CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2018

1st Edition – Issue 78

Medtronic

Errata

The original version of this edition of the CRHF Product Performance Report contained the following errors:

- the data counts on Generator pages showed worldwide (instead of the intended US only) totals
- the acute observation counts on Lead pages showed worldwide (instead of the intended US only) totals

This download file, posted on 31 May 2019 to wwwp.medtronic.com/productperformance/past-reports.html \, contains the corrected data

CRHF Product Performance Report

2018

1st Edition
Issue 78

Cutoff date for this edition is 31 January 2018 for Lead Study data and 13 April 2018 for all other data, unless otherwise stated.

Our Commitment to Quality

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

The third tenet of the mission is all about quality:

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

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

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

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

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

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

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

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

Contact Information

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

US Technical Services Department

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

Fax: 1 (800) 824-2362

International Technical Centers

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

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

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

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

Editorial Staff

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Introduction

For 35 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.

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

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

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

Survival Estimates

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

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

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

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

Survival estimates for leads are based on clinical observations recorded via Medtronic's PAN Registry. This multicenter clinical study is designed to record clinical observations representative of the total clinical experience. Therefore, the lead survival estimates include both lead hardware failure and lead-related medical complications, and do not differentiate a lead hardware failure from other clinical events such as exit block, perforation, dislodgement, or concurrent pulse generator failure.

The actuarial life table method is applied to the data collected for CRT, ICD, and IPG devices and leads to provide the survival estimates included in this report. A general introduction to understanding this method of survival analysis is given later in this introduction.

ICD Charge Times

Since May 2000, Medtronic has provided important information on charge time performance of ICDs. The information provided in this report shows how ICD charge time can vary during the time a device is implanted. The information is presented in graphical format showing charge time as a function of implant time. The data for charge times are collected from devices enrolled in the PAN registry.

Introduction continued

Advisory Summaries

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

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

Performance Notes

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

How You Can Help

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

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

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

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

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

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

Overview of Survival Analysis

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

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

For CRTs, IPGs and ICDs, the events can be normal battery depletion or a device malfunction. For leads, the events are complications as defined in the study protocol.

The actuarial life table method allows Medtronic to account for devices and leads removed from service for reasons unrelated to performance and for device and leads still in service. Devices and leads removed for reasons unrelated to performance or are still in service are said to be suspended. Examples of devices and leads removed from service for reasons unrelated to performance include:

- Removed to upgrade the device or lead
- No longer in service due to the death of the patient for reasons unrelated to the device or leads
- Implanted in patients who are lost to follow-up

For each suspension, the device or lead has performed within performance limits for a period of time, after which its performance is unknown.

Confidence Intervals

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

Survival Curves in the Product Performance Report

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

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

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

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

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

Method for Estimating CRT, ICD, and IPG Device Performance

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

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

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

Categorization of Depleted and Malfunctioning Devices for Survival Analysis

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

Definition of Malfunction

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

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

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

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

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

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

Normal Battery Depletion – The condition when:

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

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

Malfunction with Compromised Therapy Function

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

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

Malfunction without Compromised Therapy Function

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

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

Expanded Malfunction Detail

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

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

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

Battery – Findings linked to the battery and its components

Software/Firmware – Findings linked to software or firmware function

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

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

Returned Product Analysis Process

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

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

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

Statistical Methods for Survival Analysis

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

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

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

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

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

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

Sample Size and How the Population and Population Samples Are Defined

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

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

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

Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion

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

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

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

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

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

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

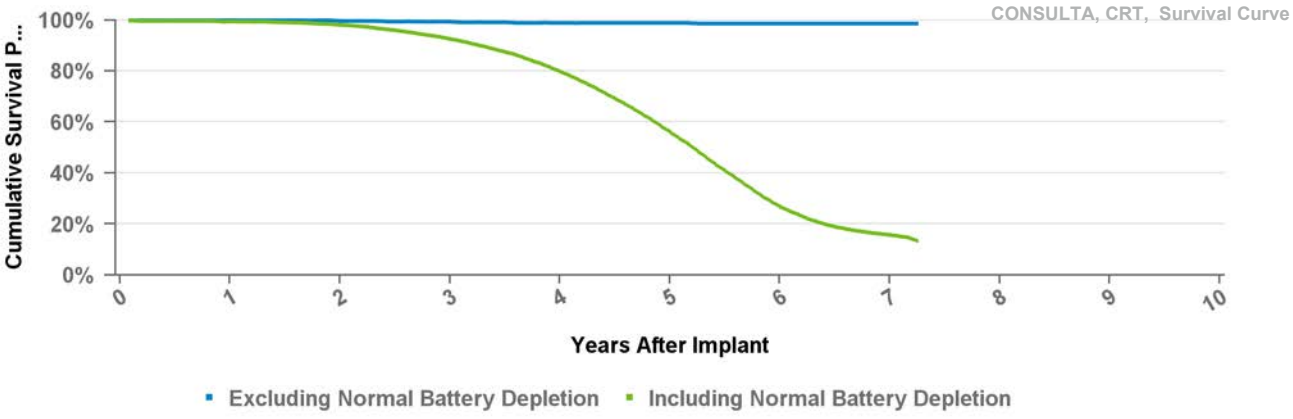
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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

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

D204TRM Consulta CRT-D

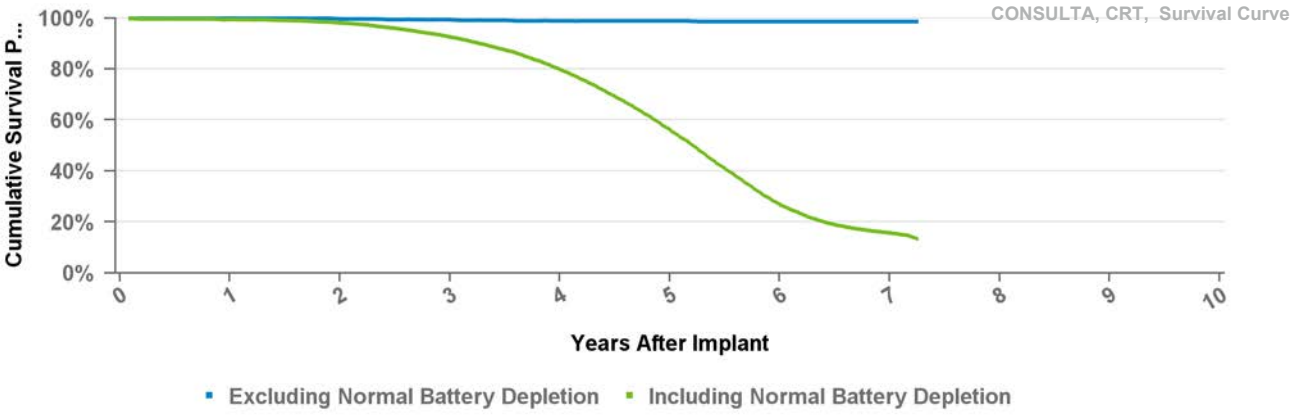
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,099	Battery Malfunction	1
Estimated Active USA Implants	1,017	Electrical Component	1
Normal Battery Depletions	442	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.995	0.981	0.926	0.798	0.561	0.268	0.157	0.133
Effective Sample Size	58003	52868	45930	35390	20225	6674	1509	287

D214TRM Consulta CRT-D

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

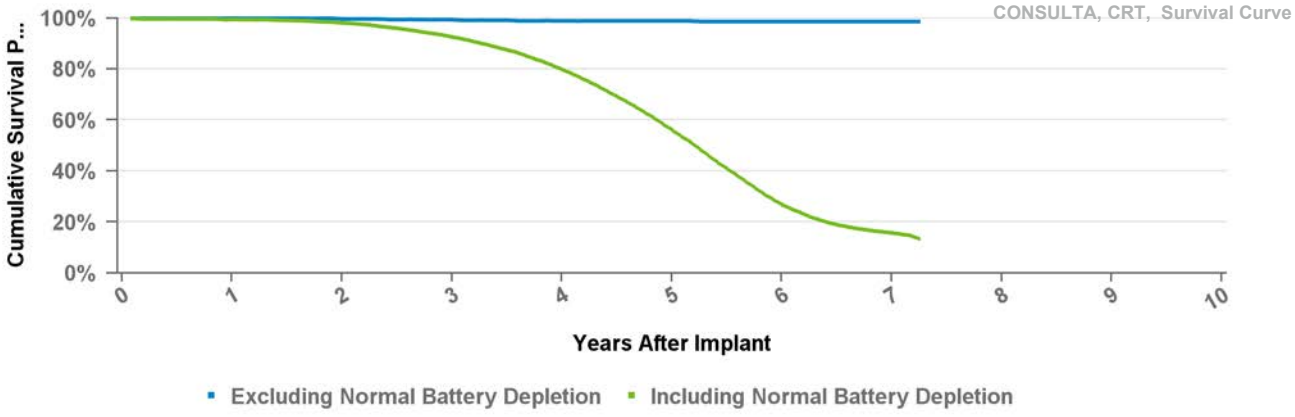


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.995	0.981	0.926	0.798	0.561	0.268	0.157	0.133
Effective Sample Size	58003	52868	45930	35390	20225	6674	1509	287

D224TRK Consulta CRT-D

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	65,979
Estimated Active USA Implants	13,163
Normal Battery Depletions	19,016

Total Malfunctions	**601**
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	**30**
Battery Malfunction	4
Electrical Component	26

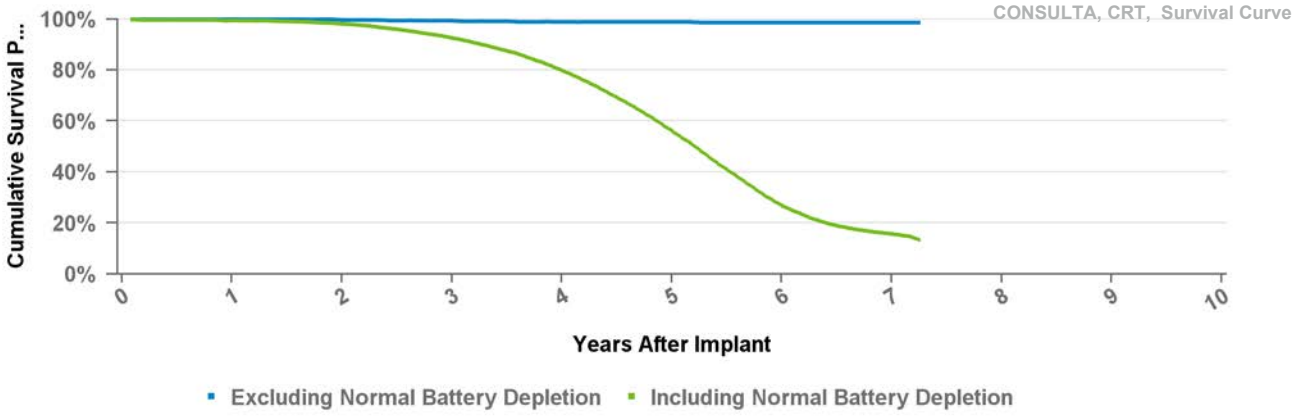


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.995	0.981	0.926	0.798	0.561	0.268	0.157	0.133
Effective Sample Size	58003	52868	45930	35390	20225	6674	1509	287

D234TRK Consulta CRT-D

US Market Release	
CE Approval Date	Mar-08
Registered USA Implants	3
Estimated Active USA Implants	1
Normal Battery Depletions	0

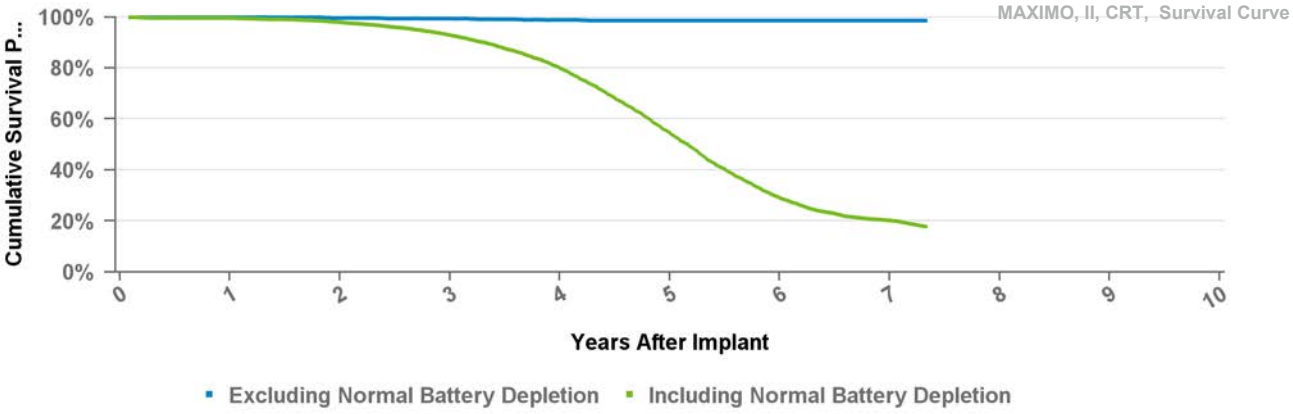
Total Malfunctions	**0**
Therapy Function Not Compromised	**0**
Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	1	0.997	0.993	0.989	0.988	0.987	0.987	0.987
Including NBD	0.995	0.981	0.926	0.798	0.561	0.268	0.157	0.133
Effective Sample Size	58003	52868	45930	35390	20225	6674	1509	287

D264TRM Maximo II CRT-D

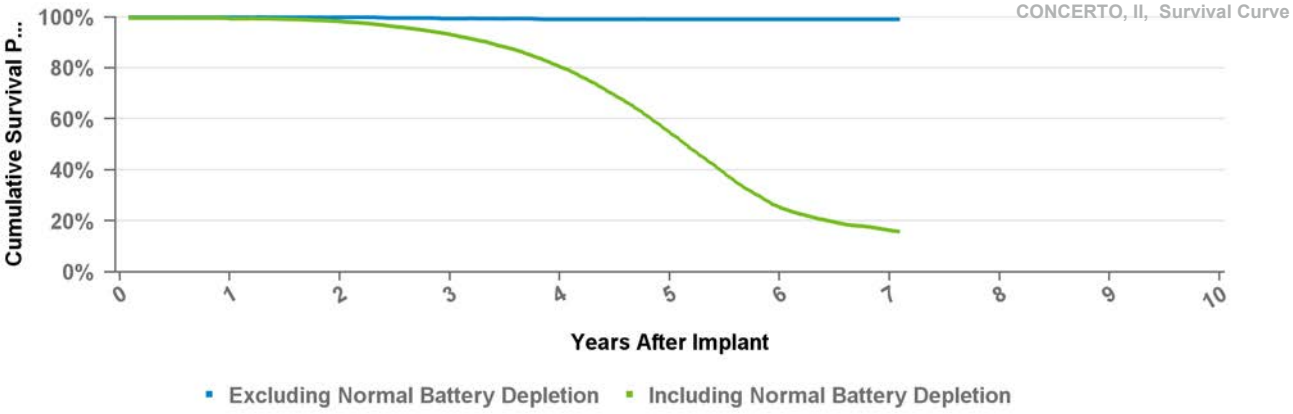
US Market Release	Jan-12	**Total Malfunctions**	**1**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other Malfunction	1
Estimated Active USA Implants	4	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	1	0.997	0.994	0.988	0.987	0.987	0.987	0.987
Including NBD	0.996	0.98	0.929	0.8	0.545	0.29	0.202	0.177
Effective Sample Size	12930	11681	10180	7782	4187	1468	382	111

D274TRK Concerto II CRT-D

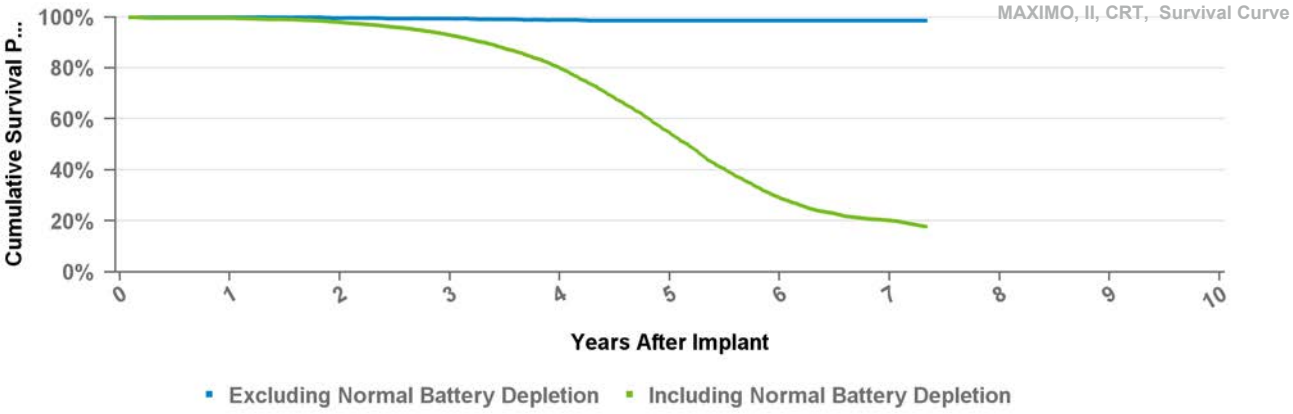
US Market Release	Aug-09	**Total Malfunctions**	**184**
CE Approval Date		**Therapy Function Not Compromised**	**174**
Registered USA Implants	30,174	Battery Malfunction	1
Estimated Active USA Implants	6,381	Electrical Component	21
Normal Battery Depletions	8,566	Poss Early Battery Depltn	151
		Software Malfunction	1
		Therapy Function Compromised	**10**
		Battery Malfunction	1
		Electrical Component	9



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	1	0.998	0.995	0.992	0.991	0.991	0.991	0.991
Including NBD	0.995	0.983	0.932	0.805	0.546	0.253	0.163	0.158
Effective Sample Size	25421	23240	20260	15510	8438	2997	501	257

D284TRK Maximo II CRT-D

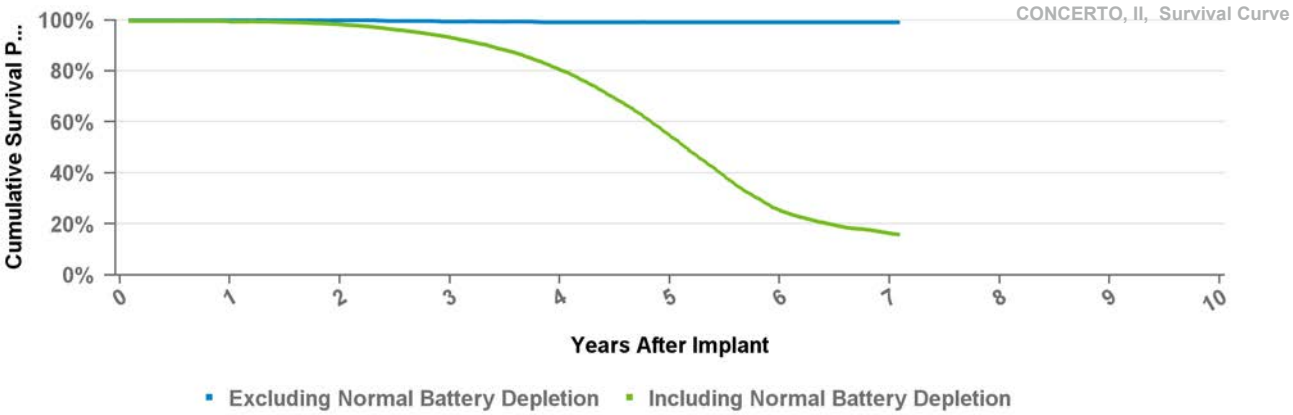
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,248	Electrical Component	6
Estimated Active USA Implants	3,362	Poss Early Battery Depltn	124
Normal Battery Depletions	4,108	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	1	0.997	0.994	0.988	0.987	0.987	0.987	0.987
Including NBD	0.996	0.98	0.929	0.8	0.545	0.29	0.202	0.177
Effective Sample Size	12930	11681	10180	7782	4187	1468	382	111

D294TRK Concerto II CRT-D

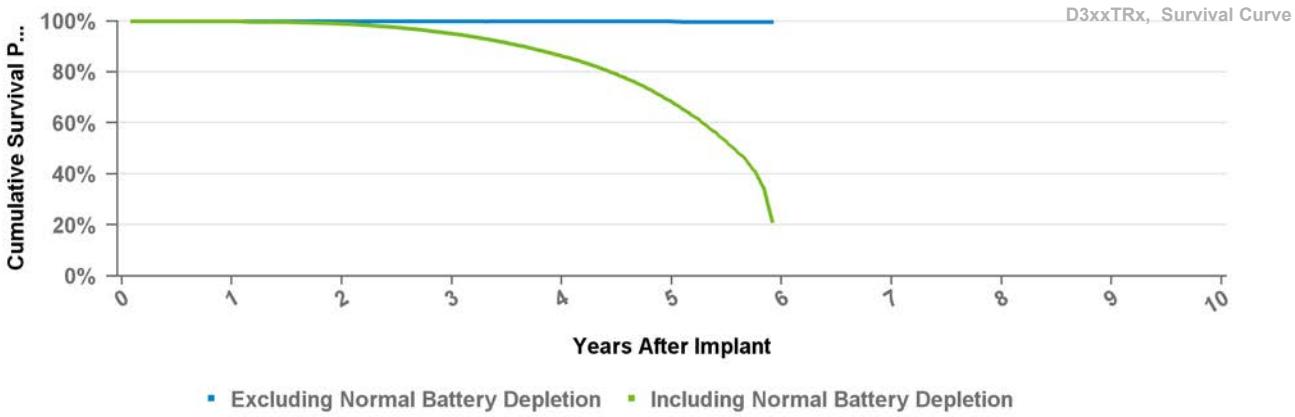
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	1	0.998	0.995	0.992	0.991	0.991	0.991	0.991
Including NBD	0.995	0.983	0.932	0.805	0.546	0.253	0.163	0.158
Effective Sample Size	25421	23240	20260	15510	8438	2997	501	257

D314TRG Protecta XT CRT-D

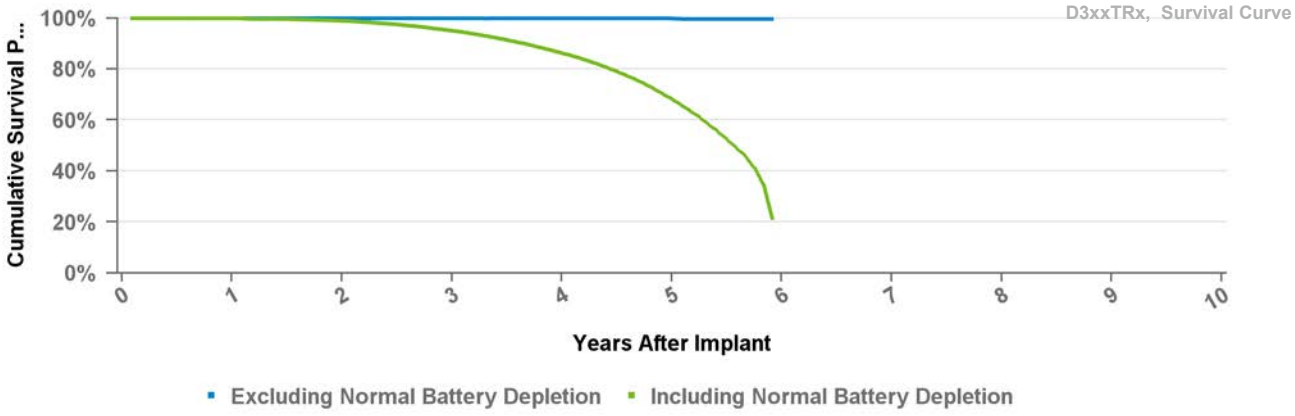
US Market Release	Mar-11	**Total Malfunctions**	**89**
CE Approval Date		**Therapy Function Not Compromised**	**73**
Registered USA Implants	42,511	Battery Malfunction	7
Estimated Active USA Implants	17,208	Electrical Component	39
Normal Battery Depletions	7,598	Other Malfunction	2
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**16**
		Battery Malfunction	8
		Electrical Component	8



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D314TRM Protecta XT CRT-D

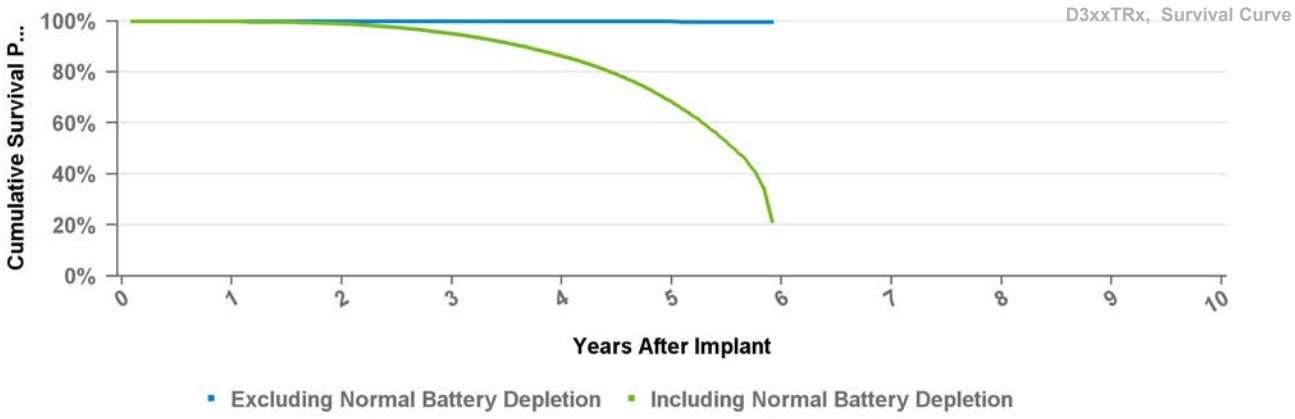
US Market Release	Nov-11	**Total Malfunctions**	**19**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,259	Battery Malfunction	4
Estimated Active USA Implants	6,228	Electrical Component	8
Normal Battery Depletions	1,837	Poss Early Battery Depltn	5
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D334TRG Protecta CRT-D

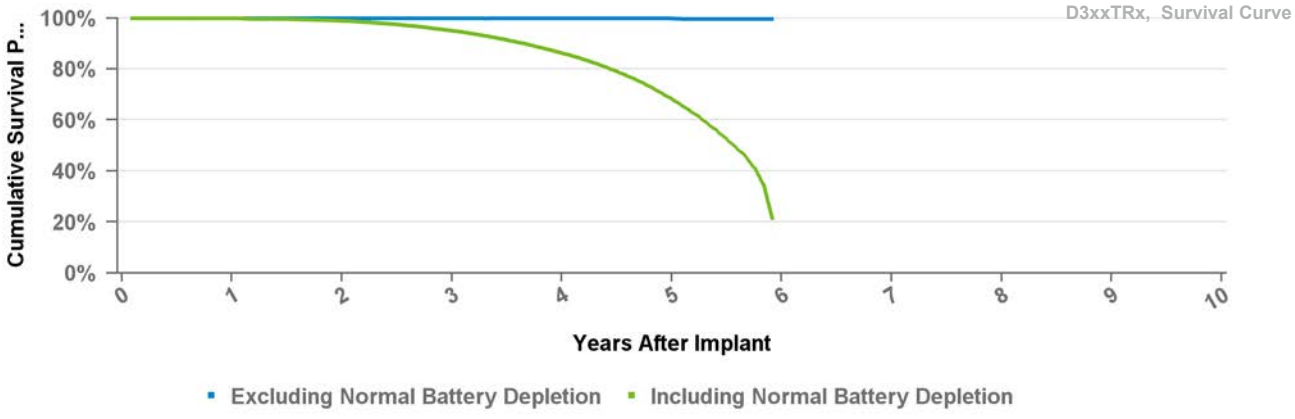
US Market Release	Mar-11	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,099	Electrical Component	8
Estimated Active USA Implants	3,592	Poss Early Battery Depltn	3
Normal Battery Depletions	1,433	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D334TRM Protecta CRT-D

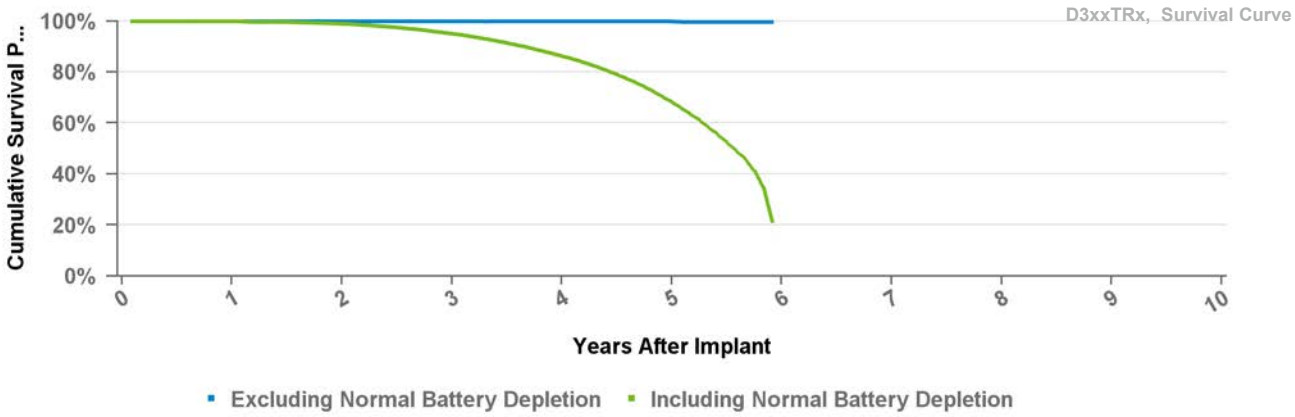
US Market Release	Nov-11	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	1,783	Battery Malfunction	3
Estimated Active USA Implants	895	Electrical Component	1
Normal Battery Depletions	302	Poss Early Battery Depltn	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D354TRG Protecta XT CRT-D

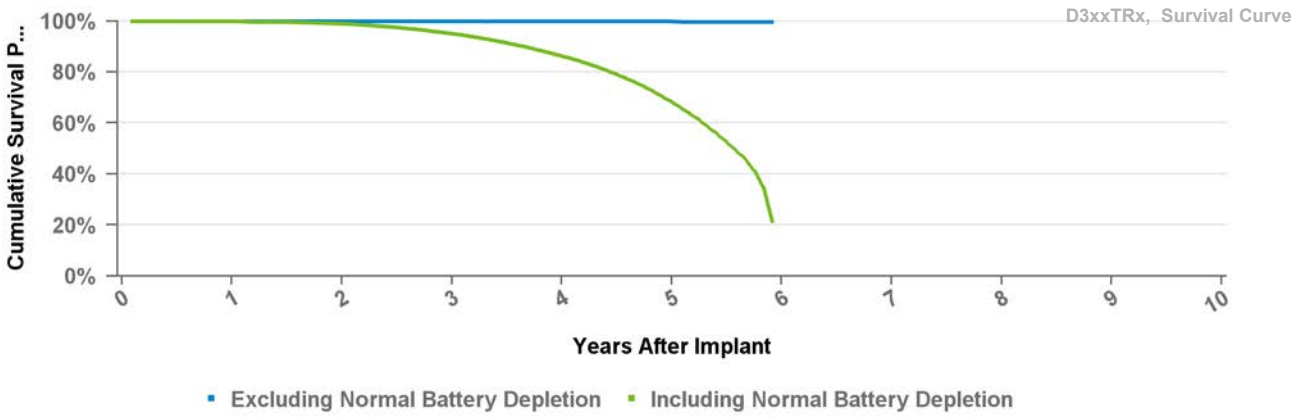
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D354TRM Protecta XT CRT-D

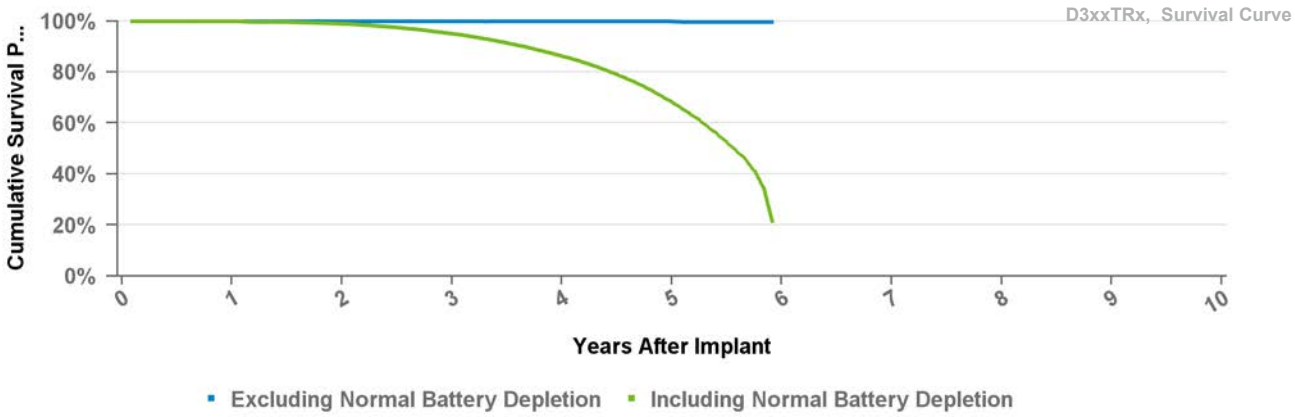
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D364TRG Protecta CRT-D

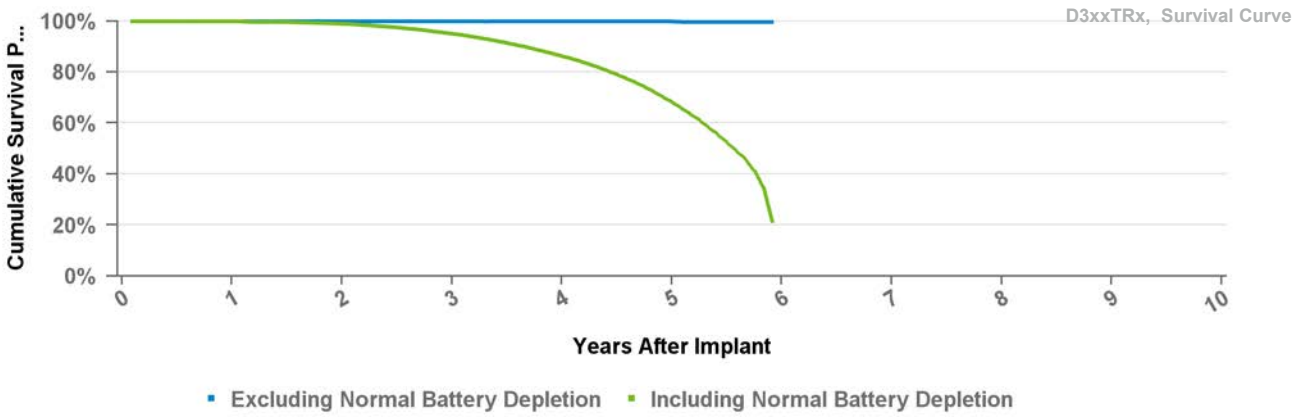
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D364TRM Protecta CRT-D

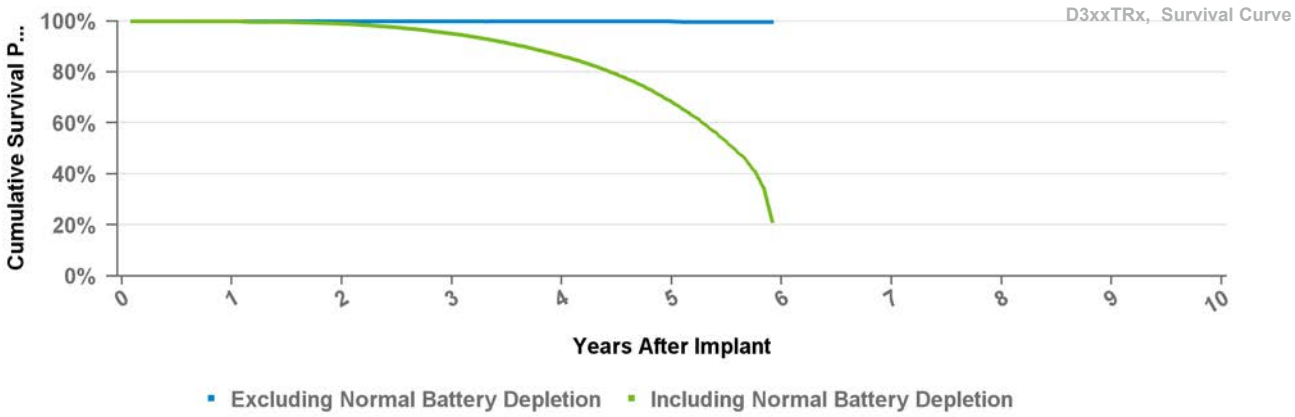
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D384TRG Cardia CRT-D

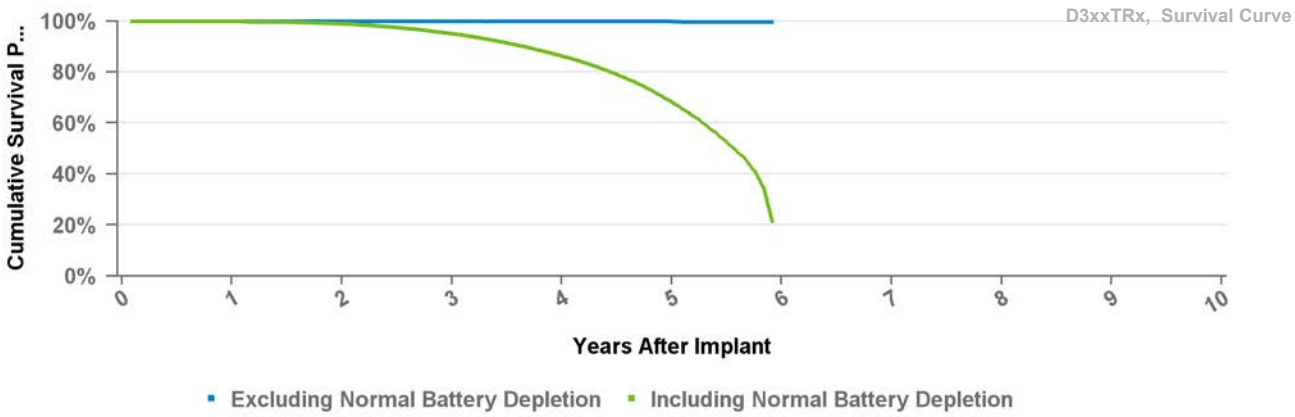
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

D394TRG Egida CRT-D

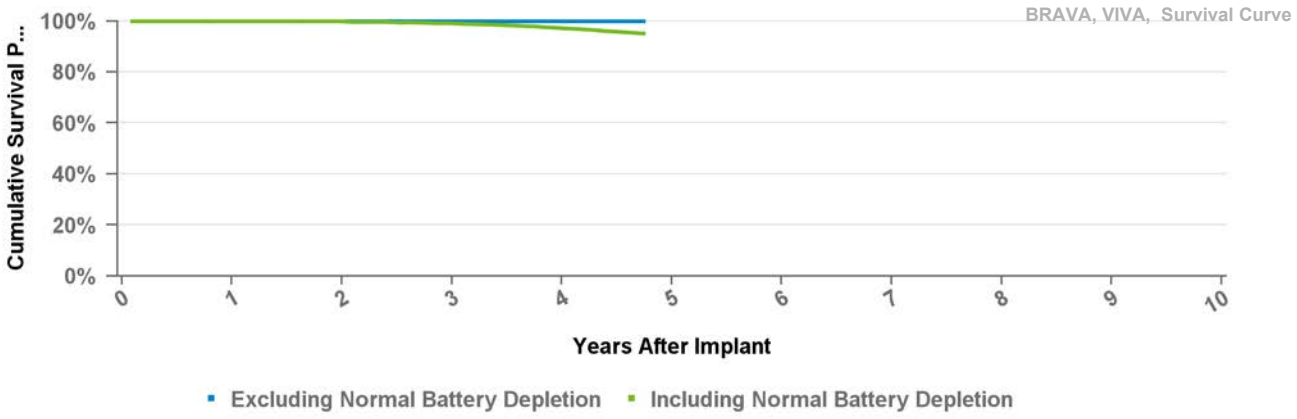
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	at 71 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.989	0.95	0.862	0.682	0.213
Effective Sample Size	56197	51747	45558	36116	19225	563

DTBA1D1 Viva XT

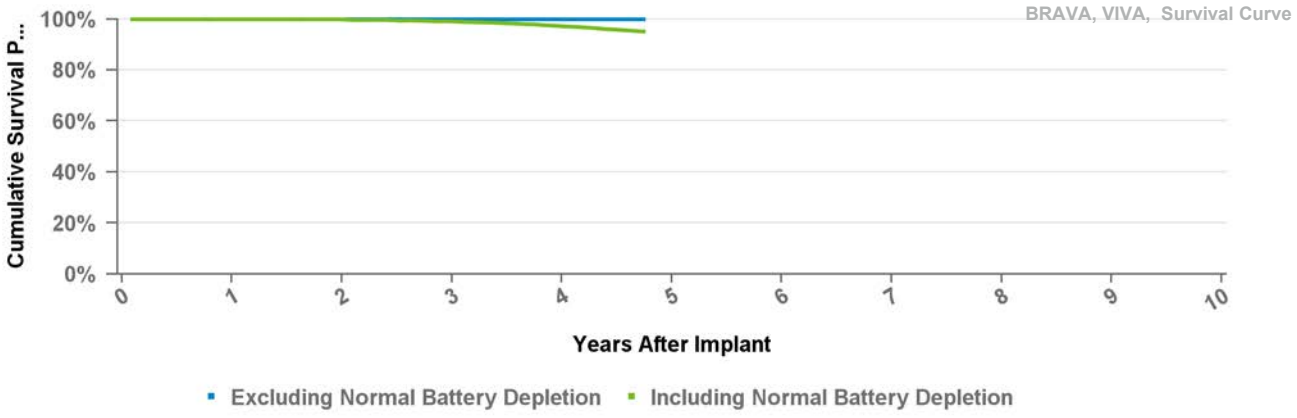
US Market Release	Jan-13	**Total Malfunctions**	**33**
CE Approval Date		**Therapy Function Not Compromised**	**28**
Registered USA Implants	54,982	Battery Malfunction	2
Estimated Active USA Implants	47,868	Electrical Component	26
Normal Battery Depletions	403	**Therapy Function Compromised**	**5**
		Battery Malfunction	4
		Electrical Component	1



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBA1D4 Viva XT

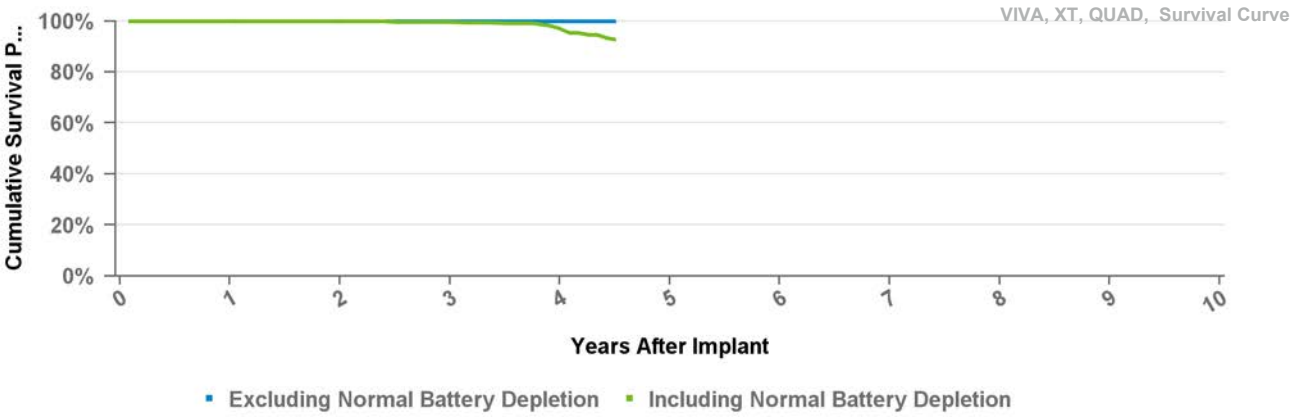
US Market Release	Jan-13	**Total Malfunctions**	**16**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	19,126	Battery Malfunction	2
Estimated Active USA Implants	16,787	Electrical Component	10
Normal Battery Depletions	136	Poss Early Battery Depltn	1
		Therapy Function Compromised	**3**
		Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBA1Q1 Viva Quad XT

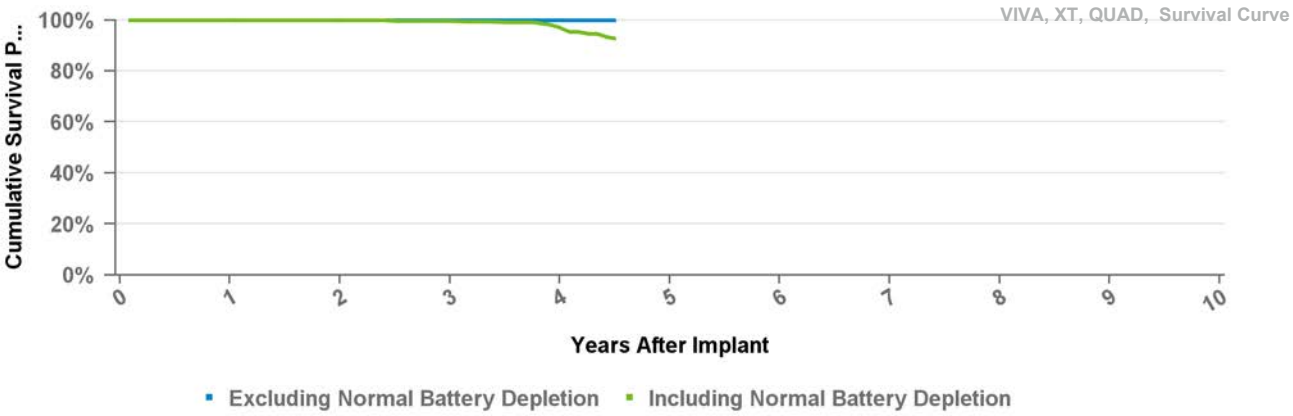
US Market Release	Jul-14	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	10,456	Electrical Component	2
Estimated Active USA Implants	9,448	Other Malfunction	1
Normal Battery Depletions	20	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTBA1QQ Viva Quad XT

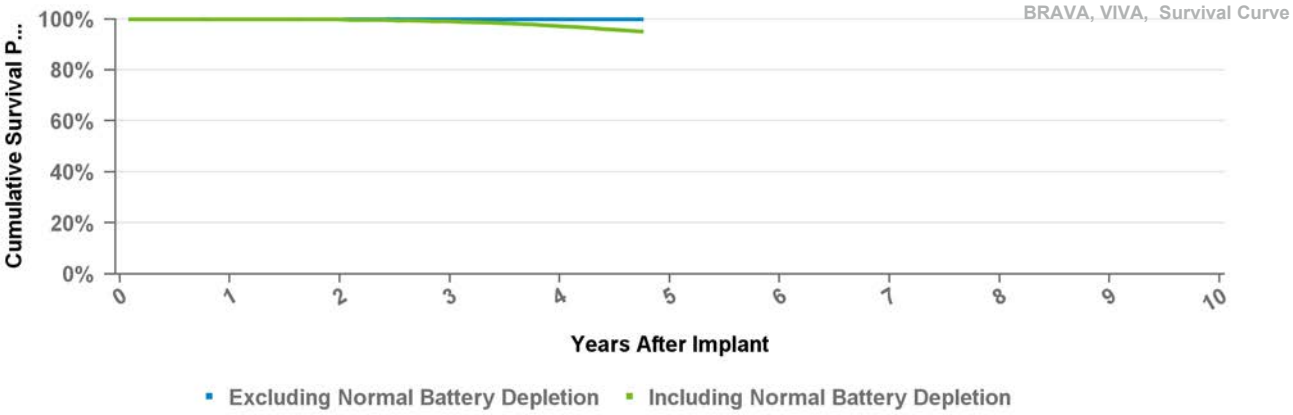
US Market Release	Jul-14	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	26,252	Electrical Component	12
Estimated Active USA Implants	24,637	Electrical Interconnect	1
Normal Battery Depletions	49	**Therapy Function Compromised**	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTBA2D1 Viva XT

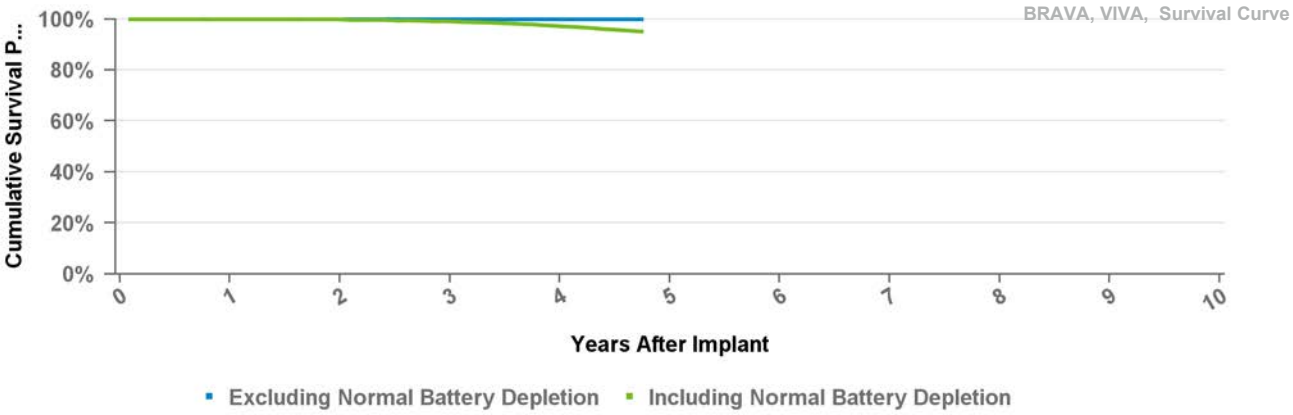
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBA2D4 Viva XT

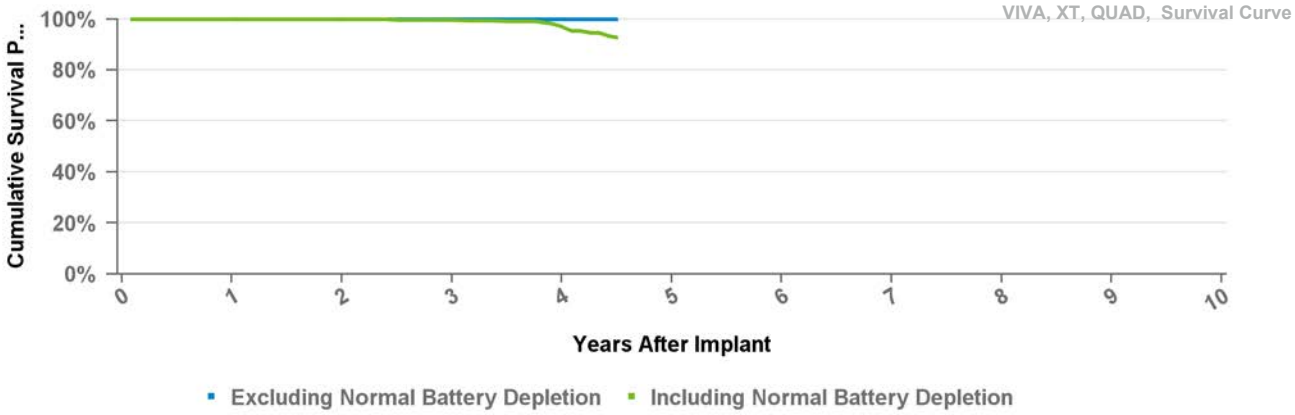
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBA2Q1 Viva Quad XT

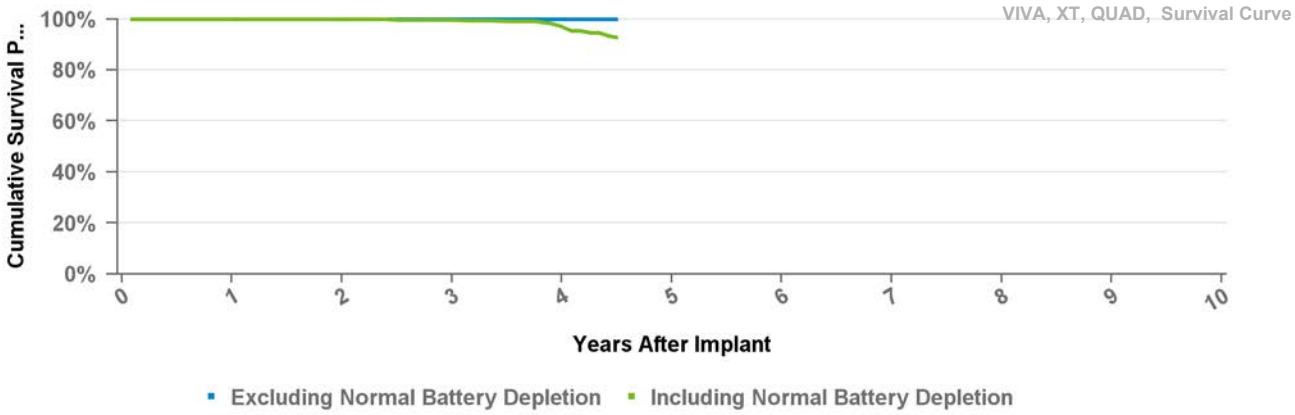
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTBA2QQ Viva Quad XT

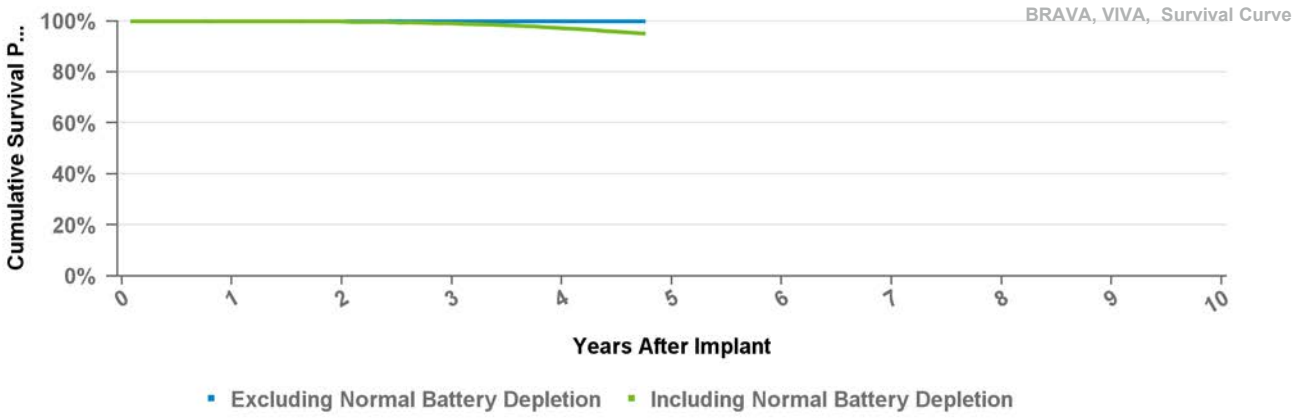
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTBB1D1 Viva S

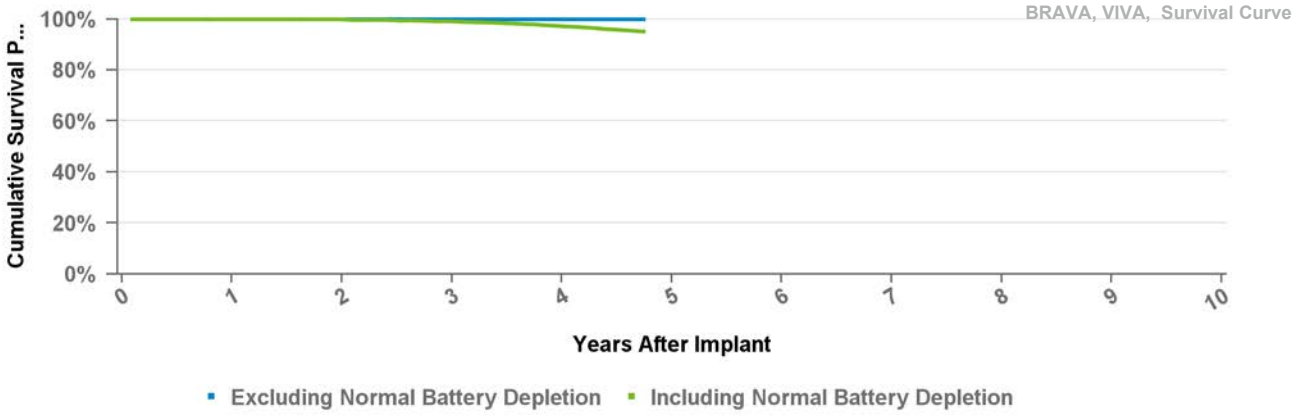
US Market Release	Jan-13	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	13,521	Battery Malfunction	3
Estimated Active USA Implants	11,434	Electrical Component	3
Normal Battery Depletions	150	Poss Early Battery Depltn	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB1D4 Viva S

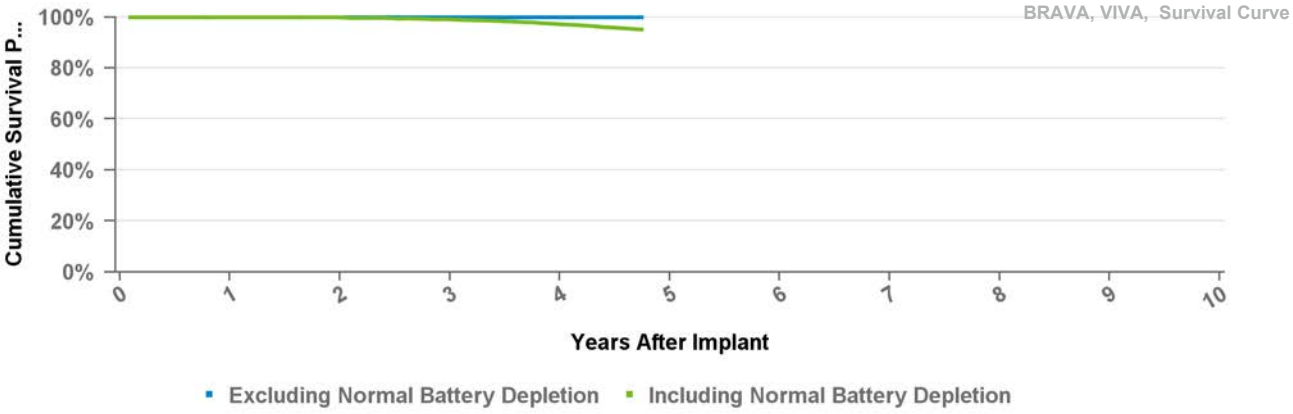
US Market Release	Jan-13	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,298	Other Malfunction	1
Estimated Active USA Implants	3,757	**Therapy Function Compromised**	**2**
Normal Battery Depletions	49	Battery Malfunction	2



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB1Q1 Viva Quad S

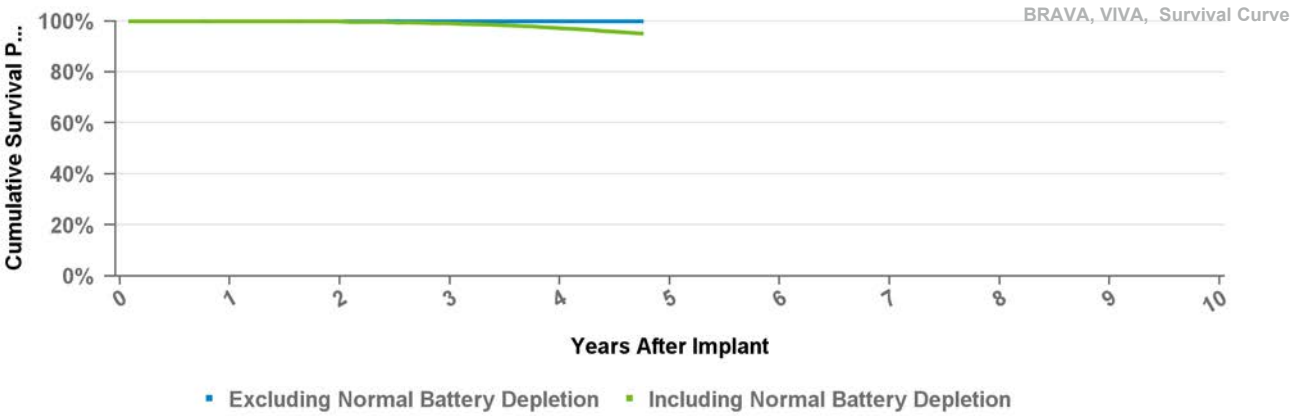
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,135	Electrical Component	1
Estimated Active USA Implants	1,937	**Therapy Function Compromised**	**0**
Normal Battery Depletions	3		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB1QQ Viva Quad S

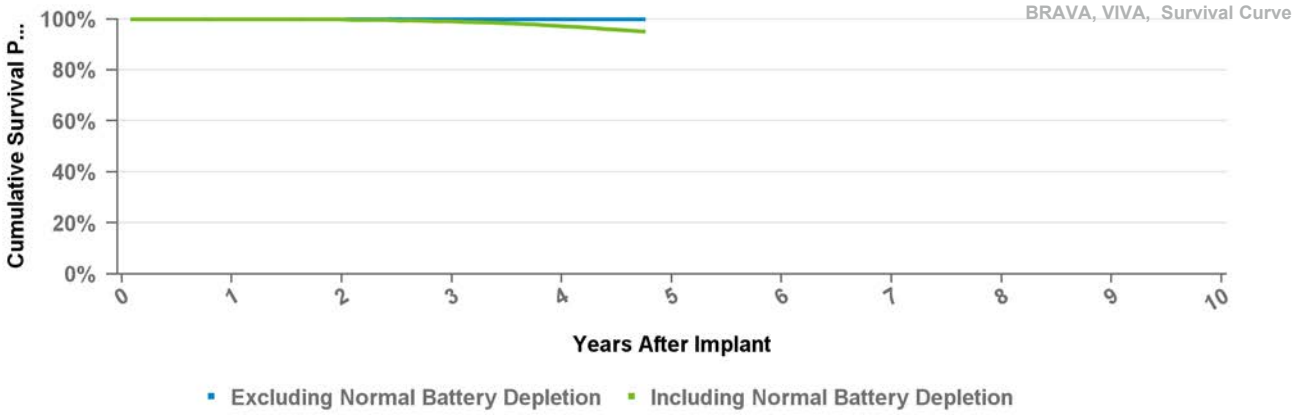
US Market Release	Jul-14	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,817	Electrical Component	2
Estimated Active USA Implants	4,506	Poss Early Battery Depltn	1
Normal Battery Depletions	8	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB2D1 Viva S

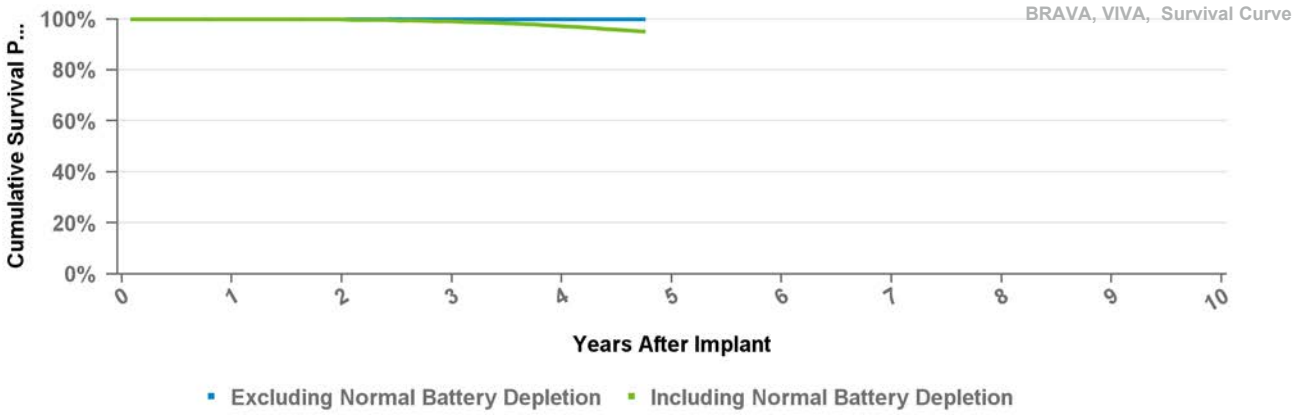
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB2D4 Viva S

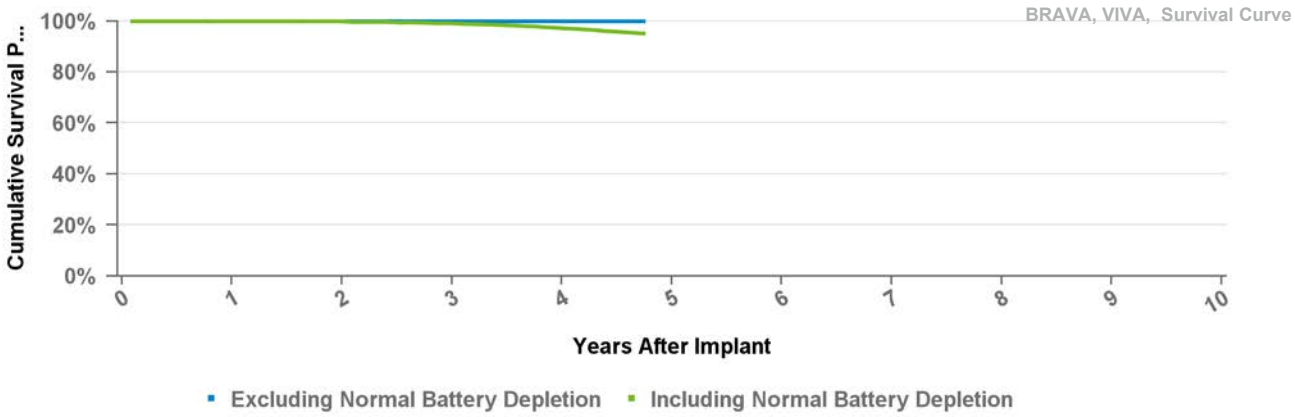
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBB2QQ Viva Quad S

