CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2017

First Edition – Issue 76

Medtronic

CRHF Product Performance Report

2017

First Edition
Issue 76

Cutoff date for this edition is 31 January 2017 for Lead Study data and 3 February 2017 for all other data, unless otherwise stated.

Our Commitment to Quality

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

The third tenet of the mission is all about quality:

"To strive without reserve for the greatest possible reliability and quality in our products, to be the unsurpassed standard of comparison, and to be recognized as a company of dedication, honesty, integrity, and service."

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

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

When a device is returned to Medtronic, laboratory technicians and engineers assess overall device function. Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate a performance concern from a customer, or to collect specific reliability data.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRHF maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

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

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

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure
Medtronic, Inc.

Contact Information

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

US Technical Services Department

Phone: 1 (800) 723-4636 (Tachy)
1 (800) 505-4636 (Brady)

Fax: 1 (800) 824-2362

International Technical Centers

Europe (Heerlen NL) +31-45-566-8844
Japan (Tokyo) +81-3-6430-7026

For questions related to returning explanted product or returning product that shows signs of malfunction, please contact:

Outside the United States:
Your Medtronic representative or international technical center at the number above.

Within the United States:
Your Medtronic representative or
CRHF Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email:
crdm.returnedproduct@medtronic.com

Editorial Staff

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Introduction

For 33 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 (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 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 CRHF 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.

Confidence Intervals

Since survival curves are based on a sample of the device and lead population, they are only estimates of survival. The larger the effective sample size, the more confident the estimate. A confidence interval can be calculated to assess the confidence in an estimate. In the Product Performance Report, Medtronic provides a 95% confidence interval. This can be interpreted as meaning that 95% of the time, the true survival of the device will fall somewhere in the interval.

Survival Curves in the Product Performance Report

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRTs, ICDs, and IPGs, and when the number entered is less than 50 for leads. The survival charts in the Product Performance Report show the effective sample size for each year interval where Medtronic has experience. When the effective sample size reaches 100 for CRTs, ICDs, and IPGs or when the number entered reaches 50 for leads, the next data point is added to the survival curve.

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

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

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

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

Method for Estimating CRT, ICD, and IPG Device Performance

The performance of CRT, ICD, and IPG devices is expressed in terms of device survival estimates, where "survival" refers to the function of the device, not the survival of the patient. These survival estimates are intended to illustrate the probability that a device will survive for a given number of years without malfunction or battery depletion.

The survival estimates are determined from the analysis of Medtronic Cardiac Rhythm and Heart Failure (CRHF's) United States device registration data and US returned product analysis data. These data are presented graphically and numerically.

Because this analysis is based on returned product analysis, the performance data does not reflect any device-related medical complications such as erosion, infection, muscle stimulation, or muscle inhibition.

Categorization of Depleted and Malfunctioning Devices for Survival Analysis

For survival estimation, every device returned to Medtronic CRHF and analyzed in the CRHF Returned Product Analysis laboratory is assigned to one of three categories. The device 1) is functioning normally, 2) has reached normal battery depletion, or 3) has malfunctioned. This categorization is combined with data from our device registry for the total number of implants and the implant durations to create the survival curves presented on the following pages.

Definition of Malfunction

Medtronic CRHF considers a device as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service. To be considered a malfunction or battery depletion, the device must have been returned to Medtronic and analyzed.

Devices damaged after explant, damaged due to failure to heed warnings or contraindications in the labeling, or damaged due to interaction with other implanted devices (including leads) are not considered device malfunctions.

A device subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRHF and found, through analysis, to actually have performed outside the performance limits established by Medtronic.

Not all malfunctions expose the patient to a loss of therapy. Some malfunctions included in the following survival estimates may not have been detected at all by the physician or the patient. These malfunctions, however, are included in the survival estimates and provide important feedback to our product development organization.

To provide insight into the nature of malfunctions, each malfunction is categorized as Malfunction with Compromised Therapy Function or Malfunction without Compromised Therapy Function.

For this report, Normal Battery Depletion, Malfunction with Compromised Therapy Function, and Malfunction without Compromised Therapy Function are defined as follows:

Normal Battery Depletion – The condition when:

(a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or
(b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information.

Medtronic CRHF establishes expected longevity by statistically characterizing the power consumed by the device and the power available from the device battery. This characterization is applied to a number of parameter configurations to derive a statistical mean longevity value and standard deviation for each parameter configuration. The statistical mean value minus three standard deviations is used as the expected longevity for determining if a battery depleted normally. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from these estimates.

Malfunction with Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation), while implanted and in service, as confirmed by returned product analysis.

Examples: Sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted delivery of therapy, intermittent malfunction where therapy is compromised while in the malfunction state.

Malfunction without Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy, while implanted and in service, as confirmed by returned product analysis.

Examples: Error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Expanded Malfunction Detail

The malfunctions are further divided into categories that identify the subject area of the malfunction. The malfunctions are divided into the following subject areas:

Electrical Component – Findings linked to electrical components such as integrated circuits, resistors, capacitors, diodes, etc.

Electrical Interconnect – Findings linked to the connections between electrical components such as wires, solder joints, wire bonds, etc.

Battery – Findings linked to the battery and its components

Software/Firmware – Findings linked to software or firmware function

Possible Early Battery Depletion – Findings where the actual reported implant time is less than 80% of the expected longevity calculated using the available device setting information with no device malfunction observed. There may not be sufficient device setting information to determine conclusively if battery depletion was normal or premature in the absence of a specific root cause finding. However, returned devices meeting the above criteria are conservatively classified as Possible Early Battery Depletion malfunctions.

Other – Findings related to other components such as insulators, grommets, setscrews, and packaging, and findings where analysis is inconclusive.

Returned Product Analysis Process

Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate a performance concern from a customer, or to collect specific reliability data.

When a device is returned with a performance concern from a customer, the general analysis process includes a preliminary analysis of the device in its as-received condition, followed by an automated functional test using test equipment equivalent to the equipment used in manufacturing.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRHF maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Statistical Methods for Survival Analysis

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions assumed distributed evenly within the intervals (Cutler-Ederer Method), is used to determine survival estimates for CRT, IPG and ICD devices. Implant times are calculated from the implant date to the earlier of the explant date or the cutoff date of the report. From this data an estimate of the probability of device survival is calculated at each monthly interval.

On the following pages, each graph includes a survival curve where events include malfunctions and normal battery depletions. This survival curve is a good representation of the probability a device will survive a period of time without malfunction and without battery depletion. For example, if a device survival probability is 95% after 5 years of service, then the device has a 5% chance of being removed due to battery depletion or malfunction in the first 5 years following implant.

In addition, a second curve is included to show survival excluding normal battery depletion. This curve is a good representation of the probability for a device to survive without malfunction. This curve includes only malfunctions as events and excludes normal battery depletion.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRT, ICD, and IPG devices. The survival charts in the Product Performance Report show the effective sample size for each year interval where we have experience. When the effective sample size reaches 100, the next data point is added to the survival curve.

Although the report provides tabular data in one-year intervals, the curves are actually computed and plotted using one-month intervals.

The data in the tables are rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have one or more malfunctions or battery depletions. This occurs because, even with the malfunctions or battery depletions, the data rounds to 100%.

Sample Size and How the Population and Population Samples Are Defined

The population sample from which the survival estimates are derived is comprised of the devices registered as implanted in the United States as of the report cutoff date. The number of registered implants, as well as an estimate of the number that remain in active service, is listed for each model. To be included in the population, the device must have been registered with Medtronic's registration system and implanted for at least one day.

This sample based on US implants is considered to be representative of the worldwide population, and therefore the survival estimates shown in this report should be representative of the performance worldwide of these models.

A CRT, ICD, or IPG model or model family will be included in this report when it has accumulated at least 10,000 implant months and will remain in the report as long as at least 500 devices remain active.

Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion

The tables on the following pages show the actual number of malfunctions and battery depletions recorded by the analysis lab for US registered devices. Since not all devices are returned to Medtronic CRHF for analysis, these numbers underestimate the true number of malfunctions and battery depletions. To more accurately estimate the all-cause device survival probabilities, the number of malfunctions and battery depletions used to plot each interval of the all-cause survival curves is adjusted (multiplied) by a factor that is based on an estimate of the magnitude of underreporting. The magnitude of underreporting is estimated by comparing data in Medtronic's Device And Registrant Tracking (DART) system with data from Returned Product Analysis.

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

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

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

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

No adjustment for underreporting is applied to the malfunction-free survival curve because a method for estimating malfunction-only underreporting has not been developed.

Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

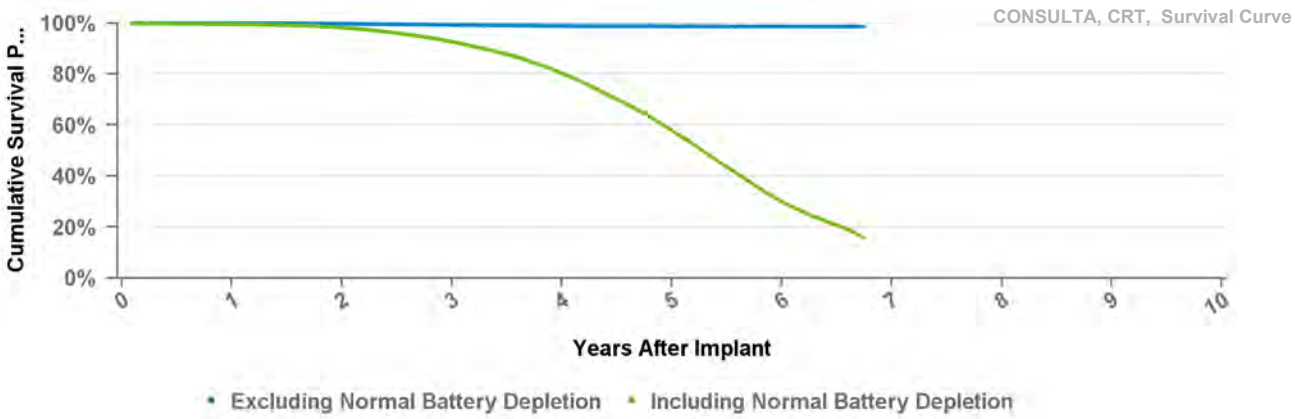
Devices are at times removed from service for reasons other than device malfunction or battery depletion. Examples are devices removed from service due to non-device related patient mortality and devices removed due to changes in the patient's medical condition. Because an accurate estimate of device survival depends on an accurate estimate of the number of devices in service, it is important not to overstate the number of devices in service.

Medtronic addresses this under reporting to ensure the number of devices in service is not overstated . Regular updates obtained from the Social Security Administration about deceased persons are used to update Medtronic's DART data about patients who have died but whose deaths had not been reported to Medtronic. In addition, the patient mortality rate derived from our DART system is monitored and compared to published mortality rates for comparable patient populations. If, during calculation of the survival curves, the patient mortality indicated by the data in DART is significantly different from published rates, an adjustment is applied to correct the difference. The correction factor for under reporting devices is also applied to account for devices that were removed and not reported or returned.

CRT-D

D204TRM Consulta CRT-D

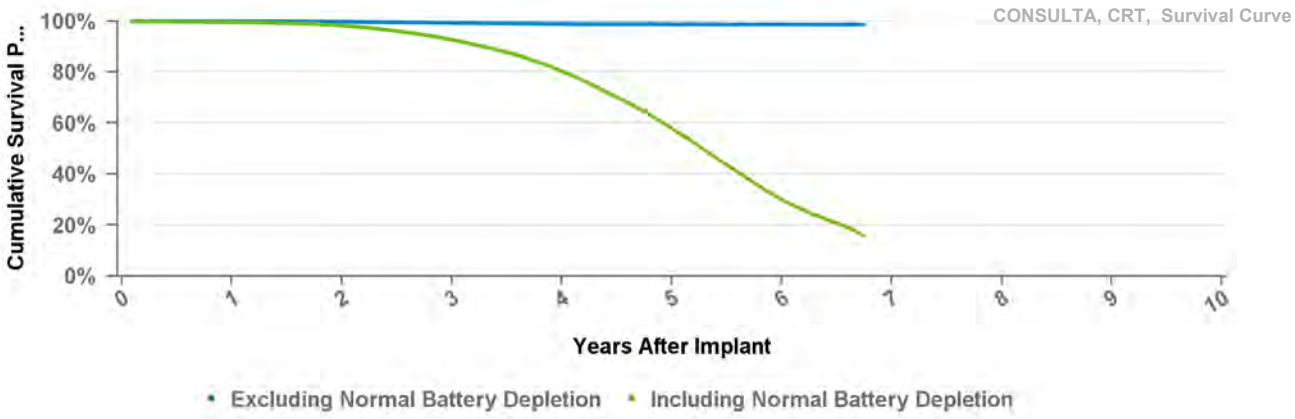
US Market Release	Jan-12	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,099	Electrical Component	1
Estimated Active USA Implants	1,463	Poss Early Battery Depltn	1
Normal Battery Depletions	170	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.6%
Including NBD	99.5%	98.2%	92.7%	80.2%	57.8%	29.9%	15.4%
Effective Sample Size	58006	52865	45937	34764	19324	5527	338

D214TRM Consulta CRT-D

US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



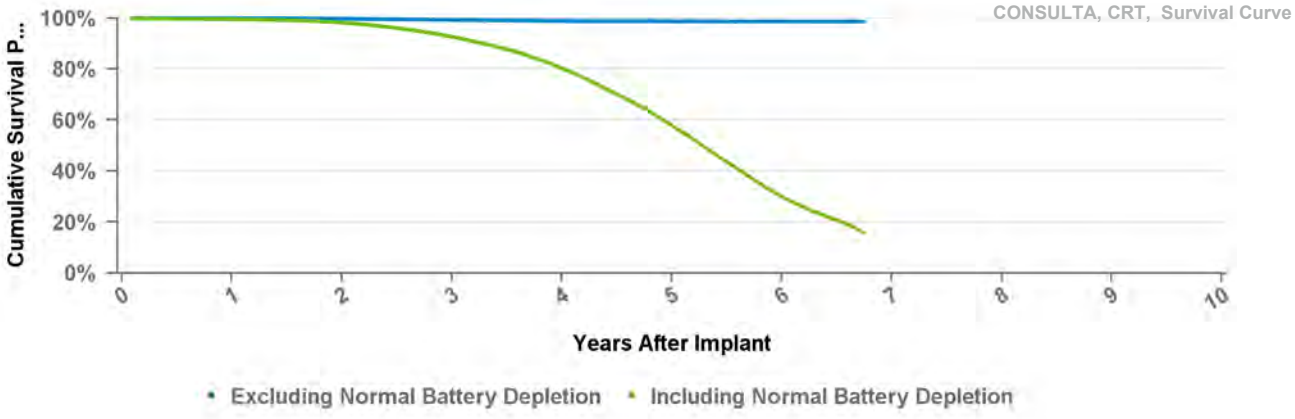
Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.6%
Including NBD	99.5%	98.2%	92.7%	80.2%	57.8%	29.9%	15.4%
Effective Sample Size	58006	52865	45937	34764	19324	5527	338

CRT-D

D224TRK Consulta CRT-D

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	65,985
Estimated Active USA Implants	16,195
Normal Battery Depletions	17,077

Total Malfunctions	**597**
Therapy Function Not Compromised	**572**
Battery Malfunction	2
Electrical Component	66
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	496
Software Malfunction	6
Therapy Function Compromised	**25**
Battery Malfunction	1
Electrical Component	24

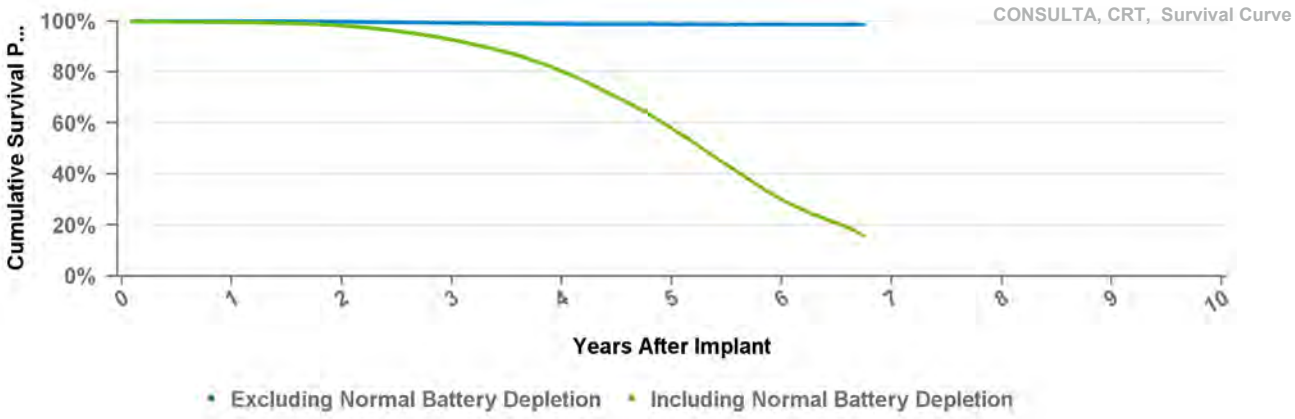


Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.6%
Including NBD	99.5%	98.2%	92.7%	80.2%	57.8%	29.9%	15.4%
Effective Sample Size	58006	52865	45937	34764	19324	5527	338

D234TRK Consulta CRT-D

US Market Release	
CE Approval Date	Mar-08
Registered USA Implants	2
Estimated Active USA Implants	1
Normal Battery Depletions	

Total Malfunctions	
Therapy Function Not Compromised	
Therapy Function Compromised	

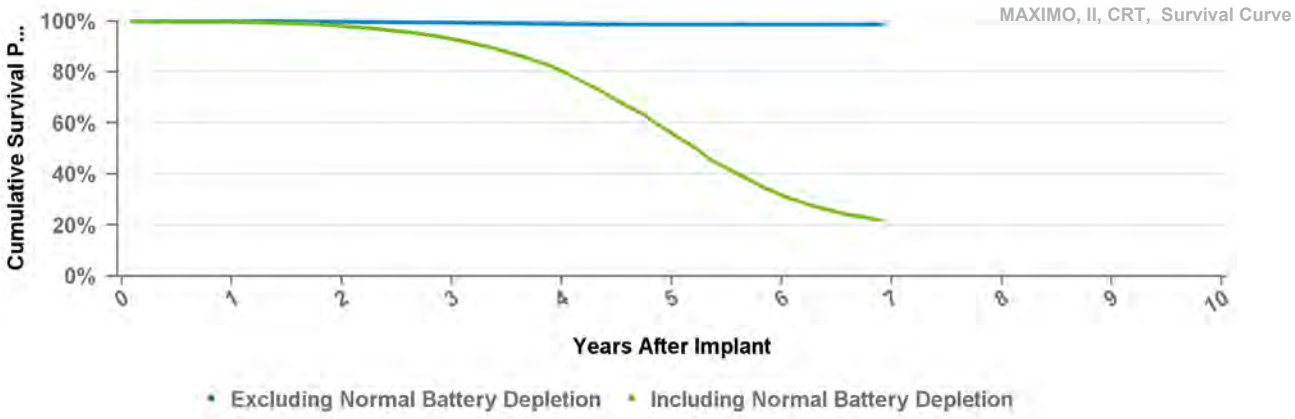


Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.6%
Including NBD	99.5%	98.2%	92.7%	80.2%	57.8%	29.9%	15.4%
Effective Sample Size	58006	52865	45937	34764	19324	5527	338

CRT-D

D264TRM Maximo II CRT-D

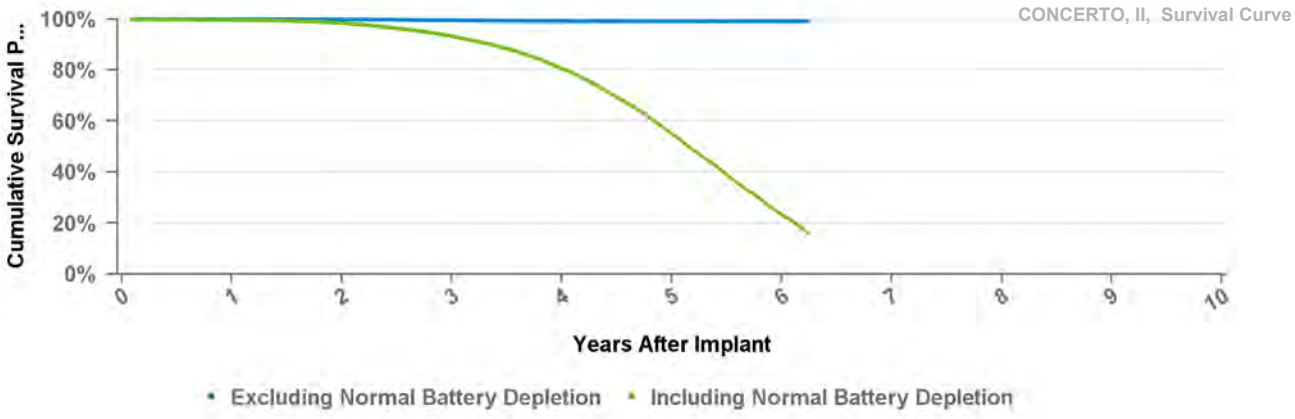
US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	15		
Estimated Active USA Implants	6	**Therapy Function Compromised**	
Normal Battery Depletions	3		



Years	1	2	3	4	5	6	at 83 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.6%	98.1%	92.9%	80.4%	55.9%	31.6%	21.9%
Effective Sample Size	12932	11684	10181	7651	3938	1183	138

D274TRK Concerto II CRT-D

US Market Release	Aug-09	**Total Malfunctions**	**184**
CE Approval Date		**Therapy Function Not Compromised**	**174**
Registered USA Implants	30,171	Battery Malfunction	1
Estimated Active USA Implants	7,190	Electrical Component	21
Normal Battery Depletions	7,962	Poss Early Battery Depltn	151
		Software Malfunction	1
		Therapy Function Compromised	**10**
		Battery Malfunction	1
		Electrical Component	9

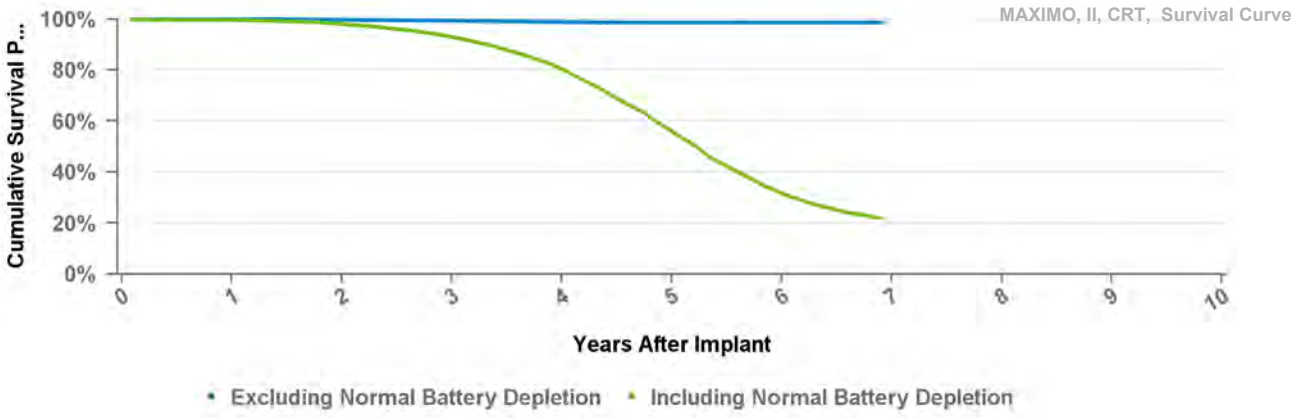


Years	1	2	3	4	5	6	at 75 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%
Including NBD	99.6%	98.4%	93.3%	80.6%	54.9%	23.2%	15.2%
Effective Sample Size	25419	23239	20262	15506	8411	1430	320

CRT-D

D284TRK Maximo II CRT-D

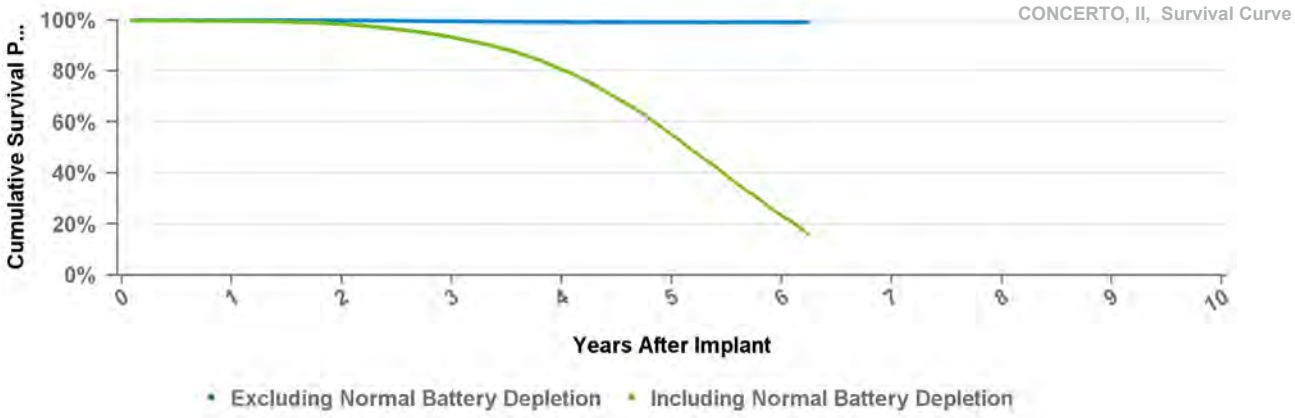
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,250	Electrical Component	6
Estimated Active USA Implants	4,042	Poss Early Battery Depltn	124
Normal Battery Depletions	3,703	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	at 83 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.6%	98.1%	92.9%	80.4%	55.9%	31.6%	21.9%
Effective Sample Size	12932	11684	10181	7651	3938	1183	138

D294TRK Concerto II CRT-D

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

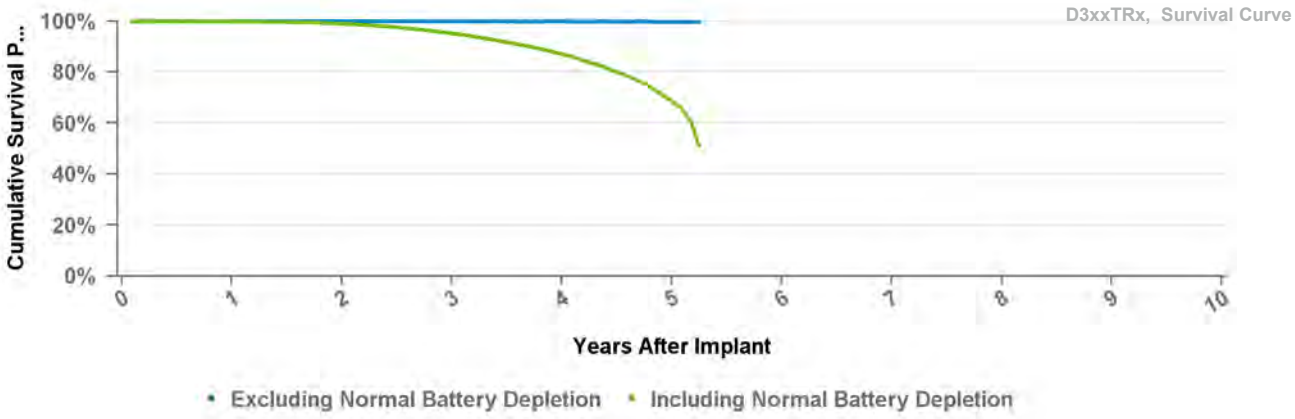


Years	1	2	3	4	5	6	at 75 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%
Including NBD	99.6%	98.4%	93.3%	80.6%	54.9%	23.2%	15.2%
Effective Sample Size	25419	23239	20262	15506	8411	1430	320

CRT-D

D314TRG Protecta XT CRT-D

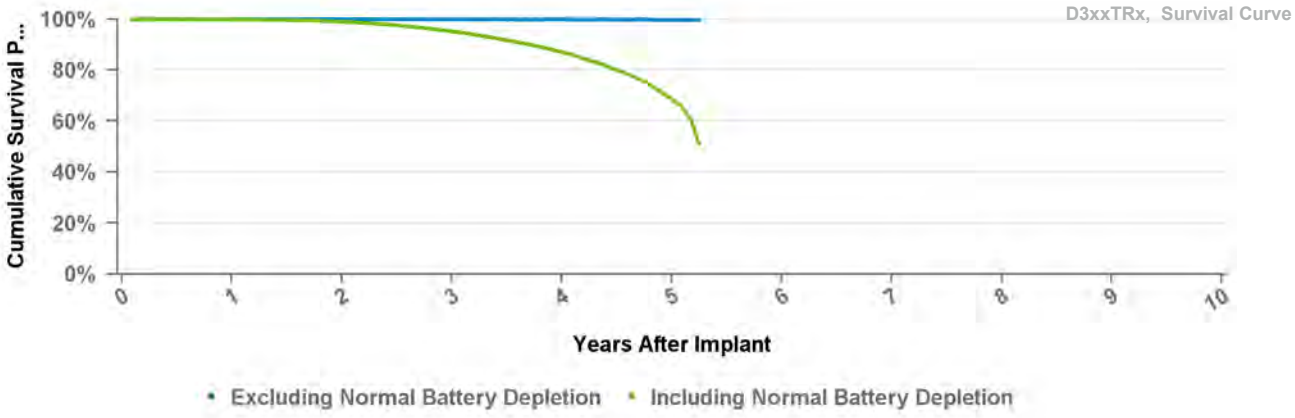
US Market Release	Mar-11	**Total Malfunctions**	**73**
CE Approval Date		**Therapy Function Not Compromised**	**62**
Registered USA Implants	42,443	Battery Malfunction	1
Estimated Active USA Implants	24,228	Electrical Component	35
Normal Battery Depletions	4,279	Other Malfunction	1
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**11**
		Battery Malfunction	3
		Electrical Component	8



Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

D314TRM Protecta XT CRT-D

US Market Release	Nov-11	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	12,248	Electrical Component	7
Estimated Active USA Implants	8,882	Poss Early Battery Depltn	5
Normal Battery Depletions	642	**Therapy Function Compromised**	**1**
		Electrical Component	1

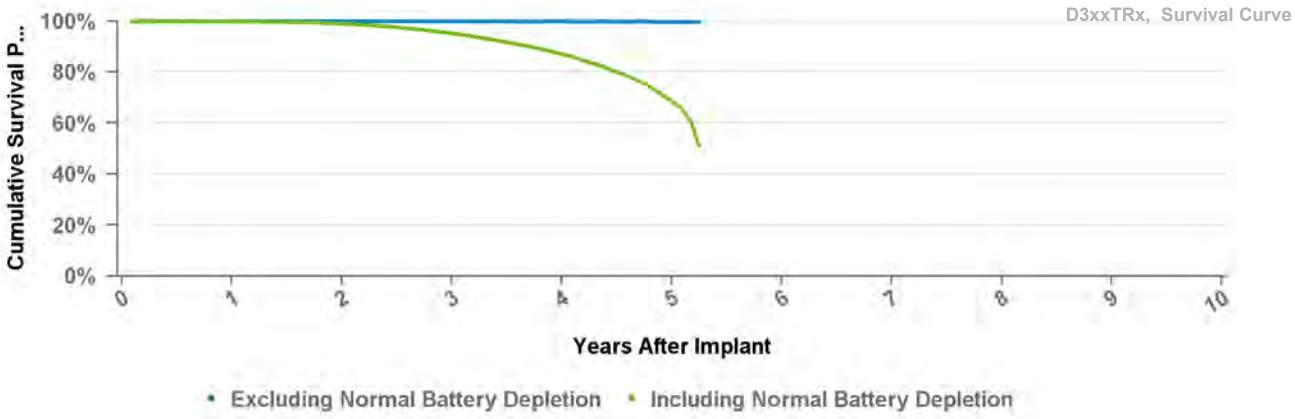


Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

CRT-D

D334TRG Protecta CRT-D

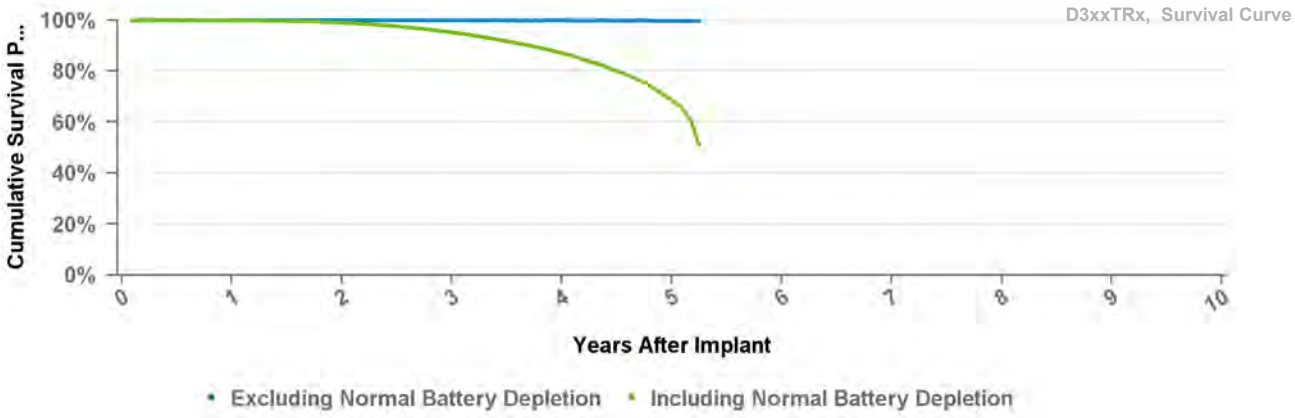
US Market Release	Mar-11	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	8,098	Electrical Component	8
Estimated Active USA Implants	4,830	Poss Early Battery Depltn	5
Normal Battery Depletions	768	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

D334TRM Protecta CRT-D

US Market Release	Nov-11	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	1,782	Electrical Component	1
Estimated Active USA Implants	1,277	Poss Early Battery Depltn	2
Normal Battery Depletions	105	**Therapy Function Compromised**	**0**

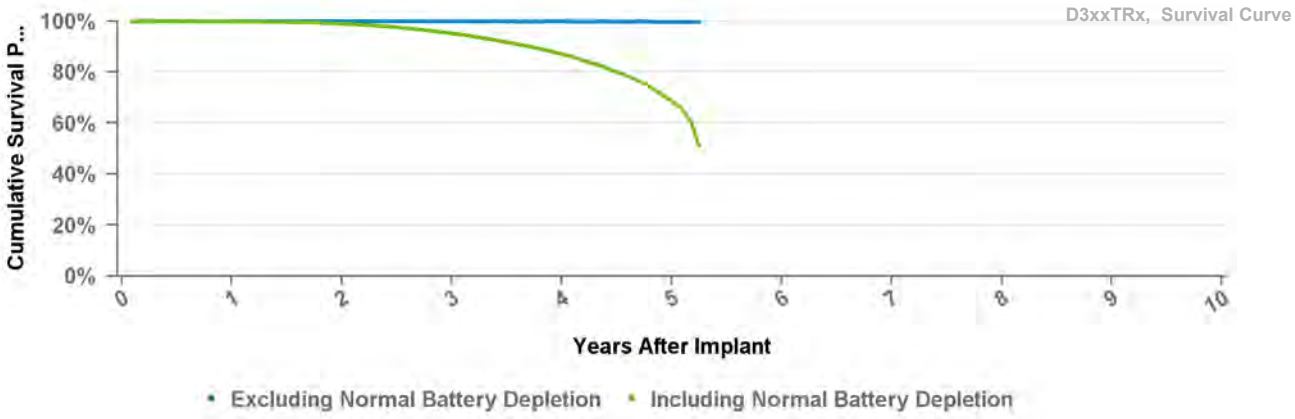


Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

CRT-D

D354TRG Protecta XT CRT-D

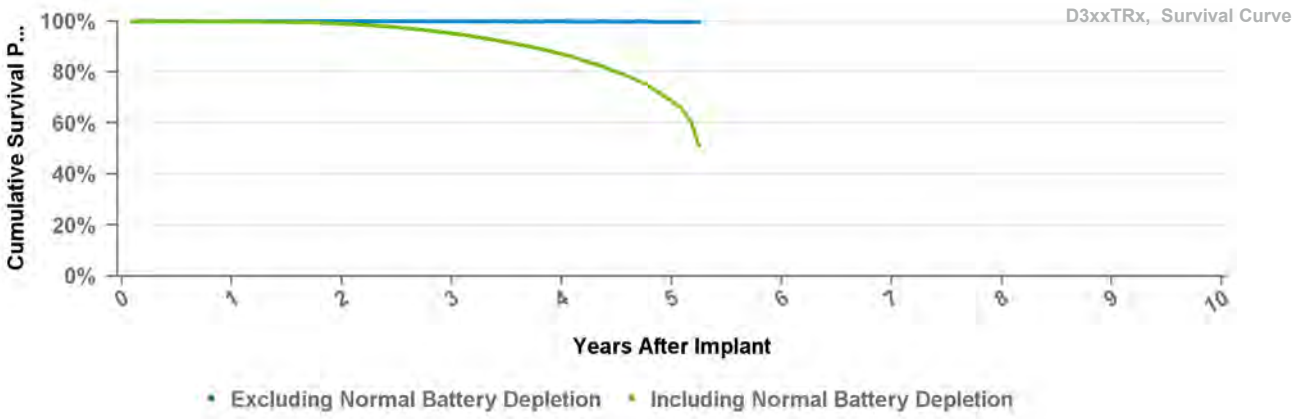
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

D354TRM Protecta XT CRT-D

US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



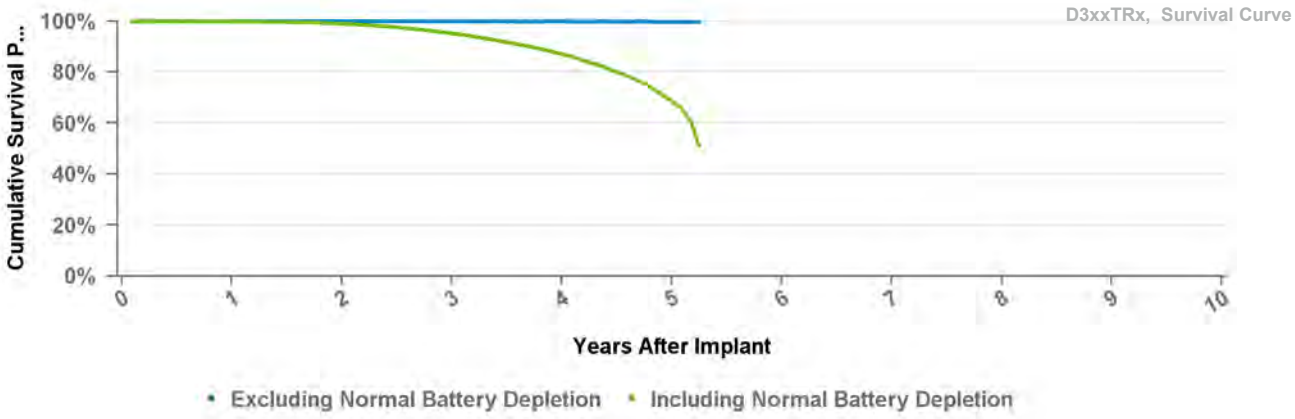
Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

CRT-D

D364TRG Protecta CRT-D

US Market Release
CE Approval Date Mar-10
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

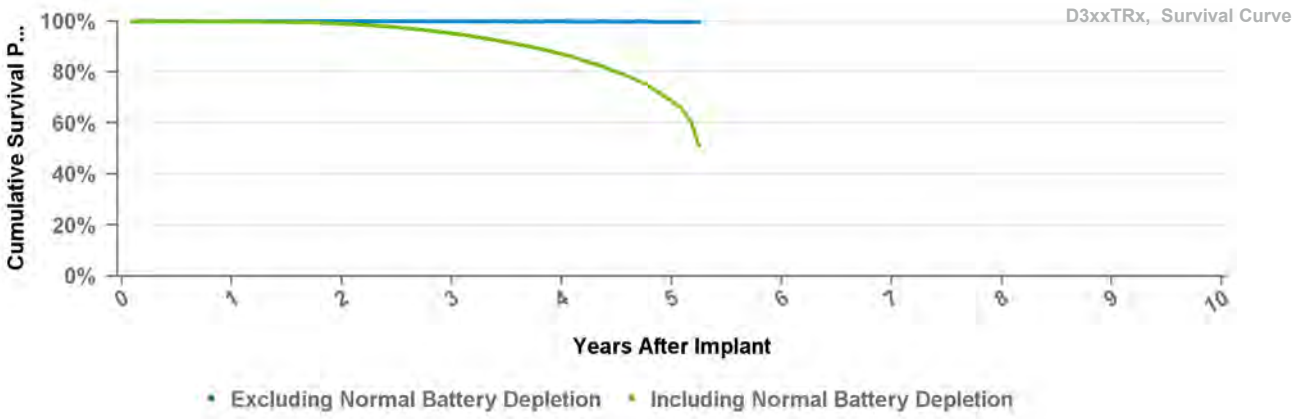


Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

D364TRM Protecta CRT-D

US Market Release
CE Approval Date Jul-10
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

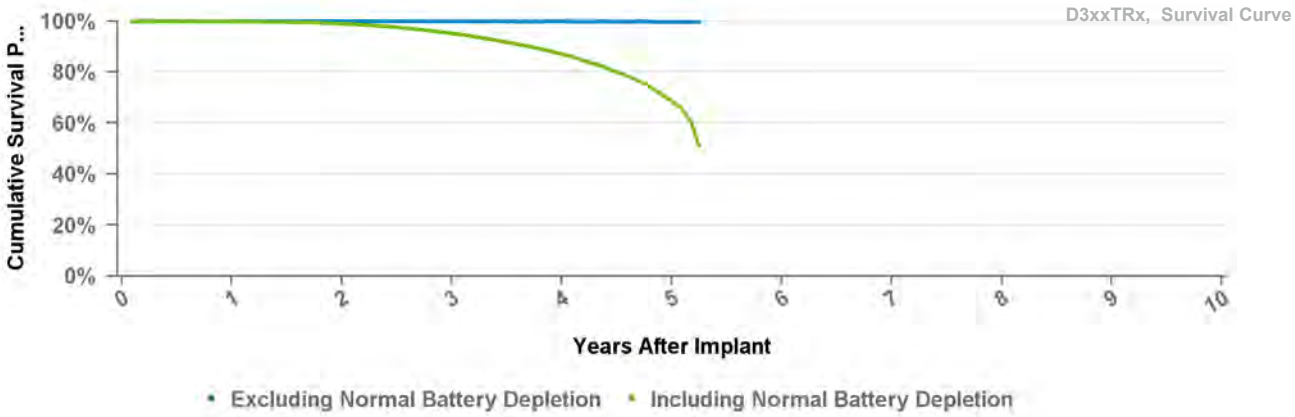


Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

CRT-D

D384TRG Cardia CRT-D

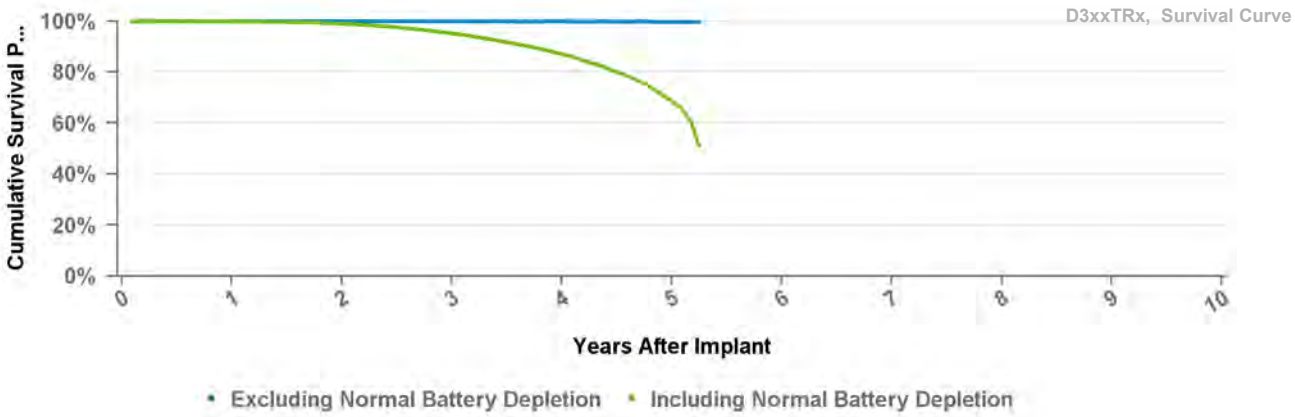
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

D394TRG Egida CRT-D

US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

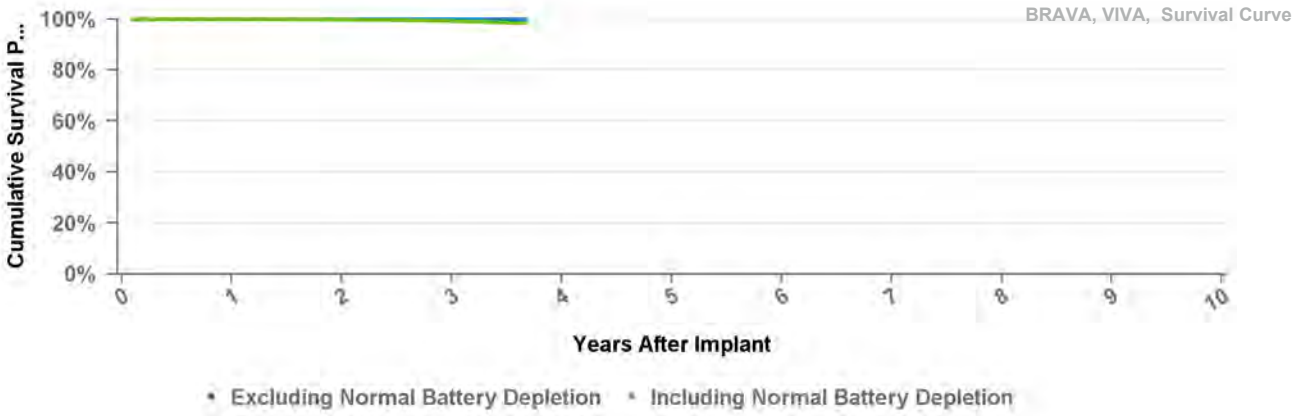


Years	1	2	3	4	5	at 63 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.0%	95.1%	87.0%	68.6%	51.1%
Effective Sample Size	56093	51626	44720	26725	3704	396

CRT-D

DTBA1D1 Viva XT

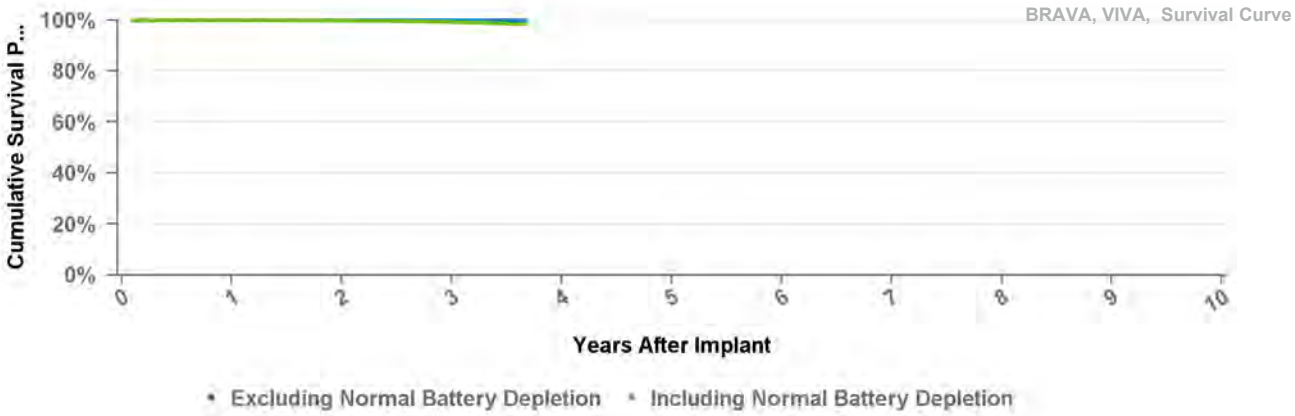
US Market Release	Jan-13	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**19**
Registered USA Implants	48,937	Battery Malfunction	2
Estimated Active USA Implants	44,376	Electrical Component	17
Normal Battery Depletions	85	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBA1D4 Viva XT

US Market Release	Jan-13	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	17,379	Battery Malfunction	1
Estimated Active USA Implants	15,749	Electrical Component	8
Normal Battery Depletions	25	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**1**
		Electrical Component	1

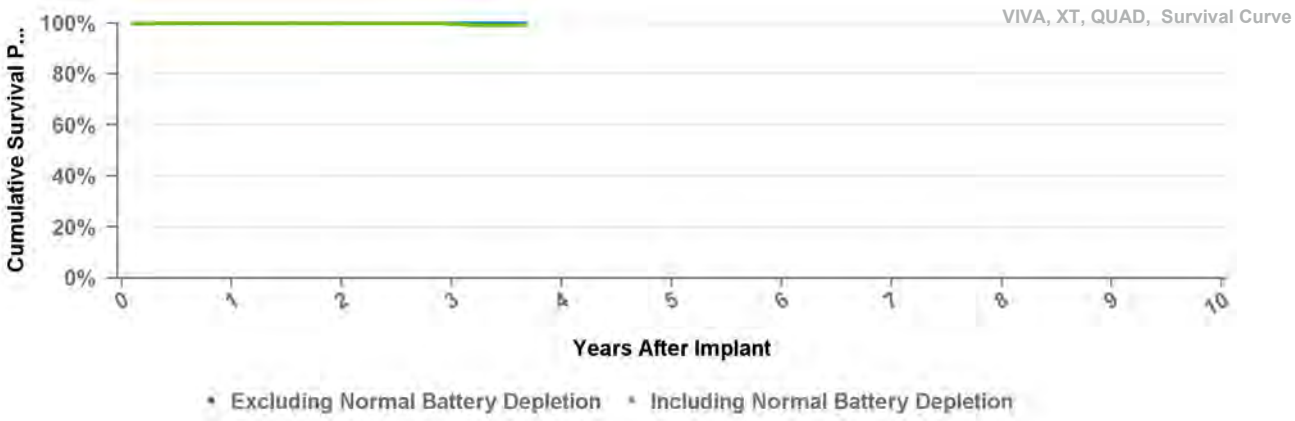


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBA1Q1 Viva Quad XT

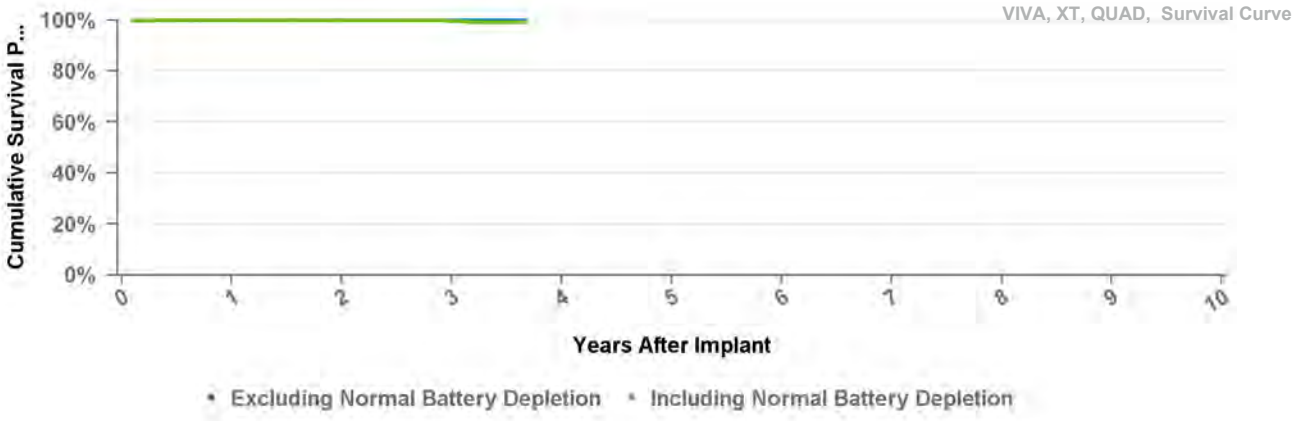
US Market Release	Jul-14	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	9,121	Electrical Component	1
Estimated Active USA Implants	8,518	Other Malfunction	1
Normal Battery Depletions	4	**Therapy Function Compromised**	**0**



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

DTBA1QQ Viva Quad XT

US Market Release	Jul-14	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	24,007	Electrical Component	8
Estimated Active USA Implants	22,981	**Therapy Function Compromised**	**0**
Normal Battery Depletions	10		



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

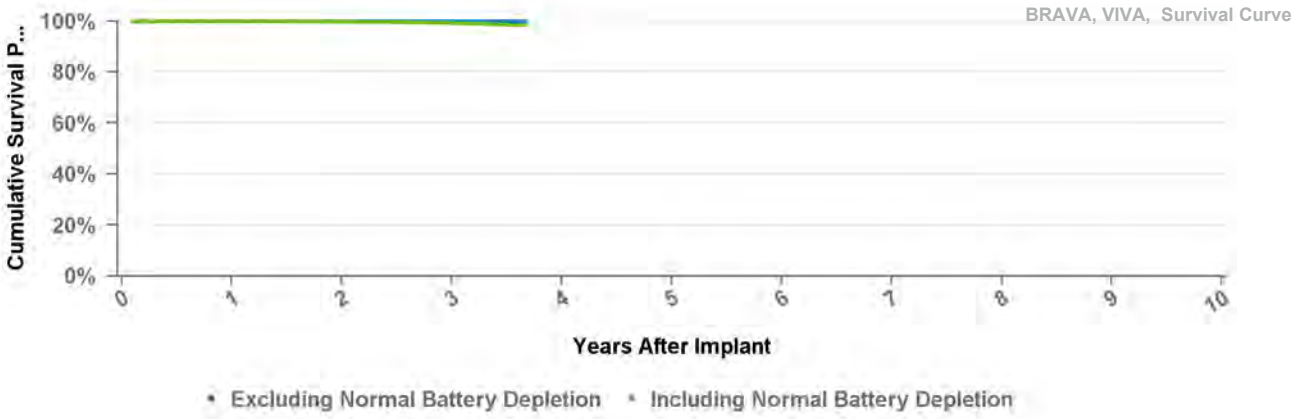
CRT-D

DTBA2D1 Viva XT

US Market Release
CE Approval Date Aug-16
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised

Therapy Function Compromised



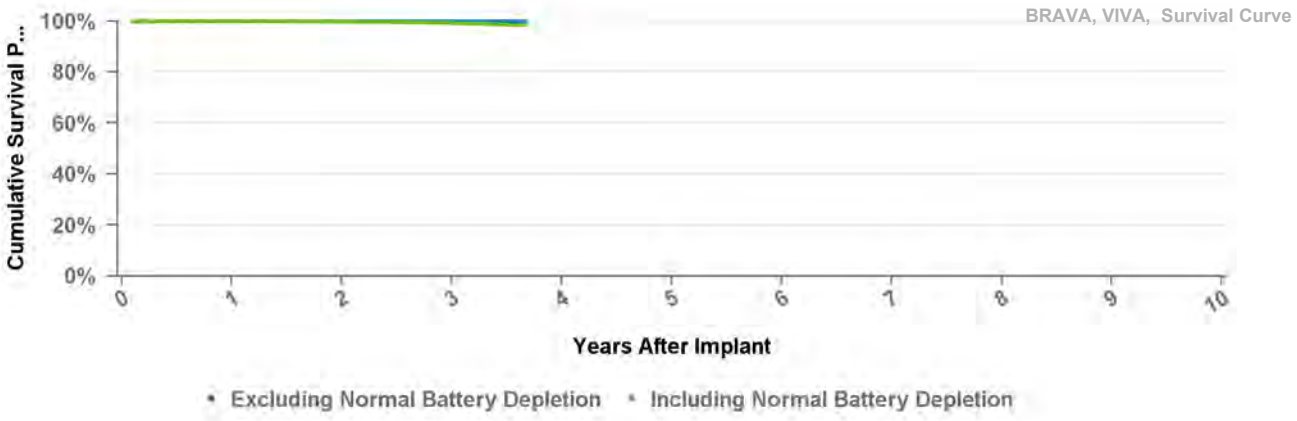
Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBA2D4 Viva XT

US Market Release
CE Approval Date Aug-12
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised

Therapy Function Compromised

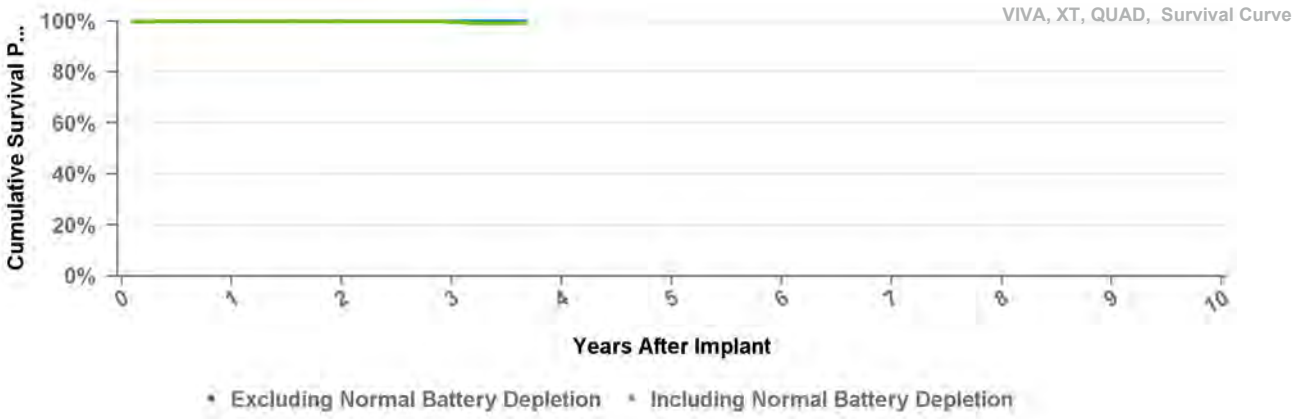


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBA2Q1 Viva Quad XT

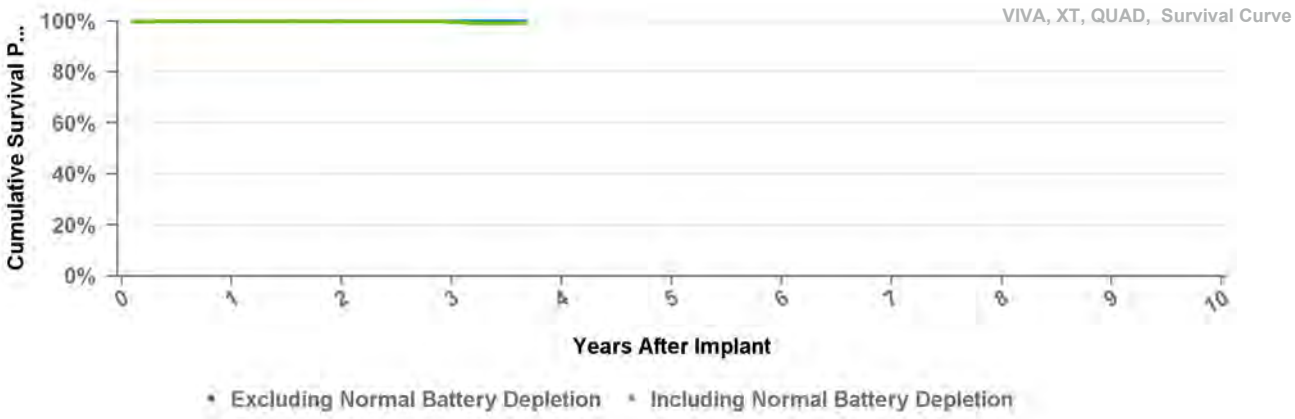
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

DTBA2QQ Viva Quad XT

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

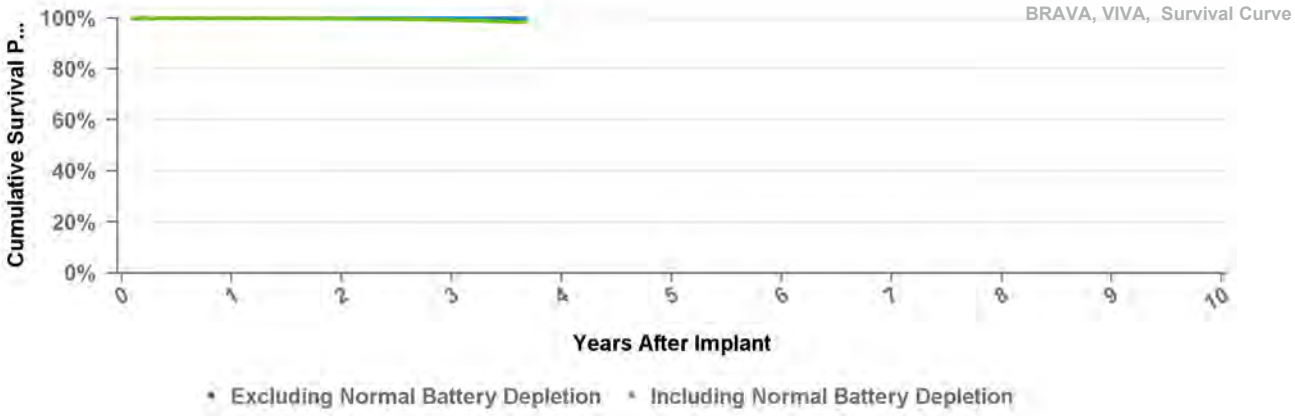


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

CRT-D

DTBB1D1 Viva S

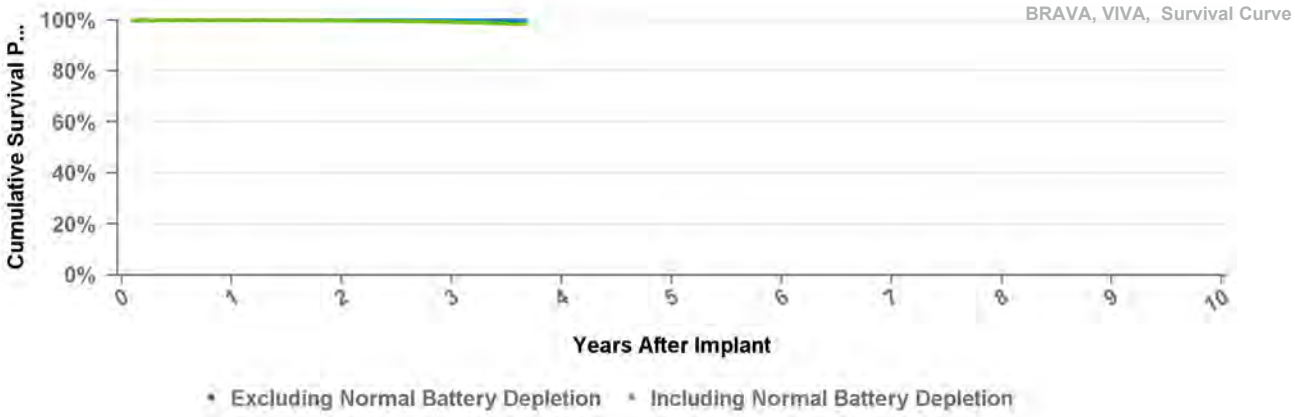
US Market Release	Jan-13	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	12,220	Electrical Component	3
Estimated Active USA Implants	10,865	**Therapy Function Compromised**	**1**
Normal Battery Depletions	38	Electrical Component	1



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBB1D4 Viva S

US Market Release	Jan-13	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,817	Other Malfunction	1
Estimated Active USA Implants	3,472	**Therapy Function Compromised**	**0**
Normal Battery Depletions	13		

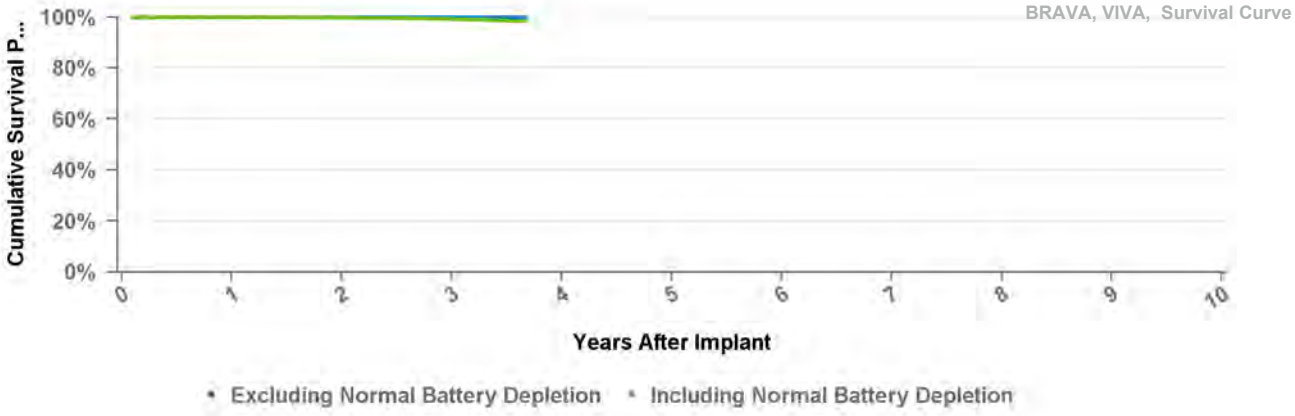


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBB1Q1 Viva Quad S

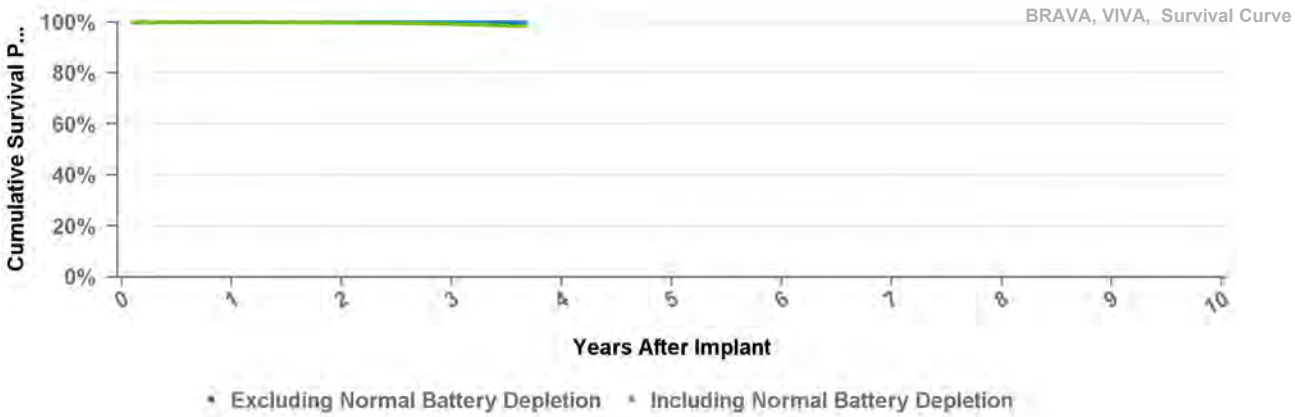
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,704	Electrical Component	1
Estimated Active USA Implants	1,596	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBB1QQ Viva Quad S

US Market Release	Jul-14	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	4,099	Electrical Component	2
Estimated Active USA Implants	3,927	**Therapy Function Compromised**	**1**
Normal Battery Depletions	1	Electrical Component	1



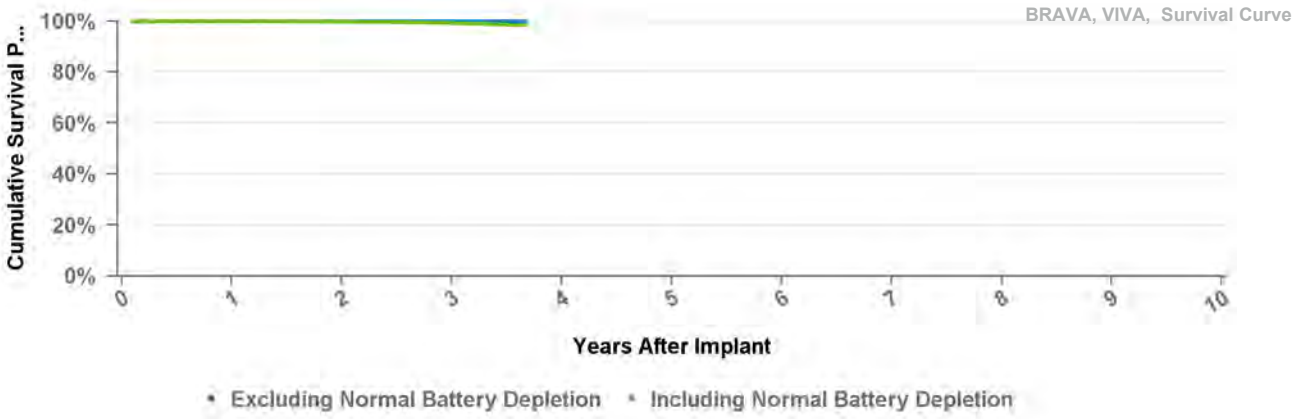
Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBB2D1 Viva S

US Market Release
CE Approval Date Aug-12
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

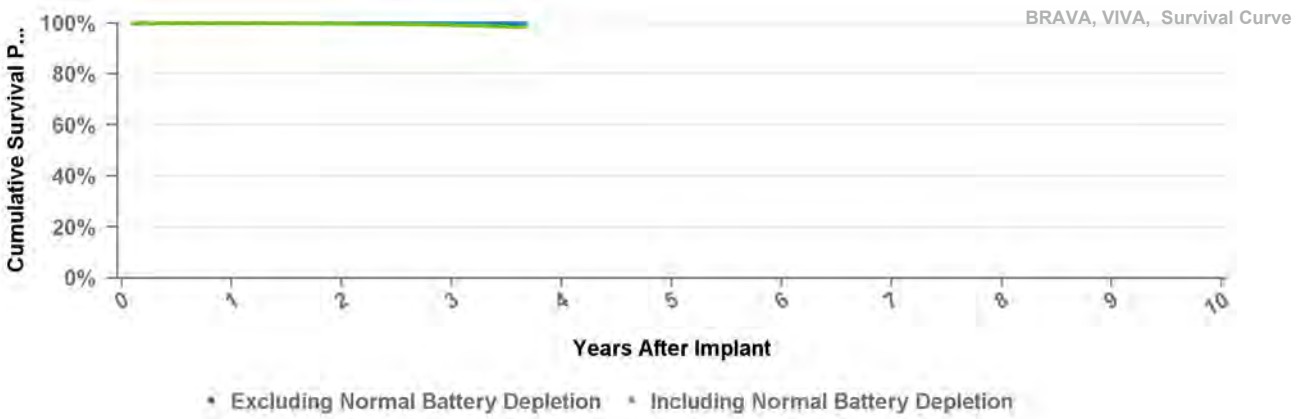


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBB2D4 Viva S

US Market Release
CE Approval Date Aug-12
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

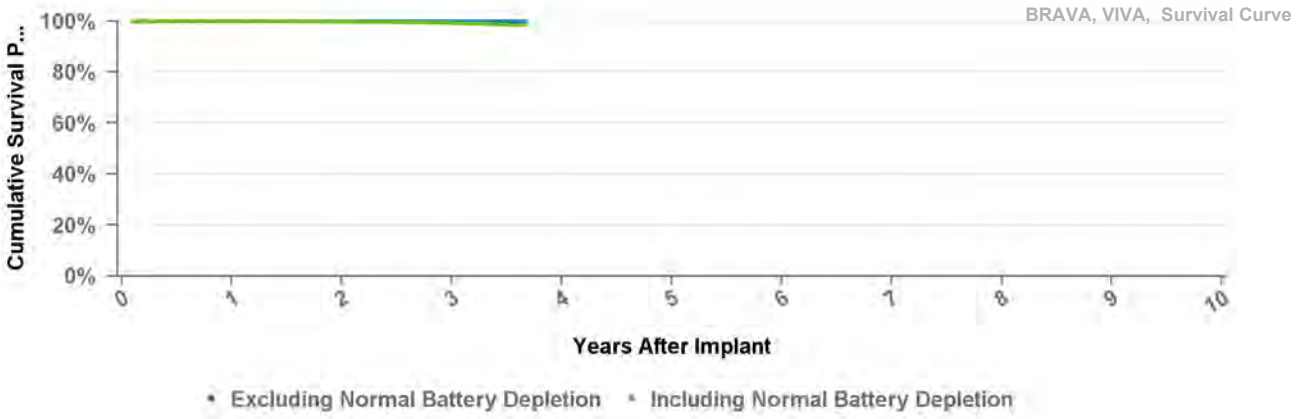


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBB2QQ Viva Quad S

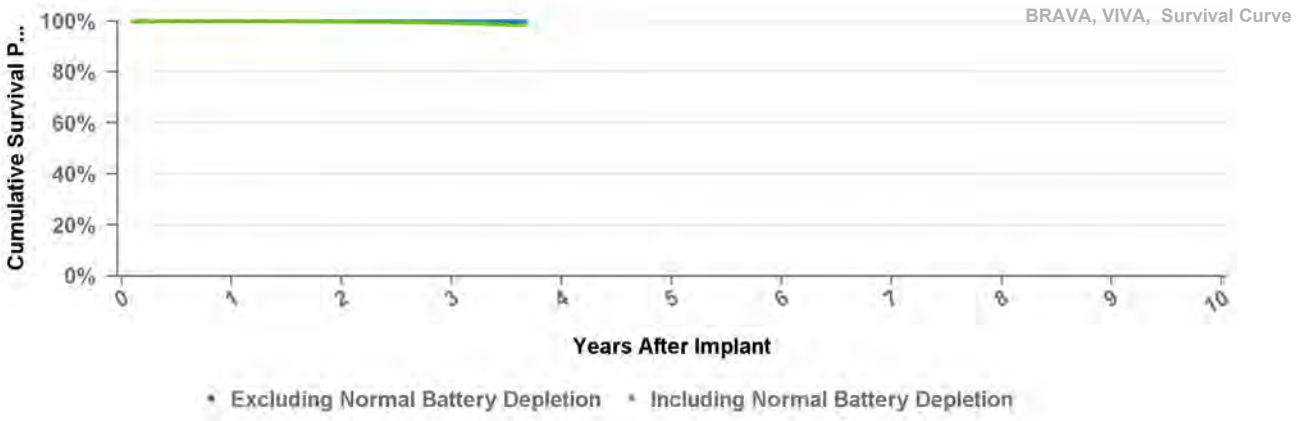
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBC2D1 Brava

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

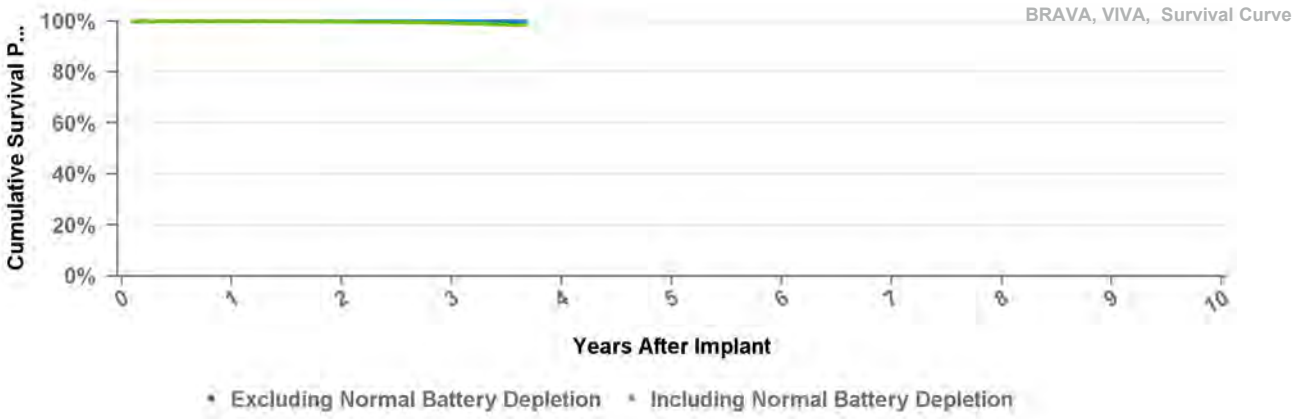


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBC2D4 Brava

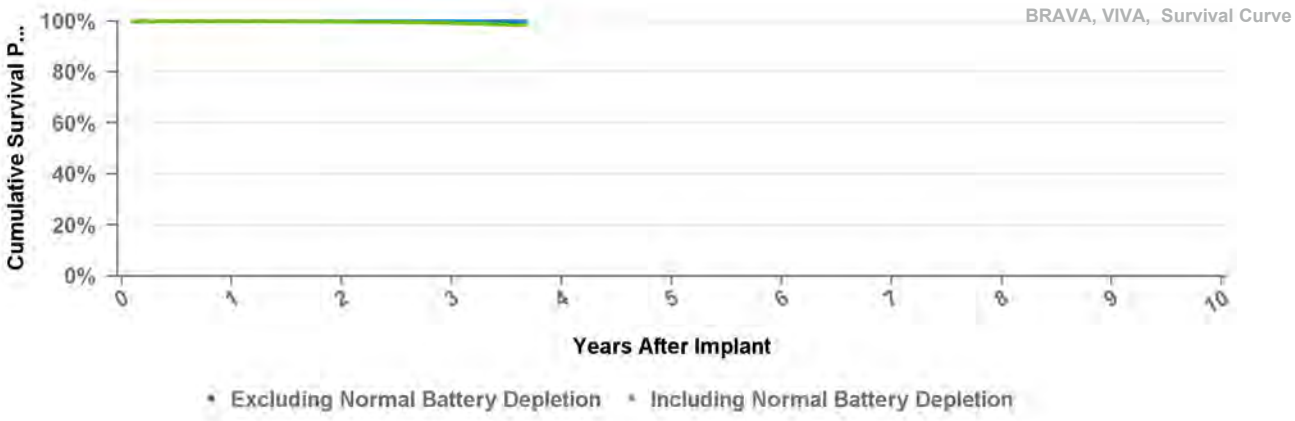
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBC2Q1 Brava Quad

