CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2019

2nd Edition – Issue 81

Medtronic

CRHF Product Performance Report

2019

2nd Edition

Issue 81

Cutoff date for this edition is 31 July 2019 for Lead Study data and 8 November 2019 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

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Europe (Heerlen NL) +31-45-566-8844
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rs.mst-techserviceseurope@medtronic.com

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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

Advisory Summaries

This Product Performance Report includes summaries of all advisories applicable to the performance of the products included in the report. An advisory is added to the report when any product affected by the advisory remains in service and at risk of experiencing the behavior described in the advisory. The advisory will remain in the report until Medtronic estimates no product affected by the advisory remains active, or the risk of experiencing the behavior described in the advisory has passed.

For most advisories, the products subject to the advisory retain essentially the same survival probability as the products of the same model(s) not affected by the advisory. For those advisories where the survival probabilities of the affected and non-affected populations do differ significantly, Medtronic will provide separate survival data for each population. The separate survival data will remain in the report until Medtronic estimates no affected product remains in active service.

Performance Notes

This report concludes with a number of Performance Notes developed by Medtronic to provide additional product performance information relevant to follow-up practice and patient management.

How You Can Help

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

Mailer kits with prepaid US postage are available for use within the United States to send CRTs, ICDs, IPGs, ICMs, and leads to Medtronic's Cardiac Rhythm and Heart Failure (CRHF) Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

If the product being returned is located outside the United States, please contact your local Medtronic representative for instructions.

Medtronic also requests the return of explanted products from non-clinical sources, such as funeral homes, and will assume responsibility for storage and disposal of the product once received.

Mailer kits can be obtained by contacting the Returned Product Lab. For information on how to contact the Lab, refer to the Contact Information page of this report.

We continually strive to improve this CRHF Product Performance Report. In keeping with this philosophy, we ask for your suggestions on the content and format of this report, as well as any information you have regarding the performance of Medtronic products. For information on how to comment on this report, see the Contact Information page.

Overview of Survival Analysis

Medtronic uses the Cutler-Ederer actuarial life table method for devices and Kaplan-Meier for leads to estimate the length of time over which they will perform within performance limits established by Medtronic. This probability to perform within performance limits over time is called the survival probability.

Devices and leads are followed until an event occurs where the device or lead ceases to operate within performance limits. The length of time from implant to the event is recorded for individual devices and leads in the population sample. The population sample for CRT, ICD, and IPG devices is made up of patients whose devices are registered as implanted in the United States. For leads, the population sample is the patients enrolled in our multicenter, international prospective Product Surveillance Registry.

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.

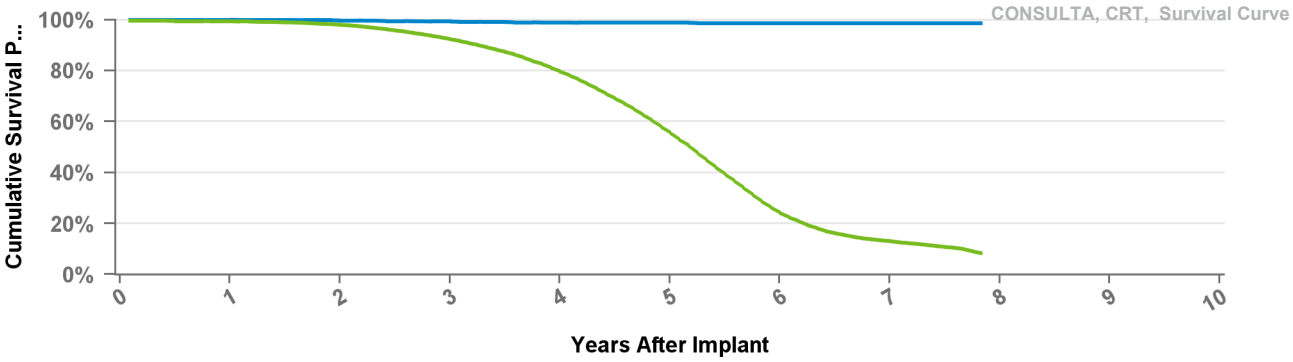
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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

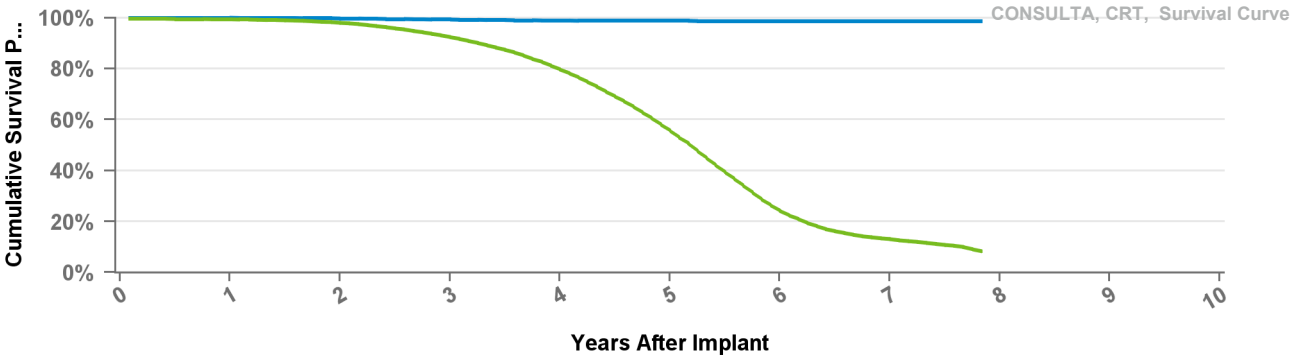
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,099	Battery Malfunction	1
Estimated Active USA Implants	655	Electrical Component	1
Normal Battery Depletions	694	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.994	0.98	0.924	0.797	0.557	0.242	0.131	0.083
Effective Sample Size	57731	52576	45650	35088	19814	6476	1857	149

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			

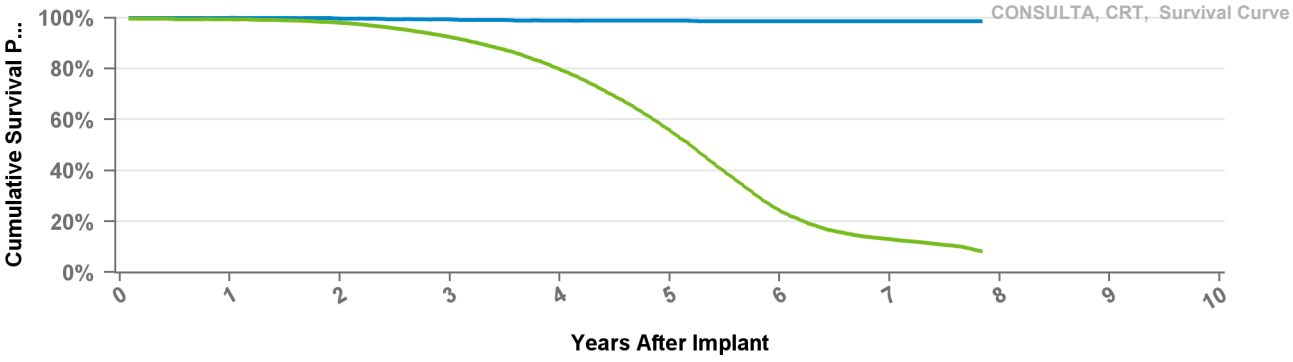


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.994	0.98	0.924	0.797	0.557	0.242	0.131	0.083
Effective Sample Size	57731	52576	45650	35088	19814	6476	1857	149

D224TRK Consulta CRT-D

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	65,980
Estimated Active USA Implants	11,655
Normal Battery Depletions	18,668

Total Malfunctions	**602**
Therapy Function Not Compromised	**571**
Battery Malfunction	2
Electrical Component	65
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	496
Software Malfunction	6
Therapy Function Compromised	**31**
Battery Malfunction	5
Electrical Component	26

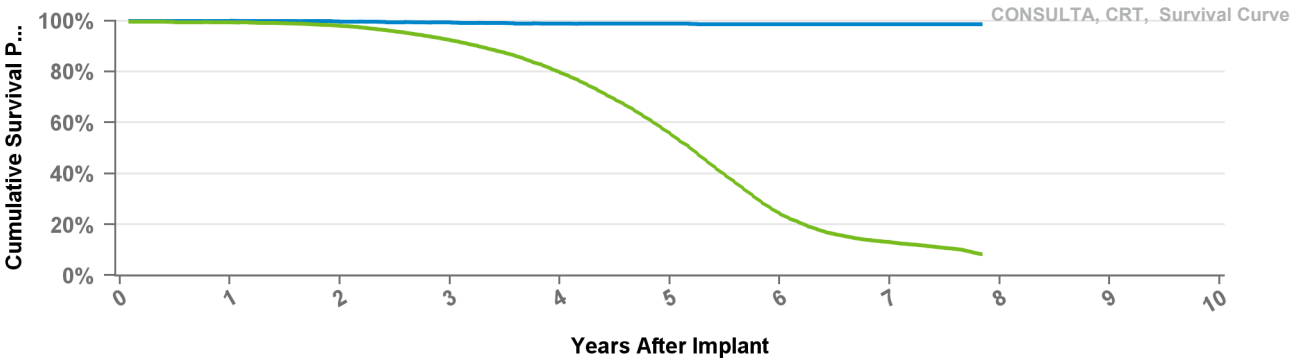


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.994	0.98	0.924	0.797	0.557	0.242	0.131	0.083
Effective Sample Size	57731	52576	45650	35088	19814	6476	1857	149

D234TRK Consulta CRT-D

US Market Release	
CE Approval Date	Mar-08
Registered USA Implants	3
Estimated Active USA Implants	1
Normal Battery Depletions	

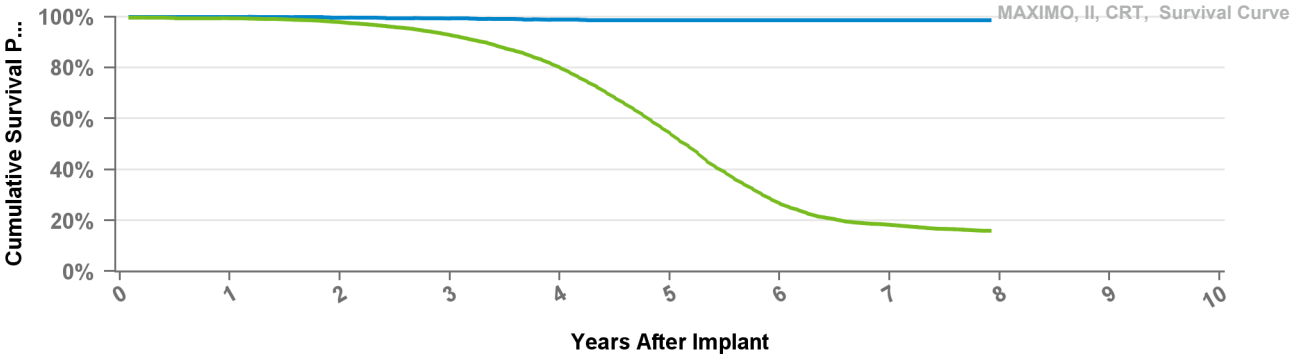
Total Malfunctions	
Therapy Function Not Compromised	
Therapy Function Compromised	



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.994	0.98	0.924	0.797	0.557	0.242	0.131	0.083
Effective Sample Size	57731	52576	45650	35088	19814	6476	1857	149

D264TRM Maximo II CRT-D

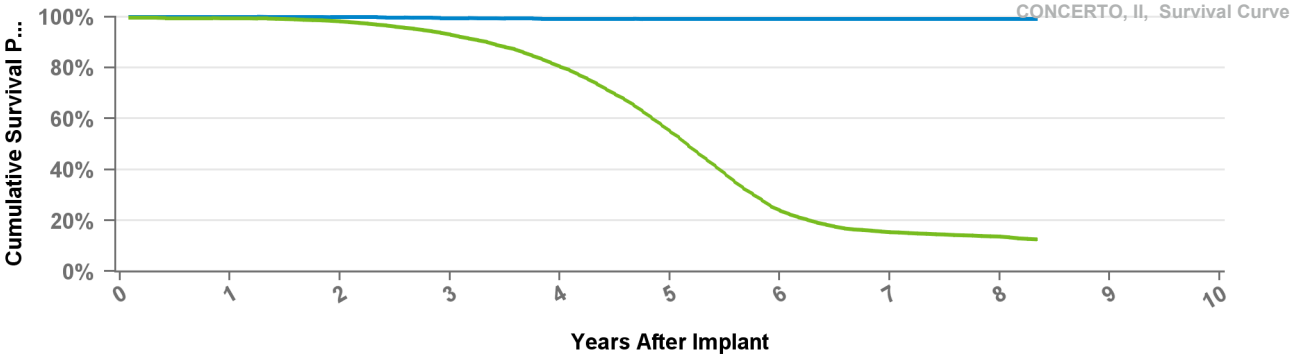
US Market Release	Jan-12	**Total Malfunctions**	**1**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other Malfunction	1
Estimated Active USA Implants	4	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	1	0.997	0.993	0.988	0.987	0.987	0.987	0.987
Including NBD	0.994	0.979	0.928	0.8	0.542	0.266	0.183	0.16
Effective Sample Size	12872	11616	10111	7710	4090	1449	607	118

D274TRK Concerto II CRT-D

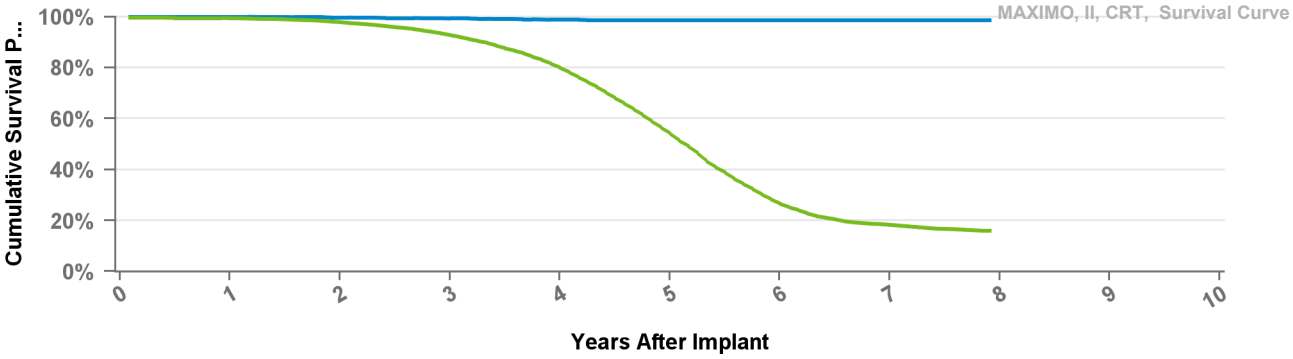
US Market Release	Aug-09	**Total Malfunctions**	**186**
CE Approval Date		**Therapy Function Not Compromised**	**175**
Registered USA Implants	30,172	Battery Malfunction	1
Estimated Active USA Implants	6,038	Electrical Component	22
Normal Battery Depletions	7,930	Poss Early Battery Depltn	151
		Software Malfunction	1
		Therapy Function Compromised	**11**
		Battery Malfunction	1
		Electrical Component	10



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	1	0.998	0.995	0.992	0.991	0.991	0.991	0.991	0.991
Including NBD	0.994	0.982	0.93	0.804	0.55	0.239	0.154	0.137	0.126
Effective Sample Size	25316	23132	20154	15380	8179	2615	1330	778	214

D284TRK Maximo II CRT-D

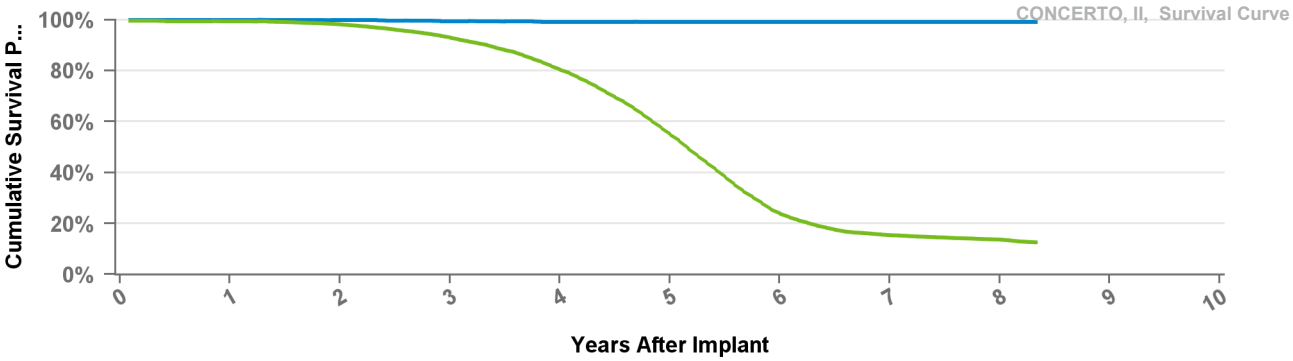
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,250	Electrical Component	6
Estimated Active USA Implants	2,940	Poss Early Battery Depltn	124
Normal Battery Depletions	4,033	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	1	0.997	0.993	0.988	0.987	0.987	0.987	0.987
Including NBD	0.994	0.979	0.928	0.8	0.542	0.266	0.183	0.16
Effective Sample Size	12872	11616	10111	7710	4090	1449	607	118

D294TRK Concerto II CRT-D

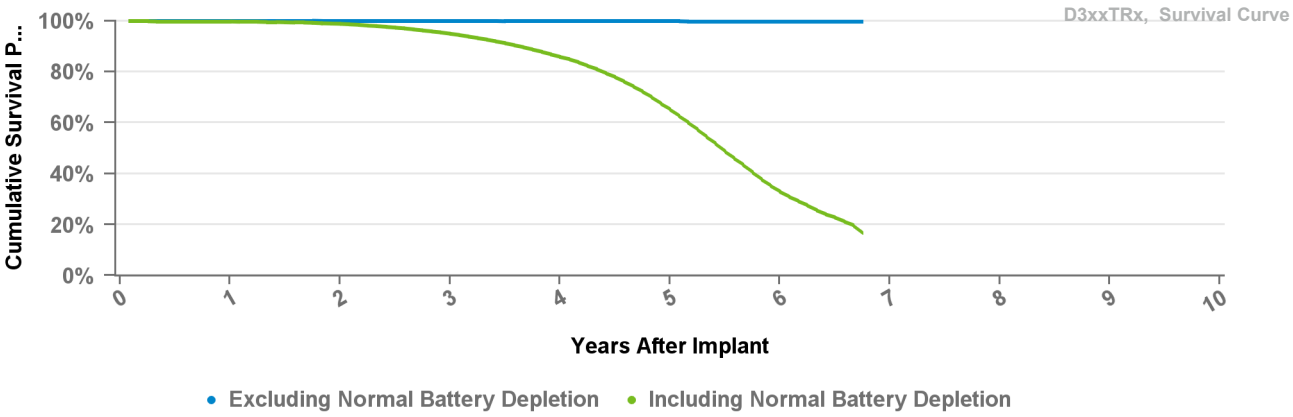
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	1	0.998	0.995	0.992	0.991	0.991	0.991	0.991	0.991
Including NBD	0.994	0.982	0.93	0.804	0.55	0.239	0.154	0.137	0.126
Effective Sample Size	25316	23132	20154	15380	8179	2615	1330	778	214

D314TRG Protecta XT CRT-D

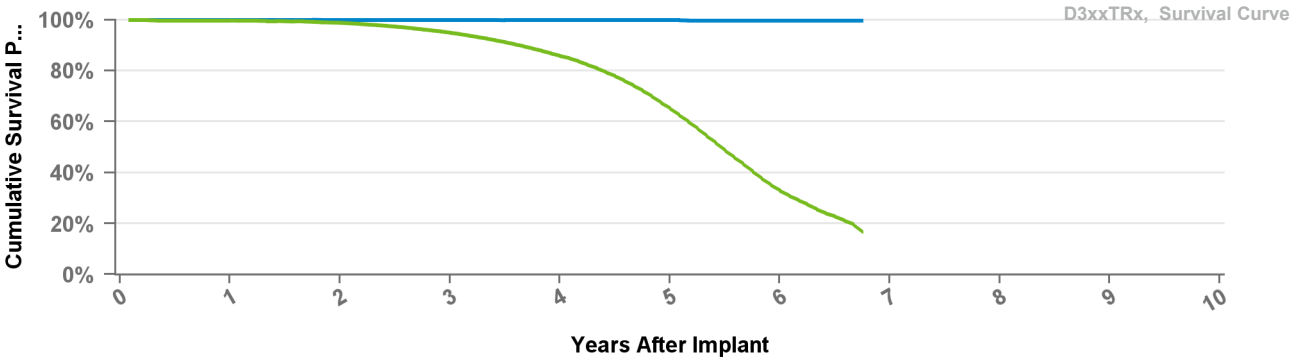
US Market Release	Mar-11	**Total Malfunctions**	**91**
CE Approval Date		**Therapy Function Not Compromised**	**73**
Registered USA Implants	42,519	Battery Malfunction	7
Estimated Active USA Implants	12,528	Electrical Component	39
Normal Battery Depletions	9,968	Other Malfunction	2
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**18**
		Battery Malfunction	10
		Electrical Component	8



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D314TRM Protecta XT CRT-D

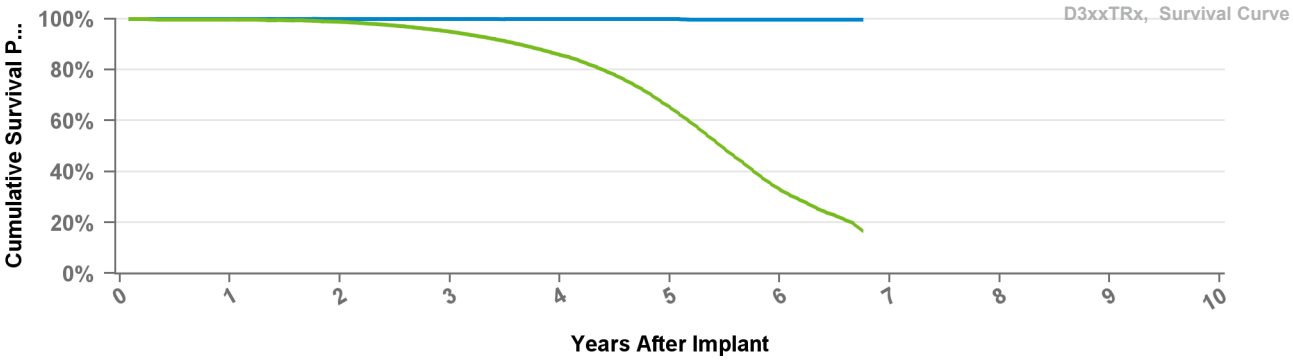
US Market Release	Nov-11	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,260	Battery Malfunction	4
Estimated Active USA Implants	3,920	Electrical Component	8
Normal Battery Depletions	3,301	Poss Early Battery Depltn	5
		Therapy Function Compromised	**3**
		Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D334TRG Protecta CRT-D

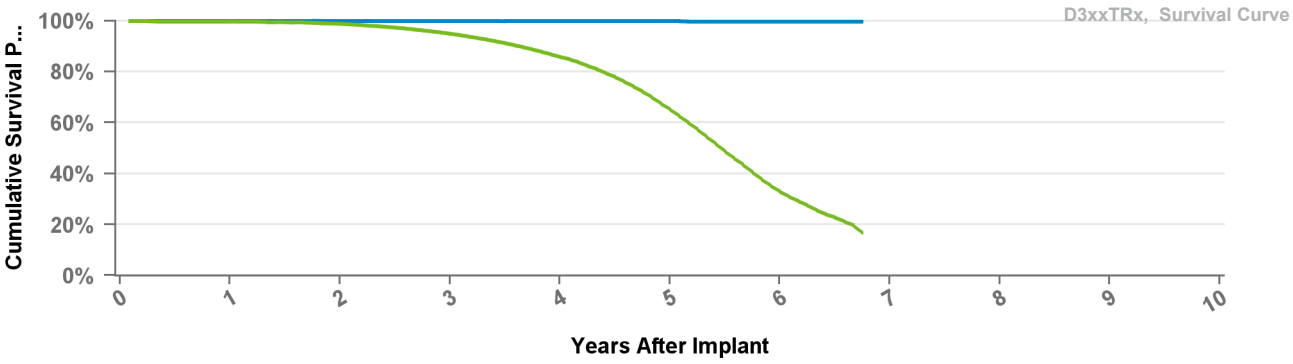
US Market Release	Mar-11	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,099	Electrical Component	8
Estimated Active USA Implants	2,665	Poss Early Battery Depltn	3
Normal Battery Depletions	1,979	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D334TRM Protecta CRT-D

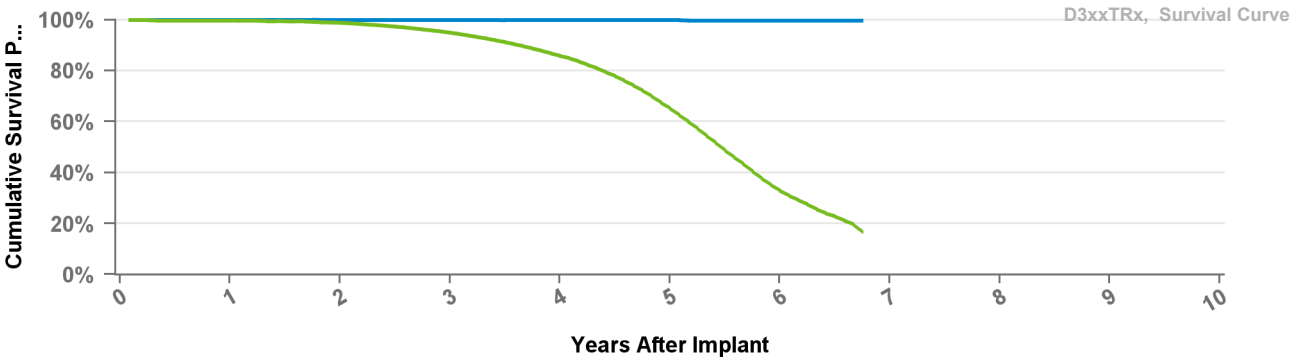
US Market Release	Nov-11	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	1,786	Battery Malfunction	3
Estimated Active USA Implants	605	Electrical Component	1
Normal Battery Depletions	520	Poss Early Battery Depltn	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D354TRG Protecta XT CRT-D

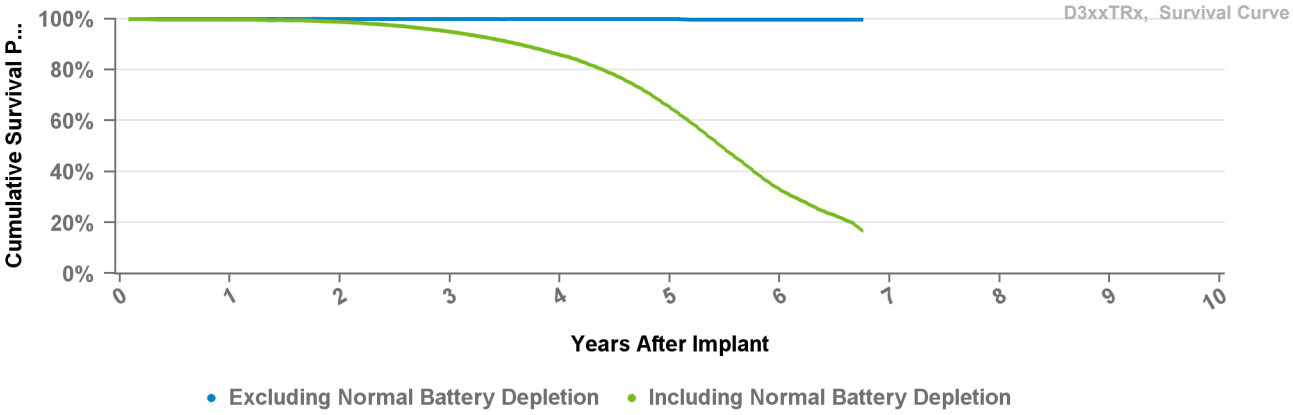
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D354TRM Protecta XT CRT-D

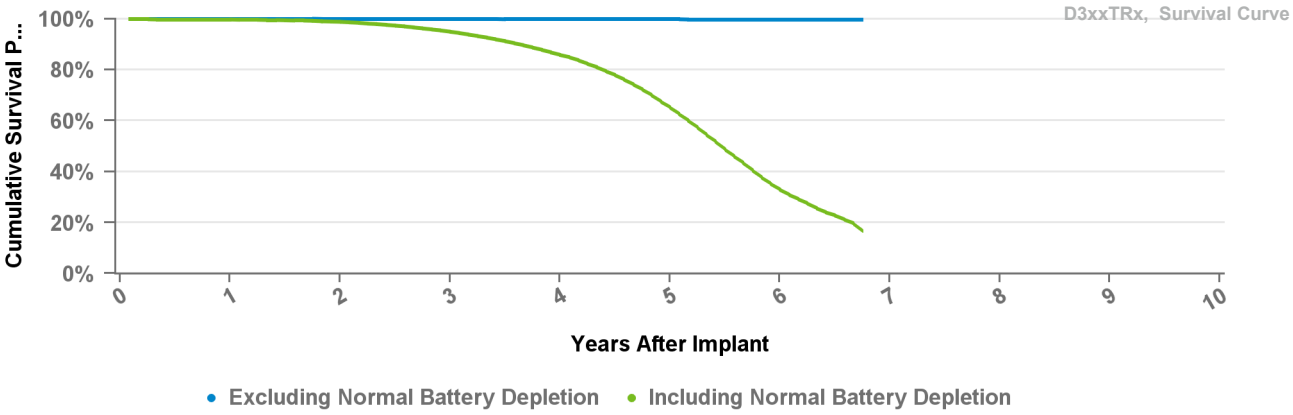
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D364TRG Protecta CRT-D

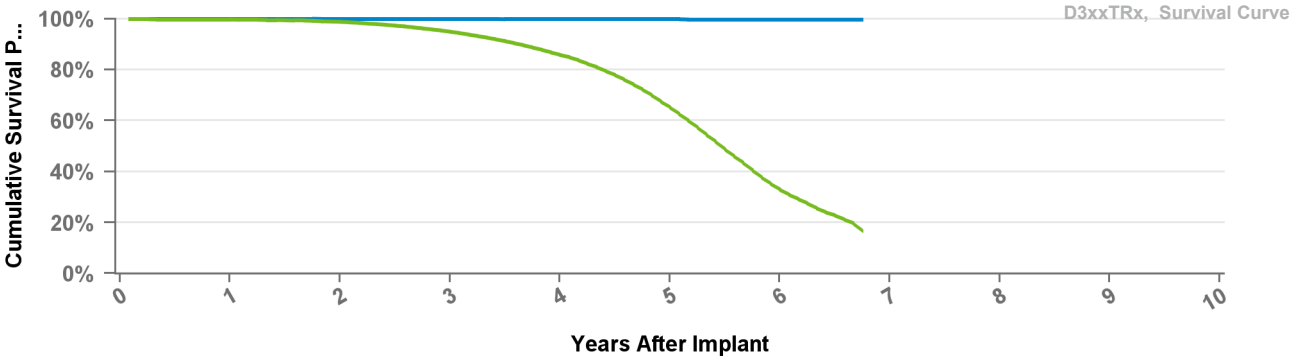
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D364TRM Protecta CRT-D

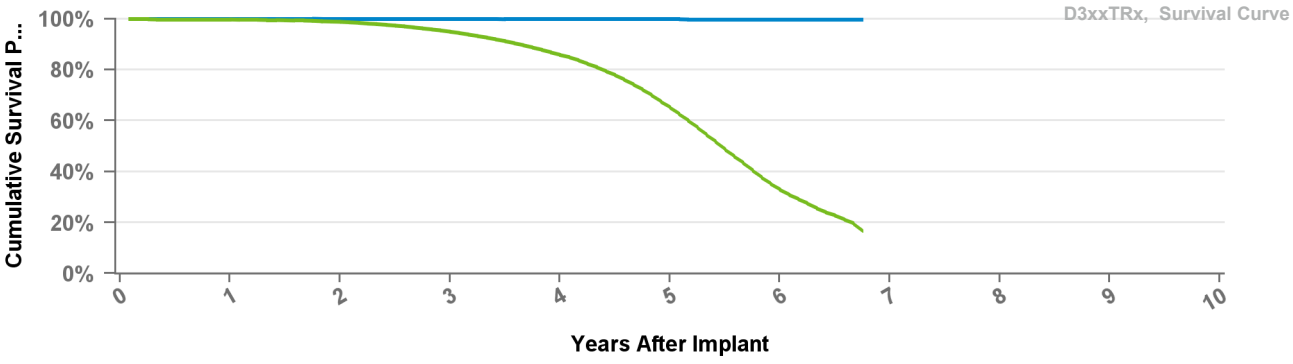
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D384TRG Cardia CRT-D

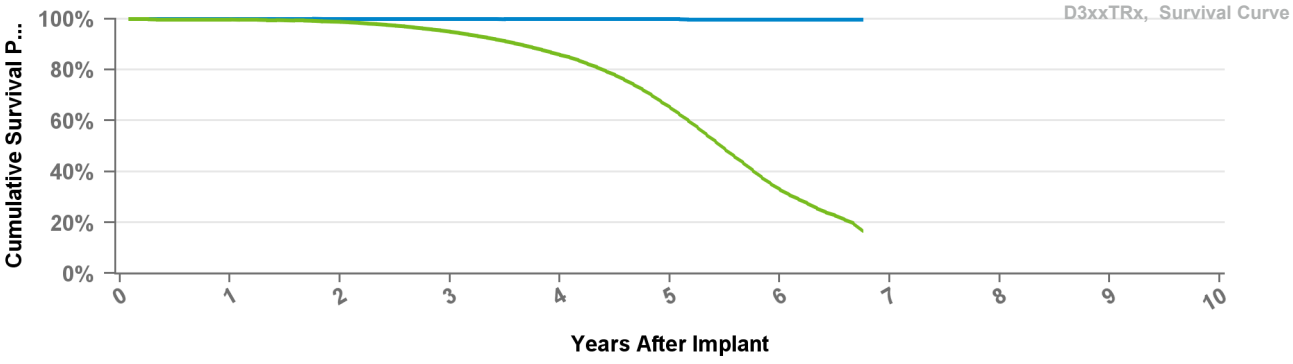
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

D394TRG Egida CRT-D

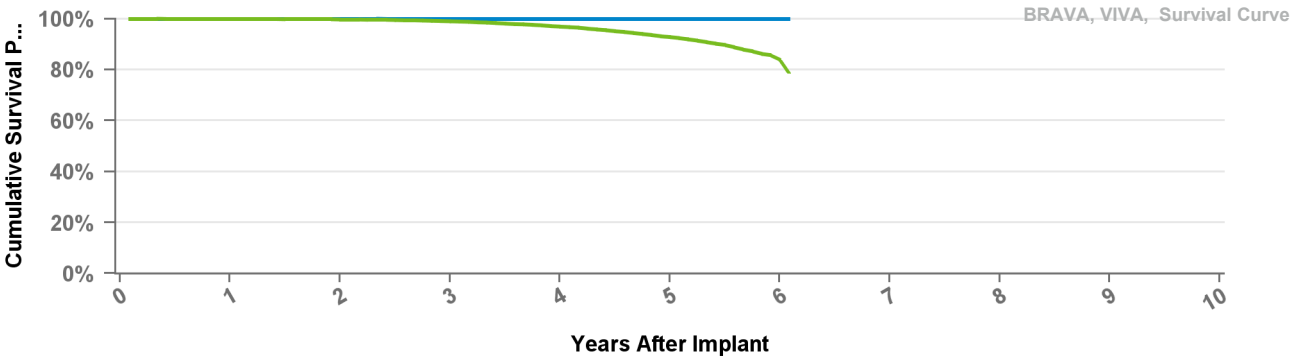
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997
Including NBD	0.997	0.988	0.949	0.858	0.652	0.329	0.166
Effective Sample Size	55733	51314	45136	35680	21663	8131	455

DTBA1D1 Viva XT

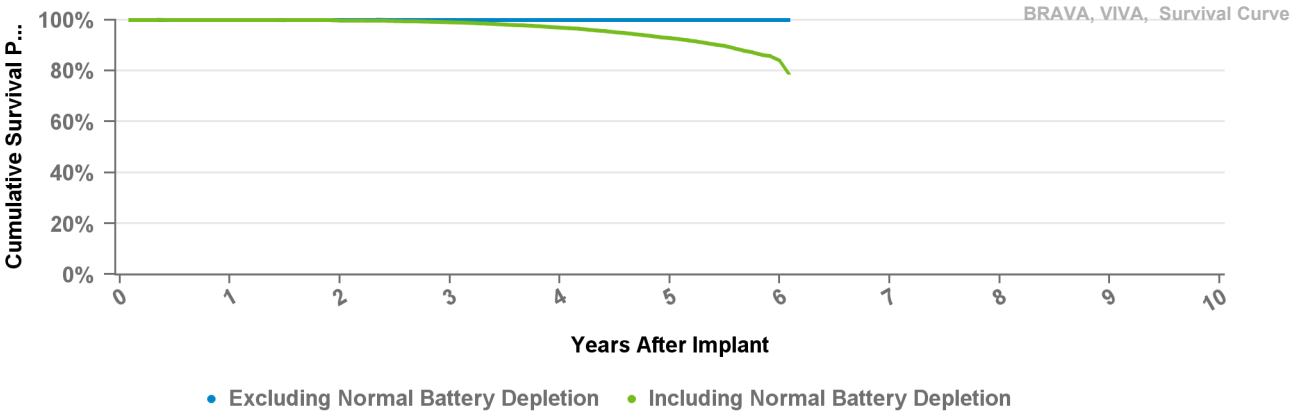
US Market Release	Jan-13	**Total Malfunctions**	**48**
CE Approval Date		**Therapy Function Not Compromised**	**37**
Registered USA Implants	57,017	Battery Malfunction	4
Estimated Active USA Implants	44,660	Electrical Component	29
Normal Battery Depletions	1,419	Other Malfunction	3
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**11**
		Battery Malfunction	8
		Electrical Component	3



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBA1D4 Viva XT

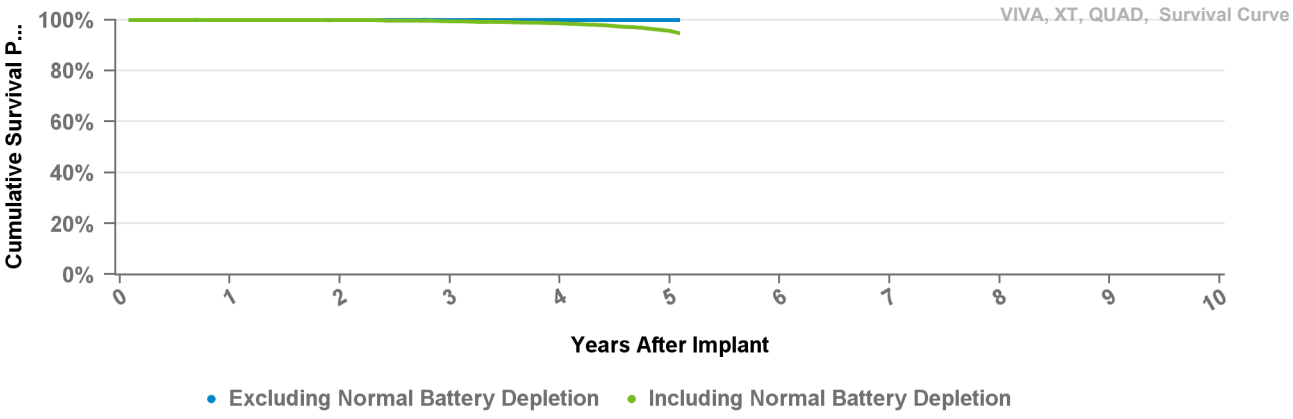
US Market Release	Jan-13	**Total Malfunctions**	**28**
CE Approval Date		**Therapy Function Not Compromised**	**22**
Registered USA Implants	20,101	Battery Malfunction	3
Estimated Active USA Implants	16,256	Electrical Component	16
Normal Battery Depletions	541	Poss Early Battery Depltn	3
		Therapy Function Compromised	**6**
		Battery Malfunction	3
		Electrical Component	3



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBA1Q1 Viva Quad XT

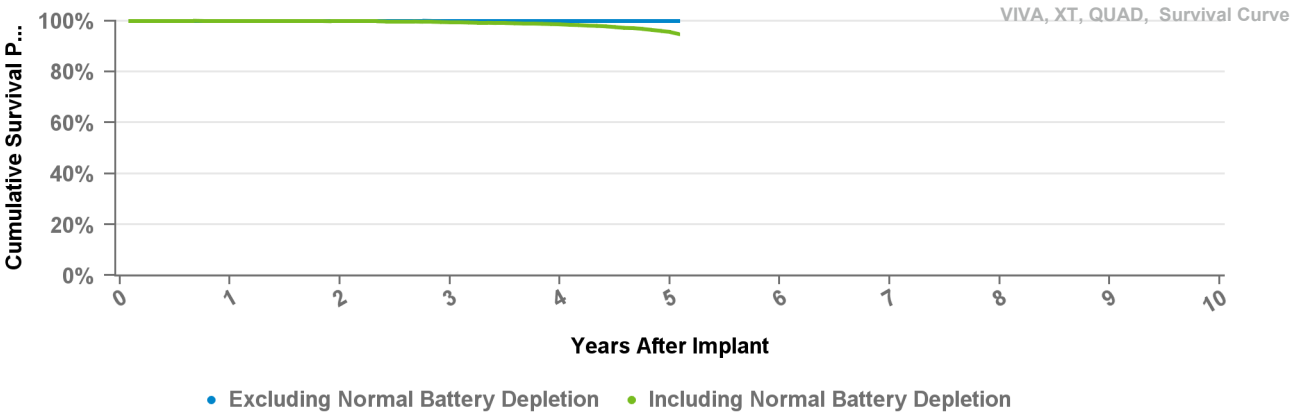
US Market Release	Jul-14	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	10,976	Electrical Component	3
Estimated Active USA Implants	9,306	Other Malfunction	1
Normal Battery Depletions	107	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

DTBA1QQ Viva Quad XT

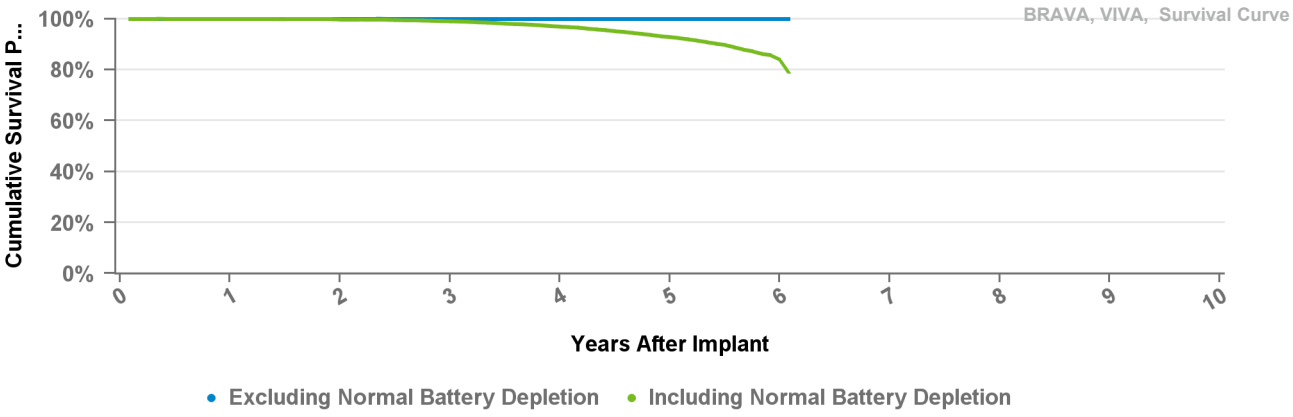
US Market Release	Jul-14	**Total Malfunctions**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**19**
Registered USA Implants	27,415	Battery Malfunction	2
Estimated Active USA Implants	24,674	Electrical Component	14
Normal Battery Depletions	230	Electrical Interconnect	1
		Other Malfunction	2
		Therapy Function Compromised	**6**
		Battery Malfunction	4
		Electrical Component	2



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

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		

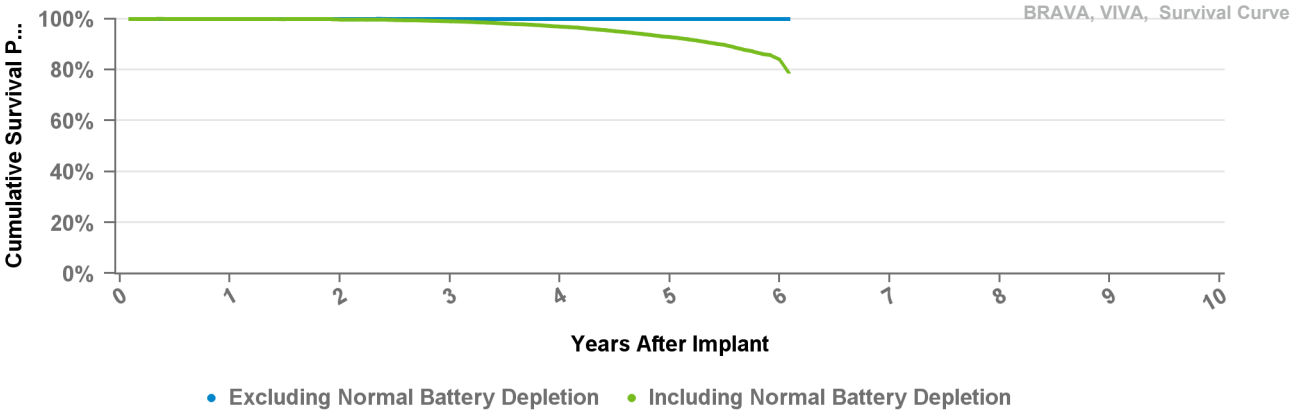


Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

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

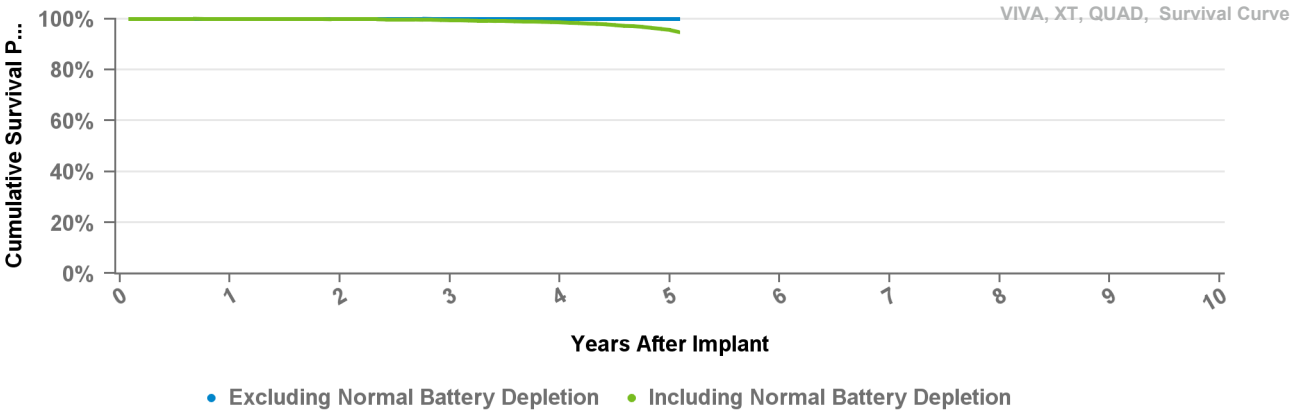


Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBA2Q1 Viva Quad XT

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

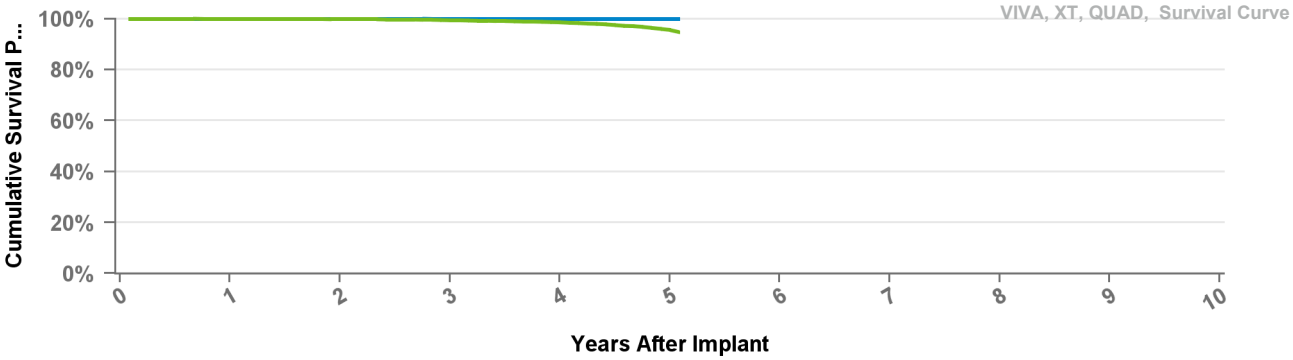
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

DTBA2QQ Viva Quad XT

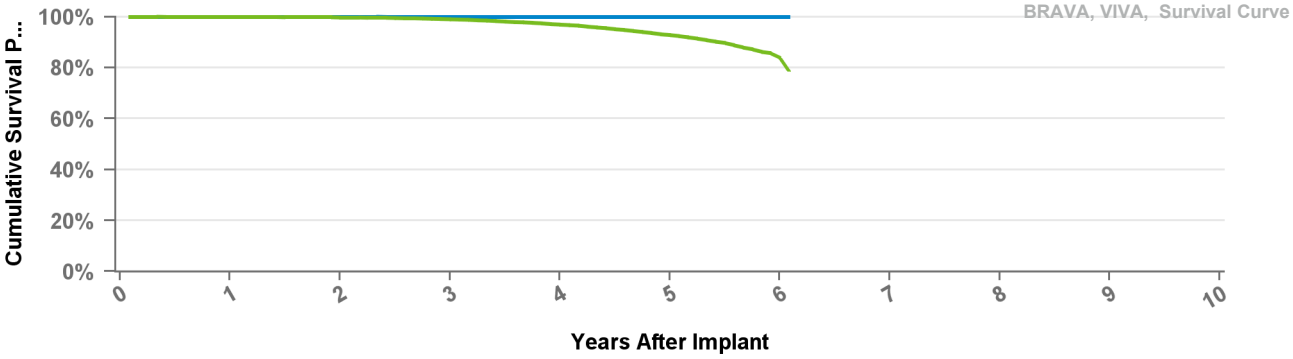
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

DTBB1D1 Viva S

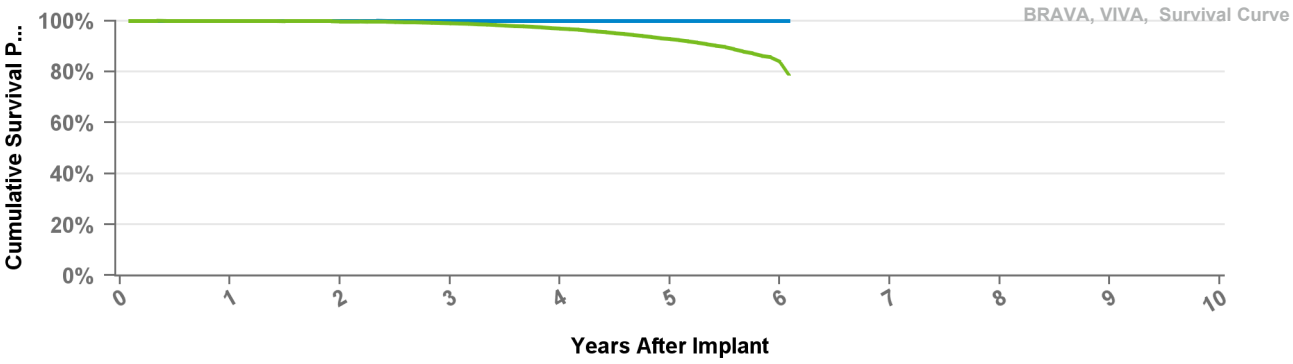
US Market Release	Jan-13	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	14,098	Battery Malfunction	5
Estimated Active USA Implants	10,502	Electrical Component	3
Normal Battery Depletions	519	Poss Early Battery Depltn	1
		Therapy Function Compromised	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB1D4 Viva S

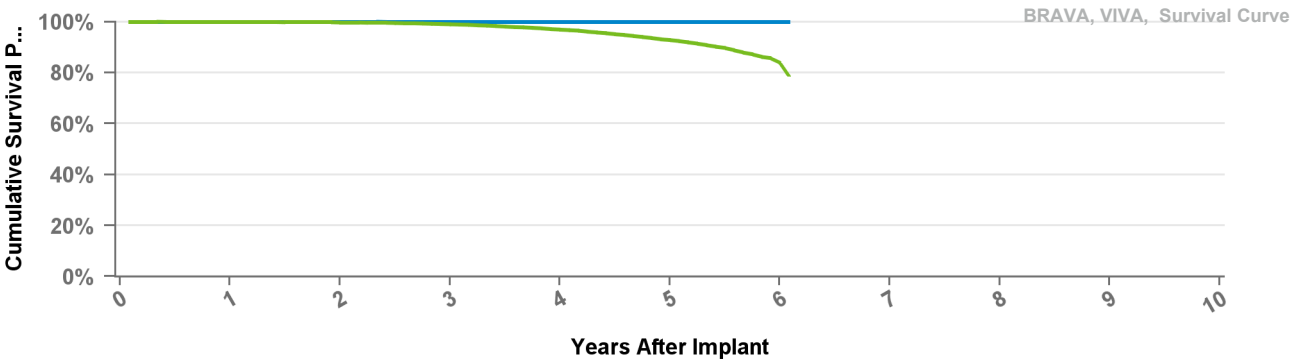
US Market Release	Jan-13	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,615	Battery Malfunction	1
Estimated Active USA Implants	3,651	Electrical Component	1
Normal Battery Depletions	185	Other Malfunction	1
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB1Q1 Viva Quad S

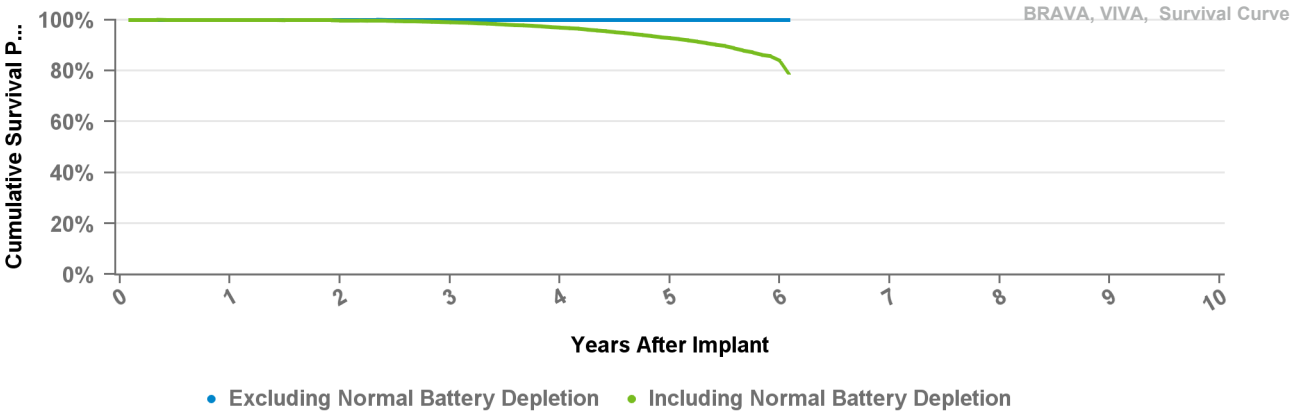
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,342	Electrical Component	1
Estimated Active USA Implants	1,979	**Therapy Function Compromised**	**0**
Normal Battery Depletions	19		



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB1QQ Viva Quad S

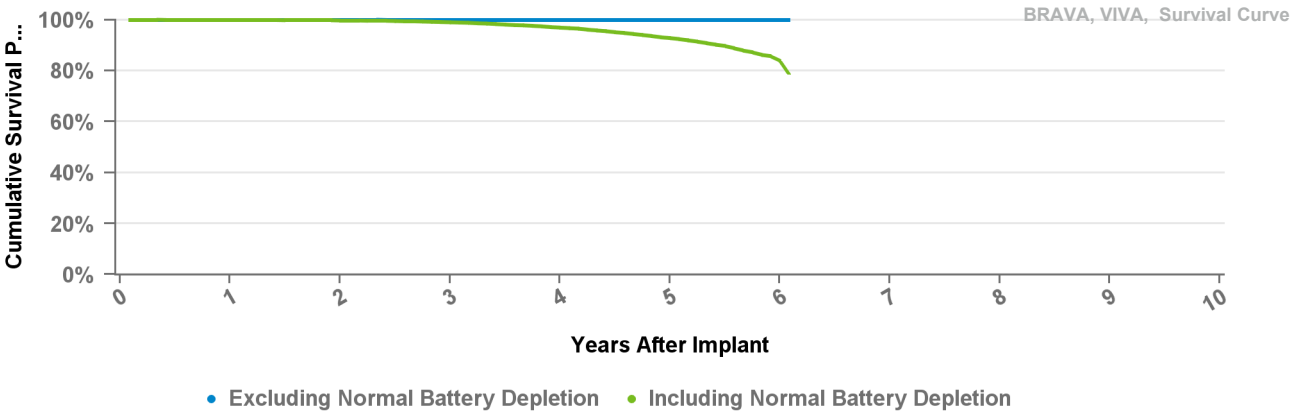
US Market Release	Jul-14	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	5,091	Battery Malfunction	1
Estimated Active USA Implants	4,542	Electrical Component	2
Normal Battery Depletions	62	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB2D1 Viva S

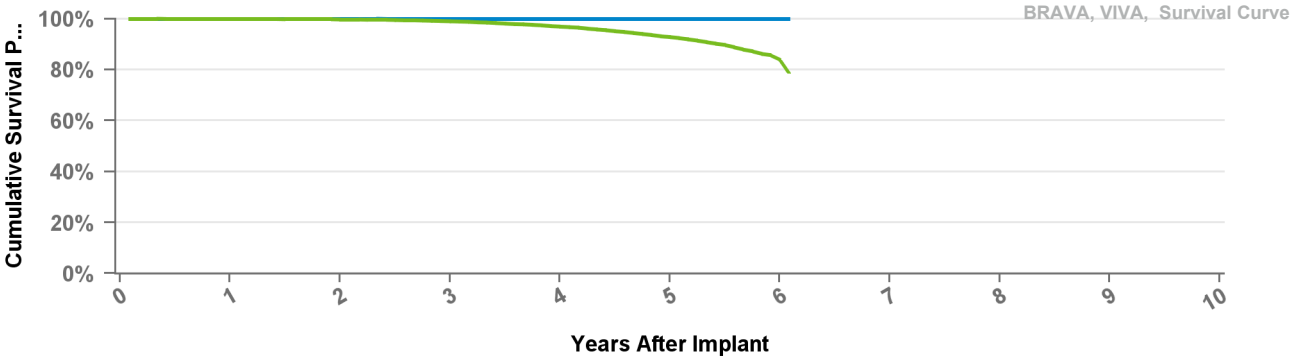
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB2D4 Viva S

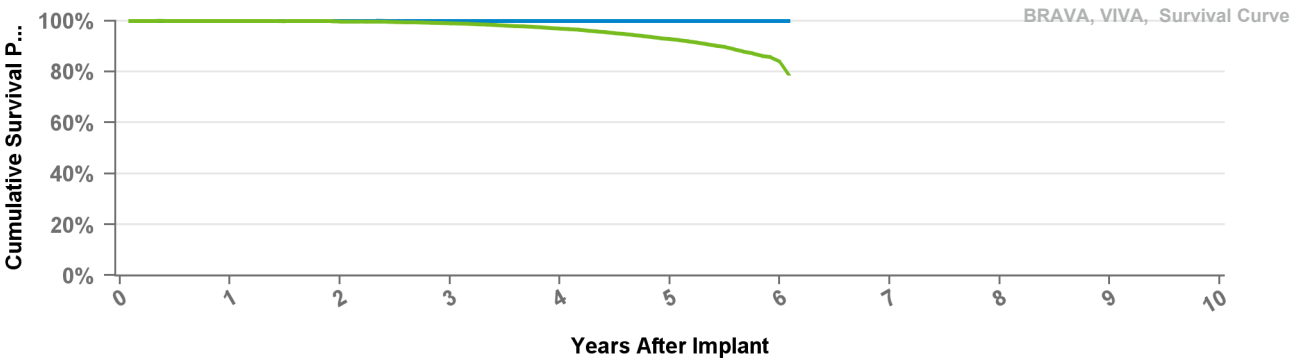
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBB2QQ Viva Quad S

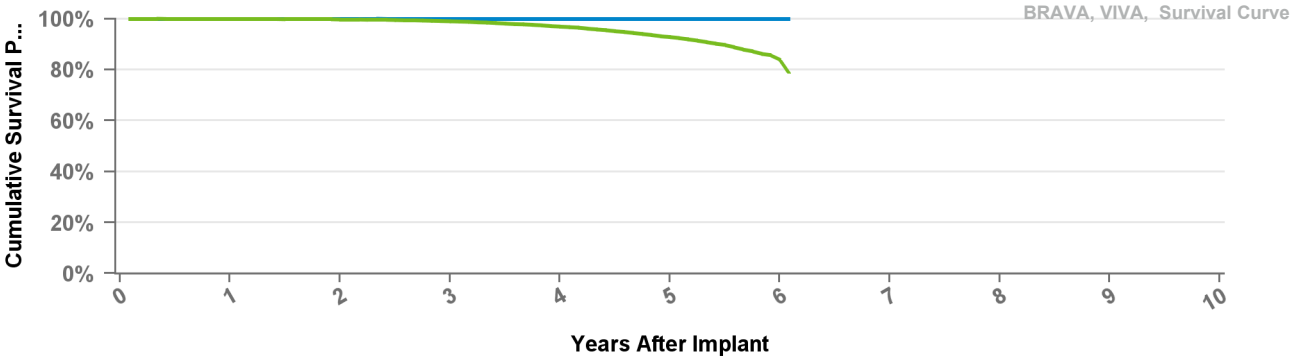
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBC2D1 Brava

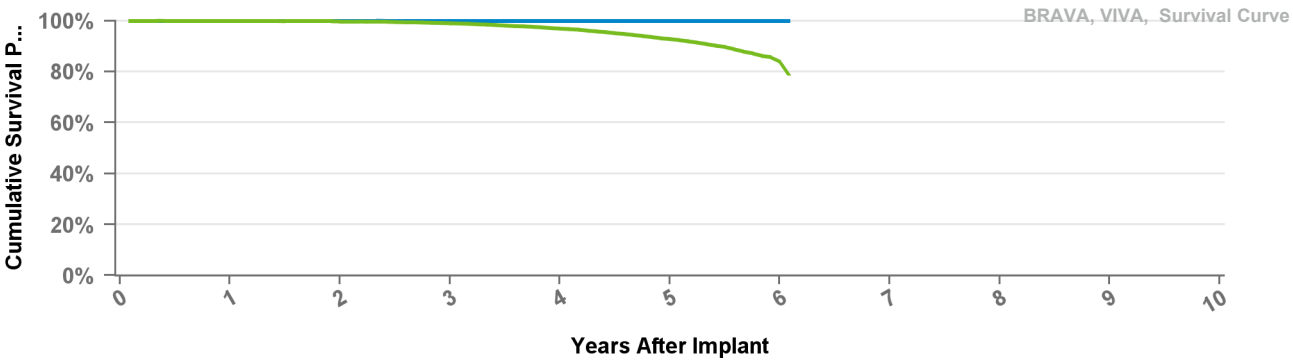
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBC2D4 Brava

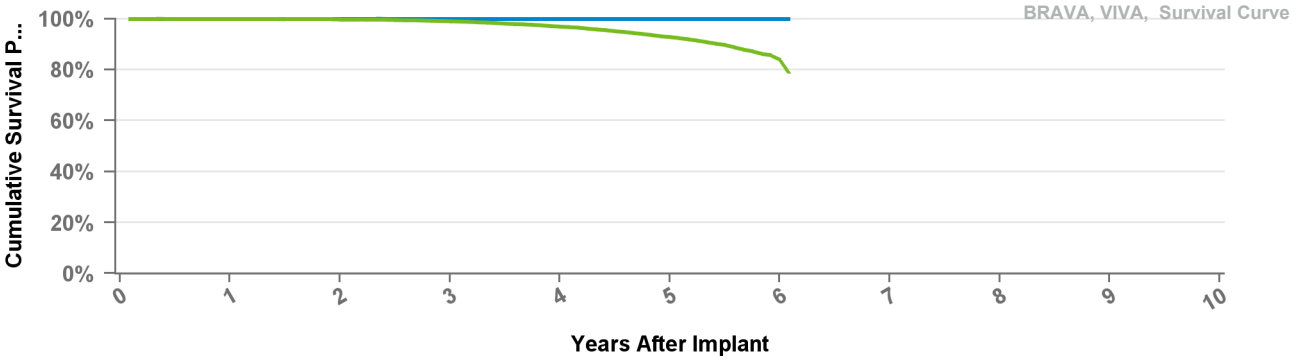
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBC2Q1 Brava Quad

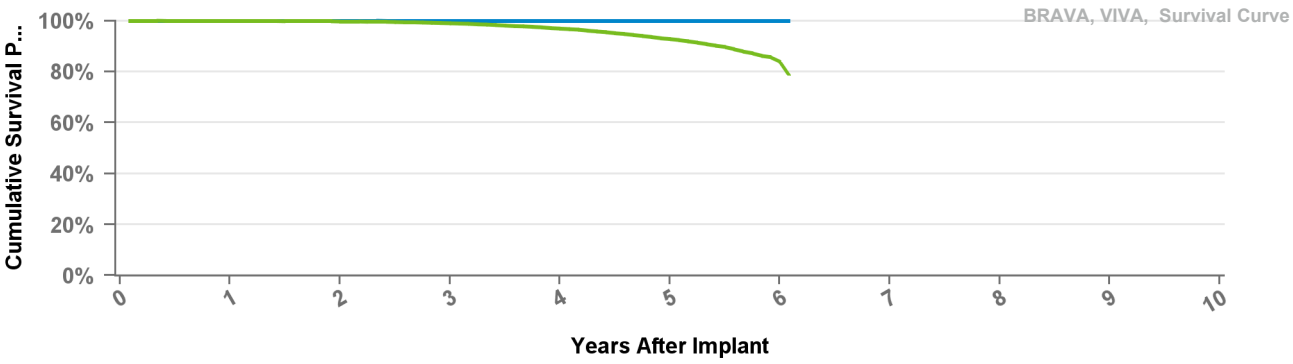
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBC2QQ Brava Quad

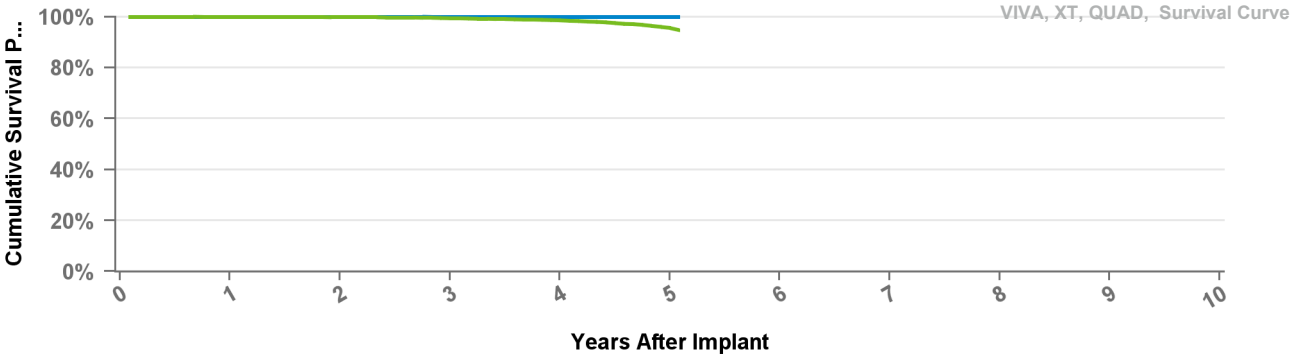
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.999
Including NBD	0.999	0.997	0.99	0.969	0.928	0.838	0.791
Effective Sample Size	90757	82292	68637	47157	25222	2398	860

