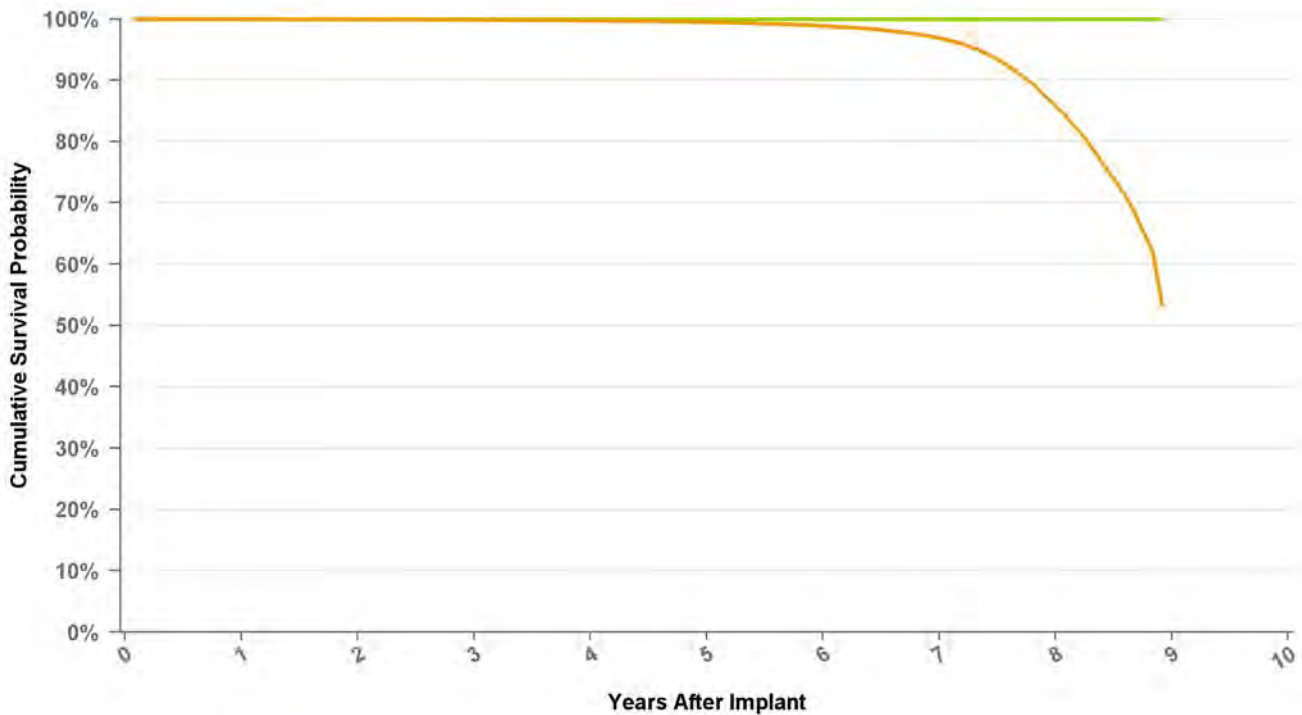
Electrical Interconnect 0

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

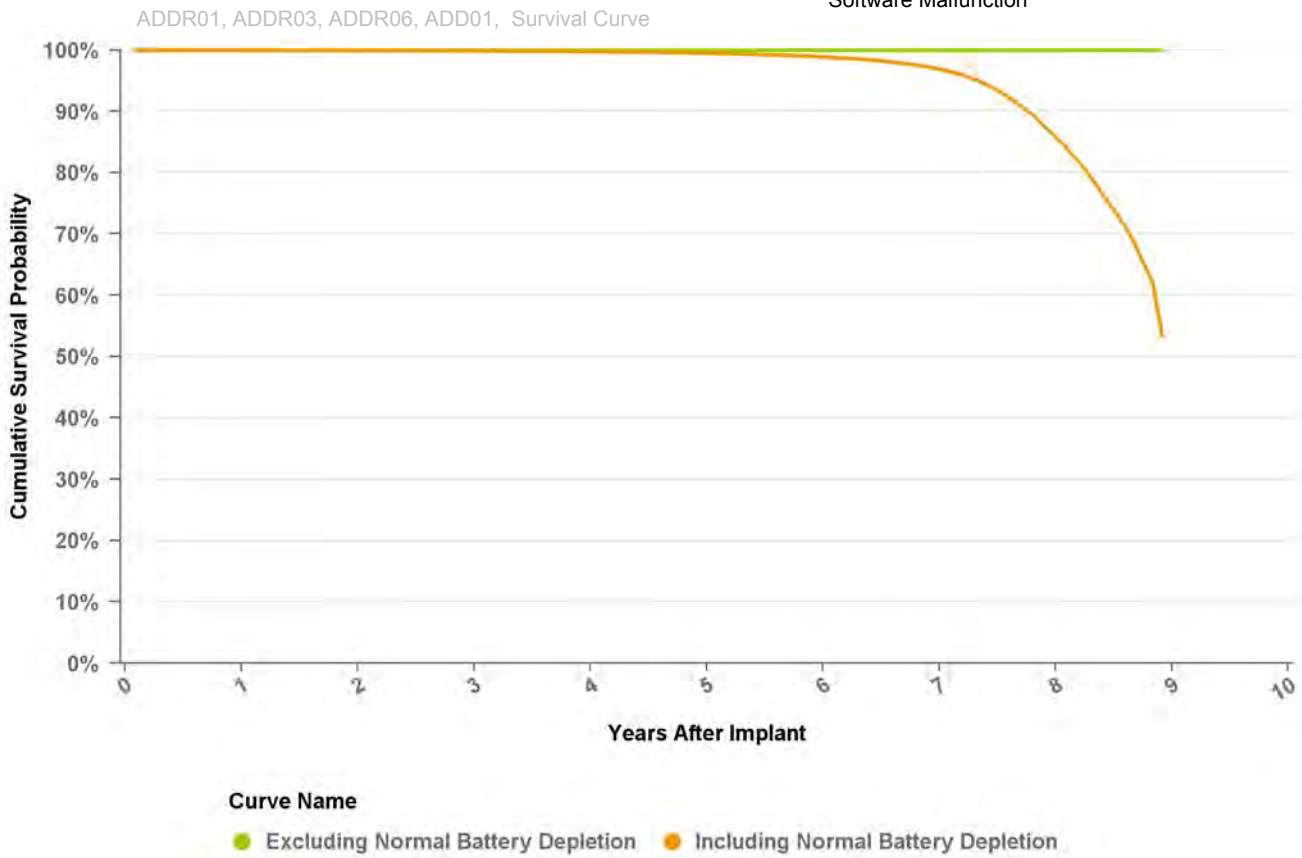
Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

Implantable Pulse Generator

ADDR01 Adapta DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	421,081
Estimated Active US Implants	307,753
Normal Battery Depletions (US)	6,149
NBG Code	DDDR

Total Malfunctions (US)	74
Therapy Not Compromised Malfunctions	49
Battery Malfunction	0
Electrical Component	47
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	25
Battery Malfunction	0
Electrical Component	20
Electrical Interconnect	3
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

Implantable Pulse Generator

ADDR03 Adapta DR

US Market Release Date 17-Jul-06

CE Market Approval Date 20-Sep-05

Registered US Implants 3,900

Estimated Active US Implants 2,639

Normal Battery Depletions (US) 110

NBG Code DDDR

Total Malfunctions (US) 2

Therapy Not Compromised Malfunctions 1

Battery Malfunction 0

Electrical Component 1

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 1

Battery Malfunction 0

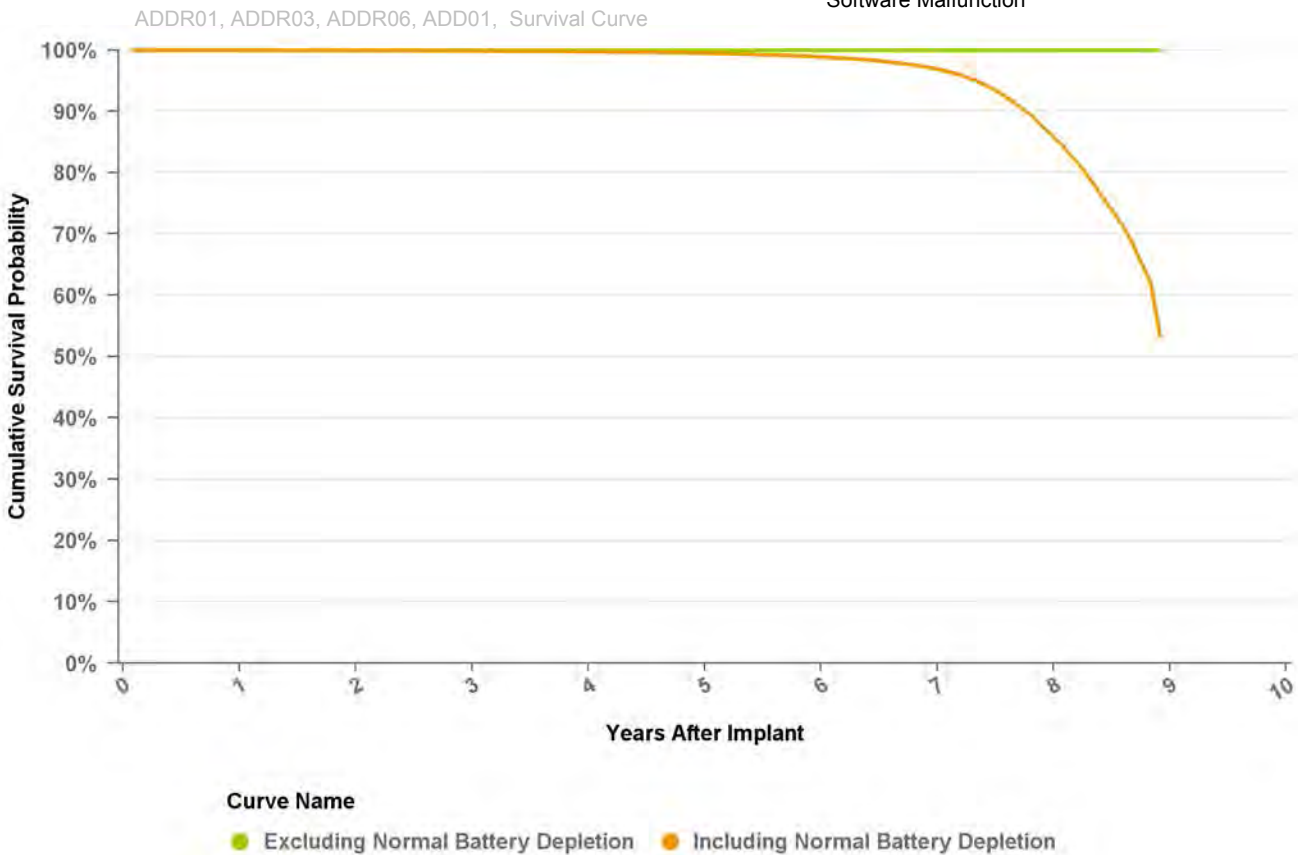
Electrical Component 1

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



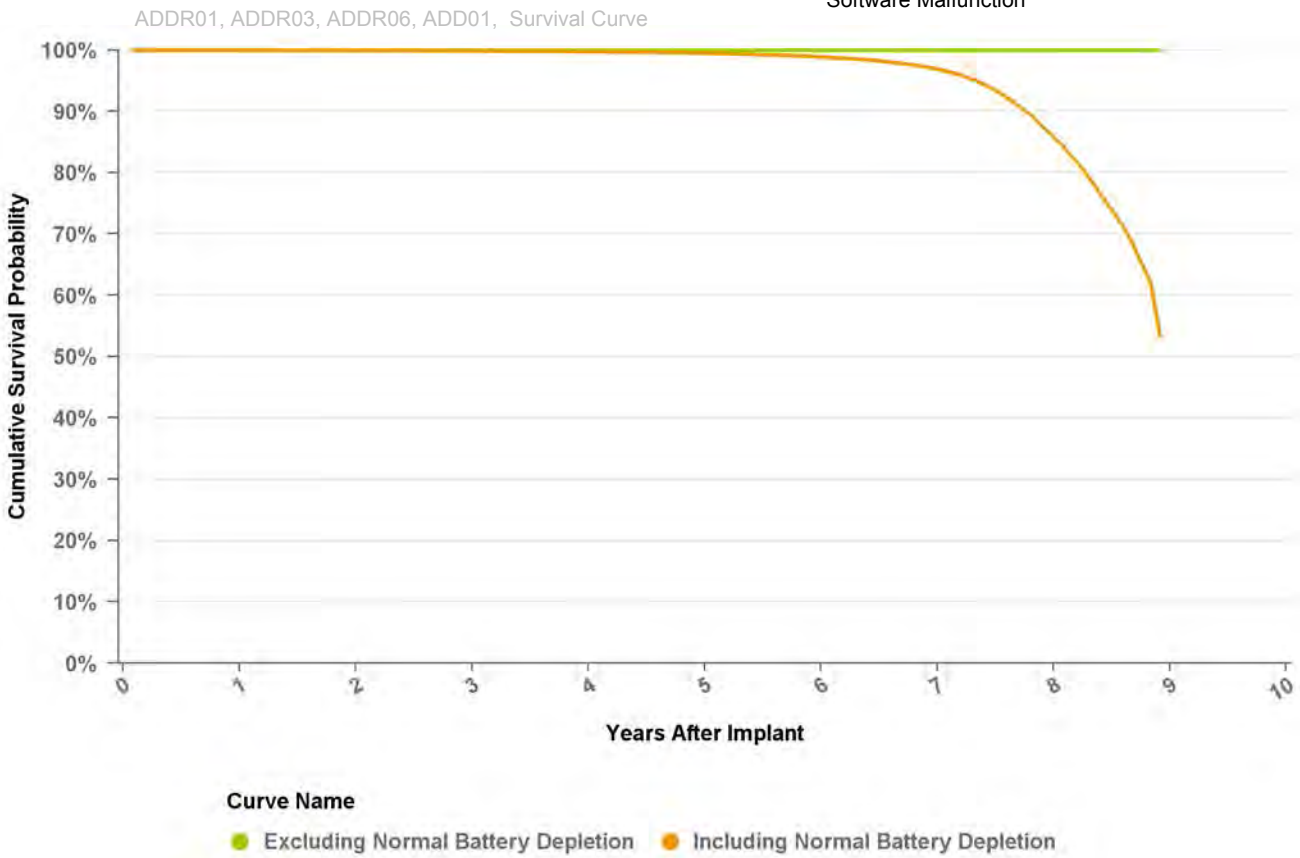
Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

Implantable Pulse Generator

ADDR06 Adapta DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	3,032
Estimated Active US Implants	1,716
Normal Battery Depletions (US)	144
NBG Code	DDDR

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



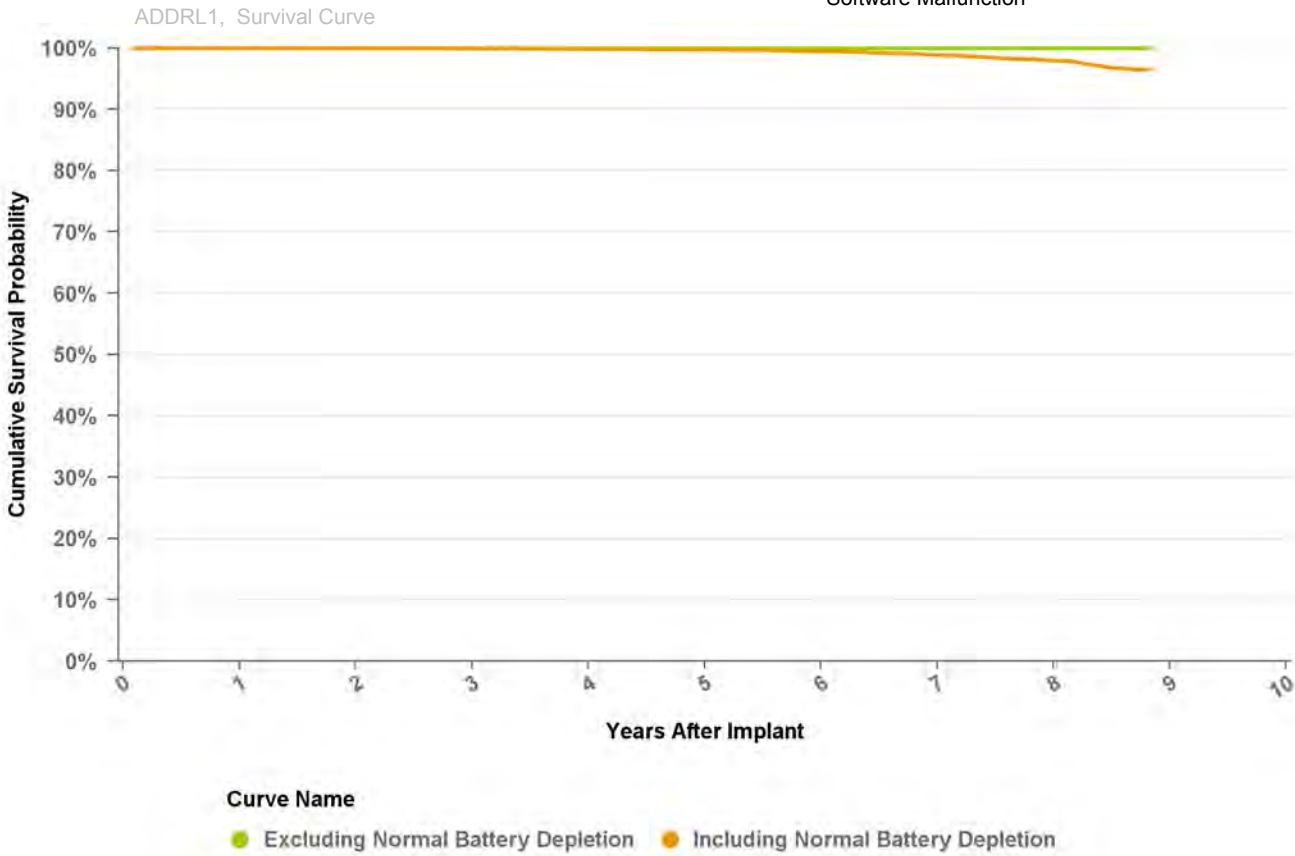
Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

Implantable Pulse Generator

ADDRL1 Adapta DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	116,626
Estimated Active US Implants	98,633
Normal Battery Depletions (US)	164
NBG Code	DDDR

Total Malfunctions (US)	11
Therapy Not Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



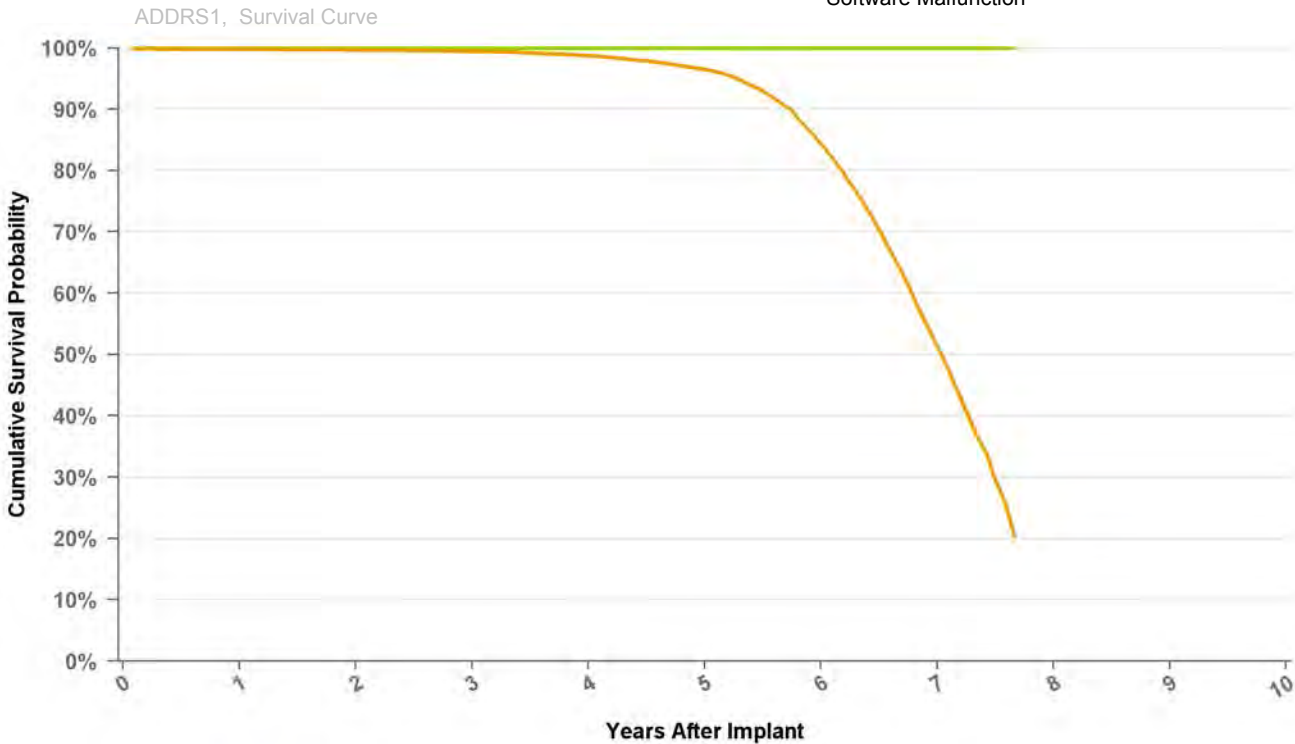
Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.4%	98.9%	97.9%	96.5%
Effective Sample Size	96180	76661	57732	40212	26031	14583	6857	2132	176

Implantable Pulse Generator

ADDRS1 Adapta DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	43,541
Estimated Active US Implants	27,029
Normal Battery Depletions (US)	2,273
NBG Code	DDDR

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	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



Curve Name
● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

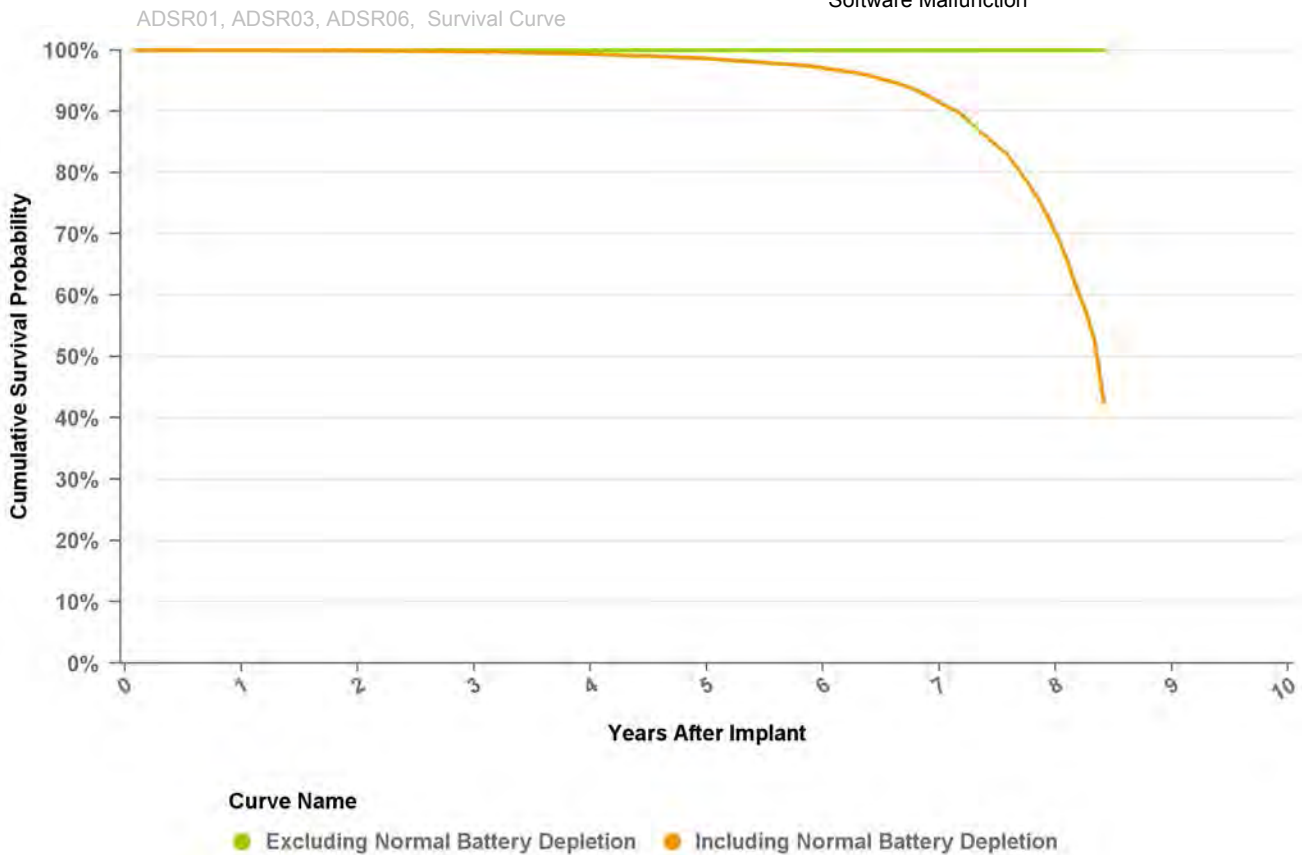
Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.4%	98.7%	96.5%	84.4%	51.5%	20.3%
Effective Sample Size	34606	28381	22648	17336	12419	7023	1961	173

Implantable Pulse Generator

ADSR01 Adapta SR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	83,727
Estimated Active US Implants	52,235
Normal Battery Depletions (US)	1,281
NBG Code	SSIR

Total Malfunctions (US)	12
Therapy Not Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



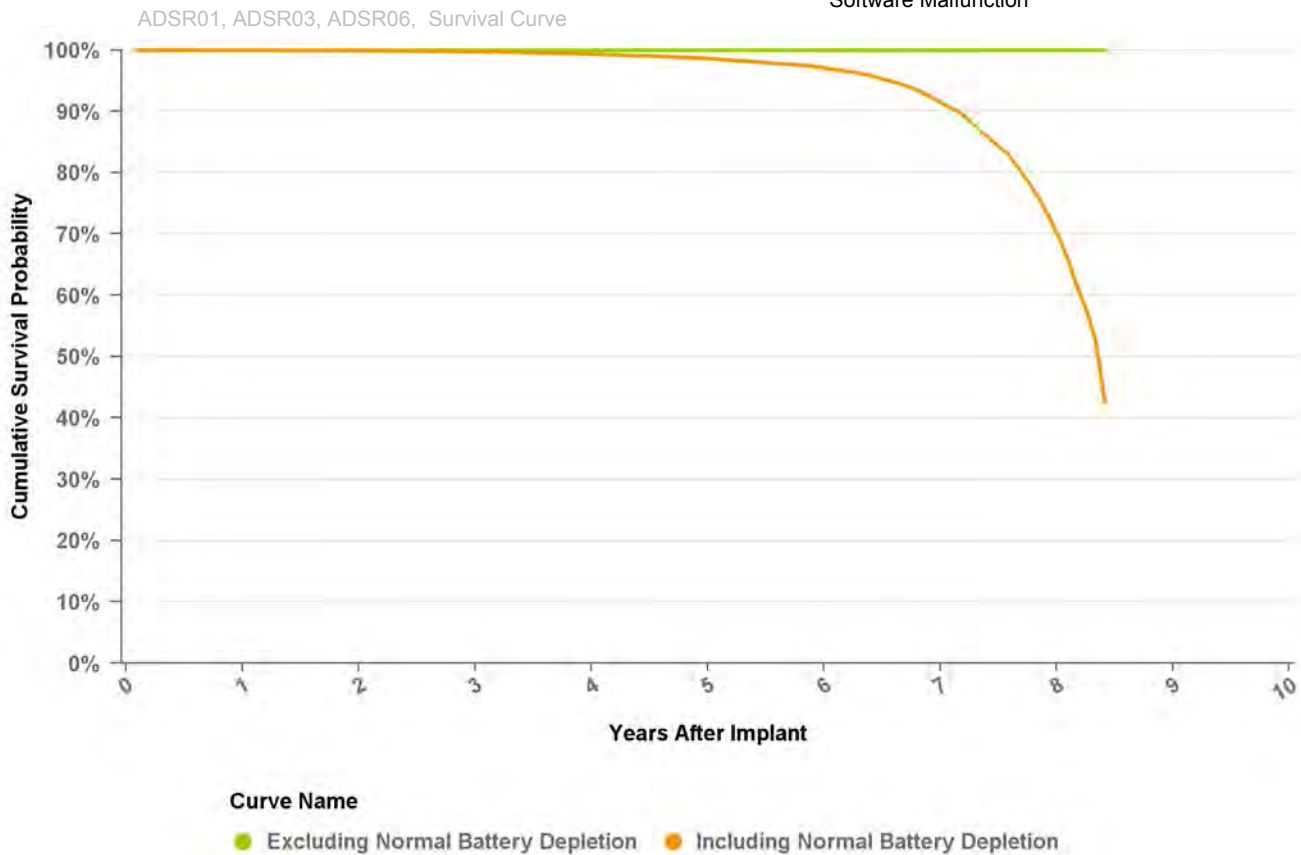
Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	91.5%	70.3%	42.6%
Effective Sample Size	64953	51039	38808	28439	20212	13398	7168	1898	283

Implantable Pulse Generator

ADSR03 Adapta SR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	1,893
Estimated Active US Implants	1,069
Normal Battery Depletions (US)	41
NBG Code	SSIR

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



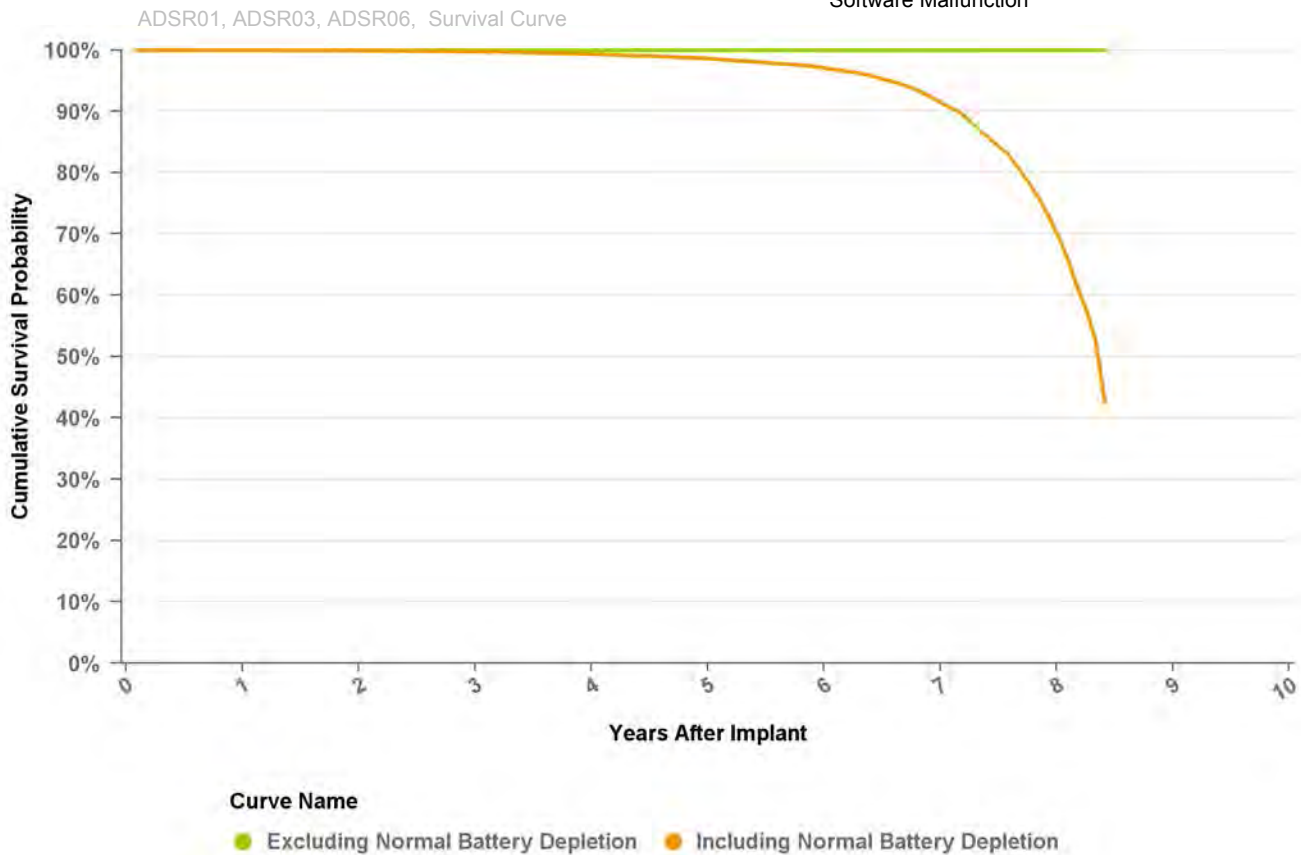
Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	91.5%	70.3%	42.6%
Effective Sample Size	64953	51039	38808	28439	20212	13398	7168	1898	283

Implantable Pulse Generator

ADSR06 Adapta SR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	2,559
Estimated Active US Implants	1,327
Normal Battery Depletions (US)	88
NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	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



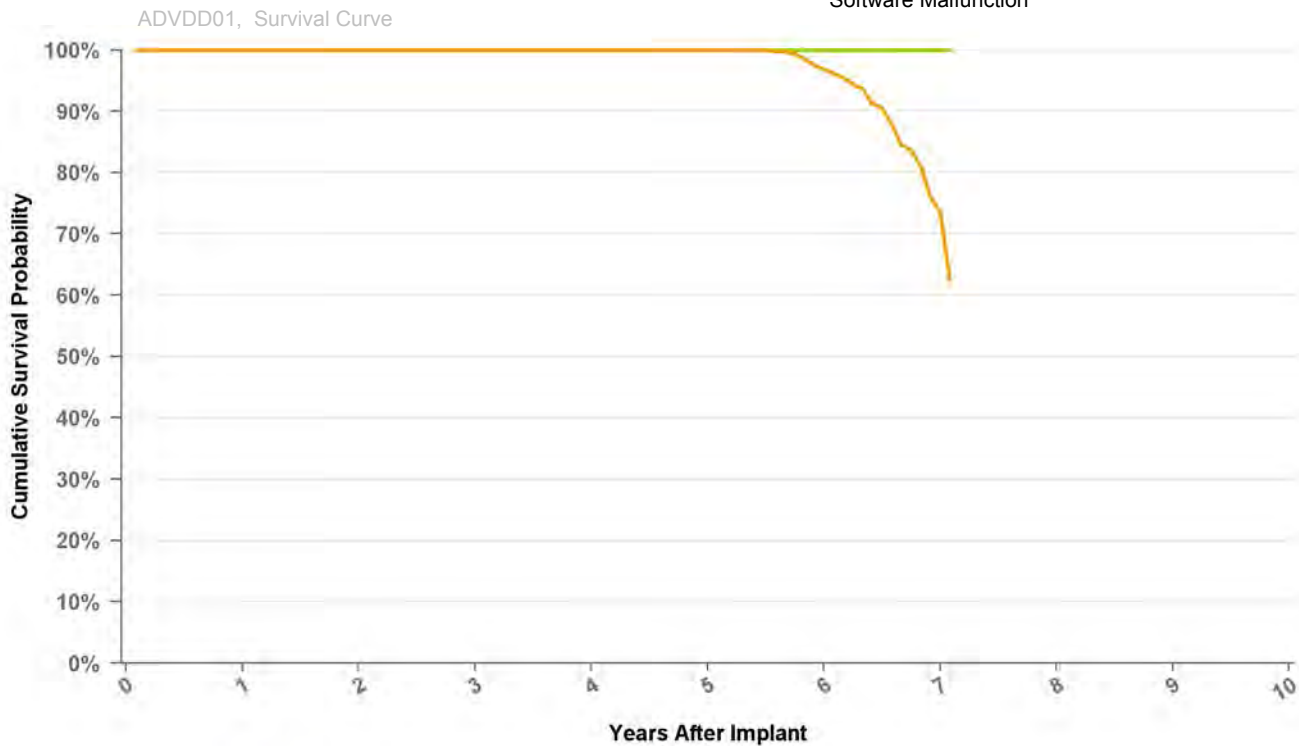
Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	91.5%	70.3%	42.6%
Effective Sample Size	64953	51039	38808	28439	20212	13398	7168	1898	283

Implantable Pulse Generator

ADVDD01 Adapta VDD

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	1,047
Estimated Active US Implants	596
Normal Battery Depletions (US)	55
NBG Code	VDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

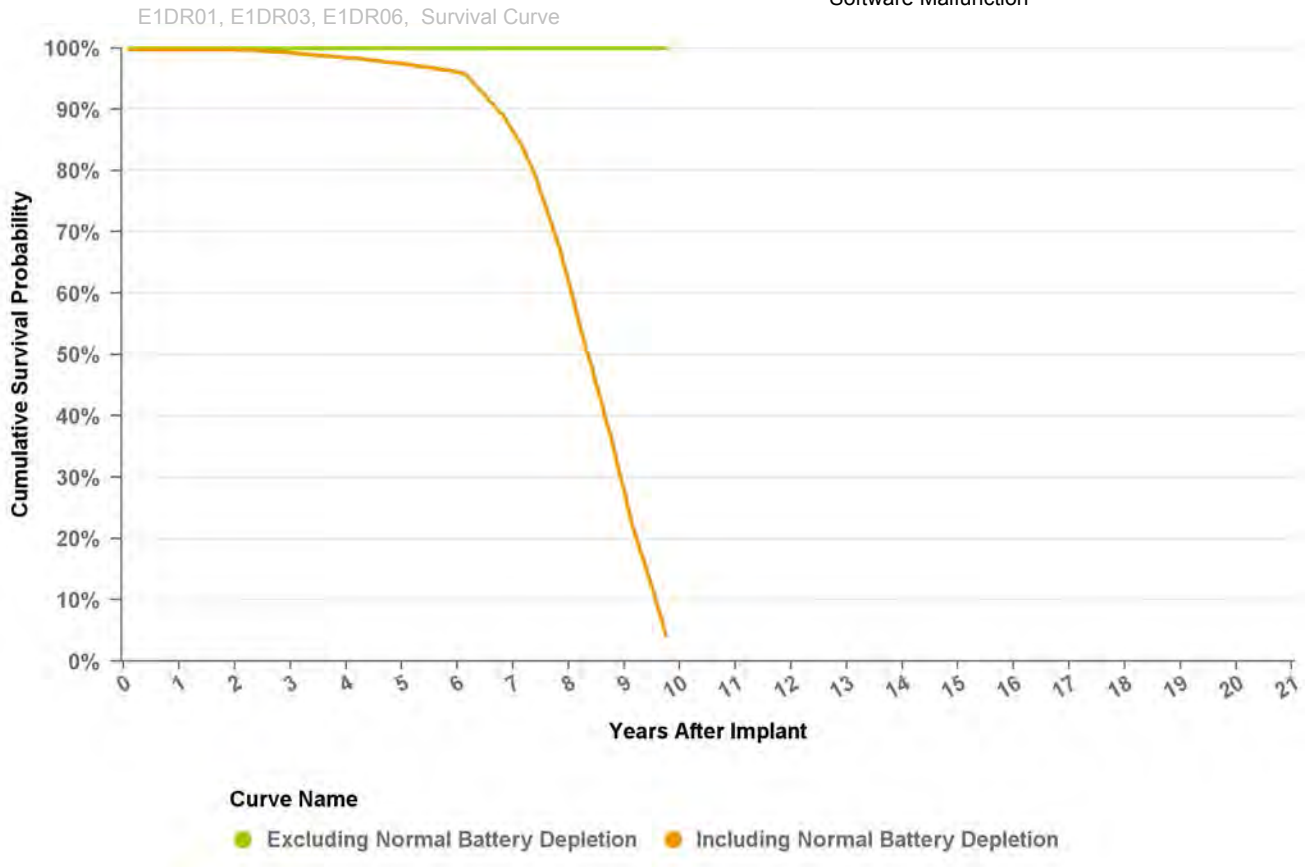
Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	96.9%	73.7%	62.6%
Effective Sample Size	872	776	631	525	413	298	134	120

Implantable Pulse Generator

E1DR01 EnPulse DR

US Market Release Date	18-Dec-03
CE Market Approval Date	
Registered US Implants	6,842
Estimated Active US Implants	552
Normal Battery Depletions (US)	1,708
NBG Code	DDDR

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



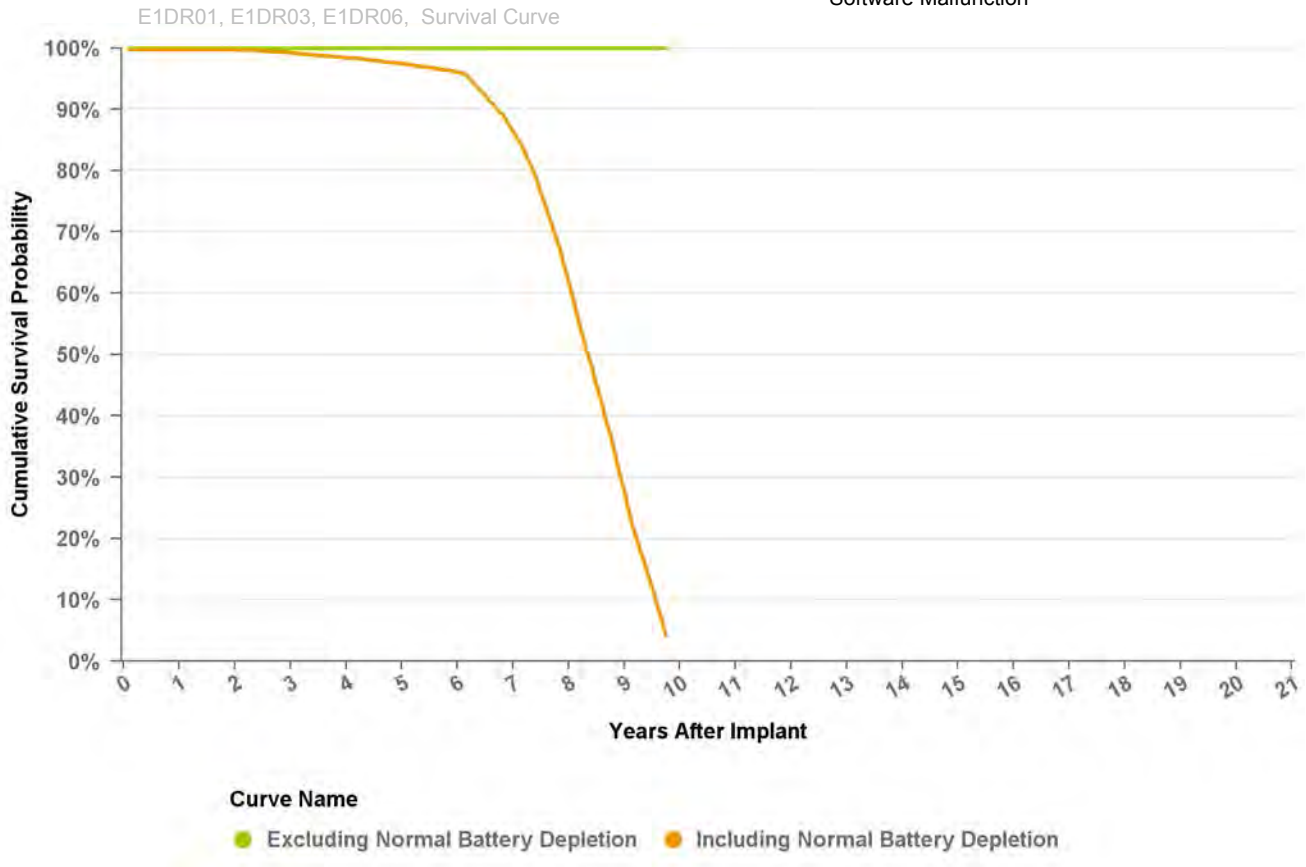
Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.4%	97.5%	96.0%	86.5%	62.1%	28.0%	4.1%
Effective Sample Size	5940	5508	5069	4611	4183	3743	3049	1956	756	115

Implantable Pulse Generator

E1DR03 EnPulse DR

US Market Release Date	18-Dec-03
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDDR

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



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.4%	97.5%	96.0%	86.5%	62.1%	28.0%	4.1%
Effective Sample Size	5940	5508	5069	4611	4183	3743	3049	1956	756	115

Implantable Pulse Generator

E1DR06 EnPulse DR

US Market Release Date 18-Dec-03

CE Market Approval Date

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code DDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

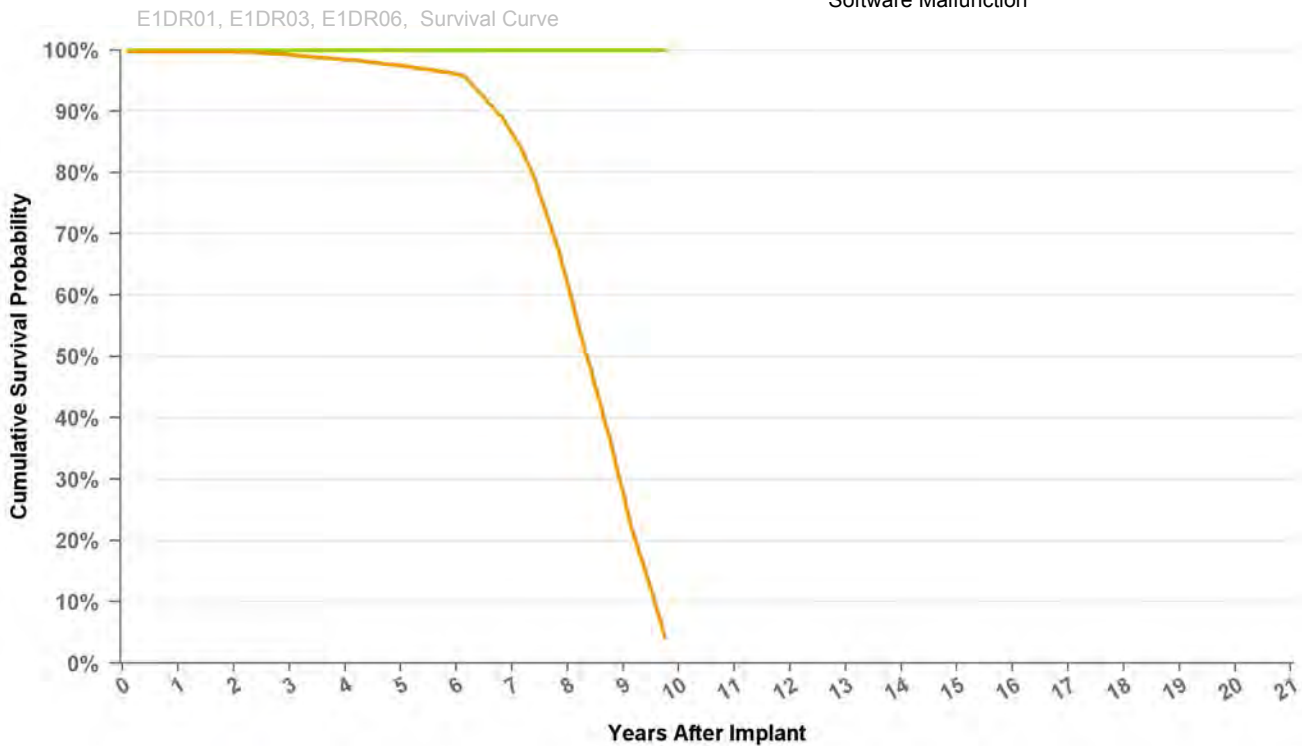
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

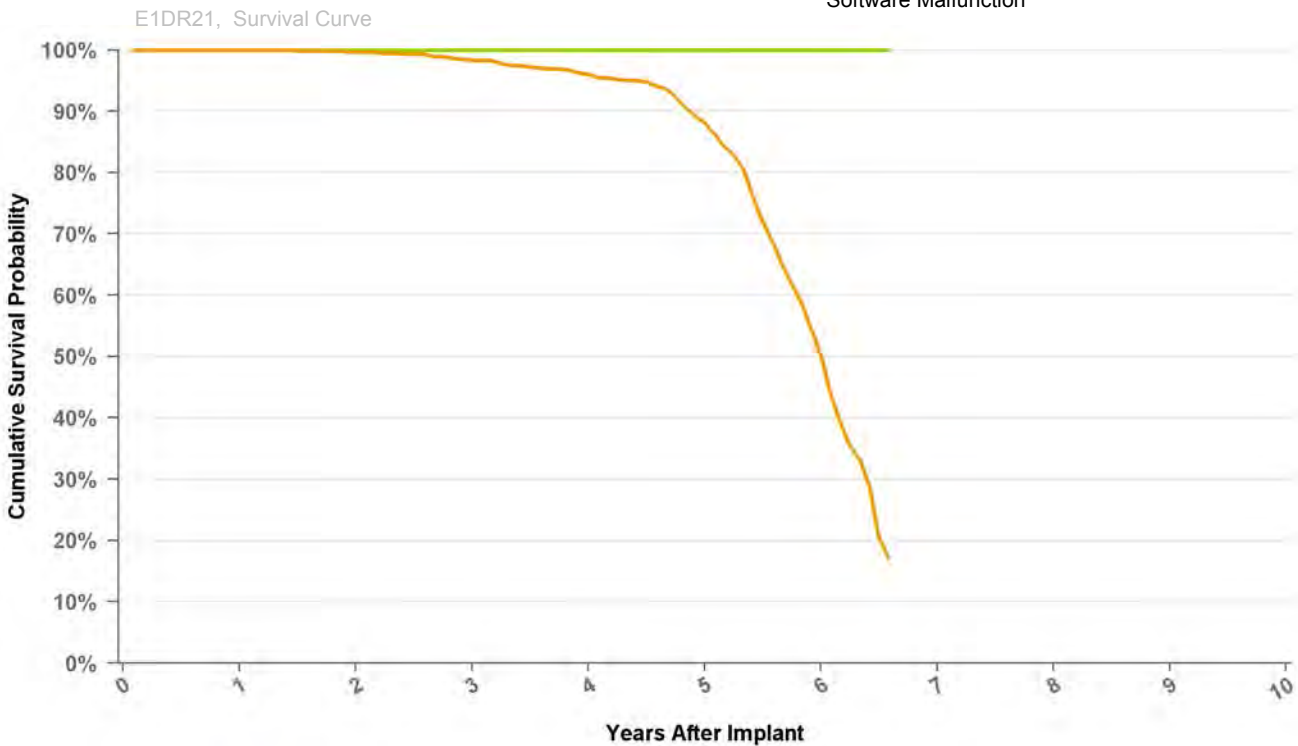
Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.4%	97.5%	96.0%	86.5%	62.1%	28.0%	4.1%
Effective Sample Size	5940	5508	5069	4611	4183	3743	3049	1956	756	115

Implantable Pulse Generator

E1DR21 EnPulse DR

US Market Release Date	18-Dec-03
CE Market Approval Date	
Registered US Implants	1,856
Estimated Active US Implants	103
Normal Battery Depletions (US)	380
NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

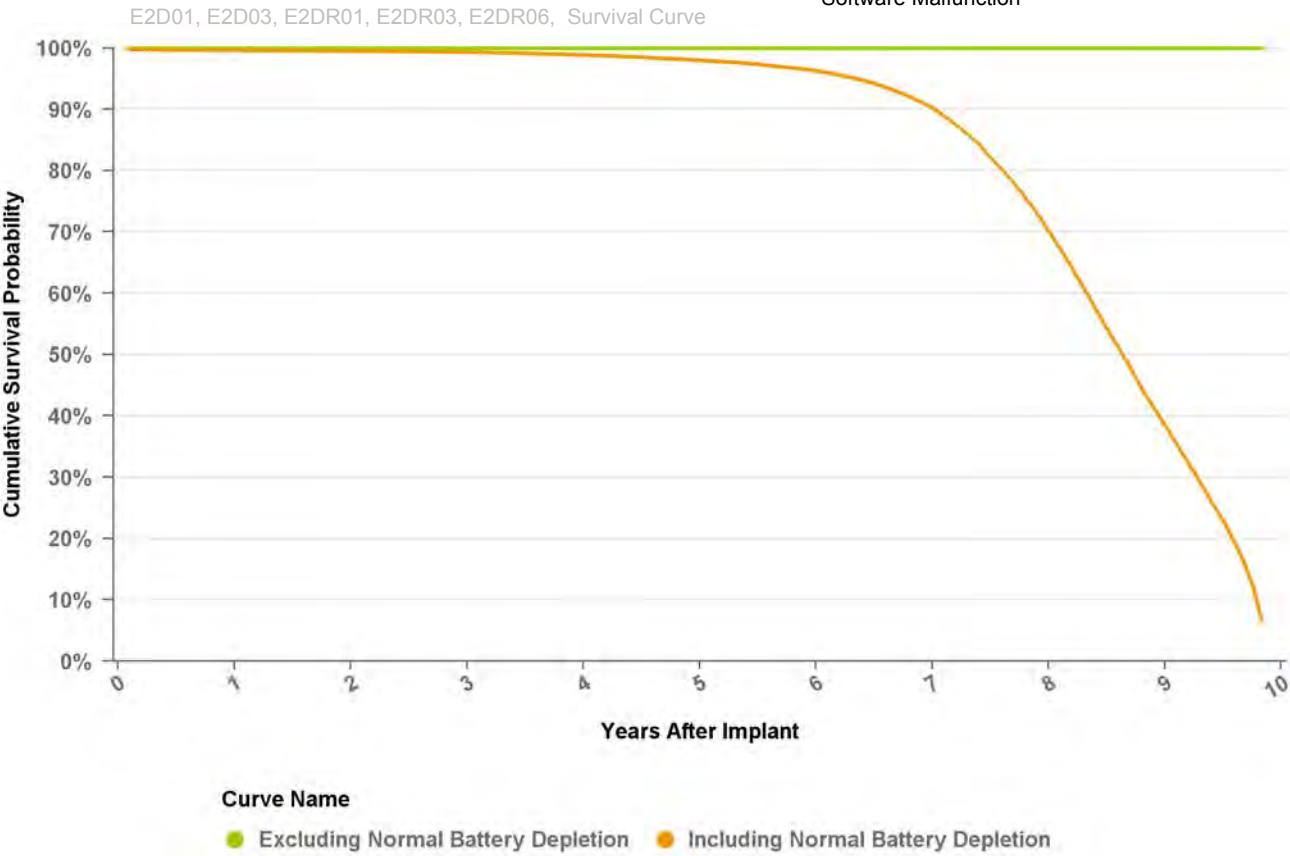
Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.6%	98.3%	96.0%	88.0%	50.3%	17.2%
Effective Sample Size	1585	1441	1286	1128	917	418	110

Implantable Pulse Generator

E2D01 EnPulse

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

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



Years	1	2	3	4	5	6	7	8	9	at 118 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%	99.5%	99.3%	98.9%	98.0%	96.3%	90.2%	70.2%	38.5%	6.7%
Effective Sample Size	87011	80130	73313	66872	60497	54311	46707	33109	15436	819

Implantable Pulse Generator

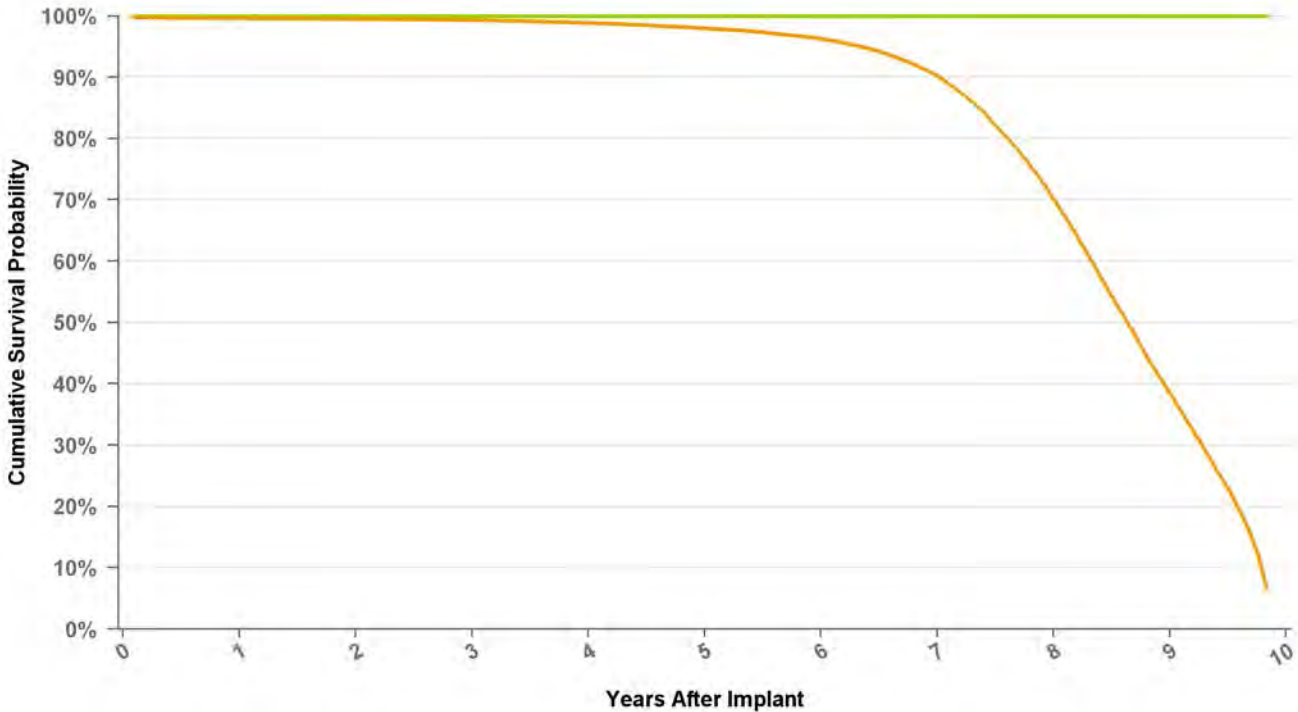
E2D03

EnPulse

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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

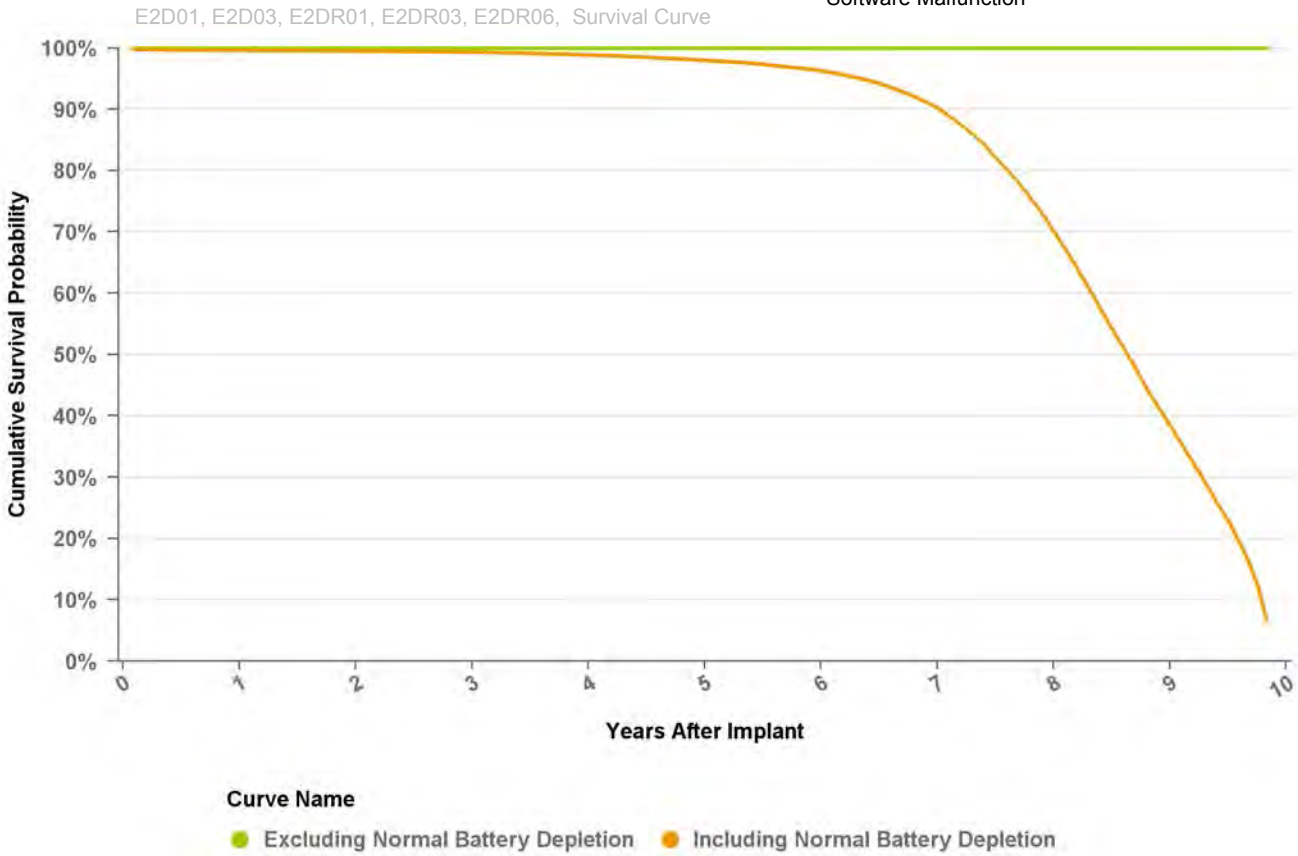
Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.3%	98.9%	98.0%	96.3%	90.2%	70.2%	38.5%	6.7%
Effective Sample Size	87011	80130	73313	66872	60497	54311	46707	33109	15436	819

Implantable Pulse Generator

E2DR01 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	97,122
Estimated Active US Implants	15,001
Normal Battery Depletions (US)	20,166
NBG Code	DDDR

Total Malfunctions (US)	27
Therapy Not Compromised Malfunctions	20
Battery Malfunction	0
Electrical Component	18
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	7
Battery Malfunction	1
Electrical Component	3
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



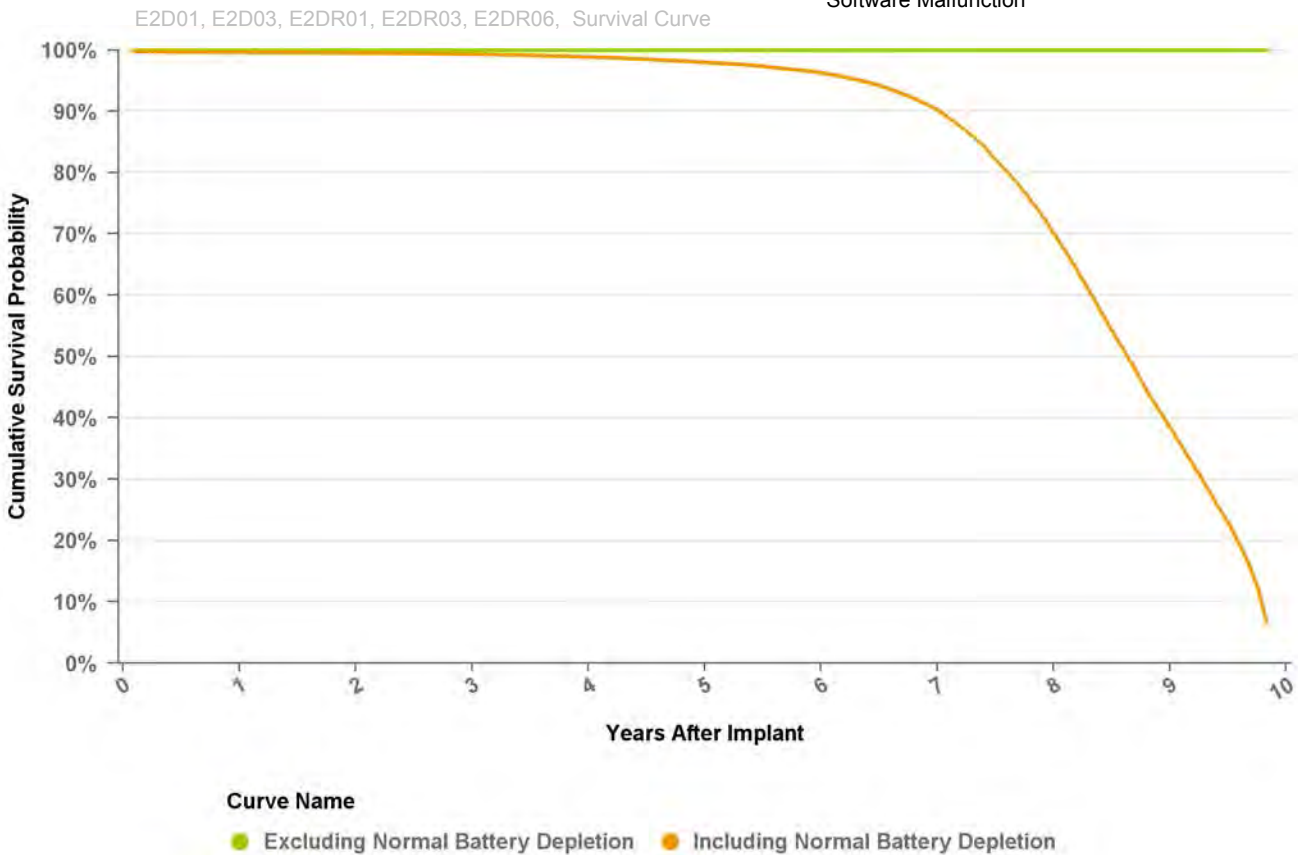
Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.3%	98.9%	98.0%	96.3%	90.2%	70.2%	38.5%	6.7%
Effective Sample Size	87011	80130	73313	66872	60497	54311	46707	33109	15436	819

Implantable Pulse Generator

E2DR03 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	2,050
Estimated Active US Implants	359
Normal Battery Depletions (US)	408
NBG Code	DDDR

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



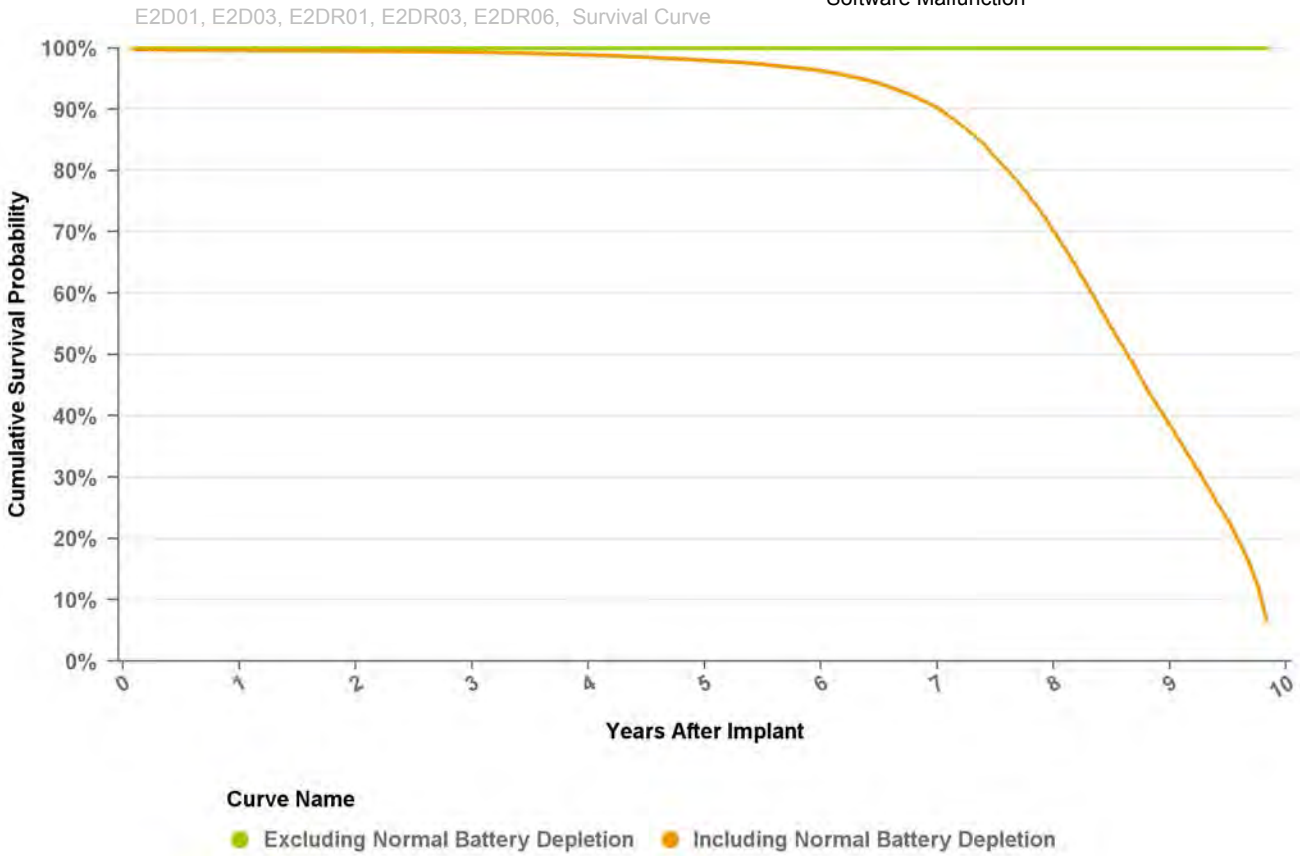
Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.3%	98.9%	98.0%	96.3%	90.2%	70.2%	38.5%	6.7%
Effective Sample Size	87011	80130	73313	66872	60497	54311	46707	33109	15436	819

Implantable Pulse Generator

E2DR06 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	1,626
Estimated Active US Implants	209
Normal Battery Depletions (US)	297
NBG Code	DDDR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	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



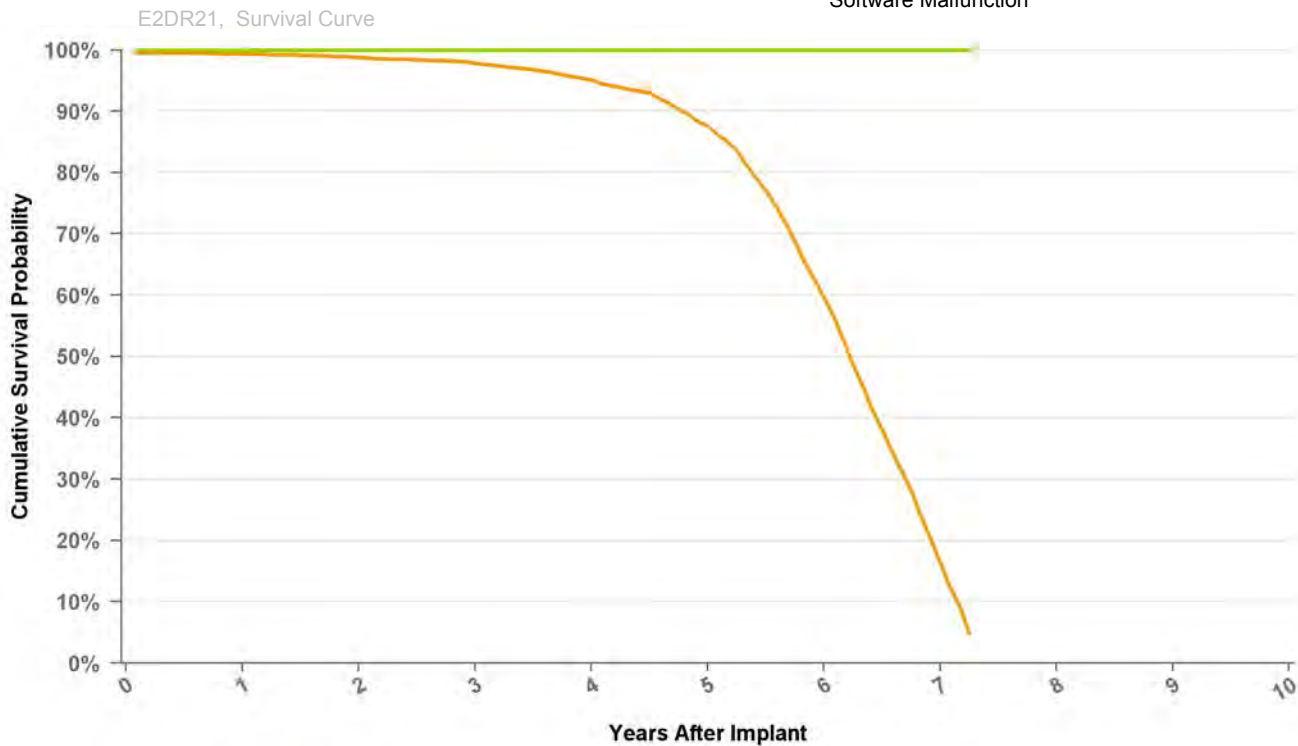
Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.3%	98.9%	98.0%	96.3%	90.2%	70.2%	38.5%	6.7%
Effective Sample Size	87011	80130	73313	66872	60497	54311	46707	33109	15436	819

Implantable Pulse Generator

E2DR21 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	12,196
Estimated Active US Implants	1,085
Normal Battery Depletions (US)	2,302
NBG Code	DDDR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

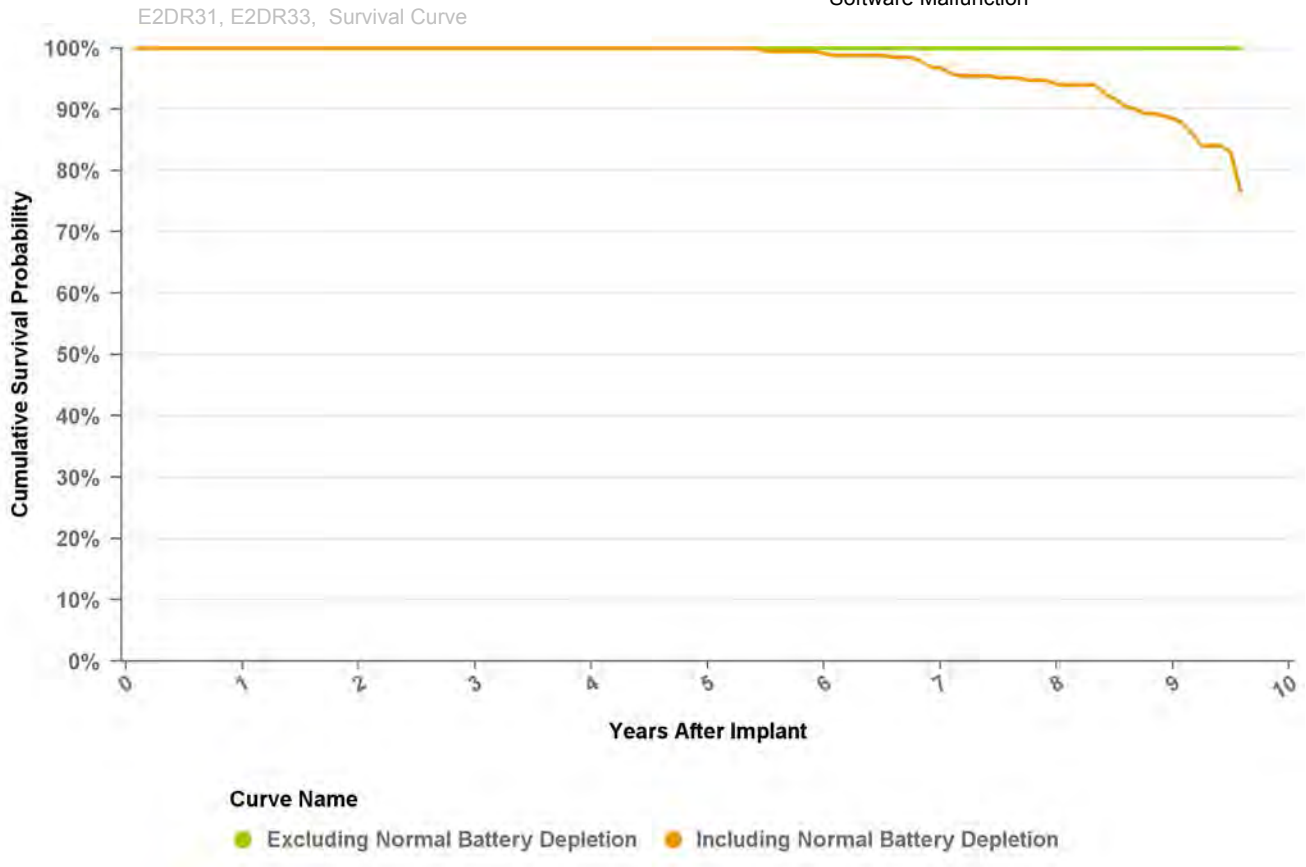
Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.3%	98.8%	97.8%	95.1%	87.6%	59.7%	16.4%	4.8%
Effective Sample Size	10134	9034	8059	6967	5683	3292	665	210

Implantable Pulse Generator

E2DR31 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	588
Estimated Active US Implants	283
Normal Battery Depletions (US)	57
NBG Code	DDDR

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



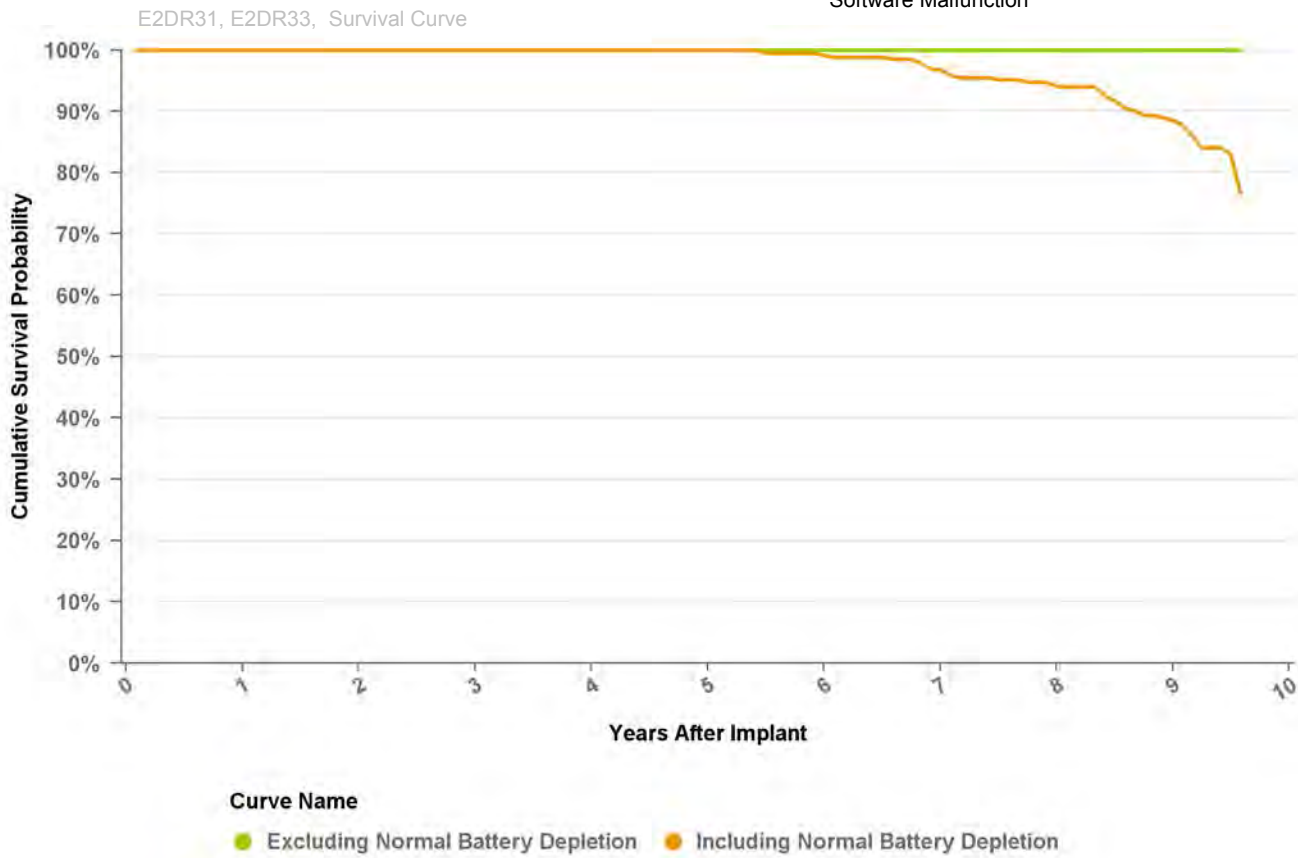
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.8%	94.0%	88.5%	76.7%
Effective Sample Size	519	485	451	411	368	328	289	254	220	109

Implantable Pulse Generator

E2DR33 EnPulse DR

US Market Release Date	20-Feb-04
CE Market Approval Date	8-Sep-03
Registered US Implants	5
Estimated Active US Implants	4
Normal Battery Depletions (US)	2
NBG Code	DDDR

