CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2020

1st Edition – Issue 82

Medtronic

CRHF Product Performance Report

2020

1st Edition

Issue 82

Cutoff date for this edition is 31 Jan 2020 for Lead Study data and 10 April 2020 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.

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

tshelp@medtronic.com

Phone:

1 (800) 723-4636 (Tachy)

1 (800) 505-4636 (Brady)

Fax:
1 (800) 824-2362

US Instrumental Technical Services

1 (800) 638-1991

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Europe (Heerlen NL) +31-45-566-8844
Japan (Tokyo) +81-3-6430-7026
rs.mst-techserviceseurope@medtronic.com

Japan (Tokyo) +81-3-6776-0047

Australia-New Zealand
au.crdmtechservices@medtronic.com

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

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

Within the United States:
Your Medtronic representative or
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 36 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.

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

Customer Communications - 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.

Customer Communications- 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.

Introduction continued

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.

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.
(c) a device is taken out of service without an associated complaint and with evidence the battery reached its elective replacement indicator(s).

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 device survival probabilities, the number of malfunctions and battery depletions used to plot each interval of the "Including Normal Battery Depletion" 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.

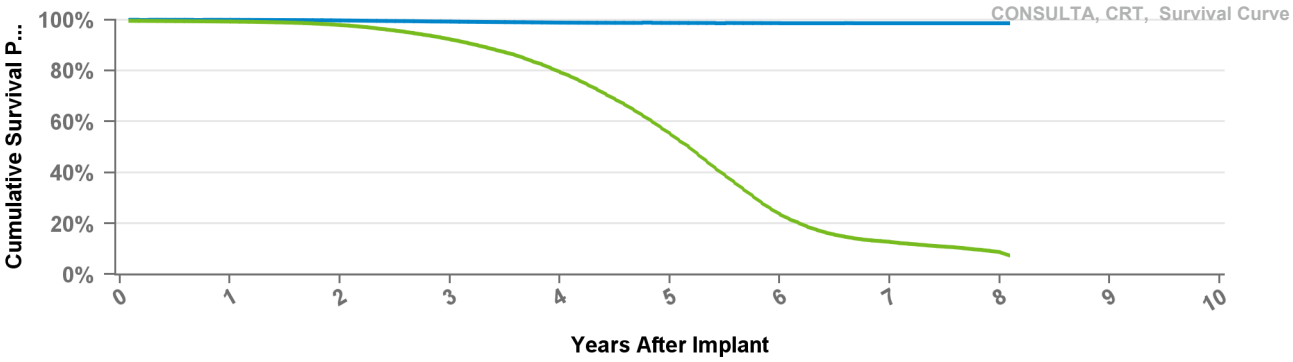
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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.

D204TRM Consulta CRT-D

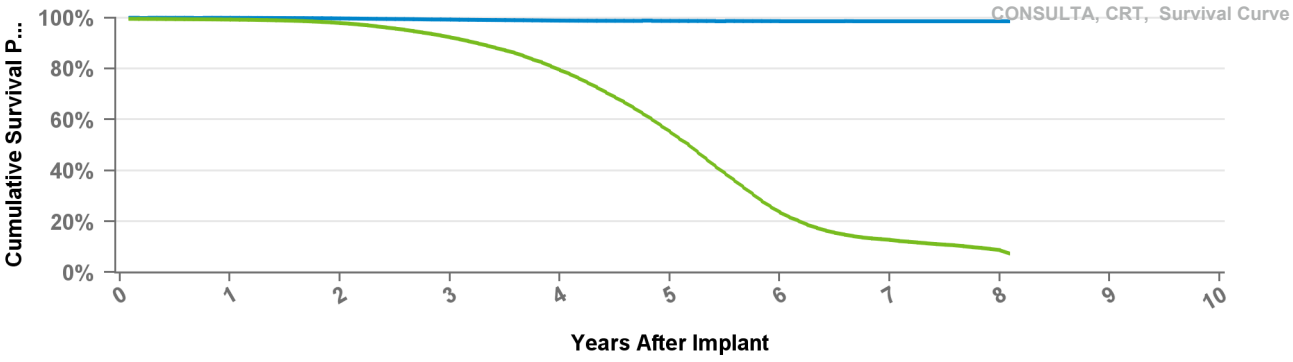
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,099	Battery Malfunction	1
Estimated Active USA Implants	590	Electrical Component	1
Normal Battery Depletions	706	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.9%	92.3%	79.4%	55.2%	23.6%	12.8%	8.8%	7.4%
Effective Sample Size	57474	52308	45402	34872	19624	6304	2100	249	111

D214TRM Consulta CRT-D

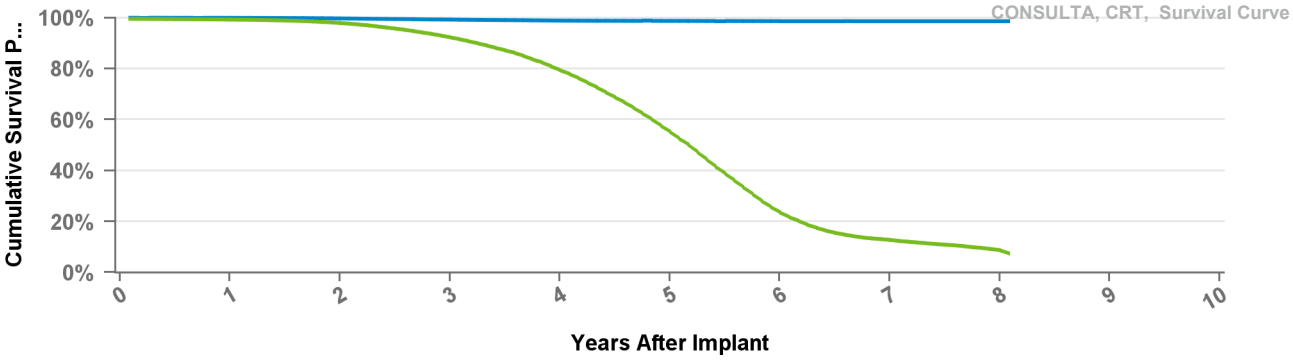
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.9%	92.3%	79.4%	55.2%	23.6%	12.8%	8.8%	7.4%
Effective Sample Size	57474	52308	45402	34872	19624	6304	2100	249	111

D224TRK Consulta CRT-D

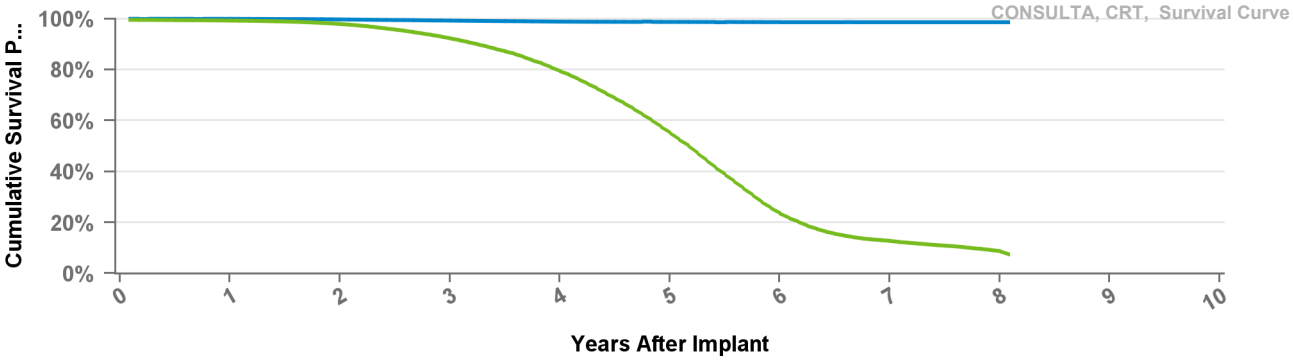
US Market Release	Sep-08	**Total Malfunctions**	**602**
CE Approval Date		**Therapy Function Not Compromised**	**571**
Registered USA Implants	65,980	Battery Malfunction	2
Estimated Active USA Implants	11,114	Electrical Component	65
Normal Battery Depletions	18,826	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	496
		Software Malfunction	6
		Therapy Function Compromised	**31**
		Battery Malfunction	5
		Electrical Component	26



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.9%	92.3%	79.4%	55.2%	23.6%	12.8%	8.8%	7.4%
Effective Sample Size	57474	52308	45402	34872	19624	6304	2100	249	111

D234TRK Consulta CRT-D

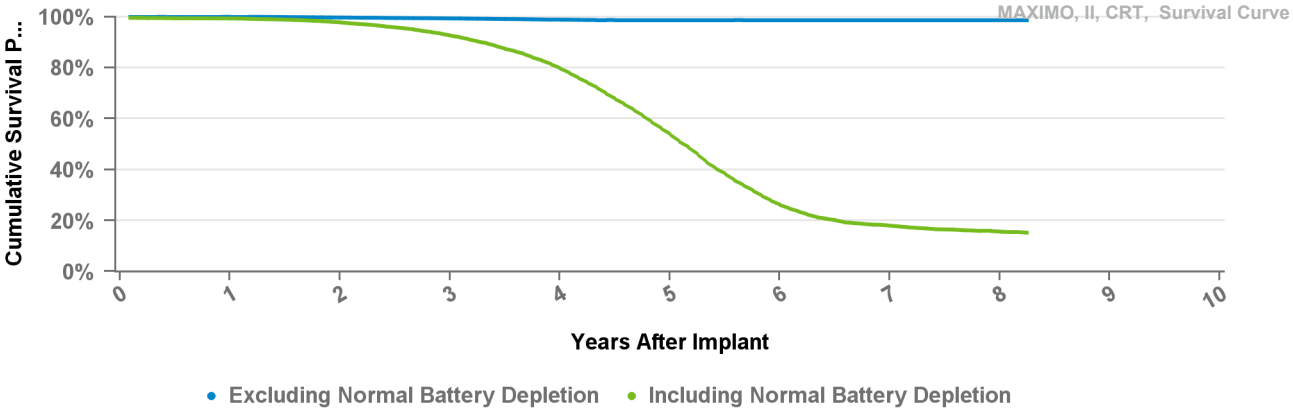
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.9%	92.3%	79.4%	55.2%	23.6%	12.8%	8.8%	7.4%
Effective Sample Size	57474	52308	45402	34872	19624	6304	2100	249	111

D264TRM Maximo II CRT-D

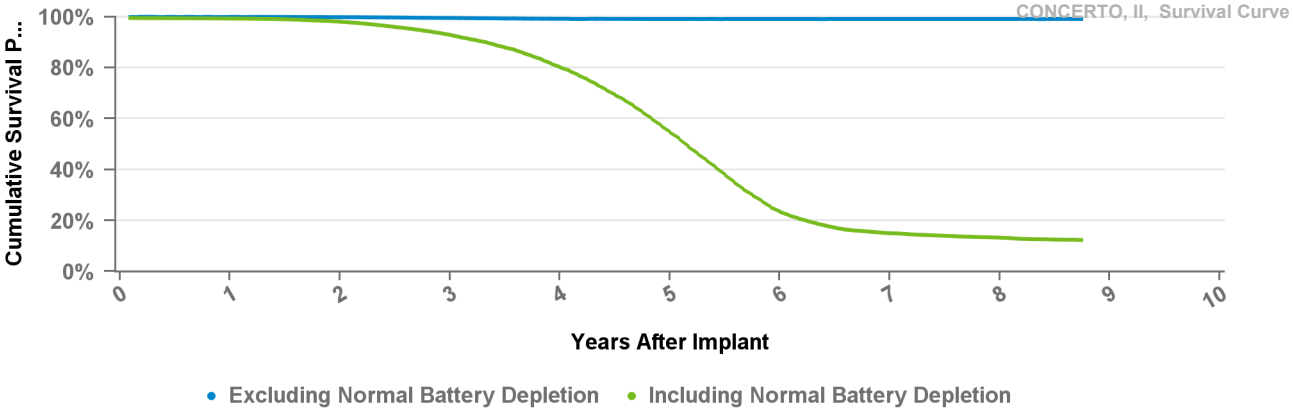
US Market Release	Jan-12	**Total Malfunctions**	**1**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other Malfunction	1
Estimated Active USA Implants	4	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.8%	92.6%	79.8%	53.9%	26.1%	18.0%	15.6%	15.2%
Effective Sample Size	12826	11569	10063	7671	4058	1425	697	250	106

D274TRK Concerto II CRT-D

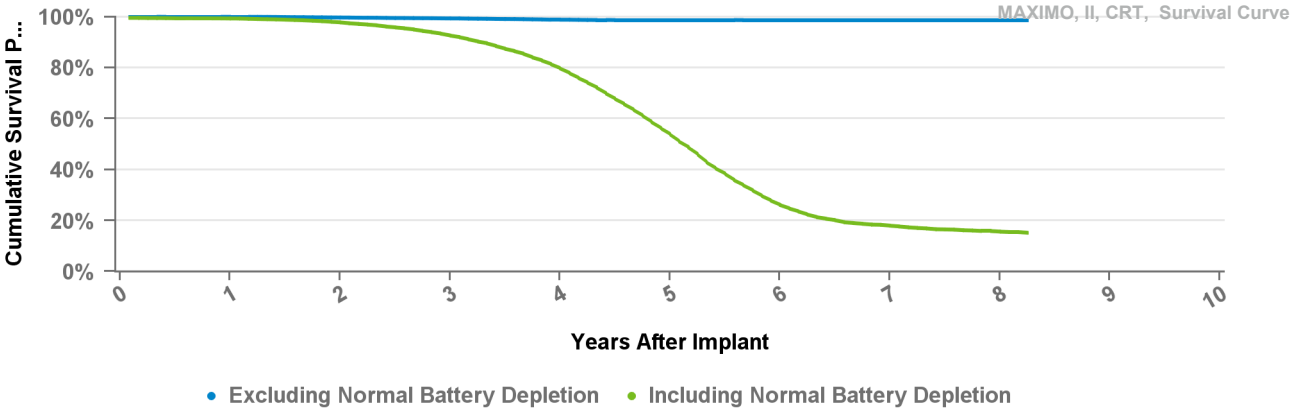
US Market Release	Aug-09	**Total Malfunctions**	**186**
CE Approval Date		**Therapy Function Not Compromised**	**175**
Registered USA Implants	30,173	Battery Malfunction	1
Estimated Active USA Implants	5,785	Electrical Component	22
Normal Battery Depletions	7,969	Poss Early Battery Depltn	151
		Software Malfunction	1
		Therapy Function Compromised	**11**
		Battery Malfunction	1
		Electrical Component	10



Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%	99.1%	99.0%
Including NBD	99.3%	98.0%	92.9%	80.2%	54.7%	23.4%	15.0%	13.3%	12.3%
Effective Sample Size	25215	23028	20060	15301	8120	2570	1290	976	166

D284TRK Maximo II CRT-D

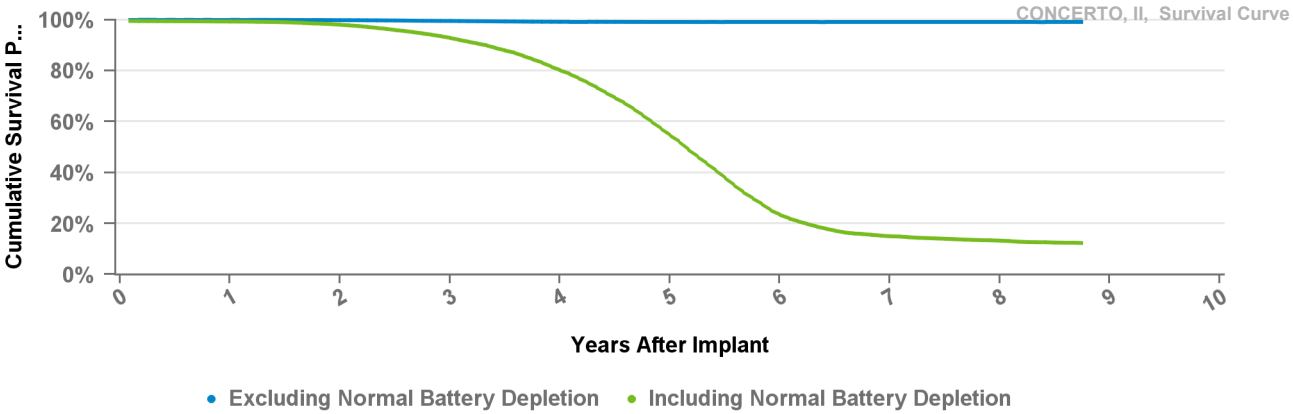
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,249	Electrical Component	6
Estimated Active USA Implants	2,822	Poss Early Battery Depltn	124
Normal Battery Depletions	4,059	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.3%	97.8%	92.6%	79.8%	53.9%	26.1%	18.0%	15.6%	15.2%
Effective Sample Size	12826	11569	10063	7671	4058	1425	697	250	106

D294TRK Concerto II CRT-D

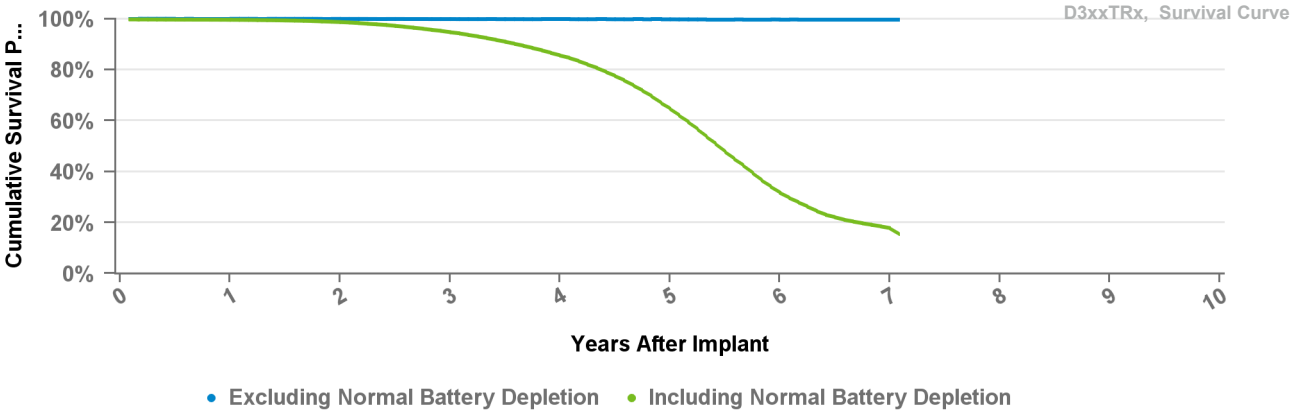
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%	99.1%	99.0%
Including NBD	99.3%	98.0%	92.9%	80.2%	54.7%	23.4%	15.0%	13.3%	12.3%
Effective Sample Size	25215	23028	20060	15301	8120	2570	1290	976	166

D314TRG Protecta XT CRT-D

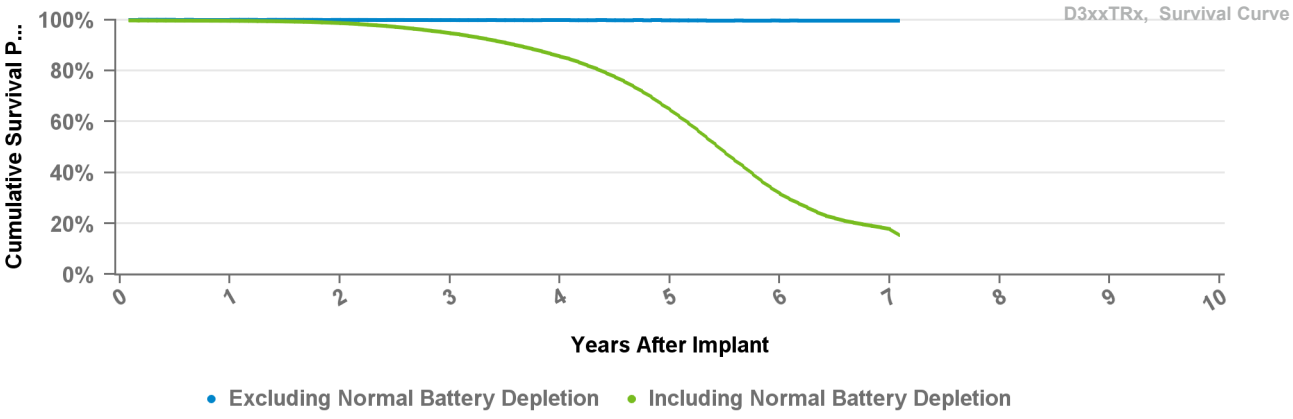
US Market Release	Mar-11	**Total Malfunctions**	**92**
CE Approval Date		**Therapy Function Not Compromised**	**73**
Registered USA Implants	42,519	Battery Malfunction	7
Estimated Active USA Implants	11,636	Electrical Component	39
Normal Battery Depletions	10,186	Other Malfunction	2
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**19**
		Battery Malfunction	11
		Electrical Component	8



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D314TRM Protecta XT CRT-D

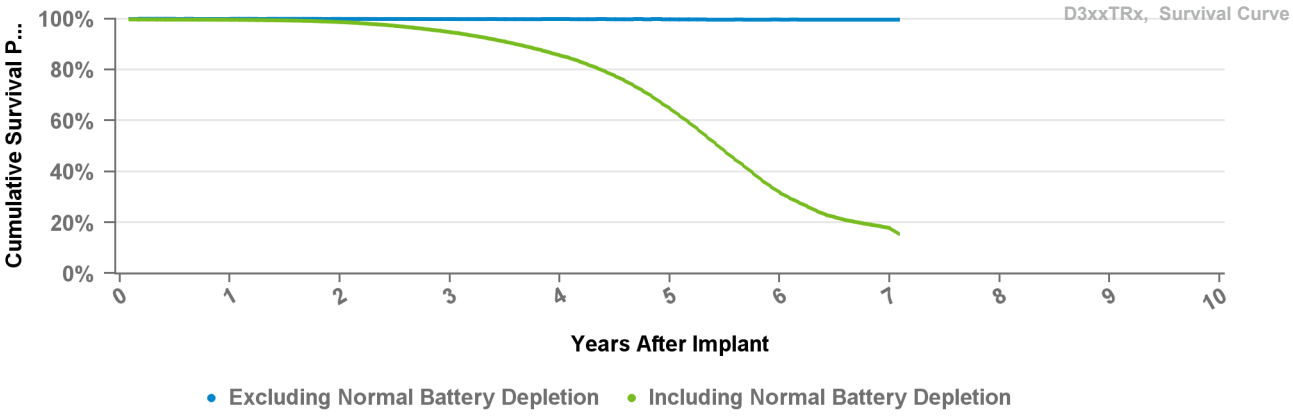
US Market Release	Nov-11	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,260	Battery Malfunction	4
Estimated Active USA Implants	3,532	Electrical Component	8
Normal Battery Depletions	3,399	Poss Early Battery Depltn	5
		Therapy Function Compromised	**3**
		Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D334TRG Protecta CRT-D

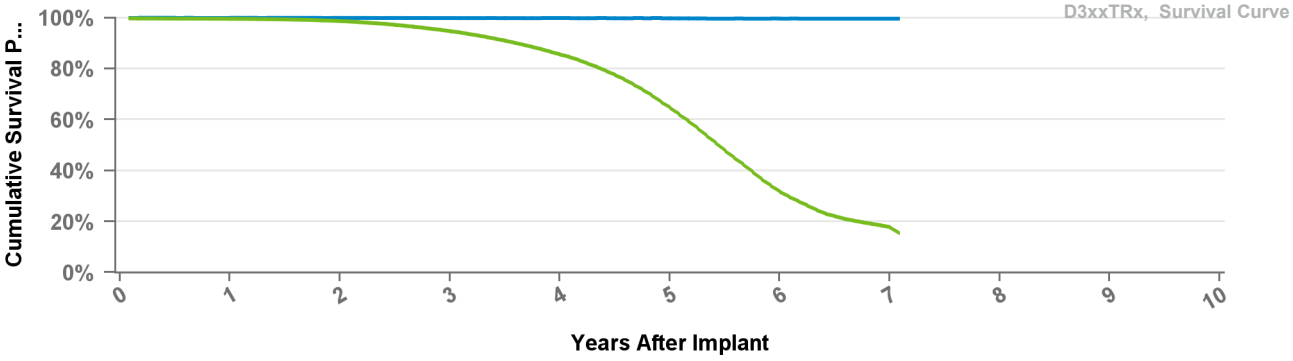
US Market Release	Mar-11	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,100	Electrical Component	8
Estimated Active USA Implants	2,455	Poss Early Battery Depltn	3
Normal Battery Depletions	2,040	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D334TRM Protecta CRT-D

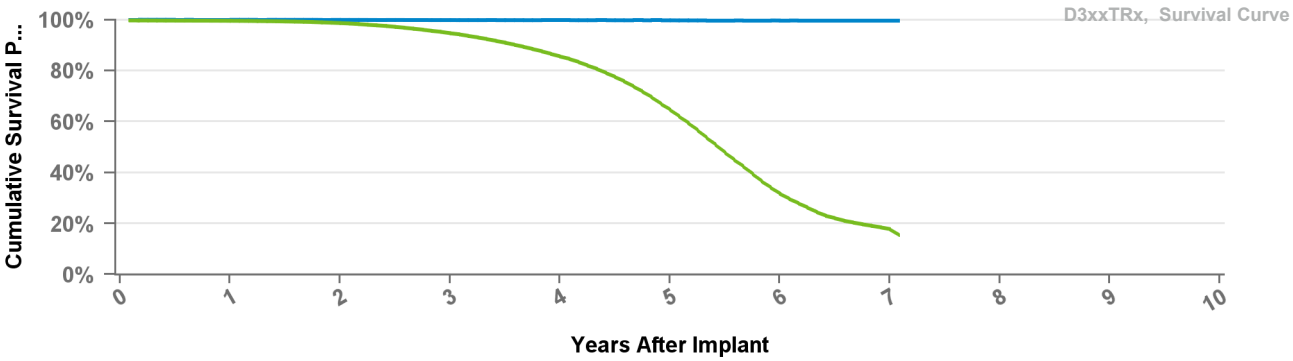
US Market Release	Nov-11	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	1,786	Battery Malfunction	3
Estimated Active USA Implants	554	Electrical Component	1
Normal Battery Depletions	539	Poss Early Battery Depltn	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D354TRG Protecta XT CRT-D

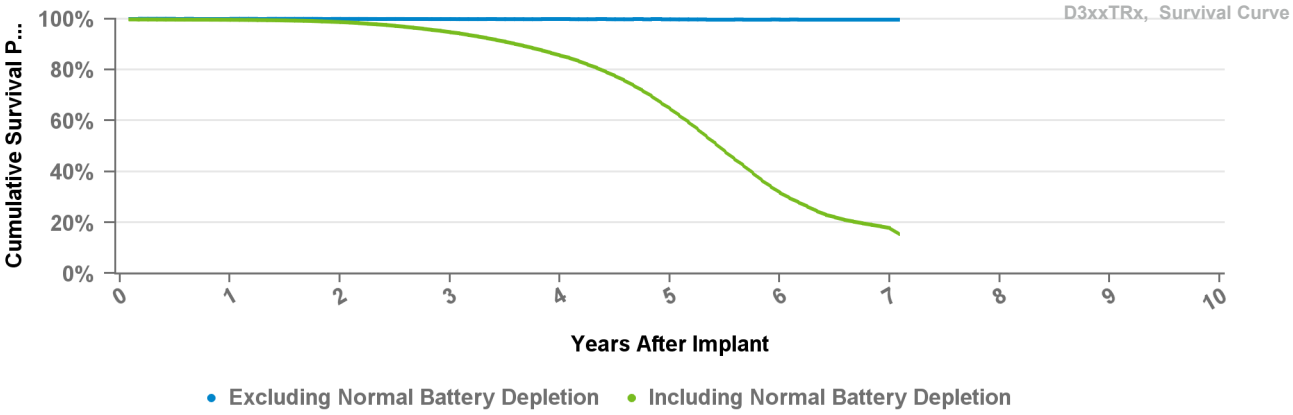
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D354TRM Protecta XT CRT-D

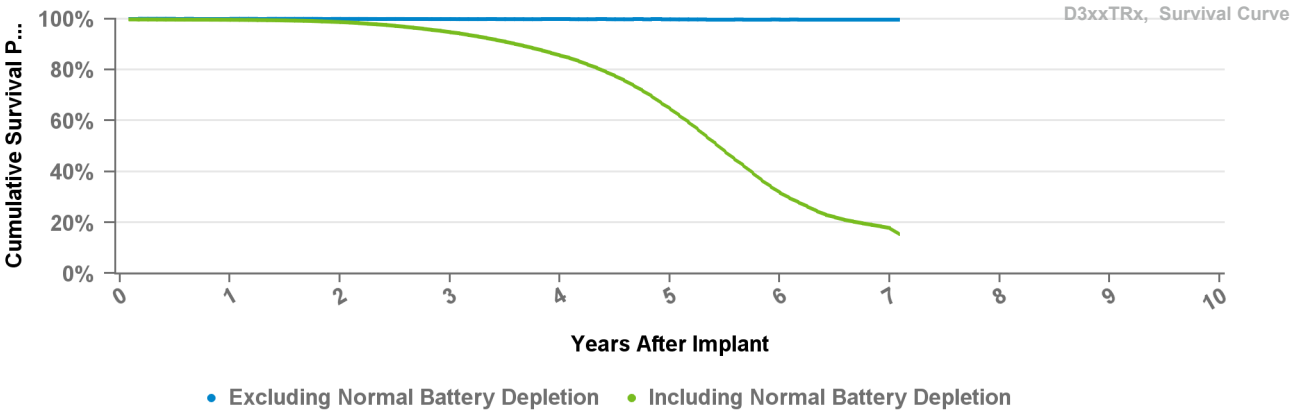
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D364TRG Protecta CRT-D

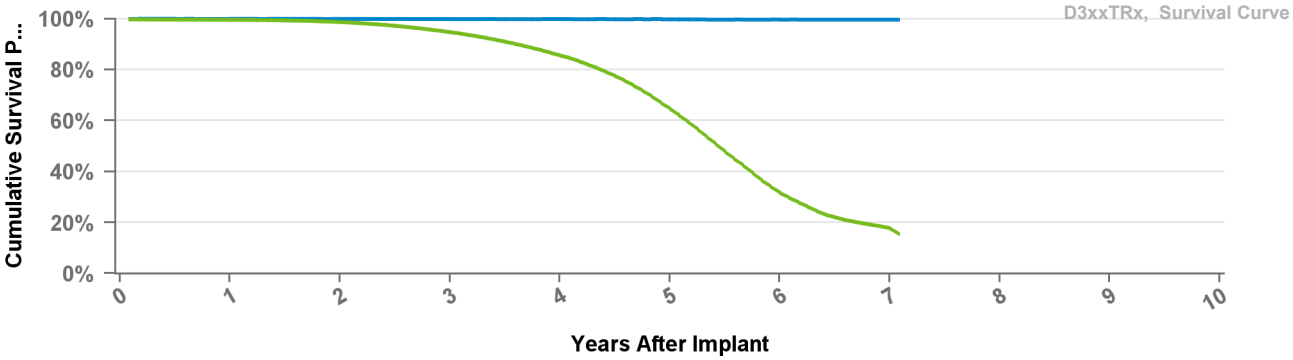
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D364TRM Protecta CRT-D

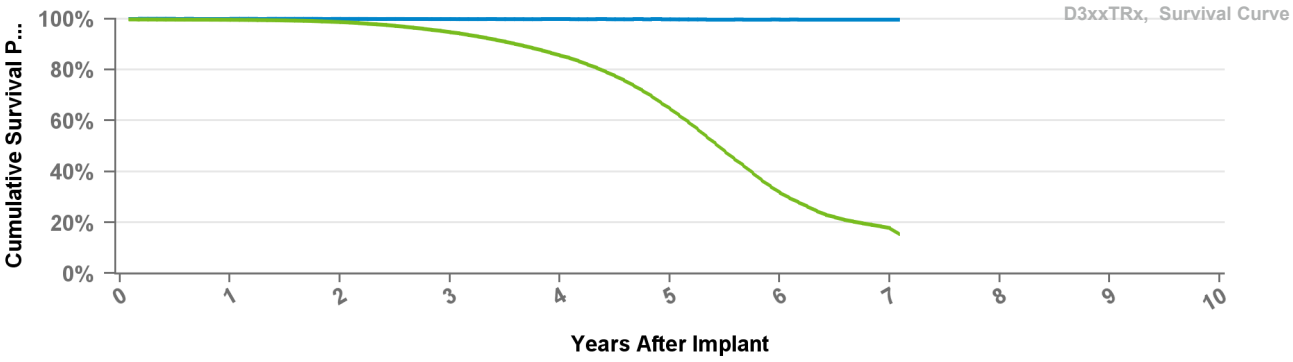
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D384TRG Cardia CRT-D

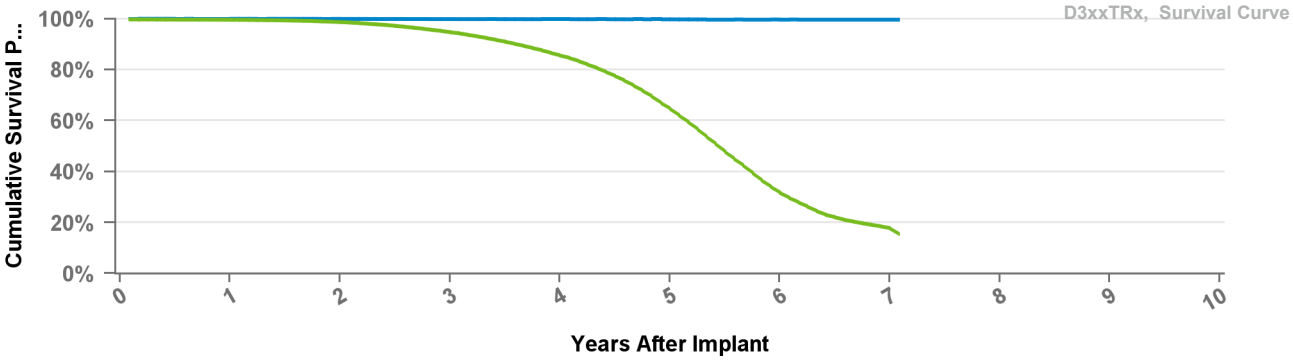
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

D394TRG Egida CRT-D

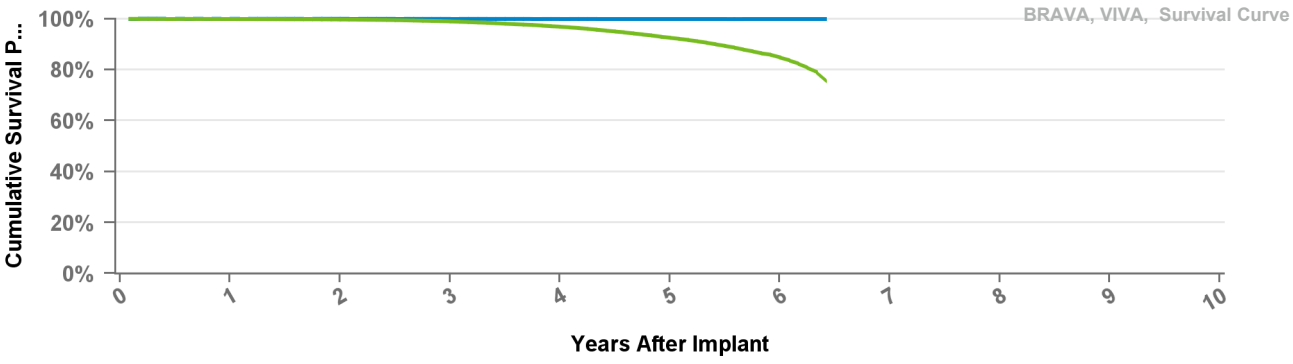
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	98.7%	94.7%	85.6%	64.7%	31.7%	17.8%	15.4%
Effective Sample Size	55304	50929	44790	35399	21406	7949	1014	282

DTBA1D1 Viva XT

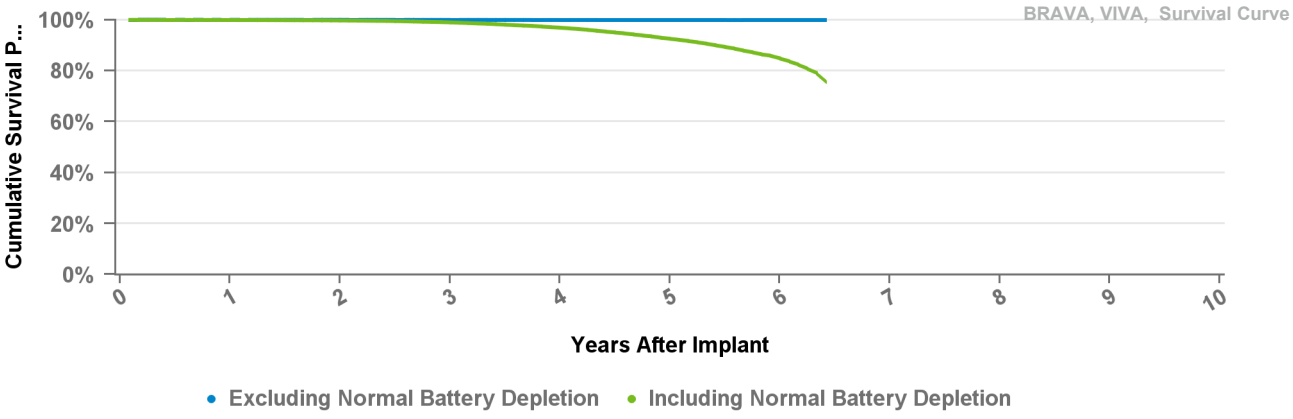
US Market Release	Jan-13	**Total Malfunctions**	**52**
CE Approval Date		**Therapy Function Not Compromised**	**39**
Registered USA Implants	57,186	Battery Malfunction	5
Estimated Active USA Implants	42,285	Electrical Component	30
Normal Battery Depletions	1,827	Other Malfunction	3
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**13**
		Battery Malfunction	10
		Electrical Component	3



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBA1D4 Viva XT

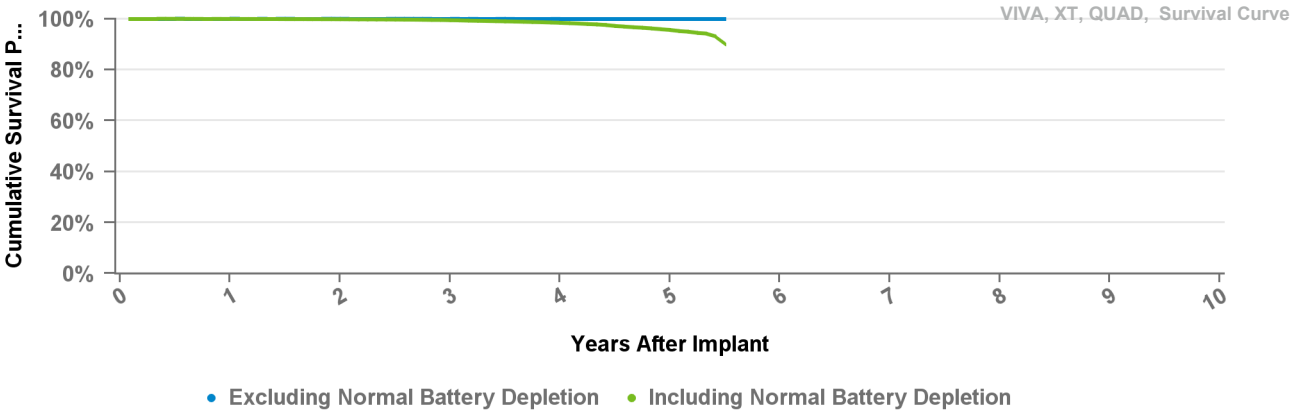
US Market Release	Jan-13	**Total Malfunctions**	**29**
CE Approval Date		**Therapy Function Not Compromised**	**23**
Registered USA Implants	20,183	Battery Malfunction	3
Estimated Active USA Implants	15,538	Electrical Component	17
Normal Battery Depletions	730	Poss Early Battery Depltn	3
		Therapy Function Compromised	**6**
		Battery Malfunction	3
		Electrical Component	3



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBA1Q1 Viva Quad XT

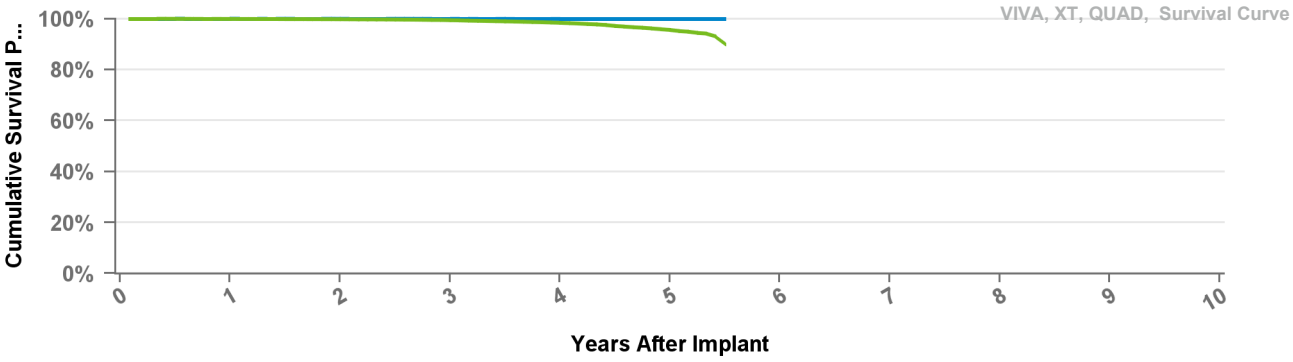
US Market Release	Jul-14	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	11,031	Battery Malfunction	1
Estimated Active USA Implants	8,946	Electrical Component	3
Normal Battery Depletions	165	Other Malfunction	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTBA1QQ Viva Quad XT

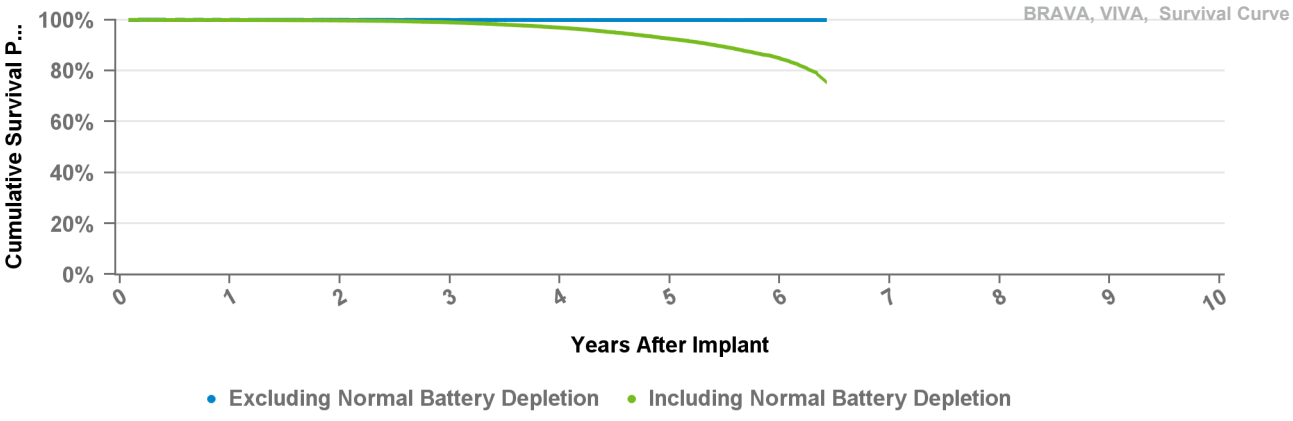
US Market Release	Jul-14	**Total Malfunctions**	**29**
CE Approval Date		**Therapy Function Not Compromised**	**23**
Registered USA Implants	27,561	Battery Malfunction	3
Estimated Active USA Implants	24,155	Electrical Component	15
Normal Battery Depletions	351	Electrical Interconnect	1
		Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**6**
		Battery Malfunction	4
		Electrical Component	2



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTBA2D1 Viva XT

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

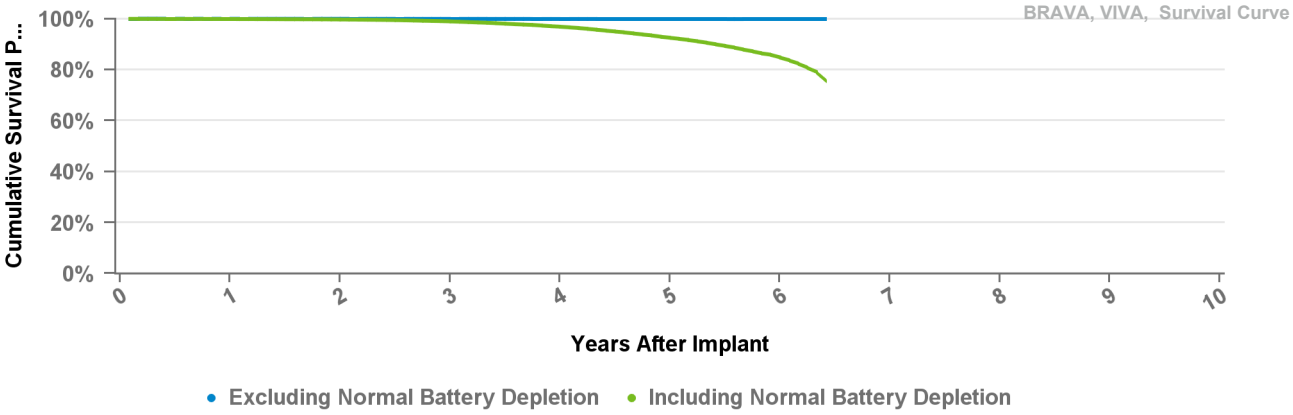


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

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

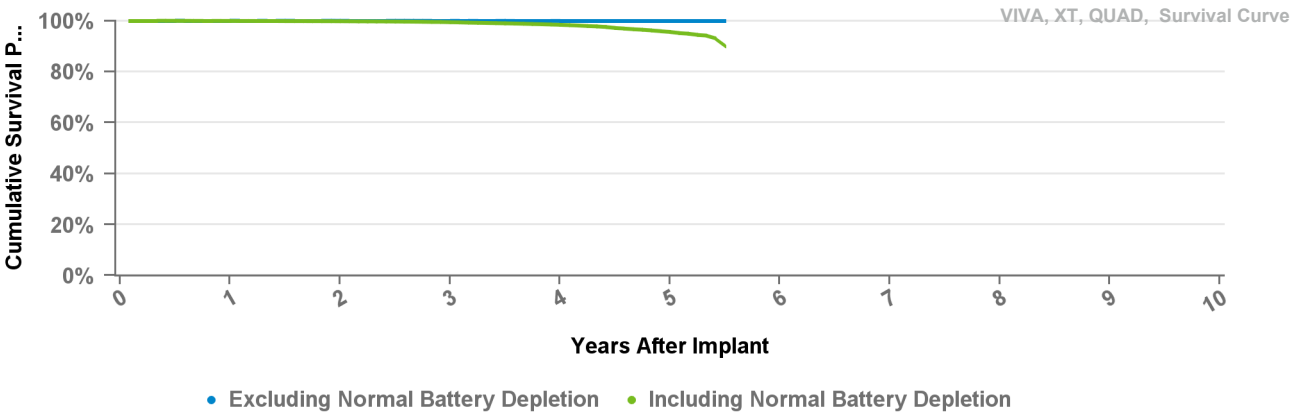


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBA2Q1 Viva Quad XT

US Market Release
CE Approval Date Sep-13
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

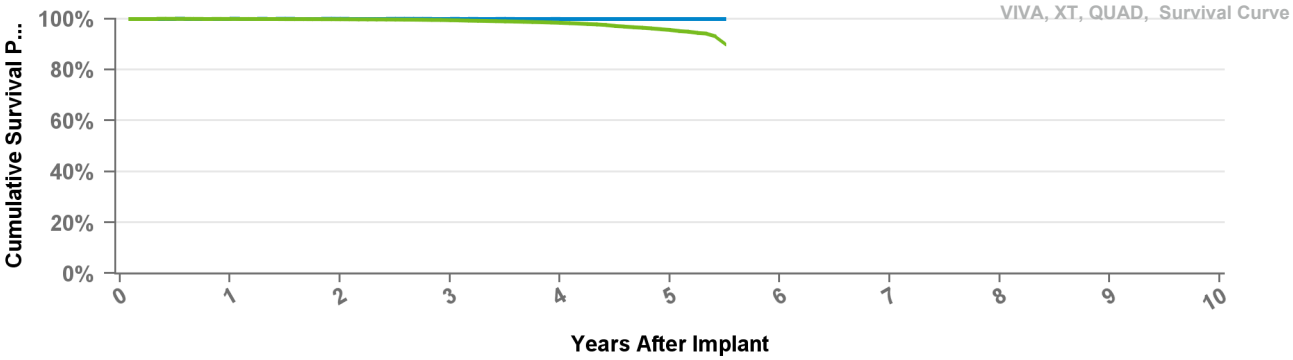
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTBA2QQ Viva Quad XT

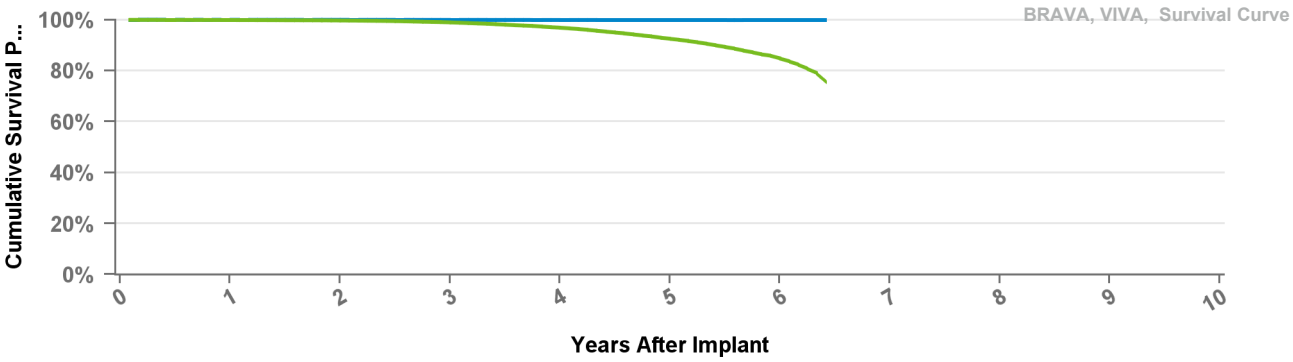
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTBB1D1 Viva S

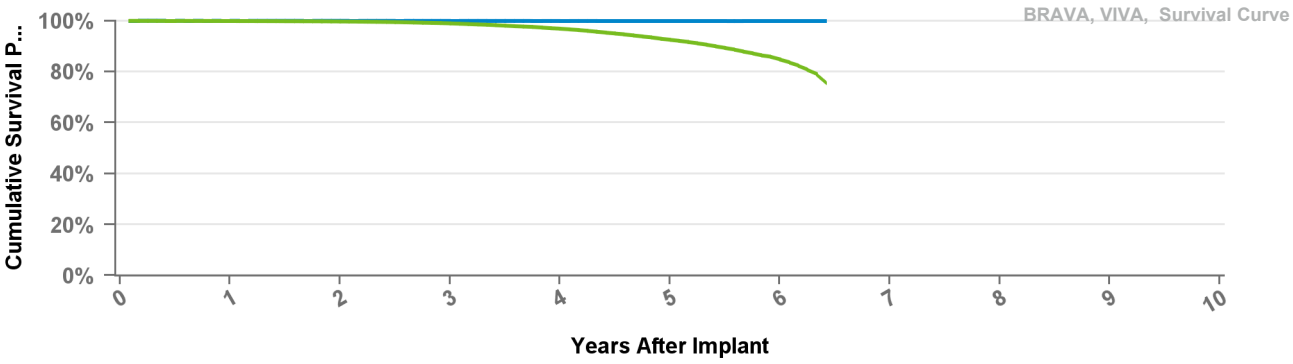
US Market Release	Jan-13	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	14,118	Battery Malfunction	5
Estimated Active USA Implants	9,824	Electrical Component	3
Normal Battery Depletions	693	Poss Early Battery Depltn	1
		Therapy Function Compromised	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBB1D4 Viva S

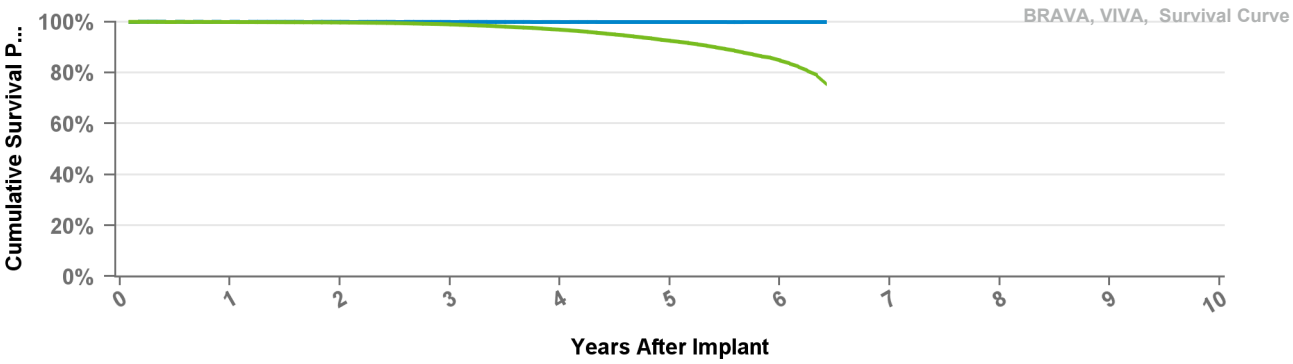
US Market Release	Jan-13	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,635	Battery Malfunction	1
Estimated Active USA Implants	3,456	Electrical Component	1
Normal Battery Depletions	245	Other Malfunction	1
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBB1Q1 Viva Quad S

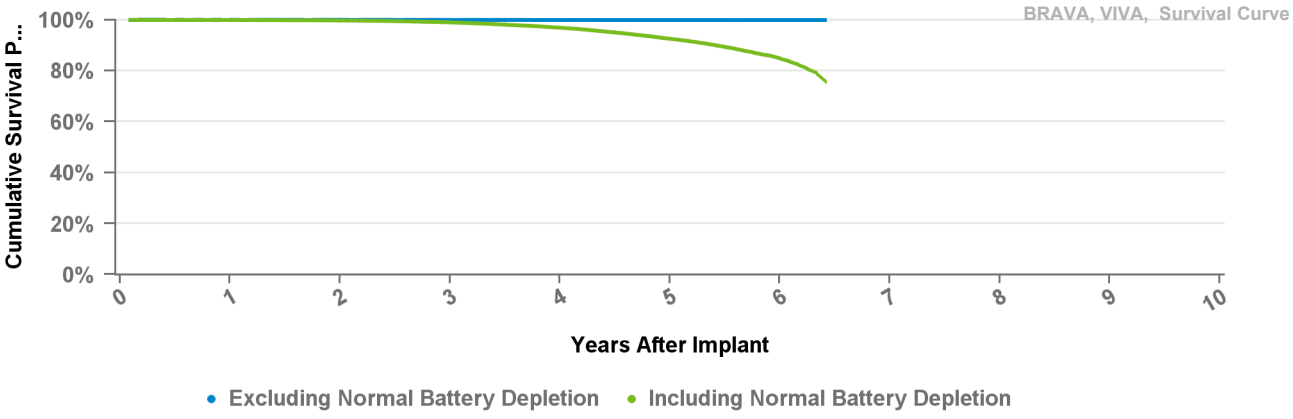
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,358	Electrical Component	1
Estimated Active USA Implants	1,913	**Therapy Function Compromised**	**0**
Normal Battery Depletions	30		



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBB1QQ Viva Quad S

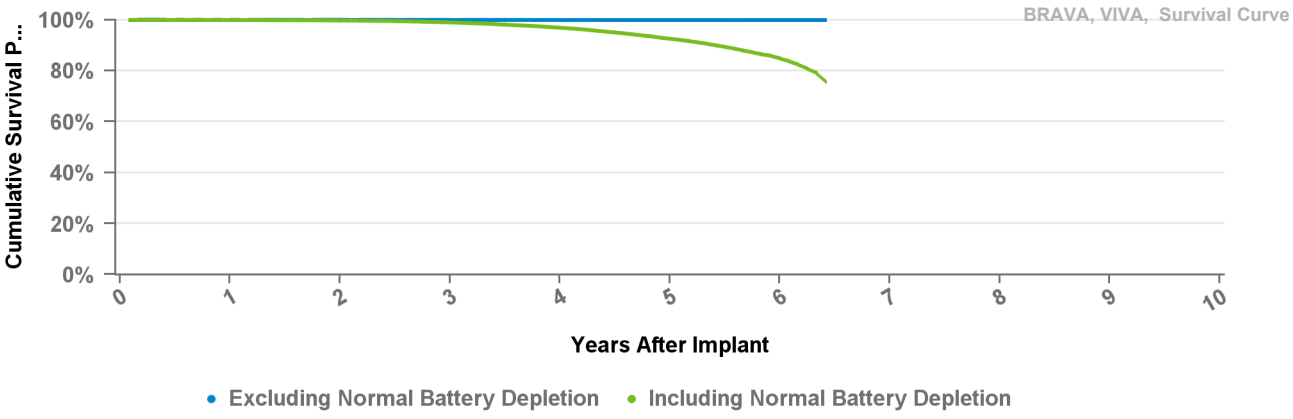
US Market Release	Jul-14	**Total Malfunctions**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	5,108	Battery Malfunction	1
Estimated Active USA Implants	4,423	Electrical Component	2
Normal Battery Depletions	103	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBB2D1 Viva 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			

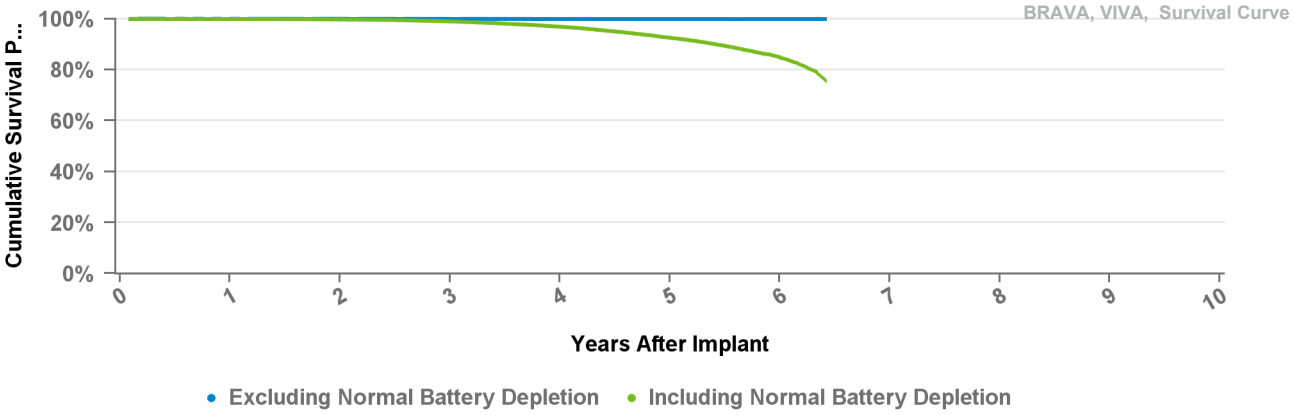


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

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

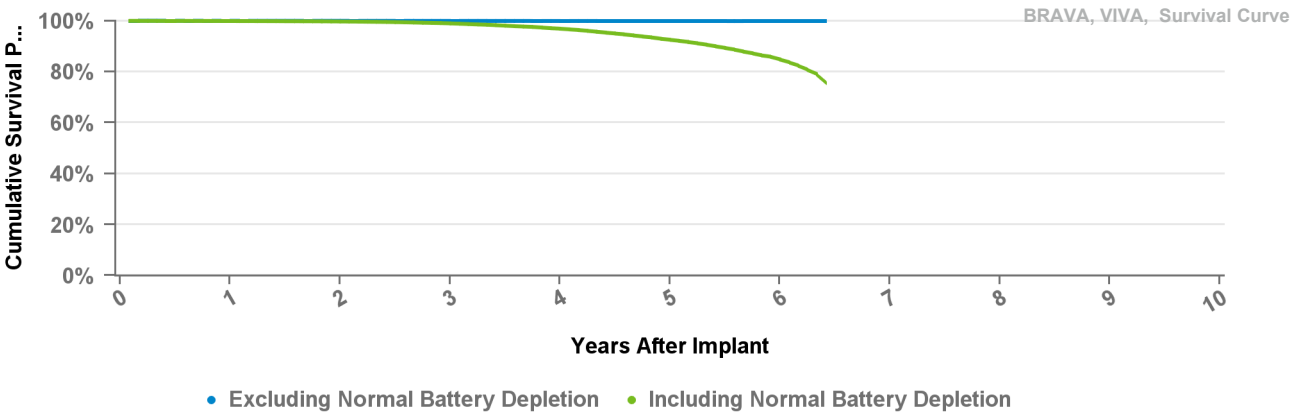


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBB2QQ Viva Quad S

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

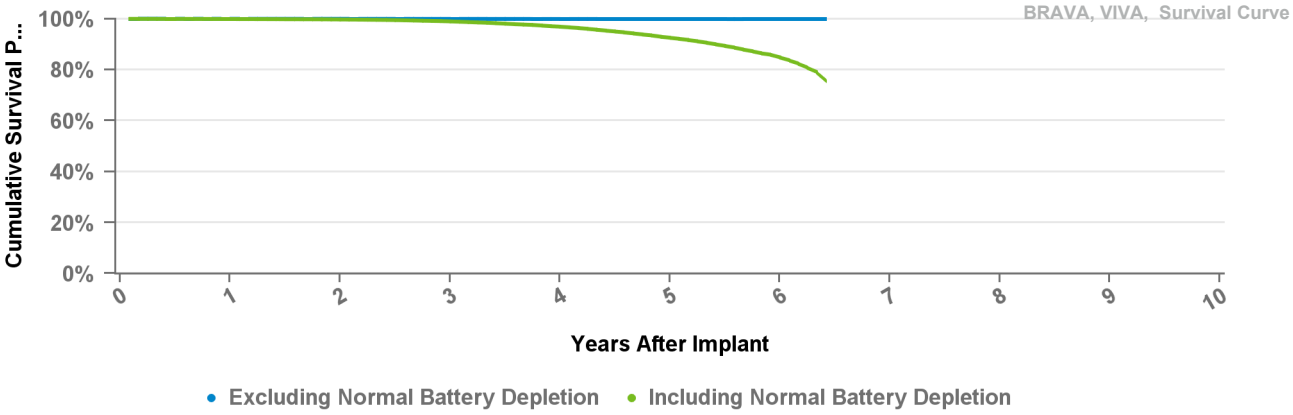
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBC2D1 Brava

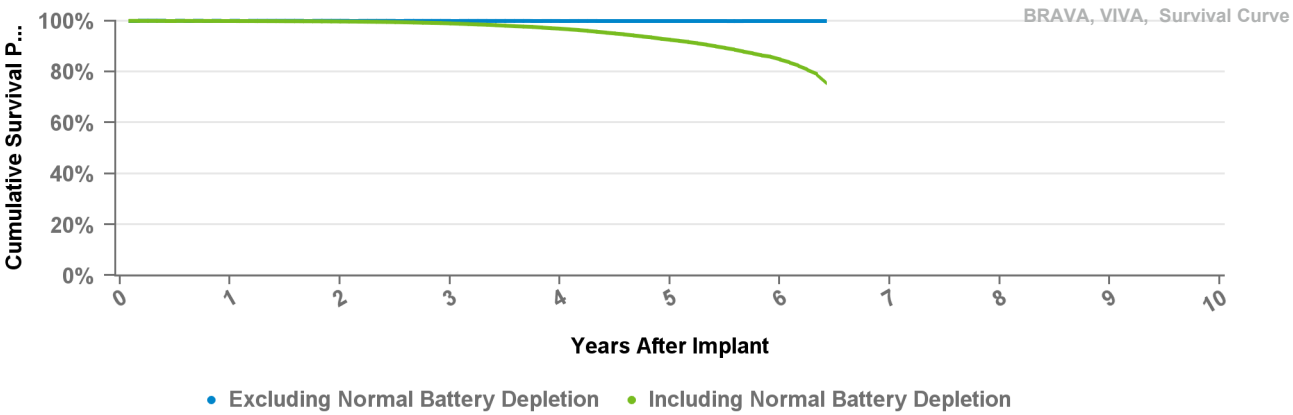
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

