CARDIAC RHYTHM & HEART FAILURE

Product Performance Report

Important Patient Management Information for Physicians

2017

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Medtronic

CRHF Product Performance Report

2017

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

Our Commitment to Quality

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

The third tenet of the mission is all about quality:

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

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

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

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

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

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

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

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

Contact Information

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

US Technical Services Department

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

Fax: 1 (800) 824-2362

International Technical Centers

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

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

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

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

Editorial Staff

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Introduction

For 34 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.

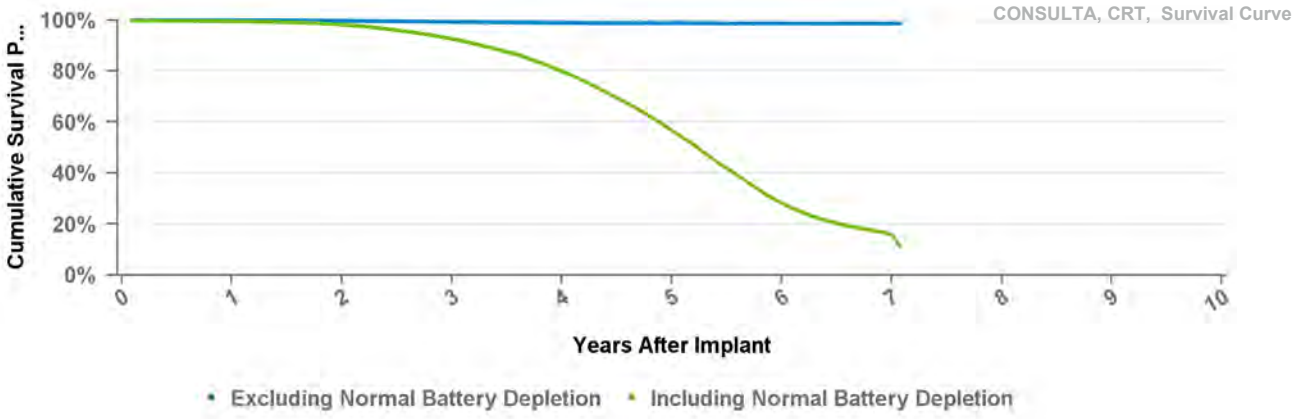
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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

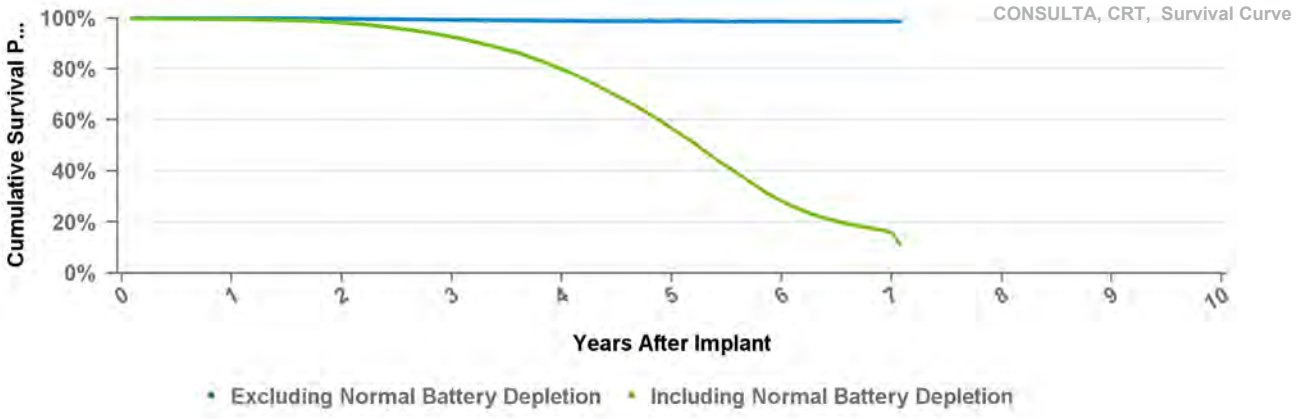
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,098	Battery Malfunction	1
Estimated Active USA Implants	1,187	Electrical Component	1
Normal Battery Depletions	326	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.5%	98.1%	92.6%	79.8%	56.6%	28.1%	15.7%	11.4%
Effective Sample Size	58004	52868	45932	35409	20008	6804	531	116

D214TRM Consulta CRT-D

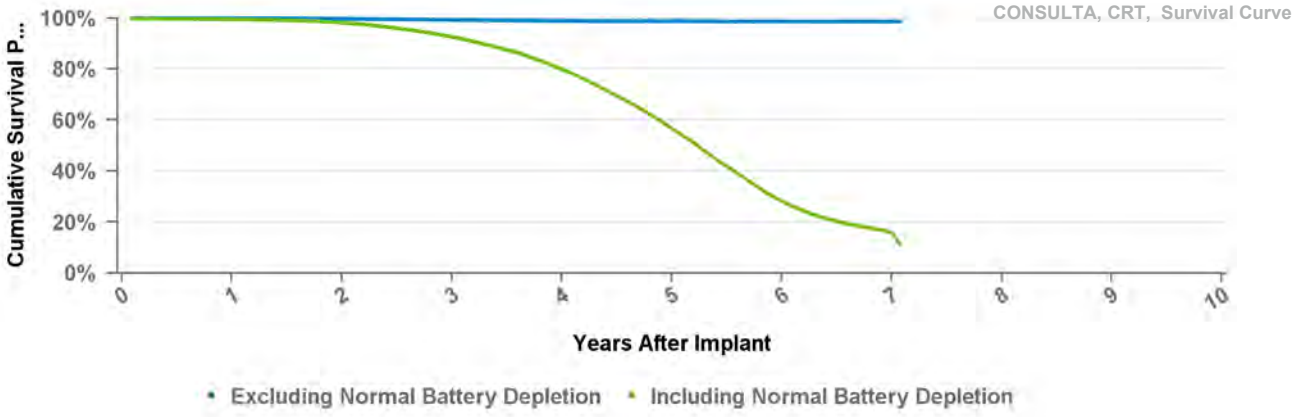
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.5%	98.1%	92.6%	79.8%	56.6%	28.1%	15.7%	11.4%
Effective Sample Size	58004	52868	45932	35409	20008	6804	531	116

D224TRK Consulta CRT-D

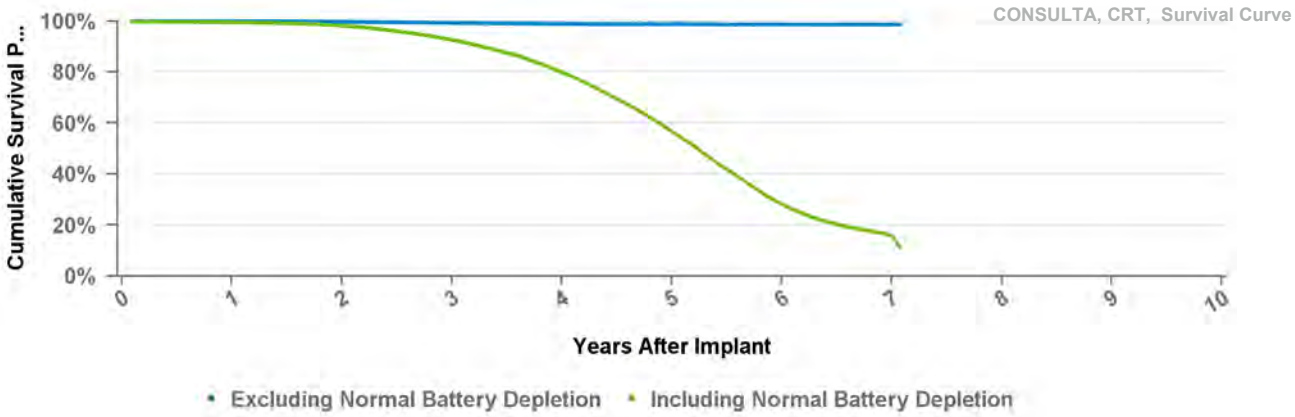
US Market Release	Sep-08	**Total Malfunctions**	**599**
CE Approval Date		**Therapy Function Not Compromised**	**572**
Registered USA Implants	65,979	Battery Malfunction	2
Estimated Active USA Implants	13,881	Electrical Component	66
Normal Battery Depletions	18,544	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	496
		Software Malfunction	6
		Therapy Function Compromised	**27**
		Battery Malfunction	2
		Electrical Component	25



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.5%	98.1%	92.6%	79.8%	56.6%	28.1%	15.7%	11.4%
Effective Sample Size	58004	52868	45932	35409	20008	6804	531	116

D234TRK Consulta CRT-D

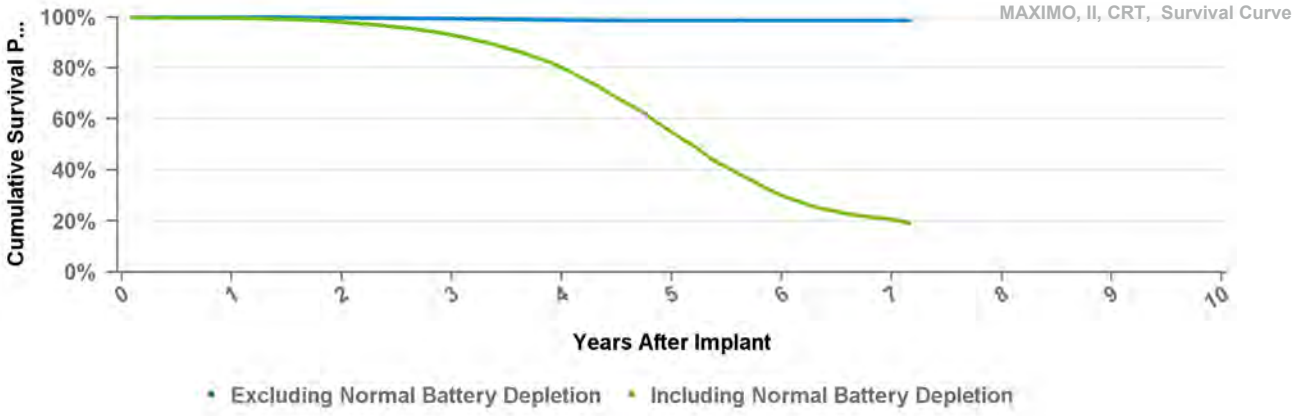
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	99.7%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%
Including NBD	99.5%	98.1%	92.6%	79.8%	56.6%	28.1%	15.7%	11.4%
Effective Sample Size	58004	52868	45932	35409	20008	6804	531	116

D264TRM Maximo II CRT-D

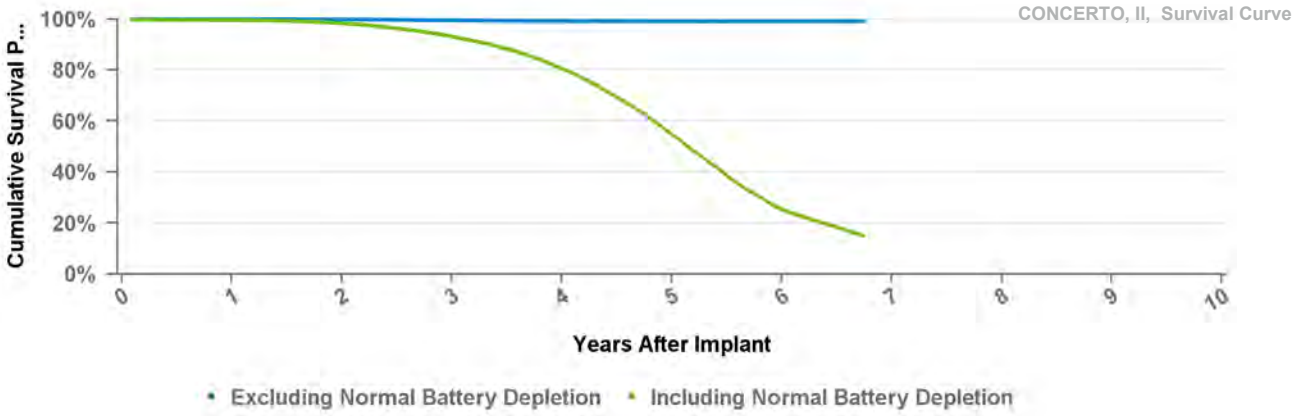
US Market Release	Jan-12	**Total Malfunctions**	**1**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other Malfunction	1
Estimated Active USA Implants	4	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.6%	98.0%	92.9%	80.1%	54.8%	29.9%	20.5%	18.9%
Effective Sample Size	12930	11681	10180	7786	4127	1385	270	139

D274TRK Concerto II CRT-D

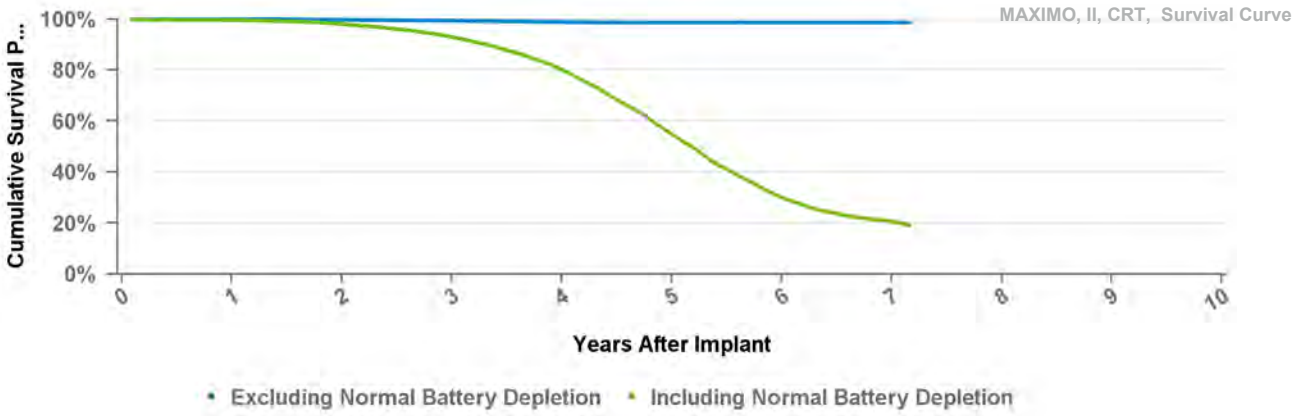
US Market Release	Aug-09	**Total Malfunctions**	**184**
CE Approval Date		**Therapy Function Not Compromised**	**174**
Registered USA Implants	30,173	Battery Malfunction	1
Estimated Active USA Implants	6,500	Electrical Component	21
Normal Battery Depletions	8,462	Poss Early Battery Depltn	151
		Software Malfunction	1
		Therapy Function Compromised	**10**
		Battery Malfunction	1
		Electrical Component	9



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%
Including NBD	99.6%	98.3%	93.2%	80.5%	54.7%	25.3%	14.9%
Effective Sample Size	25420	23240	20261	15510	8444	2827	184

D284TRK Maximo II CRT-D

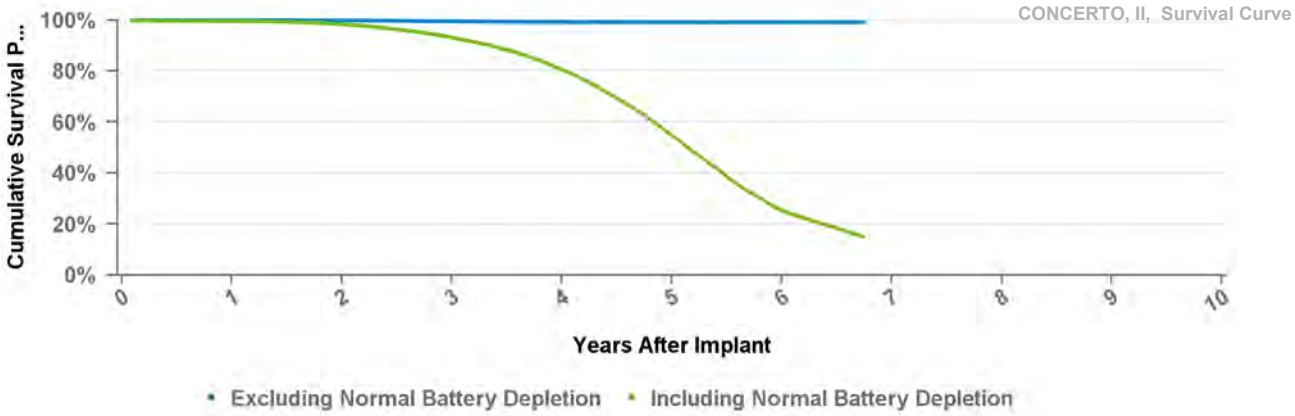
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,248	Electrical Component	6
Estimated Active USA Implants	3,540	Poss Early Battery Depltn	124
Normal Battery Depletions	3,993	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	99.7%	99.4%	98.8%	98.7%	98.7%	98.7%	98.7%
Including NBD	99.6%	98.0%	92.9%	80.1%	54.8%	29.9%	20.5%	18.9%
Effective Sample Size	12930	11681	10180	7786	4127	1385	270	139

D294TRK Concerto II CRT-D

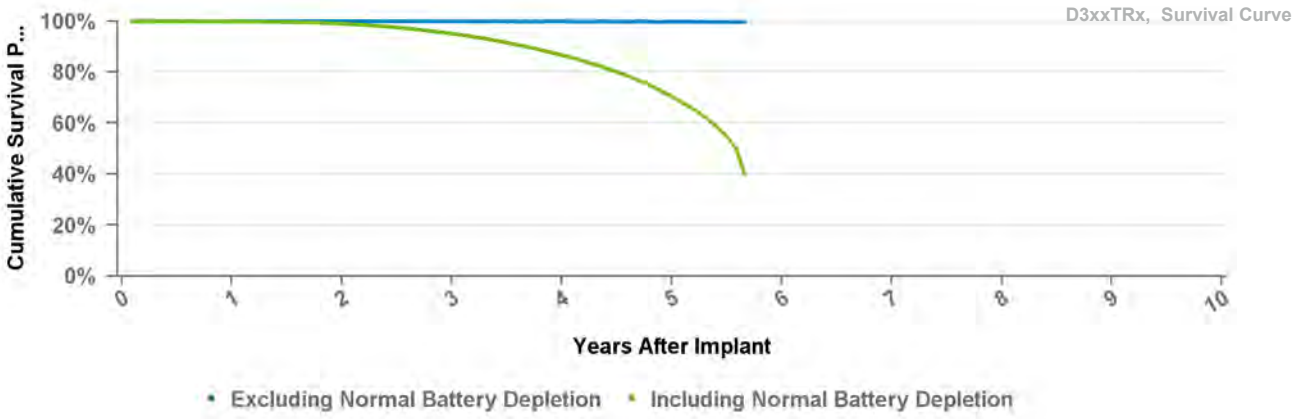
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	99.8%	99.5%	99.2%	99.1%	99.1%	99.1%
Including NBD	99.6%	98.3%	93.2%	80.5%	54.7%	25.3%	14.9%
Effective Sample Size	25420	23240	20261	15510	8444	2827	184

D314TRG Protecta XT CRT-D

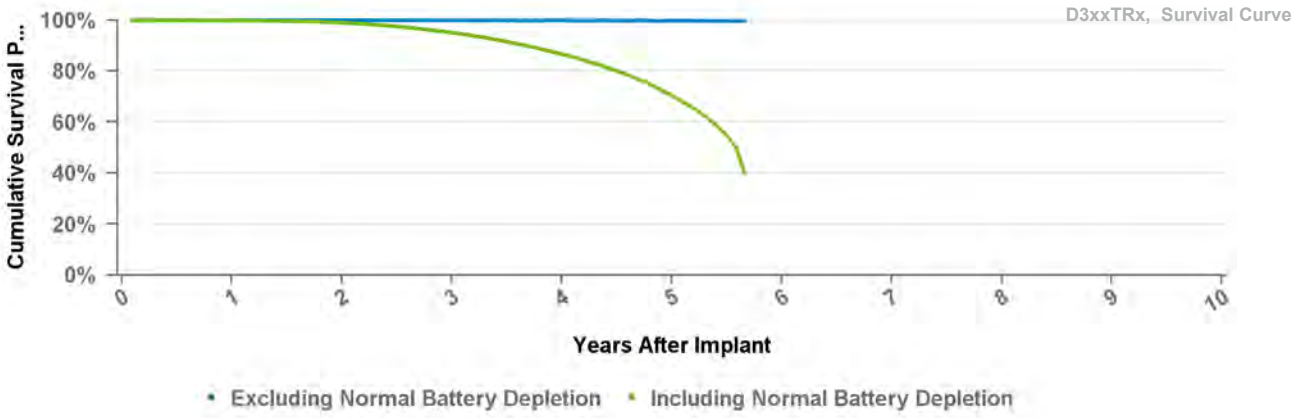
US Market Release	Mar-11	**Total Malfunctions**	**86**
CE Approval Date		**Therapy Function Not Compromised**	**72**
Registered USA Implants	42,464	Battery Malfunction	6
Estimated Active USA Implants	19,485	Electrical Component	39
Normal Battery Depletions	6,004	Other Malfunction	2
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**14**
		Battery Malfunction	6
		Electrical Component	8



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D314TRM Protecta XT CRT-D

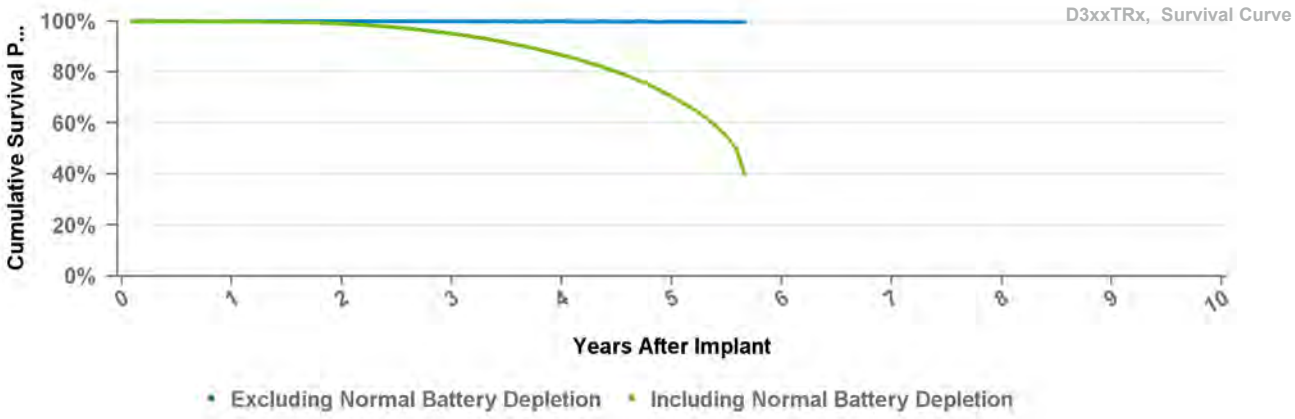
US Market Release	Nov-11	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,257	Battery Malfunction	3
Estimated Active USA Implants	7,380	Electrical Component	9
Normal Battery Depletions	1,097	Poss Early Battery Depltn	5
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D334TRG Protecta CRT-D

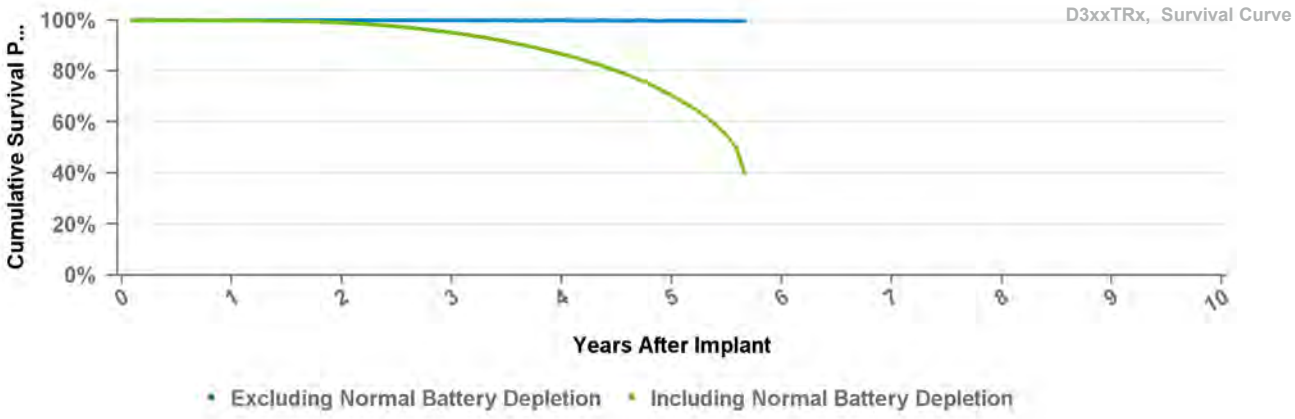
US Market Release	Mar-11	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,100	Electrical Component	8
Estimated Active USA Implants	3,993	Poss Early Battery Depltn	3
Normal Battery Depletions	1,168	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D334TRM Protecta CRT-D

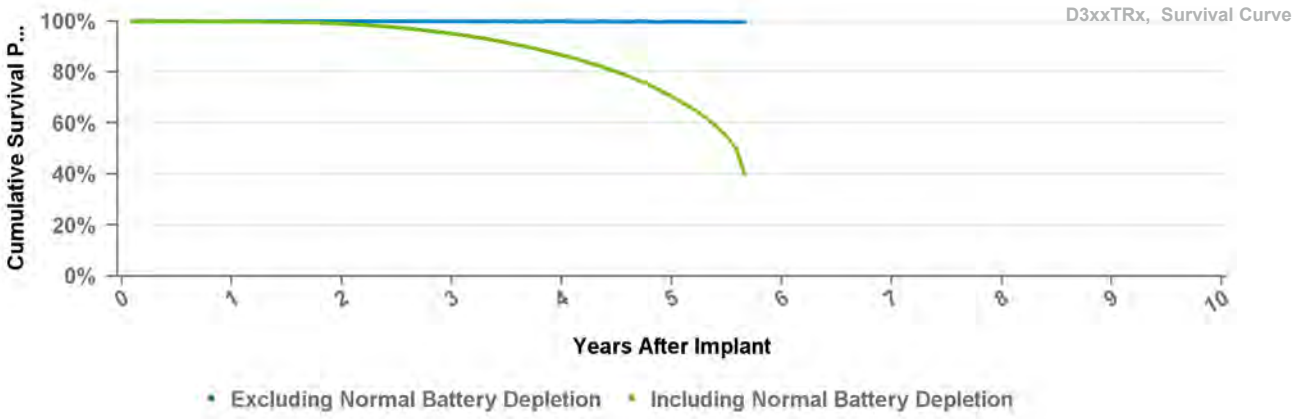
US Market Release	Nov-11	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	1,783	Battery Malfunction	3
Estimated Active USA Implants	1,033	Electrical Component	1
Normal Battery Depletions	189	Poss Early Battery Depltn	1
		Therapy Function Compromised	**1**
		Battery Malfunction	1



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D354TRG Protecta XT CRT-D

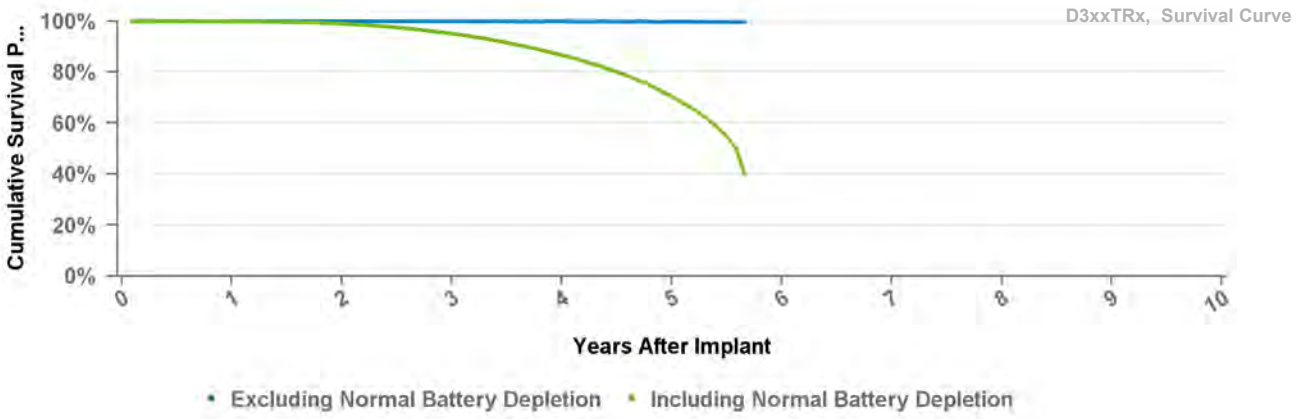
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D354TRM Protecta XT CRT-D

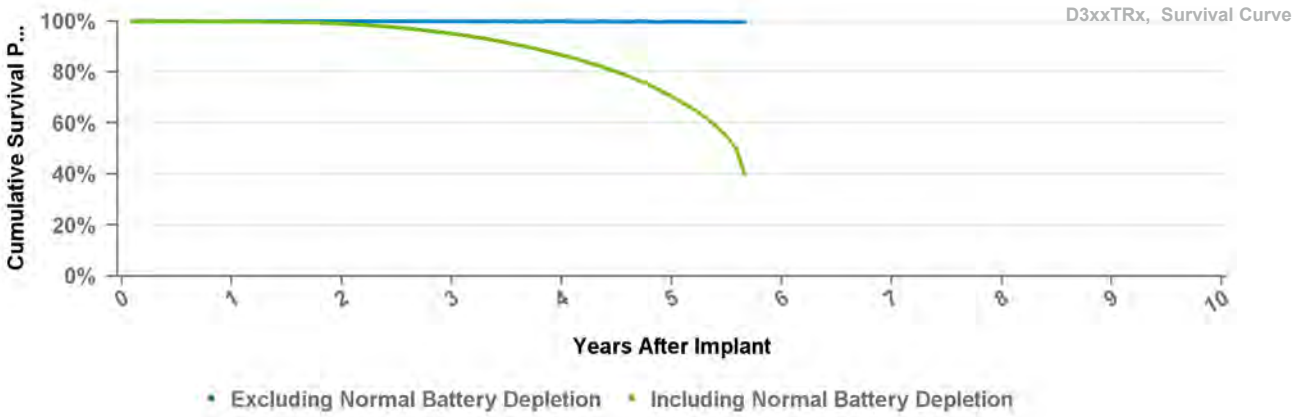
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D364TRG Protecta CRT-D

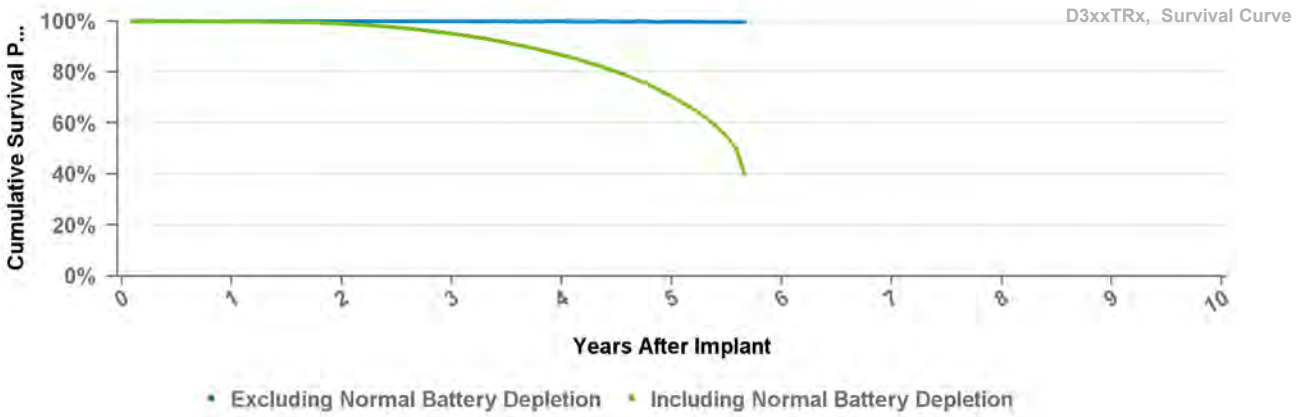
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D364TRM Protecta CRT-D

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

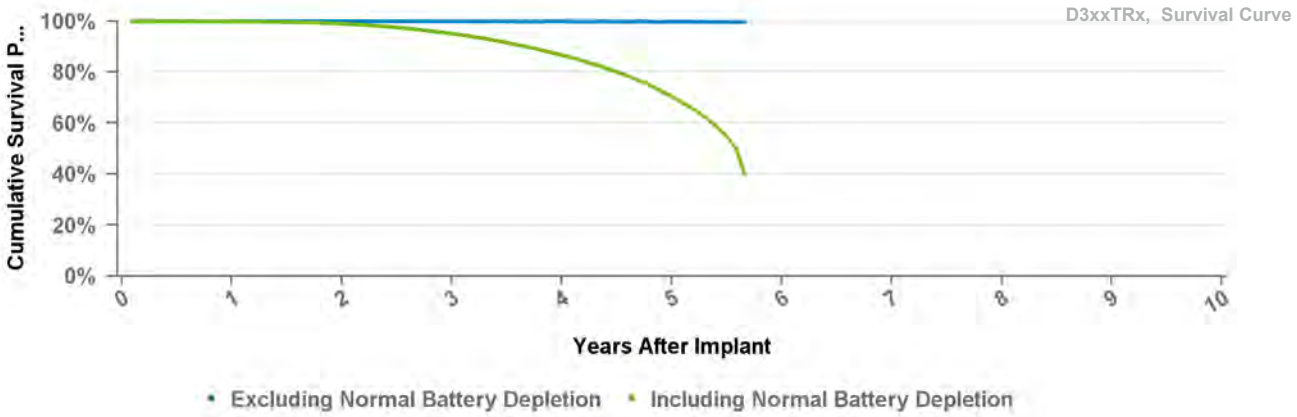


Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D384TRG Cardia CRT-D

US Market Release
CE Approval Date Jan-11
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

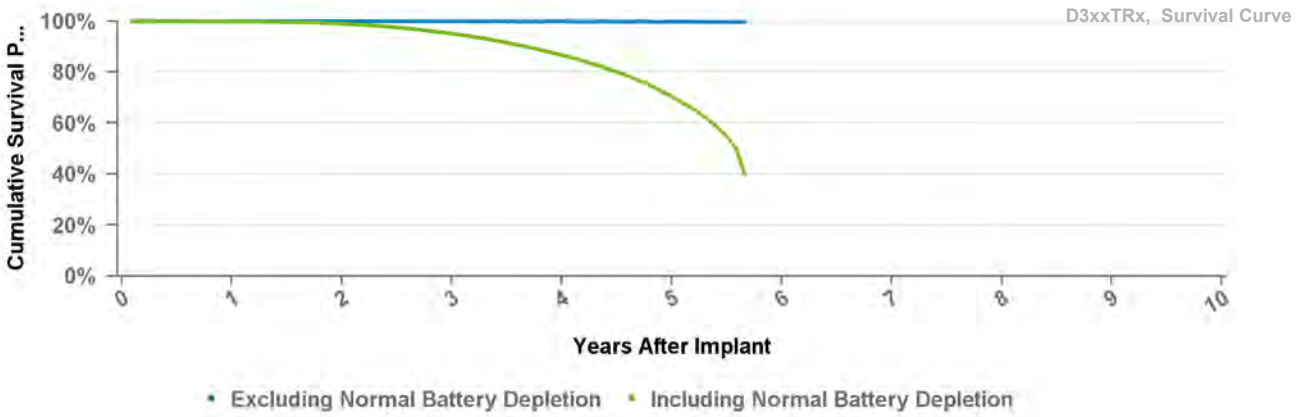


Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

D394TRG Egida CRT-D

US Market Release
CE Approval Date Jan-11
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

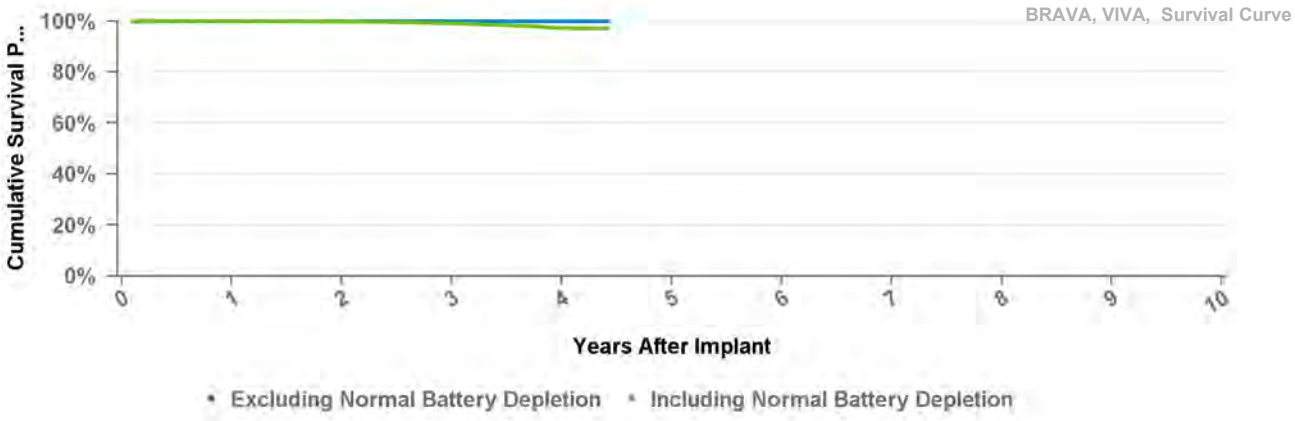
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	98.9%	95.0%	86.6%	70.3%	39.6%
Effective Sample Size	56144	51700	45521	35617	13057	748

DTBA1D1 Viva XT

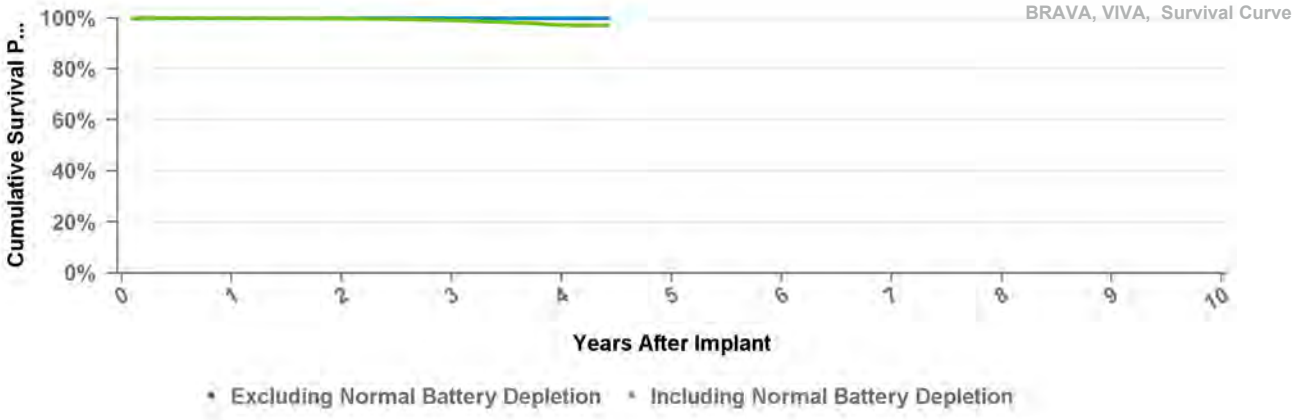
US Market Release	Jan-13	**Total Malfunctions**	**29**
CE Approval Date		**Therapy Function Not Compromised**	**26**
Registered USA Implants	53,475	Battery Malfunction	1
Estimated Active USA Implants	47,147	Electrical Component	25
Normal Battery Depletions	254	**Therapy Function Compromised**	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBA1D4 Viva XT

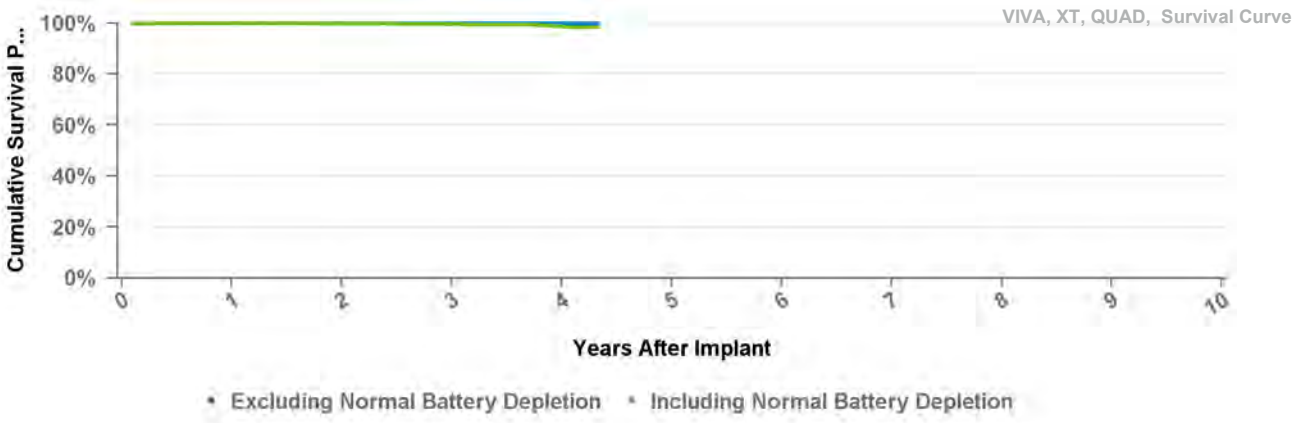
US Market Release	Jan-13	**Total Malfunctions**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	18,546	Battery Malfunction	1
Estimated Active USA Implants	16,483	Electrical Component	9
Normal Battery Depletions	68	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBA1Q1 Viva Quad XT

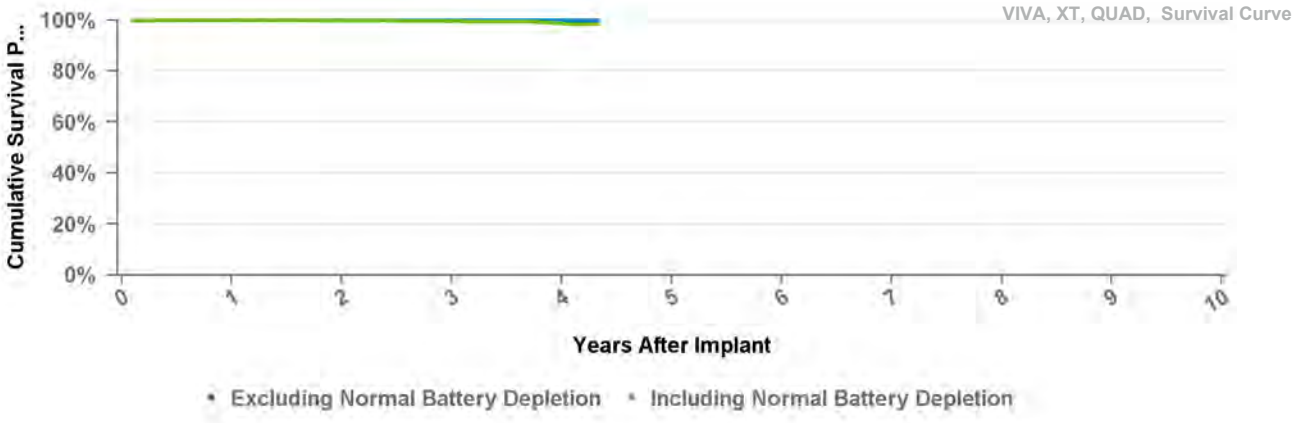
US Market Release	Jul-14	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	10,123	Electrical Component	2
Estimated Active USA Implants	9,235	Other Malfunction	1
Normal Battery Depletions	14	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTBA1QQ Viva Quad XT

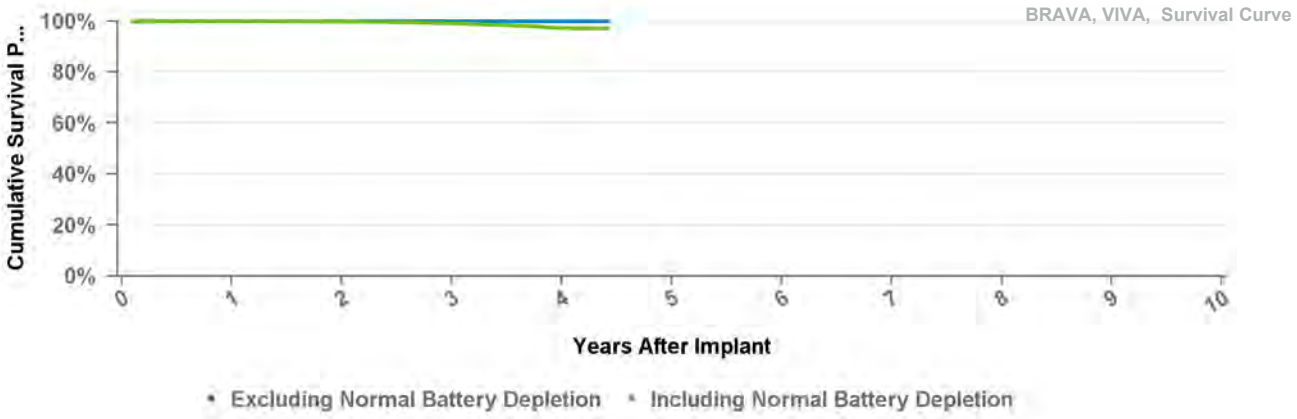
US Market Release	Jul-14	**Total Malfunctions**	**13**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	25,685	Electrical Component	11
Estimated Active USA Implants	24,238	Electrical Interconnect	1
Normal Battery Depletions	24	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTBA2D1 Viva XT

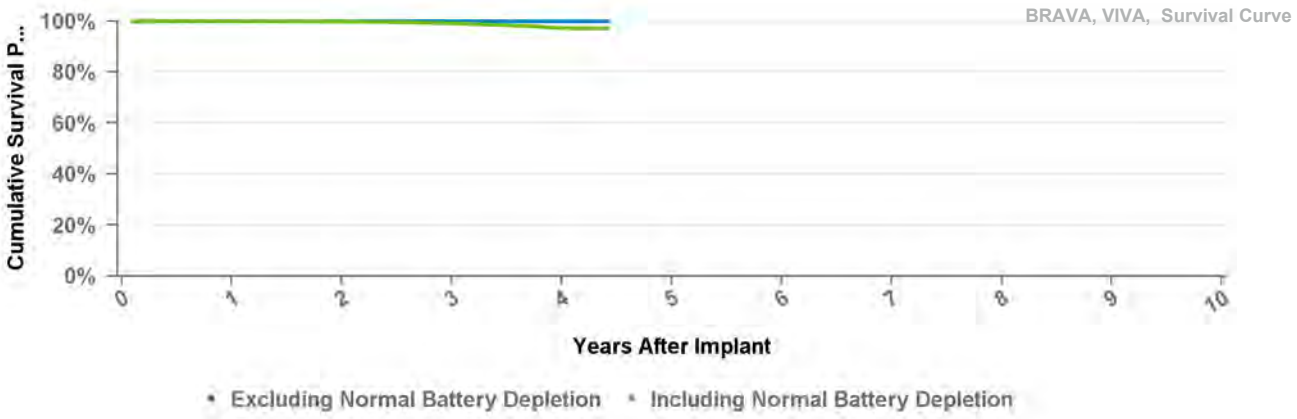
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBA2D4 Viva XT

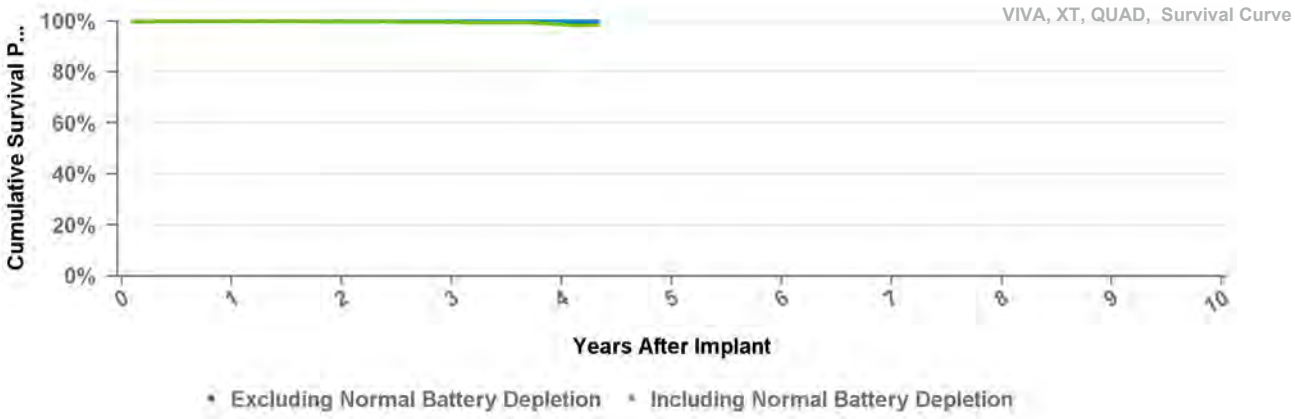
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBA2Q1 Viva Quad XT

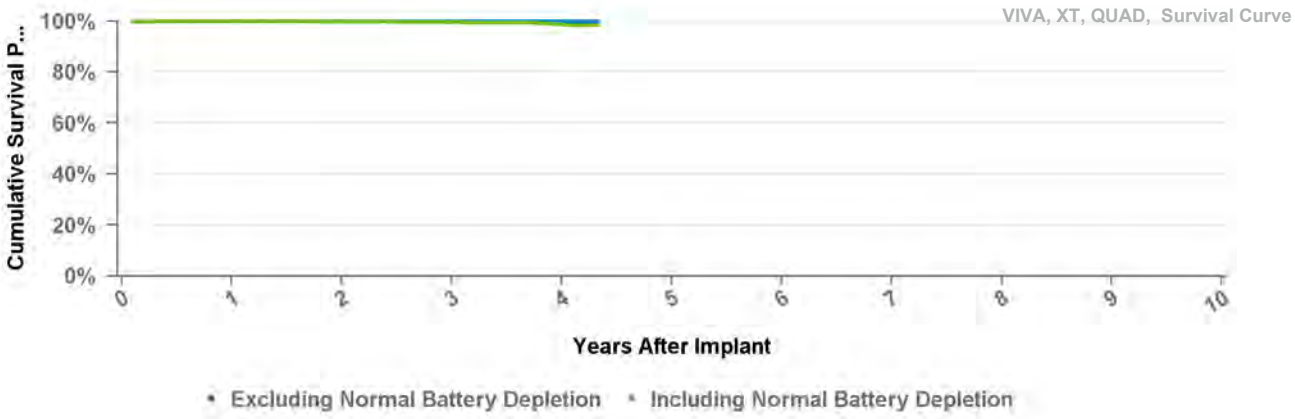
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTBA2QQ Viva Quad XT

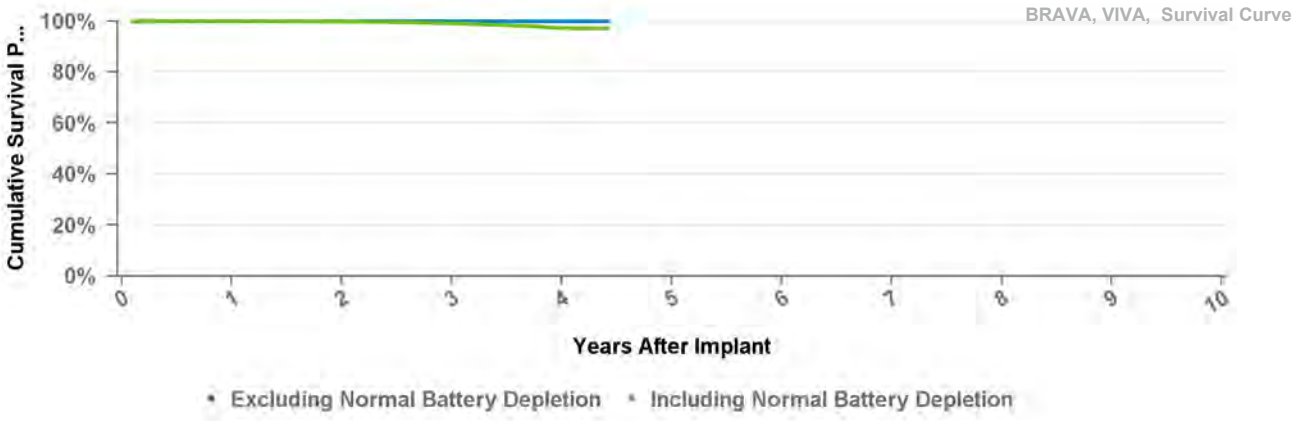
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTBB1D1 Viva S

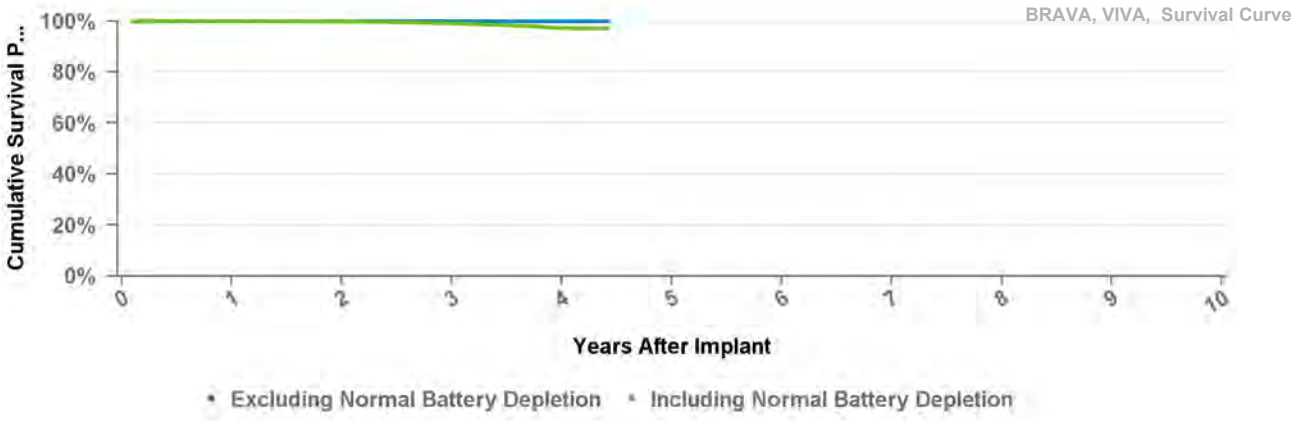
US Market Release	Jan-13	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	13,191	Battery Malfunction	1
Estimated Active USA Implants	11,319	Electrical Component	3
Normal Battery Depletions	87	Poss Early Battery Depltn	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB1D4 Viva S

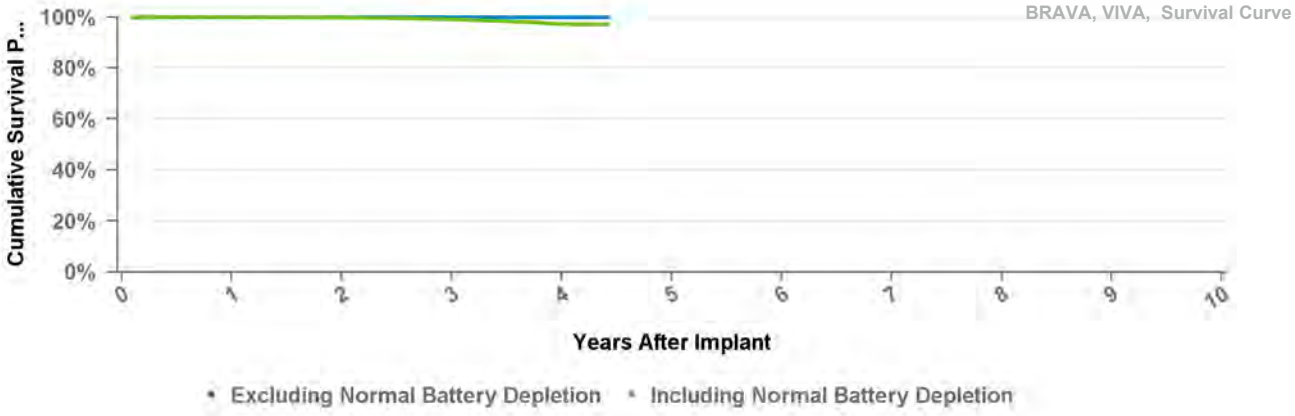
US Market Release	Jan-13	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,119	Other Malfunction	1
Estimated Active USA Implants	3,641	**Therapy Function Compromised**	**1**
Normal Battery Depletions	37	Battery Malfunction	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB1Q1 Viva Quad S

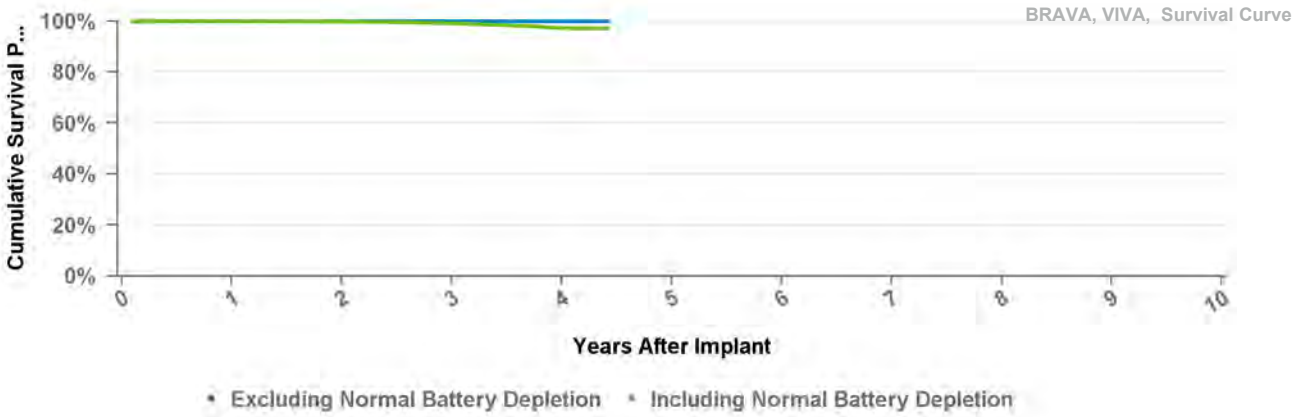
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,012	Electrical Component	1
Estimated Active USA Implants	1,839	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB1QQ Viva Quad S

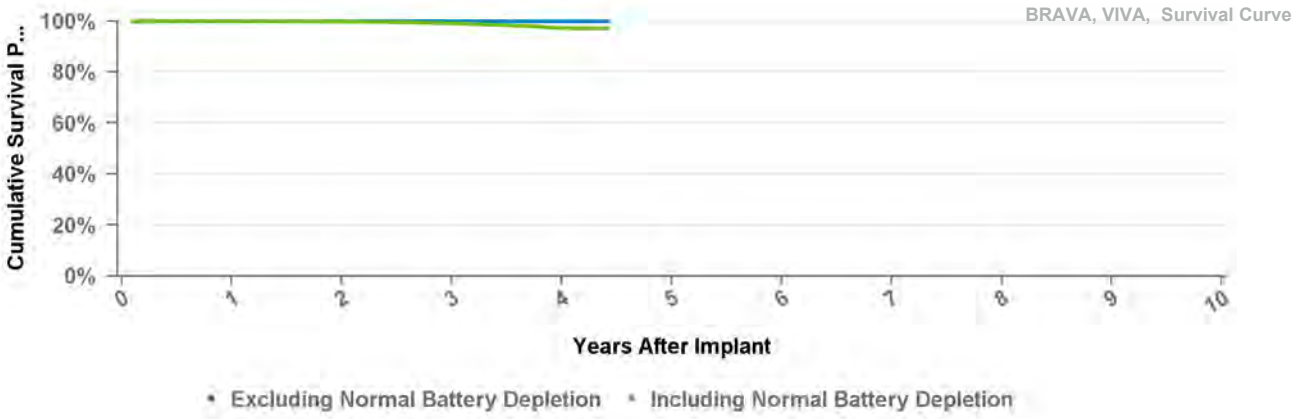
US Market Release	Jul-14	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,642	Electrical Component	2
Estimated Active USA Implants	4,368	Poss Early Battery Depltn	1
Normal Battery Depletions	2	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB2D1 Viva S

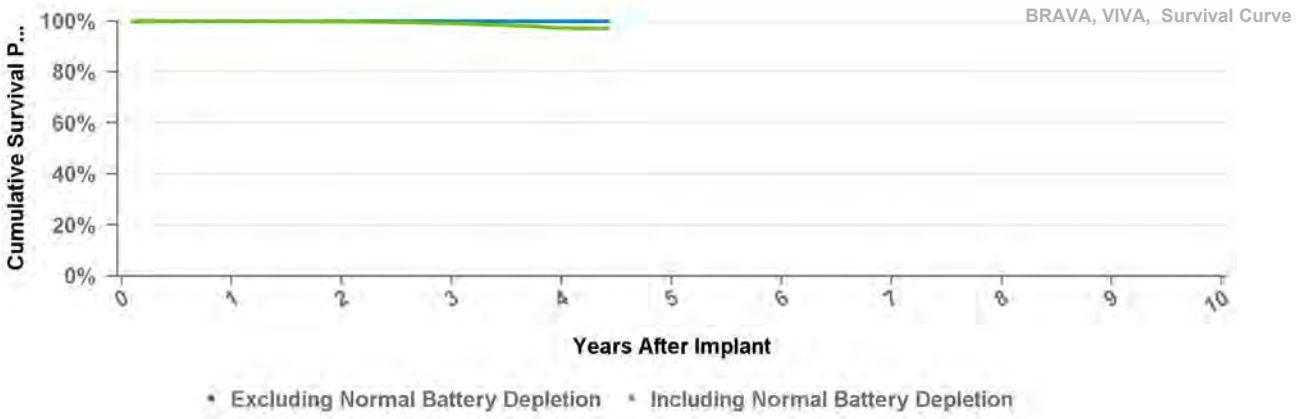
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB2D4 Viva S

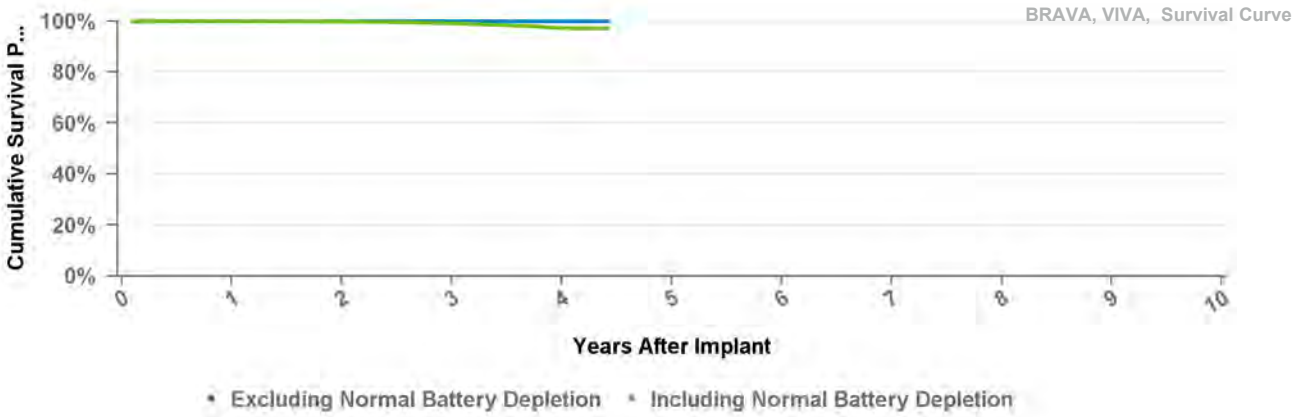
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBB2QQ Viva Quad S

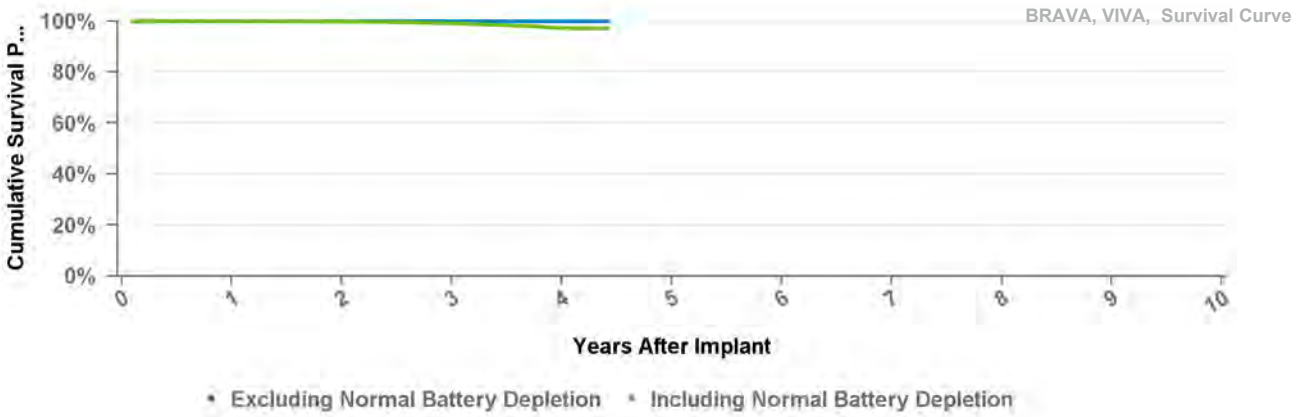
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBC2D1 Brava