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



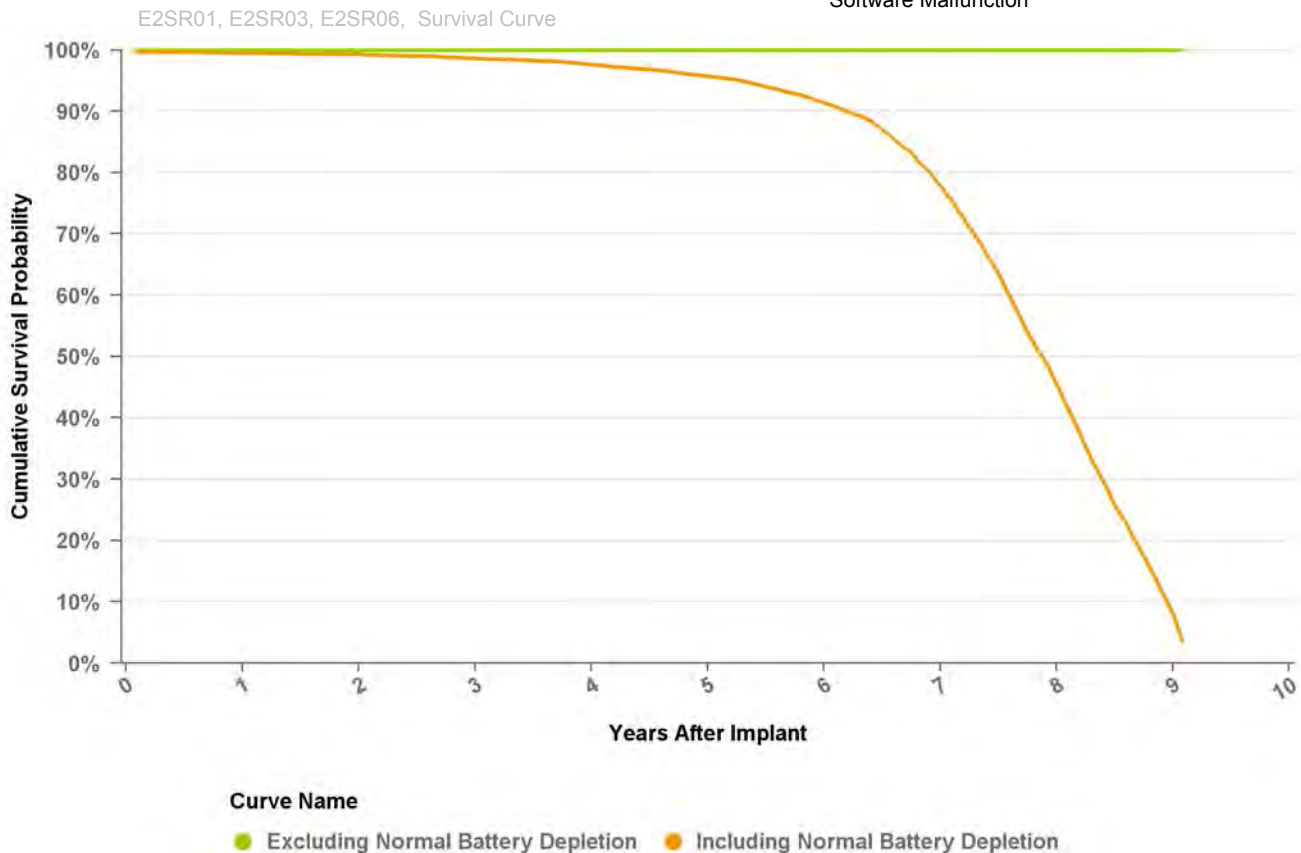
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.8%	94.0%	88.5%	76.7%
Effective Sample Size	519	485	451	411	368	328	289	254	220	109

Implantable Pulse Generator

E2SR01 EnPulse SR

US Market Release Date	18-Dec-03
CE Market Approval Date	8-Sep-03
Registered US Implants	22,531
Estimated Active US Implants	2,279
Normal Battery Depletions (US)	2,874
NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	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



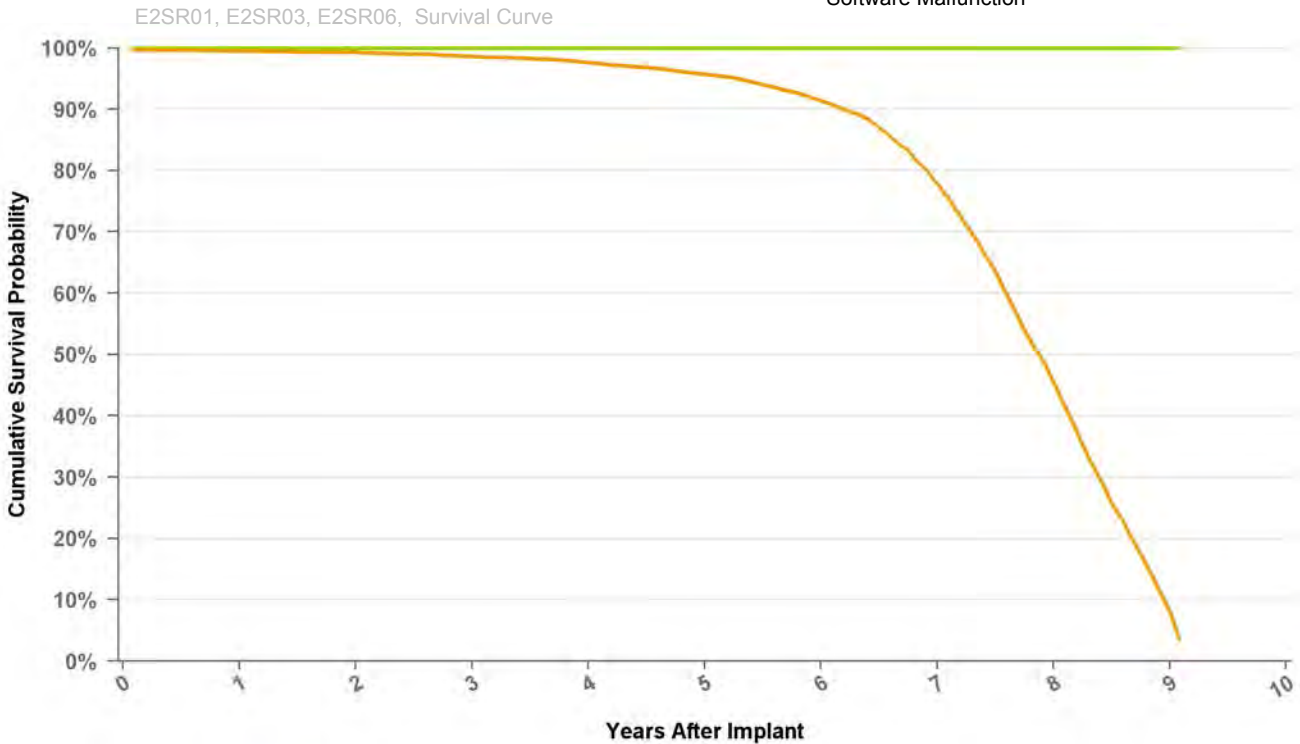
Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.6%	95.7%	91.4%	77.9%	45.6%	8.2%	3.6%
Effective Sample Size	19344	16490	14078	12017	9945	8077	5855	2800	287	115

Implantable Pulse Generator

E2SR03 EnPulse SR

US Market Release Date	18-Dec-03
CE Market Approval Date	8-Sep-03
Registered US Implants	1,099
Estimated Active US Implants	111
Normal Battery Depletions (US)	145
NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

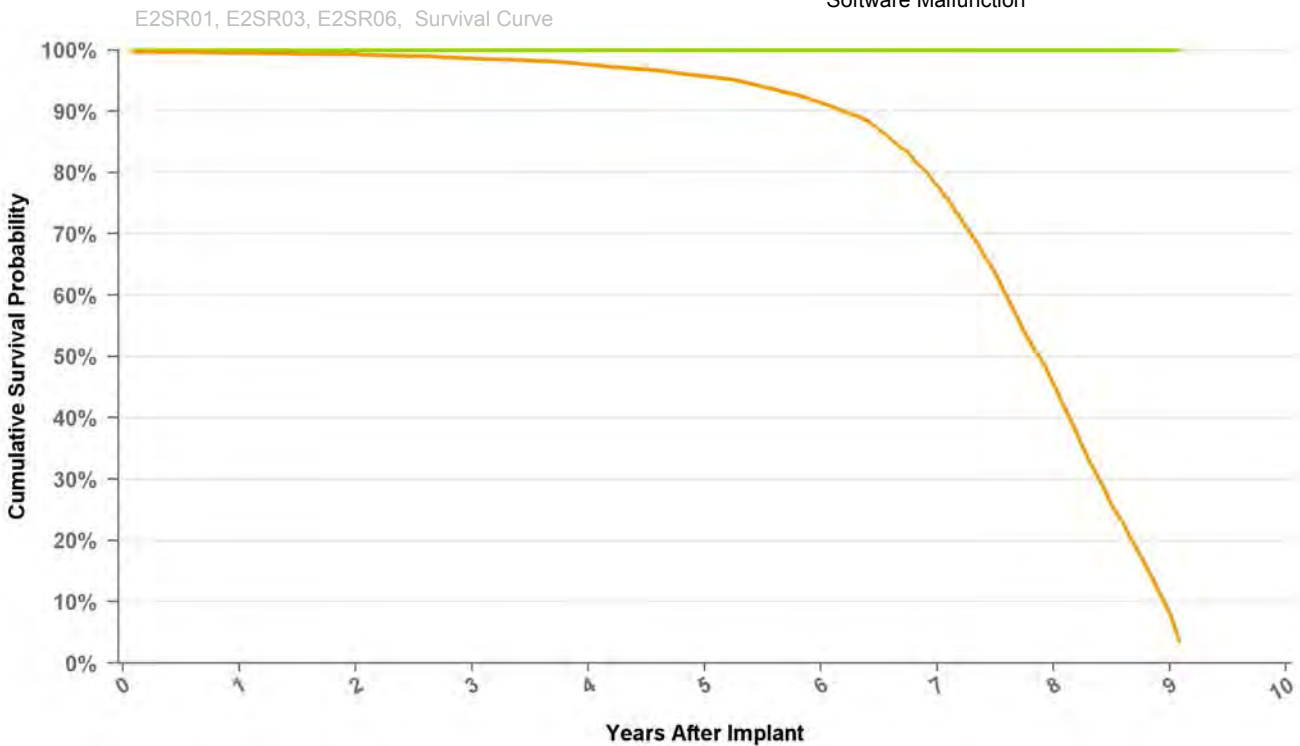
Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.6%	95.7%	91.4%	77.9%	45.6%	8.2%	3.6%
Effective Sample Size	19344	16490	14078	12017	9945	8077	5855	2800	287	115

Implantable Pulse Generator

E2SR06 EnPulse SR

US Market Release Date	18-Dec-03
CE Market Approval Date	8-Sep-03
Registered US Implants	1,750
Estimated Active US Implants	170
Normal Battery Depletions (US)	210
NBG Code	SSIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

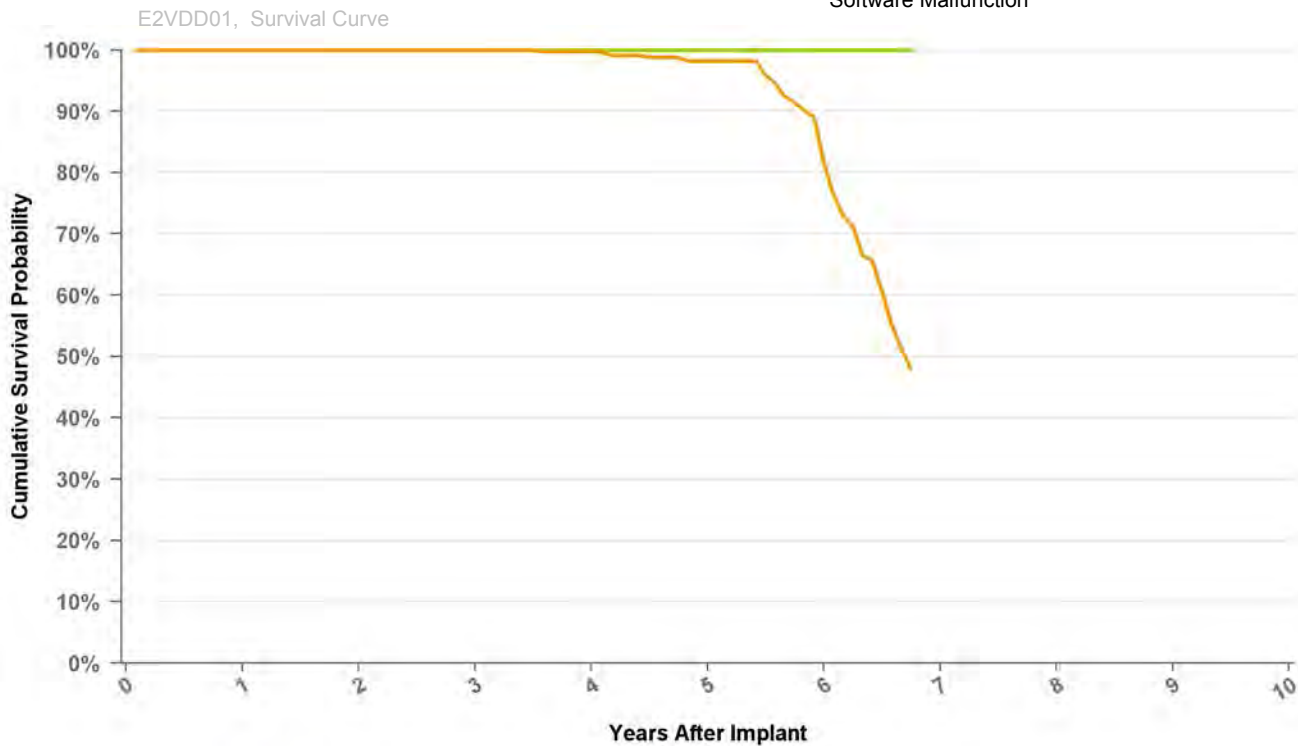
Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.6%	95.7%	91.4%	77.9%	45.6%	8.2%	3.6%
Effective Sample Size	19344	16490	14078	12017	9945	8077	5855	2800	287	115

Implantable Pulse Generator

E2VDD01 EnPulse VDD

US Market Release Date	18-Dec-03
CE Market Approval Date	8-Sep-03
Registered US Implants	554
Estimated Active US Implants	82
Normal Battery Depletions (US)	93
NBG Code	VDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



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%	99.7%	98.1%	81.7%	48.0%
Effective Sample Size	471	424	380	335	290	221	105

Implantable Pulse Generator

EMDR01 EnRhythm MRI

US Market Release Date

CE Market Approval Date 30-Sep-08

Registered US Implants 111

Estimated Active US Implants 47

Normal Battery Depletions (US) 7

NBG Code DDDRP

Total Malfunctions (US) 19

Therapy Not Compromised Malfunctions 19

Battery Malfunction 19

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 0

Battery Malfunction 0

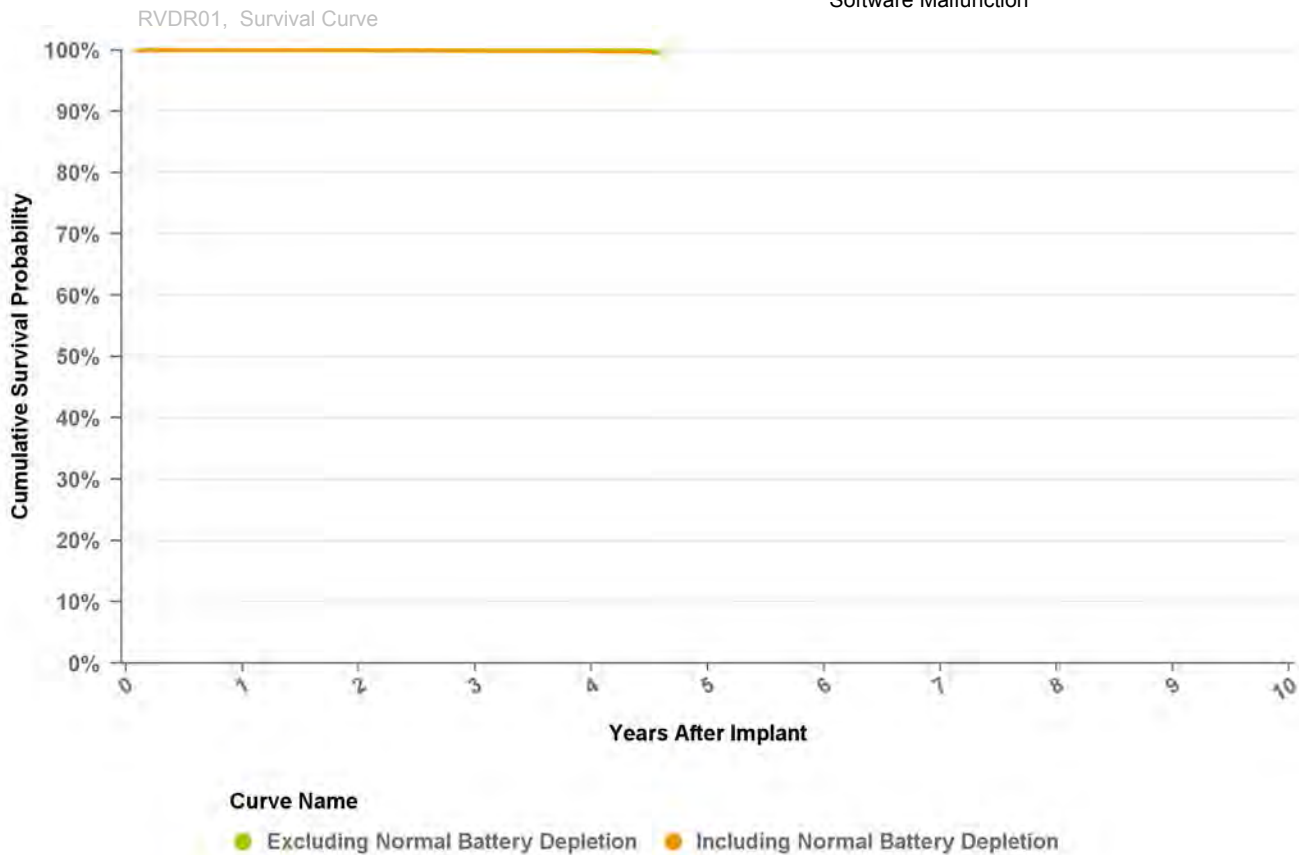
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



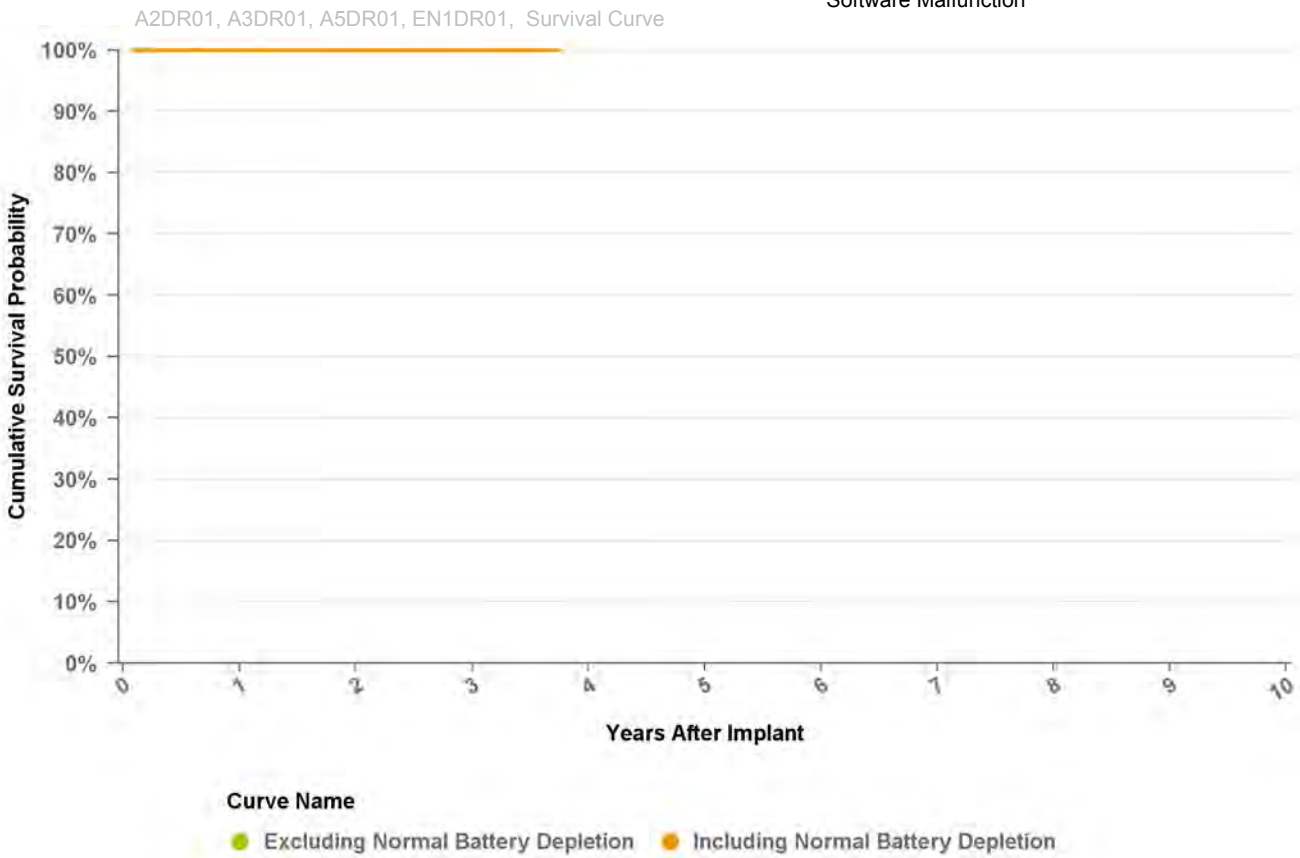
Years	1	2	3	4	at 55 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.3%
Effective Sample Size	58082	53479	37479	12913	725

Implantable Pulse Generator

EN1DR01 Ensura MRI

US Market Release Date	
CE Market Approval Date	23-Jun-10
Registered US Implants	7
Estimated Active US Implants	5
Normal Battery Depletions (US)	0
NBG Code	OOE-DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



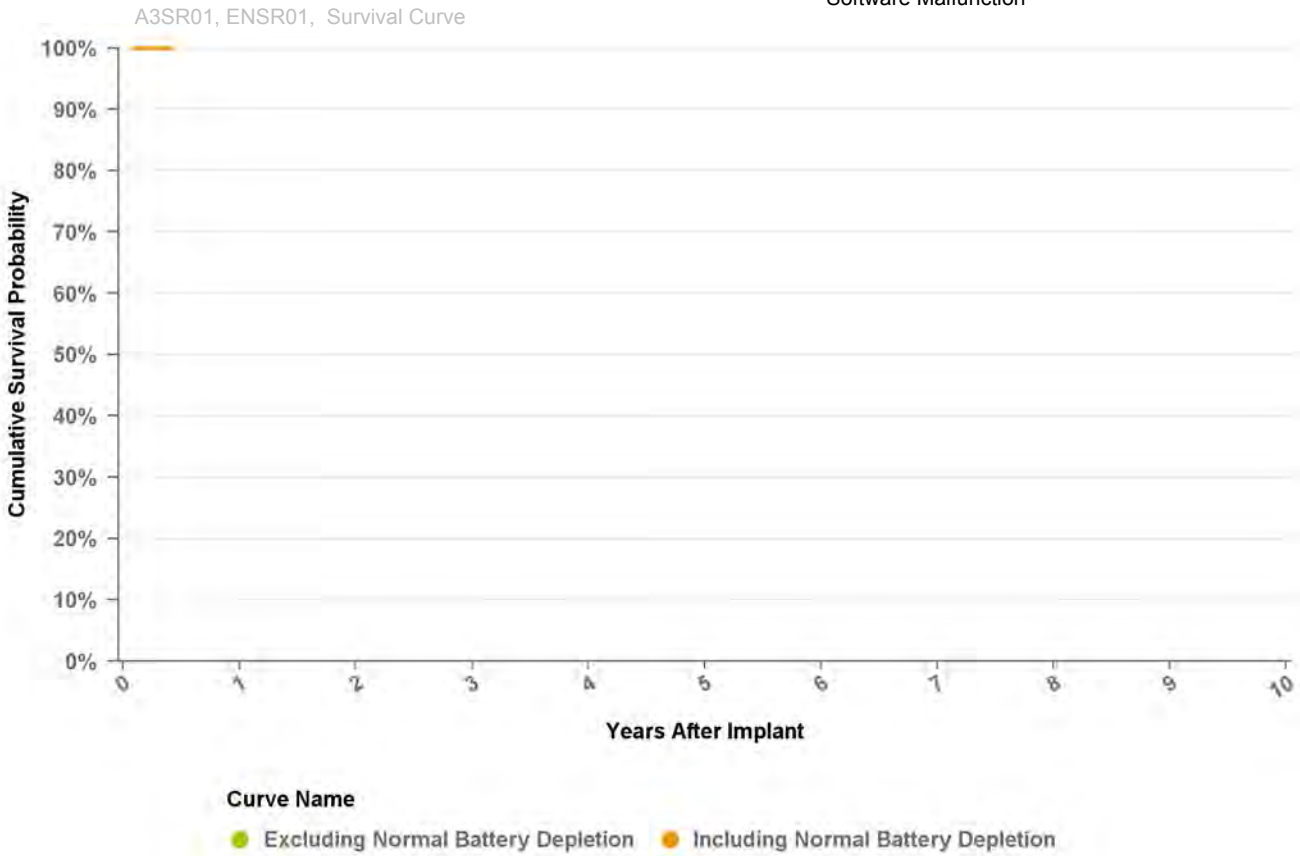
Years	1	2	3	at 45 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	55527	15601	703	125

Implantable Pulse Generator

EN1SR01 Ensura SR MRI

US Market Release Date	
CE Market Approval Date	24-Apr-14
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	VVIR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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	at 5 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	197

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

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

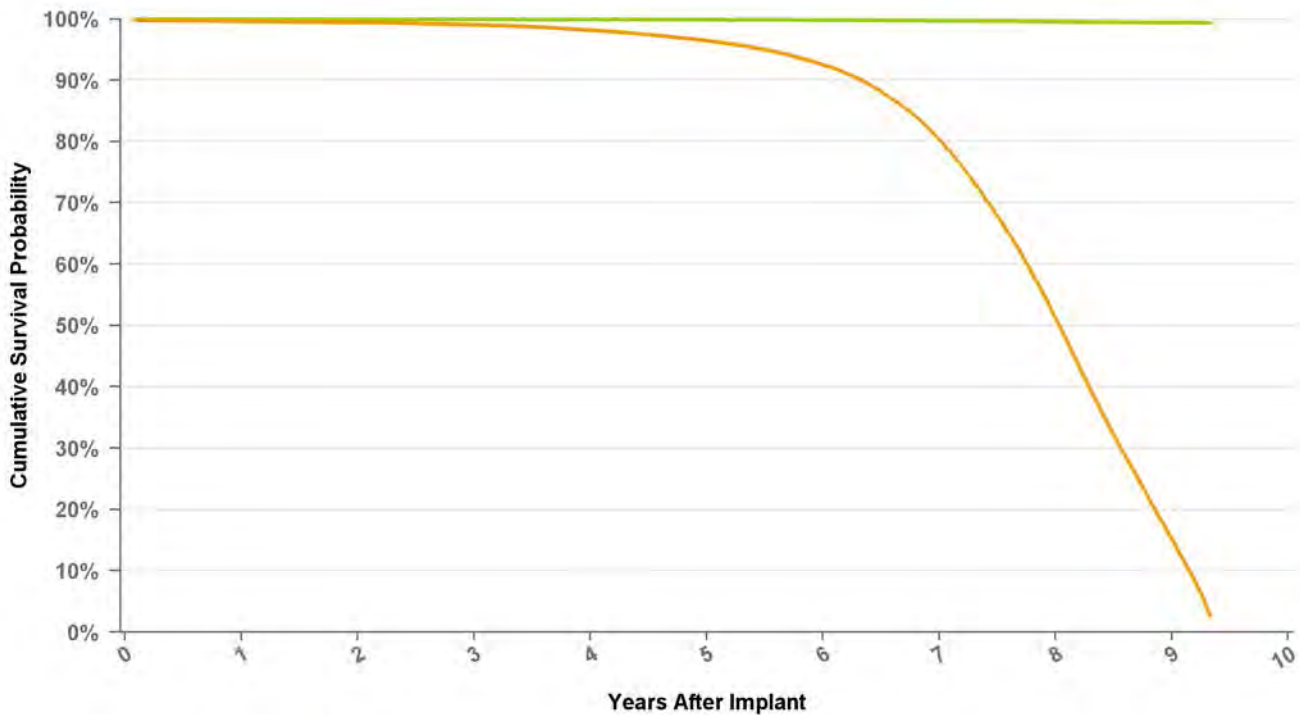
Electrical Interconnect 0

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 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	96.5%	92.5%	80.3%	51.2%	15.3%	2.6%
Effective Sample Size	163960	150346	136910	122847	108938	93802	72229	38710	8291	1661

Implantable Pulse Generator

KD701

Kappa 700 DR

US Market Release Date 29-Jan-99

CE Market Approval Date 20-Mar-98

Registered US Implants 242

Estimated Active US Implants 40

Normal Battery Depletions (US) 21

NBG Code DDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

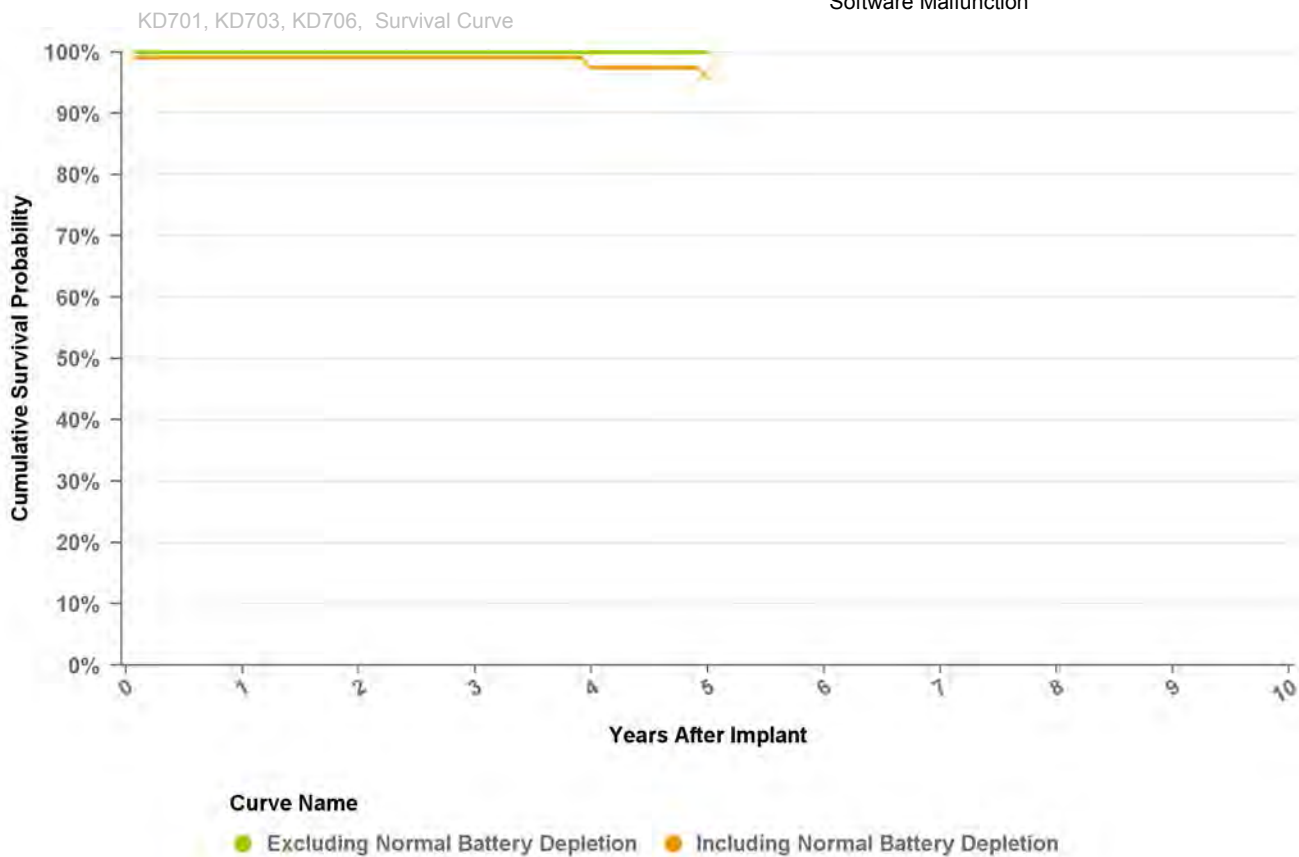
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.5%
Effective Sample Size	183	162	142	122	102

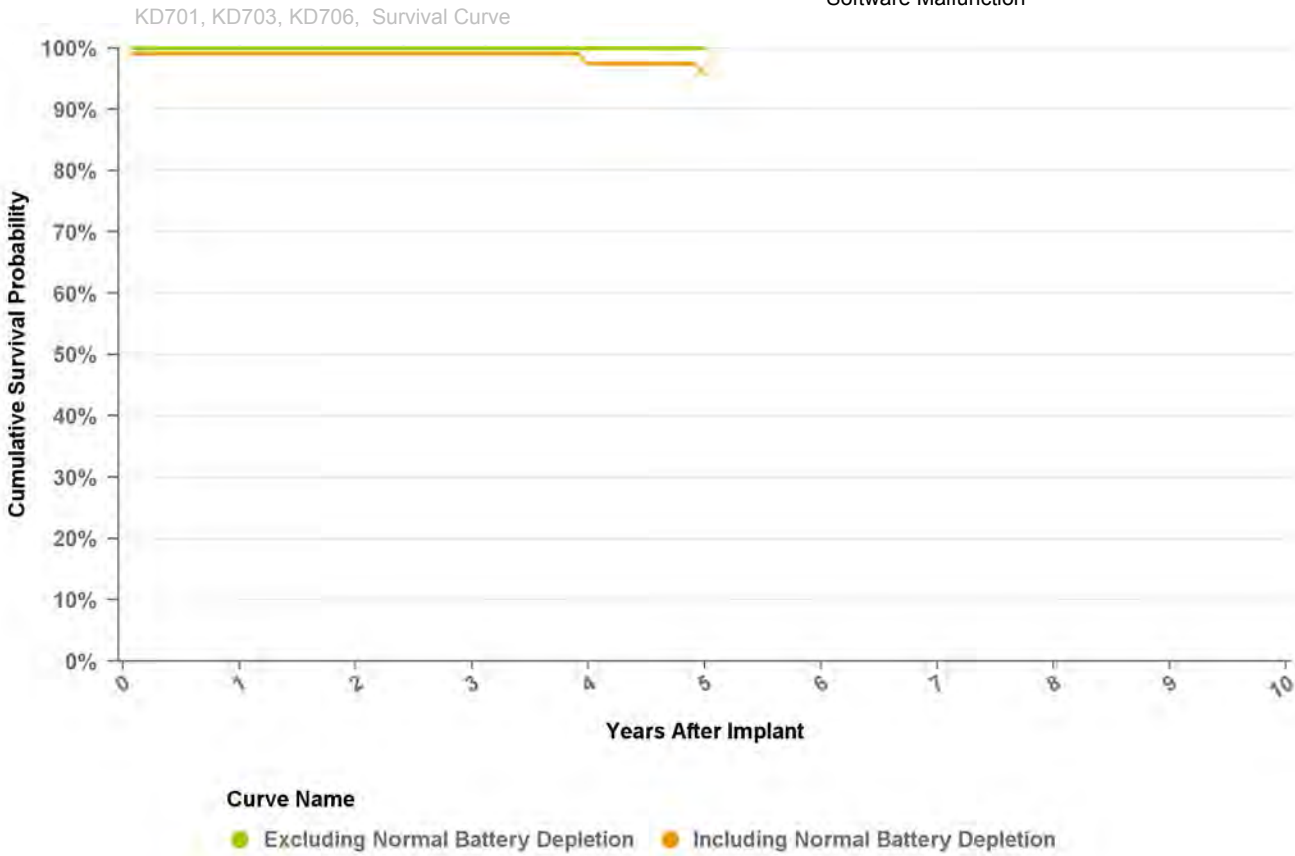
Implantable Pulse Generator

KD703

Kappa 700 DR

US Market Release Date	29-Jan-99
CE Market Approval Date	20-Mar-98
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.5%
Effective Sample Size	183	162	142	122	102

Implantable Pulse Generator

KD706

Kappa 700 DR

US Market Release Date 29-Jan-99

CE Market Approval Date 20-Mar-98

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code DDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

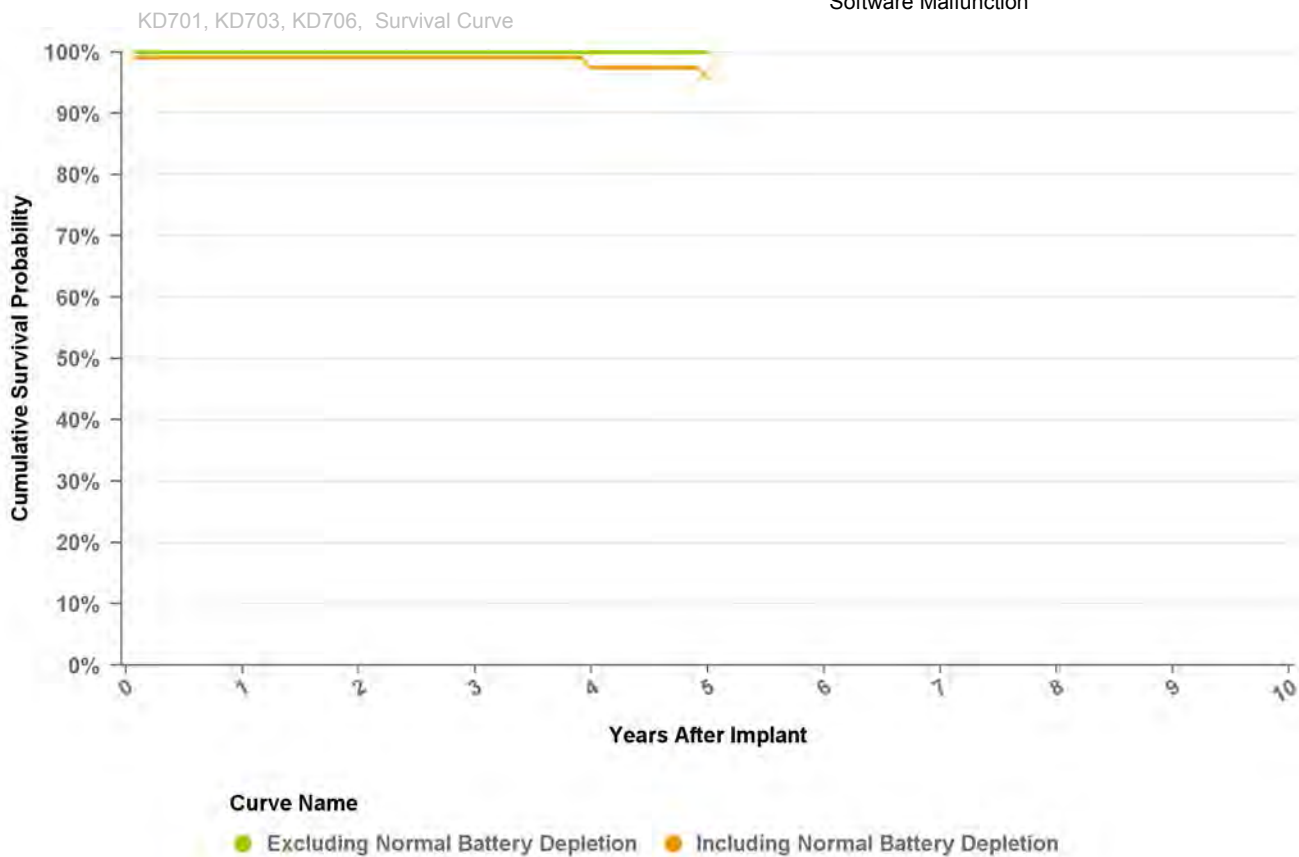
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	99.1%	99.1%	97.5%	95.5%
Effective Sample Size	183	162	142	122	102

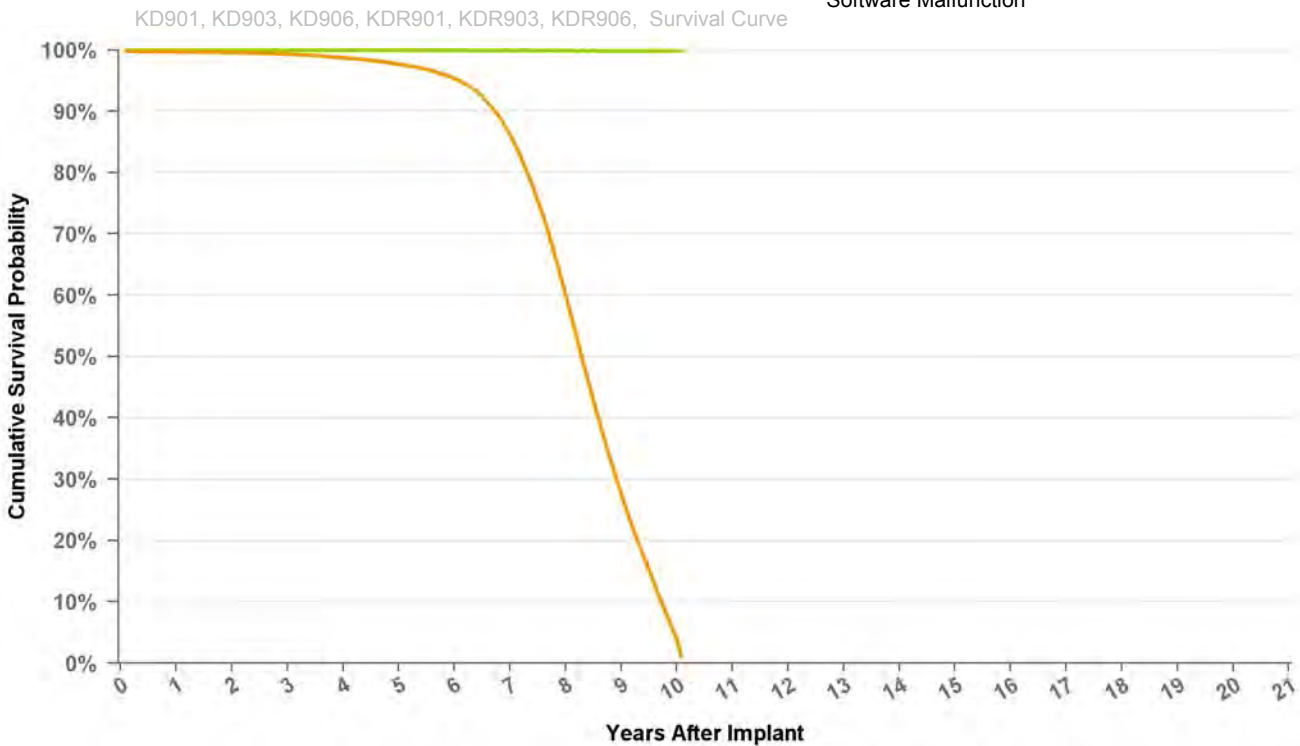
Implantable Pulse Generator

KD901

Kappa 900 D

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 121 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	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

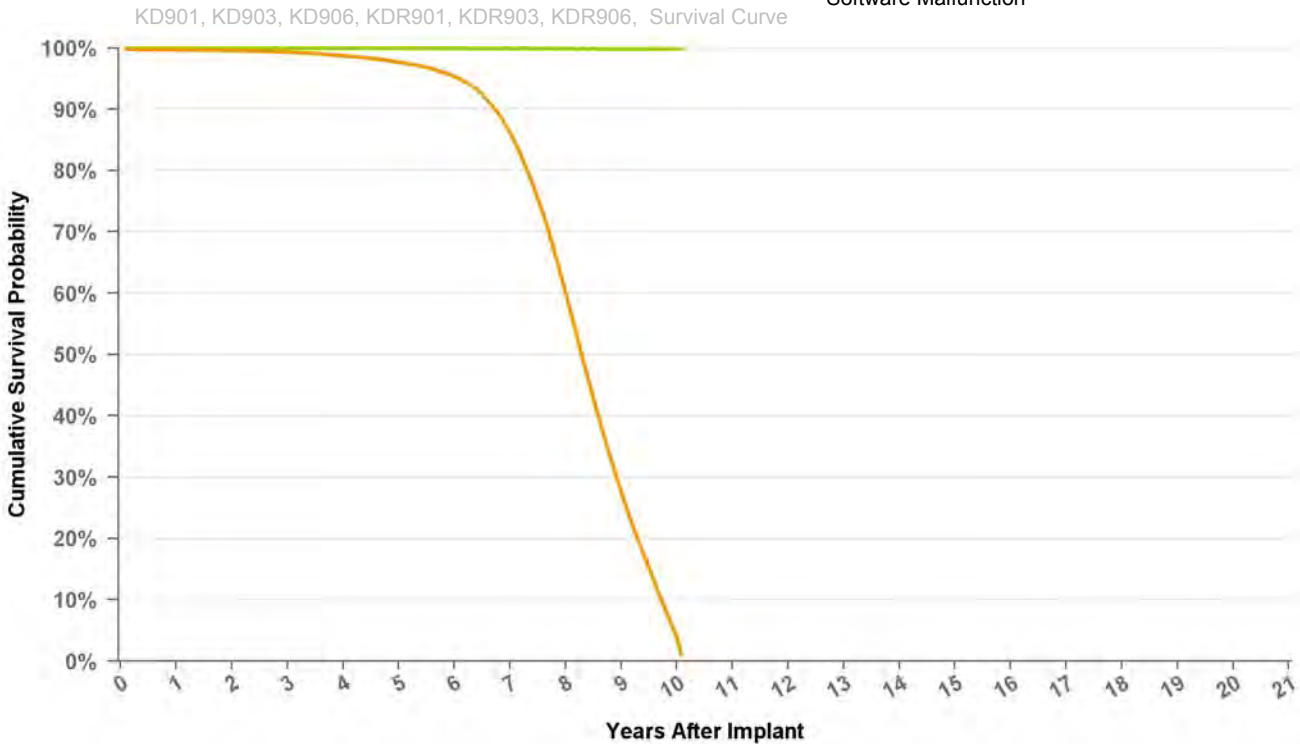
Implantable Pulse Generator

KD903

Kappa 900 D

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 121 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	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

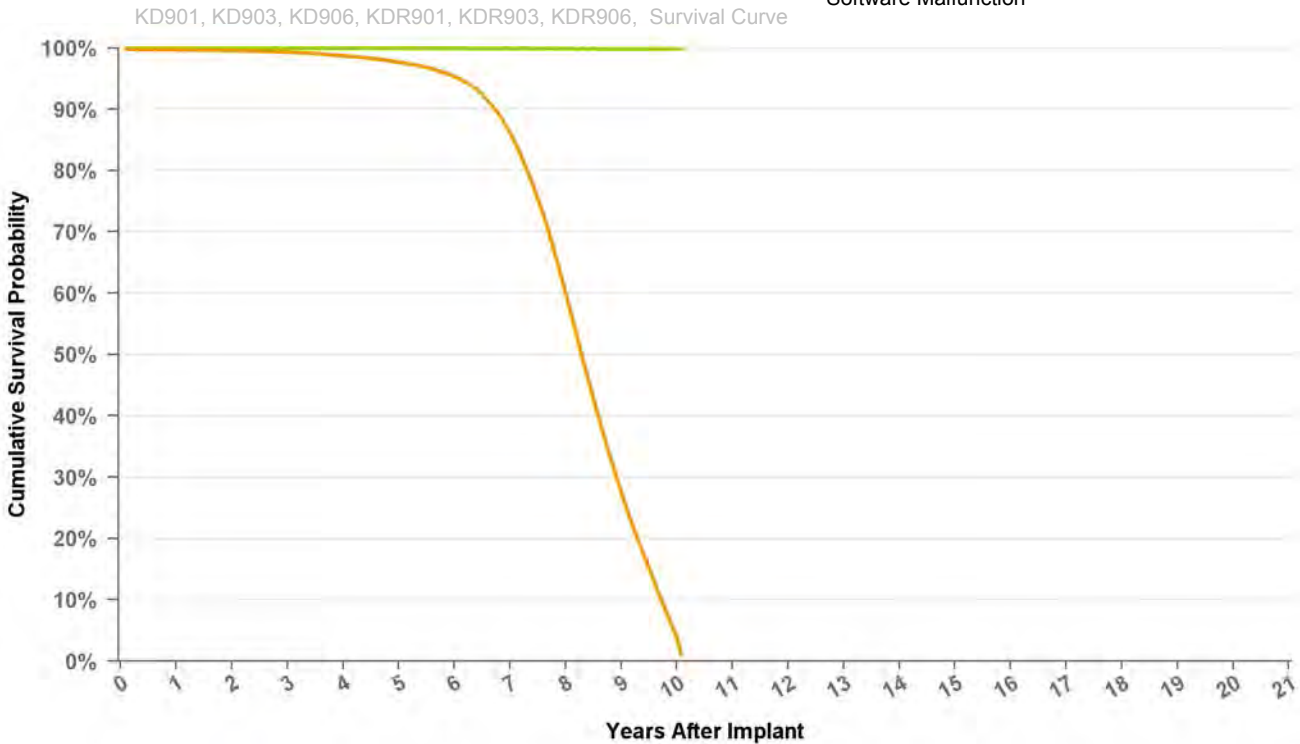
Implantable Pulse Generator

KD906

Kappa 900 D

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDD

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 121 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	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

Implantable Pulse Generator

KDR401 Kappa 400 DR

US Market Release Date 30-Jan-98

CE Market Approval Date 12-Nov-96

Registered US Implants 39,374

Estimated Active US Implants 1,952

Normal Battery Depletions (US) 7,210

NBG Code DDDR

Total Malfunctions (US) 23

Therapy Not Compromised Malfunctions 14

Battery Malfunction 0

Electrical Component 10

Electrical Interconnect 1

Other Malfunction 2

Poss Early Battery Depltn 1

Software Malfunction 0

Therapy Compromised Malfunctions 9

Battery Malfunction 0

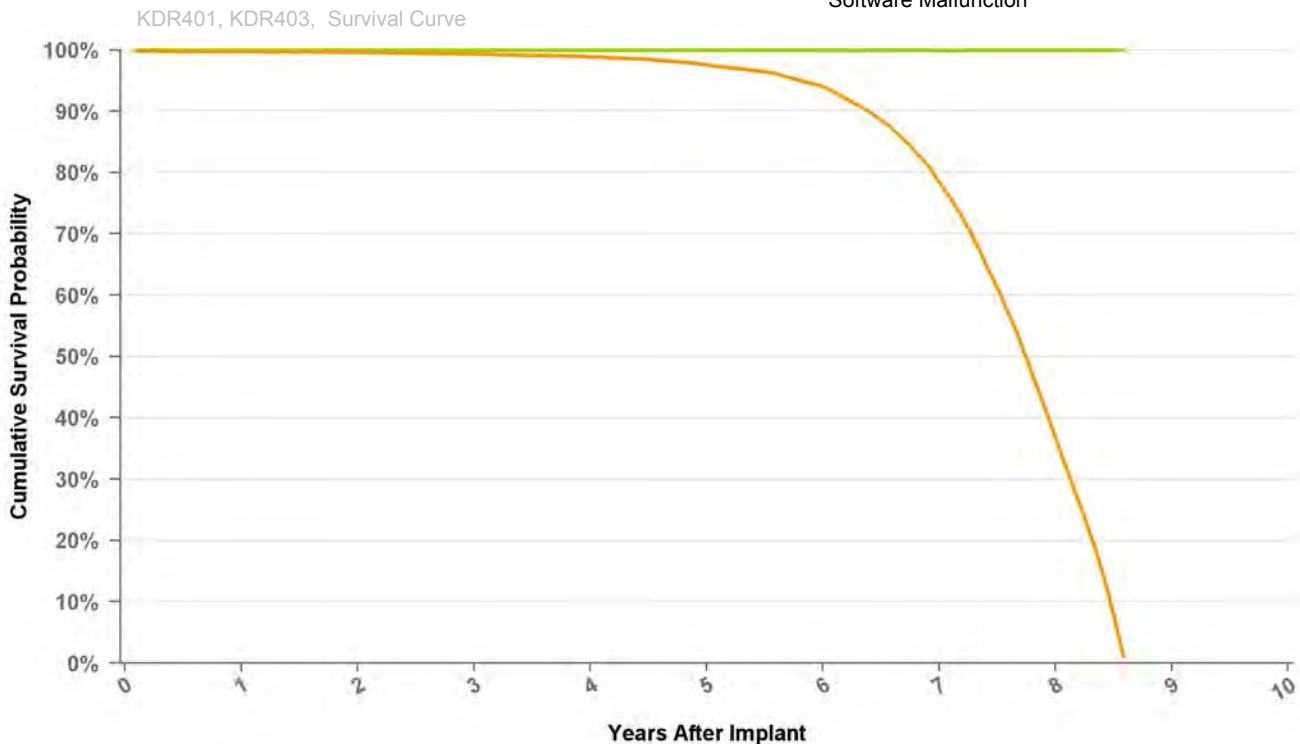
Electrical Component 6

Electrical Interconnect 3

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

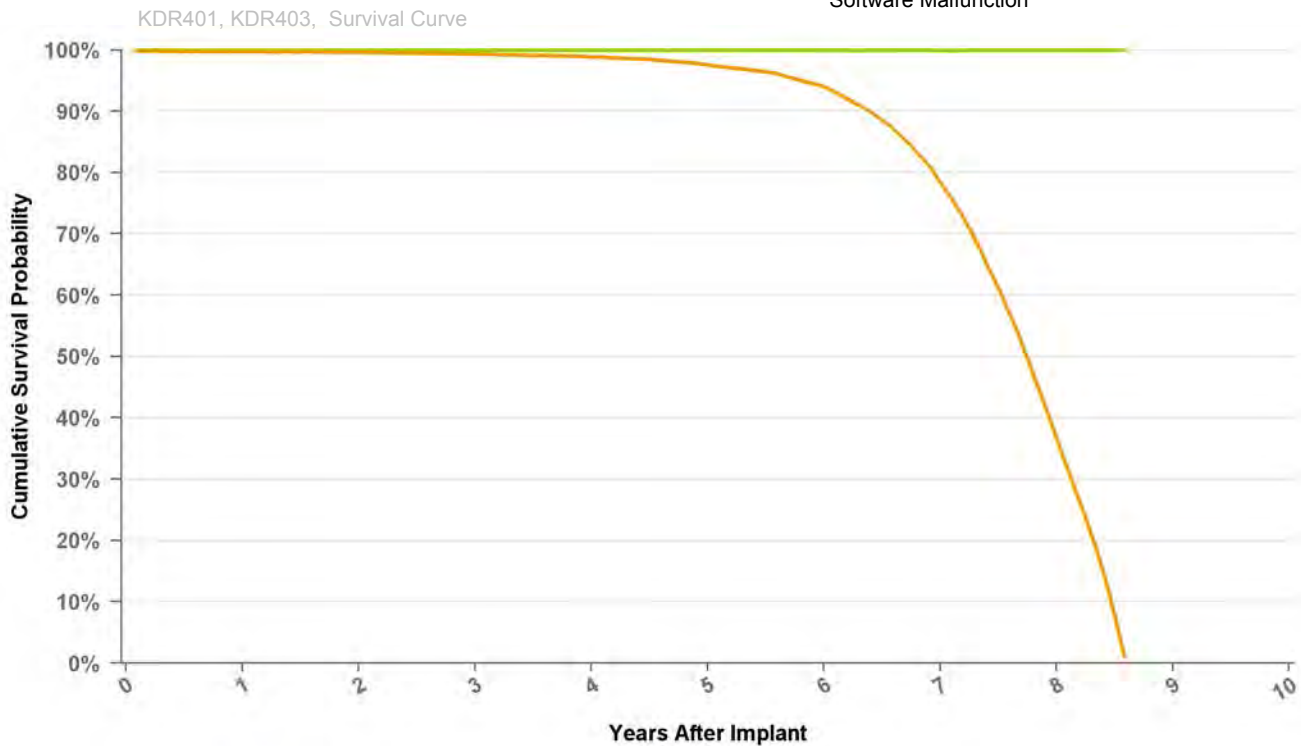
Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.9%	97.6%	94.0%	78.4%	36.8%	1.0%
Effective Sample Size	40234	37422	34641	31849	28694	24778	17987	6417	548

Implantable Pulse Generator

KDR403 Kappa 400 DR

US Market Release Date	30-Jan-98
CE Market Approval Date	12-Nov-96
Registered US Implants	7,308
Estimated Active US Implants	625
Normal Battery Depletions (US)	1,147
NBG Code	DDDR

Total Malfunctions (US)	6
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.9%	97.6%	94.0%	78.4%	36.8%	1.0%
Effective Sample Size	40234	37422	34641	31849	28694	24778	17987	6417	548

Implantable Pulse Generator

KDR700

Kappa 700 DR

US Market Release Date

CE Market Approval Date

Registered US Implants 15

Estimated Active US Implants 0

Normal Battery Depletions (US) 4

NBG Code DDD/RO

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

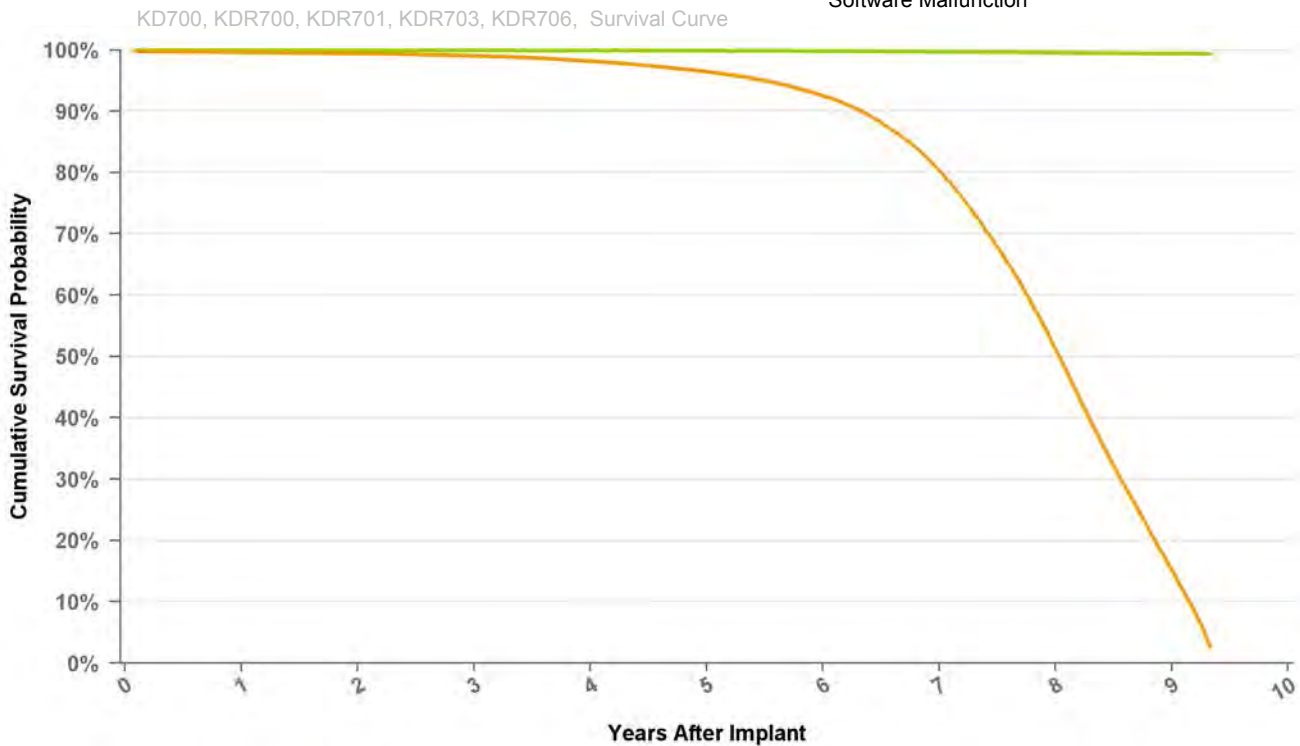
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

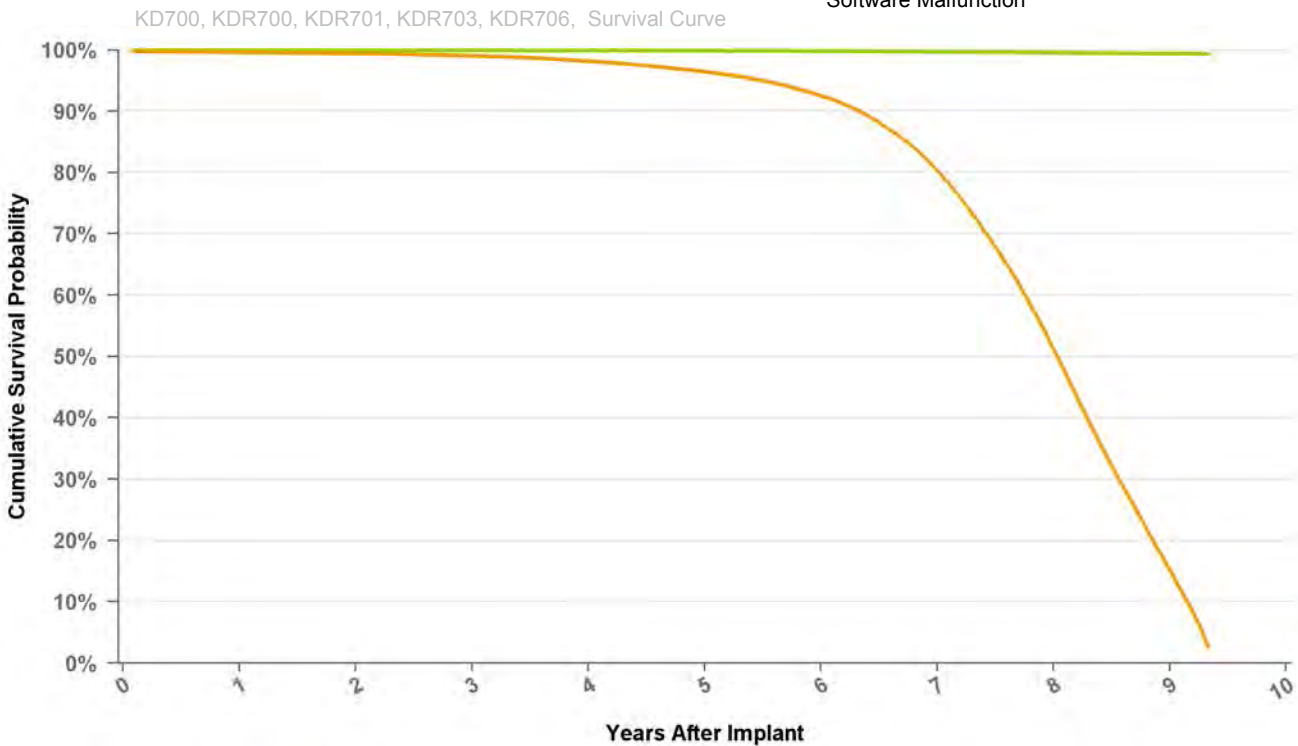
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	96.5%	92.5%	80.3%	51.2%	15.3%	2.6%
Effective Sample Size	163960	150346	136910	122847	108938	93802	72229	38710	8291	1661

Implantable Pulse Generator

KDR701 Kappa 700 DR

US Market Release Date	29-Jan-99
CE Market Approval Date	20-Mar-98
Registered US Implants	194,098
Estimated Active US Implants	11,887
Normal Battery Depletions (US)	36,844
NBG Code	DDD/RO

Total Malfunctions (US)	701
Therapy Not Compromised Malfunctions	48
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	18
Other Malfunction	3
Poss Early Battery Depltn	3
Software Malfunction	0
Therapy Compromised Malfunctions	653
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	636
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

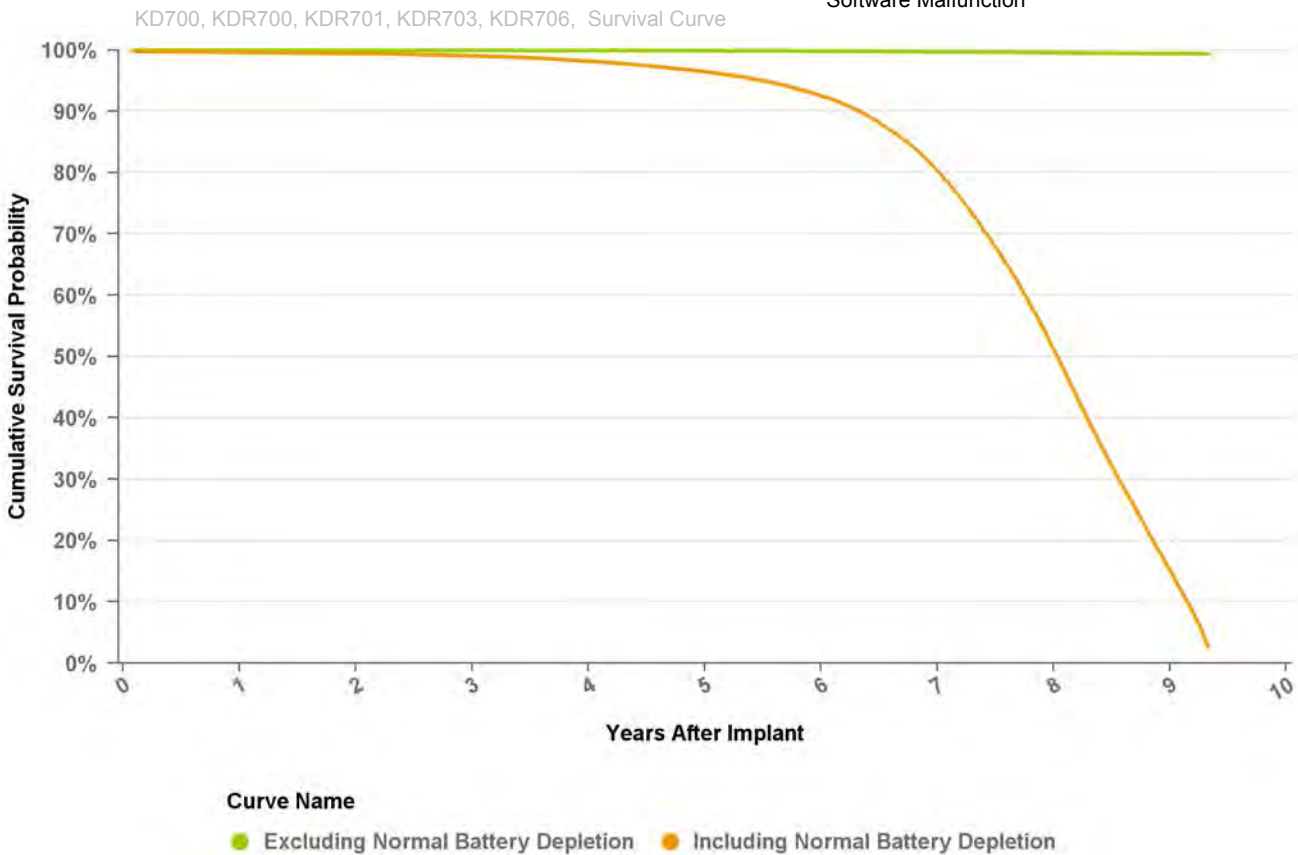
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	96.5%	92.5%	80.3%	51.2%	15.3%	2.6%
Effective Sample Size	163960	150346	136910	122847	108938	93802	72229	38710	8291	1661

Implantable Pulse Generator

KDR703 Kappa 700 DR

US Market Release Date	5-Feb-99
CE Market Approval Date	20-Mar-98
Registered US Implants	9,228
Estimated Active US Implants	550
Normal Battery Depletions (US)	1,532
NBG Code	DDD/RO

Total Malfunctions (US)	34
Therapy Not Compromised Malfunctions	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



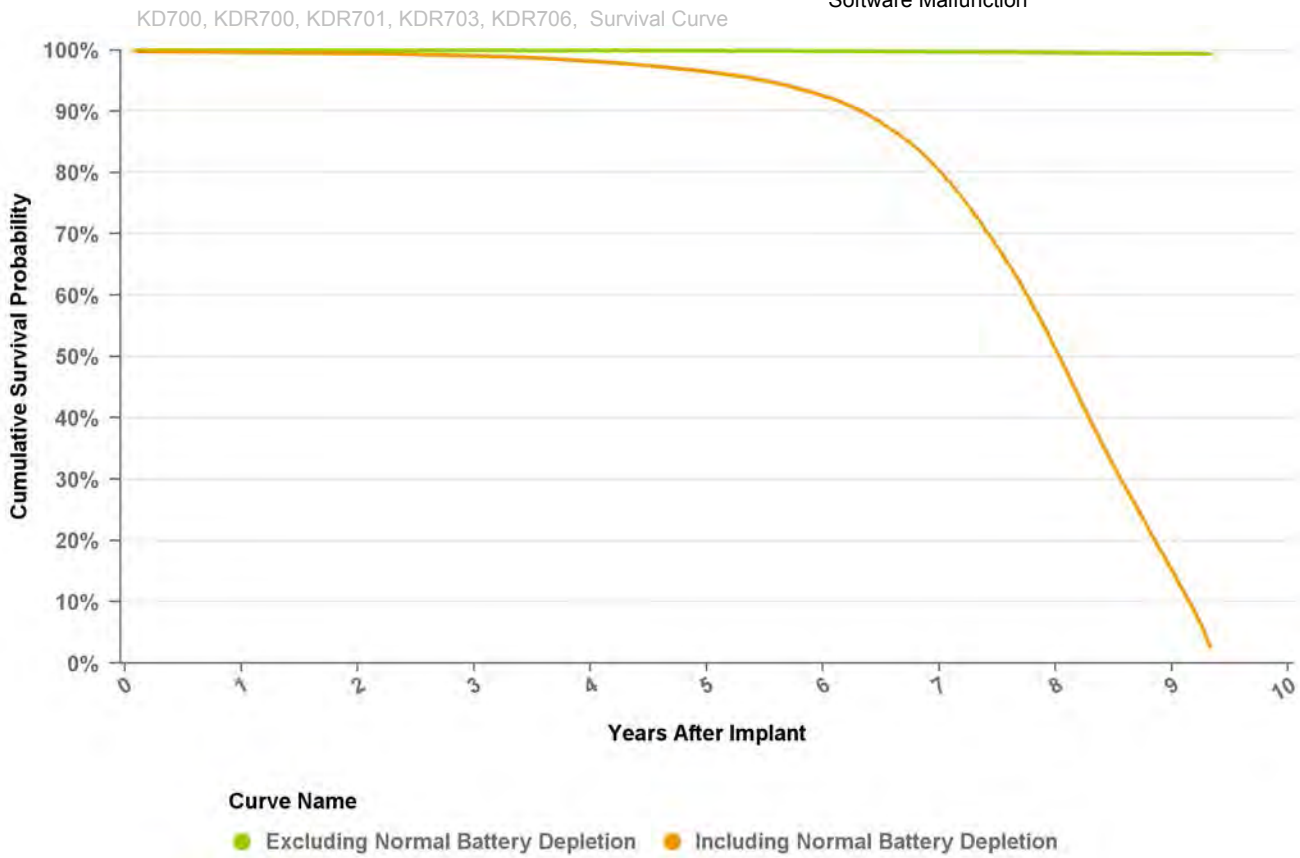
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	96.5%	92.5%	80.3%	51.2%	15.3%	2.6%
Effective Sample Size	163960	150346	136910	122847	108938	93802	72229	38710	8291	1661

Implantable Pulse Generator

KDR706 Kappa 700 DR

US Market Release Date	9-Feb-99
CE Market Approval Date	20-Mar-98
Registered US Implants	2,632
Estimated Active US Implants	127
Normal Battery Depletions (US)	403
NBG Code	DDD/RO

Total Malfunctions (US)	10
Therapy Not Compromised Malfunctions	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



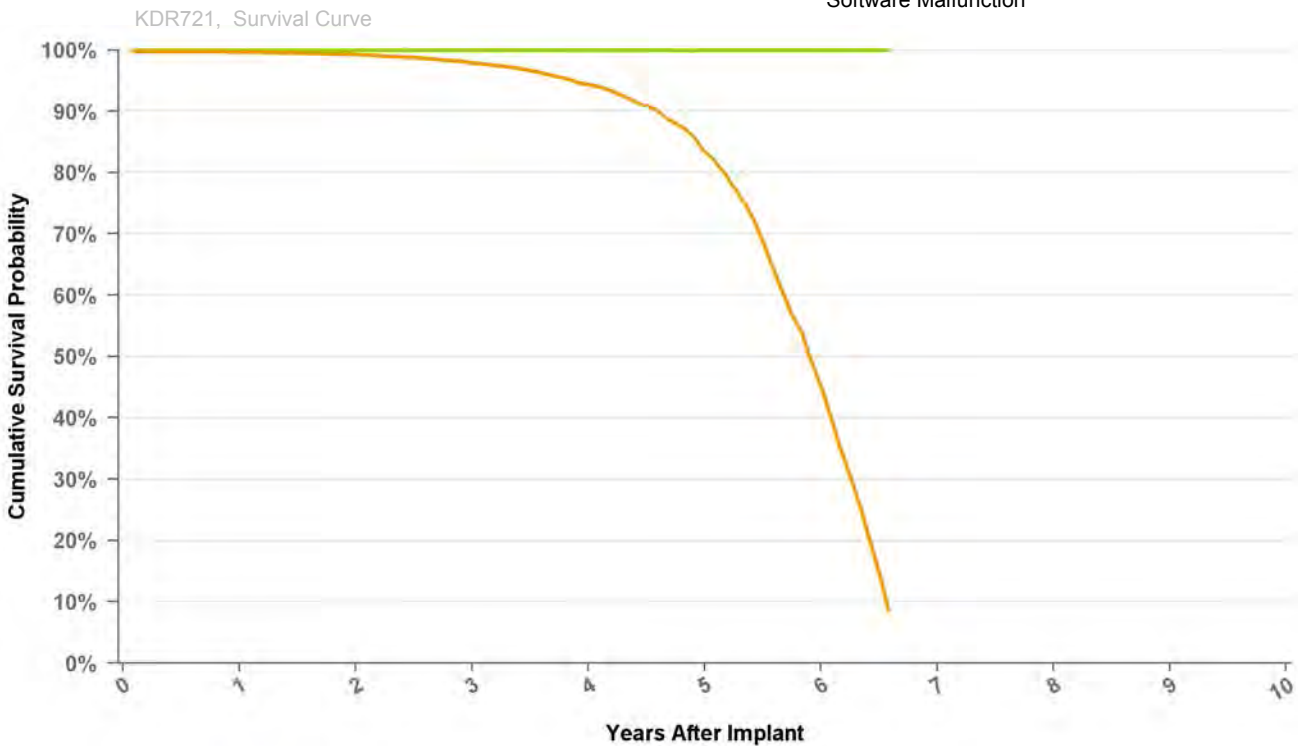
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	96.5%	92.5%	80.3%	51.2%	15.3%	2.6%
Effective Sample Size	163960	150346	136910	122847	108938	93802	72229	38710	8291	1661

Implantable Pulse Generator

KDR721 Kappa 700 DR

US Market Release Date	11-Feb-99
CE Market Approval Date	20-Mar-98
Registered US Implants	9,834
Estimated Active US Implants	509
Normal Battery Depletions (US)	1,363
NBG Code	DDD/RO

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

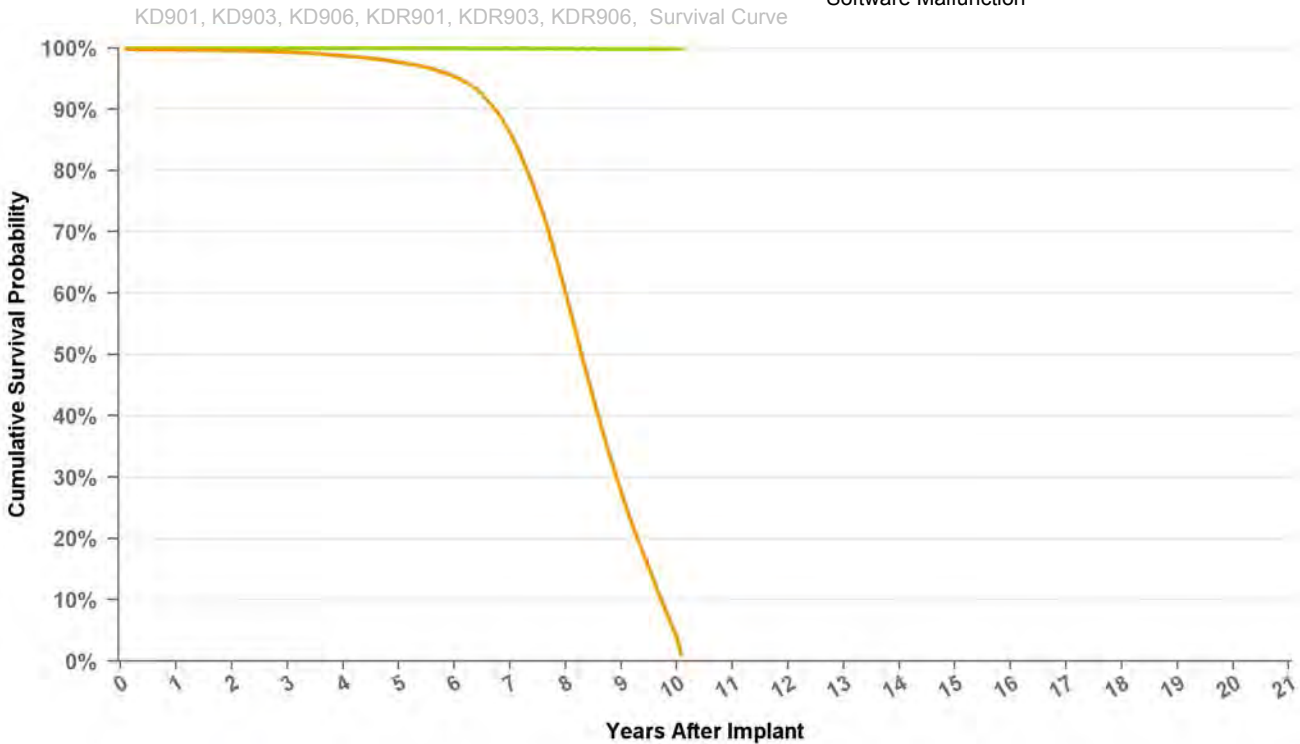
Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.3%	97.9%	94.4%	83.5%	45.3%	8.6%
Effective Sample Size	7978	7084	6198	5202	3942	1514	233

Implantable Pulse Generator

KDR901 Kappa 900 DR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	120,697
Estimated Active US Implants	10,588
Normal Battery Depletions (US)	26,563
NBG Code	DDDR

Total Malfunctions (US)	71
Therapy Not Compromised Malfunctions	21
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	4
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	50
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	40
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

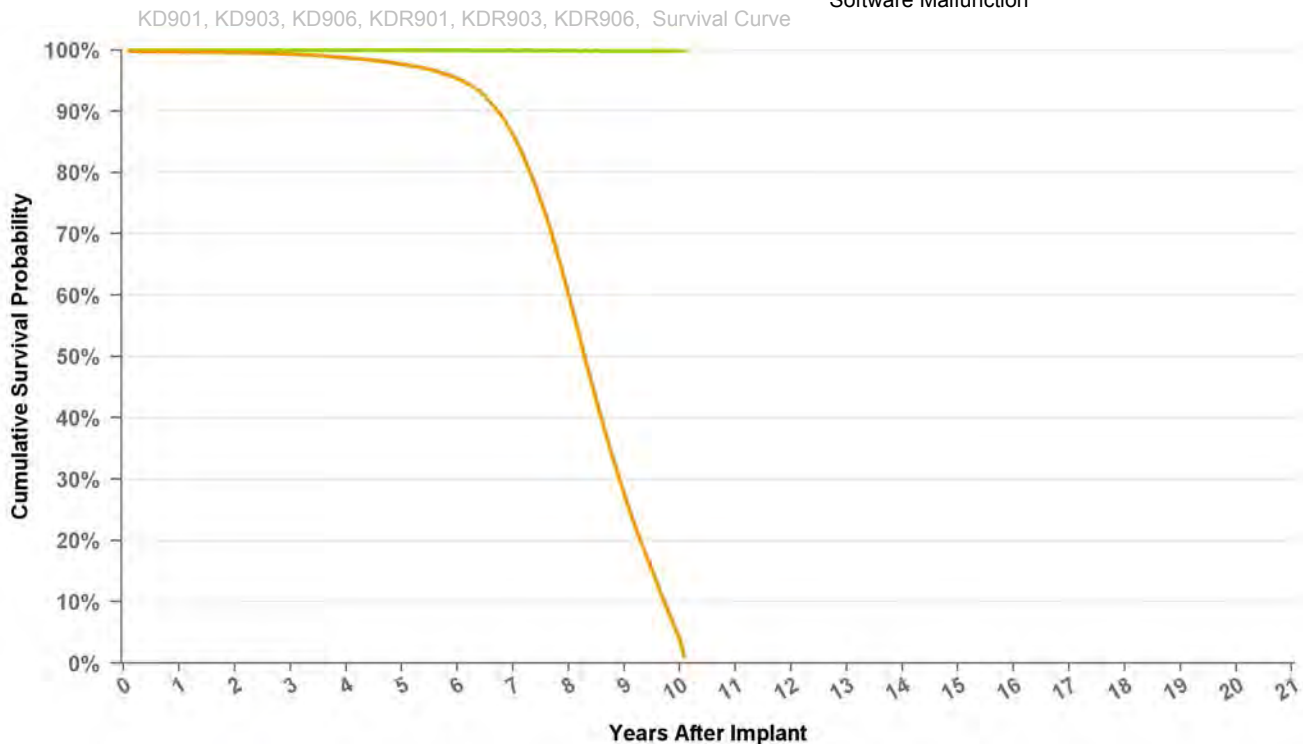
Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