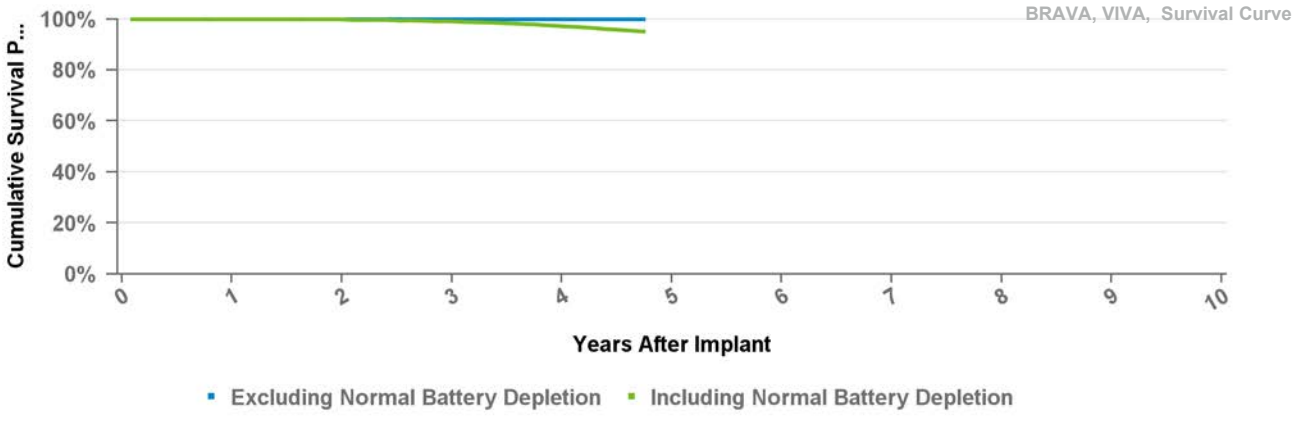
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBC2D1 Brava

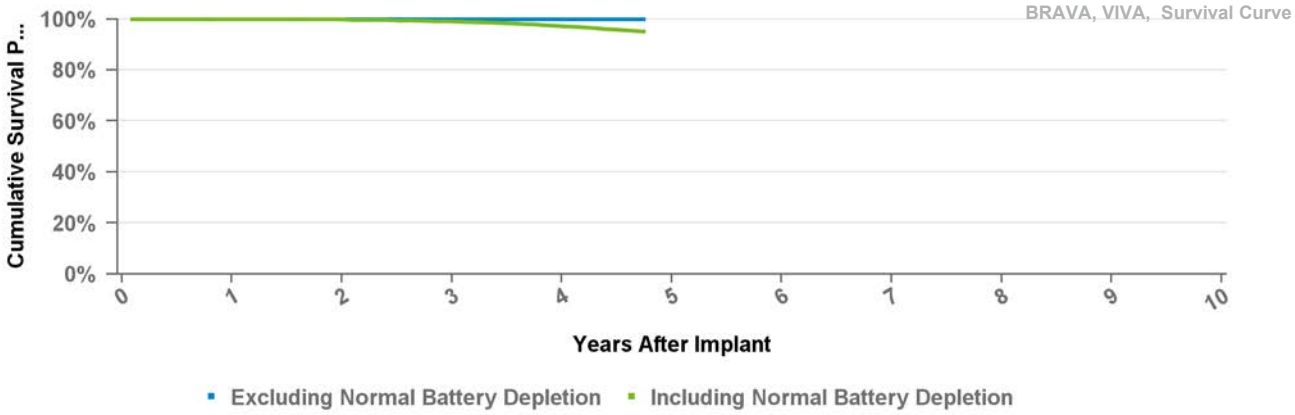
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBC2D4 Brava

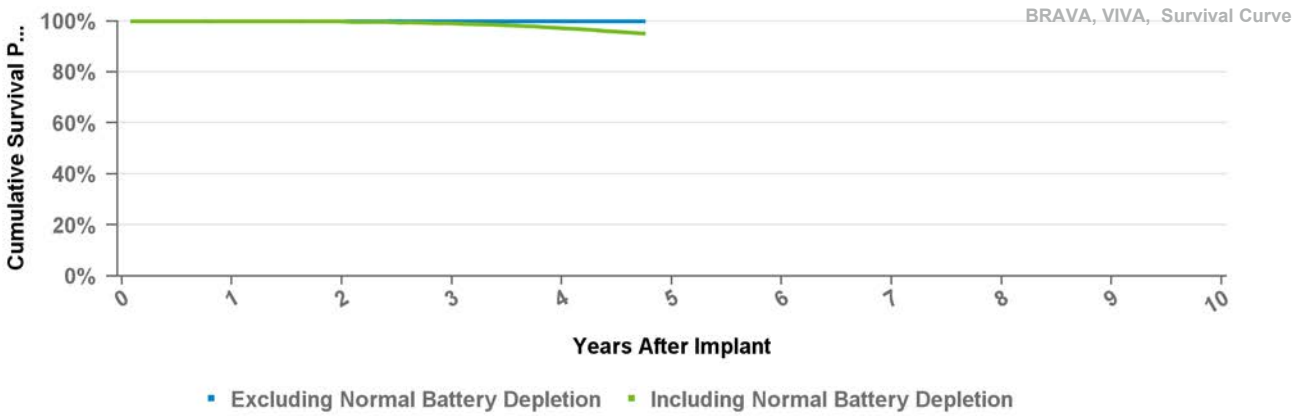
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBC2Q1 Brava Quad

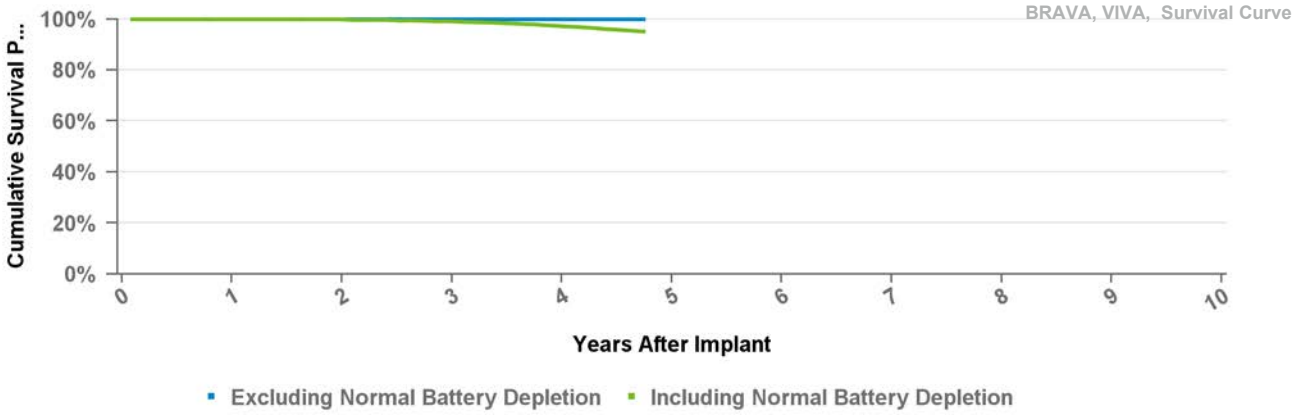
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBC2QQ Brava Quad

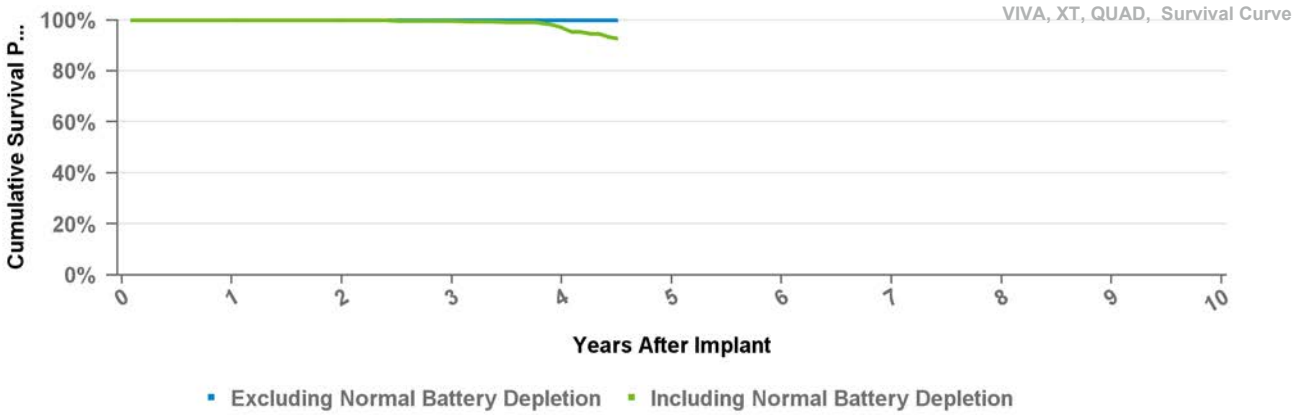
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 57 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	0.999	0.998	0.991	0.972	0.951
Effective Sample Size	85672	66175	42511	17587	904

DTBX1QQ Viva Quad C

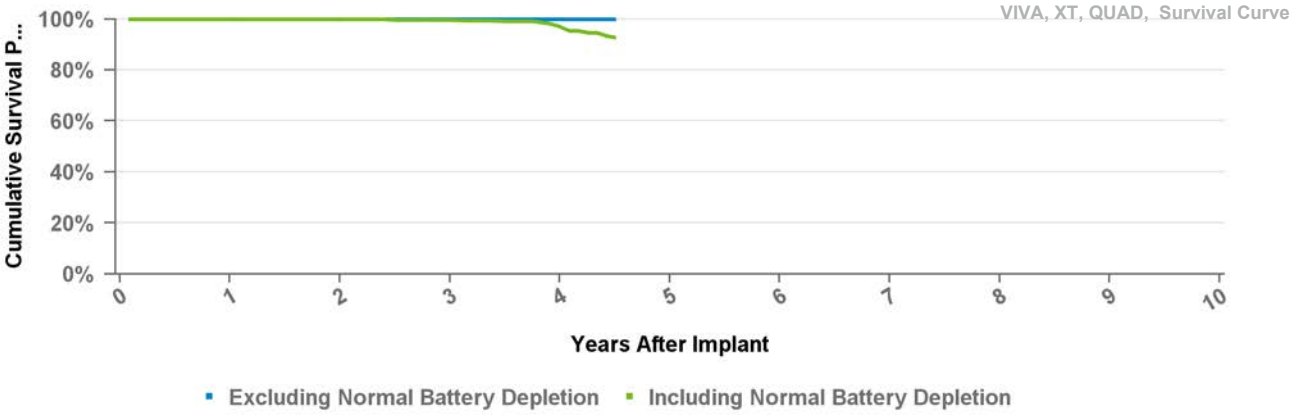
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	637	Electrical Component	1
Estimated Active USA Implants	536	**Therapy Function Compromised**	**0**
Normal Battery Depletions	12		



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTBX2QQ Viva Quad C

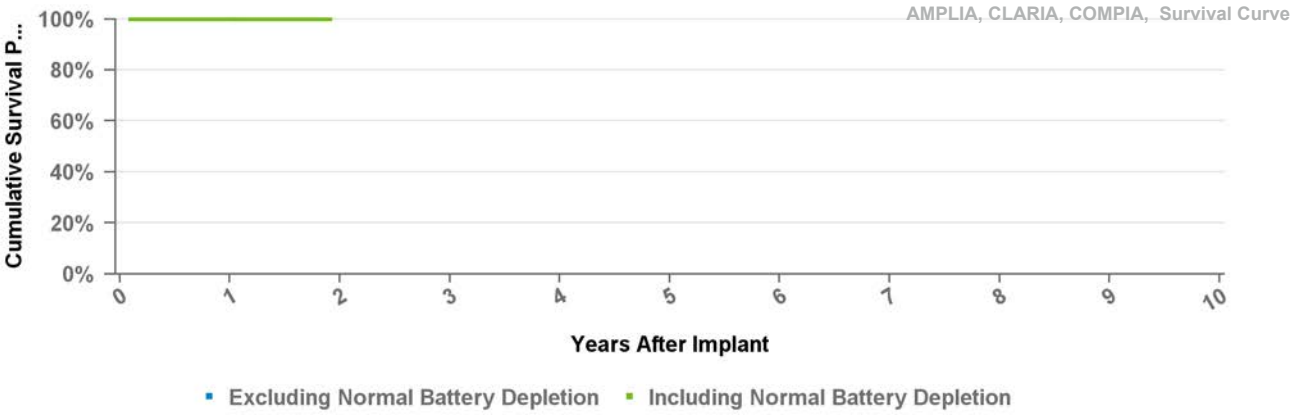
US Market Release	Jul-14	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 54 mo
Excluding NBD	1	1	1	1	1
Including NBD	1	0.998	0.996	0.97	0.927
Effective Sample Size	32838	25763	9821	177	134

DTMA1D1 Claria MRI

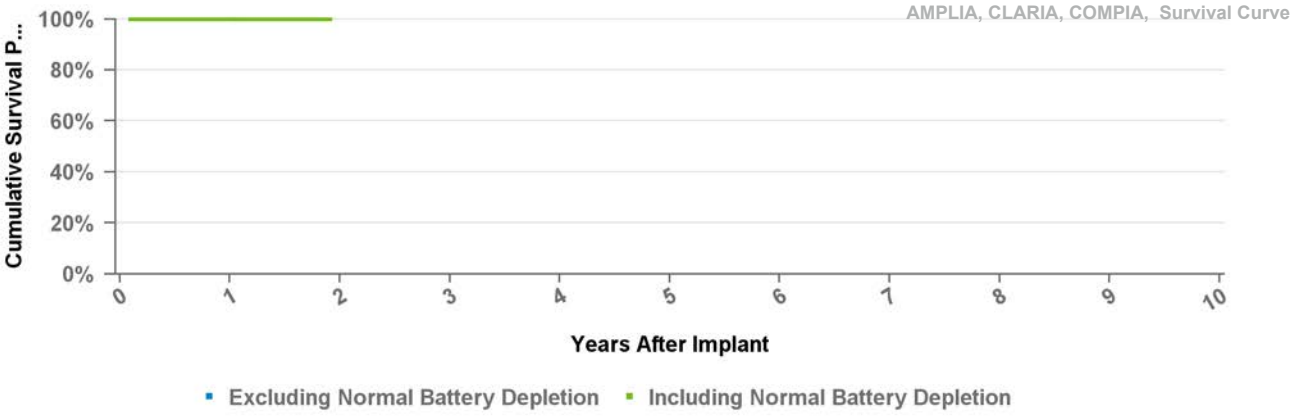
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,487		
Estimated Active USA Implants	2,438	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMA1D4 Claria MRI

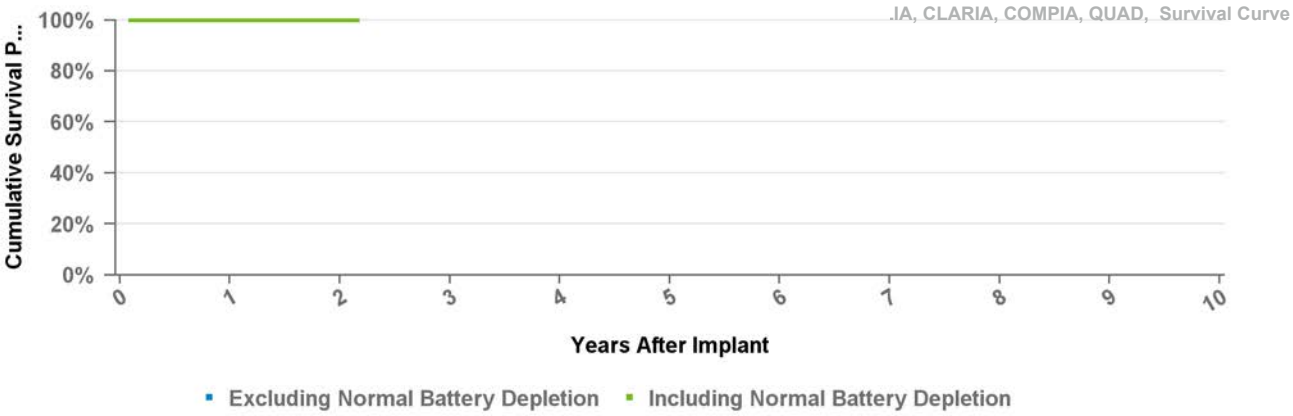
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,785		
Estimated Active USA Implants	1,754	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMA1Q1 Claria MRI

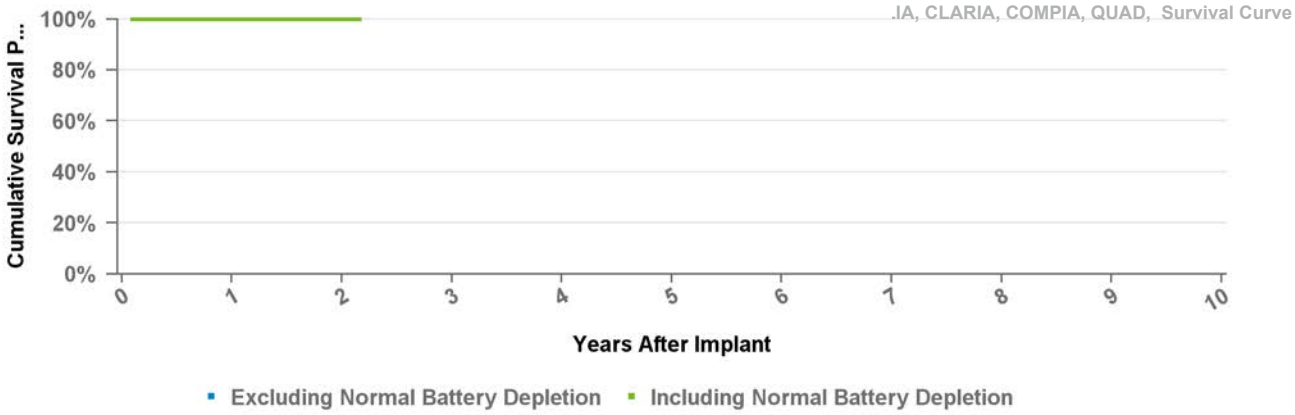
US Market Release	Dec-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,524	Other Malfunction	1
Estimated Active USA Implants	1,495	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMA1QQ Claria MRI

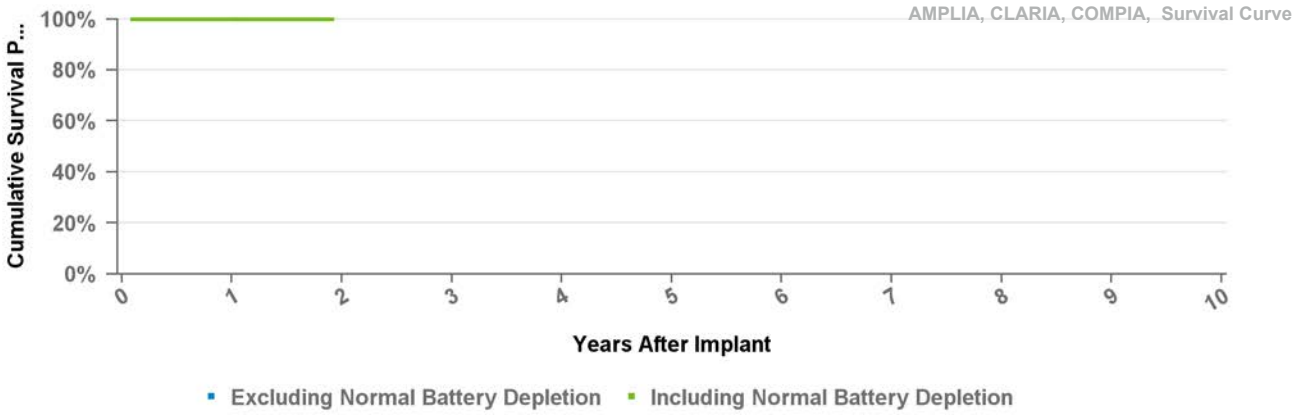
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	9,318		
Estimated Active USA Implants	9,172	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMA2D1 Claria MRI

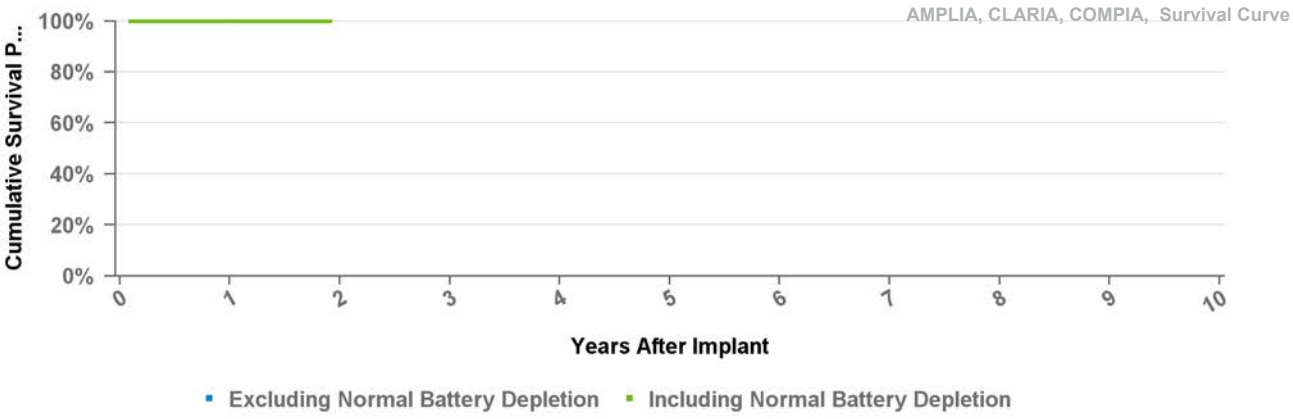
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMA2D4 Claria MRI

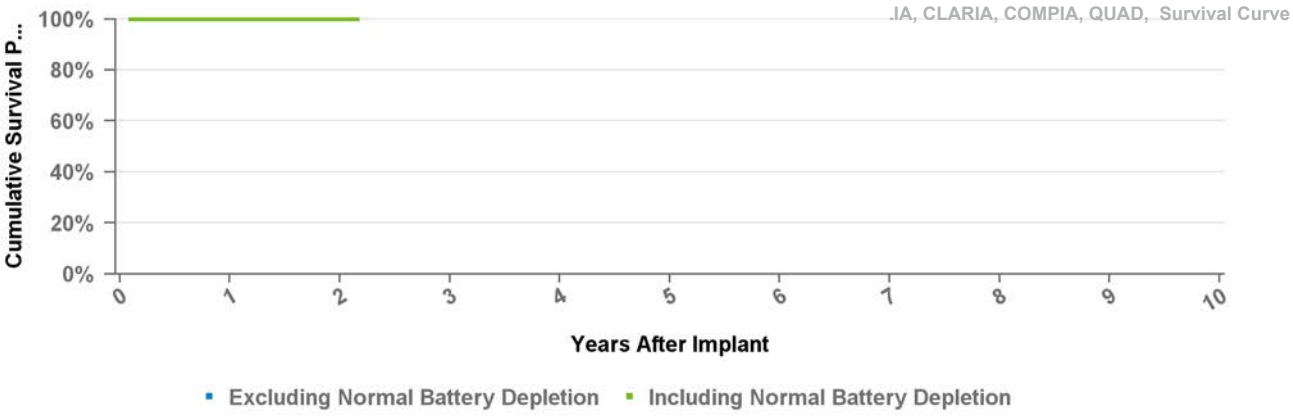
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMA2Q1 Claria MRI

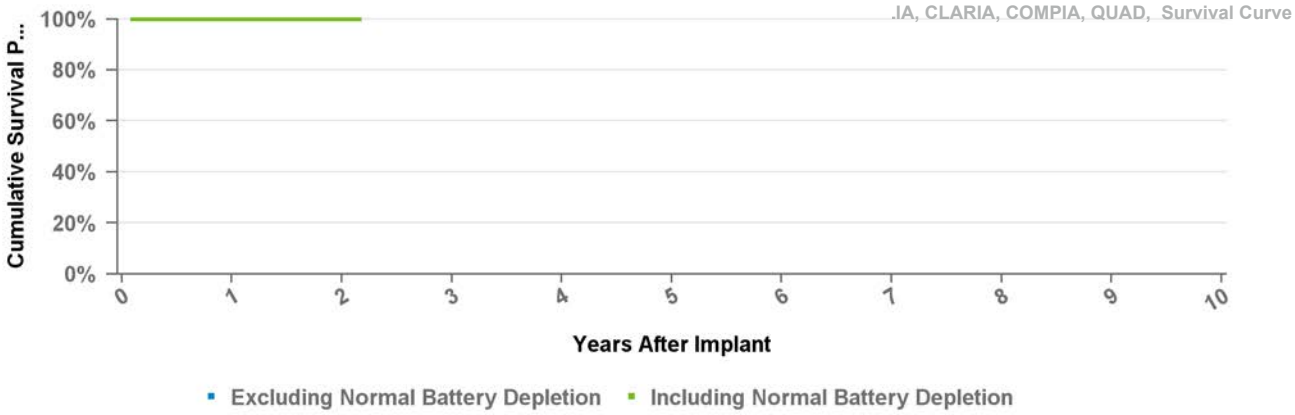
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMA2QQ Claria MRI

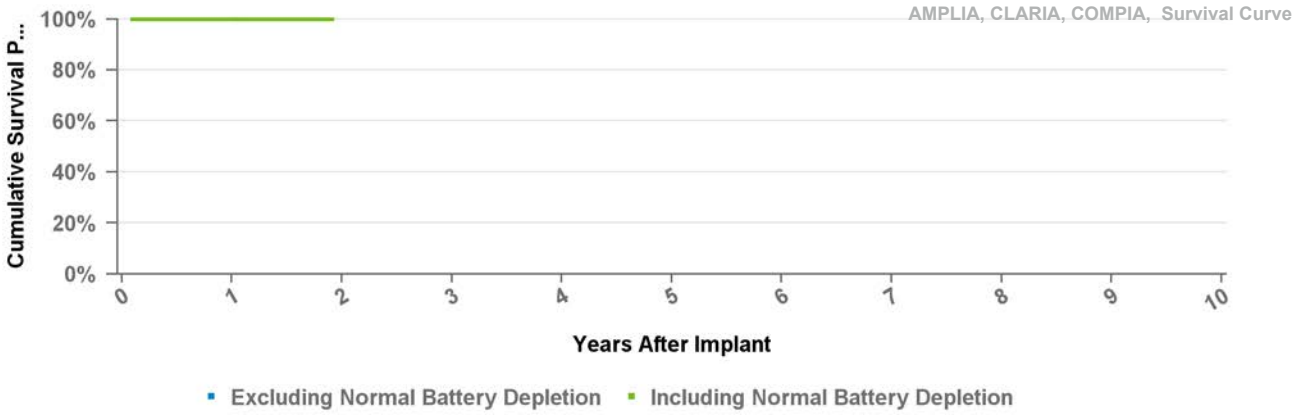
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMB1D1 Amplia MRI

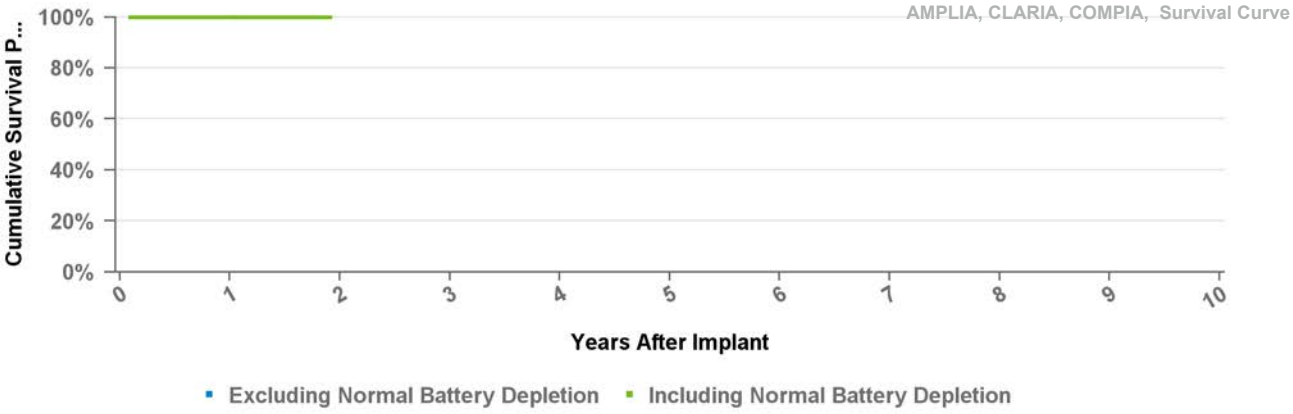
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,919		
Estimated Active USA Implants	2,853	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMB1D4 Amplia MRI

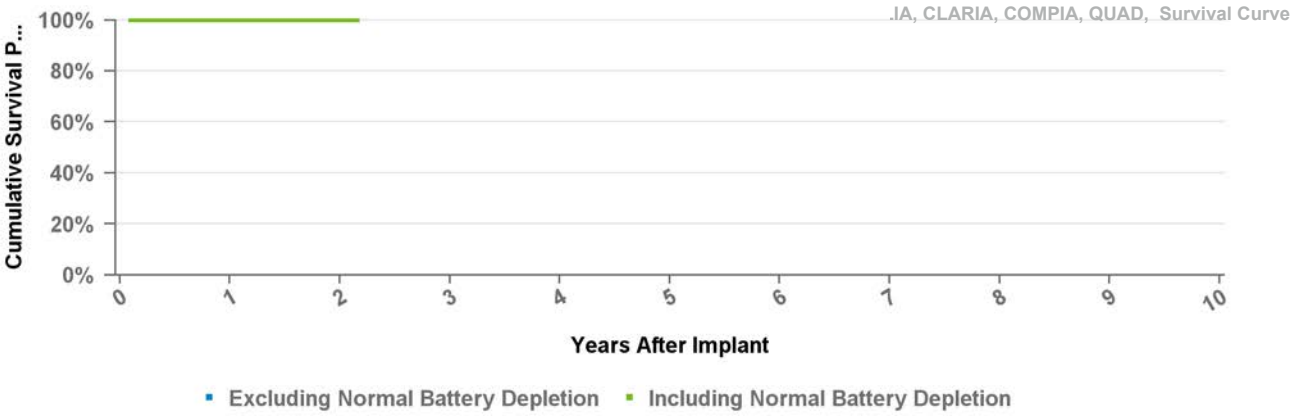
US Market Release	Feb-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,407	Electrical Component	1
Estimated Active USA Implants	3,303	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMB1Q1 Amplia MRI

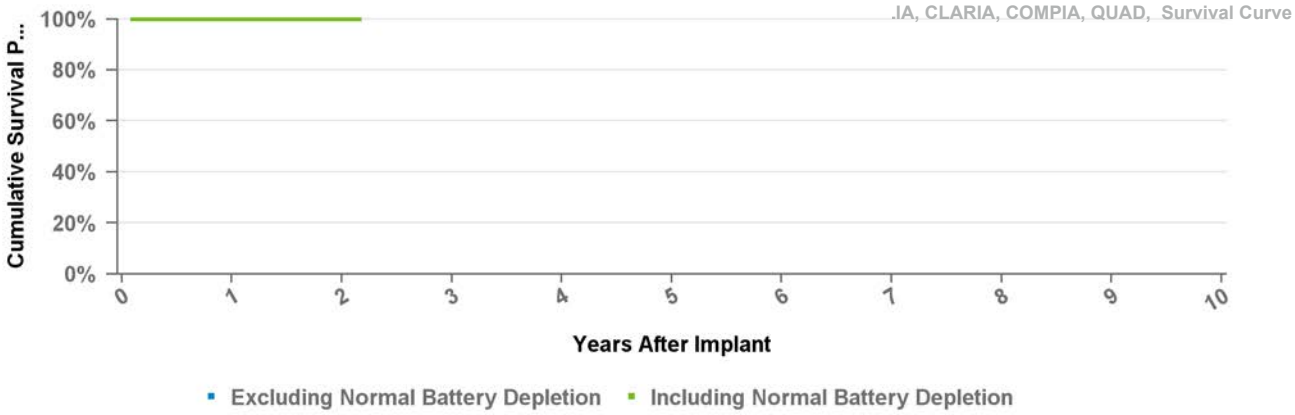
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,555		
Estimated Active USA Implants	1,507	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMB1QQ Amplia MRI

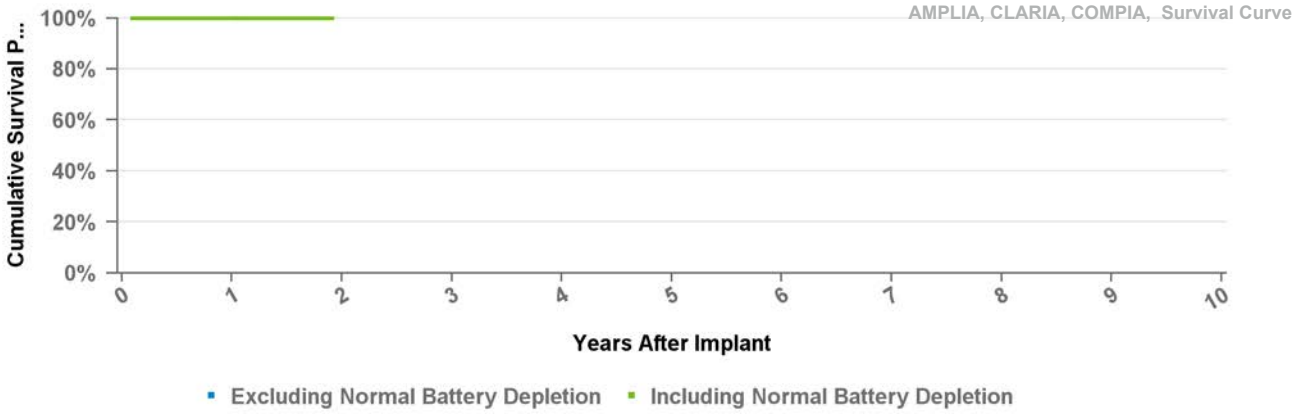
US Market Release	Feb-16	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	19,489	Electrical Component	4
Estimated Active USA Implants	18,938	Other Malfunction	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**0**



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMB2D1 Amplia MRI

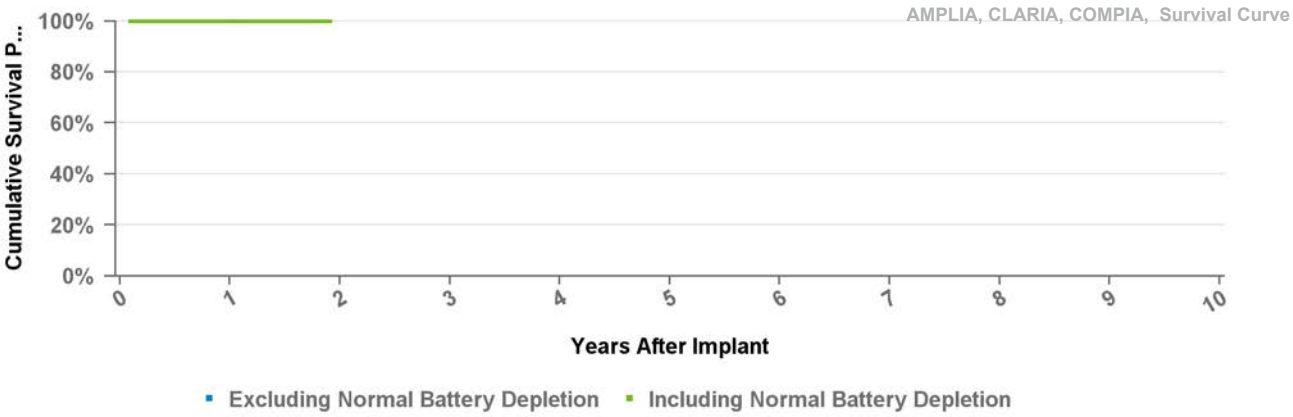
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMB2D4 Amplia MRI

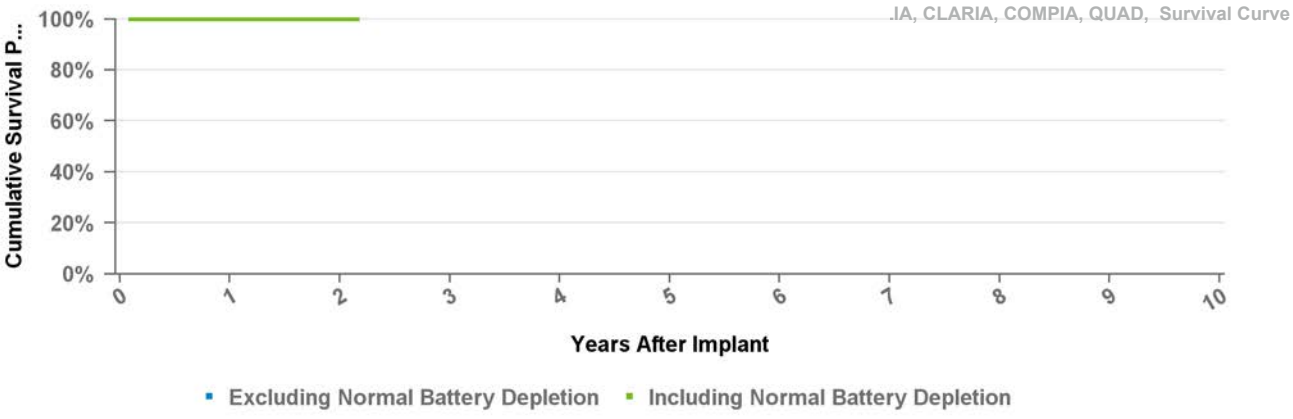
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMB2Q1 Amplia MRI

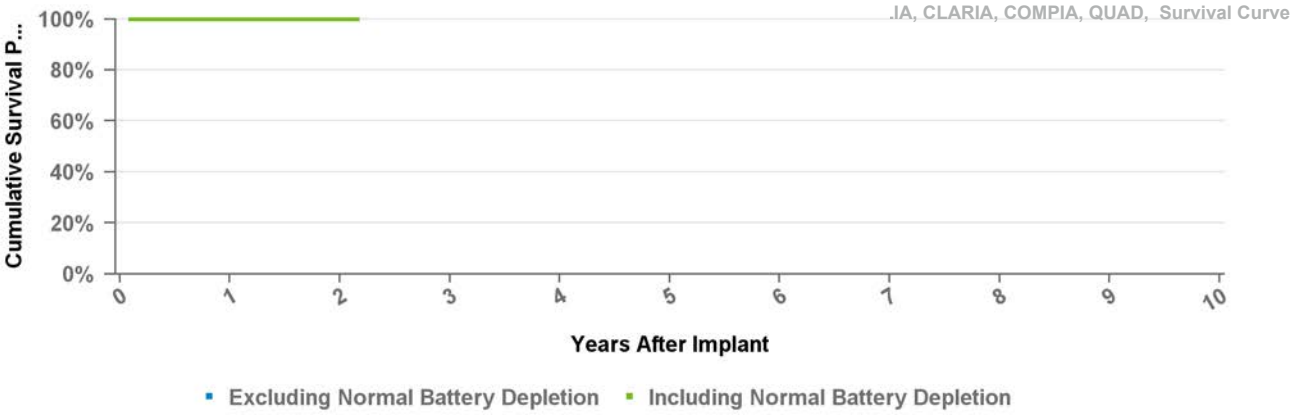
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMB2QQ Amplia MRI

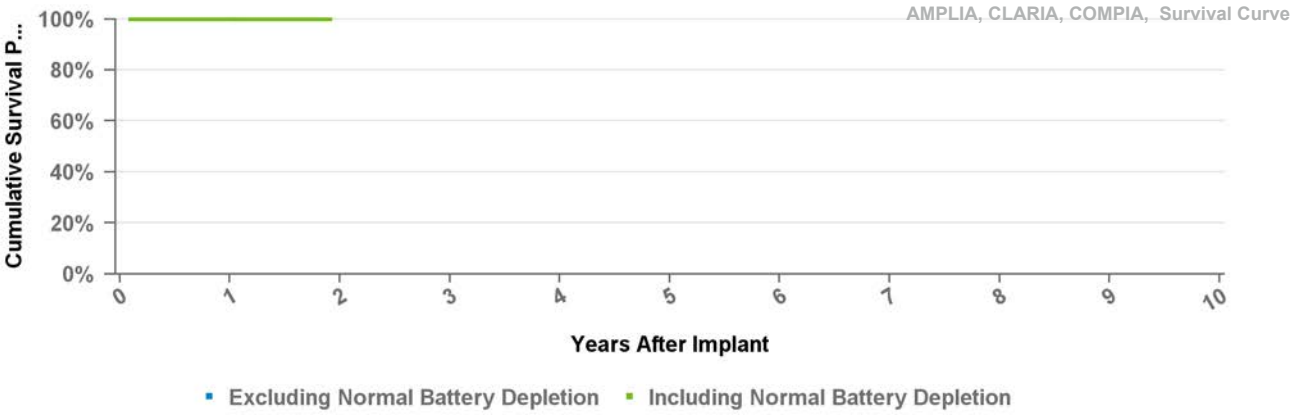
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMC1D1 Compia MRI

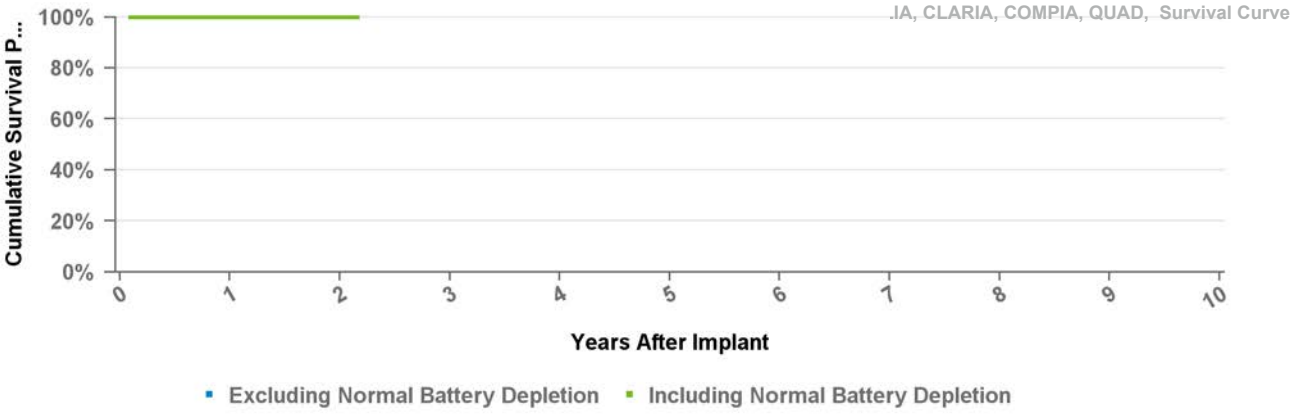
US Market Release	Dec-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	254		
Estimated Active USA Implants	252	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMC1QQ Compia MRI

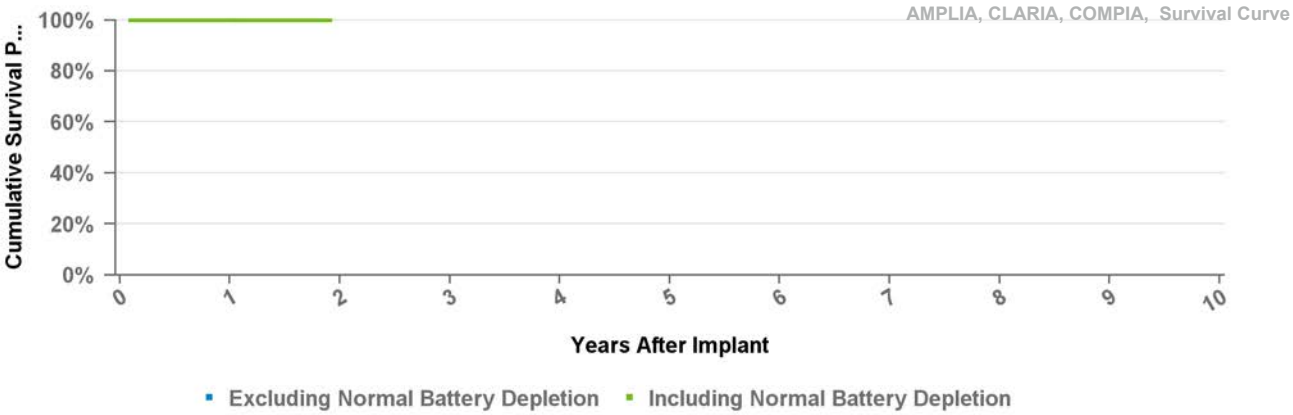
US Market Release	Feb-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	1,774	Electrical Component	2
Estimated Active USA Implants	1,731	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

DTMC2D1 Compia MRI

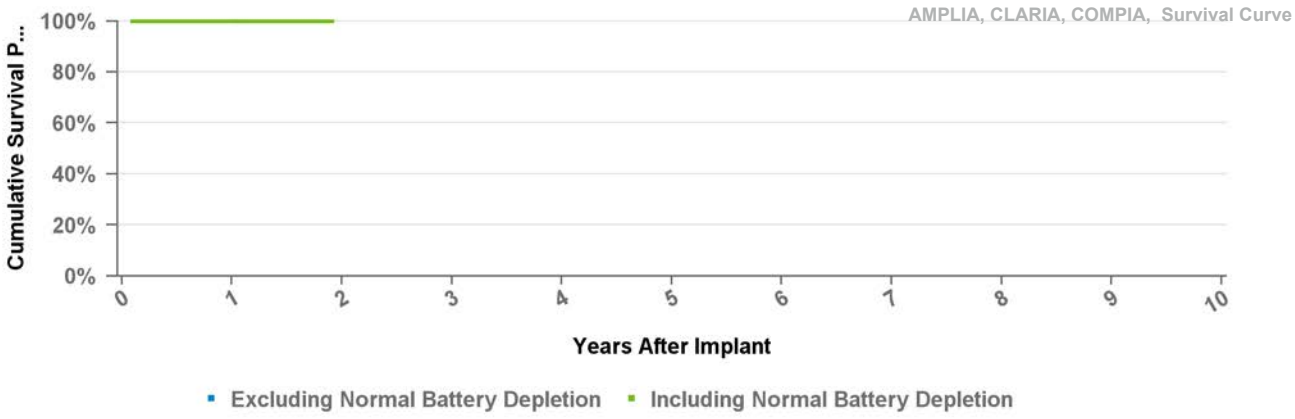
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMC2D4 Compia MRI

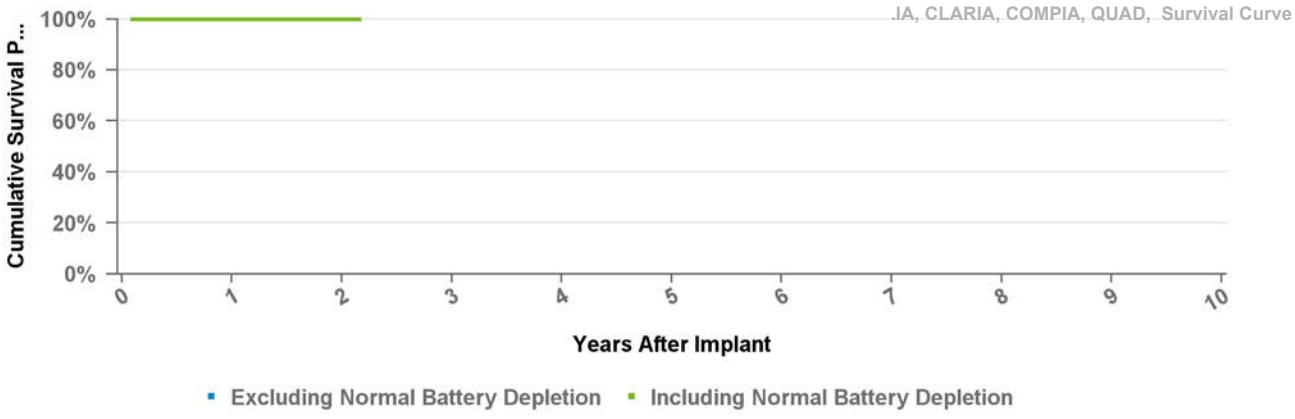
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 23 mo
Excluding NBD	1	1
Including NBD	1	0.999
Effective Sample Size	2881	131

DTMC2QQ Compia MRI

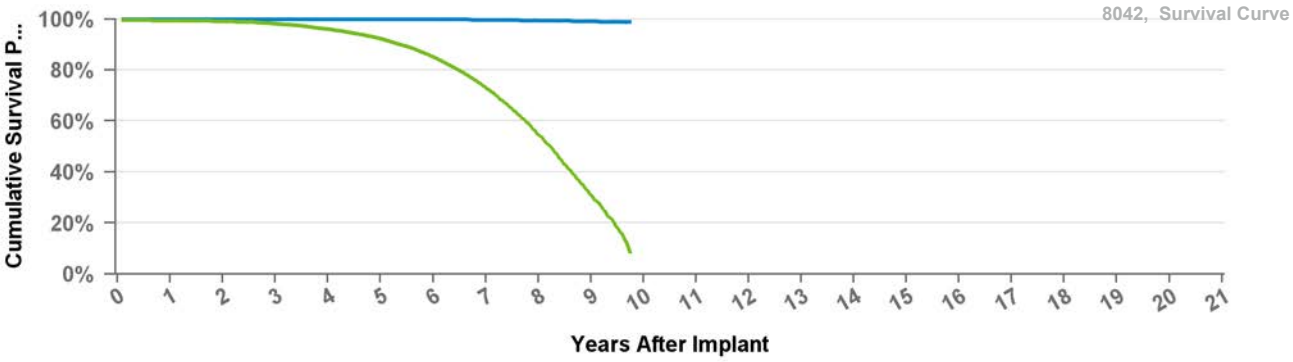
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	at 26 mo
Excluding NBD	1	1	1
Including NBD	1	1	1
Effective Sample Size	14993	1146	114

8042 InSync III

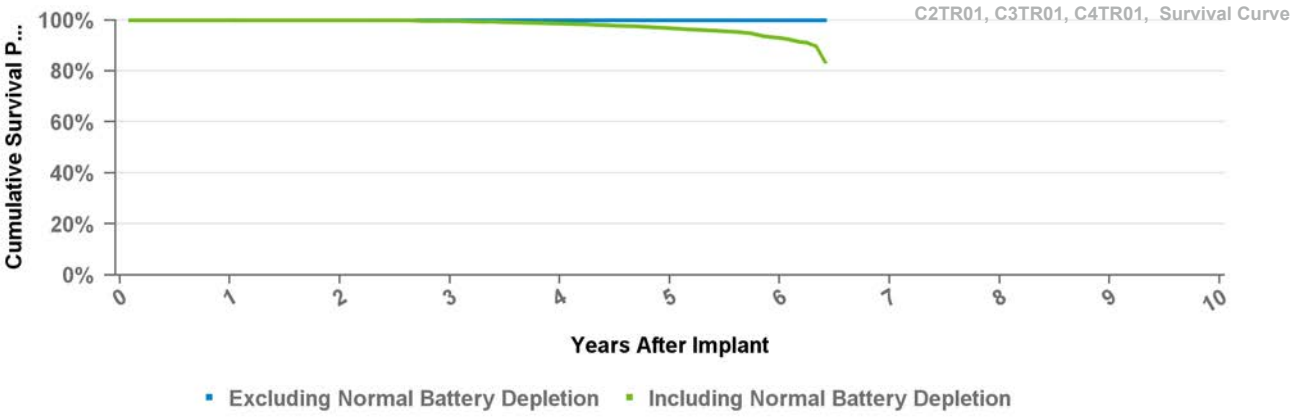
US Market Release	Feb-03	**Total Malfunctions**	**95**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**60**
Registered USA Implants	39,512	Battery Malfunction	48
Estimated Active USA Implants	5,419	Electrical Component	2
Normal Battery Depletions	5,053	Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**35**
		Battery Malfunction	23
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.994	0.991	0.988
Including NBD	0.995	0.992	0.982	0.961	0.923	0.851	0.73	0.547	0.311	0.086
Effective Sample Size	30583	26218	22543	19271	16091	12326	8793	4735	1359	107

C2TR01 Syncra CRT-P

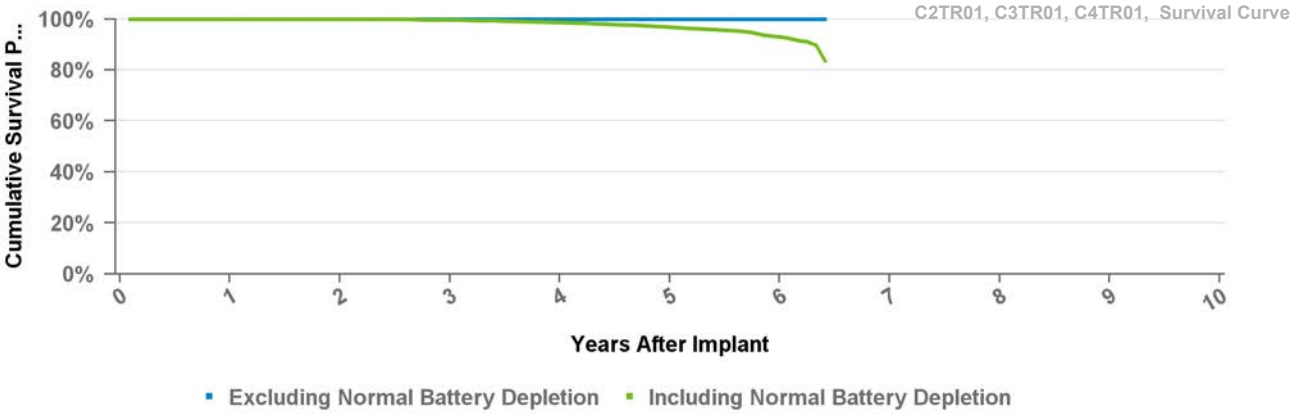
US Market Release	Mar-11	**Total Malfunctions**	**3**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**3**
Registered USA Implants	10,181	Other Malfunction	1
Estimated Active USA Implants	7,314	Poss Early Battery Depltn	2
Normal Battery Depletions	142	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	0.999	0.996	0.986	0.968	0.93	0.836
Effective Sample Size	27365	23755	18946	12870	6889	2027	256

C3TR01 Consulta CRT-P

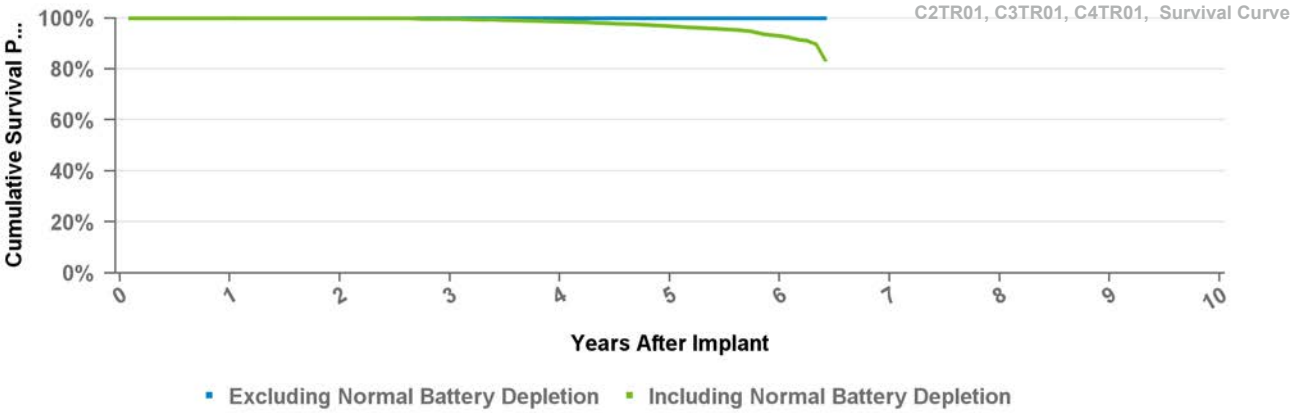
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	0.999	0.996	0.986	0.968	0.93	0.836
Effective Sample Size	27365	23755	18946	12870	6889	2027	256

C4TR01 Consulta CRT-P

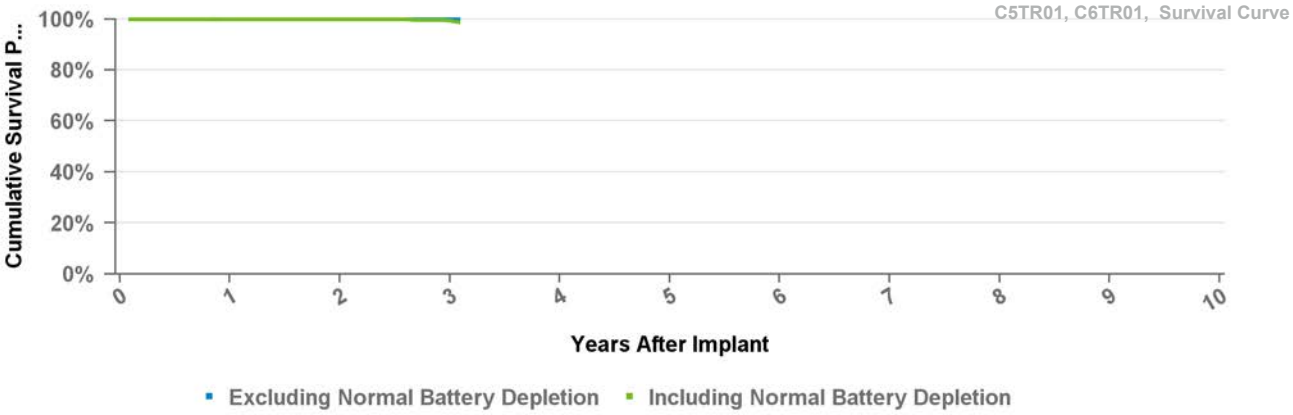
US Market Release	Mar-11	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	23,464	Electrical Component	1
Estimated Active USA Implants	18,357	Poss Early Battery Depltn	2
Normal Battery Depletions	237	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	0.999	0.996	0.986	0.968	0.93	0.836
Effective Sample Size	27365	23755	18946	12870	6889	2027	256

C5TR01 Viva CRT-P

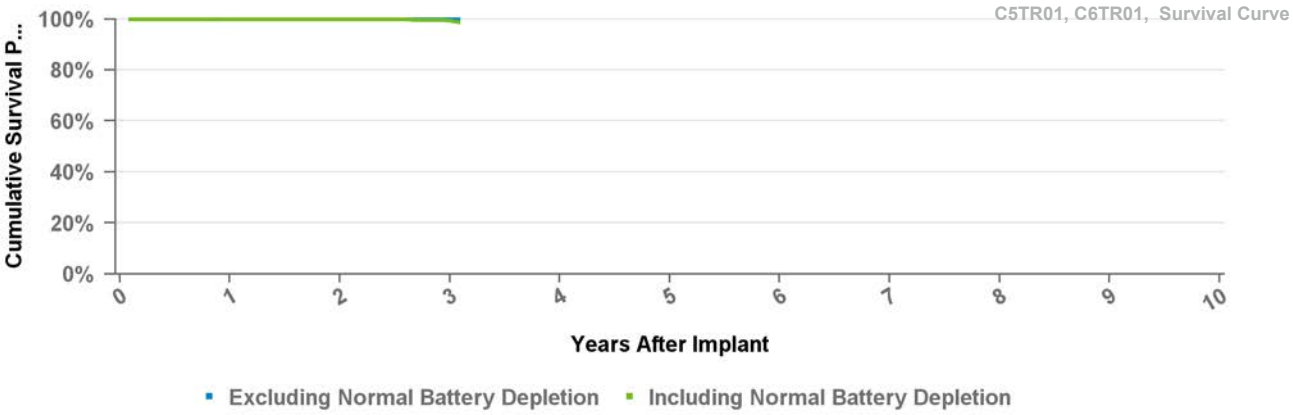
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	at 37 mo
Excluding NBD	1	1	1	1
Including NBD	0.999	0.999	0.994	0.987
Effective Sample Size	6944	3384	313	140

C6TR01 Viva CRT-P

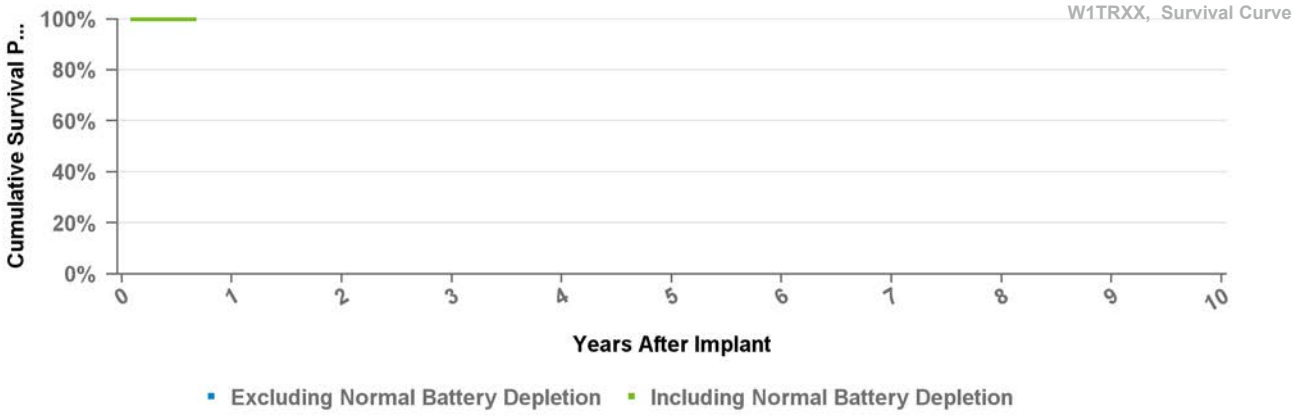
US Market Release	Jul-14	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	9,172		
Estimated Active USA Implants	8,504	**Therapy Function Compromised**	**0**
Normal Battery Depletions	7		



Years	1	2	3	at 37 mo
Excluding NBD	1	1	1	1
Including NBD	0.999	0.999	0.994	0.987
Effective Sample Size	6944	3384	313	140

W1TR01 Percepta CRTP MRI

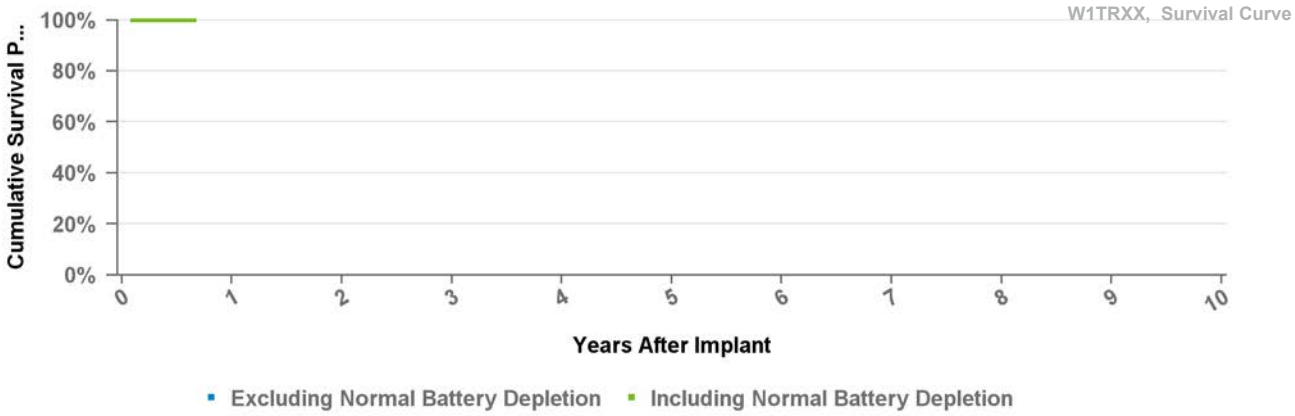
US Market Release		**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	629		
Estimated Active USA Implants	615	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W1TR02 Serena CRTP MRI

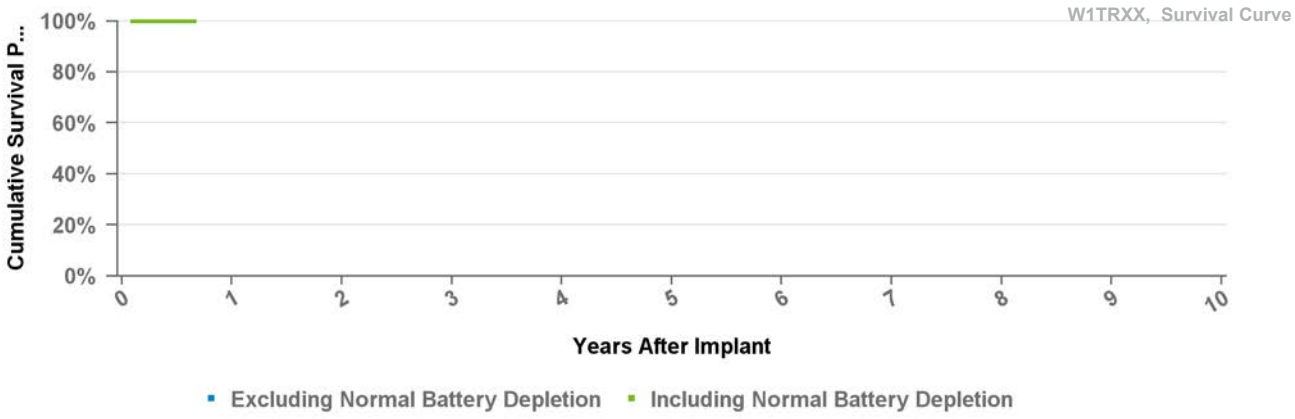
US Market Release		**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	193	Other Malfunction	1
Estimated Active USA Implants	187	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W1TR03 Solara CRTP MRI

