CARDIAC RHYTHM MANAGEMENT

Product Performance Report

Important Patient Management Information for Physicians

2023

1st Edition – Issue 88

Medtronic

CRM Product Performance Report

2023

1st Edition

Issue 88

Cutoff date for this edition is 02 December 2022 for Lead Study data and 08 May 2023 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.

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 CRM 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 CRM maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

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

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

Contact Information

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

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au.crdmtechservices@medtronic.com

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

Outside the United States:

Your Medtronic representative or international technical center at the number above.

Within the United States:

Your Medtronic representative or

CRM Returned Product Analysis Laboratory

Phone: 1 (800) 328-2518, ext. 44800

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InSync®
LINQ II™
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Micra™
Mirro MRI™
MVP®
MyCareLink Heart™
Percepta™
Primo MRI™
Protecta®
Quick Look™
Relia™
Reveal LINQ™
Revo MRI®
Secura®
Secure®
SelectSecure®
Sensia®
Sensing Assurance
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Sigma
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Introduction

For 39 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). As Transcatheter Pacing Systems (TPS) combine the pacing functions of an IPG with the therapy delivery functions of an implantable lead into a single device implanted inside the heart, TPS is subject to complications similar to pacing leads and malfunctions or battery depletion events similar to an implanted pulse generator (IPG). The TPS performance report has been developed to align with these guidelines to the extent possible due to the unique difference between TPS compared to a typical implantable device or lead.

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.

Transcatheter Pacing Systems are monitored differently. Transcatheter pacing systems (TPS) combine the pacing functions of an IPG with the therapy delivery functions of an implantable lead into a single device implanted inside the heart. To account for the shortfalls of returned product analysis due to a very small percentage of devices being returned, a study of de-identified product data on the Medtronic CareLink™ network is used. The number of devices enrolled and transmitting actively enables a population large enough to give a representative volume of normal battery depletions and to provide insight into the complications that may occur after the device was successfully implanted. TPS survival estimates include both product failures and device-related medical complications and do not differentiate product failures from these complications such as perforation, dislodgement or elevated pacing thresholds.

Introduction continued

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.

Customer Communications - Advisory Summaries

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

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

Customer Communications - Performance Notes

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

Customer Communications - Product Education Briefs

These communications are educational in nature and typically elaborate on information found in the Instructions for Use (IFU) or other approved labeling materials. A product education brief typically serves to clarify information found in labeling that may be misunderstood or misinterpreted by physicians or healthcare professionals. Product education briefs do not provide new patient management guidance, but may be used to reinforce existing recommendations already discussed in the IFU.

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 Management (CRM) 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 CRM 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, standard actuarial method for TPS 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 TPS, the population is the de-identified devices on the Medtronic CareLink™ network.

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. For TPS, the events are complications or malfunctions as defined in the methods for estimating.

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

Introduction continued

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), the TPS curves are actually computed and plotted using the standard actuarial method and 1-month intervals, 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 Management (CRM's) United States device registration data and United States returned product analysis data. These data are presented graphically and numerically.

Note: During preparation of the Issue 88 CRM PPR release, a display error with the population of the malfunctions table was identified that resulted in historical overcounting in Issue 87 and prior of some confirmed malfunctions displayed in these tables. This overcounting did not affect the survival curves. The overcounting has been corrected with the Issue 88 release.

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 analyzed in the CRM 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 CRM 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 or the device memory data 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 found, through analysis, to 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. All 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:

Method for Estimating CRT, ICD, and IPG Device Performance continued

(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

Or

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

Medtronic CRM 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. 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 or may be 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:

Battery – Findings linked to the battery and its components

Device-Related Current Pathway – Findings confirmed through device or device memory returns linked to reduced or no energy shocks and other effects (e.g., 50% drop in daily pacing lead impedance measurements not due to a lead issue)

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

Method for Estimating CRT, ICD, and IPG Device Performance continued

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

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.

Software/Firmware – Findings linked to software or firmware function

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 or device memory data 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 CRM 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 (labeled as "Including Normal Battery Depletion"). 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 (labeled as "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

Method for Estimating CRT, ICD, and IPG Device Performance continued

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 CRM for analysis, these numbers underestimate the true number of malfunctions and battery depletions. To more accurately estimate the device survival probabilities, the number of malfunctions and battery depletions used to plot each interval of the "Including Normal Battery Depletion" survival curves is adjusted (multiplied) by a factor that is based on an estimate of the magnitude of underreporting. The magnitude of underreporting is estimated by comparing data in Medtronic's Device Registration Tracking Application (DTrak) with data from Returned Product Analysis.

The DTrak system is an important element of Medtronic's Quality System. The DTrak 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 DTrak 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 DTrak 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.

Method for Estimating CRT, ICD, and IPG Device Performance continued

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.

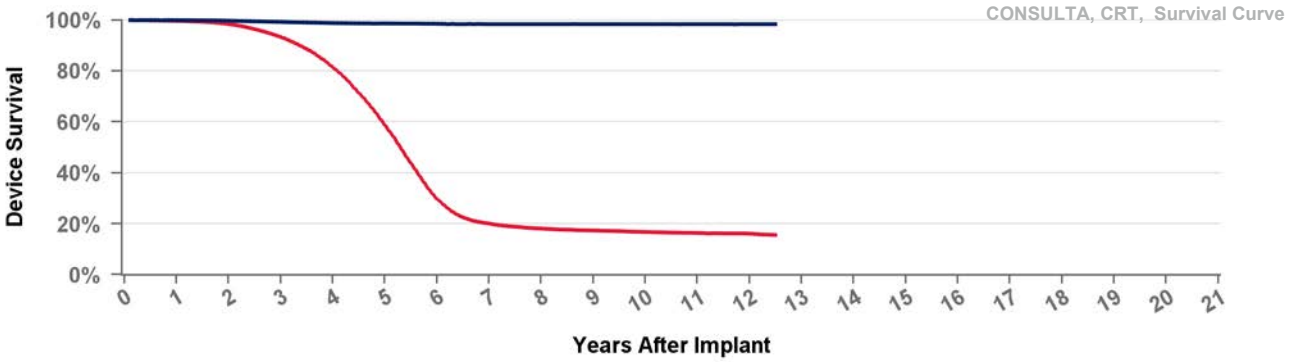
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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 third party sources such as the Social Security Administration are used to update Medtronic's DTrak data about patients who have died but whose deaths had not been reported to Medtronic. In addition, the patient mortality rate derived from our DTrak 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 DTrak is significantly different from published rates, an adjustment is applied to correct the difference. The correction factor is also applied to account for devices that were removed and not reported or returned.

D204TRM Consulta CRT-D

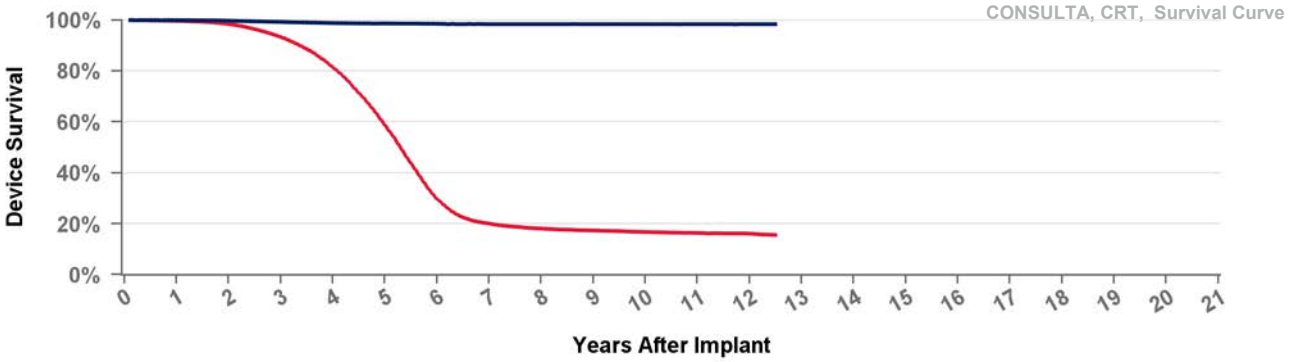
US Market Release	09Jan2012	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,048	Battery	1
Estimated Active USA Implants	259	Electrical Component	1
Normal Battery Depletions	722	Possible Early Battery Depletion	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.4%	98.4%	98.4%	98.4%	98.3%	98.3%	98.3%
Including NBD	99.7%	98.4%	93.3%	81.3%	58.9%	29.8%	20.1%	18.1%	17.4%	16.8%	16.4%	16.2%	15.6%
Effective Sample Size	56120	50207	42858	33041	19342	7426	4006	3258	2899	2497	1828	973	181

D214TRM Consulta CRT-D

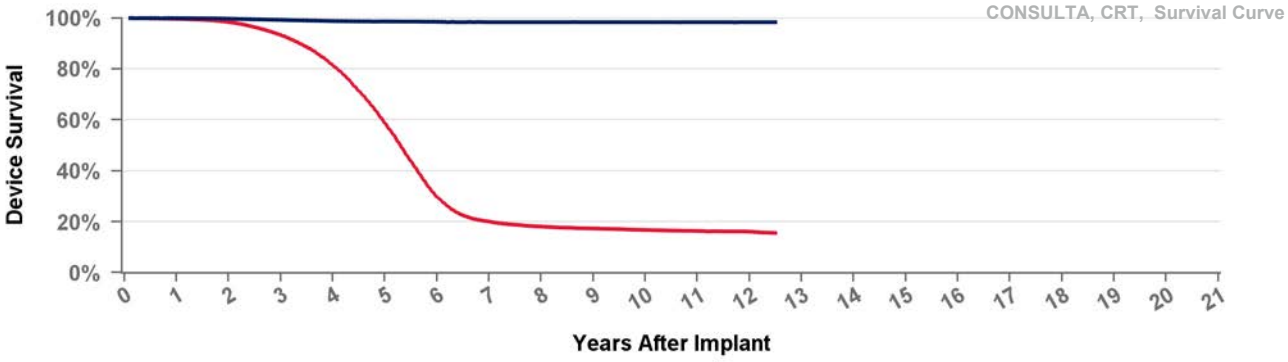
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	22Jul2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.4%	98.4%	98.4%	98.4%	98.3%	98.3%	98.3%
Including NBD	99.7%	98.4%	93.3%	81.3%	58.9%	29.8%	20.1%	18.1%	17.4%	16.8%	16.4%	16.2%	15.6%
Effective Sample Size	56120	50207	42858	33041	19342	7426	4006	3258	2899	2497	1828	973	181

D224TRK Consulta CRT-D

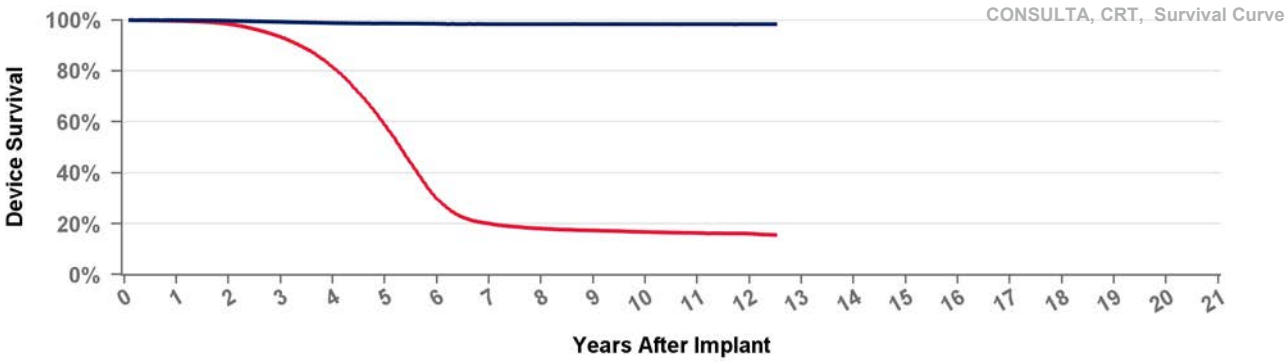
US Market Release	15Sep2008	**Total Malfunctions (USA)**	**604**
CE Approval Date		**Therapy Function Not Compromised**	**573**
Registered USA Implants	65,129	Battery	2
Estimated Active USA Implants	5,056	Electrical Component	67
Normal Battery Depletions	18,950	Electrical Interconnect	1
		Possible Early Battery Depletion	496
		Software/Firmware	6
		Other	1
		Therapy Function Compromised	**31**
		Battery	5
		Electrical Component	26



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.4%	98.4%	98.4%	98.4%	98.3%	98.3%	98.3%
Including NBD	99.7%	98.4%	93.3%	81.3%	58.9%	29.8%	20.1%	18.1%	17.4%	16.8%	16.4%	16.2%	15.6%
Effective Sample Size	56120	50207	42858	33041	19342	7426	4006	3258	2899	2497	1828	973	181

D234TRK Consulta CRT-D

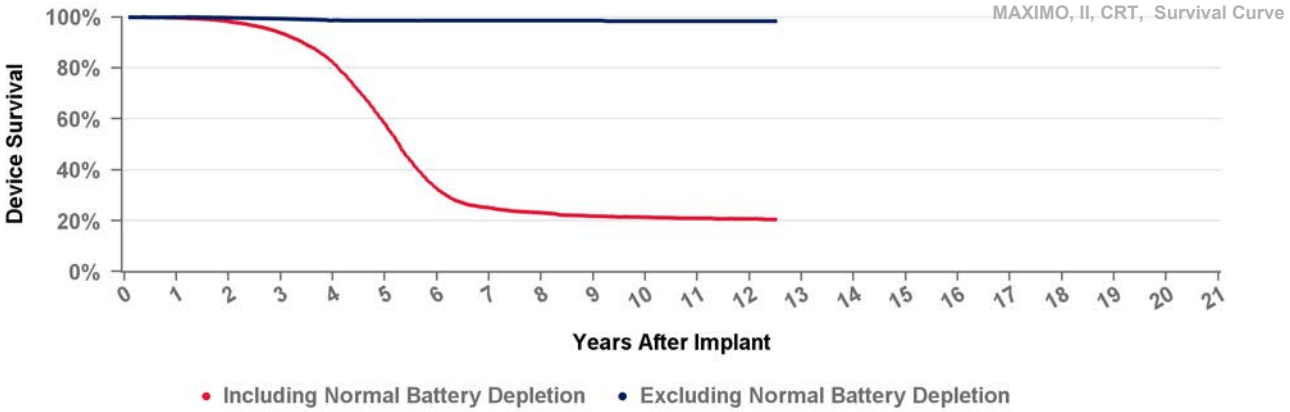
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.5%	98.4%	98.4%	98.4%	98.4%	98.3%	98.3%	98.3%
Including NBD	99.7%	98.4%	93.3%	81.3%	58.9%	29.8%	20.1%	18.1%	17.4%	16.8%	16.4%	16.2%	15.6%
Effective Sample Size	56120	50207	42858	33041	19342	7426	4006	3258	2899	2497	1828	973	181

D264TRM Maximo II CRT-D

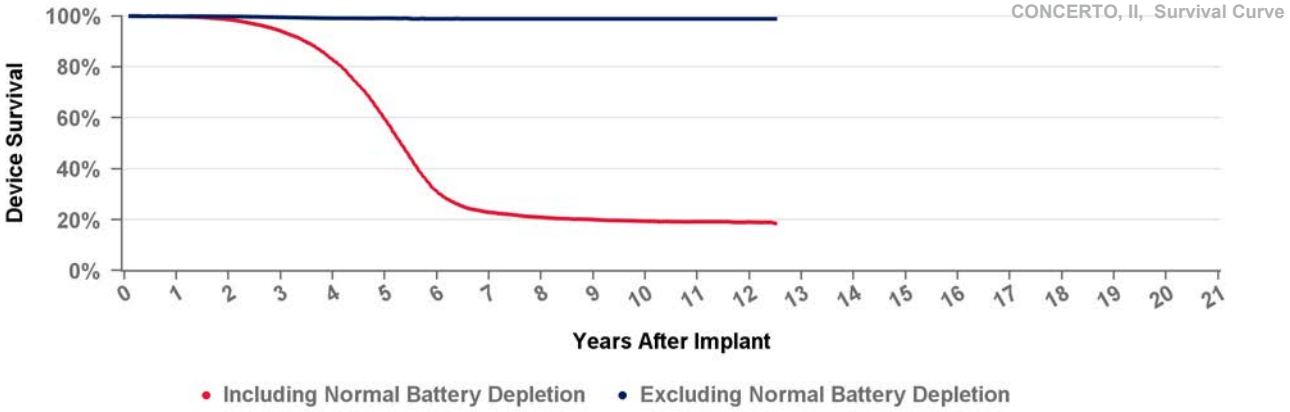
US Market Release	09Jan2012	**Total Malfunctions (USA)**	**1**
CE Approval Date	22Jul2010	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.6%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%
Including NBD	99.7%	98.3%	93.7%	82.1%	58.2%	32.4%	25.1%	23.2%	21.8%	21.4%	21.0%	20.8%	20.5%
Effective Sample Size	12499	11086	9500	7257	3990	1655	1085	908	793	701	513	250	110

D274TRK Concerto II CRT-D

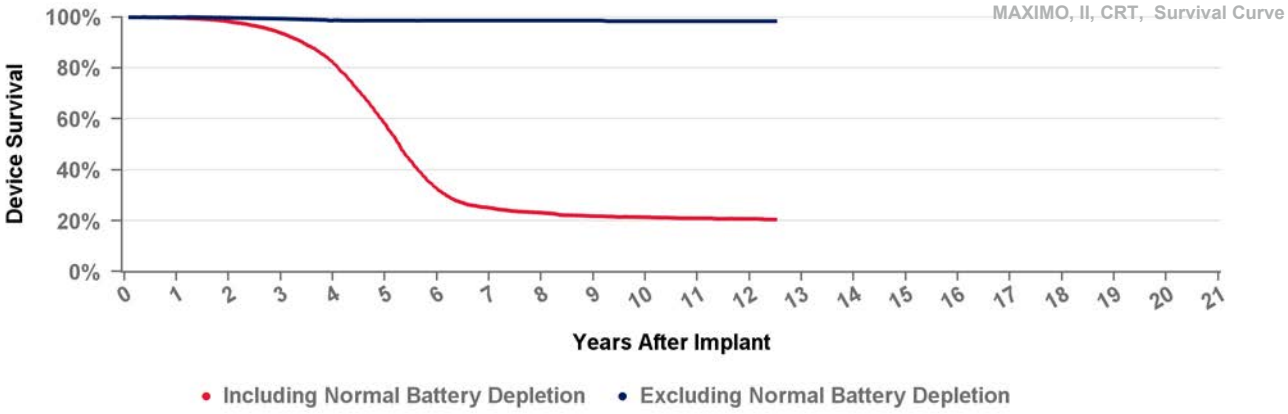
US Market Release	15Aug2009	**Total Malfunctions (USA)**	**187**
CE Approval Date		**Therapy Function Not Compromised**	**176**
Registered USA Implants	30,190	Battery	1
Estimated Active USA Implants	2,607	Electrical Component	22
Normal Battery Depletions	8,015	Possible Early Battery Depletion	152
		Software/Firmware	1
		Therapy Function Compromised	**11**
		Battery	1
		Electrical Component	10



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%
Including NBD	99.8%	98.6%	94.1%	82.7%	59.6%	30.9%	22.9%	21.0%	20.1%	19.5%	19.2%	19.1%	18.5%
Effective Sample Size	25090	22504	19400	14877	8264	3124	1899	1570	1394	1271	1159	688	185

D284TRK Maximo II CRT-D

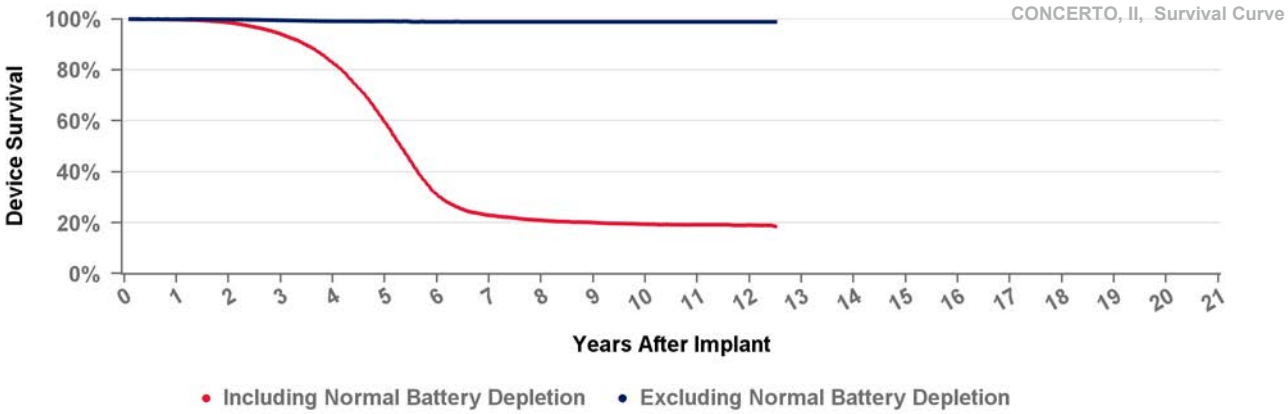
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**135**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**130**
Registered USA Implants	14,990	Electrical Component	6
Estimated Active USA Implants	1,344	Possible Early Battery Depletion	124
Normal Battery Depletions	4,080	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.6%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%	98.5%
Including NBD	99.7%	98.3%	93.7%	82.1%	58.2%	32.4%	25.1%	23.2%	21.8%	21.4%	21.0%	20.8%	20.5%
Effective Sample Size	12499	11086	9500	7257	3990	1655	1085	908	793	701	513	250	110

D294TRK Concerto II CRT-D

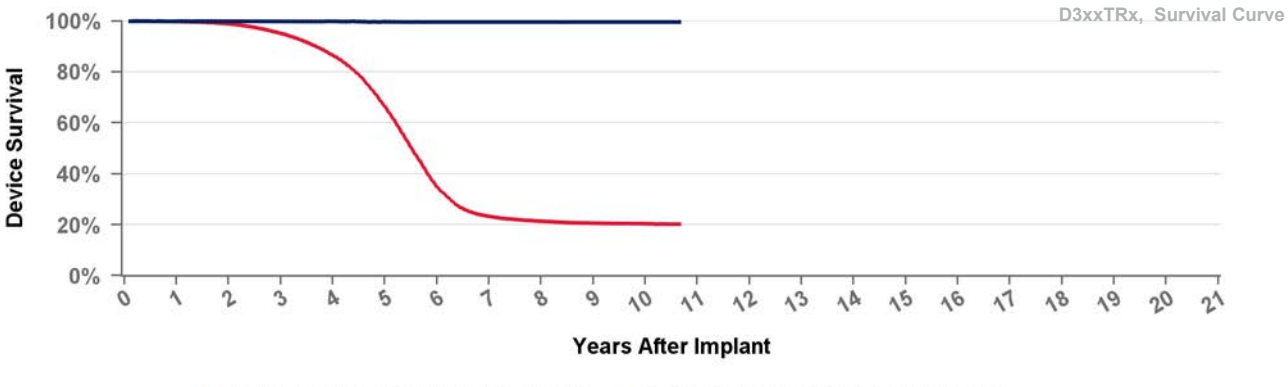
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	20Aug2008	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%	99.0%
Including NBD	99.8%	98.6%	94.1%	82.7%	59.6%	30.9%	22.9%	21.0%	20.1%	19.5%	19.2%	19.1%	18.5%
Effective Sample Size	25090	22504	19400	14877	8264	3124	1899	1570	1394	1271	1159	688	185

D314TRG Protecta XT CRT-D

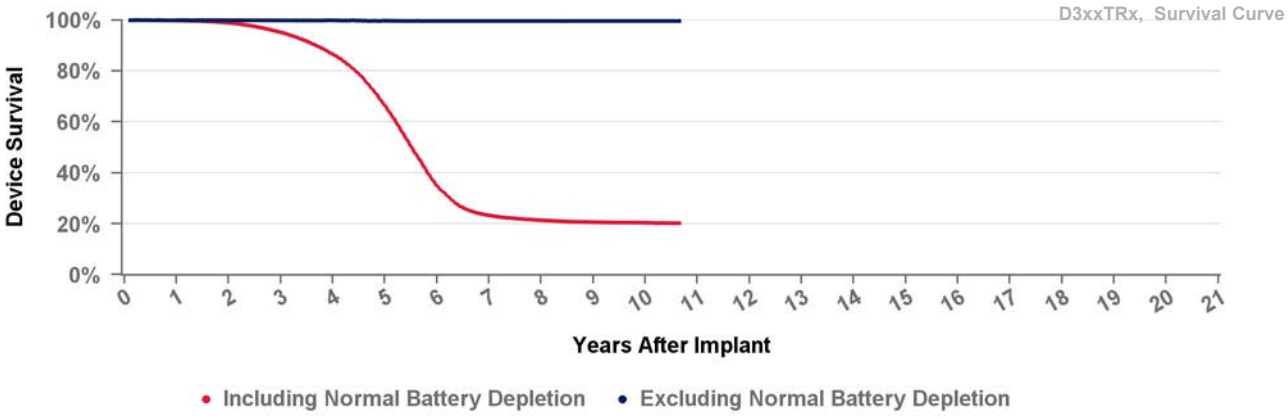
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**93**
CE Approval Date		**Therapy Function Not Compromised**	**74**
Registered USA Implants	41,865	Battery	7
Estimated Active USA Implants	4,703	Electrical Component	40
Normal Battery Depletions	10,512	Possible Early Battery Depletion	25
		Other	2
		Therapy Function Compromised	**19**
		Battery	11
		Electrical Component	8



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D314TRM Protecta XT CRT-D

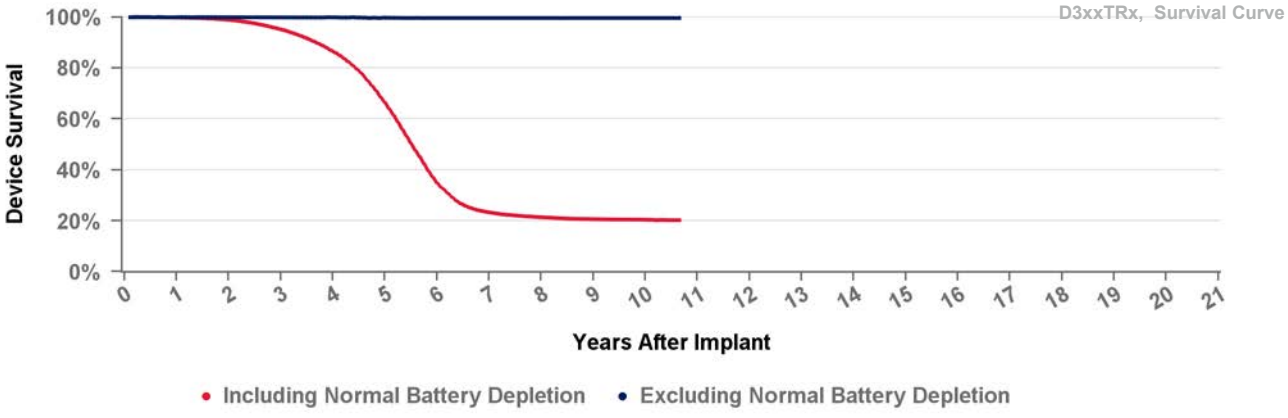
US Market Release	09Nov2011	**Total Malfunctions (USA)**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,197	Battery	4
Estimated Active USA Implants	1,468	Electrical Component	8
Normal Battery Depletions	3,510	Possible Early Battery Depletion	5
		Therapy Function Compromised	**3**
		Battery	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D334TRG Protecta CRT-D

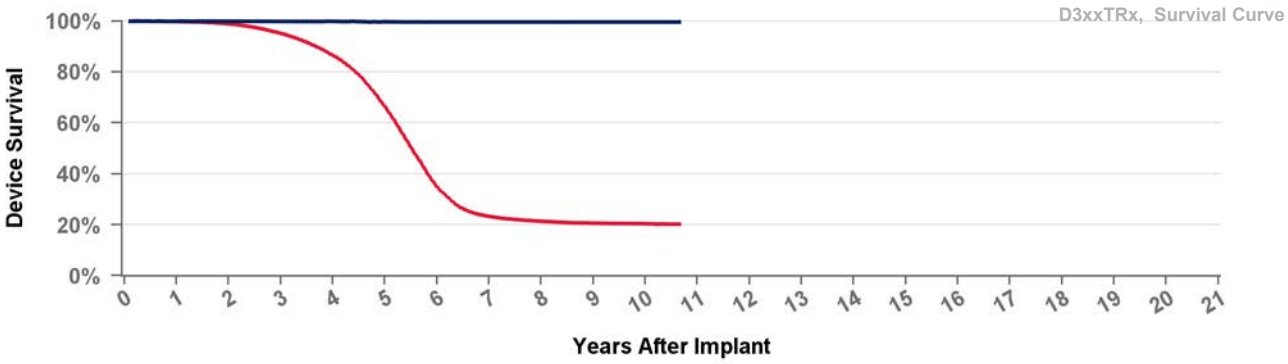
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,103	Electrical Component	8
Estimated Active USA Implants	986	Possible Early Battery Depletion	3
Normal Battery Depletions	2,167	**Therapy Function Compromised**	**3**
		Battery	1
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D334TRM Protecta CRT-D