Implantable Pulse Generator

KDR903 Kappa 900 DR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	3,172
Estimated Active US Implants	244
Normal Battery Depletions (US)	619
NBG Code	DDDR

Total Malfunctions (US)	3
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 121 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	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

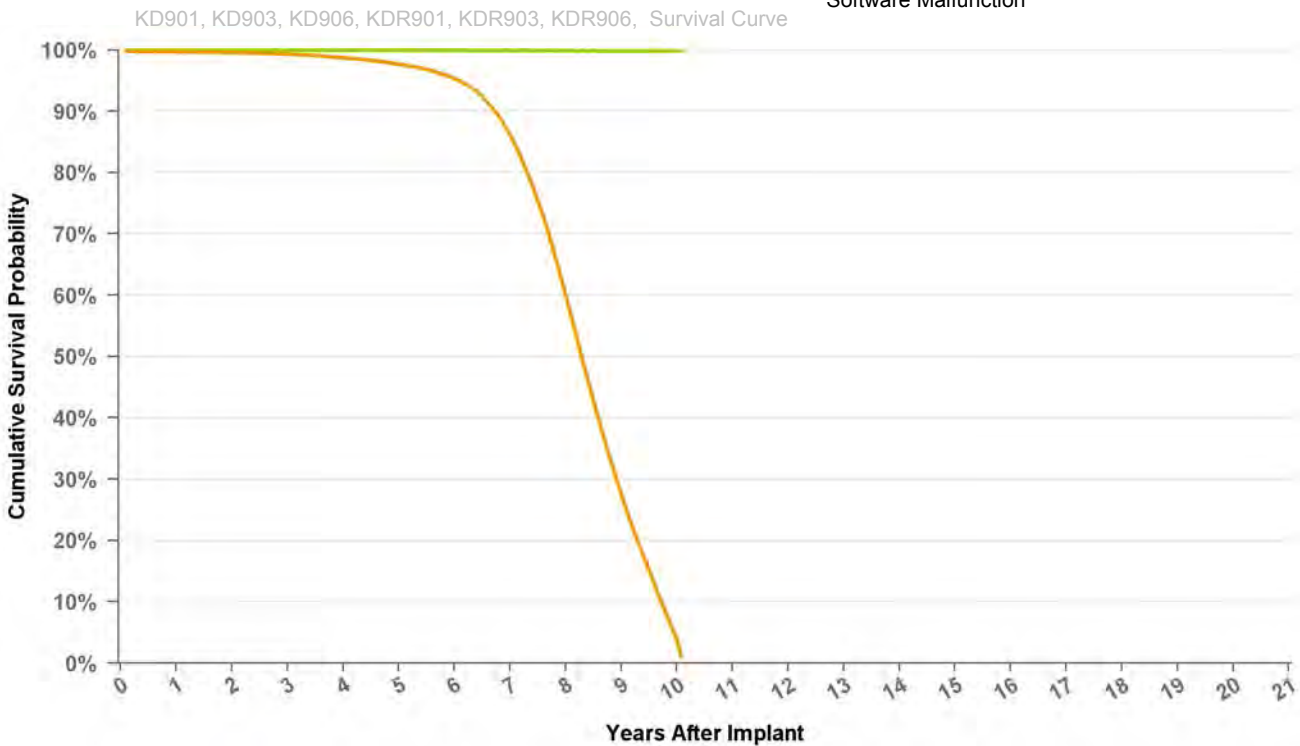
Implantable Pulse Generator

KDR906

Kappa 900 DR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	1,508
Estimated Active US Implants	93
Normal Battery Depletions (US)	301
NBG Code	DDDR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	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



Curve Name

- Excluding Normal Battery Depletion
- Including Normal Battery Depletion

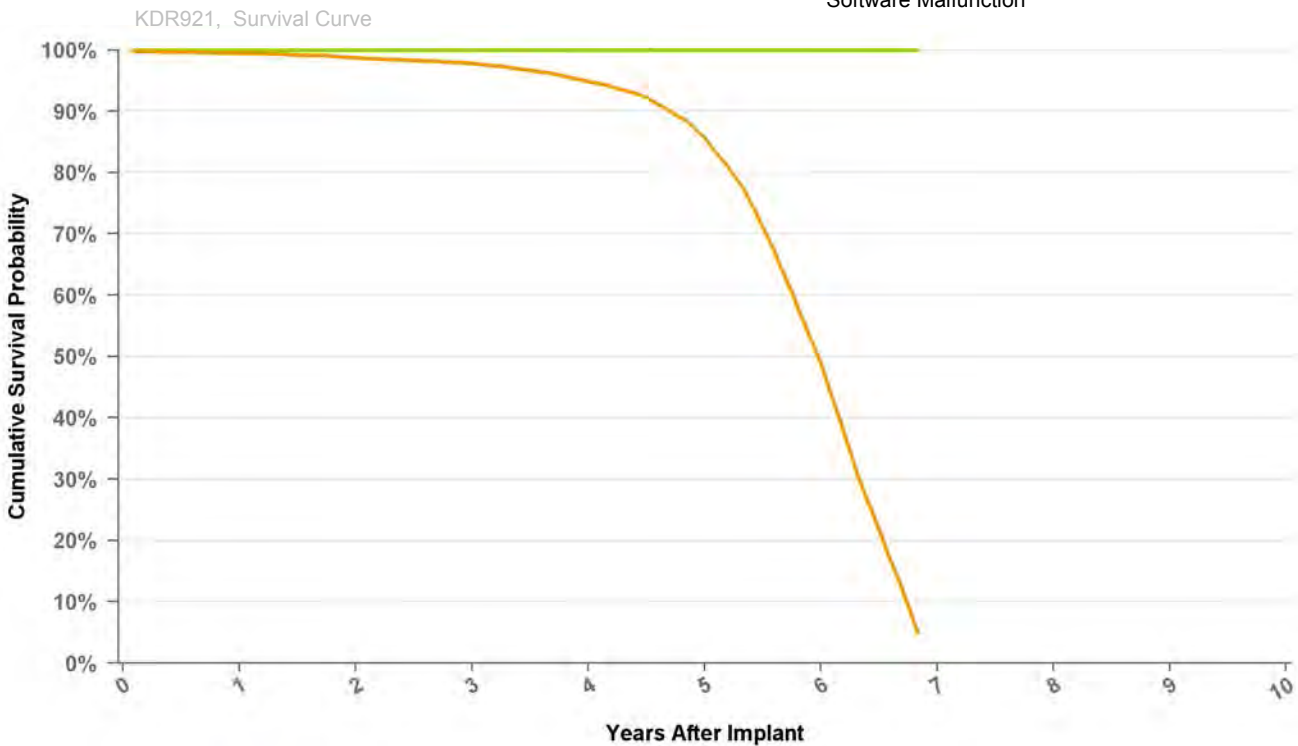
Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.7%	97.7%	95.3%	86.3%	60.1%	27.6%	3.9%	1.0%
Effective Sample Size	108113	99159	90305	81827	73519	65181	53789	33336	12671	871	384

Implantable Pulse Generator

KDR921 Kappa 900 DR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	16,325
Estimated Active US Implants	956
Normal Battery Depletions (US)	2,896
NBG Code	DDDR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.5%	98.7%	97.8%	94.8%	85.6%	49.0%	5.0%
Effective Sample Size	13524	12037	10588	9100	7192	3173	250

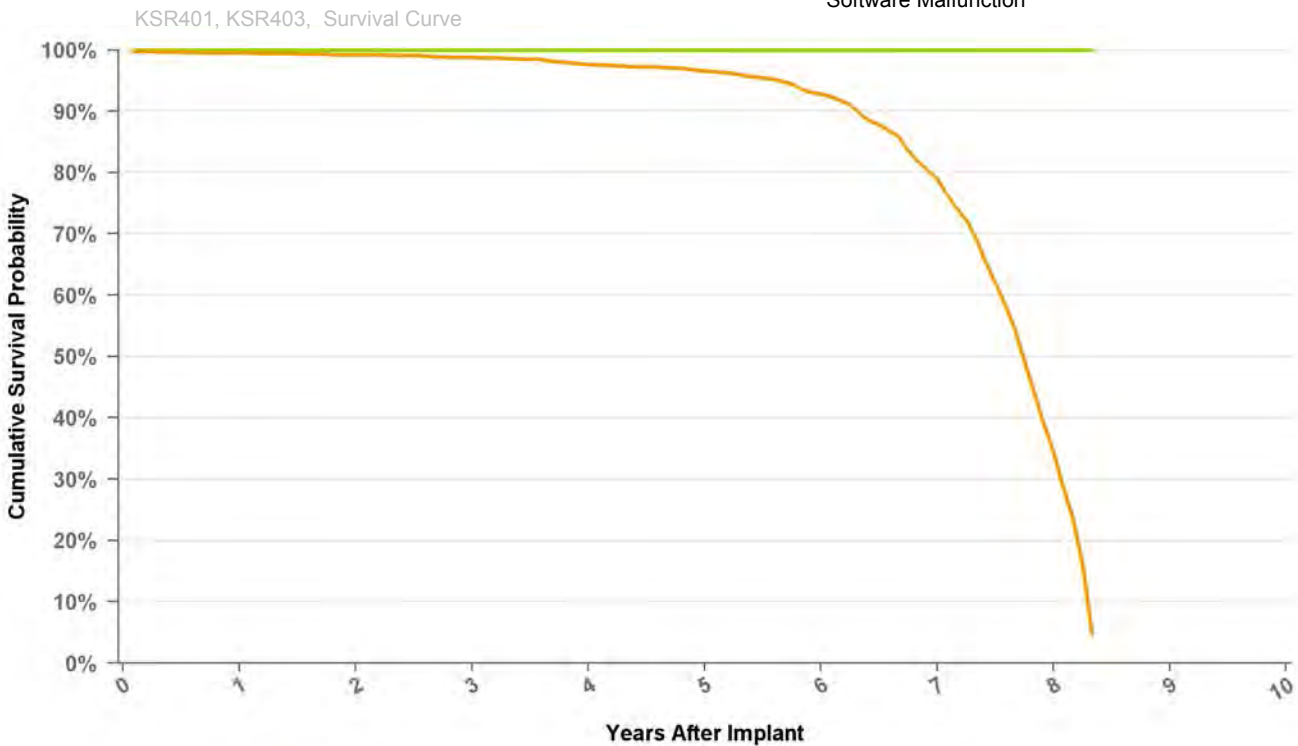
Implantable Pulse Generator

KSR401

Kappa 400 SR

US Market Release Date	18-Feb-98
CE Market Approval Date	12-Nov-96
Registered US Implants	11,787
Estimated Active US Implants	547
Normal Battery Depletions (US)	1,288
NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	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



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%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.2%	98.8%	97.6%	96.6%	92.8%	78.9%	34.6%	4.7%
Effective Sample Size	11620	10106	8796	7557	6360	5100	3517	1057	226

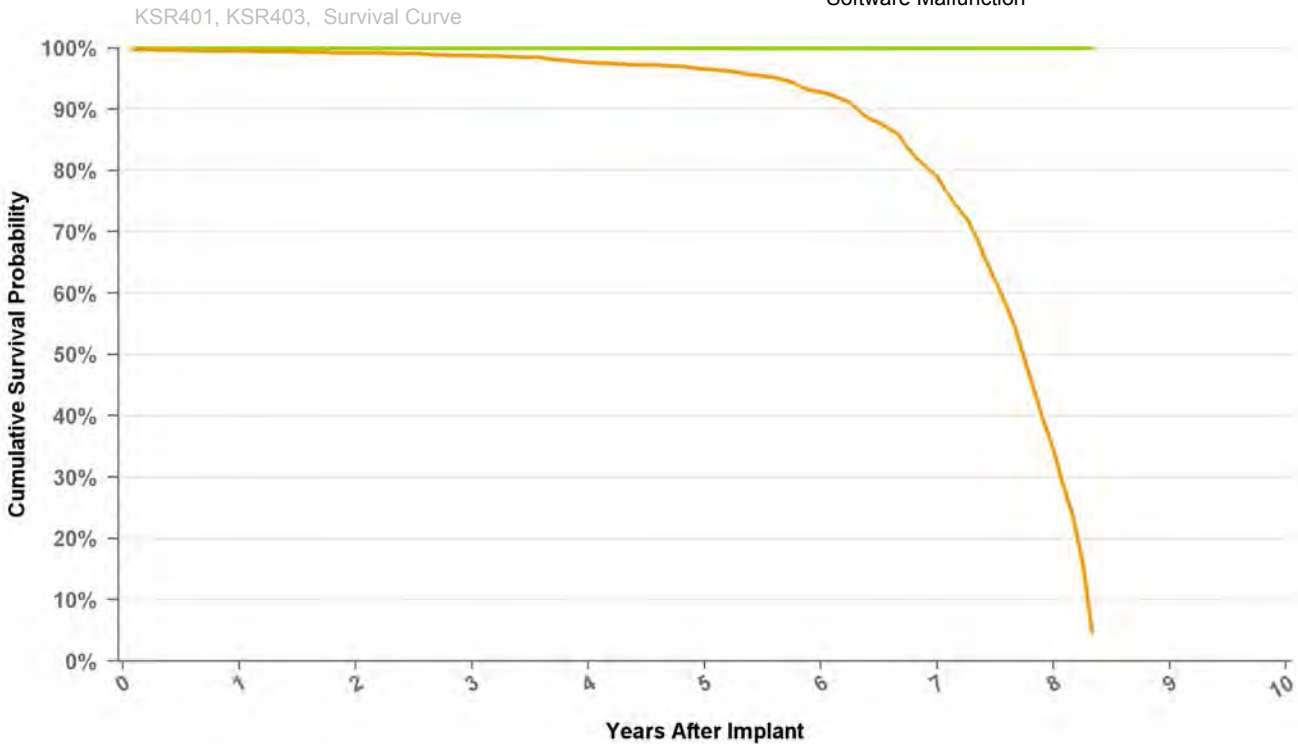
Implantable Pulse Generator

KSR403

Kappa 400 SR

US Market Release Date	24-Feb-98
CE Market Approval Date	12-Nov-96
Registered US Implants	3,622
Estimated Active US Implants	268
Normal Battery Depletions (US)	394
NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



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%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.2%	98.8%	97.6%	96.6%	92.8%	78.9%	34.6%	4.7%
Effective Sample Size	11620	10106	8796	7557	6360	5100	3517	1057	226

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

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

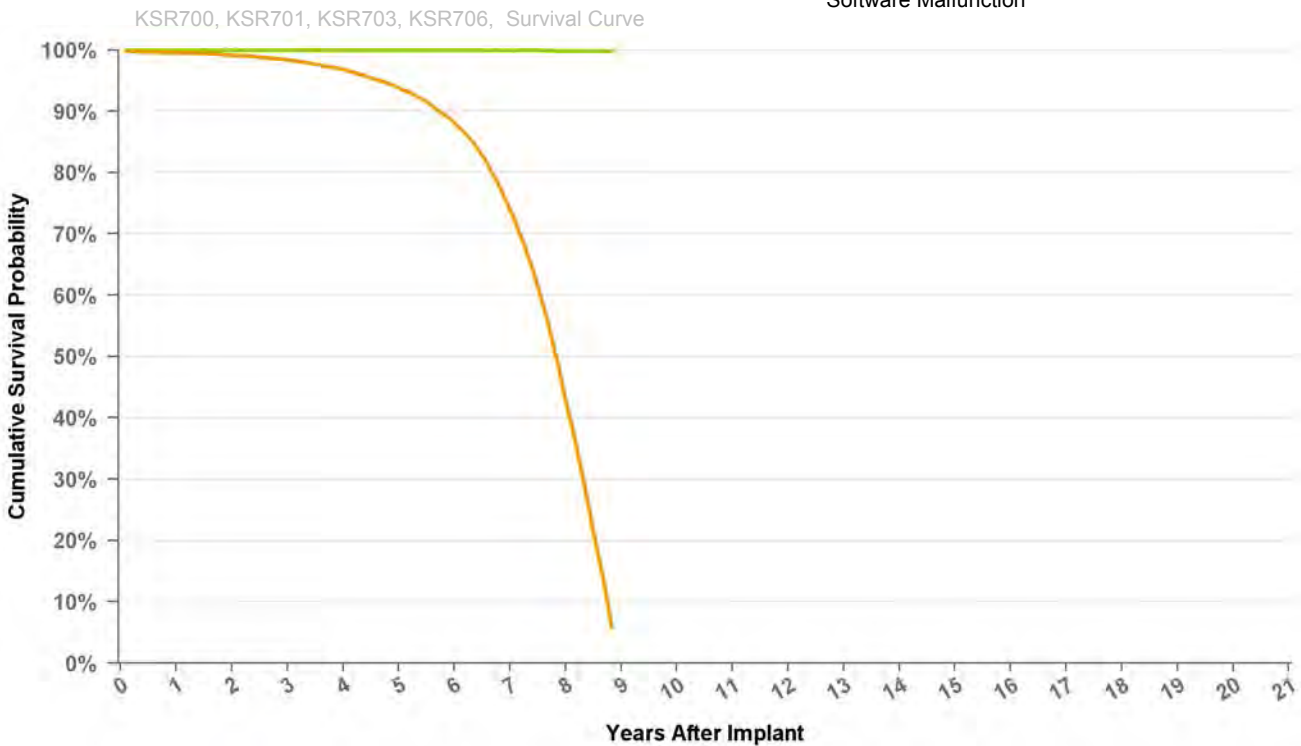
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.4%	96.8%	93.8%	88.1%	74.0%	43.0%	5.7%
Effective Sample Size	41367	35421	29991	25077	20428	16066	11132	4997	482

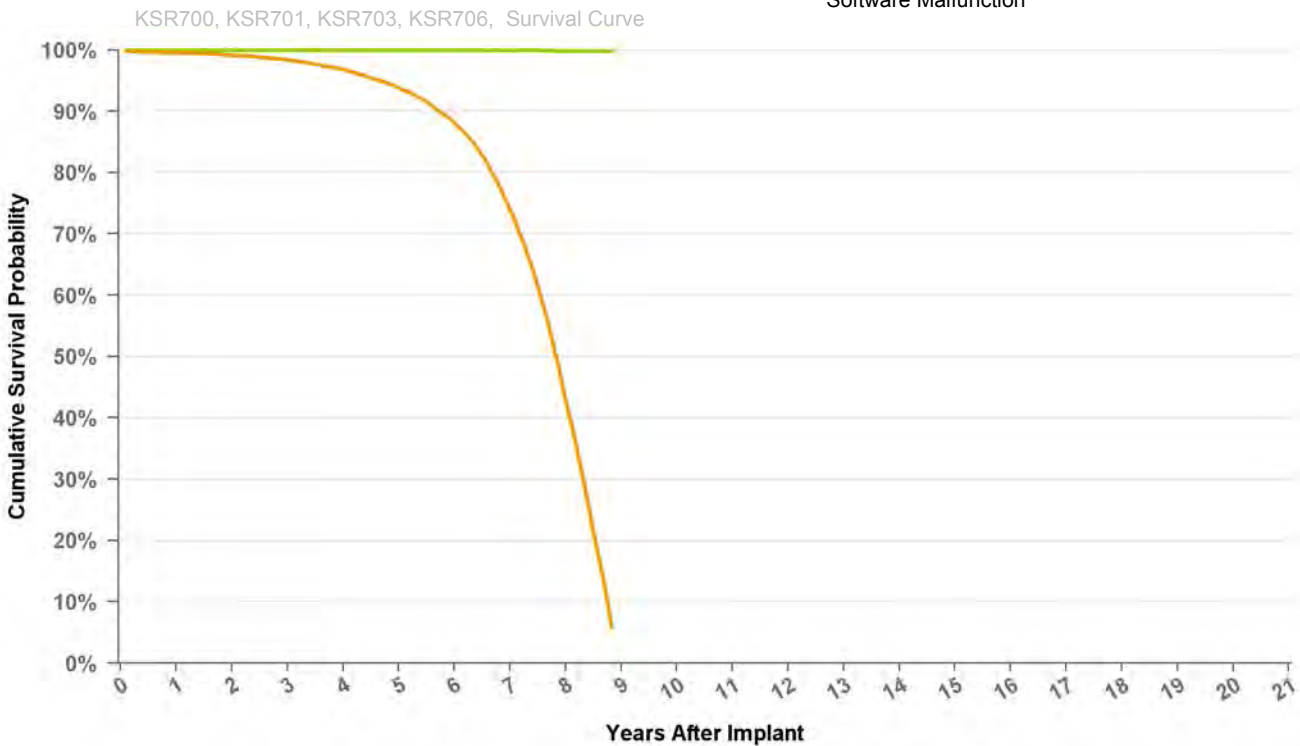
Implantable Pulse Generator

KSR701

Kappa 700 SR

US Market Release Date	29-Jan-99
CE Market Approval Date	20-Mar-98
Registered US Implants	48,459
Estimated Active US Implants	2,786
Normal Battery Depletions (US)	5,125
NBG Code	SSIR

Total Malfunctions (US)	22
Therapy Not Compromised Malfunctions	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



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%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.4%	96.8%	93.8%	88.1%	74.0%	43.0%	5.7%
Effective Sample Size	41367	35421	29991	25077	20428	16066	11132	4997	482

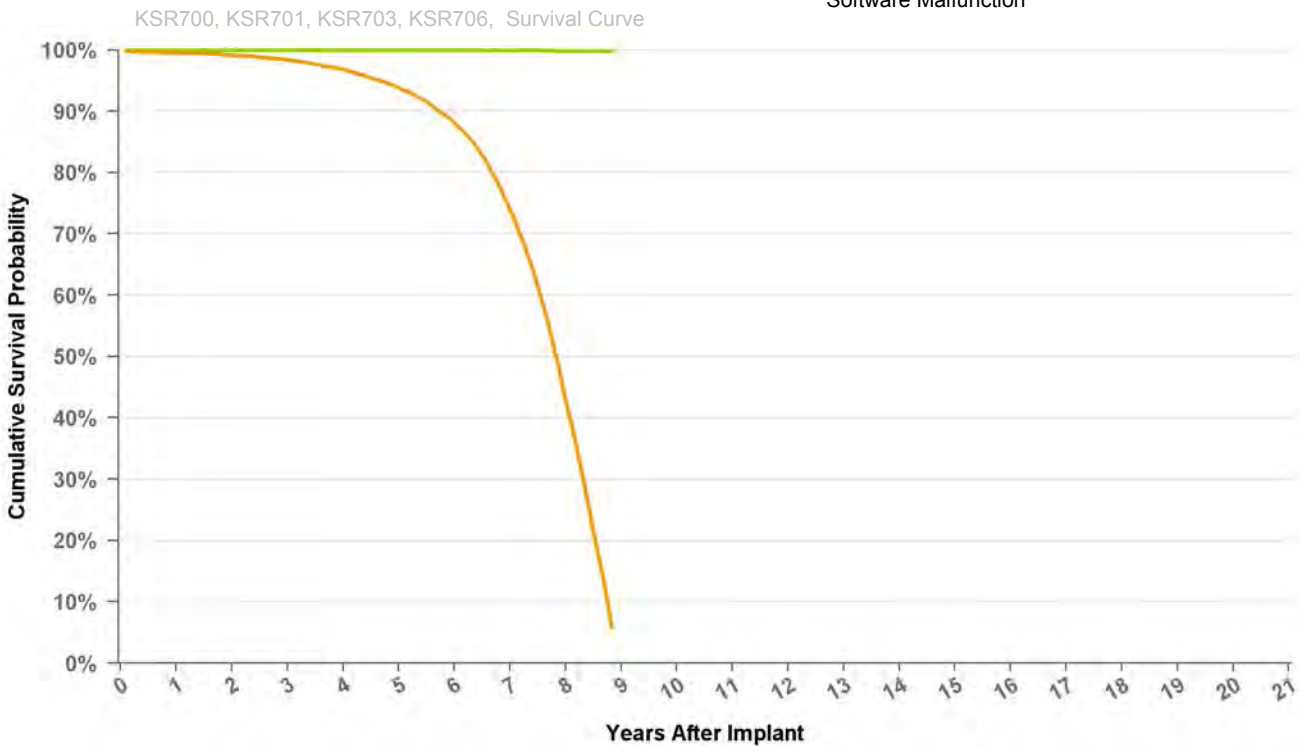
Implantable Pulse Generator

KSR703

Kappa 700 SR

US Market Release Date	8-Feb-99
CE Market Approval Date	20-Mar-98
Registered US Implants	3,605
Estimated Active US Implants	187
Normal Battery Depletions (US)	395
NBG Code	SSIR

Total Malfunctions (US)	4
Therapy Not Compromised Malfunctions	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



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%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.4%	96.8%	93.8%	88.1%	74.0%	43.0%	5.7%
Effective Sample Size	41367	35421	29991	25077	20428	16066	11132	4997	482

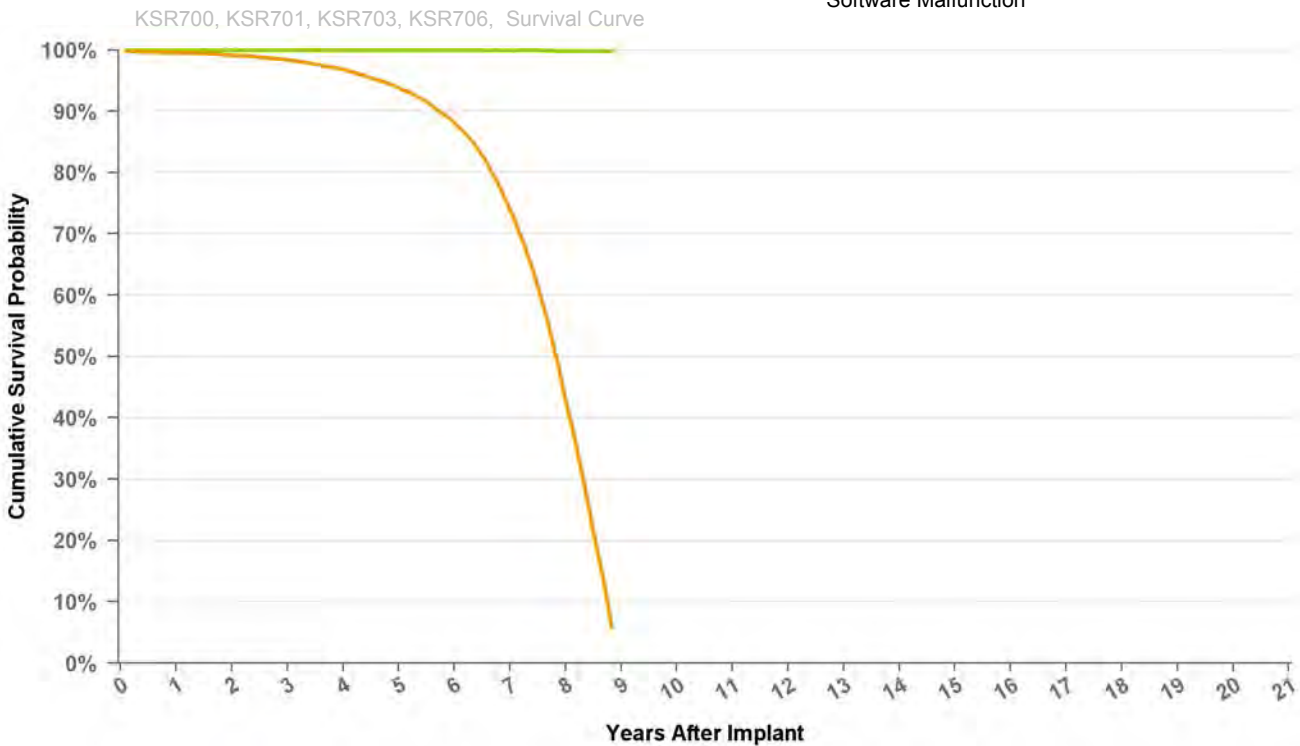
Implantable Pulse Generator

KSR706

Kappa 700 SR

US Market Release Date	9-Feb-99
CE Market Approval Date	20-Mar-98
Registered US Implants	2,920
Estimated Active US Implants	164
Normal Battery Depletions (US)	301
NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	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



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%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.4%	96.8%	93.8%	88.1%	74.0%	43.0%	5.7%
Effective Sample Size	41367	35421	29991	25077	20428	16066	11132	4997	482

Implantable Pulse Generator

KSR901

Kappa 900 SR

US Market Release Date 9-Jan-02

CE Market Approval Date 28-Sep-01

Registered US Implants 34,131

Estimated Active US Implants 2,571

Normal Battery Depletions (US) 4,174

NBG Code SSIR

Total Malfunctions (US) 15

Therapy Not Compromised Malfunctions 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

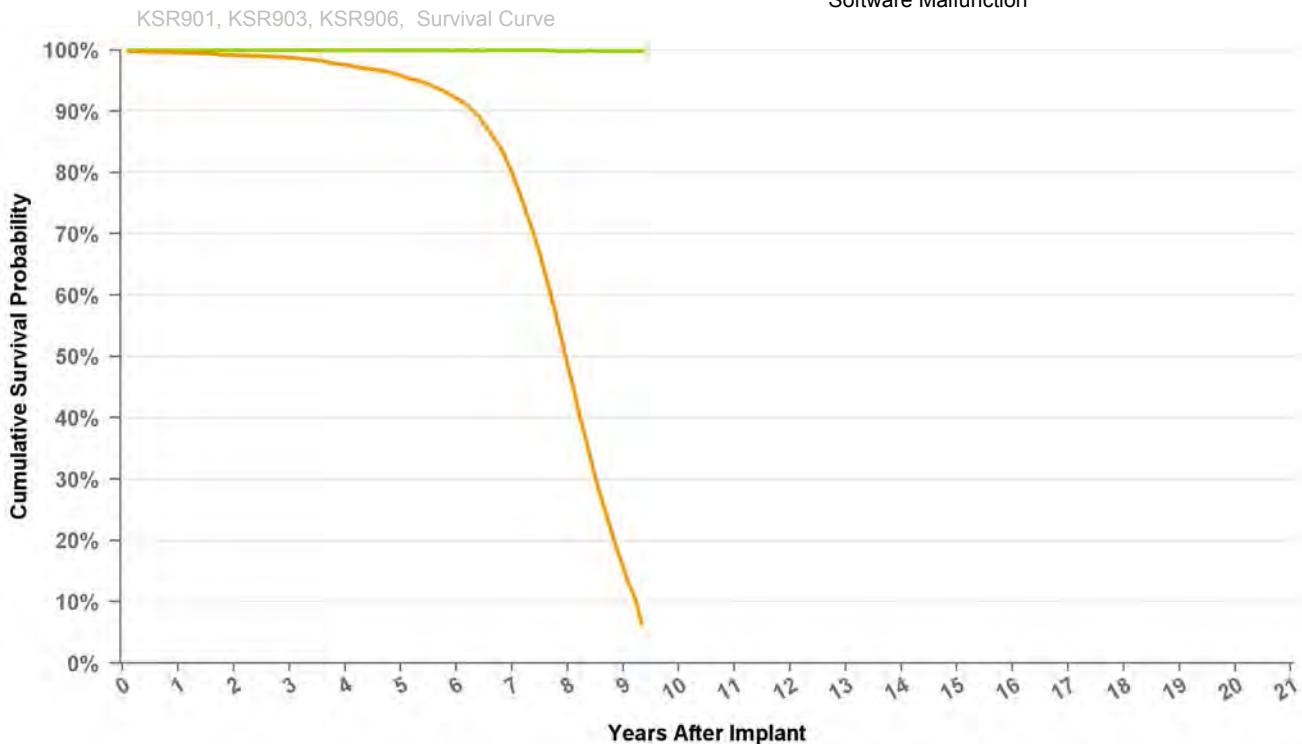
Electrical Component 0

Electrical Interconnect 8

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

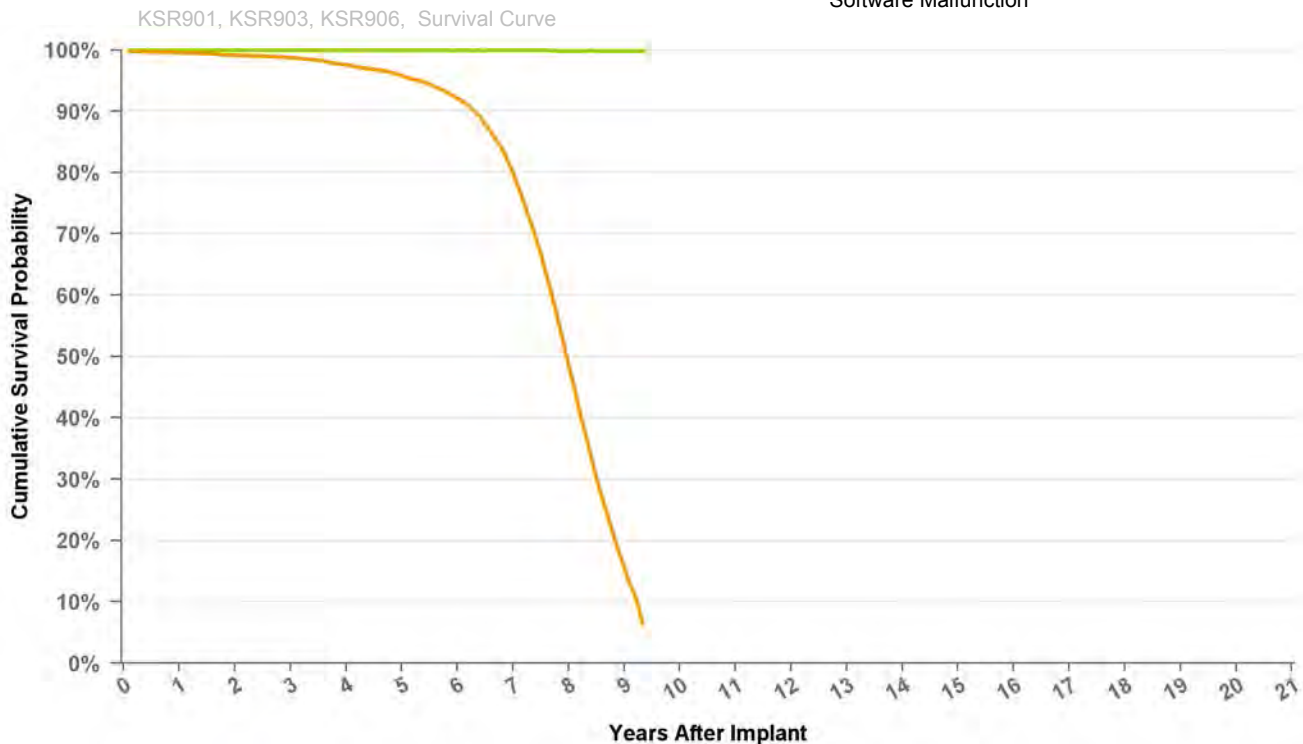
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.1%	98.7%	97.6%	95.8%	92.1%	80.1%	48.7%	15.5%	6.4%
Effective Sample Size	28005	23828	20327	17115	14294	11688	8611	4296	963	232

Implantable Pulse Generator

KSR903 Kappa 900 SR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	1,373
Estimated Active US Implants	89
Normal Battery Depletions (US)	165
NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.1%	98.7%	97.6%	95.8%	92.1%	80.1%	48.7%	15.5%	6.4%
Effective Sample Size	28005	23828	20327	17115	14294	11688	8611	4296	963	232

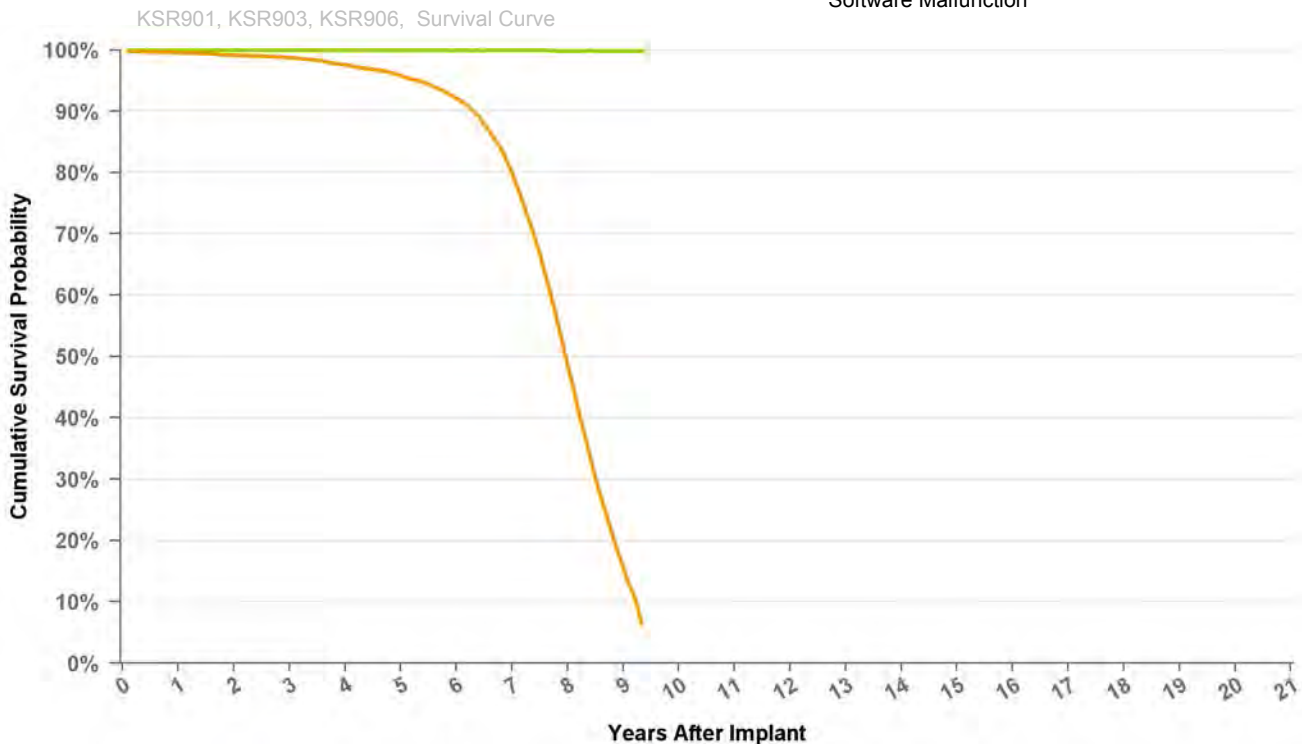
Implantable Pulse Generator

KSR906

Kappa 900 SR

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	1,320
Estimated Active US Implants	92
Normal Battery Depletions (US)	180
NBG Code	SSIR

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

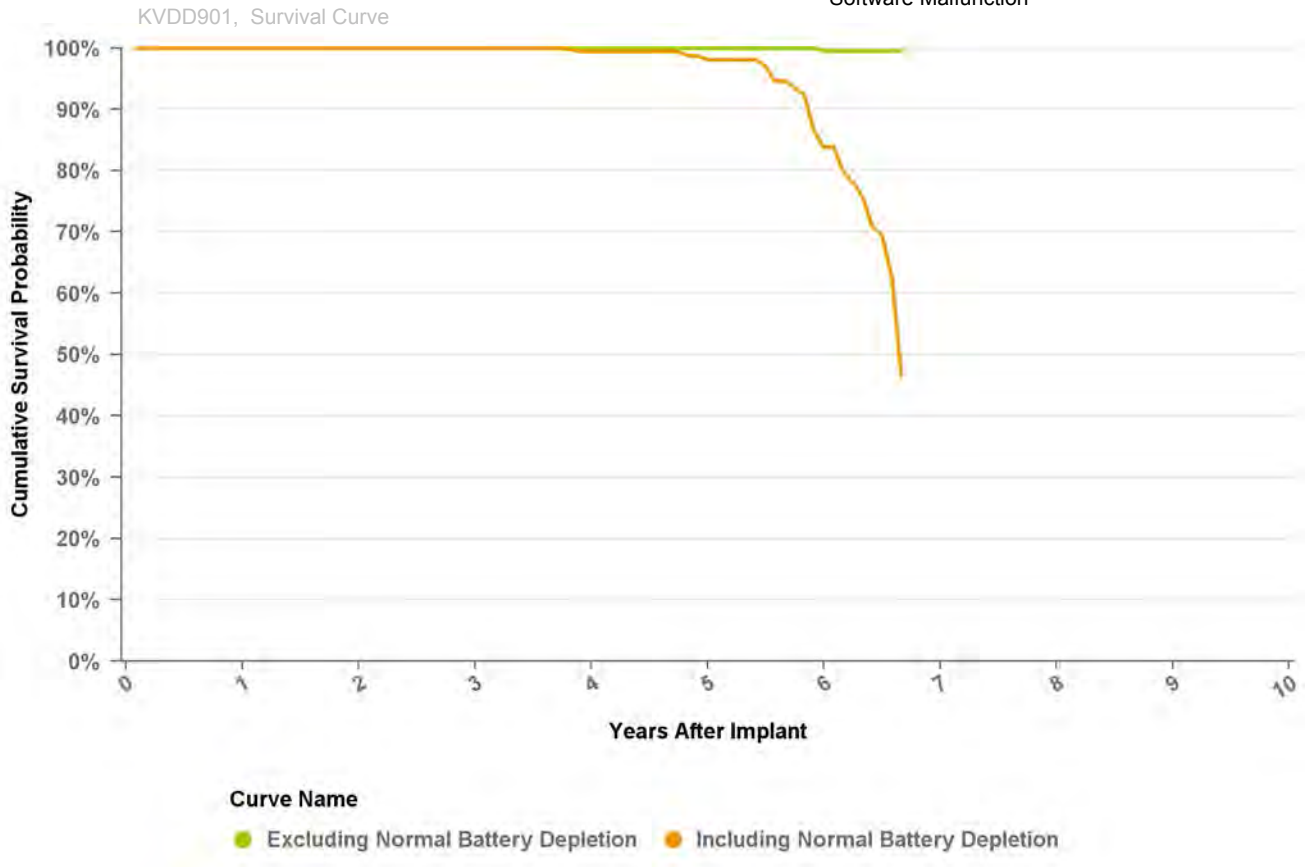
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.1%	98.7%	97.6%	95.8%	92.1%	80.1%	48.7%	15.5%	6.4%
Effective Sample Size	28005	23828	20327	17115	14294	11688	8611	4296	963	232

Implantable Pulse Generator

KVDD901 Kappa 900 VDD

US Market Release Date	9-Jan-02
CE Market Approval Date	28-Sep-01
Registered US Implants	566
Estimated Active US Implants	50
Normal Battery Depletions (US)	81
NBG Code	VDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



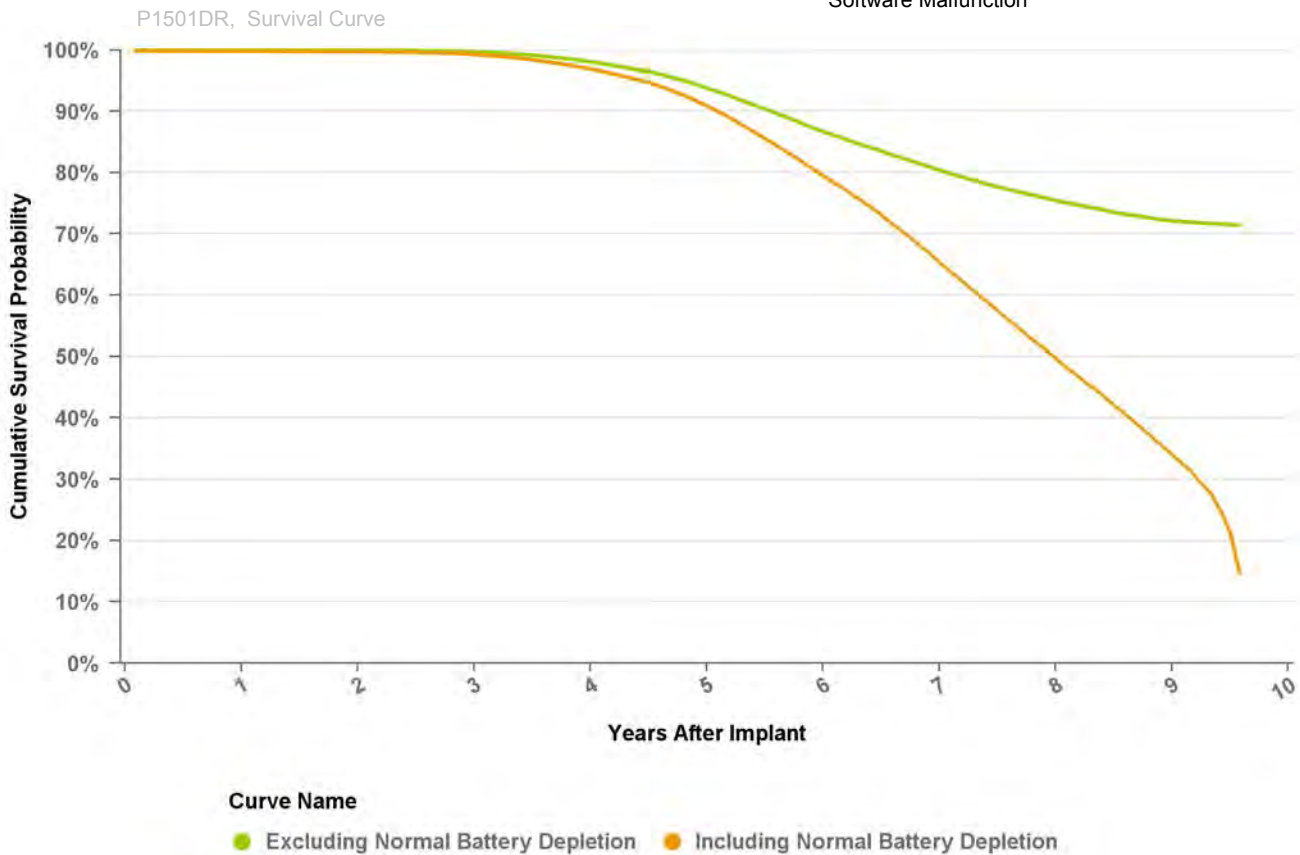
Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.6%	99.6%
Including NBD	100.0%	100.0%	100.0%	99.4%	98.0%	83.9%	46.5%
Effective Sample Size	462	419	374	326	287	204	112

Implantable Pulse Generator

P1501DR EnRhythm DR

US Market Release Date	5-May-05
CE Market Approval Date	13-Aug-04
Registered US Implants	110,096
Estimated Active US Implants	36,972
Normal Battery Depletions (US)	7,256
NBG Code	DDDRP

Total Malfunctions (US)	14,028
Therapy Not Compromised Malfunctions	13,974
Battery Malfunction	13,851
Electrical Component	56
Electrical Interconnect	2
Other Malfunction	2
Poss Early Battery Depltn	63
Software Malfunction	0
Therapy Compromised Malfunctions	54
Battery Malfunction	6
Electrical Component	37
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	99.9%	99.7%	98.1%	93.8%	86.7%	80.4%	75.5%	72.1%	71.5%
Including NBD	99.8%	99.7%	99.3%	96.9%	90.9%	79.5%	65.4%	49.7%	34.0%	14.7%
Effective Sample Size	94863	88633	82678	75395	62056	43926	28210	15767	6138	375

Implantable Pulse Generator

RED01

Relia D

US Market Release Date

CE Market Approval Date 7-May-08

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code DDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

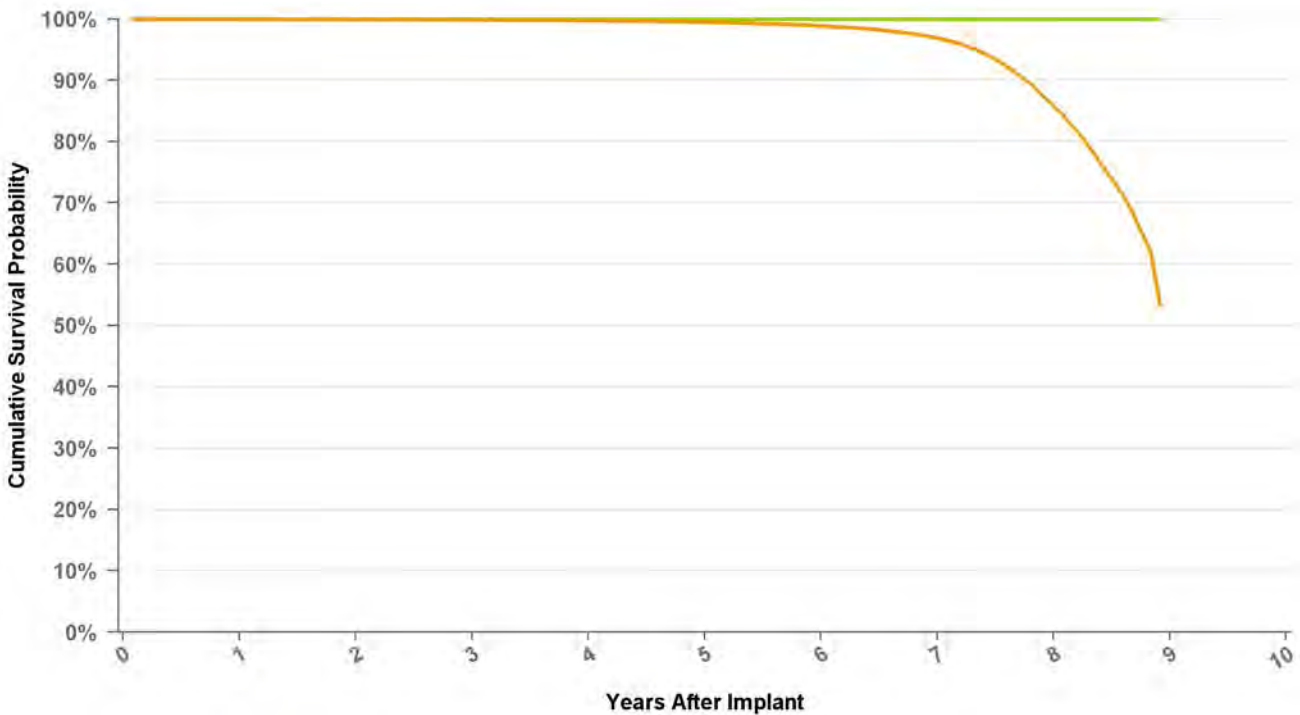
Electrical Interconnect 0

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	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

Implantable Pulse Generator

REDR01 Relia DR

US Market Release Date

CE Market Approval Date 7-May-08

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code DDDR

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

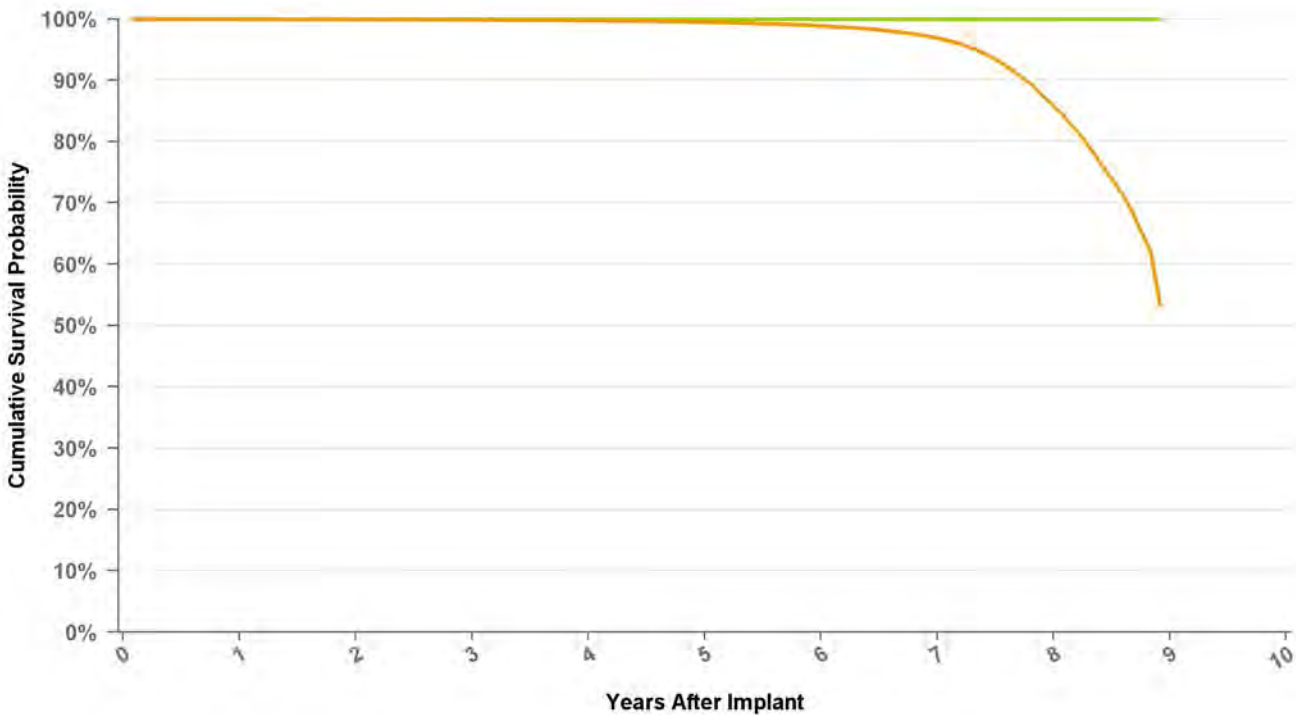
Electrical Interconnect 0

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	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.5%	98.9%	96.9%	85.8%	53.5%
Effective Sample Size	362811	311947	259347	207040	157516	108876	64861	25921	704

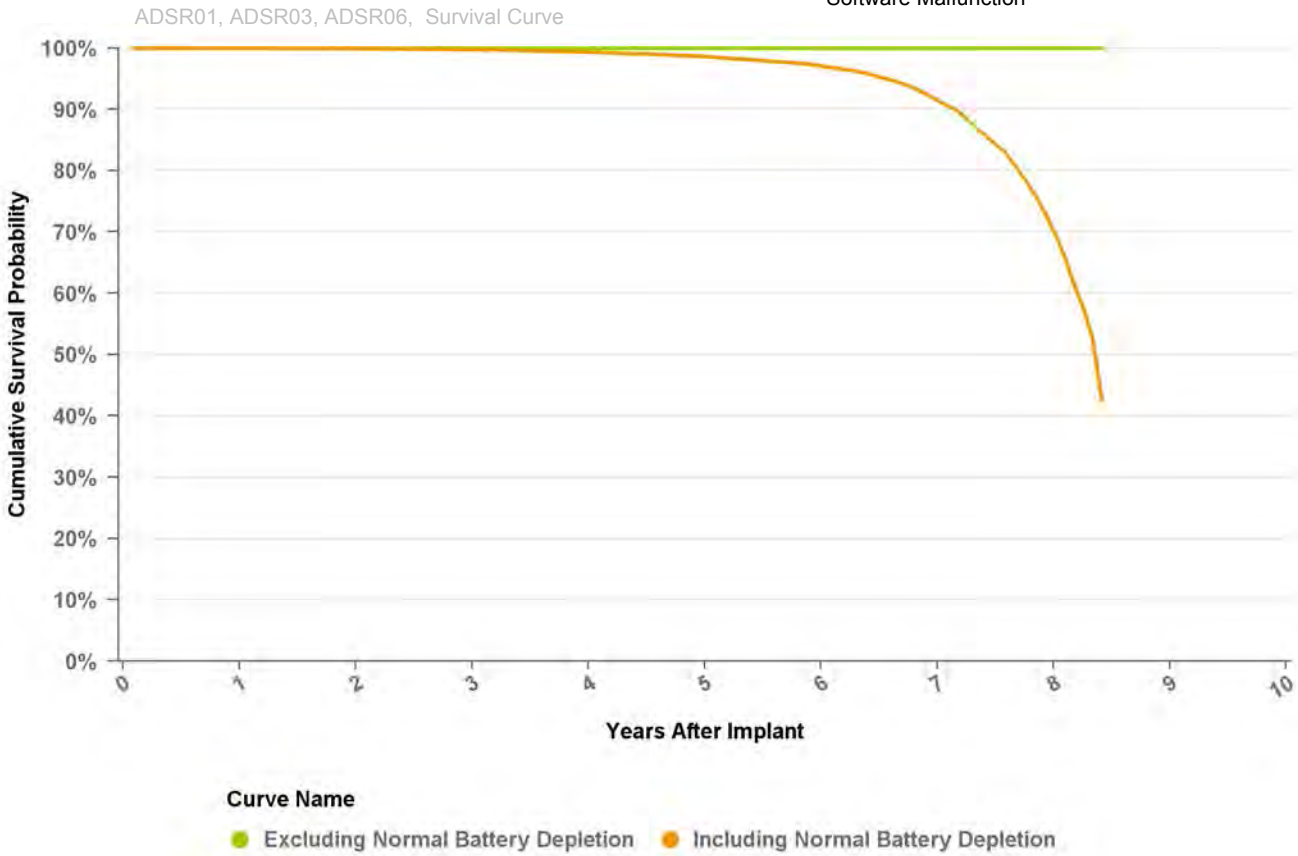
Implantable Pulse Generator

RES01

Relia S

US Market Release Date	
CE Market Approval Date	7-May-08
Registered US Implants	2
Estimated Active US Implants	1
Normal Battery Depletions (US)	0
NBG Code	AAI/VVI

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



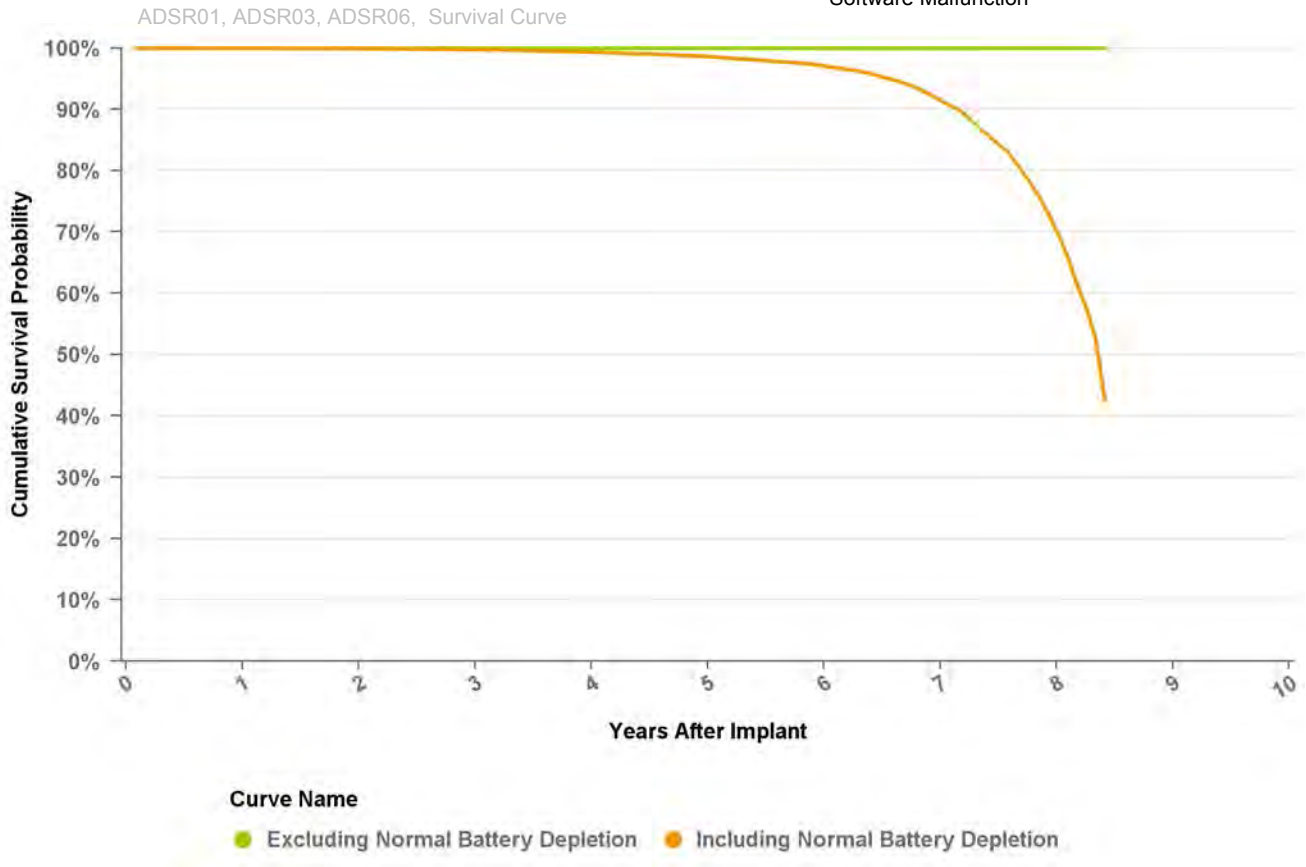
Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	91.5%	70.3%	42.6%
Effective Sample Size	64953	51039	38808	28439	20212	13398	7168	1898	283

Implantable Pulse Generator

RESR01 Relia SR

US Market Release Date	
CE Market Approval Date	7-May-08
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	AAIR/VVIR, AAI/VVI

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



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	91.5%	70.3%	42.6%
Effective Sample Size	64953	51039	38808	28439	20212	13398	7168	1898	283

Implantable Pulse Generator

REVDD01 Relia VDD

US Market Release Date

CE Market Approval Date 7-May-08

Registered US Implants 0

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code VDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions

Battery Malfunction 0

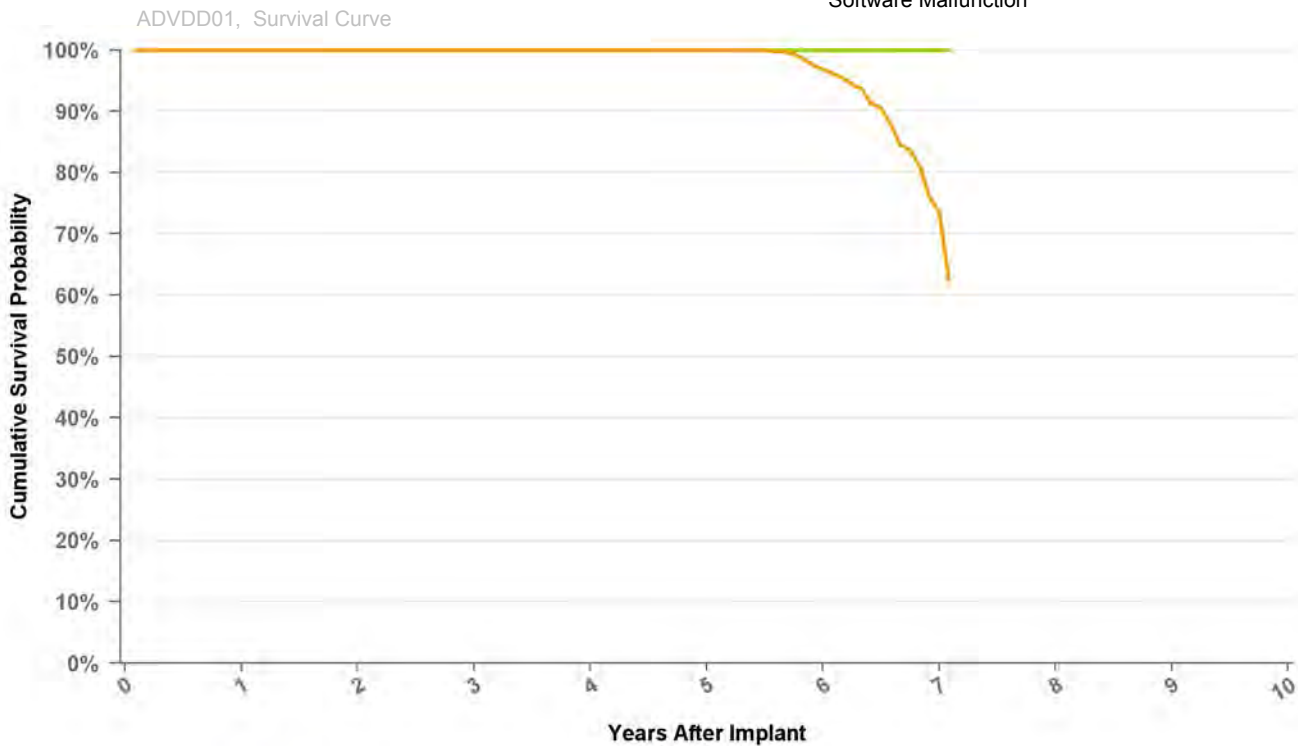
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 85 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%	100.0%	100.0%	96.9%	73.7%	62.6%
Effective Sample Size	872	776	631	525	413	298	134	120

Implantable Pulse Generator

RVDR01 Revo MRI SureScan

US Market Release Date 8-Feb-11

CE Market Approval Date

Registered US Implants 66,004

Estimated Active US Implants 58,588

Normal Battery Depletions (US) 13

NBG Code DDDRP

Total Malfunctions (US) 32

Therapy Not Compromised Malfunctions 29

Battery Malfunction 1

Electrical Component 20

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 5

Software Malfunction 3

Therapy Compromised Malfunctions 3

Battery Malfunction 0

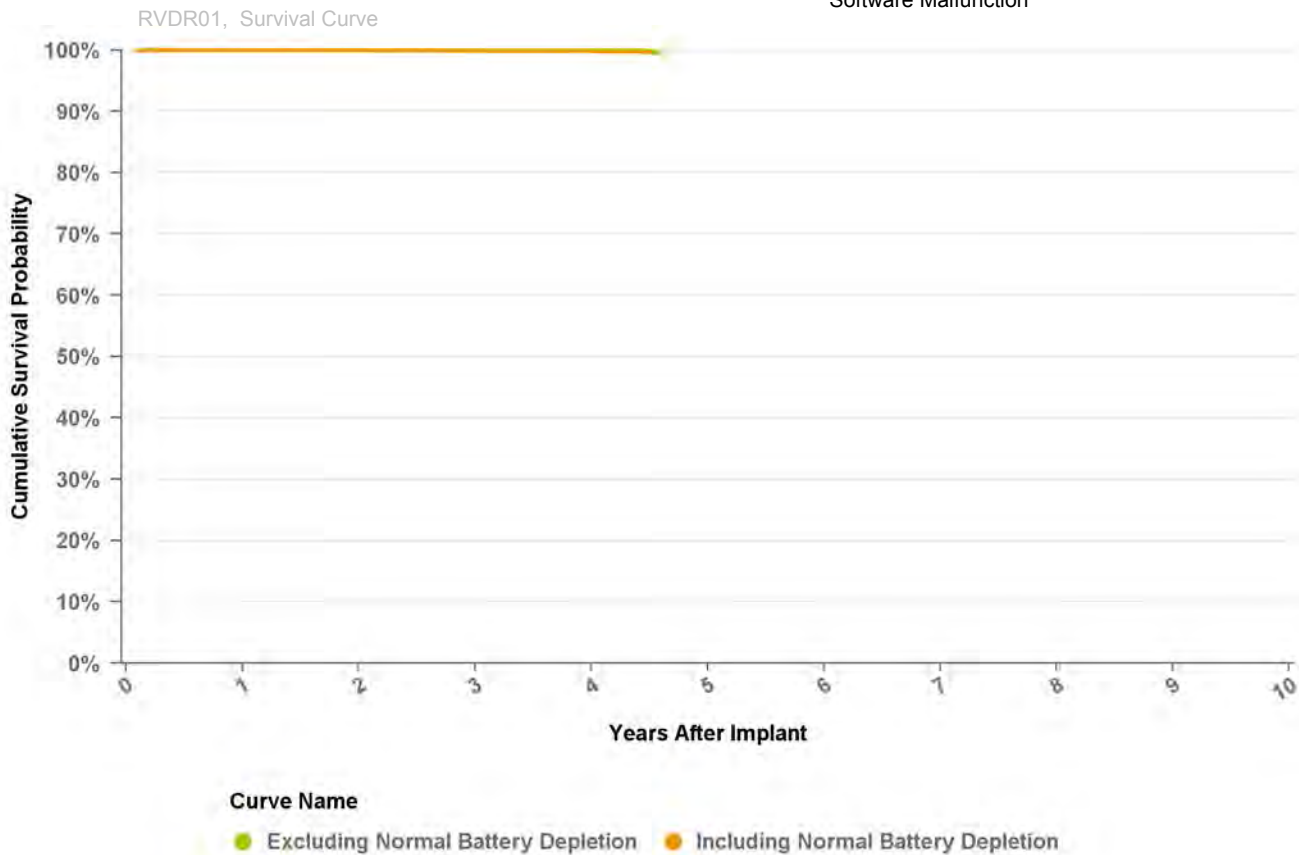
Electrical Component 3

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	3	4	at 55 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.3%
Effective Sample Size	58082	53479	37479	12913	725

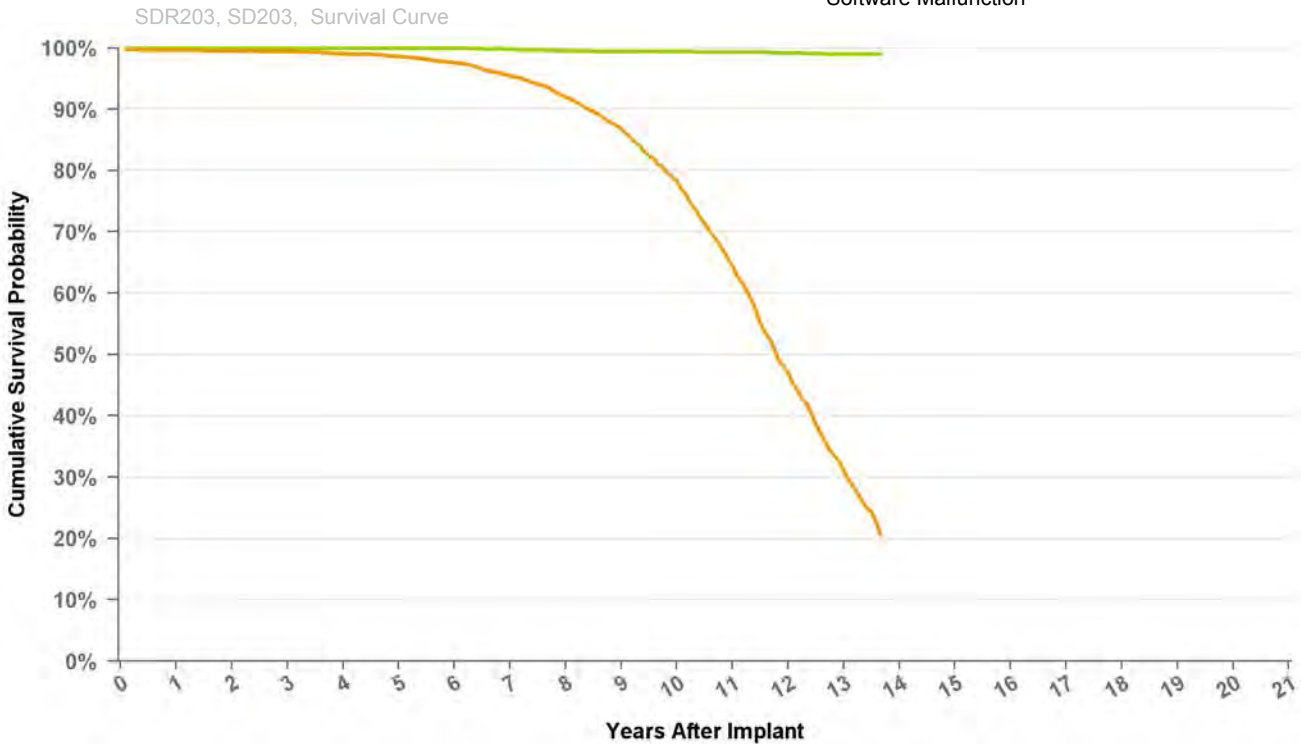
Implantable Pulse Generator

SD203

Sigma 200 D

US Market Release Date	31-Aug-99
CE Market Approval Date	17-Dec-98
Registered US Implants	228
Estimated Active US Implants	18
Normal Battery Depletions (US)	18
NBG Code	DDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



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 164 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.6%	99.5%	99.4%	99.4%	99.2%	99.0%	99.0%
Including NBD	99.7%	99.5%	99.4%	99.1%	98.6%	97.6%	95.4%	92.0%	86.8%	78.2%	64.5%	47.2%	31.1%	20.6%
Effective Sample Size	12594	11277	9975	8830	7720	6721	5724	4835	4035	3201	2218	1211	469	128

Implantable Pulse Generator

SD303

Sigma 300 D

US Market Release Date 26-Aug-99

CE Market Approval Date 17-Dec-98

Registered US Implants 130

Estimated Active US Implants 24

Normal Battery Depletions (US) 6

NBG Code DDD

Total Malfunctions (US) 1

Therapy Not Compromised Malfunctions 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

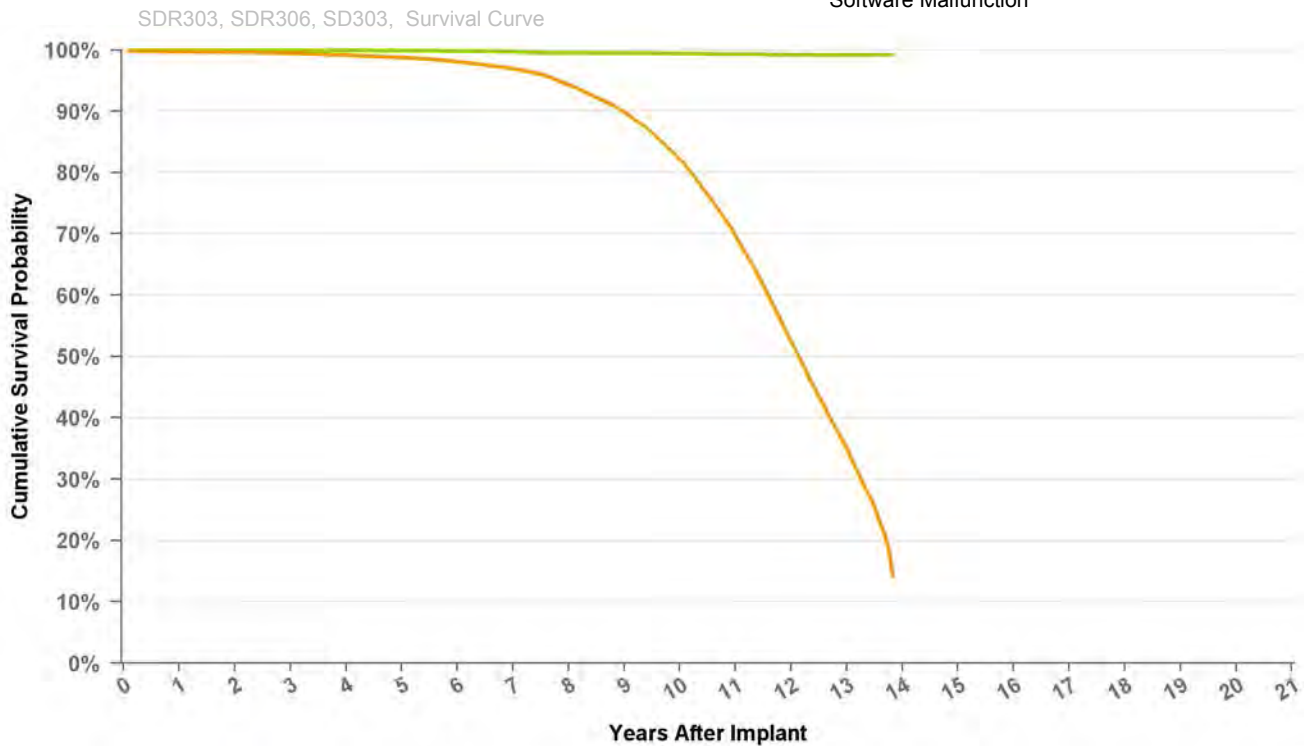
Electrical Component 0

Electrical Interconnect 1

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.5%	99.2%	98.8%	98.1%	97.0%	94.3%	89.8%	82.1%	69.8%	52.5%	35.3%	14.2%
Effective Sample Size	86322	77050	68445	60323	53003	46510	40457	34864	28429	21030	13822	7034	2329	143

Implantable Pulse Generator

SDR203

Sigma 200 DR

US Market Release Date 31-Aug-99

CE Market Approval Date 17-Dec-98

Registered US Implants 15,647

Estimated Active US Implants 1,601

Normal Battery Depletions (US) 1,319

NBG Code DDDR

Total Malfunctions (US) 42

Therapy Not Compromised Malfunctions 10

Battery Malfunction 0

Electrical Component 1

Electrical Interconnect 9

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 32

Battery Malfunction 0

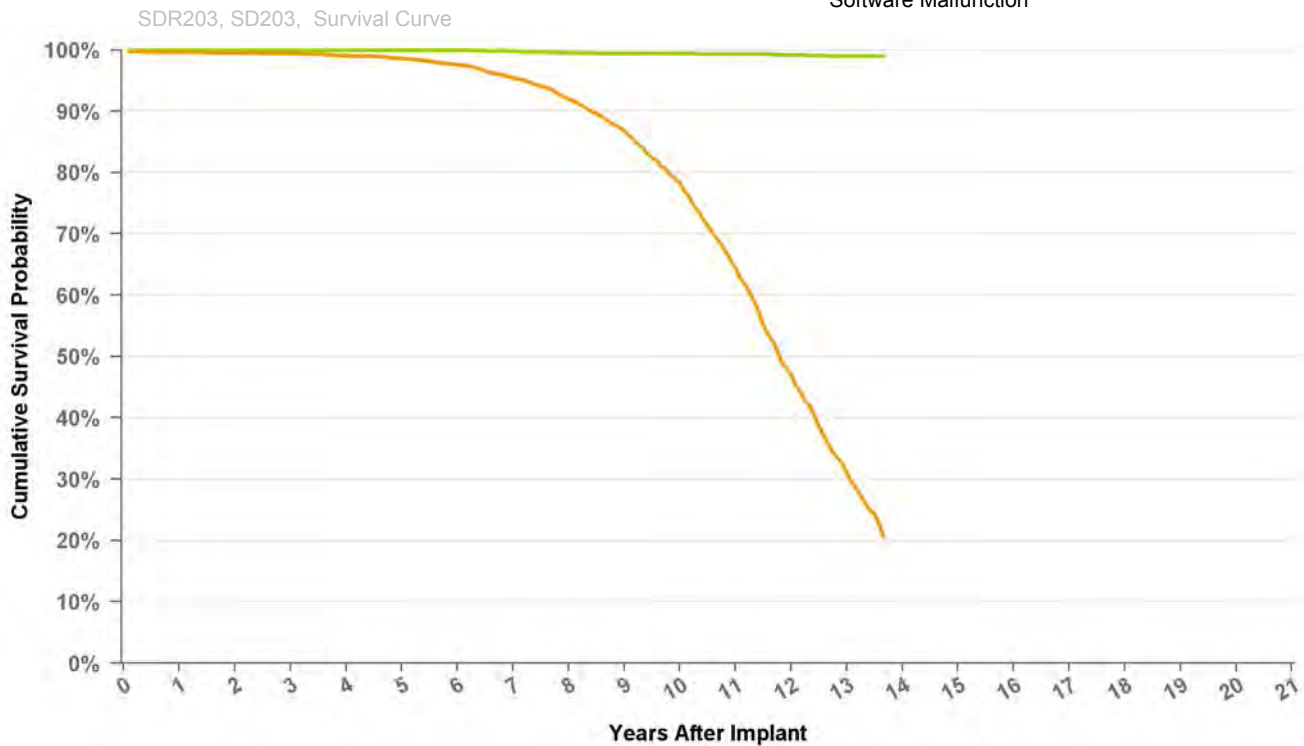
Electrical Component 2

Electrical Interconnect 29

Other Malfunction 1

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

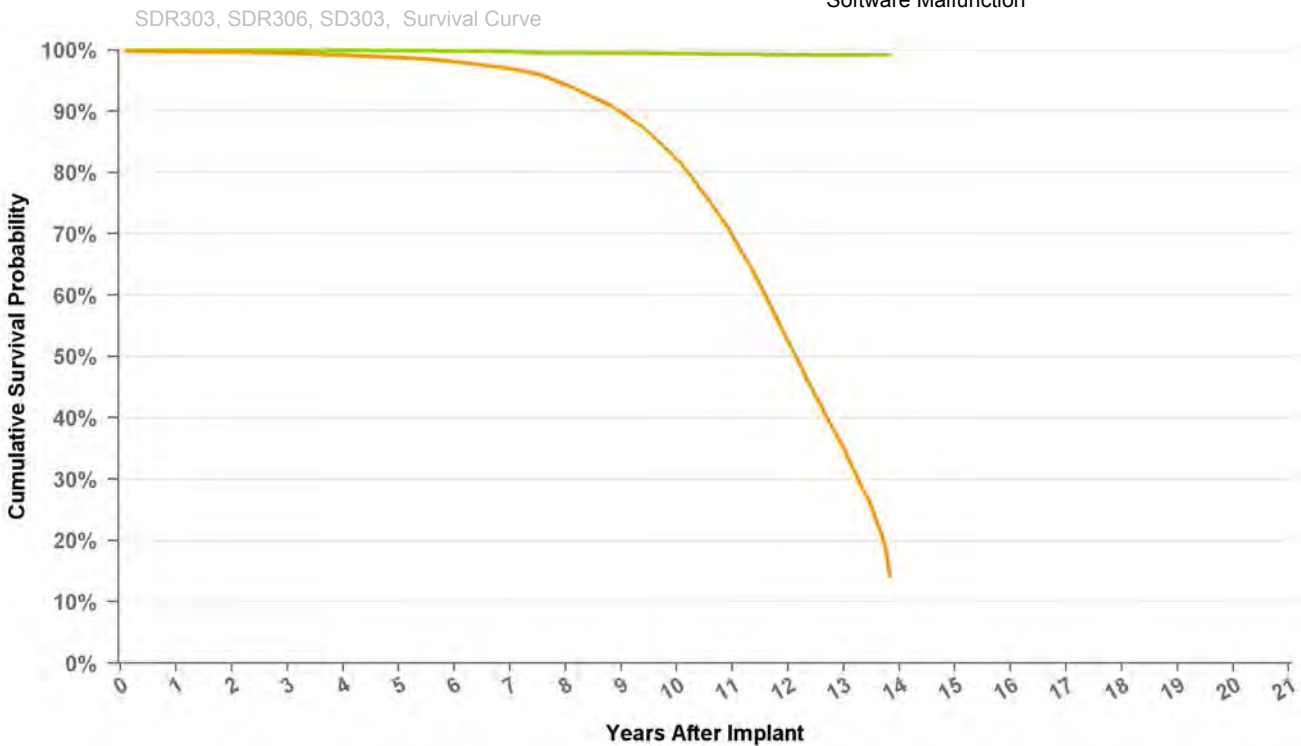
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 164 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.6%	99.5%	99.4%	99.4%	99.2%	99.0%	99.0%
Including NBD	99.7%	99.5%	99.4%	99.1%	98.6%	97.6%	95.4%	92.0%	86.8%	78.2%	64.5%	47.2%	31.1%	20.6%
Effective Sample Size	12594	11277	9975	8830	7720	6721	5724	4835	4035	3201	2218	1211	469	128