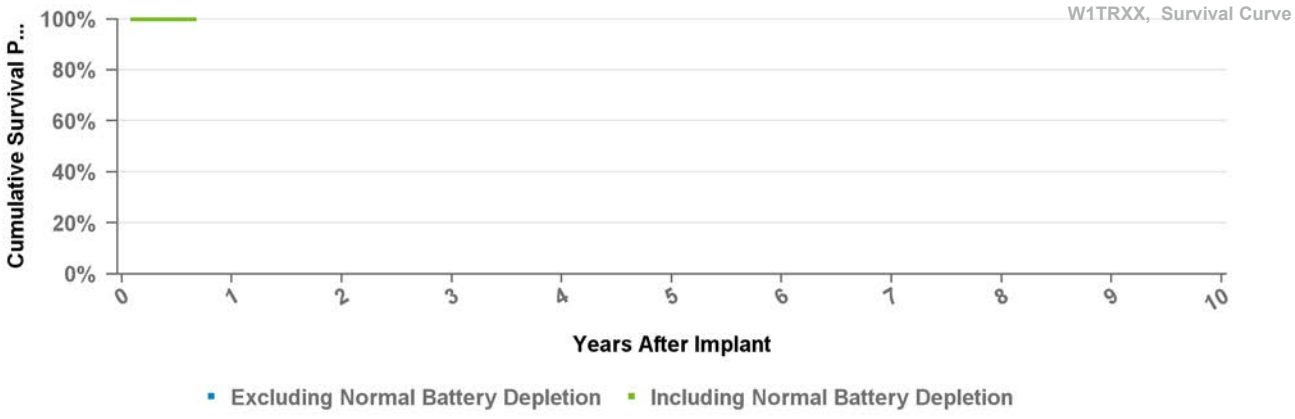
US Market Release		**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	409		
Estimated Active USA Implants	407	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W1TR04 Percepta CRTP MRI

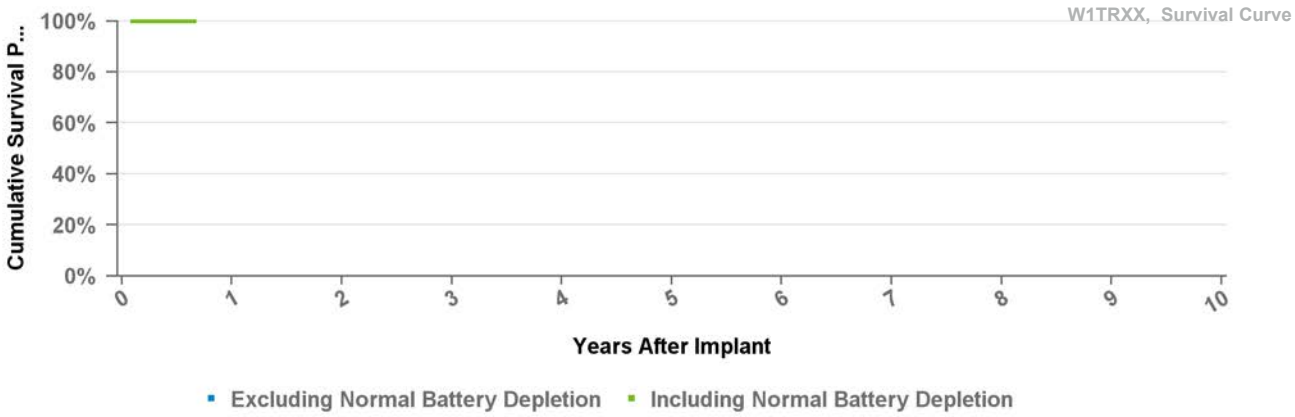
US Market Release		**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W1TR05 Serena CRTP MRI

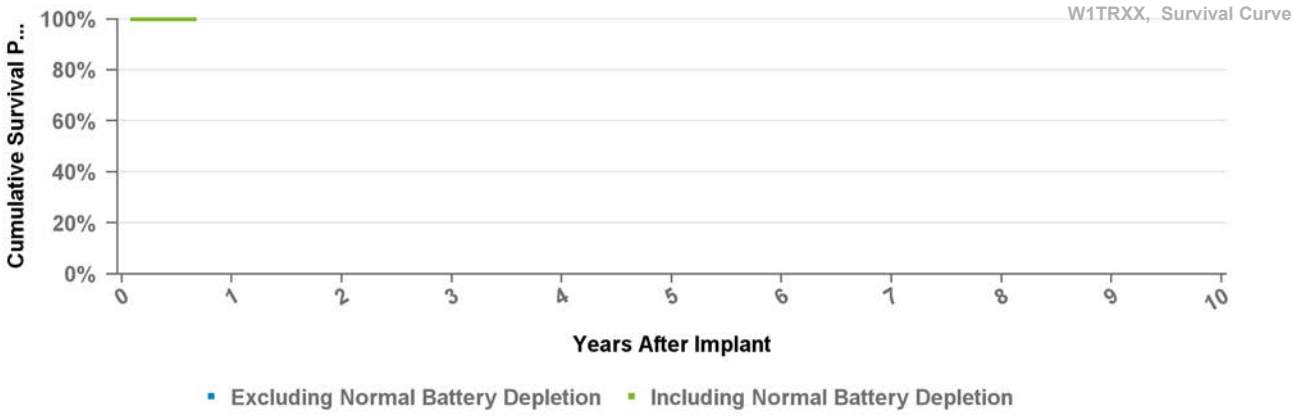
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W1TR06 Solara CRTP MRI

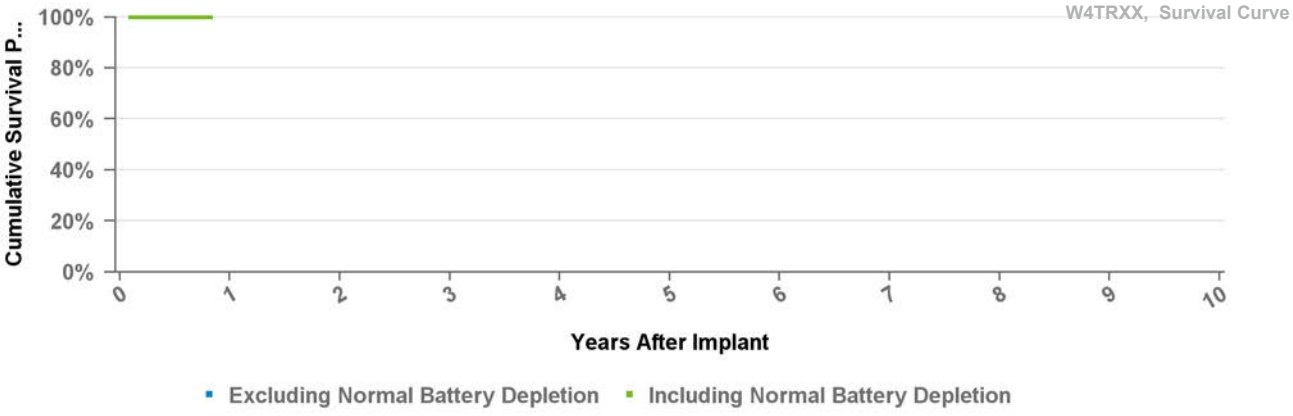
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 8 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	158

W4TR01 Percepta Quad CRTP MRI SureScan

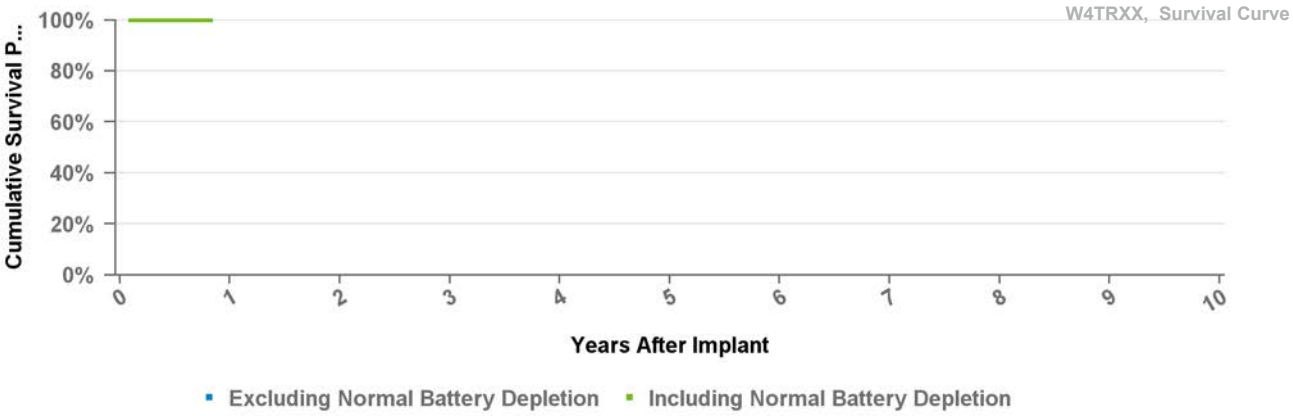
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,683	Other Malfunction	1
Estimated Active USA Implants	3,619	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

W4TR02 Serena Quad CRTP MRI SureScan

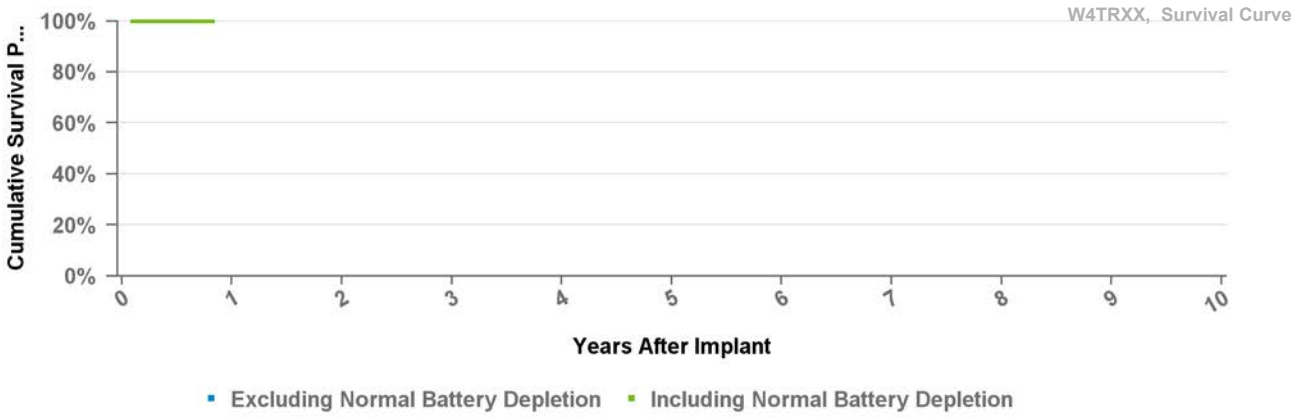
US Market Release	May-17	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	794		
Estimated Active USA Implants	785	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

W4TR03 Solara Quad CRTP MRI SureScan

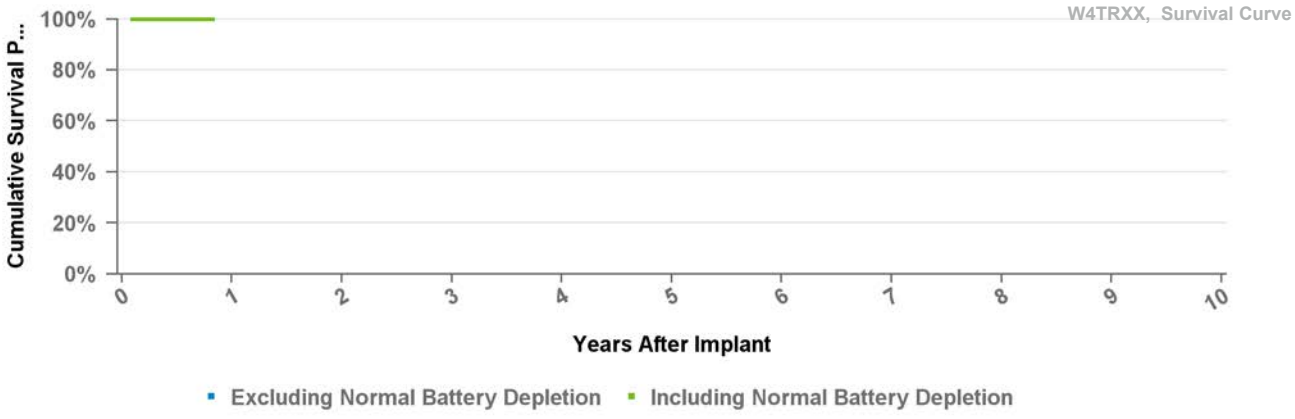
US Market Release	May-17	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,693		
Estimated Active USA Implants	1,666	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

W4TR04 Percepta Quad CRT-P MRI SureScan

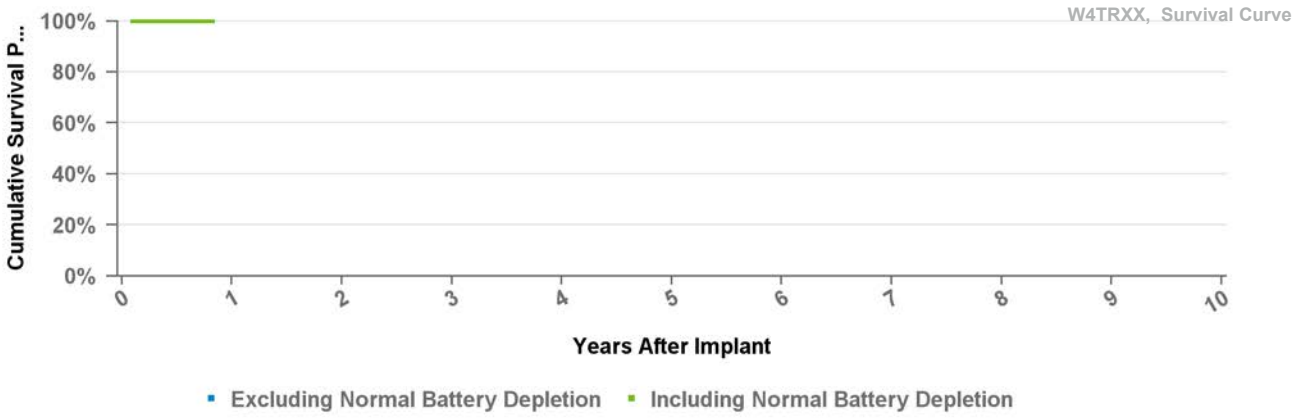
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

W4TR05 Serena Quad CRTP MRI SureScan

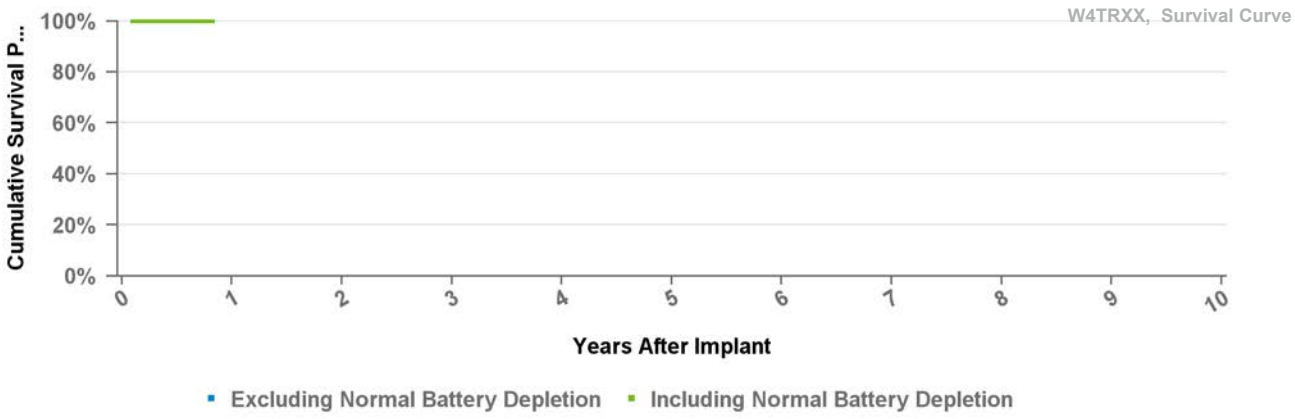
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

W4TR06 Solara Quad CRTP MRI SureScan

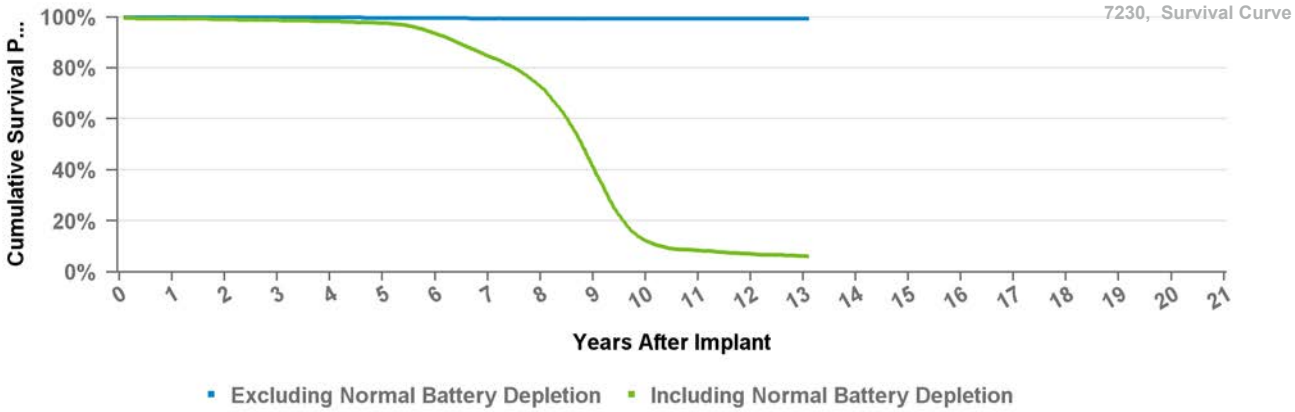
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 10 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	172

7230B Marquis VR

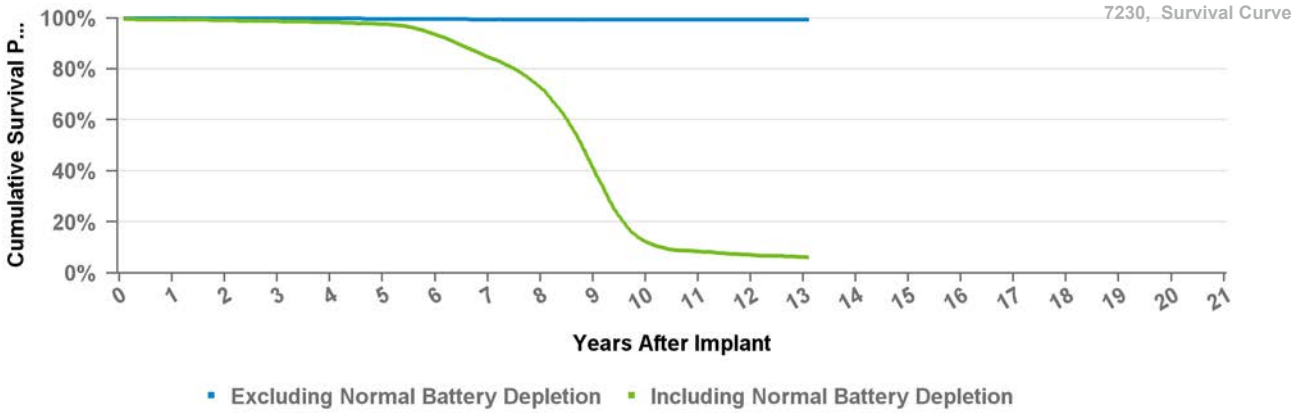
US Market Release	Dec-02	**Total Malfunctions**	**1**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**0**
Registered USA Implants	237		
Estimated Active USA Implants	11	**Therapy Function Compromised**	**1**
Normal Battery Depletions	27	Battery Malfunction	1



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 157 mo
Excluding NBD	1	0.993	0.993	0.993	0.993	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993
Including NBD	0.994	0.991	0.988	0.984	0.976	0.935	0.847	0.727	0.415	0.122	0.084	0.071	0.063	0.061
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2561	592	334	226	129	107

7230Cx Marquis VR

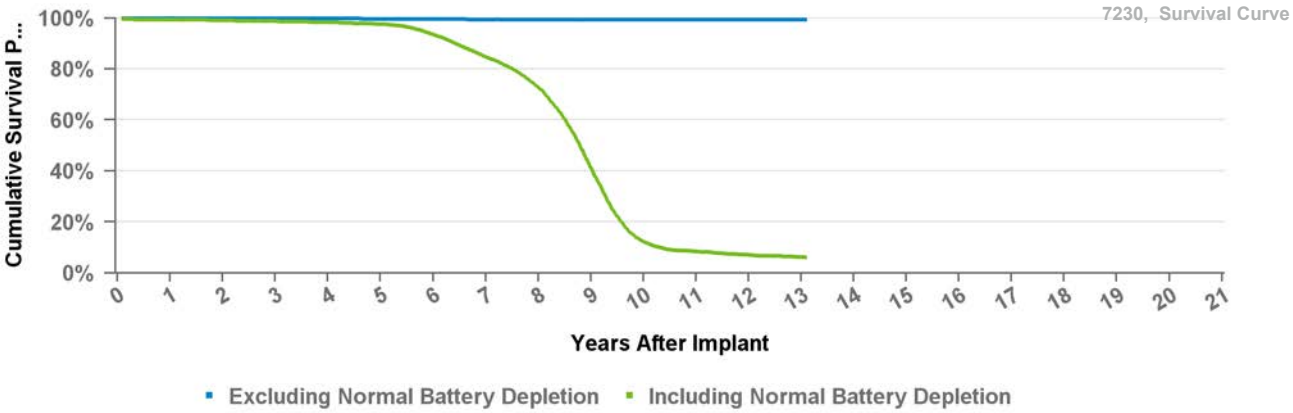
US Market Release	Dec-02	**Total Malfunctions**	**57**
CE Approval Date	Apr-02	**Therapy Function Not Compromised**	**31**
Registered USA Implants	18,517	Battery Malfunction	1
Estimated Active USA Implants	1,194	Electrical Component	14
Normal Battery Depletions	3,435	Other Malfunction	1
		Poss Early Battery Depltn	14
		Software Malfunction	1
		Therapy Function Compromised	**26**
		Battery Malfunction	17
		Electrical Component	9



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 157 mo
Excluding NBD	1	0.993	0.993	0.993	0.993	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993
Including NBD	0.994	0.991	0.988	0.984	0.976	0.935	0.847	0.727	0.415	0.122	0.084	0.071	0.063	0.061
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2561	592	334	226	129	107

7230E Marquis VR

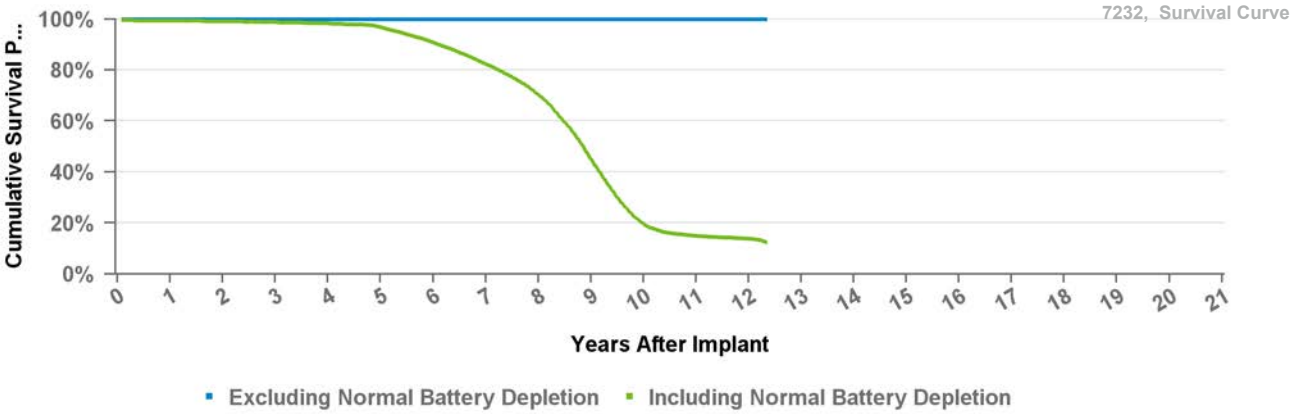
US Market Release	Dec-02	**Total Malfunctions**	**3**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**1**
Registered USA Implants	632	Electrical Component	1
Estimated Active USA Implants	39	**Therapy Function Compromised**	**2**
Normal Battery Depletions	79	Battery Malfunction	2



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 157 mo
Excluding NBD	1	0.993	0.993	0.993	0.993	0.999	0.999	0.998	0.997	0.996	0.995	0.994	0.993	0.993
Including NBD	0.994	0.991	0.988	0.984	0.976	0.935	0.847	0.727	0.415	0.122	0.084	0.071	0.063	0.061
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2561	592	334	226	129	107

7232B Maximo VR

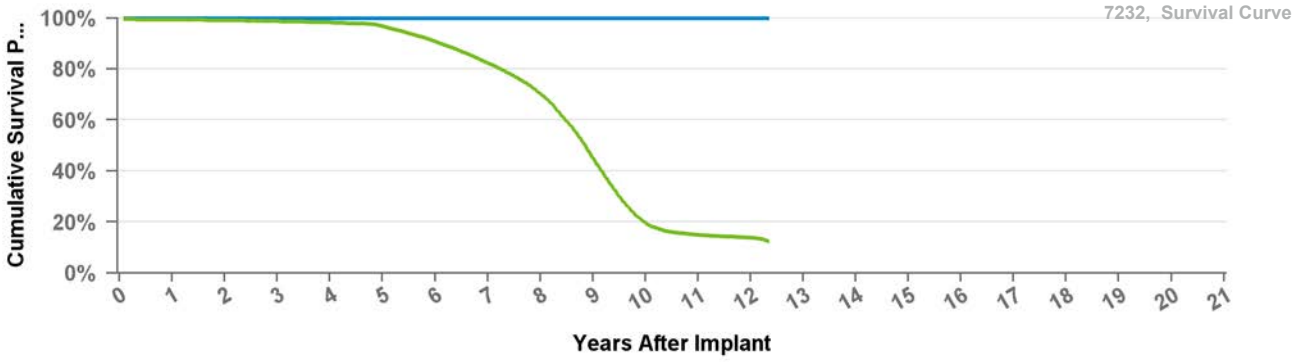
US Market Release	Oct-03	**Total Malfunctions**	**0**
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	**0**
Registered USA Implants	170		
Estimated Active USA Implants	25	**Therapy Function Compromised**	**0**
Normal Battery Depletions	37		



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 148 mo
Excluding NBD	1	0.998	0.998	0.998	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.994	0.992	0.988	0.983	0.968	0.908	0.823	0.702	0.452	0.196	0.149	0.138	0.123
Effective Sample Size	38270	34245	30527	26921	23716	20622	17424	13967	8457	3050	1671	579	106

7232Cx Maximo VR

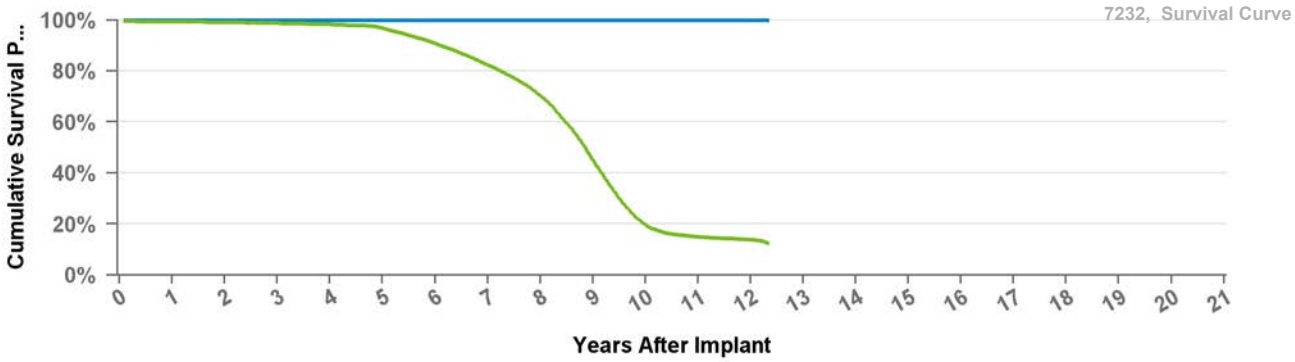
US Market Release	Oct-03	**Total Malfunctions**	**73**
CE Approval Date	Oct-03	**Therapy Function Not Compromised**	**58**
Registered USA Implants	43,671	Electrical Component	28
Estimated Active USA Implants	5,107	Other Malfunction	3
Normal Battery Depletions	10,718	Poss Early Battery Depltn	25
		Software Malfunction	2
		Therapy Function Compromised	**15**
		Electrical Component	12
		Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	1



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 148 mo
Excluding NBD	1	0.998	0.998	0.998	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.994	0.992	0.988	0.983	0.968	0.908	0.823	0.702	0.452	0.196	0.149	0.138	0.123
Effective Sample Size	38270	34245	30527	26921	23716	20622	17424	13967	8457	3050	1671	579	106

7232E Maximo VR

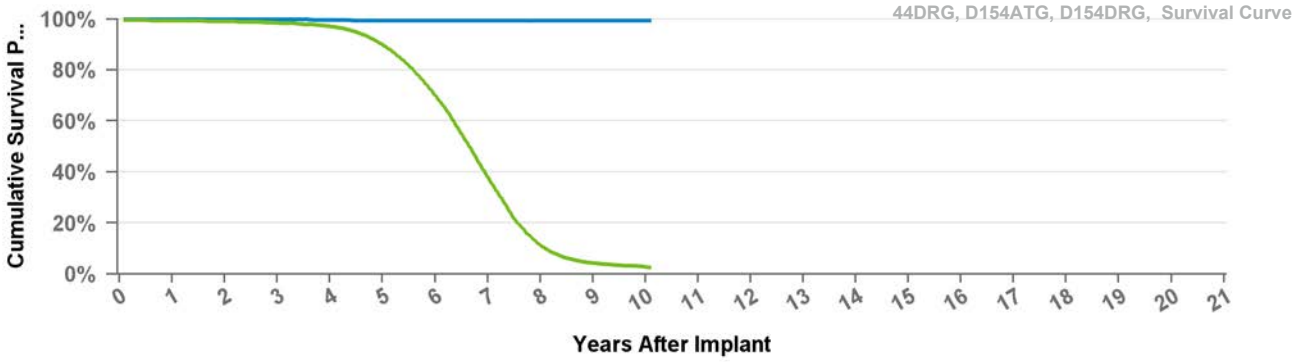
US Market Release	Oct-03	**Total Malfunctions**	**1**
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	**0**
Registered USA Implants	490		
Estimated Active USA Implants	71	**Therapy Function Compromised**	**1**
Normal Battery Depletions	85	Electrical Component	1



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 148 mo
Excluding NBD	1	0.998	0.998	0.998	0.999	0.999	0.998	0.998	0.998	0.998	0.998	0.998	0.998
Including NBD	0.994	0.992	0.988	0.983	0.968	0.908	0.823	0.702	0.452	0.196	0.149	0.138	0.123
Effective Sample Size	38270	34245	30527	26921	23716	20622	17424	13967	8457	3050	1671	579	106

D144DRG Entrust Escudo

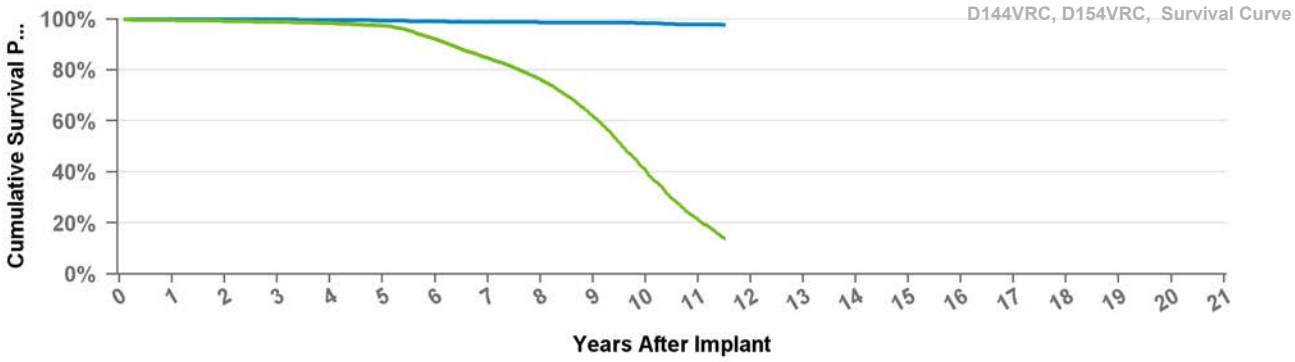
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	1	0.993	0.999	0.998	0.997	0.994	0.994	0.994	0.993	0.993	0.993
Including NBD	0.994	0.991	0.985	0.971	0.899	0.702	0.381	0.111	0.043	0.027	0.025
Effective Sample Size	24904	22703	20355	17939	14880	10819	5374	1373	389	134	101

D144VRC Entrust Escudo

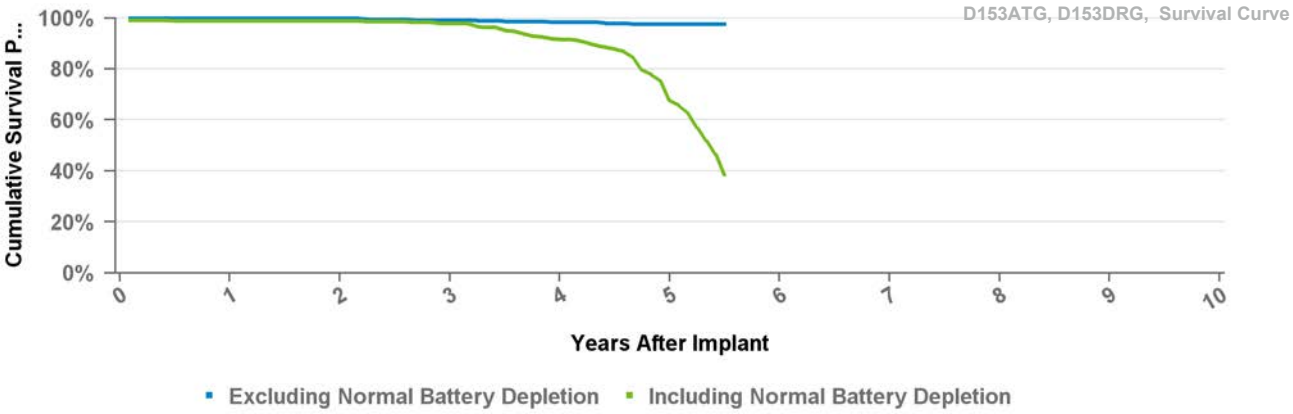
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jun-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	11	2	3	4	5	6	7	8	9	at 138 mo
Excluding NBD	0.999	0.984	0.979	0.999	0.998	0.997	0.994	0.991	0.988	0.987	0.987	0.977
Including NBD	0.996	0.992	0.989	0.984	0.974	0.921	0.847	0.762	0.618	0.407	0.212	0.139
Effective Sample Size	12683	11493	10278	9080	8016	7016	6014	5100	3862	2299	860	235

D153ATG Entrust AT

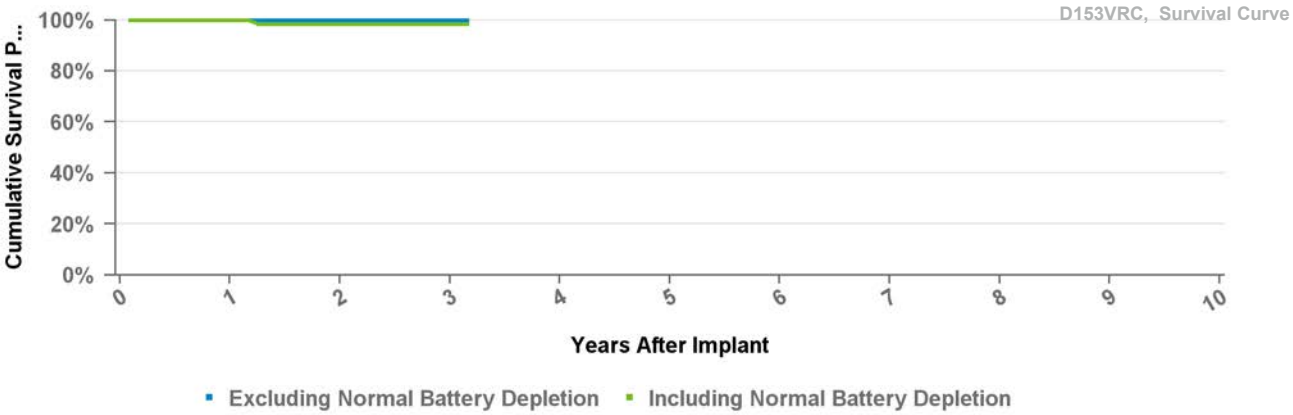
US Market Release	Jun-05	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	459	Poss Early Battery Depltn	7
Estimated Active USA Implants	26	**Therapy Function Compromised**	**1**
Normal Battery Depletions	182	Electrical Component	1



Years	1	2	3	4	5	at 66 mo
Excluding NBD	0.998	0.998	0.992	0.984	0.976	0.976
Including NBD	0.989	0.989	0.978	0.916	0.676	0.384
Effective Sample Size	413	379	342	282	199	107

D153VRC Entrust VR

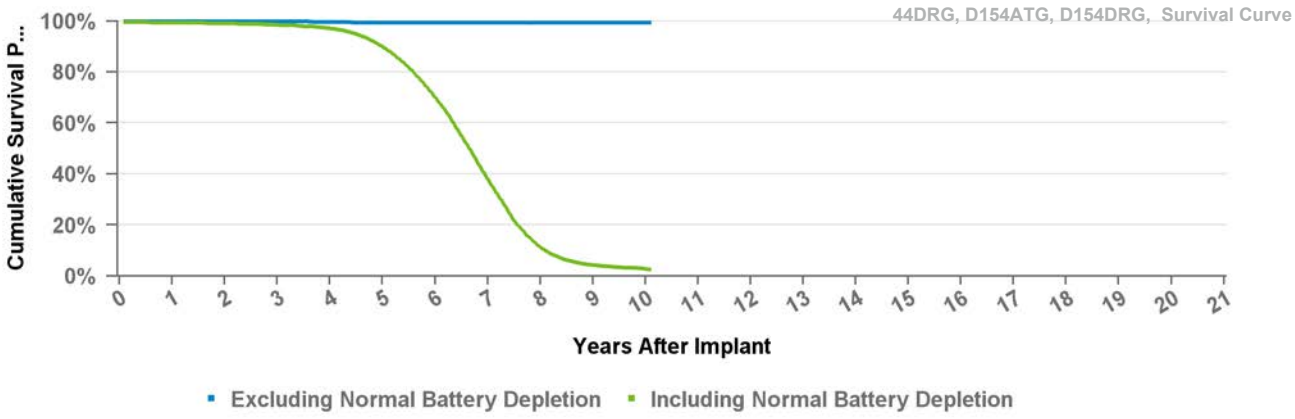
US Market Release	Jun-05	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	165	Electrical Component	1
Estimated Active USA Implants	25	**Therapy Function Compromised**	**0**
Normal Battery Depletions	27		



Years	1	2	3	at 38 mo
Excluding NBD	1	1	1	1
Including NBD	1	0.985	0.985	0.985
Effective Sample Size	141	119	104	101

D154ATG Entrust AT

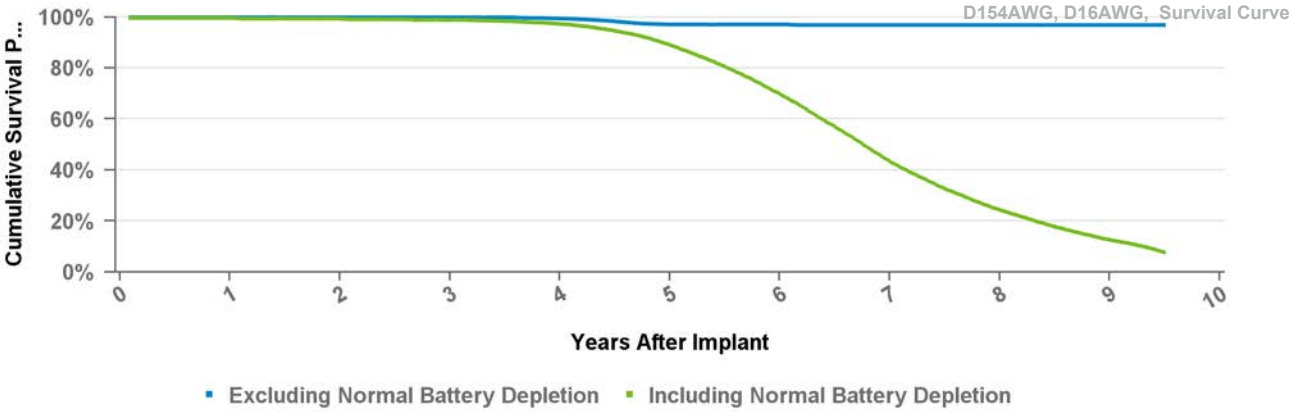
US Market Release	Jun-05	**Total Malfunctions**	**125**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**109**
Registered USA Implants	28,151	Electrical Component	30
Estimated Active USA Implants	2,301	Electrical Interconnect	1
Normal Battery Depletions	9,021	Other Malfunction	1
		Poss Early Battery Depltn	74
		Software Malfunction	3
		Therapy Function Compromised	**16**
		Electrical Component	16



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	1	0.993	0.999	0.998	0.997	0.994	0.994	0.994	0.993	0.993	0.993
Including NBD	0.994	0.991	0.985	0.971	0.899	0.702	0.381	0.111	0.043	0.027	0.025
Effective Sample Size	24904	22703	20355	17939	14880	10819	5374	1373	389	134	101

D154AWG Virtuoso DR

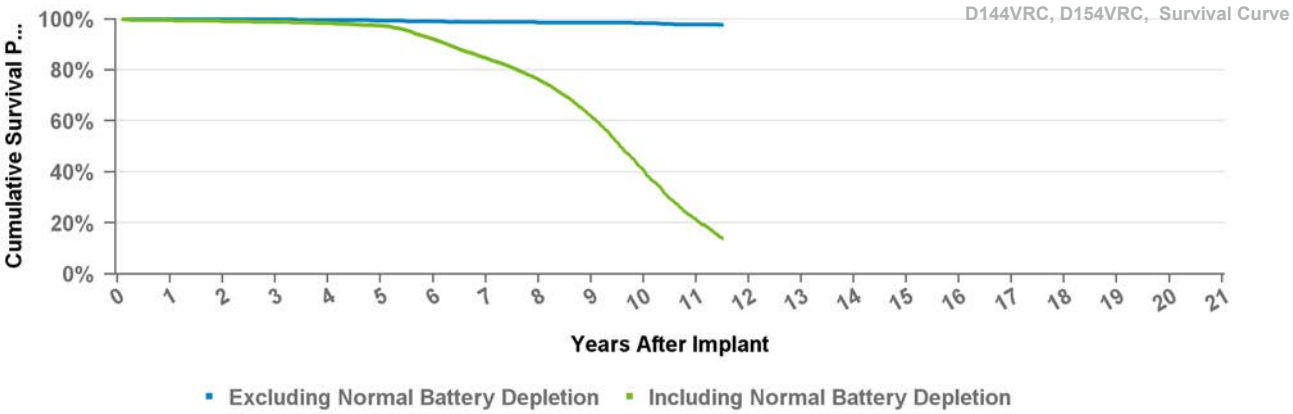
US Market Release	May-06	**Total Malfunctions**	**3,338**
CE Approval Date		**Therapy Function Not Compromised**	**3,287**
Registered USA Implants	76,856	Battery Malfunction	9
Estimated Active USA Implants	11,034	Electrical Component	3,138
Normal Battery Depletions	21,745	Electrical Interconnect	2
		Other Malfunction	3
		Poss Early Battery Depltn	132
		Software Malfunction	3
		Therapy Function Compromised	**51**
		Battery Malfunction	2
		Electrical Component	45
		Other Malfunction	3
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	1	0.999	0.999	0.994	0.971	0.97	0.969	0.969	0.968	0.968
Including NBD	0.996	0.993	0.988	0.973	0.891	0.698	0.433	0.243	0.126	0.076
Effective Sample Size	63447	58189	53026	48186	40953	29870	16937	8287	2321	256

D154VRC Entrust VR

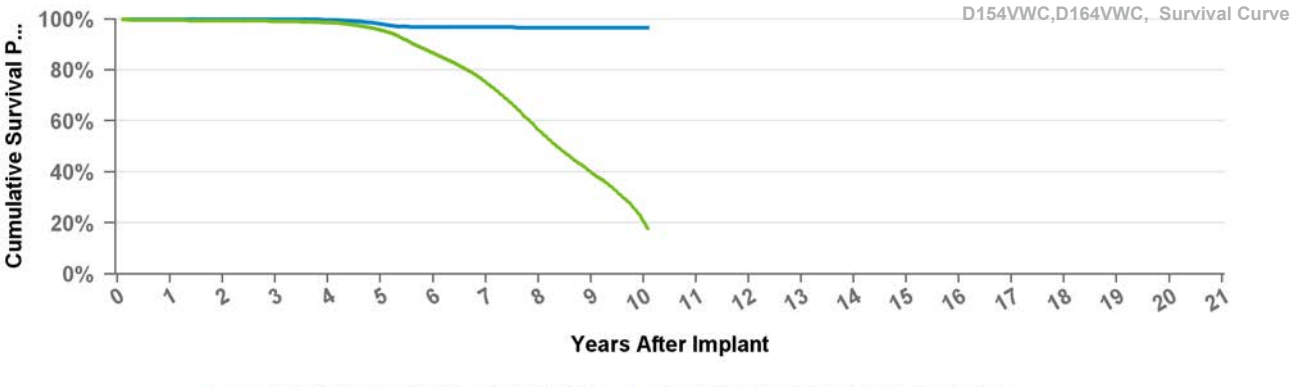
US Market Release	Jun-05	**Total Malfunctions**	**136**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**101**
Registered USA Implants	14,466	Battery Malfunction	18
Estimated Active USA Implants	2,192	Electrical Component	47
Normal Battery Depletions	3,277	Other Malfunction	12
		Poss Early Battery Depltn	24
		Therapy Function Compromised	**35**
		Battery Malfunction	4
		Electrical Component	27
		Other Malfunction	4



Years	1	10	11	2	3	4	5	6	7	8	9	at 138 mo
Excluding NBD	0.999	0.984	0.979	0.999	0.998	0.997	0.994	0.991	0.988	0.987	0.987	0.977
Including NBD	0.996	0.992	0.989	0.984	0.974	0.921	0.847	0.762	0.618	0.407	0.212	0.139
Effective Sample Size	12683	11493	10278	9080	8016	7016	6014	5100	3862	2299	860	235

D154VWC Virtuoso VR

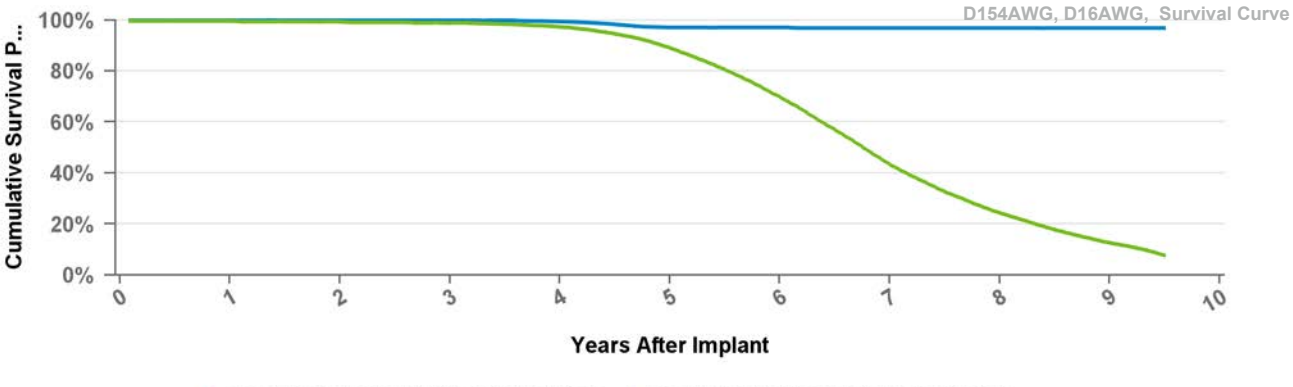
US Market Release	May-06	**Total Malfunctions**	**689**
CE Approval Date		**Therapy Function Not Compromised**	**669**
Registered USA Implants	33,147	Battery Malfunction	12
Estimated Active USA Implants	7,520	Electrical Component	637
Normal Battery Depletions	7,123	Electrical Interconnect	1
		Other Malfunction	4
		Poss Early Battery Depltn	15
		Therapy Function Compromised	**20**
		Battery Malfunction	3
		Electrical Component	17



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	1	0.967	0.999	0.999	0.997	0.981	0.969	0.968	0.967	0.967	0.967
Including NBD	0.996	0.994	0.992	0.986	0.957	0.866	0.751	0.566	0.398	0.208	0.179
Effective Sample Size	28610	26096	23781	21754	19336	16197	13139	9165	4776	784	432

D164AWG Virtuoso DR

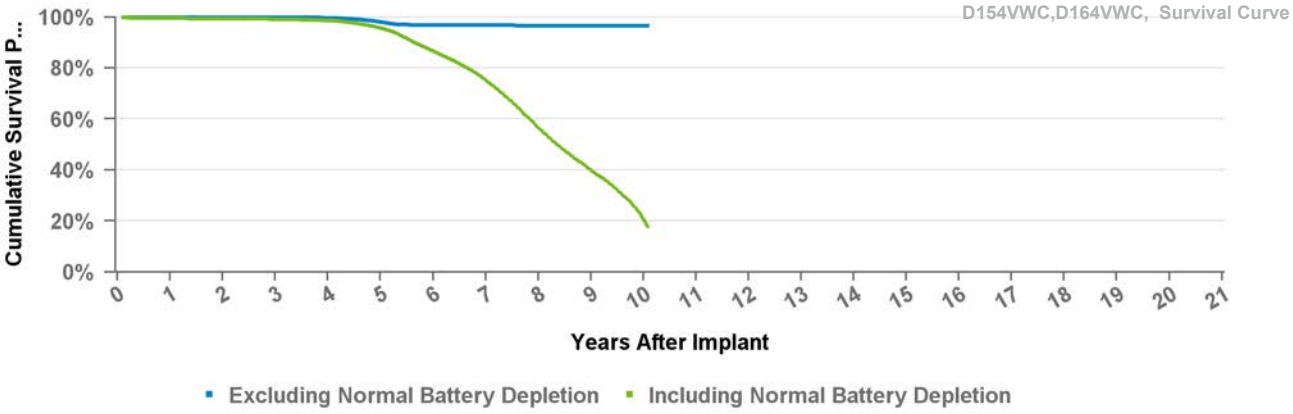
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**0**
Registered USA Implants	10		
Estimated Active USA Implants	3	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	1	0.999	0.999	0.994	0.971	0.97	0.969	0.969	0.968	0.968
Including NBD	0.996	0.993	0.988	0.973	0.891	0.698	0.433	0.243	0.126	0.076
Effective Sample Size	63447	58189	53026	48186	40953	29870	16937	8287	2321	256

D164VWC Virtuoso VR

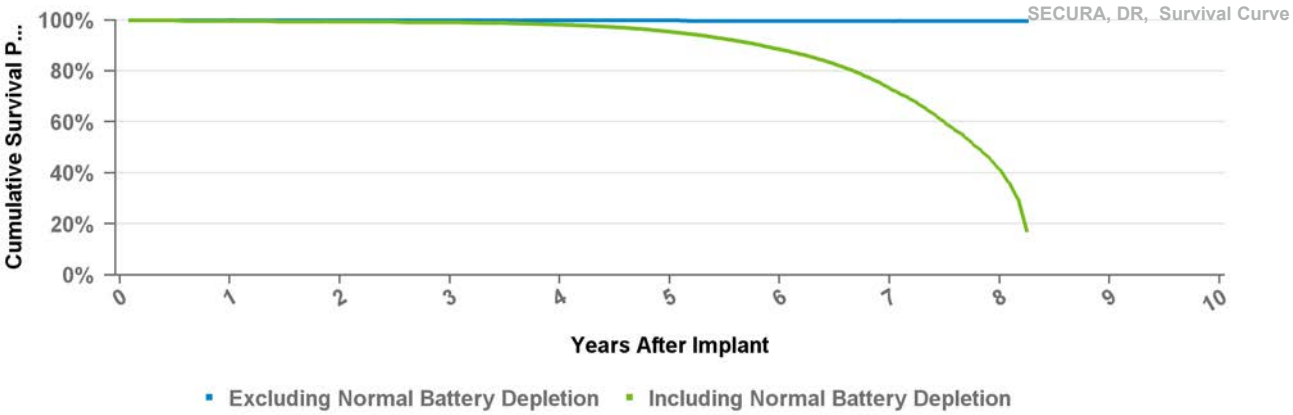
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	1	0.967	0.999	0.999	0.997	0.981	0.969	0.968	0.967	0.967	0.967
Including NBD	0.996	0.994	0.992	0.986	0.957	0.866	0.751	0.566	0.398	0.208	0.179
Effective Sample Size	28610	26096	23781	21754	19336	16197	13139	9165	4776	784	432

D204DRM Secura DR

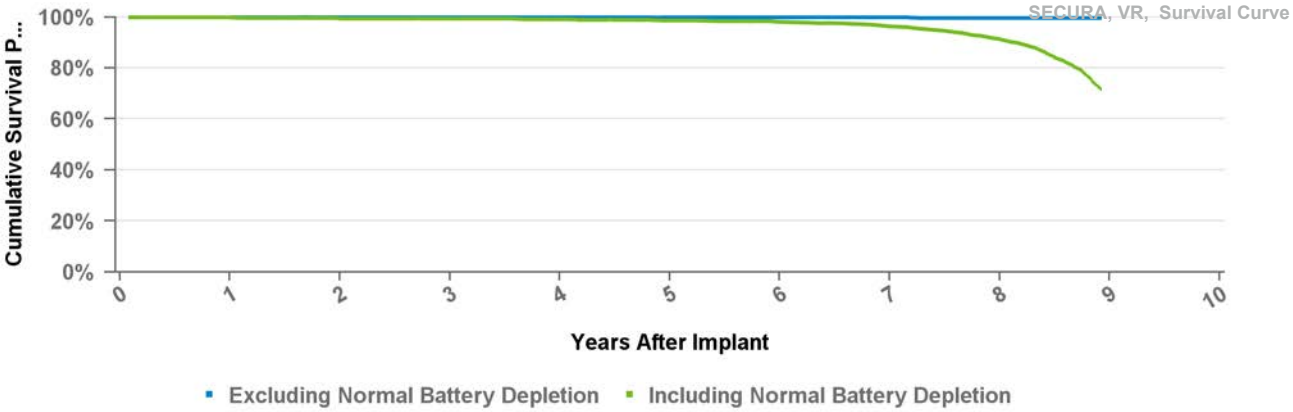
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,880	Other Malfunction	1
Estimated Active USA Implants	1,461	**Therapy Function Compromised**	**2**
Normal Battery Depletions	28	Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.996	0.996
Including NBD	0.996	0.994	0.991	0.982	0.954	0.885	0.731	0.415	0.172
Effective Sample Size	45377	42526	39931	37053	32749	25289	14523	2048	238

D204VRM Secura VR

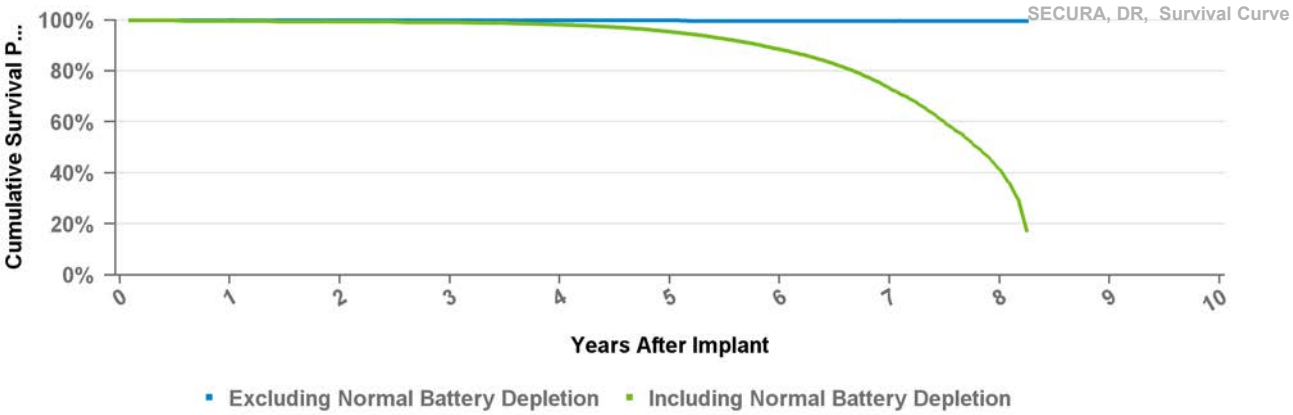
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,184	Electrical Component	1
Estimated Active USA Implants	969	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.995	0.994	0.991	0.987	0.981	0.963	0.913	0.716
Effective Sample Size	18307	17102	16123	15025	13373	11130	8279	3525	210

D214DRM Secura DR

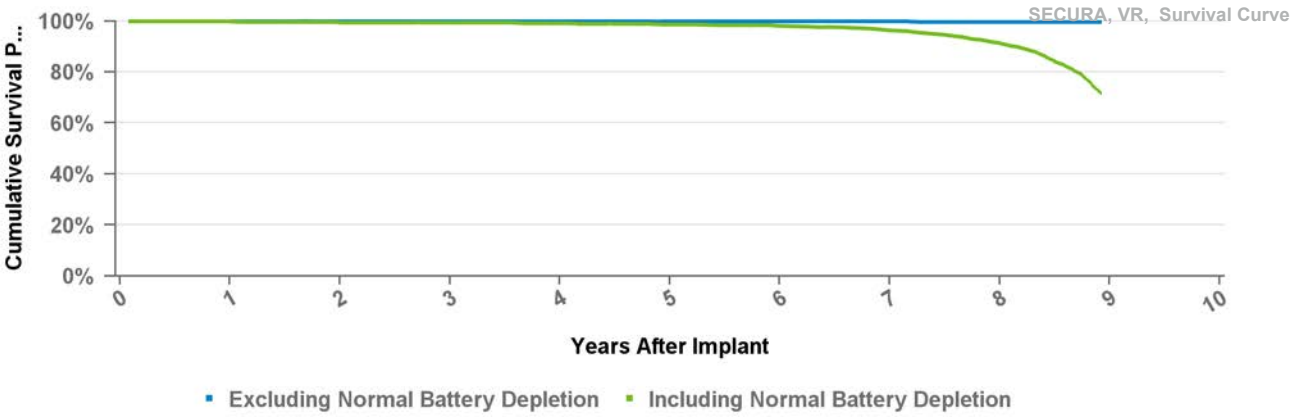
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.996	0.996
Including NBD	0.996	0.994	0.991	0.982	0.954	0.885	0.731	0.415	0.172
Effective Sample Size	45377	42526	39931	37053	32749	25289	14523	2048	238

D214VRM Secura VR

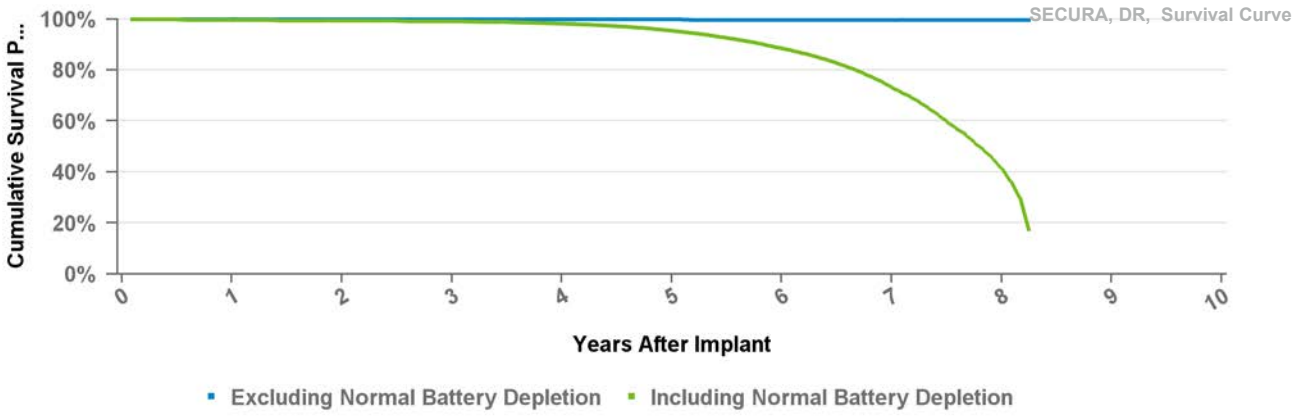
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.995	0.994	0.991	0.987	0.981	0.963	0.913	0.716
Effective Sample Size	18307	17102	16123	15025	13373	11130	8279	3525	210

D224DRG Secura DR

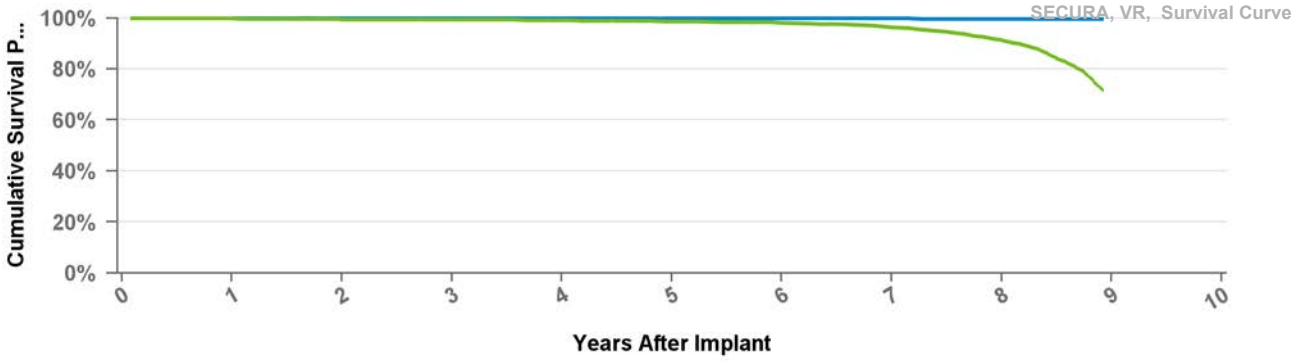
US Market Release	Sep-08	**Total Malfunctions**	**136**
CE Approval Date		**Therapy Function Not Compromised**	**110**
Registered USA Implants	49,903	Battery Malfunction	11
Estimated Active USA Implants	17,761	Electrical Component	36
Normal Battery Depletions	6,733	Other Malfunction	4
		Poss Early Battery Depltn	50
		Software Malfunction	9
		Therapy Function Compromised	**26**
		Battery Malfunction	10
		Electrical Component	13
		Other Malfunction	1
		Poss Early Battery Depltn	1
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.996	0.996
Including NBD	0.996	0.994	0.991	0.982	0.954	0.885	0.731	0.415	0.172
Effective Sample Size	45377	42526	39931	37053	32749	25289	14523	2048	238

D224VRC Secura VR

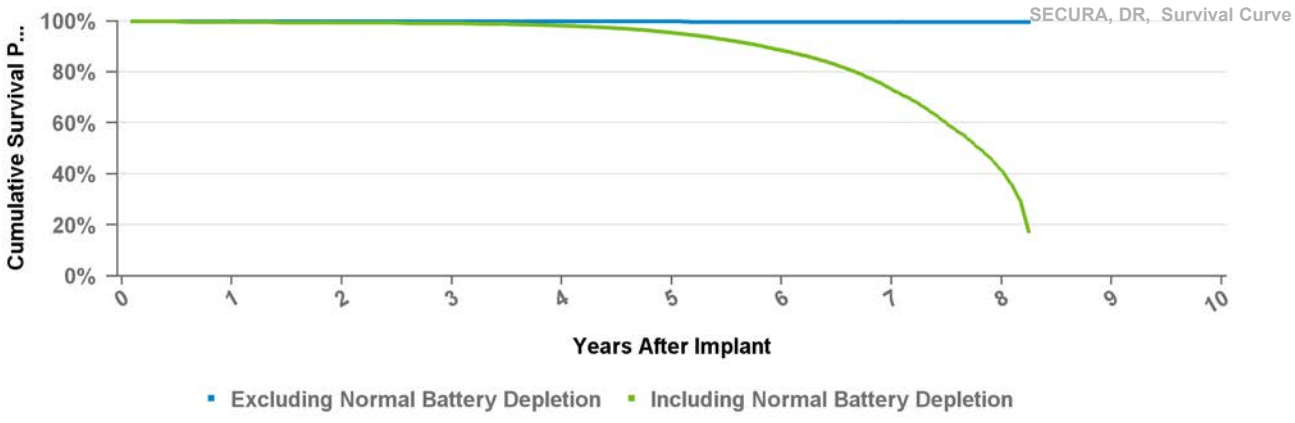
US Market Release	Sep-08	**Total Malfunctions**	**39**
CE Approval Date		**Therapy Function Not Compromised**	**32**
Registered USA Implants	20,043	Battery Malfunction	13
Estimated Active USA Implants	11,197	Electrical Component	8
Normal Battery Depletions	554	Other Malfunction	1
		Poss Early Battery Depltn	8
		Software Malfunction	2
		Therapy Function Compromised	**7**
		Electrical Component	5
		Poss Early Battery Depltn	1
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.995	0.994	0.991	0.987	0.981	0.963	0.913	0.716
Effective Sample Size	18307	17102	16123	15025	13373	11130	8279	3525	210