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			

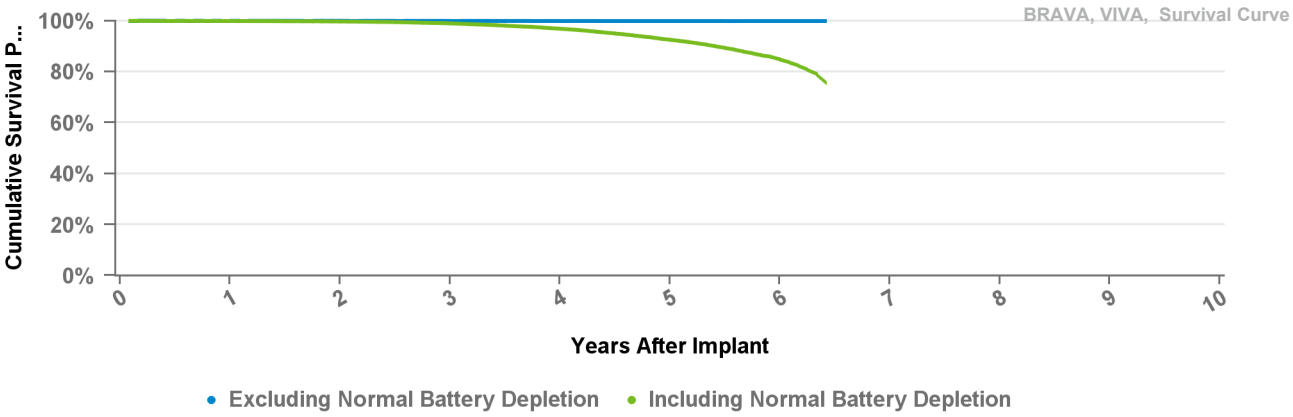


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBC2Q1 Brava Quad

US Market Release
CE Approval Date Sep-13
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

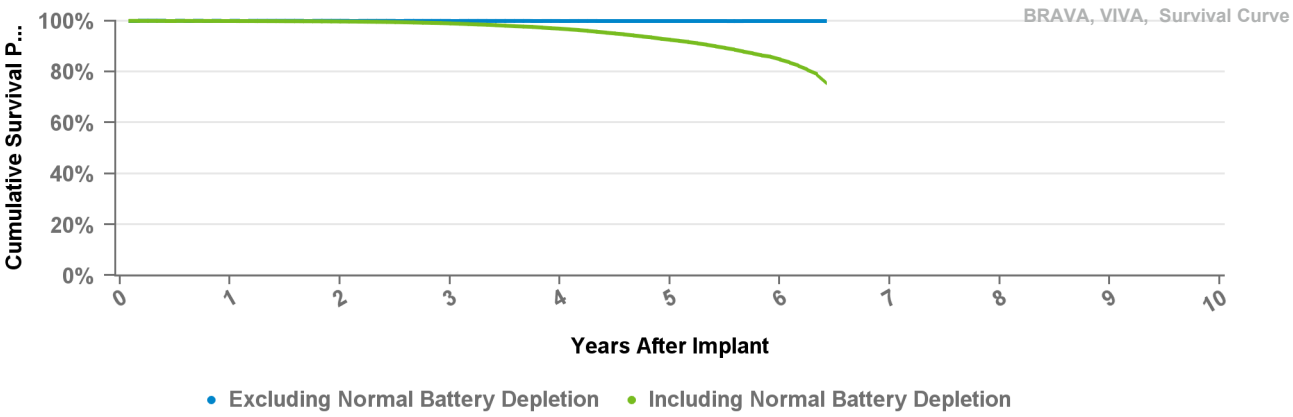


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBC2QQ Brava Quad

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

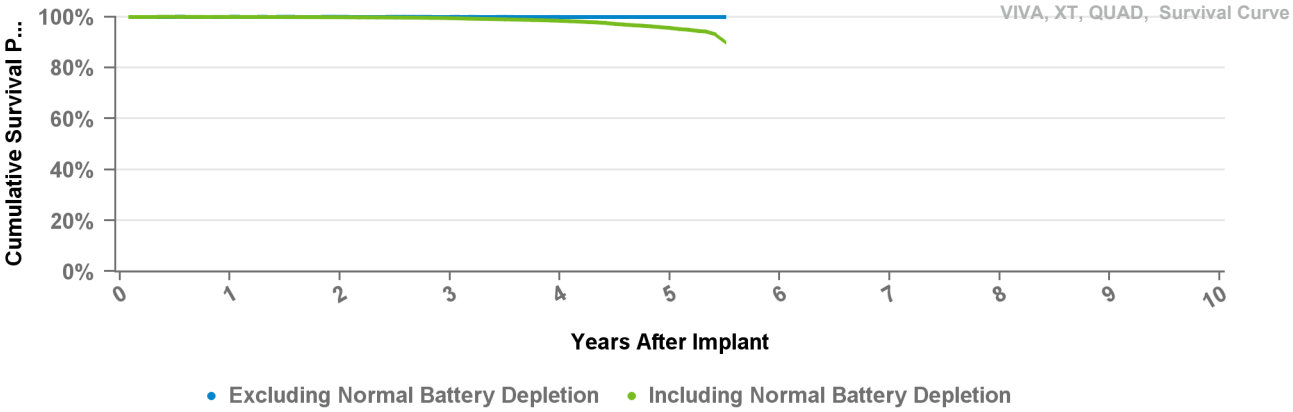
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.0%	96.9%	92.5%	84.8%	75.5%
Effective Sample Size	90039	82693	72023	53586	31723	9697	1305

DTBX1QQ Viva Quad C

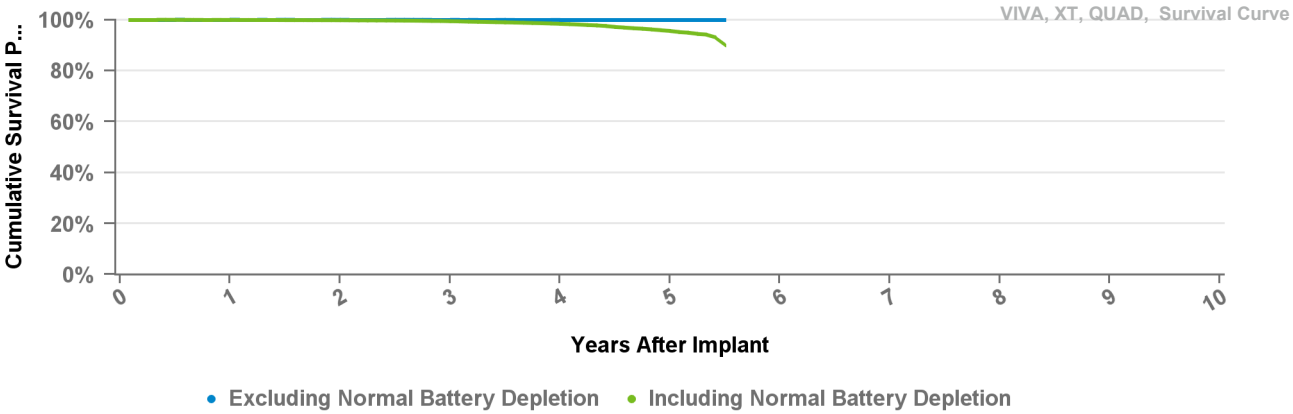
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	637	Electrical Component	1
Estimated Active USA Implants	393	**Therapy Function Compromised**	**0**
Normal Battery Depletions	74		



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTBX2QQ Viva Quad C

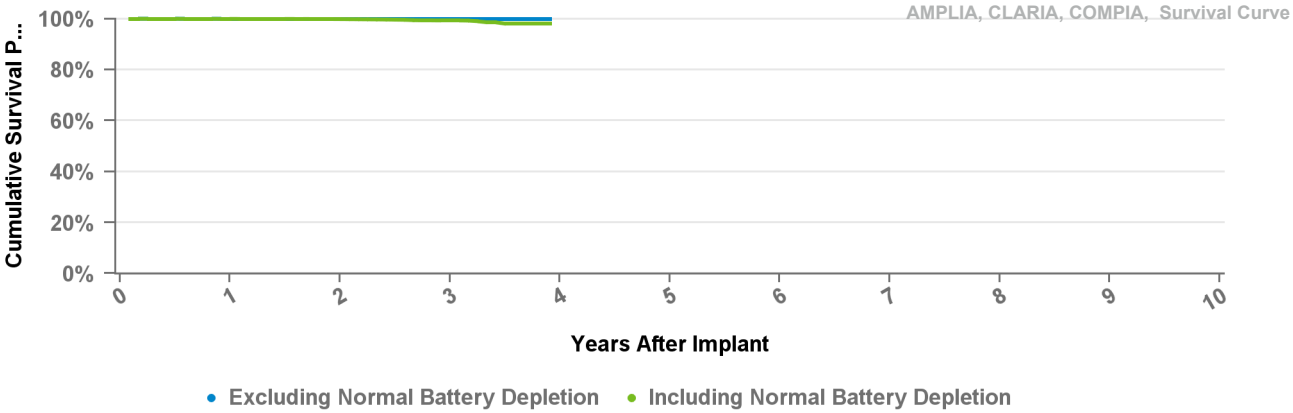
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.6%	90.0%
Effective Sample Size	34826	32307	29044	22220	7104	246

DTMA1D1 Claria MRI

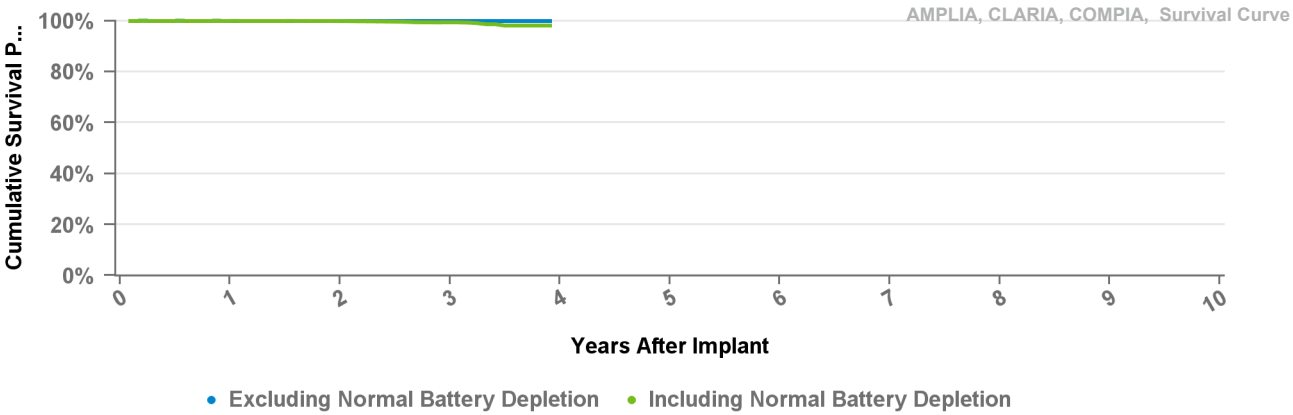
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	8,631		
Estimated Active USA Implants	8,097	**Therapy Function Compromised**	
Normal Battery Depletions	6		



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMA1D4 Claria MRI

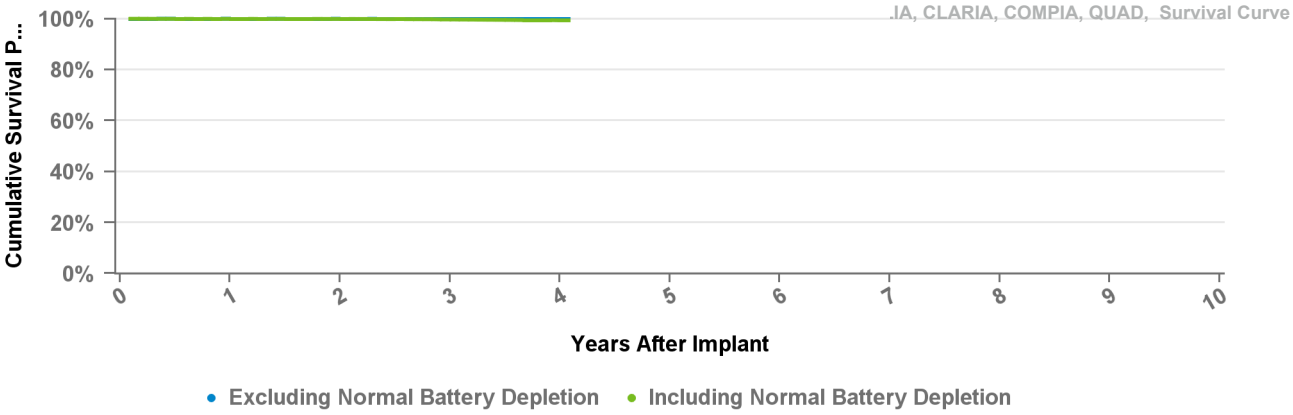
US Market Release	Dec-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	7,844	Electrical Component	1
Estimated Active USA Implants	7,419	**Therapy Function Compromised**	**1**
Normal Battery Depletions	6	Electrical Interconnect	1



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMA1Q1 Claria MRI

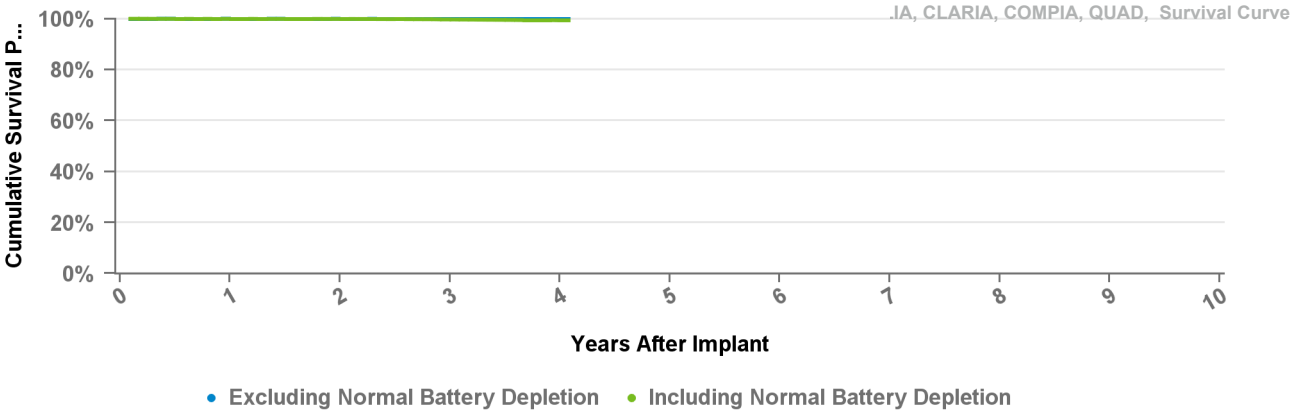
US Market Release	Dec-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	6,187	Electrical Interconnect	1
Estimated Active USA Implants	5,870	Other Malfunction	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMA1QQ Claria MRI

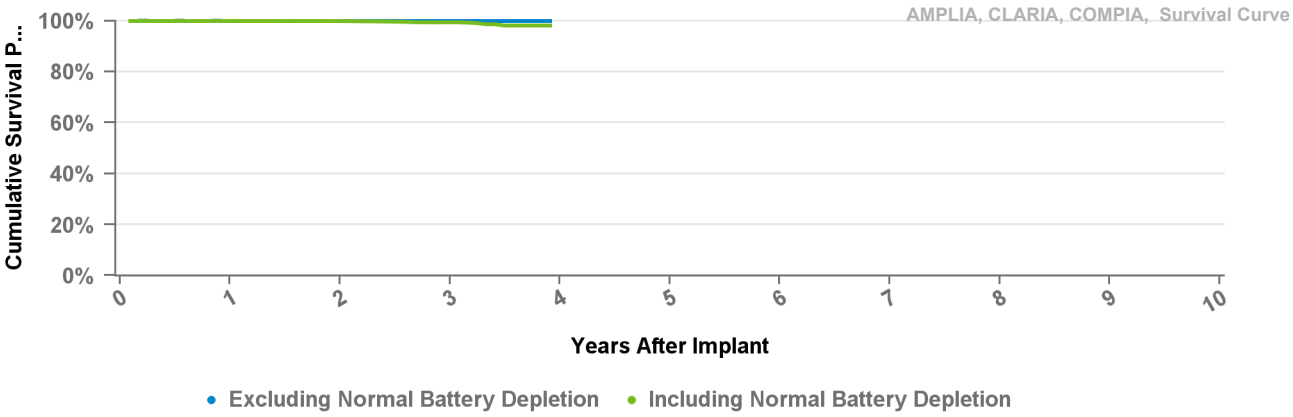
US Market Release	Dec-16	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	39,937	Electrical Component	1
Estimated Active USA Implants	38,542	**Therapy Function Compromised**	**2**
Normal Battery Depletions	12	Electrical Component	2



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMA2D1 Claria MRI

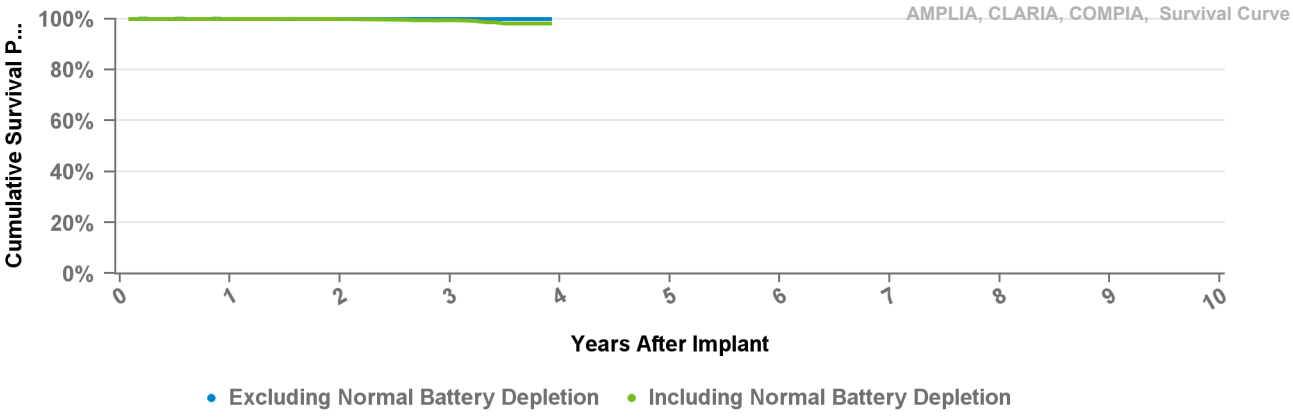
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

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			

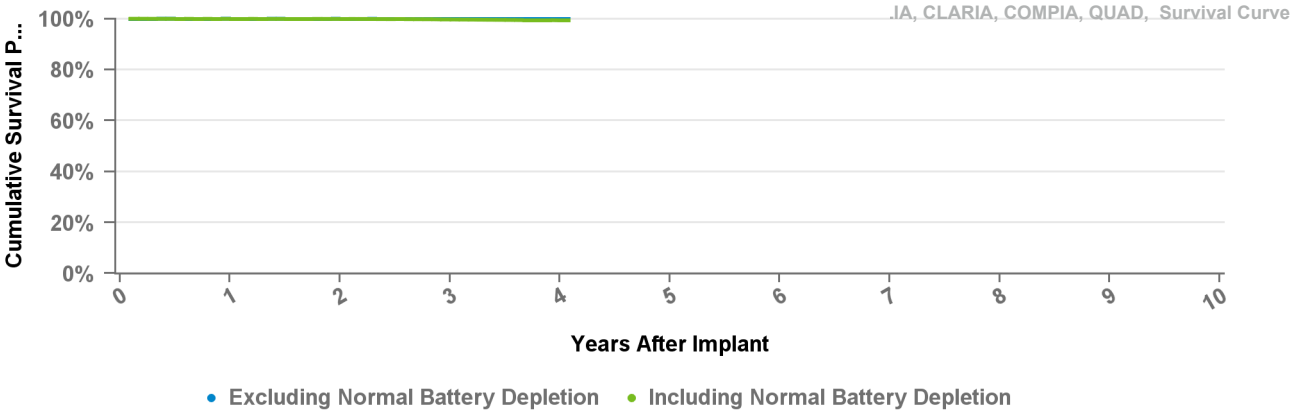


Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMA2Q1 Claria MRI

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

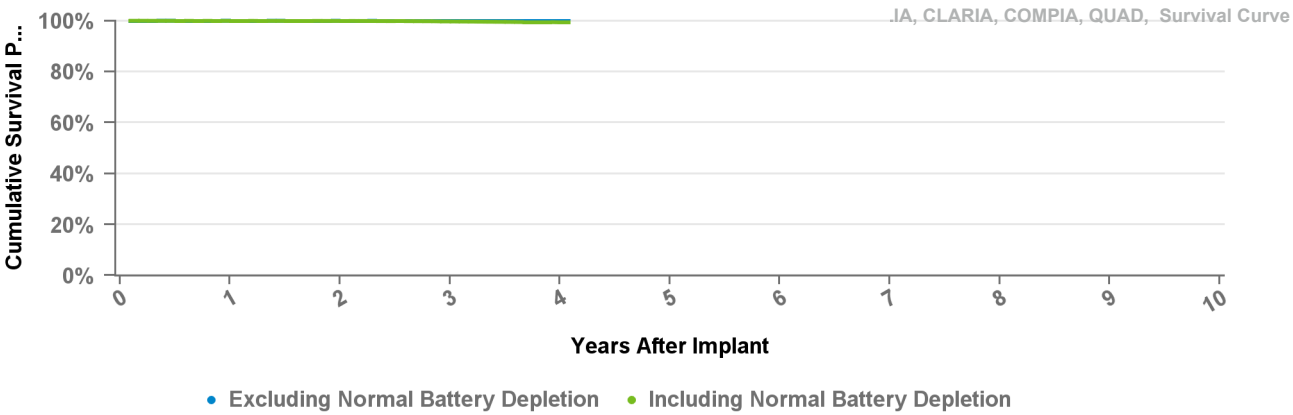


Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMA2QQ Claria MRI

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

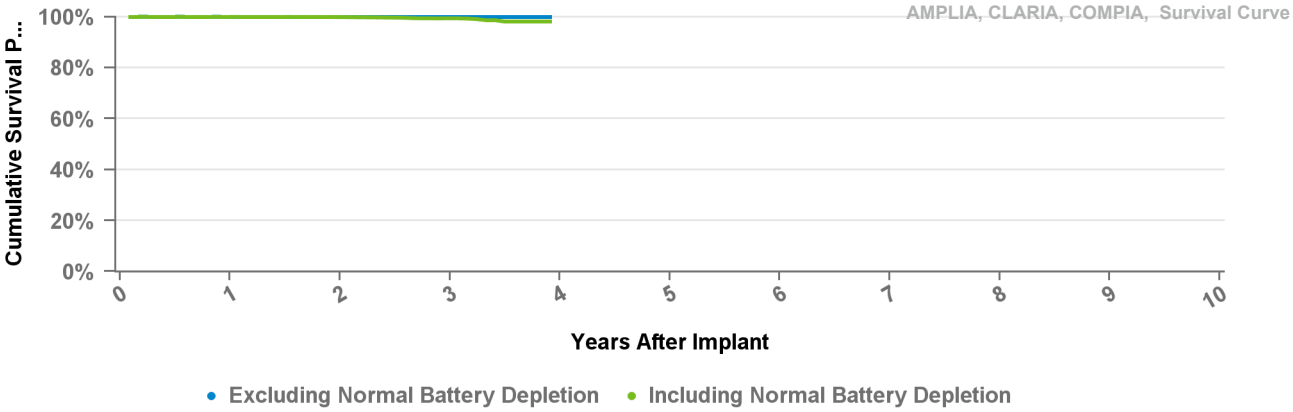
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMB1D1 Amplia MRI

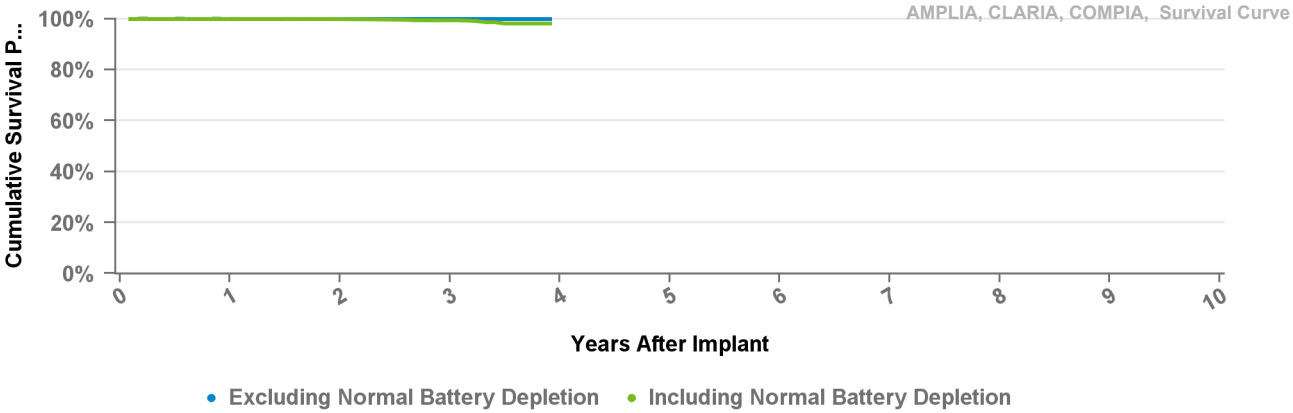
US Market Release	Dec-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,796	Other Malfunction	1
Estimated Active USA Implants	4,462	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMB1D4 Amplia MRI

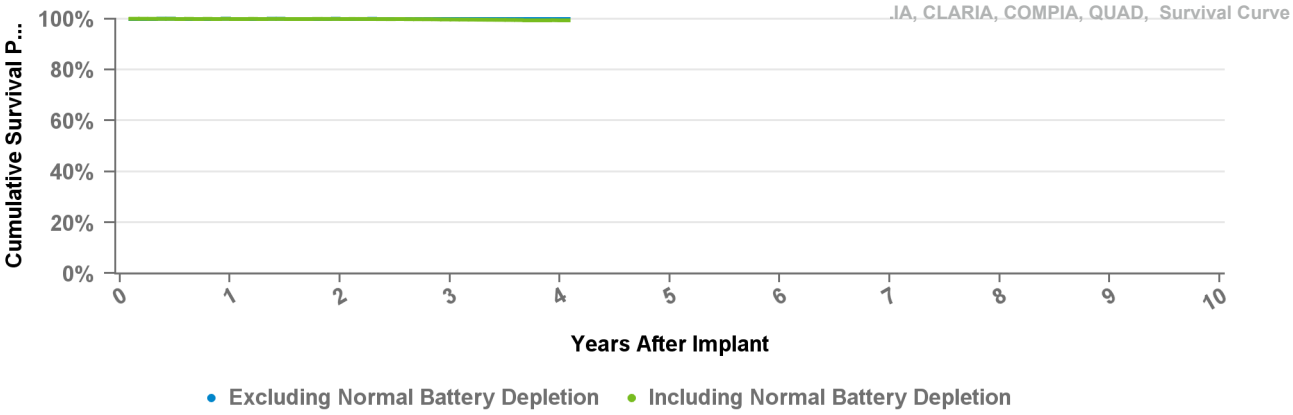
US Market Release	Feb-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	5,195	Electrical Component	2
Estimated Active USA Implants	4,736	**Therapy Function Compromised**	**0**
Normal Battery Depletions	18		



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMB1Q1 Amplia MRI

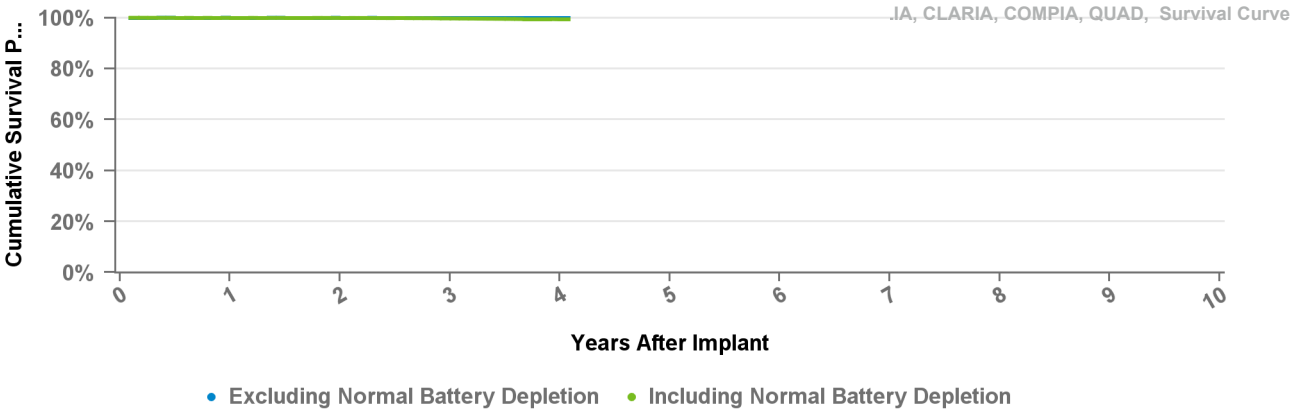
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,861		
Estimated Active USA Implants	2,644	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMB1QQ Amplia MRI

US Market Release	Feb-16	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	25,963	Electrical Component	7
Estimated Active USA Implants	24,446	Other Malfunction	5
Normal Battery Depletions	37	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**

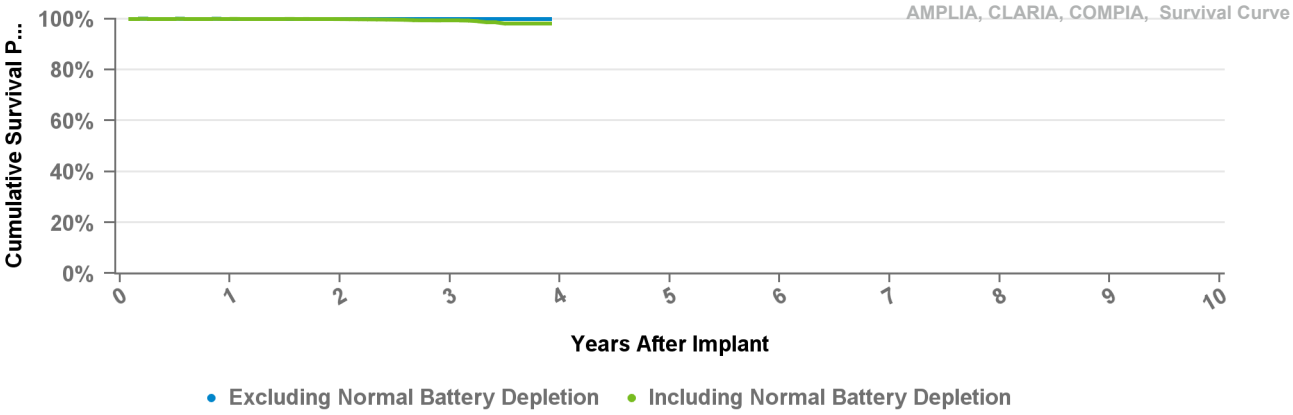


Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMB2D1 Amplia MRI

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

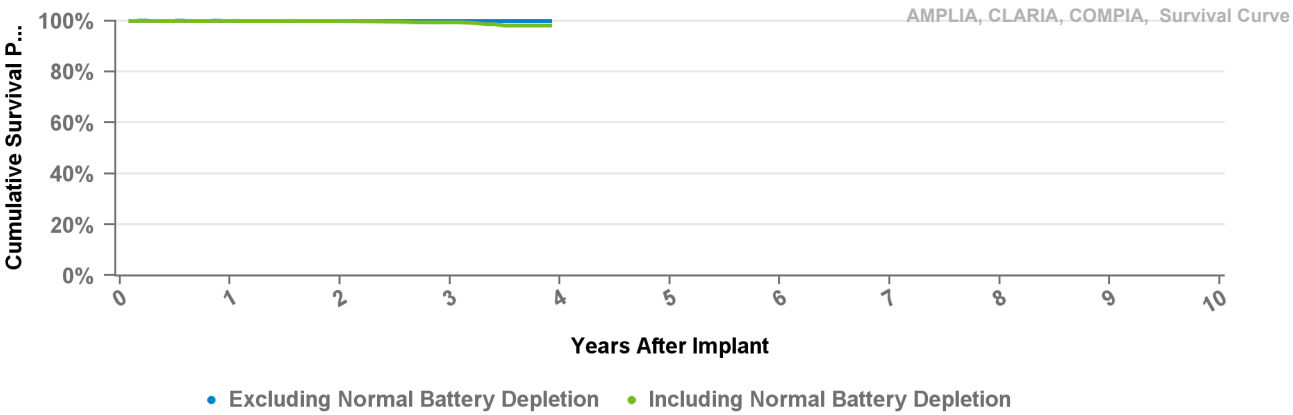


Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMB2D4 Amplia MRI

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

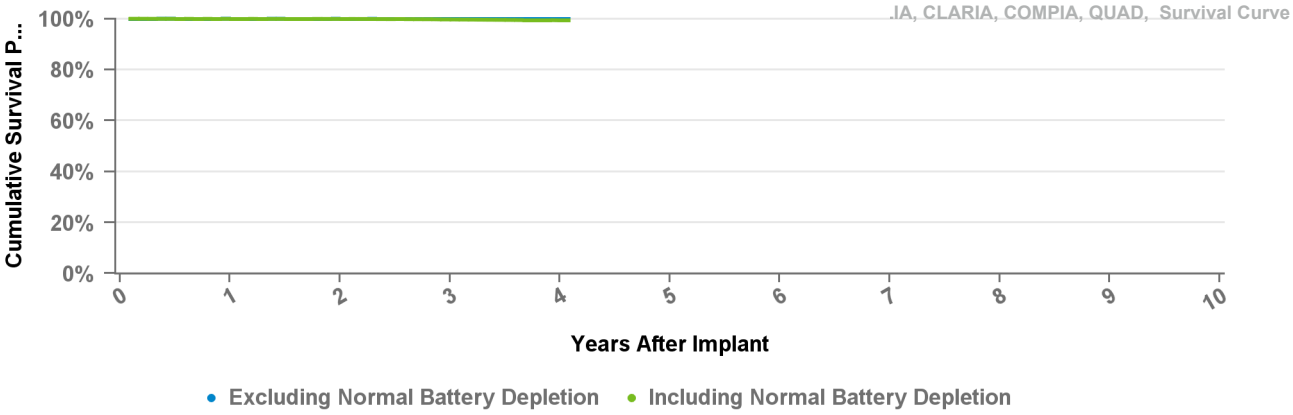
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMB2Q1 Amplia MRI

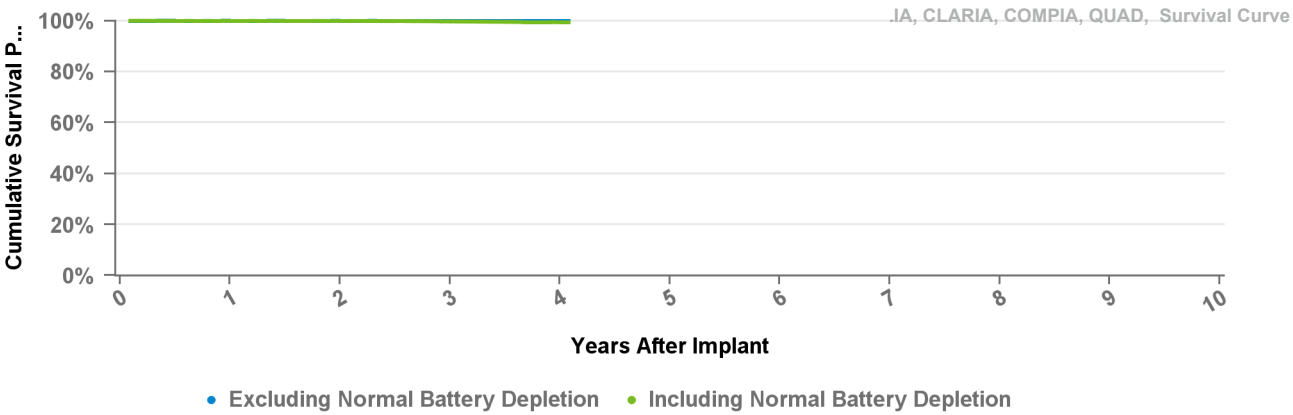
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMB2QQ Amplia MRI

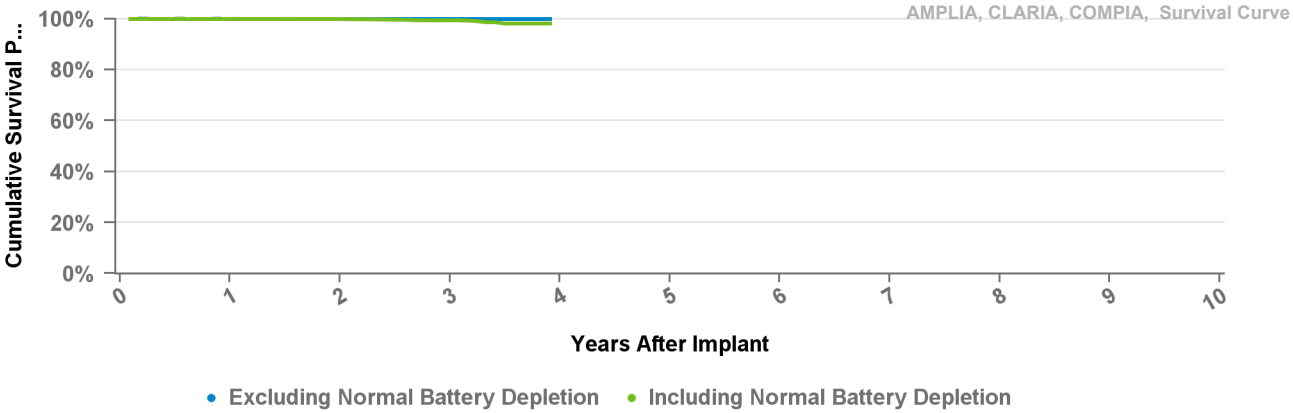
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMC1D1 Compia MRI

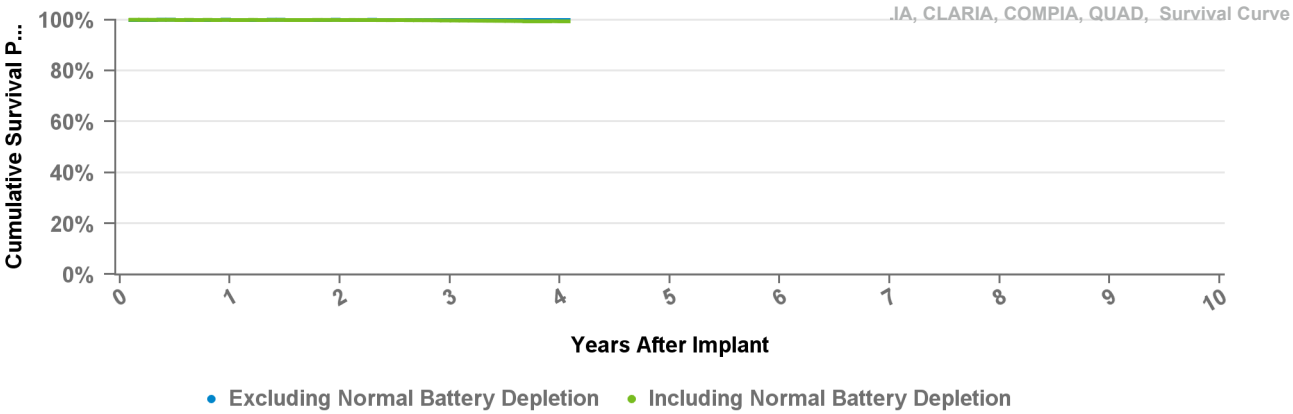
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	602		
Estimated Active USA Implants	559	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMC1QQ Compia MRI

US Market Release	Feb-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	3,123	Electrical Component	2
Estimated Active USA Implants	2,938	**Therapy Function Compromised**	**0**
Normal Battery Depletions	3		

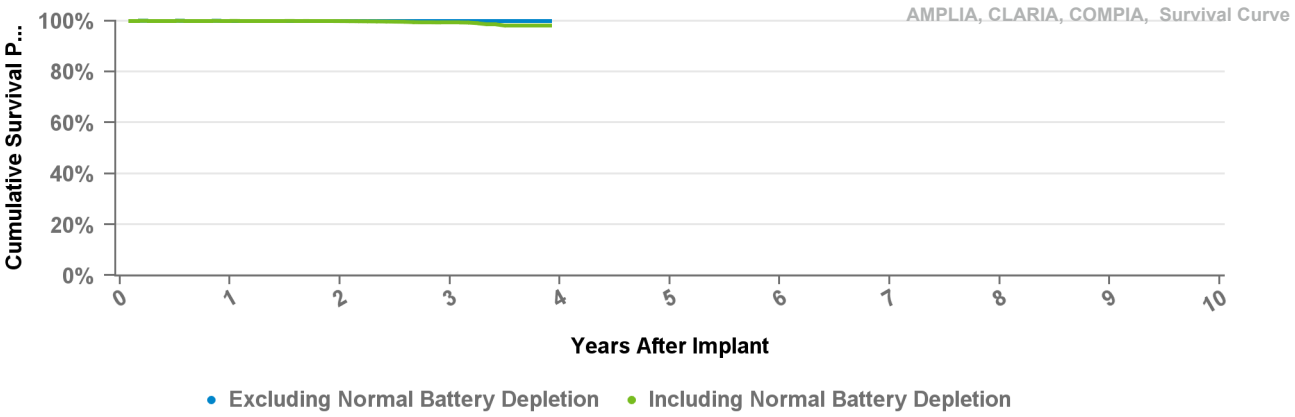


Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

DTMC2D1 Compia MRI

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

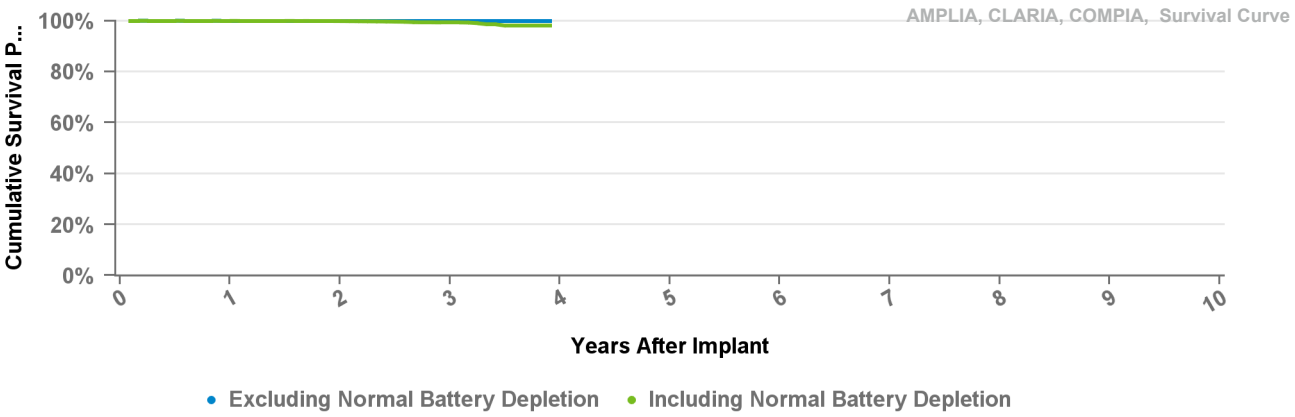


Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMC2D4 Compia MRI

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

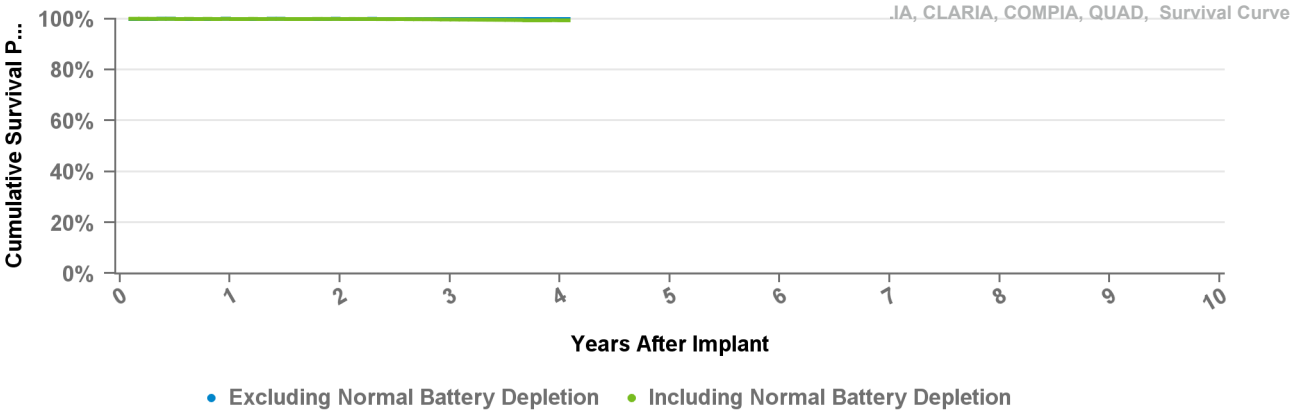
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.3%	98.1%
Effective Sample Size	18878	10278	2561	105

DTMC2QQ Compia MRI

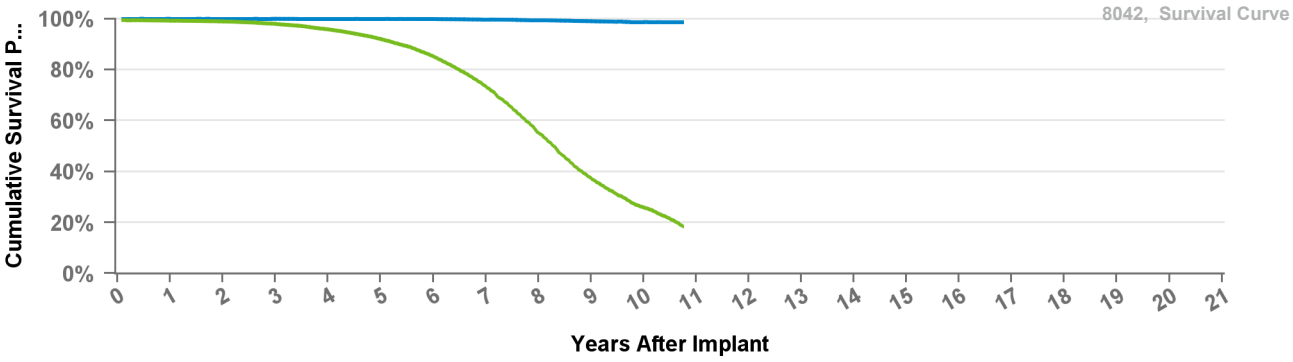
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	54094	32542	14048	960	356

8042 InSync III

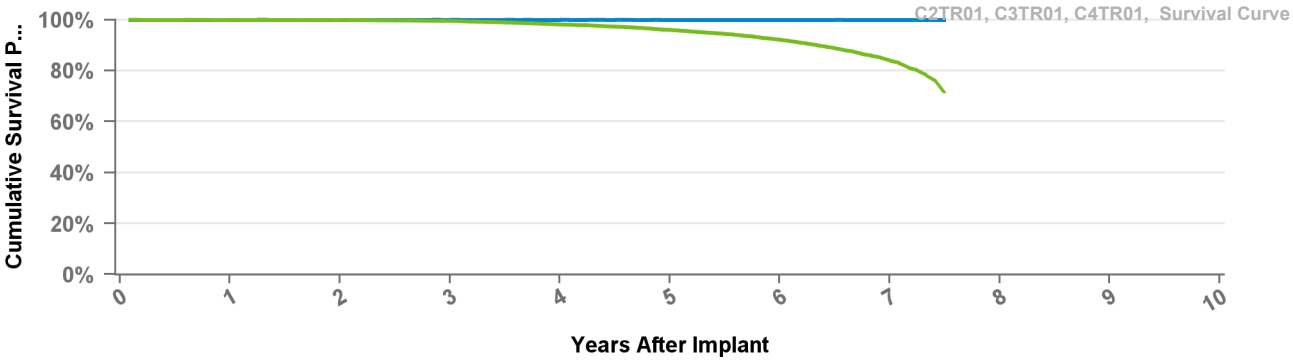
US Market Release	Feb-03	**Total Malfunctions**	**114**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**66**
Registered USA Implants	39,412	Battery Malfunction	54
Estimated Active USA Implants	4,461	Electrical Component	2
Normal Battery Depletions	5,148	Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**48**
		Battery Malfunction	36
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.4%	99.0%	98.7%	98.6%
Including NBD	99.3%	98.9%	98.0%	95.8%	92.0%	85.2%	73.3%	55.3%	37.3%	25.9%	18.4%
Effective Sample Size	30302	25940	22267	19023	15868	12135	8622	5550	3143	1206	161

C2TR01 Syncra CRT-P

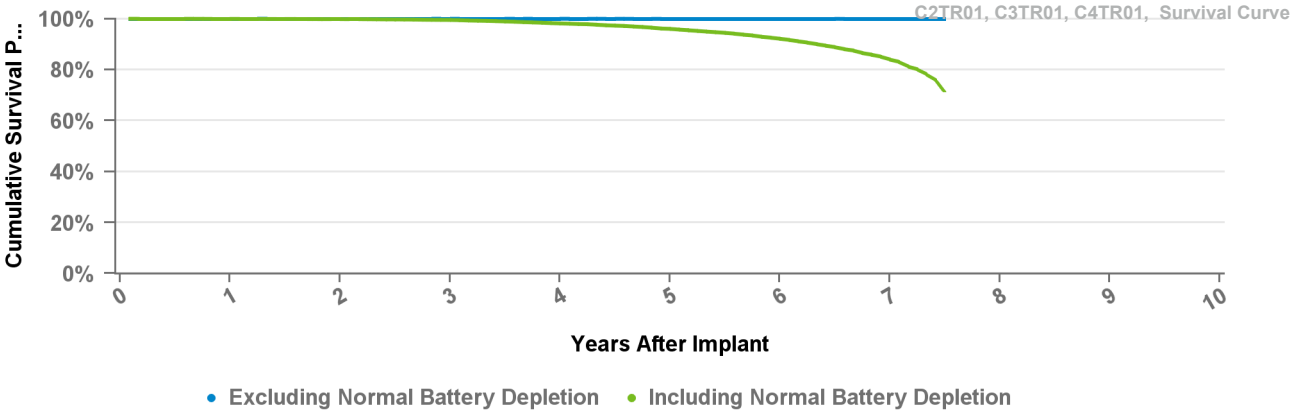
US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,229	Other Malfunction	1
Estimated Active USA Implants	5,990	Poss Early Battery Depltn	5
Normal Battery Depletions	399	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.2%	96.0%	92.1%	84.0%	71.6%
Effective Sample Size	26798	24066	21419	18088	13540	7989	2626	415

C3TR01 Consulta CRT-P

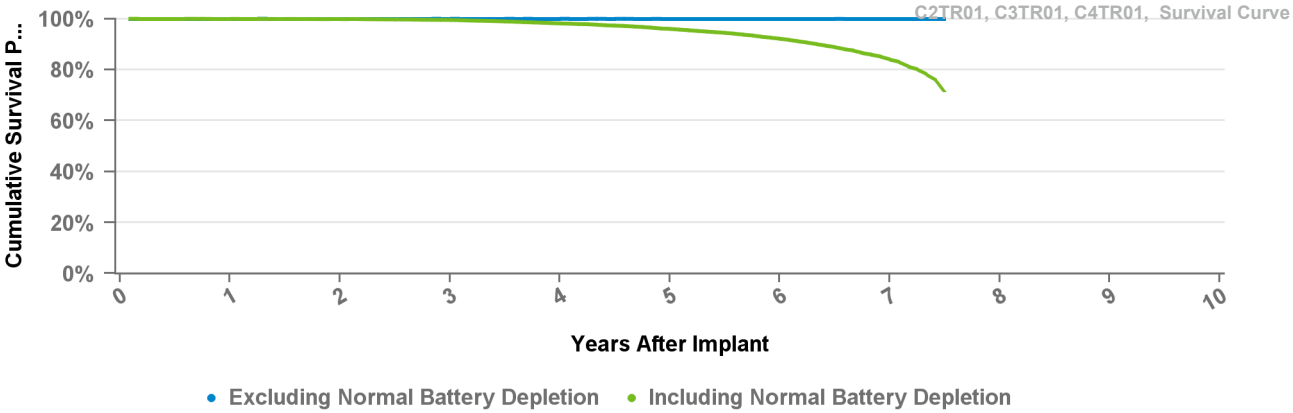
US Market Release		**Total Malfunctions**	
CE Approval Date	May-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.2%	96.0%	92.1%	84.0%	71.6%
Effective Sample Size	26798	24066	21419	18088	13540	7989	2626	415

C4TR01 Consulta CRT-P

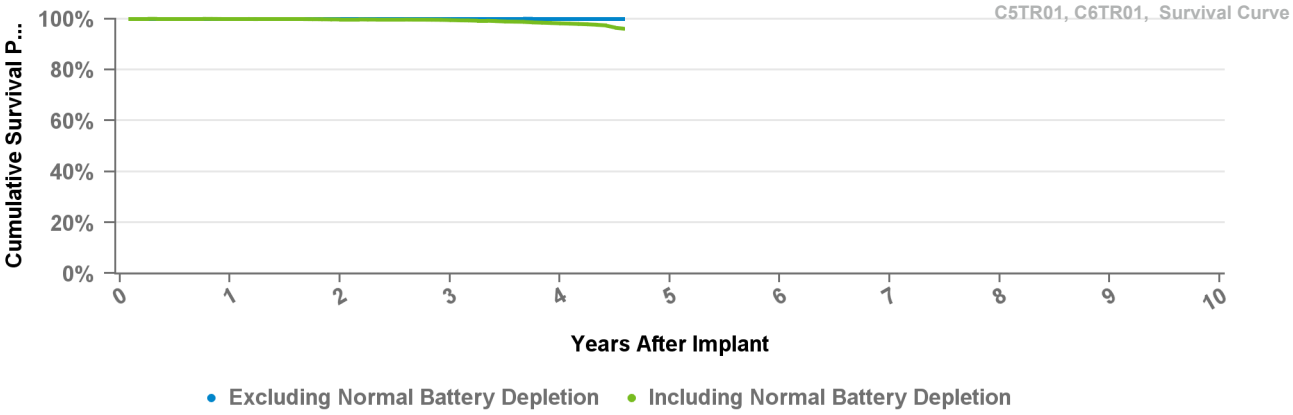
US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	23,539	Poss Early Battery Depltn	5
Estimated Active USA Implants	15,599	**Therapy Function Compromised**	**1**
Normal Battery Depletions	773	Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.2%	96.0%	92.1%	84.0%	71.6%
Effective Sample Size	26798	24066	21419	18088	13540	7989	2626	415

C5TR01 Viva CRT-P

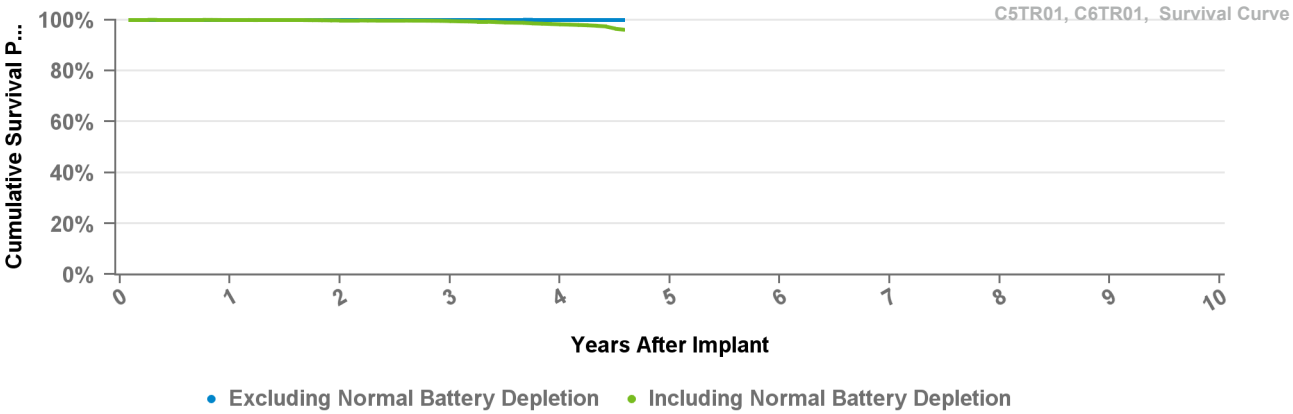
US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 55 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	98.2%	96.0%
Effective Sample Size	7659	6876	5404	2144	217

C6TR01 Viva CRT-P

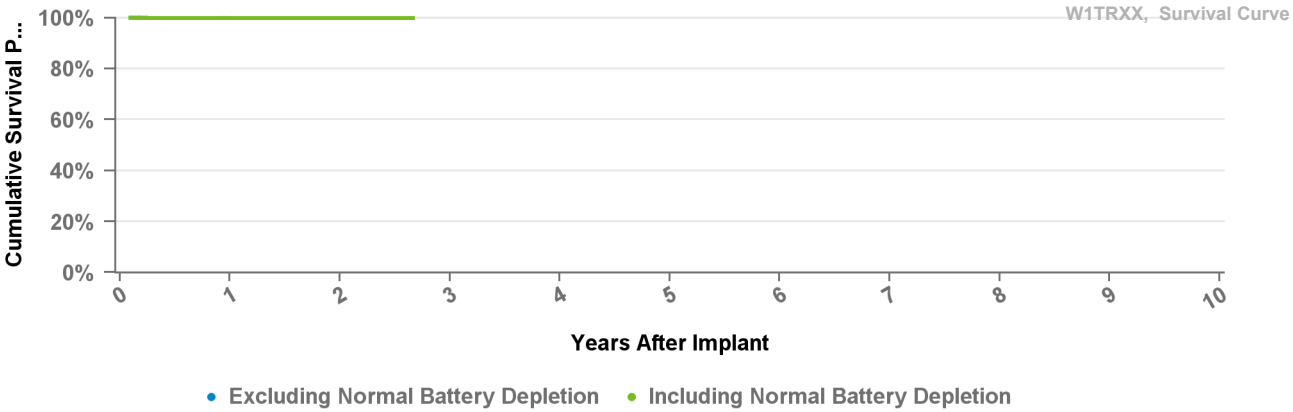
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,298	Poss Early Battery Depltn	1
Estimated Active USA Implants	7,889	**Therapy Function Compromised**	**0**
Normal Battery Depletions	57		



Years	1	2	3	4	at 55 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	98.2%	96.0%
Effective Sample Size	7659	6876	5404	2144	217

W1TR01 Percepta CRTP MRI

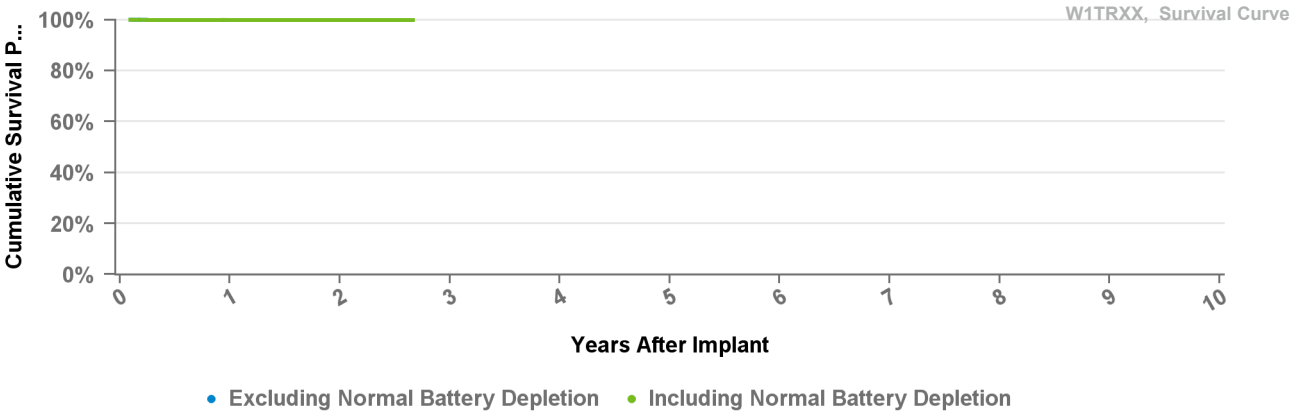
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,786	Other Malfunction	1
Estimated Active USA Implants	4,545	**Therapy Function Compromised**	**1**
Normal Battery Depletions	1	Electrical Component	1



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W1TR02 Serena CRTP MRI

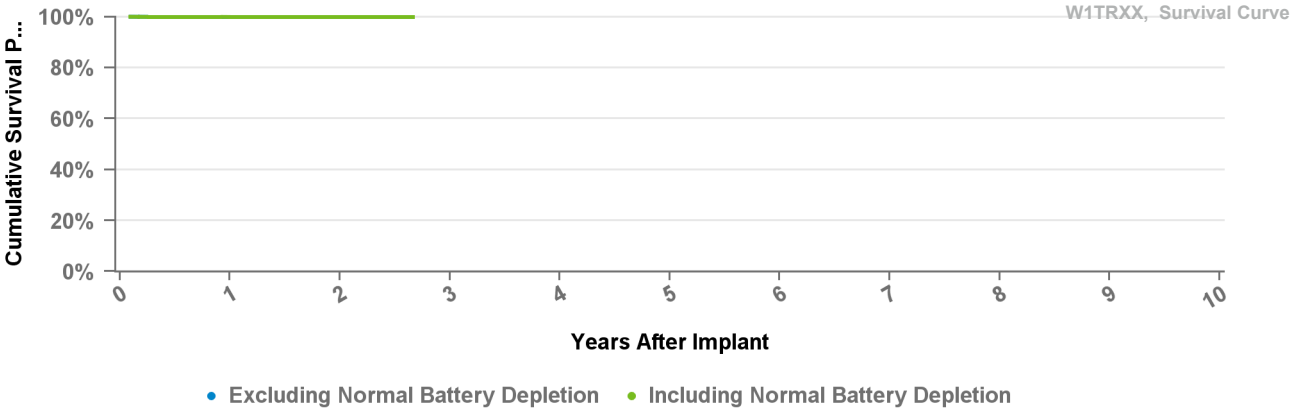
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,110	Other Malfunction	1
Estimated Active USA Implants	1,041	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W1TR03 Solara CRTP MRI

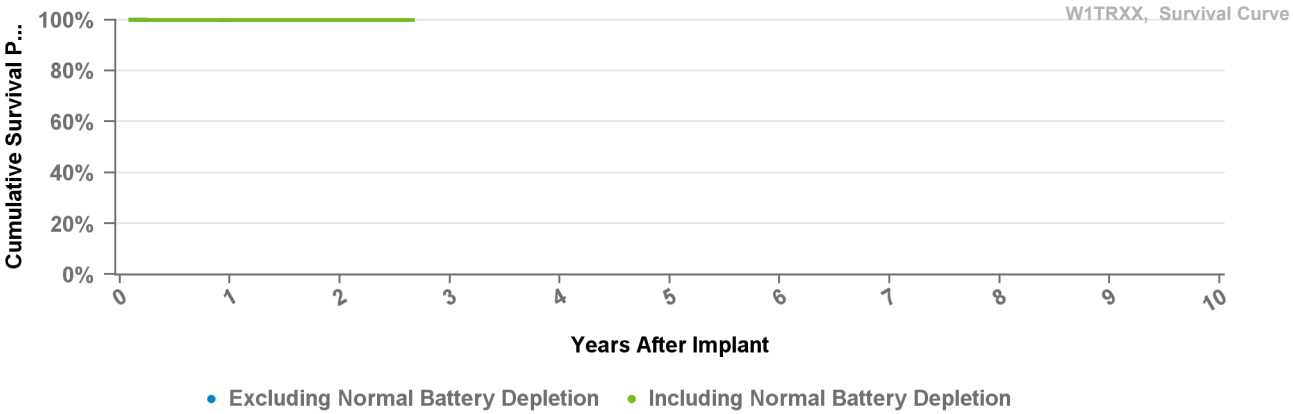
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,920	Electrical Component	1
Estimated Active USA Implants	1,807	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W1TR04 Percepta CRTP MRI