Implantable Pulse Generator

SDR303 Sigma 300 DR

US Market Release Date	26-Aug-99
CE Market Approval Date	17-Dec-98
Registered US Implants	105,525
Estimated Active US Implants	17,247
Normal Battery Depletions (US)	7,852
NBG Code	DDD/RO

Total Malfunctions (US)	279
Therapy Not Compromised Malfunctions	62
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	51
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	217
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	209
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

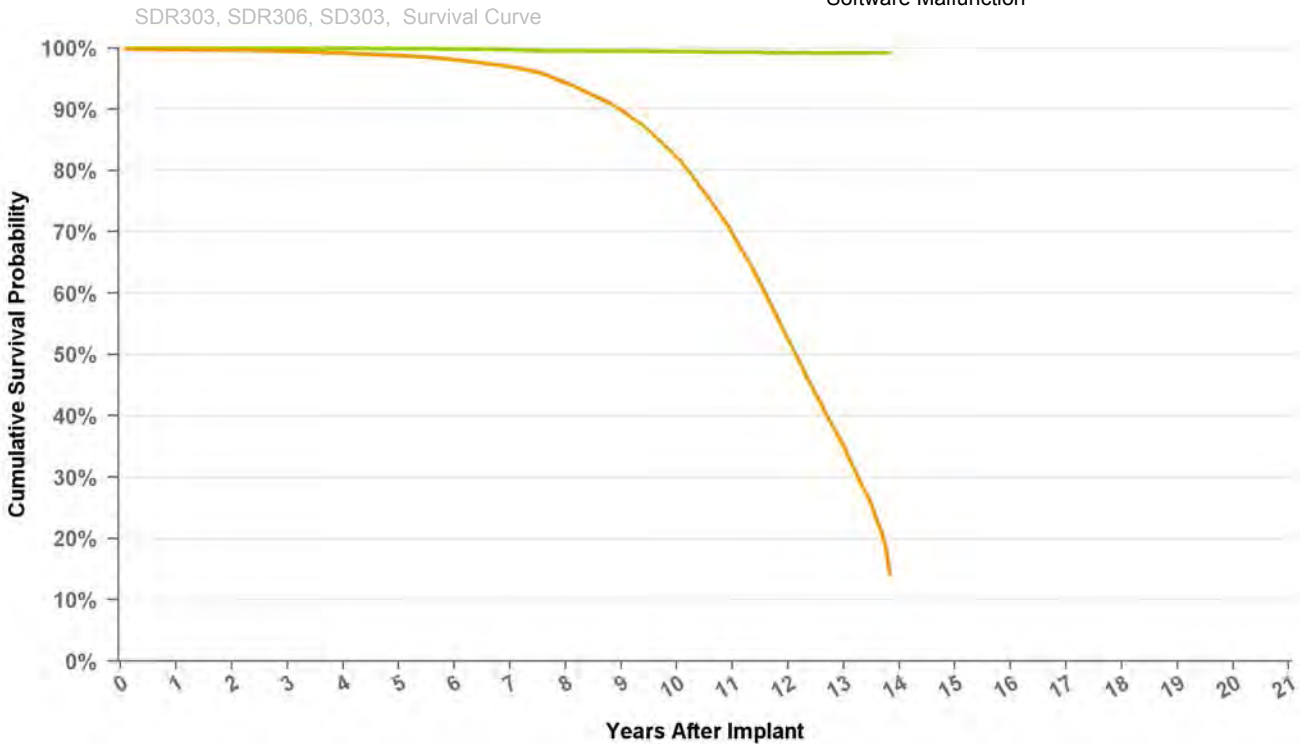
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 166 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.5%	99.2%	98.8%	98.1%	97.0%	94.3%	89.8%	82.1%	69.8%	52.5%	35.3%	14.2%
Effective Sample Size	86322	77050	68445	60323	53003	46510	40457	34864	28429	21030	13822	7034	2329	143

Implantable Pulse Generator

SDR306 Sigma 300 DR

US Market Release Date	30-Aug-99
CE Market Approval Date	17-Dec-98
Registered US Implants	1,209
Estimated Active US Implants	111
Normal Battery Depletions (US)	153
NBG Code	DDD/RO

Total Malfunctions (US)	5
Therapy Not Compromised Malfunctions	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



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%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.7%	99.7%	99.5%	99.2%	98.8%	98.1%	97.0%	94.3%	89.8%	82.1%	69.8%	52.5%	35.3%	14.2%
Effective Sample Size	86322	77050	68445	60323	53003	46510	40457	34864	28429	21030	13822	7034	2329	143

Implantable Pulse Generator

SED01

Sensia D

US Market Release Date 17-Jul-06

CE Market Approval Date 20-Sep-05

Registered US Implants 5

Estimated Active US Implants 4

Normal Battery Depletions (US) 0

NBG Code DDD

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

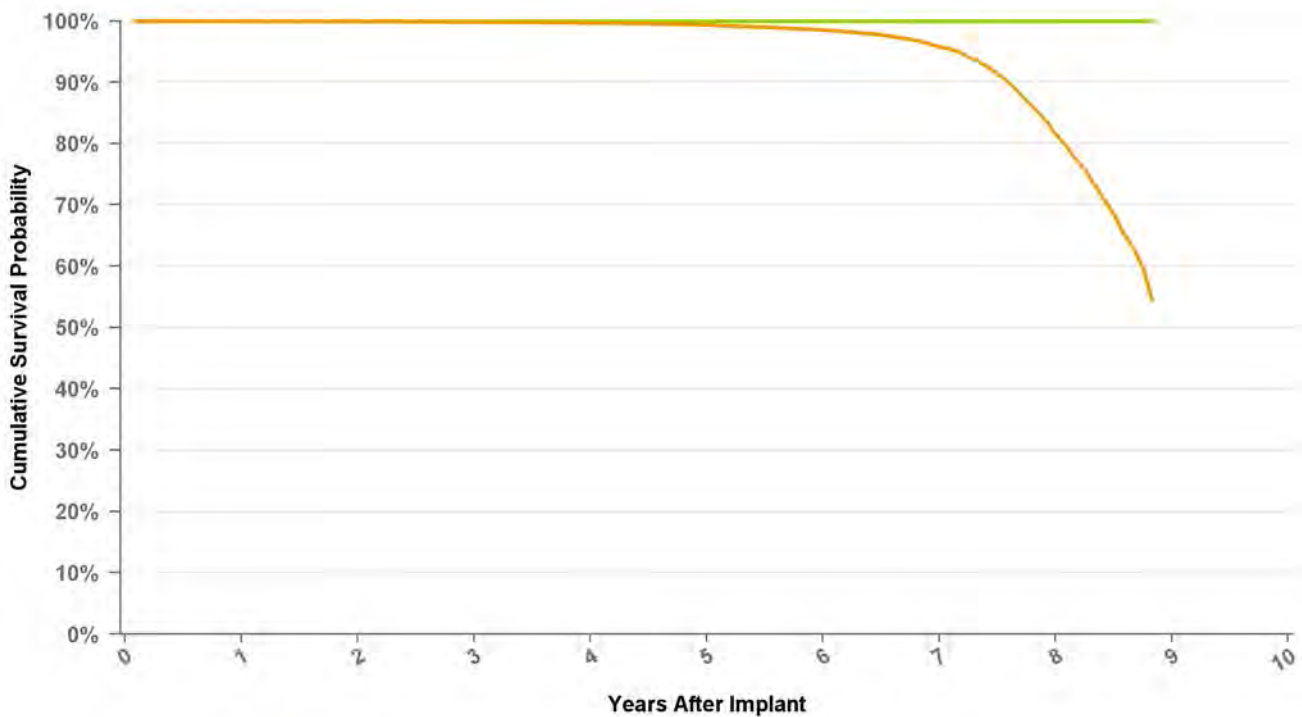
Electrical Interconnect 0

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

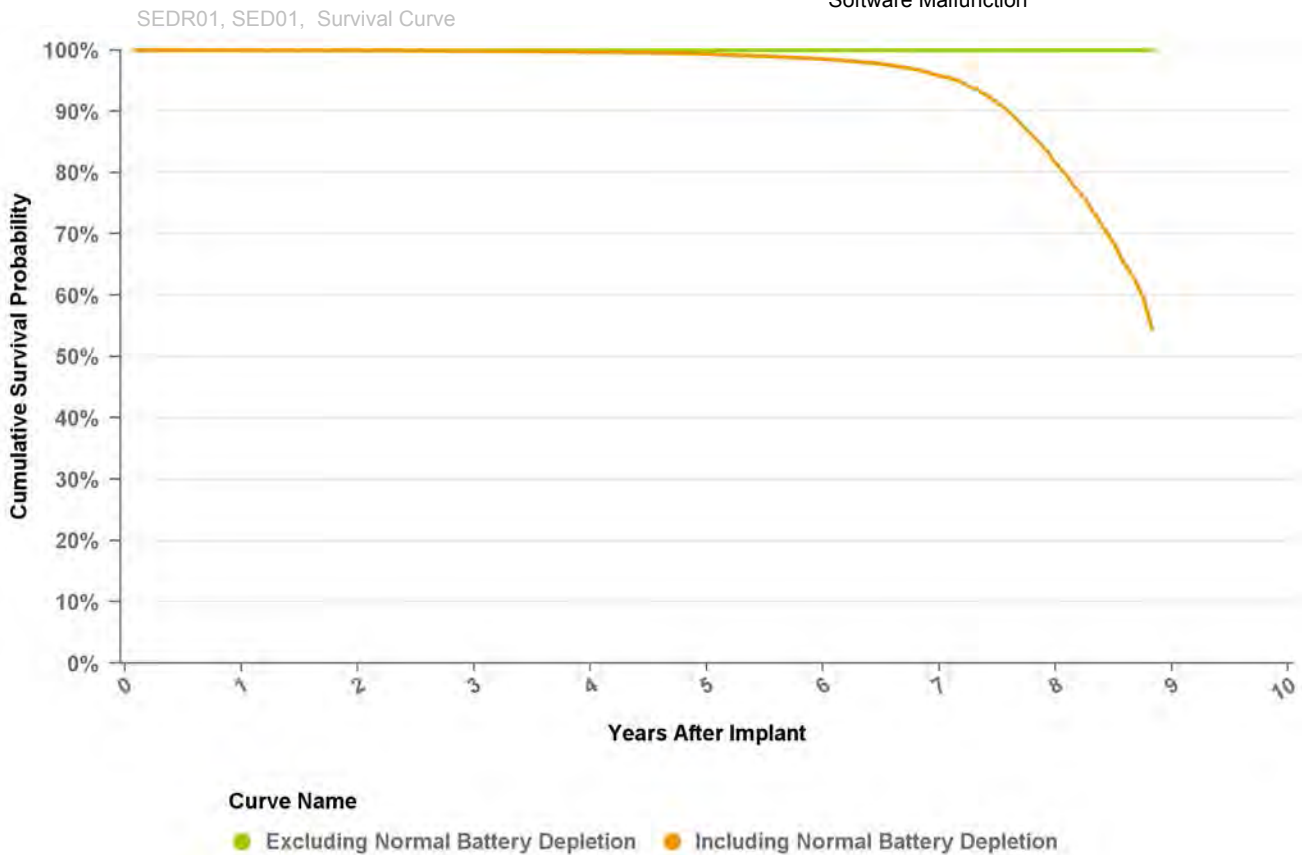
Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.4%	98.5%	95.8%	81.7%	54.4%
Effective Sample Size	117184	99391	81989	65040	48963	33765	19019	6482	313

Implantable Pulse Generator

SEDR01 Sensia DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	145,152
Estimated Active US Implants	92,448
Normal Battery Depletions (US)	2,387
NBG Code	DDDR

Total Malfunctions (US)	29
Therapy Not Compromised Malfunctions	16
Battery Malfunction	0
Electrical Component	13
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	13
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	2
Other Malfunction	5
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%	99.7%	99.4%	98.5%	95.8%	81.7%	54.4%
Effective Sample Size	117184	99391	81989	65040	48963	33765	19019	6482	313

Implantable Pulse Generator

SEDRL1 Sensia DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0
NBG Code	DDDR

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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

Excluding NBD

Including NBD

Effective Sample Size

Implantable Pulse Generator

SES01

Sensia S

US Market Release Date 17-Jul-06

CE Market Approval Date 20-Sep-05

Registered US Implants 6

Estimated Active US Implants 0

Normal Battery Depletions (US) 0

NBG Code SSI

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 0

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 0

Battery Malfunction 0

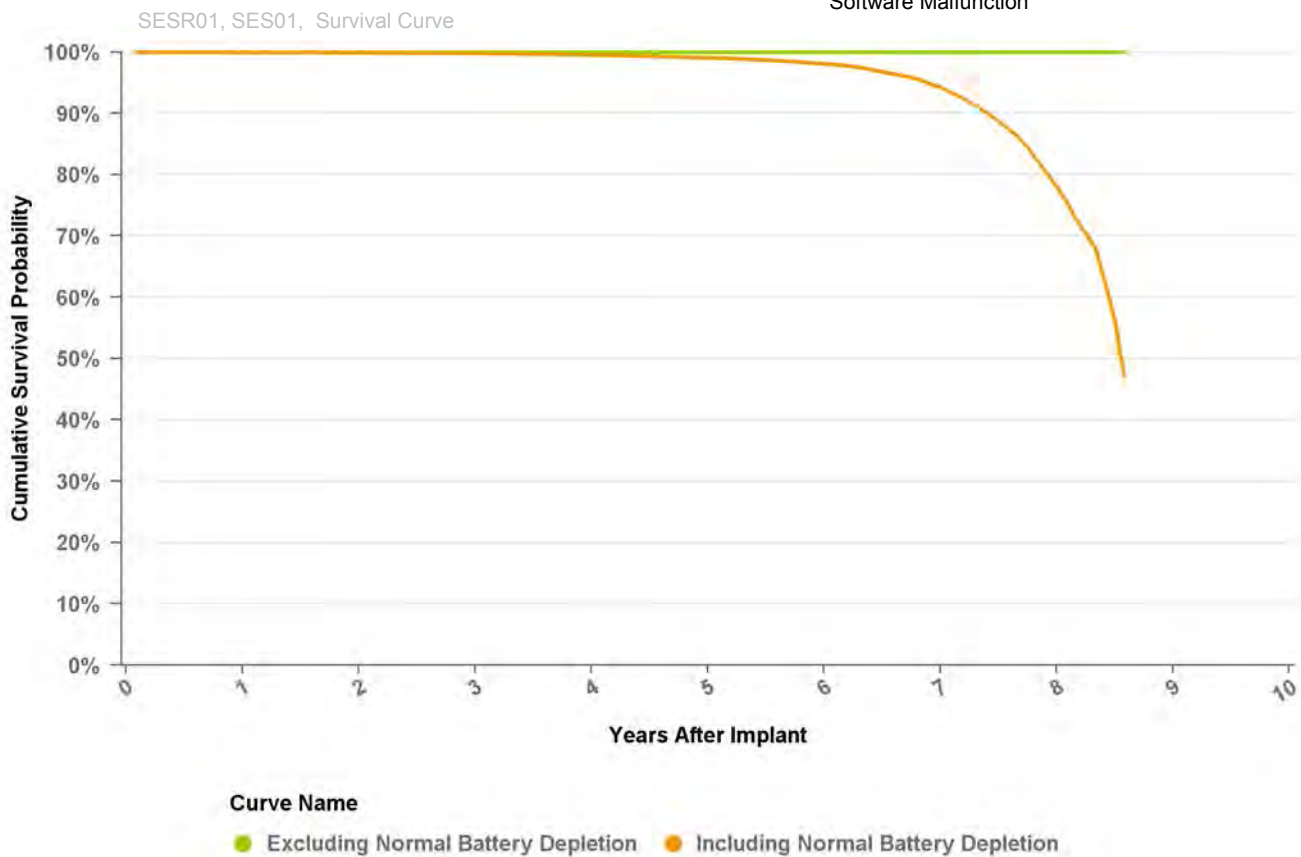
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



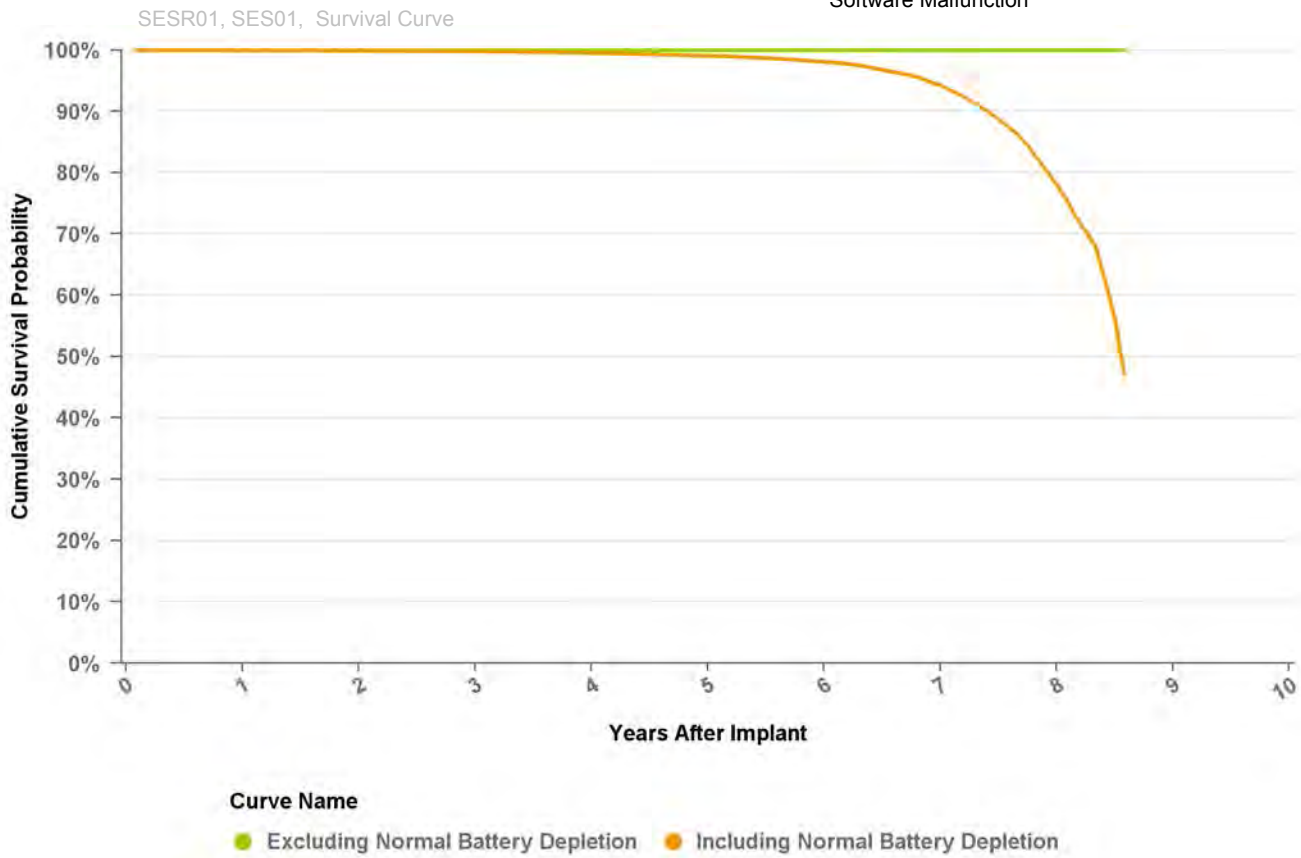
Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.5%	99.1%	98.1%	94.3%	78.1%	47.2%
Effective Sample Size	79399	63416	48826	35783	25074	16100	8268	2256	172

Implantable Pulse Generator

SESR01 Sensia SR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	108,474
Estimated Active US Implants	64,280
Normal Battery Depletions (US)	1,302
NBG Code	SSIR

Total Malfunctions (US)	11
Therapy Not Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	7
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



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.5%	99.1%	98.1%	94.3%	78.1%	47.2%
Effective Sample Size	79399	63416	48826	35783	25074	16100	8268	2256	172

Implantable Pulse Generator

SS103

Sigma 100 S

US Market Release Date 30-Aug-99

CE Market Approval Date 17-Dec-98

Registered US Implants 800

Estimated Active US Implants 74

Normal Battery Depletions (US) 28

NBG Code SSI

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

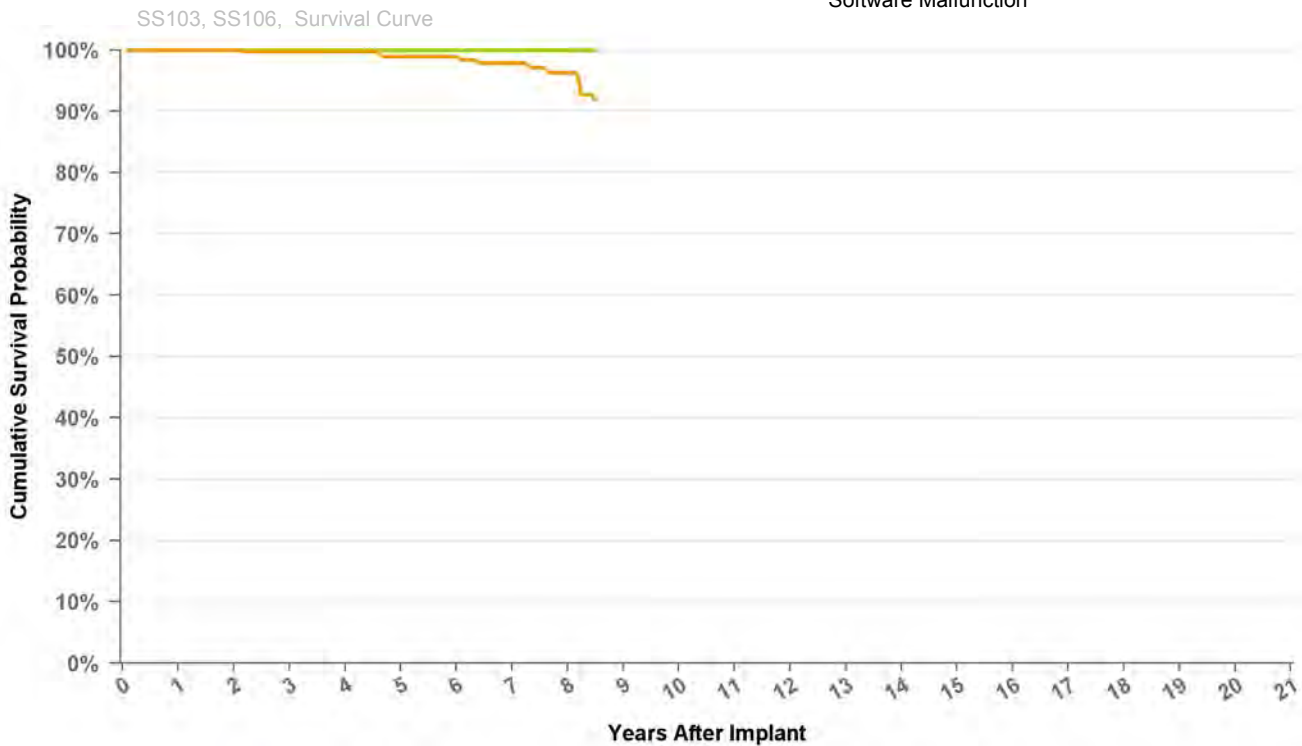
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	98.9%	98.9%	97.8%	96.3%	91.8%
Effective Sample Size	560	449	363	287	219	184	150	118	100

Implantable Pulse Generator

SS106

Sigma 100 S

US Market Release Date 30-Aug-99

CE Market Approval Date 17-Dec-98

Registered US Implants 68

Estimated Active US Implants 2

Normal Battery Depletions (US) 8

NBG Code SSI

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 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

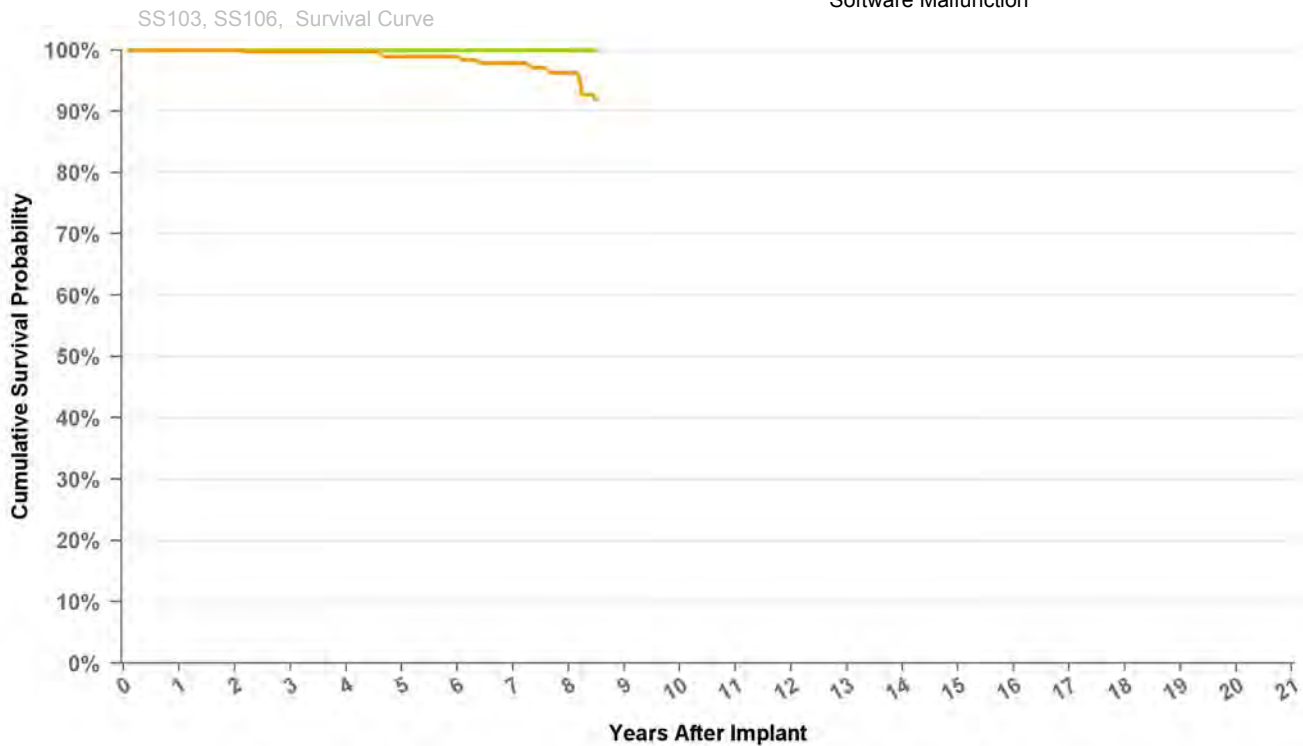
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	98.9%	98.9%	97.8%	96.3%	91.8%
Effective Sample Size	560	449	363	287	219	184	150	118	100

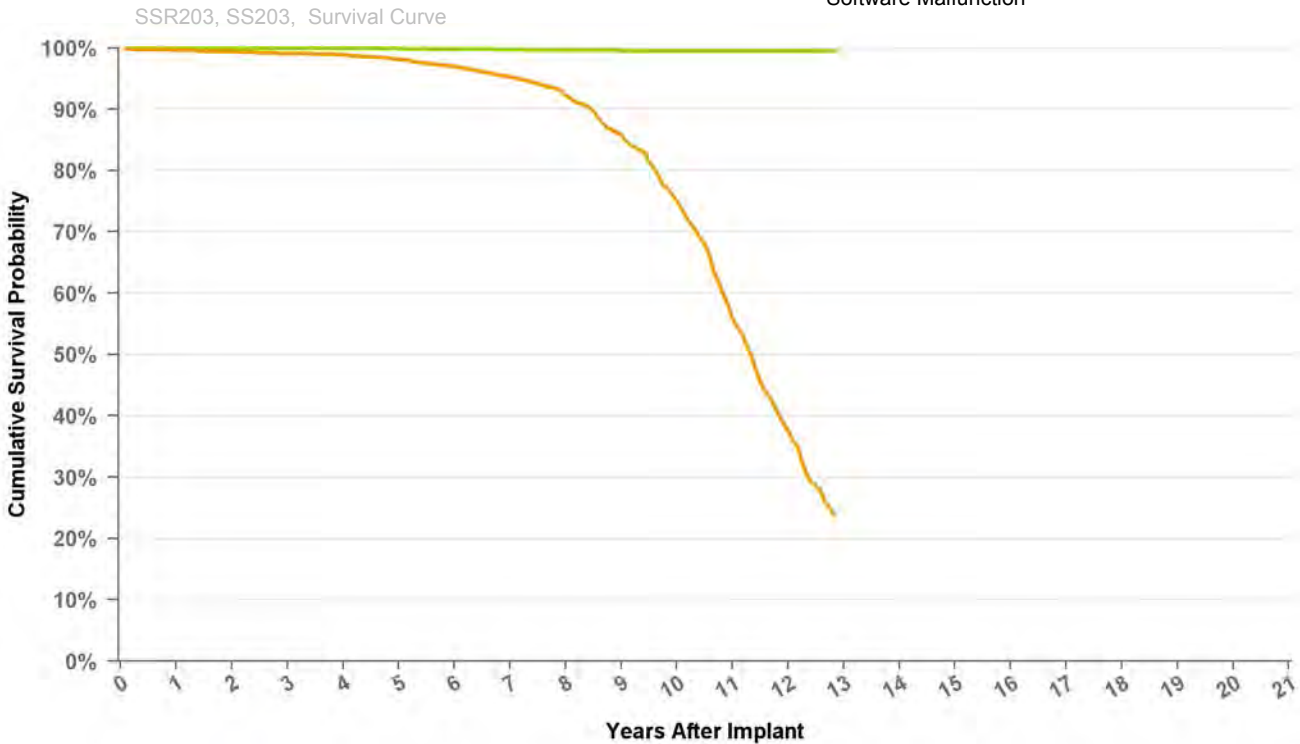
Implantable Pulse Generator

SS203

Sigma 200 S

US Market Release Date	30-Aug-99
CE Market Approval Date	
Registered US Implants	5
Estimated Active US Implants	0
Normal Battery Depletions (US)	1
NBG Code	SSI

Total Malfunctions (US)	0
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 154 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.2%	98.9%	98.1%	97.1%	95.3%	92.2%	85.8%	75.1%	56.0%	37.6%	23.9%
Effective Sample Size	8685	7229	6048	5043	4174	3460	2812	2324	1822	1339	802	338	106

Implantable Pulse Generator

SS303

Sigma 300 S

US Market Release Date 15-Sep-99

CE Market Approval Date 17-Dec-98

Registered US Implants 222

Estimated Active US Implants 38

Normal Battery Depletions (US) 0

NBG Code SSI

Total Malfunctions (US) 0

Therapy Not Compromised Malfunctions 0

Battery Malfunction 0

Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0

Therapy Compromised Malfunctions 0

Battery Malfunction 0

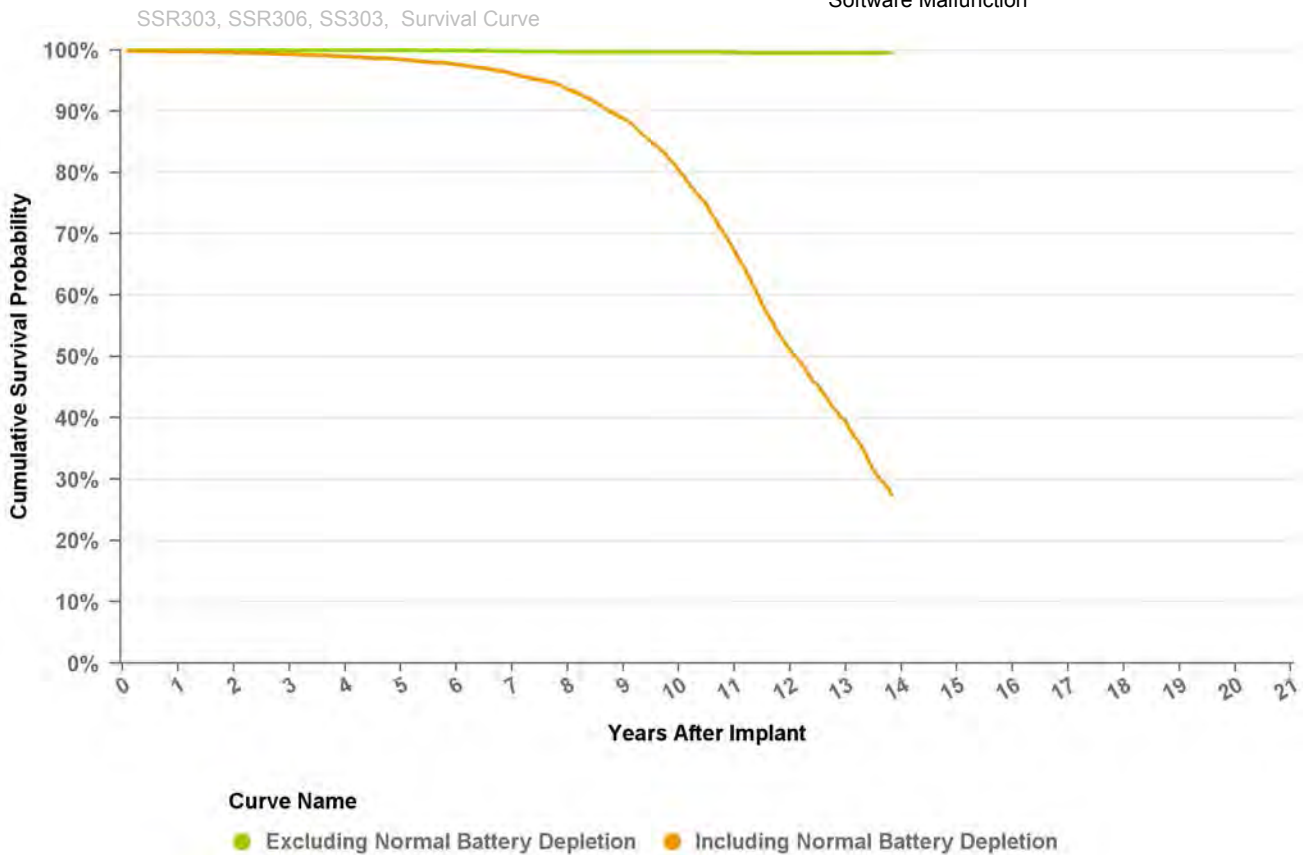
Electrical Component 0

Electrical Interconnect 0

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



Years	1	2	3	4	5	6	7	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%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.5%	97.6%	96.2%	93.6%	88.8%	80.5%	67.3%	51.2%	39.5%	27.4%
Effective Sample Size	39659	33127	27629	23028	19235	16035	13377	11052	8504	6135	3794	1929	733	124

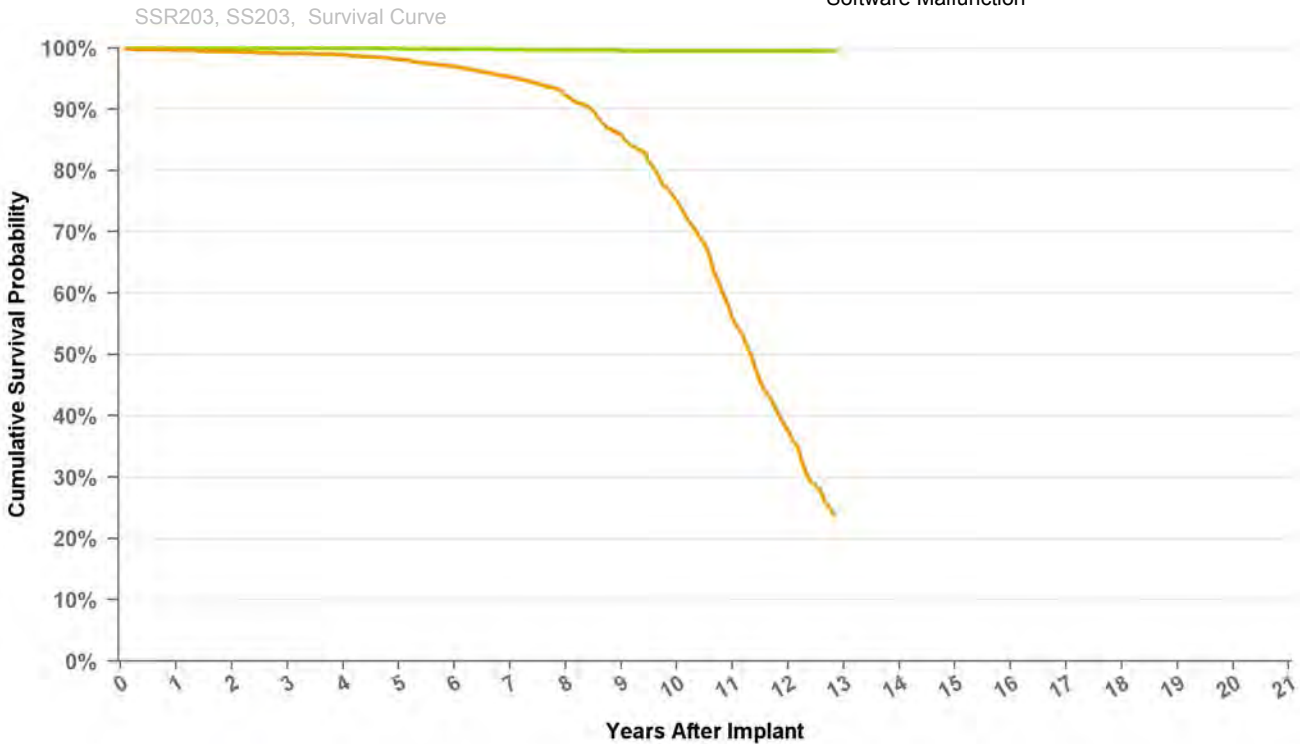
Implantable Pulse Generator

SSR203

Sigma 200 SR

US Market Release Date	2-Sep-99
CE Market Approval Date	
Registered US Implants	12,125
Estimated Active US Implants	960
Normal Battery Depletions (US)	620
NBG Code	SSIR

Total Malfunctions (US)	14
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 154 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.2%	98.9%	98.1%	97.1%	95.3%	92.2%	85.8%	75.1%	56.0%	37.6%	23.9%
Effective Sample Size	8685	7229	6048	5043	4174	3460	2812	2324	1822	1339	802	338	106

Implantable Pulse Generator

SSR303

Sigma 300 SR

US Market Release Date 30-Aug-99

CE Market Approval Date 17-Dec-98

Registered US Implants 51,688

Estimated Active US Implants 5,945

Normal Battery Depletions (US) 2,272

NBG Code SSIR

Total Malfunctions (US) 57

Therapy Not Compromised Malfunctions 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

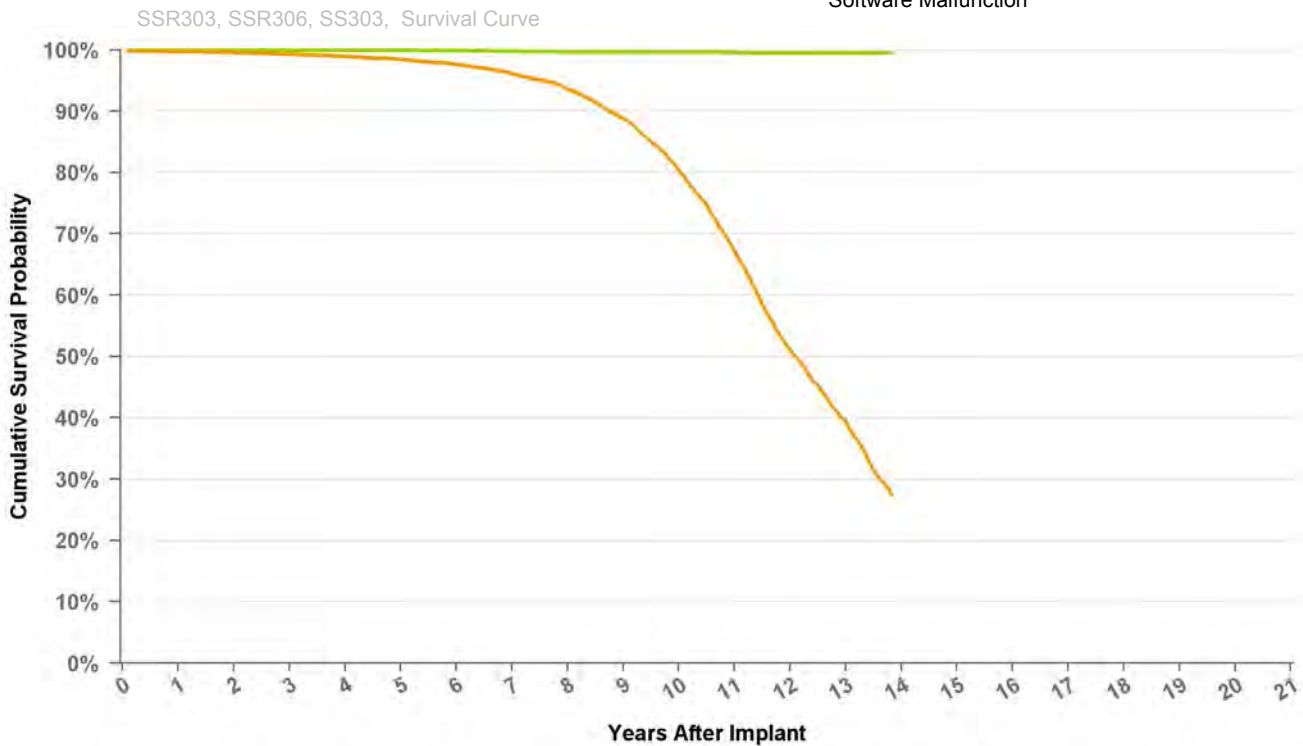
Electrical Component 3

Electrical Interconnect 40

Other Malfunction 0

Poss Early Battery Depltn 0

Software Malfunction 0



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%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.5%	97.6%	96.2%	93.6%	88.8%	80.5%	67.3%	51.2%	39.5%	27.4%
Effective Sample Size	39659	33127	27629	23028	19235	16035	13377	11052	8504	6135	3794	1929	733	124

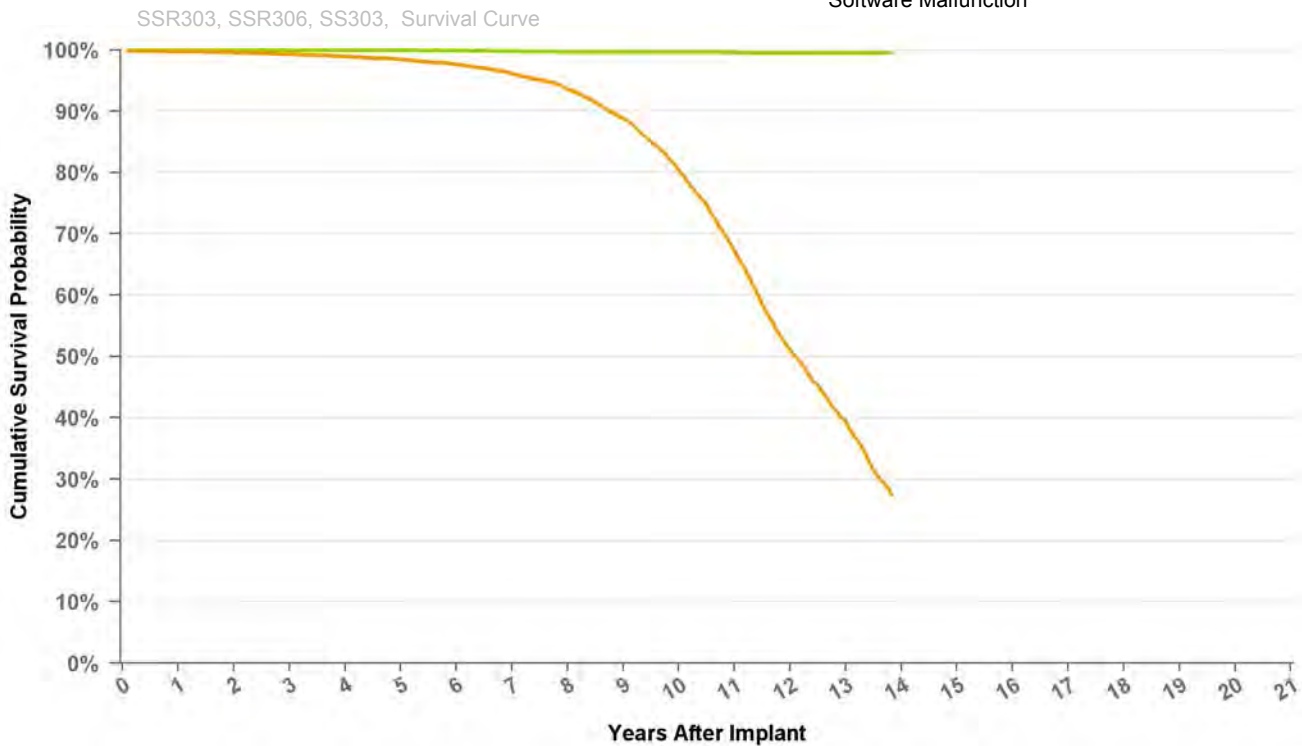
Implantable Pulse Generator

SSR306

Sigma 300 SR

US Market Release Date	7-Sep-99
CE Market Approval Date	17-Dec-98
Registered US Implants	2,218
Estimated Active US Implants	195
Normal Battery Depletions (US)	143
NBG Code	SSIR

Total Malfunctions (US)	2
Therapy Not Compromised Malfunctions	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



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

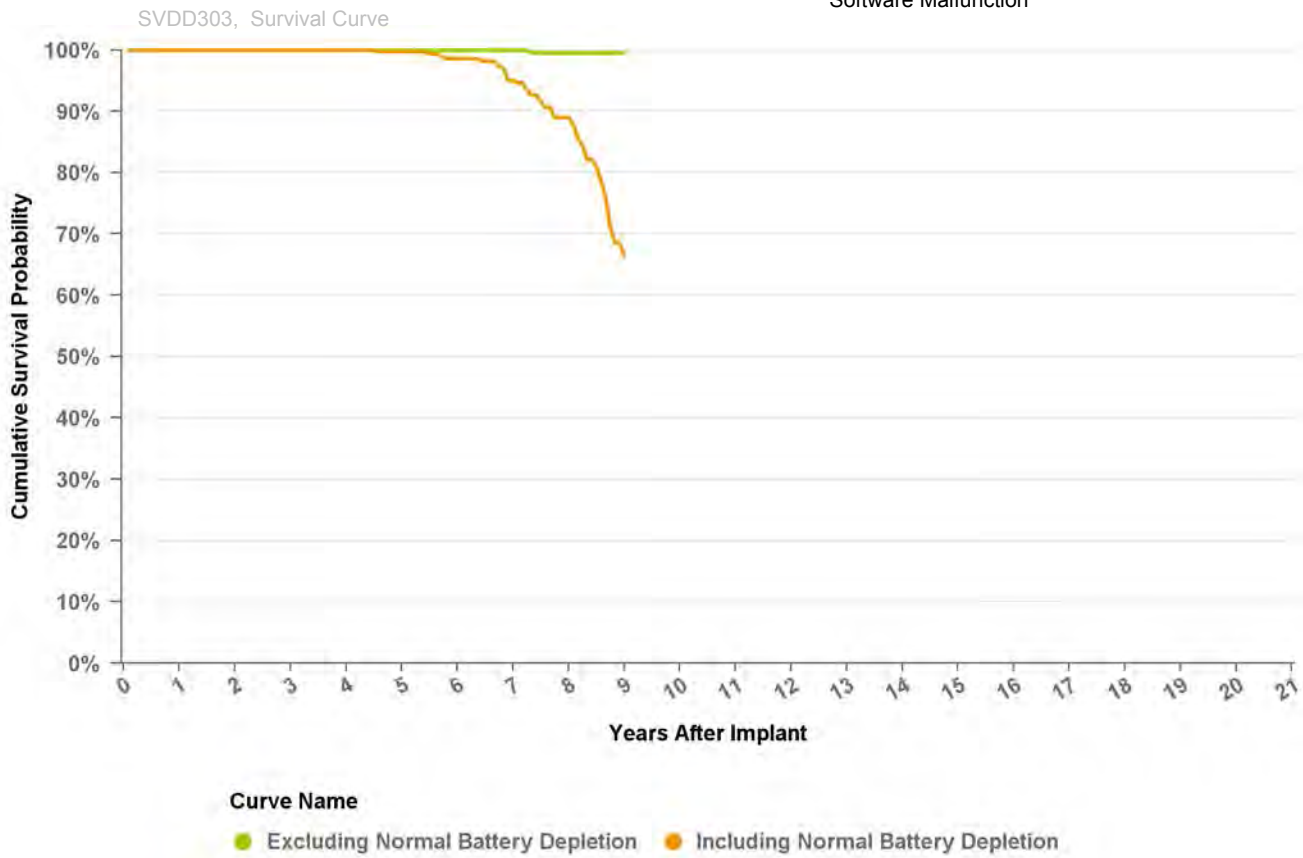
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 166 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.5%	97.6%	96.2%	93.6%	88.8%	80.5%	67.3%	51.2%	39.5%	27.4%
Effective Sample Size	39659	33127	27629	23028	19235	16035	13377	11052	8504	6135	3794	1929	733	124

Implantable Pulse Generator

SVDD303 **Sigma 300 VDD**

US Market Release Date	15-Sep-99
CE Market Approval Date	17-Dec-98
Registered US Implants	651
Estimated Active US Implants	45
Normal Battery Depletions (US)	80
NBG Code	VDD

Total Malfunctions (US)	1
Therapy Not Compromised Malfunctions	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



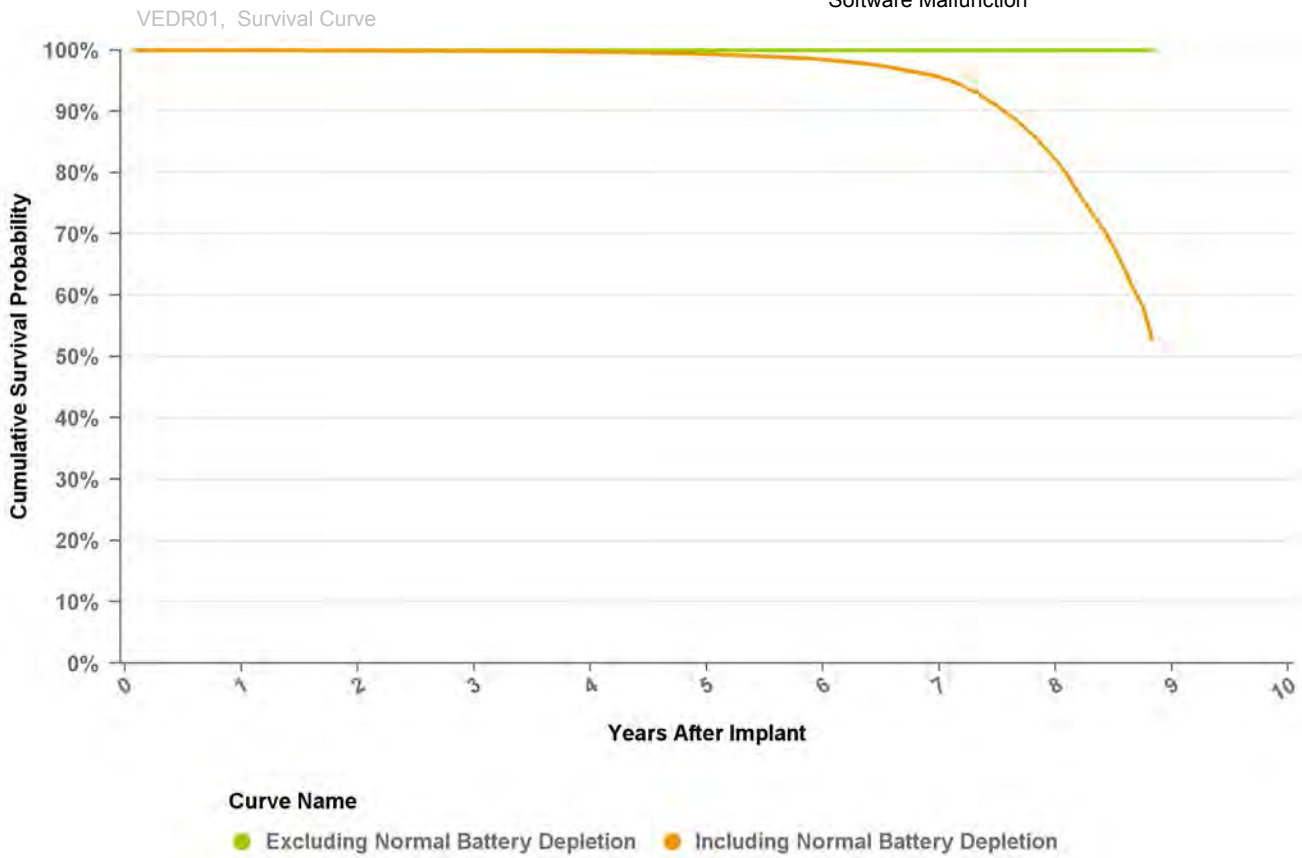
Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.5%	99.5%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.7%	98.6%	95.1%	89.0%	66.5%
Effective Sample Size	512	446	405	359	312	261	207	162	101

Implantable Pulse Generator

VEDR01 Versa DR

US Market Release Date	17-Jul-06
CE Market Approval Date	20-Sep-05
Registered US Implants	110,049
Estimated Active US Implants	70,589
Normal Battery Depletions (US)	2,554
NBG Code	DDDR

Total Malfunctions (US)	17
Therapy Not Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.3%	98.4%	95.6%	82.2%	52.8%
Effective Sample Size	91341	79483	67179	54466	42343	30638	18728	7624	440

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm and Heart Failure (CRHF) has tracked lead survival for over 32 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 required 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 committee¹. 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 include, but are 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-truncation². 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

Method for Estimating Lead Performance continued

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

Definition of Analysis Dataset

The survival estimates are derived from all device components successfully enrolled as of the data received cut-off date (e.g. date of data entry at a study site). The number of enrollments is listed for each lead model.

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

Criteria for Model Inclusion

Performance information for a model or model family will be published when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Medtronic, at its discretion, may stop providing updated performance information on lead models that received original US market-release approval 20 or more years ago.

Returned Product Analysis Results

Although the returned product analysis data is not used to generate the survival estimates, the data provides valuable insight into the causes of lead malfunction.

For reporting returned product analysis results, Medtronic 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

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

In the first weeks following lead implantation, physiologic responses and lead performance can vary until long-term lead stability is attained. Acute (defined as the first month after implant) lead performance may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. After a period of time, the implant and the lead performance stabilizes. It is for this reason that the Product Surveillance Registry results, which are intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

Information about the clinical experience in the first month of service is included in our reporting. The source for this information is Medtronic's complaint handling system database. The information is summarized in tables titled "US Reports of Acute Lead Observations."

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

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

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

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

Estimated Number of Implanted and Active Leads in the United States

In addition to providing the number of leads enrolled in the PSR, we also provide the number of leads registered as implanted and the number remaining active in the United States based on the status recorded in the Medtronic Device and Registrant Tracking system.

Footnotes:

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

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

LEFT HEART PACING LEAD

2187

Distribution Data

US Market Release	28-Aug-01
CE Approval Date	
Registered US Implants	11,983
Estimated Active US	1,974

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 Polarity	Unipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	139
Cumulative Months of Follow-Up	6,622
Number of Leads Active in Study	8

Product Surveillance Registry Qualifying Complications

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

2

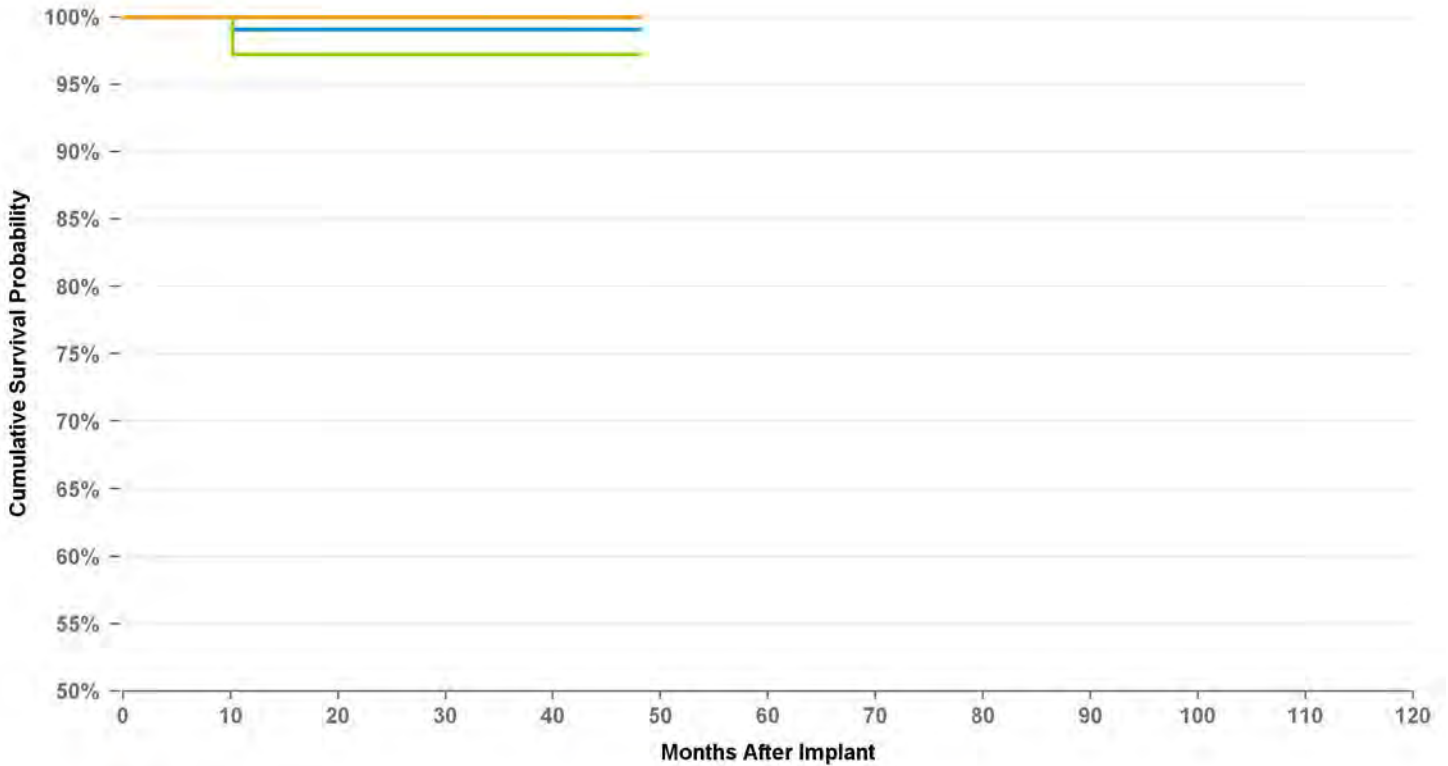
US Acute Lead Observations

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
%	99.1%	99.1%	99.1%	99.1%
#	104	86	65	53

LEFT HEART PACING LEAD

4193

Distribution Data

US Market Release	3-May-02
CE Approval Date	22-Dec-00
Registered US Implants	100,813
Estimated Active US	26,094

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 Polarity	Unipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	753
Cumulative Months of Follow-Up	33,198
Number of Leads Active in Study	101

Product Surveillance Registry Qualifying Complications

42

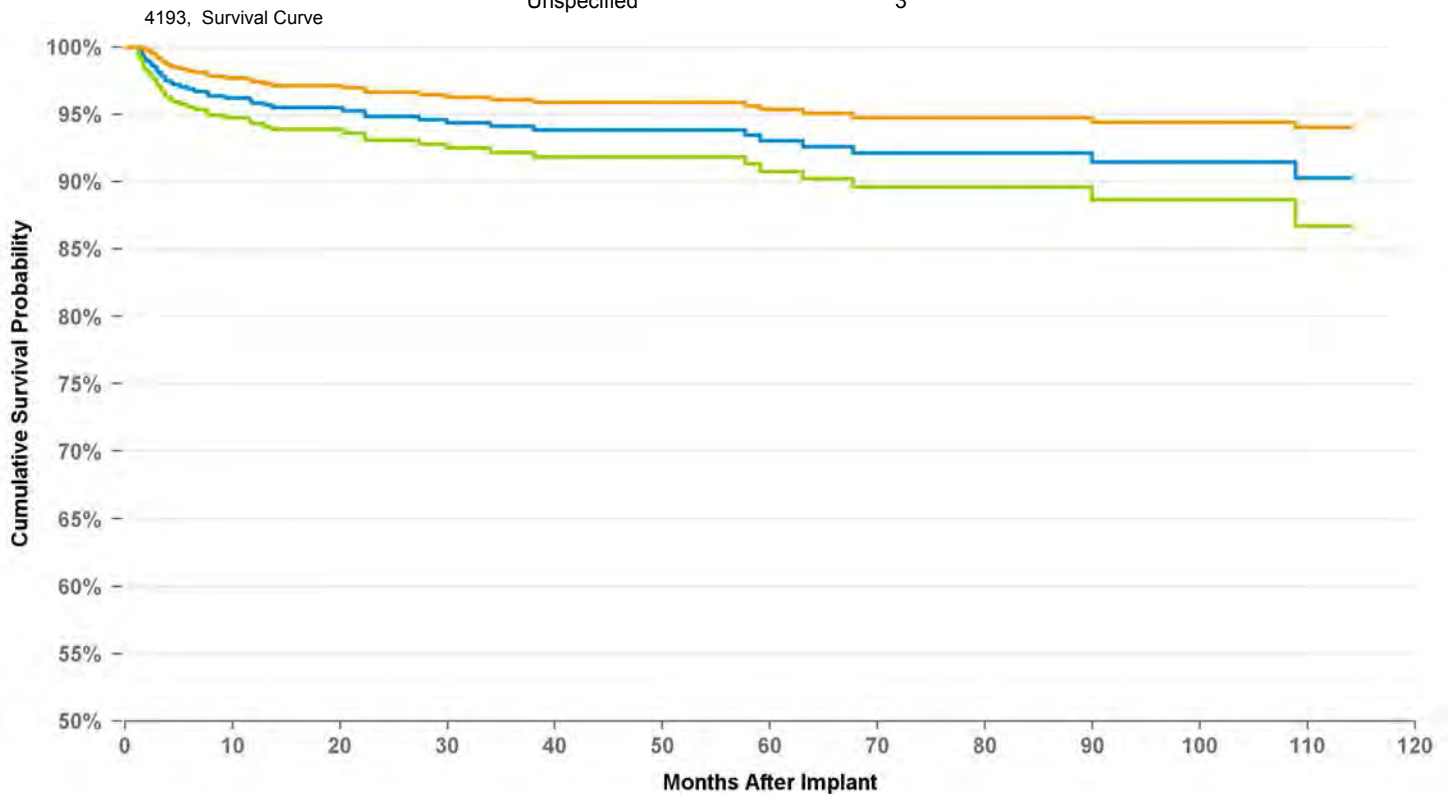
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	14
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	14
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	18
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	66
Crimp Weld Bond	0
Insulation Breach	13
Other	48



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 114 mo
%	95.9%	94.9%	94.1%	93.8%	93.0%	92.2%	92.2%	91.5%	91.5%	90.3%
#	579	429	350	276	219	174	141	113	71	54

LEFT HEART PACING LEAD

4194

Distribution Data

US Market Release	24-Aug-04
CE Approval Date	14-Jul-03
Registered US Implants	113,969
Estimated Active US	56,821

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,530
Cumulative Months of Follow-Up	57,298
Number of Leads Active in Study	670

Product Surveillance Registry Qualifying Complications

47

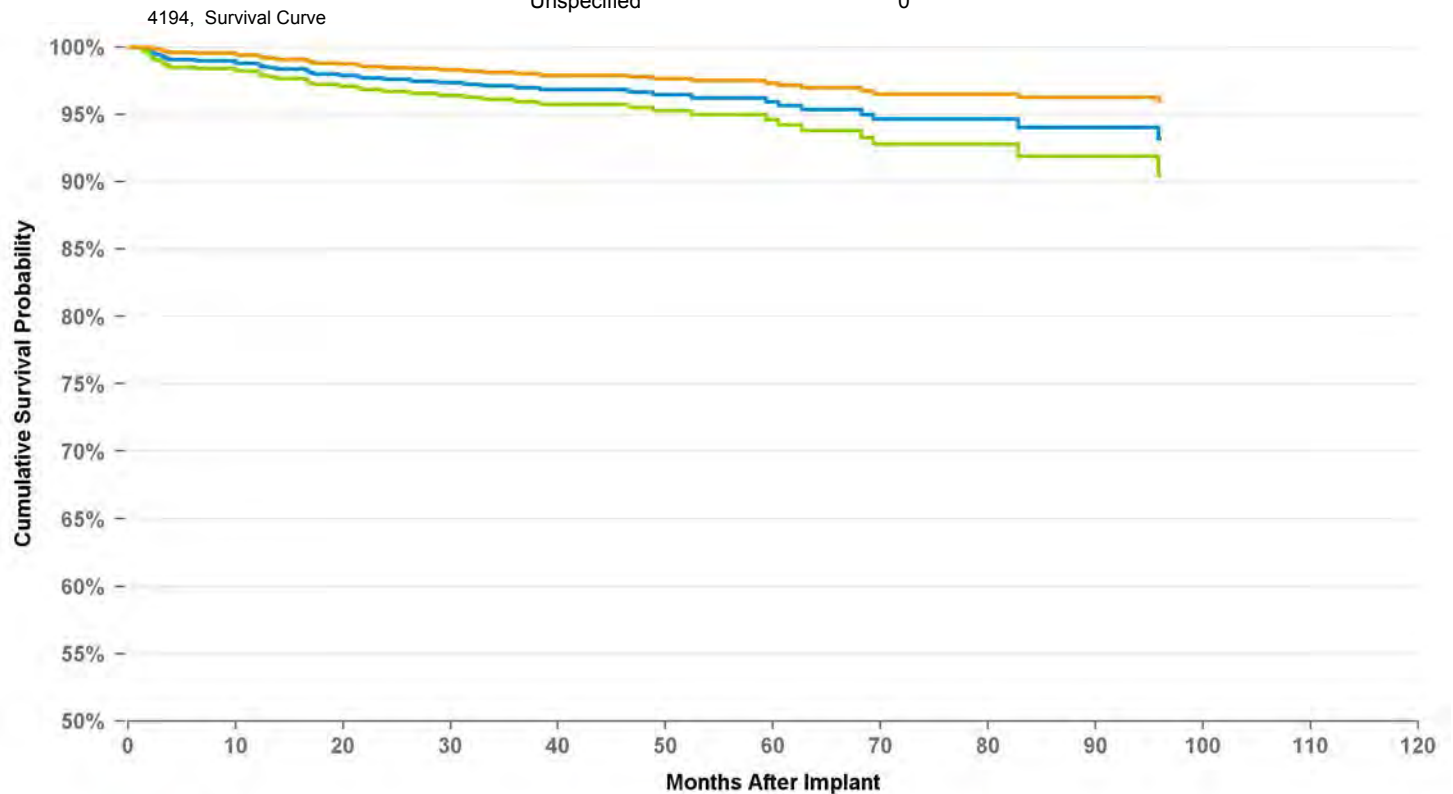
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	12
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	1
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	22
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	47
Failure To Capture	42
Failure To Sense	0
Impedance Abnormal	7
Insulation Breach	0
Lead Dislodgement	146
Oversensing	2
Unspecified	5

USA Returned Product Analysis

Conductor Fracture	19
Crimp Weld Bond	0
Insulation Breach	81
Other	9



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 96 mo
%	98.8%	97.6%	97.0%	96.6%	96.0%	94.6%	94.0%	93.2%
#	1,219	920	709	498	311	180	120	72

LEFT HEART PACING LEAD

4195

Distribution Data

US Market Release	15-Aug-08
CE Approval Date	13-May-05
Registered US Implants	17,080
Estimated Active US	11,779

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 Polarity	Unipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,458
Cumulative Months of Follow-Up	48,282
Number of Leads Active in Study	753

Product Surveillance Registry Qualifying Complications

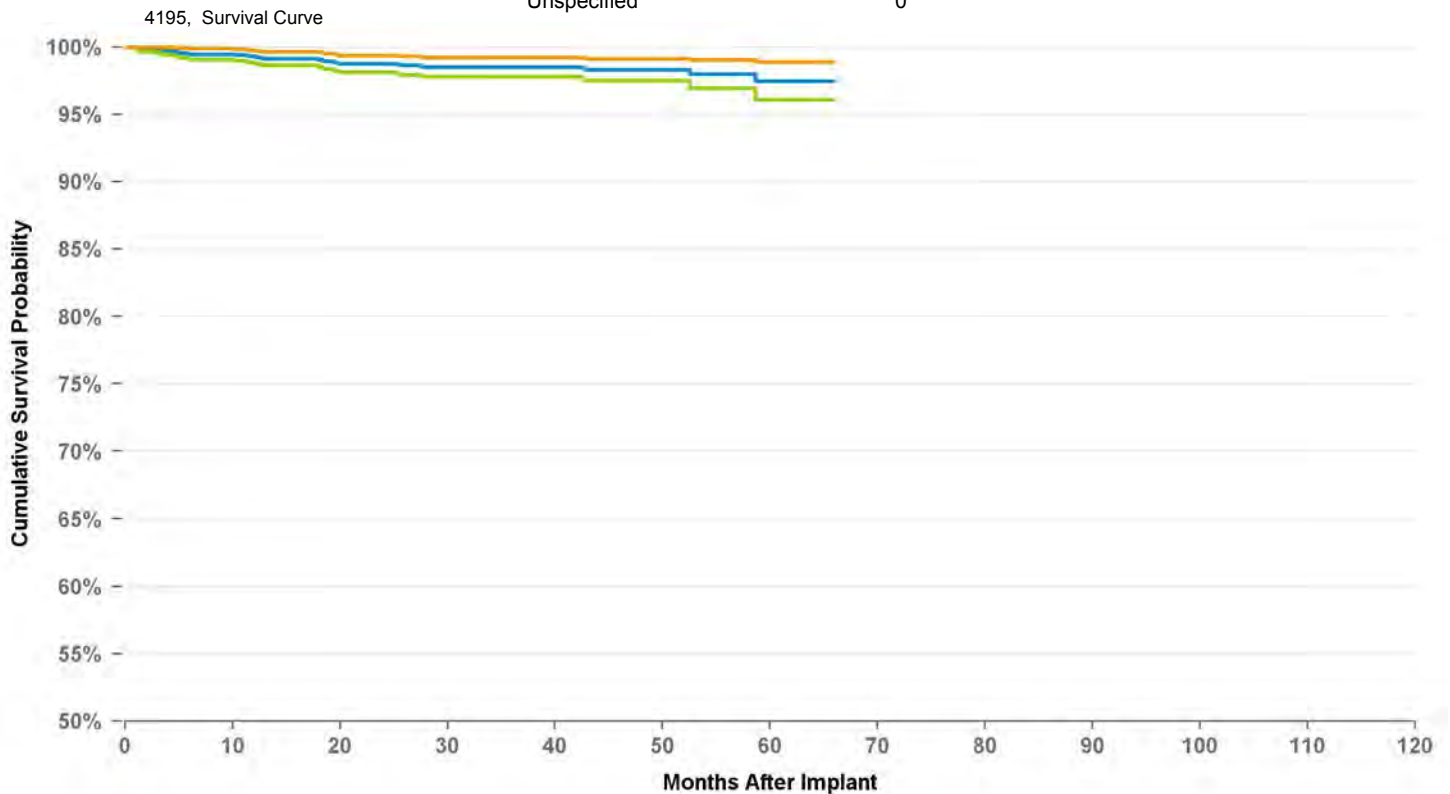
	20
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	8
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	4
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	29
Failure To Capture	19
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	29
Oversensing	0
Unspecified	1

USA Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	1
Other	4



Graph Name

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

Years	1	2	3	4	5	at 66 mo
%	99.3%	98.7%	98.5%	98.3%	97.5%	97.5%
#	1,178	904	633	354	168	88

LEFT HEART PACING LEAD

4196

Distribution Data

US Market Release	15-May-09
CE Approval Date	24-Jul-07
Registered US Implants	63,800
Estimated Active US	46,755

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,122
Cumulative Months of Follow-Up	64,953
Number of Leads Active in Study	874

Product Surveillance Registry Qualifying Complications

60

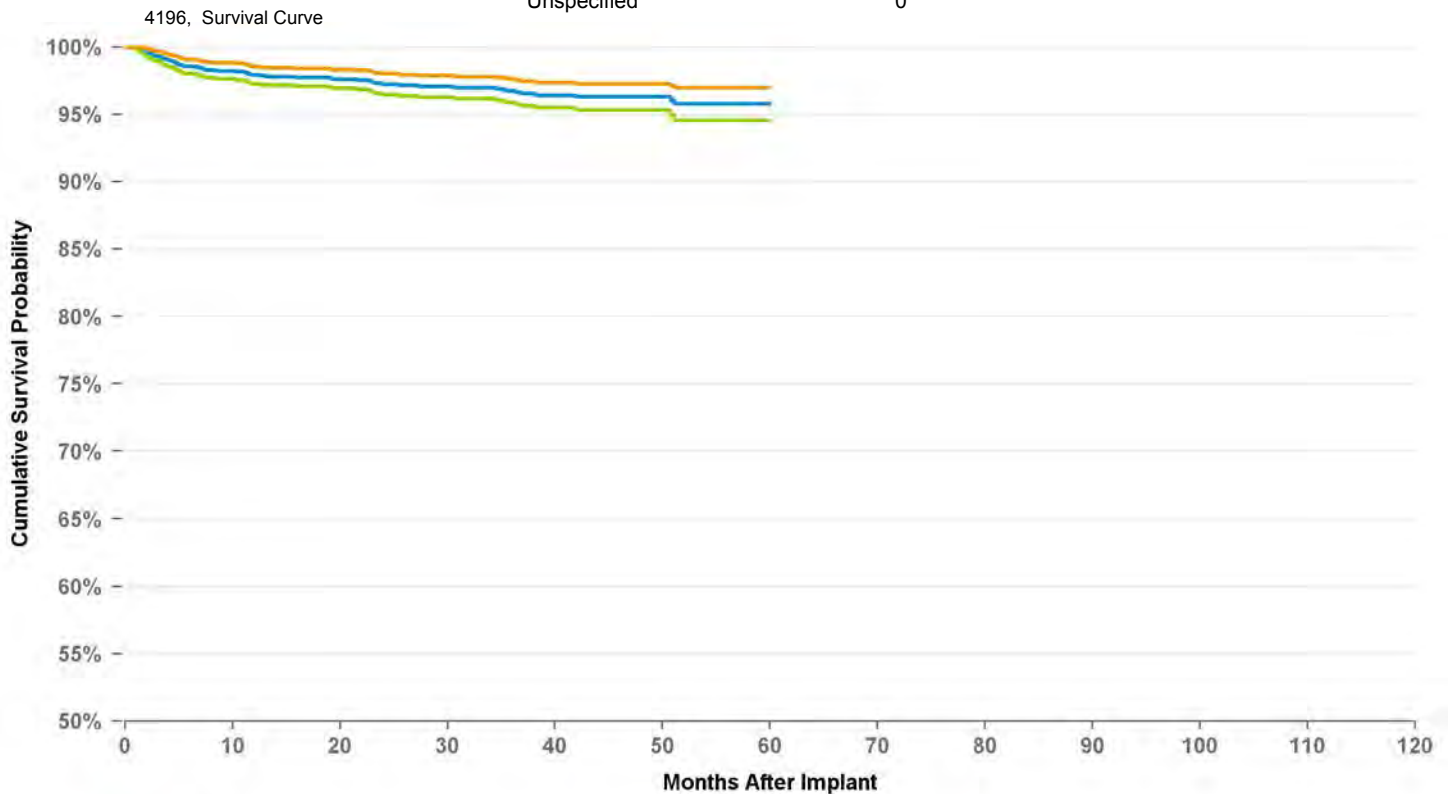
Cardiac Perforation	0
Conductor Fracture	2
Electrical Abandonment	0
Extracardiac Stimulation	13
Failure To Capture	18
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	22
Medical Judgment	0
Other Complication	3
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	81
Failure To Capture	50
Failure To Sense	1
Impedance Abnormal	7
Insulation Breach	2
Lead Dislodgement	183
Oversensing	1
Unspecified	3

USA Returned Product Analysis

Conductor Fracture	17
Crimp Weld Bond	0
Insulation Breach	0
Other	12



Graph Name

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

Years	1	2	3	4	at 60 mo
%	97.9%	97.2%	96.8%	96.3%	95.8%
#	1,676	1,245	889	452	97

LEFT HEART PACING LEAD

4296

Distribution Data

US Market Release	1-Apr-11
CE Approval Date	18-Dec-09
Registered US Implants	30,207
Estimated Active US	26,149

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 Polarity	Dual Electrodes

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,370
Cumulative Months of Follow-Up	24,372
Number of Leads Active in Study	901