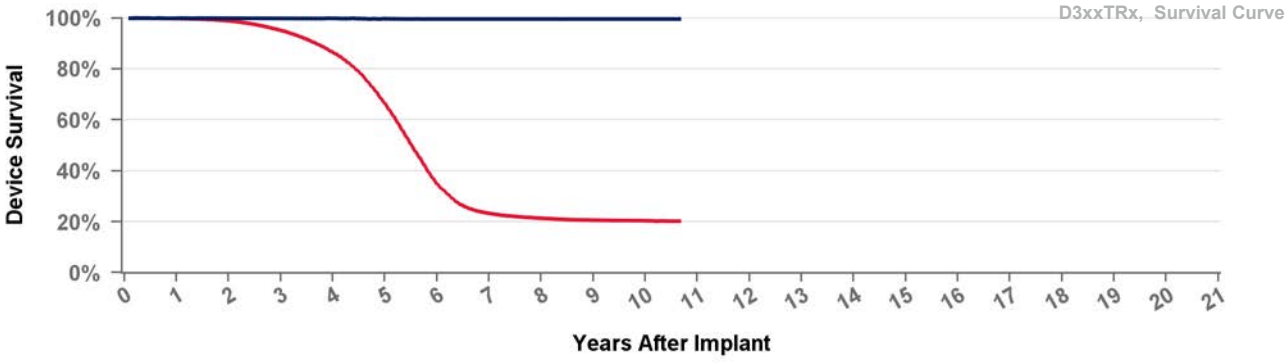
US Market Release	09Nov2011	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	1,785	Battery	3
Estimated Active USA Implants	250	Electrical Component	1
Normal Battery Depletions	572	Possible Early Battery Depletion	2
		Therapy Function Compromised	**2**
		Battery	2



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D354TRG Protecta XT CRT-D

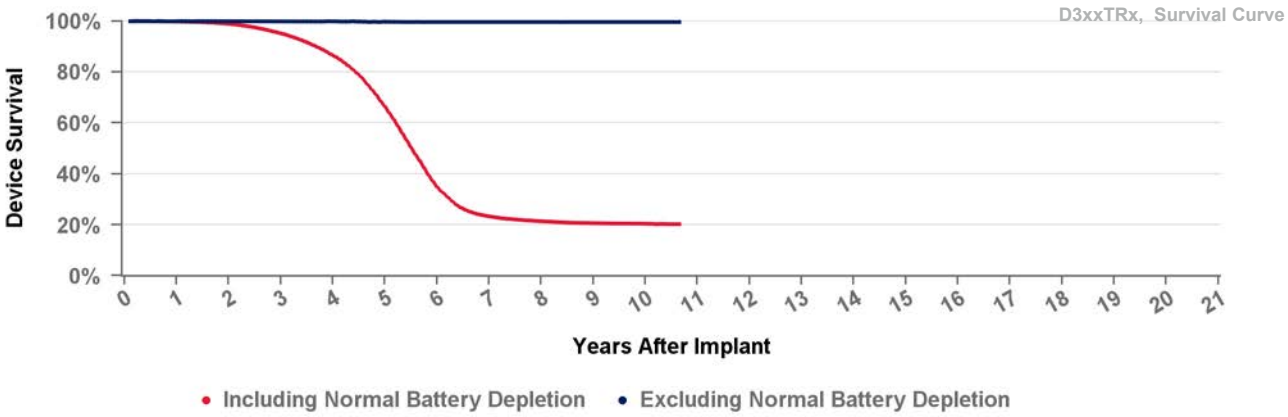
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	25Mar2010	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D354TRM Protecta XT CRT-D

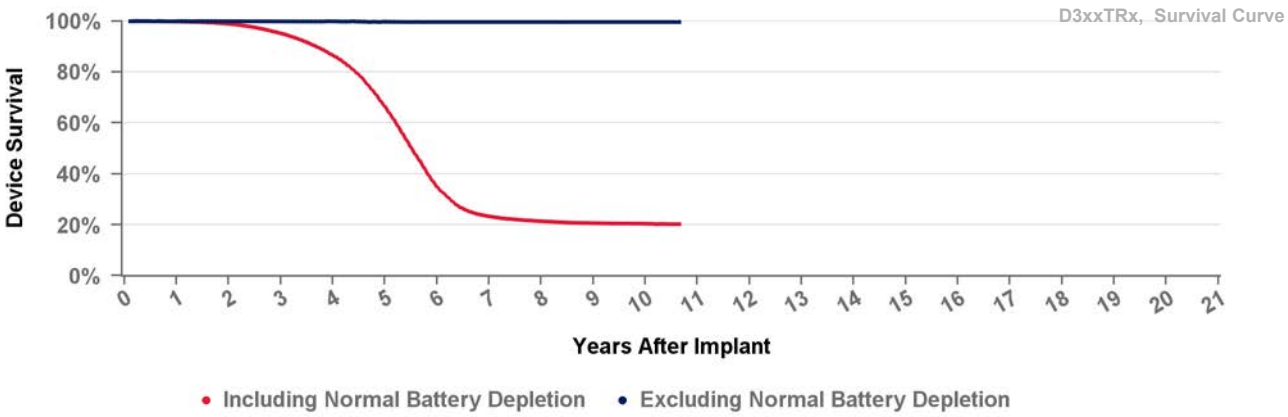
US Market Release
CE Approval Date 15Jul2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D364TRG Protecta CRT-D

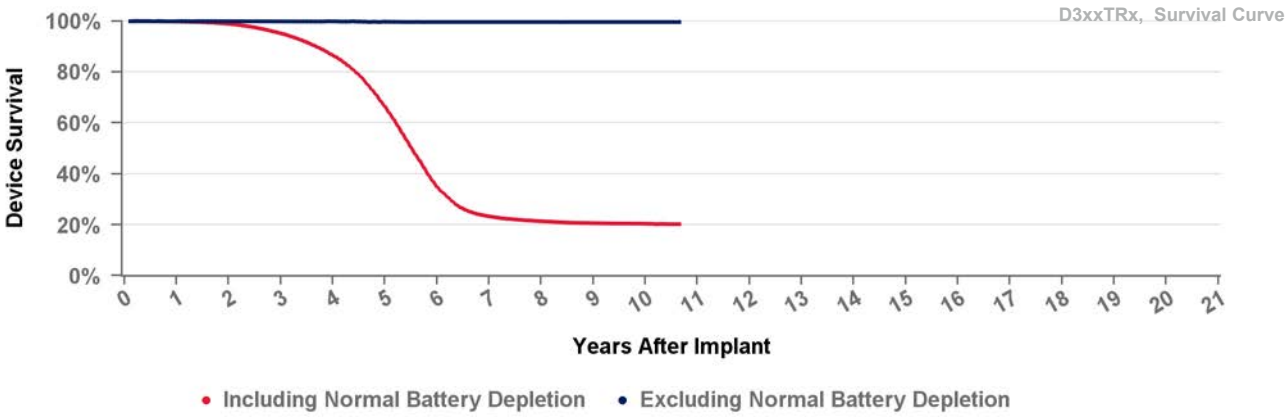
US Market Release
CE Approval Date 25Mar2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D364TRM Protecta CRT-D

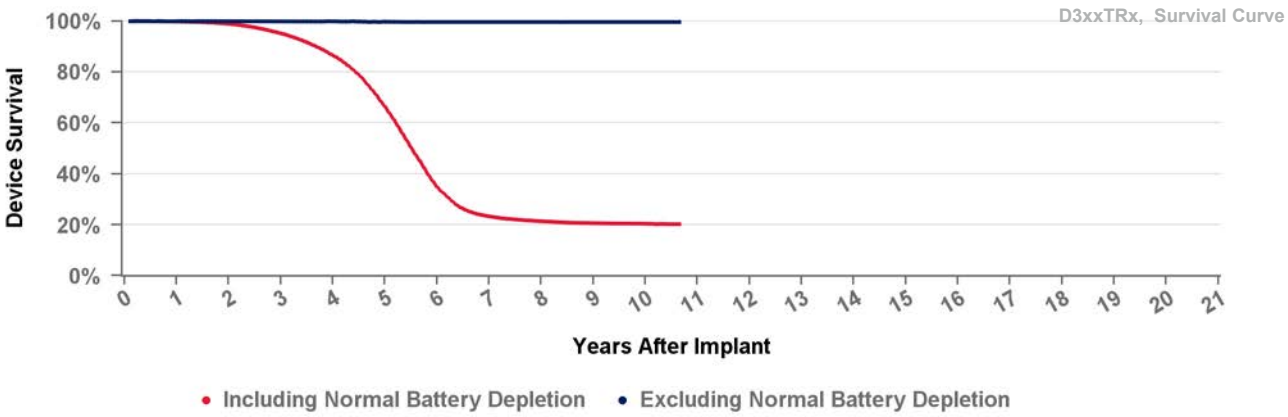
US Market Release
CE Approval Date 15Jul2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D384TRG Cardia CRT-D

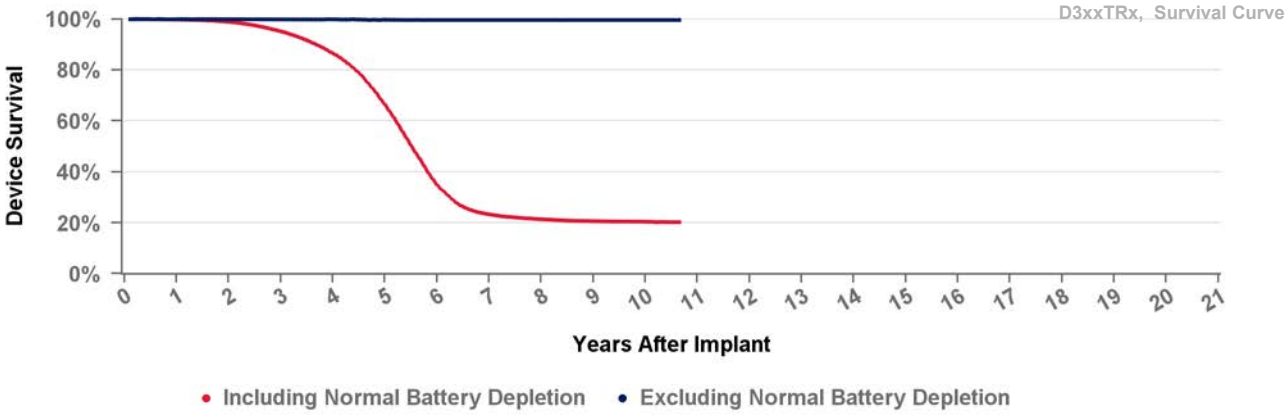
US Market Release
CE Approval Date 12Jan2011
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

D394TRG Egida CRT-D

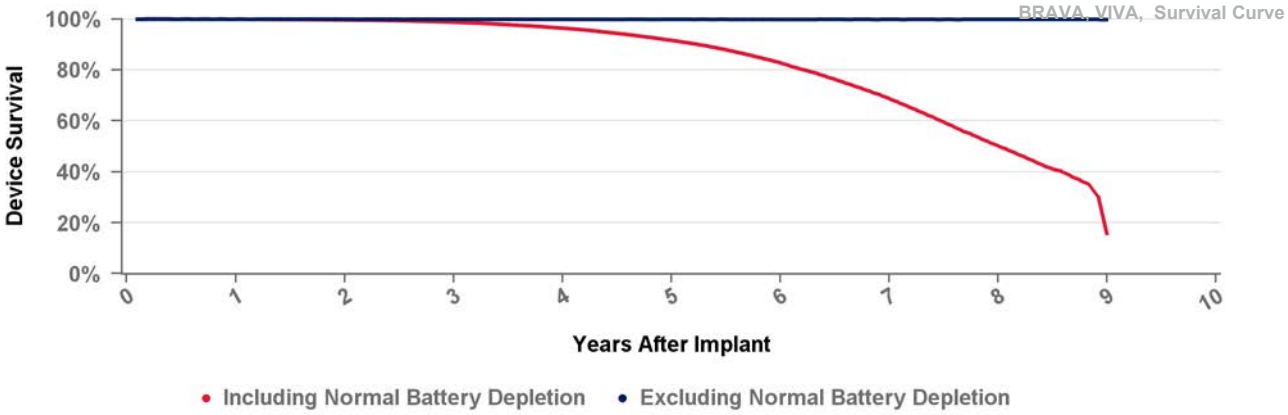
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.5%	35.0%	23.3%	21.4%	20.7%	20.4%	20.3%
Effective Sample Size	54161	48933	42288	33507	21023	8847	4811	3971	3460	2382	296

DTBA1D1 Viva XT

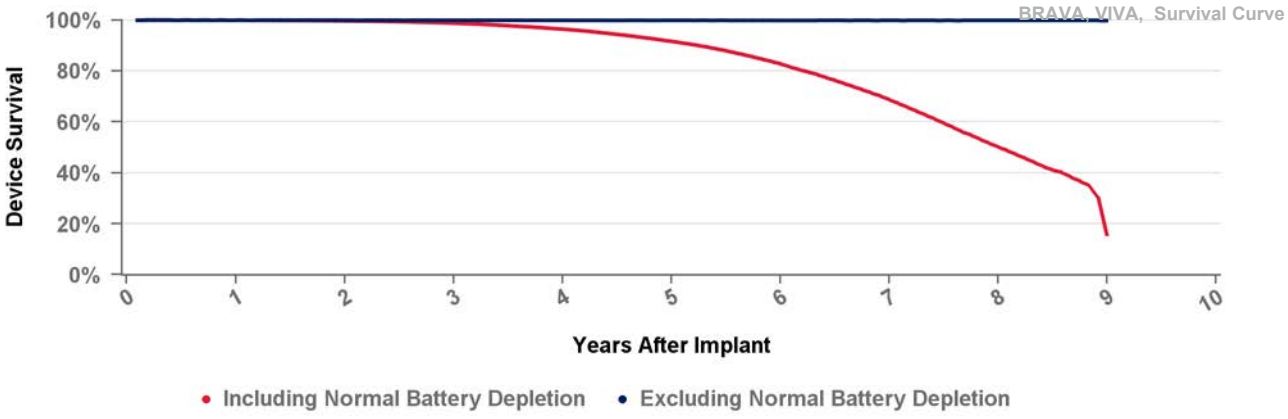
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**68**
CE Approval Date		**Therapy Function Not Compromised**	**45**
Registered USA Implants	110,561	Battery	11
Estimated Active USA Implants	34,420	Electrical Component	31
Normal Battery Depletions	12,462	Possible Early Battery Depletion	1
		Other	2
		Therapy Function Compromised	**23**
		Battery	18
		Device-Related Current Pathway	1
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBA1D4 Viva XT

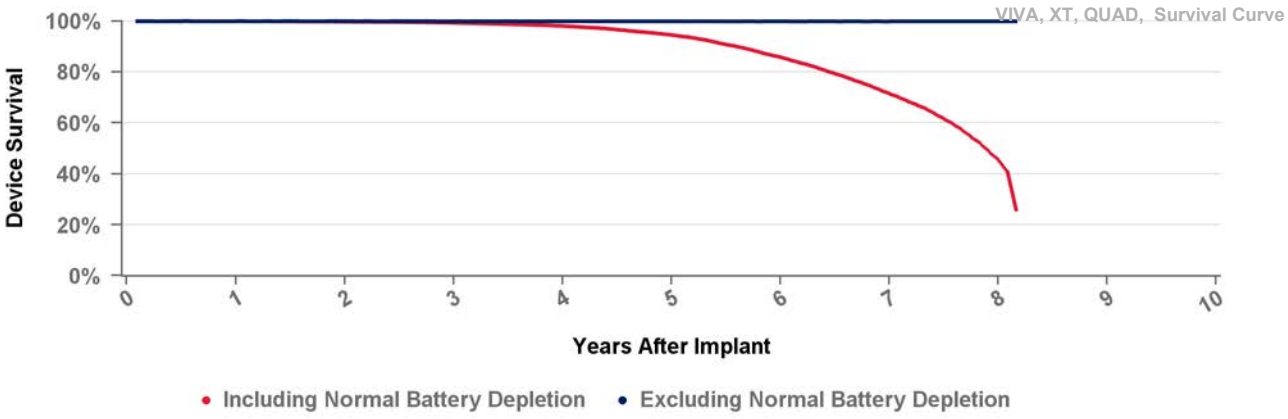
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**32**
CE Approval Date		**Therapy Function Not Compromised**	**24**
Registered USA Implants	37,782	Battery	6
Estimated Active USA Implants	10,737	Electrical Component	15
Normal Battery Depletions	5,688	Possible Early Battery Depletion	3
		Therapy Function Compromised	**8**
		Battery	5
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBA1Q1 Viva Quad XT

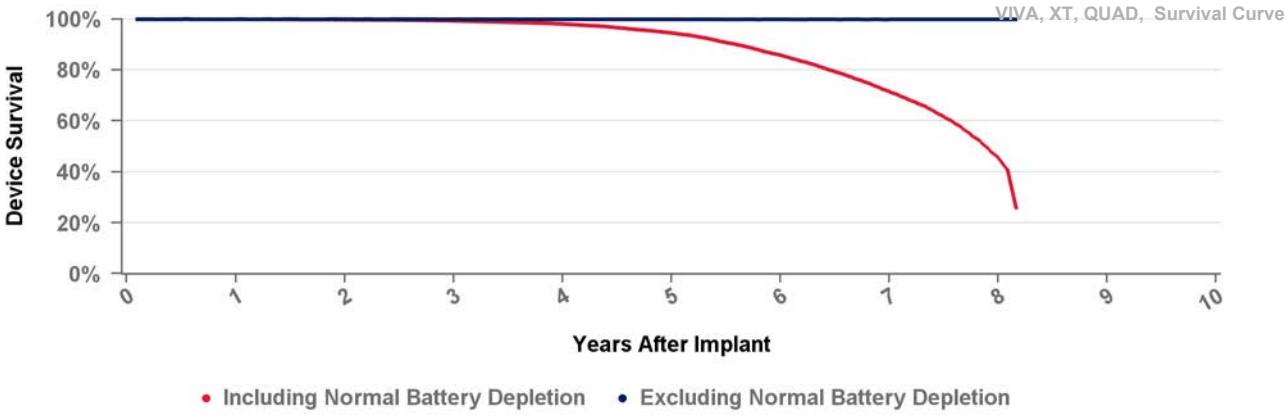
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	21,346	Battery	3
Estimated Active USA Implants	7,519	Electrical Component	3
Normal Battery Depletions	2,175	Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**4**
		Battery	3
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTBA1QQ Viva Quad XT

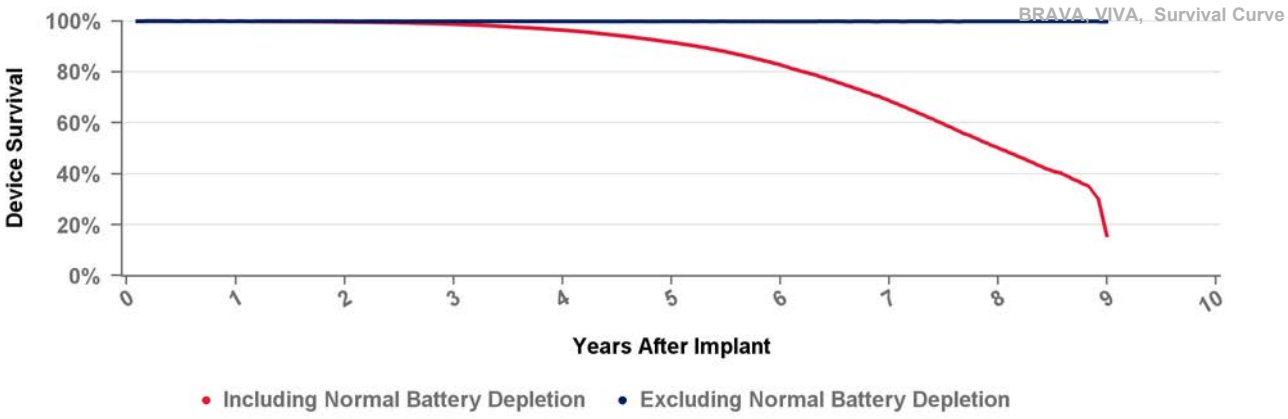
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**46**
CE Approval Date		**Therapy Function Not Compromised**	**35**
Registered USA Implants	53,399	Battery	11
Estimated Active USA Implants	20,860	Electrical Component	19
Normal Battery Depletions	6,212	Electrical Interconnect	1
		Possible Early Battery Depletion	3
		Other	1
		Therapy Function Compromised	**11**
		Battery	8
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTBA2D1 Viva XT

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	29Aug2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

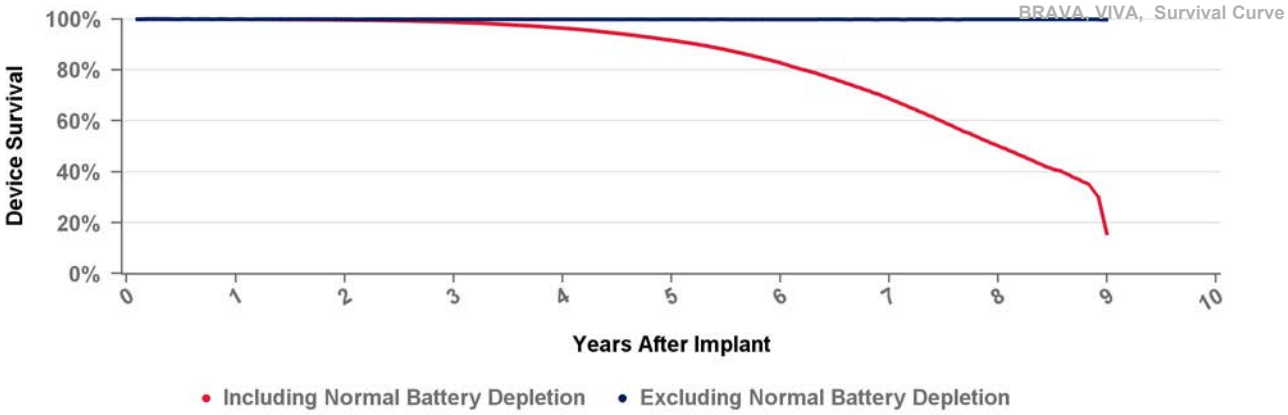


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBA2D4 Viva XT

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

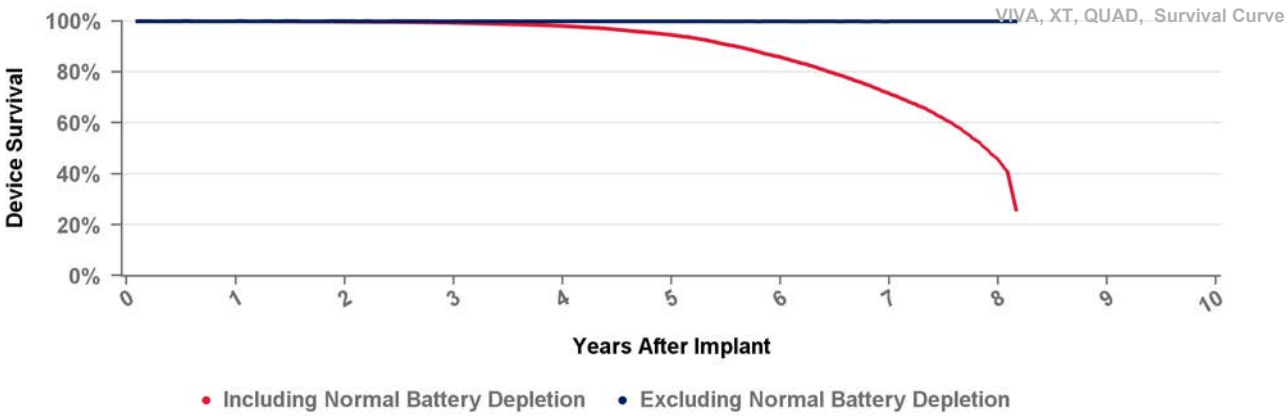


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBA2Q1 Viva Quad XT

US Market Release
CE Approval Date 12Sep2013
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

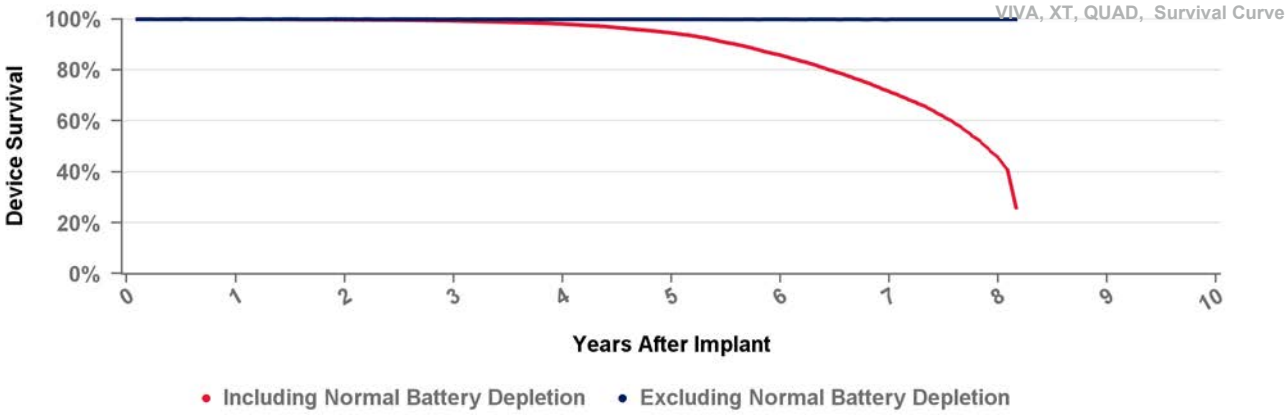
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTBA2QQ Viva Quad XT

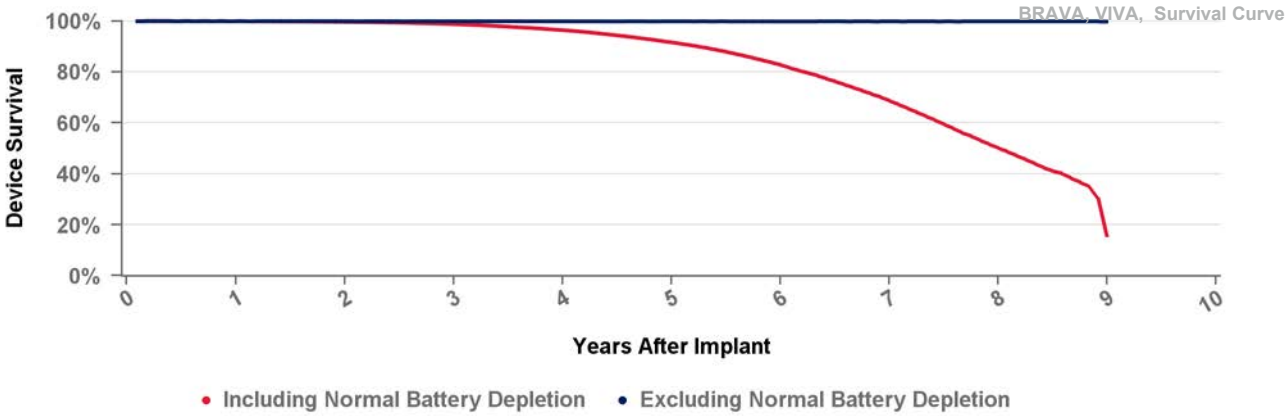
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	08Aug2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTBB1D1 Viva S