US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

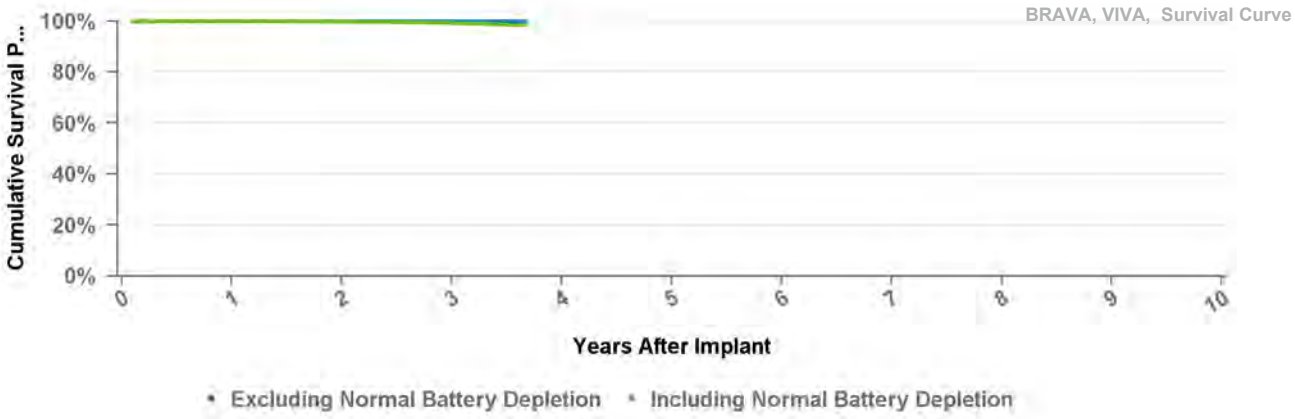


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

CRT-D

DTBC2QQ Brava Quad

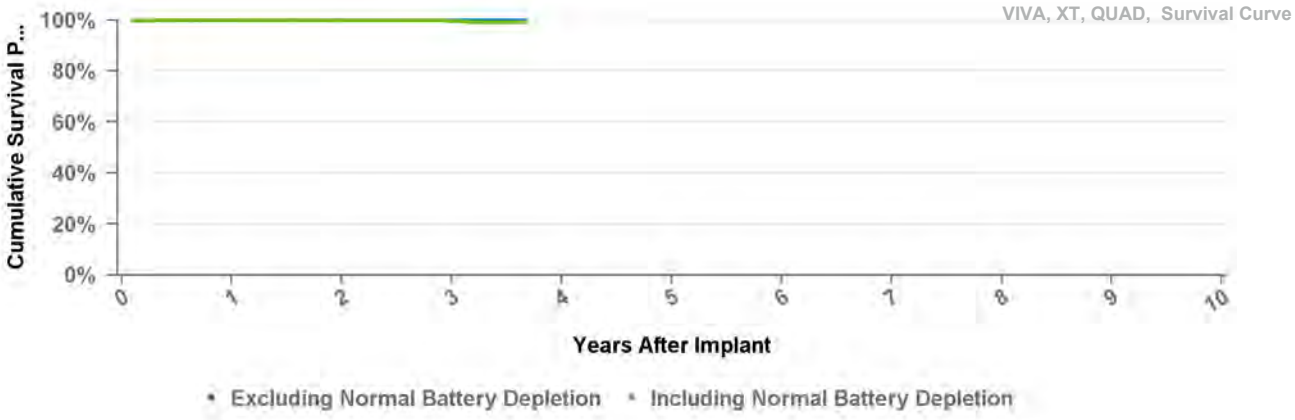
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.2%	98.3%
Effective Sample Size	65282	40549	13789	195

DTBX1QQ Viva Quad C

US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	638	Electrical Component	1
Estimated Active USA Implants	571	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		

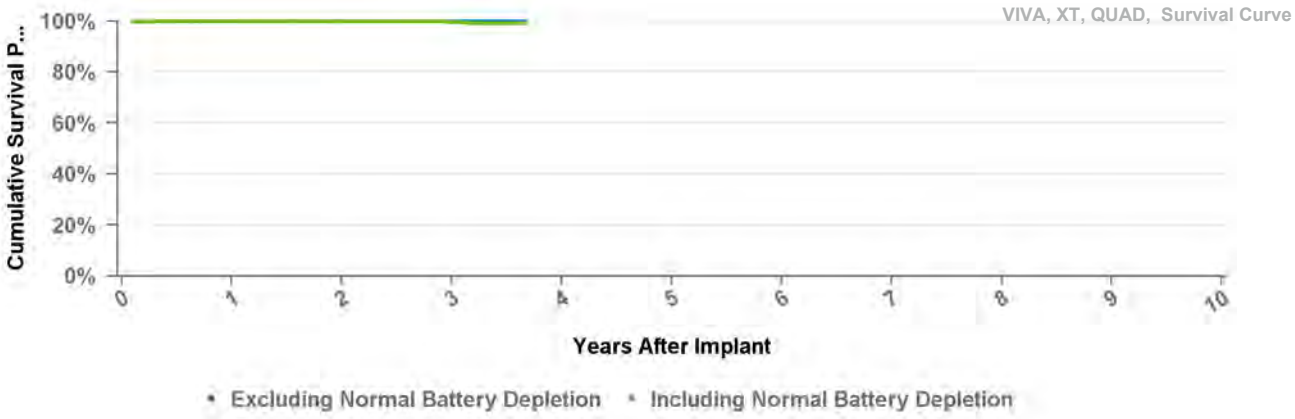


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

CRT-D

DTBX2QQ Viva Quad C

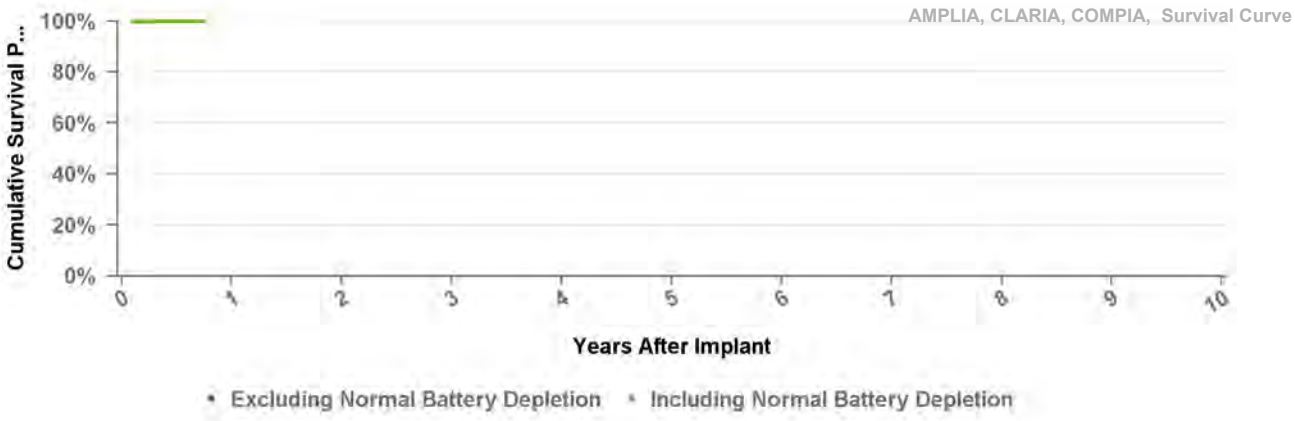
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%	99.2%
Effective Sample Size	24335	7359	632	177

DTMA1D1 Claria MRI

US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	5	**Therapy Function Compromised**	
Normal Battery Depletions			

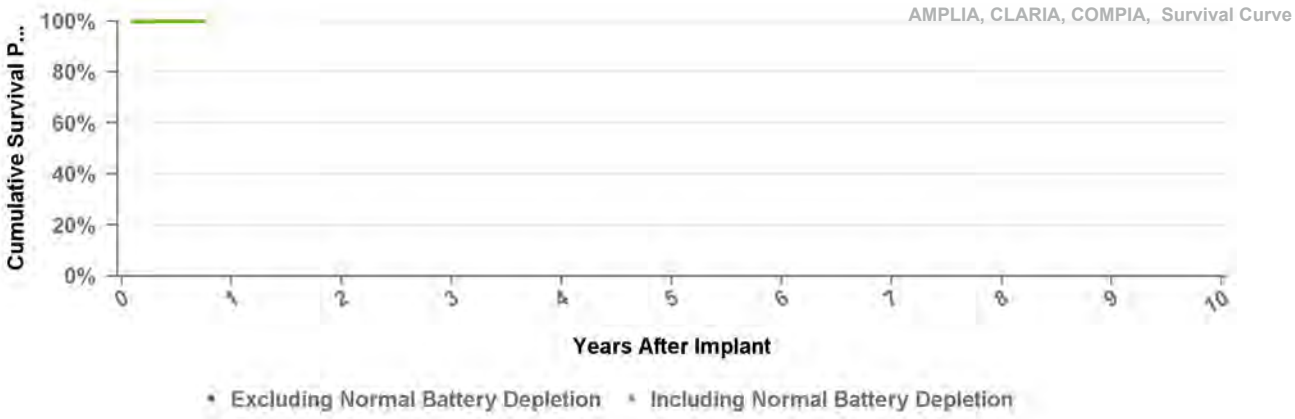


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMA1D4 Claria MRI

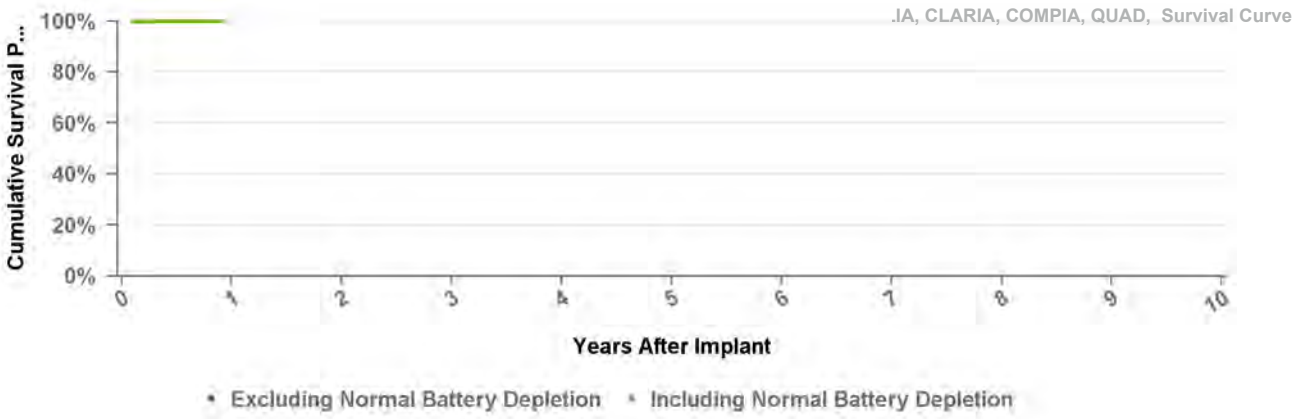
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

DTMA1Q1 Claria MRI

US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants	6	**Therapy Function Compromised**	
Normal Battery Depletions			

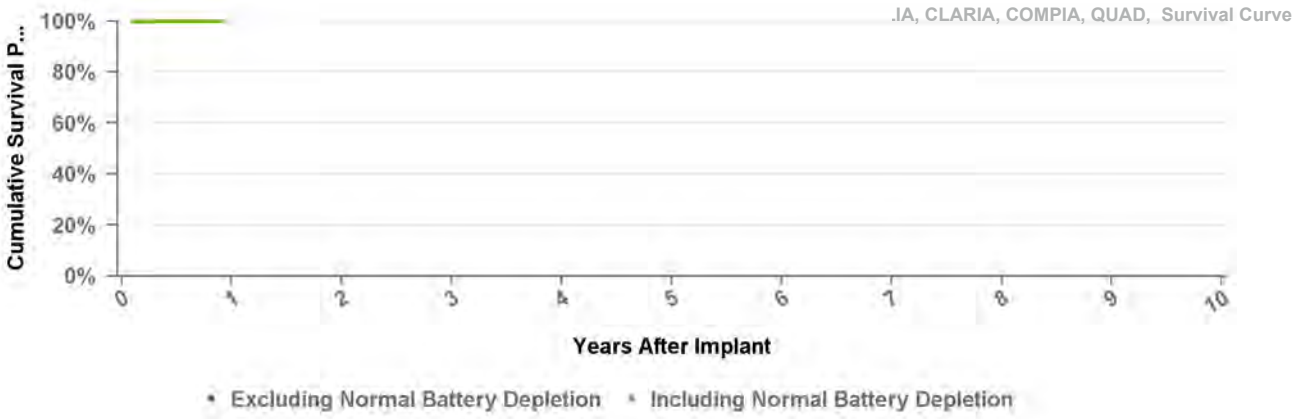


Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

CRT-D

DTMA1QQ Claria MRI

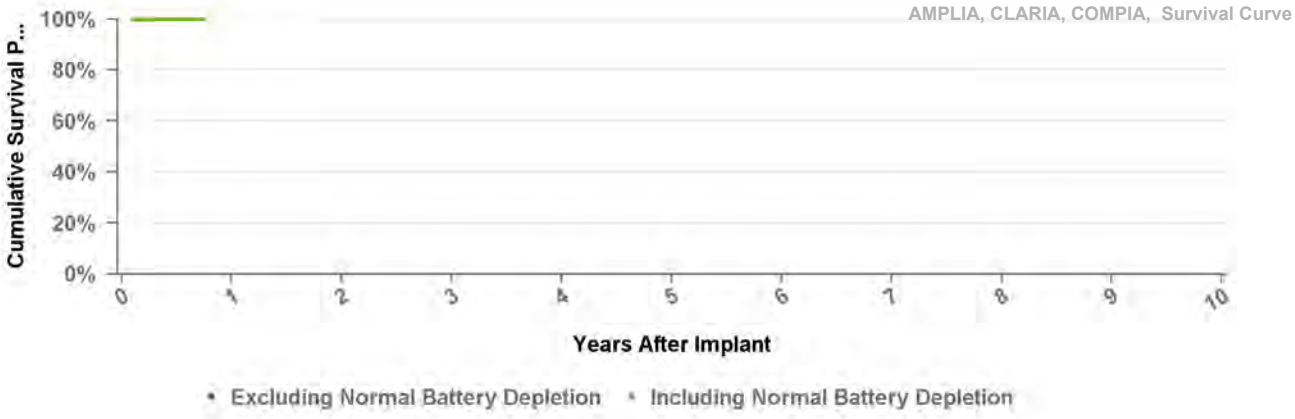
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	15		
Estimated Active USA Implants	15	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

DTMA2D1 Claria MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

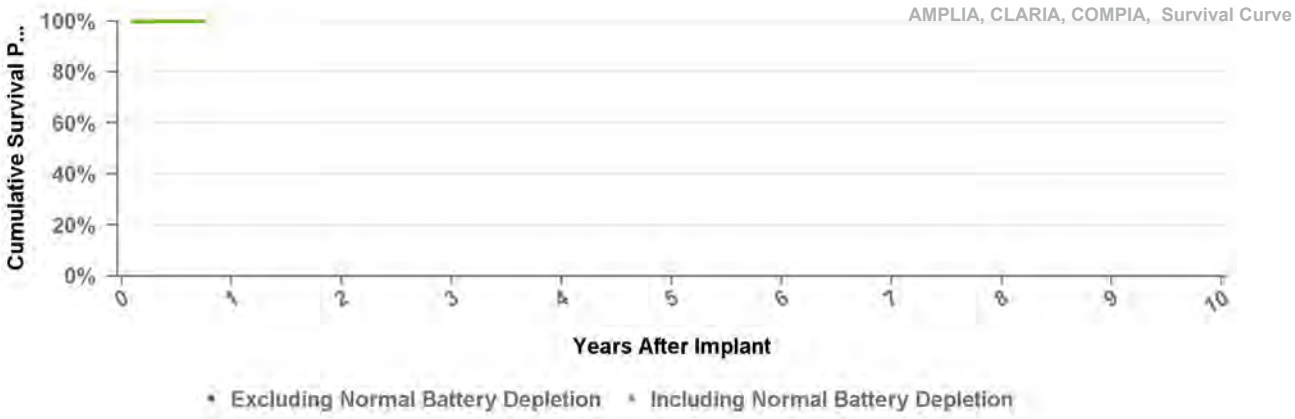


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMA2D4 Claria MRI

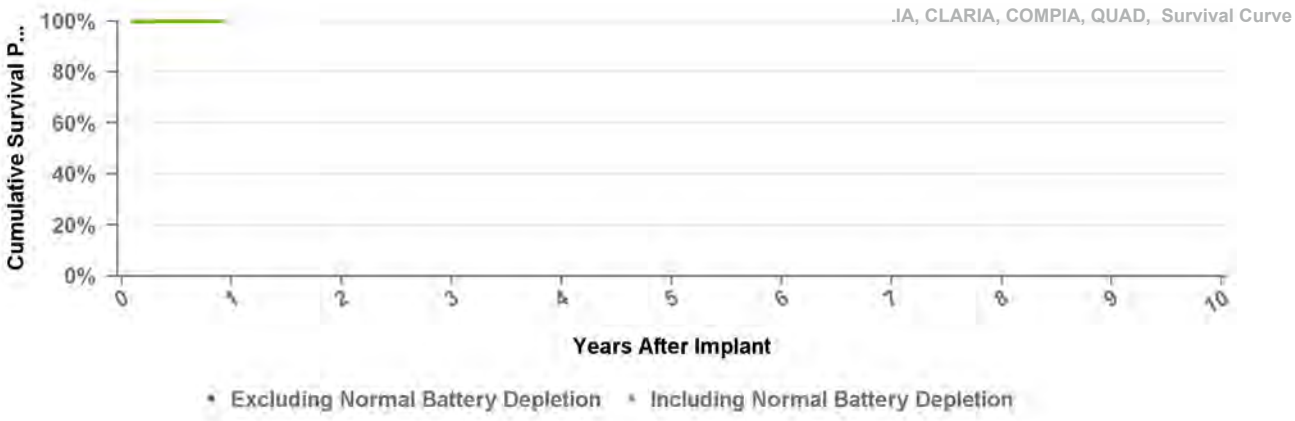
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

DTMA2Q1 Claria MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

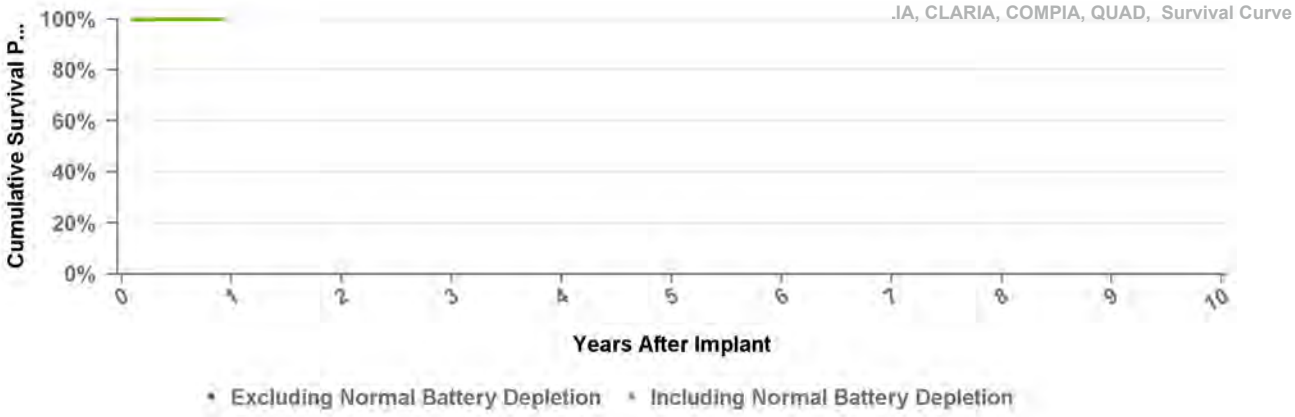


Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

CRT-D

DTMA2QQ Claria MRI

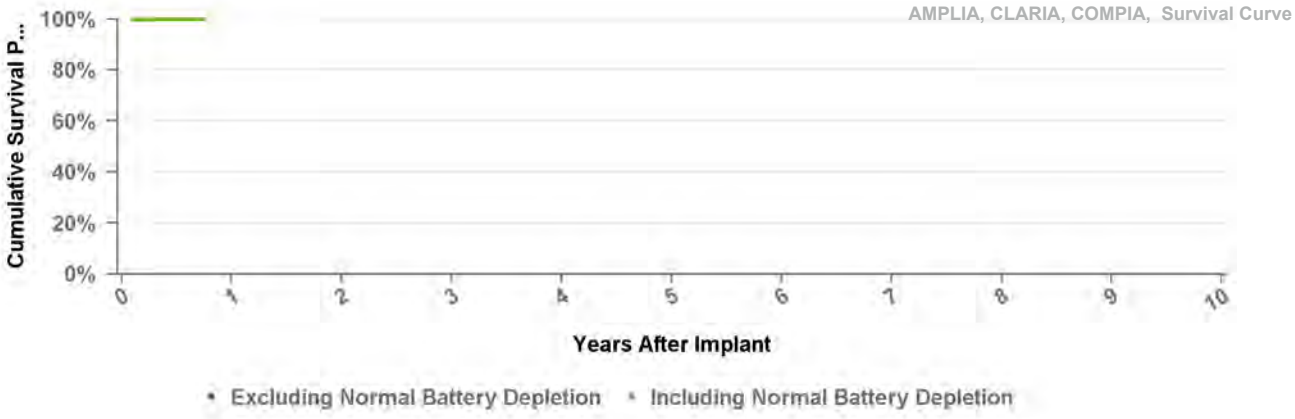
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

DTMB1D1 Amplia MRI

US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	244		
Estimated Active USA Implants	244	**Therapy Function Compromised**	
Normal Battery Depletions			

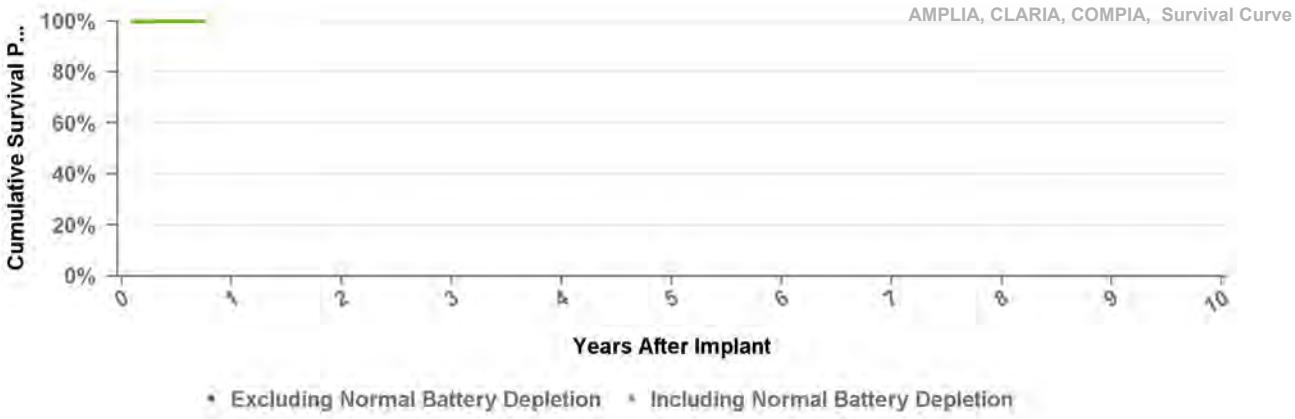


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMB1D4 Amplia MRI

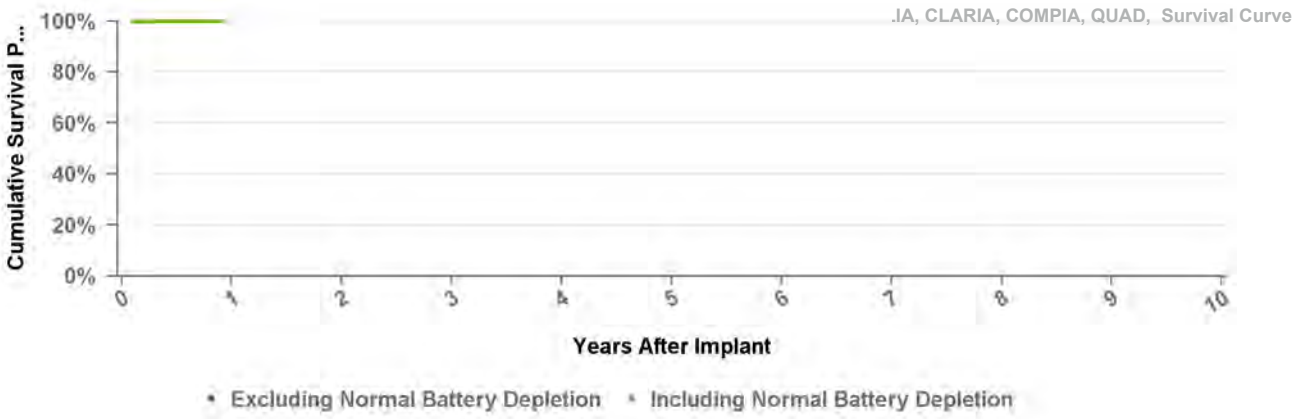
US Market Release	Feb-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,145		
Estimated Active USA Implants	1,123	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

DTMB1Q1 Amplia MRI

US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	156		
Estimated Active USA Implants	153	**Therapy Function Compromised**	
Normal Battery Depletions			

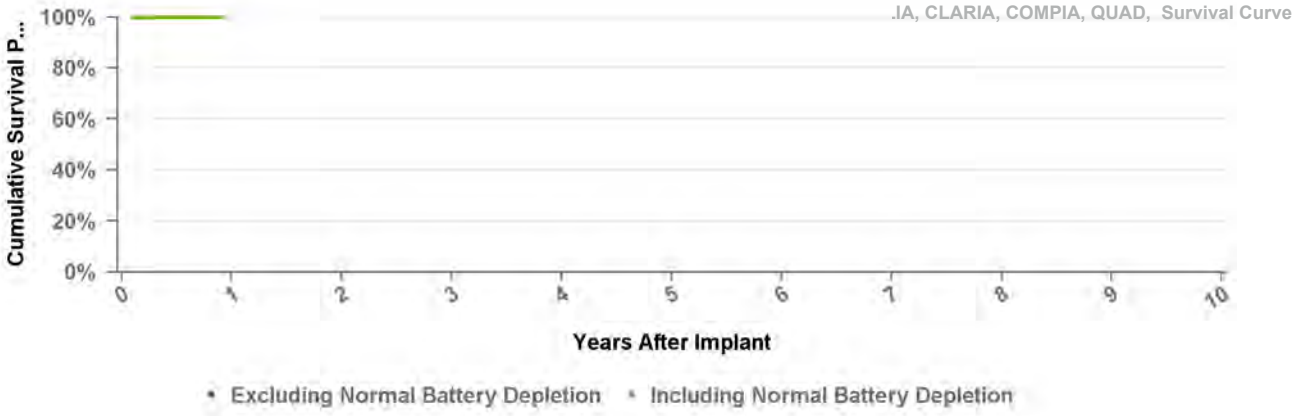


Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

CRT-D

DTMB1QQ Amplia MRI

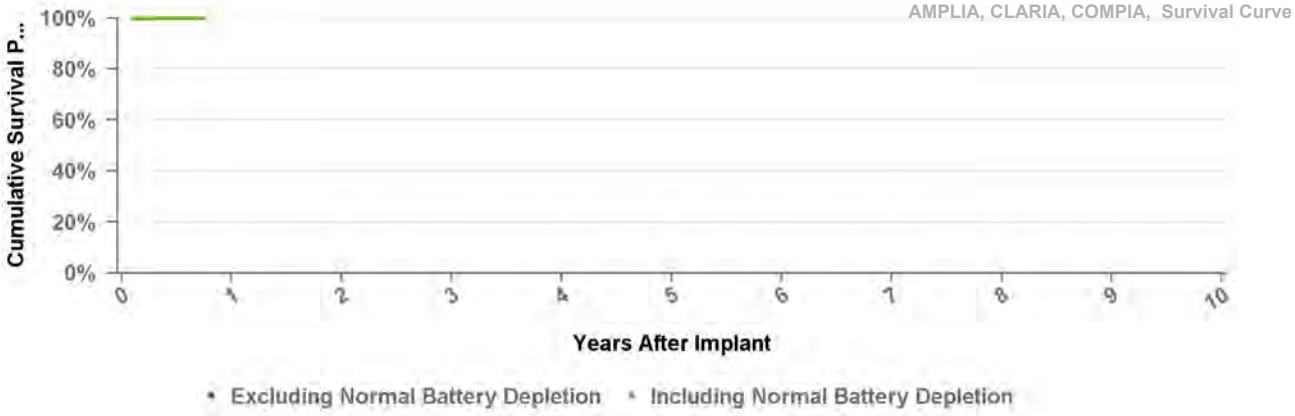
US Market Release	Feb-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	10,081	Electrical Component	1
Estimated Active USA Implants	9,925	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

DTMB2D1 Amplia MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

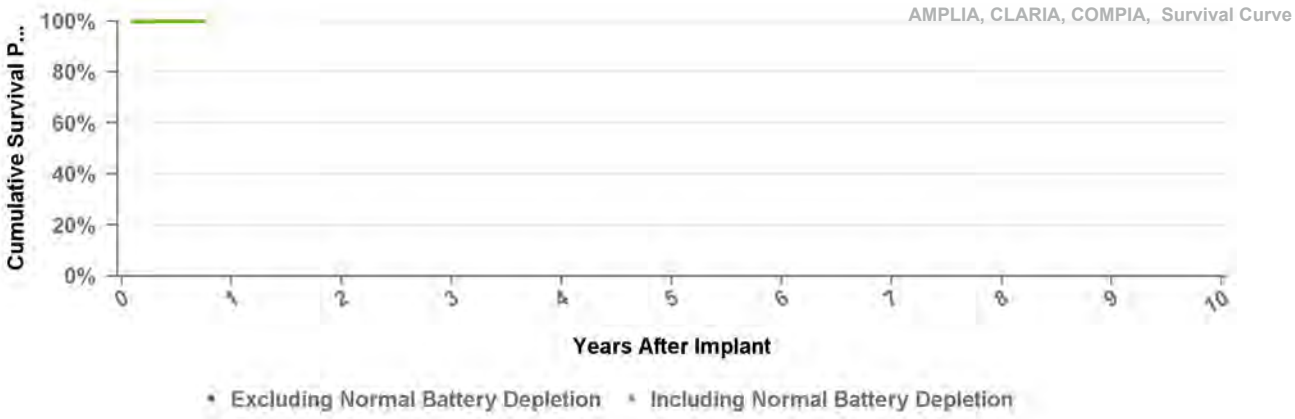


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMB2D4 Amplia MRI

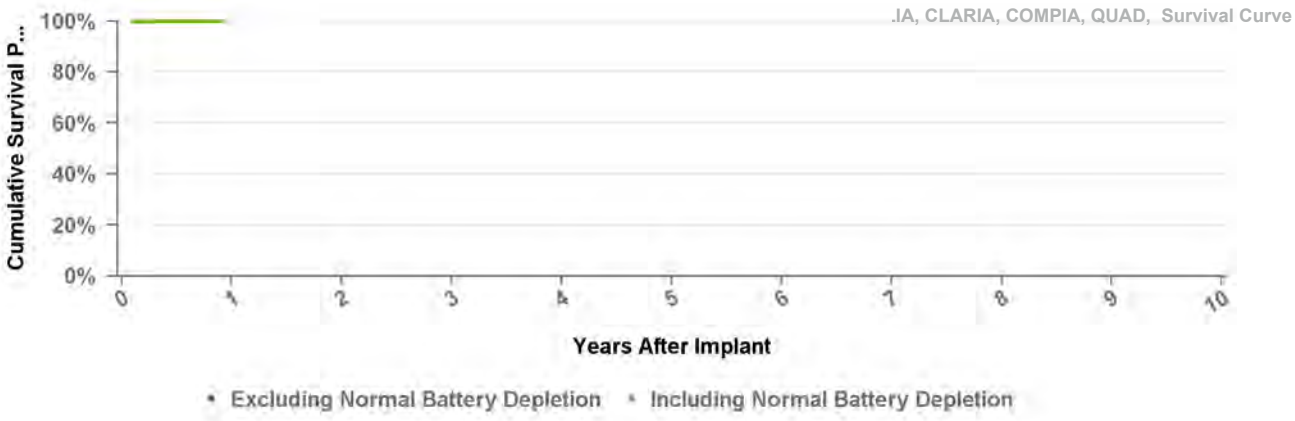
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

DTMB2Q1 Amplia MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

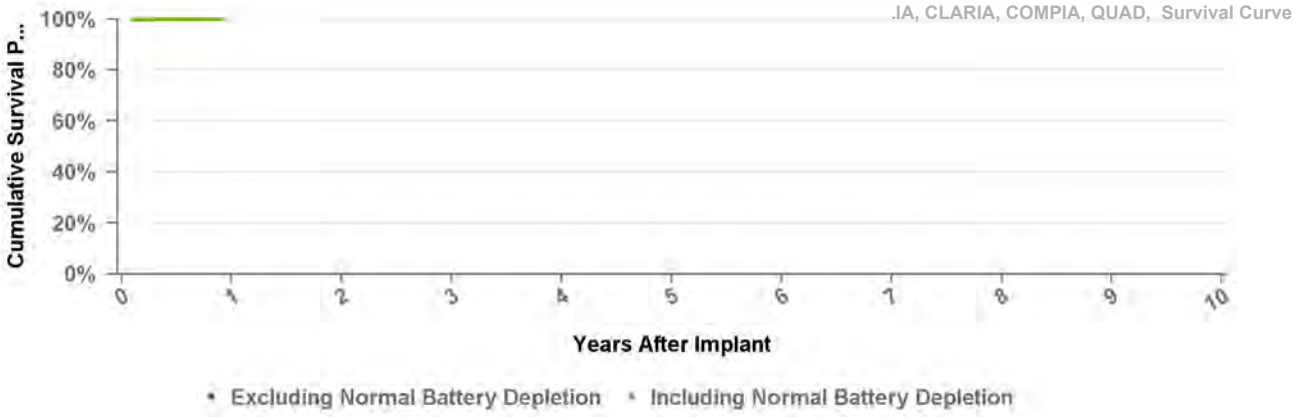


Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

CRT-D

DTMB2QQ Amplia MRI

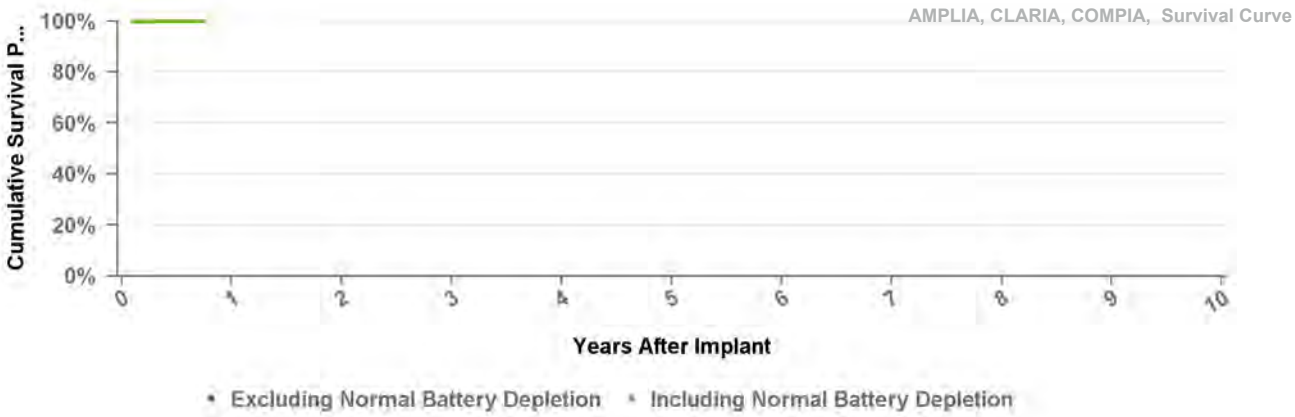
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

DTMC1D1 Compia MRI

US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	8		
Estimated Active USA Implants	8	**Therapy Function Compromised**	
Normal Battery Depletions			

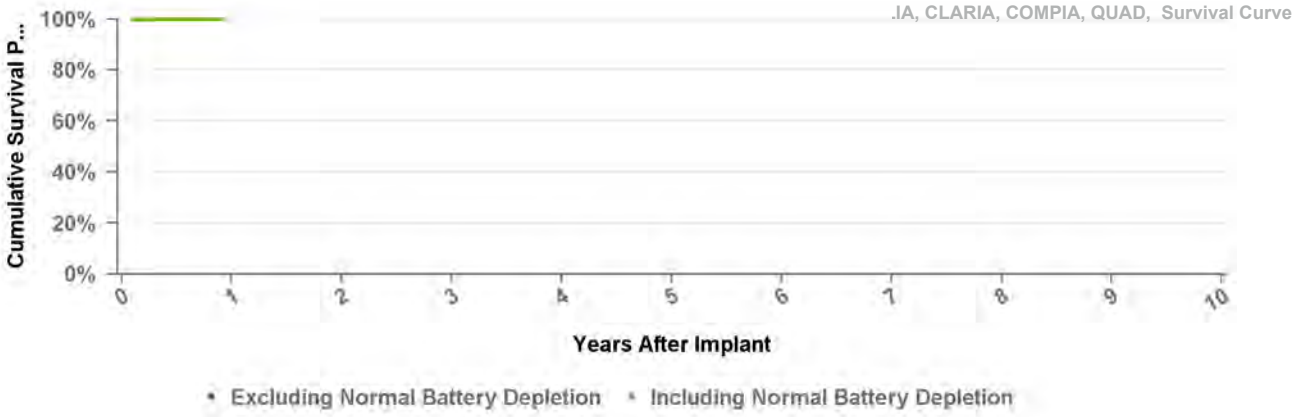


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMC1QQ Compia MRI

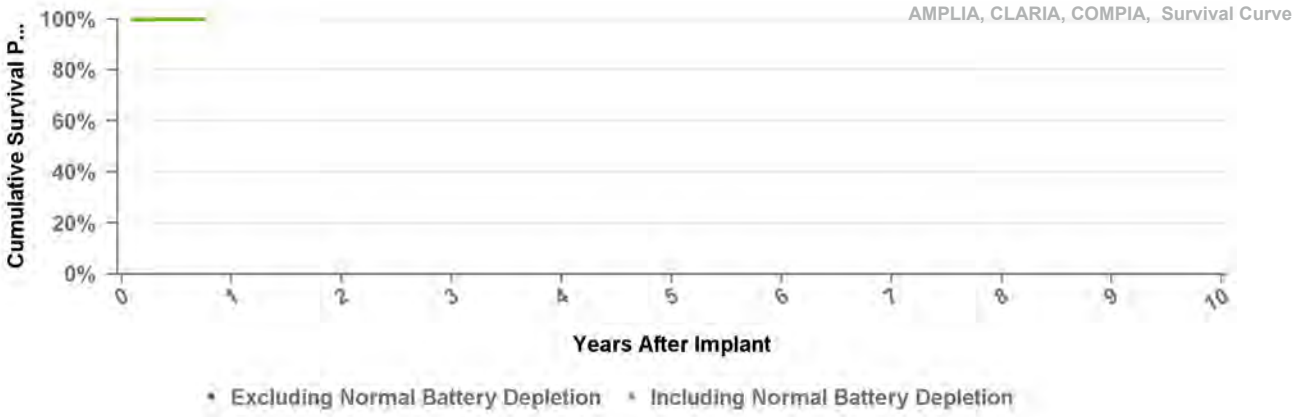
US Market Release	Feb-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	715		
Estimated Active USA Implants	707	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

DTMC2D4 Compia MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

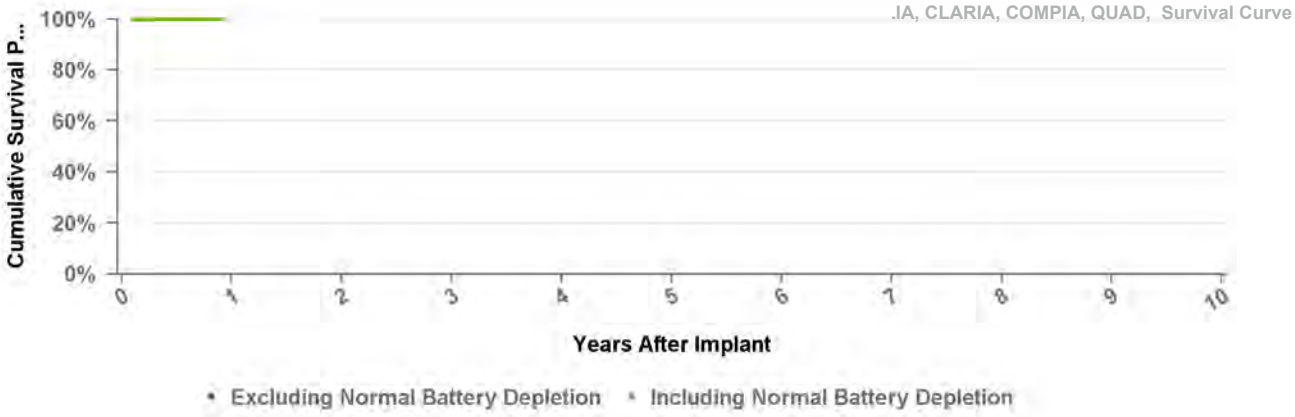


Years	at 9 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	111

CRT-D

DTMC2QQ Compia MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

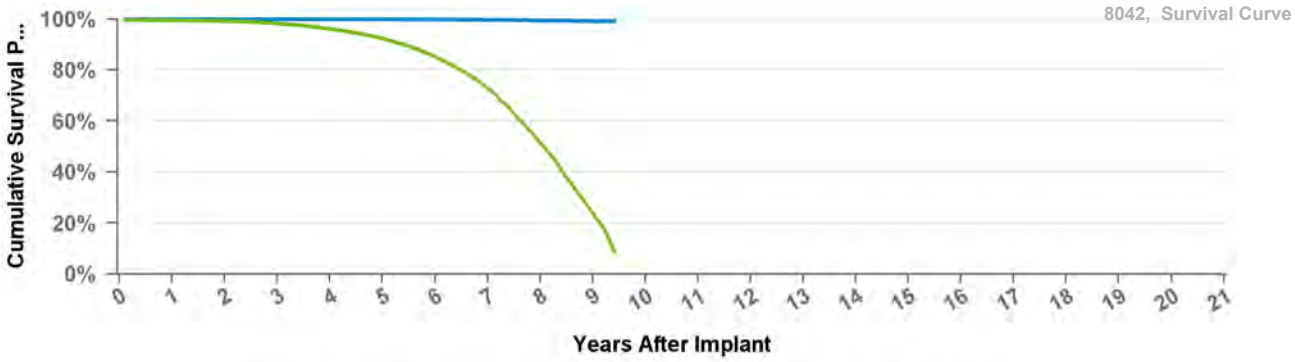


Years	at 11 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	296

CRT-P

8042 InSync III

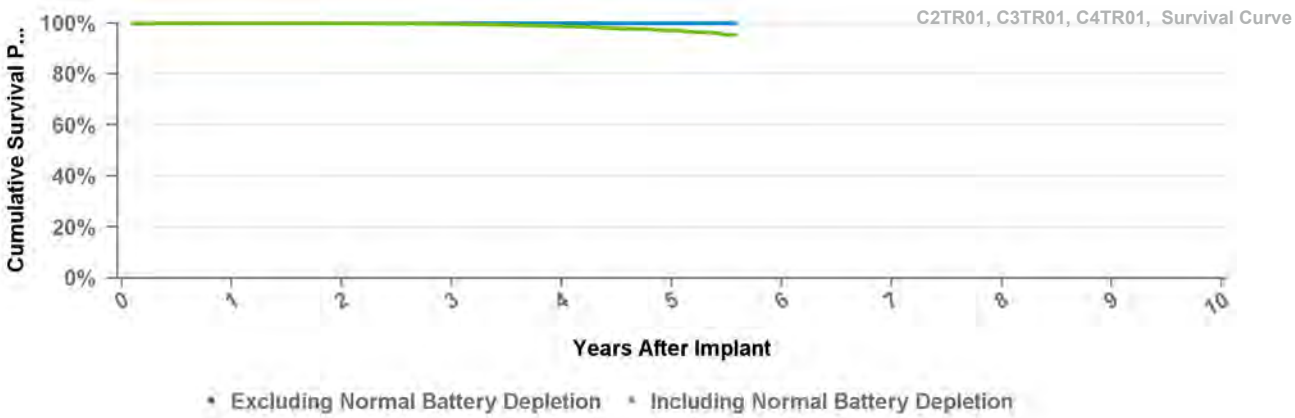
US Market Release	Feb-03	**Total Malfunctions**	**77**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**47**
Registered USA Implants	39,511	Battery Malfunction	35
Estimated Active USA Implants	6,101	Electrical Component	2
Normal Battery Depletions	4,697	Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**30**
		Battery Malfunction	18
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.4%	99.1%	99.1%
Including NBD	99.5%	99.2%	98.3%	96.2%	92.3%	85.2%	72.7%	51.4%	23.8%	8.5%
Effective Sample Size	30583	26216	22545	19277	16093	12321	7340	3319	778	138

C2TR01 Syncra CRT-P

US Market Release	Mar-11	**Total Malfunctions**	**1**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,808	Other Malfunction	1
Estimated Active USA Implants	7,410	**Therapy Function Compromised**	**0**
Normal Battery Depletions	64		

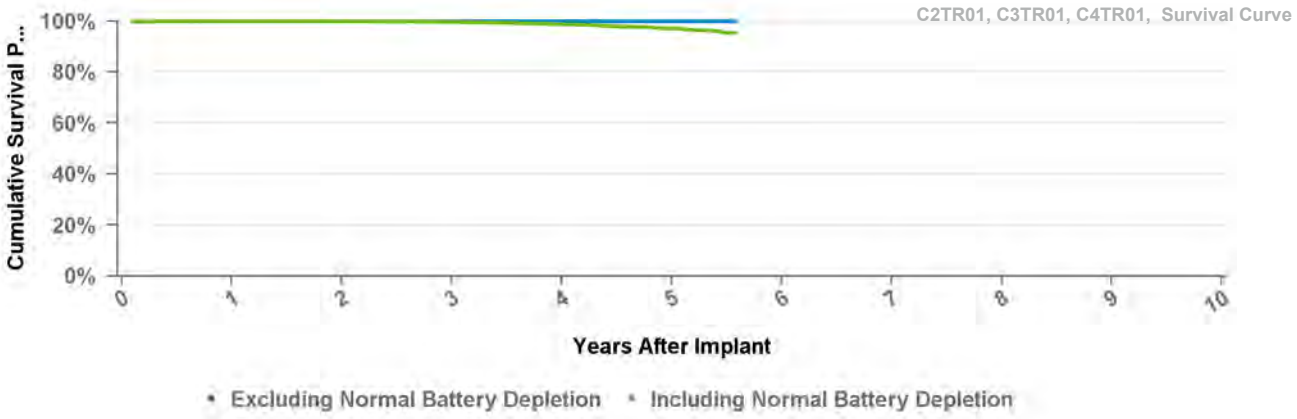


Years	1	2	3	4	5	at 67 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	95.3%
Effective Sample Size	25825	20375	13907	7821	2754	312

CRT-P

C3TR01 Consulta CRT-P

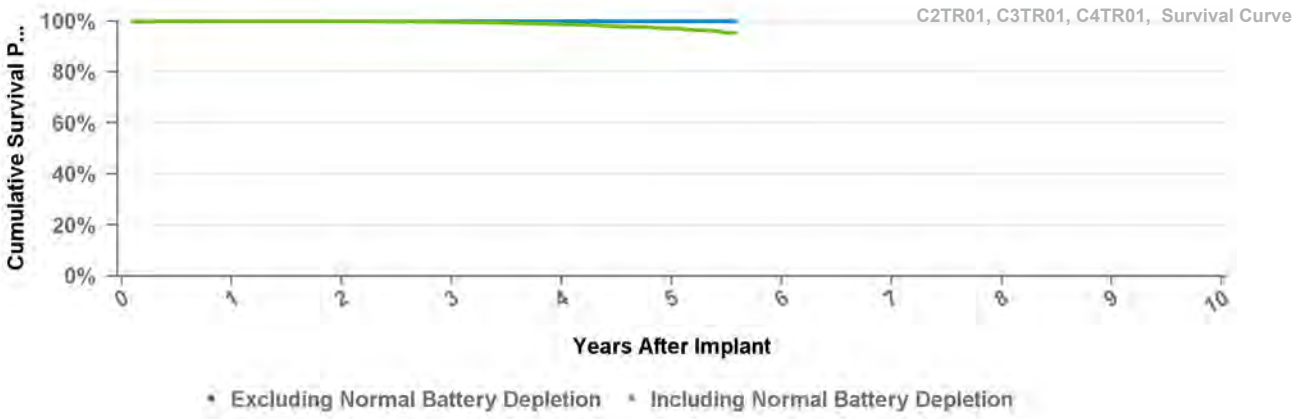
US Market Release		**Total Malfunctions**	
CE Approval Date	May-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 67 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	95.3%
Effective Sample Size	25825	20375	13907	7821	2754	312

C4TR01 Consulta CRT-P

US Market Release	Mar-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	22,454		
Estimated Active USA Implants	18,399	**Therapy Function Compromised**	
Normal Battery Depletions	94		

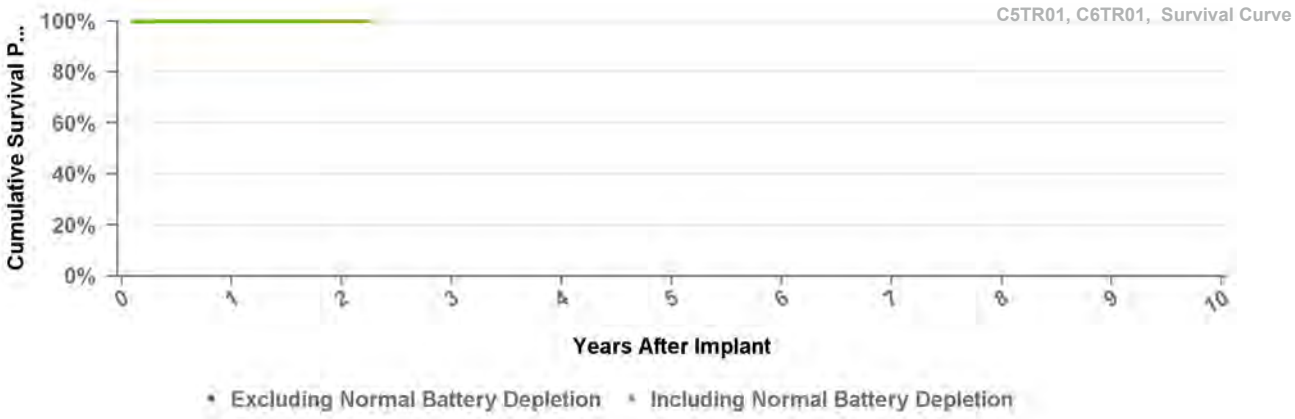


Years	1	2	3	4	5	at 67 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.1%	95.3%
Effective Sample Size	25825	20375	13907	7821	2754	312

CRT-P

C5TR01 Viva CRT-P

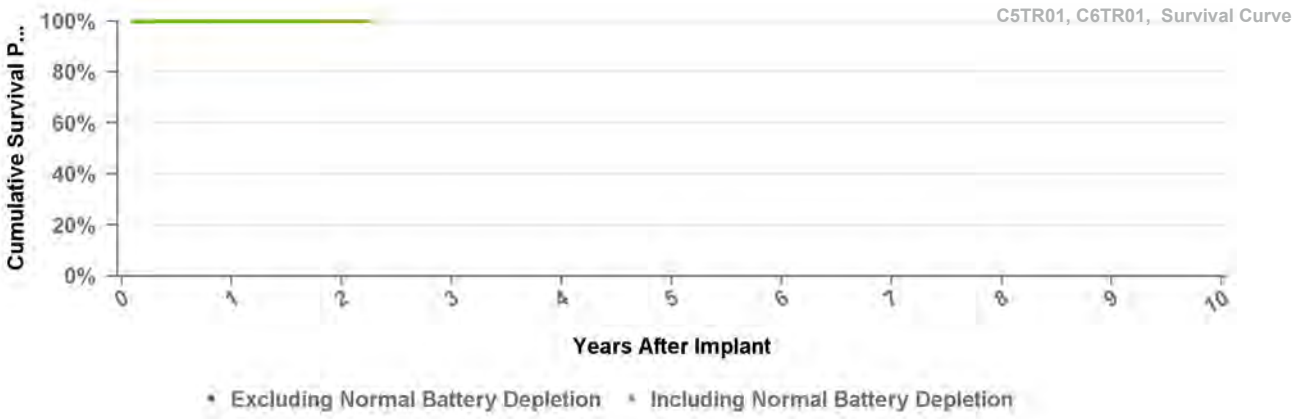
US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	3368	415	115

C6TR01 Viva CRT-P

US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	6,874		
Estimated Active USA Implants	6,540	**Therapy Function Compromised**	
Normal Battery Depletions	2		

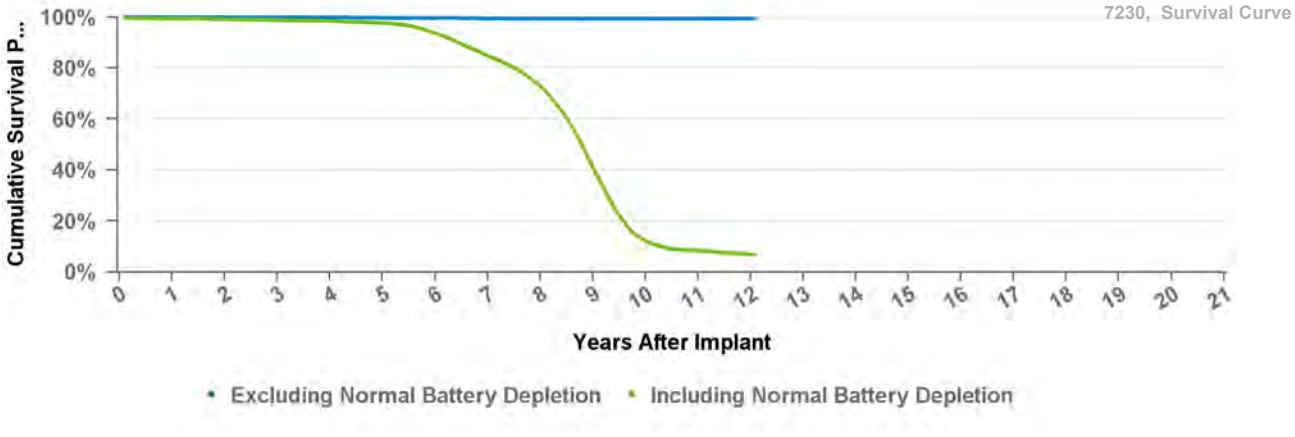


Years	1	2	at 27 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	3368	415	115

ICD

7230B Marquis VR

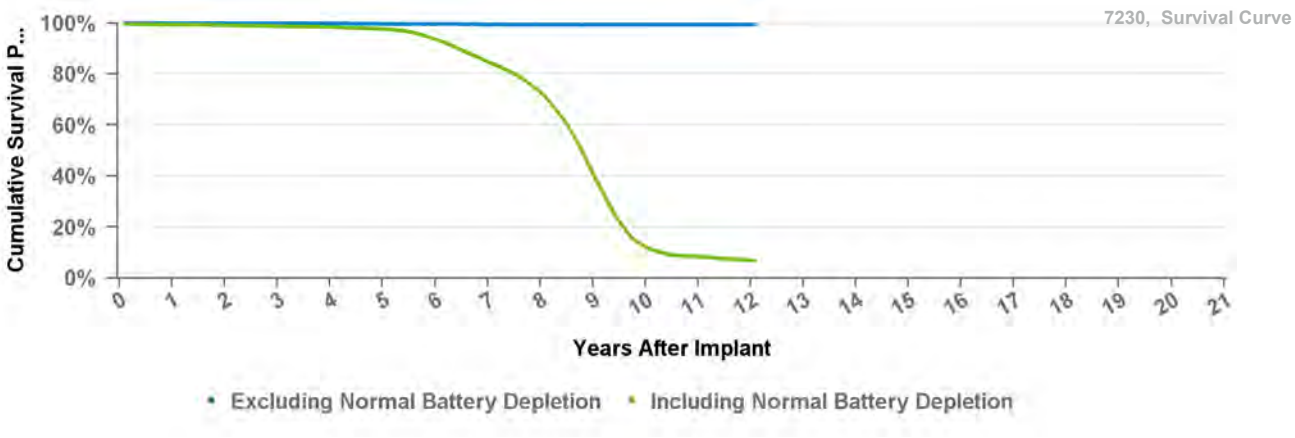
US Market Release	Dec-02	**Total Malfunctions**	**1**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**0**
Registered USA Implants	237		
Estimated Active USA Implants	12	**Therapy Function Compromised**	**1**
Normal Battery Depletions	27	Battery Malfunction	1



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 145 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.7%	41.4%	12.1%	8.3%	6.9%	6.7%
Effective Sample Size	16509	12760	10567	9431	8388	7289	6059	4822	2559	586	328	138	102

7230Cx Marquis VR

US Market Release	Dec-02	**Total Malfunctions**	**57**
CE Approval Date	Apr-02	**Therapy Function Not Compromised**	**31**
Registered USA Implants	18,517	Battery Malfunction	1
Estimated Active USA Implants	1,230	Electrical Component	14
Normal Battery Depletions	3,416	Other Malfunction	1
		Poss Early Battery Depltn	14
		Software Malfunction	1
		Therapy Function Compromised	**26**
		Battery Malfunction	17
		Electrical Component	9

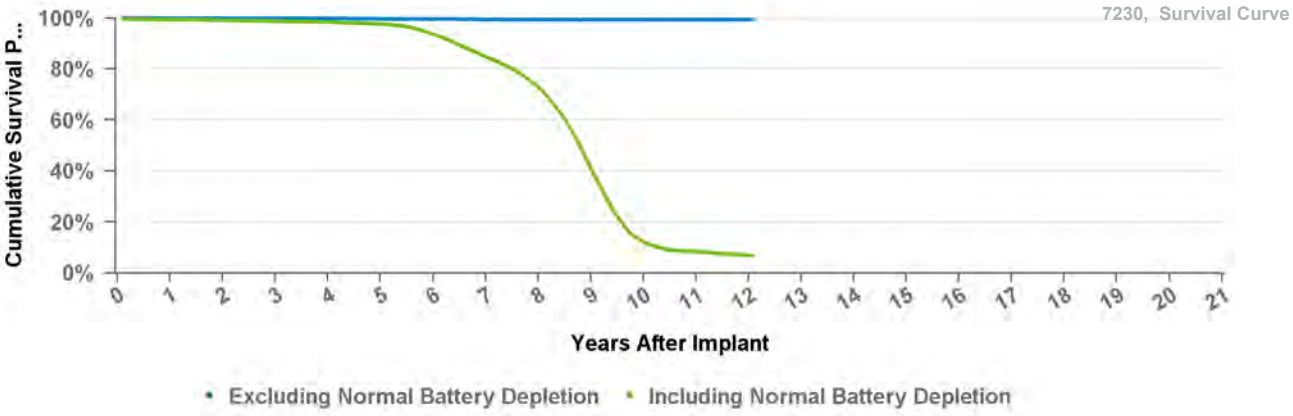


Years	1	10	11	12	2	3	4	5	6	7	8	9	at 145 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.7%	41.4%	12.1%	8.3%	6.9%	6.7%
Effective Sample Size	16509	12760	10567	9431	8388	7289	6059	4822	2559	586	328	138	102

ICD

7230E Marquis VR

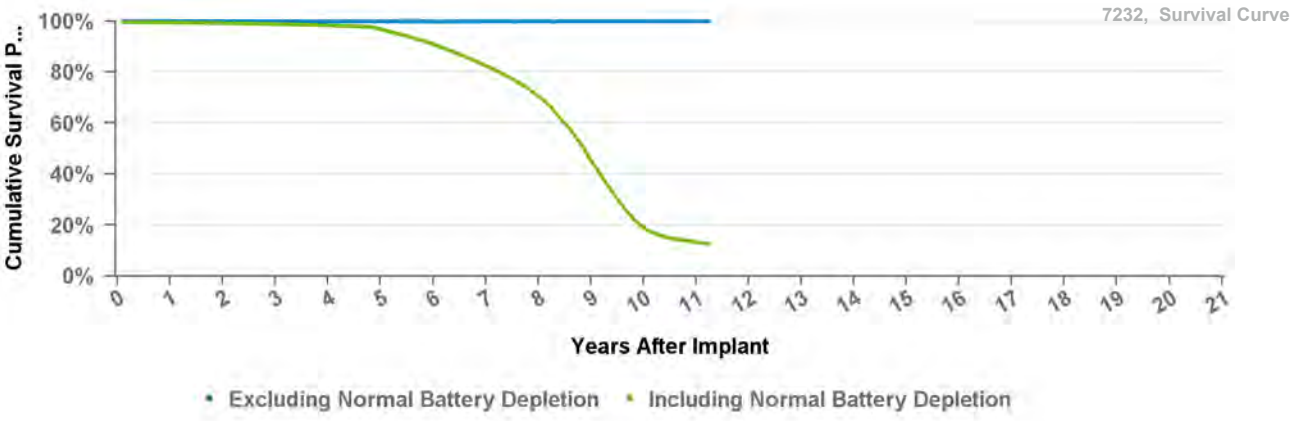
US Market Release	Dec-02	**Total Malfunctions**	**3**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**1**
Registered USA Implants	632	Electrical Component	1
Estimated Active USA Implants	41	**Therapy Function Compromised**	**2**
Normal Battery Depletions	78	Battery Malfunction	2



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 145 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.7%	93.6%	84.7%	72.7%	41.4%	12.1%	8.3%	6.9%	6.7%
Effective Sample Size	16509	12760	10567	9431	8388	7289	6059	4822	2559	586	328	138	102

7232B Maximo VR

US Market Release	Oct-03	**Total Malfunctions**	
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	
Registered USA Implants	170		
Estimated Active USA Implants	35	**Therapy Function Compromised**	
Normal Battery Depletions	31		



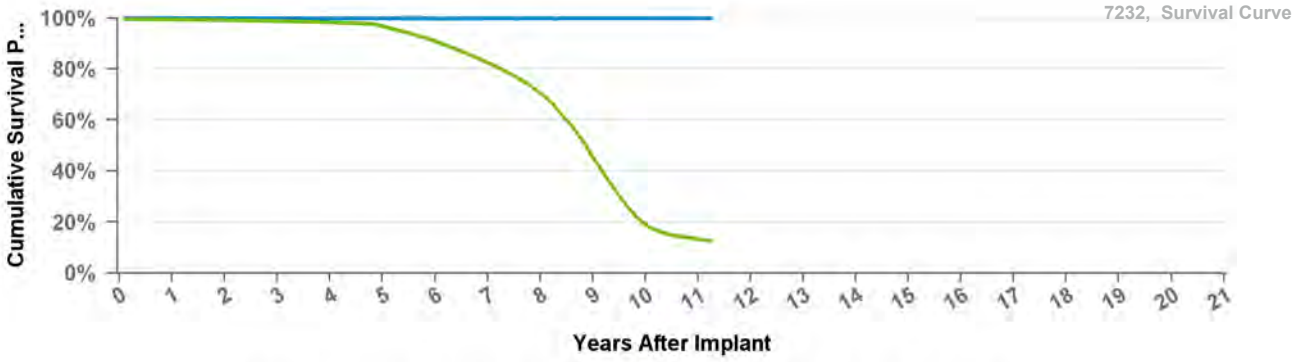
Years	1	10	11	2	3	4	5	6	7	8	9	at 135 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.4%	45.6%	19.1%	13.2%	12.4%
Effective Sample Size	38271	34245	30527	26918	23713	20612	17411	13927	8247	2683	642	233

ICD

7232Cx Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-03
Registered USA Implants	43,671
Estimated Active USA Implants	5,491
Normal Battery Depletions	10,440

Total Malfunctions	**73**
Therapy Function Not Compromised	**58**
Electrical Component	28
Other Malfunction	3
Poss Early Battery Depltn	25
Software Malfunction	2
Therapy Function Compromised	**15**
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	1

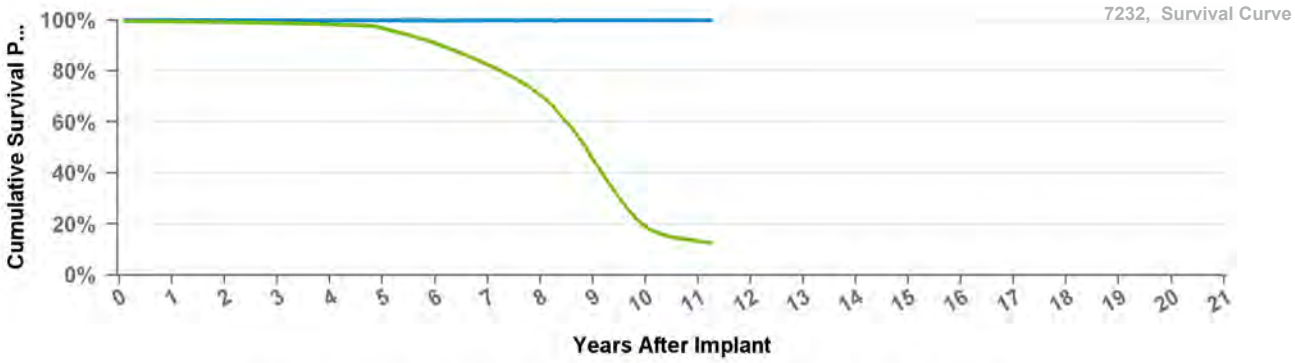


Years	1	10	11	2	3	4	5	6	7	8	9	at 135 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.4%	45.6%	19.1%	13.2%	12.4%
Effective Sample Size	38271	34245	30527	26918	23713	20612	17411	13927	8247	2683	642	233

7232E Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-04
Registered USA Implants	490
Estimated Active USA Implants	92
Normal Battery Depletions	75

Total Malfunctions	**1**
Therapy Function Not Compromised	**0**
Therapy Function Compromised	**1**
Electrical Component	1

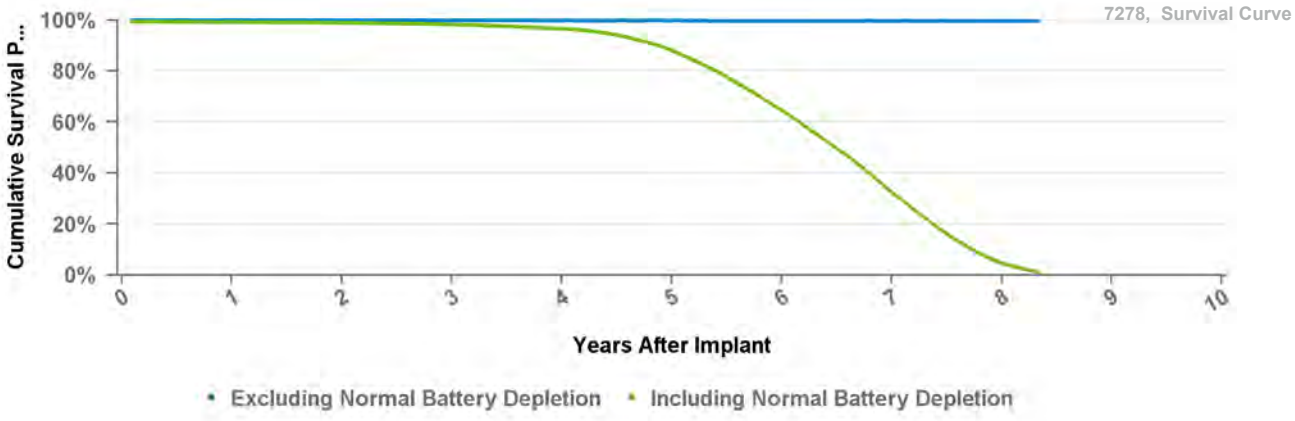


Years	1	10	11	2	3	4	5	6	7	8	9	at 135 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.9%	82.4%	70.4%	45.6%	19.1%	13.2%	12.4%
Effective Sample Size	38271	34245	30527	26918	23713	20612	17411	13927	8247	2683	642	233

ICD

7278 Maximo DR

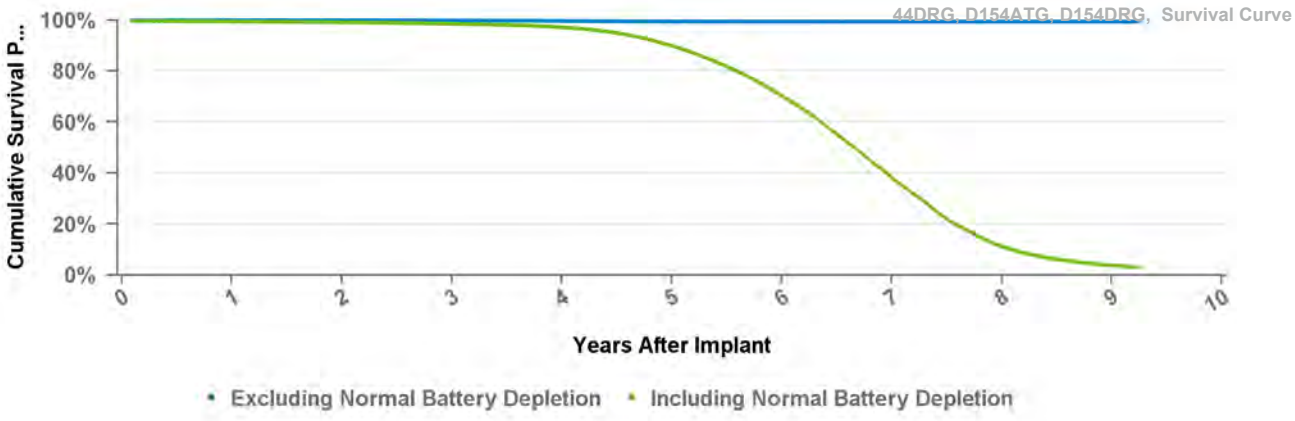
US Market Release	Oct-03	**Total Malfunctions**	**70**
CE Approval Date	Oct-03	**Therapy Function Not Compromised**	**60**
Registered USA Implants	37,642	Electrical Component	24
Estimated Active USA Implants	2,680	Other Malfunction	2
Normal Battery Depletions	10,809	Poss Early Battery Depltn	34
		Therapy Function Compromised	**10**
		Electrical Component	9
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.2%	98.9%	98.3%	96.6%	88.0%	64.5%	32.4%	4.6%	1.0%
Effective Sample Size	32689	29143	26022	22811	18809	12486	5602	659	137

D144DRG Entrust Escudo

US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

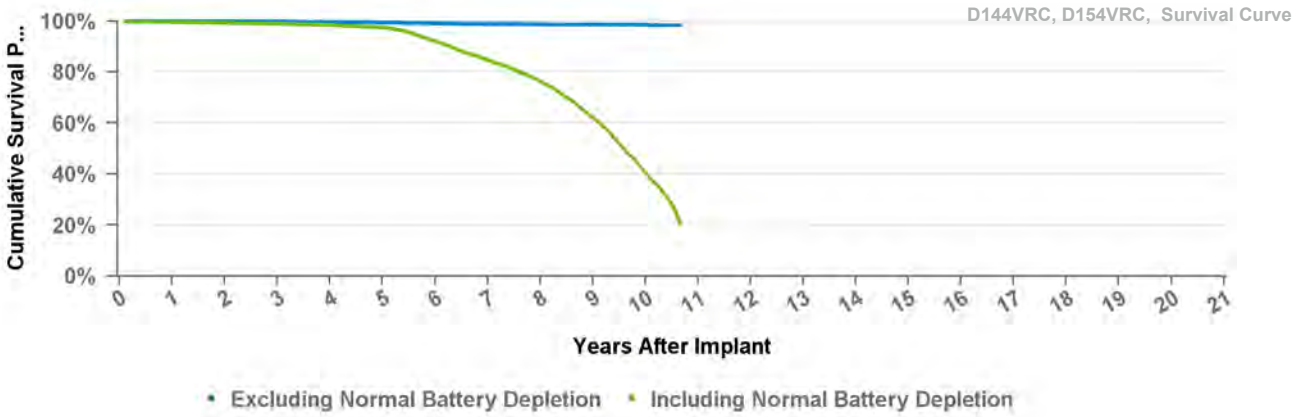


Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.3%	38.1%	11.1%	3.8%	3.0%
Effective Sample Size	24904	22703	20356	17939	14879	10821	5373	1363	243	130

ICD

D144VRC Entrust Escudo

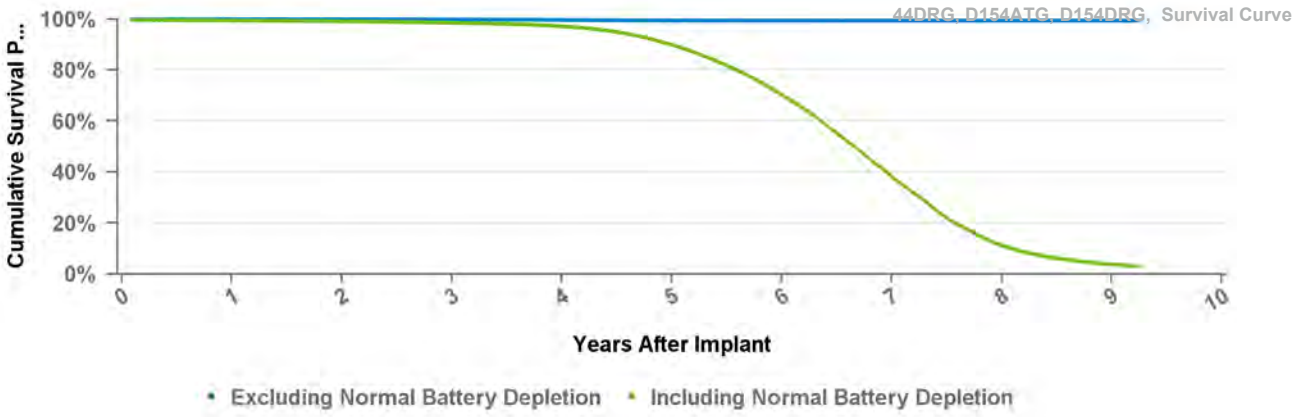
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 128 mo
Excluding NBD	99.9%	98.5%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.4%
Including NBD	99.6%	99.3%	98.9%	98.5%	97.5%	92.1%	84.8%	76.2%	61.9%	40.7%	20.2%
Effective Sample Size	12679	11485	10268	9071	8007	7007	6006	5094	3700	1907	143

D154ATG Entrust AT

US Market Release	Jun-05	**Total Malfunctions**	**125**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**109**
Registered USA Implants	28,151	Electrical Component	30
Estimated Active USA Implants	2,365	Electrical Interconnect	1
Normal Battery Depletions	8,990	Other Malfunction	1
		Poss Early Battery Depltn	74
		Software Malfunction	3
		Therapy Function Compromised	**16**
		Electrical Component	16