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

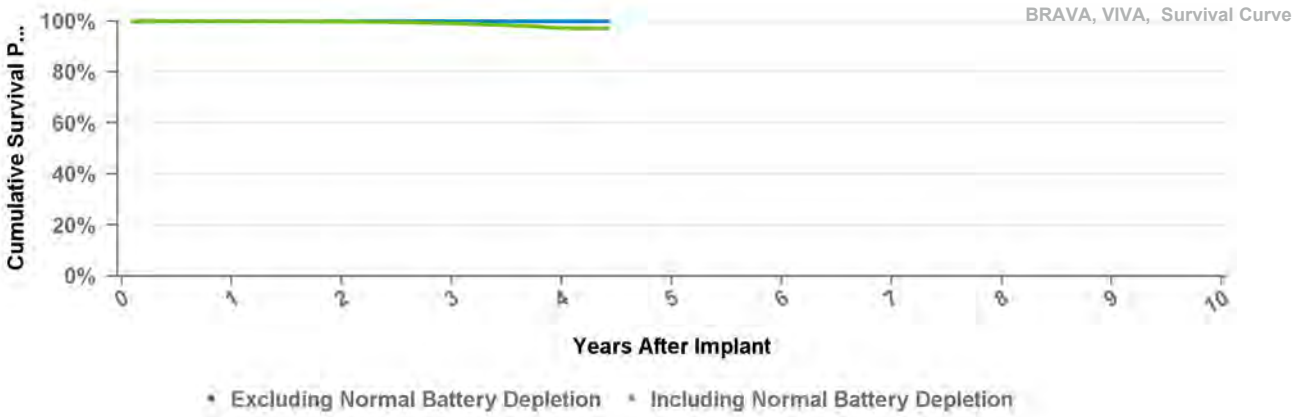


Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBC2D4 Brava

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

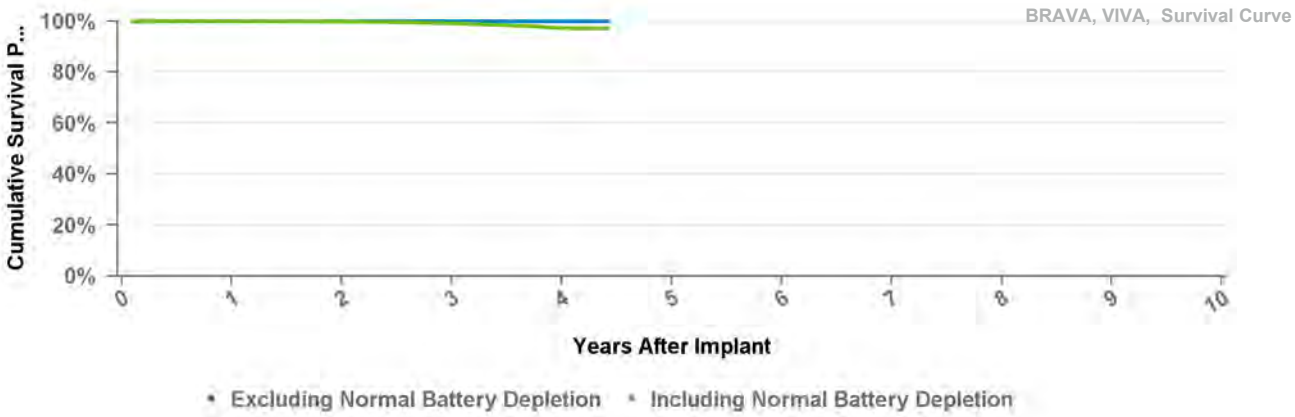


Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBC2Q1 Brava Quad

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

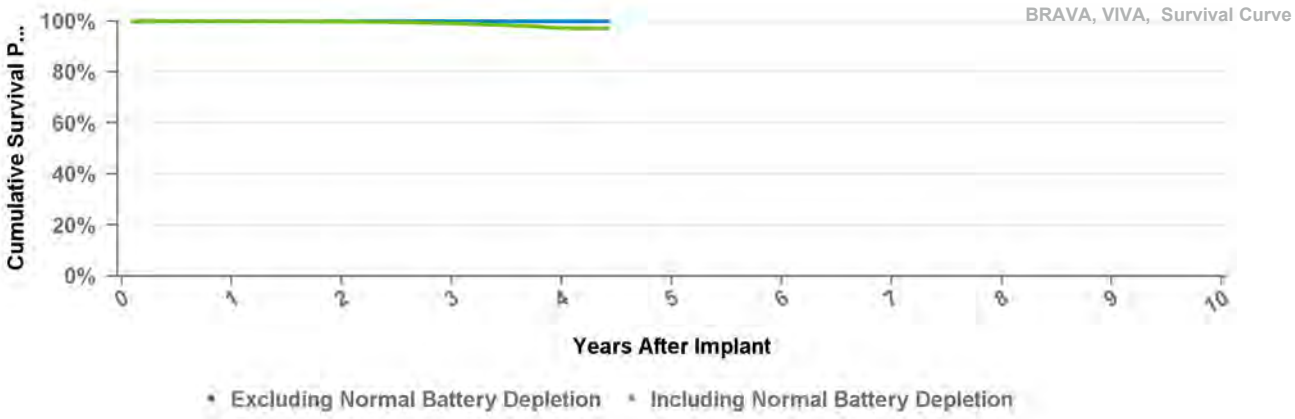
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBC2QQ Brava Quad

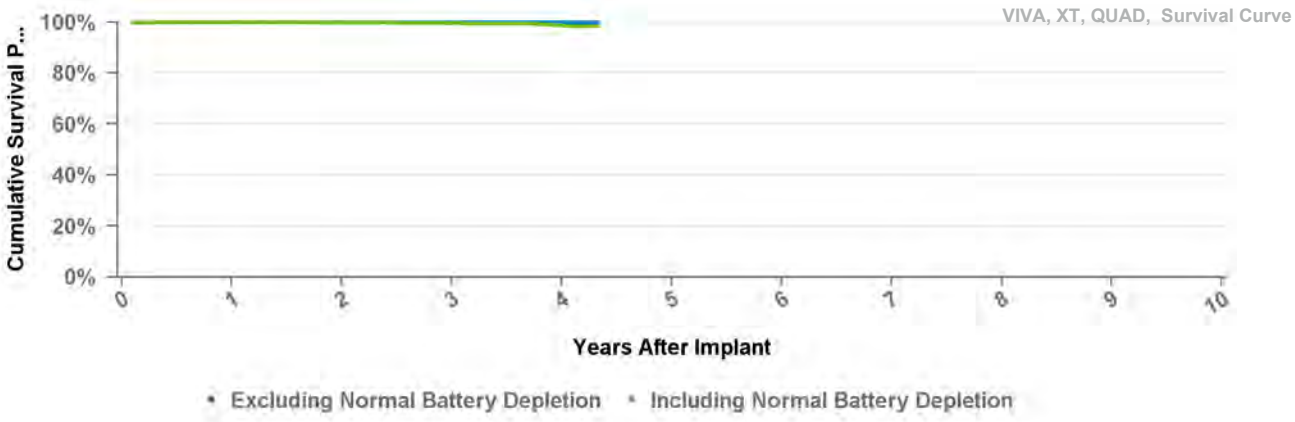
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.1%	97.3%	97.0%
Effective Sample Size	79642	56824	33071	6896	109

DTBX1QQ Viva Quad C

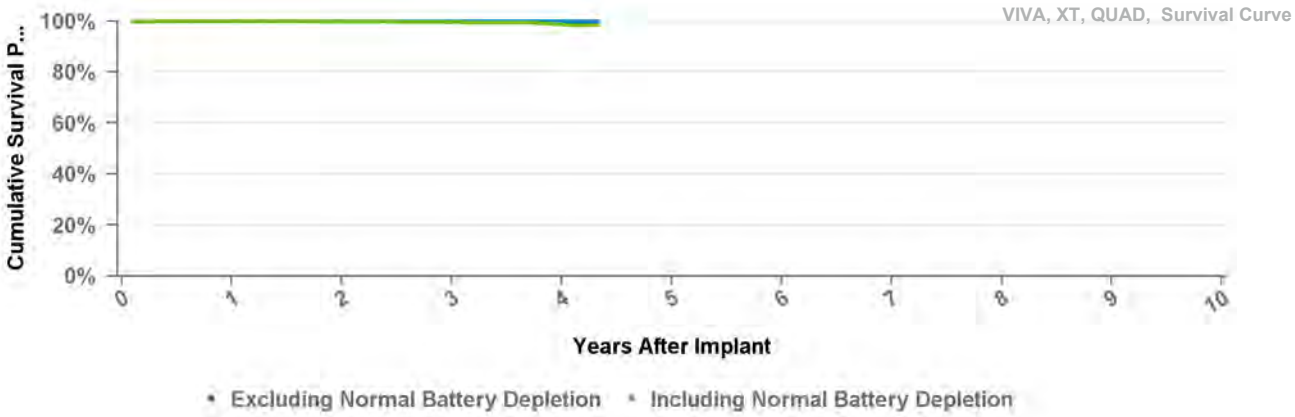
US Market Release	Jul-14	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	637	Electrical Component	1
Estimated Active USA Implants	553	**Therapy Function Compromised**	**0**
Normal Battery Depletions	6		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTBX2QQ Viva Quad C

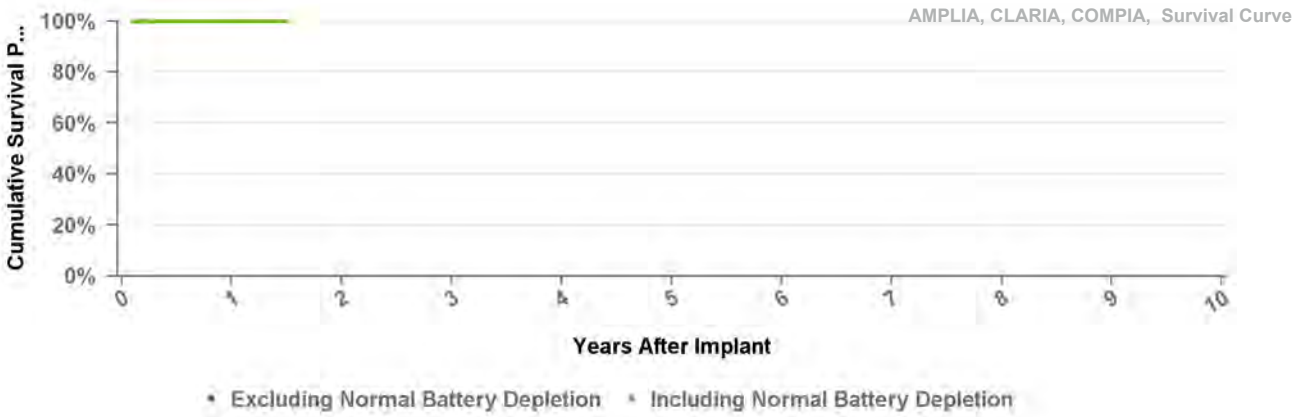
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.6%	98.7%	98.3%
Effective Sample Size	30998	19342	3340	493	171

DTMA1D1 Claria MRI

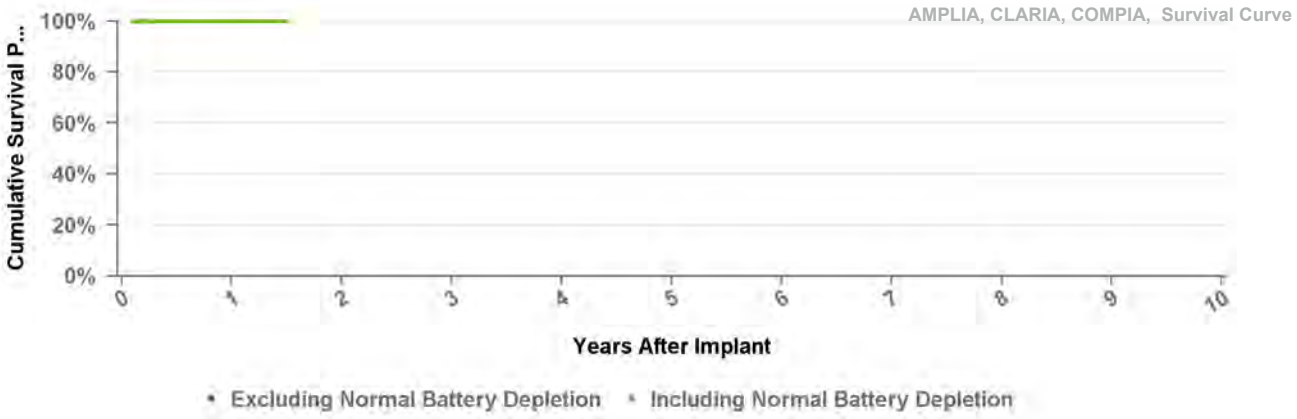
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,160		
Estimated Active USA Implants	1,146	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMA1D4 Claria MRI

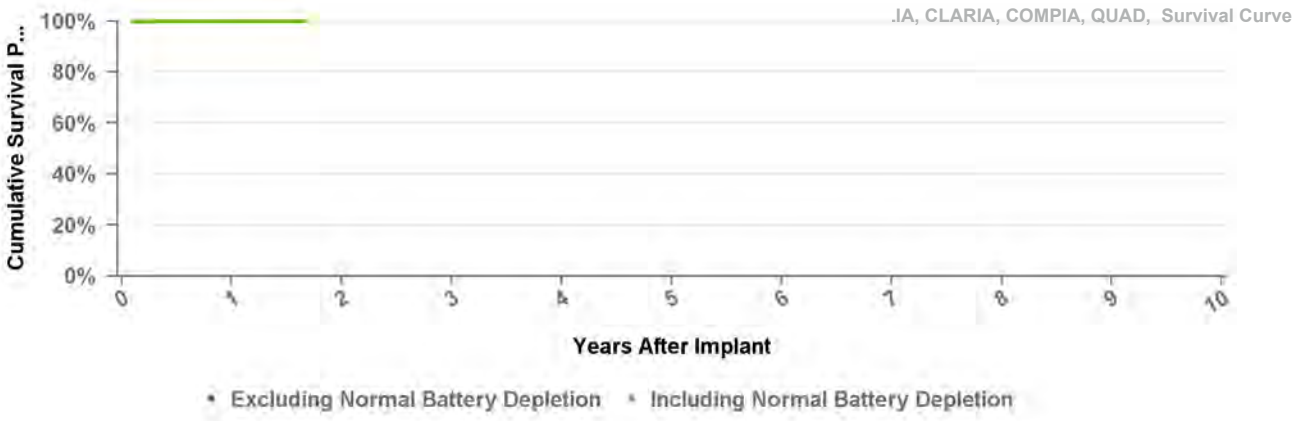
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	709		
Estimated Active USA Implants	700	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMA1Q1 Claria MRI

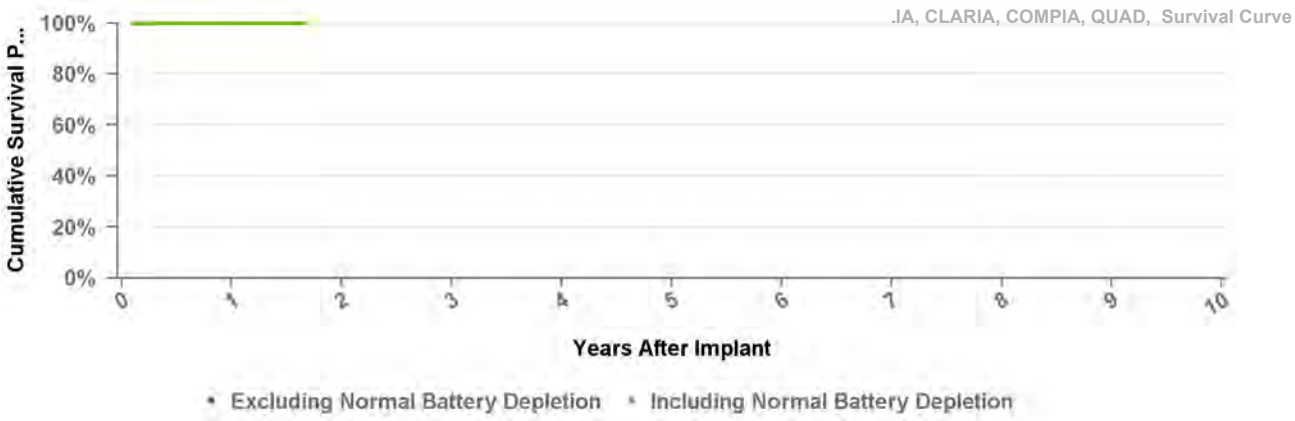
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	717		
Estimated Active USA Implants	706	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMA1QQ Claria MRI

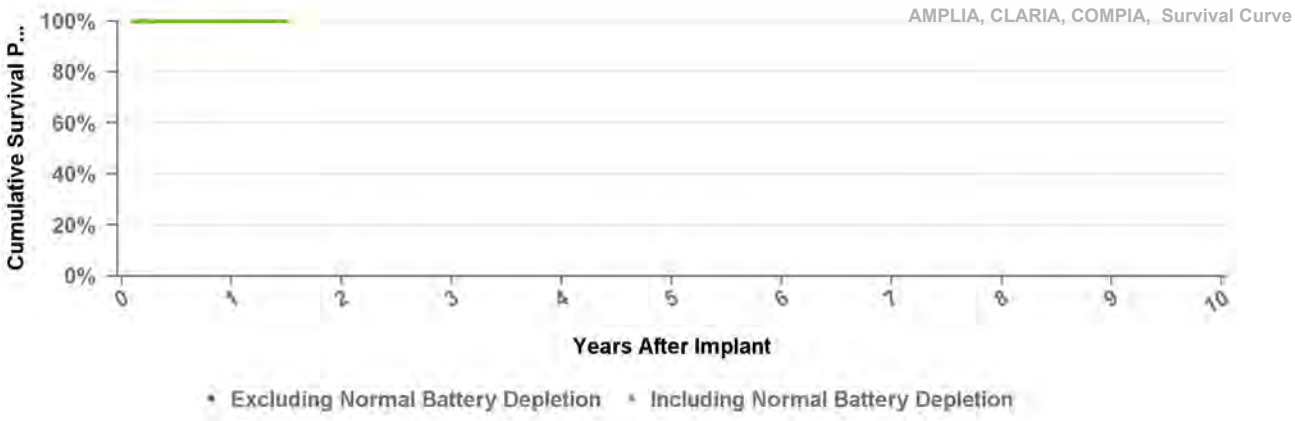
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	4,425		
Estimated Active USA Implants	4,374	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMA2D1 Claria MRI

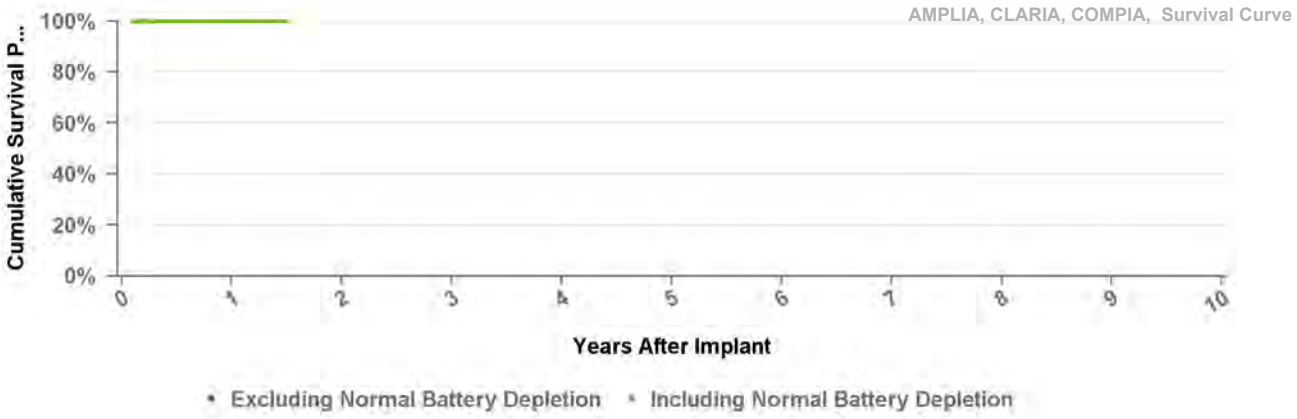
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMA2D4 Claria MRI

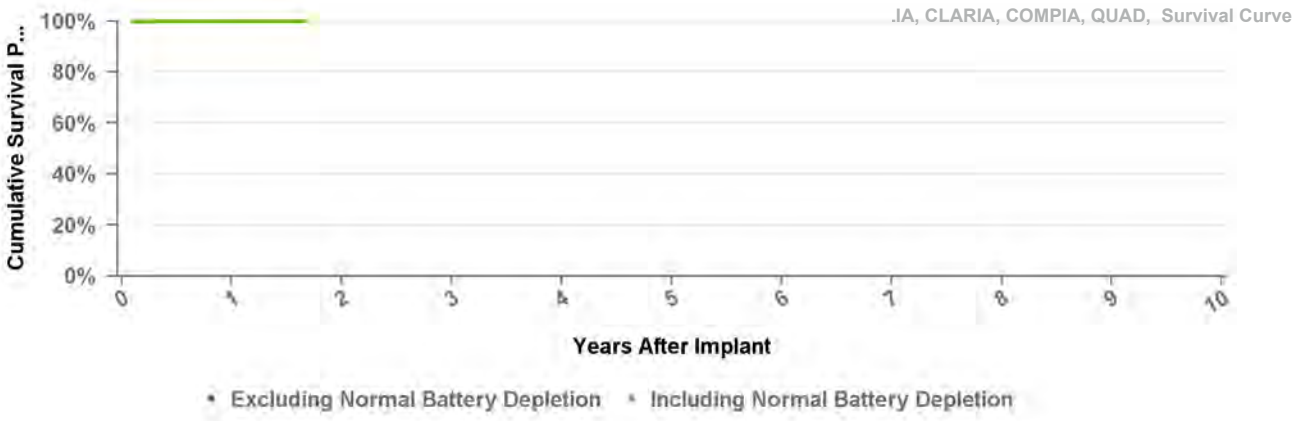
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMA2Q1 Claria MRI

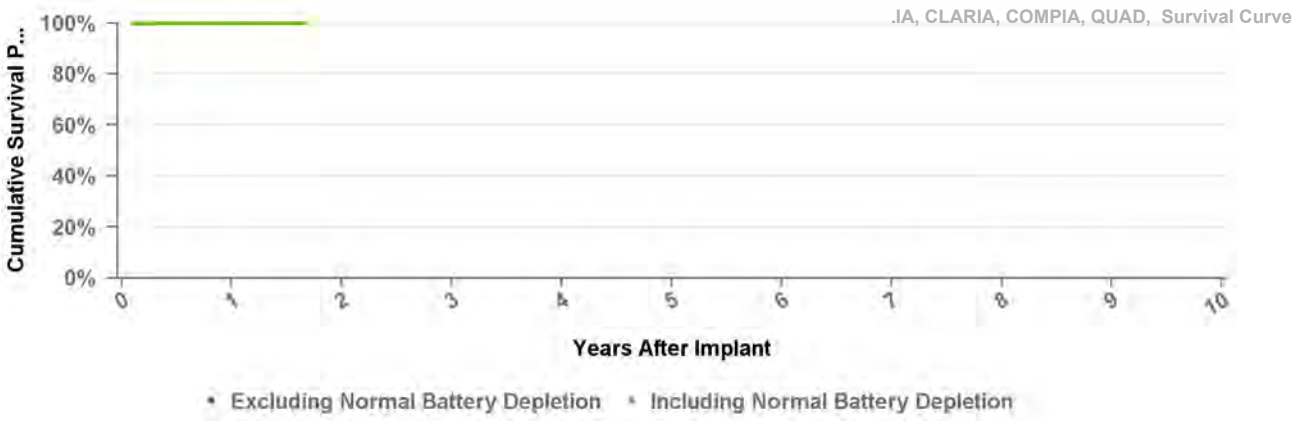
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMA2QQ Claria MRI

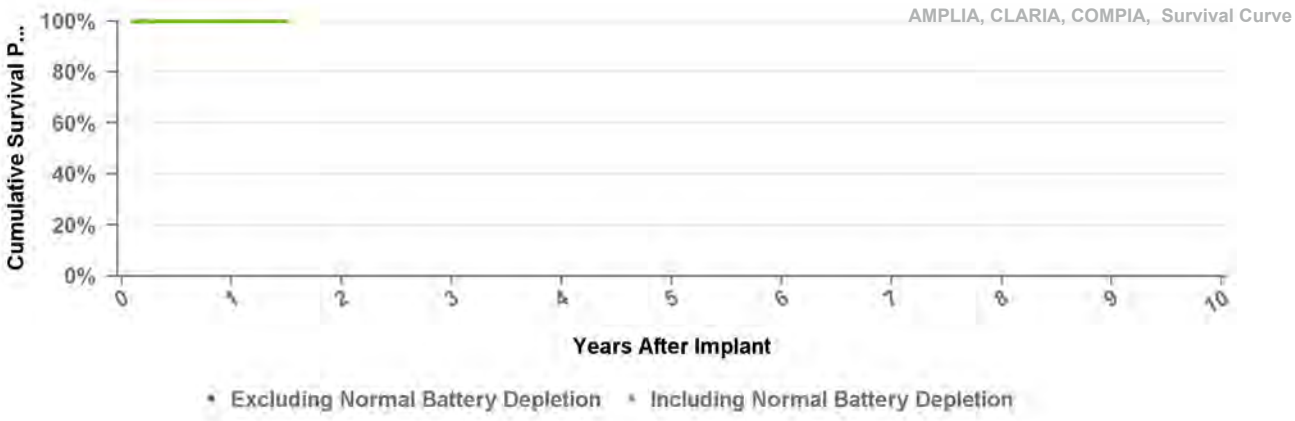
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMB1D1 Amplia MRI

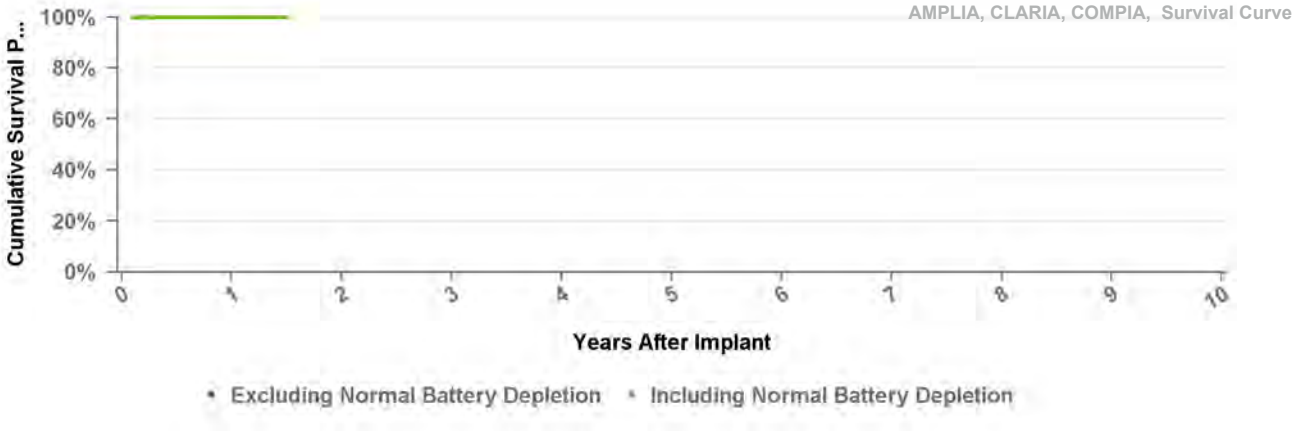
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,153		
Estimated Active USA Implants	2,118	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMB1D4 Amplia MRI

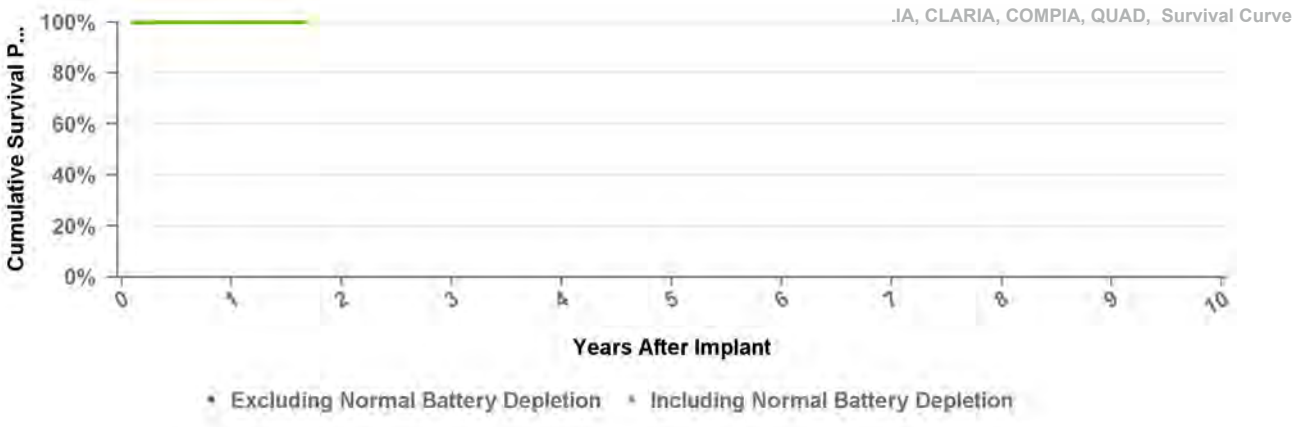
US Market Release	Feb-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,661	Electrical Component	1
Estimated Active USA Implants	2,592	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMB1Q1 Amplia MRI

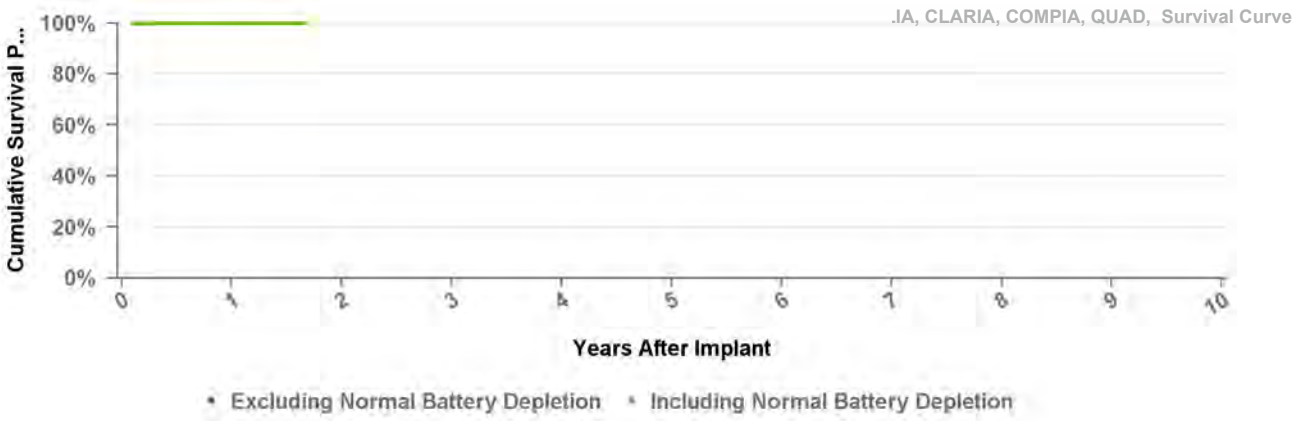
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,171		
Estimated Active USA Implants	1,145	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMB1QQ Amplia MRI

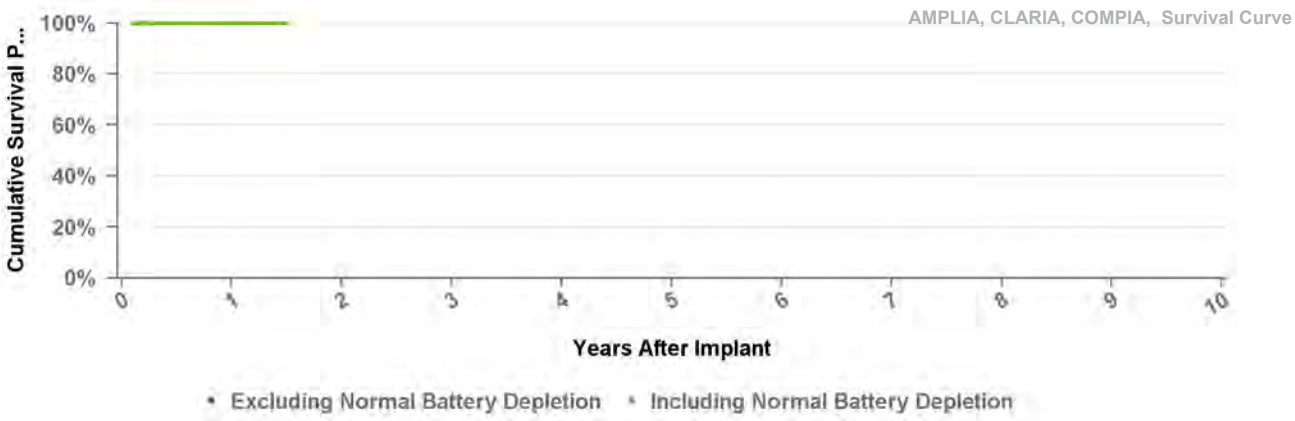
US Market Release	Feb-16	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	17,123	Electrical Component	4
Estimated Active USA Implants	16,726	Other Malfunction	1
Normal Battery Depletions		**Therapy Function Compromised**	**0**



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMB2D1 Amplia MRI

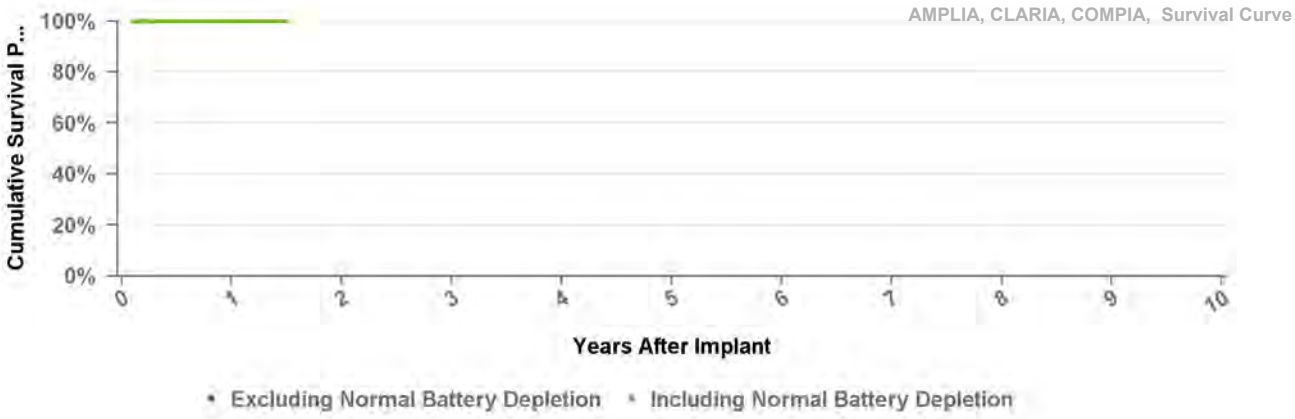
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMB2D4 Amplia MRI

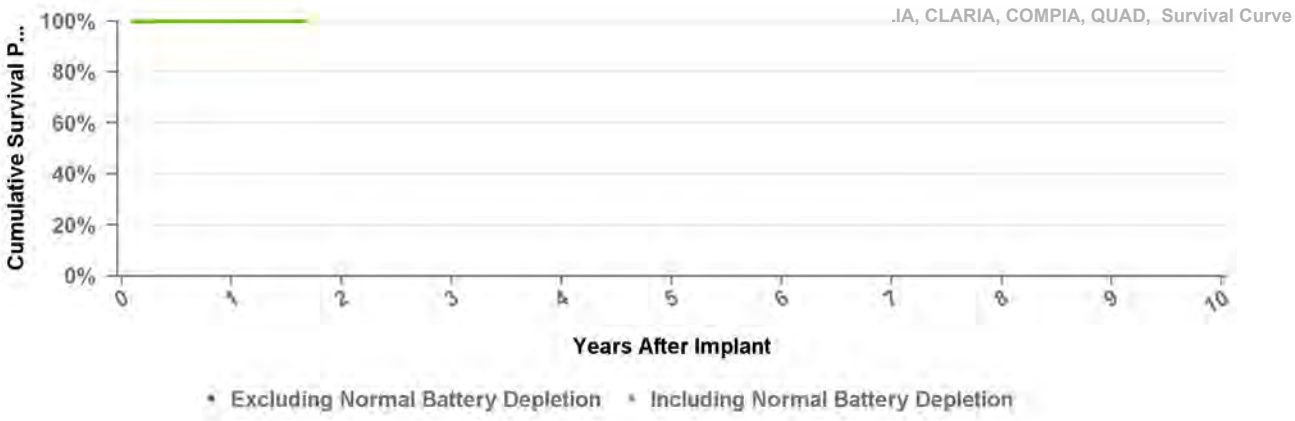
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMB2Q1 Amplia MRI

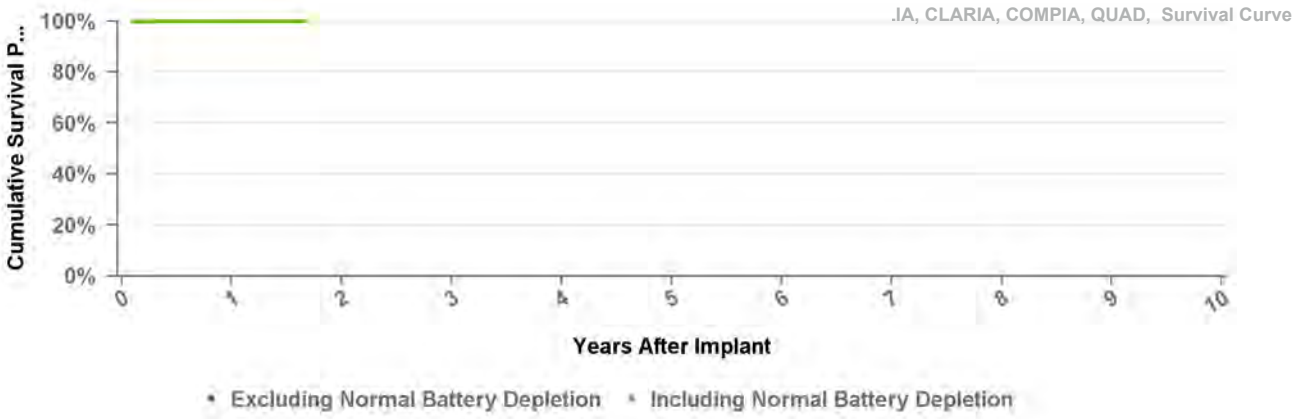
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMB2QQ Amplia MRI

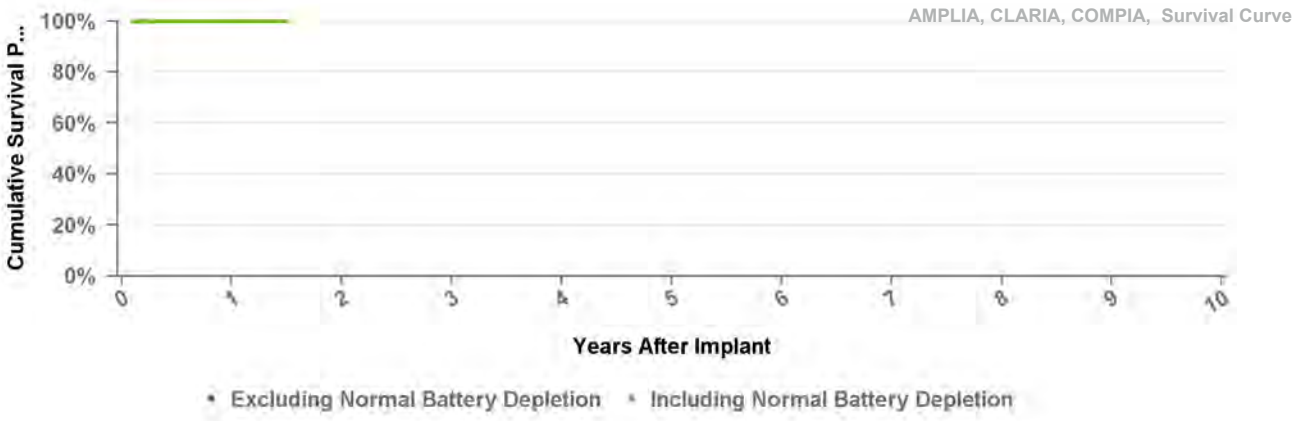
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMC1D1 Compia MRI

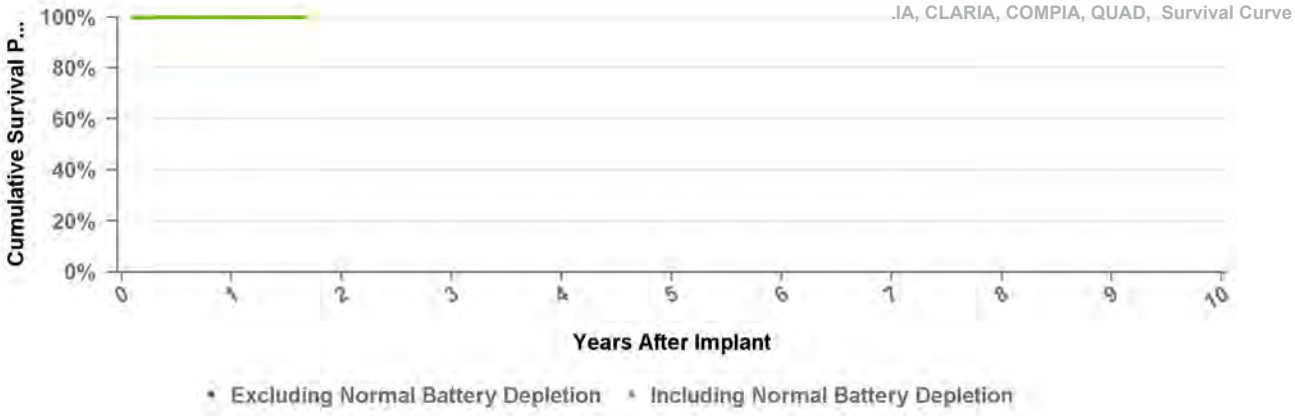
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	134		
Estimated Active USA Implants	133	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMC1QQ Compia MRI

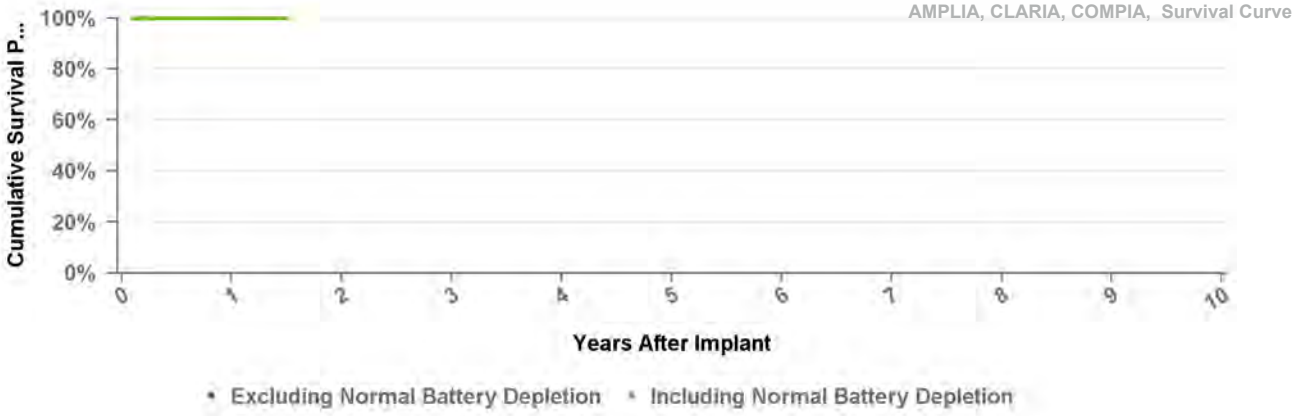
US Market Release	Feb-16	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,410	Electrical Component	1
Estimated Active USA Implants	1,381	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

DTMC2D1 Compia MRI

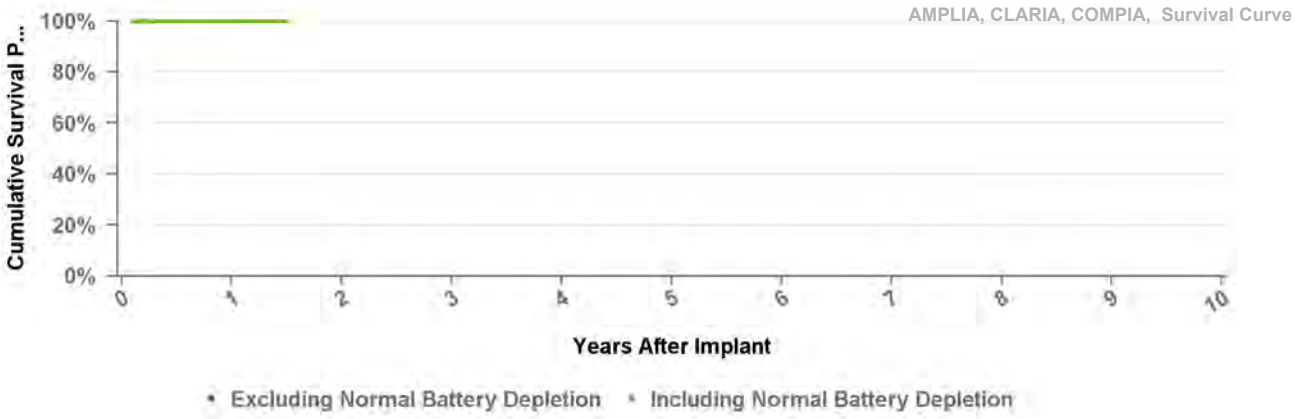
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMC2D4 Compia MRI

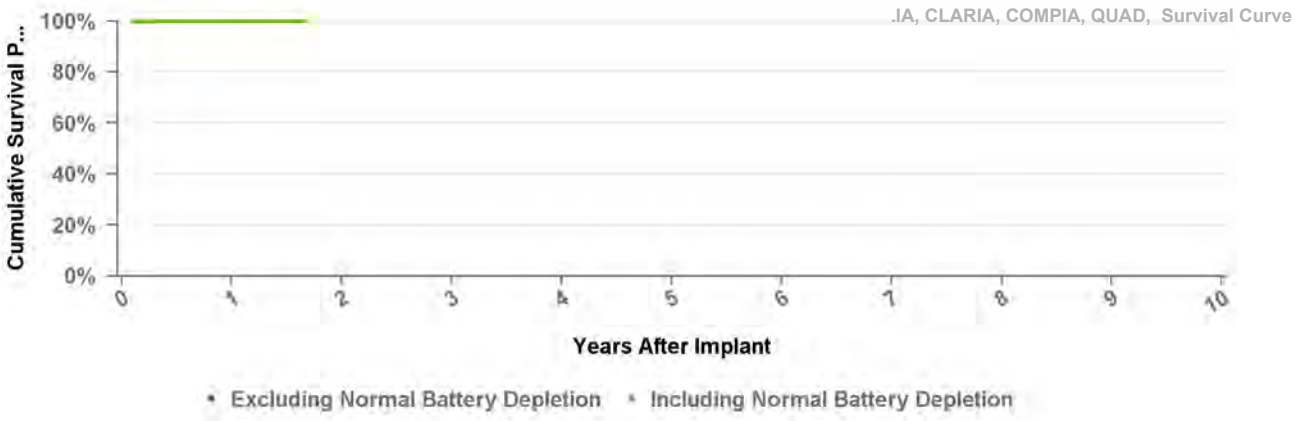
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 18 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	716	106

DTMC2QQ Compia MRI

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

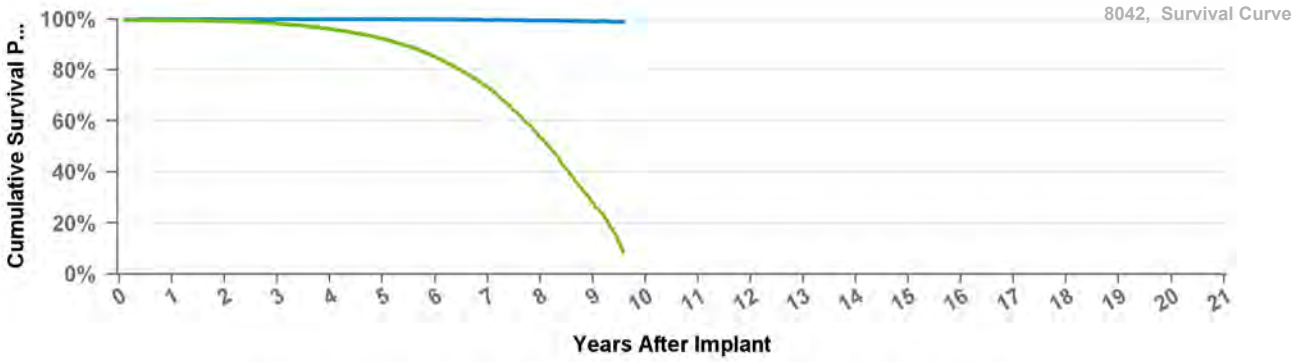


Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	7584	256

CRT-P

8042 InSync III

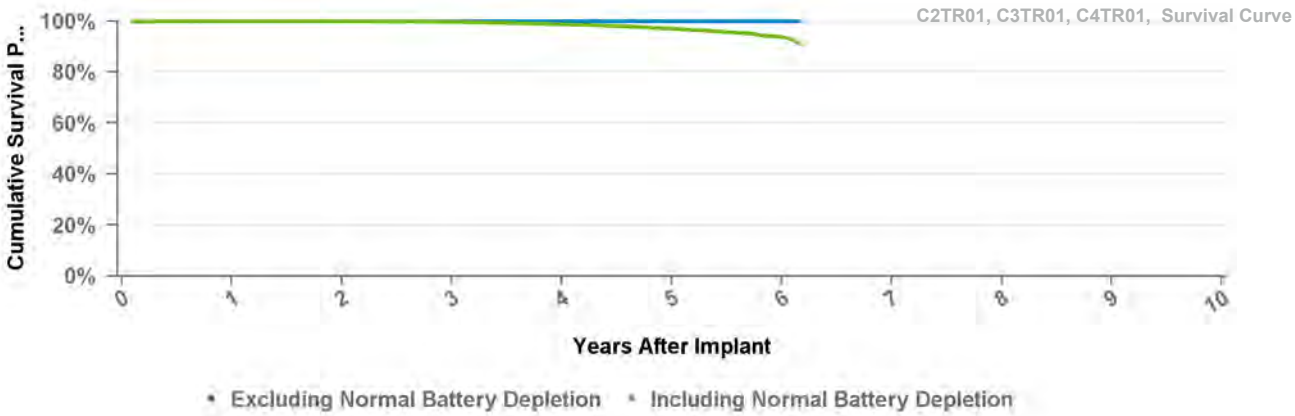
US Market Release	Feb-03	**Total Malfunctions**	**88**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**53**
Registered USA Implants	39,510	Battery Malfunction	41
Estimated Active USA Implants	5,622	Electrical Component	2
Normal Battery Depletions	4,931	Electrical Interconnect	3
		Other 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 115 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.4%	99.1%	98.9%
Including NBD	99.5%	99.2%	98.2%	96.1%	92.3%	85.1%	73.0%	53.6%	27.9%	8.6%
Effective Sample Size	30583	26218	22544	19276	16095	12329	8654	4092	1092	119

C2TR01 Syncra CRT-P

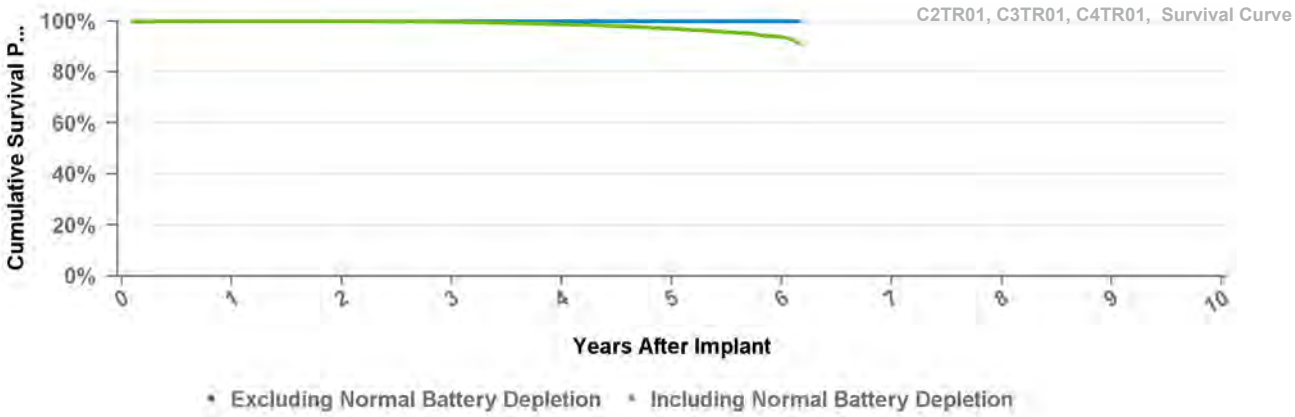
US Market Release	Mar-11	**Total Malfunctions**	**1**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	10,121	Other Malfunction	1
Estimated Active USA Implants	7,405	**Therapy Function Compromised**	**0**
Normal Battery Depletions	105		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.0%	93.7%	90.6%
Effective Sample Size	27153	22762	17627	11200	5593	989	308

C3TR01 Consulta CRT-P

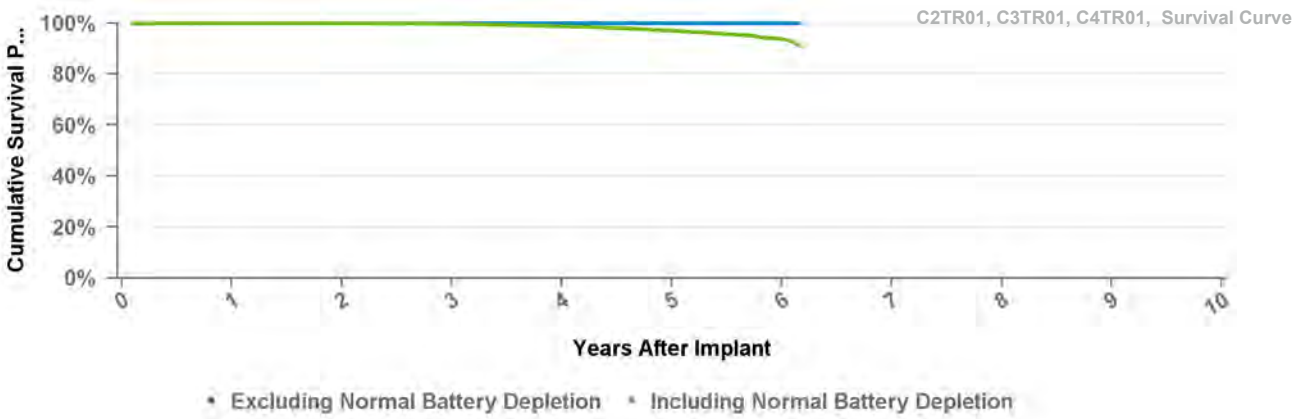
US Market Release		**Total Malfunctions**	
CE Approval Date	May-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.0%	93.7%	90.6%
Effective Sample Size	27153	22762	17627	11200	5593	989	308

C4TR01 Consulta CRT-P

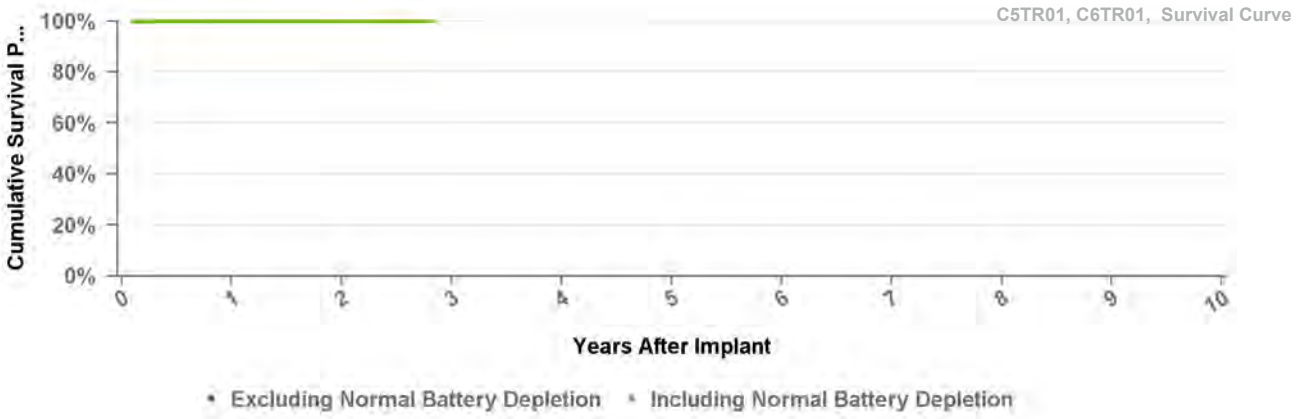
US Market Release	Mar-11	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	23,332	Electrical Component	1
Estimated Active USA Implants	18,560	Poss Early Battery Depltn	1
Normal Battery Depletions	165	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	98.7%	97.0%	93.7%	90.6%
Effective Sample Size	27153	22762	17627	11200	5593	989	308

C5TR01 Viva CRT-P

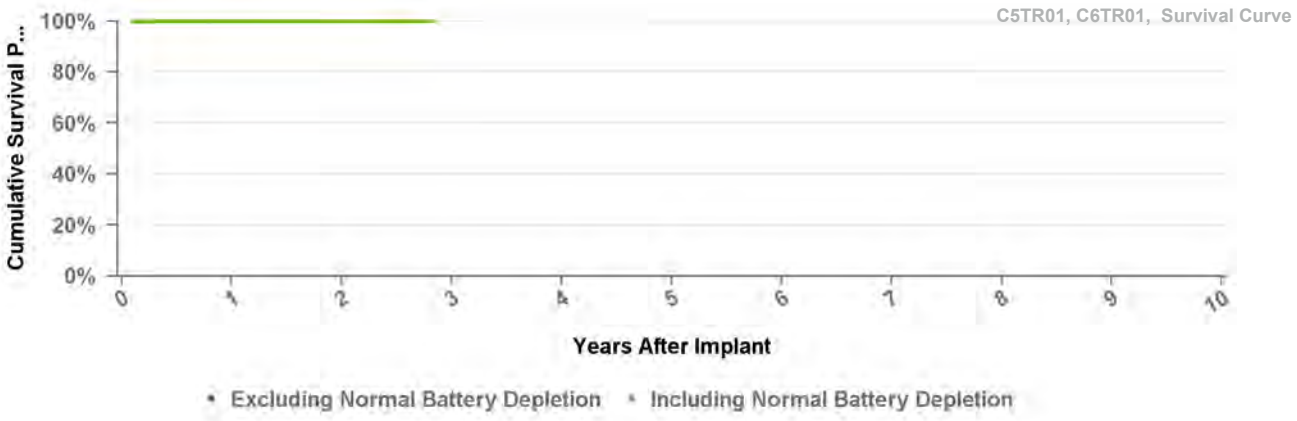
US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	5686	2066	136

C6TR01 Viva CRT-P

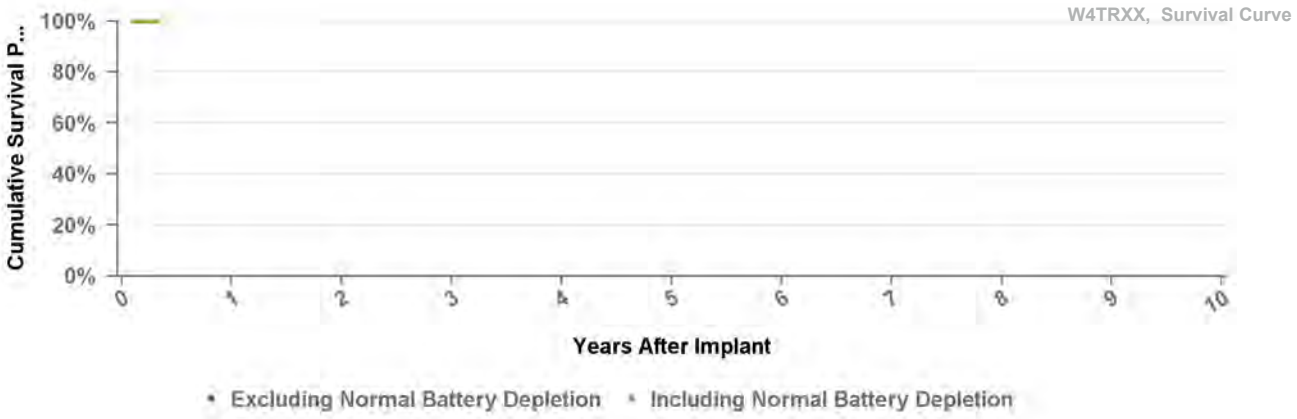
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	8,899		
Estimated Active USA Implants	8,335	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	5686	2066	136

W4TR01 Percepta Quad CRTP MRI SureScan

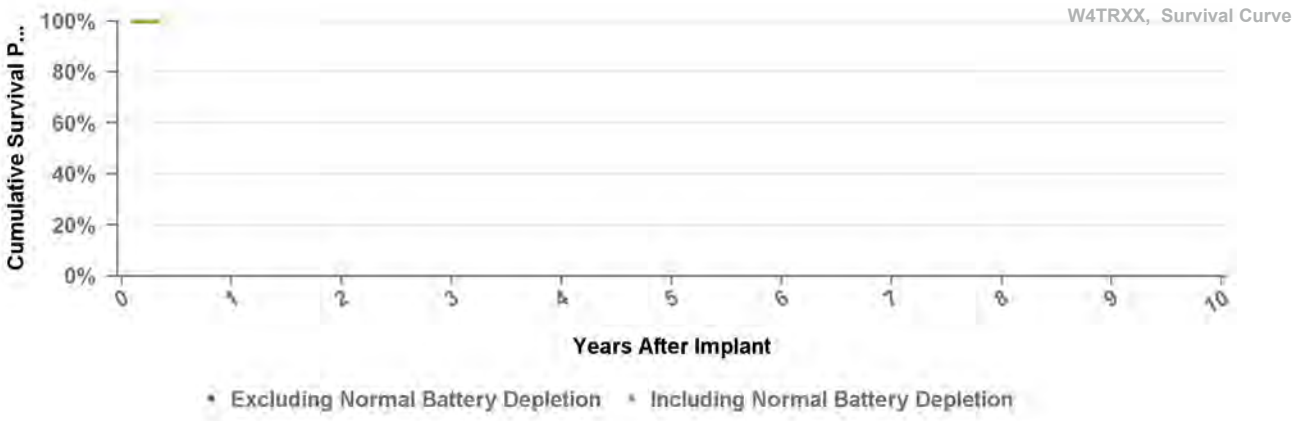
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,371		
Estimated Active USA Implants	1,358	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

W4TR02 Serena Quad CRTP MRI SureScan

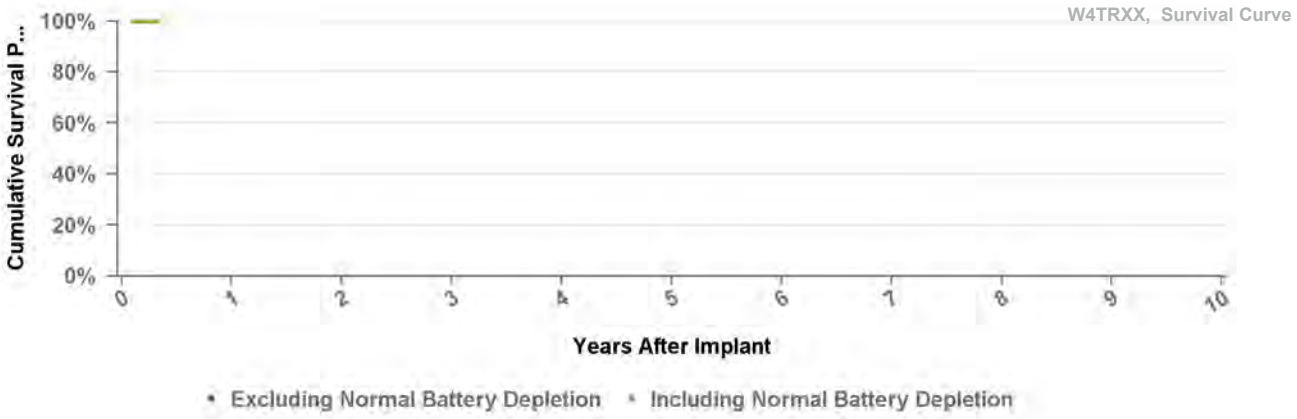
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	321		
Estimated Active USA Implants	319	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

W4TR03 Solara Quad CRTP MRI SureScan

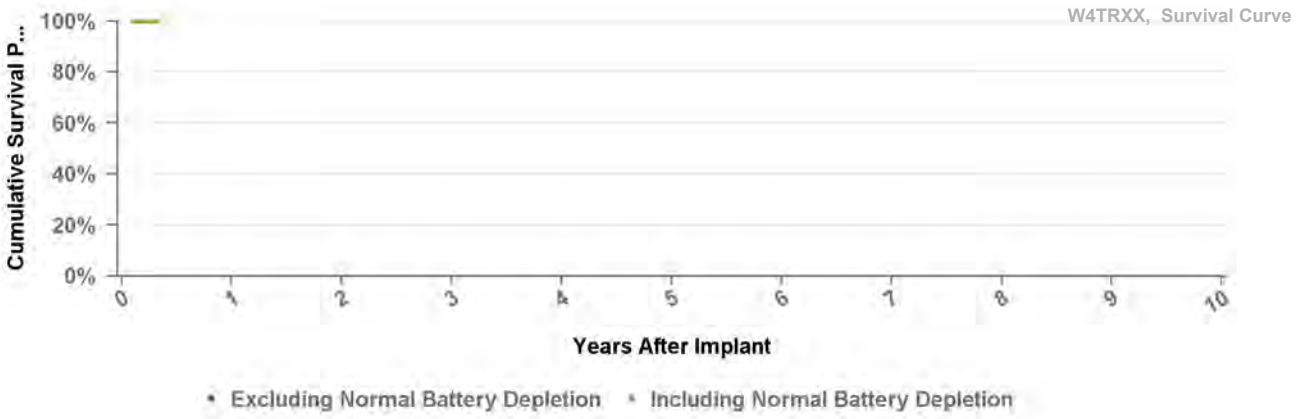
US Market Release	May-17	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	725		
Estimated Active USA Implants	717	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

W4TR04 Percepta Quad CRT-P MRI SureScan

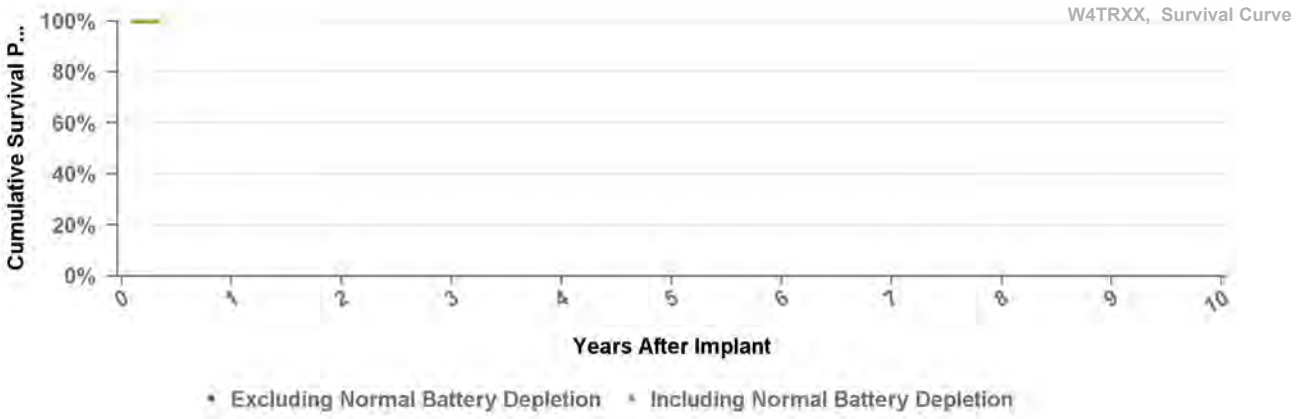
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