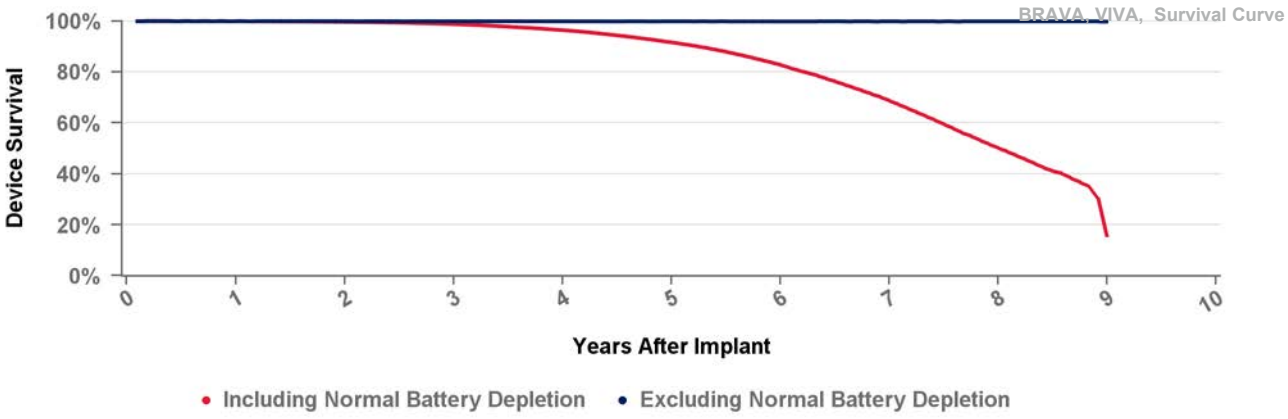
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**16**
Registered USA Implants	27,548	Battery	9
Estimated Active USA Implants	7,018	Electrical Component	4
Normal Battery Depletions	4,002	Possible Early Battery Depletion	2
		Other	1
		Therapy Function Compromised	**4**
		Battery	3
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB1D4 Viva S

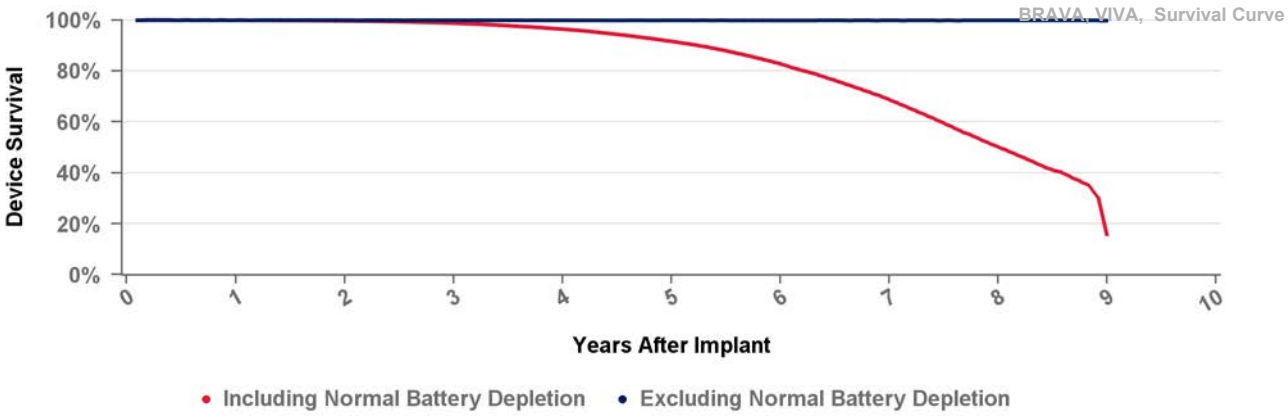
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	8,836	Battery	3
Estimated Active USA Implants	2,222	Electrical Component	2
Normal Battery Depletions	1,488	Other	1
		Therapy Function Compromised	**3**
		Battery	3



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB1Q1 Viva Quad S

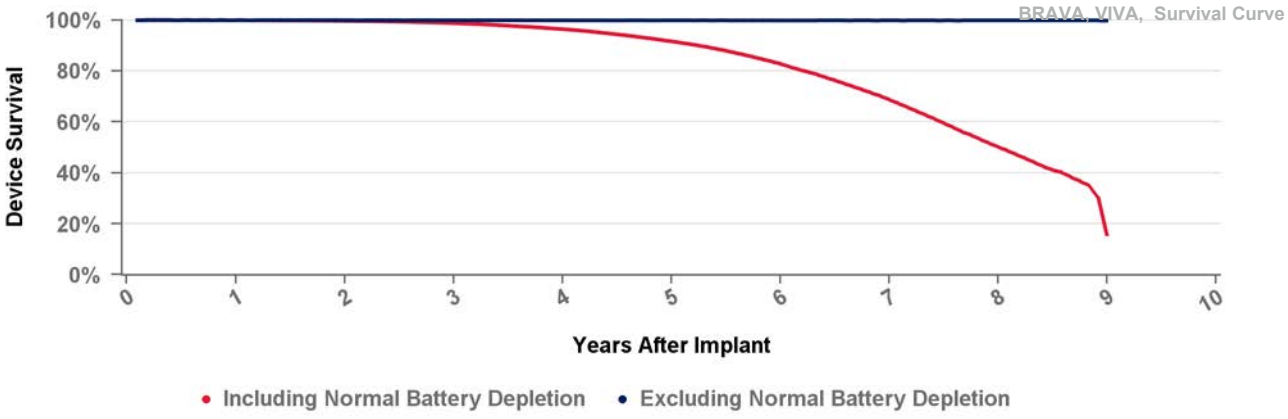
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	4,537	Battery	1
Estimated Active USA Implants	1,537	Electrical Component	1
Normal Battery Depletions	586	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB1QQ Viva Quad S

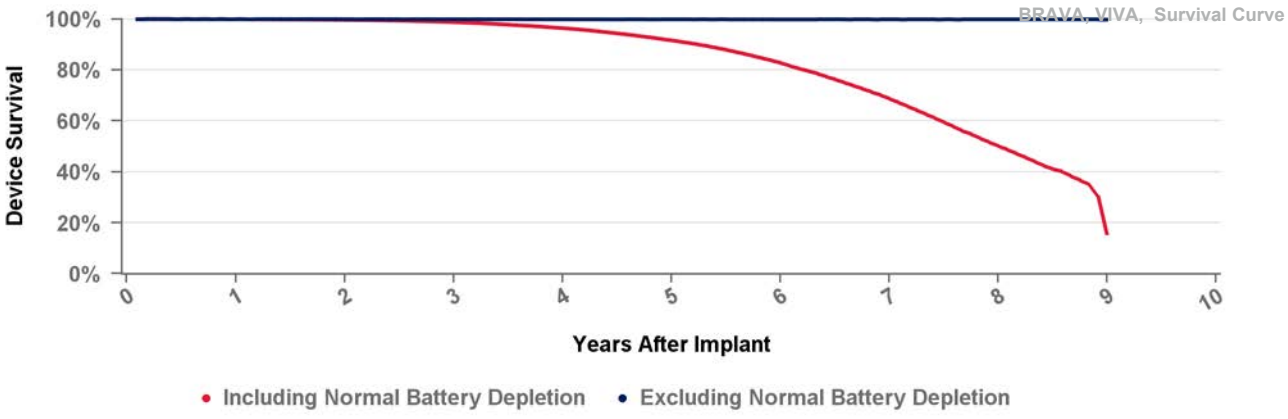
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	9,869	Battery	1
Estimated Active USA Implants	3,585	Electrical Component	3
Normal Battery Depletions	1,408	Possible Early Battery Depletion	2
		Other	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB2D1 Viva S

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	08Aug2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

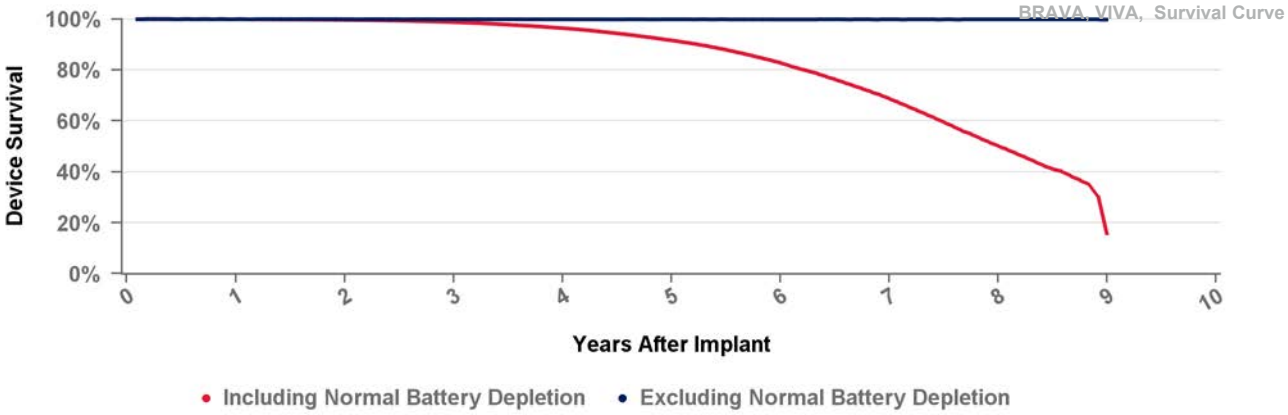


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB2D4 Viva S

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

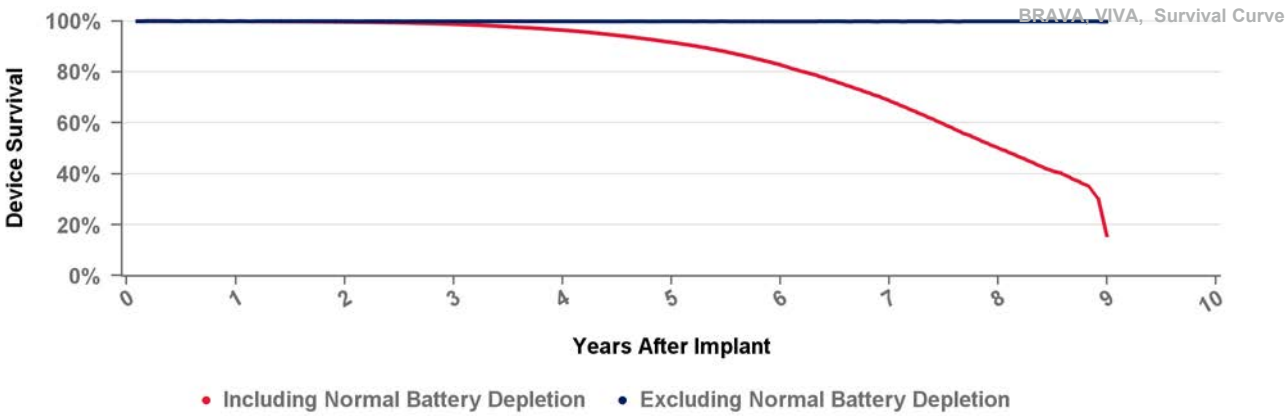


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBB2QQ Viva Quad S

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

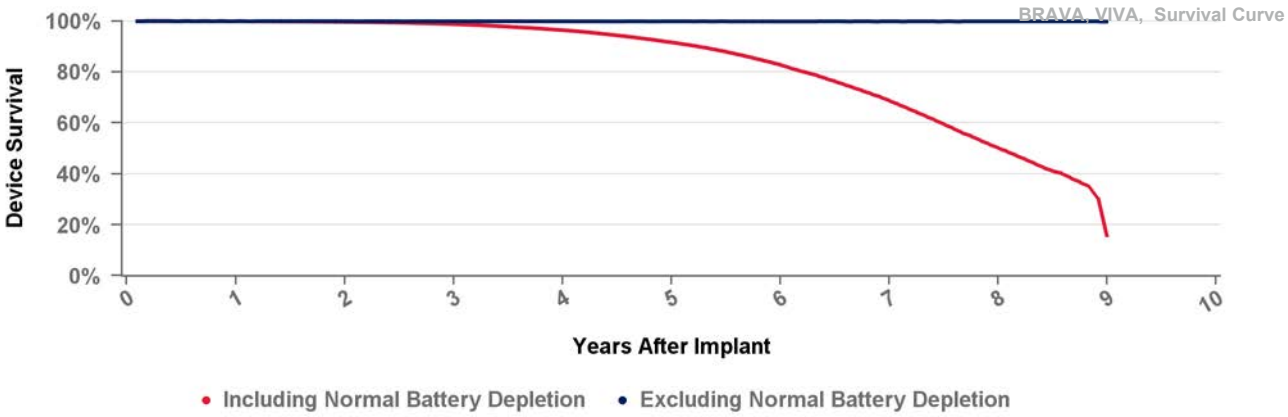


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBC2D1 Brava

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

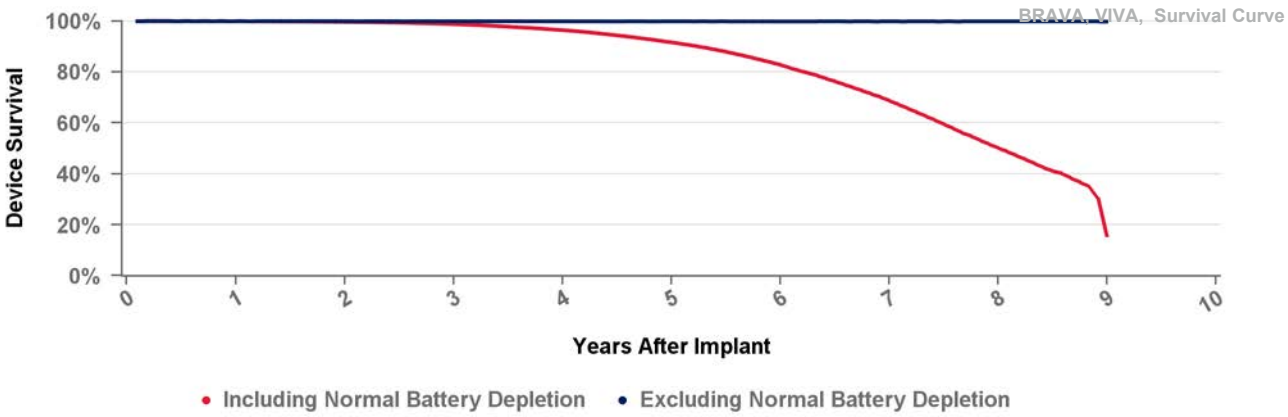


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBC2D4 Brava

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

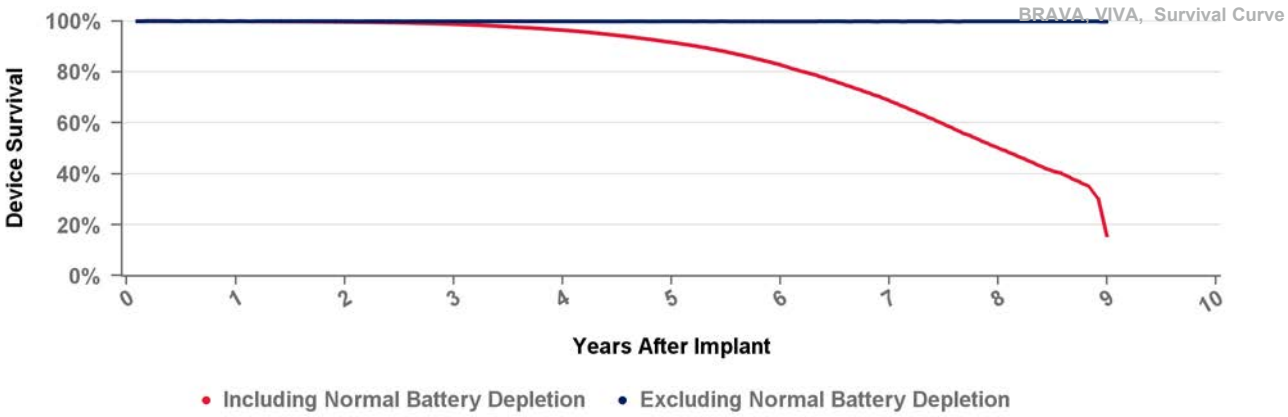


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBC2Q1 Brava Quad

US Market Release
CE Approval Date 12Sep2013
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

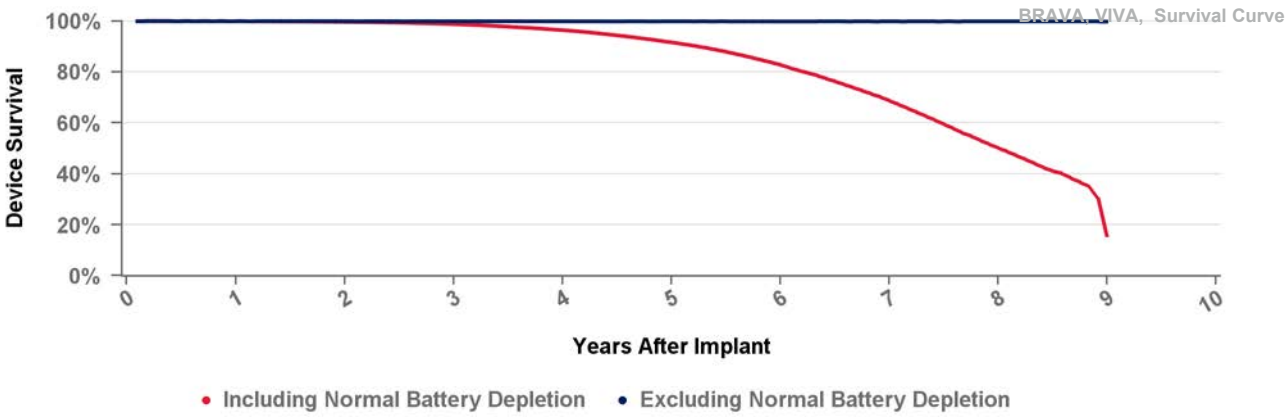


Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBC2QQ Brava Quad

US Market Release
CE Approval Date 08Aug2012
Registered USA Implants 2
Estimated Active USA Implants
Normal Battery Depletions

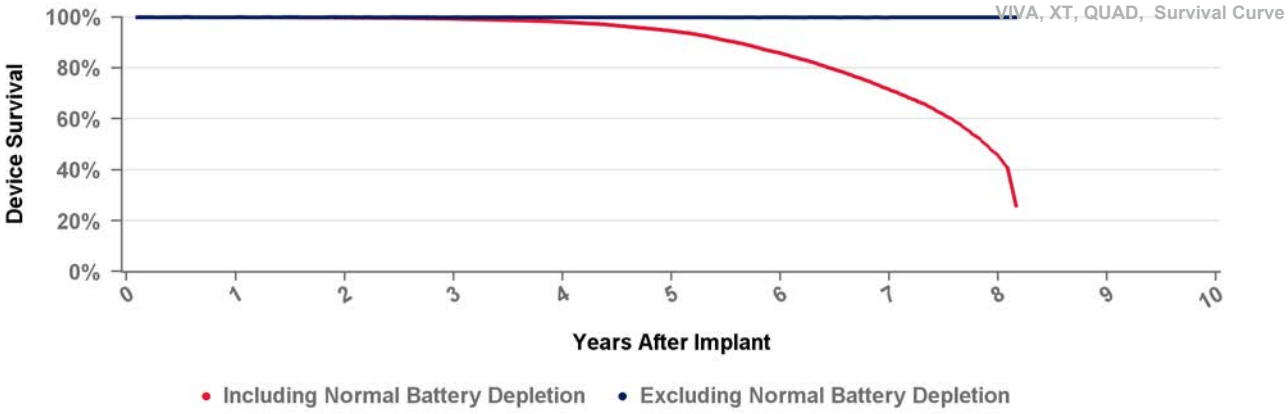
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.6%	82.8%	68.7%	50.1%	15.7%
Effective Sample Size	86457	78603	71150	62767	52645	39251	22476	8147	121

DTBX1QQ Viva Quad C

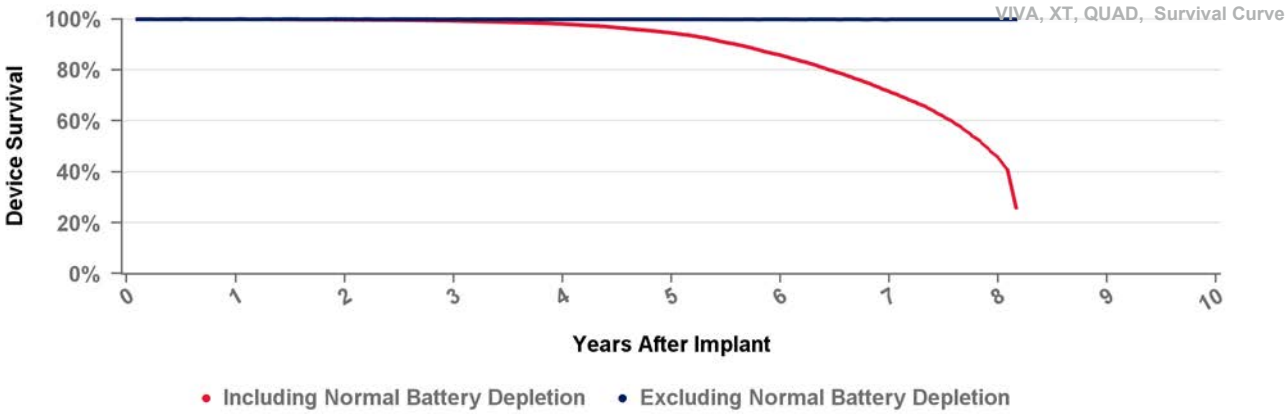
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,276	Electrical Component	1
Estimated Active USA Implants	144	**Therapy Function Compromised**	**0**
Normal Battery Depletions	382		



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTBX2QQ Viva Quad C

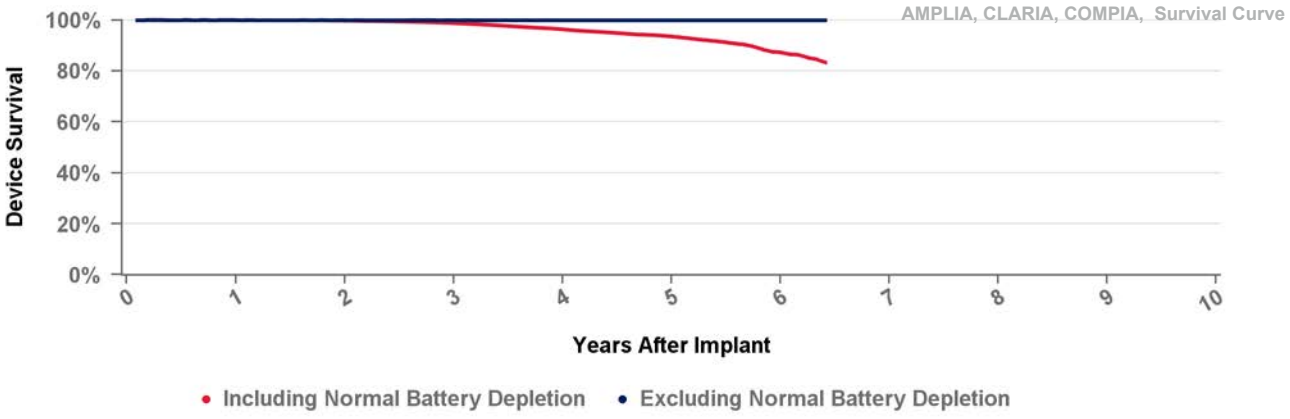
US Market Release	03Jul2014	**Total Malfunctions (USA)**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.8%	99.3%	98.1%	94.5%	85.8%	71.5%	45.4%	25.9%
Effective Sample Size	33783	31354	28911	25964	22271	17131	10154	1262	189

DTMA1D1 Claria MRI

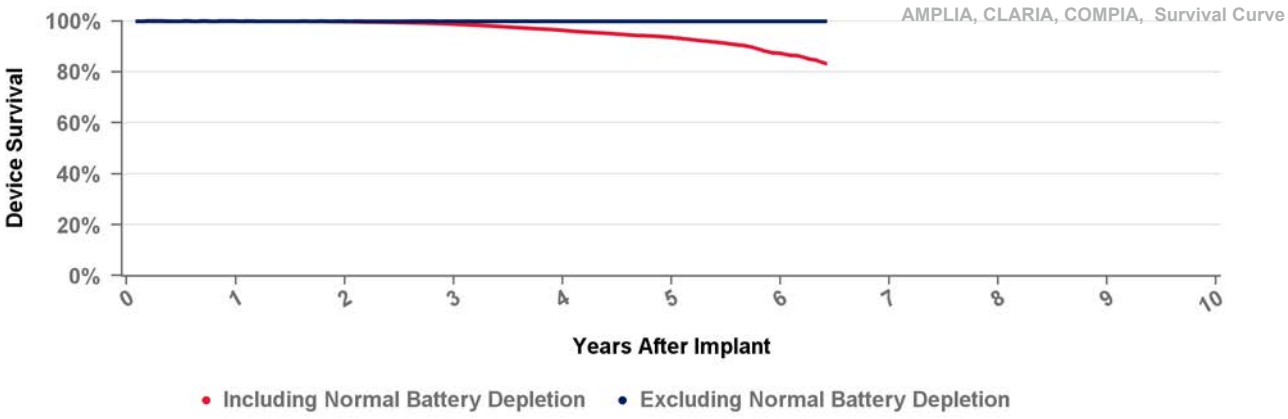
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	18,485	Battery	4
Estimated Active USA Implants	14,342	Electrical Component	1
Normal Battery Depletions	259	Electrical Interconnect	1
		Other	1
		Therapy Function Compromised	**1**
		Battery	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMA1D4 Claria MRI

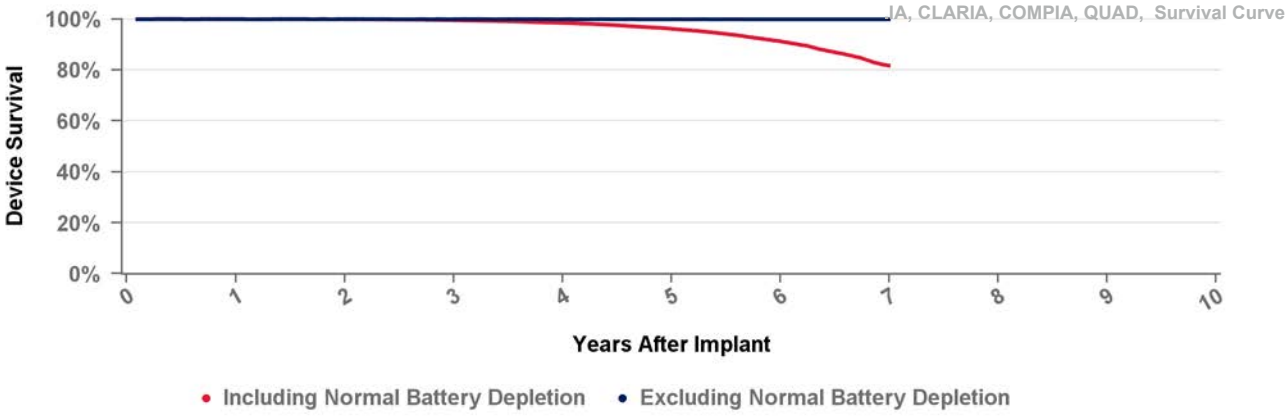
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	16,739	Battery	1
Estimated Active USA Implants	13,534	Electrical Component	3
Normal Battery Depletions	214	**Therapy Function Compromised**	**6**
		Battery	1
		Device-Related Current Pathway	2
		Electrical Component	2
		Electrical Interconnect	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMA1Q1 Claria MRI

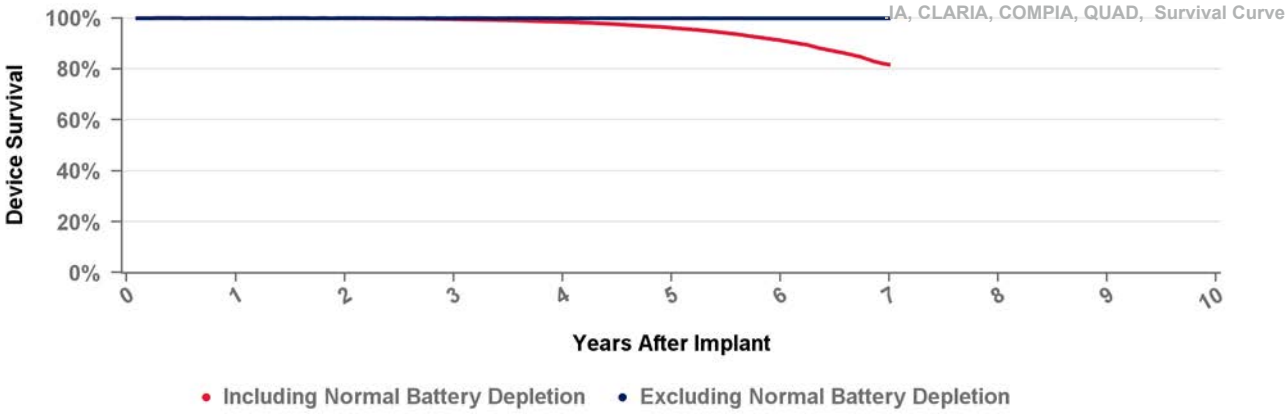
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	12,424	Electrical Interconnect	1
Estimated Active USA Implants	9,951	Possible Early Battery Depletion	1
Normal Battery Depletions	113	Other	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMA1QQ Claria MRI