DTBX1QQ Viva Quad C

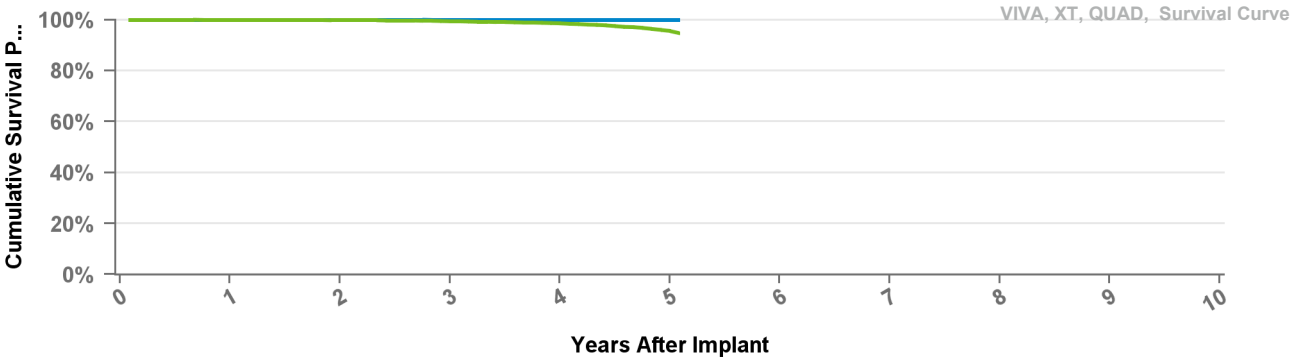
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	637	Electrical Component	1
Estimated Active USA Implants	455	**Therapy Function Compromised**	**0**
Normal Battery Depletions	57		



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

DTBX2QQ Viva Quad C

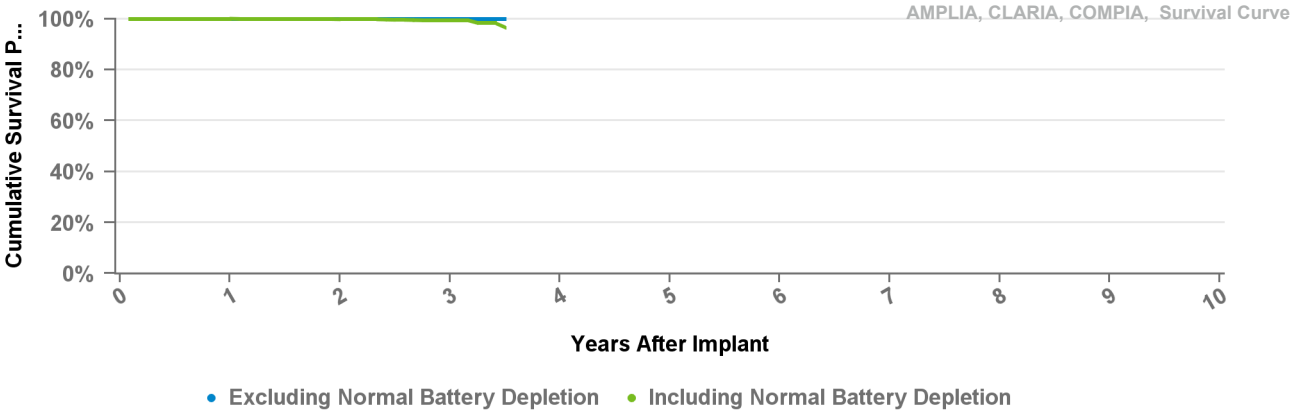
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 61 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.998	0.994	0.986	0.956	0.947
Effective Sample Size	34790	32140	27730	16804	1723	633

DTMA1D1 Claria MRI

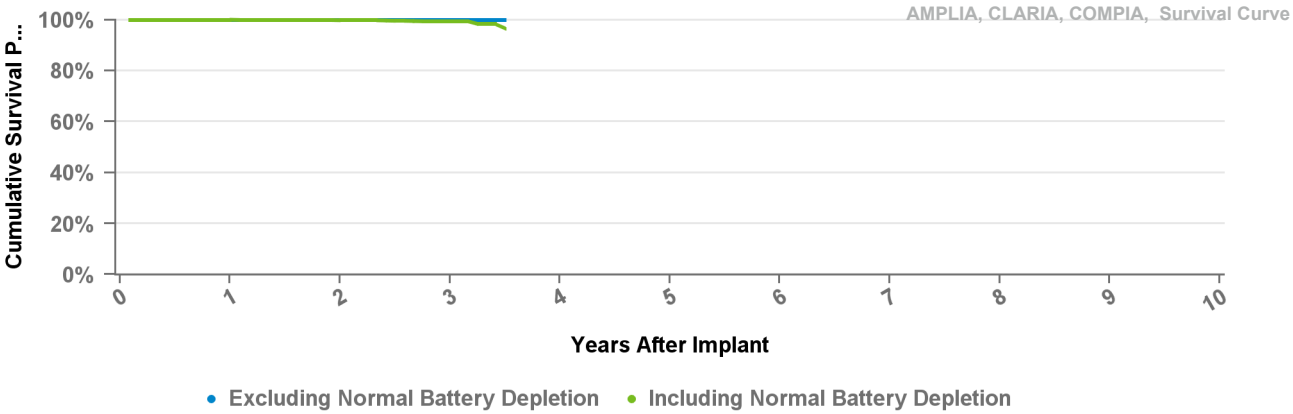
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	7,449		
Estimated Active USA Implants	7,080	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMA1D4 Claria MRI

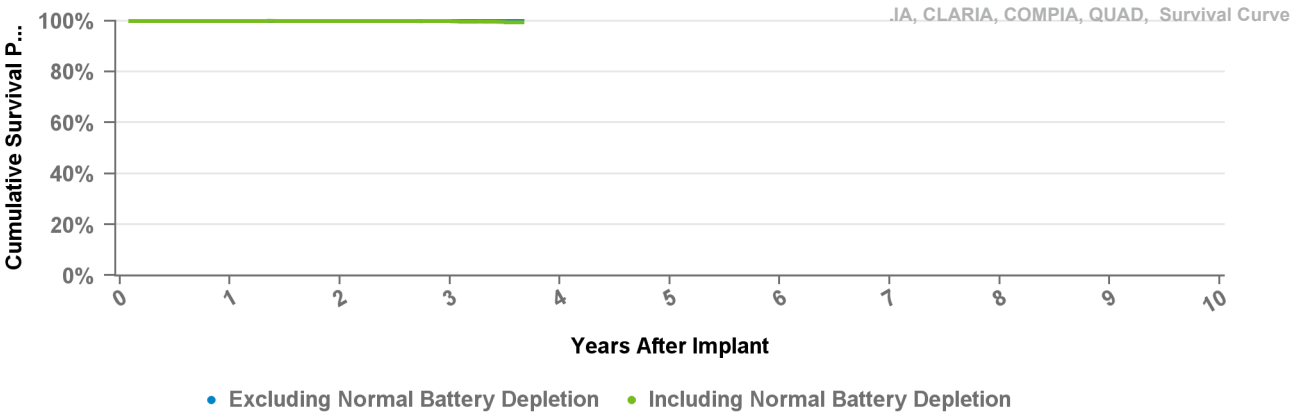
US Market Release	Dec-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	6,613	Electrical Component	1
Estimated Active USA Implants	6,323	**Therapy Function Compromised**	**0**
Normal Battery Depletions	3		



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMA1Q1 Claria MRI

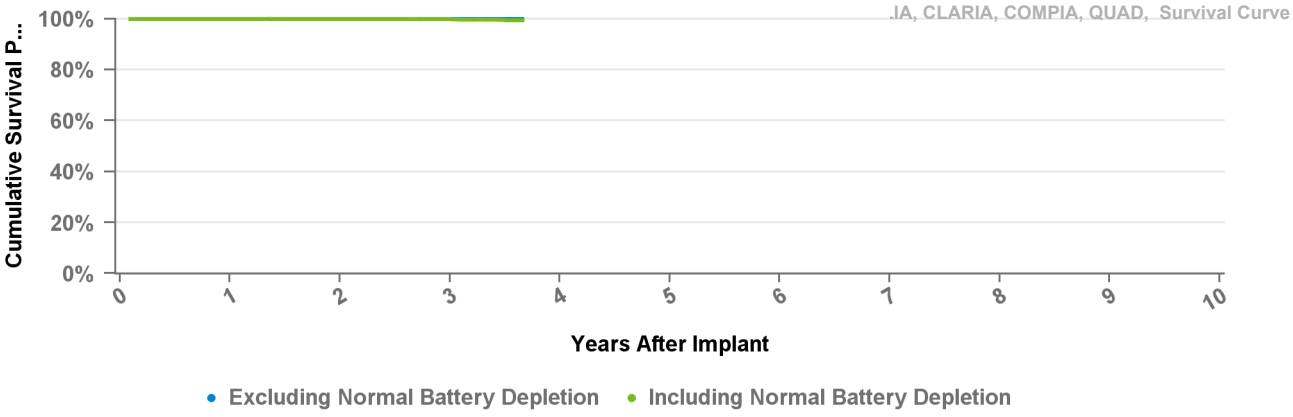
US Market Release	Dec-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	5,245	Electrical Interconnect	1
Estimated Active USA Implants	5,033	Other Malfunction	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**0**



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMA1QQ Claria MRI

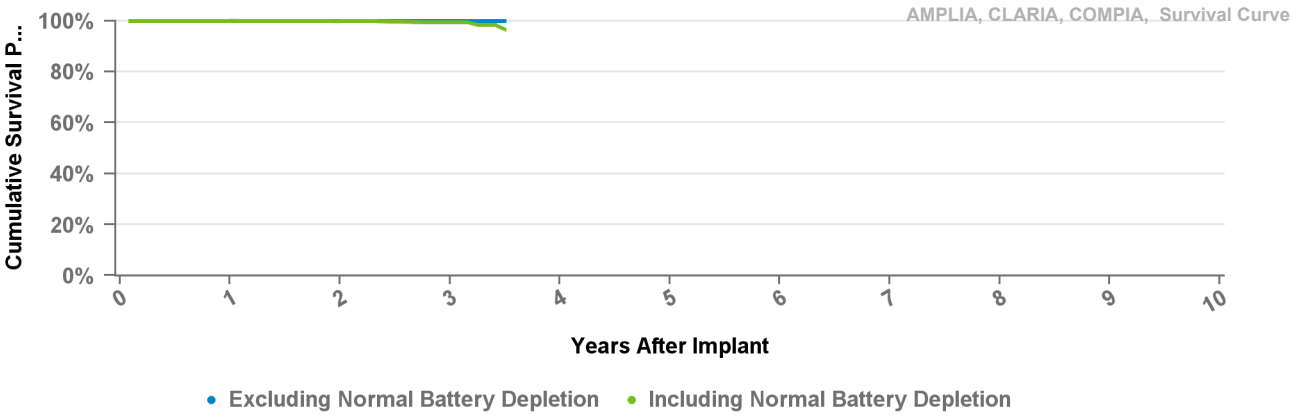
US Market Release	Dec-16	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	32,954	Electrical Component	1
Estimated Active USA Implants	31,980	**Therapy Function Compromised**	**2**
Normal Battery Depletions	6	Electrical Component	2



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMA2D1 Claria MRI

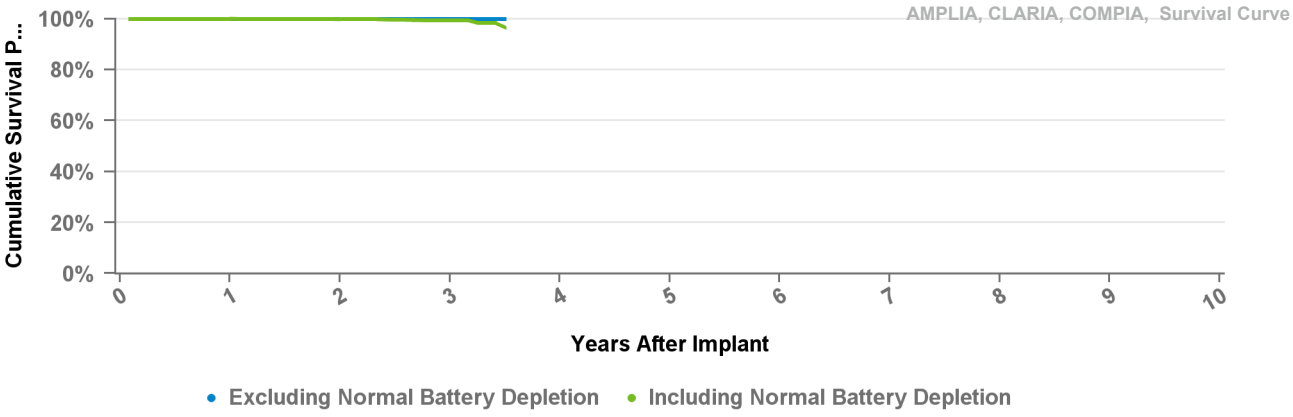
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMA2D4 Claria MRI

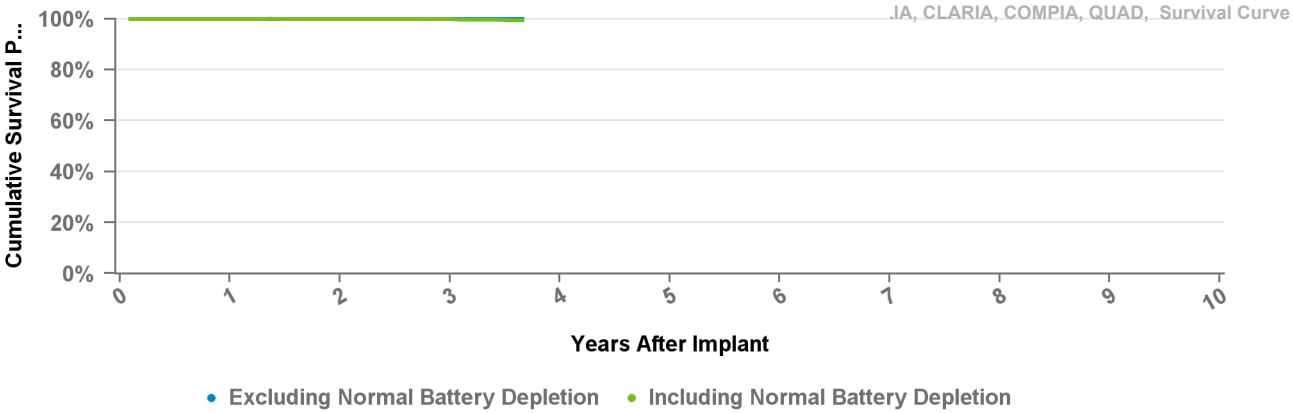
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMA2Q1 Claria MRI

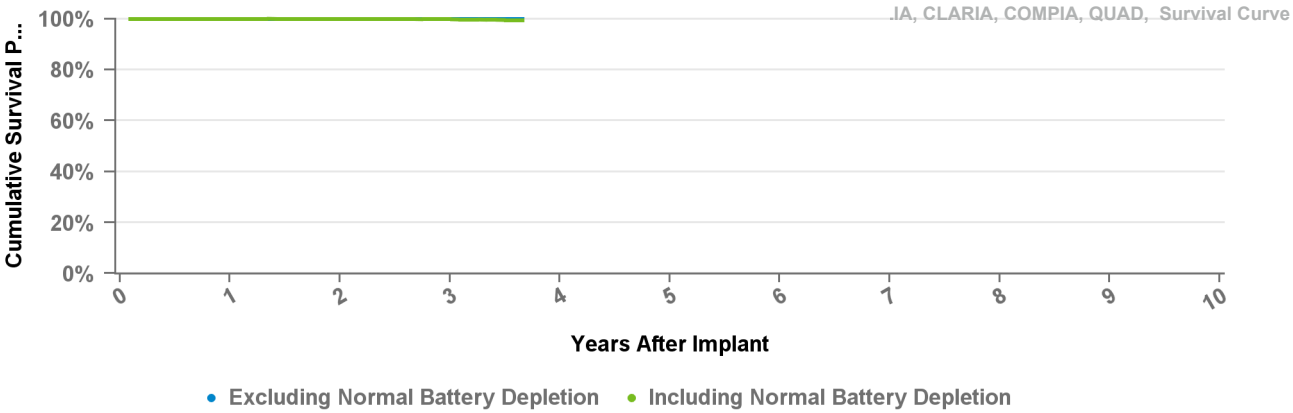
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMA2QQ Claria MRI

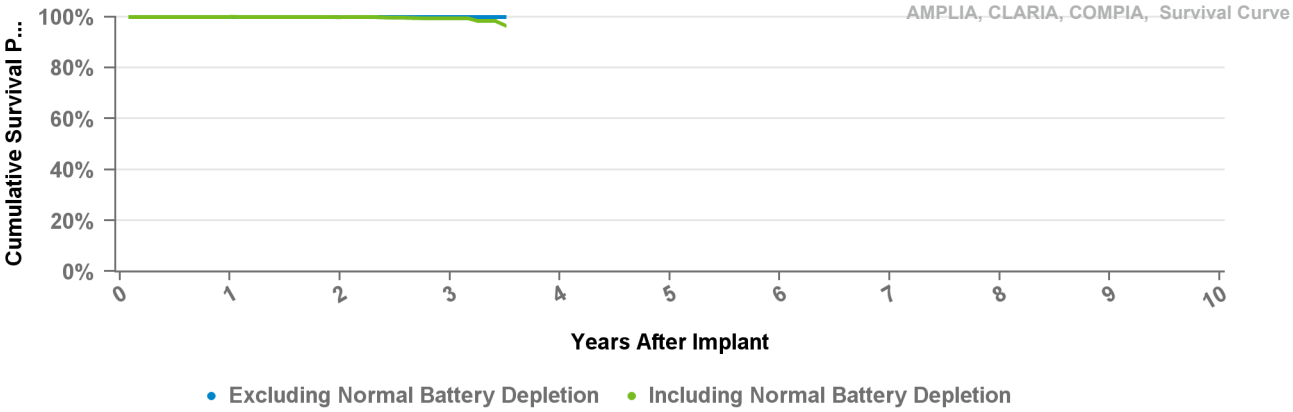
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMB1D1 Amplia MRI

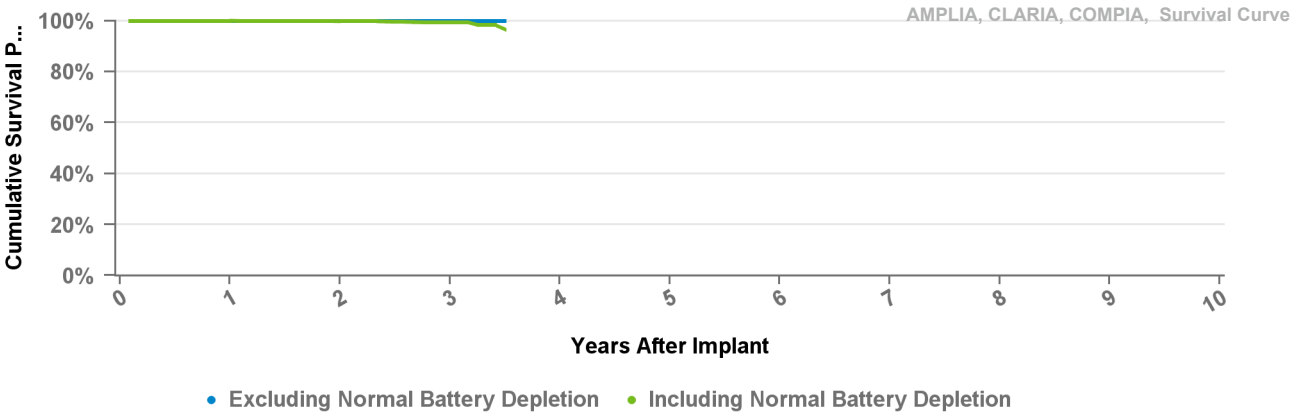
US Market Release	Dec-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,508	Other Malfunction	1
Estimated Active USA Implants	4,269	**Therapy Function Compromised**	**0**
Normal Battery Depletions	3		



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMB1D4 Amplia MRI

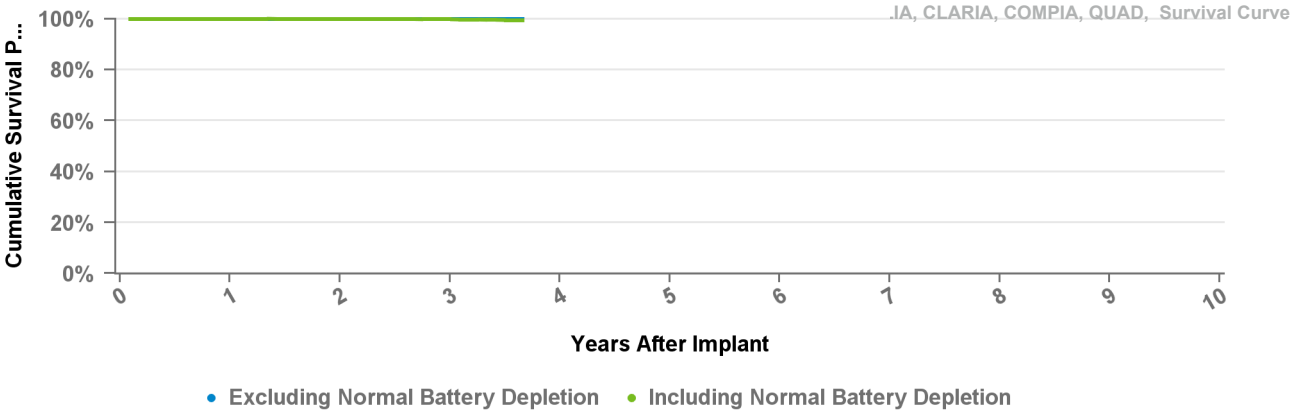
US Market Release	Feb-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	4,883	Electrical Component	2
Estimated Active USA Implants	4,552	**Therapy Function Compromised**	**0**
Normal Battery Depletions	10		



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMB1Q1 Amplia MRI

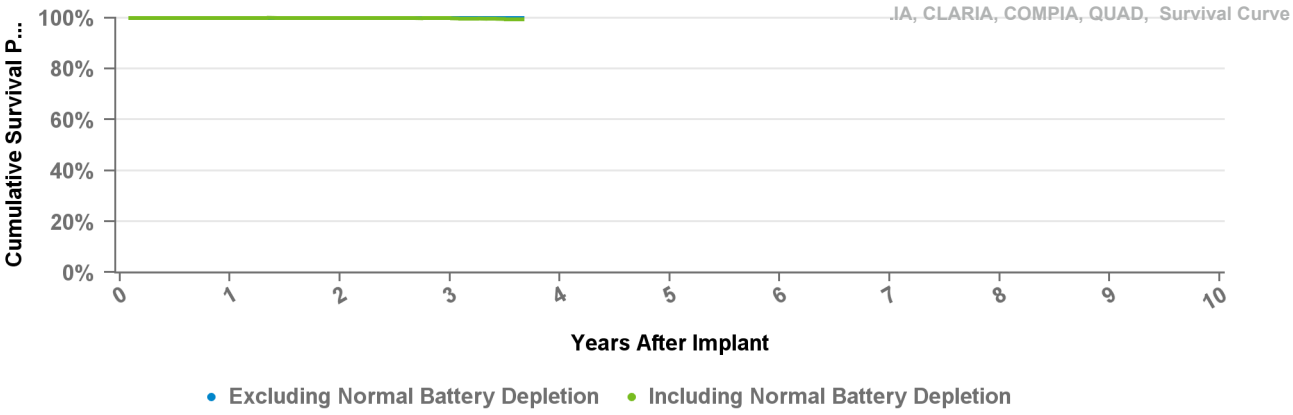
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,620		
Estimated Active USA Implants	2,457	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMB1QQ Amplia MRI

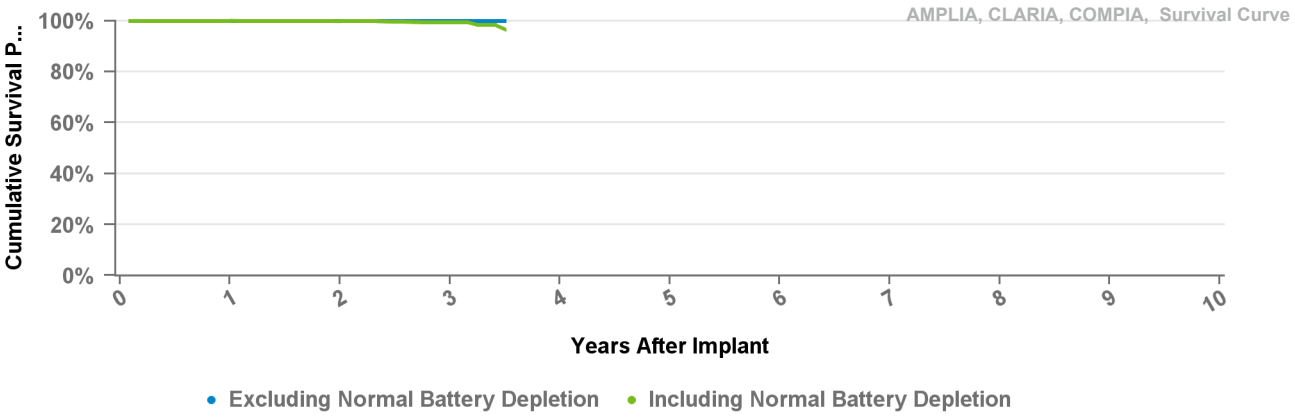
US Market Release	Feb-16	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	24,758	Electrical Component	7
Estimated Active USA Implants	23,552	Other Malfunction	5
Normal Battery Depletions	21	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMB2D1 Amplia MRI

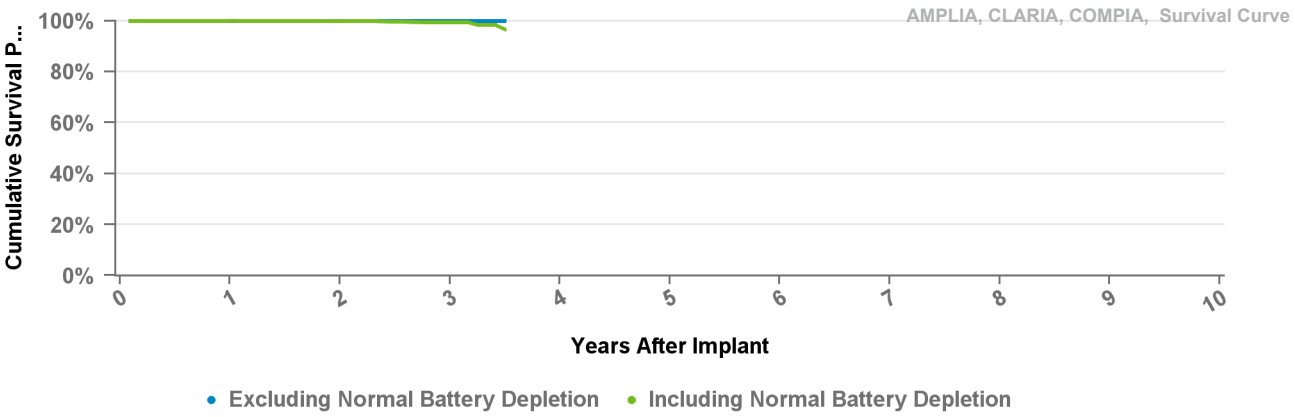
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMB2D4 Amplia MRI

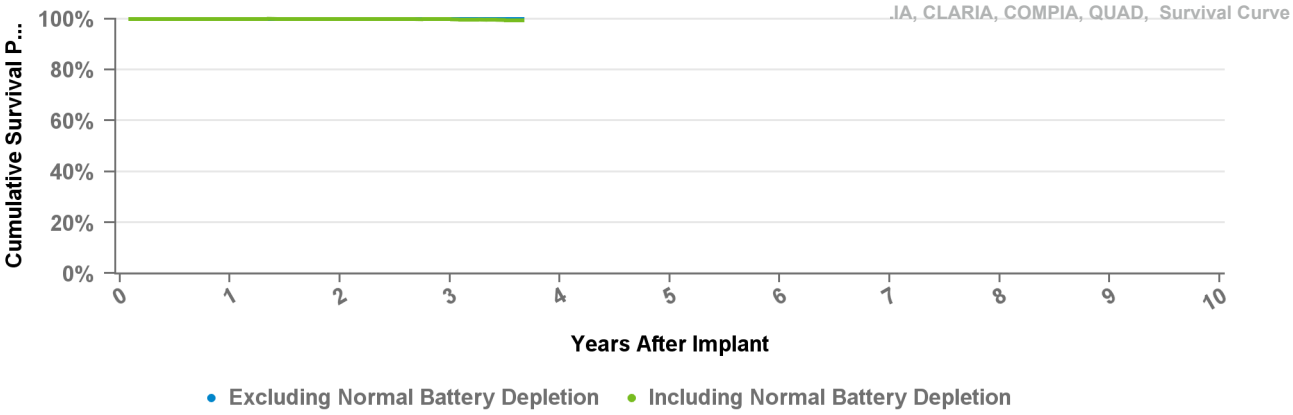
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMB2Q1 Amplia MRI

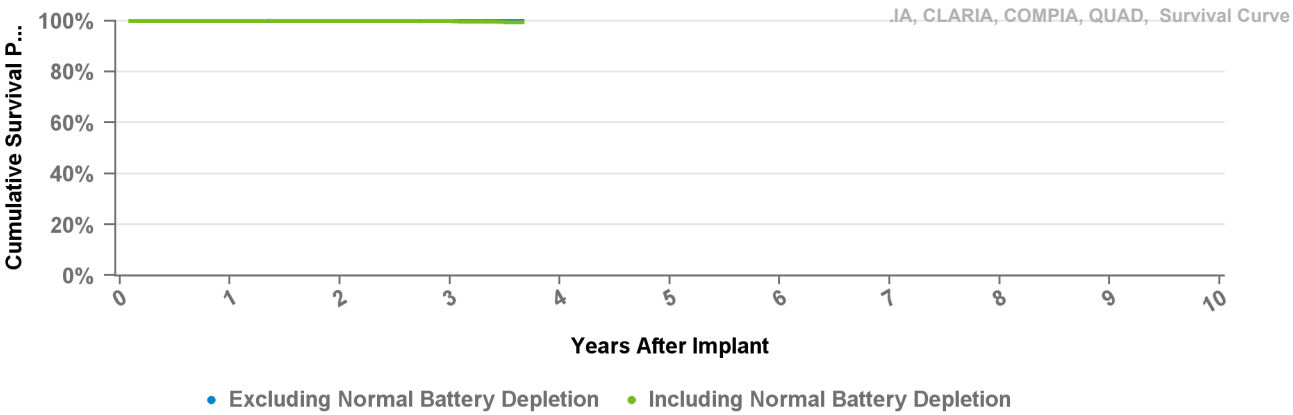
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMB2QQ Amplia MRI

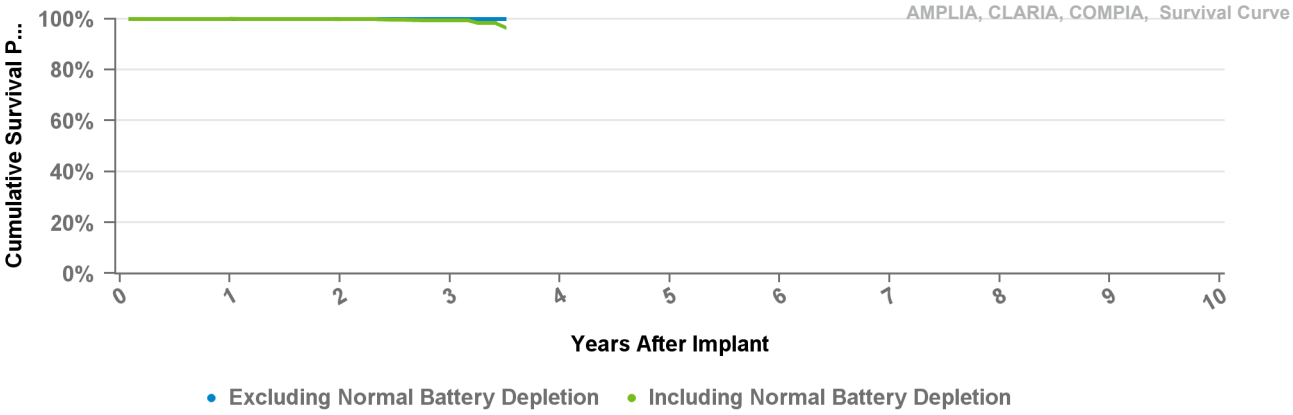
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMC1D1 Compia MRI

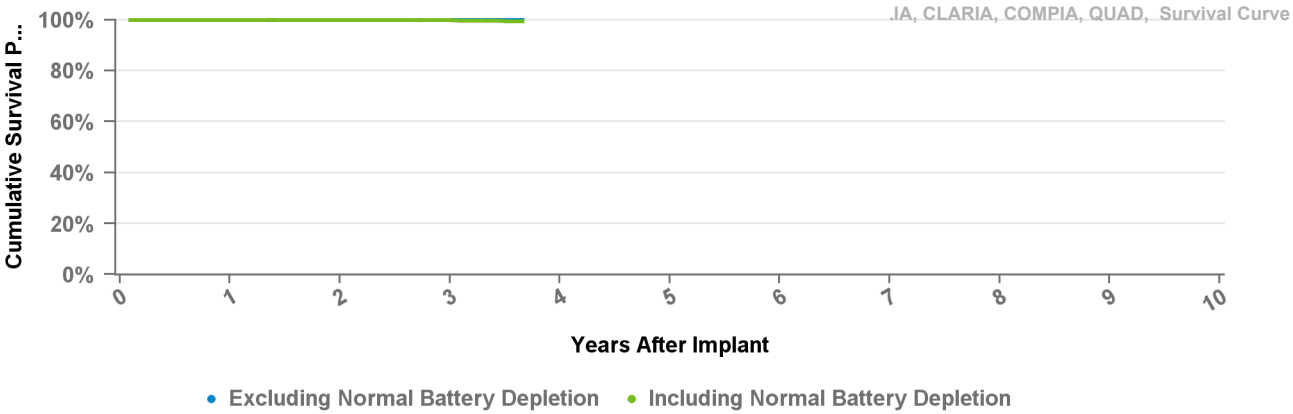
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	552		
Estimated Active USA Implants	526	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMC1QQ Compia MRI

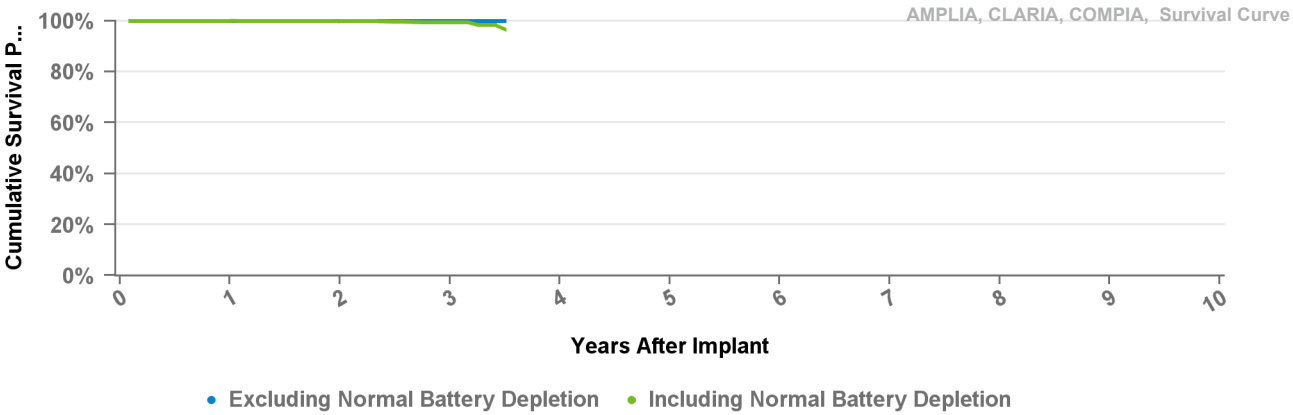
US Market Release	Feb-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,889	Electrical Component	2
Estimated Active USA Implants	2,747	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

DTMC2D1 Compia MRI

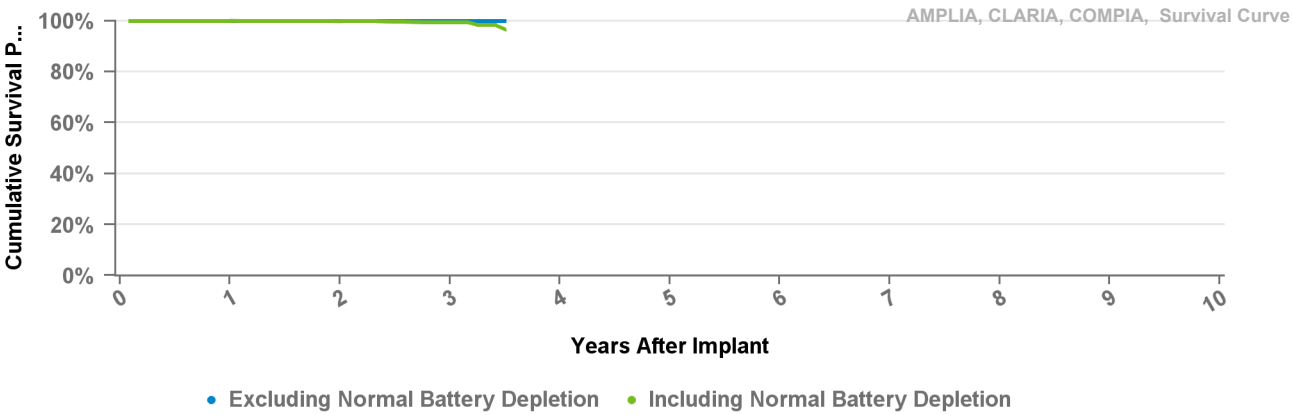
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMC2D4 Compia MRI

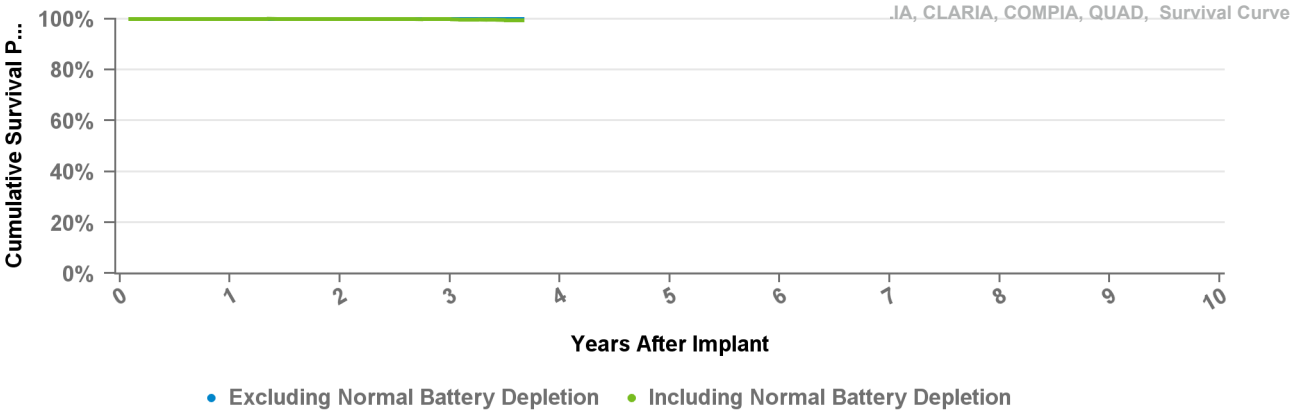
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 42 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.998	0.994	0.965
Effective Sample Size	15782	6911	727	108

DTMC2QQ Compia MRI

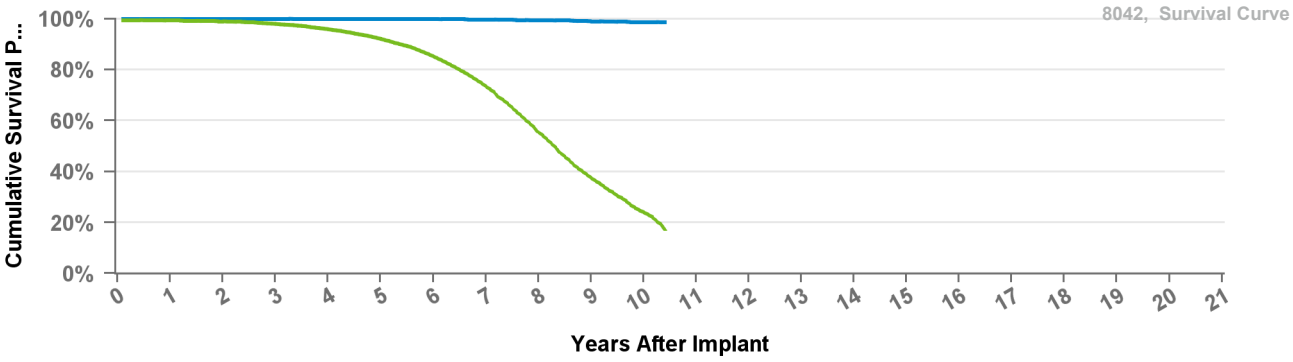
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 44 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.995
Effective Sample Size	45124	24823	7501	325

8042 InSync III

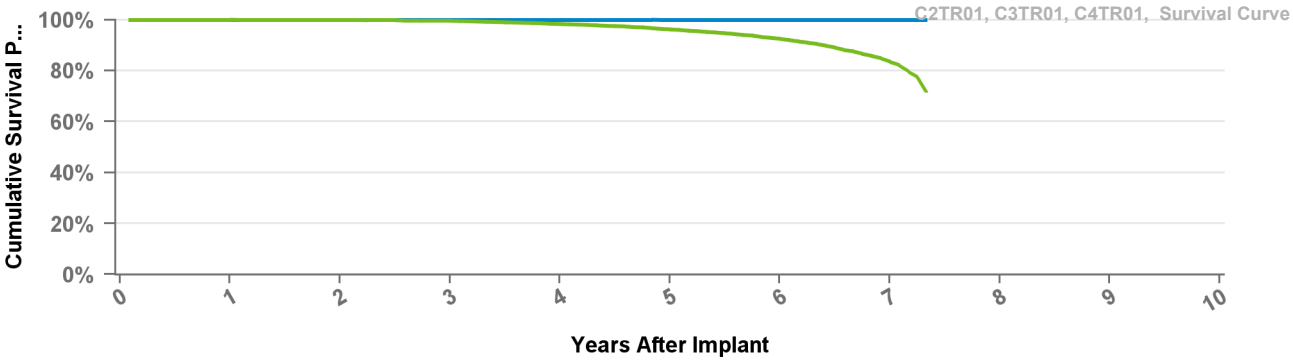
US Market Release	Feb-03	**Total Malfunctions**	**112**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**65**
Registered USA Implants	39,395	Battery Malfunction	53
Estimated Active USA Implants	4,671	Electrical Component	2
Normal Battery Depletions	5,089	Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**47**
		Battery Malfunction	35
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.994	0.99	0.987	0.986
Including NBD	0.993	0.99	0.98	0.959	0.921	0.852	0.734	0.555	0.375	0.24	0.172
Effective Sample Size	30360	26002	22334	19088	15926	12180	8666	5587	3073	730	156

C2TR01 Syncra CRT-P

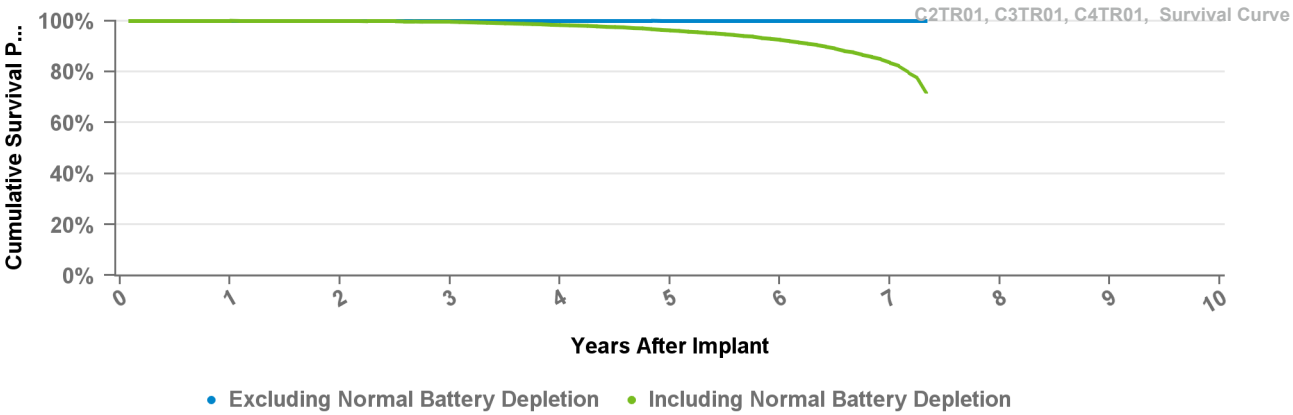
US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,229	Other Malfunction	1
Estimated Active USA Implants	6,449	Poss Early Battery Depltn	5
Normal Battery Depletions	324	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999	0.999
Including NBD	1	0.999	0.996	0.983	0.962	0.925	0.835	0.72
Effective Sample Size	27149	24376	21413	17404	12619	6789	1726	255

C3TR01 Consulta CRT-P

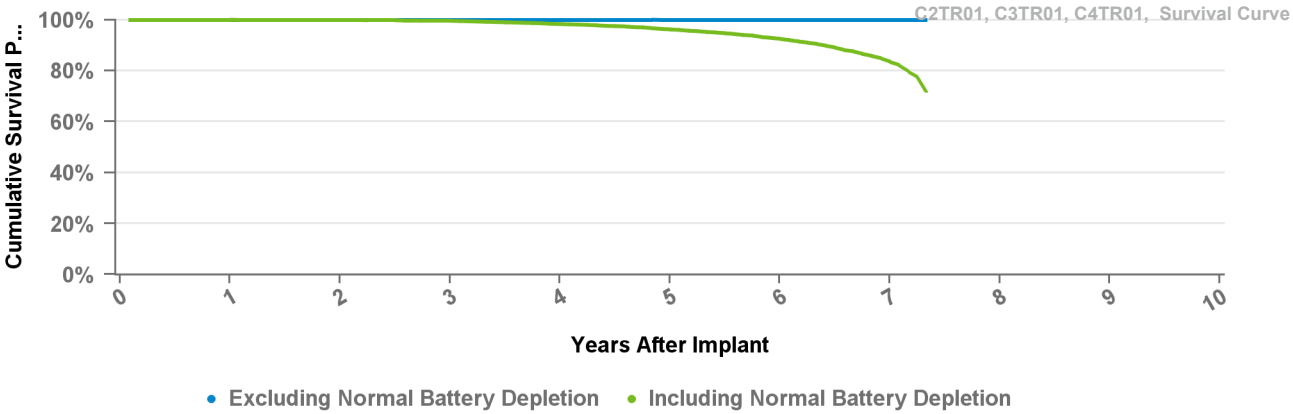
US Market Release		**Total Malfunctions**	
CE Approval Date	May-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999	0.999
Including NBD	1	0.999	0.996	0.983	0.962	0.925	0.835	0.72
Effective Sample Size	27149	24376	21413	17404	12619	6789	1726	255

C4TR01 Consulta CRT-P

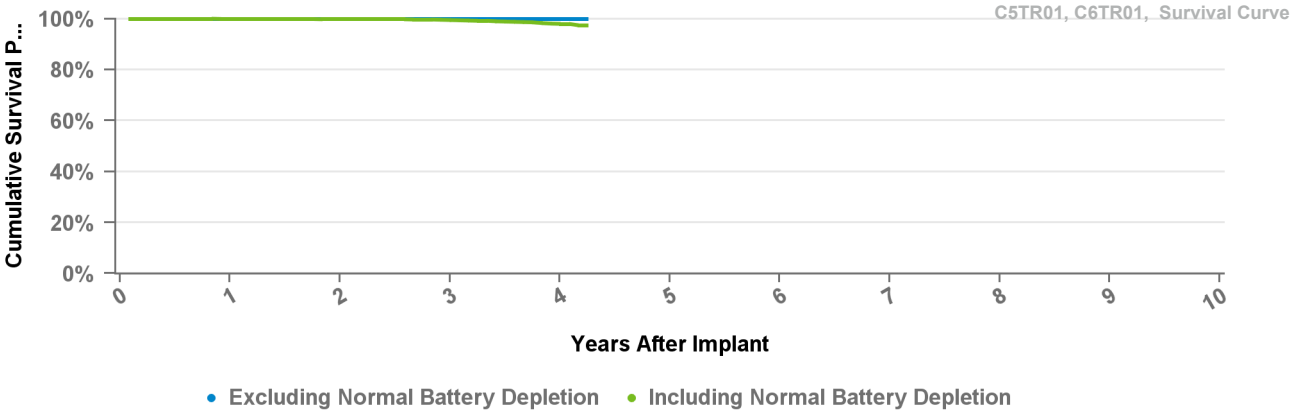
US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	23,539	Poss Early Battery Depltn	6
Estimated Active USA Implants	16,517	**Therapy Function Compromised**	**0**
Normal Battery Depletions	642		



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999	0.999
Including NBD	1	0.999	0.996	0.983	0.962	0.925	0.835	0.72
Effective Sample Size	27149	24376	21413	17404	12619	6789	1726	255

C5TR01 Viva CRT-P

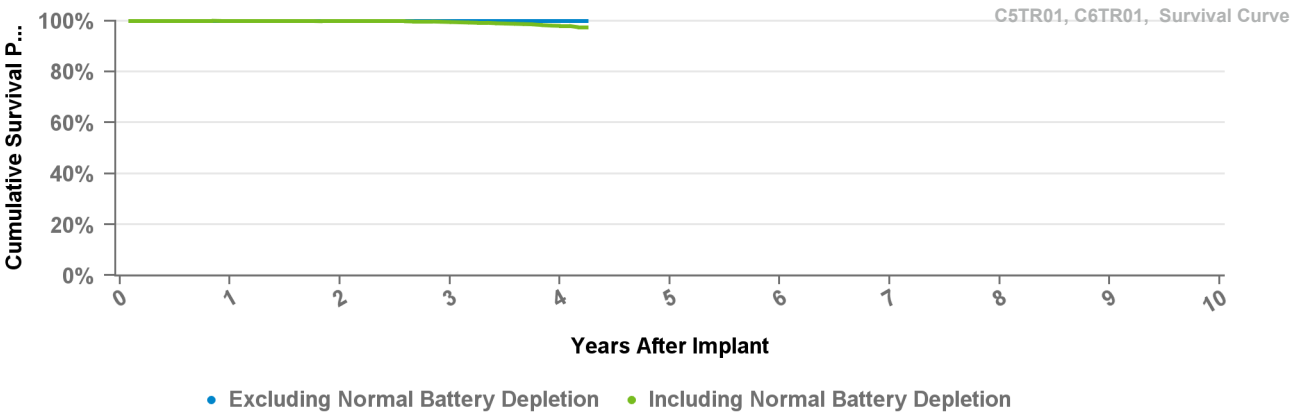
US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	1	1	1	1	1
Including NBD	0.999	0.998	0.995	0.98	0.974
Effective Sample Size	7676	6846	4182	839	132

C6TR01 Viva CRT-P

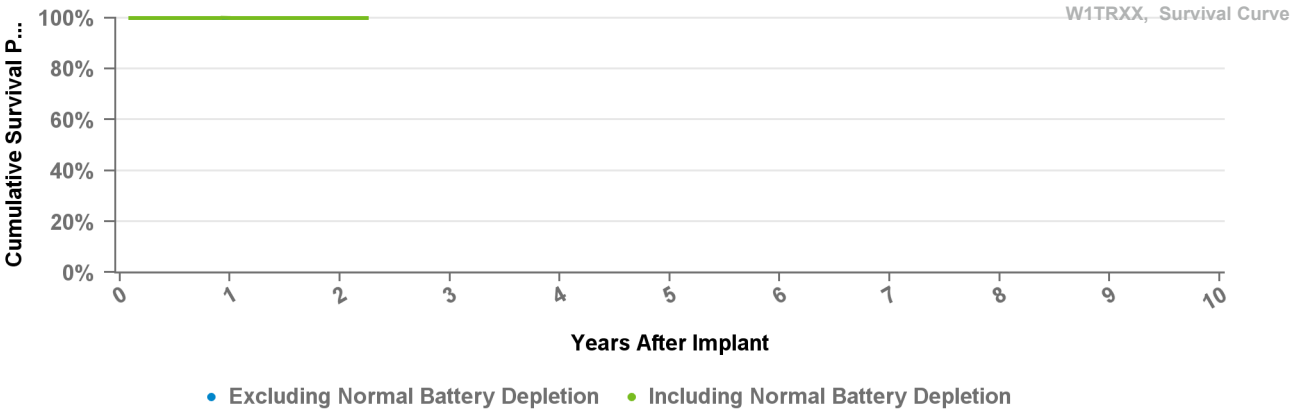
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	9,298		
Estimated Active USA Implants	8,127	**Therapy Function Compromised**	
Normal Battery Depletions	41		



Years	1	2	3	4	at 51 mo
Excluding NBD	1	1	1	1	1
Including NBD	0.999	0.998	0.995	0.98	0.974
Effective Sample Size	7676	6846	4182	839	132

W1TR01 Percepta CRTP MRI

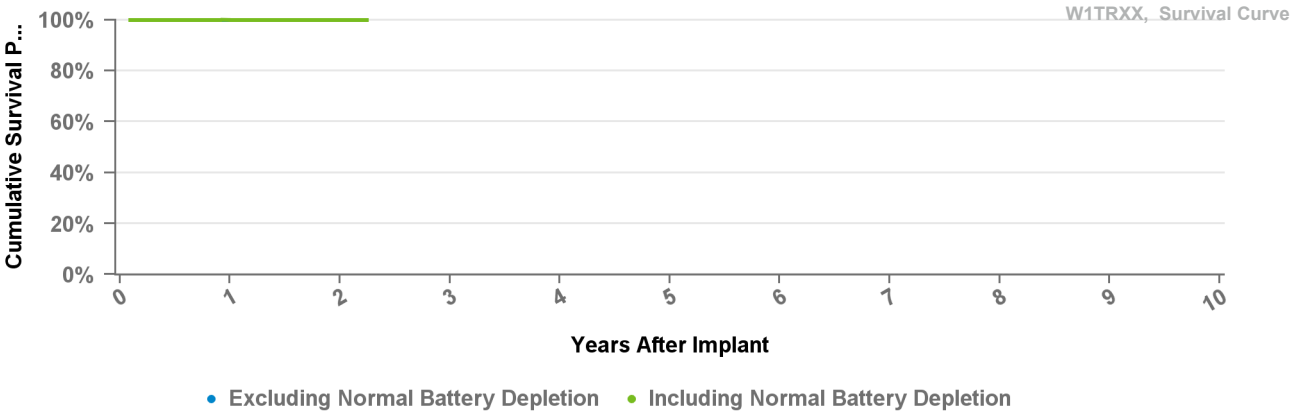
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,844	Other Malfunction	1
Estimated Active USA Implants	3,676	**Therapy Function Compromised**	**1**
Normal Battery Depletions	1	Electrical Component	1



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W1TR02 Serena CRTP MRI

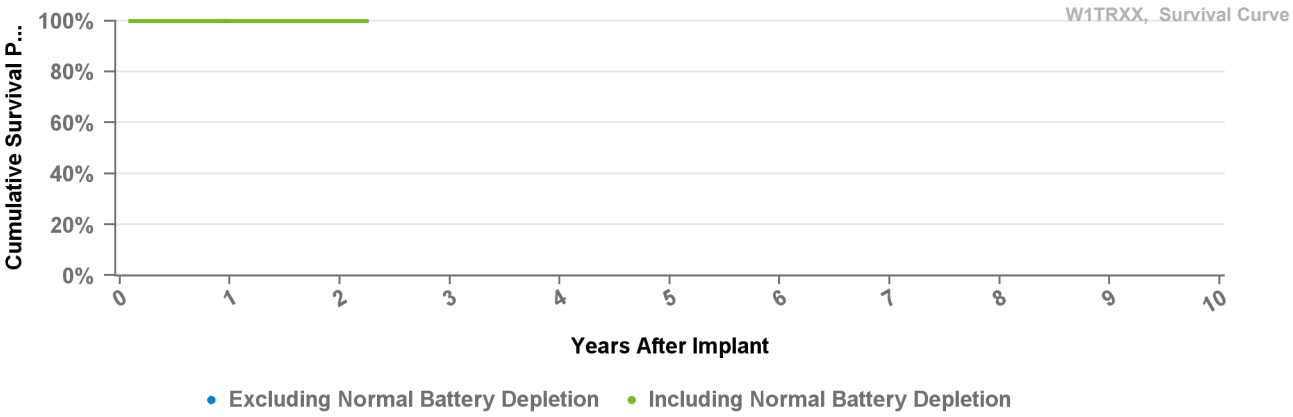
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	926	Other Malfunction	1
Estimated Active USA Implants	883	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W1TR03 Solara CRTP MRI

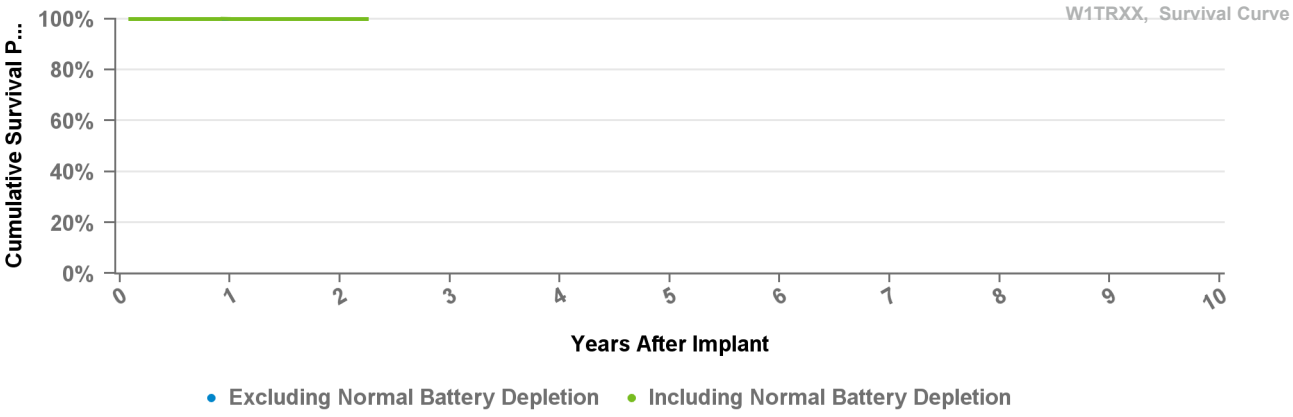
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,628		
Estimated Active USA Implants	1,543	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W1TR04 Percepta CRTP MRI

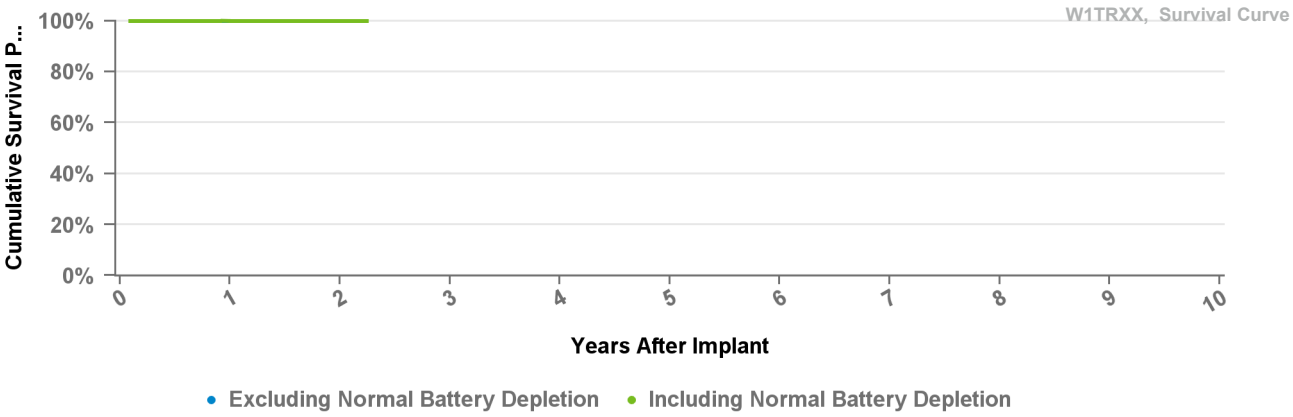
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W1TR05 Serena CRTP MRI

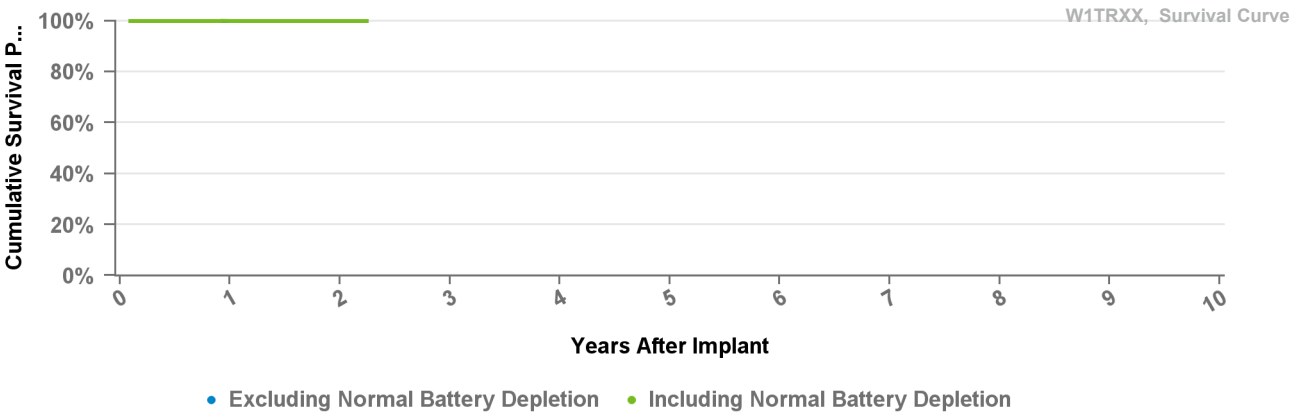
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W1TR06 Solara CRTP MRI

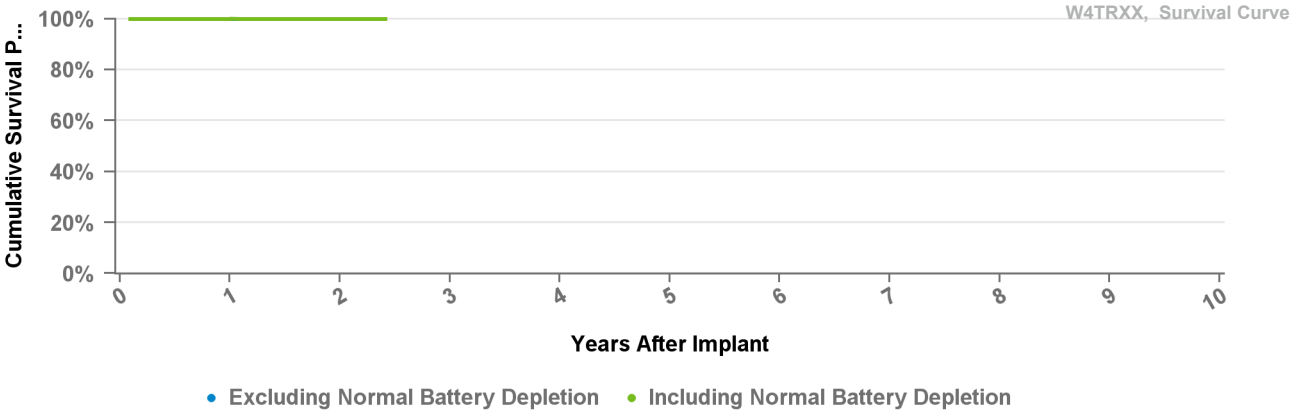
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 27 mo
Excluding NBD	1	1	1
Including NBD	0.999	0.999	0.999
Effective Sample Size	2909	425	122

W4TR01 Percepta Quad CRTP MRI SureScan

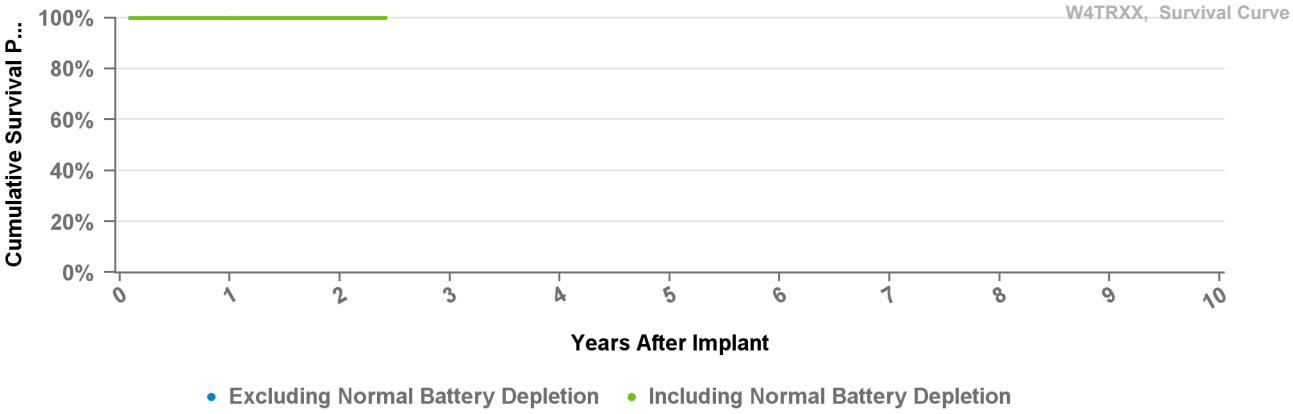
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	15,308	Electrical Component	1
Estimated Active USA Implants	14,713	Other Malfunction	1
Normal Battery Depletions		**Therapy Function Compromised**	**0**



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

W4TR02 Serena Quad CRTP MRI SureScan

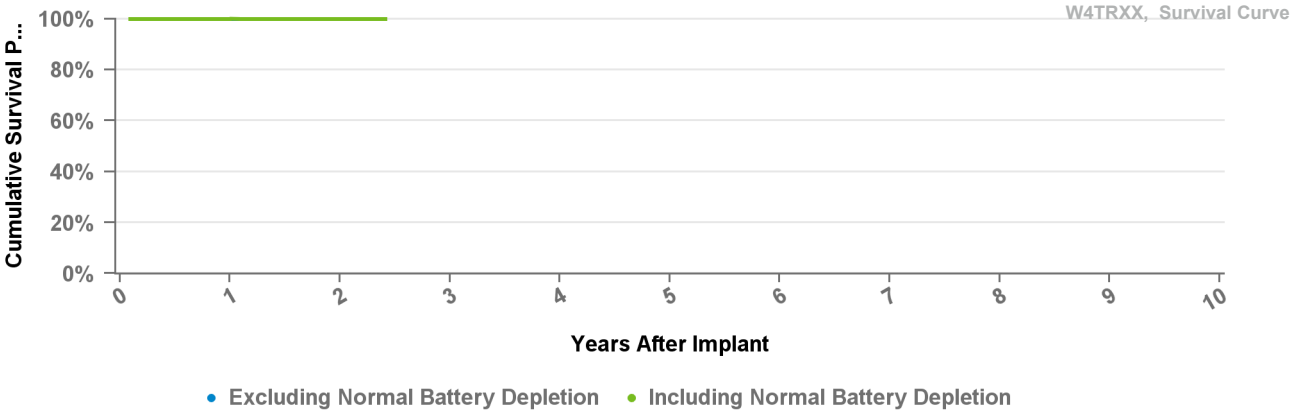
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	3,056		
Estimated Active USA Implants	2,938	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