W4TR05 Serena Quad CRTP MRI SureScan

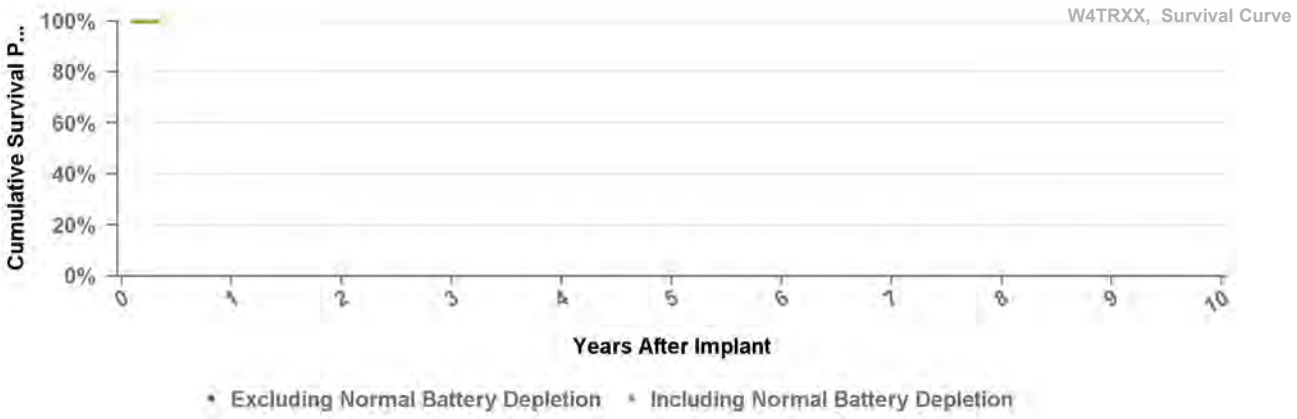
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

W4TR06 Solara Quad CRTP MRI SureScan

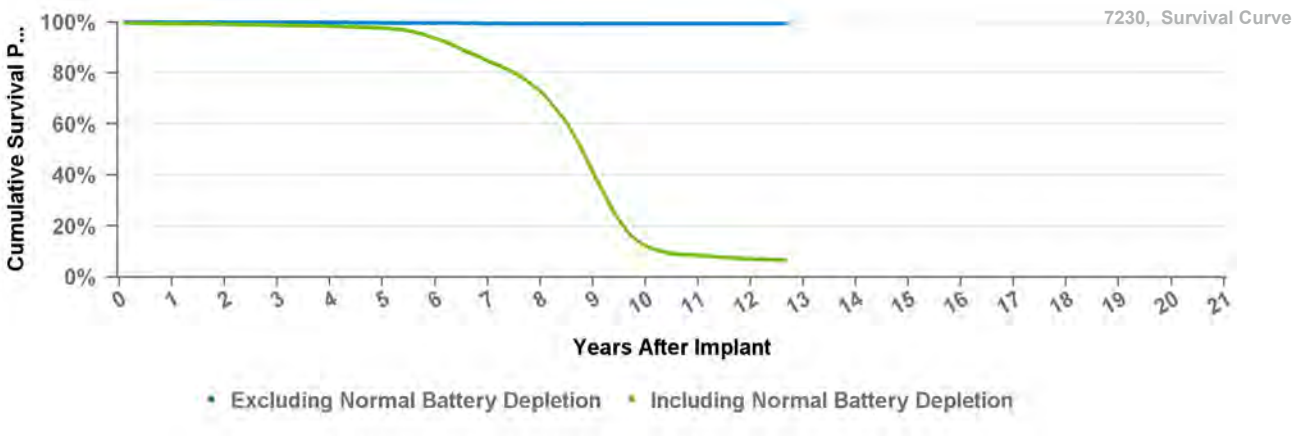
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	379

7230B Marquis VR

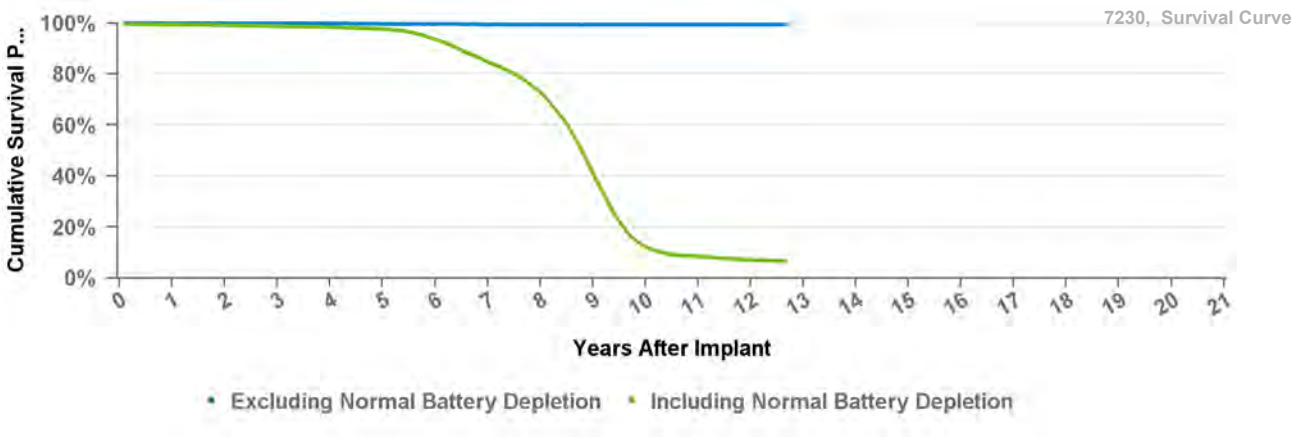
US Market Release	Dec-02	**Total Malfunctions**	**1**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**0**
Registered USA Implants	237		
Estimated Active USA Implants	11	**Therapy Function Compromised**	**1**
Normal Battery Depletions	27	Battery Malfunction	1



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 152 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.6%	93.5%	84.7%	72.7%	41.5%	12.2%	8.4%	7.1%	6.5%
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2560	591	332	223	120

7230Cx Marquis VR

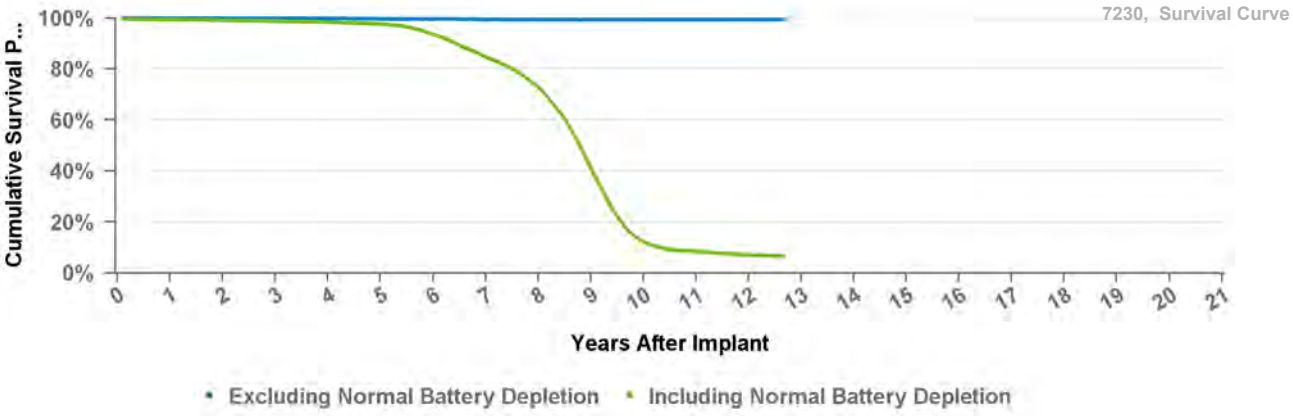
US Market Release	Dec-02	**Total Malfunctions**	**57**
CE Approval Date	Apr-02	**Therapy Function Not Compromised**	**31**
Registered USA Implants	18,517	Battery Malfunction	1
Estimated Active USA Implants	1,202	Electrical Component	14
Normal Battery Depletions	3,431	Other Malfunction	1
		Poss Early Battery Depltn	14
		Software Malfunction	1
		Therapy Function Compromised	**26**
		Battery Malfunction	17
		Electrical Component	9



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 152 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.6%	93.5%	84.7%	72.7%	41.5%	12.2%	8.4%	7.1%	6.5%
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2560	591	332	223	120

7230E Marquis VR

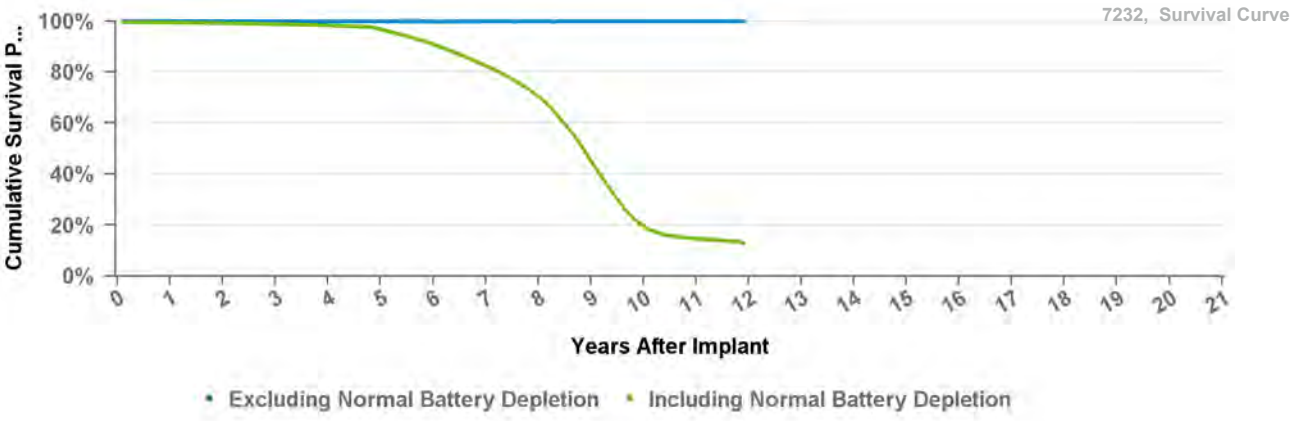
US Market Release	Dec-02	**Total Malfunctions**	**3**
CE Approval Date	Aug-02	**Therapy Function Not Compromised**	**1**
Registered USA Implants	632	Electrical Component	1
Estimated Active USA Implants	40	**Therapy Function Compromised**	**2**
Normal Battery Depletions	78	Battery Malfunction	2



Years	1	10	11	12	2	3	4	5	6	7	8	9	at 152 mo
Excluding NBD	100.0%	99.3%	99.3%	99.3%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.8%	98.4%	97.6%	93.5%	84.7%	72.7%	41.5%	12.2%	8.4%	7.1%	6.5%
Effective Sample Size	16508	12760	10566	9431	8386	7286	6056	4819	2560	591	332	223	120

7232B Maximo VR

US Market Release	Oct-03	**Total Malfunctions**	
CE Approval Date	Oct-04	**Therapy Function Not Compromised**	
Registered USA Implants	170		
Estimated Active USA Implants	28	**Therapy Function Compromised**	
Normal Battery Depletions	35		

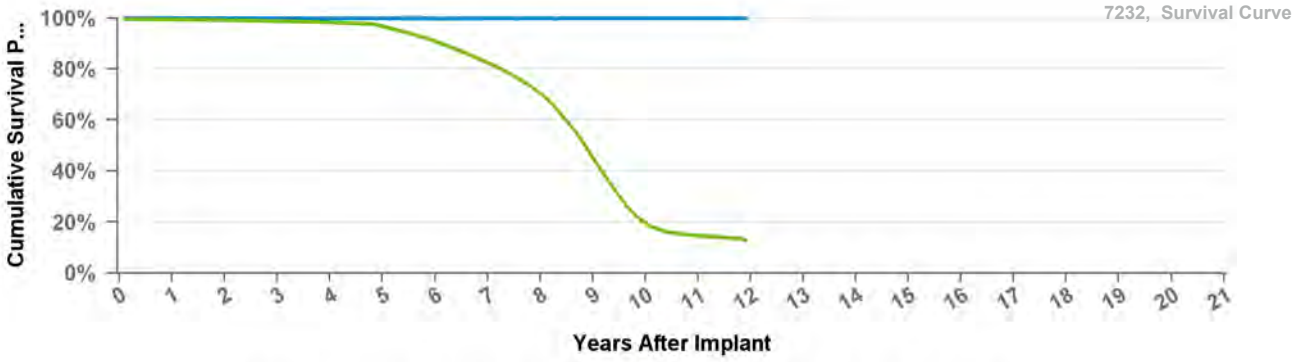


Years	1	10	11	2	3	4	5	6	7	8	9	at 143 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.8%	82.4%	70.3%	45.3%	19.5%	14.6%	12.6%
Effective Sample Size	38271	34246	30528	26920	23715	20621	17420	13966	8434	2968	1424	161

7232Cx Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-03
Registered USA Implants	43,671
Estimated Active USA Implants	5,193
Normal Battery Depletions	10,648

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

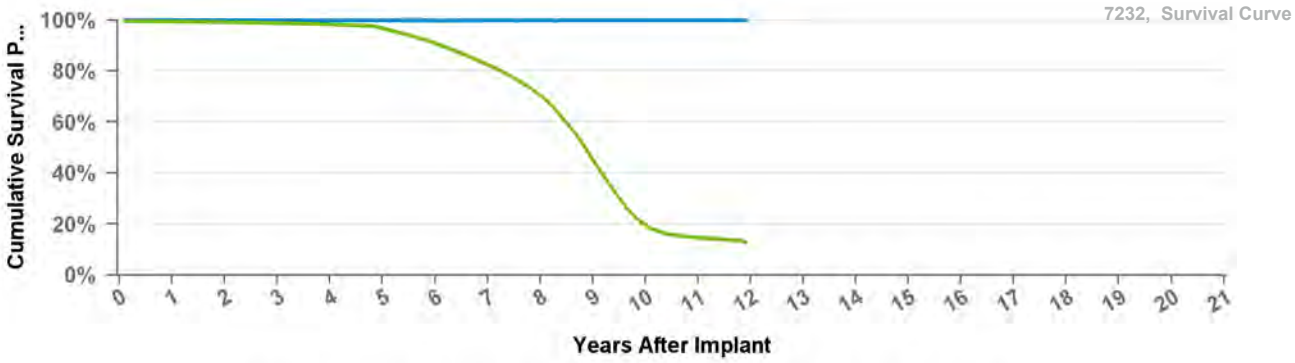


Years	1	10	11	2	3	4	5	6	7	8	9	at 143 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.8%	82.4%	70.3%	45.3%	19.5%	14.6%	12.6%
Effective Sample Size	38271	34246	30528	26920	23715	20621	17420	13966	8434	2968	1424	161

7232E Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-04
Registered USA Implants	490
Estimated Active USA Implants	74
Normal Battery Depletions	83

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

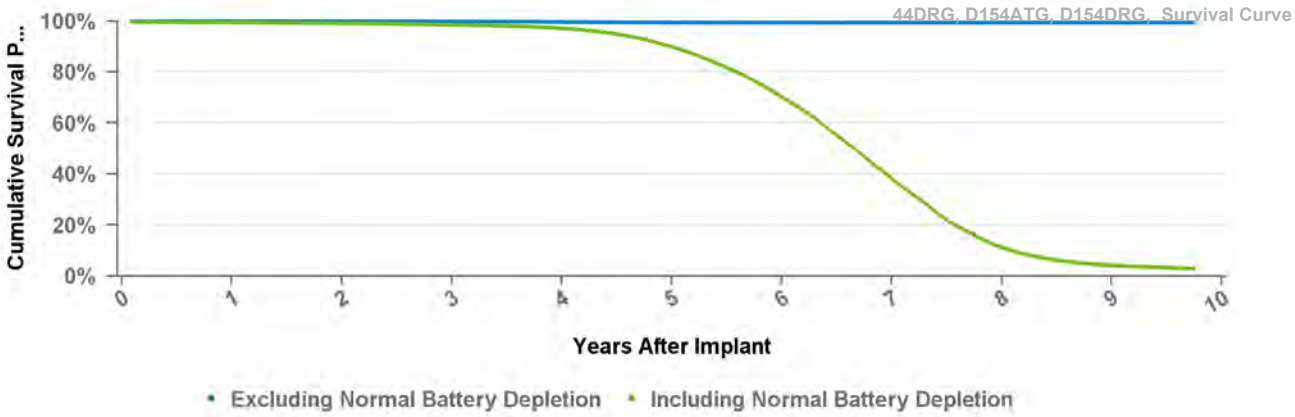


Years	1	10	11	2	3	4	5	6	7	8	9	at 143 mo
Excluding NBD	100.0%	99.8%	99.8%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.4%	99.2%	98.8%	98.3%	96.8%	90.8%	82.4%	70.3%	45.3%	19.5%	14.6%	12.6%
Effective Sample Size	38271	34246	30528	26920	23715	20621	17420	13966	8434	2968	1424	161

D144DRG Entrust Escudo

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

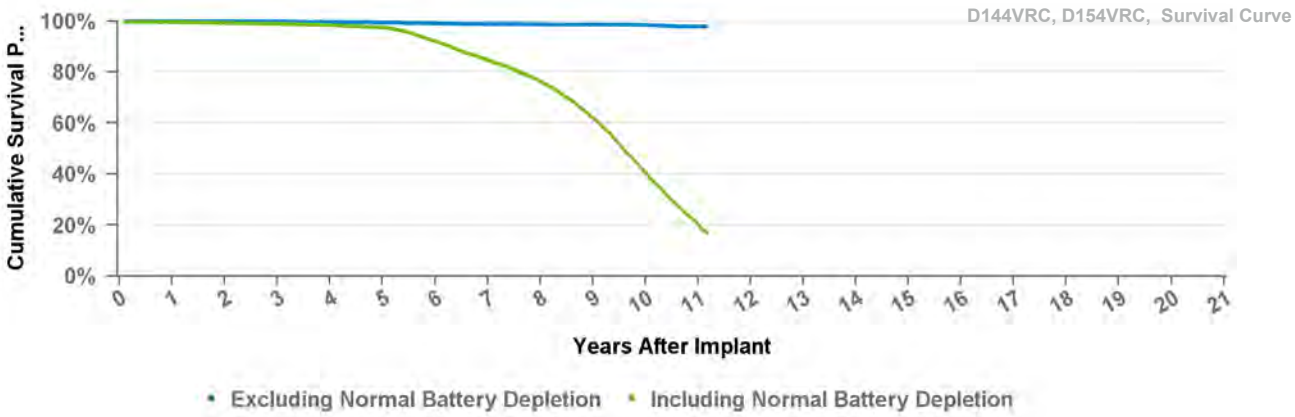


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.2%	38.1%	11.1%	4.2%	2.8%
Effective Sample Size	24904	22702	20354	17938	14878	10817	5370	1367	366	102

D144VRC Entrust Escudo

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

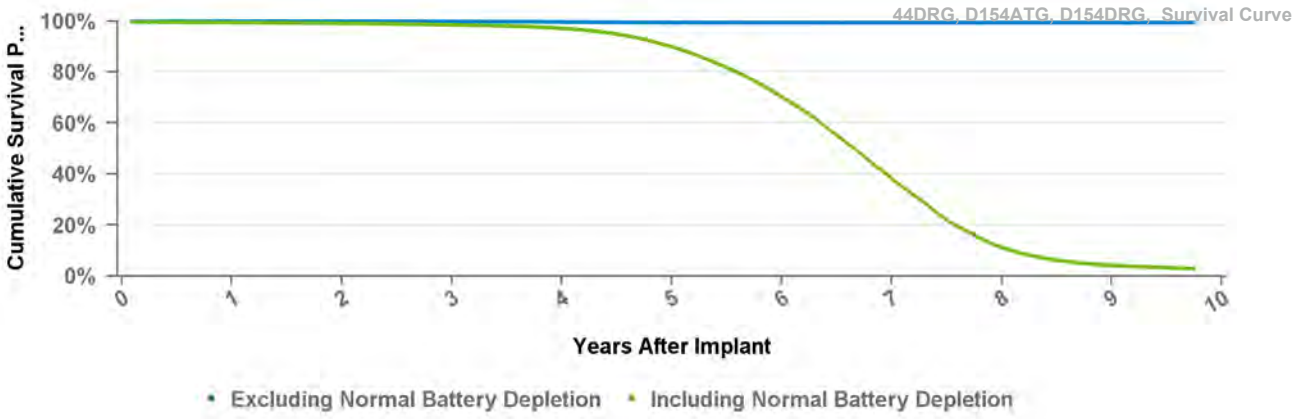
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	10	11	2	3	4	5	6	7	8	9	at 134 mo
Excluding NBD	99.9%	98.4%	97.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	97.9%
Including NBD	99.6%	99.2%	98.9%	98.4%	97.5%	92.1%	84.8%	76.2%	61.8%	40.8%	20.4%	16.9%
Effective Sample Size	12683	11492	10275	9077	8014	7014	6012	5100	3864	2175	614	218

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	2,310	Electrical Interconnect	1
Normal Battery Depletions	9,012	Other Malfunction	1
		Poss Early Battery Depltn	74
		Software Malfunction	3
		Therapy Function Compromised	**16**
		Electrical Component	16

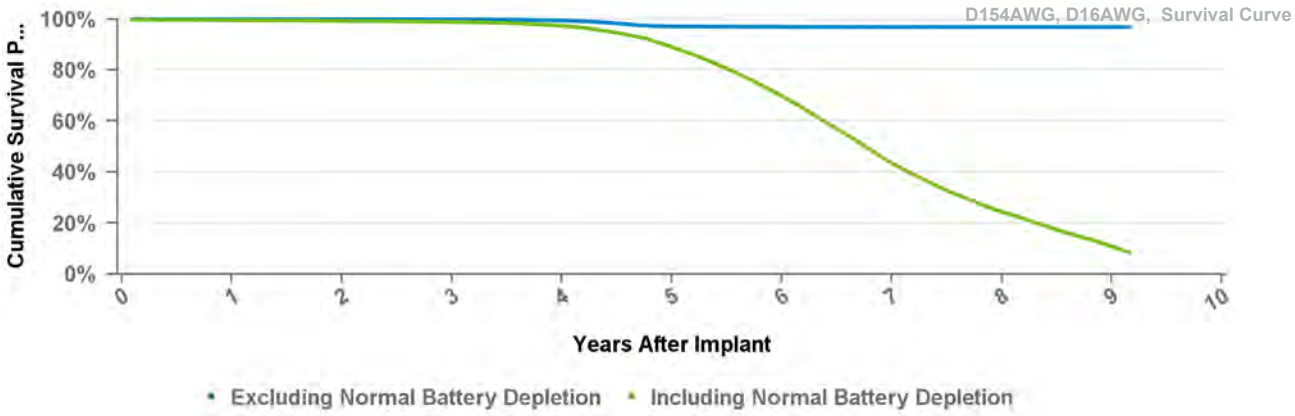


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.4%	99.1%	98.5%	97.1%	89.9%	70.2%	38.1%	11.1%	4.2%	2.8%
Effective Sample Size	24904	22702	20354	17938	14878	10817	5370	1367	366	102

D154AWG Virtuoso DR

US Market Release	May-06
CE Approval Date	
Registered USA Implants	76,858
Estimated Active USA Implants	11,539
Normal Battery Depletions	21,403

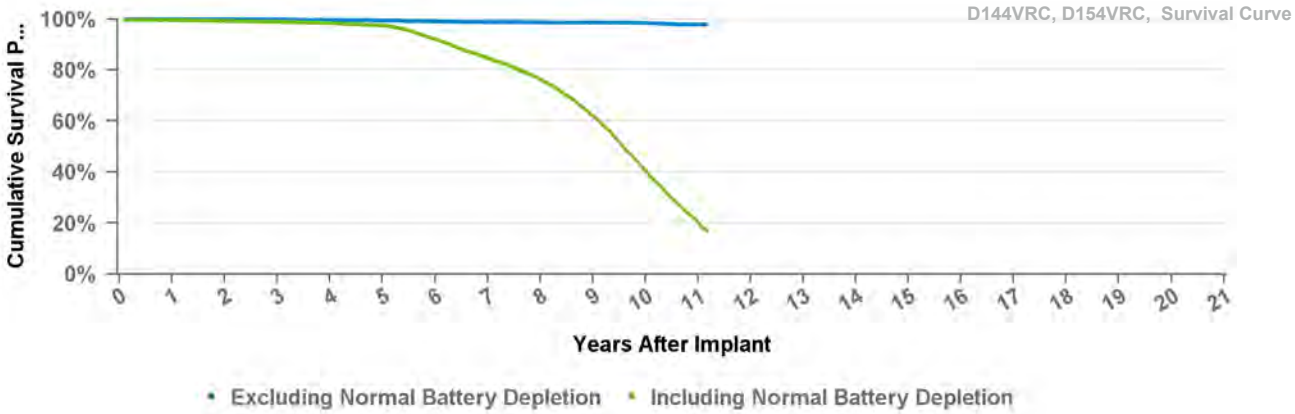
Total Malfunctions	**3,336**
Therapy Function Not Compromised	**3,292**
Battery Malfunction	8
Electrical Component	3,143
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	132
Software Malfunction	3
Therapy Function Compromised	**44**
Battery Malfunction	1
Electrical Component	40
Other Malfunction	2
Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	97.0%	96.9%	96.9%	96.8%	96.8%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.3%	24.4%	10.9%	8.3%
Effective Sample Size	63444	58187	53026	48190	40957	29875	16943	8158	1187	422

D154VRC Entrust VR

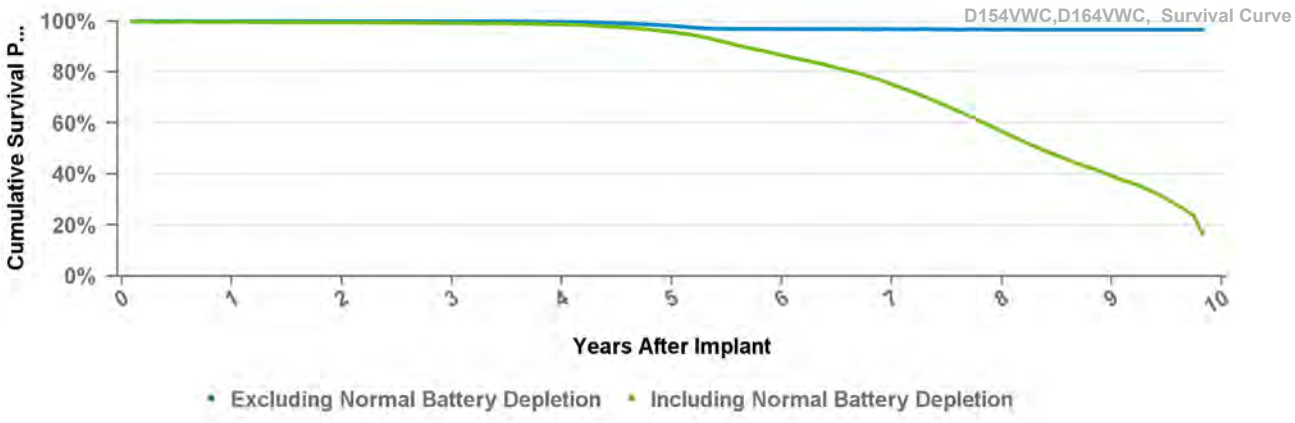
US Market Release	Jun-05	**Total Malfunctions**	**133**
CE Approval Date	Feb-05	**Therapy Function Not Compromised**	**98**
Registered USA Implants	14,466	Battery Malfunction	15
Estimated Active USA Implants	2,355	Electrical Component	47
Normal Battery Depletions	3,142	Other Malfunction	12
		Poss Early 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 134 mo
Excluding NBD	99.9%	98.4%	97.9%	99.9%	99.8%	99.7%	99.4%	99.1%	98.8%	98.7%	98.7%	97.9%
Including NBD	99.6%	99.2%	98.9%	98.4%	97.5%	92.1%	84.8%	76.2%	61.8%	40.8%	20.4%	16.9%
Effective Sample Size	12683	11492	10275	9077	8014	7014	6012	5100	3864	2175	614	218

D154VWC Virtuoso VR

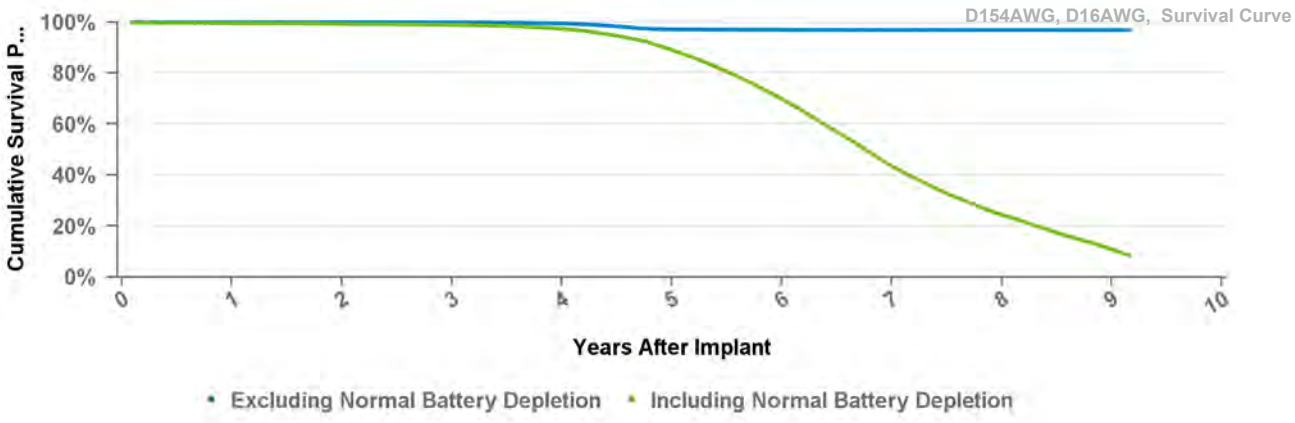
US Market Release	May-06	**Total Malfunctions**	**689**
CE Approval Date		**Therapy Function Not Compromised**	**671**
Registered USA Implants	33,145	Battery Malfunction	13
Estimated Active USA Implants	8,180	Electrical Component	638
Normal Battery Depletions	6,683	Electrical Interconnect	1
		Other Malfunction	4
		Poss Early Battery Depltn	15
		Therapy Function Compromised	**18**
		Battery Malfunction	1
		Electrical Component	17



Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%	96.7%
Including NBD	99.6%	99.4%	99.2%	98.6%	95.7%	86.6%	75.1%	56.6%	39.2%	16.2%
Effective Sample Size	28607	26092	23778	21751	19335	16192	13135	9026	3905	224

D164AWG Virtuoso DR

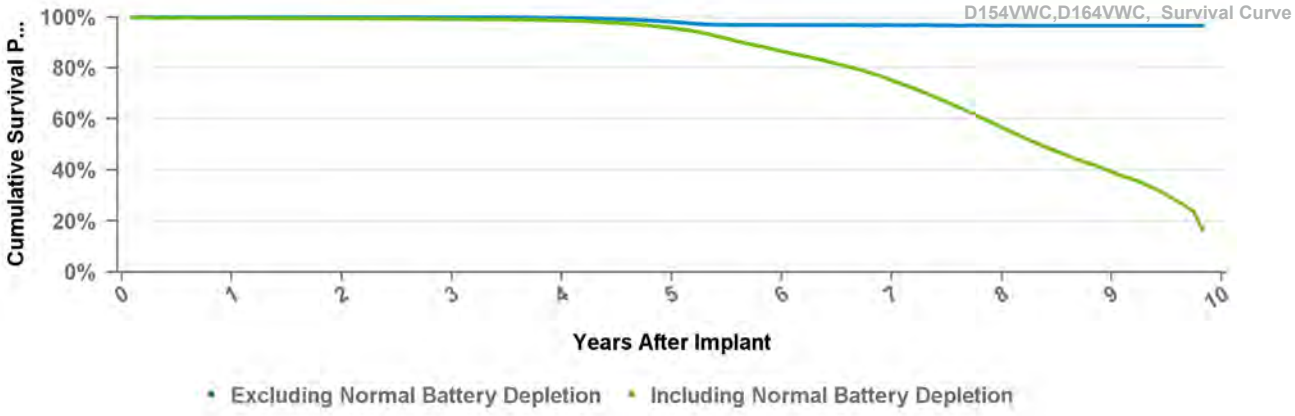
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	
Registered USA Implants	10		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	4		



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	97.0%	96.9%	96.9%	96.8%	96.8%
Including NBD	99.6%	99.3%	98.9%	97.4%	89.1%	69.8%	43.3%	24.4%	10.9%	8.3%
Effective Sample Size	63444	58187	53026	48190	40957	29875	16943	8158	1187	422

D164VWC Virtuoso VR

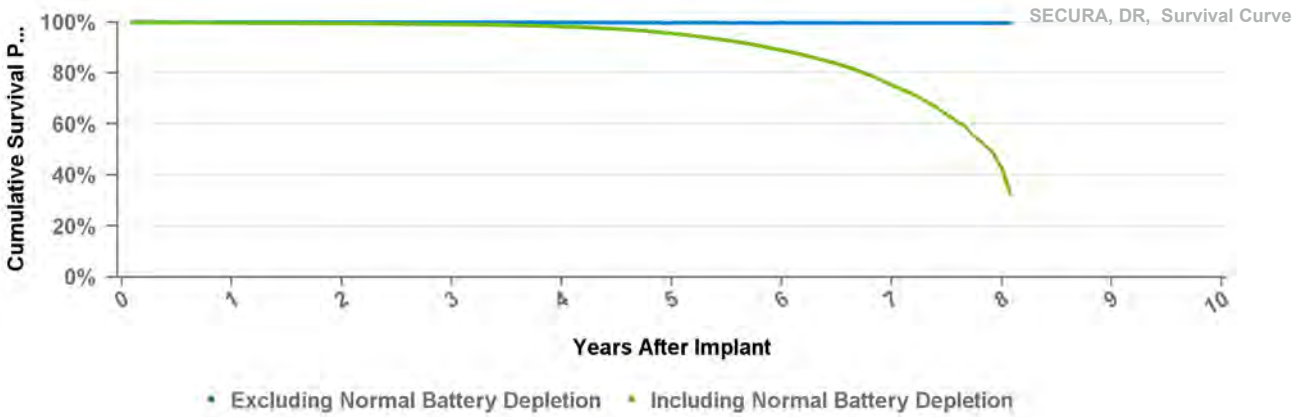
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.9%	96.8%	96.7%	96.7%	96.7%
Including NBD	99.6%	99.4%	99.2%	98.6%	95.7%	86.6%	75.1%	56.6%	39.2%	16.2%
Effective Sample Size	28607	26092	23778	21751	19335	16192	13135	9026	3905	224

D204DRM Secura DR

US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,879	Other Malfunction	1
Estimated Active USA Implants	1,508	**Therapy Function Compromised**	**2**
Normal Battery Depletions	15	Electrical Component	2

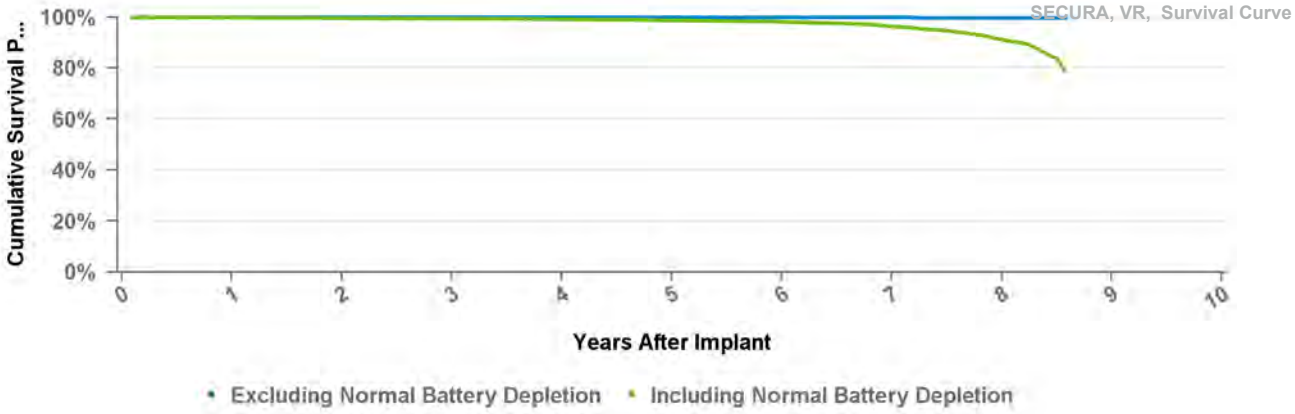


Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.4%	99.1%	98.2%	95.5%	88.9%	75.2%	43.0%	32.4%
Effective Sample Size	45362	42511	39918	37006	31897	24297	11000	802	376

ICD

D204VRM Secura VR

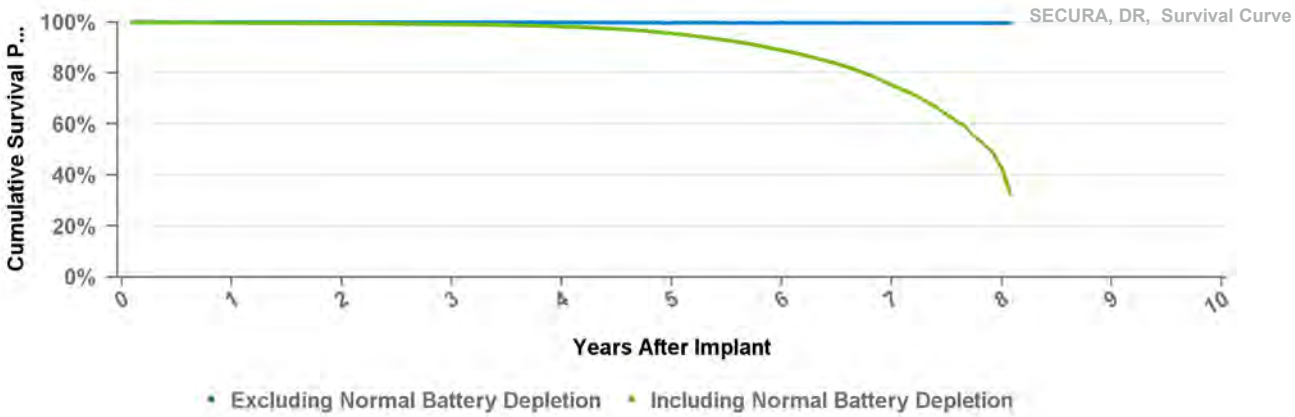
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,184	Electrical Component	1
Estimated Active USA Implants	981	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.7%	98.1%	96.3%	91.2%	78.7%
Effective Sample Size	18304	17100	16122	14989	12812	10495	6544	2116	252

D214DRM Secura DR

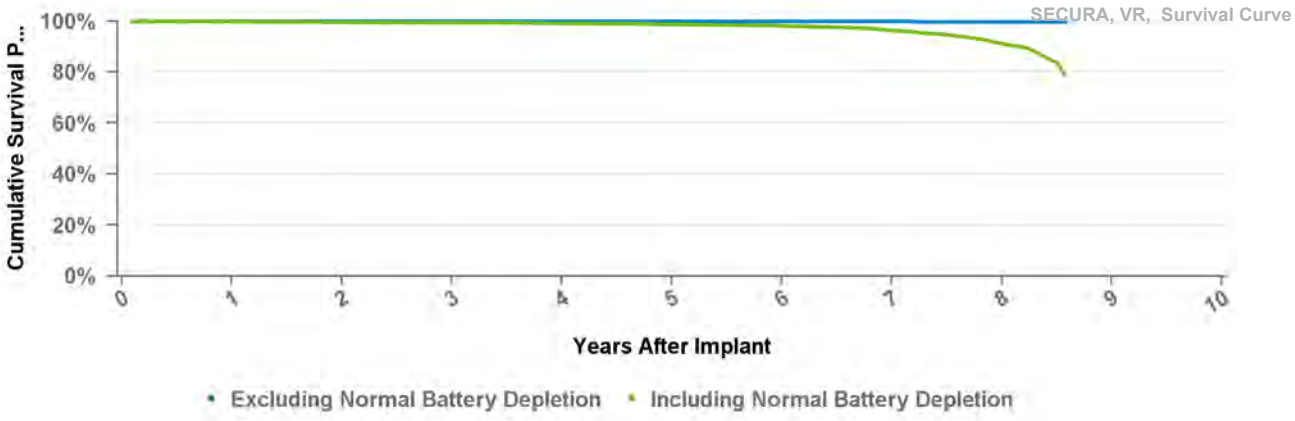
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.4%	99.1%	98.2%	95.5%	88.9%	75.2%	43.0%	32.4%
Effective Sample Size	45362	42511	39918	37006	31897	24297	11000	802	376

D214VRM Secura VR

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

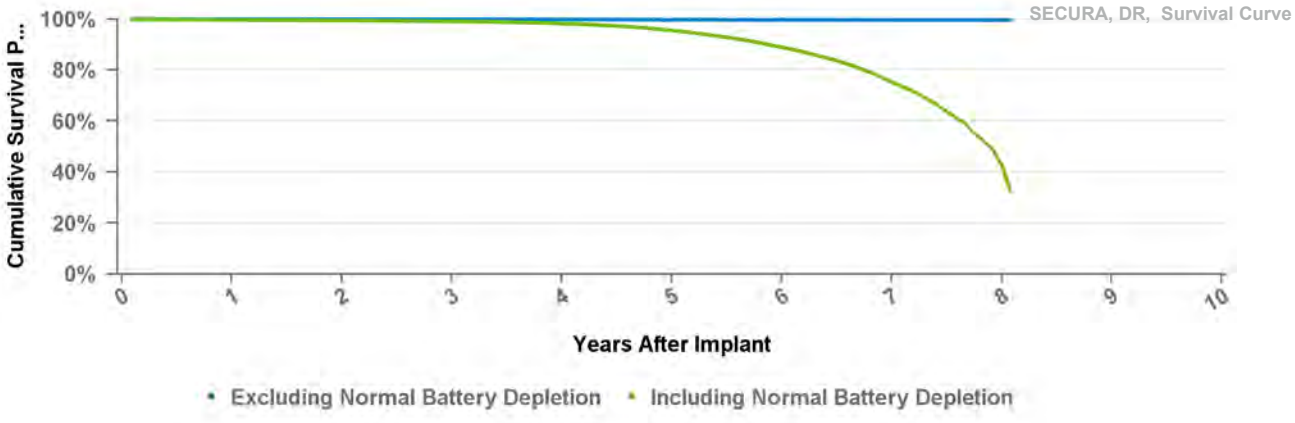


Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.7%	98.1%	96.3%	91.2%	78.7%
Effective Sample Size	18304	17100	16122	14989	12812	10495	6544	2116	252

D224DRG Secura DR

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	49,901
Estimated Active USA Implants	20,305
Normal Battery Depletions	5,011

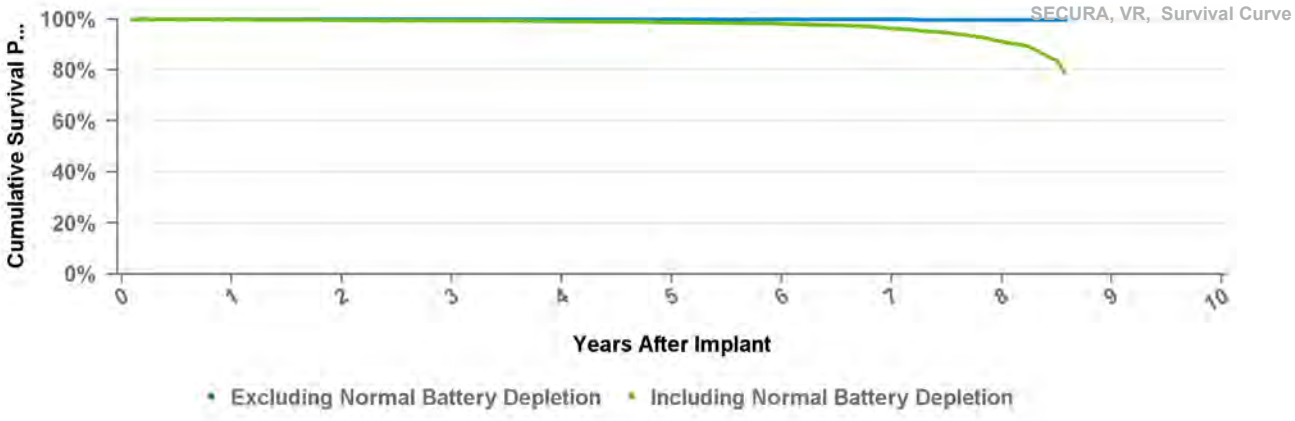
Total Malfunctions	**130**
Therapy Function Not Compromised	**110**
Battery Malfunction	10
Electrical Component	36
Other Malfunction	5
Poss Early Battery Depltn	50
Software Malfunction	9
Therapy Function Compromised	**20**
Battery Malfunction	4
Electrical Component	14
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.4%	99.1%	98.2%	95.5%	88.9%	75.2%	43.0%	32.4%
Effective Sample Size	45362	42511	39918	37006	31897	24297	11000	802	376

D224VRC Secura VR

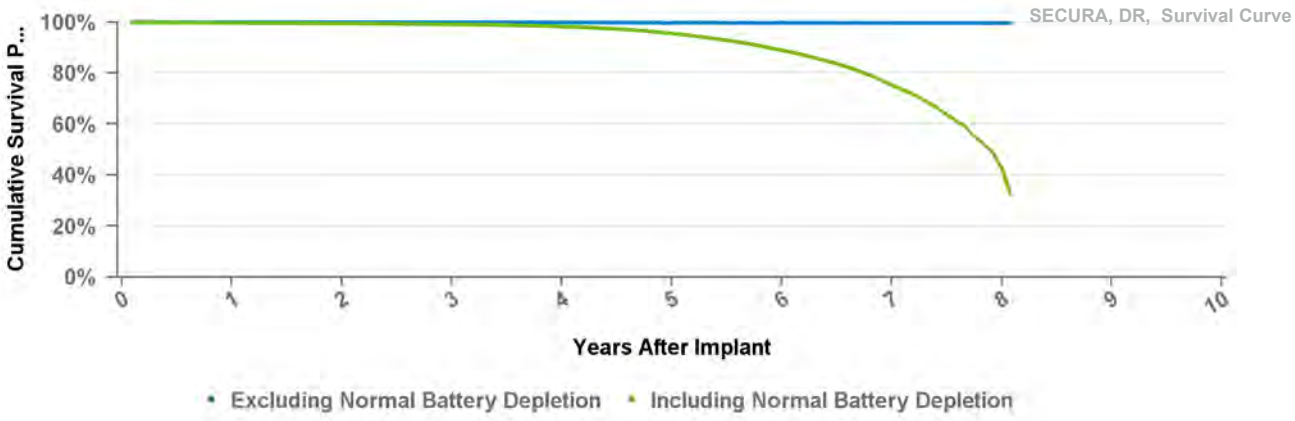
US Market Release	Sep-08	**Total Malfunctions**	**38**
CE Approval Date		**Therapy Function Not Compromised**	**32**
Registered USA Implants	20,042	Battery Malfunction	13
Estimated Active USA Implants	11,890	Electrical Component	8
Normal Battery Depletions	381	Other Malfunction	1
		Poss Early Battery Depltn	8
		Software Malfunction	2
		Therapy Function Compromised	**6**
		Electrical Component	5
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.7%	98.1%	96.3%	91.2%	78.7%
Effective Sample Size	18304	17100	16122	14989	12812	10495	6544	2116	252

D234DRG Secura DR

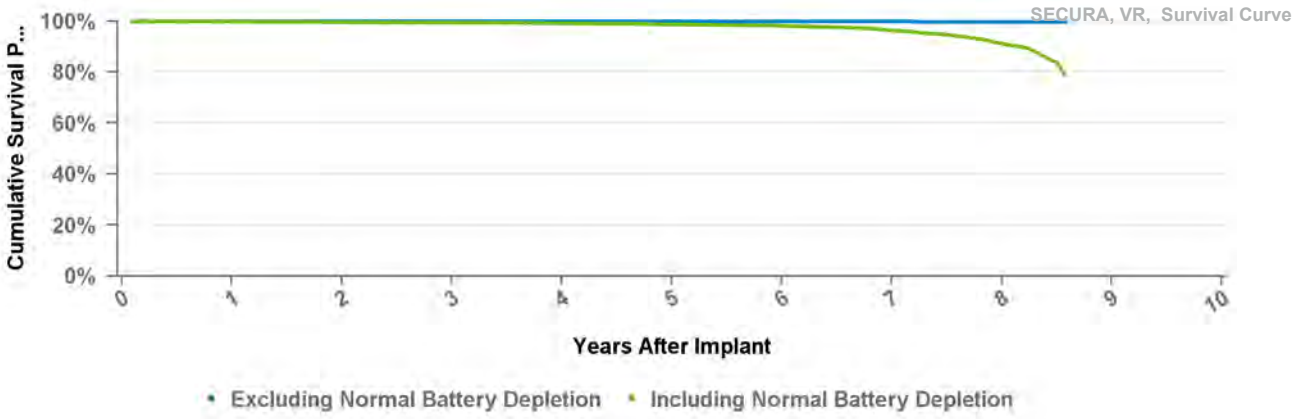
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.4%	99.1%	98.2%	95.5%	88.9%	75.2%	43.0%	32.4%
Effective Sample Size	45362	42511	39918	37006	31897	24297	11000	802	376

D234VRC Secura VR

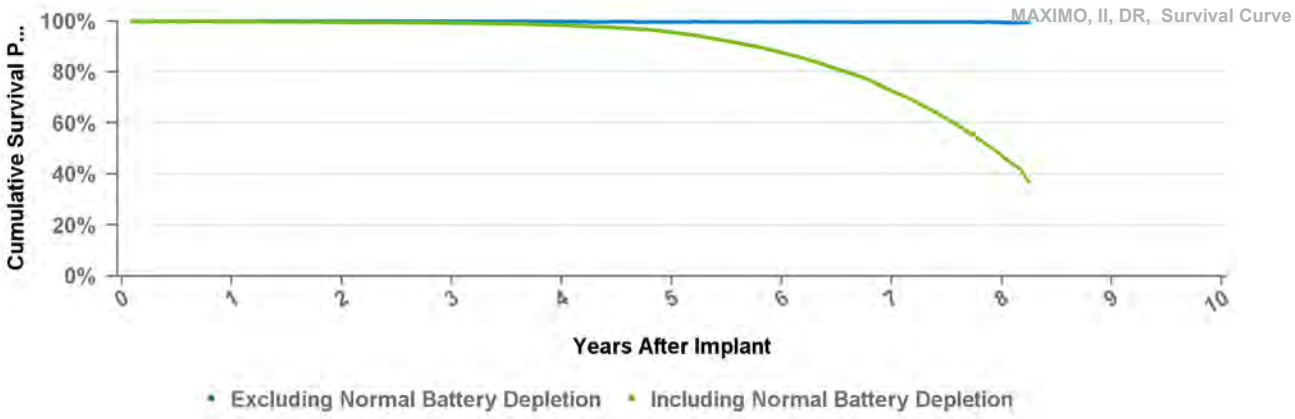
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.4%	99.1%	98.7%	98.1%	96.3%	91.2%	78.7%
Effective Sample Size	18304	17100	16122	14989	12812	10495	6544	2116	252

D264DRM Maximo II DR

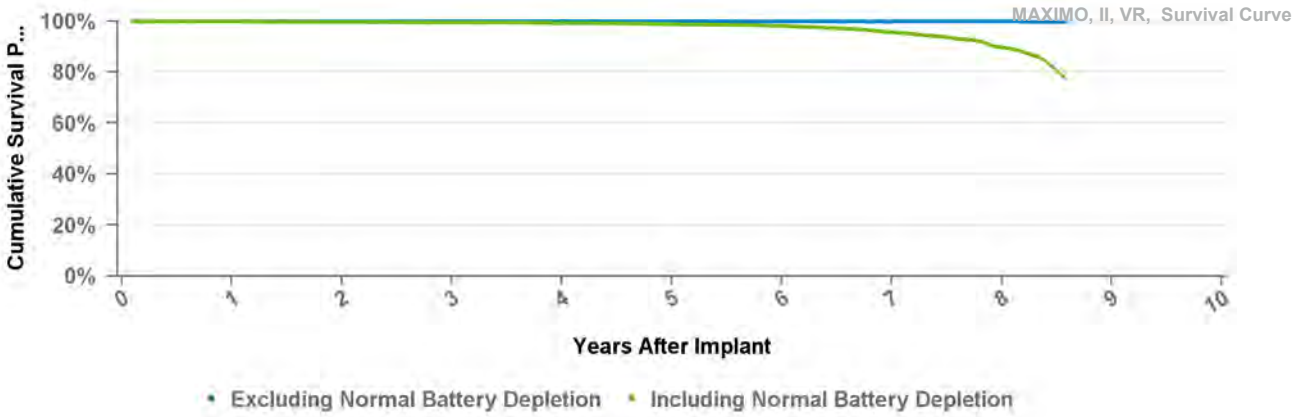
US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	4	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%
Including NBD	99.8%	99.5%	99.2%	98.4%	95.6%	87.6%	72.5%	47.2%	37.0%
Effective Sample Size	17578	16424	15440	14309	12256	8828	4183	688	198

D264VRM Maximo II VR

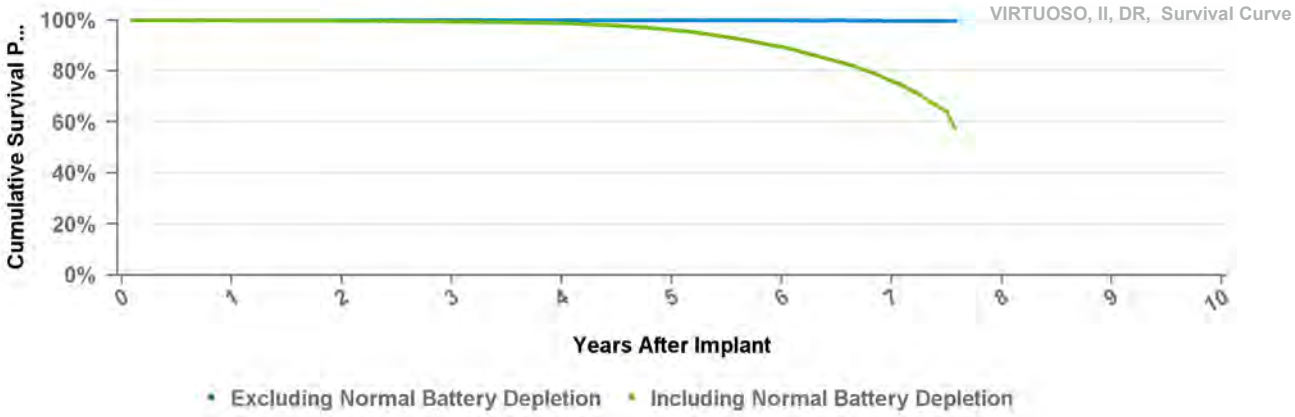
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.5%	99.3%	98.8%	98.1%	95.6%	89.7%	77.2%
Effective Sample Size	11249	10546	9933	9214	8053	6489	4099	1433	167

D274DRG Virtuoso II DR

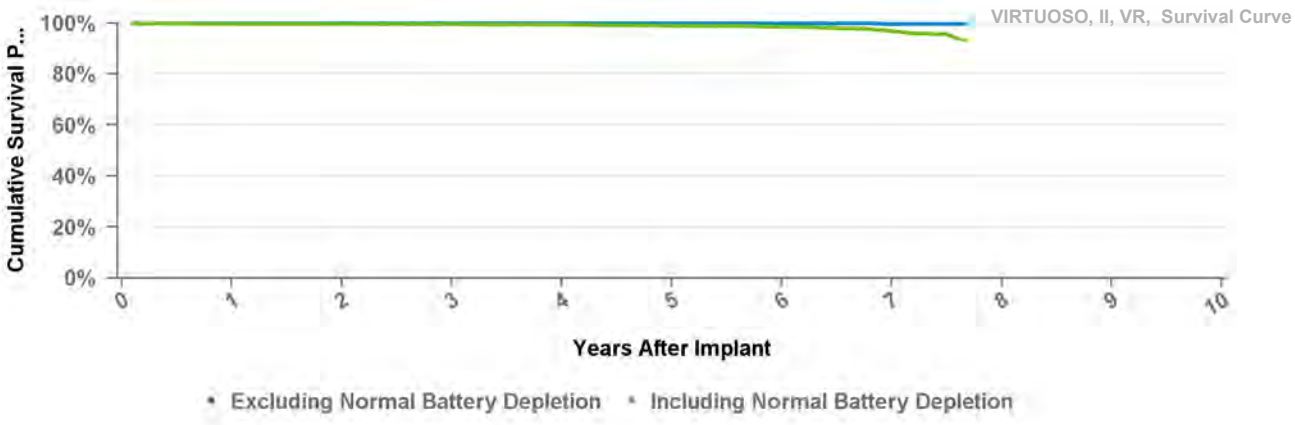
US Market Release	Aug-09	**Total Malfunctions**	**34**
CE Approval Date		**Therapy Function Not Compromised**	**28**
Registered USA Implants	22,235	Battery Malfunction	9
Estimated Active USA Implants	9,666	Electrical Component	11
Normal Battery Depletions	1,803	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**6**
		Battery Malfunction	3
		Electrical Component	2
		Other Malfunction	1



Years	1	2	3	4	5	6	7	at 91 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.7%
Including NBD	99.8%	99.7%	99.3%	98.7%	96.1%	89.5%	76.0%	57.6%
Effective Sample Size	19347	18169	17104	15898	14182	11149	4136	399

D274VRC Virtuoso II VR

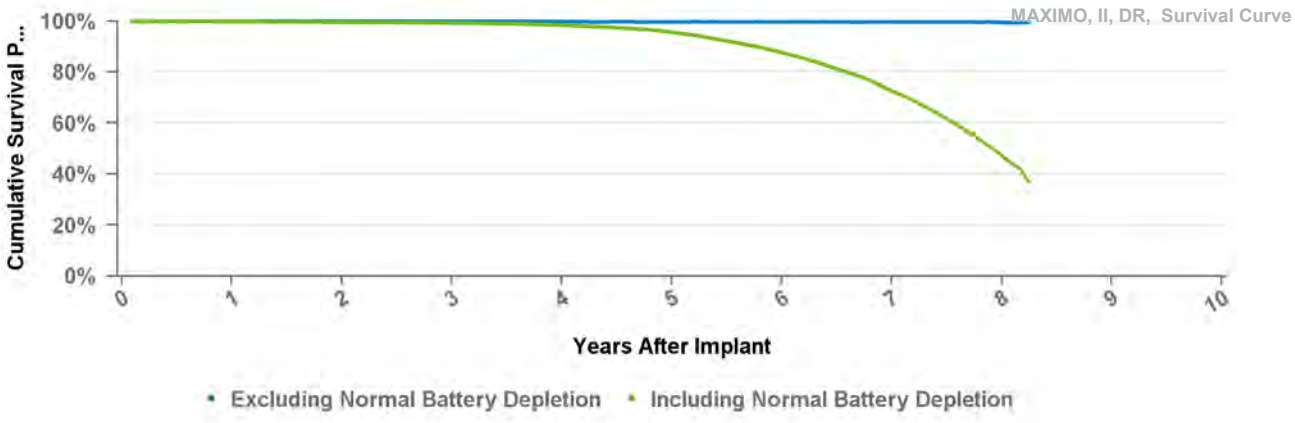
US Market Release	Aug-09	**Total Malfunctions**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	9,119	Battery Malfunction	6
Estimated Active USA Implants	5,864	Electrical Component	4
Normal Battery Depletions	97	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**2**
		Battery Malfunction	1
		Electrical Component	1



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.5%	99.4%	98.9%	98.5%	96.8%	93.2%
Effective Sample Size	7793	7318	6908	6428	5931	5149	2470	305

D284DRG Maximo II DR

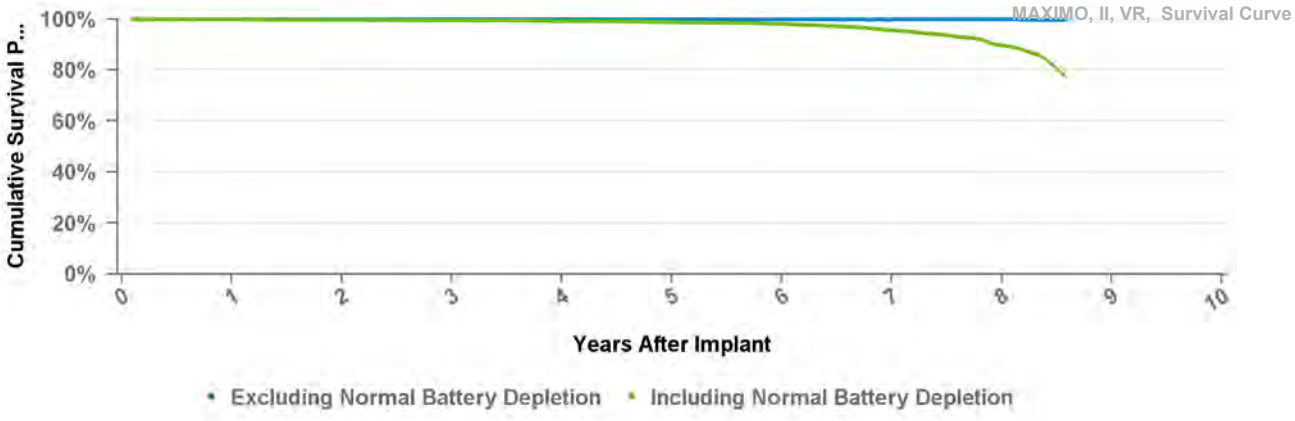
US Market Release	Sep-08	**Total Malfunctions**	**56**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**46**
Registered USA Implants	20,088	Battery Malfunction	1
Estimated Active USA Implants	8,185	Electrical Component	13
Normal Battery Depletions	2,313	Other Malfunction	2
		Poss Early Battery Depltn	30
		Therapy Function Compromised	**10**
		Battery Malfunction	4
		Electrical Component	5
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%	99.5%	99.5%
Including NBD	99.8%	99.5%	99.2%	98.4%	95.6%	87.6%	72.5%	47.2%	37.0%
Effective Sample Size	17578	16424	15440	14309	12256	8828	4183	688	198

D284VRC Maximo II VR

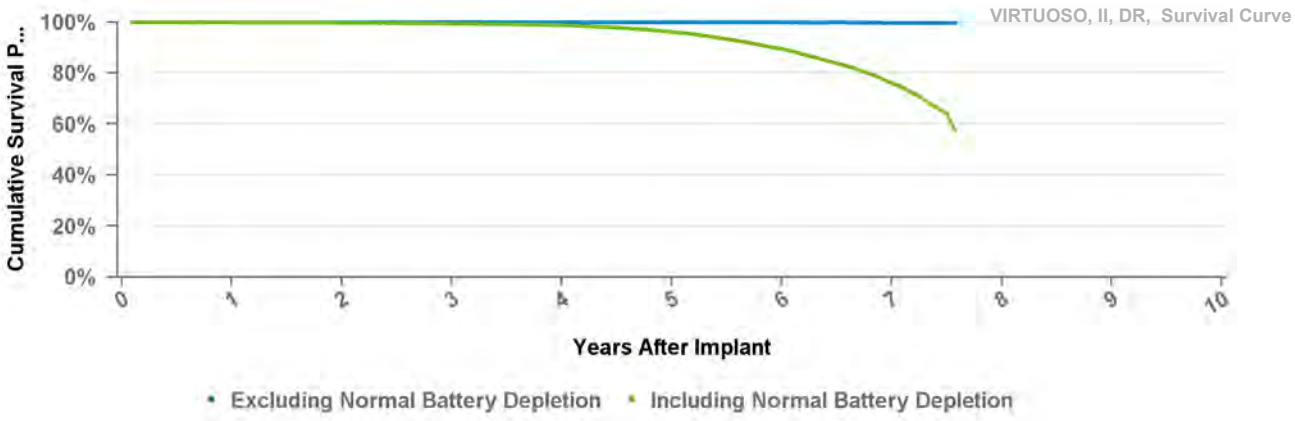
US Market Release	Sep-08	**Total Malfunctions**	**21**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**17**
Registered USA Implants	13,036	Battery Malfunction	5
Estimated Active USA Implants	7,839	Electrical Component	6
Normal Battery Depletions	333	Poss Early Battery Depltn	3
		Software Malfunction	3
		Therapy Function Compromised	**4**
		Battery Malfunction	1
		Electrical Component	2
		Software Malfunction	1



Years	1	2	3	4	5	6	7	8	at 103 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.8%	99.6%	99.5%	99.3%	98.8%	98.1%	95.6%	89.7%	77.2%
Effective Sample Size	11249	10546	9933	9214	8053	6489	4099	1433	167

D294DRG Virtuoso II DR

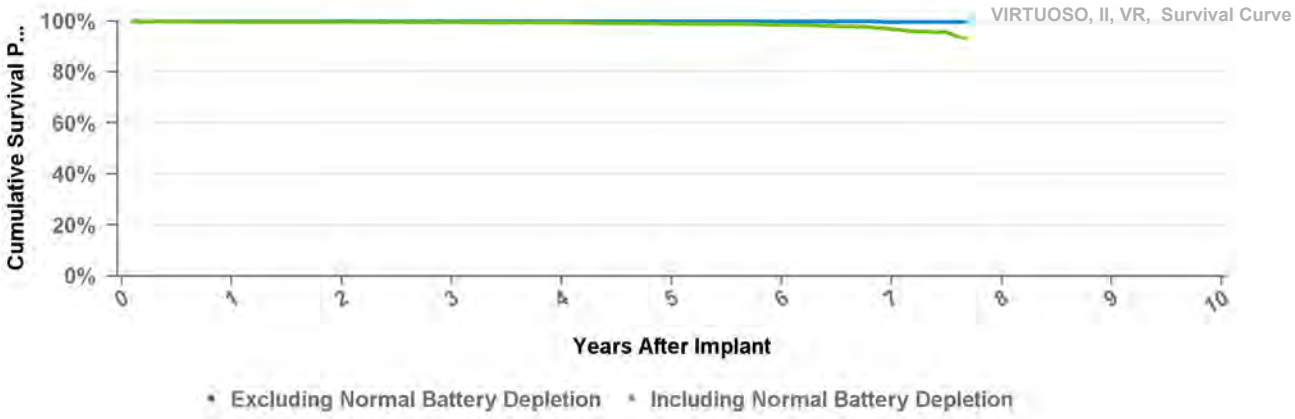
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 91 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.7%
Including NBD	99.8%	99.7%	99.3%	98.7%	96.1%	89.5%	76.0%	57.6%
Effective Sample Size	19347	18169	17104	15898	14182	11149	4136	399

D294VRC Virtuoso II VR

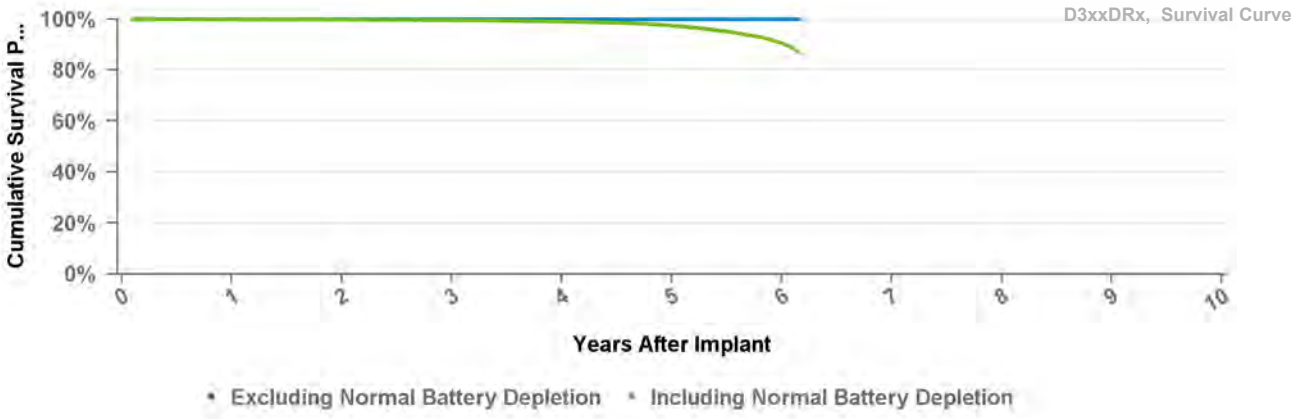
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 92 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.7%	99.7%	99.5%	99.4%	98.9%	98.5%	96.8%	93.2%
Effective Sample Size	7793	7318	6908	6428	5931	5149	2470	305