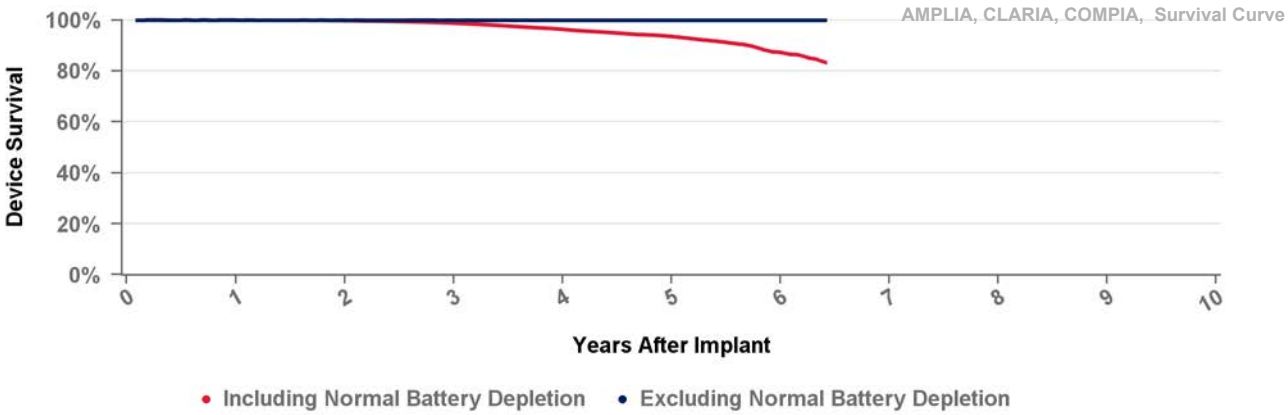
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**27**
CE Approval Date		**Therapy Function Not Compromised**	**18**
Registered USA Implants	79,512	Battery	1
Estimated Active USA Implants	67,204	Electrical Component	11
Normal Battery Depletions	621	Electrical Interconnect	1
		Possible Early Battery Depletion	1
		Software/Firmware	1
		Other	3
		Therapy Function Compromised	**9**
		Device-Related Current Pathway	4
		Electrical Component	5



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMA2D1 Claria MRI

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	29Aug2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMA2D4 Claria MRI

US Market Release

CE Approval Date 19Feb2016

Registered USA Implants

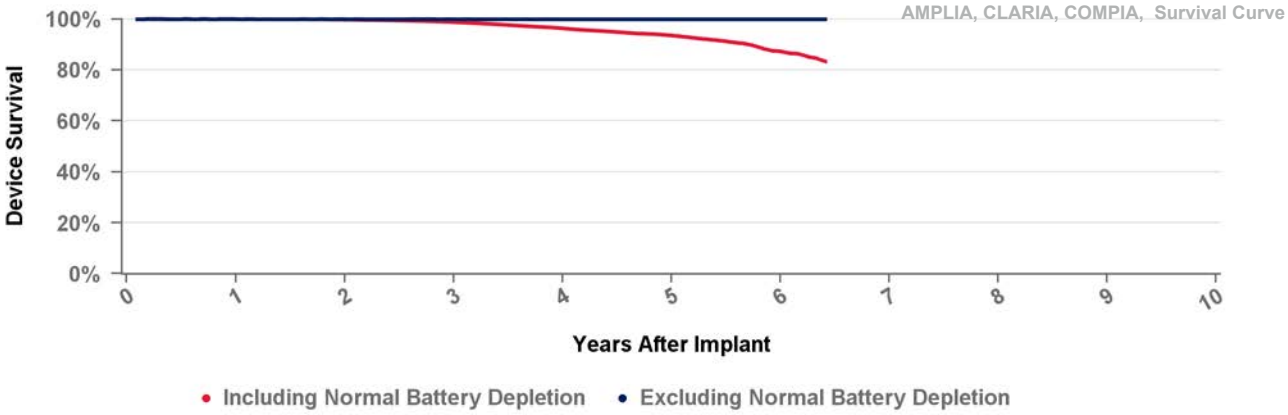
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

Therapy Function Compromised



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMA2Q1 Claria MRI

US Market Release

CE Approval Date 29Aug2016

Registered USA Implants

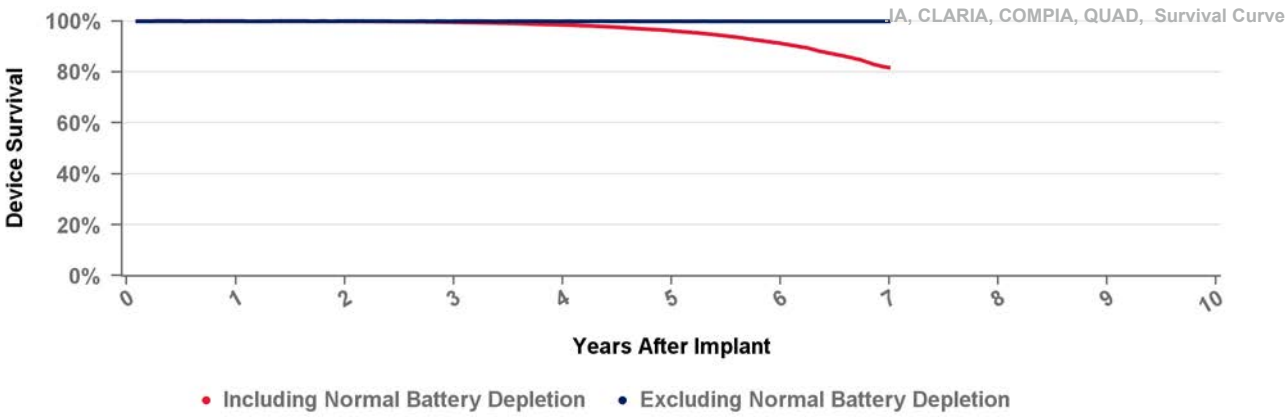
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

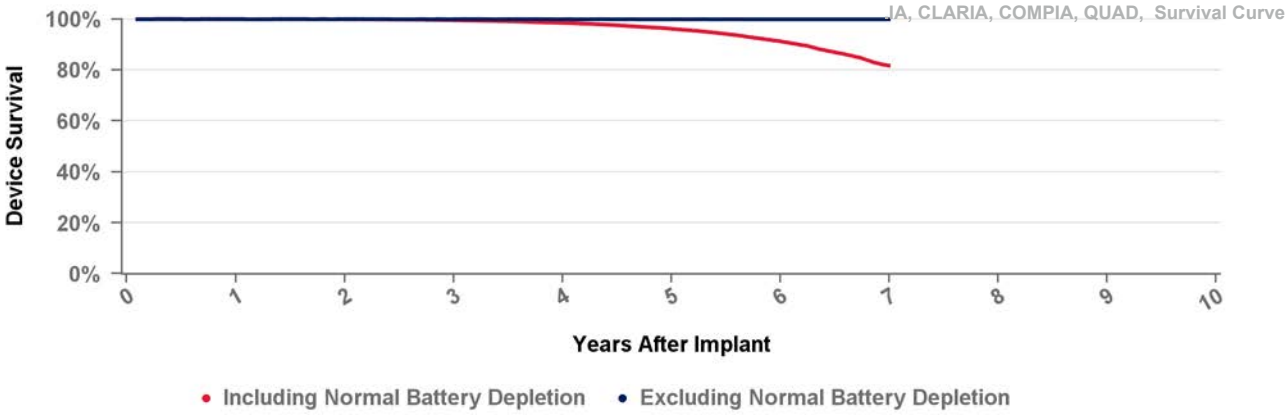
Therapy Function Compromised



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMA2QQ Claria MRI

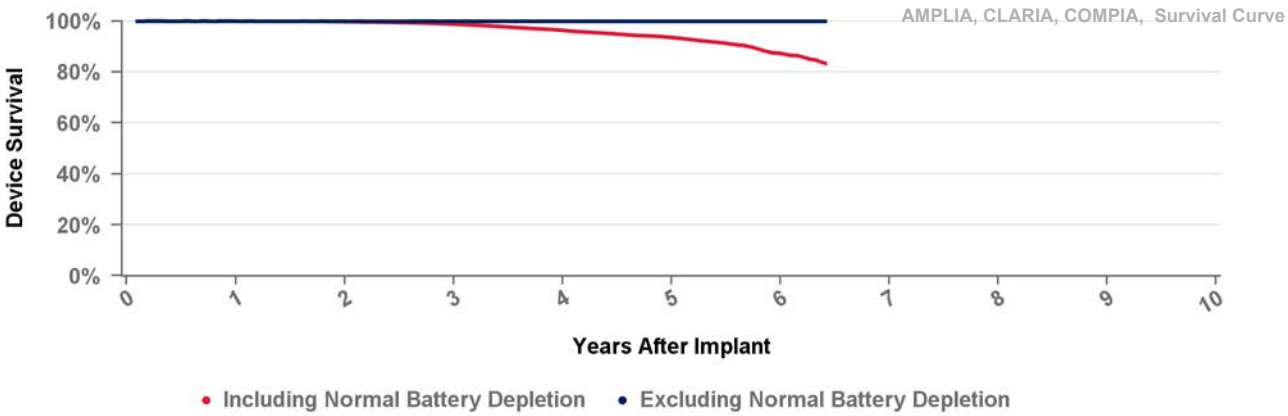
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMB1D1 Amplia MRI

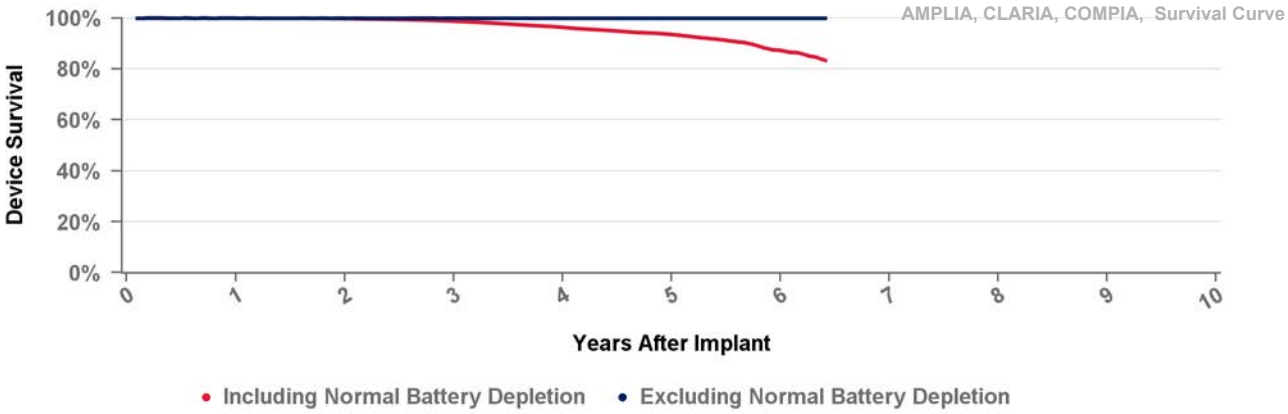
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	8,965	Battery	1
Estimated Active USA Implants	6,204	Electrical Component	2
Normal Battery Depletions	201	Other	1
		Therapy Function Compromised	**1**
		Battery	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMB1D4 Amplia MRI

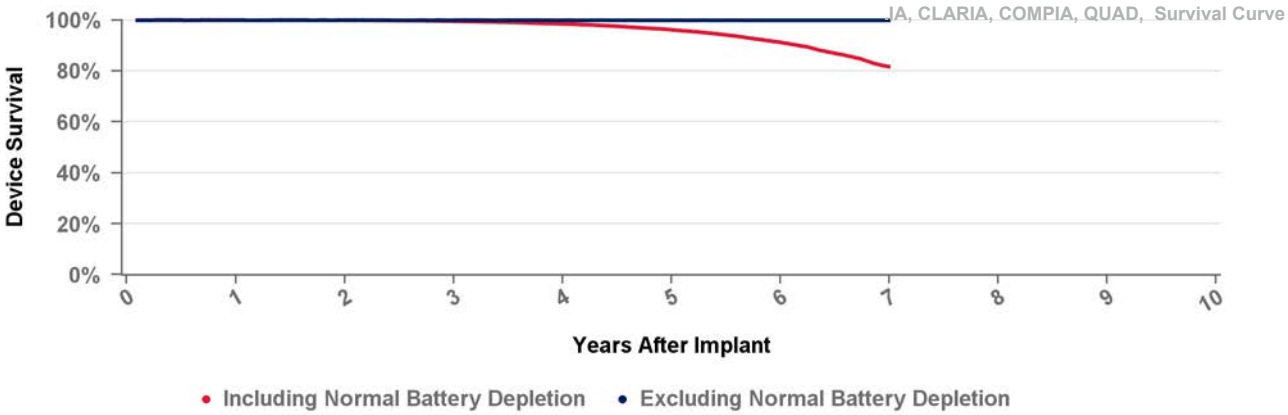
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	9,589	Electrical Component	2
Estimated Active USA Implants	6,155	**Therapy Function Compromised**	**1**
Normal Battery Depletions	314	Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMB1Q1 Amplia MRI

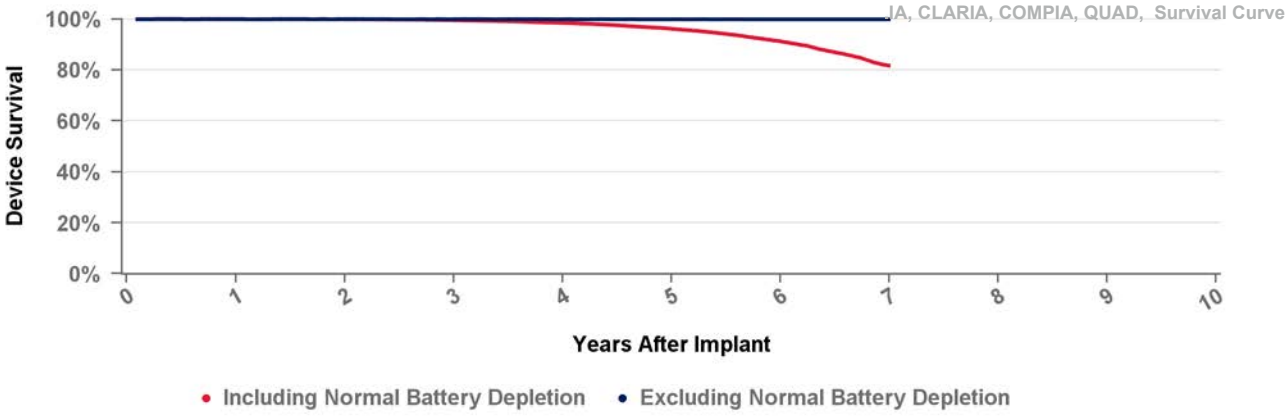
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	5,708		
Estimated Active USA Implants	4,068	**Therapy Function Compromised**	**1**
Normal Battery Depletions	104	Battery	1



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMB1QQ Amplia MRI

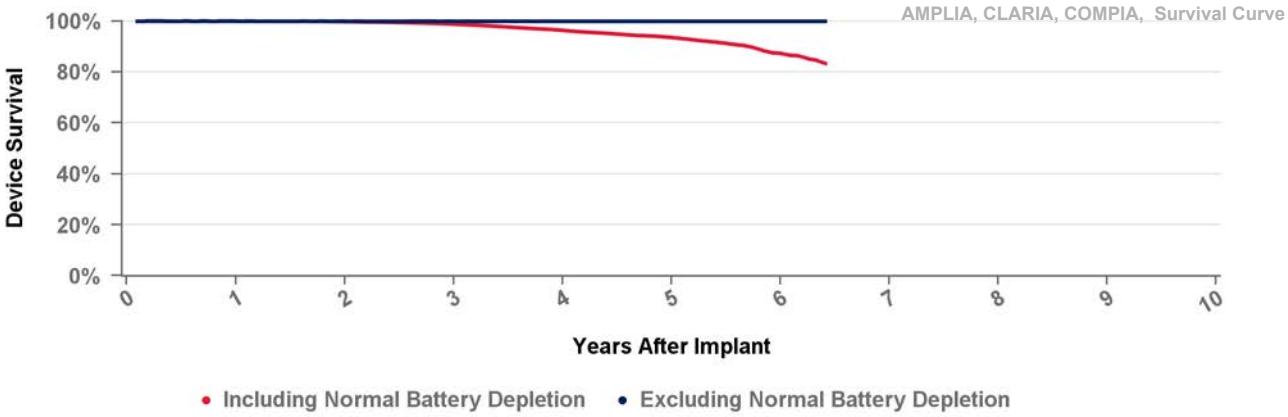
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**36**
CE Approval Date		**Therapy Function Not Compromised**	**29**
Registered USA Implants	48,612	Battery	13
Estimated Active USA Implants	33,137	Electrical Component	10
Normal Battery Depletions	1,474	Possible Early Battery Depletion	3
		Other	3
		Therapy Function Compromised	**7**
		Battery	6
		Device-Related Current Pathway	1



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMB2D1 Amplia MRI

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	29Aug2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

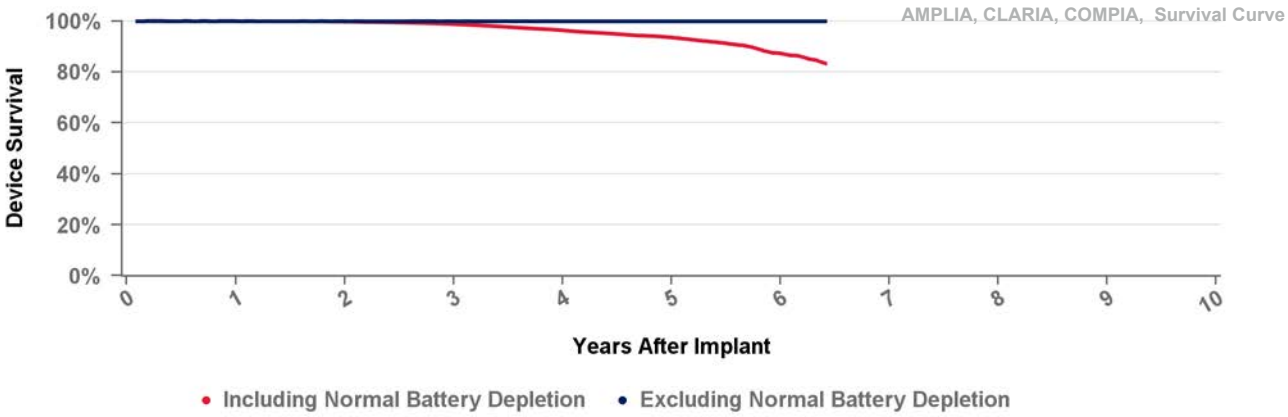


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMB2D4 Amplia MRI

US Market Release
CE Approval Date 19Feb2016
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

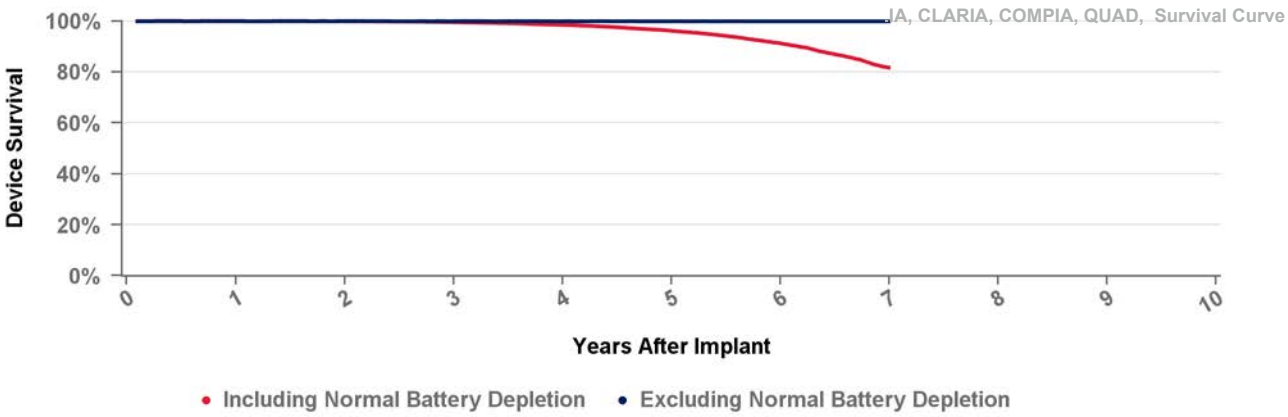


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMB2Q1 Amplia MRI

US Market Release
CE Approval Date 29Aug2016
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

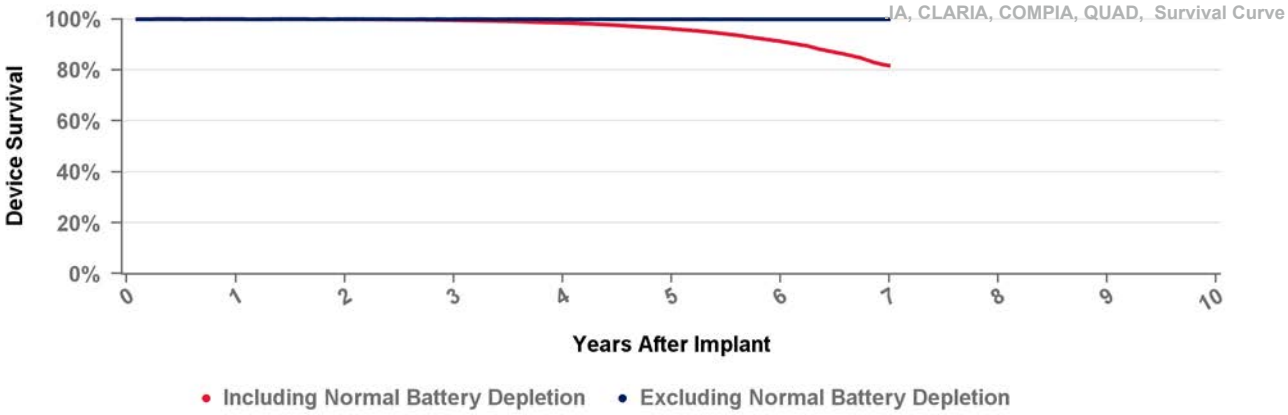
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMB2QQ Amplia MRI

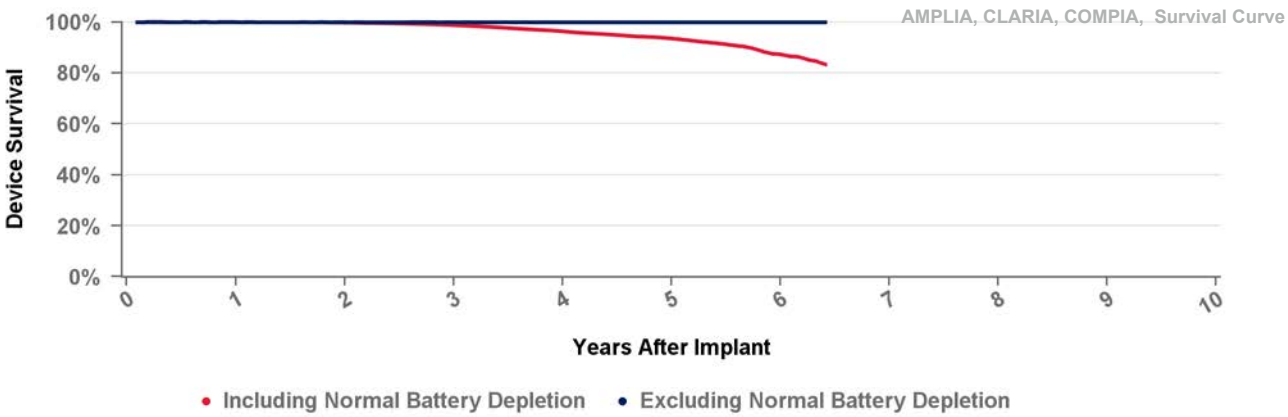
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMC1D1 Compia MRI

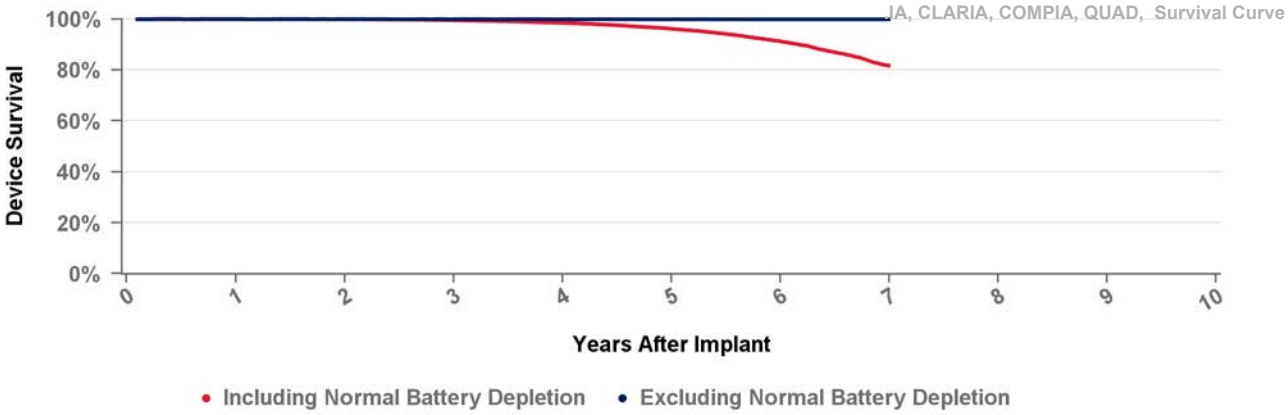
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,323		
Estimated Active USA Implants	965	**Therapy Function Compromised**	**1**
Normal Battery Depletions	33	Device-Related Current Pathway	1



Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMC1QQ Compia MRI

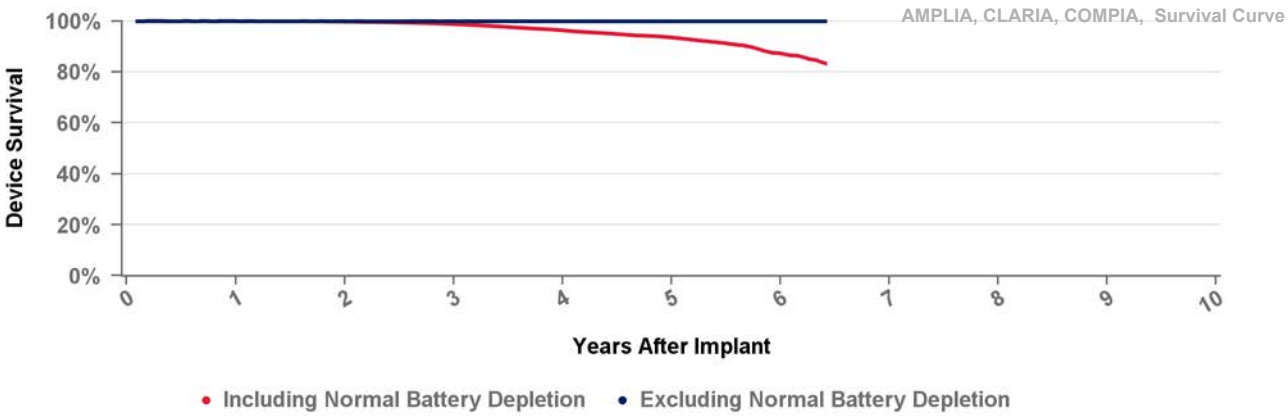
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	6,236	Battery	1
Estimated Active USA Implants	4,558	Electrical Component	2
Normal Battery Depletions	211	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTMC2D1 Compia MRI

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	29Aug2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