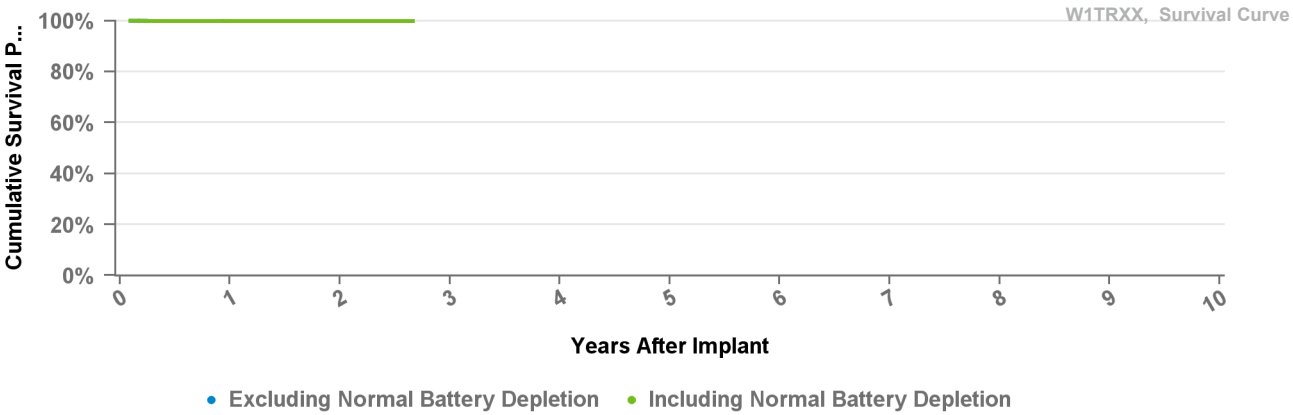
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W1TR05 Serena CRTP MRI

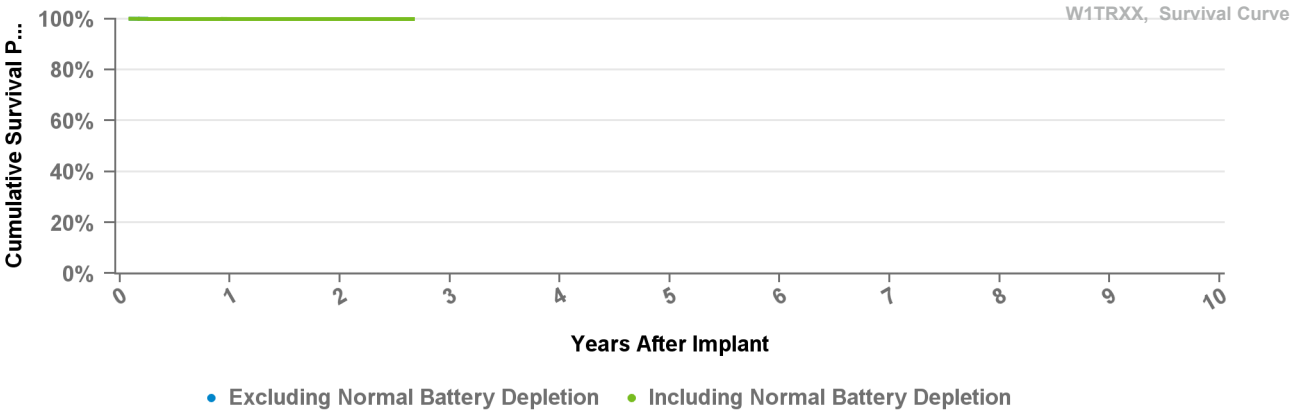
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W1TR06 Solara CRTP MRI

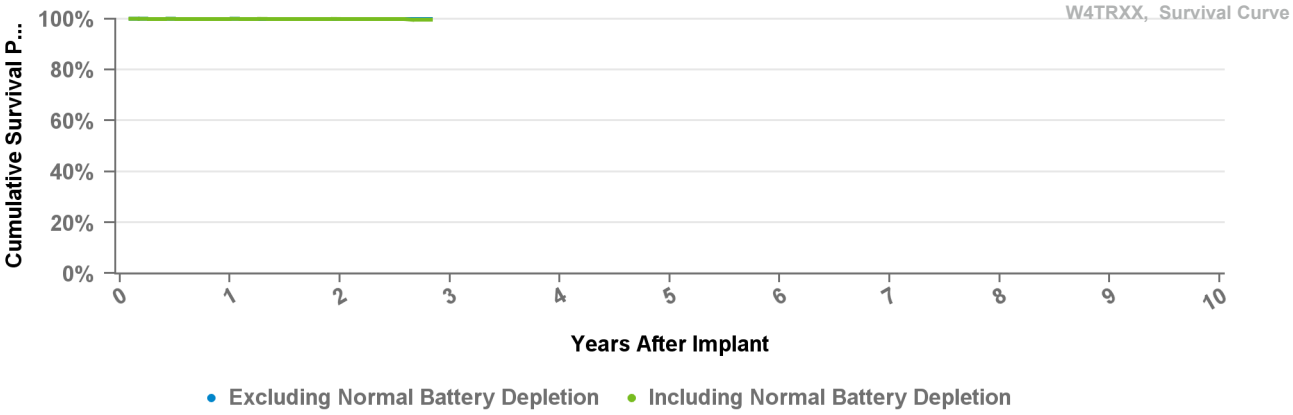
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 32 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	4160	1200	123

W4TR01 Percepta Quad CRTP MRI SureScan

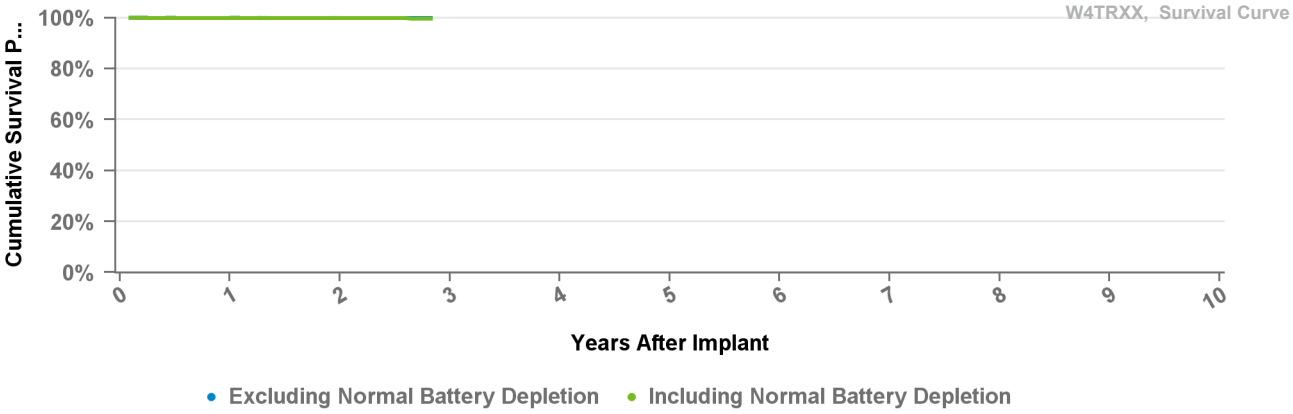
US Market Release	May-17	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	18,593	Electrical Component	2
Estimated Active USA Implants	17,730	Other Malfunction	1
Normal Battery Depletions	3	**Therapy Function Compromised**	**0**



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

W4TR02 Serena Quad CRTP MRI SureScan

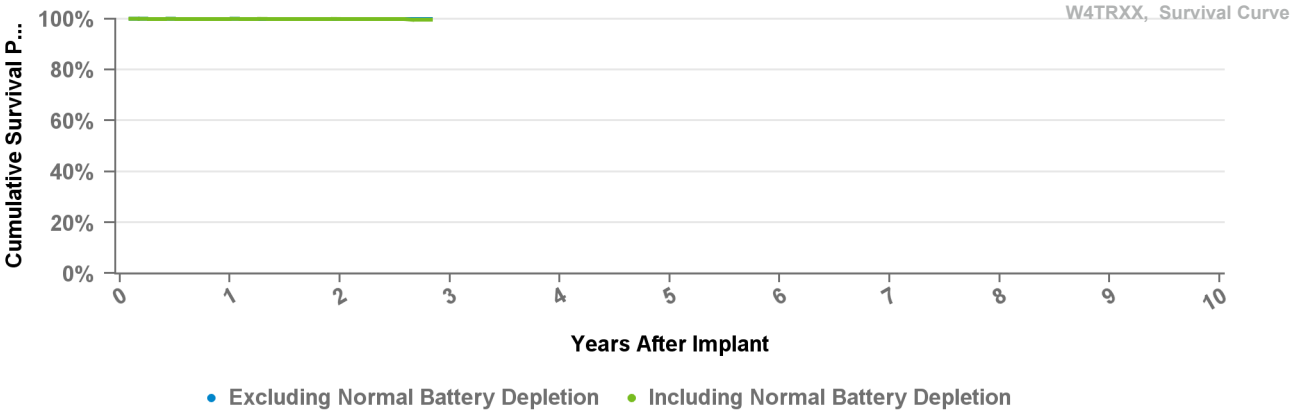
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	3,517		
Estimated Active USA Implants	3,341	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

W4TR03 Solara Quad CRTP MRI SureScan

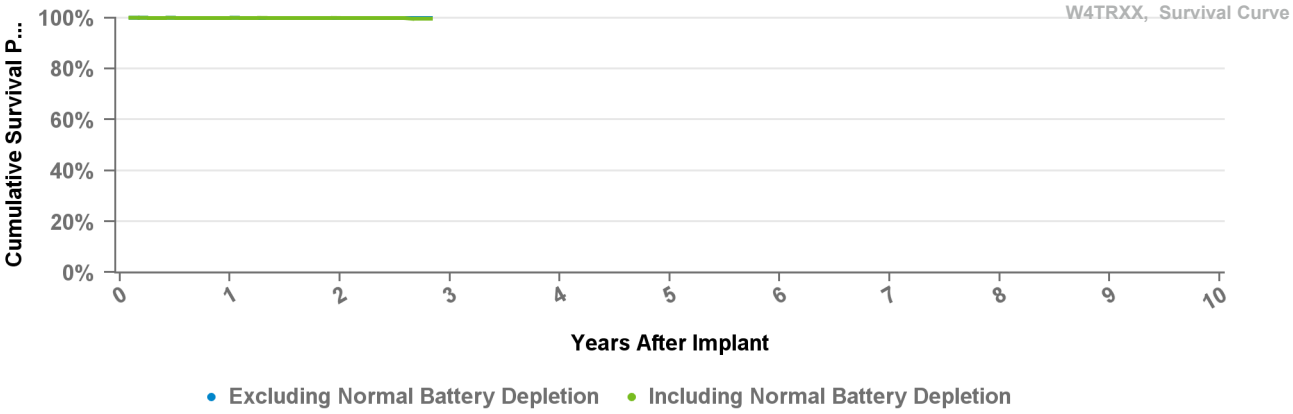
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	5,311		
Estimated Active USA Implants	5,013	**Therapy Function Compromised**	**2**
Normal Battery Depletions		Electrical Component	1
		Poss Early Battery Depltn	1



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

W4TR04 Percepta Quad CRT-P MRI SureScan

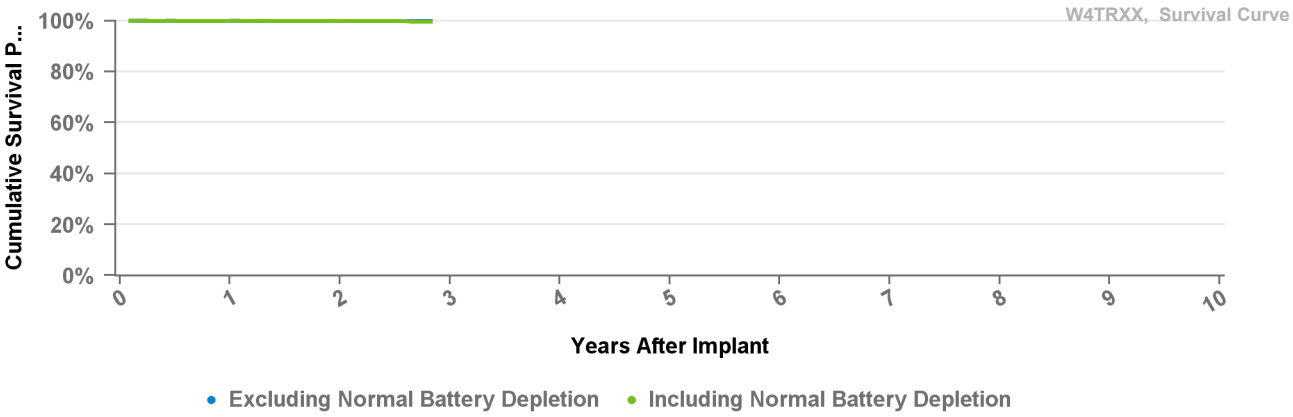
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

W4TR05 Serena Quad CRTP MRI SureScan

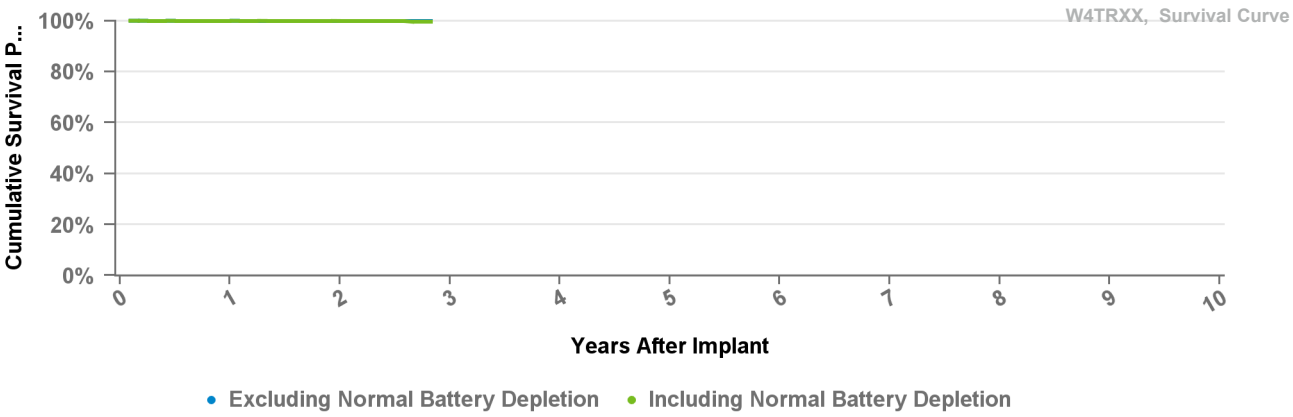
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

W4TR06 Solara Quad CRTP MRI SureScan

US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

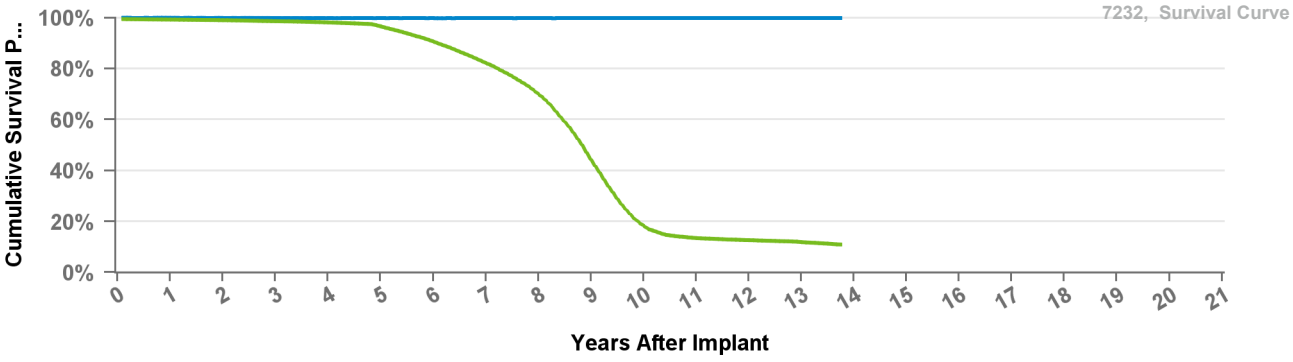


Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.5%
Effective Sample Size	15338	5781	115

7232Cx Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-03
Registered USA Implants	43,451
Estimated Active USA Implants	4,619
Normal Battery Depletions	10,238

Total Malfunctions	**72**
Therapy Function Not Compromised	**57**
Electrical Component	28
Other Malfunction	2
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

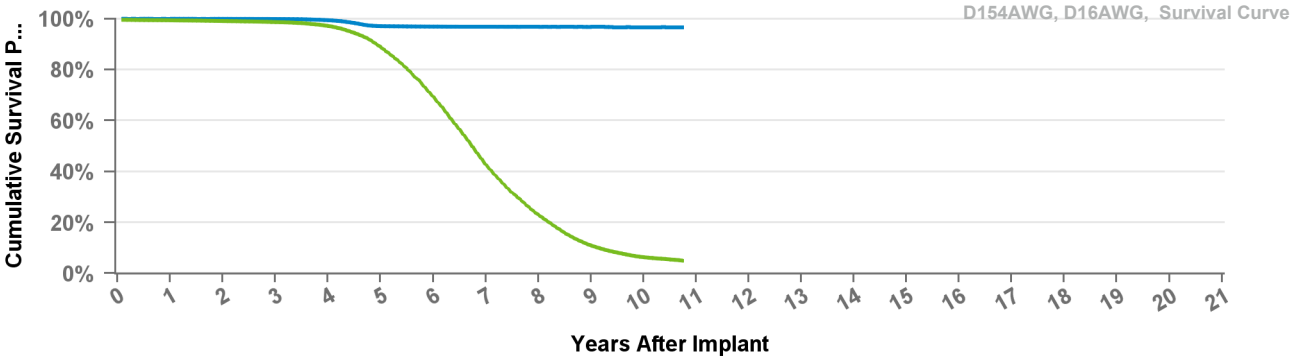


Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 165 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.3%	99.0%	98.6%	98.2%	96.6%	90.7%	82.2%	70.0%	44.5%	18.3%	13.5%	12.7%	11.9%	11.0%
Effective Sample Size	37916	33916	30217	26622	23430	20350	17170	13697	8090	2760	1669	1251	784	144

D164AWG Virtuoso DR

US Market Release	
CE Approval Date	Mar-06
Registered USA Implants	10
Estimated Active USA Implants	3
Normal Battery Depletions	3

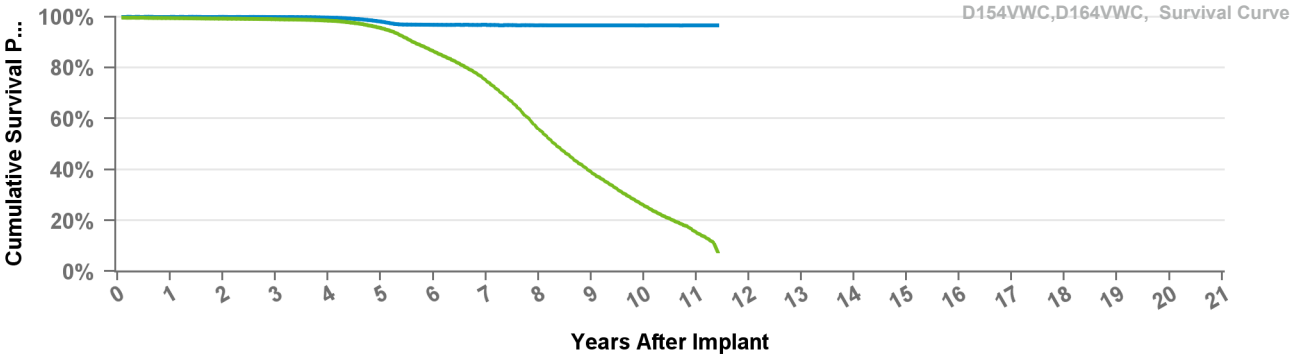
Total Malfunctions	
Therapy Function Not Compromised	
Therapy Function Compromised	



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.9%	96.8%	96.8%	96.7%	96.7%
Including NBD	99.4%	99.1%	98.7%	97.2%	88.8%	69.6%	42.8%	22.9%	11.0%	6.4%	5.0%
Effective Sample Size	63040	57789	52618	47768	40542	29401	16260	7438	2950	1314	290

D164VWC Virtuoso VR

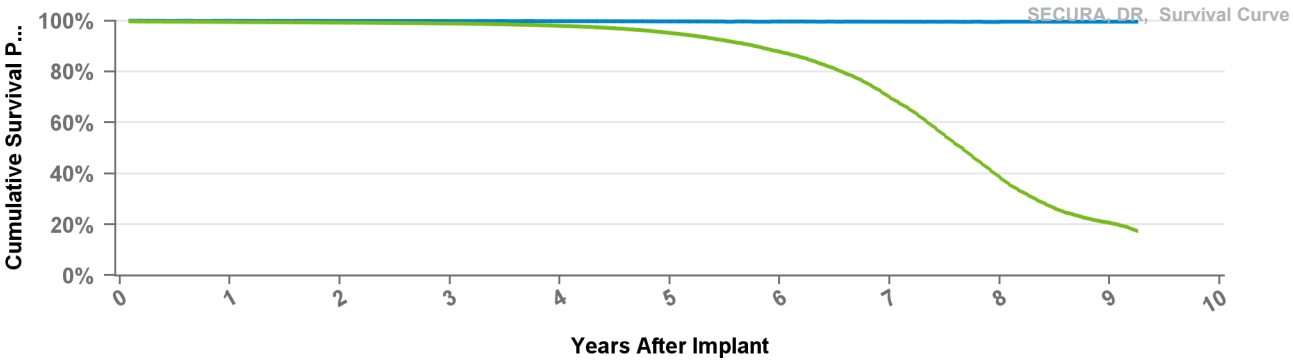
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 137 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.8%	96.8%	96.6%	96.6%	96.6%	96.6%	96.6%
Including NBD	99.5%	99.3%	99.0%	98.5%	95.6%	86.4%	74.9%	56.0%	39.0%	25.9%	15.3%	7.8%
Effective Sample Size	28358	25839	23525	21502	19105	15968	12879	8859	5528	3247	939	110

D204DRM Secura DR

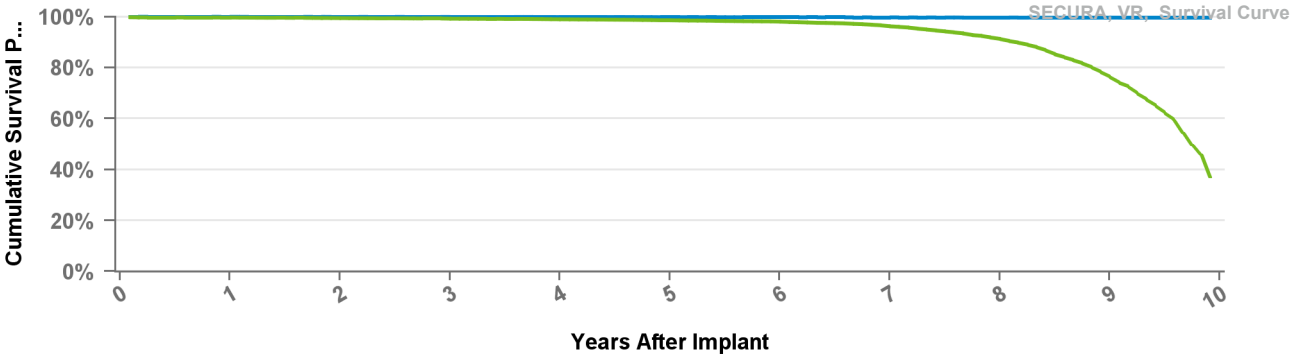
US Market Release	Jan-12	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,878	Other Malfunction	1
Estimated Active USA Implants	965	**Therapy Function Compromised**	**3**
Normal Battery Depletions	180	Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%	99.5%
Including NBD	99.5%	99.3%	98.9%	98.0%	95.2%	87.8%	69.9%	38.5%	20.7%	17.4%
Effective Sample Size	44814	41943	39379	36540	32706	26427	16893	6413	1434	267

D204VRM Secura VR

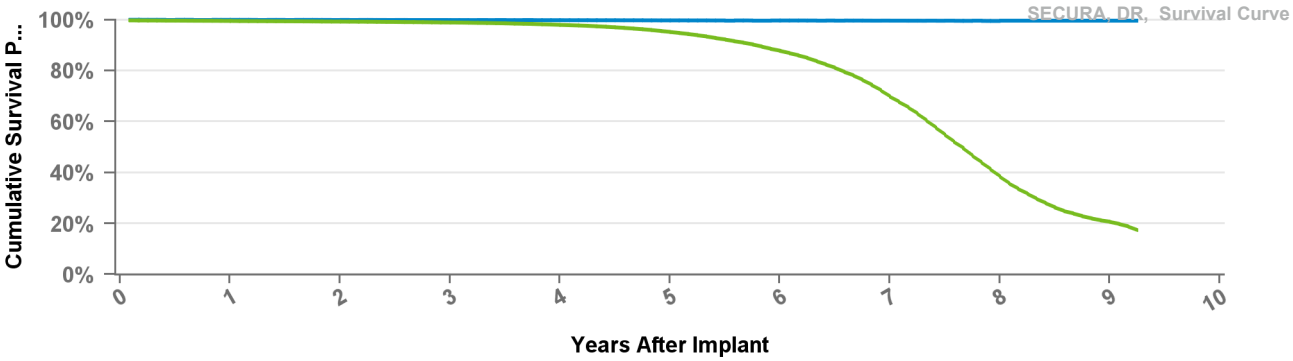
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,184	Electrical Component	1
Estimated Active USA Implants	870	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.3%	99.0%	98.6%	98.1%	96.2%	91.3%	76.4%	37.1%
Effective Sample Size	17988	16787	15808	14730	13519	12269	10500	7633	3803	294

D214DRM Secura DR

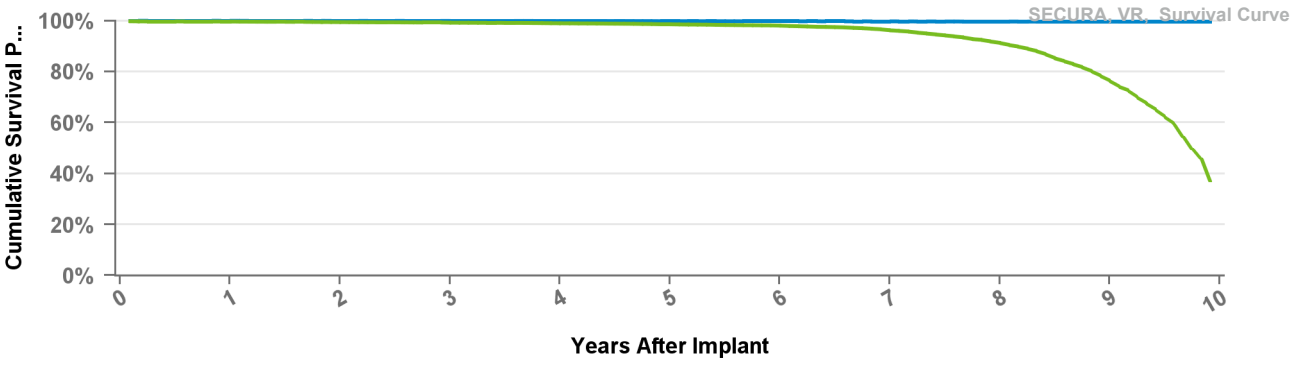
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%	99.5%
Including NBD	99.5%	99.3%	98.9%	98.0%	95.2%	87.8%	69.9%	38.5%	20.7%	17.4%
Effective Sample Size	44814	41943	39379	36540	32706	26427	16893	6413	1434	267

D214VRM Secura VR

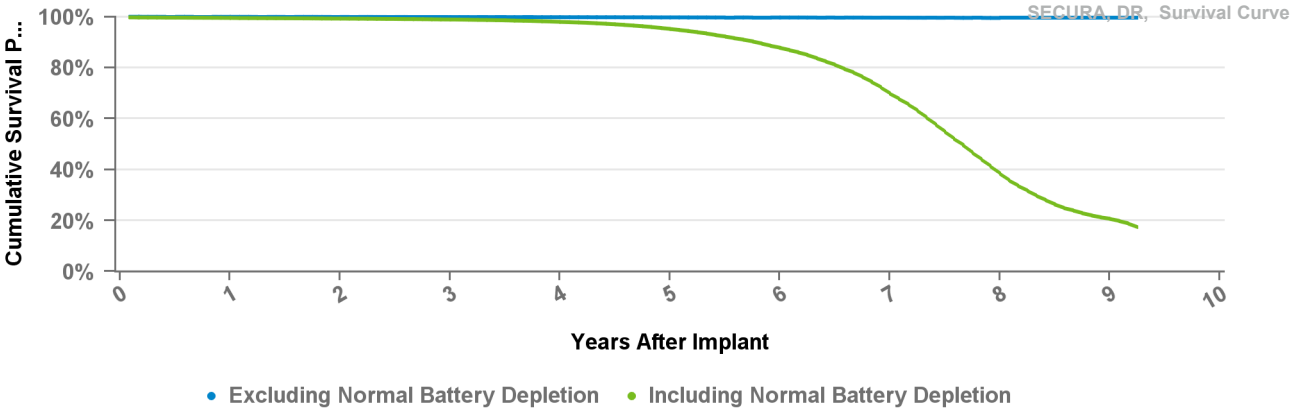
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.3%	99.0%	98.6%	98.1%	96.2%	91.3%	76.4%	37.1%
Effective Sample Size	17988	16787	15808	14730	13519	12269	10500	7633	3803	294

D224DRG Secura DR

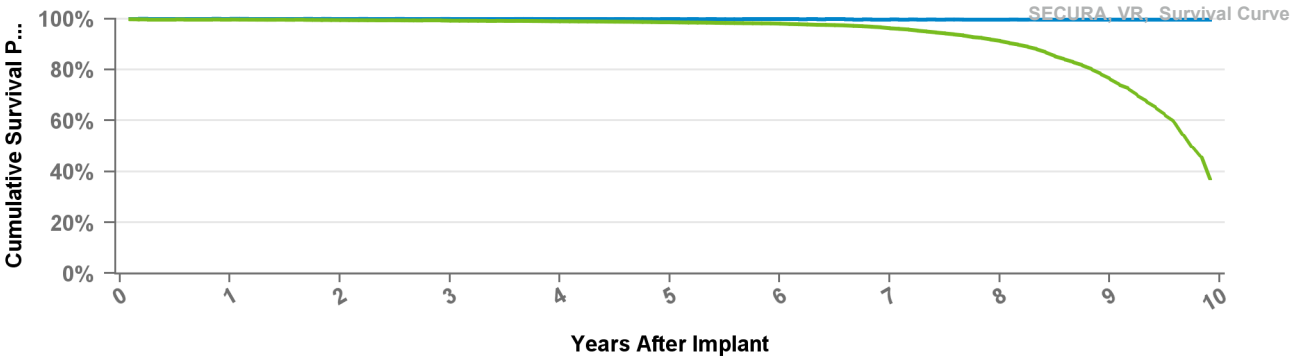
US Market Release	Sep-08	**Total Malfunctions**	**151**
CE Approval Date		**Therapy Function Not Compromised**	**115**
Registered USA Implants	49,914	Battery Malfunction	14
Estimated Active USA Implants	11,377	Electrical Component	38
Normal Battery Depletions	9,789	Other Malfunction	4
		Poss Early Battery Depltn	50
		Software Malfunction	9
		Therapy Function Compromised	**36**
		Battery Malfunction	20
		Electrical Component	13
		Other Malfunction	1
		Poss Early Battery Depltn	1
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%	99.5%
Including NBD	99.5%	99.3%	98.9%	98.0%	95.2%	87.8%	69.9%	38.5%	20.7%	17.4%
Effective Sample Size	44814	41943	39379	36540	32706	26427	16893	6413	1434	267

D224VRC Secura VR

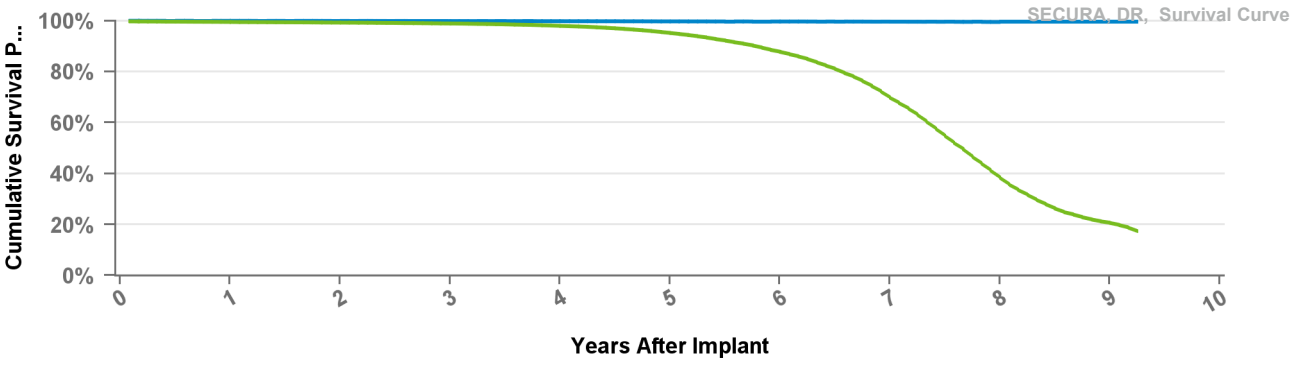
US Market Release	Sep-08	**Total Malfunctions**	**51**
CE Approval Date		**Therapy Function Not Compromised**	**35**
Registered USA Implants	20,044	Battery Malfunction	14
Estimated Active USA Implants	7,099	Electrical Component	10
Normal Battery Depletions	1,526	Other Malfunction	1
		Poss Early Battery Depltn	8
		Software Malfunction	2
		Therapy Function Compromised	**16**
		Battery Malfunction	8
		Electrical Component	6
		Poss Early Battery Depltn	1
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.3%	99.0%	98.6%	98.1%	96.2%	91.3%	76.4%	37.1%
Effective Sample Size	17988	16787	15808	14730	13519	12269	10500	7633	3803	294

D234DRG Secura DR

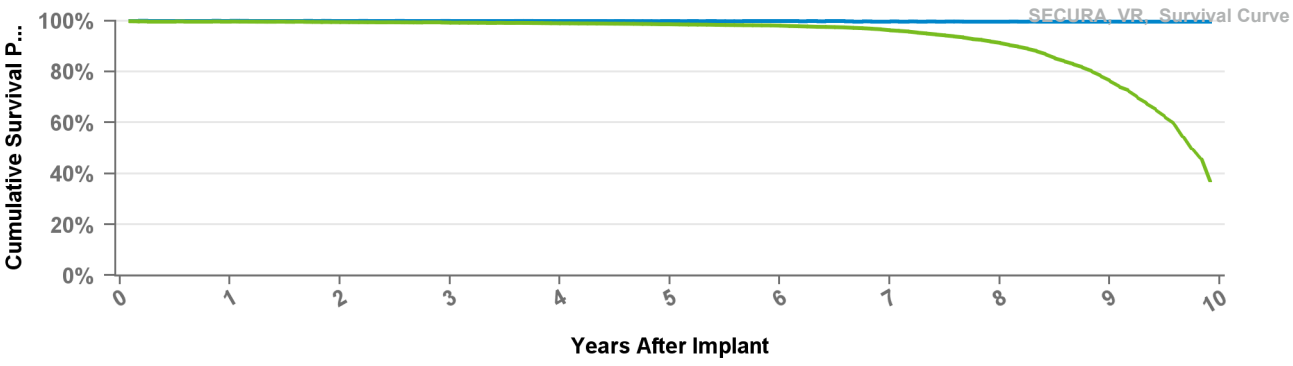
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%	99.5%
Including NBD	99.5%	99.3%	98.9%	98.0%	95.2%	87.8%	69.9%	38.5%	20.7%	17.4%
Effective Sample Size	44814	41943	39379	36540	32706	26427	16893	6413	1434	267

D234VRC Secura VR

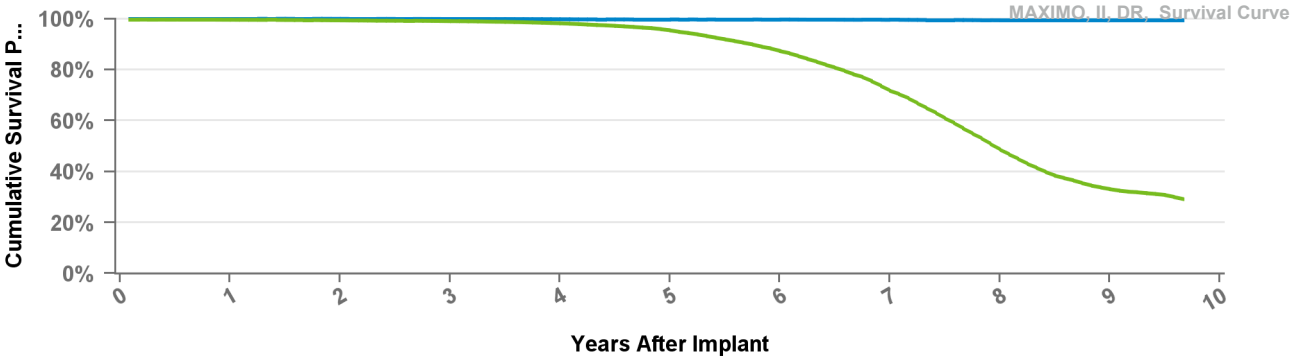
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.7%	99.5%	99.3%	99.0%	98.6%	98.1%	96.2%	91.3%	76.4%	37.1%
Effective Sample Size	17988	16787	15808	14730	13519	12269	10500	7633	3803	294

D264DRM Maximo II DR

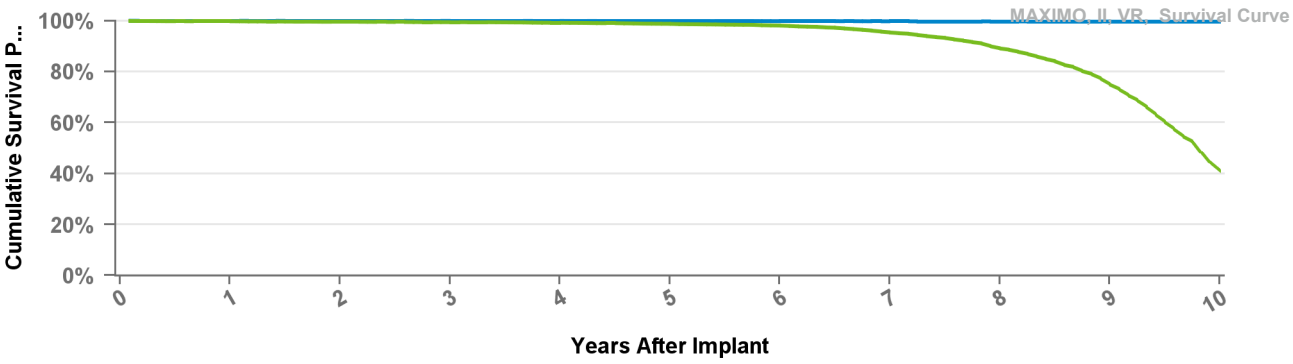
US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	95.5%	87.3%	71.8%	48.7%	33.1%	29.2%
Effective Sample Size	17375	16213	15236	14148	12653	10047	6169	2641	911	139

D264VRM Maximo II VR

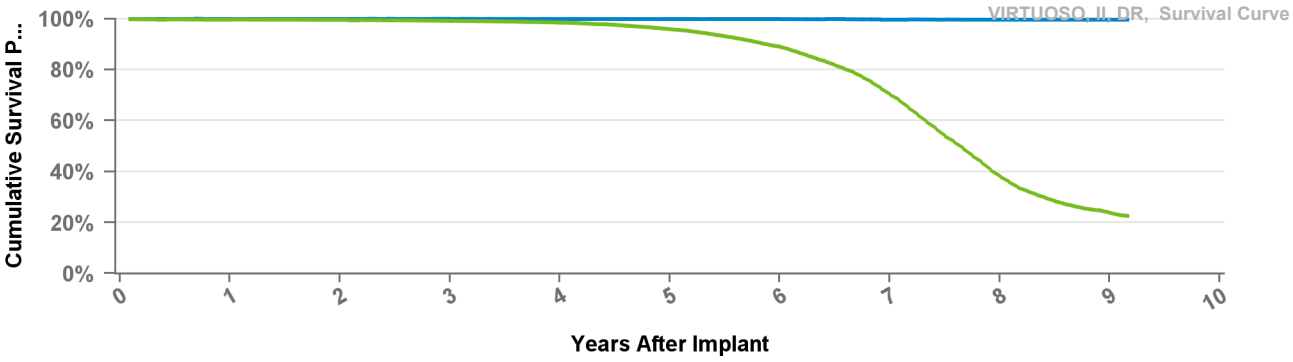
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 120 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.4%	89.2%	75.0%	41.1%
Effective Sample Size	11060	10364	9750	9064	8327	7542	6424	4663	2243	169

D274DRG Virtuoso II DR

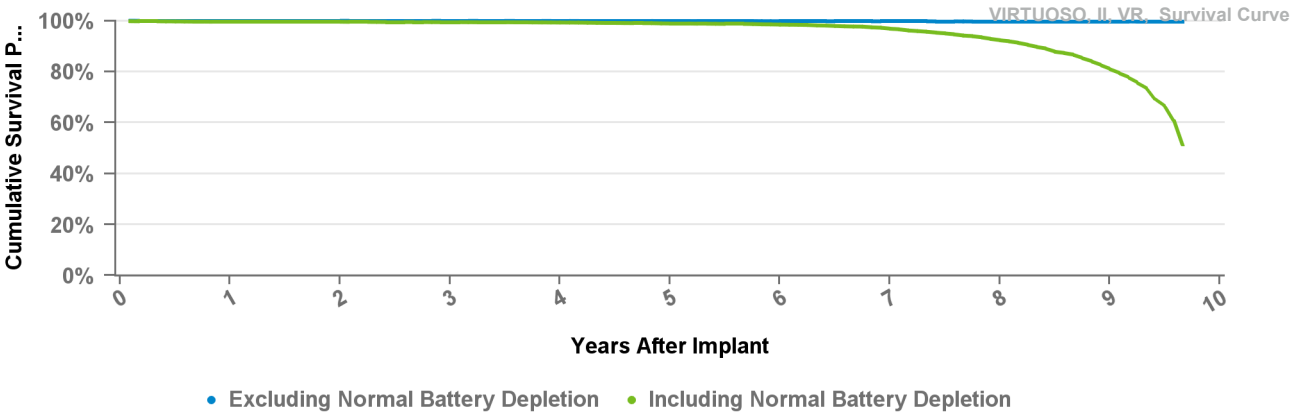
US Market Release	Aug-09	**Total Malfunctions**	**46**
CE Approval Date		**Therapy Function Not Compromised**	**29**
Registered USA Implants	22,232	Battery Malfunction	10
Estimated Active USA Implants	5,282	Electrical Component	11
Normal Battery Depletions	4,211	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**17**
		Battery Malfunction	14
		Electrical Component	2
		Other Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.5%	95.9%	89.0%	70.3%	38.1%	23.8%	22.6%
Effective Sample Size	19082	17910	16856	15662	13955	11211	7197	3118	714	257

D274VRC Virtuoso II VR

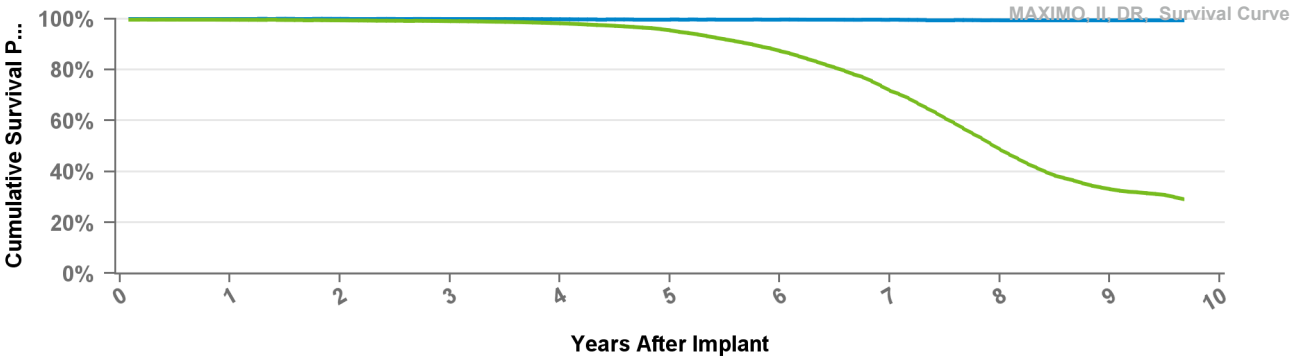
US Market Release	Aug-09	**Total Malfunctions**	**19**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	9,122	Battery Malfunction	5
Estimated Active USA Implants	3,454	Electrical Component	4
Normal Battery Depletions	559	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**7**
		Battery Malfunction	6
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	99.6%	99.4%	99.3%	98.9%	98.5%	96.9%	92.4%	81.1%	51.2%
Effective Sample Size	7648	7178	6768	6300	5813	5284	4691	3820	1790	131

D284DRG Maximo II DR

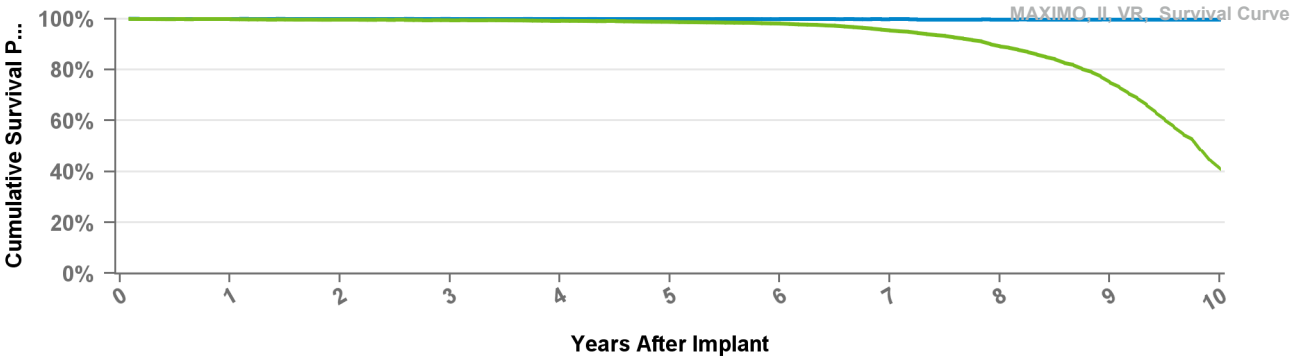
US Market Release	Sep-08	**Total Malfunctions**	**71**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**54**
Registered USA Implants	20,096	Battery Malfunction	7
Estimated Active USA Implants	4,969	Electrical Component	15
Normal Battery Depletions	3,426	Other Malfunction	2
		Poss Early Battery Depltn	30
		Therapy Function Compromised	**17**
		Battery Malfunction	11
		Electrical Component	5
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%
Including NBD	99.6%	99.4%	99.1%	98.2%	95.5%	87.3%	71.8%	48.7%	33.1%	29.2%
Effective Sample Size	17375	16213	15236	14148	12653	10047	6169	2641	911	139

D284VRC Maximo II VR

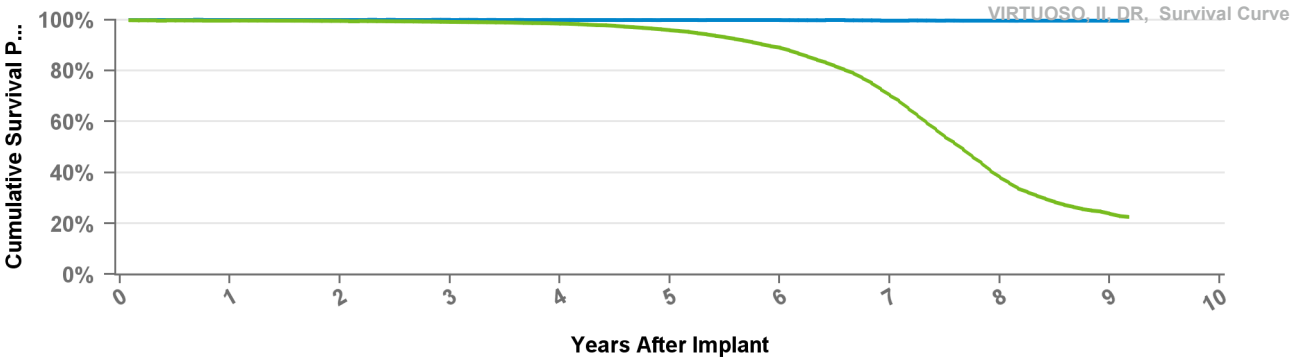
US Market Release	Sep-08	**Total Malfunctions**	**28**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**22**
Registered USA Implants	13,028	Battery Malfunction	9
Estimated Active USA Implants	4,921	Electrical Component	6
Normal Battery Depletions	1,137	Poss Early Battery Depltn	4
		Software Malfunction	3
		Therapy Function Compromised	**6**
		Battery Malfunction	3
		Electrical Component	2
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 120 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.4%	89.2%	75.0%	41.1%
Effective Sample Size	11060	10364	9750	9064	8327	7542	6424	4663	2243	169

D294DRG Virtuoso II DR

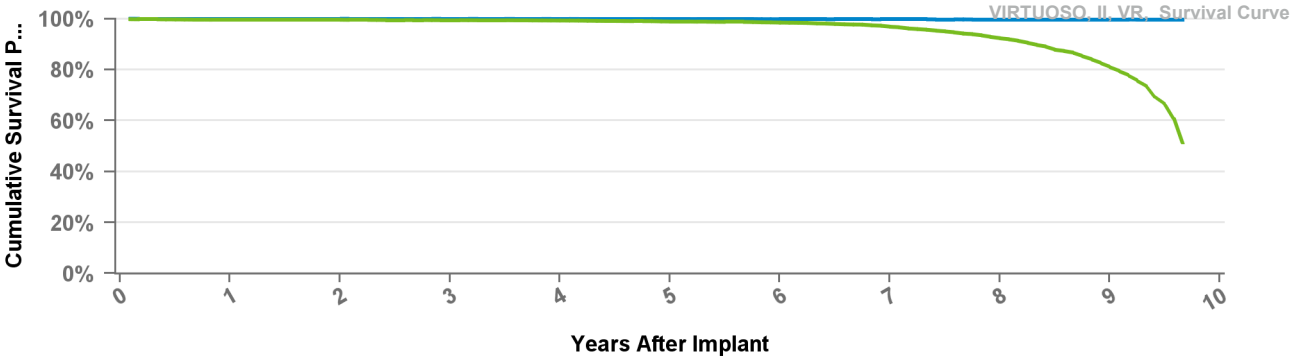
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.1%	98.5%	95.9%	89.0%	70.3%	38.1%	23.8%	22.6%
Effective Sample Size	19082	17910	16856	15662	13955	11211	7197	3118	714	257

D294VRC Virtuoso II VR

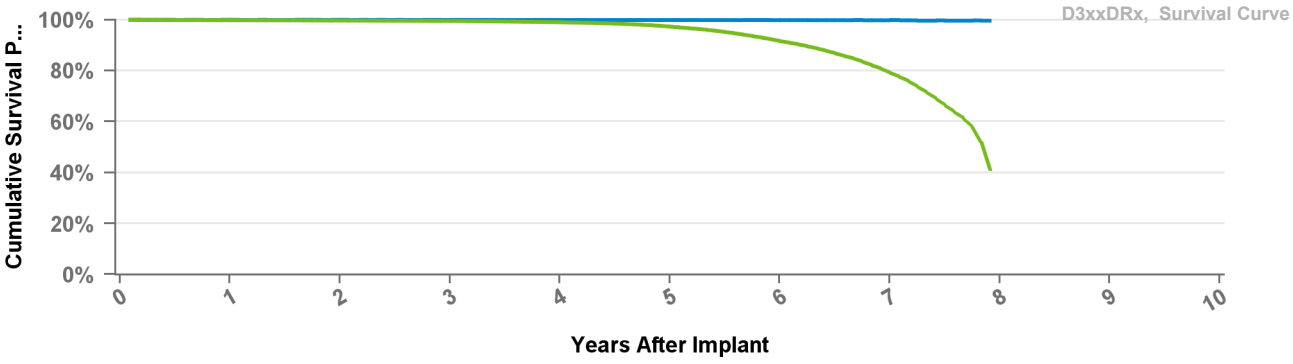
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.6%	99.6%	99.4%	99.3%	98.9%	98.5%	96.9%	92.4%	81.1%	51.2%
Effective Sample Size	7648	7178	6768	6300	5813	5284	4691	3820	1790	131

D314DRG Protecta XT DR

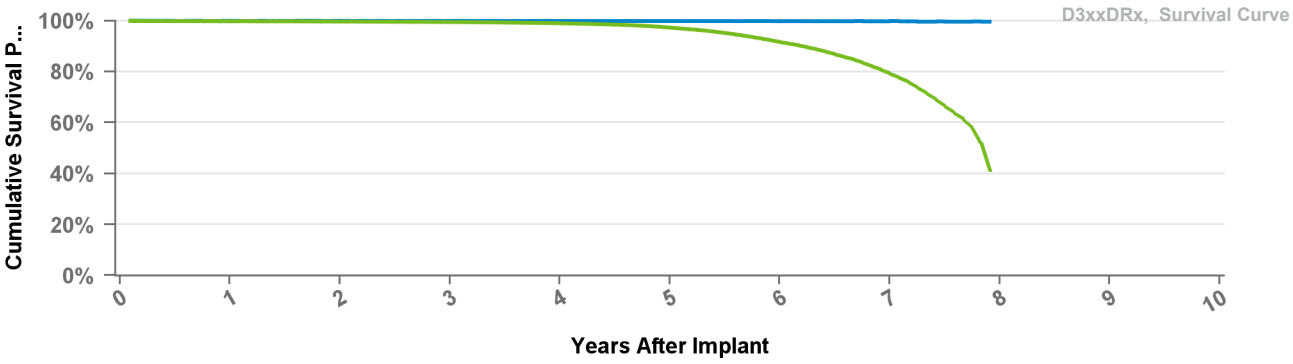
US Market Release	Mar-11	**Total Malfunctions**	**67**
CE Approval Date		**Therapy Function Not Compromised**	**40**
Registered USA Implants	34,844	Battery Malfunction	8
Estimated Active USA Implants	13,875	Electrical Component	26
Normal Battery Depletions	3,134	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**27**
		Battery Malfunction	20
		Electrical Component	7



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D314DRM Protecta XT DR

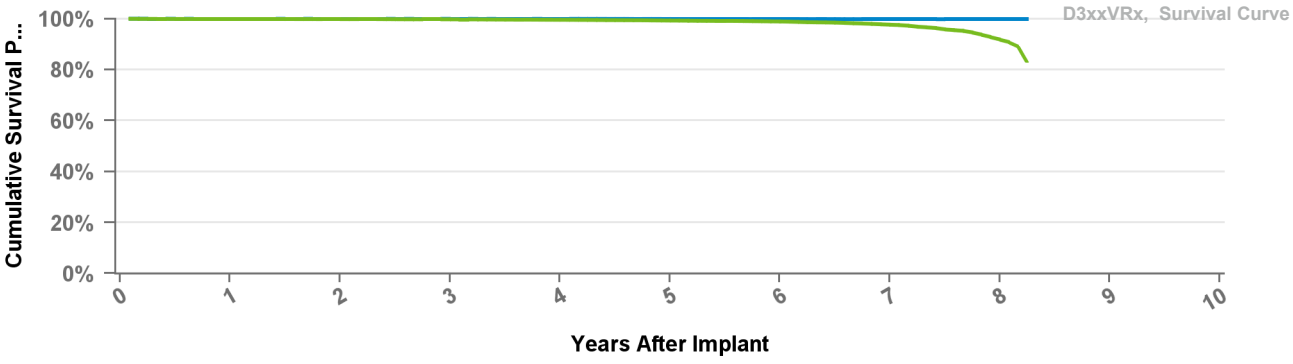
US Market Release	Nov-11	**Total Malfunctions**	**22**
CE Approval Date		**Therapy Function Not Compromised**	**15**
Registered USA Implants	13,924	Battery Malfunction	2
Estimated Active USA Implants	7,159	Electrical Component	12
Normal Battery Depletions	952	Other Malfunction	1
		Therapy Function Compromised	**7**
		Battery Malfunction	7



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D314VRG Protecta XT VR

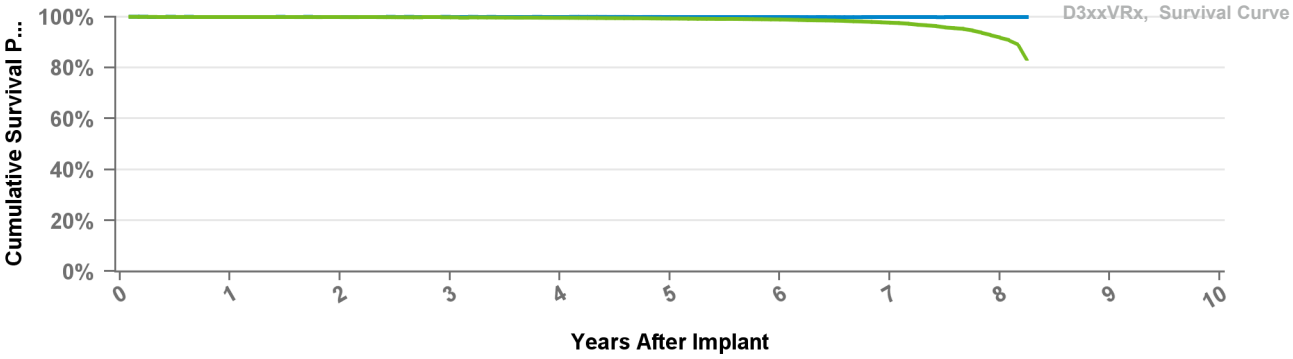
US Market Release	Mar-11	**Total Malfunctions**	**22**
CE Approval Date		**Therapy Function Not Compromised**	**16**
Registered USA Implants	14,221	Battery Malfunction	6
Estimated Active USA Implants	8,893	Electrical Component	9
Normal Battery Depletions	249	Other Malfunction	1
		Therapy Function Compromised	**6**
		Battery Malfunction	5
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D314VRM Protecta XT VR

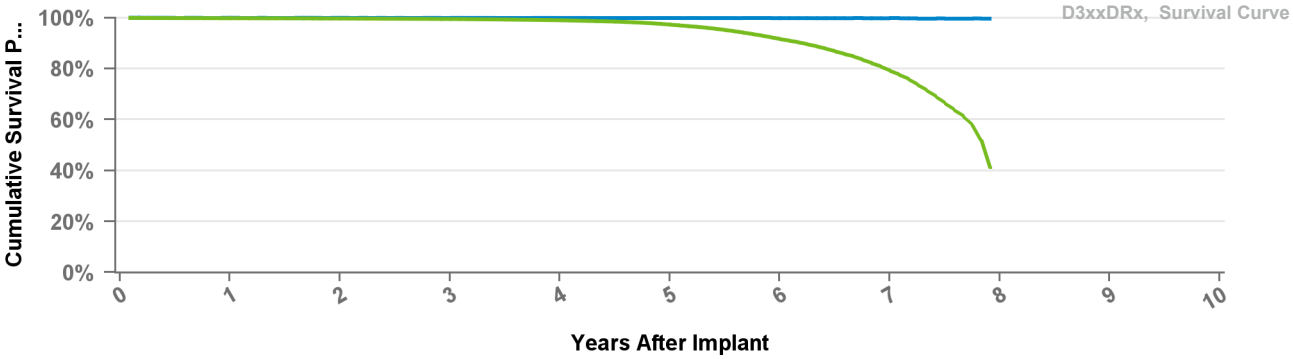
US Market Release	May-12	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	7,375	Electrical Component	2
Estimated Active USA Implants	5,391	Poss Early Battery Depltn	1
Normal Battery Depletions	57	**Therapy Function Compromised**	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D334DRG Protecta DR

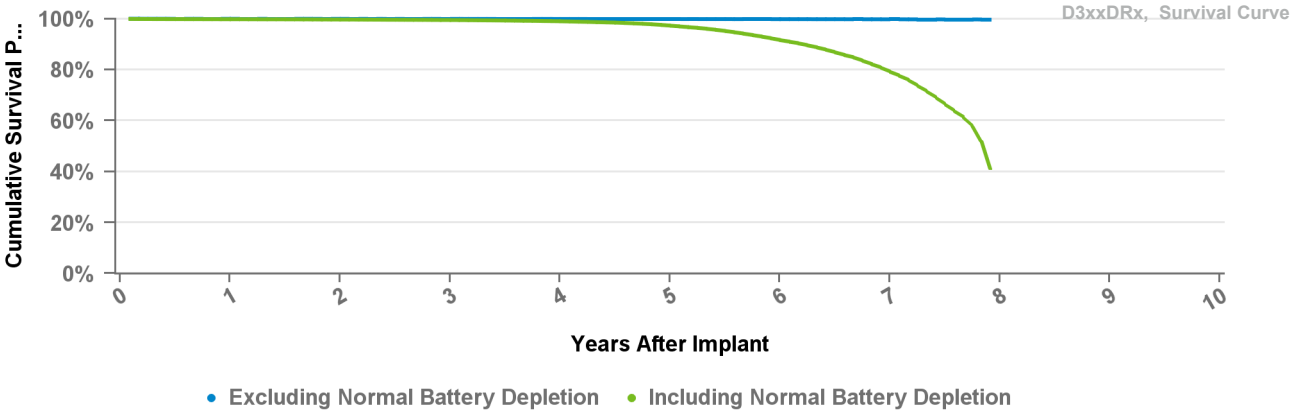
US Market Release	Mar-11	**Total Malfunctions**	**19**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	10,689	Battery Malfunction	2
Estimated Active USA Implants	4,207	Electrical Component	6
Normal Battery Depletions	1,317	Poss Early Battery Depltn	1
		Therapy Function Compromised	**10**
		Battery Malfunction	7
		Electrical Component	3



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D334DRM Protecta DR

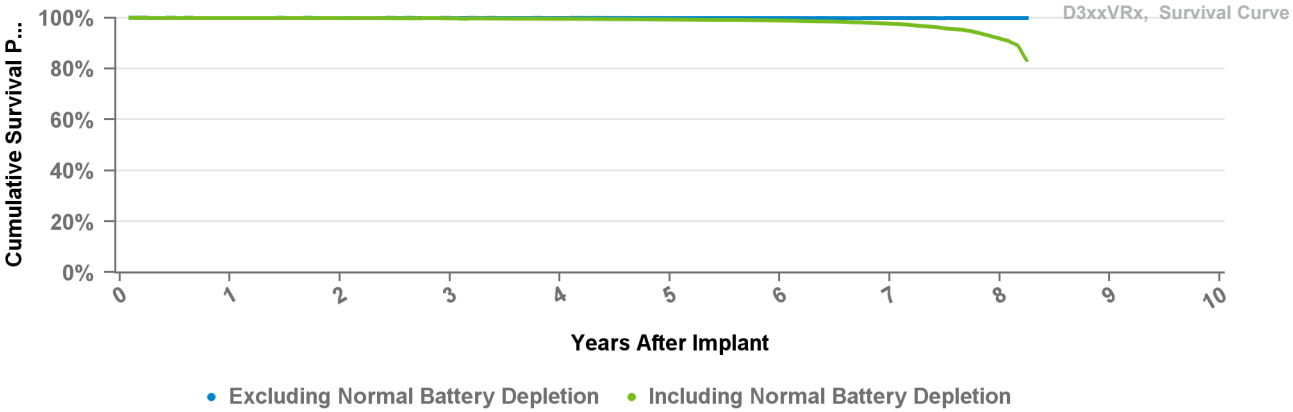
US Market Release	Nov-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,991		
Estimated Active USA Implants	1,478	**Therapy Function Compromised**	
Normal Battery Depletions	322		