Product Surveillance Registry Qualifying Complications

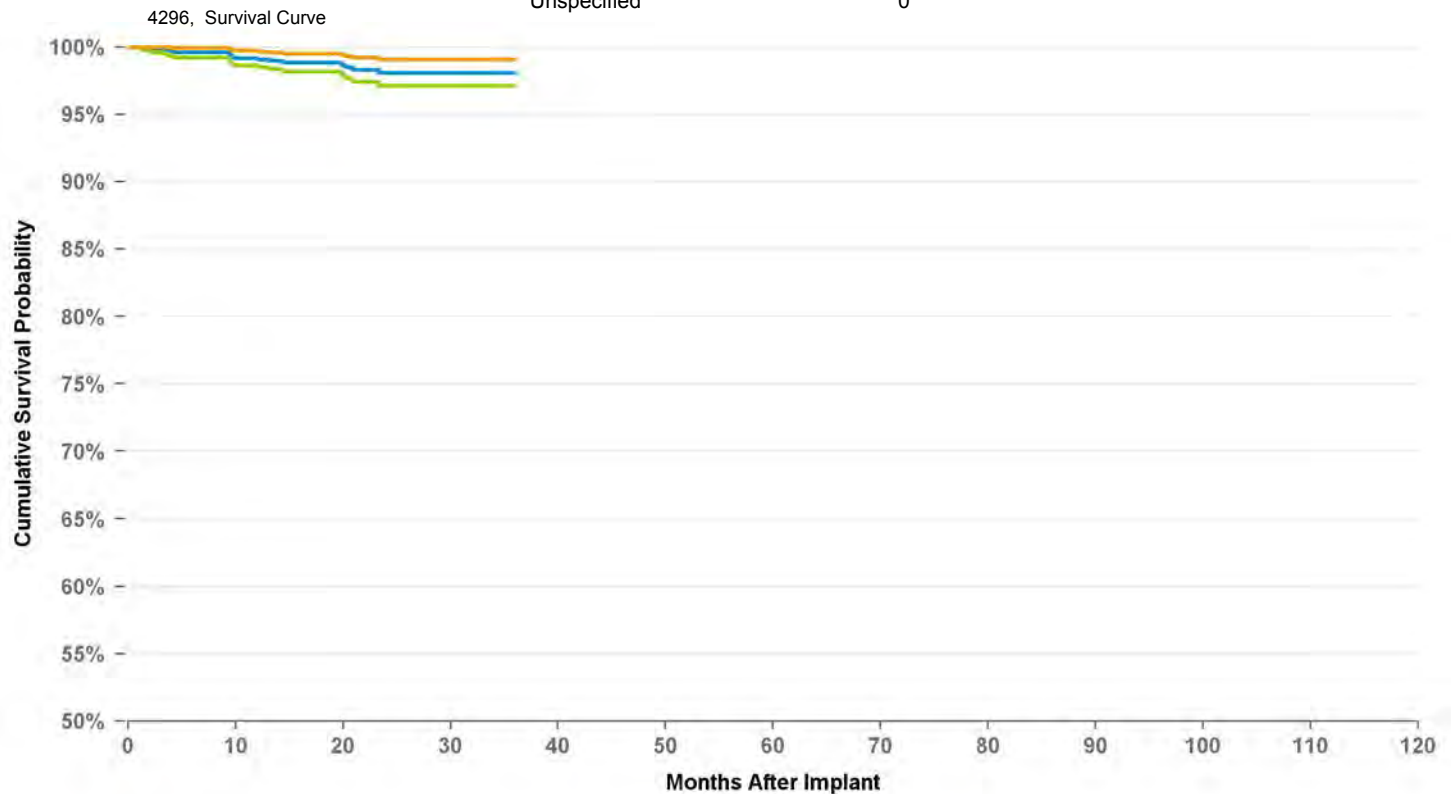
	18
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	6
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	8
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	46
Failure To Capture	21
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	4
Lead Dislodgement	103
Oversensing	0
Unspecified	0

USA Returned Product Analysis

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



Graph Name

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

Years	1	2	at 36 mo
%	99.1%	98.1%	98.1%
#	891	433	96

LEFT HEART PACING LEAD

4298

Distribution Data

US Market Release	1-Aug-14
CE Approval Date	1-Jan-13
Registered US Implants	18,309
Estimated Active US	17,793

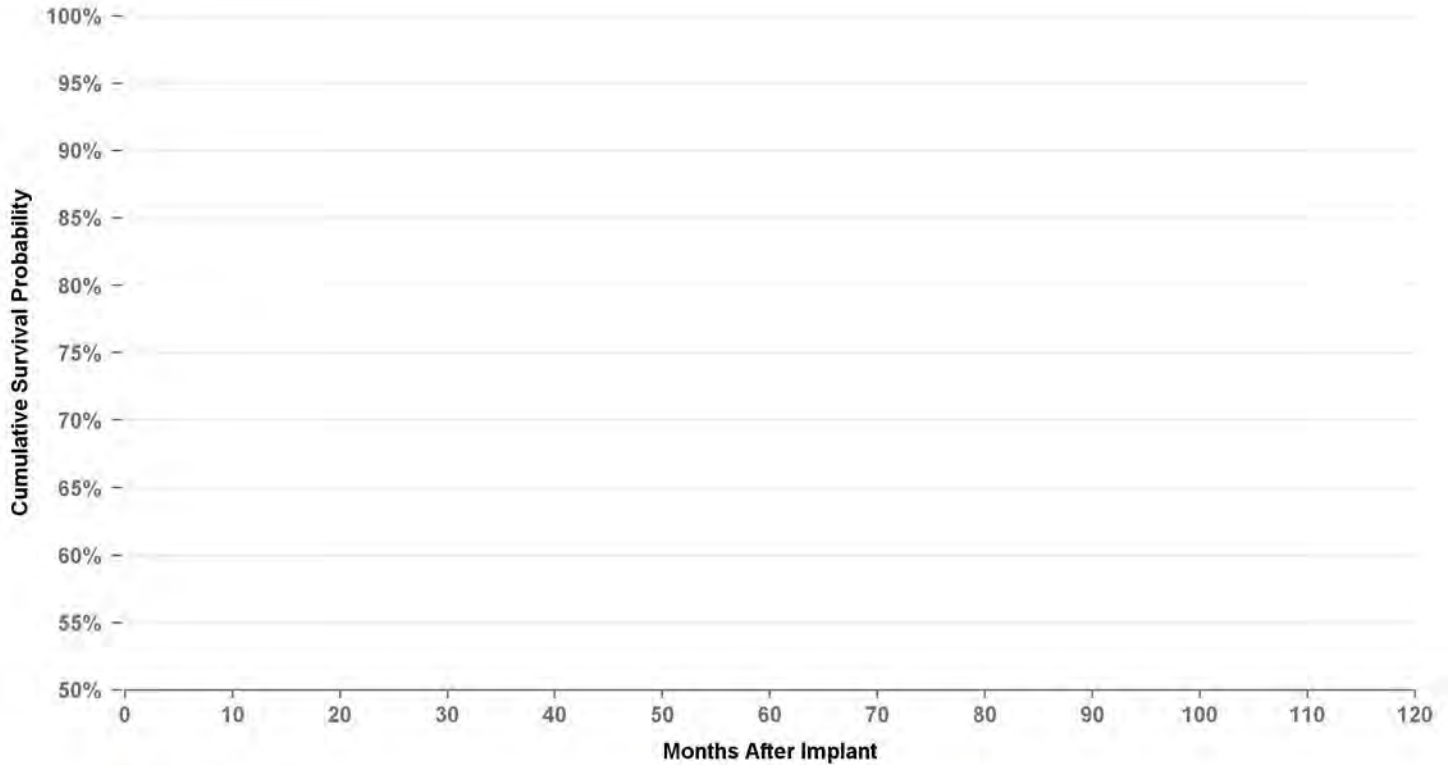
Product Characteristics

Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	449
Cumulative Months of Follow-Up	437
Number of Leads Active in Study	430

4298, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance Registry Qualifying Complications

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	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

3

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	35
Failure To Capture	22
Failure To Sense	0
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	36
Oversensing	0
Unspecified	0

USA Returned Product Analysis

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

LEFT HEART PACING LEAD

4396

Distribution Data

US Market Release	31-Mar-11
CE Approval Date	18-Dec-09
Registered US Implants	6,389
Estimated Active US	5,427

Product Characteristics

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	398
Cumulative Months of Follow-Up	7,344
Number of Leads Active in Study	270

Product Surveillance Registry Qualifying Complications

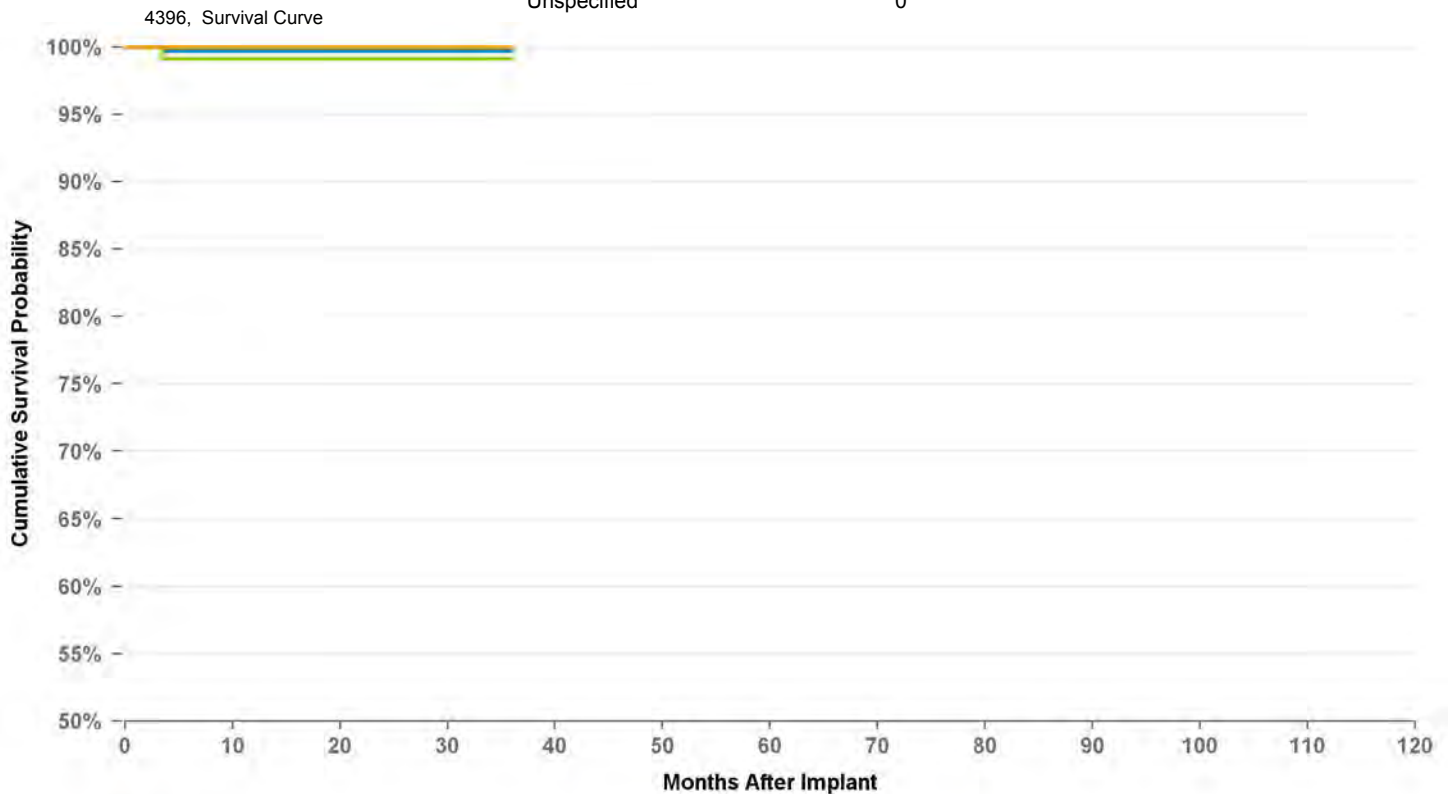
	1
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	12
Failure To Capture	5
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	30
Oversensing	0
Unspecified	0

USA Returned Product Analysis

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



Graph Name

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

Years	1	2	at 36 mo
%	99.7%	99.7%	99.7%
#	241	118	50

LEFT HEART PACING LEAD

4398

Distribution Data

US Market Release	10-Dec-14
CE Approval Date	1-Jan-13
Registered US Implants	2,583
Estimated Active US	2,527

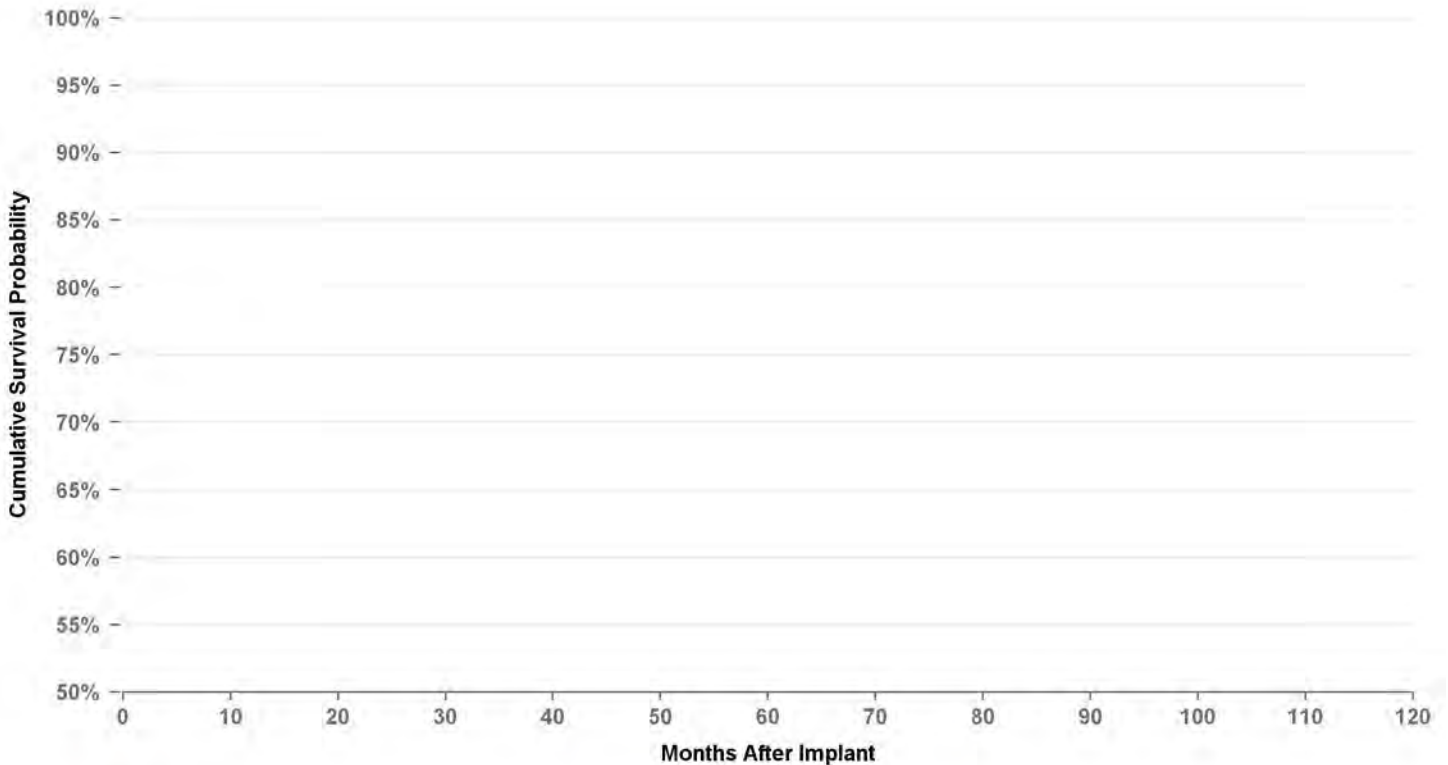
Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	82
Cumulative Months of Follow-Up	160
Number of Leads Active in Study	76

4398, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	13
Failure To Capture	7
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	4
Oversensing	0
Unspecified	0

USA Returned Product Analysis

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

LEFT HEART PACING LEAD

4598

Distribution Data

US Market Release	10-Dec-14
CE Approval Date	1-Jan-13
Registered US Implants	5,212
Estimated Active US	5,123

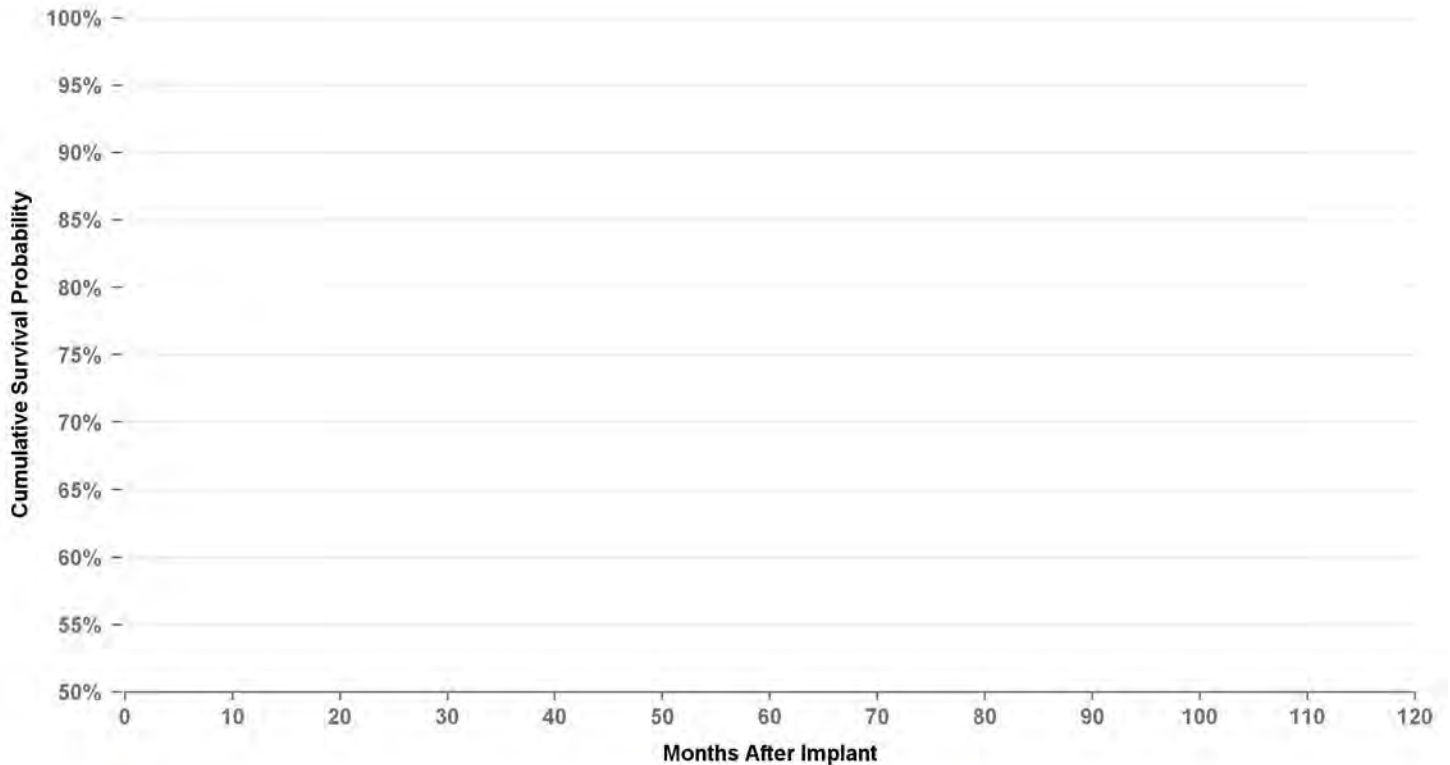
Product Characteristics

Fixation Type	Canted
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarity	Quad Pole

Product Surveillance Registry Results

Number of Leads Enrolled in Study	117
Cumulative Months of Follow-Up	164
Number of Leads Active in Study	115

4598, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	2
Insulation Breach	0
Lead Dislodgement	11
Oversensing	0
Unspecified	0

USA Returned Product Analysis

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

DEFIBRILLATION LEAD

6721

Distribution Data

US Market Release	31-Mar-94
CE Approval Date	1-Jan-93
Registered US Implants	3,031
Estimated Active US	1,034

Product Characteristics

Fixation Type	Suture
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Epi Patch
Lead Tip Location	Epicardial
Pace/Sense Polarity	n/a

Product Surveillance Registry Results

Number of Leads Enrolled in Study	410
Cumulative Months of Follow-Up	23,527
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

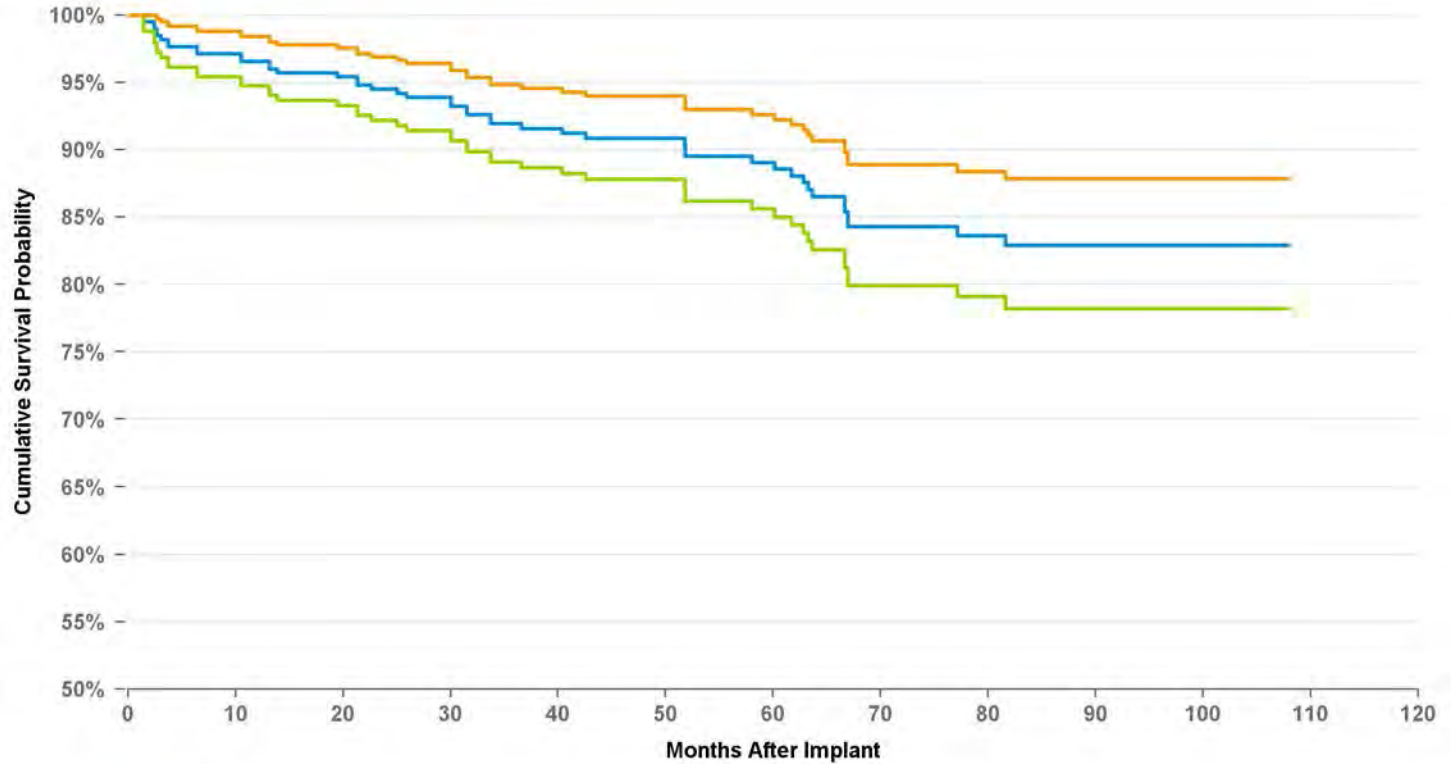
US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	5
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	14
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
%	96.6%	94.5%	91.9%	90.8%	89.0%	84.3%	82.9%	82.9%	82.9%
#	342	312	267	215	184	131	98	63	55

DEFIBRILLATION LEAD

6930

Distribution Data

US Market Release	2-Sep-04
CE Approval Date	
Registered US Implants	354
Estimated Active US	130

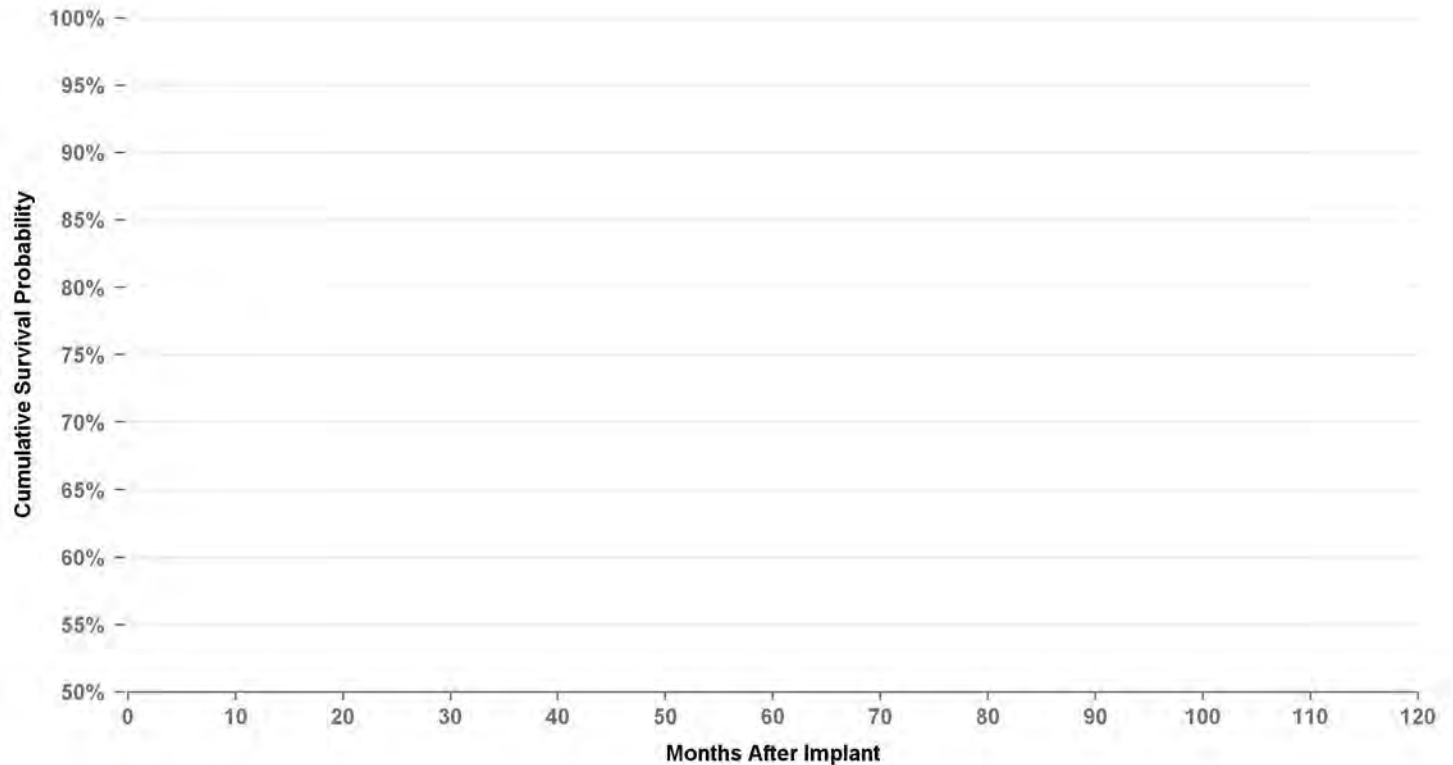
Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	221
Number of Leads Active in Study	1

6930, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	5
Crimp Weld Bond	0
Insulation Breach	0
Other	0

DEFIBRILLATION LEAD

6931

Distribution Data

US Market Release	2-Sep-04
CE Approval Date	
Registered US Implants	8,082
Estimated Active US	2,556
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	305
Cumulative Months of Follow-Up	15,962
Number of Leads Active in Study	46

Product Surveillance Registry Qualifying Complications

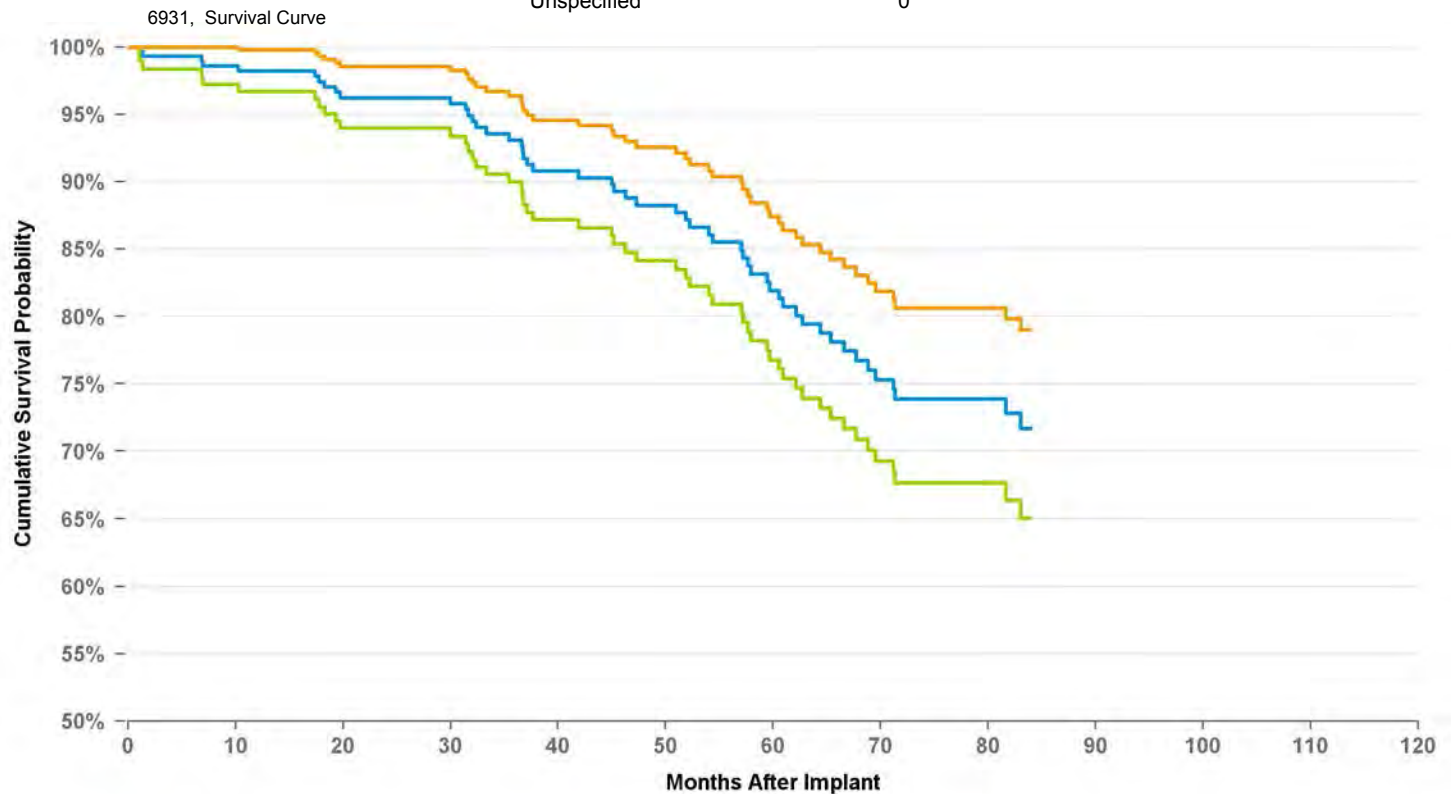
	57
Cardiac Perforation	0
Conductor Fracture	35
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	9
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	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	601
Crimp Weld Bond	0
Insulation Breach	1
Other	5



Graph Name

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

Years	1	2	3	4	5	6	at 84 mo
%	98.2%	96.2%	93.1%	88.3%	81.9%	73.8%	71.7%
#	268	236	206	163	132	97	58

DEFIBRILLATION LEAD

6932

Distribution Data

US Market Release	6-Aug-96
CE Approval Date	
Registered US Implants	14,900
Estimated Active US	3,402

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	420
Cumulative Months of Follow-Up	25,831
Number of Leads Active in Study	29

Product Surveillance Registry Qualifying Complications

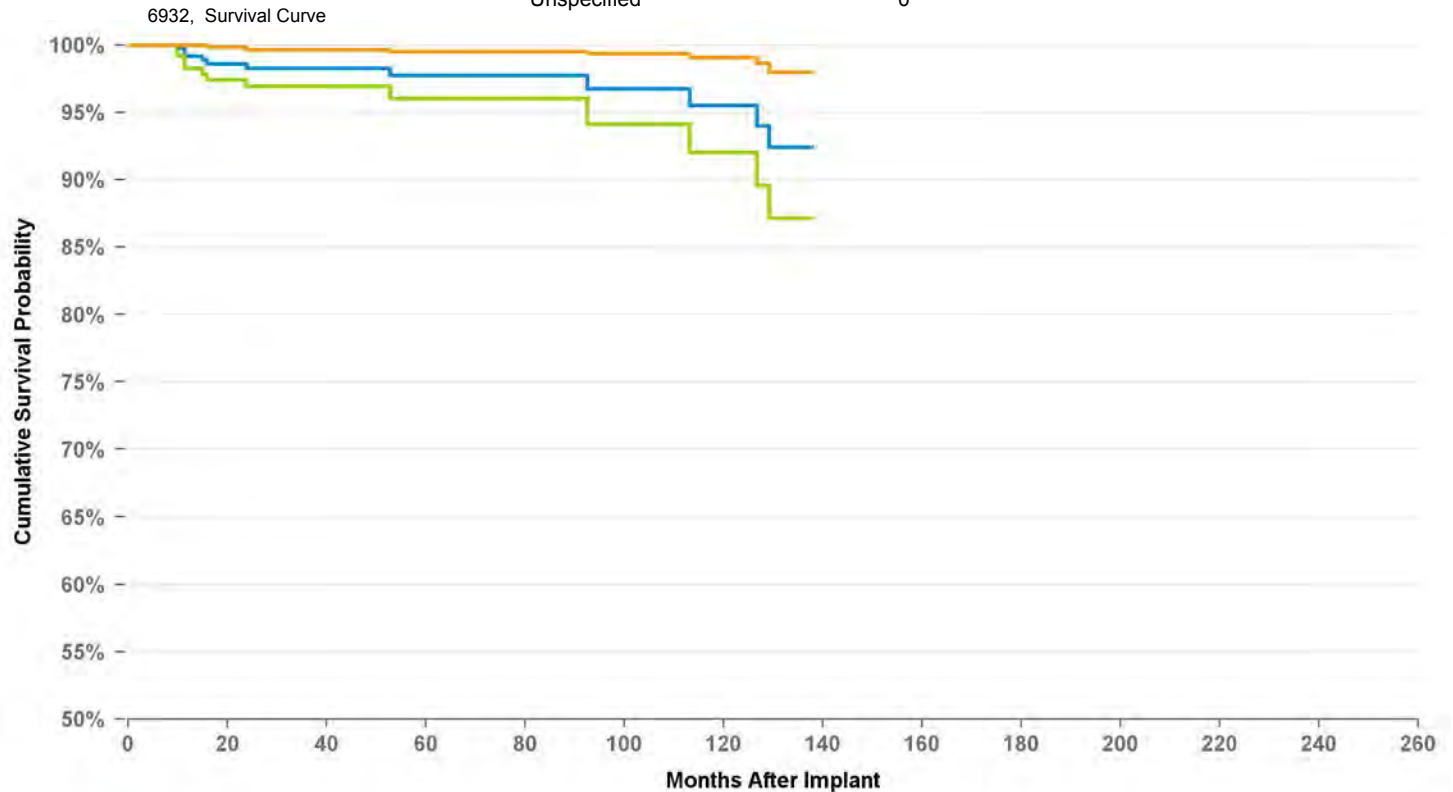
	11
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication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



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
%	99.2%	98.3%	98.3%	98.3%	97.7%	97.7%	97.7%	96.7%	96.7%	95.5%	92.4%	92.4%
#	364	305	242	203	157	125	105	91	81	68	56	54

DEFIBRILLATION LEAD

6933

Distribution Data

US Market Release	20-Apr-94
CE Approval Date	
Registered US Implants	7,983
Estimated Active US	572

Product Characteristics

Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarity	One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	970
Cumulative Months of Follow-Up	54,326
Number of Leads Active in Study	9

Product Surveillance Registry Qualifying Complications

Total	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

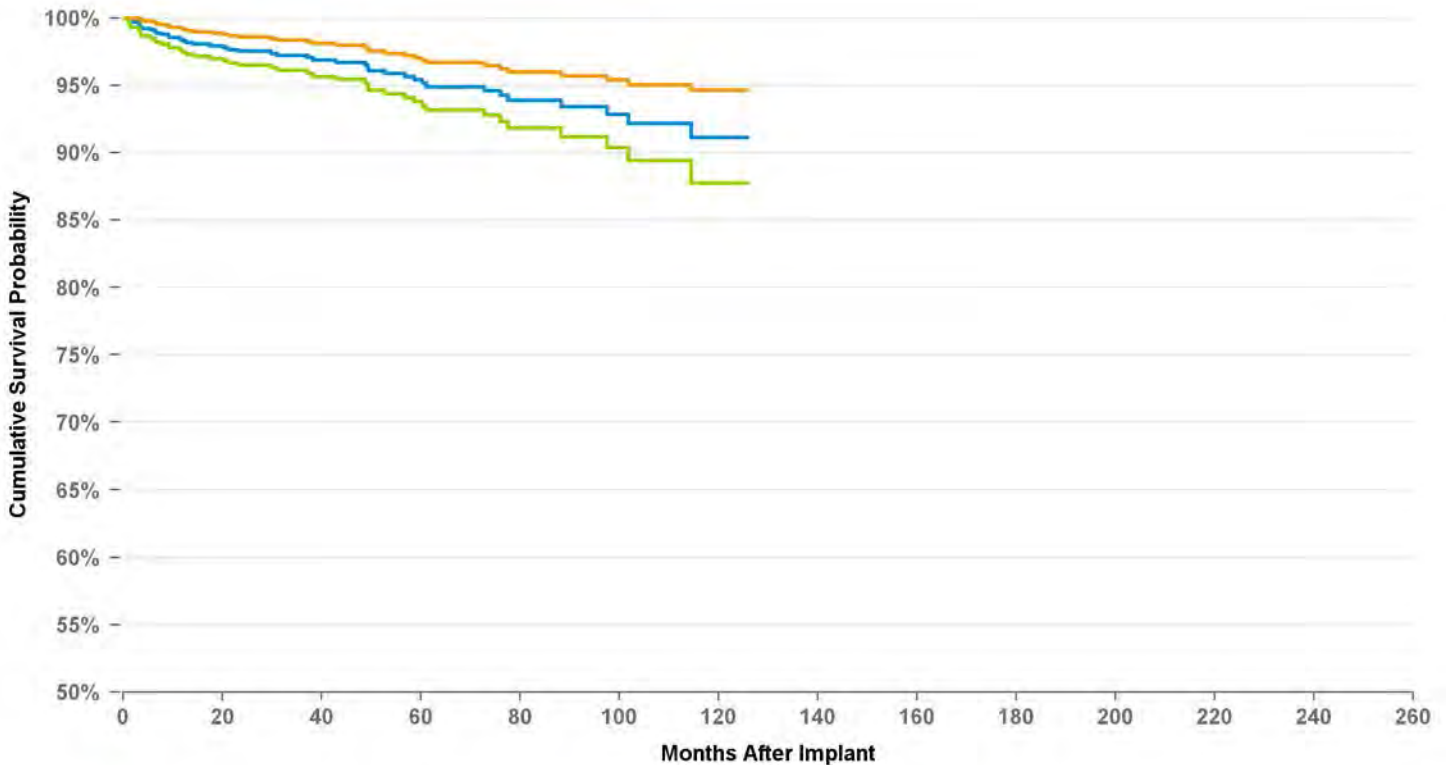
US Acute Lead Observations

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%
#	823	692	577	484	388	312	219	170	111	72	57

DEFIBRILLATION LEAD

6935

Distribution Data

US Market Release	1-Nov-08
CE Approval Date	31-Mar-08
Registered US Implants	52,824
Estimated Active US	44,130

Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,407
Cumulative Months of Follow-Up	69,762
Number of Leads Active in Study	1,342

Product Surveillance Registry Qualifying Complications

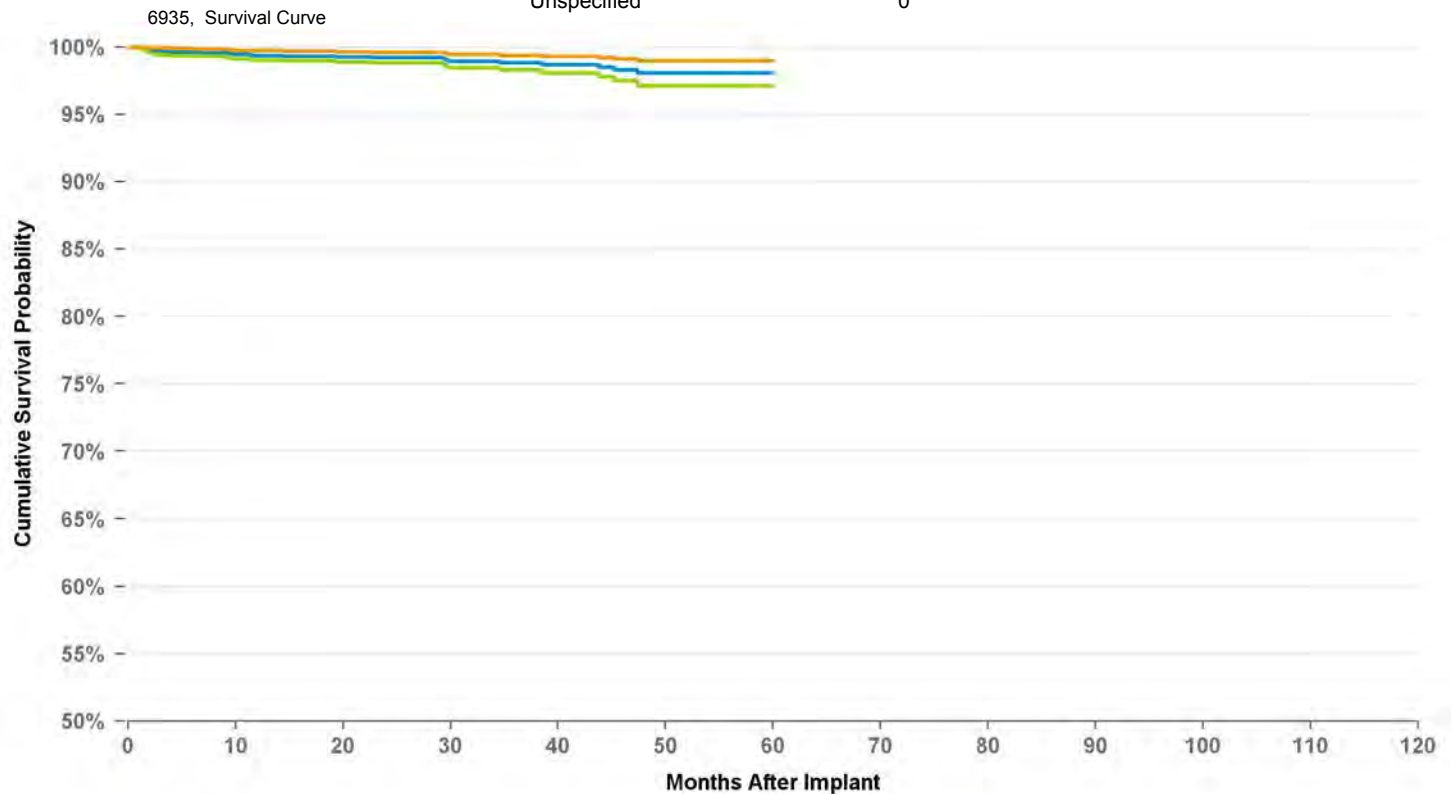
	27
Cardiac Perforation	0
Conductor Fracture	8
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	8
Medical Judgment	0
Other Complication	1
Oversensing	4
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	19
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	20
Failure To Sense	6
Impedance Abnormal	14
Insulation Breach	1
Lead Dislodgement	38
Oversensing	42
Unspecified	5

USA Returned Product Analysis

Conductor Fracture	154
Crimp Weld Bond	0
Insulation Breach	6
Other	40



Graph Name

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

Years	1	2	3	4	at 60 mo
%	99.4%	99.2%	98.8%	98.1%	98.1%
#	1,982	1,389	792	373	112

DEFIBRILLATION LEAD

6935M

Distribution Data

US Market Release	2-Aug-12
CE Approval Date	12-Jul-12
Registered US Implants	67,236
Estimated Active US	64,108

Product Characteristics

Fixation Type	Active Screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,449
Cumulative Months of Follow-Up	18,482
Number of Leads Active in Study	2,194

Product Surveillance Registry Qualifying Complications

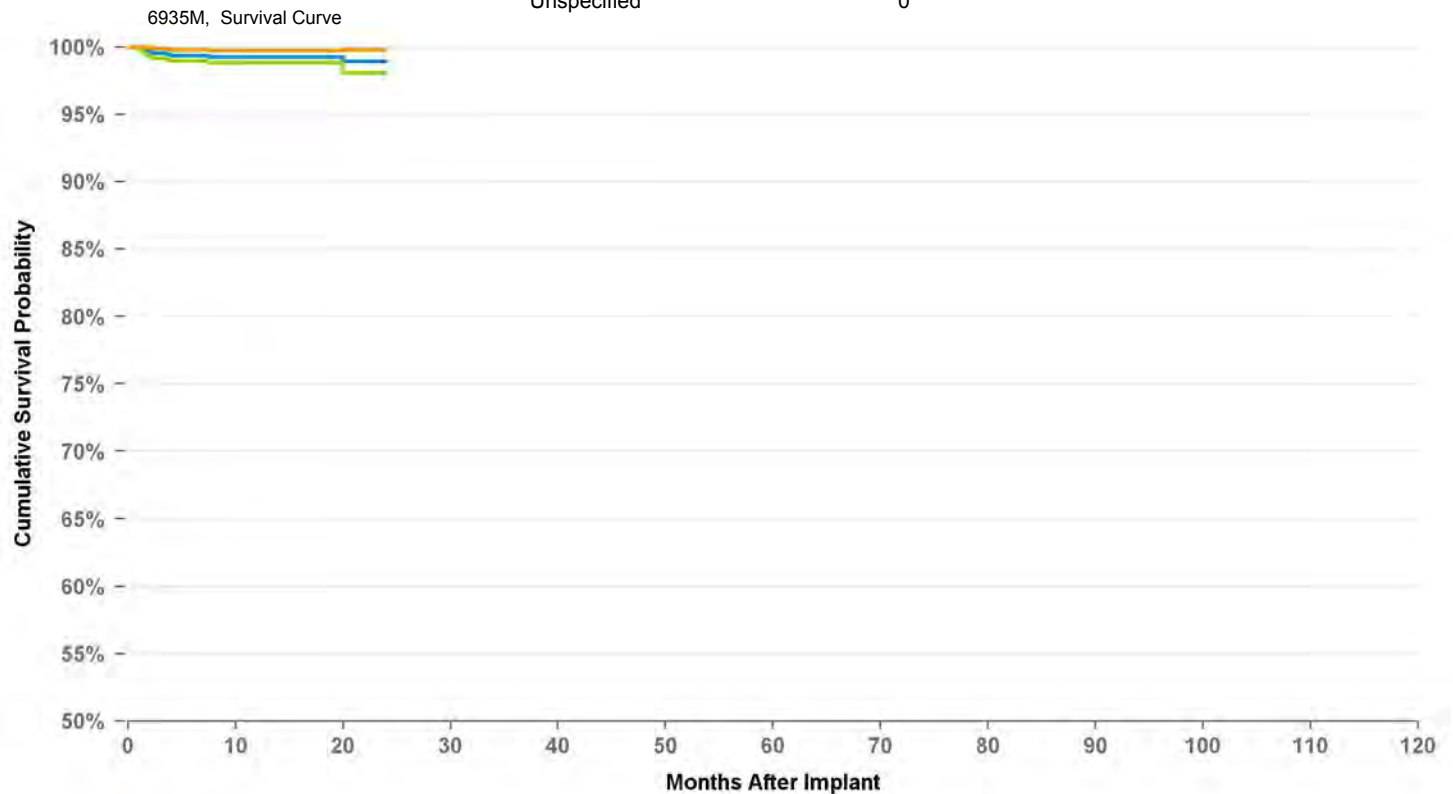
	11
Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	2
Oversensing	1
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	19
Conductor Fracture	1
Extracardiac Stimulation	5
Failure To Capture	48
Failure To Sense	9
Impedance Abnormal	10
Insulation Breach	1
Lead Dislodgement	77
Oversensing	45
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	24
Crimp Weld Bond	0
Insulation Breach	1
Other	7



Graph Name

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

Years	1	at 24 mo
%	99.3%	98.9%
#	691	133

DEFIBRILLATION LEAD

6937

Distribution Data

US Market Release	22-Mar-96
CE Approval Date	19-Apr-94
Registered US Implants	2,058
Estimated Active US	313

Product Characteristics

Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarity	One Coil

Product Surveillance Registry Results

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

Product Surveillance Registry Qualifying Complications

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

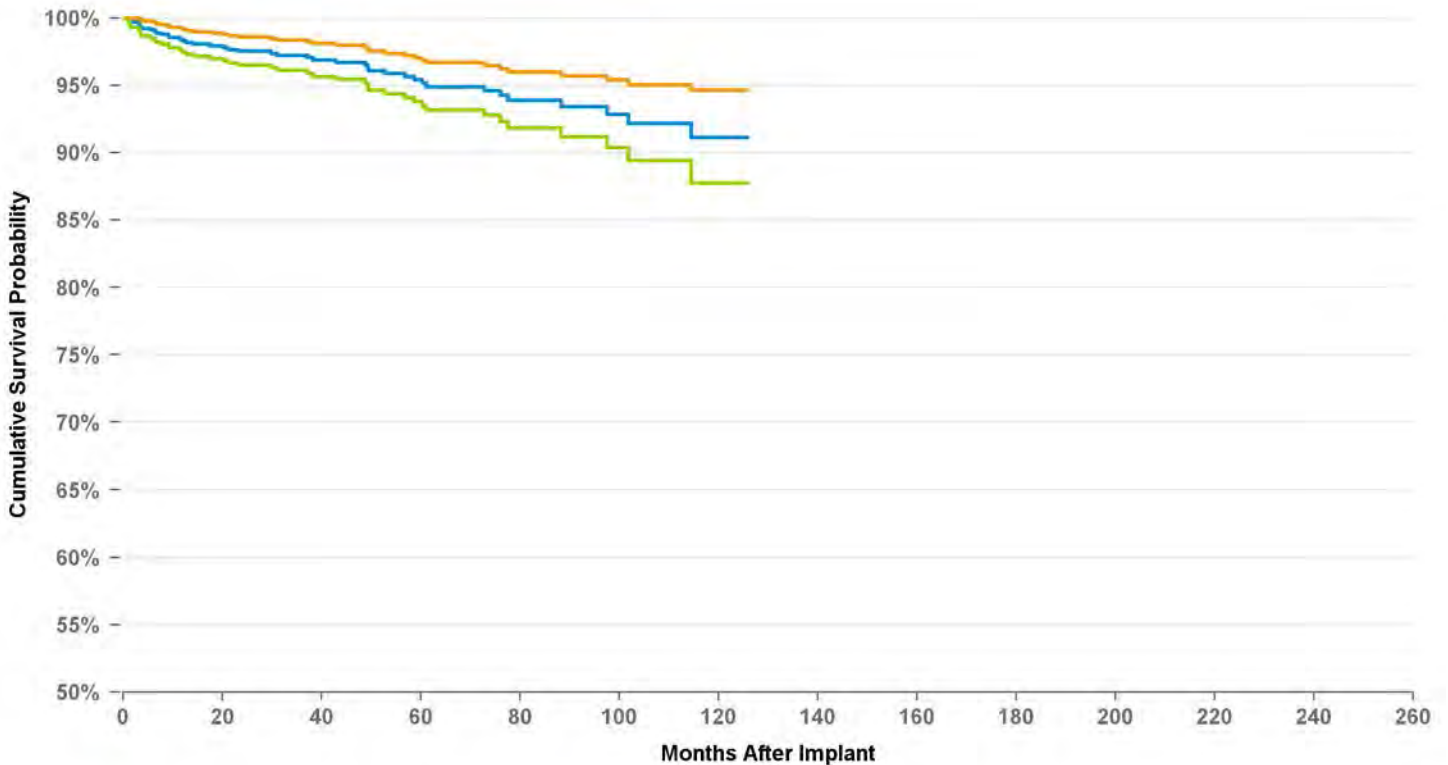
US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	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%
#	823	692	577	484	388	312	219	170	111	72	57

DEFIBRILLATION LEAD

6937A

Distribution Data

US Market Release	6-Apr-01
CE Approval Date	
Registered US Implants	2,159
Estimated Active US	1,276
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarity	One Coil

Product Surveillance 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	3
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	2

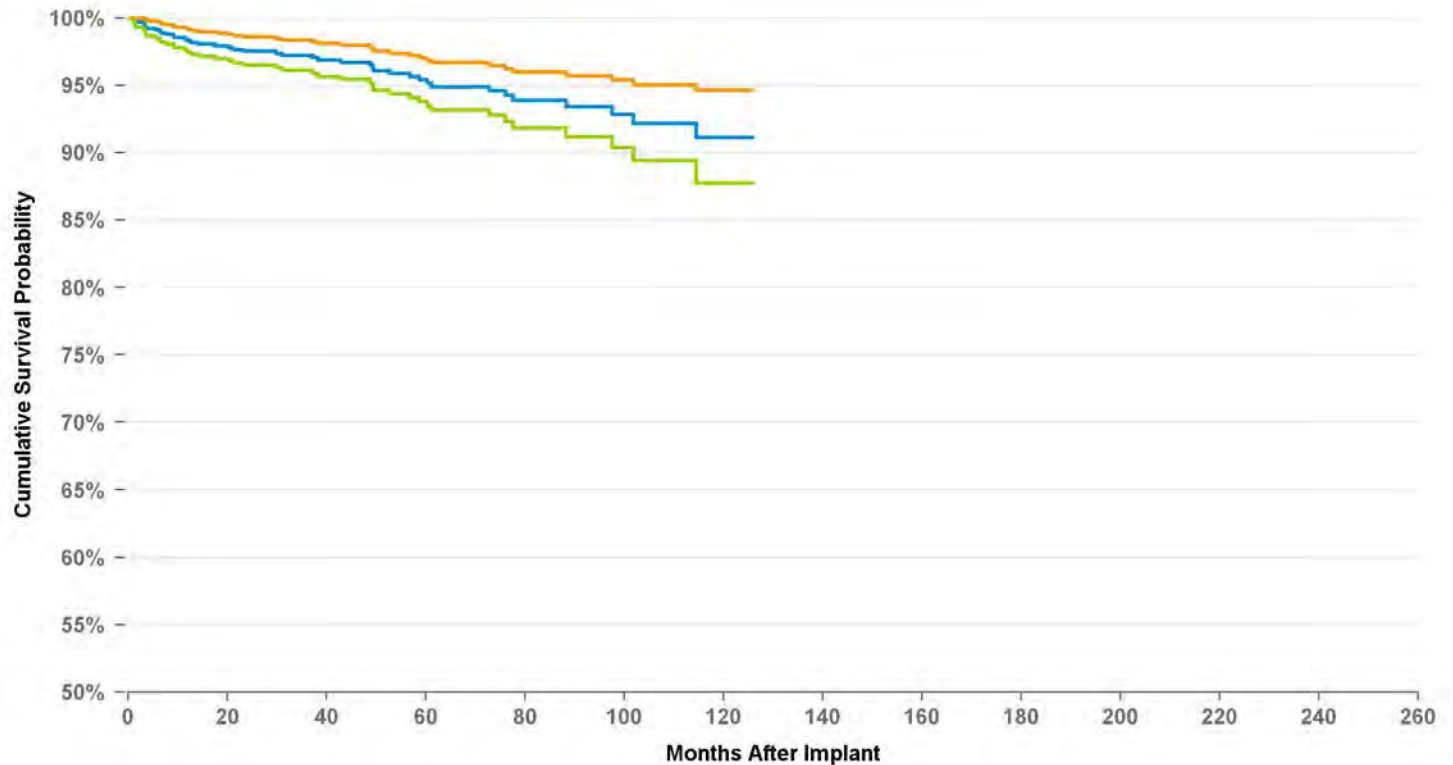
Product Surveillance Registry Results

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

USA Returned Product Analysis

Conductor Fracture	5
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%
#	823	692	577	484	388	312	219	170	111	72	57

DEFIBRILLATION LEAD

6942

Distribution Data

US Market Release	18-Jul-97
CE Approval Date	
Registered US Implants	17,685
Estimated Active US	4,169

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Integrated Bipolar/ Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	361
Cumulative Months of Follow-Up	19,403
Number of Leads Active in Study	13

Product Surveillance Registry Qualifying Complications

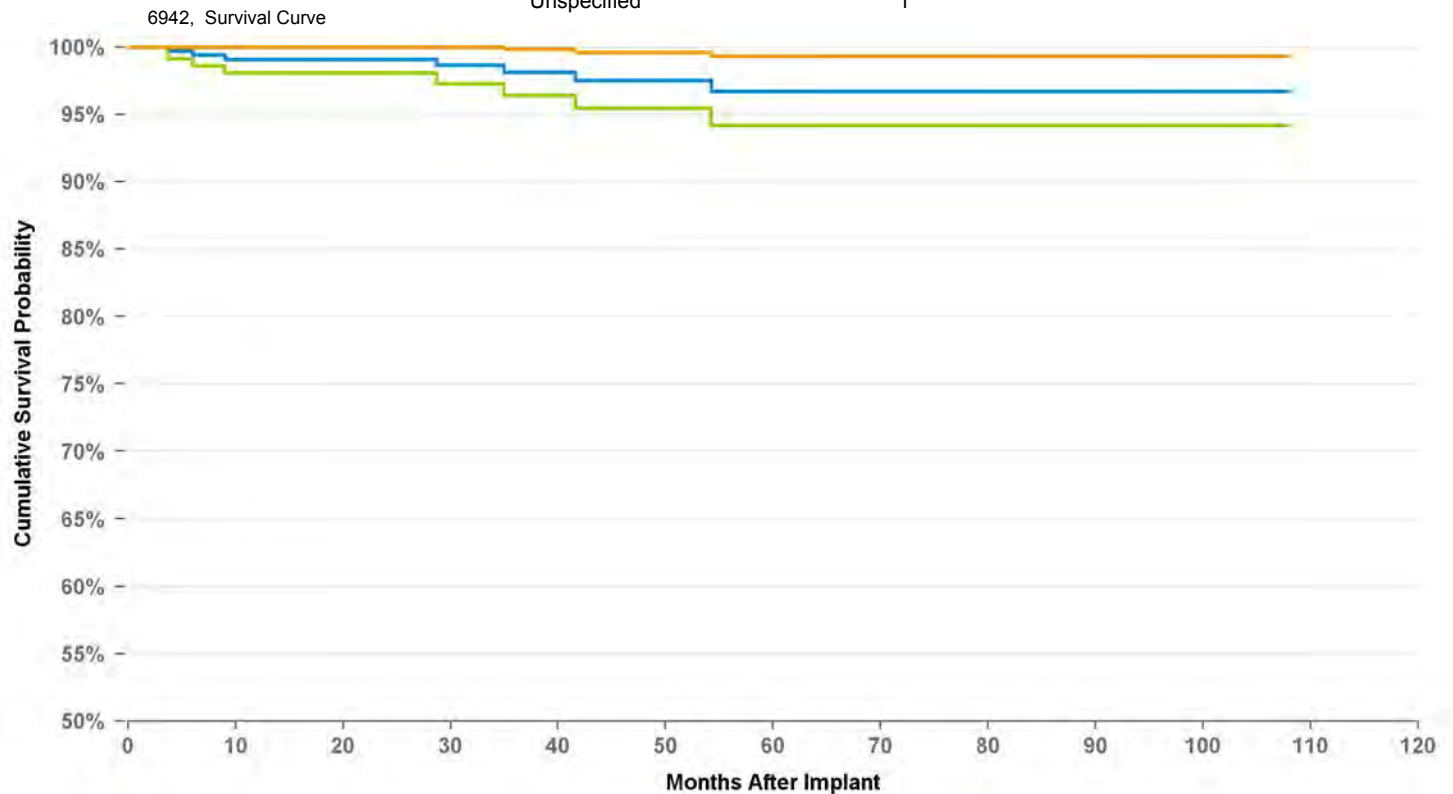
	7
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	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	16
Crimp Weld Bond	1
Insulation Breach	26
Other	4



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%
#	307	238	180	140	113	96	75	64	53

DEFIBRILLATION LEAD

6943

Distribution Data

US Market Release	6-Oct-97
CE Approval Date	
Registered US Implants	20,590
Estimated Active US	4,979

Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,336
Cumulative Months of Follow-Up	84,915
Number of Leads Active in Study	130

Product Surveillance Registry Qualifying Complications

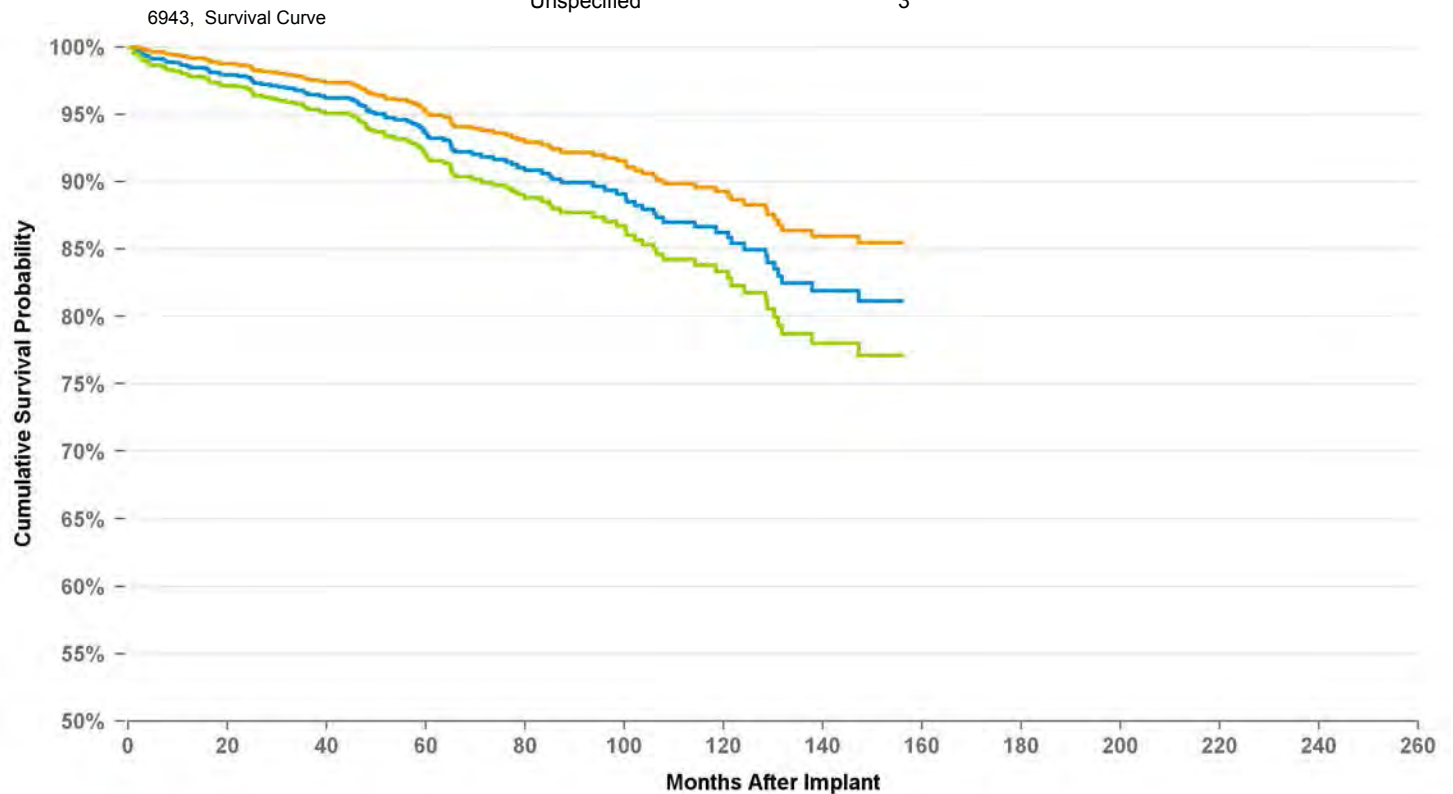
	104
Cardiac Perforation	0
Conductor Fracture	29
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	9
Failure To Sense	7
Impedance Abnormal	8
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	2
Medical Judgment	0
Other Complication	3
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	83
Crimp Weld Bond	1
Insulation Breach	31
Other	5



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
%	98.6%	97.7%	96.6%	95.6%	93.5%	91.9%	90.6%	89.7%	87.0%	86.3%	82.5%	81.9%	81.2%
#	1,179	986	863	715	597	485	397	326	271	206	155	114	67

DEFIBRILLATION LEAD

6944

Distribution Data

US Market Release	13-Dec-00
CE Approval Date	5-Nov-99
Registered US Implants	44,137
Estimated Active US	20,541

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	579
Cumulative Months of Follow-Up	23,038
Number of Leads Active in Study	218

Product Surveillance Registry Qualifying Complications

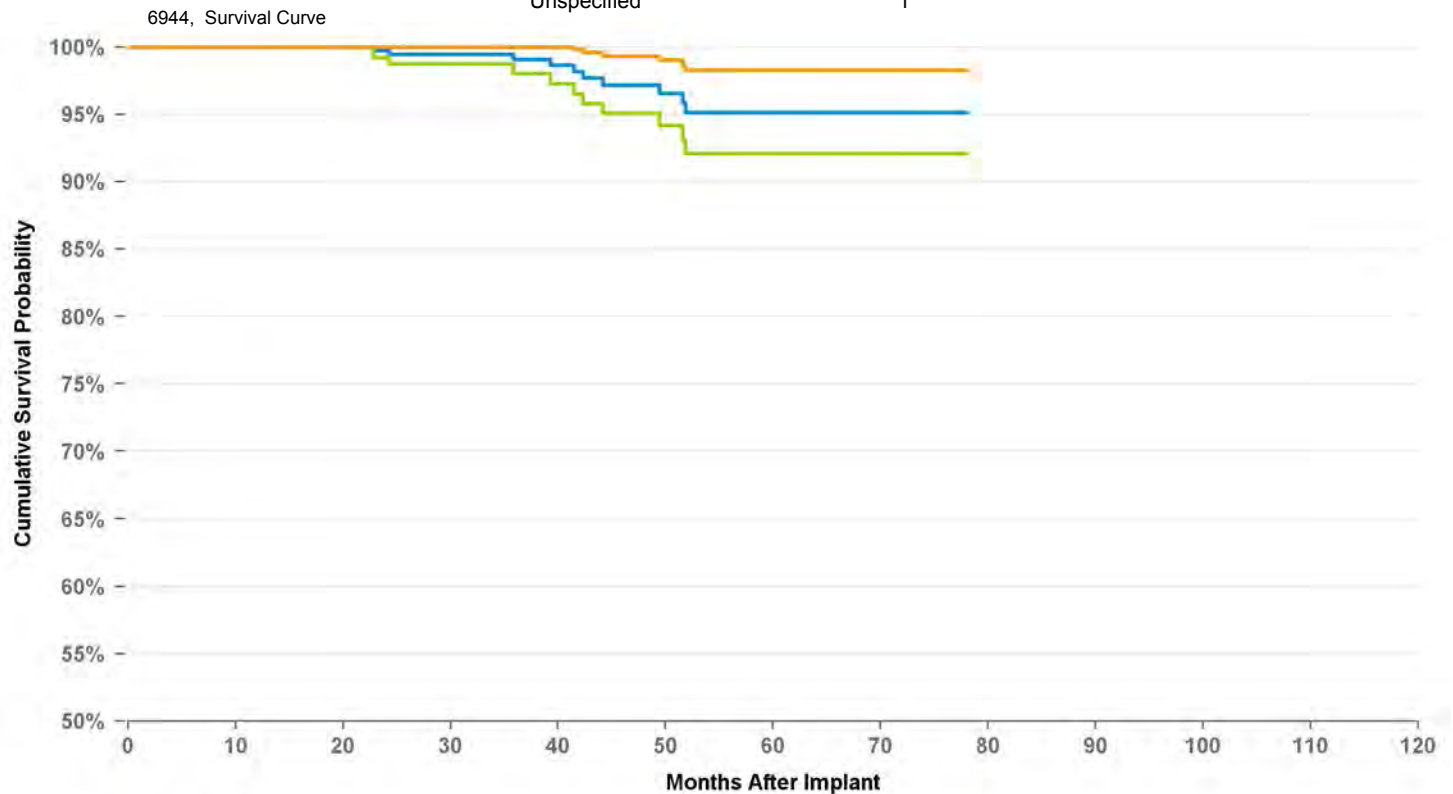
	14
Cardiac Perforation	0
Conductor Fracture	8
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	1

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	16
Failure To Sense	3
Impedance Abnormal	9
Insulation Breach	0
Lead Dislodgement	22
Oversensing	11
Unspecified	6

USA Returned Product Analysis

Conductor Fracture	148
Crimp Weld Bond	1
Insulation Breach	4
Other	6



Graph Name

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

Years	1	2	3	4	5	6	at 78 mo
%	100.0%	99.7%	99.1%	97.2%	95.1%	95.1%	95.1%
#	484	376	260	165	80	61	55

DEFIBRILLATION LEAD

6945

Distribution Data

US Market Release	26-Sep-97
CE Approval Date	
Registered US Implants	42,724
Estimated Active US	10,090

Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Integrated Bipolar/ Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,189
Cumulative Months of Follow-Up	66,625
Number of Leads Active in Study	87

Product Surveillance Registry Qualifying Complications

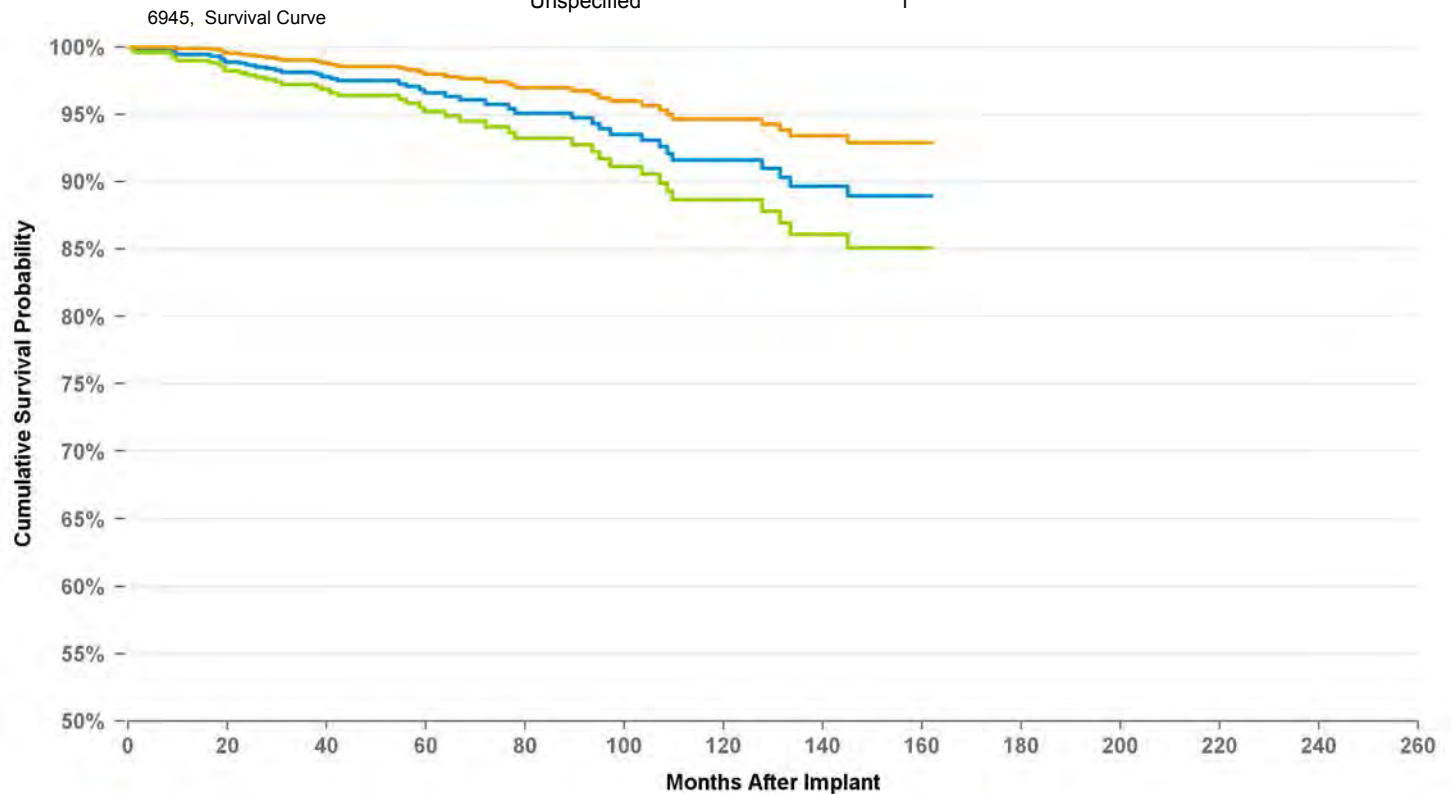
Total	44
Cardiac Perforation	0
Conductor Fracture	11
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	4
Impedance Abnormal	6
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other 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	8
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	142
Crimp Weld Bond	1
Insulation Breach	45
Other	6



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	at 162 mo
%	99.4%	98.7%	98.1%	97.5%	96.6%	95.8%	95.1%	93.9%	92.6%	91.6%	90.3%	89.7%	88.9%	88.9%
#	1,023	829	660	528	408	312	274	230	186	155	132	113	82	63

DEFIBRILLATION LEAD

6947

Distribution Data

US Market Release	12-Nov-01
CE Approval Date	4-Oct-01
Registered US Implants	371,089
Estimated Active US	215,338

Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,808
Cumulative Months of Follow-Up	167,985
Number of Leads Active in Study	1,538

Product Surveillance Registry Qualifying Complications

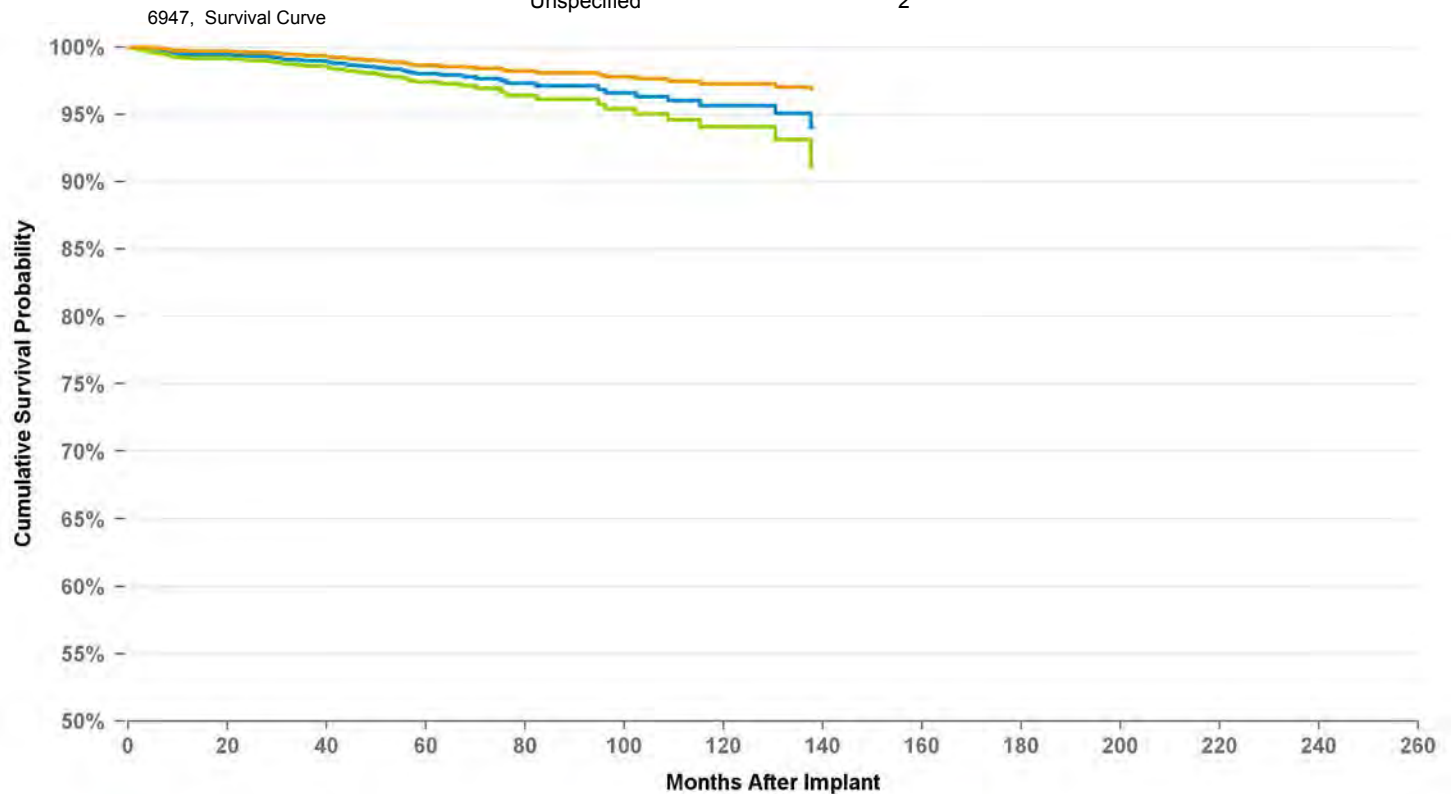
	56
Cardiac Perforation	0
Conductor Fracture	16
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	6
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	5
Lead Dislodgement	5
Medical Judgment	0
Other Complication	3
Oversensing	15
Unspecified	2

US Acute Lead Observations

Cardiac Perforation	28
Conductor Fracture	20
Extracardiac Stimulation	2
Failure To Capture	75
Failure To Sense	30
Impedance Abnormal	55
Insulation Breach	4
Lead Dislodgement	114
Oversensing	124
Unspecified	22

USA Returned Product Analysis

Conductor Fracture	732
Crimp Weld Bond	4
Insulation Breach	66
Other	214



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
%	99.5%	99.3%	99.0%	98.5%	98.0%	97.7%	97.1%	96.8%	96.3%	95.7%	95.1%	94.0%
#	3,207	2,581	2,077	1,523	979	523	399	342	279	179	94	55

DEFIBRILLATION LEAD

6947M

Distribution Data

US Market Release	13-Feb-12
CE Approval Date	12-Mar-10
Registered US Implants	68,494
Estimated Active US	63,166

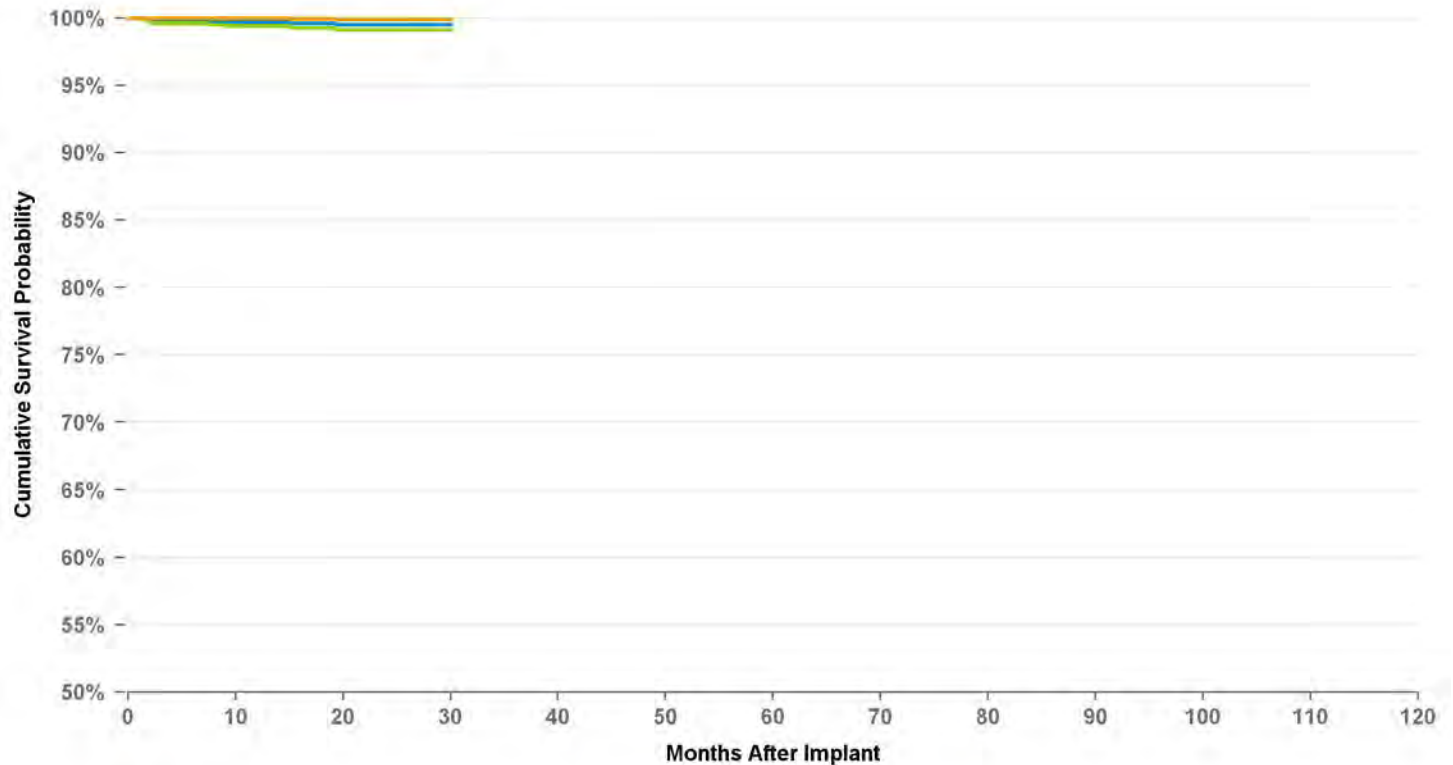
Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,826
Cumulative Months of Follow-Up	33,961
Number of Leads Active in Study	1,370