D234DRG Secura DR

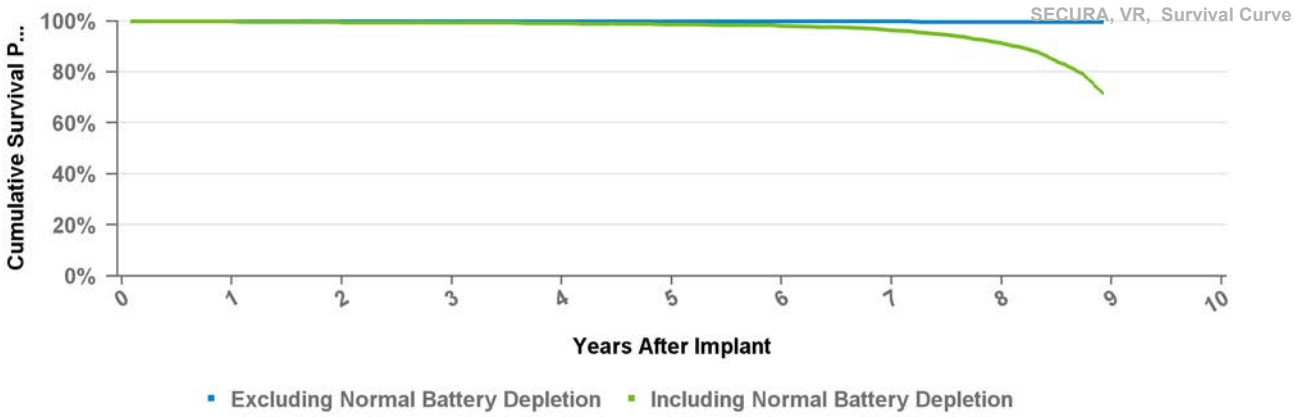
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	0.999	0.999	0.998	0.998	0.997	0.997	0.996	0.996
Including NBD	0.996	0.994	0.991	0.982	0.954	0.885	0.731	0.415	0.172
Effective Sample Size	45377	42526	39931	37053	32749	25289	14523	2048	238

D234VRC Secura VR

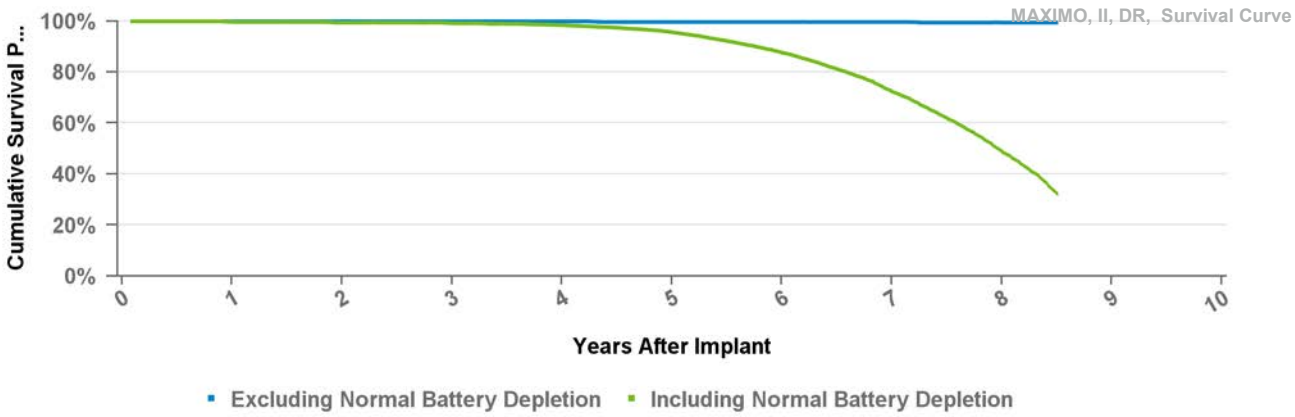
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.998	0.998	0.998	0.997	0.997
Including NBD	0.998	0.995	0.994	0.991	0.987	0.981	0.963	0.913	0.716
Effective Sample Size	18307	17102	16123	15025	13373	11130	8279	3525	210

D264DRM Maximo II DR

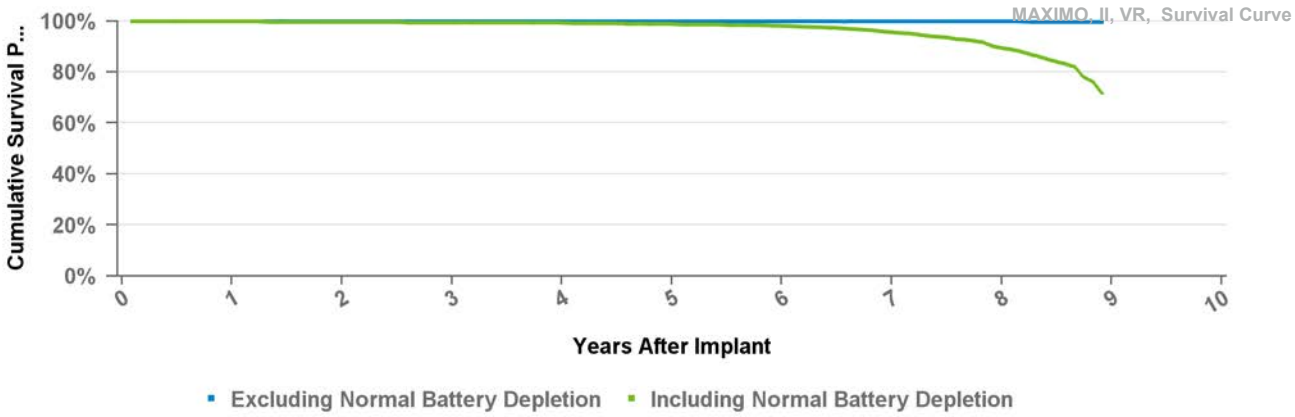
US Market Release	Jan-12	**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	7		
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	1	1	0.999	0.998	0.997	0.997	0.996	0.994	0.994
Including NBD	0.997	0.995	0.992	0.984	0.956	0.876	0.724	0.488	0.322
Effective Sample Size	17584	16429	15445	14339	12587	9432	4983	1240	217

D264VRM Maximo II VR

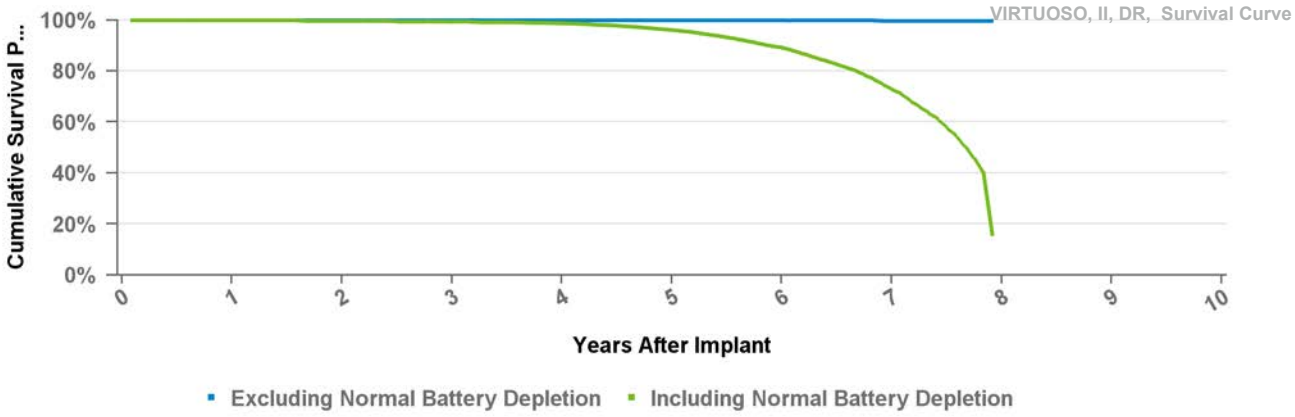
US Market Release	May-12	**Total Malfunctions**	**0**
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.996	0.995	0.993	0.988	0.981	0.956	0.894	0.718
Effective Sample Size	11250	10547	9935	9238	8298	6959	4971	2298	148

D274DRG Virtuoso II DR

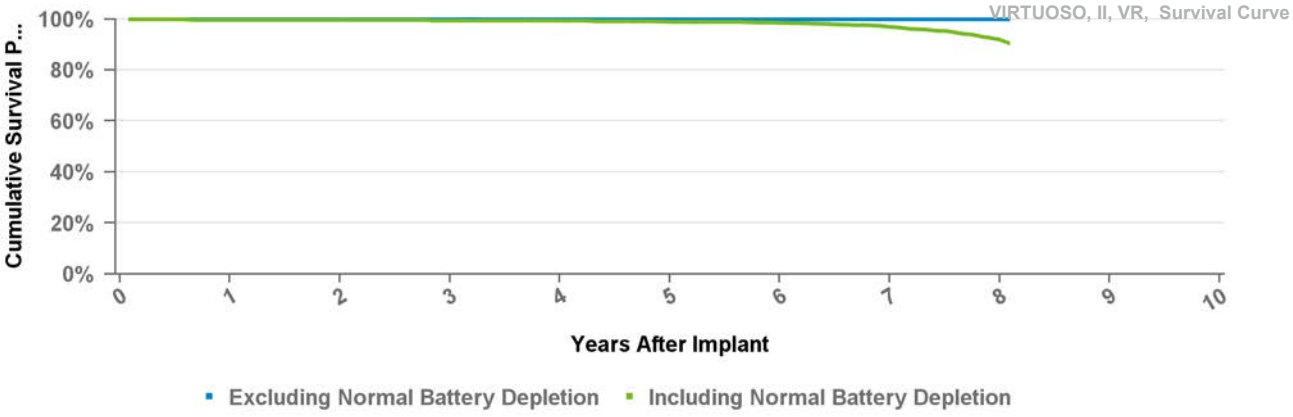
US Market Release	Aug-09	**Total Malfunctions**	**37**
CE Approval Date		**Therapy Function Not Compromised**	**30**
Registered USA Implants	22,238	Battery Malfunction	11
Estimated Active USA Implants	8,298	Electrical Component	11
Normal Battery Depletions	2,680	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**7**
		Battery Malfunction	4
		Electrical Component	2
		Other Malfunction	1



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.997
Including NBD	0.998	0.997	0.993	0.987	0.961	0.892	0.728	0.158
Effective Sample Size	19349	18171	17106	15896	14180	11421	6040	133

D274VRC Virtuoso II VR

US Market Release	Aug-09	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	9,121	Battery Malfunction	5
Estimated Active USA Implants	5,622	Electrical Component	4
Normal Battery Depletions	137	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**3**
		Battery Malfunction	2
		Electrical Component	1

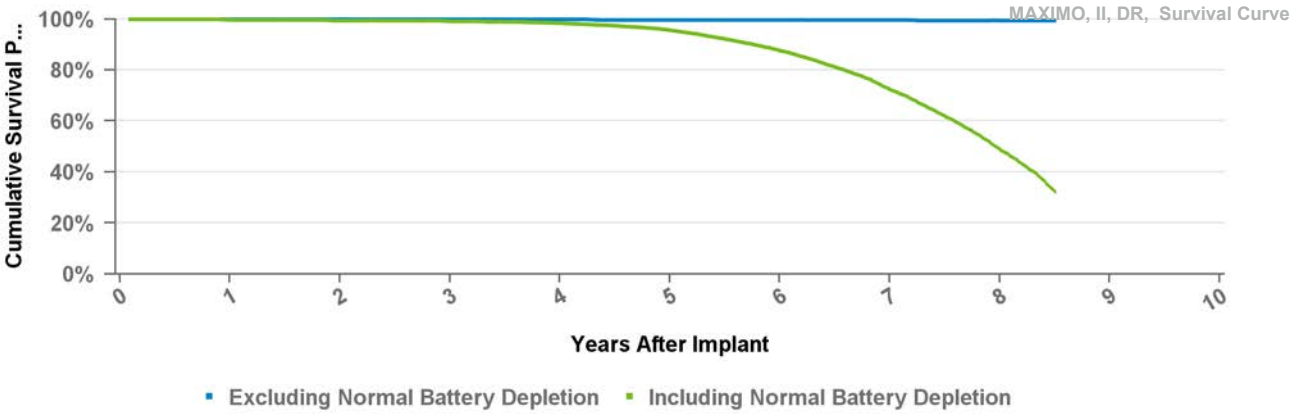


Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.998	0.998	0.998
Including NBD	0.997	0.997	0.995	0.994	0.989	0.985	0.969	0.919	0.905
Effective Sample Size	7795	7319	6909	6429	5932	5368	3666	560	271

D284DRG Maximo II DR

US Market Release	Sep-08
CE Approval Date	Mar-08
Registered USA Implants	20,093
Estimated Active USA Implants	7,357
Normal Battery Depletions	2,677

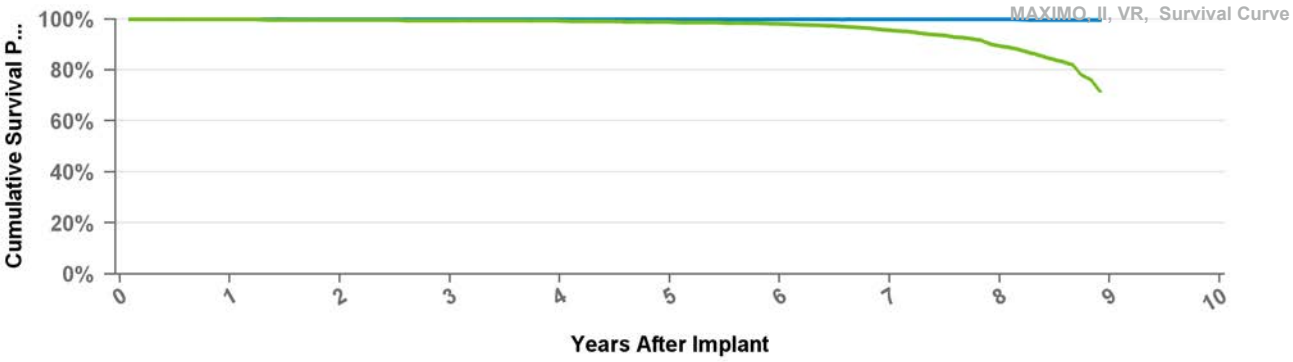
Total Malfunctions	**63**
Therapy Function Not Compromised	**51**
Battery Malfunction	5
Electrical Component	14
Other Malfunction	2
Poss Early Battery Depltn	30
Therapy Function Compromised	**12**
Battery Malfunction	6
Electrical Component	5
Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	1	1	0.999	0.998	0.997	0.997	0.996	0.994	0.994
Including NBD	0.997	0.995	0.992	0.984	0.956	0.876	0.724	0.488	0.322
Effective Sample Size	17584	16429	15445	14339	12587	9432	4983	1240	217

D284VRC Maximo II VR

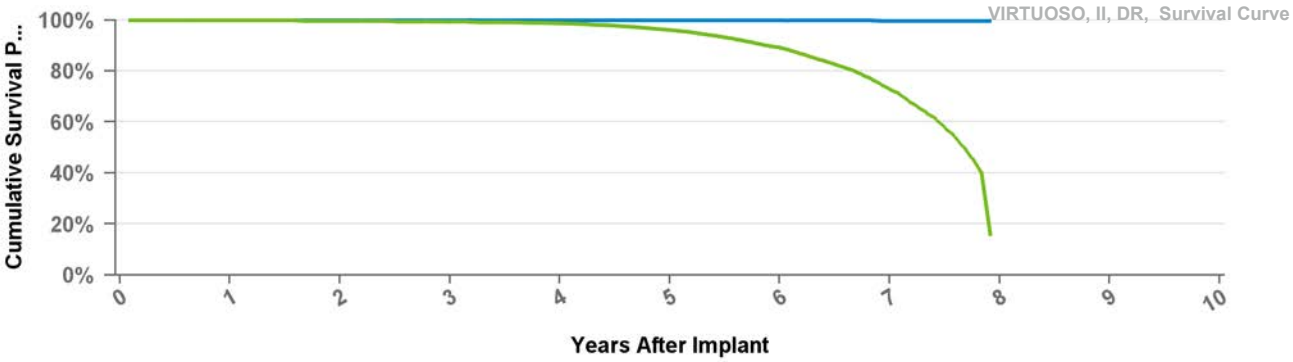
US Market Release	Sep-08	**Total Malfunctions**	**22**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**17**
Registered USA Implants	13,037	Battery Malfunction	5
Estimated Active USA Implants	7,413	Electrical Component	6
Normal Battery Depletions	453	Poss Early Battery Depltn	3
		Software Malfunction	3
		Therapy Function Compromised	**5**
		Battery Malfunction	2
		Electrical Component	2
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	0.999	0.999	0.999	0.999	0.999	0.998	0.998	0.997
Including NBD	0.998	0.996	0.995	0.993	0.988	0.981	0.956	0.894	0.718
Effective Sample Size	11250	10547	9935	9238	8298	6959	4971	2298	148

D294DRG Virtuoso II DR

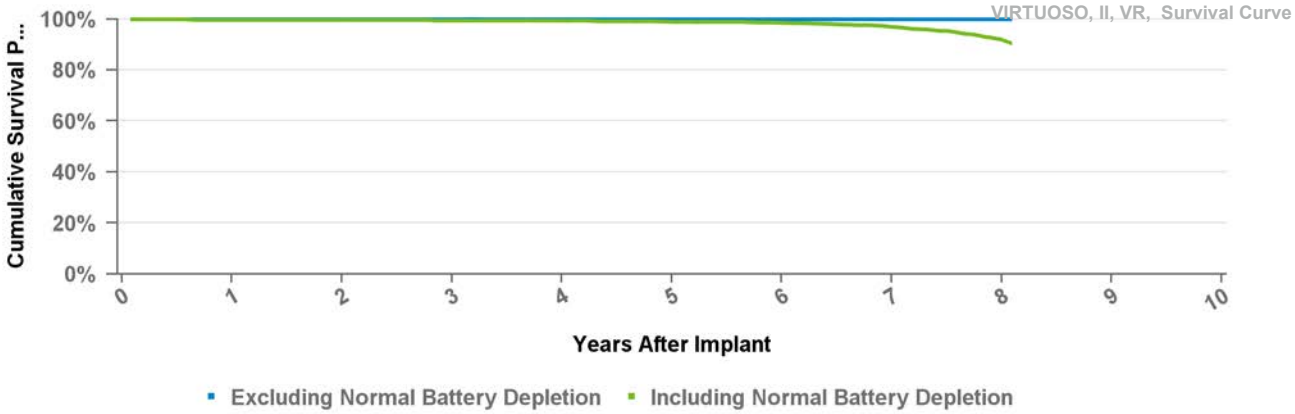
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	at 95 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.997	0.997
Including NBD	0.998	0.997	0.993	0.987	0.961	0.892	0.728	0.158
Effective Sample Size	19349	18171	17106	15896	14180	11421	6040	133

D294VRC Virtuoso II VR

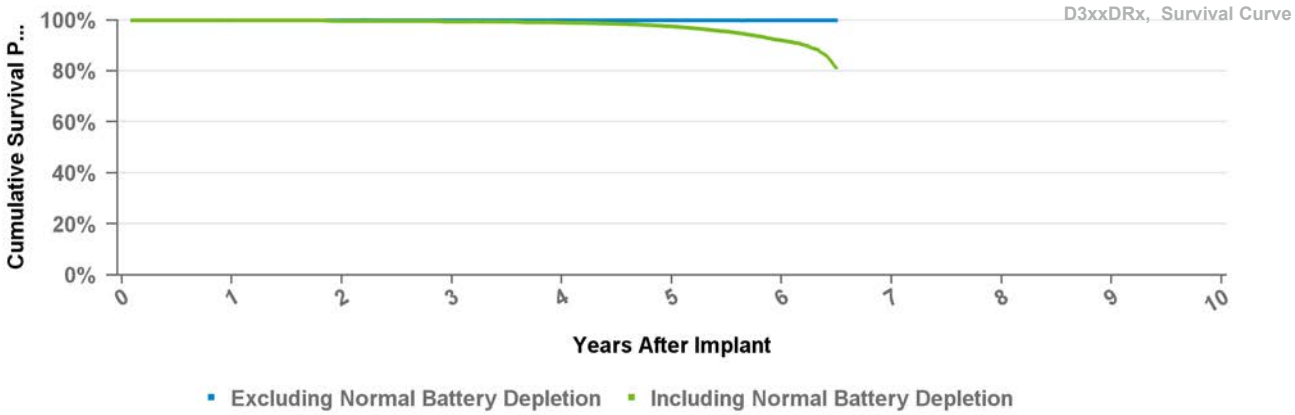
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	1	1	1	0.999	0.999	0.998	0.998	0.998	0.998
Including NBD	0.997	0.997	0.995	0.994	0.989	0.985	0.969	0.919	0.905
Effective Sample Size	7795	7319	6909	6429	5932	5368	3666	560	271

D314DRG Protecta XT DR

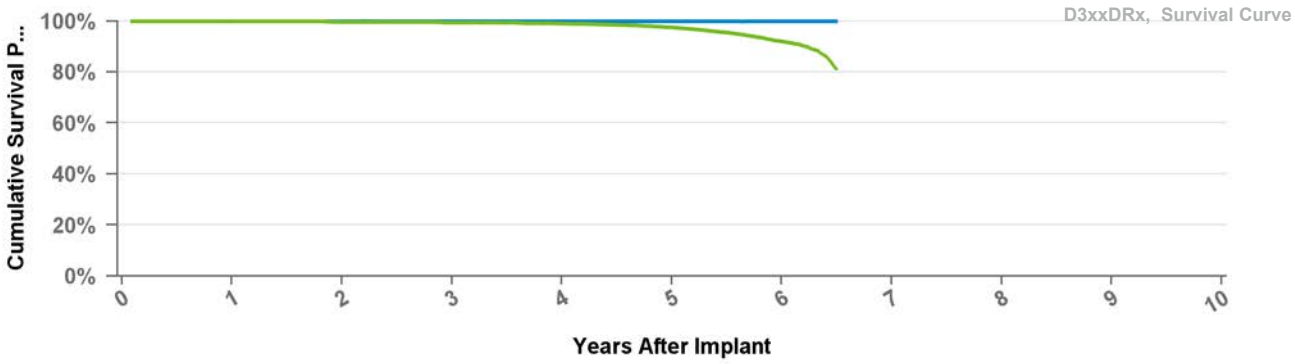
US Market Release	Mar-11	**Total Malfunctions**	**46**
CE Approval Date		**Therapy Function Not Compromised**	**37**
Registered USA Implants	34,836	Battery Malfunction	7
Estimated Active USA Implants	23,578	Electrical Component	24
Normal Battery Depletions	904	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**9**
		Battery Malfunction	2
		Electrical Component	7



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D314DRM Protecta XT DR

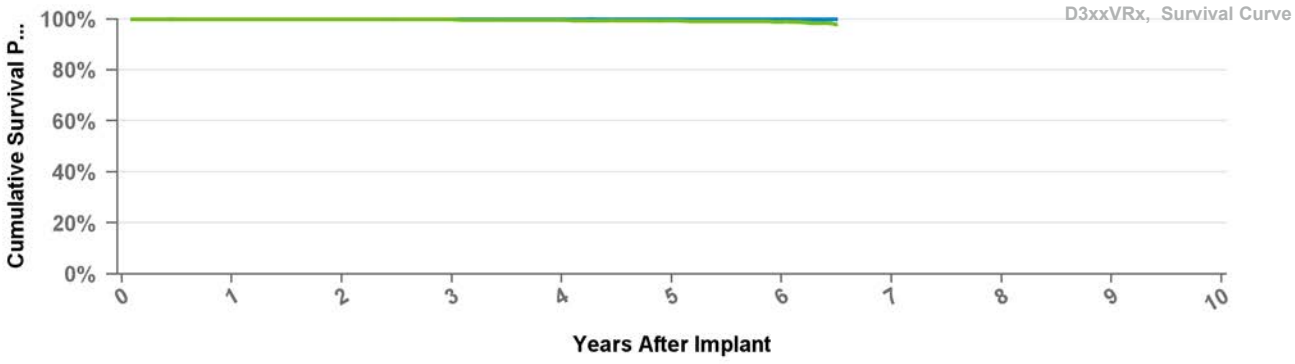
US Market Release	Nov-11	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	13,925	Battery Malfunction	2
Estimated Active USA Implants	10,941	Electrical Component	11
Normal Battery Depletions	134	Other Malfunction	1
		Therapy Function Compromised	**1**
		Battery Malfunction	1



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D314VRG Protecta XT VR

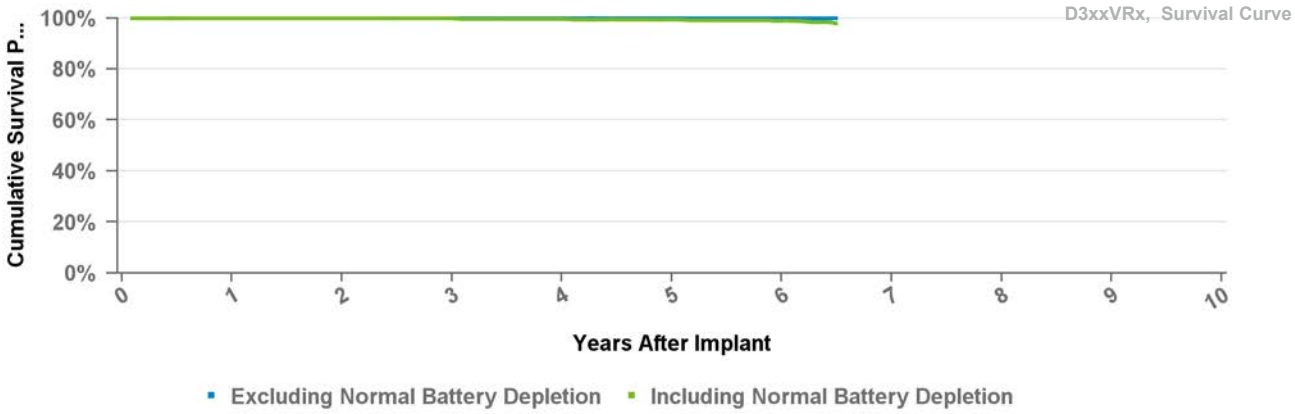
US Market Release	Mar-11	**Total Malfunctions**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	14,217	Battery Malfunction	3
Estimated Active USA Implants	10,849	Electrical Component	8
Normal Battery Depletions	56	Other Malfunction	1
		Therapy Function Compromised	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D314VRM Protecta XT VR

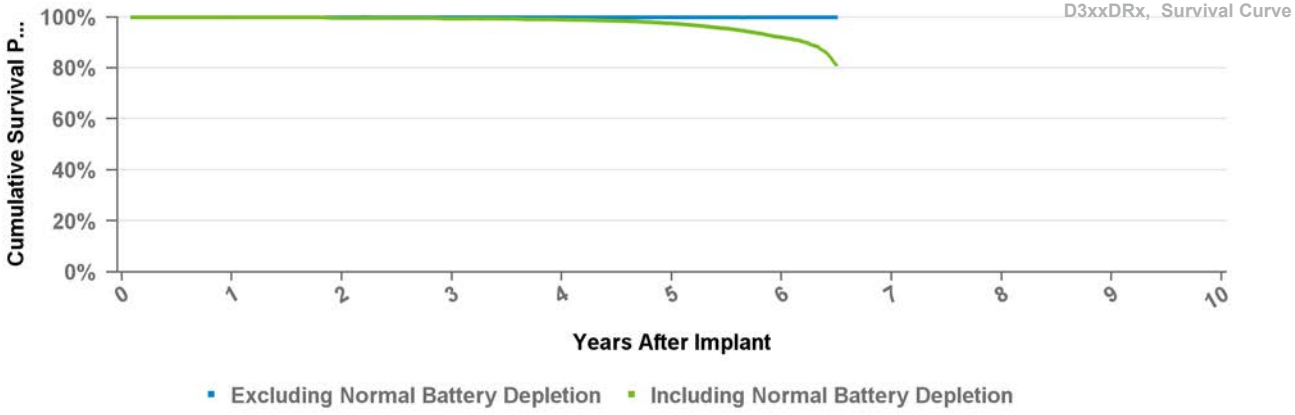
US Market Release	May-12	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,376	Electrical Component	2
Estimated Active USA Implants	5,965	**Therapy Function Compromised**	**2**
Normal Battery Depletions	19	Electrical Component	2



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D334DRG Protecta DR

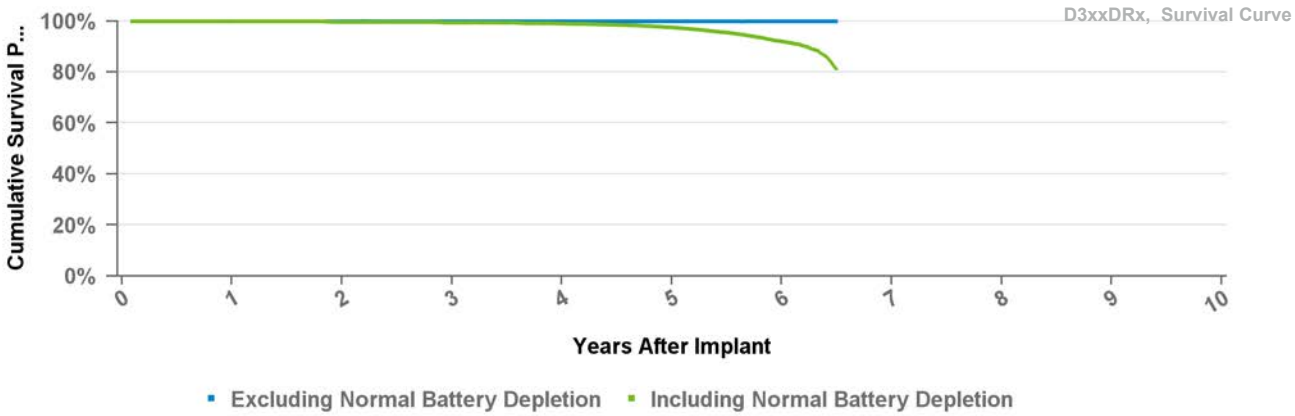
US Market Release	Mar-11	**Total Malfunctions**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	10,692	Battery Malfunction	2
Estimated Active USA Implants	7,189	Electrical Component	4
Normal Battery Depletions	397	Poss Early Battery Depltn	1
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D334DRM Protecta DR

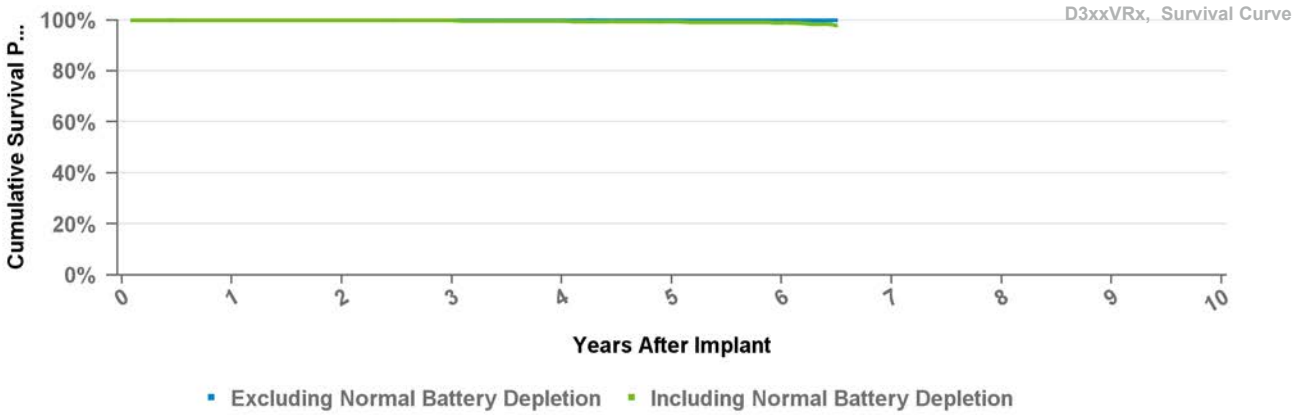
US Market Release	Nov-11	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,992		
Estimated Active USA Implants	2,415	**Therapy Function Compromised**	**0**
Normal Battery Depletions	47		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D334VRG Protecta VR

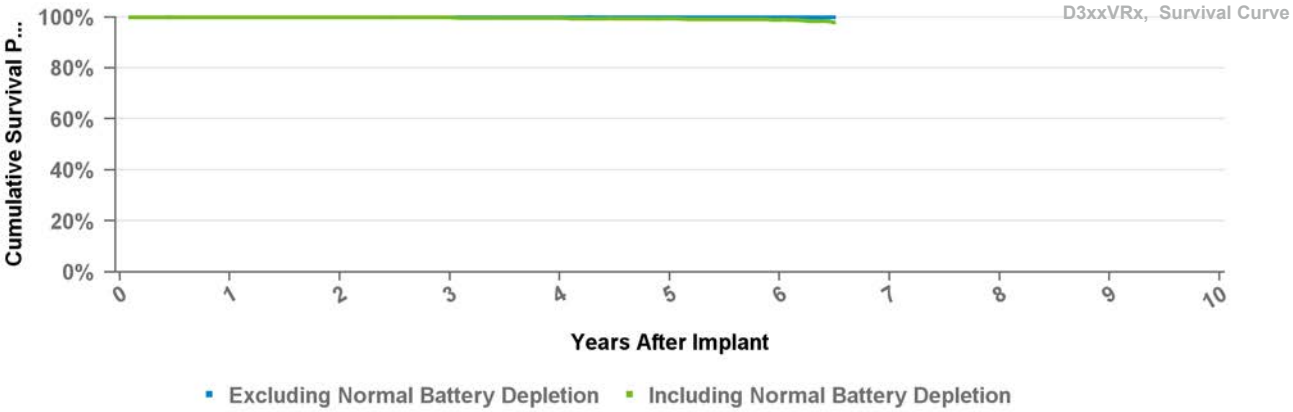
US Market Release	Mar-11	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	6,483	Battery Malfunction	1
Estimated Active USA Implants	5,051	Electrical Component	3
Normal Battery Depletions	18	**Therapy Function Compromised**	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D334VRM Protecta VR

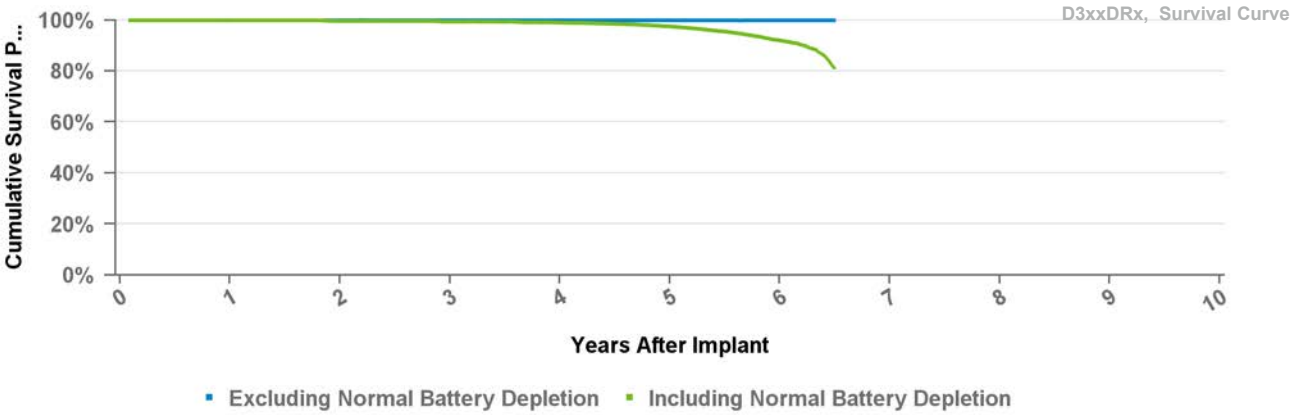
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,162	Other Malfunction	1
Estimated Active USA Implants	1,765	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D354DRG Protecta XT DR

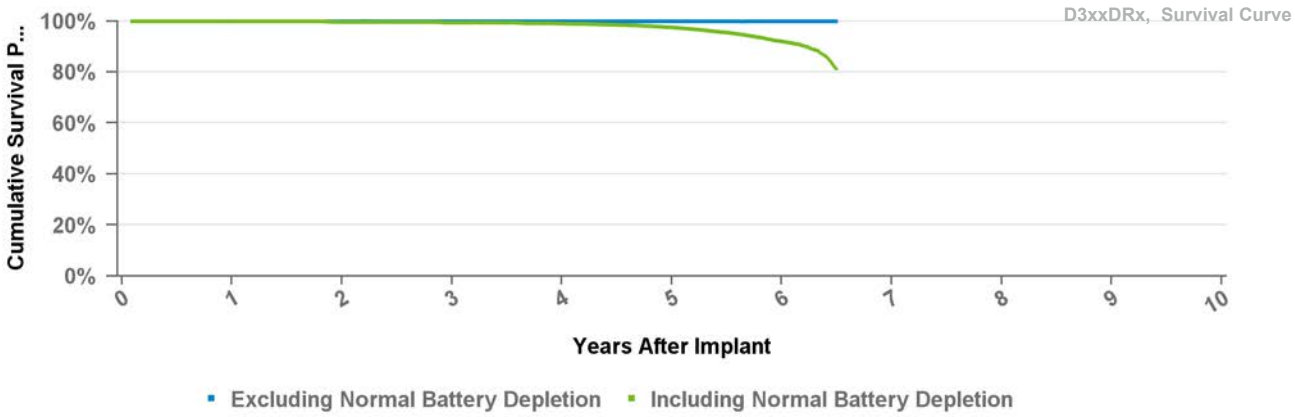
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	4		
Estimated Active USA Implants	3	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D354DRM Protecta XT DR

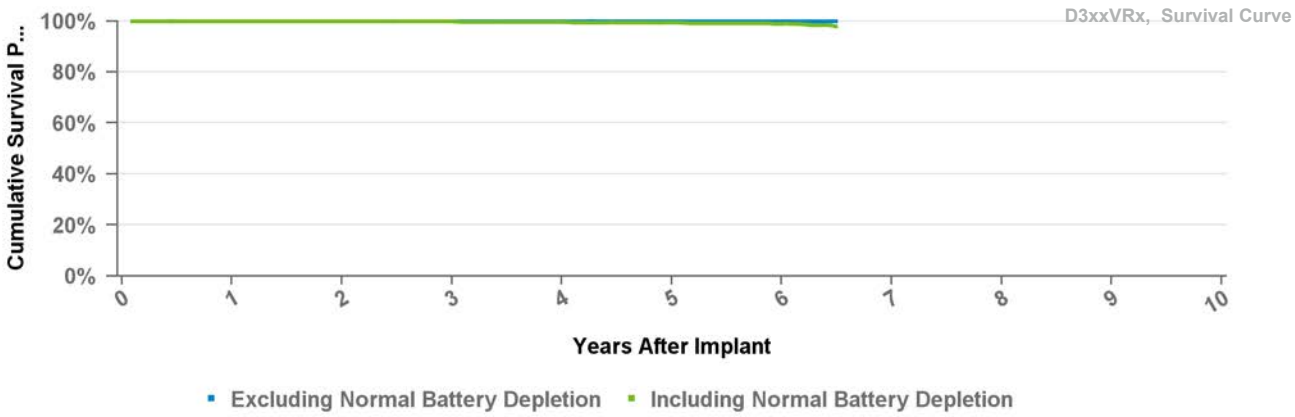
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D354VRG Protecta XT VR

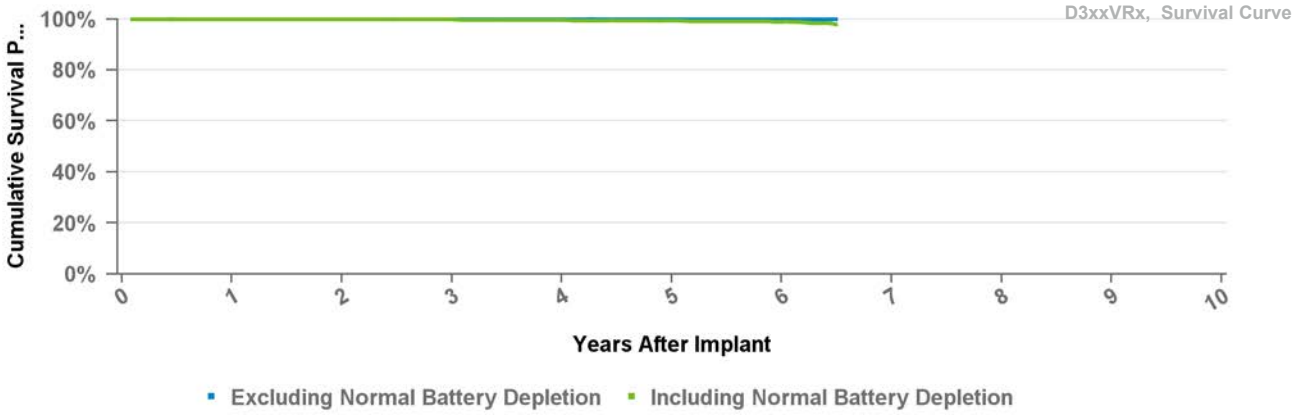
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D354VRM Protecta XT VR

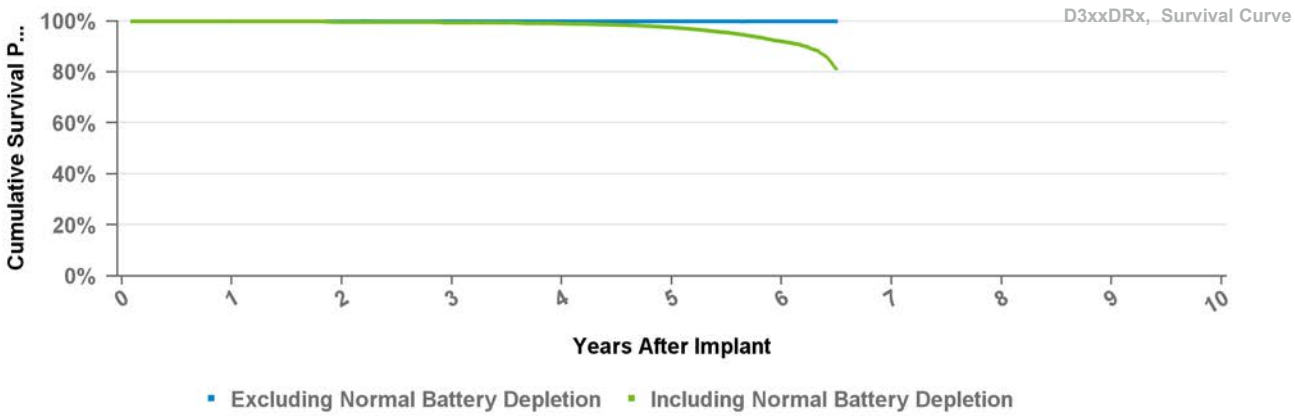
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D364DRG Protecta DR

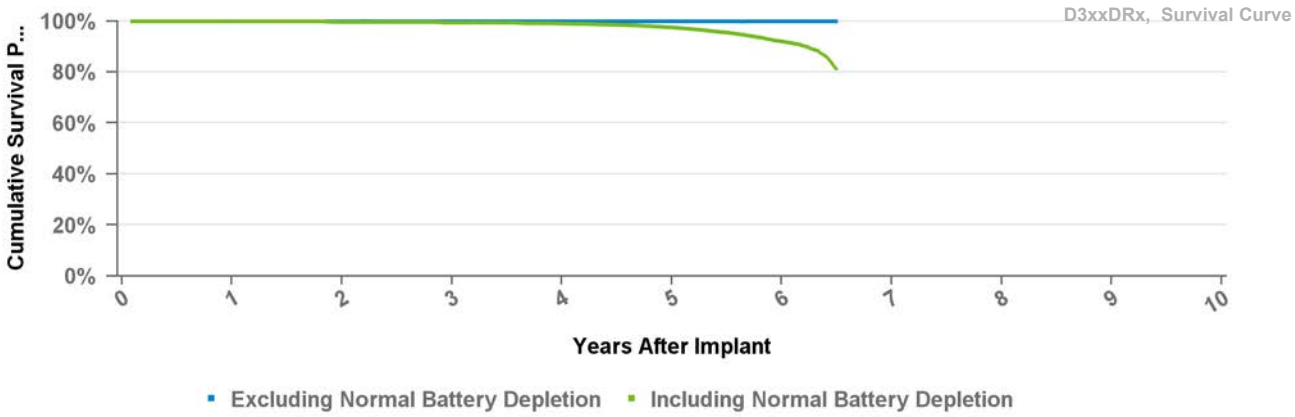
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D364DRM Protecta DR

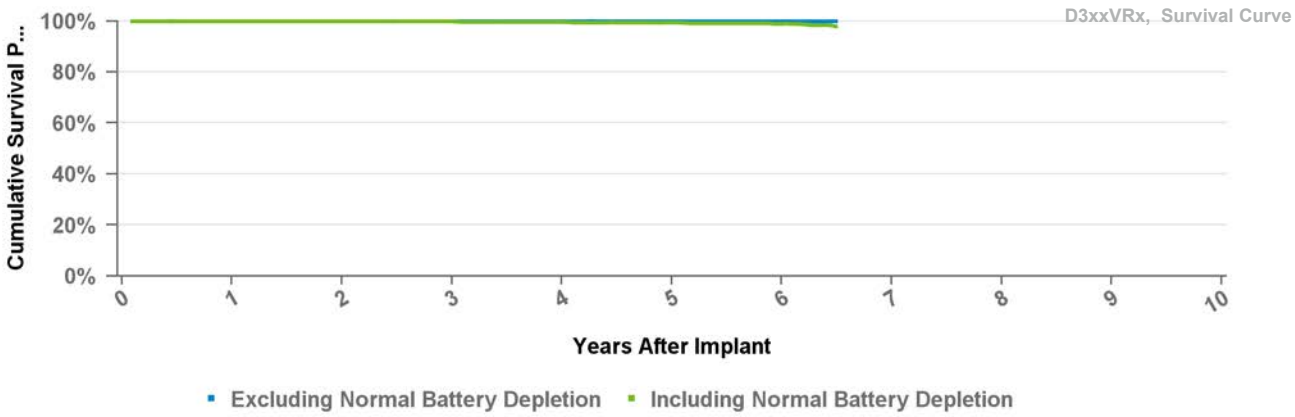
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D364VRG Protecta VR

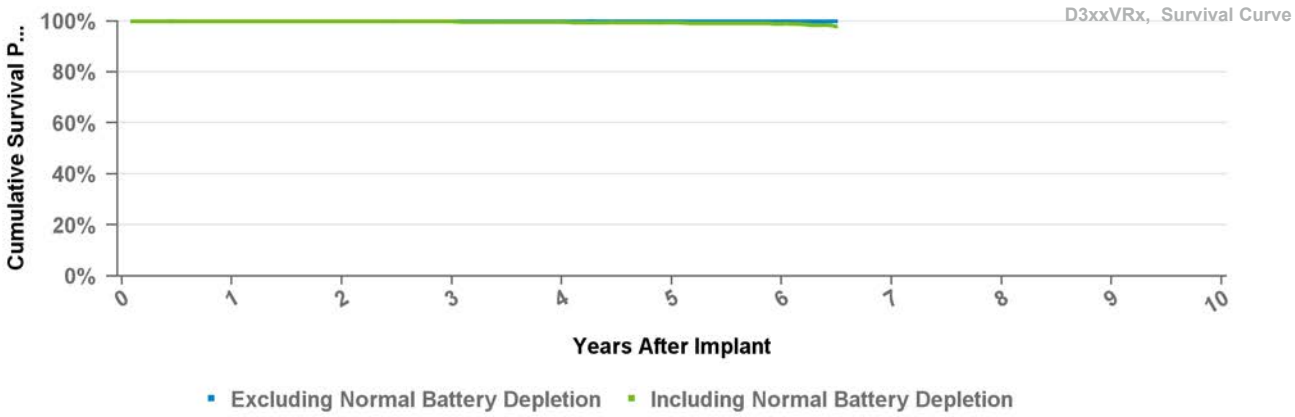
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D364VRM Protecta VR

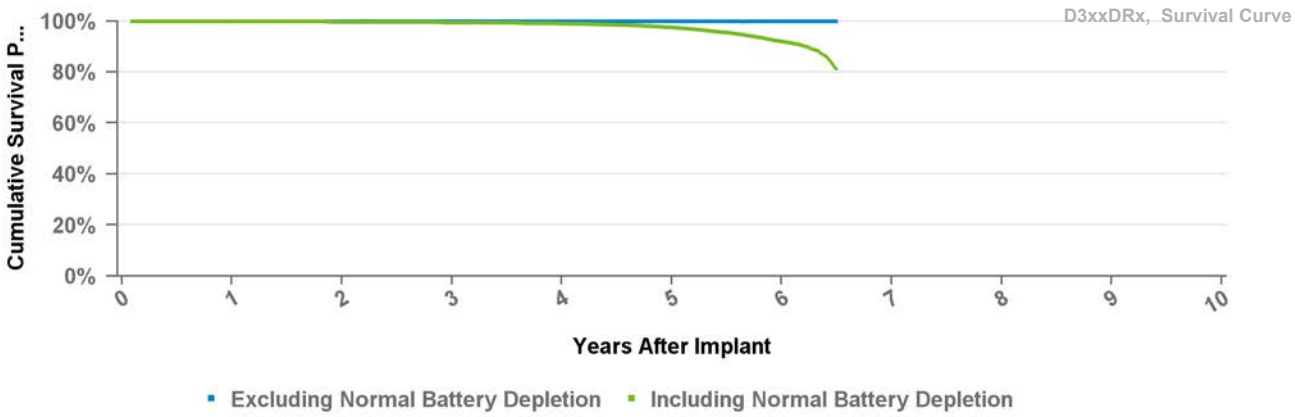
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D384DRG Cardia DR

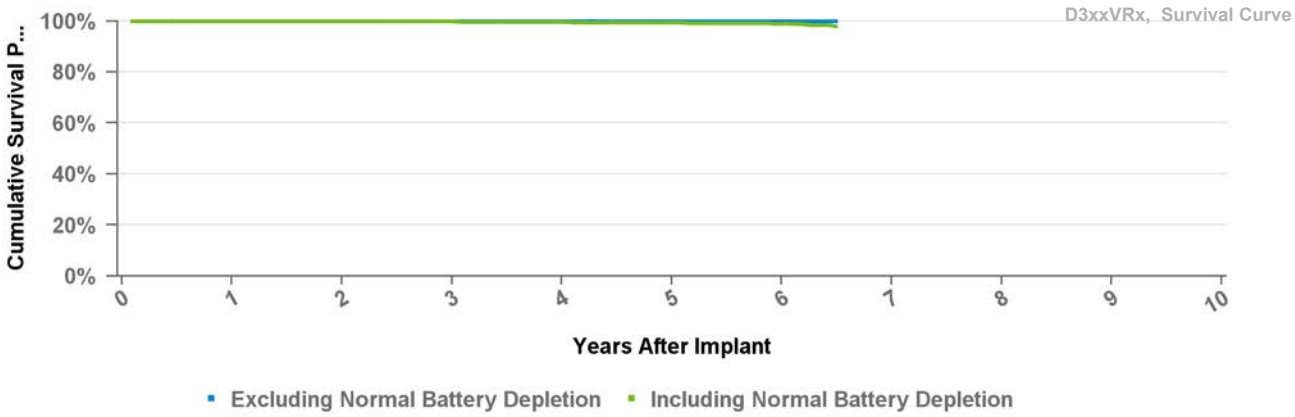
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D384VRG Cardia VR

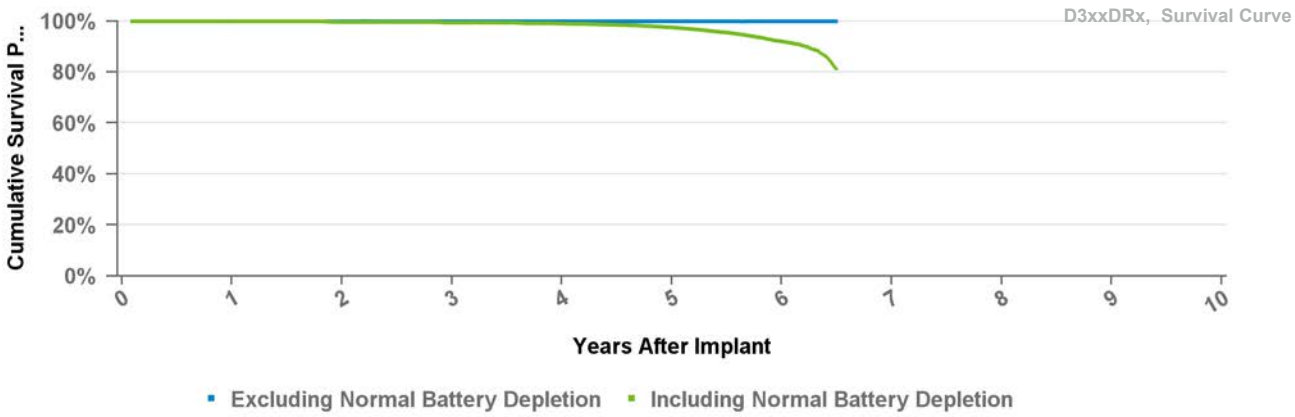
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

D394DRG Egida DR

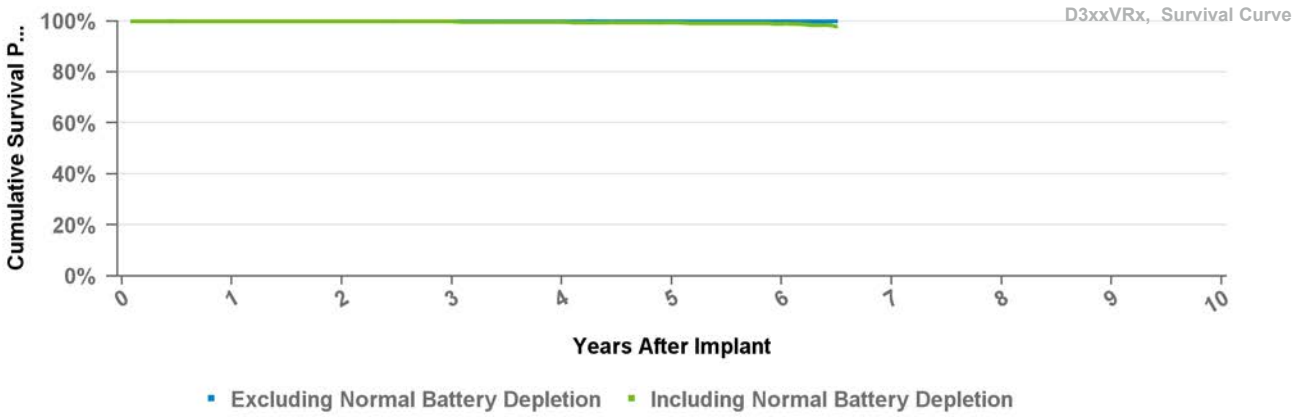
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	0.999	0.999	0.999	0.998	0.998
Including NBD	0.998	0.997	0.995	0.99	0.975	0.92	0.813
Effective Sample Size	55780	52410	49131	44777	33401	9651	1036

D394VRG Egida VR

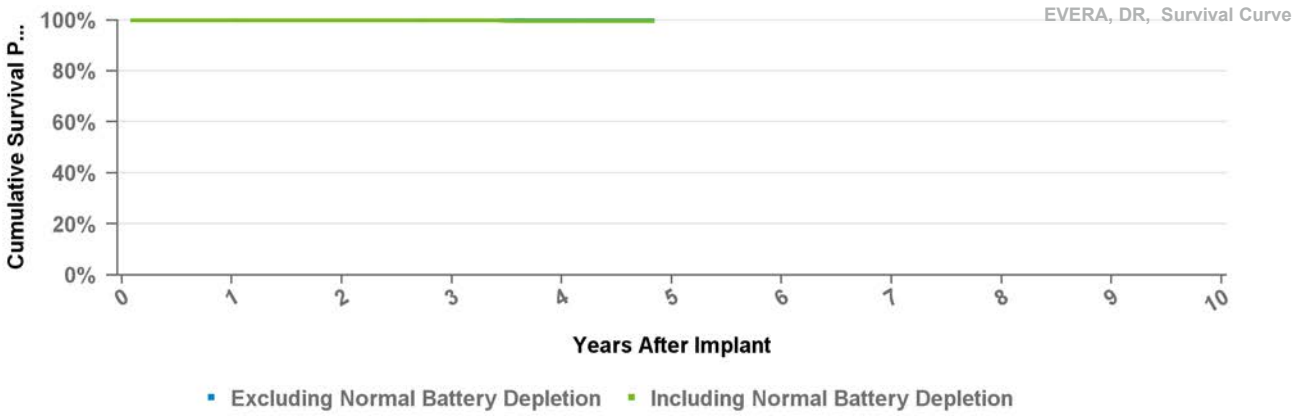
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	1	1	1	1	0.999	0.999	0.999
Including NBD	0.999	0.999	0.998	0.996	0.993	0.99	0.978
Effective Sample Size	26703	25030	23514	21249	15531	4436	521

DDBB1D1 Evera XT

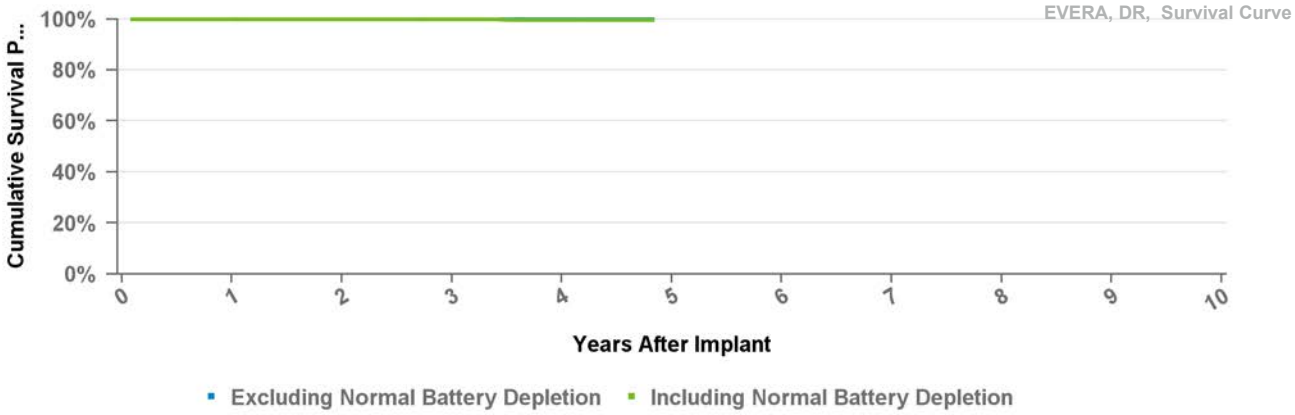
US Market Release	Apr-13	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	40,399	Battery Malfunction	4
Estimated Active USA Implants	36,245	Electrical Component	7
Normal Battery Depletions	34	**Therapy Function Compromised**	**4**
		Battery Malfunction	3
		Electrical Interconnect	1



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDBB1D4 Evera XT

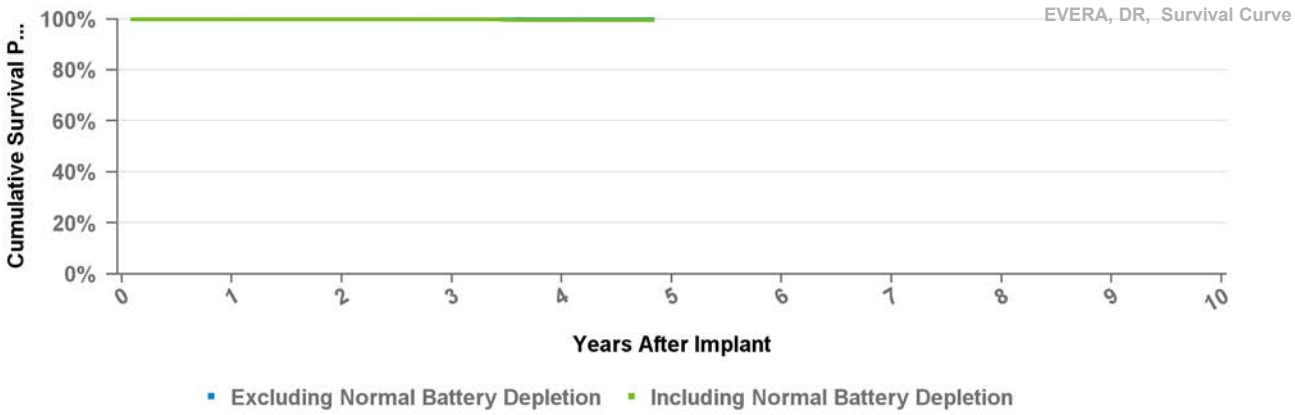
US Market Release	Apr-13	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	29,649	Battery Malfunction	3
Estimated Active USA Implants	26,801	Electrical Component	4
Normal Battery Depletions	17	Electrical Interconnect	1
		Other Malfunction	1
		Therapy Function Compromised	**6**
		Battery Malfunction	3
		Electrical Component	3



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDBB2D1 Evera XT

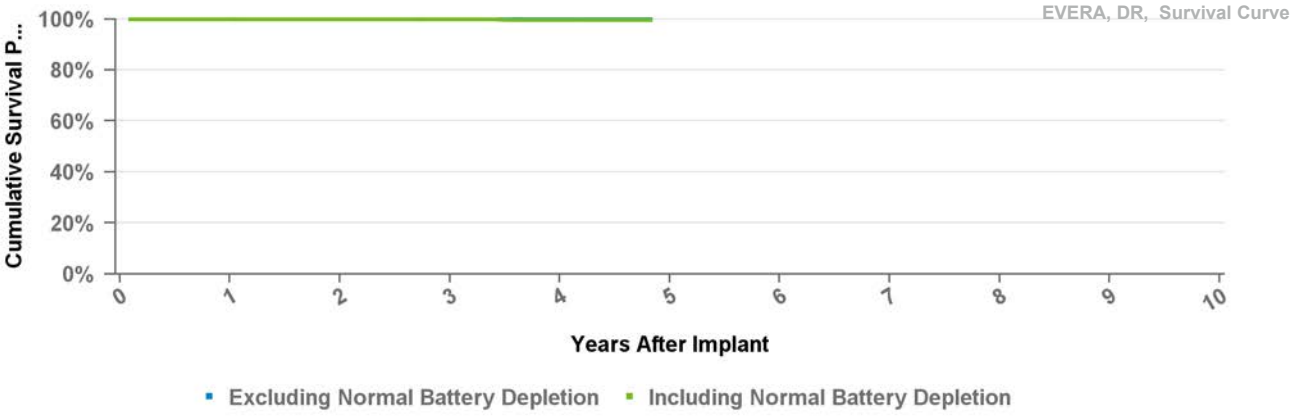
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDBB2D4 Evera XT

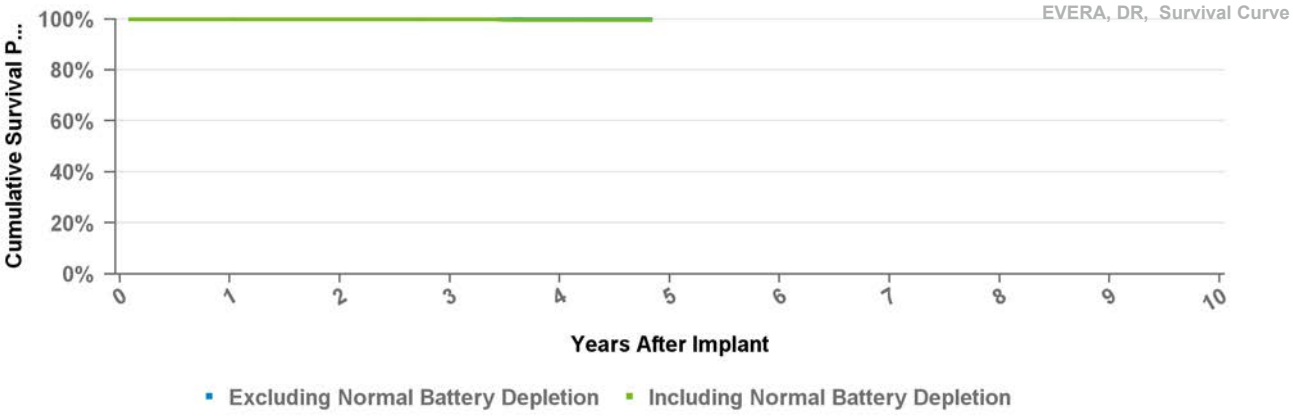
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDBC3D1 Evera S

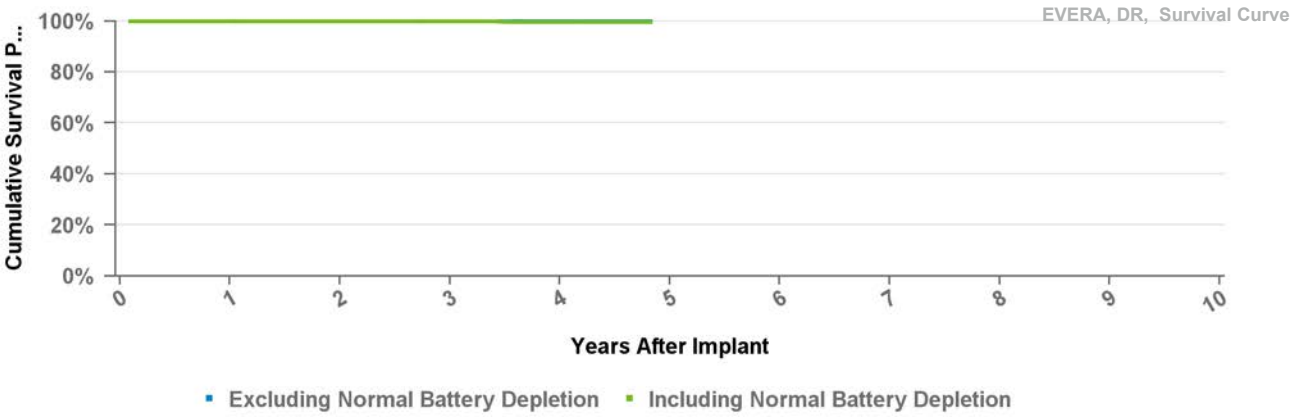
US Market Release	Apr-13	**Total Malfunctions**	**3**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,891	Electrical Component	2
Estimated Active USA Implants	7,082	**Therapy Function Compromised**	**1**
Normal Battery Depletions	8	Electrical Component	1