D314DRG Protecta XT DR

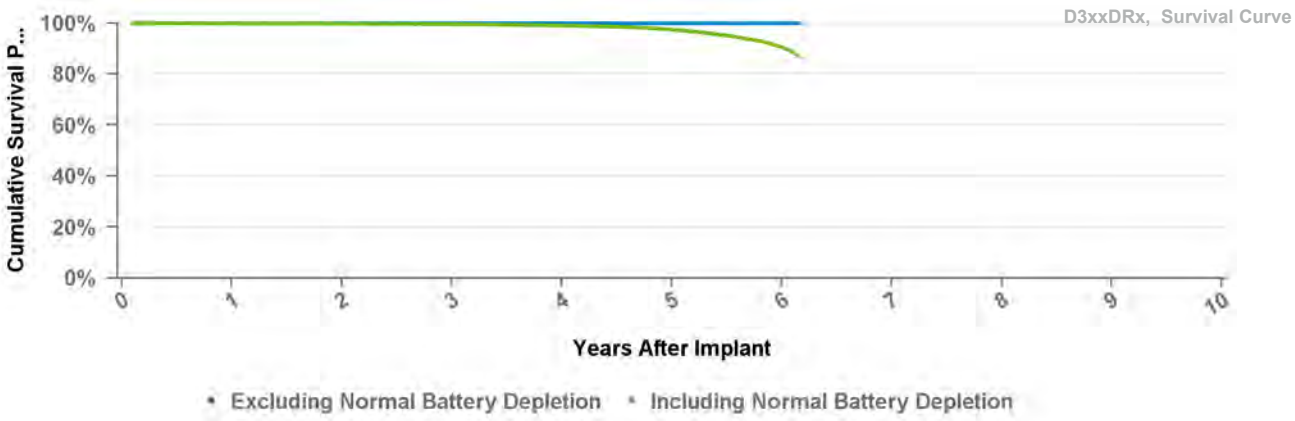
US Market Release	Mar-11	**Total Malfunctions**	**42**
CE Approval Date		**Therapy Function Not Compromised**	**34**
Registered USA Implants	34,828	Battery Malfunction	5
Estimated Active USA Implants	24,912	Electrical Component	24
Normal Battery Depletions	609	Other Malfunction	1
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**8**
		Battery Malfunction	1
		Electrical Component	7



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D314DRM Protecta XT DR

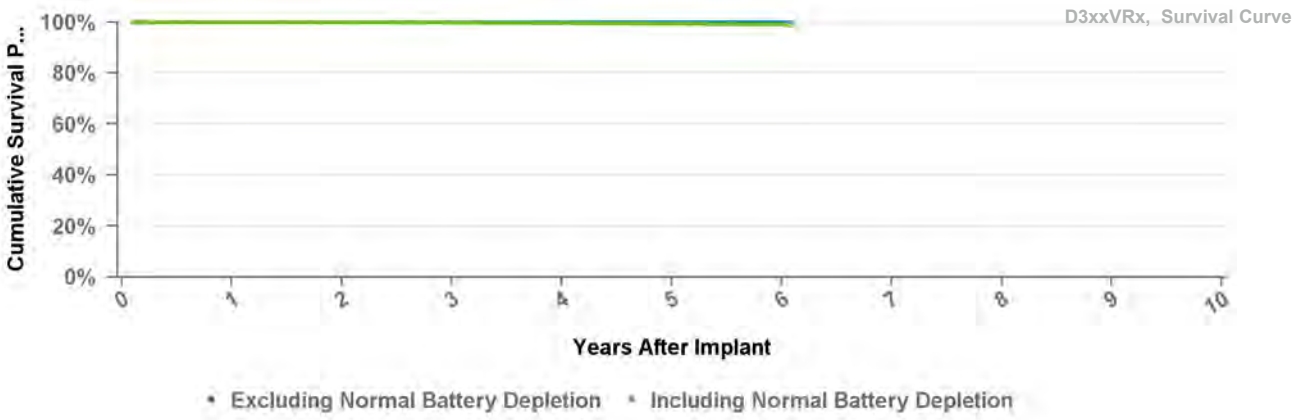
US Market Release	Nov-11	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	13,922	Electrical Component	11
Estimated Active USA Implants	11,276	Other Malfunction	1
Normal Battery Depletions	80	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D314VRG Protecta XT VR

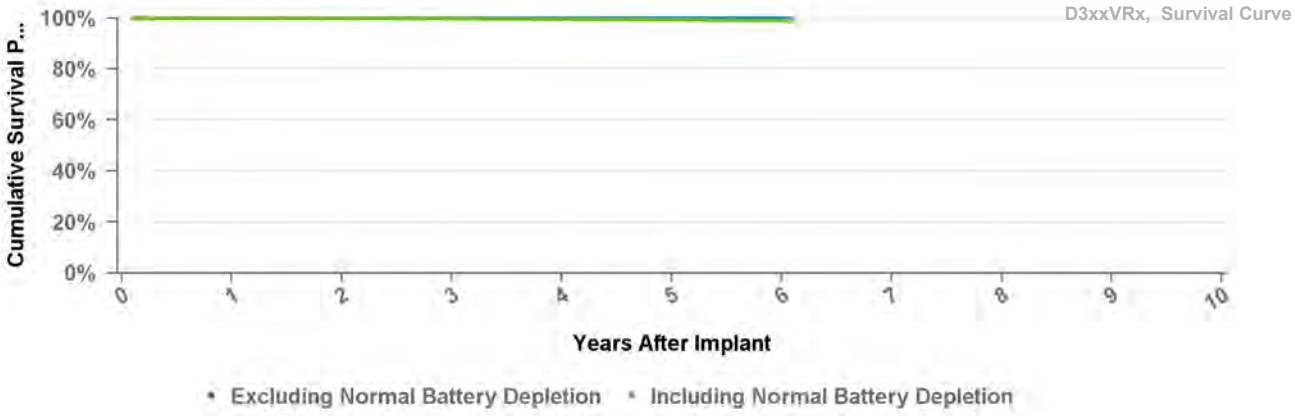
US Market Release	Mar-11	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	14,213	Battery Malfunction	2
Estimated Active USA Implants	11,015	Electrical Component	8
Normal Battery Depletions	44	Other Malfunction	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D314VRM Protecta XT VR

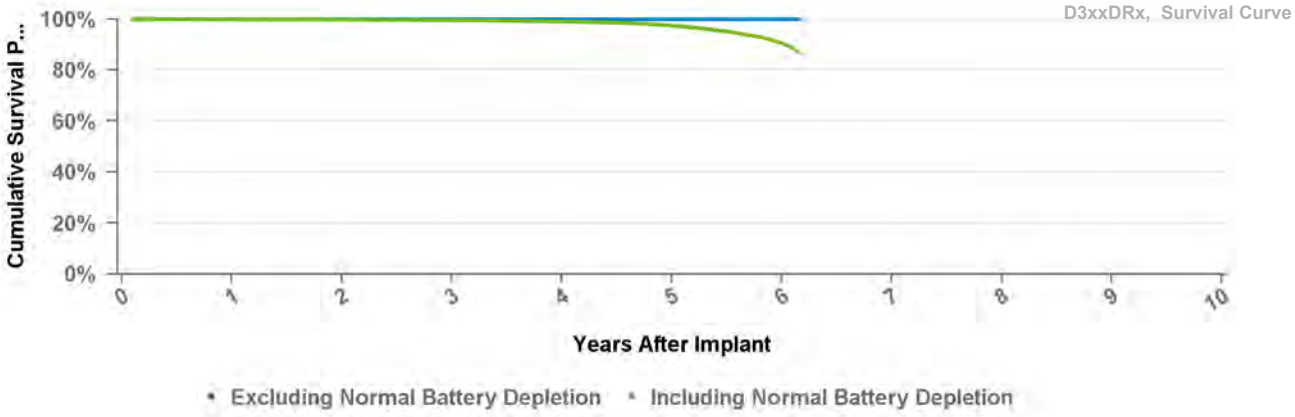
US Market Release	May-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,372	Electrical Component	2
Estimated Active USA Implants	6,031	**Therapy Function Compromised**	**1**
Normal Battery Depletions	16	Electrical Component	1



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D334DRG Protecta DR

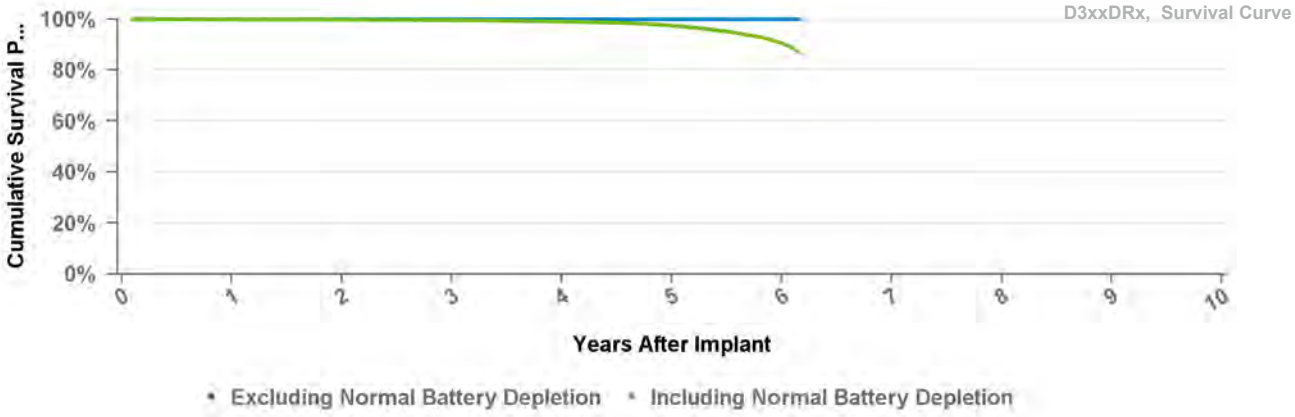
US Market Release	Mar-11	**Total Malfunctions**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	10,694	Battery Malfunction	1
Estimated Active USA Implants	7,687	Electrical Component	5
Normal Battery Depletions	256	Poss Early Battery Depltn	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D334DRM Protecta DR

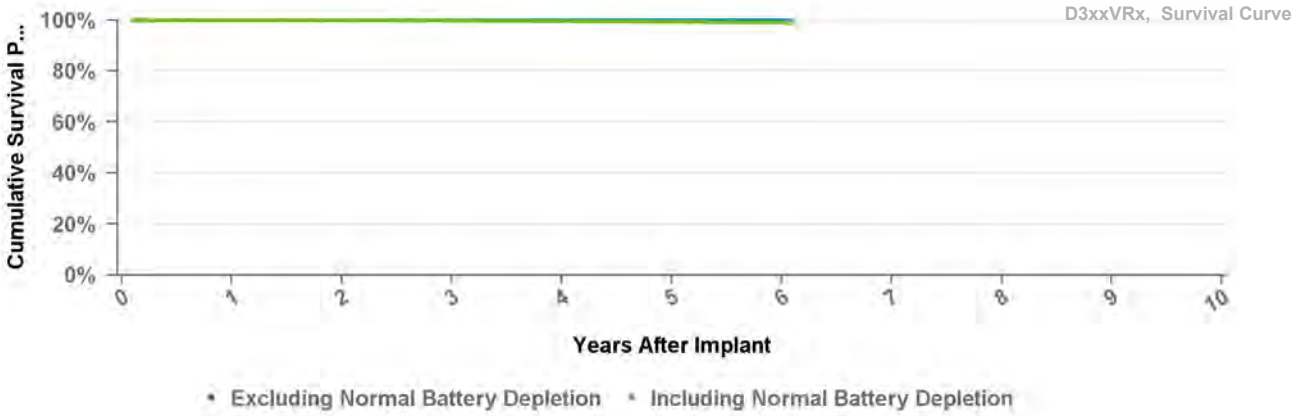
US Market Release	Nov-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	2,992		
Estimated Active USA Implants	2,490	**Therapy Function Compromised**	
Normal Battery Depletions	30		



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D334VRG Protecta VR

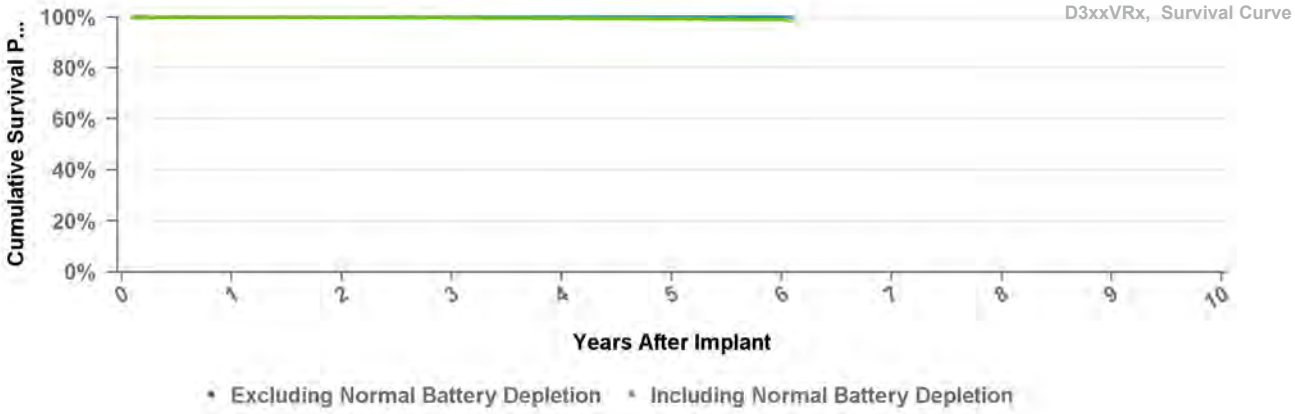
US Market Release	Mar-11	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	6,484	Battery Malfunction	1
Estimated Active USA Implants	5,137	Electrical Component	3
Normal Battery Depletions	13	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D334VRM Protecta VR

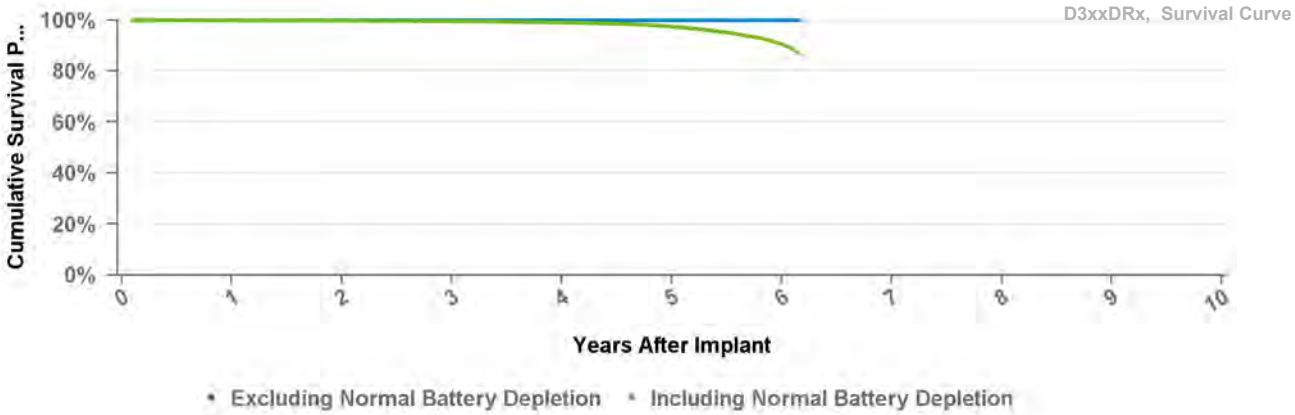
US Market Release	May-12	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,162	Other Malfunction	1
Estimated Active USA Implants	1,793	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D354DRG Protecta XT DR

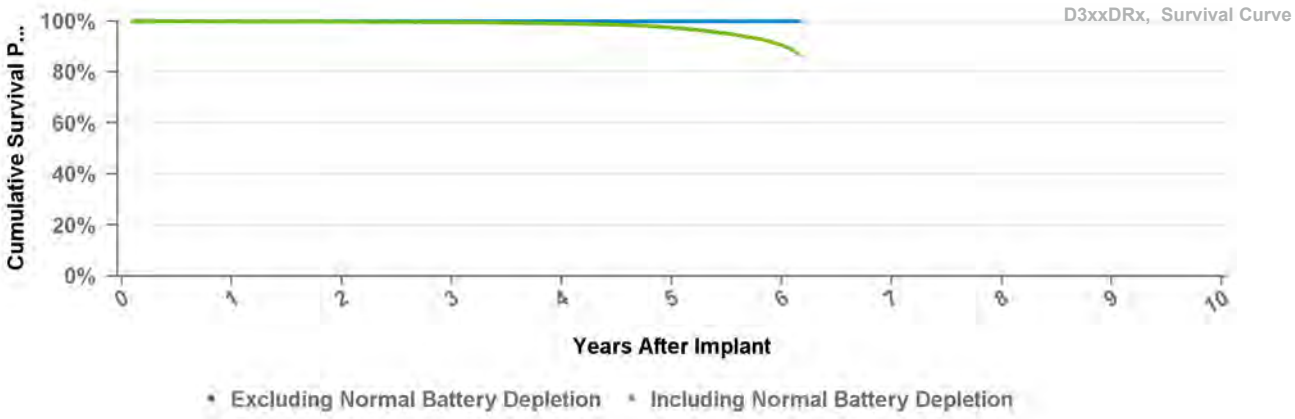
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D354DRM Protecta XT DR

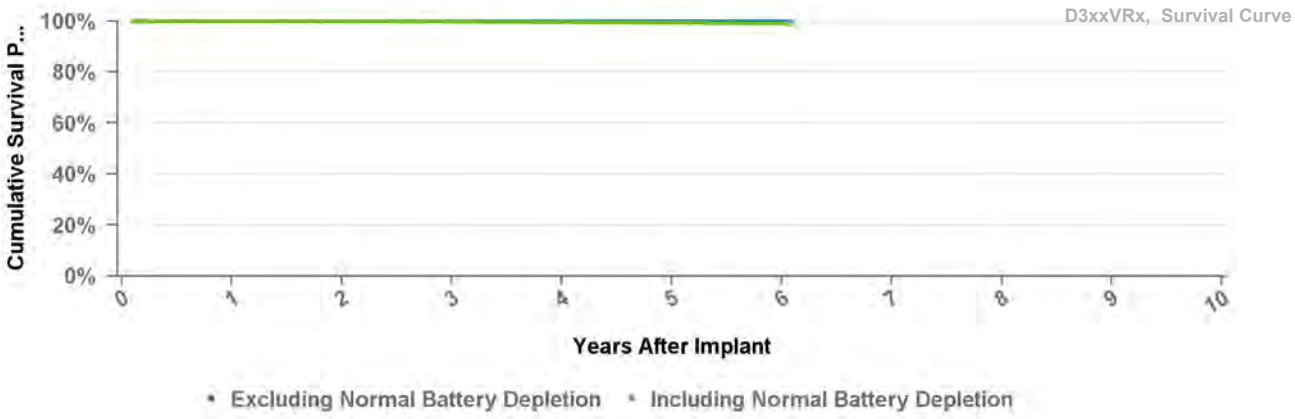
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D354VRG Protecta XT VR

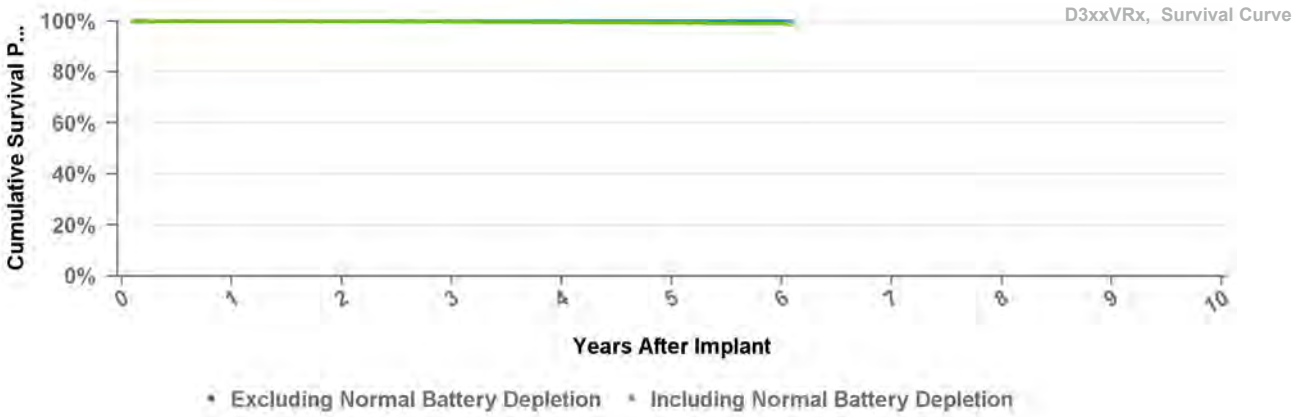
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D354VRM Protecta XT VR

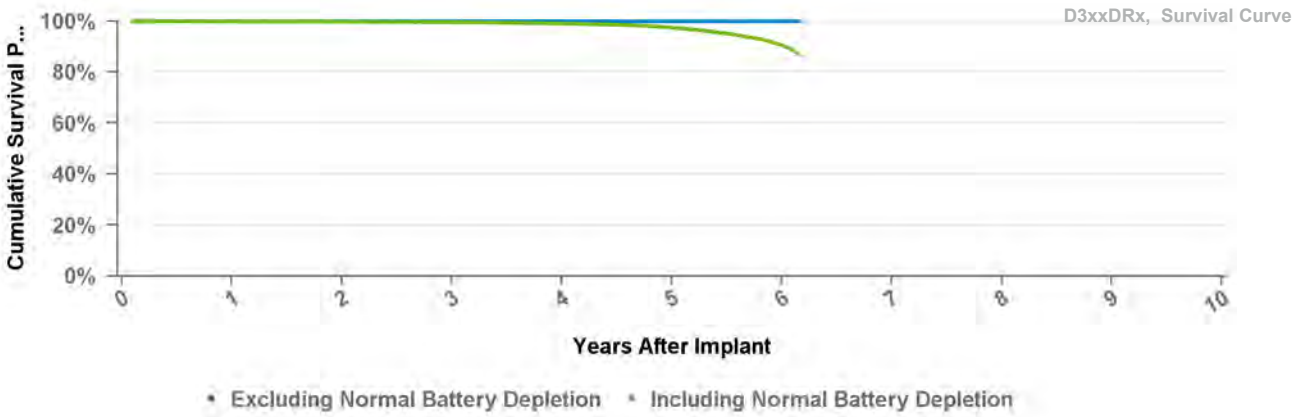
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	0	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D364DRG Protecta DR

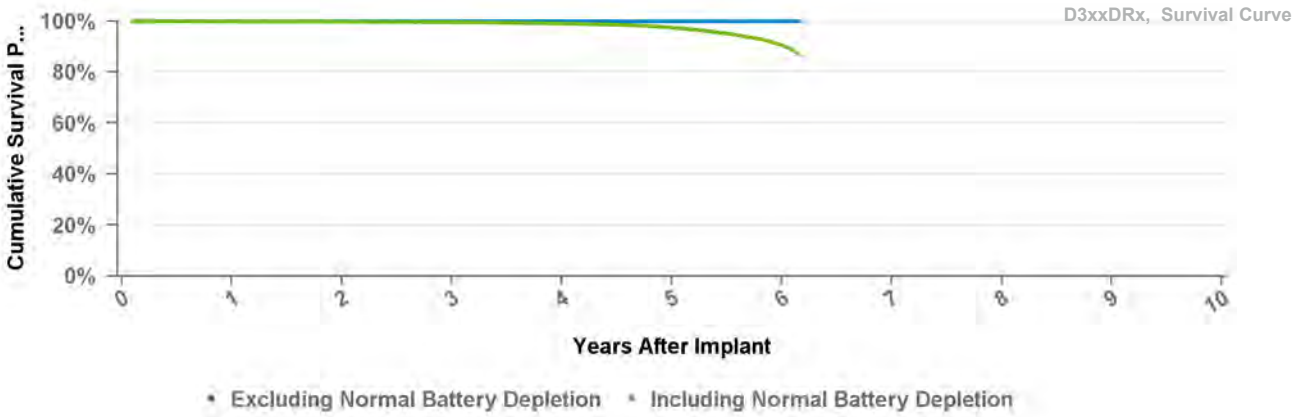
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D364DRM Protecta DR

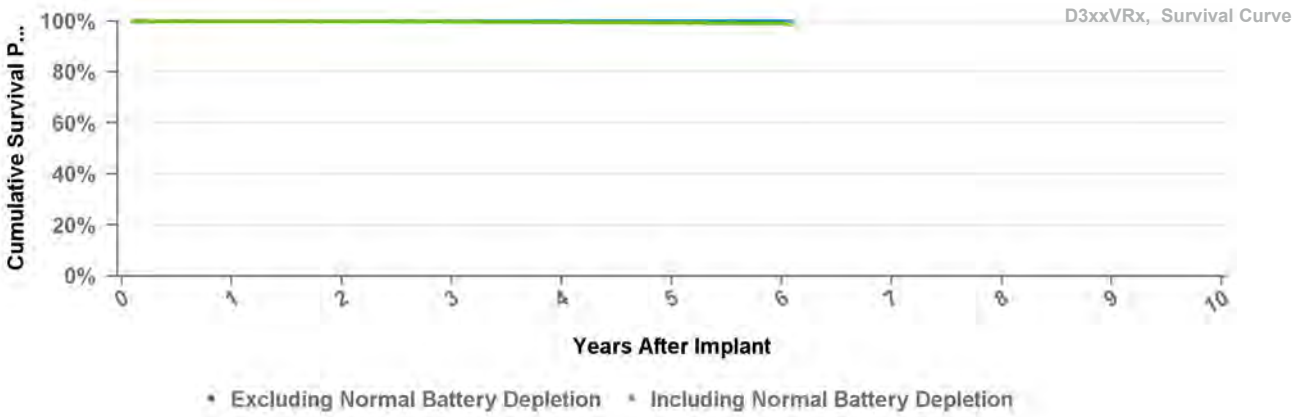
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D364VRG Protecta VR

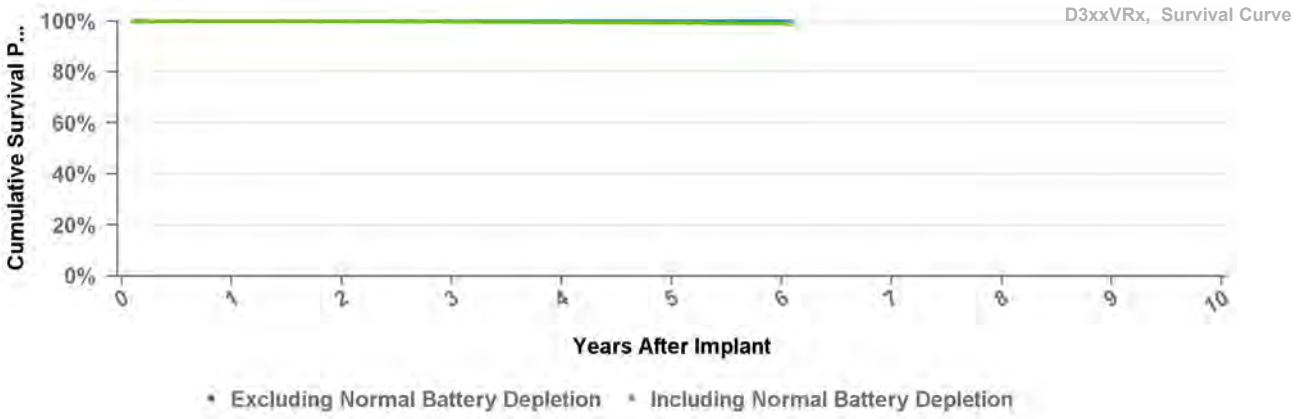
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D364VRM Protecta VR

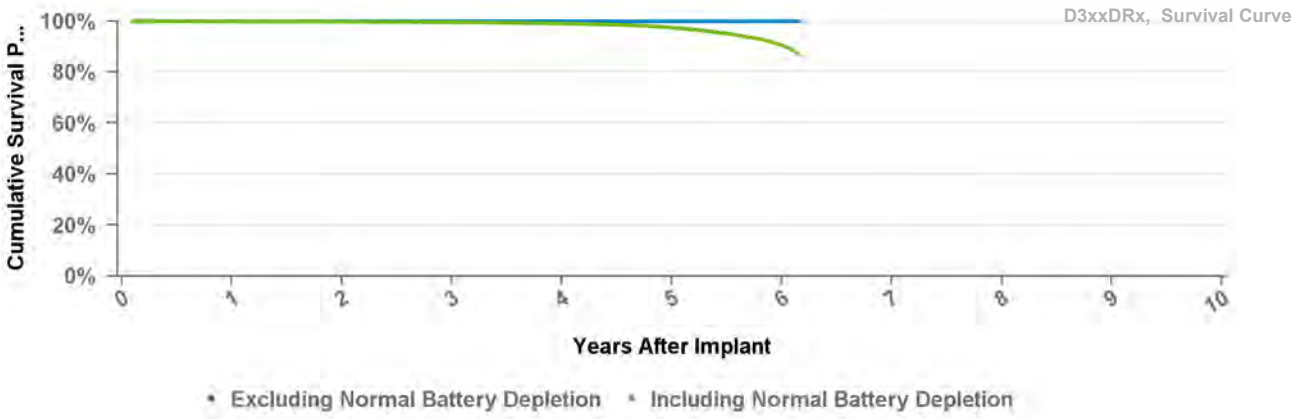
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D384DRG Cardia DR

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



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

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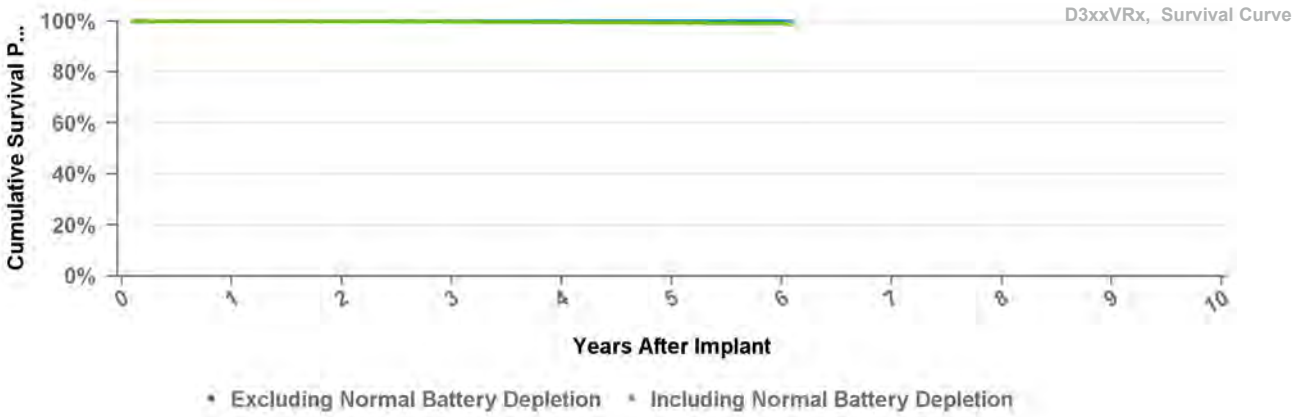
D384VRG Cardia VR

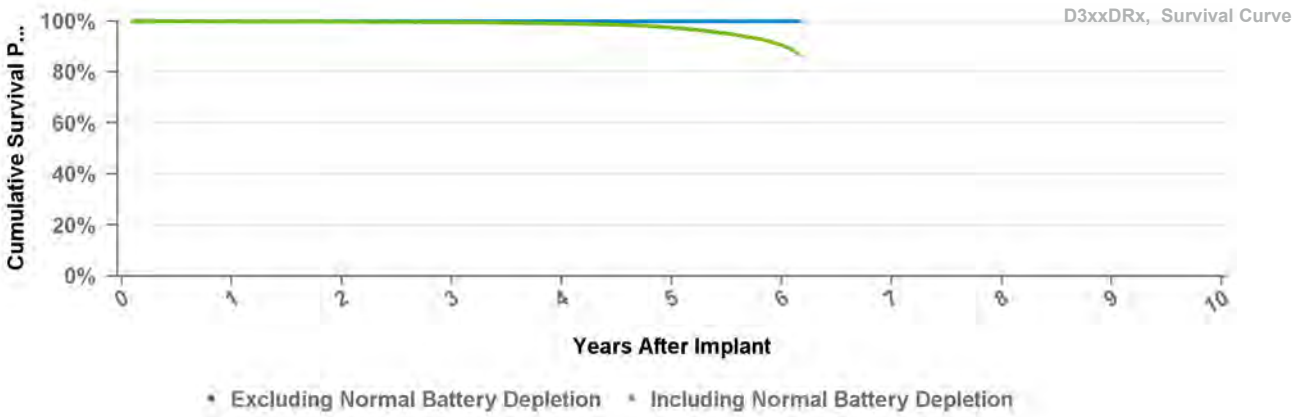
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

D394DRG Egida DR

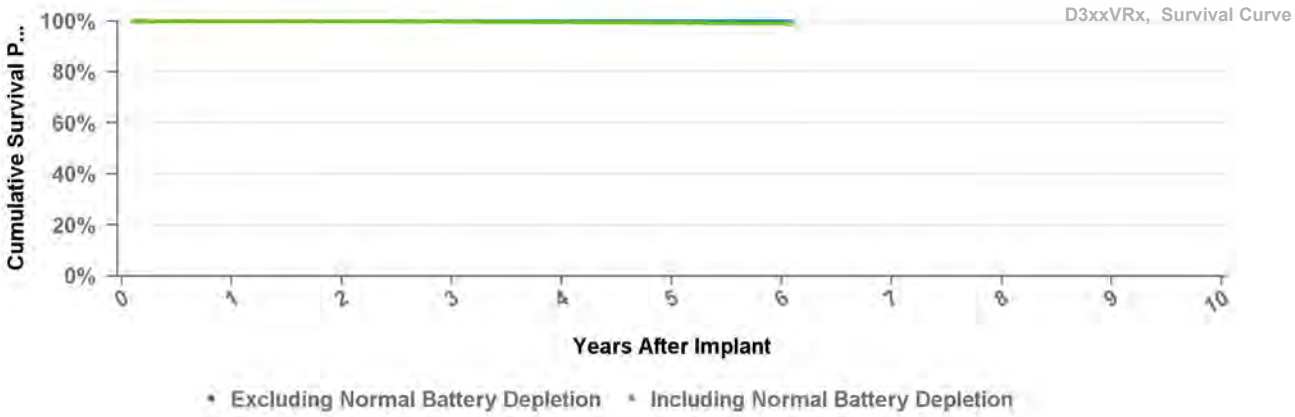
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.0%	97.4%	90.4%	86.3%
Effective Sample Size	55768	52385	48882	43367	23552	2513	358

D394VRG Egida VR

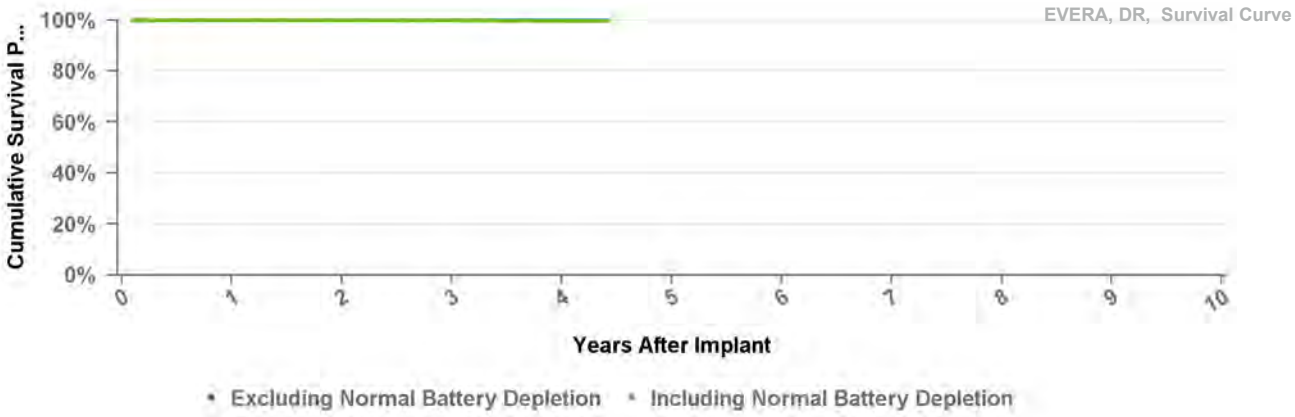
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 73 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	99.1%	98.4%
Effective Sample Size	26695	25014	23263	20230	10338	1000	472

DDBB1D1 Evera XT

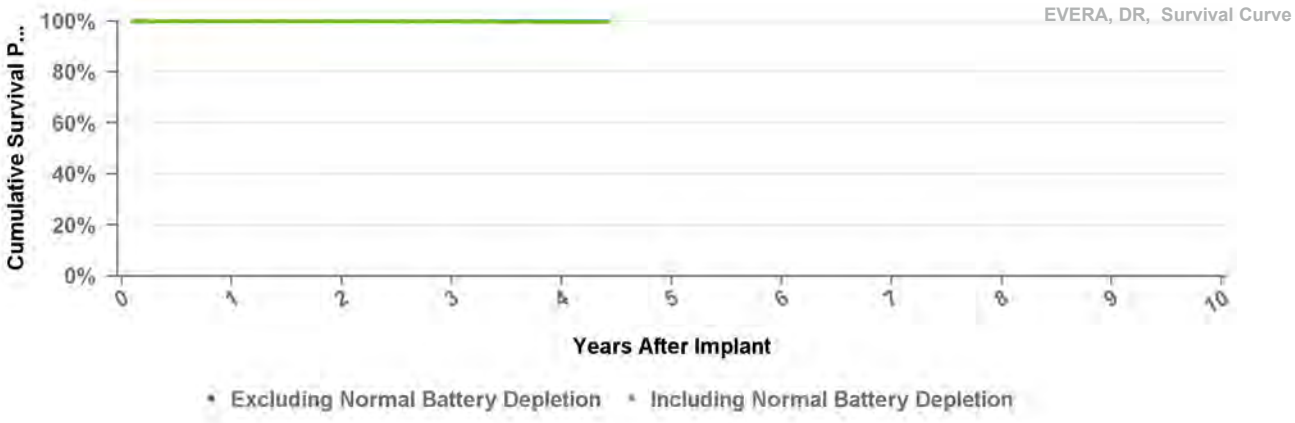
US Market Release	Apr-13	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	38,868	Battery Malfunction	3
Estimated Active USA Implants	35,171	Electrical Component	6
Normal Battery Depletions	27	**Therapy Function Compromised**	**3**
		Battery Malfunction	1
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDBB1D4 Evera XT

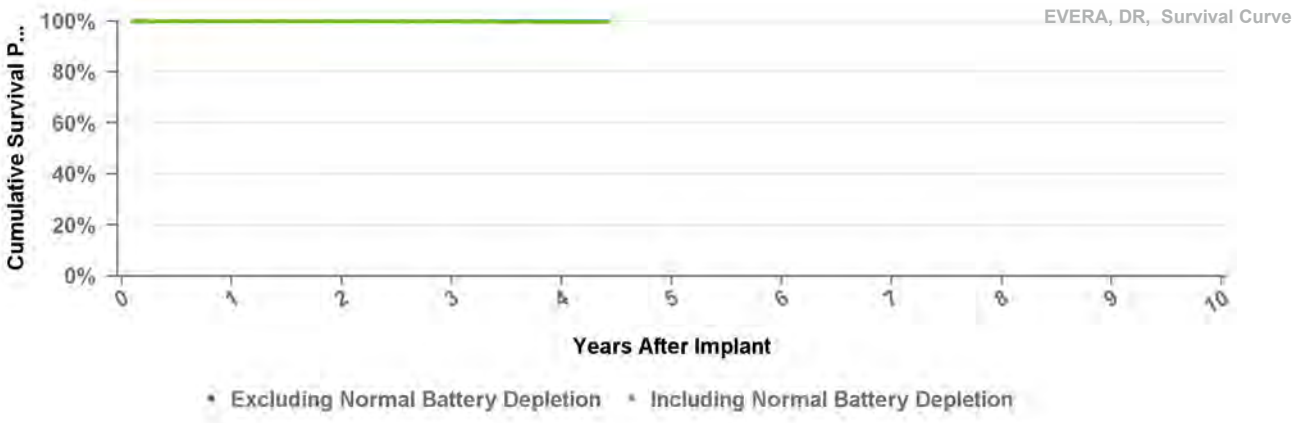
US Market Release	Apr-13	**Total Malfunctions**	**11**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	29,303	Battery Malfunction	1
Estimated Active USA Implants	26,727	Electrical Component	4
Normal Battery Depletions	13	Electrical Interconnect	1
		Other Malfunction	1
		Therapy Function Compromised	**4**
		Battery Malfunction	2
		Electrical Component	2



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDBB2D1 Evera XT

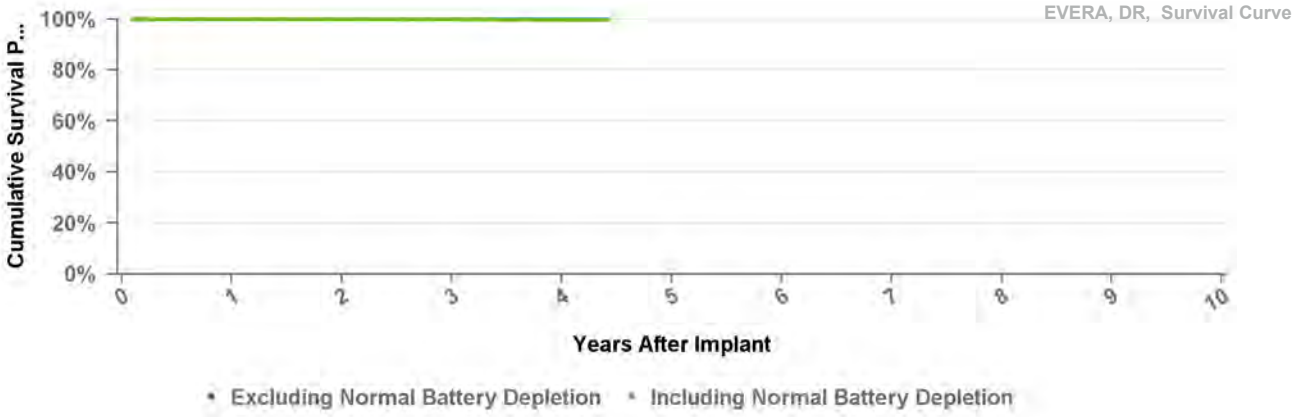
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDBB2D4 Evera XT

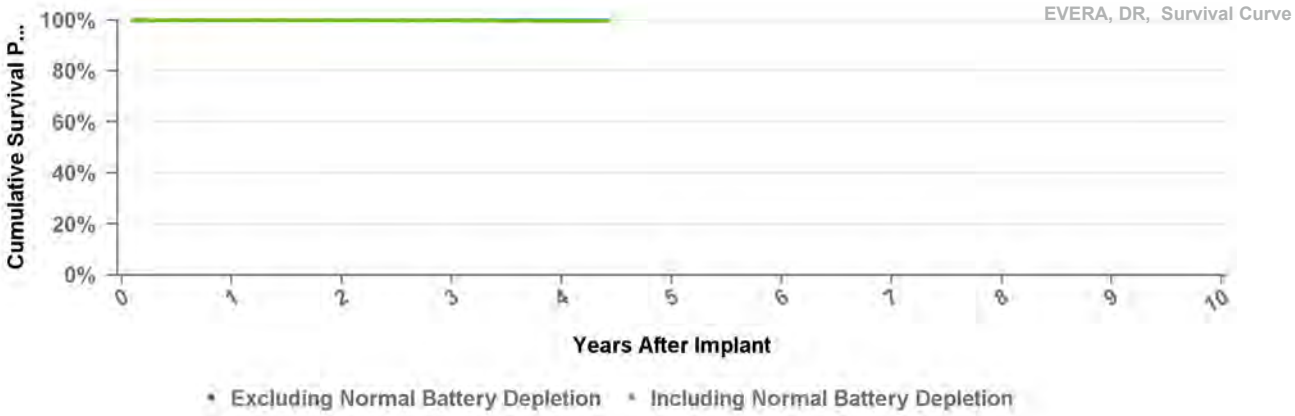
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDBC3D1 Evera S

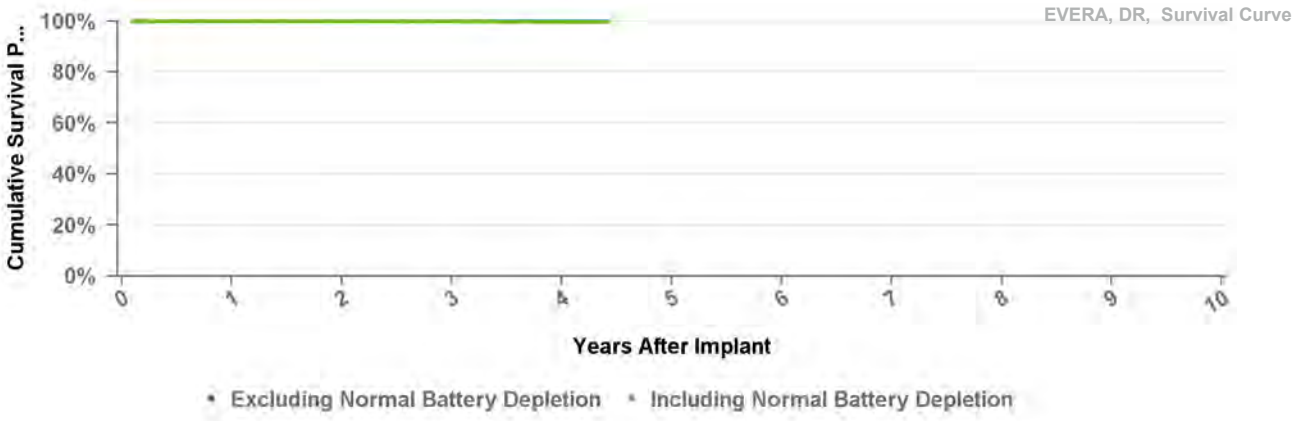
US Market Release	Apr-13	**Total Malfunctions**	**2**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,596	Electrical Component	2
Estimated Active USA Implants	6,858	**Therapy Function Compromised**	**0**
Normal Battery Depletions	6		



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDBC3D4 Evera S

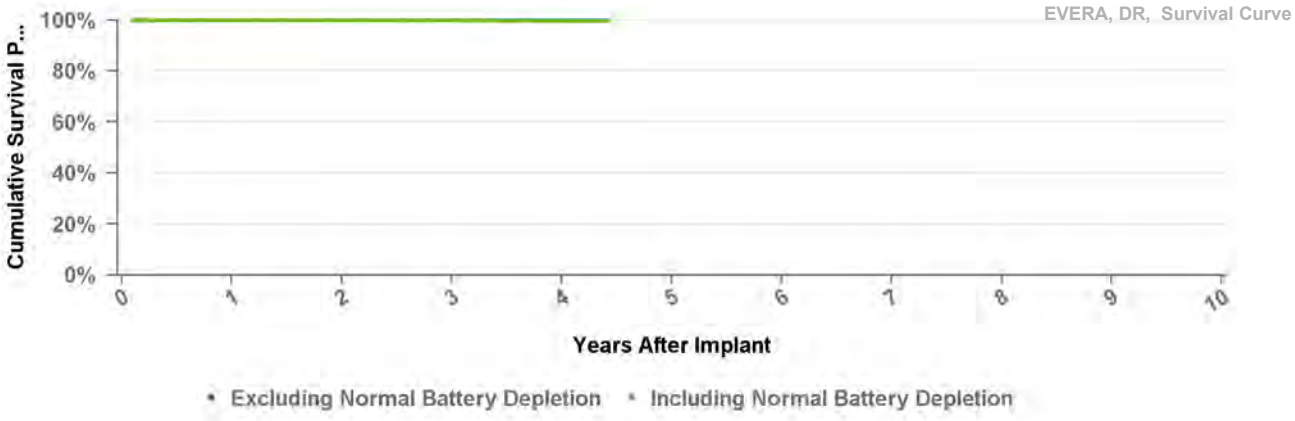
US Market Release	Apr-13	**Total Malfunctions**	**4**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**4**
Registered USA Implants	5,637	Battery Malfunction	2
Estimated Active USA Implants	5,109	Electrical Component	2
Normal Battery Depletions	2	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMB1D1 Evera MRI XT

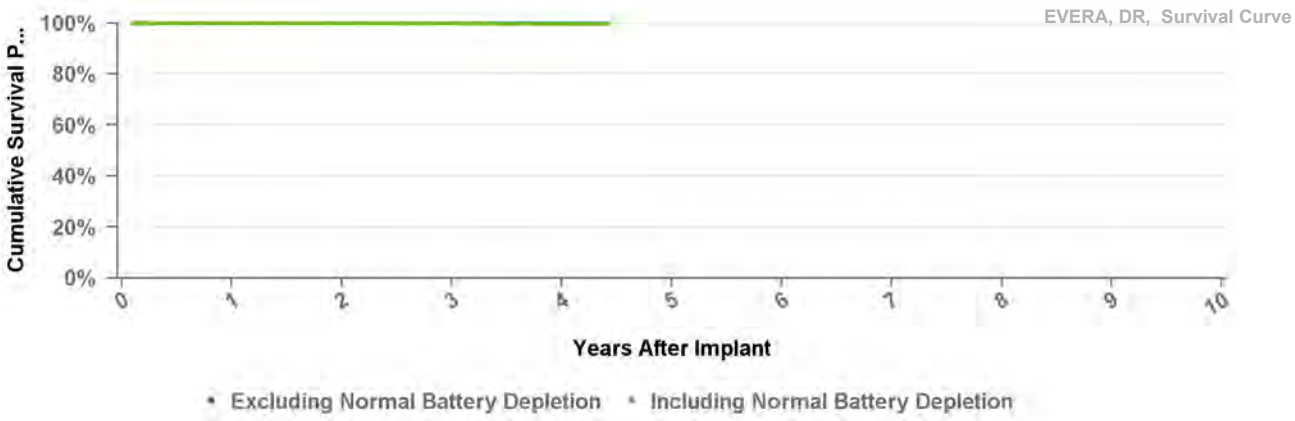
US Market Release	Oct-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	7,945	Other Malfunction	2
Estimated Active USA Implants	7,824	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMB1D4 Evera MRI XT

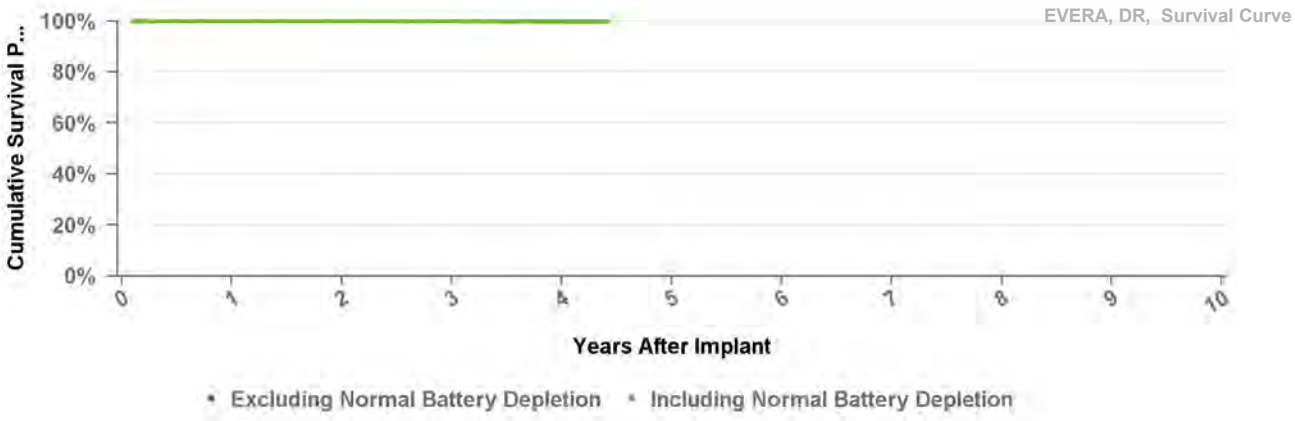
US Market Release	Sep-15	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	29,770	Electrical Component	5
Estimated Active USA Implants	28,861	Electrical Interconnect	1
Normal Battery Depletions	7	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMB2D1 Evera MRI XT

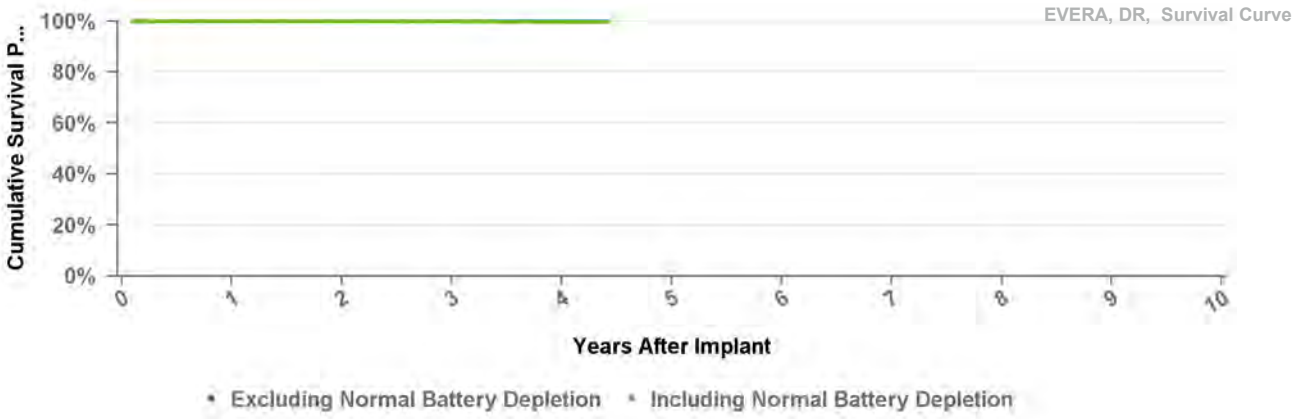
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	29		
Estimated Active USA Implants	29	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMB2D4 Evera MRI XT

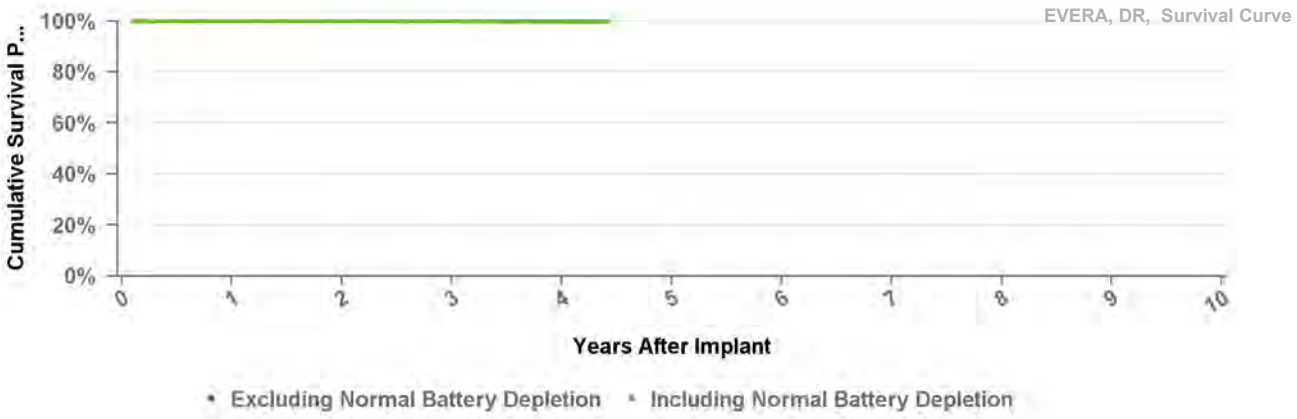
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMC3D1 Evera MRI S

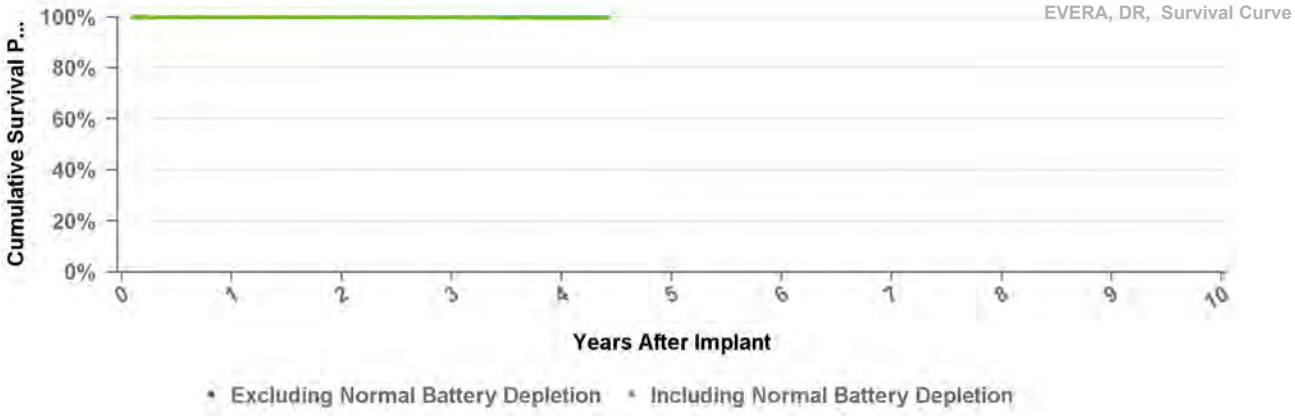
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	592		
Estimated Active USA Implants	587	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DDMC3D4 Evera MRI

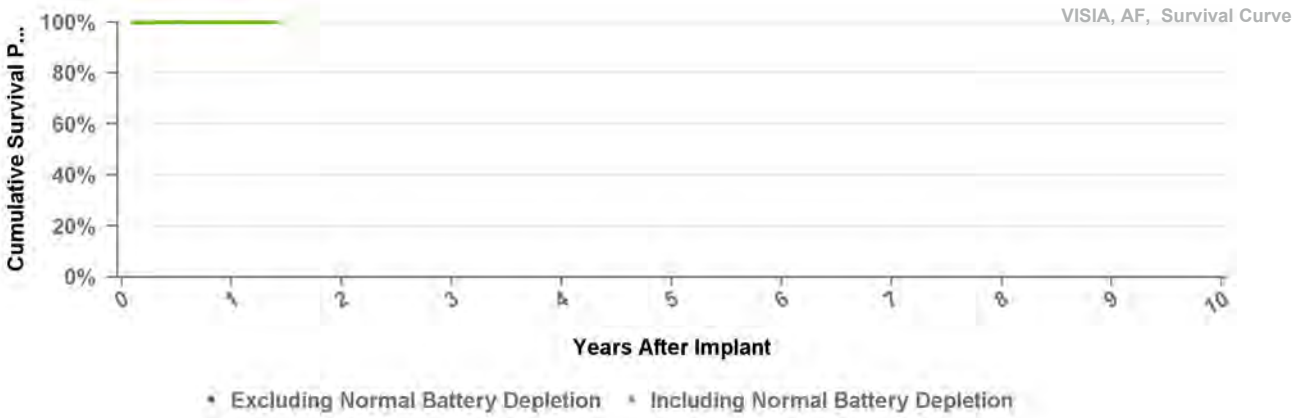
US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,938	Electrical Component	1
Estimated Active USA Implants	1,873	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	85760	54454	28570	6296	145

DVAB1D1 Visia AF

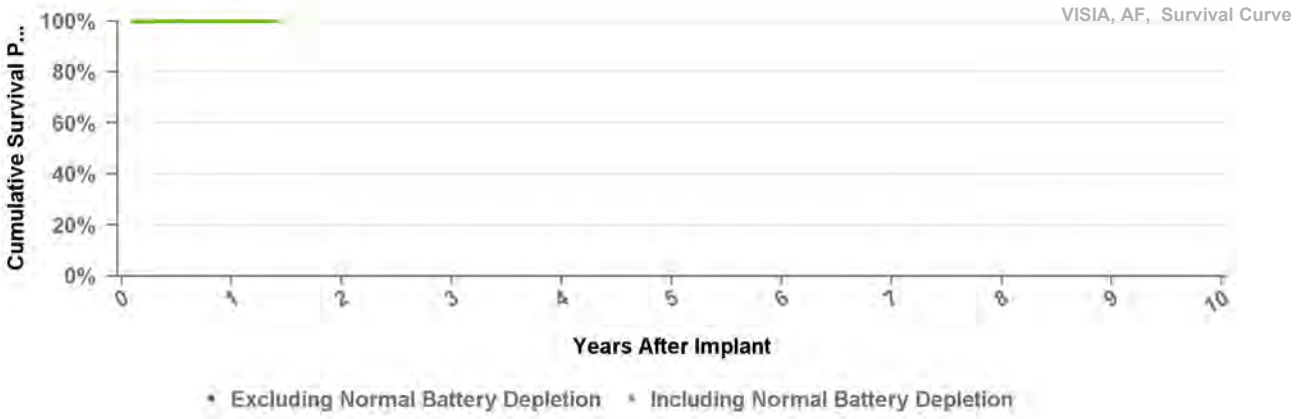
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,757		
Estimated Active USA Implants	1,702	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVAB1D4 Visia AF

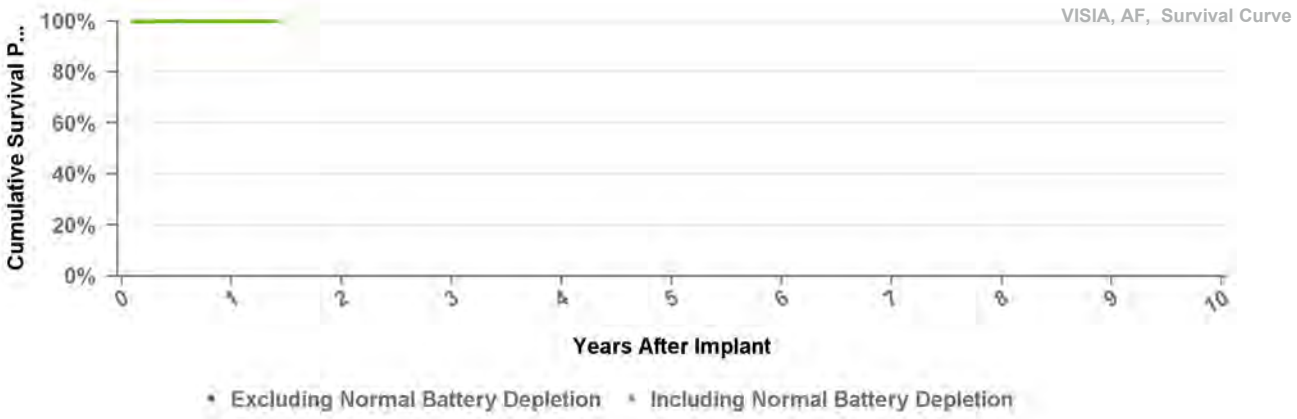
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,292		
Estimated Active USA Implants	1,263	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVAB2D1 Visia AF XT

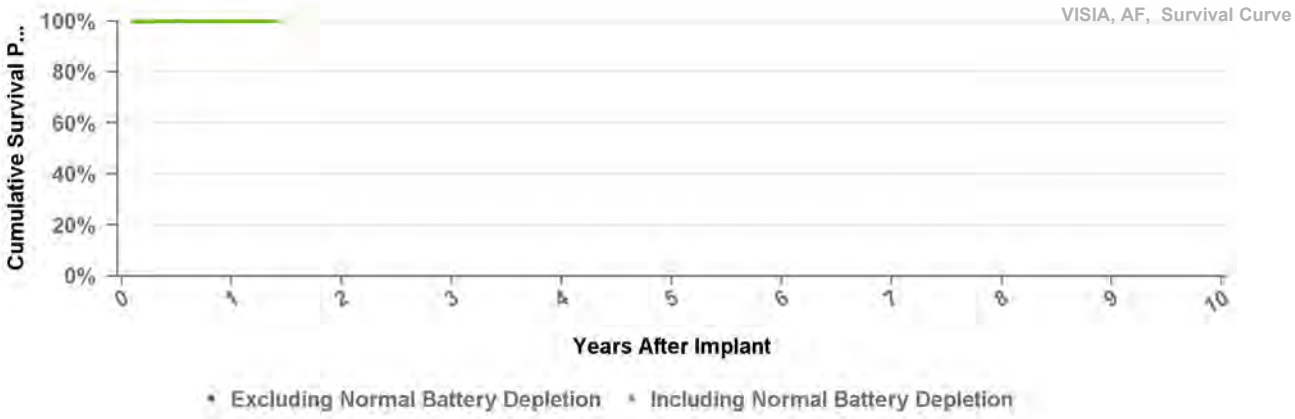
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVAC3D1 Visia AF S

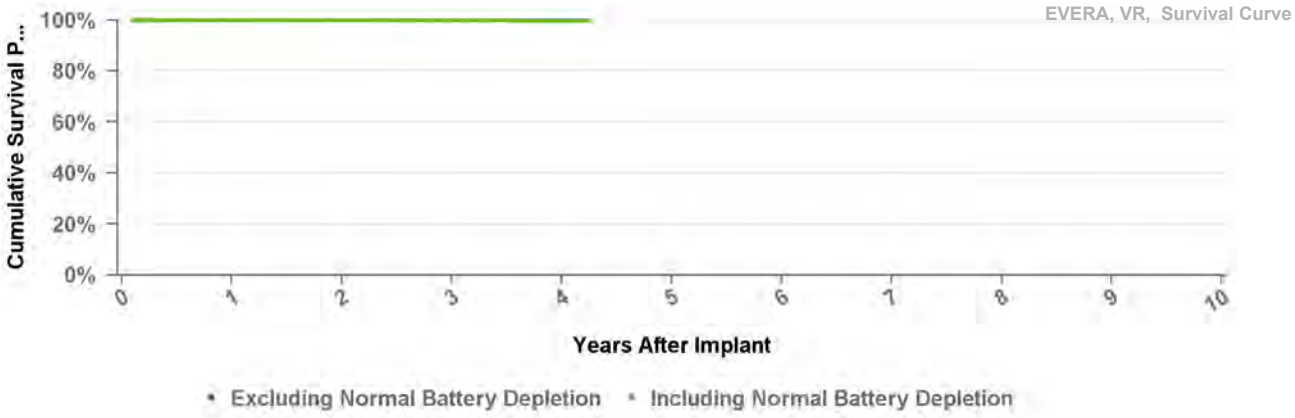
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVBB1D1 Evera XT