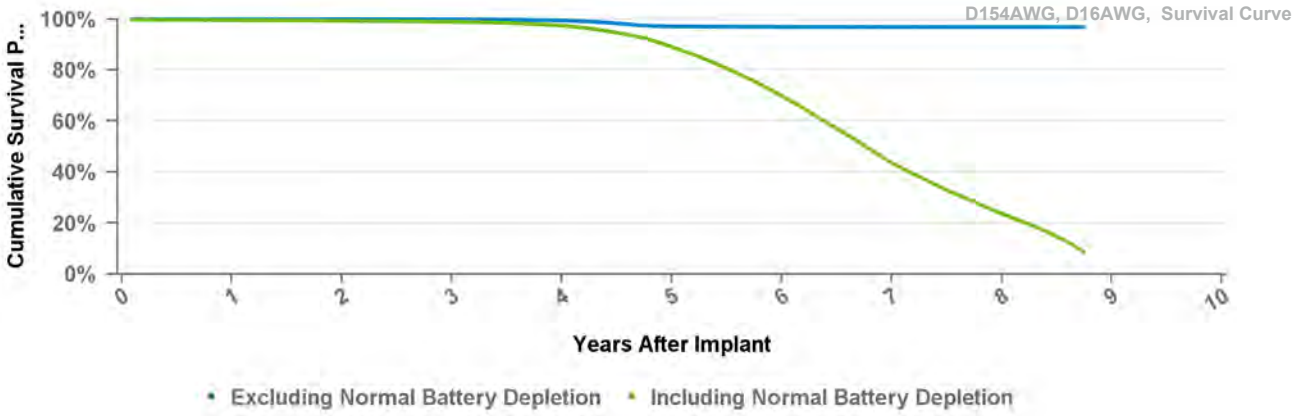
Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.3%	38.1%	11.1%	3.8%	3.0%
Effective Sample Size	24904	22703	20356	17939	14879	10821	5373	1363	243	130

ICD

D154AWG Virtuoso DR

US Market Release	May-06
CE Approval Date	
Registered USA Implants	76,857
Estimated Active USA Implants	12,965
Normal Battery Depletions	20,560

Total Malfunctions	**3,334**
Therapy Function Not Compromised	**3,291**
Battery Malfunction	8
Electrical Component	3,142
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	132
Software Malfunction	3
Therapy Function Compromised	**43**
Electrical Component	40
Other Malfunction	2
Poss Early Battery Depltn	1



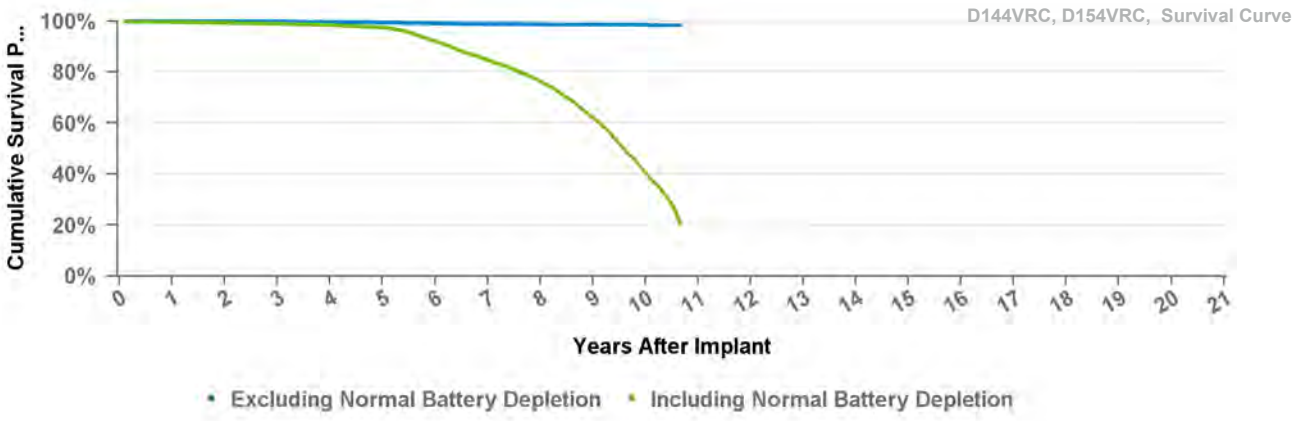
Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.8%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.5%	23.6%	8.3%
Effective Sample Size	63436	58180	53019	48182	40953	29876	16947	5787	523

ICD

D154VRC Entrust VR

US Market Release	Jun-05
CE Approval Date	Feb-05
Registered USA Implants	14,465
Estimated Active USA Implants	2,949
Normal Battery Depletions	2,754

Total Malfunctions	**119**
Therapy Function Not Compromised	**92**
Battery Malfunction	12
Electrical Component	47
Other Malfunction	9
Poss Early Battery Depltn	24
Therapy Function Compromised	**27**
Battery Malfunction	1
Electrical Component	25
Other Malfunction	1

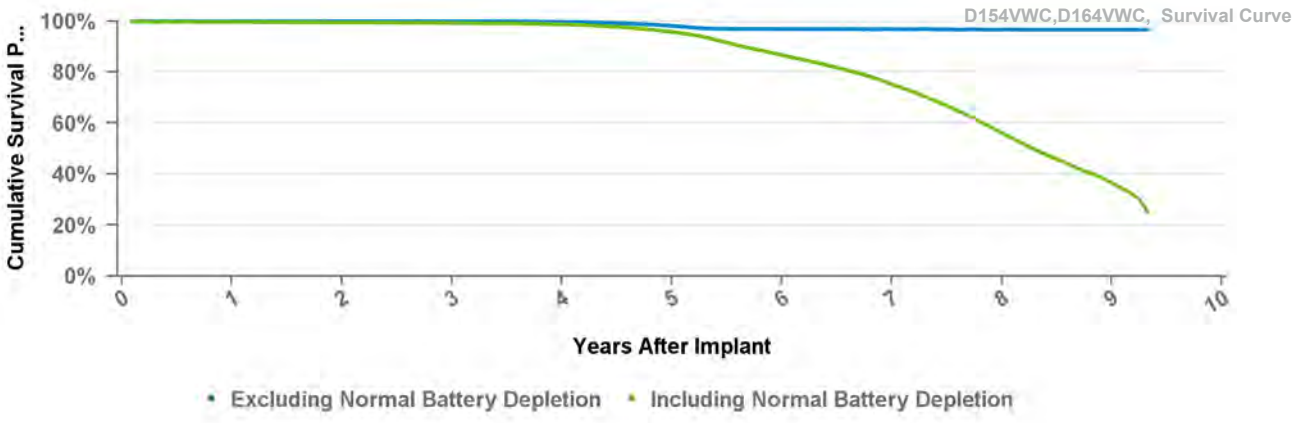


Years	1	10	2	3	4	5	6	7	8	9	at 128 mo
Excluding NBD	99.9%	98.5%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	98.4%
Including NBD	99.6%	99.3%	98.9%	98.5%	97.5%	92.1%	84.8%	76.2%	61.9%	40.7%	20.2%
Effective Sample Size	12679	11485	10268	9071	8007	7007	6006	5094	3700	1907	143

ICD

D154VWC Virtuoso VR

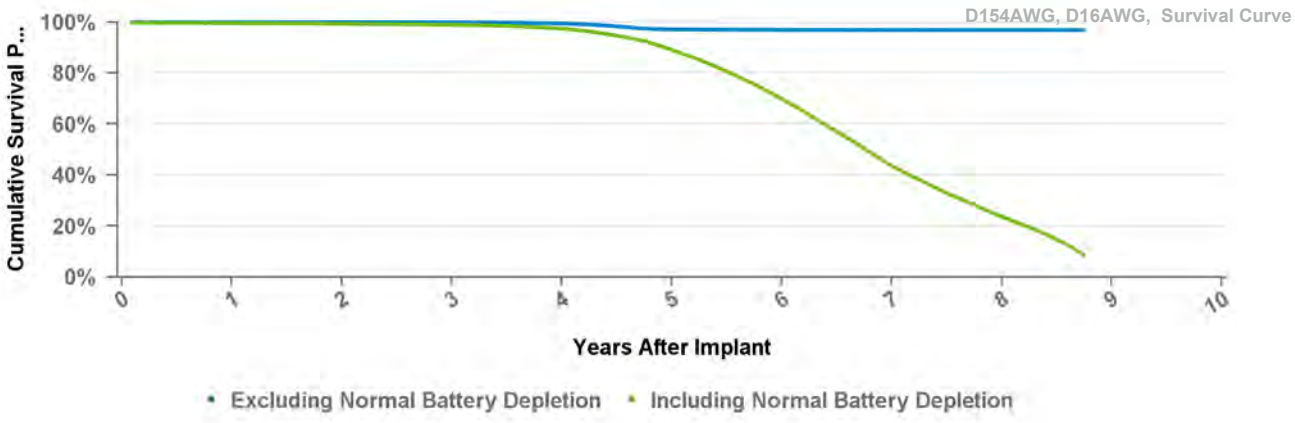
US Market Release	May-06	**Total Malfunctions**	**686**
CE Approval Date		**Therapy Function Not Compromised**	**668**
Registered USA Implants	33,145	Battery Malfunction	11
Estimated Active USA Implants	9,631	Electrical Component	637
Normal Battery Depletions	5,849	Electrical Interconnect	1
		Other Malfunction	4
		Poss Early Battery Depltn	15
		Therapy Function Compromised	**18**
		Battery Malfunction	1
		Electrical Component	17



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%	96.7%
Including NBD	99.7%	99.5%	99.2%	98.7%	95.8%	86.6%	75.2%	56.0%	36.4%	24.9%
Effective Sample Size	28603	26086	23768	21742	19326	16187	13119	7344	1839	306

D164AWG Virtuoso DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	
Registered USA Implants	10		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	4		

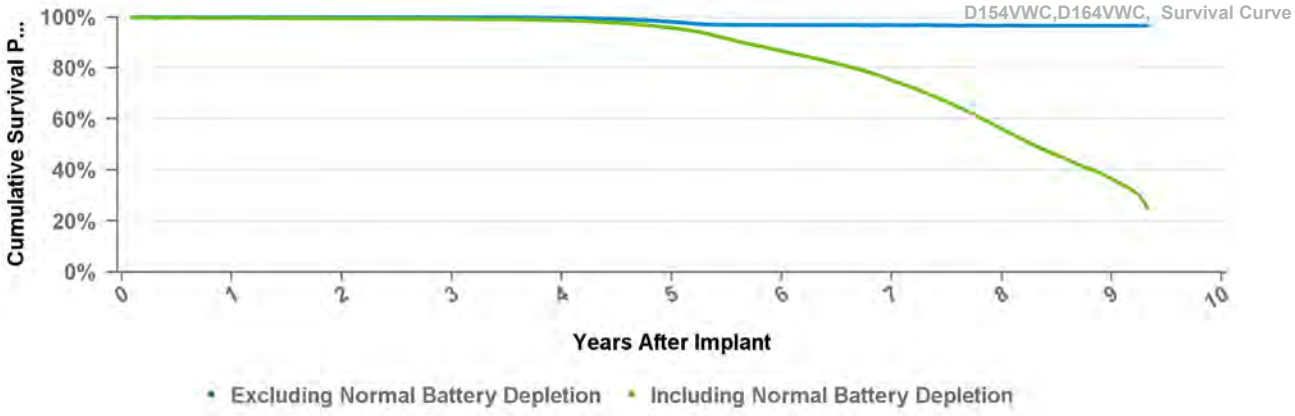


Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.9%	96.8%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.5%	23.6%	8.3%
Effective Sample Size	63436	58180	53019	48182	40953	29876	16947	5787	523

ICD

D164VWC Virtuoso VR

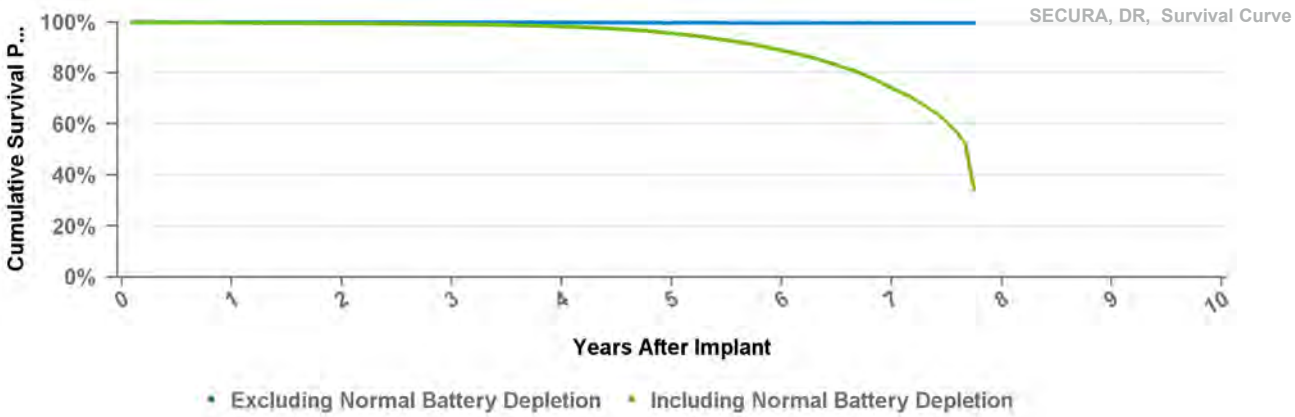
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%	96.7%
Including NBD	99.7%	99.5%	99.2%	98.7%	95.8%	86.6%	75.2%	56.0%	36.4%	24.9%
Effective Sample Size	28603	26086	23768	21742	19326	16187	13119	7344	1839	306

D204DRM Secura DR

US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,882	Other Malfunction	1
Estimated Active USA Implants	1,572	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Component	2

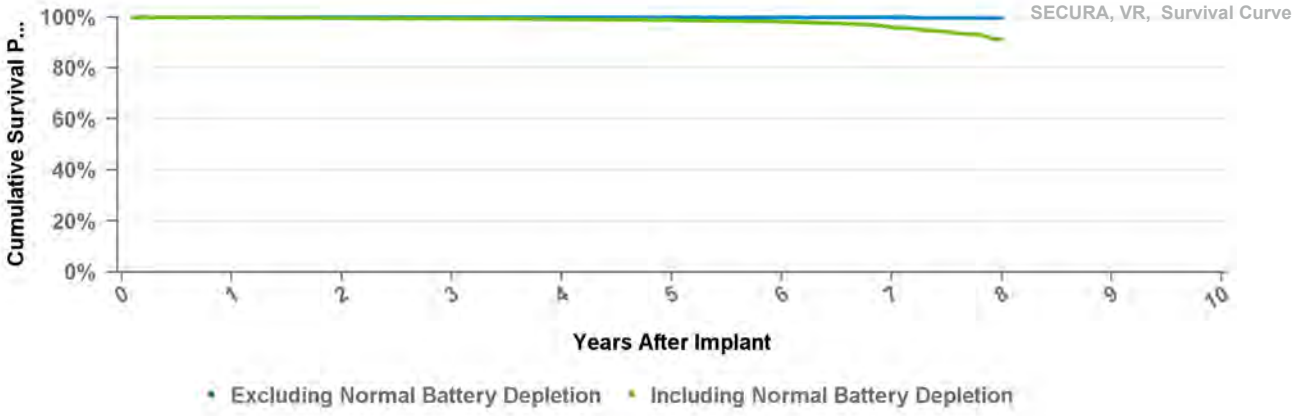


Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.9%	74.0%	33.9%
Effective Sample Size	45339	42488	39845	35870	30102	19610	5673	120

ICD

D204VRM Secura VR

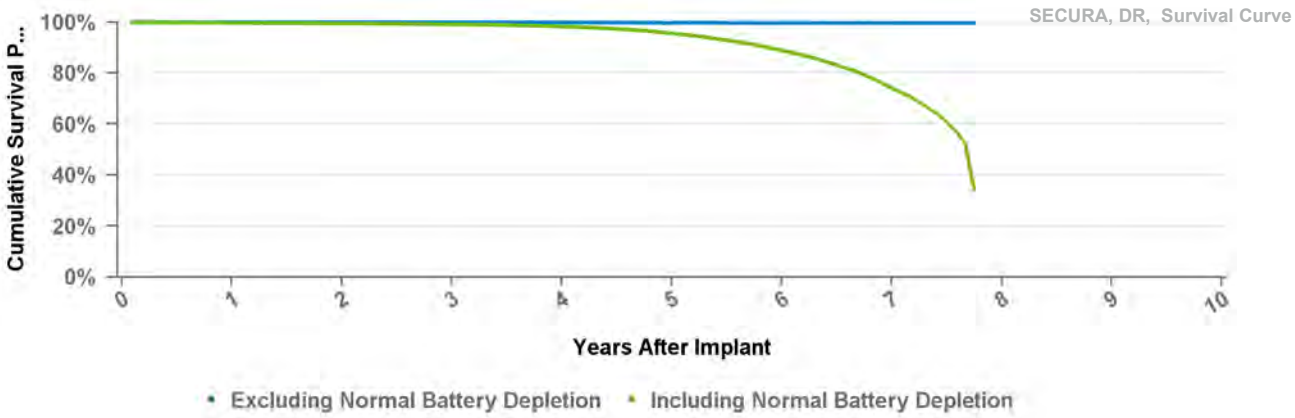
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,185	Electrical Component	1
Estimated Active USA Implants	1,002	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	96.0%	91.2%
Effective Sample Size	18312	17108	16055	14130	11803	8411	3747	207

D214DRM Secura DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

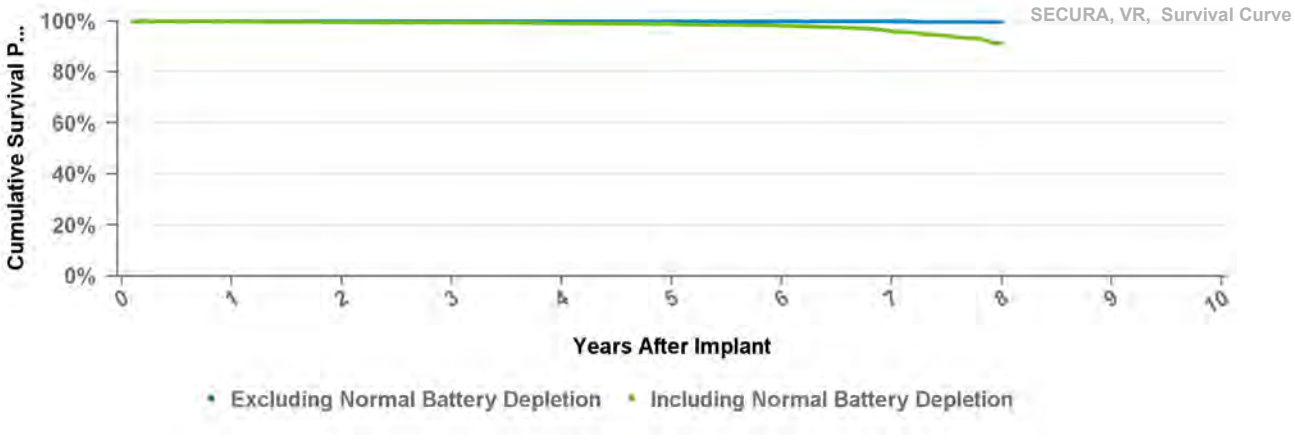


Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.9%	74.0%	33.9%
Effective Sample Size	45339	42488	39845	35870	30102	19610	5673	120

ICD

D214VRM Secura VR

US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



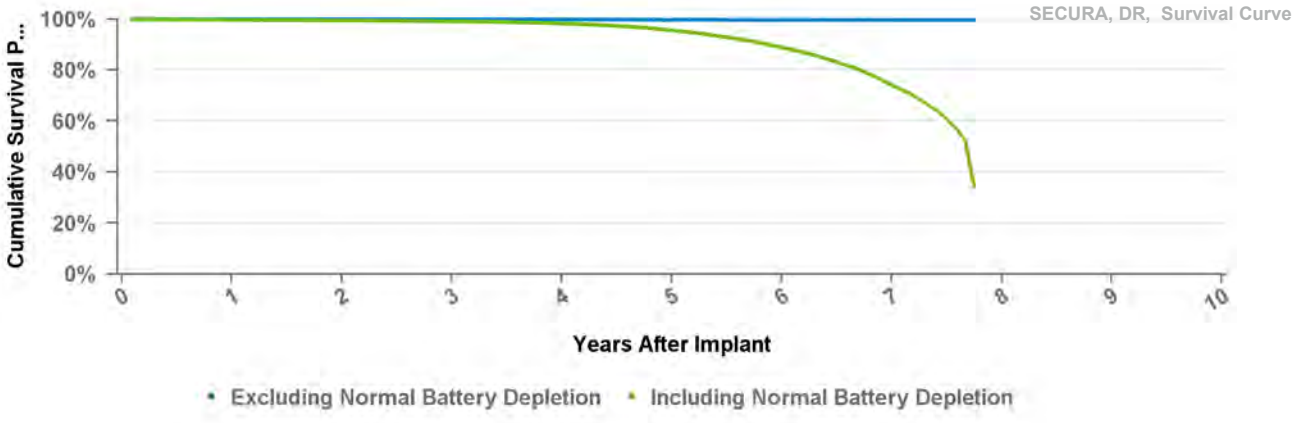
Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	96.0%	91.2%
Effective Sample Size	18312	17108	16055	14130	11803	8411	3747	207

ICD

D224DRG Secura DR

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	49,895
Estimated Active USA Implants	25,193
Normal Battery Depletions	3,659

Total Malfunctions	**120**
Therapy Function Not Compromised	**101**
Battery Malfunction	4
Electrical Component	33
Other Malfunction	5
Poss Early Battery Depltn	50
Software Malfunction	9
Therapy Function Compromised	**19**
Battery Malfunction	4
Electrical Component	13
Poss Early Battery Depltn	1
Software Malfunction	1

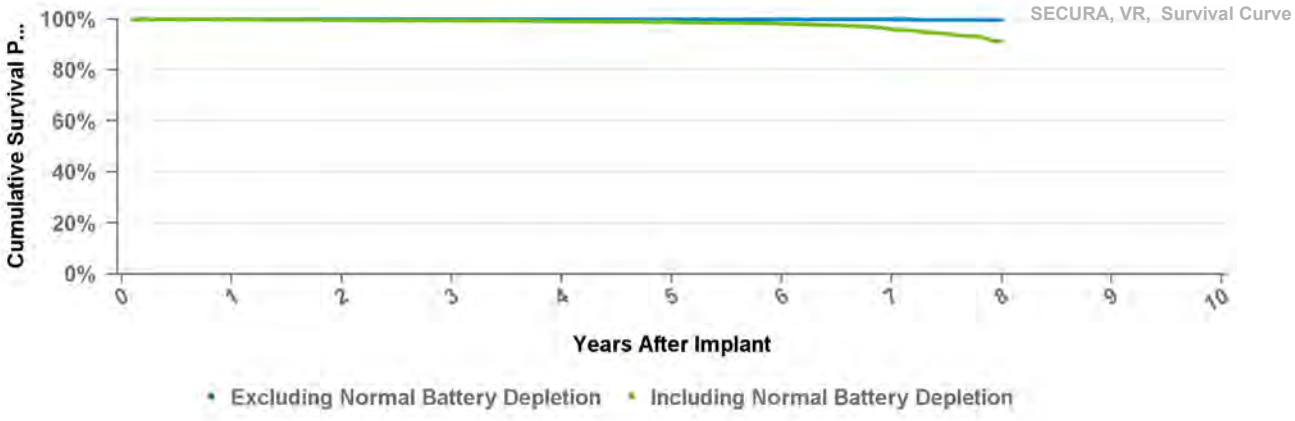


Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.9%	74.0%	33.9%
Effective Sample Size	45339	42488	39845	35870	30102	19610	5673	120

ICD

D224VRC Secura VR

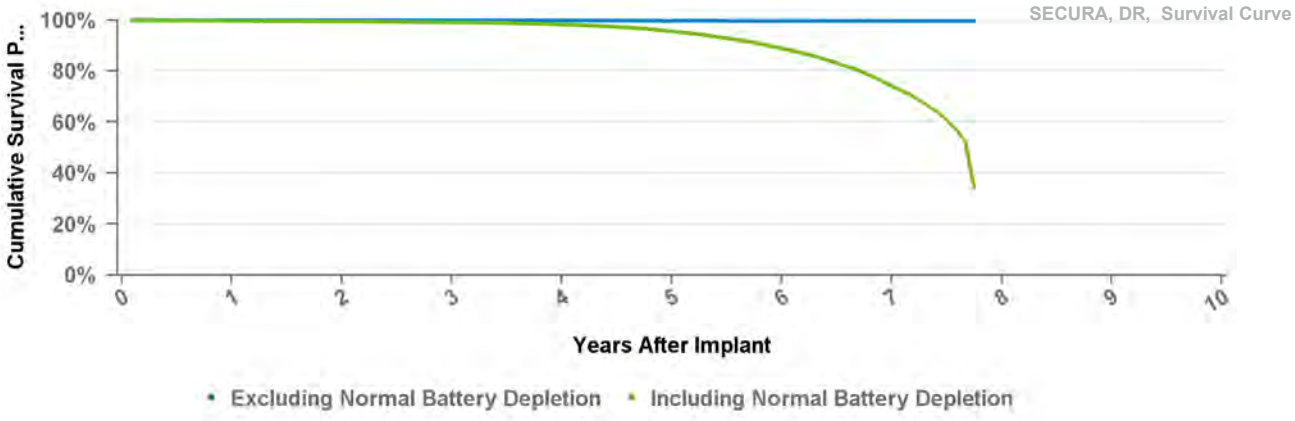
US Market Release	Sep-08	**Total Malfunctions**	**37**
CE Approval Date		**Therapy Function Not Compromised**	**31**
Registered USA Implants	20,060	Battery Malfunction	12
Estimated Active USA Implants	12,870	Electrical Component	8
Normal Battery Depletions	230	Other Malfunction	1
		Poss Early Battery Depltn	8
		Software Malfunction	2
		Therapy Function Compromised	**6**
		Electrical Component	5
		Software Malfunction	1



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	96.0%	91.2%
Effective Sample Size	18312	17108	16055	14130	11803	8411	3747	207

D234DRG Secura DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

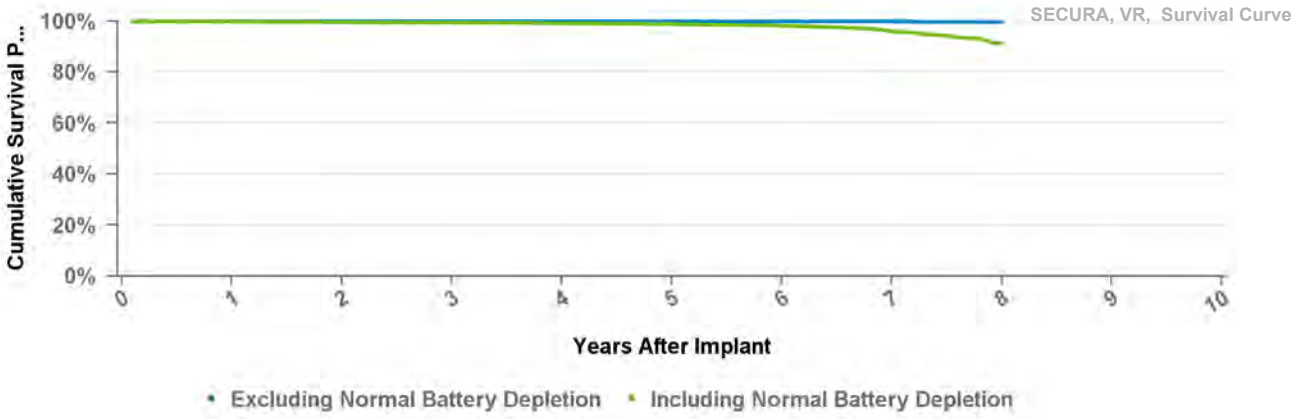


Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.2%	95.6%	88.9%	74.0%	33.9%
Effective Sample Size	45339	42488	39845	35870	30102	19610	5673	120

ICD

D234VRC Secura VR

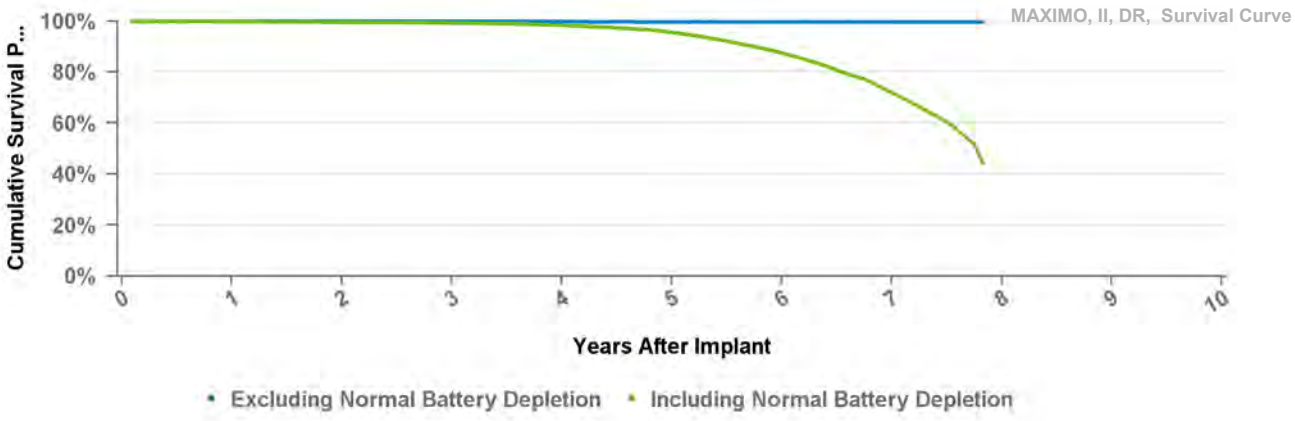
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.8%	98.2%	96.0%	91.2%
Effective Sample Size	18312	17108	16055	14130	11803	8411	3747	207

D264DRM Maximo II DR

US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants	5	**Therapy Function Compromised**	
Normal Battery Depletions			

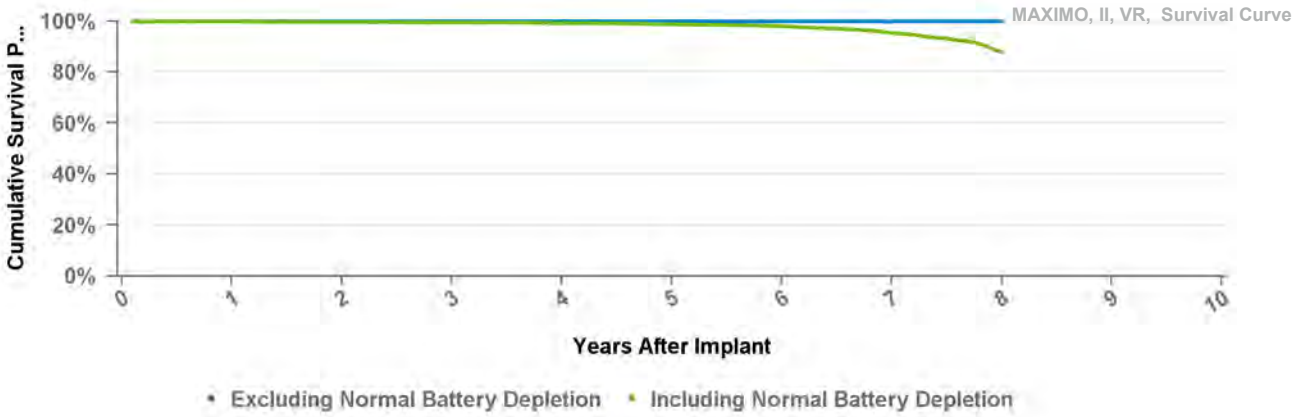


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.5%	99.2%	98.3%	95.6%	87.4%	71.9%	44.4%
Effective Sample Size	17577	16422	15422	13803	11374	7266	2593	166

ICD

D264VRM Maximo II VR

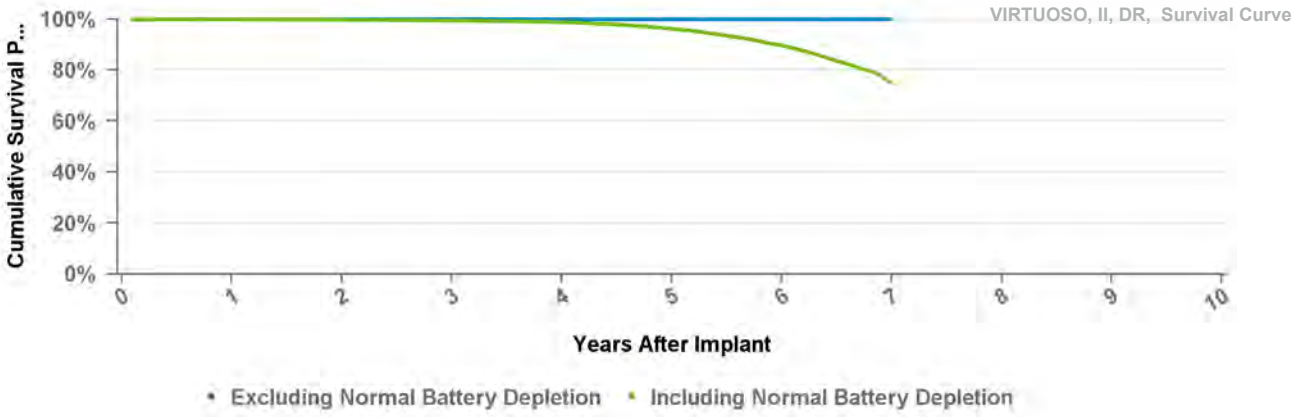
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.5%	99.2%	98.7%	98.0%	95.3%	87.7%
Effective Sample Size	11249	10546	9888	8791	7308	5179	2494	132

D274DRG Virtuoso II DR

US Market Release	Aug-09	**Total Malfunctions**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**22**
Registered USA Implants	22,231	Battery Malfunction	4
Estimated Active USA Implants	12,101	Electrical Component	10
Normal Battery Depletions	1,186	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**3**
		Electrical Component	2
		Other Malfunction	1

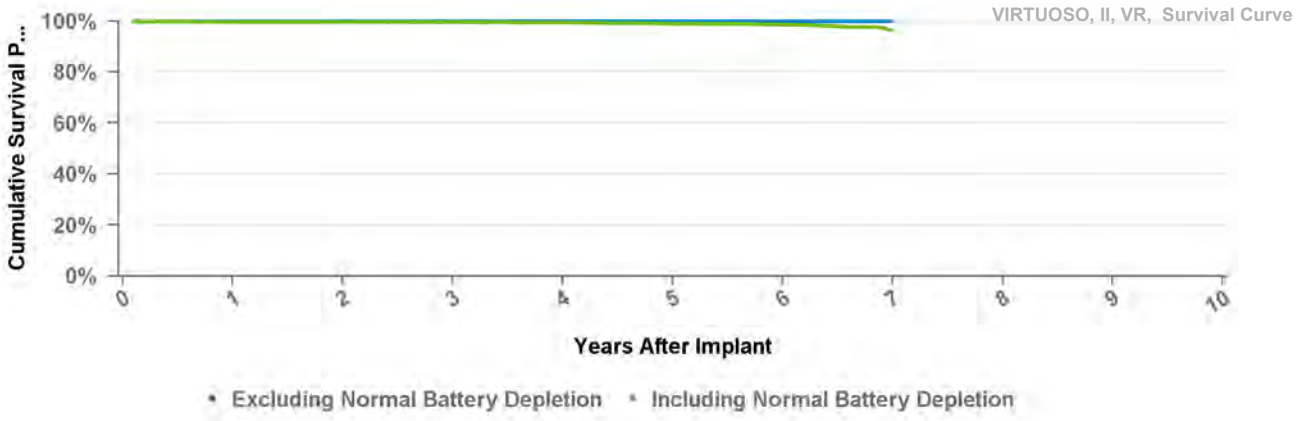


Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%
Including NBD	99.9%	99.7%	99.4%	98.8%	96.1%	89.7%	74.5%
Effective Sample Size	19335	18158	17093	15889	14046	8213	462

ICD

D274VRC Virtuoso II VR

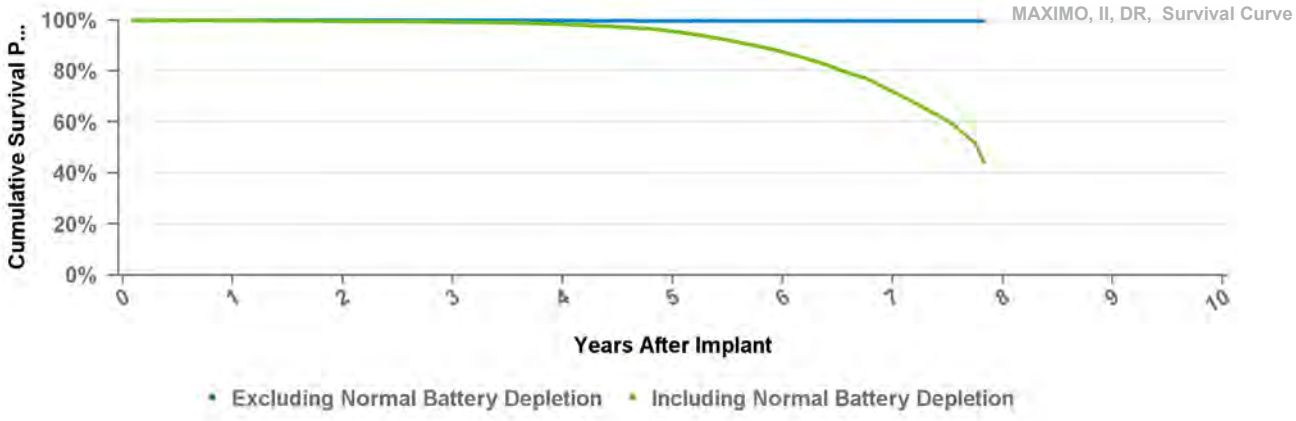
US Market Release	Aug-09	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	9,118	Battery Malfunction	5
Estimated Active USA Implants	6,197	Electrical Component	4
Normal Battery Depletions	57	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.0%	98.6%	96.2%
Effective Sample Size	7792	7317	6907	6427	5848	3664	290

D284DRG Maximo II DR

US Market Release	Sep-08	**Total Malfunctions**	**48**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**42**
Registered USA Implants	20,087	Battery Malfunction	1
Estimated Active USA Implants	9,897	Electrical Component	11
Normal Battery Depletions	1,726	Poss Early Battery Depltn	30
		Therapy Function Compromised	**6**
		Electrical Component	5
		Poss Early Battery Depltn	1

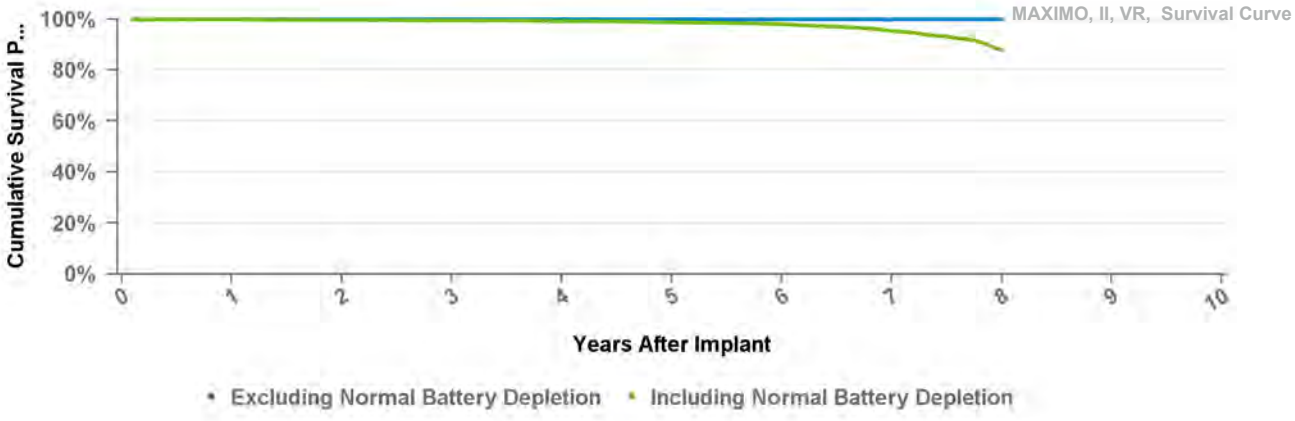


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.5%	99.2%	98.3%	95.6%	87.4%	71.9%	44.4%
Effective Sample Size	17577	16422	15422	13803	11374	7266	2593	166

ICD

D284VRC Maximo II VR

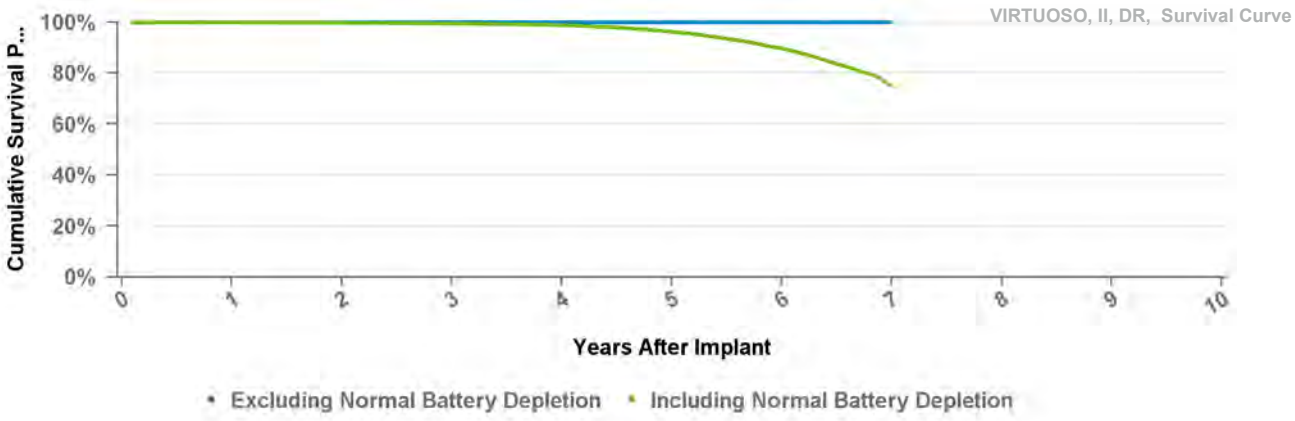
US Market Release	Sep-08	**Total Malfunctions**	**18**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**14**
Registered USA Implants	13,038	Battery Malfunction	4
Estimated Active USA Implants	8,504	Electrical Component	4
Normal Battery Depletions	203	Poss Early Battery Depltn	3
		Software Malfunction	3
		Therapy Function Compromised	**4**
		Battery Malfunction	1
		Electrical Component	2
		Software Malfunction	1



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.8%	99.6%	99.5%	99.2%	98.7%	98.0%	95.3%	87.7%
Effective Sample Size	11249	10546	9888	8791	7308	5179	2494	132

D294DRG Virtuoso II DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

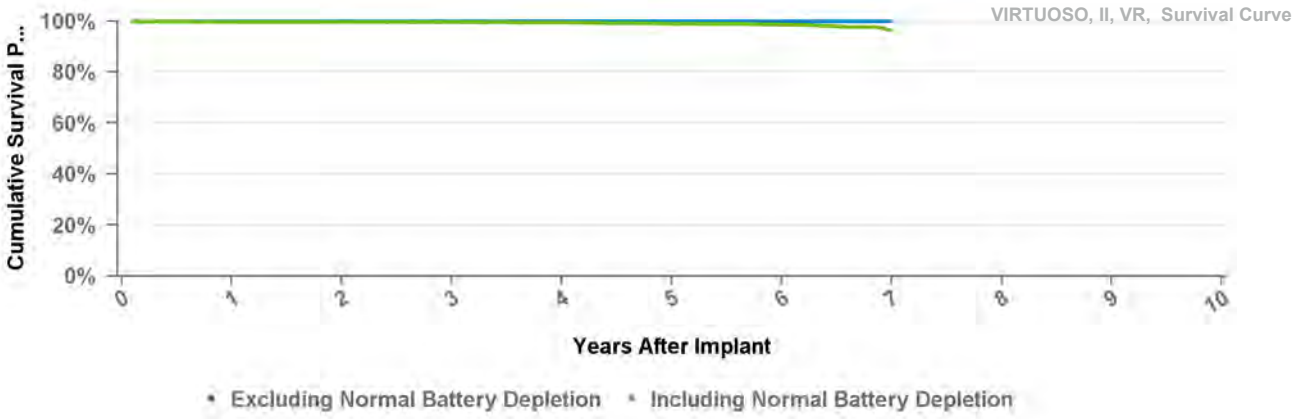


Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%
Including NBD	99.9%	99.7%	99.4%	98.8%	96.1%	89.7%	74.5%
Effective Sample Size	19335	18158	17093	15889	14046	8213	462

ICD

D294VRC Virtuoso II VR

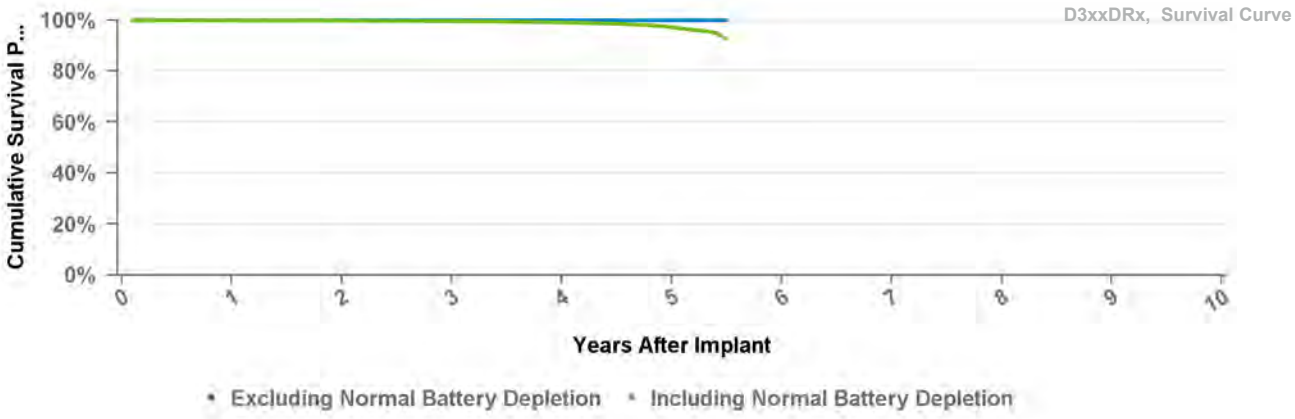
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.6%	99.4%	99.0%	98.6%	96.2%
Effective Sample Size	7792	7317	6907	6427	5848	3664	290

D314DRG Protecta XT DR

US Market Release	Mar-11	**Total Malfunctions**	**36**
CE Approval Date		**Therapy Function Not Compromised**	**30**
Registered USA Implants	34,814	Battery Malfunction	3
Estimated Active USA Implants	26,820	Electrical Component	23
Normal Battery Depletions	314	Other Malfunction	1
		Poss Early Battery Depltn	3
		Therapy Function Compromised	**6**
		Electrical Component	6

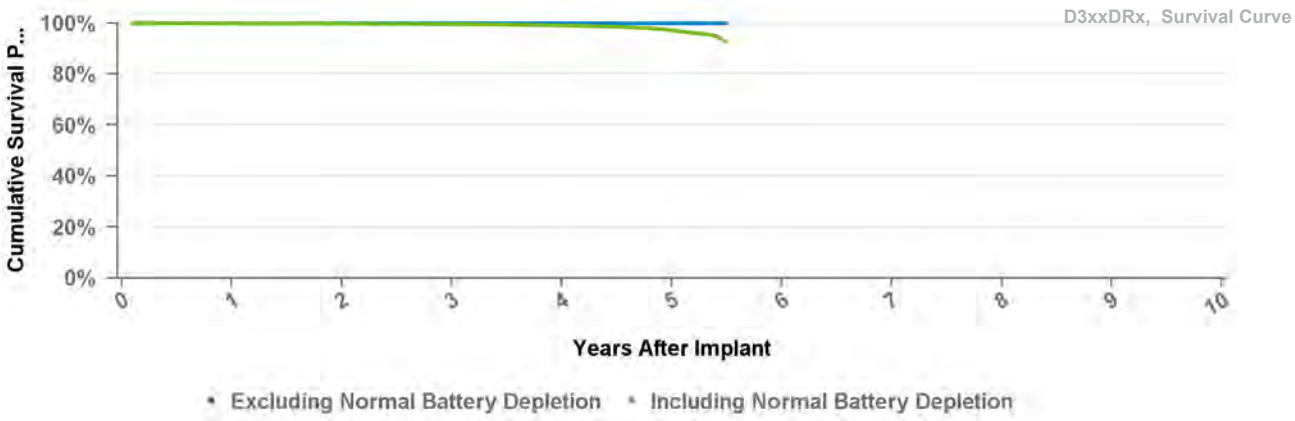


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D314DRM Protecta XT DR

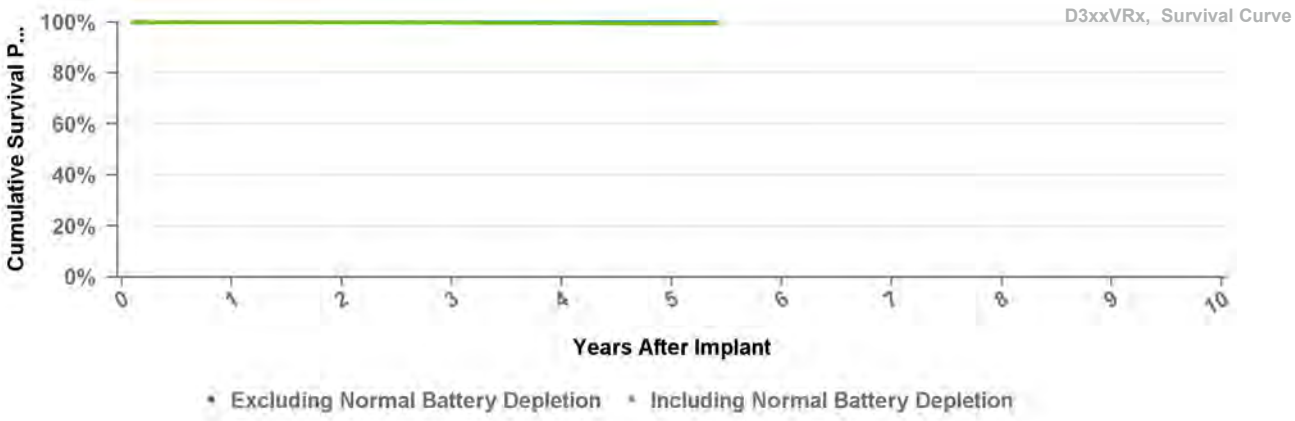
US Market Release	Nov-11	**Total Malfunctions**	**11**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	13,911	Electrical Component	10
Estimated Active USA Implants	11,708	Other Malfunction	1
Normal Battery Depletions	41	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

D314VRG Protecta XT VR

US Market Release	Mar-11	**Total Malfunctions**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	14,208	Electrical Component	7
Estimated Active USA Implants	11,388	Other Malfunction	1
Normal Battery Depletions	30	**Therapy Function Compromised**	**1**
		Electrical Component	1

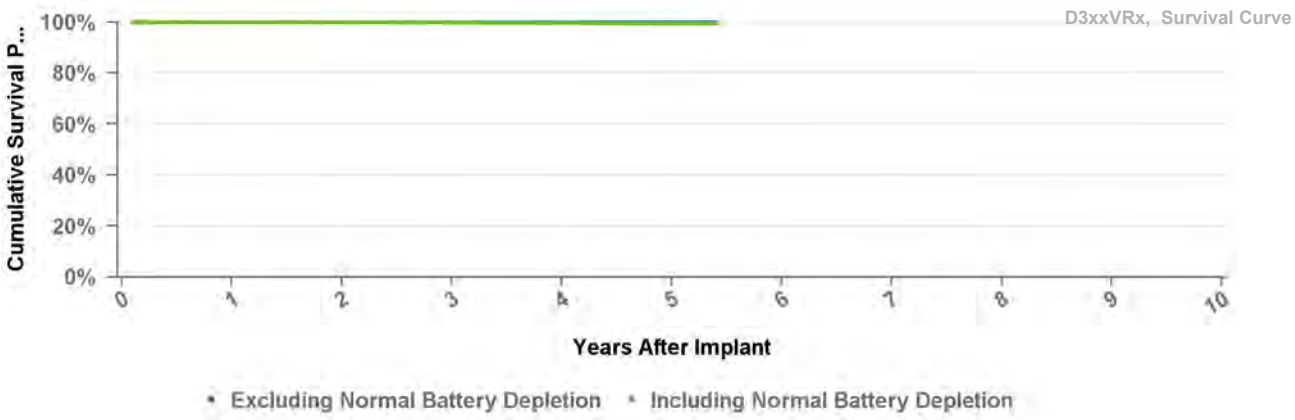


Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

ICD

D314VRM Protecta XT VR

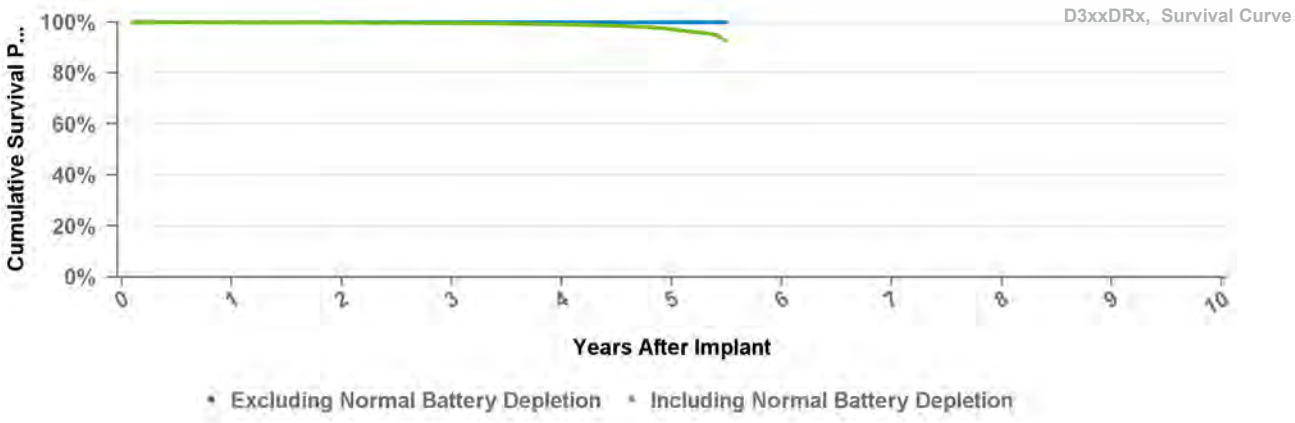
US Market Release	May-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,371	Electrical Component	2
Estimated Active USA Implants	6,182	**Therapy Function Compromised**	**1**
Normal Battery Depletions	9	Electrical Component	1



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

D334DRG Protecta DR

US Market Release	Mar-11	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,691	Electrical Component	5
Estimated Active USA Implants	8,369	Poss Early Battery Depltn	1
Normal Battery Depletions	110	**Therapy Function Compromised**	**2**
		Electrical Component	2

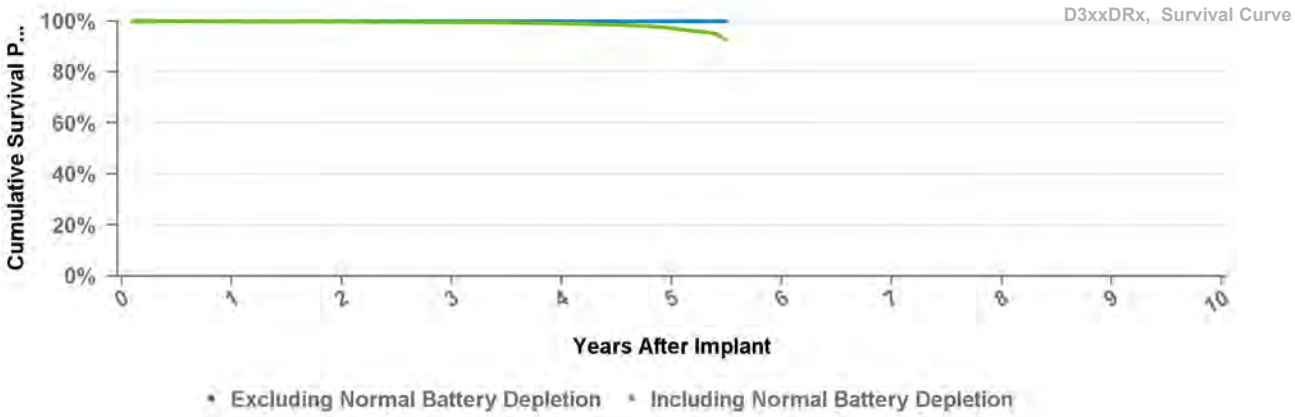


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D334DRM Protecta DR

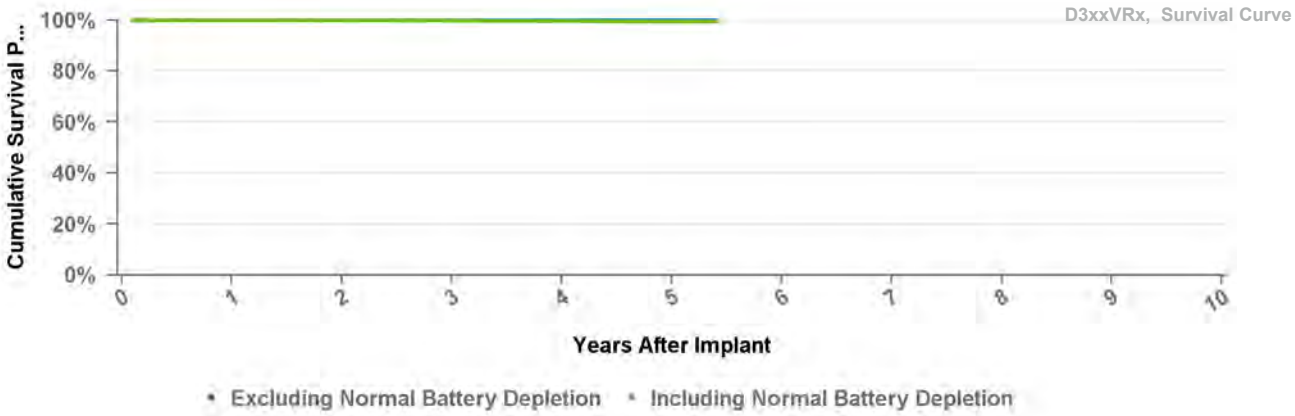
US Market Release	Nov-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,991		
Estimated Active USA Implants	2,581	**Therapy Function Compromised**	
Normal Battery Depletions	12		



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

D334VRG Protecta VR

US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	6,484	Battery Malfunction	1
Estimated Active USA Implants	5,270	Electrical Component	3
Normal Battery Depletions	11	Poss Early Battery Depltn	1
		Therapy Function Compromised	**1**
		Electrical Component	1

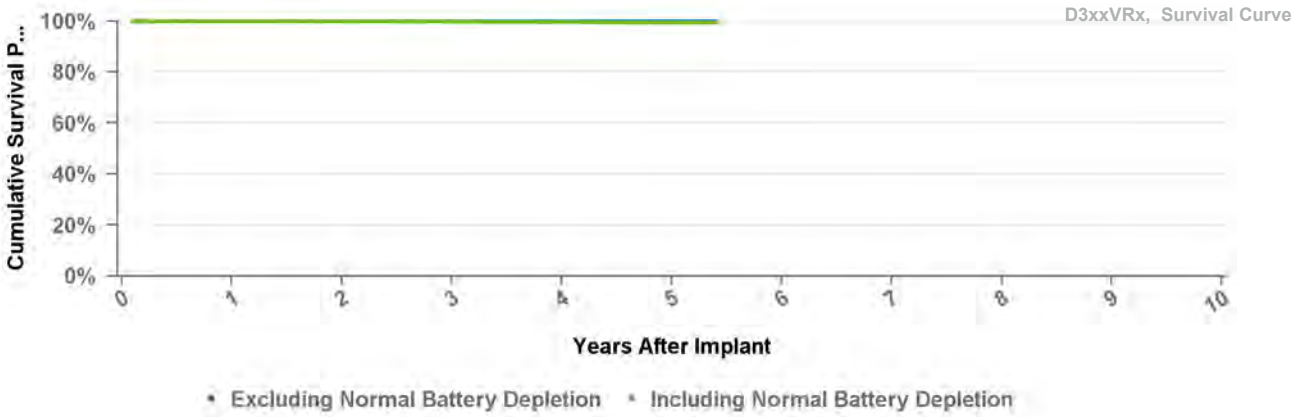


Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

ICD

D334VRM Protecta VR

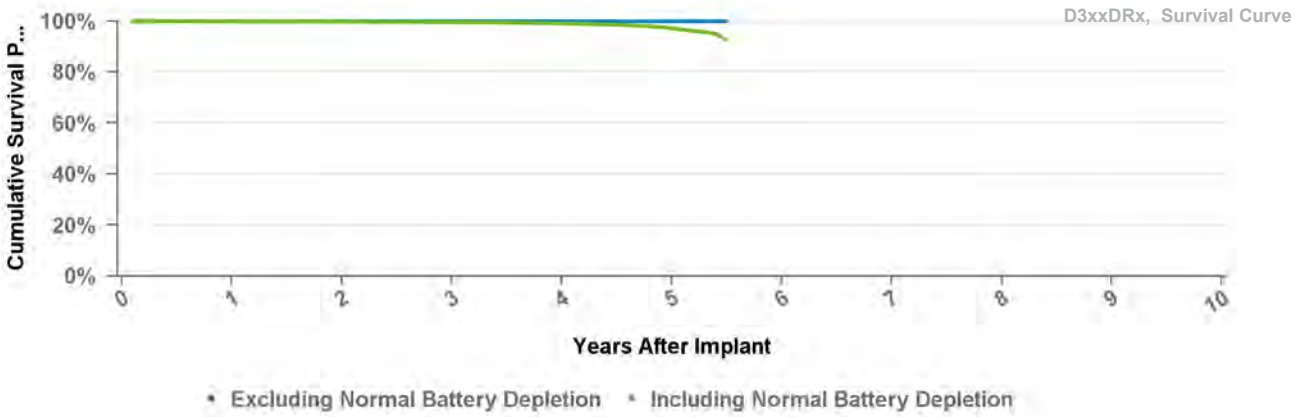
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,160		
Estimated Active USA Implants	1,841	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

D354DRG Protecta XT DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			

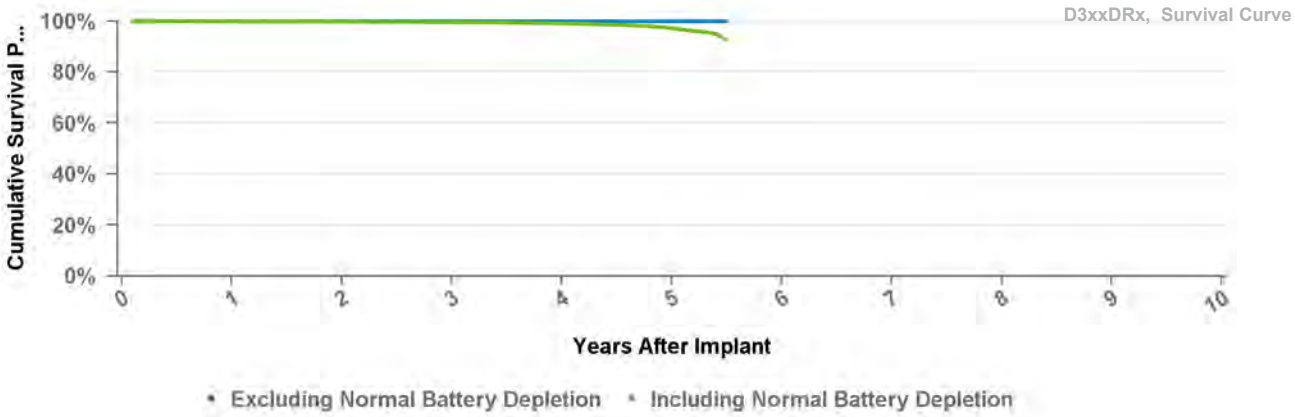


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D354DRM Protecta XT DR

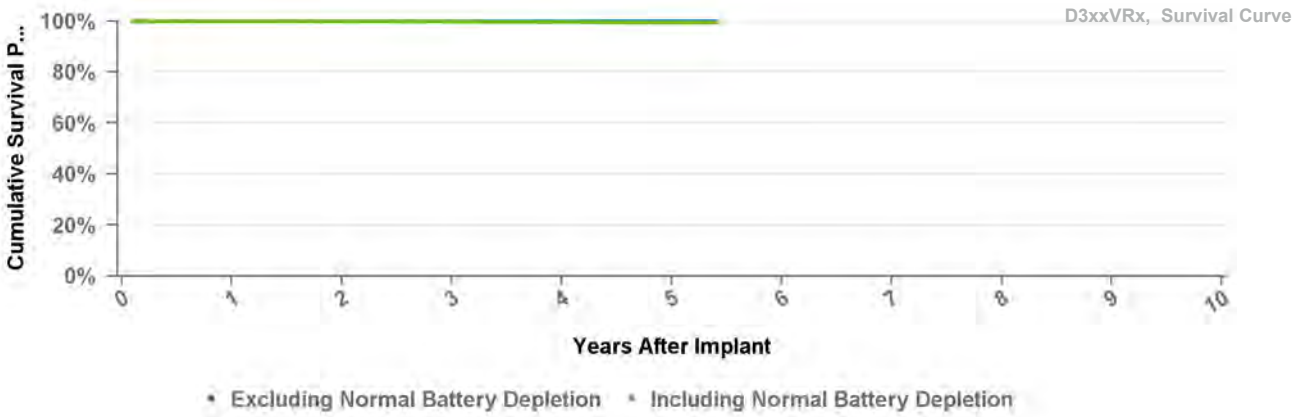
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

D354VRG Protecta XT VR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

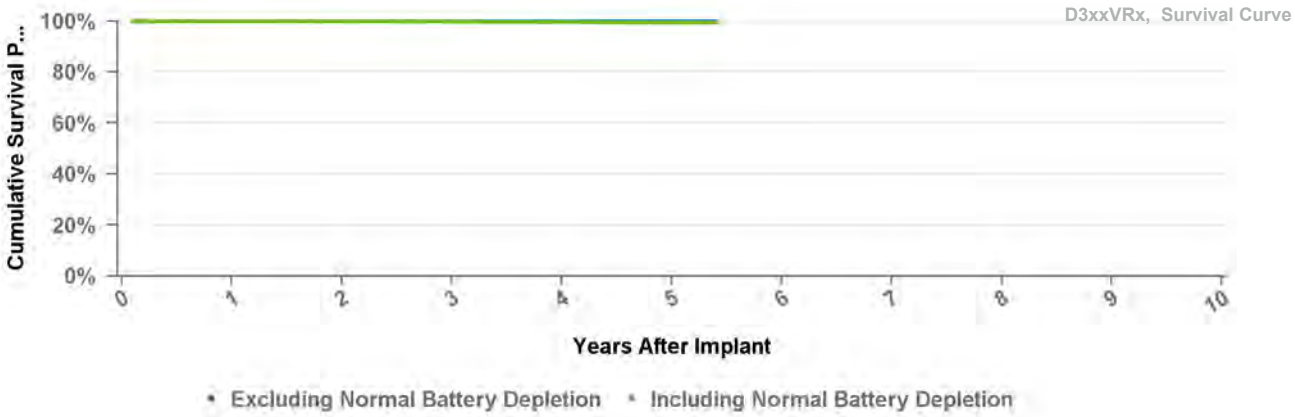


Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

ICD

D354VRM Protecta XT VR

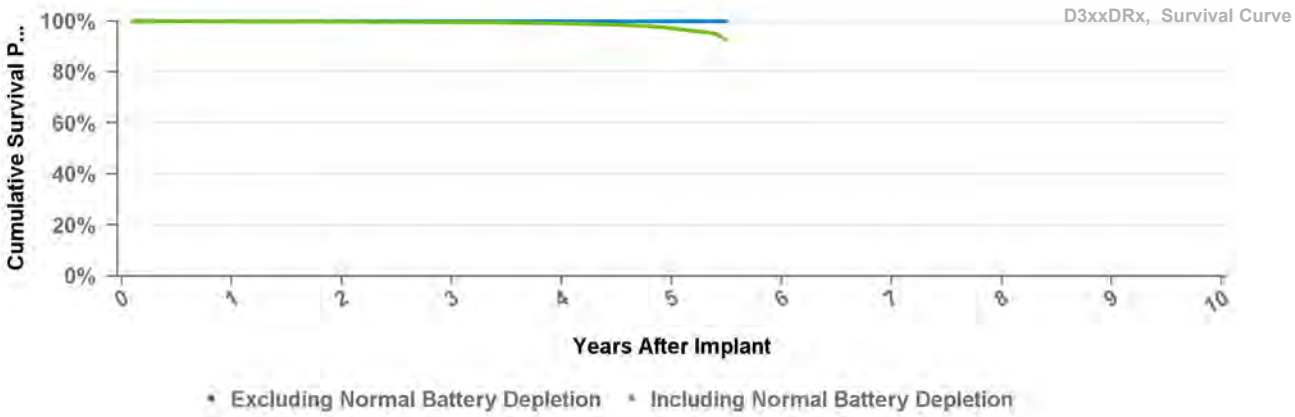
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

D364DRG Protecta DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			

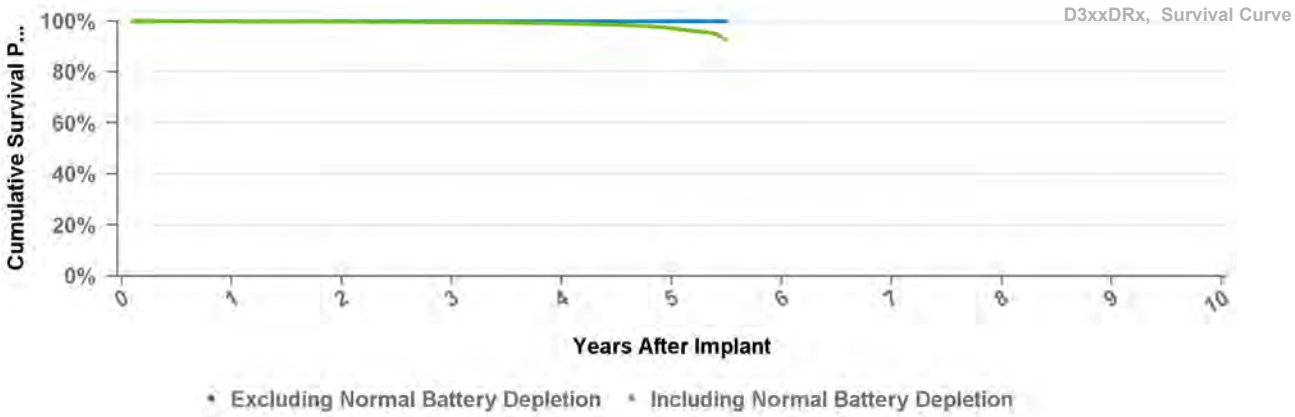


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D364DRM Protecta DR

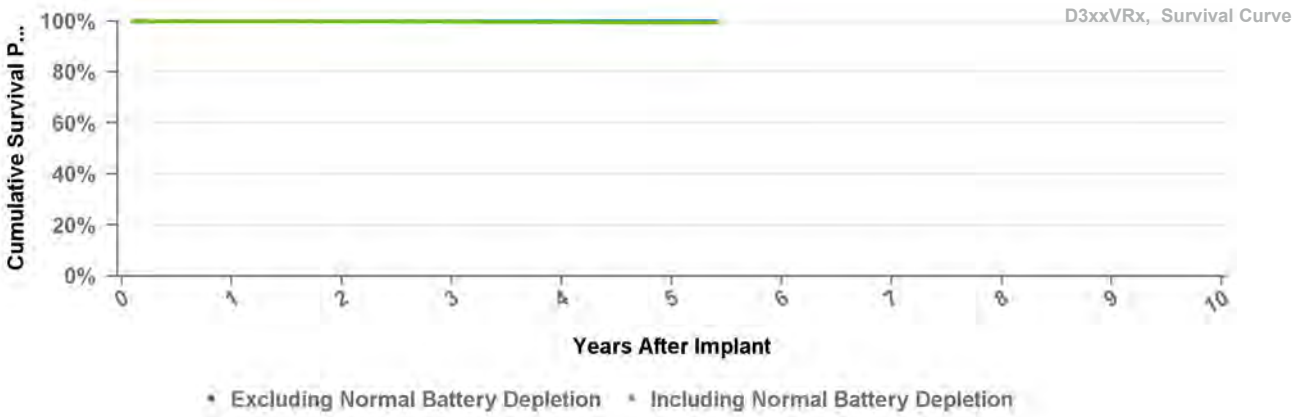
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

D364VRG Protecta VR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			

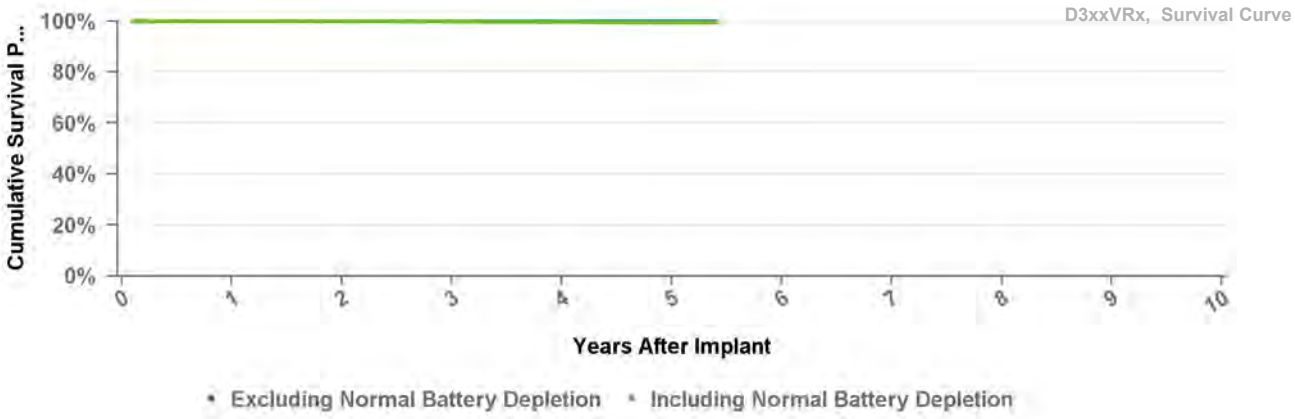


Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

ICD

D364VRM Protecta VR

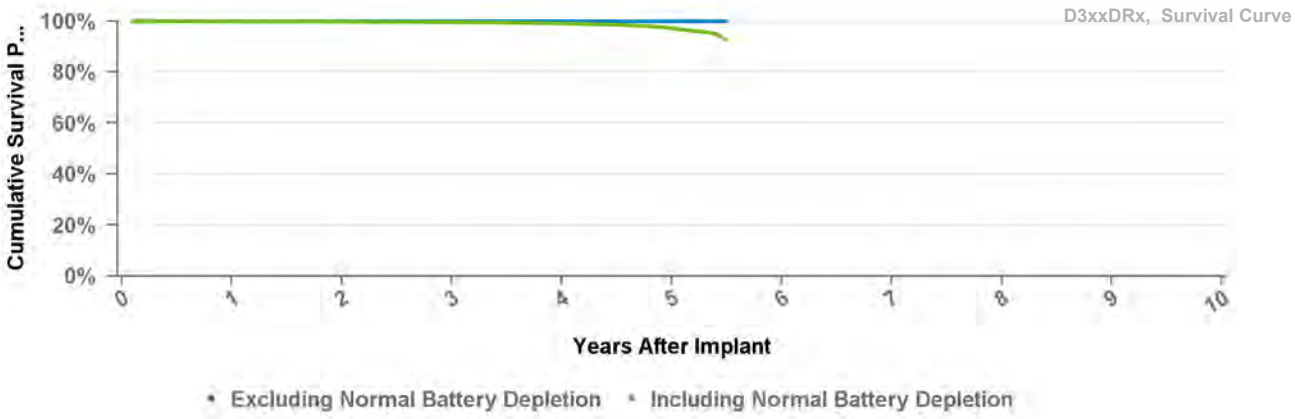
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