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDBC3D4 Evera S

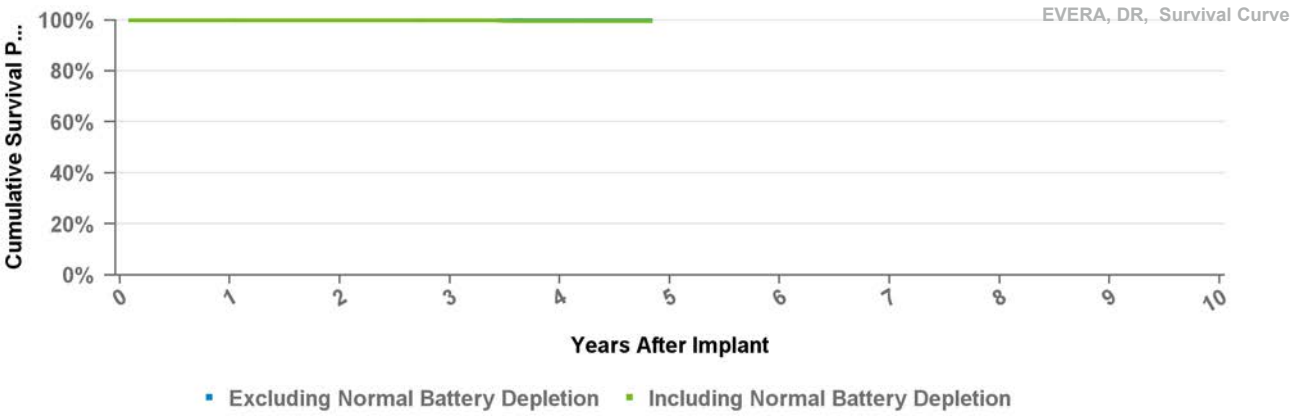
US Market Release	Apr-13	**Total Malfunctions**	**4**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**4**
Registered USA Implants	5,789	Battery Malfunction	2
Estimated Active USA Implants	5,206	Electrical Component	2
Normal Battery Depletions	4	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMB1D1 Evera MRI XT

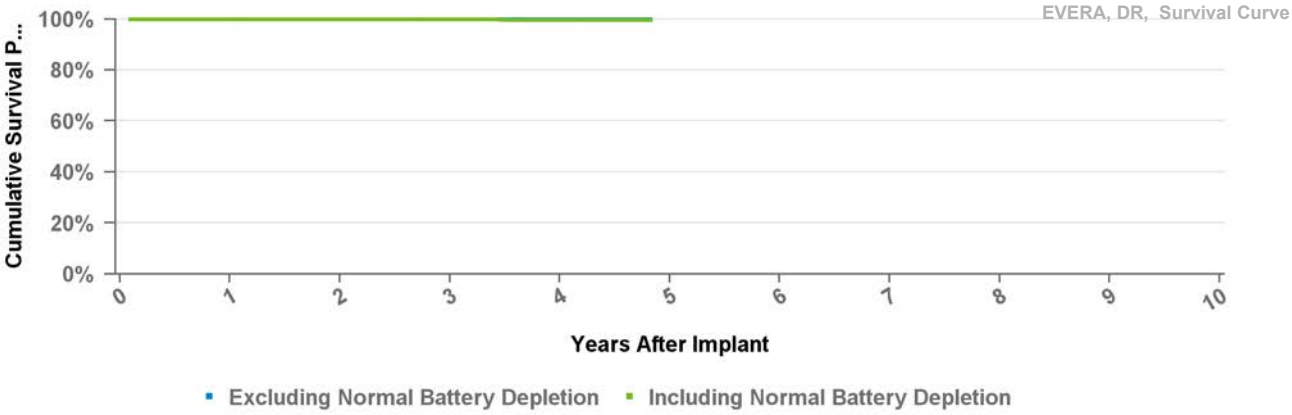
US Market Release	Oct-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	12,229	Electrical Interconnect	1
Estimated Active USA Implants	11,999	Other Malfunction	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMB1D4 Evera MRI XT

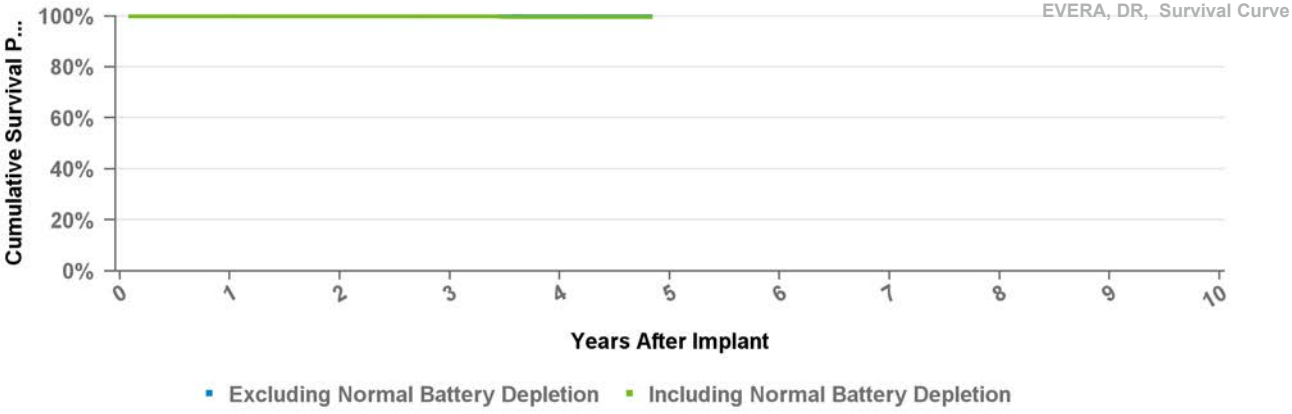
US Market Release	Sep-15	**Total Malfunctions**	**7**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	36,777	Electrical Component	6
Estimated Active USA Implants	35,502	Electrical Interconnect	1
Normal Battery Depletions	11	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMB2D1 Evera MRI XT

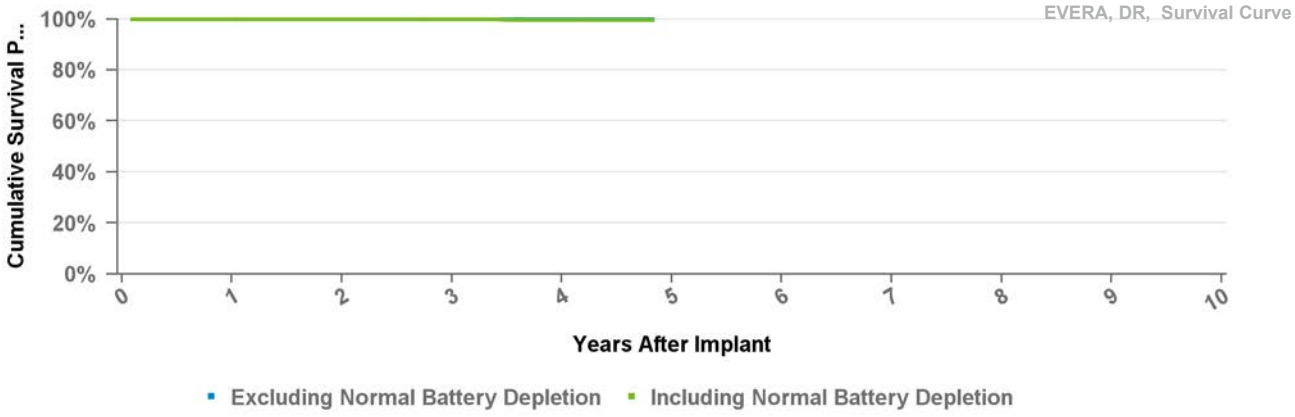
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	246		
Estimated Active USA Implants	243	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMB2D4 Evera MRI XT

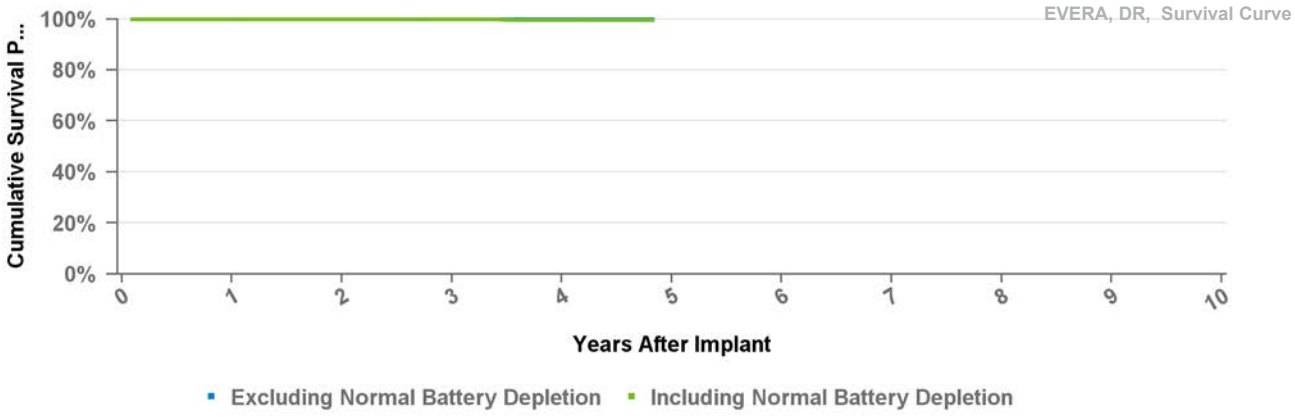
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMC3D1 Evera MRI S

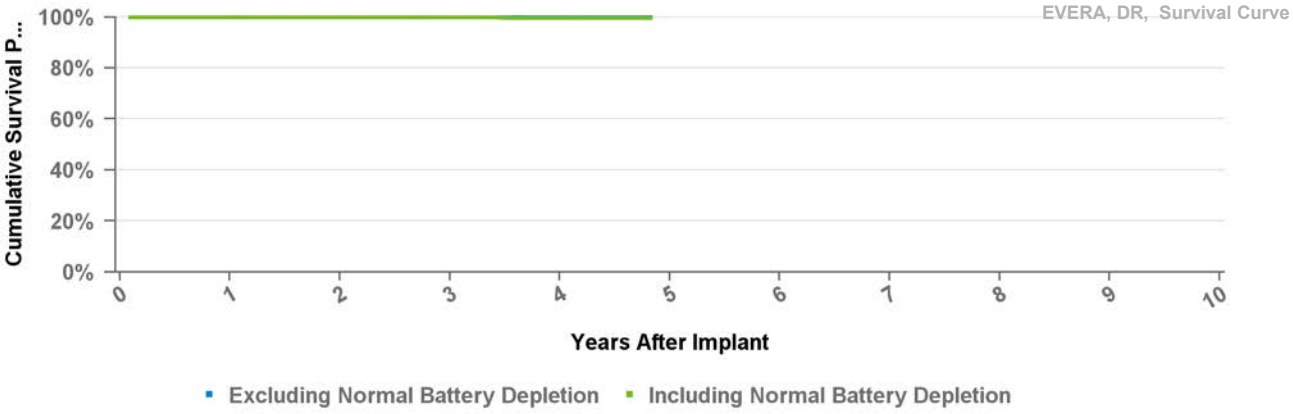
US Market Release	Oct-16	**Total Malfunctions**	**0**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,015		
Estimated Active USA Implants	1,001	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DDMC3D4 Evera MRI

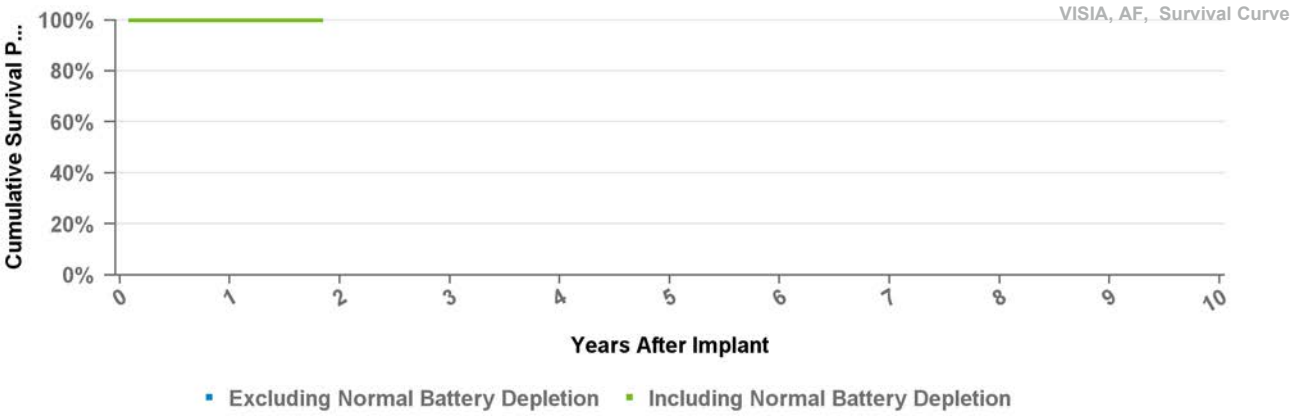
US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,420	Electrical Component	1
Estimated Active USA Implants	2,328	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 58 mo
Excluding NBD	1	1	1	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	100599	67018	39395	15556	345

DVAB1D1 Visia AF

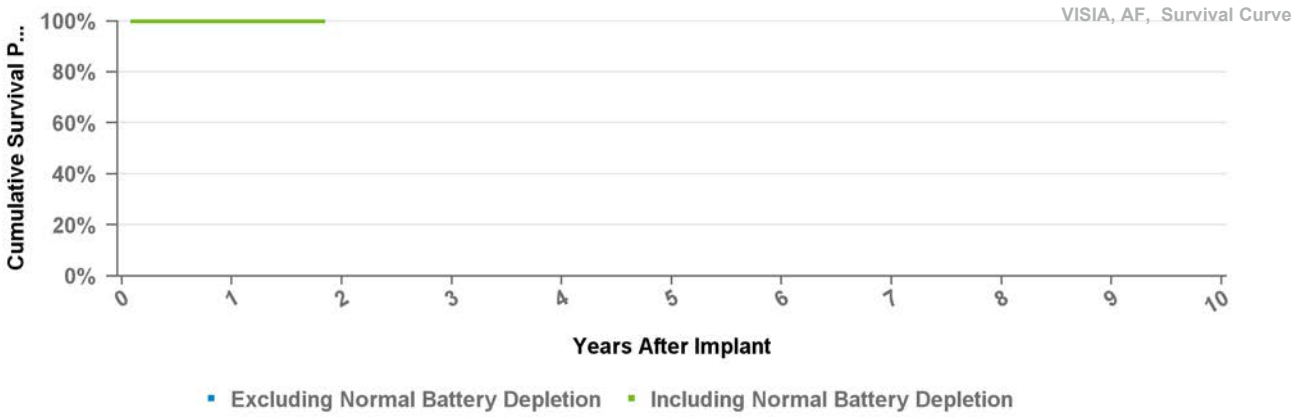
US Market Release	Jan-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,184		
Estimated Active USA Implants	2,105	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVAB1D4 Visia AF

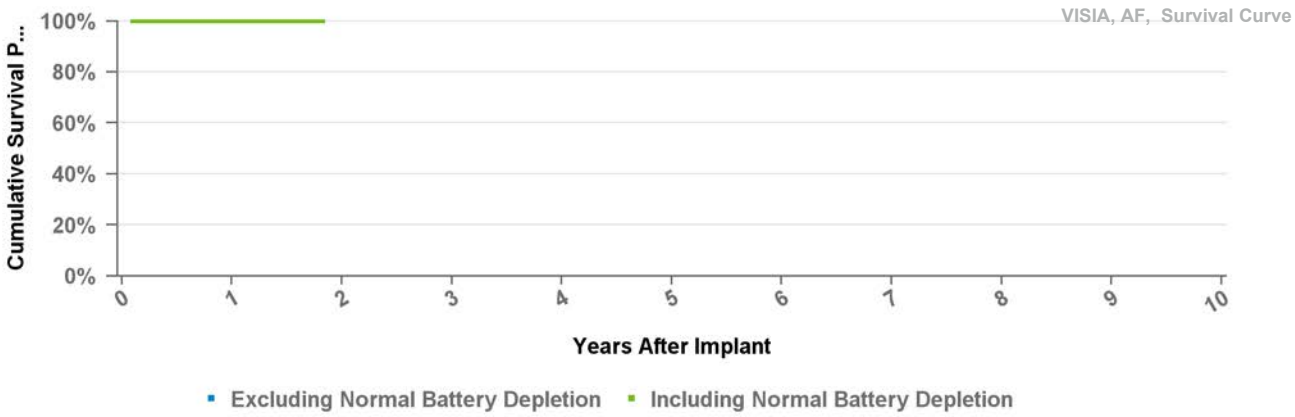
US Market Release	Jan-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,561		
Estimated Active USA Implants	1,515	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVAB2D1 Visia AF XT

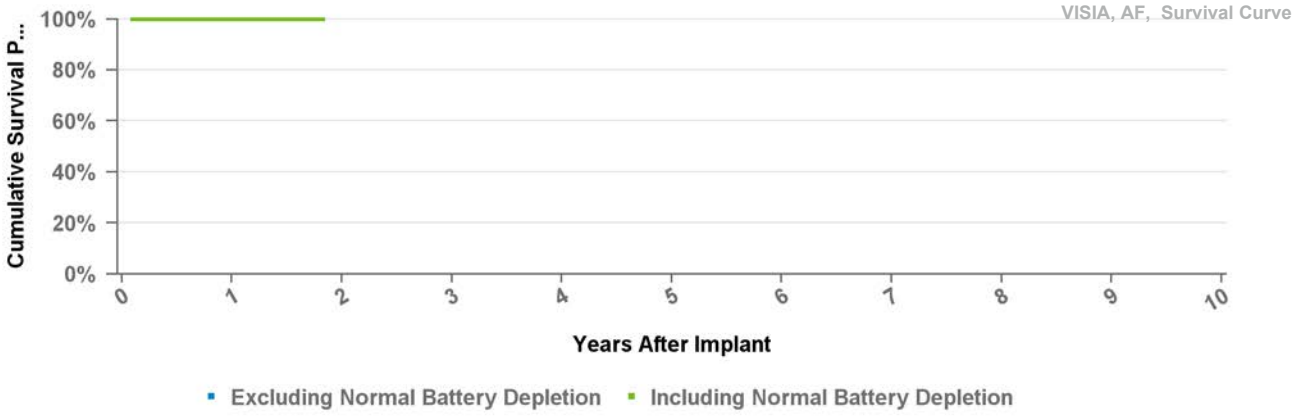
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVAC3D1 Visia AF S

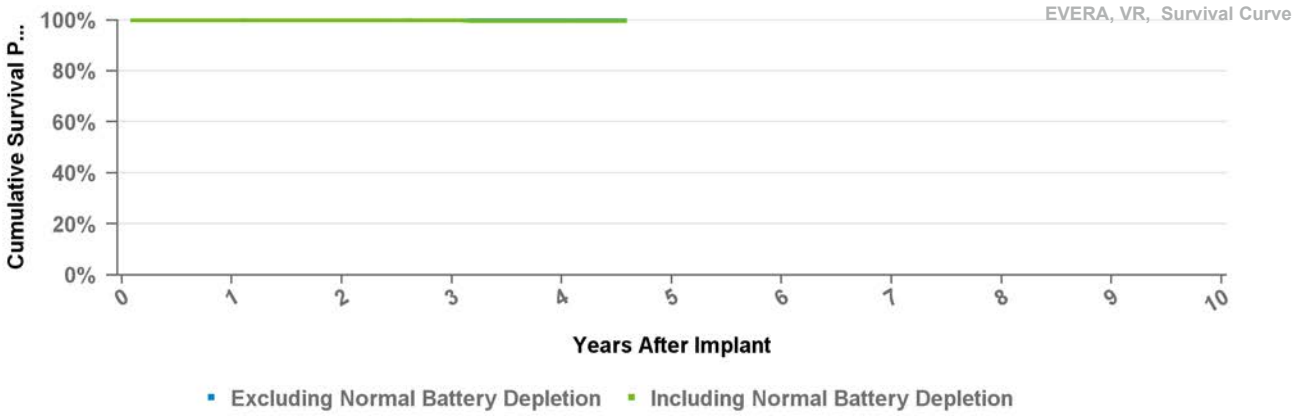
US Market Release	Jan-16	**Total Malfunctions**	**0**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVBB1D1 Evera XT

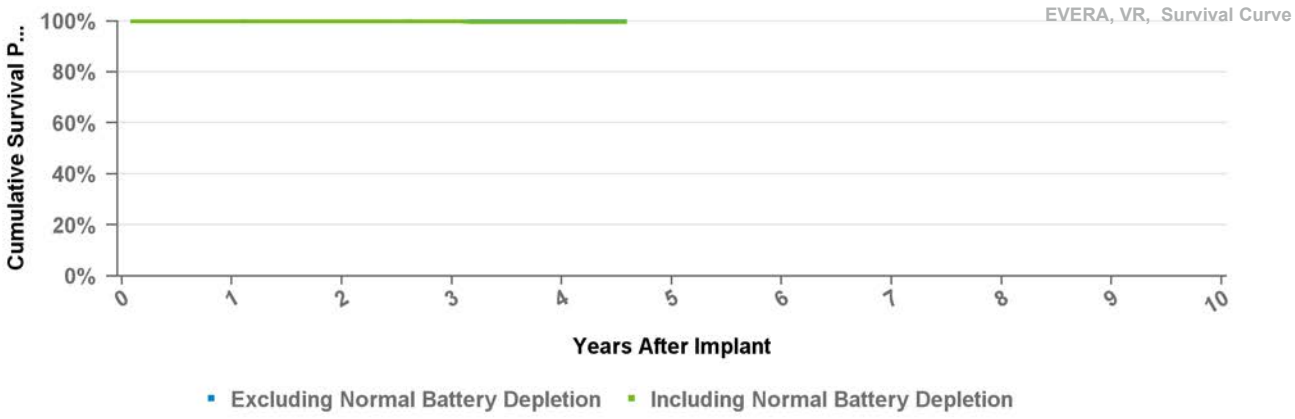
US Market Release	Apr-13	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	16,068	Battery Malfunction	2
Estimated Active USA Implants	14,188	Electrical Component	4
Normal Battery Depletions	9	**Therapy Function Compromised**	**2**
		Electrical Component	2



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVBB1D4 Evera XT

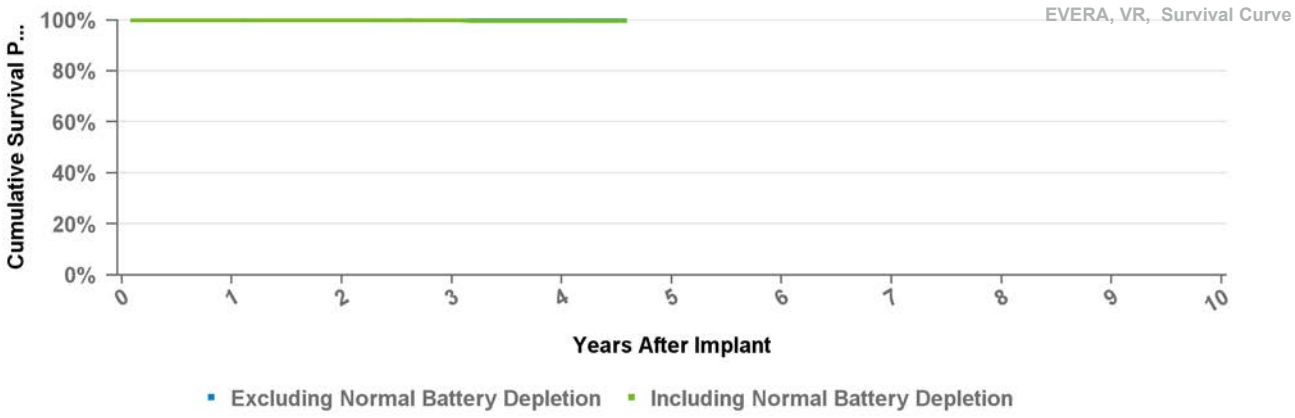
US Market Release	Apr-13	**Total Malfunctions**	**22**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	22,329	Battery Malfunction	8
Estimated Active USA Implants	20,114	Electrical Component	7
Normal Battery Depletions	12	Other Malfunction	2
		Therapy Function Compromised	**5**
		Battery Malfunction	5



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVBB2D1 Evera XT

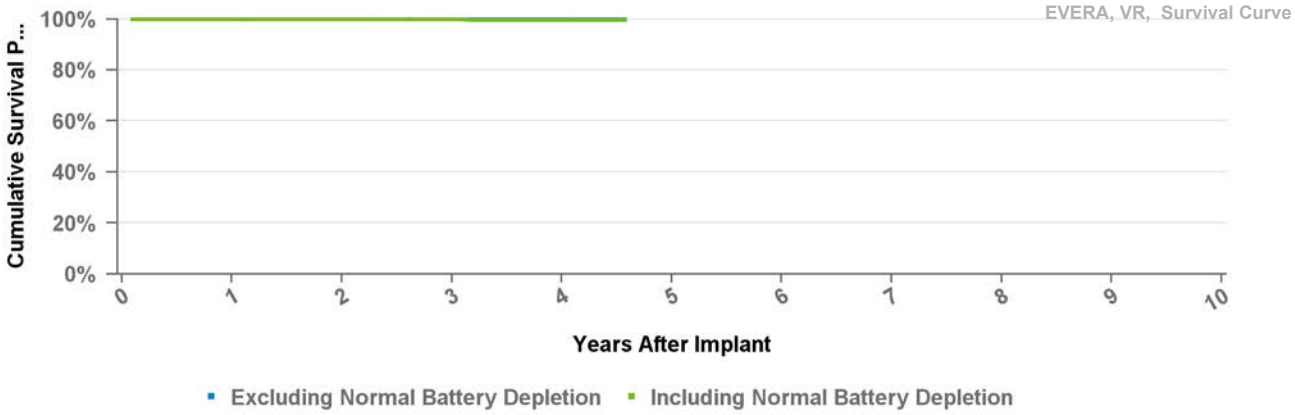
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVBB2D4 Evera XT

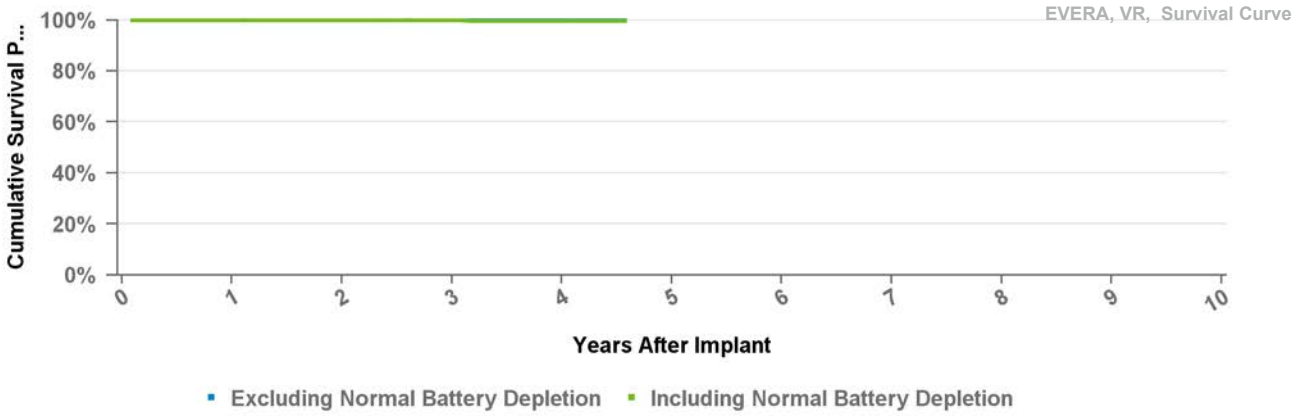
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVBC3D1 Evera S

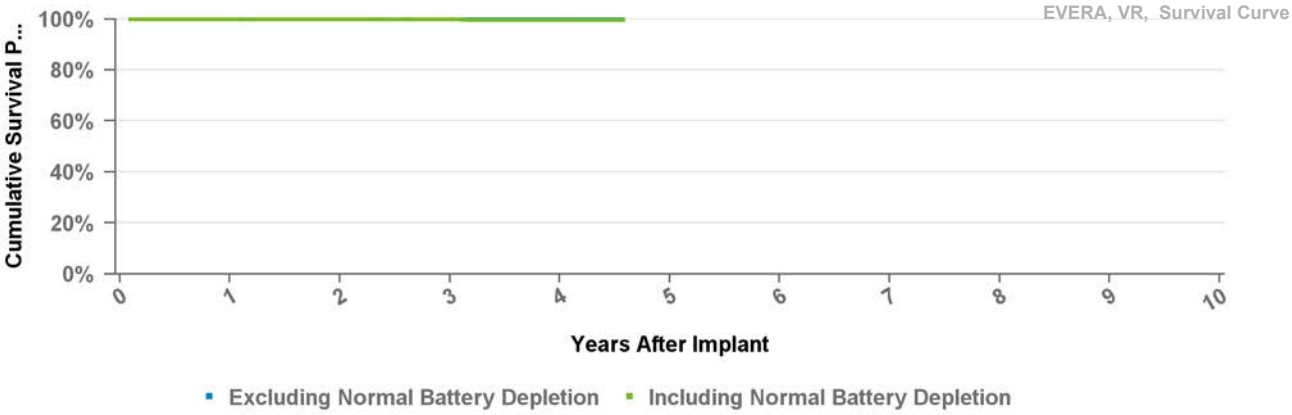
US Market Release	Apr-13	**Total Malfunctions**	**5**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**4**
Registered USA Implants	4,460	Battery Malfunction	2
Estimated Active USA Implants	3,979	Electrical Component	2
Normal Battery Depletions	2	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVBC3D4 Evera S

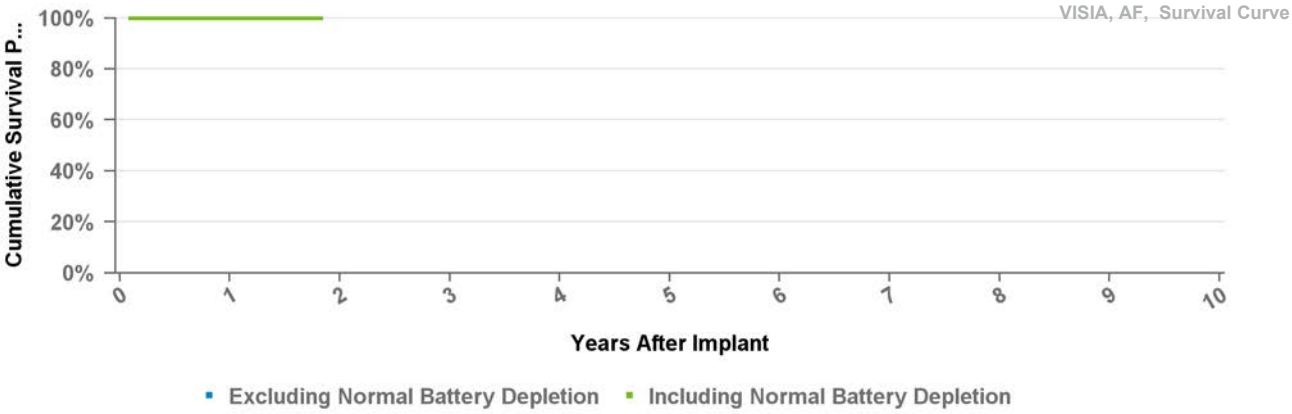
US Market Release	Apr-13	**Total Malfunctions**	**3**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**3**
Registered USA Implants	5,470	Battery Malfunction	2
Estimated Active USA Implants	4,931	Electrical Component	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVFB1D1 Visia MRI AF

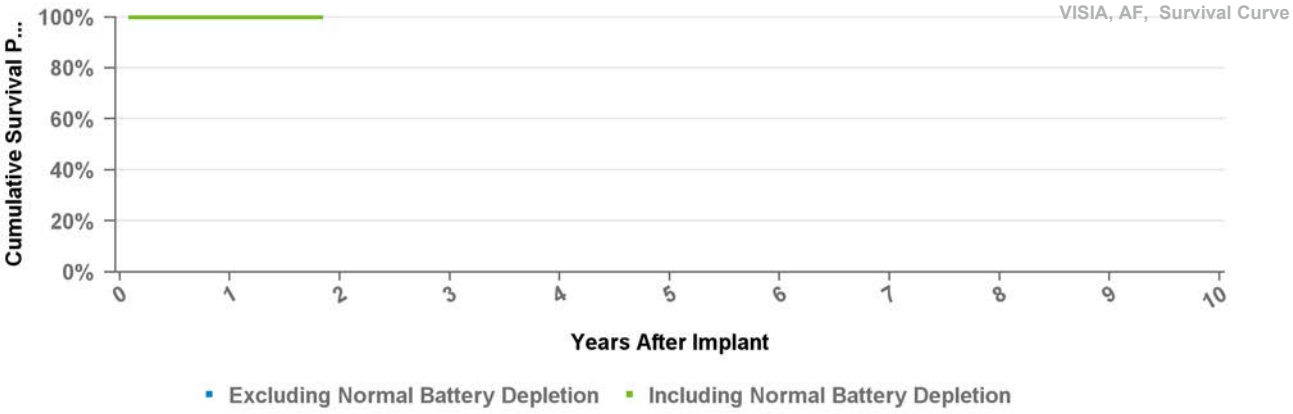
US Market Release	Oct-16	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	3,757		
Estimated Active USA Implants	3,707	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVFB1D4 Visia MRI AF

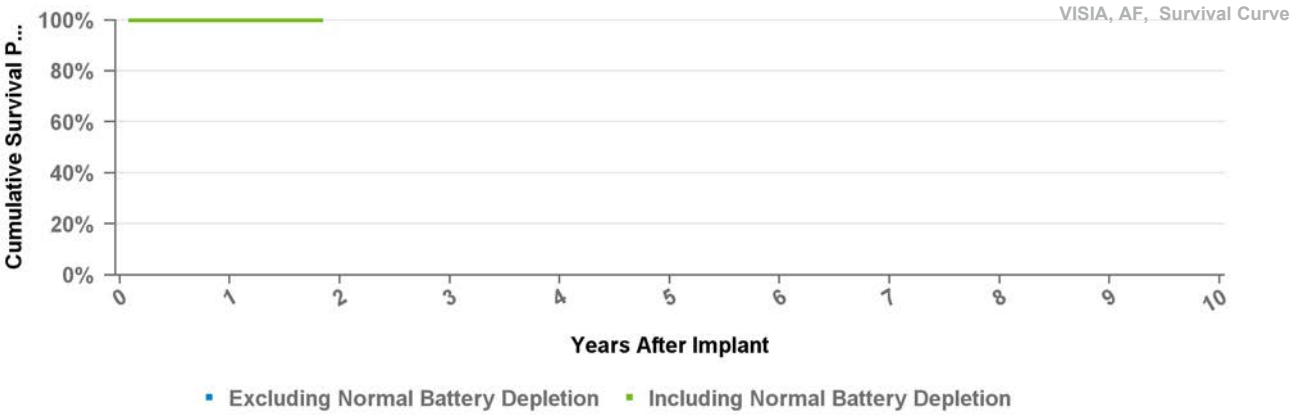
US Market Release	Jan-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	18,623	Electrical Component	2
Estimated Active USA Implants	18,165	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVFB2D1 Visia MRI AF XT

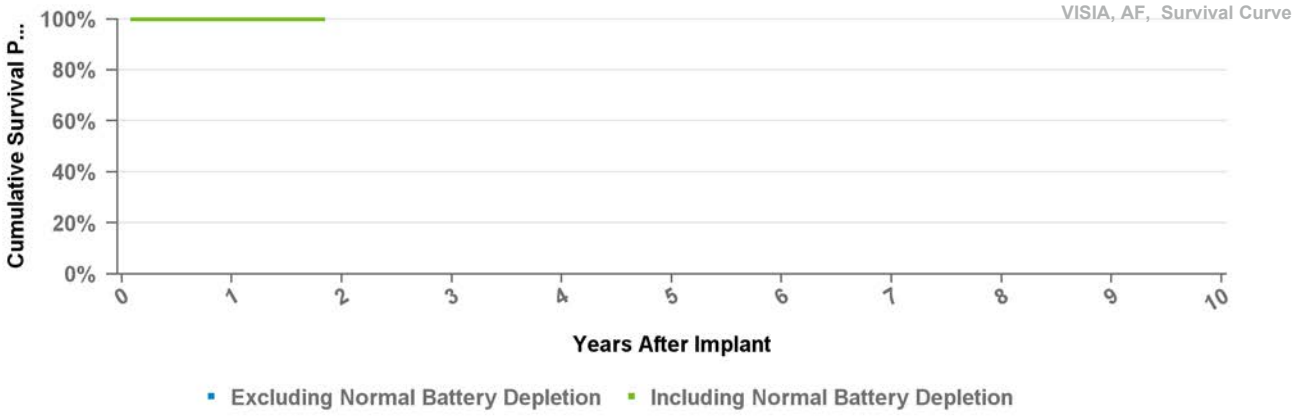
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVFB2D4 Visia MRI AF XT

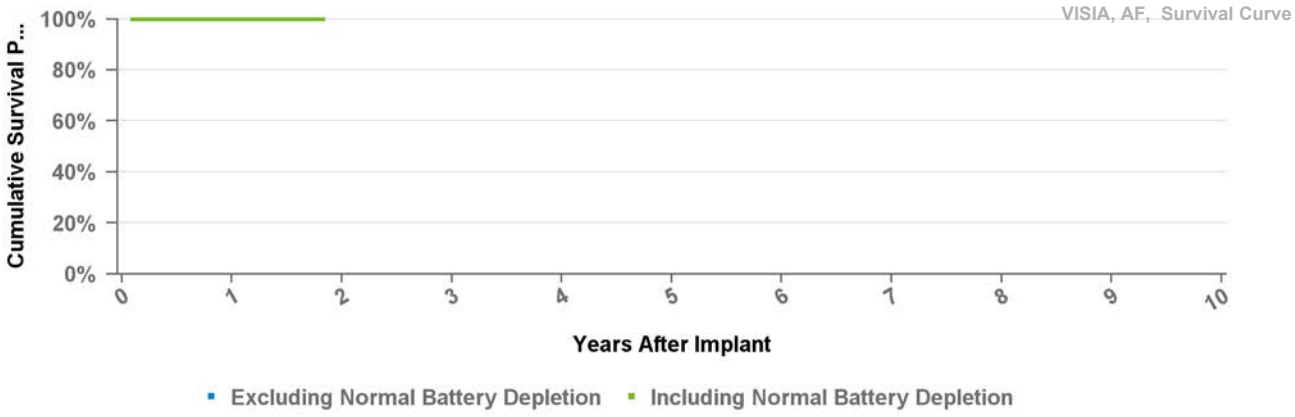
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVFC3D1 Visia MRI AF S

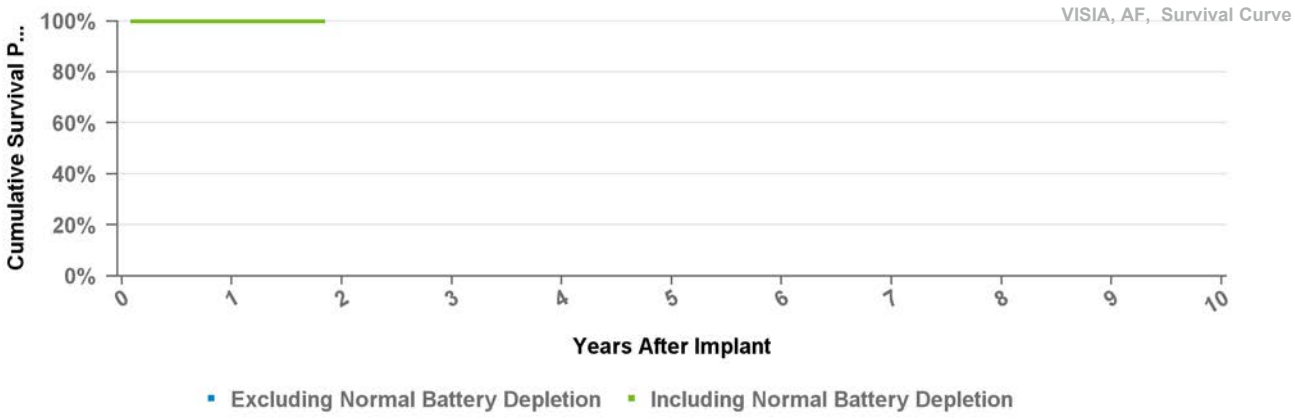
US Market Release	Oct-16	**Total Malfunctions**	**0**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	192		
Estimated Active USA Implants	191	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVFC3D4 Visia MRI AF S

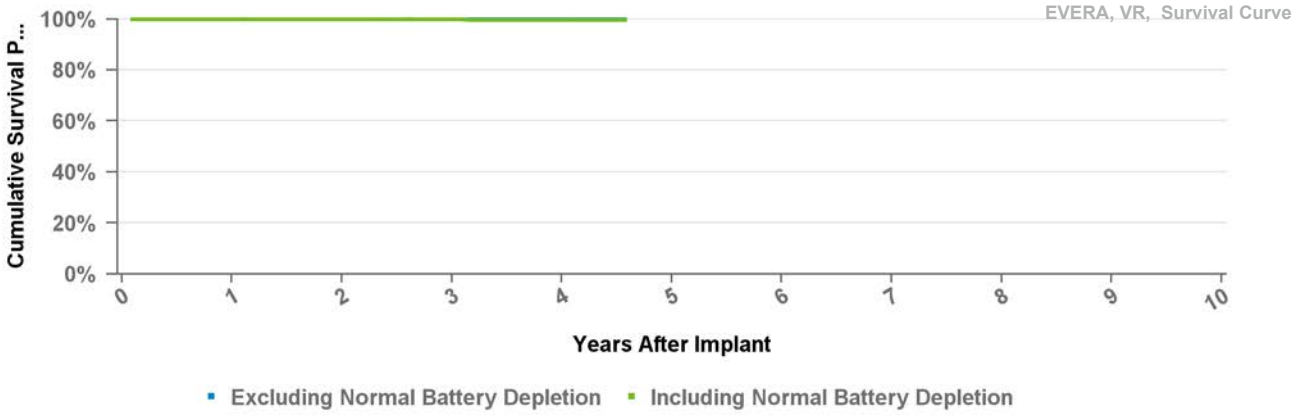
US Market Release	Jan-16	**Total Malfunctions**	**0**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**0**
Registered USA Implants	319		
Estimated Active USA Implants	315	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	at 22 mo
Excluding NBD	1	1
Including NBD	1	1
Effective Sample Size	10791	264

DVMB1D4 Evera MRI XT

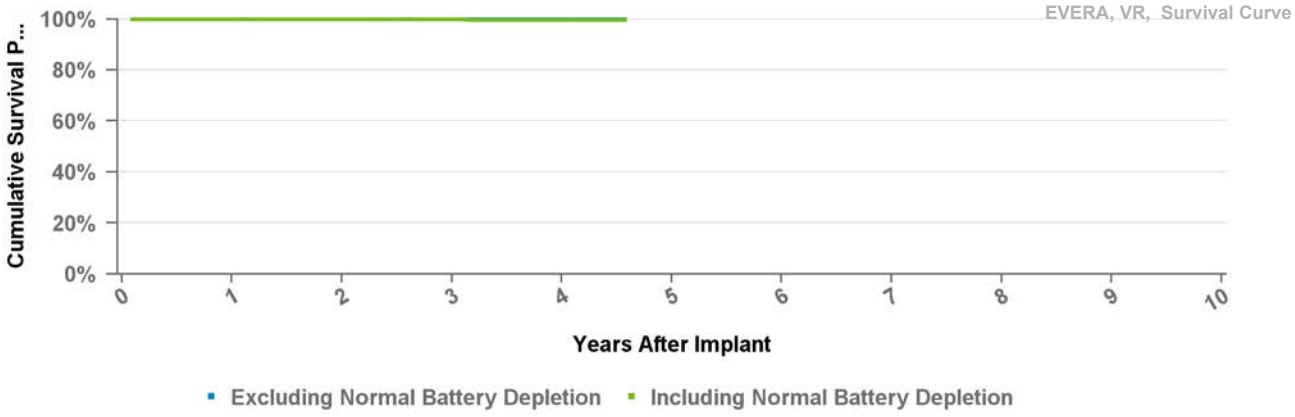
US Market Release	Sep-15	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	10,574	Electrical Component	2
Estimated Active USA Implants	10,001	**Therapy Function Compromised**	**1**
Normal Battery Depletions	3	Battery Malfunction	1



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVMB2D4 Evera MRI XT

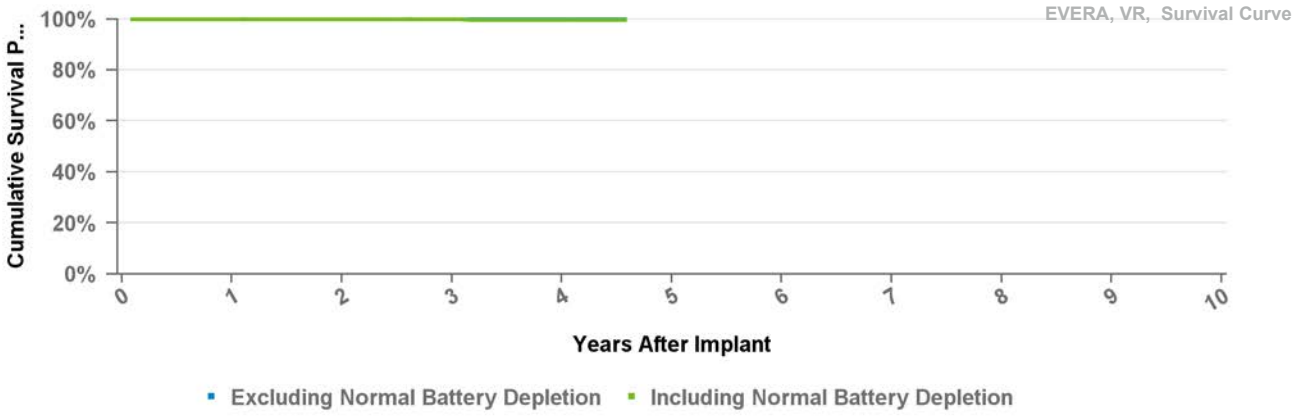
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVMC3D1 Evera MRI S

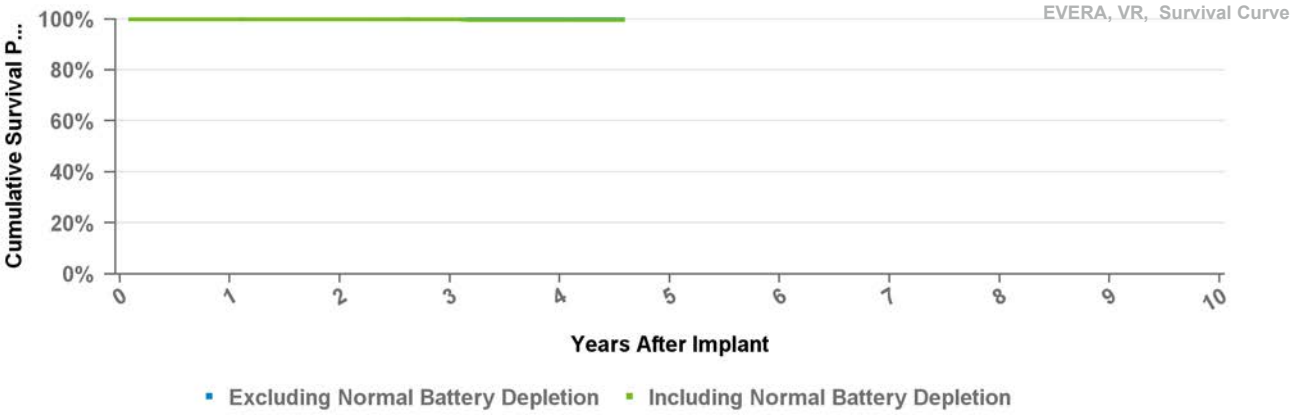
US Market Release	Oct-16	**Total Malfunctions**	**0**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

DVMC3D4 Evera MRI S

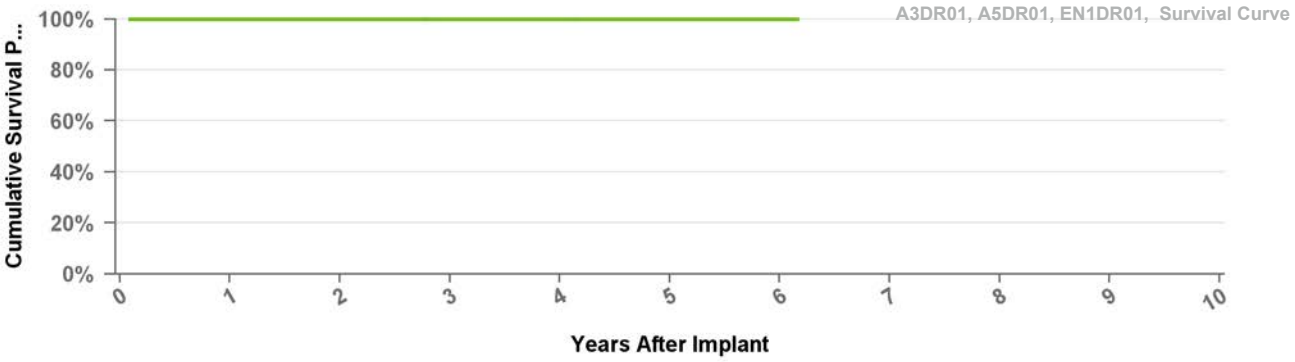
US Market Release	Sep-15	**Total Malfunctions**	**0**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	at 55 mo
Excluding NBD	1	1	0.999	0.999	0.999
Including NBD	1	0.999	0.998	0.997	0.996
Effective Sample Size	53254	43304	23923	7496	432

A2DR01 Advisa DR MRI

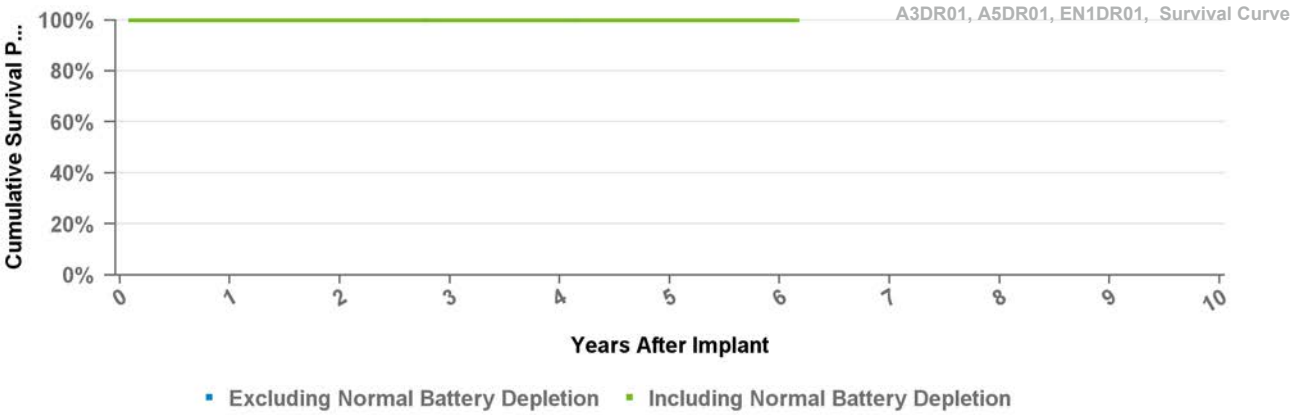
US Market Release	Jan-13	**Total Malfunctions**	**37**
CE Approval Date		**Therapy Function Not Compromised**	**34**
Registered USA Implants	329,702	Battery Malfunction	1
Estimated Active USA Implants	313,070	Electrical Component	22
Normal Battery Depletions	57	Electrical Interconnect	2
		Other Malfunction	1
		Poss Early Battery Depltn	6
		Software Malfunction	2
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.998	0.998	0.998
Effective Sample Size	247015	156907	80949	28484	2291	235	124

A3DR01 Advisa DR MRI

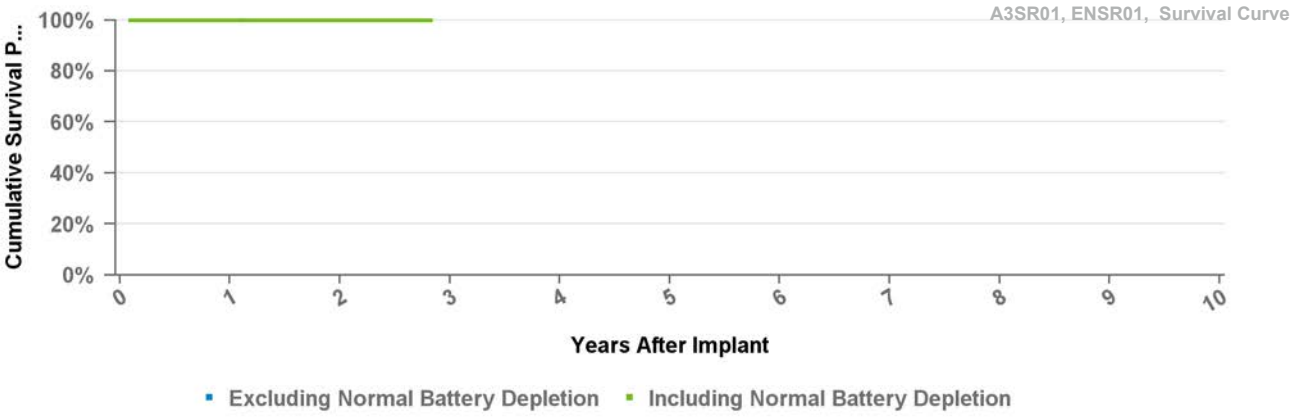
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	**0**
Registered USA Implants	11		
Estimated Active USA Implants	6	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.998	0.998	0.998
Effective Sample Size	247015	156907	80949	28484	2291	235	124

A3SR01 Advisa SR MRI

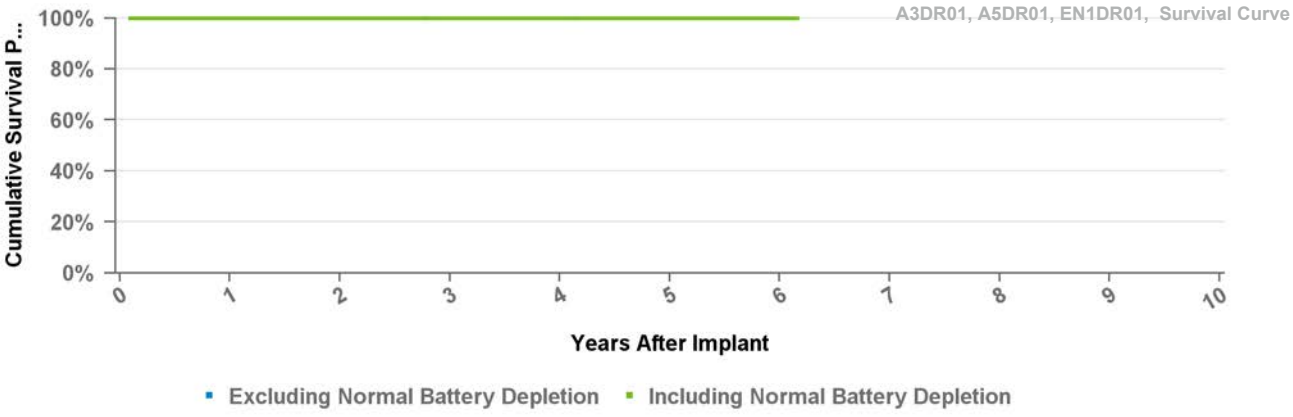
US Market Release	Mar-15	**Total Malfunctions**	**6**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**6**
Registered USA Implants	26,040	Electrical Component	2
Estimated Active USA Implants	24,585	Other Malfunction	2
Normal Battery Depletions	3	Poss Early Battery Depltn	2
		Therapy Function Compromised	**0**



Years	1	2	at 34 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	16149	5668	197

A4DR01 Advisa DR

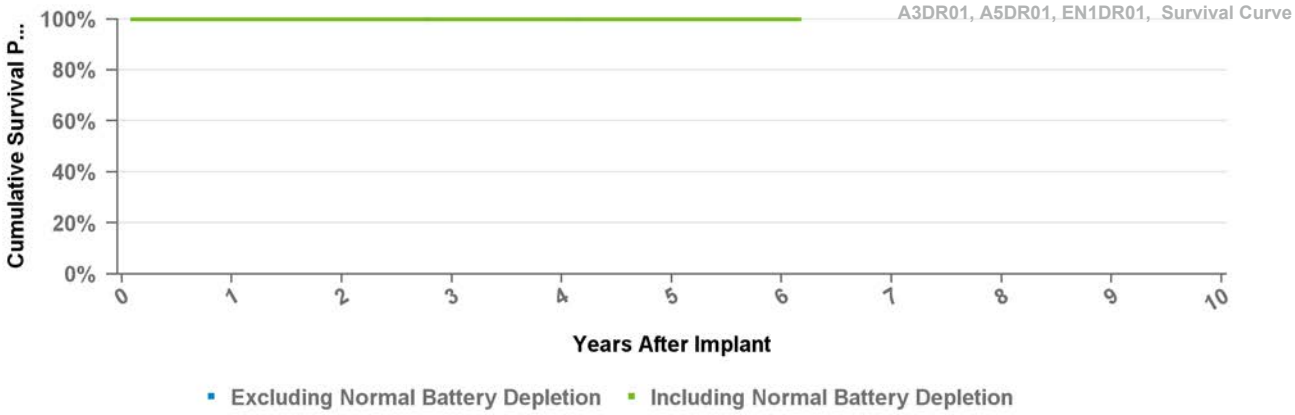
US Market Release	Apr-11	**Total Malfunctions**	**0**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,536		
Estimated Active USA Implants	1,277	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.998	0.998	0.998
Effective Sample Size	247015	156907	80949	28484	2291	235	124

A5DR01 Advisa DR

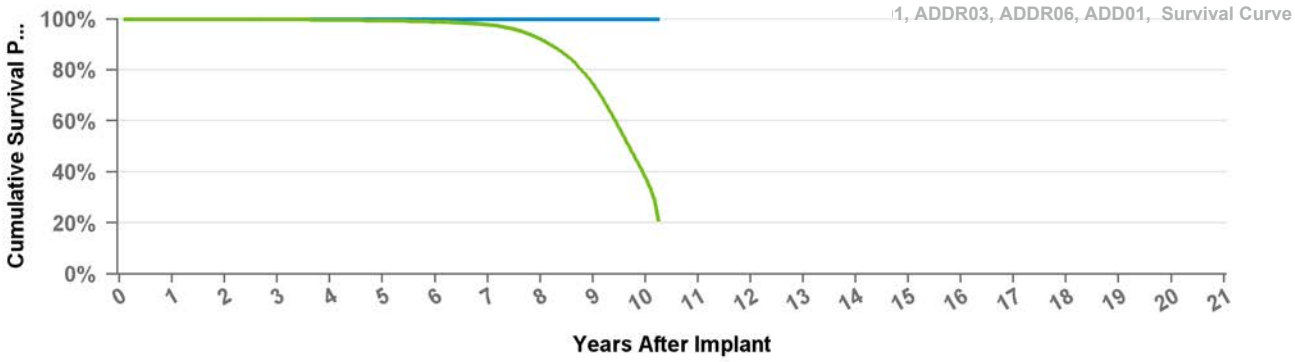
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.998	0.998	0.998
Effective Sample Size	247015	156907	80949	28484	2291	235	124

ADD01 Adapta D

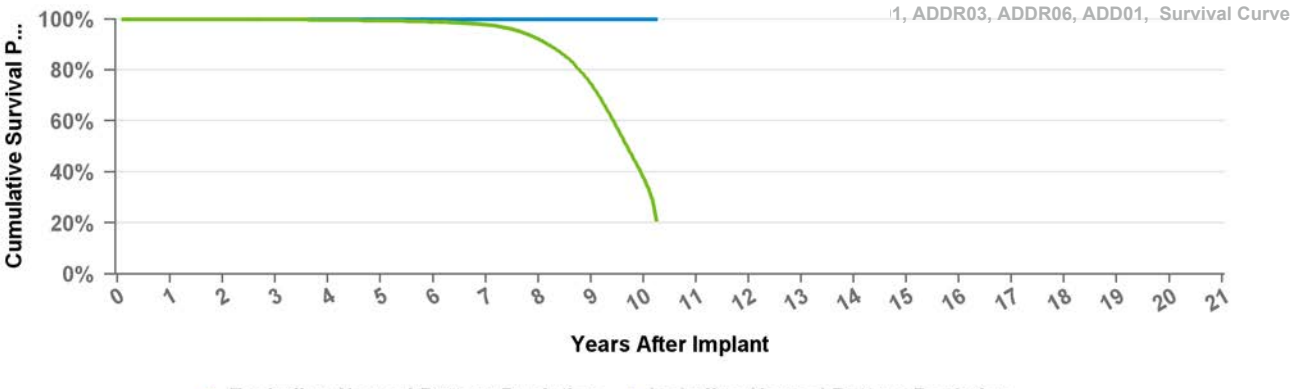
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

ADDR01 Adapta DR

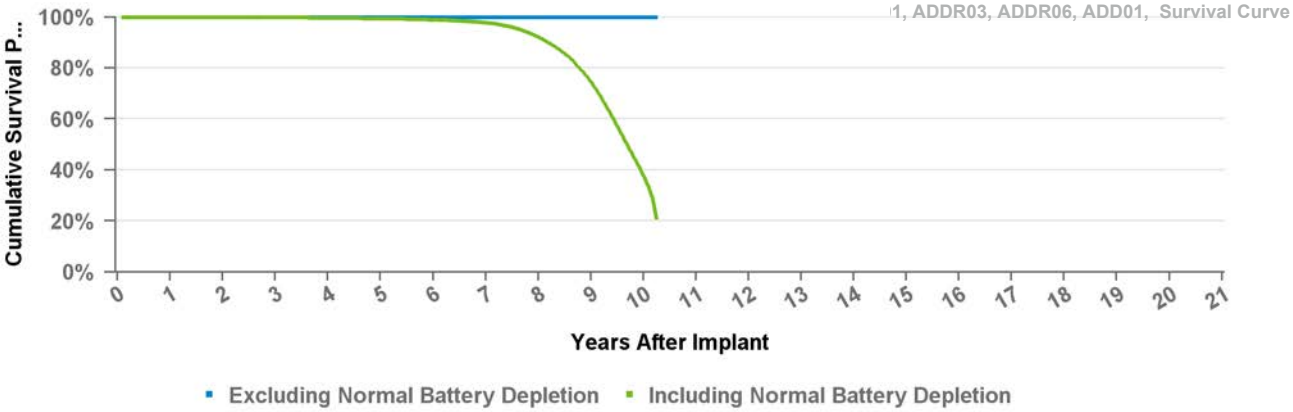
US Market Release	Jul-06	**Total Malfunctions**	**82**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**56**
Registered USA Implants	456,773	Electrical Component	52
Estimated Active USA Implants	294,620	Electrical Interconnect	1
Normal Battery Depletions	21,828	Other Malfunction	1
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**26**
		Electrical Component	21
		Electrical Interconnect	3
		Other Malfunction	2



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

ADDR03 Adapta DR

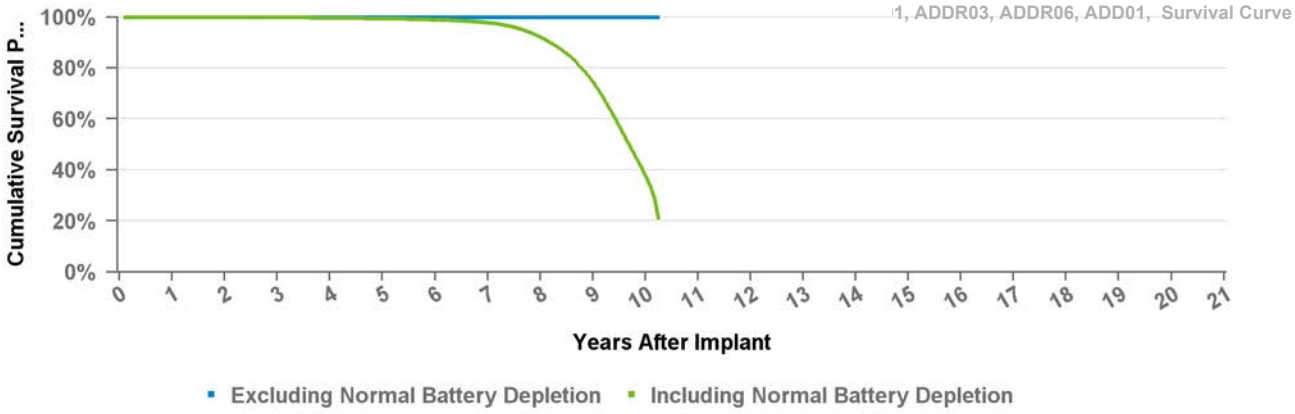
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,381	Electrical Component	1
Estimated Active USA Implants	2,568	**Therapy Function Compromised**	**1**
Normal Battery Depletions	305	Electrical Component	1