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D334VRG Protecta VR

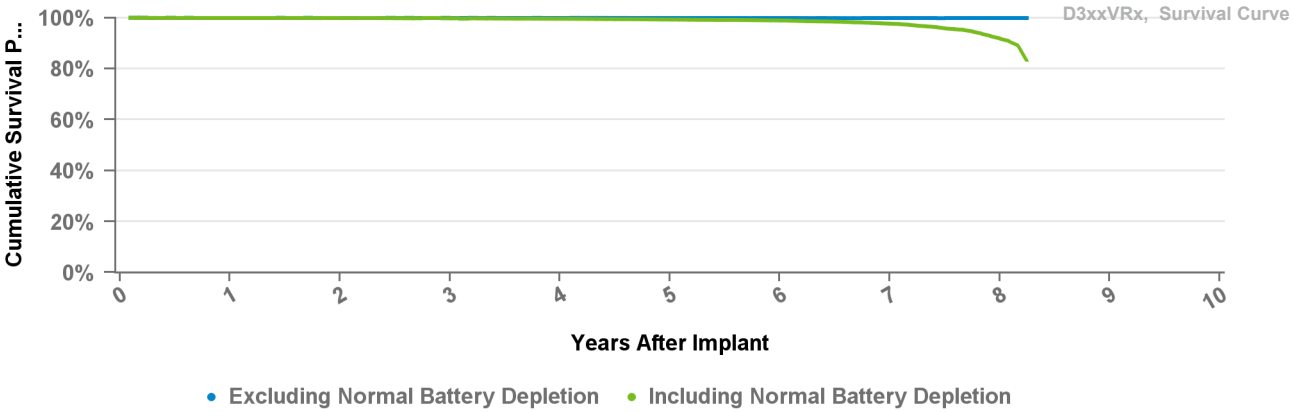
US Market Release	Mar-11	**Total Malfunctions**	**11**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	6,479	Battery Malfunction	2
Estimated Active USA Implants	4,179	Electrical Component	4
Normal Battery Depletions	106	**Therapy Function Compromised**	**5**
		Battery Malfunction	3
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D334VRM Protecta VR

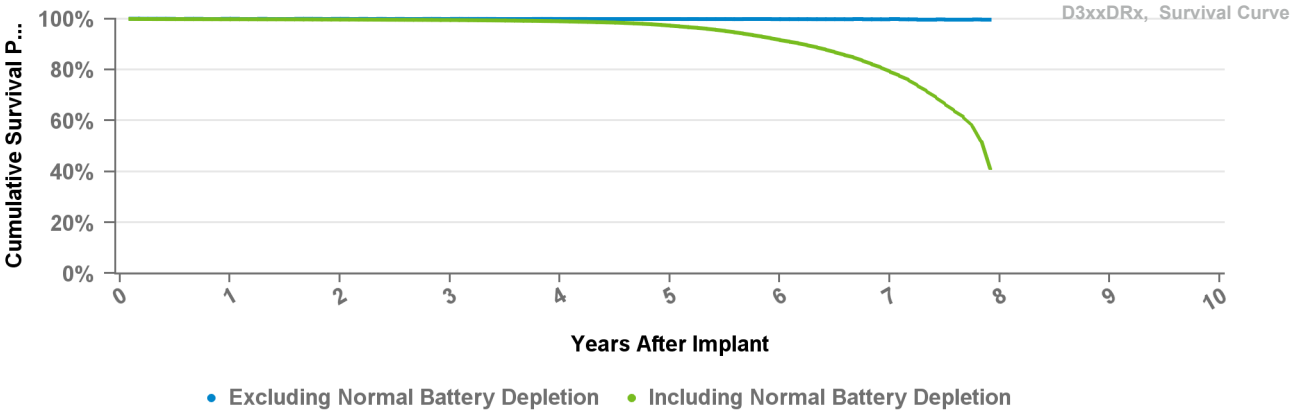
US Market Release	May-12	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,162	Other Malfunction	1
Estimated Active USA Implants	1,593	**Therapy Function Compromised**	**1**
Normal Battery Depletions	22	Battery Malfunction	1



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D354DRG Protecta XT DR

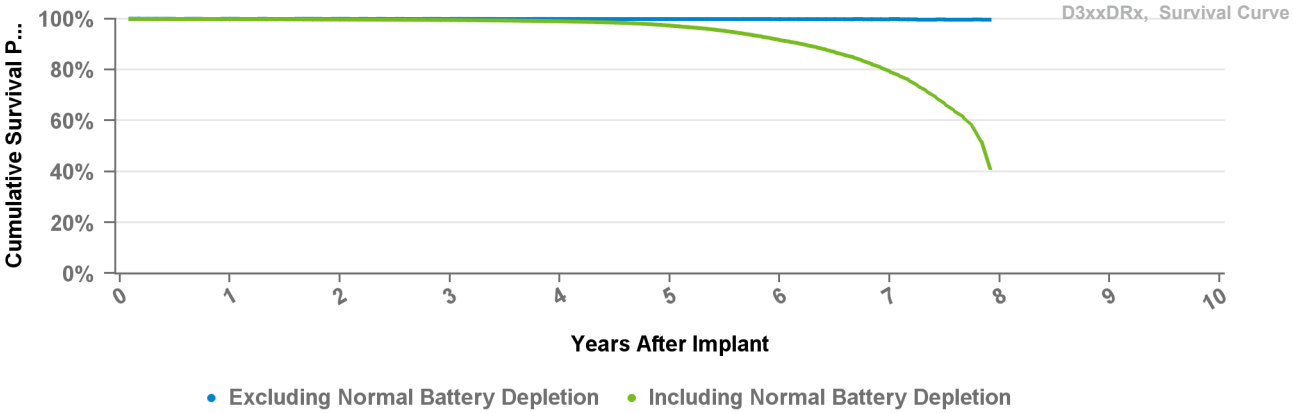
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D354DRM Protecta XT DR

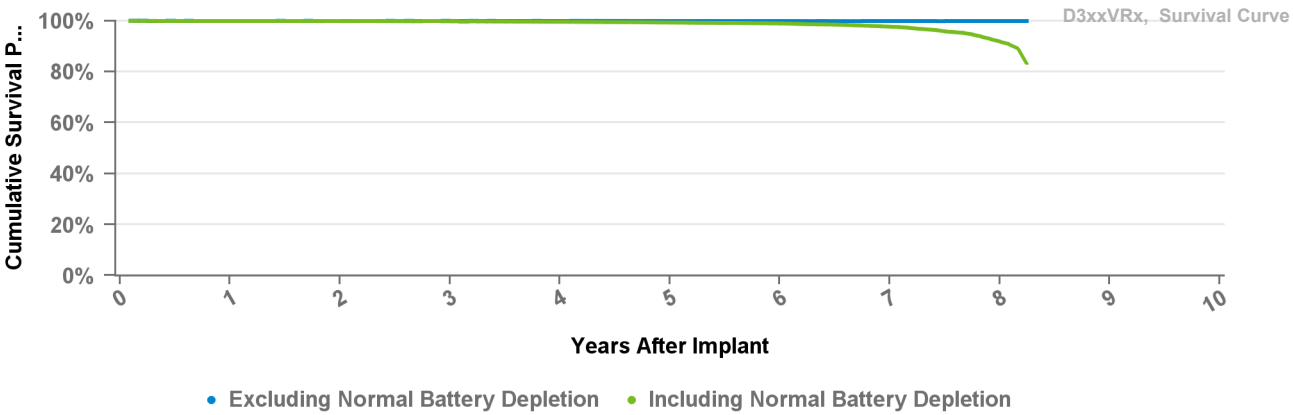
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D354VRG Protecta XT VR

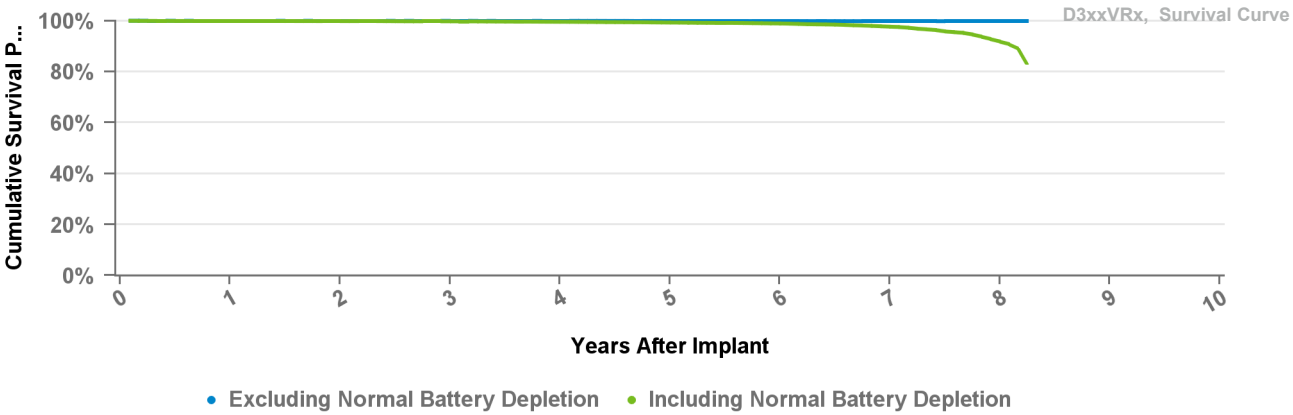
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D354VRM Protecta XT VR

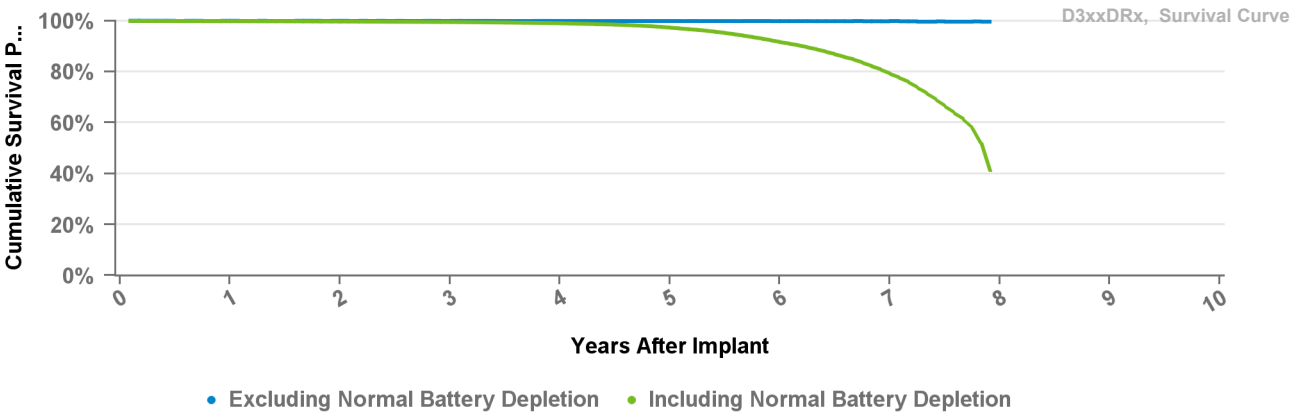
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D364DRG Protecta DR

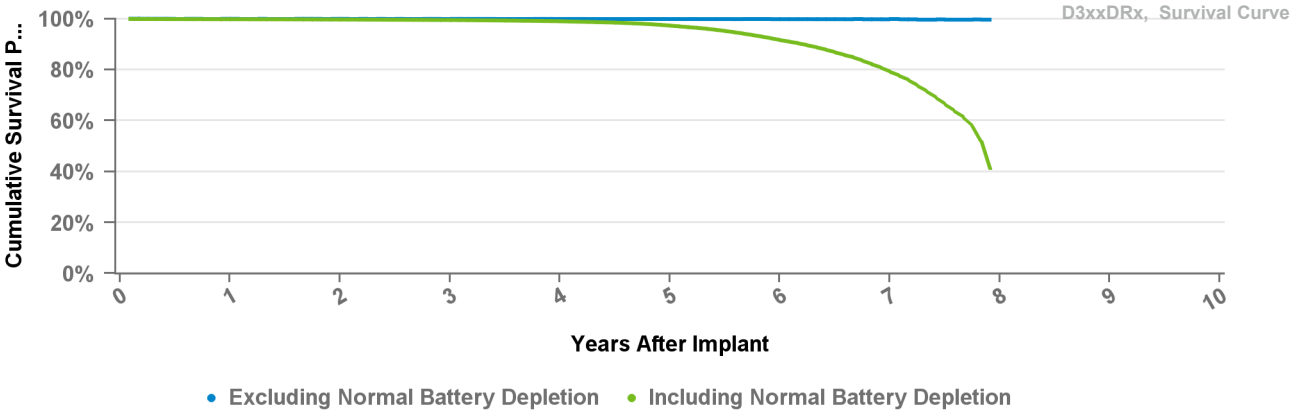
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D364DRM Protecta DR

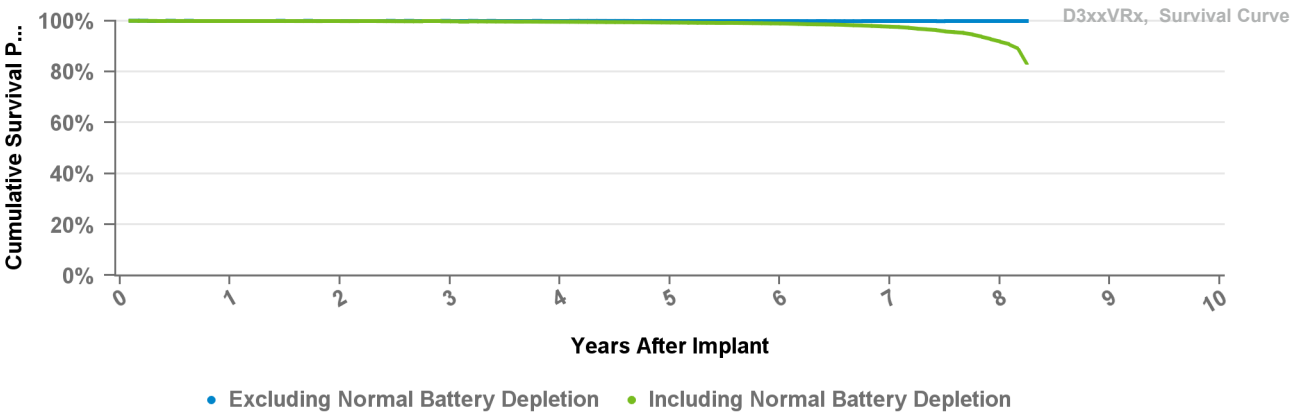
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D364VRG Protecta VR

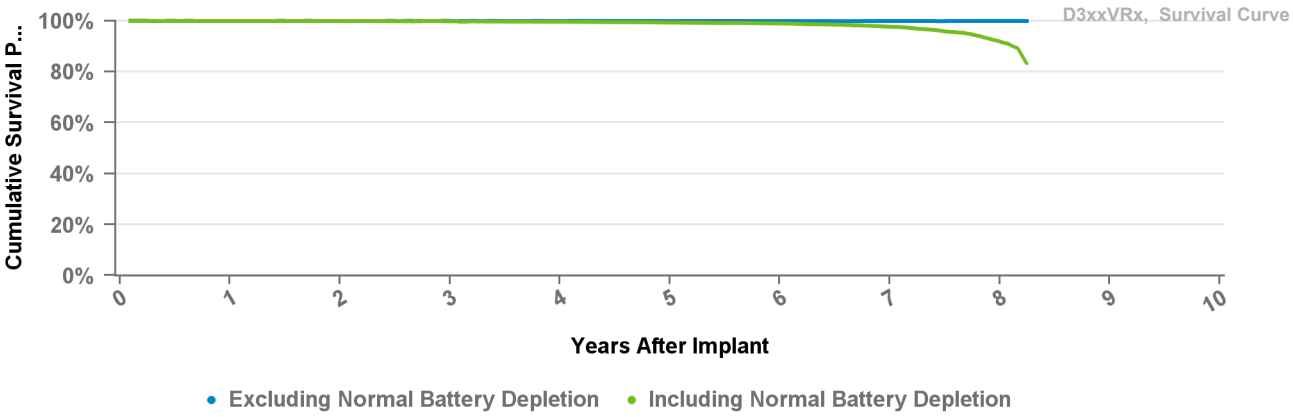
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D364VRM Protecta VR

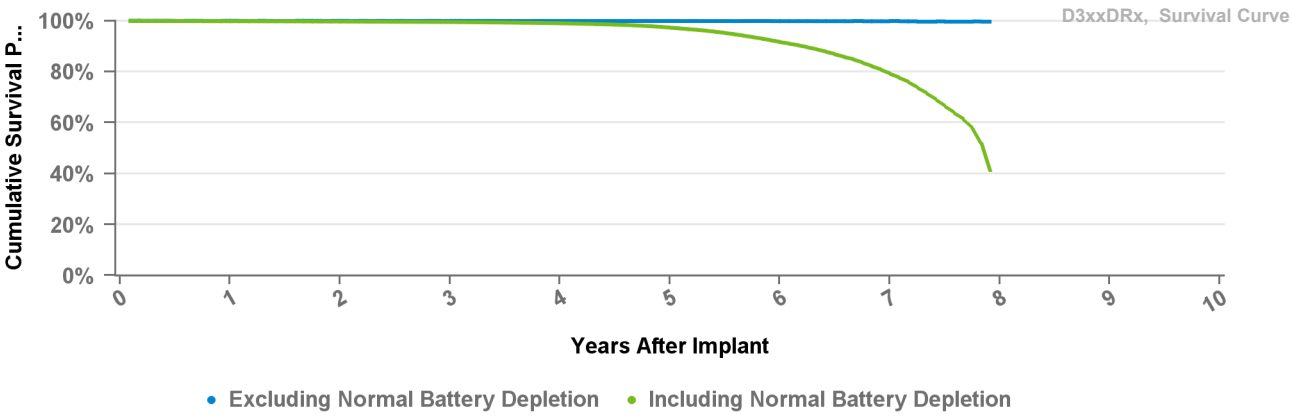
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D384DRG Cardia DR

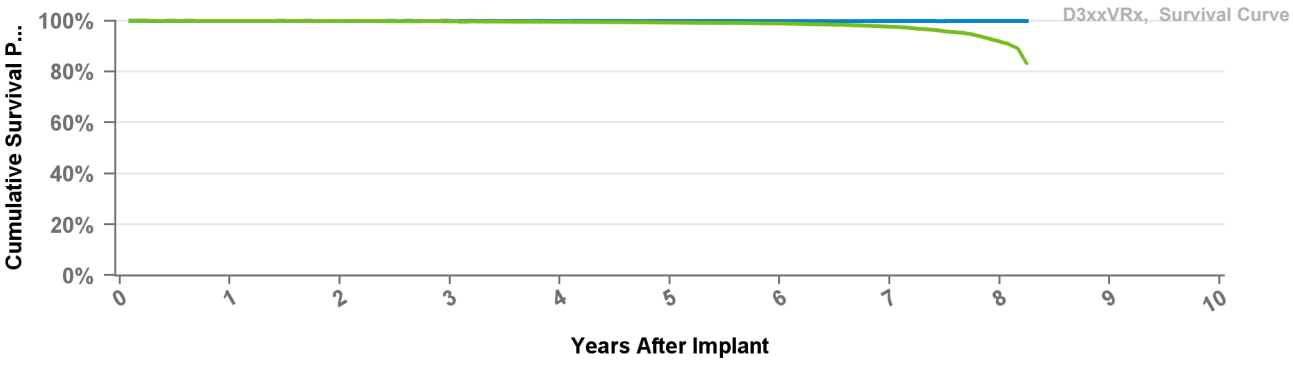
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D384VRG Cardia VR

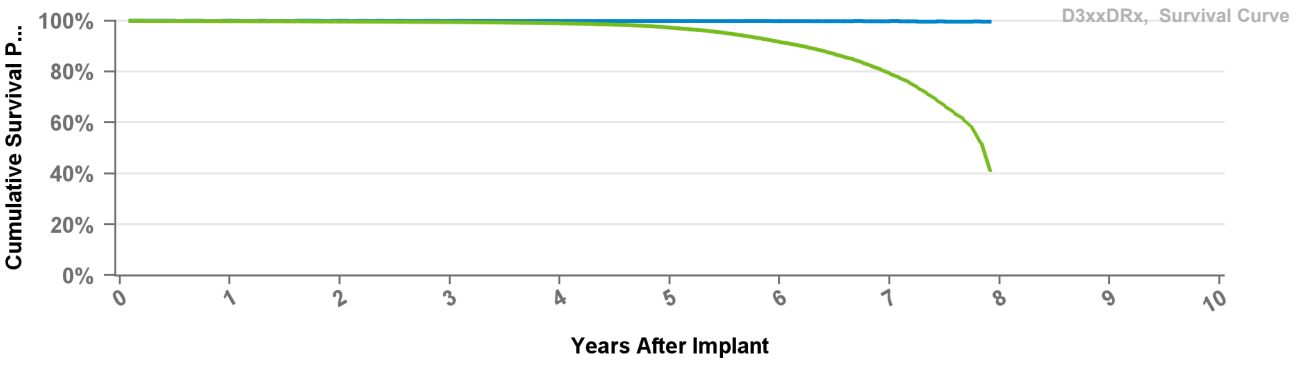
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

D394DRG Egida DR

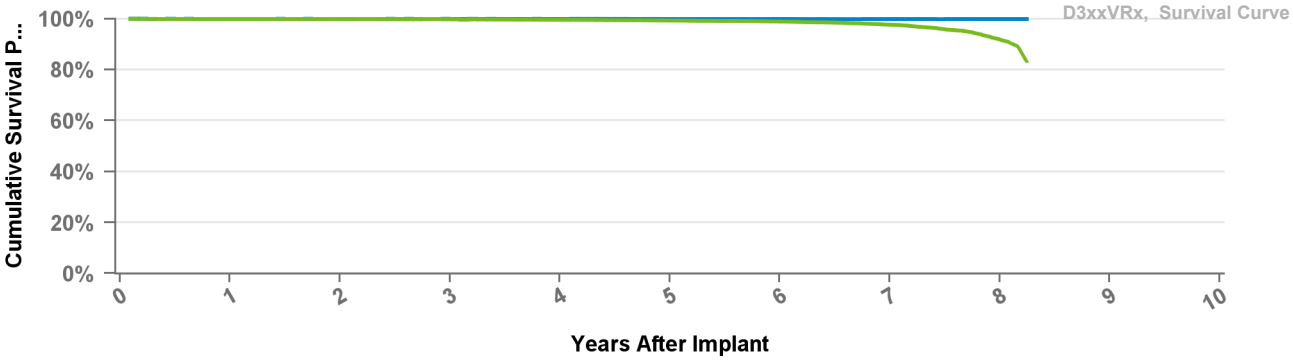
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.3%	91.6%	79.2%	41.1%
Effective Sample Size	54709	51405	48237	44751	40271	32671	17201	588

D394VRG Egida VR

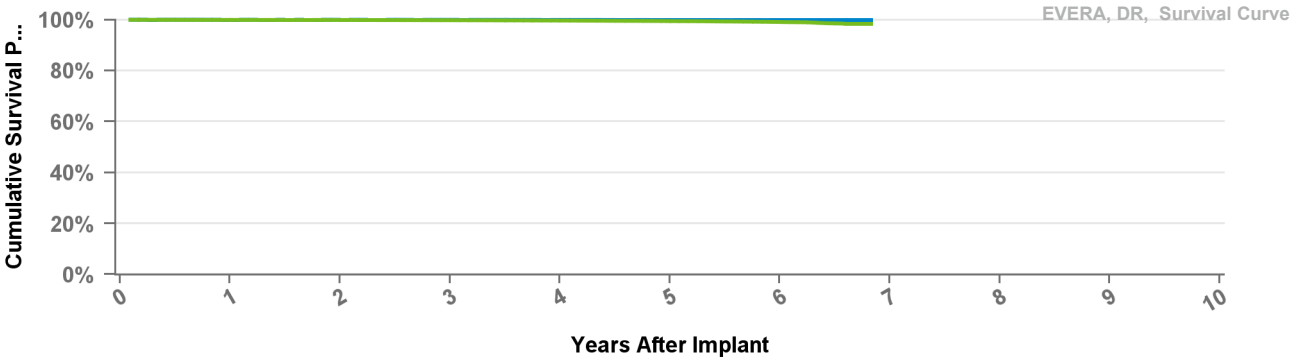
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.9%	97.7%	91.8%	83.2%
Effective Sample Size	26155	24512	23099	21502	19777	17685	12054	1993	171

DDBB1D1 Evera XT

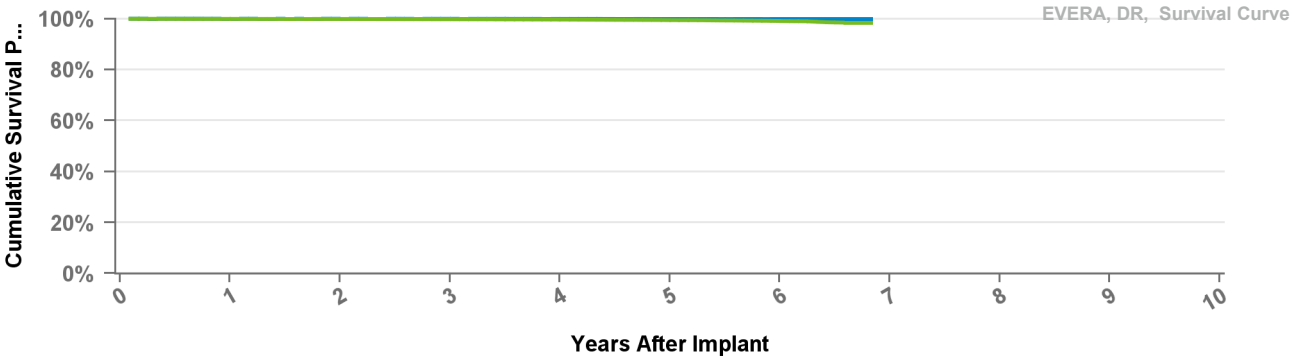
US Market Release	Apr-13	**Total Malfunctions**	**37**
CE Approval Date		**Therapy Function Not Compromised**	**21**
Registered USA Implants	43,062	Battery Malfunction	10
Estimated Active USA Implants	35,362	Electrical Component	10
Normal Battery Depletions	107	Other Malfunction	1
		Therapy Function Compromised	**16**
		Battery Malfunction	11
		Electrical Component	2
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDBB1D4 Evera XT

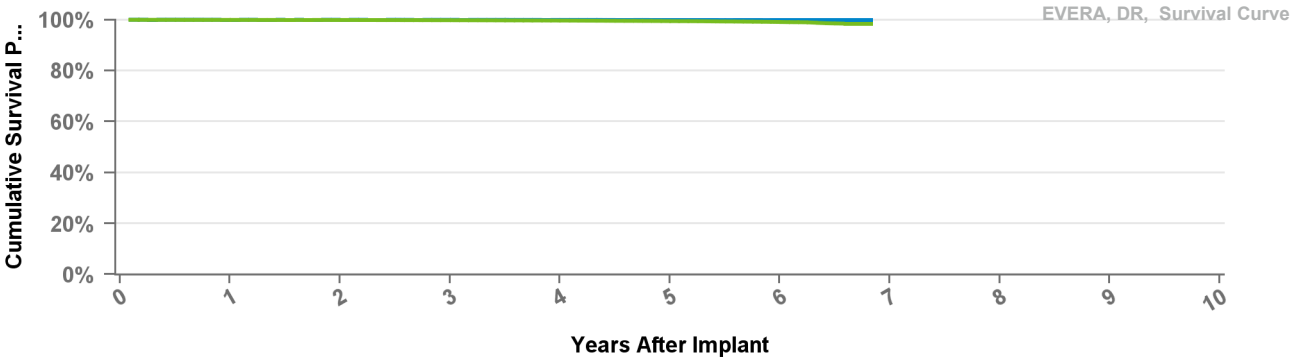
US Market Release	Apr-13	**Total Malfunctions**	**33**
CE Approval Date		**Therapy Function Not Compromised**	**20**
Registered USA Implants	30,426	Battery Malfunction	12
Estimated Active USA Implants	26,024	Electrical Component	5
Normal Battery Depletions	58	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**13**
		Battery Malfunction	10
		Electrical Component	3



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDBB2D1 Evera XT

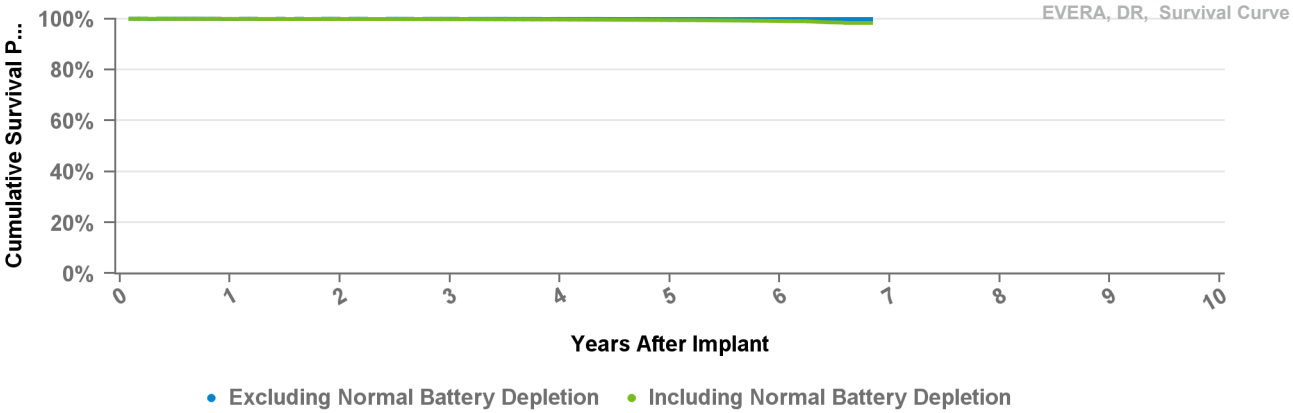
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDBB2D4 Evera XT

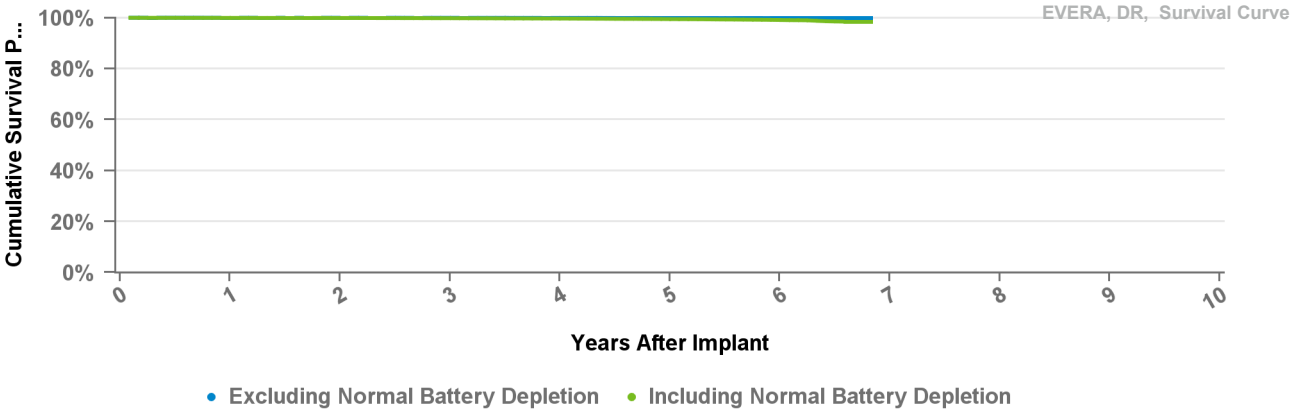
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDBC3D1 Evera S

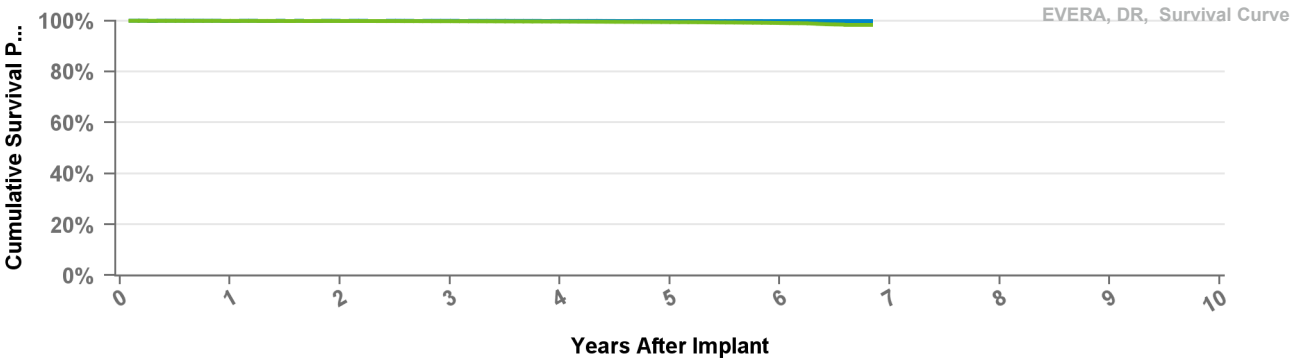
US Market Release	Apr-13	**Total Malfunctions**	**9**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**4**
Registered USA Implants	8,432	Battery Malfunction	2
Estimated Active USA Implants	6,941	Electrical Component	2
Normal Battery Depletions	20	**Therapy Function Compromised**	**5**
		Battery Malfunction	4
		Electrical Component	1



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDBC3D4 Evera S

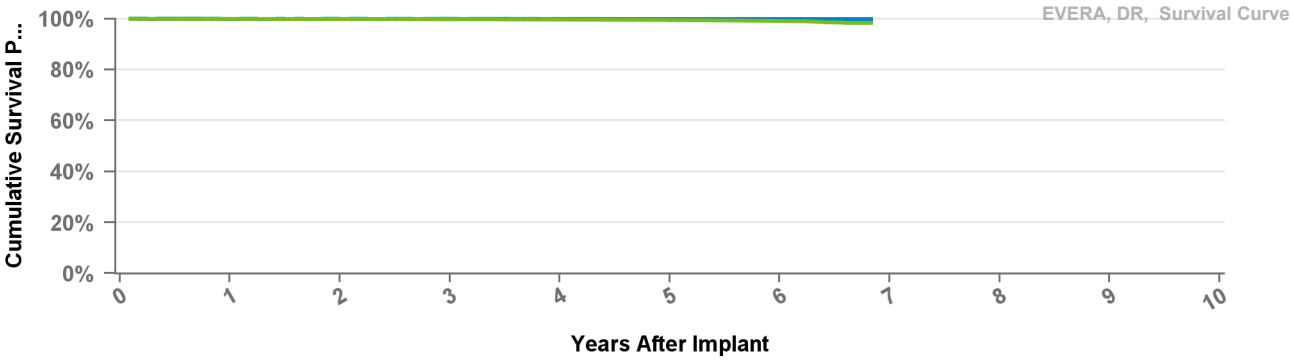
US Market Release	Apr-13	**Total Malfunctions**	**8**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**4**
Registered USA Implants	6,053	Battery Malfunction	2
Estimated Active USA Implants	5,146	Electrical Component	2
Normal Battery Depletions	13	**Therapy Function Compromised**	**4**
		Battery Malfunction	3
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMB1D1 Evera MRI XT

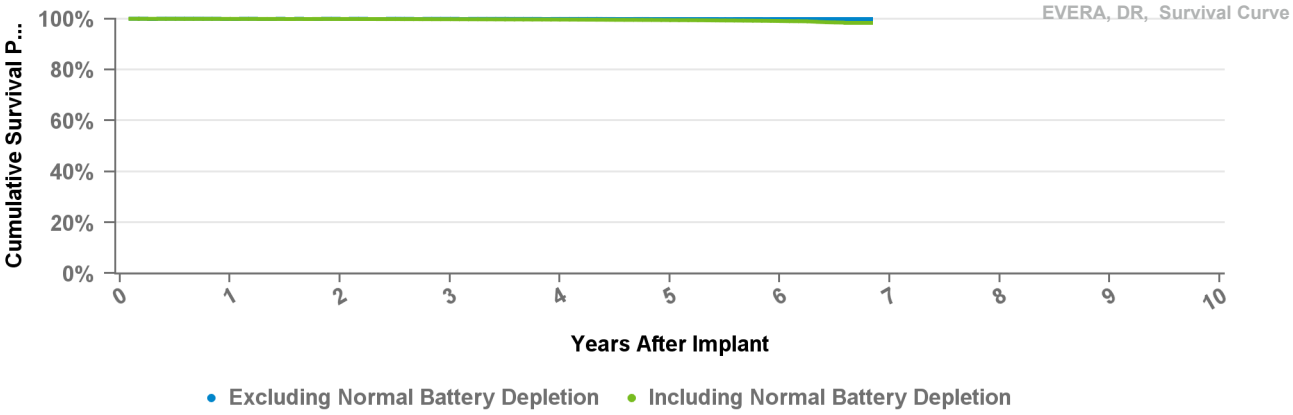
US Market Release	Oct-16	**Total Malfunctions**	**7**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	28,618	Battery Malfunction	1
Estimated Active USA Implants	26,996	Electrical Component	2
Normal Battery Depletions	4	Electrical Interconnect	1
		Other Malfunction	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMB1D4 Evera MRI XT

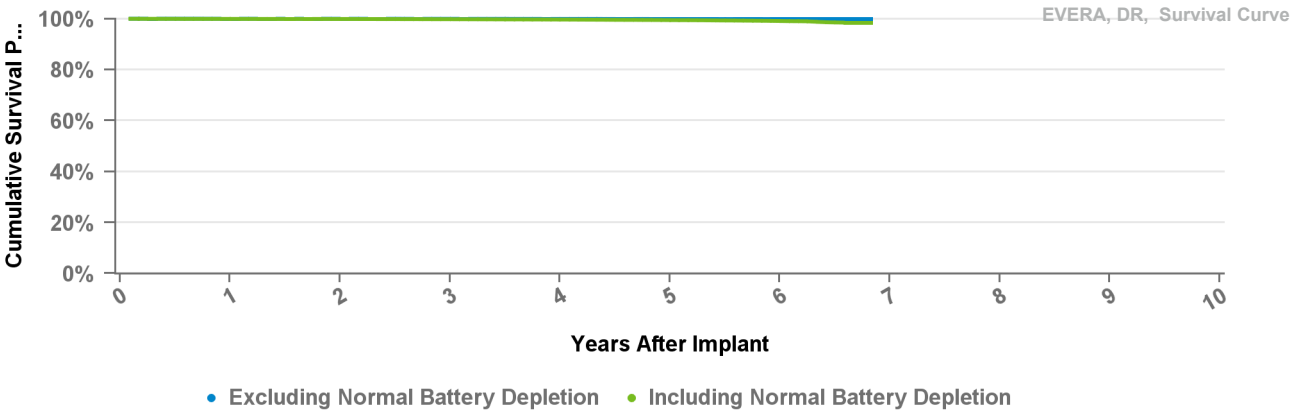
US Market Release	Sep-15	**Total Malfunctions**	**22**
CE Approval Date		**Therapy Function Not Compromised**	**18**
Registered USA Implants	71,327	Battery Malfunction	4
Estimated Active USA Implants	67,310	Electrical Component	11
Normal Battery Depletions	35	Electrical Interconnect	2
		Other Malfunction	1
		Therapy Function Compromised	**4**
		Battery Malfunction	3
		Electrical Component	1



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMB2D1 Evera MRI XT

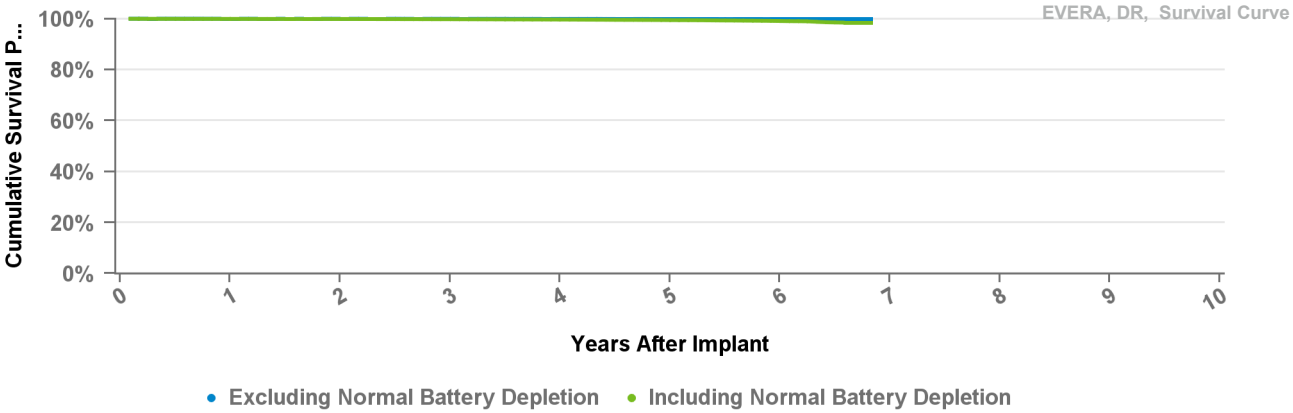
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	1,761		
Estimated Active USA Implants	1,691	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMB2D4 Evera MRI XT

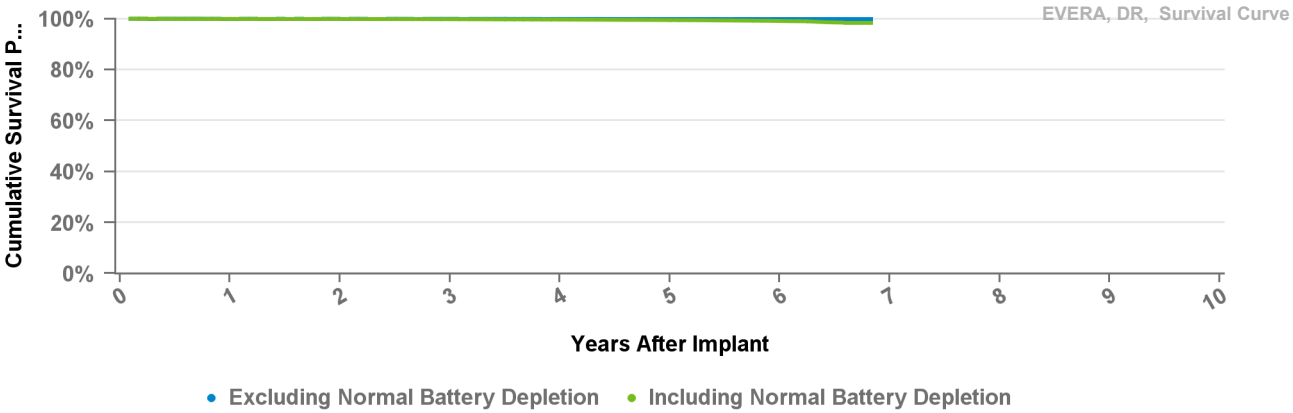
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMC3D1 Evera MRI S

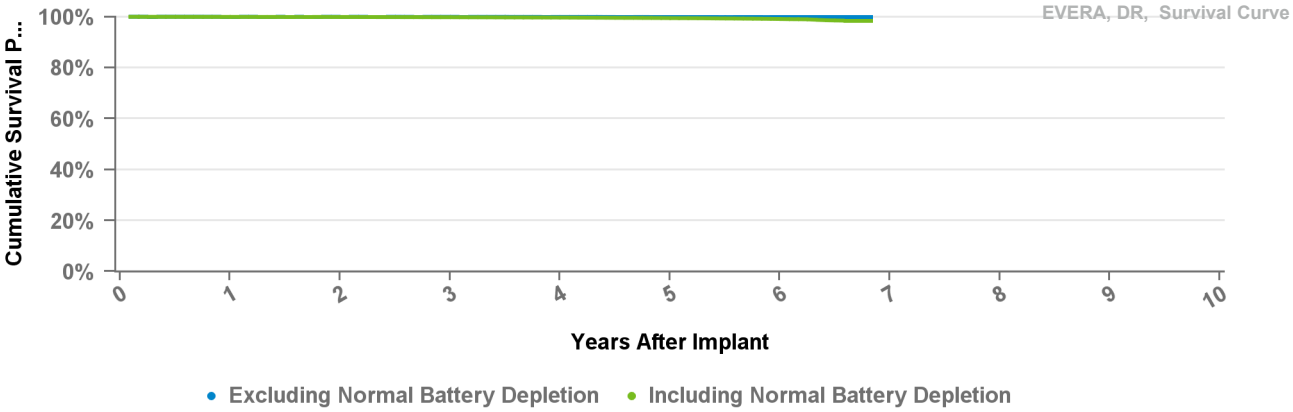
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	2,719		
Estimated Active USA Implants	2,578	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMC3D4 Evera MRI

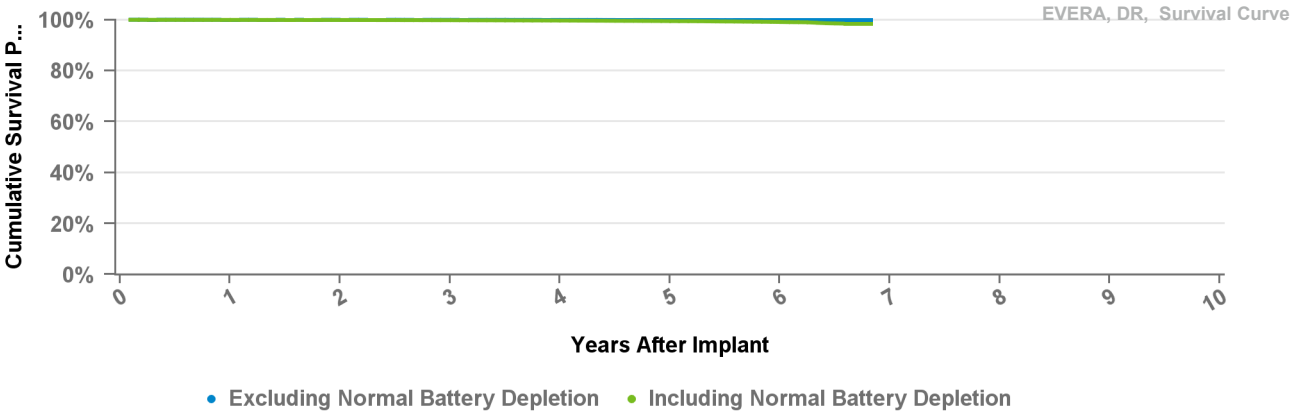
US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,988	Electrical Component	1
Estimated Active USA Implants	4,688	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMD3D1 Primo

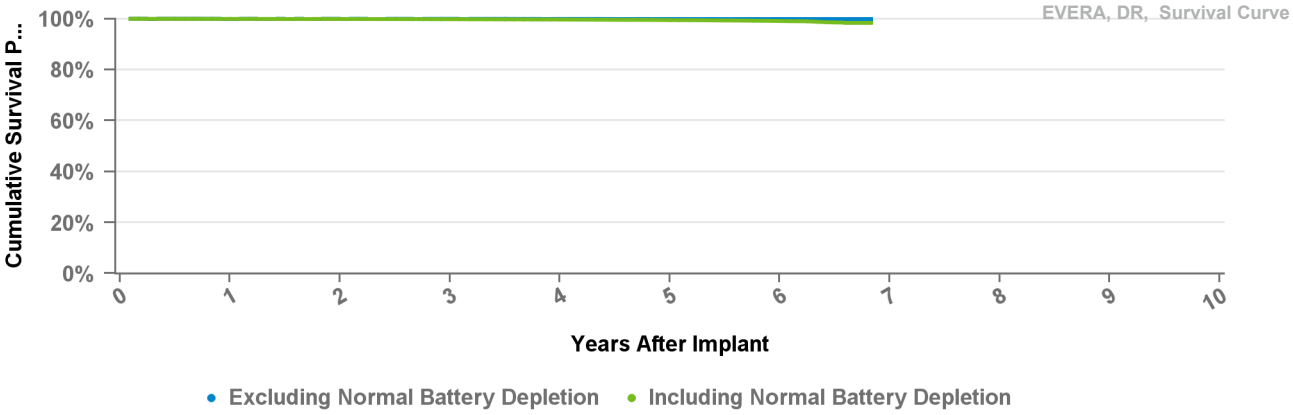
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	124		
Estimated Active USA Implants	116	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDMD3D4 Primo

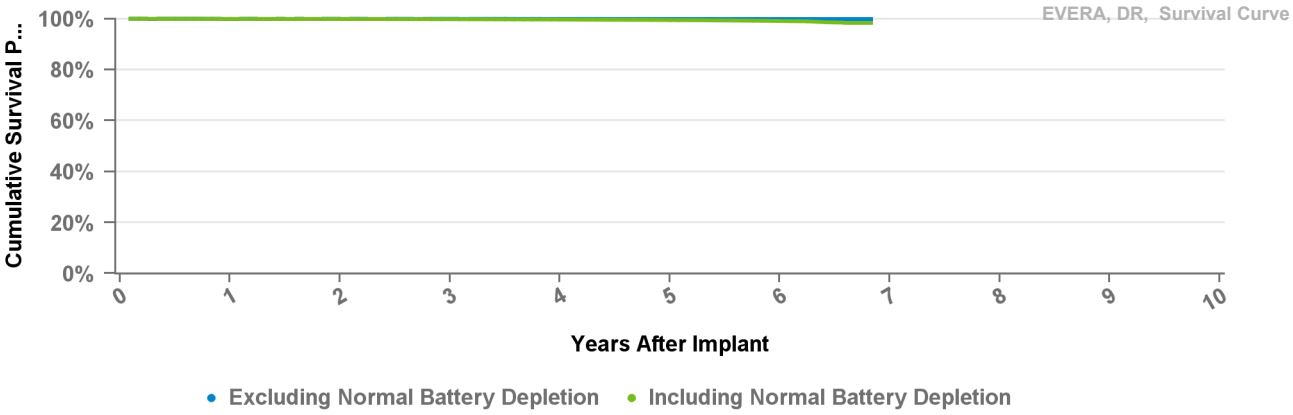
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	202		
Estimated Active USA Implants	197	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DDME3D4 Mirro

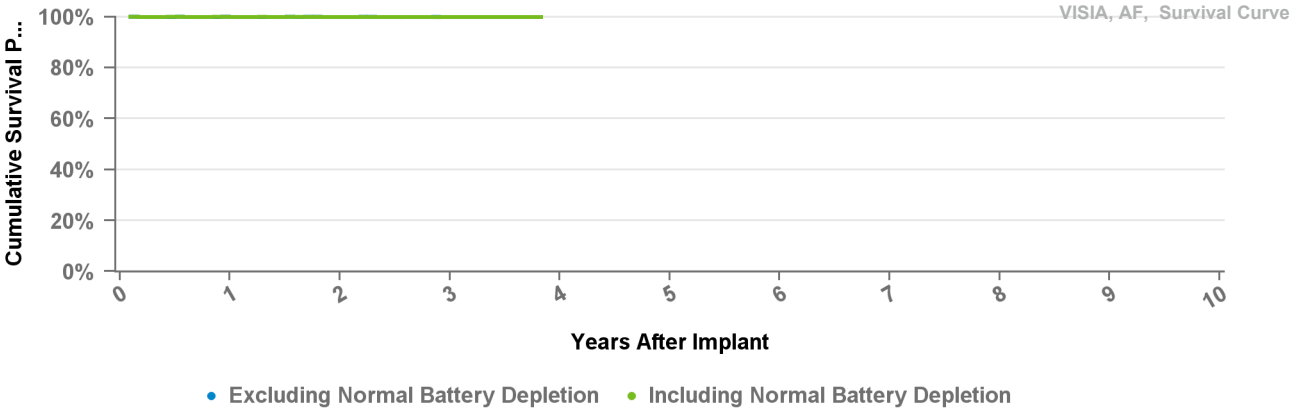
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	98.5%
Effective Sample Size	161237	126089	92126	61159	35800	13865	163

DVAB1D1 Visia AF

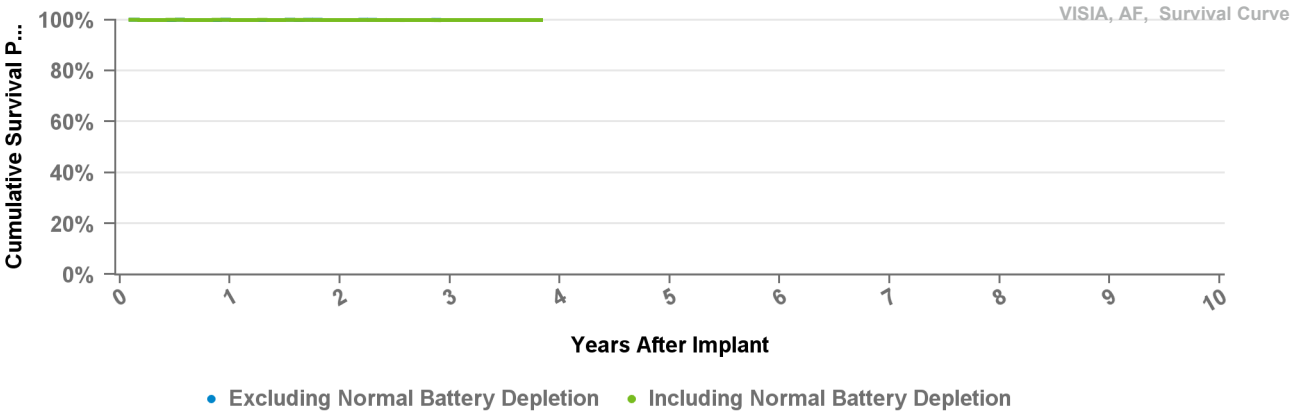
US Market Release	Jan-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,018	Battery Malfunction	1
Estimated Active USA Implants	2,737	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVAB1D4 Visia AF

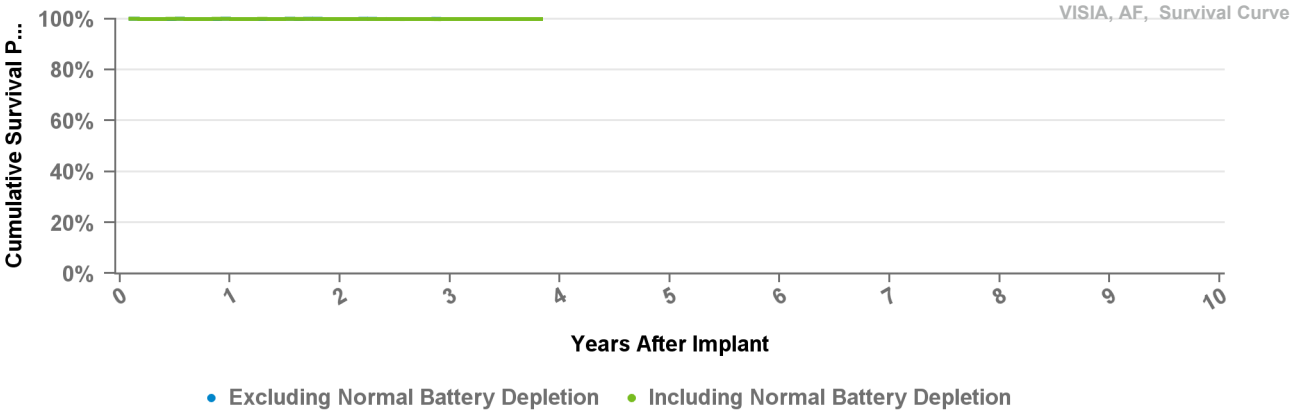
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,022		
Estimated Active USA Implants	1,877	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVAB2D1 Visia AF XT

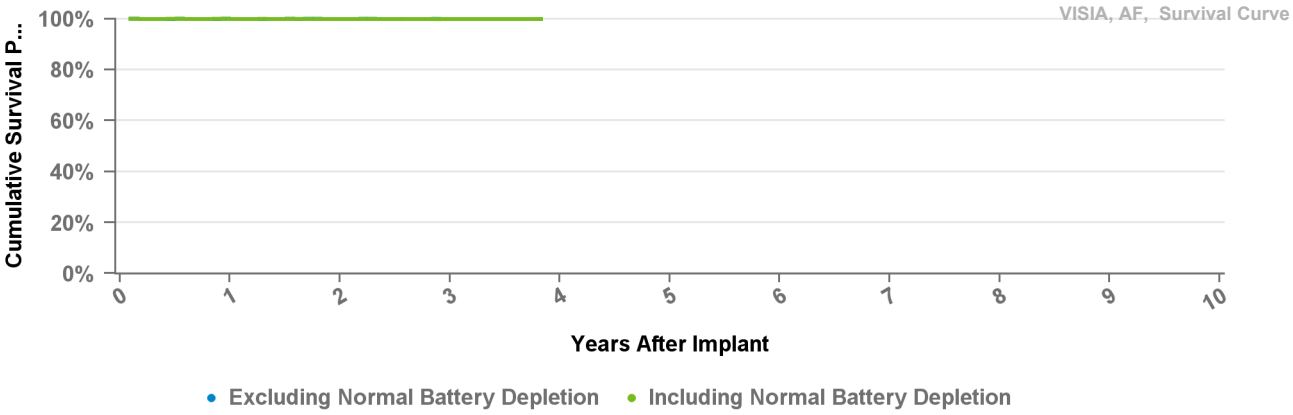
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVAC3D1 Visia AF S

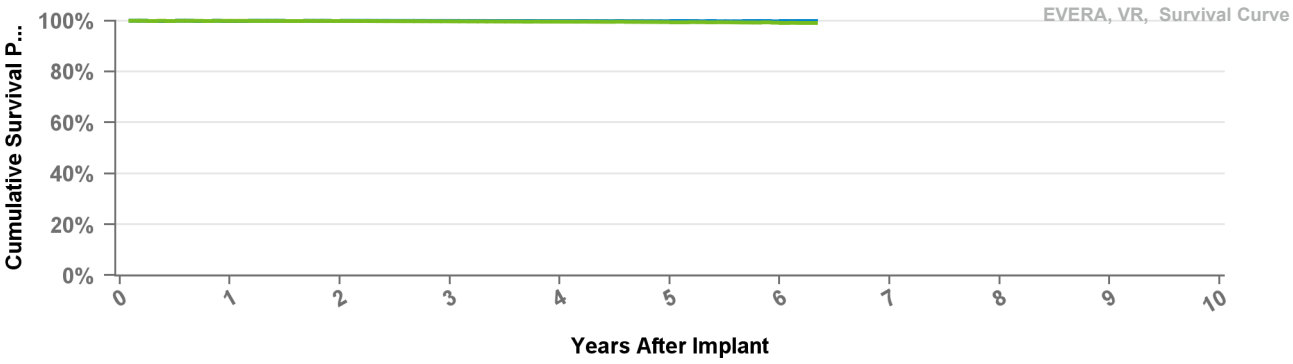
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVBB1D1 Evera XT

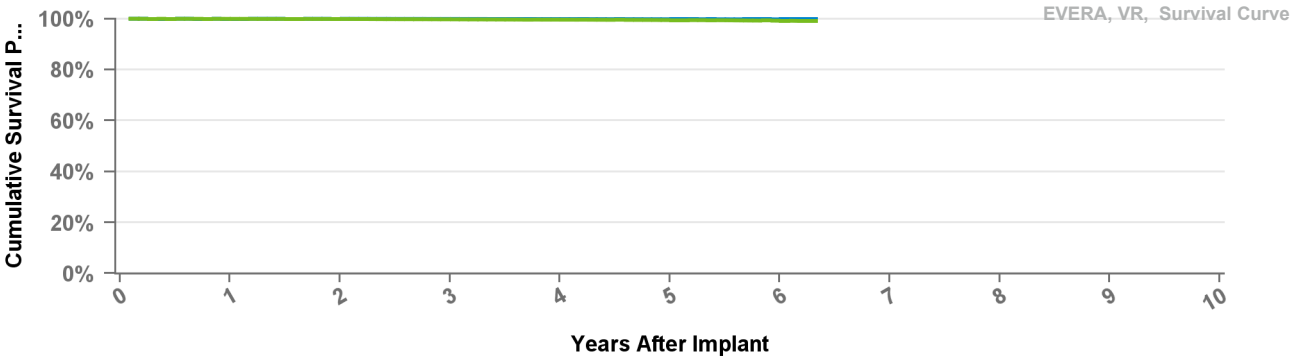
US Market Release	Apr-13	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**15**
Registered USA Implants	16,122	Battery Malfunction	10
Estimated Active USA Implants	13,018	Electrical Component	5
Normal Battery Depletions	13	**Therapy Function Compromised**	**5**
		Battery Malfunction	3
		Electrical Component	2



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVBB1D4 Evera XT

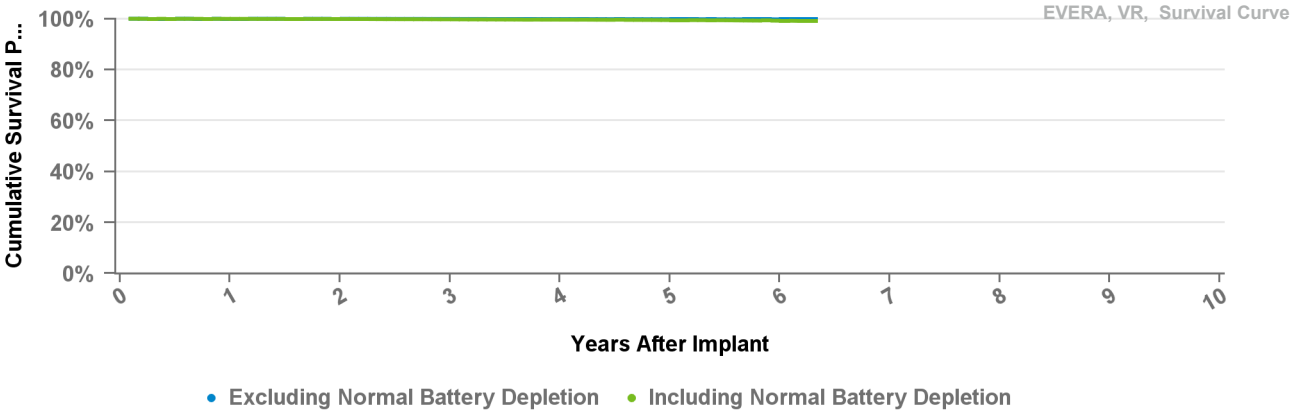
US Market Release	Apr-13	**Total Malfunctions**	**43**
CE Approval Date		**Therapy Function Not Compromised**	**31**
Registered USA Implants	22,380	Battery Malfunction	19
Estimated Active USA Implants	19,161	Electrical Component	7
Normal Battery Depletions	24	Other Malfunction	5
		Therapy Function Compromised	**12**
		Battery Malfunction	11
		Electrical Component	1



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVBB2D1 Evera XT

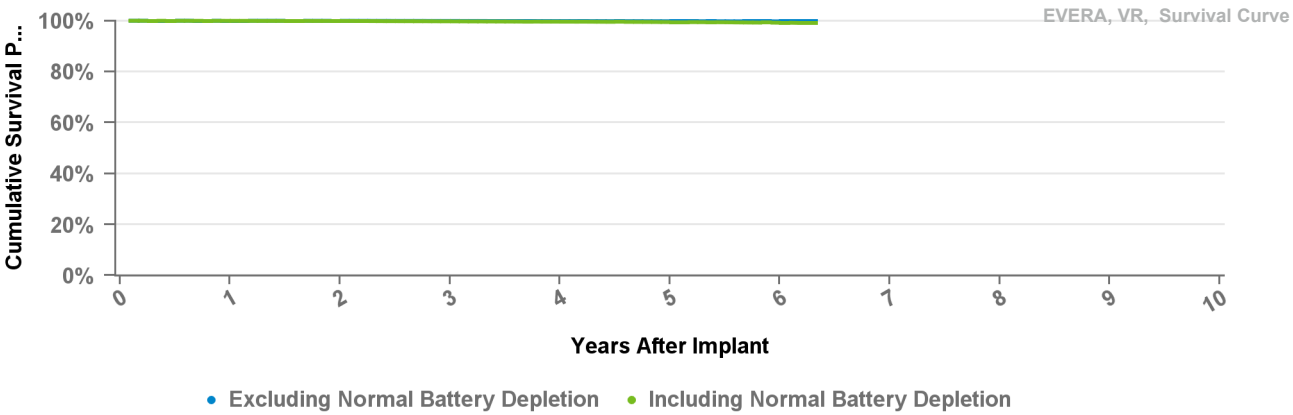
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVBB2D4 Evera XT

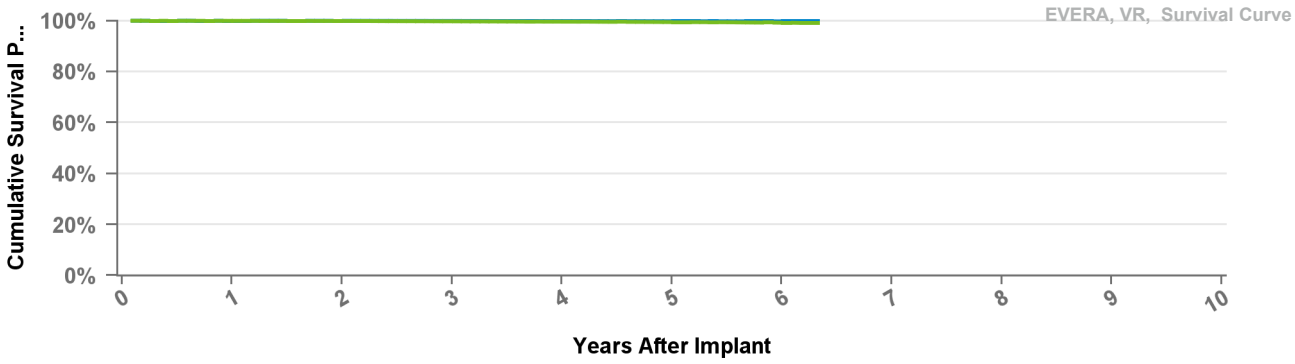
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVBC3D1 Evera S