D384DRG Cardia DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

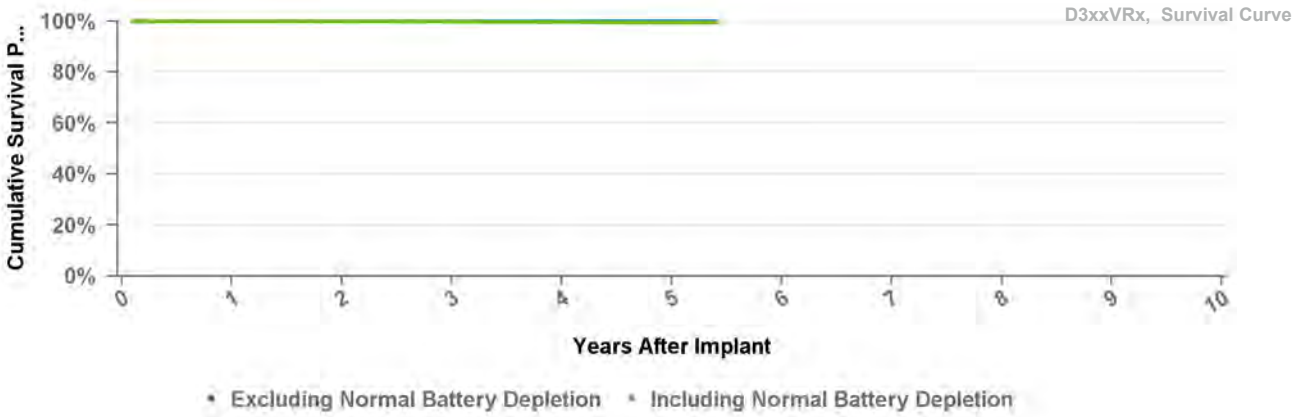


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D384VRG Cardia VR

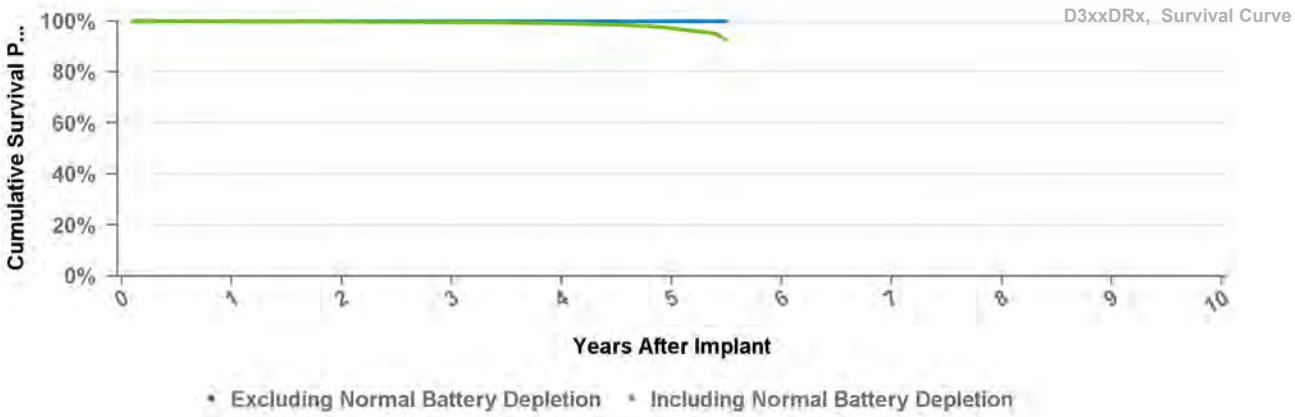
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

D394DRG Egida DR

US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

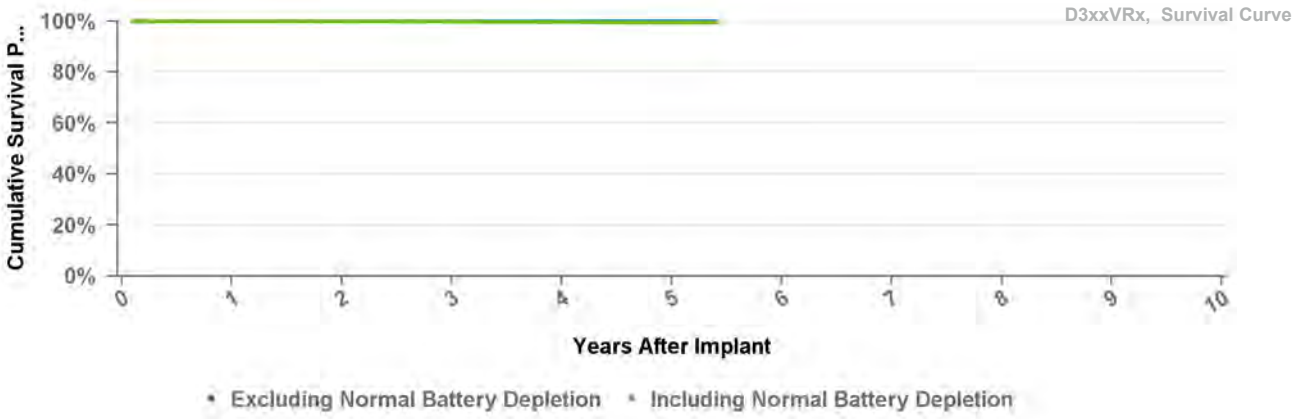


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	99.1%	97.2%	92.1%
Effective Sample Size	55724	52226	47430	31965	8496	541

ICD

D394VRG Egida VR

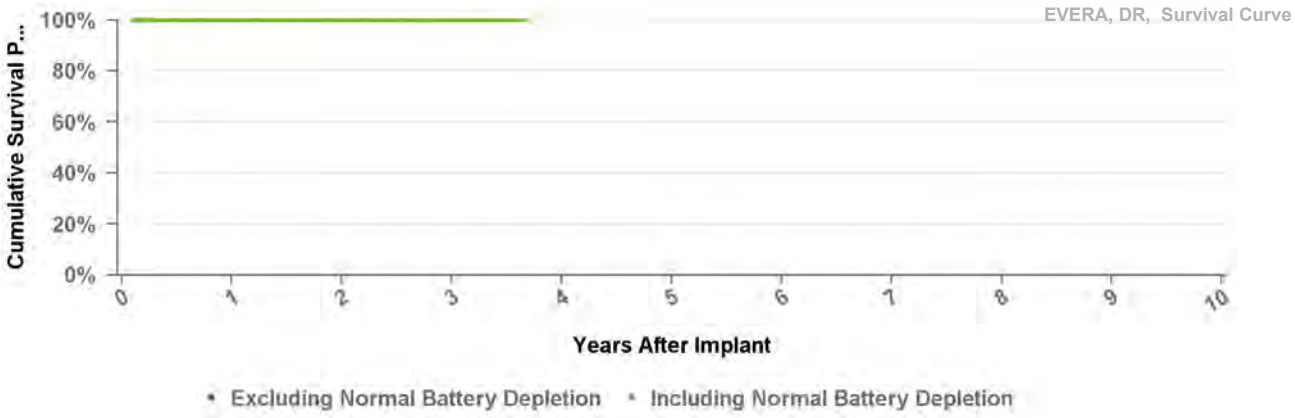
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	99.3%
Effective Sample Size	26672	24853	22210	14266	3386	348

DDBB1D1 Evera XT

US Market Release	Apr-13	**Total Malfunctions**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	35,397	Battery Malfunction	2
Estimated Active USA Implants	32,736	Electrical Component	5
Normal Battery Depletions	14	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1

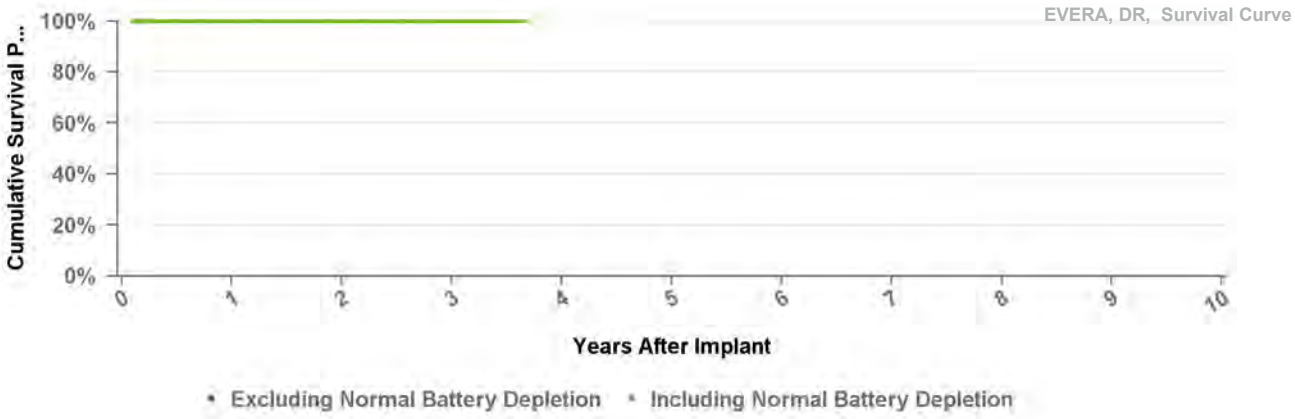


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DDBB1D4 Evera XT

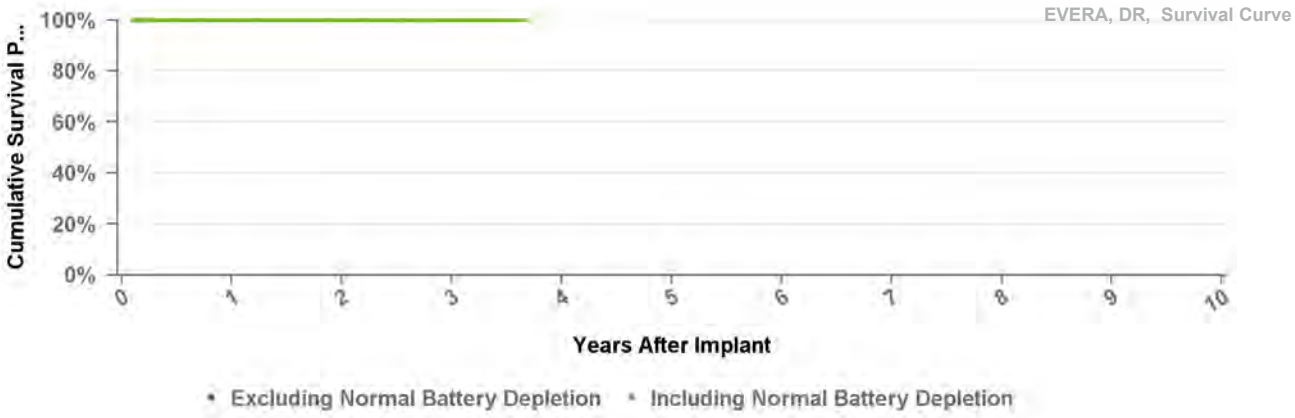
US Market Release	Apr-13	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	28,437	Electrical Component	2
Estimated Active USA Implants	26,439	Electrical Interconnect	1
Normal Battery Depletions	9	Other Malfunction	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

DDBB2D1 Evera XT

US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

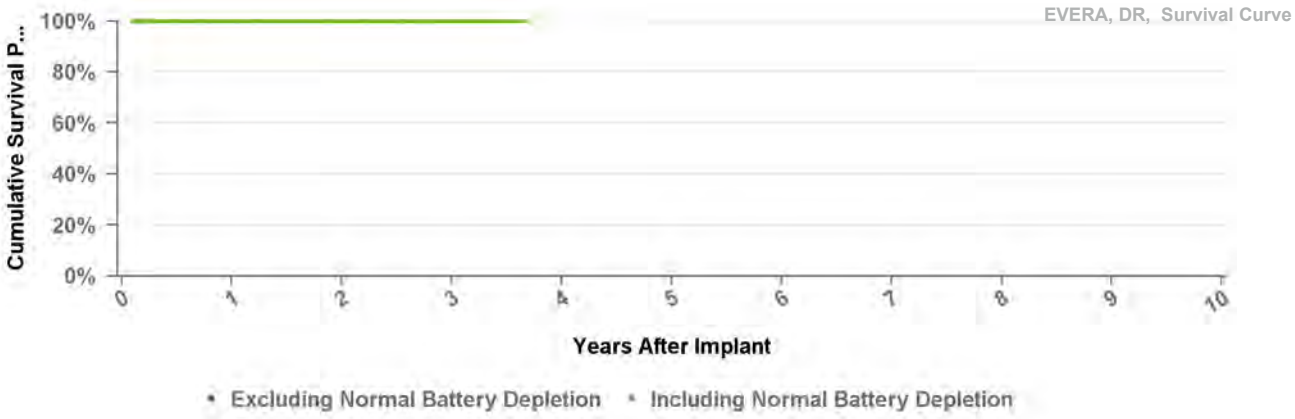


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DDBB2D4 Evera XT

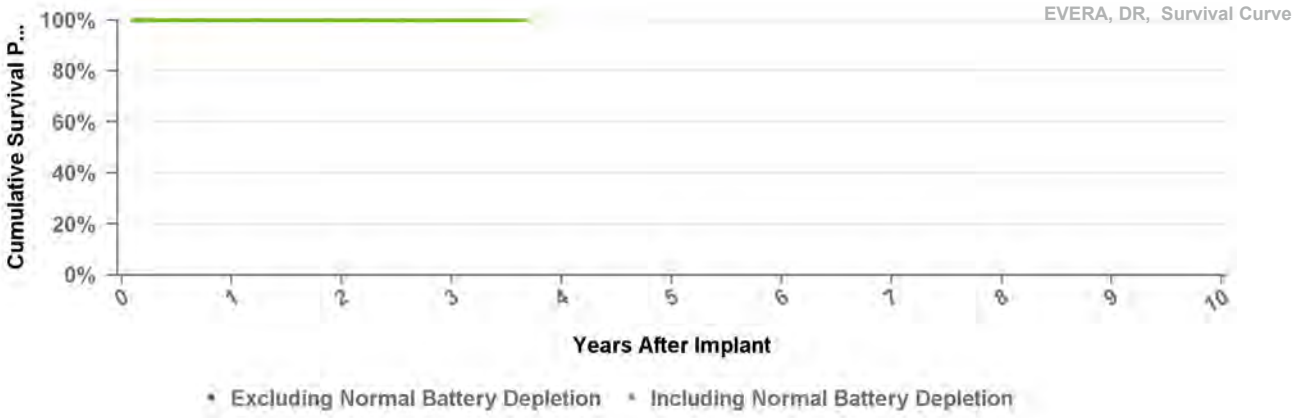
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

DDBC3D1 Evera S

US Market Release	Apr-13	**Total Malfunctions**	**2**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**2**
Registered USA Implants	6,835	Electrical Component	2
Estimated Active USA Implants	6,289	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		

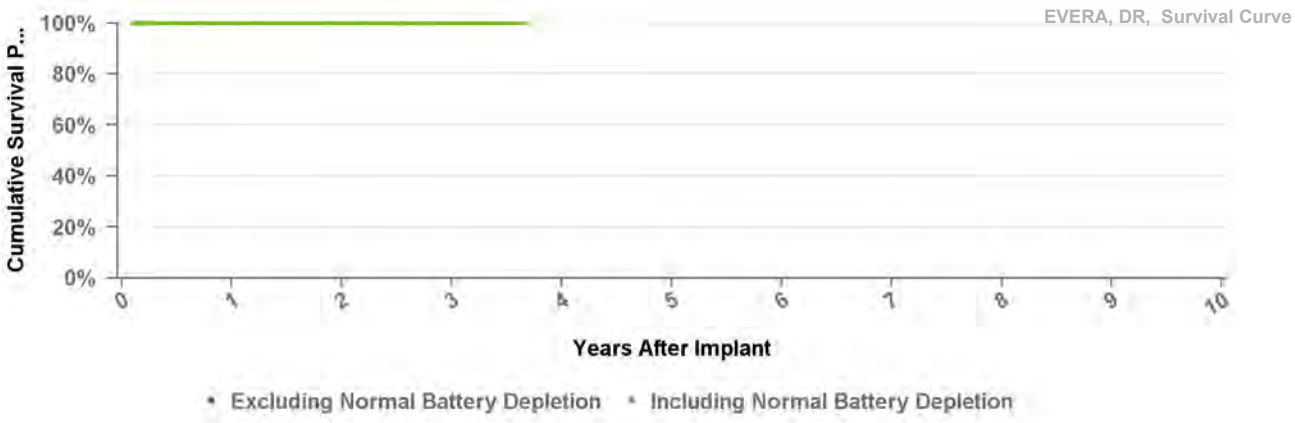


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DDBC3D4 Evera S

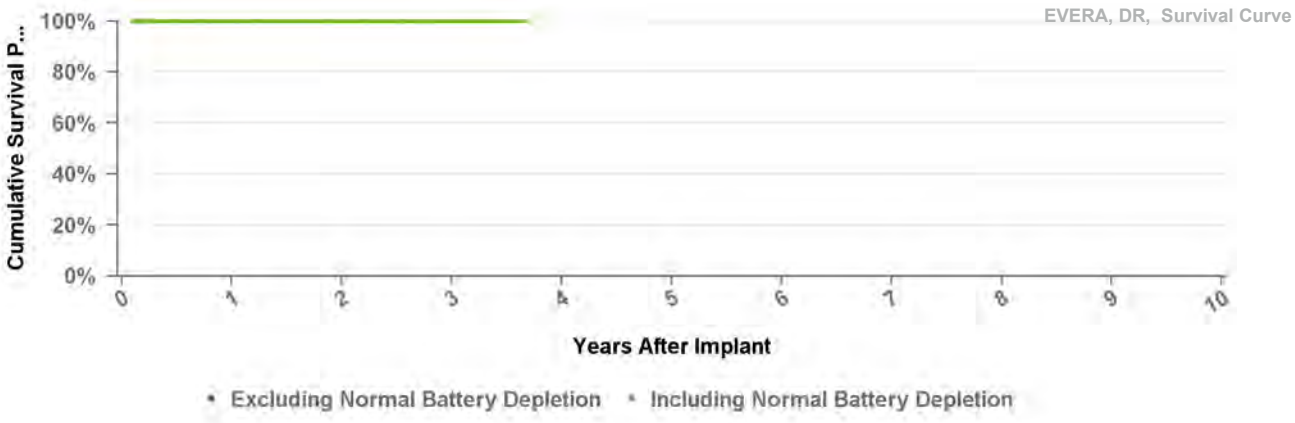
US Market Release	Apr-13	**Total Malfunctions**	**2**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**2**
Registered USA Implants	5,272	Battery Malfunction	1
Estimated Active USA Implants	4,854	Electrical Component	1
Normal Battery Depletions	3	**Therapy Function Compromised**	**0**



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

DDMB1D1 Evera MRI XT

US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,592		
Estimated Active USA Implants	1,587	**Therapy Function Compromised**	
Normal Battery Depletions			

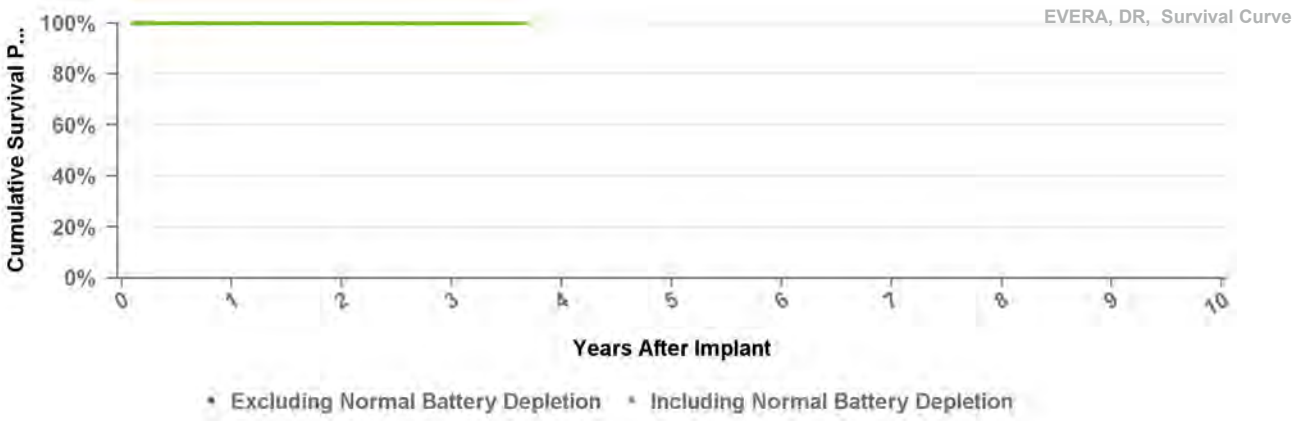


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DDMB1D4 Evera MRI XT

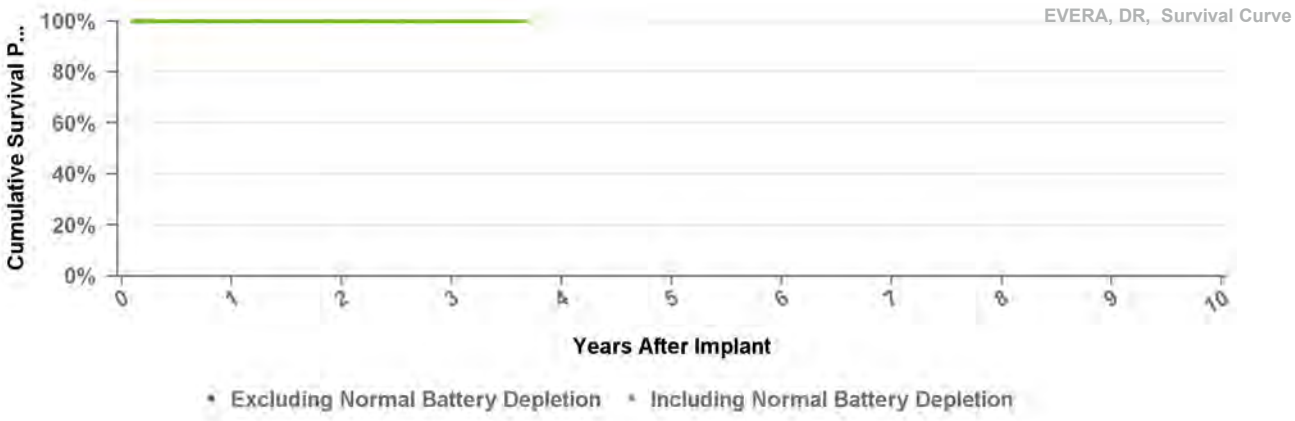
US Market Release	Sep-15	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	17,740	Electrical Component	3
Estimated Active USA Implants	17,344	Electrical Interconnect	1
Normal Battery Depletions	2	**Therapy Function Compromised**	**0**



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

DDMB2D4 Evera MRI XT

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

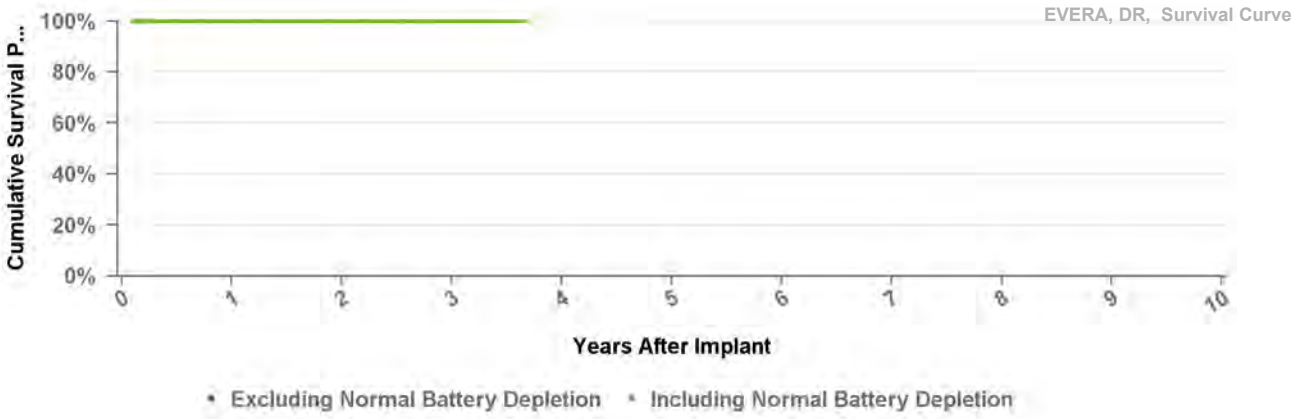


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DDMC3D1 Evera MRI S

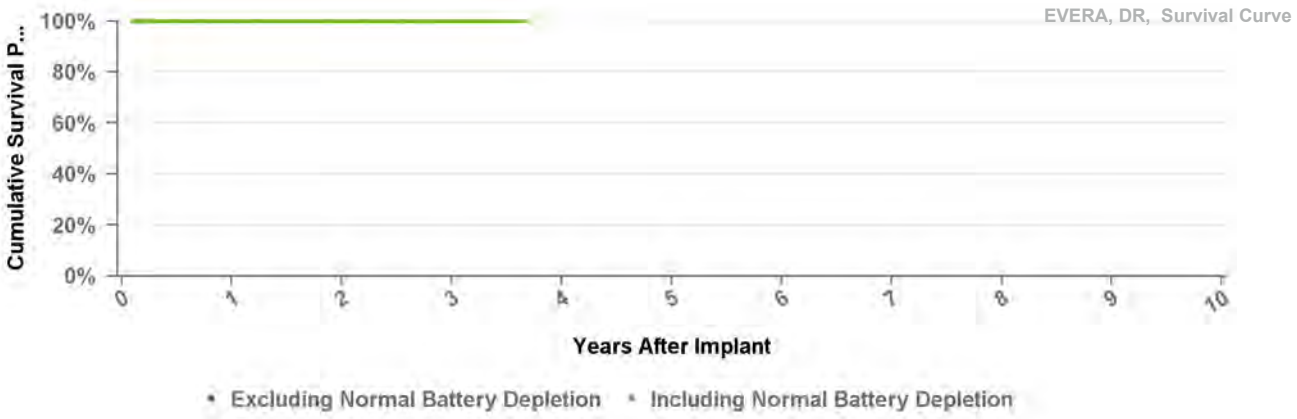
US Market Release	Oct-16	**Total Malfunctions**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**
Registered USA Implants	91	
Estimated Active USA Implants	91	**Therapy Function Compromised**
Normal Battery Depletions		



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

DDMC3D4 Evera MRI

US Market Release	Sep-15	**Total Malfunctions**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**
Registered USA Implants	1,164	
Estimated Active USA Implants	1,139	**Therapy Function Compromised**
Normal Battery Depletions		

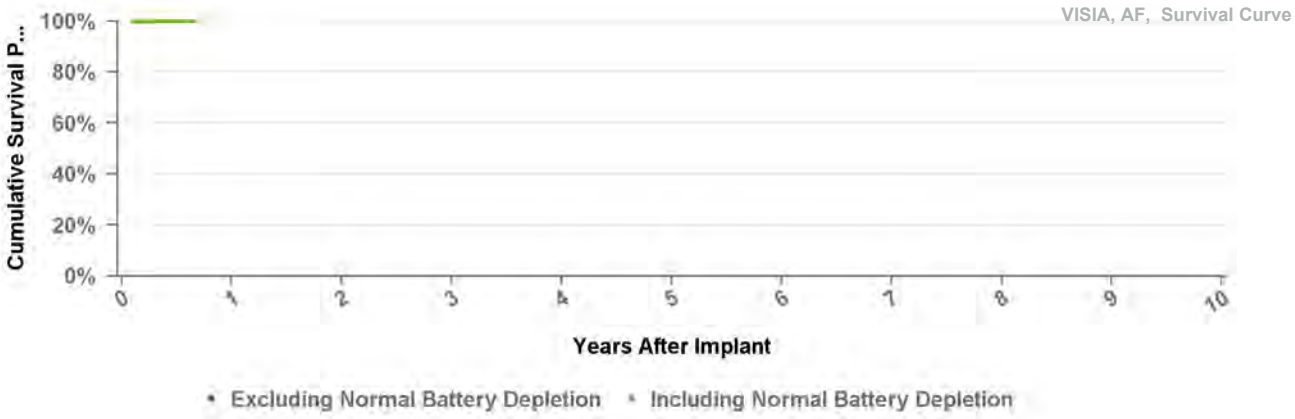


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	63542	35888	11840	175

ICD

DVAB1D1 Visia AF

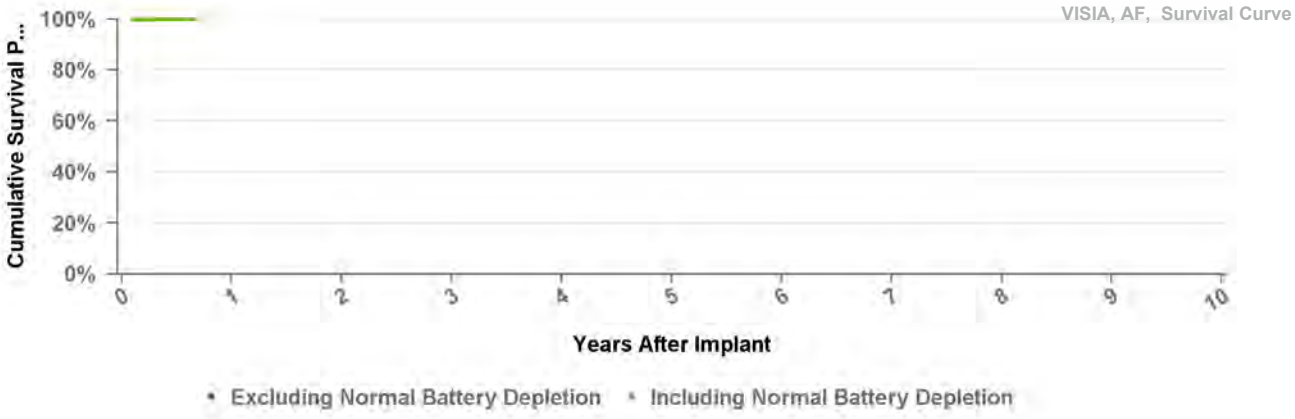
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	873		
Estimated Active USA Implants	865	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

DVAB1D4 Visia AF

US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	579		
Estimated Active USA Implants	570	**Therapy Function Compromised**	
Normal Battery Depletions			

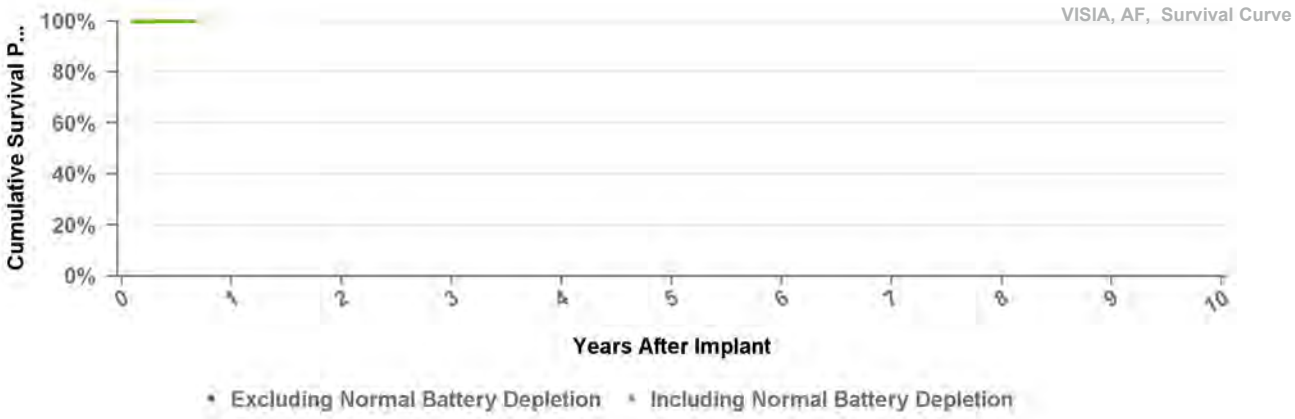


Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

ICD

DVAB2D1 Visia AF XT

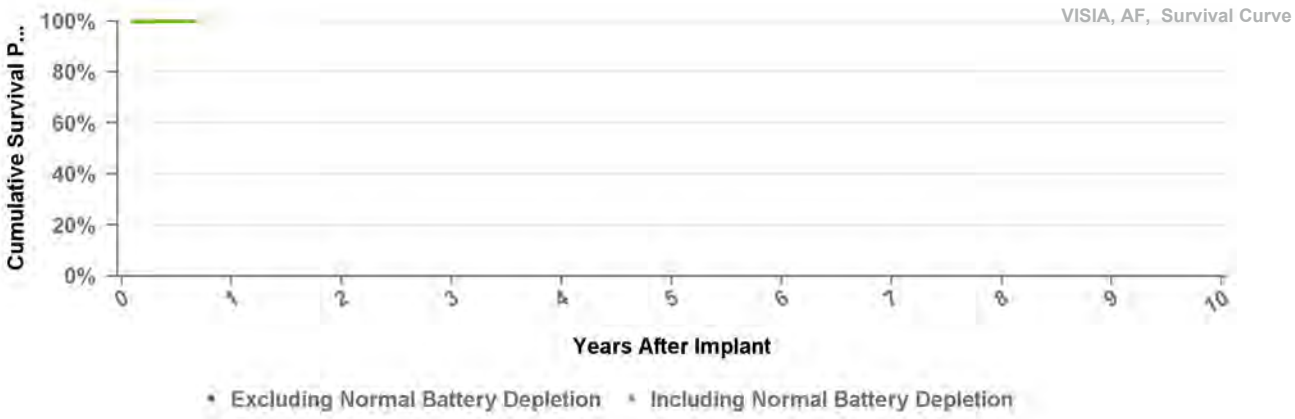
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

DVAC3D1 Visia AF S

US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

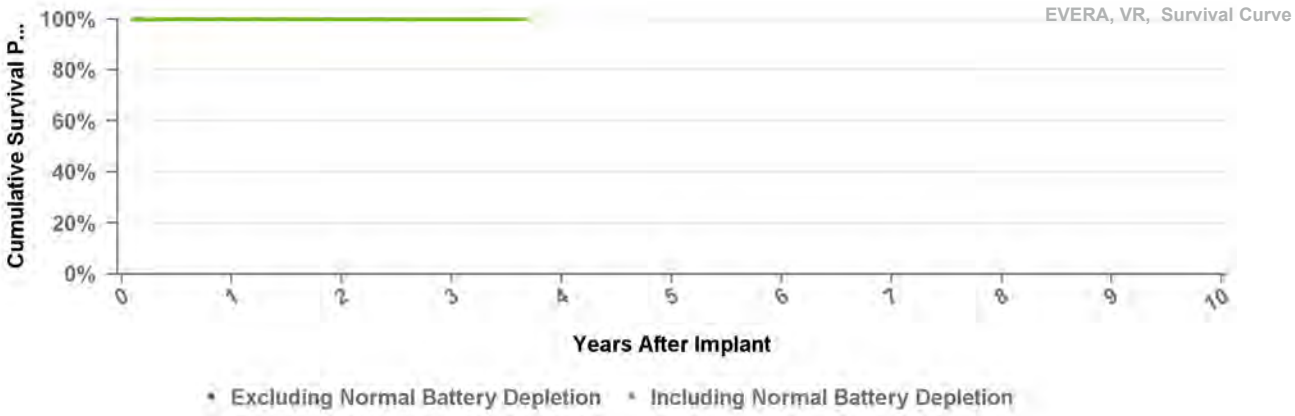


Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

ICD

DVBB1D1 Evera XT

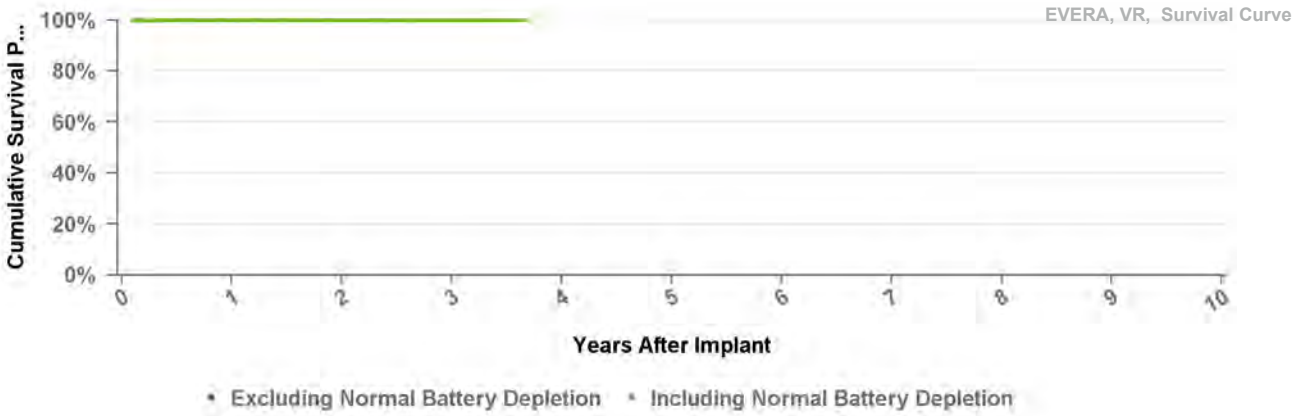
US Market Release	Apr-13	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	15,634	Battery Malfunction	1
Estimated Active USA Implants	14,395	Electrical Component	3
Normal Battery Depletions	7	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

DVBB1D4 Evera XT

US Market Release	Apr-13	**Total Malfunctions**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**10**
Registered USA Implants	22,151	Battery Malfunction	3
Estimated Active USA Implants	20,563	Electrical Component	5
Normal Battery Depletions	6	Other Malfunction	2
		Therapy Function Compromised	**0**

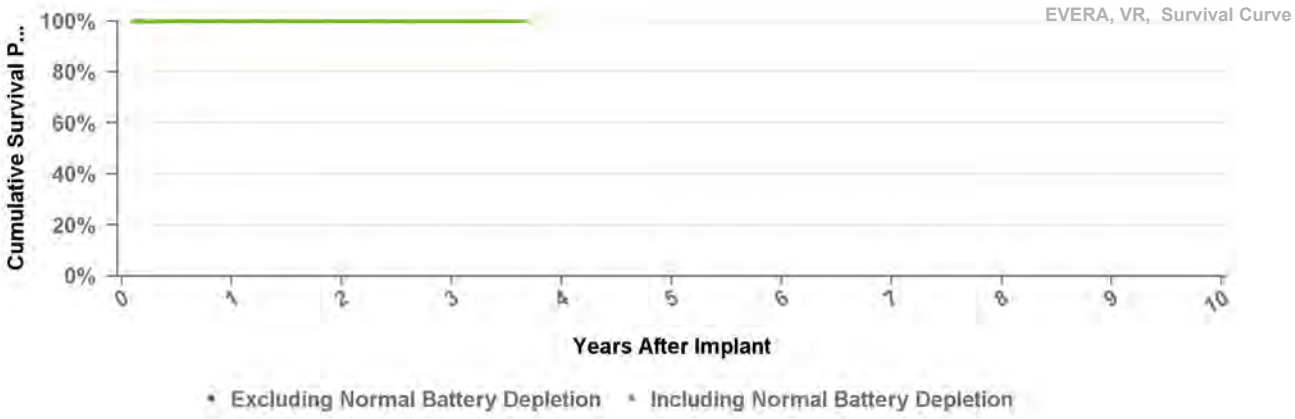


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

ICD

DVBB2D1 Evera XT

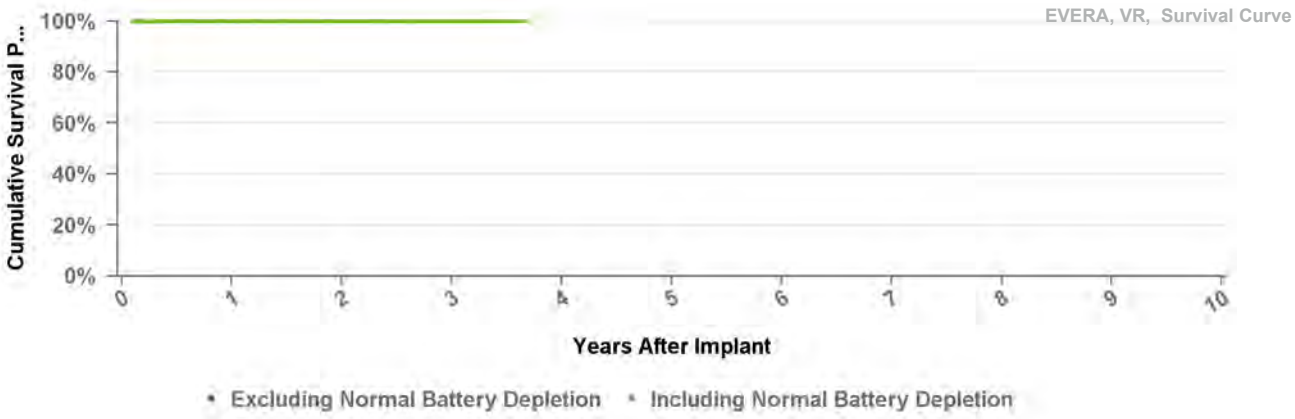
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

DVBB2D4 Evera XT

US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

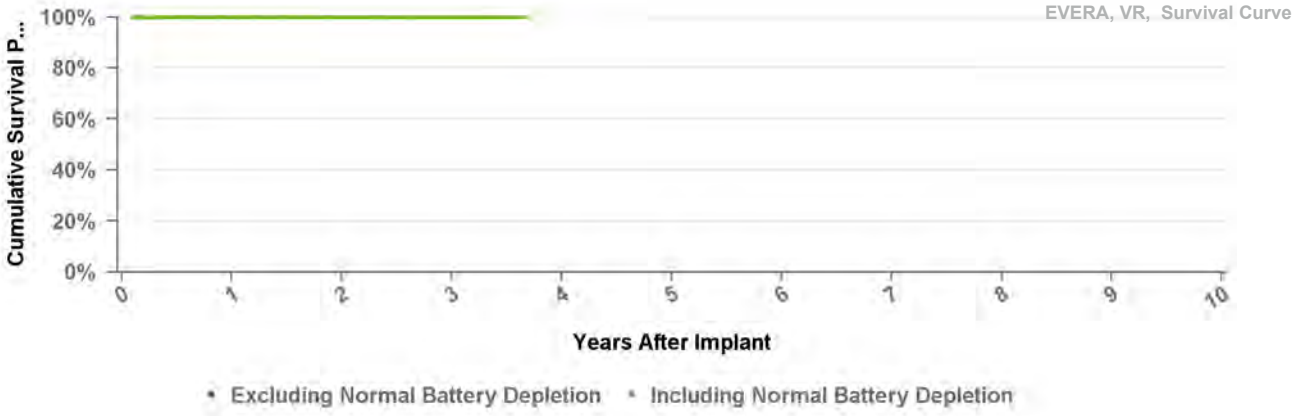


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

ICD

DVBC3D1 Evera S

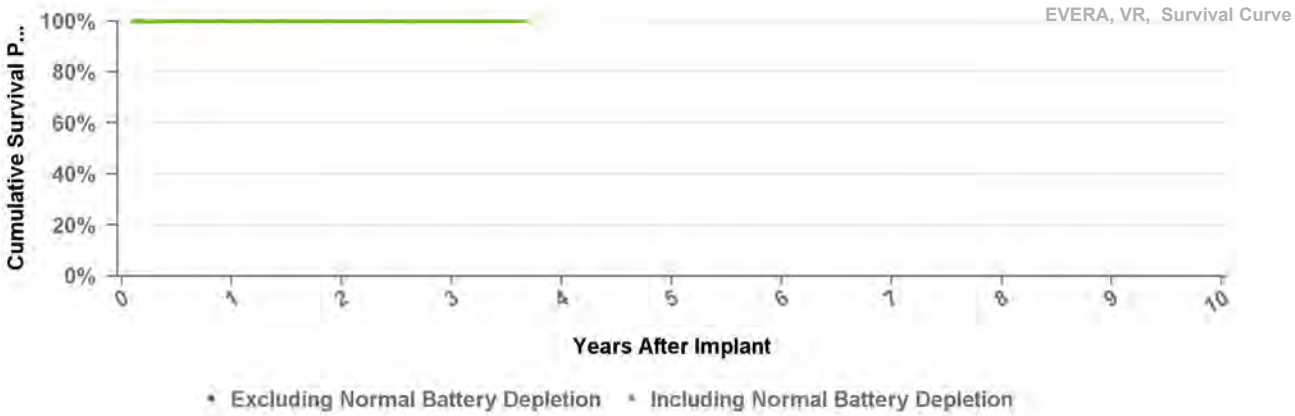
US Market Release	Apr-13	**Total Malfunctions**	**1**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,013	Electrical Component	1
Estimated Active USA Implants	3,724	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

DVBC3D4 Evera S

US Market Release	Apr-13	**Total Malfunctions**	**1**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**1**
Registered USA Implants	5,163	Battery Malfunction	1
Estimated Active USA Implants	4,785	**Therapy Function Compromised**	**0**
Normal Battery Depletions			

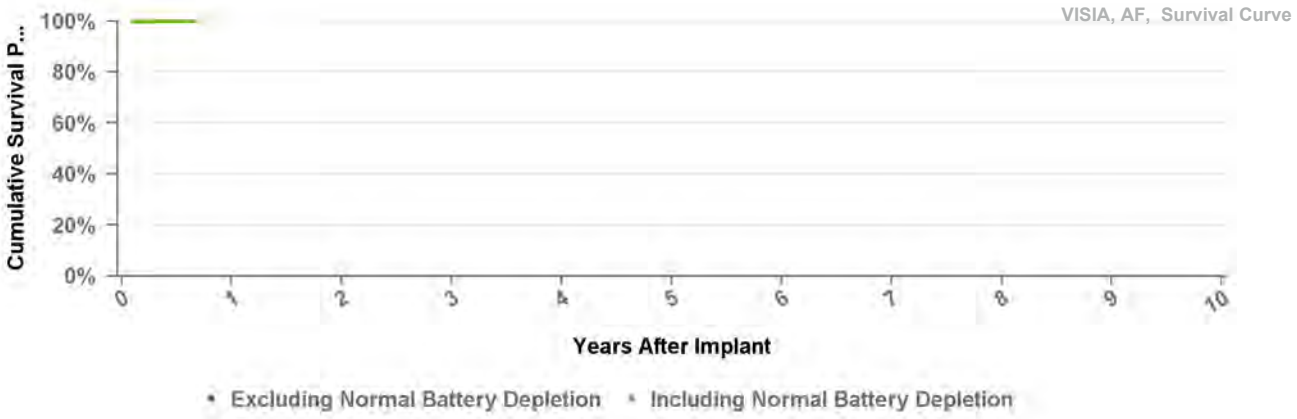


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

ICD

DVFB1D4 Visia MRI AF

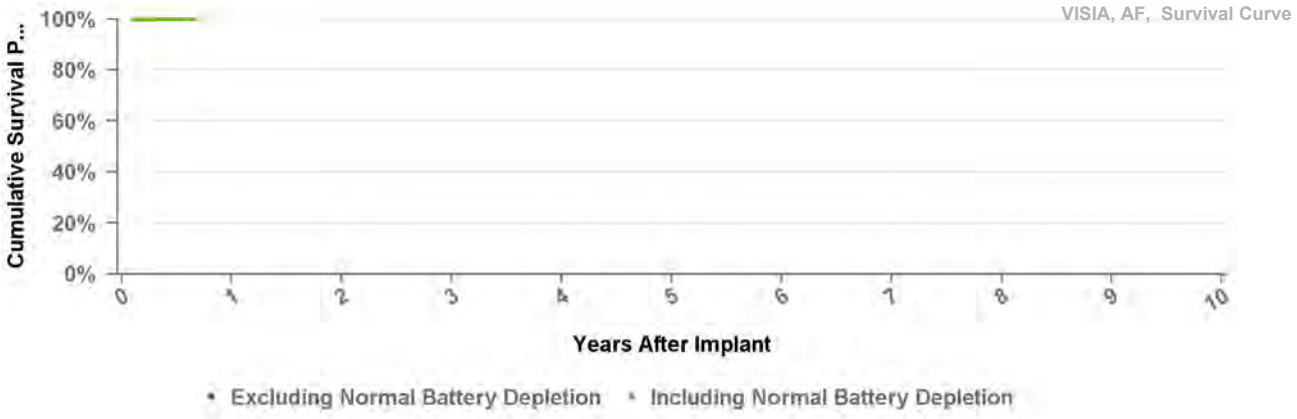
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	5,192		
Estimated Active USA Implants	5,138	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

DVFB2D4 Visia MRI AF XT

US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

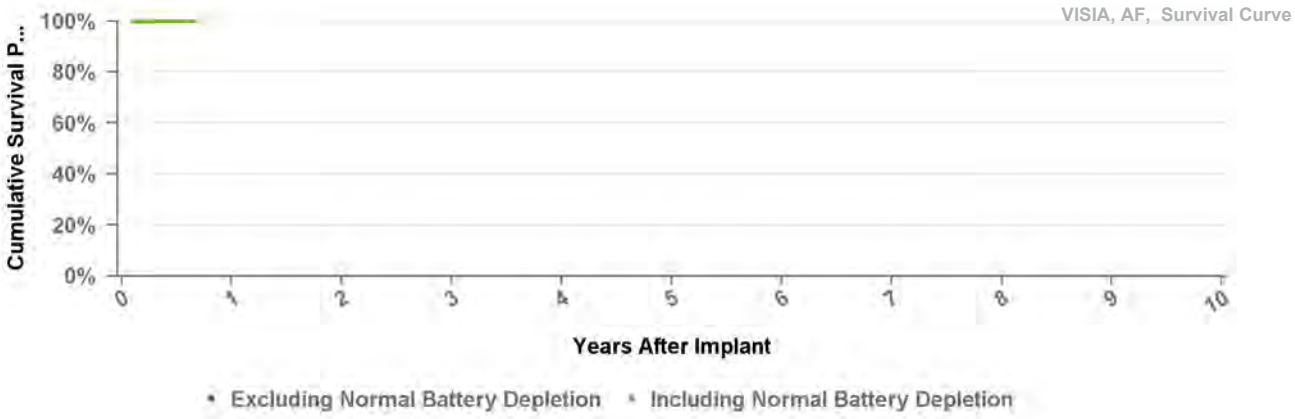


Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

ICD

DVFC3D4 Visia MRI AF S

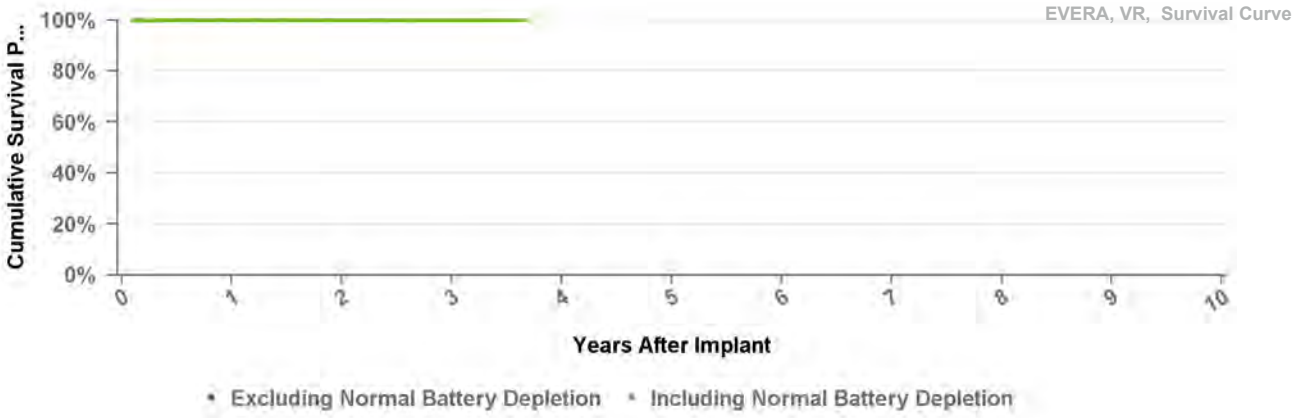
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	159

DVMB1D4 Evera MRI XT

US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,518	Electrical Component	1
Estimated Active USA Implants	9,278	**Therapy Function Compromised**	**0**
Normal Battery Depletions			

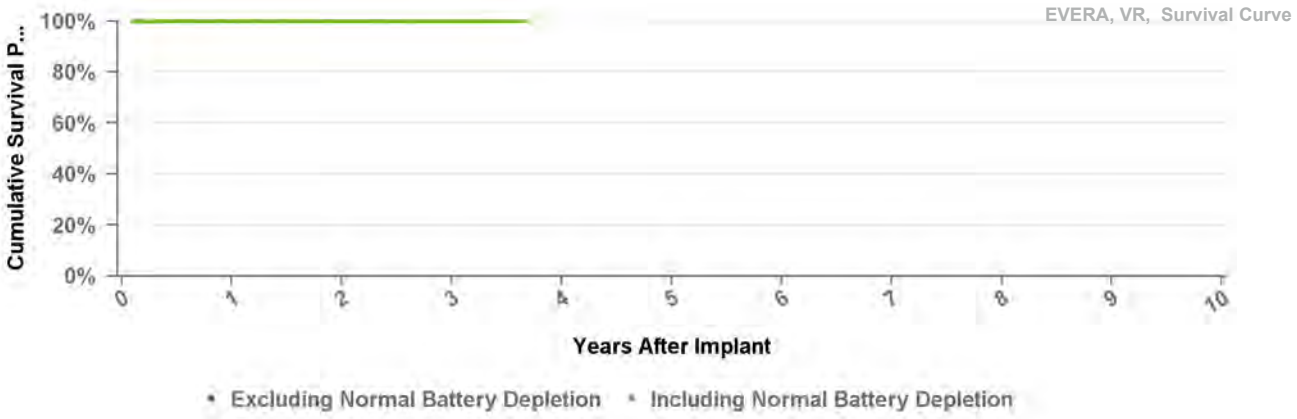


Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

ICD

DVMB2D4 Evera MRI XT

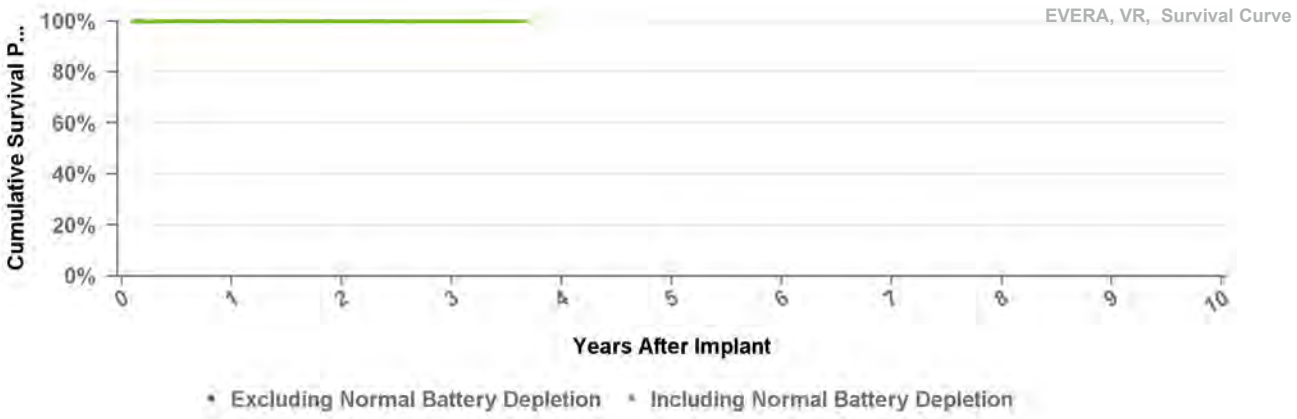
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

DVMC3D4 Evera MRI S

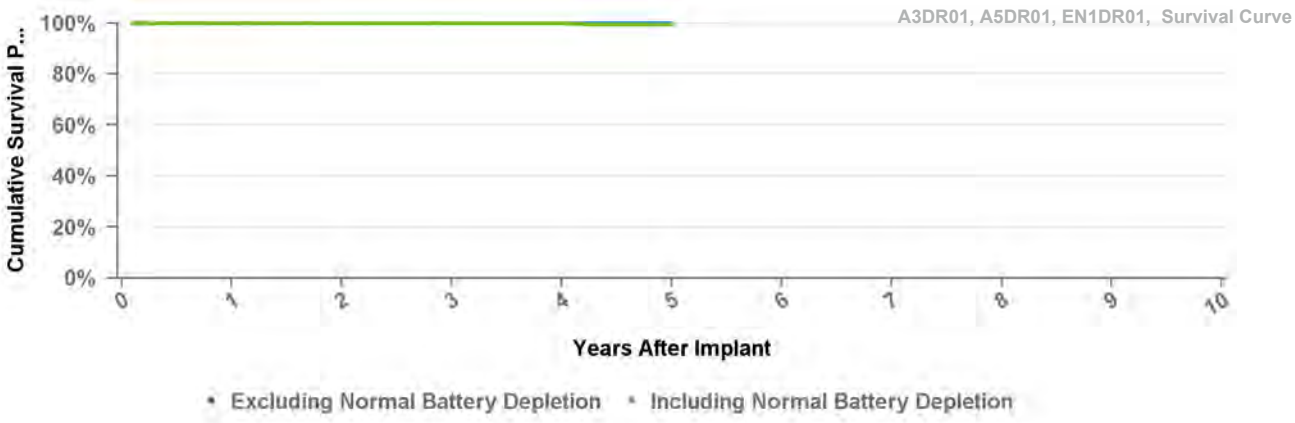
US Market Release	Sep-15	**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	42777	22808	6724	112

A2DR01 Advisa DR MRI

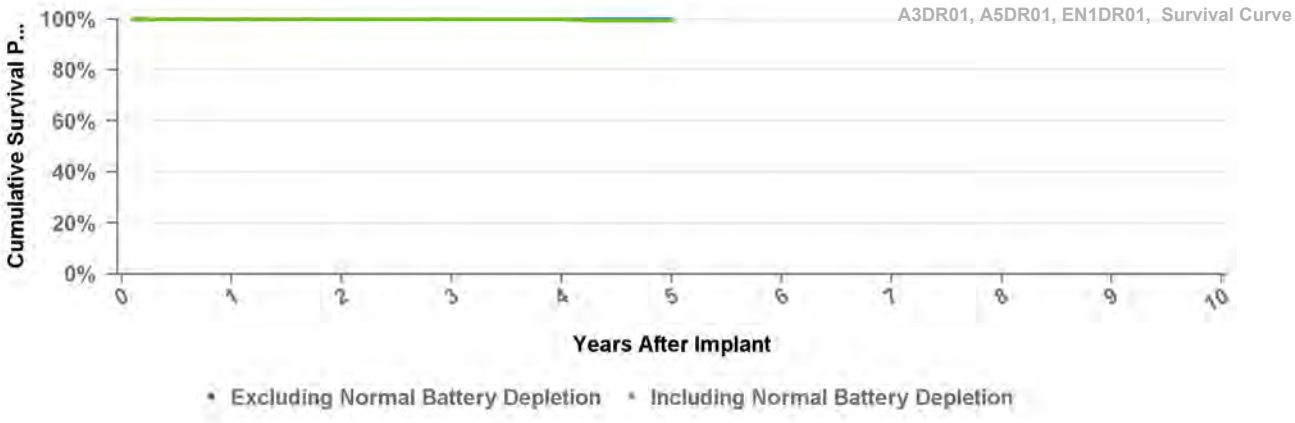
US Market Release	Jan-13	**Total Malfunctions**	**21**
CE Approval Date		**Therapy Function Not Compromised**	**19**
Registered USA Implants	231,452	Electrical Component	10
Estimated Active USA Implants	222,019	Electrical Interconnect	2
Normal Battery Depletions	11	Other Malfunction	1
		Poss Early Battery Depltn	4
		Software Malfunction	2
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.4%
Effective Sample Size	144625	69438	22514	916	119

A3DR01 Advisa DR MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	
Normal Battery Depletions	1		

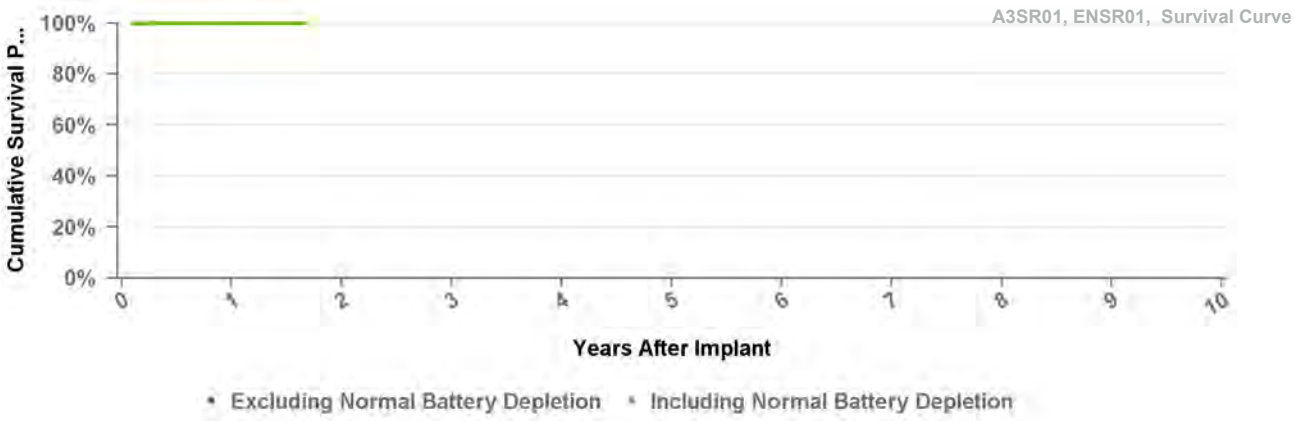


Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.4%
Effective Sample Size	144625	69438	22514	916	119

IPG

A3SR01 Advisa SR MRI

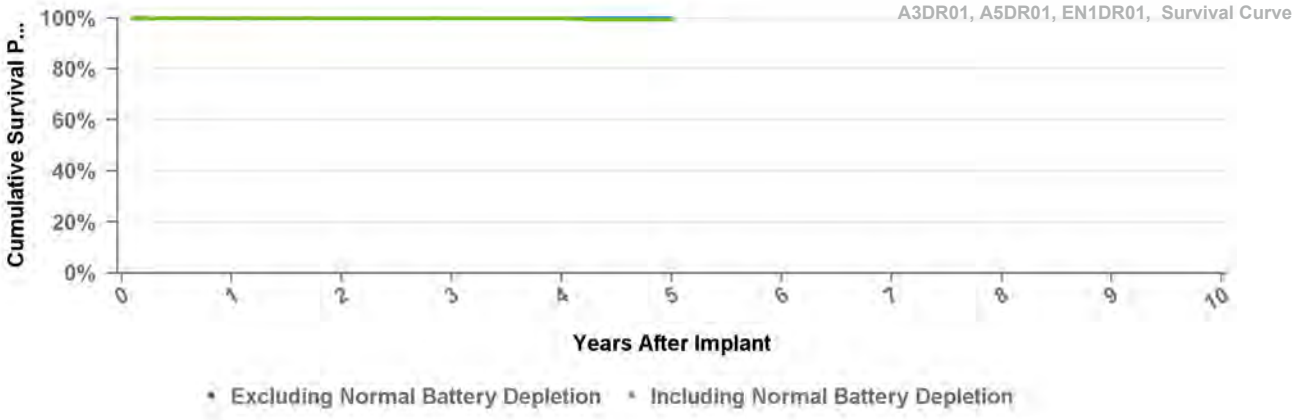
US Market Release	Mar-15	**Total Malfunctions**	**2**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**2**
Registered USA Implants	14,342	Electrical Component	1
Estimated Active USA Implants	13,773	Poss Early Battery Depltn	1
Normal Battery Depletions		**Therapy Function Compromised**	**0**



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	4191	198

A4DR01 Advisa DR

US Market Release	Apr-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,535		
Estimated Active USA Implants	1,312	**Therapy Function Compromised**	
Normal Battery Depletions	2		

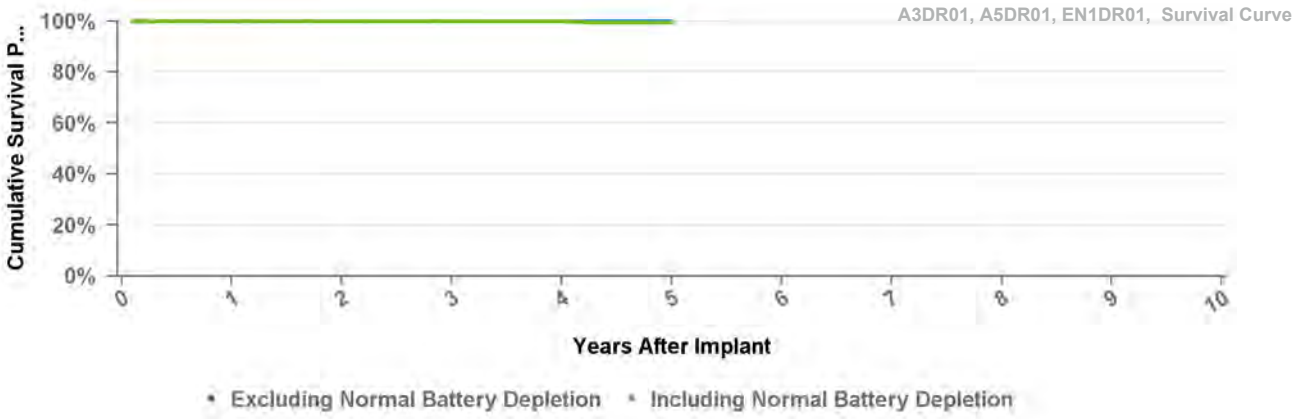


Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.4%
Effective Sample Size	144625	69438	22514	916	119

IPG

A5DR01 Advisa DR

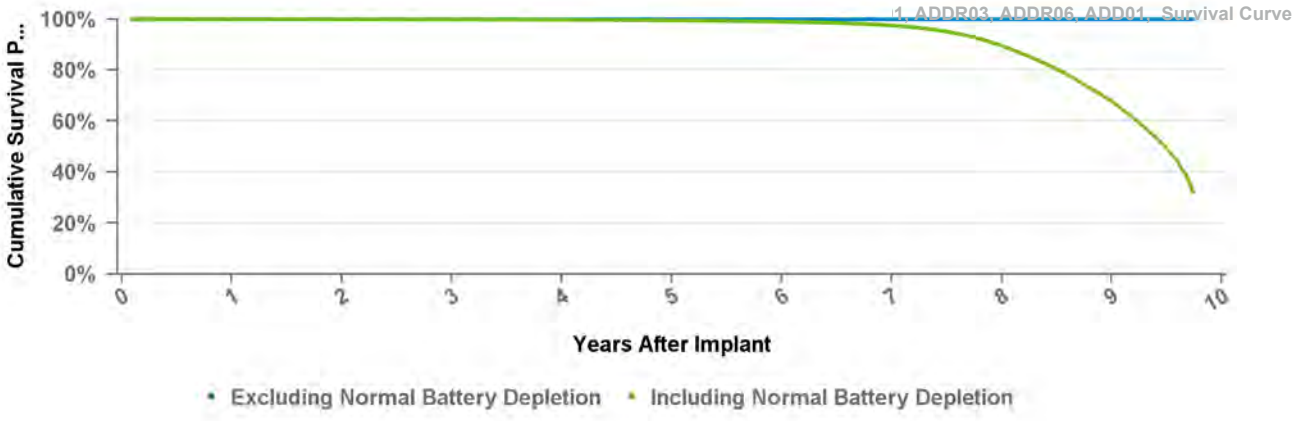
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.4%
Effective Sample Size	144625	69438	22514	916	119

ADD01 Adapta D

US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

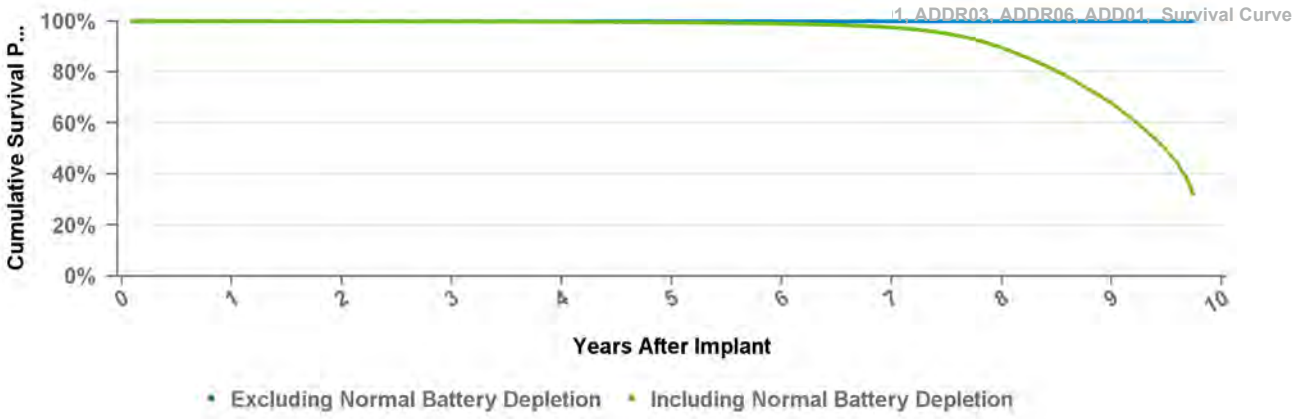


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

IPG

ADDR01 Adapta DR

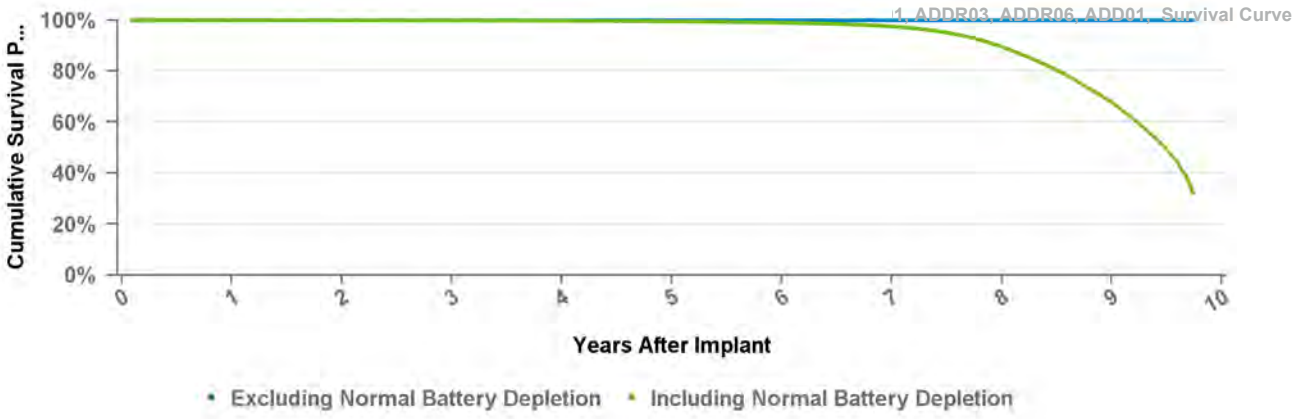
US Market Release	Jul-06	**Total Malfunctions**	**76**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**51**
Registered USA Implants	445,020	Electrical Component	49
Estimated Active USA Implants	303,849	Electrical Interconnect	1
Normal Battery Depletions	13,734	Other Malfunction	1
		Therapy Function Compromised	**25**
		Electrical Component	20
		Electrical Interconnect	3
		Other Malfunction	2



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	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

ADDR03 Adapta DR

US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,239	Electrical Component	1
Estimated Active USA Implants	2,663	**Therapy Function Compromised**	**1**
Normal Battery Depletions	198	Electrical Component	1

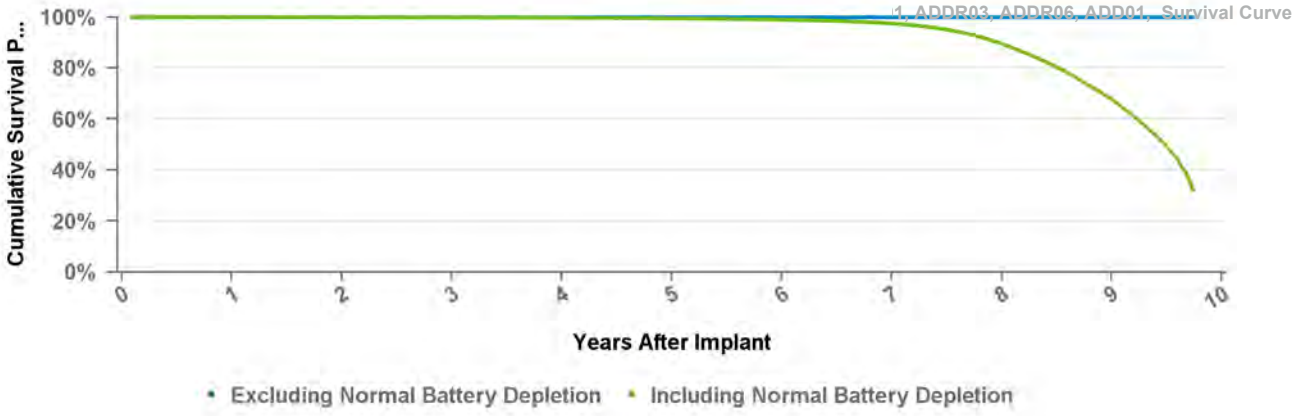


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

IPG

ADDR06 Adapta DR

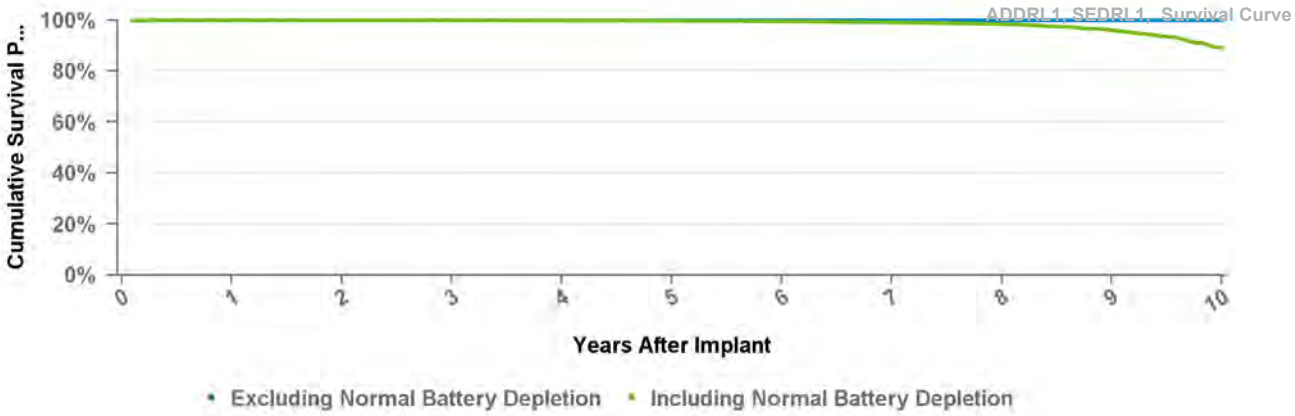
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,225	Electrical Component	1
Estimated Active USA Implants	1,646	**Therapy Function Compromised**	**0**
Normal Battery Depletions	229		



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	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

ADDRL1 Adapta DR

US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**10**
Registered USA Implants	129,675	Electrical Component	9
Estimated Active USA Implants	107,361	Electrical Interconnect	1
Normal Battery Depletions	361	**Therapy Function Compromised**	**4**
		Electrical Component	1
		Electrical Interconnect	1
		Other Malfunction	2

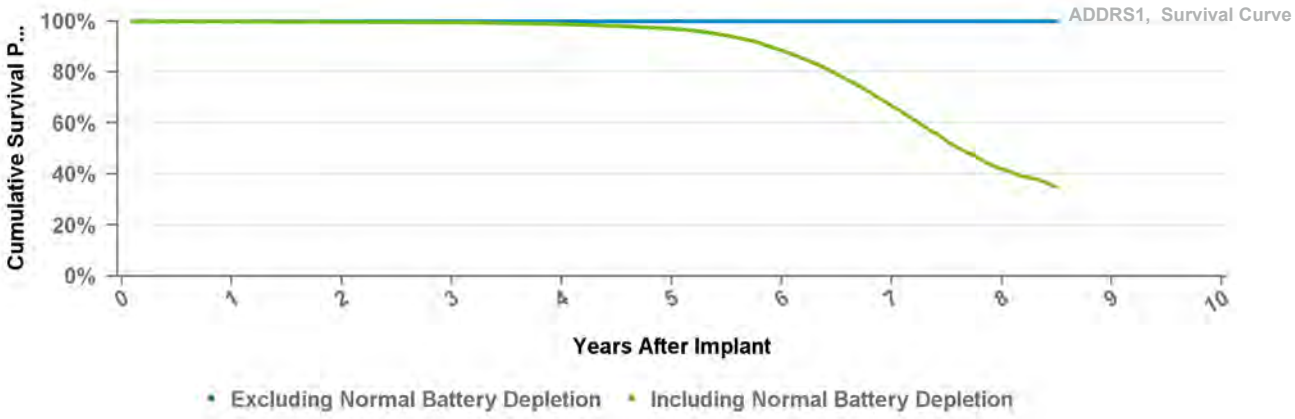


Years	1	2	3	4	5	6	7	8	9	at 120 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.1%	98.4%	96.1%	89.1%
Effective Sample Size	111924	95814	77635	59511	42086	27873	16006	7777	2763	182