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

ADDR06 Adapta DR

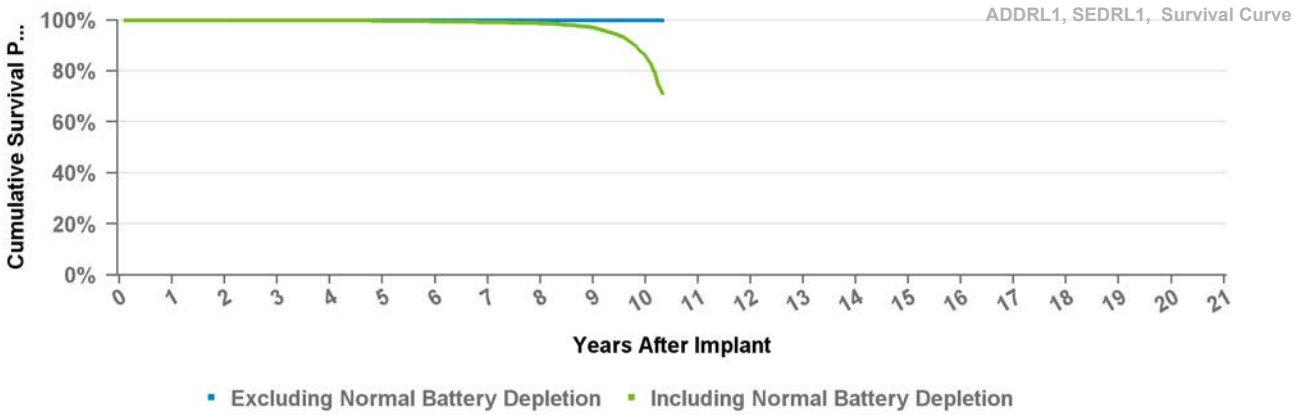
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,360	Electrical Component	1
Estimated Active USA Implants	1,610	**Therapy Function Compromised**	**0**
Normal Battery Depletions	290		



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

ADDRL1 Adapta DR

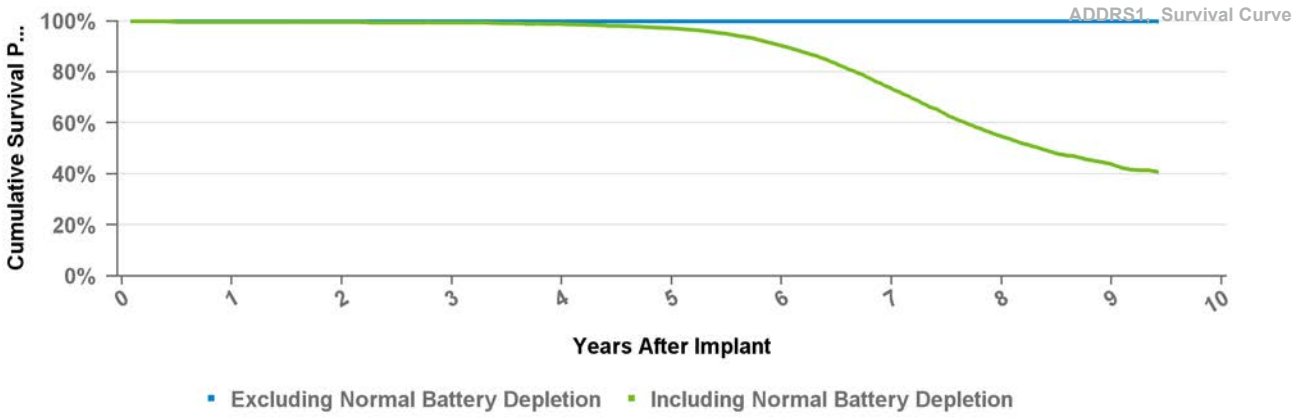
US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**10**
Registered USA Implants	136,668	Electrical Component	9
Estimated Active USA Implants	110,748	Electrical Interconnect	1
Normal Battery Depletions	810	**Therapy Function Compromised**	**4**
		Electrical Component	1
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	10	2	3	4	5	6	7	8	9	at 124 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.998	0.997	0.995	0.992	0.987	0.971	0.859	0.711
Effective Sample Size	121305	108419	93451	76410	58784	41832	27495	15664	7031	1463	244

ADDRS1 Adapta DR

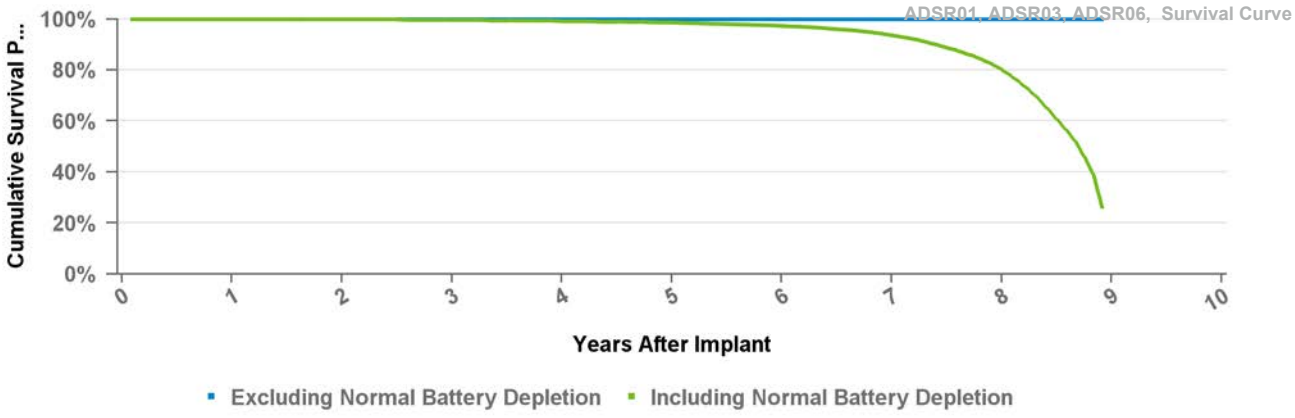
US Market Release	Jul-06	**Total Malfunctions**	**10**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**6**
Registered USA Implants	47,921	Electrical Component	5
Estimated Active USA Implants	27,343	Poss Early Battery Depltn	1
Normal Battery Depletions	3,571	**Therapy Function Compromised**	**4**
		Electrical Component	2
		Other Malfunction	2



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	0.997	0.996	0.994	0.988	0.972	0.903	0.734	0.547	0.438	0.408
Effective Sample Size	40240	35766	31318	26538	21328	15560	8969	3641	774	121

ADSR01 Adapta SR

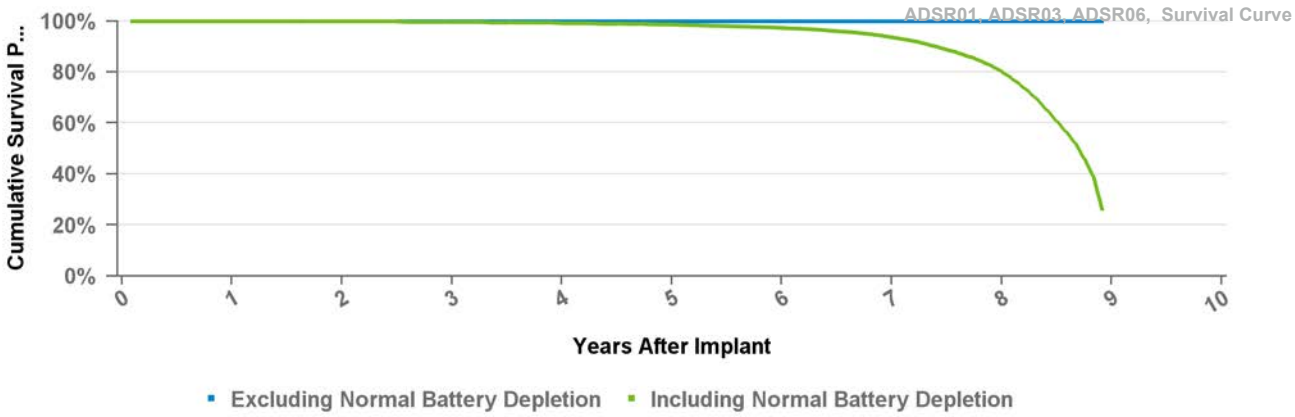
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**11**
Registered USA Implants	91,836	Electrical Component	7
Estimated Active USA Implants	52,562	Electrical Interconnect	1
Normal Battery Depletions	3,038	Poss Early Battery Depltn	3
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.996	0.992	0.986	0.973	0.936	0.801	0.26
Effective Sample Size	74263	64348	54135	42511	32353	23265	15133	7242	460

ADSR03 Adapta SR

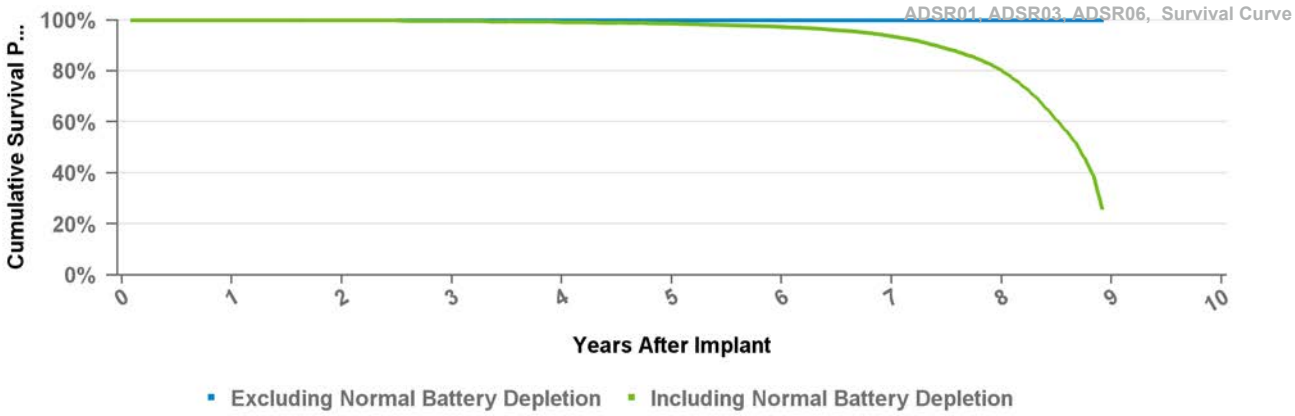
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,022		
Estimated Active USA Implants	989	**Therapy Function Compromised**	**0**
Normal Battery Depletions	103		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.996	0.992	0.986	0.973	0.936	0.801	0.26
Effective Sample Size	74263	64348	54135	42511	32353	23265	15133	7242	460

ADSR06 Adapta SR

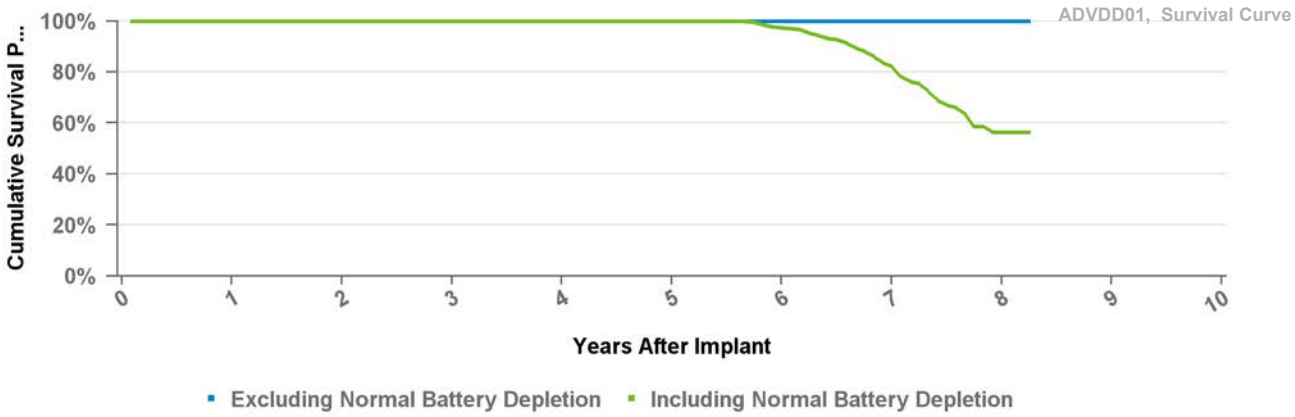
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,752	Electrical Component	2
Estimated Active USA Implants	1,242	**Therapy Function Compromised**	**0**
Normal Battery Depletions	161		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.996	0.992	0.986	0.973	0.936	0.801	0.26
Effective Sample Size	74263	64348	54135	42511	32353	23265	15133	7242	460

ADVDD01 Adapta VDD

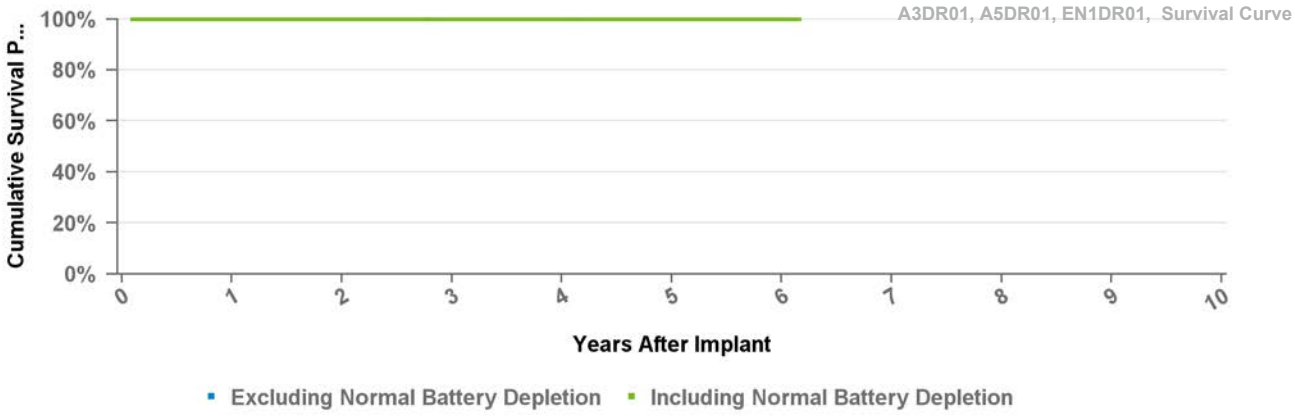
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,367		
Estimated Active USA Implants	711	**Therapy Function Compromised**	**0**
Normal Battery Depletions	74		



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	1	1	1	1	1	0.973	0.821	0.563	0.563
Effective Sample Size	1164	1066	929	817	677	534	347	134	103

EN1DR01 Ensura MRI

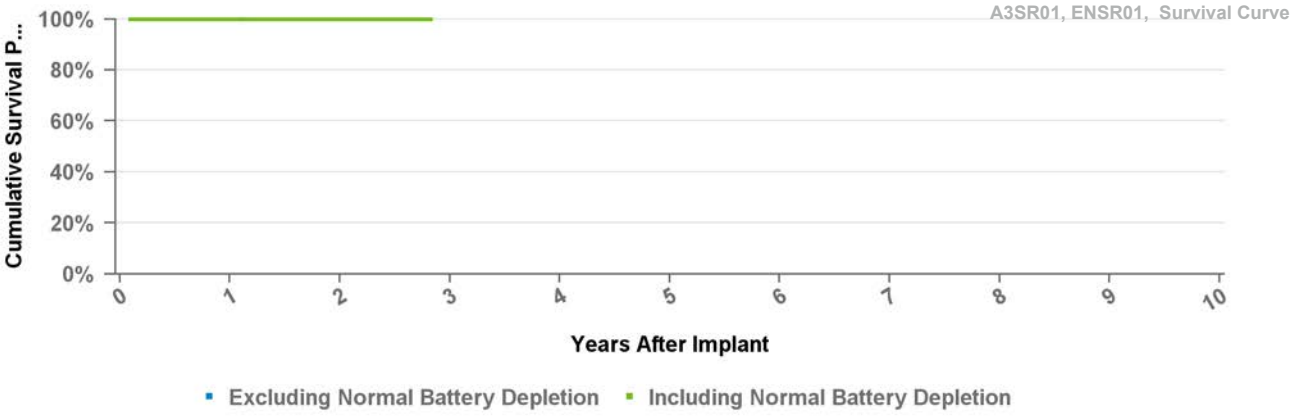
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	**0**
Registered USA Implants	11		
Estimated Active USA Implants	9	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.999	0.998	0.998	0.998
Effective Sample Size	247015	156907	80949	28484	2291	235	124

EN1SR01 Ensura SR MRI

US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		

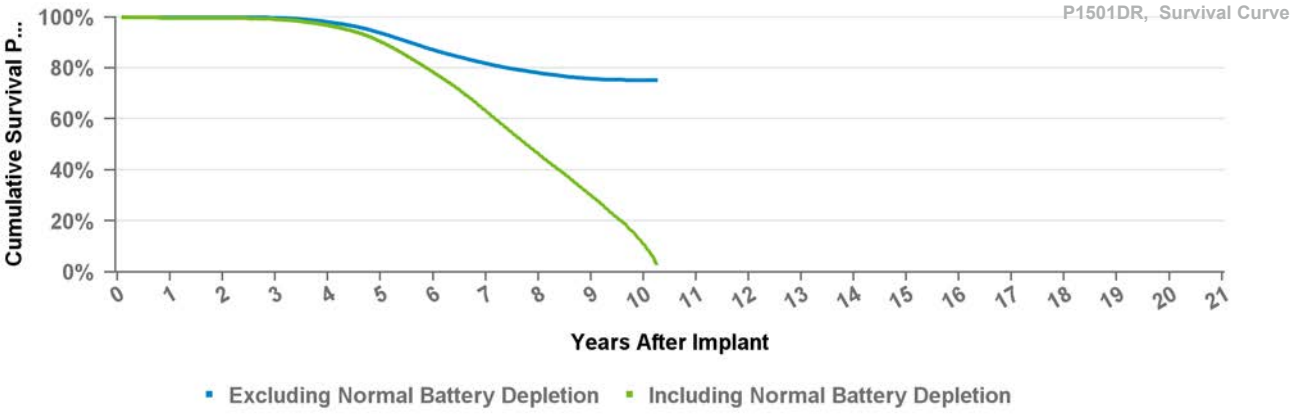


Years	1	2	at 34 mo
Excluding NBD	1	1	1
Including NBD	1	0.999	0.999
Effective Sample Size	16149	5668	197

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	110,093
Estimated Active USA Implants	22,263
Normal Battery Depletions	16,154

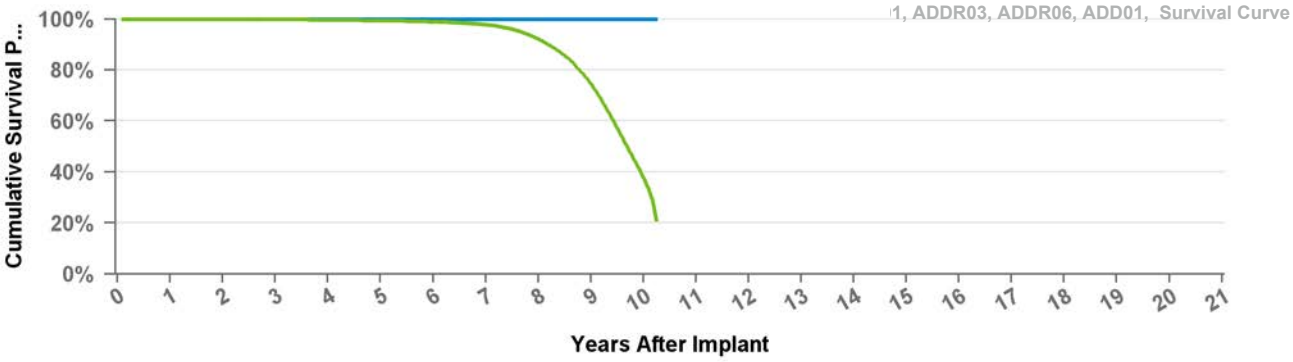
Total Malfunctions	**15,026**
Therapy Function Not Compromised	**14,971**
Battery Malfunction	14,843
Electrical Component	58
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	67
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	0.999	0.753	0.999	0.997	0.98	0.937	0.871	0.818	0.781	0.758	0.752
Including NBD	0.997	0.996	0.991	0.967	0.903	0.783	0.631	0.463	0.299	0.111	0.032
Effective Sample Size	95567	89233	83193	76177	66162	52126	37527	21702	9783	1839	380

RED01 Relia D

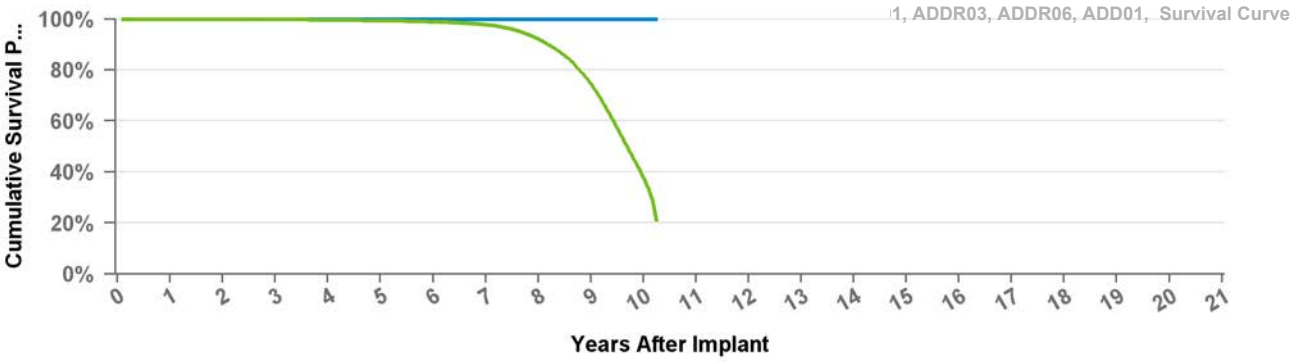
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

REDR01 Relia DR

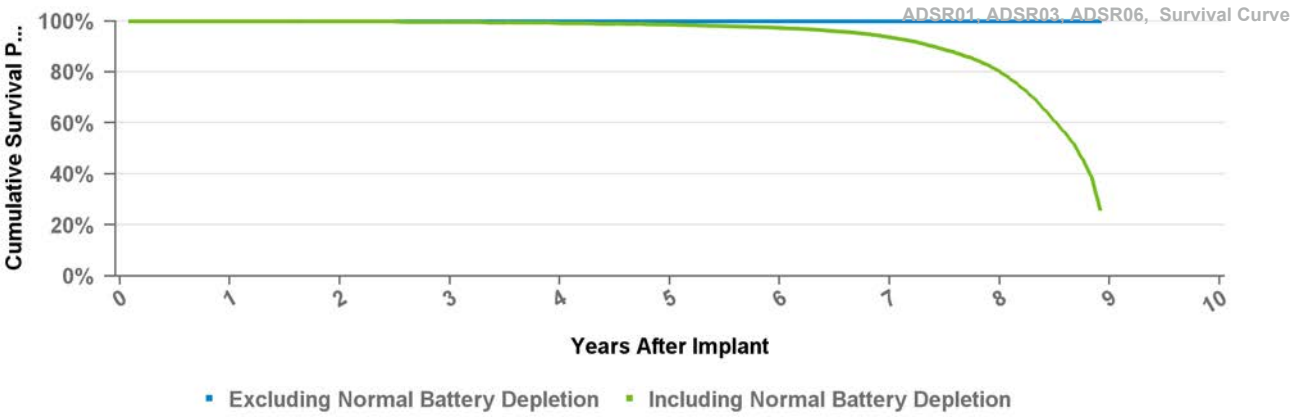
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.99	0.978	0.921	0.748	0.379	0.21
Effective Sample Size	406652	371553	335060	294086	248968	201895	155431	102508	46273	6591	1263

RES01 Relia S

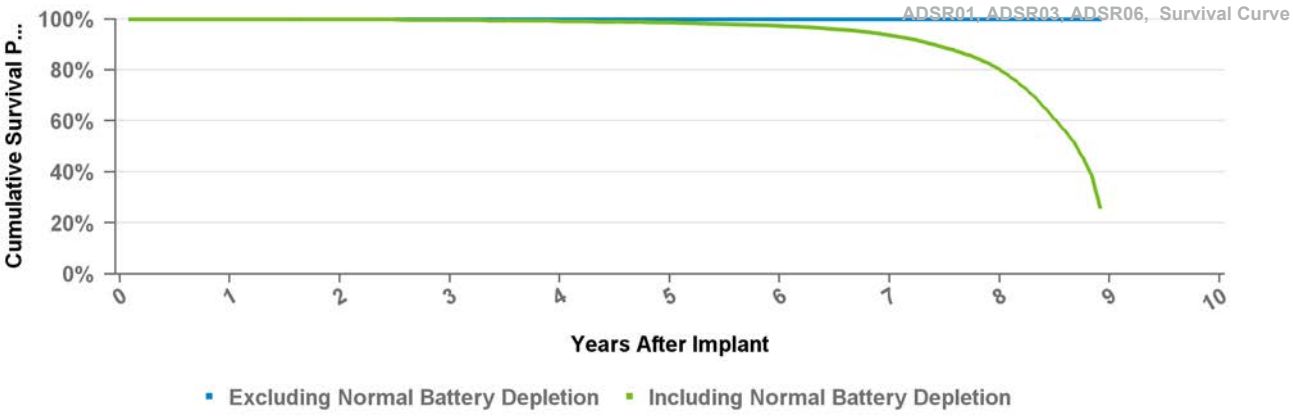
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.996	0.992	0.986	0.973	0.936	0.801	0.26
Effective Sample Size	74263	64348	54135	42511	32353	23265	15133	7242	460

RESR01 Relia SR

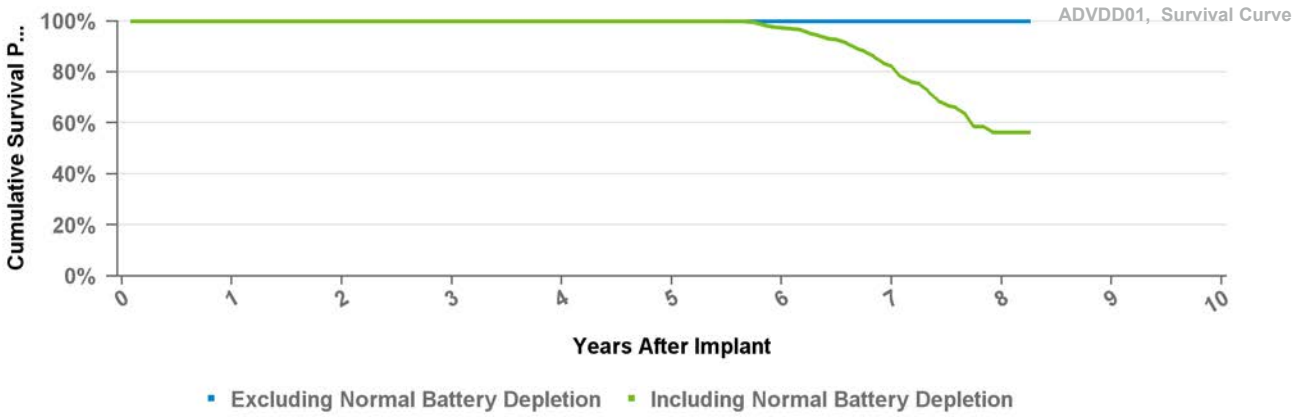
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.996	0.992	0.986	0.973	0.936	0.801	0.26
Effective Sample Size	74263	64348	54135	42511	32353	23265	15133	7242	460

REVDD01 Relia VDD

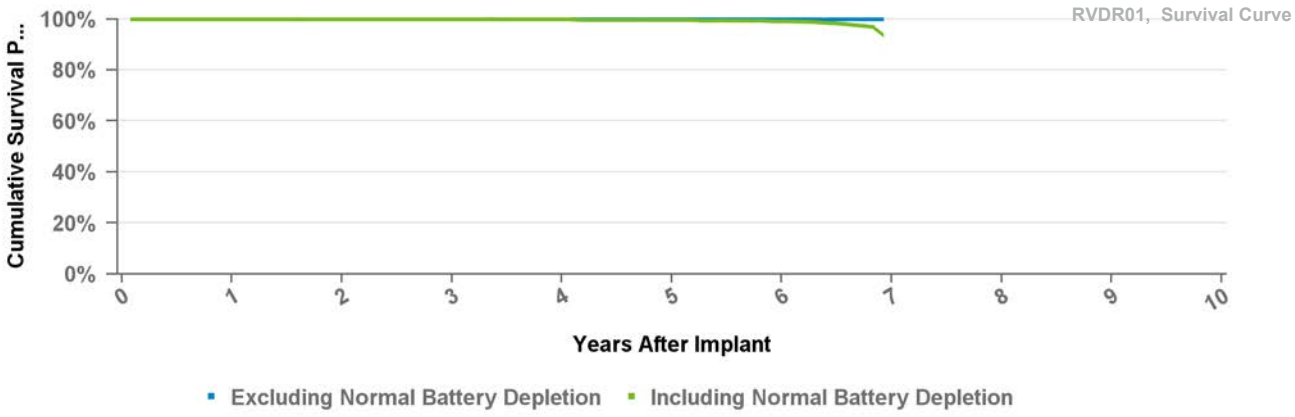
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	May-08	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	1	1	1	1	1	1	1	1	1
Including NBD	1	1	1	1	1	0.973	0.821	0.563	0.563
Effective Sample Size	1164	1066	929	817	677	534	347	134	103

RVDR01 Revo MRI SureScan

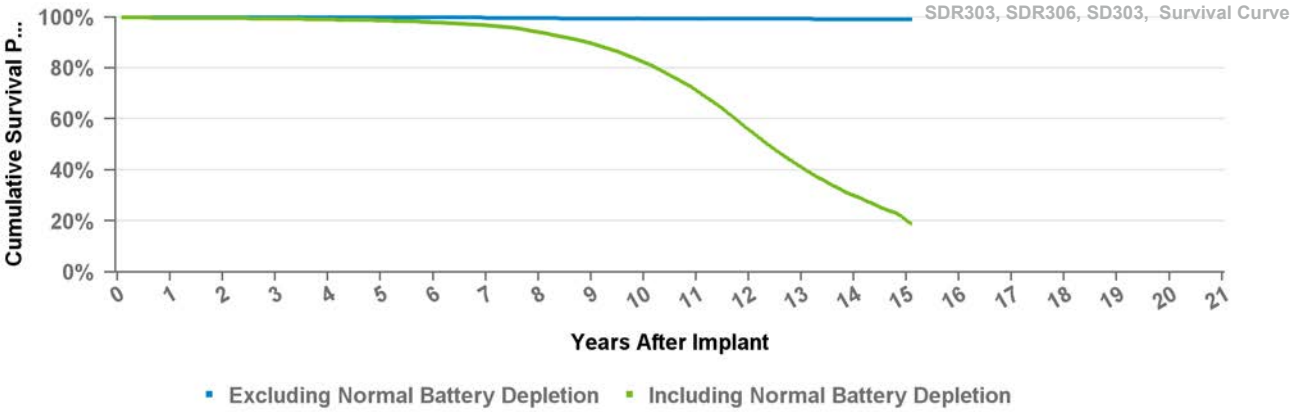
US Market Release	Feb-11	**Total Malfunctions**	**64**
CE Approval Date		**Therapy Function Not Compromised**	**61**
Registered USA Implants	68,905	Battery Malfunction	1
Estimated Active USA Implants	58,026	Electrical Component	32
Normal Battery Depletions	225	Other Malfunction	1
		Poss Early Battery Depltn	24
		Software Malfunction	3
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	at 83 mo
Excluding NBD	1	1	1	0.999	0.999	0.999	0.998
Including NBD	1	0.999	0.999	0.998	0.996	0.992	0.937
Effective Sample Size	60993	57558	54051	50468	42936	20136	504

SD303 Sigma 300 D

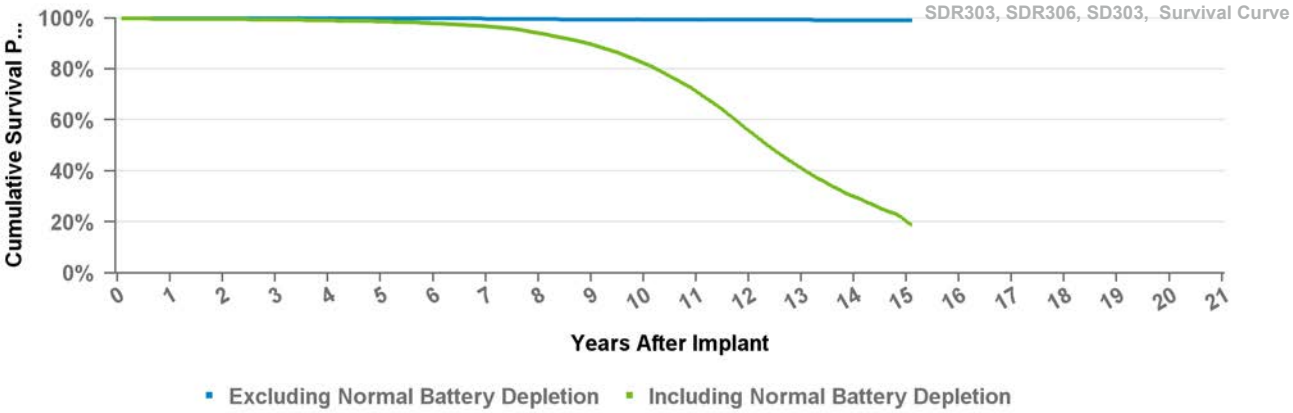
US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	21	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Interconnect	2



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	1	0.994	0.994	0.993	0.993	0.992	0.992	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.992
Including NBD	0.997	0.996	0.994	0.991	0.987	0.979	0.968	0.941	0.897	0.823	0.712	0.557	0.411	0.299	0.201	0.189
Effective Sample Size	88291	78247	69203	60879	53405	46774	40577	35102	30216	25210	19257	11992	6314	2719	378	221

SDR303 Sigma 300 DR

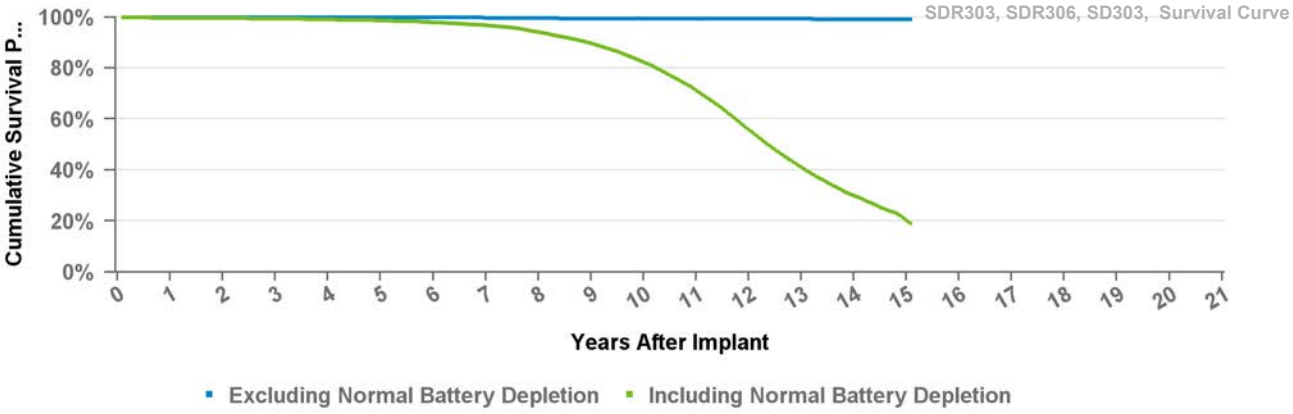
US Market Release	Aug-99	**Total Malfunctions**	**286**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**60**
Registered USA Implants	105,517	Electrical Component	9
Estimated Active USA Implants	12,895	Electrical Interconnect	49
Normal Battery Depletions	10,311	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**226**
		Electrical Component	7
		Electrical Interconnect	218
		Other Malfunction	1



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	1	0.994	0.994	0.993	0.993	0.992	0.992	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.992
Including NBD	0.997	0.996	0.994	0.991	0.987	0.979	0.968	0.941	0.897	0.823	0.712	0.557	0.411	0.299	0.201	0.189
Effective Sample Size	88291	78247	69203	60879	53405	46774	40577	35102	30216	25210	19257	11992	6314	2719	378	221

SDR306 Sigma 300 DR

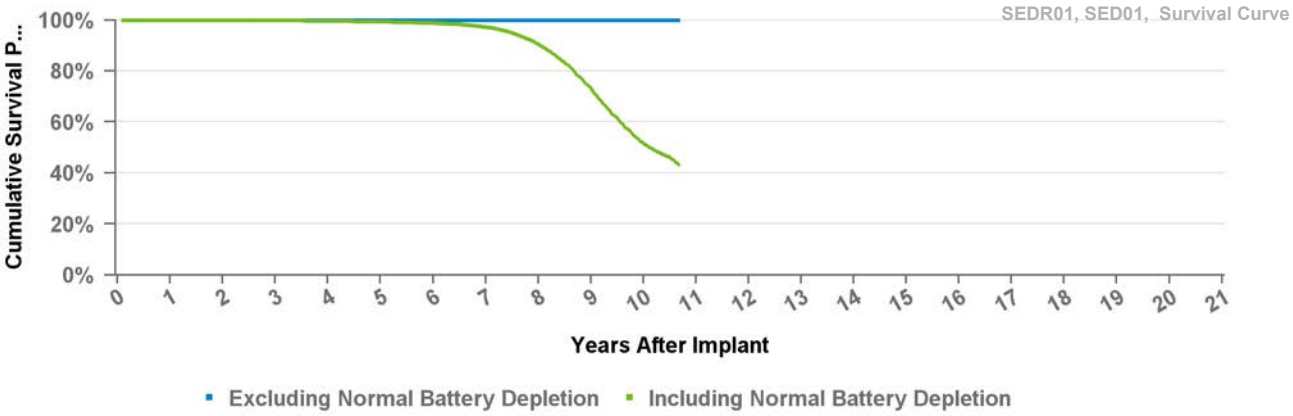
US Market Release	Aug-99	**Total Malfunctions**	**5**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,209		
Estimated Active USA Implants	82	**Therapy Function Compromised**	**5**
Normal Battery Depletions	167	Electrical Interconnect	5



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	1	0.994	0.994	0.993	0.993	0.992	0.992	1	1	0.999	0.999	0.998	0.997	0.996	0.995	0.992
Including NBD	0.997	0.996	0.994	0.991	0.987	0.979	0.968	0.941	0.897	0.823	0.712	0.557	0.411	0.299	0.201	0.189
Effective Sample Size	88291	78247	69203	60879	53405	46774	40577	35102	30216	25210	19257	11992	6314	2719	378	221

SED01 Sensia D

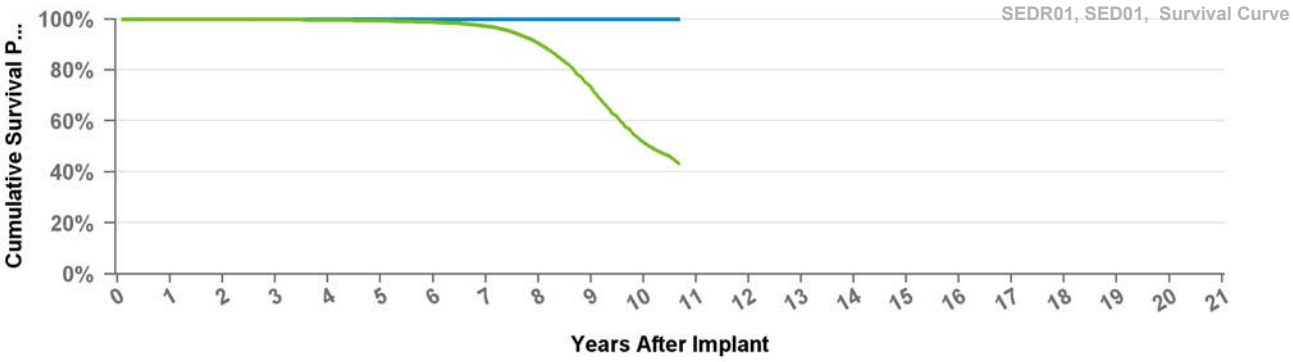
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	7		
Estimated Active USA Implants	3	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	10	2	3	4	5	6	7	8	9	at 128 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.988	0.972	0.904	0.732	0.515	0.432
Effective Sample Size	127373	117060	103788	90028	75951	61746	47121	31171	13972	3409	321

SEDR01 Sensia DR

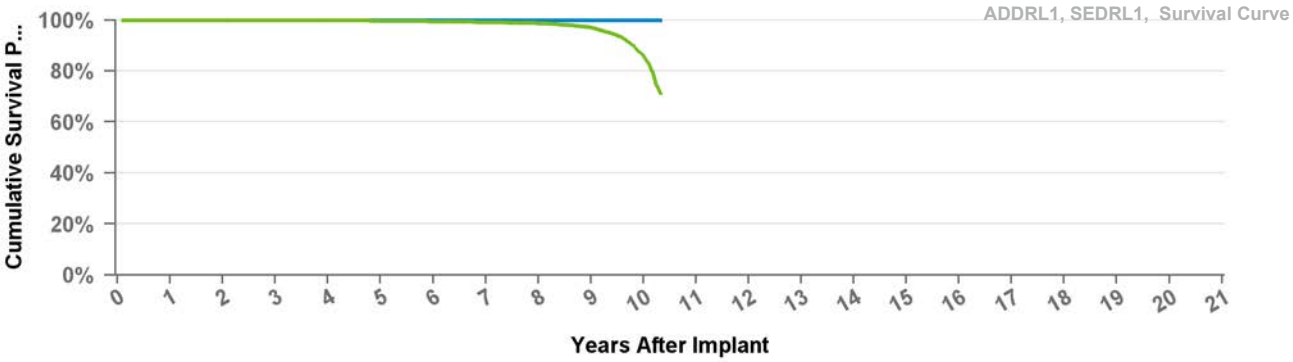
US Market Release	Jul-06	**Total Malfunctions**	**32**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,311	Electrical Component	15
Estimated Active USA Implants	81,125	Electrical Interconnect	1
Normal Battery Depletions	7,376	Other Malfunction	1
		Therapy Function Compromised	**15**
		Electrical Component	6
		Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	1



Years	1	10	2	3	4	5	6	7	8	9	at 128 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.994	0.988	0.972	0.904	0.732	0.515	0.432
Effective Sample Size	127373	117060	103788	90028	75951	61746	47121	31171	13972	3409	321

SEDRL1 Sensia DR

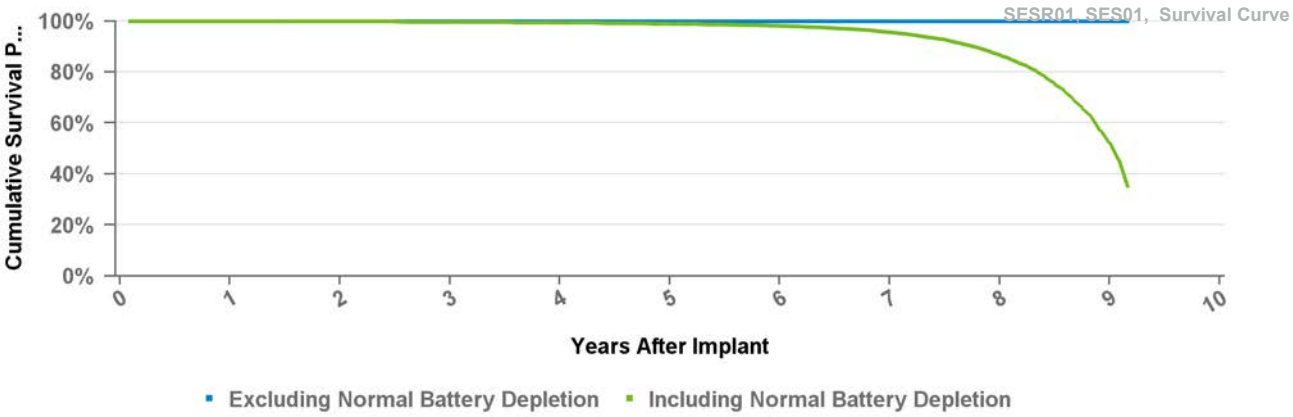
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	2	3	4	5	6	7	8	9	at 124 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	1	1	0.999	0.998	0.997	0.995	0.992	0.987	0.971	0.859	0.711
Effective Sample Size	121305	108419	93451	76410	58784	41832	27495	15664	7031	1463	244

SES01 Sensia S

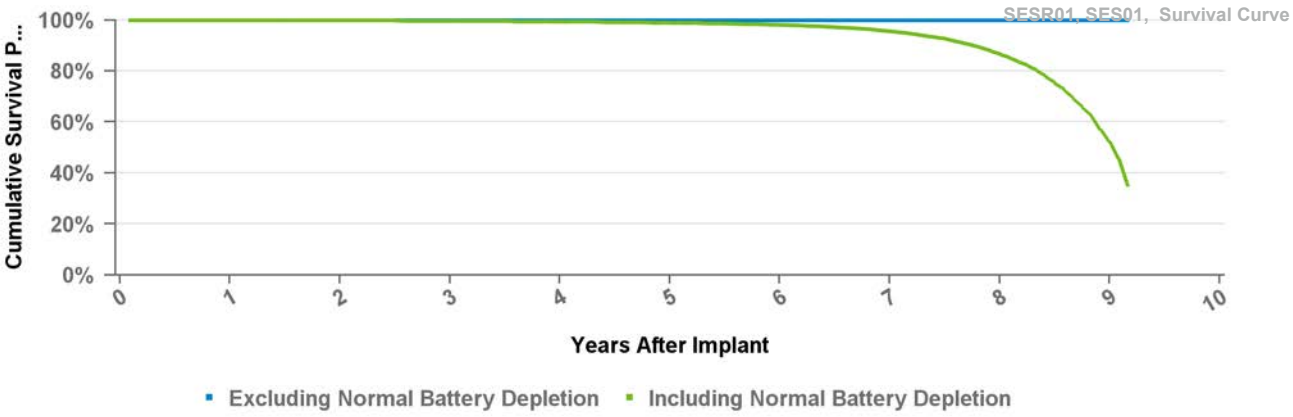
US Market Release	Jul-06	**Total Malfunctions**	**0**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**0**
Registered USA Implants	7		
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.997	0.994	0.989	0.981	0.956	0.866	0.524	0.352
Effective Sample Size	88334	76822	64804	52016	40675	30044	20068	10609	1710	554

SESR01 Sensia SR

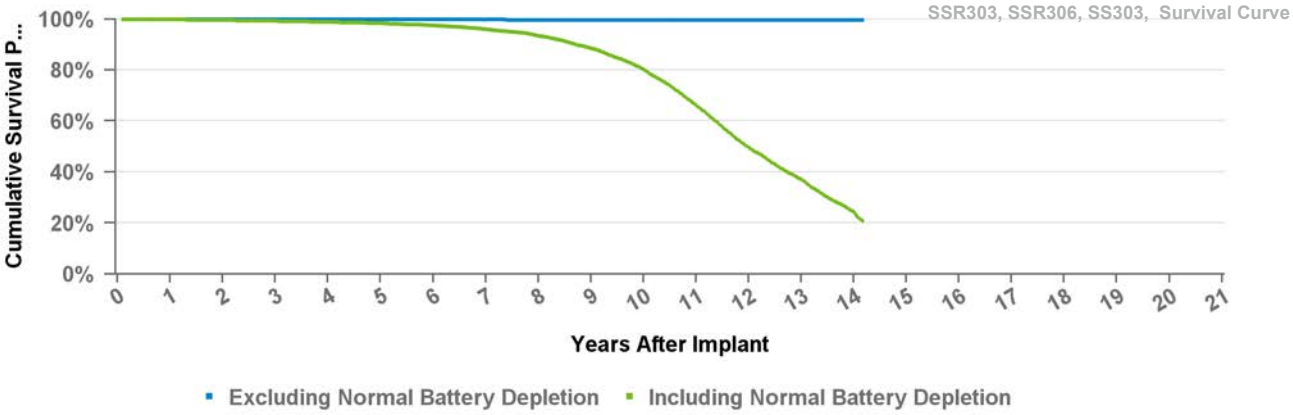
US Market Release	Jul-06	**Total Malfunctions**	**13**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**10**
Registered USA Implants	116,528	Electrical Component	8
Estimated Active USA Implants	62,485	Other Malfunction	1
Normal Battery Depletions	3,649	Poss Early Battery Depltn	1
		Therapy Function Compromised	**3**
		Electrical Component	2
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.998	0.997	0.994	0.989	0.981	0.956	0.866	0.524	0.352
Effective Sample Size	88334	76822	64804	52016	40675	30044	20068	10609	1710	554

SS303 Sigma 300 S

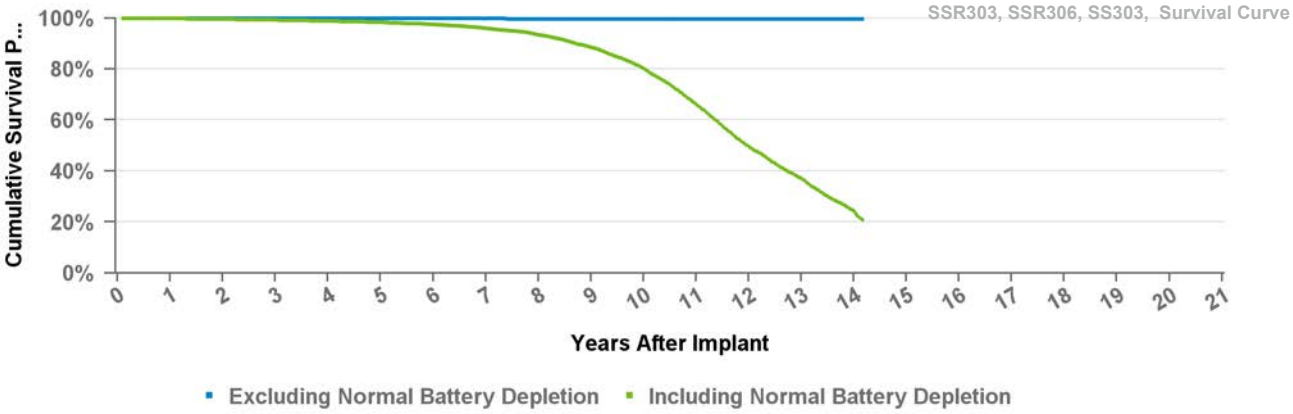
US Market Release	Sep-99	**Total Malfunctions**	**0**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	249		
Estimated Active USA Implants	48	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 170 mo
Excluding NBD	1	0.997	0.996	0.996	0.996	0.996	1	1	1	1	0.999	0.998	0.997	0.997	0.996
Including NBD	0.998	0.996	0.993	0.989	0.984	0.975	0.96	0.934	0.885	0.802	0.661	0.496	0.371	0.243	0.206
Effective Sample Size	41043	33917	28097	23364	19471	16198	13471	11207	9116	7028	4722	2573	1235	282	161

SSR303 Sigma 300 SR

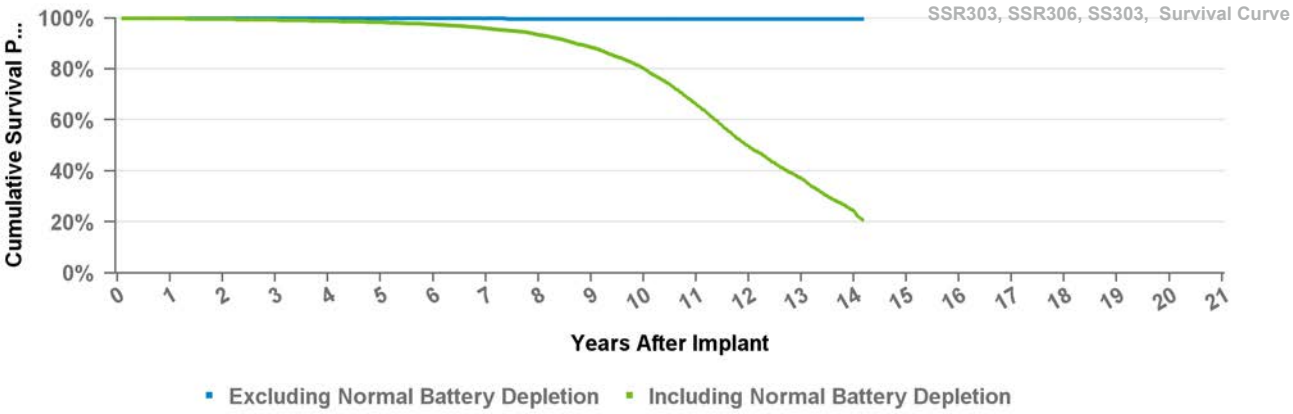
US Market Release	Aug-99	**Total Malfunctions**	**58**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**11**
Registered USA Implants	51,671	Electrical Interconnect	10
Estimated Active USA Implants	4,695	Other Malfunction	1
Normal Battery Depletions	2,926	**Therapy Function Compromised**	**47**
		Electrical Component	3
		Electrical Interconnect	44



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 170 mo
Excluding NBD	1	0.997	0.996	0.996	0.996	0.996	1	1	1	1	0.999	0.998	0.997	0.997	0.996
Including NBD	0.998	0.996	0.993	0.989	0.984	0.975	0.96	0.934	0.885	0.802	0.661	0.496	0.371	0.243	0.206
Effective Sample Size	41043	33917	28097	23364	19471	16198	13471	11207	9116	7028	4722	2573	1235	282	161

SSR306 Sigma 300 SR

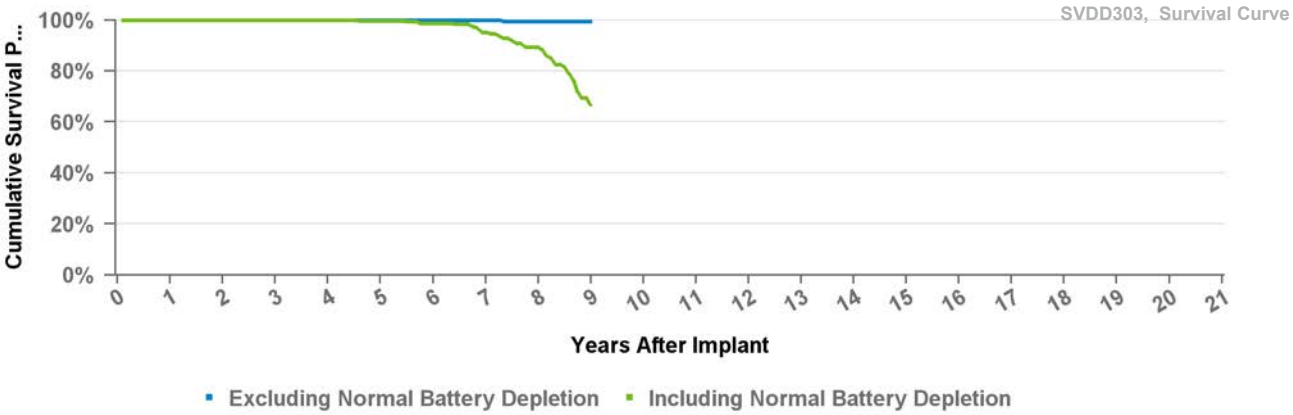
US Market Release	Sep-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,216	Electrical Component	1
Estimated Active USA Implants	156	**Therapy Function Compromised**	**1**
Normal Battery Depletions	160	Electrical Interconnect	1



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 170 mo
Excluding NBD	1	0.997	0.996	0.996	0.996	0.996	1	1	1	1	0.999	0.998	0.997	0.997	0.996
Including NBD	0.998	0.996	0.993	0.989	0.984	0.975	0.96	0.934	0.885	0.802	0.661	0.496	0.371	0.243	0.206
Effective Sample Size	41043	33917	28097	23364	19471	16198	13471	11207	9116	7028	4722	2573	1235	282	161

SVDD303 Sigma 300 VDD

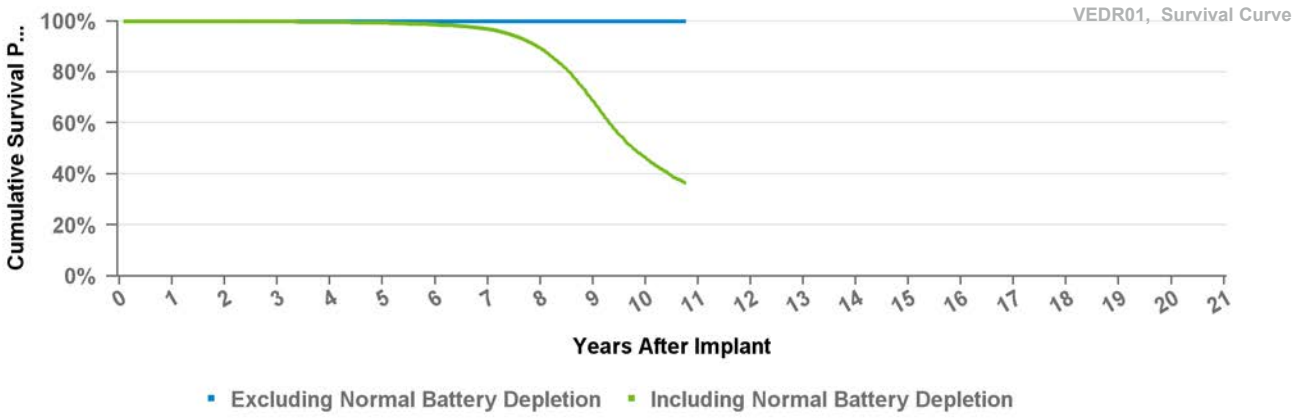
US Market Release	Sep-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	653		
Estimated Active USA Implants	42	**Therapy Function Compromised**	**1**
Normal Battery Depletions	82	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	1	1	1	1	1	1	1	0.995	0.995
Including NBD	1	1	1	1	0.997	0.987	0.952	0.892	0.666
Effective Sample Size	531	461	413	365	317	265	211	166	105

VEDR01 Versa DR

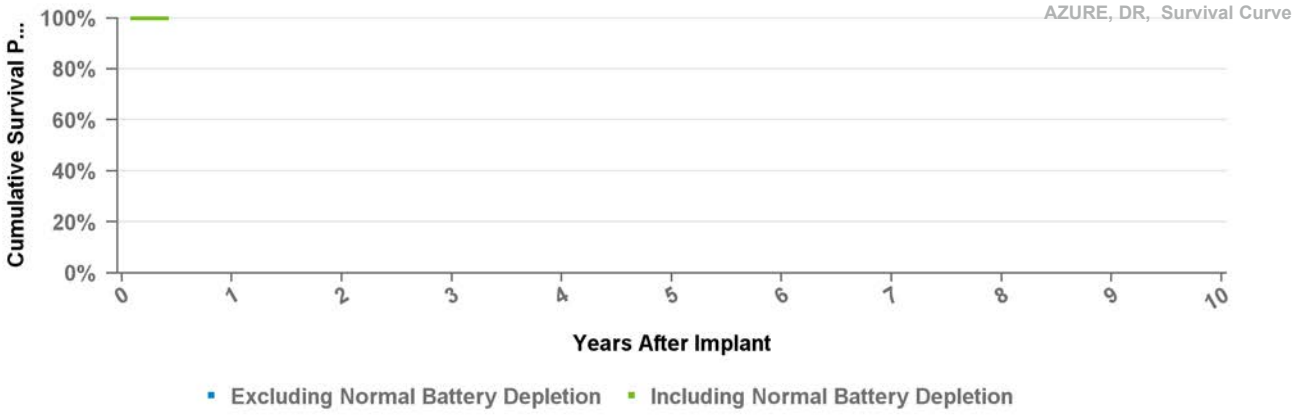
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**9**
Registered USA Implants	118,129	Electrical Component	7
Estimated Active USA Implants	65,564	Electrical Interconnect	2
Normal Battery Depletions	7,472	**Therapy Function Compromised**	**8**
		Electrical Component	4
		Other Malfunction	4



Years	1	10	2	3	4	5	6	7	8	9	at 129 mo
Excluding NBD	1	1	1	1	1	1	1	1	1	1	1
Including NBD	0.999	0.999	0.998	0.997	0.993	0.986	0.968	0.893	0.689	0.463	0.364
Effective Sample Size	100986	90790	81785	72407	62587	52263	41012	27885	12739	3485	203

W1DR01 Azure XT

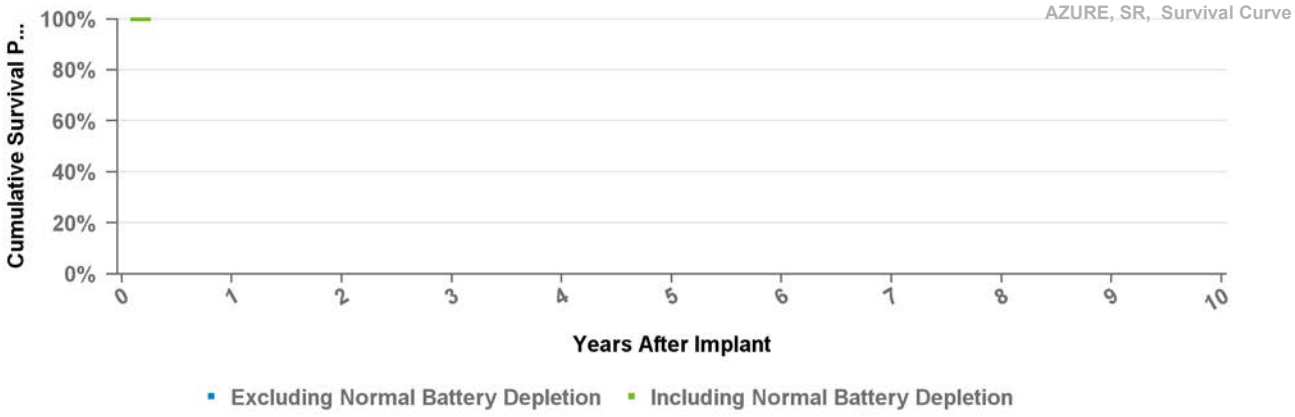
US Market Release	Aug-17	**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	10,346		
Estimated Active USA Implants	10,283	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 5 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	105

W1SR01 Azure XT

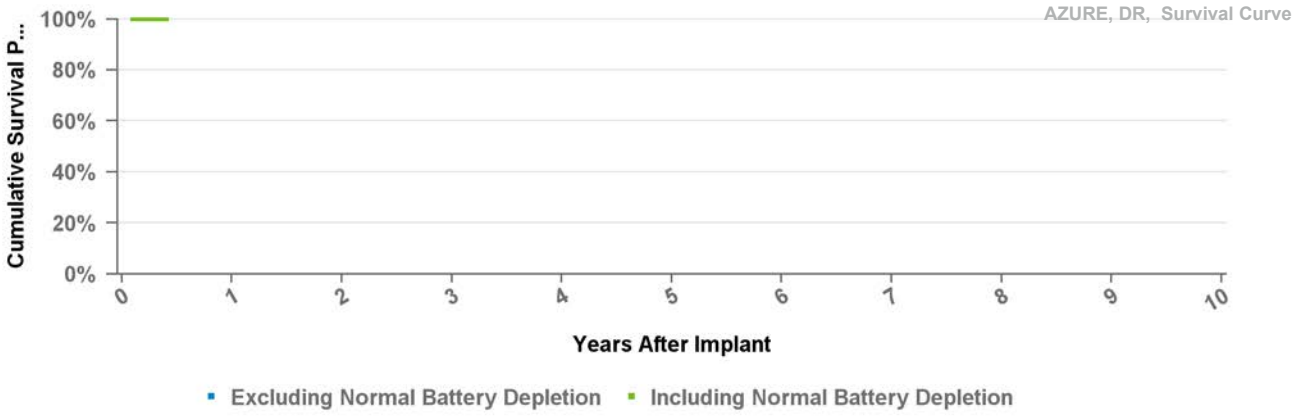
US Market Release	Aug-17	**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	856		
Estimated Active USA Implants	848	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 3 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	264

W2DR01 Azure XT

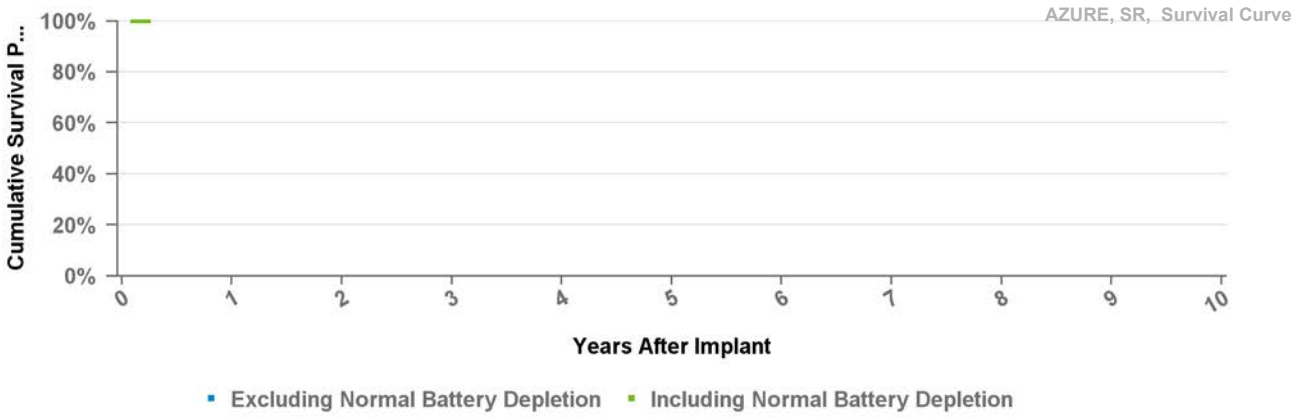
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 5 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	105

W2SR01 Azure XT

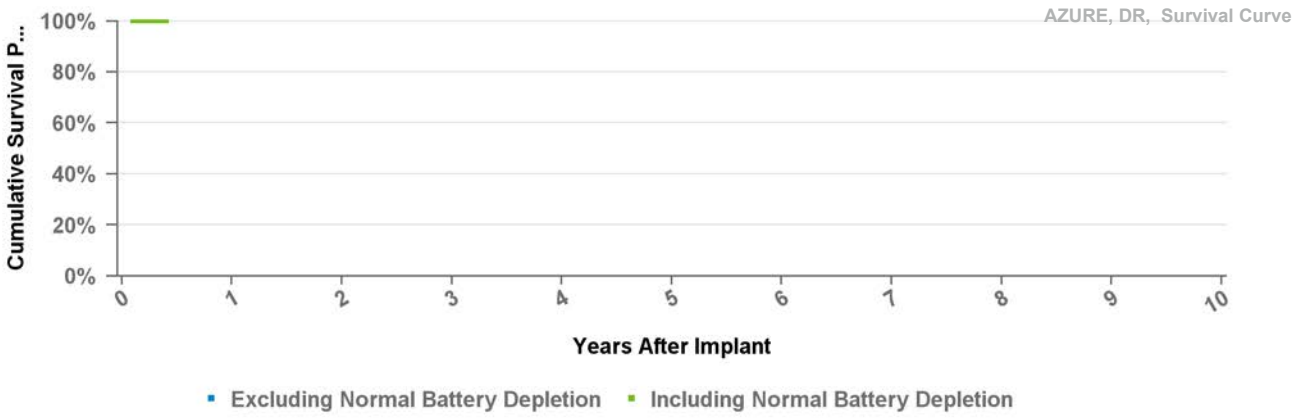
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 3 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	264

W3DR01 Azure S

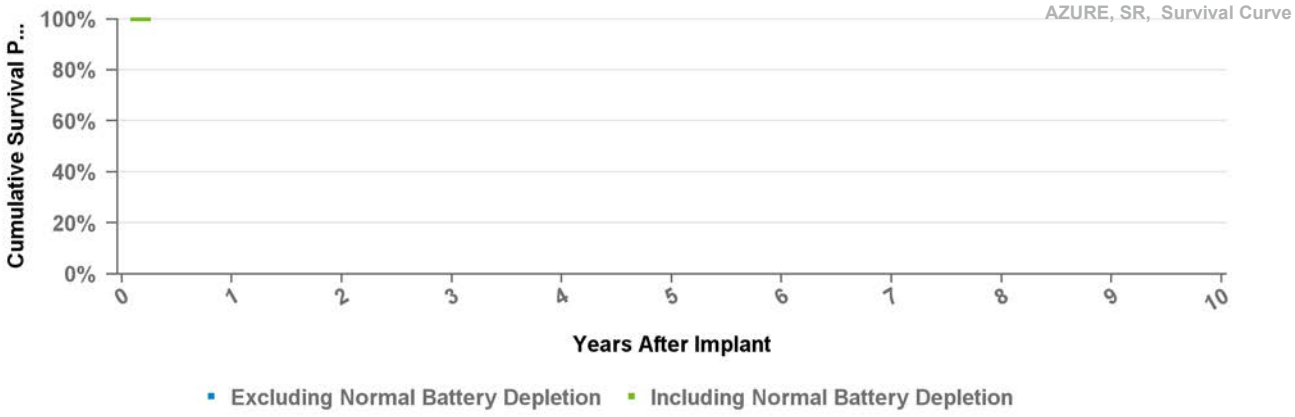
US Market Release	Aug-17	**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,117		
Estimated Active USA Implants	2,101	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 5 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	105

W3SR01 Azure S

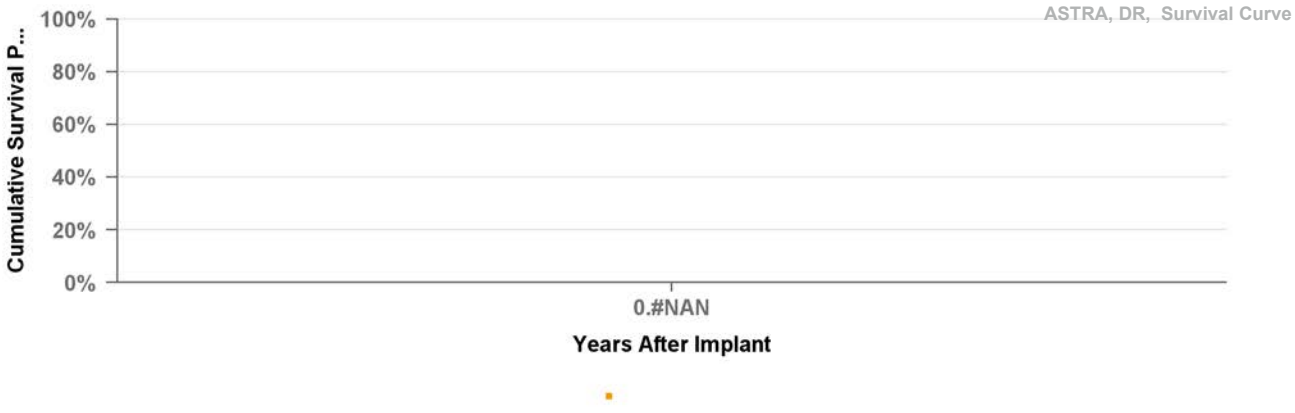
US Market Release	Aug-17	**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	316		
Estimated Active USA Implants	311	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	at 3 mo
Excluding NBD	1
Including NBD	1
Effective Sample Size	264

X2DR01 Astra XT DR MRI SureScan

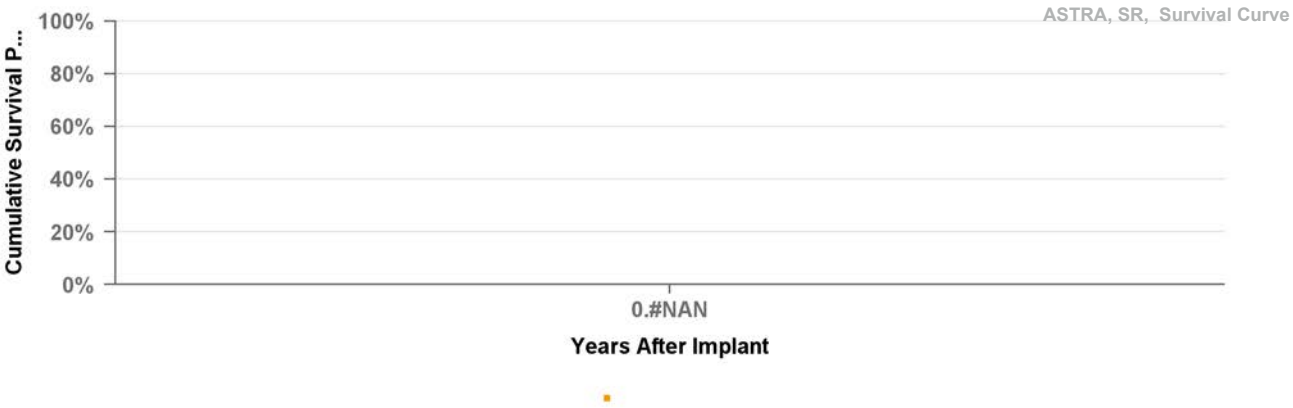
US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

US Market Release		**Total Malfunctions**	**0**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**0**
Registered USA Implants	0		
Estimated Active USA Implants	0	**Therapy Function Compromised**	**0**
Normal Battery Depletions	0		



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 32 years with its multicenter, global chronic lead studies.