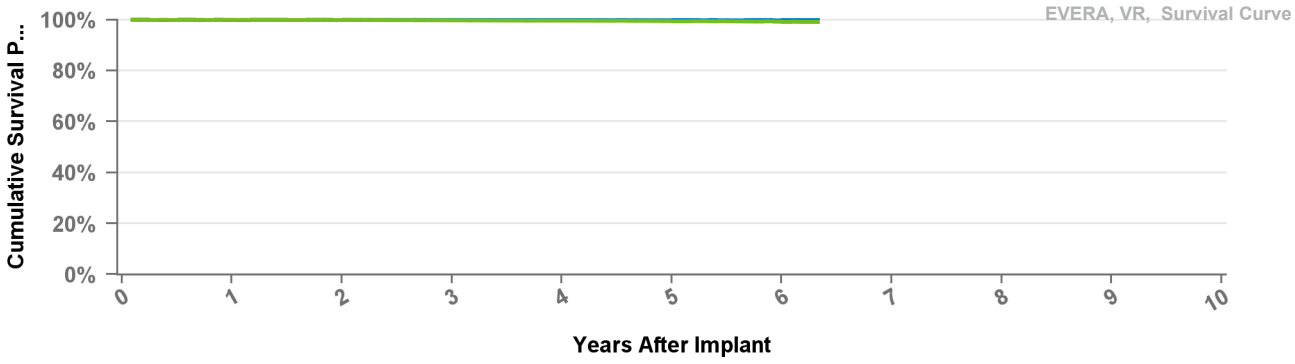
US Market Release	Apr-13	**Total Malfunctions**	**16**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**12**
Registered USA Implants	4,633	Battery Malfunction	11
Estimated Active USA Implants	3,778	Electrical Component	1
Normal Battery Depletions	3	**Therapy Function Compromised**	**4**
		Battery Malfunction	3
		Electrical Component	1



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVBC3D4 Evera S

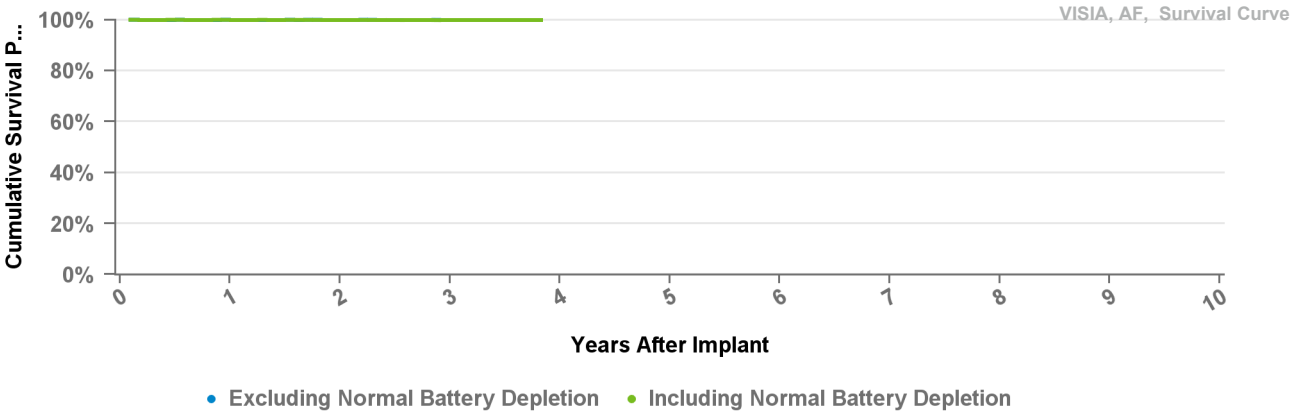
US Market Release	Apr-13	**Total Malfunctions**	**8**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**6**
Registered USA Implants	5,612	Battery Malfunction	4
Estimated Active USA Implants	4,806	Electrical Component	2
Normal Battery Depletions	5	**Therapy Function Compromised**	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVFB1D1 Visia MRI AF

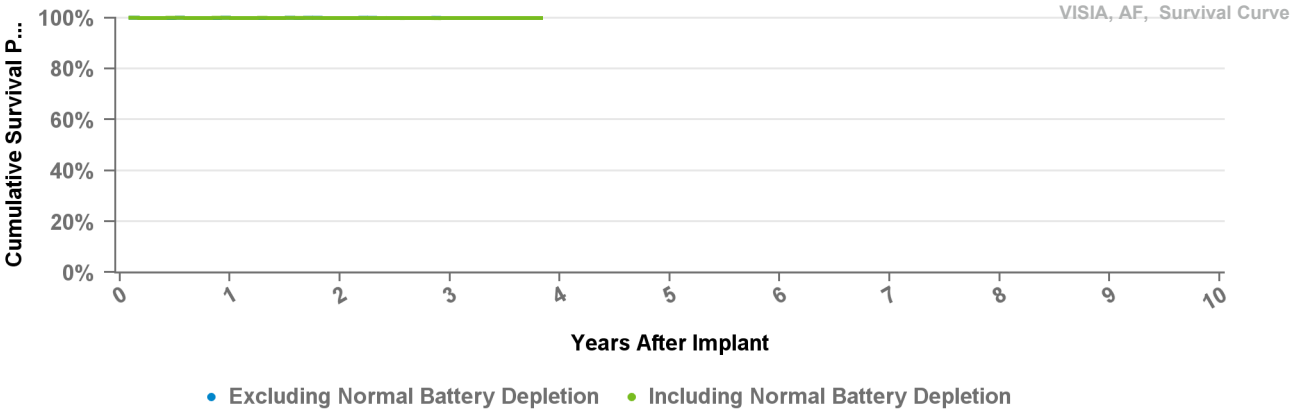
US Market Release	Oct-16	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	11,674	Battery Malfunction	1
Estimated Active USA Implants	11,102	Electrical Component	1
Normal Battery Depletions	5	Other Malfunction	1
		Therapy Function Compromised	**0**



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVFB1D4 Visia MRI AF

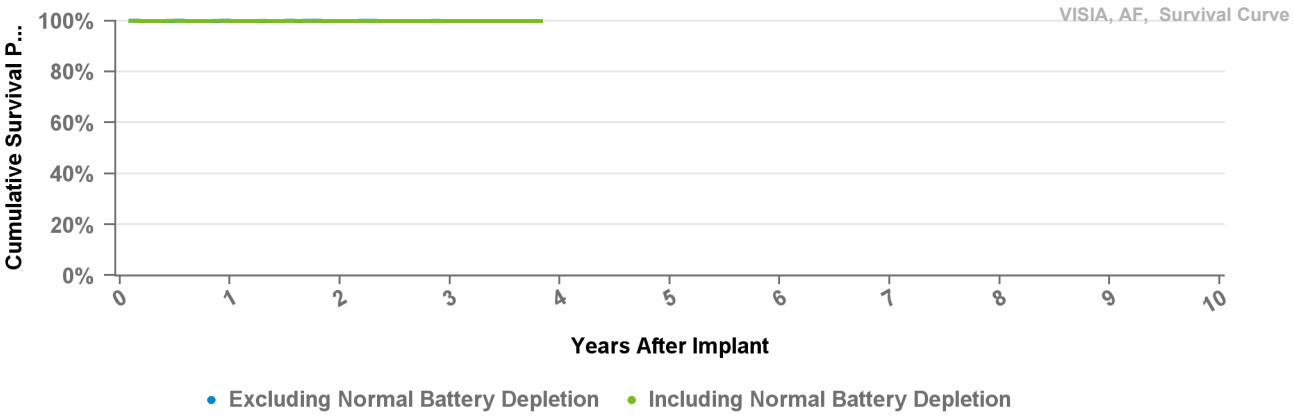
US Market Release	Jan-16	**Total Malfunctions**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	38,053	Battery Malfunction	3
Estimated Active USA Implants	36,068	Electrical Component	3
Normal Battery Depletions	2	Other Malfunction	2
		Therapy Function Compromised	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVFB2D1 Visia MRI AF XT

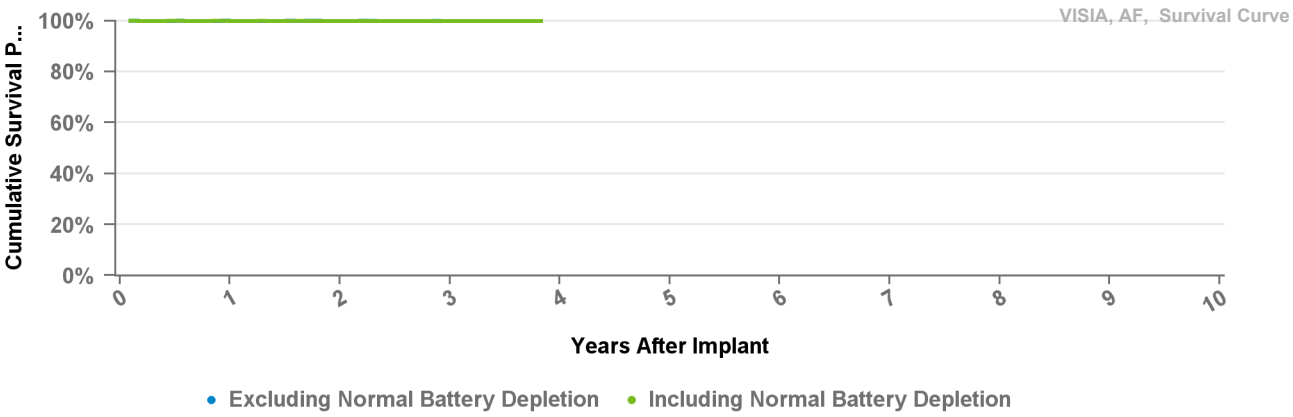
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVFB2D4 Visia MRI AF XT

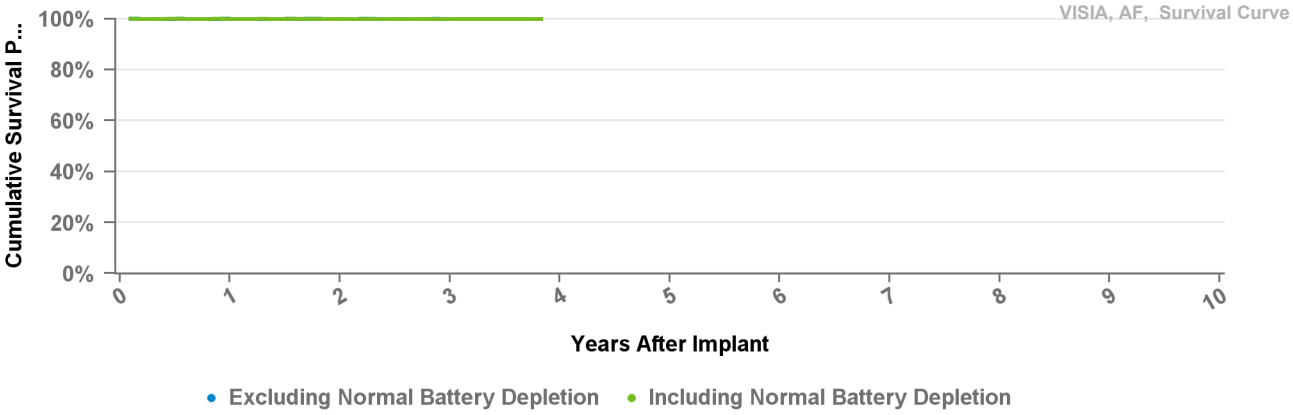
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVFC3D1 Visia MRI AF S

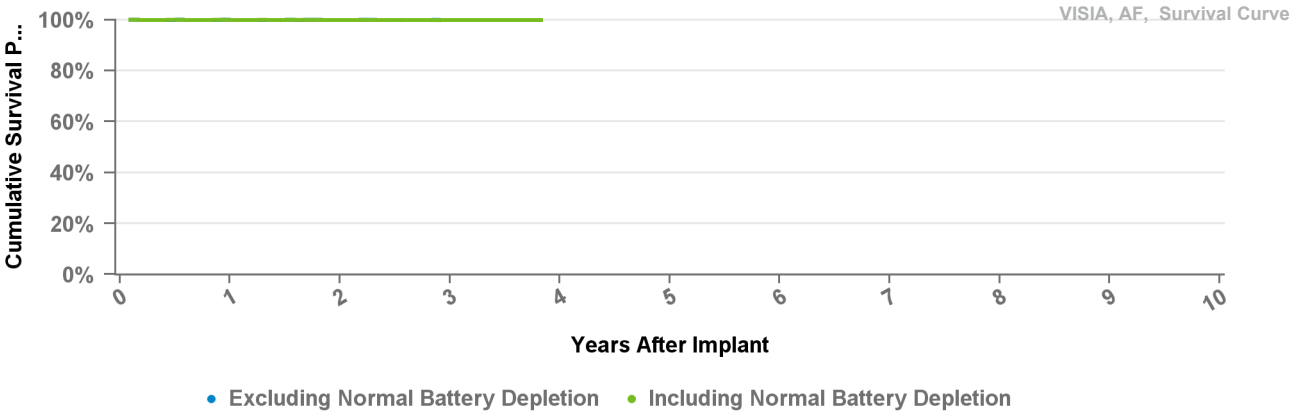
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	954		
Estimated Active USA Implants	915	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVFC3D4 Visia MRI AF S

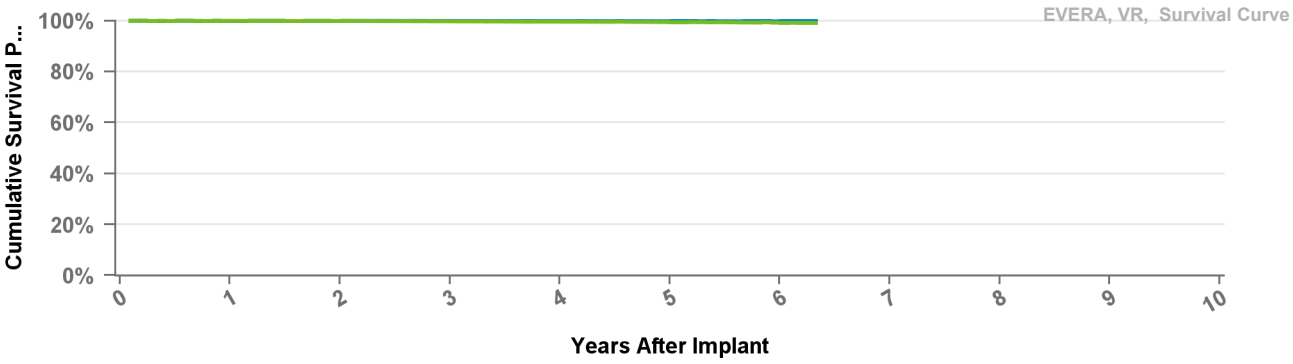
US Market Release	Jan-16	**Total Malfunctions**	**1**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**1**
Registered USA Implants	325	Battery Malfunction	1
Estimated Active USA Implants	314	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.8%
Effective Sample Size	40941	25534	9900	177

DVMB1D4 Evera MRI XT

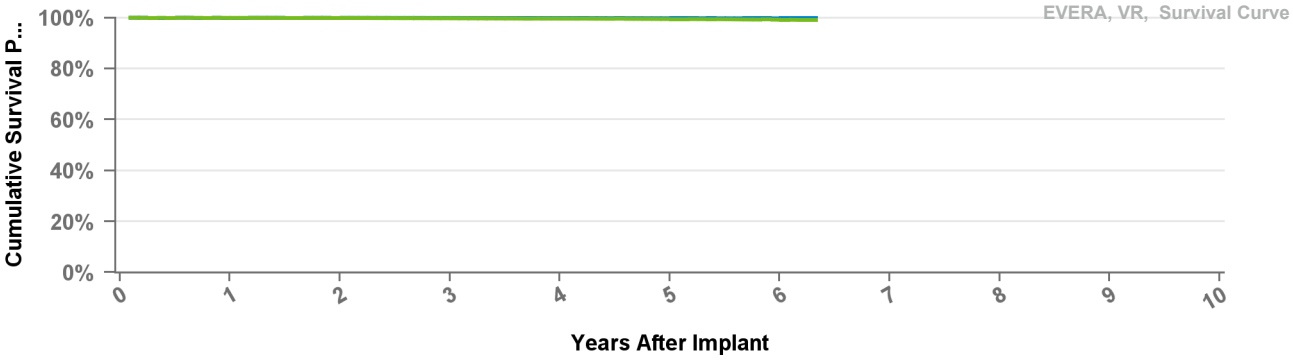
US Market Release	Sep-15	**Total Malfunctions**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,619	Battery Malfunction	1
Estimated Active USA Implants	9,602	Electrical Component	3
Normal Battery Depletions	7	Other Malfunction	2
		Therapy Function Compromised	**3**
		Battery Malfunction	3



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMB2D1 Evera MRI XT

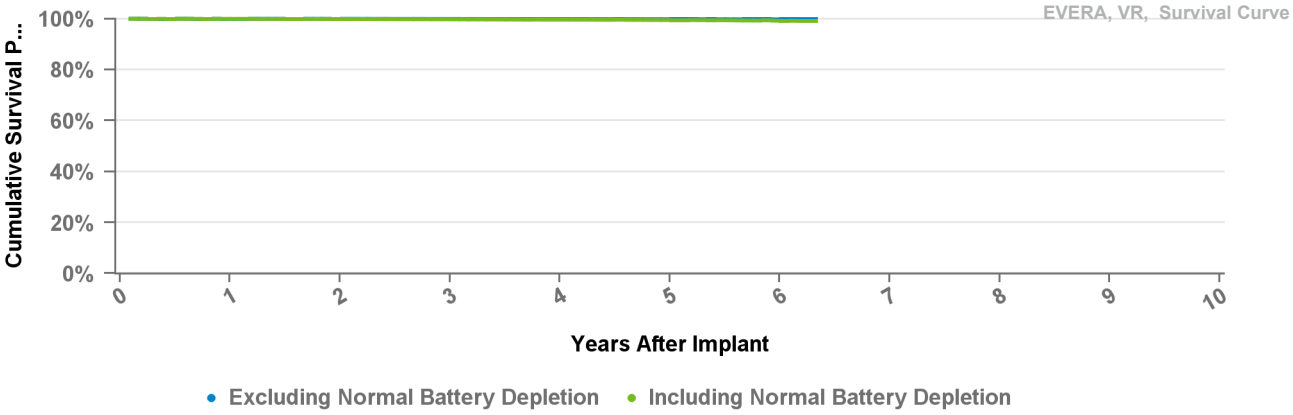
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMB2D4 Evera MRI XT

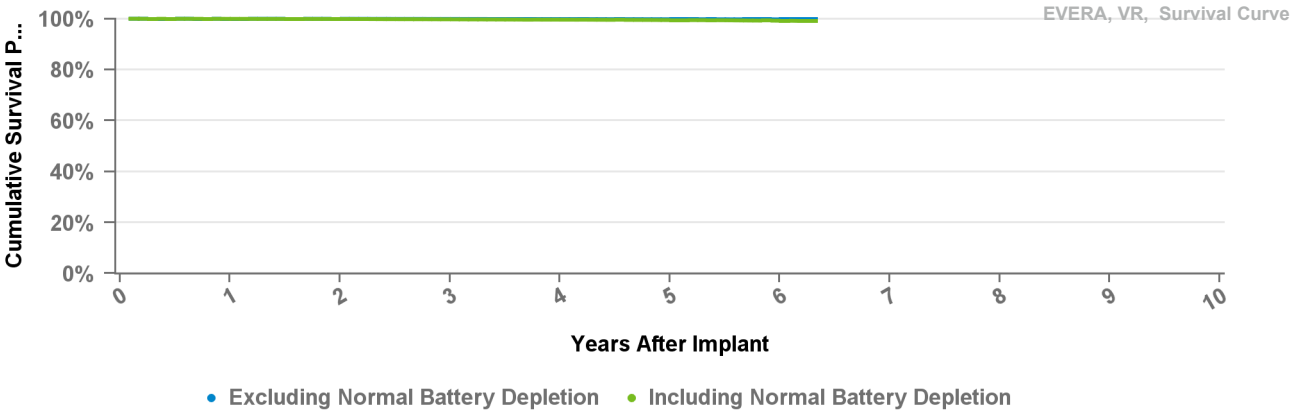
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMC3D1 Evera MRI S

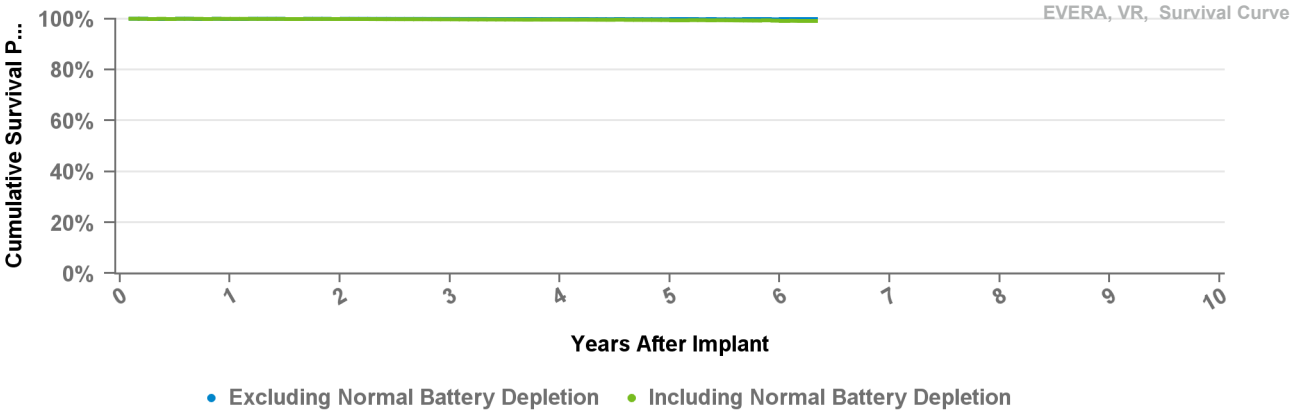
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMC3D4 Evera MRI S

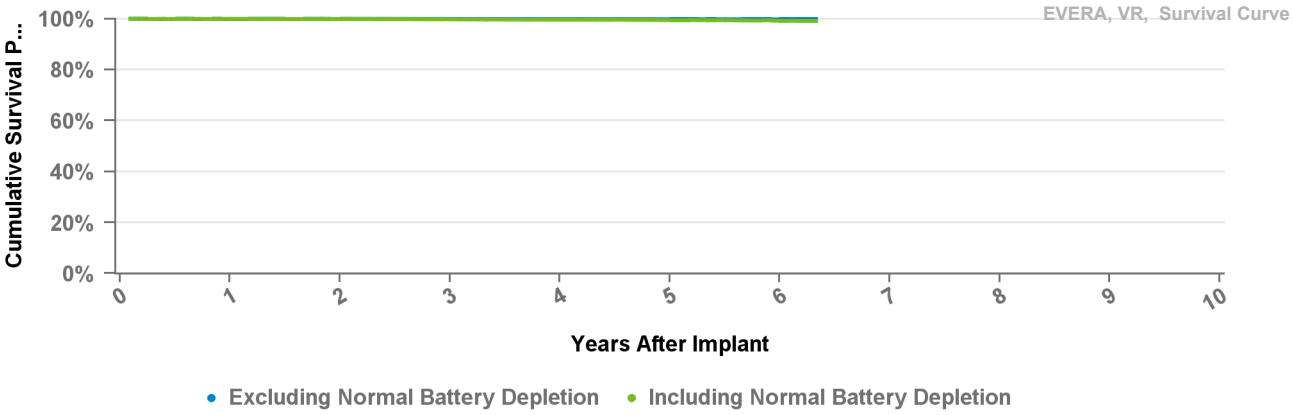
US Market Release	Sep-15	**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMD3D1 Primo

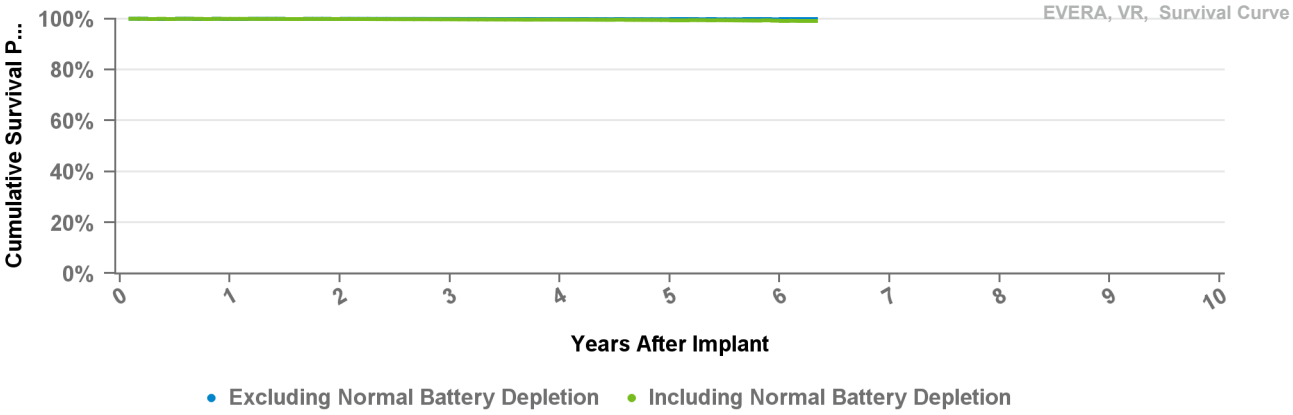
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	59		
Estimated Active USA Implants	57	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVMD3D4 Primo

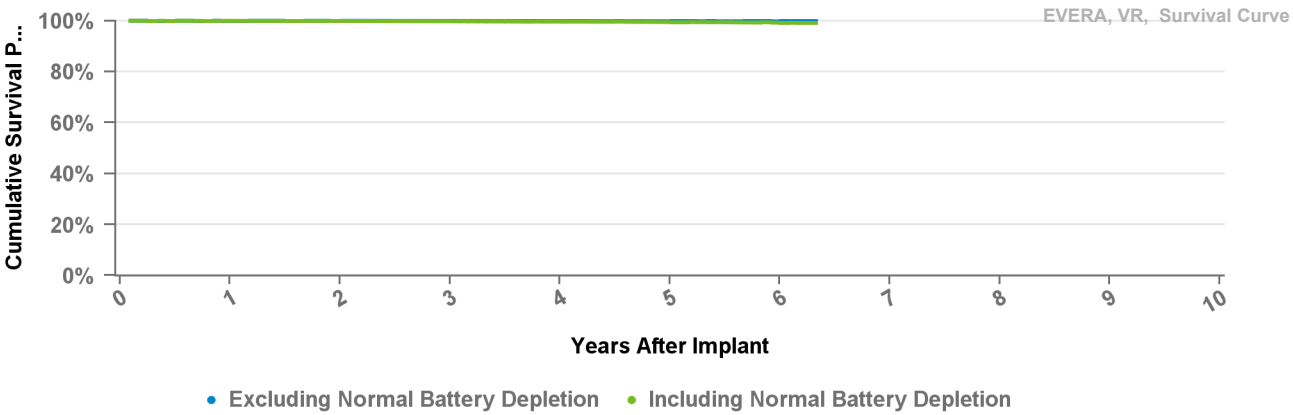
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	79		
Estimated Active USA Implants	77	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVME3D1 Mirro

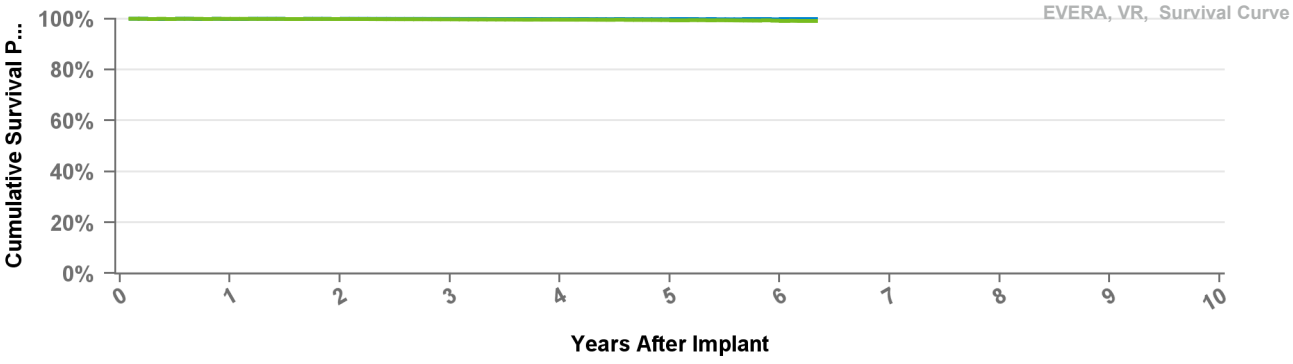
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

DVME3D4 Mirro

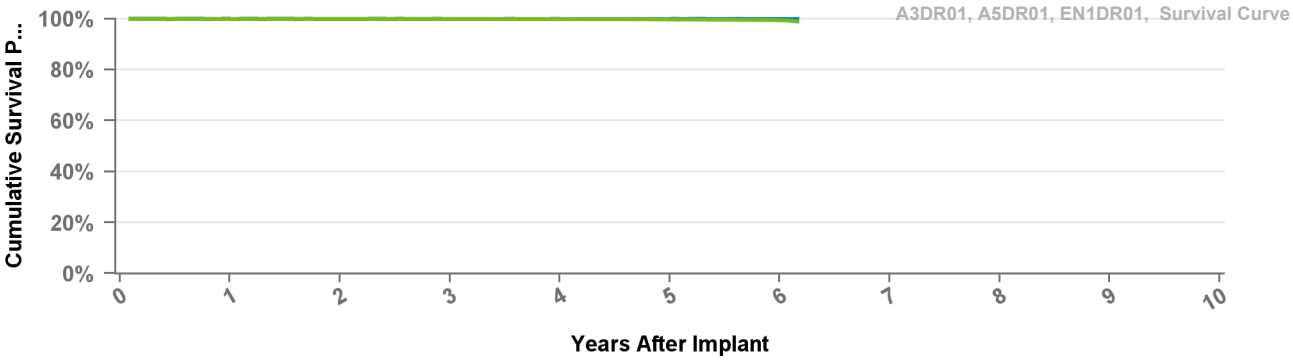
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.5%	99.2%	99.1%
Effective Sample Size	53483	50187	46957	37653	19769	4595	553

A2DR01 Advisa DR MRI

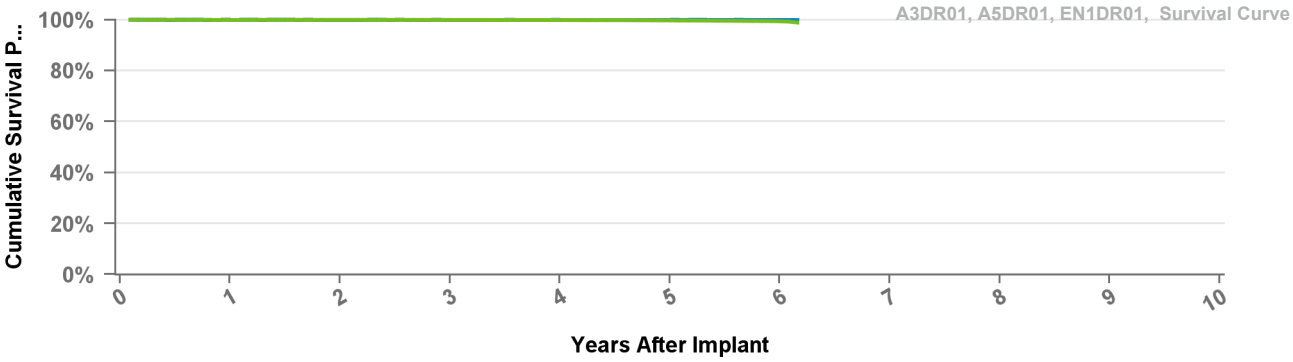
US Market Release	Jan-13	**Total Malfunctions**	**53**
CE Approval Date		**Therapy Function Not Compromised**	**49**
Registered USA Implants	346,324	Battery Malfunction	1
Estimated Active USA Implants	316,421	Electrical Component	29
Normal Battery Depletions	262	Electrical Interconnect	2
		Other Malfunction	1
		Poss Early Battery Depltn	14
		Software Malfunction	2
		Therapy Function Compromised	**4**
		Electrical Component	4



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	98.8%
Effective Sample Size	315579	293918	214626	129594	57251	7650	2275

A3DR01 Advisa DR MRI

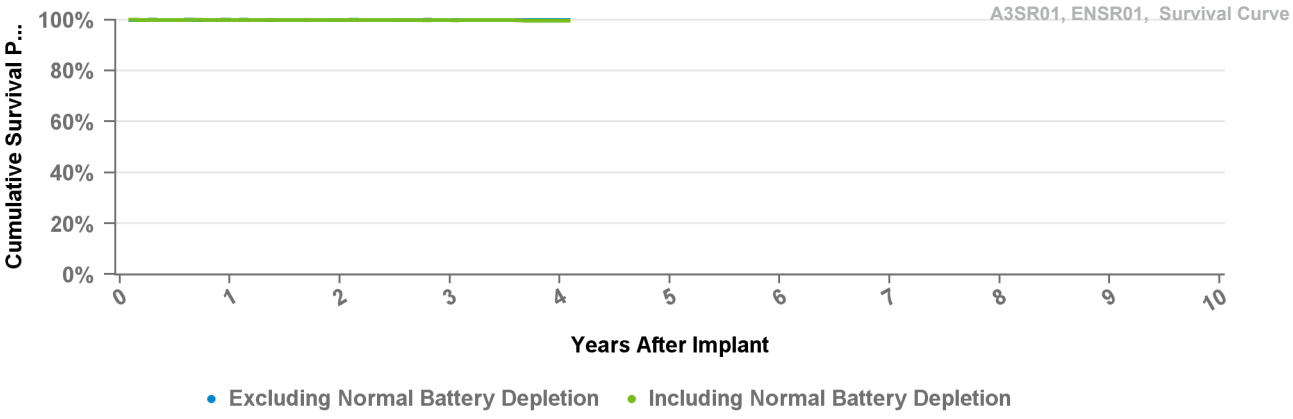
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	17		
Estimated Active USA Implants	9	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	98.8%
Effective Sample Size	315579	293918	214626	129594	57251	7650	2275

A3SR01 Advisa SR MRI

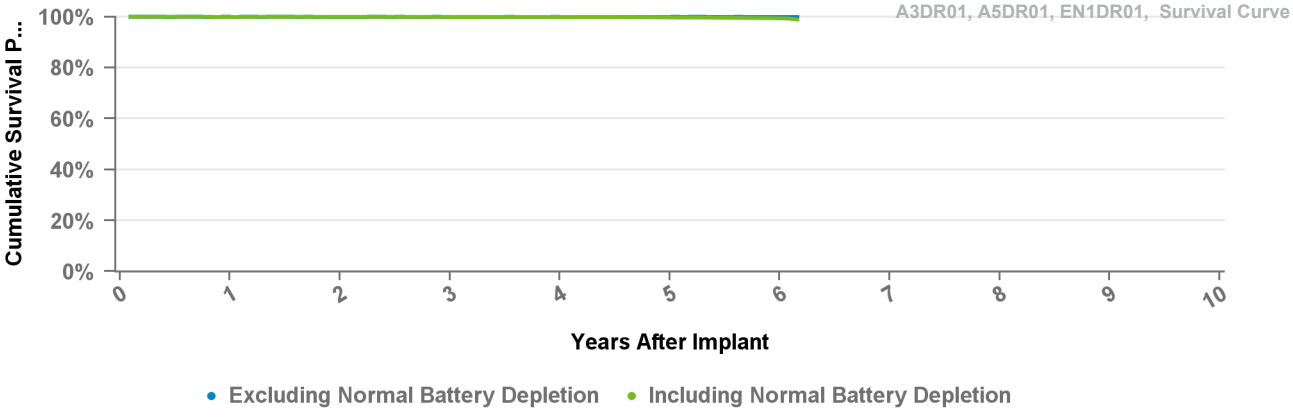
US Market Release	Mar-15	**Total Malfunctions**	**9**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**8**
Registered USA Implants	28,510	Electrical Component	3
Estimated Active USA Implants	25,538	Electrical Interconnect	1
Normal Battery Depletions	16	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Effective Sample Size	22971	19758	10798	1156	424

A5DR01 Advisa DR

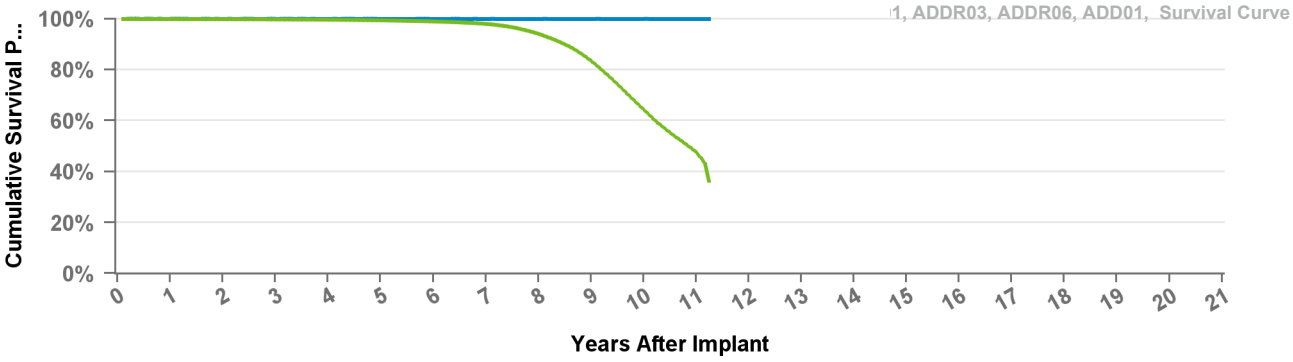
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	98.8%
Effective Sample Size	315579	293918	214626	129594	57251	7650	2275

ADD01 Adapta D

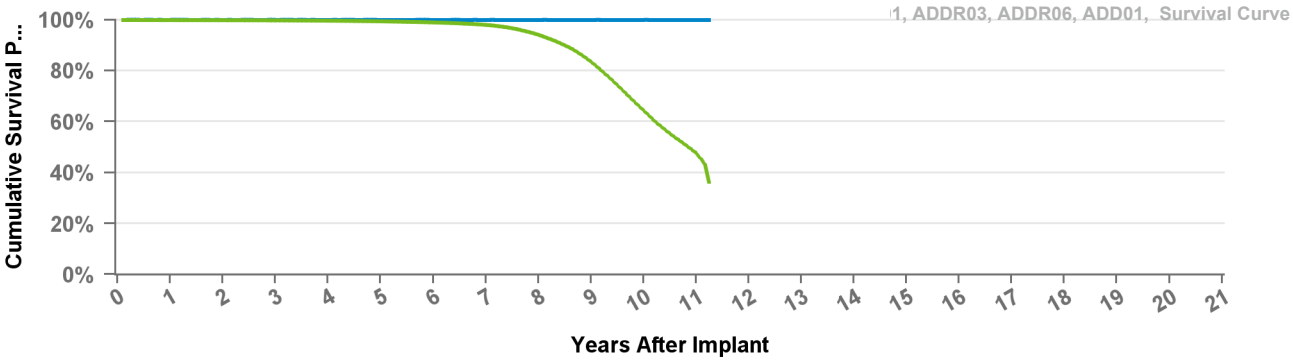
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

ADDR01 Adapta DR

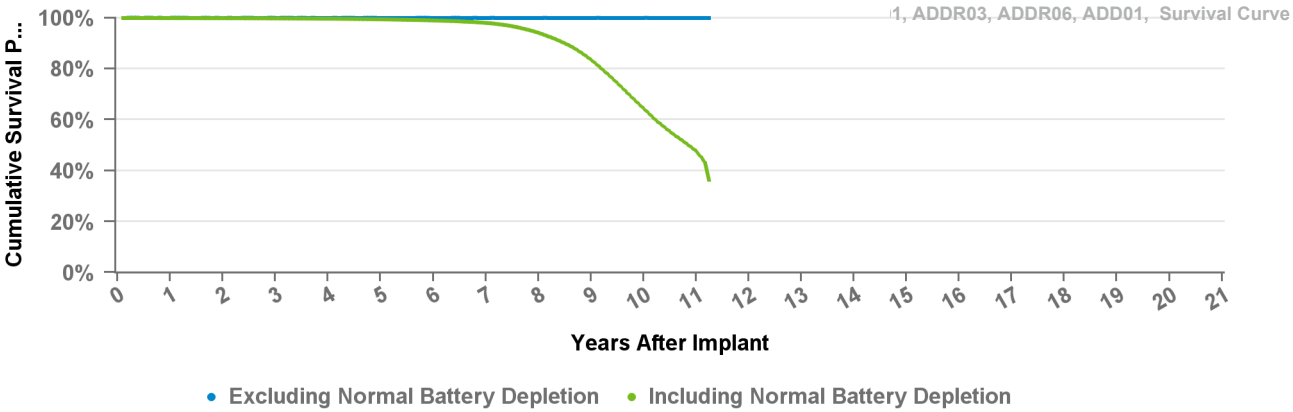
US Market Release	Jul-06	**Total Malfunctions**	**93**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**65**
Registered USA Implants	459,981	Electrical Component	56
Estimated Active USA Implants	264,689	Electrical Interconnect	1
Normal Battery Depletions	27,709	Other Malfunction	1
		Poss Early Battery Depltn	7
		Therapy Function Compromised	**28**
		Electrical Component	23
		Electrical Interconnect	3
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

ADDR03 Adapta DR

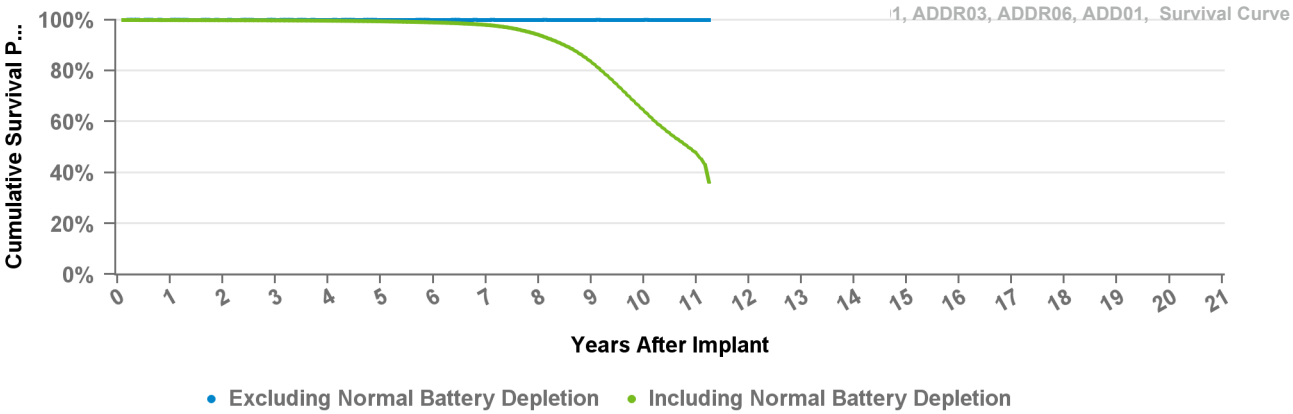
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,487	Electrical Component	1
Estimated Active USA Implants	2,342	**Therapy Function Compromised**	**1**
Normal Battery Depletions	386	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

ADDR06 Adapta DR

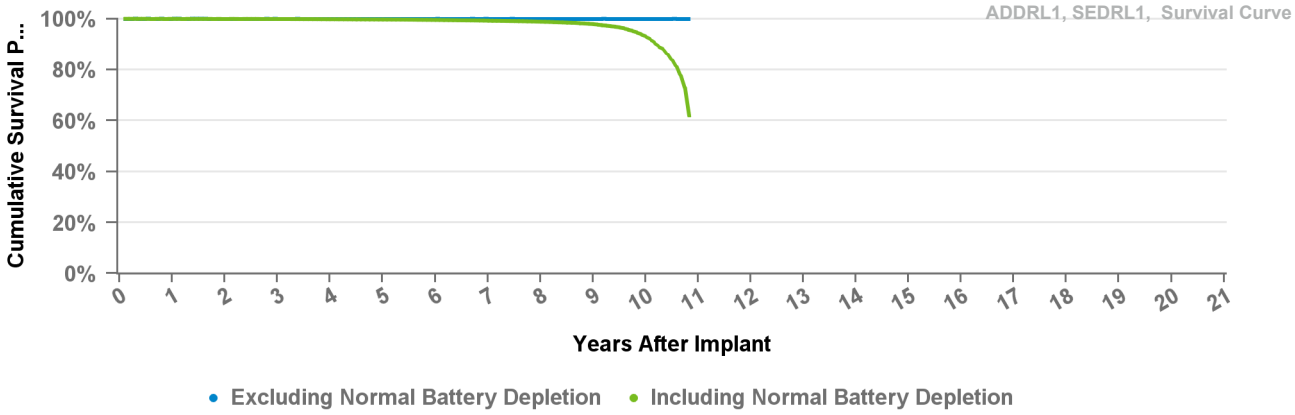
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,465	Electrical Component	1
Estimated Active USA Implants	1,461	**Therapy Function Compromised**	**0**
Normal Battery Depletions	327		



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

ADDRL1 Adapta L DR

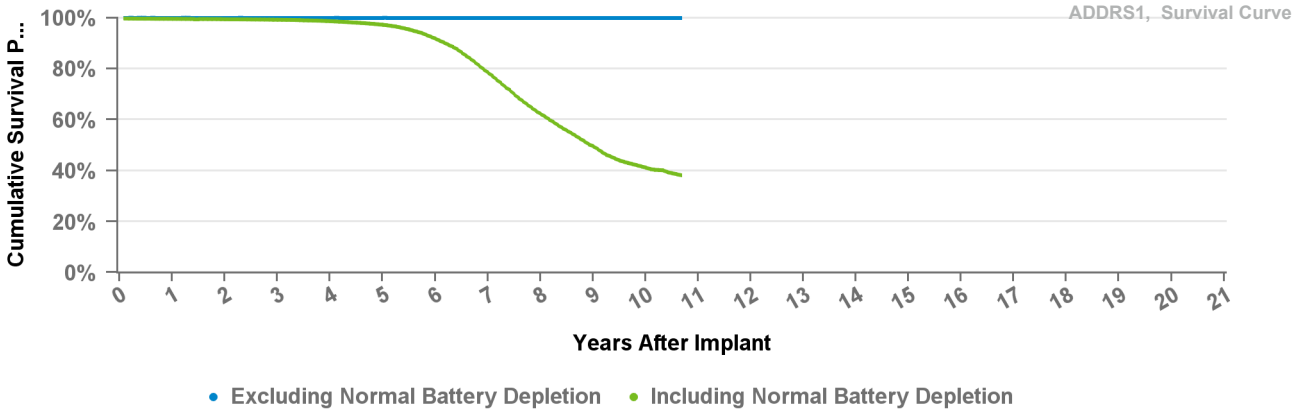
US Market Release	Jul-06	**Total Malfunctions**	**21**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**14**
Registered USA Implants	138,308	Electrical Component	12
Estimated Active USA Implants	102,527	Electrical Interconnect	1
Normal Battery Depletions	2,224	Poss Early Battery Depltn	1
		Therapy Function Compromised	**7**
		Electrical Component	4
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	98.8%	97.9%	93.0%	62.0%
Effective Sample Size	121088	114223	105452	93596	79667	63882	47573	32272	19374	8256	713

ADDRS1 Adapta S DR

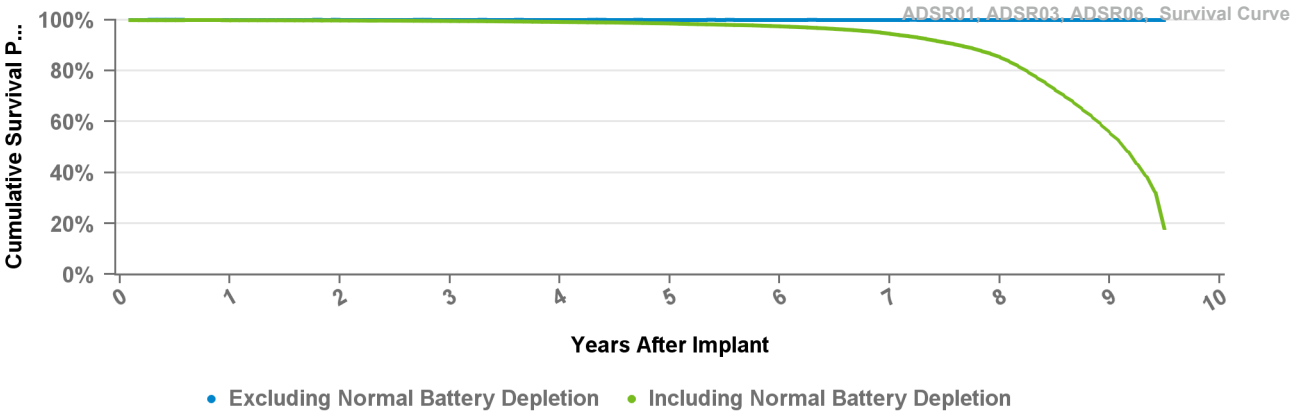
US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**8**
Registered USA Implants	49,042	Electrical Component	5
Estimated Active USA Implants	24,002	Poss Early Battery Depltn	3
Normal Battery Depletions	4,761	**Therapy Function Compromised**	**6**
		Electrical Component	4
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 128 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	99.6%	99.4%	99.2%	98.7%	97.2%	91.8%	78.4%	62.2%	49.6%	41.2%	38.2%
Effective Sample Size	41227	37827	34401	30883	26999	21540	14377	8238	3997	1357	188

ADSR01 Adapta SR

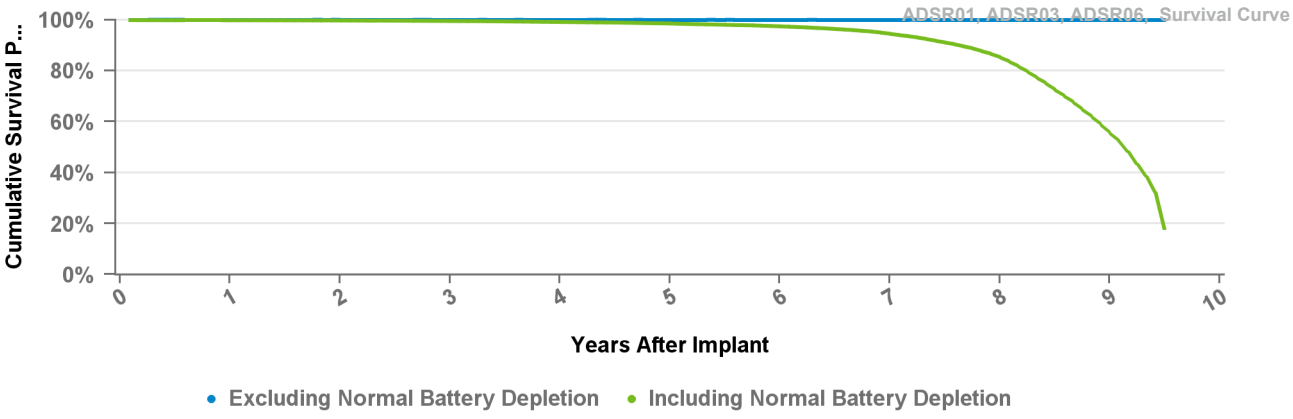
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**11**
Registered USA Implants	93,031	Electrical Component	6
Estimated Active USA Implants	47,334	Electrical Interconnect	1
Normal Battery Depletions	3,917	Poss Early Battery Depltn	4
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.4%	94.5%	85.3%	55.6%	18.0%
Effective Sample Size	73776	64880	57419	49840	41650	31875	22585	13082	3791	327

ADSR03 Adapta SR

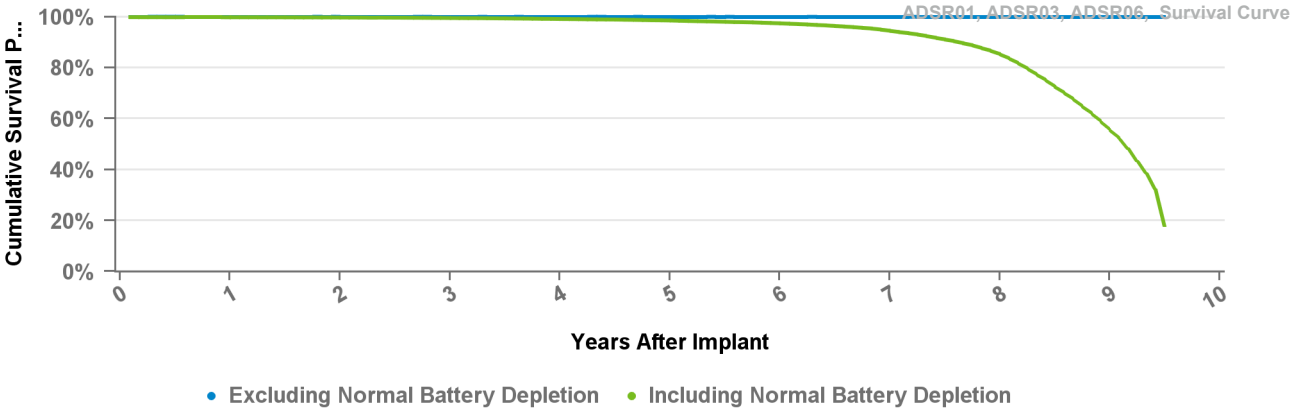
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	2,087		
Estimated Active USA Implants	901	**Therapy Function Compromised**	
Normal Battery Depletions	135		



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.4%	94.5%	85.3%	55.6%	18.0%
Effective Sample Size	73776	64880	57419	49840	41650	31875	22585	13082	3791	327

ADSR06 Adapta SR

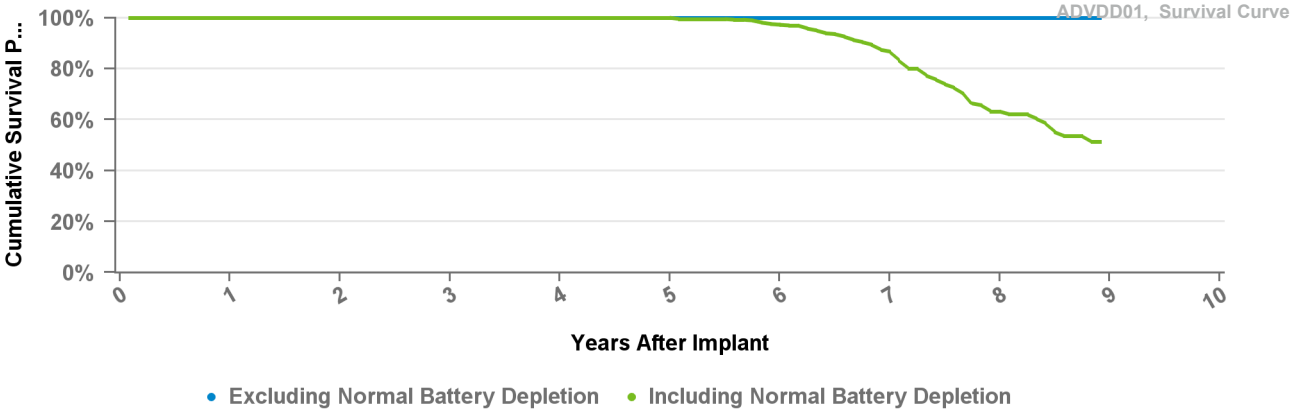
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,830	Electrical Component	2
Estimated Active USA Implants	1,137	**Therapy Function Compromised**	**0**
Normal Battery Depletions	201		



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.4%	94.5%	85.3%	55.6%	18.0%
Effective Sample Size	73776	64880	57419	49840	41650	31875	22585	13082	3791	327

ADVDD01 Adapta VDD

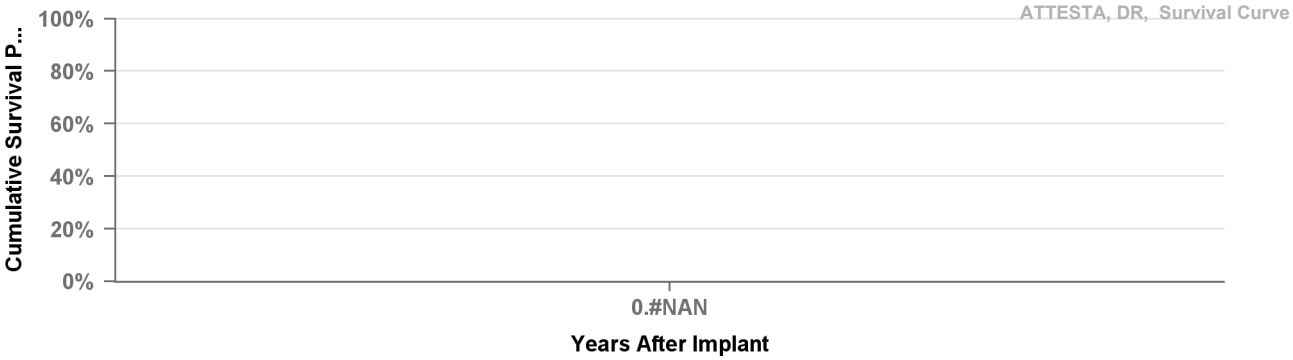
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,413		
Estimated Active USA Implants	671	**Therapy Function Compromised**	
Normal Battery Depletions	86		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.2%	86.7%	63.2%	51.2%
Effective Sample Size	1220	1123	994	906	799	676	469	229	105

ATDR01 Attesta DR MRI

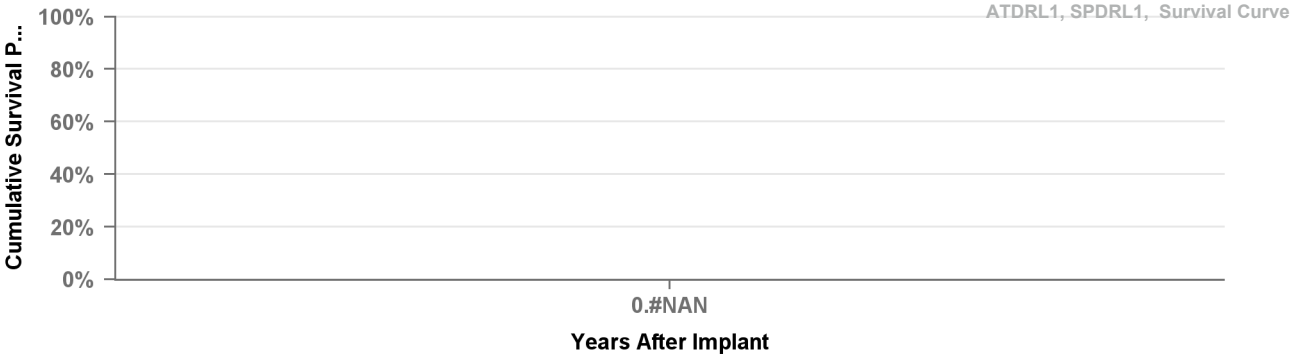
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATDRL1 Attesta L DR MRI

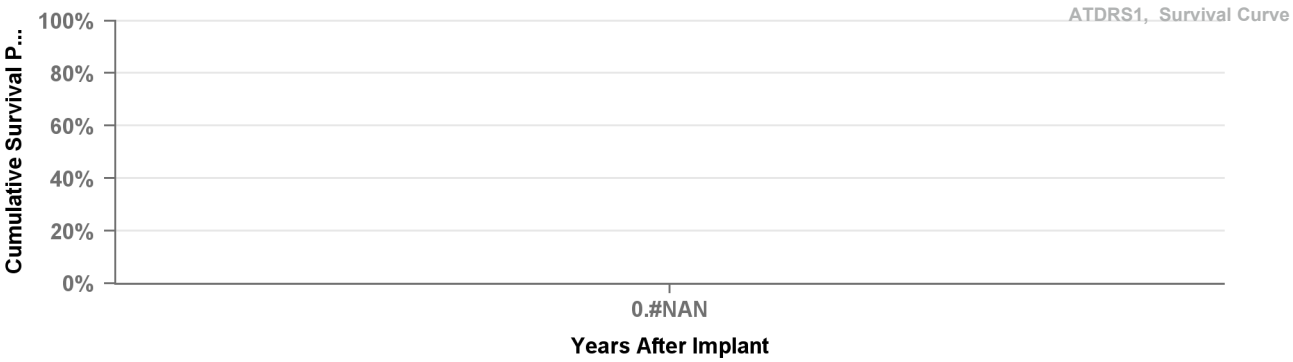
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATDRS1 Attesta S DR MRI

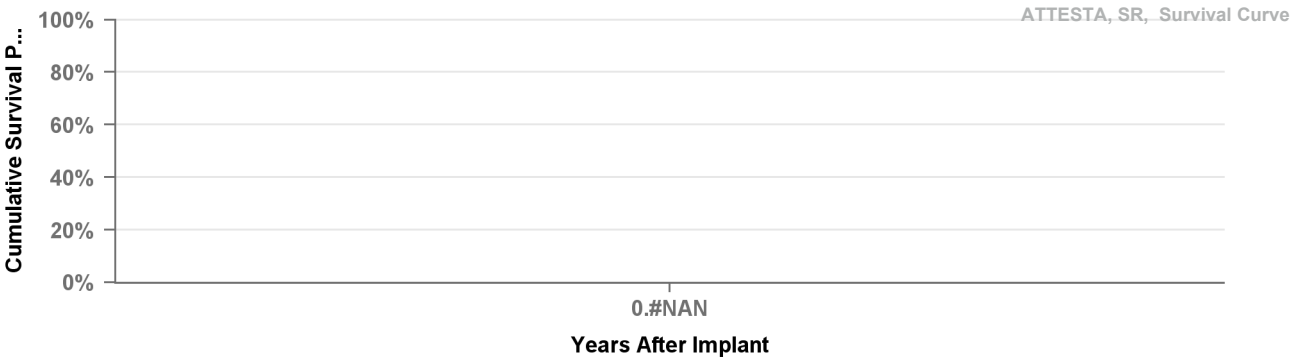
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATSR01 Attesta SR MRI

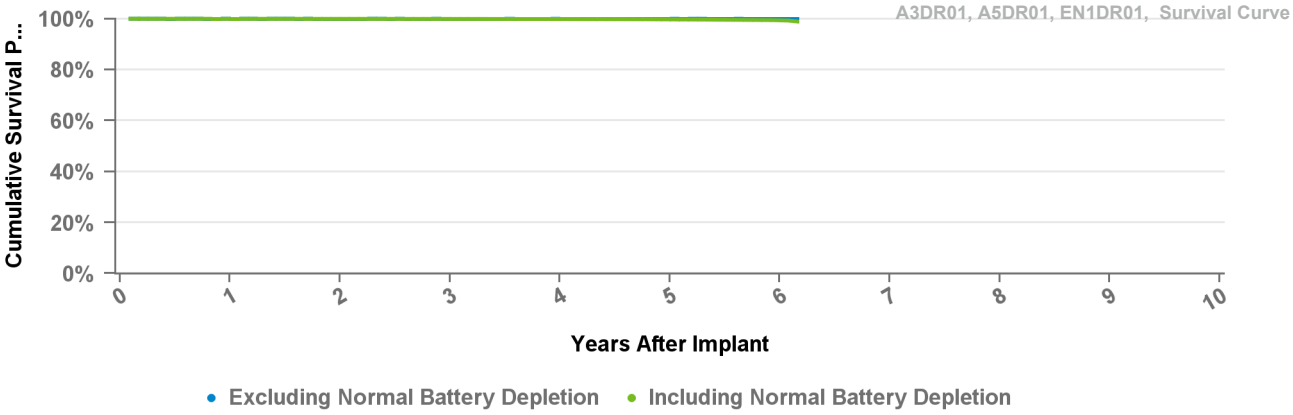
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