6947M, Survival Curve



Graph Name

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

Years	1	2	at 30 mo
%	99.7%	99.5%	99.5%
#	1,295	656	299

Product Surveillance Registry Qualifying Complications

	7
Cardiac Perforation	0
Conductor Fracture	1
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	0
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	18
Conductor Fracture	6
Extracardiac Stimulation	7
Failure To Capture	45
Failure To Sense	13
Impedance Abnormal	13
Insulation Breach	0
Lead Dislodgement	87
Oversensing	30
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	28
Crimp Weld Bond	0
Insulation Breach	3
Other	9

DEFIBRILLATION LEAD

6948

Distribution Data

US Market Release	2-Sep-04
CE Approval Date	
Registered US Implants	10,378
Estimated Active US	3,589

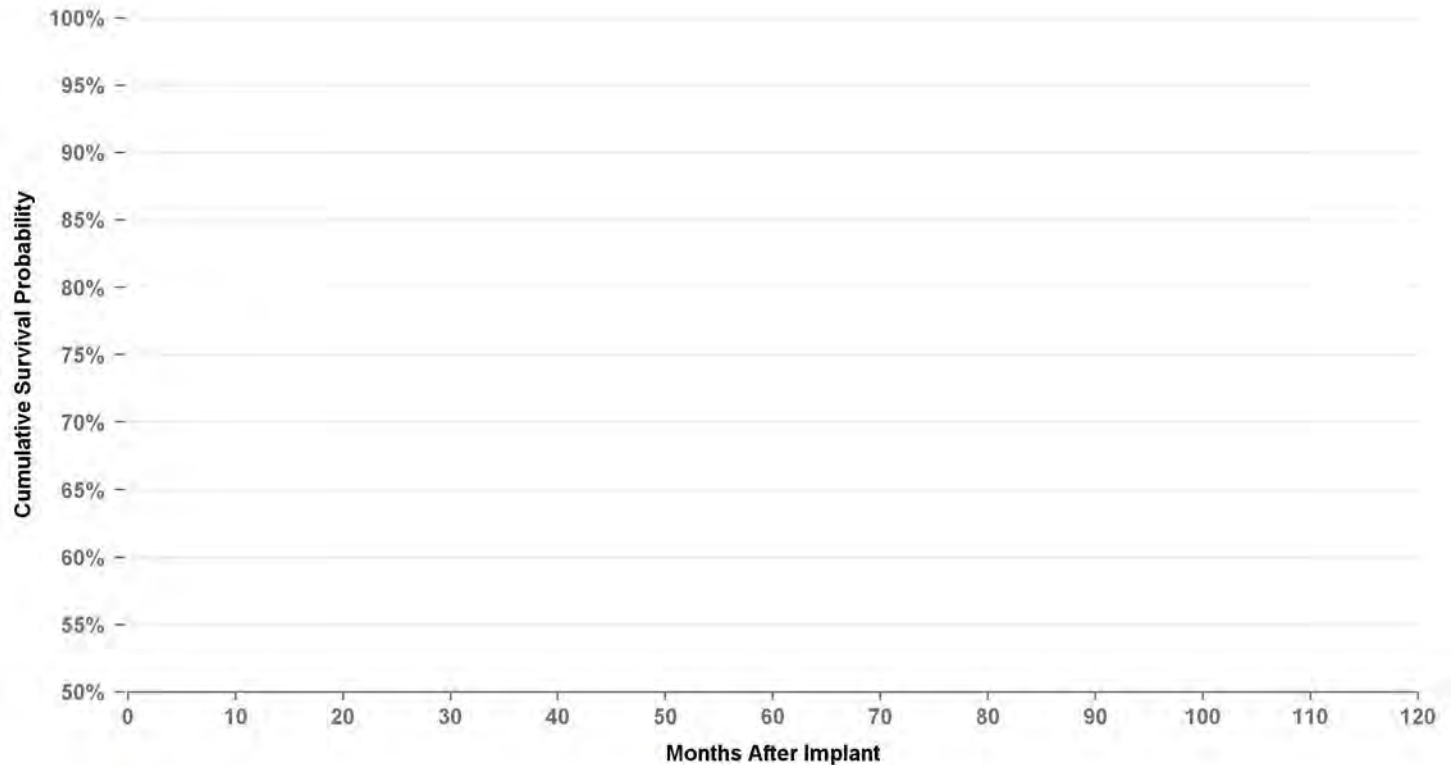
Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,859
Number of Leads Active in Study	11

6948, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	181
Crimp Weld Bond	0
Insulation Breach	2
Other	2

DEFIBRILLATION LEAD

6949

Distribution Data

US Market Release	2-Sep-04
CE Approval Date	
Registered US Implants	186,752
Estimated Active US	55,350

Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	True Bipolar/Two Coils

Product Surveillance Registry Results

Number of Leads Enrolled in Study	938
Cumulative Months of Follow-Up	46,511
Number of Leads Active in Study	220

Product Surveillance Registry Qualifying Complications

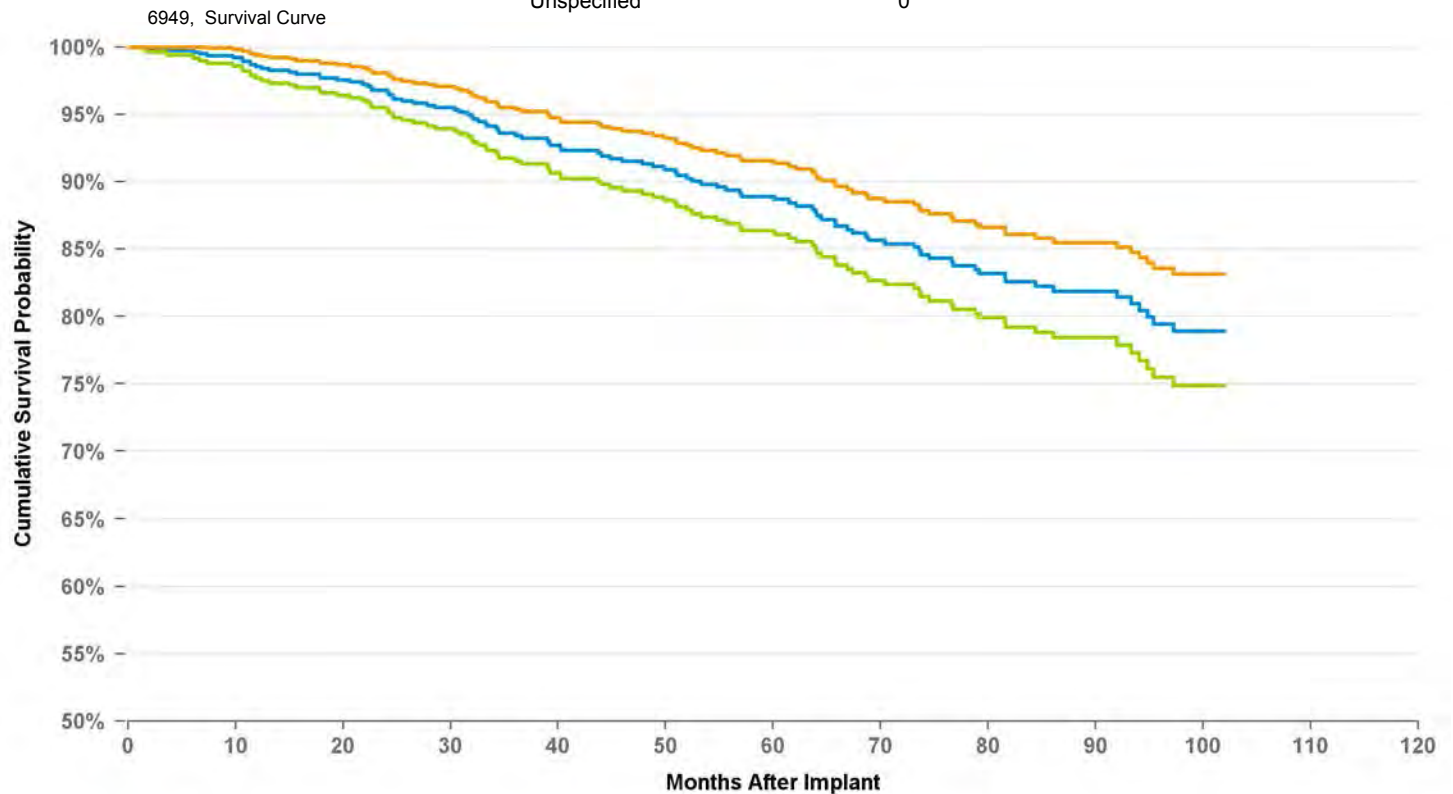
	97
Cardiac Perforation	0
Conductor Fracture	52
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	6
Impedance Abnormal	16
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	2
Oversensing	15
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	10
Conductor Fracture	44
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	19
Impedance Abnormal	17
Insulation Breach	6
Lead Dislodgement	22
Oversensing	30
Unspecified	25

USA Returned Product Analysis

Conductor Fracture	7,274
Crimp Weld Bond	3
Insulation Breach	33
Other	70



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
%	98.5%	96.8%	93.6%	91.3%	88.9%	85.4%	82.6%	79.4%	78.9%
#	803	656	545	451	360	282	184	91	67

DEFIBRILLATION LEAD

6996

Distribution Data

US Market Release	11-Jun-01
CE Approval Date	19-Dec-97
Registered US Implants	4,435
Estimated Active US	2,429

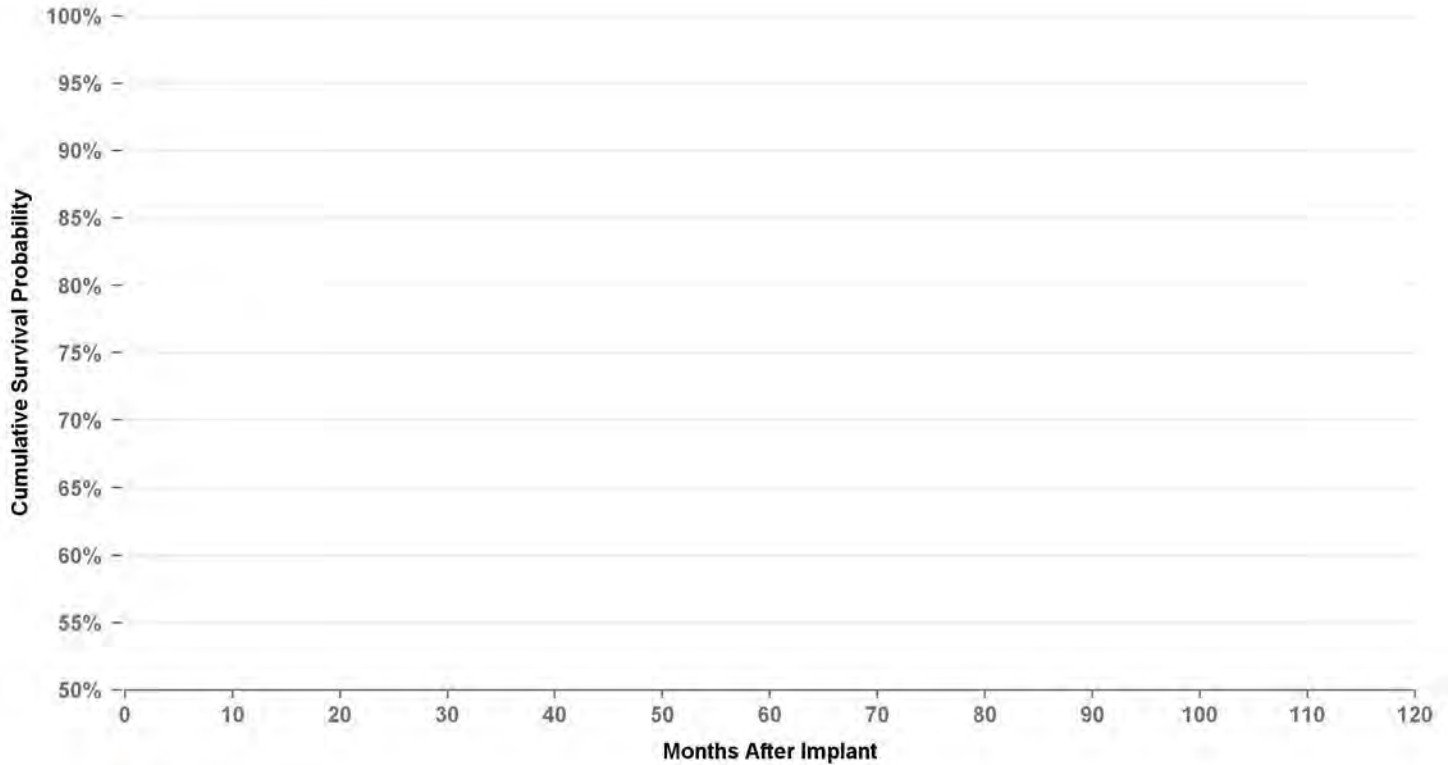
Product Characteristics

Fixation Type	Suture on Anchor Sleeve
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Subcutaneous
Lead Tip Location	Defibrillation
Pace/Sense Polarity	One Coil

Product Surveillance Registry Results

Number of Leads Enrolled in Study	45
Cumulative Months of Follow-Up	1,523
Number of Leads Active in Study	14

6996, Survival Curve



Graph Name

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

Years

%

#

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	1
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	25
Crimp Weld Bond	0
Insulation Breach	0
Other	0

PACING LEAD

3830

ATRIAL PLACEMENT

Distribution Data

US Market Release	3-Aug-05
CE Approval Date	31-Jan-03
Registered US Implants	25,141
Estimated Active US	17,647

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	879
Cumulative Months of Follow-Up	35,193
Number of Leads Active in Study	461

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	2
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

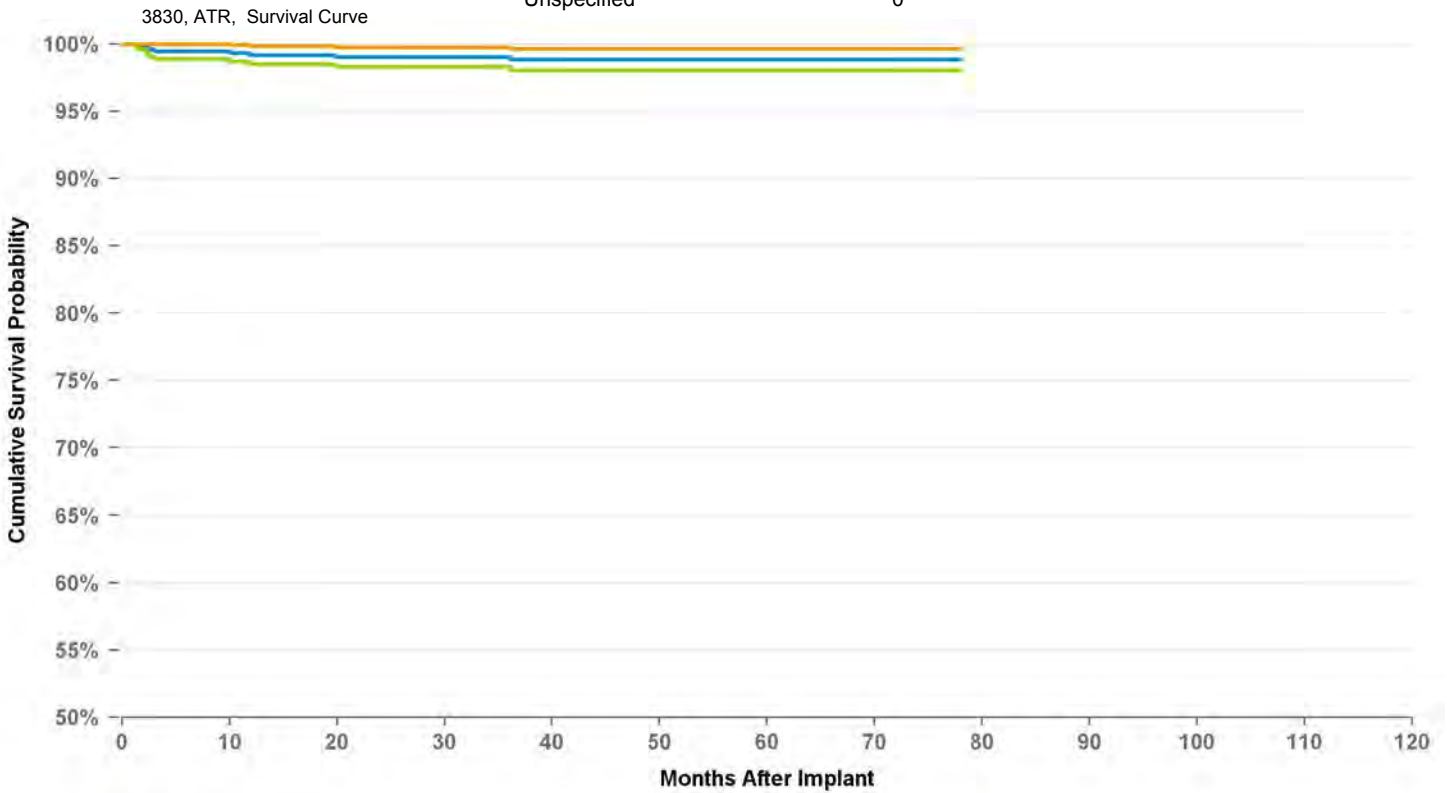
11

US Acute Lead Observations

Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	37
Oversensing	3
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	23
Other	3



Graph Name

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

Years	1	2	3	4	5	6	at 78 mo
%	99.2%	99.0%	99.0%	98.8%	98.8%	98.8%	98.8%
#	749	628	527	291	135	65	56

PACING LEAD

3830

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	3-Aug-05
CE Approval Date	31-Jan-03
Registered US Implants	25,141
Estimated Active US	17,647

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	582
Cumulative Months of Follow-Up	22,640
Number of Leads Active in Study	310

Product Surveillance Registry Qualifying Complications

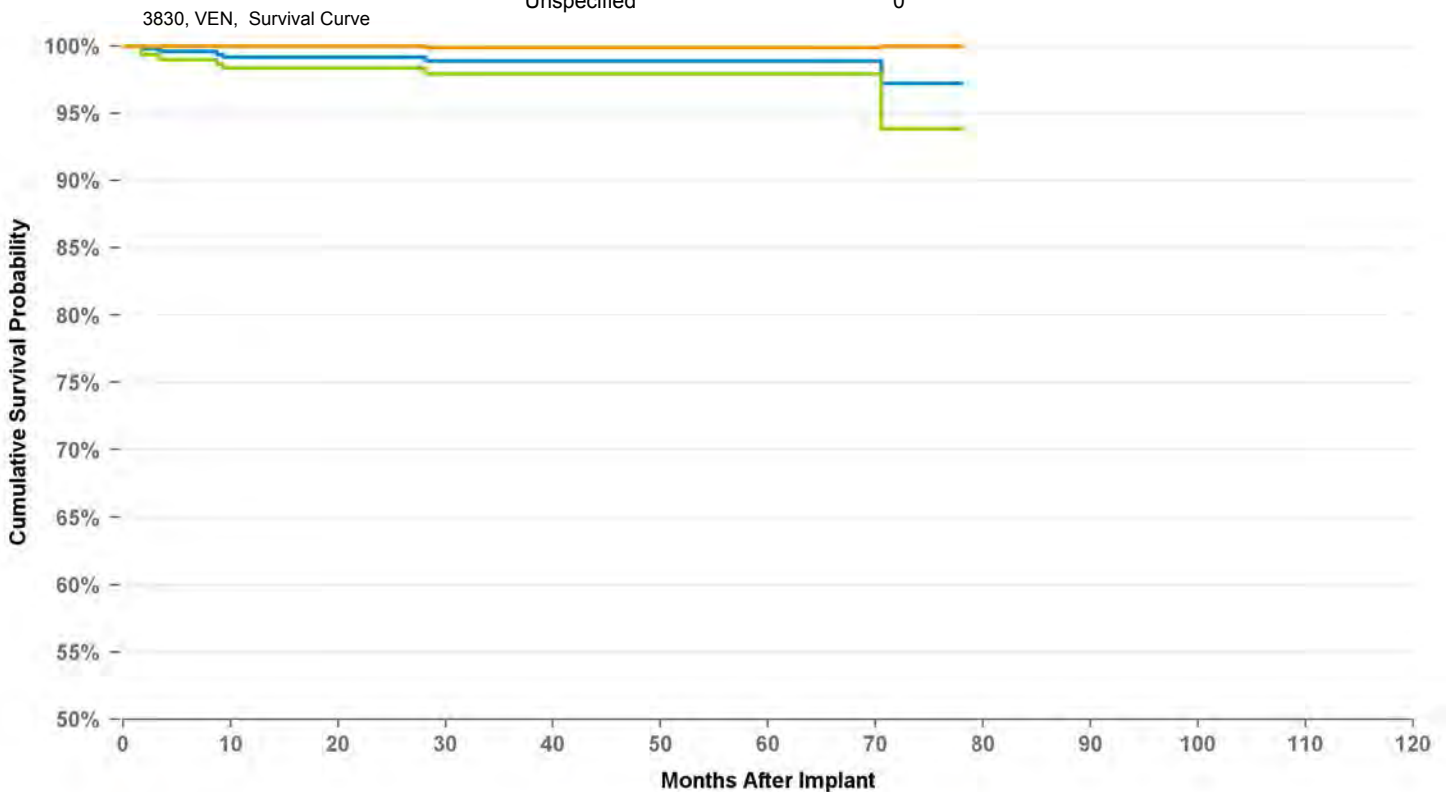
Cardiac Perforation	7
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	37
Oversensing	3
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	23
Other	3



Graph Name

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

Years	1	2	3	4	5	6	at 78 mo
%	99.2%	99.2%	98.9%	98.9%	98.9%	97.2%	97.2%
#	477	398	320	167	91	54	51

PACING LEAD

4024

Distribution Data

US Market Release	1-Oct-91
CE Approval Date	
Registered US Implants	218,694
Estimated Active US	29,777

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,219
Cumulative Months of Follow-Up	25,314
Number of Leads Active in Study	4

Product Surveillance Registry Qualifying Complications

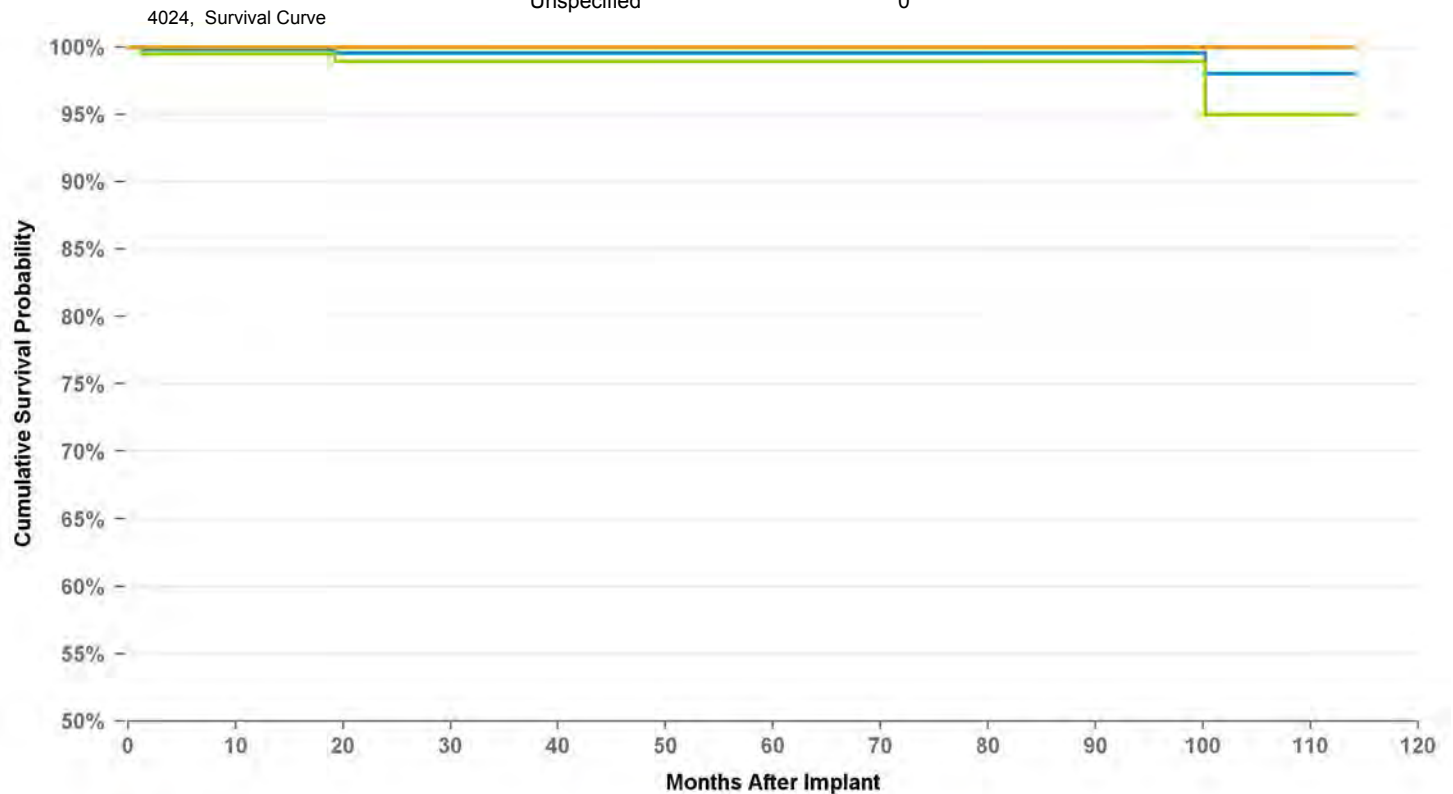
	4
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	13
Conductor Fracture	11
Extracardiac Stimulation	2
Failure To Capture	104
Failure To Sense	16
Impedance Abnormal	8
Insulation Breach	1
Lead Dislodgement	49
Oversensing	2
Unspecified	20

USA Returned Product Analysis

Conductor Fracture	29
Crimp Weld Bond	0
Insulation Breach	216
Other	12



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 114 mo
%	99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	98.0%	98.0%
#	432	323	252	184	147	118	94	70	60	50

PACING LEAD

4068

ATRIAL PLACEMENT

Distribution Data

US Market Release	29-Mar-96
CE Approval Date	
Registered US Implants	124,288
Estimated Active US	22,704

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,430
Cumulative Months of Follow-Up	125,607
Number of Leads Active in Study	156

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	0
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	3
Failure To Capture	23
Failure To Sense	15
Impedance Abnormal	13
Insulation Breach (ESC)	2
Insulation Breach (MIO)	2
Insulation Breach (not further defined)	2
Lead Dislodgement	8
Medical Judgment	0
Other Complication	0
Oversensing	18
Unspecified	3

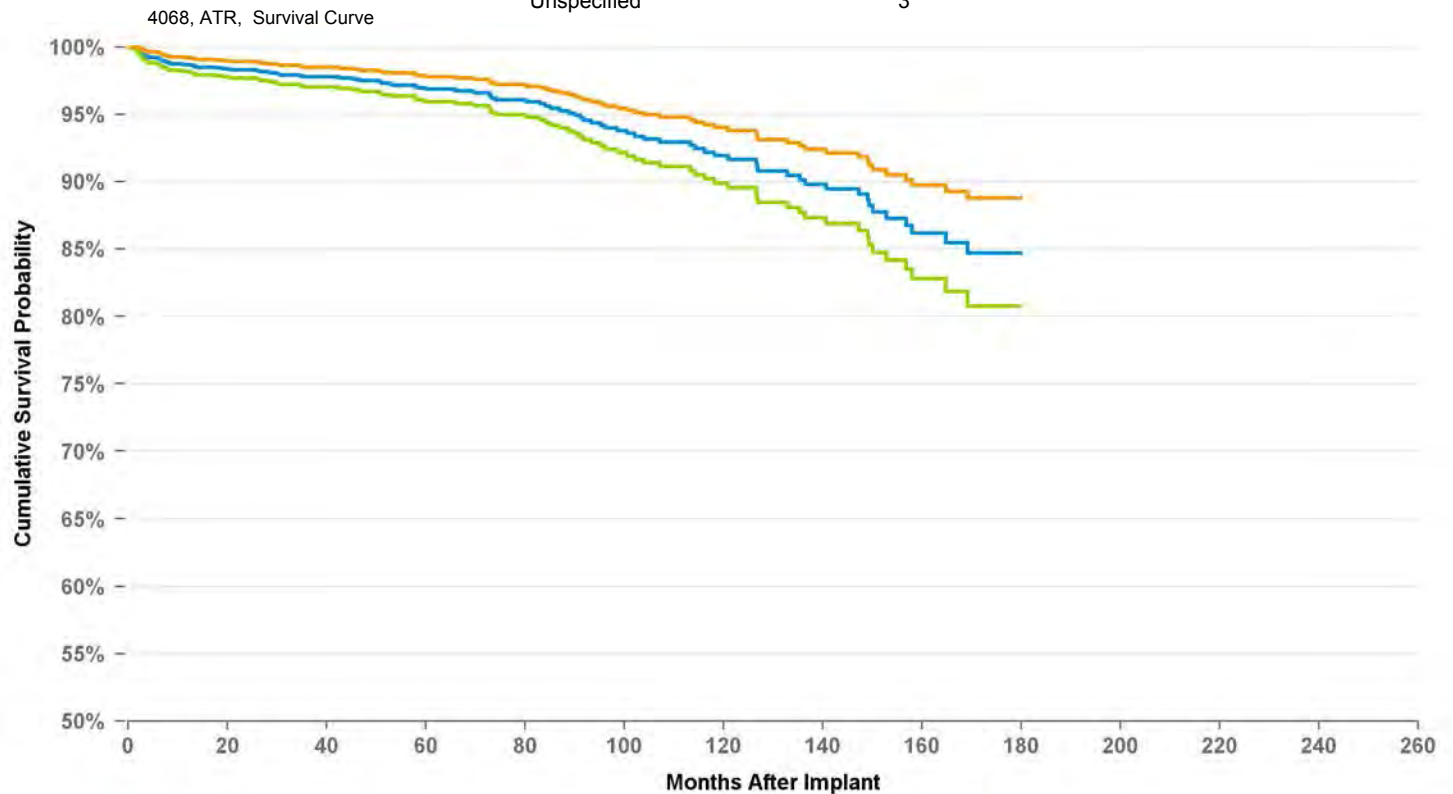
93

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	54
Crimp Weld Bond	0
Insulation Breach	216
Other	94



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 180 mo
%	98.7%	98.3%	97.8%	97.5%	96.9%	96.6%	95.8%	94.2%	92.9%	91.9%	90.8%	89.5%	87.3%	85.5%	84.7%
#	1,612	1,397	1,198	1,021	874	737	586	486	402	342	289	230	159	103	65

PACING LEAD

4068

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	29-Mar-96
CE Approval Date	
Registered US Implants	124,288
Estimated Active US	22,704

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,808
Cumulative Months of Follow-Up	92,354
Number of Leads Active in Study	69

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	24
Failure To Sense	5
Impedance Abnormal	22
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	2
Oversensing	10
Unspecified	2

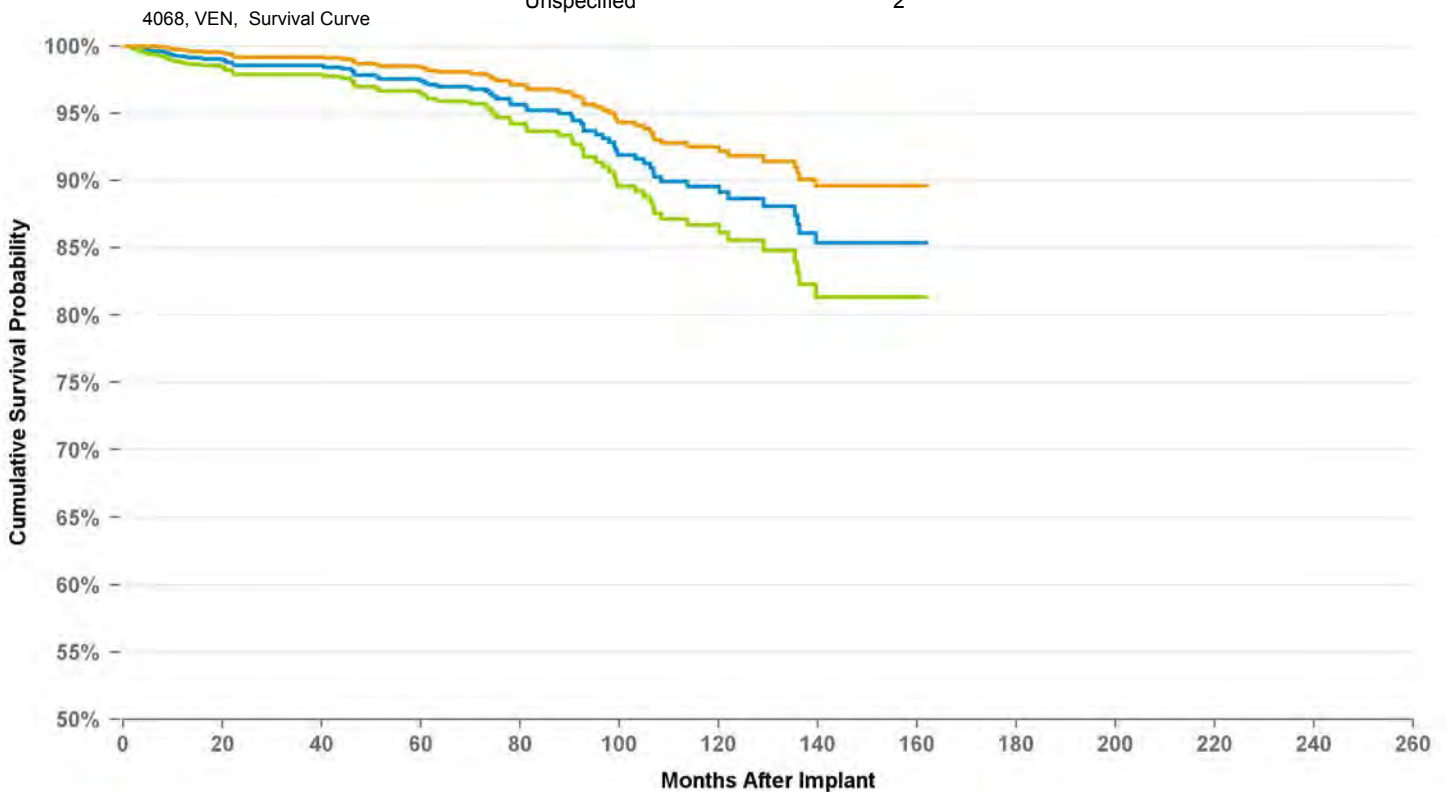
71

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	54
Crimp Weld Bond	0
Insulation Breach	216
Other	94



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	at 162 mo
%	99.2%	98.5%	98.5%	97.8%	97.4%	96.8%	95.2%	93.4%	90.3%	89.6%	88.1%	85.4%	85.4%	85.4%
#	1,292	1,112	966	804	668	533	422	331	263	200	140	99	68	56

PACING LEAD

4073

Distribution Data

US Market Release	23-Jun-02
CE Approval Date	1-Feb-02
Registered US Implants	771
Estimated Active US	305

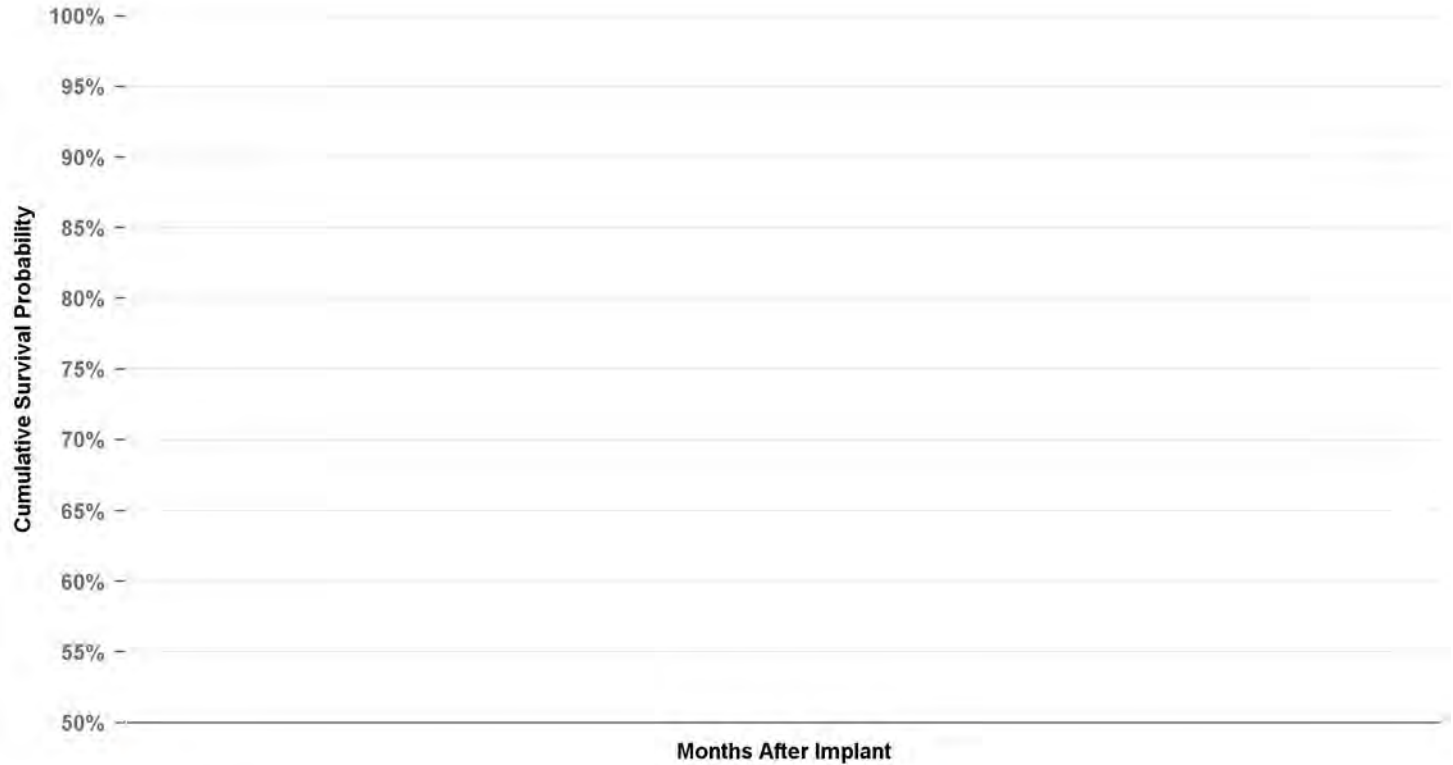
Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance Registry Results

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

4073, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	0

USA Returned Product Analysis

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

PACING LEAD

4074

ATRIAL PLACEMENT

Distribution Data

US Market Release	23-Jun-02
CE Approval Date	1-Feb-02
Registered US Implants	103,552
Estimated Active US	58,507

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	17,011
Number of Leads Active in Study	116

Product Surveillance Registry Qualifying Complications

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

2

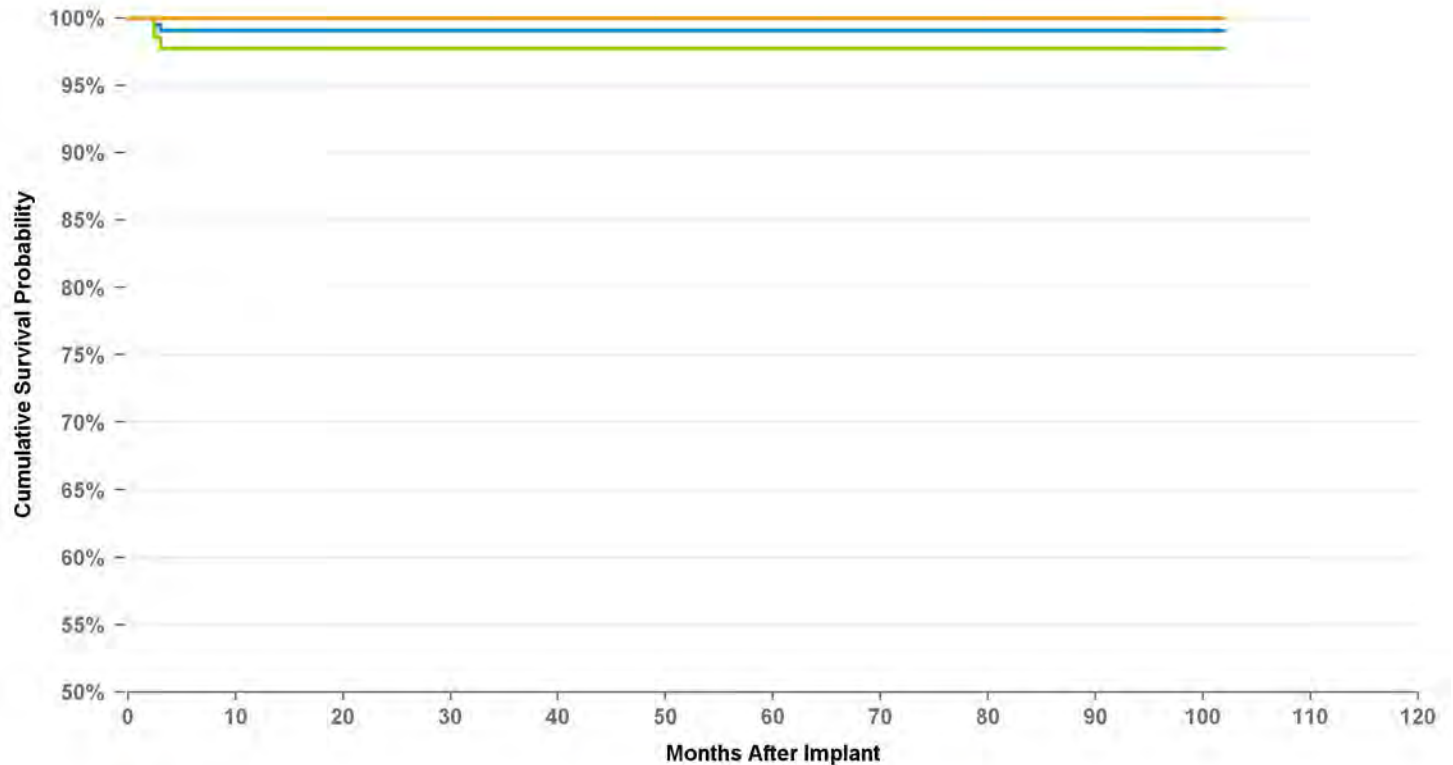
US Acute Lead Observations

Cardiac Perforation	17
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	46
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	55
Oversensing	1
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	0
Insulation Breach	30
Other	0

4074, 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	at 102 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	201	191	184	167	152	140	123	90	69

PACING LEAD

4074

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	23-Jun-02
CE Approval Date	1-Feb-02
Registered US Implants	103,552
Estimated Active US	58,507

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,089
Cumulative Months of Follow-Up	45,069
Number of Leads Active in Study	520

Product Surveillance Registry Qualifying Complications

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	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

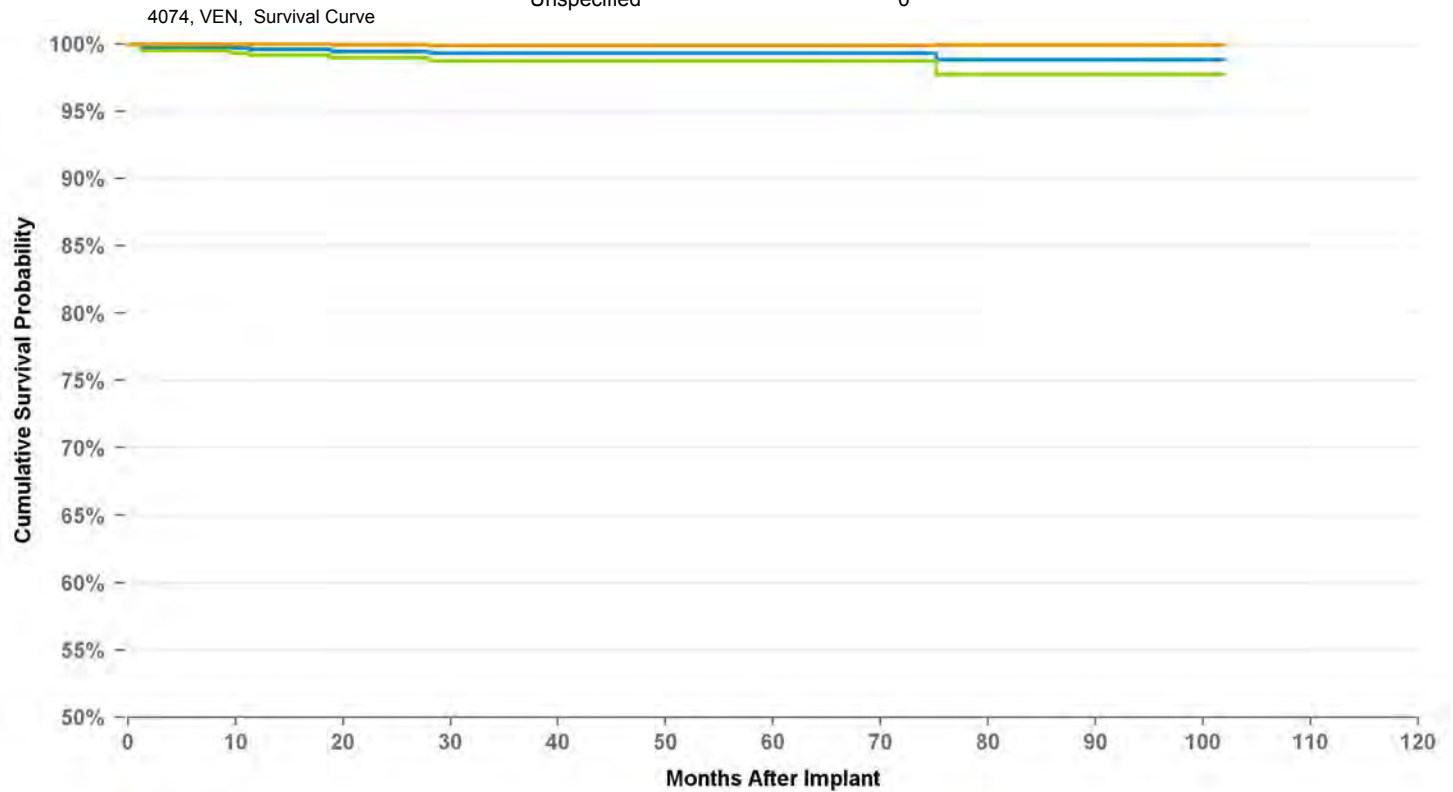
7

US Acute Lead Observations

Cardiac Perforation	17
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	46
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	55
Oversensing	1
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	0
Insulation Breach	30
Other	0



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
%	99.6%	99.4%	99.3%	99.3%	99.3%	99.3%	98.8%	98.8%	98.8%
#	897	690	481	355	266	219	162	94	68

PACING LEAD

4076

ATRIAL PLACEMENT

Distribution Data

US Market Release	25-Feb-04
CE Approval Date	14-Jun-04
Registered US Implants	519,023
Estimated Active US	361,468

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,762
Cumulative Months of Follow-Up	102,862
Number of Leads Active in Study	1,598

Product Surveillance Registry Qualifying Complications

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

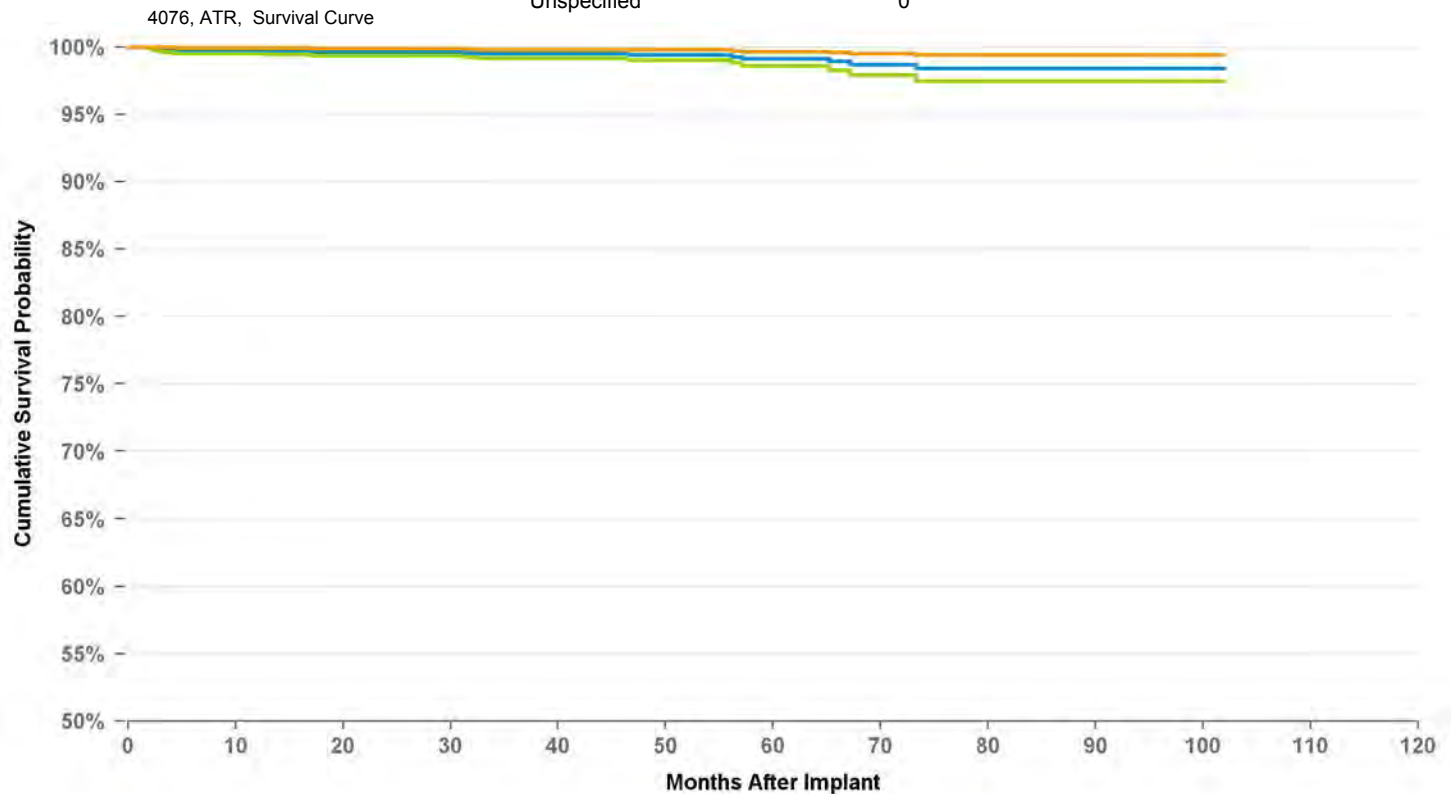
17

US Acute Lead Observations

Cardiac Perforation	75
Conductor Fracture	4
Extracardiac Stimulation	12
Failure To Capture	98
Failure To Sense	27
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	236
Oversensing	15
Unspecified	12

USA Returned Product Analysis

Conductor Fracture	62
Crimp Weld Bond	1
Insulation Breach	66
Other	22



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%	99.6%	99.5%	99.4%	99.1%	98.7%	98.4%	98.4%	98.4%
#	2,134	1,660	1,300	981	585	300	212	98	55

PACING LEAD

4076

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	25-Feb-04
CE Approval Date	14-Jun-04
Registered US Implants	519,023
Estimated Active US	361,468

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,444
Cumulative Months of Follow-Up	67,467
Number of Leads Active in Study	606

Product Surveillance Registry Qualifying Complications

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	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

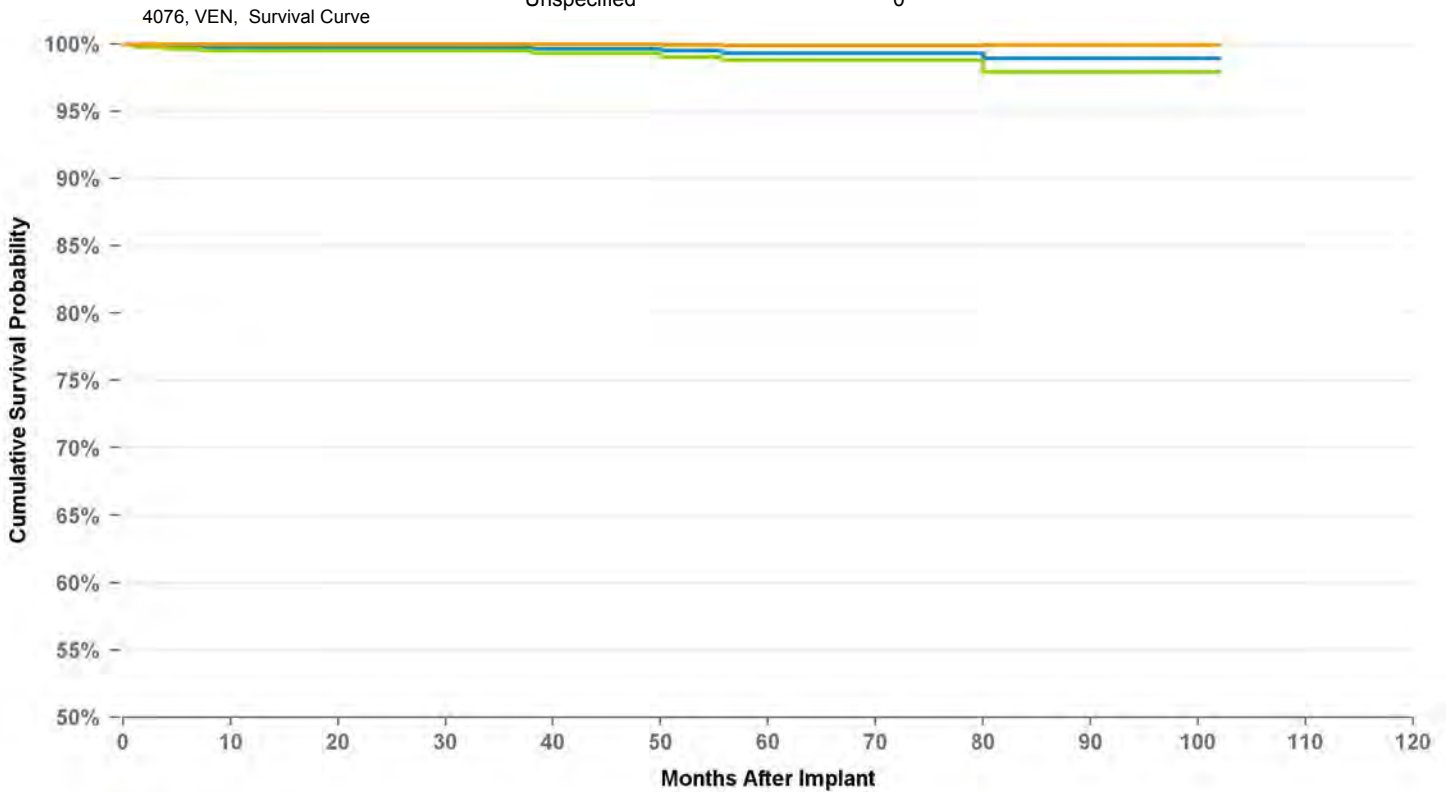
7

US Acute Lead Observations

Cardiac Perforation	75
Conductor Fracture	4
Extracardiac Stimulation	12
Failure To Capture	98
Failure To Sense	27
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	236
Oversensing	15
Unspecified	12

USA Returned Product Analysis

Conductor Fracture	62
Crimp Weld Bond	1
Insulation Breach	66
Other	22



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
%	99.8%	99.8%	99.8%	99.6%	99.3%	99.3%	98.9%	98.9%	98.9%
#	1,203	1,017	875	718	473	287	200	104	65

PACING LEAD

4092

Distribution Data

US Market Release	17-Sep-98
CE Approval Date	15-Apr-98
Registered US Implants	184,935
Estimated Active US	70,564

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,179
Cumulative Months of Follow-Up	66,646
Number of Leads Active in Study	37

Product Surveillance Registry Qualifying Complications

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

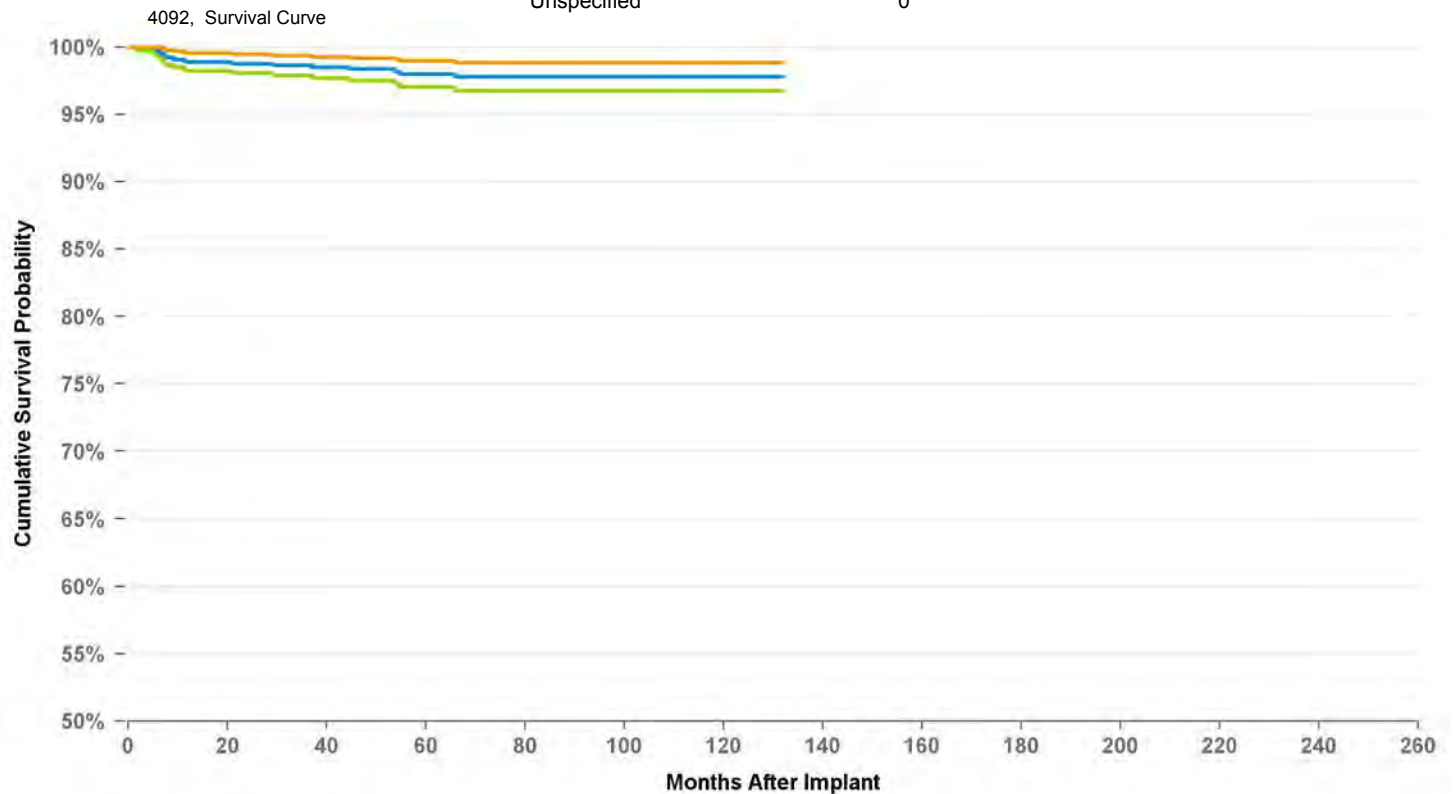
18

US Acute Lead Observations

Cardiac Perforation	3
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	34
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	32
Oversensing	1
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	0
Insulation Breach	62
Other	2



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%
#	932	816	725	622	507	394	322	259	210	130	64

PACING LEAD

4524

Distribution Data

US Market Release	1-Oct-91
CE Approval Date	
Registered US Implants	100,336
Estimated Active US	17,626

Product Characteristics

Fixation Type	J-Shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	918
Cumulative Months of Follow-Up	23,510
Number of Leads Active in Study	25

Product Surveillance Registry Qualifying Complications

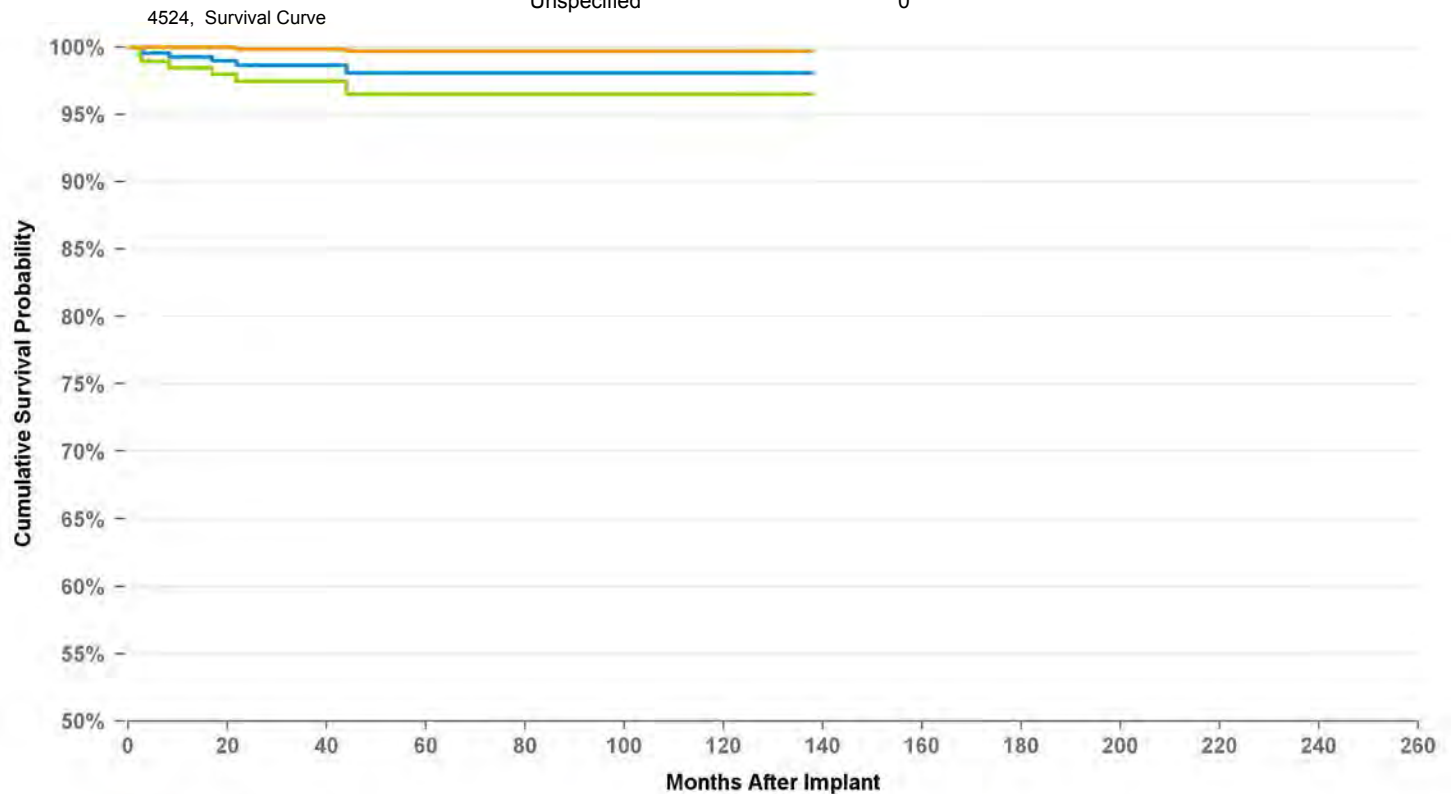
	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	16
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	89
Other	3



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%
#	364	276	217	163	131	106	86	75	66	55	53	52

PACING LEAD

4558M

Distribution Data

US Market Release	14-Nov-94
CE Approval Date	
Registered US Implants	19,590
Estimated Active US	2,804
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	540
Cumulative Months of Follow-Up	18,671
Number of Leads Active in Study	1

Product Surveillance 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

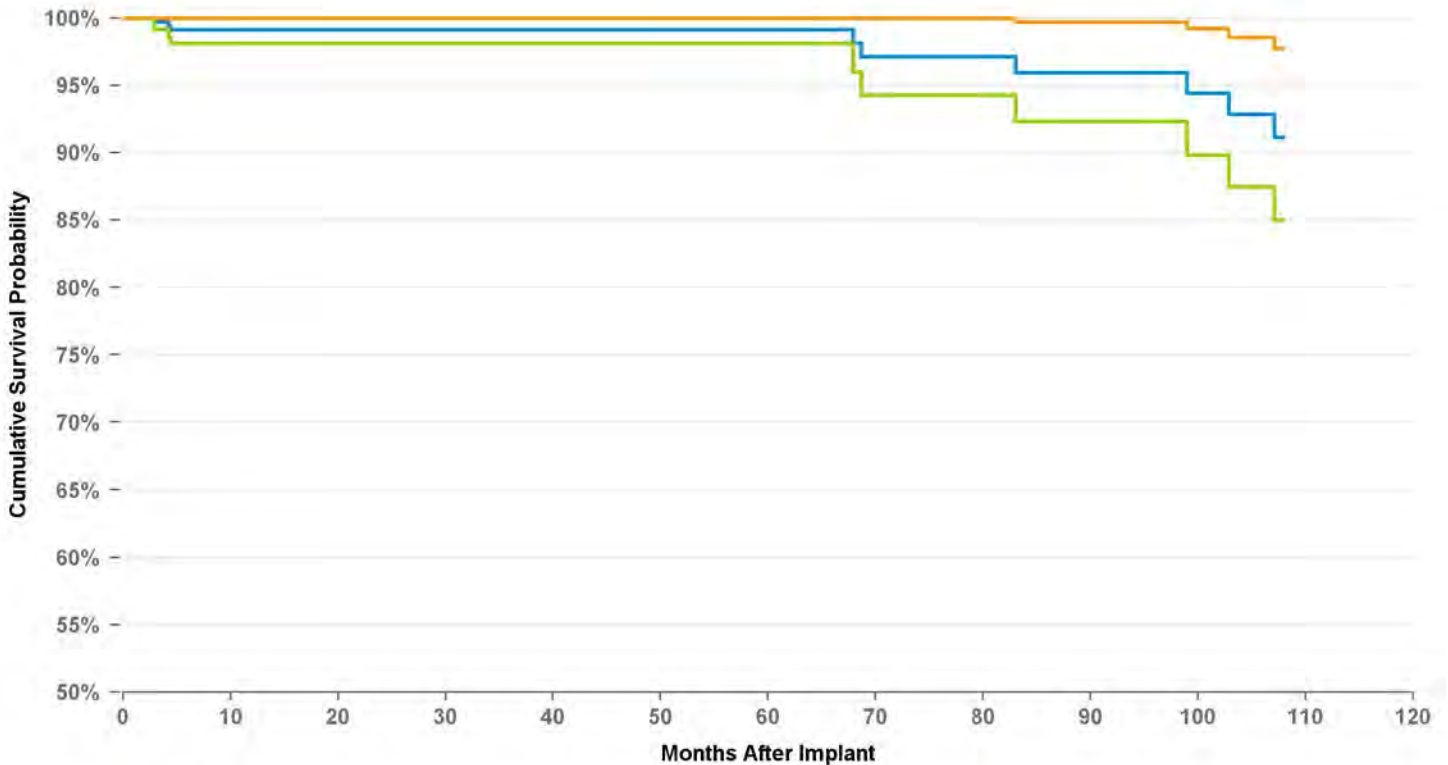
US Acute Lead Observations

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	28
Other	21

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	2-Jan-97
CE Approval Date	
Registered US Implants	69,217
Estimated Active US	16,111

Product Characteristics

Fixation Type	J-shape, screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	670
Cumulative Months of Follow-Up	31,881
Number of Leads Active in Study	12

Product Surveillance Registry Qualifying Complications

37

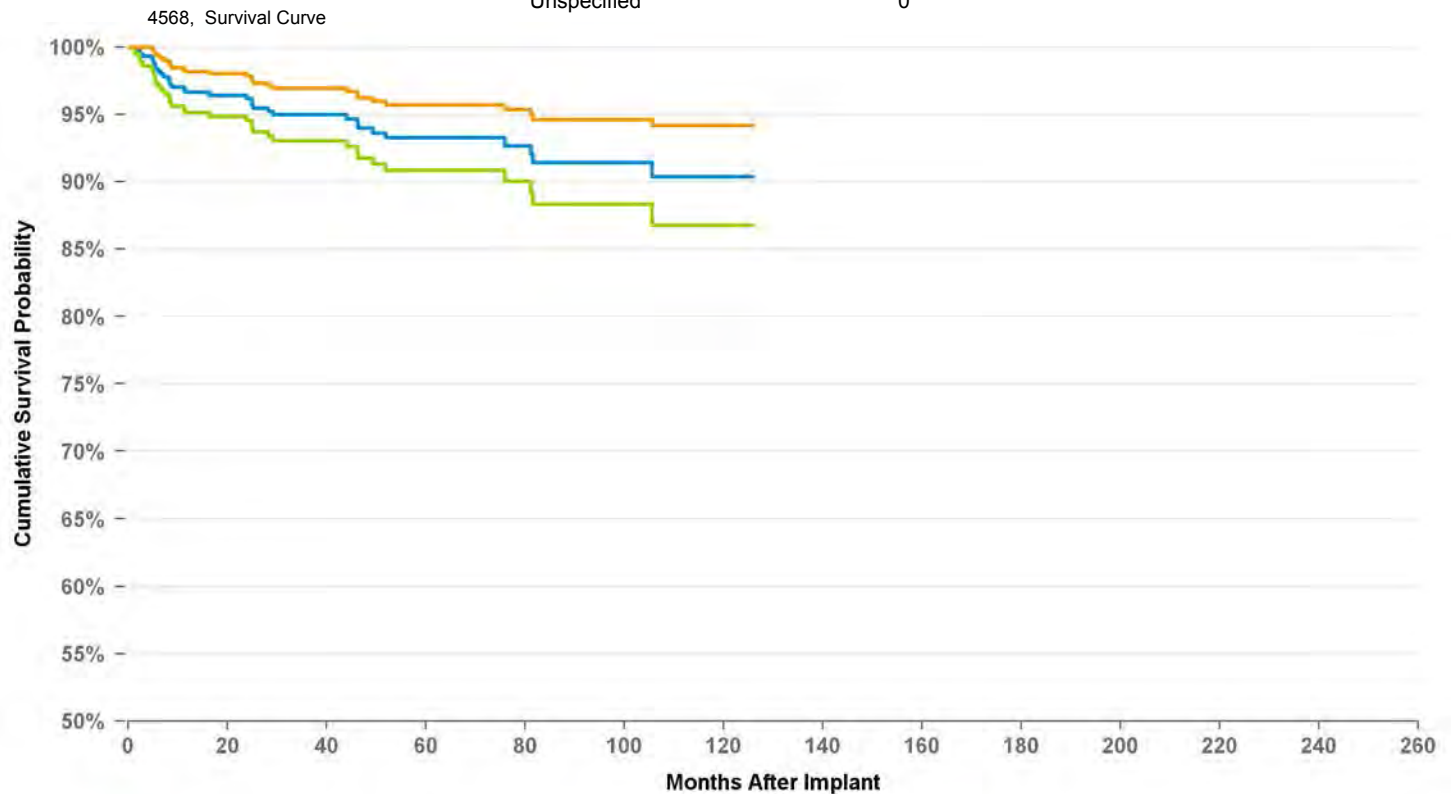
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	19
Failure To Sense	4
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	9
Medical Judgment	1
Other Complication	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	8
Crimp Weld Bond	0
Insulation Breach	106
Other	52



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
%	96.6%	96.2%	95.0%	94.0%	93.3%	93.3%	91.4%	91.4%	90.4%	90.4%	90.4%
#	491	416	326	276	228	172	138	106	84	63	51

PACING LEAD

4574

Distribution Data

US Market Release	23-Jun-02
CE Approval Date	1-Feb-02
Registered US Implants	70,808
Estimated Active US	43,342

Product Characteristics

Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	795
Cumulative Months of Follow-Up	16,912
Number of Leads Active in Study	550

Product Surveillance Registry Qualifying Complications

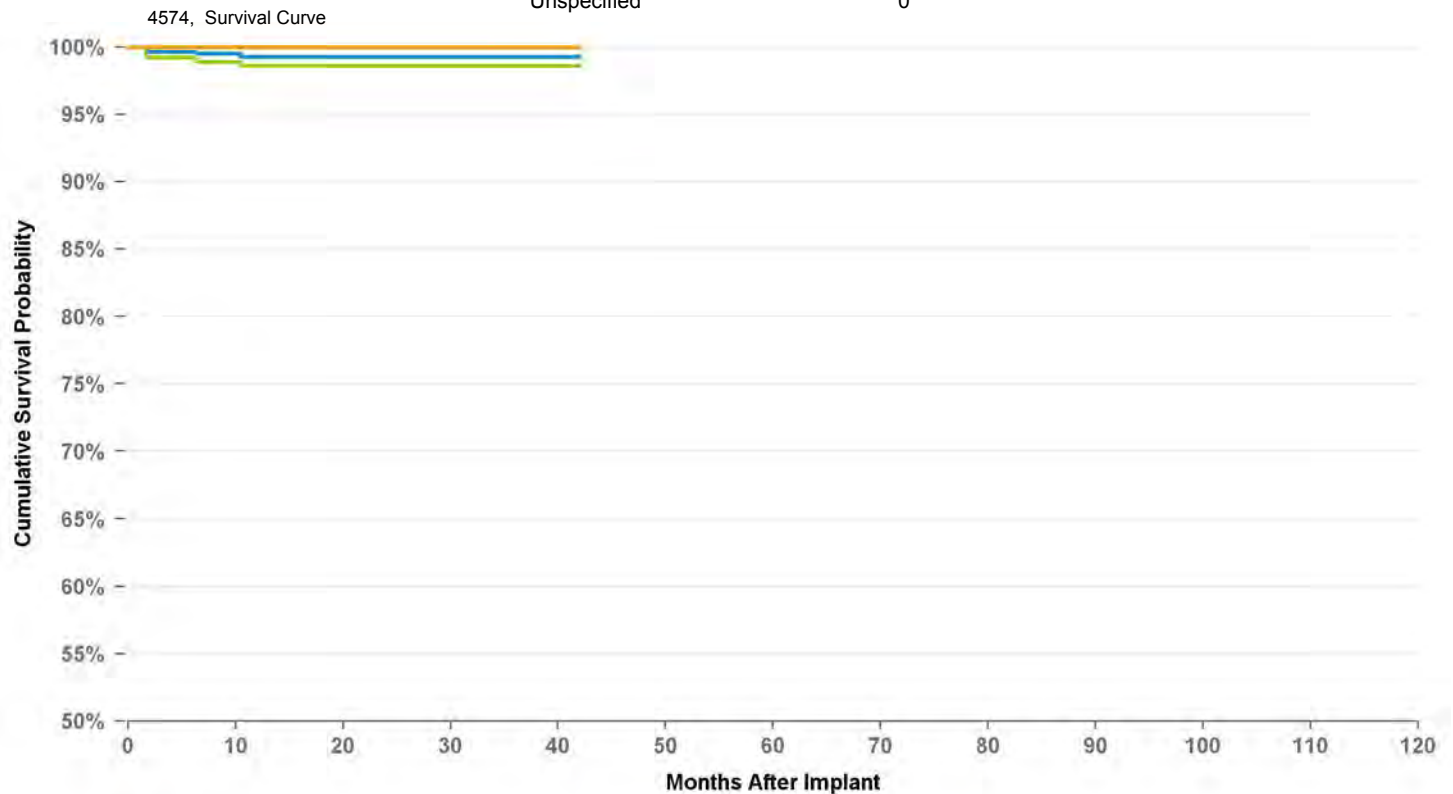
	4
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	26
Failure To Sense	9
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	68
Oversensing	1
Unspecified	4

USA Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	8
Other	0



Graph Name

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

Years	1	2	3	at 42 mo
%	99.3%	99.3%	99.3%	99.3%
#	500	321	150	100

PACING LEAD

4592

Distribution Data

US Market Release	5-Oct-98
CE Approval Date	15-Apr-98
Registered US Implants	88,741
Estimated Active US	35,565

Product Characteristics

Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	333
Cumulative Months of Follow-Up	16,401
Number of Leads Active in Study	58

Product Surveillance Registry Qualifying Complications

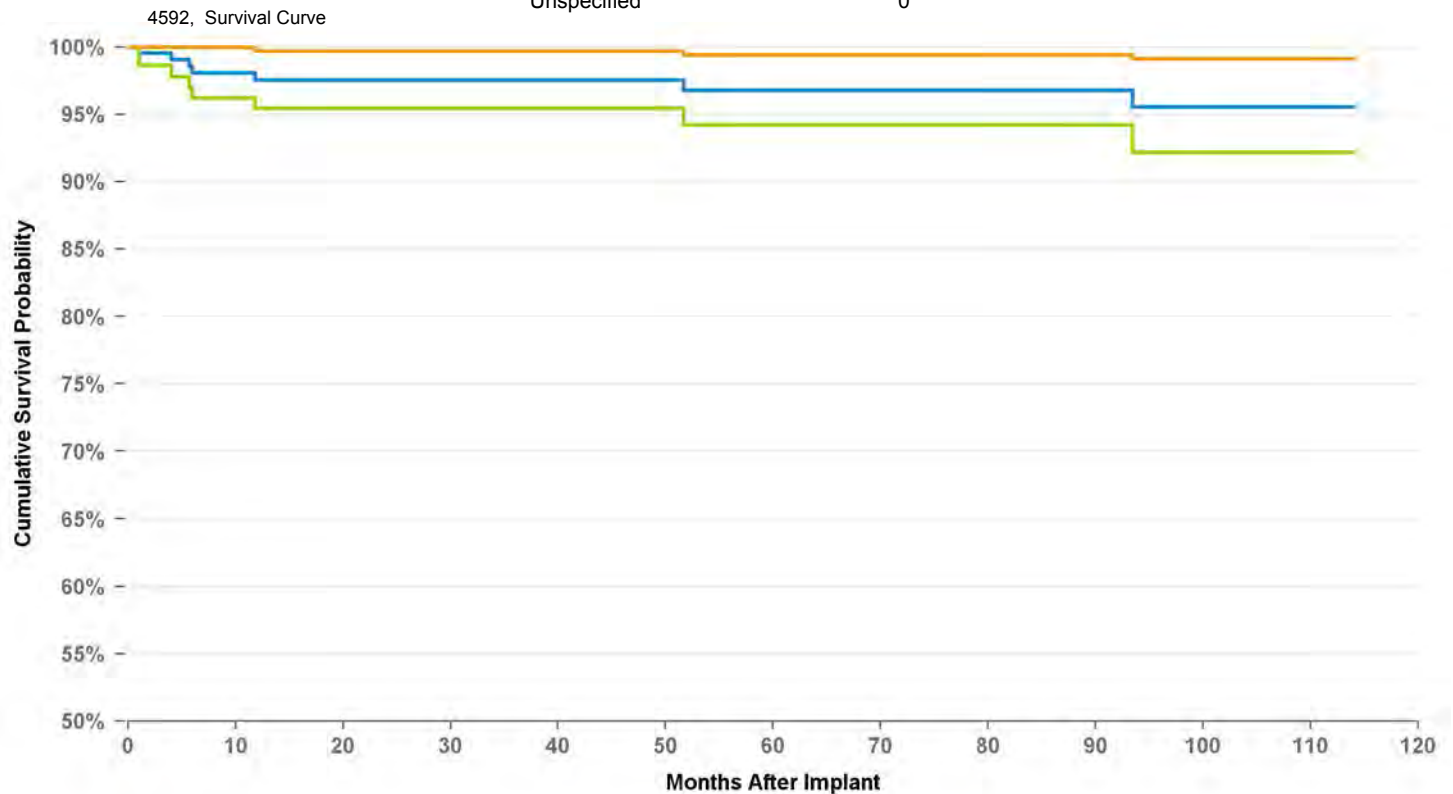
	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	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	34
Oversensing	2
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	8
Crimp Weld Bond	0
Insulation Breach	22
Other	1



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 114 mo
%	97.6%	97.6%	97.6%	97.6%	96.8%	96.8%	96.8%	95.6%	95.6%	95.6%
#	214	181	157	141	115	100	81	71	61	52

PACING LEAD

5033

Distribution Data

US Market Release	9-Feb-96
CE Approval Date	
Registered US Implants	2,343
Estimated Active US	367
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance 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