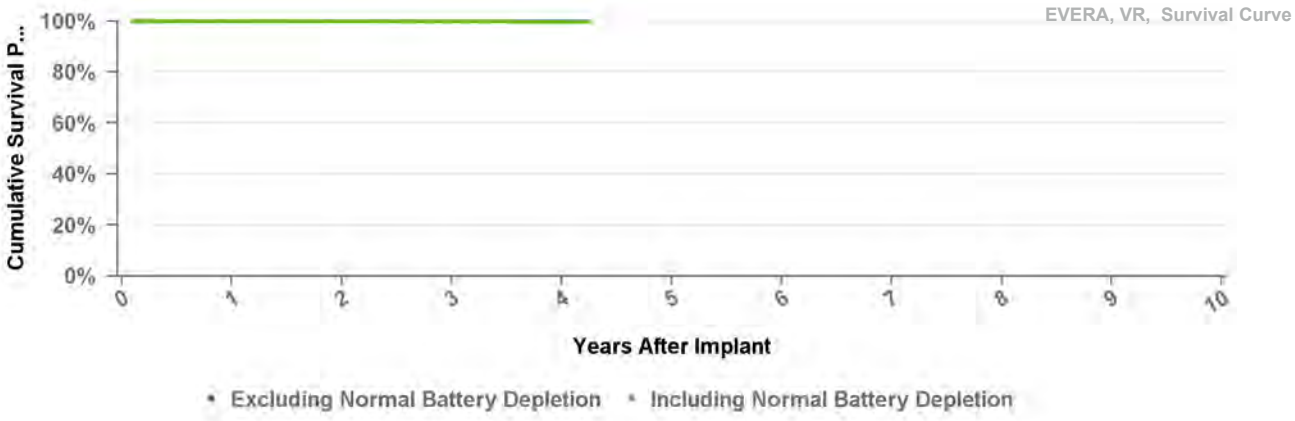
US Market Release	Apr-13	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	16,000	Battery Malfunction	1
Estimated Active USA Implants	14,331	Electrical Component	4
Normal Battery Depletions	9	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVBB1D4 Evera XT

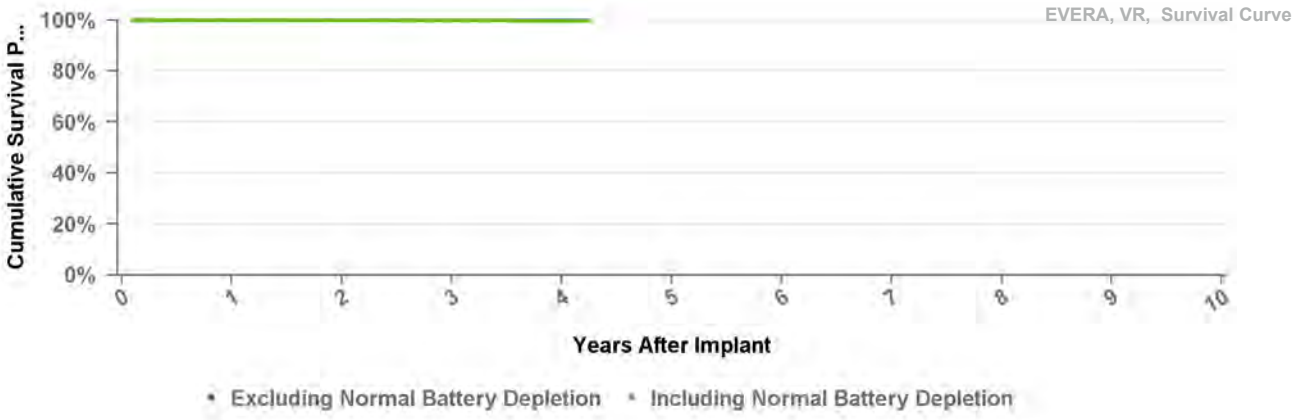
US Market Release	Apr-13	**Total Malfunctions**	**16**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	22,296	Battery Malfunction	4
Estimated Active USA Implants	20,280	Electrical Component	7
Normal Battery Depletions	7	Other Malfunction	2
		Therapy Function Compromised	**3**
		Battery Malfunction	3



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVBB2D1 Evera XT

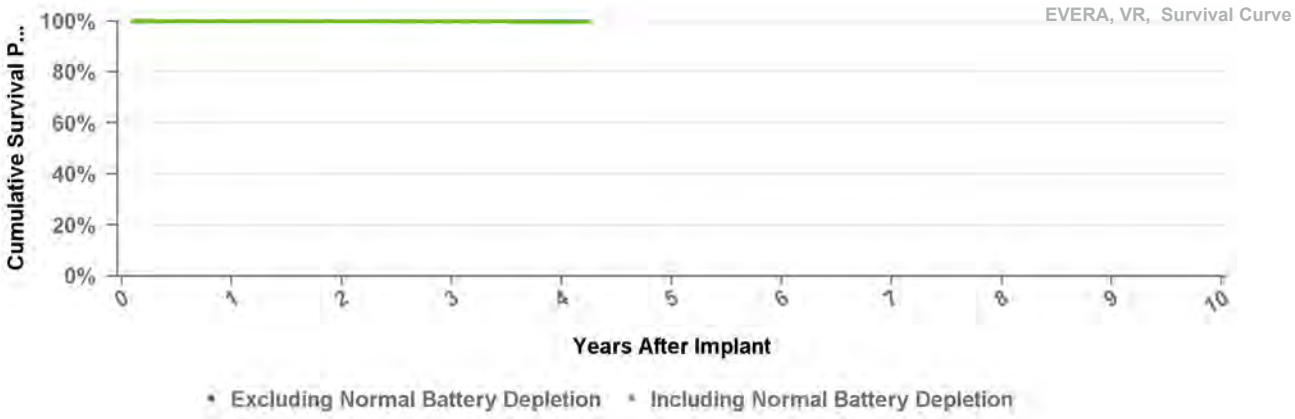
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVBB2D4 Evera XT

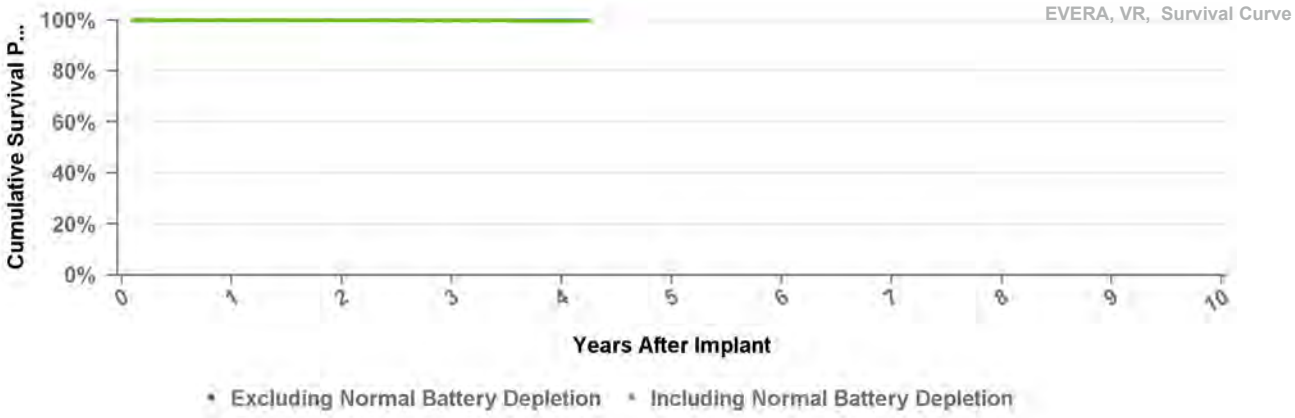
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVBC3D1 Evera S

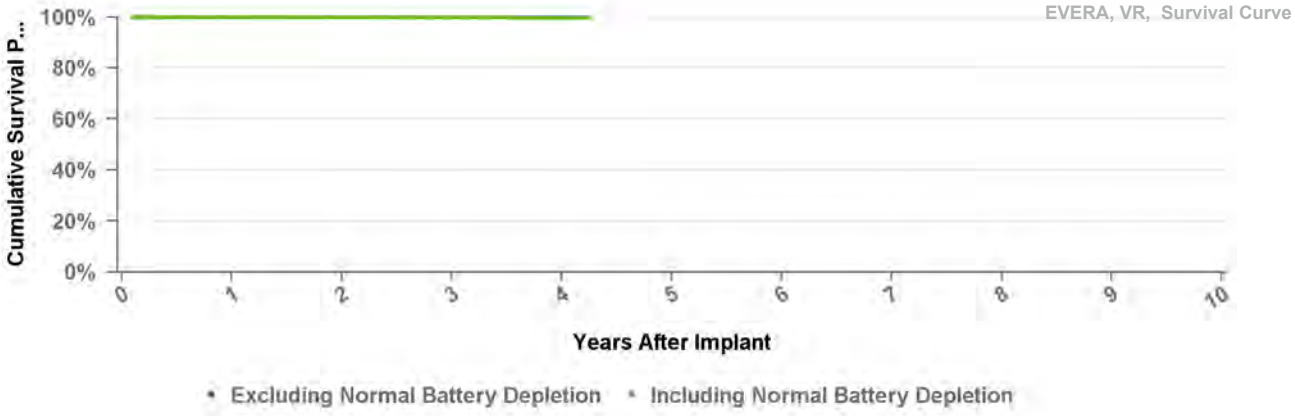
US Market Release	Apr-13	**Total Malfunctions**	**4**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,329	Battery Malfunction	2
Estimated Active USA Implants	3,907	Electrical Component	1
Normal Battery Depletions	2	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVBC3D4 Evera S

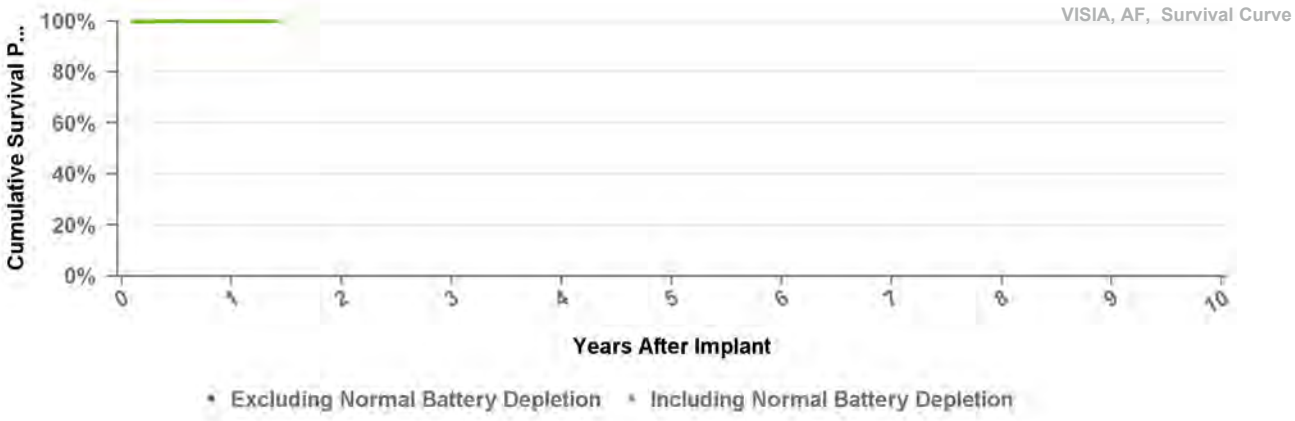
US Market Release	Apr-13	**Total Malfunctions**	**1**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**1**
Registered USA Implants	5,396	Battery Malfunction	1
Estimated Active USA Implants	4,904	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVFB1D4 Visia MRI AF

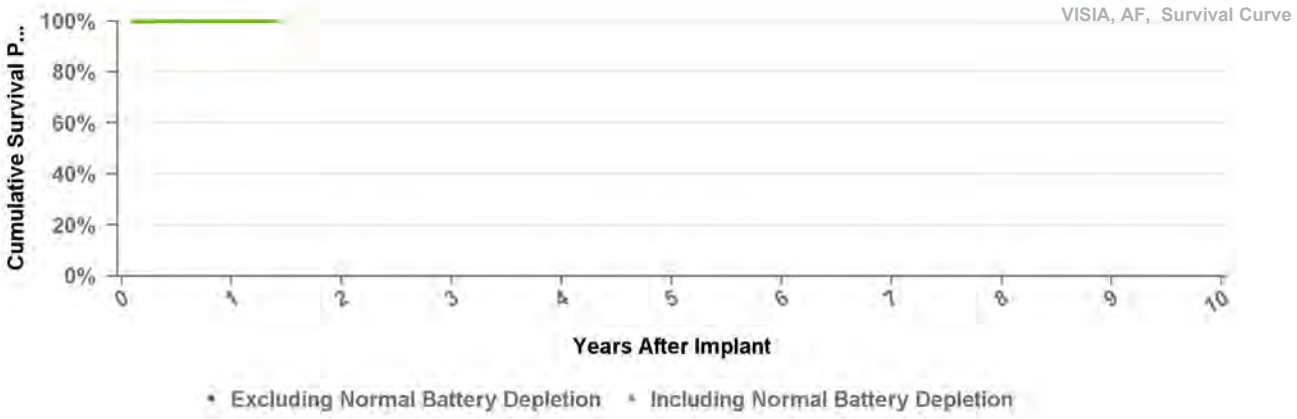
US Market Release	Jan-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	13,597	Electrical Component	2
Estimated Active USA Implants	13,334	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVFB2D4 Visia MRI AF XT

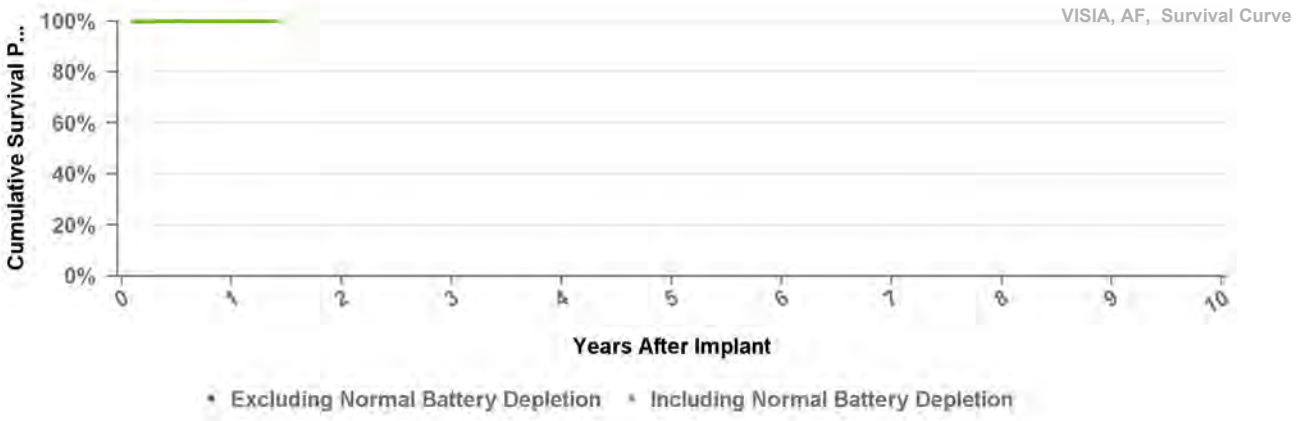
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVFC3D4 Visia MRI AF S

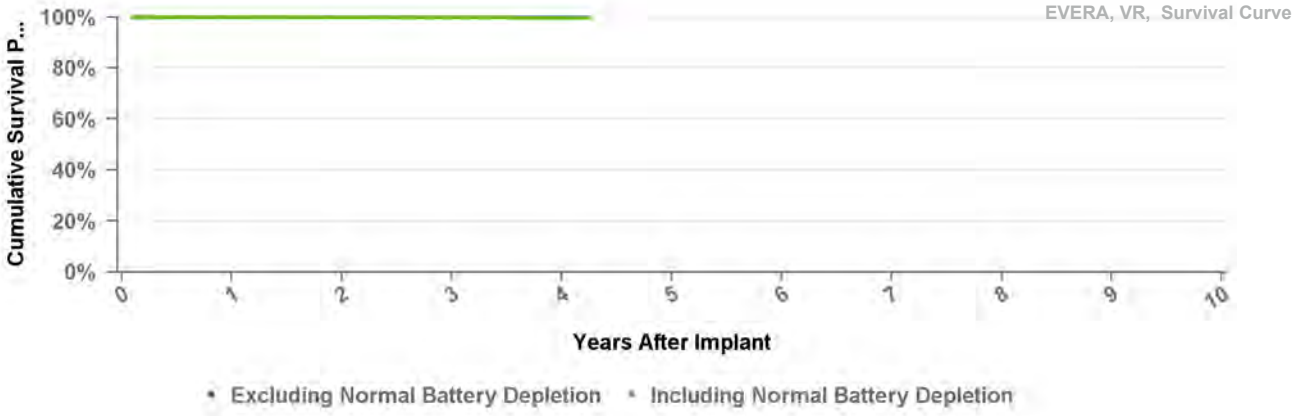
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants	259		
Estimated Active USA Implants	255	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3993	129

DVMB1D4 Evera MRI XT

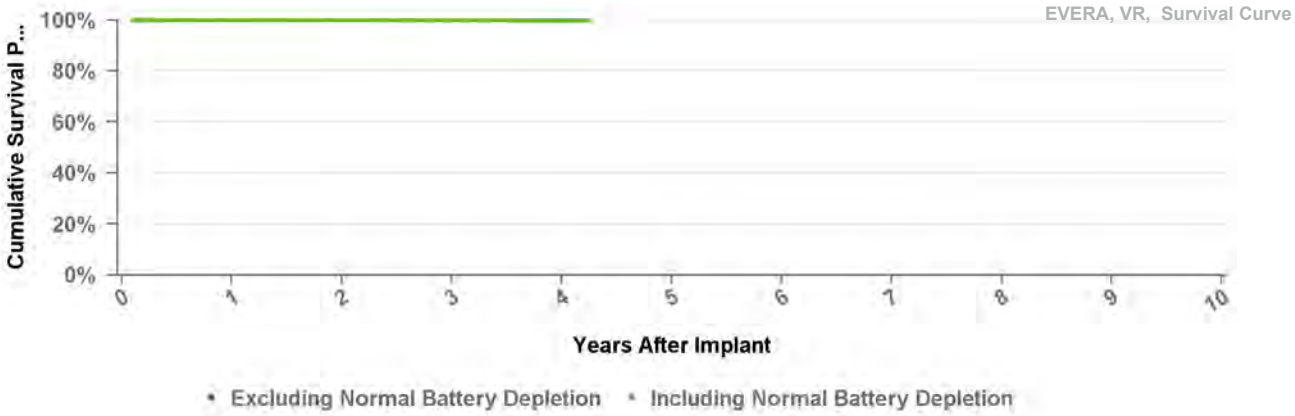
US Market Release	Sep-15	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	10,410	Electrical Component	1
Estimated Active USA Implants	9,970	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVMB2D4 Evera MRI XT

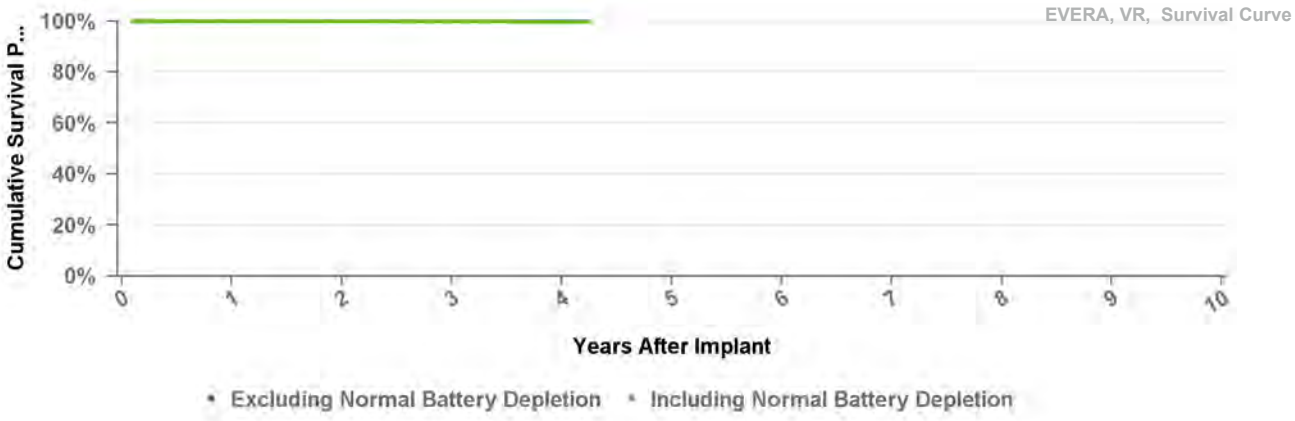
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

DVMC3D4 Evera MRI S

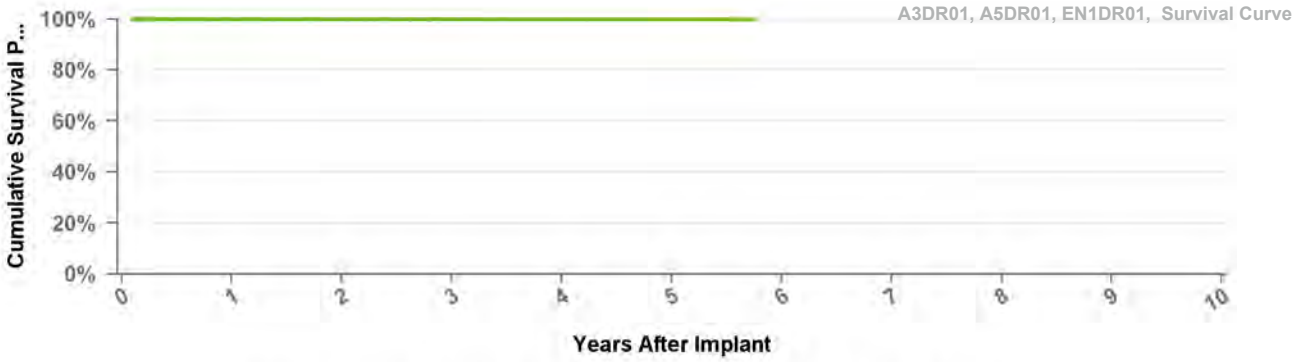
US Market Release	Sep-15	**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.7%
Effective Sample Size	52016	35574	16857	2592	144

A2DR01 Advisa DR MRI

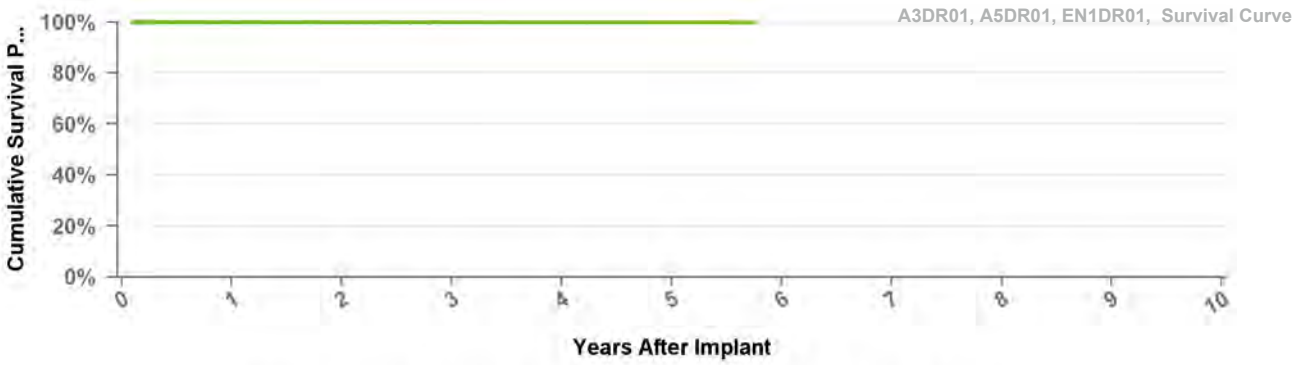
US Market Release	Jan-13	**Total Malfunctions**	**30**
CE Approval Date		**Therapy Function Not Compromised**	**27**
Registered USA Implants	300,065	Battery Malfunction	1
Estimated Active USA Implants	286,034	Electrical Component	17
Normal Battery Depletions	24	Electrical Interconnect	2
		Other Malfunction	1
		Poss Early Battery Depltn	4
		Software Malfunction	2
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	207718	122534	52911	14877	659	110

A3DR01 Advisa DR MRI

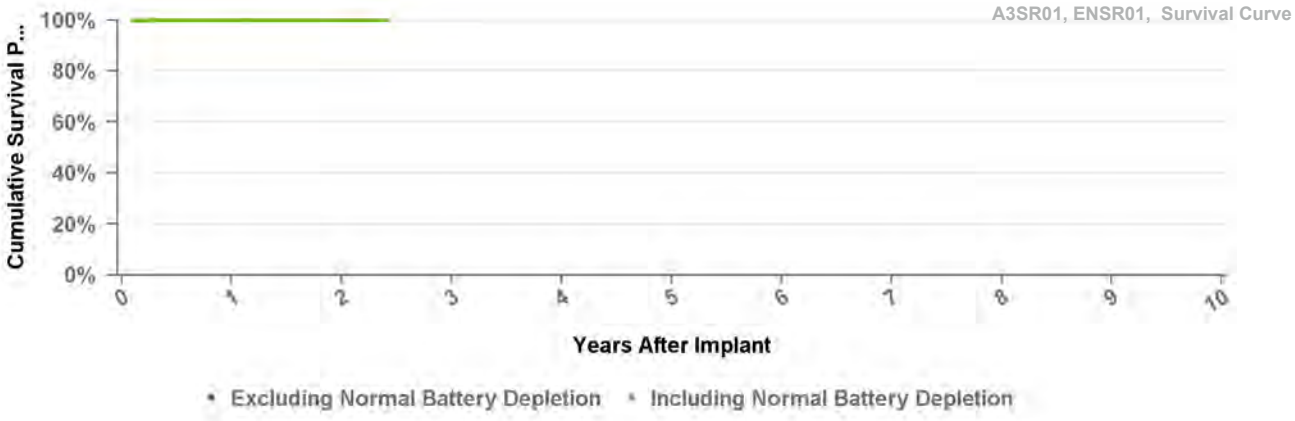
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	207718	122534	52911	14877	659	110

A3SR01 Advisa SR MRI

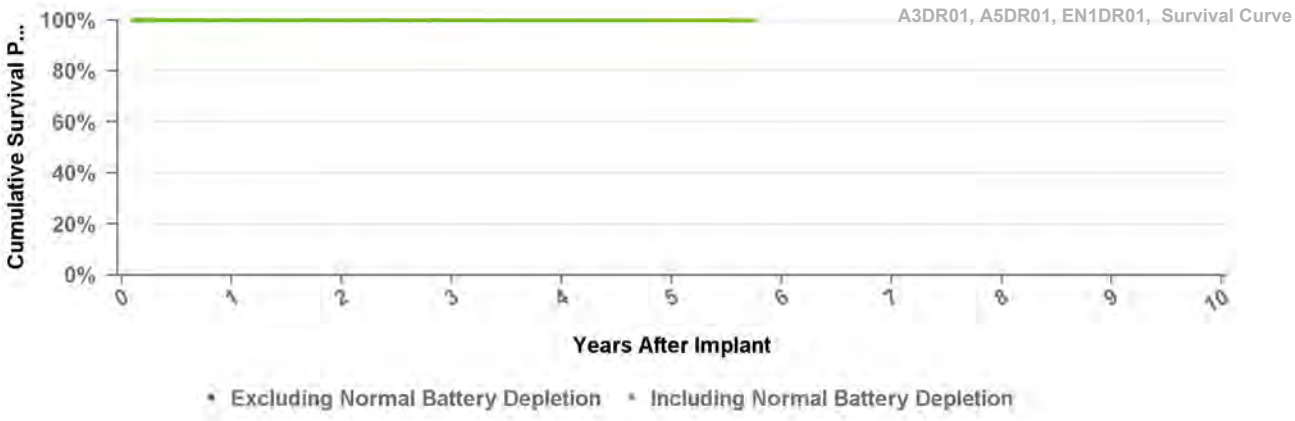
US Market Release	Mar-15	**Total Malfunctions**	**5**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**5**
Registered USA Implants	22,503	Electrical Component	2
Estimated Active USA Implants	21,353	Other Malfunction	2
Normal Battery Depletions		Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	11457	2325	175

A4DR01 Advisa DR

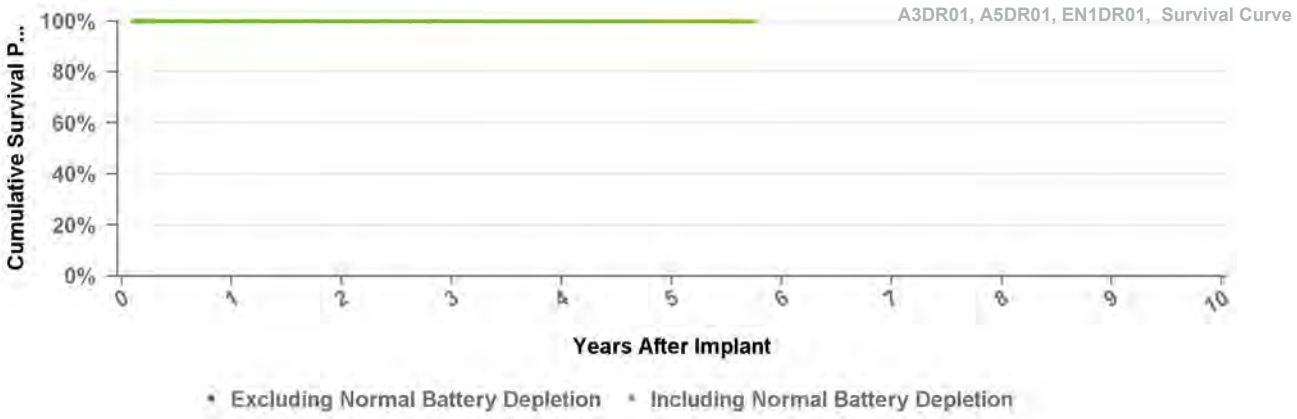
US Market Release	Apr-11	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,536		
Estimated Active USA Implants	1,286	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	207718	122534	52911	14877	659	110

A5DR01 Advisa DR

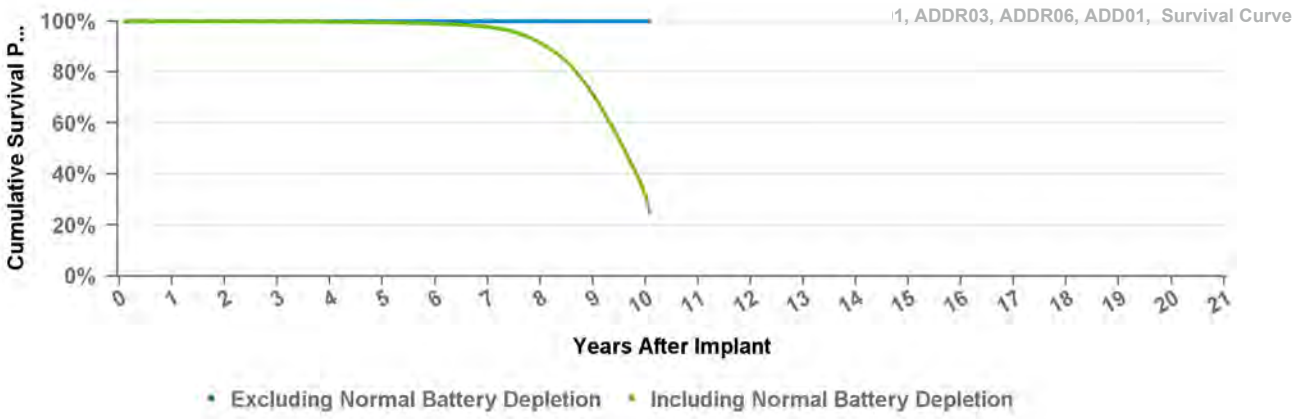
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	207718	122534	52911	14877	659	110

ADD01 Adapta D

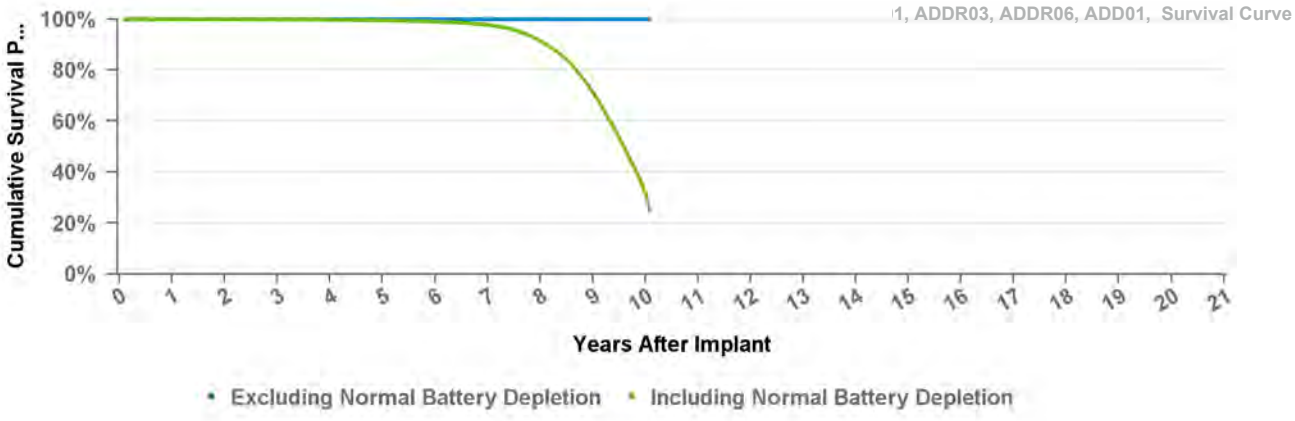
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

ADDR01 Adapta DR

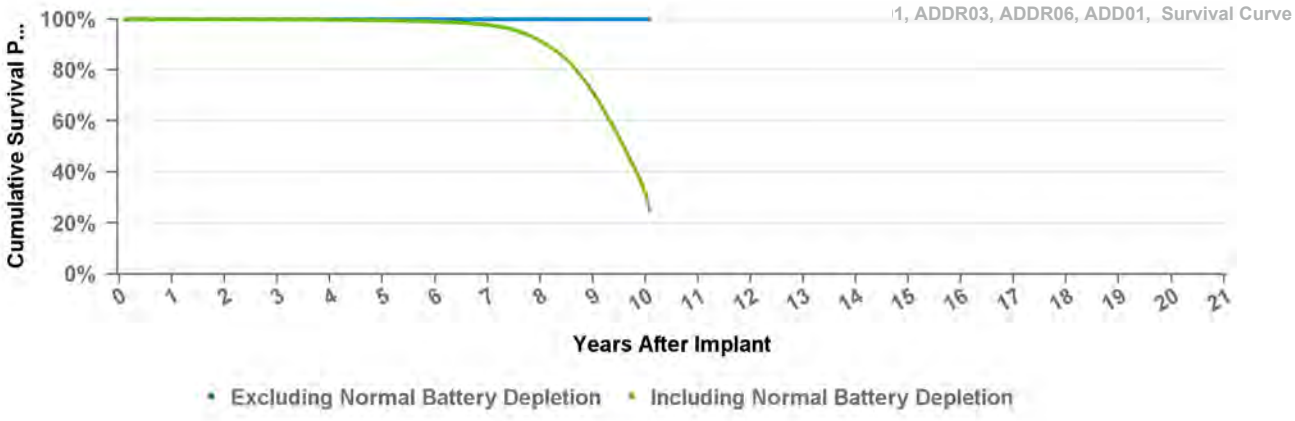
US Market Release	Jul-06	**Total Malfunctions**	**80**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**54**
Registered USA Implants	453,573	Electrical Component	51
Estimated Active USA Implants	297,437	Electrical Interconnect	1
Normal Battery Depletions	18,954	Other Malfunction	1
		Poss Early Battery Depltn	1
		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 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

ADDR03 Adapta DR

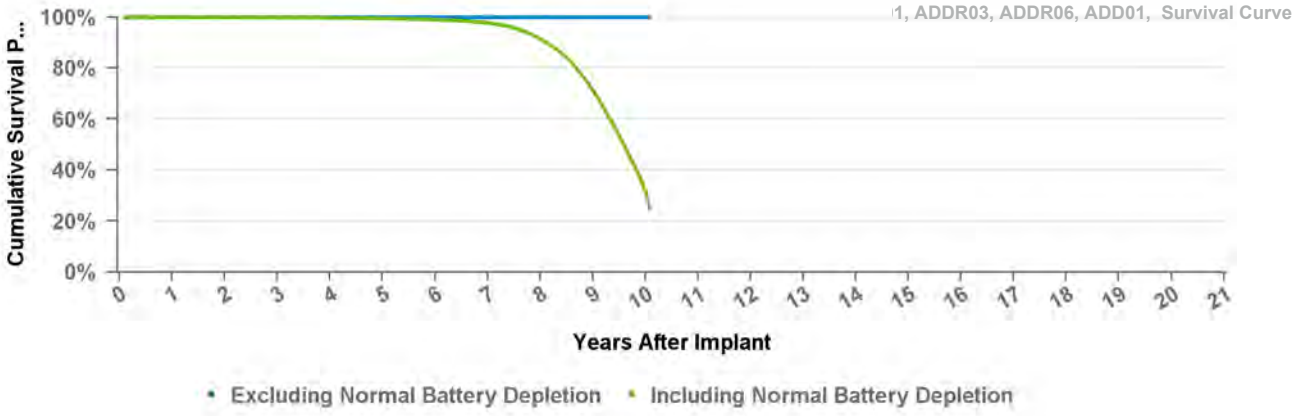
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,356	Electrical Component	1
Estimated Active USA Implants	2,603	**Therapy Function Compromised**	**1**
Normal Battery Depletions	263	Electrical Component	1



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

ADDR06 Adapta DR

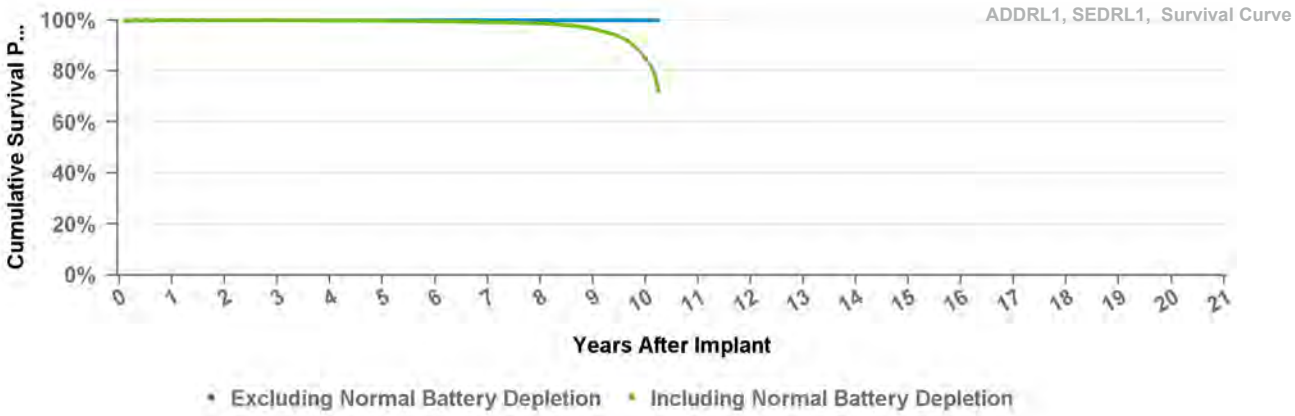
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,318	Electrical Component	1
Estimated Active USA Implants	1,619	**Therapy Function Compromised**	**0**
Normal Battery Depletions	267		



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

ADDRL1 Adapta DR

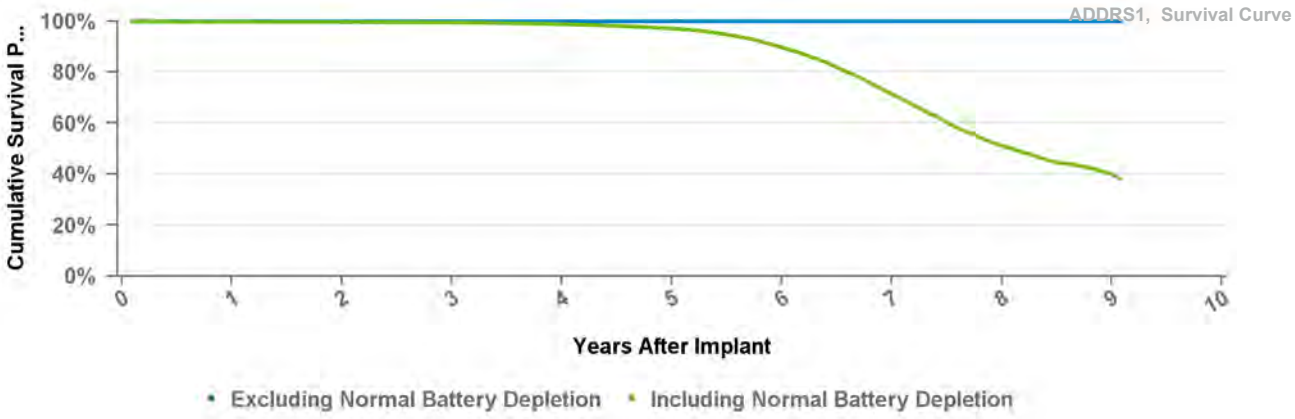
US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**10**
Registered USA Implants	134,705	Electrical Component	9
Estimated Active USA Implants	109,899	Electrical Interconnect	1
Normal Battery Depletions	570	**Therapy Function Compromised**	**4**
		Electrical Component	1
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.7%	96.7%	85.1%	72.1%
Effective Sample Size	118552	104290	88641	70446	52665	36361	23194	12484	5275	852	173

ADDRS1 Adapta DR

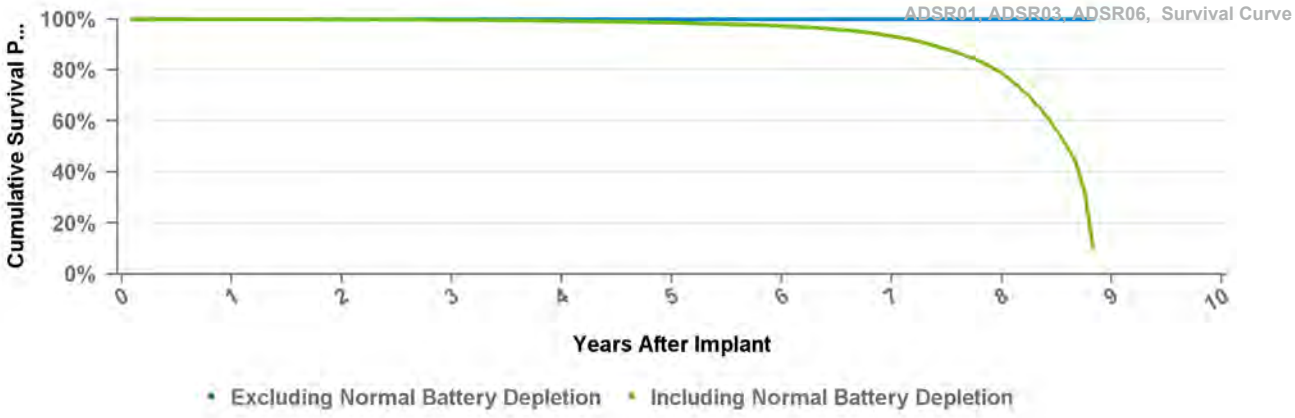
US Market Release	Jul-06	**Total Malfunctions**	**10**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**6**
Registered USA Implants	47,437	Electrical Component	5
Estimated Active USA Implants	27,497	Poss Early Battery Depltn	1
Normal Battery Depletions	3,281	**Therapy Function Compromised**	**4**
		Electrical Component	2
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.6%	99.4%	98.8%	97.1%	89.6%	71.3%	51.1%	40.0%	37.8%
Effective Sample Size	39468	34806	30086	24839	19797	13978	7549	2493	229	144

ADSR01 Adapta SR

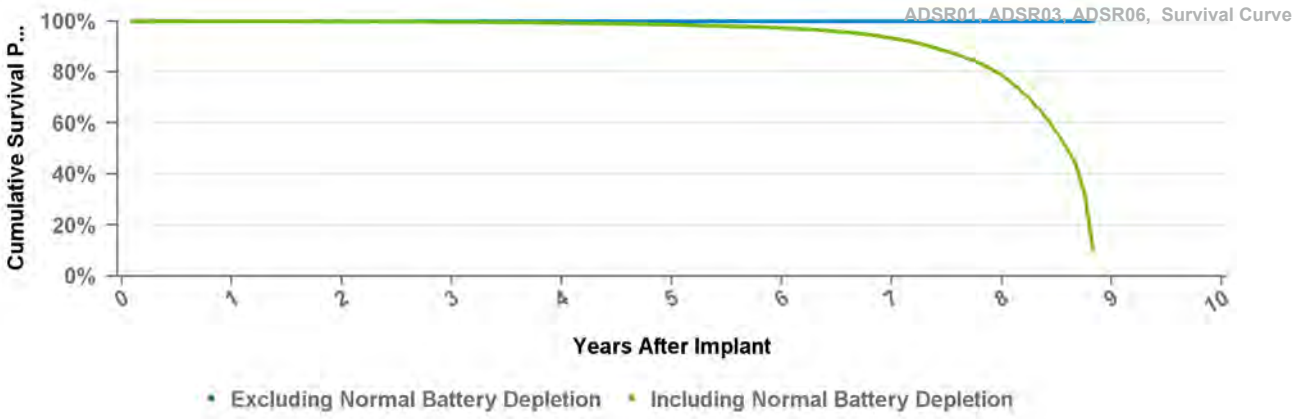
US Market Release	Jul-06	**Total Malfunctions**	**15**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**9**
Registered USA Implants	91,149	Electrical Component	7
Estimated Active USA Implants	52,650	Electrical Interconnect	1
Normal Battery Depletions	2,760	Poss Early Battery Depltn	1
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.2%	98.6%	97.3%	93.3%	78.7%	10.1%
Effective Sample Size	73627	63299	51406	39963	29886	21133	13590	6057	182

ADSR03 Adapta SR

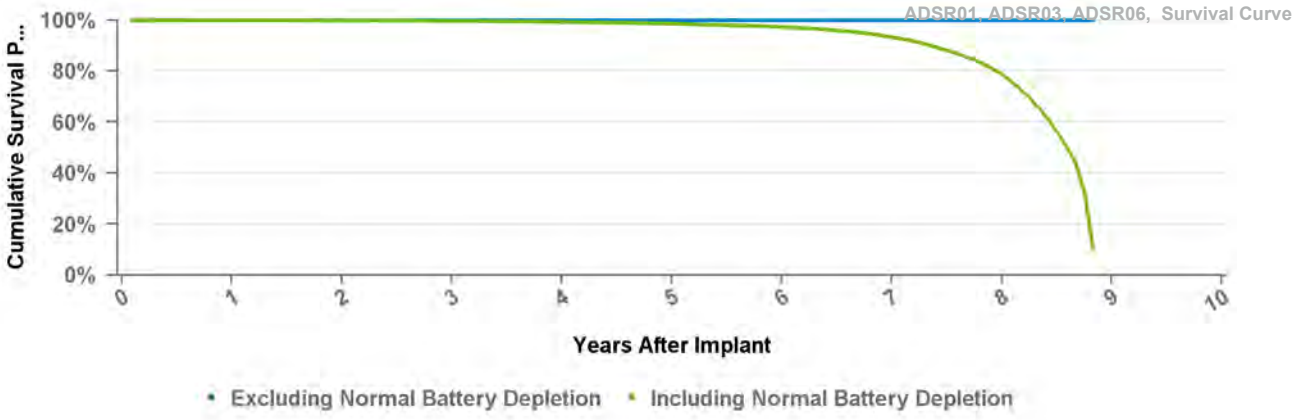
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	2,016		
Estimated Active USA Implants	999	**Therapy Function Compromised**	
Normal Battery Depletions	93		



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.2%	98.6%	97.3%	93.3%	78.7%	10.1%
Effective Sample Size	73627	63299	51406	39963	29886	21133	13590	6057	182

ADSR06 Adapta SR

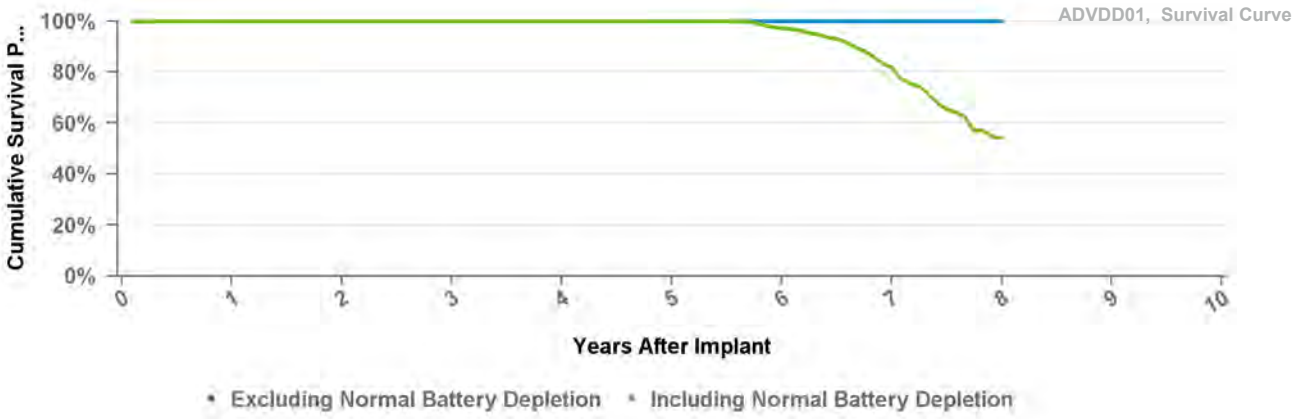
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,729	Electrical Component	2
Estimated Active USA Implants	1,255	**Therapy Function Compromised**	**0**
Normal Battery Depletions	143		



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.2%	98.6%	97.3%	93.3%	78.7%	10.1%
Effective Sample Size	73627	63299	51406	39963	29886	21133	13590	6057	182

ADVDD01 Adapta VDD

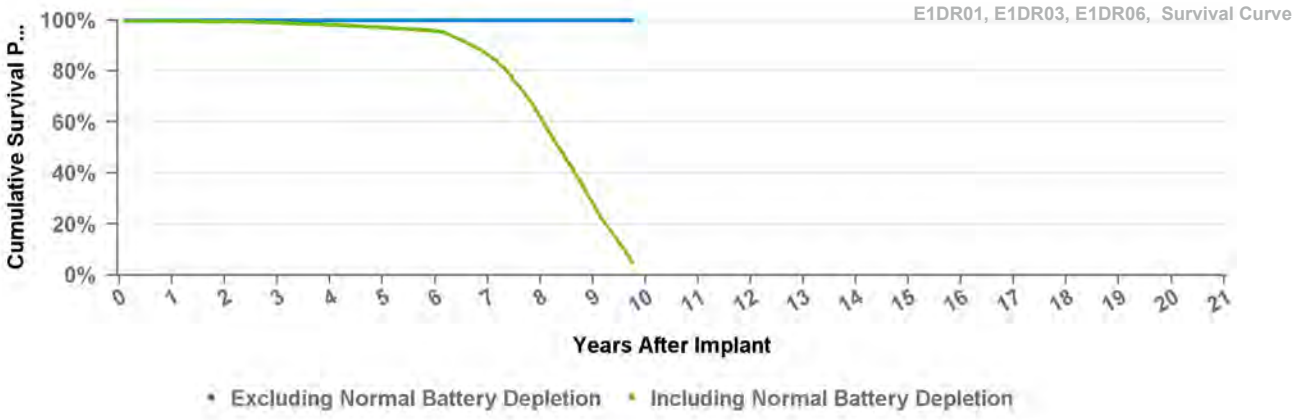
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,338		
Estimated Active USA Implants	701	**Therapy Function Compromised**	
Normal Battery Depletions	70		



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.2%	81.7%	54.3%
Effective Sample Size	1139	1043	904	786	634	508	320	109

E1DR01 EnPulse DR

US Market Release	Dec-03	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	6,842	Electrical Component	1
Estimated Active USA Implants	511	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1,722		

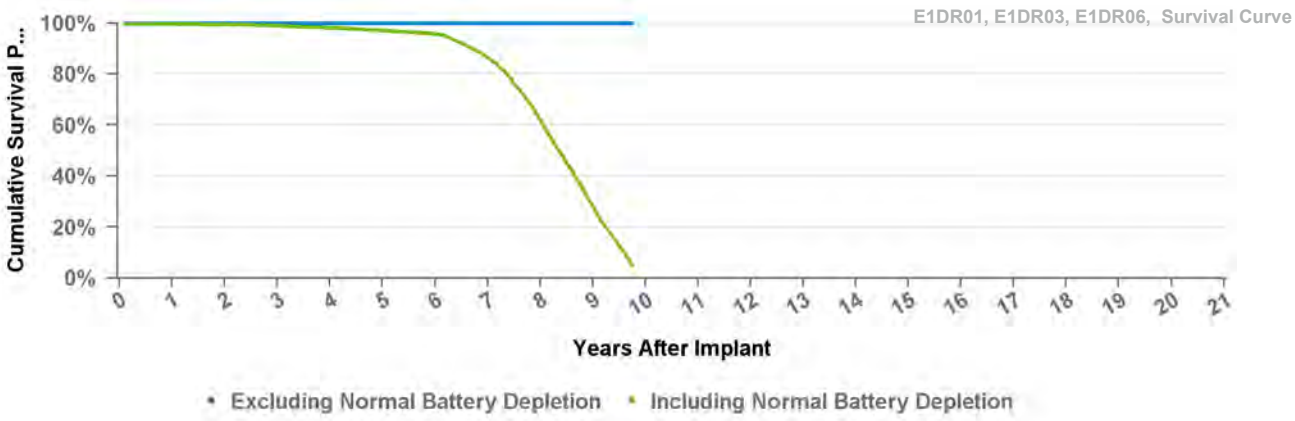


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.0%	98.1%	97.1%	95.7%	86.4%	62.2%	28.4%	5.1%
Effective Sample Size	6002	5549	5099	4634	4199	3758	3068	1975	772	133

E1DR03 EnPulse DR

US Market Release Dec-03
CE Approval Date
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

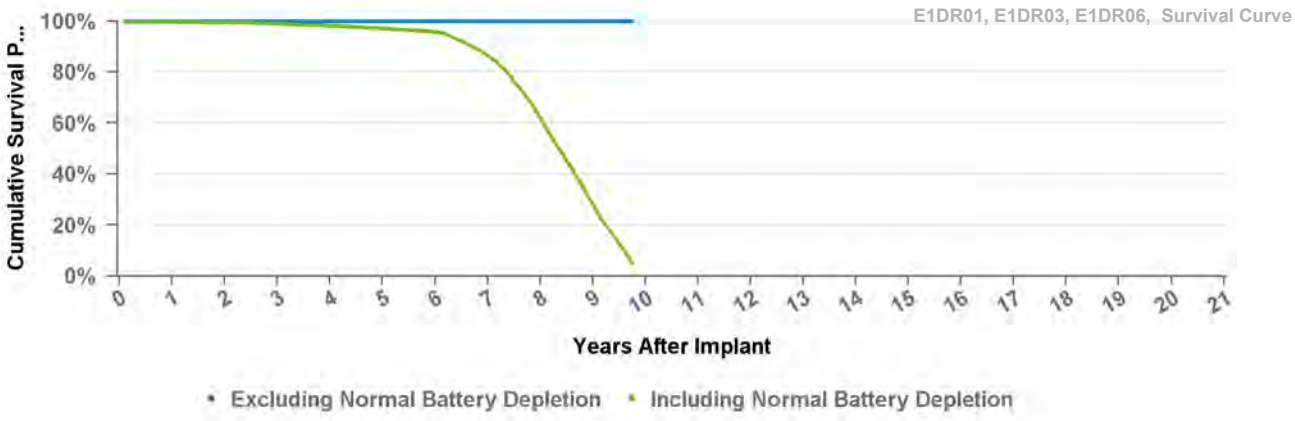


Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.0%	98.1%	97.1%	95.7%	86.4%	62.2%	28.4%	5.1%
Effective Sample Size	6002	5549	5099	4634	4199	3758	3068	1975	772	133

E1DR06 EnPulse DR

US Market Release Dec-03
CE Approval Date
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

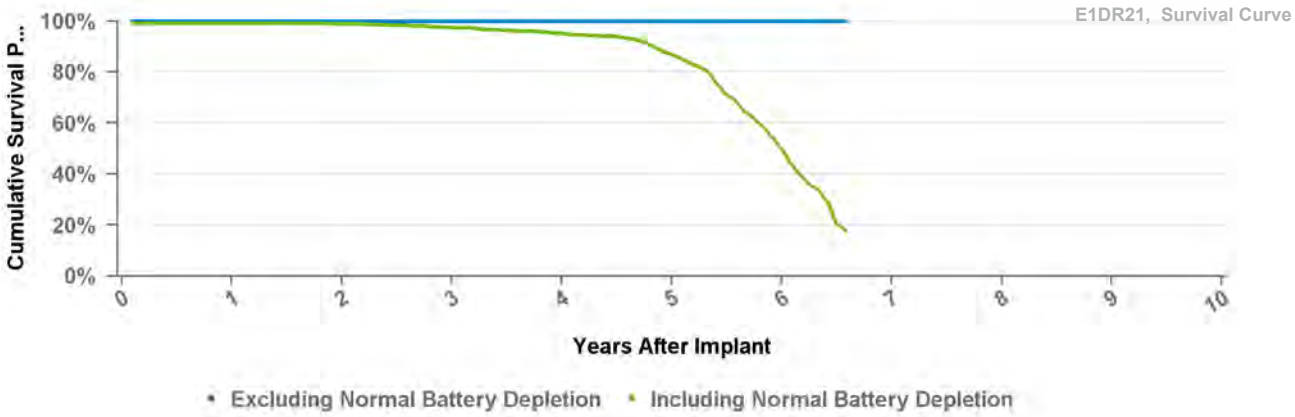
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.6%	99.5%	99.0%	98.1%	97.1%	95.7%	86.4%	62.2%	28.4%	5.1%
Effective Sample Size	6002	5549	5099	4634	4199	3758	3068	1975	772	133

E1DR21 EnPulse DR

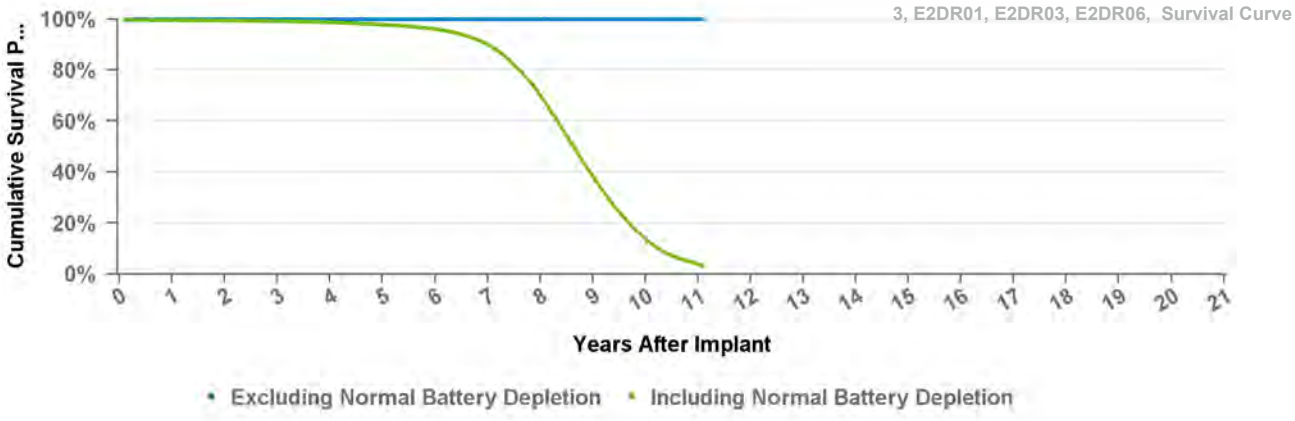
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,856		
Estimated Active USA Implants	98	**Therapy Function Compromised**	
Normal Battery Depletions	383		



Years	1	2	3	4	5	6	at 79 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.2%	98.8%	97.4%	95.2%	86.9%	49.9%	17.4%
Effective Sample Size	1594	1440	1282	1123	910	417	111

E2D01 EnPulse

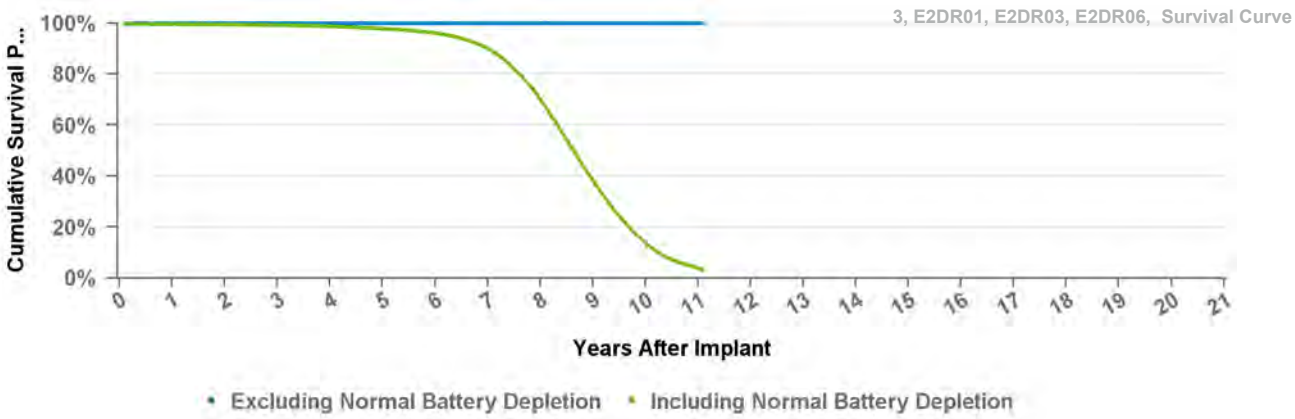
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	11	2	3	4	5	6	7	8	9	at 133 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.0%	70.1%	38.4%	13.7%	3.7%	3.0%
Effective Sample Size	87938	80802	73859	67310	60879	54639	46996	33354	15985	4717	681	396

E2D03 EnPulse

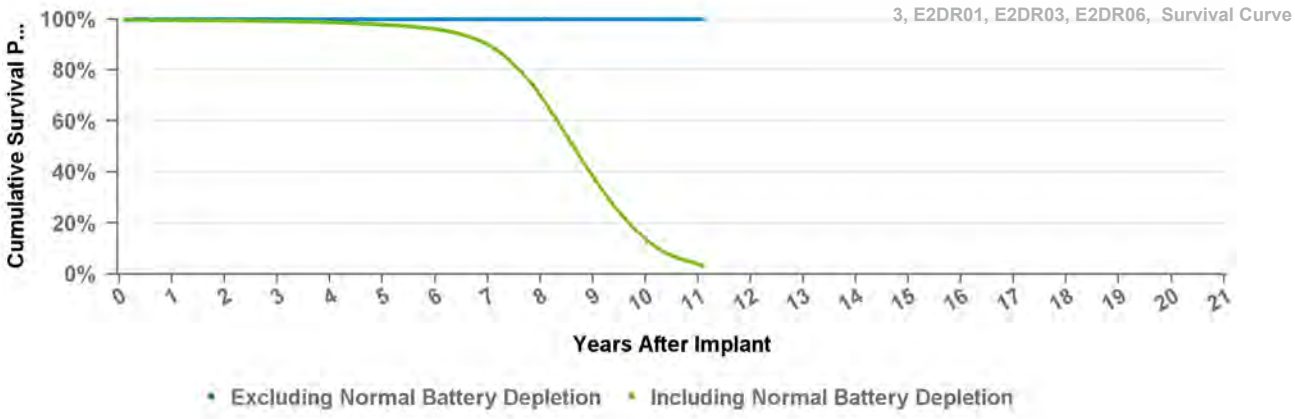
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	11	2	3	4	5	6	7	8	9	at 133 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.0%	70.1%	38.4%	13.7%	3.7%	3.0%
Effective Sample Size	87938	80802	73859	67310	60879	54639	46996	33354	15985	4717	681	396

E2DR01 EnPulse DR

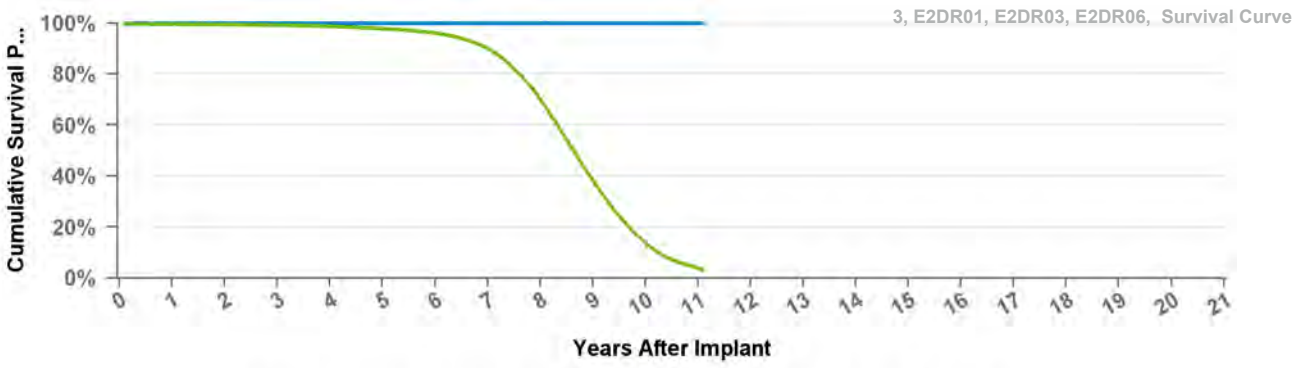
US Market Release	Feb-04	**Total Malfunctions**	**27**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**20**
Registered USA Implants	97,415	Electrical Component	18
Estimated Active USA Implants	11,184	Other Malfunction	1
Normal Battery Depletions	22,465	Poss Early Battery Depltn	1
		Therapy Function Compromised	**7**
		Battery Malfunction	1
		Electrical Component	3
		Electrical Interconnect	3



Years	1	10	11	2	3	4	5	6	7	8	9	at 133 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.0%	70.1%	38.4%	13.7%	3.7%	3.0%
Effective Sample Size	87938	80802	73859	67310	60879	54639	46996	33354	15985	4717	681	396

E2DR03 EnPulse DR

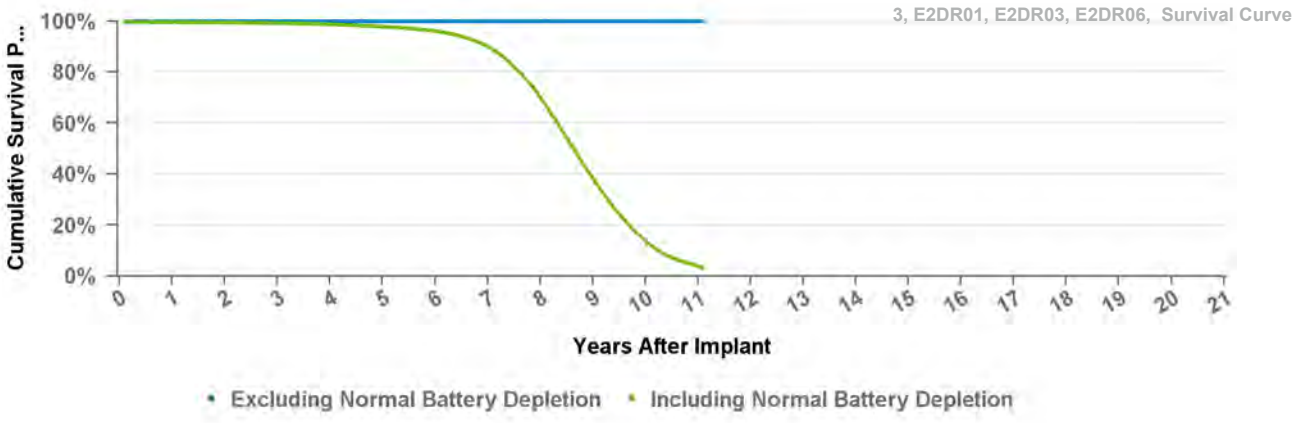
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	2,050		
Estimated Active USA Implants	276	**Therapy Function Compromised**	
Normal Battery Depletions	446		