Leads Performance Analysis

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

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. While IPGs and ICDs have a battery that will deplete after a predictable length of time, a lead's longevity cannot be predicted easily based on mechanical measurements, nor are there simple indicators that a lead is approaching the end of its service life. Therefore, regular monitoring while implanted, and evaluation of lead integrity upon IPG or ICD replacement, is necessary to determine if a lead may be approaching the end of its service life.

Shortfalls Of Using Returned Product And Complaints To Estimate Lead Performance

Leads and lead segments returned to Medtronic are analyzed to determine whether or not they meet performance limits established by Medtronic. Although returned product analyses are valuable for gaining insight into lead failure mechanisms, this data cannot be used by itself for determining the survival probability of leads because only a small fraction of leads are explanted and returned for analysis. Some leads are modified due to adverse device effect, however may not be explanted. Additionally, those leads that are returned cannot be assumed to be statistically representative of the performance of the total population for a given lead model. Partial or total lead extraction can result in significant damage to a lead, making a definitive analysis of a suspected failure, and its cause, impossible.

To account for the under reporting inherent with lead survival analysis based solely on returned product, some manufacturers add reported complaints where adverse product performance is evident but the product itself has not been returned. The improvement to the accuracy of survival estimates depends on the degree to which all complaints are actually communicated to the manufacturer. Since not all complaints are communicated to the manufacturer, adding complaints to the survival analysis does not completely solve the under reporting problem.

Lead survival probabilities are more appropriately determined through a prospective clinical surveillance study that includes active follow up with the patients. Although Medtronic monitors returned product analysis and complaints, these are not used to determine lead survival estimates.

Medtronic consolidated all cardiac rhythm surveillance registries into the PAN Registry. The PAN Registry is a patient centric surveillance platform which follows patients implanted with Medtronic cardiac rhythm product(s). The Product Performance Report (PPR) tracks PAN Registry enrolled patients to monitor lead performance status in vivo. The PAN Registry is designed to record clinical observations representative of the total clinical experience. Lead survival estimates include both lead hardware failure and lead-related clinical events that are classified as product performance events, and do not differentiate a lead hardware failure from other clinical events such as Failure to capture, perforation, dislodgement, or concurrent pulse generator failure.

PAN Registry

Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study since 1983 and has evaluated the performance of more than 95,000 leads, with data reported from countries around the world. Throughout this time period, Medtronic has continually worked to adapt systems and processes to more effectively monitor product performance following market release. The following summarizes current registry requirements.

Method for Estimating Lead Performance continued

Medtronic's product surveillance registry is a world-wide study that has a prospective, non-randomized, observational design. A key purpose of the registry is to provide continuing evaluation and periodic reporting of the long-term reliability and performance of Medtronic market-released cardiac rhythm therapy products. Product-related adverse events, indicating the status of the product, are collected to measure product survival probabilities. The data gathered may also be used to support the design and development of new cardiac therapy products. The registry is designed to continue indefinitely, encompassing new products as they become commercially available.

To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria. Patients are enrolled upon implantation of a Medtronic Cardiac rhythm product. Every effort is made to ensure participants are representative of the range of clinical environments in which Medtronic cardiac rhythm products are used. Eligible products for enrollment include Medtronic market-released cardiac rhythm therapy products for which additional information to further characterize product performance following market release is desired. Number of enrollments is reviewed regularly to ensure adequate sample size is obtained for each individual product. Enrollment may be capped and follow-up discontinued when sufficient duration and precision is achieved to effectively characterize product survivability.

Enrolled patients are followed in accordance with the standard care practices of their care provider from their implant date until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum annual follow-up requirement. Product-related adverse events, system modifications and changes in patient status (e.g. death and withdrawal from the study) are required to be reported upon occurrence. This active surveillance model ensures a robust dataset for effectively monitoring product performance.

Patients are eligible for enrollment if:

- Patient is intended to be implanted or is within 30 days post-implant of a Medtronic market-released cardiac lead connected to a market-released CRT, ICD, or IPG device, and the lead is used for a pacing, sensing, or defibrillation application, or
- Patient participated in a qualifying investigational study of a Medtronic cardiac rhythm product that is now market-released; complete implant and follow-up data are available; and the data can be appropriately and legally released

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

Lead Complications

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

Method for Estimating Lead Performance continued

All reported lead-related adverse events are classified by the reporting investigator and are adjudicated by an independent event adjudication committee[1]. A lead-related event with at least one of the following classifications that is adjudicated by the committee as a complication and occurs more than 30 days after implant is considered a product performance event and will contribute to the survival analysis endpoint. Events with an onset date of 30 days or less after the implant are considered procedure related and therefore are not included as product performance events. Product performance events include, but are not limited to:

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Elevated pacing thresholds
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 - 2,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20 - 200 ohms)
- Lead Insulation breach
- Lead Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement
- Structural Lead Failure

Data Analysis Methods

The performance of leads is expressed in terms of lead survival estimates, where "survival" refers to the function of the lead, not the survival of the patient.. These survival estimates are intended to illustrate the probability that a lead will survive for a given number of years without a chronic lead-related complication.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases in the PAN Registry, active surveillance of a device starts after the device was implanted. The survival probability of such device is conditional on survival to the time when the device enters the Registry. This phenomenon is called Left-truncation[2]. PPR lead survival analysis is estimated using the Kaplan-Meier method, a statistical method to incorporate data from these retrospectively enrolled devices, left-truncated data, was applied. The statistical technique uses data from existing devices while appropriately adjusting the device survival curves for the time the device was not actively followed in the registry. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

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

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

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

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

Method for Estimating Lead Performance continued

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

Definition of Analysis Dataset

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

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

Criteria for Model Inclusion

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

Returned Product Analysis Results

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

For reporting returned product analysis results, Medtronic CRHF considers a lead as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service. To be considered a malfunction for returned product analysis reporting, the lead must have been returned to Medtronic and analyzed.

The results of the analysis is presented in four categories. The lead reporting categories are:

> **Conductor Fracture**: Conductor malfunction with complete or intermittent loss of continuity that could interrupt current flow (e.g., fractured conductors), including those associated with clavicle flex fatigue or crush damage.
>
> **Insulation Breach**: A malfunction of the insulation allowing inappropriate entry of body fluids or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, abrasions, and material degradation.
>
> **Crimps/Welds/Bonds**: Any malfunction in a conductor or lead body associated with a point of connection.
>
> **Other:** Malfunctions of specific lead mechanical attributes, such as sensors, connectors, seal rings, or malfunction modes not included in the three categories above.

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

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

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

Method for Estimating Lead Performance continued

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

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

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

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

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

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

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

Estimated Number of Implanted and Active Leads in the United States

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

Footnotes:

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

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

3830 SelectSecure

US Market Release	03Aug2005
CE Approval	31Jan2003
Registered USA Implants	37,163
Estimated Active USA Implants	27,949
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	19
Crimp Weld Bond	
Insulation Breach	34
Other	3

US Acute Lead Observations

Cardiac Perforation	9
Conductor Fracture	2
Extracardiac Stimulation	2
Failure To Capture	79
Failure To Sense	4
Impedance Abnormal	
Insulation Breach	1
Lead Dislodgement	101
Oversensing	13
Unspecified	2

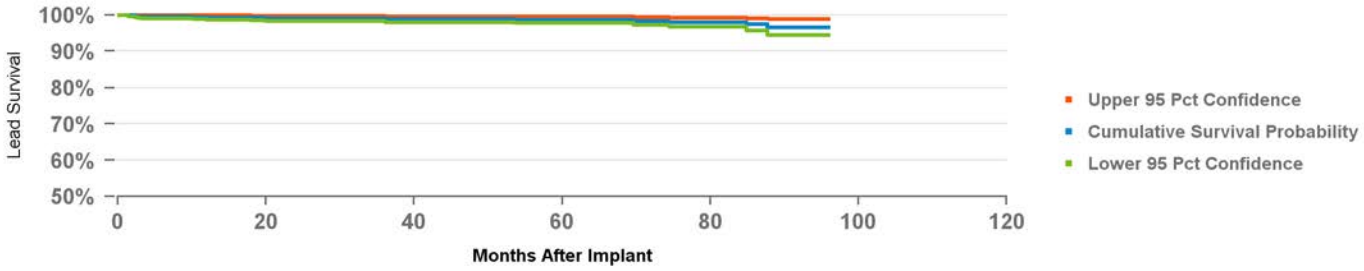
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,016
Cumulative Months of Followup	48,914
Number of Leads Active in Study	465

Qualifying Complications 17

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



Years	1	2	3	4	5	6	7	at 96 mo
%	99.3%	99.0%	99.0%	98.8%	98.6%	98.3%	98.0%	96.6%
#	838	705	609	483	403	305	150	63

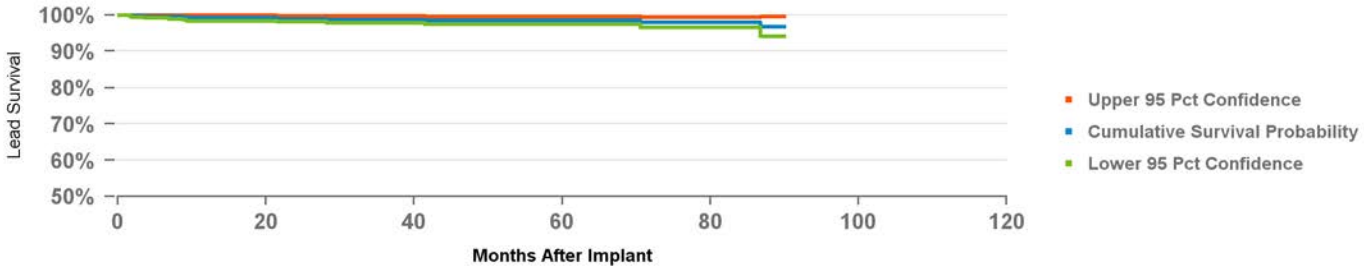
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	761
Cumulative Months of Followup	32,259
Number of Leads Active in Study	382

Qualifying Complications 10

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



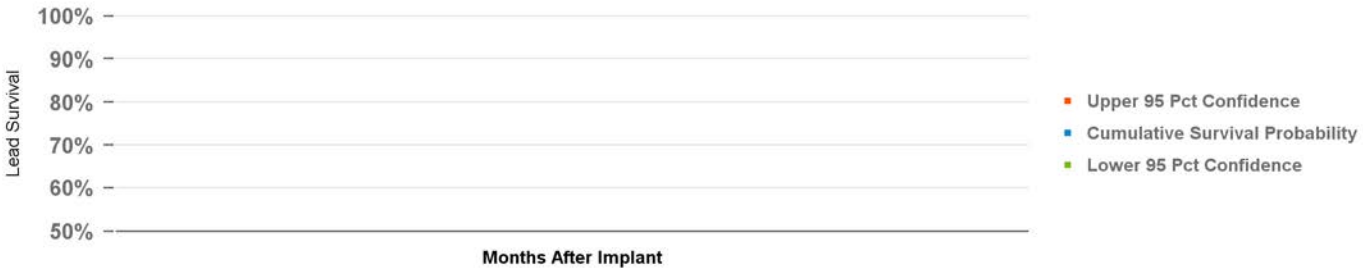
Years	1	2	3	4	5	6	7	at 90 mo
%	99.1%	98.9%	98.7%	98.4%	98.4%	97.9%	97.9%	96.8%
#	560	476	401	305	247	180	94	52

4073 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	771
Estimated Active USA Implants	279
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	119,708
Estimated Active USA Implants	70,043
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	9
Crimp Weld Bond	
Insulation Breach	35
Other	

US Acute Lead Observations

Cardiac Perforation	21
Conductor Fracture	1
Extracardiac Stimulation	3
Failure To Capture	73
Failure To Sense	3
Impedance Abnormal	4
Insulation Breach	
Lead Dislodgement	91
Oversensing	4
Unspecified	

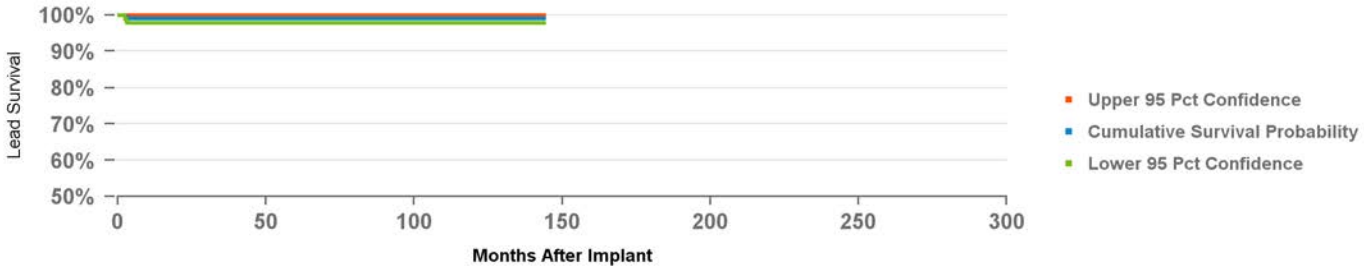
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Followup	23,130
Number of Leads Active in Study	104

Qualifying Complications 2

Failure To Sense	1	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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%
#	214	205	198	183	167	158	148	134	122	112	74	60

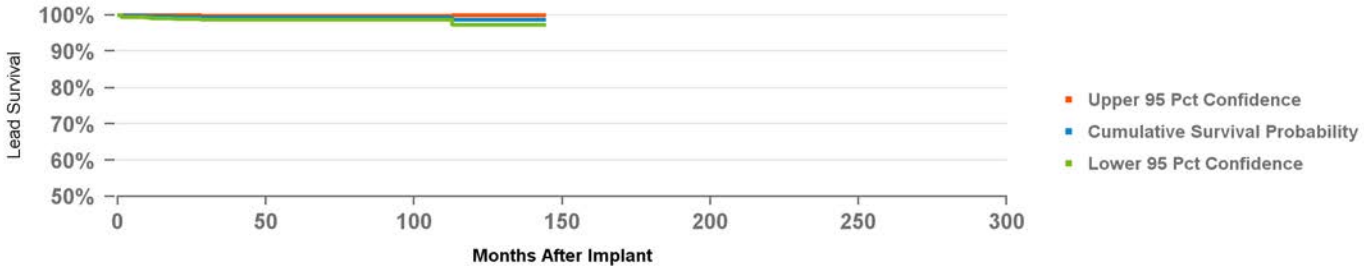
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,124
Cumulative Months of Followup	60,823
Number of Leads Active in Study	378

Qualifying Complications 8

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



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%	99.3%	99.3%	99.3%	98.7%	98.7%	98.7%
#	982	815	676	548	376	274	210	182	159	132	83	52

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	580,077
Estimated Active USA Implants	399,644
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	84
Crimp Weld Bond	1
Insulation Breach	112
Other	22

US Acute Lead Observations

Cardiac Perforation	101
Conductor Fracture	5
Extracardiac Stimulation	17
Failure To Capture	134
Failure To Sense	51
Impedance Abnormal	18
Insulation Breach	1
Lead Dislodgement	339
Oversensing	34
Unspecified	12

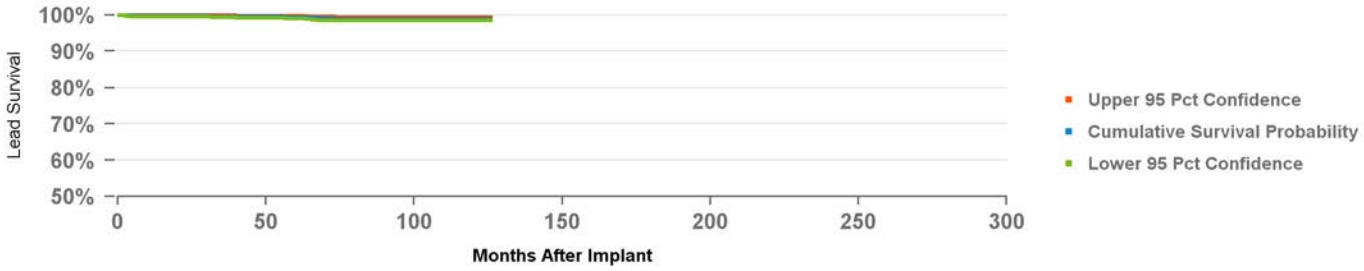
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,341
Cumulative Months of Followup	164,633
Number of Leads Active in Study	1,487

Qualifying Complications 18

Cardiac Perforation	1	Insulation Breach	2
Conductor Fracture	2	Lead Dislodgement	5
Failure To Capture	4	Oversensing	1
Failure To Sense	3		



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.8%	99.7%	99.6%	99.5%	99.3%	99.1%	99.0%	99.0%	99.0%	99.0%	99.0%
#	2,812	2,431	2,058	1,620	1,143	832	582	314	196	112	67

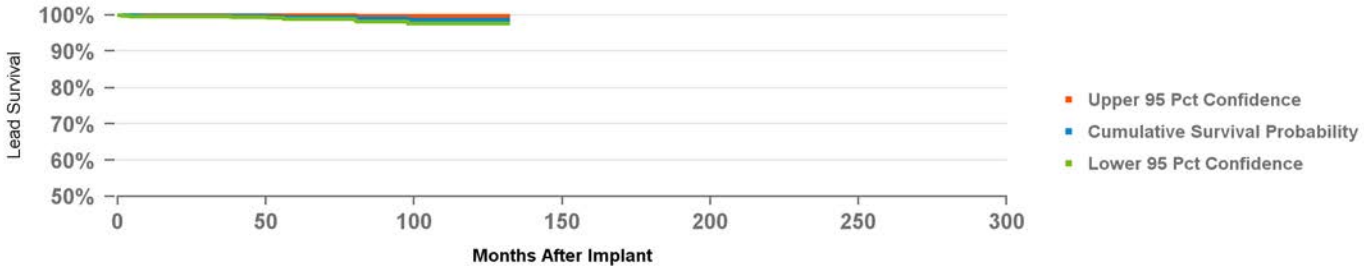
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,535
Cumulative Months of Followup	87,096
Number of Leads Active in Study	450

Qualifying Complications 9

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



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.8%	99.8%	99.8%	99.7%	99.4%	99.4%	99.0%	99.0%	98.6%	98.6%	98.6%
#	1,311	1,160	1,030	837	638	535	409	259	177	107	51

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	187,213
Estimated Active USA Implants	66,970
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	17
Crimp Weld Bond	
Insulation Breach	79
Other	2

US Acute Lead Observations

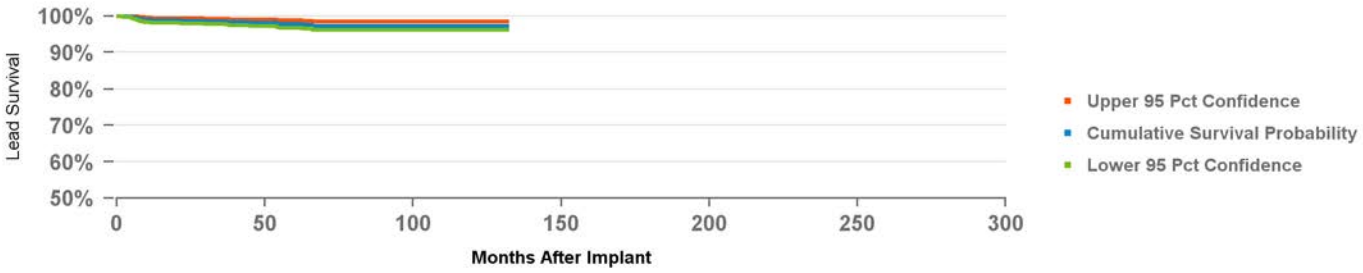
Cardiac Perforation	4
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Failure To Sense	
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,189
Cumulative Months of Followup	67,692
Number of Leads Active in Study	32

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%
#	943	840	745	630	507	393	321	260	211	131	67

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	82,489
Estimated Active USA Implants	52,047
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	12
Other	

US Acute Lead Observations

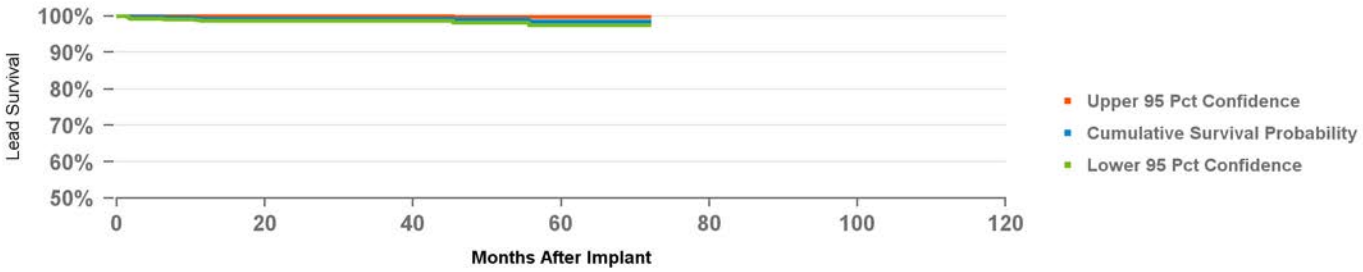
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	49
Failure To Sense	14
Impedance Abnormal	3
Insulation Breach	
Lead Dislodgement	118
Oversensing	1
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,061
Cumulative Months of Followup	34,596
Number of Leads Active in Study	627

Qualifying Complications 8

Conductor Fracture	2	Lead Dislodgement	5
Failure To Capture	1		



Years	1	2	3	4	5	at 72 mo
%	99.3%	99.3%	99.3%	99.0%	98.5%	98.5%
#	795	579	418	301	183	74

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	89,535
Estimated Active USA Implants	33,729
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	9
Crimp Weld Bond	
Insulation Breach	28
Other	

US Acute Lead Observations

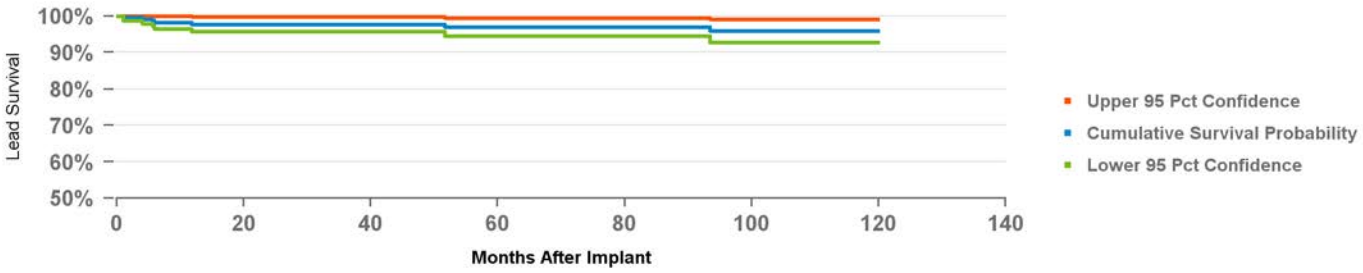
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	10
Failure To Sense	2
Impedance Abnormal	
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	352
Cumulative Months of Followup	18,709
Number of Leads Active in Study	60

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%	96.9%	96.9%	96.9%	95.9%	95.9%	95.9%
#	235	212	185	160	130	111	87	76	63	50

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	99,450
Estimated Active USA Implants	33,883
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	1
Insulation Breach	38
Other	3

US Acute Lead Observations

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

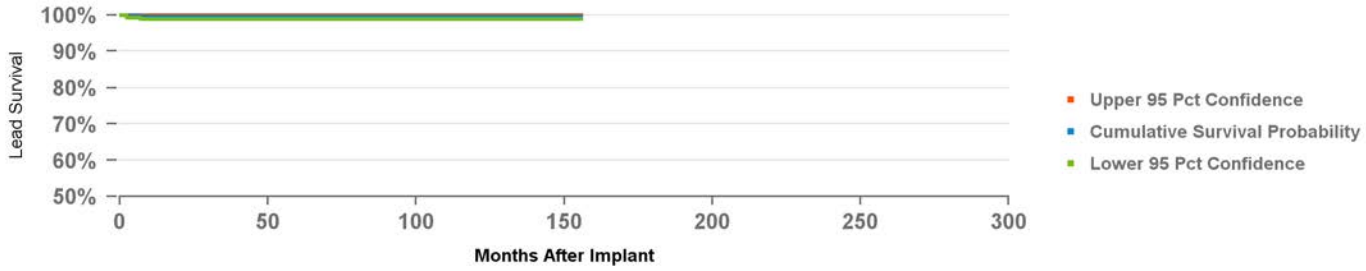
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Cumulative Months of Followup	38,690
Number of Leads Active in Study	64

Qualifying Complications 2

Failure To Capture	1	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
#	412	392	359	323	289	252	219	185	152	128	107	90	57

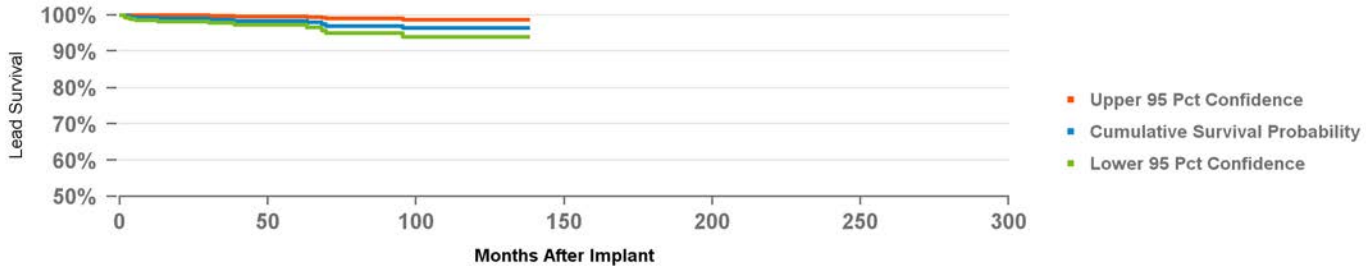
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	985
Cumulative Months of Followup	33,420
Number of Leads Active in Study	36

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%
#	481	396	308	265	227	187	162	137	103	83	63	50

5072 SureFix

US Market Release	05Jun1998
CE Approval	25Sep1997
Registered USA Implants	10,056
Estimated Active USA Implants	3,069
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	9
Other	

US Acute Lead Observations

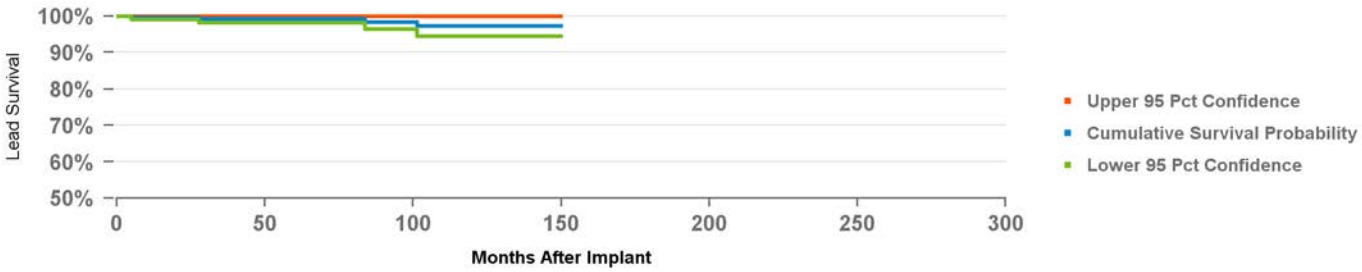
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	2
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	2
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	519
Cumulative Months of Followup	23,332
Number of Leads Active in Study	14

Qualifying Complications 4

Cardiac Perforation	1
Failure To Capture	2
Failure To Sense	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.7%	99.7%	99.2%	99.2%	99.2%	99.2%	98.4%	98.4%	97.3%	97.3%	97.3%	97.3%	97.3%
#	265	236	219	193	158	137	109	92	81	72	63	53	51

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	2,346,371
Estimated Active USA Implants	1,528,342
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	873
Crimp Weld Bond	
Insulation Breach	904
Other	223

US Acute Lead Observations

Cardiac Perforation	788
Conductor Fracture	21
Extracardiac Stimulation	58
Failure To Capture	879
Failure To Sense	280
Impedance Abnormal	58
Insulation Breach	9
Lead Dislodgement	2,303
Oversensing	218
Unspecified	31

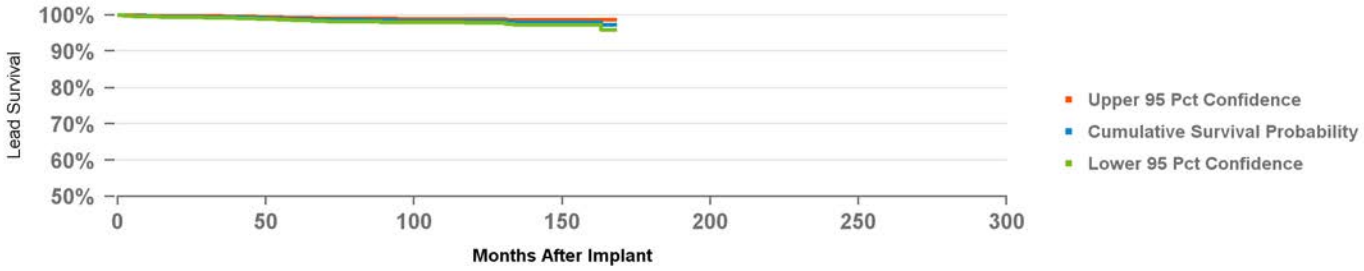
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	7,984
Cumulative Months of Followup	324,408
Number of Leads Active in Study	3,806

Qualifying Complications 56

Cardiac Perforation	2	Impedance Abnormal	6
Conductor Fracture	10	Insulation Breach	1
Extracardiac Stimulation	2	Lead Dislodgement	16
Failure To Capture	8	Oversensing	3
Failure To Sense	4	Other Complication	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.6%	99.6%	99.4%	99.2%	98.9%	98.6%	98.6%	98.4%	98.4%	98.3%	98.1%	98.0%	98.0%	97.3%
#	5,798	4,469	3,569	2,739	1,940	1,463	1,081	775	586	464	340	205	114	57

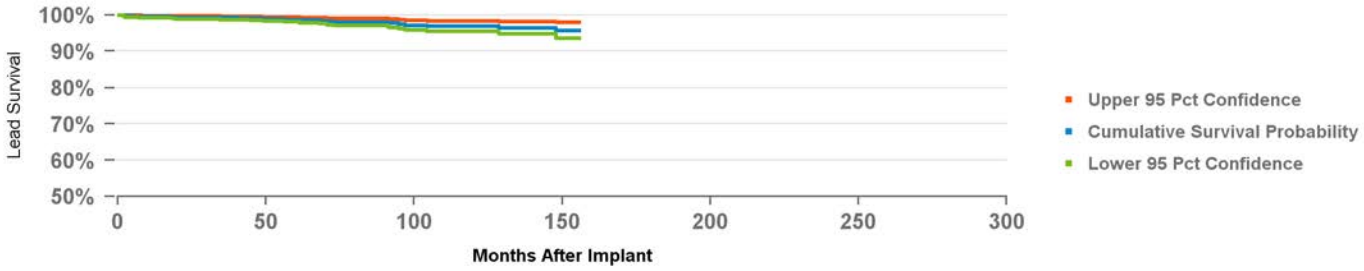
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,522
Cumulative Months of Followup	104,025
Number of Leads Active in Study	720

Qualifying Complications 27

Cardiac Perforation	1	Impedance Abnormal	4
Conductor Fracture	6	Lead Dislodgement	3
Failure To Capture	10	Oversensing	1
Failure To Sense	1	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.3%	99.2%	99.0%	98.7%	98.2%	98.0%	97.5%	96.9%	96.9%	96.4%	96.4%	95.7%
#	1,715	1,395	1,137	840	596	485	395	298	234	198	159	109	64

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	208,528
Estimated Active USA Implants	184,327
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	60
Crimp Weld Bond	
Insulation Breach	103
Other	12

US Acute Lead Observations

Cardiac Perforation	214
Conductor Fracture	2
Extracardiac Stimulation	17
Failure To Capture	140
Failure To Sense	28
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	308
Oversensing	30
Unspecified	

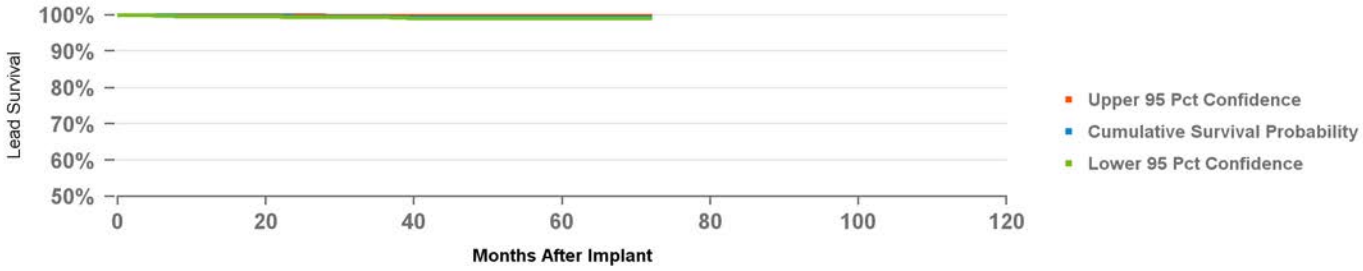
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,094
Cumulative Months of Followup	126,427
Number of Leads Active in Study	1,574

Qualifying Complications 15

Conductor Fracture	2	Lead Dislodgement	11
Failure To Capture	1	Oversensing	1



Years	1	2	3	4	5	at 72 mo
%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
#	2,683	2,314	1,957	1,474	603	61

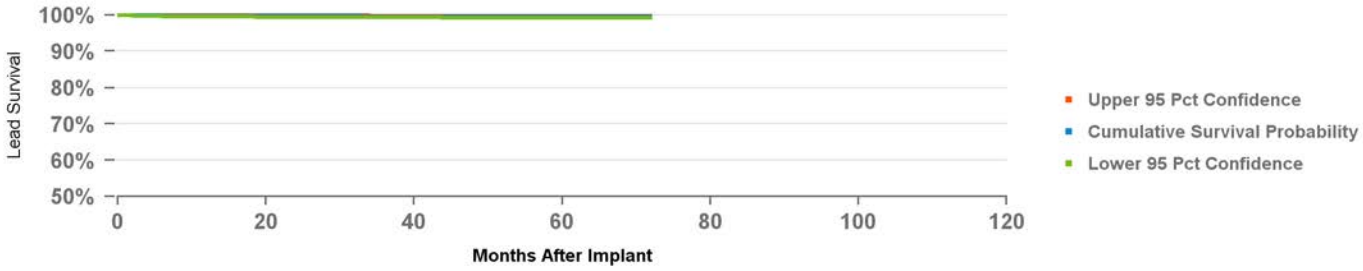
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,040
Cumulative Months of Followup	125,580
Number of Leads Active in Study	1,547

Qualifying Complications 12

Conductor Fracture	1	Impedance Abnormal	1
Failure To Capture	6	Lead Dislodgement	3
Failure To Sense	1		



Years	1	2	3	4	5	at 72 mo
%	99.8%	99.7%	99.6%	99.5%	99.5%	99.5%
#	2,660	2,301	1,943	1,467	599	60

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	141,291
Estimated Active USA Implants	52,837
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	22
Crimp Weld Bond	
Insulation Breach	58
Other	3

US Acute Lead Observations

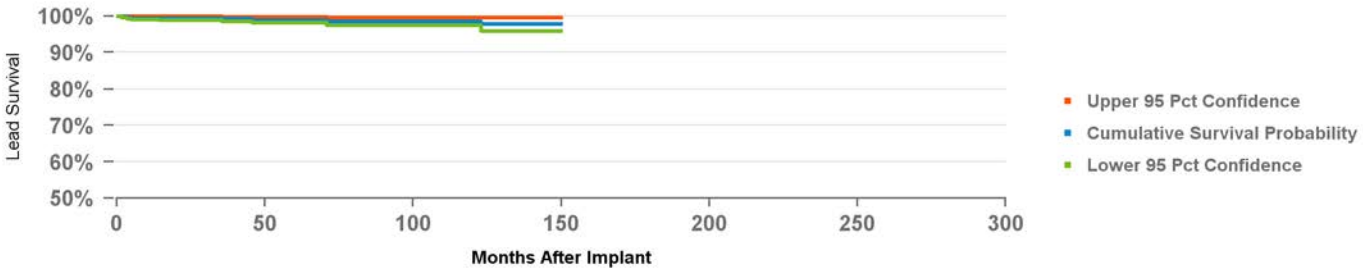
Cardiac Perforation	7
Conductor Fracture	2
Extracardiac Stimulation	3
Failure To Capture	49
Failure To Sense	7
Impedance Abnormal	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified	9

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Followup	52,607
Number of Leads Active in Study	38

Qualifying Complications 10

Extracardiac Stimulation	1	Impedance Abnormal	1
Failure To Capture	3	Lead Dislodgement	5



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.8%	97.8%	97.8%
#	826	659	523	422	329	255	207	163	136	118	95	70	61

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,527
Estimated Active USA Implants	24,308
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	18
Crimp Weld Bond	
Insulation Breach	30
Other	2

US Acute Lead Observations

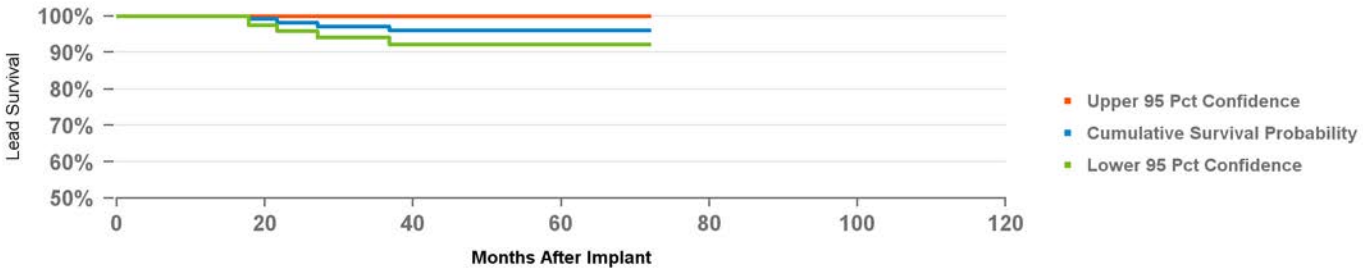
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	
Lead Dislodgement	38
Oversensing	
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	361
Cumulative Months of Followup	8,761
Number of Leads Active in Study	10

Qualifying Complications 5

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



Years	1	2	3	4	5	at 72 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%
#	152	117	93	79	62	50

5592 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	37,291
Estimated Active USA Implants	17,039
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	4
Other	1

US Acute Lead Observations

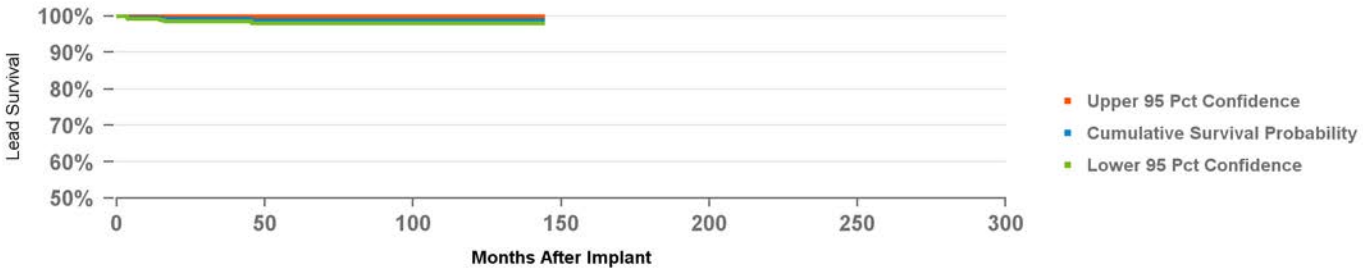
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	3
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	43
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	709
Cumulative Months of Followup	36,646
Number of Leads Active in Study	46

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%
#	533	442	358	299	236	183	152	132	112	97	80	54

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,591
Estimated Active USA Implants	9,524
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	
Insulation Breach	13
Other	

US Acute Lead Observations

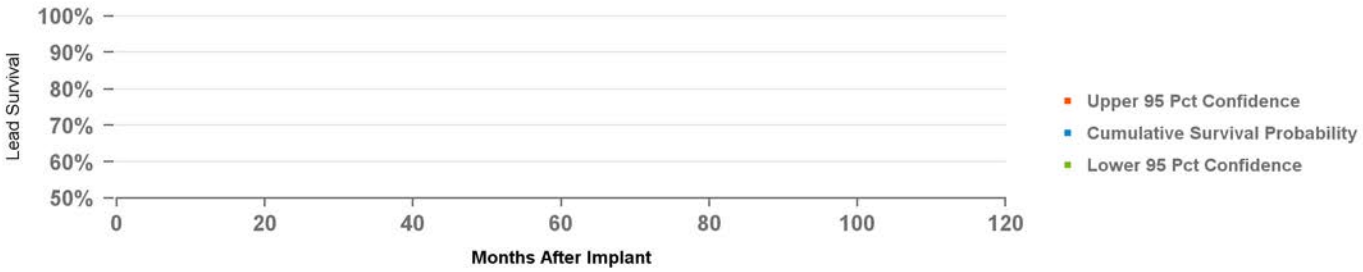
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	4
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	14
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	31
Cumulative Months of Followup	2,595
Number of Leads Active in Study	9

Qualifying Complications 2

Conductor Fracture	1
Oversensing	1



Years	at 0 mo
%	100.0%
#	

6940 CapSureFix

US Market Release	09Oct1998
CE Approval	
Registered USA Implants	25,370
Estimated Active USA Implants	5,218
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp Weld Bond	
Insulation Breach	24
Other	12

US Acute Lead Observations

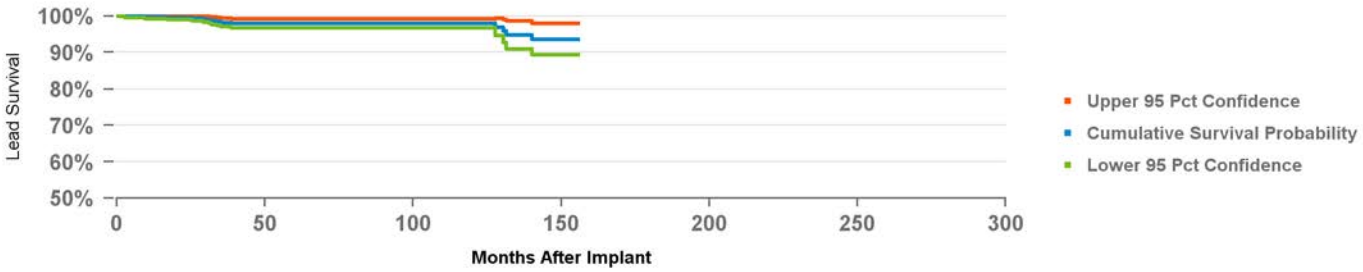
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	
Impedance Abnormal	1
Insulation Breach	
Lead Dislodgement	6
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	849
Cumulative Months of Followup	44,130
Number of Leads Active in Study	27

Qualifying Complications 14

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.7%	99.5%	98.2%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	94.7%	93.6%	93.6%
#	648	529	434	353	279	219	190	151	125	96	80	70	52

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,204
Estimated Active USA Implants	1,100
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	
Insulation Breach	1
Other	

US Acute Lead Observations

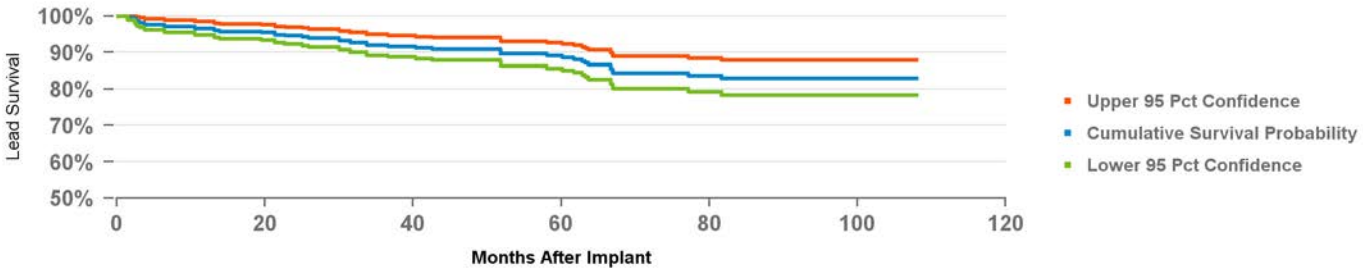
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	8
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	416
Cumulative Months of Followup	23,730
Number of Leads Active in Study	6

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%	92.0%	90.9%	89.1%	84.4%	83.0%	83.0%	83.0%
#	344	315	269	217	185	132	99	64	56

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	120
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

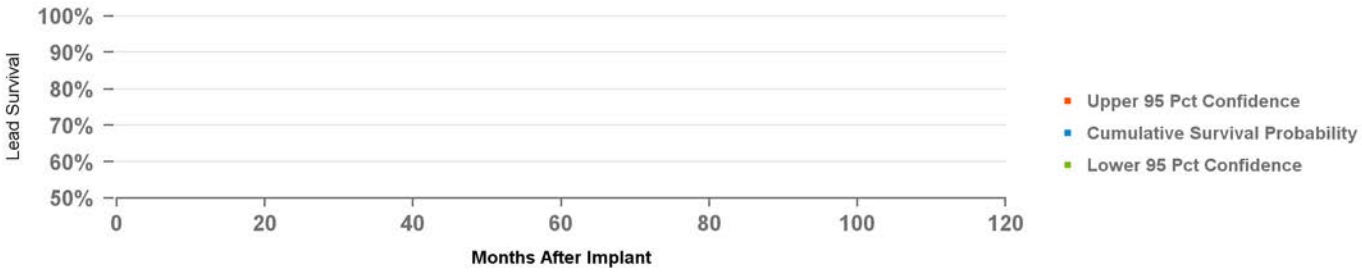
Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

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	262
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	8,075
Estimated Active USA Implants	2,209
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	640
Crimp Weld Bond	
Insulation Breach	1
Other	5

US Acute Lead Observations

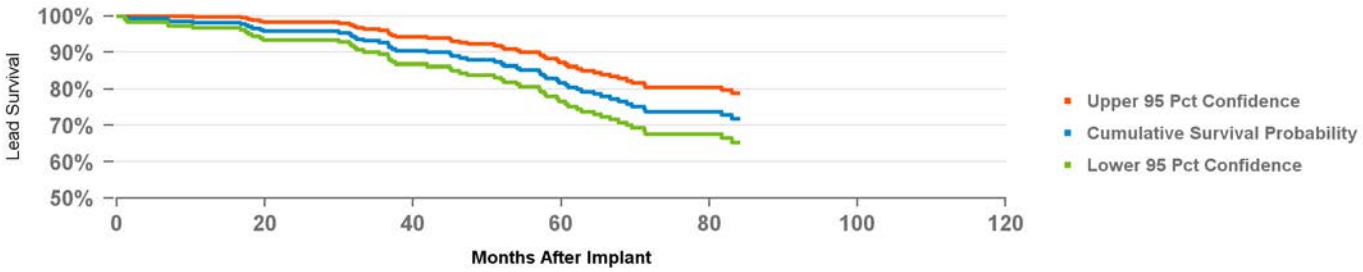
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	1
Oversensing	3
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	310
Cumulative Months of Followup	17,162
Number of Leads Active in Study	26

Qualifying Complications 59

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



Years	1	2	3	4	5	6	at 84 mo
%	98.2%	95.9%	92.7%	87.9%	81.8%	73.8%	71.9%
#	271	240	209	168	137	99	64

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	57,947
Estimated Active USA Implants	46,331
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	255
Crimp Weld Bond	
Insulation Breach	9
Other	40

US Acute Lead Observations

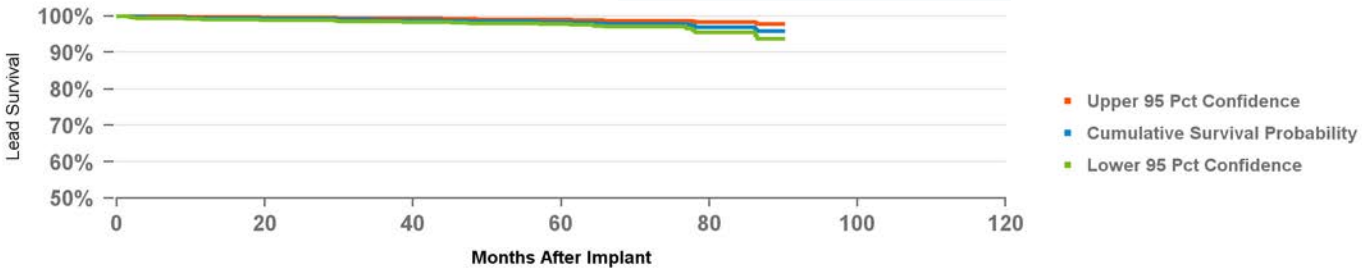
Cardiac Perforation	21
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	23
Failure To Sense	8
Impedance Abnormal	17
Insulation Breach	1
Lead Dislodgement	52
Oversensing	51
Unspecified	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,606
Cumulative Months of Followup	106,913
Number of Leads Active in Study	1,046

Qualifying Complications 37

Cardiac Perforation	1
Conductor Fracture	14
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	3
Lead Dislodgement	7
Oversensing	6
Other Complication	1



Years	1	2	3	4	5	6	7	at 90 mo
%	99.4%	99.2%	98.9%	98.6%	98.4%	97.9%	96.9%	95.8%
#	2,205	1,771	1,402	1,056	678	369	175	81

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	160,934
Estimated Active USA Implants	152,029
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	158
Crimp Weld Bond	
Insulation Breach	4
Other	17

US Acute Lead Observations

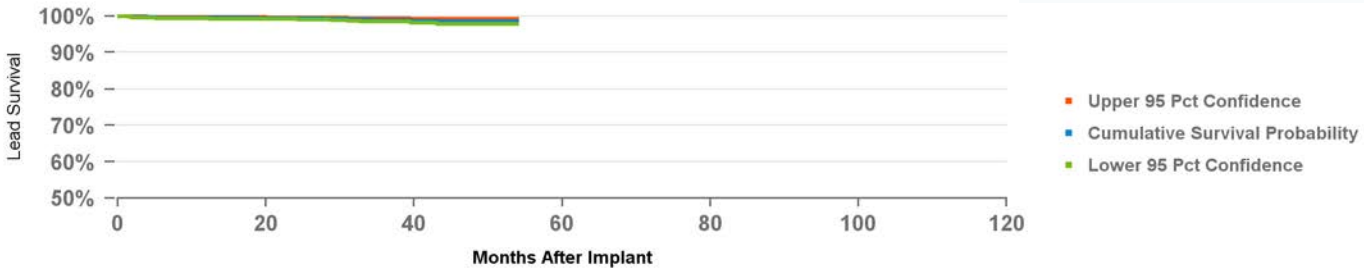
Cardiac Perforation	78
Conductor Fracture	6
Extracardiac Stimulation	11
Failure To Capture	136
Failure To Sense	33
Impedance Abnormal	43
Insulation Breach	1
Lead Dislodgement	234
Oversensing	104
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	5,369
Cumulative Months of Followup	108,397
Number of Leads Active in Study	3,996

Qualifying Complications 37

Cardiac Perforation	1	Impedance Abnormal	3
Conductor Fracture	9	Insulation Breach	1
Failure To Capture	8	Lead Dislodgement	12
Failure To Sense	1	Oversensing	1
		Other Complication	1



Years	1	2	3	4	at 54 mo
%	99.5%	99.4%	98.9%	98.5%	98.5%
#	3,544	1,945	906	240	77

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	2,418
Estimated Active USA Implants	1,430
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

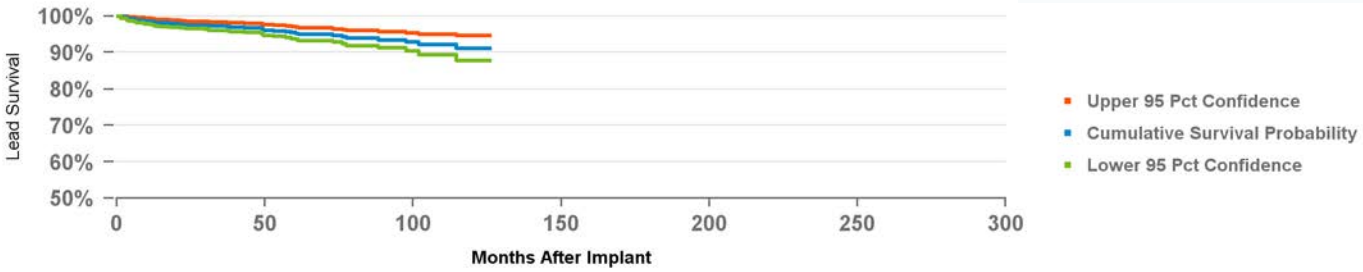
Cardiac Perforation	
Conductor Fracture	3
Extracardiac Stimulation	
Failure To Capture	
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	
Oversensing	
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	121
Cumulative Months of Followup	13,292
Number of Leads Active in Study	13

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	10	at 126 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	827	695	581	489	390	311	217	168	109	71	56

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,835
Estimated Active USA Implants	19,780
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	186
Crimp Weld Bond	1
Insulation Breach	4
Other	6

US Acute Lead Observations

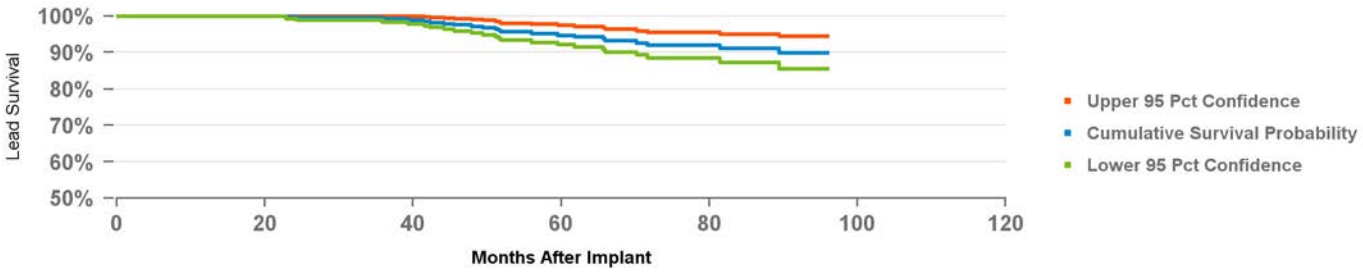
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	17
Failure To Sense	3
Impedance Abnormal	11
Insulation Breach	
Lead Dislodgement	24
Oversensing	13
Unspecified	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	610
Cumulative Months of Followup	30,266
Number of Leads Active in Study	160

Qualifying Complications 27

Conductor Fracture	14	Impedance Abnormal	4
Failure To Capture	4	Oversensing	3
Failure To Sense	1	Unspecified	1



Years	1	2	3	4	5	6	7	at 96 mo
%	100.0%	99.8%	99.2%	97.2%	94.7%	91.9%	91.1%	89.9%
#	523	434	355	283	197	140	90	58

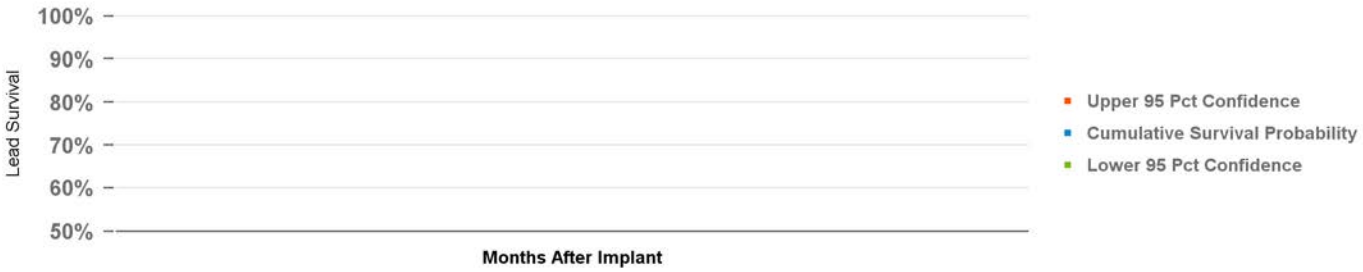
6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	946
Estimated Active USA Implants	932
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	3
Oversensing	4
Unspecified	



Years	at	mo
%		
#		

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	374,402
Estimated Active USA Implants	203,768
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	984
Crimp Weld Bond	4
Insulation Breach	86
Other	215

US Acute Lead Observations

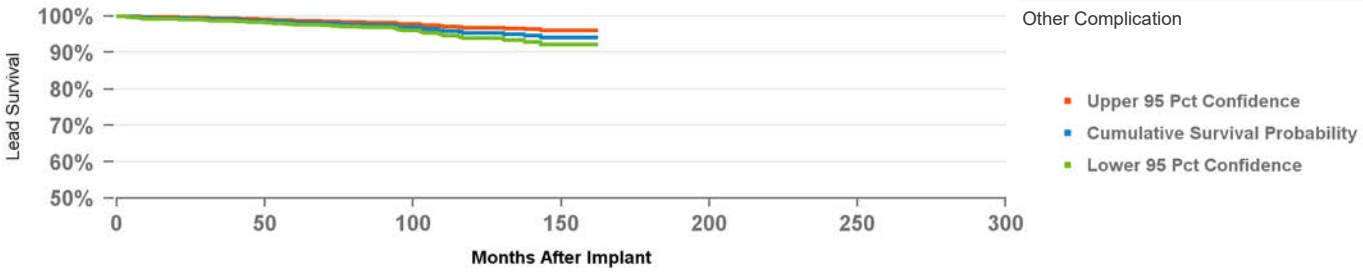
Cardiac Perforation	28
Conductor Fracture	23
Extracardiac Stimulation	2
Failure To Capture	79
Failure To Sense	35
Impedance Abnormal	58
Insulation Breach	4
Lead Dislodgement	121
Oversensing	128
Unspecified	22

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,315
Cumulative Months of Followup	225,634
Number of Leads Active in Study	1,286

Qualifying Complications 74

Conductor Fracture	27
Failure To Capture	4
Failure To Sense	2
Impedance Abnormal	11
Insulation Breach	5
Lead Dislodgement	5
Oversensing	17
Unspecified	2
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	98.0%	97.5%	97.0%	96.3%	95.4%	95.0%	94.1%	94.1%	94.1%
#	3,656	3,107	2,634	2,184	1,697	1,264	837	494	313	213	153	102	78	51

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	101,512
Estimated Active USA Implants	91,988
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	81
Crimp Weld Bond	
Insulation Breach	9
Other	16