IPG

ADDRS1 Adapta DR

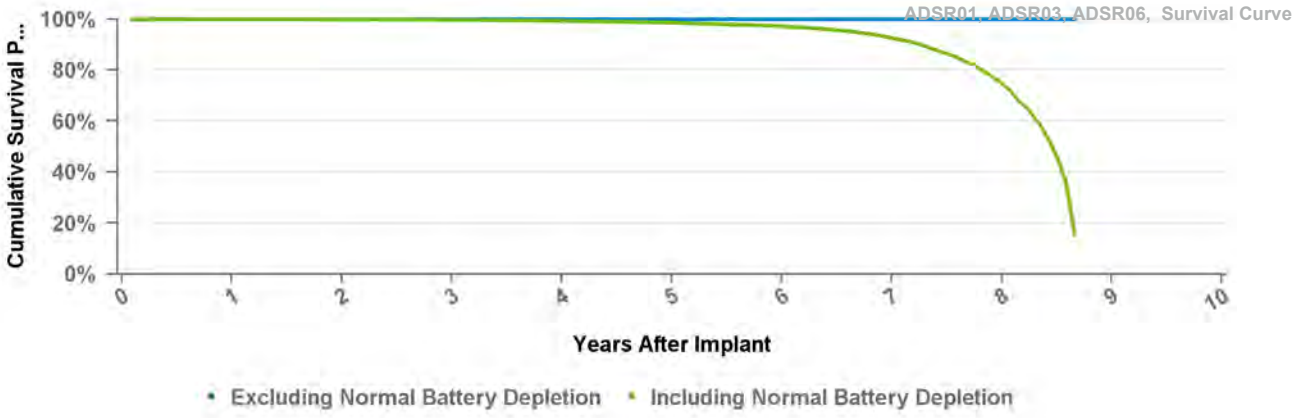
US Market Release	Jul-06	**Total Malfunctions**	**10**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**6**
Registered USA Implants	46,244	Electrical Component	5
Estimated Active USA Implants	27,504	Poss Early Battery Depltn	1
Normal Battery Depletions	2,870	**Therapy Function Compromised**	**4**
		Electrical Component	2
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.6%	99.4%	98.8%	97.0%	88.4%	66.7%	41.9%	34.6%
Effective Sample Size	37970	32879	27419	22084	17002	11403	5117	948	189

ADSR01 Adapta SR

US Market Release	Jul-06	**Total Malfunctions**	**13**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**7**
Registered USA Implants	89,163	Electrical Component	5
Estimated Active USA Implants	52,883	Electrical Interconnect	1
Normal Battery Depletions	2,228	Poss Early Battery Depltn	1
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1

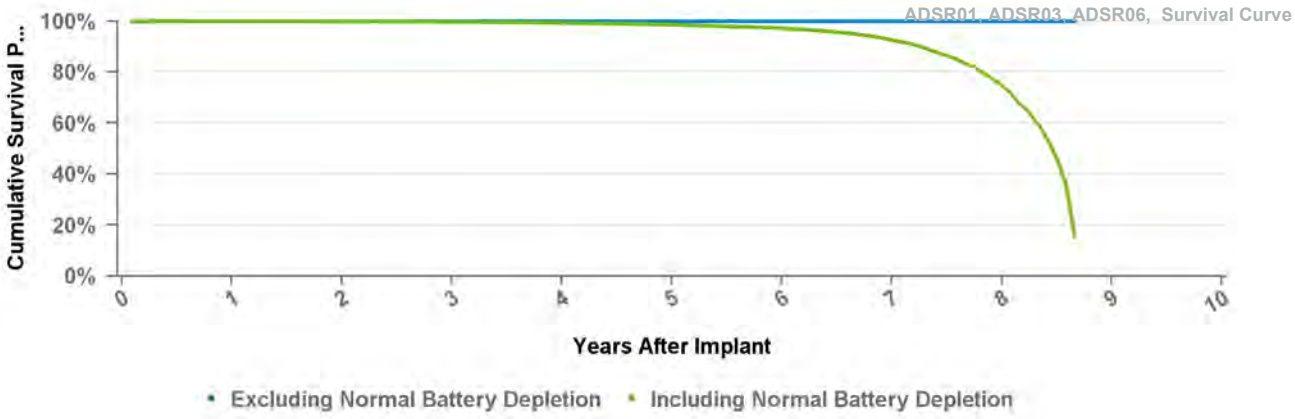


Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.6%	74.6%	15.1%
Effective Sample Size	71852	59394	46649	35517	25834	17933	10892	3948	174

IPG

ADSR03 Adapta SR

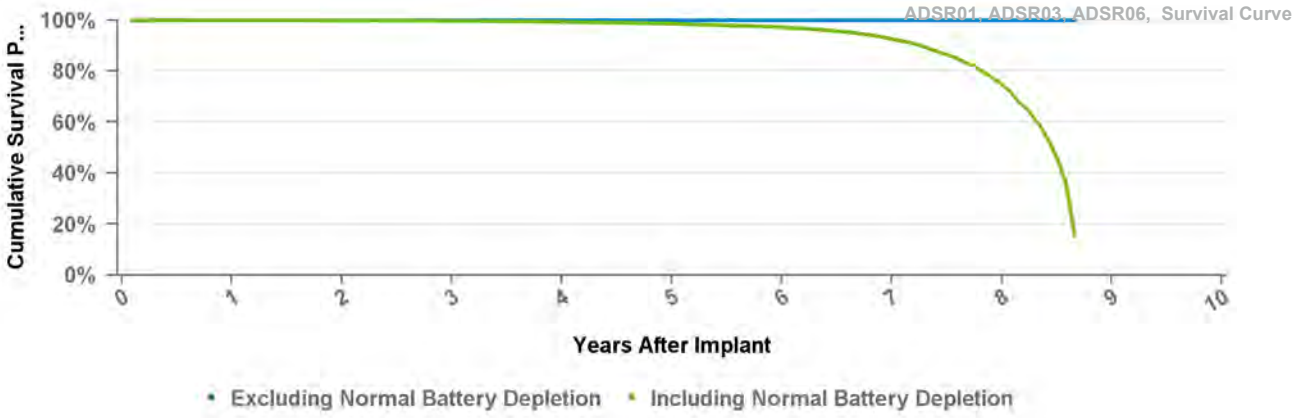
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,981		
Estimated Active USA Implants	1,024	**Therapy Function Compromised**	
Normal Battery Depletions	71		



Years	1	2	3	4	5	6	7	8	at 104 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%	92.6%	74.6%	15.1%
Effective Sample Size	71852	59394	46649	35517	25834	17933	10892	3948	174

ADSR06 Adapta SR

US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,681	Electrical Component	2
Estimated Active USA Implants	1,287	**Therapy Function Compromised**	**0**
Normal Battery Depletions	123		

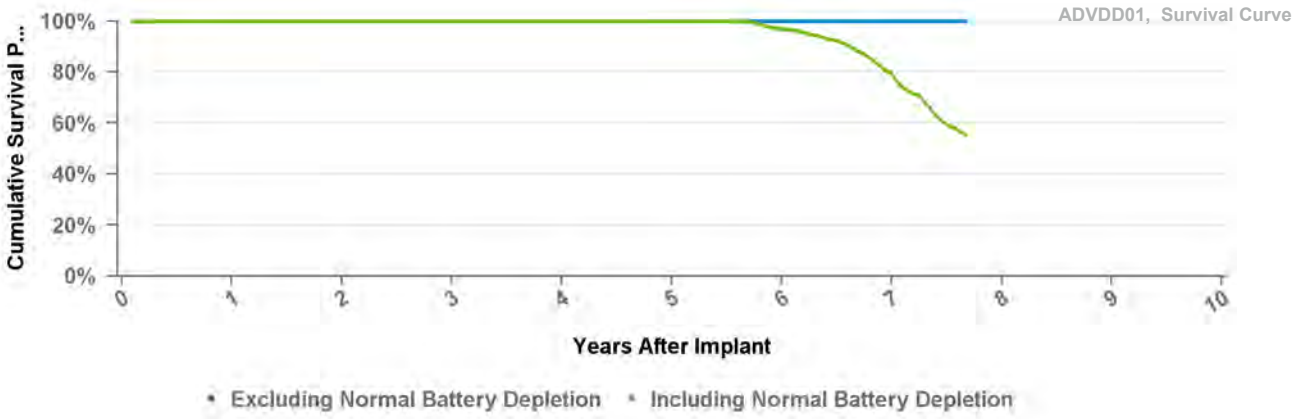


Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.6%	74.6%	15.1%
Effective Sample Size	71852	59394	46649	35517	25834	17933	10892	3948	174

IPG

ADVDD01 Adapta VDD

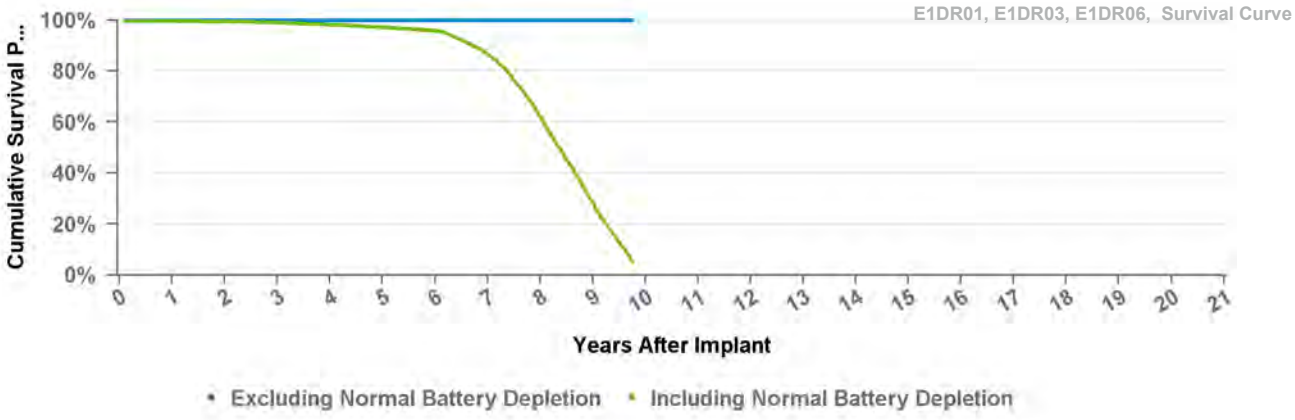
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,303		
Estimated Active USA Implants	691	**Therapy Function Compromised**	
Normal Battery Depletions	68		



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	100.0%	100.0%	100.0%	100.0%	100.0%	96.9%	79.4%	55.2%
Effective Sample Size	1123	1000	858	713	586	459	265	110

E1DR01 EnPulse DR

US Market Release	Dec-03	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	6,842	Electrical Component	1
Estimated Active USA Implants	520	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1,718		

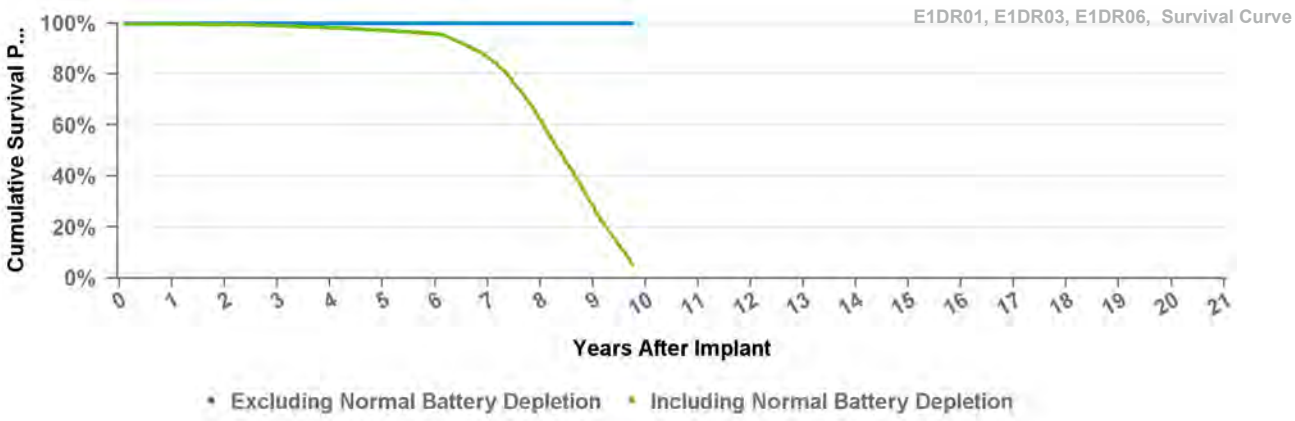


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.5%	5.3%
Effective Sample Size	6002	5549	5101	4635	4200	3759	3069	1976	777	138

IPG

E1DR03 EnPulse DR

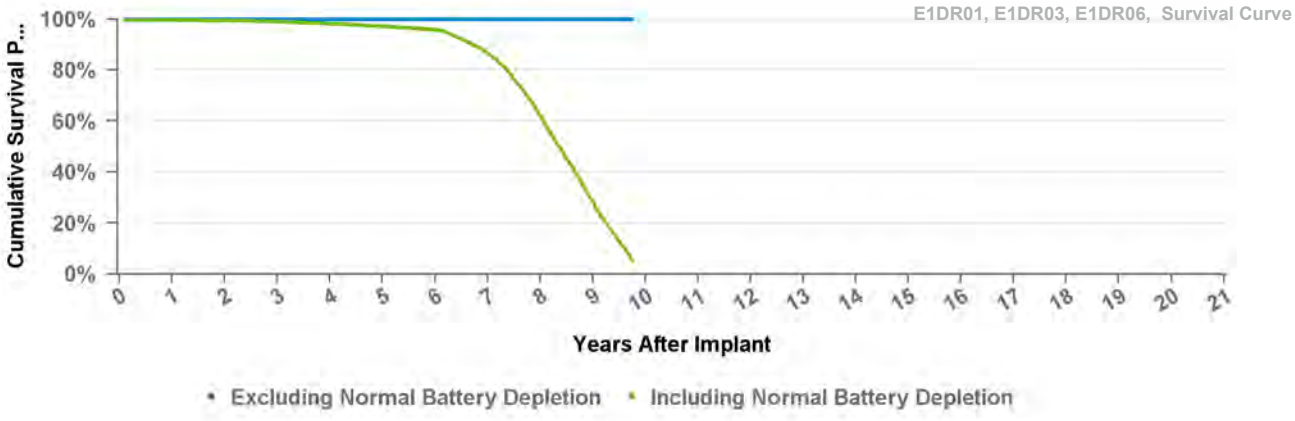
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.5%	5.3%
Effective Sample Size	6002	5549	5101	4635	4200	3759	3069	1976	777	138

E1DR06 EnPulse DR

US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

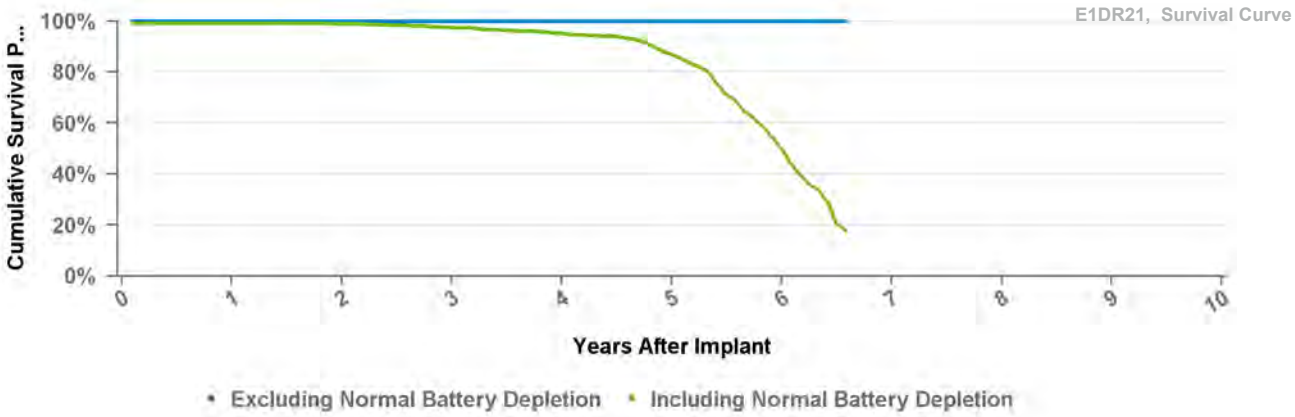


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.1%	98.2%	97.2%	95.8%	86.5%	62.3%	28.5%	5.3%
Effective Sample Size	6002	5549	5101	4635	4200	3759	3069	1976	777	138

IPG

E1DR21 EnPulse DR

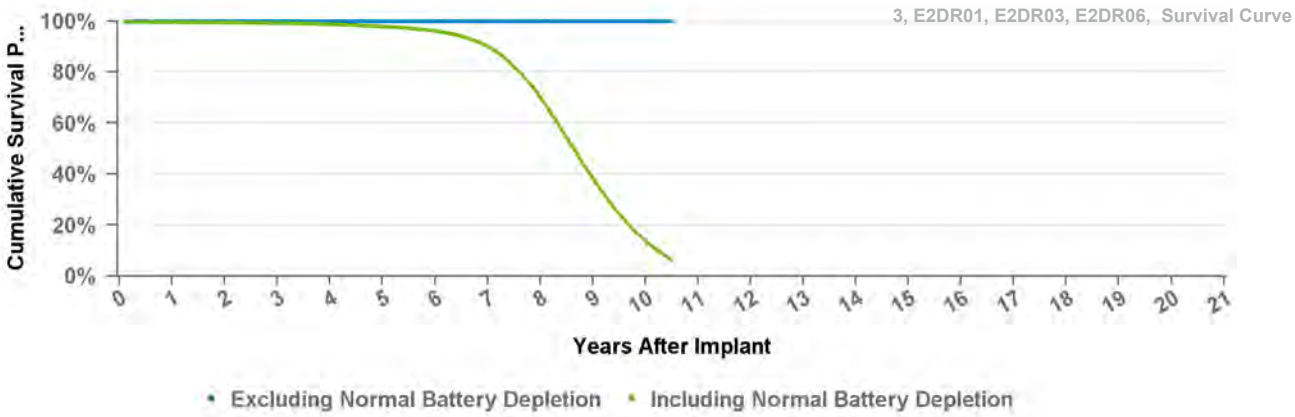
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,856		
Estimated Active USA Implants	99	**Therapy Function Compromised**	
Normal Battery Depletions	383		



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	99.2%	98.8%	97.4%	95.2%	86.9%	49.9%	17.4%
Effective Sample Size	1594	1440	1282	1123	910	417	111

E2D01 EnPulse

US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

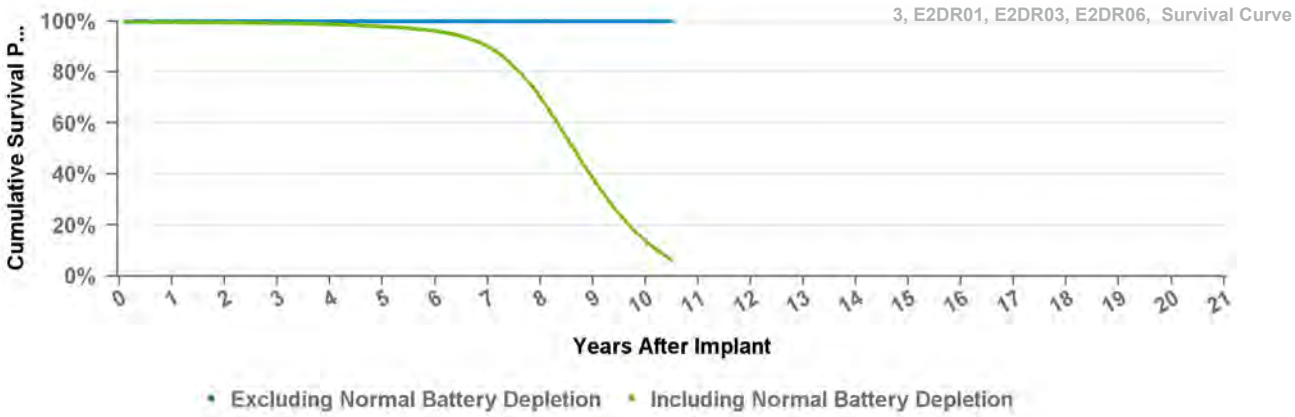


Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.2%	38.5%	13.7%	5.9%
Effective Sample Size	87966	80833	73890	67344	60914	54678	47031	33381	15995	4628	881

IPG

E2D03 EnPulse

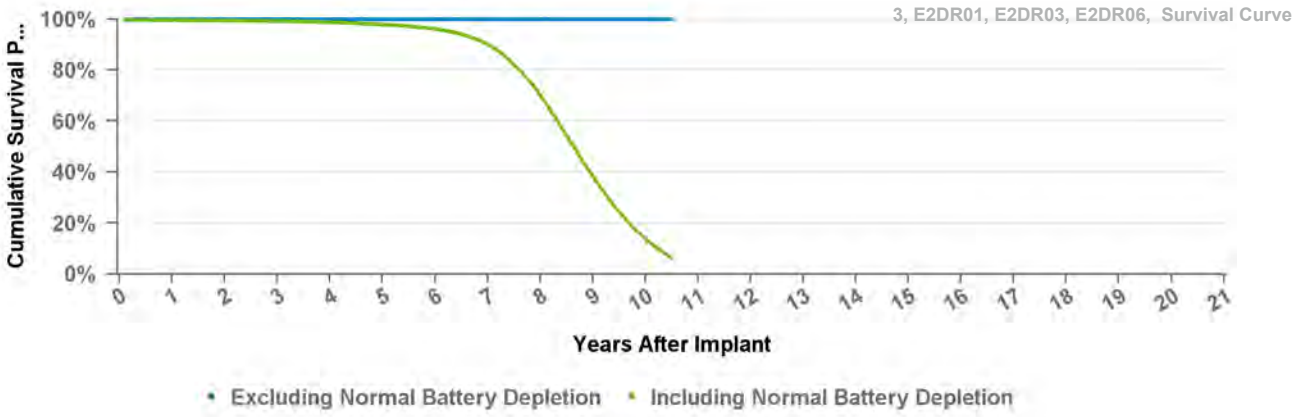
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.2%	38.5%	13.7%	5.9%
Effective Sample Size	87966	80833	73890	67344	60914	54678	47031	33381	15995	4628	881

E2DR01 EnPulse DR

US Market Release	Feb-04	**Total Malfunctions**	**27**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**20**
Registered USA Implants	97,447	Electrical Component	18
Estimated Active USA Implants	11,656	Other Malfunction	1
Normal Battery Depletions	22,201	Poss Early Battery Depltn	1
		Therapy Function Compromised	**7**
		Battery Malfunction	1
		Electrical Component	3
		Electrical Interconnect	3

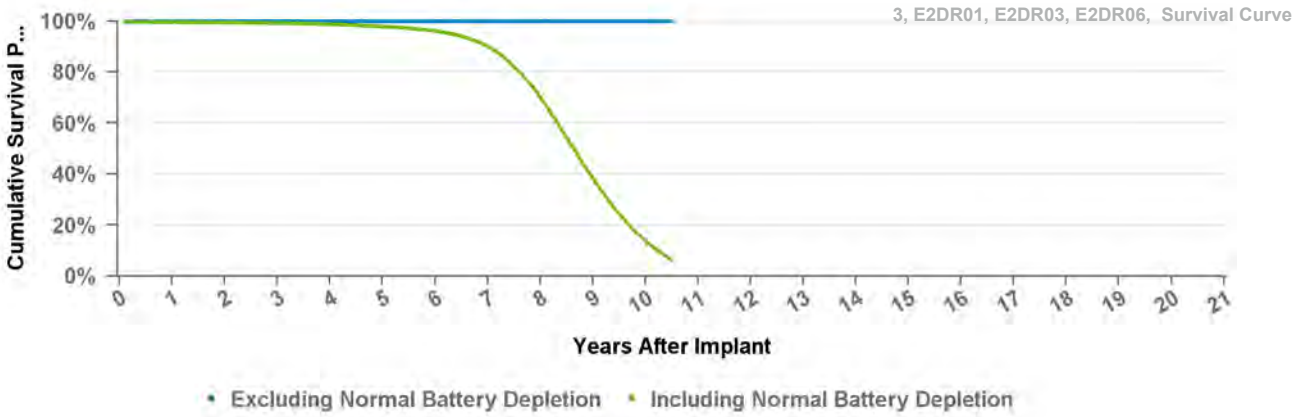


Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.2%	38.5%	13.7%	5.9%
Effective Sample Size	87966	80833	73890	67344	60914	54678	47031	33381	15995	4628	881

IPG

E2DR03 EnPulse DR

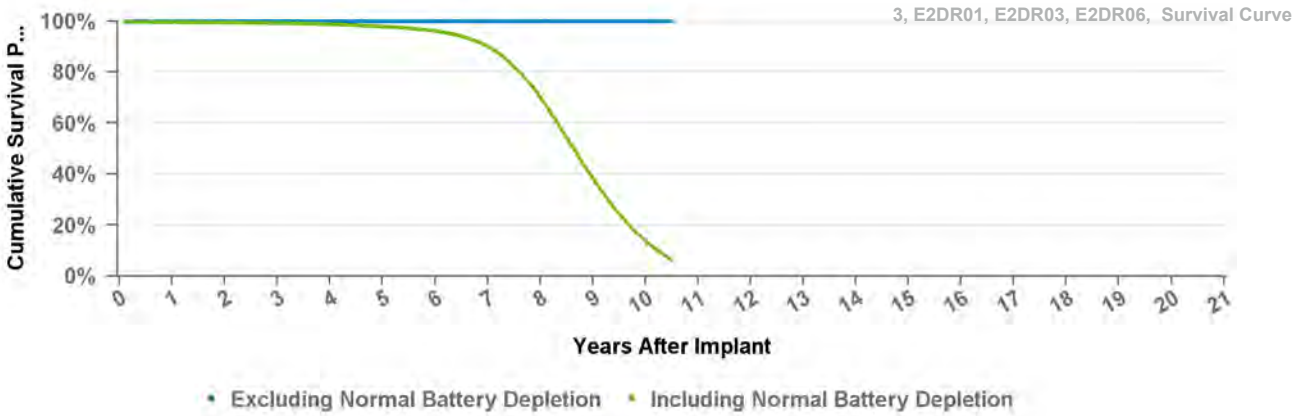
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	2,050		
Estimated Active USA Implants	281	**Therapy Function Compromised**	
Normal Battery Depletions	444		



Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.2%	38.5%	13.7%	5.9%
Effective Sample Size	87966	80833	73890	67344	60914	54678	47031	33381	15995	4628	881

E2DR06 EnPulse DR

US Market Release	Feb-04	**Total Malfunctions**	**2**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,624	Poss Early Battery Depltn	1
Estimated Active USA Implants	172	**Therapy Function Compromised**	**1**
Normal Battery Depletions	314	Electrical Interconnect	1

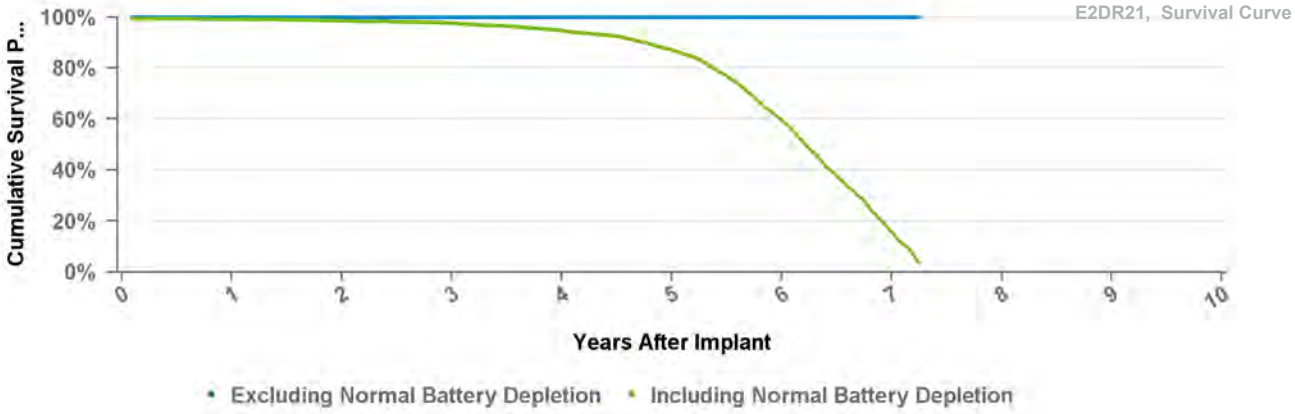


Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.1%	70.2%	38.5%	13.7%	5.9%
Effective Sample Size	87966	80833	73890	67344	60914	54678	47031	33381	15995	4628	881

IPG

E2DR21 EnPulse DR

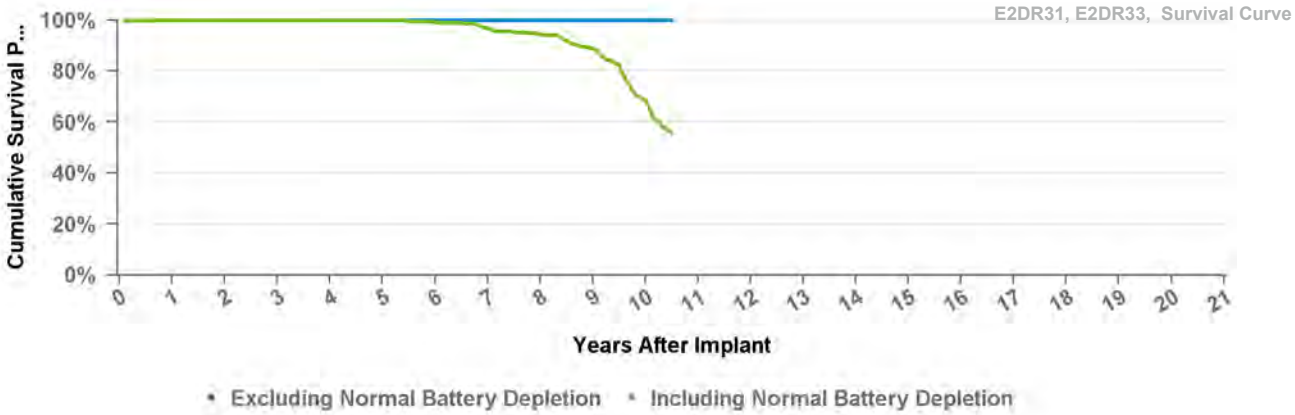
US Market Release	Feb-04	**Total Malfunctions**	**1**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**0**
Registered USA Implants	12,201		
Estimated Active USA Implants	1,058	**Therapy Function Compromised**	**1**
Normal Battery Depletions	2,318	Electrical Component	1



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	99.1%	98.6%	97.6%	94.8%	87.2%	59.5%	15.7%	3.7%
Effective Sample Size	10178	9055	8062	6959	5660	3267	637	182

E2DR31 EnPulse DR

US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	588		
Estimated Active USA Implants	208	**Therapy Function Compromised**	
Normal Battery Depletions	105		

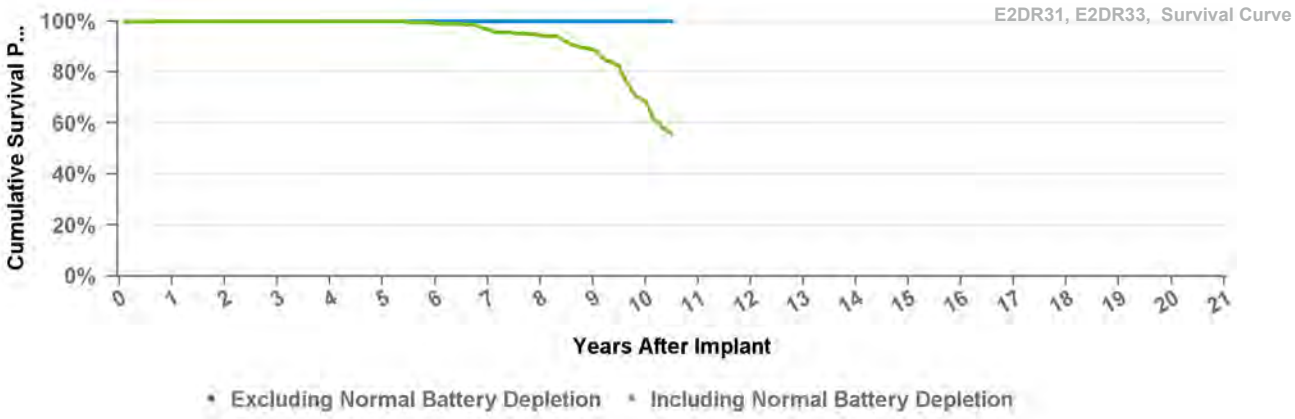


Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.9%	94.1%	88.8%	68.4%	55.4%
Effective Sample Size	523	489	455	414	372	334	295	259	227	160	105

IPG

E2DR33 EnPulse DR

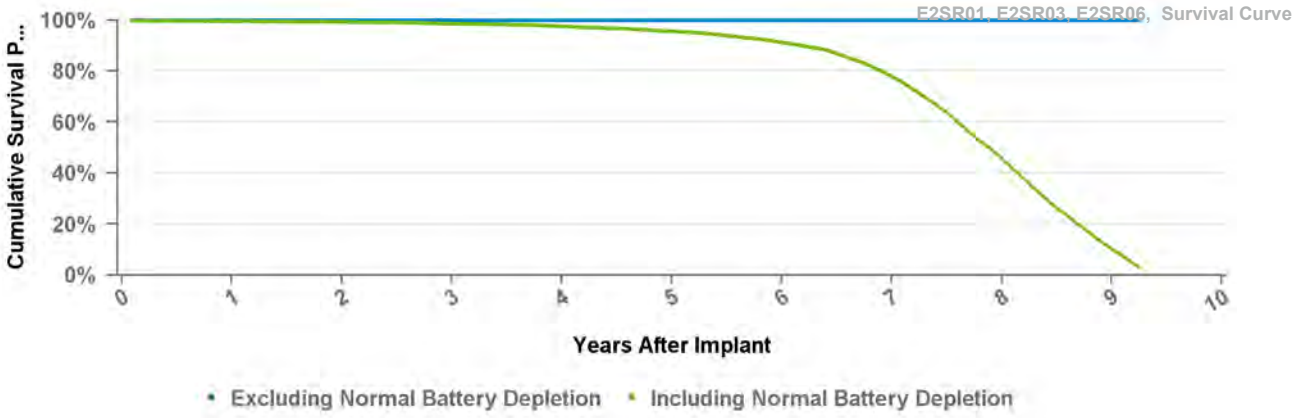
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	4	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	10	2	3	4	5	6	7	8	9	at 126 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.1%	96.9%	94.1%	88.8%	68.4%	55.4%
Effective Sample Size	523	489	455	414	372	334	295	259	227	160	105

E2SR01 EnPulse SR

US Market Release	Dec-03	**Total Malfunctions**	**4**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**3**
Registered USA Implants	22,701	Electrical Component	2
Estimated Active USA Implants	2,120	Poss Early Battery Depltn	1
Normal Battery Depletions	2,996	**Therapy Function Compromised**	**1**
		Other Malfunction	1

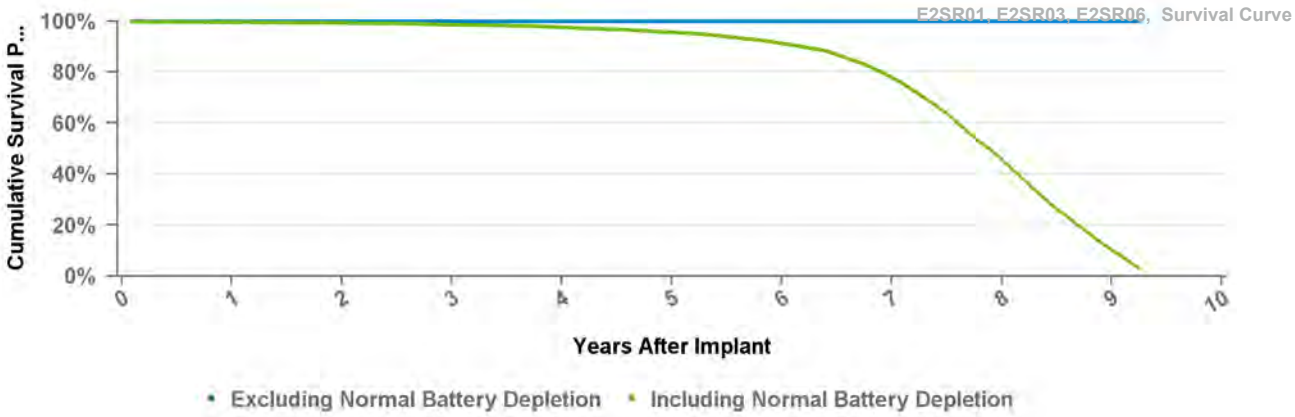


Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.8%	45.7%	10.1%	2.7%
Effective Sample Size	19747	16790	14315	12200	10094	8203	5950	2851	441	134

IPG

E2SR03 EnPulse SR

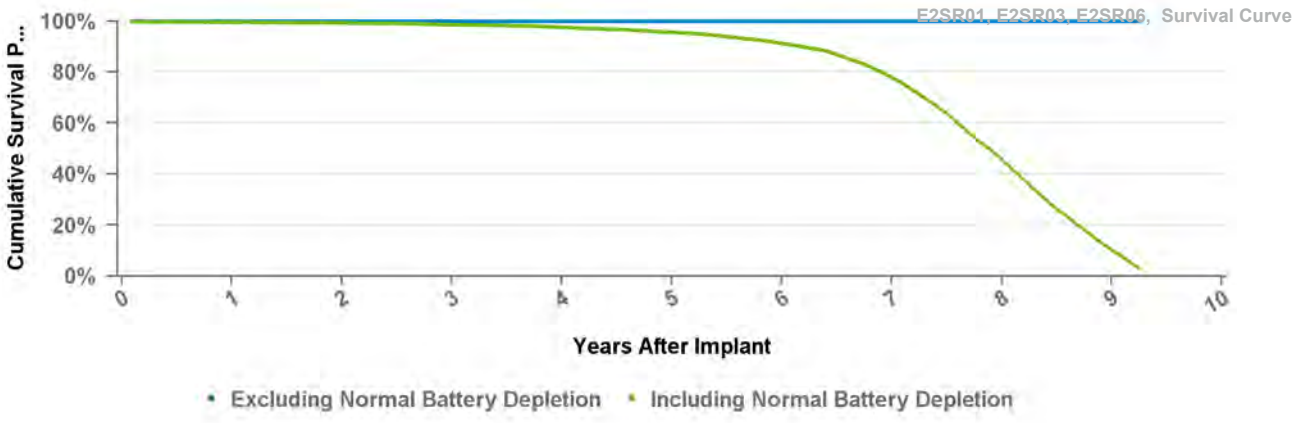
US Market Release	Dec-03	**Total Malfunctions**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**
Registered USA Implants	1,099	
Estimated Active USA Implants	102	**Therapy Function Compromised**
Normal Battery Depletions	151	



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.8%	45.7%	10.1%	2.7%
Effective Sample Size	19747	16790	14315	12200	10094	8203	5950	2851	441	134

E2SR06 EnPulse SR

US Market Release	Dec-03	**Total Malfunctions**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**
Registered USA Implants	1,752	
Estimated Active USA Implants	143	**Therapy Function Compromised**
Normal Battery Depletions	221	

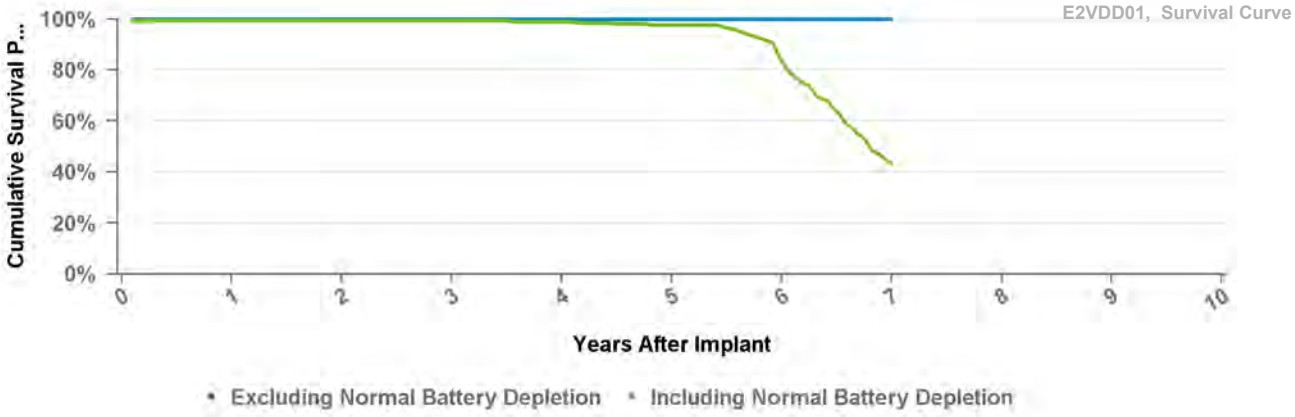


Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	98.6%	97.5%	95.6%	91.2%	77.8%	45.7%	10.1%	2.7%
Effective Sample Size	19747	16790	14315	12200	10094	8203	5950	2851	441	134

IPG

E2VDD01 EnPulse VDD

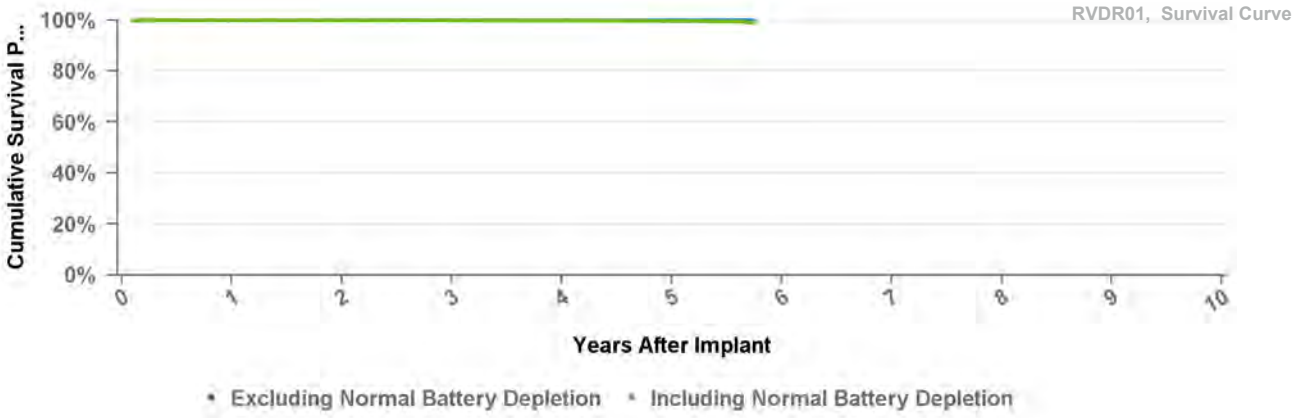
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	642		
Estimated Active USA Implants	94	**Therapy Function Compromised**	
Normal Battery Depletions	97		



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.4%	99.4%	99.4%	98.9%	97.6%	83.4%	42.9%
Effective Sample Size	554	500	450	400	351	275	103

EMDR01 EnRhythm MRI

US Market Release		**Total Malfunctions**	**23**
CE Approval Date	Sep-08	**Therapy Function Not Compromised**	**23**
Registered USA Implants	111	Battery Malfunction	23
Estimated Active USA Implants	25	**Therapy Function Compromised**	**0**
Normal Battery Depletions	12		

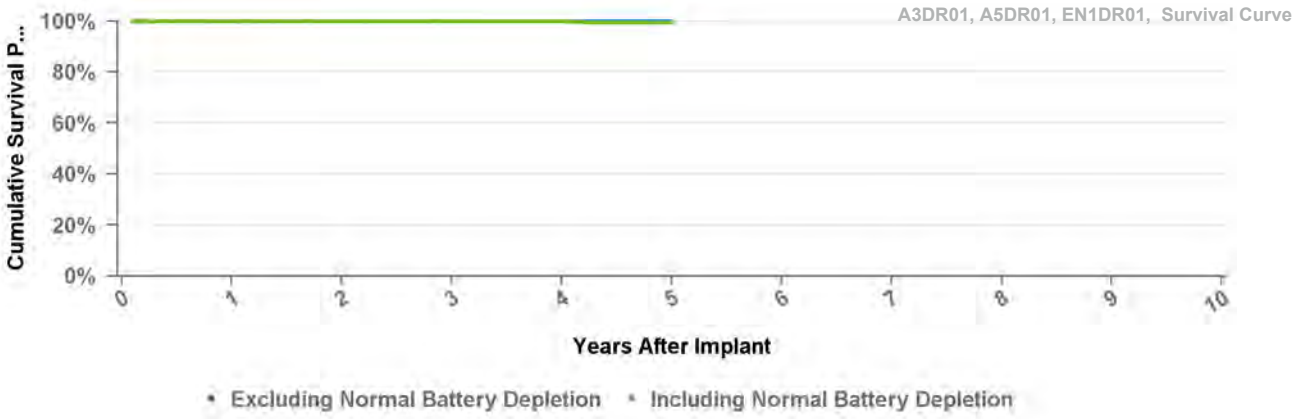


Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	98.8%
Effective Sample Size	60049	56315	52432	41493	17177	1323

IPG

EN1DR01 Ensura MRI

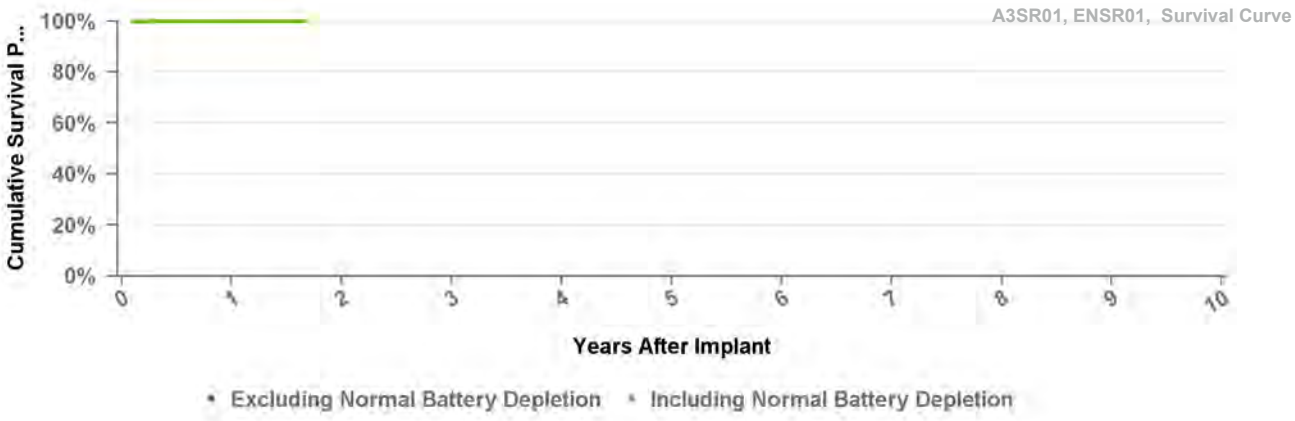
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	
Registered USA Implants	8		
Estimated Active USA Implants	6	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 60 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.4%
Effective Sample Size	144625	69438	22514	916	119

EN1SR01 Ensura SR MRI

US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

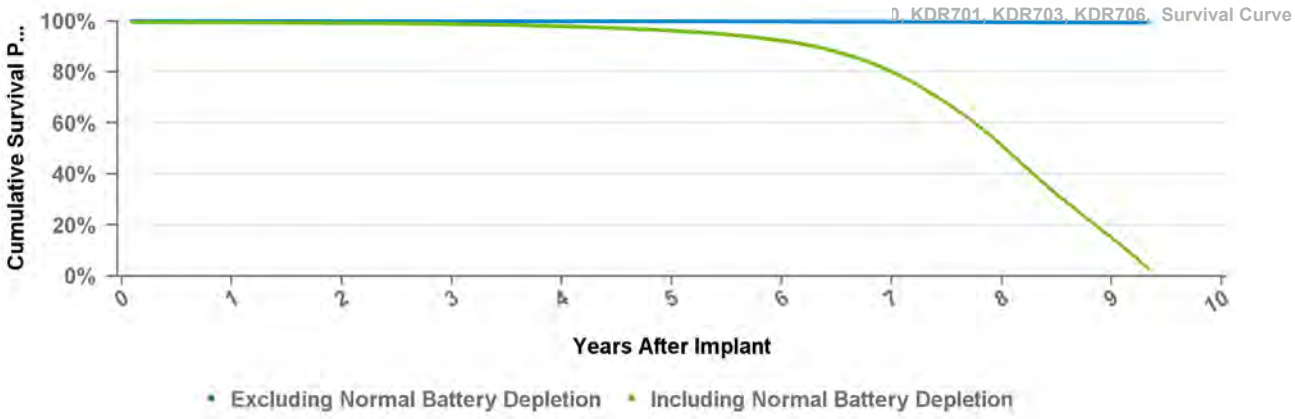


Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	4191	198

IPG

KD700 Kappa 700 DR

US Market Release	**Total Malfunctions**
CE Approval Date	**Therapy Function Not Compromised**
Registered USA Implants	
Estimated Active USA Implants	**Therapy Function Compromised**
Normal Battery Depletions	



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	99.4%	99.2%	98.8%	97.9%	96.2%	92.3%	80.1%	51.1%	14.9%	2.6%
Effective Sample Size	167645	152726	138235	123727	109556	94147	72300	38576	8048	1729

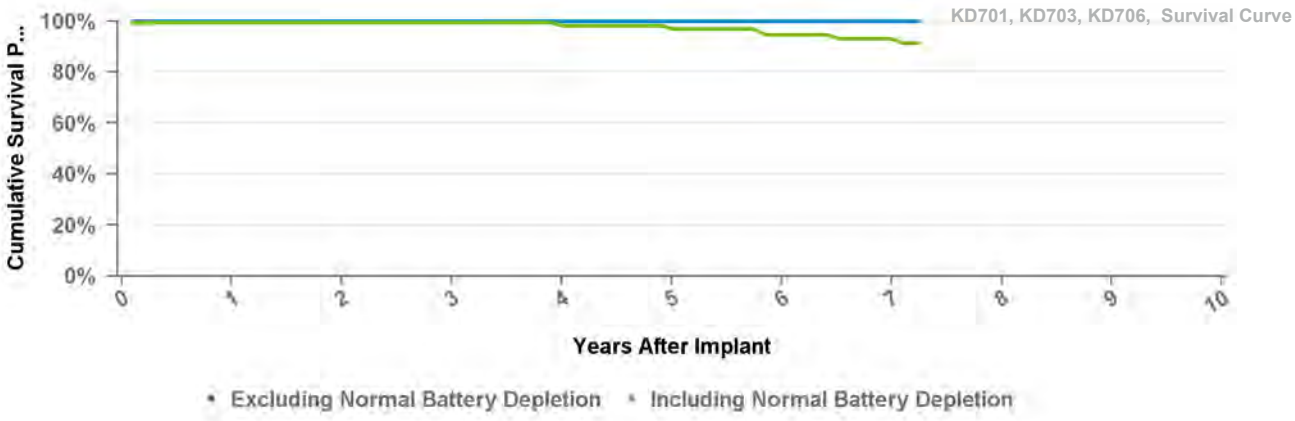
KD701 Kappa 700 DR

US Market Release	Jan-99
CE Approval Date	Mar-98
Registered USA Implants	317
Estimated Active USA Implants	57
Normal Battery Depletions	21

Total Malfunctions

Therapy Function Not Compromised

Therapy Function Compromised

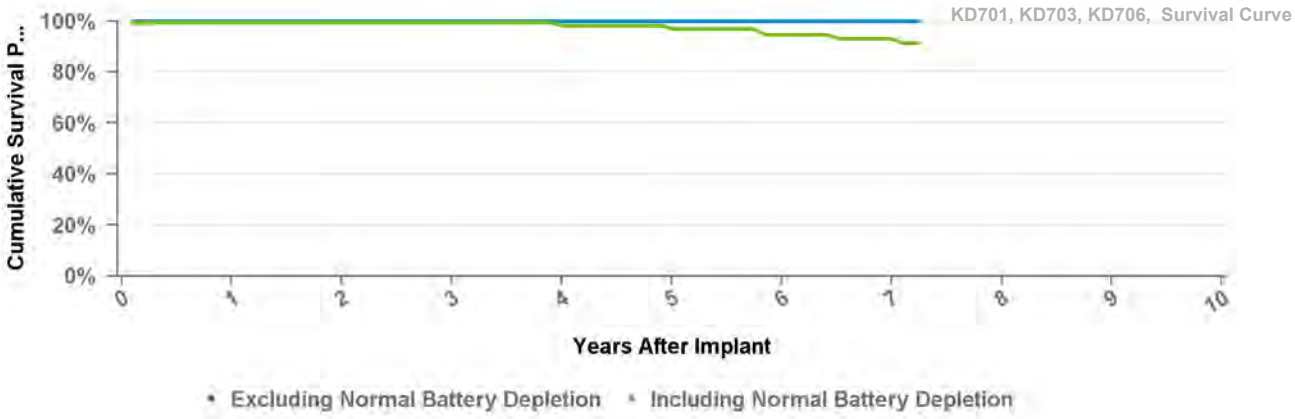


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.3%	99.3%	99.3%	98.2%	96.9%	94.7%	93.1%	91.4%
Effective Sample Size	256	227	195	173	153	130	108	100

IPG

KD703 Kappa 700 DR

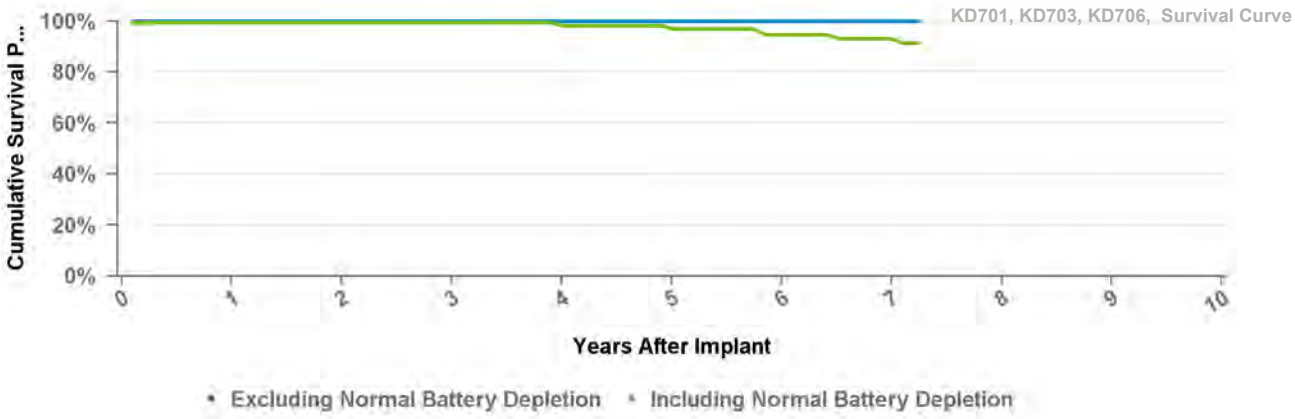
US Market Release	Jan-99	**Total Malfunctions**	
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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%	99.3%	99.3%	98.2%	96.9%	94.7%	93.1%	91.4%
Effective Sample Size	256	227	195	173	153	130	108	100

KD706 Kappa 700 DR

US Market Release	Jan-99	**Total Malfunctions**	
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

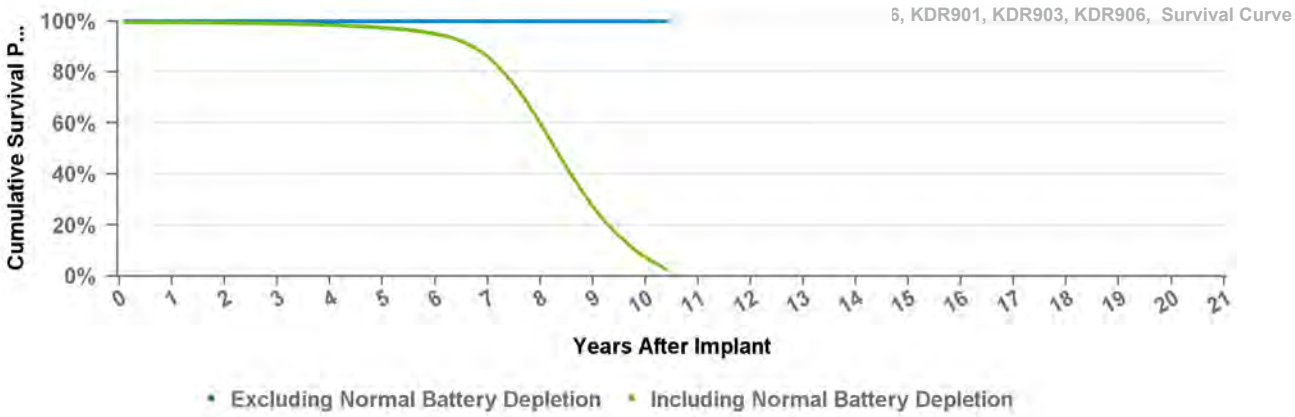


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.3%	99.3%	99.3%	98.2%	96.9%	94.7%	93.1%	91.4%
Effective Sample Size	256	227	195	173	153	130	108	100

IPG

KD901 Kappa 900 D

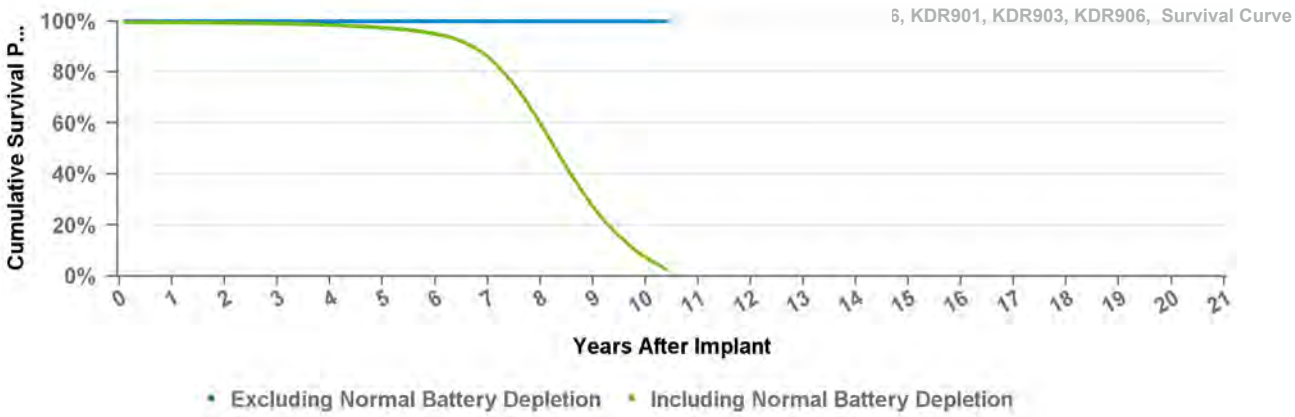
US Market Release	Jan-02	**Total Malfunctions**	
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

KD903 Kappa 900 D

US Market Release	Jan-02	**Total Malfunctions**	
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

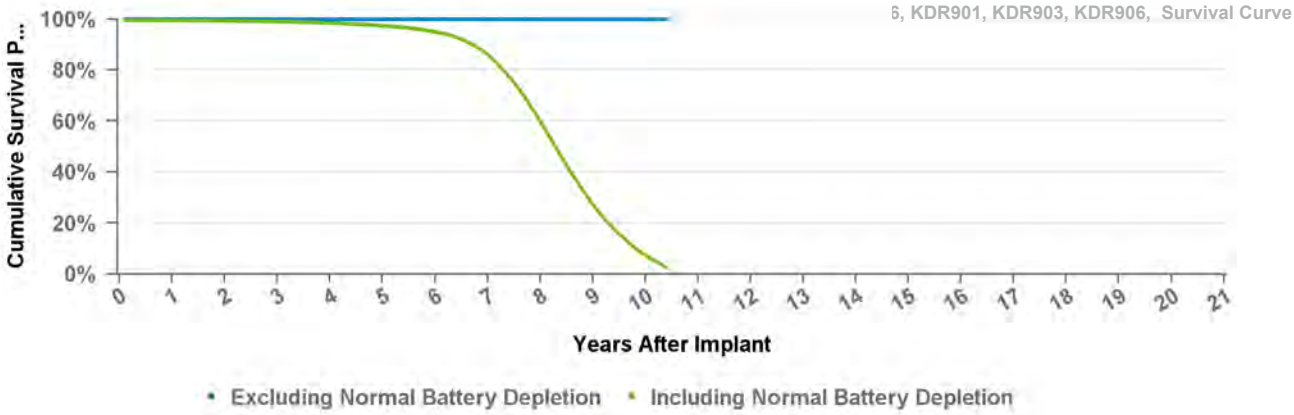


Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

IPG

KD906 Kappa 900 D

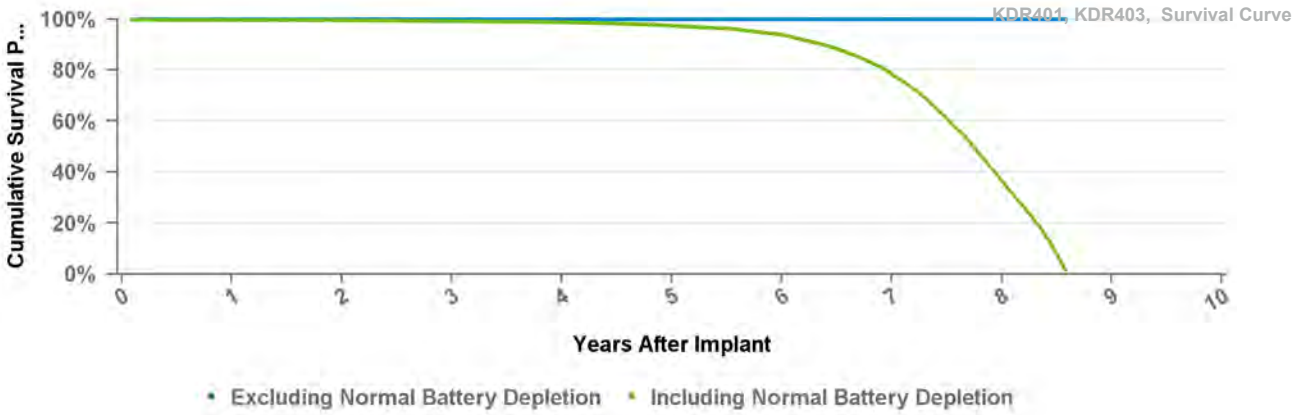
US Market Release	Jan-02	**Total Malfunctions**	
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

KDR401 Kappa 400 DR

US Market Release	Jan-98	**Total Malfunctions**	**23**
CE Approval Date	Nov-96	**Therapy Function Not Compromised**	**14**
Registered USA Implants	39,352	Electrical Component	10
Estimated Active USA Implants	1,856	Electrical Interconnect	1
Normal Battery Depletions	7,238	Other Malfunction	2
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**9**
		Electrical Component	6
		Electrical Interconnect	3

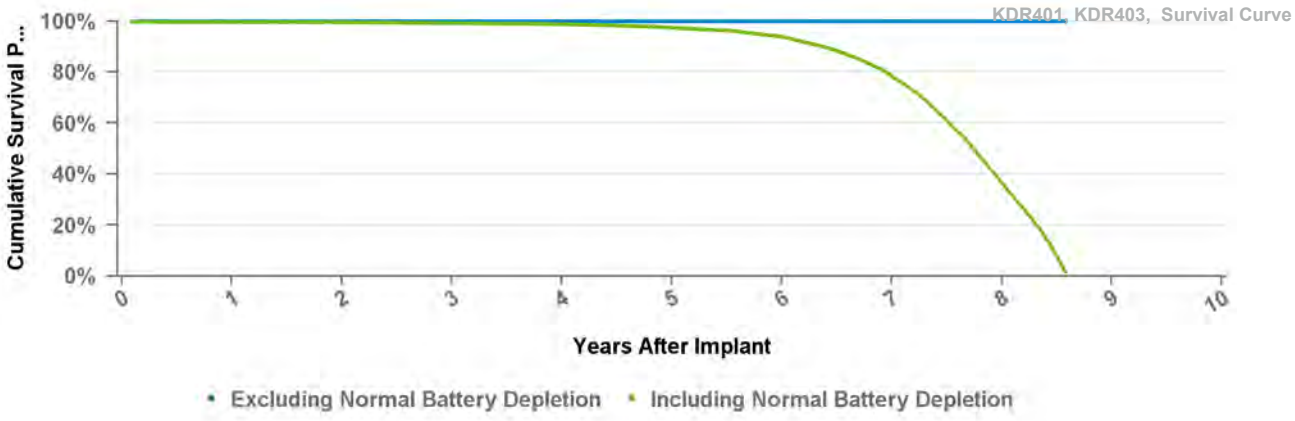


Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.4%	93.9%	78.2%	36.8%	1.4%
Effective Sample Size	41421	38325	35196	32191	28858	24936	18091	6472	563

IPG

KDR403 Kappa 400 DR

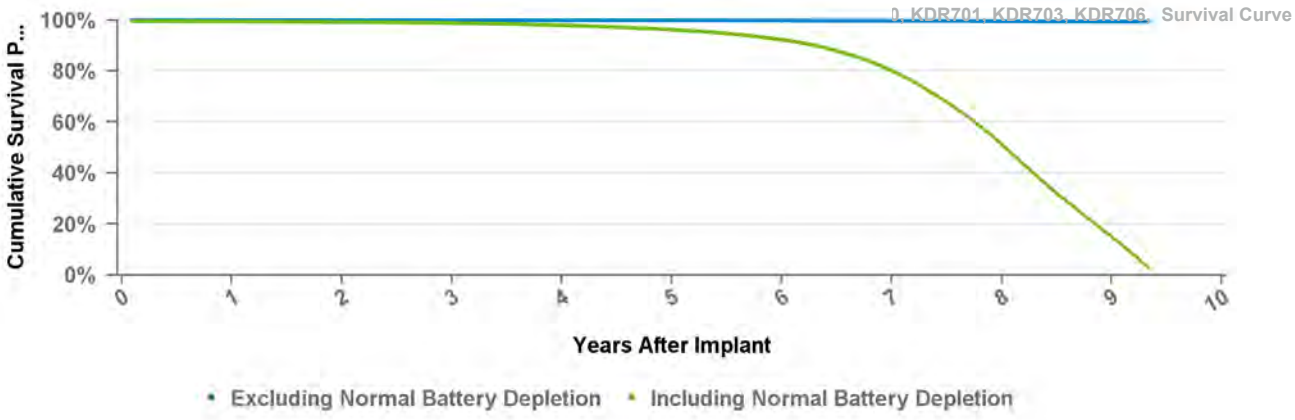
US Market Release	Jan-98	**Total Malfunctions**	**6**
CE Approval Date	Nov-96	**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,305	Electrical Component	1
Estimated Active USA Implants	533	Poss Early Battery Depltn	1
Normal Battery Depletions	1,193	**Therapy Function Compromised**	**4**
		Electrical Component	1
		Electrical Interconnect	3



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.4%	93.9%	78.2%	36.8%	1.4%
Effective Sample Size	41421	38325	35196	32191	28858	24936	18091	6472	563

KDR700 Kappa 700 DR

US Market Release		**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	15		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	4		



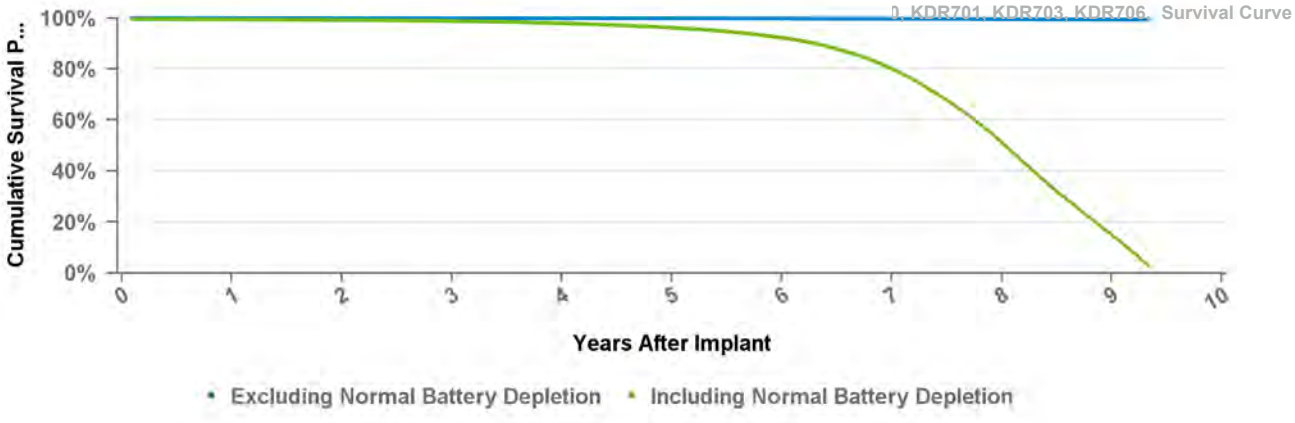
Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	97.9%	96.2%	92.3%	80.1%	51.1%	14.9%	2.6%
Effective Sample Size	167645	152726	138235	123727	109556	94147	72300	38576	8048	1729

IPG

KDR701 Kappa 700 DR

US Market Release	Jan-99
CE Approval Date	Mar-98
Registered USA Implants	194,278
Estimated Active USA Implants	11,072
Normal Battery Depletions	37,229

Total Malfunctions	**699**
Therapy Function Not Compromised	**46**
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	18
Other Malfunction	1
Poss Early Battery Depltn	3
Therapy Function Compromised	**653**
Electrical Component	16
Electrical Interconnect	636
Poss Early Battery Depltn	1

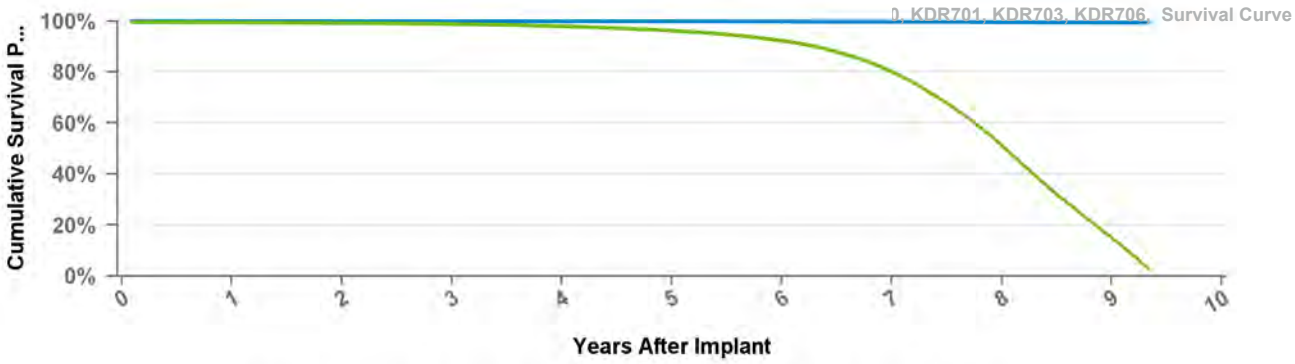


Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	97.9%	96.2%	92.3%	80.1%	51.1%	14.9%	2.6%
Effective Sample Size	167645	152726	138235	123727	109556	94147	72300	38576	8048	1729

IPG

KDR703 Kappa 700 DR

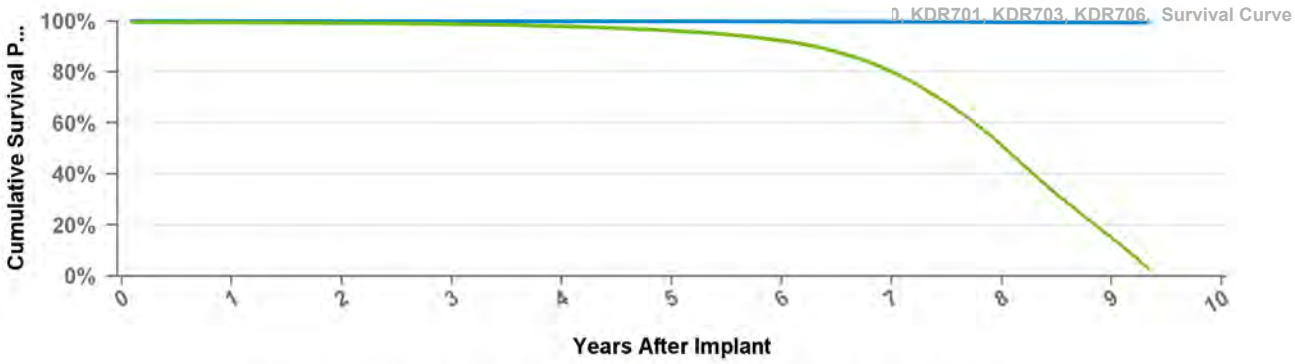
US Market Release	Feb-99	**Total Malfunctions**	**34**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**4**
Registered USA Implants	9,278	Electrical Component	3
Estimated Active USA Implants	544	Poss Early Battery Depltn	1
Normal Battery Depletions	1,543	**Therapy Function Compromised**	**30**
		Electrical Component	1
		Electrical Interconnect	29



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	99.4%	99.2%	98.8%	97.9%	96.2%	92.3%	80.1%	51.1%	14.9%	2.6%
Effective Sample Size	167645	152726	138235	123727	109556	94147	72300	38576	8048	1729

KDR706 Kappa 700 DR

US Market Release	Feb-99	**Total Malfunctions**	**10**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,638	Electrical Interconnect	1
Estimated Active USA Implants	119	**Therapy Function Compromised**	**9**
Normal Battery Depletions	406	Electrical Interconnect	9

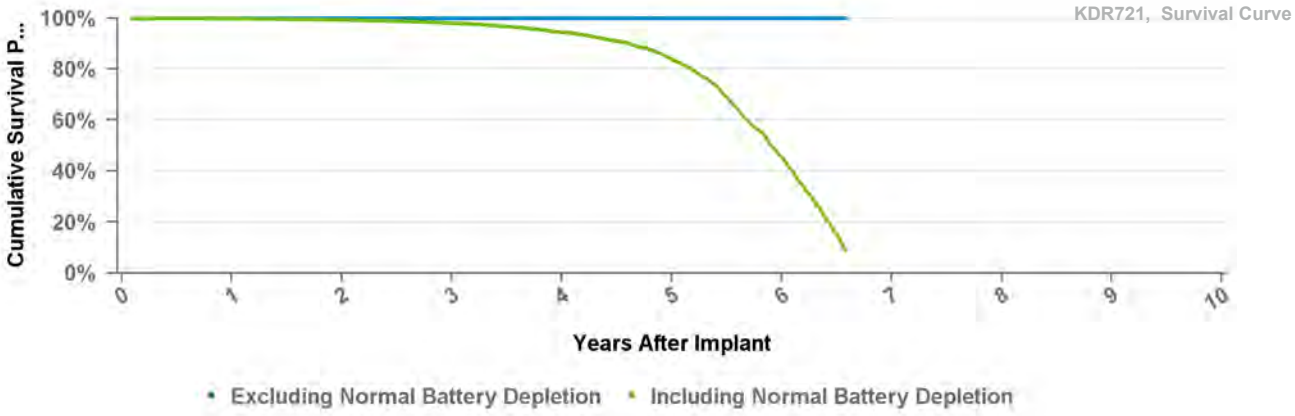


Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.4%	99.2%	98.8%	97.9%	96.2%	92.3%	80.1%	51.1%	14.9%	2.6%
Effective Sample Size	167645	152726	138235	123727	109556	94147	72300	38576	8048	1729

IPG

KDR721 Kappa 700 DR

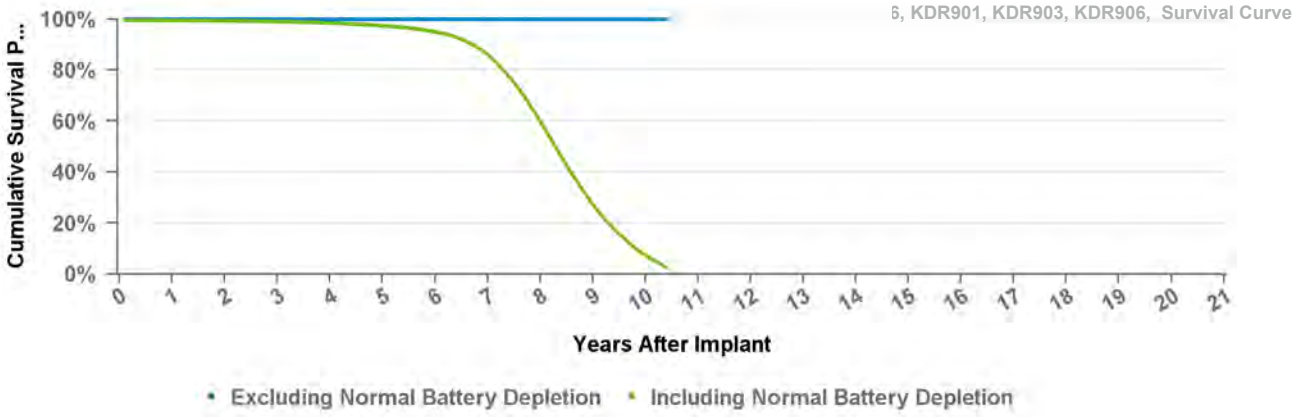
US Market Release	Feb-99	**Total Malfunctions**	**5**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,828	Electrical Component	1
Estimated Active USA Implants	481	**Therapy Function Compromised**	**4**
Normal Battery Depletions	1,366	Electrical Interconnect	4



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	99.8%	99.3%	98.0%	94.4%	83.7%	45.7%	8.9%
Effective Sample Size	8254	7241	6278	5251	3977	1530	237