W4TR03 Solara Quad CRTP MRI SureScan

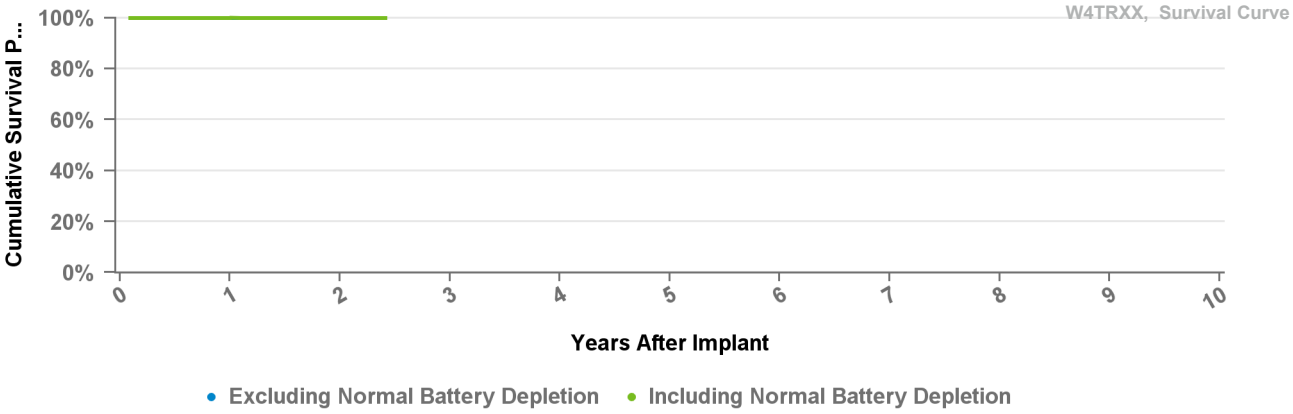
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	4,631		
Estimated Active USA Implants	4,419	**Therapy Function Compromised**	**2**
Normal Battery Depletions		Electrical Component	1
		Poss Early Battery Depltn	1



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

W4TR04 Percepta Quad CRT-P MRI SureScan

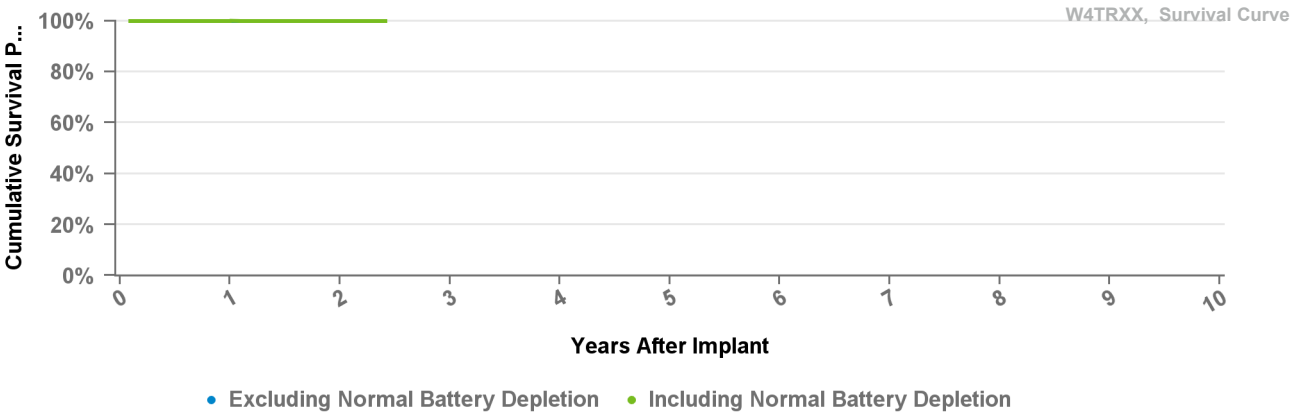
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

W4TR05 Serena Quad CRTP MRI SureScan

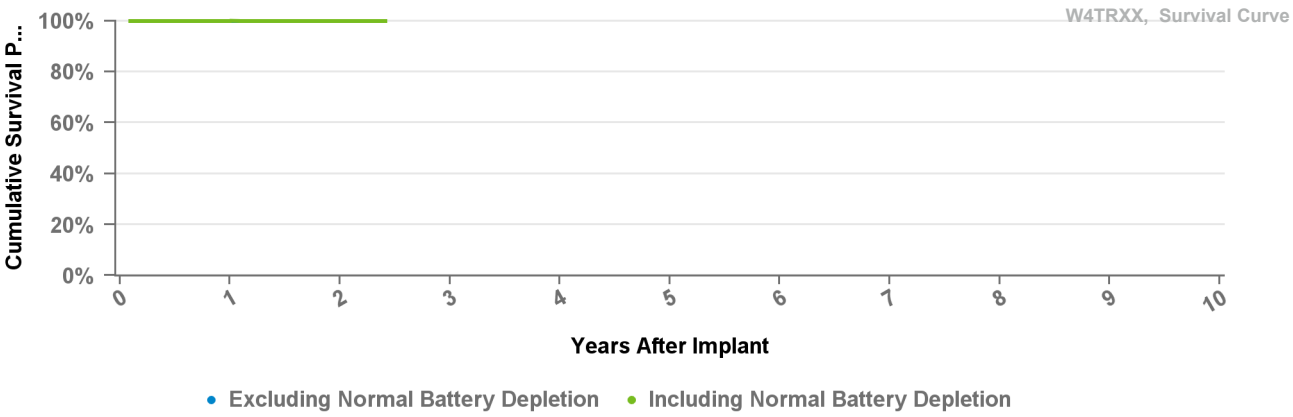
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

W4TR06 Solara Quad CRTP MRI SureScan

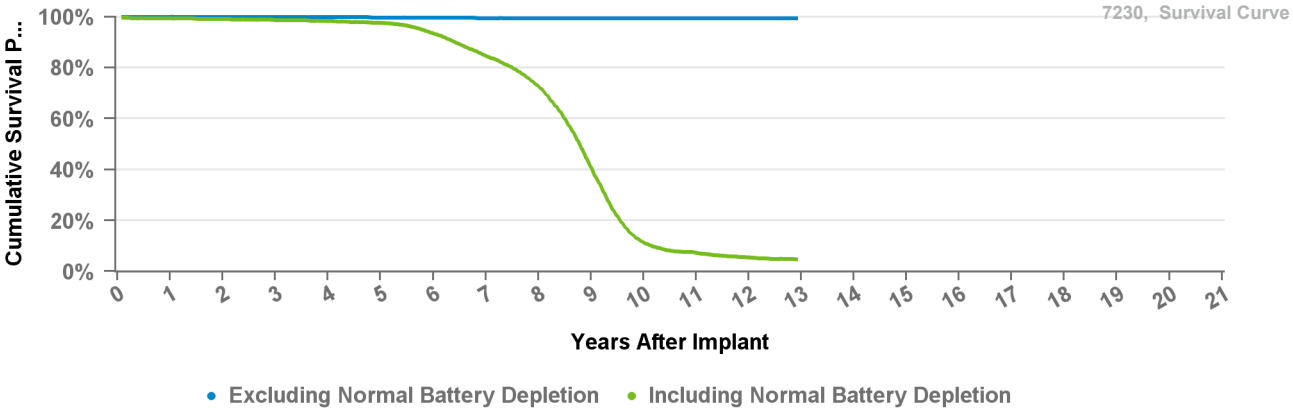
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 29 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	11353	2662	100

7230B Marquis VR

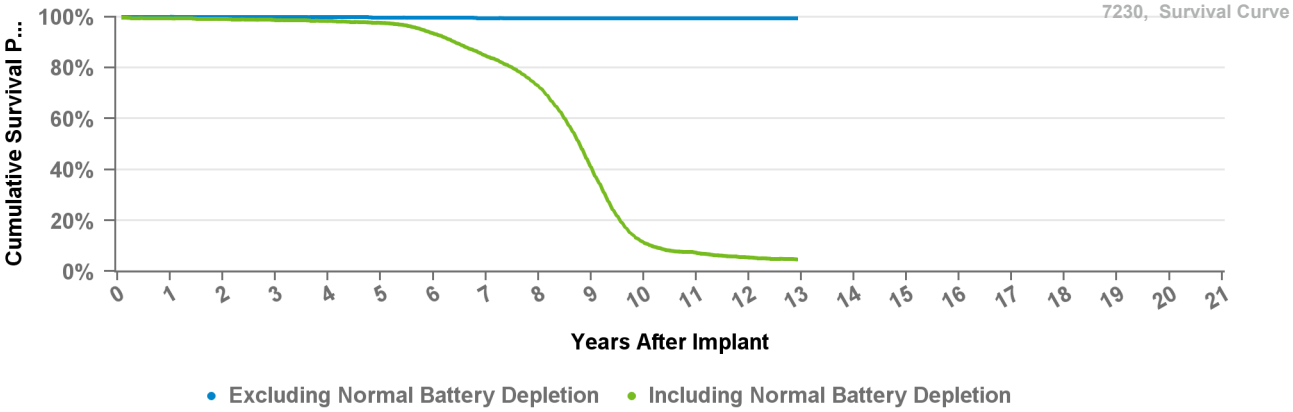
US Market Release	Dec-02	**Total Malfunctions**	**1**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**0**
Registered USA Implants	237		
Estimated Active USA Implants	11	**Therapy Function Compromised**	**1**
Normal Battery Depletions	25	Battery Malfunction	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 155 mo
Excluding NBD	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.994	0.994	0.994	0.994	0.994
Including NBD	0.994	0.991	0.987	0.983	0.976	0.934	0.846	0.726	0.411	0.113	0.073	0.055	0.047
Effective Sample Size	16319	12600	10434	9306	8273	7178	5962	4734	2490	522	264	157	104

7230Cx Marquis VR

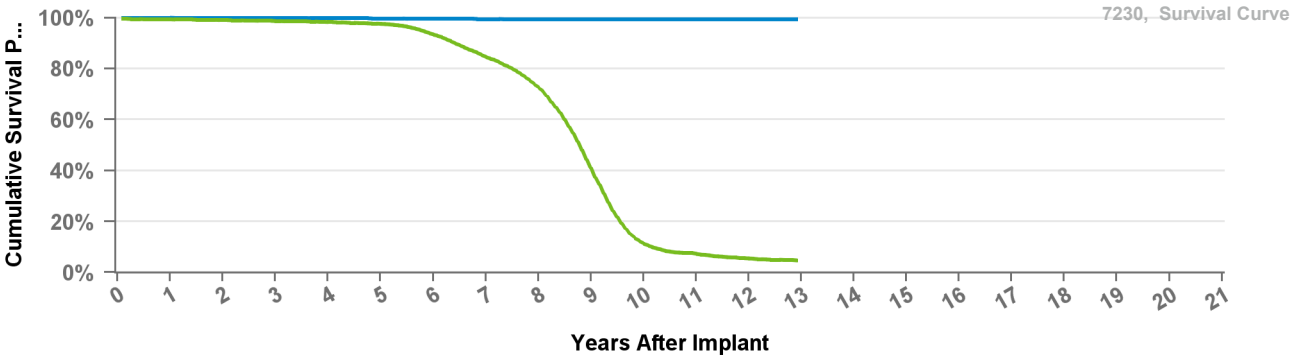
US Market Release	Dec-02	**Total Malfunctions**	**54**
CE Approval Date	Apr-02	**Therapy Function Not Compromised**	**30**
Registered USA Implants	18,337	Battery Malfunction	1
Estimated Active USA Implants	1,132	Electrical Component	14
Normal Battery Depletions	3,350	Poss Early Battery Depltn	14
		Software Malfunction	1
		Therapy Function Compromised	**24**
		Battery Malfunction	15
		Electrical Component	9



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 155 mo
Excluding NBD	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.994	0.994	0.994	0.994	0.994
Including NBD	0.994	0.991	0.987	0.983	0.976	0.934	0.846	0.726	0.411	0.113	0.073	0.055	0.047
Effective Sample Size	16319	12600	10434	9306	8273	7178	5962	4734	2490	522	264	157	104

7230E Marquis VR

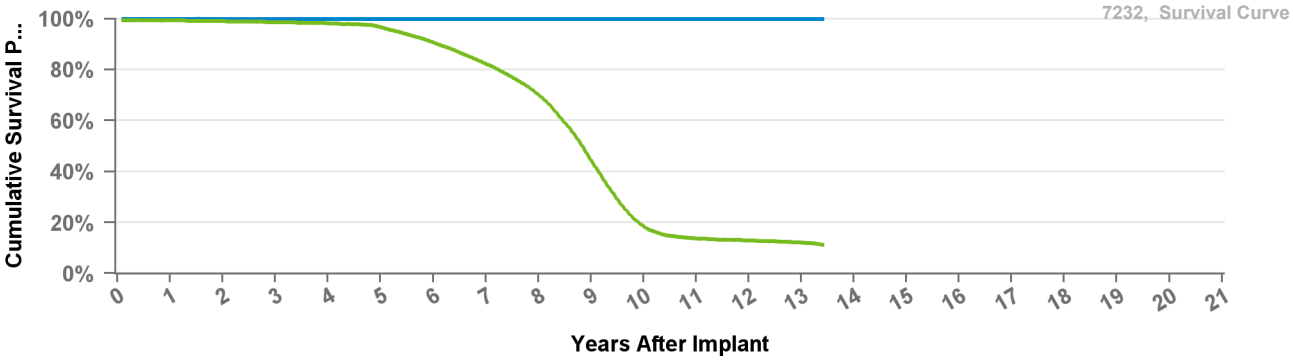
US Market Release	Dec-02	**Total Malfunctions**	**3**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**1**
Registered USA Implants	625	Electrical Component	1
Estimated Active USA Implants	35	**Therapy Function Compromised**	**2**
Normal Battery Depletions	75	Battery Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 155 mo
Excluding NBD	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.994	0.994	0.994	0.994	0.994
Including NBD	0.994	0.991	0.987	0.983	0.976	0.934	0.846	0.726	0.411	0.113	0.073	0.055	0.047
Effective Sample Size	16319	12600	10434	9306	8273	7178	5962	4734	2490	522	264	157	104

7232B Maximo VR

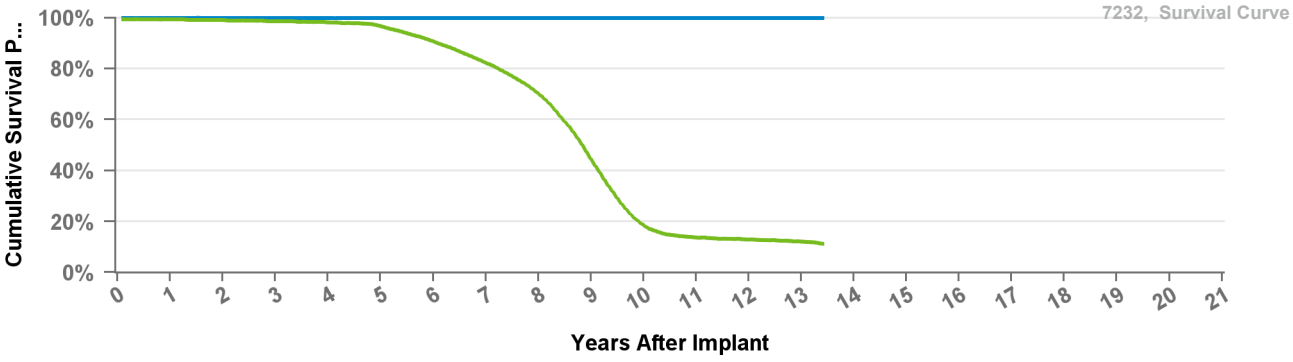
US Market Release	Oct-03	**Total Malfunctions**	
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	
Registered USA Implants	170		
Estimated Active USA Implants	22	**Therapy Function Compromised**	
Normal Battery Depletions	34		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 161 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.993	0.991	0.987	0.982	0.967	0.907	0.822	0.701	0.446	0.185	0.137	0.129	0.121	0.112
Effective Sample Size	37962	33964	30266	26674	23484	20403	17220	13744	8134	2797	1686	1216	599	131

7232Cx Maximo VR

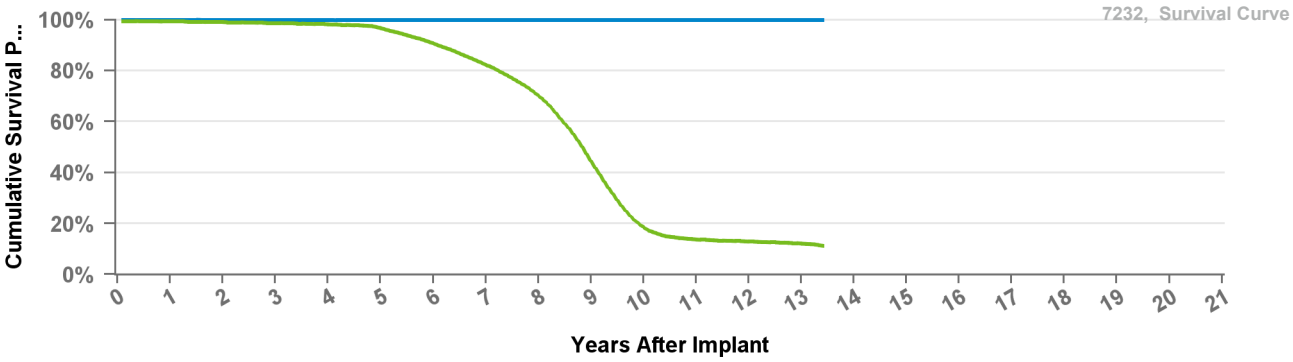
US Market Release	Oct-03	**Total Malfunctions**	**72**
CE Approval Date	Oct-03	**Therapy Function Not Compromised**	**57**
Registered USA Implants	43,453	Electrical Component	28
Estimated Active USA Implants	4,729	Other Malfunction	2
Normal Battery Depletions	10,217	Poss Early Battery Depltn	25
		Software 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 161 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.993	0.991	0.987	0.982	0.967	0.907	0.822	0.701	0.446	0.185	0.137	0.129	0.121	0.112
Effective Sample Size	37962	33964	30266	26674	23484	20403	17220	13744	8134	2797	1686	1216	599	131

7232E Maximo VR

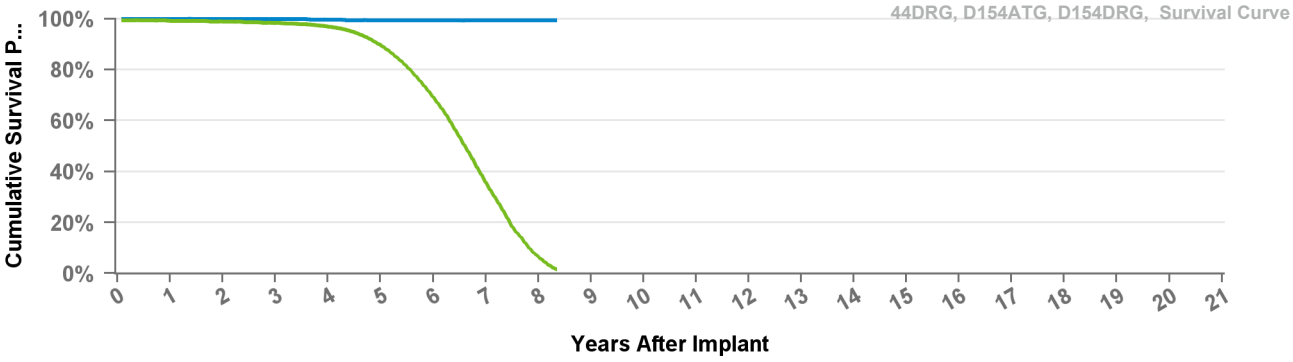
US Market Release	Oct-03	**Total Malfunctions**	**1**
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	**0**
Registered USA Implants	489		
Estimated Active USA Implants	61	**Therapy Function Compromised**	**1**
Normal Battery Depletions	86	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 161 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.993	0.991	0.987	0.982	0.967	0.907	0.822	0.701	0.446	0.185	0.137	0.129	0.121	0.112
Effective Sample Size	37962	33964	30266	26674	23484	20403	17220	13744	8134	2797	1686	1216	599	131

D144DRG Entrust Escudo

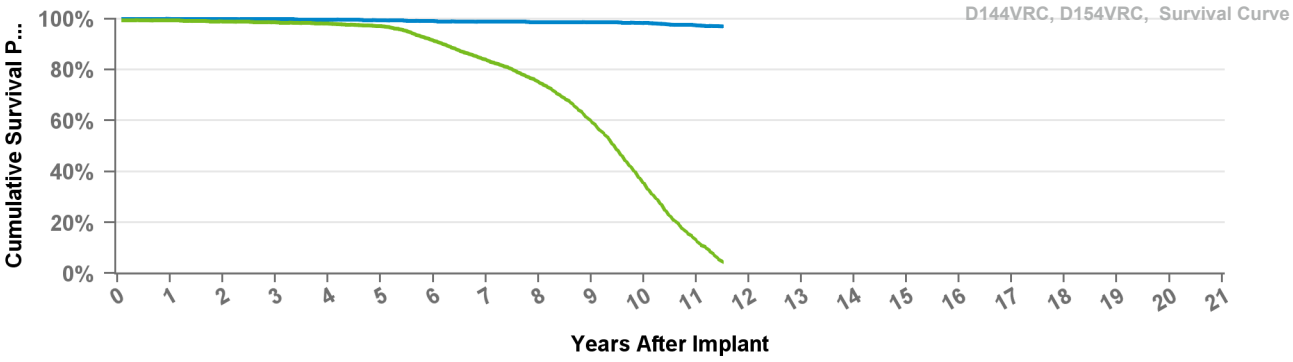
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	1	0.999	0.998	0.996	0.994	0.994	0.993	0.993	0.993
Including NBD	0.992	0.989	0.983	0.969	0.896	0.694	0.359	0.064	0.016
Effective Sample Size	24758	22548	20183	17741	14622	10455	4861	734	183

D144VRC Entrust Escudo

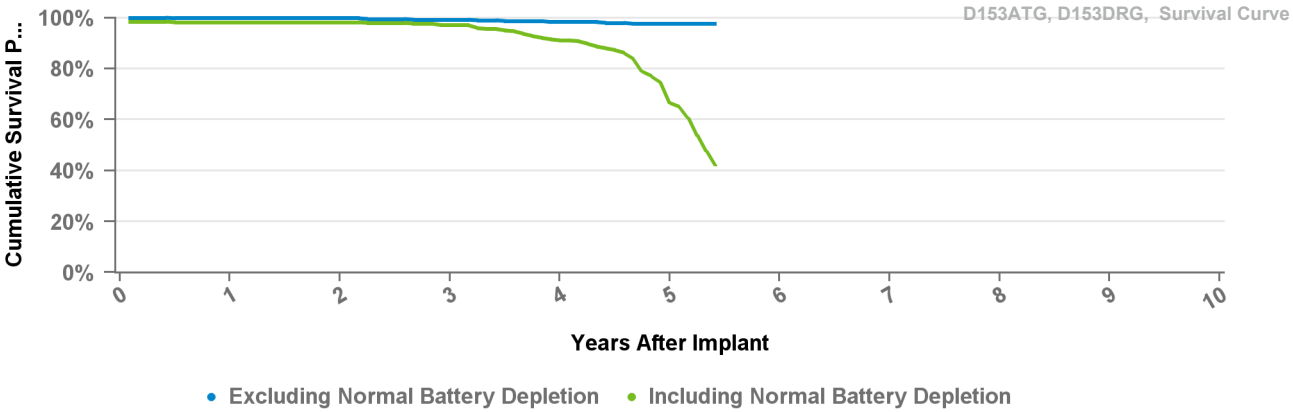
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
Excluding NBD	0.999	0.999	0.998	0.997	0.994	0.991	0.988	0.987	0.986	0.983	0.974	0.97
Including NBD	0.993	0.989	0.986	0.981	0.971	0.914	0.839	0.751	0.597	0.357	0.129	0.045
Effective Sample Size	12523	11342	10133	8922	7844	6821	5808	4855	3500	1839	515	127

D153ATG Entrust AT

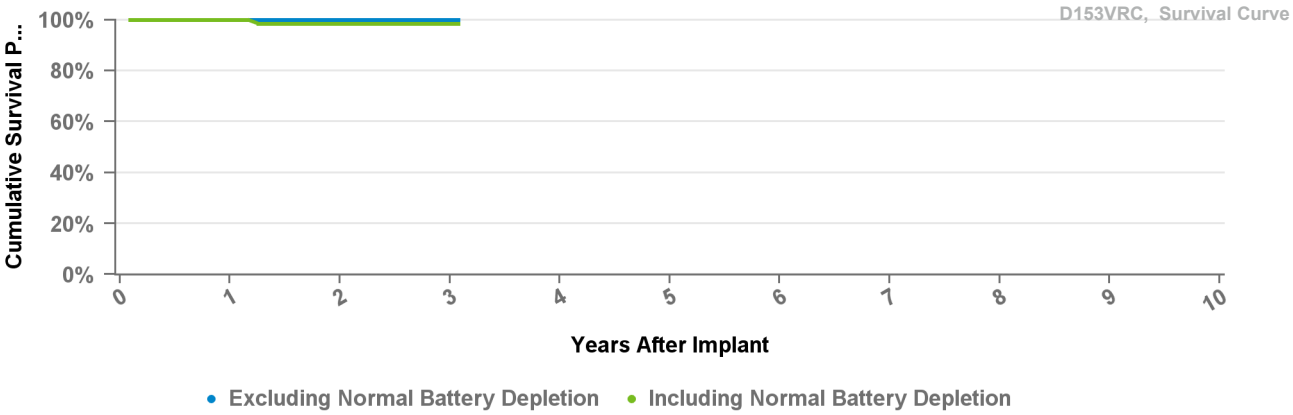
US Market Release	Jun-05	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	459	Poss Early Battery Depltn	7
Estimated Active USA Implants	12	**Therapy Function Compromised**	**1**
Normal Battery Depletions	179	Electrical Component	1



Years	1	2	3	4	5	at 65 mo
Excluding NBD	0.998	0.998	0.992	0.983	0.976	0.976
Including NBD	0.982	0.982	0.971	0.911	0.666	0.422
Effective Sample Size	408	374	337	276	192	105

D153VRC Entrust VR

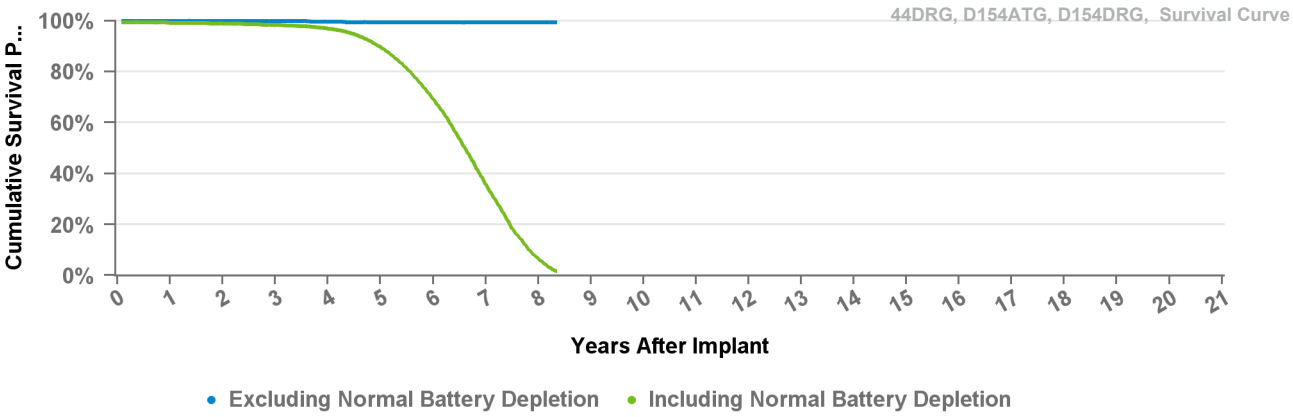
US Market Release	Jun-05	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	165	Electrical Component	1
Estimated Active USA Implants	7	**Therapy Function Compromised**	**0**
Normal Battery Depletions	28		



Years	1	2	3	at 37 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.985	0.985	0.985
Effective Sample Size	141	119	102	100

D154ATG Entrust AT

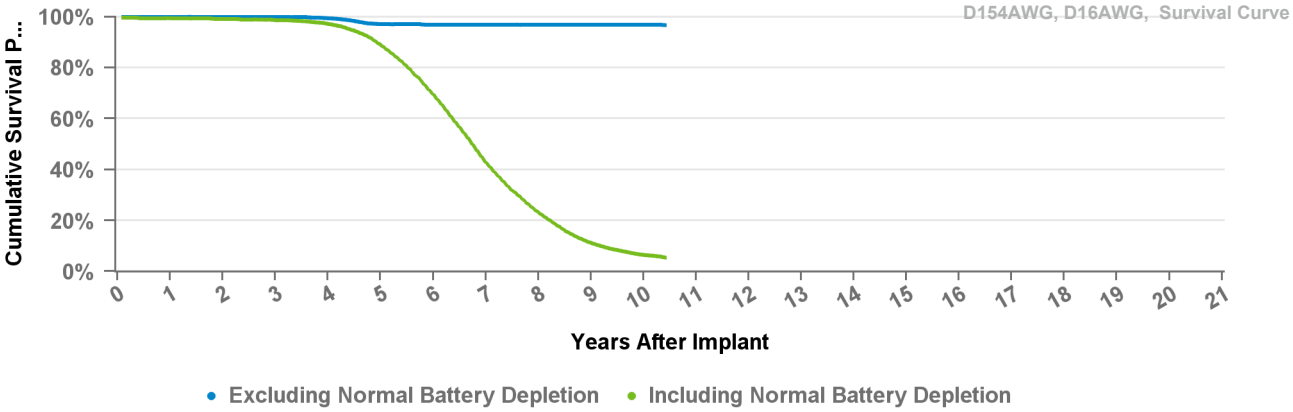
US Market Release	Jun-05	**Total Malfunctions**	**125**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**109**
Registered USA Implants	28,091	Electrical Component	30
Estimated Active USA Implants	904	Electrical Interconnect	1
Normal Battery Depletions	8,745	Other Malfunction	1
		Poss Early Battery Depltn	74
		Software Malfunction	3
		Therapy Function Compromised	**16**
		Electrical Component	16



Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	1	0.999	0.998	0.996	0.994	0.994	0.993	0.993	0.993
Including NBD	0.992	0.989	0.983	0.969	0.896	0.694	0.359	0.064	0.016
Effective Sample Size	24758	22548	20183	17741	14622	10455	4861	734	183

D154AWG Virtuoso DR

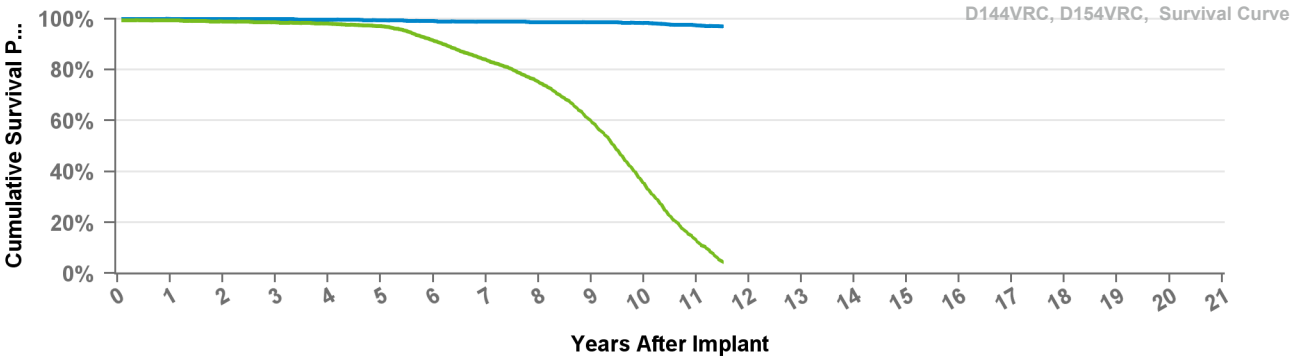
US Market Release	May-06	**Total Malfunctions**	**3,334**
CE Approval Date		**Therapy Function Not Compromised**	**3,282**
Registered USA Implants	76,726	Battery Malfunction	9
Estimated Active USA Implants	9,724	Electrical Component	3,133
Normal Battery Depletions	21,014	Electrical Interconnect	2
		Other Malfunction	3
		Poss Early Battery Depltn	132
		Software Malfunction	3
		Therapy Function Compromised	**52**
		Battery Malfunction	3
		Electrical Component	45
		Other Malfunction	3
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	1	0.999	0.999	0.994	0.971	0.969	0.969	0.968	0.968	0.968	0.967
Including NBD	0.994	0.991	0.987	0.972	0.889	0.697	0.43	0.231	0.112	0.065	0.054
Effective Sample Size	63126	57878	52707	47865	40635	29481	16331	7506	2982	1216	248

D154VRC Entrust VR

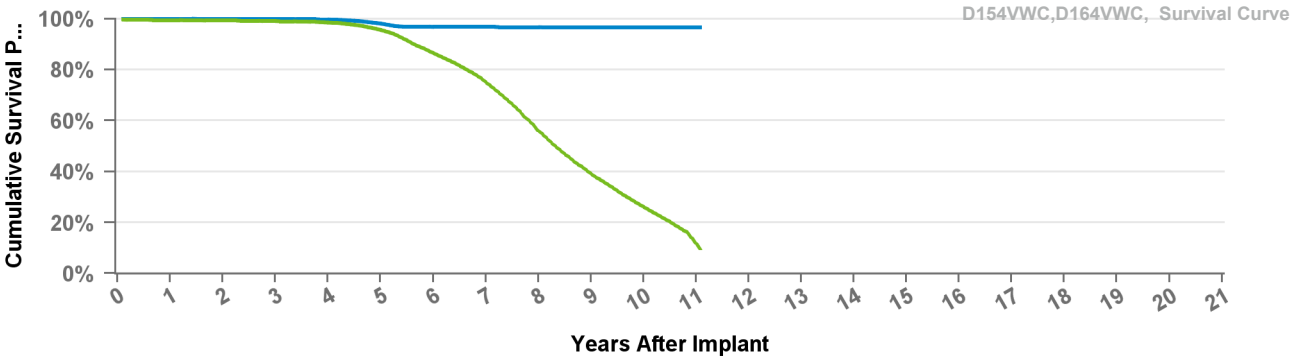
US Market Release	Jun-05	**Total Malfunctions**	**151**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**98**
Registered USA Implants	14,386	Battery Malfunction	16
Estimated Active USA Implants	930	Electrical Component	47
Normal Battery Depletions	3,175	Other Malfunction	11
		Poss Early Battery Depltn	24
		Therapy Function Compromised	**53**
		Battery Malfunction	22
		Electrical Component	27
		Other Malfunction	4



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
Excluding NBD	0.999	0.999	0.998	0.997	0.994	0.991	0.988	0.987	0.986	0.983	0.974	0.97
Including NBD	0.993	0.989	0.986	0.981	0.971	0.914	0.839	0.751	0.597	0.357	0.129	0.045
Effective Sample Size	12523	11342	10133	8922	7844	6821	5808	4855	3500	1839	515	127

D154VWC Virtuoso VR

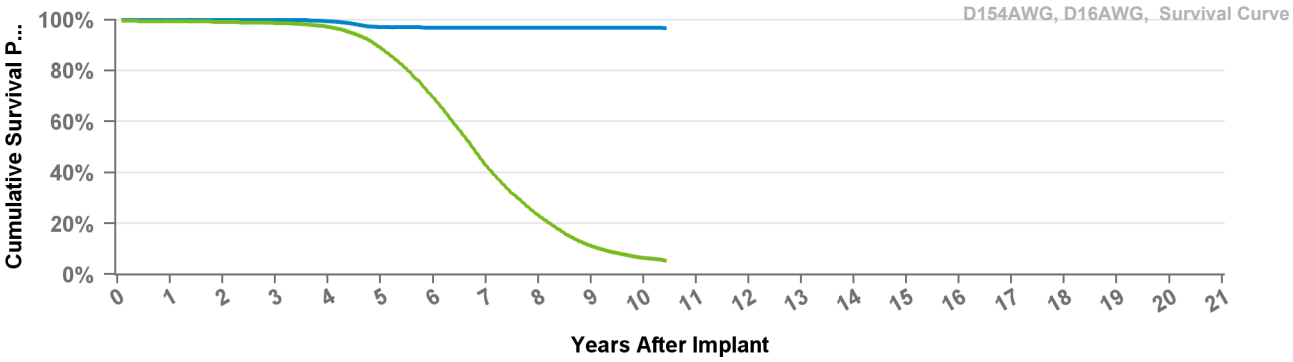
US Market Release	May-06	**Total Malfunctions**	**694**
CE Approval Date		**Therapy Function Not Compromised**	**672**
Registered USA Implants	33,084	Battery Malfunction	12
Estimated Active USA Implants	6,050	Electrical Component	640
Normal Battery Depletions	7,497	Electrical Interconnect	1
		Other Malfunction	4
		Poss Early Battery Depltn	15
		Therapy Function Compromised	**22**
		Battery Malfunction	5
		Electrical Component	17



Years	1	2	3	4	5	6	7	8	9	10	11	at 133 mo
Excluding NBD	1	0.999	0.999	0.997	0.981	0.968	0.968	0.967	0.966	0.966	0.966	0.966
Including NBD	0.995	0.993	0.991	0.985	0.956	0.865	0.75	0.561	0.391	0.261	0.119	0.097
Effective Sample Size	28416	25901	23591	21569	19165	16021	12928	8902	5552	3197	402	208

D164AWG Virtuoso DR

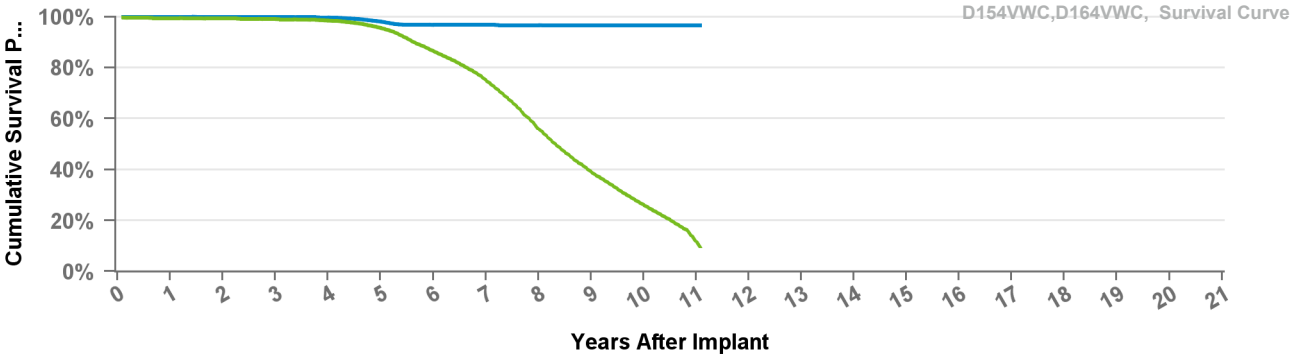
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	
Registered USA Implants	10		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	3		



Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	1	0.999	0.999	0.994	0.971	0.969	0.969	0.968	0.968	0.968	0.967
Including NBD	0.994	0.991	0.987	0.972	0.889	0.697	0.43	0.231	0.112	0.065	0.054
Effective Sample Size	63126	57878	52707	47865	40635	29481	16331	7506	2982	1216	248

D164VWC Virtuoso VR

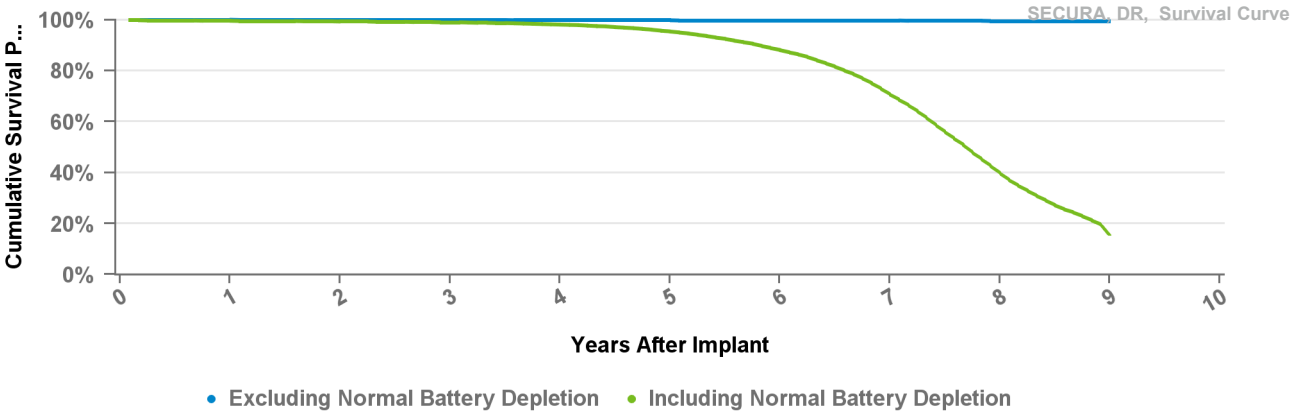
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 133 mo
Excluding NBD	1	0.999	0.999	0.997	0.981	0.968	0.968	0.967	0.966	0.966	0.966	0.966
Including NBD	0.995	0.993	0.991	0.985	0.956	0.865	0.75	0.561	0.391	0.261	0.119	0.097
Effective Sample Size	28416	25901	23591	21569	19165	16021	12928	8902	5552	3197	402	208

D204DRM Secura DR

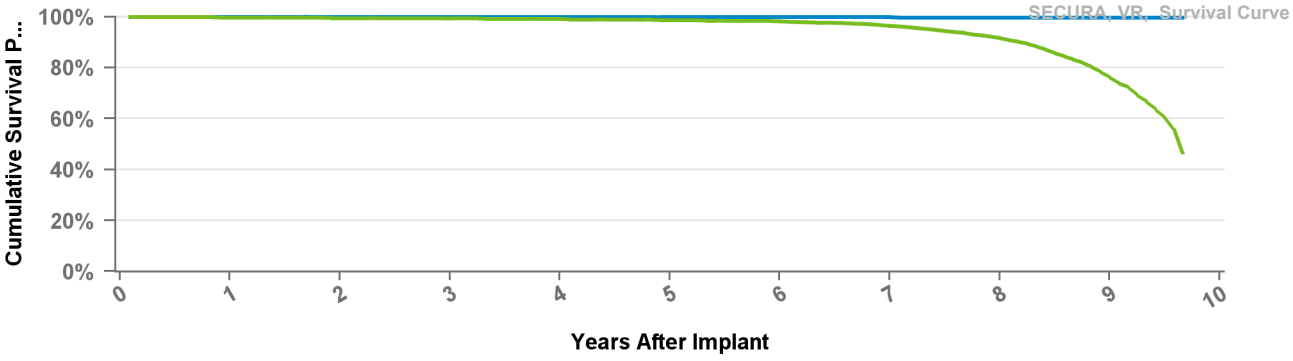
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,879	Other Malfunction	1
Estimated Active USA Implants	1,126	**Therapy Function Compromised**	**2**
Normal Battery Depletions	118	Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.995	0.995
Including NBD	0.996	0.993	0.99	0.981	0.954	0.881	0.707	0.398	0.158
Effective Sample Size	45126	42267	39685	36826	32972	26687	16845	6428	147

D204VRM Secura VR

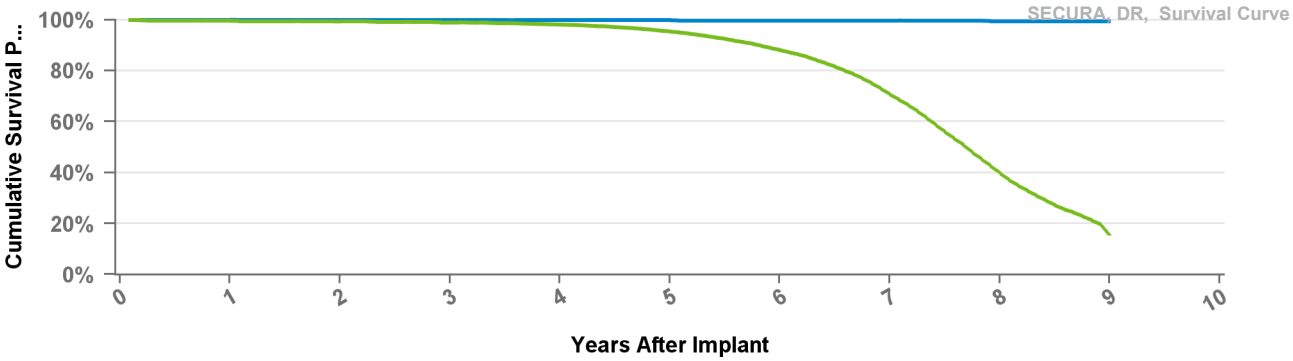
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,184	Electrical Component	1
Estimated Active USA Implants	918	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997	0.996
Including NBD	0.997	0.995	0.993	0.991	0.987	0.982	0.964	0.916	0.762	0.465
Effective Sample Size	18211	17005	16024	14931	13703	12426	10262	7348	2878	335

D214DRM Secura DR

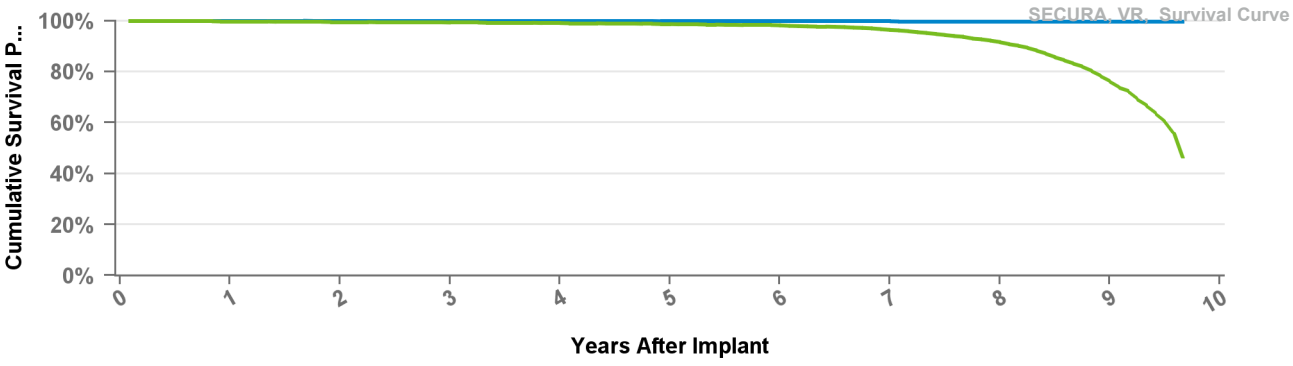
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.995	0.995
Including NBD	0.996	0.993	0.99	0.981	0.954	0.881	0.707	0.398	0.158
Effective Sample Size	45126	42267	39685	36826	32972	26687	16845	6428	147

D214VRM Secura VR

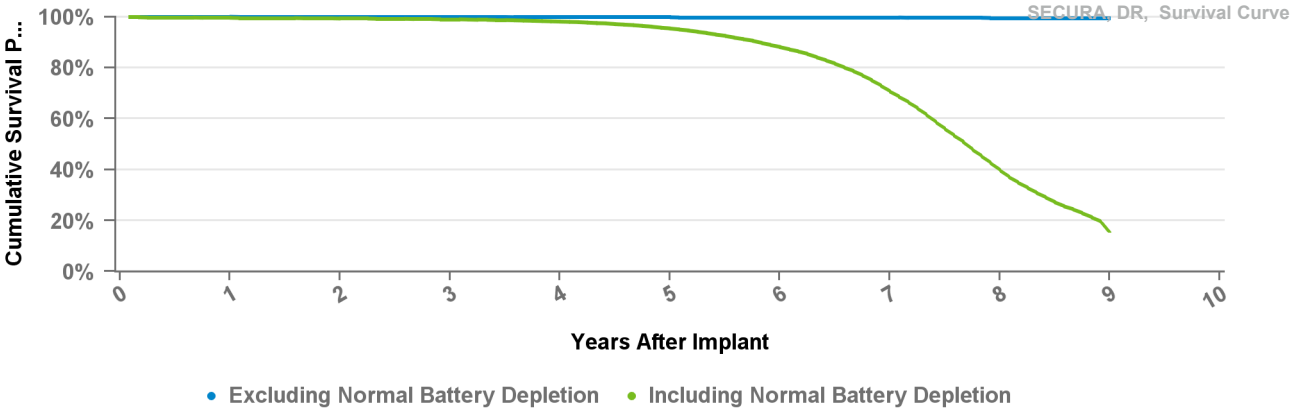
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997	0.996
Including NBD	0.997	0.995	0.993	0.991	0.987	0.982	0.964	0.916	0.762	0.465
Effective Sample Size	18211	17005	16024	14931	13703	12426	10262	7348	2878	335

D224DRG Secura DR

US Market Release	Sep-08	**Total Malfunctions**	**148**
CE Approval Date		**Therapy Function Not Compromised**	**115**
Registered USA Implants	49,913	Battery Malfunction	14
Estimated Active USA Implants	12,403	Electrical Component	38
Normal Battery Depletions	9,454	Other Malfunction	4
		Poss Early Battery Depltn	50
		Software Malfunction	9
		Therapy Function Compromised	**33**
		Battery Malfunction	17
		Electrical Component	13
		Other Malfunction	1
		Poss Early Battery Depltn	1
		Software Malfunction	1

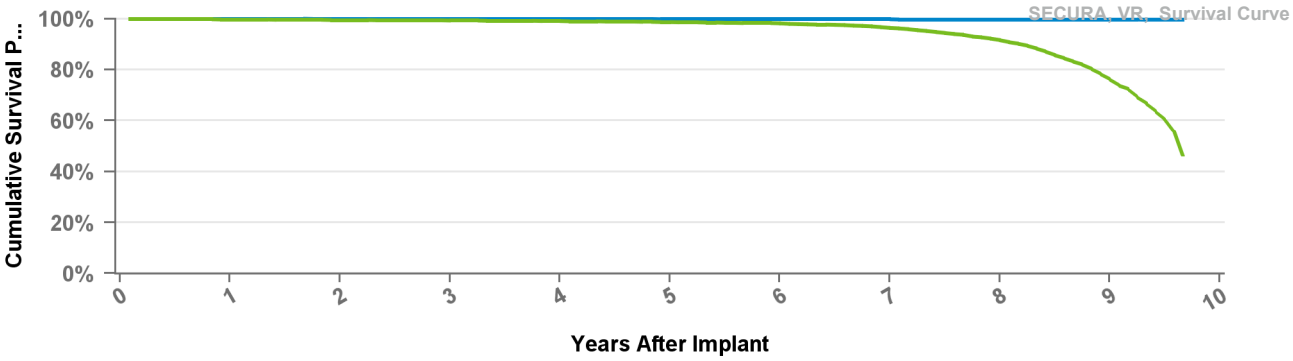


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.995	0.995
Including NBD	0.996	0.993	0.99	0.981	0.954	0.881	0.707	0.398	0.158
Effective Sample Size	45126	42267	39685	36826	32972	26687	16845	6428	147

D224VRC Secura VR

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	20,045
Estimated Active USA Implants	8,159
Normal Battery Depletions	1,284

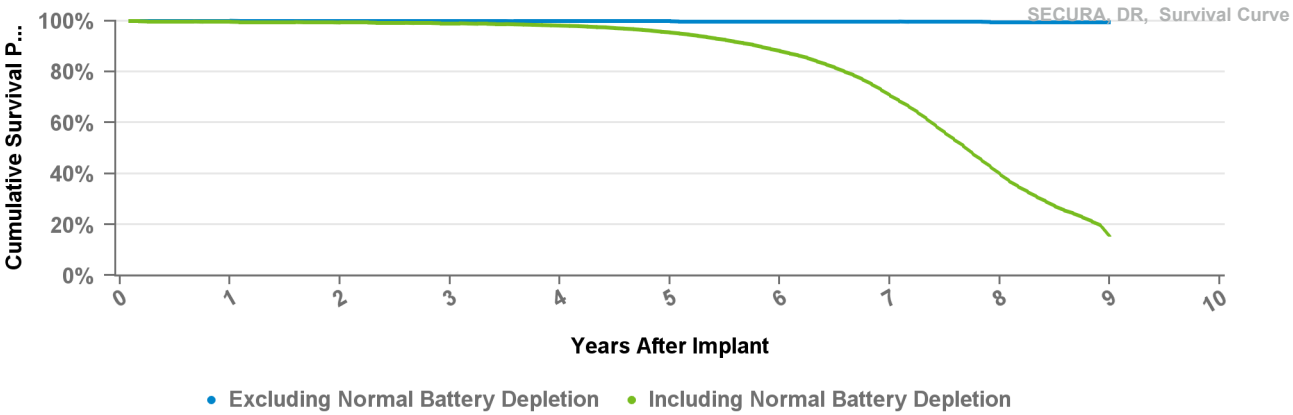
Total Malfunctions	**50**
Therapy Function Not Compromised	**35**
Battery Malfunction	14
Electrical Component	10
Other Malfunction	1
Poss Early Battery Depltn	8
Software Malfunction	2
Therapy Function Compromised	**15**
Battery Malfunction	7
Electrical Component	6
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997	0.996
Including NBD	0.997	0.995	0.993	0.991	0.987	0.982	0.964	0.916	0.762	0.465
Effective Sample Size	18211	17005	16024	14931	13703	12426	10262	7348	2878	335

D234DRG Secura DR

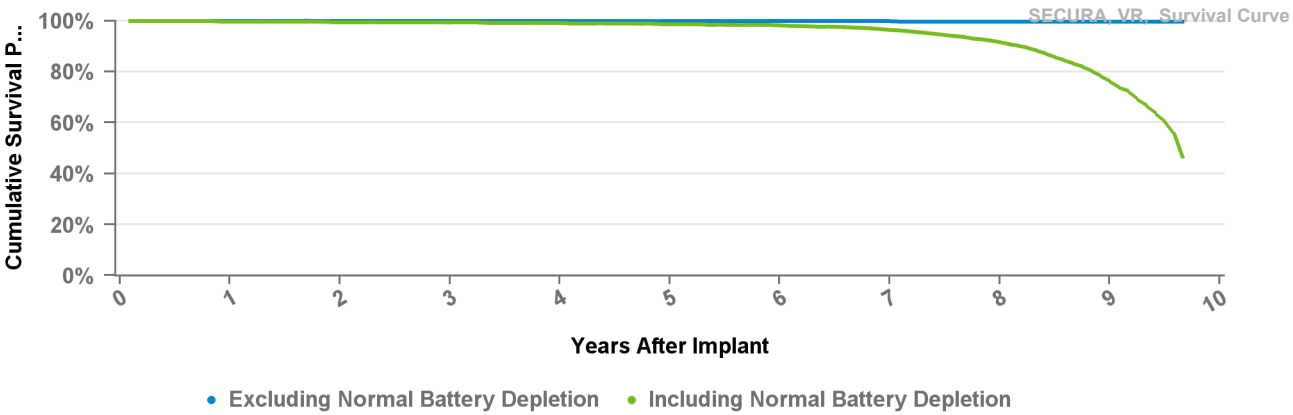
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.995	0.995
Including NBD	0.996	0.993	0.99	0.981	0.954	0.881	0.707	0.398	0.158
Effective Sample Size	45126	42267	39685	36826	32972	26687	16845	6428	147

D234VRC Secura VR

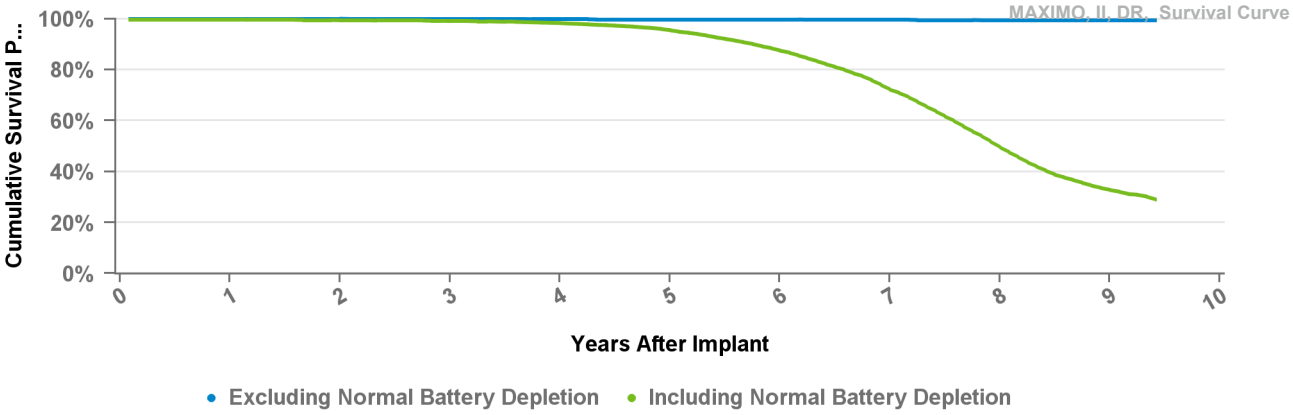
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997	0.996
Including NBD	0.997	0.995	0.993	0.991	0.987	0.982	0.964	0.916	0.762	0.465
Effective Sample Size	18211	17005	16024	14931	13703	12426	10262	7348	2878	335

D264DRM Maximo II DR

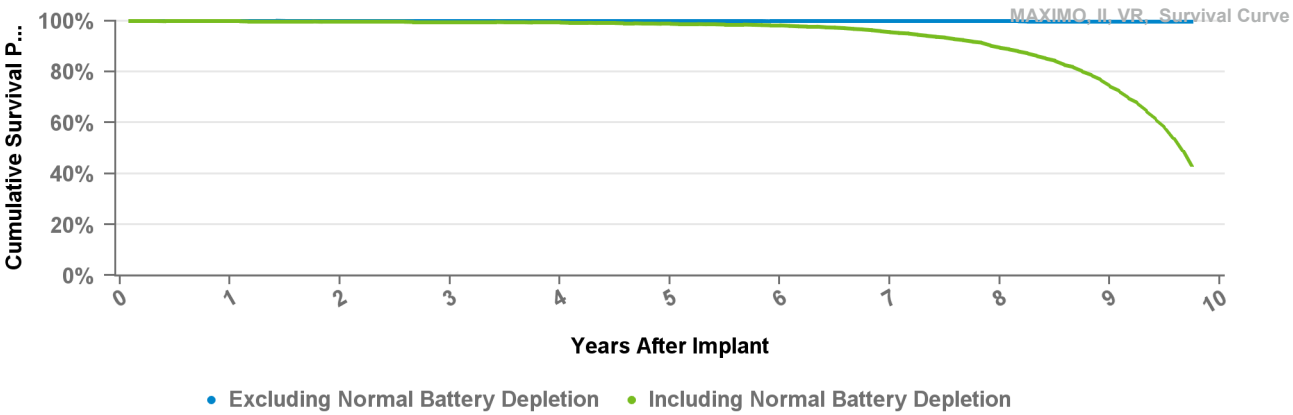
US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	0.999	0.998	0.997	0.997	0.996	0.994	0.994	0.994
Including NBD	0.997	0.994	0.991	0.983	0.955	0.875	0.722	0.496	0.328	0.29
Effective Sample Size	17491	16333	15352	14255	12753	10144	6153	2548	642	104

D264VRM Maximo II VR

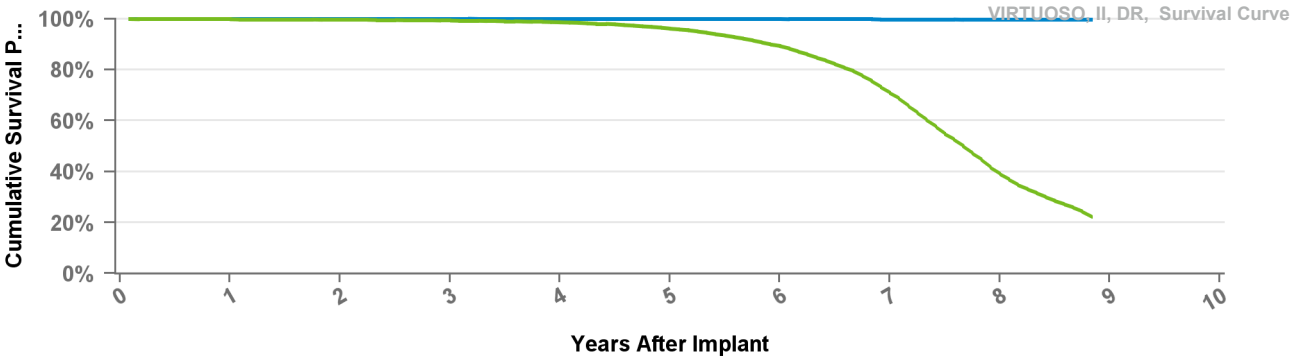
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	1	0.999	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.996	0.995	0.993	0.988	0.982	0.955	0.894	0.743	0.432
Effective Sample Size	11185	10486	9873	9182	8433	7631	6341	4419	1769	142

D274DRG Virtuoso II DR

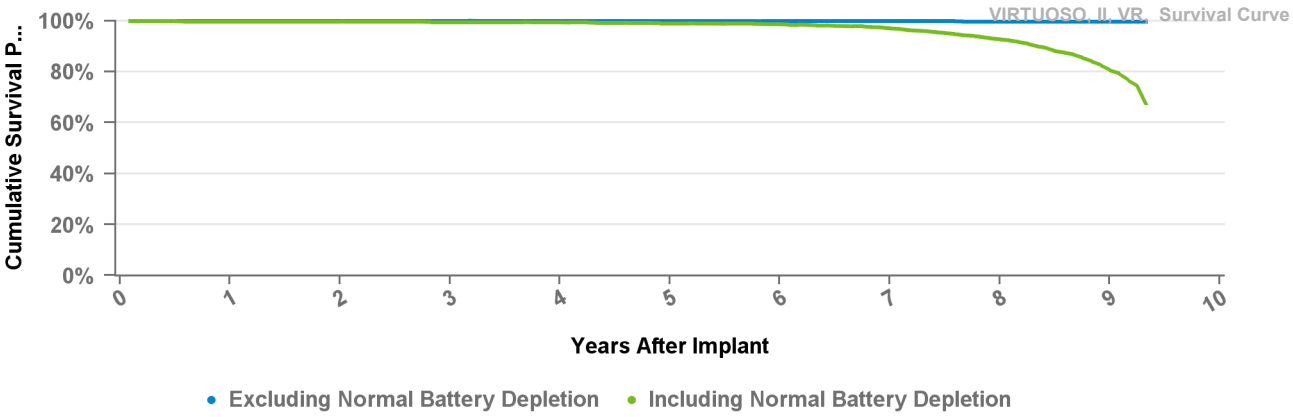
US Market Release	Aug-09	**Total Malfunctions**	**46**
CE Approval Date		**Therapy Function Not Compromised**	**29**
Registered USA Implants	22,232	Battery Malfunction	10
Estimated Active USA Implants	5,731	Electrical Component	11
Normal Battery Depletions	4,087	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**17**
		Battery Malfunction	14
		Electrical Component	2
		Other Malfunction	1



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.996	0.996
Including NBD	0.998	0.996	0.993	0.986	0.961	0.893	0.709	0.391	0.222
Effective Sample Size	19243	18070	17009	15804	14086	11327	7304	3109	253

D274VRC Virtuoso II VR

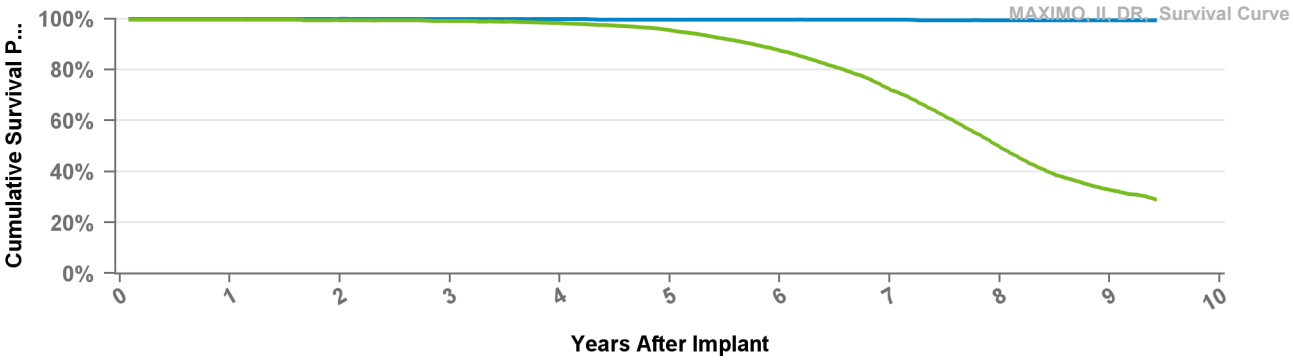
US Market Release	Aug-09	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	9,125	Battery Malfunction	6
Estimated Active USA Implants	4,093	Electrical Component	4
Normal Battery Depletions	420	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**5**
		Battery Malfunction	4
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.998	0.997	0.997	0.997
Including NBD	0.997	0.997	0.995	0.994	0.99	0.986	0.97	0.927	0.806	0.674
Effective Sample Size	7758	7286	6877	6401	5907	5369	4770	3723	1068	215

D284DRG Maximo II DR

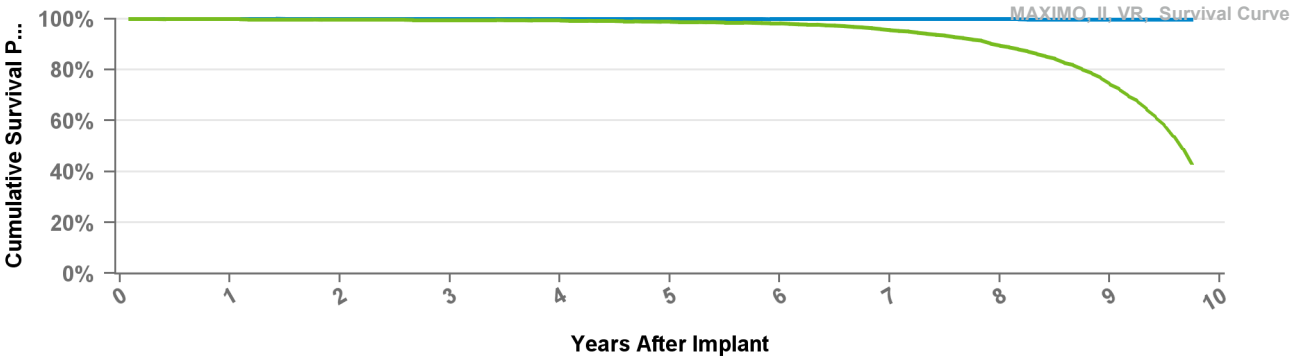
US Market Release	Sep-08	**Total Malfunctions**	**70**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**53**
Registered USA Implants	20,090	Battery Malfunction	6
Estimated Active USA Implants	5,412	Electrical Component	15
Normal Battery Depletions	3,319	Other Malfunction	2
		Poss Early 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 113 mo
Excluding NBD	1	1	0.999	0.998	0.997	0.997	0.996	0.994	0.994	0.994
Including NBD	0.997	0.994	0.991	0.983	0.955	0.875	0.722	0.496	0.328	0.29
Effective Sample Size	17491	16333	15352	14255	12753	10144	6153	2548	642	104