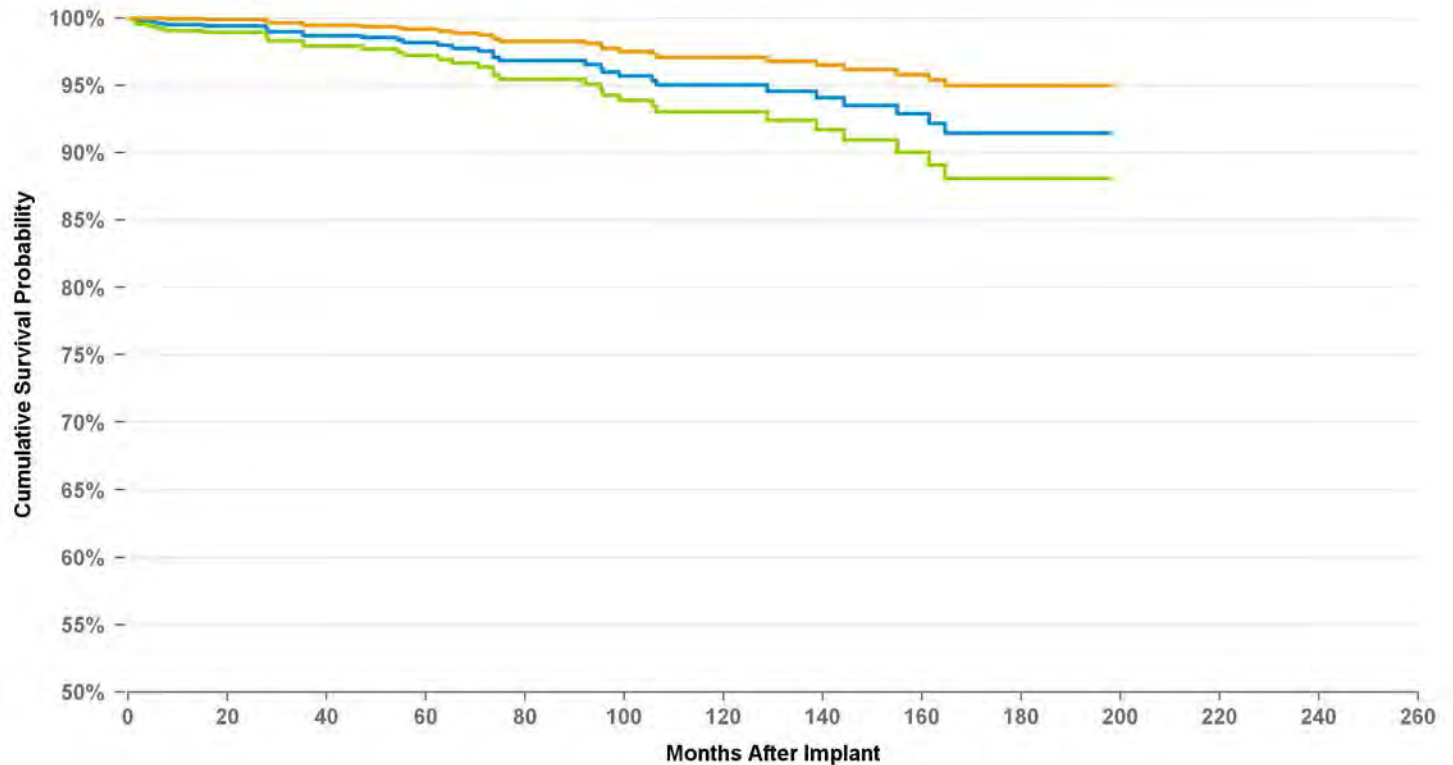
USA Returned Product Analysis

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,901
Cumulative Months of Follow-Up	77,505
Number of Leads Active in Study	28

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	16	at 198 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%	91.5%
#	902	762	672	584	510	436	379	326	276	236	197	169	146	119	101	68	51

PACING LEAD

5034

ATRIAL PLACEMENT

Distribution Data

US Market Release	9-Feb-96
CE Approval Date	
Registered US Implants	55,384
Estimated Active US	9,460
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Qualifying Complications

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

6

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

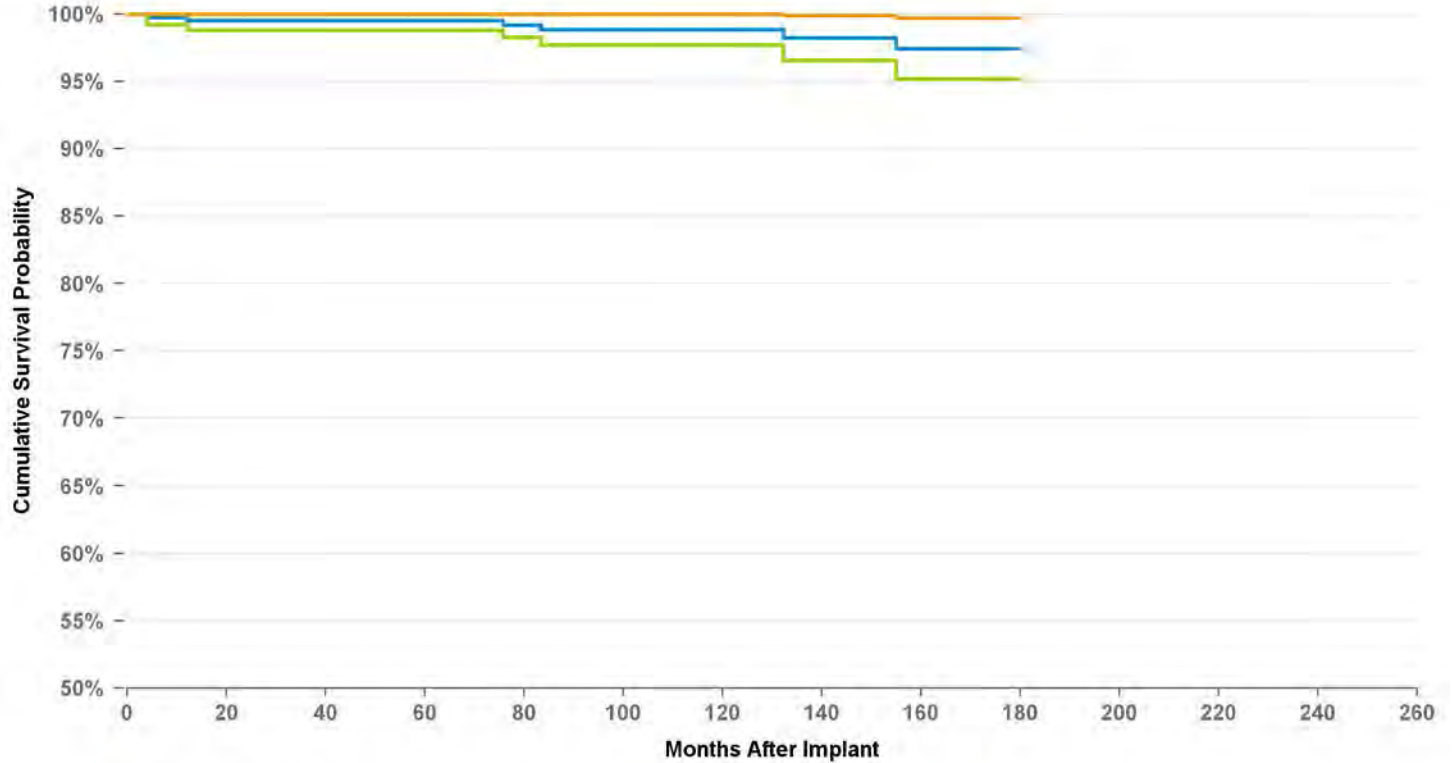
USA Returned Product Analysis

Conductor Fracture	18
Crimp Weld Bond	0
Insulation Breach	15
Other	7

Product Surveillance Registry Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	47,376
Number of Leads Active in Study	78

5034, 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 180 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%	97.4%
#	383	382	379	376	358	334	297	253	212	187	156	138	123	92	53

PACING LEAD

5034

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	9-Feb-96
CE Approval Date	
Registered US Implants	55,384
Estimated Active US	9,460
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,213
Cumulative Months of Follow-Up	28,180
Number of Leads Active in Study	8

Product Surveillance Registry Qualifying Complications

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

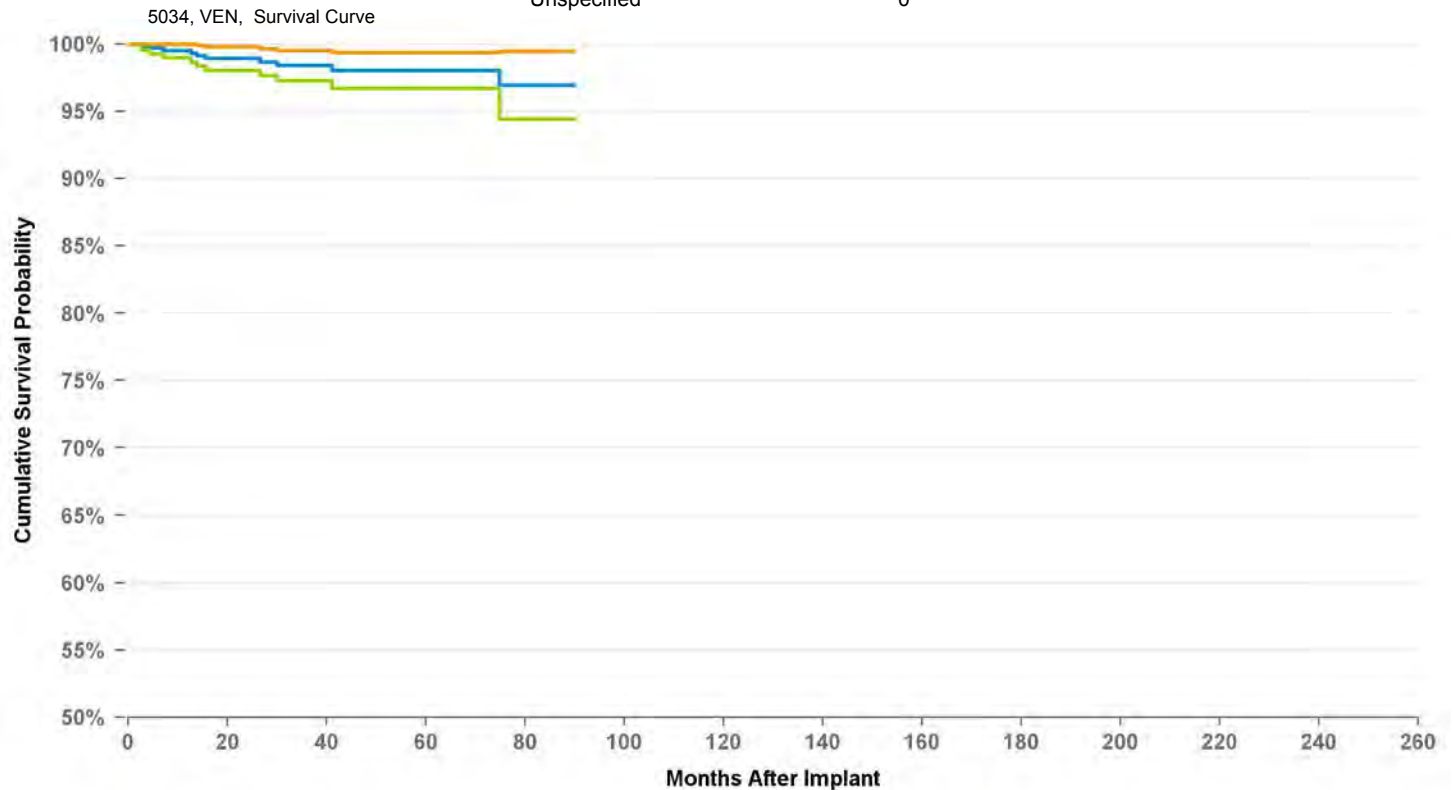
11

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	18
Crimp Weld Bond	0
Insulation Breach	15
Other	7



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

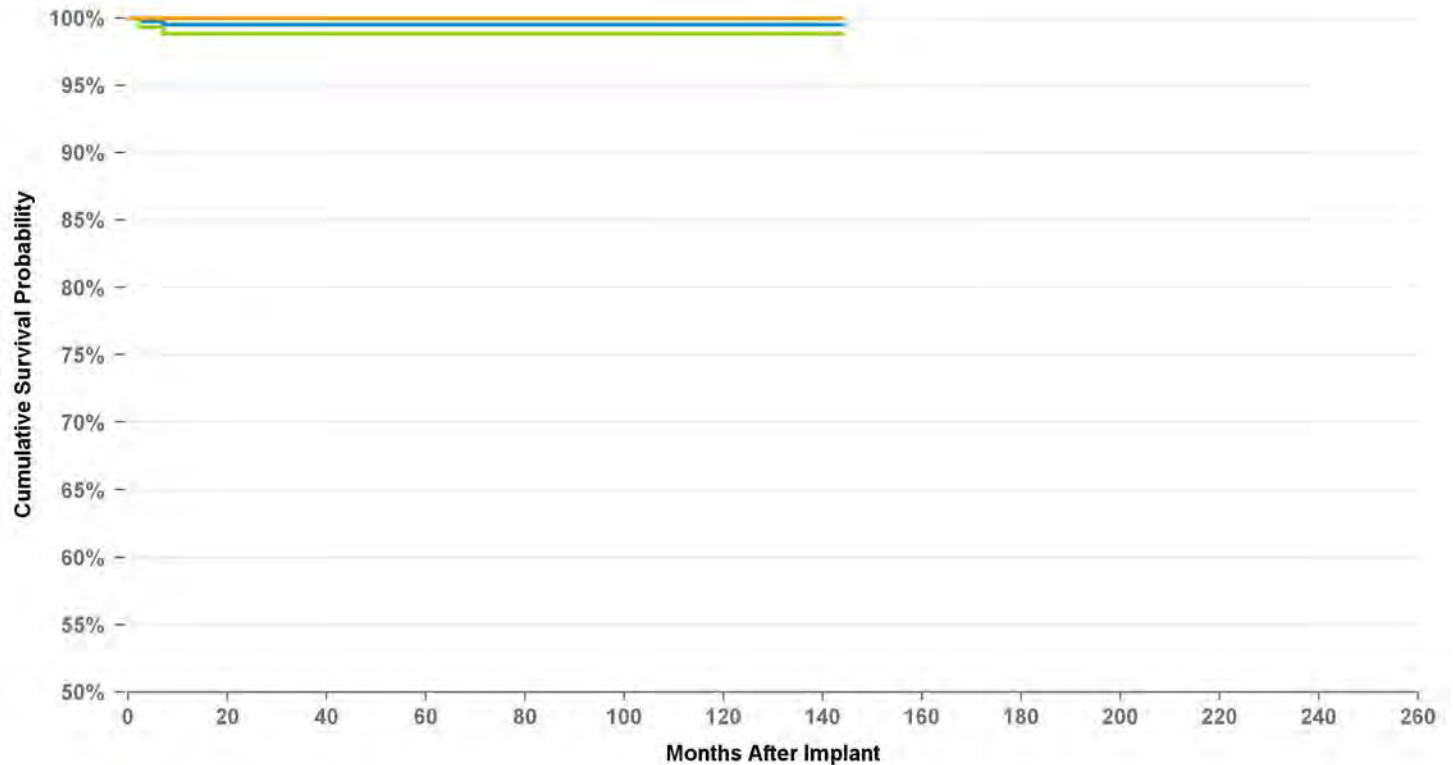
Distribution Data

US Market Release	3-Jun-98
CE Approval Date	5-Jun-97
Registered US Implants	98,885
Estimated Active US	35,509
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	36,440
Number of Leads Active in Study	87

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	11	at 144 mo
%	99.5%	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	151	112	80	53

Product Surveillance Registry Qualifying Complications

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

2

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	1
Lead Dislodgement	29
Oversensing	0
Unspecified	9

USA Returned Product Analysis

Conductor Fracture	12
Crimp Weld Bond	1
Insulation Breach	33
Other	3

PACING LEAD

5054

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	3-Jun-98
CE Approval Date	5-Jun-97
Registered US Implants	98,885
Estimated Active US	35,509

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	982
Cumulative Months of Follow-Up	32,077
Number of Leads Active in Study	52

Product Surveillance Registry Qualifying Complications

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

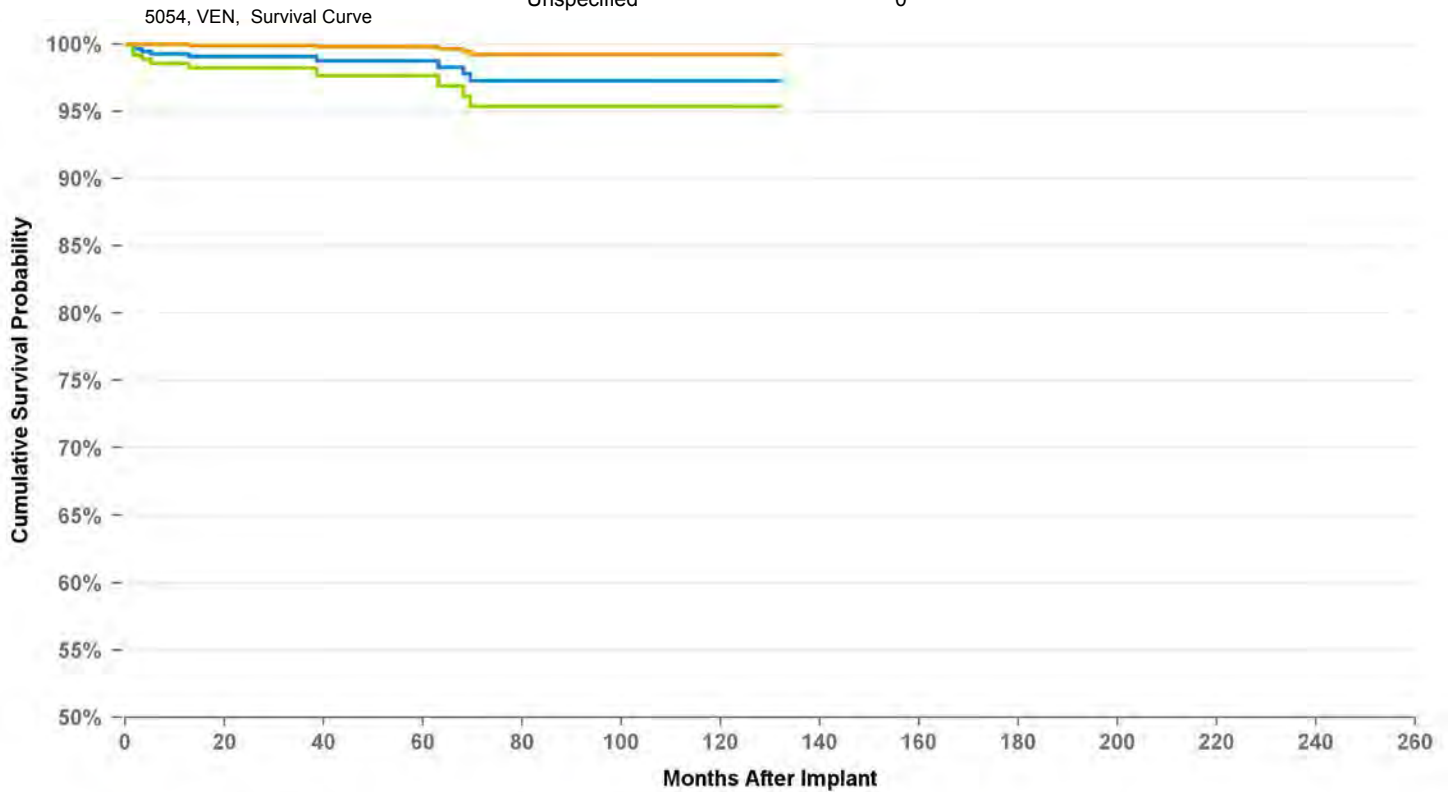
9

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	1
Lead Dislodgement	29
Oversensing	0
Unspecified	9

USA Returned Product Analysis

Conductor Fracture	12
Crimp Weld Bond	1
Insulation Breach	33
Other	3



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
%	99.3%	99.1%	99.1%	98.7%	98.7%	97.3%	97.3%	97.3%	97.3%	97.3%	97.3%
#	477	389	302	260	226	188	163	136	95	68	51

PACING LEAD

5068

ATRIAL PLACEMENT

Distribution Data

US Market Release	2-Jan-97
CE Approval Date	
Registered US Implants	102,365
Estimated Active US	22,179
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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	981
Cumulative Months of Follow-Up	27,150
Number of Leads Active in Study	28

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
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

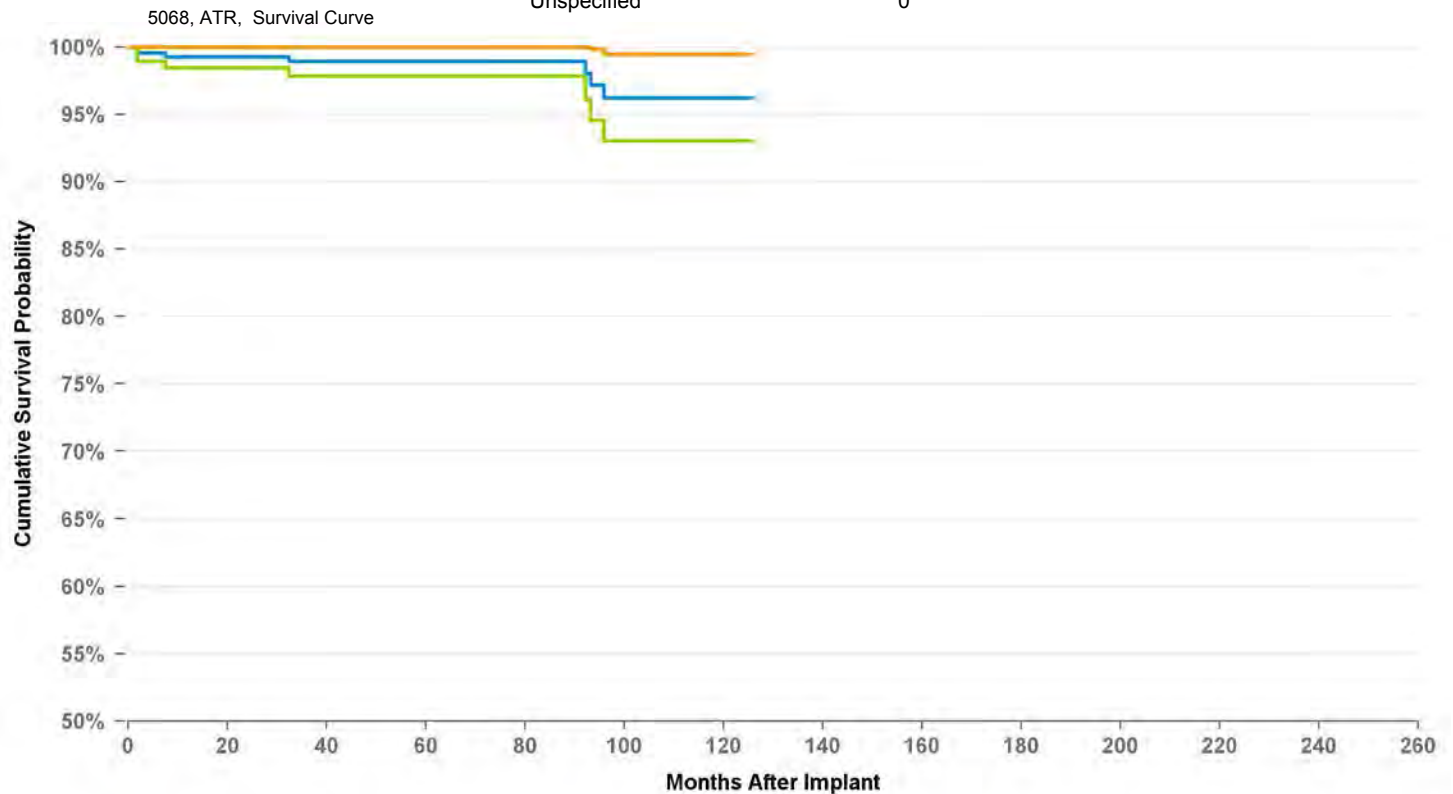
8

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	45
Crimp Weld Bond	2
Insulation Breach	59
Other	82



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%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	96.2%	96.2%	96.2%	96.2%
#	357	309	260	227	194	155	128	99	67	57	50

PACING LEAD

5068

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	2-Jan-97
CE Approval Date	
Registered US Implants	102,365
Estimated Active US	22,179

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,371
Cumulative Months of Follow-Up	31,981
Number of Leads Active in Study	42

Product Surveillance Registry Qualifying Complications

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

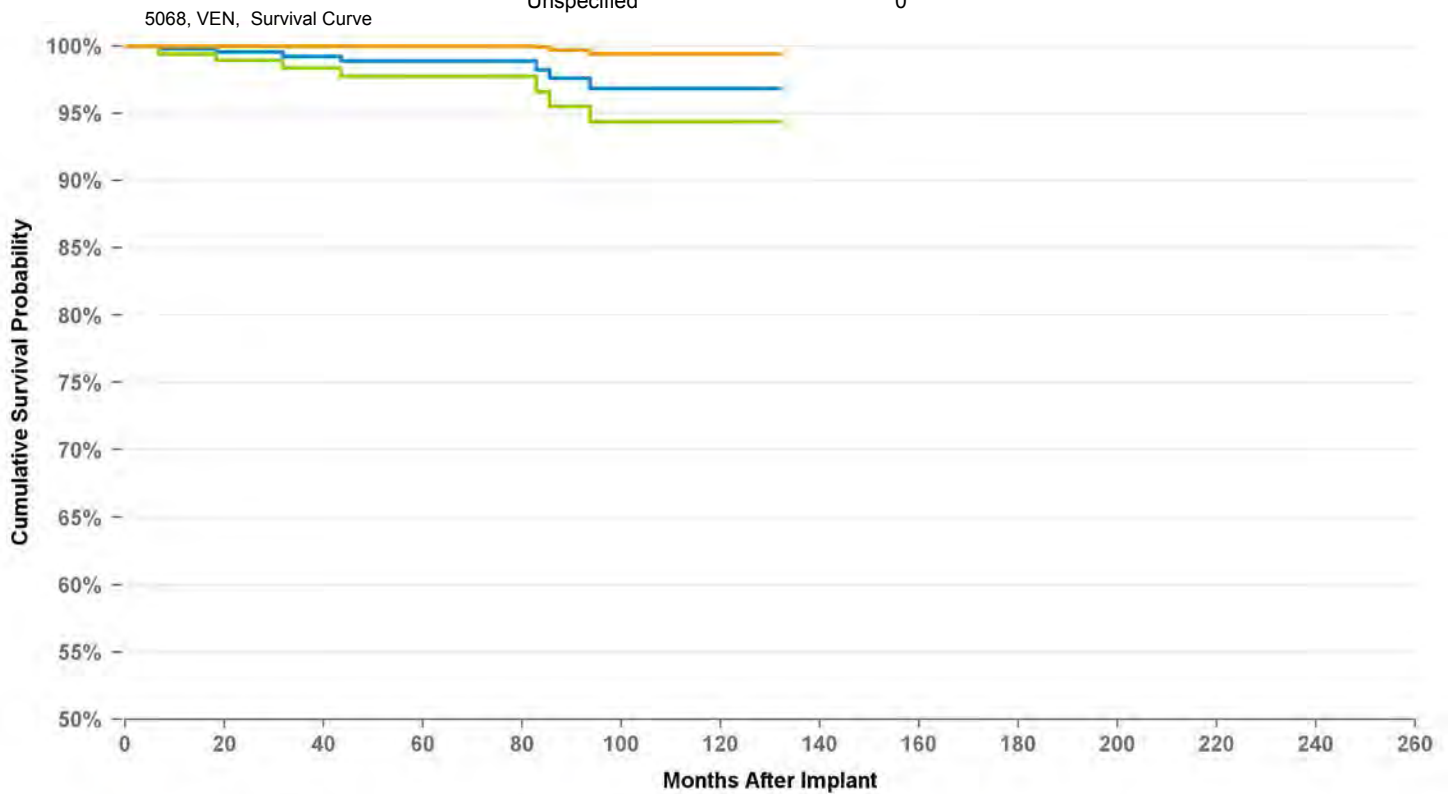
9

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	45
Crimp Weld Bond	2
Insulation Breach	59
Other	82



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
%	99.8%	99.6%	99.2%	98.9%	98.9%	98.9%	98.2%	96.9%	96.9%	96.9%	96.9%
#	451	359	291	246	223	189	151	125	103	83	64

PACING LEAD

5072

Distribution Data

US Market Release	5-Jun-98
CE Approval Date	25-Sep-97
Registered US Implants	10,054
Estimated Active US	3,347

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	514
Cumulative Months of Follow-Up	22,993
Number of Leads Active in Study	13

Product Surveillance Registry Qualifying Complications

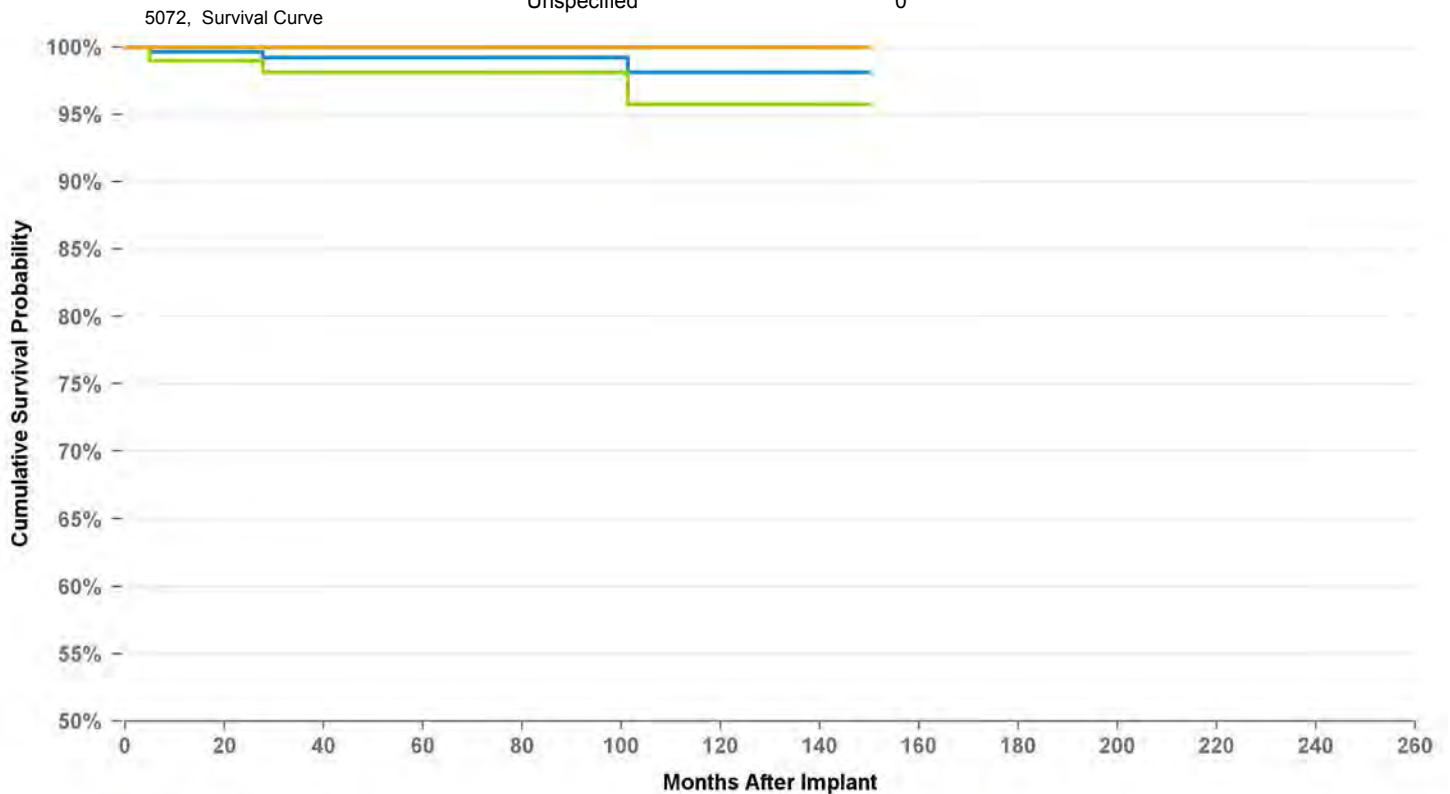
	3
Cardiac Perforation	1
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication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



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%	99.7%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.1%	98.1%	98.1%	98.1%	98.1%
#	261	233	216	191	157	136	109	93	83	73	63	54	52

PACING LEAD

5076

ATRIAL PLACEMENT

Distribution Data

US Market Release	31-Aug-00
CE Approval Date	12-Aug-99
Registered US Implants	1,871,477
Estimated Active US	1,134,484

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	5,747
Cumulative Months of Follow-Up	208,187
Number of Leads Active in Study	2,992

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	1
Conductor Fracture	7
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

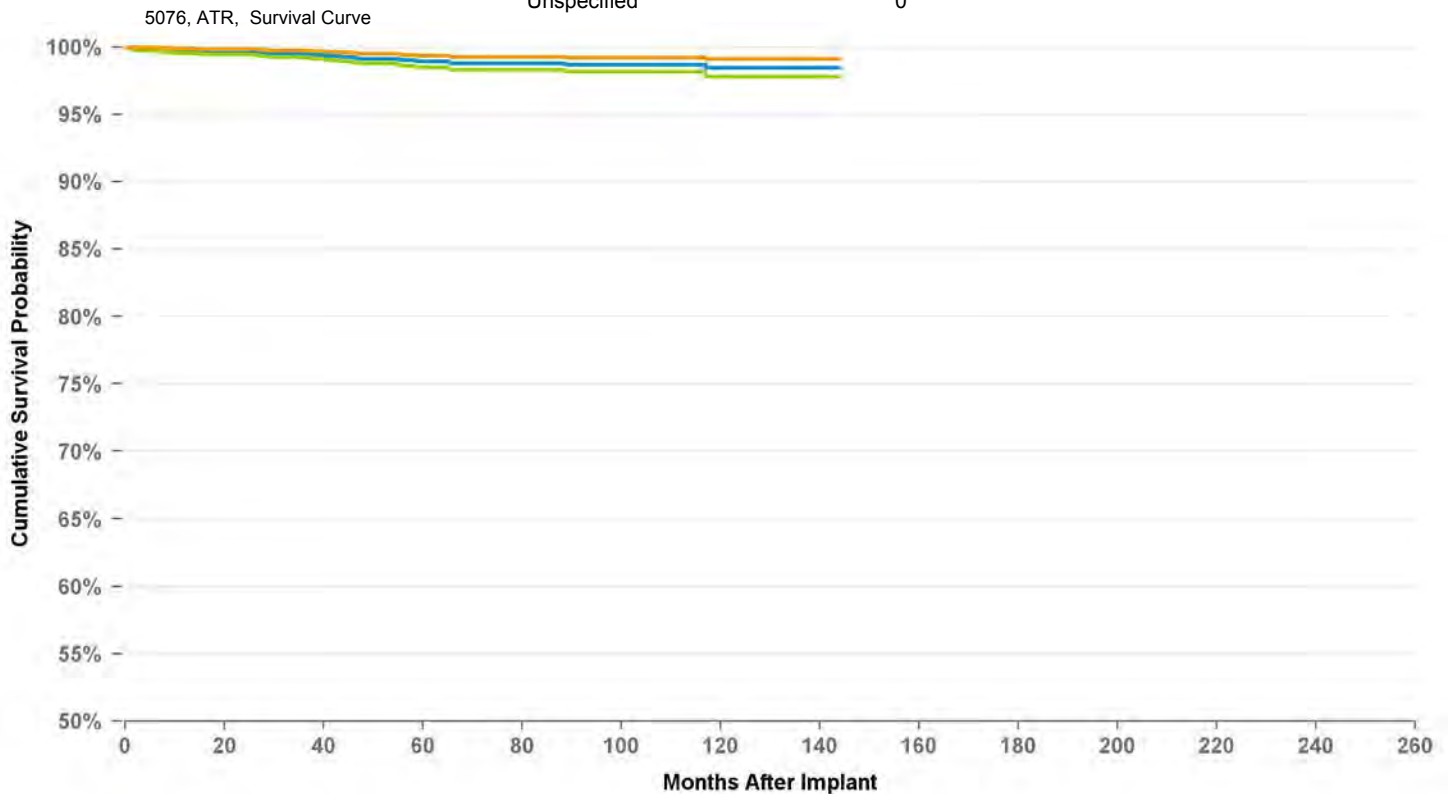
32

US Acute Lead Observations

Cardiac Perforation	372
Conductor Fracture	17
Extracardiac Stimulation	28
Failure To Capture	434
Failure To Sense	80
Impedance Abnormal	32
Insulation Breach	8
Lead Dislodgement	1,153
Oversensing	75
Unspecified	31

USA Returned Product Analysis

Conductor Fracture	625
Crimp Weld Bond	0
Insulation Breach	638
Other	200



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%	99.6%	99.5%	99.1%	98.9%	98.8%	98.8%	98.7%	98.7%	98.5%	98.5%	98.5%
#	3,802	2,745	2,086	1,654	1,270	991	838	668	452	297	163	84

PACING LEAD

5076

VENTRICULAR PLACEMENT

Distribution Data

US Market Release	31-Aug-00
CE Approval Date	12-Aug-99
Registered US Implants	1,871,477
Estimated Active US	1,134,484

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,208
Cumulative Months of Follow-Up	82,360
Number of Leads Active in Study	712

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	1
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	9
Failure To Sense	1
Impedance Abnormal	4
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

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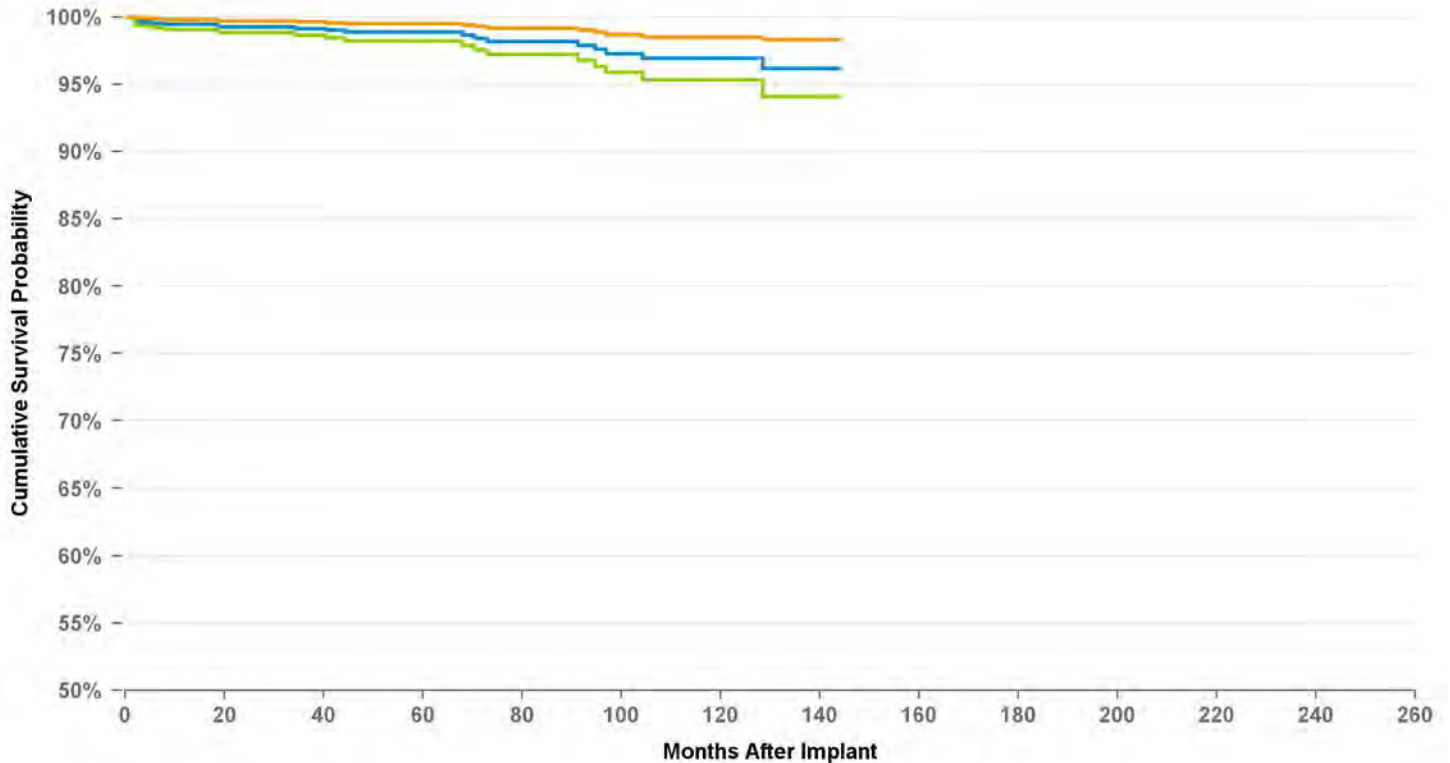
US Acute Lead Observations

Cardiac Perforation	372
Conductor Fracture	17
Extracardiac Stimulation	28
Failure To Capture	434
Failure To Sense	80
Impedance Abnormal	32
Insulation Breach	8
Lead Dislodgement	1,153
Oversensing	75
Unspecified	31

USA Returned Product Analysis

Conductor Fracture	625
Crimp Weld Bond	0
Insulation Breach	638
Other	200

5076, 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	at 144 mo
%	99.4%	99.3%	99.1%	98.9%	98.9%	98.4%	98.2%	97.6%	96.9%	96.9%	96.2%	96.2%
#	1,455	1,026	789	622	504	417	349	279	205	158	95	57

PACING LEAD

Distribution Data

US Market Release	8-Feb-11
CE Approval Date	21-Jan-09
Registered US Implants	207,734
Estimated Active US	190,419

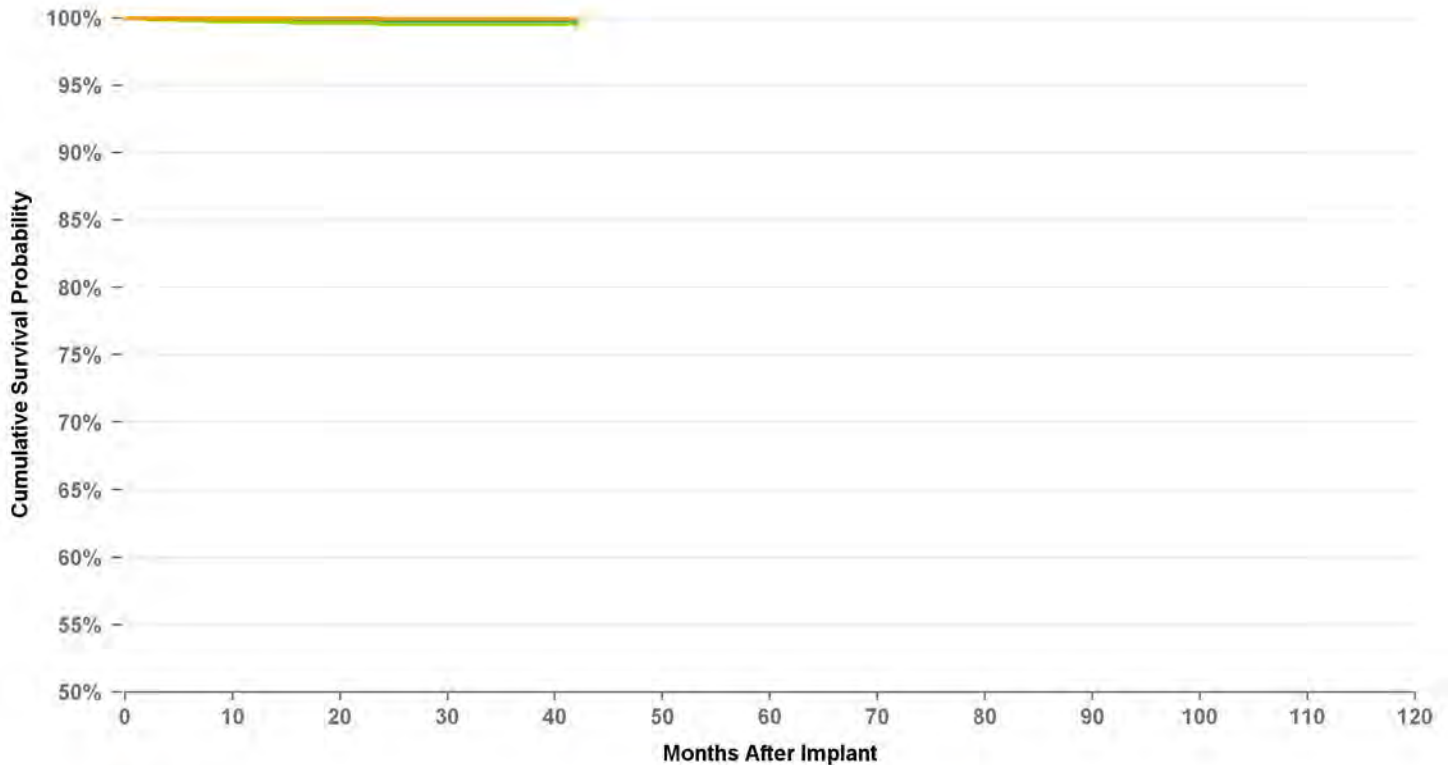
Product Characteristics

Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,972
Cumulative Months of Follow-Up	73,763
Number of Leads Active in Study	2,083

5086MRI, ATR, Survival Curve



Graph Name

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

Years	1	2	3	at 42 mo
%	99.9%	99.7%	99.7%	99.7%
#	2,456	1,704	554	154

5086MRI

Product Surveillance Registry Qualifying Complications

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	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations

Cardiac Perforation	210
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	139
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	305
Oversensing	30
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	21
Crimp Weld Bond	0
Insulation Breach	46
Other	11

PACING LEAD

Distribution Data

US Market Release	8-Feb-11
CE Approval Date	21-Jan-09
Registered US Implants	207,734
Estimated Active US	190,419

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 Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,958
Cumulative Months of Follow-Up	73,634
Number of Leads Active in Study	2,075

5086MRI

Product Surveillance Registry Qualifying Complications

Cardiac Perforation	0
Conductor Fracture	0
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	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

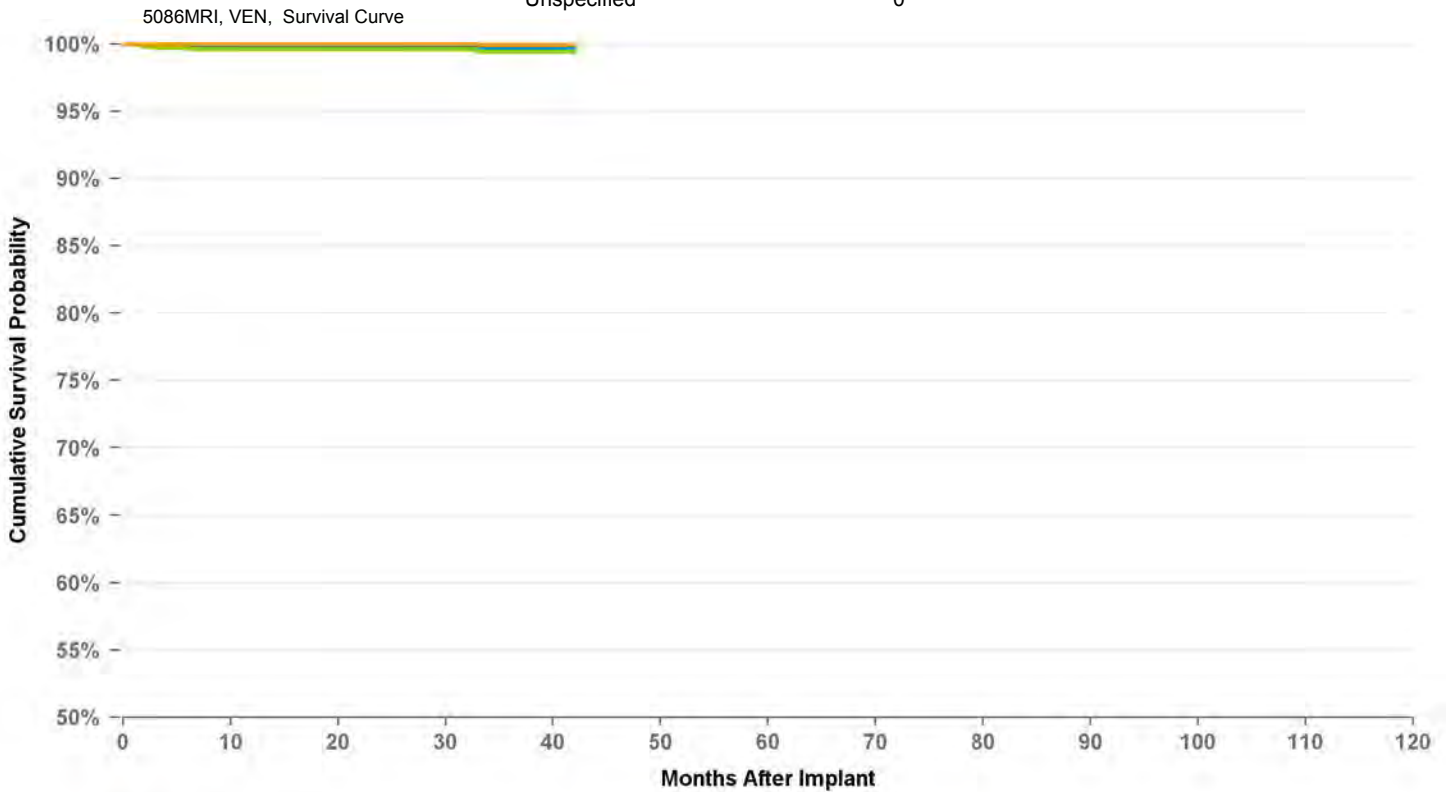
VENTRICULAR PLACEMENT

US Acute Lead Observations

Cardiac Perforation	210
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	139
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	305
Oversensing	30
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	21
Crimp Weld Bond	0
Insulation Breach	46
Other	11



Graph Name

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

Years	1	2	3	at 42 mo
%	99.8%	99.8%	99.7%	99.7%
#	2,448	1,703	556	157

PACING LEAD

5092

Distribution Data

US Market Release	3-Jun-98
CE Approval Date	25-Sep-97
Registered US Implants	139,822
Estimated Active US	54,890

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,202
Cumulative Months of Follow-Up	50,314
Number of Leads Active in Study	104

Product Surveillance Registry Qualifying Complications

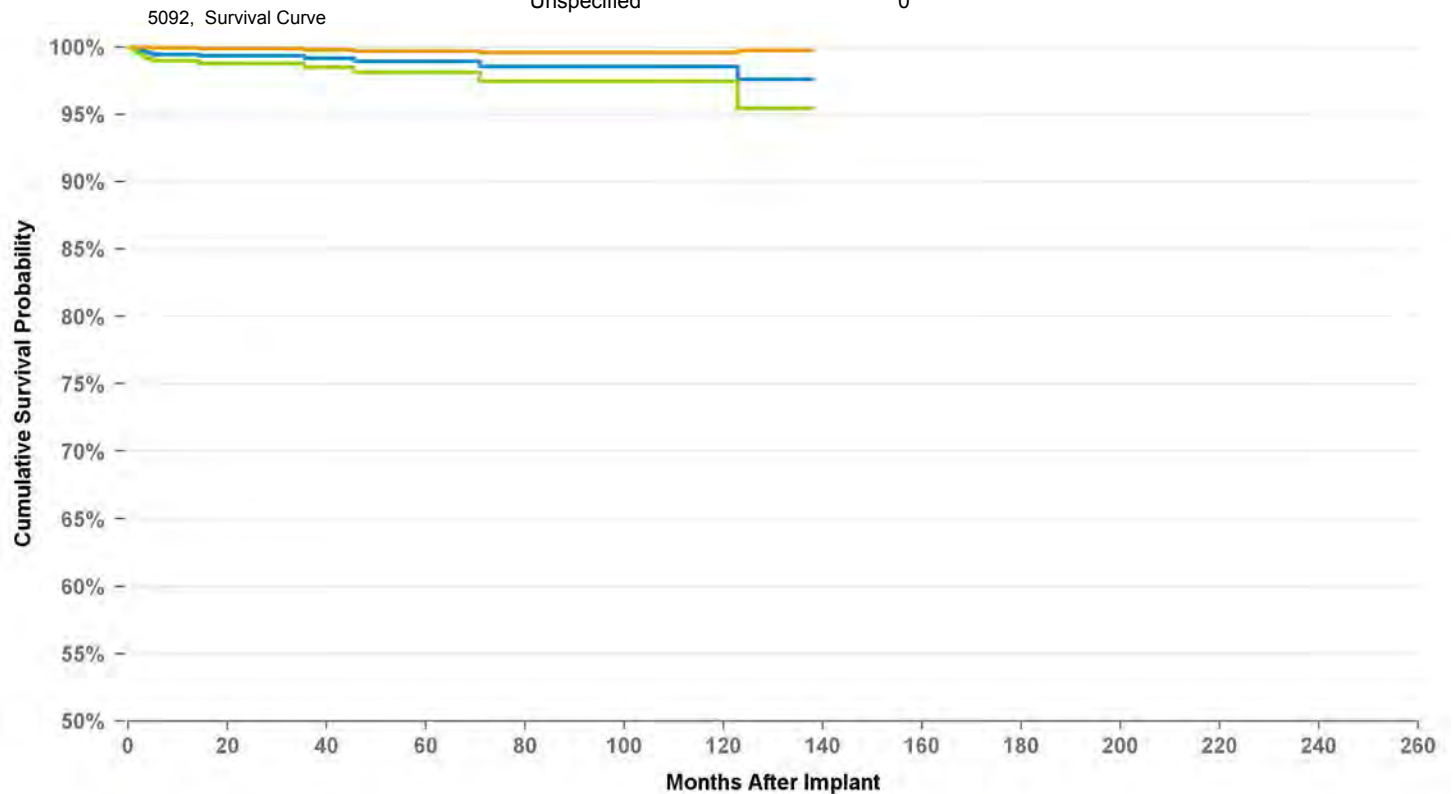
	10
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	48
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	65
Oversensing	1
Unspecified	9

USA Returned Product Analysis

Conductor Fracture	17
Crimp Weld Bond	0
Insulation Breach	45
Other	3



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
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.6%	97.6%
#	821	653	508	410	321	252	205	159	126	103	77	63

PACING LEAD

5534

Distribution Data

US Market Release	9-Feb-96
CE Approval Date	
Registered US Implants	25,823
Estimated Active US	5,364
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance 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

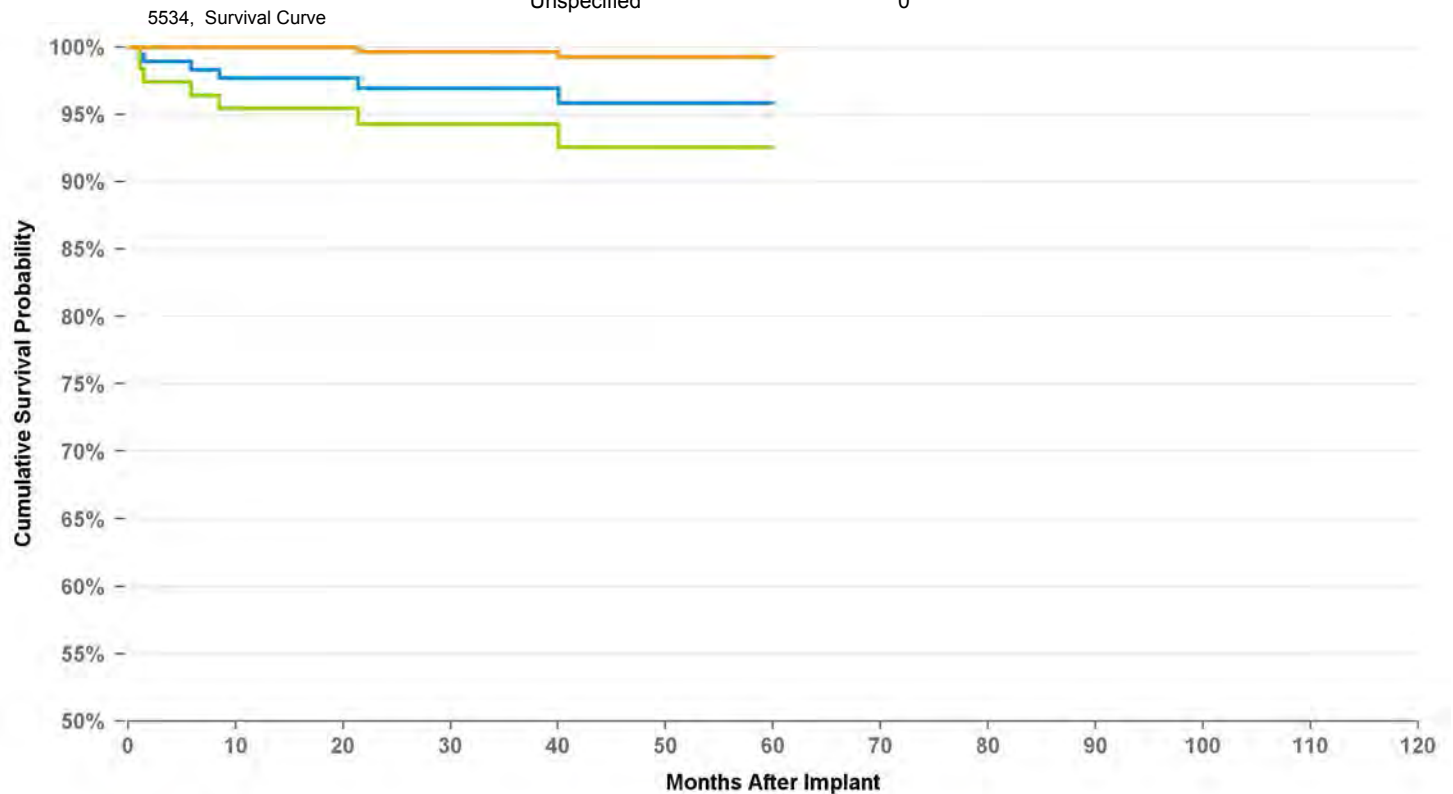
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	268
Cumulative Months of Follow-Up	9,641
Number of Leads Active in Study	4

USA Returned Product Analysis

Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	6
Other	4



Graph Name

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

Years	1	2	3	4	at 60 mo
%	97.7%	96.9%	96.9%	95.9%	95.9%
#	149	127	98	79	55

PACING LEAD

5554

Distribution Data

US Market Release	3-Jun-98
CE Approval Date	5-Jun-97
Registered US Implants	64,005
Estimated Active US	25,467

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	357
Cumulative Months of Follow-Up	8,412
Number of Leads Active in Study	11

Product Surveillance Registry Qualifying Complications

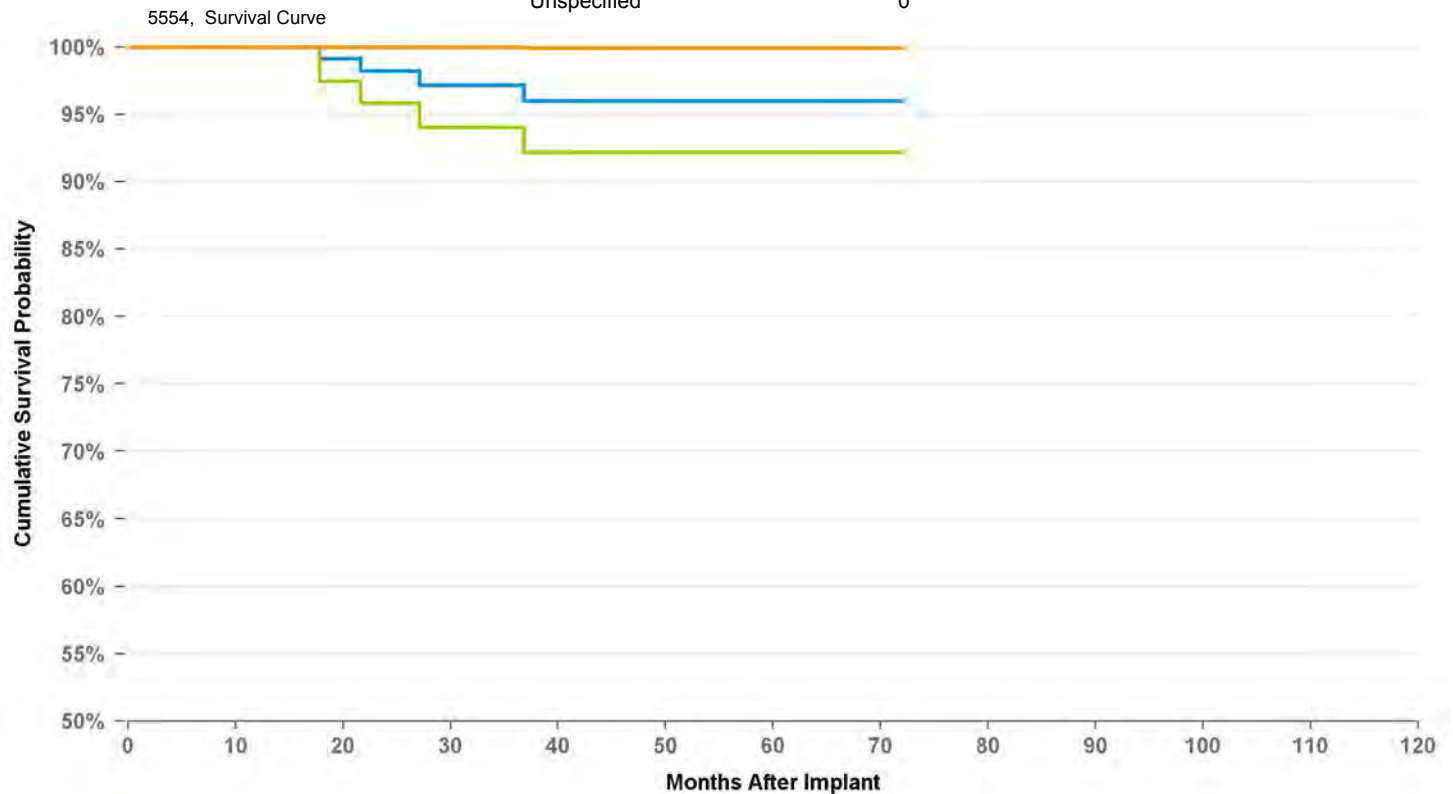
	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	37
Oversensing	0
Unspecified	3

USA Returned Product Analysis

Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	27
Other	2



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
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%
#	150	111	84	74	59	50

PACING LEAD

5568

Distribution Data

US Market Release	2-Jan-97
CE Approval Date	14-Aug-96
Registered US Implants	96,611
Estimated Active US	45,630

Product Characteristics

Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,152
Cumulative Months of Follow-Up	37,384
Number of Leads Active in Study	131

Product Surveillance Registry Qualifying Complications

17

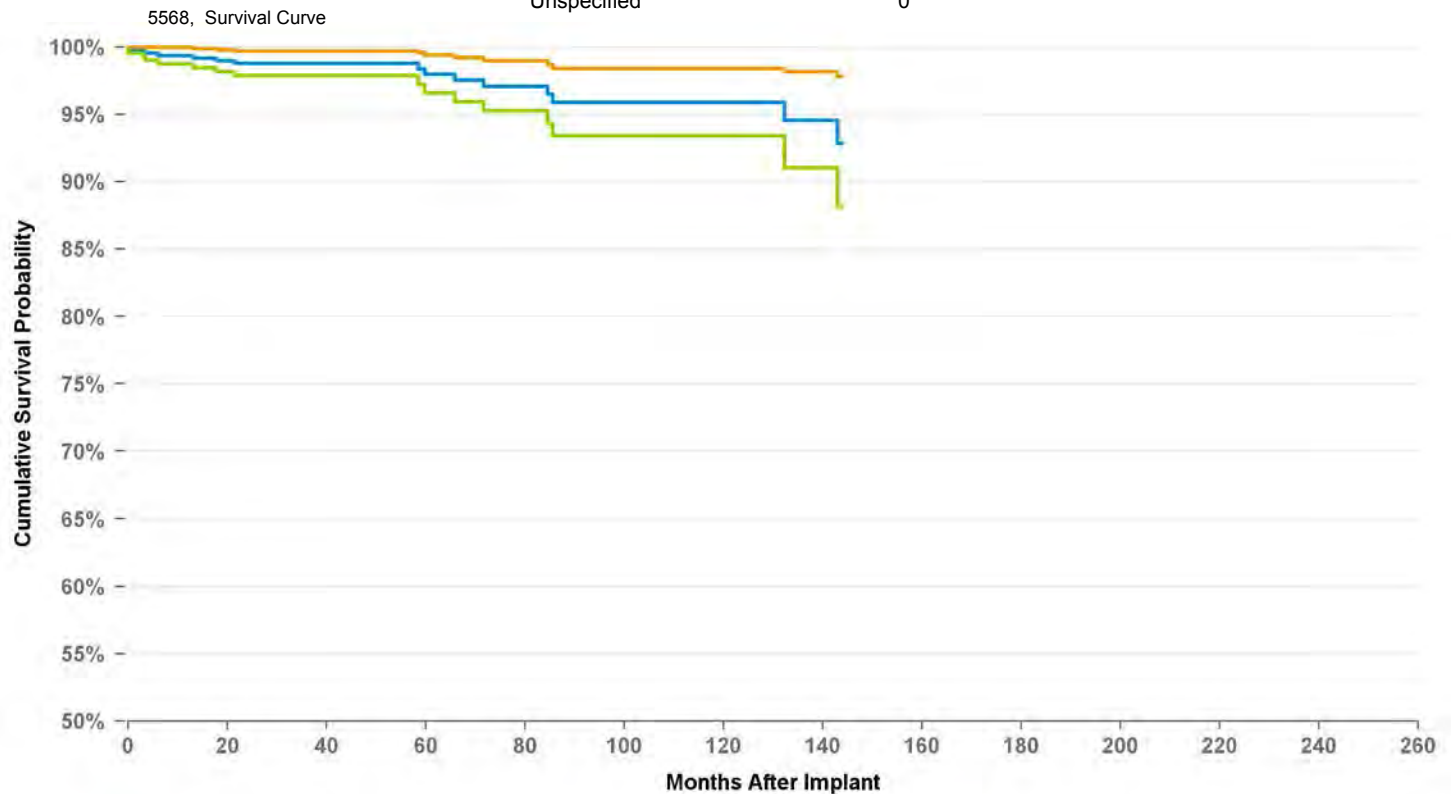
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication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

US Acute Lead Observations

Cardiac Perforation	14
Conductor Fracture	0
Extracardiac Stimulation	2
Failure To Capture	26
Failure To Sense	3
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	42
Oversensing	3
Unspecified	4

USA Returned Product Analysis

Conductor Fracture	20
Crimp Weld Bond	0
Insulation Breach	43
Other	38



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
%	99.4%	98.8%	98.8%	98.8%	98.0%	97.1%	97.1%	95.9%	95.9%	95.9%	95.9%	92.9%
#	558	455	378	303	244	195	152	128	106	85	66	51

PACING LEAD

5592

Distribution Data

US Market Release	3-Jun-98
CE Approval Date	25-Sep-97
Registered US Implants	36,646
Estimated Active US	17,449
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance 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

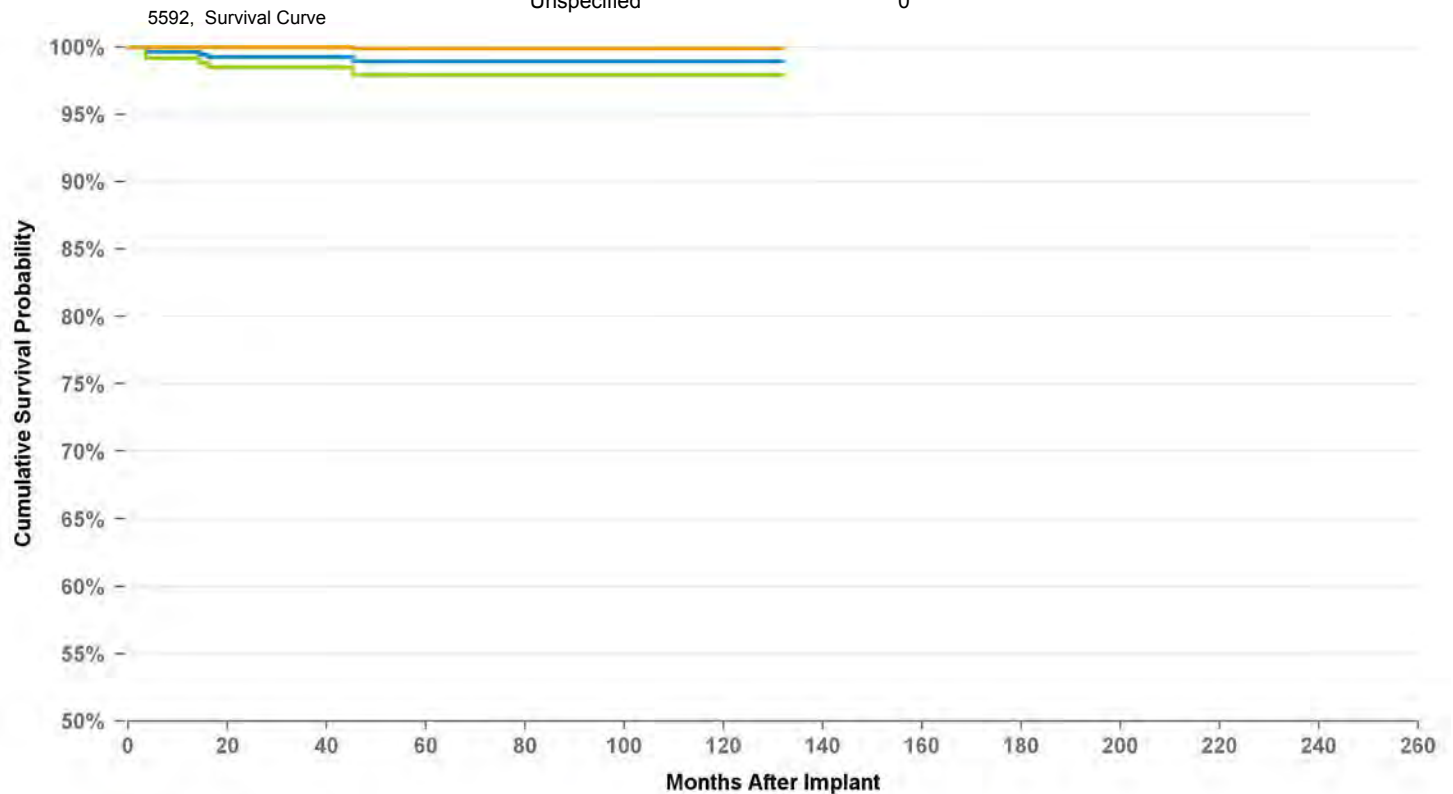
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	40
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	704
Cumulative Months of Follow-Up	33,793
Number of Leads Active in Study	117

USA Returned Product Analysis

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



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
%	99.6%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	524	433	344	288	231	175	142	118	93	74	52

PACING LEAD

5594

Distribution Data

US Market Release	25-Jun-01
CE Approval Date	23-Mar-01
Registered US Implants	17,347
Estimated Active US	9,974

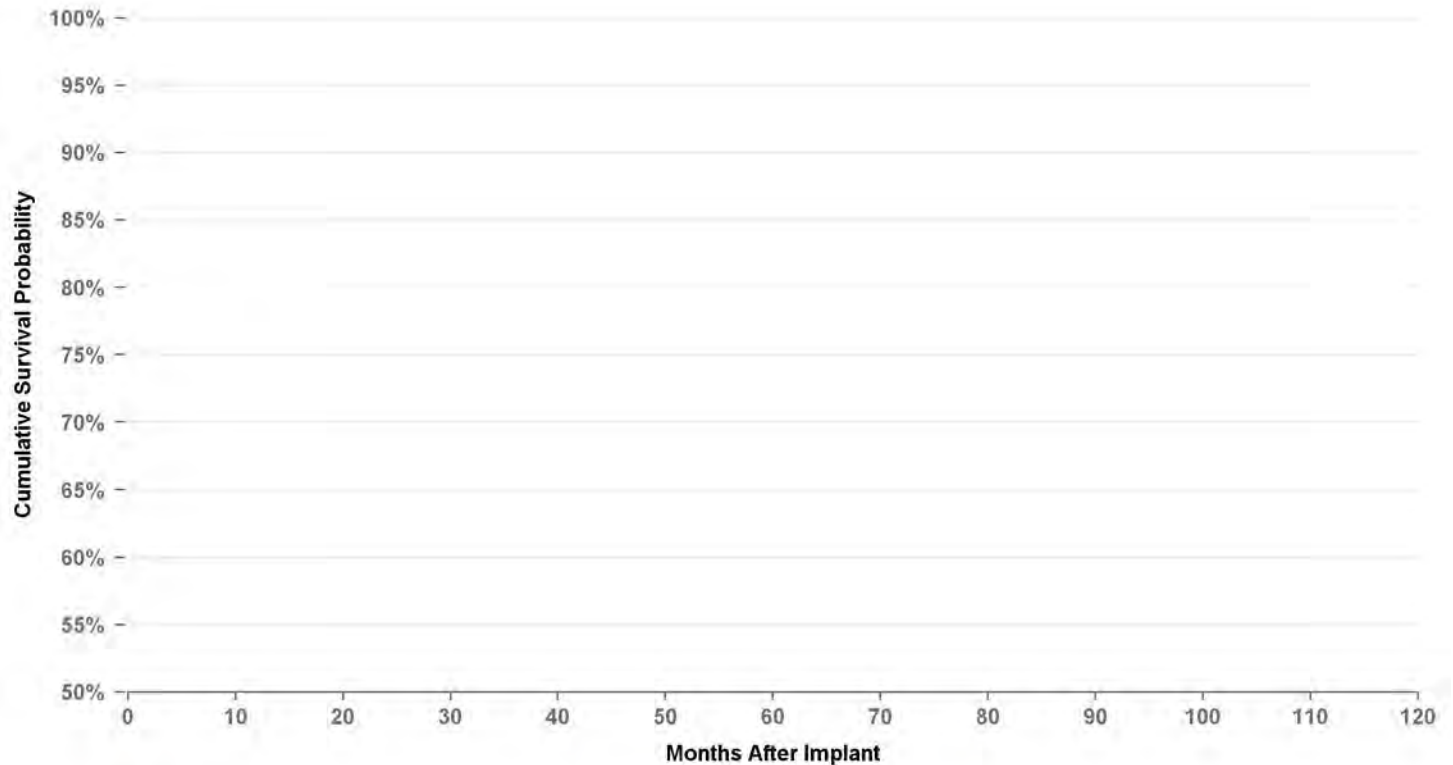
Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	25
Cumulative Months of Follow-Up	1,771
Number of Leads Active in Study	9

5594, Survival Curve



Graph Name

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

Years

%

#

Product Surveillance 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	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	13
Oversensing	0
Unspecified	2

USA Returned Product Analysis

Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	10
Other	1

PACING LEAD

6940

Distribution Data

US Market Release	9-Oct-98
CE Approval Date	
Registered US Implants	25,380
Estimated Active US	5,653
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Qualifying Complications

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

US Acute Lead Observations

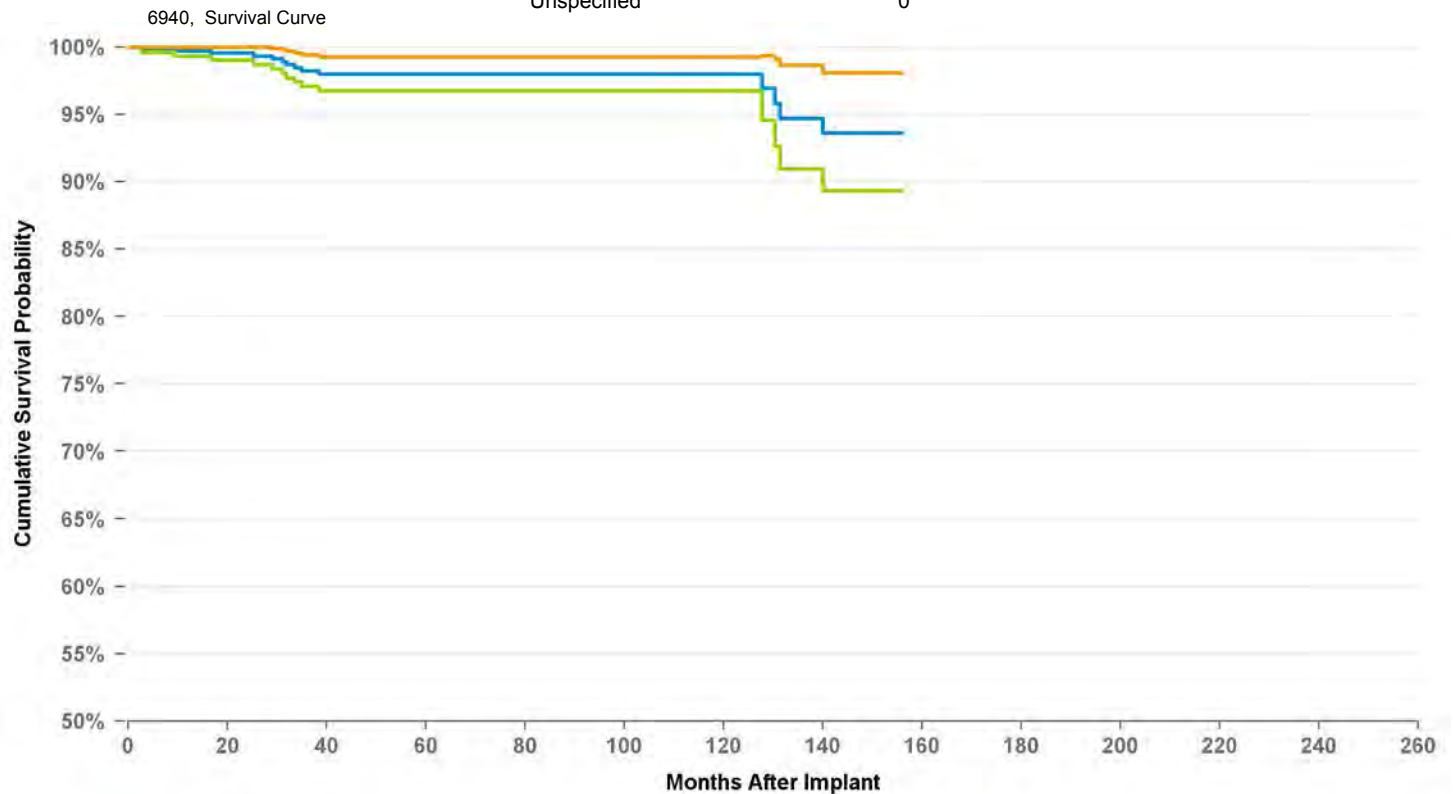
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	20
Other	12

Product Surveillance Registry Results

Number of Leads Enrolled in Study	844
Cumulative Months of Follow-Up	43,266
Number of Leads Active in Study	41



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
%	99.7%	99.5%	98.2%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	94.7%	93.6%	93.6%
#	641	514	422	349	279	218	189	153	126	96	80	70	51

EPI MYOCARDIAL LEAD

4965

Distribution Data

US Market Release	6-Sep-96
CE Approval Date	1-Jan-93
Registered US Implants	22,203
Estimated Active US	8,845

Product Characteristics

Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	231
Cumulative Months of Follow-Up	6,924
Number of Leads Active in Study	9