KDR901 Kappa 900 DR

US Market Release	Jan-02	**Total Malfunctions**	**70**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**20**
Registered USA Implants	120,909	Electrical Component	16
Estimated Active USA Implants	9,544	Electrical Interconnect	4
Normal Battery Depletions	27,181	**Therapy Function Compromised**	**50**
		Electrical Component	10
		Electrical Interconnect	40

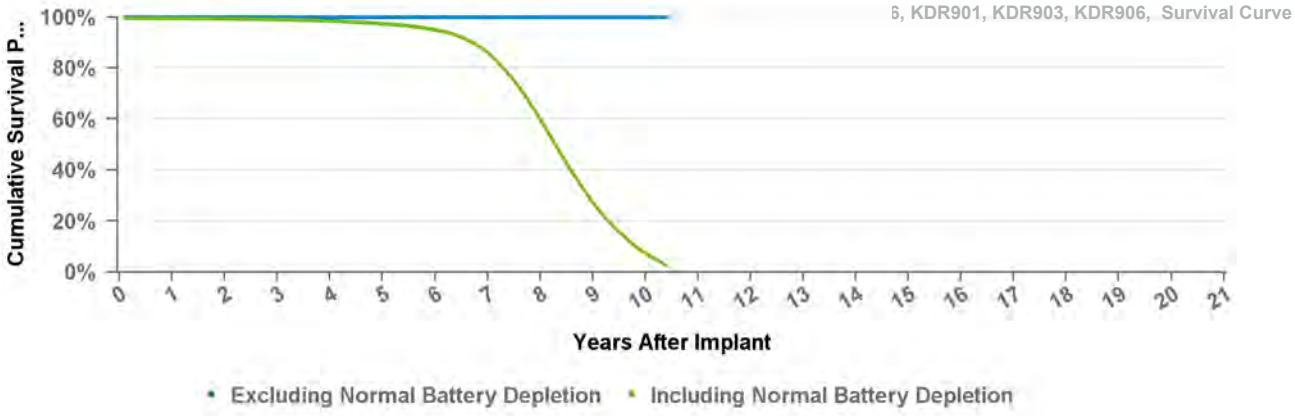


Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

IPG

KDR903 Kappa 900 DR

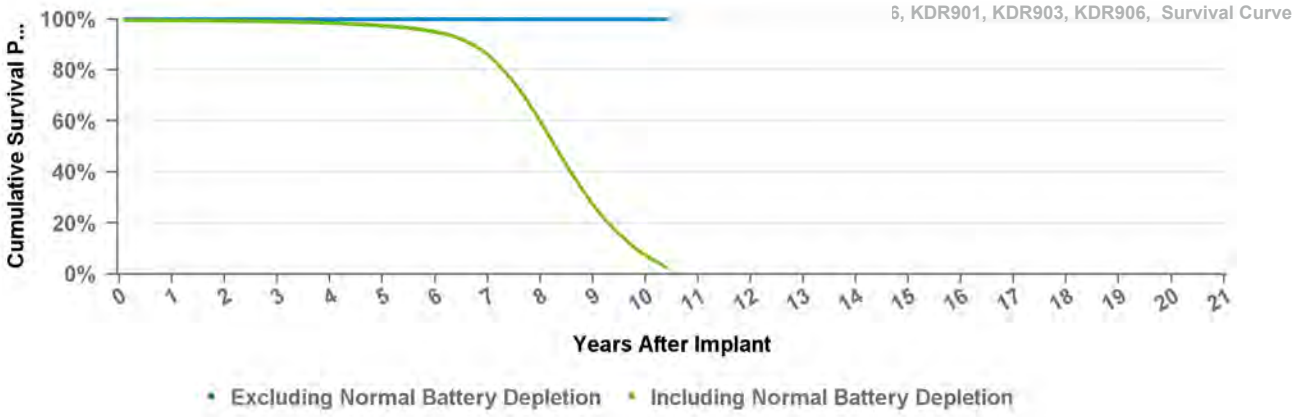
US Market Release	Jan-02	**Total Malfunctions**	**3**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3,183		
Estimated Active USA Implants	234	**Therapy Function Compromised**	**3**
Normal Battery Depletions	621	Electrical Interconnect	3



Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

KDR906 Kappa 900 DR

US Market Release	Jan-02	**Total Malfunctions**	**2**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,510		
Estimated Active USA Implants	89	**Therapy Function Compromised**	**2**
Normal Battery Depletions	303	Electrical Interconnect	2

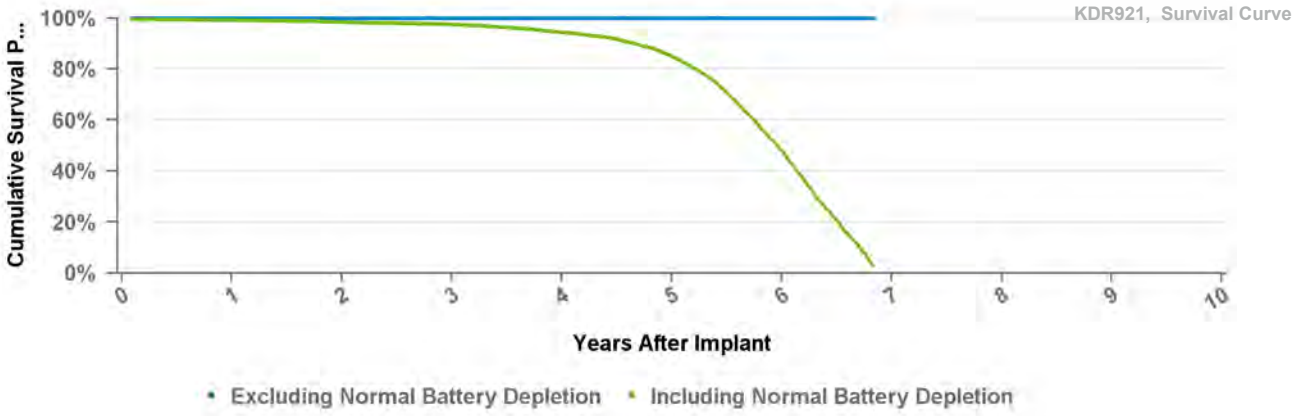


Years	1	10	2	3	4	5	6	7	8	9	at 125 mo
Excluding NBD	100.0%	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.3%	99.0%	98.4%	97.4%	95.0%	85.9%	59.9%	27.5%	7.3%	2.0%
Effective Sample Size	109129	99802	90749	82082	73618	65173	53726	33247	12731	2554	519

IPG

KDR921 Kappa 900 DR

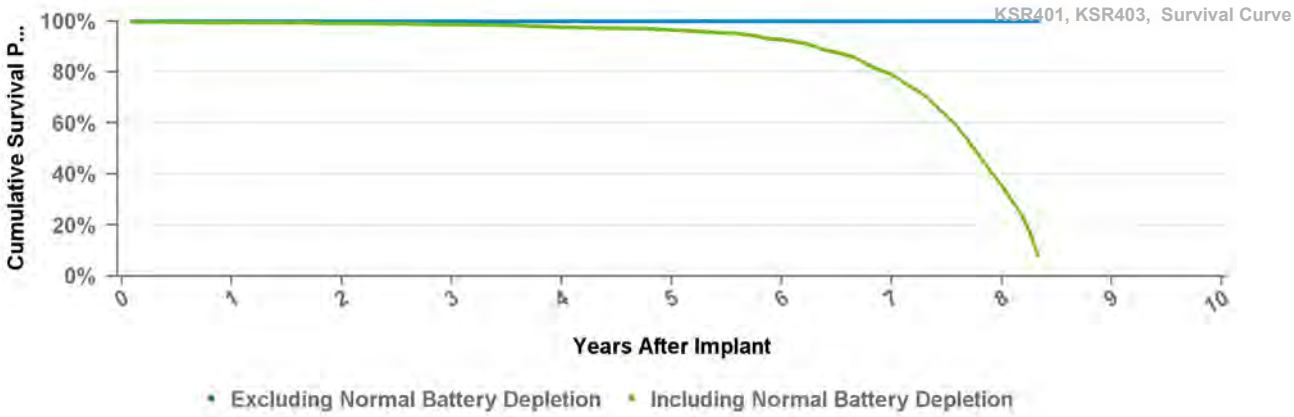
US Market Release	Jan-02	**Total Malfunctions**	**4**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**1**
Registered USA Implants	16,324	Electrical Component	1
Estimated Active USA Implants	911	**Therapy Function Compromised**	**3**
Normal Battery Depletions	2,910	Electrical Interconnect	3



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	99.2%	98.4%	97.5%	94.4%	85.0%	48.2%	2.9%
Effective Sample Size	13656	12087	10613	9080	7142	3106	184

KSR401 Kappa 400 SR

US Market Release	Feb-98	**Total Malfunctions**	**4**
CE Approval Date	Nov-96	**Therapy Function Not Compromised**	**4**
Registered USA Implants	11,785	Electrical Component	3
Estimated Active USA Implants	513	Poss Early Battery Depltn	1
Normal Battery Depletions	1,297	**Therapy Function Compromised**	**0**

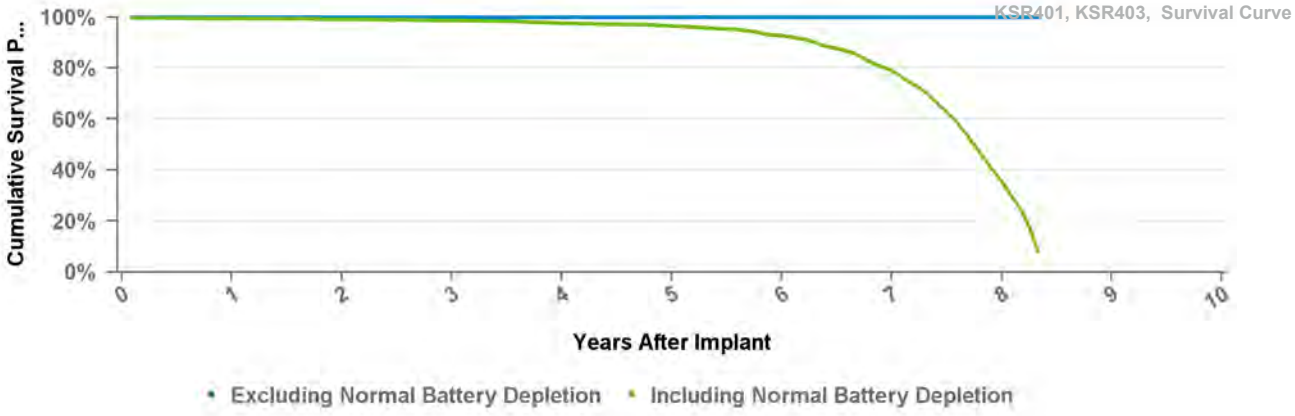


Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.1%	98.7%	97.6%	96.5%	92.7%	79.0%	35.8%	8.1%
Effective Sample Size	12153	10501	9014	7722	6470	5190	3595	1120	281

IPG

KSR403 Kappa 400 SR

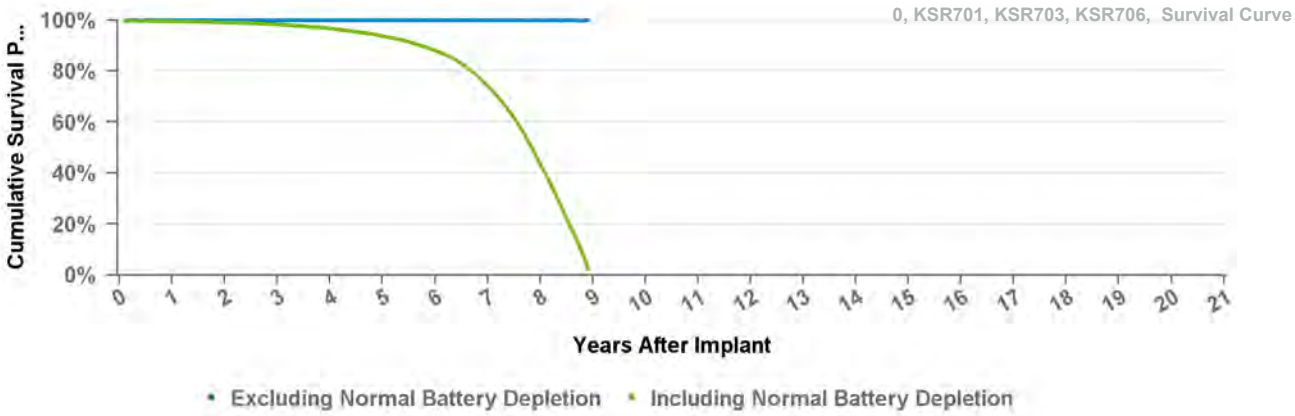
US Market Release	Feb-98	**Total Malfunctions**	**1**
CE Approval Date	Nov-96	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3,622		
Estimated Active USA Implants	239	**Therapy Function Compromised**	**1**
Normal Battery Depletions	405	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.1%	98.7%	97.6%	96.5%	92.7%	79.0%	35.8%	8.1%
Effective Sample Size	12153	10501	9014	7722	6470	5190	3595	1120	281

KSR701 Kappa 700 SR

US Market Release	Jan-99	**Total Malfunctions**	**22**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**3**
Registered USA Implants	48,612	Electrical Component	1
Estimated Active USA Implants	2,660	Electrical Interconnect	1
Normal Battery Depletions	5,197	Poss Early Battery Depltn	1
		Therapy Function Compromised	**19**
		Electrical Component	2
		Electrical Interconnect	17

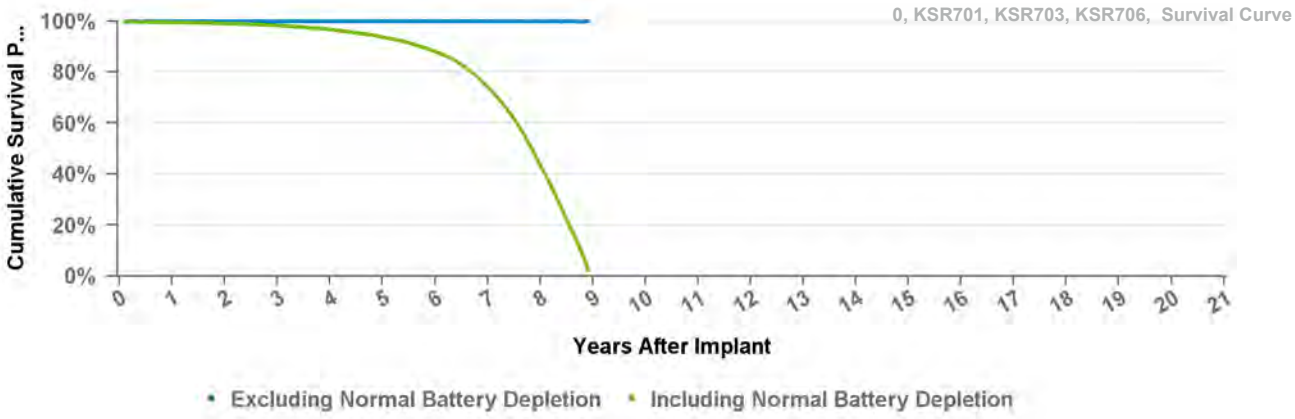


Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.4%	2.1%
Effective Sample Size	43180	36556	30662	25557	20812	16332	11324	5108	280

IPG

KSR703 Kappa 700 SR

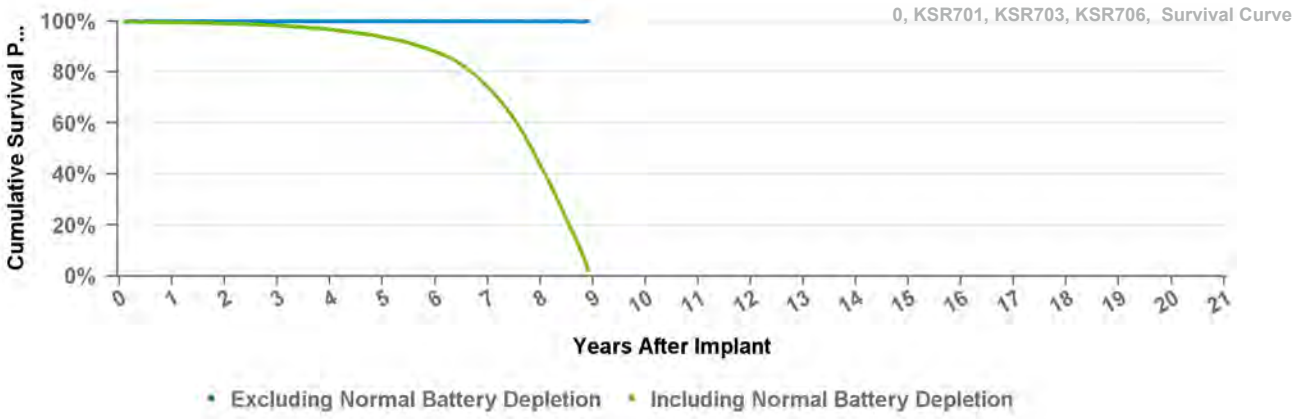
US Market Release	Feb-99	**Total Malfunctions**	**4**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3,654		
Estimated Active USA Implants	192	**Therapy Function Compromised**	**4**
Normal Battery Depletions	402	Electrical Component	1
		Electrical Interconnect	3



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%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.4%	2.1%
Effective Sample Size	43180	36556	30662	25557	20812	16332	11324	5108	280

KSR706 Kappa 700 SR

US Market Release	Feb-99	**Total Malfunctions**	**2**
CE Approval Date	Mar-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,935	Electrical Component	1
Estimated Active USA Implants	159	**Therapy Function Compromised**	**1**
Normal Battery Depletions	302	Electrical Component	1



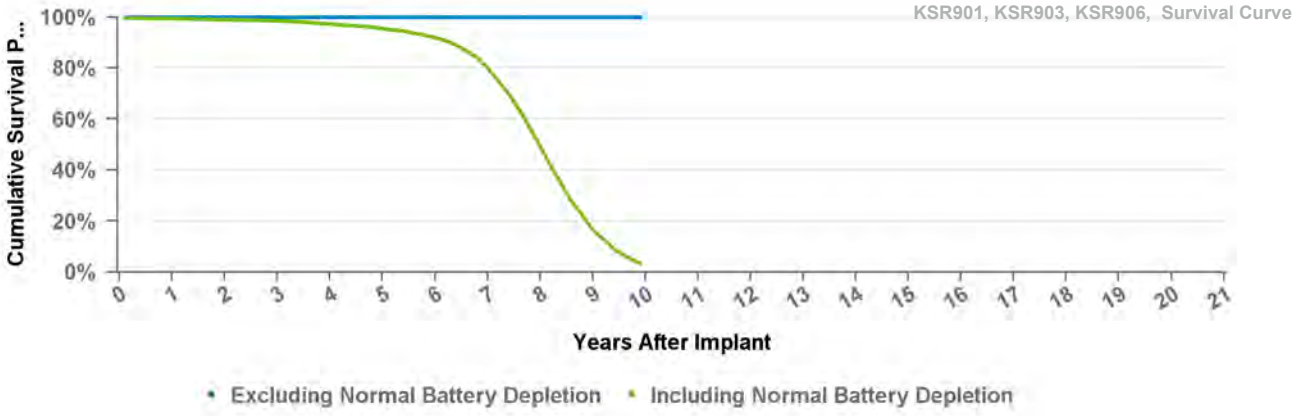
Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	99.5%	99.1%	98.3%	96.7%	93.6%	88.1%	74.0%	43.4%	2.1%
Effective Sample Size	43180	36556	30662	25557	20812	16332	11324	5108	280

IPG

KSR901 Kappa 900 SR

US Market Release	Jan-02	**Total Malfunctions**	**15**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**7**
Registered USA Implants	34,313	Electrical Component	6
Estimated Active USA Implants	2,450	Poss Early Battery Depltn	1
Normal Battery Depletions	4,265	**Therapy Function Compromised**	**8**
		Electrical Interconnect	8

KSR901, KSR903, KSR906, Survival Curve

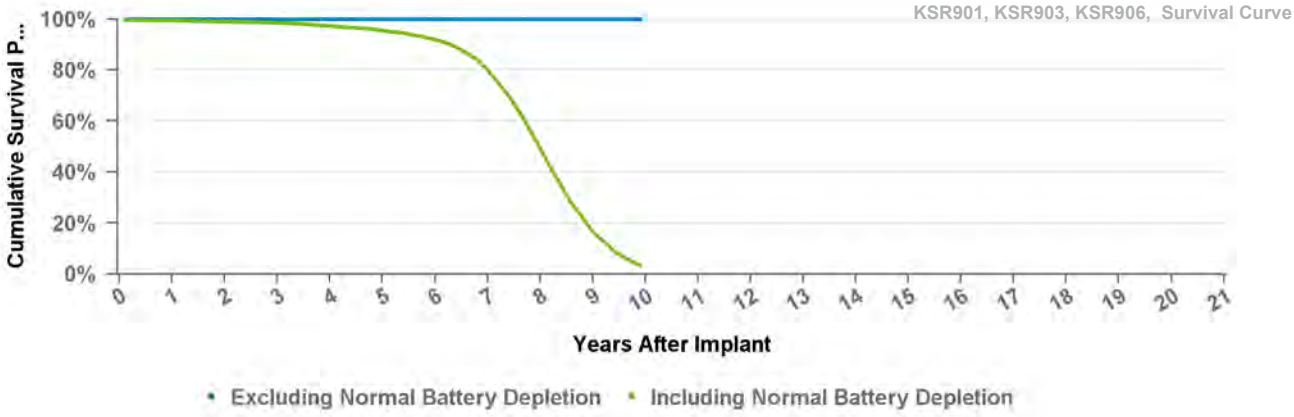


Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.4%	98.9%	98.5%	97.2%	95.5%	91.9%	80.0%	49.2%	16.7%	3.0%
Effective Sample Size	28635	24217	20635	17358	14465	11822	8728	4392	1109	111

KSR903 Kappa 900 SR

US Market Release	Jan-02	**Total Malfunctions**	**1**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,381	Electrical Component	1
Estimated Active USA Implants	87	**Therapy Function Compromised**	**0**
Normal Battery Depletions	166		

KSR901, KSR903, KSR906, Survival Curve

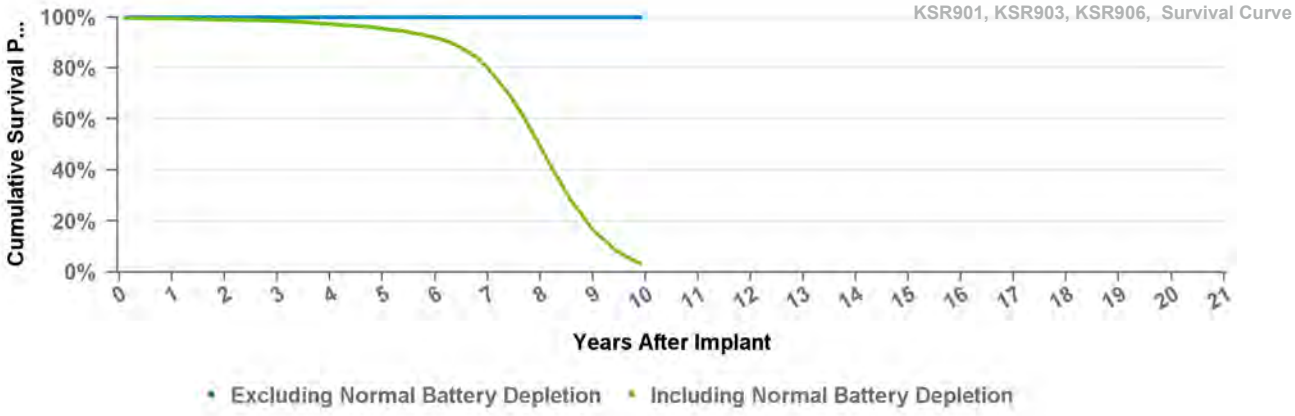


Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.4%	98.9%	98.5%	97.2%	95.5%	91.9%	80.0%	49.2%	16.7%	3.0%
Effective Sample Size	28635	24217	20635	17358	14465	11822	8728	4392	1109	111

IPG

KSR906 Kappa 900 SR

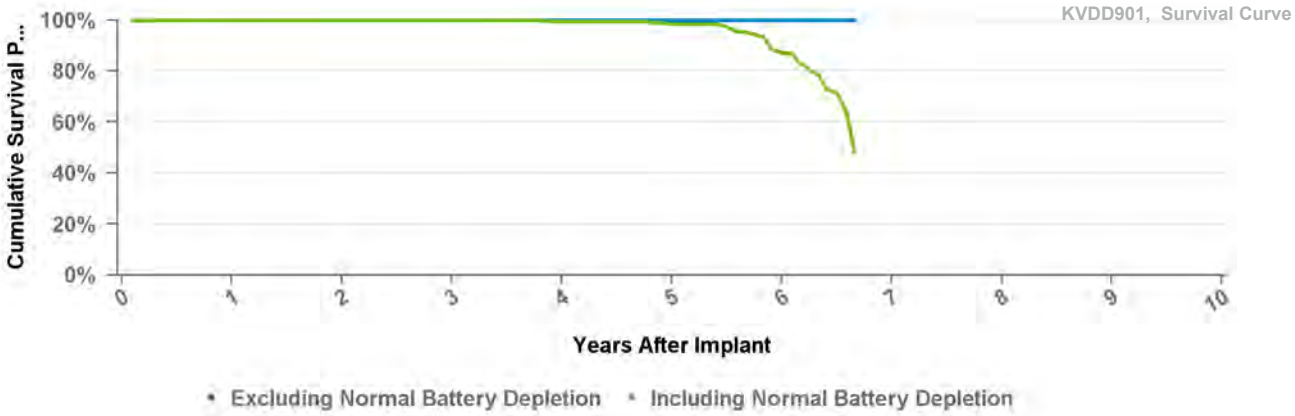
US Market Release	Jan-02	**Total Malfunctions**	**1**
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,321		
Estimated Active USA Implants	90	**Therapy Function Compromised**	**1**
Normal Battery Depletions	184	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 119 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	99.4%	98.9%	98.5%	97.2%	95.5%	91.9%	80.0%	49.2%	16.7%	3.0%
Effective Sample Size	28635	24217	20635	17358	14465	11822	8728	4392	1109	111

KVDD901 Kappa 900 VDD

US Market Release	Jan-02	**Total Malfunctions**	
CE Approval Date	Sep-01	**Therapy Function Not Compromised**	
Registered USA Implants	639		
Estimated Active USA Implants	57	**Therapy Function Compromised**	
Normal Battery Depletions	85		



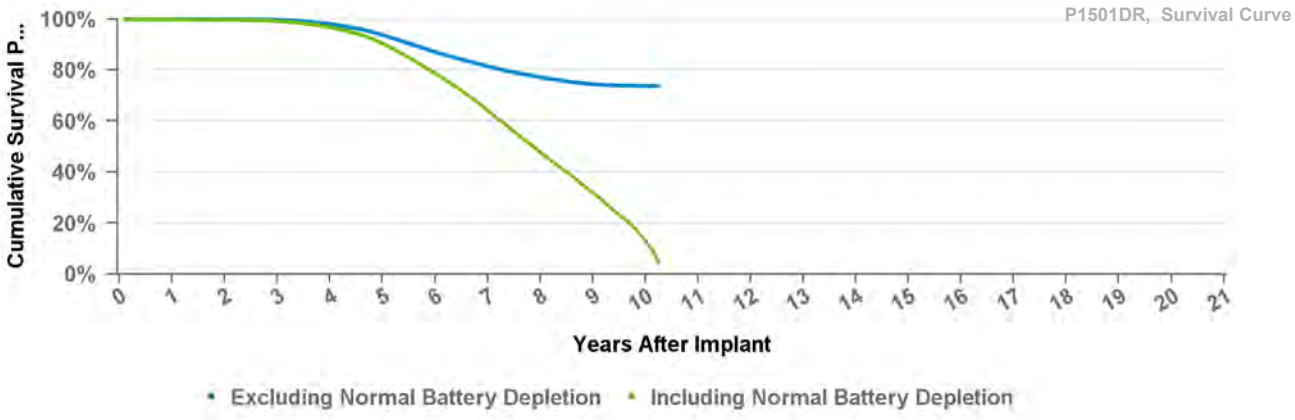
Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.5%	98.3%	87.1%	48.0%
Effective Sample Size	532	480	429	375	330	241	131

IPG

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	110,110
Estimated Active USA Implants	27,431
Normal Battery Depletions	12,998

Total Malfunctions	**14,827**
Therapy Function Not Compromised	**14,772**
Battery Malfunction	14,645
Electrical Component	58
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	66
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2

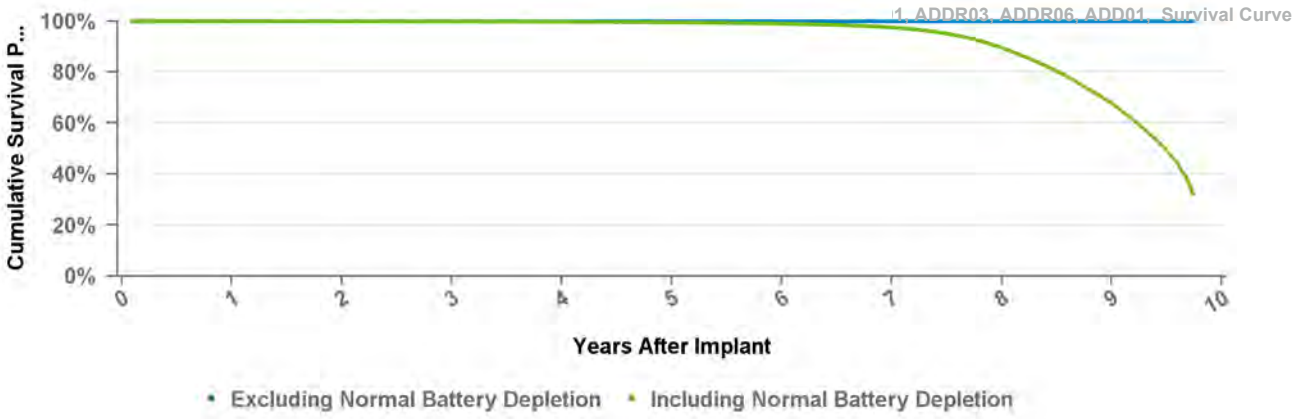


Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	99.9%	73.8%	99.9%	99.7%	98.0%	93.7%	87.0%	81.4%	77.2%	74.4%	73.8%
Including NBD	99.8%	99.7%	99.2%	96.8%	90.4%	78.6%	64.1%	47.7%	31.7%	13.2%	4.5%
Effective Sample Size	95556	89218	83172	76154	66149	51230	33982	19249	8949	1690	315

IPG

RED01 Relia D

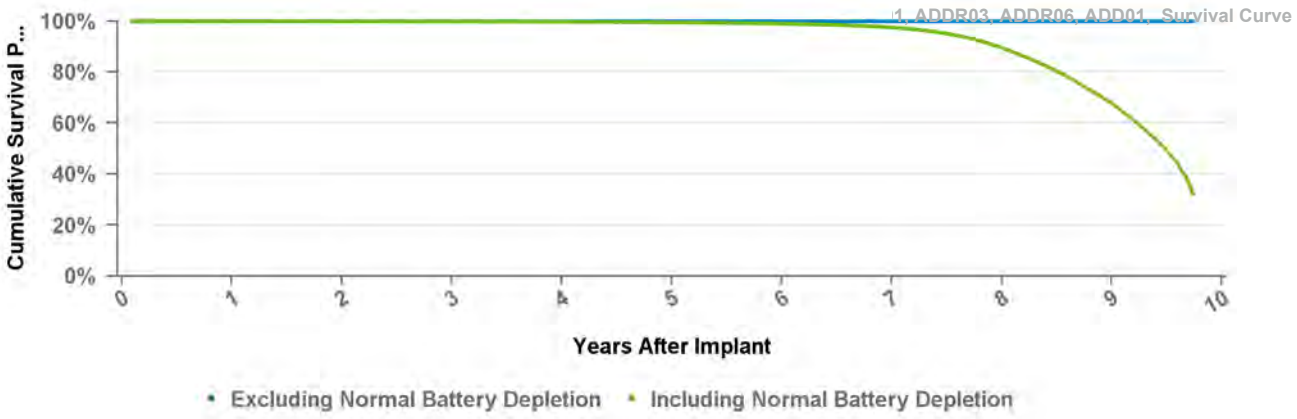
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

REDR01 Relia DR

US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			

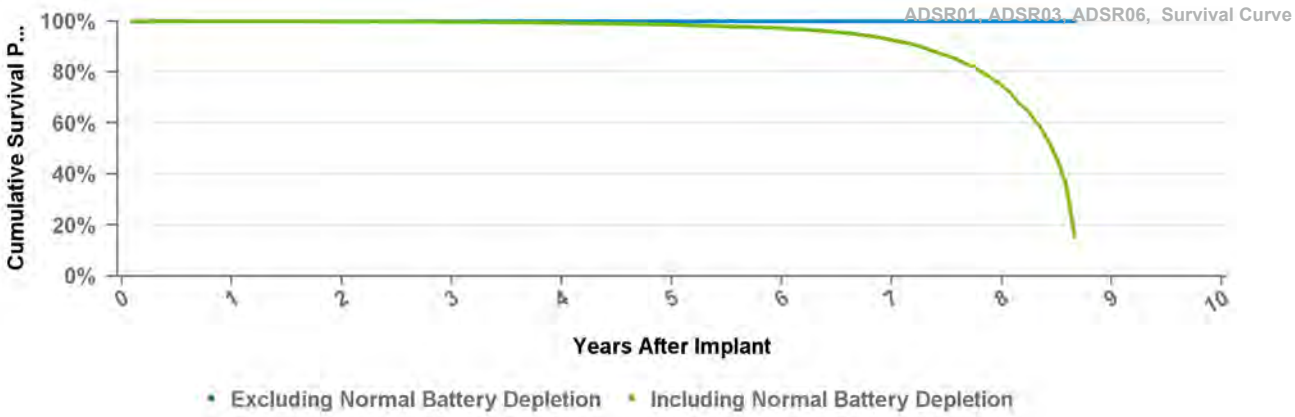


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	97.5%	89.5%	67.6%	31.8%
Effective Sample Size	391219	351238	305594	256863	207122	160306	111057	62859	20294	1041

IPG

RES01 Relia S

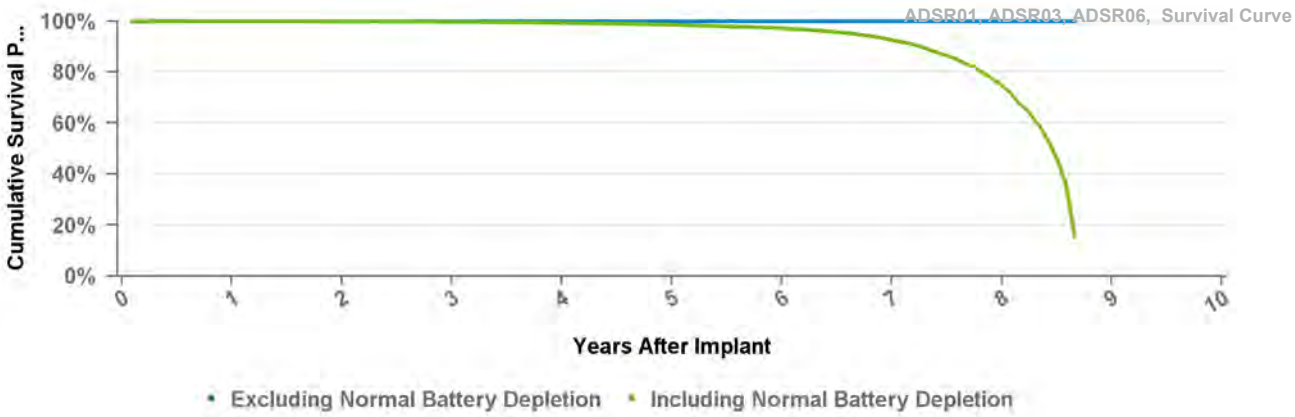
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 104 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%	92.6%	74.6%	15.1%
Effective Sample Size	71852	59394	46649	35517	25834	17933	10892	3948	174

RESR01 Relia SR

US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

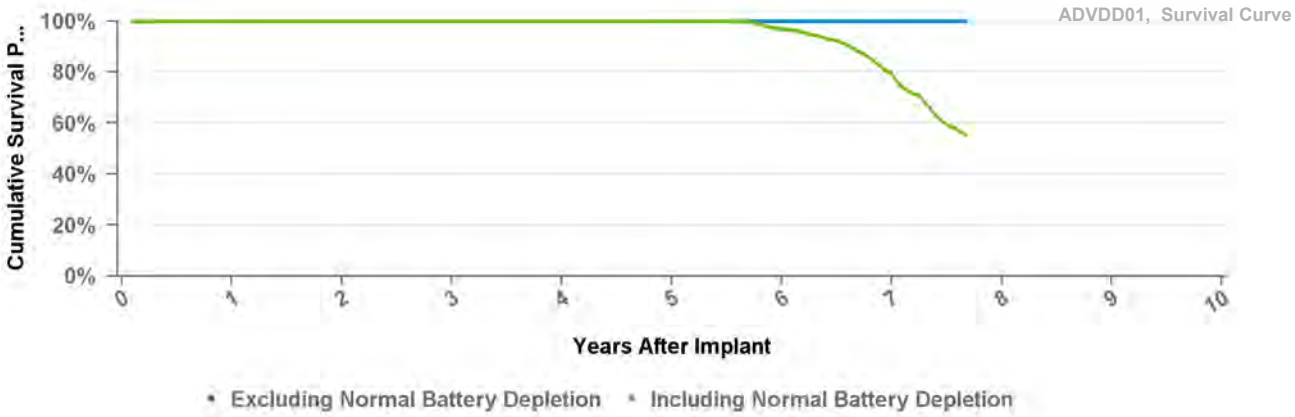


Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.6%	97.1%	92.6%	74.6%	15.1%
Effective Sample Size	71852	59394	46649	35517	25834	17933	10892	3948	174

IPG

REVDD01 Relia VDD

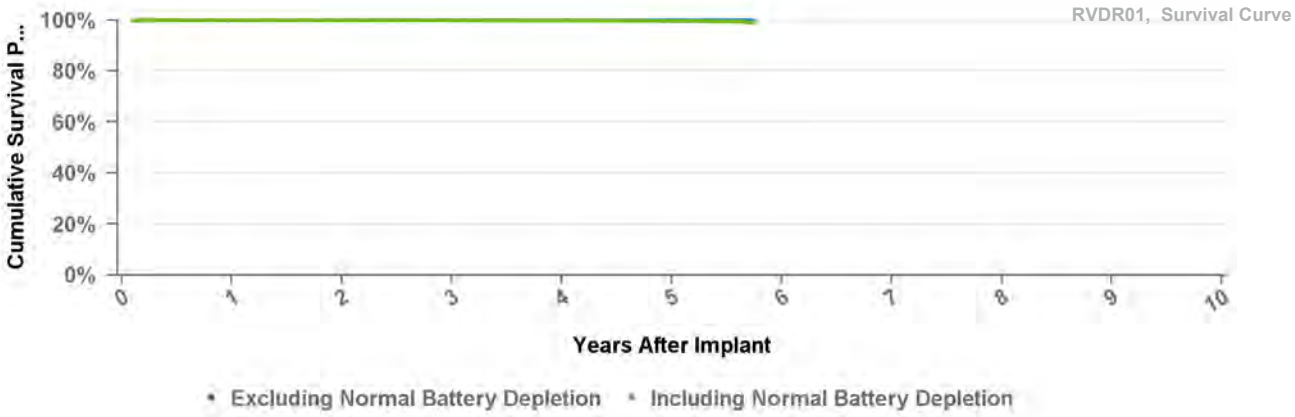
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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	100.0%	100.0%	100.0%	100.0%	100.0%	96.9%	79.4%	55.2%
Effective Sample Size	1123	1000	858	713	586	459	265	110

RVDR01 Revo MRI SureScan

US Market Release	Feb-11	**Total Malfunctions**	**50**
CE Approval Date		**Therapy Function Not Compromised**	**47**
Registered USA Implants	67,923	Battery Malfunction	1
Estimated Active USA Implants	58,712	Electrical Component	29
Normal Battery Depletions	47	Poss Early Battery Depltn	14
		Software Malfunction	3
		Therapy Function Compromised	**3**
		Electrical Component	3

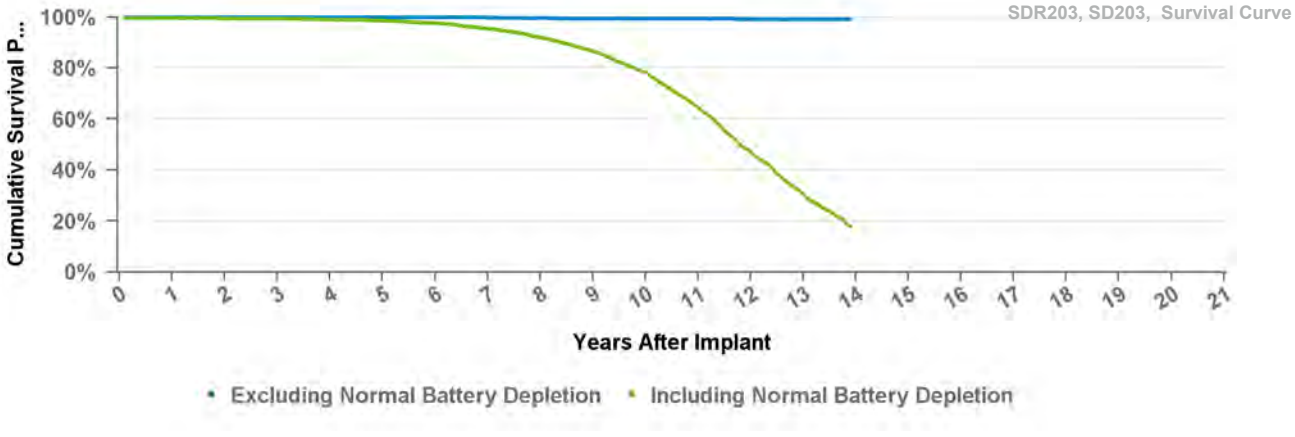


Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	98.8%
Effective Sample Size	60049	56315	52432	41493	17177	1323

IPG

SD203 Sigma 200 D

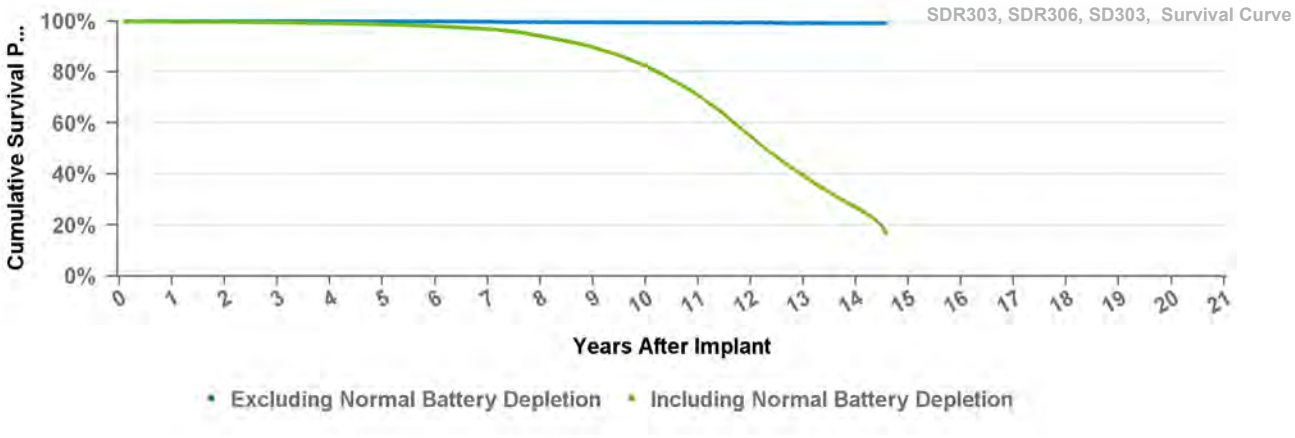
US Market Release	Aug-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	226		
Estimated Active USA Implants	16	**Therapy Function Compromised**	**1**
Normal Battery Depletions	19	Electrical Interconnect	1



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 167 mo
Excluding NBD	100.0%	99.4%	99.4%	99.2%	99.1%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.1%
Including NBD	99.6%	99.5%	99.4%	99.0%	98.6%	97.6%	95.4%	91.9%	86.7%	78.0%	64.5%	47.2%	30.4%	17.6%
Effective Sample Size	12993	11524	10117	8937	7804	6770	5739	4826	4015	3183	2275	1303	586	130

SD303 Sigma 300 D

US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	21	**Therapy Function Compromised**	**2**
Normal Battery Depletions	7	Electrical Interconnect	2

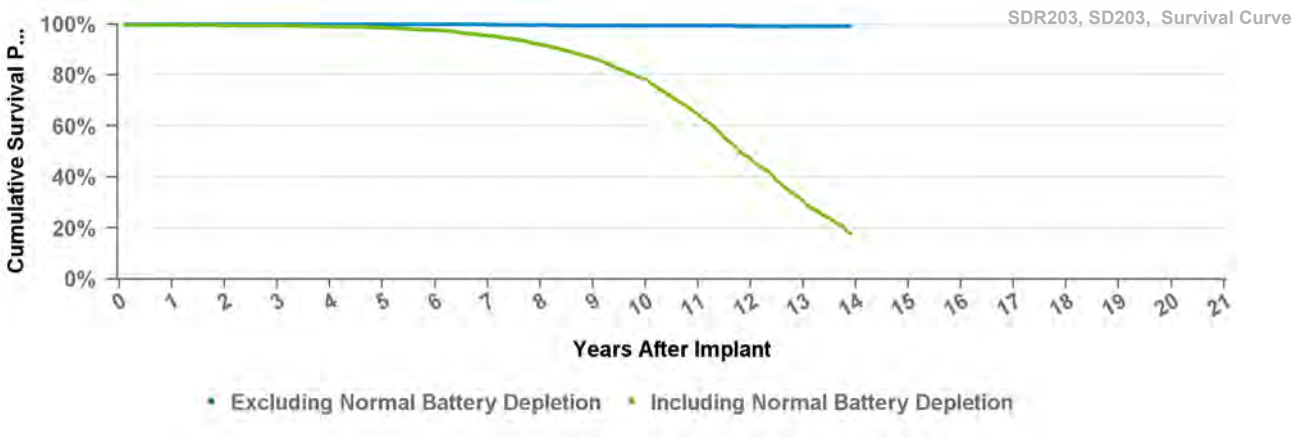


Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 175 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.3%	70.8%	54.6%	39.5%	26.9%	16.6%
Effective Sample Size	88298	78253	69207	60878	53401	46768	40570	35095	30115	23984	17015	9831	4679	1315	148

IPG

SDR203 Sigma 200 DR

US Market Release	Aug-99	**Total Malfunctions**	**41**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**10**
Registered USA Implants	15,632	Electrical Component	1
Estimated Active USA Implants	1,354	Electrical Interconnect	9
Normal Battery Depletions	1,424	**Therapy Function Compromised**	**31**
		Electrical Component	2
		Electrical Interconnect	28
		Other Malfunction	1

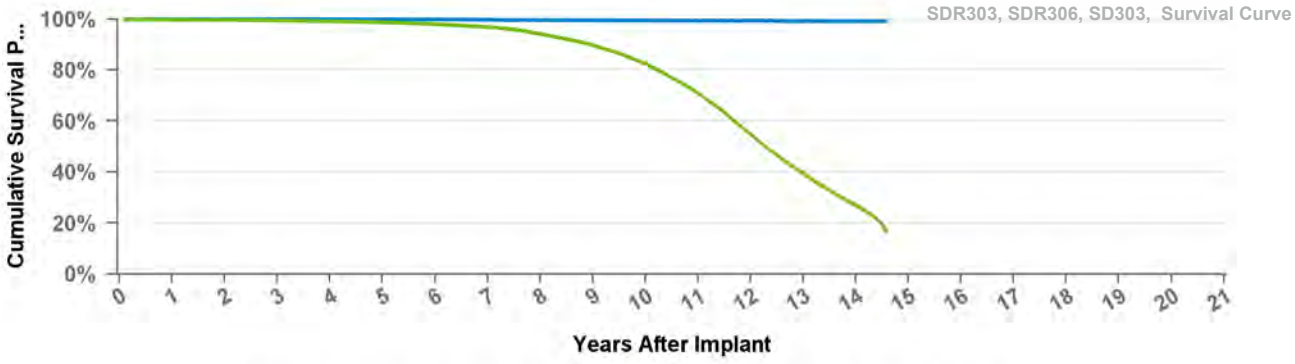


Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 167 mo
Excluding NBD	100.0%	99.4%	99.4%	99.2%	99.1%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.1%
Including NBD	99.6%	99.5%	99.4%	99.0%	98.6%	97.6%	95.4%	91.9%	86.7%	78.0%	64.5%	47.2%	30.4%	17.6%
Effective Sample Size	12993	11524	10117	8937	7804	6770	5739	4826	4015	3183	2275	1303	586	130

IPG

SDR303 Sigma 300 DR

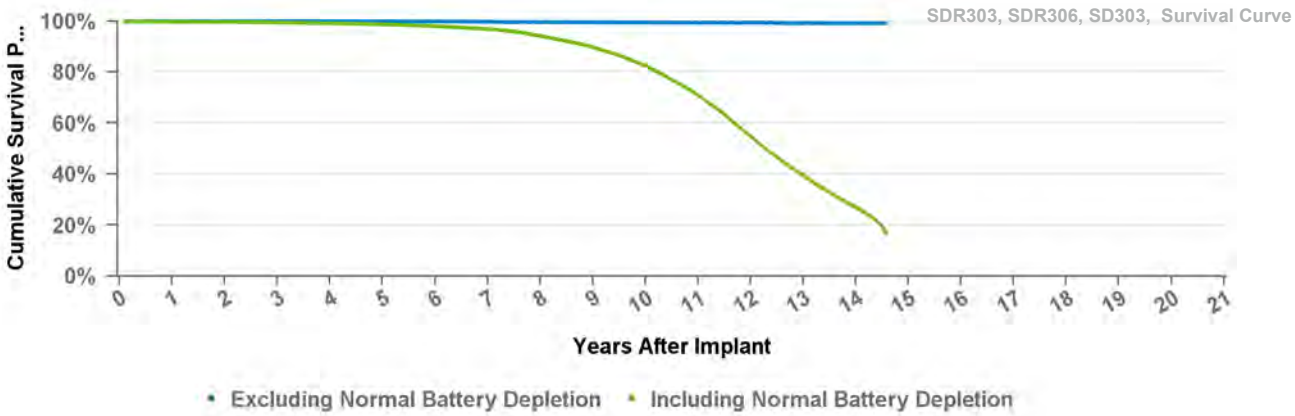
US Market Release	Aug-99	**Total Malfunctions**	**284**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**60**
Registered USA Implants	105,513	Electrical Component	9
Estimated Active USA Implants	14,567	Electrical Interconnect	49
Normal Battery Depletions	9,293	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**224**
		Electrical Component	7
		Electrical Interconnect	216
		Other Malfunction	1



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 175 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.3%	70.8%	54.6%	39.5%	26.9%	16.6%
Effective Sample Size	88298	78253	69207	60878	53401	46768	40570	35095	30115	23984	17015	9831	4679	1315	148

SDR306 Sigma 300 DR

US Market Release	Aug-99	**Total Malfunctions**	**5**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,209		
Estimated Active USA Implants	94	**Therapy Function Compromised**	**5**
Normal Battery Depletions	161	Electrical Interconnect	5

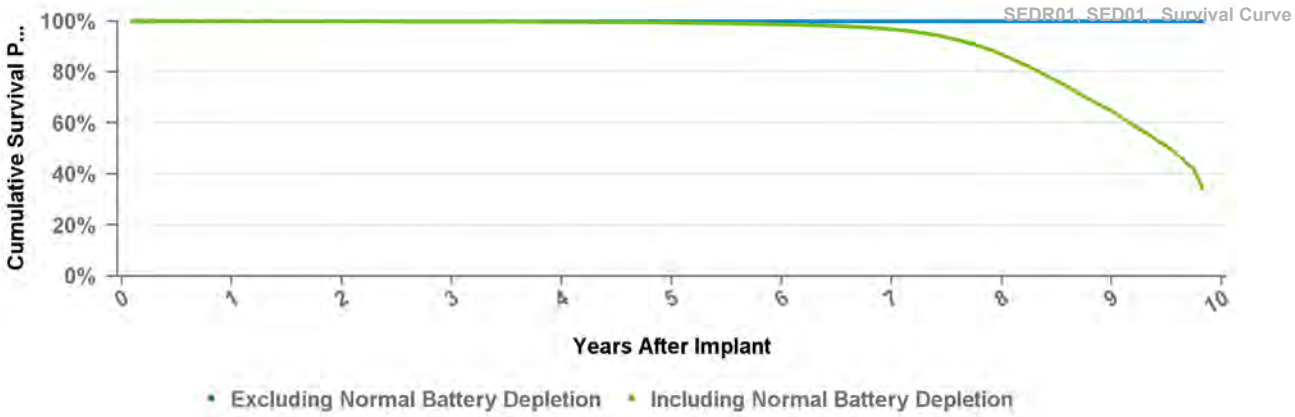


Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 175 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.3%	70.8%	54.6%	39.5%	26.9%	16.6%
Effective Sample Size	88298	78253	69207	60878	53401	46768	40570	35095	30115	23984	17015	9831	4679	1315	148

IPG

SED01 Sensia D

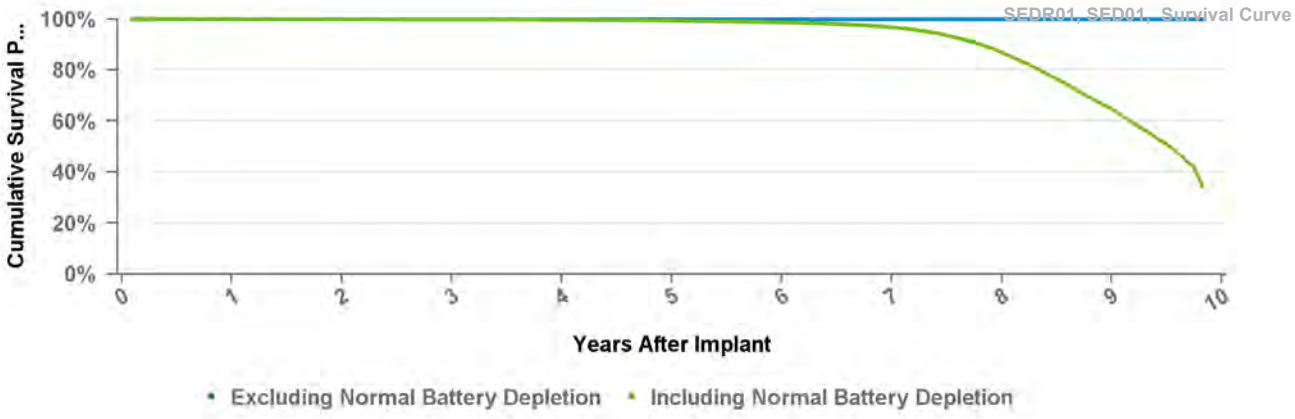
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	4	**Therapy Function Compromised**	
Normal Battery Depletions			



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	99.9%	99.9%	99.8%	99.7%	99.4%	98.7%	96.7%	86.9%	64.8%	34.1%
Effective Sample Size	125503	110302	94629	78931	63637	48522	33736	17948	5089	132

SEDR01 Sensia DR

US Market Release	Jul-06	**Total Malfunctions**	**30**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**16**
Registered USA Implants	149,196	Electrical Component	14
Estimated Active USA Implants	87,013	Electrical Interconnect	1
Normal Battery Depletions	4,972	Other Malfunction	1
		Therapy Function Compromised	**14**
		Electrical Component	6
		Electrical Interconnect	3
		Other Malfunction	5

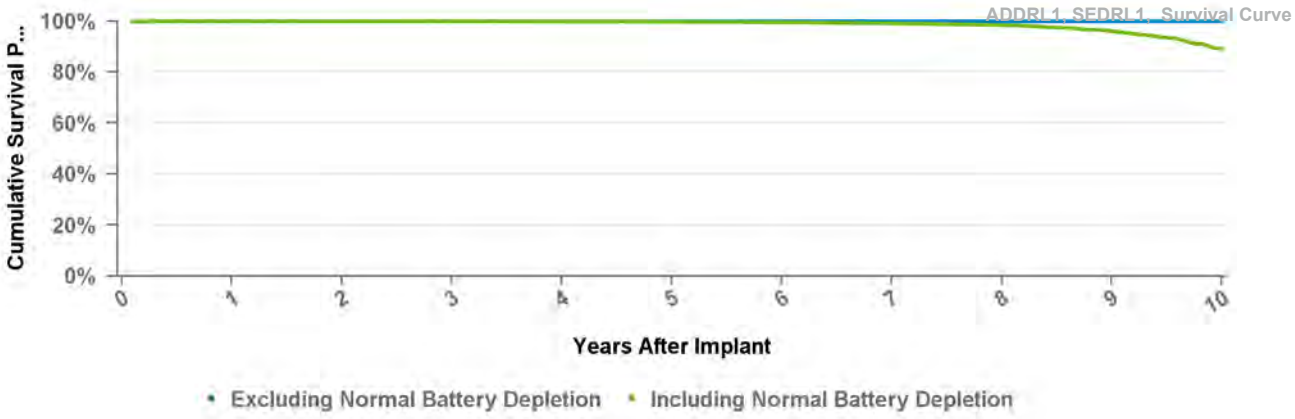


Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.7%	96.7%	86.9%	64.8%	34.1%
Effective Sample Size	125503	110302	94629	78931	63637	48522	33736	17948	5089	132

IPG

SEDRL1 Sensia DR

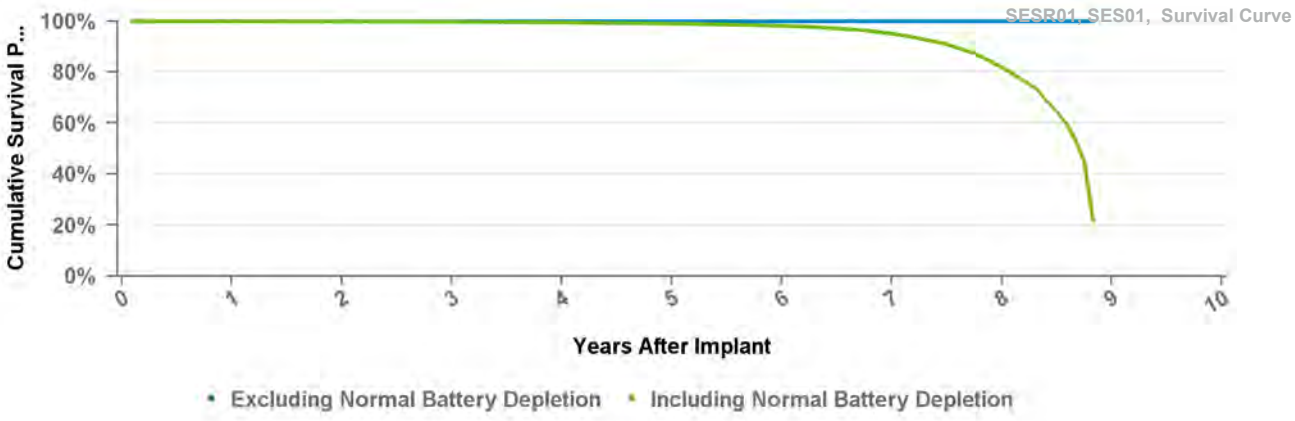
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 120 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.1%	98.4%	96.1%	89.1%
Effective Sample Size	111924	95814	77635	59511	42086	27873	16006	7777	2763	182

SES01 Sensia S

US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			

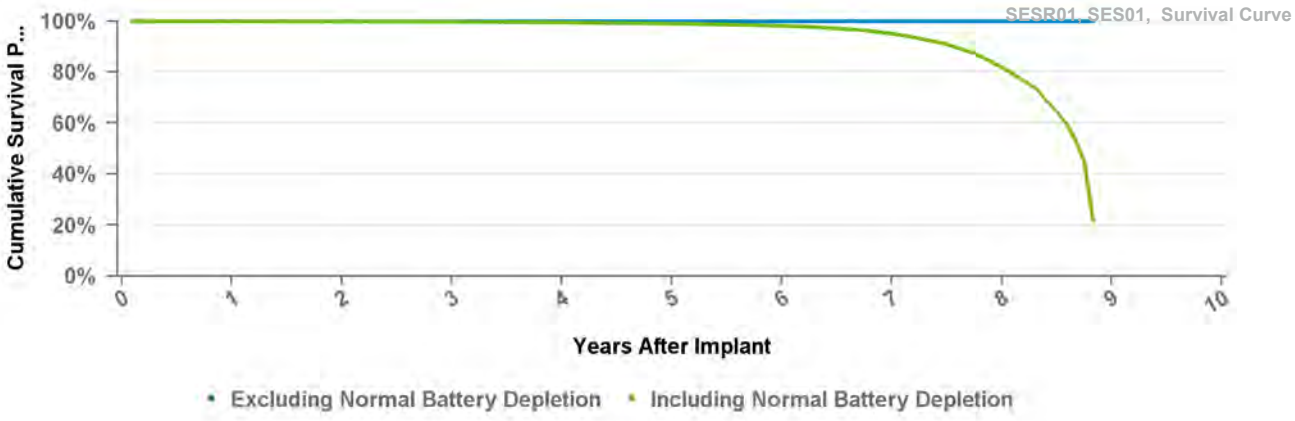


Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.4%	99.0%	98.1%	95.0%	81.8%	21.6%
Effective Sample Size	86056	71707	57343	44466	32800	22622	13801	5426	170

IPG

SESR01 Sensia SR

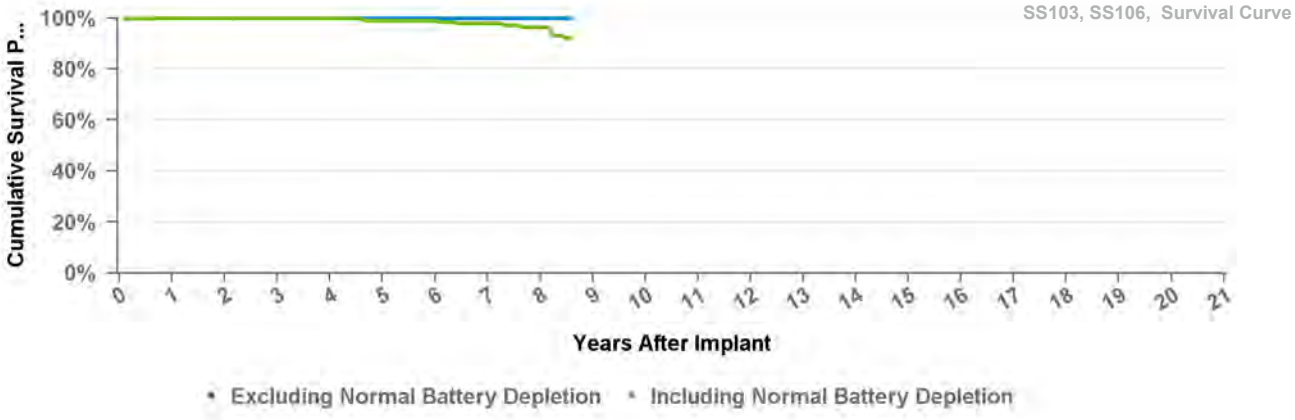
US Market Release	Jul-06	**Total Malfunctions**	**11**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**8**
Registered USA Implants	114,036	Electrical Component	7
Estimated Active USA Implants	63,871	Other Malfunction	1
Normal Battery Depletions	2,495	**Therapy Function Compromised**	**3**
		Electrical Component	2
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.4%	99.0%	98.1%	95.0%	81.8%	21.6%
Effective Sample Size	86056	71707	57343	44466	32800	22622	13801	5426	170

SS103 Sigma 100 S

US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	774		
Estimated Active USA Implants	68	**Therapy Function Compromised**	
Normal Battery Depletions	34		

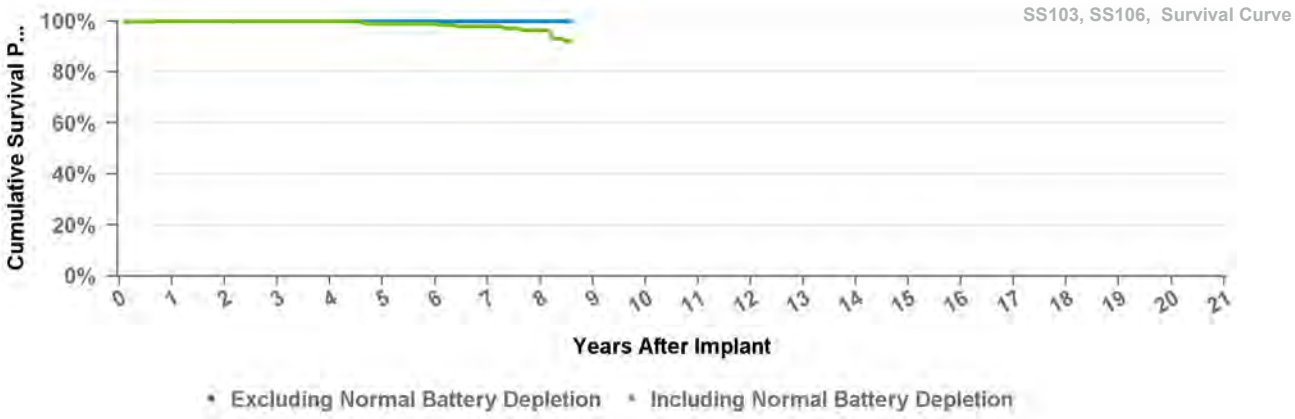


Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	92.1%
Effective Sample Size	600	473	371	294	225	189	154	122	101

IPG

SS106 Sigma 100 S

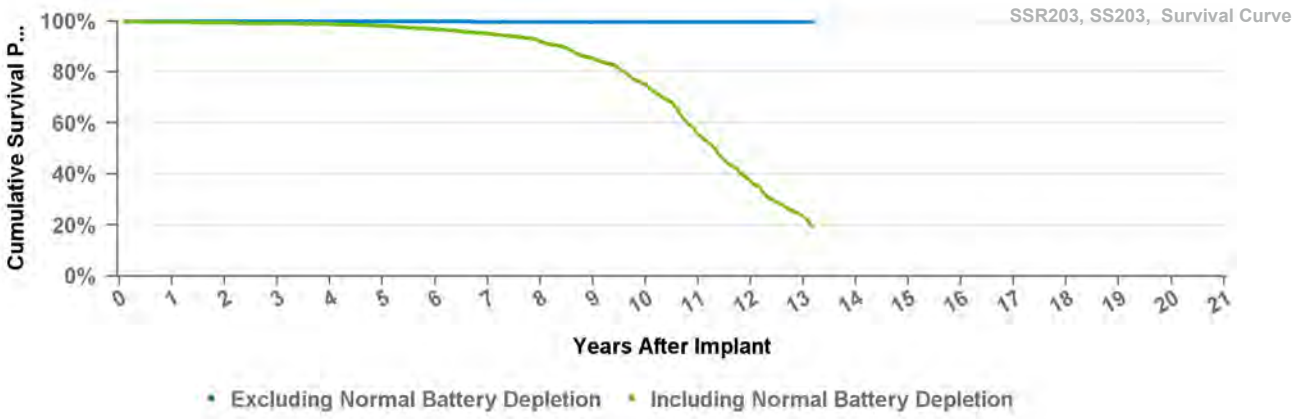
US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	68		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	8		



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	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	92.1%
Effective Sample Size	600	473	371	294	225	189	154	122	101

SS203 Sigma 200 S

US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		

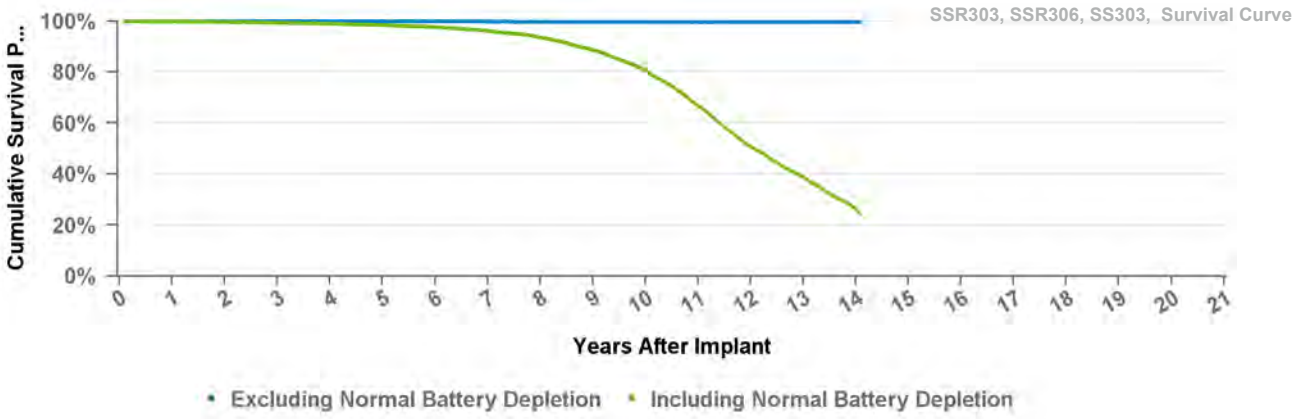


Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 158 mo
Excluding NBD	100.0%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.8%	98.1%	96.9%	95.1%	91.9%	85.3%	74.7%	55.6%	36.9%	23.2%	19.3%
Effective Sample Size	9080	7460	6152	5106	4214	3485	2816	2324	1817	1337	826	396	148	108

IPG

SS303 Sigma 300 S

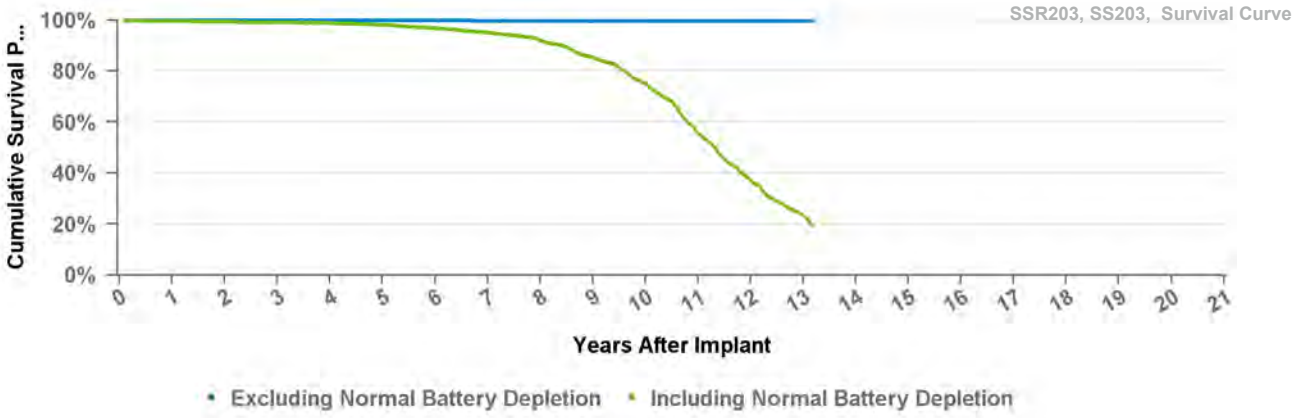
US Market Release	Sep-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	248		
Estimated Active USA Implants	49	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 169 mo
Excluding NBD	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.5%	66.7%	50.7%	38.8%	26.4%	24.3%
Effective Sample Size	41049	33923	28101	23368	19477	16207	13478	11214	9119	6860	4409	2386	1139	193	141

SSR203 Sigma 200 SR

US Market Release	Sep-99	**Total Malfunctions**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	12,119		
Estimated Active USA Implants	855	**Therapy Function Compromised**	**14**
Normal Battery Depletions	667	Electrical Interconnect	14

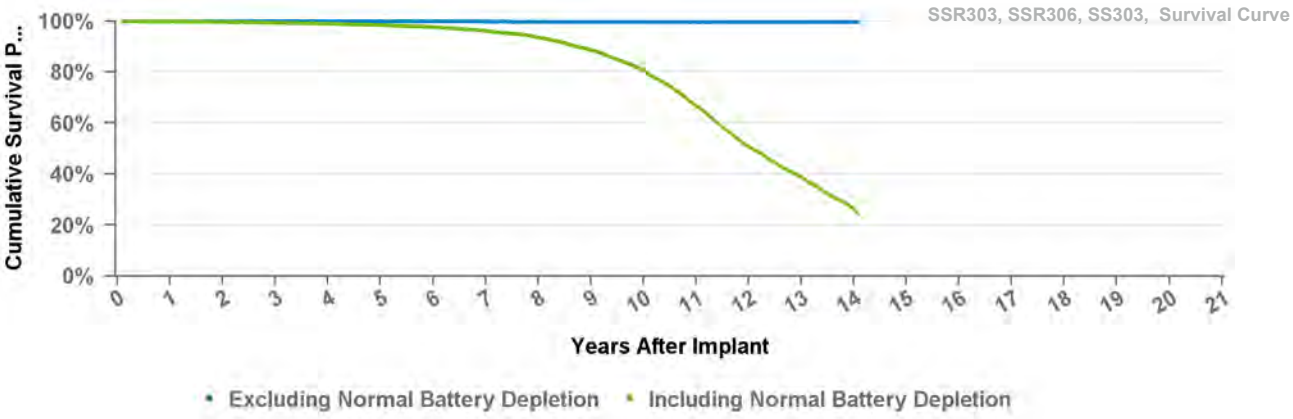


Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 158 mo
Excluding NBD	100.0%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.8%	98.1%	96.9%	95.1%	91.9%	85.3%	74.7%	55.6%	36.9%	23.2%	19.3%
Effective Sample Size	9080	7460	6152	5106	4214	3485	2816	2324	1817	1337	826	396	148	108

IPG

SSR303 Sigma 300 SR

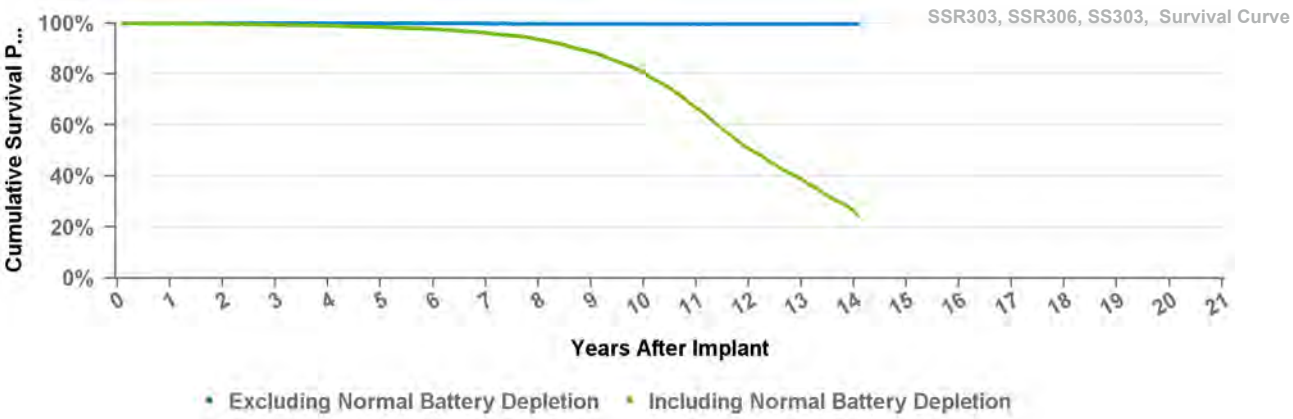
US Market Release	Aug-99	**Total Malfunctions**	**56**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**10**
Registered USA Implants	51,673	Electrical Interconnect	9
Estimated Active USA Implants	5,102	Other Malfunction	1
Normal Battery Depletions	2,671	**Therapy Function Compromised**	**46**
		Electrical Component	3
		Electrical Interconnect	43



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 169 mo
Excluding NBD	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.5%	66.7%	50.7%	38.8%	26.4%	24.3%
Effective Sample Size	41049	33923	28101	23368	19477	16207	13478	11214	9119	6860	4409	2386	1139	193	141

SSR306 Sigma 300 SR

US Market Release	Sep-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,216	Electrical Component	1
Estimated Active USA Implants	165	**Therapy Function Compromised**	**1**
Normal Battery Depletions	154	Electrical Interconnect	1

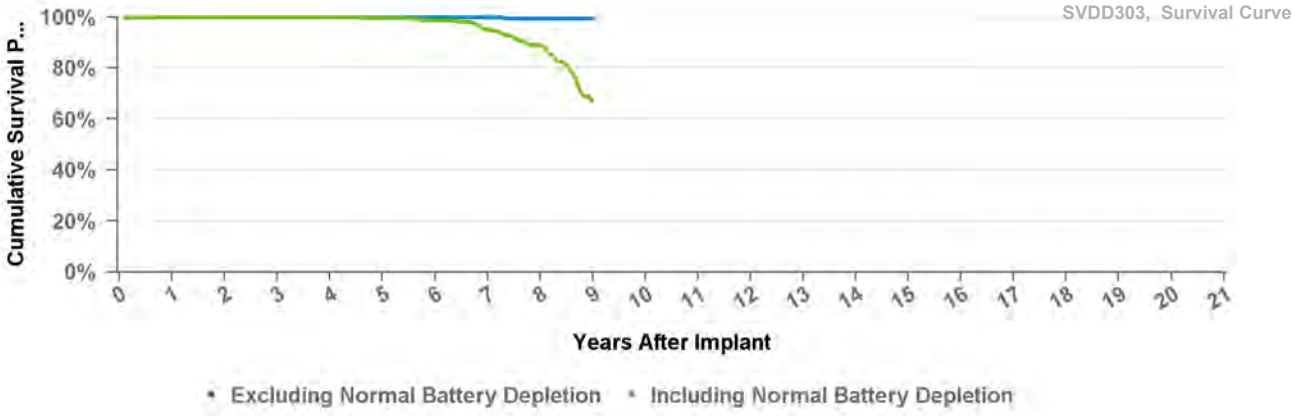


Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 169 mo
Excluding NBD	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.5%	66.7%	50.7%	38.8%	26.4%	24.3%
Effective Sample Size	41049	33923	28101	23368	19477	16207	13478	11214	9119	6860	4409	2386	1139	193	141

IPG

SVDD303 Sigma 300 VDD

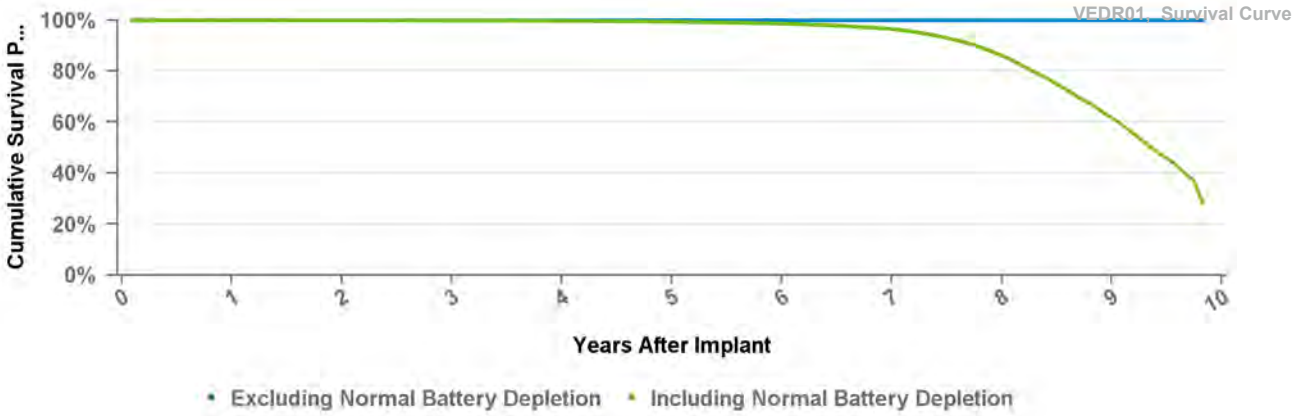
US Market Release	Sep-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	651		
Estimated Active USA Implants	42	**Therapy Function Compromised**	**1**
Normal Battery Depletions	82	Electrical Interconnect	1



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%	89.1%	66.9%
Effective Sample Size	529	459	411	363	315	263	209	164	103

VEDR01 Versa DR

US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**9**
Registered USA Implants	114,861	Electrical Component	7
Estimated Active USA Implants	67,354	Electrical Interconnect	2
Normal Battery Depletions	5,129	**Therapy Function Compromised**	**8**
		Electrical Component	4
		Other Malfunction	4



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	99.9%	99.9%	99.8%	99.7%	99.3%	98.6%	96.4%	86.0%	61.6%	28.0%
Effective Sample Size	96636	86514	75921	64990	53468	42216	30463	17472	5676	169

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 require to inform Medtronic whenever a lead event has occurred, a lead is modified, or when a patient is no longer participating. Timely, accurate, and complete reporting and analysis of safety information for surveillance is crucial for the protection of patients, clinicians, and the sponsor Medtronic continually evaluates the quality and integrity of the data through a combination of on-site and centralized monitoring activities.