Years	1	10	11	2	3	4	5	6	7	8	9	at 133 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.0%	70.1%	38.4%	13.7%	3.7%	3.0%
Effective Sample Size	87938	80802	73859	67310	60879	54639	46996	33354	15985	4717	681	396

E2DR06 EnPulse DR

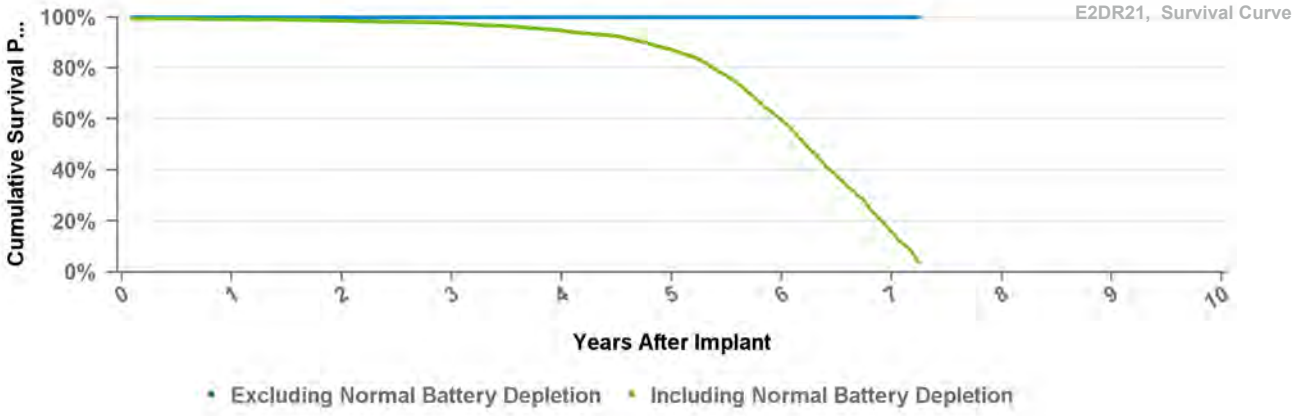
US Market Release	Feb-04	**Total Malfunctions**	**2**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,625	Poss Early Battery Depltn	1
Estimated Active USA Implants	163	**Therapy Function Compromised**	**1**
Normal Battery Depletions	320	Electrical Interconnect	1



Years	1	10	11	2	3	4	5	6	7	8	9	at 133 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.4%	99.2%	98.7%	97.8%	96.1%	90.0%	70.1%	38.4%	13.7%	3.7%	3.0%
Effective Sample Size	87938	80802	73859	67310	60879	54639	46996	33354	15985	4717	681	396

E2DR21 EnPulse DR

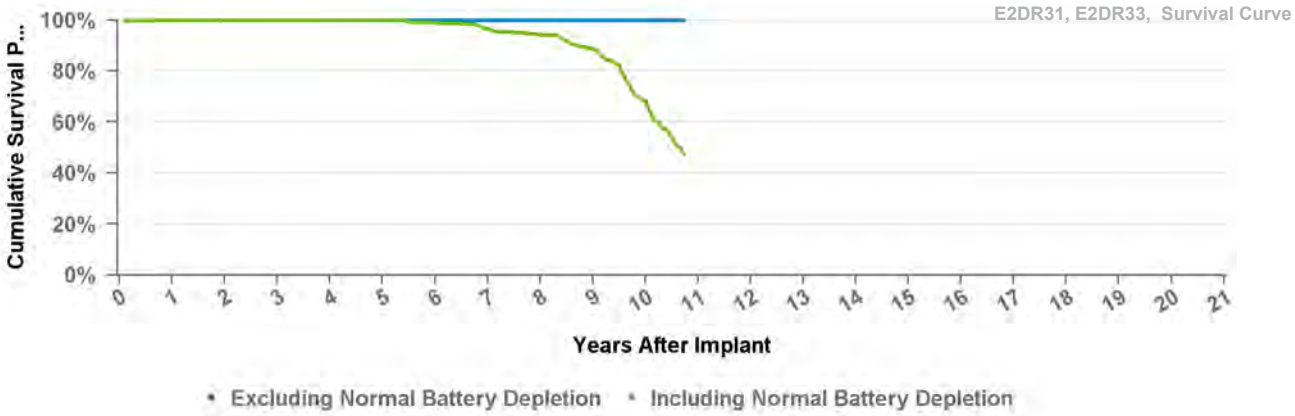
US Market Release	Feb-04	**Total Malfunctions**	**1**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**0**
Registered USA Implants	12,201		
Estimated Active USA Implants	1,050	**Therapy Function Compromised**	**1**
Normal Battery Depletions	2,322	Electrical Component	1



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.1%	98.6%	97.6%	94.8%	87.3%	59.5%	15.7%	3.7%
Effective Sample Size	10179	9055	8062	6959	5665	3271	638	183

E2DR31 EnPulse DR

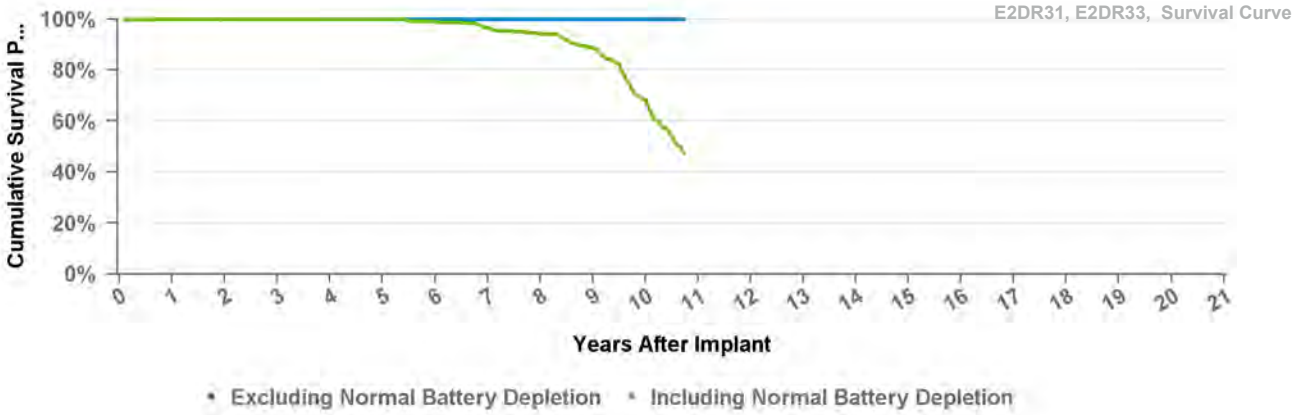
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	588		
Estimated Active USA Implants	172	**Therapy Function Compromised**	
Normal Battery Depletions	133		



Years	1	10	2	3	4	5	6	7	8	9	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.8%	99.8%	99.8%	98.9%	96.7%	94.0%	88.7%	68.1%	47.2%
Effective Sample Size	523	489	457	417	375	337	298	261	229	161	104

E2DR33 EnPulse DR

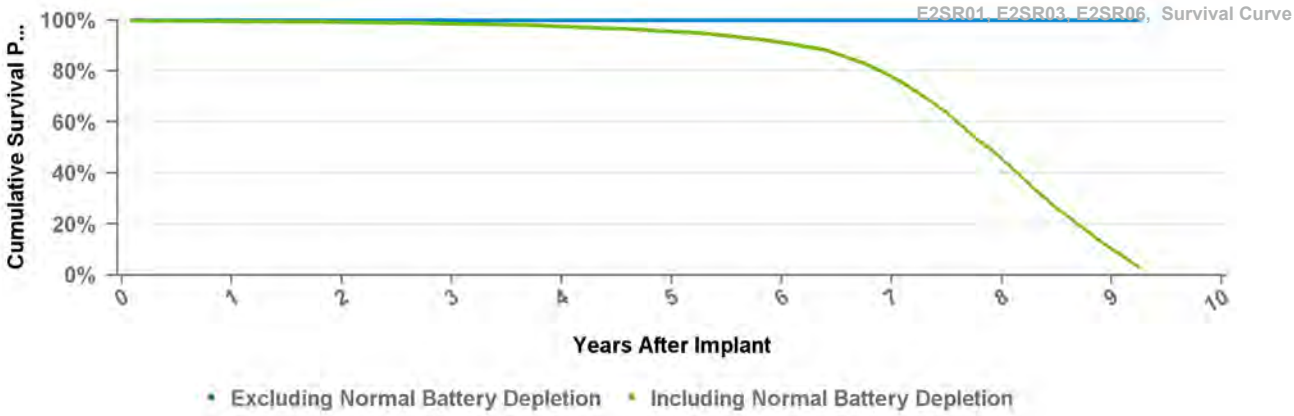
US Market Release	Feb-04	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	4	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	10	2	3	4	5	6	7	8	9	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.8%	99.8%	99.8%	99.8%	98.9%	96.7%	94.0%	88.7%	68.1%	47.2%
Effective Sample Size	523	489	457	417	375	337	298	261	229	161	104

E2SR01 EnPulse SR

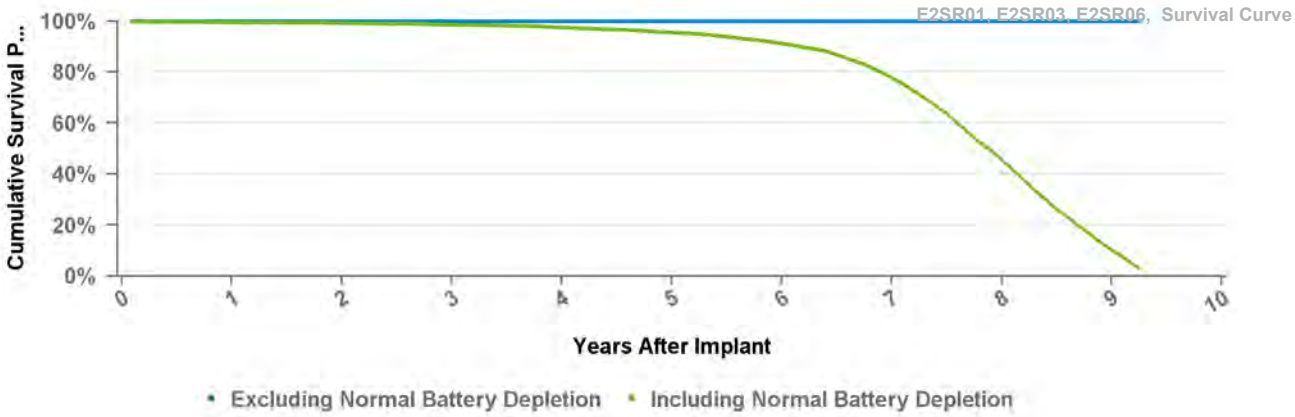
US Market Release	Dec-03	**Total Malfunctions**	**4**
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	**3**
Registered USA Implants	22,680	Electrical Component	2
Estimated Active USA Implants	2,095	Poss Early Battery Depltn	1
Normal Battery Depletions	3,014	**Therapy Function Compromised**	**1**
		Other Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.2%	98.6%	97.5%	95.5%	91.1%	77.7%	45.6%	10.1%	2.8%
Effective Sample Size	19729	16770	14296	12183	10079	8190	5939	2844	442	136

E2SR03 EnPulse SR

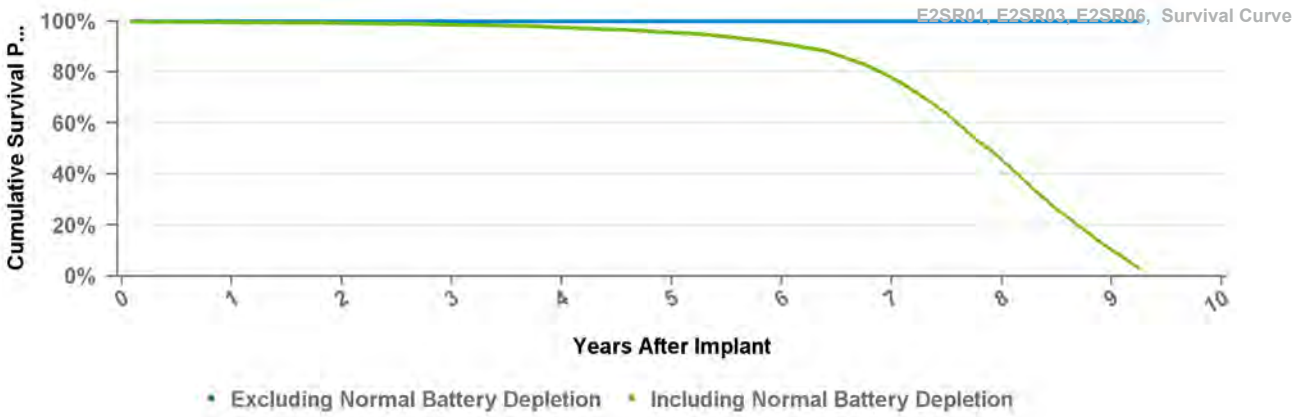
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	1,099		
Estimated Active USA Implants	99	**Therapy Function Compromised**	
Normal Battery Depletions	151		



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.2%	98.6%	97.5%	95.5%	91.1%	77.7%	45.6%	10.1%	2.8%
Effective Sample Size	19729	16770	14296	12183	10079	8190	5939	2844	442	136

E2SR06 EnPulse SR

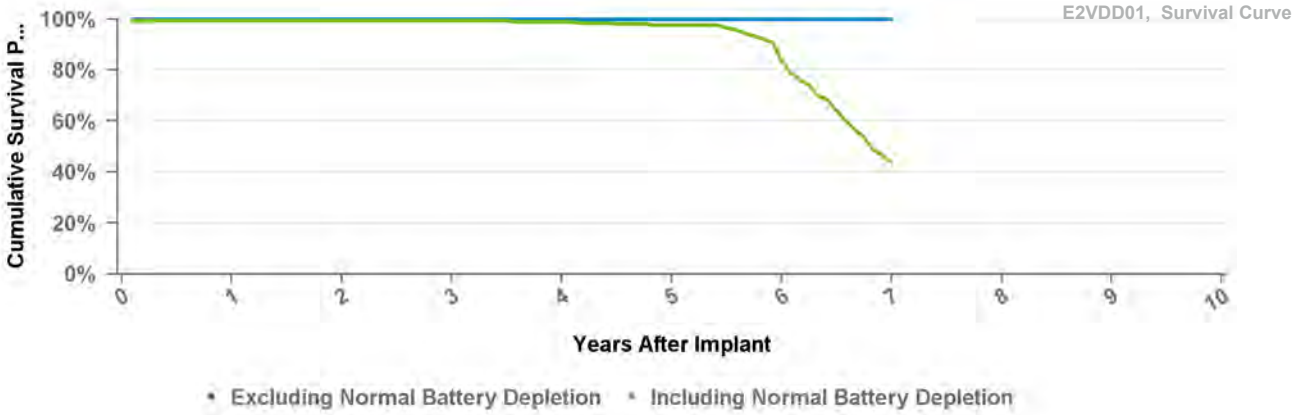
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	1,752		
Estimated Active USA Implants	139	**Therapy Function Compromised**	
Normal Battery Depletions	224		



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.2%	98.6%	97.5%	95.5%	91.1%	77.7%	45.6%	10.1%	2.8%
Effective Sample Size	19729	16770	14296	12183	10079	8190	5939	2844	442	136

E2VDD01 EnPulse VDD

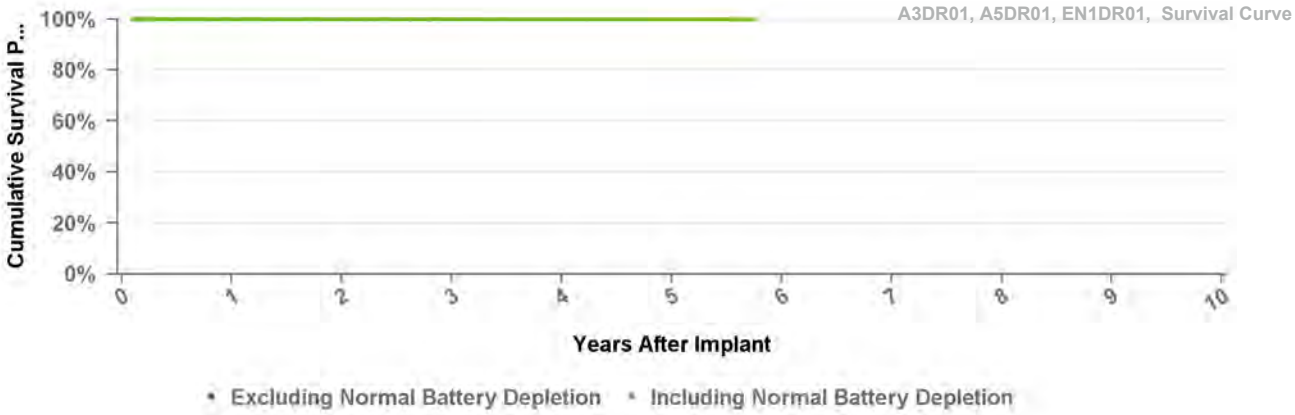
US Market Release	Dec-03	**Total Malfunctions**	
CE Approval Date	Sep-03	**Therapy Function Not Compromised**	
Registered USA Implants	645		
Estimated Active USA Implants	96	**Therapy Function Compromised**	
Normal Battery Depletions	97		



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.4%	99.4%	99.4%	98.9%	97.6%	83.6%	43.4%
Effective Sample Size	558	504	454	404	355	280	106

EN1DR01 Ensura MRI

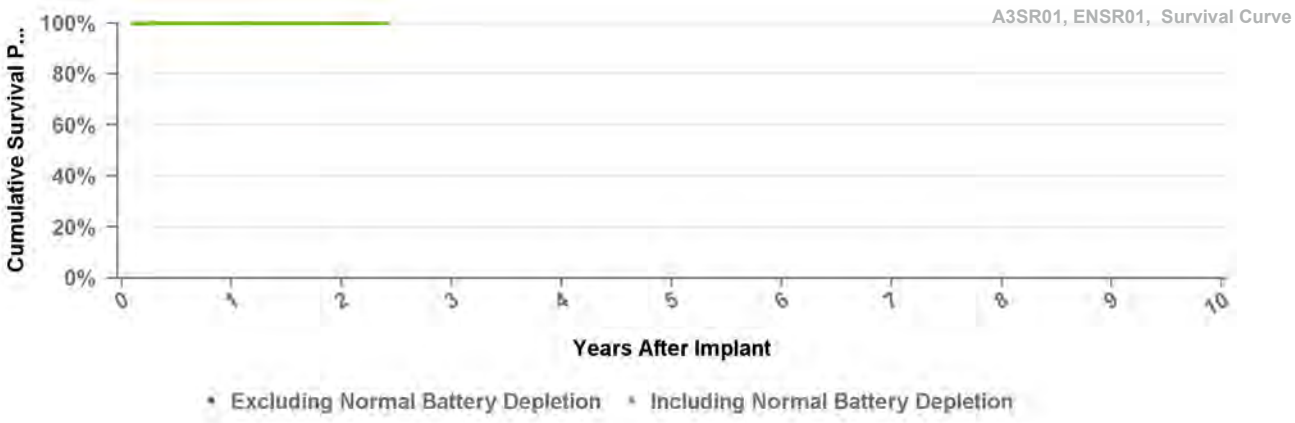
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	
Registered USA Implants	8		
Estimated Active USA Implants	6	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	207718	122534	52911	14877	659	110

EN1SR01 Ensura SR MRI

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

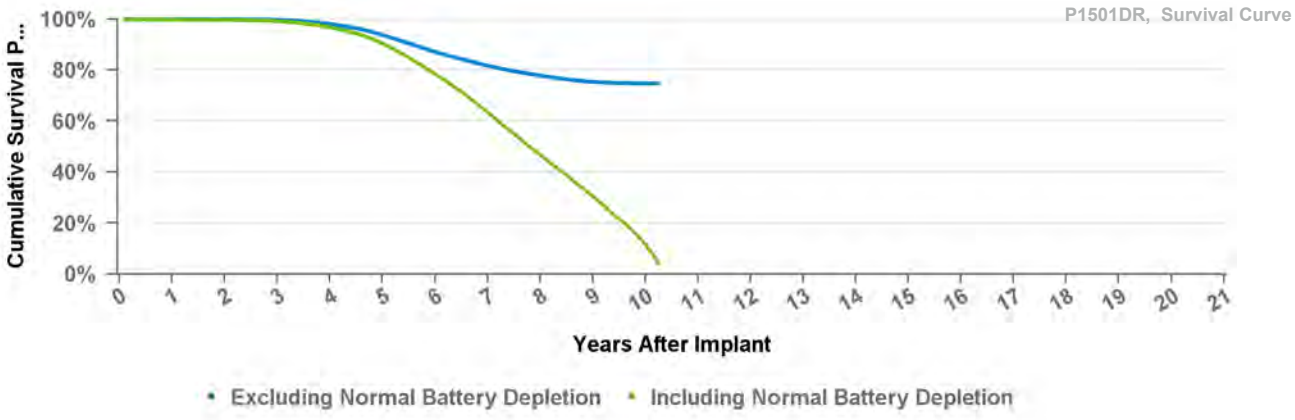


Years	1	2	at 29 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	11457	2325	175

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	110,099
Estimated Active USA Implants	23,745
Normal Battery Depletions	15,179

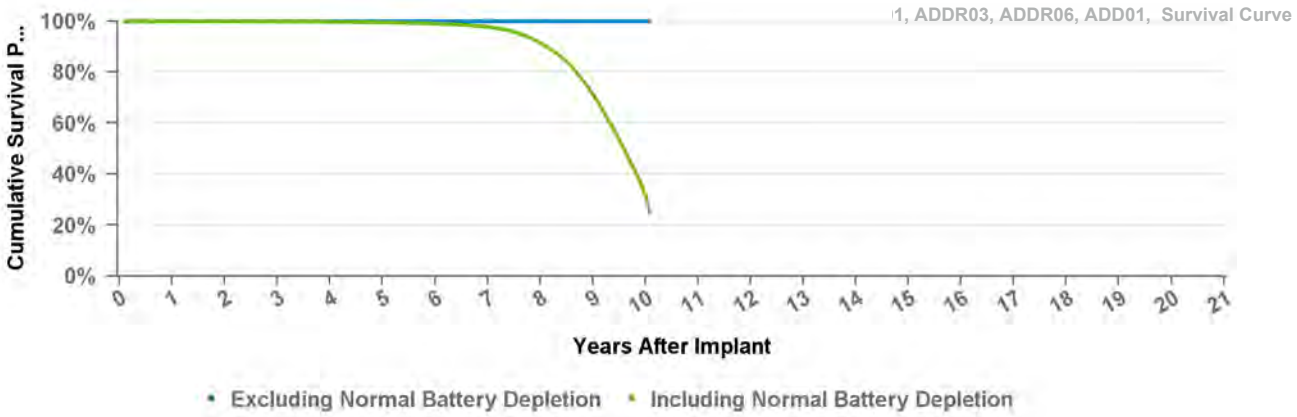
Total Malfunctions	**14,997**
Therapy Function Not Compromised	**14,942**
Battery Malfunction	14,814
Electrical Component	58
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	67
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	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	99.9%	74.8%	99.9%	99.7%	98.0%	93.7%	87.1%	81.7%	77.8%	75.3%	74.8%
Including NBD	99.7%	99.6%	99.1%	96.7%	90.3%	78.3%	63.2%	46.6%	30.3%	11.5%	3.9%
Effective Sample Size	95559	89225	83187	76172	66157	52138	36404	20803	9403	1883	379

RED01 Relia D

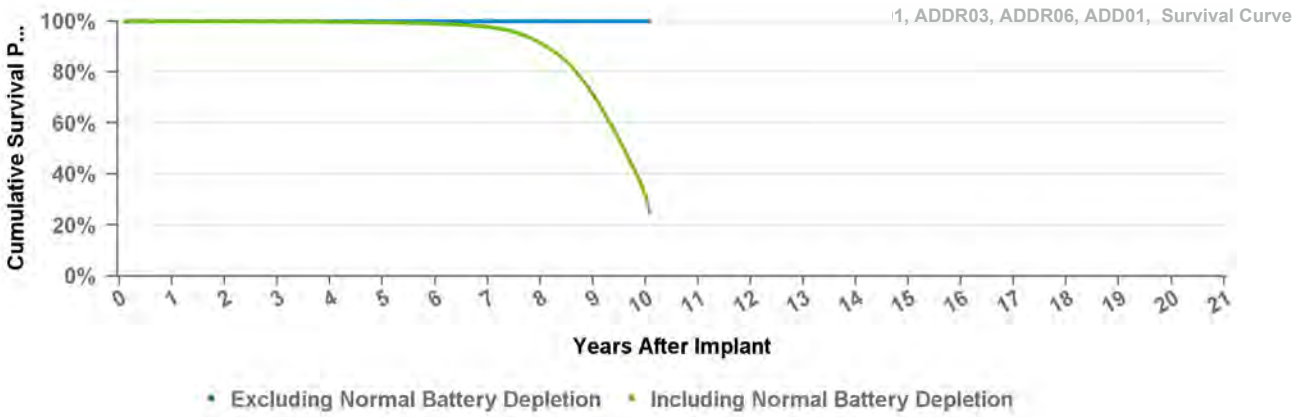
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

REDR01 Relia DR

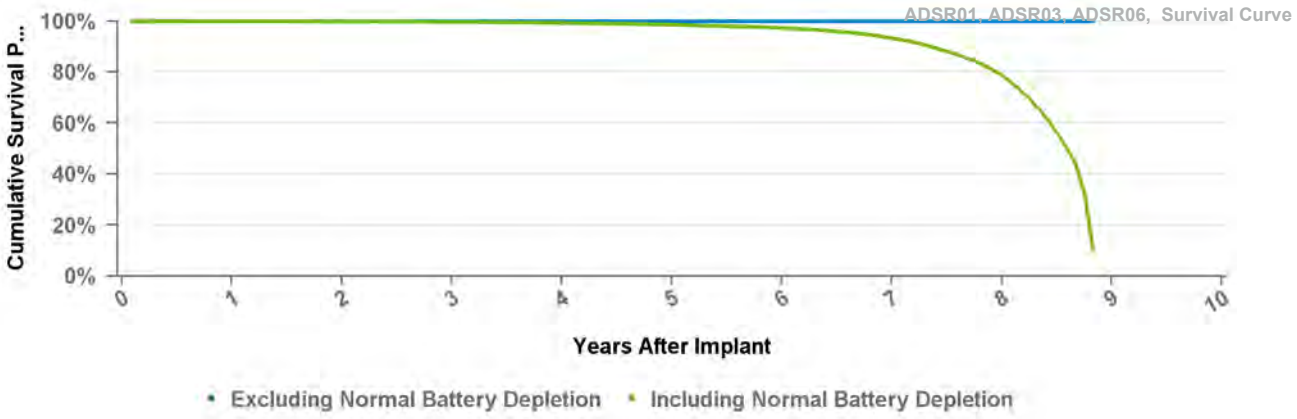
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	2	3	4	5	6	7	8	9	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	91.4%	71.4%	31.7%	24.7%
Effective Sample Size	402550	365056	327198	281707	234582	186941	139988	88426	35105	2976	1408

RES01 Relia S

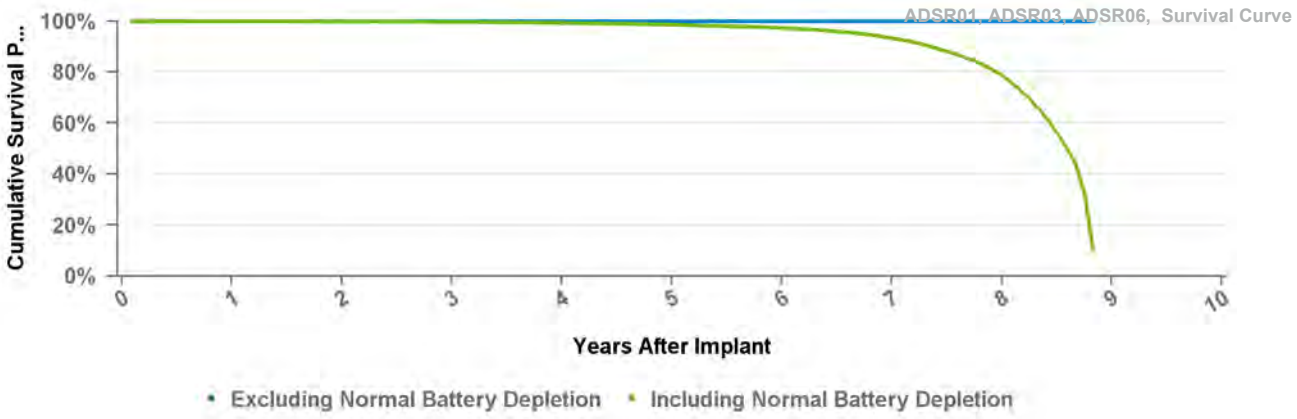
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.2%	98.6%	97.3%	93.3%	78.7%	10.1%
Effective Sample Size	73627	63299	51406	39963	29886	21133	13590	6057	182

RESR01 Relia SR

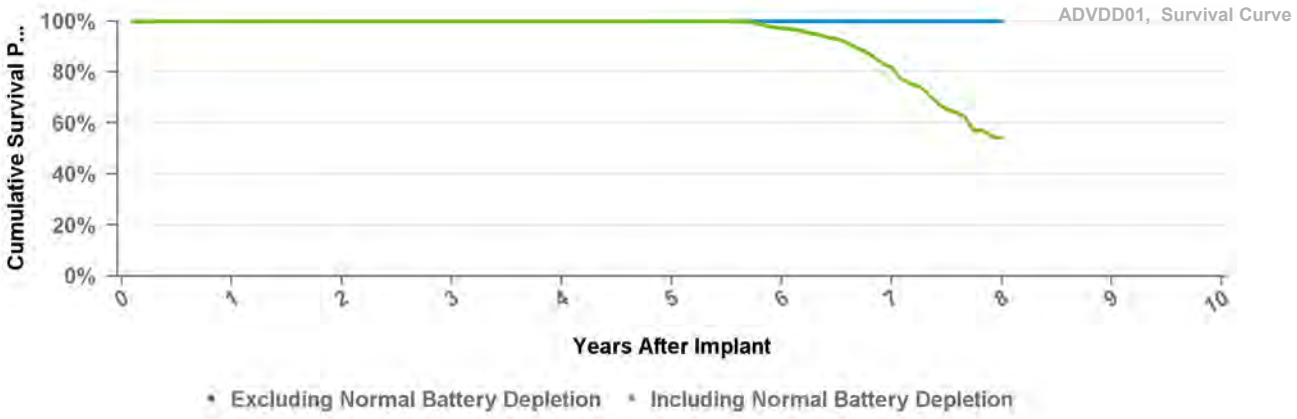
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.2%	98.6%	97.3%	93.3%	78.7%	10.1%
Effective Sample Size	73627	63299	51406	39963	29886	21133	13590	6057	182

REVDD01 Relia VDD

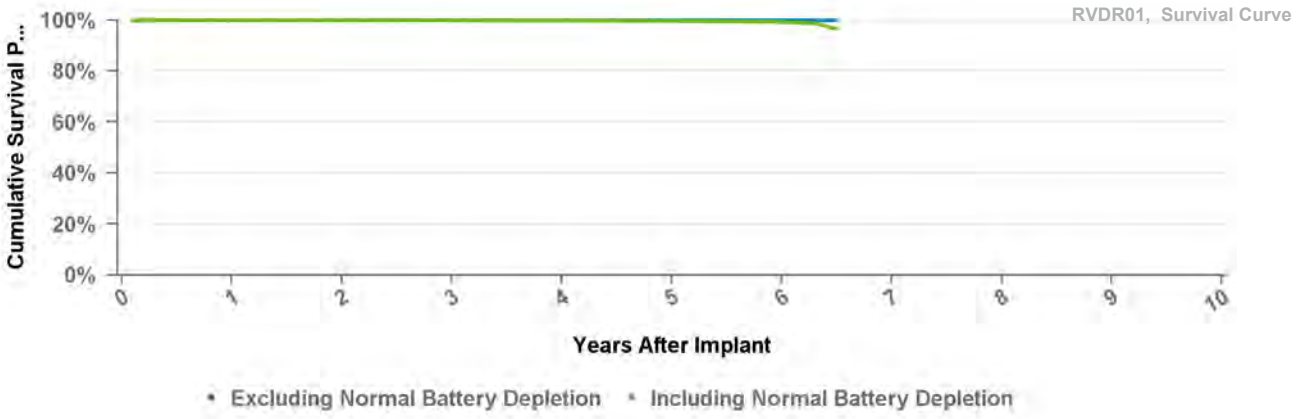
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 96 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.2%	81.7%	54.3%
Effective Sample Size	1139	1043	904	786	634	508	320	109

RVDR01 Revo MRI SureScan

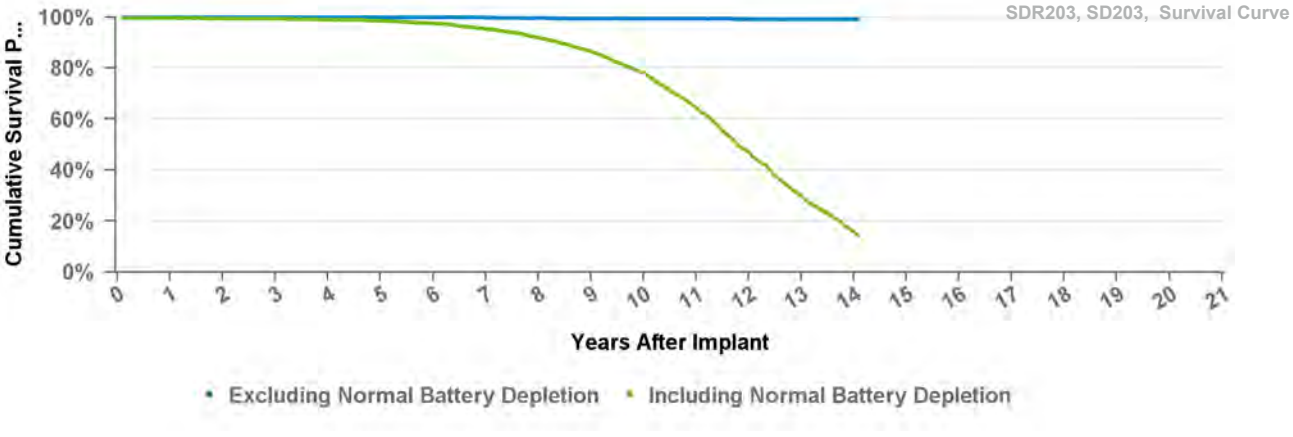
US Market Release	Feb-11	**Total Malfunctions**	**55**
CE Approval Date		**Therapy Function Not Compromised**	**52**
Registered USA Implants	68,631	Battery Malfunction	1
Estimated Active USA Implants	58,378	Electrical Component	32
Normal Battery Depletions	124	Poss Early Battery Depltn	16
		Software Malfunction	3
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.2%	96.5%
Effective Sample Size	60709	57035	53573	49241	33999	10557	319

SD203 Sigma 200 D

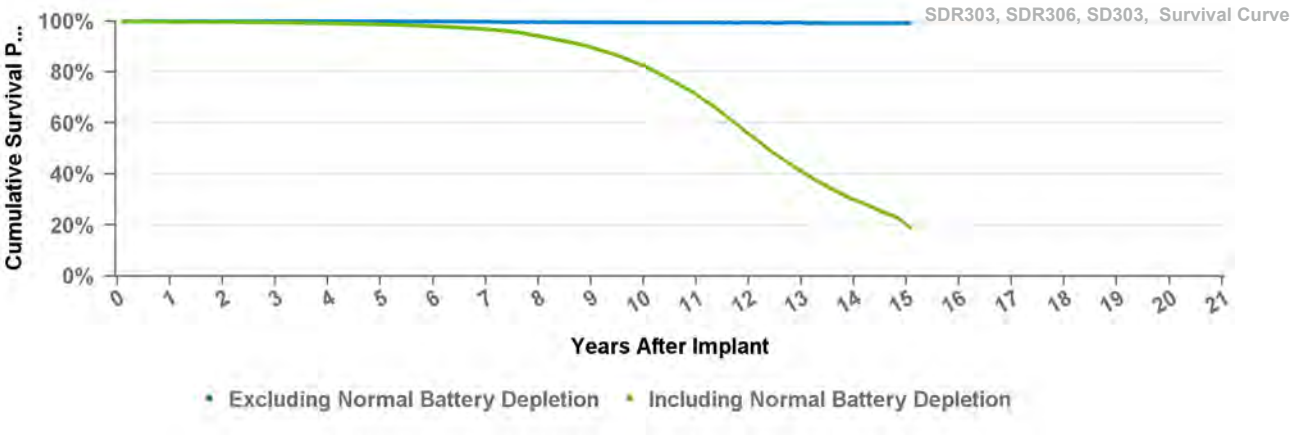
US Market Release	Aug-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	226		
Estimated Active USA Implants	16	**Therapy Function Compromised**	**1**
Normal Battery Depletions	19	Electrical Interconnect	1



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 169 mo
Excluding NBD	100.0%	99.4%	99.4%	99.2%	99.1%	99.1%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.1%
Including NBD	99.6%	99.4%	99.3%	99.0%	98.5%	97.5%	95.4%	91.9%	86.6%	77.9%	64.4%	47.0%	29.7%	15.6%	13.9%
Effective Sample Size	12993	11522	10113	8933	7800	6766	5735	4822	4011	3179	2271	1296	593	135	105

SD303 Sigma 300 D

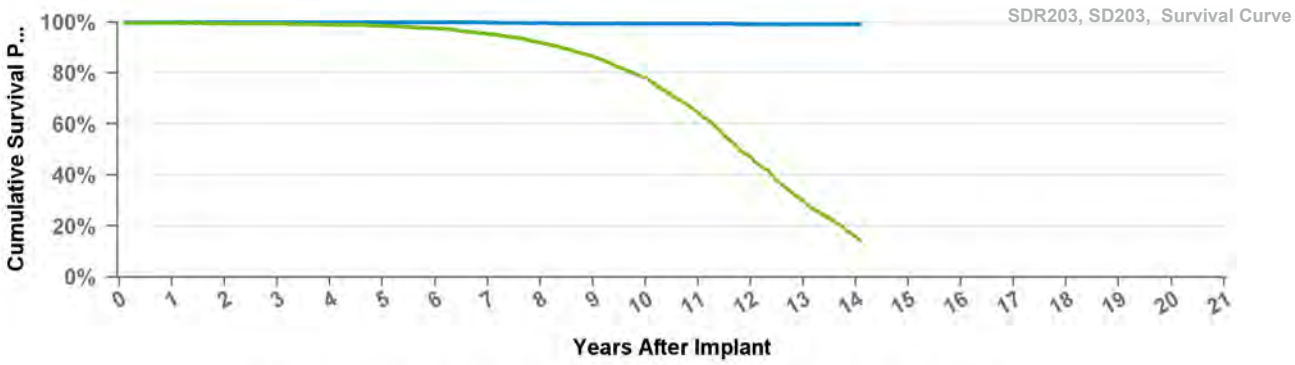
US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	21	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Interconnect	2



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.4%	71.1%	55.7%	41.1%	29.9%	20.1%	18.5%
Effective Sample Size	88289	78246	69203	60876	53402	46771	40573	35097	30208	25063	18681	11478	6028	2495	294	164

SDR203 Sigma 200 DR

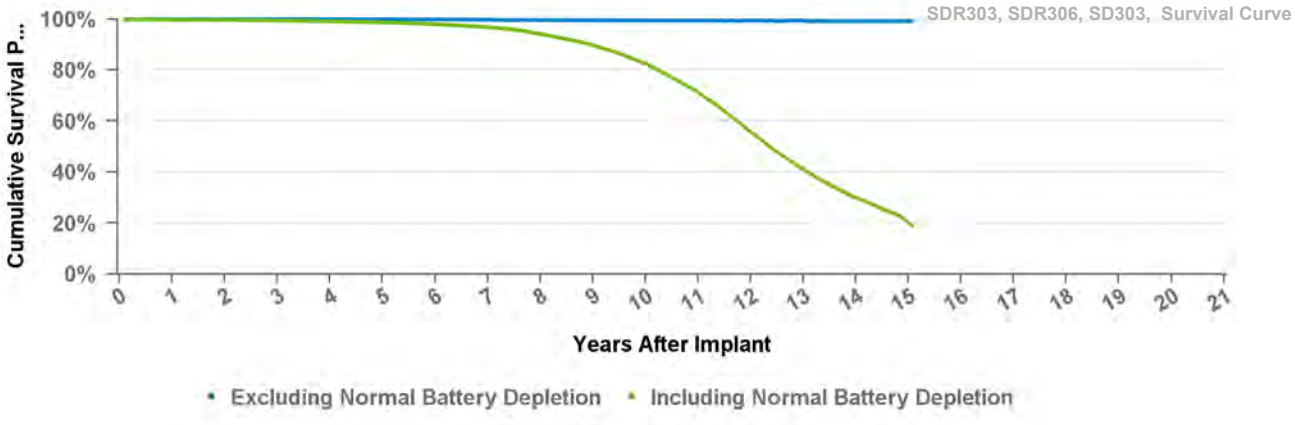
US Market Release	Aug-99	**Total Malfunctions**	**41**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**10**
Registered USA Implants	15,632	Electrical Component	1
Estimated Active USA Implants	1,296	Electrical Interconnect	9
Normal Battery Depletions	1,459	**Therapy Function Compromised**	**31**
		Electrical Component	2
		Electrical Interconnect	28
		Other Malfunction	1



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 169 mo
Excluding NBD	100.0%	99.4%	99.4%	99.2%	99.1%	99.1%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.6%	99.5%	99.1%
Including NBD	99.6%	99.4%	99.3%	99.0%	98.5%	97.5%	95.4%	91.9%	86.6%	77.9%	64.4%	47.0%	29.7%	15.6%	13.9%
Effective Sample Size	12993	11522	10113	8933	7800	6766	5735	4822	4011	3179	2271	1296	593	135	105

SDR303 Sigma 300 DR

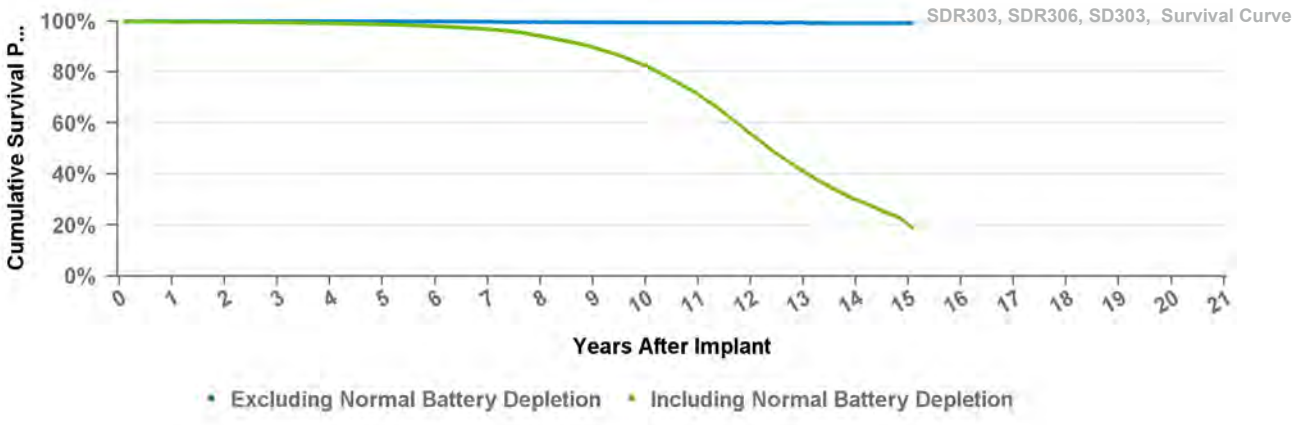
US Market Release	Aug-99	**Total Malfunctions**	**284**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**60**
Registered USA Implants	105,516	Electrical Component	9
Estimated Active USA Implants	13,375	Electrical Interconnect	49
Normal Battery Depletions	9,986	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**224**
		Electrical Component	7
		Electrical Interconnect	216
		Other Malfunction	1



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.4%	71.1%	55.7%	41.1%	29.9%	20.1%	18.5%
Effective Sample Size	88289	78246	69203	60876	53402	46771	40573	35097	30208	25063	18681	11478	6028	2495	294	164

SDR306 Sigma 300 DR

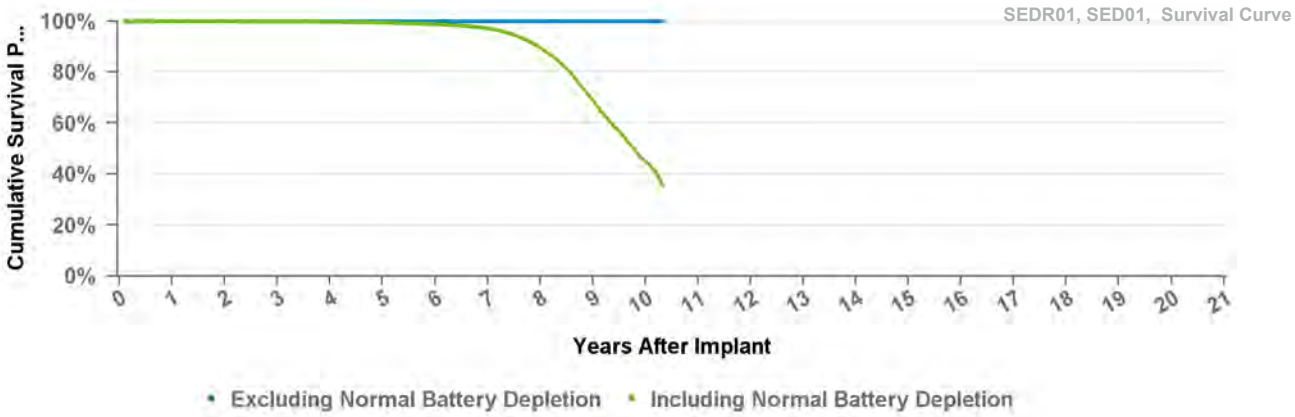
US Market Release	Aug-99	**Total Malfunctions**	**5**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,209		
Estimated Active USA Implants	85	**Therapy Function Compromised**	**5**
Normal Battery Depletions	165	Electrical Interconnect	5



Years	1	10	11	12	13	14	15	2	3	4	5	6	7	8	9	at 181 mo
Excluding NBD	100.0%	99.4%	99.4%	99.3%	99.3%	99.2%	99.2%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%
Including NBD	99.7%	99.6%	99.4%	99.1%	98.7%	98.0%	96.8%	94.1%	89.7%	82.4%	71.1%	55.7%	41.1%	29.9%	20.1%	18.5%
Effective Sample Size	88289	78246	69203	60876	53402	46771	40573	35097	30208	25063	18681	11478	6028	2495	294	164

SED01 Sensia D

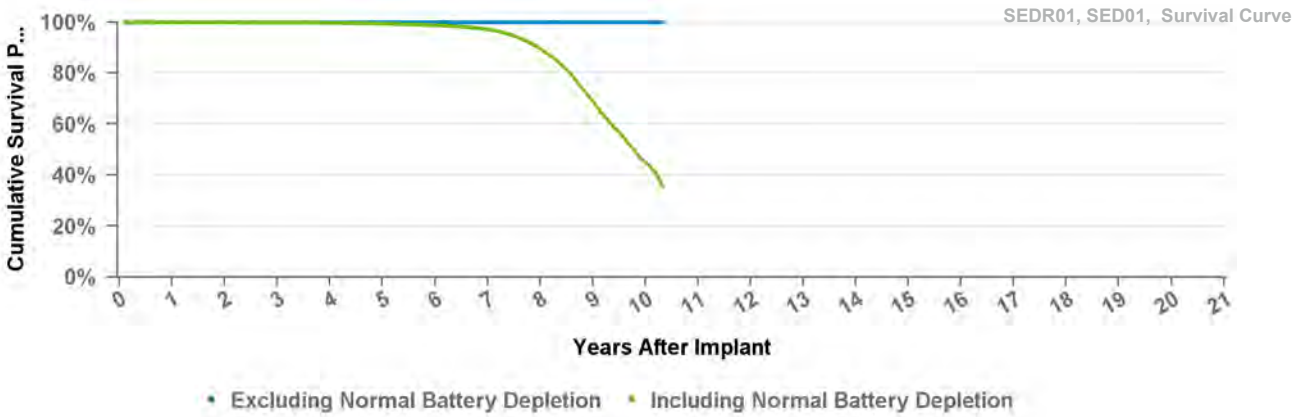
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	10	2	3	4	5	6	7	8	9	at 124 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.7%	97.1%	89.4%	69.1%	45.0%	35.3%
Effective Sample Size	127276	114858	100859	86087	71579	56904	42270	26426	9905	1506	130

SEDR01 Sensia DR

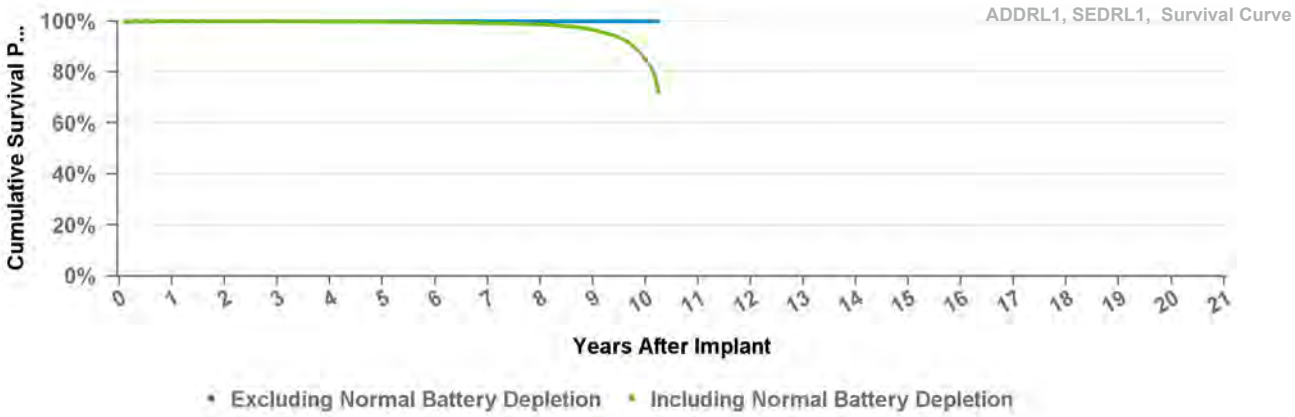
US Market Release	Jul-06	**Total Malfunctions**	**32**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,298	Electrical Component	15
Estimated Active USA Implants	82,561	Electrical Interconnect	1
Normal Battery Depletions	6,536	Other Malfunction	1
		Therapy 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 124 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.7%	97.1%	89.4%	69.1%	45.0%	35.3%
Effective Sample Size	127276	114858	100859	86087	71579	56904	42270	26426	9905	1506	130

SEDRL1 Sensia DR

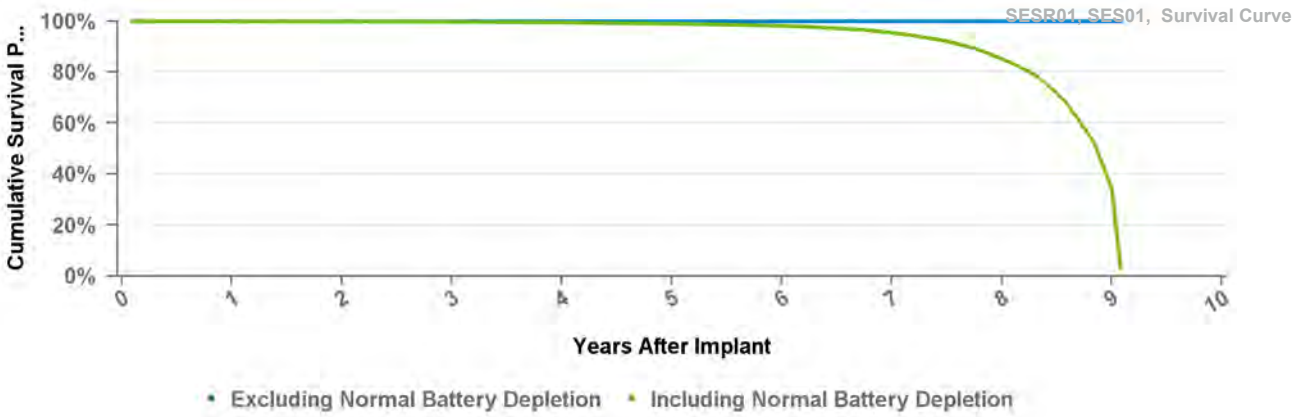
US Market Release	Jul-06	**Total Malfunctions**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**
Registered USA Implants	1	
Estimated Active USA Implants	1	**Therapy Function Compromised**
Normal Battery Depletions		



Years	1	10	2	3	4	5	6	7	8	9	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.7%	96.7%	85.1%	72.1%
Effective Sample Size	118552	104290	88641	70446	52665	36361	23194	12484	5275	852	173

SES01 Sensia S

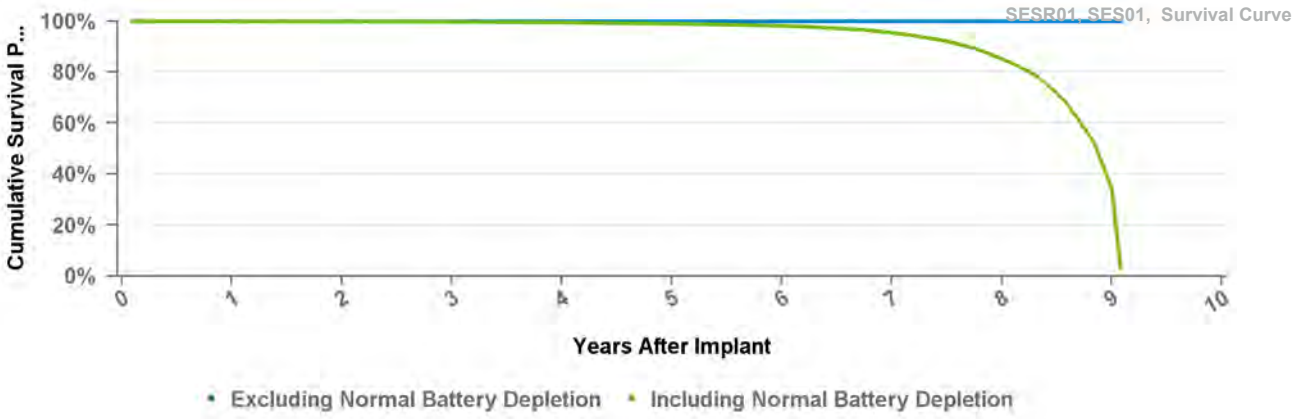
US Market Release	Jul-06	**Total Malfunctions**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**
Registered USA Implants	6	
Estimated Active USA Implants	1	**Therapy Function Compromised**
Normal Battery Depletions		



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.4%	98.9%	98.1%	95.4%	85.1%	34.8%	3.0%
Effective Sample Size	87750	75457	62100	49348	37821	27116	17705	8607	552	117

SESR01 Sensia SR

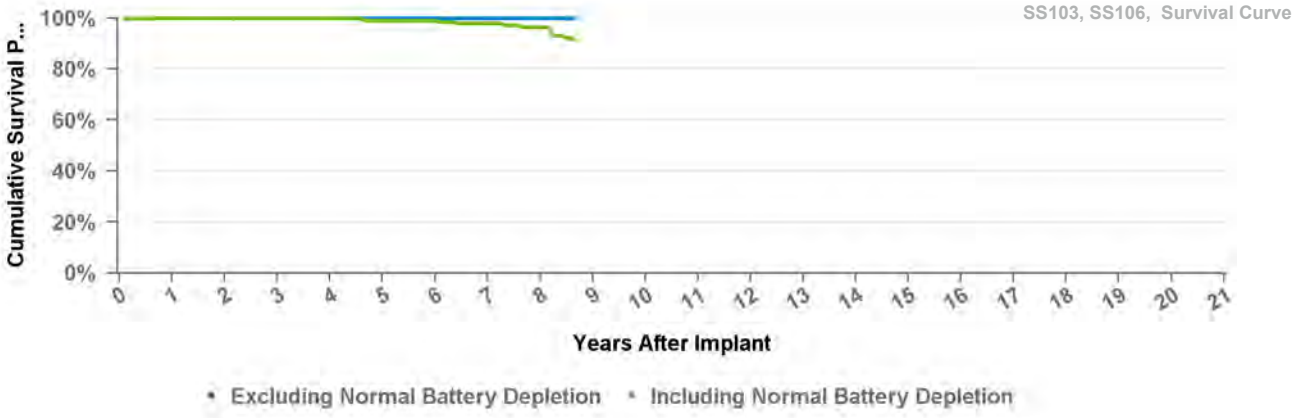
US Market Release	Jul-06	**Total Malfunctions**	**12**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**9**
Registered USA Implants	115,836	Electrical Component	8
Estimated Active USA Implants	62,730	Other Malfunction	1
Normal Battery Depletions	3,229	**Therapy Function Compromised**	**3**
		Electrical Component	2
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.4%	98.9%	98.1%	95.4%	85.1%	34.8%	3.0%
Effective Sample Size	87750	75457	62100	49348	37821	27116	17705	8607	552	117

SS103 Sigma 100 S

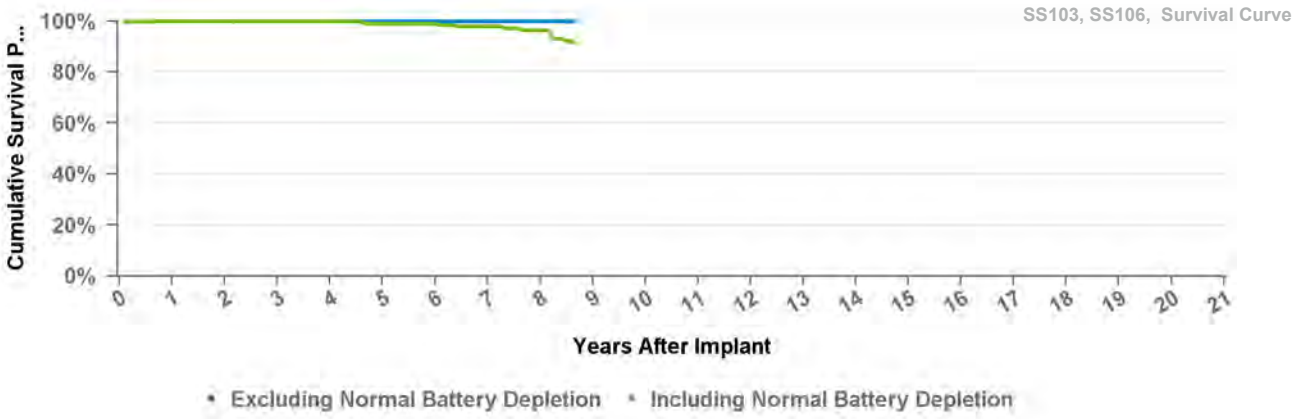
US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	774		
Estimated Active USA Implants	68	**Therapy Function Compromised**	
Normal Battery Depletions	34		



Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	91.2%
Effective Sample Size	600	473	371	294	225	189	154	122	100

SS106 Sigma 100 S

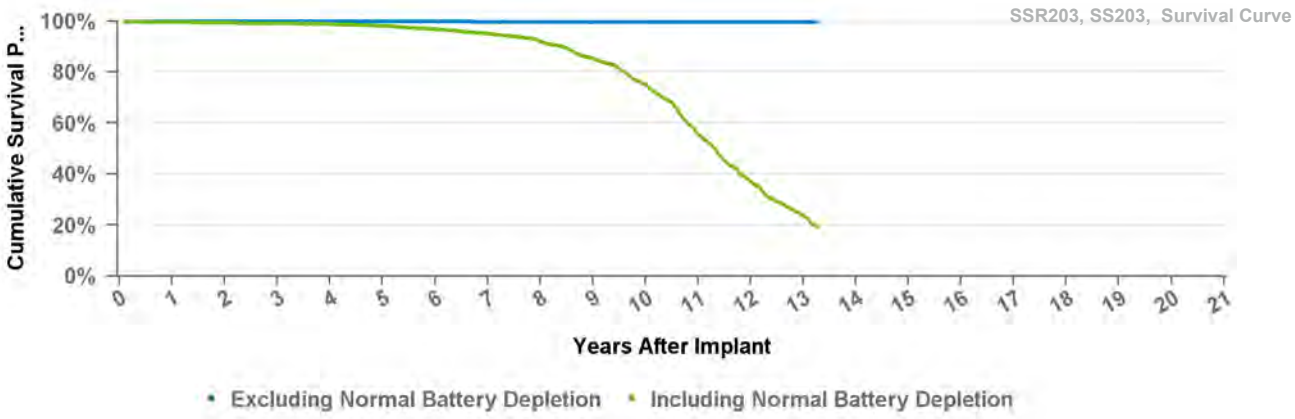
US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	68		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	8		



Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.0%	99.0%	97.9%	96.4%	91.2%
Effective Sample Size	600	473	371	294	225	189	154	122	100

SS203 Sigma 200 S

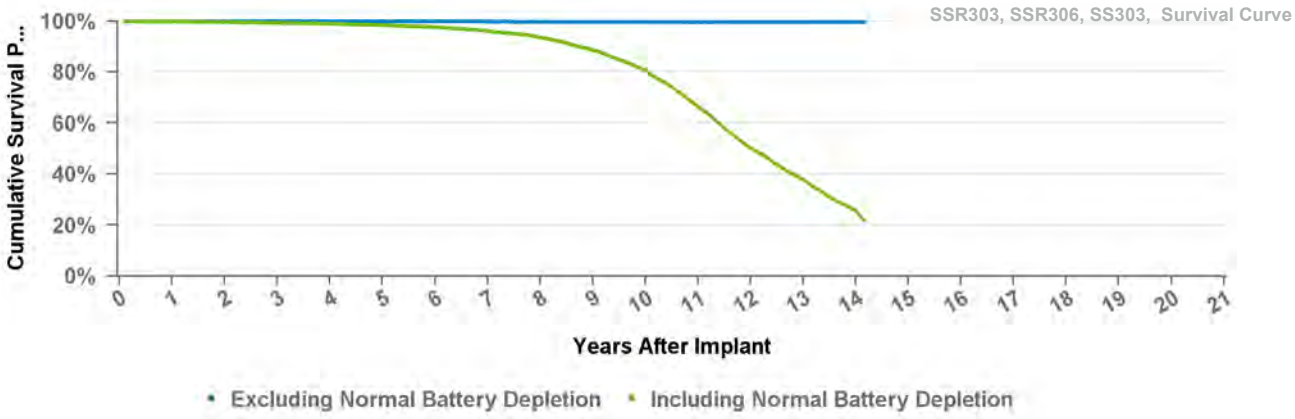
US Market Release	Aug-99	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 159 mo
Excluding NBD	100.0%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.8%	98.1%	96.9%	95.1%	91.9%	85.3%	74.7%	55.6%	36.9%	23.4%	19.2%
Effective Sample Size	9080	7460	6152	5106	4214	3485	2816	2324	1817	1337	826	406	175	114

SS303 Sigma 300 S

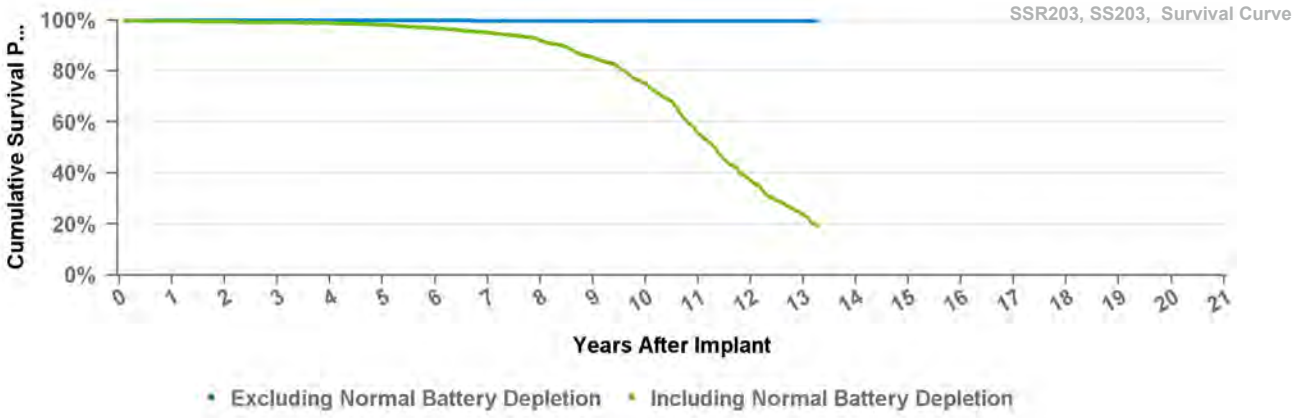
US Market Release	Sep-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	249		
Estimated Active USA Implants	48	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 170 mo
Excluding NBD	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.4%	66.4%	50.1%	37.7%	25.6%	21.6%
Effective Sample Size	41042	33917	28097	23364	19473	16202	13474	11210	9119	7033	4677	2593	1215	292	154

SSR203 Sigma 200 SR

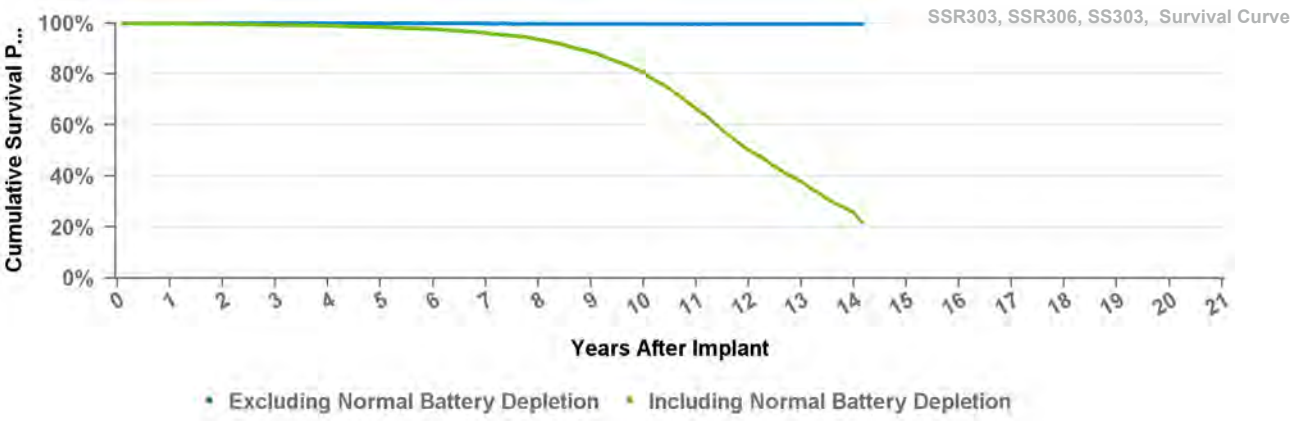
US Market Release	Sep-99	**Total Malfunctions**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	12,119		
Estimated Active USA Implants	844	**Therapy Function Compromised**	**14**
Normal Battery Depletions	674	Electrical Interconnect	14