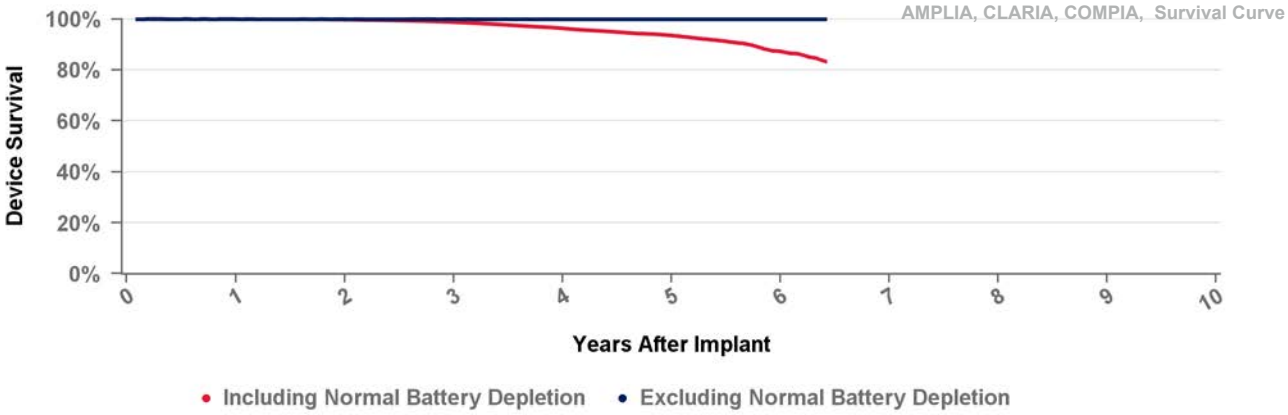


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMC2D4 Compia MRI

US Market Release
CE Approval Date 19Feb2016
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

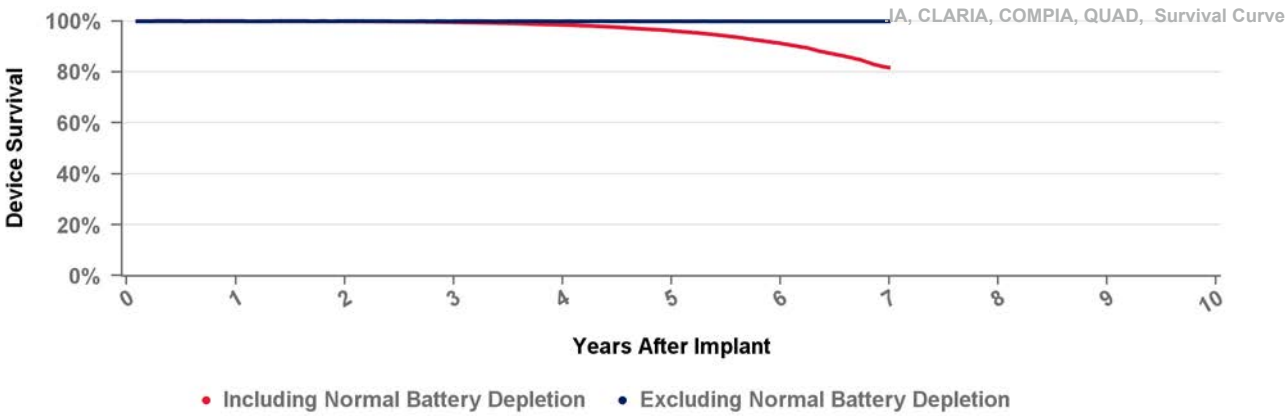


Years	1	2	3	4	5	6	at 77 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.3%	93.5%	87.3%	83.2%
Effective Sample Size	35512	27877	20341	13621	7113	1586	195

DTMC2QQ Compia MRI

US Market Release
CE Approval Date 19Feb2016
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

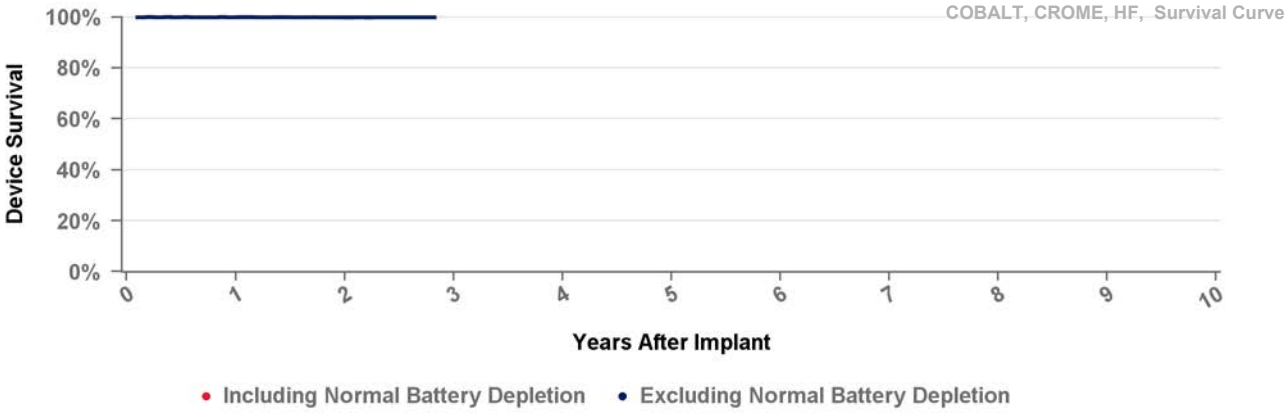
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.5%	96.2%	91.3%	81.7%
Effective Sample Size	101195	83323	63803	42877	24731	9944	375

DTPA2D1 Cobalt XT HF

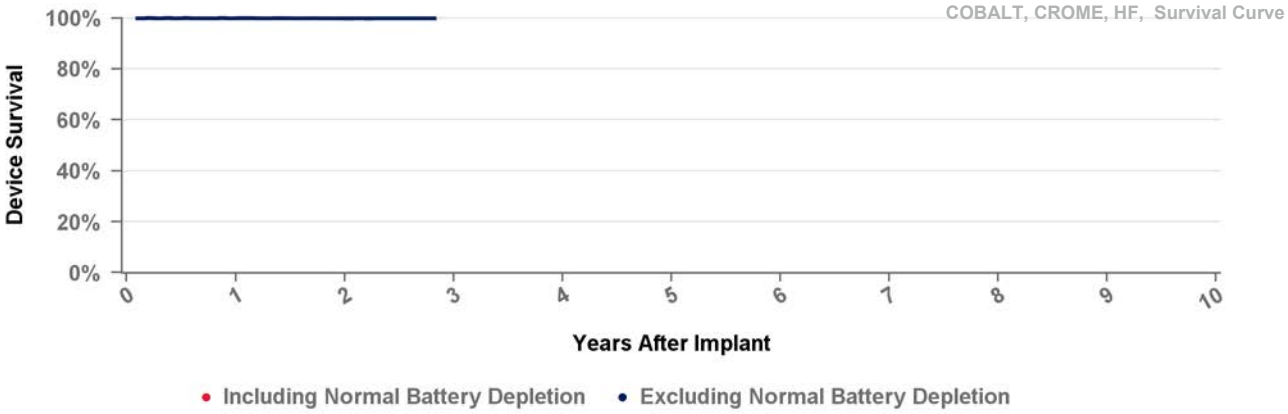
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,441	Other	1
Estimated Active USA Implants	2,338	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPA2D4 Cobalt XT HF

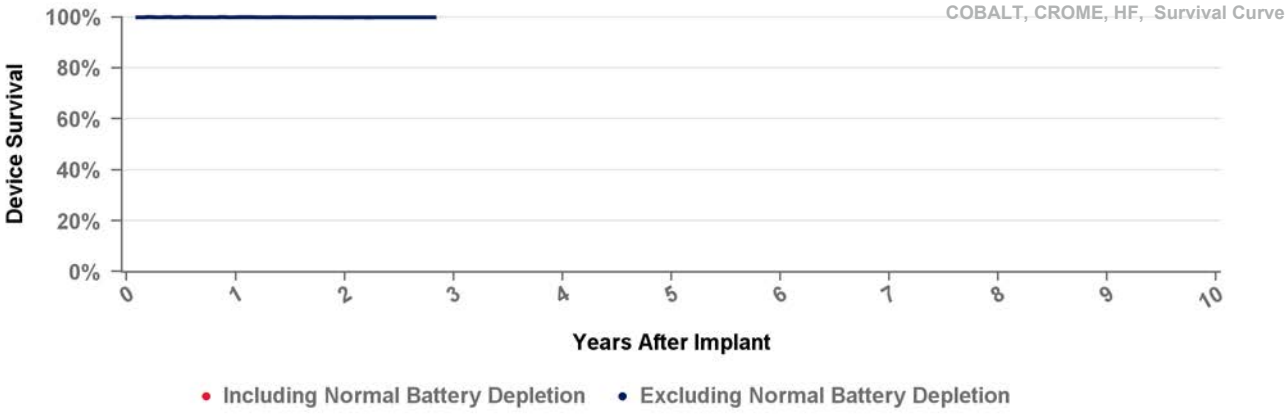
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,535	Electrical Interconnect	1
Estimated Active USA Implants	2,429	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPA2Q1 Cobalt XT HF Quad

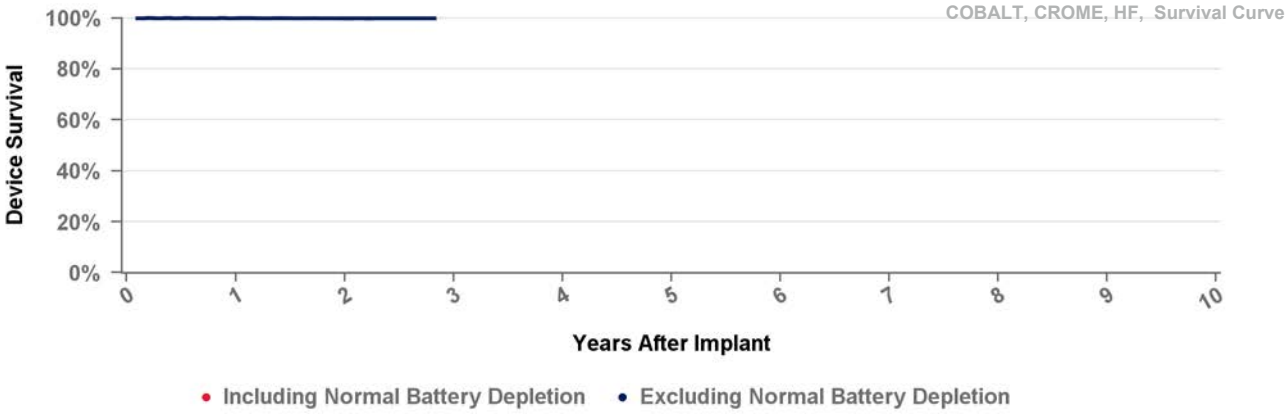
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,715	Software/Firmware	1
Estimated Active USA Implants	1,633	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPA2QQ Cobalt XT HF Quad

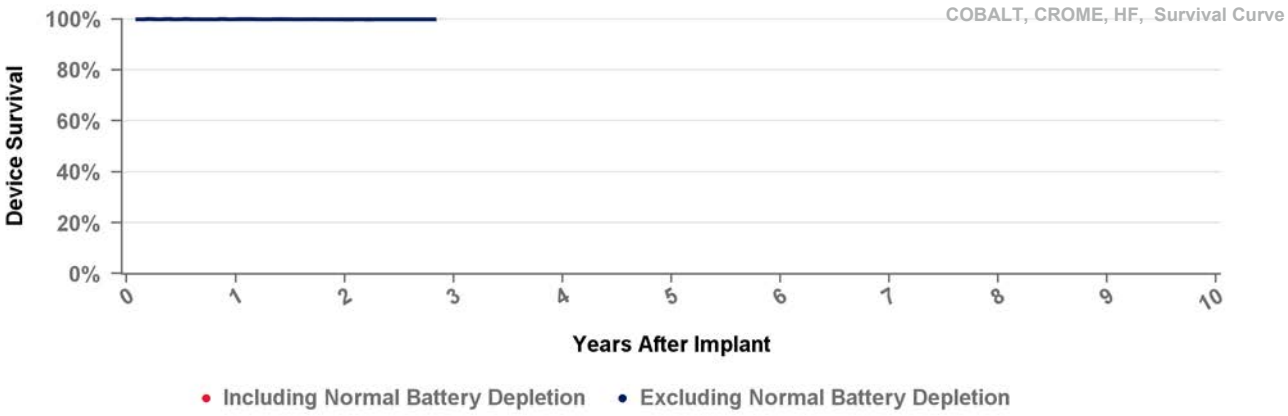
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**3**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**2**
Registered USA Implants	15,522	Electrical Component	1
Estimated Active USA Implants	15,094	Software/Firmware	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPB2D1 Cobalt HF

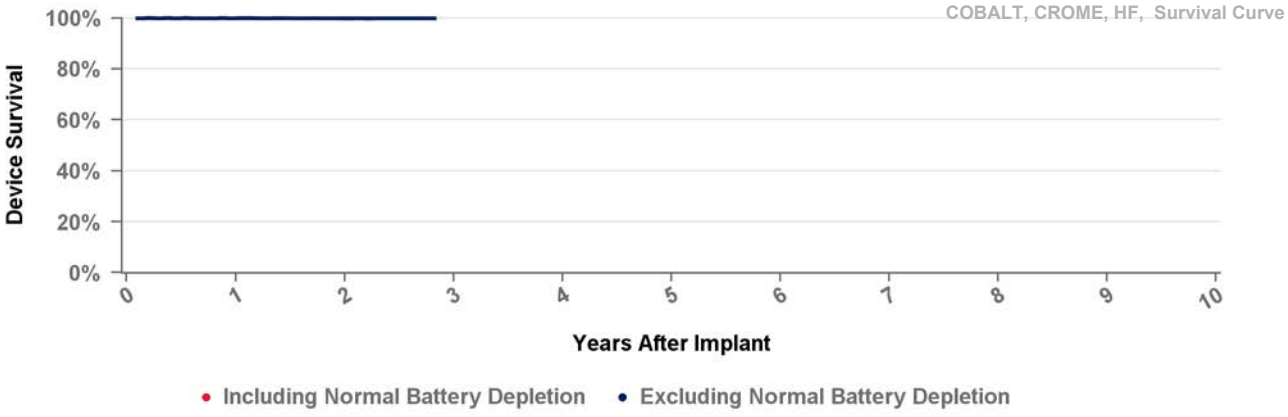
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**3**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,680	Electrical Component	1
Estimated Active USA Implants	2,504	**Therapy Function Compromised**	**2**
Normal Battery Depletions	1	Electrical Component	1
		Electrical Interconnect	1



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPB2D4 Cobalt HF

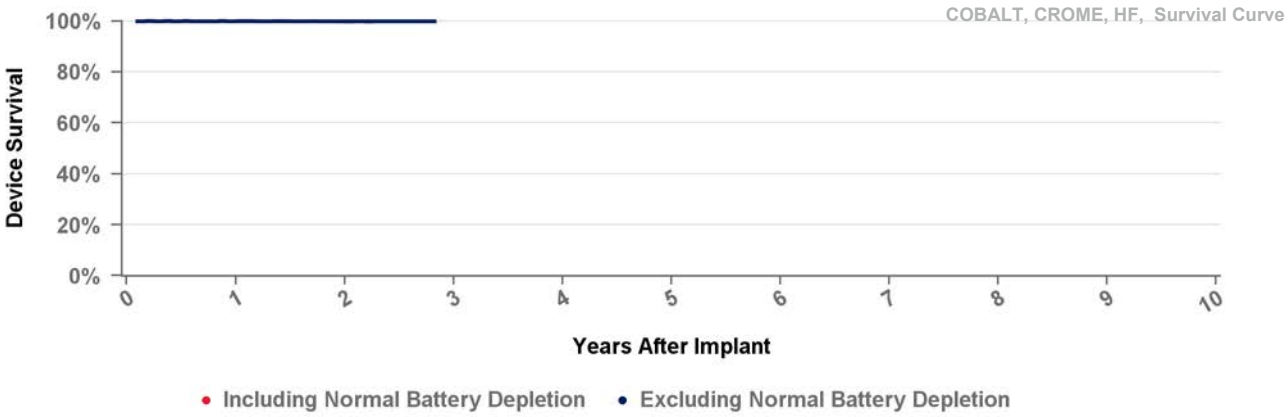
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**5**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**4**
Registered USA Implants	2,631	Electrical Interconnect	3
Estimated Active USA Implants	2,475	Software/Firmware	1
Normal Battery Depletions	1	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPB2Q1 Cobalt HF Quad

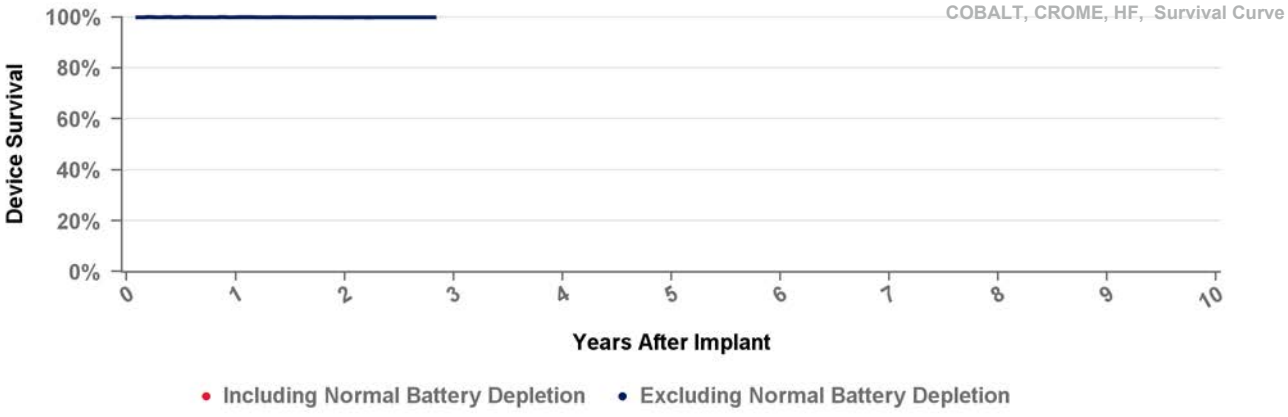
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	1,783		
Estimated Active USA Implants	1,666	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPB2QQ Cobalt HF Quad

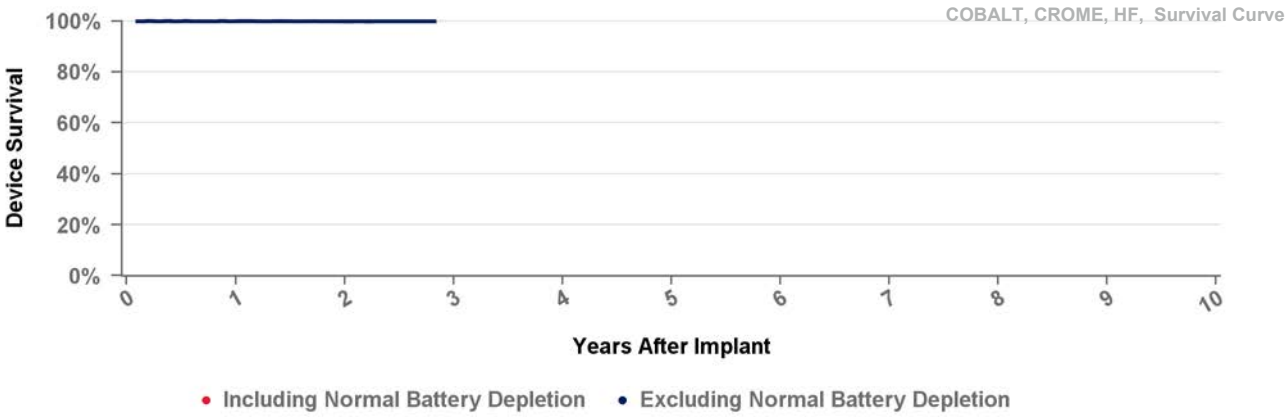
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**8**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**3**
Registered USA Implants	14,218	Electrical Component	1
Estimated Active USA Implants	13,572	Electrical Interconnect	1
Normal Battery Depletions	4	Other	1
		Therapy Function Compromised	**5**
		Electrical Component	2
		Electrical Interconnect	3



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPC2D1 Crome HF

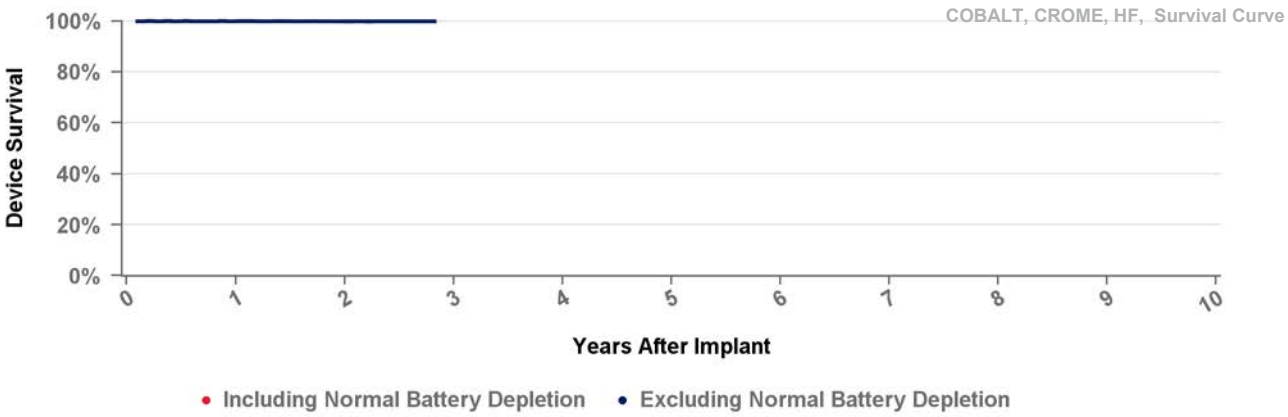
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	206		
Estimated Active USA Implants	188	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPC2D4 Crome HF

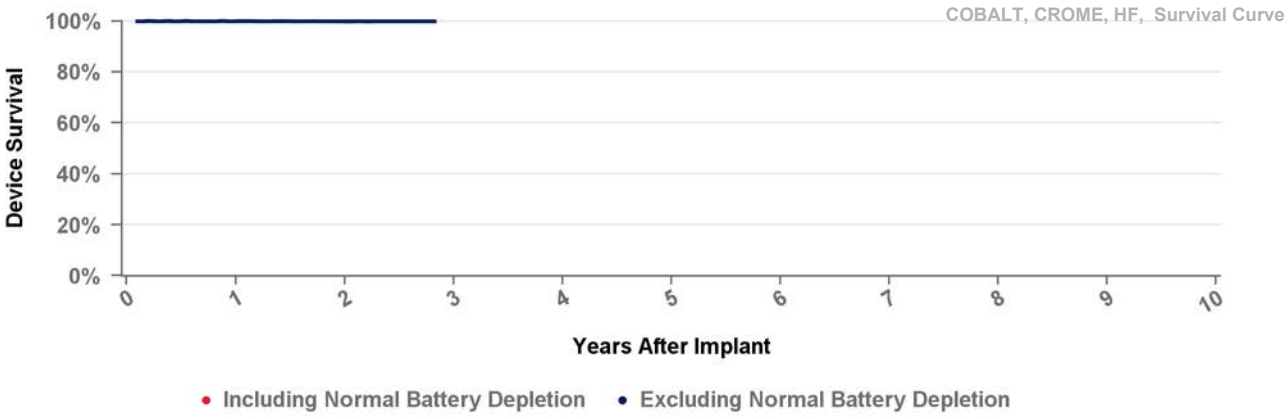
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	186		
Estimated Active USA Implants	173	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPC2Q1 Crome HF Quad

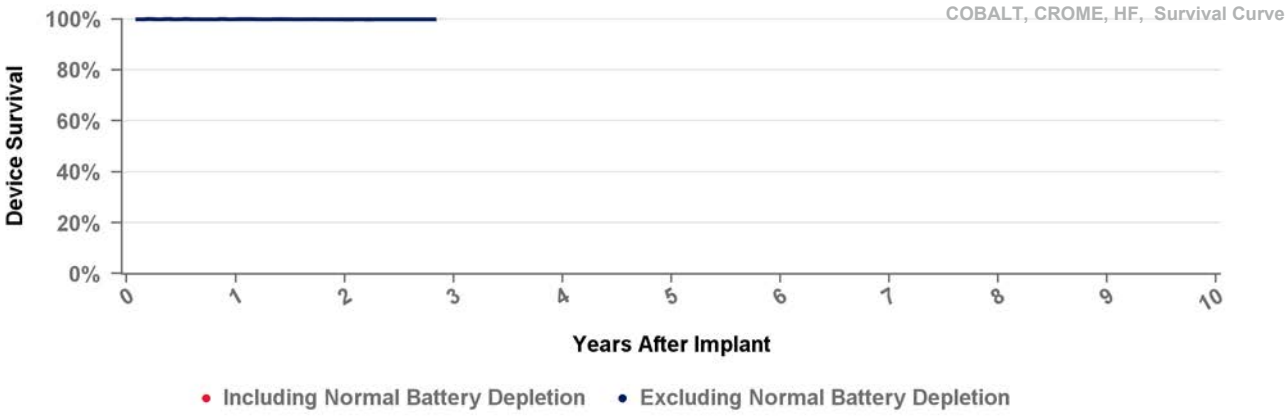
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	96		
Estimated Active USA Implants	92	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

DTPC2QQ Crome HF Quad

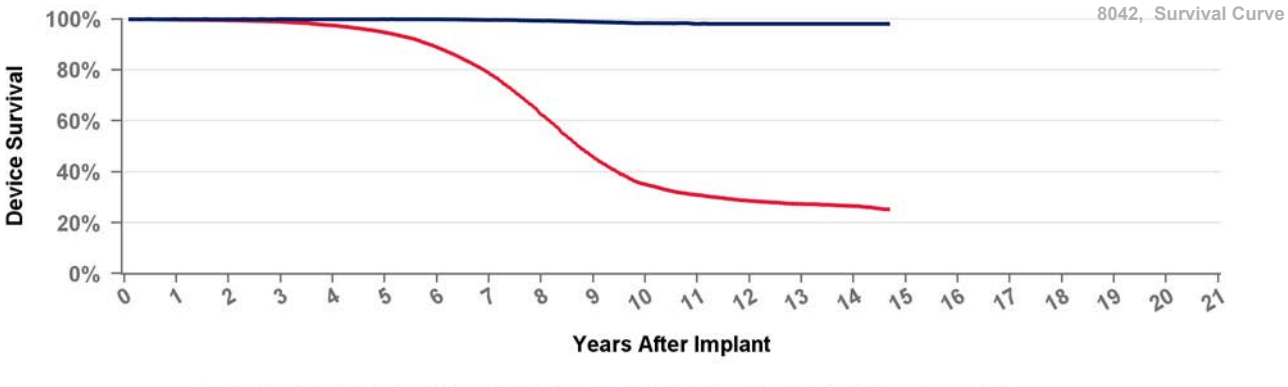
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	903		
Estimated Active USA Implants	863	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	25114	8576	212

8042 InSync III

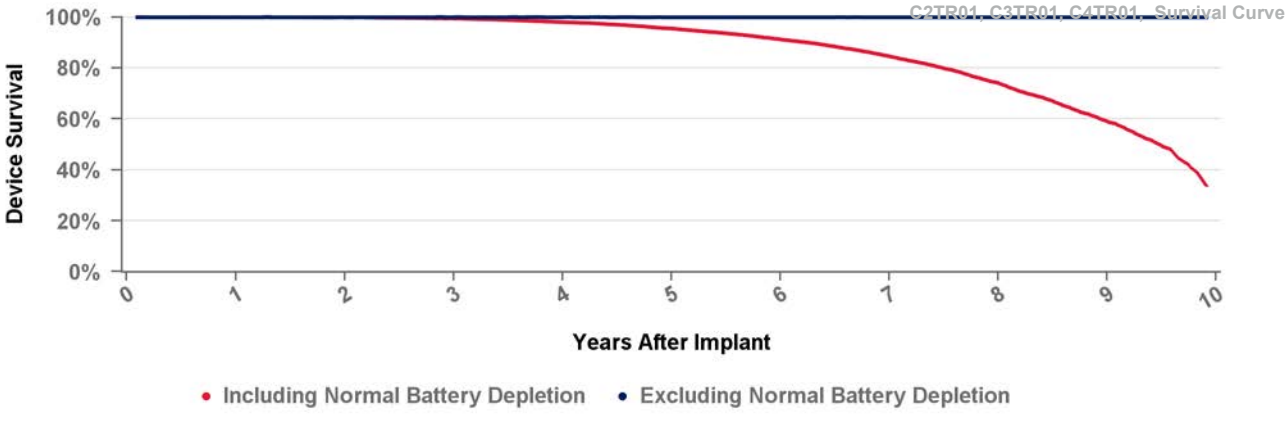
US Market Release	25Feb2003	**Total Malfunctions (USA)**	**116**
CE Approval Date	07Feb2001	**Therapy Function Not Compromised**	**67**
Registered USA Implants	39,276	Battery	55
Estimated Active USA Implants	1,876	Electrical Component	2
Normal Battery Depletions	5,246	Electrical Interconnect	3
		Possible Early Battery Depletion	2
		Other	5
		Therapy Function Compromised	**49**
		Battery	37
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.7%	99.3%	98.9%	98.5%	98.2%	98.2%	98.2%	98.2%	98.2%
Including NBD	99.8%	99.5%	99.0%	97.5%	94.7%	88.9%	78.6%	62.6%	45.7%	35.1%	30.9%	28.6%	27.4%	26.6%	25.2%
Effective Sample Size	30382	26389	22924	19730	16593	12737	9039	5905	3405	2138	1609	1271	836	346	113