Lead Complications

Chronic lead performance is characterized by estimating lead related complication free survival probabilities. For analysis purposes, the complication criteria, which align with the AdvaMed 'Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads', are defined below. These criteria do not, however, enable a lead integrity or "hardware" failure to be conclusively differentiated from other clinical events such as an undetected lead dislodgement, perforation, or concurrent pulse generator failure manifested as a sensing or capture problem.

Method for Estimating Lead Performance continued

All reported lead-related adverse events are classified by the reporting investigator and are adjudicated by an independent event adjudication committee[1]. A lead-related event with at least one of the following classifications that is adjudicated by the committee as a complication and occurs more than 30 days after implant is considered a product performance event and will contribute to the survival analysis endpoint. Events with an onset date of 30 days or less after the implant are considered procedure related and therefore are not included as product performance events. Product performance events 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-truncation[2]. PPR lead survival analysis is estimated using the Kaplan-Meier method, a statistical method to incorporate data from these retrospectively enrolled devices, left-truncated data, was applied. The statistical technique uses data from existing devices while appropriately adjusting the device survival curves for the time the device was not actively followed in the registry. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

On the following pages, each graph includes a survival curve for each lead model. The survival estimates is the probability that a lead is free of a product performance event at a given time point. For example, if a survival probability is 95% after 5 years of service, then the lead has a 5% chance of experiencing a lead-related complication in the first 5 years following implant.

The data in the tables is rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have one or more complications. This occurs because even with the complications, the data rounds to 100%.

The survival curves are statistical estimates. As sample size increases and performance experience accumulates, the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.

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

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.

Pacing Leads

3830 SelectSecure

US Market Release	Aug-05
CE Approval	Jan-03
Registered USA Implants	28,018
Estimated Active USA Implants	19,678
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	12
Insulation Breach	29
Other	3

US Acute Lead Observations

Cardiac Perforation	8
Conductor Fracture	2
Failure To Capture	35
Failure To Sense	3
Insulation Breach	1
Lead Dislodgement	53
Oversensing	5
Unspecified	2

Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	968
Cumulative Months of Followup	43,430
Number of Leads Active in Study	478

Qualifying Complications

13

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

Years	1	2	3	4	5	6	at 84 mo
%	99.2%	98.9%	98.9%	98.8%	98.5%	98.5%	98.5%
#	797	684	577	466	336	158	68

Ventricular Placement

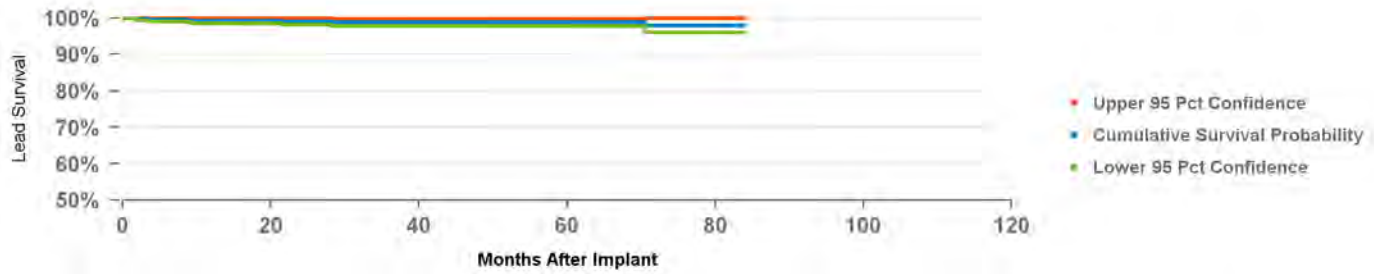
Product Surveillance Registry Results

Number of Leads Enrolled in Study	662
Cumulative Months of Followup	28,440
Number of Leads Active in Study	324

Qualifying Complications

8

Failure To Capture	2
Impedance Out of Range	1
Lead Dislodgement	4
Other	1



Years	1	2	3	4	5	6	at 84 mo
%	99.2%	99.0%	98.8%	98.8%	98.8%	98.0%	98.0%
#	518	454	373	286	206	95	54

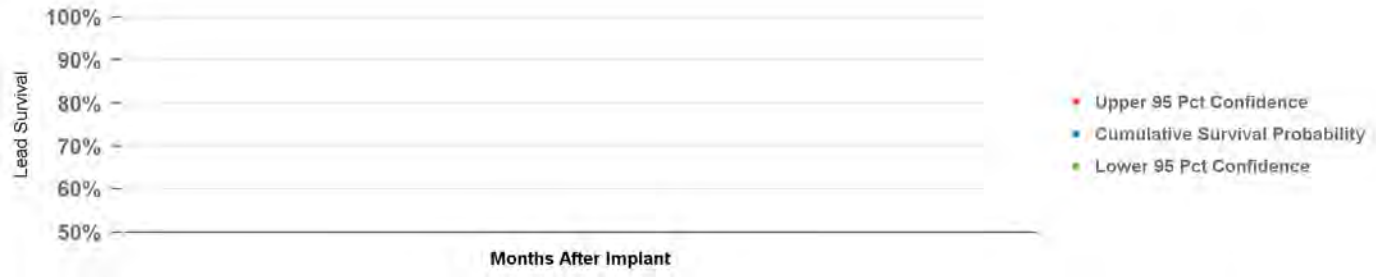
Pacing Leads

4073 CapSure Sense

US Market Release	Jun-02
CE Approval	Feb-02
Registered USA Implants	770
Estimated Active USA Implants	289
Fixation Type	Tines
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations



Years	at	mo
%		
#		

Pacing Leads

4074 CapSure Sense

US Market Release	Jun-02
CE Approval	Feb-02
Registered USA Implants	110,136
Estimated Active USA Implants	62,324
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Insulation Breach	34

US Acute Lead Observations

Cardiac Perforation	19
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	60
Failure To Sense	1
Impedance Abnormal	3
Lead Dislodgement	70
Oversensing	3

Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Followup	21,793
Number of Leads Active in Study	114

Qualifying Complications 1

Failure To Sense	1

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
#	214	205	198	179	162	154	146	131	118	87	60

Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,108
Cumulative Months of Followup	55,235
Number of Leads Active in Study	431

Qualifying Complications 8

Conductor Fracture	1
Failure To Capture	2

Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	2
Other	1

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	99.4%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.6%	98.6%
#	951	781	610	447	314	239	198	179	150	102	62

Pacing Leads

4076 CapSureFix Novus

US Market Release	Feb-04
CE Approval	Jun-04
Registered USA Implants	540,878
Estimated Active USA Implants	369,150
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	76
Crimp Weld Bond	1
Insulation Breach	90
Other	21

US Acute Lead Observations

Cardiac Perforation	85
Conductor Fracture	5
Extracardiac Stimulation	13
Failure To Capture	105
Failure To Sense	31
Impedance Abnormal	14
Insulation Breach	1
Lead Dislodgement	259
Oversensing	16
Unspecified	12

Atrial Placement

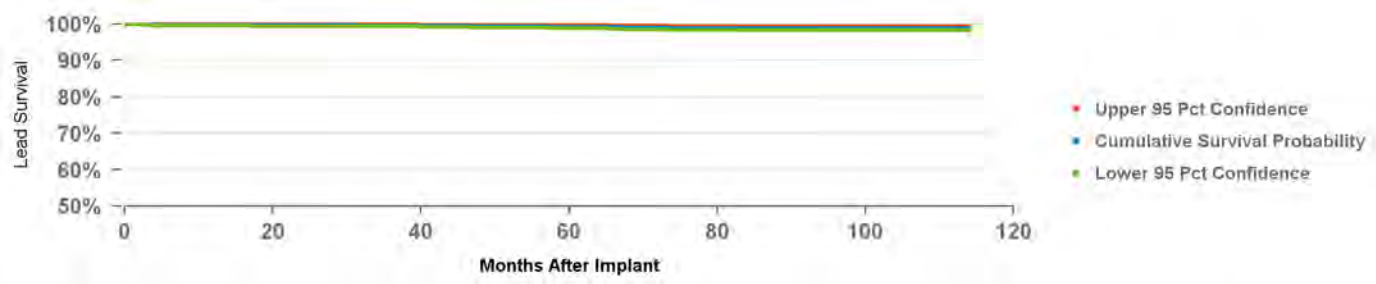
Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,143
Cumulative Months of Followup	140,663
Number of Leads Active in Study	1,592

Qualifying Complications

17

Cardiac Perforation	1	Insulation Breach	2
Conductor Fracture	2	Lead Dislodgement	5
Failure To Capture	3	Oversensing	1
Failure To Sense	3		



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.8%	99.7%	99.6%	99.4%	99.3%	99.0%	98.9%	98.9%	98.9%	98.9%
#	2,629	2,203	1,752	1,308	952	664	348	216	119	72

Ventricular Placement

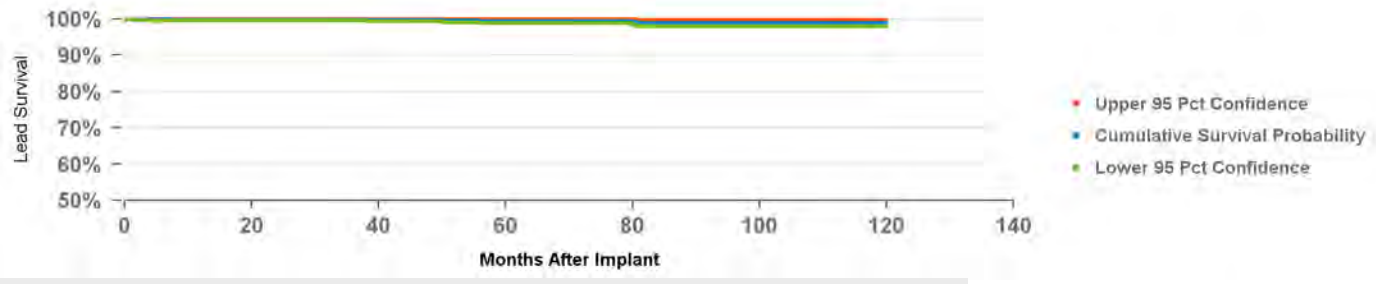
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,507
Cumulative Months of Followup	80,506
Number of Leads Active in Study	537

Qualifying Complications

8

Conductor Fracture	1	Impedance Out of Range	2
Extracardiac Stimulation	1	Lead Dislodgement	1
Failure To Capture	3		



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.8%	99.8%	99.8%	99.7%	99.4%	99.4%	98.9%	98.9%	98.9%	98.9%
#	1,297	1,135	965	786	611	493	288	197	126	59

Pacing Leads

4092 CapSure SP Novus

US Market Release	Sep-98
CE Approval	Apr-98
Registered USA Implants	186,941
Estimated Active USA Implants	68,554
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	17
Insulation Breach	66
Other	2

US Acute Lead Observations

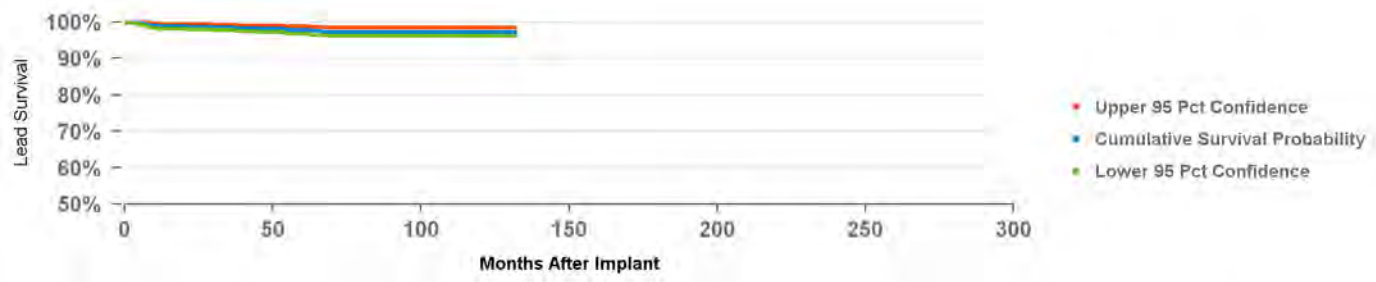
Cardiac Perforation	3
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,187
Cumulative Months of Followup	67,221
Number of Leads Active in Study	36

Qualifying Complications 21

Conductor Fracture	3	Impedance Out of Range	1
Extracardiac Stimulation	1	Lead Dislodgement	4
Failure To Capture	12		



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.8%	98.7%	98.5%	98.1%	97.8%	97.3%	97.3%	97.3%	97.3%	97.3%	97.3%
#	942	834	734	622	506	393	320	259	211	130	67

Pacing Leads

4568 CapSureFix

US Market Release	Jan-97
CE Approval	
Registered USA Implants	69,467
Estimated Active USA Implants	15,184
Fixation Type	J-shape, screw in
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Insulation Breach	113
Other	52

US Acute Lead Observations

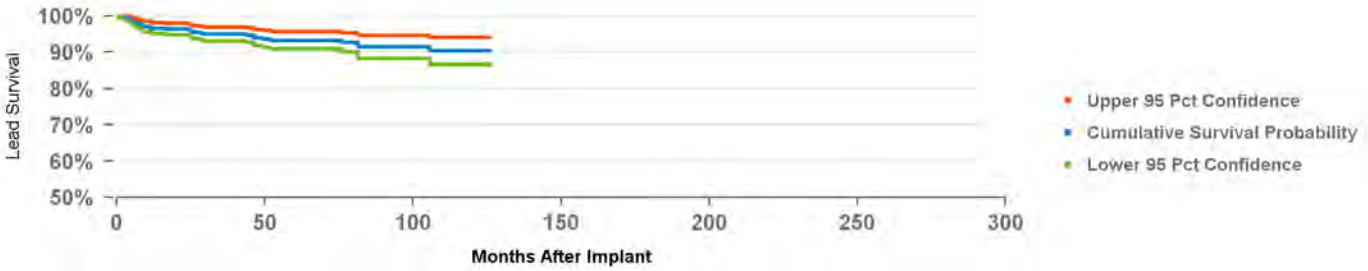
Cardiac Perforation	3
Conductor Fracture	1
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	2
Lead Dislodgement	4
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	671
Cumulative Months of Followup	32,022
Number of Leads Active in Study	9

Qualifying Complications 38

Conductor Fracture	1	Impedance Out of Range	3
Failure To Capture	20	Lead Dislodgement	9
Failure To Sense	4	Medical Judgment	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	96.6%	96.2%	95.0%	94.0%	93.2%	93.2%	91.4%	91.4%	90.4%	90.4%	90.4%
#	493	419	328	276	228	173	139	105	84	63	51

4574 CapSure Sense

US Market Release	Jun-02
CE Approval	Feb-02
Registered USA Implants	75,460
Estimated Active USA Implants	46,153
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Insulation Breach	11

US Acute Lead Observations

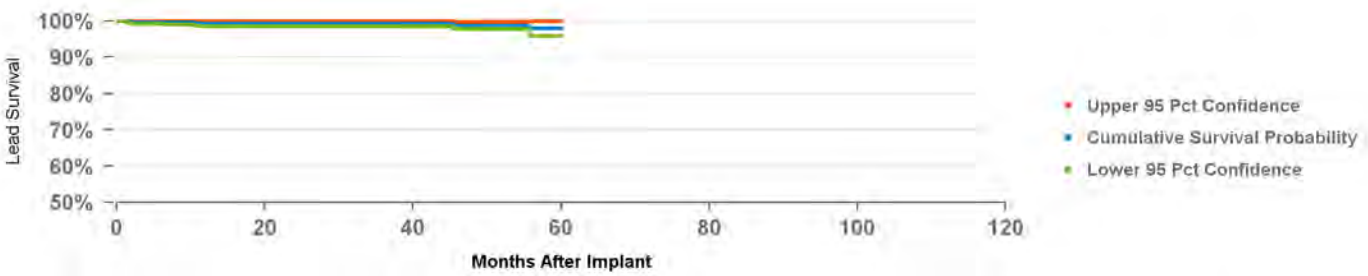
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	34
Failure To Sense	12
Impedance Abnormal	1
Lead Dislodgement	85
Oversensing	1
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	962
Cumulative Months of Followup	26,694
Number of Leads Active in Study	616

Qualifying Complications 8

Conductor Fracture	2	Lead Dislodgement	5
Failure To Capture	1		



Years	1	2	3	4	at 60 mo
%	99.2%	99.2%	99.2%	98.8%	97.9%
#	701	457	319	191	68

Pacing Leads

4592 CapSure SP Novus

US Market Release	Oct-98
CE Approval	Apr-98
Registered USA Implants	89,445
Estimated Active USA Implants	34,502
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Insulation Breach	27

US Acute Lead Observations

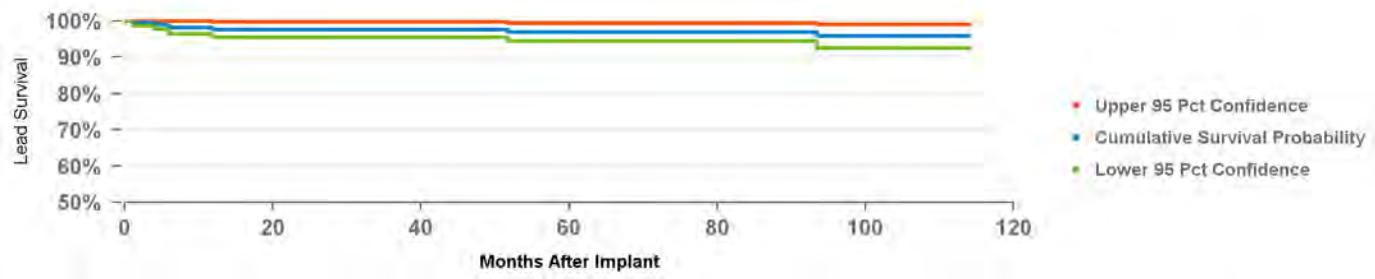
Failure To Capture	10
Failure To Sense	2
Insulation Breach	1
Lead Dislodgement	36
Oversensing	2
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	347
Cumulative Months of Followup	17,859
Number of Leads Active in Study	62

Qualifying Complications 7

Failure To Capture	4
Failure To Sense	1
Lead Dislodgement	2



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	97.6%	97.6%	97.6%	97.6%	96.9%	96.9%	96.9%	95.8%	95.8%	95.8%
#	231	201	168	151	124	107	86	74	63	55

Pacing Leads

5054 CapSure Z Novus

US Market Release	Jun-98
CE Approval	Jun-97
Registered USA Implants	99,529
Estimated Active USA Implants	34,668
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp Weld Bond	1
Insulation Breach	35
Other	3

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	1
Failure To Capture	23
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	29
Unspecified	9

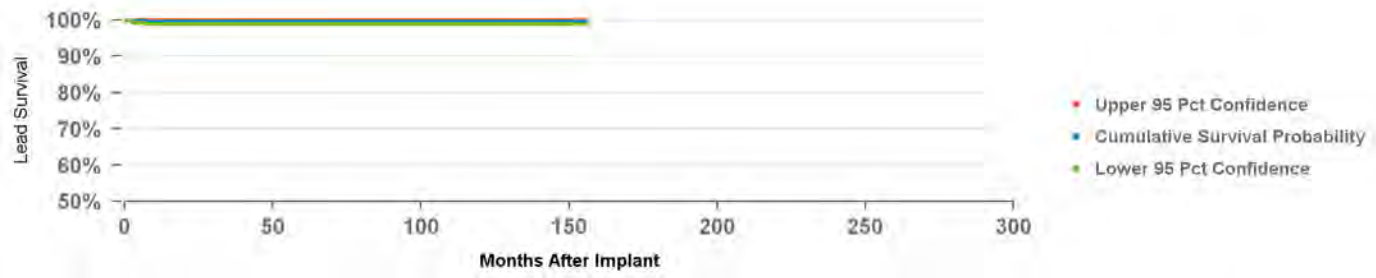
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Cumulative Months of Followup	38,130
Number of Leads Active in Study	69

Qualifying Complications 2

Failure To Capture	1	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 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%	99.5%
#	412	392	359	322	289	252	219	185	152	128	104	79	50

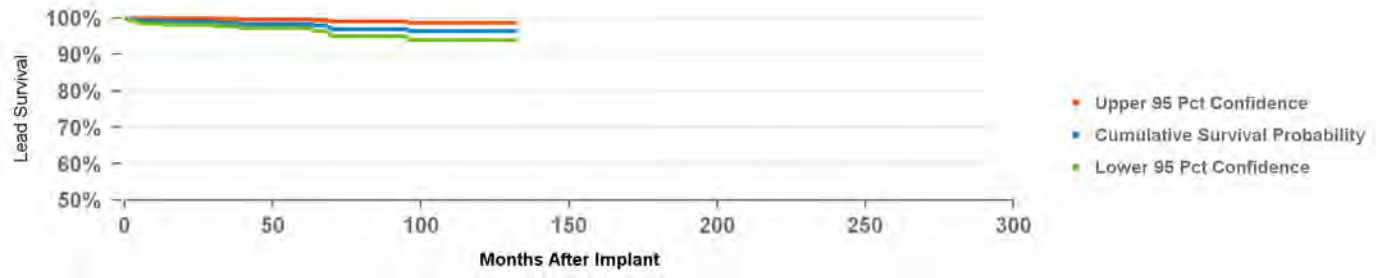
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	984
Cumulative Months of Followup	33,036
Number of Leads Active in Study	37

Qualifying Complications 11

Failure To Capture	7	Impedance Out of Range	1
Failure To Sense	2	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.3%	99.1%	98.8%	98.4%	98.4%	97.0%	97.0%	96.3%	96.3%	96.3%	96.3%
#	481	394	306	263	225	187	162	137	102	82	60

Pacing Leads

5068 CapSureFix

US Market Release	Jan-97
CE Approval	
Registered USA Implants	102,344
Estimated Active USA Implants	21,102
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	47
Crimp Weld Bond	2
Insulation Breach	65
Other	82

US Acute Lead Observations

Cardiac Perforation	18
Conductor Fracture	4
Failure To Capture	31
Failure To Sense	5
Impedance Abnormal	1
Insulation Breach	1
Lead Dislodgement	20
Oversensing	1
Unspecified	7

Atrial Placement

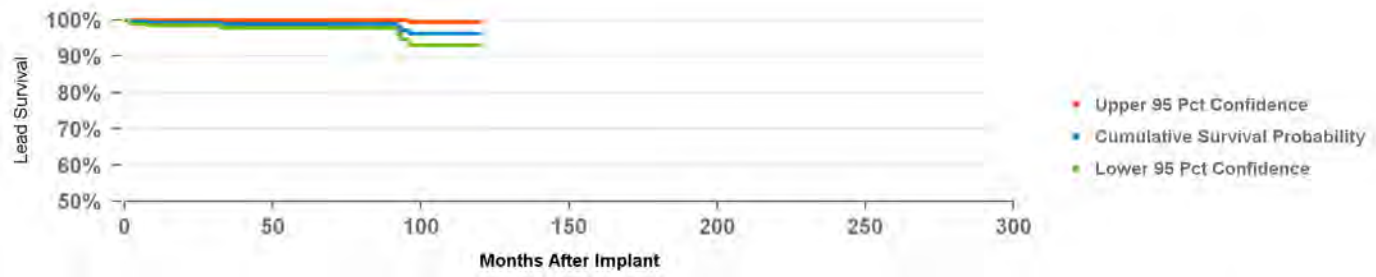
Product Surveillance Registry Results

Number of Leads Enrolled in Study	985
Cumulative Months of Followup	27,702
Number of Leads Active in Study	24

Qualifying Complications

8

Failure To Capture	3
Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	2
Oversensing	1



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.3%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	96.2%	96.2%	96.2%
#	364	316	265	229	196	156	129	99	66	56

Ventricular Placement

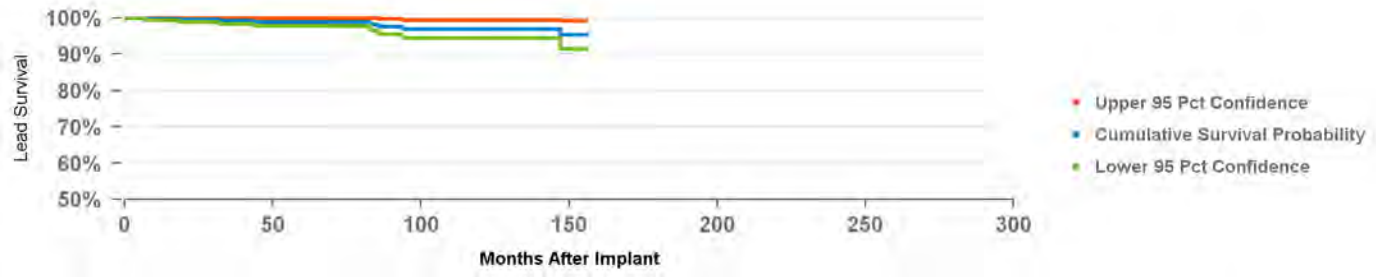
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,373
Cumulative Months of Followup	33,497
Number of Leads Active in Study	35

Qualifying Complications

9

Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	2
Impedance Out of Range	1
Insulation Breach	2
Lead Dislodgement	1
Oversensing	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.8%	99.6%	99.2%	98.9%	98.9%	98.9%	98.2%	96.9%	96.9%	96.9%	96.9%	96.9%	95.3%
#	454	364	293	247	222	188	151	126	105	89	73	61	54

Pacing Leads

5072 SureFix

US Market Release	Jun-98
CE Approval	Sep-97
Registered USA Implants	10,053
Estimated Active USA Implants	3,169
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Insulation Breach	9

US Acute Lead Observations

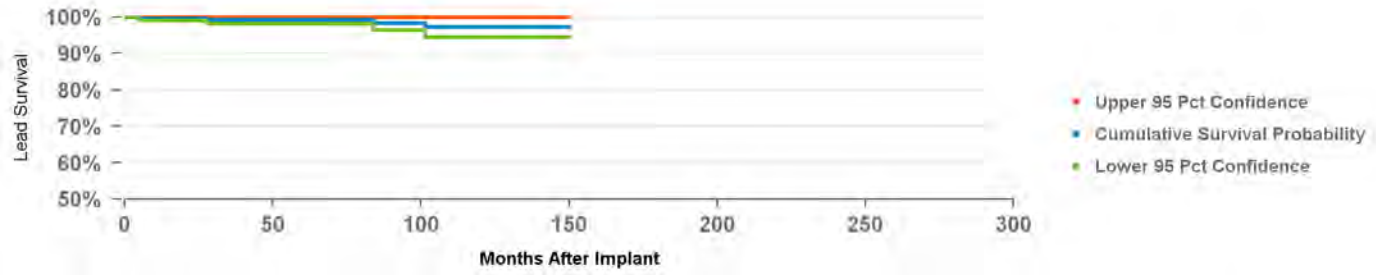
Failure To Capture	2
Lead Dislodgement	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	517
Cumulative Months of Followup	23,196
Number of Leads Active in Study	13

Qualifying Complications 4

Cardiac Perforation	1
Failure To Capture	2
Failure To Sense	1



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%	98.4%	98.4%	97.3%	97.3%	97.3%	97.3%	97.3%
#	265	236	218	192	158	136	109	92	81	72	63	53	51

Pacing Leads

5076 CapSureFix Novus

US Market Release	Aug-00
CE Approval	Aug-99
Registered USA Implants	2,133,965
Estimated Active USA Implants	1,348,691
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	750
Insulation Breach	749
Other	205

US Acute Lead Observations

Cardiac Perforation	600
Conductor Fracture	21
Extracardiac Stimulation	48
Failure To Capture	676
Failure To Sense	173
Impedance Abnormal	44
Insulation Breach	9
Lead Dislodgement	1,760
Oversensing	136
Unspecified	31

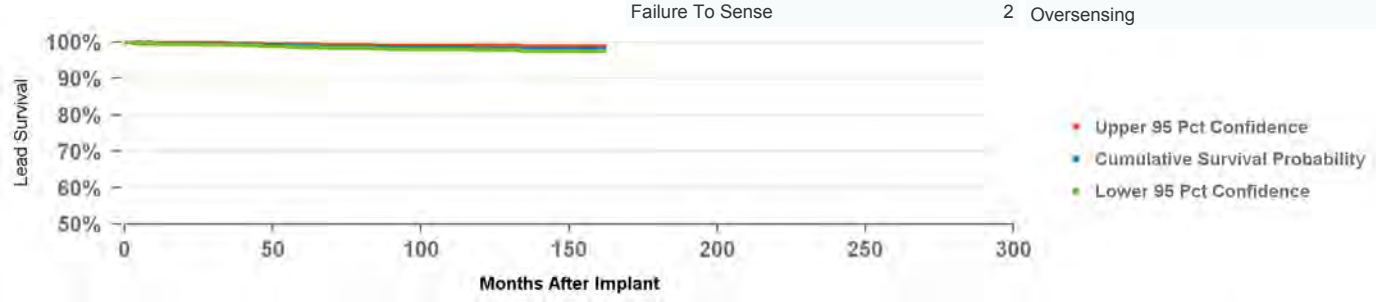
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	7,272
Cumulative Months of Followup	275,934
Number of Leads Active in Study	3,763

Qualifying Complications 46

Cardiac Perforation	2	Impedance Out of Range	4
Conductor Fracture	8	Insulation Breach	1
Extracardiac Stimulation	2	Lead Dislodgement	15
Failure To Capture	8	Other	2
Failure To Sense	2	Oversensing	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.6%	99.5%	99.4%	99.2%	98.9%	98.7%	98.6%	98.5%	98.5%	98.4%	98.4%	98.1%	98.1%	98.1%
#	4,962	3,891	3,021	2,123	1,652	1,236	922	721	570	414	266	150	81	59

Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,346
Cumulative Months of Followup	96,740
Number of Leads Active in Study	645

Qualifying Complications 25

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	4	Lead Dislodgement	3
Failure To Capture	10	Other	1
Failure To Sense	1	Oversensing	1

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.3%	99.2%	98.9%	98.9%	98.4%	98.1%	97.6%	97.0%	97.0%	96.5%	96.5%	95.5%
#	1,653	1,337	1,021	683	557	457	362	292	231	187	145	93	53

Pacing Leads

5086MRI CapsureFix Novus MRI

US Market Release	Feb-11
CE Approval	Jan-09
Registered USA Implants	208,438
Estimated Active USA Implants	187,092
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	30
Insulation Breach	77
Other	12

US Acute Lead Observations

Cardiac Perforation	212
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	140
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	308
Oversensing	30

Atrial Placement

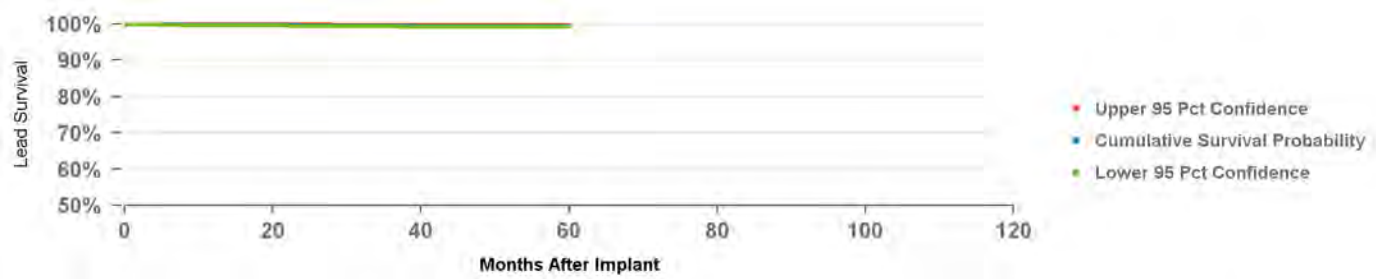
Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,081
Cumulative Months of Followup	110,182
Number of Leads Active in Study	1,840

Qualifying Complications

14

Conductor Fracture	2	Lead Dislodgement	10
Failure To Capture	1	Oversensing	1



Years	1	2	3	4	at 60 mo
%	99.8%	99.6%	99.6%	99.5%	99.5%
#	2,662	2,273	1,748	963	87

Ventricular Placement

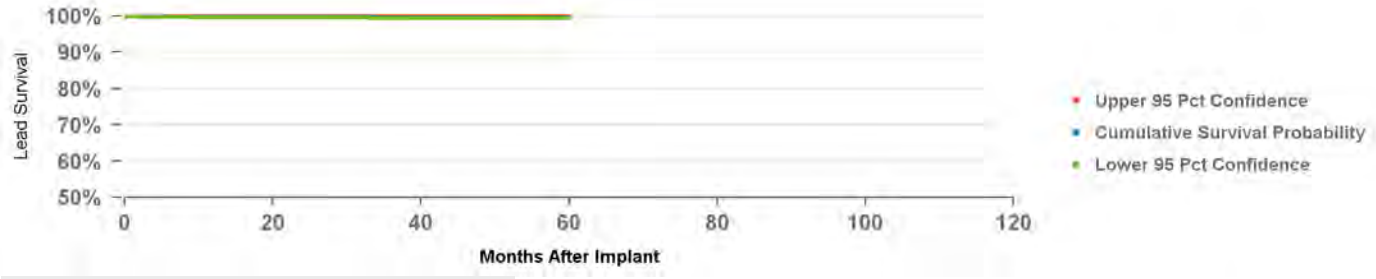
Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,034
Cumulative Months of Followup	109,440
Number of Leads Active in Study	1,806

Qualifying Complications

10

Failure To Capture	5	Impedance Out of Range	1
Failure To Sense	1	Lead Dislodgement	3



Years	1	2	3	4	at 60 mo
%	99.8%	99.7%	99.6%	99.6%	99.6%
#	2,650	2,258	1,730	952	86

Pacing Leads

5092 CapSure SP Novus

US Market Release	Jun-98
CE Approval	Sep-97
Registered USA Implants	140,987
Estimated Active USA Implants	53,761
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	20
Insulation Breach	50
Other	3

US Acute Lead Observations

Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	49
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified	9

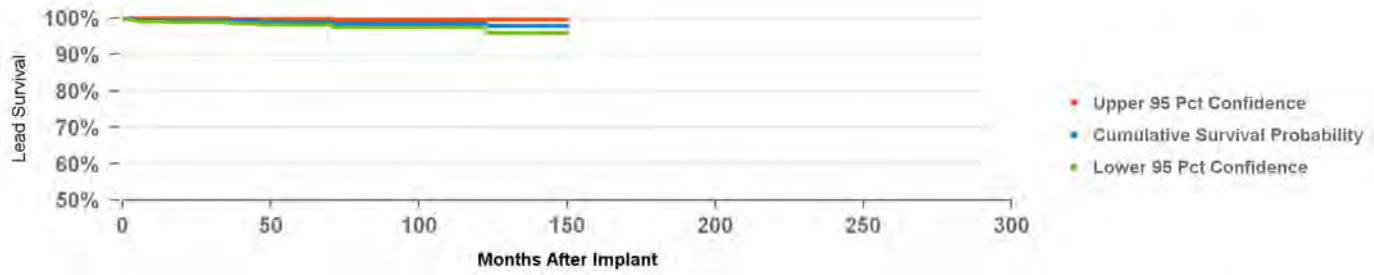
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,207
Cumulative Months of Followup	52,197
Number of Leads Active in Study	43

Qualifying Complications

10

Extracardiac Stimulation	1	Impedance Out of Range	1
Failure To Capture	3	Lead Dislodgement	5



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.7%	97.7%	97.7%
#	825	658	519	415	325	252	207	163	136	118	95	70	61

5554 CapSure Z Novus

US Market Release	Jun-98
CE Approval	Jun-97
Registered USA Implants	64,449
Estimated Active USA Implants	24,800
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Insulation Breach	30
Other	2

US Acute Lead Observations

Conductor Fracture	1
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Lead Dislodgement	38
Unspecified	3

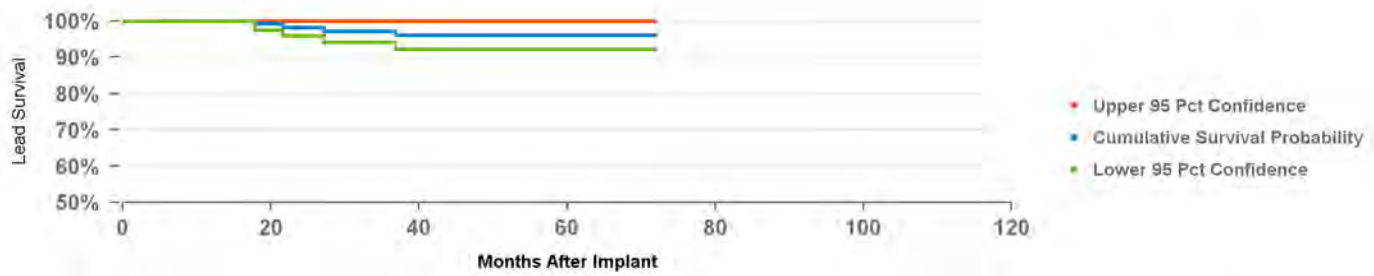
Product Surveillance Registry Results

Number of Leads Enrolled in Study	359
Cumulative Months of Followup	8,572
Number of Leads Active in Study	9

Qualifying Complications

5

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



Years	1	2	3	4	5	at 72 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%
#	151	114	88	77	60	50

Pacing Leads

5592 CapSure SP Novus

US Market Release	Jun-98
CE Approval	Sep-97
Registered USA Implants	37,160
Estimated Active USA Implants	17,268
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Insulation Breach	4
Other	1

US Acute Lead Observations

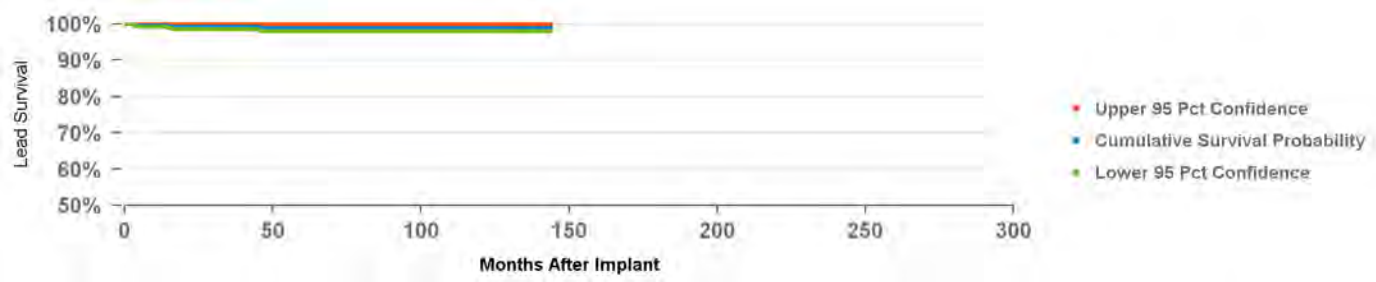
Cardiac Perforation	1
Failure To Capture	4
Failure To Sense	3
Lead Dislodgement	43
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	707
Cumulative Months of Followup	36,123
Number of Leads Active in Study	47

Qualifying Complications 5

Failure To Capture	3
Lead Dislodgement	2



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.6%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	531	441	356	291	233	181	150	131	109	94	79	54

5594 CapSure SP Novus

US Market Release	Jun-01
CE Approval	Mar-01
Registered USA Implants	17,575
Estimated Active USA Implants	9,739
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

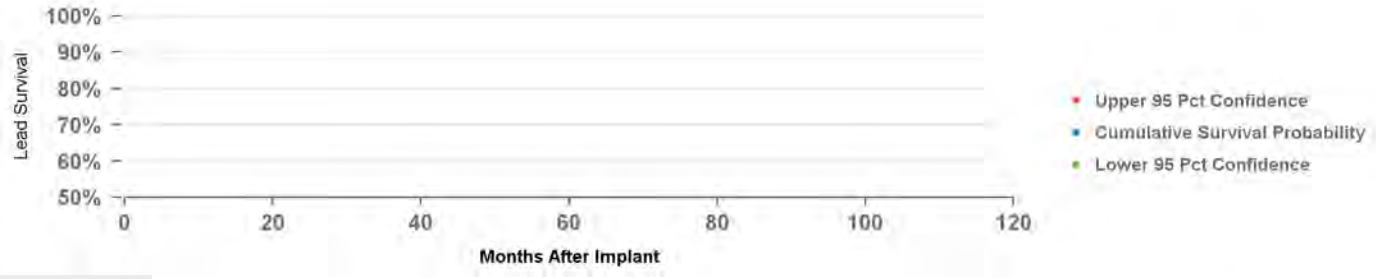
Conductor Fracture	13
Insulation Breach	12

US Acute Lead Observations

Failure To Capture	4
Lead Dislodgement	14
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	28
Cumulative Months of Followup	2,047
Number of Leads Active in Study	9



Years	at 0 mo
%	100.0%
#	

Pacing Leads

6940 CapSureFix

US Market Release	Oct-98
CE Approval	
Registered USA Implants	25,368
Estimated Active USA Implants	5,365
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Insulation Breach	21
Other	12

US Acute Lead Observations

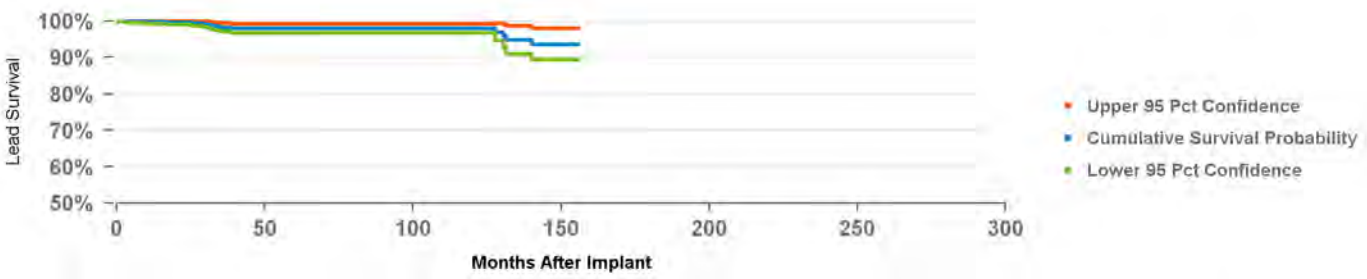
Conductor Fracture	1
Failure To Capture	1
Impedance Abnormal	1
Lead Dislodgement	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	848
Cumulative Months of Followup	43,778
Number of Leads Active in Study	33

Qualifying Complications 14

Conductor Fracture	1
Failure To Capture	1
Failure To Sense	3
Lead Dislodgement	3
Oversensing	6



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%
#	645	527	429	347	278	218	188	151	125	96	80	70	52

Defibrillation Leads

6721 Epicardial Patch

US Market Release	Mar-94
CE Approval	Jan-93
Registered USA Implants	3,137
Estimated Active USA Implants	1,062
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	14
Insulation Breach	1

US Acute Lead Observations

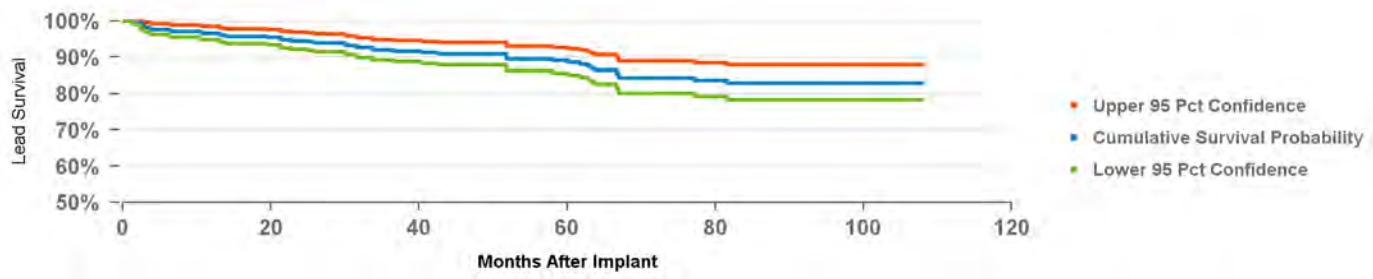
Cardiac Perforation	1
Conductor Fracture	2
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	8
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	415
Cumulative Months of Followup	23,685
Number of Leads Active in Study	5

Qualifying Complications 47

Conductor Fracture	21
Failure To Capture	8
Impedance Out of Range	4
Insulation Breach	2
Oversensing	12



Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.5%	92.0%	90.9%	89.1%	84.4%	83.0%	83.0%	83.0%
#	344	315	269	216	185	132	99	64	55

6930 Sprint Fidelis

US Market Release	Sep-04
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	123
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

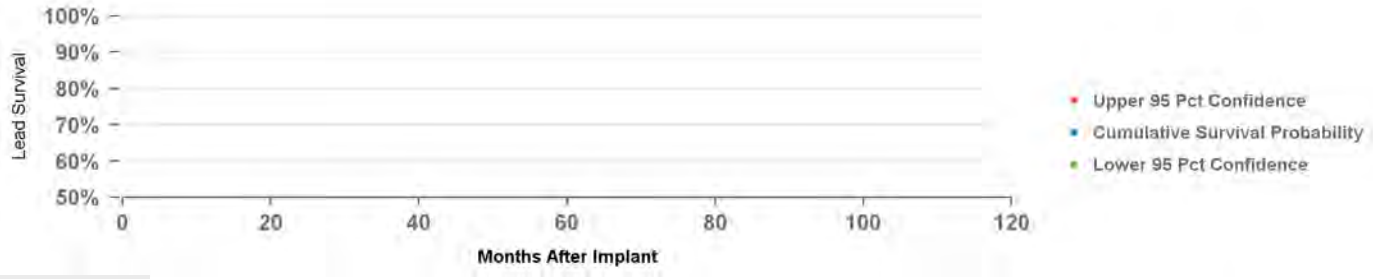
Conductor Fracture	5

US Acute Lead Observations

Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Followup	256
Number of Leads Active in Study	1



Years	at 0 mo
%	100.0%
#	

Defibrillation Leads

6931 Sprint Fidelis

US Market Release	Sep-04
CE Approval	
Registered USA Implants	8,075
Estimated Active USA Implants	2,330
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	627
Insulation Breach	1
Other	5

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	2
Failure To Capture	1
Failure To Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified	1

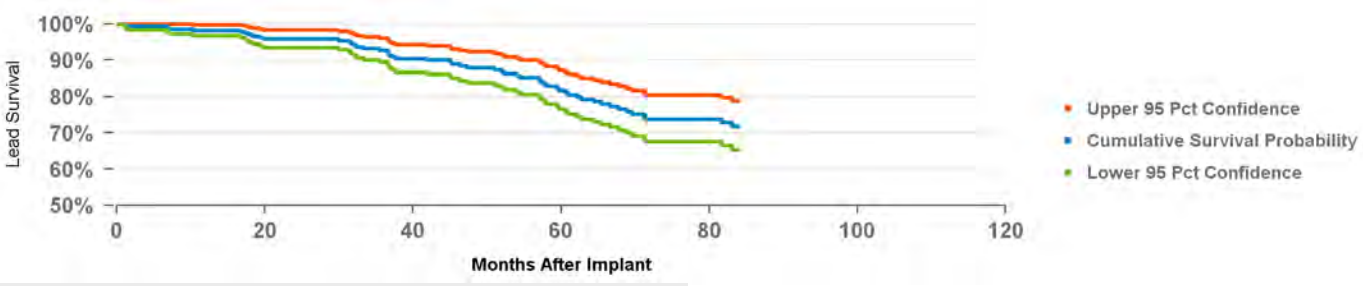
Product Surveillance Registry Results

Number of Leads Enrolled in Study	308
Cumulative Months of Followup	16,782
Number of Leads Active in Study	29

Qualifying Complications

59

Conductor Fracture	36
Failure To Capture	3
Failure To Sense	1
Impedance Out of Range	10
Lead Dislodgement	2
Oversensing	7



Years	1	2	3	4	5	6	at 84 mo
%	98.2%	95.8%	92.7%	87.9%	81.8%	73.8%	71.8%
#	270	238	209	167	136	99	61

6935 Sprint Quattro Secure S

US Market Release	Nov-08
CE Approval	Mar-08
Registered USA Implants	55,655
Estimated Active USA Implants	45,235
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	213
Insulation Breach	8
Other	40

US Acute Lead Observations

Cardiac Perforation	21
Conductor Fracture	1
Failure To Capture	20
Failure To Sense	8
Impedance Abnormal	17
Insulation Breach	1
Lead Dislodgement	42
Oversensing	49
Unspecified	5

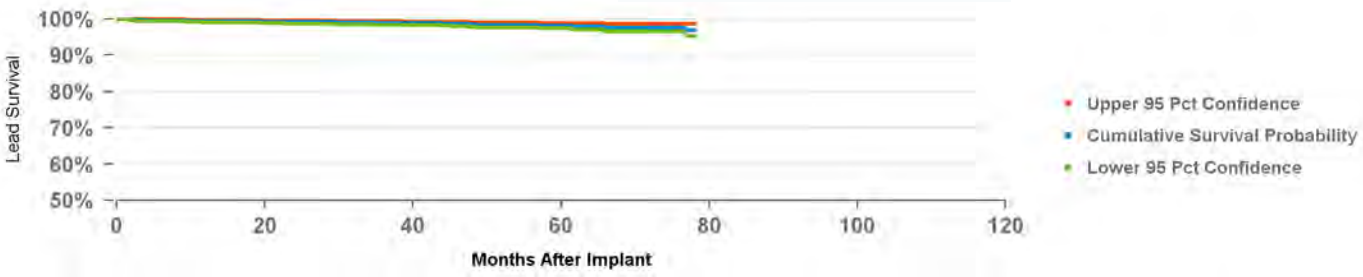
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,529
Cumulative Months of Followup	93,525
Number of Leads Active in Study	1,171

Qualifying Complications

34

Cardiac Perforation	1
Conductor Fracture	13
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	1
Impedance Out of Range	2
Lead Dislodgement	7
Other	1
Oversensing	6



Years	1	2	3	4	5	6	at 78 mo
%	99.4%	99.2%	98.9%	98.5%	98.2%	97.6%	97.0%
#	2,143	1,704	1,281	803	426	197	108

Defibrillation Leads

6935M Sprint Quattro Secure S

US Market Release	Aug-12
CE Approval	Jul-12
Registered USA Implants	114,336
Estimated Active USA Implants	108,393
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	84
Insulation Breach	2
Other	9

US Acute Lead Observations

Cardiac Perforation	50
Conductor Fracture	3
Extracardiac Stimulation	8
Failure To Capture	105
Failure To Sense	17
Impedance Abnormal	29
Insulation Breach	1
Lead Dislodgement	152
Oversensing	75

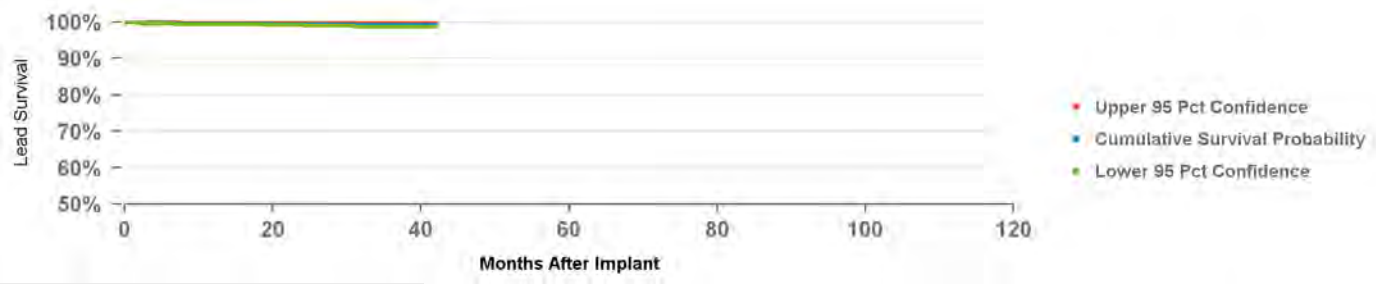
Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,616
Cumulative Months of Followup	63,880
Number of Leads Active in Study	3,804

Qualifying Complications

19

Cardiac Perforation	1
Conductor Fracture	4
Failure To Capture	4
Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	7
Oversensing	1



Years	1	2	3	at 42 mo
%	99.6%	99.4%	99.1%	99.1%
#	2,280	997	276	89

6937A Transvene SVC-CS

US Market Release	Apr-01
CE Approval	
Registered USA Implants	2,297
Estimated Active USA Implants	1,351
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	5

US Acute Lead Observations

Conductor Fracture	3
Unspecified	2

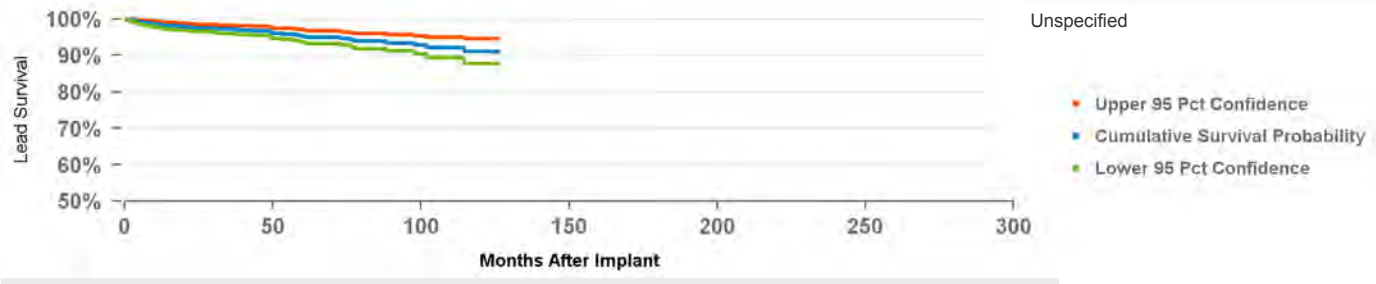
Product Surveillance Registry Results

Number of Leads Enrolled in Study	972
Cumulative Months of Followup	54,349
Number of Leads Active in Study	10

Qualifying Complications

48

Conductor Fracture	16
Extracardiac Stimulation	4
Failure To Capture	6
Failure To Sense	1
Impedance Out of Range	3
Insulation Breach	2
Lead Dislodgement	1
Other	1
Oversensing	10
Unspecified	4



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%
#	826	693	579	487	386	310	217	168	109	71	56

Defibrillation Leads

6942 Sprint

US Market Release	Jul-97
CE Approval	
Registered USA Implants	17,673
Estimated Active USA Implants	3,952
Fixation Type	Tines
Pace Sense Polarity	Integrated Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Crimp Weld Bond	1
Insulation Breach	26
Other	4

US Acute Lead Observations

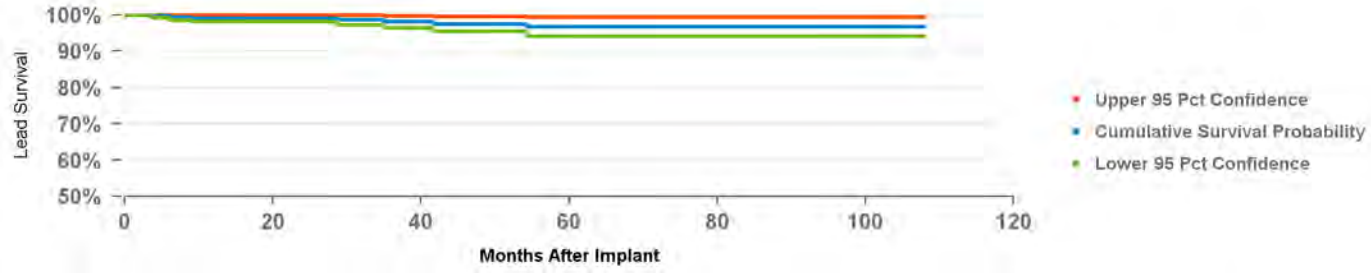
Conductor Fracture	1
Failure To Capture	4
Impedance Abnormal	2
Lead Dislodgement	1
Oversensing	2
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	364
Cumulative Months of Followup	19,474
Number of Leads Active in Study	14

Qualifying Complications 7

Conductor Fracture	1
Failure To Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified	1



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%
#	311	241	184	140	113	93	72	63	51

6943 Sprint

US Market Release	Oct-97
CE Approval	
Registered USA Implants	20,581
Estimated Active USA Implants	4,720
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	88
Crimp Weld Bond	1
Insulation Breach	32
Other	4

US Acute Lead Observations

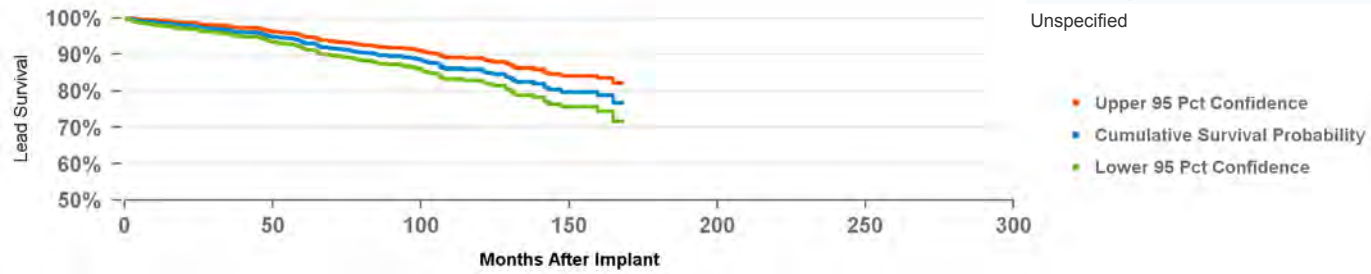
Cardiac Perforation	1
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	1
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,340
Cumulative Months of Followup	85,454
Number of Leads Active in Study	110

Qualifying Complications 111

Conductor Fracture	31
Failure To Capture	11
Failure To Sense	7
Impedance Out of Range	9
Insulation Breach	2
Lead Dislodgement	2
Other	2
Oversensing	44
Unspecified	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	98.5%	97.7%	96.5%	95.4%	93.3%	91.4%	90.2%	89.2%	86.2%	85.9%	82.6%	80.5%	79.9%	76.8%
#	1,161	978	853	702	584	477	395	325	271	215	180	137	88	52

Defibrillation Leads

6944 Sprint Quattro

US Market Release	Dec-00
CE Approval	Nov-99
Registered USA Implants	44,757
Estimated Active USA Implants	20,263
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	164
Crimp Weld Bond	1
Insulation Breach	4
Other	6

US Acute Lead Observations

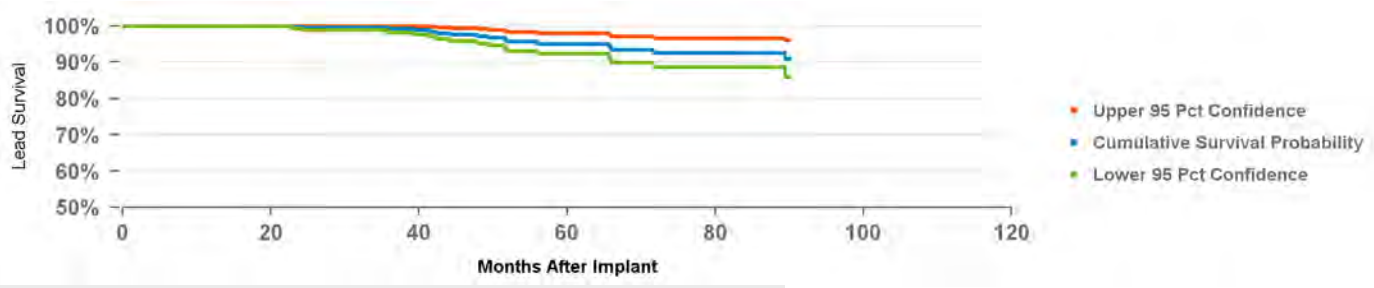
Conductor Fracture	2
Failure To Capture	16
Failure To Sense	3
Impedance Abnormal	11
Lead Dislodgement	22
Oversensing	13
Unspecified	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	600
Cumulative Months of Followup	26,607
Number of Leads Active in Study	201

Qualifying Complications 21

Conductor Fracture	12	Impedance Out of Range	3
Failure To Capture	2	Oversensing	2
Failure To Sense	1	Unspecified	1



Years	1	2	3	4	5	6	7	at 90 mo
%	100.0%	99.8%	99.2%	97.2%	95.1%	92.5%	92.5%	90.8%
#	511	411	314	218	134	92	62	50

Defibrillation Leads

6945 Sprint

US Market Release	Sep-97
CE Approval	
Registered USA Implants	42,695
Estimated Active USA Implants	9,565
Fixation Type	Active Screw In
Pace Sense Polarity	Integrated Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	147
Crimp Weld Bond	1
Insulation Breach	46
Other	6

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

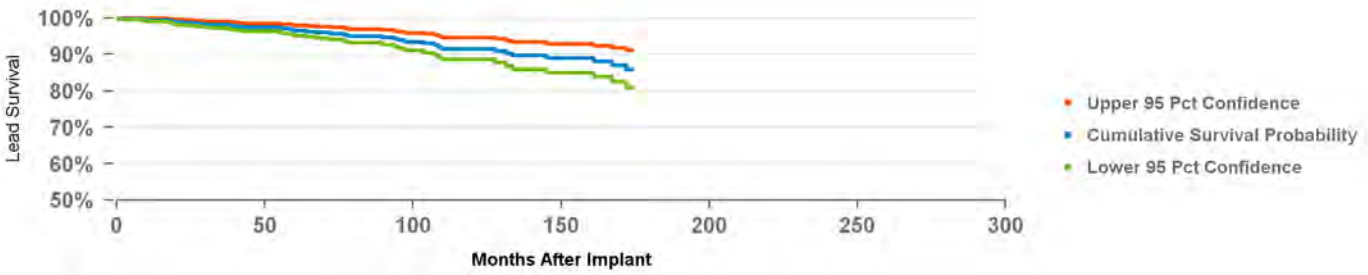
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,199
Cumulative Months of Followup	67,766
Number of Leads Active in Study	81

Qualifying Complications

45

Conductor Fracture	11
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	4
Impedance Out of Range	7
Oversensing	19
Unspecified	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	99.4%	98.6%	98.1%	97.5%	96.5%	95.7%	95.0%	93.9%	92.5%	91.5%	90.3%	89.6%	88.9%	87.0%	85.9%
#	1,024	832	658	521	403	313	273	229	186	155	133	118	94	64	53

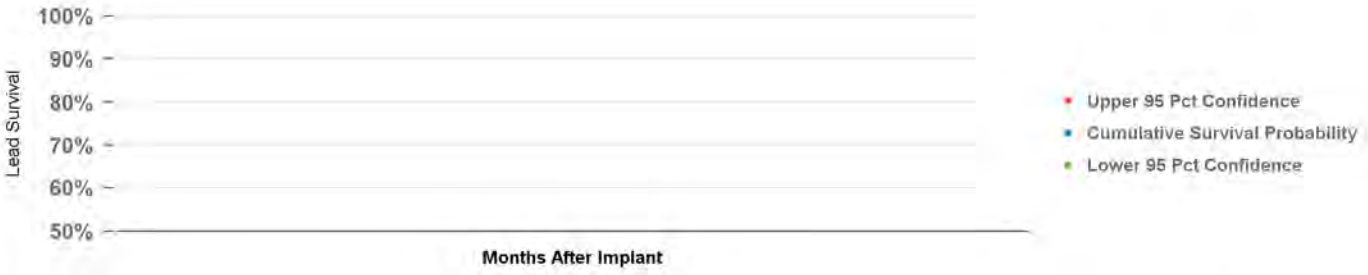
6946M Sprint Quattro

US Market Release	Jan-16
CE Approval	Sep-13
Registered USA Implants	228
Estimated Active USA Implants	224
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations

Lead Dislodgement	1
Oversensing	2



Years	at mo
%	
#	

Defibrillation Leads

6947 Sprint Quattro Secure

US Market Release	Nov-01
CE Approval	Oct-01
Registered USA Implants	373,104
Estimated Active USA Implants	207,968
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	850
Crimp Weld Bond	4
Insulation Breach	79
Other	215

US Acute Lead Observations

Cardiac Perforation	28
Conductor Fracture	21
Extracardiac Stimulation	2
Failure To Capture	77
Failure To Sense	34
Impedance Abnormal	56
Insulation Breach	4
Lead Dislodgement	115
Oversensing	126
Unspecified	22

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,131
Cumulative Months of Followup	204,747
Number of Leads Active in Study	1,419

Qualifying Complications

64

Conductor Fracture	22
Failure To Capture	3
Failure To Sense	2
Impedance Out of Range	10
Insulation Breach	5
Lead Dislodgement	5
Oversensing	15
Unspecified	2

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.3%	99.1%	98.7%	98.3%	98.0%	97.4%	97.1%	96.6%	96.1%	95.7%	94.7%	94.7%
#	3,506	2,977	2,470	1,945	1,491	1,004	577	369	294	205	150	81	50

Defibrillation Leads

6947M Sprint Quattro Secure

US Market Release	Feb-12
CE Approval	Mar-10
Registered USA Implants	87,514
Estimated Active USA Implants	79,905
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	49
Insulation Breach	5
Other	11

US Acute Lead Observations

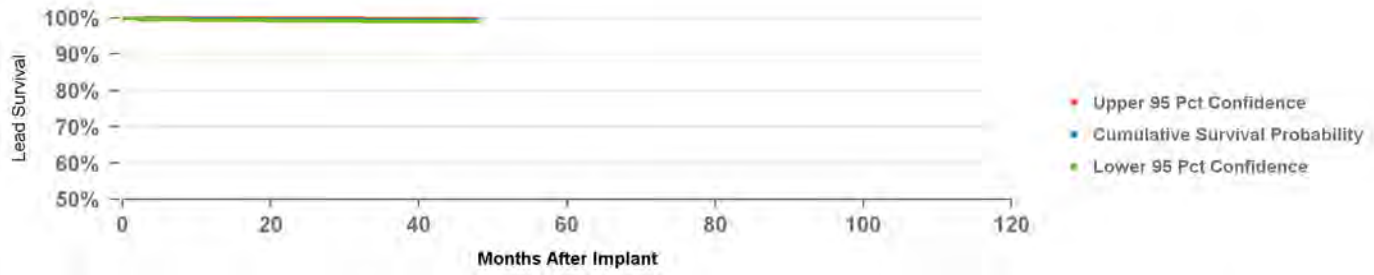
Cardiac Perforation	23
Conductor Fracture	9
Extracardiac Stimulation	10
Failure To Capture	71
Failure To Sense	20
Impedance Abnormal	19
Lead Dislodgement	128
Oversensing	44

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,960
Cumulative Months of Followup	58,044
Number of Leads Active in Study	1,225

Qualifying Complications 9

Conductor Fracture	2
Failure To Capture	4
Failure To Sense	2
Other	1



Years	1	2	3	at 48 mo
%	99.7%	99.5%	99.4%	99.4%
#	1,551	1,226	898	245

6948 Sprint Fidelis

US Market Release	Sep-04
CE Approval	
Registered USA Implants	10,373
Estimated Active USA Implants	3,332
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	192
Insulation Breach	3
Other	2

US Acute Lead Observations

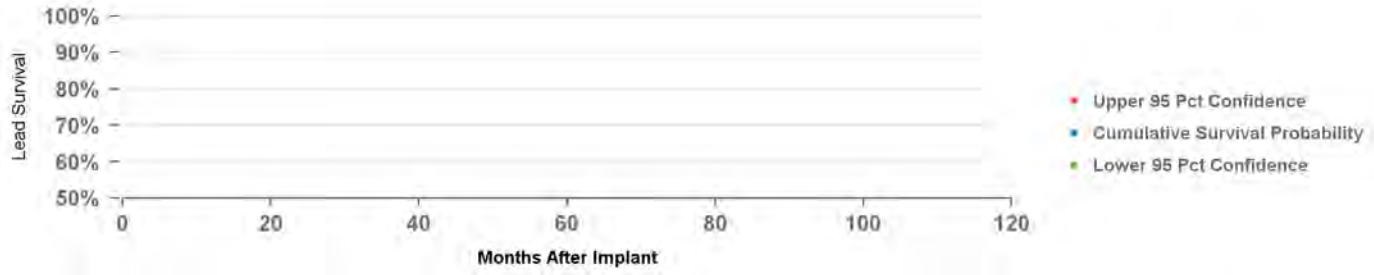
Conductor Fracture	2
Failure To Capture	7
Lead Dislodgement	7
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Cumulative Months of Followup	2,050
Number of Leads Active in Study	8

Qualifying Complications 4

Conductor Fracture	3
Impedance Out of Range	1



Years	at 0 mo
%	100.0%
#	

Defibrillation Leads

6949 Sprint Fidelis

US Market Release	Sep-04
CE Approval	
Registered USA Implants	186,704
Estimated Active USA Implants	50,440
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7,509
Crimp Weld Bond	3
Insulation Breach	36
Other	70

US Acute Lead Observations

Cardiac Perforation	10
Conductor Fracture	45
Failure To Capture	31
Failure To Sense	19
Impedance Abnormal	17
Insulation Breach	5
Lead Dislodgement	22
Oversensing	31
Unspecified	25

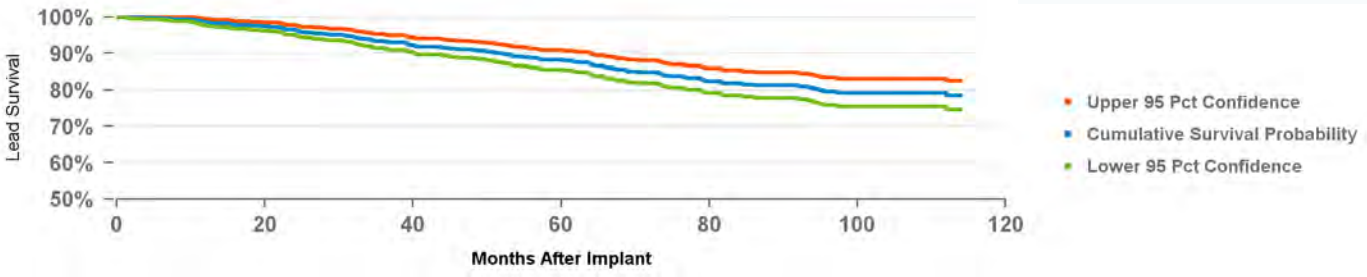
Product Surveillance Registry Results

Number of Leads Enrolled in Study	954
Cumulative Months of Followup	50,198
Number of Leads Active in Study	167

Qualifying Complications

105

Conductor Fracture	58
Failure To Capture	4
Failure To Sense	6
Impedance Out of Range	18
Insulation Breach	2
Lead Dislodgement	1
Other	1
Oversensing	15



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	98.5%	96.5%	93.3%	90.9%	88.3%	84.9%	81.9%	79.6%	79.2%	78.6%
#	825	701	590	466	380	296	200	137	79	61

6996 Sub-Q Lead

US Market Release	Jun-01
CE Approval	Dec-97
Registered USA Implants	4,689
Estimated Active USA Implants	2,567
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	28

US Acute Lead Observations

Cardiac Perforation	1
Failure To Capture	1
Impedance Abnormal	8
Lead Dislodgement	1

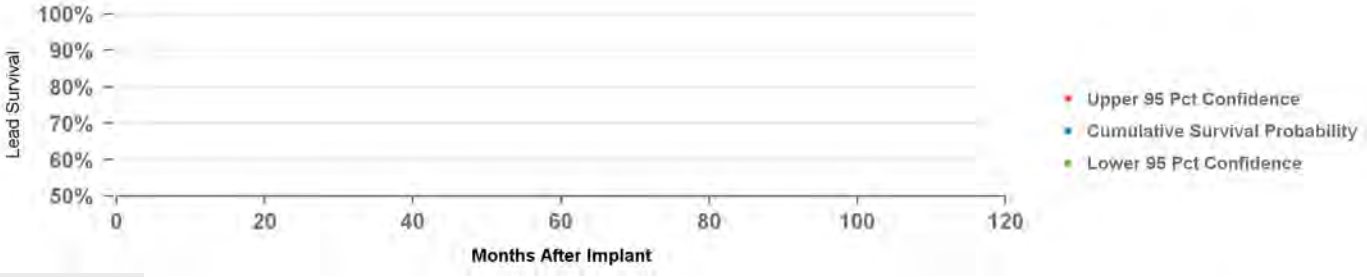
Product Surveillance Registry Results

Number of Leads Enrolled in Study	46
Cumulative Months of Followup	1,781
Number of Leads Active in Study	9

Qualifying Complications

2

Conductor Fracture	1
Impedance Out of Range	1



Years	at 0 mo
%	100.0%
#	

Left Heart Leads

2187 Attain LV

US Market Release	Aug-01
CE Approval	
Registered USA Implants	11,980
Estimated Active USA Implants	1,849
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	1
Insulation Breach	1
Other	4