EN1DR01 Ensura MRI

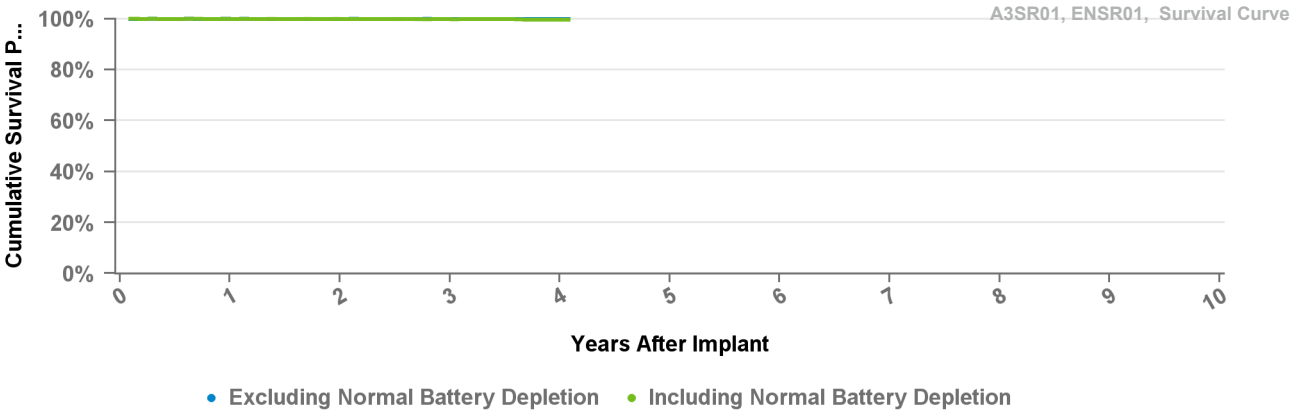
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	
Registered USA Implants	18		
Estimated Active USA Implants	14	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	98.8%
Effective Sample Size	315579	293918	214626	129594	57251	7650	2275

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			

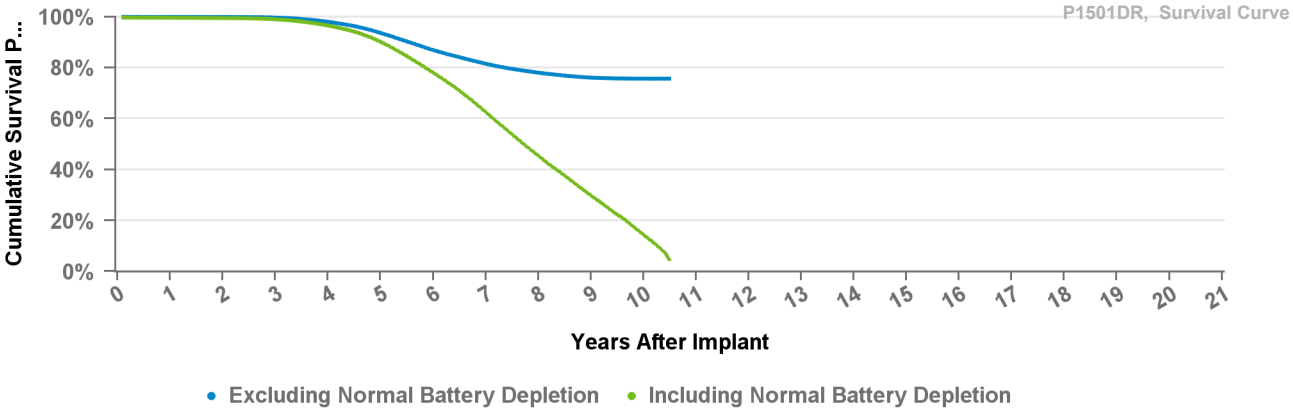


Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.8%	99.8%
Effective Sample Size	22971	19758	10798	1156	424

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	109,812
Estimated Active USA Implants	17,645
Normal Battery Depletions	16,983

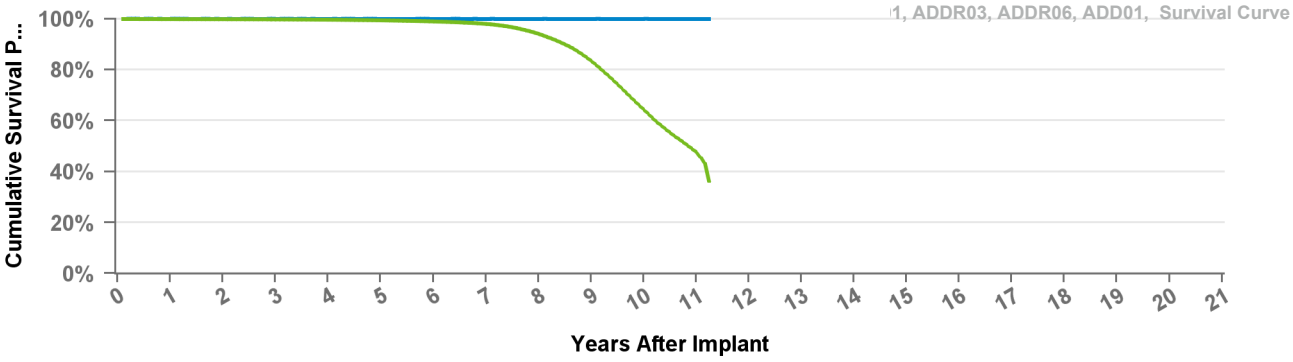
Total Malfunctions	**15,068**
Therapy Function Not Compromised	**15,013**
Battery Malfunction	14,882
Electrical Component	59
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	69
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
Excluding NBD	99.9%	99.9%	99.7%	98.0%	93.6%	86.9%	81.5%	78.0%	76.1%	75.7%	75.7%
Including NBD	99.6%	99.5%	99.0%	96.5%	90.1%	78.0%	62.5%	45.4%	29.7%	14.3%	4.6%
Effective Sample Size	94564	88256	82223	75218	65266	51255	36875	23533	13017	3736	580

RED01 Relia D

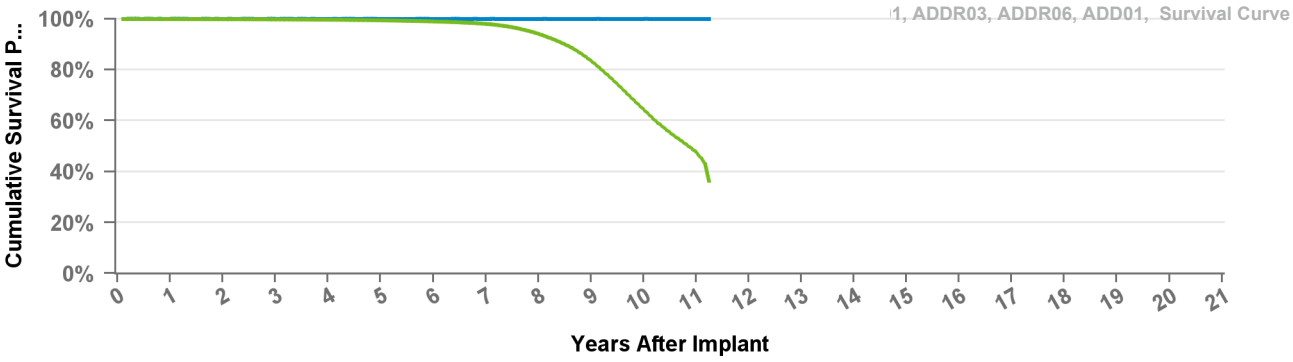
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

REDR01 Relia DR

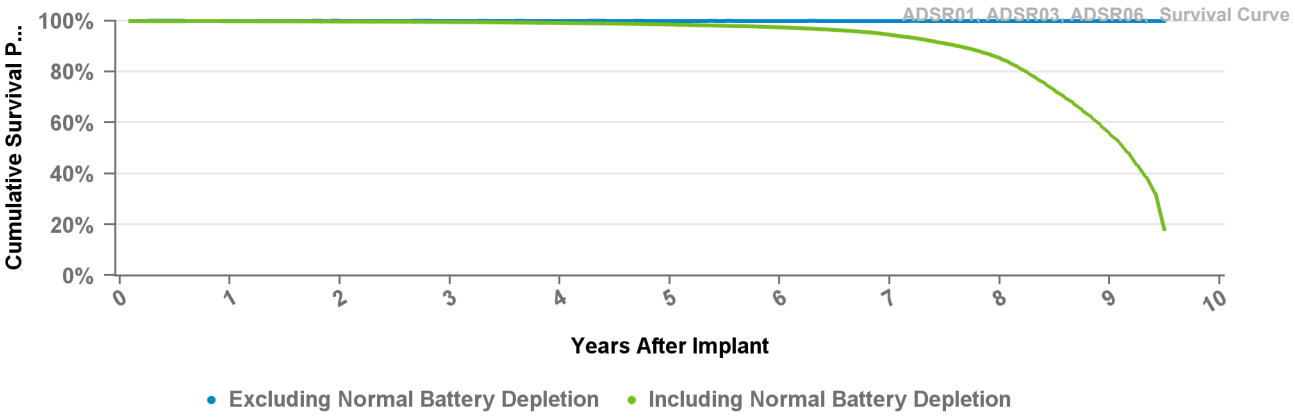
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 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%	100.0%
Including NBD	99.9%	99.8%	99.8%	99.6%	99.4%	98.9%	98.0%	94.1%	83.5%	64.3%	47.6%	36.2%
Effective Sample Size	402042	378318	352367	322388	290900	254401	211848	162849	105699	46350	7003	504

RES01 Relia S

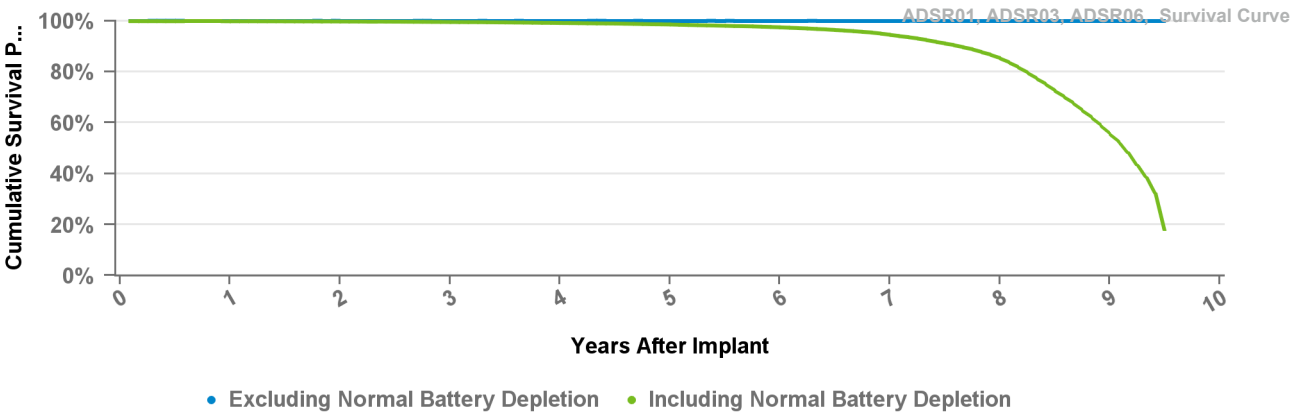
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.4%	94.5%	85.3%	55.6%	18.0%
Effective Sample Size	73776	64880	57419	49840	41650	31875	22585	13082	3791	327

RESR01 Relia SR

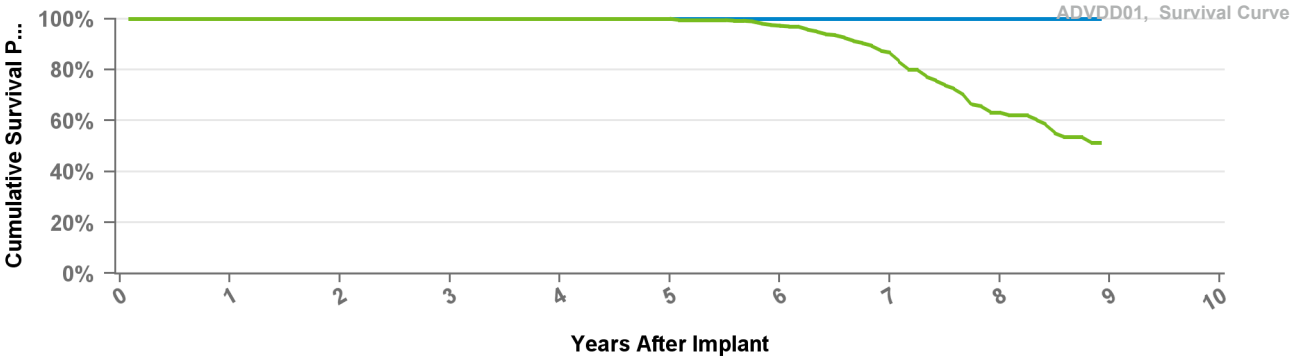
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.4%	94.5%	85.3%	55.6%	18.0%
Effective Sample Size	73776	64880	57419	49840	41650	31875	22585	13082	3791	327

REVDD01 Relia VDD

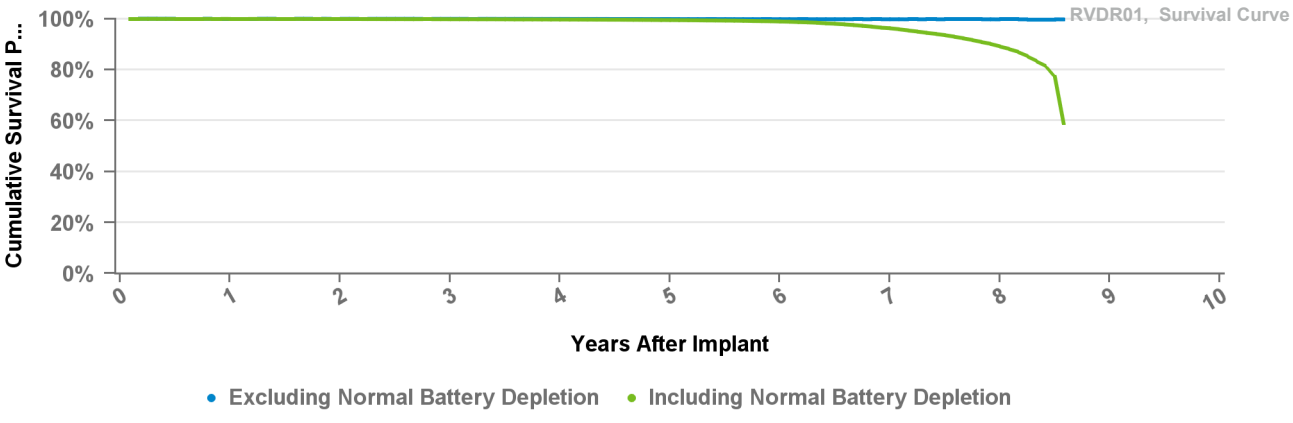
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.2%	86.7%	63.2%	51.2%
Effective Sample Size	1220	1123	994	906	799	676	469	229	105

RVDR01 Revo MRI SureScan

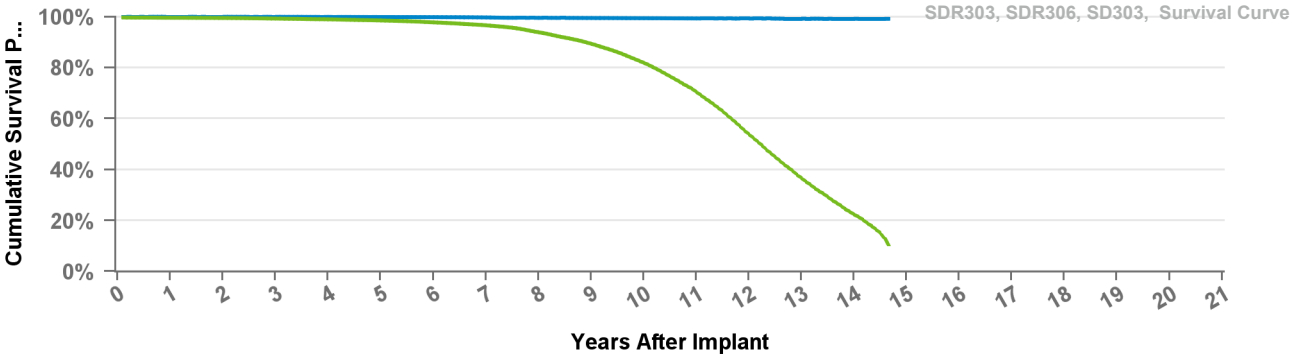
US Market Release	Feb-11	**Total Malfunctions**	**105**
CE Approval Date		**Therapy Function Not Compromised**	**102**
Registered USA Implants	69,167	Battery Malfunction	1
Estimated Active USA Implants	50,369	Electrical Component	39
Normal Battery Depletions	2,108	Other Malfunction	1
		Poss Early Battery Depltn	58
		Software Malfunction	3
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	98.9%	96.3%	89.1%	59.0%
Effective Sample Size	59993	56640	53790	50503	46601	42411	34129	11962	378

SD303 Sigma 300 D

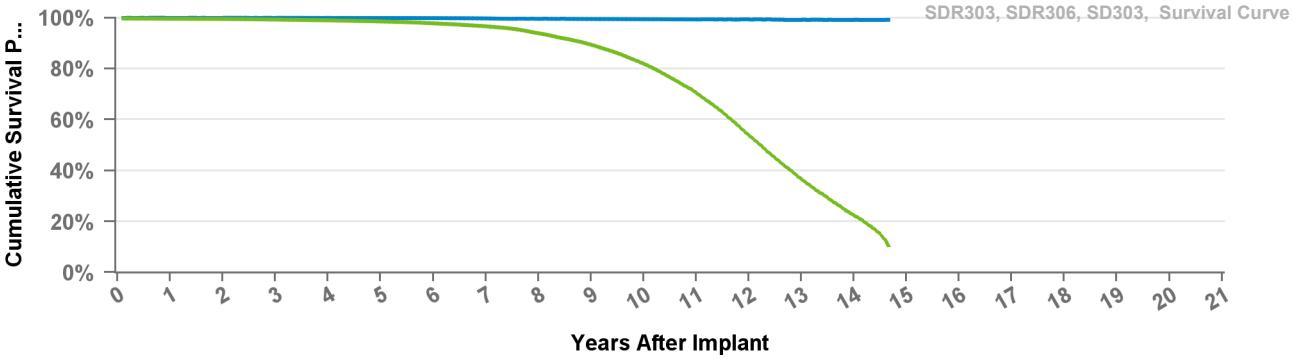
US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	20	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Interconnect	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.6%	99.5%	99.3%	99.0%	98.6%	97.8%	96.7%	93.9%	89.4%	81.9%	70.5%	53.9%	36.6%	22.4%	10.4%
Effective Sample Size	86959	76982	68012	59772	52352	45772	39618	34184	29330	24366	18657	11382	5632	2038	255

SDR303 Sigma 300 DR

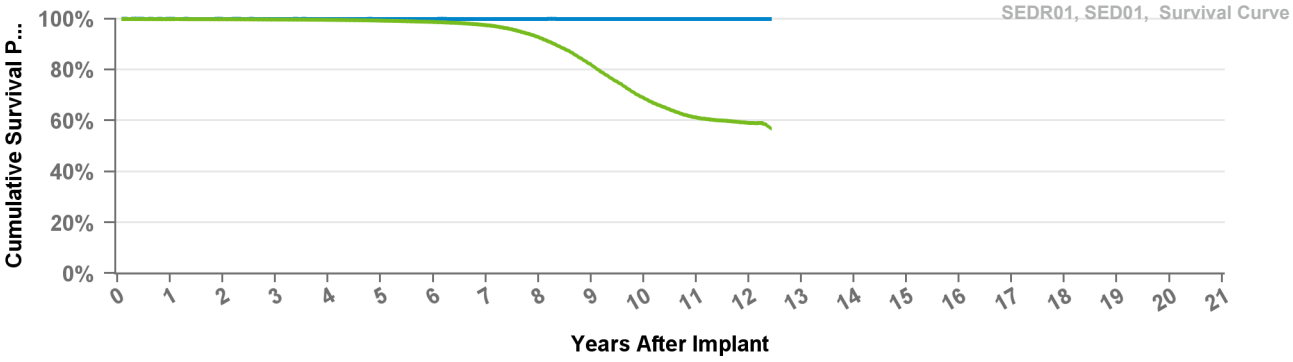
US Market Release	Aug-99	**Total Malfunctions**	**288**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**62**
Registered USA Implants	104,531	Electrical Component	9
Estimated Active USA Implants	10,653	Electrical Interconnect	51
Normal Battery Depletions	10,895	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**226**
		Electrical Component	7
		Electrical Interconnect	218
		Other Malfunction	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.6%	99.5%	99.3%	99.0%	98.6%	97.8%	96.7%	93.9%	89.4%	81.9%	70.5%	53.9%	36.6%	22.4%	10.4%
Effective Sample Size	86959	76982	68012	59772	52352	45772	39618	34184	29330	24366	18657	11382	5632	2038	255

SED01 Sensia D

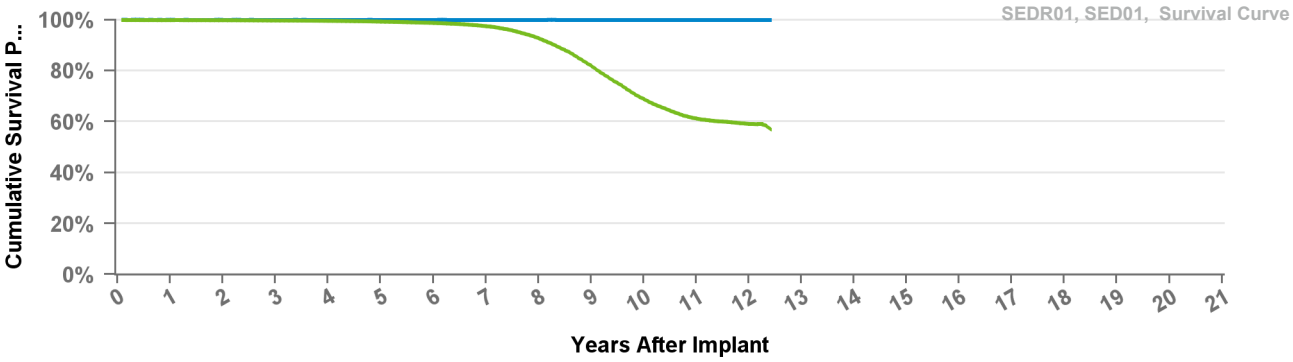
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 149 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%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.7%	99.6%	99.3%	98.8%	97.5%	92.7%	81.9%	68.9%	61.2%	59.1%	56.8%
Effective Sample Size	124218	114901	106937	99268	88725	77146	64333	49845	32959	17945	7269	1693	150

SEDR01 Sensia DR

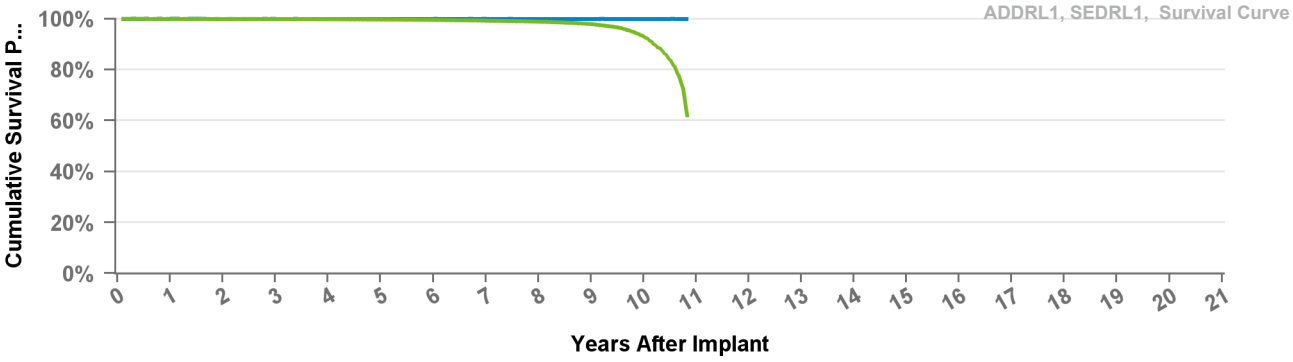
US Market Release	Jul-06	**Total Malfunctions**	**32**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,283	Electrical Component	15
Estimated Active USA Implants	70,651	Electrical Interconnect	1
Normal Battery Depletions	9,473	Other Malfunction	1
		Therapy Function Compromised	**15**
		Electrical Component	6
		Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 149 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%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.7%	99.6%	99.3%	98.8%	97.5%	92.7%	81.9%	68.9%	61.2%	59.1%	56.8%
Effective Sample Size	124218	114901	106937	99268	88725	77146	64333	49845	32959	17945	7269	1693	150

SEDRL1 Sensia L DR

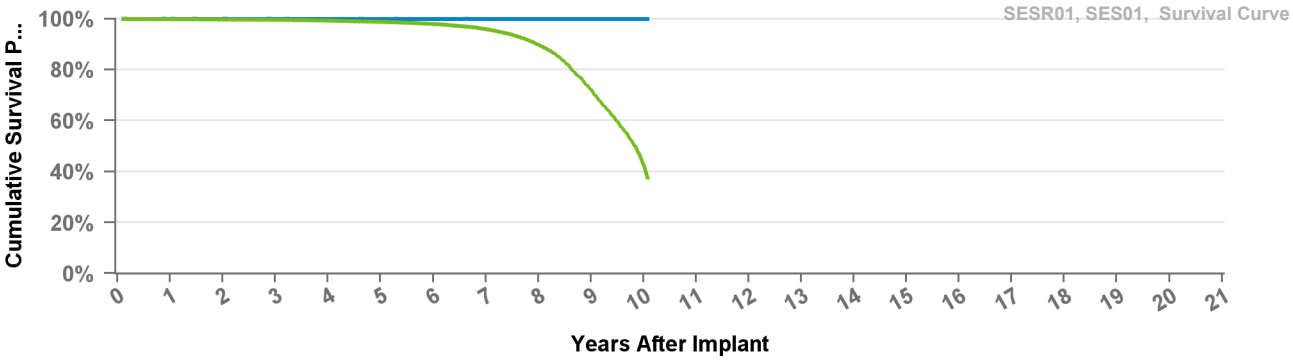
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 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%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	98.8%	97.9%	93.0%	62.0%
Effective Sample Size	121088	114223	105452	93596	79667	63882	47573	32272	19374	8256	713

SES01 Sensia S

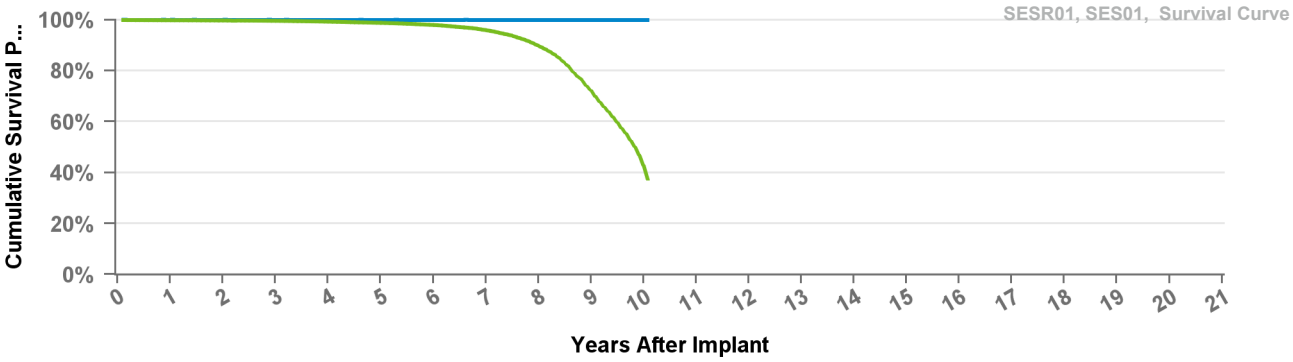
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	9		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.6%	99.3%	98.8%	98.0%	95.9%	89.7%	72.3%	42.9%	37.5%
Effective Sample Size	86915	76736	68142	59373	50232	39919	29964	19714	9080	1075	537

SESR01 Sensia SR

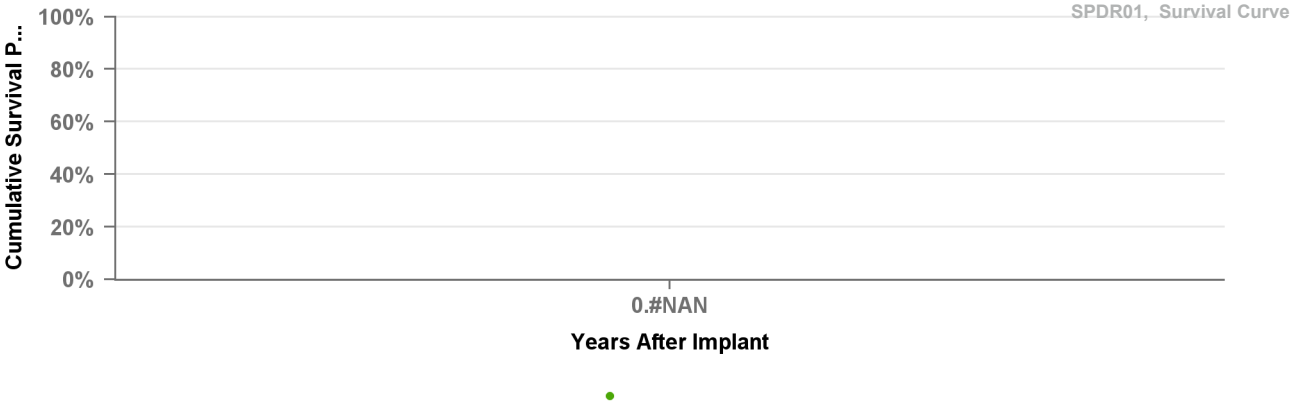
US Market Release	Jul-06	**Total Malfunctions**	**16**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**12**
Registered USA Implants	117,232	Electrical Component	7
Estimated Active USA Implants	54,939	Other Malfunction	1
Normal Battery Depletions	5,112	Poss Early Battery Depltn	4
		Therapy Function Compromised	**4**
		Electrical Component	3
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.6%	99.3%	98.8%	98.0%	95.9%	89.7%	72.3%	42.9%	37.5%
Effective Sample Size	86915	76736	68142	59373	50232	39919	29964	19714	9080	1075	537

SPDR01 Sphera DR MRI

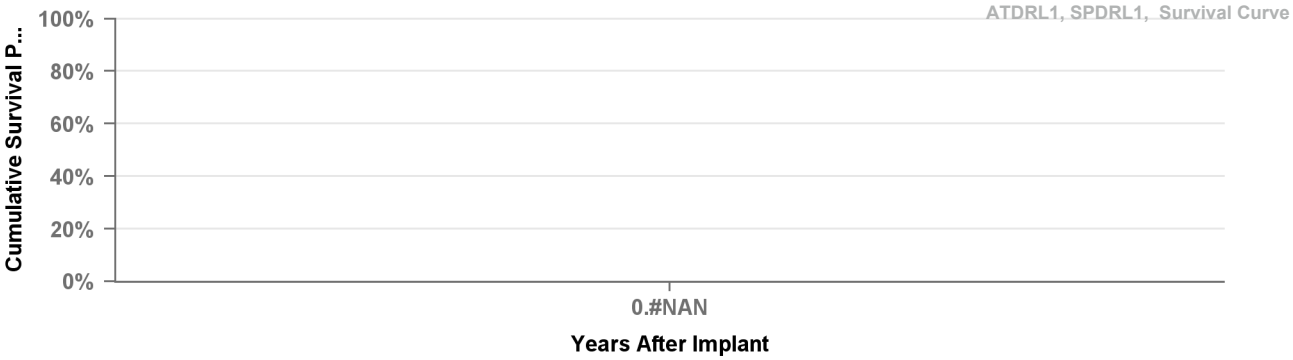
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPDRL1 Sphera L DR MRI

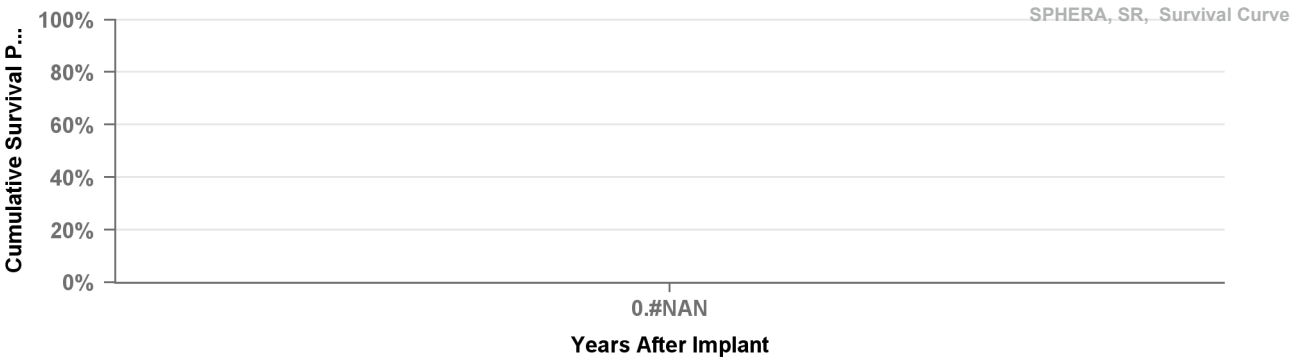
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPSR01 Sphera SR MRI

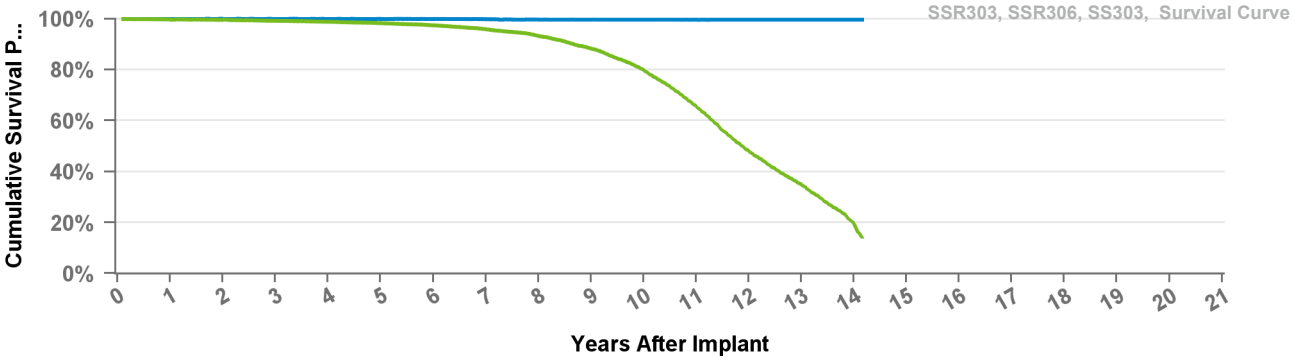
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SS303 Sigma 300 S

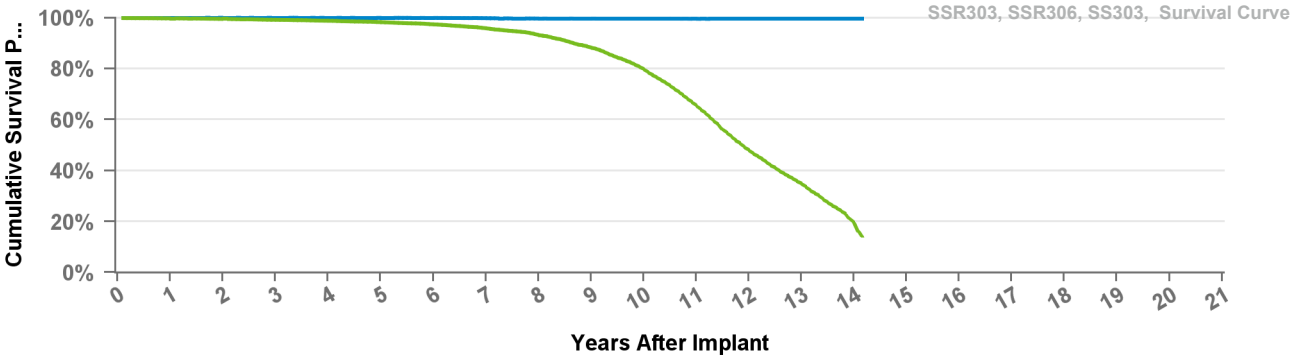
US Market Release	Sep-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	248		
Estimated Active USA Implants	46	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.5%	99.2%	98.8%	98.3%	97.4%	95.9%	93.2%	88.2%	79.8%	65.5%	48.0%	34.9%	19.5%	14.1%
Effective Sample Size	40552	33476	27697	23003	19132	15896	13197	10959	8898	6834	4655	2626	1333	235	107

SSR303 Sigma 300 SR

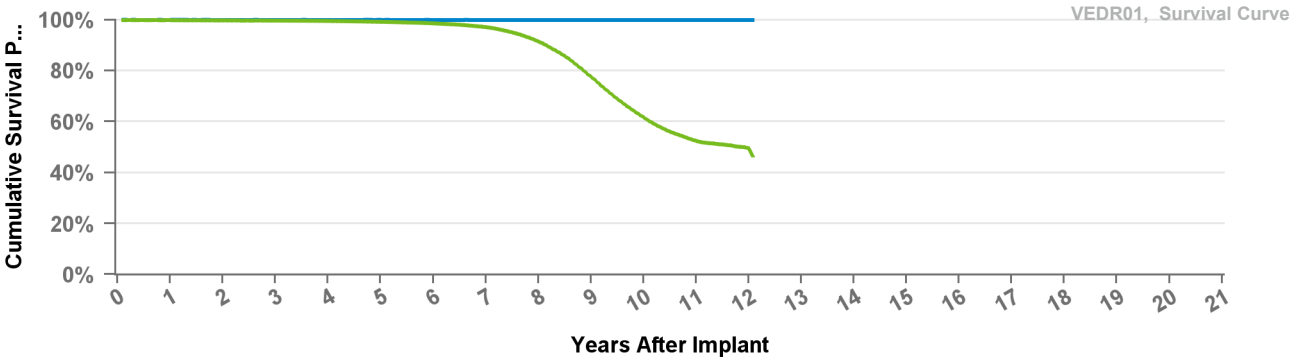
US Market Release	Aug-99	**Total Malfunctions**	**58**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**11**
Registered USA Implants	51,232	Electrical Interconnect	10
Estimated Active USA Implants	4,148	Other Malfunction	1
Normal Battery Depletions	3,008	**Therapy Function Compromised**	**47**
		Electrical Component	3
		Electrical Interconnect	44



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.5%	99.2%	98.8%	98.3%	97.4%	95.9%	93.2%	88.2%	79.8%	65.5%	48.0%	34.9%	19.5%	14.1%
Effective Sample Size	40552	33476	27697	23003	19132	15896	13197	10959	8898	6834	4655	2626	1333	235	107

VEDR01 Versa DR

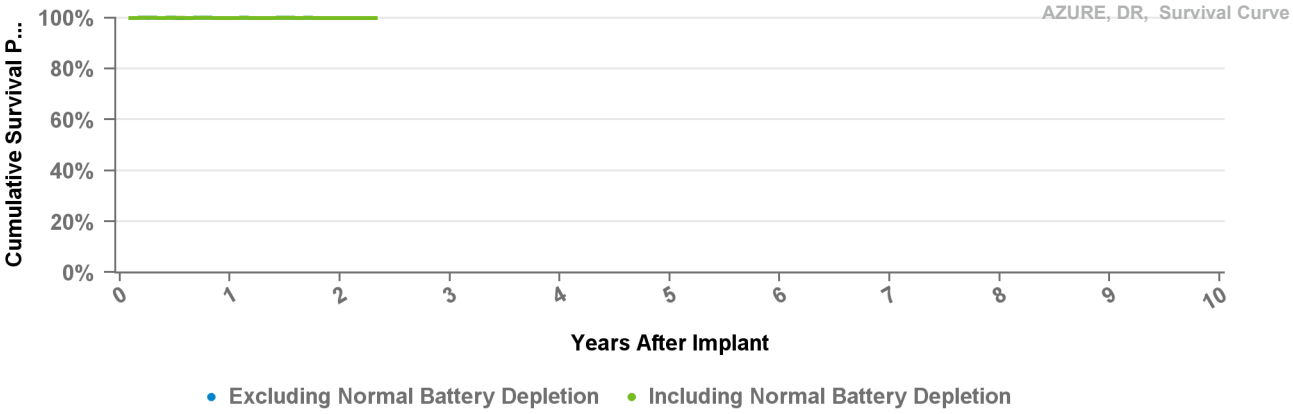
US Market Release	Jul-06	**Total Malfunctions**	**24**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**12**
Registered USA Implants	118,710	Electrical Component	8
Estimated Active USA Implants	57,753	Electrical Interconnect	2
Normal Battery Depletions	9,148	Poss Early Battery Depltn	2
		Therapy Function Compromised	**12**
		Electrical Component	8
		Other Malfunction	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.7%	99.5%	99.2%	98.6%	97.1%	91.4%	77.6%	61.7%	52.4%	49.5%	46.5%
Effective Sample Size	100513	93331	85342	76946	69600	61866	52698	41099	26324	13252	4620	426	151

W1DR01 Azure XT DR

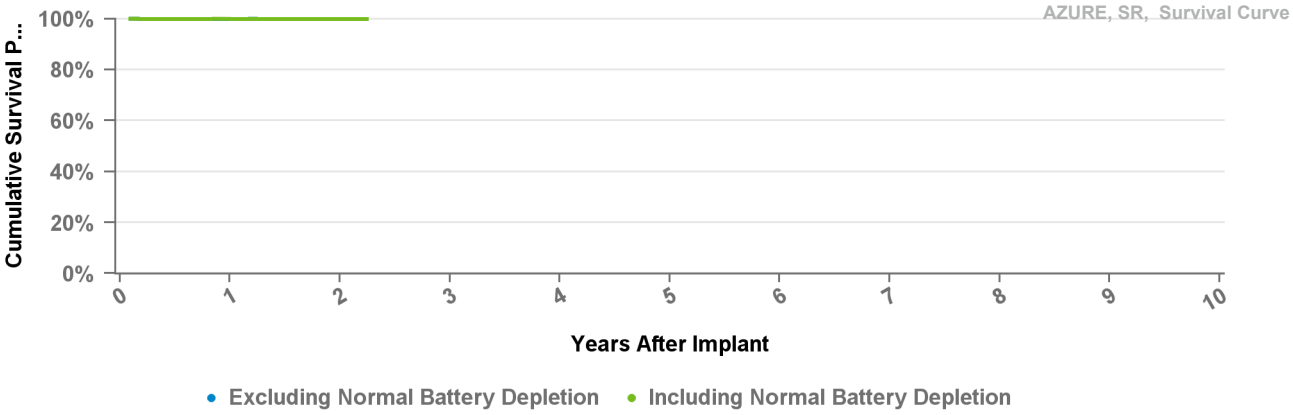
US Market Release	Aug-17	**Total Malfunctions**	**26**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**22**
Registered USA Implants	199,280	Electrical Component	10
Estimated Active USA Implants	193,218	Other Malfunction	12
Normal Battery Depletions	1	**Therapy Function Compromised**	**4**
		Electrical Component	4



Years	1	2	at 28 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	104361	14456	560

W1SR01 Azure XT SR

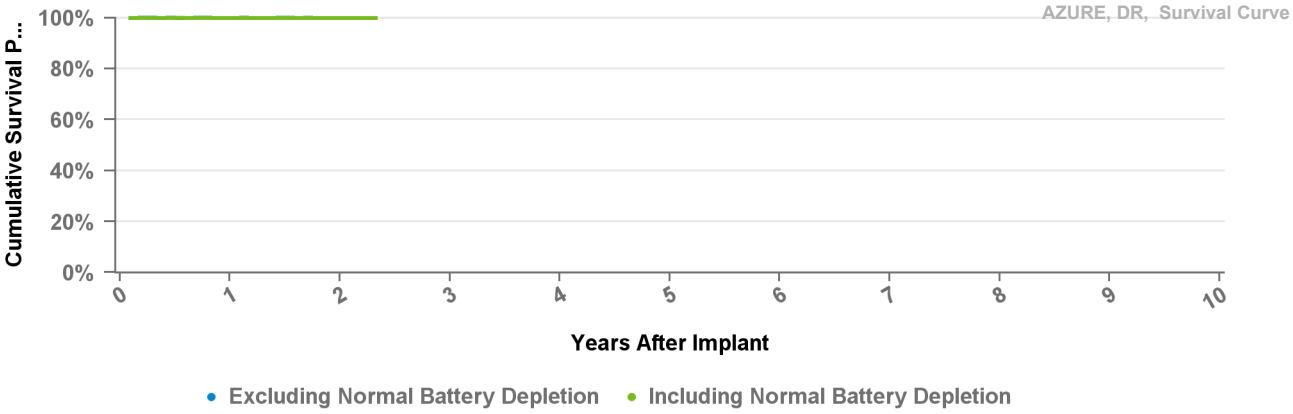
US Market Release	Aug-17	**Total Malfunctions**	**2**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**2**
Registered USA Implants	17,553	Electrical Component	1
Estimated Active USA Implants	16,568	Other Malfunction	1
Normal Battery Depletions	2	**Therapy Function Compromised**	**0**



Years	1	2	at 27 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	9678	1320	206

W2DR01 Azure XT DR

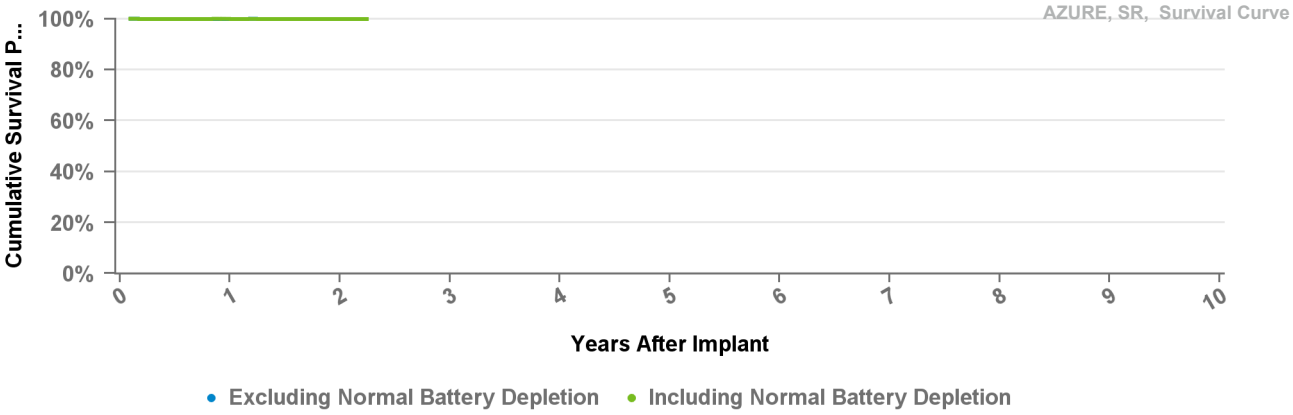
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 28 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	104361	14456	560

W2SR01 Azure XT SR

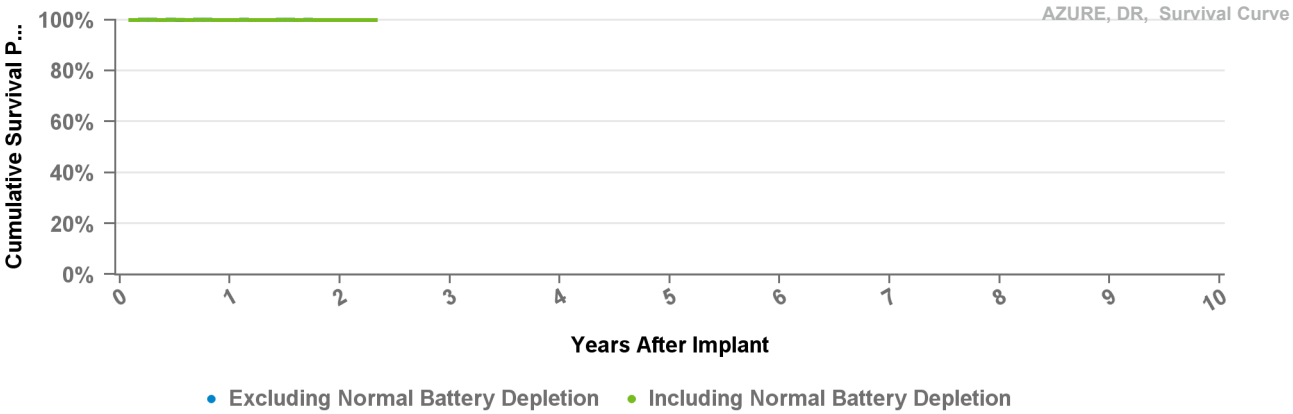
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	9678	1320	206

W3DR01 Azure S DR

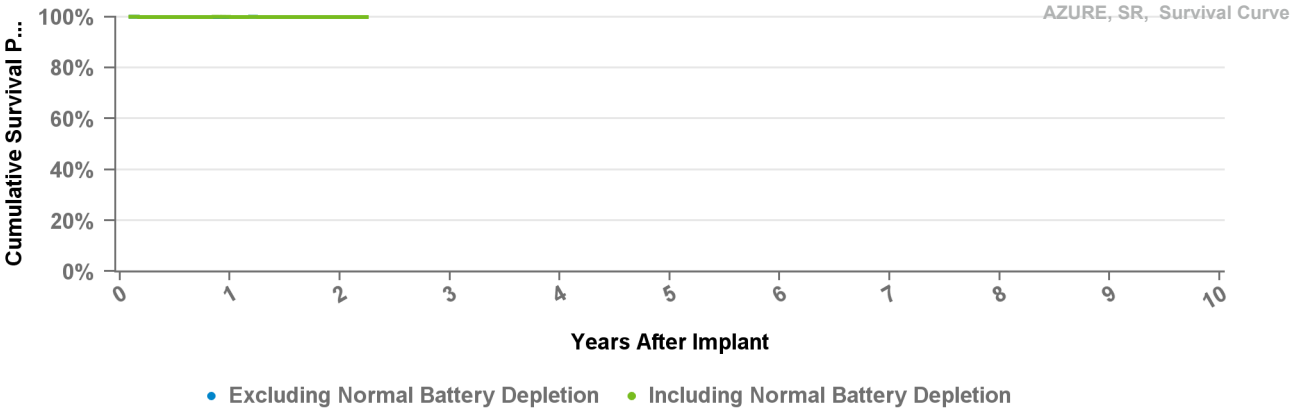
US Market Release	Aug-17	**Total Malfunctions**	**2**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**2**
Registered USA Implants	23,989	Electrical Component	2
Estimated Active USA Implants	23,227	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 28 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	104361	14456	560

W3SR01 Azure S SR

US Market Release	Aug-17	**Total Malfunctions**	**1**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,268	Electrical Component	1
Estimated Active USA Implants	4,030	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	9678	1320	206

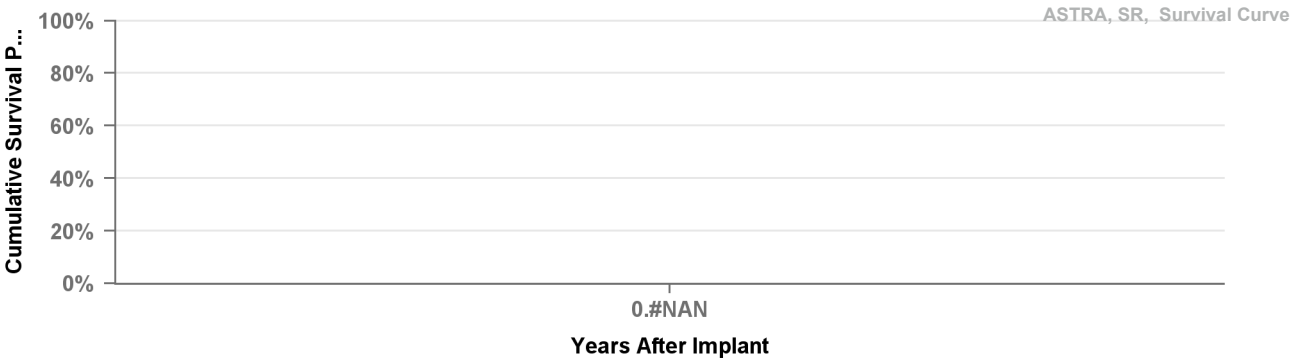
X2DR01 Astra XT DR MRI SureScan

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			

Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

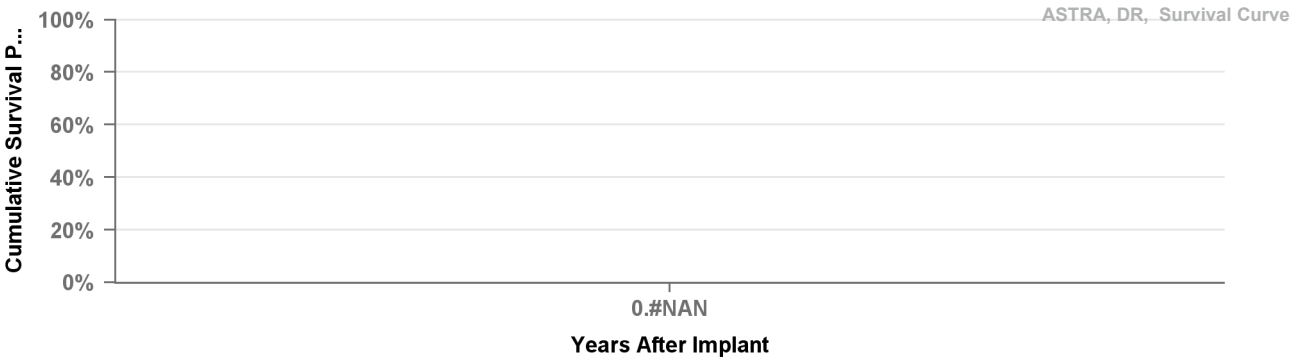
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3DR01 Astra S DR

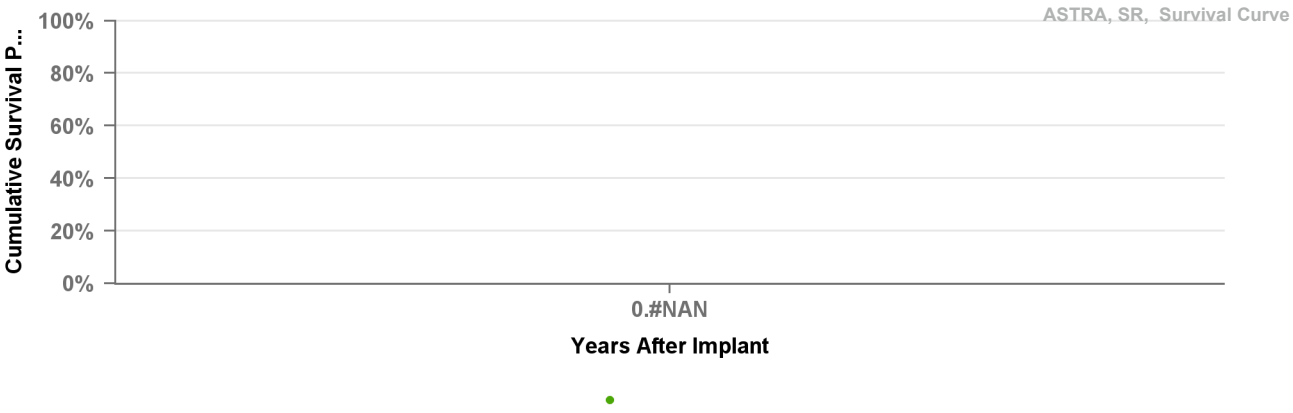
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3SR01 Astra S SR

US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm and Heart Failure (CRHF) has tracked lead survival for over 36 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 131,000 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.