C2TR01 Syncra CRT-P

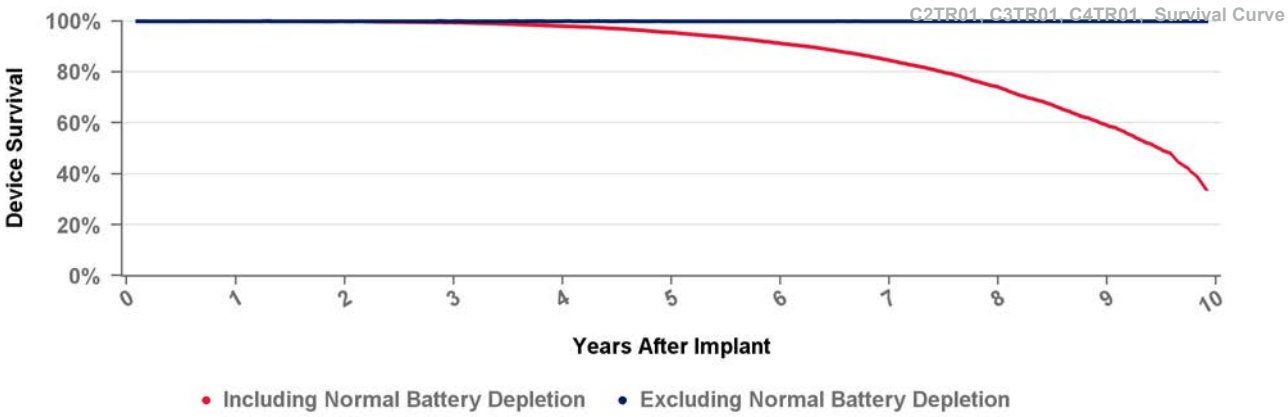
US Market Release	22Mar2011	**Total Malfunctions (USA)**	**7**
CE Approval Date	11May2010	**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,235	Possible Early Battery Depletion	5
Estimated Active USA Implants	2,438	Other	1
Normal Battery Depletions	894	**Therapy Function Compromised**	**1**
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	98.0%	95.5%	91.2%	84.6%	74.1%	59.0%	33.8%
Effective Sample Size	26180	23386	20948	18300	15659	12955	9647	5844	2450	175

C3TR01 Consulta CRT-P

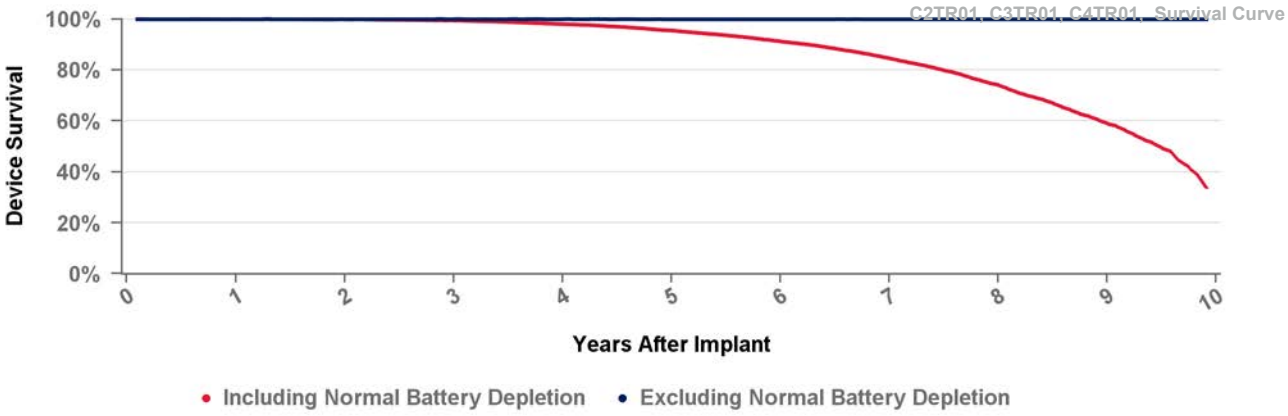
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	11May2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	98.0%	95.5%	91.2%	84.6%	74.1%	59.0%	33.8%
Effective Sample Size	26180	23386	20948	18300	15659	12955	9647	5844	2450	175

C4TR01 Consulta CRT-P

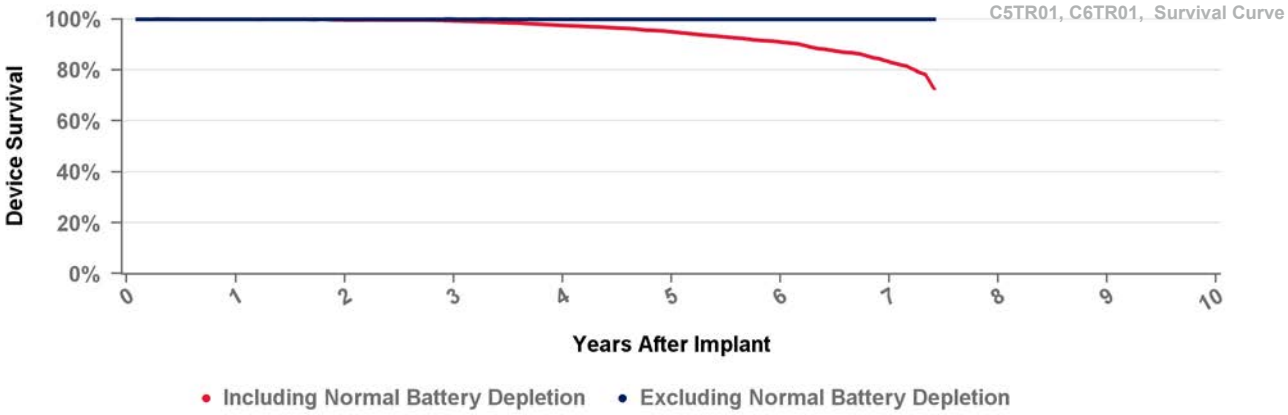
US Market Release	22Mar2011	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	23,406	Possible Early Battery Depletion	5
Estimated Active USA Implants	6,534	**Therapy Function Compromised**	**3**
Normal Battery Depletions	1,900	Electrical Component	2
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	98.0%	95.5%	91.2%	84.6%	74.1%	59.0%	33.8%
Effective Sample Size	26180	23386	20948	18300	15659	12955	9647	5844	2450	175

C5TR01 Viva CRT-P

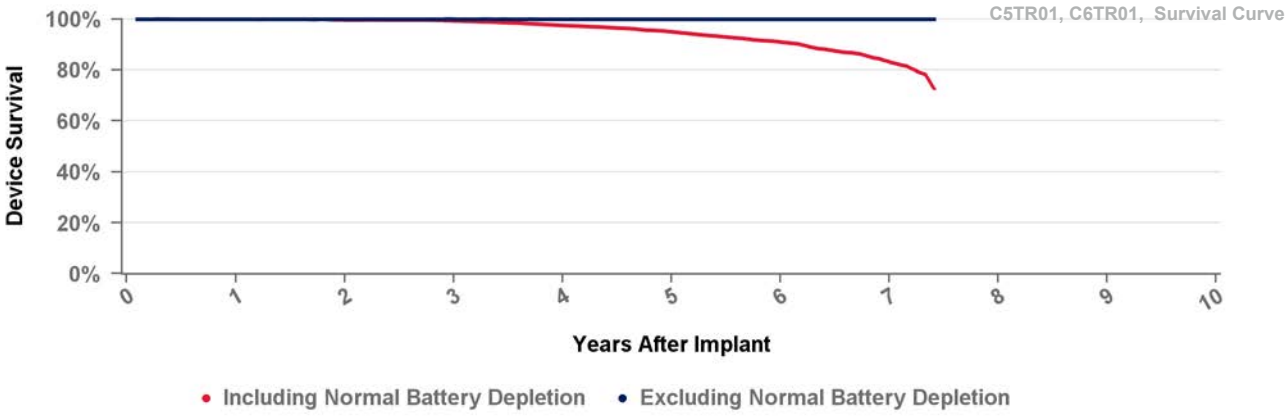
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	04Apr2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.3%	97.5%	95.0%	91.0%	83.1%	72.6%
Effective Sample Size	7368	6607	5921	5148	4403	3288	1092	260

C6TR01 Viva CRT-P

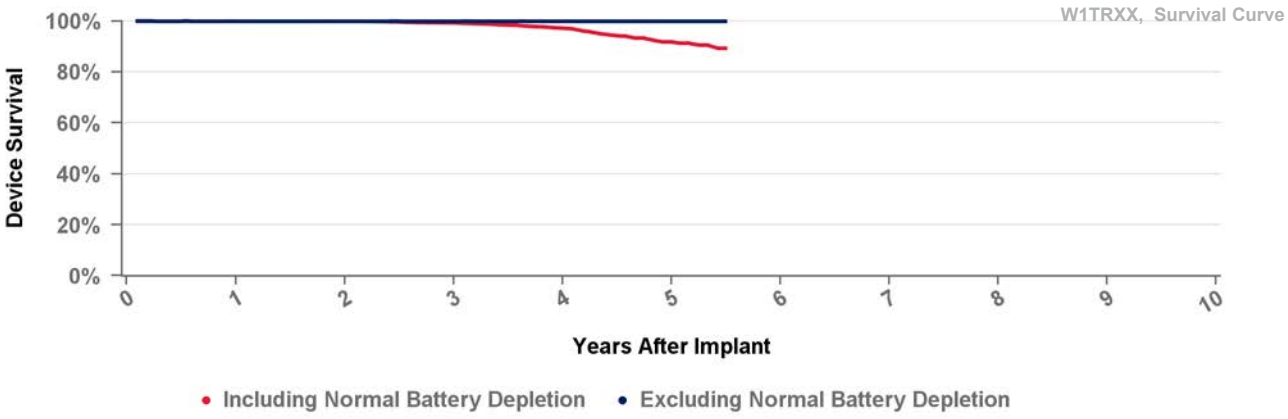
US Market Release	09Jul2014	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	9,197	Possible Early Battery Depletion	5
Estimated Active USA Implants	4,455	**Therapy Function Compromised**	**0**
Normal Battery Depletions	384		



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.3%	97.5%	95.0%	91.0%	83.1%	72.6%
Effective Sample Size	7368	6607	5921	5148	4403	3288	1092	260

W1TR01 Percepta CRTP MRI

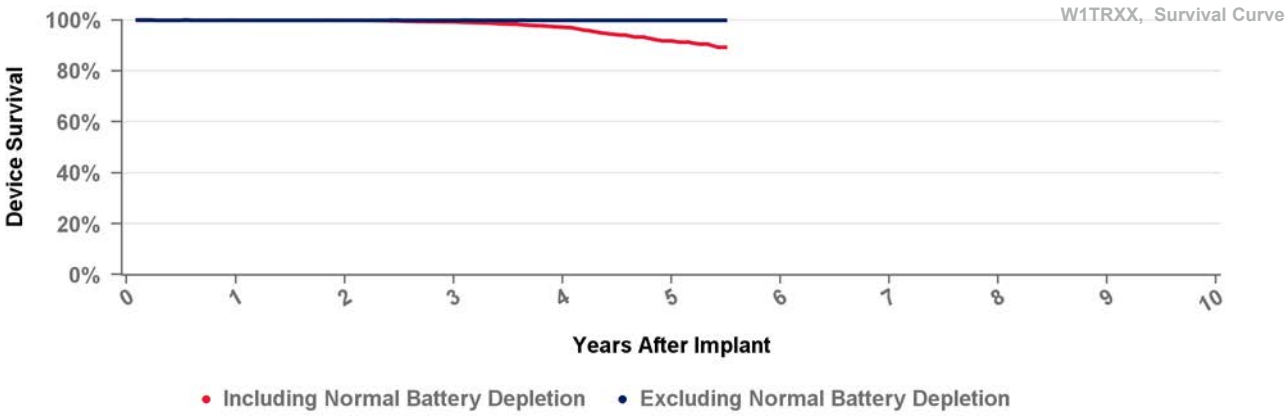
US Market Release	06May2017	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	13,150	Electrical Component	1
Estimated Active USA Implants	11,221	Possible Early Battery Depletion	1
Normal Battery Depletions	72	Other	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W1TR02 Serena CRTP MRI

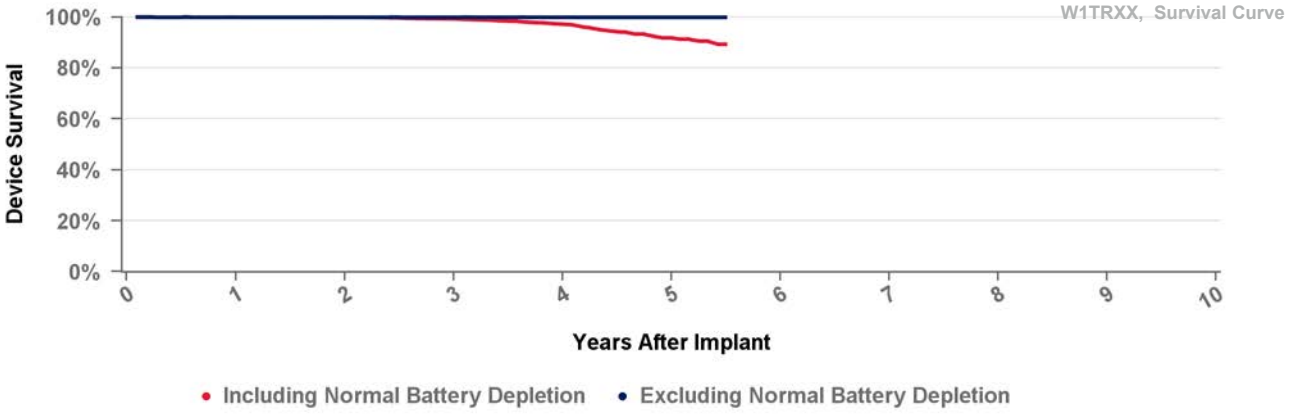
US Market Release	06May2017	**Total Malfunctions (USA)**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,541	Electrical Component	1
Estimated Active USA Implants	2,094	Other	1
Normal Battery Depletions	17	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W1TR03 Solara CRTP MRI

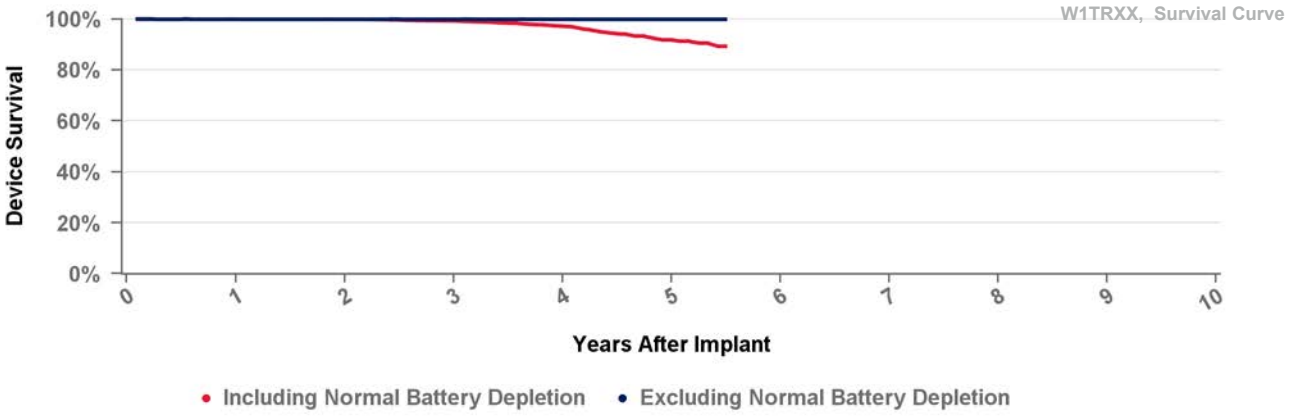
US Market Release	06May2017	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,437	Electrical Component	1
Estimated Active USA Implants	2,708	**Therapy Function Compromised**	**0**
Normal Battery Depletions	36		



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W1TR04 Percepta CRTP MRI

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	10Feb2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

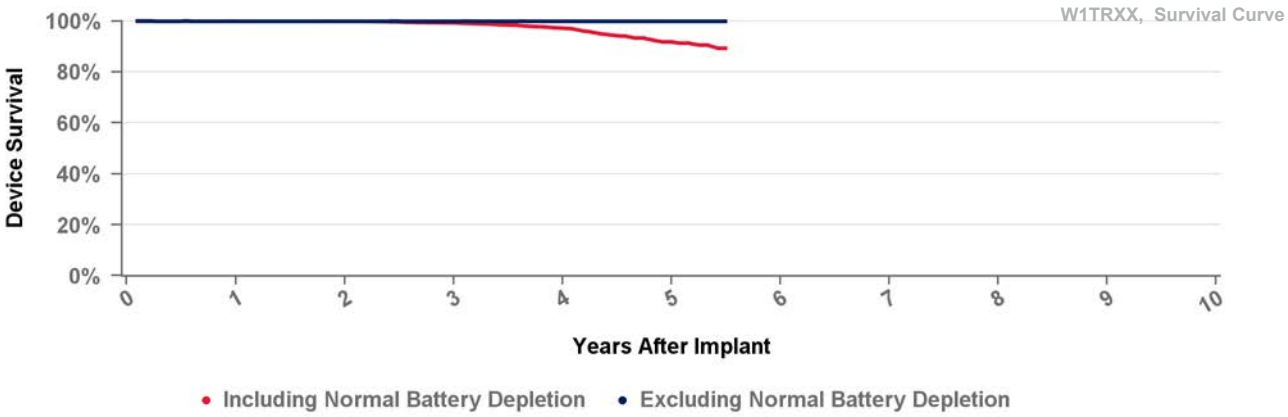


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W1TR05 Serena CRTP MRI

US Market Release
CE Approval Date 10Feb2017
Registered USA Implants 1
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

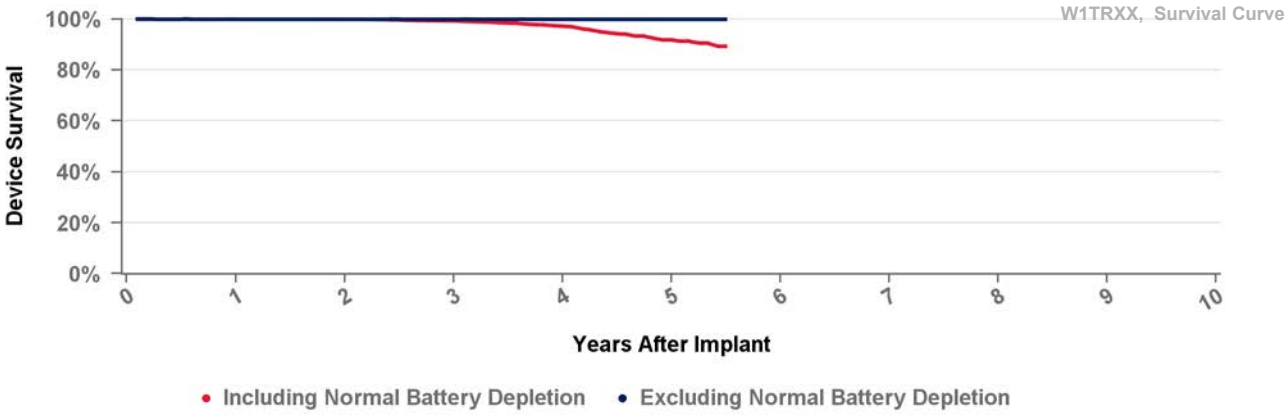


Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W1TR06 Solara CRTP MRI

US Market Release
CE Approval Date 10Feb2017
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

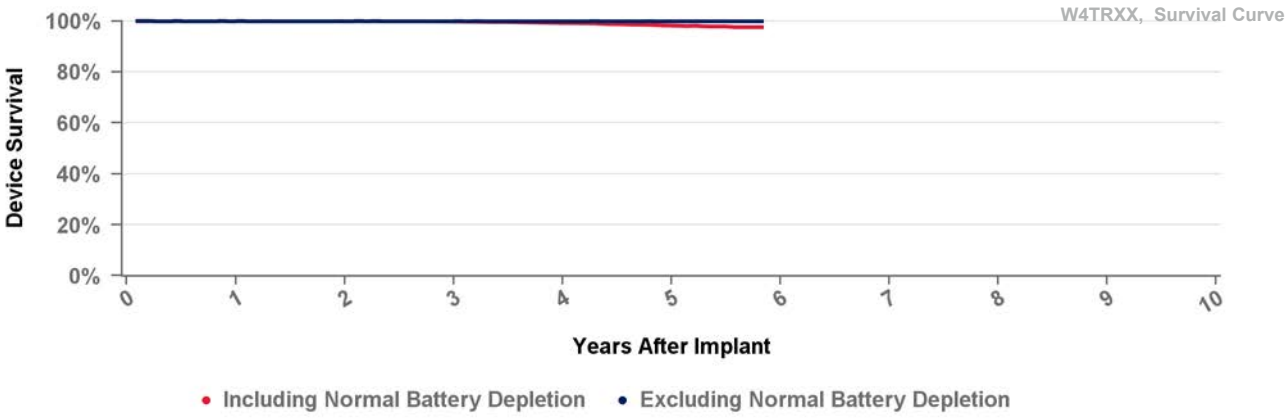
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.3%	97.2%	91.8%	89.3%
Effective Sample Size	13569	9536	6001	3103	800	159

W4TR01 Percepta Quad CRTP MRI SureScan

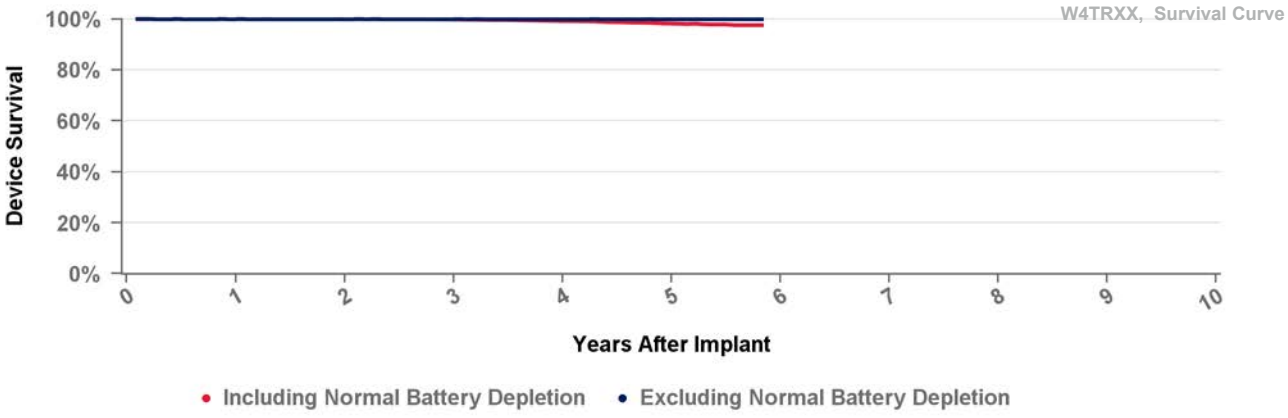
US Market Release	06May2017	**Total Malfunctions (USA)**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	47,669	Electrical Component	7
Estimated Active USA Implants	40,917	Possible Early Battery Depletion	1
Normal Battery Depletions	80	Other	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

W4TR02 Serena Quad CRTP MRI SureScan

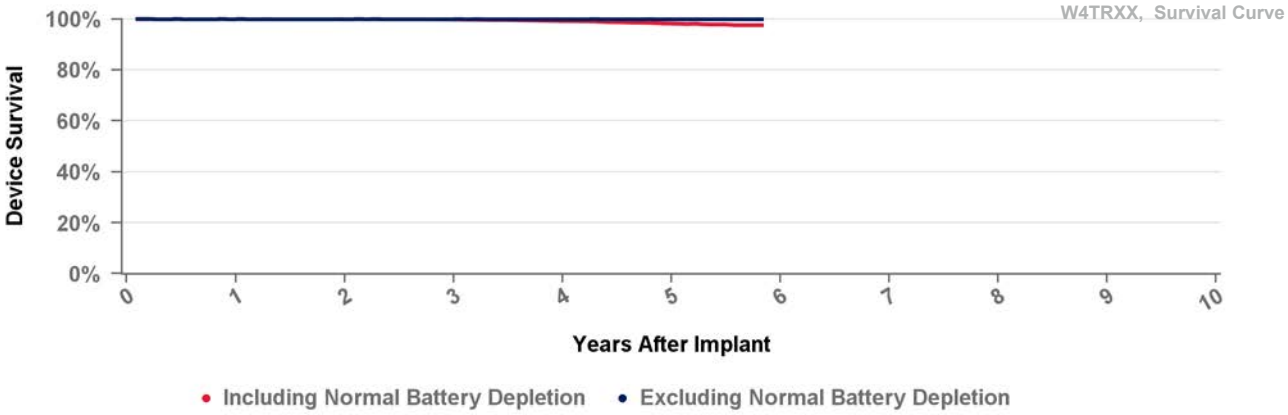
US Market Release	06May2017	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	7,240	Electrical Component	1
Estimated Active USA Implants	6,021	**Therapy Function Compromised**	**0**
Normal Battery Depletions	13		



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

W4TR03 Solara Quad CRTP MRI SureScan

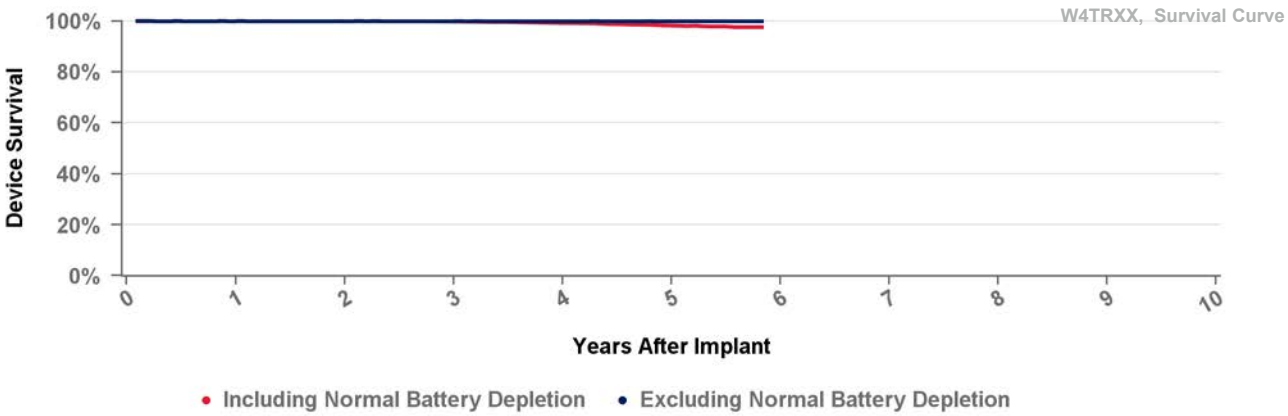
US Market Release	06May2017	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	9,420		
Estimated Active USA Implants	7,563	**Therapy Function Compromised**	**3**
Normal Battery Depletions	23	Electrical Component	2
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

W4TR04 Percepta Quad CRT-P MRI SureScan

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	10Feb2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			