D284VRC Maximo II VR

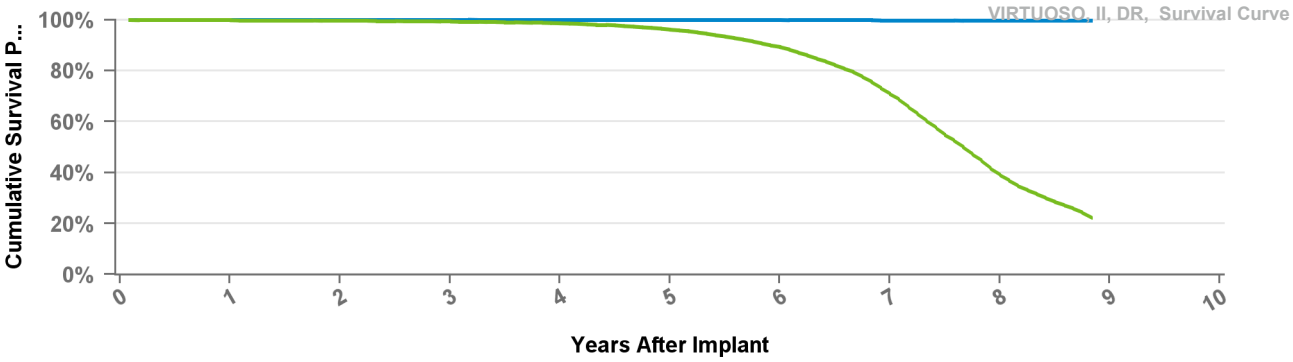
US Market Release	Sep-08	**Total Malfunctions**	**27**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**21**
Registered USA Implants	13,031	Battery Malfunction	8
Estimated Active USA Implants	5,528	Electrical Component	6
Normal Battery Depletions	993	Poss Early Battery Depltn	4
		Software 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 117 mo
Excluding NBD	1	0.999	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.996	0.995	0.993	0.988	0.982	0.955	0.894	0.743	0.432
Effective Sample Size	11185	10486	9873	9182	8433	7631	6341	4419	1769	142

D294DRG Virtuoso II DR

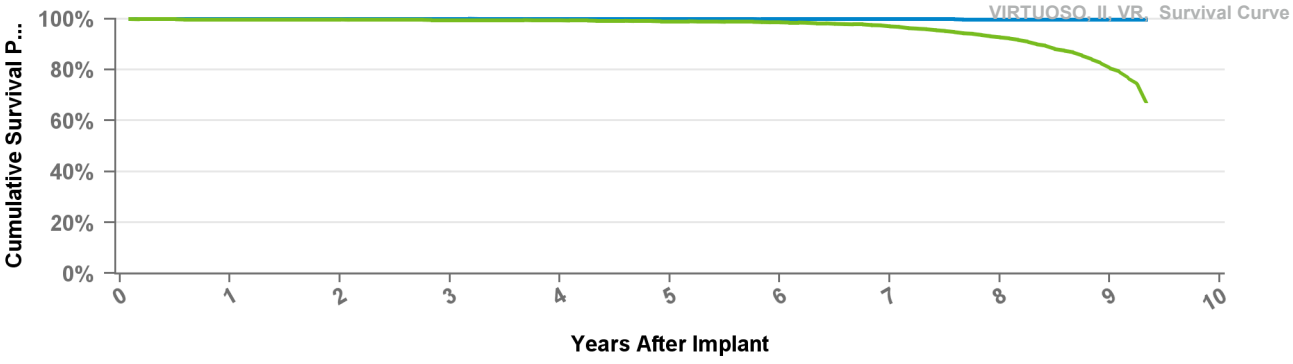
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.996	0.996
Including NBD	0.998	0.996	0.993	0.986	0.961	0.893	0.709	0.391	0.222
Effective Sample Size	19243	18070	17009	15804	14086	11327	7304	3109	253

D294VRC Virtuoso II VR

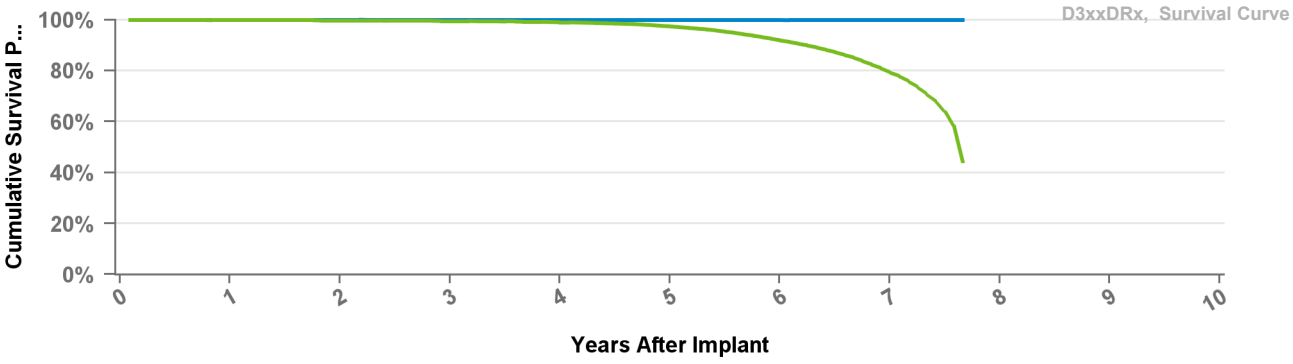
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.998	0.997	0.997	0.997
Including NBD	0.997	0.997	0.995	0.994	0.99	0.986	0.97	0.927	0.806	0.674
Effective Sample Size	7758	7286	6877	6401	5907	5369	4770	3723	1068	215

D314DRG Protecta XT DR

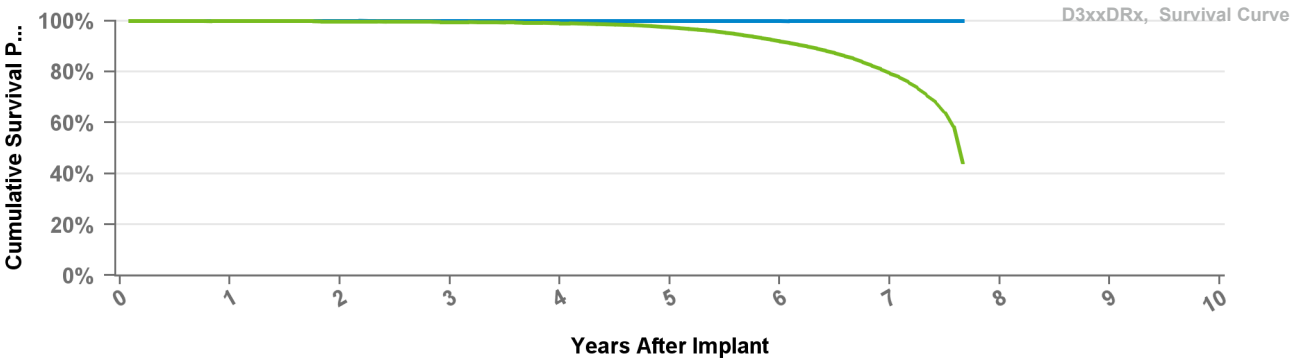
US Market Release	Mar-11	**Total Malfunctions**	**60**
CE Approval Date		**Therapy Function Not Compromised**	**39**
Registered USA Implants	34,839	Battery Malfunction	7
Estimated Active USA Implants	16,144	Electrical Component	26
Normal Battery Depletions	2,612	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**21**
		Battery Malfunction	14
		Electrical Component	7



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D314DRM Protecta XT DR

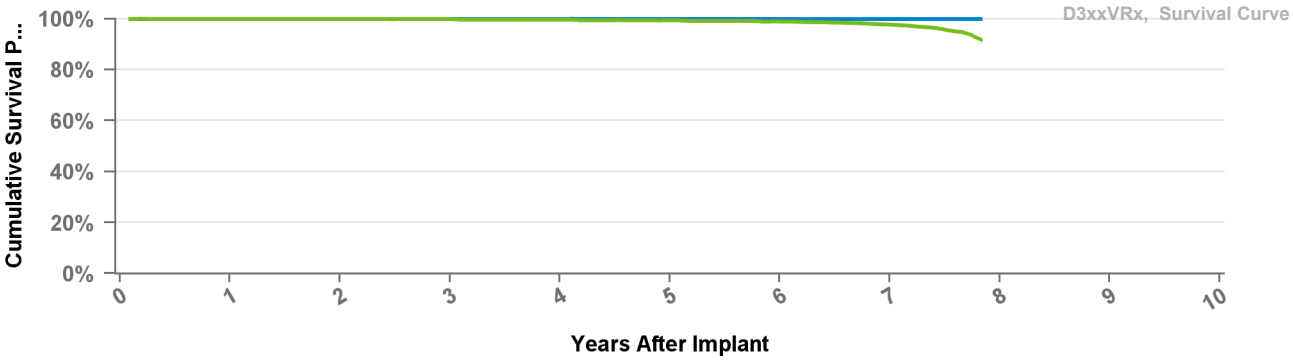
US Market Release	Nov-11	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	13,923	Battery Malfunction	1
Estimated Active USA Implants	8,440	Electrical Component	12
Normal Battery Depletions	671	Other Malfunction	1
		Therapy Function Compromised	**4**
		Battery Malfunction	4



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D314VRG Protecta XT VR

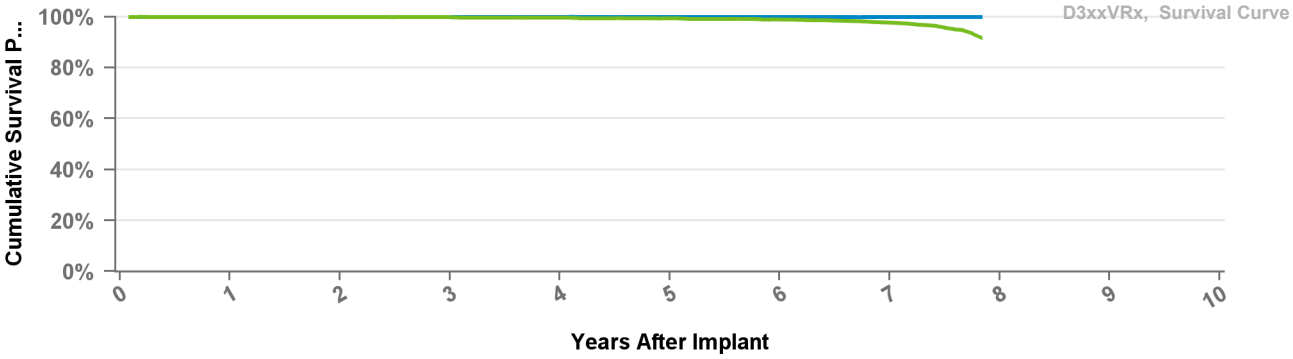
US Market Release	Mar-11	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	14,218	Battery Malfunction	4
Estimated Active USA Implants	9,675	Electrical Component	9
Normal Battery Depletions	172	Other Malfunction	1
		Therapy Function Compromised	**6**
		Battery Malfunction	5
		Electrical Component	1



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D314VRM Protecta XT VR

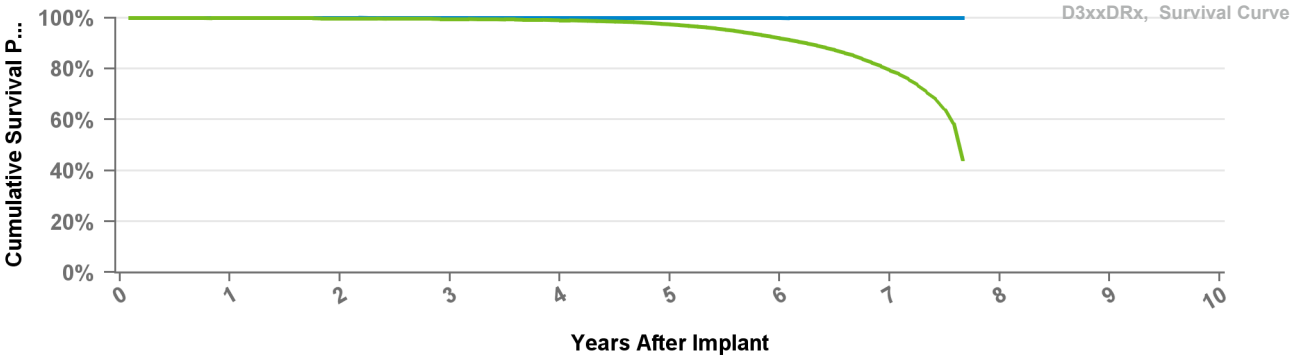
US Market Release	May-12	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	7,374	Electrical Component	2
Estimated Active USA Implants	5,646	Poss Early Battery Depltn	1
Normal Battery Depletions	38	**Therapy Function Compromised**	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D334DRG Protecta DR

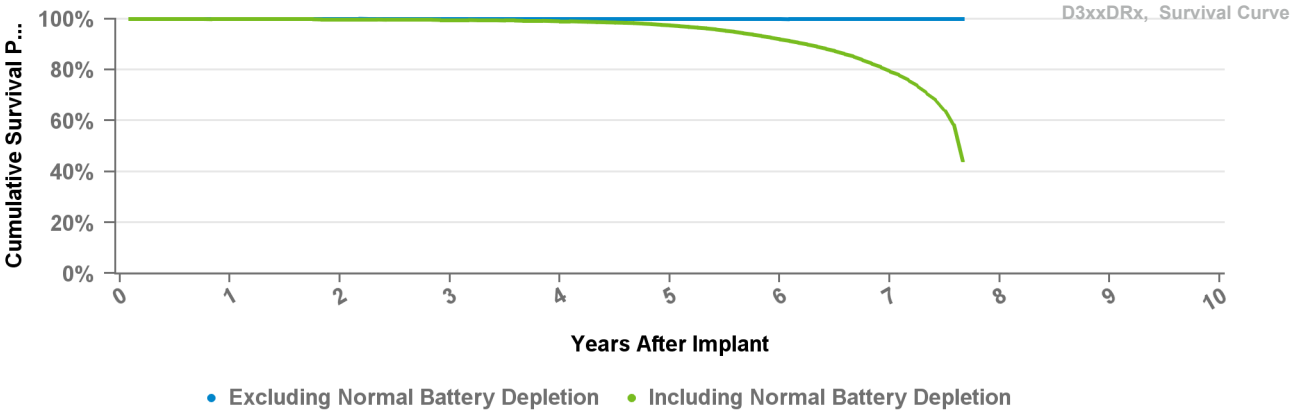
US Market Release	Mar-11	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**10**
Registered USA Implants	10,689	Battery Malfunction	3
Estimated Active USA Implants	4,859	Electrical Component	6
Normal Battery Depletions	1,100	Poss Early Battery Depltn	1
		Therapy Function Compromised	**8**
		Battery Malfunction	5
		Electrical Component	3



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D334DRM Protecta DR

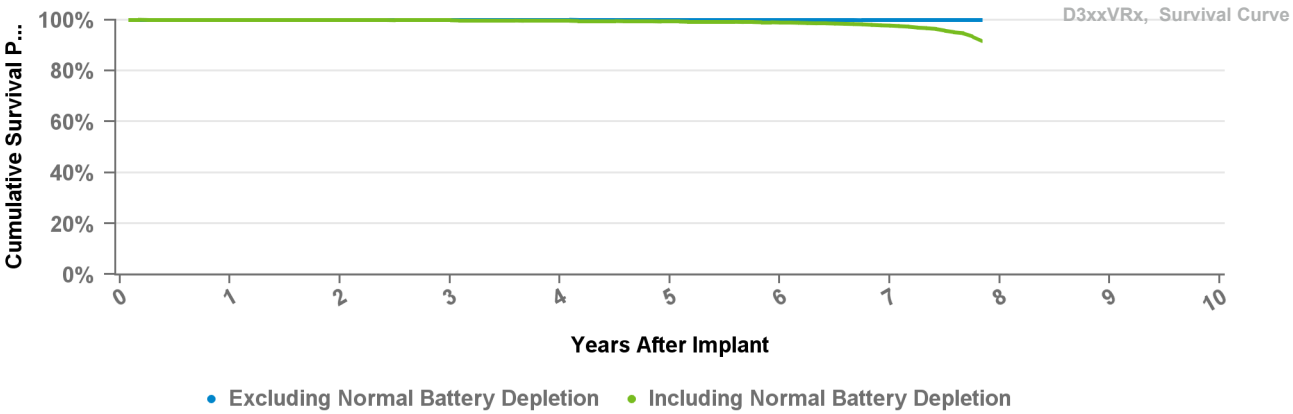
US Market Release	Nov-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,991		
Estimated Active USA Implants	1,768	**Therapy Function Compromised**	
Normal Battery Depletions	233		



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D334VRG Protecta VR

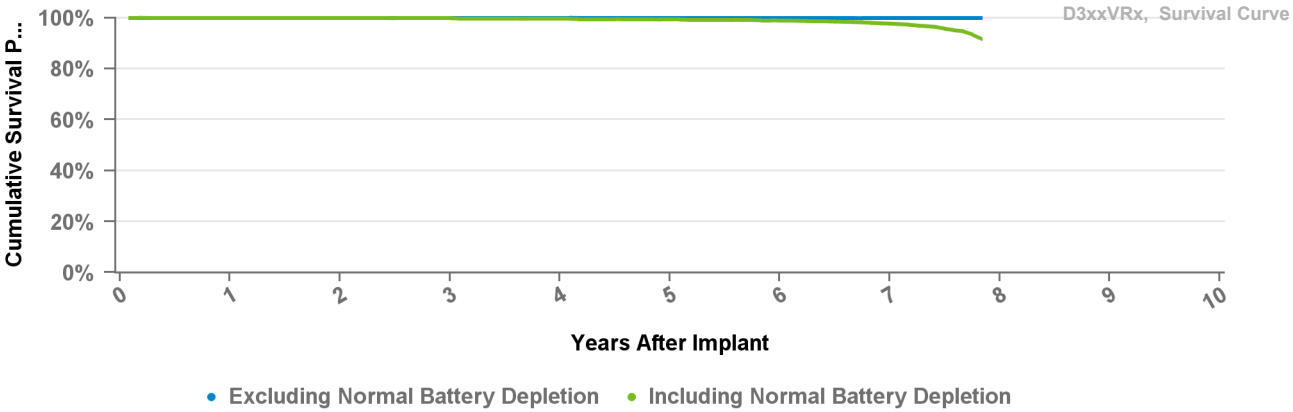
US Market Release	Mar-11	**Total Malfunctions**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	6,481	Battery Malfunction	1
Estimated Active USA Implants	4,512	Electrical Component	4
Normal Battery Depletions	73	**Therapy Function Compromised**	**5**
		Battery Malfunction	3
		Electrical Component	2



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D334VRM Protecta VR

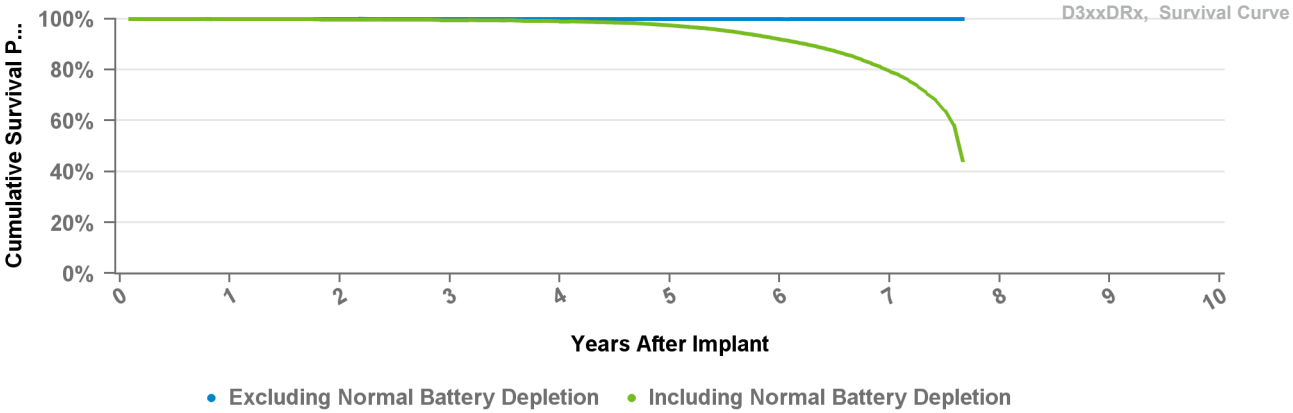
US Market Release	May-12	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,162	Other Malfunction	1
Estimated Active USA Implants	1,664	**Therapy Function Compromised**	**1**
Normal Battery Depletions	15	Battery Malfunction	1



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D354DRG Protecta XT DR

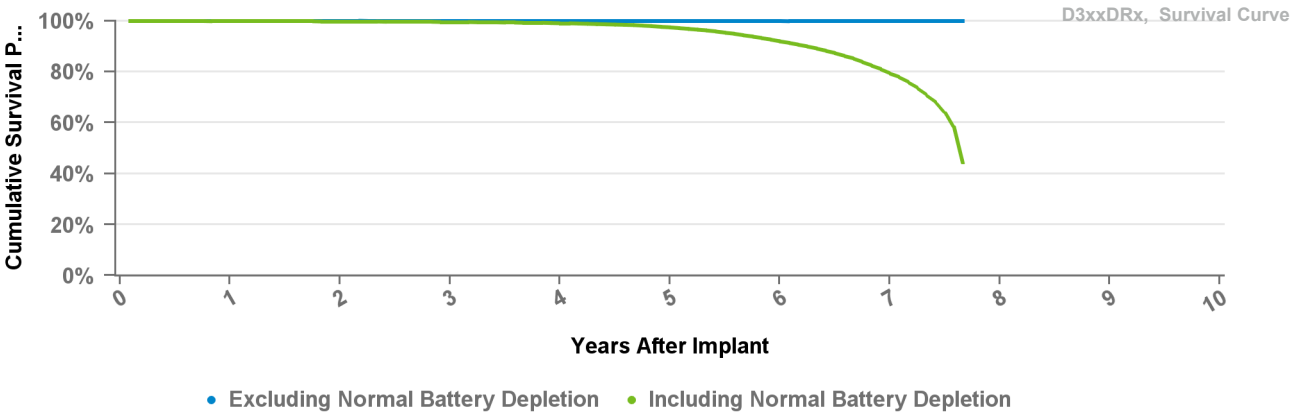
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D354DRM Protecta XT DR

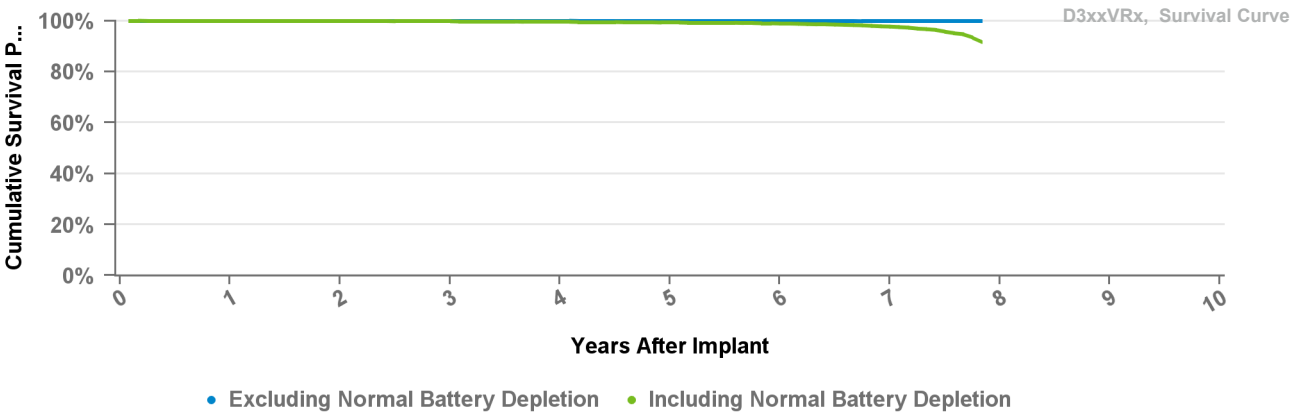
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D354VRG Protecta XT VR

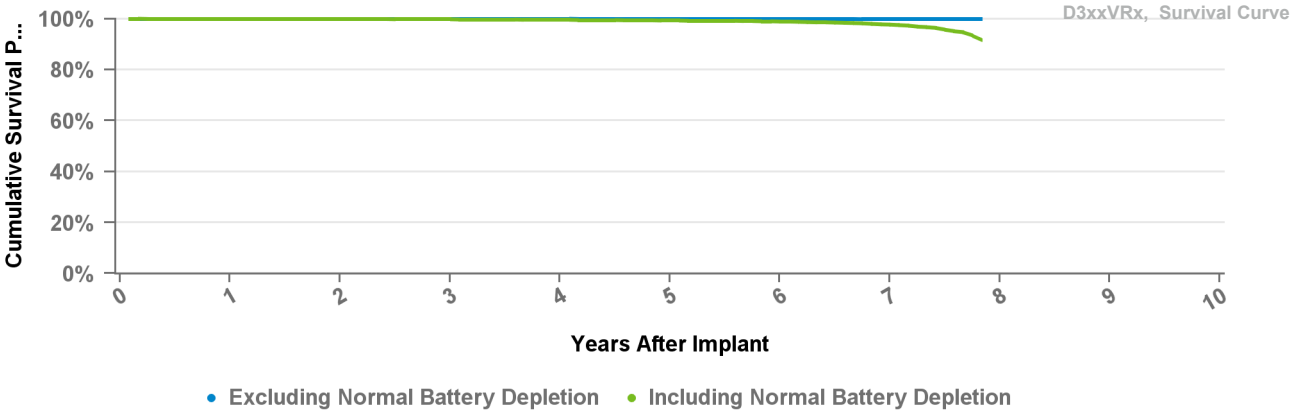
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D354VRM Protecta XT VR

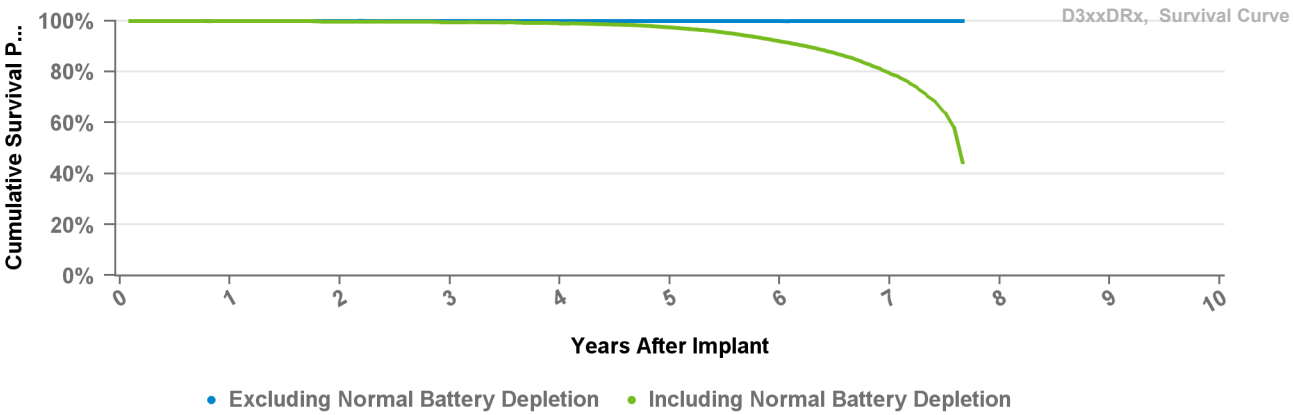
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D364DRG Protecta DR

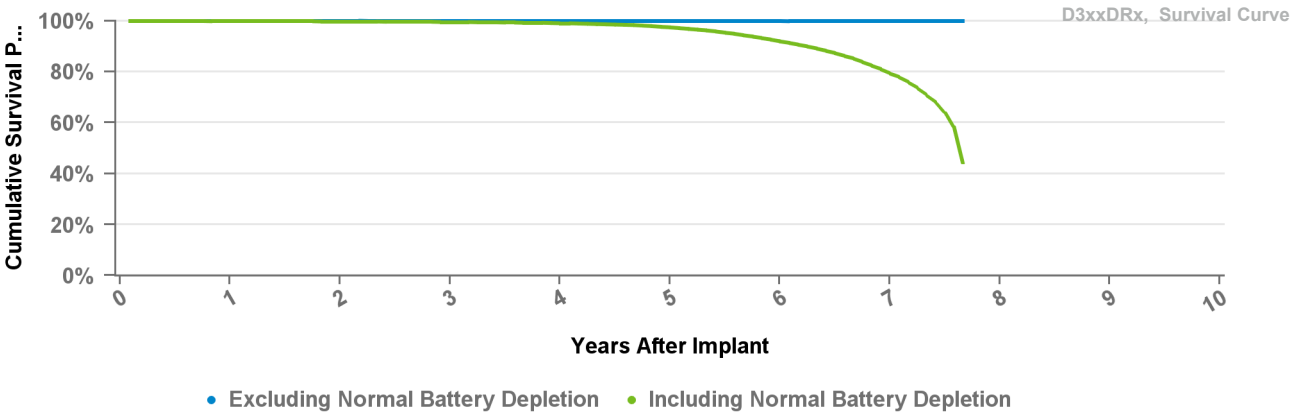
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D364DRM Protecta DR

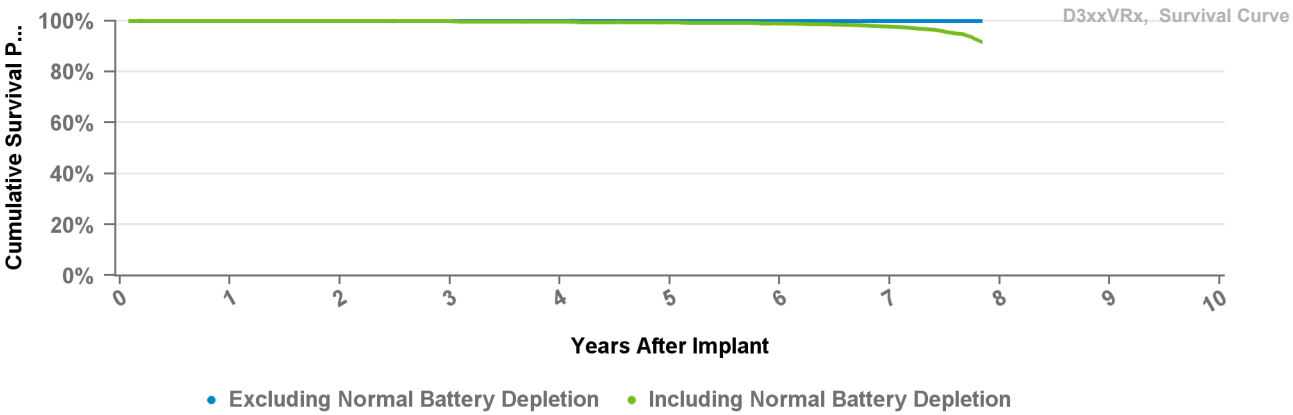
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D364VRG Protecta VR

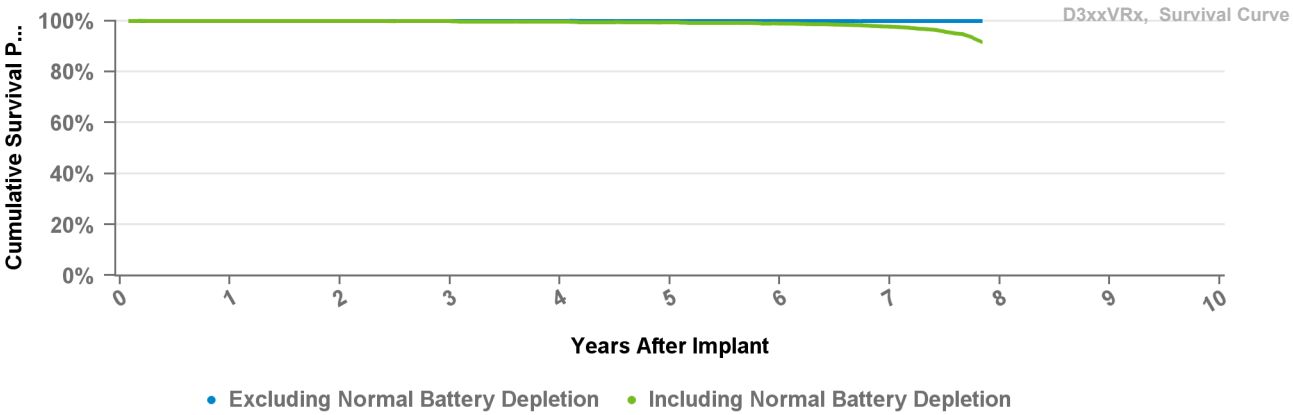
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D364VRM Protecta VR

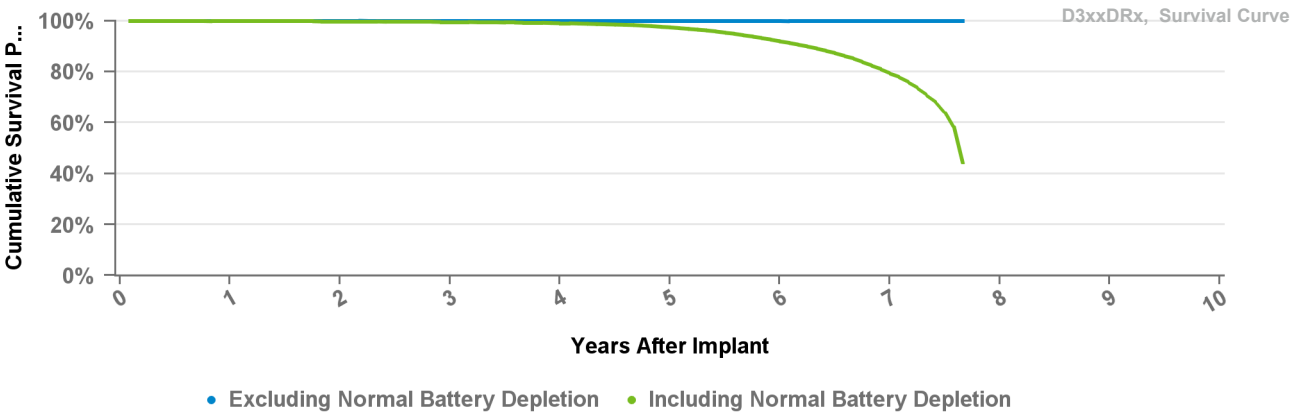
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D384DRG Cardia DR

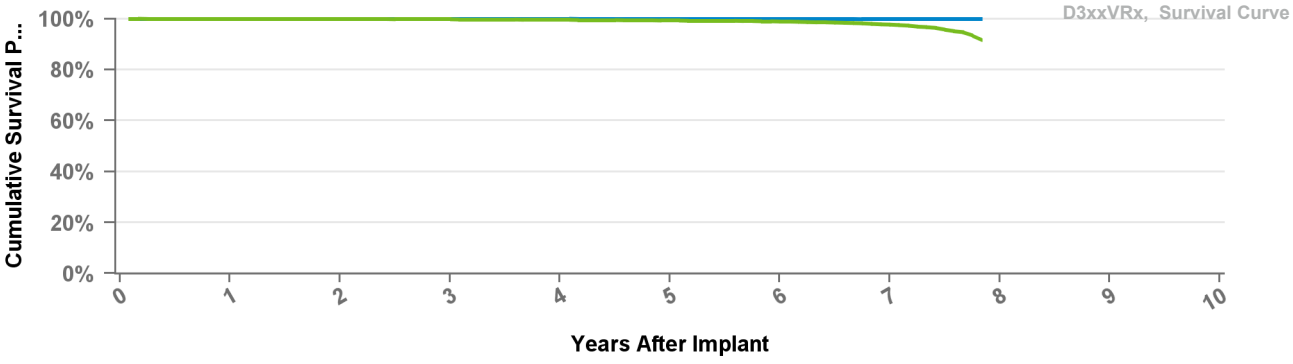
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D384VRG Cardia VR

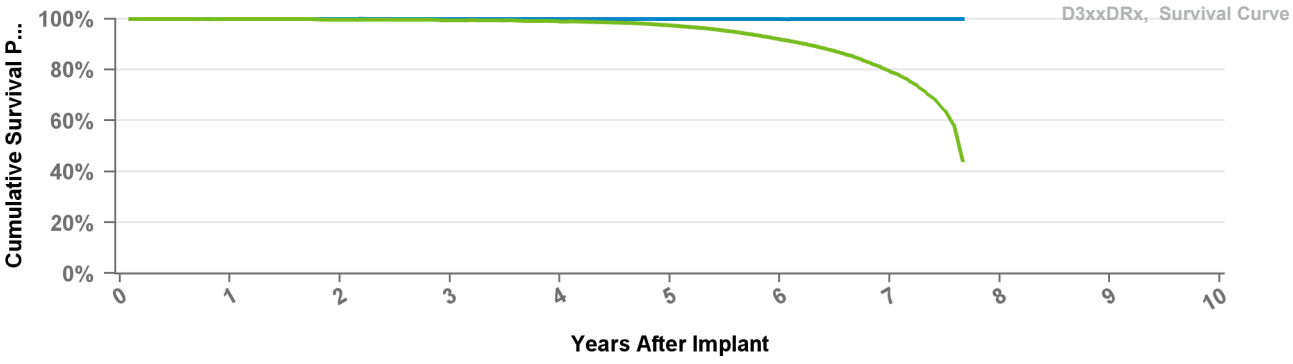
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

D394DRG Egida DR

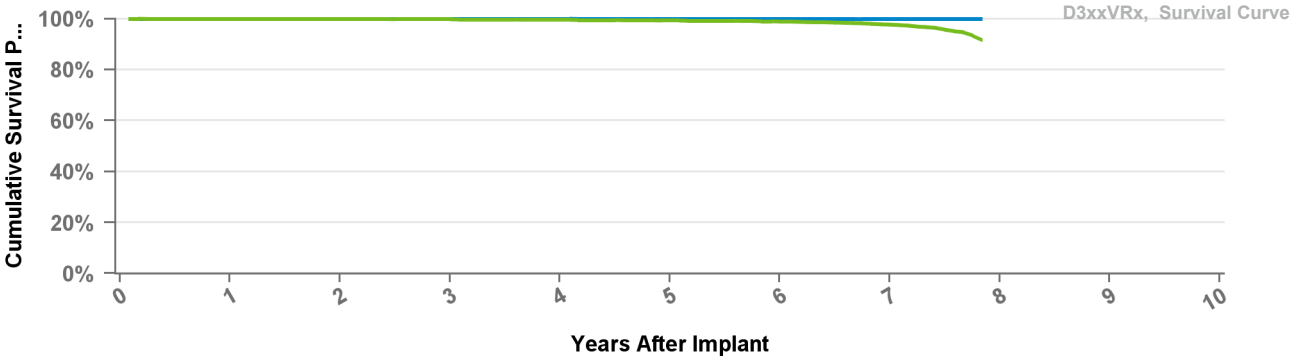
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.974	0.919	0.793	0.442
Effective Sample Size	55263	51924	48716	45184	40680	32474	12027	356

D394VRG Egida VR

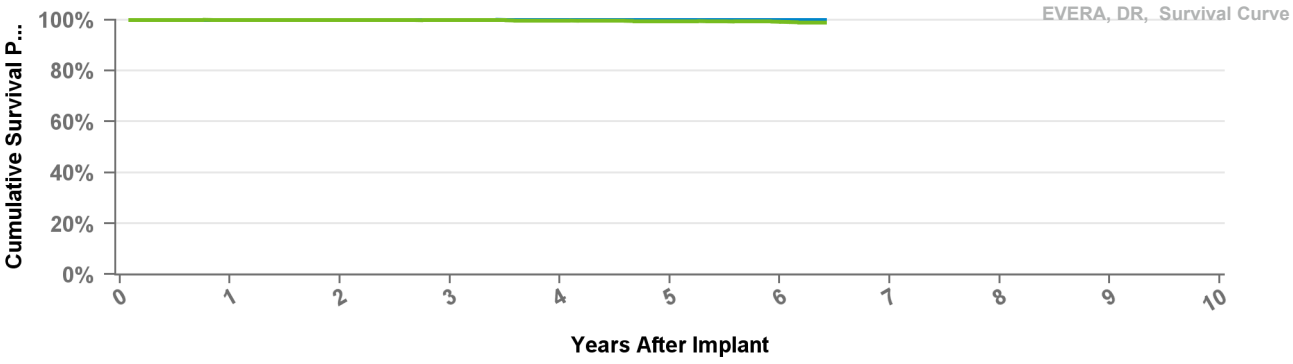
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.998	0.998
Including NBD	0.999	0.999	0.998	0.996	0.993	0.989	0.977	0.916
Effective Sample Size	26484	24822	23383	21757	19994	17304	8216	617

DDBB1D1 Evera XT

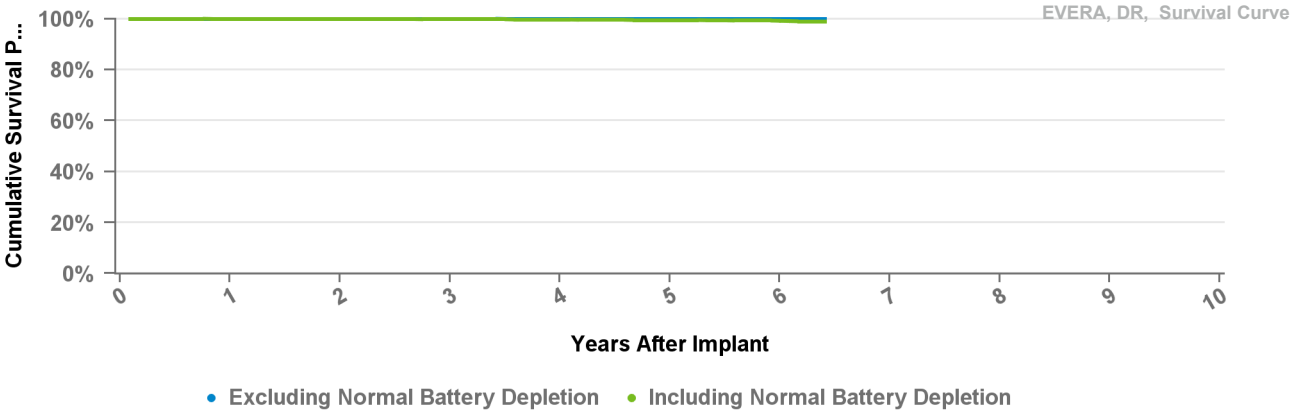
US Market Release	Apr-13	**Total Malfunctions**	**31**
CE Approval Date		**Therapy Function Not Compromised**	**18**
Registered USA Implants	42,899	Battery Malfunction	7
Estimated Active USA Implants	36,139	Electrical Component	10
Normal Battery Depletions	86	Other Malfunction	1
		Therapy Function Compromised	**13**
		Battery Malfunction	8
		Electrical Component	2
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDBB1D4 Evera XT

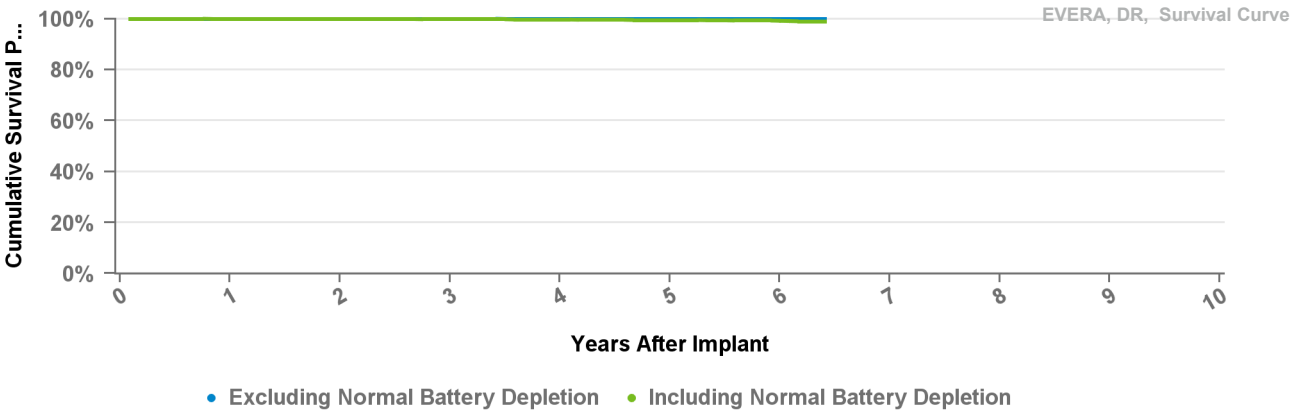
US Market Release	Apr-13	**Total Malfunctions**	**26**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	30,378	Battery Malfunction	7
Estimated Active USA Implants	26,382	Electrical Component	5
Normal Battery Depletions	40	Electrical Interconnect	1
		Other Malfunction	1
		Therapy Function Compromised	**12**
		Battery Malfunction	9
		Electrical Component	3



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDBB2D1 Evera XT

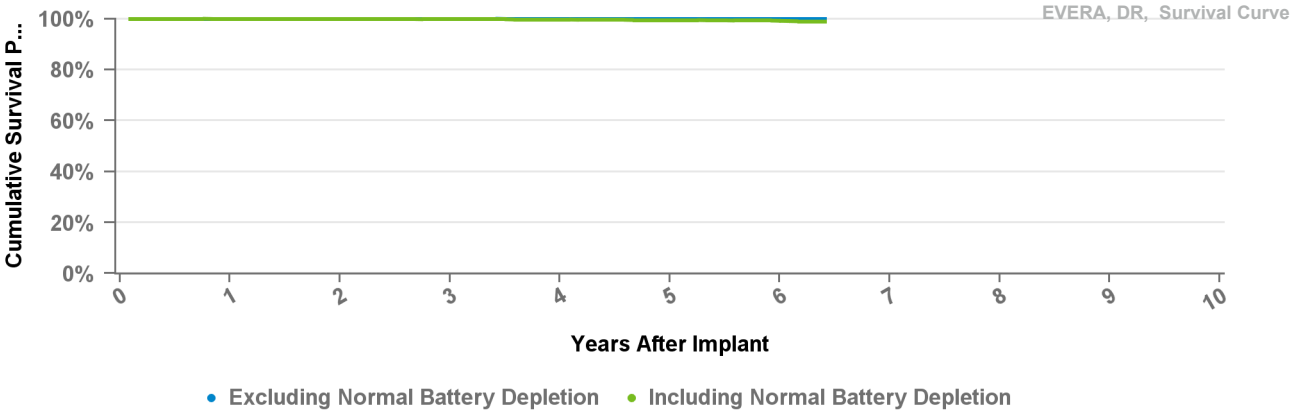
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDBB2D4 Evera XT

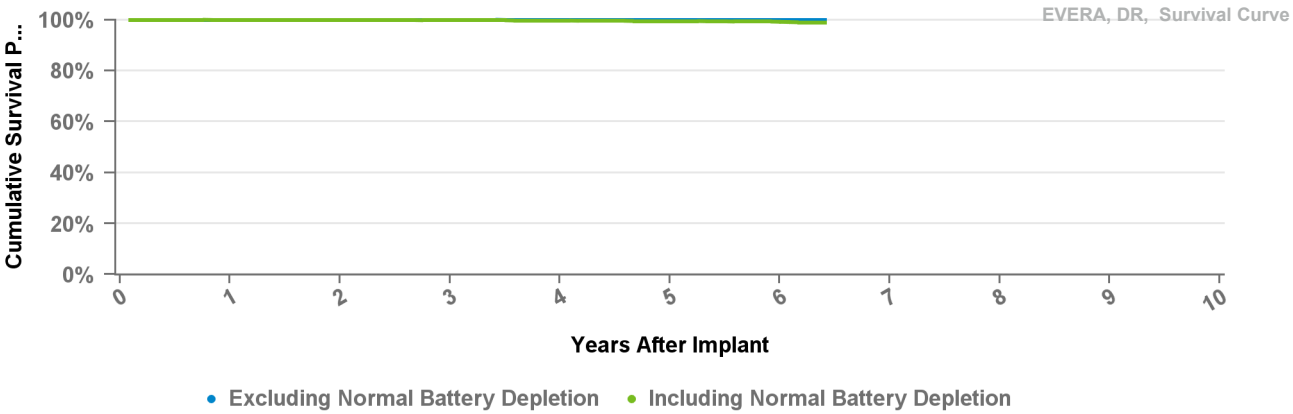
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDBC3D1 Evera S

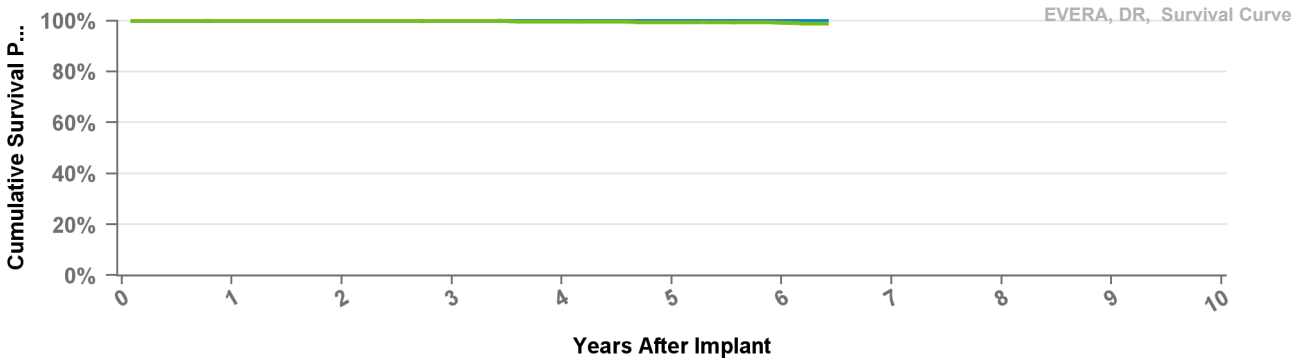
US Market Release	Apr-13	**Total Malfunctions**	**8**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**4**
Registered USA Implants	8,401	Battery Malfunction	2
Estimated Active USA Implants	7,081	Electrical Component	2
Normal Battery Depletions	14	**Therapy Function Compromised**	**4**
		Battery Malfunction	3
		Electrical Component	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDBC3D4 Evera S

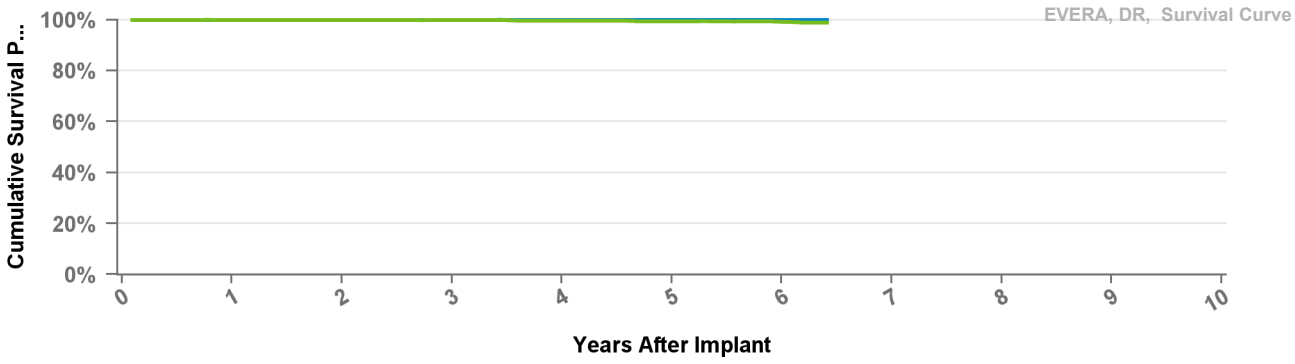
US Market Release	Apr-13	**Total Malfunctions**	**7**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**4**
Registered USA Implants	6,038	Battery Malfunction	2
Estimated Active USA Implants	5,218	Electrical Component	2
Normal Battery Depletions	7	**Therapy Function Compromised**	**3**
		Battery Malfunction	2
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMB1D1 Evera MRI XT

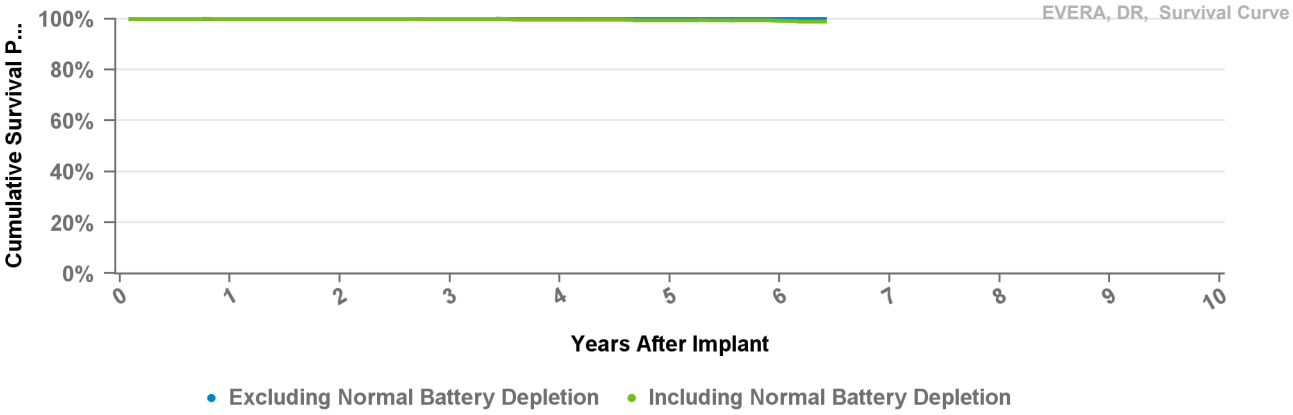
US Market Release	Oct-16	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	26,004	Battery Malfunction	1
Estimated Active USA Implants	24,882	Electrical Interconnect	1
Normal Battery Depletions	3	Other Malfunction	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMB1D4 Evera MRI XT

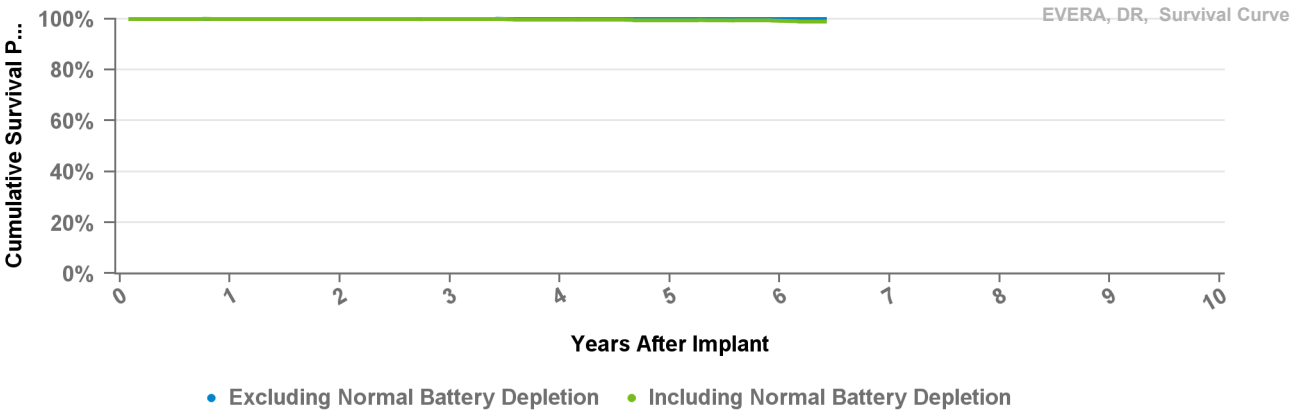
US Market Release	Sep-15	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	63,862	Battery Malfunction	3
Estimated Active USA Implants	60,599	Electrical Component	11
Normal Battery Depletions	29	Electrical Interconnect	2
		Other Malfunction	1
		Therapy Function Compromised	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMB2D1 Evera MRI XT

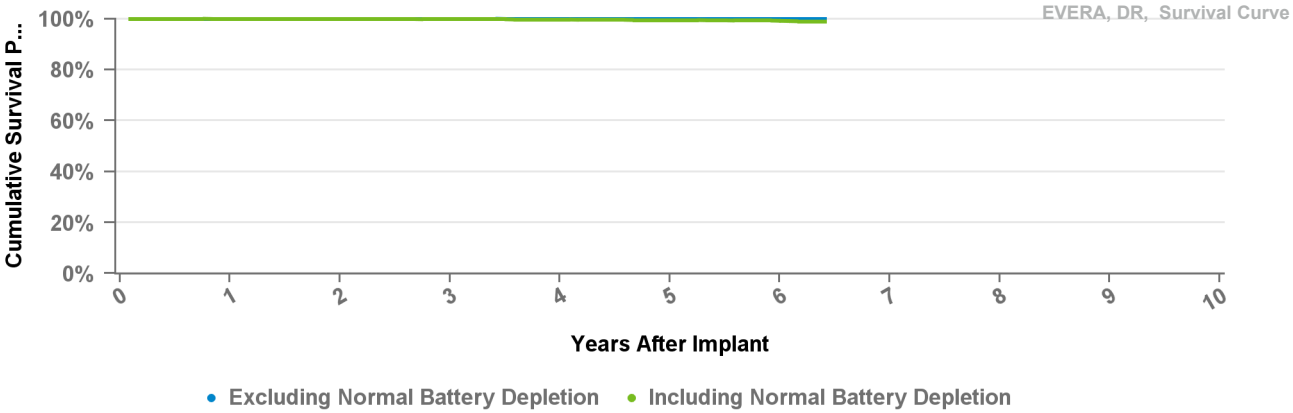
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	1,442		
Estimated Active USA Implants	1,395	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMB2D4 Evera MRI XT

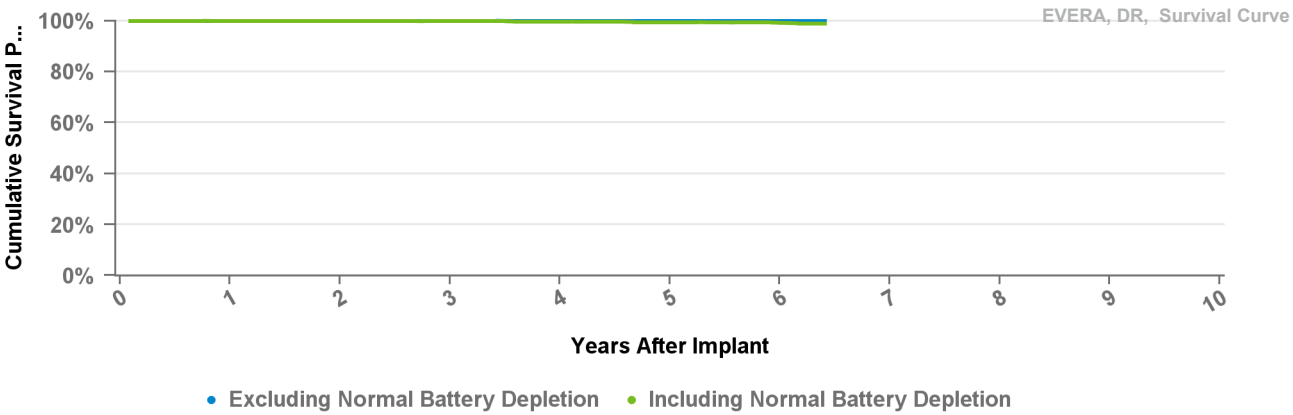
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMC3D1 Evera MRI S

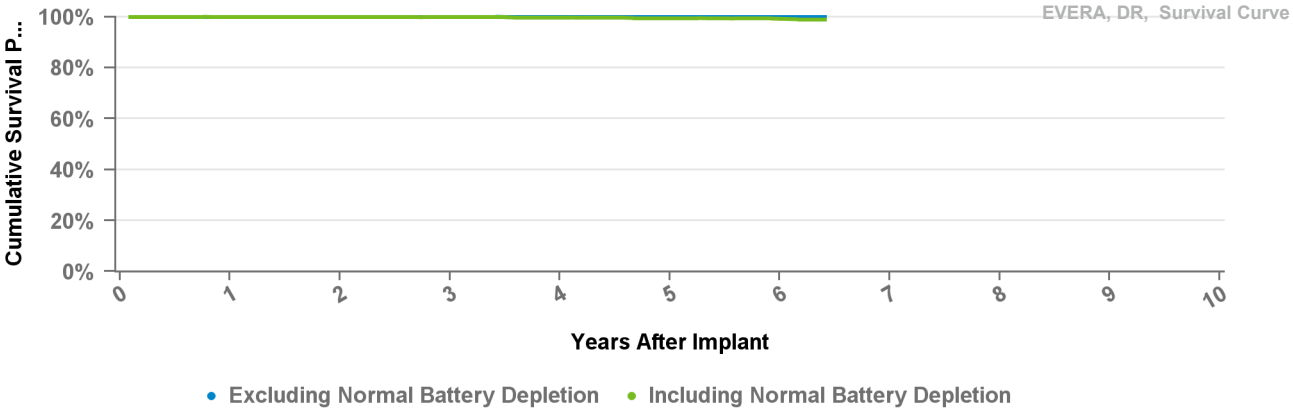
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	2,455		
Estimated Active USA Implants	2,366	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMC3D4 Evera MRI

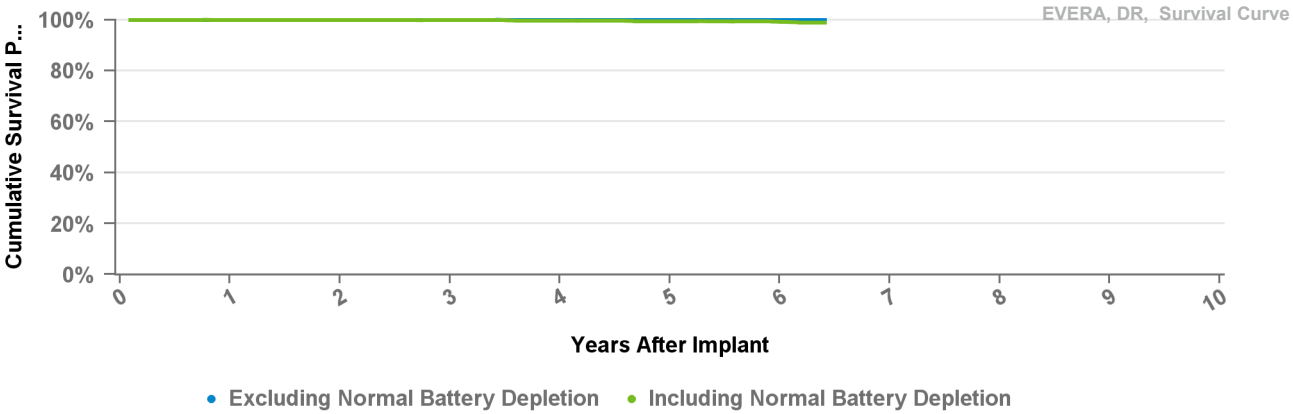
US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,369	Electrical Component	1
Estimated Active USA Implants	4,135	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDMD3D4 Primo

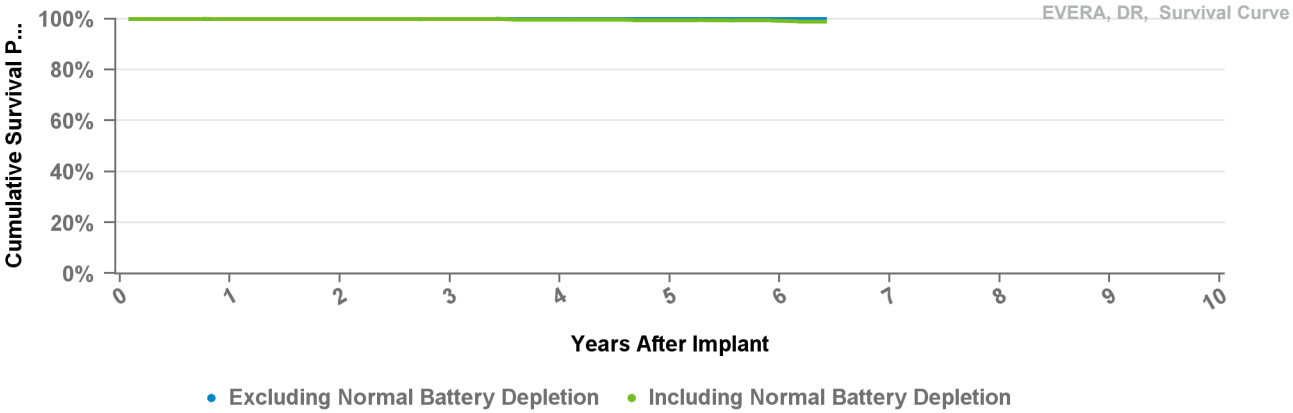
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	129		
Estimated Active USA Implants	127	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DDME3D4 Mirro

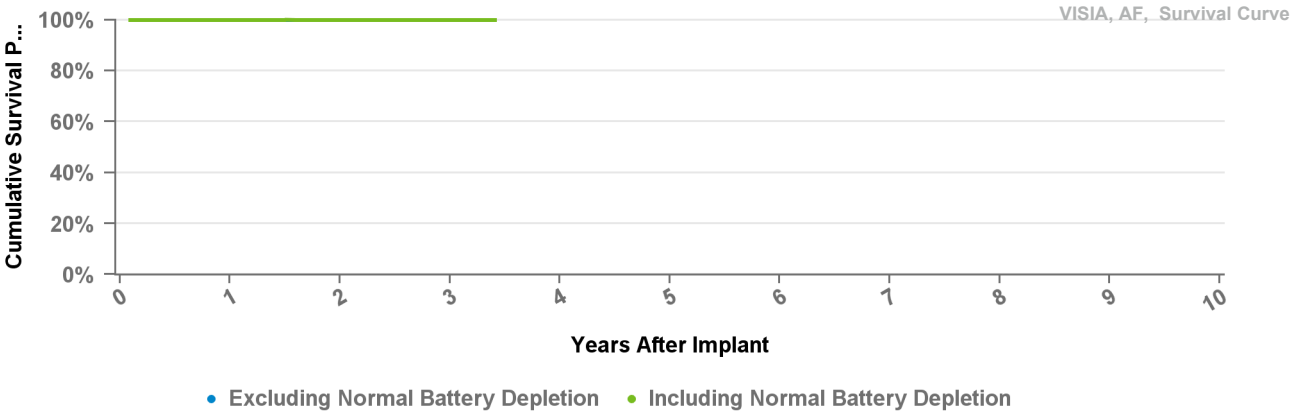
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.997	0.995	0.992	0.99
Effective Sample Size	149115	113833	79818	50625	26709	6068	149

DVAB1D1 Visia AF

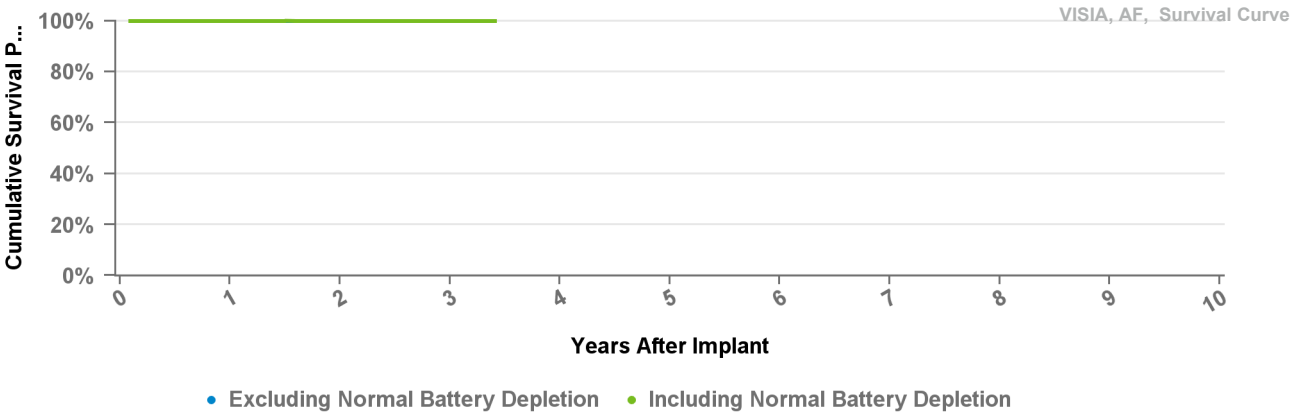
US Market Release	Jan-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,963	Battery Malfunction	1
Estimated Active USA Implants	2,739	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVAB1D4 Visia AF