US Acute Lead Observations

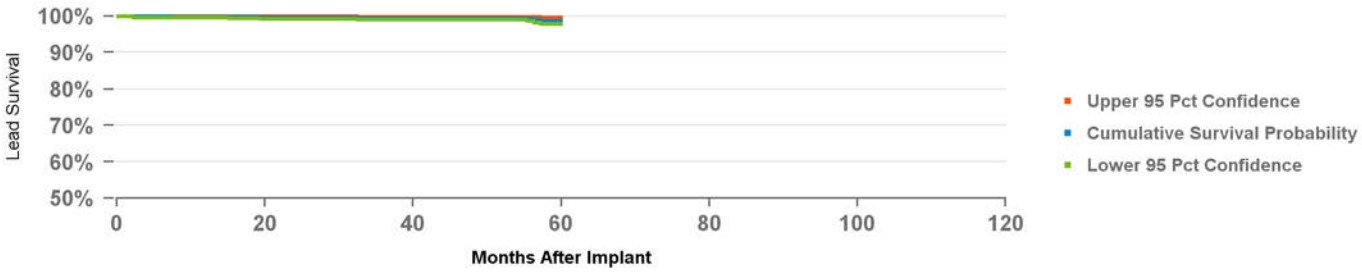
Cardiac Perforation	26
Conductor Fracture	9
Extracardiac Stimulation	10
Failure To Capture	79
Failure To Sense	30
Impedance Abnormal	23
Insulation Breach	
Lead Dislodgement	160
Oversensing	51
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,019
Cumulative Months of Followup	72,498
Number of Leads Active in Study	1,090

Qualifying Complications 12

Conductor Fracture	5
Failure To Capture	4
Failure To Sense	2
Other Complication	1



Years	1	2	3	4	at 60 mo
%	99.7%	99.5%	99.4%	99.4%	98.7%
#	1,639	1,338	1,101	764	271

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,374
Estimated Active USA Implants	3,192
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	200
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

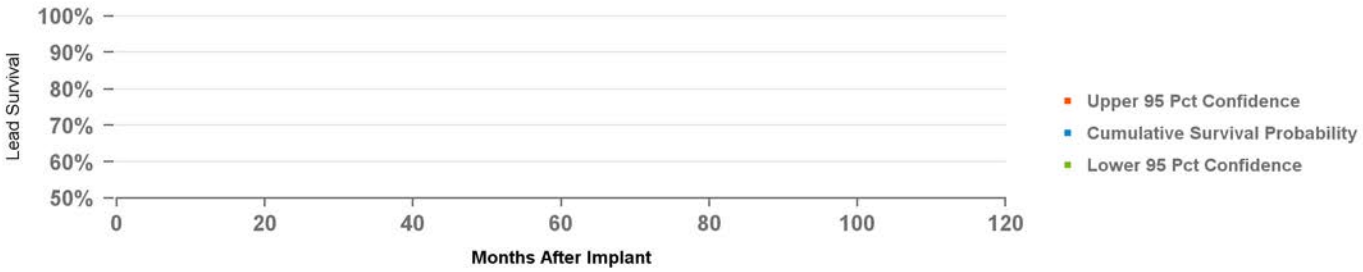
Cardiac Perforation	
Conductor Fracture	2
Extracardiac Stimulation	
Failure To Capture	7
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	7
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Cumulative Months of Followup	2,171
Number of Leads Active in Study	7

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	186,700
Estimated Active USA Implants	47,972
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7,666
Crimp Weld Bond	3
Insulation Breach	37
Other	85

US Acute Lead Observations

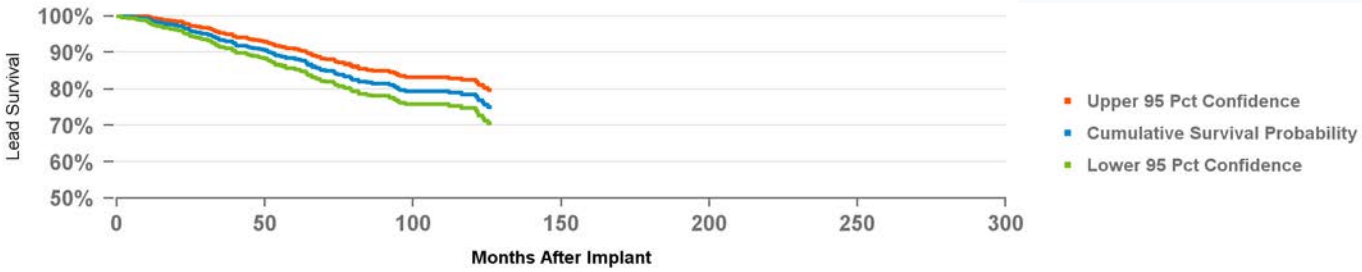
Cardiac Perforation	10
Conductor Fracture	46
Extracardiac Stimulation	
Failure To Capture	31
Failure To Sense	19
Impedance Abnormal	18
Insulation Breach	5
Lead Dislodgement	22
Oversensing	32
Unspecified	25

Product Surveillance Registry Results

Number of Leads Enrolled in Study	970
Cumulative Months of Followup	52,863
Number of Leads Active in Study	123

Qualifying Complications 113

Conductor Fracture	63
Failure To Capture	4
Failure To Sense	6
Impedance Abnormal	19
Insulation Breach	2
Lead Dislodgement	1
Oversensing	17
Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.5%	96.5%	93.3%	90.9%	88.4%	85.0%	82.1%	79.9%	79.5%	78.6%	75.1%
#	840	721	613	508	394	309	207	143	93	61	50

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	4,892
Estimated Active USA Implants	2,691
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	29
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

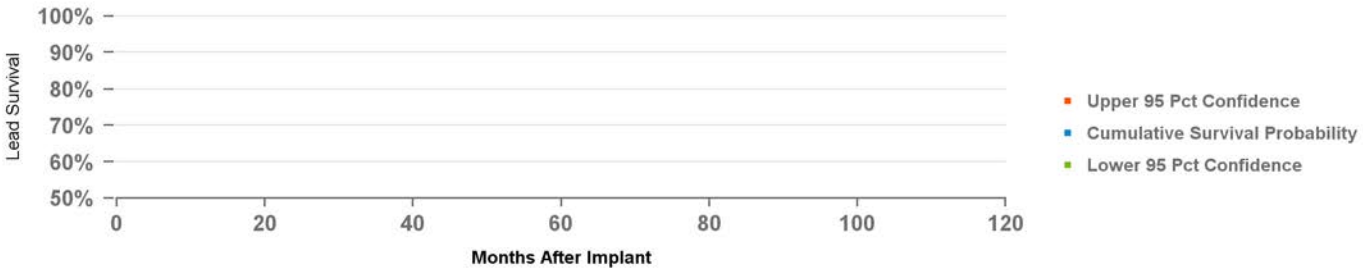
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	
Failure To Capture	1
Failure To Sense	
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	1
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	50
Cumulative Months of Followup	2,080
Number of Leads Active in Study	8

Qualifying Complications 2

Conductor Fracture	1
Impedance Abnormal	1



Years	at 0 mo
%	100.0%
#	

2187 Attain LV

US Market Release	28Aug2001
CE Approval	
Registered USA Implants	11,980
Estimated Active USA Implants	1,795
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	4

US Acute Lead Observations

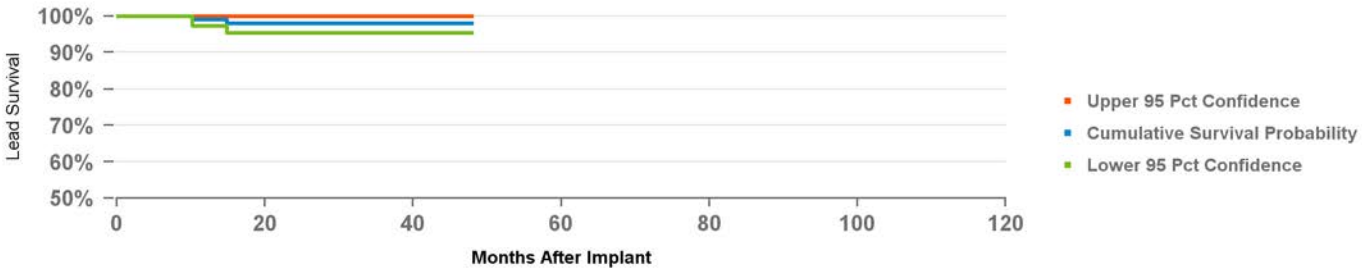
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	9
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	139
Cumulative Months of Followup	6,776
Number of Leads Active in Study	7

Qualifying Complications 3

Failure To Capture	3



Years	1	2	3	at 48 mo
%	99.1%	98.0%	98.0%	98.0%
#	105	89	68	55

4193 Attain OTW

US Market Release	03May2002
CE Approval	22Dec2000
Registered USA Implants	100,807
Estimated Active USA Implants	23,754
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	76
Crimp Weld Bond	
Insulation Breach	25
Other	46

US Acute Lead Observations

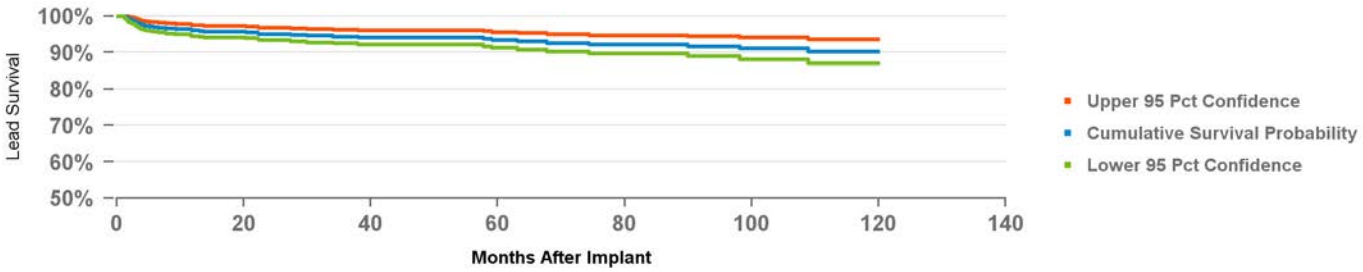
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	18
Failure To Capture	11
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	45
Oversensing	1
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	796
Cumulative Months of Followup	38,496
Number of Leads Active in Study	88

Qualifying Complications 46

Conductor Fracture	1	Impedance Abnormal	2
Extracardiac Stimulation	9	Lead Dislodgement	14
Failure To Capture	17	Unspecified	3



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.0%	95.0%	94.3%	94.1%	93.3%	92.6%	92.1%	91.6%	91.0%	90.3%
#	629	487	409	317	247	206	165	134	87	60

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	114,945
Estimated Active USA Implants	53,233
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	29
Crimp Weld Bond	
Insulation Breach	119
Other	7

US Acute Lead Observations

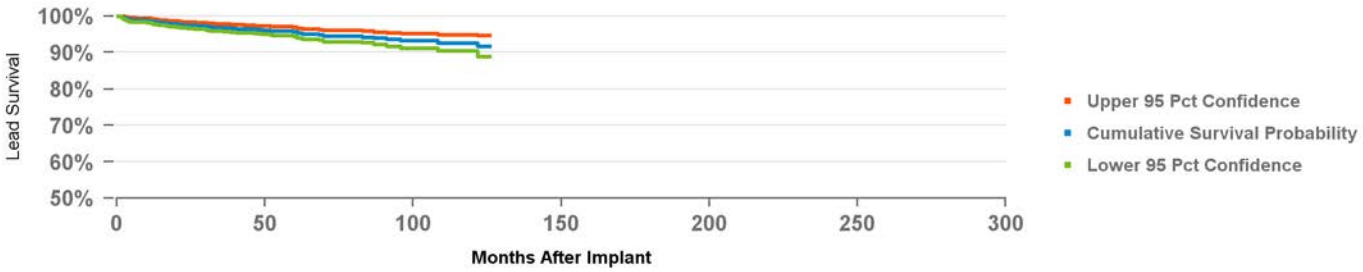
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	49
Failure To Capture	42
Failure To Sense	
Impedance Abnormal	8
Insulation Breach	
Lead Dislodgement	151
Oversensing	2
Unspecified	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,616
Cumulative Months of Followup	78,178
Number of Leads Active in Study	438

Qualifying Complications 62

Conductor Fracture	2	Insulation Breach	2
Extracardiac Stimulation	11	Lead Dislodgement	28
Failure To Capture	18	Insulation Breach Esc	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.6%	97.4%	96.7%	96.2%	95.6%	94.4%	94.2%	93.1%	93.1%	92.6%	91.7%
#	1,346	1,121	918	746	555	420	256	163	98	66	53

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,366
Estimated Active USA Implants	11,119
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7
Crimp Weld Bond	
Insulation Breach	2
Other	4

US Acute Lead Observations

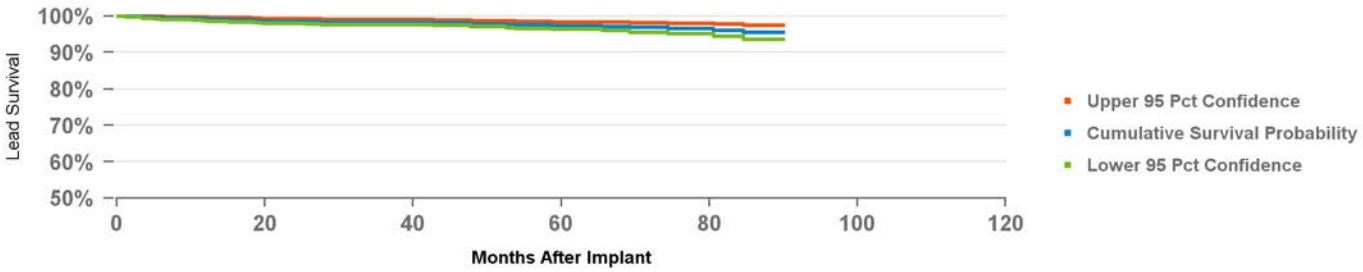
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	30
Failure To Capture	21
Failure To Sense	
Impedance Abnormal	4
Insulation Breach	
Lead Dislodgement	30
Oversensing	
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,485
Cumulative Months of Followup	67,536
Number of Leads Active in Study	451

Qualifying Complications 33

Conductor Fracture	3	Impedance Abnormal	2
Extracardiac Stimulation	12	Insulation Breach	5
Failure To Capture	6	Lead Dislodgement	5



Years	1	2	3	4	5	6	7	at 90 mo
%	99.2%	98.6%	98.3%	97.9%	97.4%	96.8%	96.1%	95.5%
#	1,262	1,075	904	675	479	300	158	90

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	68,025
Estimated Active USA Implants	47,379
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	21
Crimp Weld Bond	
Insulation Breach	1
Other	12

US Acute Lead Observations

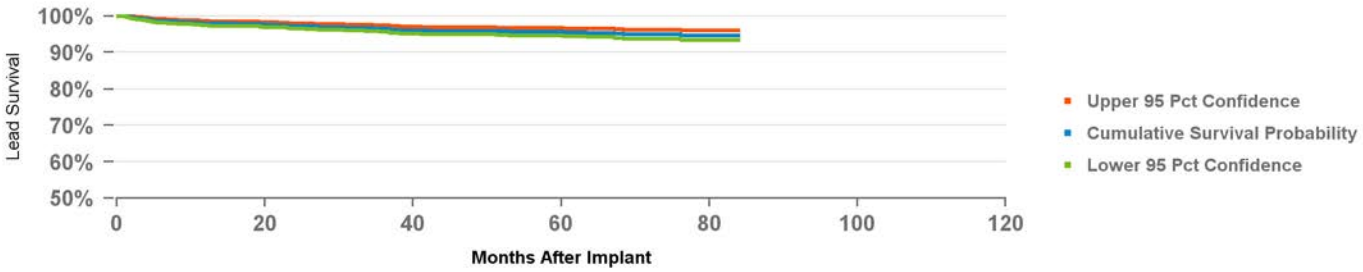
Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	89
Failure To Capture	58
Failure To Sense	1
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	205
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,250
Cumulative Months of Followup	89,803
Number of Leads Active in Study	569

Qualifying Complications 76

Conductor Fracture	3
Extracardiac Stimulation	13
Failure To Capture	33
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	21
Other Complication	3



Years	1	2	3	4	5	6	at 84 mo
%	98.0%	97.3%	96.6%	95.9%	95.7%	95.0%	94.7%
#	1,843	1,439	1,104	829	617	400	152

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	34,255
Estimated Active USA Implants	28,269
Fixation Type	Double Curve
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp Weld Bond	2
Insulation Breach	
Other	4

US Acute Lead Observations

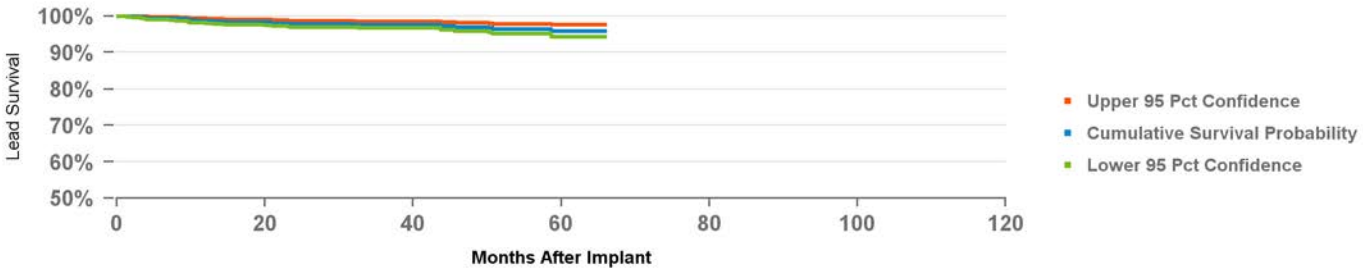
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	57
Failure To Capture	27
Failure To Sense	
Impedance Abnormal	9
Insulation Breach	4
Lead Dislodgement	116
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,441
Cumulative Months of Followup	47,170
Number of Leads Active in Study	608

Qualifying Complications 34

Extracardiac Stimulation	12	Lead Dislodgement	13
Failure To Capture	8	Other Complication	1



Years	1	2	3	4	5	at 66 mo
%	98.6%	97.8%	97.6%	97.0%	95.9%	95.9%
#	1,121	891	686	391	172	59

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	52,266
Estimated Active USA Implants	49,297
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	
Insulation Breach	1
Other	14

US Acute Lead Observations

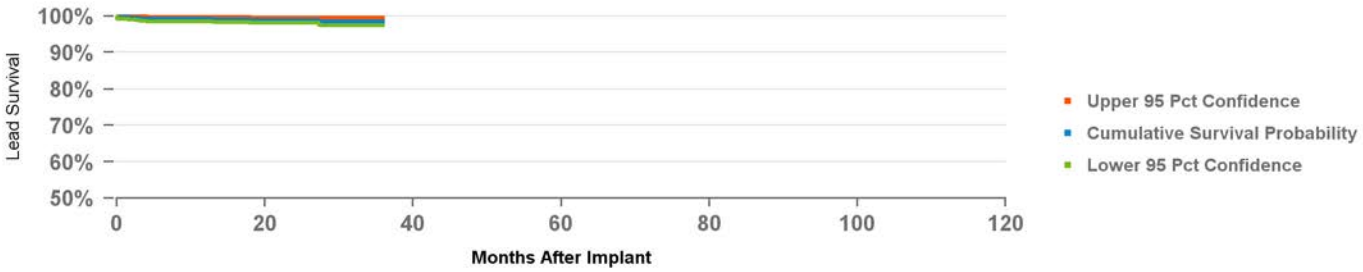
Cardiac Perforation	3
Conductor Fracture	1
Extracardiac Stimulation	120
Failure To Capture	64
Failure To Sense	
Impedance Abnormal	16
Insulation Breach	
Lead Dislodgement	98
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,435
Cumulative Months of Followup	22,963
Number of Leads Active in Study	1,143

Qualifying Complications 12

Extracardiac Stimulation	2
Lead Dislodgement	10



Years	1	2	at 36 mo
%	99.2%	98.9%	98.5%
#	855	371	58

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	7,602
Estimated Active USA Implants	6,126
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	1

US Acute Lead Observations

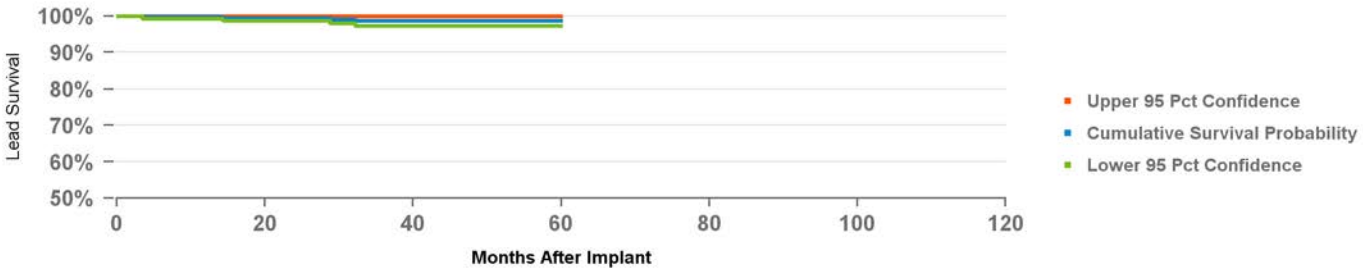
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	16
Failure To Capture	7
Failure To Sense	
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	33
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	445
Cumulative Months of Followup	14,767
Number of Leads Active in Study	208

Qualifying Complications 4

Failure To Capture	3	Lead Dislodgement	1



Years	1	2	3	4	at 60 mo
%	99.8%	99.5%	98.6%	98.6%	98.6%
#	349	268	197	119	59

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	13,020
Estimated Active USA Implants	12,414
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	
Insulation Breach	
Other	3

US Acute Lead Observations

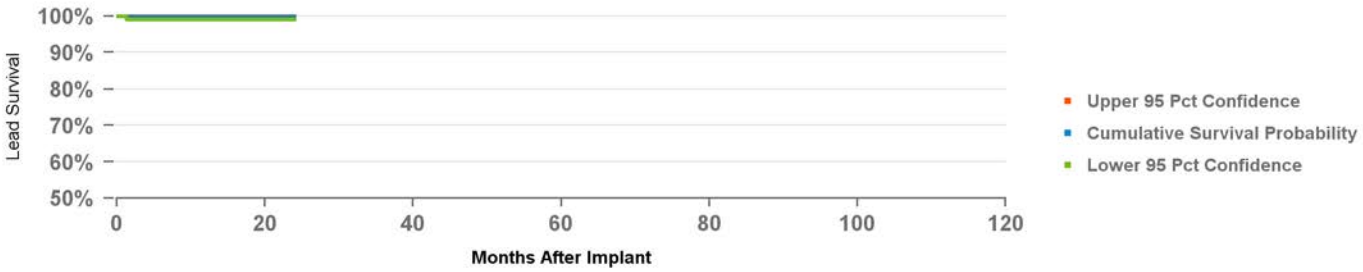
Cardiac Perforation	2
Conductor Fracture	
Extracardiac Stimulation	40
Failure To Capture	22
Failure To Sense	
Impedance Abnormal	4
Insulation Breach	
Lead Dislodgement	12
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	530
Cumulative Months of Followup	5,488
Number of Leads Active in Study	454

1

Lead Dislodgement	1



Years	1	at 24 mo
%	99.7%	99.7%
#	187	66

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	25,448
Estimated Active USA Implants	24,395
Fixation Type	Canted
Pace Sense Polarity	Quad Pole
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp Weld Bond	
Insulation Breach	1
Other	1

US Acute Lead Observations

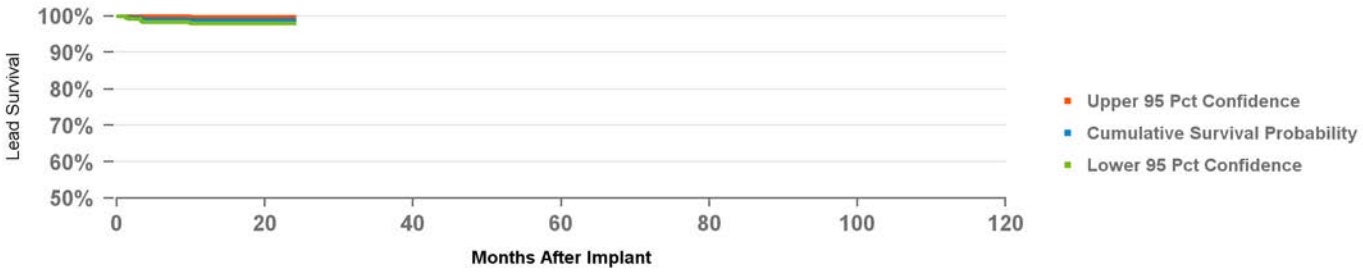
Cardiac Perforation	4
Conductor Fracture	1
Extracardiac Stimulation	45
Failure To Capture	23
Failure To Sense	
Impedance Abnormal	5
Insulation Breach	
Lead Dislodgement	27
Oversensing	1
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	723
Cumulative Months of Followup	9,097
Number of Leads Active in Study	609

Qualifying Complications 6

Failure To Sense	1	Lead Dislodgement	5



Years	1	at 24 mo
%	98.9%	98.9%
#	344	111

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	23,027
Estimated Active USA Implants	8,591
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	258
Crimp Weld Bond	1
Insulation Breach	52
Other	

US Acute Lead Observations

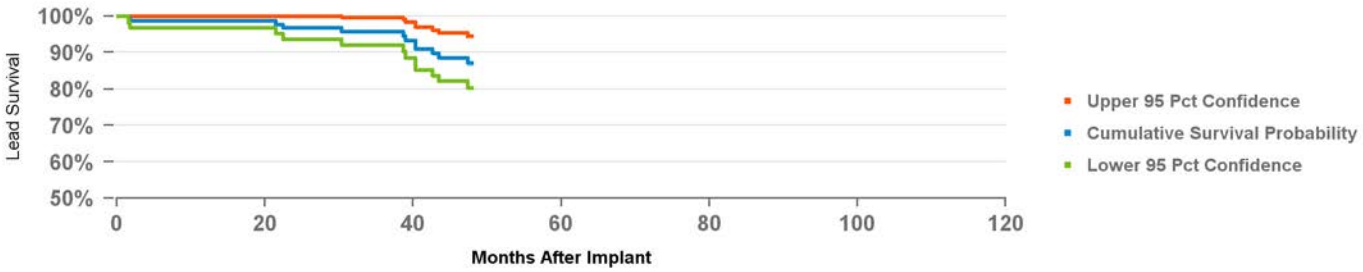
Cardiac Perforation	
Conductor Fracture	1
Extracardiac Stimulation	
Failure To Capture	6
Failure To Sense	5
Impedance Abnormal	11
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	232
Cumulative Months of Followup	7,161
Number of Leads Active in Study	5

Qualifying Complications 16

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



Years	1	2	3	at 48 mo
%	98.6%	96.7%	95.7%	87.1%
#	131	111	91	67

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	44,028
Estimated Active USA Implants	27,021
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	87
Crimp Weld Bond	
Insulation Breach	47
Other	1

US Acute Lead Observations

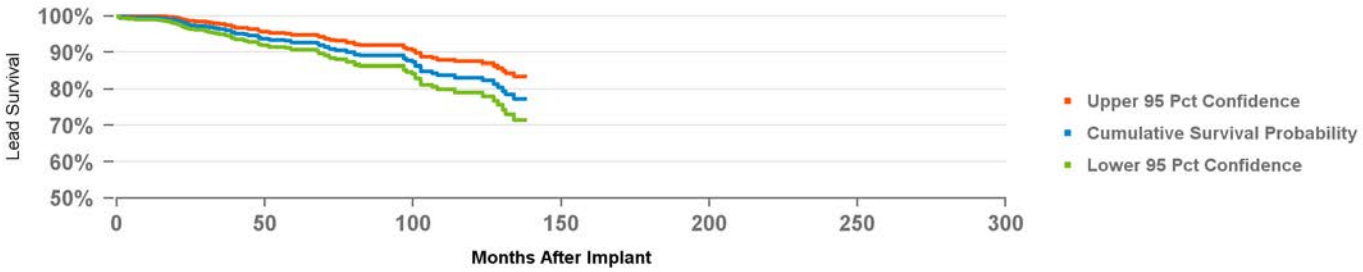
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	2
Failure To Capture	40
Failure To Sense	2
Impedance Abnormal	5
Insulation Breach	1
Lead Dislodgement	6
Oversensing	14
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	990
Cumulative Months of Followup	54,706
Number of Leads Active in Study	261

Qualifying Complications 84

Conductor Fracture	23	Impedance Abnormal	4
Extracardiac Stimulation	2	Insulation Breach	3
Failure To Capture	27	Oversensing	21
Failure To Sense	3	Other Complication	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.5%	97.6%	96.4%	94.0%	92.8%	90.9%	89.1%	89.1%	84.4%	83.2%	78.5%	77.3%
#	763	669	579	488	414	322	259	199	137	96	63	54

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	52,663
Estimated Active USA Implants	16,397
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	24
Crimp Weld Bond	
Insulation Breach	2
Other	1

US Acute Lead Observations

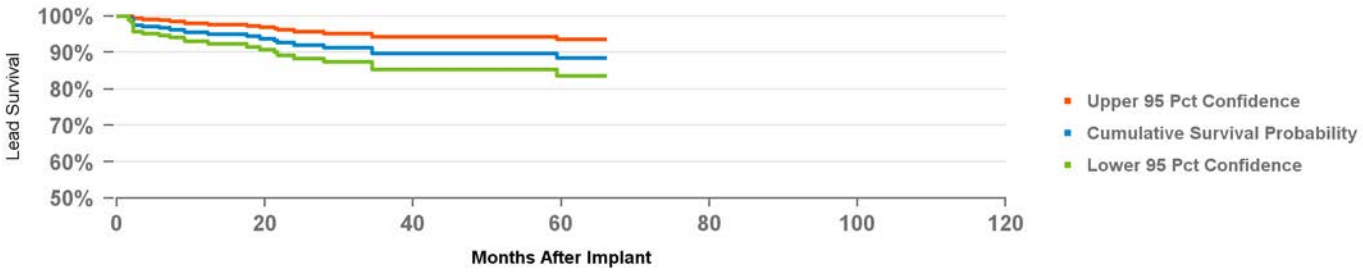
Cardiac Perforation	1
Conductor Fracture	
Extracardiac Stimulation	6
Failure To Capture	63
Failure To Sense	3
Impedance Abnormal	6
Insulation Breach	
Lead Dislodgement	
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	430
Cumulative Months of Followup	11,626
Number of Leads Active in Study	107

Qualifying Complications 28

Conductor Fracture	3	Impedance Abnormal	1
Failure To Capture	19	Lead Dislodgement	1
Failure To Sense	2	Oversensing	2



Years	1	2	3	4	5	at 66 mo
%	95.5%	92.0%	89.7%	89.7%	88.5%	88.5%
#	214	158	125	91	63	50

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	10,152
Estimated Active USA Implants	3,593
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	2
Other	

US Acute Lead Observations

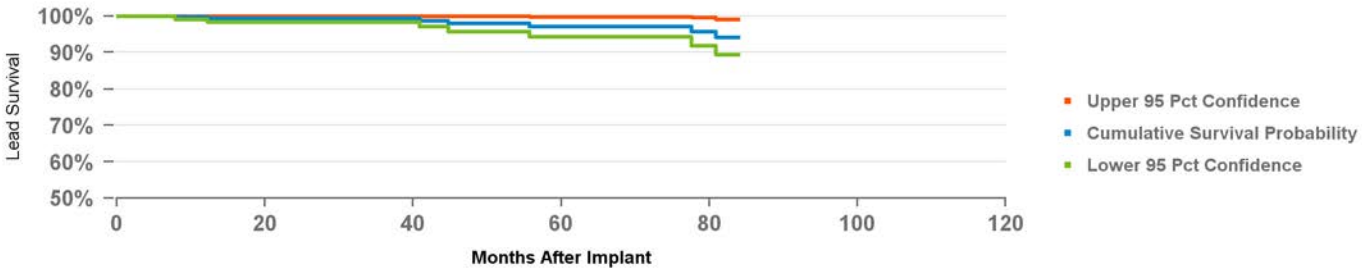
Cardiac Perforation	
Conductor Fracture	
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	2
Impedance Abnormal	
Insulation Breach	
Lead Dislodgement	6
Oversensing	
Unspecified	

Product Surveillance Registry Results

Number of Leads Enrolled in Study	567
Cumulative Months of Followup	15,737
Number of Leads Active in Study	3

Qualifying Complications 8

Conductor Fracture	3
Failure To Capture	2
Failure To Sense	3



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.3%	99.3%	97.9%	97.0%	97.0%	94.1%
#	292	222	164	132	105	77	55

ICD and CRT-D Charge Time Performance

Medtronic continues its commitment to providing updated information on charge time performance.

Introduction

Information on charge time performance of Medtronic products is presented in this section of the CRHF Product Performance Report. Medtronic implemented the collection of charge time data on July 1, 1999. The data are collected via our ongoing active clinical study of long-term system performance called the Product Surveillance Registry. The study protocol requests device data be routinely taken and sent to Medtronic at no more than 6-month intervals.

In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available in a 6-month interval, a conservative approach has been adopted whereby only the maximum charge time in each 6-month interval is reported. As charge time is directly proportional to the time elapsed since the last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.

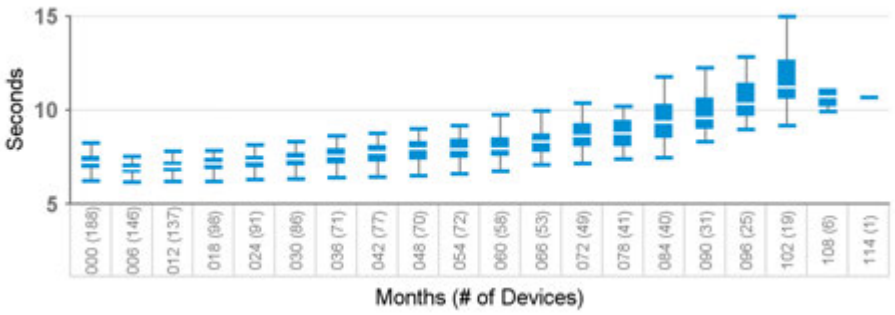
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

Charge time data for ICD and CRT-D models are presented using boxplots at 6-month intervals. The shaded box on the plots represents the middle half of the data – the Interquartile Range (IQR). The white line in the middle of each box is the median charge time. The top of the box representing the IQR is the third quartile or the 75th percentile (i.e., 75% of all charge times fall below this line), whereas the bottom of the box represents the first quartile or the 25th percentile. Vertical lines are drawn from the quartiles to the farthest value not more than 1.5 times the interquartile range. Any values more extreme than the vertical lines are considered outliers.

ICD AND CRT-D CHARGE TIME

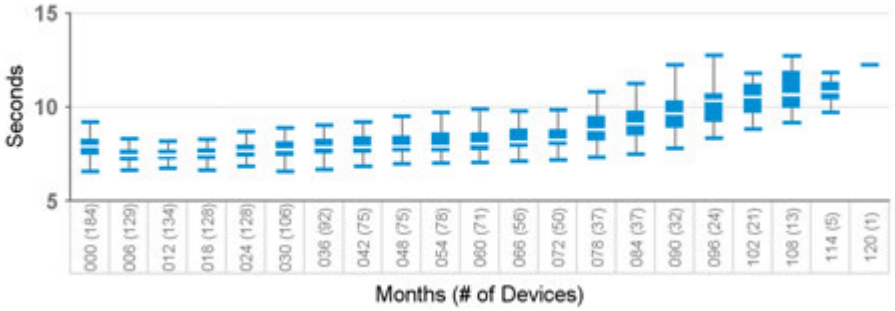
7230

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



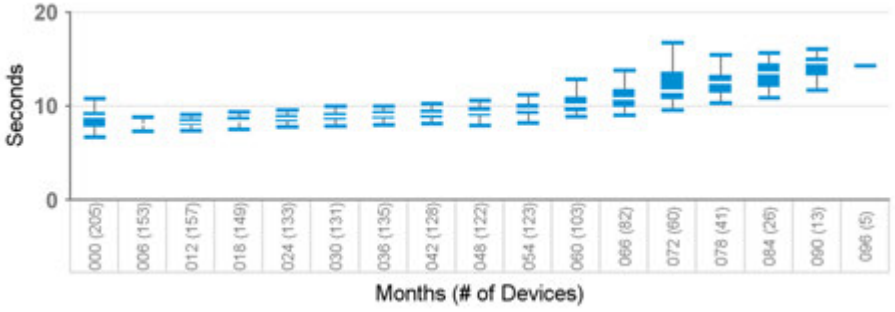
7232

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



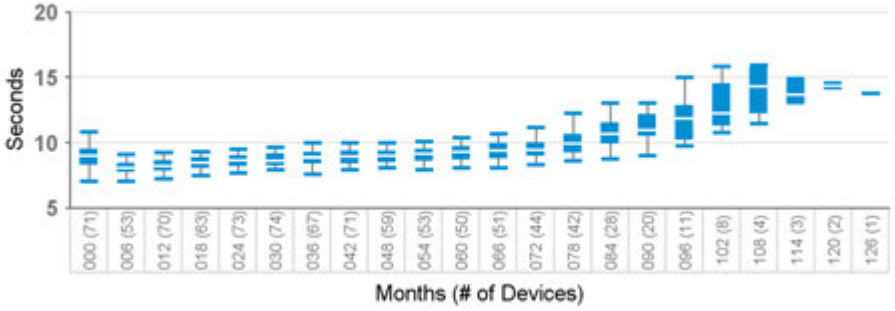
D144DRG, D154ATG, D154DRG

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT



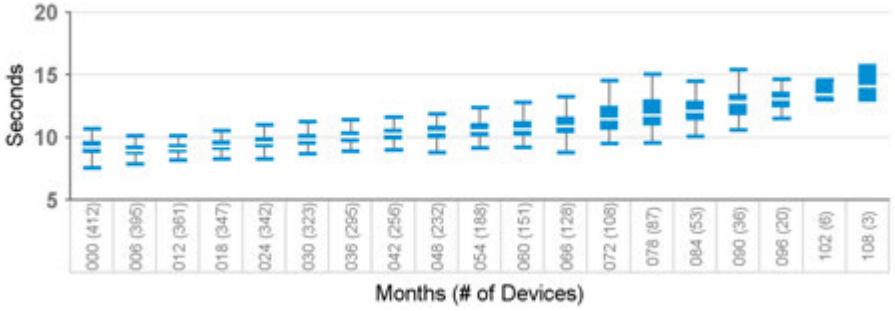
D144VRC, D154VRC

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



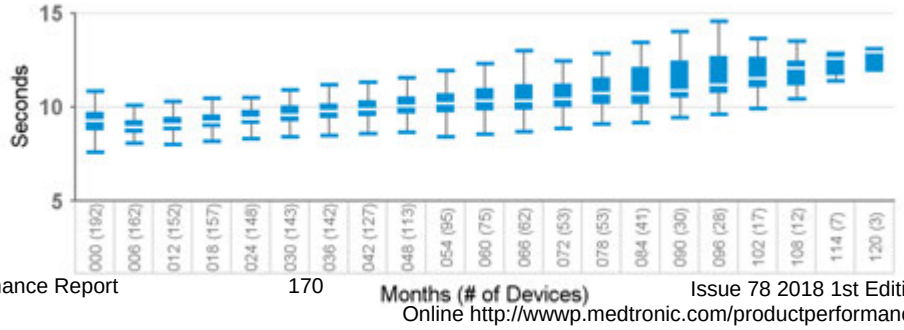
D154AWG, D164AWG

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



D154VWC, D164VWC

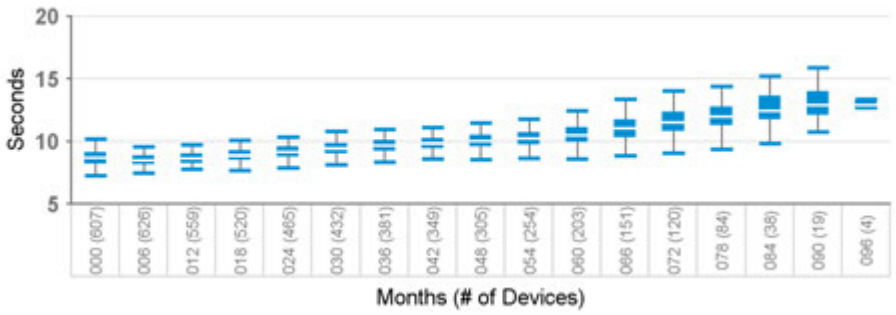
Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



ICD AND CRT-D CHARGE TIME

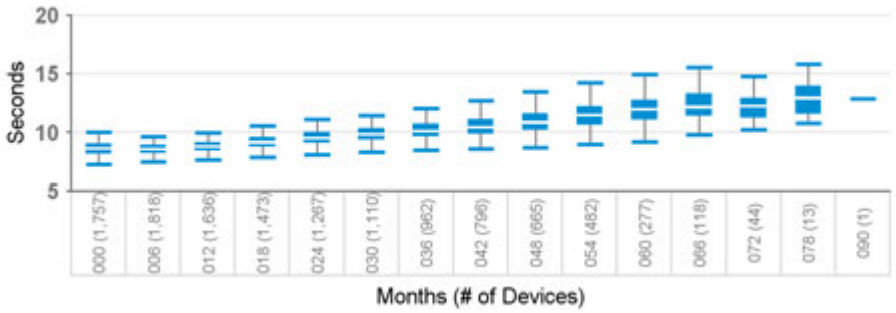
D204DRM, D214DRM, D224DRG, D234DRG

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



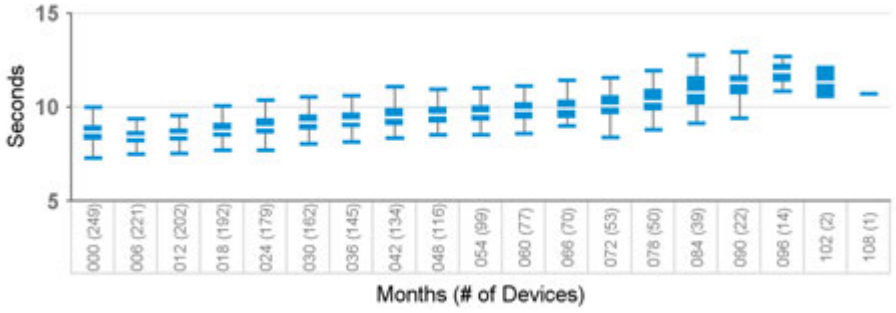
D204TRM, D214TRM, D224TRK, D234TRK

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



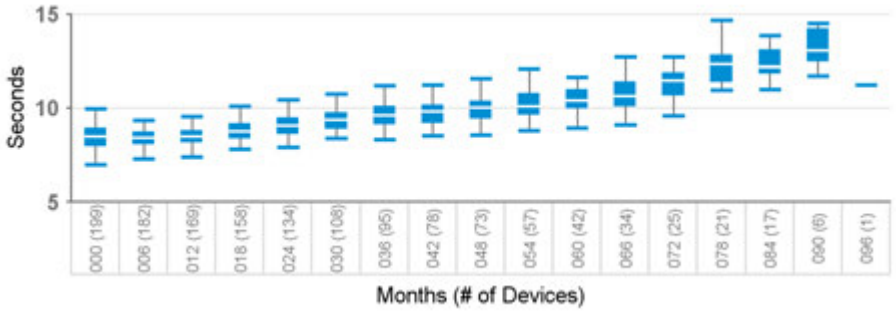
D204VRM, D214VRM, D224VRC, D234VRC

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



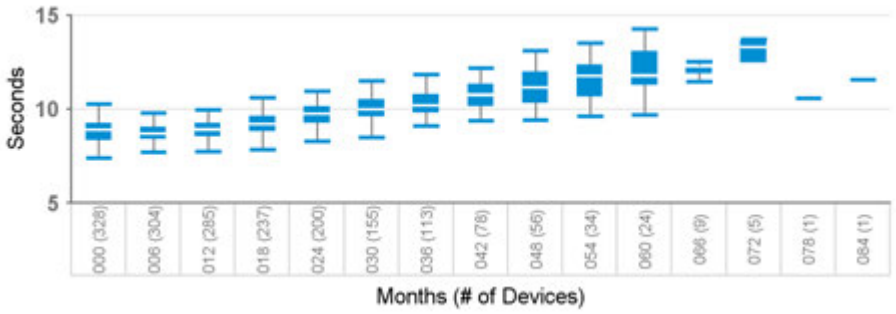
D264DRG, D284DRG, D384DRx, D394DRx

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



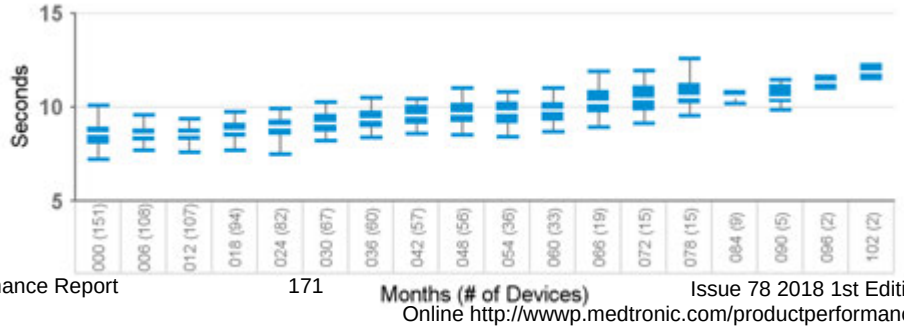
D264TRM, D284TRK, D384TRx, D394TRx

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

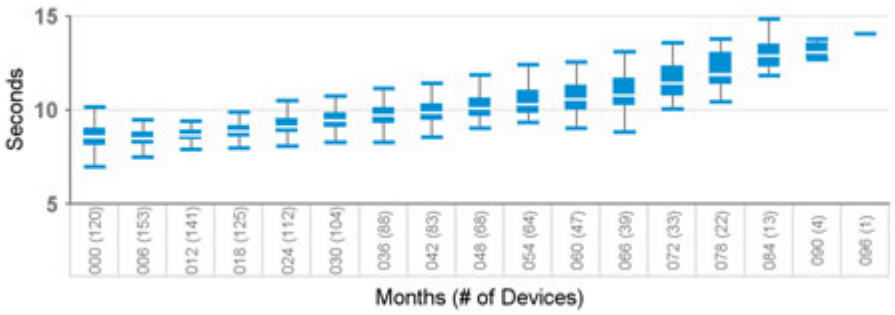
Model Number	Brand
D264VRM	Maximo II VR
D284VRC	Maximo II VR
D384VRG	Cardia VR
D394VRG	Egida VR



ICD AND CRT-D CHARGE TIME

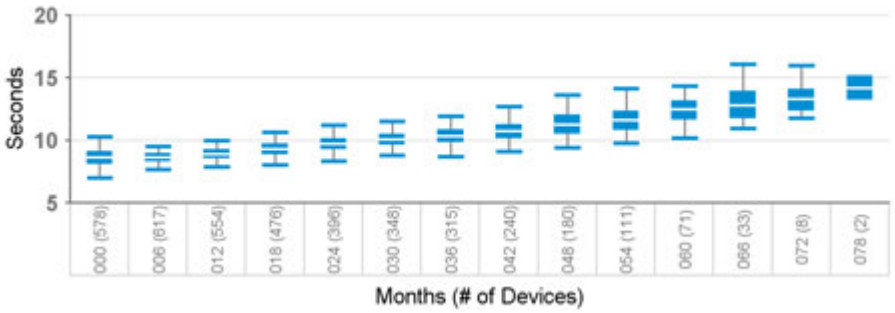
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



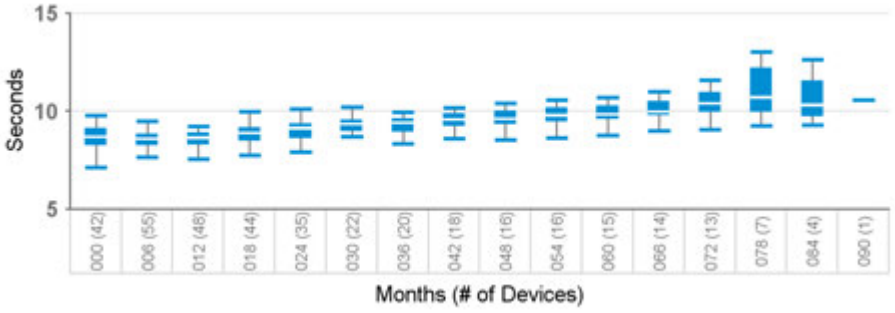
D274TRK, D294TRK

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



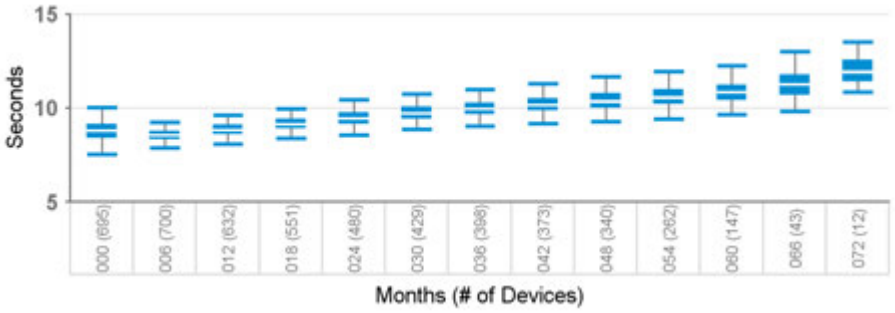
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



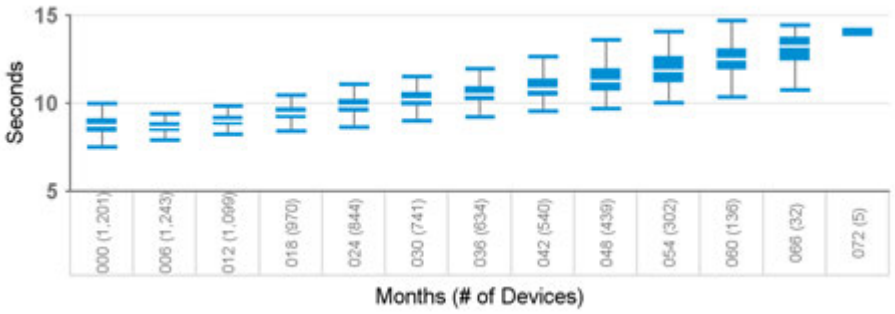
D314DRx

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



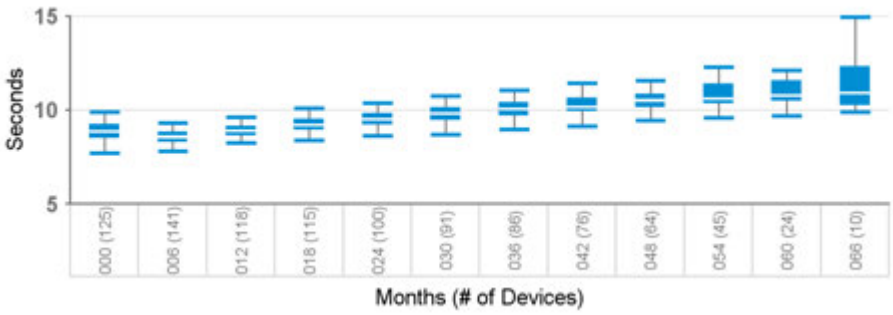
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR

ICD AND CRT-D CHARGE TIME

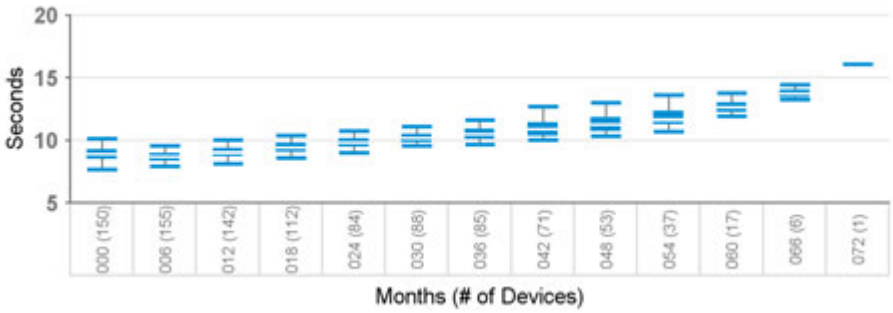
D334DRx, D364DRx

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



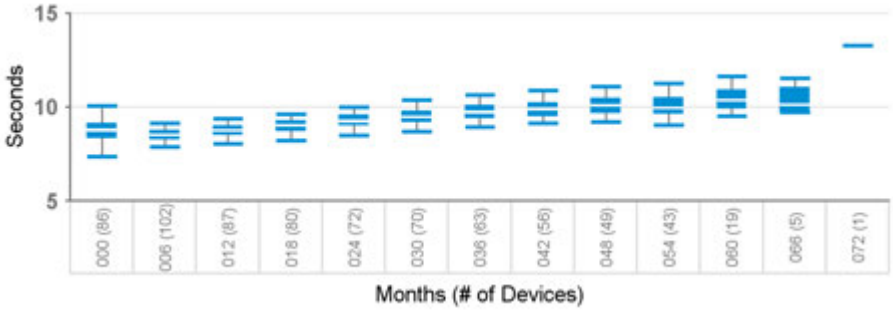
D334TRx, D364TRx

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



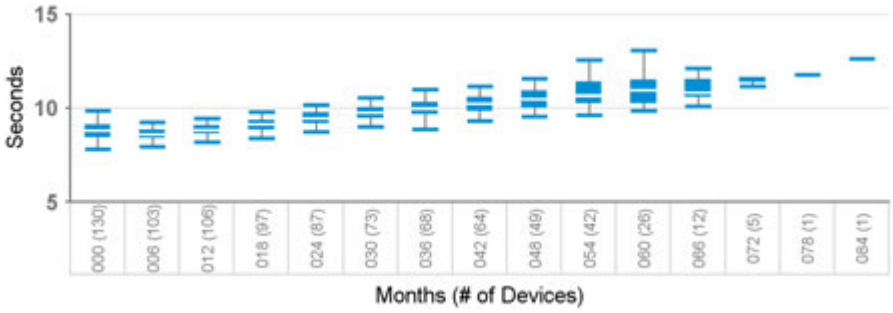
D334VRx, D364VRx

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



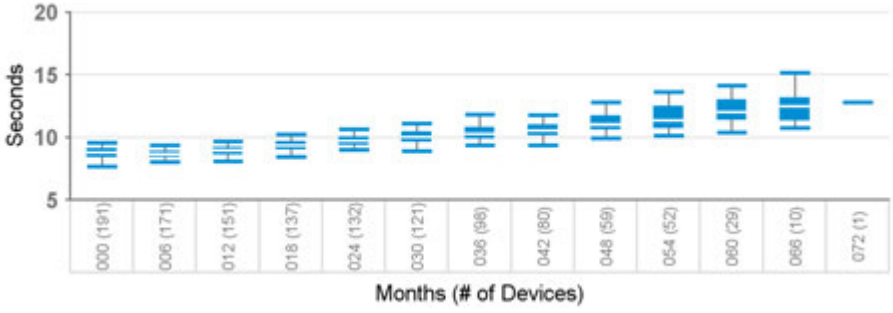
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



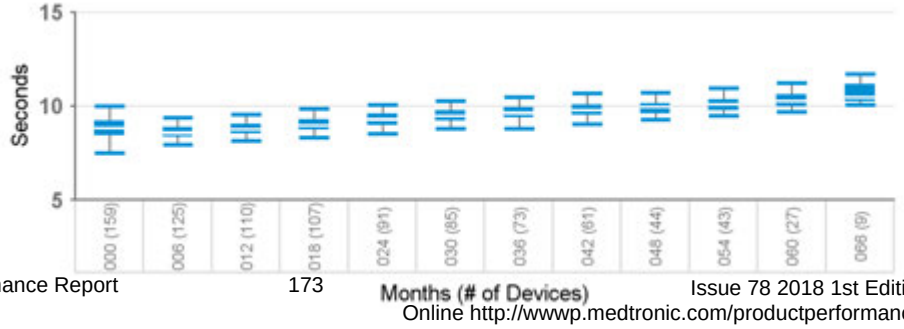
D354TRx

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



D354VRx

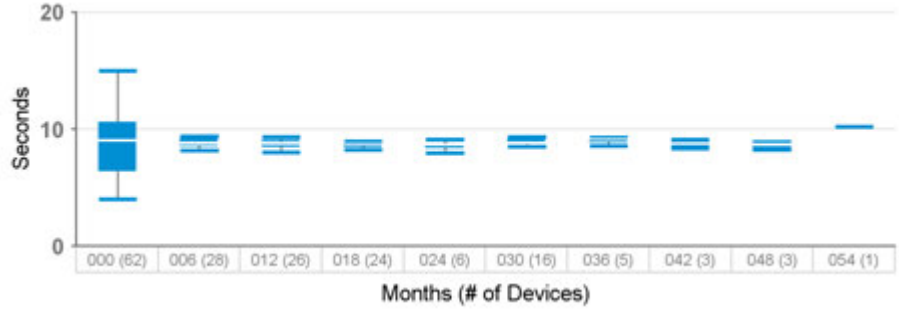
Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



ICD AND CRT-D CHARGE TIME

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



ICD AND CRT-D CHARGE TIME

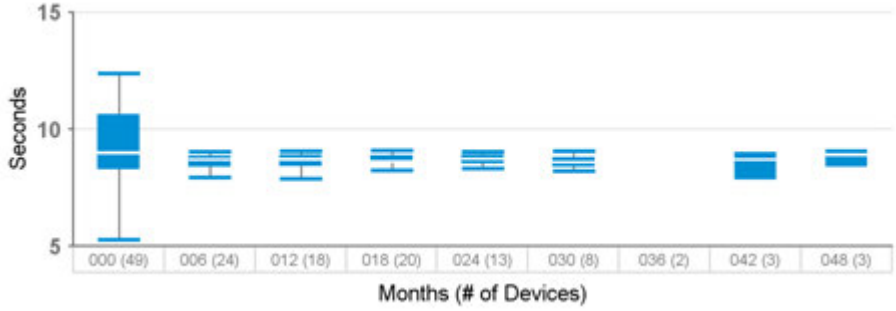
DTxxxxx, CRT-D

Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava
DTBC2D4	Brava
DTBC2Q1	Brava Quad
DTBC2QQ	Brava Quad
DTBX1QQ	Viva Quad C
DTBX2QQ	Viva Quad C
DTMA1D1	Claria MRI
DTMA1D4	Claria MRI
DTMA1Q1	Claria MRI
DTMA1QQ	Claria MRI
DTMA2D1	Claria MRI
DTMA2D4	Claria MRI
DTMA2Q1	Claria MRI
DTMA2QQ	Claria MRI
DTMB1D1	Amplia MRI
DTMB1D4	Amplia MRI
DTMB1Q1	Amplia MRI
DTMB1QQ	Amplia MRI
DTMB2D1	Amplia MRI
DTMB2D4	Amplia MRI
DTMB2Q1	Amplia MRI
DTMB2QQ	Amplia MRI
DTMC1D1	Compia MRI
DTMC1QQ	Compia MRI
DTMC2D1	Compia MRI
DTMC2D4	Compia MRI
DTMC2QQ	Compia MRI

ICD AND CRT-D CHARGE TIME

DVxxxxx, VR

Model Number	Brand
DVAB1D1	Visia AF
DVAB1D4	Visia AF
DVAB2D1	Visia AF XT
DVAC3D1	Visia AF S
DVBB1D1	Evera XT
DVBB1D4	Evera XT
DVBB2D1	Evera XT
DVBB2D4	Evera XT
DVBC3D1	Evera S
DVBC3D4	Evera S
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
DVMB2D4	Evera MRI XT
DVMC3D1	Evera MRI S
DVMC3D4	Evera MRI S



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 on home page of this web site 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 752devices, there have been zero confirmed failures (0%) through April 23, 2018. An estimated 651 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**	**651**	**0%** Worldwide

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

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

Potential Loss of Device Functionality

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

Original Date of Advisory: January 2018

Product

A subset of 48 Medtronic Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs) underwent a specific sequence of manufacturing processes that could result in an unexpected loss of device functionality, including high-voltage therapy. You may use the "Search for Information by Serial Number" tool on home page of this web site to determine if a specific device is affected. No other Medtronic devices are included in this advisory.

Advisory

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

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

Patient Management Recommendations

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

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

Status Update

Within the 48 devices, there has been 1 confirmed failure (2.1%) through April 23, 2018. An estimated 8 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**	**8**	**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 April 2018

Medtronic has now obtained the necessary regulatory approvals and is ready to begin applying a programmer software update (SW034 Software Version 8.2) to correct this software issue in the devices. In addition, as previously described in the original advisory letter, the software update also addresses a transient mode switch behavior that may occur in MRI Quadripolar CRT-D device models (Claria MRI™, Amplia MRI™ and Compia MRI™). Deployment of the software is complete in many parts of the world. Full deployment worldwide is expected by November 2018.

Once installed by a Medtronic Representative on the programmer, an in-clinic device interrogation will update the patient's device automatically. To prevent possible recurrence of the issues, the patient must continue to be programmed only with programmers that have this 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 not updated with SW034 Software Version 8.2.

Directions on how to apply this update to patient devices and to verify that devices are operating correctly can be found at http://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/claria-mri-crt-d-surescan.html. If you have any questions, or if we can be of further assistance, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

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.

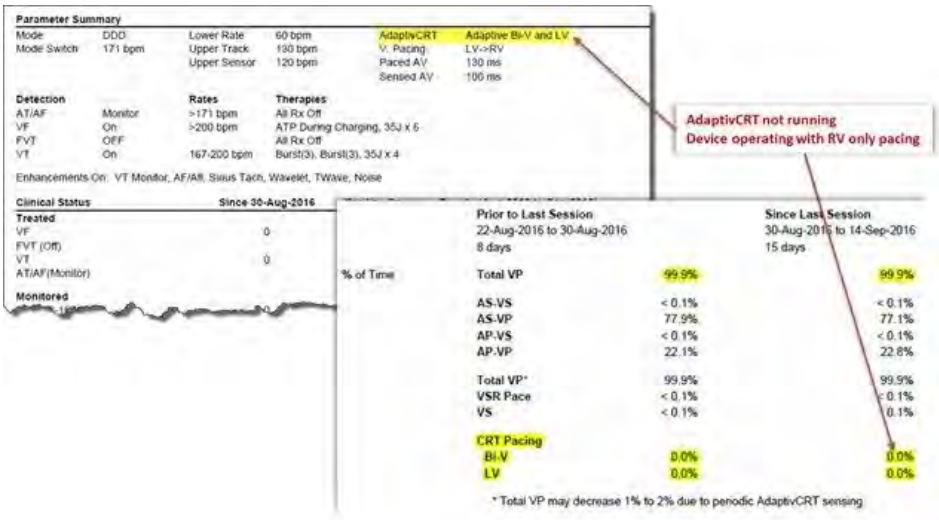
Until the software update has been approved and the affected device models receive the update, follow the programming recommendations provided below. These recommendations also apply to any new device implants.

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.

Status Update

Within the 78 devices, there have been 10 confirmed failures (13%) through April 23, 2018. Medtronic modeling predicts an additional three (3) failures may occur in the remaining active population. An estimated 32 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	**32** Worldwide	**0.13%**

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 April 23, 2018, approximately 10,300 devices remain active worldwide, from an original implant population of 96,800. In the United States, 4,200 active devices remain. Our modeling predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency. InSync III CRT-pacemakers are no longer distributed.

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)	**146** Worldwide (**70** United States)	**10,300** Worldwide (**4,200** United States)	**0.15%** Worldwide (**0.20%** 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 April 23, 2018, 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 (**75** United States)	**2,700** Worldwide (**300** 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 April 23, 2018, of the initial implant population of 205,600 in the United States, approximately 53,500 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 75.1% (+4.8/-4.5%) 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)	**6,878** Worldwide **(4,945** United States)	**72,800** Worldwide (**53,500** 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.

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

Purpose of this Information

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

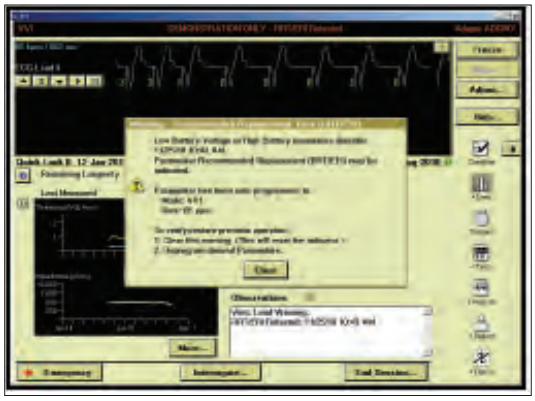
Background

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

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

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

Example 1 – Programmer Software Detects Measurement Lock-up ERI

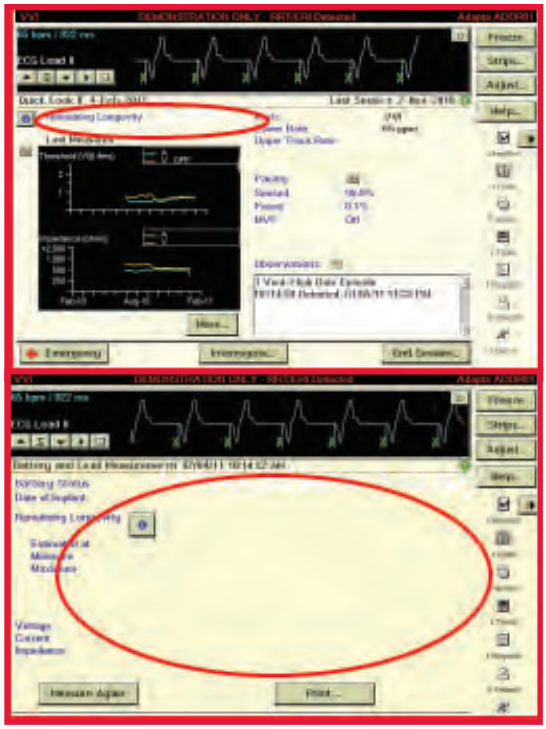


Reset Method for Kappa and EnPulse

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

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

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



Clinical Management of VCM near Elective Replacement

Background

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

Device Longevity and VCM Behavior

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

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

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

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

Table: IPG Therapy Parameter Changes at ERI

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

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

Follow-Up Considerations

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

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

General Follow-Up and Replacement of ICD Leads

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

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

Follow-Up of Chronically Implanted Leads

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

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

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

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

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

General Criteria for Lead Replacement

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

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

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

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

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

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

Clinical Management of High-Voltage Lead System Oversensing

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

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

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

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

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

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

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

Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRHF Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

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

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

Mailer kits can be obtained by contacting the Returned Product Lab.

CRHF Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

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