Years	1	10	11	12	13	2	3	4	5	6	7	8	9	at 159 mo
Excluding NBD	100.0%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%
Including NBD	99.6%	99.4%	99.1%	98.8%	98.1%	96.9%	95.1%	91.9%	85.3%	74.7%	55.6%	36.9%	23.4%	19.2%
Effective Sample Size	9080	7460	6152	5106	4214	3485	2816	2324	1817	1337	826	406	175	114

SSR303 Sigma 300 SR

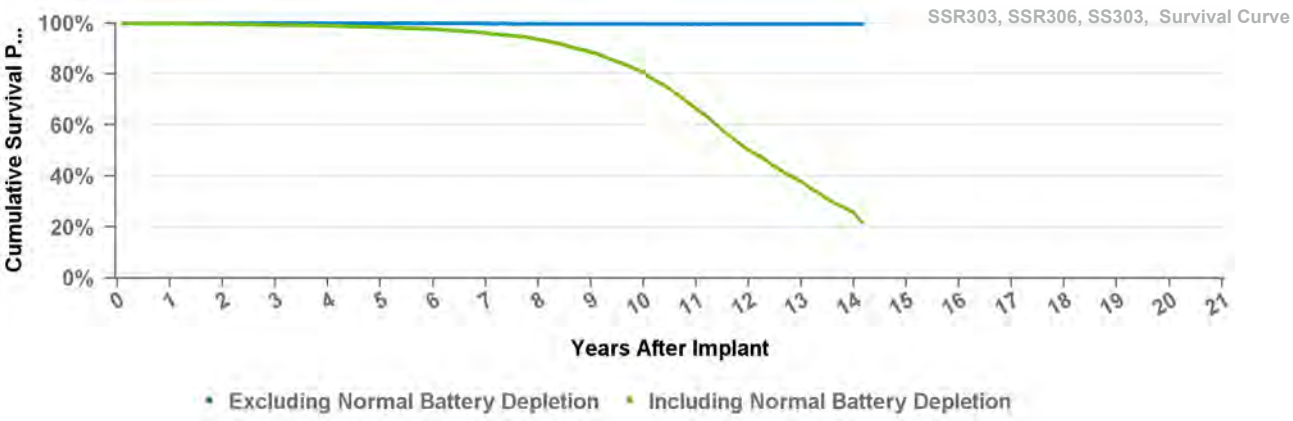
US Market Release	Aug-99	**Total Malfunctions**	**58**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**11**
Registered USA Implants	51,670	Electrical Interconnect	10
Estimated Active USA Implants	4,812	Other Malfunction	1
Normal Battery Depletions	2,839	**Therapy Function Compromised**	**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	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.4%	66.4%	50.1%	37.7%	25.6%	21.6%
Effective Sample Size	41042	33917	28097	23364	19473	16202	13474	11210	9119	7033	4677	2593	1215	292	154

SSR306 Sigma 300 SR

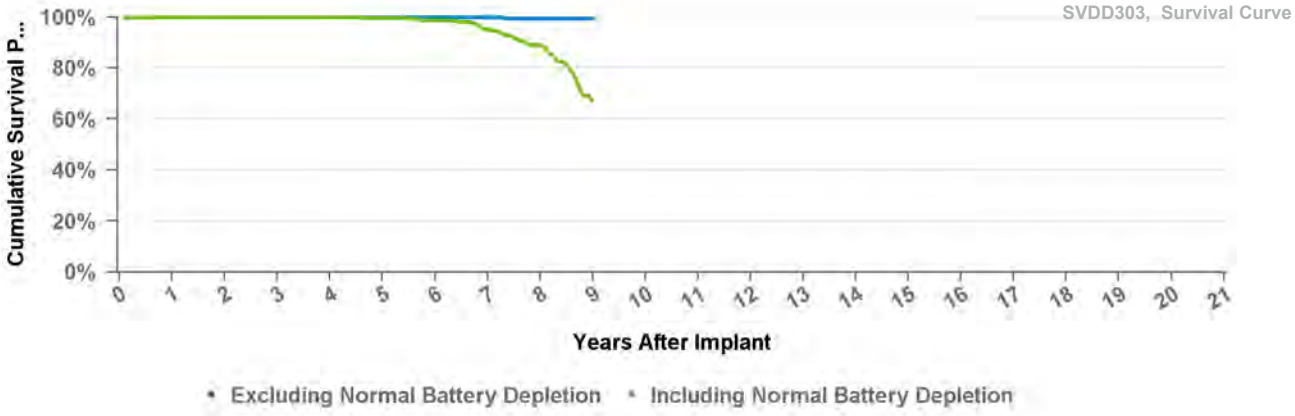
US Market Release	Sep-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,216	Electrical Component	1
Estimated Active USA Implants	158	**Therapy Function Compromised**	**1**
Normal Battery Depletions	159	Electrical Interconnect	1



Years	1	10	11	12	13	14	2	3	4	5	6	7	8	9	at 170 mo
Excluding NBD	100.0%	99.7%	99.6%	99.6%	99.6%	99.6%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.9%	98.4%	97.6%	96.1%	93.5%	88.6%	80.4%	66.4%	50.1%	37.7%	25.6%	21.6%
Effective Sample Size	41042	33917	28097	23364	19473	16202	13474	11210	9119	7033	4677	2593	1215	292	154

SVDD303 Sigma 300 VDD

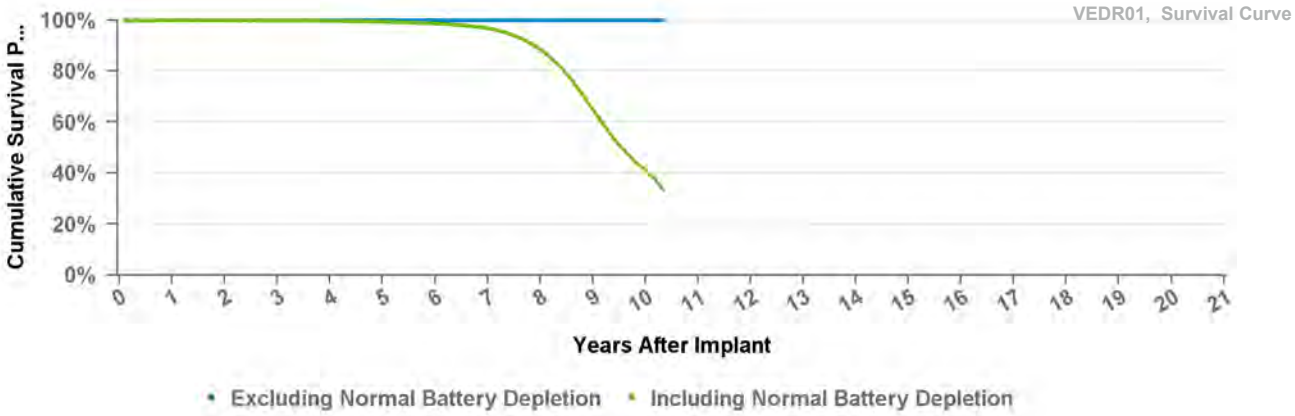
US Market Release	Sep-99	**Total Malfunctions**	**1**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	652		
Estimated Active USA Implants	42	**Therapy Function Compromised**	**1**
Normal Battery Depletions	82	Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.5%	99.5%
Including NBD	100.0%	100.0%	100.0%	100.0%	99.7%	98.6%	95.1%	89.2%	67.1%
Effective Sample Size	530	460	412	364	316	264	210	165	104

VEDR01 Versa DR

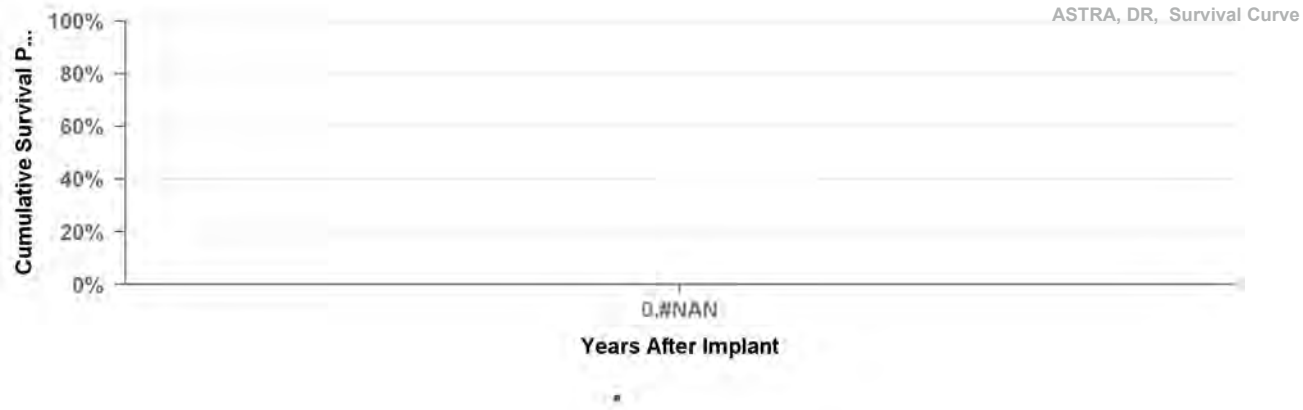
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**9**
Registered USA Implants	117,238	Electrical Component	7
Estimated Active USA Implants	65,936	Electrical Interconnect	2
Normal Battery Depletions	6,718	**Therapy Function Compromised**	**8**
		Electrical Component	4
		Other Malfunction	4



Years	1	10	2	3	4	5	6	7	8	9	at 124 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.3%	98.6%	96.8%	88.4%	65.1%	41.2%	33.5%
Effective Sample Size	99454	89487	79976	69923	59497	48577	37246	24204	9692	1909	383

X2DR01 Astra XT DR MRI SureScan

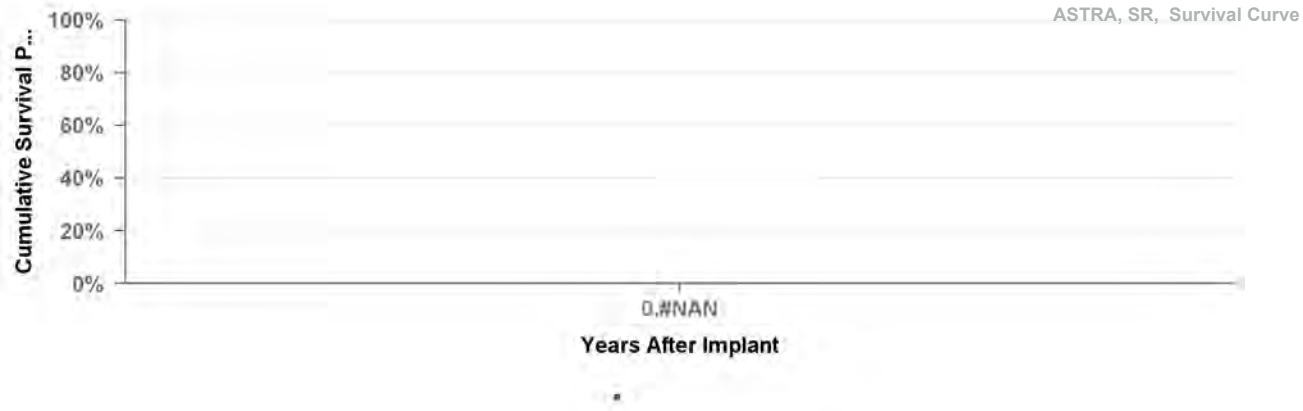
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

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



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm and Heart Failure (CRHF) has tracked lead survival for over 32 years with its multicenter, global chronic lead studies.

Leads Performance Analysis

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

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

Shortfalls Of Using Returned Product And Complaints To Estimate Lead Performance

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

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

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

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

PAN Registry

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

Method for Estimating Lead Performance continued

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

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

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

Patients are eligible for enrollment if:

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

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

Lead Complications

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

Method for Estimating Lead Performance continued

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

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

Data Analysis Methods

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

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

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

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

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

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

Method for Estimating Lead Performance continued

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

Definition of Analysis Dataset

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

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

Criteria for Model Inclusion

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

Returned Product Analysis Results

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

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

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

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

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

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

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

Method for Estimating Lead Performance continued

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

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

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

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

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

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

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

Estimated Number of Implanted and Active Leads in the United States

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

Footnotes:

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

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

Pacing Leads

3830 SelectSecure

US Market Release	8/3/2005
CE Approval	1/31/2003
Registered USA Implants	32,791
Estimated Active USA Implants	23,884
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	0
Insulation Breach	30
Other	3

US Acute Lead Observations

Cardiac Perforation	9
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	49
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	73
Oversensing	9
Unspecified	2

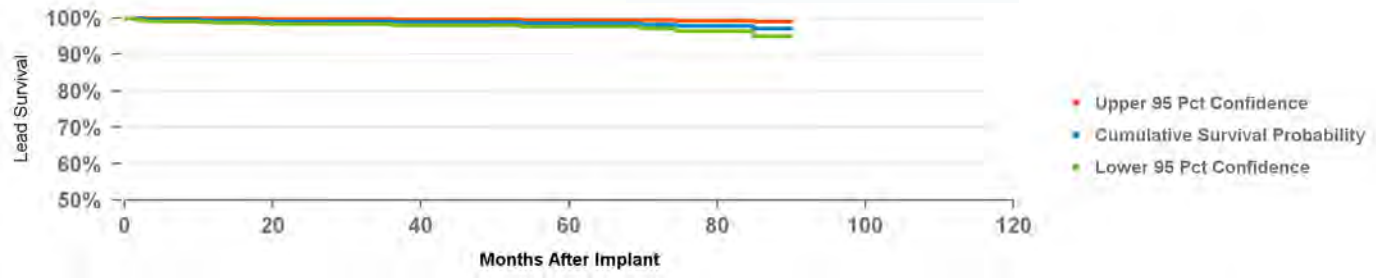
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	992
Cumulative Months of Followup	46,492
Number of Leads Active in Study	462

Qualifying Complications

	15		
Cardiac Perforation	1	Impedance Out of Range	2
Conductor Fracture	2	Lead Dislodgement	3
Extracardiac Stimulation	1		
Failure To Capture	3		
Failure To Sense	3		



Years	1	2	3	4	5	6	7	at 90 mo
%	99.2%	99.0%	99.0%	98.8%	98.6%	98.2%	97.8%	97.0%
#	811	695	597	470	390	242	106	64

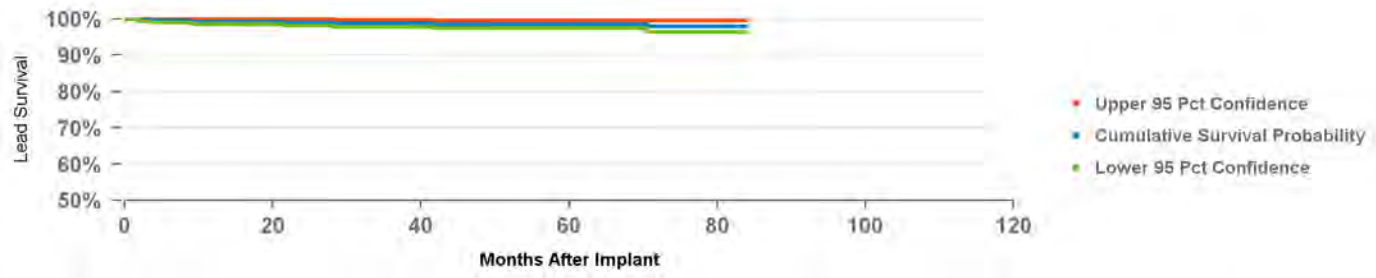
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	713
Cumulative Months of Followup	30,338
Number of Leads Active in Study	350

Qualifying Complications

	9		
Failure To Capture	3	Impedance Out of Range	1
		Lead Dislodgement	4
		Other	1



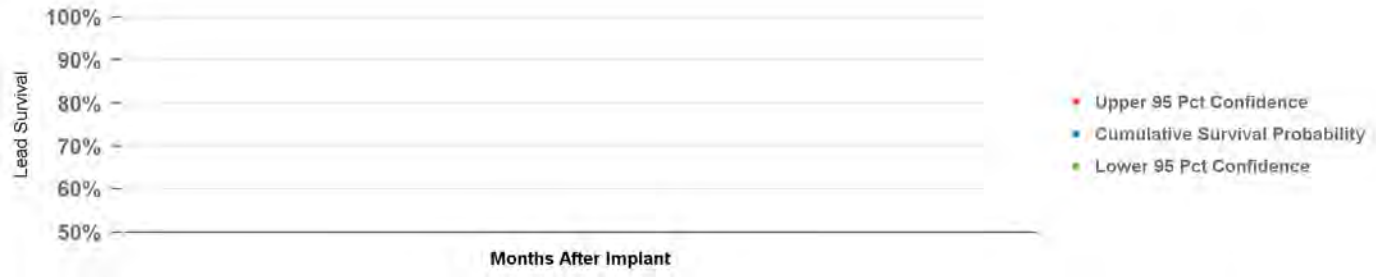
Years	1	2	3	4	5	6	at 84 mo
%	99.3%	99.1%	98.8%	98.5%	98.5%	98.0%	98.0%
#	536	464	388	293	239	144	72

4073 CapSure Sense

US Market Release	6/23/2002
CE Approval	2/1/2002
Registered USA Implants	770
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	6/23/2002
CE Approval	2/1/2002
Registered USA Implants	116,142
Estimated Active USA Implants	66,971
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Crimp Weld Bond	0
Insulation Breach	35
Other	0

US Acute Lead Observations

Cardiac Perforation	20
Conductor Fracture	1
Extracardiac Stimulation	2
Failure To Capture	66
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	83
Oversensing	3
Unspecified	0

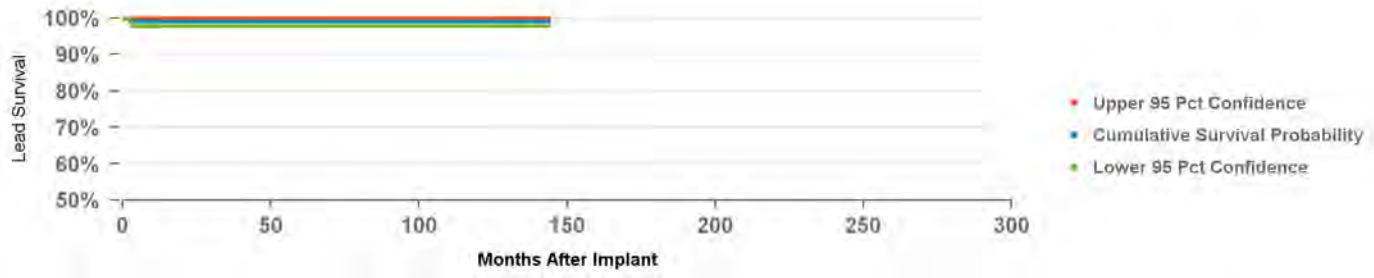
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Followup	22,634
Number of Leads Active in Study	107

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	147	132	120	108	68	50

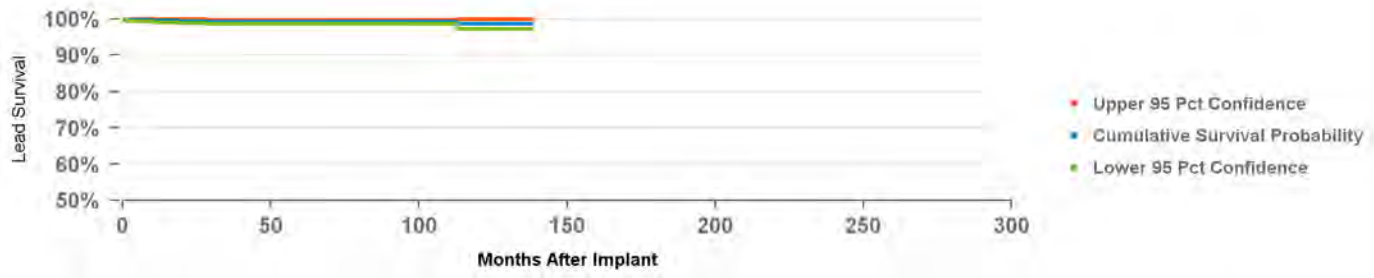
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,119
Cumulative Months of Followup	59,108
Number of Leads Active in Study	394

Qualifying Complications 8

Conductor Fracture	1
Failure To Capture	2
Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	2
Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.5%	99.4%	99.3%	99.3%	99.3%	99.3%	99.3%	99.3%	99.3%	98.6%	98.6%	98.6%
#	979	811	668	514	352	255	204	181	158	124	74	55

Pacing Leads

4076 CapSureFix Novus

US Market Release	2/25/2004
CE Approval	6/14/2004
Registered USA Implants	564,427
Estimated Active USA Implants	385,996
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	79
Crimp Weld Bond	1
Insulation Breach	105
Other	22

US Acute Lead Observations

Cardiac Perforation	94
Conductor Fracture	5
Extracardiac Stimulation	14
Failure To Capture	119
Failure To Sense	44
Impedance Abnormal	16
Insulation Breach	1
Lead Dislodgement	297
Oversensing	23
Unspecified	12

Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,252
Cumulative Months of Followup	153,805
Number of Leads Active in Study	1,545

Qualifying Complications

17

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

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.8%	99.7%	99.6%	99.5%	99.3%	99.1%	99.0%	99.0%	99.0%	99.0%
#	2,725	2,343	1,940	1,477	1,044	757	490	251	165	73

Ventricular Placement

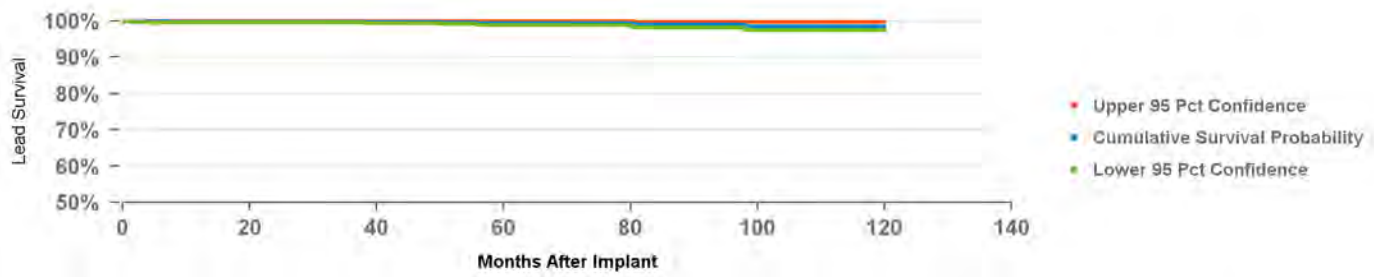
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,518
Cumulative Months of Followup	84,215
Number of Leads Active in Study	482

Qualifying Complications

9

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



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.8%	99.8%	99.8%	99.7%	99.4%	99.4%	99.0%	99.0%	98.5%	98.5%
#	1,305	1,153	1,006	804	626	528	374	226	162	76

4092 CapSure SP Novus

US Market Release	9/17/1998
CE Approval	4/15/1998
Registered USA Implants	187,187
Estimated Active USA Implants	67,189
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	17
Crimp Weld Bond	0
Insulation Breach	76
Other	2

US Acute Lead Observations

Cardiac Perforation	4
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	35
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified	2

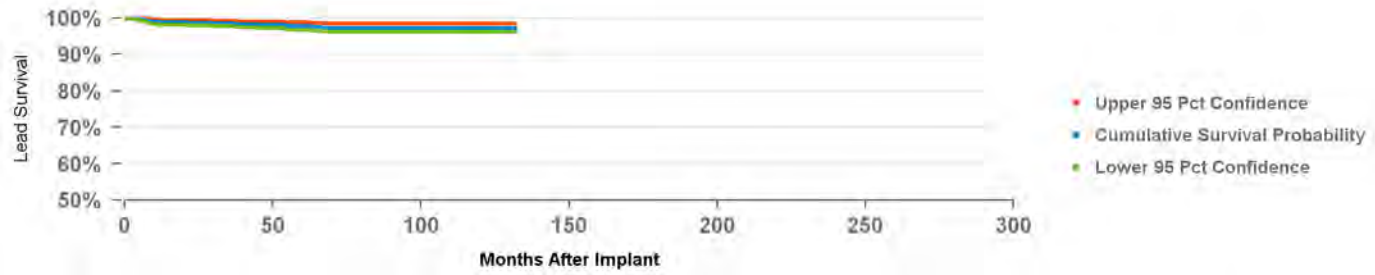
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,188
Cumulative Months of Followup	67,538
Number of Leads Active in Study	33

Qualifying Complications

21

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



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.8%	98.7%	98.5%	98.1%	97.8%	97.3%	97.3%	97.3%	97.3%	97.3%	97.3%
#	943	840	745	628	507	393	320	259	211	130	67

4568 CapSureFix

US Market Release	1/2/1997
CE Approval	
Registered USA Implants	69,452
Estimated Active USA Implants	14,734
Fixation Type	J-shape, screw in
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	119
Other	52

US Acute Lead Observations

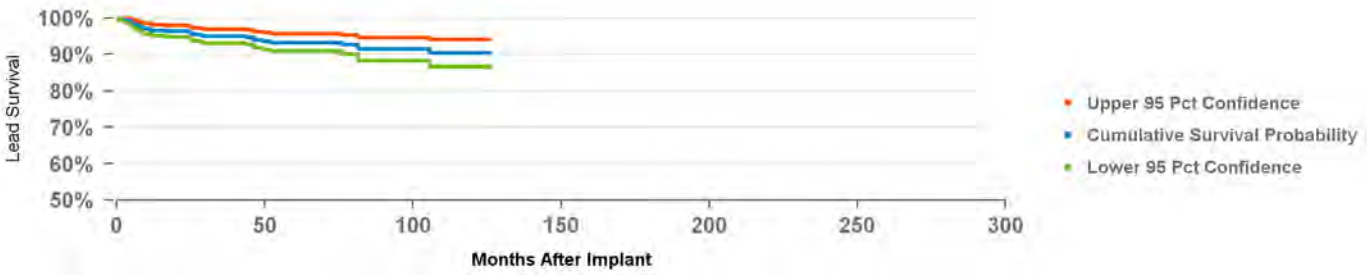
Cardiac Perforation	3
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	4
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	671
Cumulative Months of Followup	32,103
Number of Leads Active in Study	8

Qualifying Complications 38

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



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	96.6%	96.2%	95.0%	94.0%	93.2%	93.2%	91.4%	91.4%	90.4%	90.4%	90.4%
#	493	419	329	277	228	173	139	105	84	63	51

4574 CapSure Sense

US Market Release	6/23/2002
CE Approval	2/1/2002
Registered USA Implants	79,784
Estimated Active USA Implants	49,557
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	12
Other	0

US Acute Lead Observations

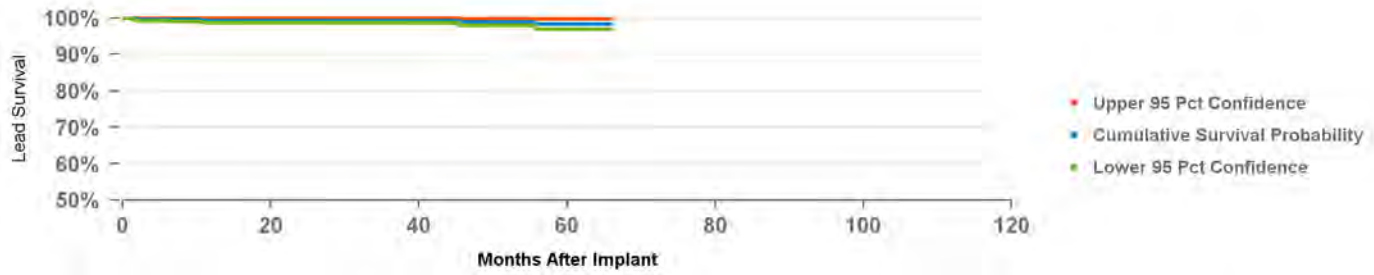
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	42
Failure To Sense	13
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	103
Oversensing	1
Unspecified	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,001
Cumulative Months of Followup	31,123
Number of Leads Active in Study	606

Qualifying Complications 8

Conductor Fracture	2	Lead Dislodgement	5
Failure To Capture	1		



Years	1	2	3	4	5	at 66 mo
%	99.3%	99.3%	99.3%	98.9%	98.3%	98.3%
#	761	528	381	250	114	76

Pacing Leads

4592 CapSure SP Novus

US Market Release	10/5/1998
CE Approval	4/15/1998
Registered USA Implants	89,518
Estimated Active USA Implants	33,848
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

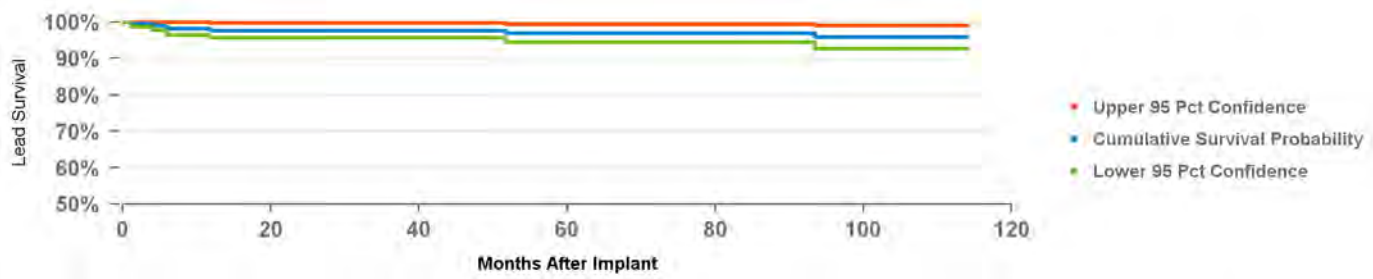
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	10
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	348
Cumulative Months of Followup	18,332
Number of Leads Active in Study	59

Qualifying Complications 8

Failure To Capture	5
Failure To Sense	1
Lead Dislodgement	2



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	97.6%	97.6%	97.6%	97.6%	96.9%	96.9%	96.9%	95.8%	95.8%	95.8%
#	233	208	179	156	125	109	85	75	63	55

5054 CapSure Z Novus

US Market Release	6/3/1998
CE Approval	6/5/1997
Registered USA Implants	99,432
Estimated Active USA Implants	33,999
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	1
Insulation Breach	35
Other	3

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	23
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	1
Lead Dislodgement	29
Oversensing	0
Unspecified	9

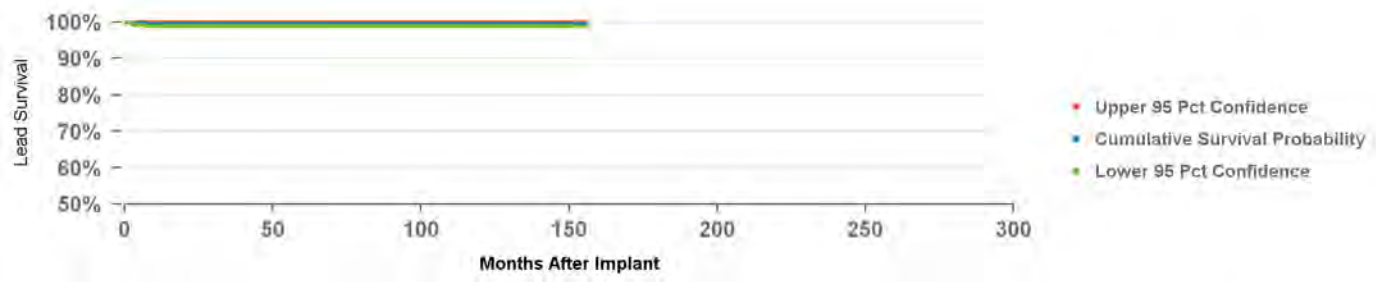
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Cumulative Months of Followup	38,604
Number of Leads Active in Study	65

Qualifying Complications 2

Failure To Capture	1	Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
#	412	392	359	322	289	252	219	185	152	128	107	89	56

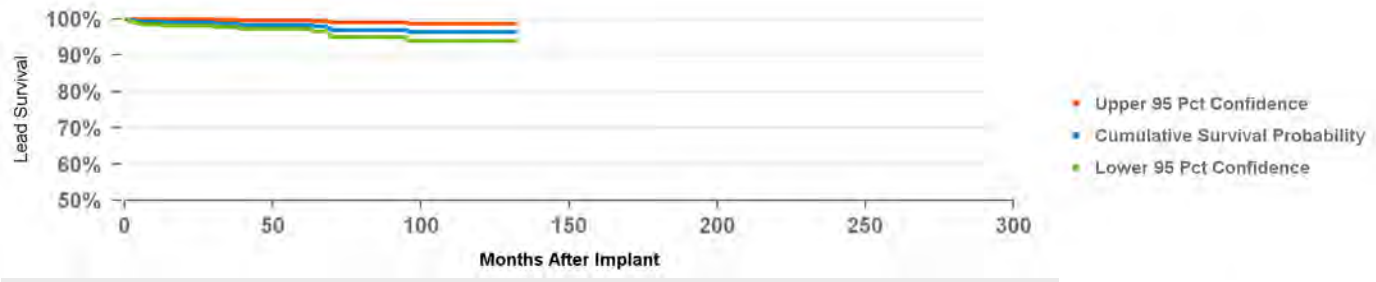
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	985
Cumulative Months of Followup	33,230
Number of Leads Active in Study	37

Qualifying Complications 11

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



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.3%	99.1%	98.8%	98.4%	98.4%	97.0%	97.0%	96.3%	96.3%	96.3%	96.3%
#	481	396	308	264	226	187	162	137	103	83	62

5072 SureFix

US Market Release	6/5/1998
CE Approval	9/25/1997
Registered USA Implants	10,055
Estimated Active USA Implants	3,088
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	9
Other	0

US Acute Lead Observations

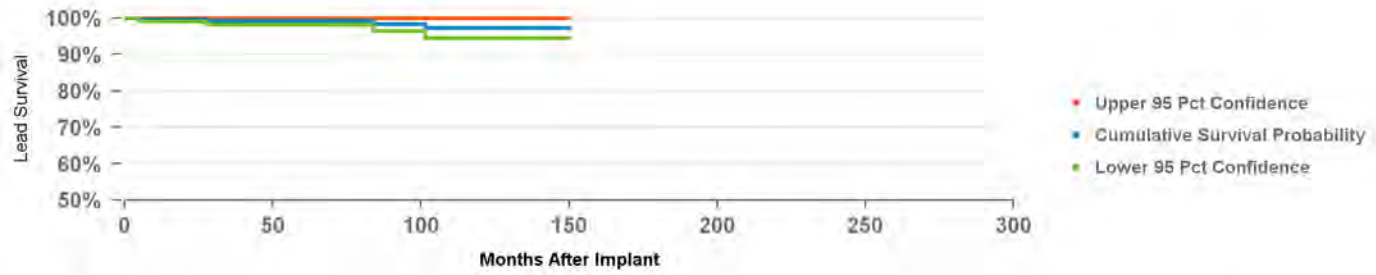
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	2
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	518
Cumulative Months of Followup	23,230
Number of Leads Active in Study	13

Qualifying Complications 4

Cardiac Perforation	1
Failure To Capture	2
Failure To Sense	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.7%	99.7%	99.2%	99.2%	99.2%	99.2%	98.4%	98.4%	97.3%	97.3%	97.3%	97.3%	97.3%
#	265	236	218	193	158	137	109	92	81	72	63	53	51

Pacing Leads

5076 CapSureFix Novus

US Market Release	8/31/2000
CE Approval	8/12/1999
Registered USA Implants	2,268,673
Estimated Active USA Implants	1,459,257
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	819
Crimp Weld Bond	0
Insulation Breach	837
Other	218

US Acute Lead Observations

Cardiac Perforation	705
Conductor Fracture	21
Extracardiac Stimulation	54
Failure To Capture	790
Failure To Sense	232
Impedance Abnormal	54
Insulation Breach	9
Lead Dislodgement	2,065
Oversensing	184
Unspecified	31

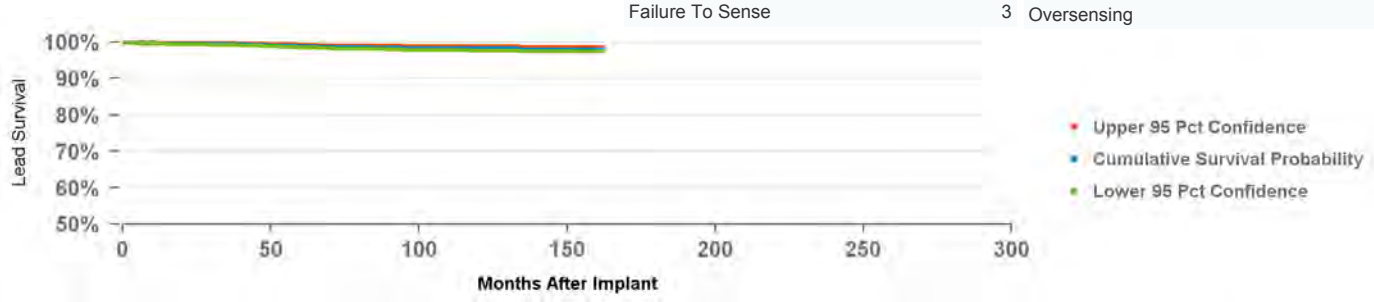
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	7,696
Cumulative Months of Followup	303,710
Number of Leads Active in Study	3,822

Qualifying Complications 52

Cardiac Perforation	2	Impedance Out of Range	6
Conductor Fracture	9	Insulation Breach	1
Extracardiac Stimulation	2	Lead Dislodgement	15
Failure To Capture	8	Other	3
Failure To Sense	3	Oversensing	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.6%	99.6%	99.5%	99.2%	98.9%	98.6%	98.6%	98.4%	98.4%	98.3%	98.3%	98.1%	98.1%	98.1%
#	5,424	4,203	3,378	2,440	1,797	1,380	1,022	741	580	456	301	187	94	71

Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,405
Cumulative Months of Followup	100,861
Number of Leads Active in Study	656

Qualifying Complications 26

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	5	Lead Dislodgement	3
Failure To Capture	10	Other	1
Failure To Sense	1	Oversensing	1

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.3%	99.2%	99.0%	98.8%	98.3%	98.1%	97.5%	96.9%	96.9%	96.5%	96.5%	95.7%
#	1,692	1,374	1,107	750	582	473	376	295	232	197	151	100	58

5086MRI CapsureFix Novus MRI

US Market Release	2/8/2011
CE Approval	1/21/2009
Registered USA Implants	208,433
Estimated Active USA Implants	185,031
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	47
Crimp Weld Bond	0
Insulation Breach	89
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	0

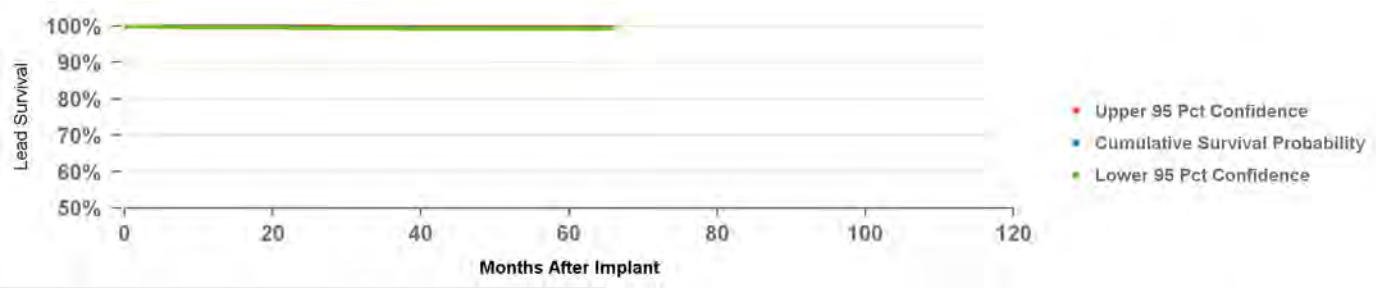
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,092
Cumulative Months of Followup	121,298
Number of Leads Active in Study	1,649

Qualifying Complications 14

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



Years	1	2	3	4	5	at 66 mo
%	99.8%	99.6%	99.6%	99.5%	99.5%	99.5%
#	2,677	2,305	1,916	1,340	396	73

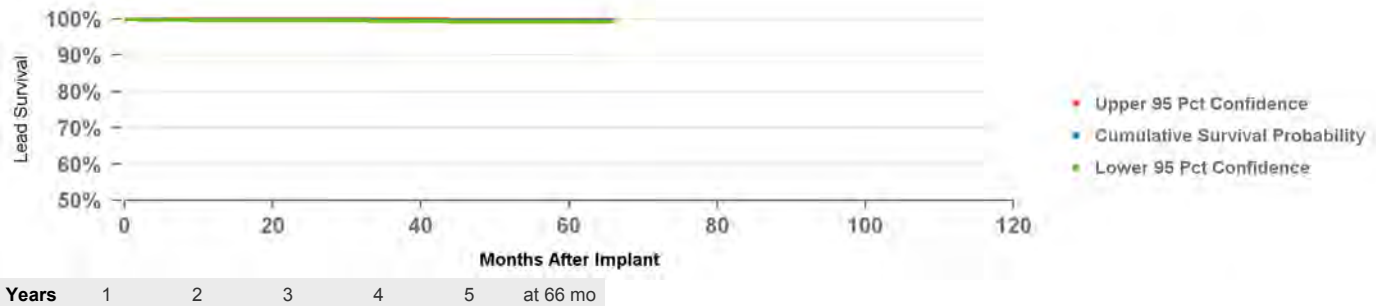
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,036
Cumulative Months of Followup	120,669
Number of Leads Active in Study	1,616

Qualifying Complications 11

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



Years	1	2	3	4	5	at 66 mo
%	99.8%	99.7%	99.6%	99.5%	99.5%	99.5%
#	2,660	2,298	1,900	1,334	399	73

Pacing Leads

5092 CapSure SP Novus

US Market Release	6/3/1998
CE Approval	9/25/1997
Registered USA Implants	141,221
Estimated Active USA Implants	52,986
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	22
Crimp Weld Bond	0
Insulation Breach	55
Other	3

US Acute Lead Observations

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

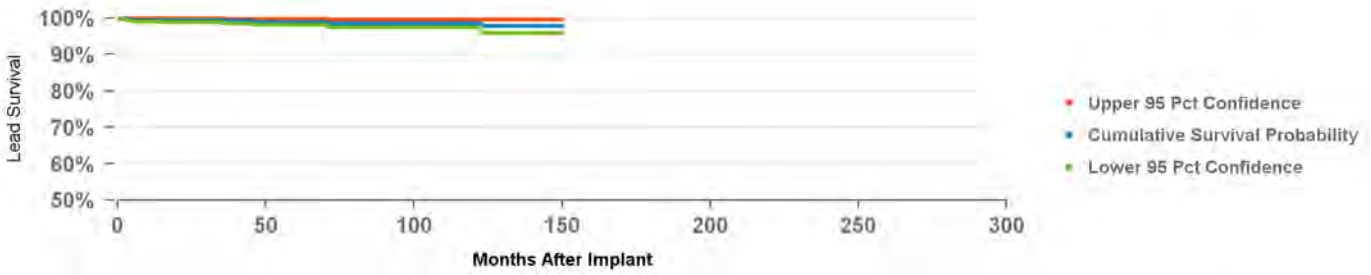
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,207
Cumulative Months of Followup	52,419
Number of Leads Active in Study	42

Qualifying Complications

10

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.7%	97.7%	97.7%
#	825	658	522	418	325	253	207	163	136	118	95	70	61

Pacing Leads

5554 CapSure Z Novus

US Market Release	6/3/1998
CE Approval	6/5/1997
Registered USA Implants	64,491
Estimated Active USA Implants	24,351
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Crimp Weld Bond	0
Insulation Breach	30
Other	2

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	38
Oversensing	0
Unspecified	3

Product Surveillance Registry Results

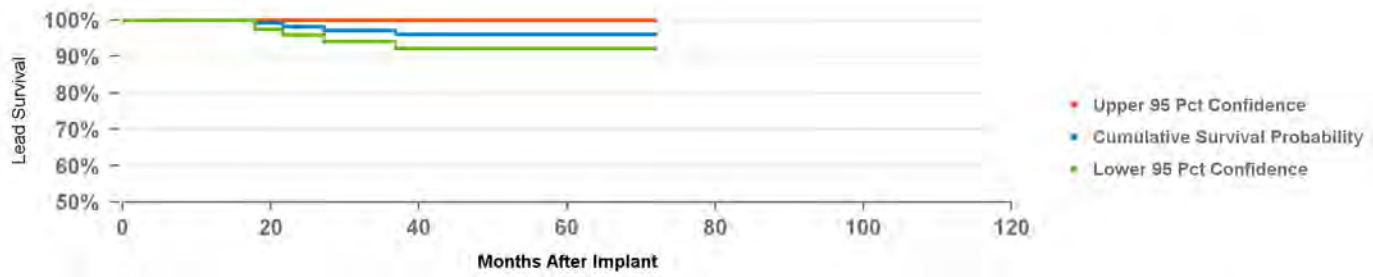
Number of Leads Enrolled in Study	360
Cumulative Months of Followup	8,660
Number of Leads Active in Study	10

Qualifying Complications

Failure To Capture	2

5

Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	1



Years	1	2	3	4	5	at 72 mo
%	100.0%	98.2%	97.2%	96.0%	96.0%	96.0%
#	151	116	91	78	60	50

Pacing Leads

5592 CapSure SP Novus

US Market Release	6/3/1998
CE Approval	9/25/1997
Registered USA Implants	37,285
Estimated Active USA Implants	17,106
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

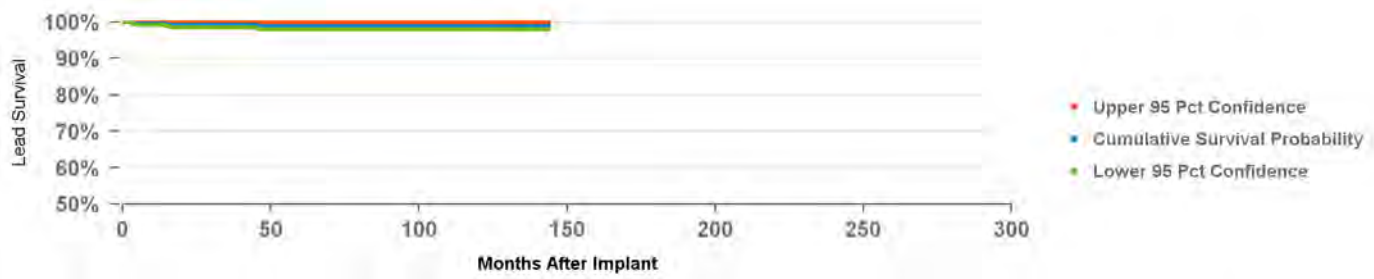
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	43
Oversensing	1
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	708
Cumulative Months of Followup	36,391
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%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	532	441	357	293	236	183	151	132	110	95	79	54

5594 CapSure SP Novus

US Market Release	6/25/2001
CE Approval	3/23/2001
Registered USA Implants	17,590
Estimated Active USA Implants	9,573
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	13
Other	0

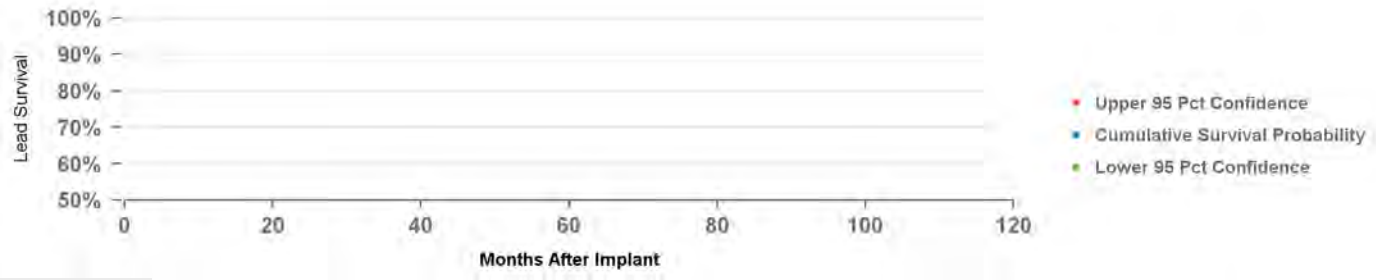
US Acute Lead Observations

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	31
Cumulative Months of Followup	2,570
Number of Leads Active in Study	9

1	
Oversensing	1



Years	at 0 mo
%	100.0%
#	

Pacing Leads

6940 CapSureFix

US Market Release	10/9/1998
CE Approval	
Registered USA Implants	25,369
Estimated Active USA Implants	5,254
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	23
Other	12

US Acute Lead Observations

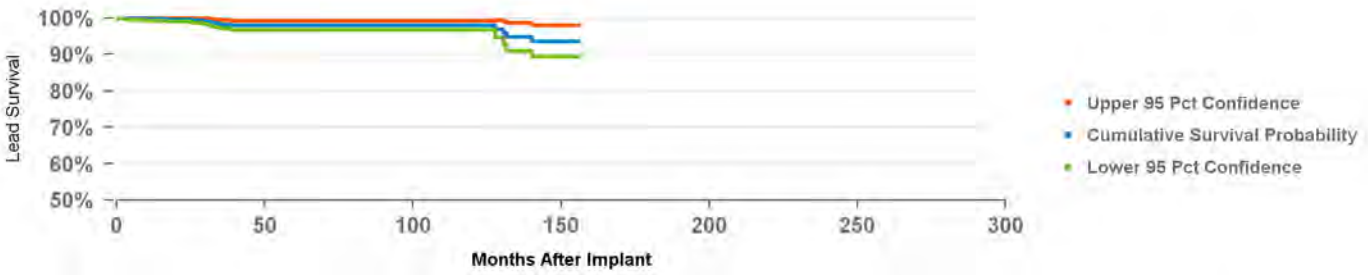
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	848
Cumulative Months of Followup	44,002
Number of Leads Active in Study	29

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%
#	647	527	434	350	278	219	189	151	125	96	80	70	52

Defibrillation Leads

6721 Epicardial Patch

US Market Release	3/31/1994
CE Approval	1/1/1993
Registered USA Implants	3,178
Estimated Active USA Implants	1,077
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	0
Insulation Breach	1
Other	0

US Acute Lead Observations

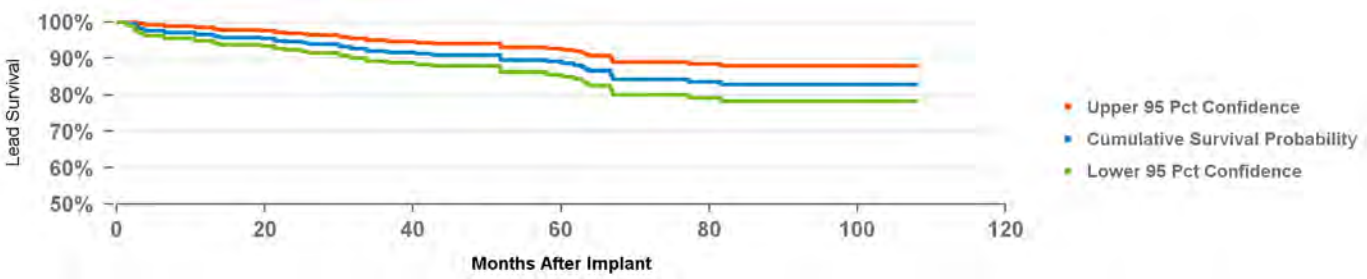
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	415
Cumulative Months of Followup	23,713
Number of Leads Active in Study	5

Qualifying Complications 47

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



Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.5%	92.0%	90.9%	89.1%	84.4%	83.0%	83.0%	83.0%
#	344	315	269	216	185	132	99	64	56

Defibrillation Leads

6930 Sprint Fidelis

US Market Release	9/2/2004
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	121
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

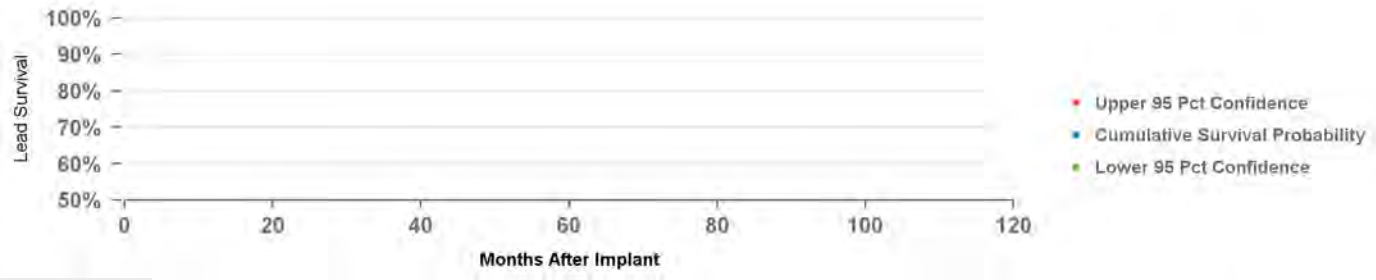
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	0
Other	0

US Acute Lead Observations

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

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%
#	

Defibrillation Leads

6931 Sprint Fidelis

US Market Release	9/2/2004
CE Approval	
Registered USA Implants	8,075
Estimated Active USA Implants	2,233
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	634
Crimp Weld Bond	0
Insulation Breach	1
Other	5

US Acute Lead Observations

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

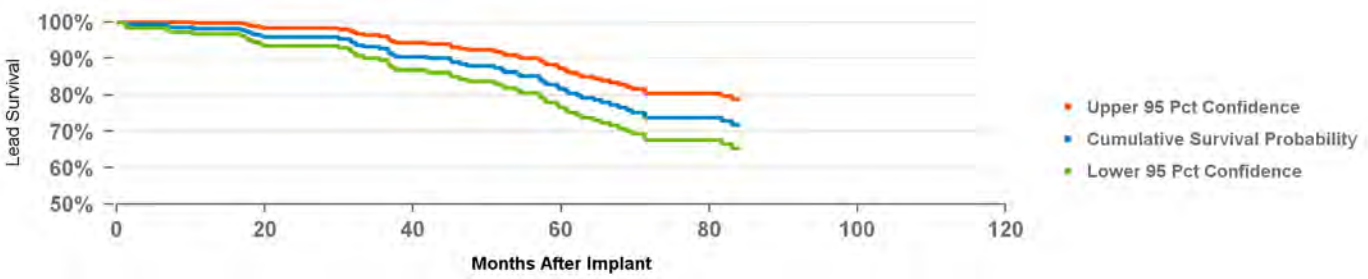
Product Surveillance Registry Results

Number of Leads Enrolled in Study	309
Cumulative Months of Followup	17,021
Number of Leads Active in Study	29

Qualifying Complications

59

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



Years	1	2	3	4	5	6	at 84 mo
%	98.2%	95.9%	92.7%	87.9%	81.8%	73.8%	71.9%
#	271	239	209	167	137	99	64

Defibrillation Leads

6935 Sprint Quattro Secure S

US Market Release	11/1/2008
CE Approval	3/31/2008
Registered USA Implants	57,173
Estimated Active USA Implants	45,901
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	244
Crimp Weld Bond	0
Insulation Breach	8
Other	40

US Acute Lead Observations

Cardiac Perforation	21
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	22
Failure To Sense	8
Impedance Abnormal	17
Insulation Breach	1
Lead Dislodgement	51
Oversensing	50
Unspecified	5

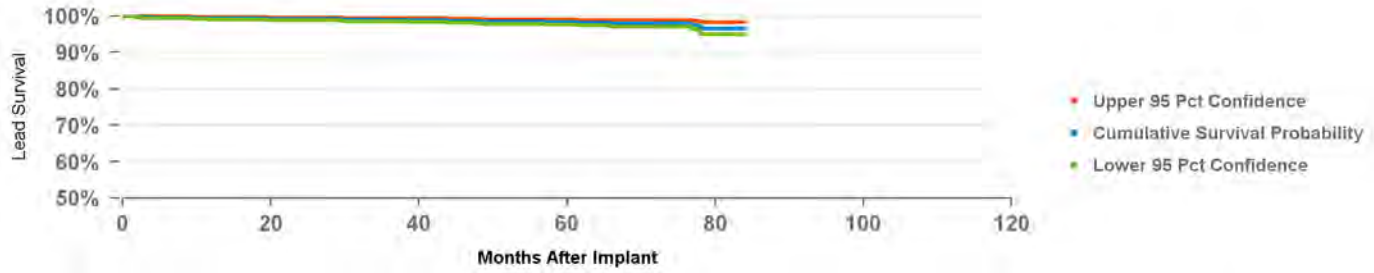
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,580
Cumulative Months of Followup	101,342
Number of Leads Active in Study	1,129

Qualifying Complications

35

Cardiac Perforation	1
Conductor Fracture	14
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	1
Impedance Out of Range	2
Lead Dislodgement	7
Other	1
Oversensing	6



Years	1	2	3	4	5	6	at 84 mo
%	99.4%	99.2%	98.9%	98.6%	98.3%	97.9%	96.6%
#	2,183	1,745	1,375	964	547	288	101

Defibrillation Leads

6935M Sprint Quattro Secure S

US Market Release	8/2/2012
CE Approval	7/12/2012
Registered USA Implants	144,111
Estimated Active USA Implants	136,200
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	126
Crimp Weld Bond	0
Insulation Breach	2
Other	15

US Acute Lead Observations

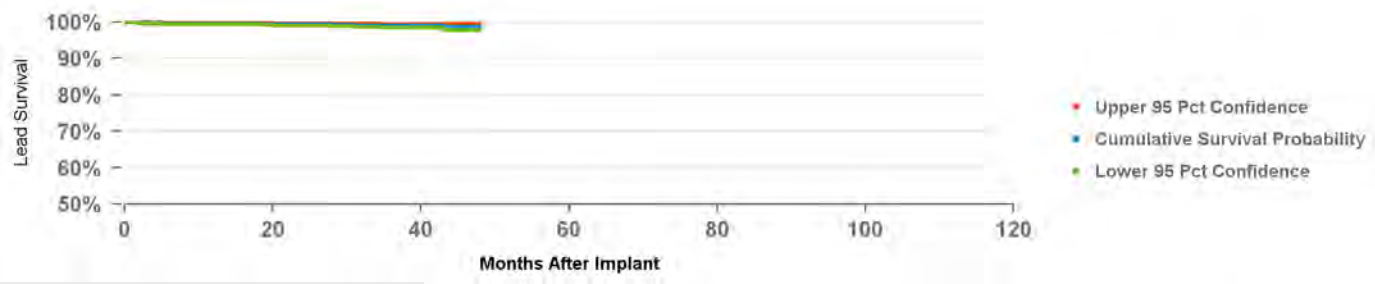
Cardiac Perforation	71
Conductor Fracture	4
Extracardiac Stimulation	10
Failure To Capture	123
Failure To Sense	23
Impedance Abnormal	40
Insulation Breach	1
Lead Dislodgement	210
Oversensing	89
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	5,083
Cumulative Months of Followup	87,306
Number of Leads Active in Study	4,010

Qualifying Complications 28

Cardiac Perforation	1	Impedance Out of Range	2
Conductor Fracture	5	Insulation Breach	1
Failure To Capture	7	Lead Dislodgement	10
Failure To Sense	1	Oversensing	1



Years	1	2	3	at 48 mo
%	99.6%	99.4%	99.0%	98.6%
#	2,958	1,493	588	91

Defibrillation Leads

6937A Transvene SVC-CS

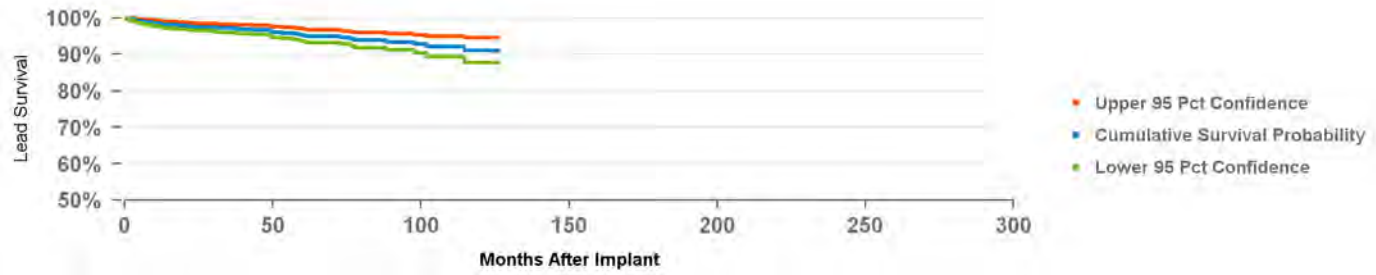
US Market Release	4/6/2001
CE Approval	
Registered USA Implants	2,370
Estimated Active USA Implants	1,393
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

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



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	826	694	580	487	389	310	217	168	109	71	56

Defibrillation Leads

6943 Sprint

US Market Release	10/6/1997
CE Approval	
Registered USA Implants	20,581
Estimated Active USA Implants	4,633
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	89
Crimp Weld Bond	1
Insulation Breach	33
Other	4

US Acute Lead Observations

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

Product Surveillance Registry Results

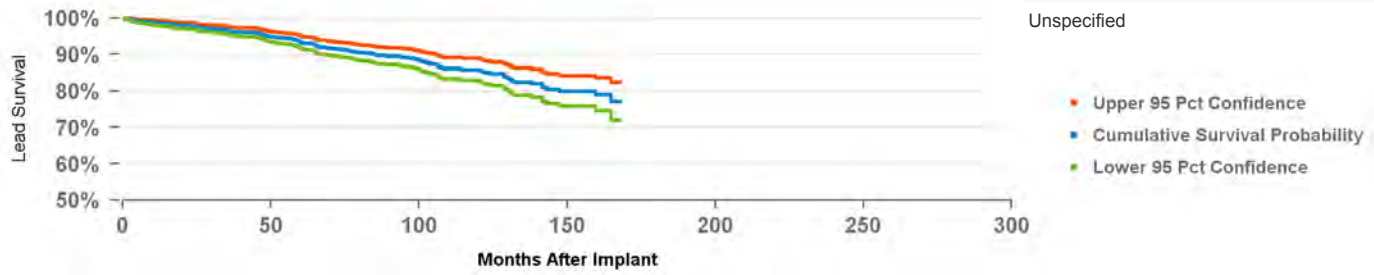
Number of Leads Enrolled in Study	1,339
Cumulative Months of Followup	85,794
Number of Leads Active in Study	70

Qualifying Complications

Conductor Fracture	32
Failure To Capture	12
Failure To Sense	7

113

Impedance Out of Range	9
Insulation Breach	2
Lead Dislodgement	2
Other	2
Oversensing	44
Unspecified	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	98.5%	97.7%	96.5%	95.4%	93.3%	91.4%	90.1%	89.2%	86.2%	85.9%	82.5%	80.5%	79.9%	77.1%
#	1,161	981	855	702	584	477	394	324	270	214	182	143	95	57

Defibrillation Leads

6944 Sprint Quattro

US Market Release	12/13/2000
CE Approval	11/5/1999
Registered USA Implants	44,822
Estimated Active USA Implants	19,889
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	177
Crimp Weld Bond	1
Insulation Breach	4
Other	6

US Acute Lead Observations

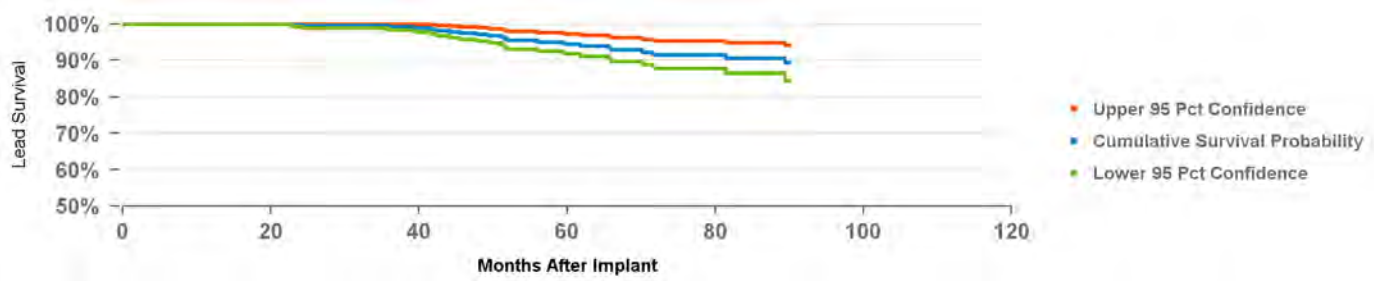
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	16
Failure To Sense	3
Impedance Abnormal	11
Insulation Breach	0
Lead Dislodgement	24
Oversensing	13
Unspecified	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	605
Cumulative Months of Followup	29,183
Number of Leads Active in Study	167

Qualifying Complications 27

Conductor Fracture	14	Impedance Out of Range	4
Failure To Capture	4	Oversensing	3
Failure To Sense	1	Unspecified	1



Years	1	2	3	4	5	6	7	at 90 mo
%	100.0%	99.8%	99.2%	97.1%	94.5%	91.5%	90.5%	89.3%
#	519	428	349	266	183	125	82	63

Defibrillation Leads

6945 Sprint

US Market Release	9/26/1997
CE Approval	
Registered USA Implants	42,696
Estimated Active USA Implants	9,335
Fixation Type	Active Screw In
Pace Sense Polarity	Integrated Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	153
Crimp Weld Bond	1
Insulation Breach	47
Other	6

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	2
Lead Dislodgement	4
Oversensing	8
Unspecified	2

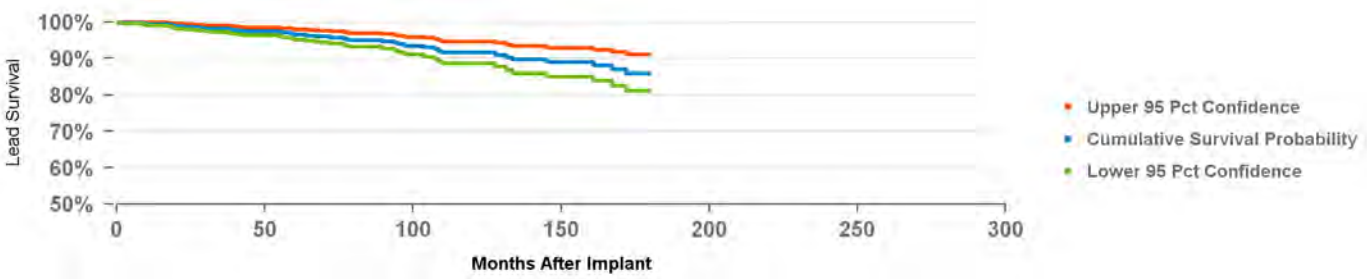
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,203
Cumulative Months of Followup	68,223
Number of Leads Active in Study	76

Qualifying Complications

46

Conductor Fracture	12
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	4
Impedance Out of Range	7
Oversensing	19
Unspecified	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 180 mo
%	99.4%	98.6%	98.1%	97.5%	96.5%	95.7%	95.0%	93.9%	92.5%	91.5%	90.3%	89.6%	88.9%	87.1%	86.0%
#	1,024	832	664	525	403	313	274	229	186	155	133	118	94	68	51