Product Surveillance Registry Qualifying Complications

13

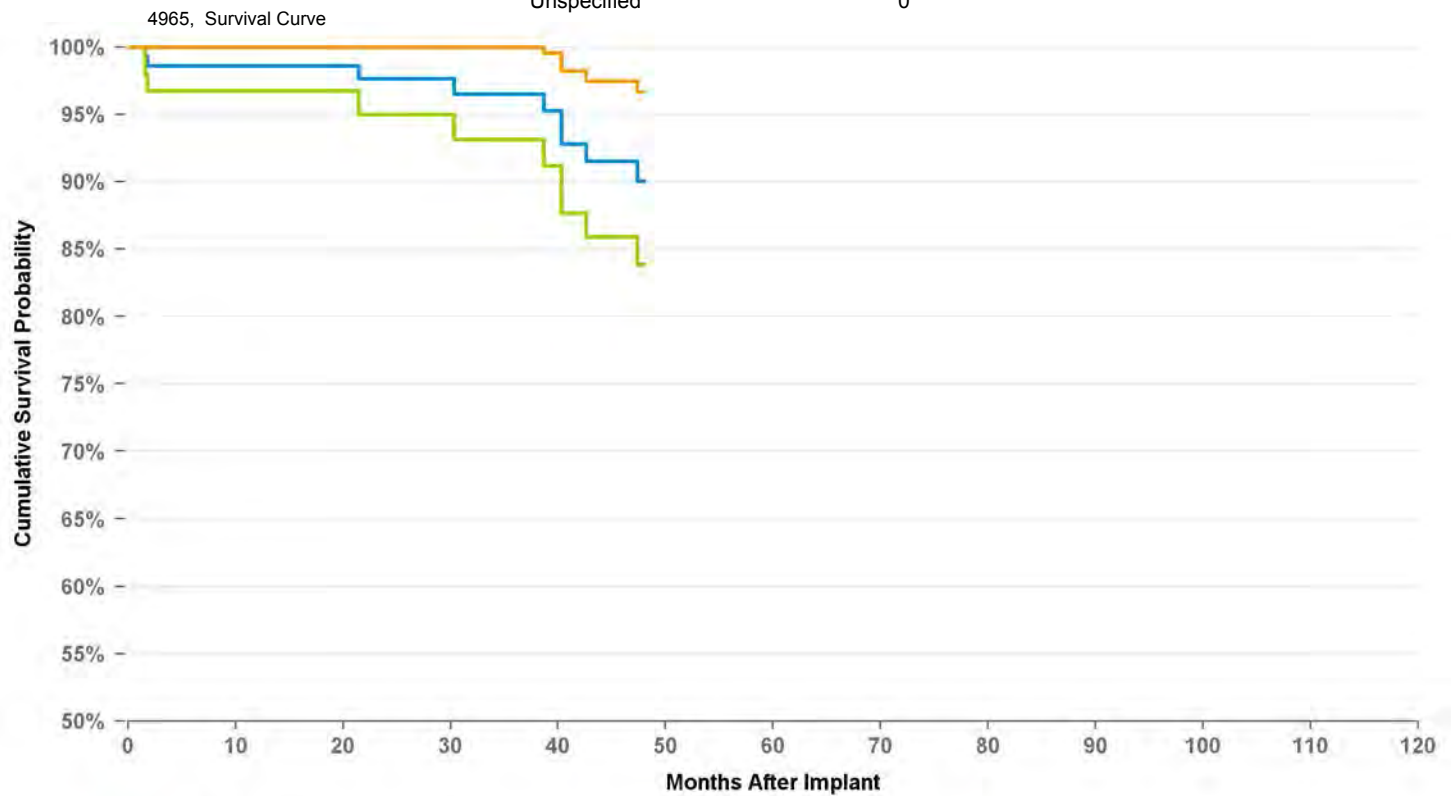
Cardiac Perforation	0
Conductor Fracture	6
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	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	209
Crimp Weld Bond	1
Insulation Breach	43
Other	0



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%
#	128	108	86	64

EPI MYOCARDIAL LEAD

4968

Distribution Data

US Market Release	16-Sep-99
CE Approval Date	21-Apr-98
Registered US Implants	36,185
Estimated Active US	21,813

Product Characteristics

Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarity	Bipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	887
Cumulative Months of Follow-Up	45,079
Number of Leads Active in Study	293

Product Surveillance Registry Qualifying Complications

63

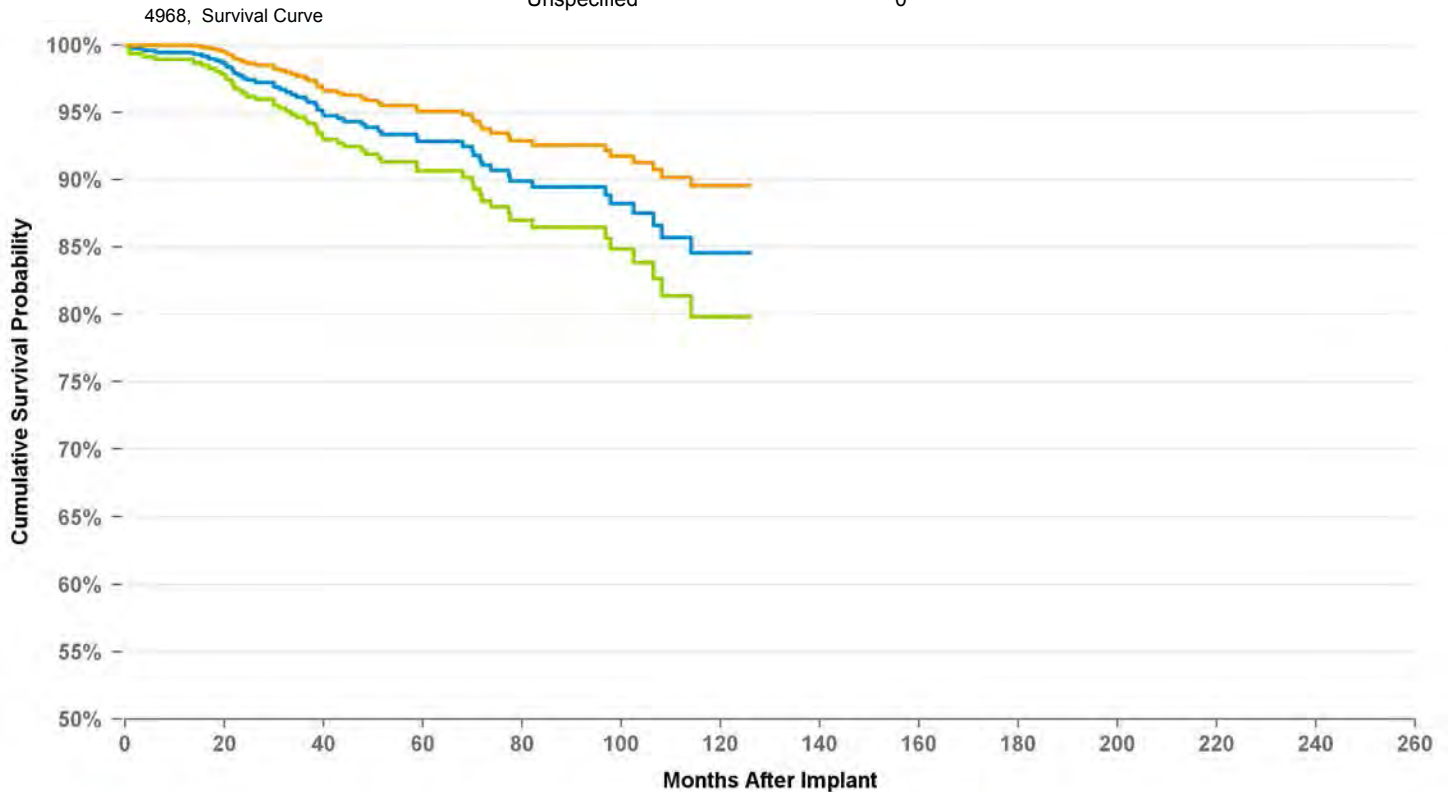
Cardiac Perforation	0
Conductor Fracture	15
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	20
Failure To Sense	3
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	3
Lead Dislodgement	0
Medical Judgment	0
Other Complication	2
Oversensing	14
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	1
Failure To Capture	23
Failure To Sense	1
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	5
Oversensing	9
Unspecified	0

USA Returned Product Analysis

Conductor Fracture	51
Crimp Weld Bond	0
Insulation Breach	32
Other	1



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
%	99.5%	97.6%	96.1%	94.1%	92.8%	91.1%	89.5%	89.5%	86.6%	84.6%	84.6%
#	686	602	510	396	317	240	188	143	86	61	52

EPI MYOCARDIAL LEAD

5071

Distribution Data

US Market Release	3-Dec-92
CE Approval Date	1-Jan-93
Registered US Implants	49,214
Estimated Active US	15,137

Product Characteristics

Fixation Type	Fixed Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Myocardial
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Unipolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	375
Cumulative Months of Follow-Up	8,274
Number of Leads Active in Study	88

Product Surveillance Registry Qualifying Complications

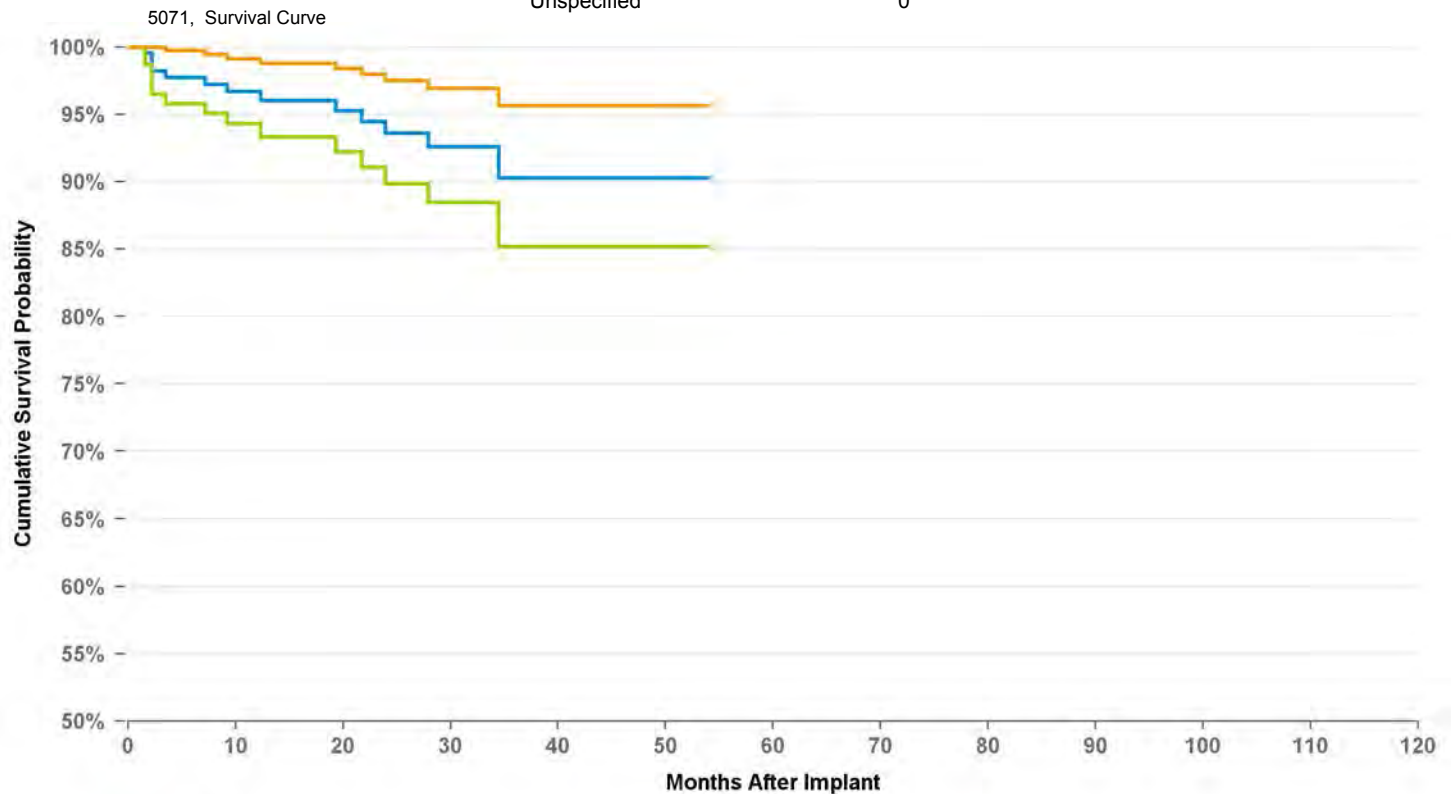
	20
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	15
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	5
Failure To Capture	48
Failure To Sense	2
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1

USA Returned Product Analysis

Conductor Fracture	17
Crimp Weld Bond	0
Insulation Breach	2
Other	0



Graph Name

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

Years	1	2	3	4	at 54 mo
%	96.7%	93.6%	90.3%	90.3%	90.3%
#	160	109	76	60	51

VDD SINGLE PASS LEAD

5032

Distribution Data

US Market Release	22-Mar-96
CE Approval Date	
Registered US Implants	5,214
Estimated Active US	914
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Quadripolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	287
Number of Leads Active in Study	0

Product Surveillance Registry Qualifying Complications

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

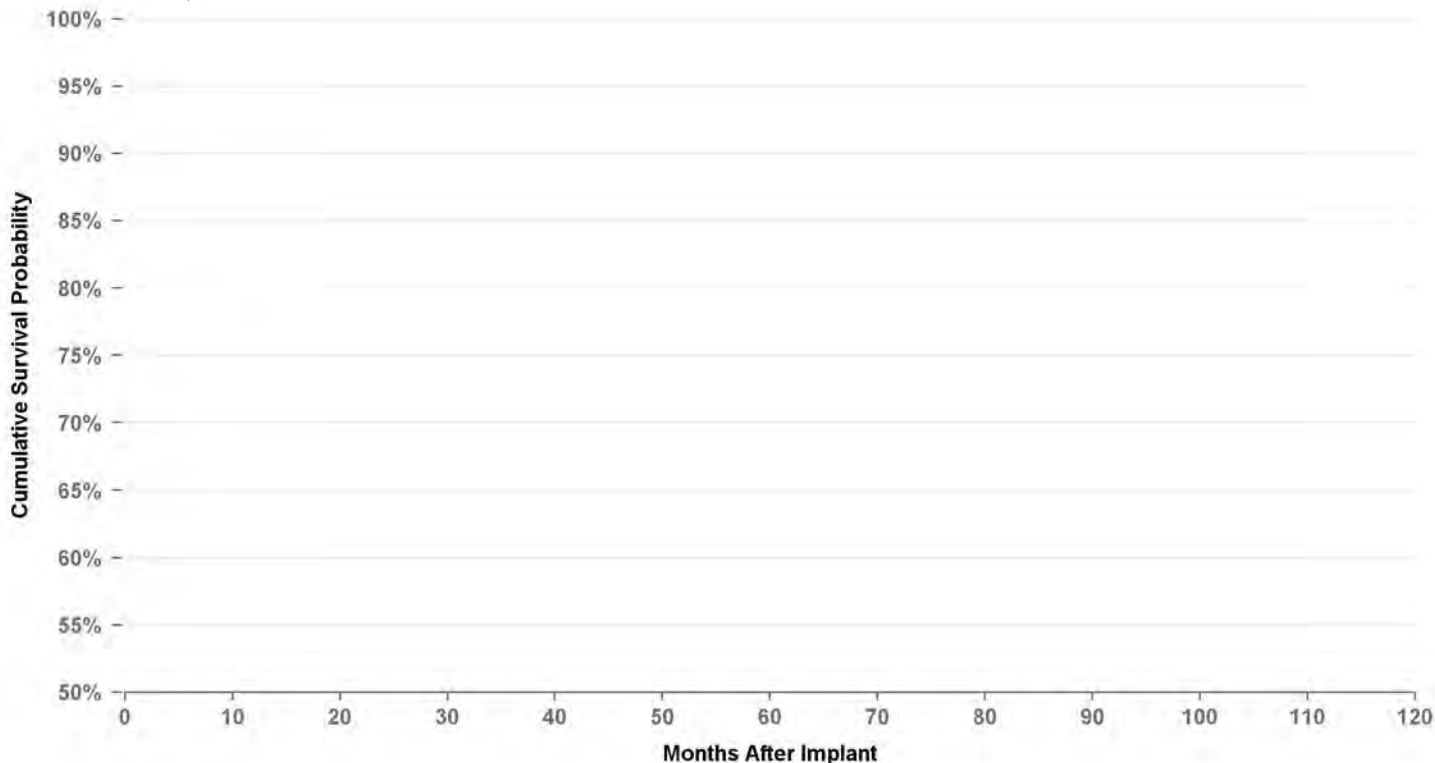
US Acute Lead Observations

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

USA Returned Product Analysis

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

5032, Survival Curve



Graph Name

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

Years

%

#

VDD SINGLE PASS LEAD

5038

Distribution Data

US Market Release	10-Sep-98
CE Approval Date	15-Apr-97
Registered US Implants	9,289
Estimated Active US	3,137

Product Characteristics

Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarity	Quadripolar

Product Surveillance Registry Results

Number of Leads Enrolled in Study	567
Cumulative Months of Follow-Up	15,671
Number of Leads Active in Study	6

Product Surveillance Registry Qualifying Complications

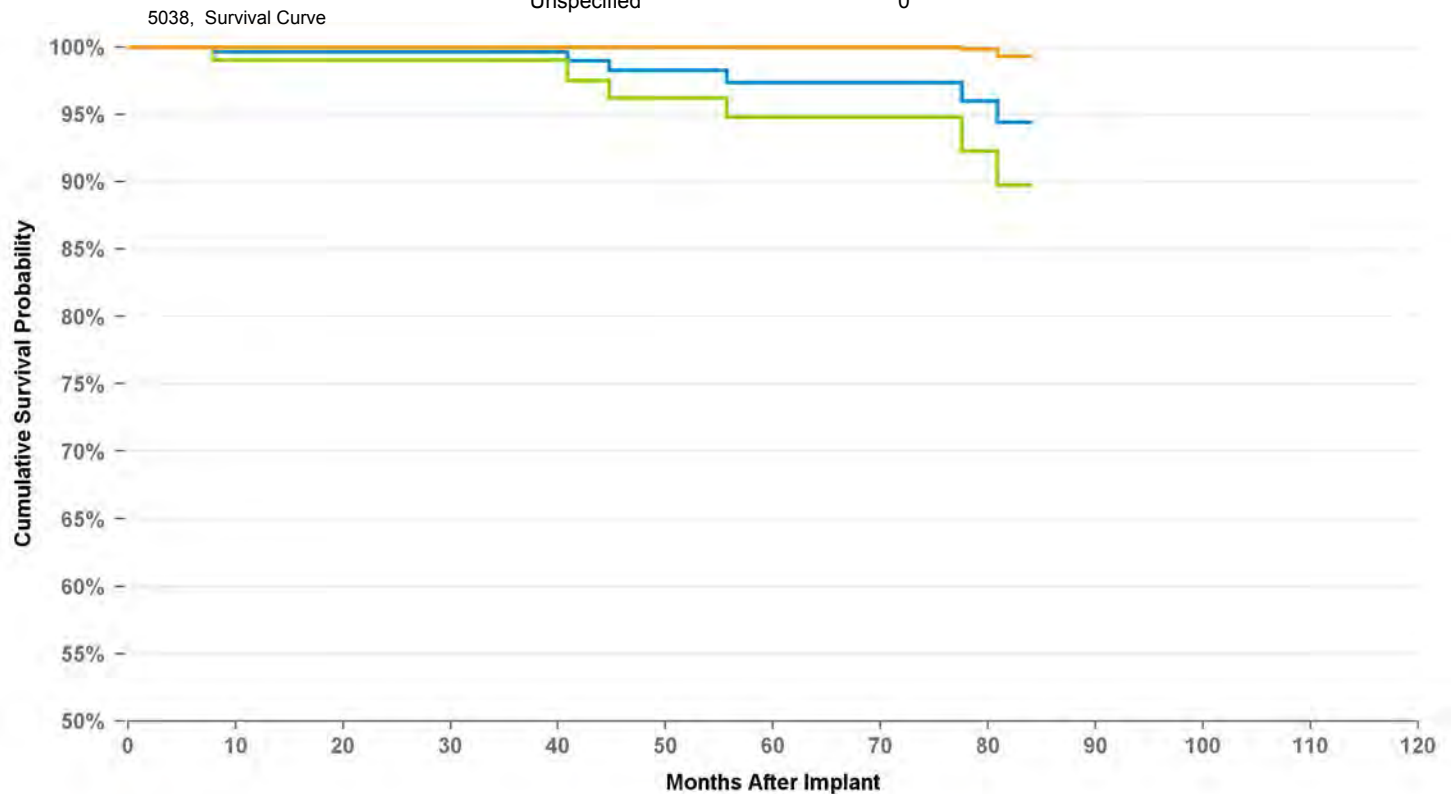
	7
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication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

USA Returned Product Analysis

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



Graph Name

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

Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.7%	99.7%	98.2%	97.4%	97.4%	94.4%
#	291	219	161	131	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.

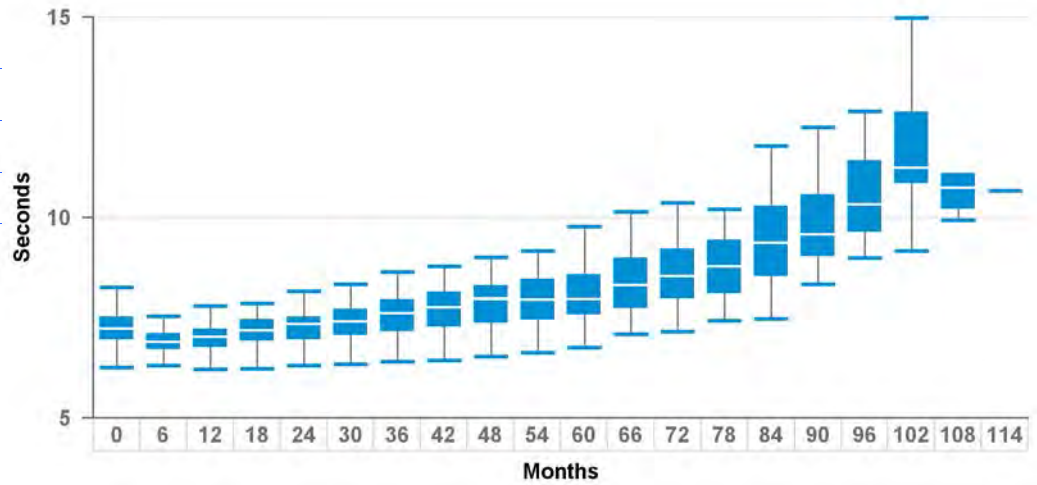
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available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

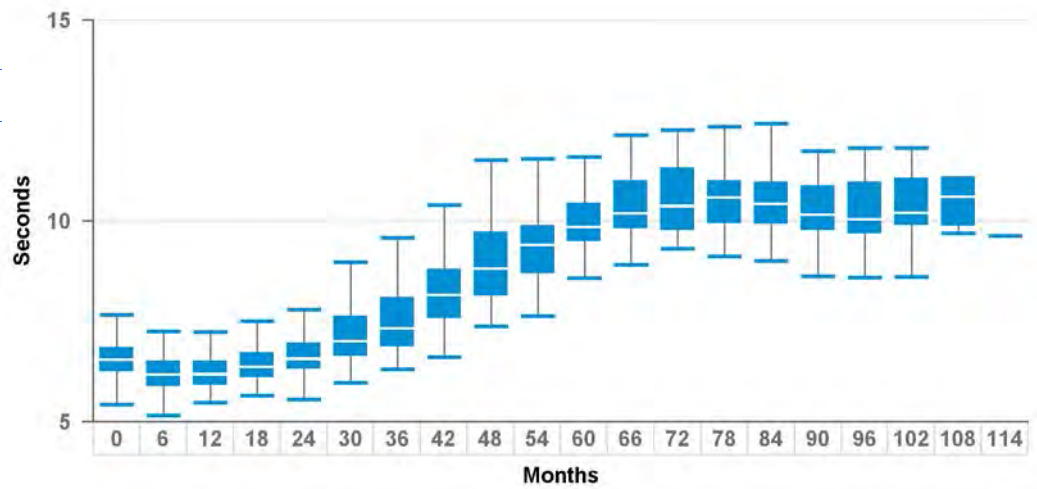
7230 Charge Time

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



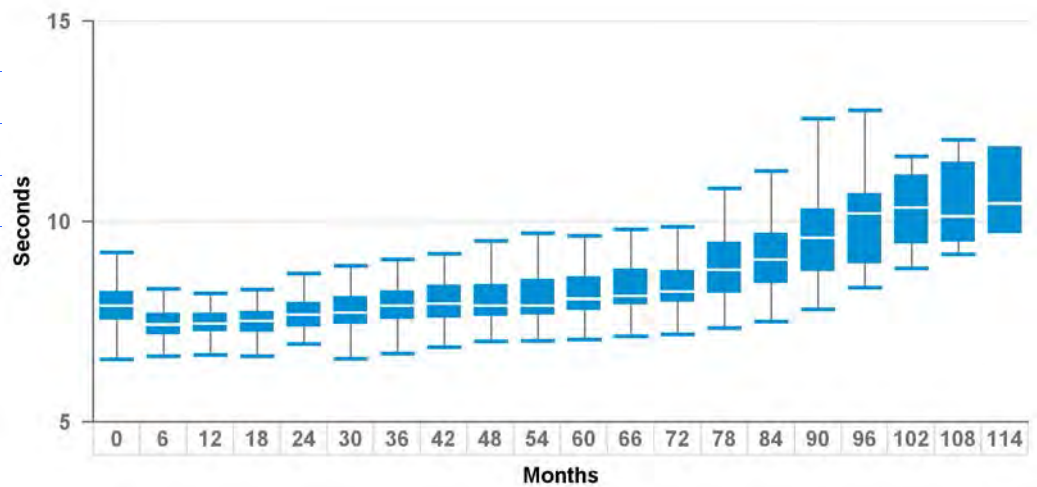
7231 Charge Time

Model Number	Brand
7231Cx	GEM III VR



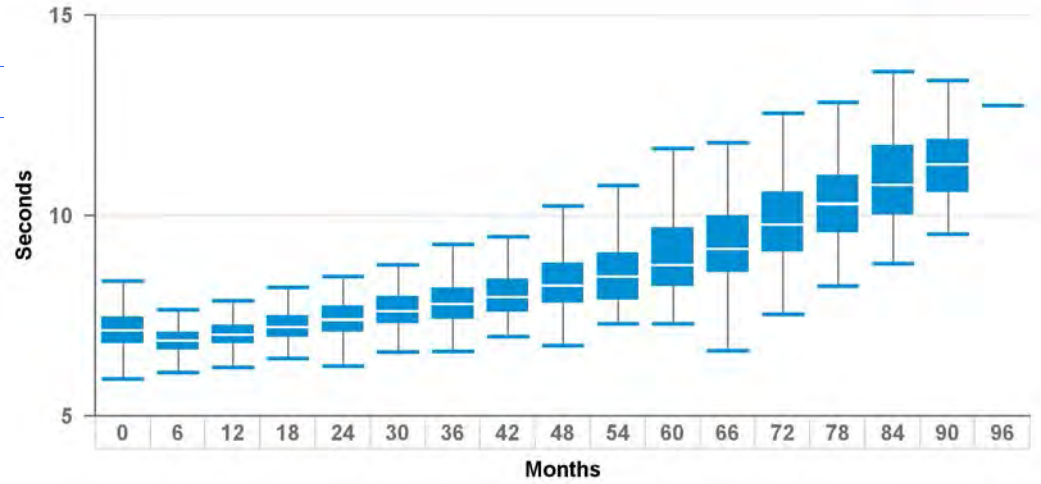
7232 Charge Time

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



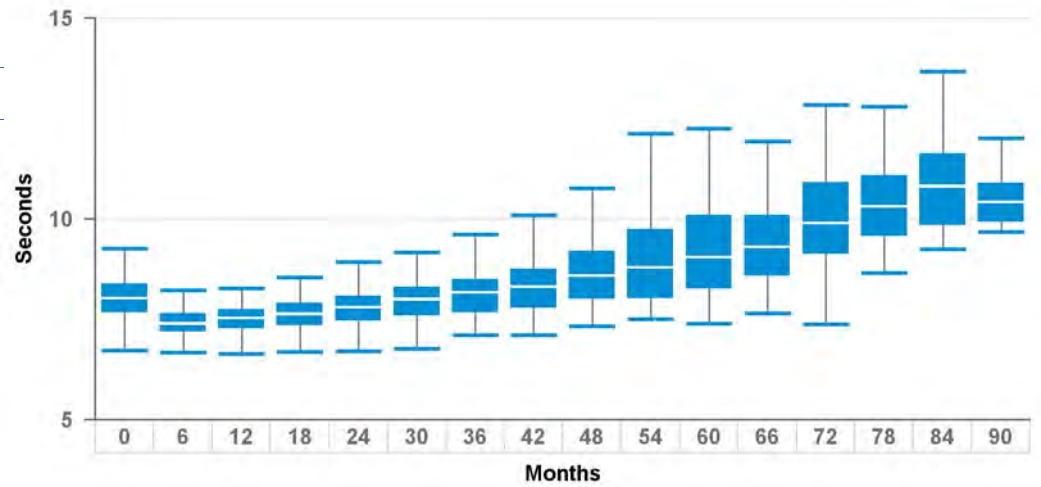
7274 Charge Time

Model Number	Brand
7274	Marquis DR



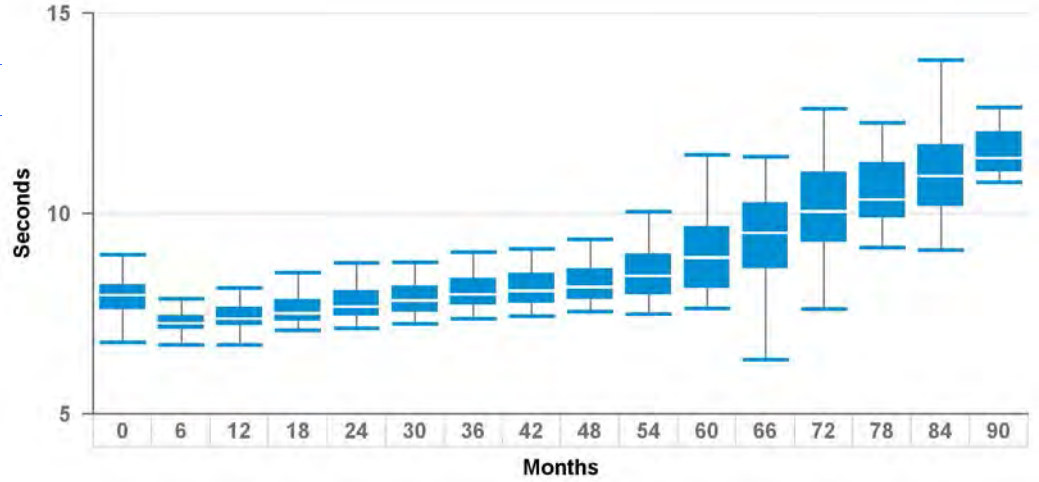
7278 Charge Time

Model Number	Brand
7278	Maximo DR



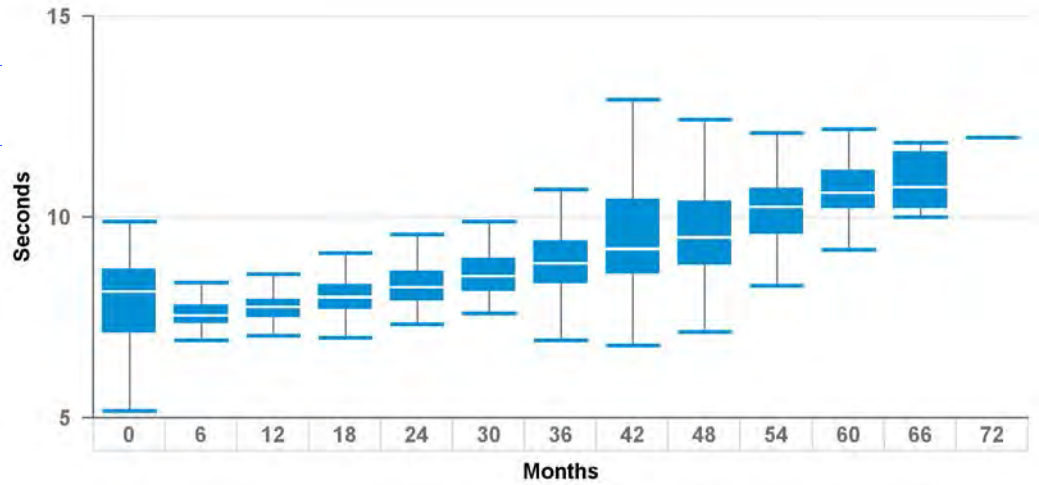
7288 Charge Time

Model Number	Brand
7288	Intrinsic



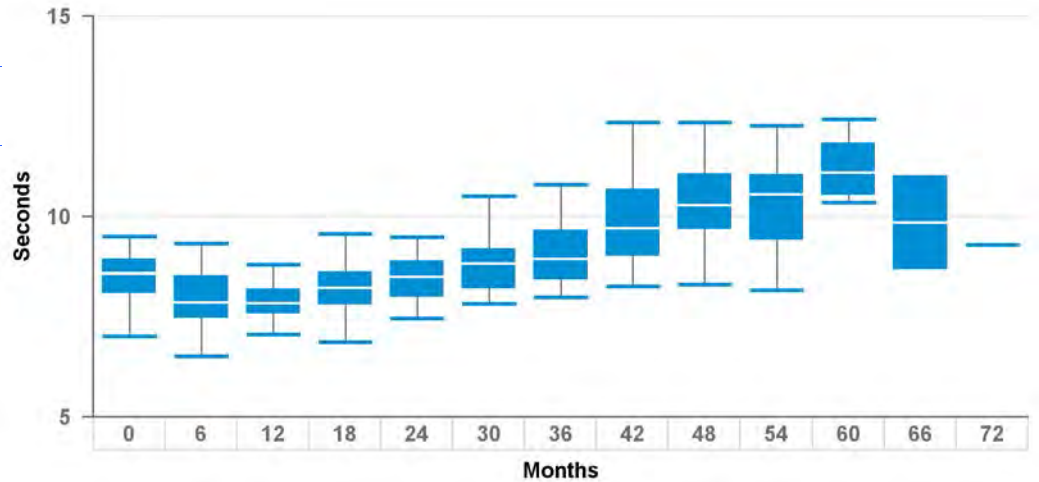
7299 Charge Time

Model Number	Brand
7299	InSync Sentry



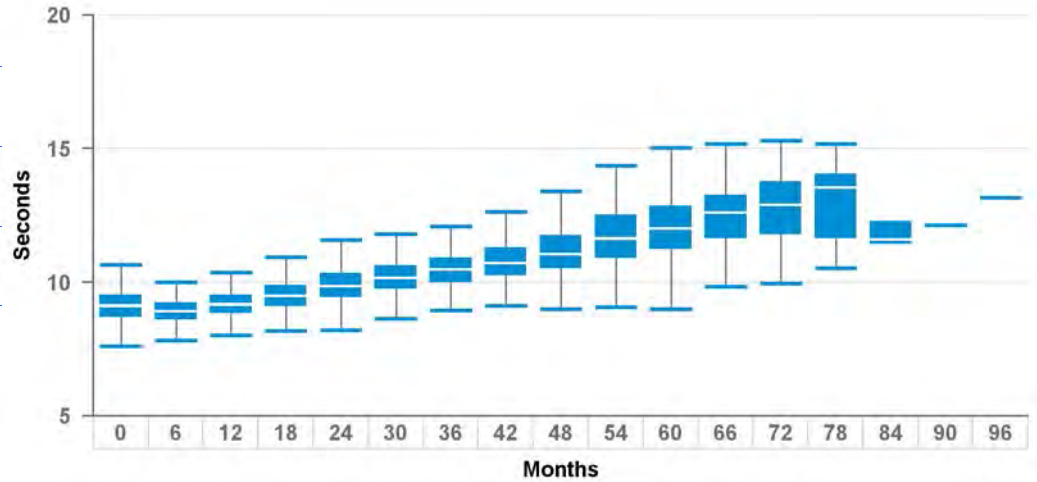
7304 Charge Time

Model Number	Brand
7304	InSync Maximo



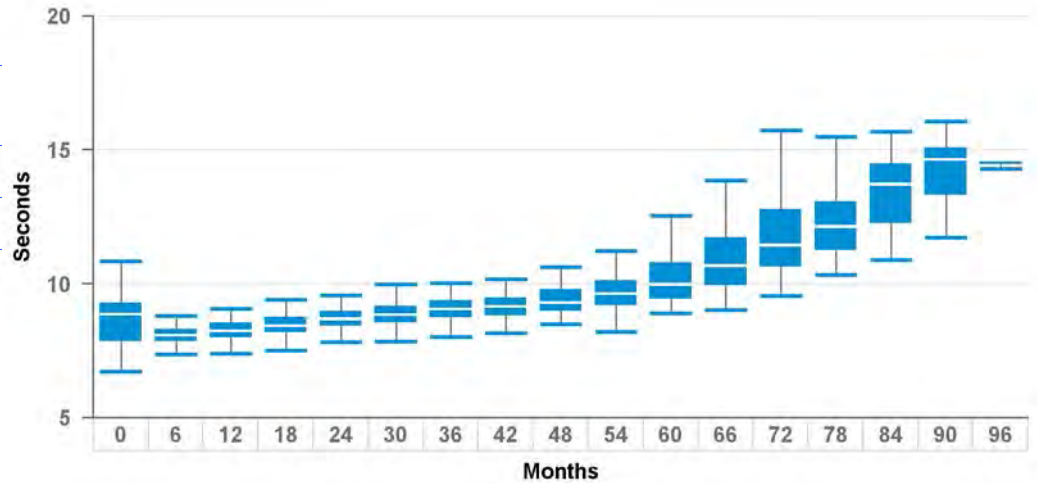
C154DWK, C164AWK, C174AWK Charge Time

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



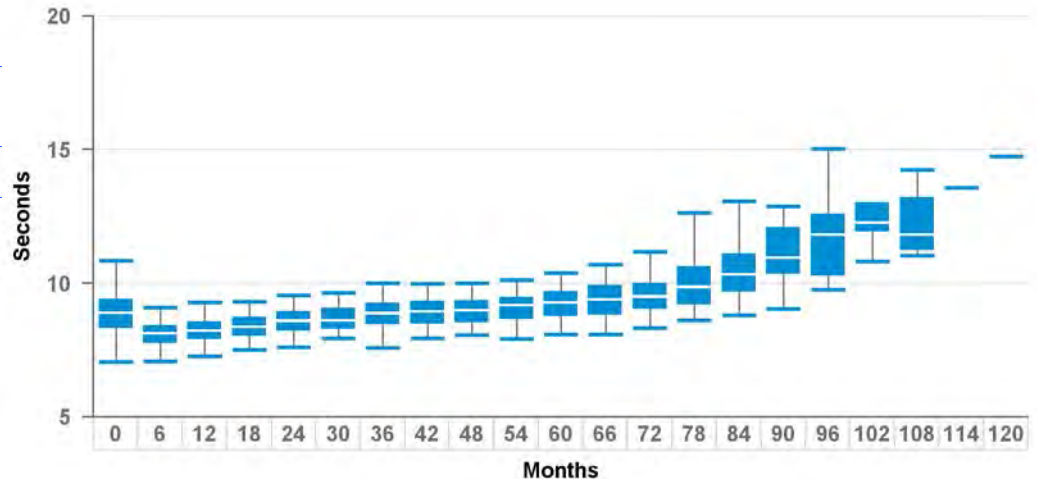
D144DRG, D154ATG, D154DRG Charge Time

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



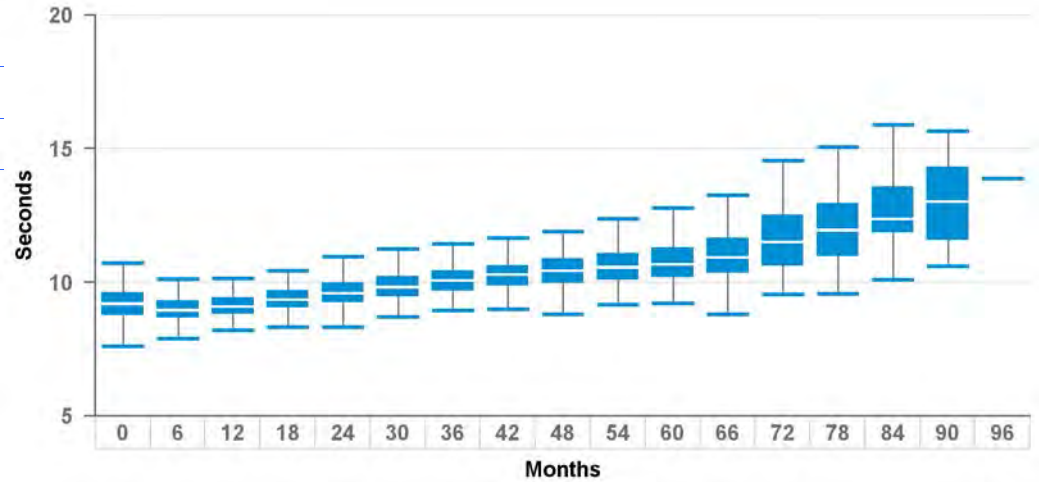
D144VRC, D154VRC Charge Time

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



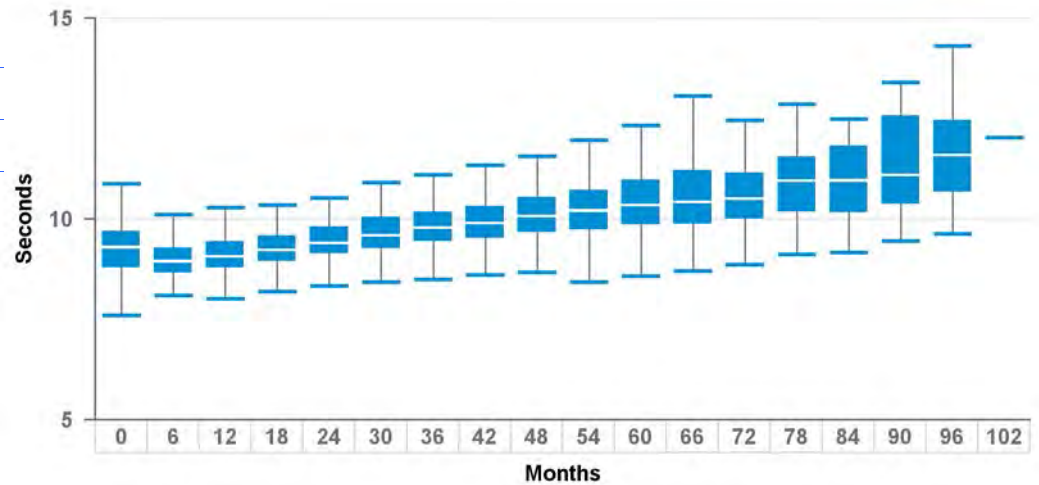
D154AWG, D164AWG Charge Time

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



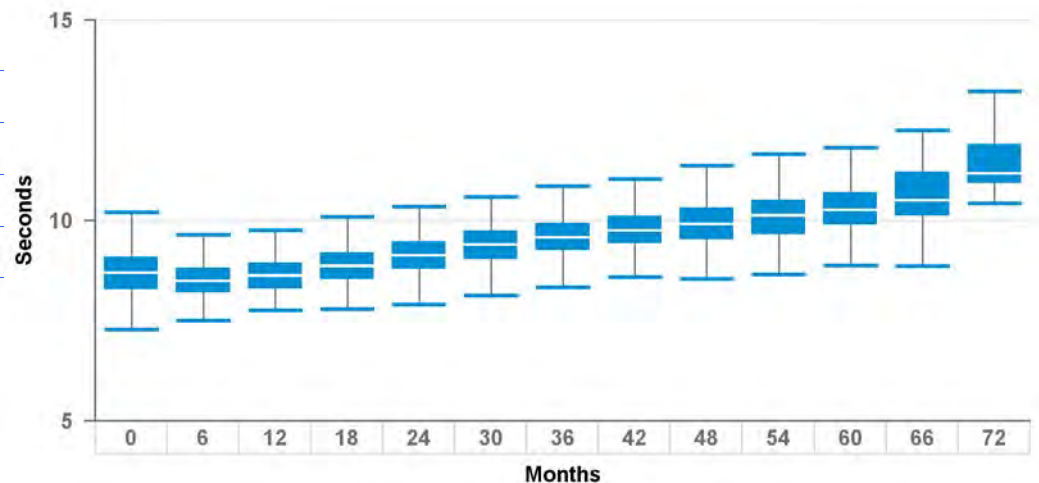
D154VWC, D164VWC Charge Time

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



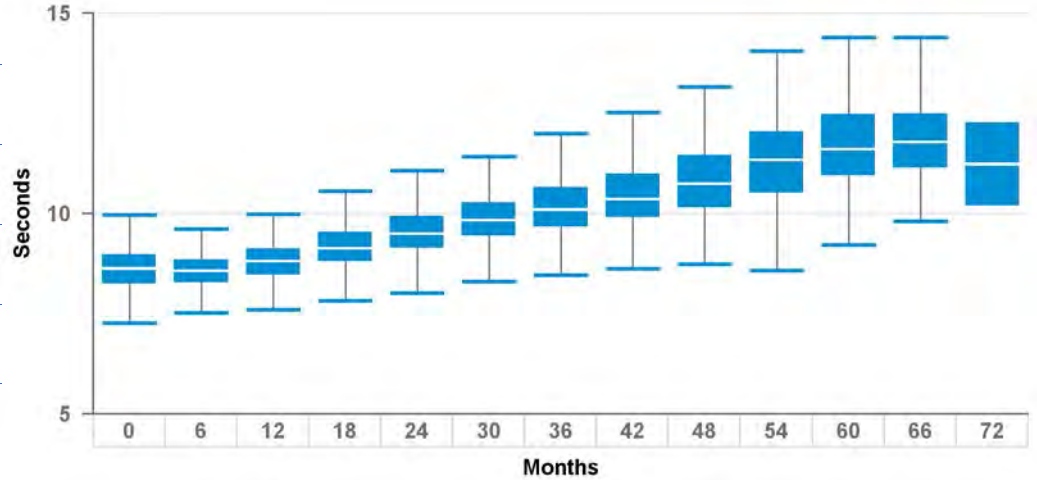
D204DRM, D214DRM, D224DRG, D234DRG Charge Time

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



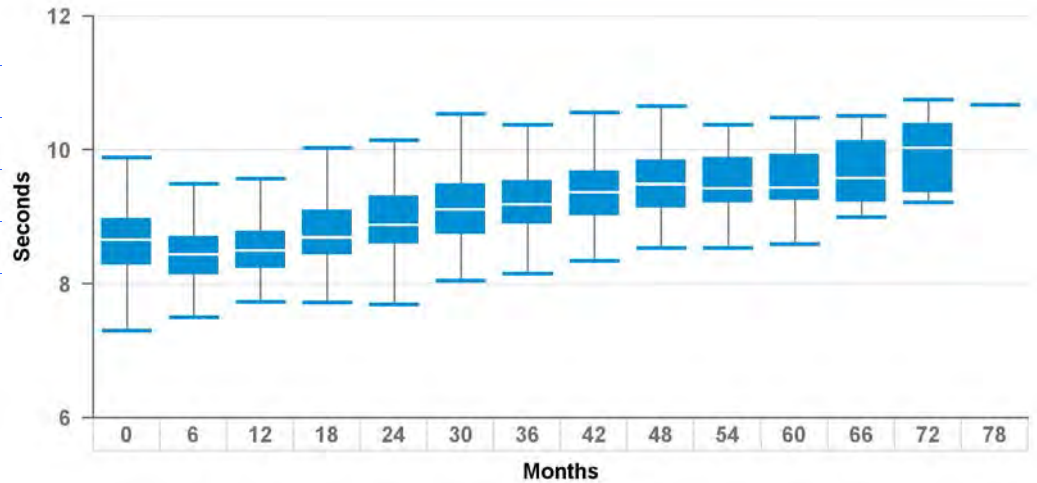
D204TRM, D214TRM, D224TRK, D234TRK Charge Time

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



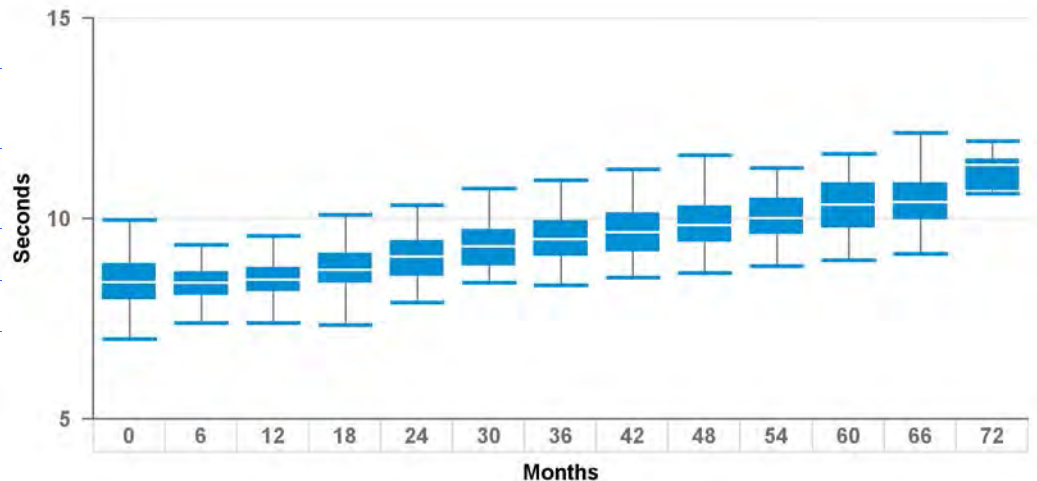
D204VRM, D214VRM, D224VRC, D234VRC Charge Time

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



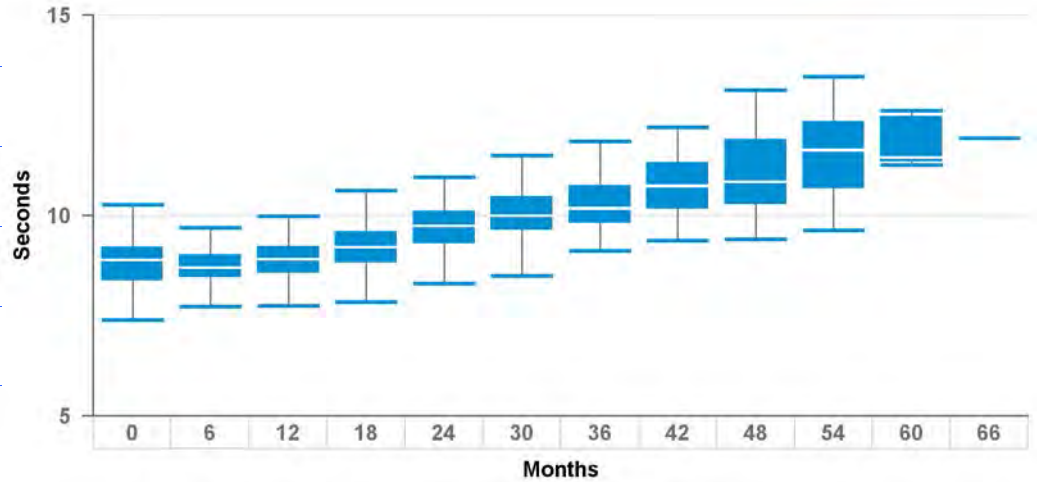
D264DRG, D284DRG, D384DRx, D394DRx Charge Time

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



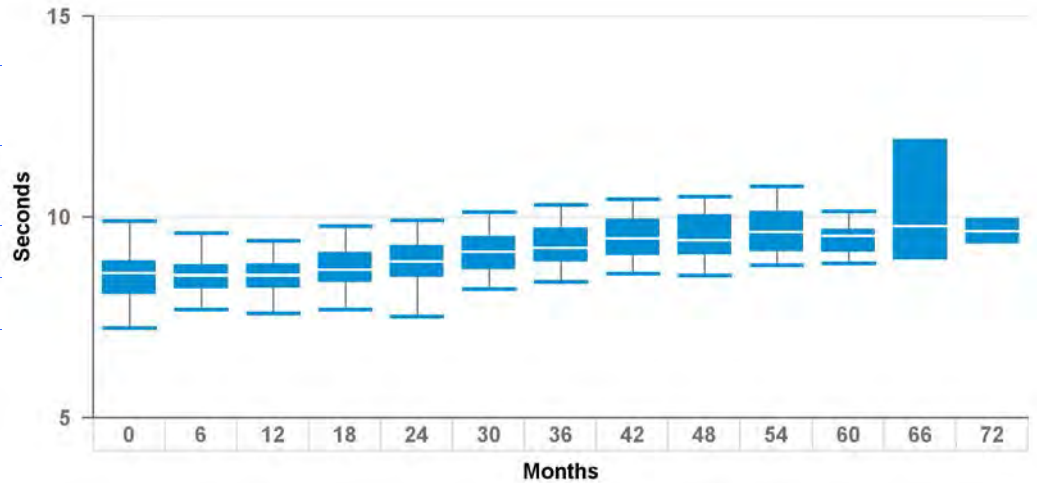
D264TRM, D284TRK, D384TRx, D394TRx Charge Time

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



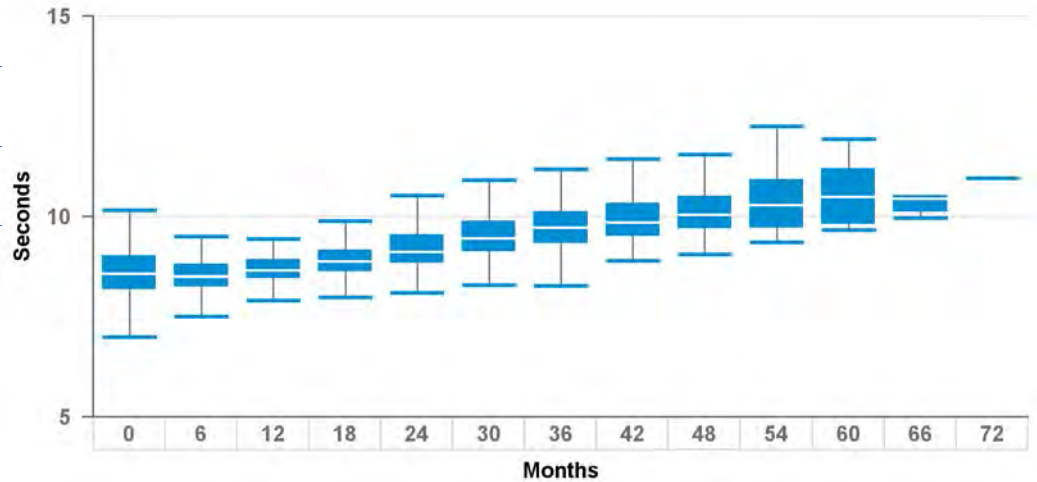
D264VRM, D284VRC, D384VRx, D394VRx Charge Time

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



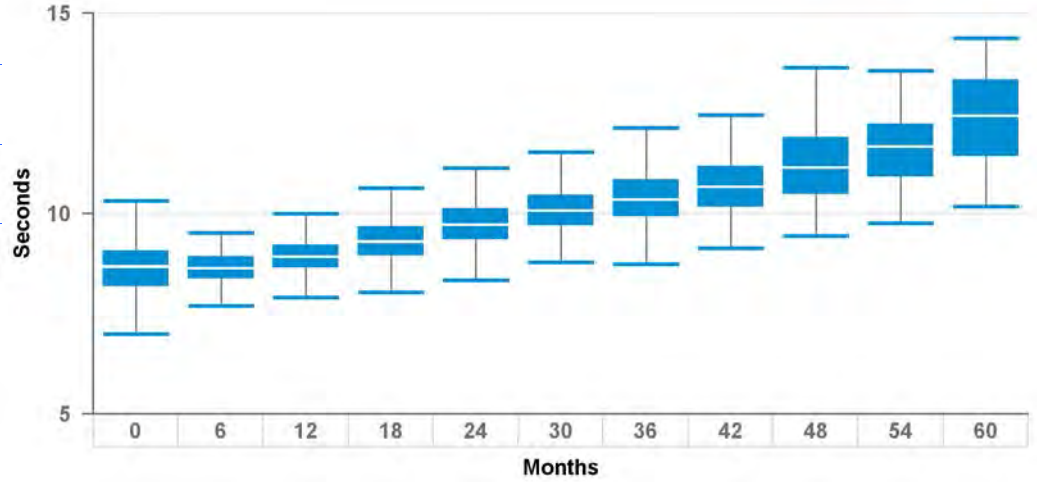
D274DRG, D294DRG Charge Time

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



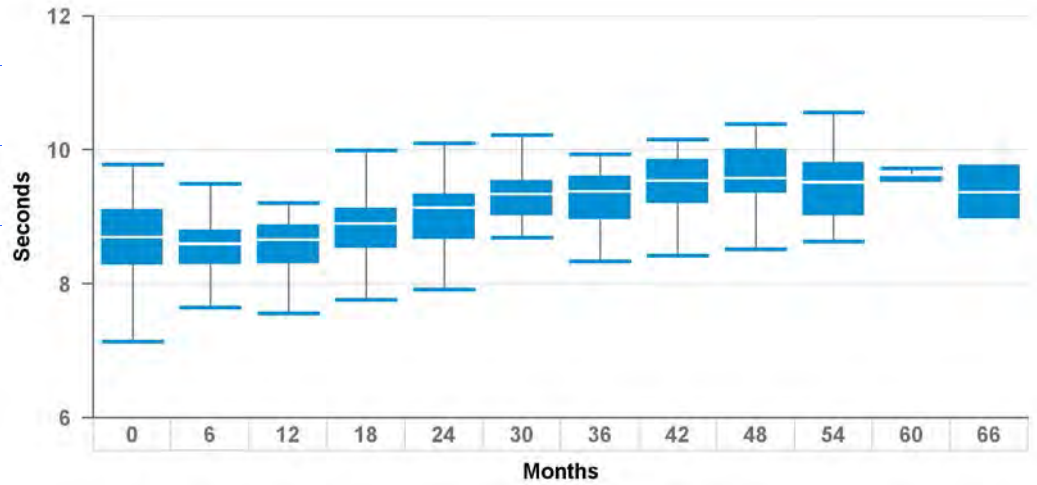
D274TRK, D294TRK Charge Time

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



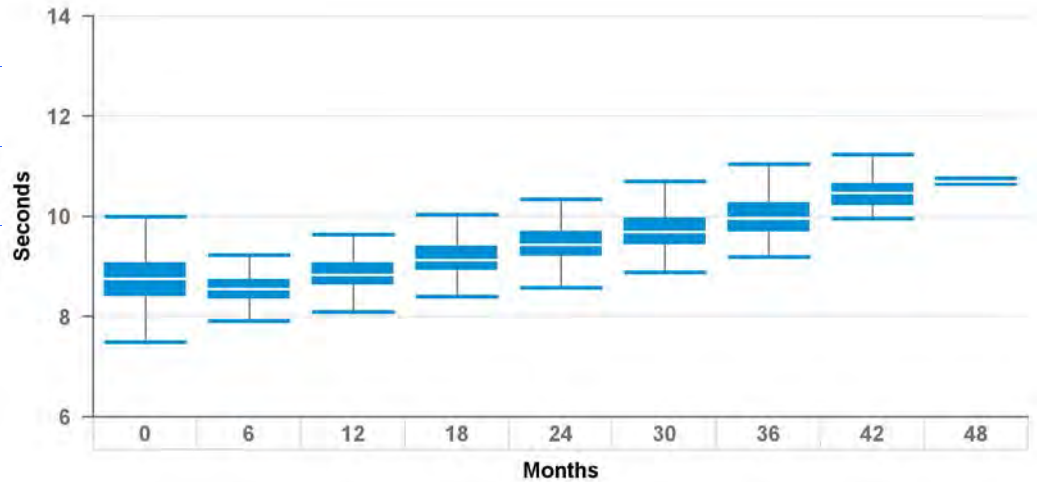
D274VRC, D294VRC Charge Time

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



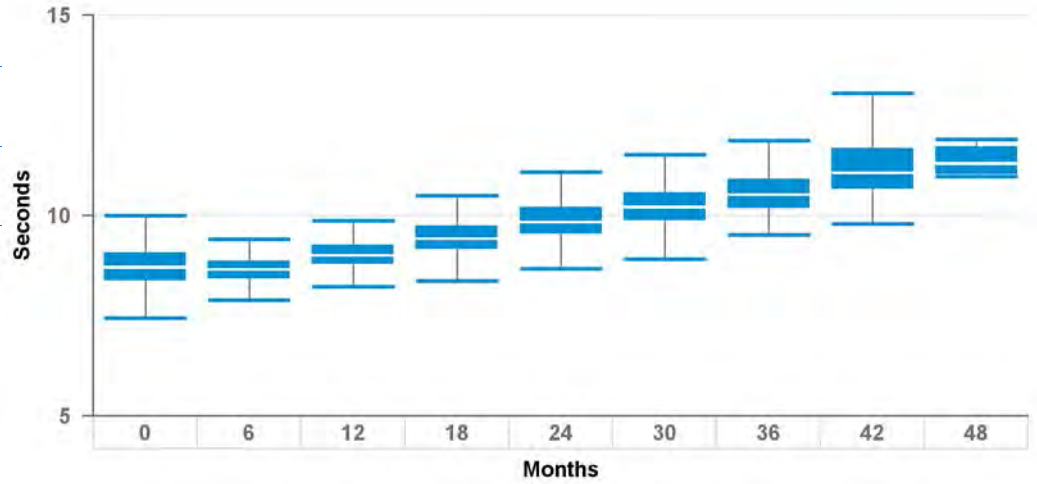
D314DRx Charge Time

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



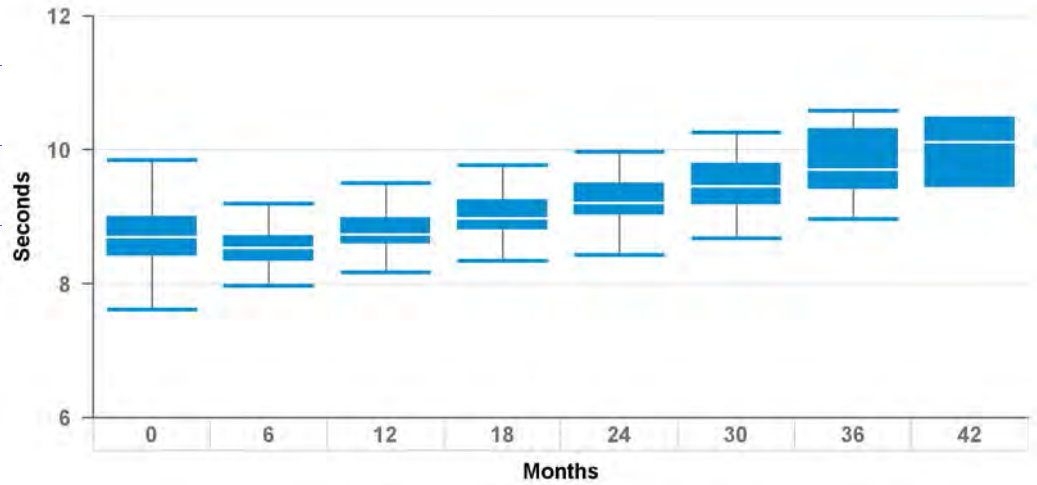
D314TRx Charge Time

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



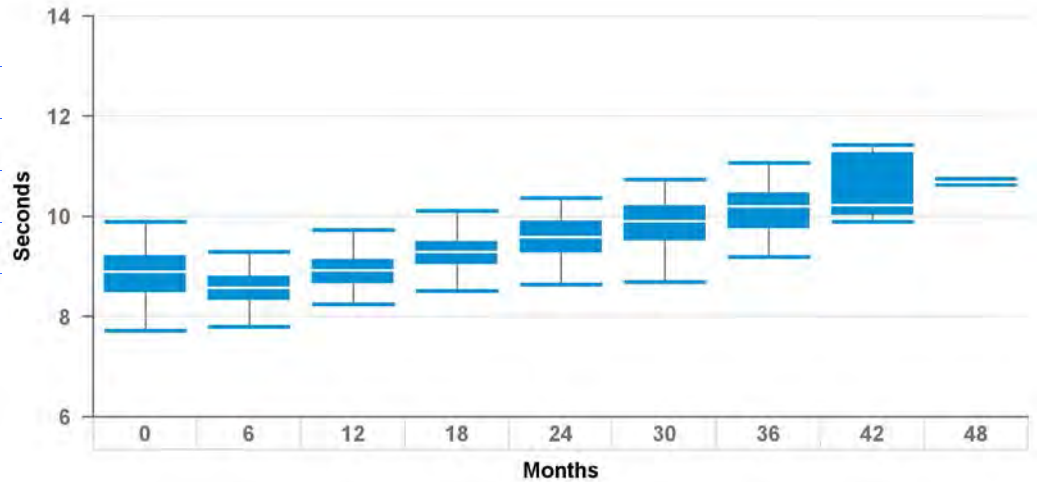
D314VRx Charge Time

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



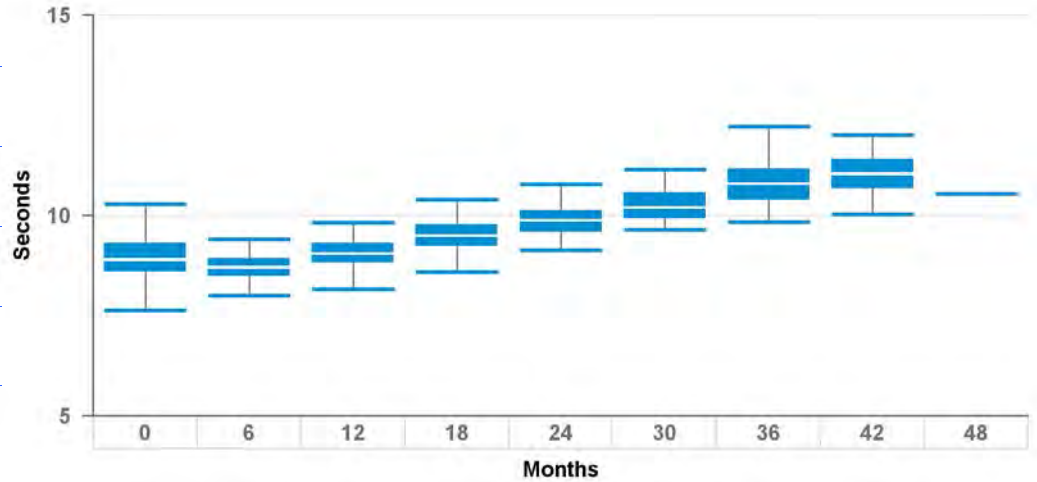
D334DRx, D364DRx Charge Time

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



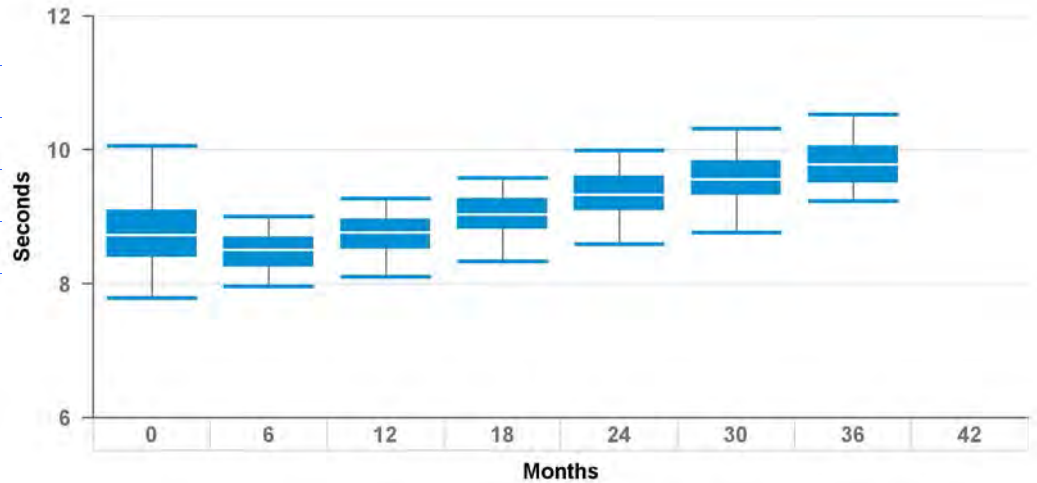
D334TRx, D364TRx Charge Time

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



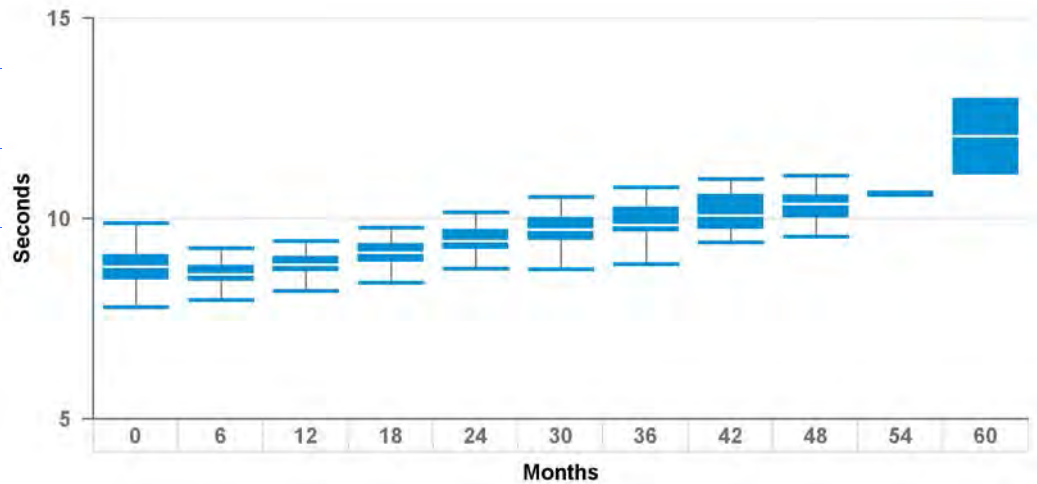
D334VRx, D364VRx Charge Time

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



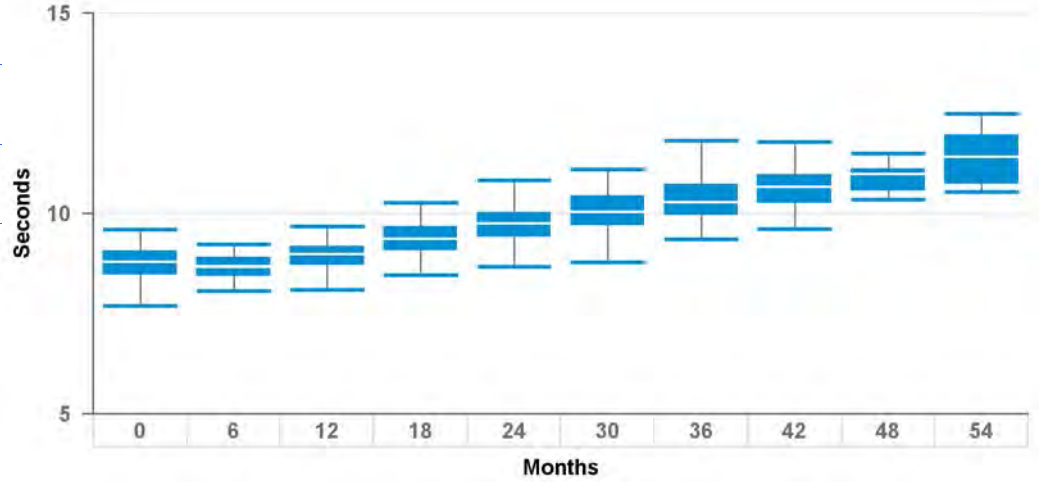
D354DRx Charge Time

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



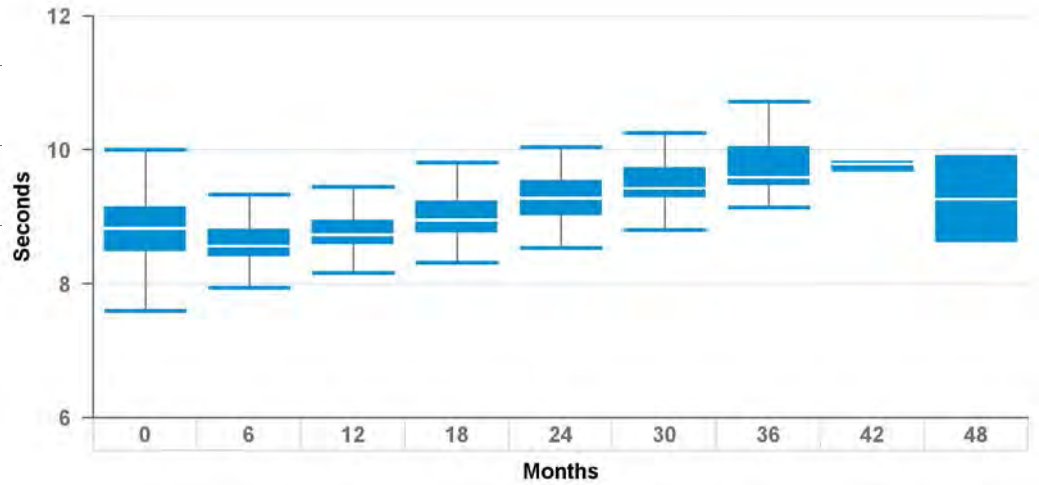
D354TRx Charge Time

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



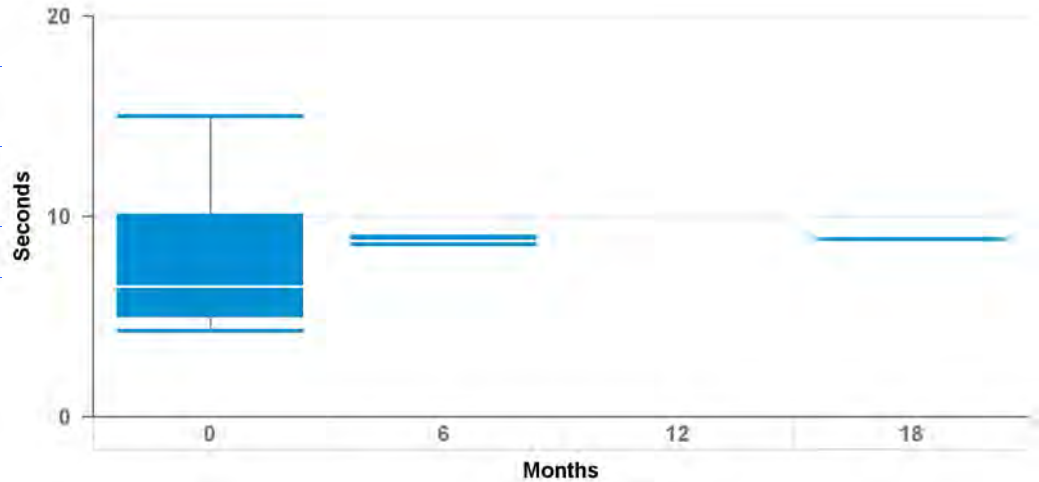
D354VRx Charge Time

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



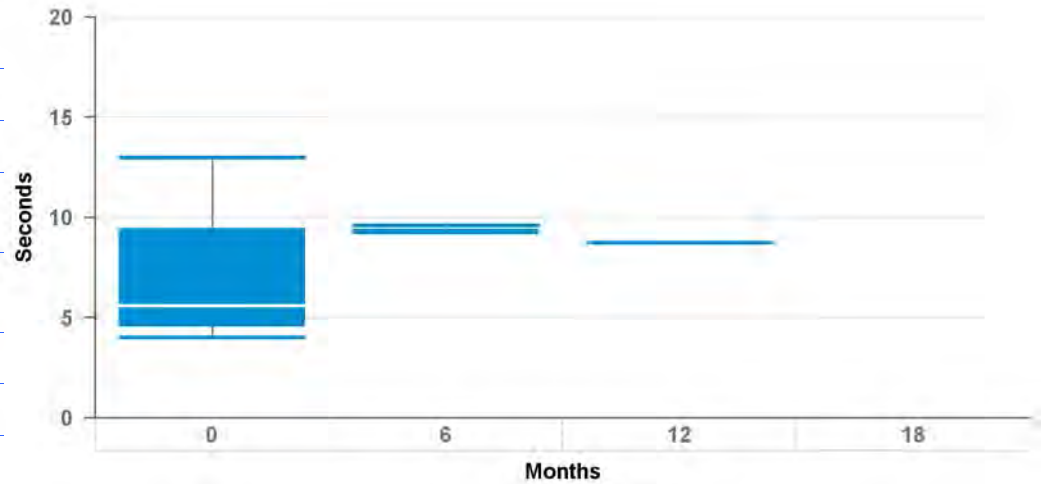
DDxxxx, DR Charge Time

Model Number	Brand
DDMB1D4	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D4	Evera MRI



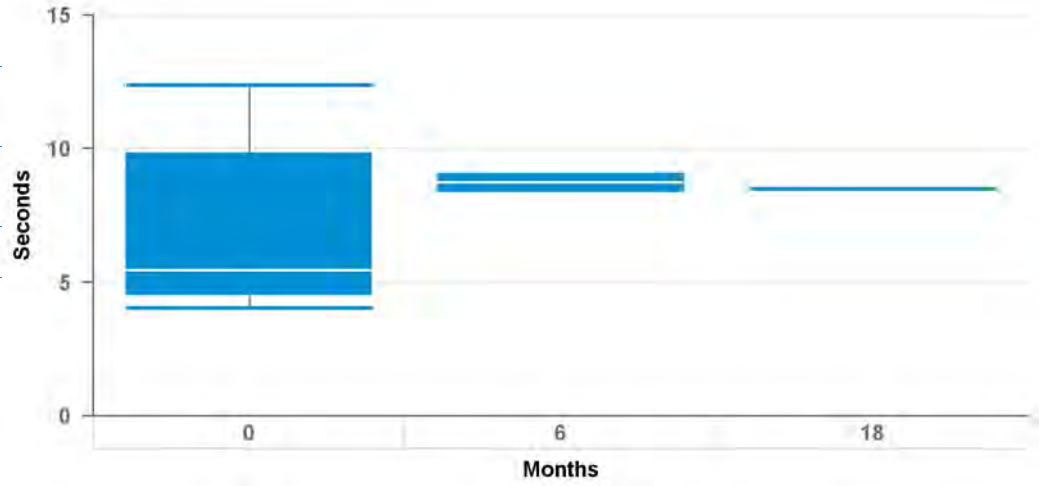
DTxxxx, CRT-D Charge Time

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
DTBX1QQ	Viva Quad C
DTBX2QQ	Viva Quad C



DVxxxxx, VR Charge Time

Model Number	Brand
DVMB1D4	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D4	Evera MRI S



Advisories

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 October 14, 2015, 536 of the 779 devices have been returned from field inventory. Medtronic estimates the remaining 226 devices (41 in the U.S.) have been implanted. **There have been no reported or confirmed device failures or patient injuries.**

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
Up to 779 Worldwide (44 United States)	0 Worldwide (0 United States)	190 Worldwide (35 United States)	0% Worldwide (0% United States)

Advisories

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 October 1, 2015, there have been 93 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)	93 Worldwide (73 United States)	11,400 Worldwide (7,300 United States)	0.13% Worldwide (0.16% United States)

Advisories

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.

Advisories

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

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.

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 October 1, 2015, 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)	16,403 Worldwide	5,515	6.1%	0	50,500 Worldwide

Advisories

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	50,500 Worldwide

¹The 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.

²Accounts for underreporting of impedance ERIs based on the fraction of replaced devices in the U.S. registration system that are subsequently returned.

Advisories

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 October 14, 2015, Medtronic has observed 459 Kappa devices and 312 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.79% (Kappa) and 2.1% (Sigma) of the original affected implant population.

Advisories

Four hundred twenty-two (422) of the Kappa devices (0.72%) and 244 of the Sigma devices (1.6%) 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, none of the Kappa devices and less than 100 Sigma devices remain implanted worldwide.

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 (222 United States) with information indicating a clinical presentation. An additional 37 worldwide (25 US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	No active population remains	0.70% Worldwide (1.19% United States)	N/A
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (3,700 United States)	244 Worldwide (53 United States) with information indicating a clinical presentation. An additional 68 worldwide (17 US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	less than 100 Worldwide	1.6% Worldwide (1.4% United States)	4.8%

Advisories

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 fractures¹. 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

Advisories

Status Update

As of October 14, 2015, of the initial implant population of 205,600 in the United States, approximately 63,100 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 78.9% (+4.3/-4.0%) at 102 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 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)	6,647 Worldwide (4,764 United States)	85,800 Worldwide (63,100 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.

Advisories

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 October 14, 2015, 844 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred seventy-nine(479) of the Sigma devices (1.1%) 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.

Advisories

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 3,200 remain implanted. Approximately 800 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)	479 Worldwide (96 United States) with information indicating a clinical presentation. An additional 365 Worldwide (66 US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	3,200 Worldwide (800 United States)	1.1% Worldwide (1.0% 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.

Reset Method for Kappa and EnPulse

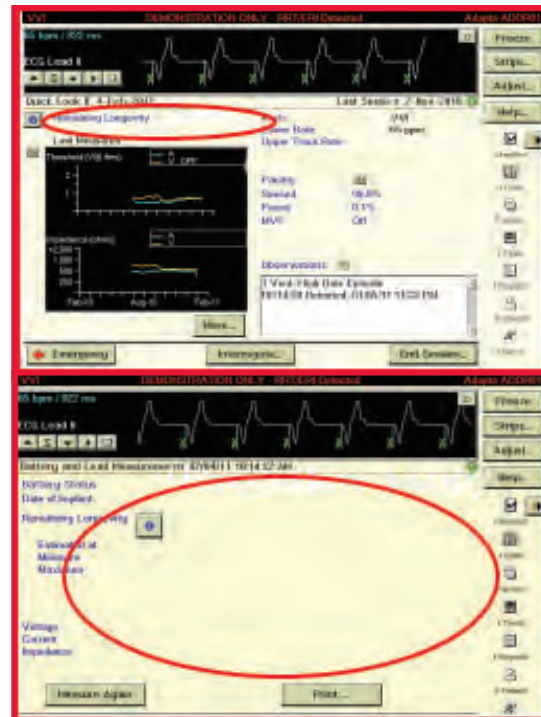
A service tool continues to be available through Medtronic Technical Services to clear the measurement lock-up issue for Kappa and EnPulse devices.

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 1 – Programmer Software Detects Measurement Lock-up ERI



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, Katsiyannis 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
Email: crdm.returnedproduct@medtronic.com



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