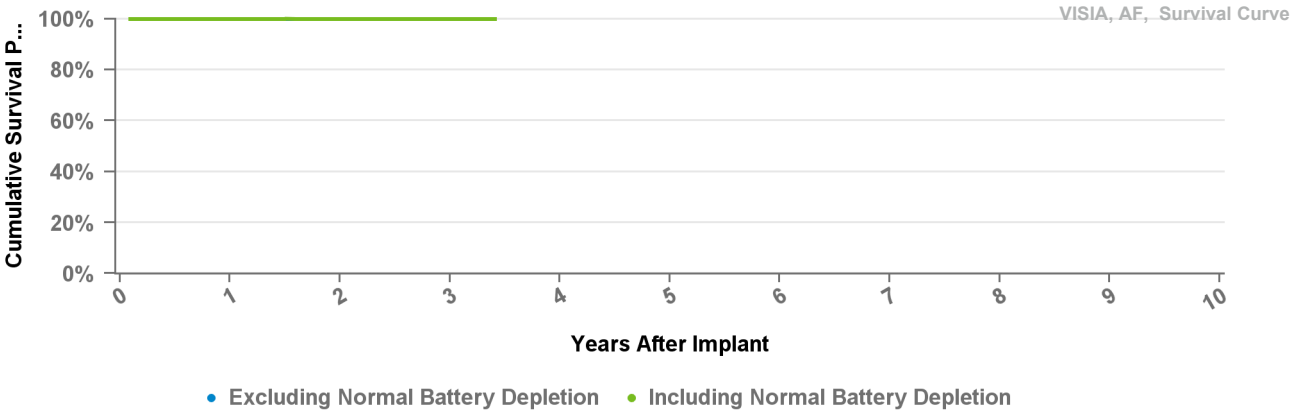
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,979		
Estimated Active USA Implants	1,856	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVAB2D1 Visia AF XT

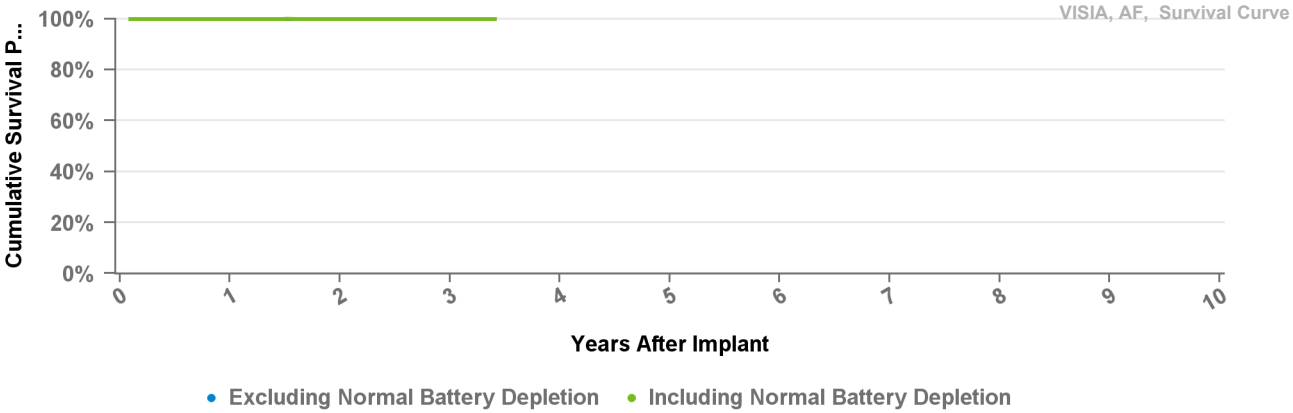
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVAC3D1 Visia AF S

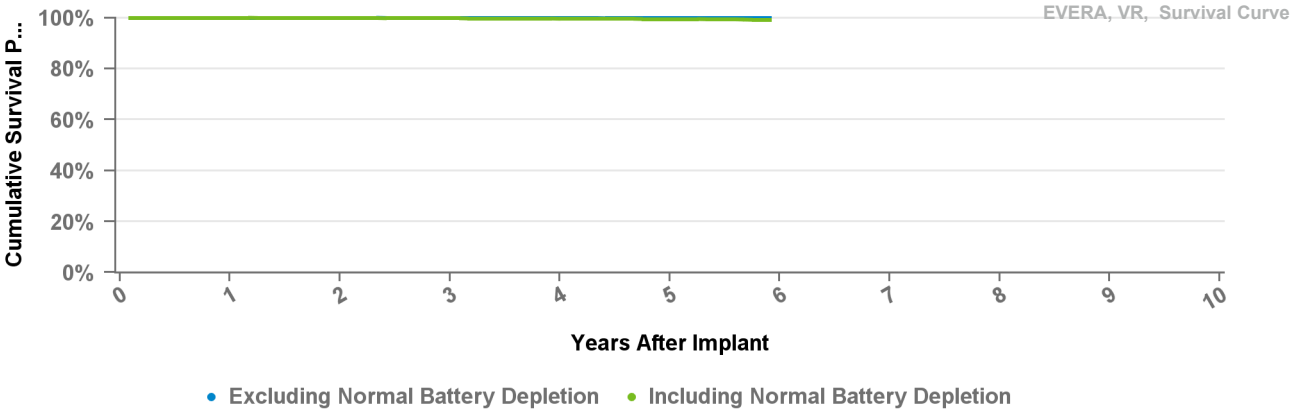
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVBB1D1 Evera XT

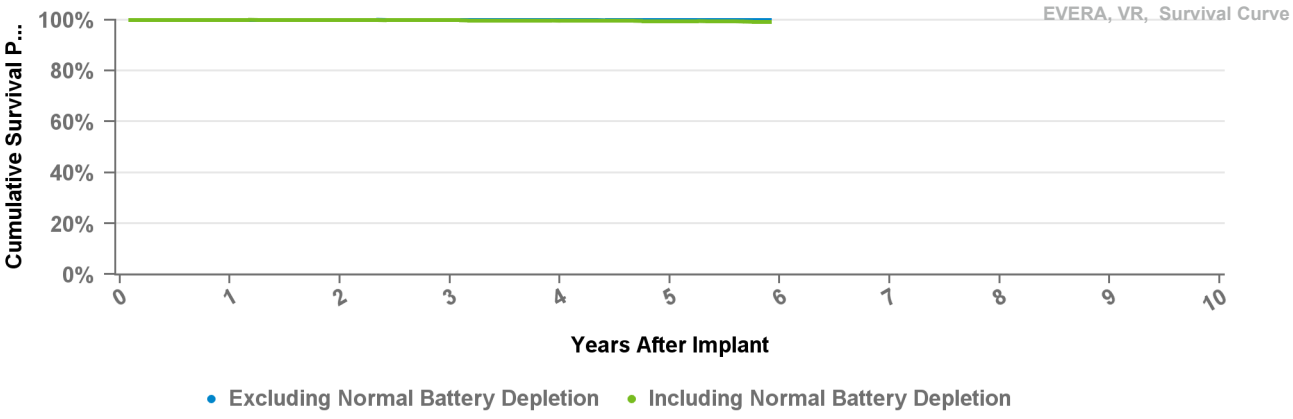
US Market Release	Apr-13	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	16,120	Battery Malfunction	7
Estimated Active USA Implants	13,278	Electrical Component	5
Normal Battery Depletions	12	**Therapy Function Compromised**	**3**
		Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVBB1D4 Evera XT

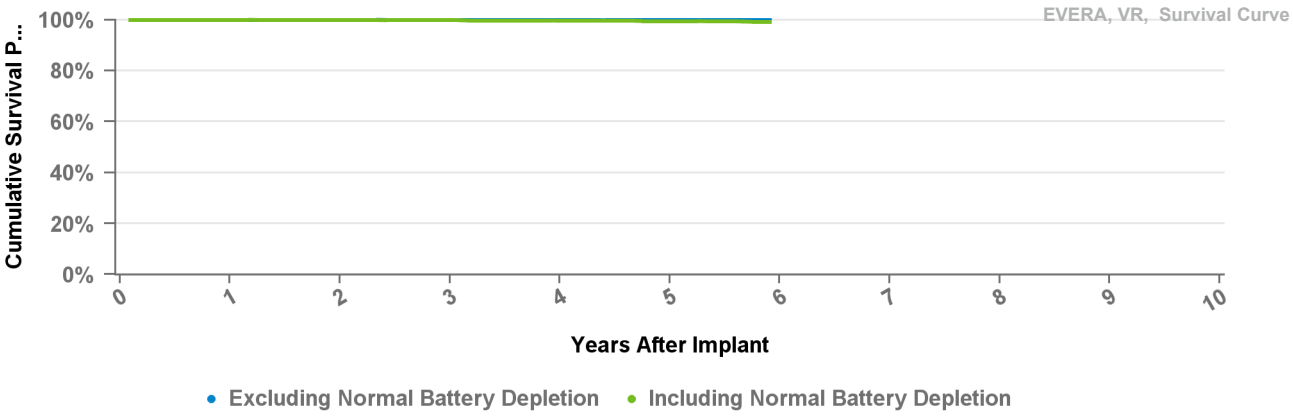
US Market Release	Apr-13	**Total Malfunctions**	**39**
CE Approval Date		**Therapy Function Not Compromised**	**28**
Registered USA Implants	22,379	Battery Malfunction	16
Estimated Active USA Implants	19,437	Electrical Component	7
Normal Battery Depletions	20	Other Malfunction	5
		Therapy Function Compromised	**11**
		Battery Malfunction	10
		Electrical Component	1



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVBB2D1 Evera XT

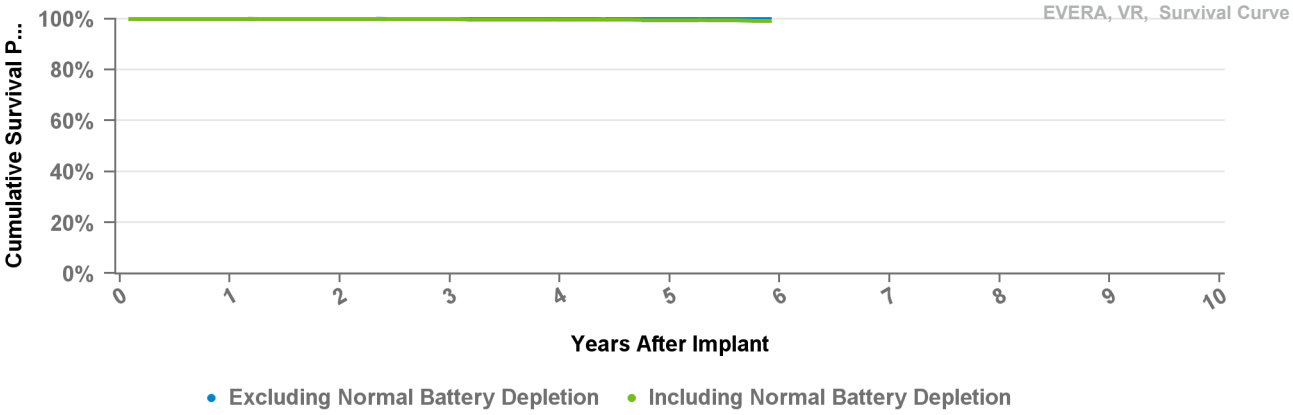
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVBB2D4 Evera XT

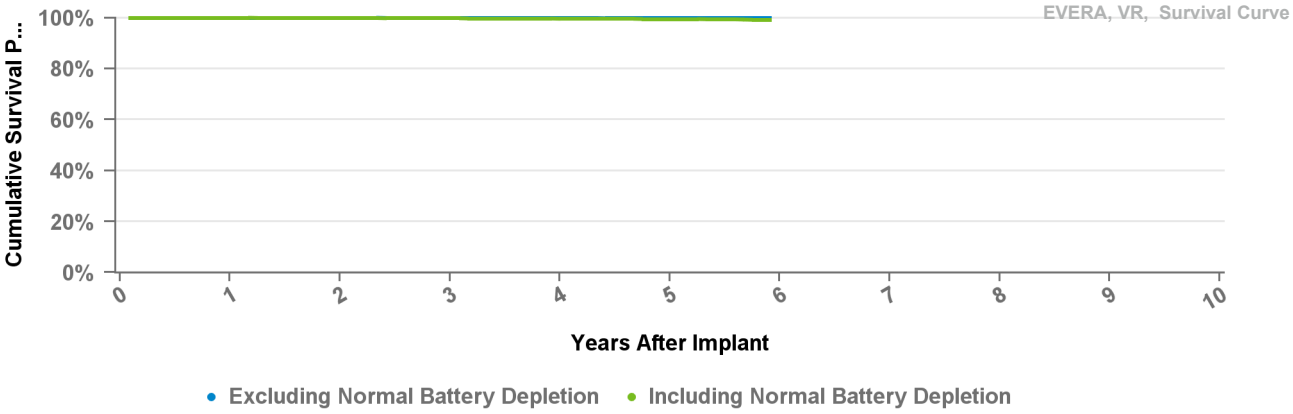
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVBC3D1 Evera S

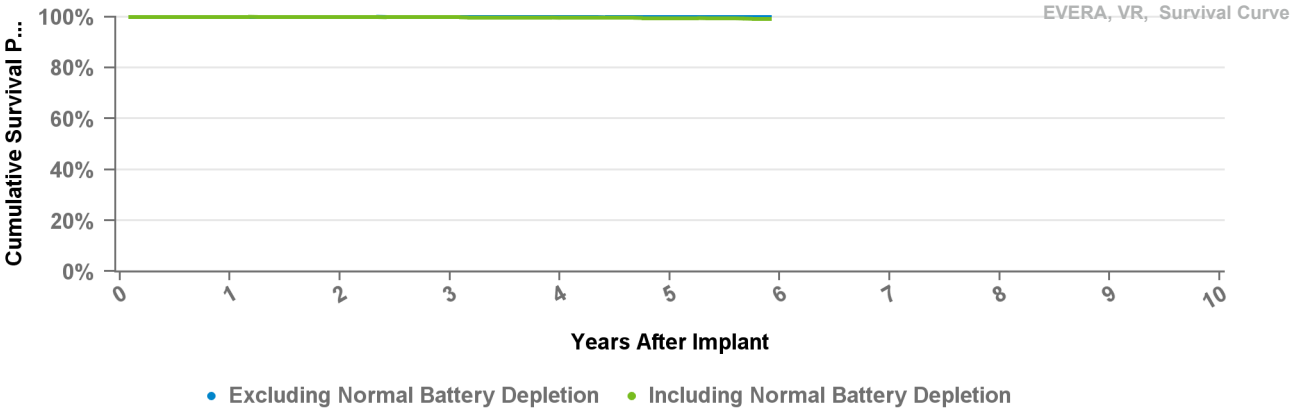
US Market Release	Apr-13	**Total Malfunctions**	**13**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**9**
Registered USA Implants	4,620	Battery Malfunction	8
Estimated Active USA Implants	3,842	Electrical Component	1
Normal Battery Depletions	3	**Therapy Function Compromised**	**4**
		Battery Malfunction	3
		Electrical Component	1



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVBC3D4 Evera S

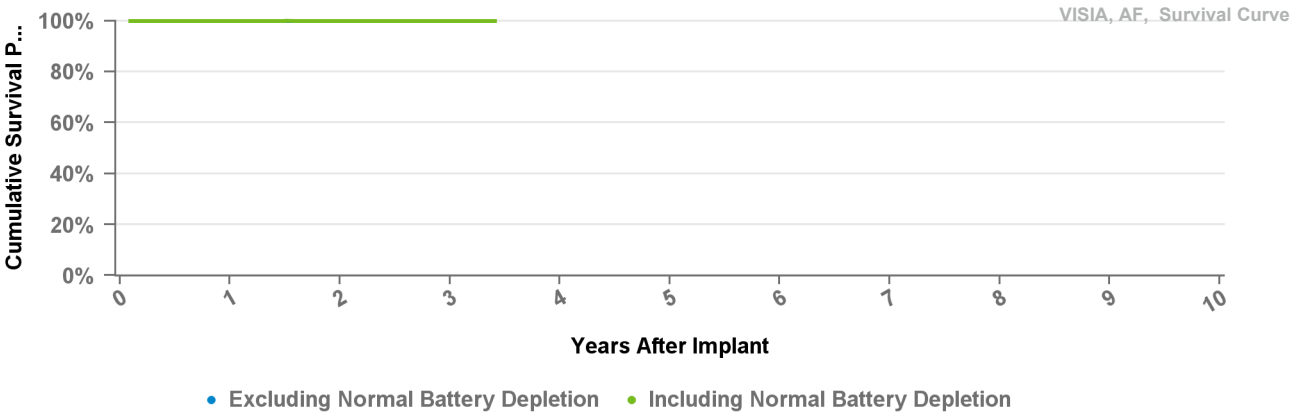
US Market Release	Apr-13	**Total Malfunctions**	**8**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**6**
Registered USA Implants	5,608	Battery Malfunction	4
Estimated Active USA Implants	4,872	Electrical Component	2
Normal Battery Depletions	5	**Therapy Function Compromised**	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVFB1D1 Visia MRI AF

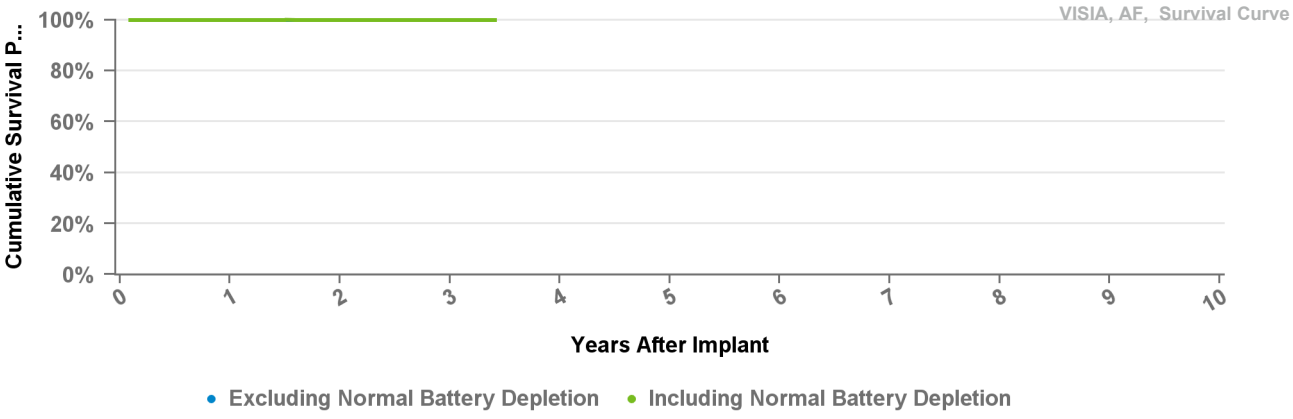
US Market Release	Oct-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,934	Battery Malfunction	1
Estimated Active USA Implants	9,523	**Therapy Function Compromised**	**0**
Normal Battery Depletions	3		



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVFB1D4 Visia MRI AF

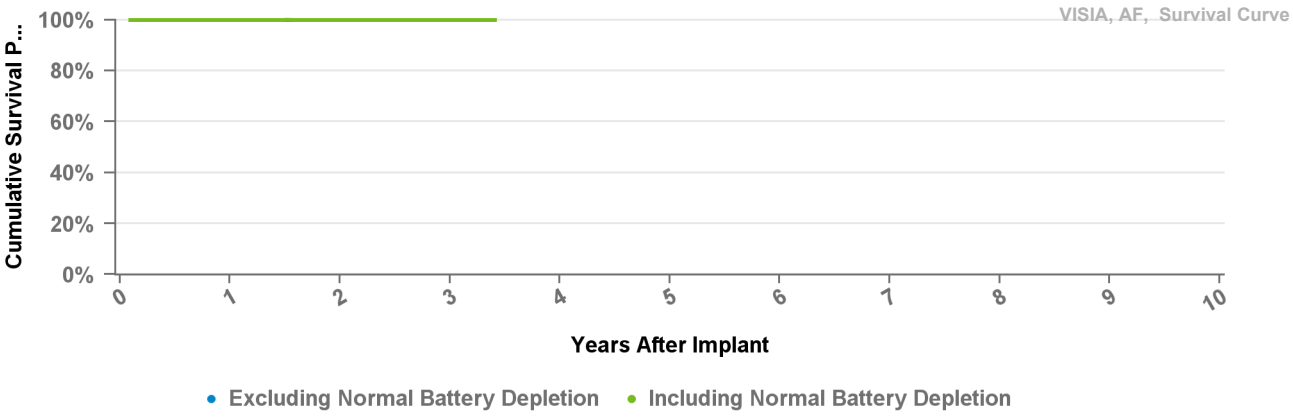
US Market Release	Jan-16	**Total Malfunctions**	**7**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	34,443	Battery Malfunction	1
Estimated Active USA Implants	32,848	Electrical Component	2
Normal Battery Depletions	2	Other Malfunction	2
		Therapy Function Compromised	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVFB2D1 Visia MRI AF XT

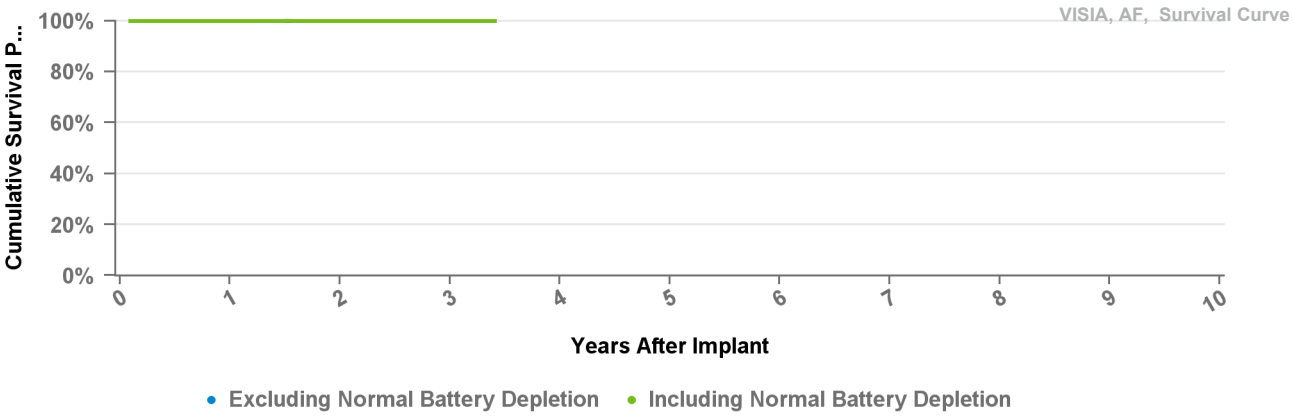
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVFB2D4 Visia MRI AF XT

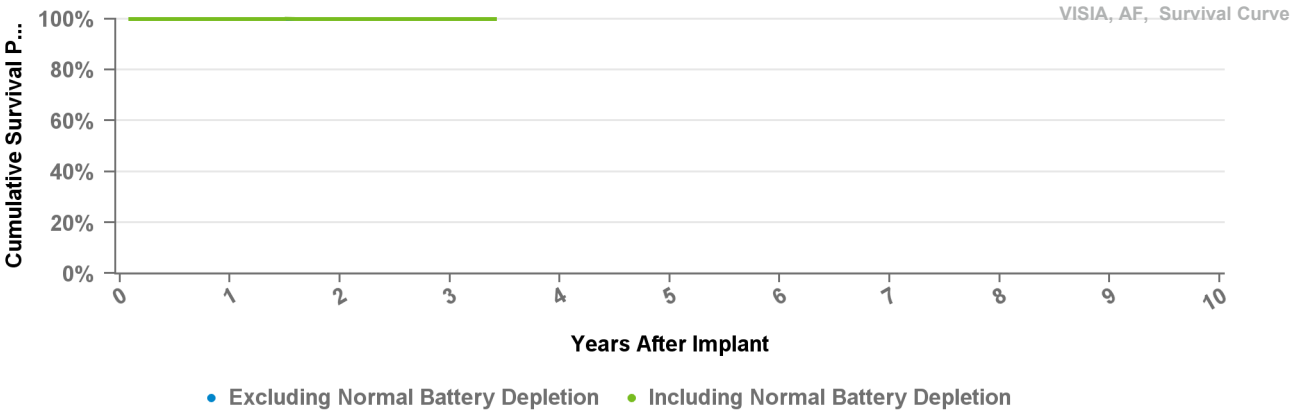
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVFC3D1 Visia MRI AF S

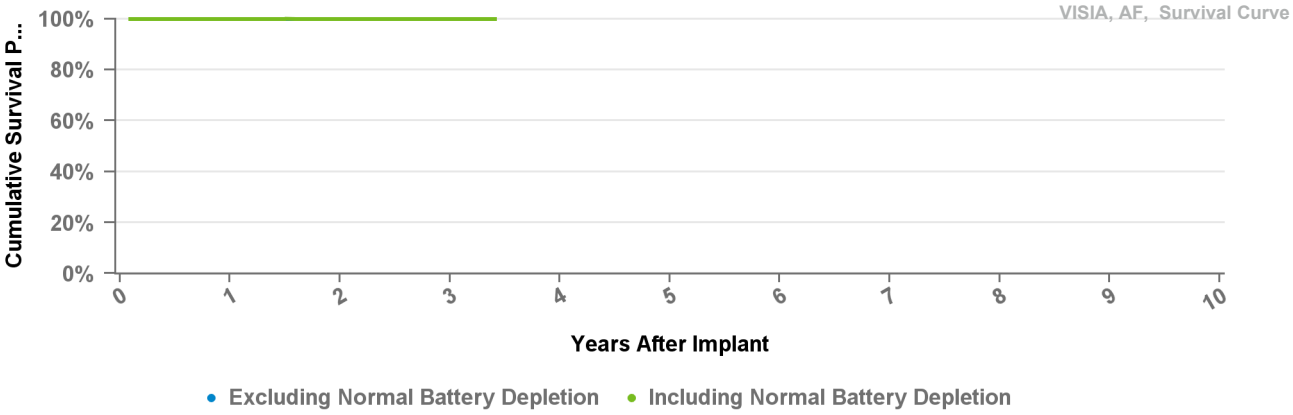
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	787		
Estimated Active USA Implants	761	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVFC3D4 Visia MRI AF S

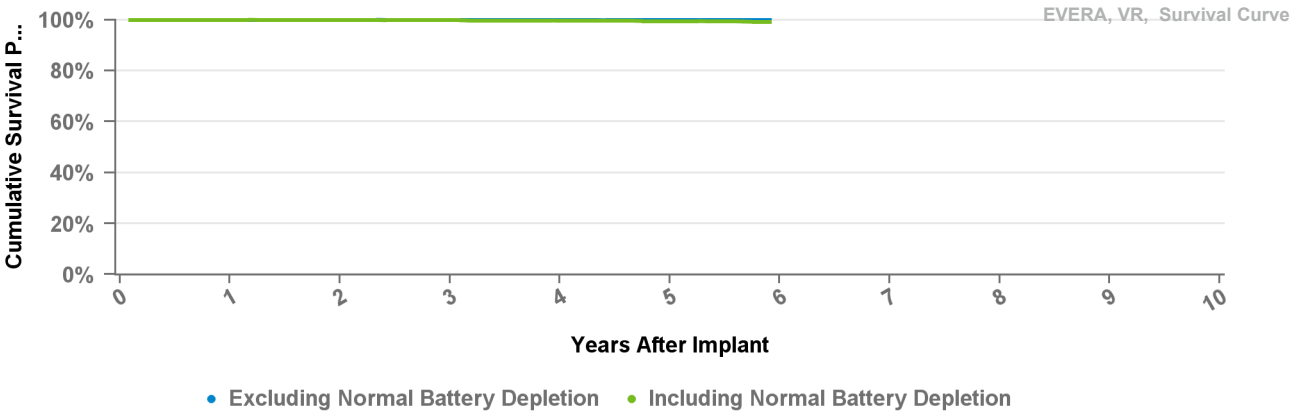
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants	326		
Estimated Active USA Implants	315	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.999	0.999
Effective Sample Size	34890	19180	3980	163

DVMB1D4 Evera MRI XT

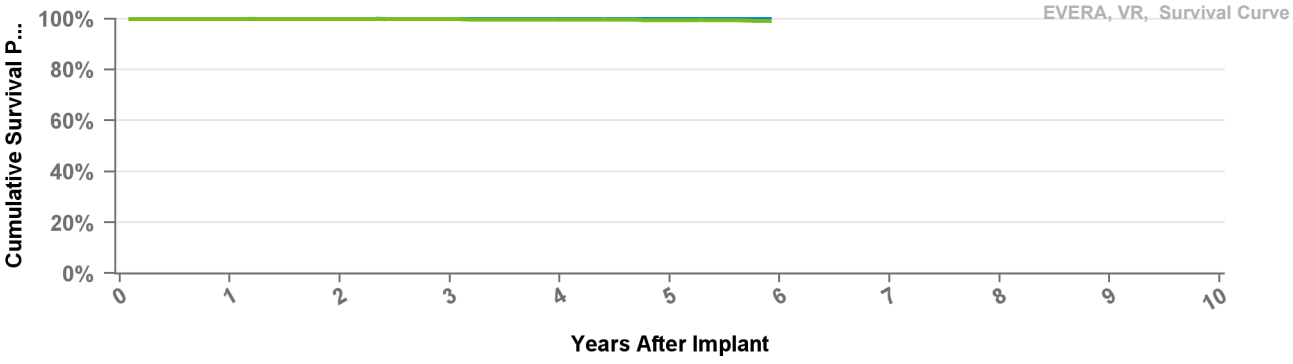
US Market Release	Sep-15	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,611	Battery Malfunction	1
Estimated Active USA Implants	9,694	Electrical Component	3
Normal Battery Depletions	5	Other Malfunction	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMB2D1 Evera MRI XT

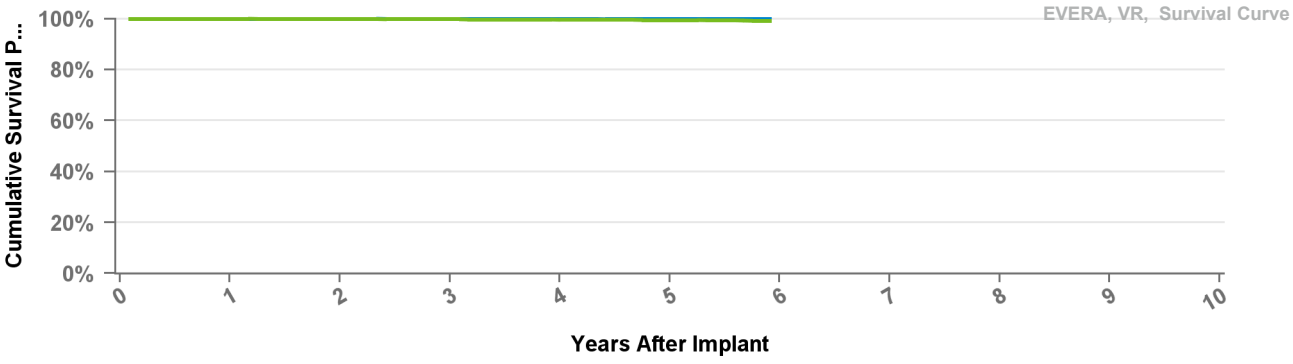
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMB2D4 Evera MRI XT

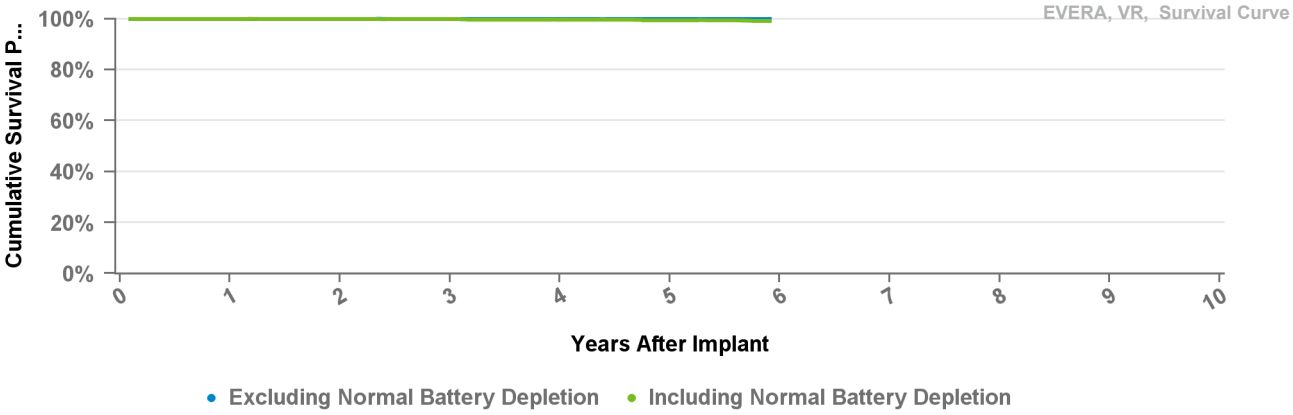
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMC3D1 Evera MRI S

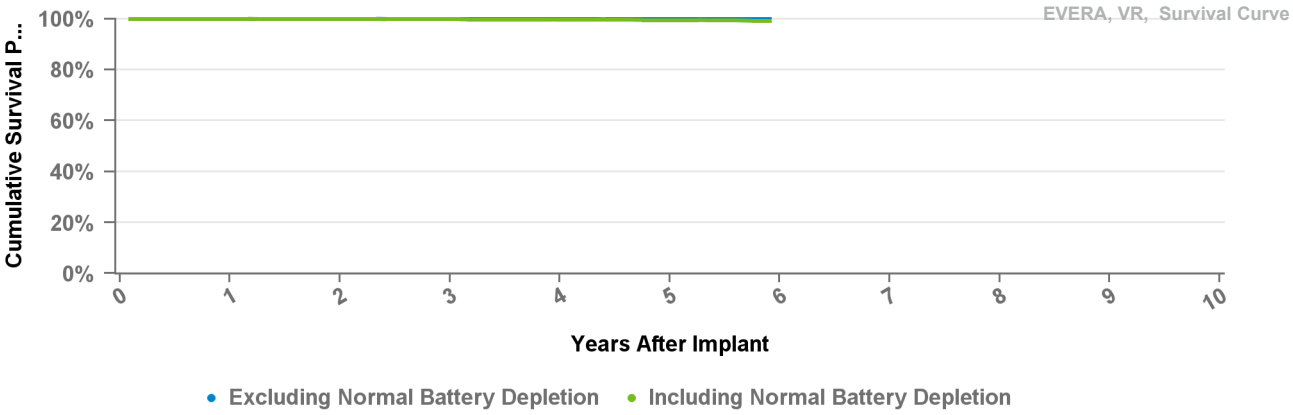
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMC3D4 Evera MRI S

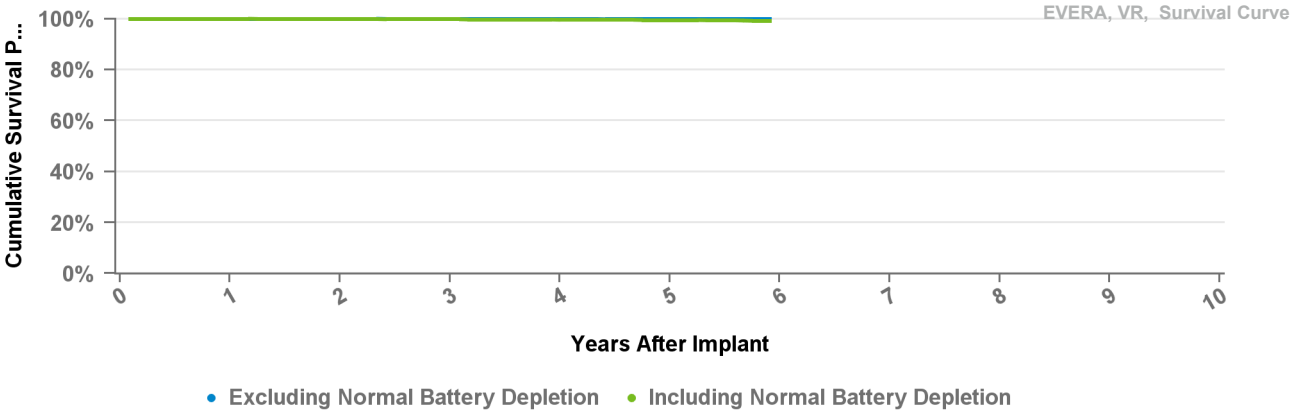
US Market Release	Sep-15	**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMD3D1 Primo

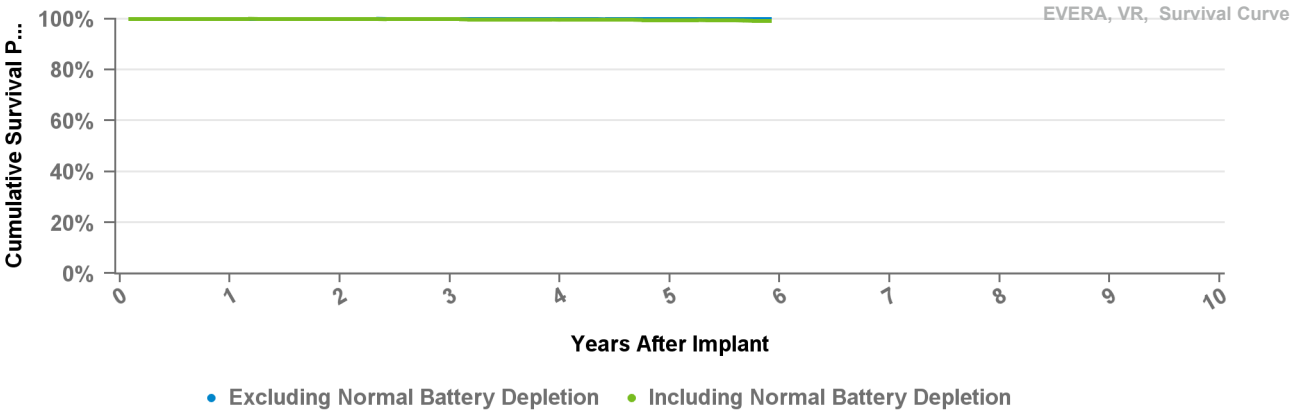
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	32		
Estimated Active USA Implants	30	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVMD3D4 Primo

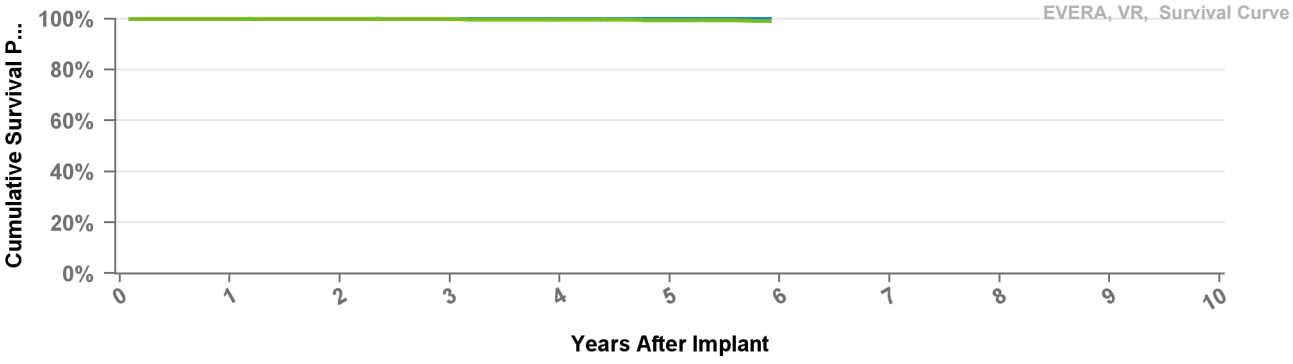
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	42		
Estimated Active USA Implants	41	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

DVME3D4 Mirro

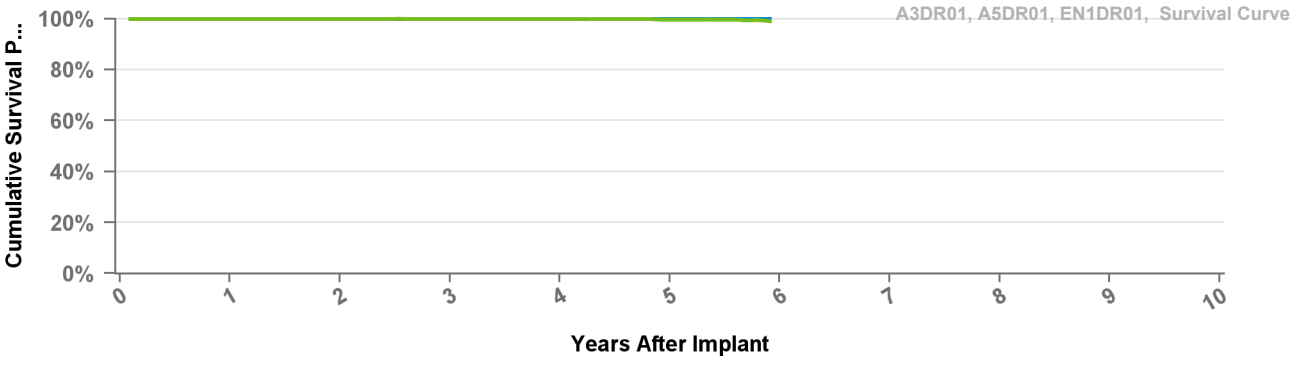
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	0.999	0.999	0.998	0.998
Including NBD	1	0.999	0.998	0.996	0.995	0.992
Effective Sample Size	53510	50194	45732	30600	13338	791

A2DR01 Advisa DR MRI

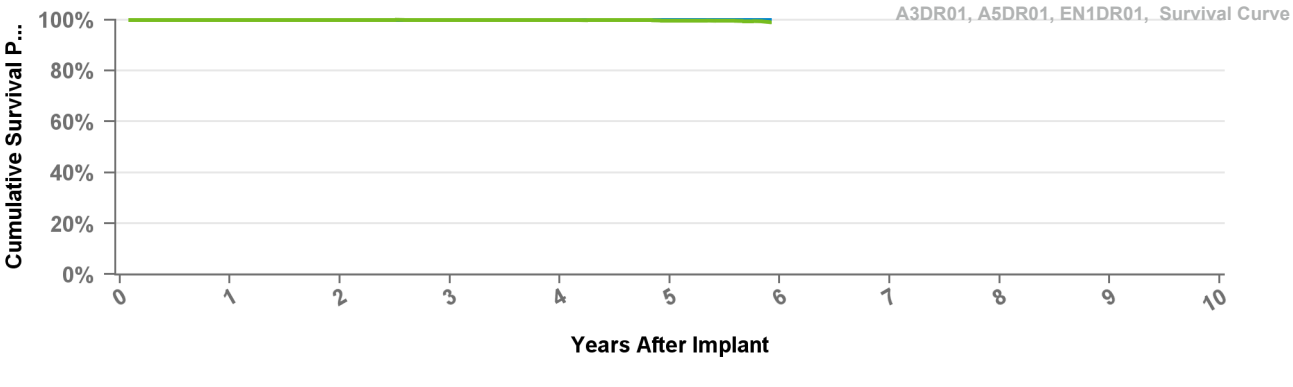
US Market Release	Jan-13	**Total Malfunctions**	**49**
CE Approval Date		**Therapy Function Not Compromised**	**45**
Registered USA Implants	345,135	Battery Malfunction	1
Estimated Active USA Implants	318,638	Electrical Component	28
Normal Battery Depletions	190	Electrical Interconnect	2
		Other Malfunction	1
		Poss Early Battery Depltn	11
		Software Malfunction	2
		Therapy Function Compromised	**4**
		Electrical Component	4



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.997	0.99
Effective Sample Size	314396	274043	183158	101971	35340	576

A3DR01 Advisa DR MRI

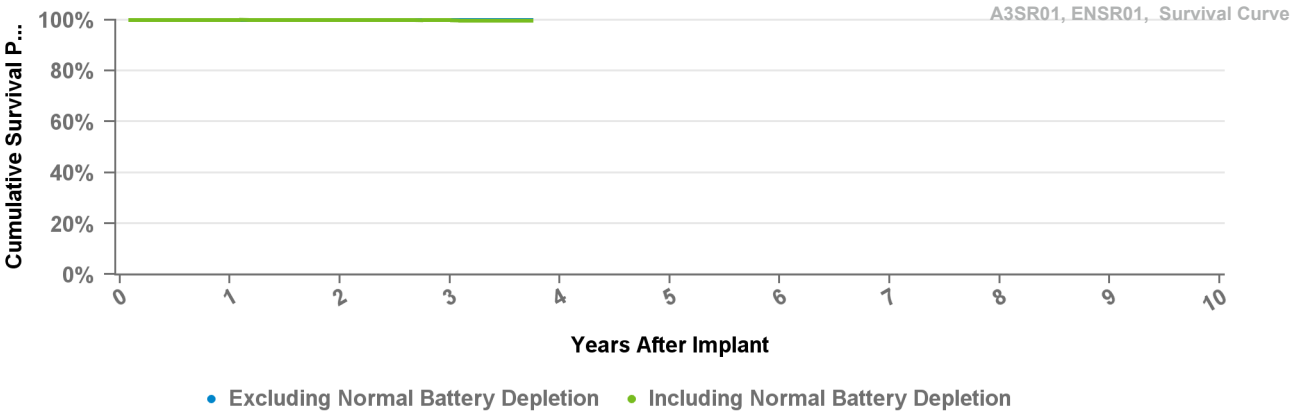
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	15		
Estimated Active USA Implants	8	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.997	0.99
Effective Sample Size	314396	274043	183158	101971	35340	576

A3SR01 Advisa SR MRI

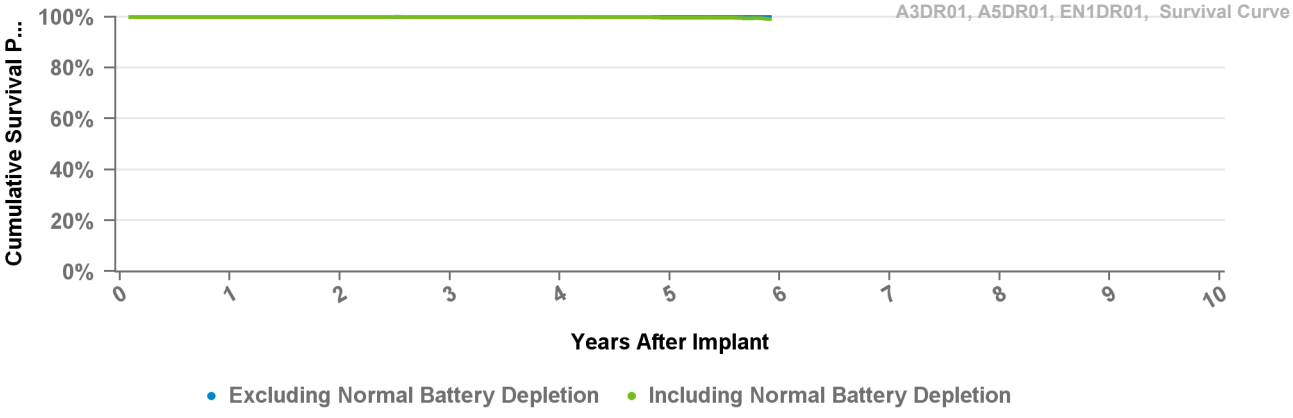
US Market Release	Mar-15	**Total Malfunctions**	**8**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**7**
Registered USA Implants	28,386	Electrical Component	2
Estimated Active USA Implants	25,766	Electrical Interconnect	1
Normal Battery Depletions	14	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	at 45 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.997
Effective Sample Size	22862	17726	7377	415

A5DR01 Advisa DR

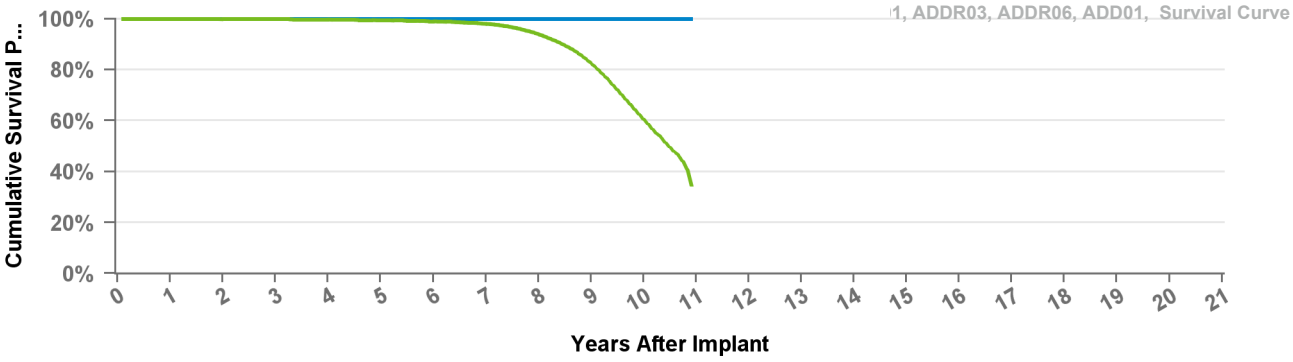
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.997	0.99
Effective Sample Size	314396	274043	183158	101971	35340	576

ADD01 Adapta D

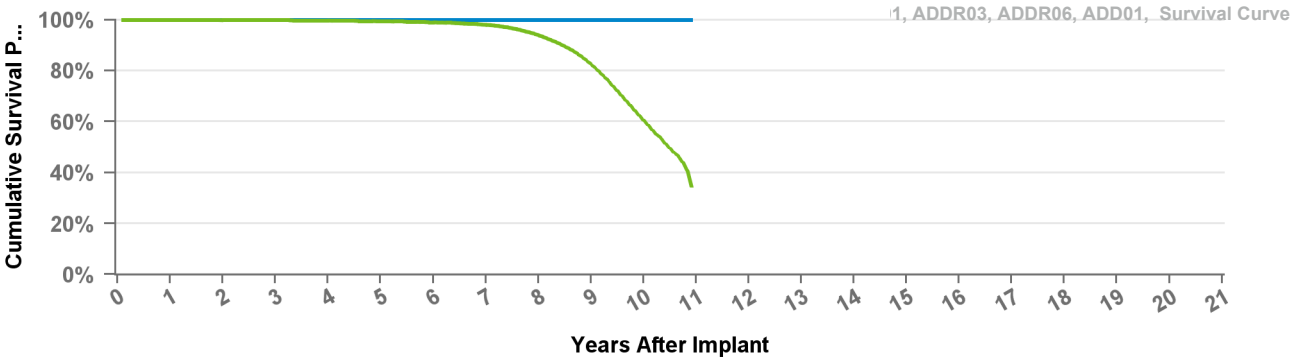
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

ADDR01 Adapta DR

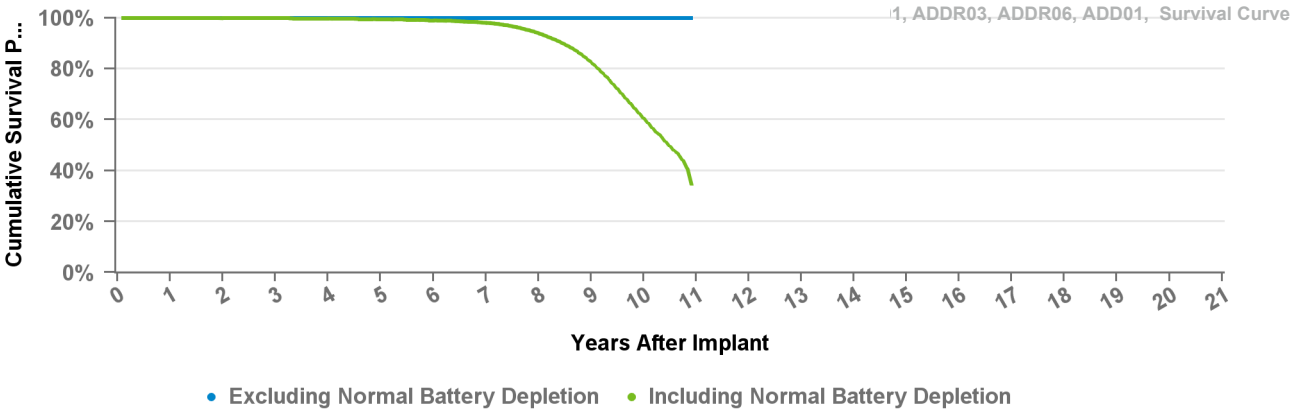
US Market Release	Jul-06	**Total Malfunctions**	**92**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**64**
Registered USA Implants	459,709	Electrical Component	56
Estimated Active USA Implants	275,981	Electrical Interconnect	1
Normal Battery Depletions	26,119	Other Malfunction	1
		Poss Early Battery Depltn	6
		Therapy Function Compromised	**28**
		Electrical Component	23
		Electrical Interconnect	3
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

ADDR03 Adapta DR

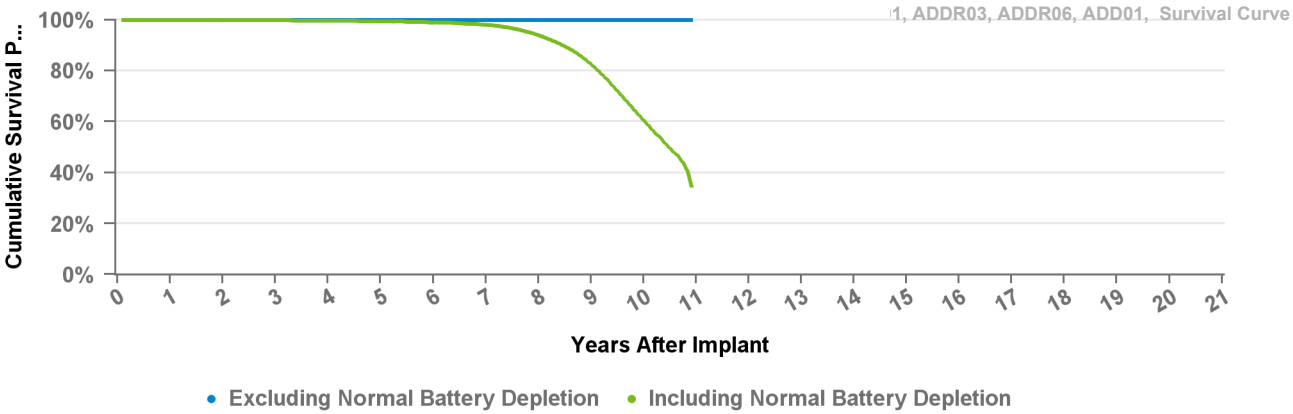
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,470	Electrical Component	1
Estimated Active USA Implants	2,407	**Therapy Function Compromised**	**1**
Normal Battery Depletions	376	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

ADDR06 Adapta DR

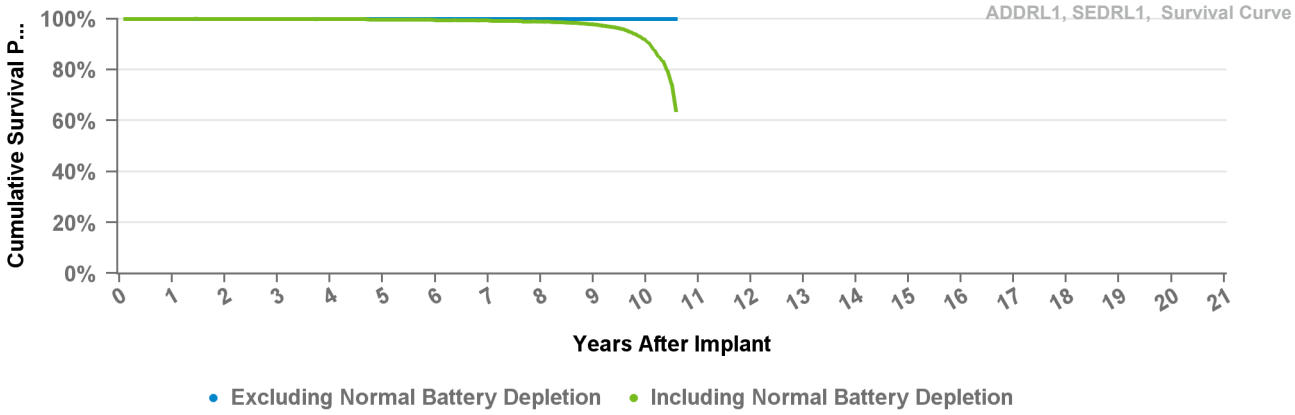
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,448	Electrical Component	1
Estimated Active USA Implants	1,483	**Therapy Function Compromised**	**0**
Normal Battery Depletions	321		



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

ADDRL1 Adapta L DR

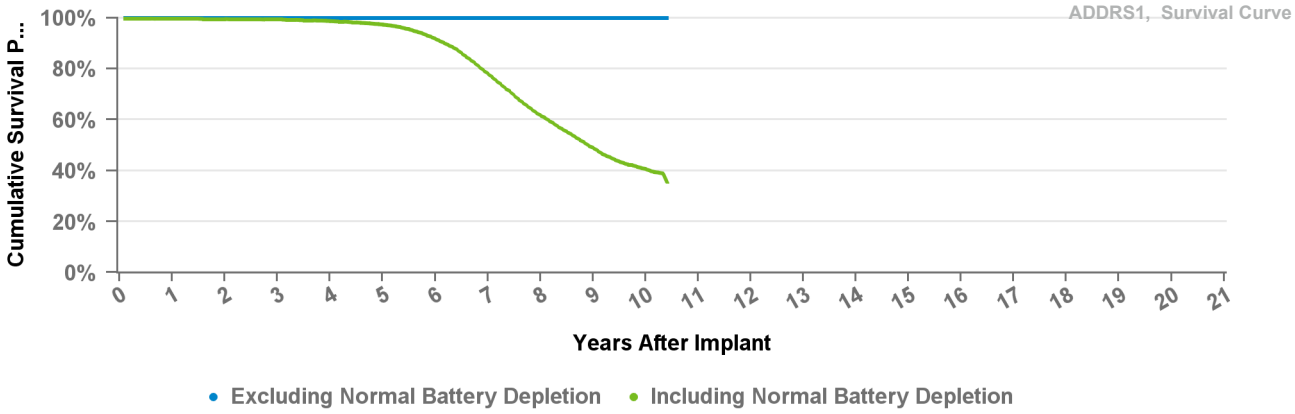
US Market Release	Jul-06	**Total Malfunctions**	**19**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**13**
Registered USA Implants	138,221	Electrical Component	11
Estimated Active USA Implants	105,853	Electrical Interconnect	1
Normal Battery Depletions	1,895	Poss Early Battery Depltn	1
		Therapy Function Compromised	**6**
		Electrical Component	3
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	1	0.999	0.999	0.998	0.997	0.995	0.993	0.989	0.978	0.915	0.639
Effective Sample Size	122151	114496	104223	91227	76804	60075	43597	28405	16045	5504	572

ADDRS1 Adapta S DR

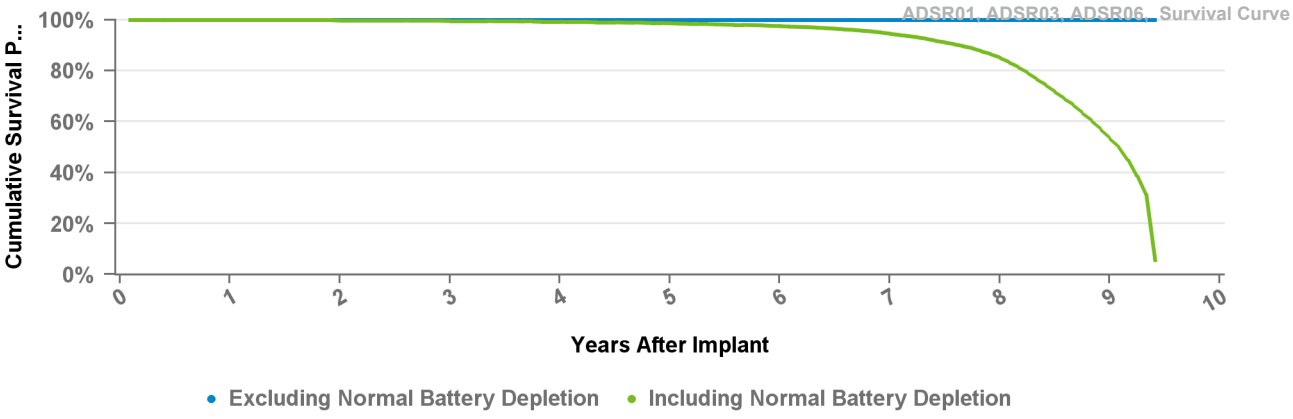
US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**8**
Registered USA Implants	48,862	Electrical Component	5
Estimated Active USA Implants	25,175	Poss Early Battery Depltn	3
Normal Battery Depletions	4,459	**Therapy Function Compromised**	**6**
		Electrical Component	4
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.996	0.995	0.993	0.987	0.973	0.917	0.78	0.616	0.489	0.406	0.355
Effective Sample Size	41468	37863	34214	30541	26455	20609	13622	7414	3314	754	104

ADSR01 Adapta SR

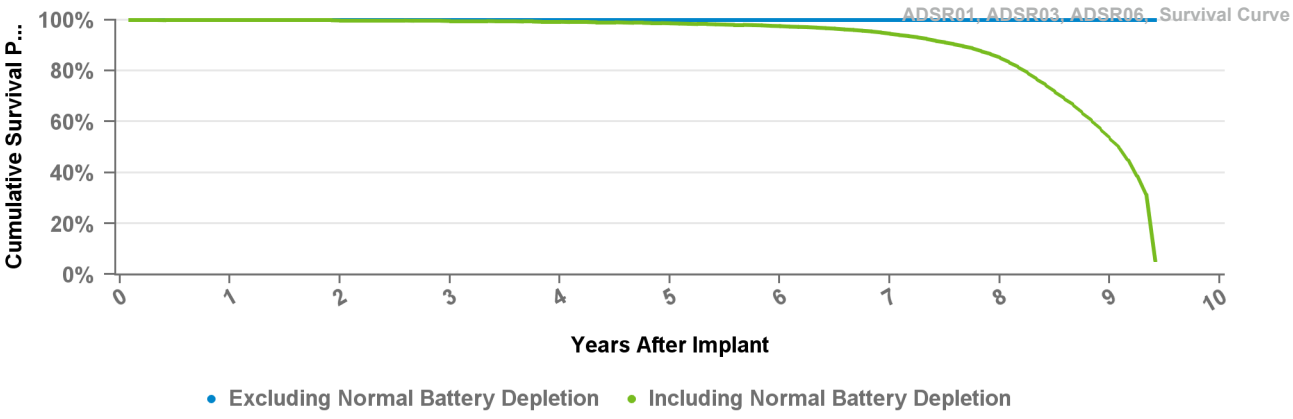
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**11**
Registered USA Implants	92,827	Electrical Component	6
Estimated Active USA Implants	49,415	Electrical Interconnect	1
Normal Battery Depletions	3,640	Poss Early Battery Depltn	4
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.997	0.995	0.992	0.986	0.975	0.945	0.851	0.534	0.053
Effective Sample Size	74379	65417	57710	49941	40411	30809	21579	12142	3134	148

ADSR03 Adapta SR

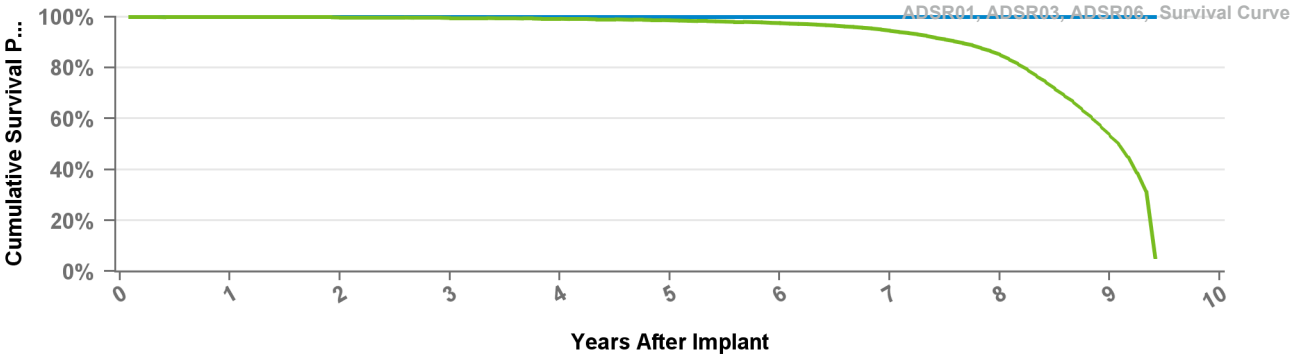
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	2,076		
Estimated Active USA Implants	933	**Therapy Function Compromised**	
Normal Battery Depletions	126		



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.997	0.995	0.992	0.986	0.975	0.945	0.851	0.534	0.053
Effective Sample Size	74379	65417	57710	49941	40411	30809	21579	12142	3134	148

ADSR06 Adapta SR

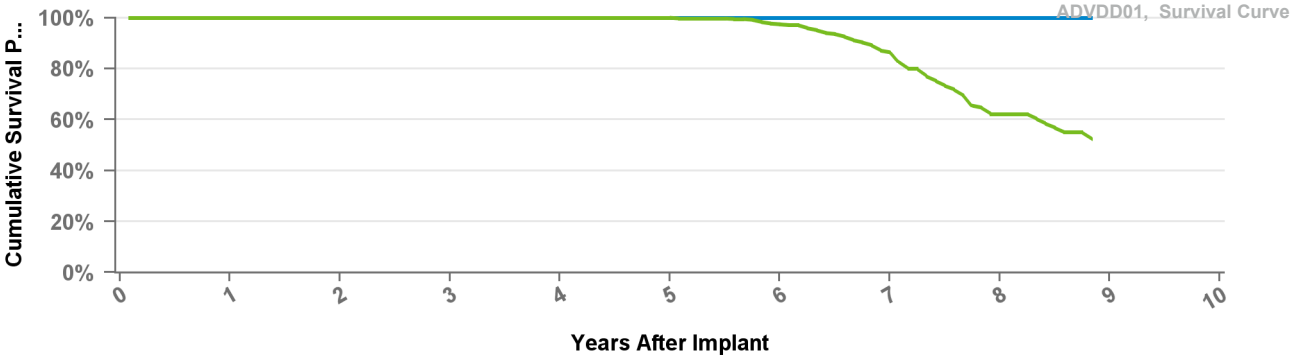
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,817	Electrical Component	2
Estimated Active USA Implants	1,178	**Therapy Function Compromised**	**0**
Normal Battery Depletions	191		



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.997	0.995	0.992	0.986	0.975	0.945	0.851	0.534	0.053
Effective Sample Size	74379	65417	57710	49941	40411	30809	21579	12142	3134	148

ADVDD01 Adapta VDD

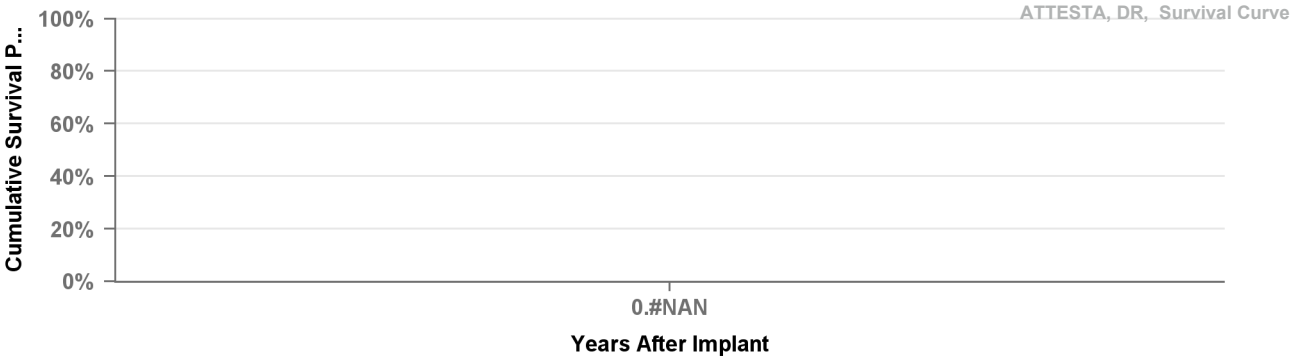
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,410		
Estimated Active USA Implants	695	**Therapy Function Compromised**	
Normal Battery Depletions	81		



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	1	1	1	1	1	0.974	0.864	0.622	0.524
Effective Sample Size	1220	1112	989	904	793	664	444	213	105