3830 SelectSecure

US Market Release	03Aug2005
CE Approval	31Jan2003
Registered USA Implants	64,960
Estimated Active USA Implants	52,639
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	27
Crimp Weld Bond	
Insulation Breach	43
Other	8

US Acute Lead Observations

Cardiac Perforation	24
Conductor Fracture	2
Extracardiac Stimulation	5
Failure To Capture	219
Failure To Sense	17
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	261
Oversensing	50
Unspecified	2

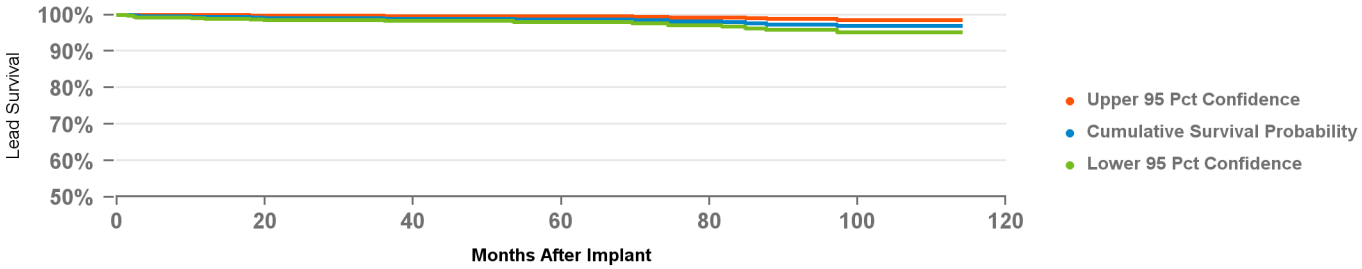
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Followup	59,755
Number of Leads Active in Study	538

Qualifying Complications 18

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



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.4%	99.1%	99.1%	99.0%	98.8%	98.5%	97.9%	97.3%	96.9%	96.9%
#	956	787	656	524	446	363	297	228	101	59

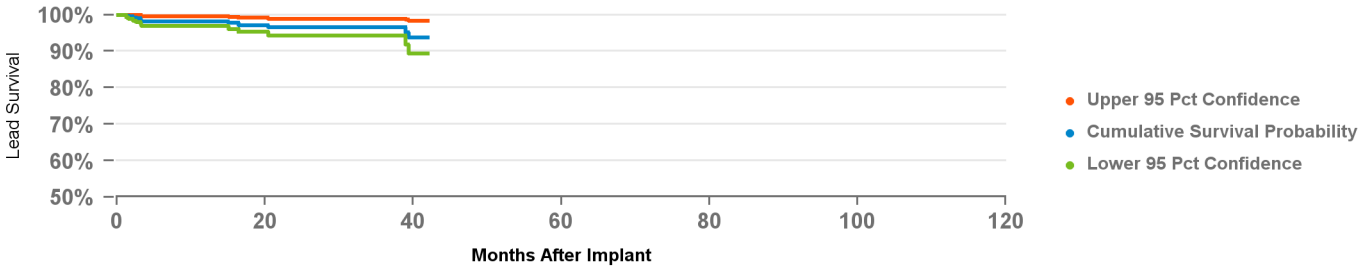
His Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	693
Cumulative Months of Followup	8,914
Number of Leads Active in Study	585

Qualifying Complications 13

Failure To Capture	11
Lead Dislodgement	1
Oversensing	1



Years	1	2	3	at 42 mo
%	98.2%	96.6%	96.6%	93.8%
#	240	131	78	55

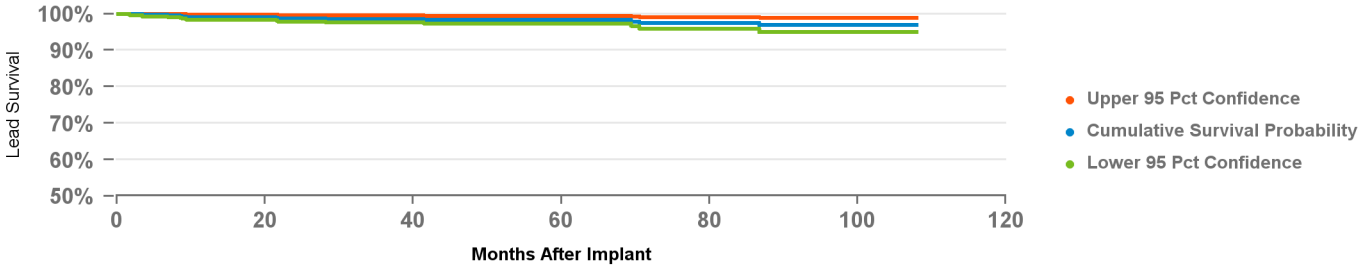
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,008
Cumulative Months of Followup	38,848
Number of Leads Active in Study	542

Qualifying Complications 13

Failure To Capture	6
Impedance Abnormal	1
Lead Dislodgement	5
Other Complication	1



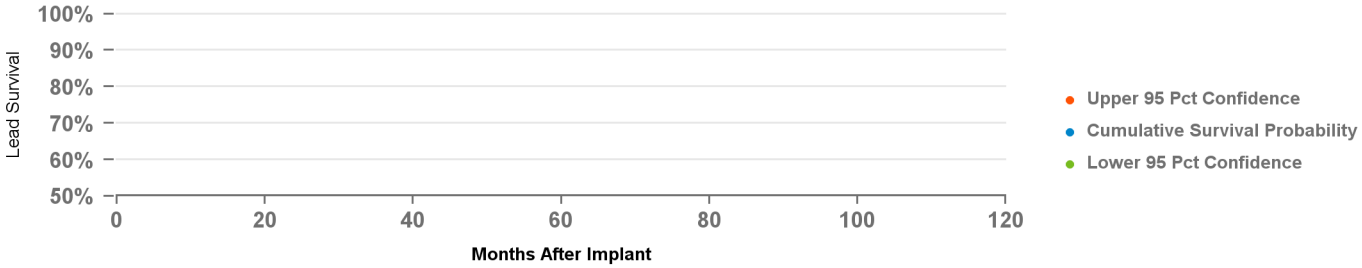
Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.1%	98.8%	98.5%	98.3%	98.3%	97.4%	97.4%	96.9%	96.9%
#	654	535	434	332	278	212	170	123	56

4073 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	771
Estimated Active USA Implants	246
Fixation Type	Tines
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations



Years	at mo
%	
#	

4074 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	135,936
Estimated Active USA Implants	81,237
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	45
Other	

US Acute Lead Observations

Cardiac Perforation	27
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	115
Failure To Sense	6
Impedance Abnormal	3
Insulation Breach	
Lead Dislodgement	150
Oversensing	7
Unspecified	

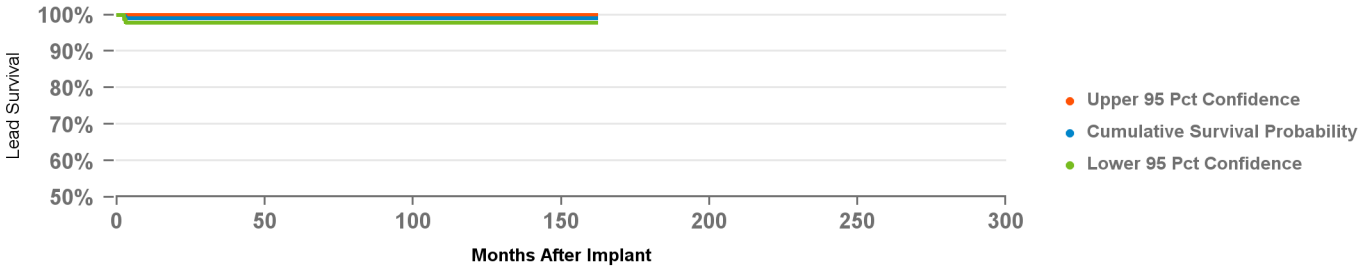
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Followup	25,425
Number of Leads Active in Study	96

Qualifying Complications 2

Failure To Sense	1
Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	214	205	198	183	167	158	148	135	127	115	106	102	68	58

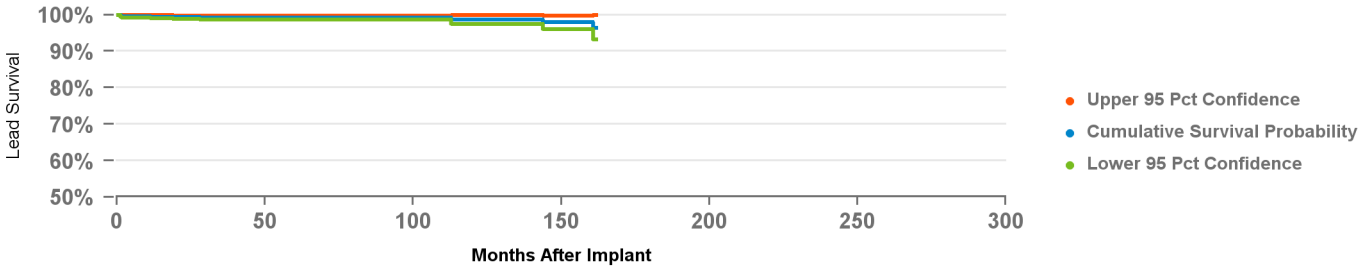
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,173
Cumulative Months of Followup	69,143
Number of Leads Active in Study	298

Qualifying Complications 11

Conductor Fracture	1
Failure To Capture	3
Impedance Abnormal	2
Insulation Breach	2
Lead Dislodgement	2
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.4%	99.3%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.6%	98.6%	97.9%	97.9%	96.5%
#	1,022	845	702	593	462	358	272	221	174	147	137	122	71	57

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	658,808
Estimated Active USA Implants	452,402
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	100
Crimp Weld Bond	1
Insulation Breach	151
Other	20

US Acute Lead Observations

Cardiac Perforation	153
Conductor Fracture	10
Extracardiac Stimulation	21
Failure To Capture	195
Failure To Sense	86
Impedance Abnormal	33
Insulation Breach	1
Lead Dislodgement	535
Oversensing	67
Unspecified	10

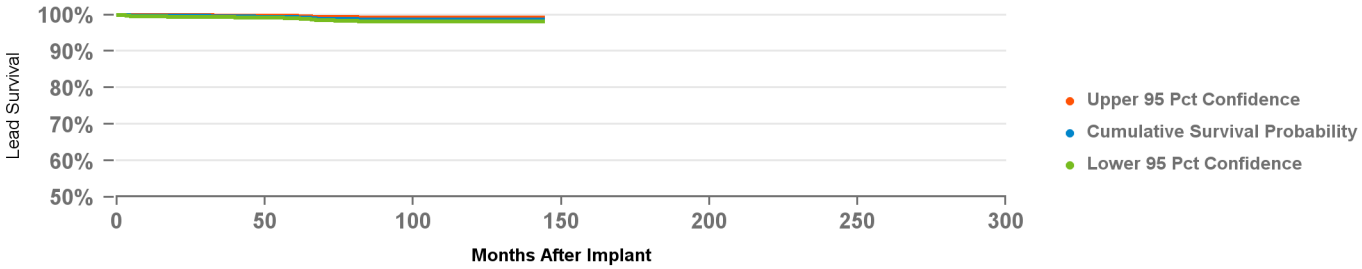
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,880
Cumulative Months of Followup	205,898
Number of Leads Active in Study	1,570

Qualifying Complications 25

Cardiac Perforation	1	Insulation Breach	2
Conductor Fracture	2	Lead Dislodgement	7
Failure To Capture	8	Oversensing	1
Failure To Sense	3	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.8%	99.7%	99.6%	99.5%	99.4%	98.9%	98.7%	98.7%	98.7%	98.7%	98.7%	98.7%
#	3,135	2,713	2,343	1,989	1,610	1,227	849	598	422	231	129	73

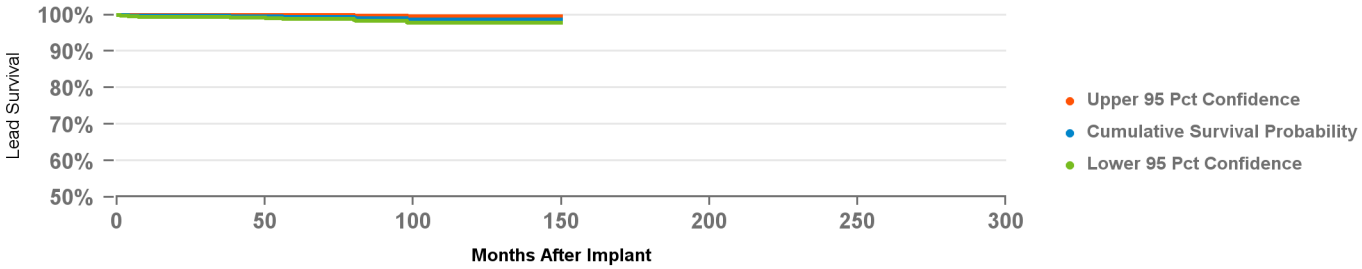
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,674
Cumulative Months of Followup	98,275
Number of Leads Active in Study	463

Qualifying Complications 11

Conductor Fracture	1	Impedance Abnormal	2
Extracardiac Stimulation	1	Lead Dislodgement	1
Failure To Capture	5	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.7%	99.7%	99.7%	99.6%	99.4%	99.4%	99.0%	99.0%	98.7%	98.7%	98.7%	98.7%	98.7%
#	1,383	1,191	1,061	897	727	592	452	360	291	191	126	81	59

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	185,516
Estimated Active USA Implants	61,446
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	19
Crimp Weld Bond	
Insulation Breach	90
Other	

US Acute Lead Observations

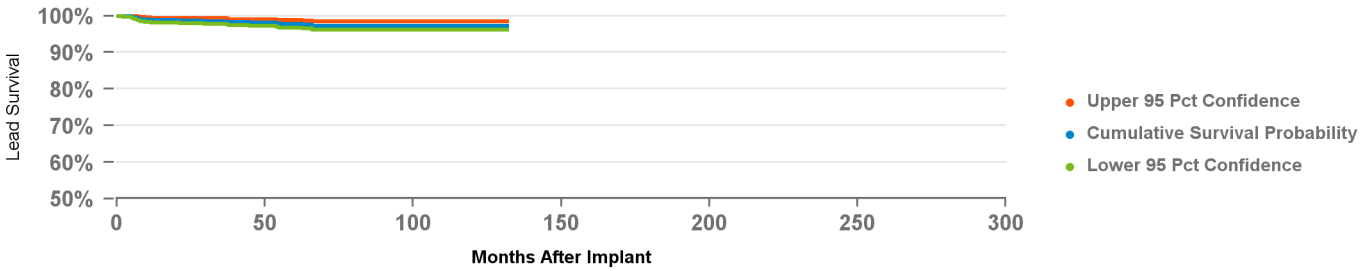
Cardiac Perforation	4
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Failure To Sense	
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,199
Cumulative Months of Followup	69,124
Number of Leads Active in Study	37

Qualifying Complications 21

Conductor Fracture	3	Impedance Abnormal	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%	97.4%	97.4%	97.4%	97.4%	97.4%	97.4%
#	952	849	757	647	528	402	327	266	218	134	68

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	95,419
Estimated Active USA Implants	61,724
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	11
Crimp Weld Bond	
Insulation Breach	16
Other	

US Acute Lead Observations

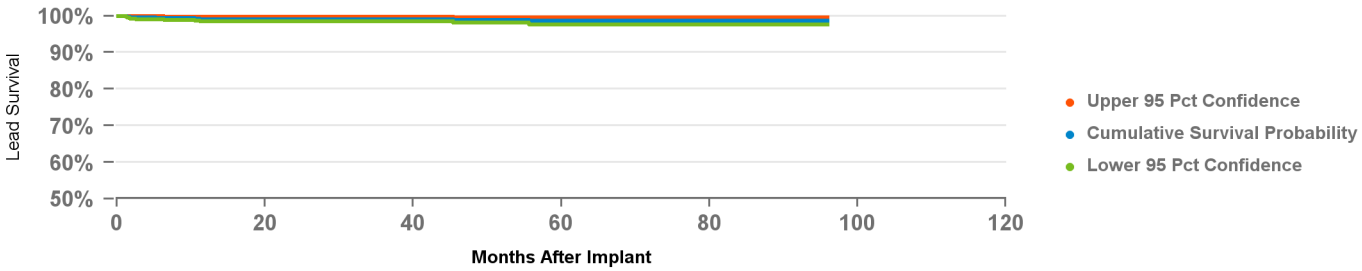
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	75
Failure To Sense	31
Impedance Abnormal	3
Insulation Breach	
Lead Dislodgement	179
Oversensing	5
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,230
Cumulative Months of Followup	48,995
Number of Leads Active in Study	607

Qualifying Complications 11

Conductor Fracture	2
Failure To Capture	2
Lead Dislodgement	7



Years	1	2	3	4	5	6	7	at 96 mo
%	99.1%	99.1%	99.1%	98.9%	98.6%	98.6%	98.6%	98.6%
#	973	732	593	447	306	219	125	63

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	88,220
Estimated Active USA Implants	30,972
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	30
Other	

US Acute Lead Observations

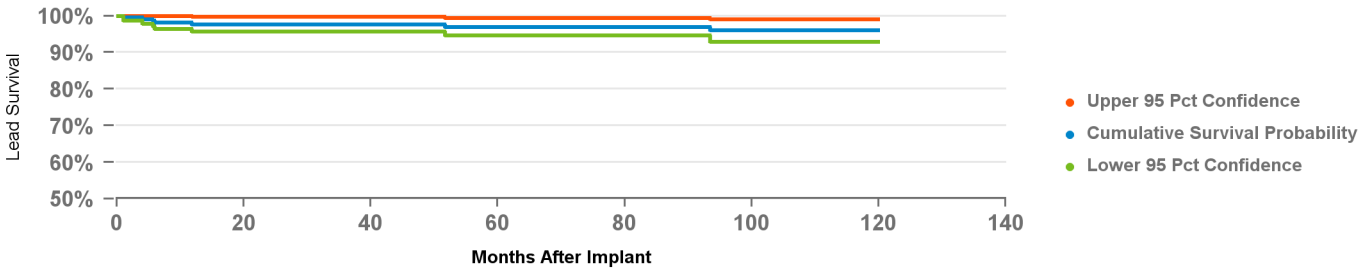
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	10
Failure To Sense	2
Impedance Abnormal	
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	357
Cumulative Months of Followup	20,326
Number of Leads Active in Study	42

Qualifying Complications 8

Failure To Capture	5	Lead Dislodgement	2
Failure To Sense	1		



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	97.7%	97.7%	97.7%	97.7%	97.0%	97.0%	97.0%	96.0%	96.0%	96.0%
#	246	221	198	180	153	125	96	84	68	52

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	98,882
Estimated Active USA Implants	31,121
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	1
Insulation Breach	43
Other	

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	23
Failure To Sense	
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	30
Oversensing	
Unspecified	9

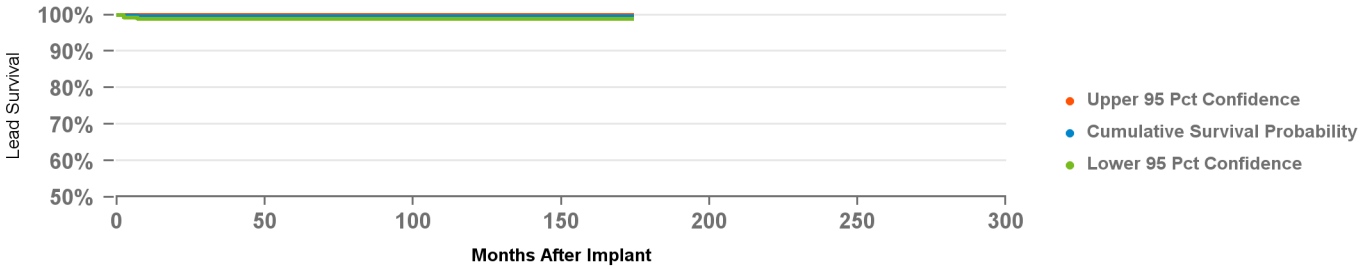
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Cumulative Months of Followup	40,343
Number of Leads Active in Study	47

Qualifying Complications 2

Failure To Capture	1	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 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%	99.5%	99.5%
#	412	392	359	323	290	253	219	185	152	128	107	92	74	64	56

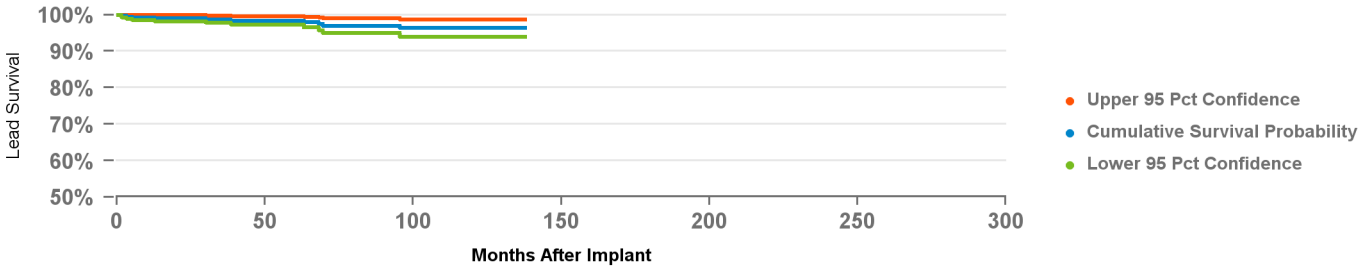
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	988
Cumulative Months of Followup	34,312
Number of Leads Active in Study	29

Qualifying Complications 11

Failure To Capture	7	Impedance Abnormal	1
Failure To Sense	2	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.3%	99.1%	98.8%	98.4%	98.4%	97.0%	97.0%	96.3%	96.3%	96.3%	96.3%	96.3%
#	483	398	309	267	233	192	165	137	103	83	64	51

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	2,697,765
Estimated Active USA Implants	1,788,609
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,112
Crimp Weld Bond	
Insulation Breach	1,174
Other	180

US Acute Lead Observations

Cardiac Perforation	1,137
Conductor Fracture	25
Extracardiac Stimulation	86
Failure To Capture	1,407
Failure To Sense	562
Impedance Abnormal	149
Insulation Breach	11
Lead Dislodgement	3,524
Oversensing	440
Unspecified	26

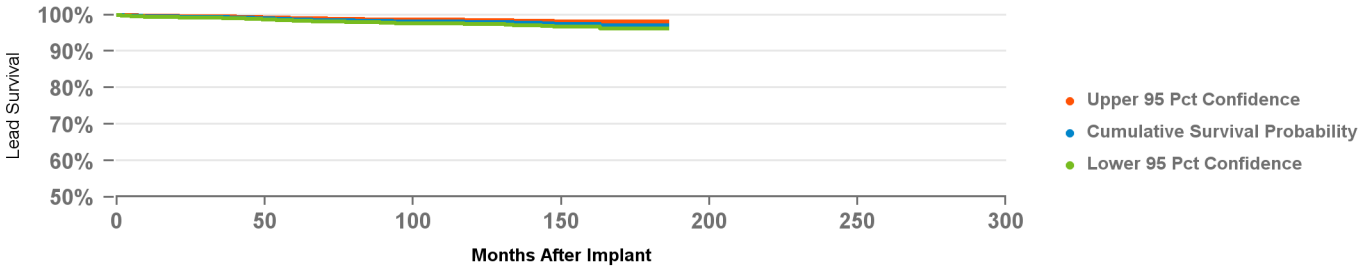
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	9,567
Cumulative Months of Followup	417,965
Number of Leads Active in Study	4,316

Qualifying Complications 83

Cardiac Perforation	2	Impedance Abnormal	7
Conductor Fracture	11	Insulation Breach	2
Extracardiac Stimulation	3	Lead Dislodgement	29
Failure To Capture	14	Oversensing	4
Failure To Sense	6	Other Complication	5



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.6%	99.4%	99.3%	99.1%	98.7%	98.6%	98.3%	98.2%	98.2%	98.1%	97.9%	97.6%	97.5%	97.2%	97.2%	97.2%
#	7,077	5,760	4,666	3,585	2,808	2,072	1,403	1,019	733	505	373	290	202	119	66	55

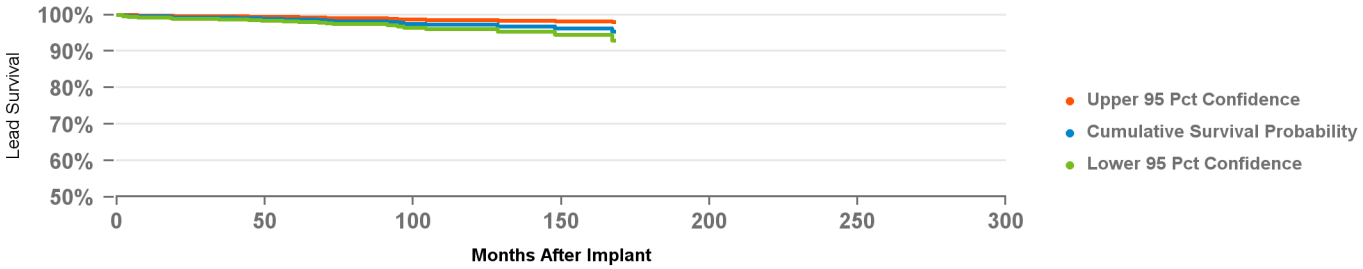
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,054
Cumulative Months of Followup	123,039
Number of Leads Active in Study	968

Qualifying Complications 31

Cardiac Perforation	1	Impedance Abnormal	4
Conductor Fracture	6	Lead Dislodgement	5
Failure To Capture	12	Oversensing	1
Failure To Sense	1	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.5%	99.2%	99.2%	99.0%	98.7%	98.3%	98.2%	97.7%	97.2%	97.2%	96.8%	96.8%	96.3%	95.4%
#	2,011	1,509	1,237	1,003	847	639	440	336	260	202	164	129	93	61

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	208,610
Estimated Active USA Implants	175,872
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	87
Crimp Weld Bond	
Insulation Breach	145
Other	11

US Acute Lead Observations

Cardiac Perforation	214
Conductor Fracture	2
Extracardiac Stimulation	18
Failure To Capture	142
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	309
Oversensing	31
Unspecified	

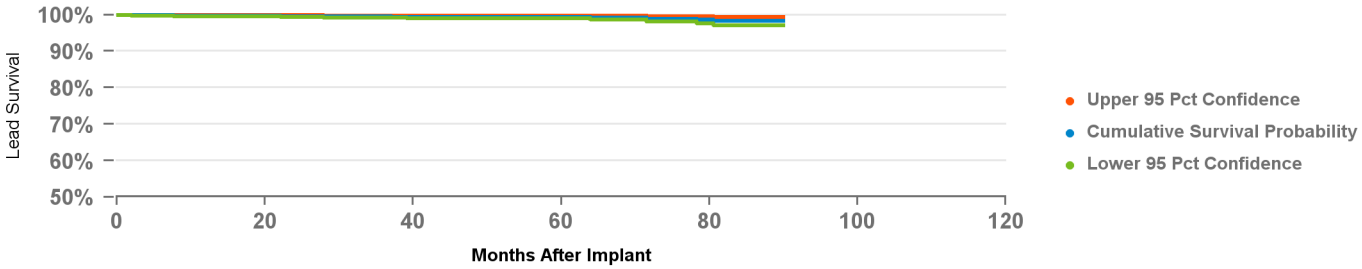
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,114
Cumulative Months of Followup	130,316
Number of Leads Active in Study	1,478

Qualifying Complications 19

Conductor Fracture	3	Lead Dislodgement	11
Failure To Capture	3	Oversensing	1
		Other Complication	1



Years	1	2	3	4	5	6	7	at 90 mo
%	99.8%	99.6%	99.6%	99.4%	99.4%	98.9%	98.3%	98.3%
#	2,695	2,282	1,881	1,423	671	243	161	111

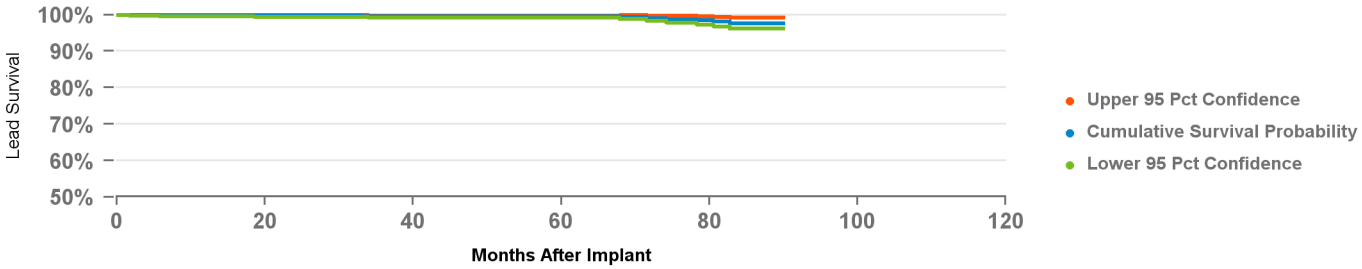
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,053
Cumulative Months of Followup	128,922
Number of Leads Active in Study	1,453

Qualifying Complications 19

Conductor Fracture	2	Impedance Abnormal	2
Failure To Capture	8	Lead Dislodgement	3
Failure To Sense	1	Oversensing	2
		Other Complication	1



Years	1	2	3	4	5	6	7	at 90 mo
%	99.7%	99.7%	99.6%	99.6%	99.6%	99.1%	97.7%	97.7%
#	2,663	2,258	1,860	1,416	659	237	161	112

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	140,132
Estimated Active USA Implants	48,838
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	23
Crimp Weld Bond	
Insulation Breach	65
Other	1

US Acute Lead Observations

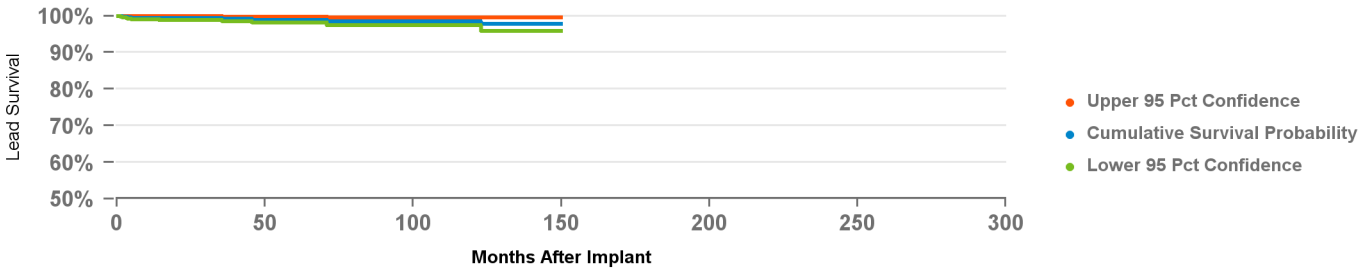
Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	49
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,213
Cumulative Months of Followup	53,454
Number of Leads Active in Study	32

Qualifying Complications 10

Extracardiac Stimulation	1	Impedance Abnormal	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%	98.6%	98.6%	98.6%	98.6%	98.6%	97.8%	97.8%	97.8%
#	830	662	525	428	339	263	211	164	136	118	95	70	61

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,426
Estimated Active USA Implants	22,429
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	21
Crimp Weld Bond	
Insulation Breach	37
Other	

US Acute Lead Observations

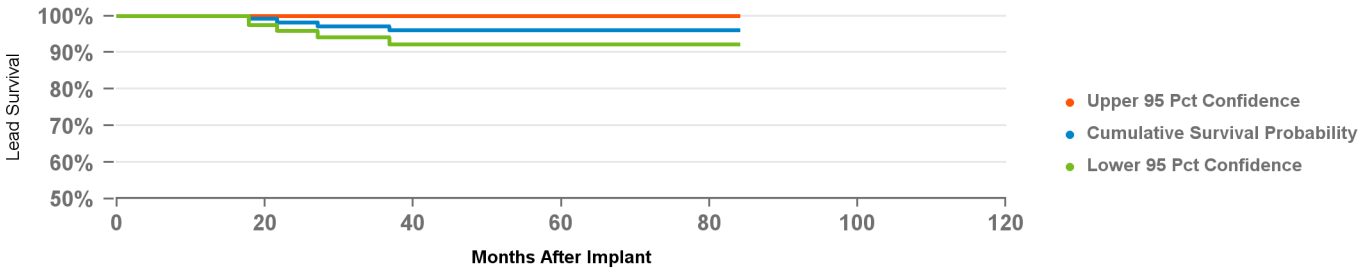
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	
Lead Dislodgement	38
Oversensing	
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	364
Cumulative Months of Followup	9,077
Number of Leads Active in Study	11

Qualifying Complications 5

Failure To Capture	2
Impedance Abnormal	1
Lead Dislodgement	1
Oversensing	1



Years	1	2	3	4	5	6	at 84 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%	96.0%
#	156	120	94	82	66	55	51

5592 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	36,930
Estimated Active USA Implants	15,767
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	6
Other	

US Acute Lead Observations

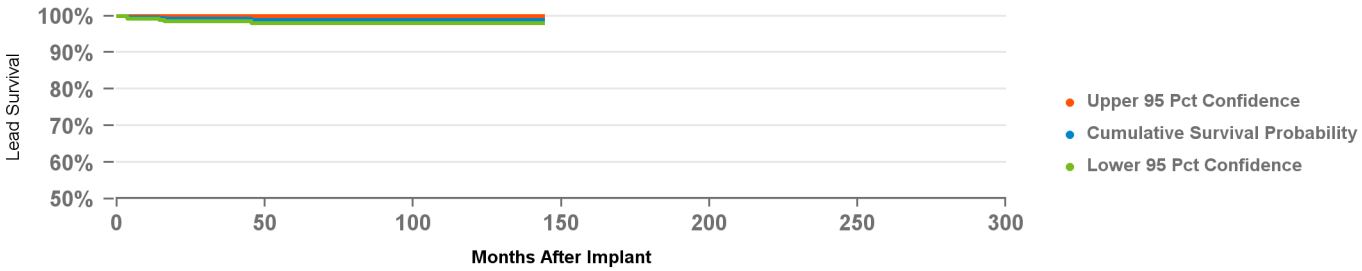
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	3
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	43
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	718
Cumulative Months of Followup	37,768
Number of Leads Active in Study	40

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%	99.3%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	538	446	361	306	251	191	152	134	114	99	84	58

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,588
Estimated Active USA Implants	8,793
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp Weld Bond	
Insulation Breach	17
Other	

US Acute Lead Observations

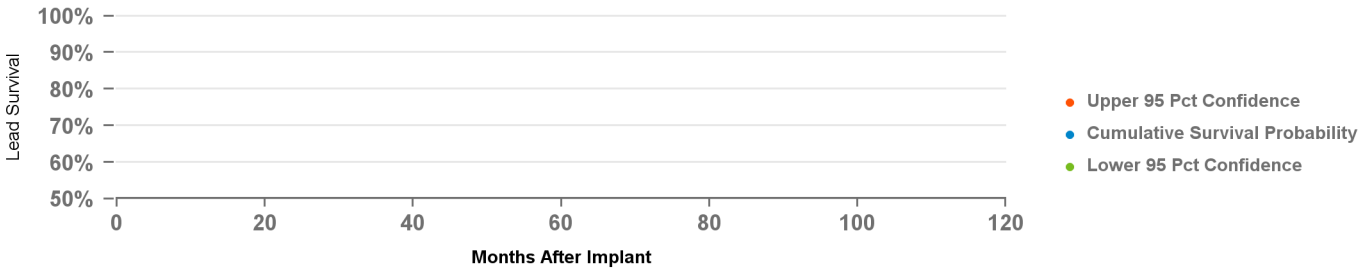
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	14
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	37
Cumulative Months of Followup	3,471
Number of Leads Active in Study	10

Qualifying Complications 3

Conductor Fracture	1
Insulation Breach	1
Oversensing	1



Years	at 0 mo
%	100.0%
#	

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,204
Estimated Active USA Implants	1,094
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	
Insulation Breach	1
Other	

US Acute Lead Observations

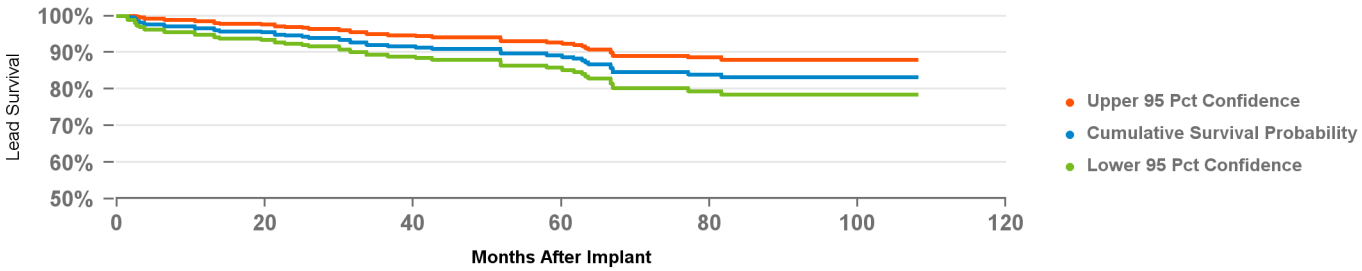
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	17
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	417
Cumulative Months of Followup	23,931
Number of Leads Active in Study	7

Qualifying Complications 47

Conductor Fracture	21	Impedance Abnormal	4
Failure To Capture	8	Insulation Breach	2
		Oversensing	12



Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.6%	92.1%	91.0%	89.2%	84.5%	83.1%	83.1%	83.1%
#	349	319	271	217	186	133	99	64	56

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	350
Estimated Active USA Implants	109
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

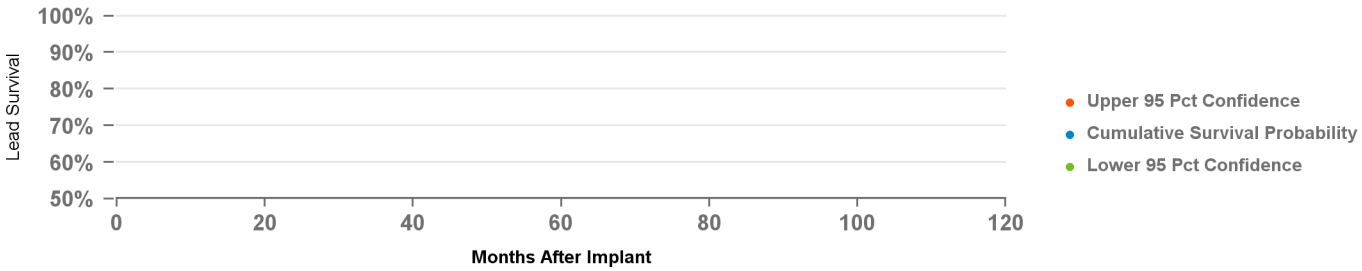
Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Followup	293
Number of Leads Active in Study	1



Years	at 0 mo
%	100.0%
#	

6931 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	8,057
Estimated Active USA Implants	1,927
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	649
Crimp Weld Bond	
Insulation Breach	1
Other	5

US Acute Lead Observations

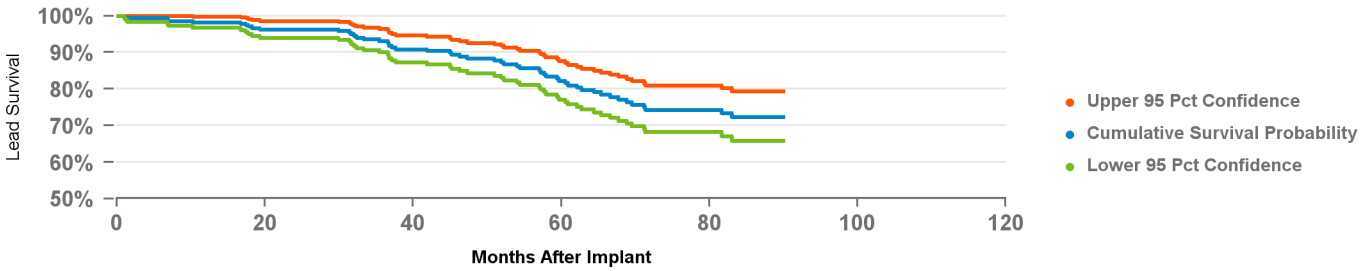
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	1
Oversensing	3
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	311
Cumulative Months of Followup	17,687
Number of Leads Active in Study	16

Qualifying Complications 58

Conductor Fracture	35	Impedance Abnormal	10
Failure To Capture	3	Lead Dislodgement	2
Failure To Sense	1	Oversensing	7



Years	1	2	3	4	5	6	7	at 90 mo
%	98.2%	96.2%	93.1%	88.3%	82.2%	74.3%	72.3%	72.3%
#	272	242	214	170	139	103	68	52

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	61,326
Estimated Active USA Implants	46,450
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	355
Crimp Weld Bond	
Insulation Breach	11
Other	41

US Acute Lead Observations

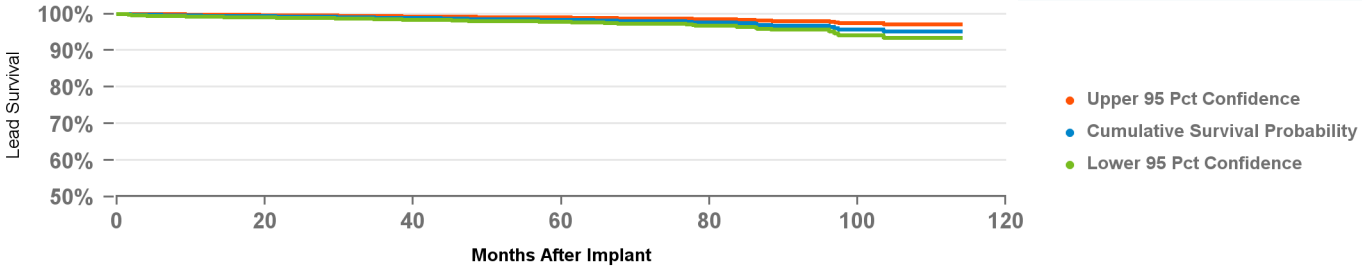
Cardiac Perforation	24
Conductor Fracture	3
Extracardiac Stimulation	1
Failure To Capture	27
Failure To Sense	12
Impedance Abnormal	25
Insulation Breach	1
Lead Dislodgement	58
Oversensing	61
Unspecified	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,734
Cumulative Months of Followup	129,726
Number of Leads Active in Study	893

Qualifying Complications 49

Cardiac Perforation	1
Conductor Fracture	18
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	6
Lead Dislodgement	7
Oversensing	7
Unspecified	1
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.5%	99.2%	98.9%	98.6%	98.4%	98.0%	97.4%	96.8%	95.3%	95.3%
#	2,346	1,882	1,501	1,170	951	765	493	254	114	66

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	236,743
Estimated Active USA Implants	220,286
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	350
Crimp Weld Bond	
Insulation Breach	16
Other	59

US Acute Lead Observations

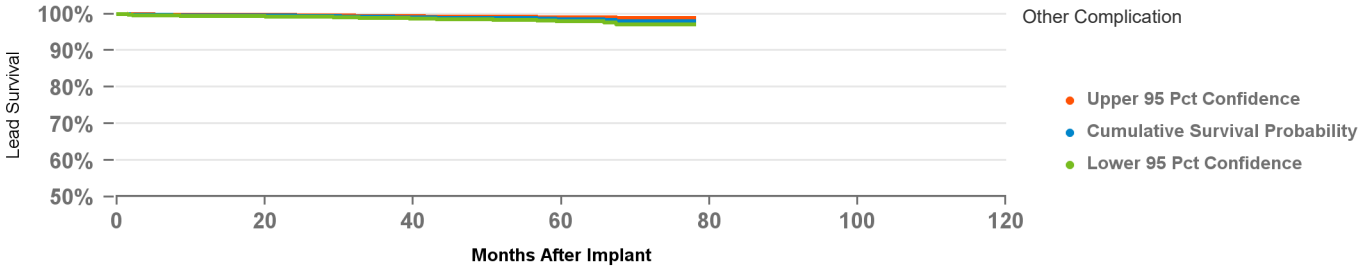
Cardiac Perforation	113
Conductor Fracture	8
Extracardiac Stimulation	21
Failure To Capture	217
Failure To Sense	66
Impedance Abnormal	60
Insulation Breach	2
Lead Dislodgement	375
Oversensing	186
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	6,507
Cumulative Months of Followup	200,903
Number of Leads Active in Study	4,065

Qualifying Complications 54

Cardiac Perforation	1
Conductor Fracture	15
Extracardiac Stimulation	1
Failure To Capture	12
Failure To Sense	1
Impedance Abnormal	4
Insulation Breach	2
Lead Dislodgement	13
Oversensing	2
Unspecified	1
Other Complication	2



Years	1	2	3	4	5	6	at 78 mo
%	99.6%	99.5%	99.2%	98.9%	98.6%	98.0%	98.0%
#	4,933	3,864	2,650	1,459	685	181	61

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	2,634
Estimated Active USA Implants	1,557
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

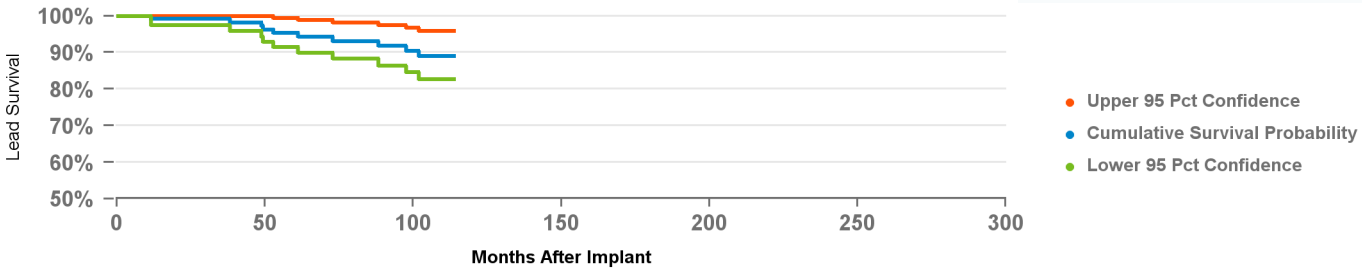
Cardiac Perforation	
Conductor Fracture	3
Extracardiac Stimulation	
Failure To Capture	
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	122
Cumulative Months of Followup	13,706
Number of Leads Active in Study	9

Qualifying Complications 14

Conductor Fracture	5
Impedance Abnormal	1
Insulation Breach	2
Lead Dislodgement	1
Unspecified	4
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.1%	99.1%	99.1%	98.2%	95.3%	94.3%	93.1%	91.8%	89.0%	89.0%
#	117	114	110	104	92	82	76	69	55	50

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,776
Estimated Active USA Implants	18,283
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	204
Crimp Weld Bond	1
Insulation Breach	4
Other	4

US Acute Lead Observations

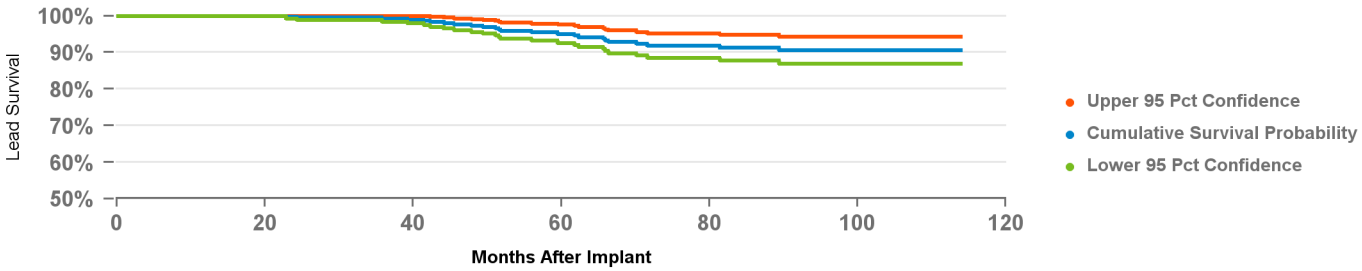
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	17
Failure To Sense	3
Impedance Abnormal	10
Insulation Breach	
Lead Dislodgement	24
Oversensing	18
Unspecified	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	619
Cumulative Months of Followup	33,828
Number of Leads Active in Study	123

Qualifying Complications 29

Conductor Fracture	16	Impedance Abnormal	4
Failure To Capture	4	Oversensing	3
Failure To Sense	1	Unspecified	1



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	100.0%	99.8%	99.2%	97.3%	95.1%	91.8%	91.2%	90.5%	90.5%	90.5%
#	531	445	373	301	236	184	140	100	72	59

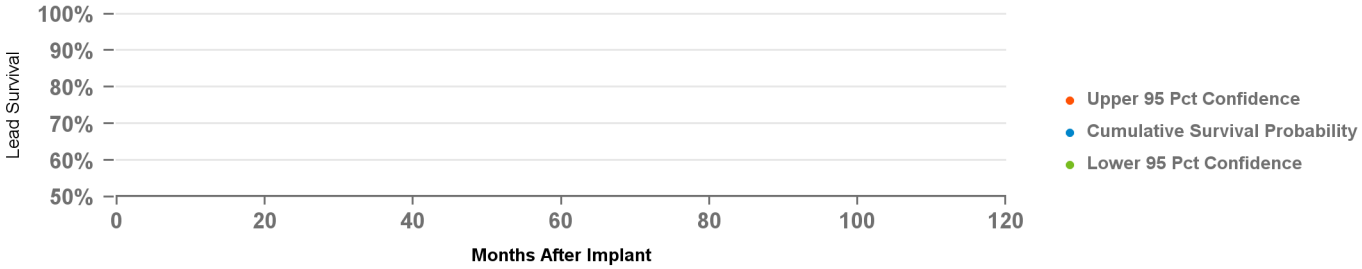
6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	2,215
Estimated Active USA Implants	2,131
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations

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



Years	at	mo
%		
#		

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	374,976
Estimated Active USA Implants	188,756
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,195
Crimp Weld Bond	4
Insulation Breach	97
Other	189

US Acute Lead Observations

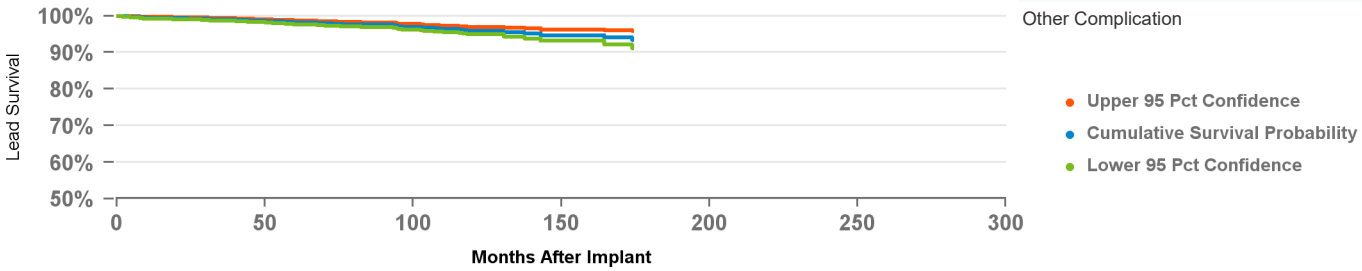
Cardiac Perforation	29
Conductor Fracture	25
Extracardiac Stimulation	2
Failure To Capture	81
Failure To Sense	34
Impedance Abnormal	59
Insulation Breach	4
Lead Dislodgement	122
Oversensing	140
Unspecified	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,445
Cumulative Months of Followup	257,153
Number of Leads Active in Study	1,038

Qualifying Complications 88

Conductor Fracture	31
Failure To Capture	7
Failure To Sense	2
Impedance Abnormal	12
Insulation Breach	5
Lead Dislodgement	5
Oversensing	19
Unspecified	3
Other Complication	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	97.9%	97.6%	97.1%	96.6%	95.9%	95.4%	94.7%	94.7%	94.1%	93.4%
#	3,834	3,304	2,797	2,353	1,953	1,561	1,157	893	614	323	174	110	90	70	60

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	118,538
Estimated Active USA Implants	104,466
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	160
Crimp Weld Bond	
Insulation Breach	12
Other	27

US Acute Lead Observations

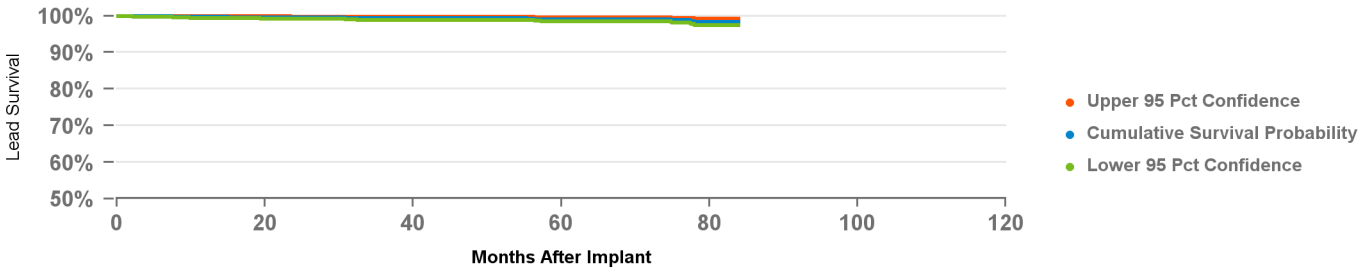
Cardiac Perforation	32
Conductor Fracture	9
Extracardiac Stimulation	10
Failure To Capture	96
Failure To Sense	36
Impedance Abnormal	26
Insulation Breach	
Lead Dislodgement	201
Oversensing	72
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,136
Cumulative Months of Followup	96,581
Number of Leads Active in Study	906

Qualifying Complications 17

Conductor Fracture	9
Failure To Capture	4
Failure To Sense	2
Lead Dislodgement	1
Other Complication	1



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.5%	99.3%	99.3%	99.0%	99.0%	98.3%
#	1,737	1,453	1,258	1,007	823	584	162

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,341
Estimated Active USA Implants	2,768
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	207
Crimp Weld Bond	
Insulation Breach	3
Other	4

US Acute Lead Observations

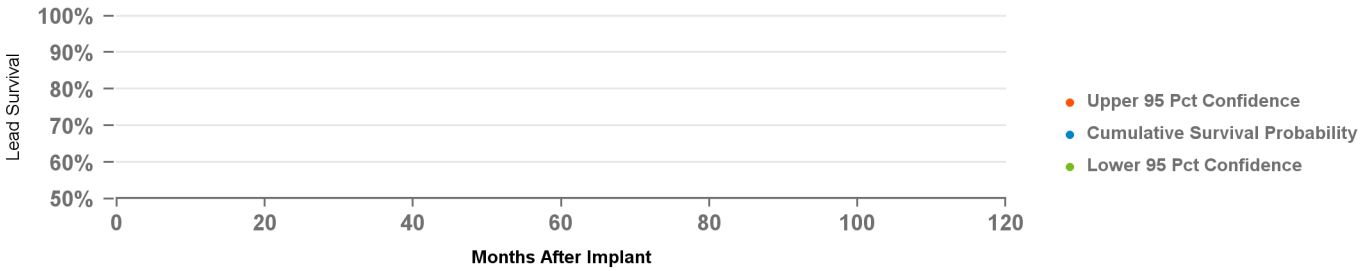
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	7
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	7
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Cumulative Months of Followup	2,278
Number of Leads Active in Study	5

Qualifying Complications 4

Conductor Fracture	3	Impedance Abnormal	1



Years	at 0 mo
%	100.0%
#	

6949 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	185,957
Estimated Active USA Implants	41,559
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7,887
Crimp Weld Bond	3
Insulation Breach	37
Other	99

US Acute Lead Observations

Cardiac Perforation	10
Conductor Fracture	46
Extracardiac Stimulation	
Failure To Capture	32
Failure To Sense	19
Impedance Abnormal	19
Insulation Breach	5
Lead Dislodgement	22
Oversensing	35
Unspecified	25

Product Surveillance Registry Results

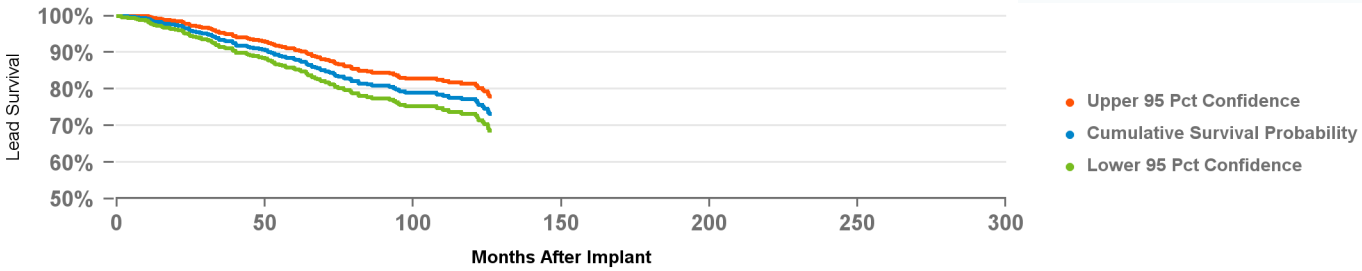
Number of Leads Enrolled in Study	978
Cumulative Months of Followup	55,317
Number of Leads Active in Study	84

Qualifying Complications

Conductor Fracture	73
Failure To Capture	5
Failure To Sense	6

128

Impedance Abnormal	19
Insulation Breach	2
Lead Dislodgement	1
Oversensing	21
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.5%	96.5%	93.4%	91.0%	88.2%	84.4%	81.5%	79.3%	78.6%	77.2%	73.1%
#	849	729	621	525	431	336	220	156	98	66	55

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	5,197
Estimated Active USA Implants	2,804
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	32
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

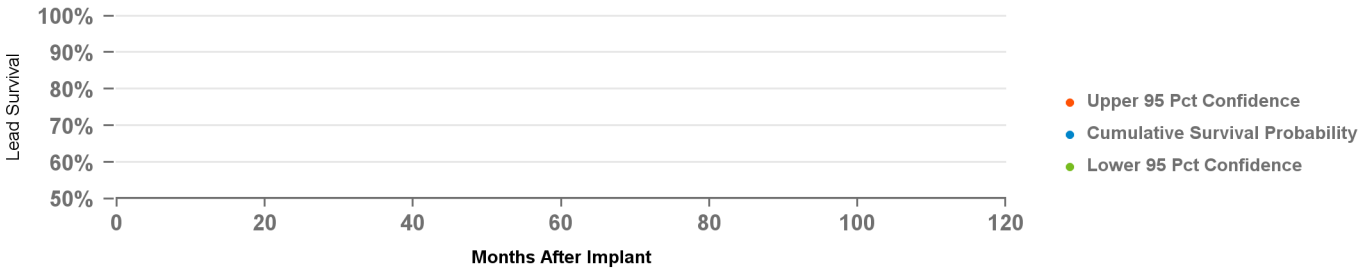
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	1
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	53
Cumulative Months of Followup	2,308
Number of Leads Active in Study	6

Qualifying Complications 3

Conductor Fracture	1
Impedance Abnormal	2



Years	at 0 mo
%	100.0%
#	

2187 Attain LV

US Market Release	28Aug2001
CE Approval	
Registered USA Implants	11,909
Estimated Active USA Implants	1,648
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

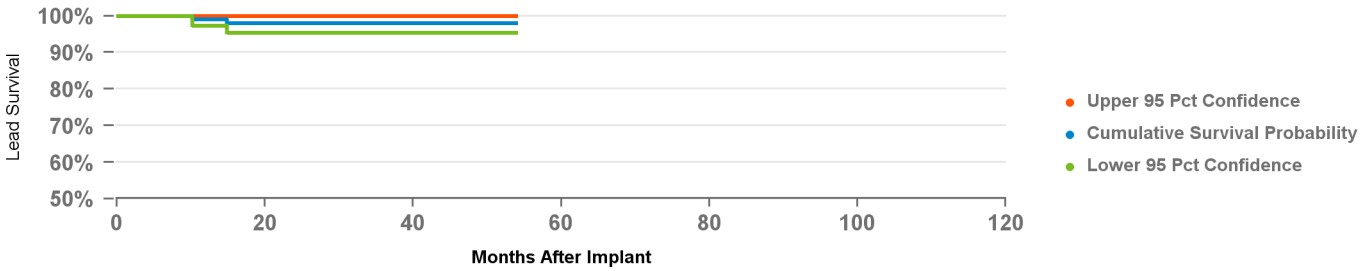
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	9
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	140
Cumulative Months of Followup	6,922
Number of Leads Active in Study	7

Qualifying Complications 3

Failure To Capture	3



Years	1	2	3	4	at 54 mo
%	99.1%	98.0%	98.0%	98.0%	98.0%
#	105	89	69	56	52

4193 Attain OTW

US Market Release	03May2002
CE Approval	22Dec2000
Registered USA Implants	100,387
Estimated Active USA Implants	21,555
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	86
Crimp Weld Bond	
Insulation Breach	30
Other	12

US Acute Lead Observations

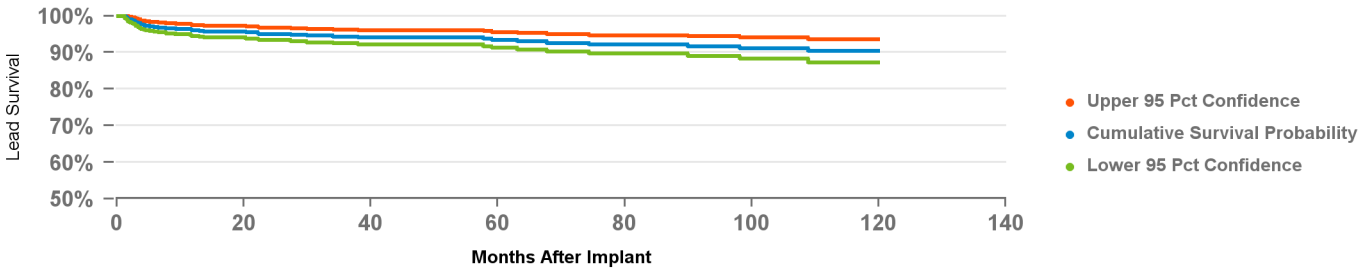
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	18
Failure To Capture	11
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	45
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	802
Cumulative Months of Followup	40,416
Number of Leads Active in Study	58

Qualifying Complications 48

Conductor Fracture	1	Impedance Abnormal	2
Extracardiac Stimulation	9	Lead Dislodgement	14
Failure To Capture	19	Unspecified	3



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.0%	95.1%	94.4%	94.1%	93.4%	92.6%	92.2%	91.7%	91.1%	90.4%
#	641	499	421	334	266	219	173	145	97	64

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	114,863
Estimated Active USA Implants	48,498
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	41
Crimp Weld Bond	
Insulation Breach	145
Other	2

US Acute Lead Observations

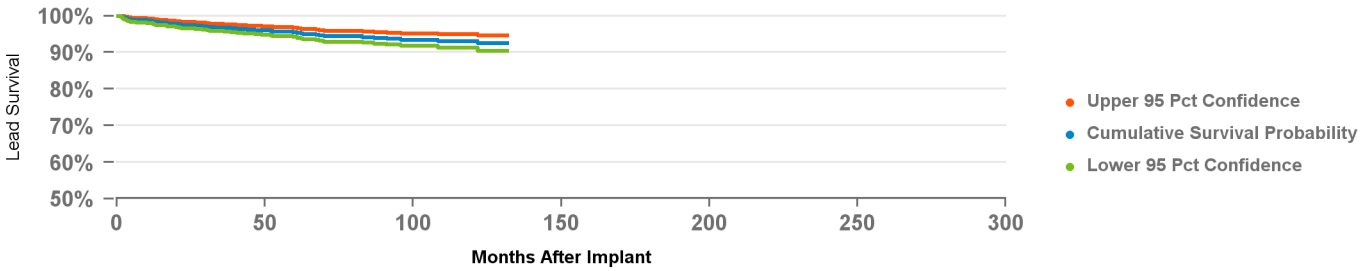
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	49
Failure To Capture	42
Failure To Sense	
Impedance Abnormal	9
Insulation Breach	
Lead Dislodgement	151
Oversensing	2
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,642
Cumulative Months of Followup	88,590
Number of Leads Active in Study	313

Qualifying Complications 65

Conductor Fracture	2	Insulation Breach	2
Extracardiac Stimulation	11	Lead Dislodgement	30
Failure To Capture	19	Insulation Breach Esc	1



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.6%	97.4%	96.7%	96.1%	95.6%	94.4%	94.2%	93.5%	93.5%	93.1%	92.6%
#	1,381	1,161	975	811	678	533	357	273	173	112	69

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,413
Estimated Active USA Implants	10,236
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

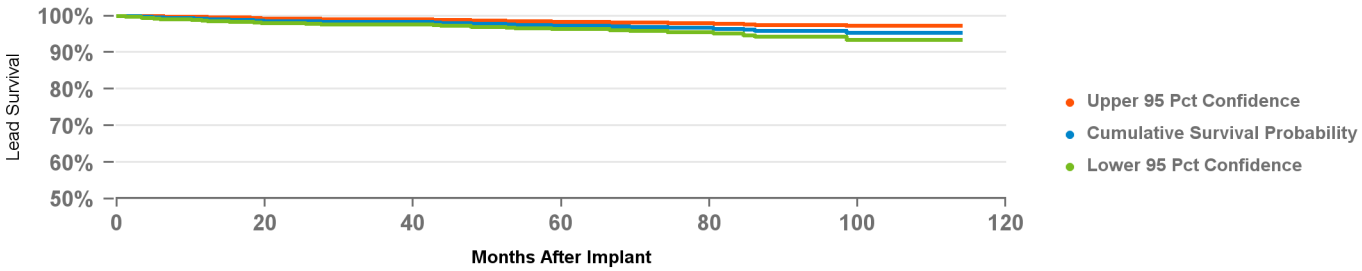
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	29
Failure To Capture	21
Failure To Sense	
Impedance Abnormal	4
Insulation Breach	
Lead Dislodgement	29
Oversensing	
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,486
Cumulative Months of Followup	76,937
Number of Leads Active in Study	334

Qualifying Complications 36

Conductor Fracture	4	Impedance Abnormal	2
Extracardiac Stimulation	13	Insulation Breach	5
Failure To Capture	7	Lead Dislodgement	5



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.2%	98.6%	98.3%	97.8%	97.3%	97.0%	96.5%	95.8%	95.3%	95.3%
#	1,270	1,089	927	736	593	444	307	184	97	59

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	69,152
Estimated Active USA Implants	44,573
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	24
Crimp Weld Bond	
Insulation Breach	2
Other	9

US Acute Lead Observations

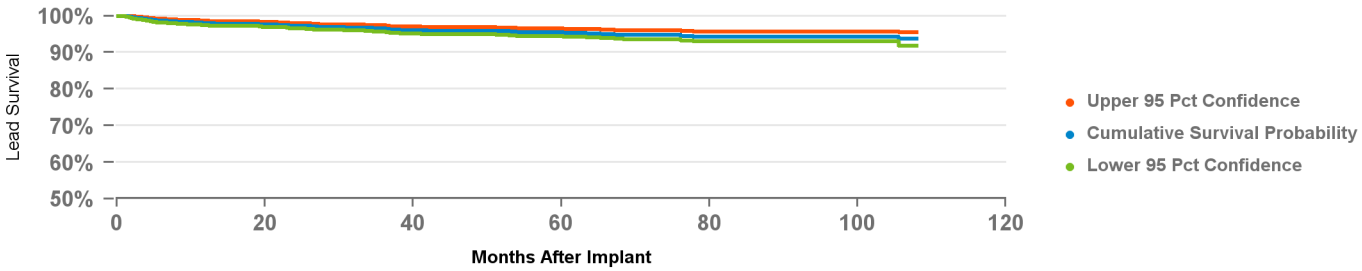
Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	94
Failure To Capture	63
Failure To Sense	1
Impedance Abnormal	10
Insulation Breach	1
Lead Dislodgement	214
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,292
Cumulative Months of Followup	102,987
Number of Leads Active in Study	417

Qualifying Complications 83

Conductor Fracture	3
Extracardiac Stimulation	14
Failure To Capture	38
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	22
Other Complication	3



Years	1	2	3	4	5	6	7	8	at 108 mo
%	98.0%	97.3%	96.5%	95.9%	95.5%	94.7%	94.4%	94.4%	93.7%
#	1,902	1,501	1,169	918	722	536	375	250	98

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	34,716
Estimated Active USA Implants	26,618
Fixation Type	Double Curve
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp Weld Bond	2
Insulation Breach	
Other	4

US Acute Lead Observations

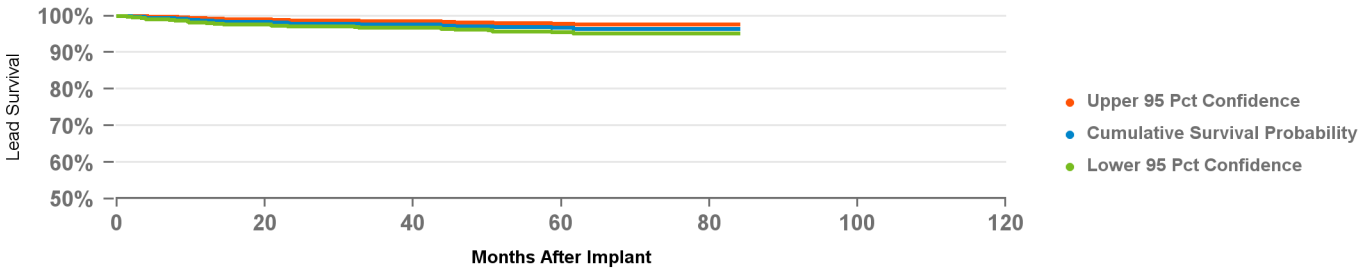
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	60
Failure To Capture	30
Failure To Sense	
Impedance Abnormal	10
Insulation Breach	4
Lead Dislodgement	115
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,458
Cumulative Months of Followup	60,064
Number of Leads Active in Study	451

Qualifying Complications 35

Extracardiac Stimulation	12	Lead Dislodgement	13
Failure To Capture	9	Other Complication	1



Years	1	2	3	4	5	6	at 84 mo
%	98.7%	97.9%	97.6%	97.2%	96.7%	96.5%	96.5%
#	1,150	920	745	620	490	279	114

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	80,775
Estimated Active USA Implants	74,475
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp Weld Bond	
Insulation Breach	
Other	16

US Acute Lead Observations

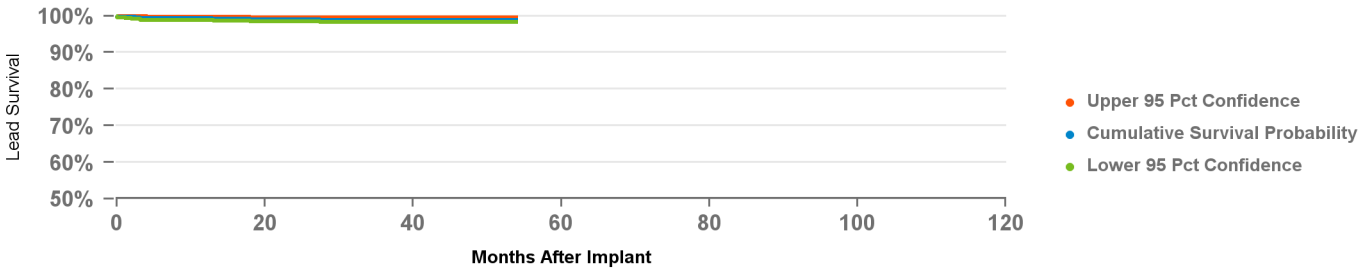
Cardiac Perforation	5
Conductor Fracture	1
Extracardiac Stimulation	178
Failure To Capture	96
Failure To Sense	1
Impedance Abnormal	24
Insulation Breach	
Lead Dislodgement	162
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,083
Cumulative Months of Followup	52,042
Number of Leads Active in Study	1,419

Qualifying Complications 16

Extracardiac Stimulation	4
Lead Dislodgement	11
Other Complication	1



Years	1	2	3	4	at 54 mo
%	99.3%	99.0%	98.9%	98.9%	98.9%
#	1,404	997	643	295	145

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	8,067
Estimated Active USA Implants	6,135
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

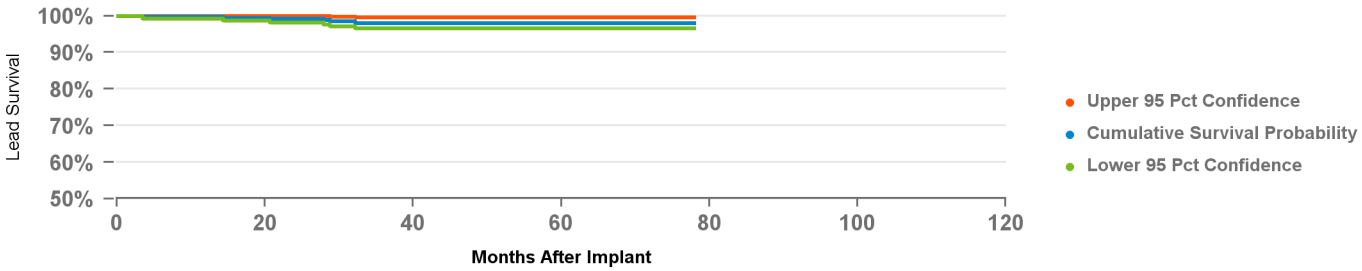
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	19
Failure To Capture	10
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	34
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	465
Cumulative Months of Followup	19,388
Number of Leads Active in Study	174

Qualifying Complications 8

Extracardiac Stimulation	1	Insulation Breach	1
Failure To Capture	4	Lead Dislodgement	2



Years	1	2	3	4	5	6	at 78 mo
%	99.8%	99.2%	98.1%	98.1%	98.1%	98.1%	98.1%
#	369	292	252	208	151	83	57

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	24,926
Estimated Active USA Implants	23,328
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp Weld Bond	
Insulation Breach	
Other	3