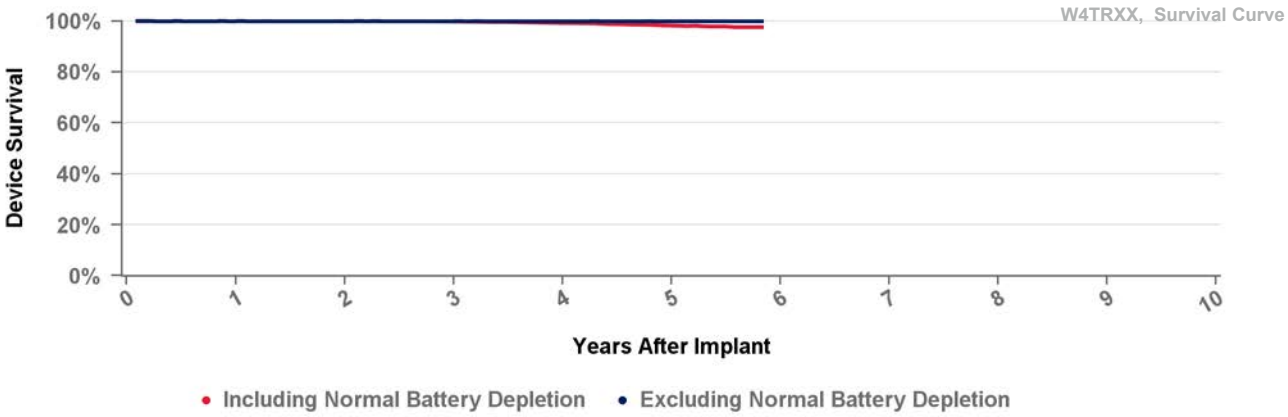


Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

W4TR05 Serena Quad CRTP MRI SureScan

US Market Release
CE Approval Date 10Feb2017
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

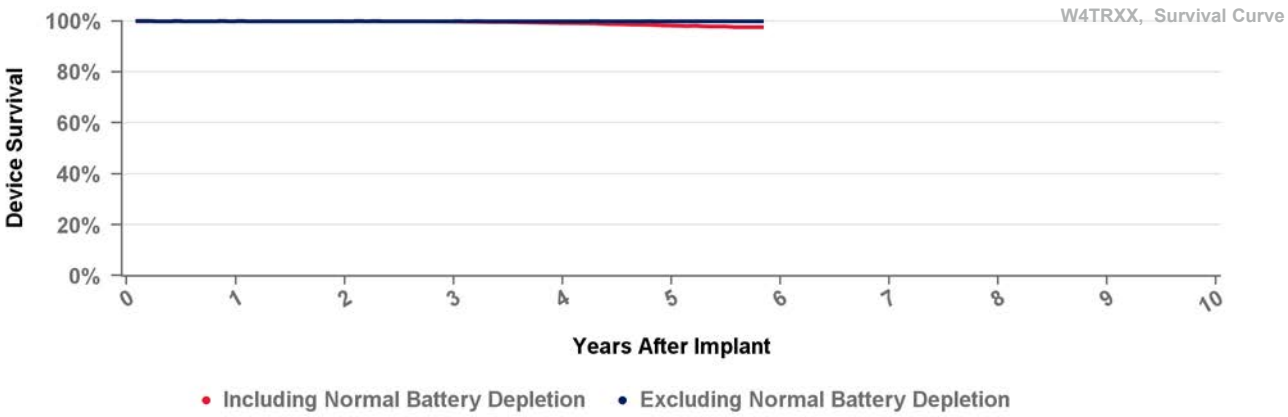


Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

W4TR06 Solara Quad CRTP MRI SureScan

US Market Release
CE Approval Date 10Feb2017
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

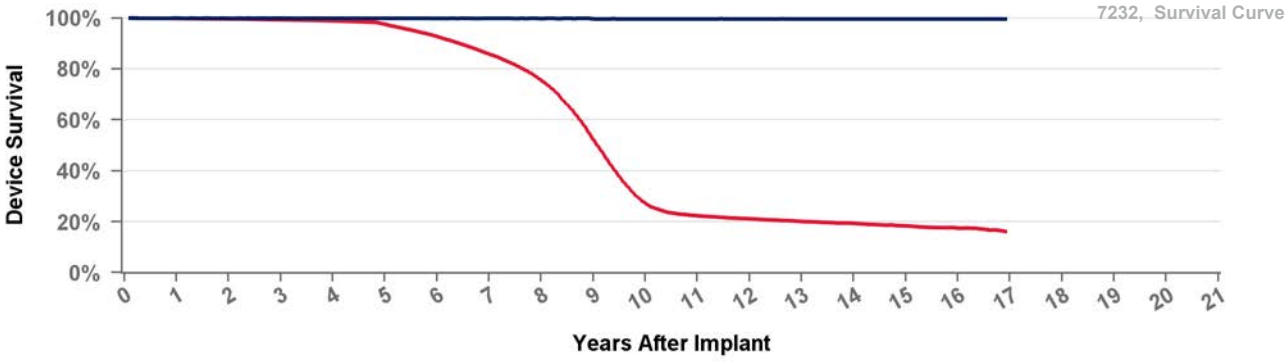
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.2%	97.6%
Effective Sample Size	46004	32455	20708	11803	4412	200

7232Cx Maximo VR

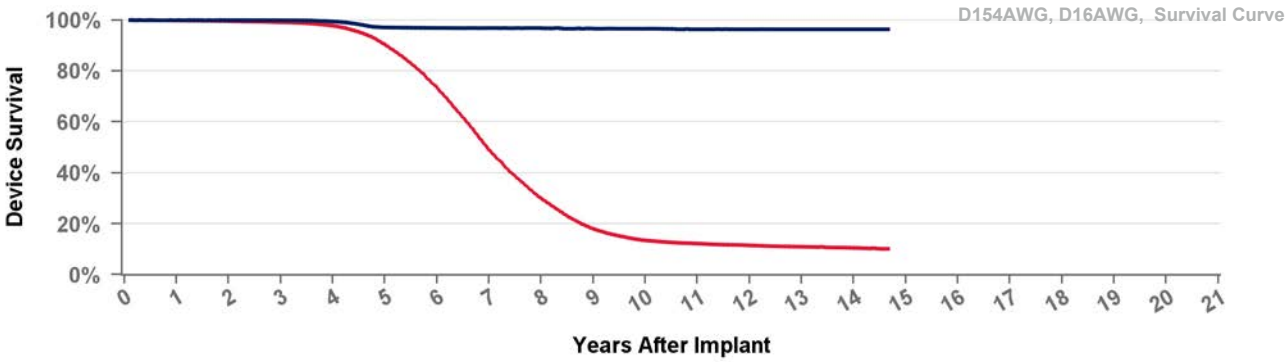
US Market Release	06Oct2003	**Total Malfunctions (USA)**	**73**
CE Approval Date	28Oct2003	**Therapy Function Not Compromised**	**58**
Registered USA Implants	43,623	Electrical Component	29
Estimated Active USA Implants	2,763	Possible Early Battery Depletion	25
Normal Battery Depletions	10,385	Software/Firmware	2
		Other	2
		Therapy Function Compromised	**15**
		Electrical Component	12
		Electrical Interconnect	1
		Possible Early Battery Depletion	1
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 203 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.3%	98.9%	97.6%	92.7%	85.8%	75.5%	52.4%	27.2%	22.4%	21.2%	20.1%	19.4%	18.4%	17.6%	16.2%
Effective Sample Size	38515	35191	31911	28427	24997	21608	18235	14649	9032	3699	2508	2010	1570	1224	907	582	136

D164AWG Virtuoso DR

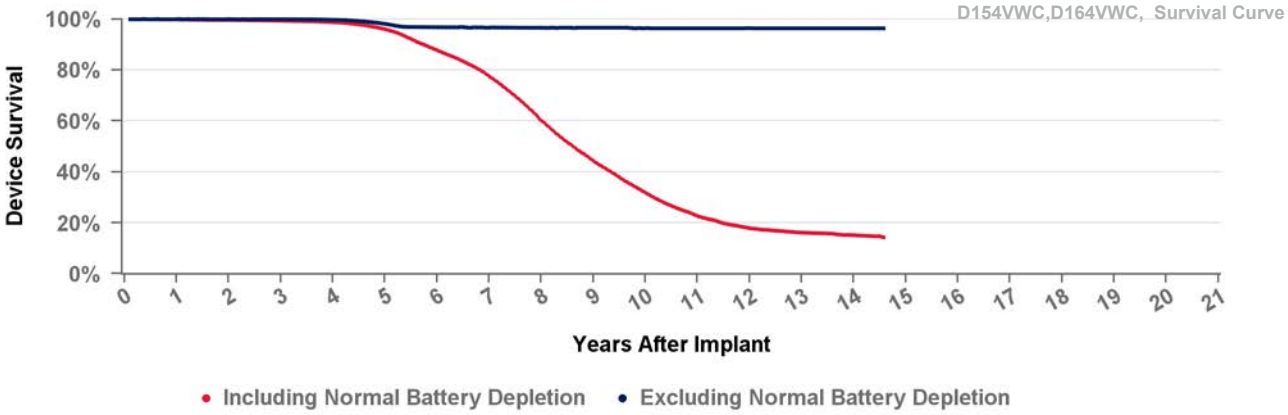
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07Mar2006	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 176 mo
Excluding NBD	100.0%	100.0%	99.9%	99.4%	97.1%	96.9%	96.8%	96.8%	96.7%	96.6%	96.5%	96.4%	96.4%	96.4%	96.4%
Including NBD	99.8%	99.6%	99.1%	97.8%	90.3%	73.4%	49.1%	29.9%	18.0%	13.5%	12.2%	11.5%	11.0%	10.5%	10.1%
Effective Sample Size	63549	58489	53187	47918	40411	29765	17354	8889	4459	2822	2329	1987	1675	1039	213

D164VWC Virtuoso VR

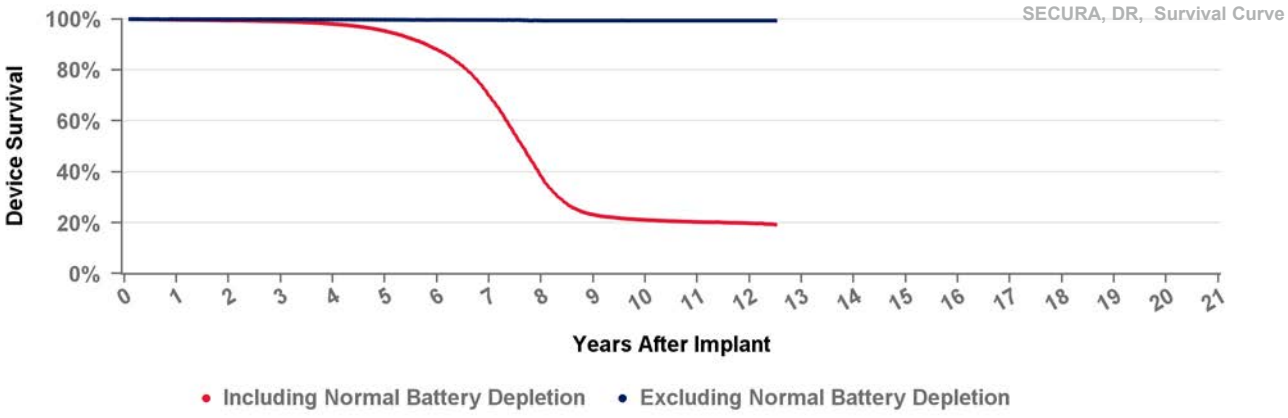
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07Mar2006	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 175 mo
Excluding NBD	100.0%	100.0%	99.9%	99.7%	98.1%	96.8%	96.7%	96.6%	96.5%	96.5%	96.4%	96.4%	96.4%	96.4%	96.4%
Including NBD	99.8%	99.6%	99.3%	98.8%	96.0%	87.7%	77.4%	60.3%	44.3%	31.8%	22.6%	17.9%	16.1%	15.1%	14.2%
Effective Sample Size	28533	26122	23727	21527	19157	16192	13280	9318	6090	3936	2463	1591	1144	623	179

D204DRM Secura DR

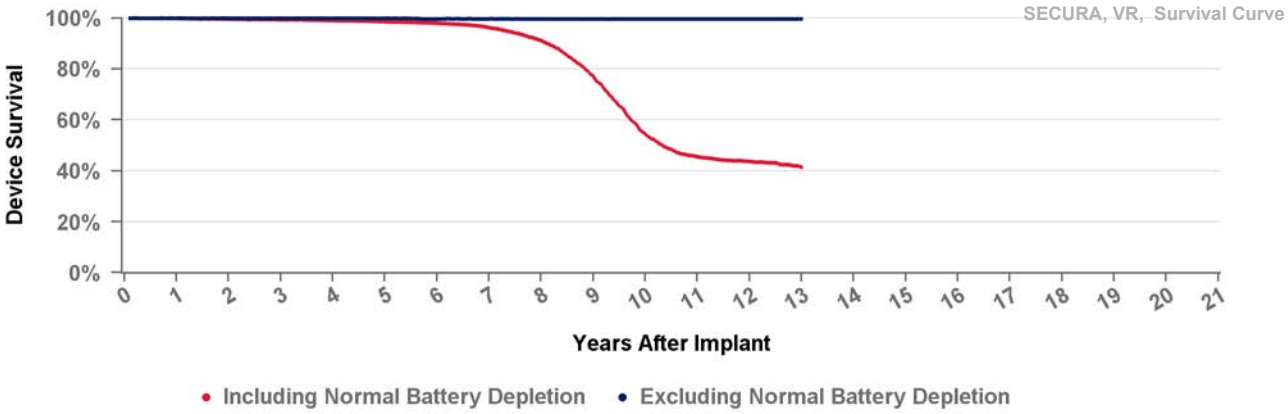
US Market Release	09Jan2012	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,850	Other	1
Estimated Active USA Implants	316	**Therapy Function Compromised**	**4**
Normal Battery Depletions	320	Battery	2
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.0%	95.3%	87.9%	70.0%	38.3%	23.2%	21.1%	20.3%	19.8%	19.3%
Effective Sample Size	44539	41184	38104	34984	31060	25090	16328	6713	3241	2529	1874	1042	104

D204VRM Secura VR

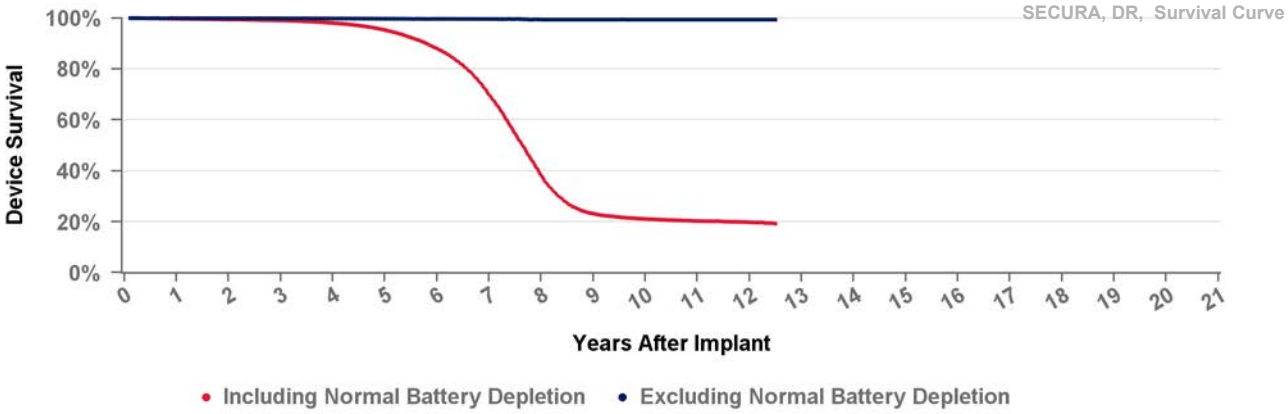
US Market Release	02May2012	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,152	Electrical Component	1
Estimated Active USA Implants	313	**Therapy Function Compromised**	**2**
Normal Battery Depletions	80	Battery	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.3%	45.5%	43.7%	41.4%
Effective Sample Size	17638	16330	15177	14072	12960	11844	10615	8585	5542	2672	1623	1017	131

D214DRM Secura DR

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	22Jul2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.0%	95.3%	87.9%	70.0%	38.3%	23.2%	21.1%	20.3%	19.8%	19.3%
Effective Sample Size	44539	41184	38104	34984	31060	25090	16328	6713	3241	2529	1874	1042	104

D214VRM Secura VR

US Market Release

CE Approval Date 17Dec2010

Registered USA Implants

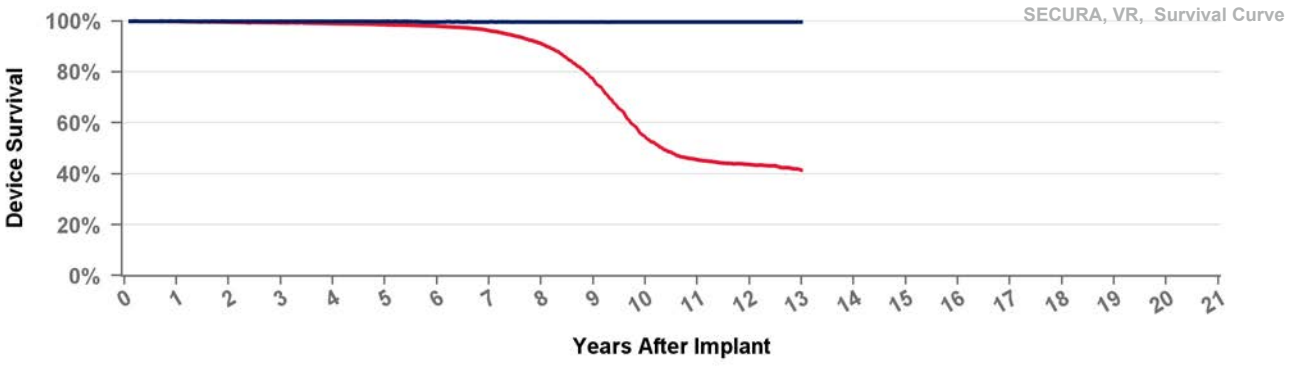
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

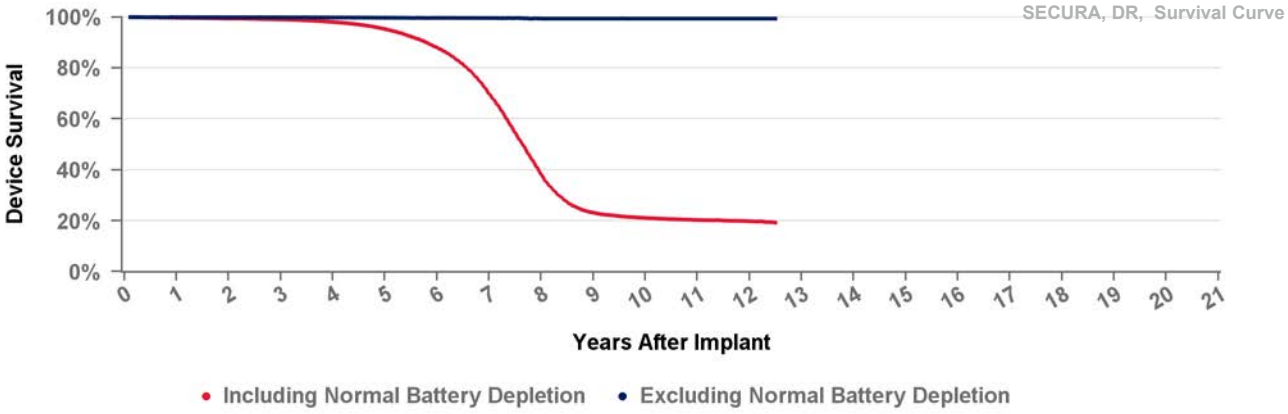
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.3%	45.5%	43.7%	41.4%
Effective Sample Size	17638	16330	15177	14072	12960	11844	10615	8585	5542	2672	1623	1017	131

D224DRG Secura DR

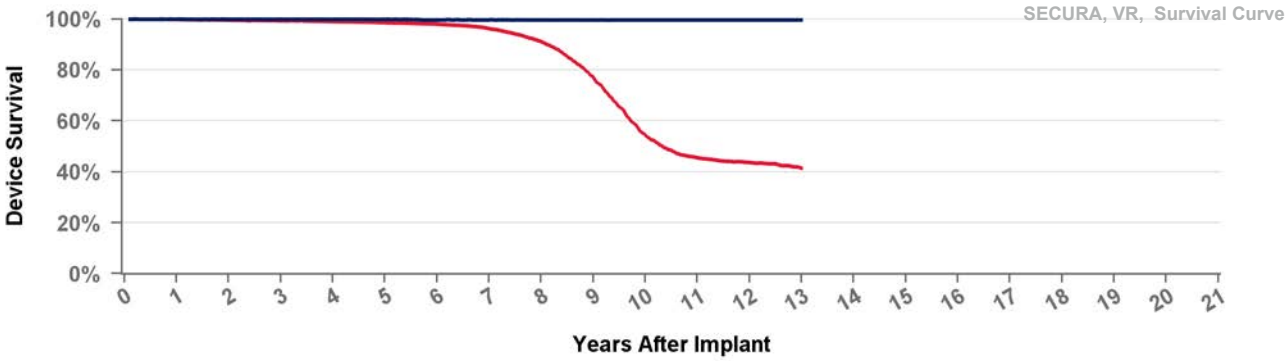
US Market Release	15Sep2008	**Total Malfunctions (USA)**	**152**
CE Approval Date		**Therapy Function Not Compromised**	**115**
Registered USA Implants	49,639	Battery	14
Estimated Active USA Implants	5,403	Electrical Component	38
Normal Battery Depletions	10,310	Possible Early Battery Depletion	50
		Software/Firmware	9
		Other	4
		Therapy Function Compromised	**37**
		Battery	21
		Electrical Component	13
		Possible Early Battery Depletion	1
		Software/Firmware	1
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.0%	95.3%	87.9%	70.0%	38.3%	23.2%	21.1%	20.3%	19.8%	19.3%
Effective Sample Size	44539	41184	38104	34984	31060	25090	16328	6713	3241	2529	1874	1042	104

D224VRC Secura VR

US Market Release	15Sep2008	**Total Malfunctions (USA)**	**52**
CE Approval Date		**Therapy Function Not Compromised**	**35**
Registered USA Implants	19,672	Battery	14
Estimated Active USA Implants	2,992	Electrical Component	10
Normal Battery Depletions	2,141	Possible Early Battery Depletion	8
		Software/Firmware	2
		Other	1
		Therapy Function Compromised	**17**
		Battery	9
		Electrical Component	6
		Possible Early Battery Depletion	1
		Software/Firmware	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.3%	45.5%	43.7%	41.4%
Effective Sample Size	17638	16330	15177	14072	12960	11844	10615	8585	5542	2672	1623	1017	131

D234DRG Secura DR

US Market Release

CE Approval Date 14Mar2008

Registered USA Implants 2

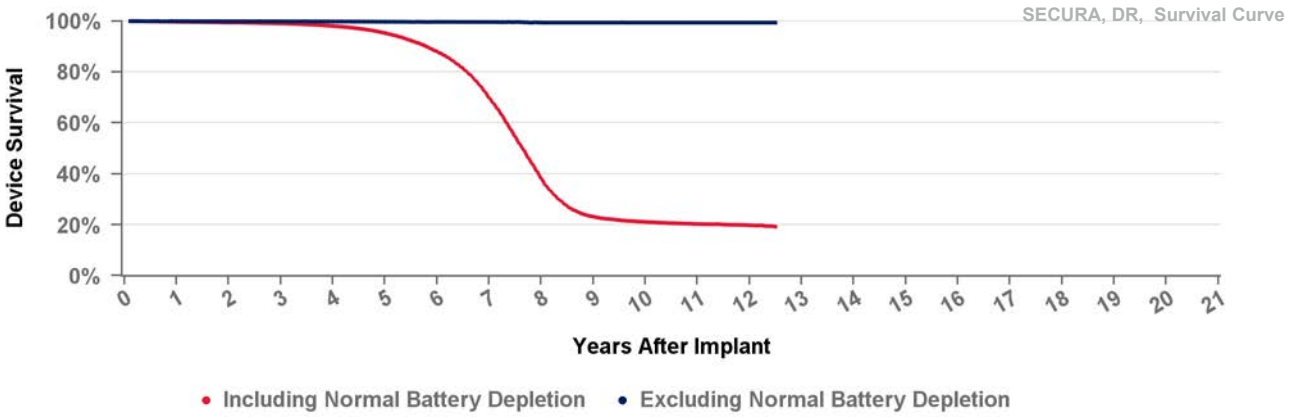
Estimated Active USA Implants 1

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.0%	95.3%	87.9%	70.0%	38.3%	23.2%	21.1%	20.3%	19.8%	19.3%
Effective Sample Size	44539	41184	38104	34984	31060	25090	16328	6713	3241	2529	1874	1042	104

D234VRC Secura VR

US Market Release

CE Approval Date 14Mar2008

Registered USA Implants

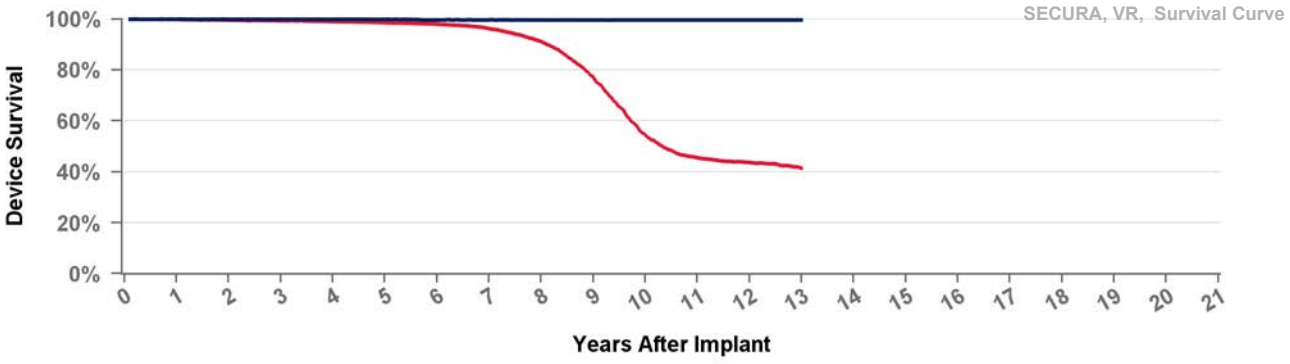
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

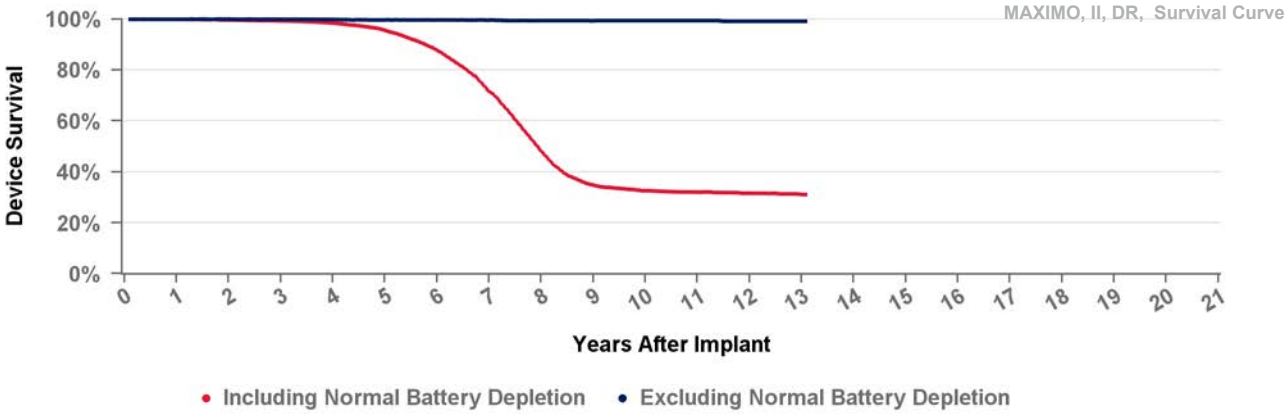
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.3%	45.5%	43.7%	41.4%
Effective Sample Size	17638	16330	15177	14072	12960	11844	10615	8585	5542	2672	1623	1017	131