ATDR01 Attesta DR MRI

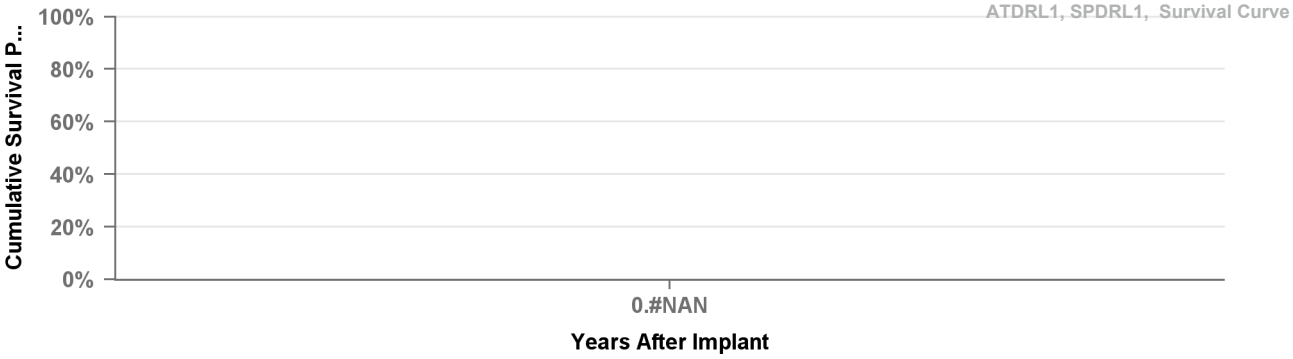
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATDRL1 Attesta L DR MRI

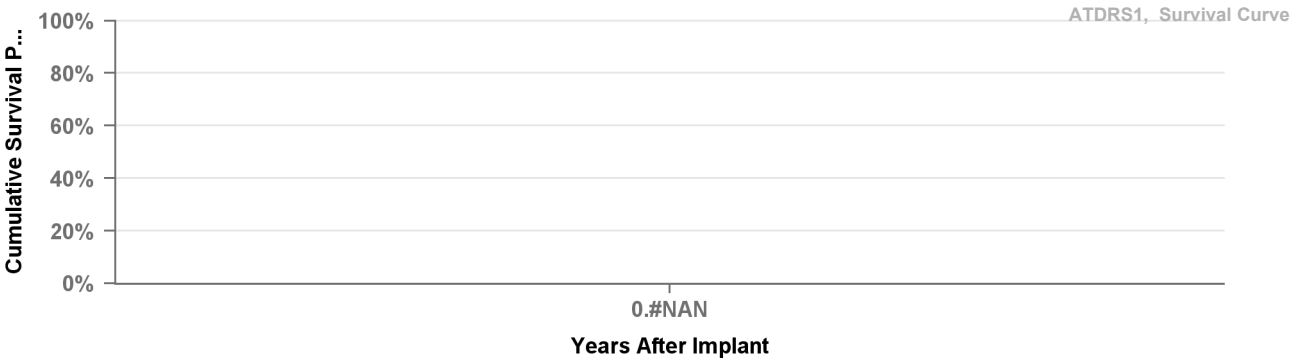
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATDRS1 Attesta S DR MRI

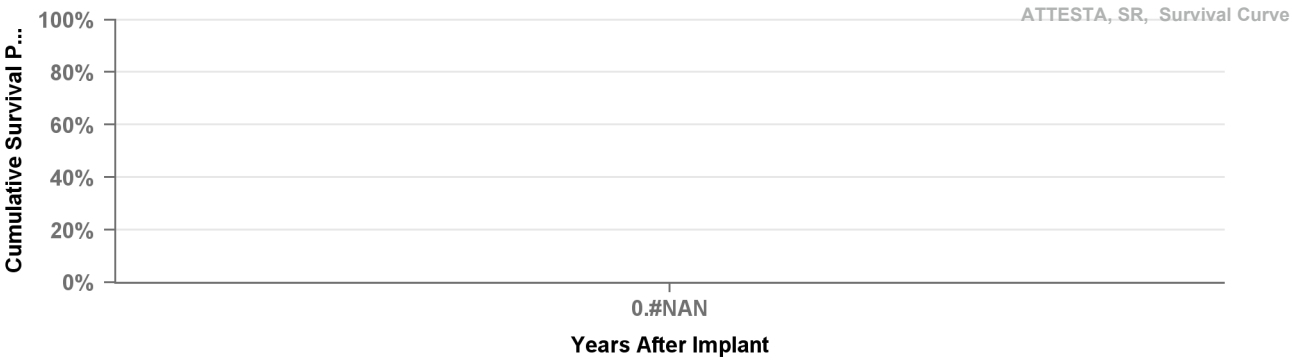
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATSR01 Attesta SR MRI

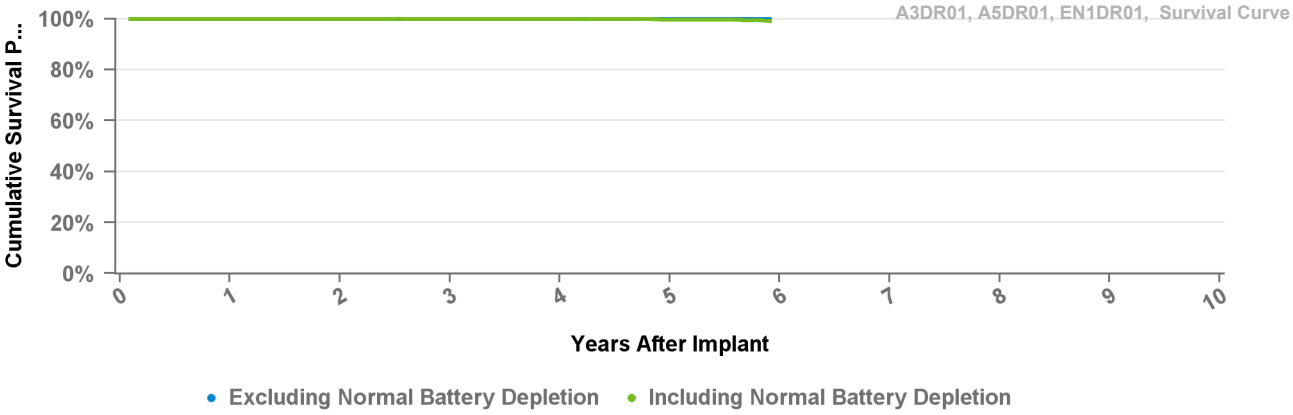
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

EN1DR01 Ensura MRI

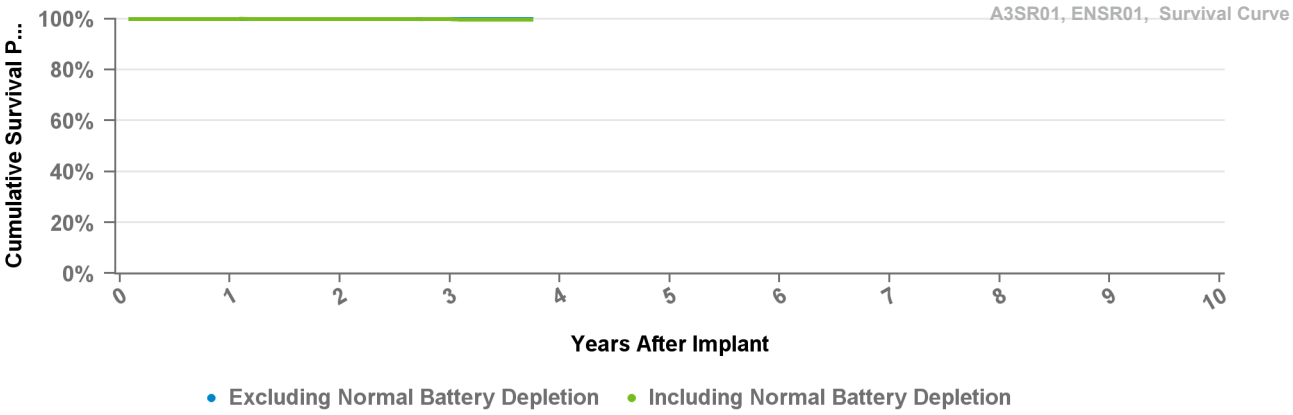
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	
Registered USA Implants	18		
Estimated Active USA Implants	14	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.997	0.99
Effective Sample Size	314396	274043	183158	101971	35340	576

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			

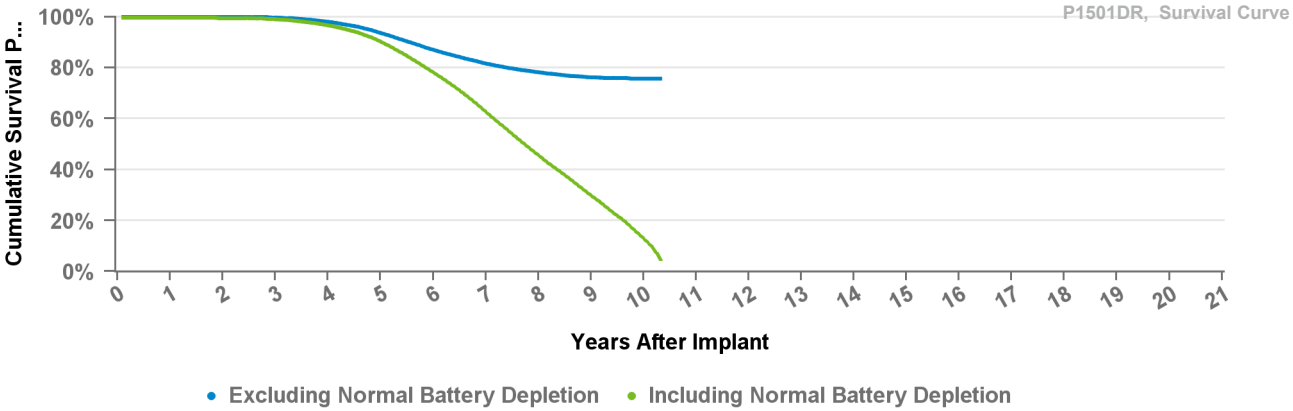


Years	1	2	3	at 45 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.999	0.998	0.997
Effective Sample Size	22862	17726	7377	415

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	109,806
Estimated Active USA Implants	18,606
Normal Battery Depletions	16,738

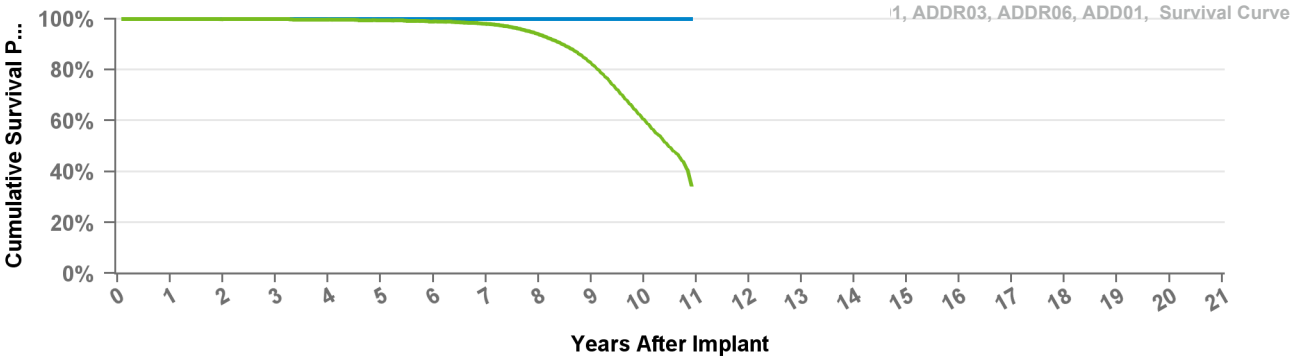
Total Malfunctions	**15,061**
Therapy Function Not Compromised	**15,006**
Battery Malfunction	14,875
Electrical Component	59
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	69
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2



Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	0.999	0.999	0.997	0.98	0.936	0.87	0.816	0.782	0.762	0.758	0.758
Including NBD	0.996	0.995	0.99	0.966	0.902	0.781	0.626	0.456	0.298	0.129	0.046
Effective Sample Size	94882	88574	82551	75550	65578	51539	37123	23752	12237	2854	590

RED01 Relia D

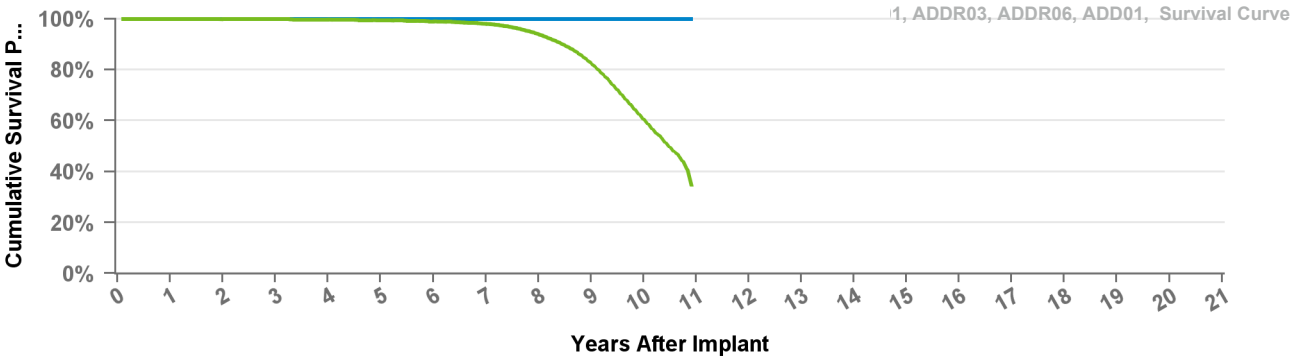
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

REDR01 Relia DR

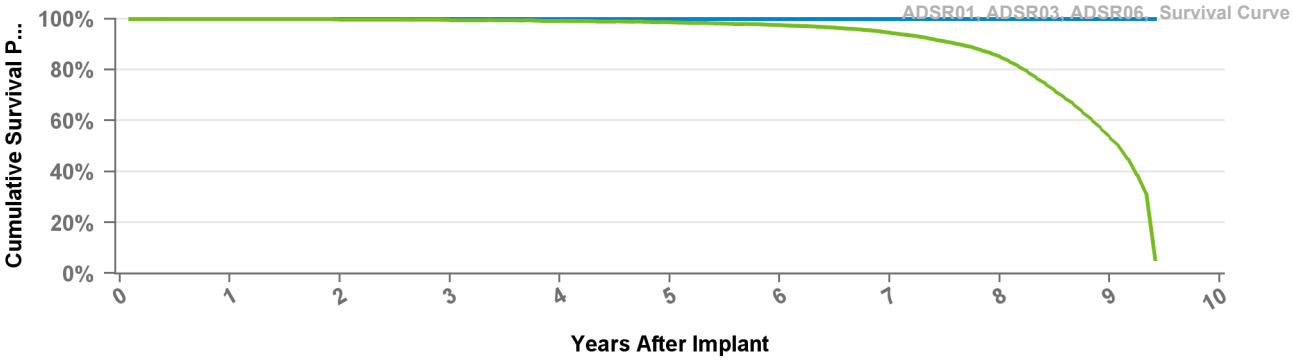
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.998	0.997	0.994	0.99	0.98	0.939	0.825	0.607	0.346
Effective Sample Size	406164	381018	352493	320552	288110	247800	203526	152893	93796	34888	994

RES01 Relia S

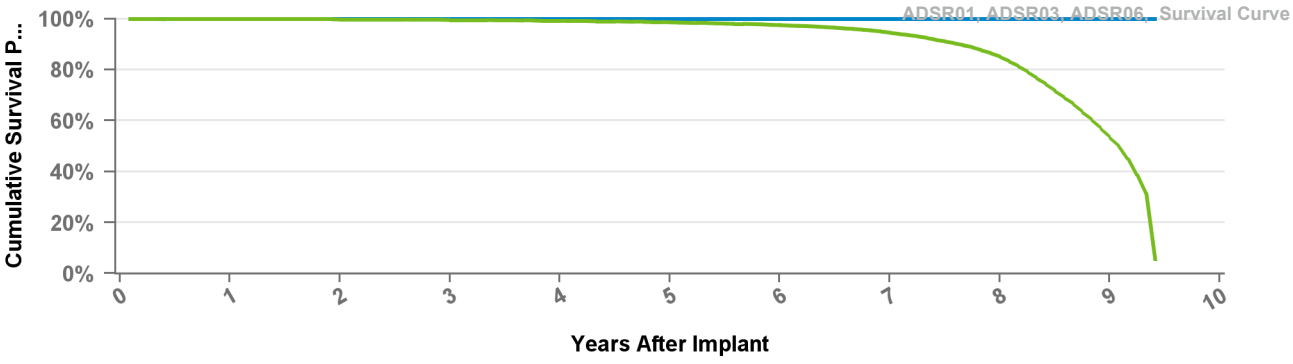
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.997	0.995	0.992	0.986	0.975	0.945	0.851	0.534	0.053
Effective Sample Size	74379	65417	57710	49941	40411	30809	21579	12142	3134	148

RESR01 Relia SR

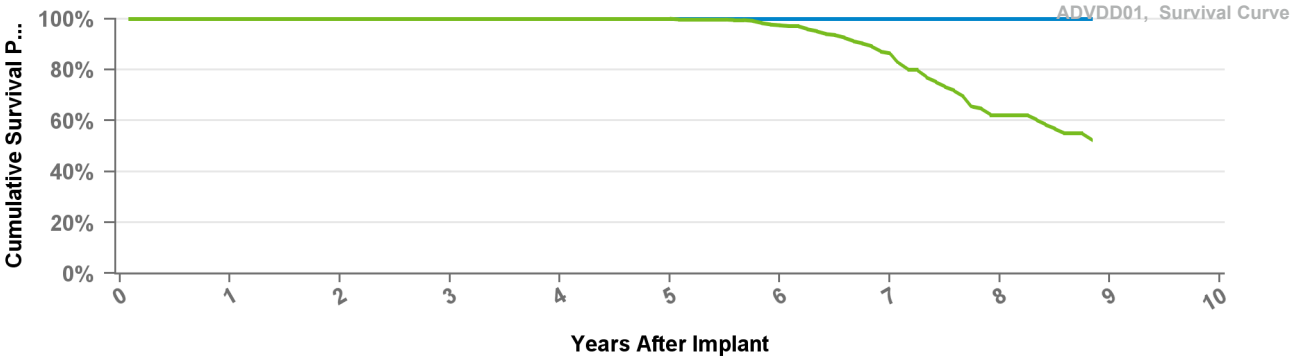
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.997	0.995	0.992	0.986	0.975	0.945	0.851	0.534	0.053
Effective Sample Size	74379	65417	57710	49941	40411	30809	21579	12142	3134	148

REVDD01 Relia VDD

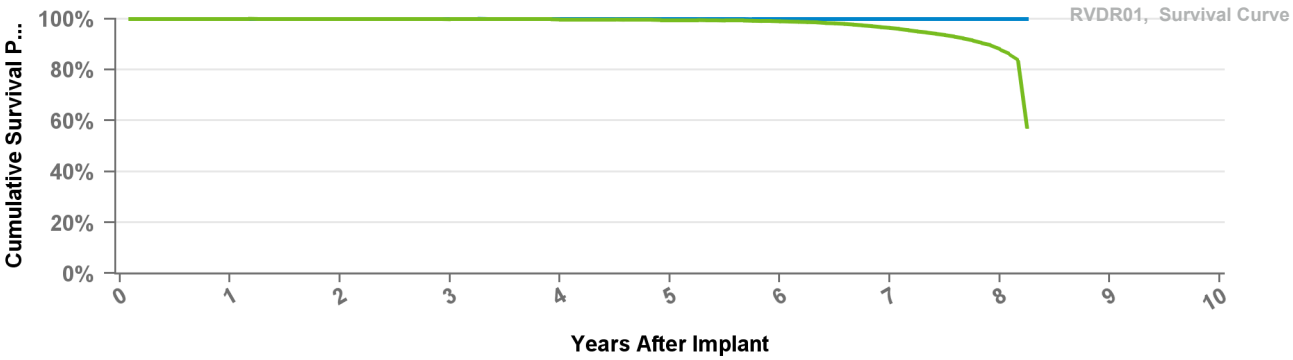
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	1	1	1	1	1	0.974	0.864	0.622	0.524
Effective Sample Size	1220	1112	989	904	793	664	444	213	105

RVDR01 Revo MRI SureScan

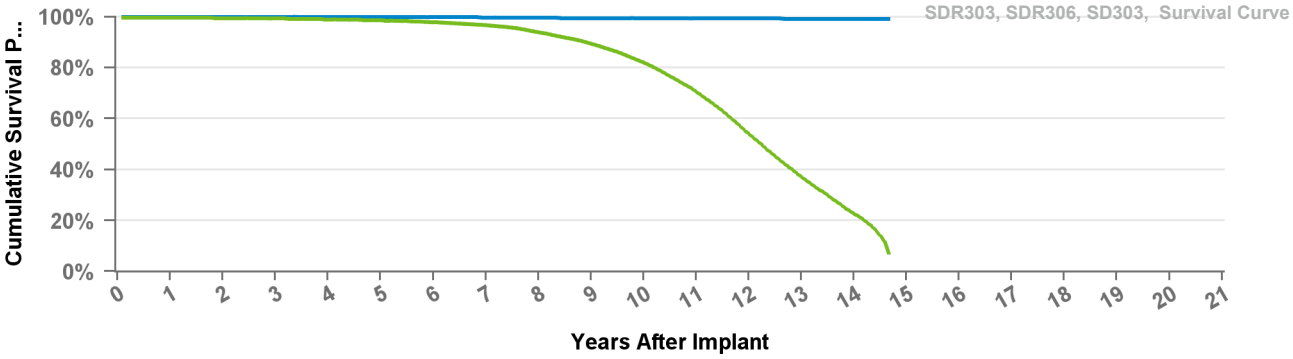
US Market Release	Feb-11	**Total Malfunctions**	**98**
CE Approval Date		**Therapy Function Not Compromised**	**95**
Registered USA Implants	69,161	Battery Malfunction	1
Estimated Active USA Implants	54,233	Electrical Component	39
Normal Battery Depletions	1,464	Other Malfunction	1
		Poss Early Battery Depltn	51
		Software Malfunction	3
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.998	0.998	0.998
Including NBD	1	0.999	0.998	0.997	0.995	0.99	0.964	0.88	0.574
Effective Sample Size	61212	57793	54891	51517	47521	43056	28101	5199	211

SD303 Sigma 300 D

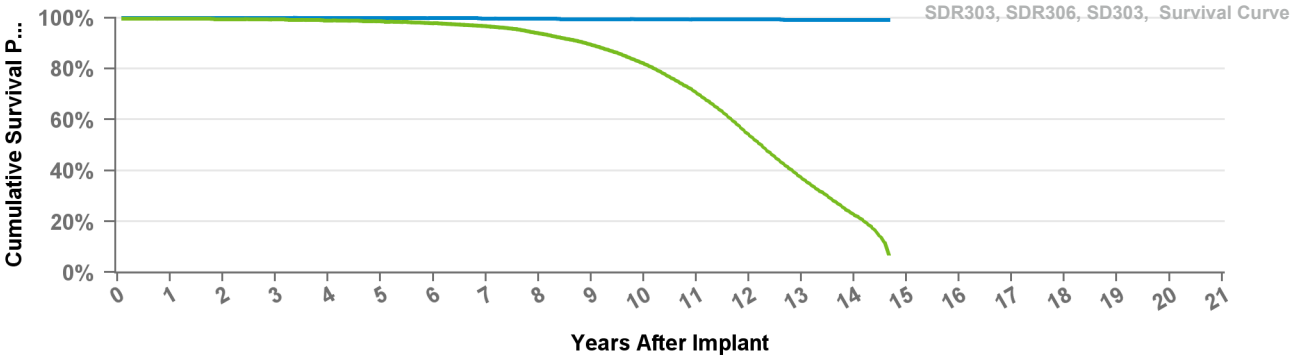
US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	21	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Interconnect	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993	0.992	0.992	0.992
Including NBD	0.996	0.995	0.993	0.99	0.986	0.978	0.967	0.939	0.894	0.82	0.705	0.54	0.371	0.226	0.073
Effective Sample Size	87010	77034	68064	59823	52406	45829	39677	34247	29397	24438	18721	11432	5718	1925	135

SDR303 Sigma 300 DR

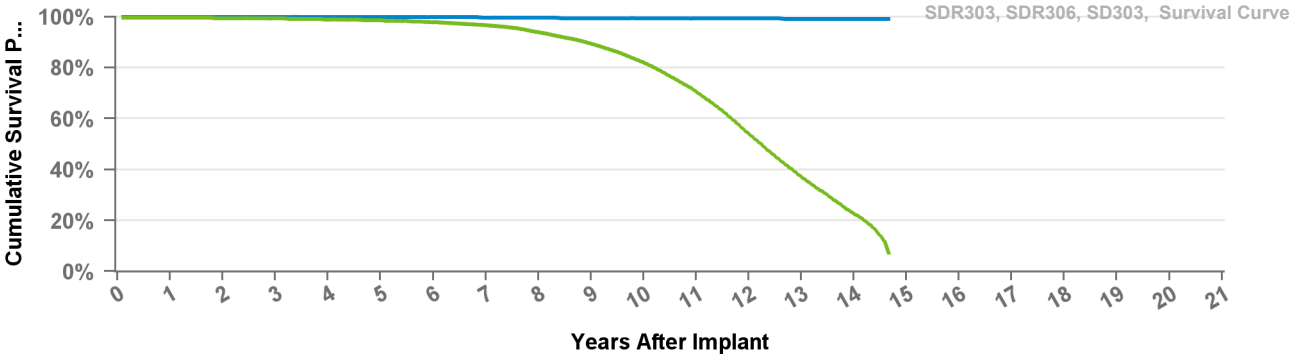
US Market Release	Aug-99	**Total Malfunctions**	**288**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**62**
Registered USA Implants	104,526	Electrical Component	9
Estimated Active USA Implants	10,934	Electrical Interconnect	51
Normal Battery Depletions	10,761	Other Malfunction	1
		Poss 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	1	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993	0.992	0.992	0.992
Including NBD	0.996	0.995	0.993	0.99	0.986	0.978	0.967	0.939	0.894	0.82	0.705	0.54	0.371	0.226	0.073
Effective Sample Size	87010	77034	68064	59823	52406	45829	39677	34247	29397	24438	18721	11432	5718	1925	135

SDR306 Sigma 300 DR

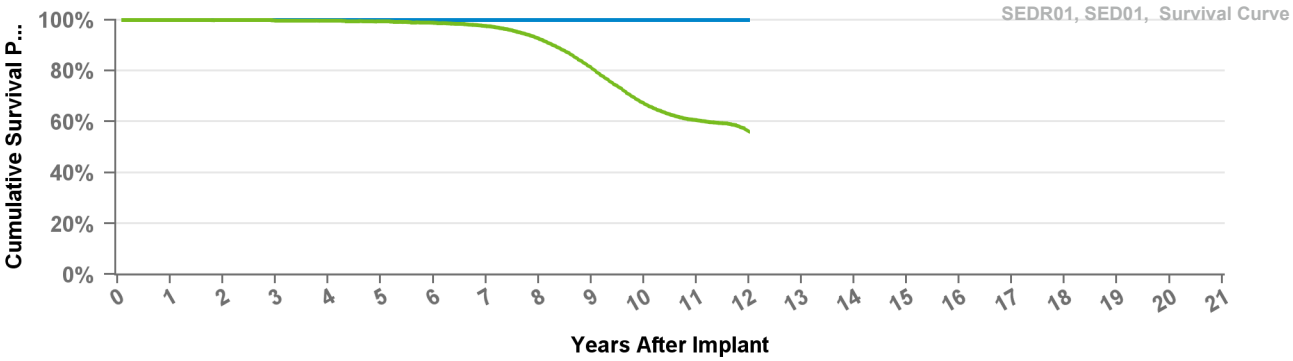
US Market Release	Aug-99	**Total Malfunctions**	**5**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,200		
Estimated Active USA Implants	77	**Therapy Function Compromised**	**5**
Normal Battery Depletions	168	Electrical Interconnect	5



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993	0.992	0.992	0.992
Including NBD	0.996	0.995	0.993	0.99	0.986	0.978	0.967	0.939	0.894	0.82	0.705	0.54	0.371	0.226	0.073
Effective Sample Size	87010	77034	68064	59823	52406	45829	39677	34247	29397	24438	18721	11432	5718	1925	135

SED01 Sensia D

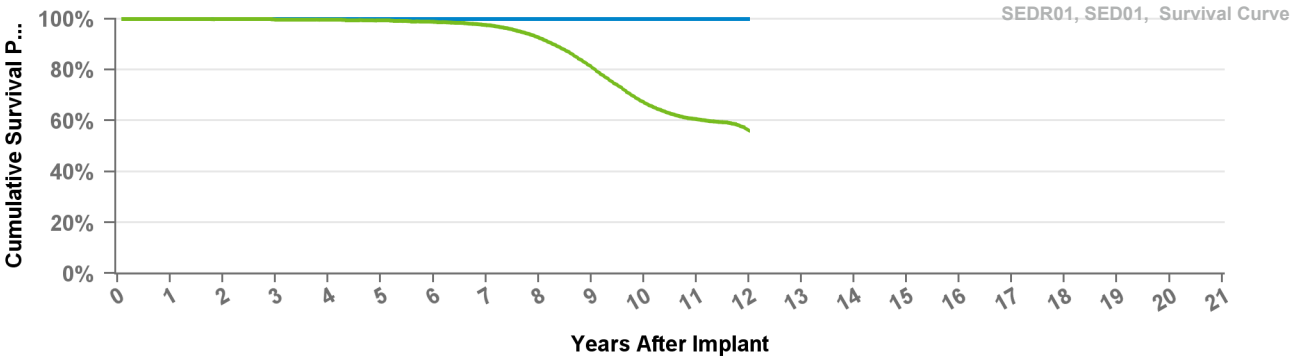
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.997	0.996	0.993	0.988	0.975	0.926	0.812	0.672	0.606	0.56
Effective Sample Size	125842	116585	108644	99269	88209	75810	62651	47272	29788	14551	4701	224

SEDR01 Sensia DR

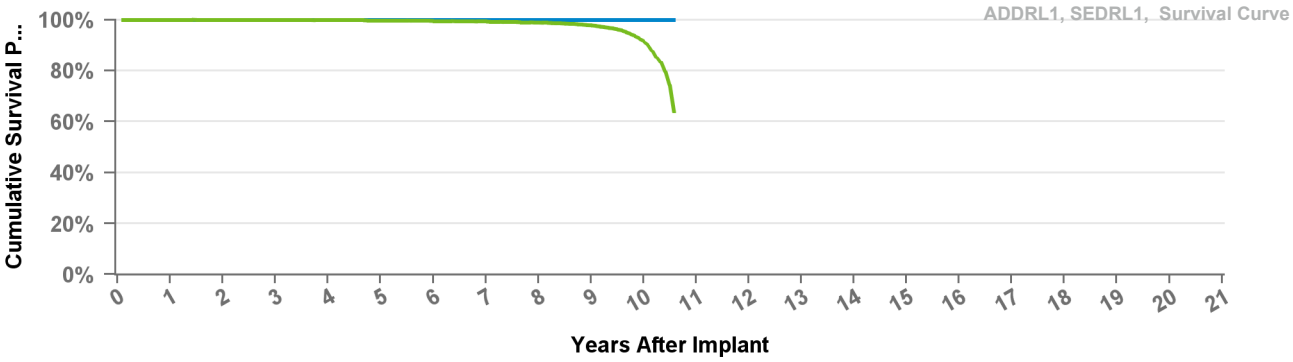
US Market Release	Jul-06	**Total Malfunctions**	**32**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,280	Electrical Component	15
Estimated Active USA Implants	74,726	Electrical Interconnect	1
Normal Battery Depletions	8,791	Other Malfunction	1
		Therapy 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	at 144 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.997	0.996	0.993	0.988	0.975	0.926	0.812	0.672	0.606	0.56
Effective Sample Size	125842	116585	108644	99269	88209	75810	62651	47272	29788	14551	4701	224

SEDRL1 Sensia L DR

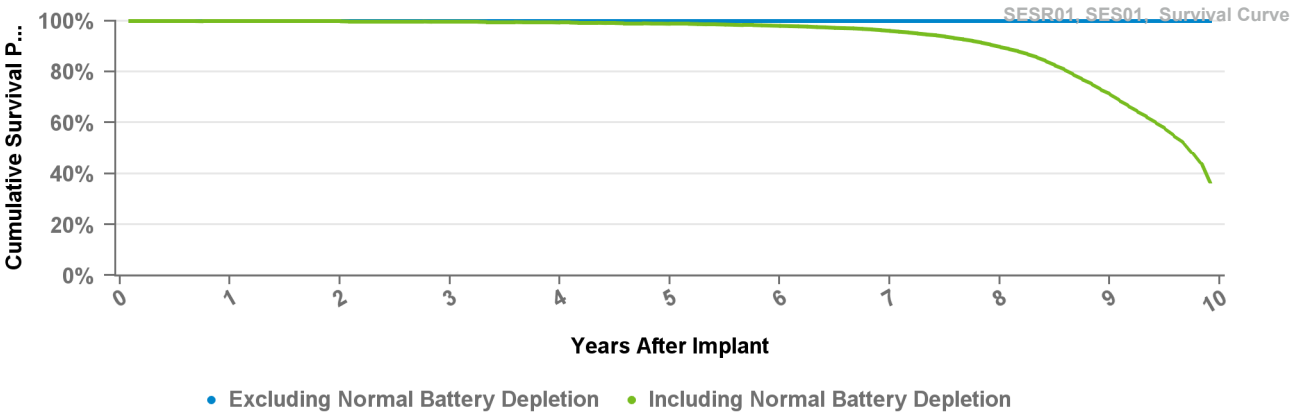
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	1	0.999	0.999	0.998	0.997	0.995	0.993	0.989	0.978	0.915	0.639
Effective Sample Size	122151	114496	104223	91227	76804	60075	43597	28405	16045	5504	572

SES01 Sensia S

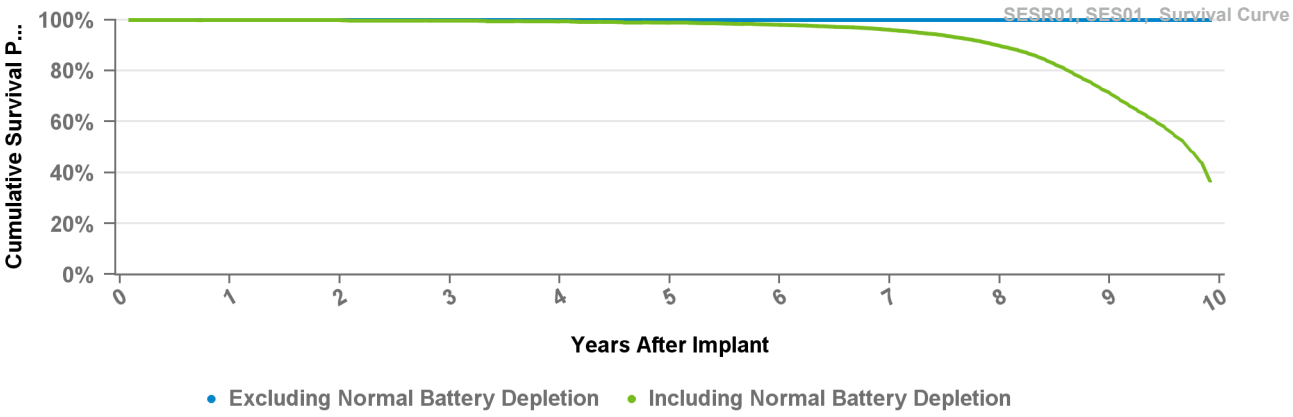
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	8		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.998	0.996	0.993	0.988	0.98	0.96	0.897	0.712	0.366
Effective Sample Size	87921	77584	68700	59630	49493	39202	29095	18385	7846	451

SESR01 Sensia SR

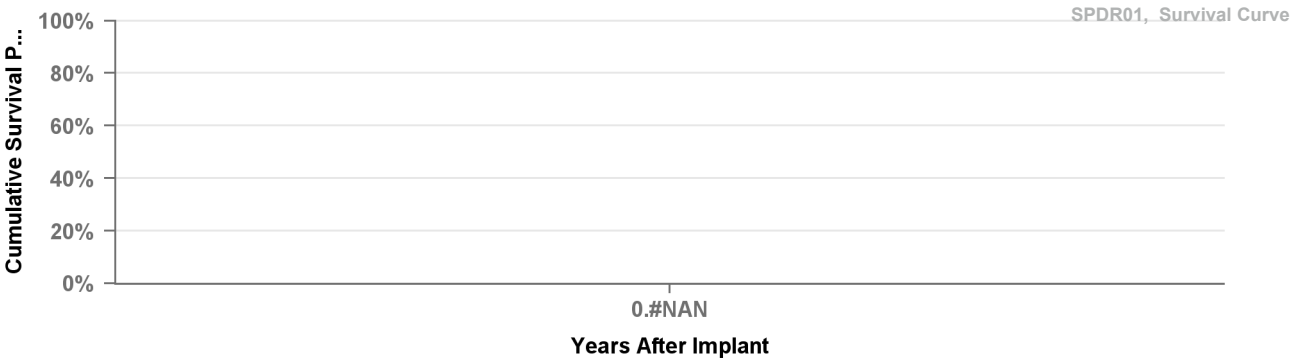
US Market Release	Jul-06	**Total Malfunctions**	**16**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**12**
Registered USA Implants	117,221	Electrical Component	7
Estimated Active USA Implants	58,050	Other Malfunction	1
Normal Battery Depletions	4,658	Poss Early Battery Depltn	4
		Therapy Function Compromised	**4**
		Electrical Component	3
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.998	0.996	0.993	0.988	0.98	0.96	0.897	0.712	0.366
Effective Sample Size	87921	77584	68700	59630	49493	39202	29095	18385	7846	451

SPDR01 Sphera DR MRI

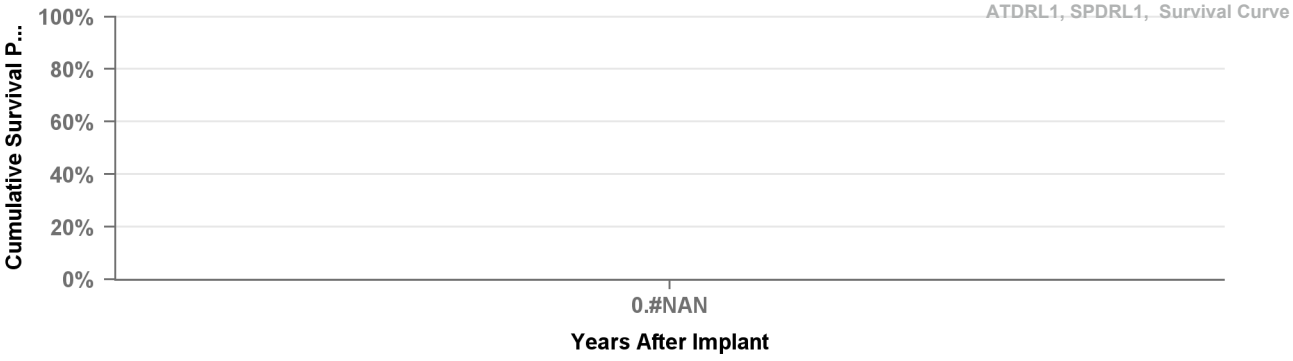
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPDRL1 Sphera L DR MRI

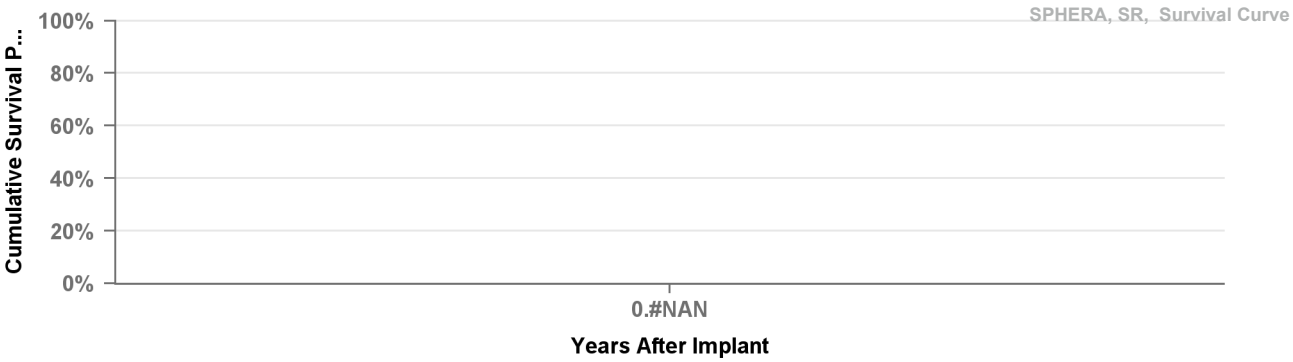
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPSR01 Sphera SR MRI

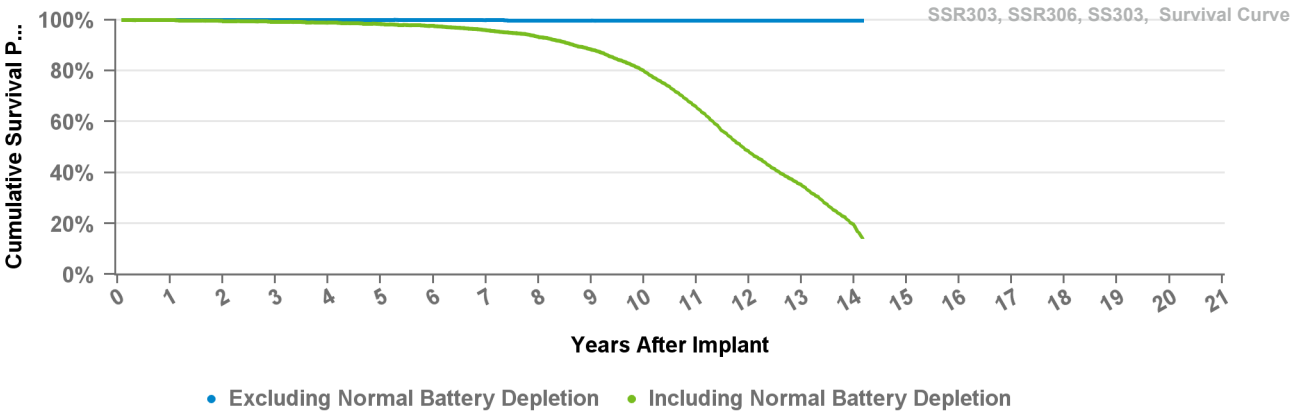
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SS303 Sigma 300 S

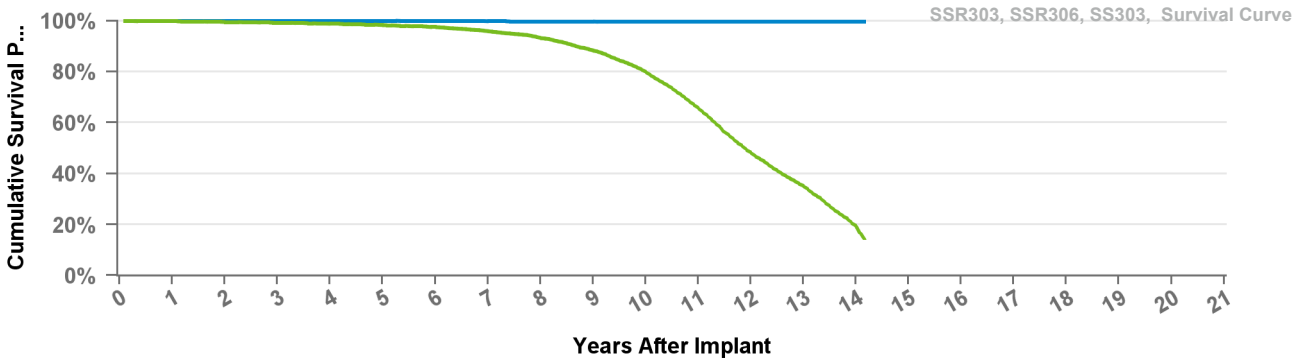
US Market Release	Sep-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	248		
Estimated Active USA Implants	46	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	1	1	1	1	1	0.999	0.998	0.997	0.997	0.996	0.996	0.996	0.996	0.996	0.996
Including NBD	0.998	0.995	0.992	0.988	0.983	0.975	0.959	0.932	0.883	0.799	0.657	0.482	0.351	0.194	0.145
Effective Sample Size	40569	33494	27719	23027	19156	15919	13220	10981	8918	6854	4669	2635	1292	264	108

SSR303 Sigma 300 SR

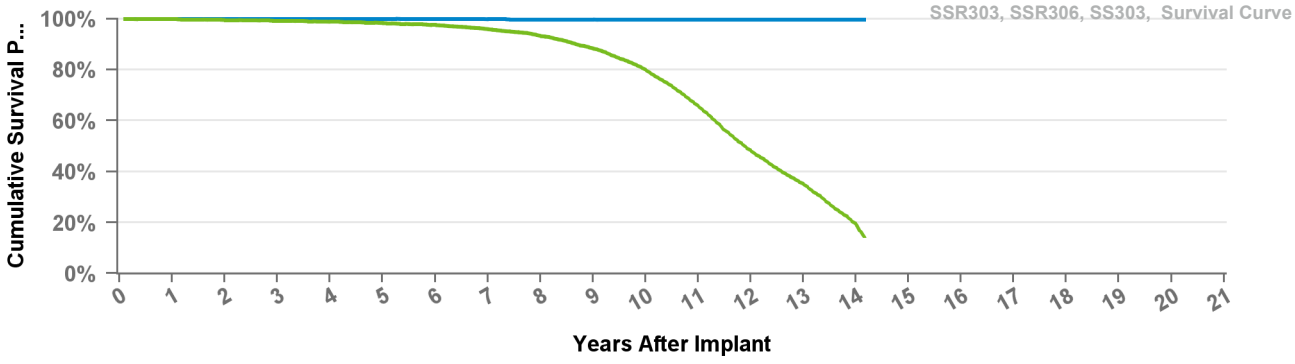
US Market Release	Aug-99	**Total Malfunctions**	**58**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**11**
Registered USA Implants	51,227	Electrical Interconnect	10
Estimated Active USA Implants	4,220	Other Malfunction	1
Normal Battery Depletions	2,972	**Therapy Function Compromised**	**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	1	1	1	1	1	0.999	0.998	0.997	0.997	0.996	0.996	0.996	0.996	0.996	0.996
Including NBD	0.998	0.995	0.992	0.988	0.983	0.975	0.959	0.932	0.883	0.799	0.657	0.482	0.351	0.194	0.145
Effective Sample Size	40569	33494	27719	23027	19156	15919	13220	10981	8918	6854	4669	2635	1292	264	108

SSR306 Sigma 300 SR

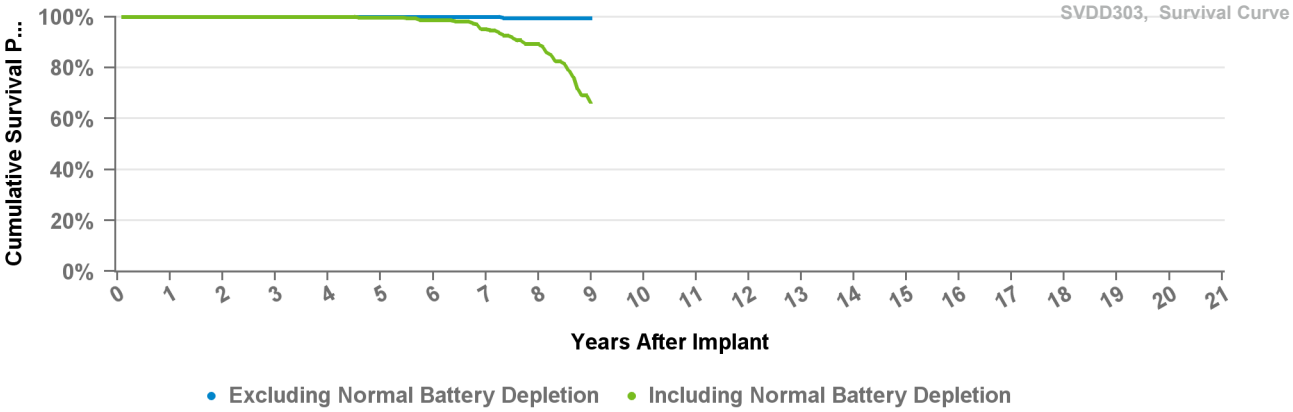
US Market Release	Sep-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,200	Electrical Component	1
Estimated Active USA Implants	148	**Therapy Function Compromised**	**1**
Normal Battery Depletions	153	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	1	1	1	1	1	0.999	0.998	0.997	0.997	0.996	0.996	0.996	0.996	0.996	0.996
Including NBD	0.998	0.995	0.992	0.988	0.983	0.975	0.959	0.932	0.883	0.799	0.657	0.482	0.351	0.194	0.145
Effective Sample Size	40569	33494	27719	23027	19156	15919	13220	10981	8918	6854	4669	2635	1292	264	108

SVDD303 Sigma 300 VDD

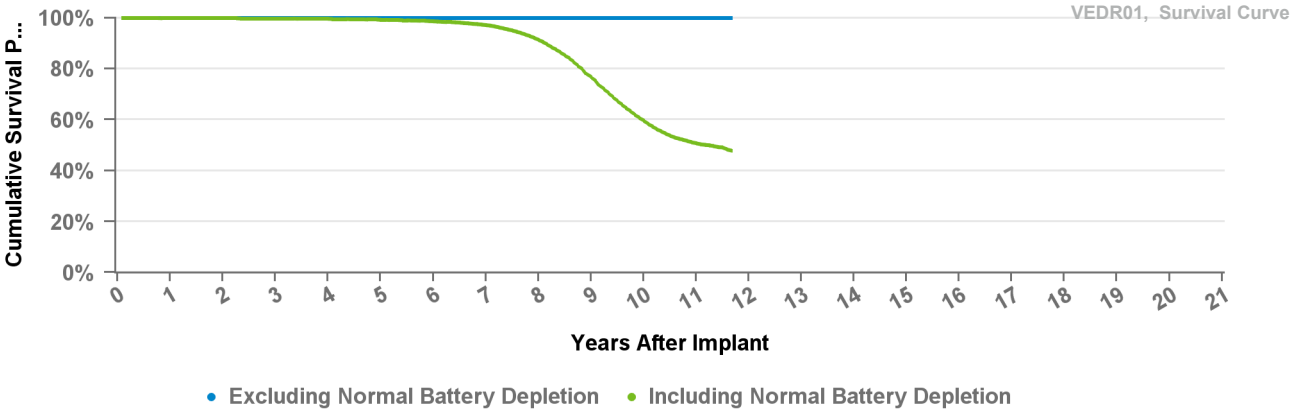
US Market Release	Sep-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	650		
Estimated Active USA Implants	42	**Therapy Function Compromised**	**1**
Normal Battery Depletions	81	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	1	1	1	1	1	1	0.995	0.995
Including NBD	1	1	1	1	0.997	0.986	0.951	0.892	0.664
Effective Sample Size	528	458	411	363	316	264	210	165	104

VEDR01 Versa DR

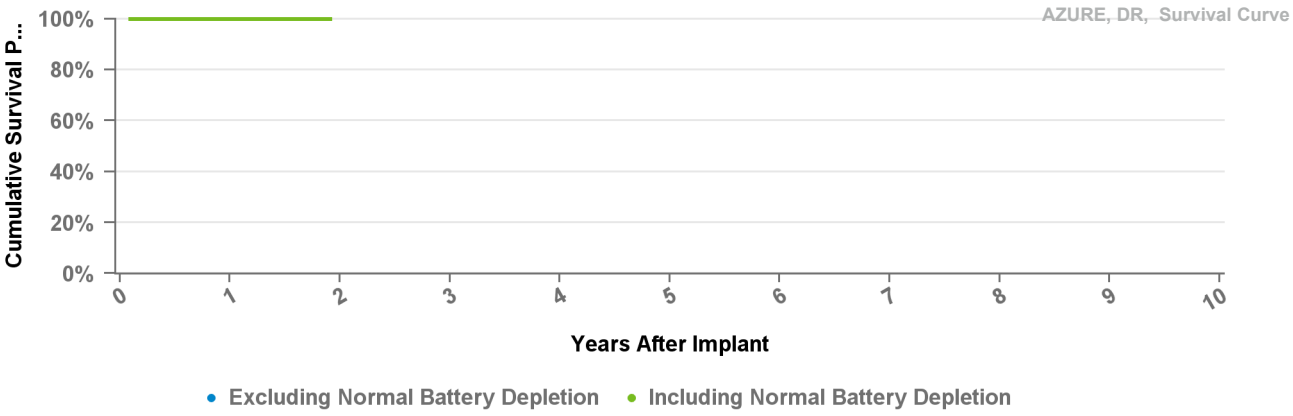
US Market Release	Jul-06	**Total Malfunctions**	**24**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**13**
Registered USA Implants	118,686	Electrical Component	9
Estimated Active USA Implants	60,573	Electrical Interconnect	2
Normal Battery Depletions	8,631	Poss Early Battery Depltn	2
		Therapy Function Compromised	**11**
		Electrical Component	7
		Other Malfunction	4



Years	1	2	3	4	5	6	7	8	9	10	11	at 140 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.998	0.998	0.997	0.996	0.992	0.986	0.971	0.913	0.767	0.596	0.507	0.478
Effective Sample Size	101479	93749	85074	76898	69180	60937	51255	38926	23814	10690	2840	357

W1DR01 Azure XT DR

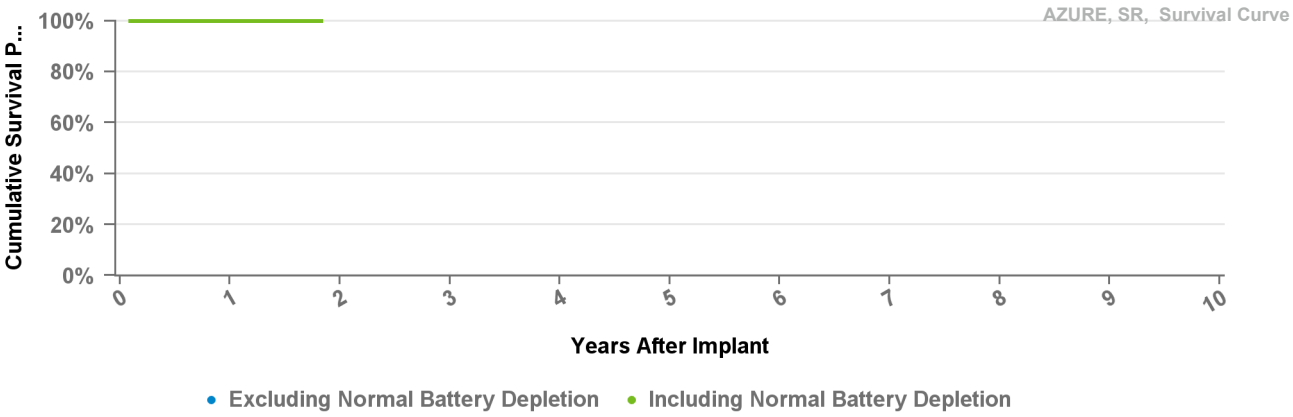
US Market Release	Aug-17	**Total Malfunctions**	**18**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**16**
Registered USA Implants	160,255	Electrical Component	9
Estimated Active USA Implants	156,207	Other Malfunction	7
Normal Battery Depletions		**Therapy Function Compromised**	**2**
		Electrical Component	2



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	64352	449

W1SR01 Azure XT SR

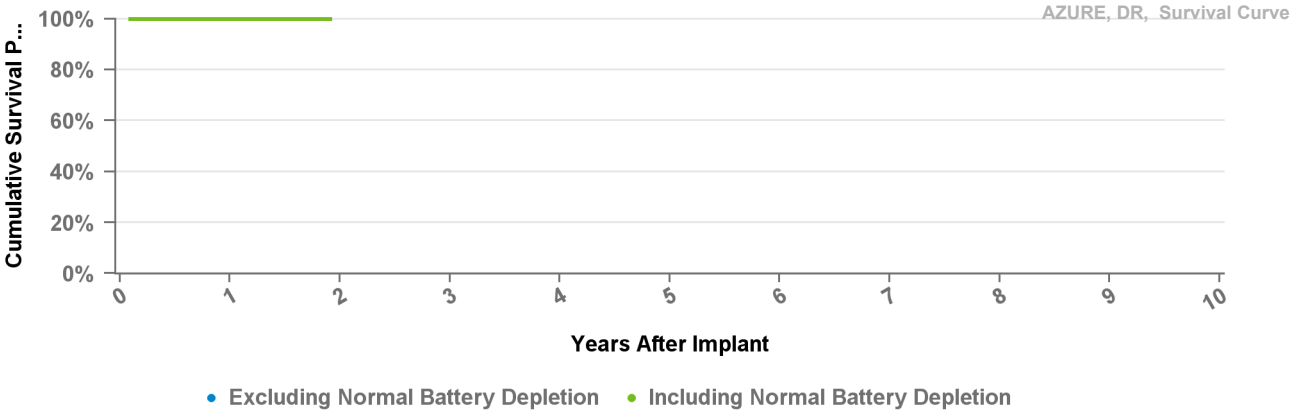
US Market Release	Aug-17	**Total Malfunctions**	**1**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**1**
Registered USA Implants	13,961	Other Malfunction	1
Estimated Active USA Implants	13,277	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	5899	192

W2DR01 Azure XT DR

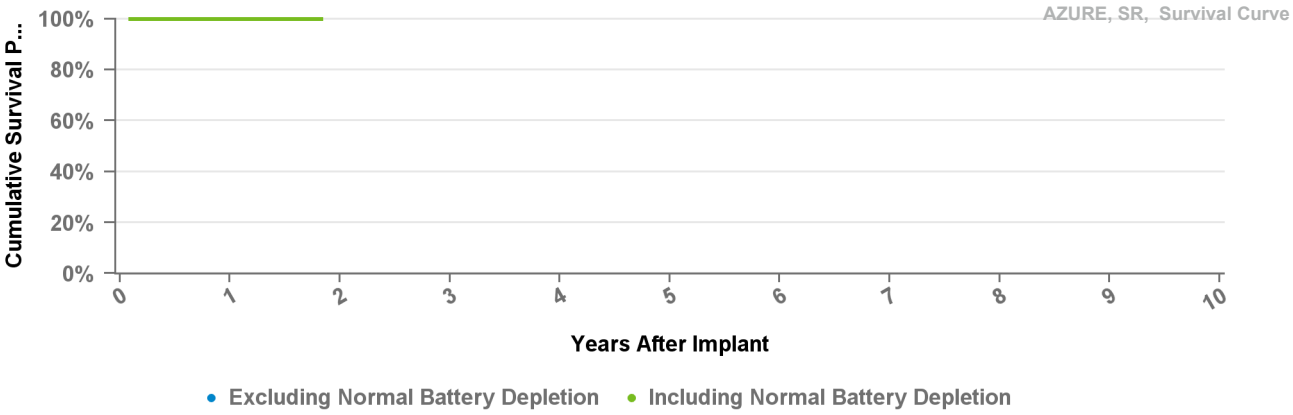
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	64352	449

W2SR01 Azure XT SR

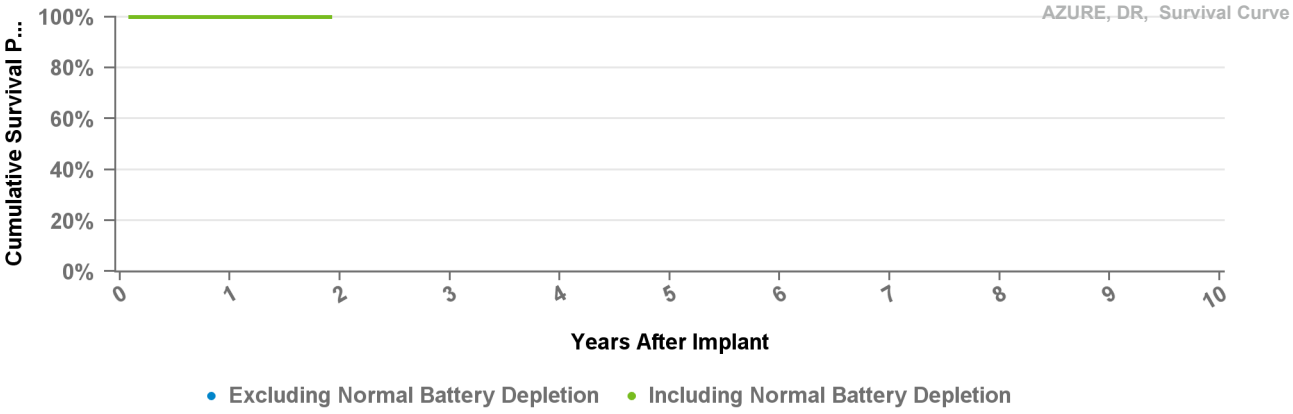
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	5899	192

W3DR01 Azure S DR

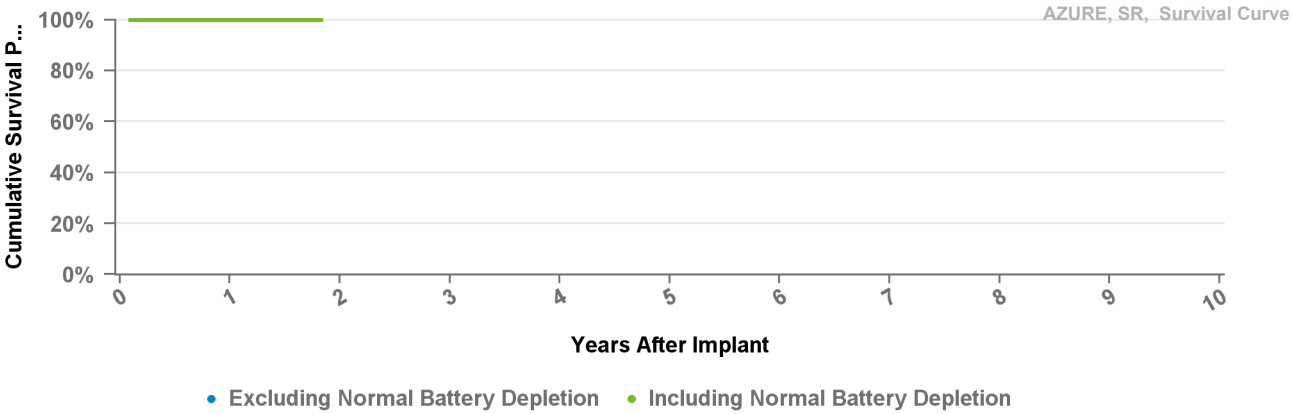
US Market Release	Aug-17	**Total Malfunctions**	**1**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**1**
Registered USA Implants	19,583	Electrical Component	1
Estimated Active USA Implants	19,061	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	64352	449

W3SR01 Azure S SR

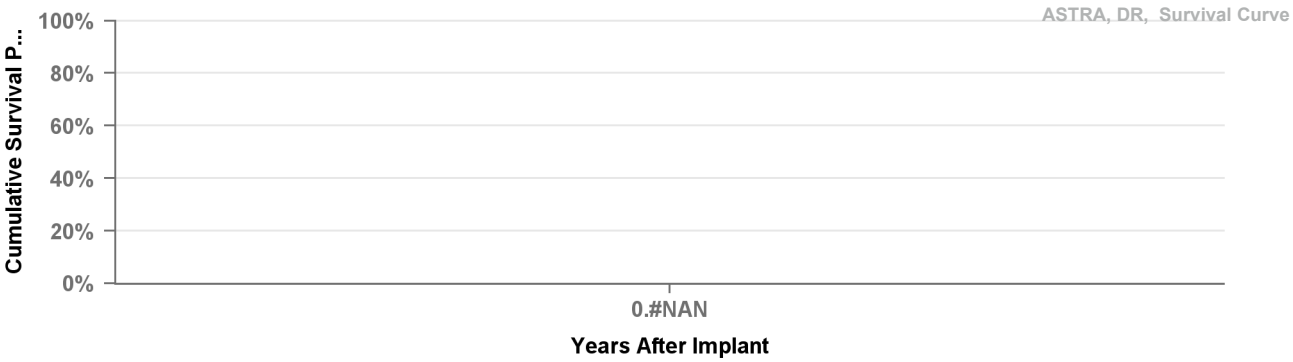
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	3,332		
Estimated Active USA Implants	3,178	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	5899	192

X2DR01 Astra XT DR MRI SureScan

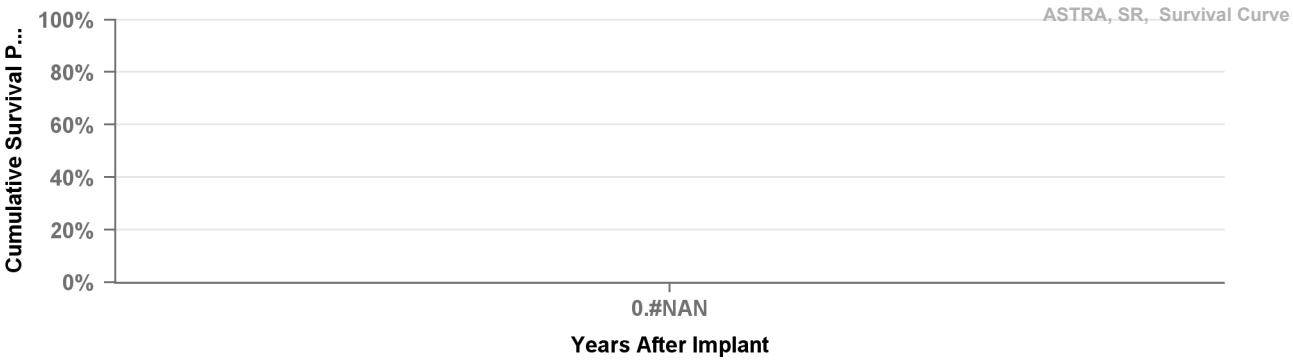
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

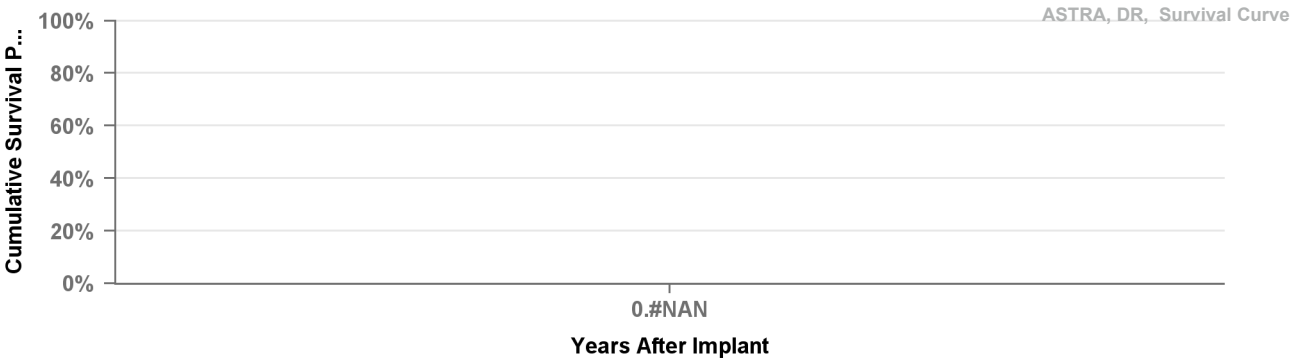
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3DR01 Astra S DR

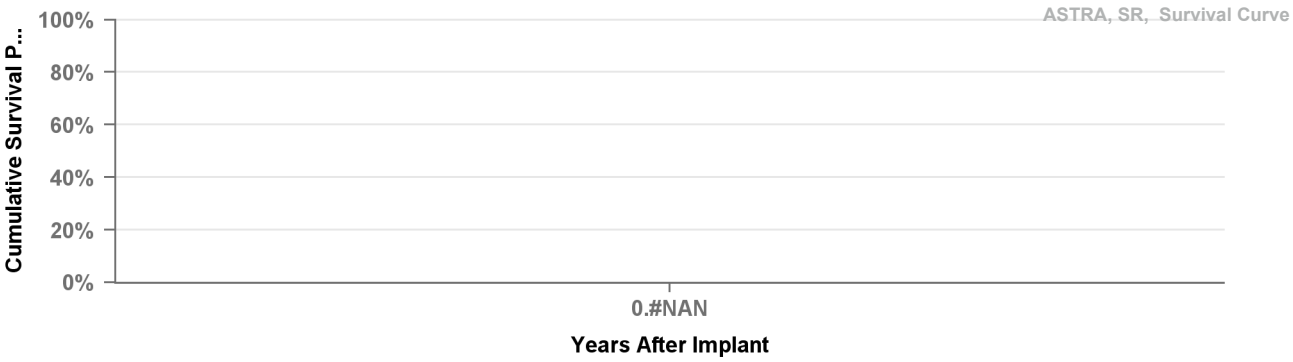
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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