Defibrillation Leads

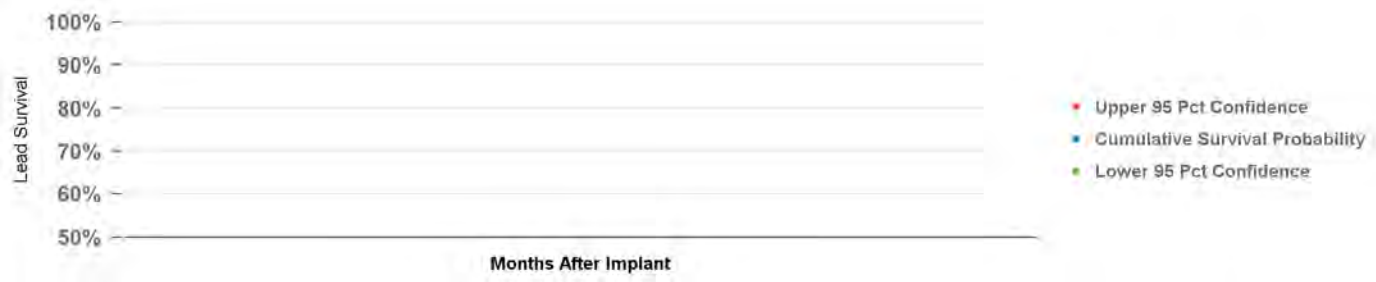
6946M Sprint Quattro

US Market Release	1/5/2016
CE Approval	9/12/2013
Registered USA Implants	640
Estimated Active USA Implants	630
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations

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



Years	at	mo
%		
#		

Defibrillation Leads

6947 Sprint Quattro Secure

US Market Release	11/12/2001
CE Approval	10/4/2001
Registered USA Implants	373,927
Estimated Active USA Implants	204,478
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	939
Crimp Weld Bond	4
Insulation Breach	82
Other	216

US Acute Lead Observations

Cardiac Perforation	28
Conductor Fracture	23
Extracardiac Stimulation	2
Failure To Capture	77
Failure To Sense	34
Impedance Abnormal	57
Insulation Breach	4
Lead Dislodgement	119
Oversensing	127
Unspecified	22

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,252
Cumulative Months of Followup	217,508
Number of Leads Active in Study	1,329

Qualifying Complications

70

Conductor Fracture	24
Failure To Capture	4
Failure To Sense	2

Impedance Out of Range	11
Insulation Breach	5
Lead Dislodgement	5
Other	1
Oversensing	16
Unspecified	2

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	98.0%	97.5%	97.0%	96.4%	95.6%	95.3%	94.4%	94.4%
#	3,596	3,057	2,585	2,074	1,641	1,162	730	415	301	210	152	102	68

Defibrillation Leads

6947M Sprint Quattro Secure

US Market Release	2/13/2012
CE Approval	3/12/2010
Registered USA Implants	96,682
Estimated Active USA Implants	87,734
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	68
Crimp Weld Bond	0
Insulation Breach	6
Other	15

US Acute Lead Observations

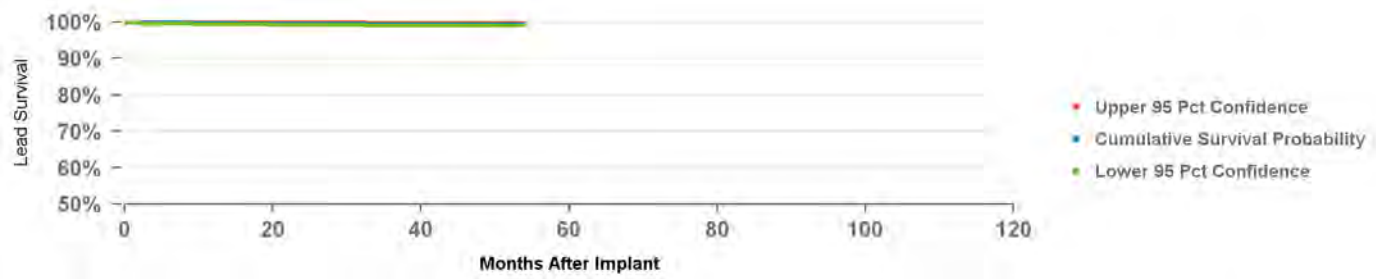
Cardiac Perforation	26
Conductor Fracture	9
Extracardiac Stimulation	10
Failure To Capture	78
Failure To Sense	24
Impedance Abnormal	21
Insulation Breach	0
Lead Dislodgement	151
Oversensing	50
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,997
Cumulative Months of Followup	66,021
Number of Leads Active in Study	1,157

Qualifying Complications 10

Conductor Fracture	3
Failure To Capture	4
Failure To Sense	2
Other	1



Years	1	2	3	4	at 54 mo
%	99.7%	99.5%	99.4%	99.4%	99.4%
#	1,596	1,286	1,046	583	259

Defibrillation Leads

6948 Sprint Fidelis

US Market Release	9/2/2004
CE Approval	
Registered USA Implants	10,373
Estimated Active USA Implants	3,223
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	195
Crimp Weld Bond	0
Insulation Breach	3
Other	2

US Acute Lead Observations

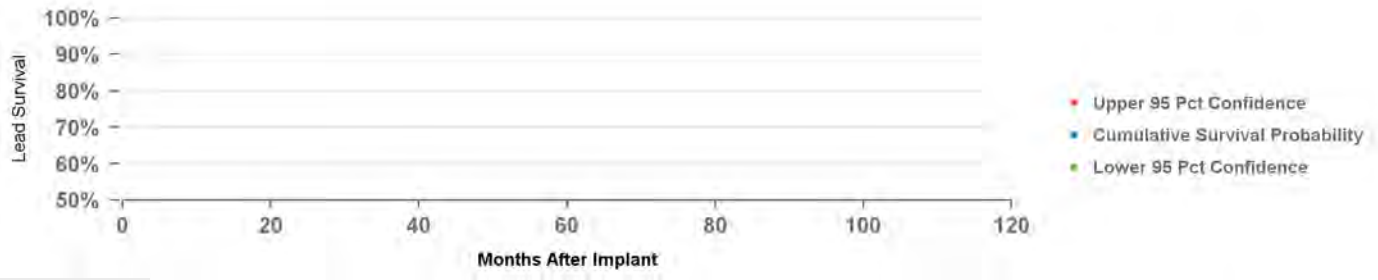
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	7
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	7
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Cumulative Months of Followup	2,114
Number of Leads Active in Study	8

Qualifying Complications 4

Conductor Fracture	3
Impedance Out of Range	1



Years	at 0 mo
%	100.0%
#	

Defibrillation Leads

6949 Sprint Fidelis

US Market Release	9/2/2004
CE Approval	
Registered USA Implants	186,702
Estimated Active USA Implants	48,609
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7,606
Crimp Weld Bond	3
Insulation Breach	37
Other	71

US Acute Lead Observations

Cardiac Perforation	10
Conductor Fracture	46
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	19
Impedance Abnormal	17
Insulation Breach	5
Lead Dislodgement	22
Oversensing	32
Unspecified	25

Product Surveillance Registry Results

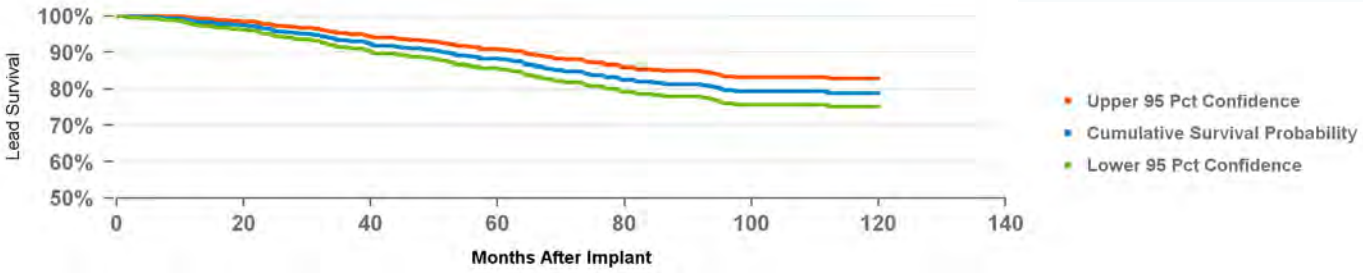
Number of Leads Enrolled in Study	963
Cumulative Months of Followup	51,979
Number of Leads Active in Study	137

Qualifying Complications

Conductor Fracture	61
Failure To Capture	4
Failure To Sense	6

109

Impedance Out of Range	19
Insulation Breach	2
Lead Dislodgement	1
Other	1
Oversensing	15



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	98.5%	96.5%	93.3%	90.9%	88.3%	85.0%	82.0%	79.8%	79.4%	79.0%
#	833	712	607	488	384	301	204	142	92	58

Defibrillation Leads

6996 Sub-Q Lead

US Market Release	6/11/2001
CE Approval	12/19/1997
Registered USA Implants	4,825
Estimated Active USA Implants	2,644
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

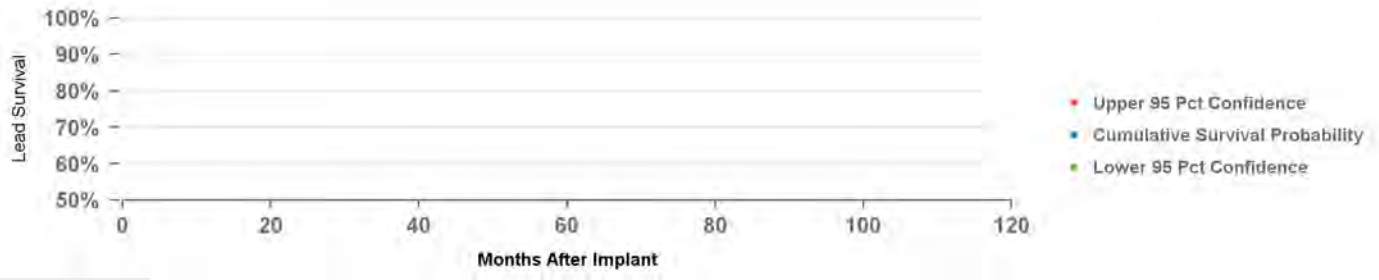
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	1
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	49
Cumulative Months of Followup	2,000
Number of Leads Active in Study	8

Qualifying Complications 2

Conductor Fracture	1
Impedance Out of Range	1



Years	at 0 mo
%	100.0%
#	

2187 Attain LV

US Market Release	8/28/2001
CE Approval	
Registered USA Implants	11,980
Estimated Active USA Implants	1,802
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

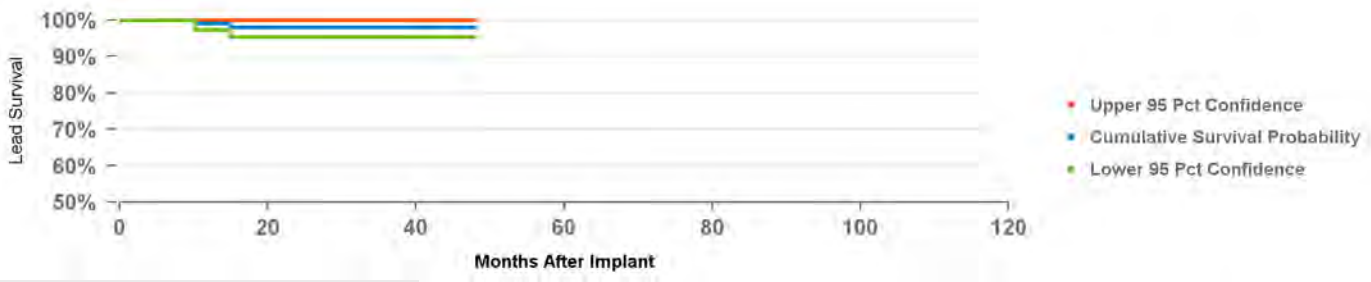
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	9
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	139
Cumulative Months of Followup	6,729
Number of Leads Active in Study	8

Qualifying Complications 3

Failure To Capture	3



Years	1	2	3	at 48 mo
%	99.1%	98.0%	98.0%	98.0%
#	105	89	68	53

Left Heart Leads

4193 Attain OTW

US Market Release	5/3/2002
CE Approval	12/22/2000
Registered USA Implants	100,807
Estimated Active USA Implants	23,905
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	74
Crimp Weld Bond	0
Insulation Breach	24
Other	46

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	18
Failure To Capture	11
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	45
Oversensing	1
Unspecified	2

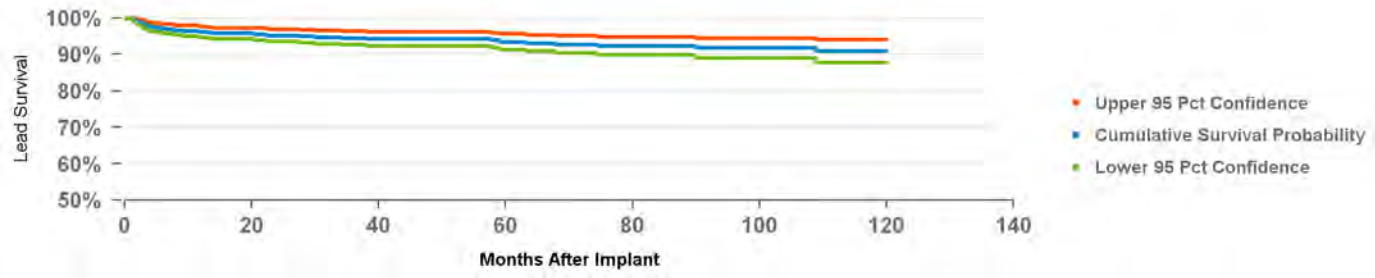
Product Surveillance Registry Results

Number of Leads Enrolled in Study	790
Cumulative Months of Followup	37,916
Number of Leads Active in Study	93

Qualifying Complications

44

Conductor Fracture	1	Impedance Out of Range	2
Extracardiac Stimulation	9	Lead Dislodgement	13
Failure To Capture	16	Unspecified	3



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.1%	95.2%	94.5%	94.2%	93.5%	92.7%	92.3%	91.7%	91.7%	90.9%
#	623	483	404	309	245	205	162	129	87	60

Left Heart Leads

4194 Attain OTW

US Market Release	8/24/2004
CE Approval	7/14/2003
Registered USA Implants	114,891
Estimated Active USA Implants	53,528
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	27
Crimp Weld Bond	0
Insulation Breach	110
Other	7

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	48
Failure To Capture	42
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	151
Oversensing	2
Unspecified	5

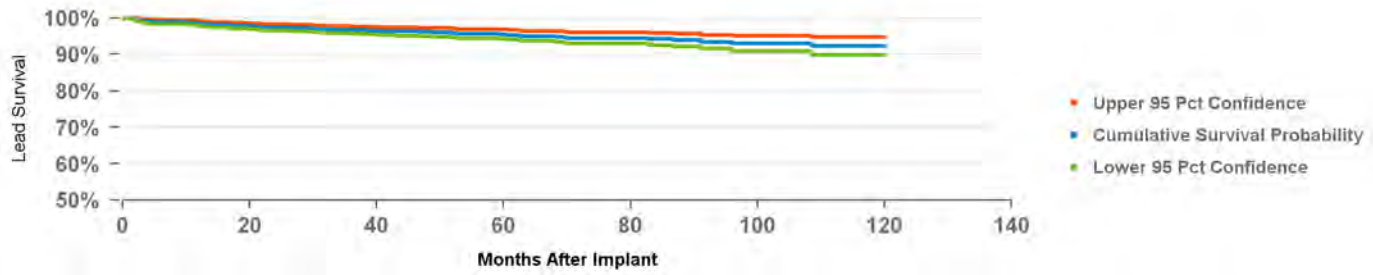
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,606
Cumulative Months of Followup	75,231
Number of Leads Active in Study	483

Qualifying Complications

61

Conductor Fracture	2	Insulation Breach	2
Extracardiac Stimulation	11	Insulation Breach ESC	1
Failure To Capture	17	Lead Dislodgement	28



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	98.6%	97.4%	96.7%	96.2%	95.6%	94.5%	94.2%	93.0%	93.0%	92.4%
#	1,337	1,105	897	690	532	384	230	146	85	59

Left Heart Leads

4195 Attain StarFix

US Market Release	8/15/2008
CE Approval	5/13/2005
Registered USA Implants	17,344
Estimated Active USA Implants	11,177
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	2
Other	4

US Acute Lead Observations

Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	30
Failure To Capture	20
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	0
Lead Dislodgement	30
Oversensing	0
Unspecified	1

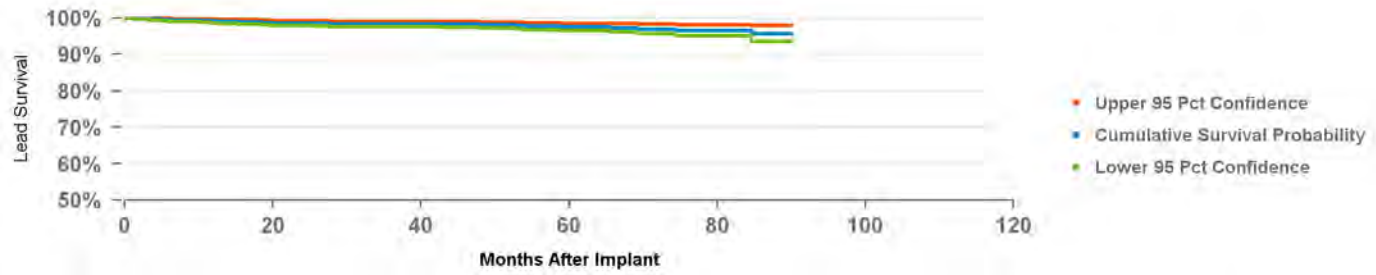
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,484
Cumulative Months of Followup	64,956
Number of Leads Active in Study	488

Qualifying Complications

30

Conductor Fracture	3
Extracardiac Stimulation	11
Failure To Capture	5
Impedance Out of Range	1
Insulation Breach	5
Lead Dislodgement	5



Years	1	2	3	4	5	6	7	at 90 mo
%	99.2%	98.6%	98.4%	98.1%	97.5%	97.0%	96.6%	95.7%
#	1,258	1,069	877	641	437	254	104	57

Left Heart Leads

4196 Attain Ability

US Market Release	5/15/2009
CE Approval	7/24/2007
Registered USA Implants	67,636
Estimated Active USA Implants	47,336
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	20
Crimp Weld Bond	0
Insulation Breach	0
Other	12

US Acute Lead Observations

Cardiac Perforation	3
Conductor Fracture	2
Extracardiac Stimulation	87
Failure To Capture	58
Failure To Sense	1
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	203
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,227
Cumulative Months of Followup	85,972
Number of Leads Active in Study	632

Qualifying Complications

Conductor Fracture	3
Extracardiac Stimulation	13
Failure To Capture	30

72

Impedance Out of Range	1
Insulation Breach	1
Lead Dislodgement	21
Other	3

Years	1	2	3	4	5	6	at 84 mo
%	98.0%	97.2%	96.5%	95.9%	95.8%	95.2%	94.9%
#	1,817	1,418	1,070	794	594	311	78

Left Heart Leads

4296 Attain Ability Plus

US Market Release	4/1/2011
CE Approval	12/18/2009
Registered USA Implants	34,098
Estimated Active USA Implants	28,302
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	0
Other	4

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	57
Failure To Capture	27
Failure To Sense	0
Impedance Abnormal	9
Insulation Breach	4
Lead Dislodgement	115
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,429
Cumulative Months of Followup	43,591
Number of Leads Active in Study	669

Qualifying Complications 32

Extracardiac Stimulation	11	Lead Dislodgement	12
Failure To Capture	8	Other	1

Years	1	2	3	4	at 60 mo
%	98.7%	97.9%	97.6%	96.9%	96.1%
#	1,112	872	612	299	78

Left Heart Leads

4298 Attain Performa

US Market Release	8/1/2014
CE Approval	1/1/2013
Registered USA Implants	45,572
Estimated Active USA Implants	43,001
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	1
Other	13

US Acute Lead Observations

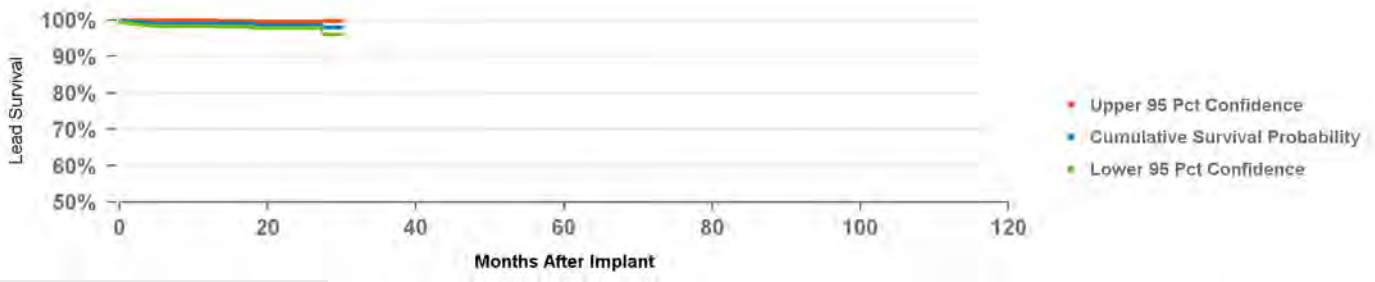
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	109
Failure To Capture	54
Failure To Sense	0
Impedance Abnormal	15
Insulation Breach	0
Lead Dislodgement	82
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,328
Cumulative Months of Followup	17,330
Number of Leads Active in Study	1,102

Qualifying Complications 11

Extracardiac Stimulation	1
Lead Dislodgement	10



Years	1	2	at 30 mo
%	99.1%	98.7%	97.9%
#	680	201	64

4396 Attain Ability Straight

US Market Release	3/31/2011
CE Approval	12/18/2009
Registered USA Implants	7,465
Estimated Active USA Implants	6,045
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

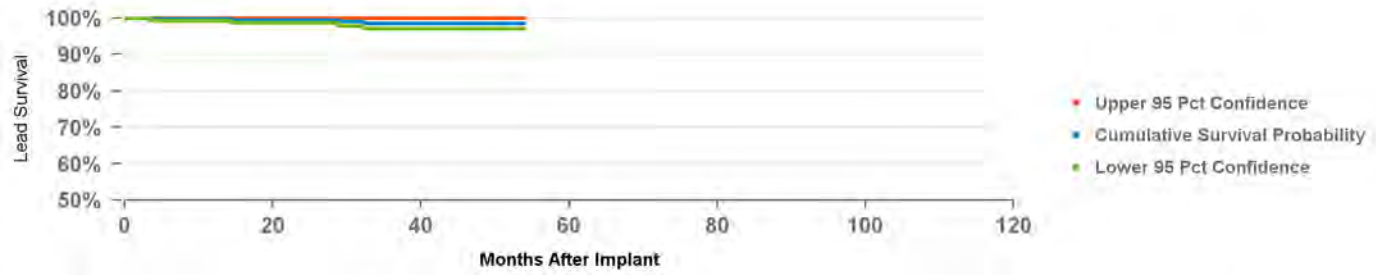
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	15
Failure To Capture	7
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	33
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	436
Cumulative Months of Followup	13,586
Number of Leads Active in Study	223

Qualifying Complications 4

Failure To Capture	3
Lead Dislodgement	1



Years	1	2	3	4	at 54 mo
%	99.7%	99.4%	98.5%	98.5%	98.5%
#	341	253	178	98	65

Left Heart Leads

4398 Attain Performa Straight

US Market Release	12/10/2014
CE Approval	1/1/2013
Registered USA Implants	10,553
Estimated Active USA Implants	10,056
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

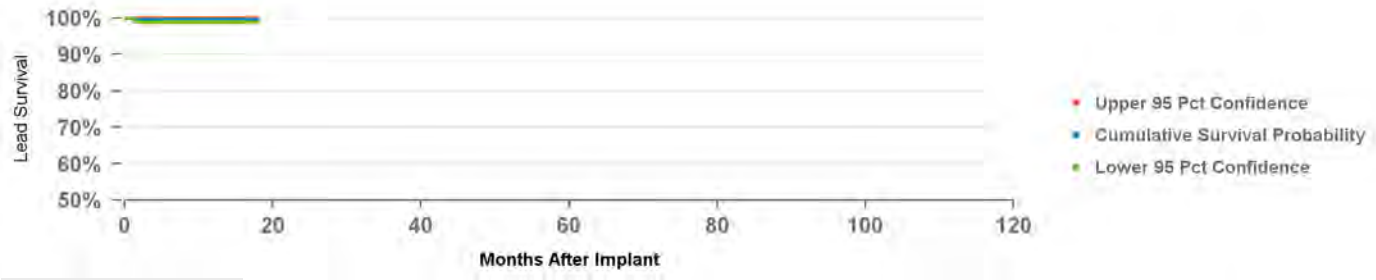
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	37
Failure To Capture	20
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	8
Oversensing	0
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	400
Cumulative Months of Followup	4,051
Number of Leads Active in Study	348

1

Lead Dislodgement	1



Years	1	at 18 mo
%	99.6%	99.6%
#	151	80

Left Heart Leads

4598 Attain Performa S

US Market Release	12/10/2014
CE Approval	1/1/2013
Registered USA Implants	20,883
Estimated Active USA Implants	20,025
Fixation Type	Canted
Pace Sense Polarity	Quad Pole
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

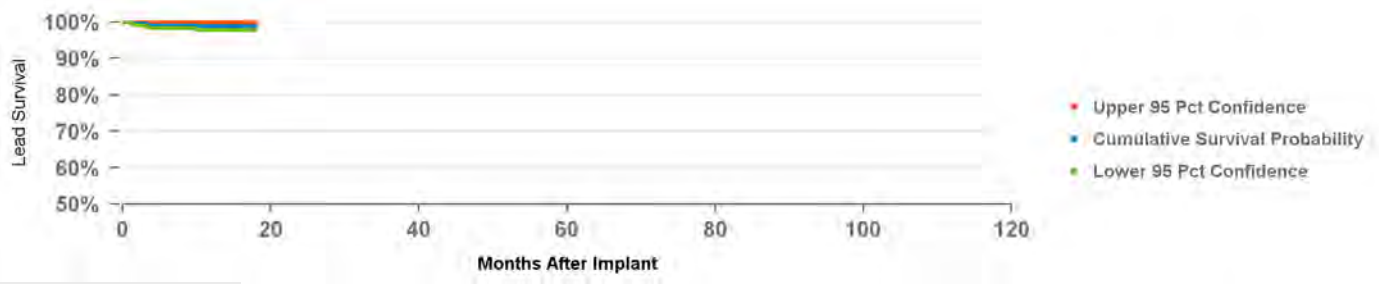
Cardiac Perforation	4
Conductor Fracture	1
Extracardiac Stimulation	37
Failure To Capture	17
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach	0
Lead Dislodgement	25
Oversensing	1
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	607
Cumulative Months of Followup	6,520
Number of Leads Active in Study	521

Qualifying Complications 5

Failure To Sense	1
Lead Dislodgement	4



Years	1	at 18 mo
%	98.8%	98.8%
#	256	137

Epi/Myocardial Leads

4965 CapSure Epi

US Market Release	9/6/1996
CE Approval	1/1/1993
Registered USA Implants	22,893
Estimated Active USA Implants	8,628
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	247
Crimp Weld Bond	1
Insulation Breach	50
Other	0

US Acute Lead Observations

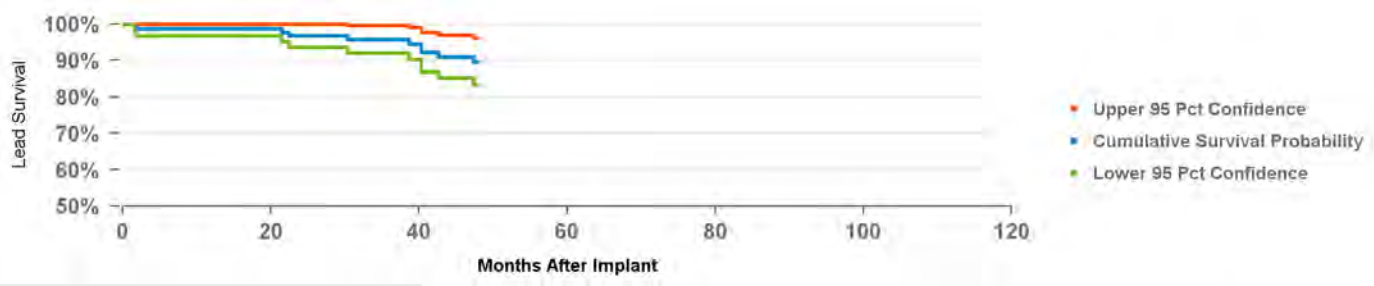
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	5
Impedance Abnormal	9
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	232
Cumulative Months of Followup	7,158
Number of Leads Active in Study	7

Qualifying Complications 14

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



Years	1	2	3	at 48 mo
%	98.6%	96.7%	95.7%	89.4%
#	131	111	91	67

Epi/Myocardial Leads

4968 CapSure Epi

US Market Release	9/16/1999
CE Approval	4/21/1998
Registered USA Implants	42,587
Estimated Active USA Implants	26,028
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	81
Crimp Weld Bond	0
Insulation Breach	45
Other	1

US Acute Lead Observations

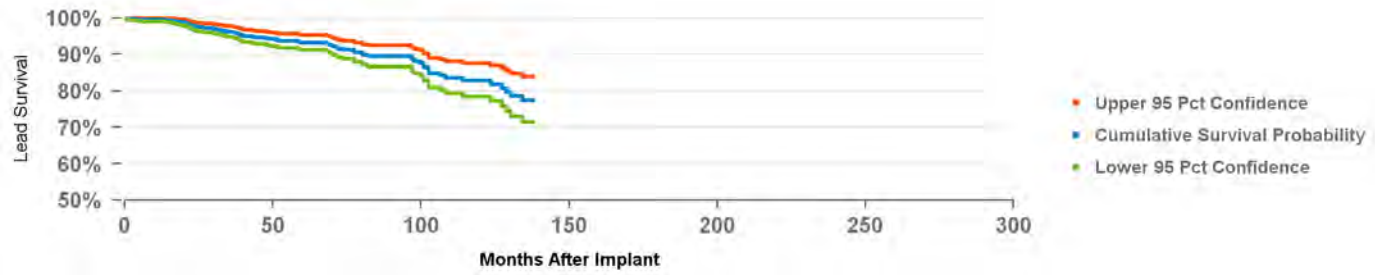
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	2
Failure To Capture	38
Failure To Sense	2
Impedance Abnormal	5
Insulation Breach	1
Lead Dislodgement	6
Oversensing	14
Unspecified	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	972
Cumulative Months of Followup	51,758
Number of Leads Active in Study	276

Qualifying Complications 78

Conductor Fracture	20	Impedance Out of Range	4
Extracardiac Stimulation	2	Insulation Breach	3
Failure To Capture	27	Other	1
Failure To Sense	3	Oversensing	18



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.5%	97.6%	96.3%	94.4%	93.3%	91.5%	89.5%	89.5%	84.3%	82.9%	78.7%	77.5%
#	752	656	554	459	374	293	234	178	121	80	59	52

Epi/Myocardial Leads

5071 Screw-in

US Market Release	12/3/1992
CE Approval	1/1/1993
Registered USA Implants	52,076
Estimated Active USA Implants	16,099
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	24
Crimp Weld Bond	0
Insulation Breach	2
Other	1

US Acute Lead Observations

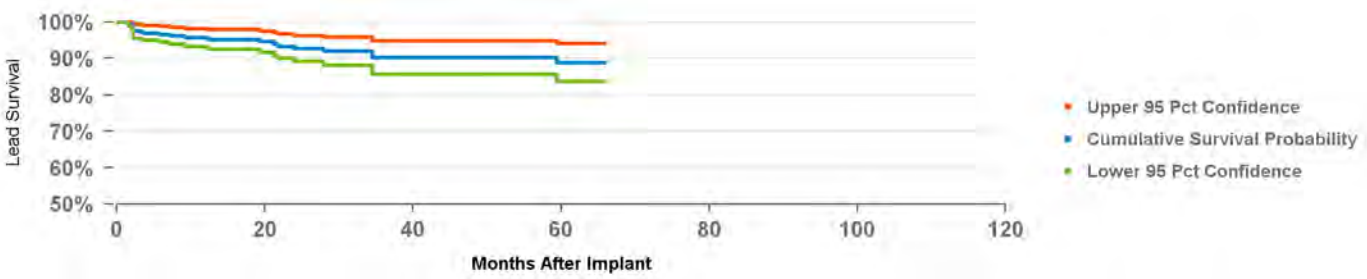
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	6
Failure To Capture	61
Failure To Sense	3
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	425
Cumulative Months of Followup	10,988
Number of Leads Active in Study	111

Qualifying Complications 25

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



Years	1	2	3	4	5	at 66 mo
%	95.7%	92.6%	90.2%	90.2%	88.8%	88.8%
#	202	152	115	80	55	50

VDD Single Pass Lead

5038 CapSure VDD-2

US Market Release	9/10/1998
CE Approval	4/15/1997
Registered USA Implants	10,070
Estimated Active USA Implants	3,530
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	0
Insulation Breach	2
Other	0

US Acute Lead Observations

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

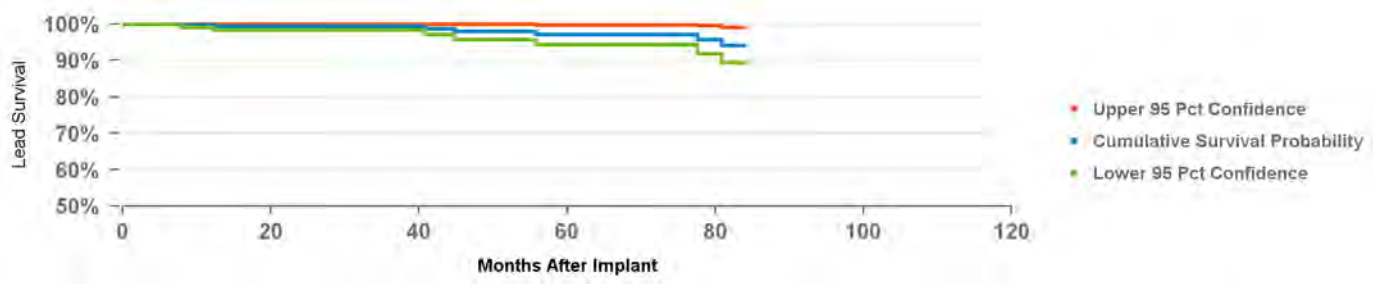
Product Surveillance Registry Results

Number of Leads Enrolled in Study	567
Cumulative Months of Followup	15,727
Number of Leads Active in Study	4

Qualifying Complications

8

Conductor Fracture	3
Failure To Capture	2
Failure To Sense	3



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.3%	99.3%	97.9%	97.0%	97.0%	94.1%
#	292	222	163	132	105	77	55

ICD and CRT-D Charge Time Performance

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

Introduction

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

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

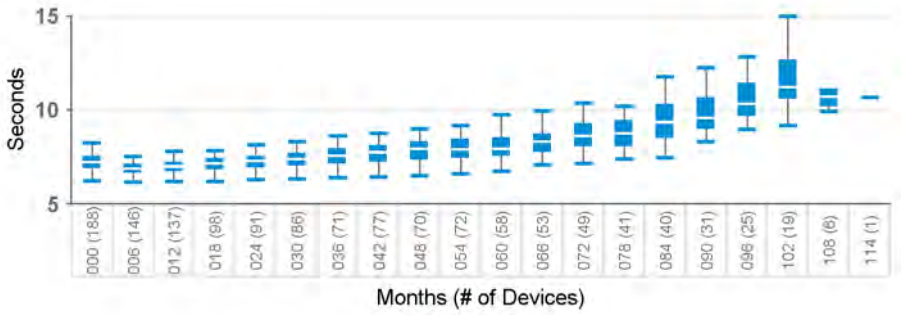
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

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

Charge Time

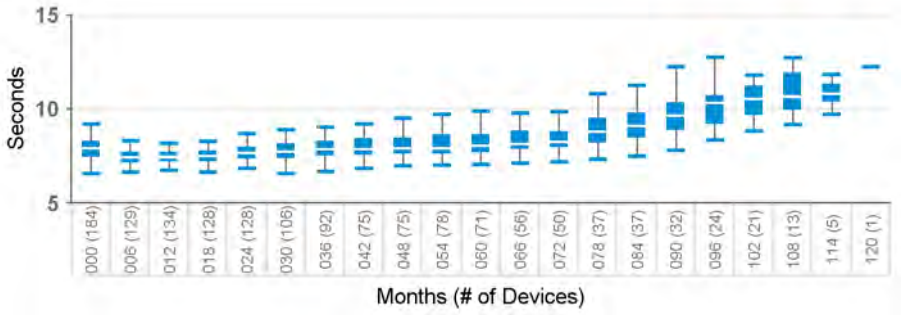
7230

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



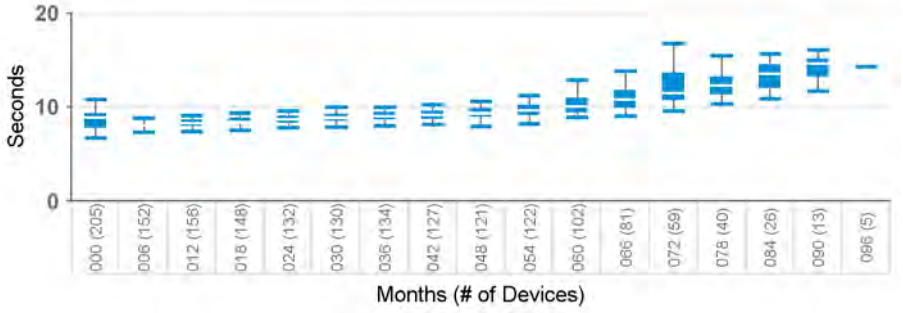
7232

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



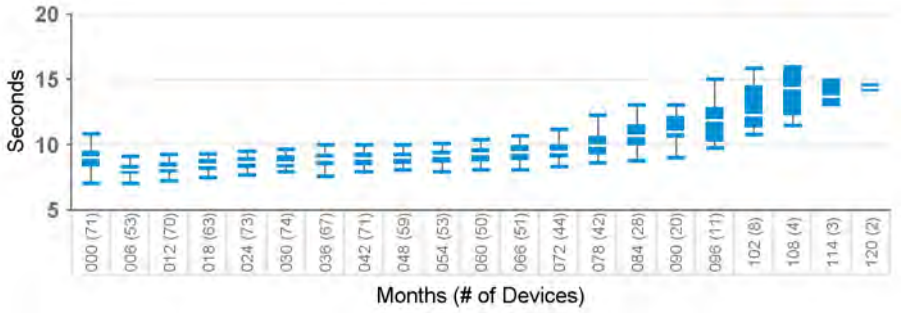
D144DRG, D154ATG, D154DRG

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT



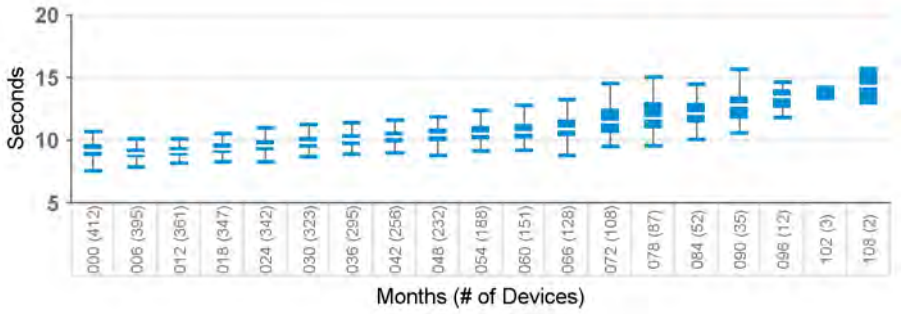
D144VRC, D154VRC

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



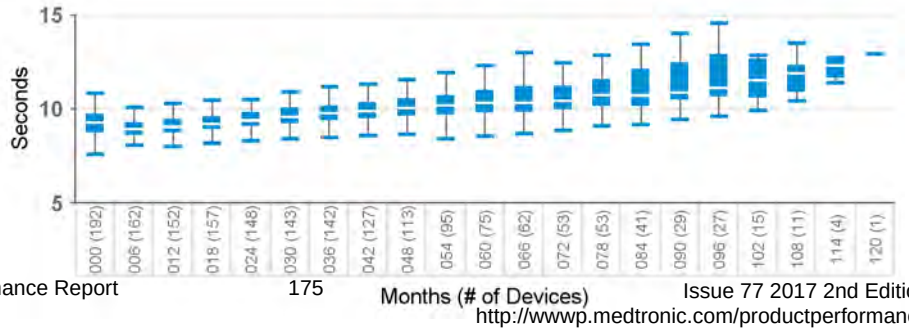
D154AWG, D164AWG

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



D154VWC, D164VWC

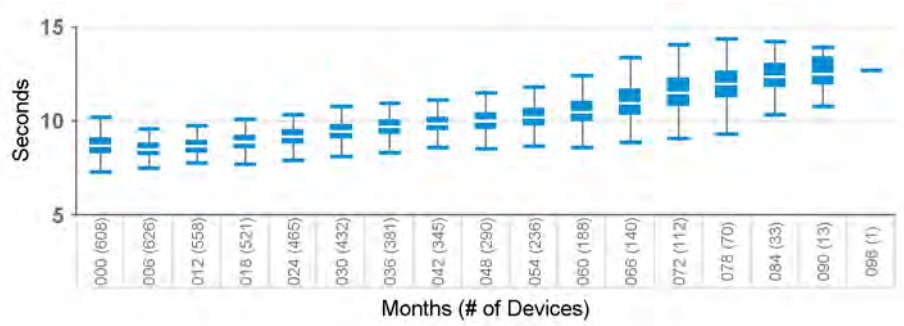
Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



Charge Time

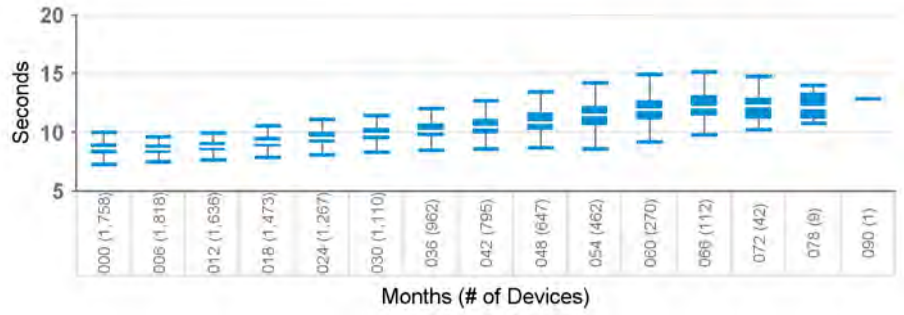
D204DRM, D214DRM, D224DRG, D234DRG

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



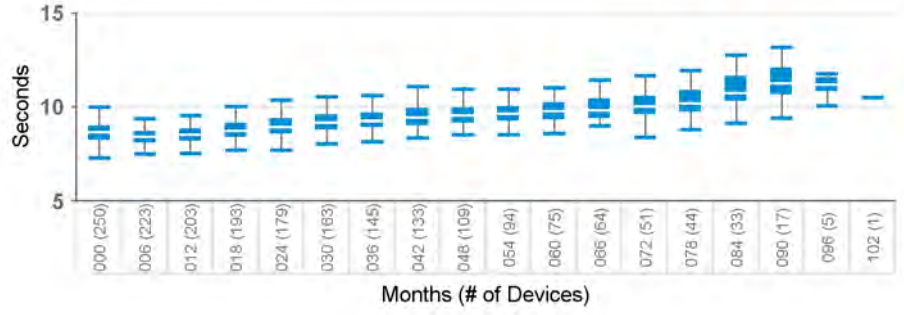
D204TRM, D214TRM, D224TRK, D234TRK

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



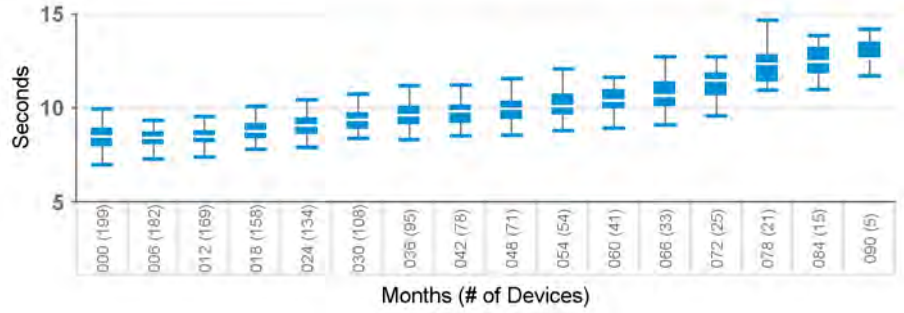
D204VRM, D214VRM, D224VRC, D234VRC

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



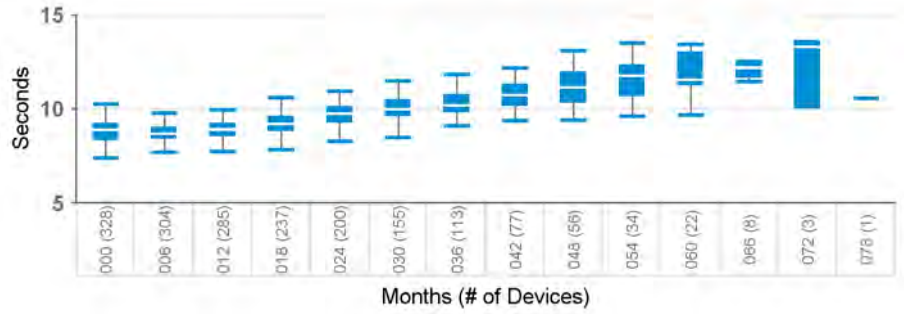
D264DRG, D284DRG, D384DRx, D394DRx

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



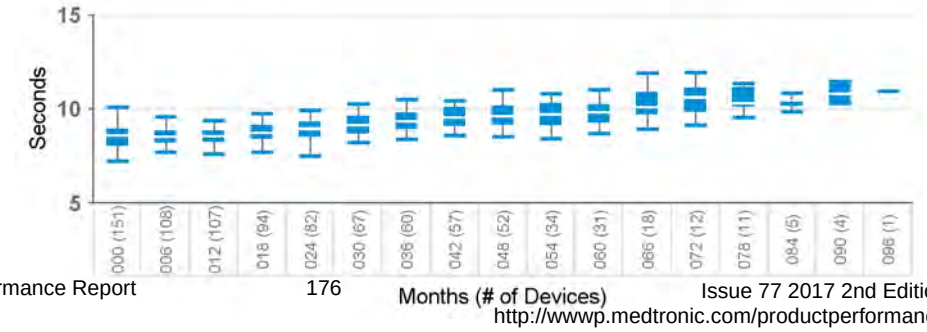
D264TRM, D284TRK, D384TRx, D394TRx

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

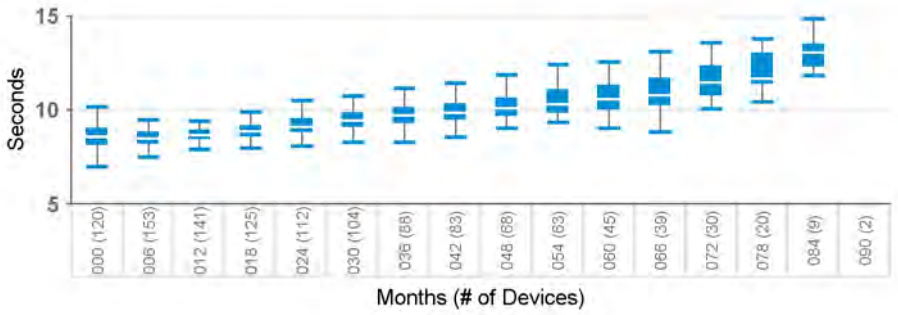
Model Number	Brand
D264VRM	Maximo II VR
D284VRC	Maximo II VR
D384VRG	Cardia VR
D394VRG	Egida VR



Charge Time

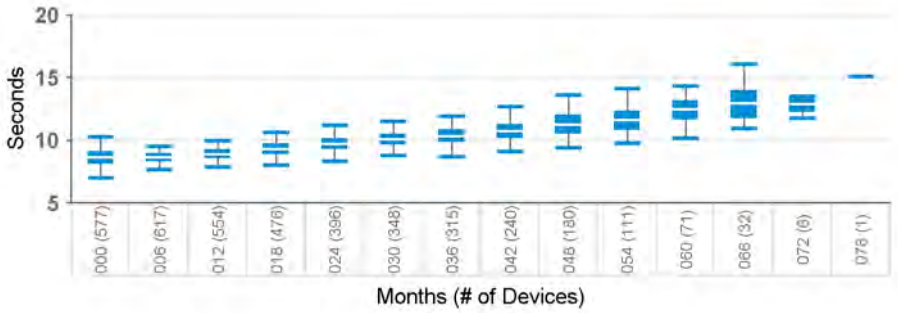
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



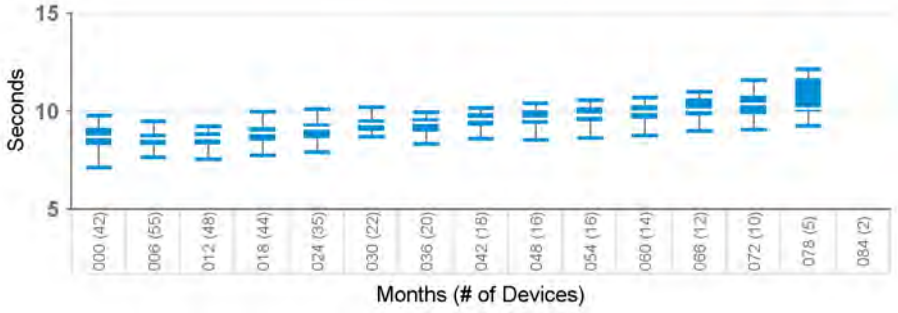
D274TRK, D294TRK

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



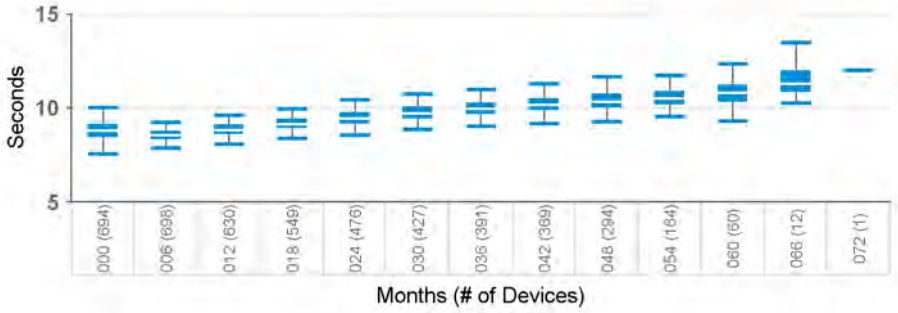
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



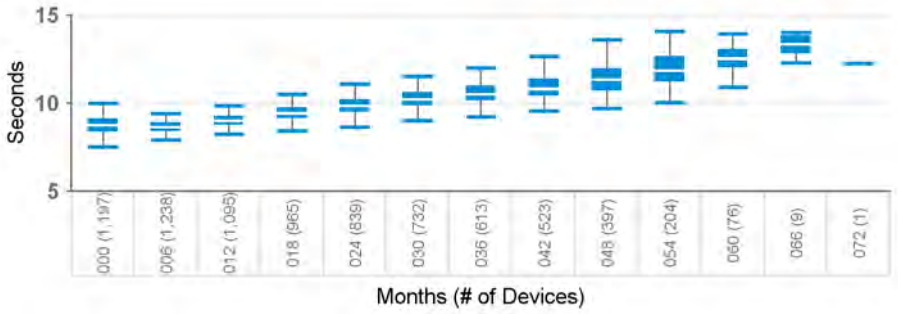
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



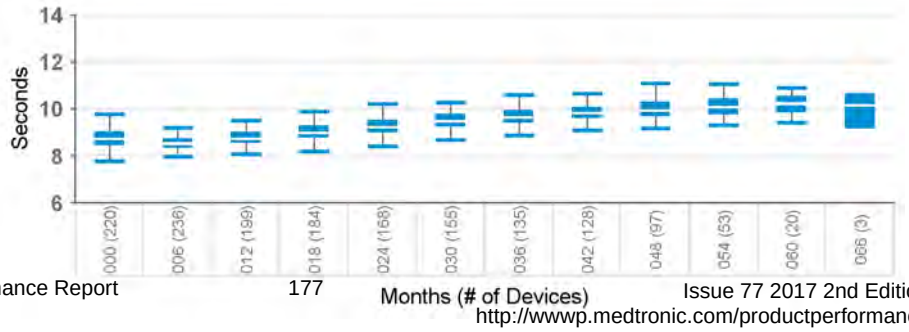
D314TRx

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



D314VRx

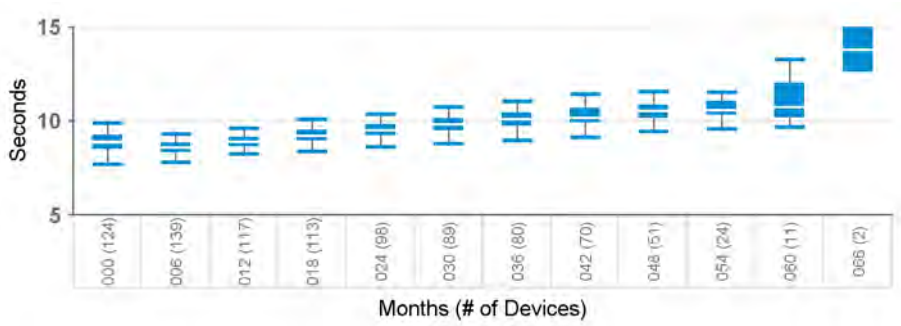
Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



Charge Time

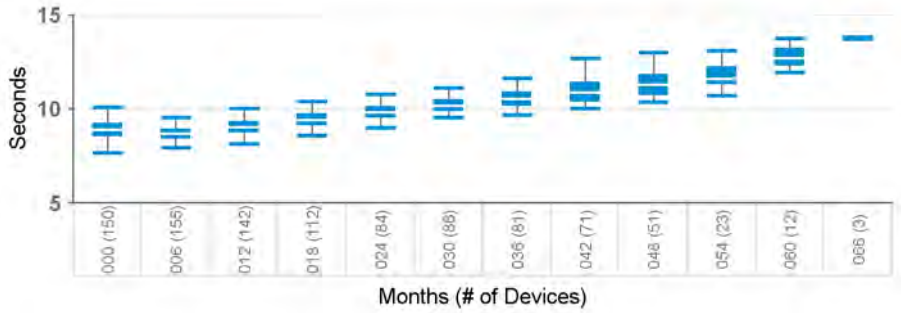
D334DRx, D364DRx

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



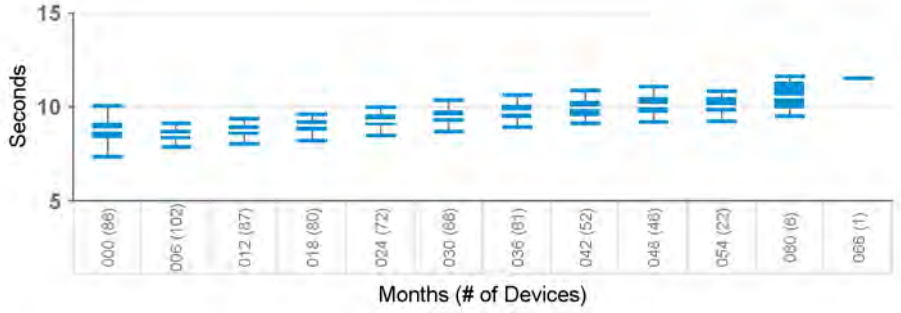
D334TRx, D364TRx

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



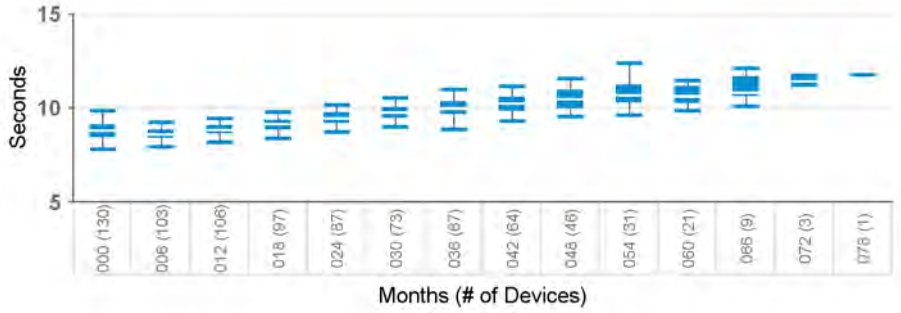
D334VRx, D364VRx

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



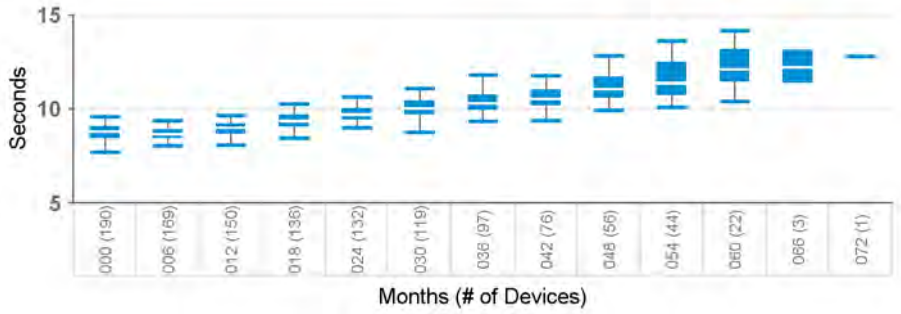
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



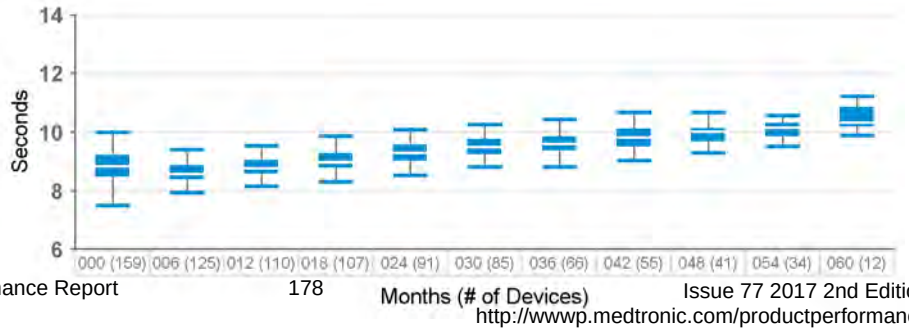
D354TRx

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



D354VRx

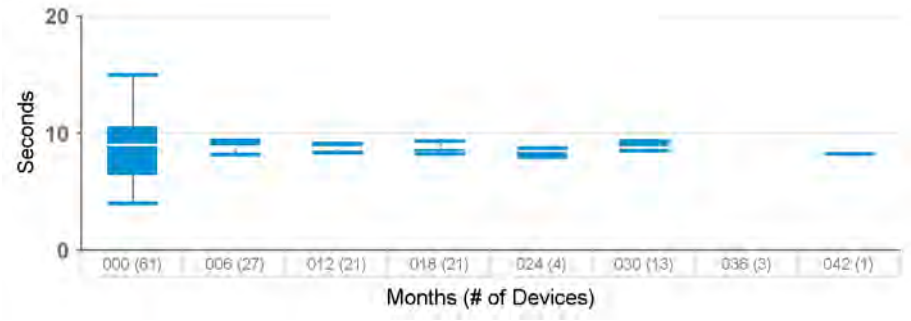
Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



Charge Time

DDxxxxx, DR

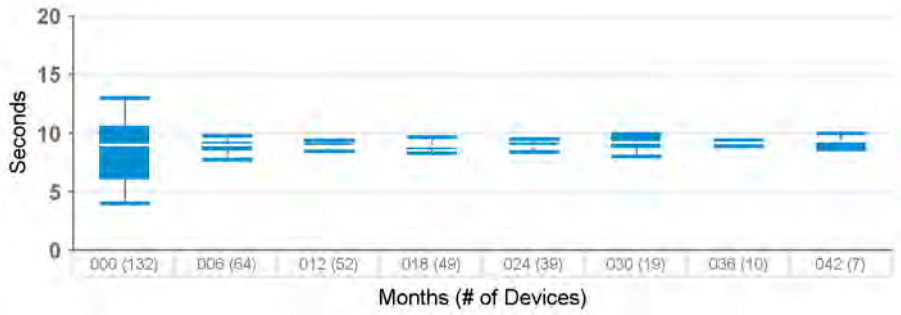
Model Number	Brand
DDBB1D1	Evera XT
DDBB1D4	Evera XT
DDBB2D1	Evera XT
DDBB2D4	Evera XT
DDBC3D1	Evera S
DDBC3D4	Evera S
DDMB1D1	Evera MRI XT
DDMB1D4	Evera MRI XT
DDMB2D1	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D1	Evera MRI S
DDMC3D4	Evera MRI



Charge Time

DTxxxxx, CRT-D

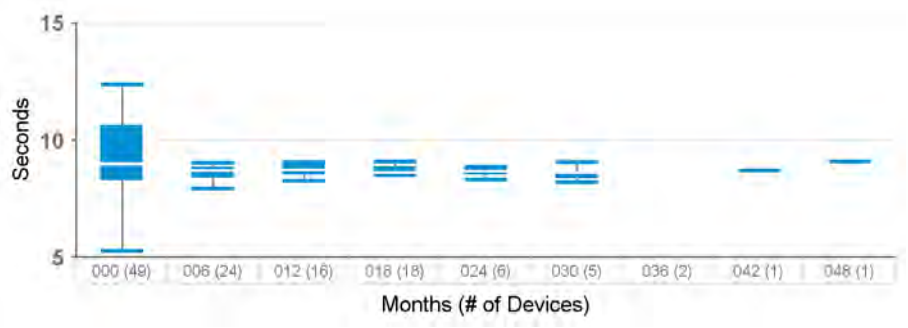
Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava
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



Charge Time

DVxxxxx, VR

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



Potential Loss of Left Ventricle Pacing Due to Software Issue

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

Original Date of Advisory: December 2016

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

Status Update April 2017

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™).

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.

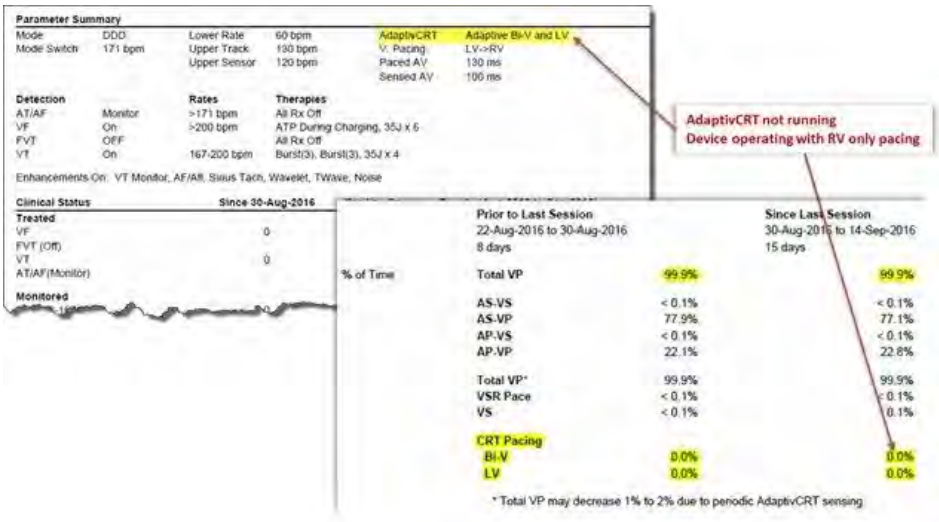
Until the software update has been approved and the affected device models receive the update, follow the programming recommendations provided below. These recommendations also apply to any new device implants.

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.

Advisories

Status Update

Within the 78 devices, there have been 10 confirmed failures (13%) through September 29, 2017. Medtronic modeling predicts an additional three (3) failures may occur in the remaining active population. An estimated 34 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	**34** 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 September 29, 2017, approximately 12,000 devices remain active worldwide, from an original implant population of 96,800. In the United States, 4,800 active devices remain. Our modeling predicts an estimated failure rate between 0.16% and 0.6% for the remaining active devices. Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency. InSync III CRT-pacemakers are no longer distributed.

Advisories

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
96,800 Worldwide (**39,900** United States)	**128** Worldwide (**70** United States)	**12,000** Worldwide (**4,800** United States)	**0.13%** Worldwide (**0.17%** 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 September 29, 2017, 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)	**4,900** Worldwide (**3,000** 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 September 29, 2017, of the initial implant population of 205,600 in the United States, approximately 54,700 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 78.6% (+4.1/-3.9%) at 114 months. As the implanted population ages and the sample size increases for each time interval, the accuracy of the estimated survival probability will increase as shown by tighter confidence intervals.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	
279,500 Worldwide (**205,600** United States)	**6,846** Worldwide **(4,918** United States)	**74,400** Worldwide (**54,700** 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.

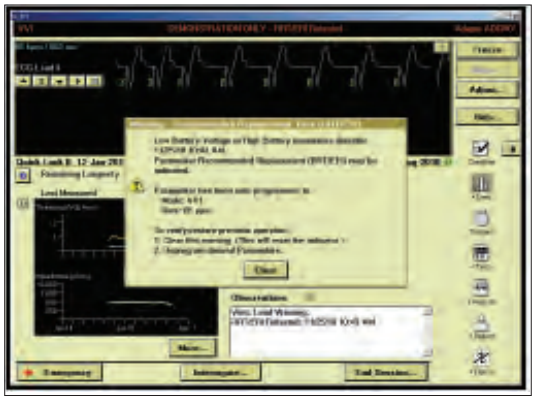
Background

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

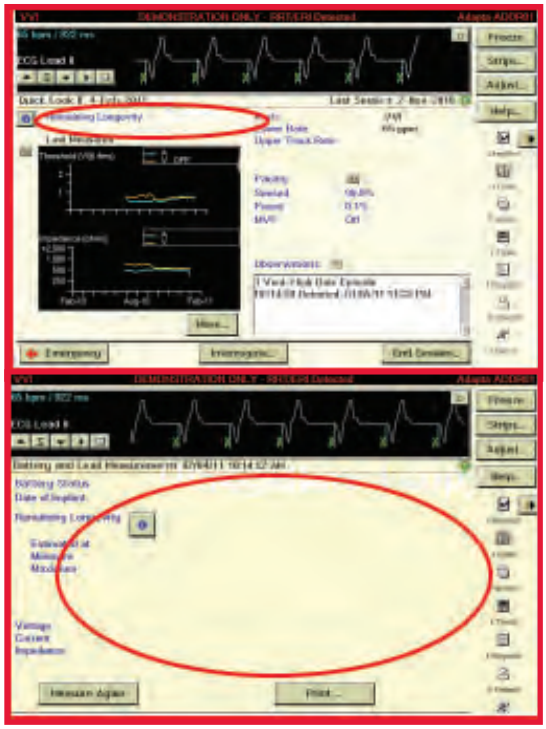


Reset Method for Kappa and EnPulse

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

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