US Acute Lead Observations

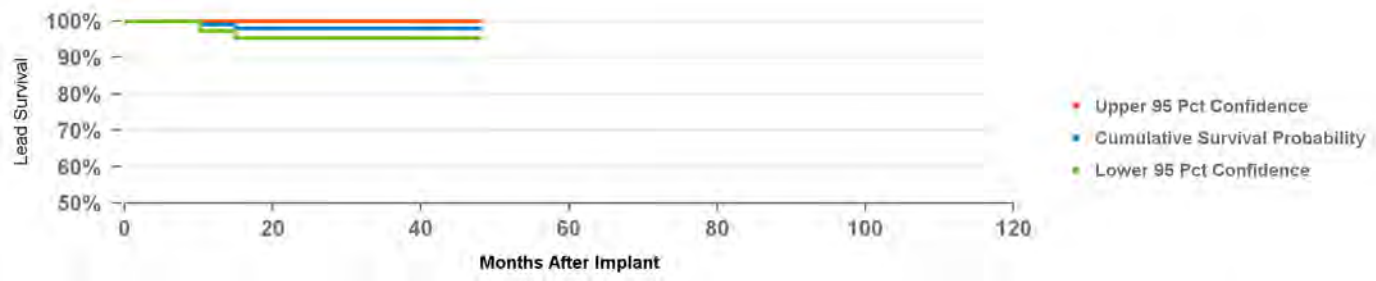
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Lead Dislodgement	9

Product Surveillance Registry Results

Number of Leads Enrolled in Study	139
Cumulative Months of Followup	6,710
Number of Leads Active in Study	8

Qualifying Complications 3

Failure To Capture	3



Years	1	2	3	at 48 mo
%	99.1%	98.0%	98.0%	98.0%
#	105	89	67	52

4193 Attain OTW

US Market Release	May-02
CE Approval	Dec-00
Registered USA Implants	100,806
Estimated Active USA Implants	24,503
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	70
Insulation Breach	19
Other	46

US Acute Lead Observations

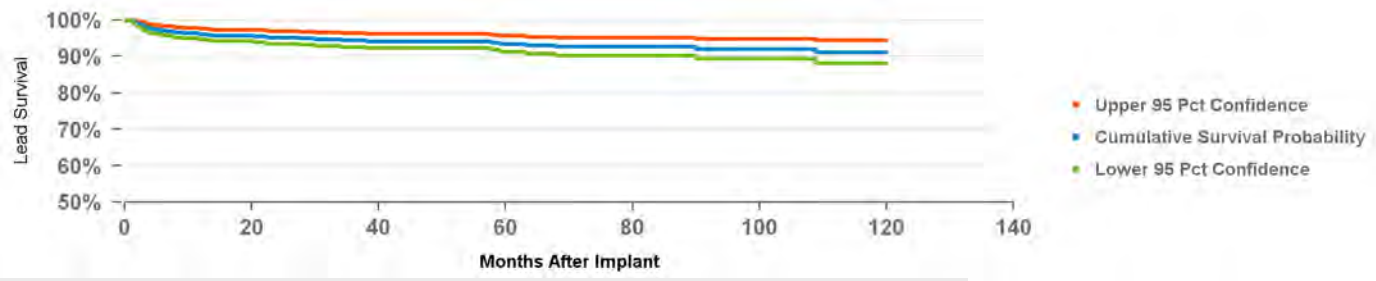
Extracardiac Stimulation	18
Failure To Capture	11
Lead Dislodgement	45
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	783
Cumulative Months of Followup	36,896
Number of Leads Active in Study	100

Qualifying Complications 41

Conductor Fracture	1	Lead Dislodgement	13
Extracardiac Stimulation	9	Unspecified	3
Failure To Capture	15		



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.1%	95.2%	94.4%	94.2%	93.4%	92.6%	92.6%	92.0%	92.0%	91.2%
#	618	474	391	299	237	194	158	125	85	57

Left Heart Leads

4194 Attain OTW

US Market Release	Aug-04
CE Approval	Jul-03
Registered USA Implants	114,686
Estimated Active USA Implants	54,551
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	24
Insulation Breach	101
Other	7

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	48
Failure To Capture	42
Impedance Abnormal	8
Lead Dislodgement	149
Oversensing	2
Unspecified	5

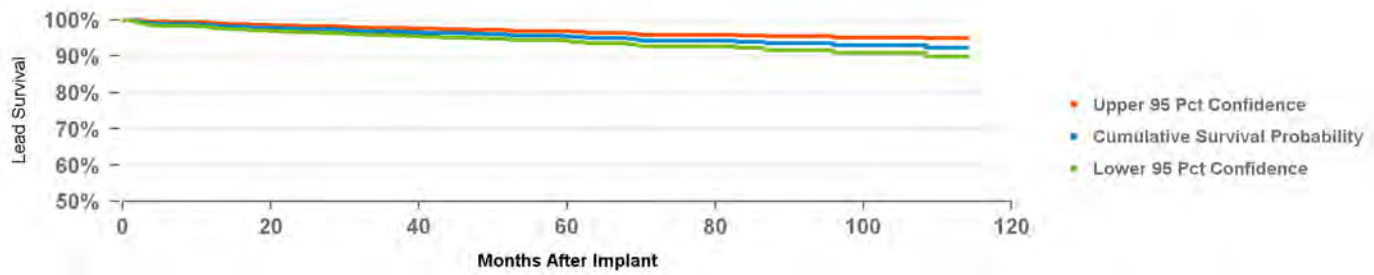
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,588
Cumulative Months of Followup	70,727
Number of Leads Active in Study	560

Qualifying Complications

59

Conductor Fracture	2	Insulation Breach	2
Extracardiac Stimulation	10	Insulation Breach ESC	1
Failure To Capture	16	Lead Dislodgement	28



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	98.6%	97.5%	96.7%	96.2%	95.5%	94.3%	94.0%	93.1%	93.1%	92.3%
#	1,320	1,078	849	629	480	319	197	126	77	60

4195 Attain StarFix

US Market Release	Aug-08
CE Approval	May-05
Registered USA Implants	17,298
Estimated Active USA Implants	11,432
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7
Insulation Breach	2
Other	4

US Acute Lead Observations

Extracardiac Stimulation	30
Failure To Capture	20
Impedance Abnormal	4
Lead Dislodgement	30
Unspecified	1

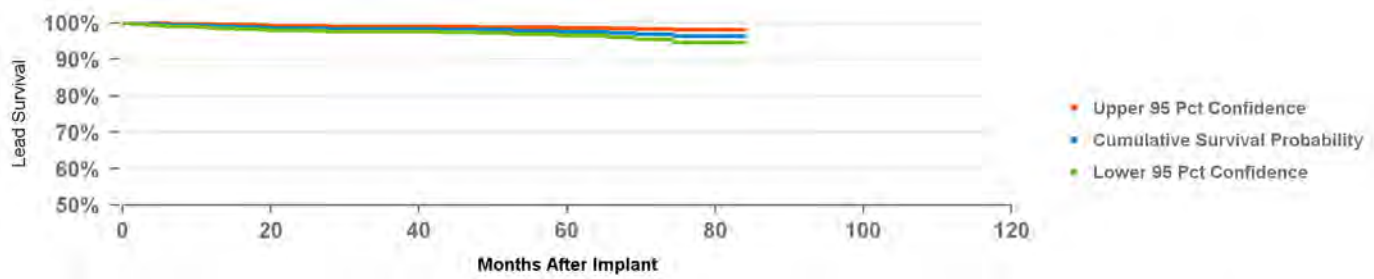
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,479
Cumulative Months of Followup	61,305
Number of Leads Active in Study	561

Qualifying Complications

27

Conductor Fracture	2	Impedance Out of Range	1
Extracardiac Stimulation	10	Insulation Breach	5
Failure To Capture	4	Lead Dislodgement	5



Years	1	2	3	4	5	6	at 84 mo
%	99.2%	98.6%	98.4%	98.1%	97.6%	96.9%	96.4%
#	1,252	1,050	845	591	377	190	61

Left Heart Leads

4196 Attain Ability

US Market Release	May-09
CE Approval	Jul-07
Registered USA Implants	66,561
Estimated Active USA Implants	47,256
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	19
Other	12

US Acute Lead Observations

Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	85
Failure To Capture	56
Failure To Sense	1
Impedance Abnormal	8
Insulation Breach	1
Lead Dislodgement	198
Oversensing	1
Unspecified	3

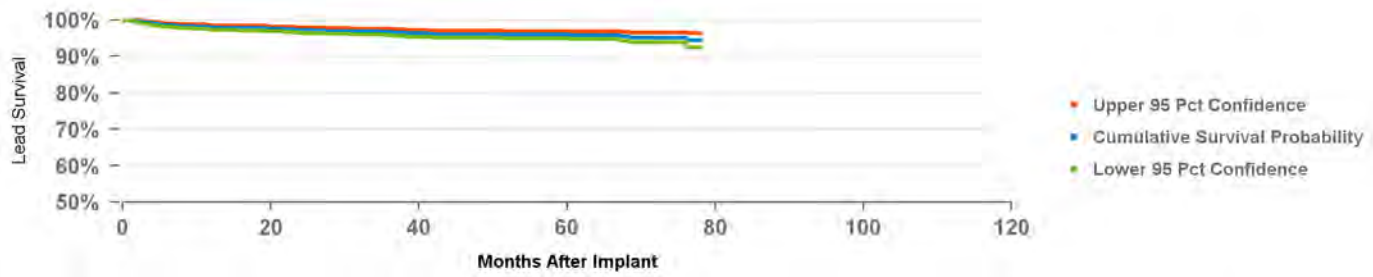
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,207
Cumulative Months of Followup	81,618
Number of Leads Active in Study	696

Qualifying Complications

69

Conductor Fracture	3
Extracardiac Stimulation	13
Failure To Capture	28
Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	21
Other	2



Years	1	2	3	4	5	6	at 78 mo
%	98.0%	97.2%	96.7%	96.1%	96.0%	95.2%	94.5%
#	1,801	1,386	1,038	750	574	194	82

4296 Attain Ability Plus

US Market Release	Apr-11
CE Approval	Dec-09
Registered USA Implants	33,000
Estimated Active USA Implants	27,772
Fixation Type	Double Curve
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp Weld Bond	2
Other	3

US Acute Lead Observations

Cardiac Perforation	2
Extracardiac Stimulation	56
Failure To Capture	25
Impedance Abnormal	8
Insulation Breach	4
Lead Dislodgement	113

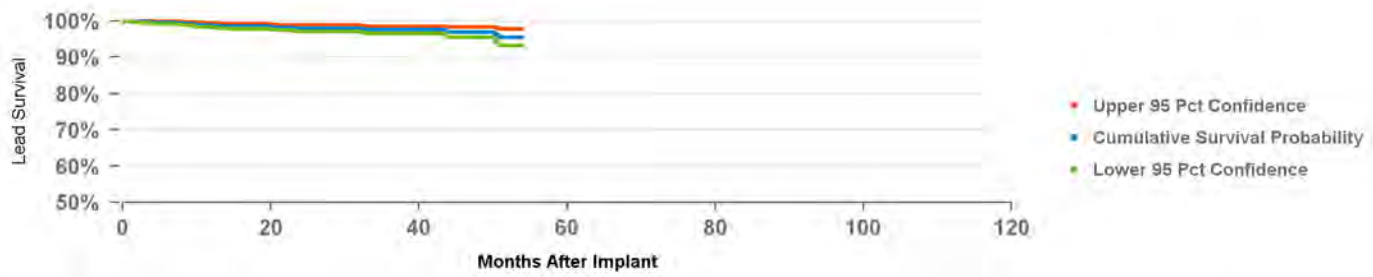
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,415
Cumulative Months of Followup	38,866
Number of Leads Active in Study	732

Qualifying Complications

30

Extracardiac Stimulation	11
Failure To Capture	7
Lead Dislodgement	11
Other	1



Years	1	2	3	4	at 54 mo
%	98.8%	97.9%	97.6%	96.9%	95.5%
#	1,098	814	464	193	73

Left Heart Leads

4298 Attain Performa

US Market Release	Aug-14
CE Approval	Jan-13
Registered USA Implants	35,222
Estimated Active USA Implants	33,478
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Other	11

US Acute Lead Observations

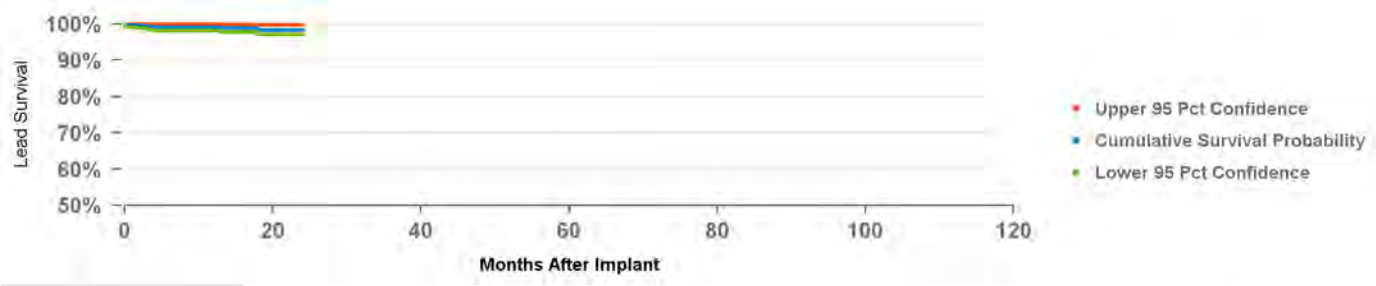
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	82
Failure To Capture	46
Impedance Abnormal	12
Lead Dislodgement	64

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,133
Cumulative Months of Followup	11,455
Number of Leads Active in Study	969

Qualifying Complications 9

Extracardiac Stimulation	1	Lead Dislodgement	8



Years	1	at 24 mo
%	99.0%	98.4%
#	446	59

4396 Attain Ability Straight

US Market Release	Mar-11
CE Approval	Dec-09
Registered USA Implants	7,150
Estimated Active USA Implants	5,890
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Other	1

US Acute Lead Observations

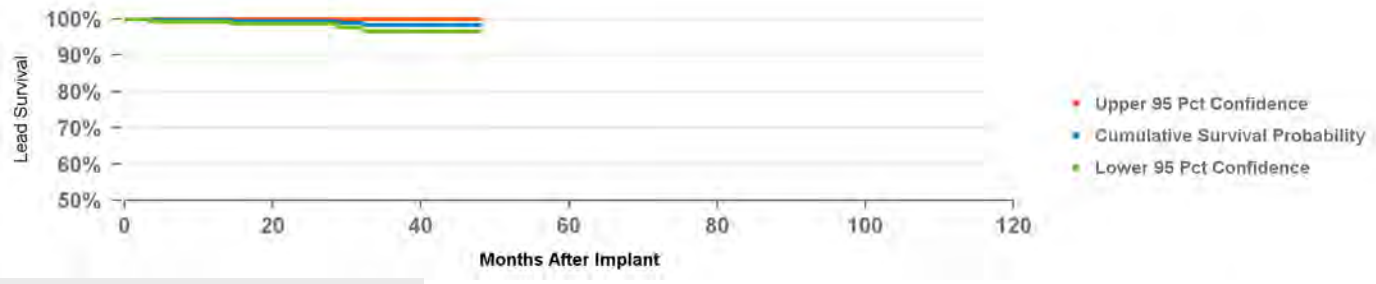
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	14
Failure To Capture	7
Lead Dislodgement	33

Product Surveillance Registry Results

Number of Leads Enrolled in Study	429
Cumulative Months of Followup	12,052
Number of Leads Active in Study	234

Qualifying Complications 4

Failure To Capture	3	Lead Dislodgement	1



Years	1	2	3	at 48 mo
%	99.7%	99.4%	98.3%	98.3%
#	331	226	143	65

Left Heart Leads

4398 Attain Performa Straight

US Market Release	Dec-14
CE Approval	Jan-13
Registered USA Implants	7,246
Estimated Active USA Implants	6,943
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

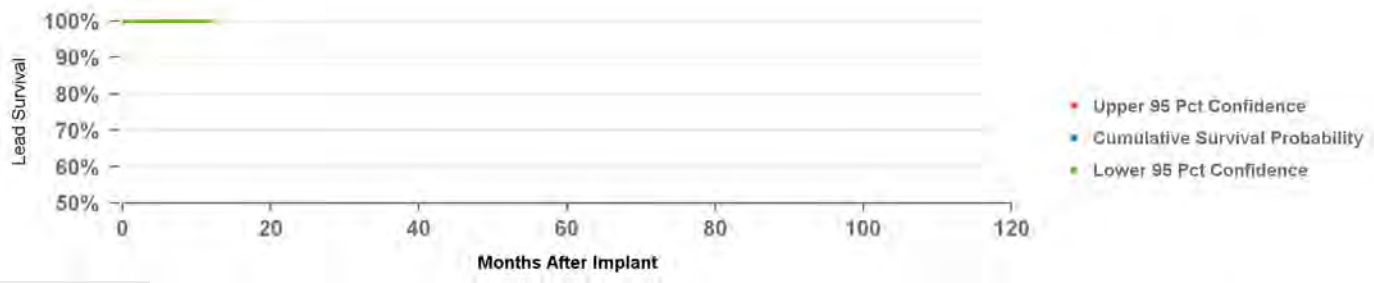
Other	3

US Acute Lead Observations

Cardiac Perforation	2
Extracardiac Stimulation	24
Failure To Capture	13
Impedance Abnormal	1
Lead Dislodgement	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	286
Cumulative Months of Followup	2,482
Number of Leads Active in Study	251



Years	at 12 mo
%	100.0%
#	80

4598 Attain Performa S

US Market Release	Dec-14
CE Approval	Jan-13
Registered USA Implants	14,460
Estimated Active USA Implants	13,919
Fixation Type	Canted
Pace Sense Polarity	Quad Pole
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Other	1

US Acute Lead Observations

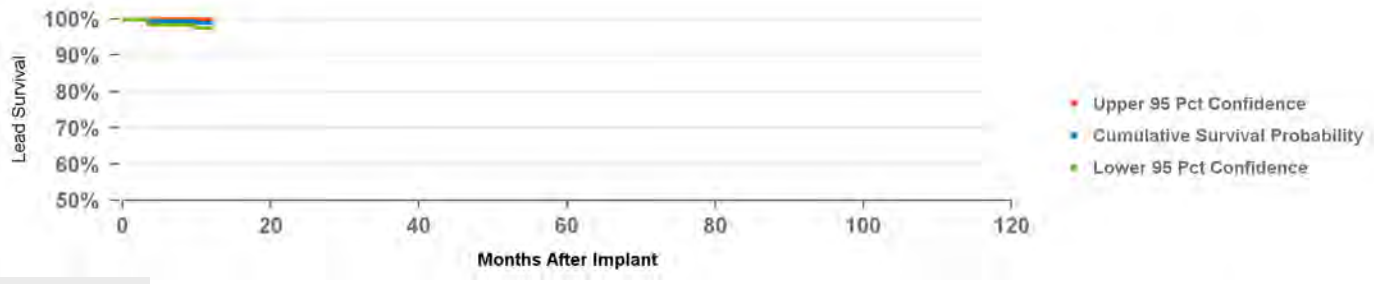
Cardiac Perforation	3
Conductor Fracture	1
Extracardiac Stimulation	27
Failure To Capture	9
Impedance Abnormal	4
Lead Dislodgement	21
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	472
Cumulative Months of Followup	3,818
Number of Leads Active in Study	421

Qualifying Complications 3

Failure To Sense	1
Lead Dislodgement	2



Years	at 12 mo
%	98.8%
#	156

Epi/Myocardial Leads

4965 CapSure Epi

US Market Release	Sep-96
CE Approval	Jan-93
Registered USA Implants	22,649
Estimated Active USA Implants	8,745
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	228
Crimp Weld Bond	1
Insulation Breach	47

US Acute Lead Observations

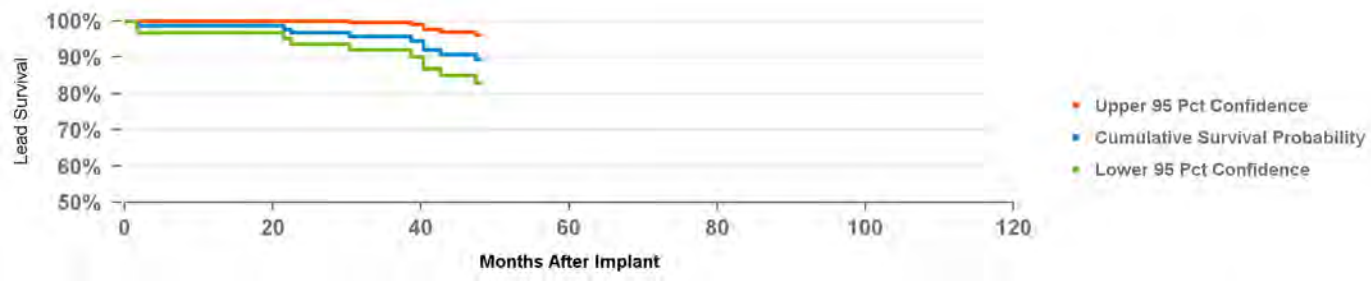
Conductor Fracture	1
Failure To Capture	6
Failure To Sense	5
Impedance Abnormal	8
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	231
Cumulative Months of Followup	7,048
Number of Leads Active in Study	6

Qualifying Complications 14

Conductor Fracture	7	Insulation Breach	1
Failure To Capture	3	Oversensing	2
Failure To Sense	1		



Years	1	2	3	at 48 mo
%	98.6%	96.7%	95.6%	89.3%
#	129	110	90	64

4968 CapSure Epi

US Market Release	Sep-99
CE Approval	Apr-98
Registered USA Implants	40,068
Estimated Active USA Implants	24,330
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	70
Insulation Breach	42
Other	1

US Acute Lead Observations

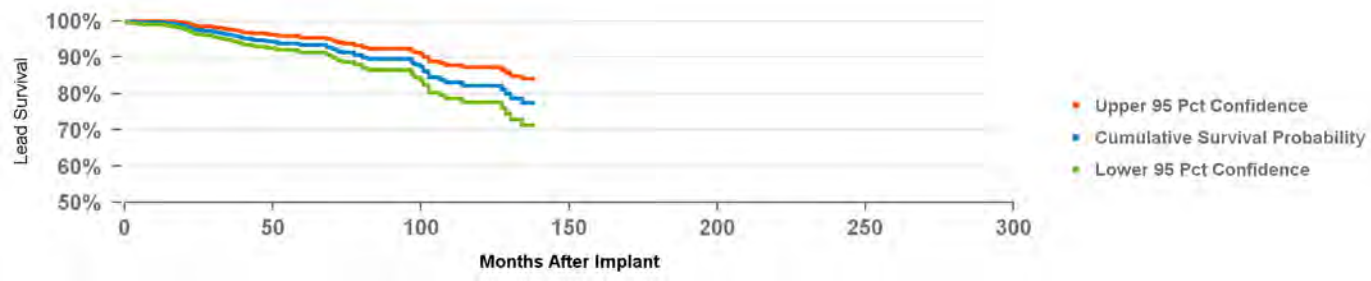
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	2
Failure To Capture	30
Failure To Sense	2
Impedance Abnormal	5
Insulation Breach	1
Lead Dislodgement	6
Oversensing	13

Product Surveillance Registry Results

Number of Leads Enrolled in Study	923
Cumulative Months of Followup	49,857
Number of Leads Active in Study	282

Qualifying Complications 74

Conductor Fracture	19	Impedance Out of Range	4
Extracardiac Stimulation	2	Insulation Breach	3
Failure To Capture	26	Other	1
Failure To Sense	3	Oversensing	16



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.5%	97.5%	96.2%	94.5%	93.3%	91.5%	89.4%	89.4%	83.9%	82.3%	78.7%	77.4%
#	727	645	549	450	363	285	222	169	108	68	55	50

Epi/Myocardial Leads

5071 Screw-in

US Market Release	Dec-92
CE Approval	Jan-93
Registered USA Implants	51,065
Estimated Active USA Implants	15,771
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	20
Insulation Breach	2

US Acute Lead Observations

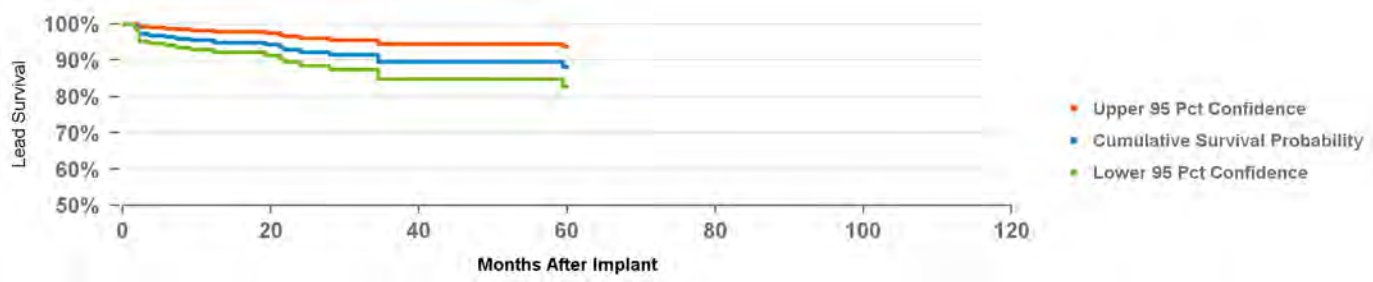
Cardiac Perforation	1
Extracardiac Stimulation	6
Failure To Capture	55
Failure To Sense	3
Impedance Abnormal	6
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	408
Cumulative Months of Followup	10,188
Number of Leads Active in Study	105

Qualifying Complications 25

Conductor Fracture	1	Impedance Out of Range	1
Failure To Capture	18	Lead Dislodgement	1
Failure To Sense	2	Oversensing	2



Years	1	2	3	4	at 60 mo
%	95.4%	92.2%	89.6%	89.6%	88.1%
#	193	141	103	72	52

VDD Single Pass Lead

5038 CapSure VDD-2

US Market Release	Sep-98
CE Approval	Apr-97
Registered USA Implants	9,906
Estimated Active USA Implants	3,433
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Insulation Breach	2

US Acute Lead Observations

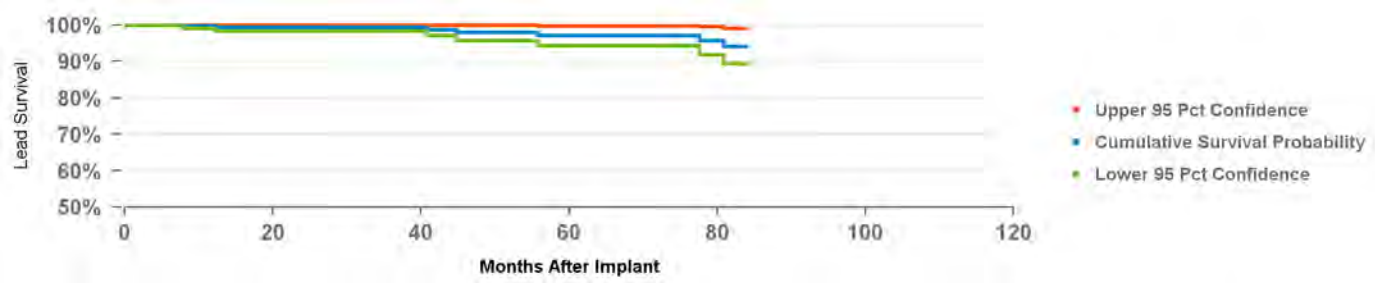
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	2
Lead Dislodgement	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	566
Cumulative Months of Followup	15,656
Number of Leads Active in Study	3

Qualifying Complications 8

Conductor Fracture	3
Failure To Capture	2
Failure To Sense	3



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.3%	99.3%	97.9%	97.0%	97.0%	94.1%
#	291	220	161	132	105	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.

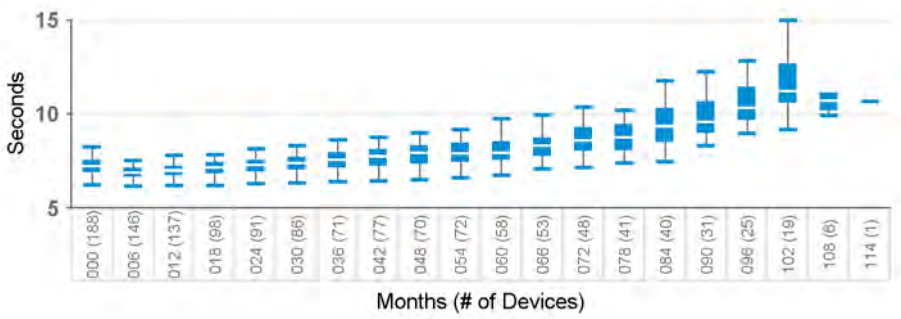
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

Charge Time

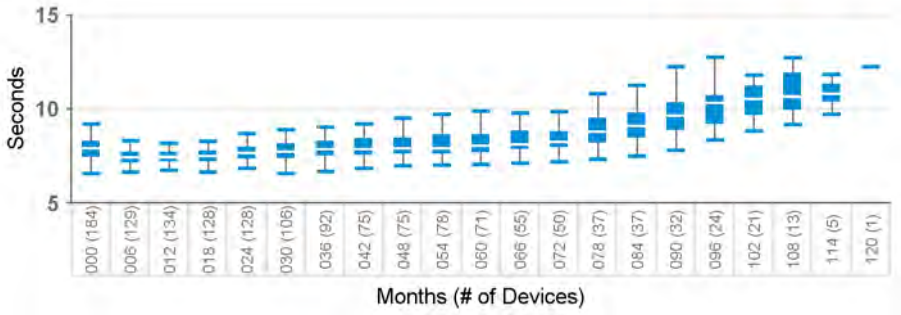
7230

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



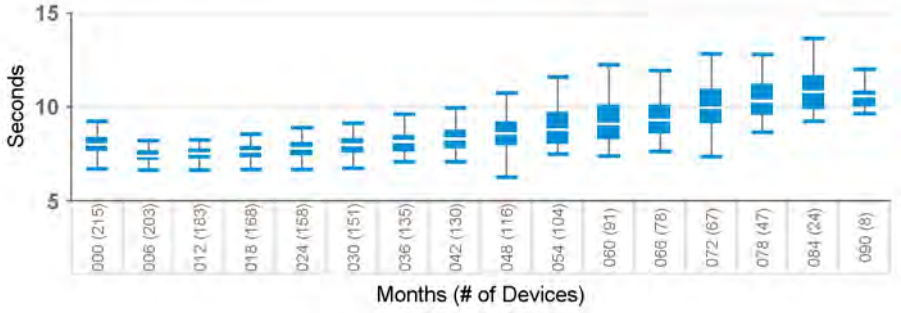
7232

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



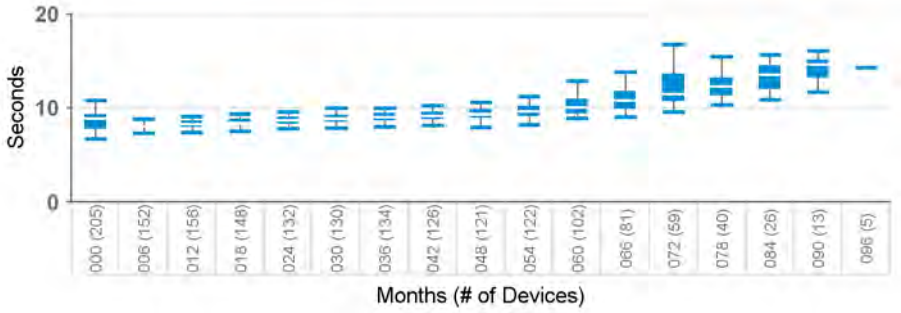
7278

Model Number	Brand
7278	Maximo DR



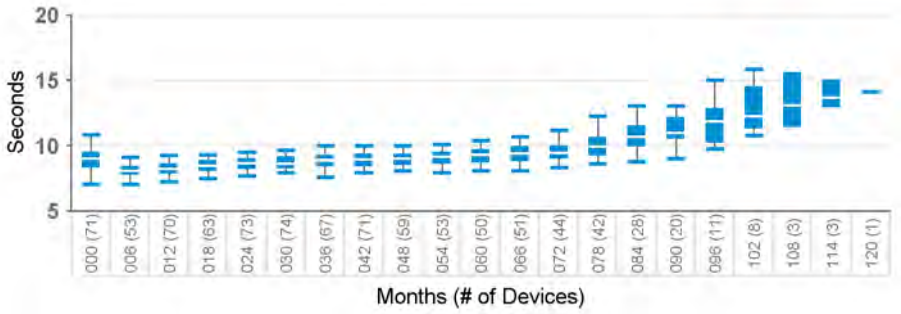
D144DRG, D154ATG, D154DRG

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT



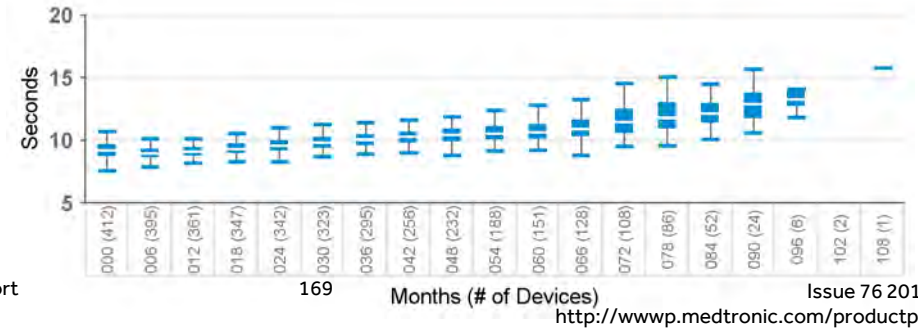
D144VRC, D154VRC

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



D154AWG, D164AWG

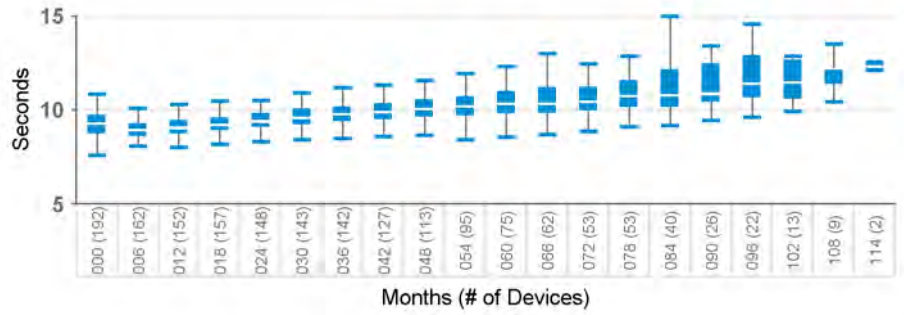
Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



Charge Time

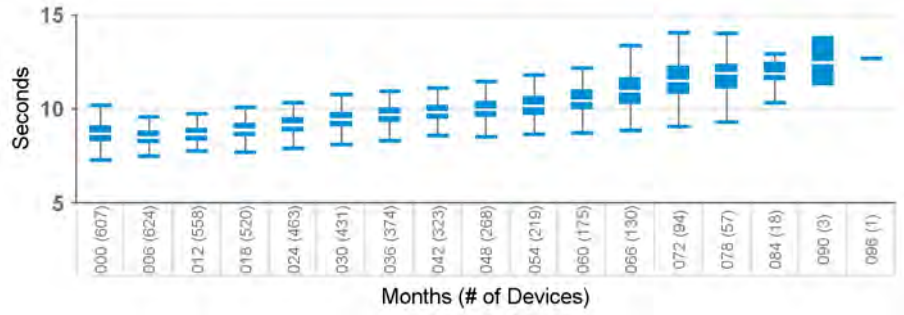
D154VWC, D164VWC

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



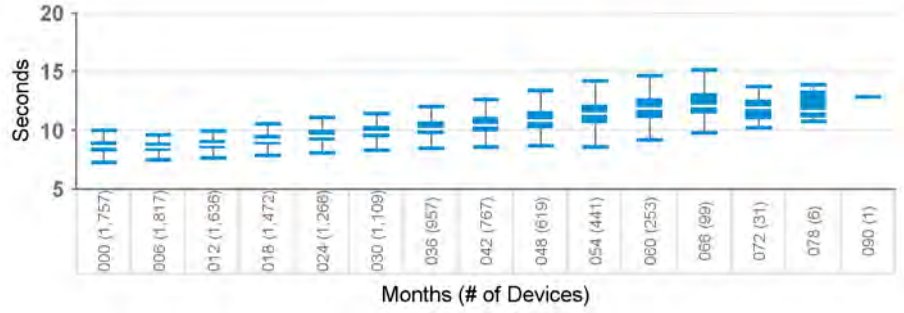
D204DRM, D214DRM, D224DRG, D234DRG

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



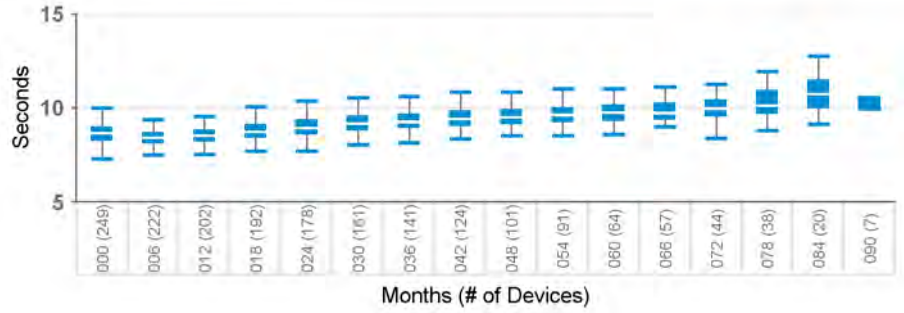
D204TRM, D214TRM, D224TRK, D234TRK

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



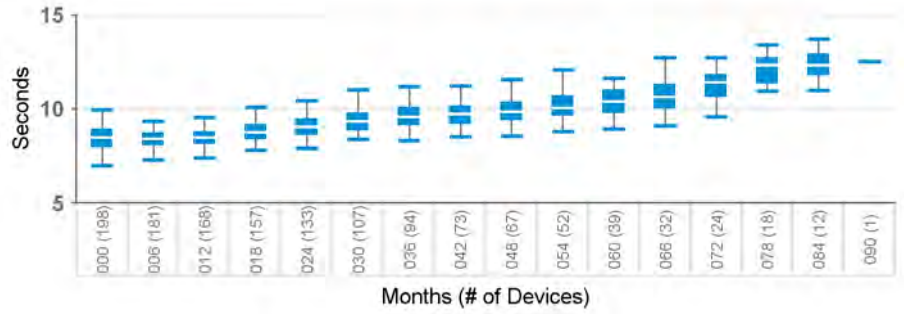
D204VRM, D214VRM, D224VRC, D234VRC

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



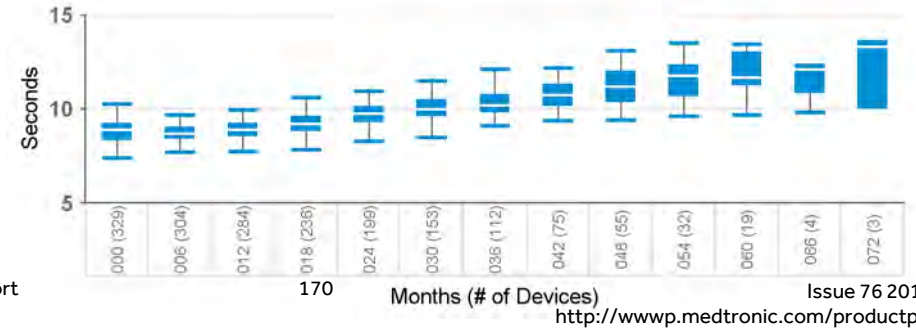
D264DRG, D284DRG, D384DRx, D394DRx

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



D264TRM, D284TRK, D384TRx, D394TRx

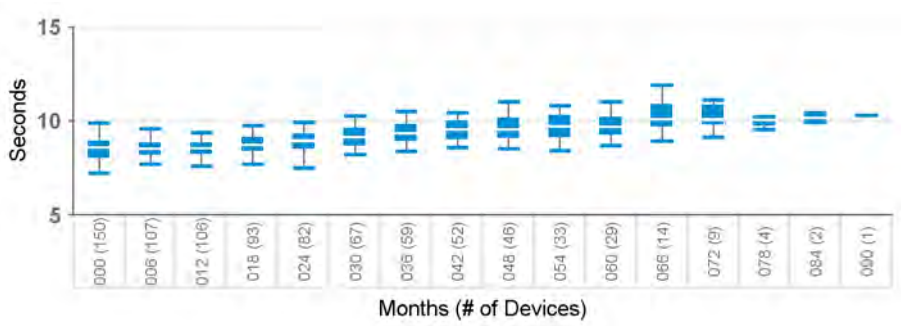
Model Number	Brand
D264TRM	Maximo II CRT-D
D284TRK	Maximo II CRT-D
D384TRG	Cardia CRT-D
D394TRG	Egida CRT-D



Charge Time

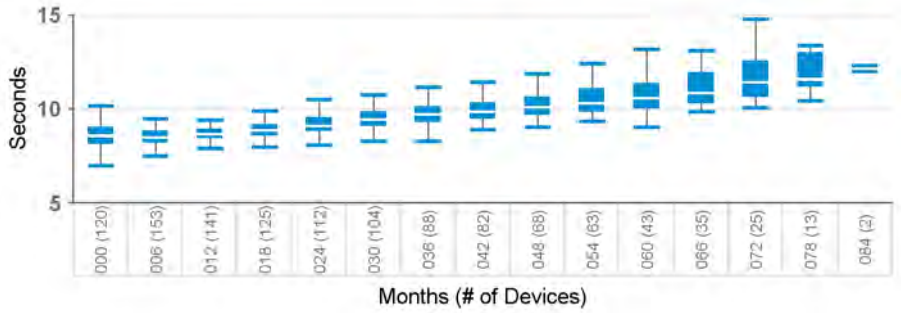
D264VRM, D284VRC, D384VRx, D394VRx

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



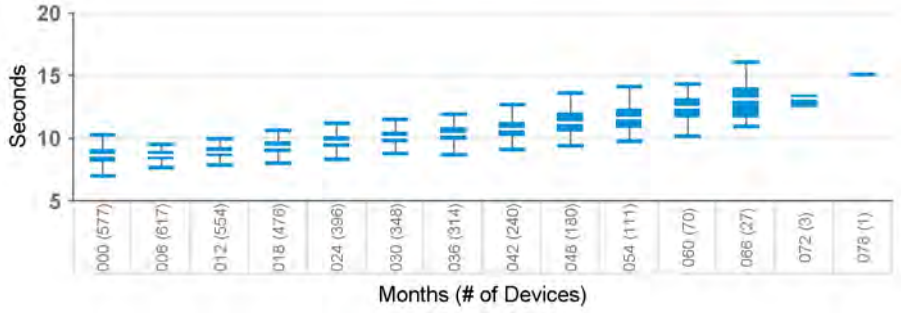
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



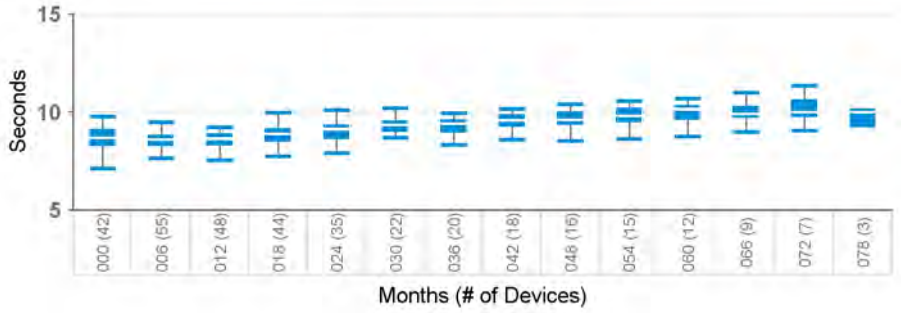
D274TRK, D294TRK

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



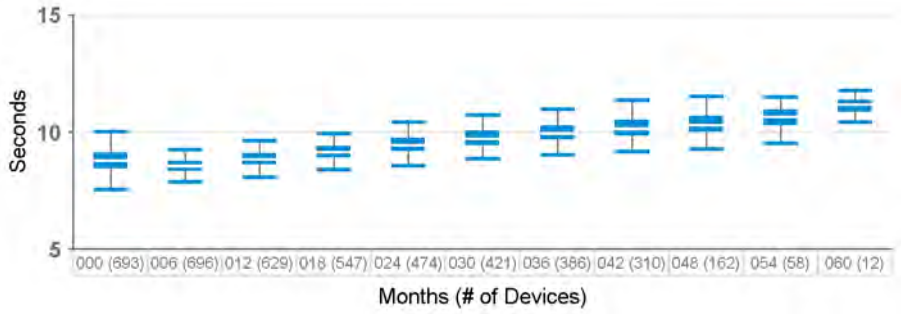
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



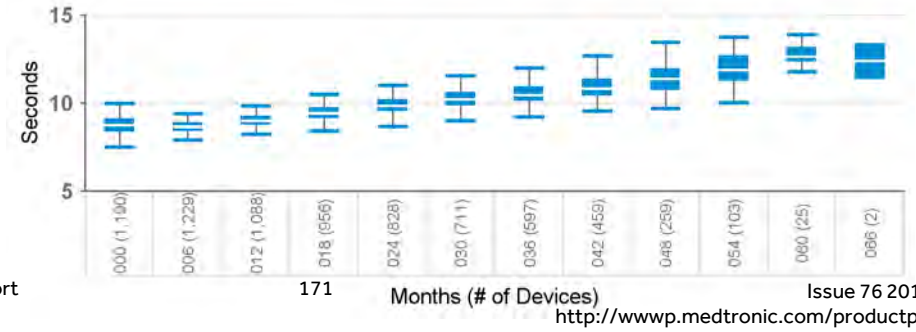
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



D314TRx

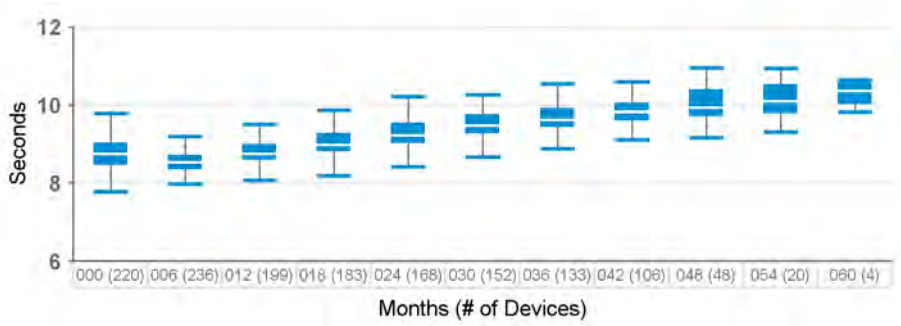
Model Number	Brand
D314TRG	Protecta XT CRT-D
D314TRM	Protecta XT CRT-D



Charge Time

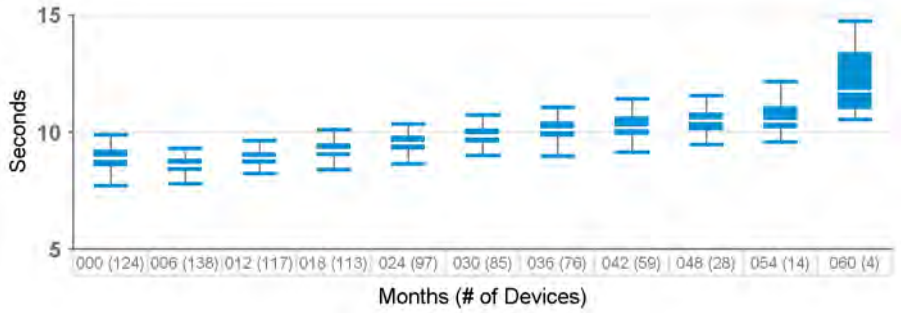
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



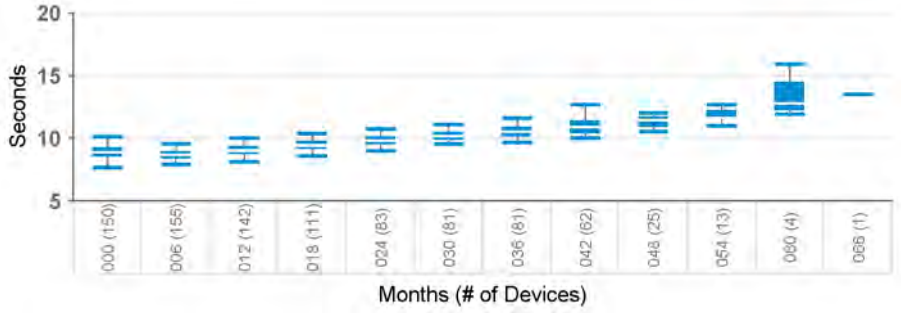
D334DRx, D364DRx

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



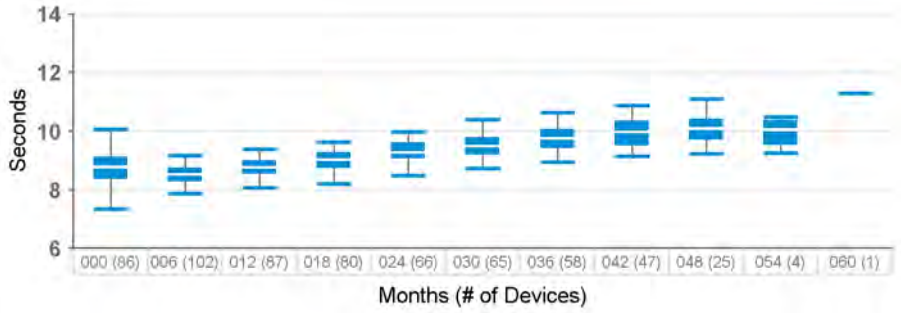
D334TRx, D364TRx

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



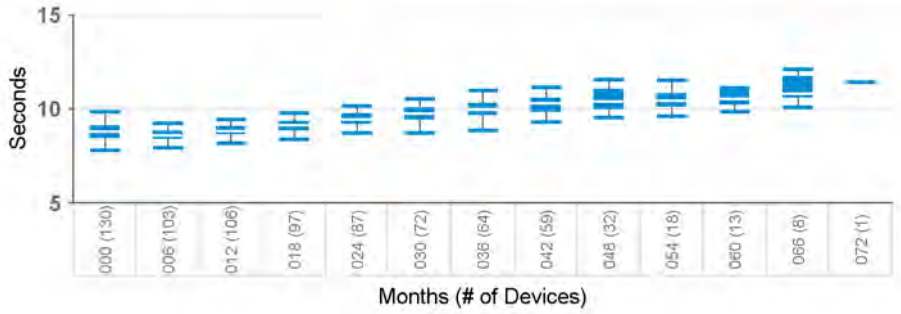
D334VRx, D364VRx

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



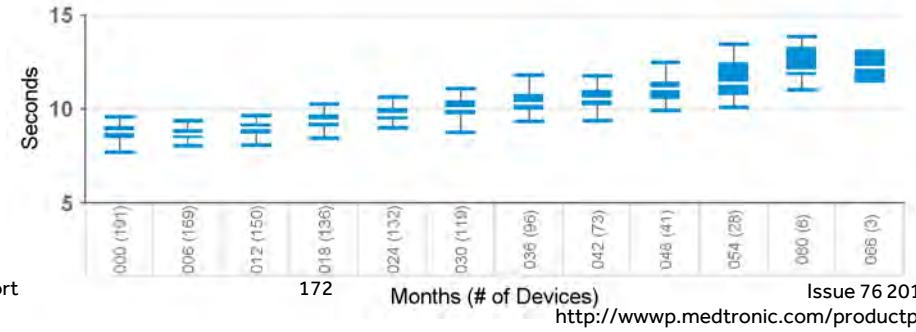
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



D354TRx

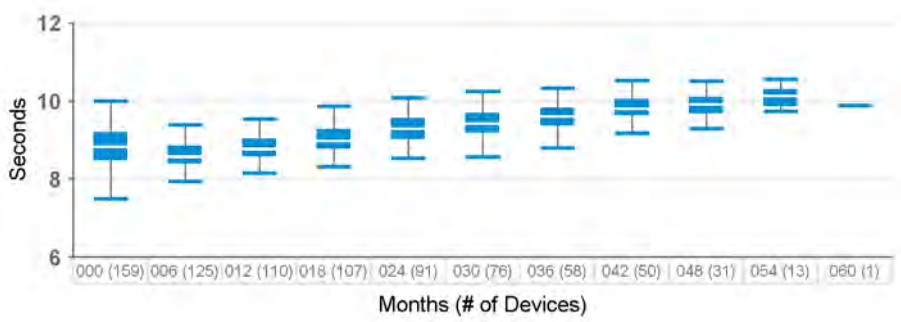
Model Number	Brand
D354TRG	Protecta XT CRT-D
D354TRM	Protecta XT CRT-D



Charge Time

D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



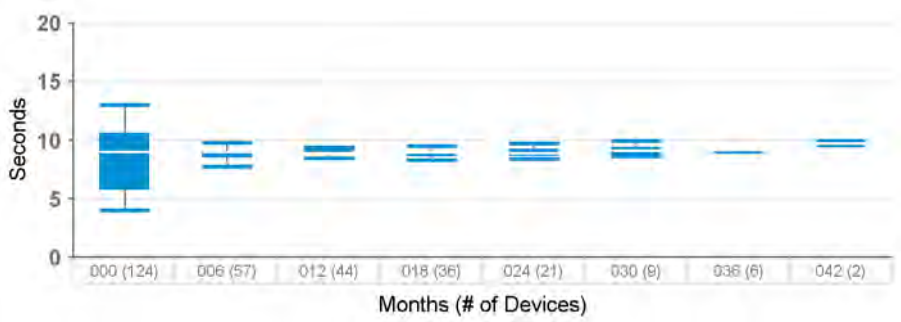
DDxxxxx, DR

Model Number	Brand
DDBB1D1	Evera XT
DDBB1D4	Evera XT
DDBB2D1	Evera XT
DDBB2D4	Evera XT
DDBC3D1	Evera S
DDBC3D4	Evera S
DDMB1D1	Evera MRI XT
DDMB1D4	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D1	Evera MRI S
DDMC3D4	Evera MRI

Charge Time

DTxxxxx, CRT-D

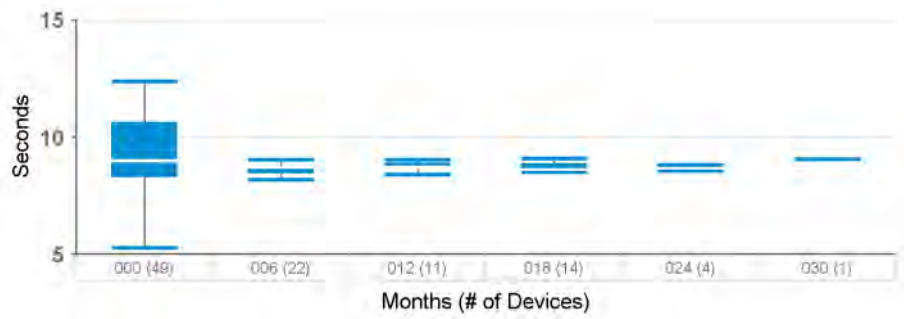
Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava
DTBC2D4	Brava
DTBC2Q1	Brava Quad
DTBC2QQ	Brava Quad
DTBX1QQ	Viva Quad C
DTBX2QQ	Viva Quad C
DTMA1D1	Claria MRI
DTMA1D4	Claria MRI
DTMA1Q1	Claria MRI
DTMA1QQ	Claria MRI
DTMA2D1	Claria MRI
DTMA2D4	Claria MRI
DTMA2Q1	Claria MRI
DTMA2QQ	Claria MRI
DTMB1D1	Amplia MRI
DTMB1D4	Amplia MRI
DTMB1Q1	Amplia MRI
DTMB1QQ	Amplia MRI
DTMB2D1	Amplia MRI
DTMB2D4	Amplia MRI
DTMB2Q1	Amplia MRI
DTMB2QQ	Amplia MRI
DTMC1D1	Compia MRI
DTMC1QQ	Compia MRI
DTMC2D4	Compia MRI
DTMC2QQ	Compia MRI



Charge Time

DVxxxxx, VR

Model Number	Brand
DVAB1D1	Visia AF
DVAB1D4	Visia AF
DVAB2D1	Visia AF XT
DVAC3D1	Visia AF S
DVBB1D1	Evera XT
DVBB1D4	Evera XT
DVBB2D1	Evera XT
DVBB2D4	Evera XT
DVBC3D1	Evera S
DVBC3D4	Evera S
DVFB1D4	Visia MRI AF
DVFB2D4	Visia MRI AF XT
DVFC3D4	Visia MRI AF S
DVMB1D4	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D4	Evera MRI S



Potential Loss of Left Ventricle Pacing Due to Software Issue

All models of Claria MRI CRT-D SureScan and Amplia MRI CRT-D SureScan devices.

Original Date of Advisory: December 2016

Product
All models of Claria MRI CRT-D SureScan and Amplia MRI CRT-D SureScan devices.

Advisory
Due to a device software issue, a loss of Left Ventricle (LV) pacing occurs following a specific device programming sequence. If it occurs, this issue can be corrected by re-programming the device. All tachyarrhythmia detection and therapy features remain fully operational.

A software update is being developed to address this issue. Further information will be communicated once the software update receives applicable regulatory approvals.

All models of Claria MRI and Amplia MRI devices are included in the affected population. This issue can only occur in devices that have been programmed from Managed Ventricular Pacing (MVP) mode to a pacing mode with AdaptivCRT enabled.

When a patient with AdaptivCRT enabled (shipped setting) is subsequently programmed to MVP mode and then re-programmed back to DDD or DDDR, AdaptivCRT is not re-enabled. When this programming sequence occurs, LV pacing is not delivered, despite parameters indicating AdaptivCRT is enabled. This will result in RV only pacing, which may be undesirable for the patient. LV pacing will remain disabled until a specific programming sequence is manually completed; refer to the Patient Management section below for details.

Through 10 November 2016, two events have been reported to Medtronic related to this issue. A review of available data revealed an overall occurrence rate of 0.38%. Medtronic has not received any reports of patient injury related to this issue.

Patient Management Recommendations
After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following options for managing patients with a device that may be susceptible to the AdaptivCRT/MVP interaction.

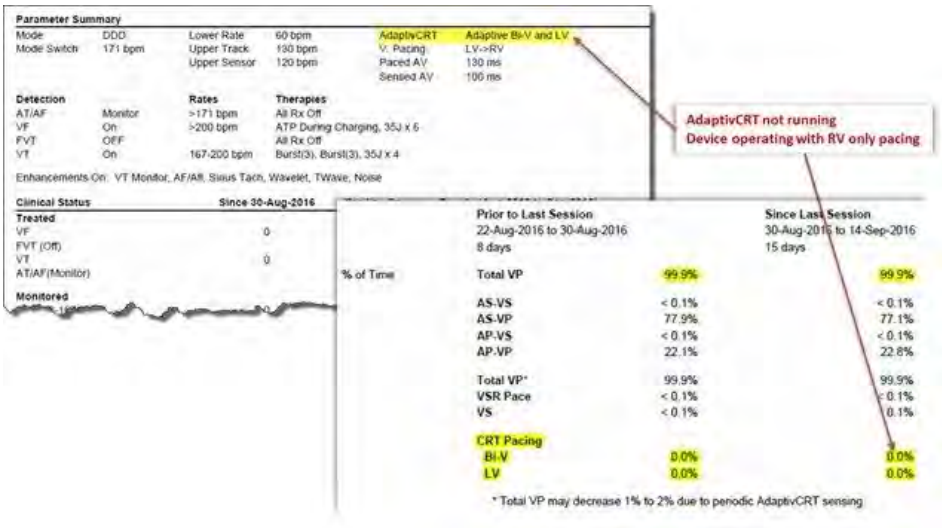
Until the software update has been approved and the affected device models receive the update, follow the programming recommendations provided below. These recommendations also apply to any new device implants.

1. **At the patient's next scheduled CareLink transmission or in-office follow-up, identify if the patient's device is operating with AdaptivCRT enabled and loss of LV-pacing. Continue this practice for all subsequent device evaluations until the software update has been implemented.**

   Using CareLink or Programmer interrogation session reports:

   - If the CRT setting is currently programmed to Adaptive Bi-V and LV or Adaptive Bi-V (Figure 1), review rate histogram CRT Pacing percentages (CRT Pacing: Bi-V and LV).
   - If Bi-V and LV pacing percentages Since Last Session are both near 0%, then the device has encountered the programming sequence and has lost LV pacing; proceed to step 2.

Figure 1



2. **For patients identified with loss of LV pacing:**

   Perform the following programming steps to restore the device to its expected operating state with AdaptivCRT enabled:

   - Select the CRT parameter window, select Nonadaptive CRT, and select PROGRAM.
   - Select the CRT parameter window, select the desired AdaptivCRT setting (Adaptive Bi-V and LV or Adaptive Bi-V), and select PROGRAM.

Until the software update is available, follow the programming steps above to avoid the loss of LV pacing.

As part of the software update previously mentioned, Medtronic will also address an unrelated transient mode switch behavior that may occur in MRI Quadripolar CRT-D device models (Claria MRI, Amplia MRI and Compia MRI). The mode switch behavior is unrelated to ventricular tachyarrhythmia detection and therapies. This behavior only occurs when a VectorExpress™ Test is started, but then aborts due to a fast or unstable rate, or due to a manual user abort (i.e., manually selecting STOP Test). Under these scenarios, the device remains in the transient mode switch state until any of the following occur:

- An automatic Atrial Capture Management™ (ACM) pacing threshold search,
- An automatic delivery of any ATP or shock therapy, or
- An in-office follow-up activity, such as a pacing parameter programming or conducting one of the following in-office tests: Sensing, Threshold, Underlying Rhythm, or CardioSync™. A "Test Started" indication is sufficient to clear the transient state.

Through 10 November 2016, Medtronic has not received any field reports or complaints of this transient mode switch behavior

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

Potential Rapid Battery Depletion Due To Circuit Component

Viva™ CRT-D and Evera™ ICD

Original Date of Advisory: August 2016

Product
A specific subset of 78 Viva CRT-D and Evera ICD may experience rapid battery depletion due to a low resistance path developing within a circuit component. You may use the "Search for Information by Serial Number" tool on home page of this web site to determine if a specific device is affected.

Advisory
Devices in the affected population may experience rapid battery depletion due to a low resistance path developing within a circuit component. This is not related to a failure within the battery.

Development of a low resistance path in the circuit component in some cases has been reported to cause battery depletion in seven (7) days or less and may present clinically during a patient follow-up visit as:

- One or more electrical resets, which will display as an observation on the programmer.
- No pacing or defibrillation therapy output.
- No telemetry.
- Programmer screen display of "SERIOUS DEVICE MEMORY FAILURE."

Patient audible alerts and CareAlerts™ may not reliably notify the patient or clinician, due to this issue.

Reported complications have included shortness of breath, pocket heating, low heart rate, and early device explant.

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 options for managing patients implanted with an affected device:

Advise patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness) or if the audible patient alert sounds.

For pacemaker-dependent patients or those at a higher risk of Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF):

- Physicians should consider device replacement.

For patients where the physician does not believe device explant is the best course of action, Medtronic offers these additional options:

- Program the audible alerts for "Low Battery Voltage RRT" to "On-High". It is possible that alerts may not sound if the battery is depleted. Therefore physicians should also consider one of the following:
  - Provide a handheld magnet to patients to frequently check device status.
    - Requires one or more audible alerts be programmed ON.
    - Device operation may be monitored frequently (e.g., daily) by patients placing the magnet over the device for **1-2 seconds and then removing the magnet**. If the device is functional, a steady tone will sound for approximately 10 seconds. If no tone or an oscillating high/low tone is heard, advise patients to seek care immediately.
  - Prescribe either a CareLink™ transmission be performed by the patient, or a maintenance transmission by the clinic, on a more frequent basis (e.g., weekly or daily) based on the unique patient considerations. The clinic should review these transmissions upon receipt.
    - If the transmission is unsuccessful the patient should be brought into the clinic for immediate follow-up as this may be an indication that the device battery has depleted to a level where it can no longer support telemetry.

- Review transmissions for any signs of this issue (e.g., one or more electrical resets, or notification that a device alert has occurred).
- Each transmission will decrease battery longevity by approximately one day.

Status Update

Within the 78 devices, there have been ten (10) confirmed failures (13%) through March 6, 2017. Medtronic modeling predicts an additional three(3) failures may occur in the remaining active population. An estimated 38 devices remain active

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
78 Worldwide	**10** Worldwide	**38** Worldwide	**13%** Worldwide

Premature RRT alert in some LINQ devices

Reveal LINQ Model LNQ11

Original Date of Advisory: February 2016

Product

All Reveal LINQ™ Insertable Cardiac Monitor (ICM)

Advisory

Medtronic has identified an issue with the sensitivity of an algorithm used in the Reveal LINQ ICM that may prematurely trigger the Recommended Replacement Time (RRT) alert in some devices. As of February 12, 2016, Medtronic had observed an occurrence rate of 0.45% of devices experiencing this issue. Battery capacity is not affected and the device will continue to support data collection and manual data transmissions. As stated in Reveal LINQ labeling, the typical device will experience an average of 3 years longevity (refer to the device labelling for the corresponding use conditions). As part of the normal behavior of the device, 30 days after RRT status is reached, Reveal LINQ devices will display an End of Service (EOS) status at which time the device disables automatic wireless alerts and transmissions. Thereafter, patients will still be able to send remote manual transmissions allowing clinics to receive alerts and stored device data. Due to the design of the RRT algorithm, devices are not susceptible to this issue until 200 days (6.5 months) post-implant. As of February 12, 2016 the earliest reported occurrence of RRT is 7.3 months post-implant, with median implant to RRT duration of 16.5 months.

Medtronic has obtained the necessary regulatory approvals to begin applying a software update to prevent and correct this issue in the field. Once installed, this software update will reset RRT & End of Service (EOS) status and re-enable wireless transmissions for devices that have experienced premature RRT /EOS. The update will also prevent the occurrence of premature RRT alerts due to this issue.

How do clinics apply this update to Reveal LINQ ICMs?

During the course of their follow-up care, patients' devices can receive the update via a programmer interrogation. Clinics with Reveal LINQ ICM patients will be contacted by Medtronic with instructions on how to install the update via the CareLink™ 2090 or Encore™ Programmer. Once programmers are updated, clinics will be provided further direction by their Medtronic Representative to contact patients who have experienced a premature RRT/EOS status in order to apply the update to individual Reveal LINQ ICMs. For new implants, the updated software will automatically be loaded on the Reveal LINQ ICM during interrogation of the device using a programmer that has previously been loaded with the new software.

As of December, 2016, patients also have the ability to receive this update via their MyCareLink™ Monitor, without the need to come into a clinic. Once the update has been installed on patients' MyCareLink Monitor, the monitor itself will automatically apply the update to their Reveal LINQ ICM. If your patient's Reveal LINQ ICM is at RRT / EOS, instruct them to complete the following activities to order to receive the update as quickly as possible:

1. Unplug the MyCareLink Patient Monitor from the wall outlet, wait 10 seconds, and then plug it back in.

2. Leave your MyCareLink Patient Monitor plugged in and untouched for 24 hours to allow software updates to be successfully installed.

3. After 24 hours have elapsed, complete a manual transmission using your MyCareLink Patient Monitor.

How can I get more information on this update?

Additional information, including direction on how to apply this update, can be found at MedtronicDiagnostics.com/us/linq-software-update or by contacting your Medtronic Representative. Medtronic Diagnostic Patient Services is available to assist patients at 800-929-4043. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Diagnostic Technical Services at 800-929-4043.

Potential High Battery Impedance

InSync® III Model 8042

Original Date of Advisory: November 2015

Product

All InSync® III Model 8042 Pacemakers

Advisory

Medtronic has identified an issue related to long-term battery performance. Through 27 October 2015, Medtronic has confirmed 30 devices (0.03%) worldwide have been impacted by this issue, for which the root cause is unexpected high battery impedance.

Unexpected high battery impedance can result in the battery's inability to supply sufficient electrical current, impacting device function. Twelve (12) of the 30 devices had reports of unexpected loss of pacing capture. The other 18 devices experienced some form of erratic behavior, including early elective replacement indication (ERI), significant fluctuations in remaining longevity estimates, and inaccurate lead impedances. Through 27 October 2015, events associated with this issue have occurred in devices with implant durations of 53 months or more. Medtronic has received one report of a patient death, where it is possible, but unconfirmed, that this issue was a contributing factor.

If pacing capture is compromised, some patients may experience a return of heart failure symptoms due to loss of biventricular pacing. In cases involving pacemaker-dependent patients, a loss of pacing capture could result in serious injury or death.

The Physician Letter for this issue is available at http://www.medtronic.com/insync-iii-crt-p

Patient Management Recommendations (As of November 2015)

We realize that each patient requires unique clinical consideration. After consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic offers the following recommendations for patients with an InSync III CRT-pacemaker:

- Prophylactic device replacement in non-pacemaker-dependent patients is not recommended.
- For pacemaker-dependent patients, physicians should carefully weigh the risks and benefits of device replacement to mitigate this issue on an individual patient basis
    - The estimated per patient mortality risk of this issue (0.007% to 0.02%) is comparable to the estimated per patient mortality risk of complications associated with an incremental, early device replacement (0.005%).
- Continue routine patient follow up in accordance with standard practice, and advise patients to seek medical attention immediately if they experience new or unexpected symptoms.

Status Update

As of March 6, 2017, approximately 13,000 devices remain active worldwide, from an original implant population of 96,800. In the United States, 5,200 active devices remain. Our modeling predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency. InSync III CRT-pacemakers are no longer distributed.

Advisories

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
96,800 Worldwide (**39,900** United States)	**114** Worldwide (**62** United States)	**13,000** Worldwide (**5,200** United States)	**0.12%** Worldwide (**0.15%** United States)

Potential Rapid Battery Depletion

EnTrust® VR/DR/AT ICDs

Original Date of Advisory: March 2012

Product

All EnTrust ICDs.

Advisory

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

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

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed. The Physician Letter is available at http://www.medtronic.com/product-advisories/entrust/physician/index.htm

Patient Management Recommendations (As of March 2012)
After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient managementrecommendations:

- 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 March 6, 2017, there have been 96 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)	**96** Worldwide (**75** United States)	**5,800** Worldwide (**3,600** United States)	**0.14%** Worldwide (**0.17%** United States)

Low Battery Voltage Displayed at Device Interrogation

EnRhythm and EnRhythm MRI Pacemakers

Original Date of Advisory: February 2010

Product

All EnRhythm and EnRhythm MRI pacemakers.

Original Advisory Information (February 2010)

Two specific battery issues with EnRhythm pacemakers were identified. The risks to patients for both issue have been addressed by a Medtronic software update. The Physician Letter is available at http://www.medtronic.com/enrhythm-advisory/physician.html

First Issue

In February 2010, Medtronic had received 62 reports (out of approximately 110,000 devices worldwide) indicating that the battery voltage at device interrogation was lower than the battery voltage that is tracked by the device to provide data for the elective replacement indicator (ERI) notification.

Medtronic's investigation found that none of these reports resulted in loss of therapy. Importantly, the original ERI notification, which uses the nightly battery voltage measurement, was unaffected and accurate. Medtronic identified the root cause as higher than expected battery impedance.

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

Second Issue

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

Software Update (As of October 2010)

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

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

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

Updated Performance Information (as of August 2011)

We now have access to battery impedance and ERI performance on more than 5000 EnRhythm devices that have received the EnRhythm software update. Our modeling based on these data shows that approximately 6-10% of devices will reach ERI within 5 years post-implant. Consistent with our previous communications, we continue to expect average device longevity to be reduced by approximately 10 –15%, with the expected average longevity remaining at 8.5 to 10.5 years, depending on device settings.[1]

Updated Patient Management Recommendations (as of August 2011)

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

- Performing a device follow-up within 90 days after the software download to identify devices that triggered ERI shortly after the software update. Subsequent follow up can be performed per standard practice. During programmer interrogation of a device at ERI, there is a slight possibility a transient drop in pacing amplitude could occur. If this is noted, either remove the programmer head or temporarily program to a higher output voltage.
- If an unanticipated ERI/EOL is declared, it is likely due to battery impedance. In such cases, additional battery capacity remains and can support device function at ERI parameters for at least one year. However, when ERI or EOL (typically 90 days after ERI) declaration is seen, schedule device replacement.

Status Update

First Issue

Included in the August 2011 Performance Update was information about the projected percentage of devices that would encounter an early ERI due to unexpected high battery impedance. As of March 6, 2017, the 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. Over 98% of the remaining active population is over 5 years post- implant.

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)	**17,801** Worldwide	**5,898**	**6.4%**	**0**	**36,500** Worldwide

Second Issue

Initial Affected Population	Number of Events of Loss of Therapy Due to Increased Rate of Lithium Depletion	Estimated Remaining Active Population
All EnRhythm pacemakers (**146,500** Worldwide)	**0** Worldwide	**36,500** Worldwide

[1] *The 8.5 year estimate represents a high use scenario (DDD, 100% pacing in atrium and ventricle with 3.0 V output in both chambers). The 10.5 year estimate represents a typical use scenario for a sinus node dysfunction patient with the MVP function ON (AAI(R) <=> DDD(R), 50% pacing in atrium and 5% pacing in ventricle with 3.0 V output in both chambers). Projections are based on modeling and not actual field returns, due to limited availability of implant experience beyond 6 years. Field performance will continue to be monitored and modeling updated to reflect actual data.*

[2] *Accounts for underreporting of impedance ERIs based on the fraction of replaced devices in the U.S. registration system that are subsequently returned.*

Potential Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Product

All Model 6930, 6931, 6948, and 6949 implantable defibrillation leads.

Advisory

There are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. These two locations account for approximately 90% of the chronic fractures identified in Returned Product Analysis (RPA). The remaining 10% of chronic fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

Patient Management Recommendations (Updated April 2011)

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

- **If a Fidelis lead fracture of any type has occurred,we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred. This data is available at http://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/sprint-fidelis-11-2015-update.html
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Status Update

As of March 9, 2017, of the initial implant population of 205,600 in the United States, approximately 56,300 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 78.6% (+4.0/-3.9%) at 114 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.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	
279,500 Worldwide (**205,600** United States)	**6,859** Worldwide **(4,895** United States)	**76,500** Worldwide (**56,300** United States)	

Footnotes:

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

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Potential Separation of Interconnect Wires (2005)

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. You may use the "Search forDevice Information" 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 March 6, 2017, 850 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred eighty-four(484) of the Sigma devices (1.1%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 366 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, less then 300 remain active worldwide.

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)	**484** Worldwide (**98** United States) with information indicating a clinical presentation. An additional **366** Worldwide (**67** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	less than 300 worldwide	**1.1%** Worldwide (**1.0%** United States)	**3.9%**

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

Purpose of this Information

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

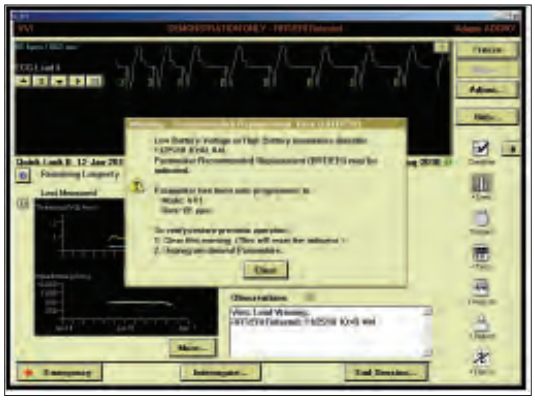
Background

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

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

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

Example 1 – Programmer Software Detects Measurement Lock-up ERI

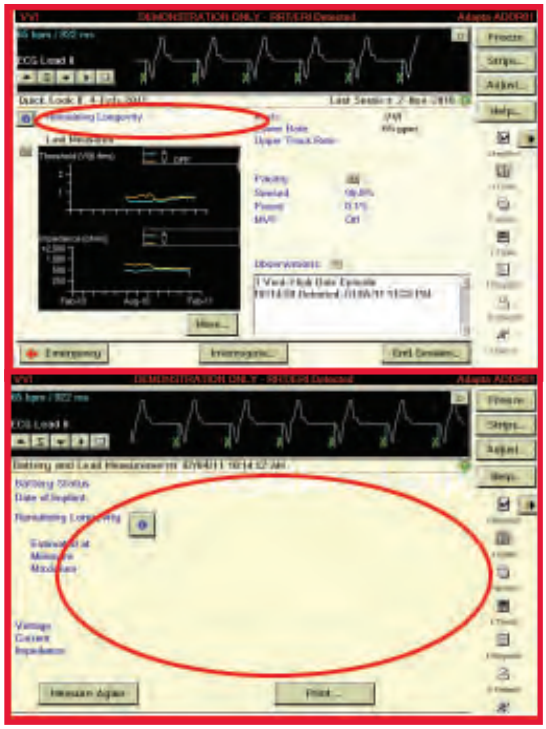


Reset Method for Kappa and EnPulse

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

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

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



Clinical Management of VCM near Elective Replacement

Background

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

Device Longevity and VCM Behavior

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

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

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

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

Table: IPG Therapy Parameter Changes at ERI

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

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

Follow-Up Considerations

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

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

General Follow-Up and Replacement of ICD Leads

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

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

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/clinic follow-up practice, and Medicare guidelines.

In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity.

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

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

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

General Criteria for Lead Replacement

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

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

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

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

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

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

Clinical Management of High-Voltage Lead System Oversensing

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

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

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

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

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

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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