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	58,098
Estimated Active USA Implants	46,768
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	24
Crimp Weld Bond	
Insulation Breach	41
Other	8

US Acute Lead Observations

Cardiac Perforation	15
Conductor Fracture	2
Extracardiac Stimulation	5
Failure To Capture	187
Failure To Sense	10
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	218
Oversensing	47
Unspecified	2

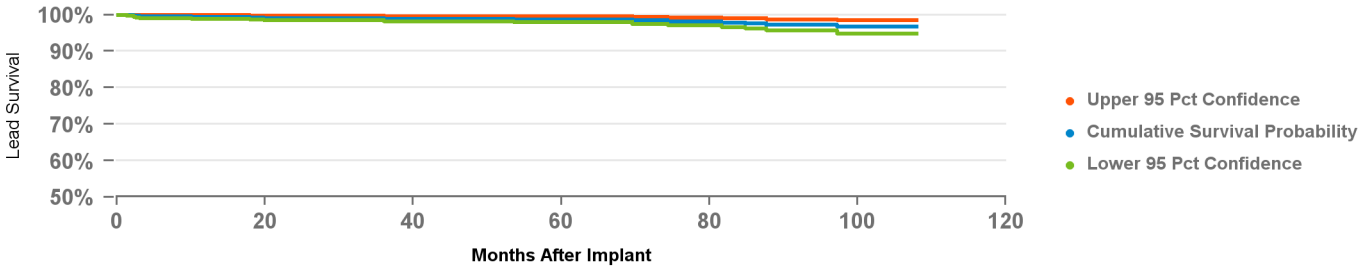
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,163
Cumulative Months of Followup	57,220
Number of Leads Active in Study	517

Qualifying Complications 18

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



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.3%	99.1%	99.1%	98.9%	98.7%	98.5%	97.9%	97.2%	96.7%
#	928	774	634	520	435	352	284	179	64

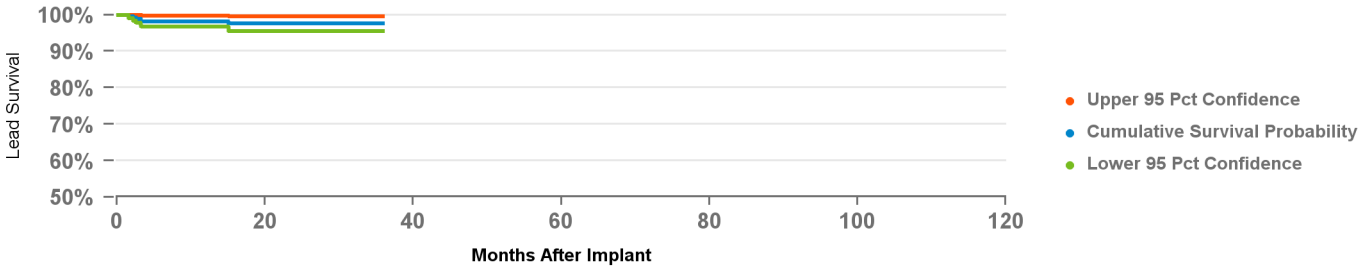
His Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	537
Cumulative Months of Followup	6,799
Number of Leads Active in Study	464

Qualifying Complications 8

Failure To Capture	6	Lead Dislodgement	1
		Oversensing	1



Years	1	2	at 36 mo
%	98.2%	97.6%	97.6%
#	178	108	68

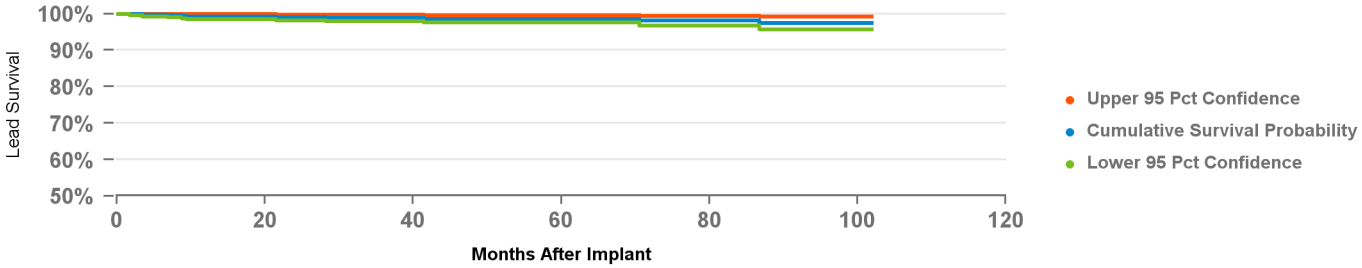
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	888
Cumulative Months of Followup	36,818
Number of Leads Active in Study	454

Qualifying Complications 10

Failure To Capture	4
Impedance Abnormal	1
Lead Dislodgement	4
Other Complication	1



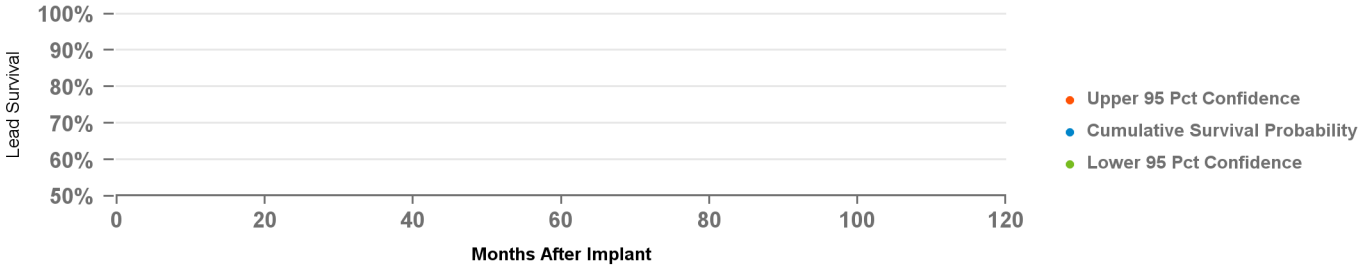
Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.2%	99.0%	98.8%	98.6%	98.6%	98.1%	98.1%	97.5%	97.5%
#	622	519	413	327	272	207	162	92	58

4073 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	771
Estimated Active USA Implants	263
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	132,863
Estimated Active USA Implants	80,244
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	41
Other	

US Acute Lead Observations

Cardiac Perforation	26
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	104
Failure To Sense	6
Impedance Abnormal	3
Insulation Breach	
Lead Dislodgement	140
Oversensing	7
Unspecified	

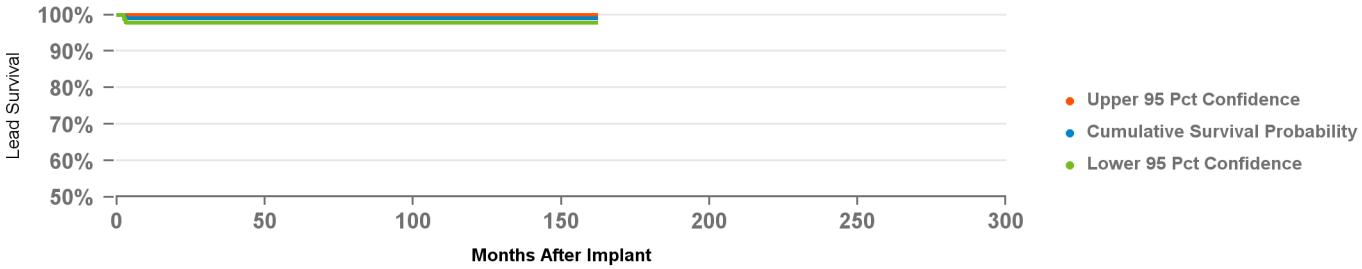
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Followup	24,976
Number of Leads Active in Study	98

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	126	114	106	93	61	54

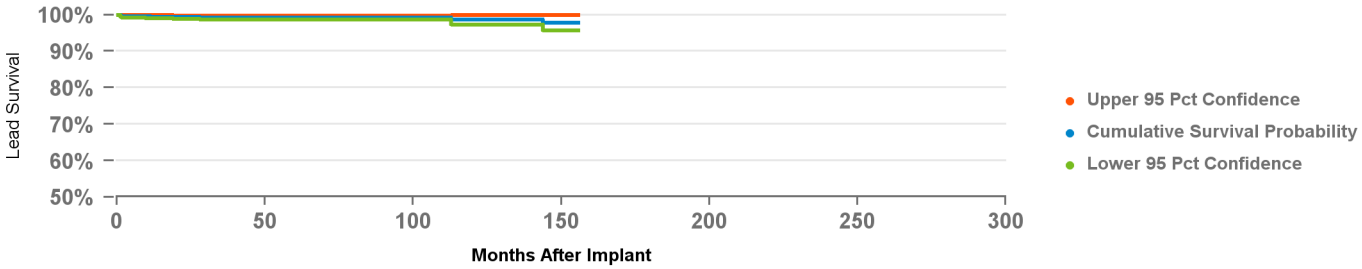
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,168
Cumulative Months of Followup	67,456
Number of Leads Active in Study	314

Qualifying Complications 10

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.4%	99.3%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.6%	98.6%	97.8%	97.8%
#	1,009	840	697	590	458	334	254	207	168	146	137	108	59

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	641,740
Estimated Active USA Implants	448,094
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	97
Crimp Weld Bond	1
Insulation Breach	140
Other	20

US Acute Lead Observations

Cardiac Perforation	142
Conductor Fracture	7
Extracardiac Stimulation	19
Failure To Capture	177
Failure To Sense	77
Impedance Abnormal	30
Insulation Breach	1
Lead Dislodgement	475
Oversensing	56
Unspecified	10

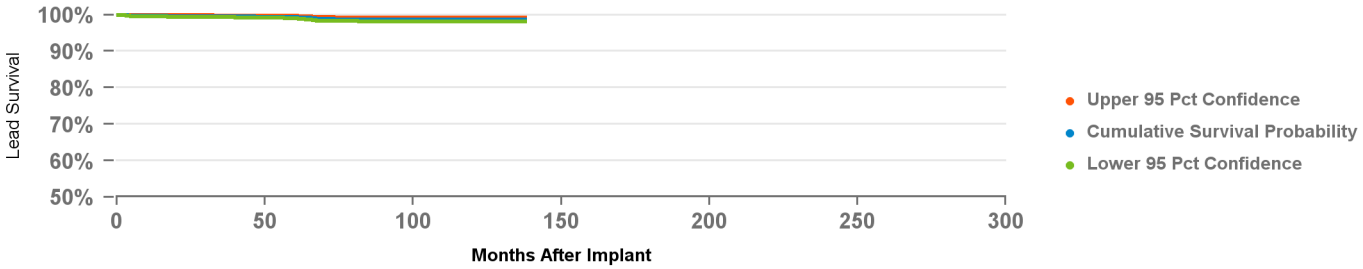
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,798
Cumulative Months of Followup	196,650
Number of Leads Active in Study	1,584

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 138 mo
%	99.8%	99.7%	99.6%	99.5%	99.3%	98.9%	98.7%	98.7%	98.7%	98.7%	98.7%	98.7%
#	3,056	2,661	2,297	1,943	1,532	1,109	770	553	365	177	115	83

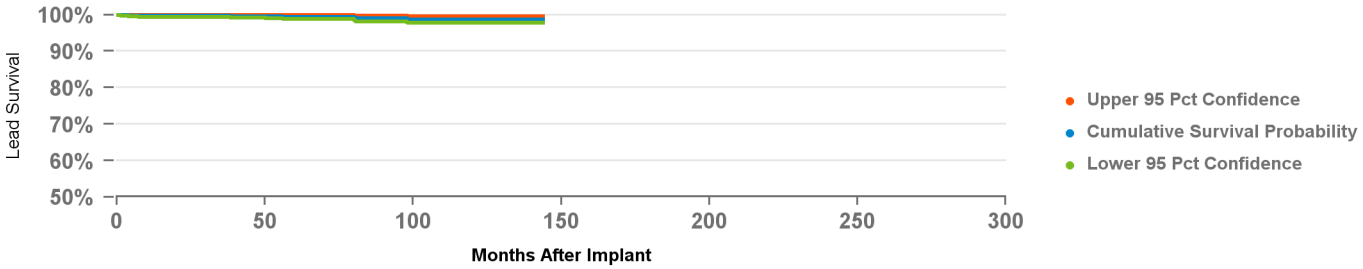
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,654
Cumulative Months of Followup	95,308
Number of Leads Active in Study	470

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	at 144 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%
#	1,346	1,181	1,050	894	716	561	443	352	266	149	113	59

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	185,510
Estimated Active USA Implants	63,403
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	18
Crimp Weld Bond	
Insulation Breach	87
Other	

US Acute Lead Observations

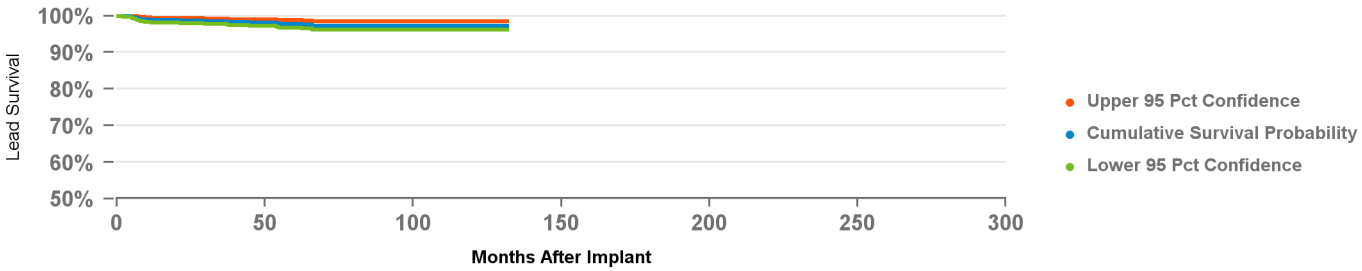
Cardiac Perforation	4
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Failure To Sense	
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,197
Cumulative Months of Followup	68,706
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%
#	950	847	754	645	523	398	325	264	215	131	68

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	92,847
Estimated Active USA Implants	60,592
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	15
Other	

US Acute Lead Observations

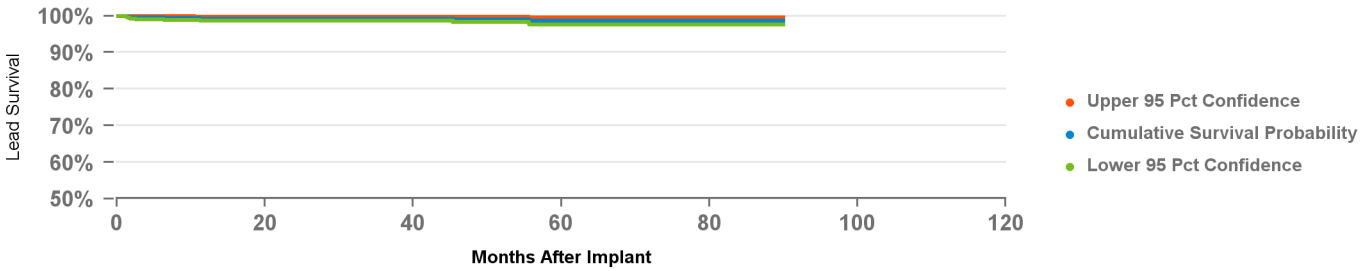
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	67
Failure To Sense	28
Impedance Abnormal	3
Insulation Breach	
Lead Dislodgement	165
Oversensing	5
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,212
Cumulative Months of Followup	46,028
Number of Leads Active in Study	630

Qualifying Complications 10

Conductor Fracture	2
Failure To Capture	1
Lead Dislodgement	7



Years	1	2	3	4	5	6	7	at 90 mo
%	99.2%	99.2%	99.2%	99.0%	98.7%	98.7%	98.7%	98.7%
#	931	706	564	414	286	193	102	61

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	88,217
Estimated Active USA Implants	31,822
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	9
Crimp Weld Bond	
Insulation Breach	30
Other	

US Acute Lead Observations

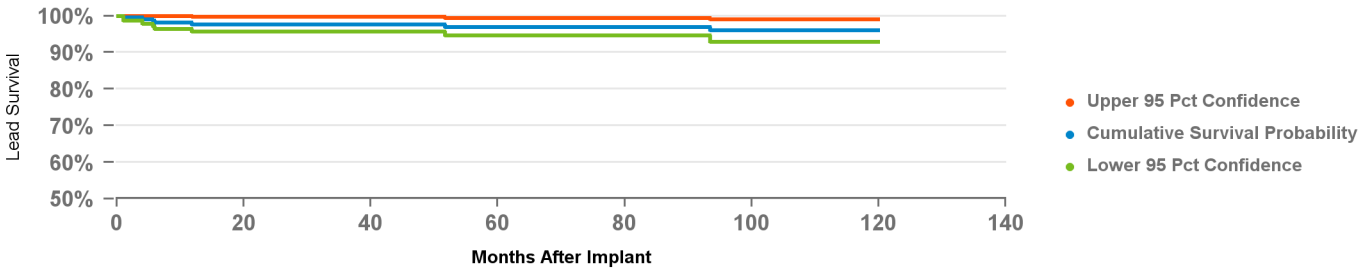
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	10
Failure To Sense	2
Impedance Abnormal	
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	356
Cumulative Months of Followup	20,061
Number of Leads Active in Study	47

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	220	195	180	148	121	95	81	66	50

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	98,628
Estimated Active USA Implants	31,918
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

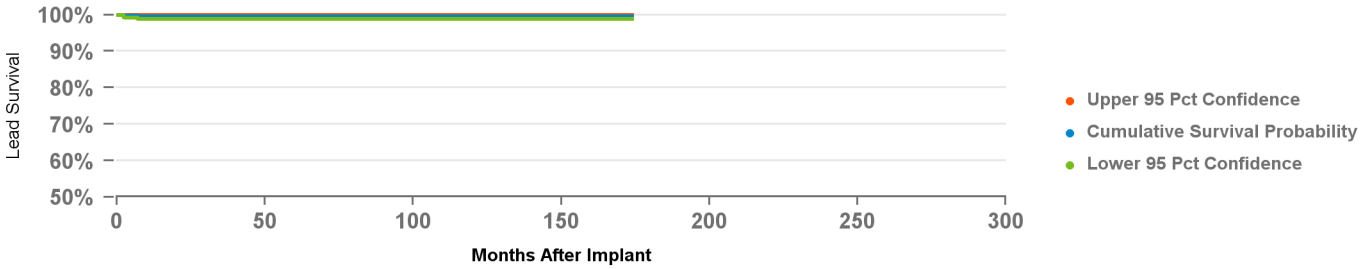
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Cumulative Months of Followup	40,141
Number of Leads Active in Study	49

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	252	219	185	152	128	107	92	74	62	55

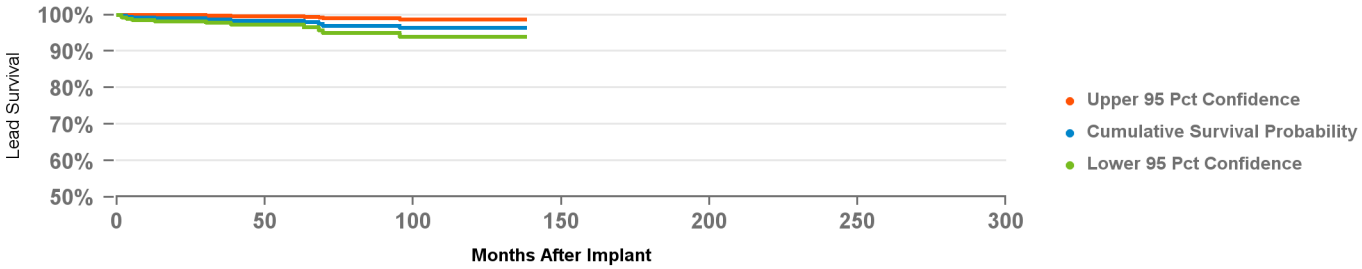
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	987
Cumulative Months of Followup	34,168
Number of Leads Active in Study	31

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	397	309	267	232	191	164	137	103	83	64	51

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	2,627,903
Estimated Active USA Implants	1,755,185
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,061
Crimp Weld Bond	
Insulation Breach	1,097
Other	176

US Acute Lead Observations

Cardiac Perforation	1,069
Conductor Fracture	22
Extracardiac Stimulation	80
Failure To Capture	1,288
Failure To Sense	495
Impedance Abnormal	135
Insulation Breach	11
Lead Dislodgement	3,252
Oversensing	400
Unspecified	26

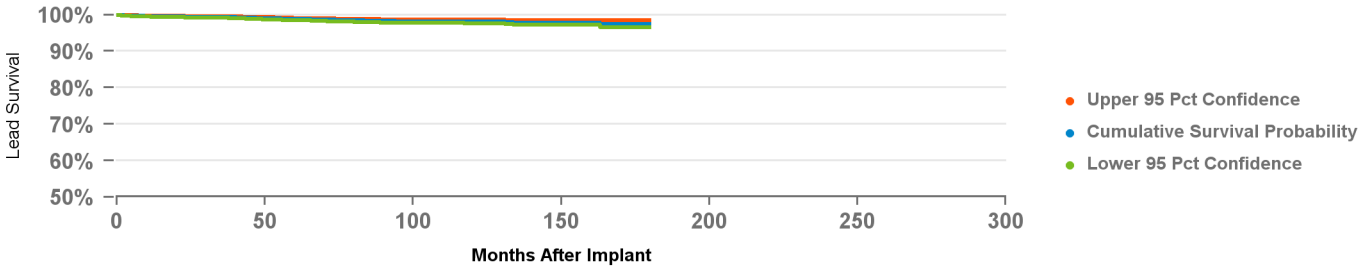
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	9,277
Cumulative Months of Followup	395,281
Number of Leads Active in Study	4,294

Qualifying Complications 74

Cardiac Perforation	2	Impedance Abnormal	6
Conductor Fracture	11	Insulation Breach	2
Extracardiac Stimulation	3	Lead Dislodgement	26
Failure To Capture	12	Oversensing	3
Failure To Sense	5	Other Complication	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 180 mo
%	99.6%	99.5%	99.4%	99.1%	98.8%	98.6%	98.4%	98.3%	98.3%	98.1%	98.0%	97.9%	97.9%	97.5%	97.5%
#	6,749	5,518	4,363	3,369	2,657	1,833	1,313	972	686	478	372	289	182	109	62

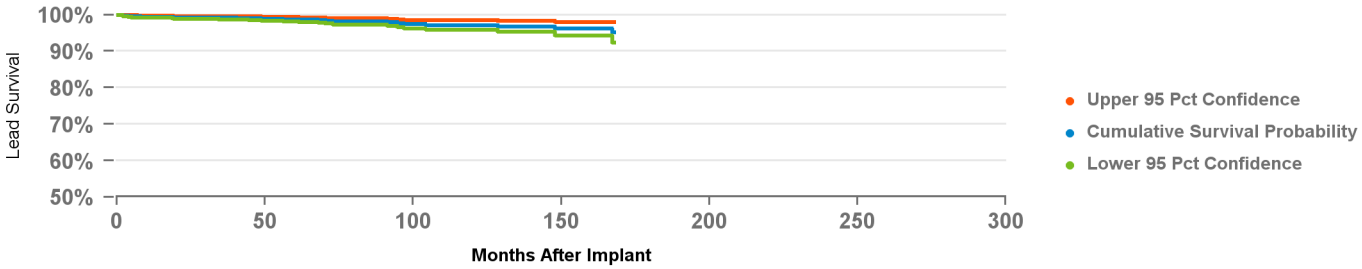
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,986
Cumulative Months of Followup	117,944
Number of Leads Active in Study	959

Qualifying Complications 30

Cardiac Perforation	1	Impedance Abnormal	4
Conductor Fracture	6	Lead Dislodgement	4
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%	99.3%	99.2%	99.0%	98.8%	98.3%	98.2%	97.7%	97.2%	97.2%	96.8%	96.8%	96.2%	95.1%
#	1,893	1,474	1,219	982	810	560	430	330	248	201	164	126	90	56

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	208,592
Estimated Active USA Implants	181,314
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	77
Crimp Weld Bond	
Insulation Breach	137
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	

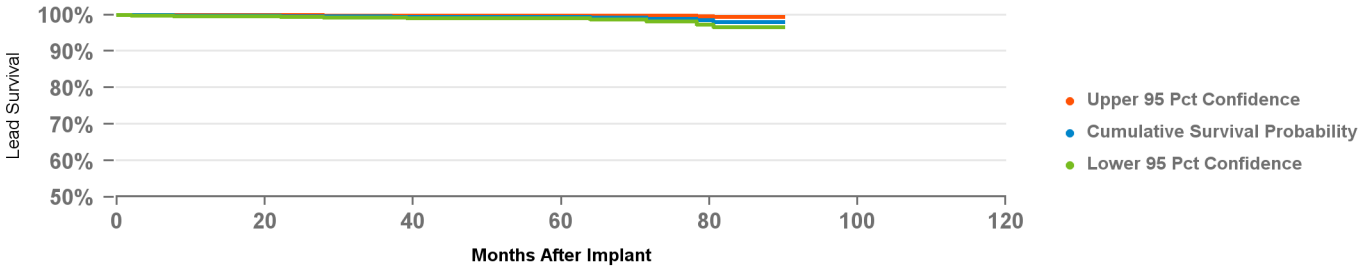
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,108
Cumulative Months of Followup	127,921
Number of Leads Active in Study	1,504

Qualifying Complications 19

Conductor Fracture	3
Failure To Capture	3
Lead Dislodgement	11
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%	98.0%	98.0%
#	2,670	2,244	1,867	1,415	656	216	116	58

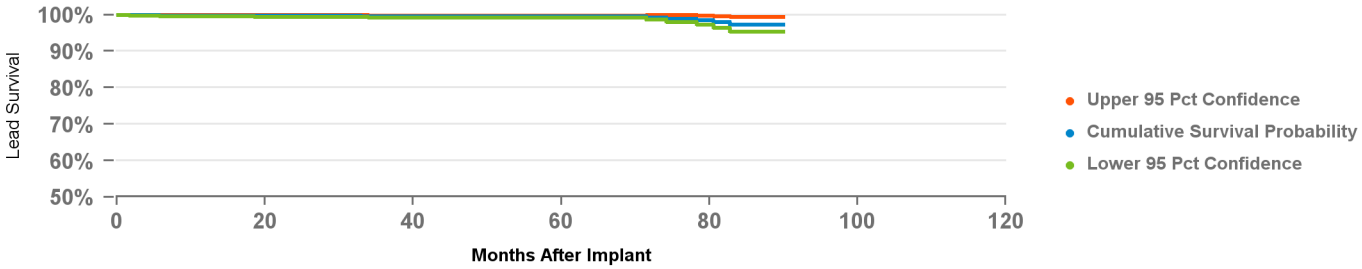
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,051
Cumulative Months of Followup	126,806
Number of Leads Active in Study	1,477

Qualifying Complications 17

Conductor Fracture	1
Failure To Capture	8
Failure To Sense	1
Impedance Abnormal	1
Lead Dislodgement	3
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%	99.3%	97.4%	97.4%
#	2,644	2,221	1,853	1,408	646	211	116	60

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	140,126
Estimated Active USA Implants	50,270
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	23
Crimp Weld Bond	
Insulation Breach	64
Other	1

US Acute Lead Observations

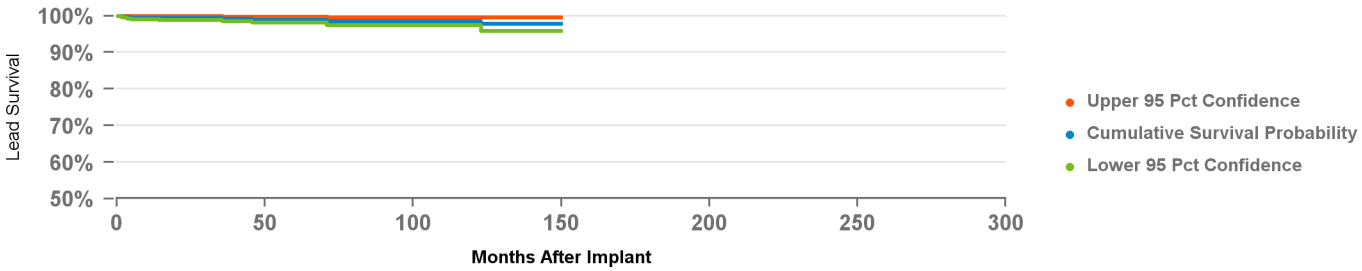
Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	49
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,213
Cumulative Months of Followup	53,286
Number of Leads Active in Study	34

Qualifying Complications 10

Extracardiac Stimulation	1
Failure To Capture	3
Impedance Abnormal	1
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%
#	828	662	525	428	338	260	210	163	136	118	95	70	61

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,309
Estimated Active USA Implants	23,000
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

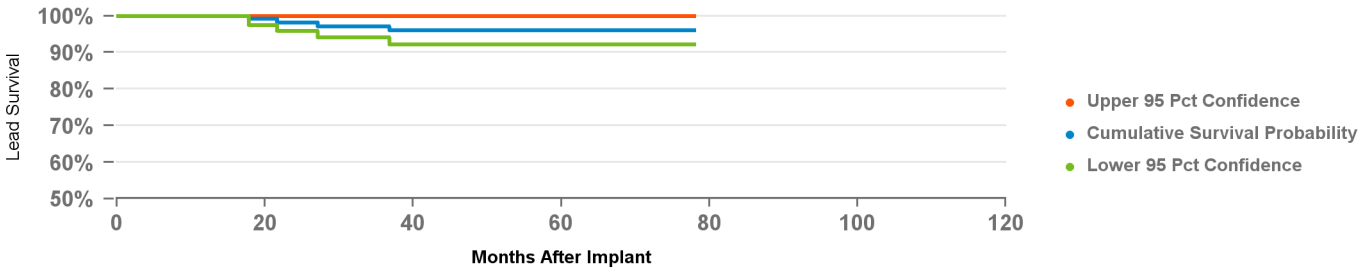
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	
Lead Dislodgement	38
Oversensing	
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	364
Cumulative Months of Followup	9,022
Number of Leads Active in Study	12

Qualifying Complications 5

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



Years	1	2	3	4	5	6	at 78 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%	96.0%
#	156	119	94	82	66	54	51

5592 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	36,927
Estimated Active USA Implants	16,217
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

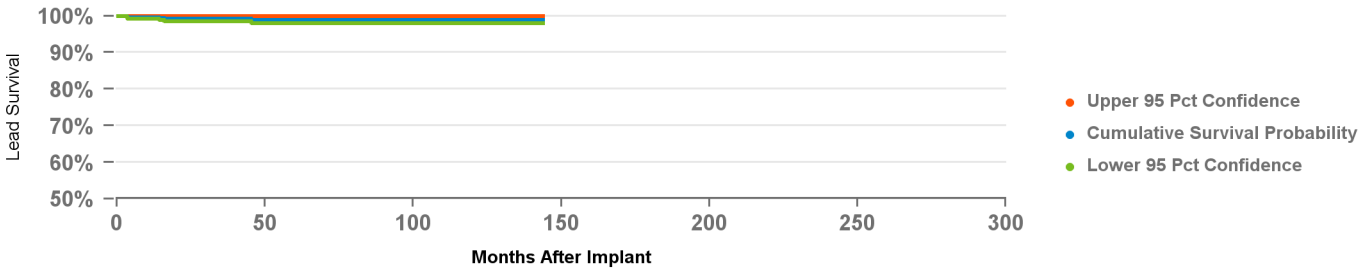
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	3
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	43
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	717
Cumulative Months of Followup	37,528
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%
#	536	445	360	306	250	185	152	134	114	99	84	57

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,588
Estimated Active USA Implants	9,097
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp Weld Bond	
Insulation Breach	16
Other	

US Acute Lead Observations

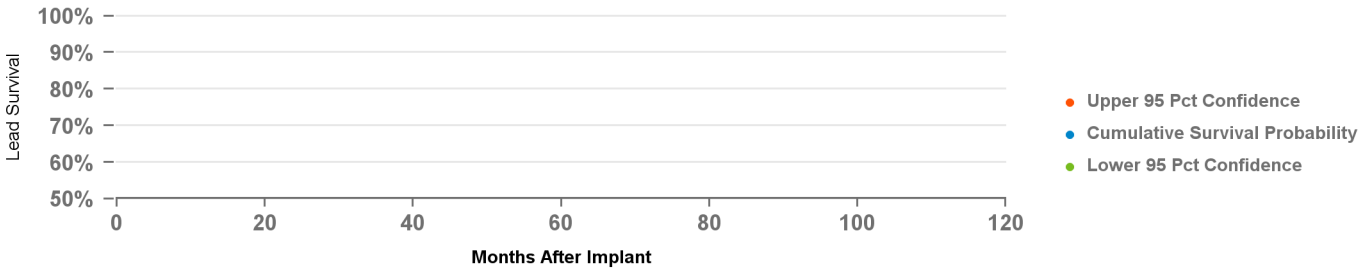
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	14
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	36
Cumulative Months of Followup	3,249
Number of Leads Active in Study	11

Qualifying Complications 2

Conductor Fracture	1	Oversensing	1



Years	at 0 mo
%	100.0%
#	

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,189
Estimated Active USA Implants	1,102
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

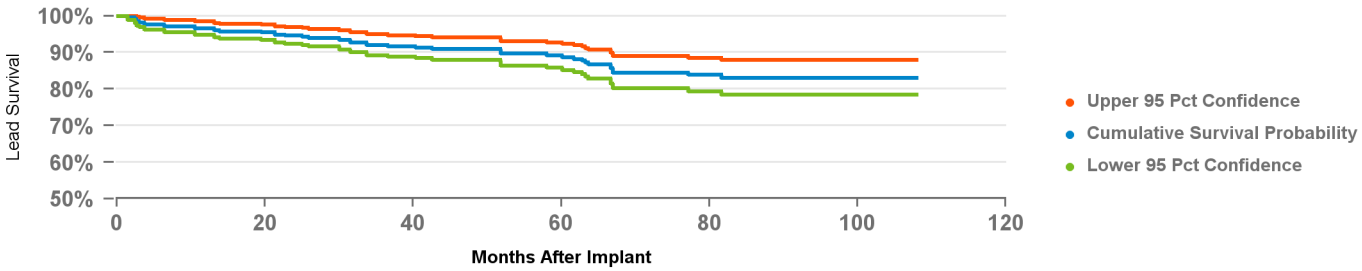
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	17
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	417
Cumulative Months of Followup	23,884
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	132	99	64	56

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	350
Estimated Active USA Implants	111
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

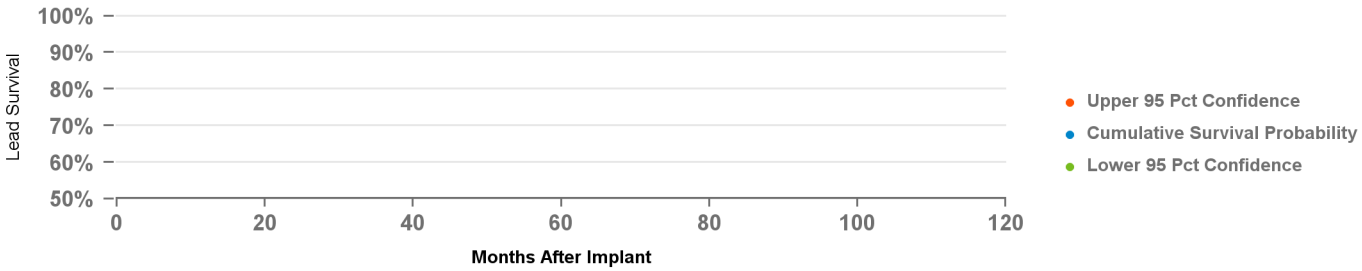
Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

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	287
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	1,969
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	647
Crimp Weld Bond	
Insulation Breach	1
Other	5

US Acute Lead Observations

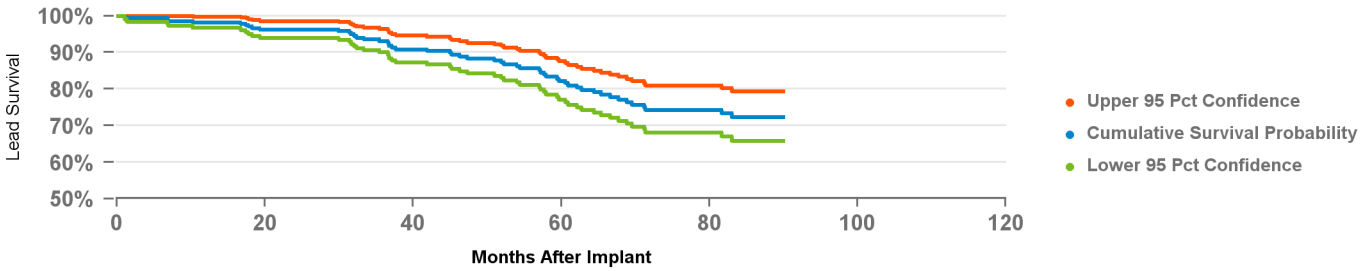
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	1
Oversensing	3
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	310
Cumulative Months of Followup	17,601
Number of Leads Active in Study	18

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	169	139	103	67	51

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	60,635
Estimated Active USA Implants	47,415
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	339
Crimp Weld Bond	
Insulation Breach	11
Other	41

US Acute Lead Observations

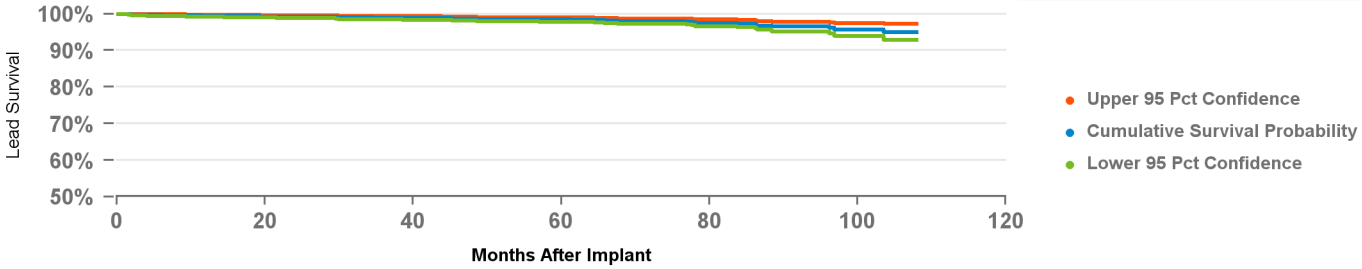
Cardiac Perforation	24
Conductor Fracture	2
Extracardiac Stimulation	1
Failure To Capture	27
Failure To Sense	9
Impedance Abnormal	24
Insulation Breach	1
Lead Dislodgement	57
Oversensing	61
Unspecified	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,712
Cumulative Months of Followup	124,683
Number of Leads Active in Study	918

Qualifying Complications 46

Cardiac Perforation	1
Conductor Fracture	17
Extracardiac Stimulation	1
Failure To Capture	5
Failure To Sense	1
Impedance Abnormal	5
Lead Dislodgement	7
Oversensing	7
Unspecified	1
Other Complication	1



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.4%	99.2%	99.0%	98.6%	98.5%	98.0%	97.3%	96.6%	95.0%
#	2,309	1,856	1,479	1,153	930	687	416	205	71

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	221,049
Estimated Active USA Implants	207,090
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	318
Crimp Weld Bond	
Insulation Breach	13
Other	48

US Acute Lead Observations

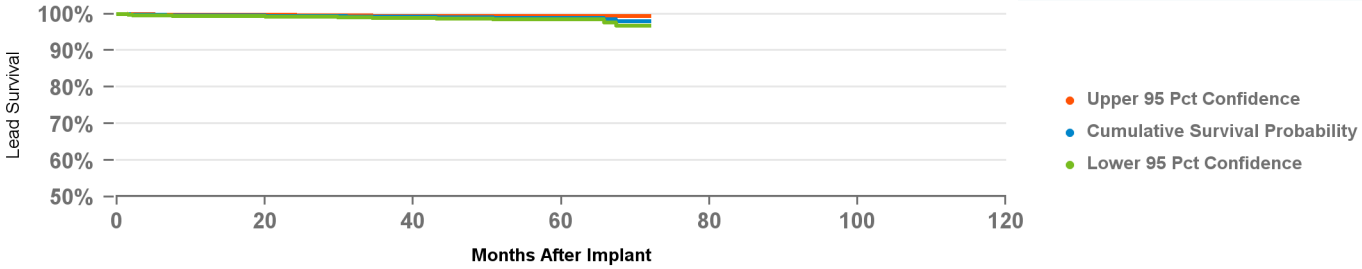
Cardiac Perforation	104
Conductor Fracture	7
Extracardiac Stimulation	19
Failure To Capture	200
Failure To Sense	57
Impedance Abnormal	55
Insulation Breach	1
Lead Dislodgement	337
Oversensing	167
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	6,331
Cumulative Months of Followup	179,033
Number of Leads Active in Study	4,140

Qualifying Complications 45

Cardiac Perforation	1	Impedance Abnormal	3
Conductor Fracture	11	Insulation Breach	2
Extracardiac Stimulation	1	Lead Dislodgement	13
Failure To Capture	10	Oversensing	2
Failure To Sense	1	Other Complication	1



Years	1	2	3	4	5	at 72 mo
%	99.6%	99.5%	99.2%	99.0%	98.9%	98.0%
#	4,709	3,565	2,193	1,110	432	69

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	2,606
Estimated Active USA Implants	1,554
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

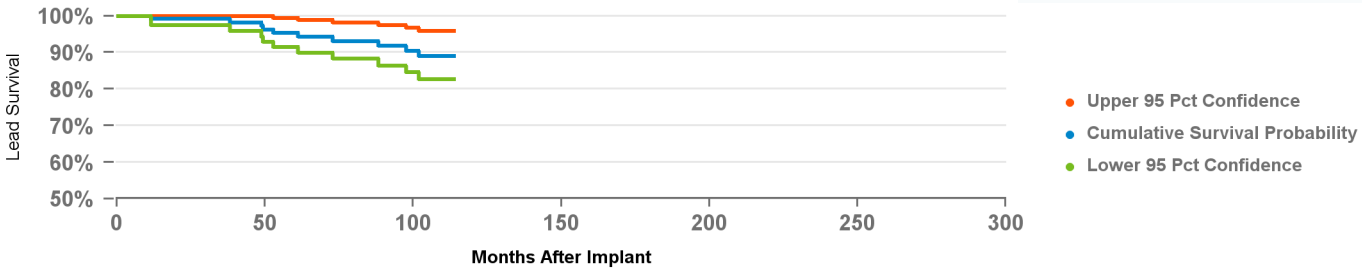
Cardiac Perforation	
Conductor Fracture	3
Extracardiac Stimulation	
Failure To Capture	
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	122
Cumulative Months of Followup	13,652
Number of Leads Active in Study	11

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	113	110	104	92	82	76	69	55	50

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,719
Estimated Active USA Implants	18,781
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	203
Crimp Weld Bond	1
Insulation Breach	4
Other	4

US Acute Lead Observations

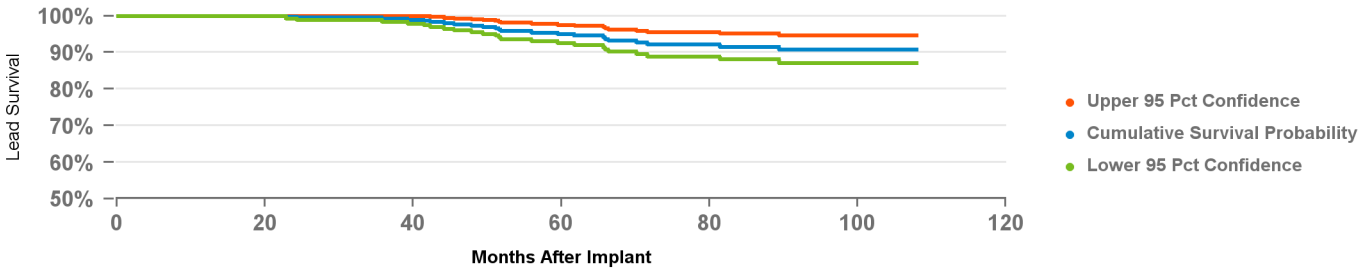
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	17
Failure To Sense	3
Impedance Abnormal	10
Insulation Breach	
Lead Dislodgement	24
Oversensing	18
Unspecified	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	618
Cumulative Months of Followup	33,100
Number of Leads Active in Study	131

Qualifying Complications 28

Conductor Fracture	15	Impedance Abnormal	4
Failure To Capture	4	Oversensing	3
Failure To Sense	1	Unspecified	1



Years	1	2	3	4	5	6	7	8	at 108 mo
%	100.0%	99.8%	99.2%	97.3%	95.0%	92.1%	91.5%	90.8%	90.8%
#	529	441	371	299	231	177	134	91	65

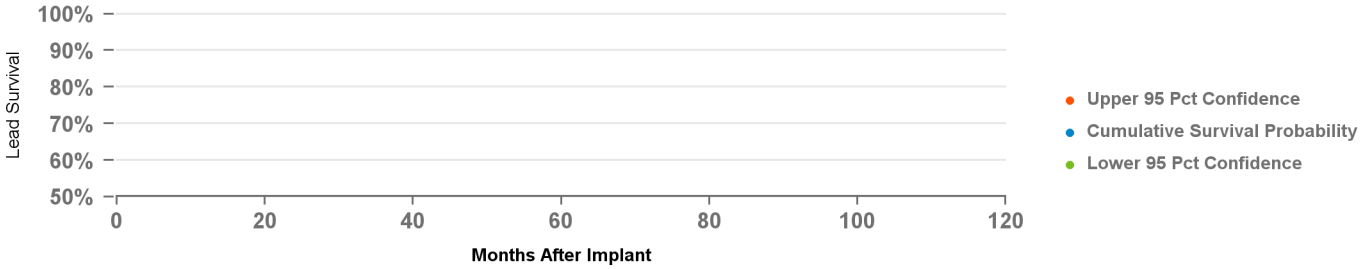
6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	1,994
Estimated Active USA Implants	1,926
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	
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	5
Oversensing	4
Unspecified	



Years	at	mo
%		
#		

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	374,694
Estimated Active USA Implants	195,023
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,147
Crimp Weld Bond	4
Insulation Breach	94
Other	188

US Acute Lead Observations

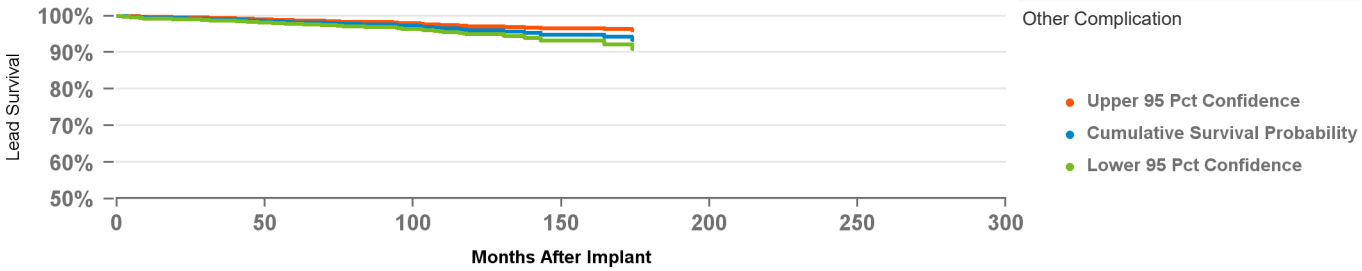
Cardiac Perforation	29
Conductor Fracture	24
Extracardiac Stimulation	2
Failure To Capture	81
Failure To Sense	34
Impedance Abnormal	59
Insulation Breach	4
Lead Dislodgement	122
Oversensing	140
Unspecified	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,436
Cumulative Months of Followup	250,575
Number of Leads Active in Study	1,105

Qualifying Complications 81

Conductor Fracture	28
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	12
Insulation Breach	5
Lead Dislodgement	5
Oversensing	18
Unspecified	3
Other Complication	2



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%	98.0%	97.6%	97.3%	96.8%	96.0%	95.7%	94.9%	94.9%	94.3%	93.5%
#	3,807	3,251	2,765	2,329	1,929	1,485	1,125	811	530	258	165	108	90	68	52

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	115,553
Estimated Active USA Implants	103,417
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	145
Crimp Weld Bond	
Insulation Breach	13
Other	23

US Acute Lead Observations

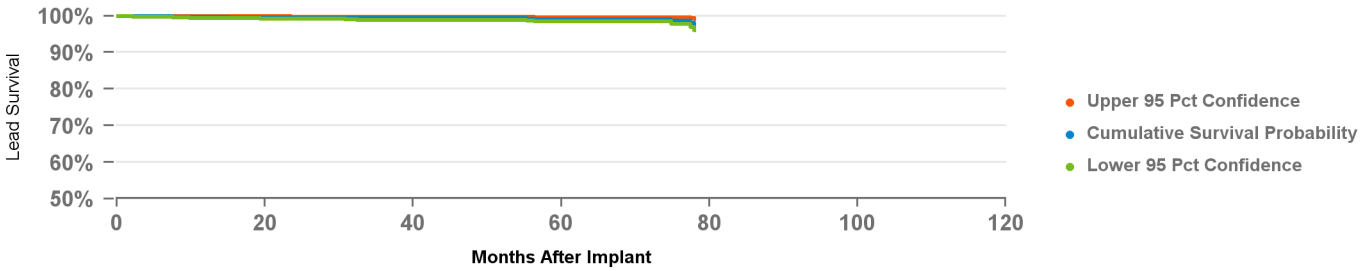
Cardiac Perforation	30
Conductor Fracture	9
Extracardiac Stimulation	10
Failure To Capture	94
Failure To Sense	34
Impedance Abnormal	26
Insulation Breach	
Lead Dislodgement	193
Oversensing	69
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,113
Cumulative Months of Followup	91,022
Number of Leads Active in Study	954

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 78 mo
%	99.7%	99.5%	99.3%	99.3%	99.0%	99.0%	97.7%
#	1,715	1,434	1,229	980	782	416	182

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,330
Estimated Active USA Implants	2,838
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	206
Crimp Weld Bond	
Insulation Breach	3
Other	4

US Acute Lead Observations

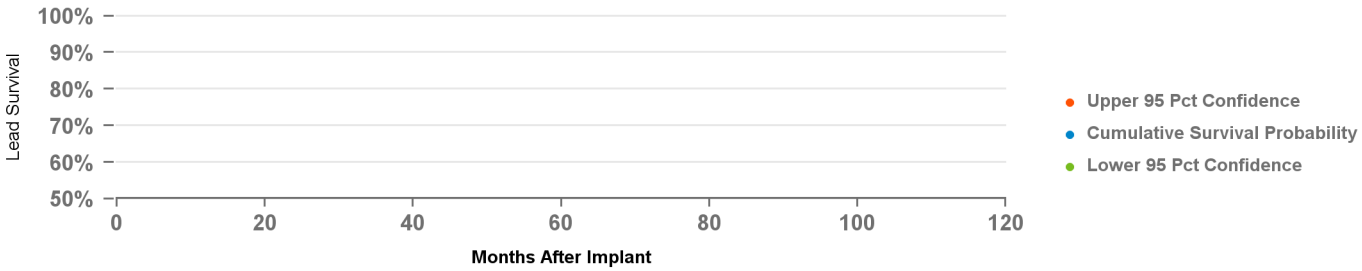
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	7
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	7
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Cumulative Months of Followup	2,255
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	185,837
Estimated Active USA Implants	42,737
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7,809
Crimp Weld Bond	3
Insulation Breach	37
Other	97

US Acute Lead Observations

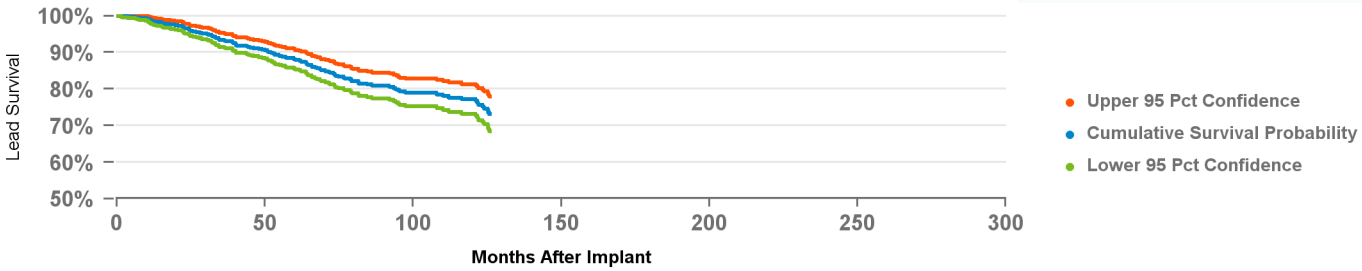
Cardiac Perforation	10
Conductor Fracture	46
Extracardiac Stimulation	
Failure To Capture	32
Failure To Sense	19
Impedance Abnormal	19
Insulation Breach	5
Lead Dislodgement	22
Oversensing	35
Unspecified	25

Product Surveillance Registry Results

Number of Leads Enrolled in Study	978
Cumulative Months of Followup	54,827
Number of Leads Active in Study	90

Qualifying Complications 126

Conductor Fracture	72
Failure To Capture	5
Failure To Sense	6
Impedance Abnormal	19
Insulation Breach	2
Lead Dislodgement	1
Oversensing	20
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%	78.5%	77.2%	73.1%
#	847	726	621	522	430	326	217	153	96	66	55

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	5,143
Estimated Active USA Implants	2,817
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	31
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

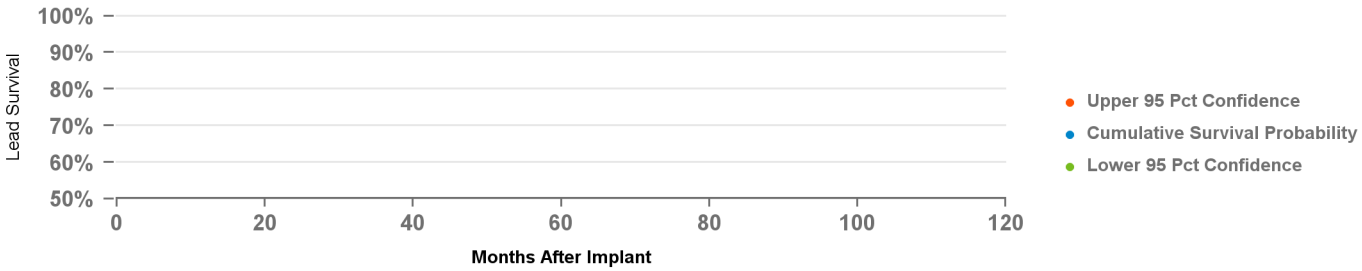
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	1
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	53
Cumulative Months of Followup	2,262
Number of Leads Active in Study	7

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	11,889
Estimated Active USA Implants	1,677
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	
Insulation Breach	1
Other	2

US Acute Lead Observations

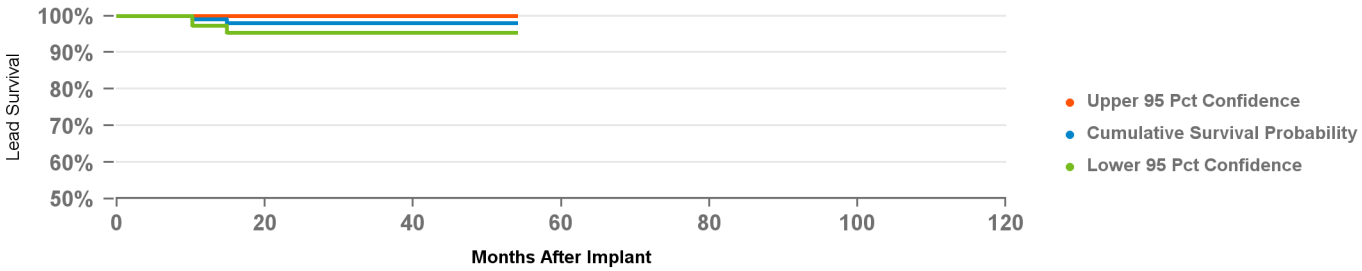
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	9
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	140
Cumulative Months of Followup	6,893
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	100,363
Estimated Active USA Implants	22,002
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	83
Crimp Weld Bond	
Insulation Breach	29
Other	12

US Acute Lead Observations

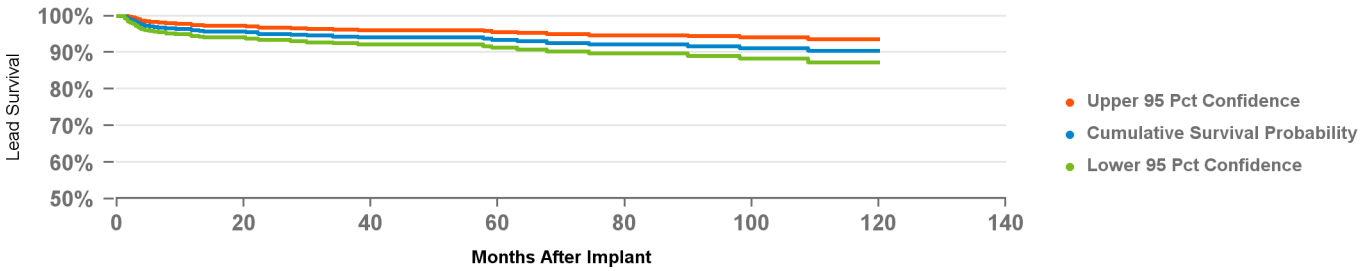
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	18
Failure To Capture	11
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	45
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	802
Cumulative Months of Followup	40,068
Number of Leads Active in Study	65

Qualifying Complications 47

Conductor Fracture	1	Impedance Abnormal	2
Extracardiac Stimulation	9	Lead Dislodgement	14
Failure To Capture	18	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%
#	639	496	419	332	264	216	173	145	95	63

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	114,795
Estimated Active USA Implants	50,180
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	37
Crimp Weld Bond	
Insulation Breach	140
Other	2

US Acute Lead Observations

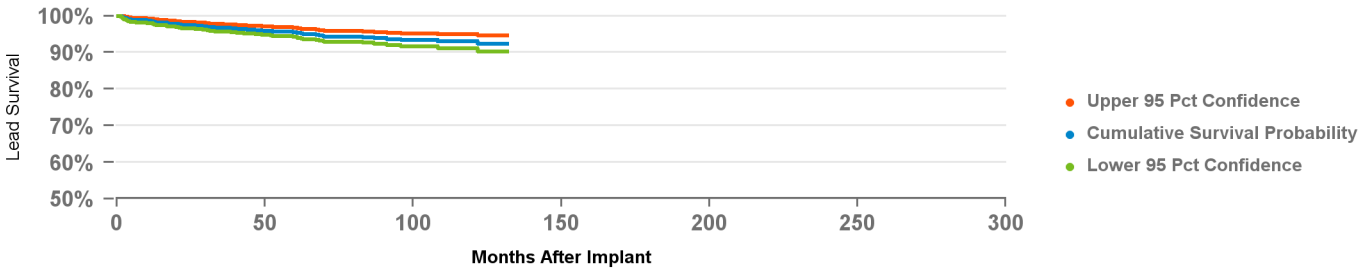
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	49
Failure To Capture	42
Failure To Sense	
Impedance Abnormal	9
Insulation Breach	
Lead Dislodgement	151
Oversensing	2
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,640
Cumulative Months of Followup	86,600
Number of Leads Active in Study	333

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%	93.4%	93.4%	93.0%	92.4%
#	1,377	1,155	969	803	667	496	340	245	153	99	61

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,404
Estimated Active USA Implants	10,662
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	9
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

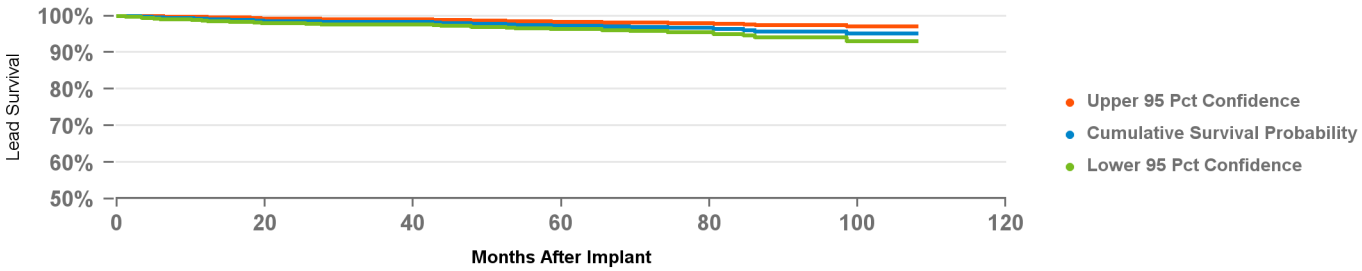
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	29
Failure To Capture	21
Failure To Sense	
Impedance Abnormal	4
Insulation Breach	
Lead Dislodgement	29
Oversensing	
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,486
Cumulative Months of Followup	75,048
Number of Leads Active in Study	352

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	at 108 mo
%	99.2%	98.6%	98.3%	97.8%	97.3%	96.9%	96.4%	95.7%	95.1%
#	1,270	1,087	922	734	578	415	278	153	62

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	68,976
Estimated Active USA Implants	46,347
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

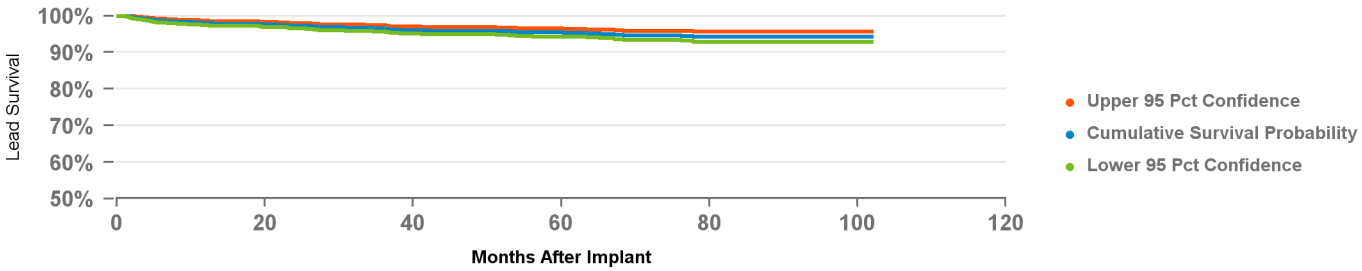
Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	94
Failure To Capture	62
Failure To Sense	1
Impedance Abnormal	10
Insulation Breach	1
Lead Dislodgement	211
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,290
Cumulative Months of Followup	100,460
Number of Leads Active in Study	445

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 102 mo
%	98.0%	97.3%	96.5%	95.9%	95.4%	94.7%	94.3%	94.3%	94.3%
#	1,897	1,490	1,158	911	706	511	353	192	108

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	34,672
Estimated Active USA Implants	27,553
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

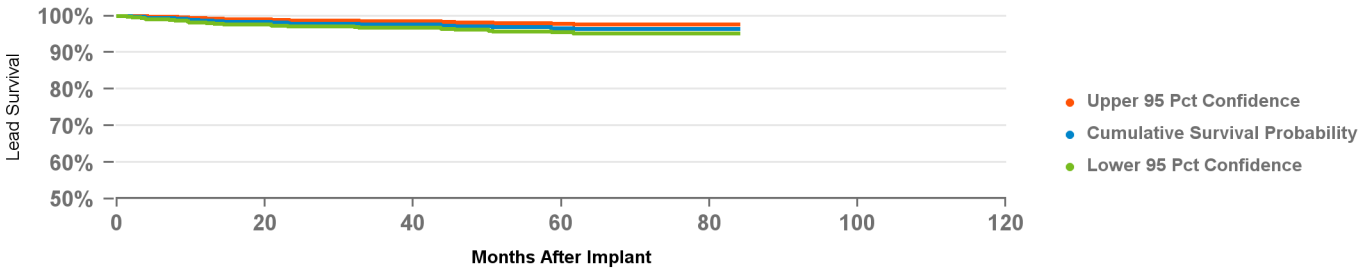
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	61
Failure To Capture	30
Failure To Sense	
Impedance Abnormal	10
Insulation Breach	4
Lead Dislodgement	115
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,456
Cumulative Months of Followup	57,484
Number of Leads Active in Study	480

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%	96.4%	96.4%
#	1,150	914	744	611	429	203	56

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	75,801
Estimated Active USA Implants	70,622
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp Weld Bond	
Insulation Breach	
Other	15

US Acute Lead Observations

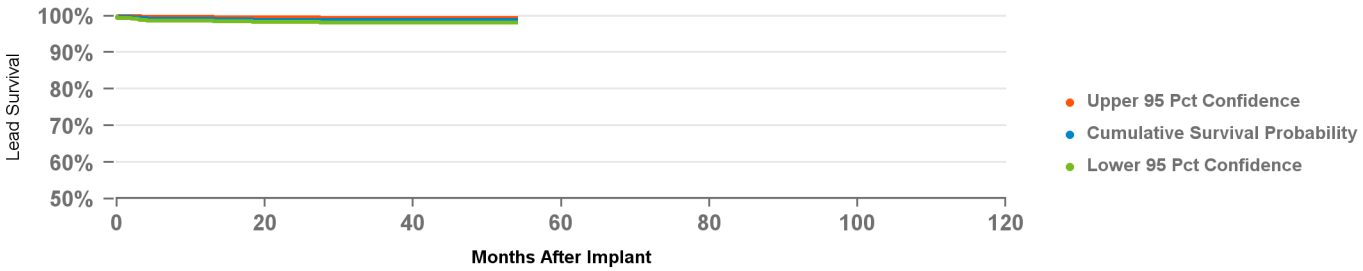
Cardiac Perforation	5
Conductor Fracture	1
Extracardiac Stimulation	170
Failure To Capture	93
Failure To Sense	1
Impedance Abnormal	23
Insulation Breach	
Lead Dislodgement	148
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,031
Cumulative Months of Followup	44,080
Number of Leads Active in Study	1,473

Qualifying Complications 16

Extracardiac Stimulation	4
Lead Dislodgement	11
Other Complication	1



Years	1	2	3	4	at 54 mo
%	99.3%	98.9%	98.8%	98.8%	98.8%
#	1,266	875	513	158	54

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	7,989
Estimated Active USA Implants	6,251
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

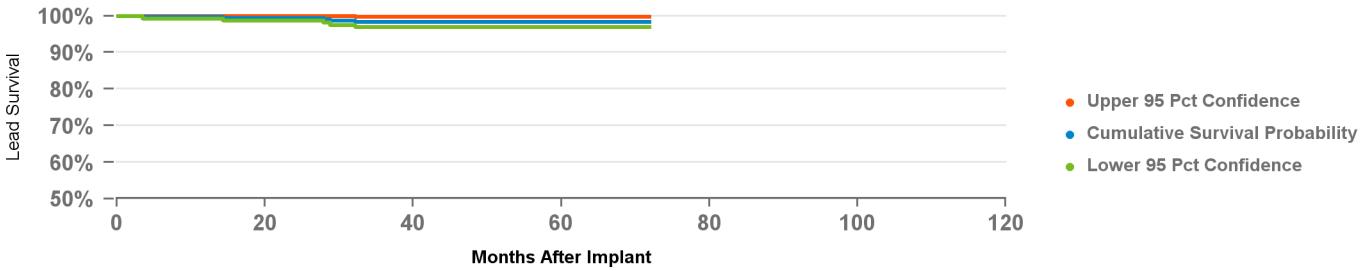
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	19
Failure To Capture	10
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	34
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	465
Cumulative Months of Followup	18,414
Number of Leads Active in Study	186

Qualifying Complications 7

Extracardiac Stimulation	1	Insulation Breach	1
Failure To Capture	3	Lead Dislodgement	2



Years	1	2	3	4	5	at 72 mo
%	99.8%	99.5%	98.4%	98.4%	98.4%	98.4%
#	366	288	246	194	130	65

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	22,779
Estimated Active USA Implants	21,522
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

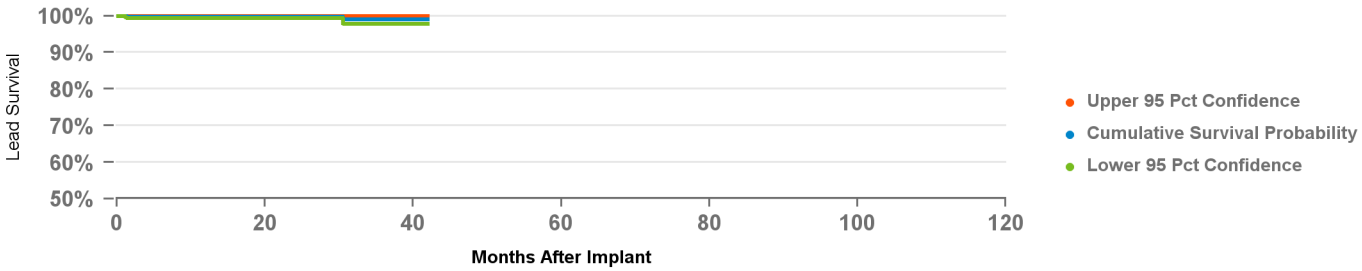
Cardiac Perforation	4
Conductor Fracture	
Extracardiac Stimulation	63
Failure To Capture	35
Failure To Sense	
Impedance Abnormal	5
Insulation Breach	
Lead Dislodgement	23
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,105
Cumulative Months of Followup	15,459
Number of Leads Active in Study	890

Qualifying Complications 4

Failure To Capture	2	Lead Dislodgement	2



Years	1	2	3	at 42 mo
%	99.8%	99.8%	99.1%	99.1%
#	504	234	102	60

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	41,957
Estimated Active USA Implants	39,704
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	4

US Acute Lead Observations

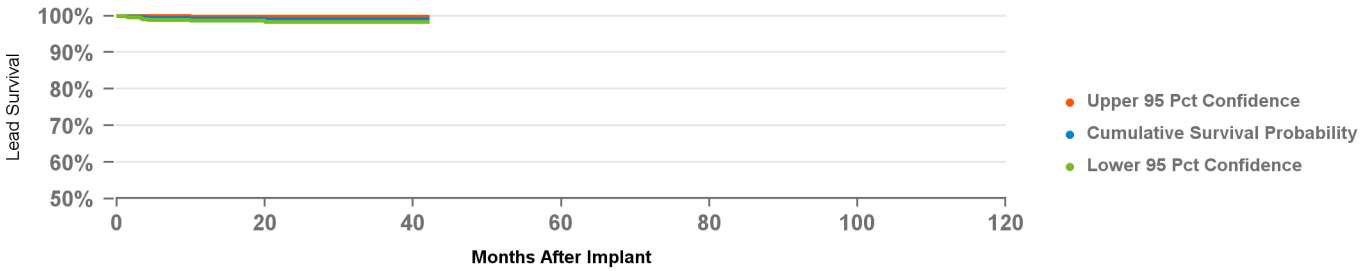
Cardiac Perforation	8
Conductor Fracture	1
Extracardiac Stimulation	69
Failure To Capture	37
Failure To Sense	
Impedance Abnormal	13
Insulation Breach	
Lead Dislodgement	42
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,174
Cumulative Months of Followup	21,840
Number of Leads Active in Study	902

Qualifying Complications 8

Extracardiac Stimulation	2	Lead Dislodgement	5
Failure To Sense	1		



Years	1	2	3	at 42 mo
%	99.2%	99.0%	99.0%	99.0%
#	684	404	184	99

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	23,252
Estimated Active USA Implants	8,363
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	276
Crimp Weld Bond	1
Insulation Breach	62
Other	

US Acute Lead Observations

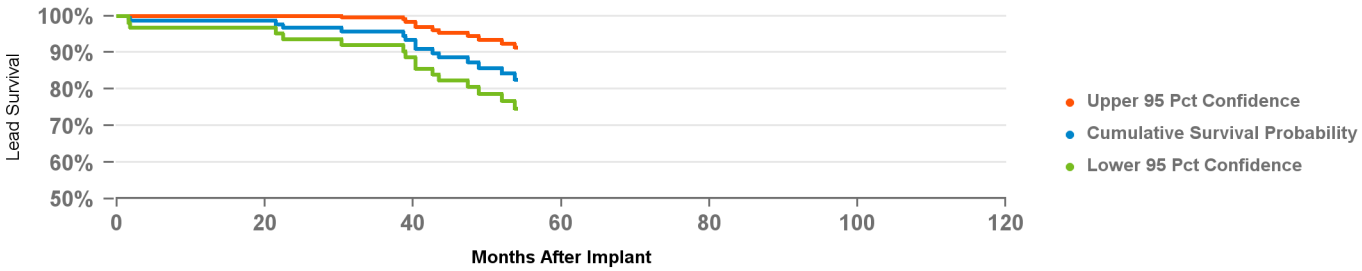
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	10
Failure To Sense	5
Impedance Abnormal	16
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	233
Cumulative Months of Followup	7,305
Number of Leads Active in Study	6

Qualifying Complications 16

Conductor Fracture	9
Failure To Capture	3
Failure To Sense	1
Insulation Breach	1
Oversensing	2



Years	1	2	3	4	at 54 mo
%	98.6%	96.8%	95.7%	87.2%	82.5%
#	132	113	93	68	50

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	48,928
Estimated Active USA Implants	30,033
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	102
Crimp Weld Bond	
Insulation Breach	52
Other	1

US Acute Lead Observations

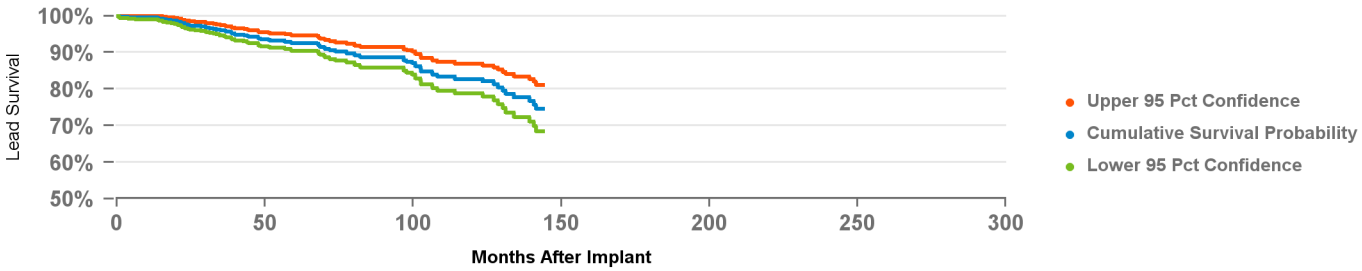
Cardiac Perforation	1
Conductor Fracture	3
Extracardiac Stimulation	4
Failure To Capture	52
Failure To Sense	5
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	6
Oversensing	21
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,019
Cumulative Months of Followup	58,381
Number of Leads Active in Study	244

Qualifying Complications 93

Conductor Fracture	26	Impedance Abnormal	5
Extracardiac Stimulation	2	Insulation Breach	3
Failure To Capture	29	Oversensing	24
Failure To Sense	3	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.5%	97.5%	96.0%	93.7%	92.5%	90.5%	88.6%	88.6%	83.9%	82.8%	78.6%	74.6%
#	807	704	615	511	429	346	283	221	149	107	74	53

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	54,075
Estimated Active USA Implants	16,726
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

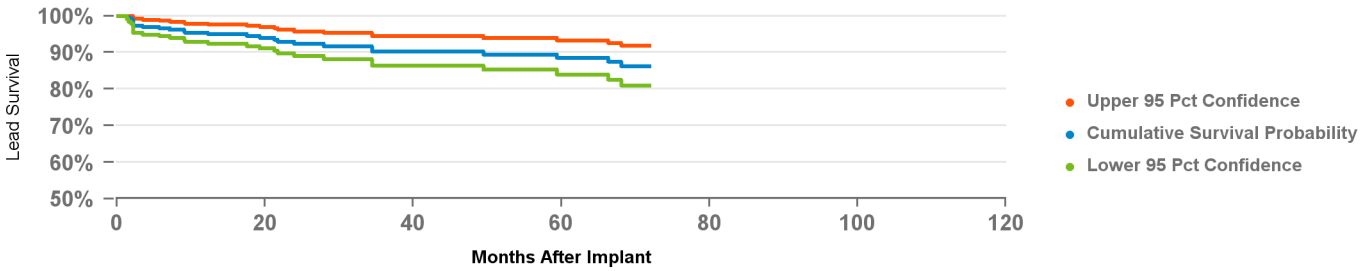
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	6
Failure To Capture	82
Failure To Sense	3
Impedance Abnormal	7
Insulation Breach	
Lead Dislodgement	2
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	446
Cumulative Months of Followup	13,488
Number of Leads Active in Study	93

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%	92.3%	90.3%	90.3%	88.5%	86.3%
#	238	181	141	111	81	59

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	10,307
Estimated Active USA Implants	3,623
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

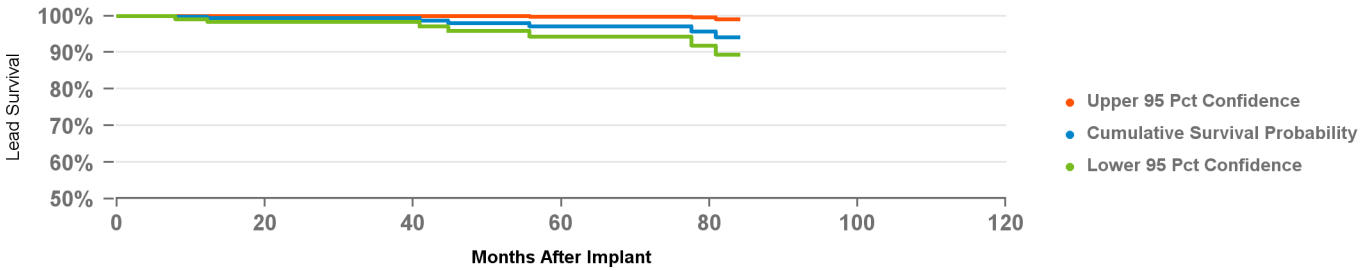
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	6
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	568
Cumulative Months of Followup	15,790
Number of Leads Active in Study	4

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	134	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.