US Acute Lead Observations

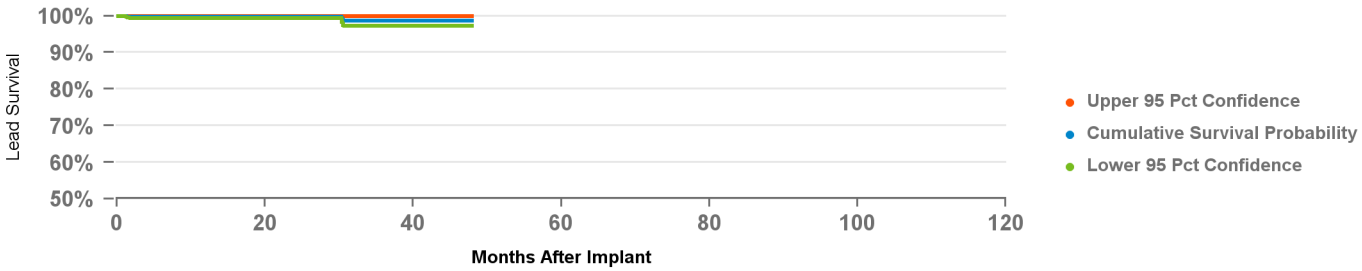
Cardiac Perforation	6
Conductor Fracture	
Extracardiac Stimulation	73
Failure To Capture	37
Failure To Sense	
Impedance Abnormal	5
Insulation Breach	
Lead Dislodgement	29
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,230
Cumulative Months of Followup	19,960
Number of Leads Active in Study	966

Qualifying Complications 7

Failure To Capture	3
Impedance Abnormal	1
Lead Dislodgement	3



Years	1	2	3	at 48 mo
%	99.7%	99.7%	98.7%	98.7%
#	636	313	152	57

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	45,599
Estimated Active USA Implants	42,771
Fixation Type	S-shape
Pace Sense Polarity	Quad Pole
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp Weld Bond	
Insulation Breach	
Other	6

US Acute Lead Observations

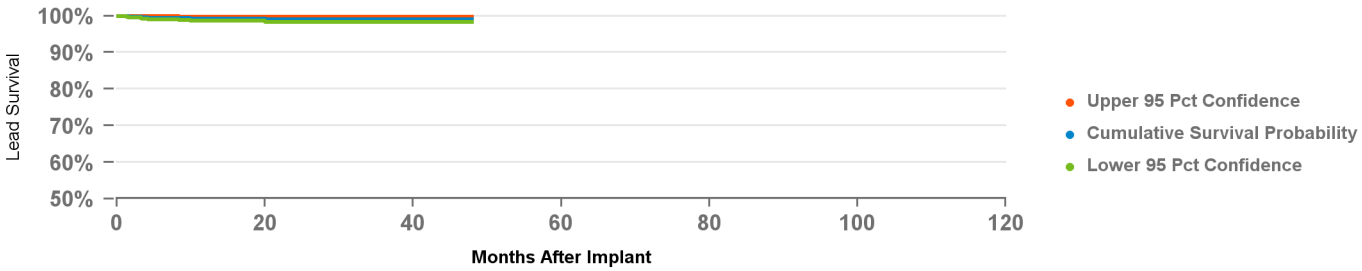
Cardiac Perforation	8
Conductor Fracture	1
Extracardiac Stimulation	77
Failure To Capture	43
Failure To Sense	
Impedance Abnormal	14
Insulation Breach	
Lead Dislodgement	48
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,223
Cumulative Months of Followup	26,383
Number of Leads Active in Study	883

Qualifying Complications 9

Extracardiac Stimulation	2	Lead Dislodgement	6
Failure To Sense	1		



Years	1	2	3	at 48 mo
%	99.2%	99.0%	99.0%	99.0%
#	817	477	260	83

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	23,375
Estimated Active USA Implants	8,278
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	283
Crimp Weld Bond	1
Insulation Breach	62
Other	

US Acute Lead Observations

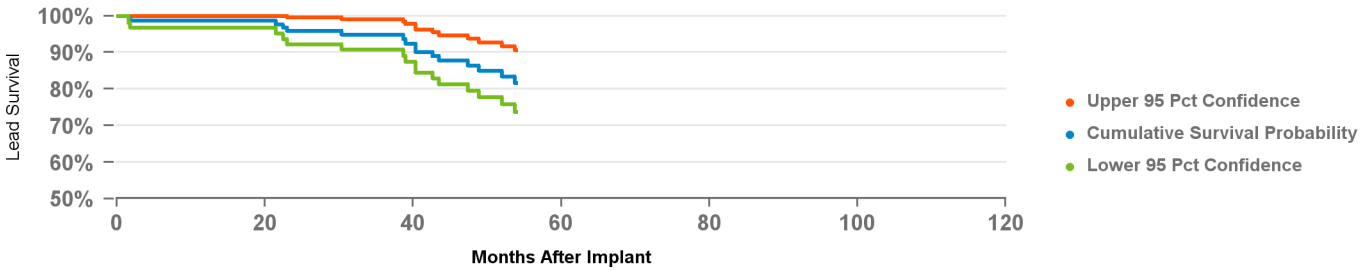
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	10
Failure To Sense	5
Impedance Abnormal	16
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	234
Cumulative Months of Followup	7,335
Number of Leads Active in Study	6

Qualifying Complications 17

Conductor Fracture	10	Insulation Breach	1
Failure To Capture	3	Oversensing	2
Failure To Sense	1		



Years	1	2	3	4	at 54 mo
%	98.6%	95.8%	94.8%	86.4%	81.7%
#	132	113	93	68	50

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	50,106
Estimated Active USA Implants	30,442
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	104
Crimp Weld Bond	
Insulation Breach	54
Other	1

US Acute Lead Observations

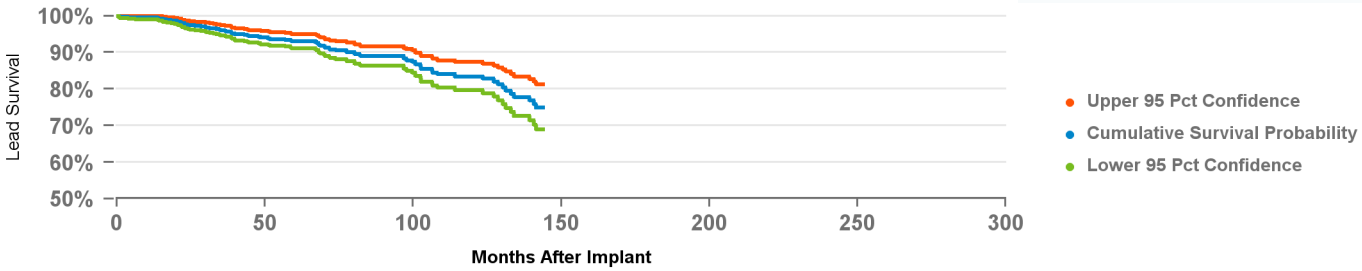
Cardiac Perforation	1
Conductor Fracture	3
Extracardiac Stimulation	4
Failure To Capture	57
Failure To Sense	5
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	6
Oversensing	21
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,023
Cumulative Months of Followup	60,089
Number of Leads Active in Study	226

Qualifying Complications 93

Conductor Fracture	24
Extracardiac Stimulation	2
Failure To Capture	29
Failure To Sense	3
Impedance Abnormal	5
Insulation Breach	3
Lead Dislodgement	1
Oversensing	24
Other Complication	2



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.5%	97.5%	96.1%	94.2%	93.0%	90.9%	89.0%	89.0%	84.5%	83.5%	79.6%	74.9%
#	819	718	632	521	440	358	297	231	161	113	82	61

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	54,438
Estimated Active USA Implants	16,487
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	25
Crimp Weld Bond	
Insulation Breach	2
Other	1

US Acute Lead Observations

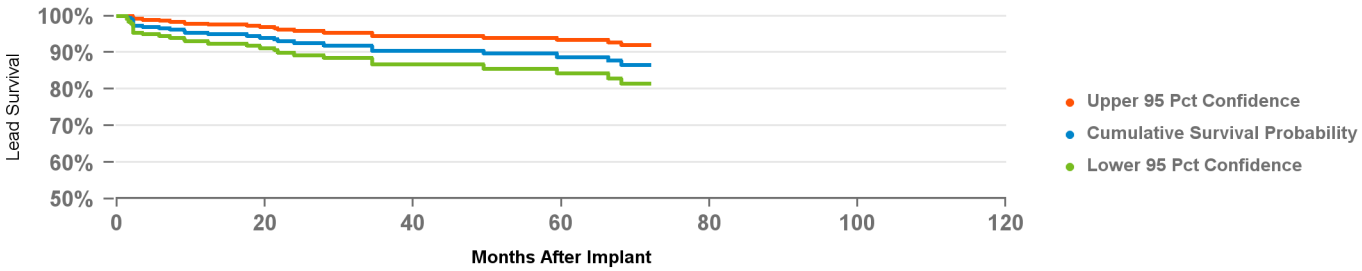
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	6
Failure To Capture	84
Failure To Sense	3
Impedance Abnormal	8
Insulation Breach	
Lead Dislodgement	2
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	447
Cumulative Months of Followup	14,100
Number of Leads Active in Study	88

Qualifying Complications 31

Conductor Fracture	3	Impedance Abnormal	1
Extracardiac Stimulation	1	Lead Dislodgement	1
Failure To Capture	20	Oversensing	2
Failure To Sense	2	Other Complication	1



Years	1	2	3	4	5	at 72 mo
%	95.4%	92.5%	90.5%	90.5%	88.7%	86.6%
#	239	186	147	115	88	62

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	10,335
Estimated Active USA Implants	3,580
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Crimp Weld Bond	
Insulation Breach	2
Other	

US Acute Lead Observations

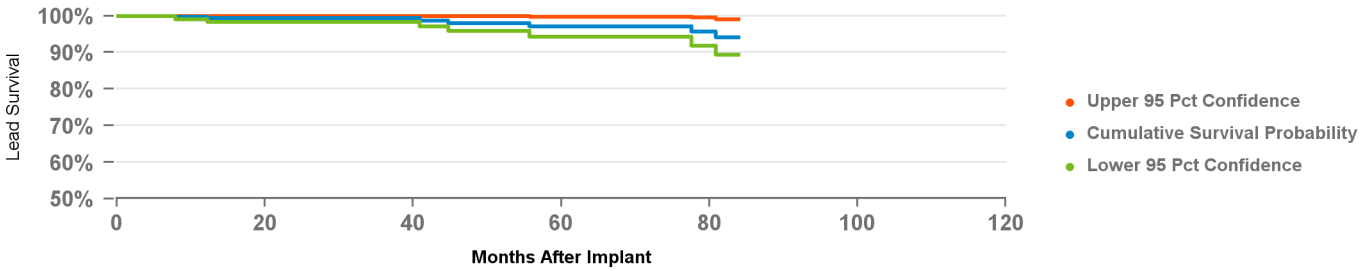
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	6
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	568
Cumulative Months of Followup	15,802
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%
#	292	222	164	135	107	78	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.

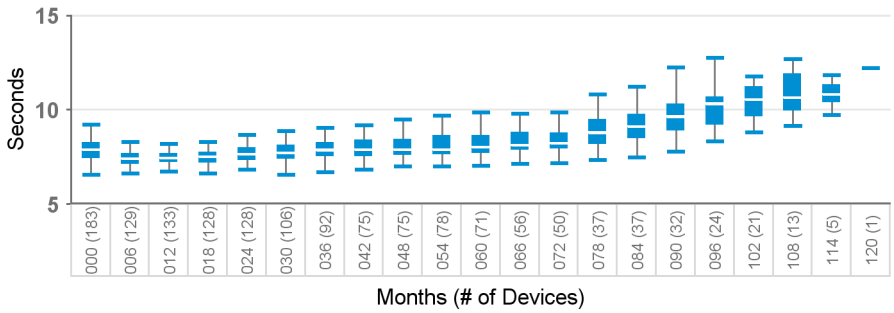
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available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

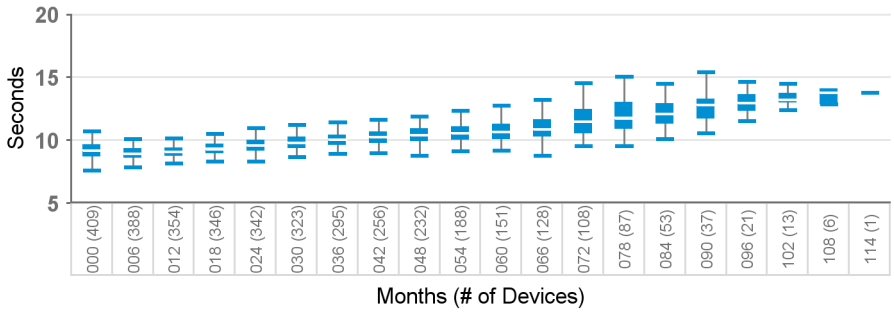
7232

Model Number	Brand
7232Cx	Maximo VR



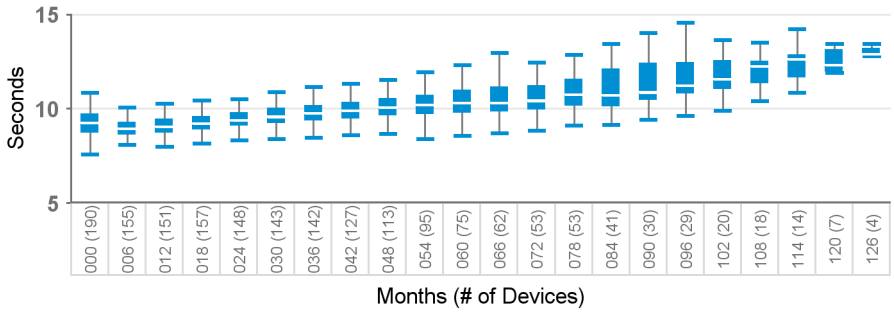
D154AWG, D164AWG

Model Number	Brand
D164AWG	Virtuoso DR



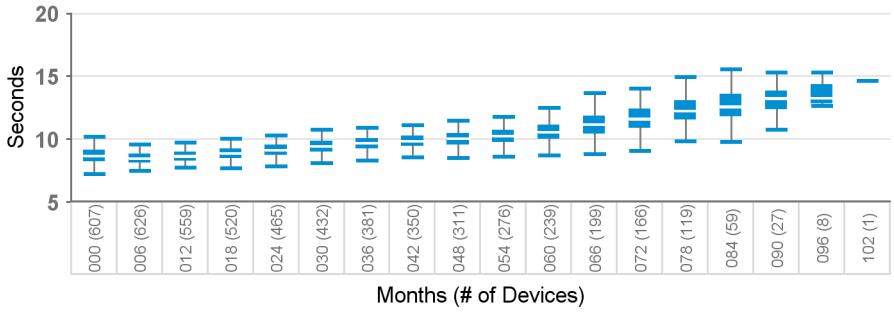
D154VWC, D164VWC

Model Number	Brand
D164VWC	Virtuoso VR



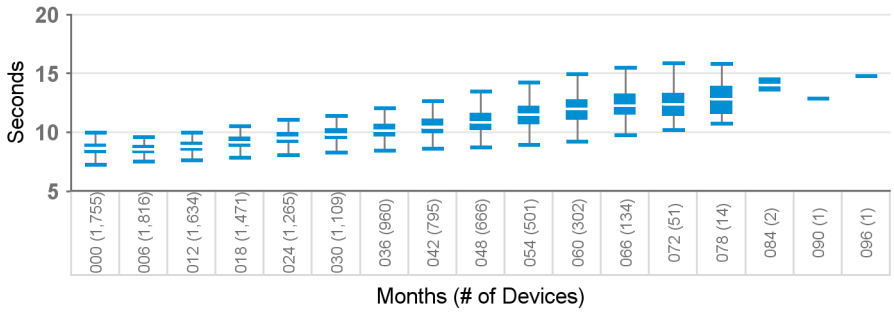
D204DRM, D214DRM, D224DRG, D234DRG

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



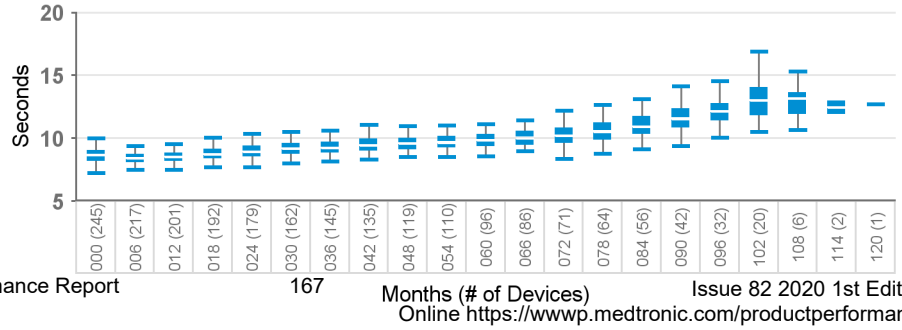
D204TRM, D214TRM, D224TRK, D234TRK

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



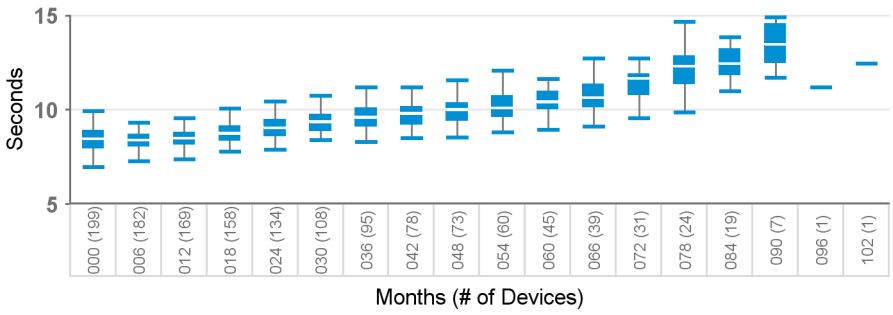
D204VRM, D214VRM, D224VRC, D234VRC

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



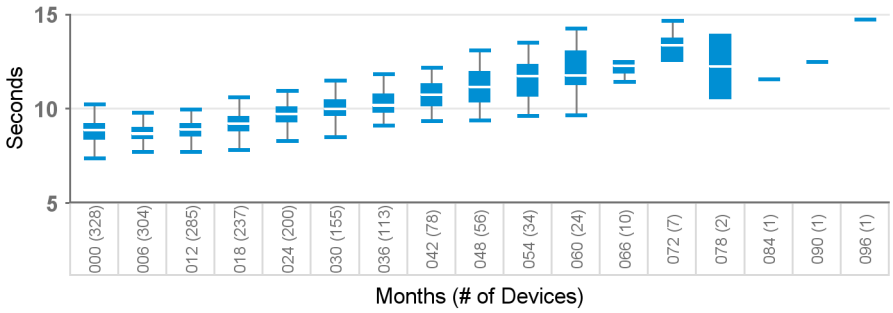
D264DRG, D284DRG, D384DRx, D394DRx

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



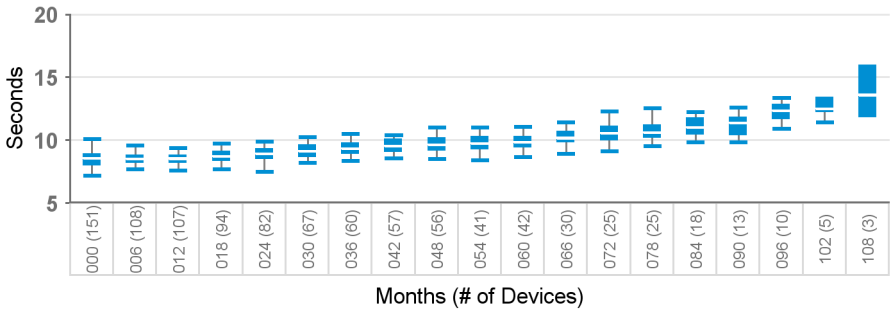
D264TRM, D284TRK, D384TRx, D394TRx

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



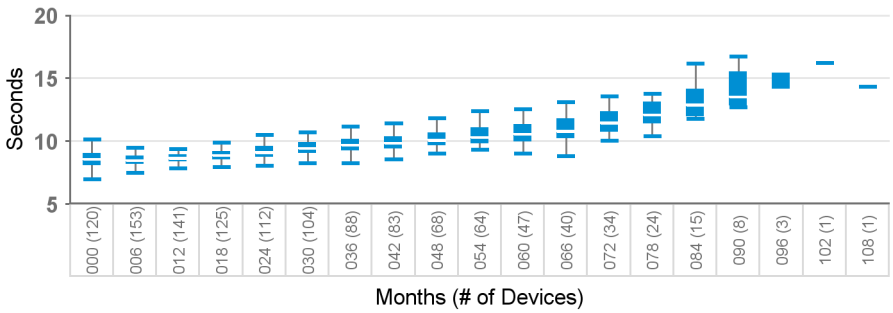
D264VRM, D284VRC, D384VRx, D394VRx

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



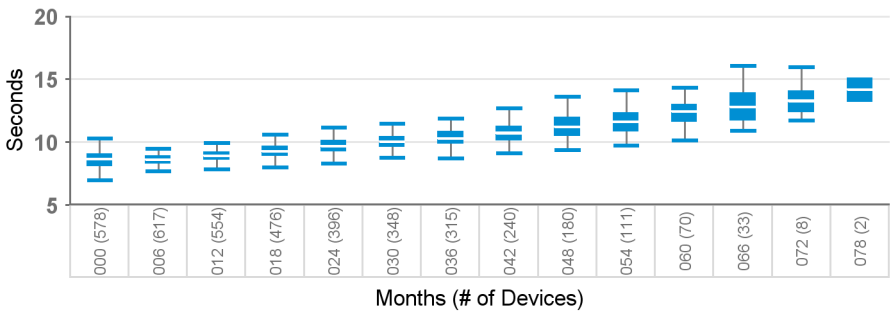
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



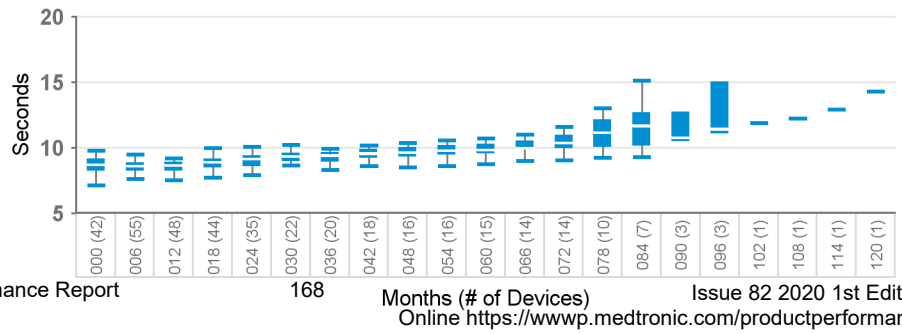
D274TRK, D294TRK

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



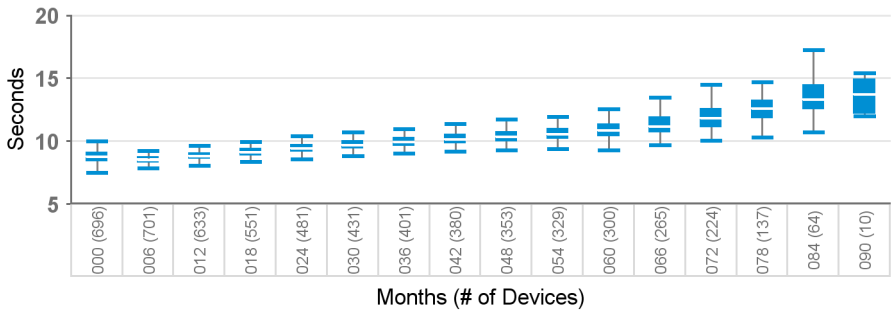
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



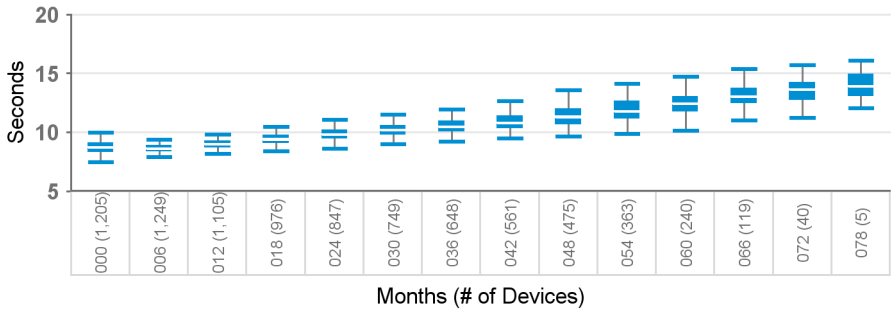
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



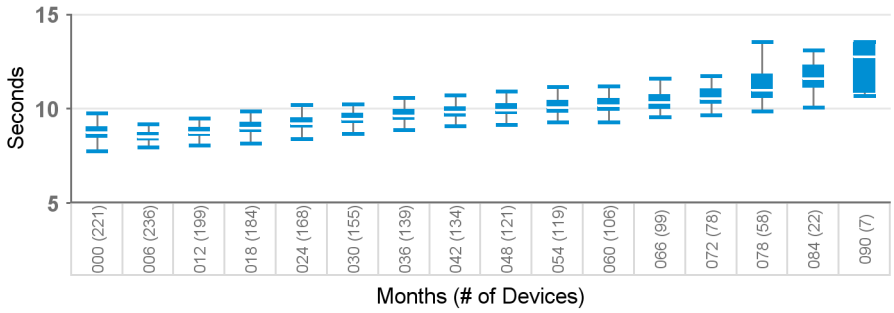
D314TRx

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



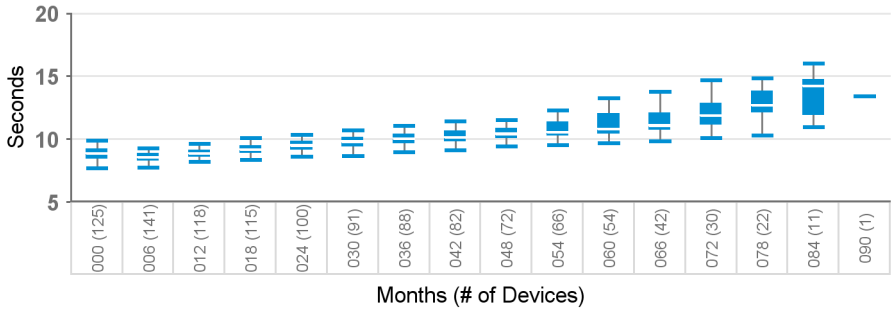
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



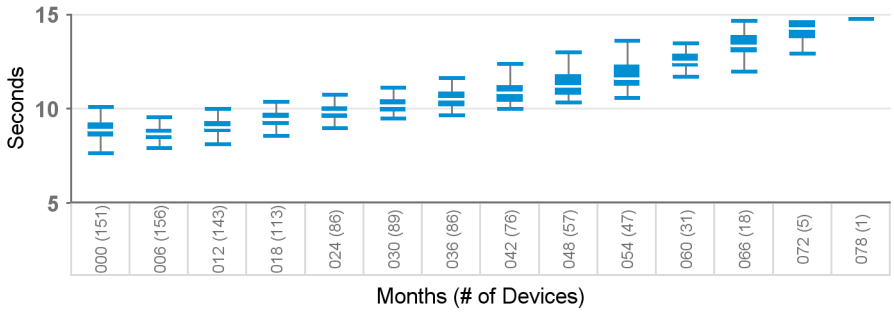
D334DRx, D364DRx

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



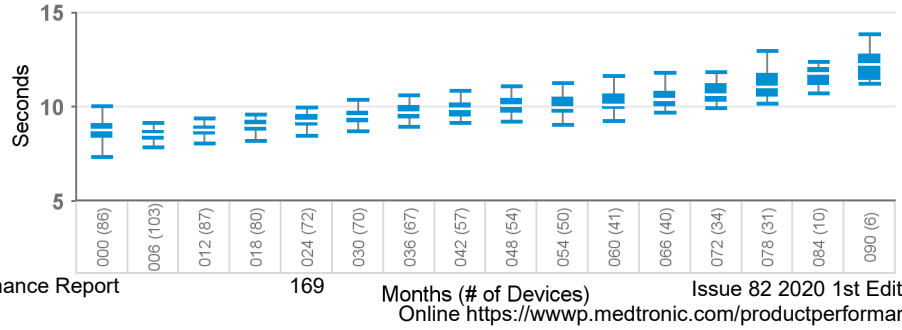
D334TRx, D364TRx

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



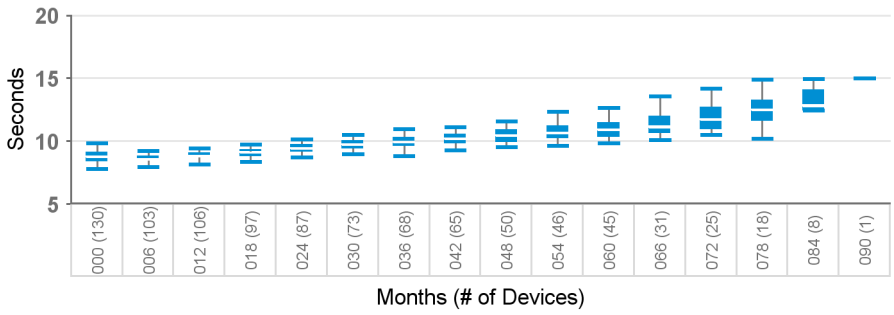
D334VRx, D364VRx

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



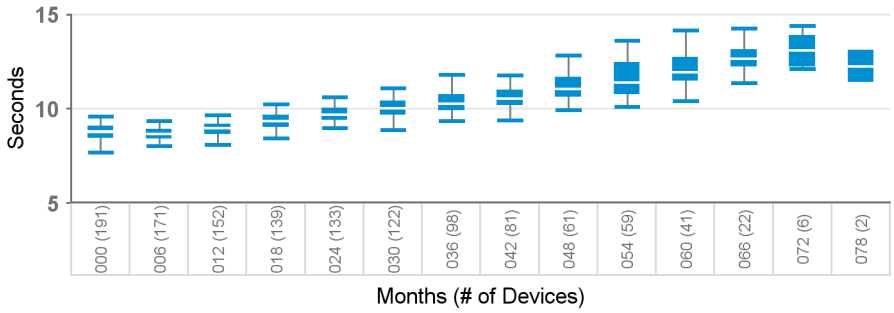
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



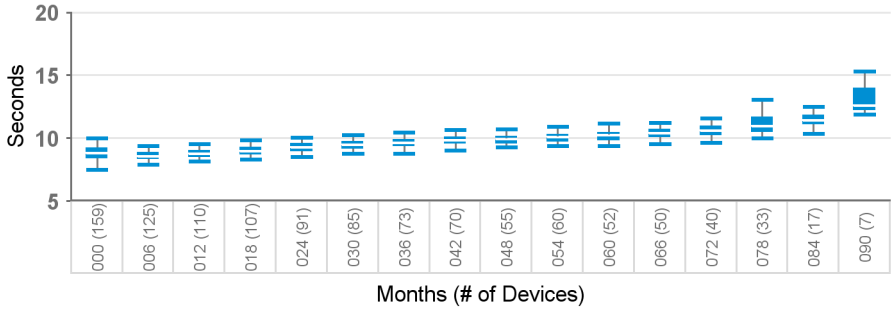
D354TRx

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



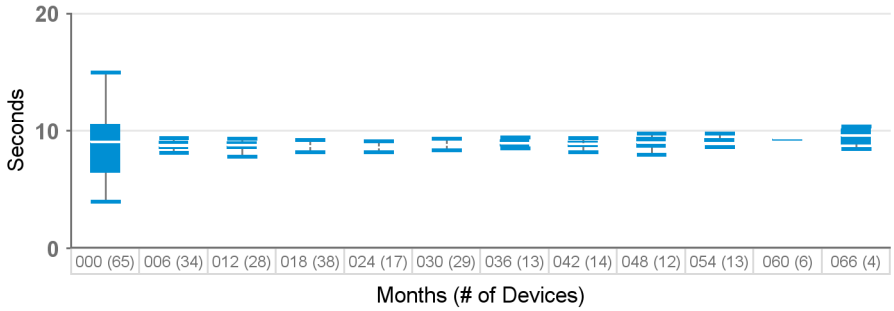
D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



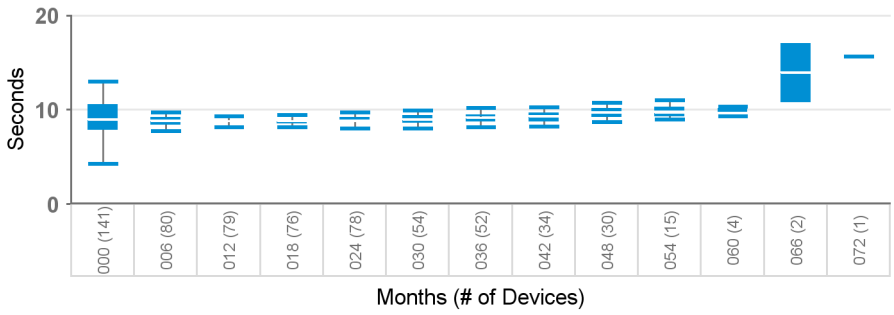
DDxxxxx, DR

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
DDMB2D1	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D1	Evera MRI S
DDMC3D4	Evera MRI
DDMD3D1	Primo
DDMD3D4	Primo
DDME3D4	Mirro



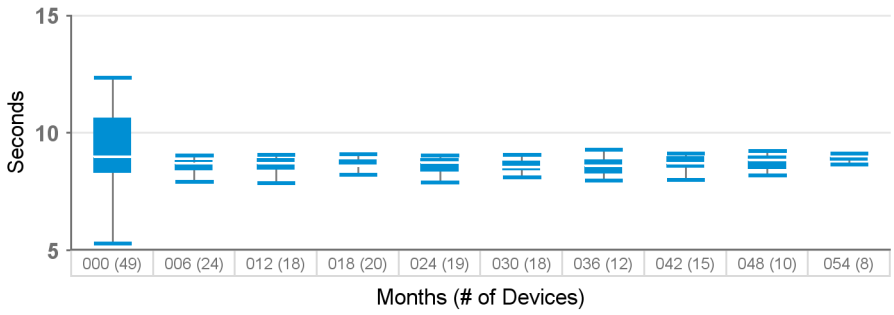
DTxxxxx, CRT-D

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
DTMC2D1	Compia MRI
DTMC2D4	Compia MRI
DTMC2QQ	Compia MRI



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
DVFB1D1	Visia MRI AF
DVFB1D4	Visia MRI AF
DVFB2D1	Visia MRI AF XT
DVFB2D4	Visia MRI AF XT
DVFC3D1	Visia MRI AF S
DVFC3D4	Visia MRI AF S
DVMB1D4	Evera MRI XT
DVMB2D1	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D1	Evera MRI S
DVMC3D4	Evera MRI S
DVMD3D1	Primo
DVMD3D4	Primo
DVME3D1	Mirro
DVME3D4	Mirro



Potential for Partial Reset During Programmer Interrogation

Claria MRI, Amplia MRI, Compia MRI and CRT-Ds

Original Date of Communication: March 2020

Model
CareLink™ 2090 Programmer with Software Application SW034 version 8.3
CareLink™ 29901 Programmer with Software Application SW034 version 8.3

STATUS UPDATE – MAY 2020

As documented in the original communication (March 2020), the risk for a partial reset on first interrogation with a programmer with software release SW034 version 8.3 is approximately 2%. As of April 24, 2020, there have been zero (0) adverse events reported as a result of this behavior.

Recommendations remain unchanged from the original posting. Medtronic recommends continued routine management of your patients. We recognize that a one-time loss of stored device information may limit your ability to assess your patient's clinical status – particularly when an audible alert, symptoms or VF shock delivery has been reported. Please work with your Medtronic Representative to identify data management options that may be available to your clinic.

ORIGINAL COMMUNICATION - MARCH 2020

This notice provides information regarding the potential for a one-time loss of diagnostic information due to a partial electrical reset that may occur for patients implanted with a Medtronic ClariaMRI, Amplia MRI or Compia MRI Cardiac Resynchronization Defibrillator (CRT-D). Based on data available as of March 2020, the calculated occurrence rate of this one-time partial reset is approximately 2%. **Device therapy and programmed settings are not affected by a partial electrical reset.**

A patient with a Claria MRI, Amplia MRI, or Compia MRI may experience a partial electrical reset when the patient has their device interrogated with a programmer that has been updated to software application SW034 version 8.3, and it is the **first** interrogation with this new software.

Background Information

Medtronic analysis identified that the 2% risk for a partial electric reset during the interrogation process is due to an uncommon scenario when a software update is installed simultaneously with routine critical memory scans. Should a reset occur, the clinician will be prompted to "Clear" the reset condition on the programmer (guidance to clear a partial reset is documented in the Instructions for Use for the above-named devices). When the "Clear" option is selected, the programmer will automatically interrogate the device again, and will successfully write the software enhancement to the device memory. Importantly, 98% of download attempts will successfully complete without an electrical reset. **Once the software update has been successfully installed into the device, the potential for a future partial reset due to this interaction no longer exists.**

Additional Details

As documented in the Instructions for Use, a partial electrical reset will result in the loss of stored diagnostic information and episodes. The device longevity estimator will show an "initializing" status for the next seven (7) days, and Recommended Replacement Time (RRT) status will continue to function as normal. Device programmed parameters, and all functions including detection and therapies are maintained. All Claria MRI, Amplia MRI and Compia MRI CRT-D devices are updated with the new software when interrogated for the first time by a programmer with software application SW034 version 8.3.

Medtronic recommends continued routine management of your patients. We recognize that a one-time loss of stored device information may limit your ability to assess your patient's clinical status – particularly when an audible alert, symptoms or VF shock delivery has been reported. Please work with your Medtronic Representative to identify data management options that may be available to your clinic.

Performance Note: Potential For Premature Battery Depletion in a Subset of ICD and CRT-D Devices

Battery Enhancements Implemented

Medtronic identified a rare failure mechanism in the battery design of specific implantable cardioverter defibrillator (ICD and cardiac resynchronization therapy defibrillator (CRT-D models that could result in rapid battery depletion. The rapid depletion is caused by a latent shorting mechanism resulting from lithium plating between the anode and cathode elements of the battery. As a result of our understanding of this phenomenon, Medtronic implemented battery design enhancements. All products currently in distribution contain the battery enhancement, however approximately 607,800 devices distributed worldwide were manufactured prior to implementing the battery enhancement and were distributed under the following brand names[1]:

- Claria MRI™/Amplia MRI™/Compia MRI™ CRT-Ds
- Viva™/Brava™ CRT-Ds
- Visia AF™/Visia AF MRI™ ICDs
- Evera™/Evera MRI™/Primo MRI™/Mirro MRI™ ICDs

Potential for Premature Battery Depletion in a subset of ICD and CRT-D devices prior to battery enhancement

Approximately 0.04% of devices exhibit this behavior. The battery continues to perform within projected estimates. There have been no reports of permanent harm to patients as a result of this issue.

Under rare circumstances, a small percentage of ICD and CRT-D devices manufactured prior to the battery enhancement may develop lithium plating. If lithium bridges between a positive (cathode) and a negative (anode) element in the battery, an internal short will develop and the battery will deplete rapidly. If this occurs, the device may not meet expected longevity or provide at least three months of device operation between the Recommended Replacement Time (RRT) and End of Service (EOS).

All events have occurred during the mid-portion of device life; typically, 1-4 years after implant. Note, there have been no reports of this issue occurring after RRT has triggered under normal conditions. Therefore, when a device reaches RRT based on its programmed settings and use conditions, the device is likely performing as expected and time between RRT and EOS should be as labeled.

Continue to Follow Normal Clinical Practice per Instructions for Use –Pay Attention to Unexpected RRT or Unexpected Changes in Longevity

- Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend prophylactic replacement of any ICD or CRT-D devices manufactured prior to the battery enhancement. Physicians can continue normal patient follow-up in accordance with standard practice.
- Where possible, take advantage of the CareLink™ home monitoring system and the low battery voltage wireless CareAlert to assist with remote management of patients.
- As always, remind patients to seek medical attention if they hear a device audible alert (shipped On with high urgency toning for low battery voltage indicator).
- At each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Monitor changes in device longevity and note any unexpected device status indicators such as RRT and/or EOS, the inability to interrogate the device or to transmit data.
- As with all unexpected events, including a rapid unexplained voltage drop, inform a Medtronic representative immediately if any of the above behaviors are observed. Further device analysis may be warranted to determine if immediate replacement is necessary.
- If there is evidence of rapid battery voltage drop, patients may need to have their devices replaced urgently as device failure may lead to intended therapy not being delivered.

Additional Details

Contact Medtronic Technical Services if you have concerns on a specific patient. A serial number look-up to assist with identifying if an ICD or CRT-D was manufactured prior to the battery enhancement is available at: https://wwwp.medtronic.com/productperformance/

Confirmed premature battery depletions, regardless of cause, are reported in our semi-annual Product Performance report under the confirmed "Malfunctions" section for each device model. Product Performance information can be accessed directly at: https://wwwp.medtronic.com/productperformance/

Q1) Can any ICD or CRT-D battery that uses lithium experience this rare, latent shorting mechanism?

Yes. Industry-wide, every ICD or CRT-D battery that uses lithium has the potential for plating to develop under normal use conditions and create an internal short. Lithium plating leading to an internal short is influenced by a number of factors including the battery design. There are differences in the battery design (e.g. layout and insulation) for each manufacturer. Note that the lithium plating phenomenon described in this Performance Note is different, and more rare, than lithium "cluster" formations that result from high current pulsing (charging) as has been described in literature.[2,3,4]

Q2) Are all device models equally susceptible to this rare failure mechanism?

Devices with higher use conditions (such as CRT-D devices) are less susceptible to the failure mode. This is because the free electrolyte element of the battery, which contributes to lithium plating, is consumed by the cathode more rapidly under high current conditions. Additionally, devices that reach RRT as expected, based on programmed settings and use conditions, are also not likely to experience lithium plating since the electrolyte is consumed as part of the normal discharge process of the battery.

[1]Device models vary by geography; not all models are available in all geographies.

[2]Aggarwal, A, et. al. Accelerated Implantable Defibrillator Battery Depletion Secondary to Lithium Cluster Formation: A Case Series. PACE 2016;39:375-7.

[3]Pokorney, SD, et. al. Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter defibrillators. Heart Rhythm 2014;11:2190-5.

[4]Hayashi, Y, et. al. A case of unexpected early battery depletion caused by lithium cluster formation in implantable cardioverter-defibrillator. J Cardiol Cases 2017;15:184-6.

STATUS UPDATE – MAY 2020

As of May 1, 2020, The Battery continues to perform within projected estimates and there have been no reports of permanent harm to patients as a result of this issue.

Confirmed premature battery depletions, regardless of cause, are reported in our semi-annual Product Performance report under the confirmed "Malfunctions" section for each device model. Product Performance information can be accessed directly at: productperformance.medtronic.com

CFx Longevity Estimator Software Error

Subset of IPG, ICD, CRT-P, CRT-D, and Micra TPS devices

Original Date of Advisory: October 2019

Affected Programmers & Remote Monitoring Software Apps	Affected Devices
2090 CareLink™ Programmer 29901 Encore™ Programmer CareLink Network Application Software 2491 CareLink SmartSync™ Device Manager MyCareLink Heart™ Mobile Application	**Subset of the following devices:** Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava™ CRT-Ds Visia AF™/ Visia AF MRI™/Evera™/ Evera MRI™/Primo MRI™/Mirro MRI™ ICDs Azure™/Astra™ IPGs Percepta™/Serena™/Solara™ CRT-Ps Micra™TPS

STATUS UPDATE – MAY 2020

As of April 22, 2020, there have been 83 total complaints received related to the software displaying a lower-than-expected longevity estimate. Within the 83 complaints reported, no patient harm was reported and two (2) devices were prematurely explanted after observing an inaccurate longevity estimate. The devices were explanted prior to the device reporting Recommended Replacement Time (RRT); i.e. the clinician took action before RRT was triggered.

As disclosed in the original communication, Medtronic remains on track to begin the release of software updates to correct for this issue in mid-calendar year 2020.

Patient management recommendations remain unchanged from the original October 2019 communication.

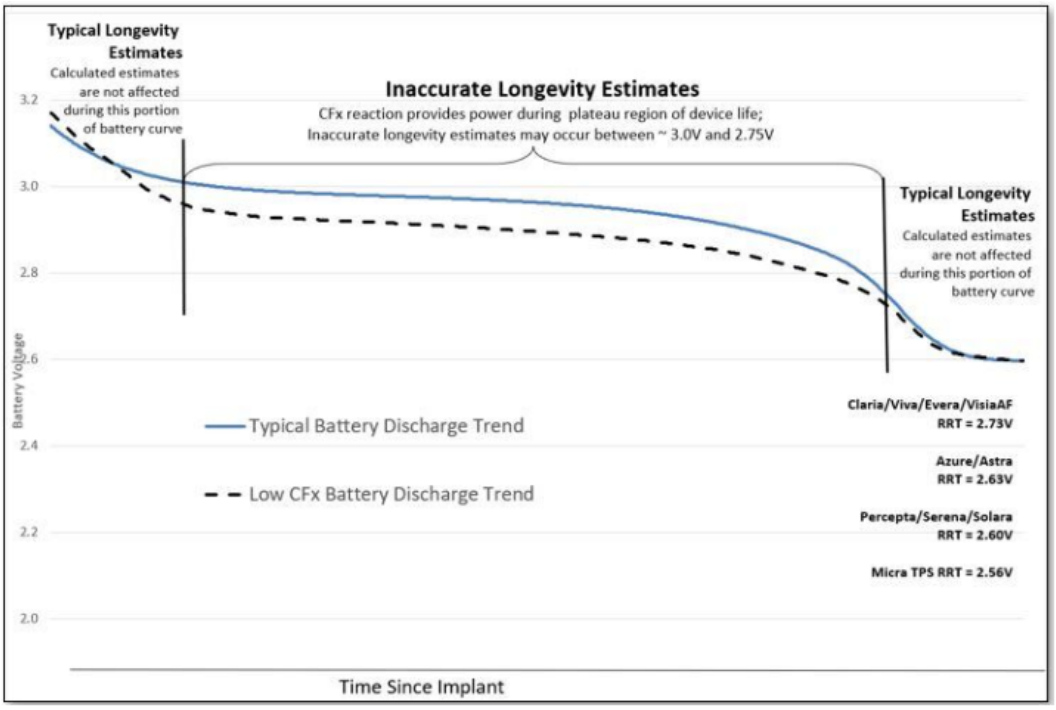
ORIGINAL ADVISORY – OCTOBER 2019

Medtronic identified the potential for Medtronic programmer and remote monitoring software applications to display an inaccurate remaining longevity estimate for a subset of implanted cardiac device models. This issue does not impact device functionality. Furthermore, the Recommended Replacement Time (RRT) remains an accurate indicator for device replacement.

Through September 18, 2019 there have been three (3) reported complaints and there have been no (0) serious adverse events or deaths.

The inaccurate longevity estimation is limited to a well-defined subset of devices manufactured between October 2018 and April 2019, and only occurs in the middle (plateau) phase of the device life, as illustrated in the graph below. Approximately 53,100 devices worldwide, out of 1.23 million distributed or sold from the identified device families, are susceptible to displaying inaccurate longevity.

The cause of the inaccurate longevity estimate is a slightly lower-than-typical discharge voltage during the plateau phase of the battery depletion curve (dashed line), compared to a typical voltage plateau (solid line), as illustrated in the graph below. During this plateau period, the Carbon Monofluoride (CFx) in the battery cathode is powering the device. Note, longevity estimates early after implantation and later in the device life are unaffected, as shown below. The battery remains within operating specifications.



Software updates to programmers and remote monitoring systems are under development to correct for the inaccuracy in longevity estimates. Medtronic is targeting regulatory approval and release of the software updates to begin in mid-2020. Once available, Medtronic will inform you of the availability of the software and work with you to install the software onto clinic and hospital programmers. Software updates to individual patient devices will not be necessary to correct this issue, since longevity estimation resides on the programmers, mobile app and the CareLink Network.

Internal analysis estimates approximately 11% of the 53,100 identified devices are projected to display an inaccurate longevity estimate before mid-2020.

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel, Medtronic provides the following guidance:

- **Prophylactic device replacement is not recommended,** as device functionality, true longevity and the RRT indicator are not impacted by the inaccurate longevity estimate.

Until the software update becomes available:

- Continue normal patient follow-up in accordance with standard practice.
- Per labeling, continue to use the RRT notification to identify when device replacement should be scheduled. Where available, utilize the low battery voltage RRT audible alert or wireless CareAlert™.
- At any time, if a lower-than-expected remaining longevity estimate occurs, contact Medtronic Technical Services for assistance – additional analysis of stored device information will be required to assess if the decreased longevity estimate is due to this issue.

Note: For Azure IPG or Percepta/Serena/Solara CRT-P patients remotely monitored via the MyCareLink Heart mobile app, patients' mobile app longevity estimates will not change until the software update has been released.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

Performance Note: Potential for no output/no telemetry condition in subset of IPG and CRT-P products due to ceramic capacitor leakage pathway

Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ CRT-P

Original Date of Communication: May 2019

Medtronic has identified a rare but potentially serious failure mode in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor. These devices continue to perform within reliability projections.

While inherently very reliable, a known failure mode of these capacitors is the potential for internal cracking that can be caused by thermal-mechanical stress during manufacturing. Under rare conditions, internal cracking within a capacitor may result in the development of a leakage pathway, causing high current drain and leading to rapid battery depletion. While the issue presents as rapid battery depletion, this is not a battery performance issue.

As of April 26, 2019, three complaints out of ~266,700 devices distributed worldwide since February 2017, have been received that included a no output /no telemetry scenario resulting from rapid battery depletion. Battery depletion due to this issue can range from several days to several weeks. One of these reported events contributed to a patient death. The three confirmed failures occurred within 9 months post implant. The projected rate for this issue is 0.0028%, with the most susceptible period for a leakage pathway to develop in the capacitor being the first 12 months post implant.

Based on the low predicted rate of failure and the recent implementation of process and component enhancements, Medtronic expects few, if any, additional events to occur. Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend device replacement. Physicians should continue normal patient follow-up in accordance with standard practice, and where possible, continue to utilize the low battery voltage wireless CareAlert™ (shipped ON), together with remote monitoring via CareLink™ home monitor or the MyCareLink Heart™ mobile app. Per the instructions for use, at each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Pay attention to any unexpected changes in remaining longevity estimates or the inability to interrogate the device and/or transmit data.

Contact Medtronic Technical Services if you have concerns on a specific patient.
Brady Technical Services |rs.techservices@medtronic.com| 800-505-4636

STATUS UPDATE – MAY 2020

As of May 1, 2020, there have been a total of 13 confirmed events worldwide associated with this failure mode. One of the additional confirmed events was reported as patient death*.

Product manufactured after June 1, 2019, is not susceptible to this issue as these products utilize a different low voltage capacitor. Product manufactured prior to June 1, 2019 (i.e. manufactured with the original low voltage capacitor) continues to perform within our reliability projections as established as part of the product development process.

Confirmed premature battery depletions, regardless of cause, are reported in our semi-annual Product Performance report under the confirmed "Malfunctions" section for each device model. Product Performance information can be accessed directly at: https://
wwwp.medtronic.com/productperformance/

*Cause of death was reported as acute cerebrovascular accident, which occurred several days prior to hospital admission. Manner of death was reported as natural; loss of pacing therapy could not be ruled out as a contributing factor.

Dual Chamber IPG Circuit Error

Adapta, Versa, Sensia, Relia, Attesta, Sphera, and Vitatron A, E, G, Q series

Original Date of Advisory: January 2019

Product

A subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q series may experience a circuit error that affects device functionality. Please note that not all devices within these brand names are affected by this recall. 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 subset, when programmed to a dual chamber mode with atrial-sensing, may experience a circuit error that affects device functionality. See Table 1 for modes that are susceptible to this circuit error. For this error to occur, a unique combination of events must take place while the device is processing an atrial-sensed event. If this error occurs, the device will be unable to provide pacing until a ventricular-sensed event (VS) is detected. Once a VS is detected, normal pacing functionality is restored immediately. If a VS is not detected, the device will withhold both atrial and ventricular pacing. In addition, until a VS is detected, the device will be unable to initiate a session with a programmer, initiate a session with a CareLink™ remote monitor, or respond to a magnet. Single chamber and dual chamber pacing modes that do not sense atrial activity are not susceptible to this circuit error (see Table 1).

Table 1: Identification of modes susceptible/not susceptible to circuit error

Modes susceptible to circuit error	Modes NOT susceptible to circuit error
DDD, DDDR	VVI, VVIR
DDI, DDIR	DVI, DVIR
VDD	AAI, AAIR
ADI, ADIR	VOO, VOOR
VDI, VDIR	AOO, AOOR
ODO	DOO, DOOR
OAO	OVO
MVP - when operating in DDD, DDDR, DDI or DDIR mode	VVT, AAT

Through 4 January 2019, Medtronic is aware of four (4) reported occurrences in two (2) patients where a pause in pacing therapy was clinically apparent due to this circuit error. These reported events occurred in three (3) devices from a total of 156,957 devices sold worldwide. No deaths have been reported as a result of this issue.

Patient risk is determined by the patient's underlying cardiac rhythm and whether the device is in a susceptible pacing mode as described above. Through our analysis of this issue, Medtronic estimates that on average, a device in a susceptible pacing mode has a 2.8% chance per month of experiencing a pacing pause of 1.5 seconds or longer. Risk is minimized in patients who have an escape rhythm adequate to prevent syncope during a loss of ventricular pacing, since a VS restores full device functionality. No risk of a pause due to this circuit error exists for patients programmed to a non-susceptible pacing mode.

The root cause for this issue is related to a design change to an integrated circuit in a subset of devices that were distributed between 10 March 2017 and 7 January 2019.

Medtronic is developing a software update that can be installed into affected devices to correct this issue. Medtronic estimates submission of this software update to regulatory agencies by the 2nd half of 2019. Upon subsequent regulatory approval, Medtronic will notify customers of its availability. Until that time, Medtronic is providing the patient management recommendations described below and depicted in Appendix A.

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), **Medtronic recommends programming to a non-susceptible pacing mode as the primary mitigation for patients implanted with an affected device until the software update has been installed.** Specific patient risk assessment and programming recommendations are outlined below and provided in Appendix A.

• For patients whose device is programmed to a non-susceptible mode (see Table 1), no action is needed at this time. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode and are continually in persistent atrial fibrillation, reprogramming the device to the non-susceptible VVI or VVIR mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode and either: have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs, programming to a non-susceptible mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

• For patients who do not tolerate programming to a non-susceptible pacing mode and either: have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs, continue clinical monitoring in a susceptible mode until the software update is available, or consider device replacement.

o The estimated per patient mortality risk due to this issue is 0.021% when programmed to a susceptible pacing mode over the estimated time until the software update becomes available. This risk is comparable to the Medtronic estimated per-patient mortality risk associated with a device replacement (0.027%) *.

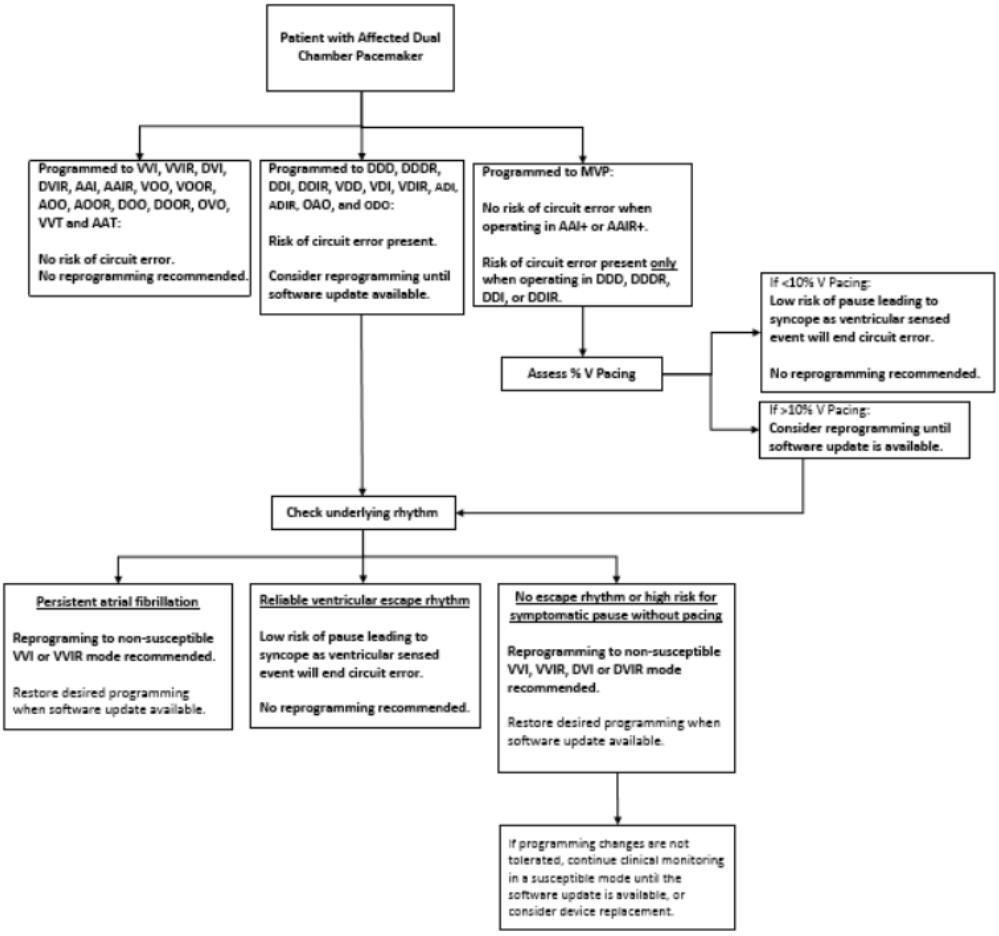
o If a patient reports symptoms consistent with a pacing pause, and you would like assistance assessing whether a patient had a pause due to this issue, contact your Medtronic representative.

• Advise patients remaining in a susceptible mode to seek immediate medical attention if they experience new or unexpected symptoms consistent with a pacing pause.

• Other than reprogramming to a non-susceptible pacing mode, no additional programming options have been identified to mitigate this issue.

*Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; MRCS: MDT2260884, Version 2.0, 11/02/2015.

Appendix A: Programming decision flow chart



STATUS UPDATE – MAY 2020

- In September 2019 Medtronic released several software updates to correct for this issue. These software applications are:
  - For Adapta/Versa/Sensia IPGs - Software model SW003 v8.2
  - For Relia IPGs - SW010 v8.2
  - For Attesta/Sphera IPGs - SW043 v8.2
  - For Vitatron IPGs – VSF20 v8.2 and FSF21 v8.2
- Once a device is interrogated by a programmer with the updated software, any pacemaker programmed to a non-susceptible pacing mode, specifically to avoid a circuit error, may be reprogrammed to any pacing mode.
- Once a device is updated (update is installed onto devices via interrogation by a programmer with one of the above software applications), if the circuit error were to occur, the pacing cycle will automatically reset; this may be observed as a single dropped beat.
- As of May 1, 2020, 89,000 devices remain active out of an original population of 156,957 devices worldwide.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
156,957 Worldwide	35 Worldwide	89,000 Worldwide	0.02%Worldwide

Potential Loss of Device Functionality Lower Risk Subset

Amplia, Claria, Compia, and Viva CRT-D, and Evera and Visia ICD

Original Date of Advisory: March 2018

Product
In January 2018, Medtronic completed notification to physicians about a subset of 48 Medtronic Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs) underwent a specific sequence of manufacturing processes that could result in an unexpected loss of device functionality, including high-voltage therapy.

Within this Lower-Risk Subset of 752 devices, if the device delivered the maximum number of shocks until battery depletion, we estimate 0.5% of these devices would experience arcing during high voltage charging, with failure occurring within the first two (2) high-voltage charges in 0.18% of the devices. See table below for comparison of device subsets.

Through 8 March 2018, there have been zero (0) complaints related to internal arcing in these 752 devices. While the risk for failure is lower in this group of devices, it is not possible to identify which of these 752 devices may fail or when they may fail. Successful delivery of previous high-voltage therapy does not ensure future performance.

You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ to determine if a specific device is affected.

January 2018 **48 Implanted Higher-Risk Devices**	**March 2018** **752 Lower-Risk Devices**
One field failure has been observed with no deaths reported 7.7% of these devices are projected to fail during the first two high-voltage charges	No field failures have been observed 0.18% of these devices are projected to fail during the first two high-voltage charges
Medtronic communicated a recommendation to strongly consider prophylactic replacement in these devices.	Patient management recommendations follow below.

Patient Management Recommendations – Lower Risk Subset
We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic provides the following recommendations to physicians for patients who have been implanted with one of the identified devices:

- Prophylactic device replacement should be considered for patients at higher risk, including patients whose clinical history indicates prior need for high-voltage therapy and/or for pacemaker-dependent patients.
- Physicians should carefully weigh the risks and benefits of device replacement. The estimated per patient risk for mortality due to this issue is 0.02% to 0.04% considering the risk of device failure and the likelihood of a patient requiring high voltage therapy. This is comparable to the estimated per patient mortality risk of complications associated with a device replacement (0.04%)[i],[ii].
- For patients in whom it is determined that replacement is not warranted:
  - Consider programming changes to reduce the potential for high-voltage charges associated with arrhythmia detection and therapies, such as enabling ATP *before* charging for fast ventricular rhythms or programming a separate fast VT via VF zone with ATP. For assistance with patient-specific programming needs, contact Medtronic Technical Services at 800-723-4636.
  - Continue three-month in-clinic or remote follow-ups to verify device functionality. Inability to interrogate a device or a failed remote monitoring transmission may be an indication that internal arcing has occurred.

Devices that have failed will not send an alert as telemetry and all device functionality is immediately lost if internal arcing occurs.

- Advise patients to seek medical attention immediately if they experience new or unexpected symptoms suspicious for a ventricular arrhythmia.

STATUS UPDATE - MAY 2020

Within the 752 lower-risk devices, there have been zero confirmed failures (0%) through April22, 2020. An estimated 508 devices remain active

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
752 Worldwide (all in USA, Puerto Rico or US Virgin Islands.)	**0**	508	**0%** Worldwide

[i]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; MRCS: MDT2260884, Version 2.0, 11/02/2015.

[ii]Birnie, D et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm, Volume 5, Issue 3, Pages 387-390.

Potential Loss of Device Functionality

Amplia, Claria, Compia, and Viva CRT-D, and Evera and Visia ICD

Original Date of Advisory: January 2018

Product
A subset of 48 Medtronic Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs) underwent a specific sequence of manufacturing processes that could result in an unexpected loss of device functionality, including high-voltage therapy. 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. No other Medtronic devices are included in this advisory.

Advisory
These 48 devices were sent through a manufacturing sequence that introduced the potential for internal arcing during highvoltage charging, leading to the immediate and permanent loss of device functionality. Through 12 January 2018, Medtronic has confirmed one (1) implanted device failure resulting in loss of high-voltage therapy related to this issue, where the patient was rescued with external defibrillation.

Due to the nature of this issue, it is not possible to identify which of these 48 devices may fail or when they may fail. Further, we cannot predict how many high-voltage charges can occur prior to a potential failure. Based on testing of a limited number of available devices that underwent this manufacturing sequence, this failure was observed during high-voltage cycle testing to battery depletion in 23% of these devices, with failure observed within the first two (2) high-voltage charges in 7.7% of the tested devices. Successful delivery of previous high-voltage therapy does not guarantee future performance.

PATIENT MANAGEMENT RECOMMENDATIONS

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic provides the following recommendation:

• Prophylactic device replacement should be strongly considered for patients who have been implanted with one of the devices in the affected subset.

STATUS UPDATE - MAY 2020

Within the 48 devices, there has been 1 confirmed failure (2.1%) through April 22,2020. An estimated 3 devices remain active.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
48 Worldwide (all USA)	**1**	**3**	**2.1%** Worldwide

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 at http://wwwp.medtronic.com/productperformance 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 - MAY 2020

Within the 78 devices, there have been 10 confirmed failures (13%) through April 22,2020. Medtronic modeling predicts an additional three (3) failures may occur in the remaining active population. An estimated 28 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	**28** Worldwide	**13%** Worldwide

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 - MAY 2020

As of April 22, 2020, approximately 900 devices remain active worldwide, from an original implant population of 96,800. In the United States, 400 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.

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)	**171** Worldwide (**95** United States)	**900** Worldwide (**400** United States)	**0.18%** Worldwide (**0.24%** United States)

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 - MAY 2020

As of April 22, 2020, of the initial implant population of 205,600 in the United States, approximately 46,000 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 73.1% (+4.9/-4.6%) at 126 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)	**7,235** Worldwide **(5,149** United States)	**63,000** Worldwide (**46,000** 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.

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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