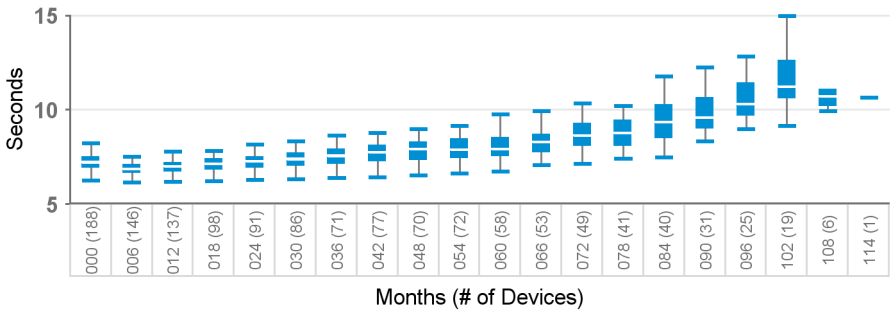
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available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

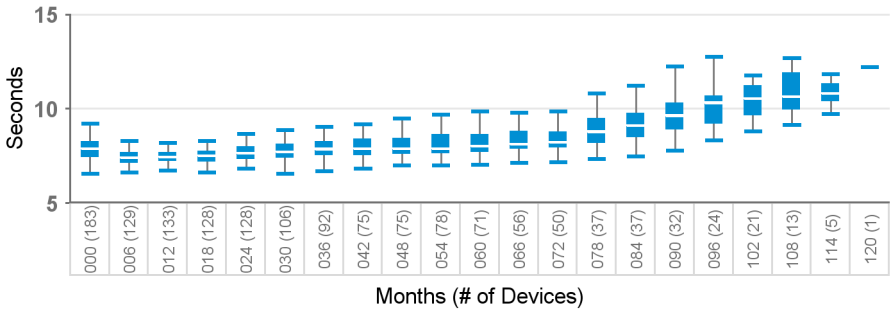
7230

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



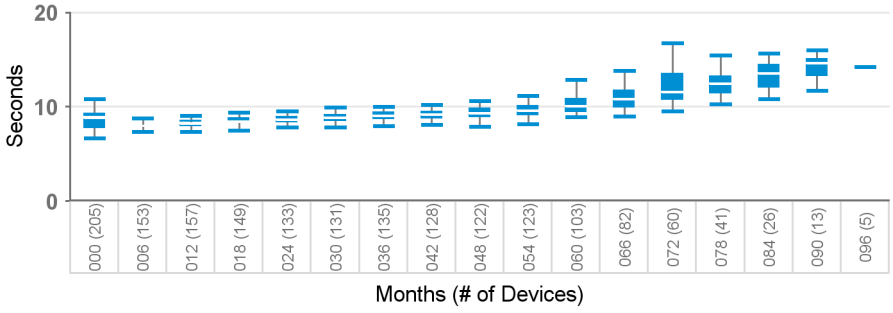
7232

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



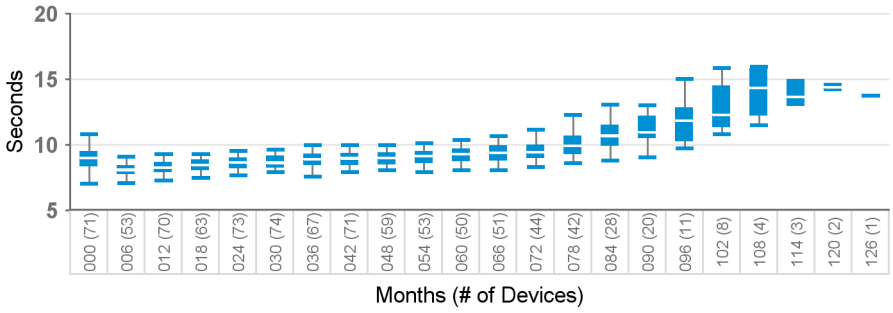
D144DRG, D154ATG, D154DRG

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT



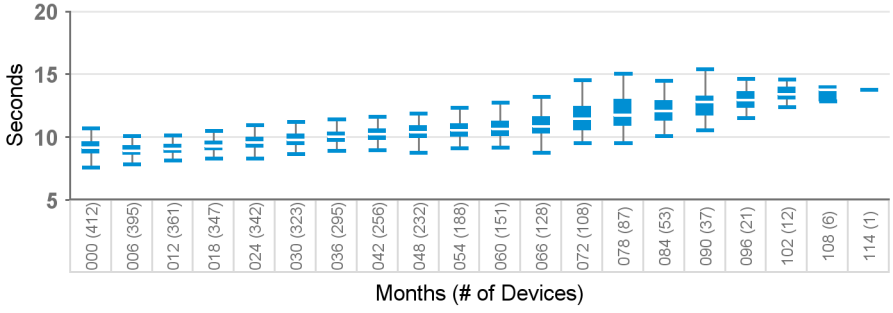
D144VRC, D154VRC

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



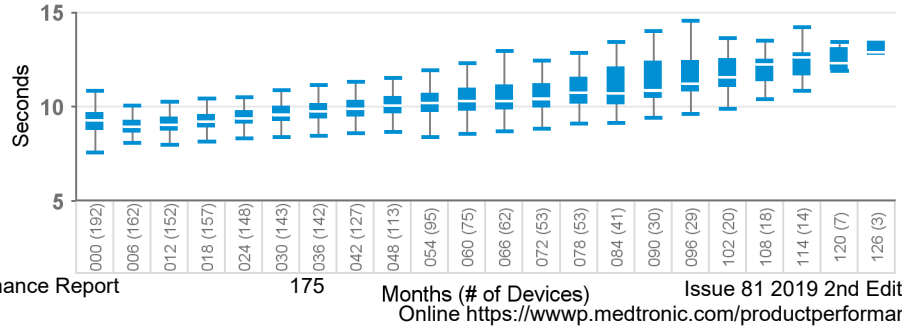
D154AWG, D164AWG

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



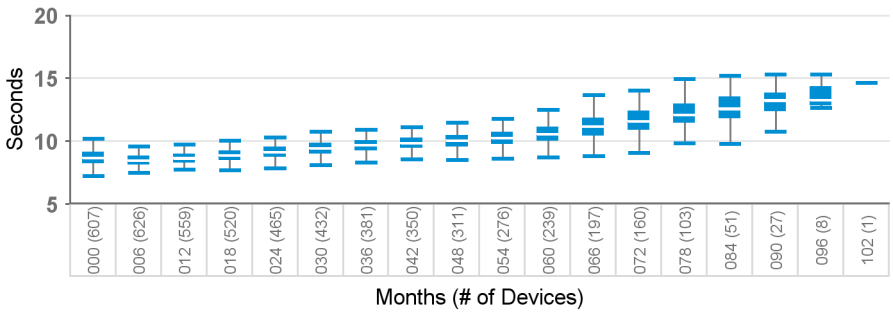
D154VWC, D164VWC

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



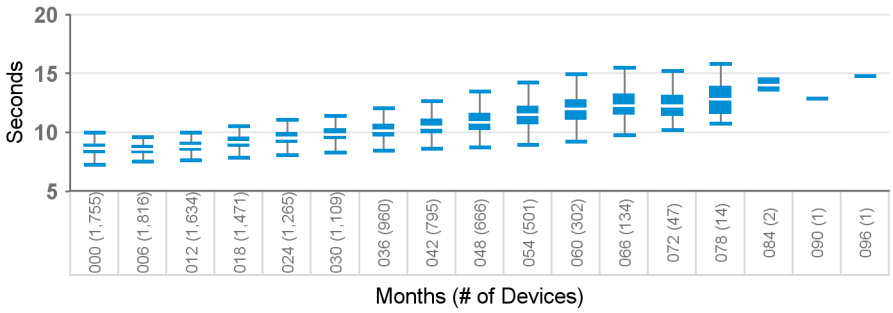
D204DRM, D214DRM, D224DRG, D234DRG

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



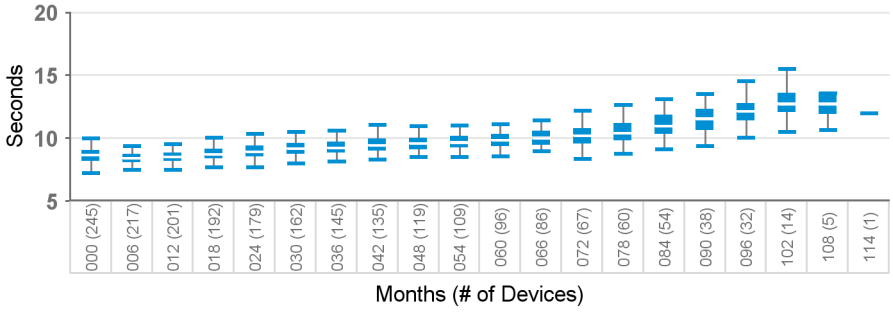
D204TRM, D214TRM, D224TRK, D234TRK

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



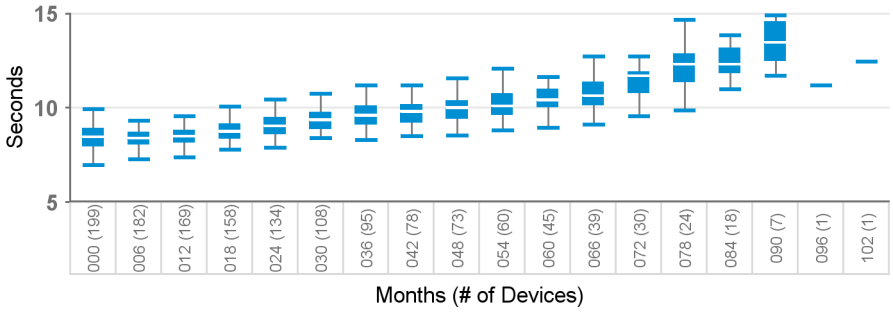
D204VRM, D214VRM, D224VRC, D234VRC

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



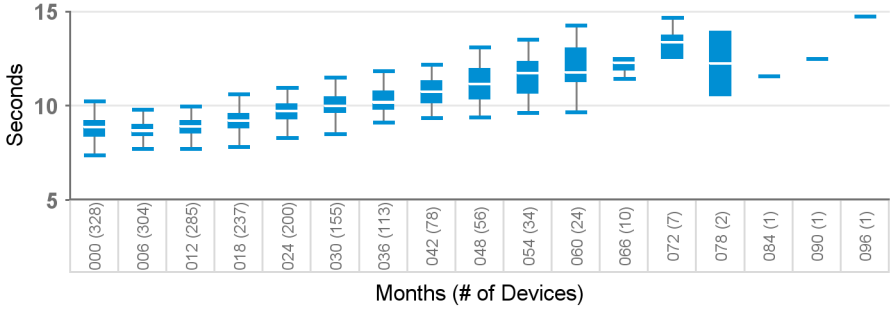
D264DRG, D284DRG, D384DRx, D394DRx

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



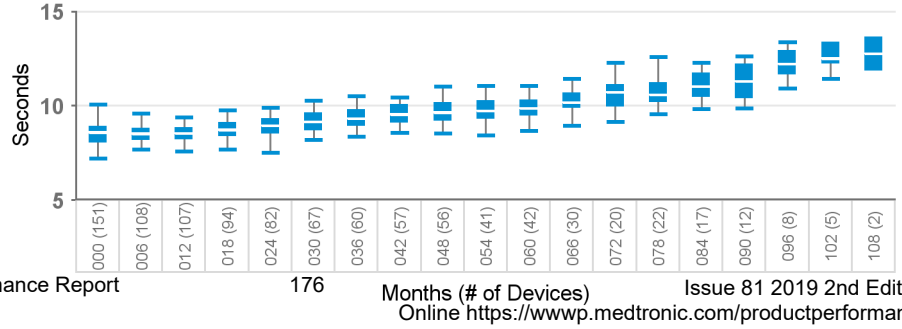
D264TRM, D284TRK, D384TRx, D394TRx

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



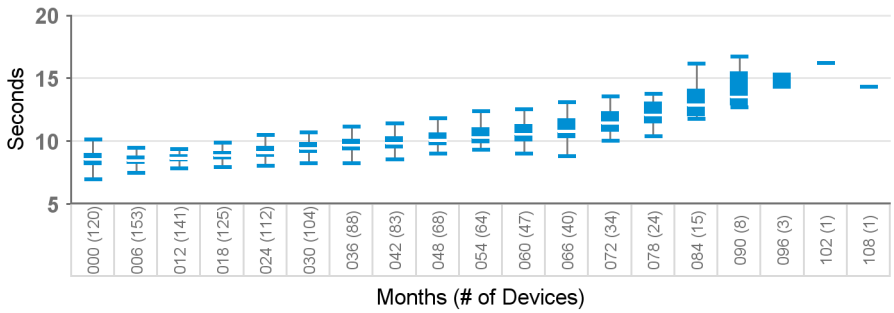
D264VRM, D284VRC, D384VRx, D394VRx

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



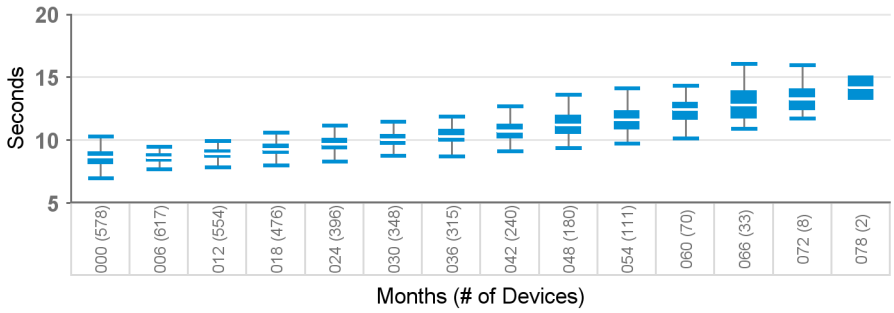
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



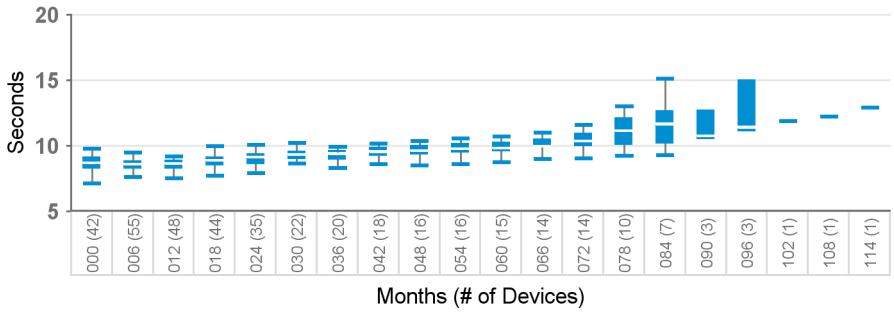
D274TRK, D294TRK

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



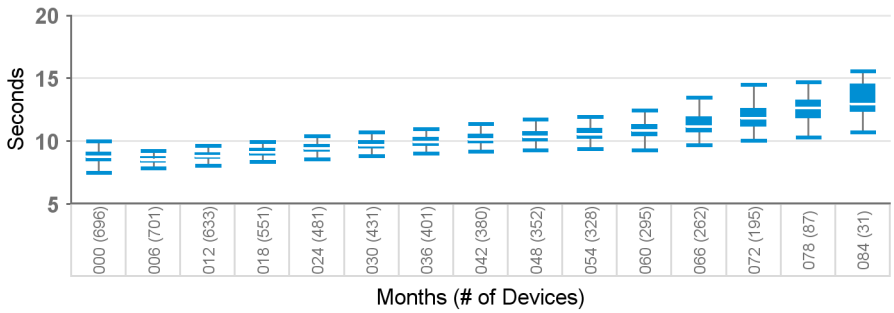
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



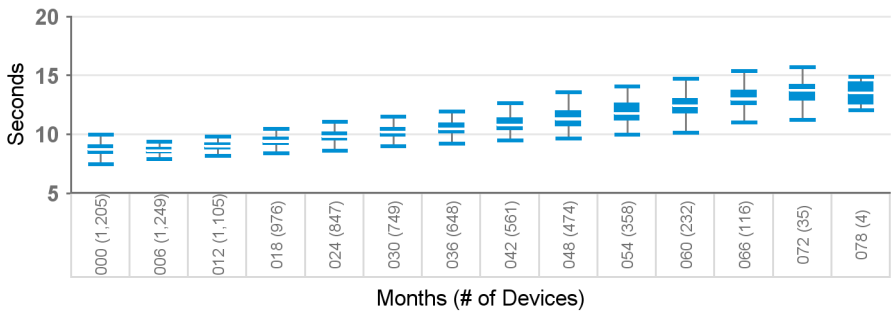
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



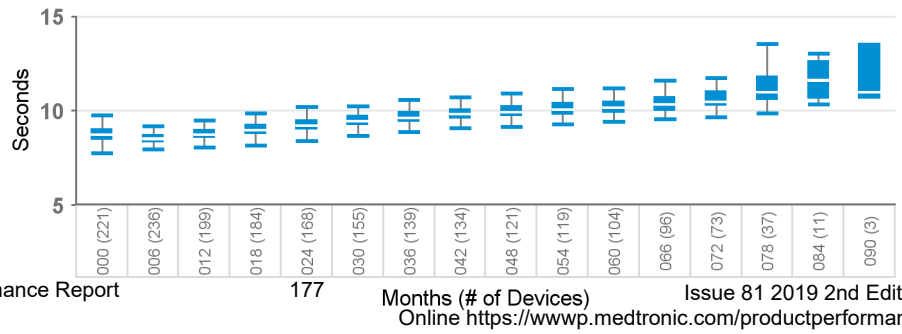
D314TRx

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



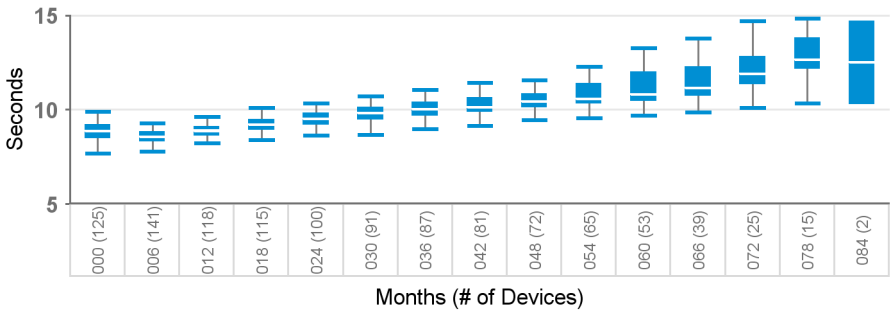
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



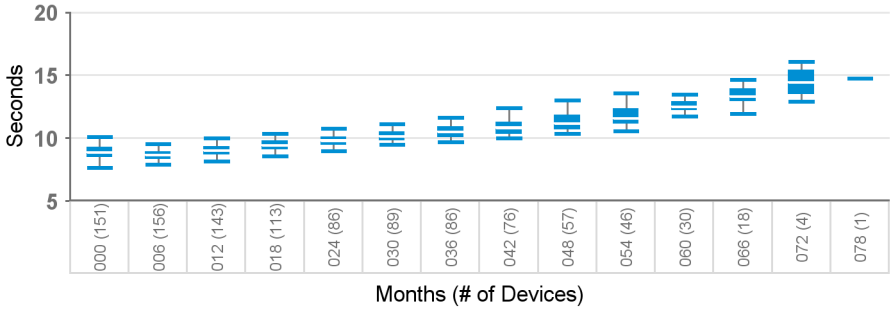
D334DRx, D364DRx

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



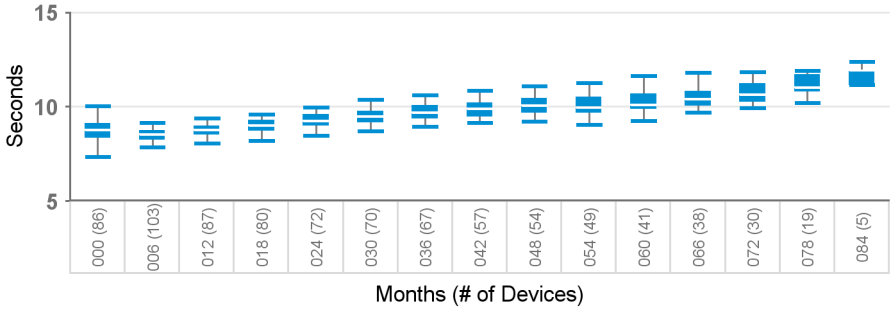
D334TRx, D364TRx

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



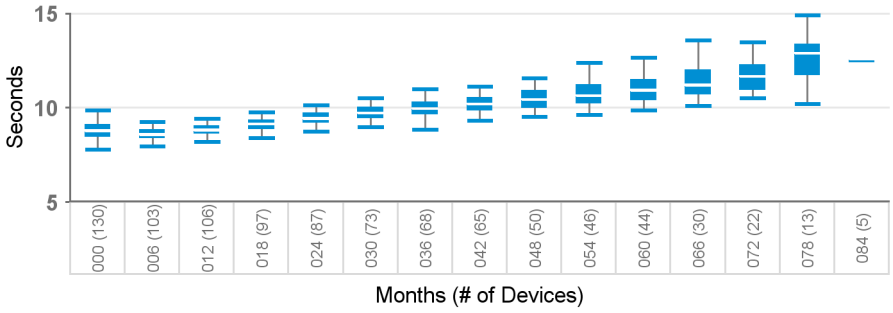
D334VRx, D364VRx

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



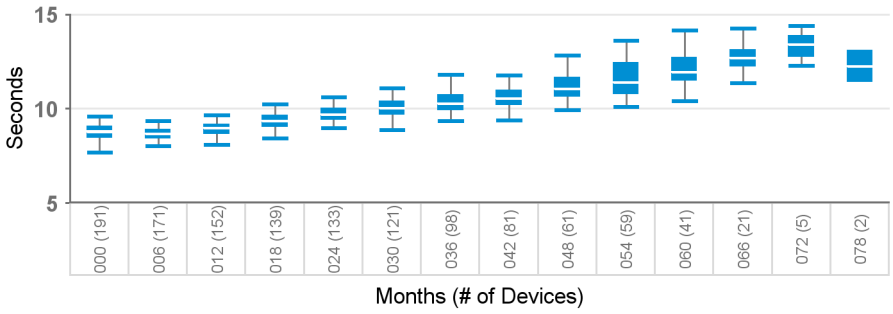
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



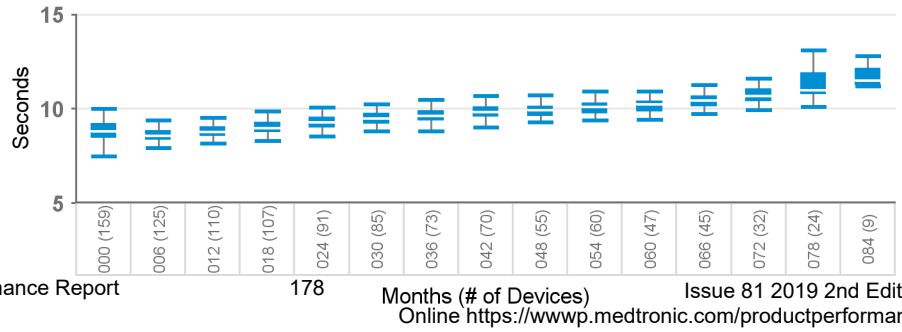
D354TRx

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



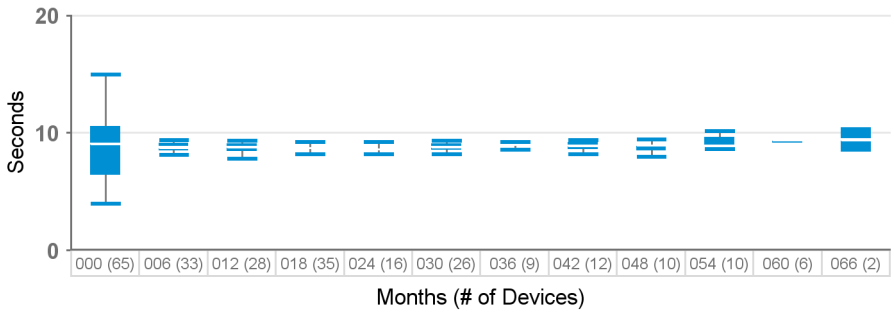
D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



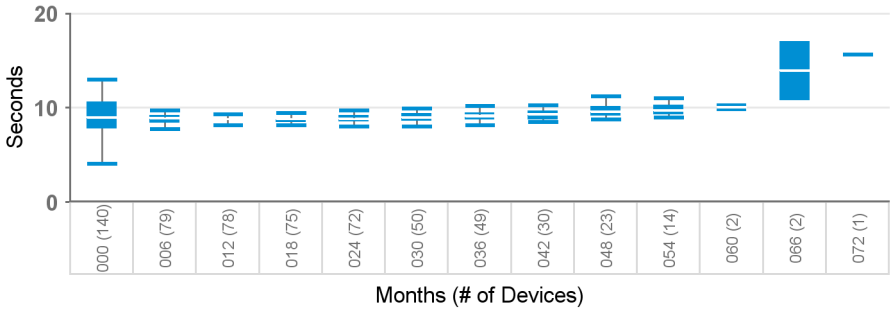
DDxxxxx, DR

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
DDMD3D4	Primo
DDME3D4	Mirro



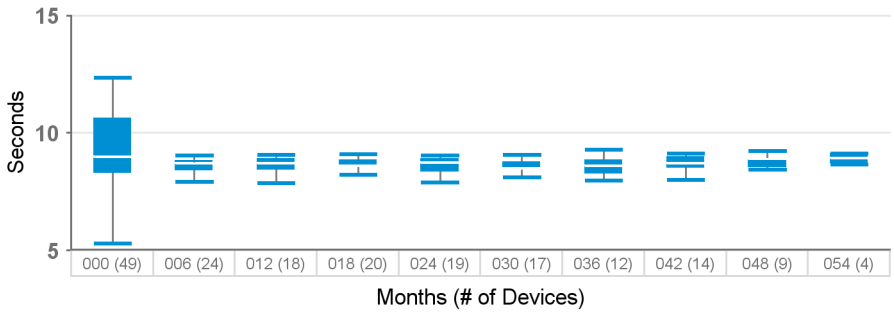
DTxxxxx, CRT-D

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
DVME3D4	Mirro



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

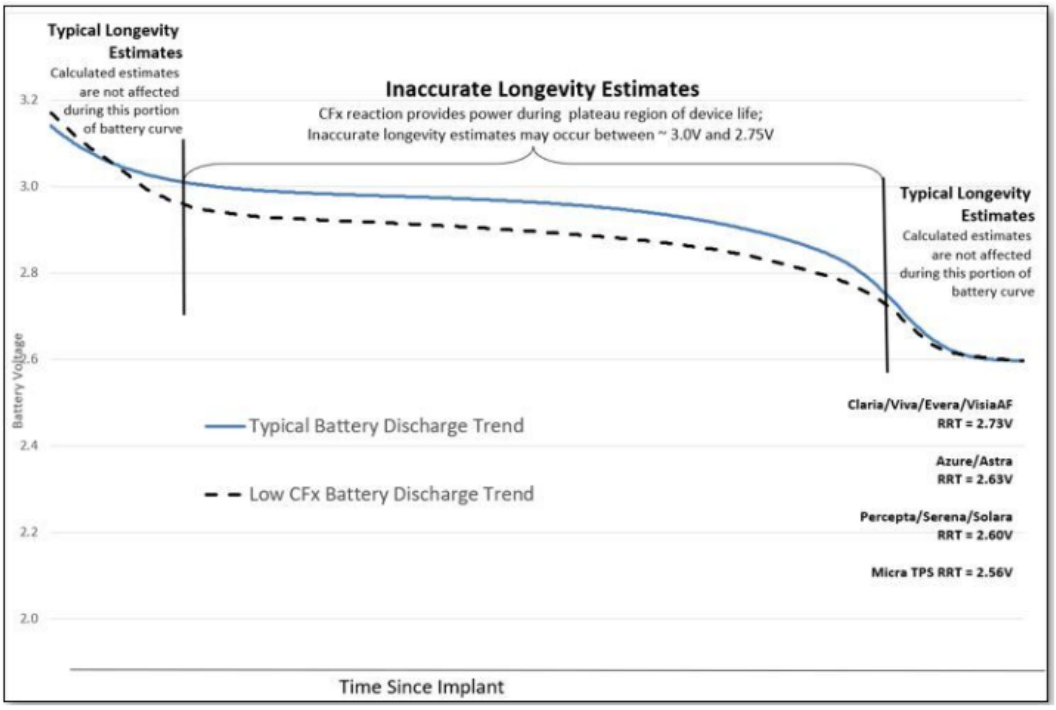
Advisory

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.

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%) *.

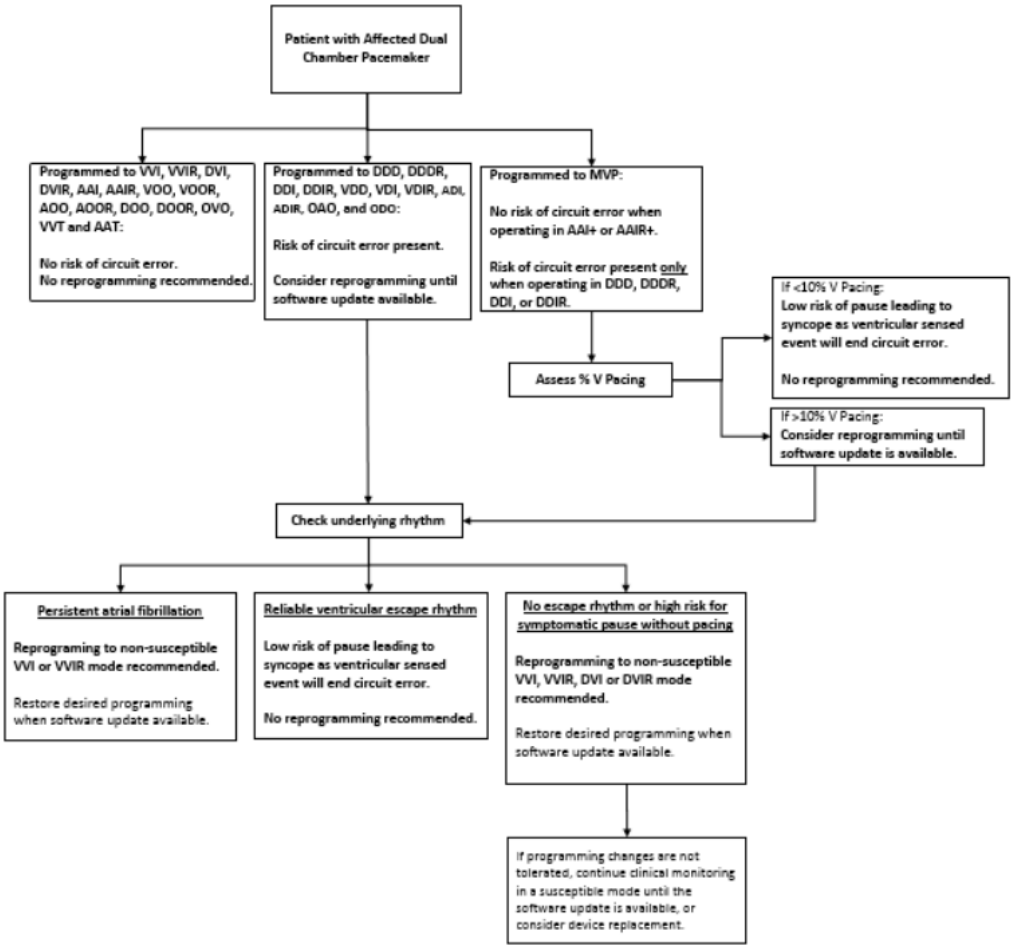
o If a patient reports symptoms consistent with a pacing pause, and you would like assistance assessing whether a patient had a pause due to this issue, contact your Medtronic representative.

• 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 - October 2019

- Medtronic received regulatory approval to distribute a software update to address the potential for a pacing pause in these devices (software models SW003 v8.2 for Adapta/Versa/Sensia; SW010 v8.2 for Relia; SW043 v8.2 for Attesta/Sphera; VSF20 v8.2 for Vitatron; and VSF21 v8.2 for Vitatron).
- Following receipt of the software update, pacemakers that were programmed to a pacing mode specifically to avoid a circuit error may be reprogrammed to any pacing mode. Once a device is updated, if the circuit error were to occur, the pacing cycle will automatically reset; this may be observed as a single dropped beat.
- As of October 9, 2019 153,000 devices remain active out of an original population of 156,957 devices world wide.

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	153,000 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.

Table – Device Subsets

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

Within the 752 lower-risk devices, there have been zero confirmed failures (0%) through October 18, 2019.
An estimated 522 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**	522	**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 High Voltage and ATP Therapy

EnTrust® and Escudo® VR/DR/AT ICDs

Original Date of Advisory: June 2018

Product

All models of EnTrust and Escudo VR/DR/AT ICDs devices.

Advisory

EnTrust and Escudo implantable cardioverter defibrillators (ICDs) have the potential for loss of high voltage and anti-tachycardia pacing therapy as they near elective replacement indicator (ERI) voltage. Under certain circumstances, the device may display an immediate End of Life (EOL) Observation with no prior ERI alert. Though no ERI alert is triggered, there may not be enough remaining battery capacity to charge the high voltage circuits, resulting in an excessive charge time EOL Observation (refer to Image 1), leading to a loss of high voltage and anti-tachycardia pacing therapy. Bradycardia therapies will continue to operate as expected.

Through June 15, 2018, Medtronic confirmed 25 charge timeout events related to this issue, with no (0) patient deaths or complications. All events occurred during routine capacitor formation or in-clinic charge testing. Twenty-one (21) events occurred with no ERI alert; four (4) events followed an ERI alert. Time from implant to the devices experiencing the issue ranges from 7.9 – 11.7 years.

EnTrust and Escudo ICDs were last manufactured in 2010. Approximately 25,000 sold devices globally are in-scope of this advisory. As of June 2018, an estimated 2,770 of those devices remained actively implanted worldwide (209 confirmed as active in the U.S.). The rate of occurrence in remaining active devices is estimated to be 0.00098 in single chamber ICDs and 0.00005 in dual chamber devices.

Patient Management Recommendations

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

- Consider scheduling an in-office patient follow-up as soon as possible to assess the potential for this issue per the steps described below.
- Ensure the *Excessive Charge Time EOL...and the Low Battery Voltage ERI...* Patient Alerts have been programmed to "On-High" (Refer to Image 2).
- Instruct patients to contact your office if they hear device alert tones. Consider utilizing the *"Demonstrate Tones..."* function to ensure patients recognize the audible tone.
- If this issue has occurred, an *"EOL: replace device immediately"* Observation will be displayed on the QuickLook report. Schedule device replacement immediately.

Additionally, Medtronic recommends the following actions to help ensure patient safety and effective high voltage therapy remain as the device battery voltage approaches its 2.61V ERI threshold.

If Battery Voltage ≤ 2.64V:

Prophylactic device replacement should be strongly considered since the device is near its elective replacement and additional programming would provide only minimal additional months of service. For patients for whom it is determined that delaying replacement is clinically desirable, contact Medtronic Technical Services.

If Battery Voltage > 2.64V:

***Step 1**: If the **Auto-Cap Formation Interval is set to "Auto"**, reprogram the value to "6" (Refer to Image 3).*

Change from an "Auto" value to a fixed numeric value will ensure that an excessive charge time will trigger an audible patient alert.

***Step 2**: Conduct an in-clinic manual high voltage charge in "Tests – Charge/Dump" (Refer to Image 4a).*

DO NOT Dump the Test Charge as it will dissipate on its own and allow for capacitor reformation to occur.

***Step 3**: Retrieve Data after the Test Charge (Refer to Image 4b)*

***- If Charge Time is less than 16 seconds**, no further action is required. Continue with routine follow-up per clinic* practice (recommend 3-month follow-up sessions per labeling).

- If Charge Time is 16 seconds or longer, or an "EOL" Observation is displayed, schedule device replacement immediately.

Status Update

As of October 15, 2019, there have been 31 confirmed events related to this issue. An estimated 800 remain active WW with less than 50 in the US.

PROGRAMMER OBSERVATION AND PROGRAMMING SCREENS

Image 1 - Excessive Charge Time EOL (Observation)

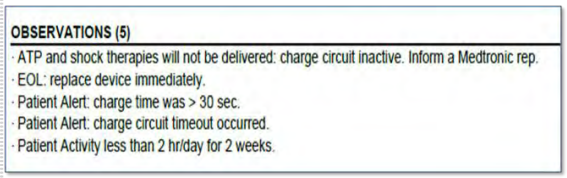


Image 2 – Excessive Charge Time EOL Alert (Programming Screen)

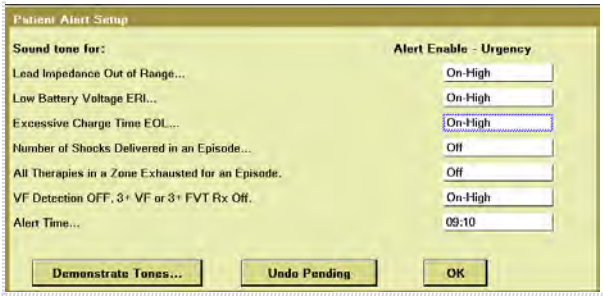
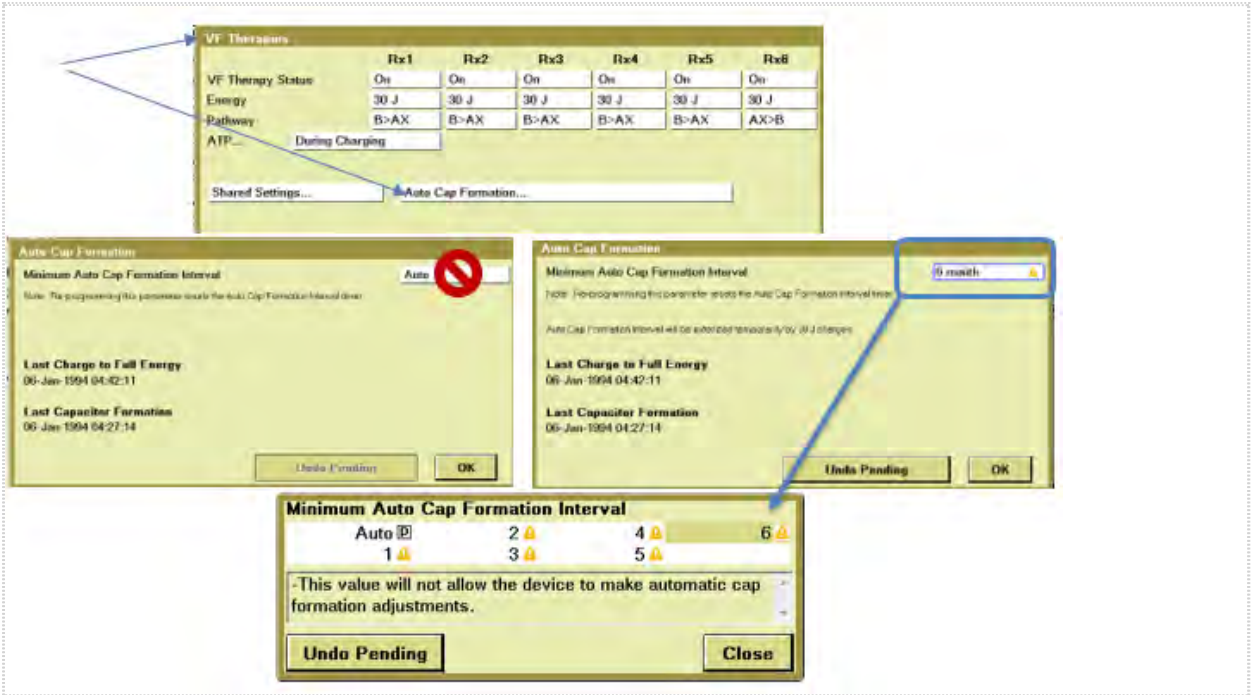
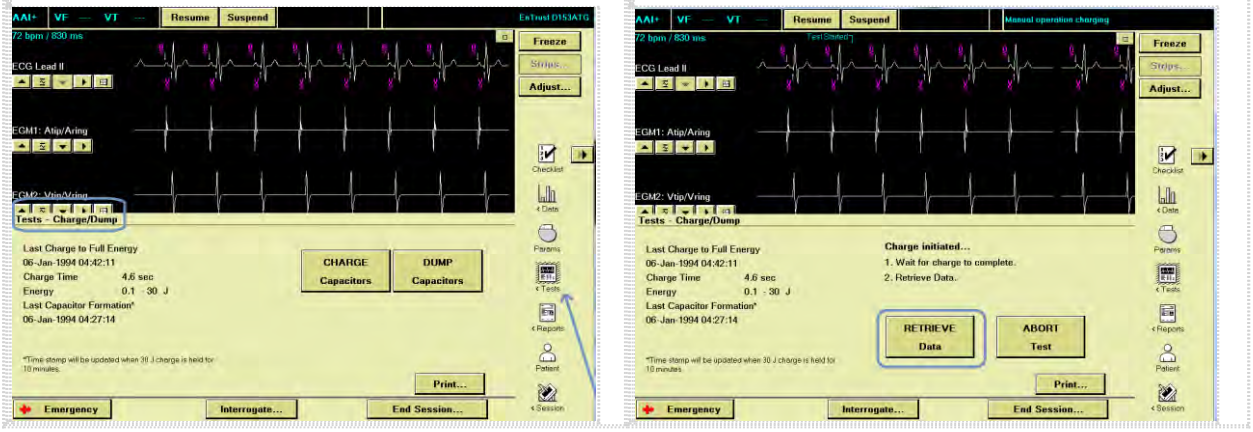


Image 3 – Programming Steps to Change Auto-Cap Formation Interval to Fixed value of 6-month intervals



Images 4a and 4b – Programming Screens to Conduct In-clinic High-Voltage Test Charge



Potential for Device Reset

Percepta™ CRT-P MRI SureScan™ and Percepta™ Quad CRT-P MRI SureScan™

Original Date of Advisory: June 2018

Product

All models of Percepta and Percepta Quad CRT-P devices.

Advisory

Percepta and Percepta Quad CRT-P devices have the potential for a device reset to occur due to a timing interaction between the EffectivCRT™ Diagnostic and the Ventricular Safety Pacing feature (VSP). When an AP-VS interval measures 100-109ms during a short, nightly device check, a single reset is generated. This reset produces a non-programmable, wireless CareAlert™, but does not alter device therapy. If the device experiences more than five resets due to this timing sequence between in-clinic device interrogations, a full reset (sometimes referred to as a power on reset) will occur. By design, a full reset automatically reverts device operation to RV-only pacing at VVI/65 until the next programmer session is conducted – at which time the full reset condition can be cleared, and the device can be reprogrammed to its prior settings.

A Software update, Application SW040 Version 8.1, is available for installation onto all CareLink™ Model 2090 and Encore™ programmers to eliminate this issue. Once installed on a programmer, an in-clinic device interrogation will update the patient's device automatically to prevent this timing interaction from generating a reset. No changes to programmed device functionality will occur as a result of this device update.

No other Medtronic pacemaker, ICD, CRT-D or CRT-P device models are susceptible to this issue.

Status Update October 2019

A Software update, Application SW040 Version 8.1, was released in June 2018 as part of the original advisory notification. This software has been deployed onto Medtronic CareLink™ Model 2090 and Encore™ programmers to eliminate this issue. An in-clinic device interrogation will update the patient's device automatically to prevent this timing interaction from generating a reset. No changes to programmed device functionality will occur as a result of this device update.

If the Patient Management guidance provided below is followed, no additional resets due to this timing interaction will occur.

Patient Management Recommendations

In consultation with the Independent Physician Quality Panel, Medtronic recommends the following actions:

- The updated Percepta CRT-P Application Software (SW040 Version 8.1) has been fully deployed worldwide onto Medtronic 2090 and Encore programmers.
- For a patient whose Percepta CRT-P device has experienced a Reset Alert or Observation:

  Consider scheduling an in-clinic device interrogation as soon as possible for the patient's device to receive the automatic update.

- For a patient whose Percepta CRT-P device has not experienced a Reset Alert or Observation:

  At their next scheduled in-clinic device interrogation, the patient's device will receive the automatic update.

How to verify a patient's device has received the software update:

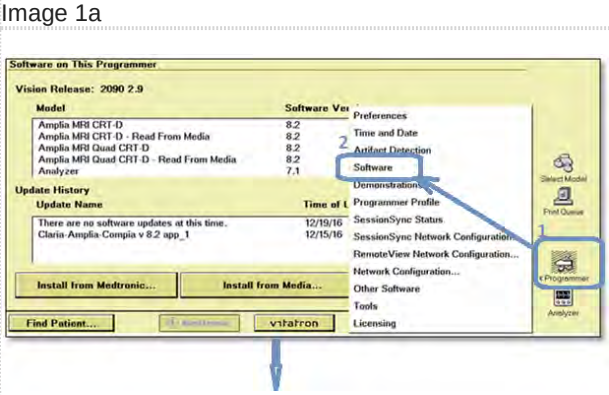
- Ensure the programmer has been updated to Percepta Application Software "Version 8.1" by viewing the software installation history under the Programmer Icon; Refer to Image 1a and 1b.
- Interrogate the patient's device; Print the Parameters Report –Verify the Device ID listed at the bottom of the printout displays "Device Configuration ID: 1-0-0"or "Device Configuration ID: 1-1-0; Refer to Images 2a and 2b.
- If the Parameters Report does not display the new Device ID number, verify that the correct software application has already been installed (SW040 Version 8.1).
- If the programmer has not been updated, install Software Application SW040 Version 8.1 and re-interrogate the patient's device.
- If the programmer has been updated and the Device Configuration ID is not 1-0-0 or1-1-0, the patient's device was unable to successfully receive the update. Contact Medtronic Technical Services for additional instructions.

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

PROGRAMMER USER SCREENS

Software Installation History Screen

Image 1a



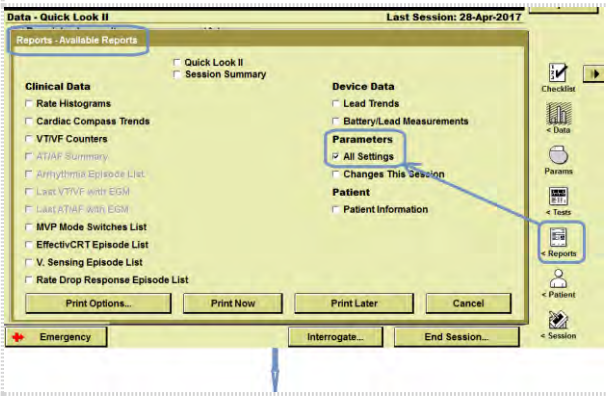


Image 1b

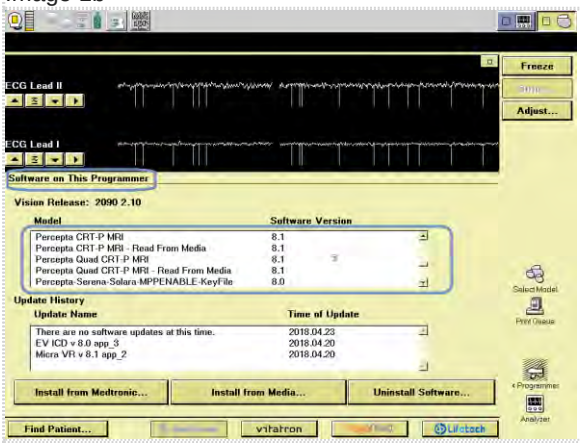
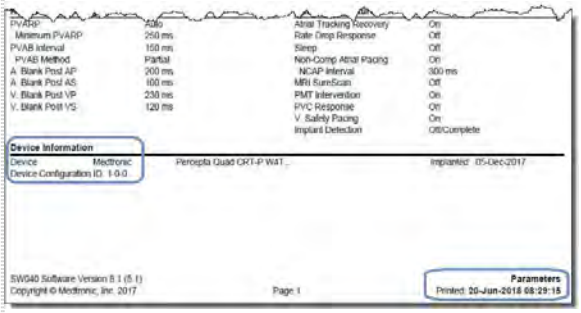


Image 2b



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

Within the 48 devices, there has been 1 confirmed failure (2.1%) through October 18,2019. An estimated 5 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**	**7**	**2.1%** Worldwide

Potential Loss of Left Ventricle Pacing Due to Software Issue

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

Original Date of Advisory: December 2016

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

Status Update October 2019

A software update, Application SW034 Version 8.2 was released in March 2017 to correct this issue. This software has been deployed onto Medtronic CareLink™ Model 2090 and Encore™ programmers. An in-clinic device interrogation with a programmer containing this software version will update the patient's device automatically. To prevent possible recurrence of the software issued described in the original advisory, the patient must continue to received device programming only from a programmer that has this software update. The loss of LV pacing issue will still occur if the specific programming sequence described in the original advisory letter is performed using a programmer that has not been updated with SW034 Software Version 8.2.

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

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

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

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

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

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

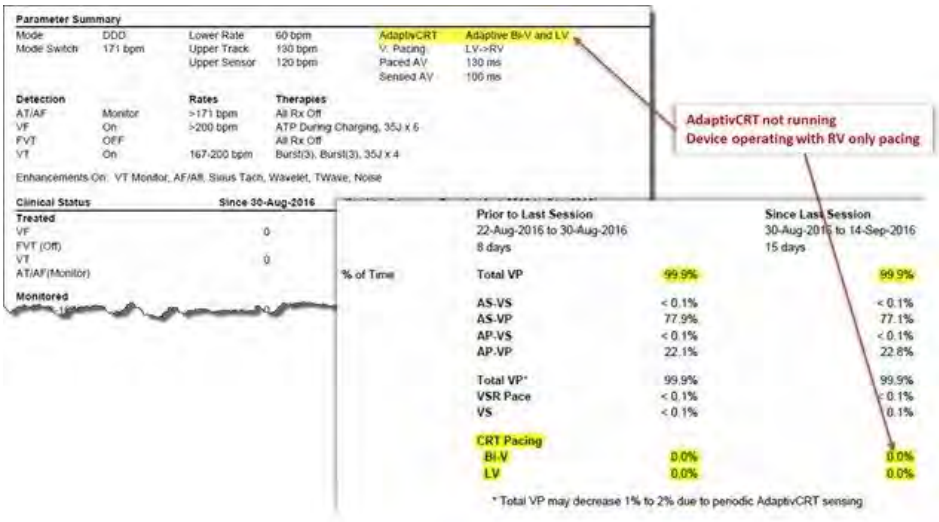
Until the software update has been approved and the affected device models receive the update, follow the programming recommendations provided below. These recommendations also apply to any new device implants.

1. **At the patient's next scheduled CareLink transmission or in-office follow-up, identify if the patient's device is operating with AdaptivCRT enabled and loss of LV-pacing. Continue this practice for all subsequent device evaluations until the software update has been implemented.**

   Using CareLink or Programmer interrogation session reports:

   - If the CRT setting is currently programmed to Adaptive Bi-V and LV or Adaptive Bi-V (Figure 1), review rate histogram CRT Pacing percentages (CRT Pacing: Bi-V and LV).
   - If Bi-V and LV pacing percentages Since Last Session are both near 0%, then the device has encountered the programming sequence and has lost LV pacing; proceed to step 2.

Figure 1



2. **For patients identified with loss of LV pacing:**

   Perform the following programming steps to restore the device to its expected operating state with AdaptivCRT enabled:

   - Select the CRT parameter window, select Nonadaptive CRT, and select PROGRAM.
   - Select the CRT parameter window, select the desired AdaptivCRT setting (Adaptive Bi-V and LV or Adaptive Bi-V), and select PROGRAM.

Until the software update is available, follow the programming steps above to avoid the loss of LV pacing.

As part of the software update previously mentioned, Medtronic will also address an unrelated transient mode switch behavior that may occur in MRI Quadripolar CRT-D device models (Claria MRI, Amplia MRI and Compia MRI). The mode switch behavior is unrelated to ventricular tachyarrhythmia detection and therapies. This behavior only occurs when a VectorExpress™ Test is started, but then aborts due to a fast or unstable rate, or due to a manual user abort (i.e., manually selecting STOP Test). Under these scenarios, the device remains in the transient mode switch state until any of the following occur:

- An automatic Atrial Capture Management™ (ACM) pacing threshold search,
- An automatic delivery of any ATP or shock therapy, or
- An in-office follow-up activity, such as a pacing parameter programming or conducting one of the following in-office tests: Sensing, Threshold, Underlying Rhythm, or CardioSync™. A "Test Started" indication is sufficient to clear the transient state.

Through 10 November 2016, Medtronic has not received any field reports or complaints of this transient mode switch behavior

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

Potential Rapid Battery Depletion Due To Circuit Component

Viva™ CRT-D and Evera™ ICD

Original Date of Advisory: August 2016

Product
A specific subset of 78 Viva CRT-D and Evera ICD may experience rapid battery depletion due to a low resistance path developing within a circuit component. You may use the "Search for Information by Serial Number" tool 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

Within the 78 devices, there have been 10 confirmed failures (13%) through October 18,2019. Medtronic modeling predicts an additional three (3) failures may occur in the remaining active population. An estimated 30 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	**30** 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

As of October 18, 2019, approximately 1,100 devices remain active worldwide, from an original implant population of 96,800. In the United States, 500 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)	**169** Worldwide (**93** United States)	**1,100** Worldwide (**500** United States)	**0.17%** Worldwide (**0.23%** United States)

Potential Rapid Battery Depletion

EnTrust® VR/DR/AT ICDs

Original Date of Advisory: March 2012

Product

All EnTrust ICDs.

Advisory

A small percentage of EnTrust ICDs may not meet expected longevity or provide at least three months of device operation between the Elective Replacement Indicator (ERI) and End of Life (EOL) due to a more-rapid-than-expected drop in battery voltage. No patient deaths or serious injuries have been reported as a result of this issue.

The reported events have involved a drop in battery voltage from ~3.0 V to ERI (2.61 V) over a time period ranging from approximately one week to six months. All reported events have occurred at least 30 months after implant.

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed. The Physician Letter is available at http://www.medtronic.com/product-advisories/entrust/physician/index.htm

Patient Management Recommendations (As of March 2012)
After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient managementrecommendations:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.
- Physicians should program the audible patient alerts for "Low Battery Voltage ERI" and "Excessive Charge Time EOL" to ON.
- Physicians should replace devices promptly after they reach ERI if the decline in voltage is more rapid than expected.
- Prophylactic replacement of EnTrust ICDs is not recommended.

Status Update
As of October 18, 2019, there have been 97 confirmed events. No patient deaths have been reported due to this issue. No reports have been made of a failure to deliver high voltage therapy.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
69,200 Worldwide (**44,300** United States)	**97** Worldwide (**74** United States)	**900** Worldwide (**less than 10** United States)	**0.14%** Worldwide (**0.17%** 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

As of October 15, 2019, of the initial implant population of 205,600 in the United States, approximately 47,000 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)	**7,200** Worldwide **(5,115** United States)	**65,000** Worldwide (**47,000** 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.

Potential For Premature Battery Depletion in a Subset of ICD and CRT-D Devices
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 names1:

- 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.

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-Pe pathway

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 – OCTOBER 2019

As of October 17, 2019, there have been six additional confirmed events (for total of nine worldwide) associated with this failure mode. One of the additional confirmed events was reported as patient death.* All events have occurred within two and ten months from the initial implant. The rate of occurrence based on accelerated test data and the additional six field failures is projected to be 0.006%.

Product manufactured as of June 1, 2019, utilizes a new low voltage capacitor; product manufactured prior to June 1, 2019, continues to perform within our reliability projections as established as part of the product development process.

*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.

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/

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

Purpose of this Information

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

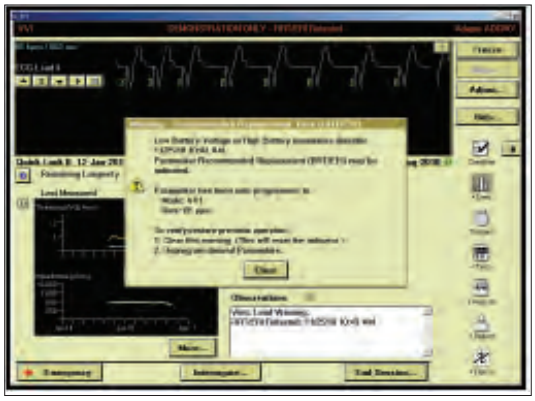
Background

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

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

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

Example 1 – Programmer Software Detects Measurement Lock-up ERI

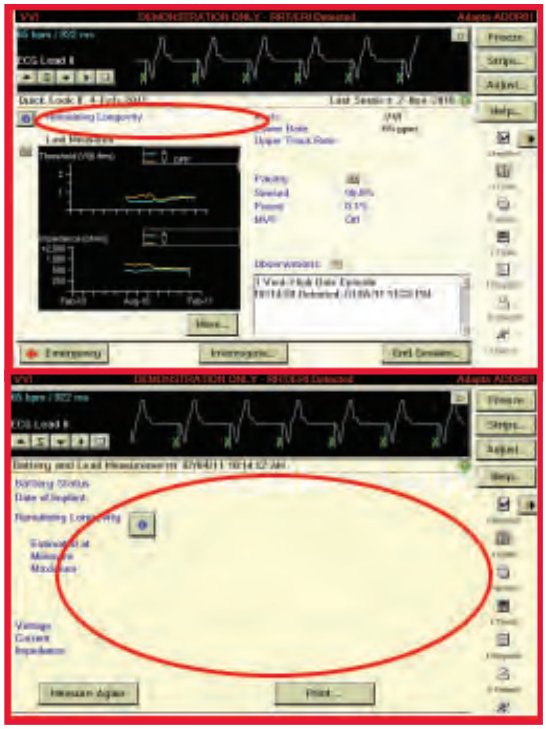


Reset Method for Kappa and EnPulse

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

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

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



Clinical Management of VCM near Elective Replacement

Background

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

Device Longevity and VCM Behavior

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

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

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

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

Table: IPG Therapy Parameter Changes at ERI

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

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

Follow-Up Considerations

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

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

General Follow-Up and Replacement of ICD Leads

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

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

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/clinic follow-up practice, and Medicare guidelines.

In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity.

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

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

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

General Criteria for Lead Replacement

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

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

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

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

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

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

Clinical Management of High-Voltage Lead System Oversensing

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

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

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

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

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

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

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

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

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

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/

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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(24-hour technical support for physicians and medical professionals)

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