D264DRM Maximo II DR

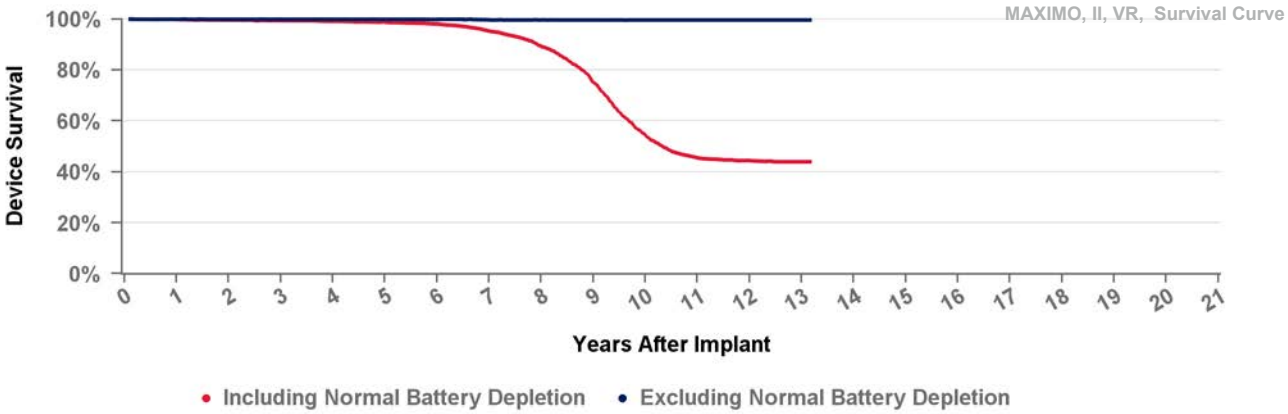
US Market Release	09Jan2012	**Total Malfunctions (USA)**	
CE Approval Date	22Jul2010	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 157 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.5%	99.3%	99.3%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.9%	99.6%	99.3%	98.4%	95.6%	87.6%	71.6%	48.3%	34.8%	32.7%	32.1%	31.6%	31.2%	31.2%
Effective Sample Size	17235	15933	14782	13615	12095	9579	5985	2802	1717	1417	1126	718	190	138

D264VRM Maximo II VR

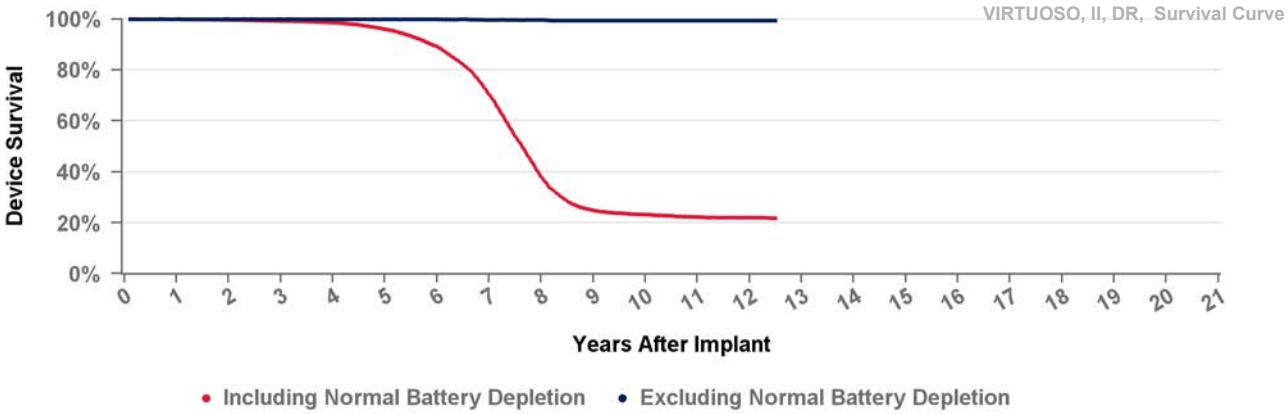
US Market Release	02May2012	**Total Malfunctions (USA)**	
CE Approval Date	17Dec2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.3%	89.2%	75.3%	54.4%	45.5%	44.4%	44.0%	44.0%
Effective Sample Size	10873	10125	9423	8722	8030	7335	6489	5253	3402	1741	1090	692	220	126

D274DRG Virtuoso II DR

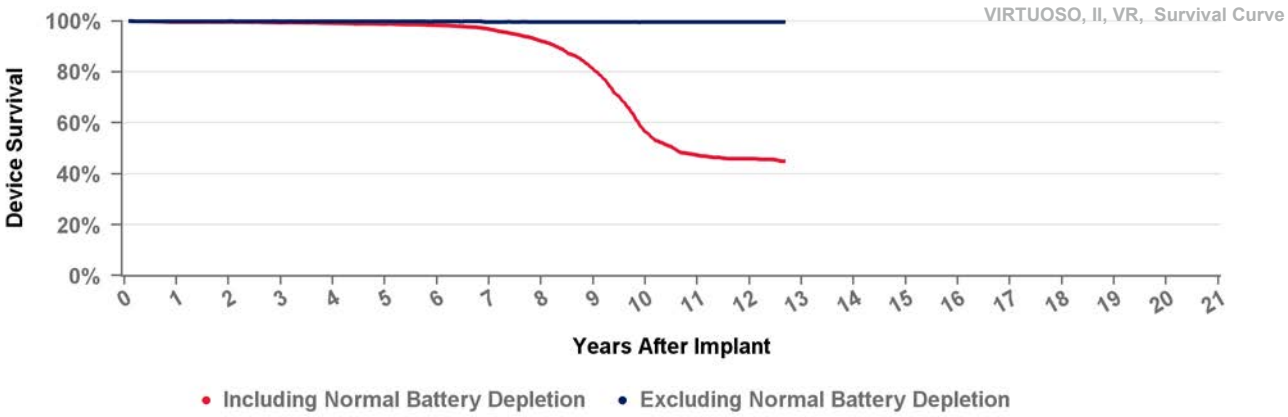
US Market Release	15Aug2009	**Total Malfunctions (USA)**	**47**
CE Approval Date		**Therapy Function Not Compromised**	**29**
Registered USA Implants	22,251	Battery	10
Estimated Active USA Implants	2,572	Electrical Component	11
Normal Battery Depletions	4,317	Possible Early Battery Depletion	7
		Software/Firmware	1
		Therapy Function Compromised	**18**
		Battery	15
		Electrical Component	2
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.9%	99.7%	99.2%	98.6%	96.0%	89.2%	70.5%	38.2%	24.9%	23.2%	22.3%	22.0%	21.8%
Effective Sample Size	19001	17630	16325	14965	13155	10488	6729	2927	1538	1305	1150	673	148

D274VRC Virtuoso II VR

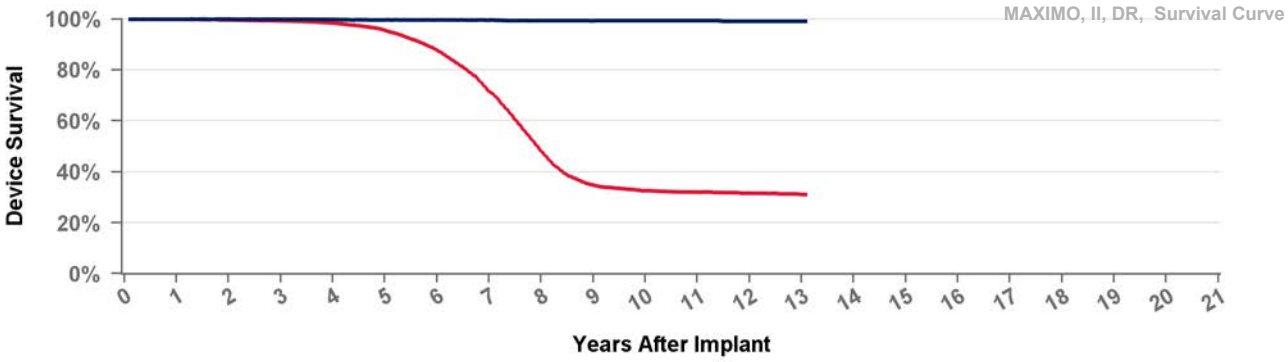
US Market Release	15Aug2009	**Total Malfunctions (USA)**	**21**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	9,131	Battery	6
Estimated Active USA Implants	1,363	Electrical Component	4
Normal Battery Depletions	884	Possible Early Battery Depletion	2
		Software/Firmware	1
		Therapy Function Compromised	**8**
		Battery	7
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.7%	99.7%	99.4%	99.2%	98.8%	98.3%	96.8%	92.1%	80.9%	56.6%	47.3%	46.0%	45.1%
Effective Sample Size	7679	7161	6654	6137	5664	5131	4570	3748	2498	1292	881	559	149

D284DRG Maximo II DR

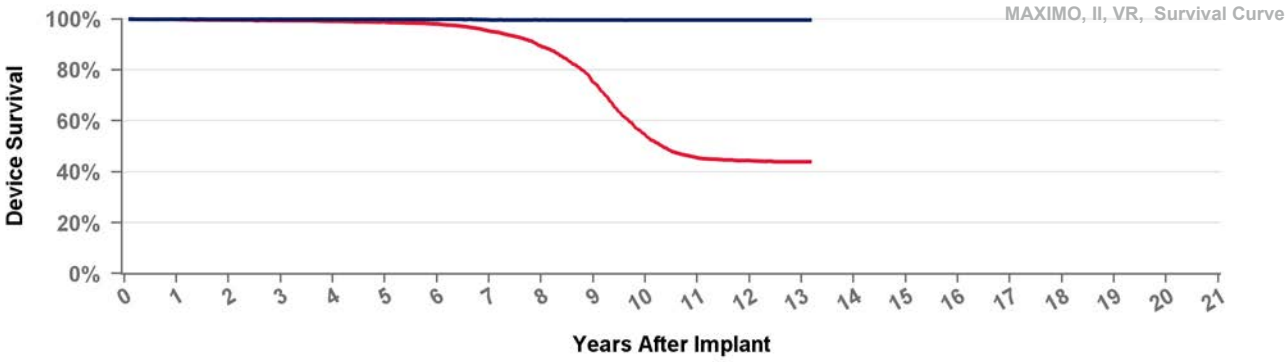
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**71**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**54**
Registered USA Implants	19,954	Battery	7
Estimated Active USA Implants	2,377	Electrical Component	15
Normal Battery Depletions	3,631	Possible Early Battery Depletion	30
		Other	2
		Therapy Function Compromised	**17**
		Battery	11
		Electrical Component	5
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 157 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.5%	99.3%	99.3%	99.3%	99.3%	99.2%	99.2%	99.2%
Including NBD	99.9%	99.6%	99.3%	98.4%	95.6%	87.6%	71.6%	48.3%	34.8%	32.7%	32.1%	31.6%	31.2%	31.2%
Effective Sample Size	17235	15933	14782	13615	12095	9579	5985	2802	1717	1417	1126	718	190	138

D284VRC Maximo II VR

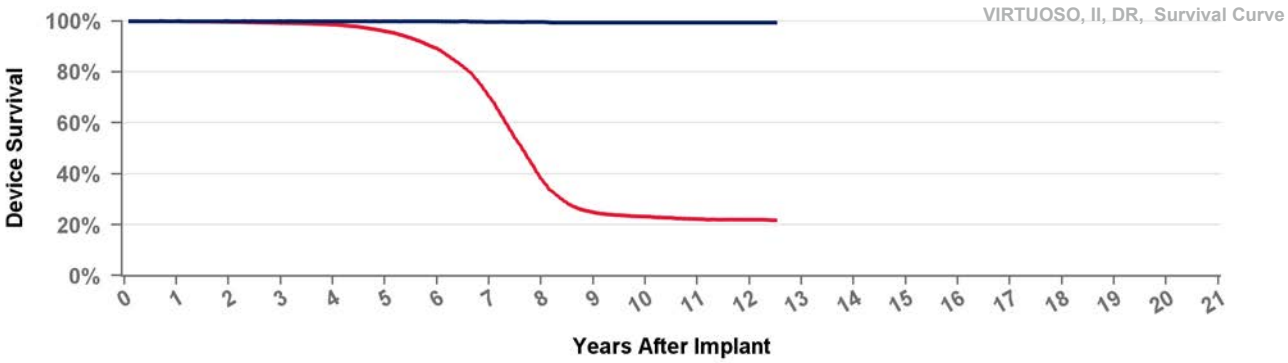
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**32**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**23**
Registered USA Implants	12,861	Battery	10
Estimated Active USA Implants	2,133	Electrical Component	6
Normal Battery Depletions	1,598	Possible Early Battery Depletion	4
		Software/Firmware	3
		Therapy Function Compromised	**9**
		Battery	6
		Electrical Component	2
		Software/Firmware	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.3%	89.2%	75.3%	54.4%	45.5%	44.4%	44.0%	44.0%
Effective Sample Size	10873	10125	9423	8722	8030	7335	6489	5253	3402	1741	1090	692	220	126

D294DRG Virtuoso II DR

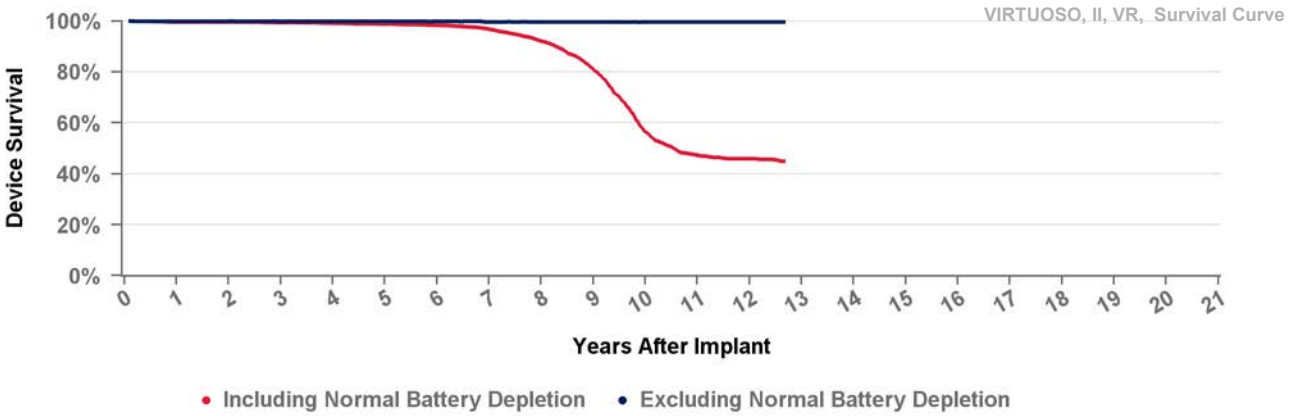
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	20Aug2008	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.9%	99.7%	99.2%	98.6%	96.0%	89.2%	70.5%	38.2%	24.9%	23.2%	22.3%	22.0%	21.8%
Effective Sample Size	19001	17630	16325	14965	13155	10488	6729	2927	1538	1305	1150	673	148

D294VRC Virtuoso II VR

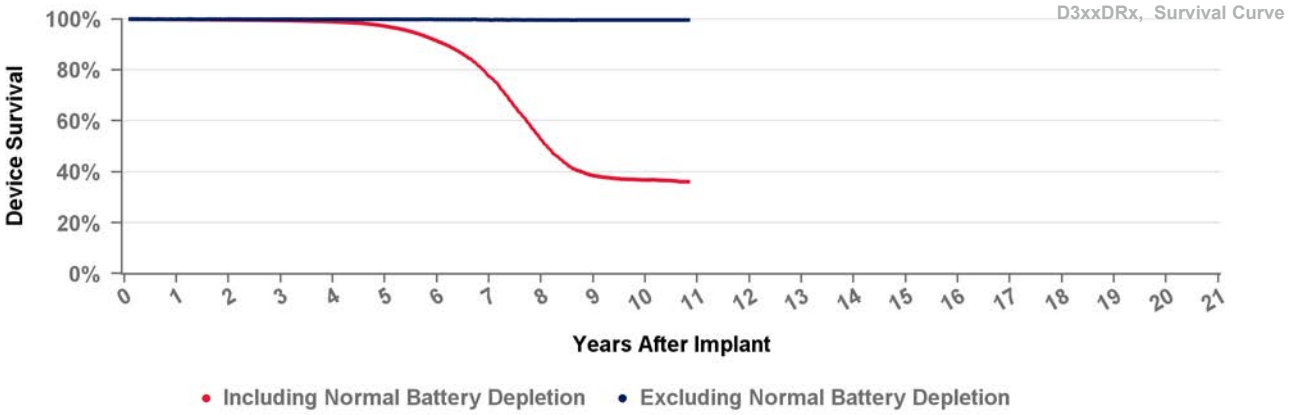
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	20Aug2008	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.7%	99.7%	99.4%	99.2%	98.8%	98.3%	96.8%	92.1%	80.9%	56.6%	47.3%	46.0%	45.1%
Effective Sample Size	7679	7161	6654	6137	5664	5131	4570	3748	2498	1292	881	559	149

D314DRG Protecta XT DR

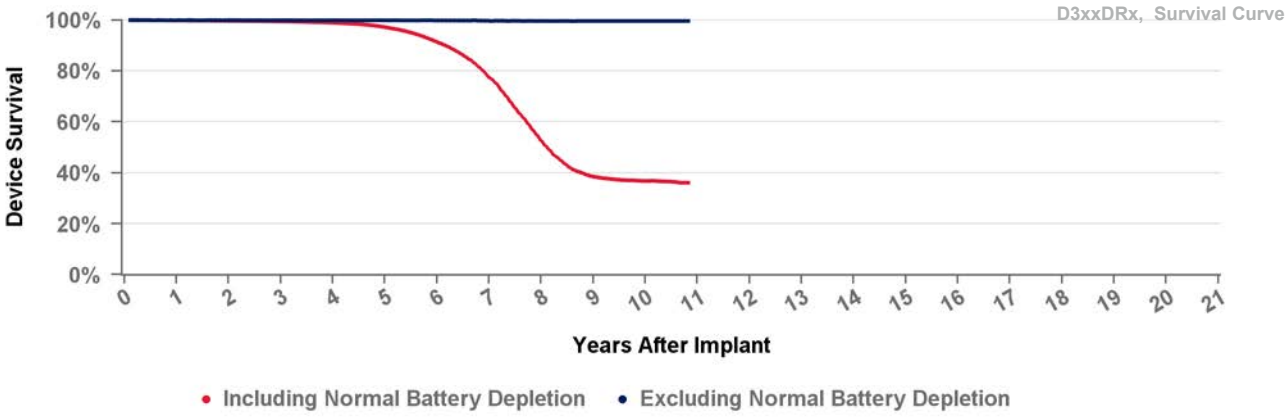
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**77**
CE Approval Date		**Therapy Function Not Compromised**	**40**
Registered USA Implants	34,745	Battery	8
Estimated Active USA Implants	4,738	Electrical Component	26
Normal Battery Depletions	4,531	Electrical Interconnect	1
		Possible Early Battery Depletion	4
		Other	1
		Therapy Function Compromised	**37**
		Battery	30
		Electrical Component	7



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D314DRM Protecta XT DR

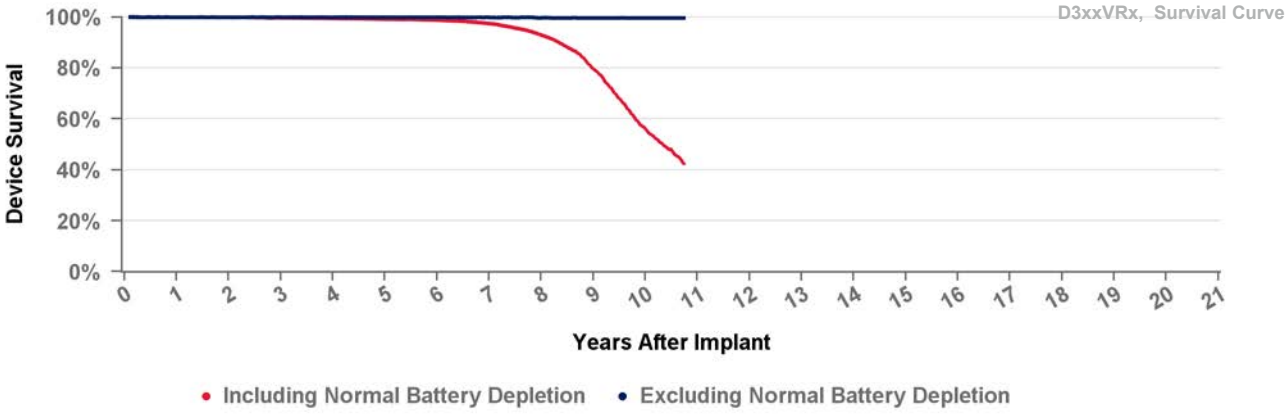
US Market Release	09Nov2011	**Total Malfunctions (USA)**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	13,914	Battery	3
Estimated Active USA Implants	2,258	Electrical Component	12
Normal Battery Depletions	1,919	Other	2
		Therapy Function Compromised	**8**
		Battery	7
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D314VRG Protecta XT VR

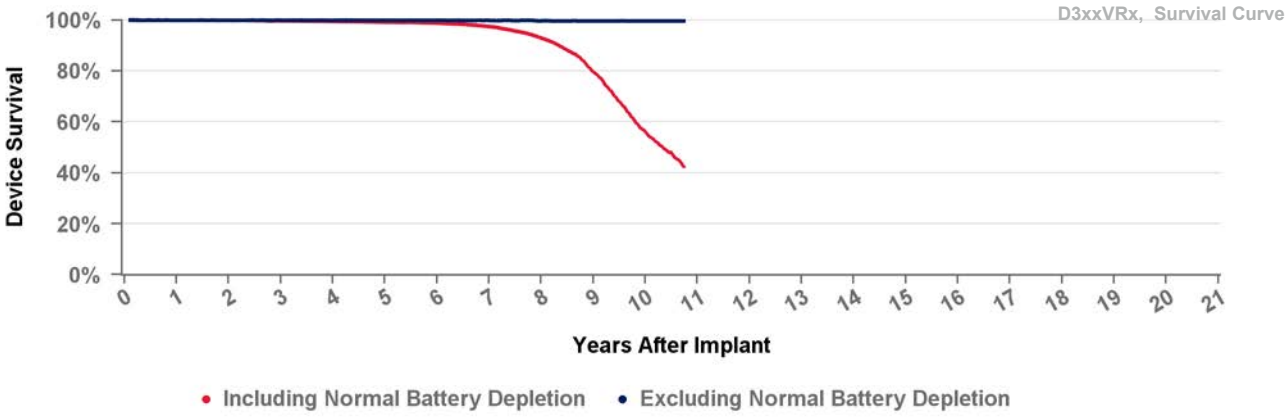
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**31**
CE Approval Date		**Therapy Function Not Compromised**	**21**
Registered USA Implants	14,092	Battery	11
Estimated Active USA Implants	2,921	Electrical Component	9
Normal Battery Depletions	1,171	Other	1
		Therapy Function Compromised	**10**
		Battery	9
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D314VRM Protecta XT VR

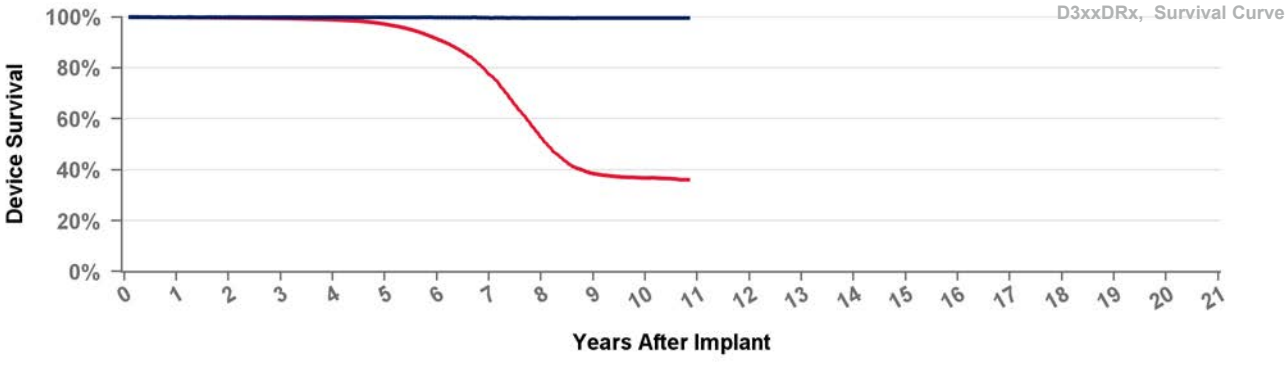
US Market Release	02May2012	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	7,334	Battery	1
Estimated Active USA Implants	1,793	Electrical Component	2
Normal Battery Depletions	642	Possible Early Battery Depletion	1
		Therapy Function Compromised	**4**
		Battery	2
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D334DRG Protecta DR

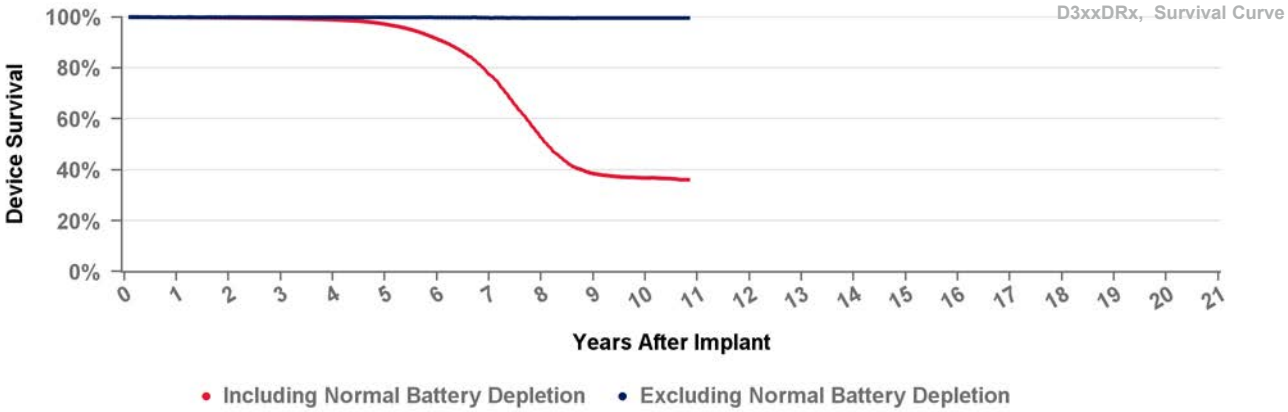
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	10,704	Battery	2
Estimated Active USA Implants	1,461	Electrical Component	6
Normal Battery Depletions	1,830	Possible Early Battery Depletion	1
		Therapy Function Compromised	**11**
		Battery	8
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D334DRM Protecta DR

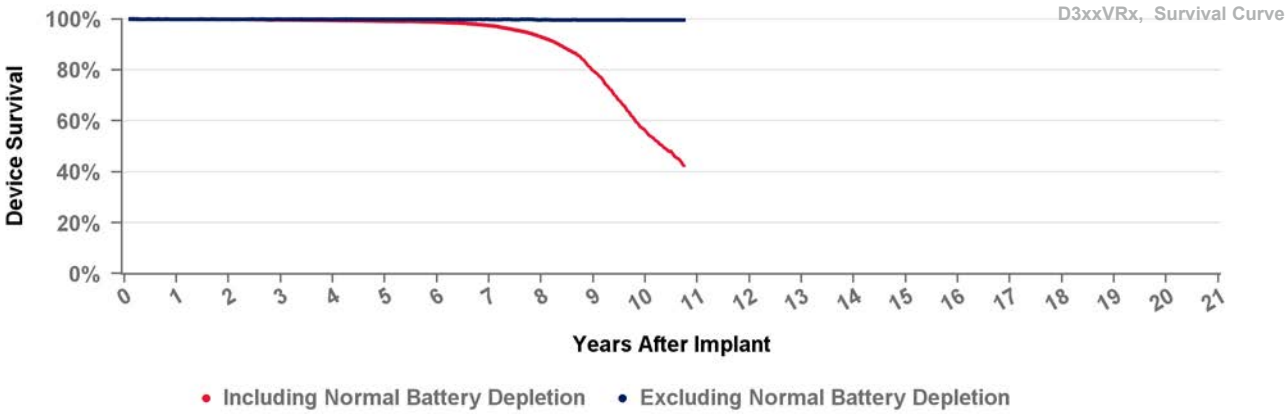
US Market Release	09Nov2011	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,997		
Estimated Active USA Implants	506	**Therapy Function Compromised**	**1**
Normal Battery Depletions	576	Battery	1



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D334VRG Protecta VR

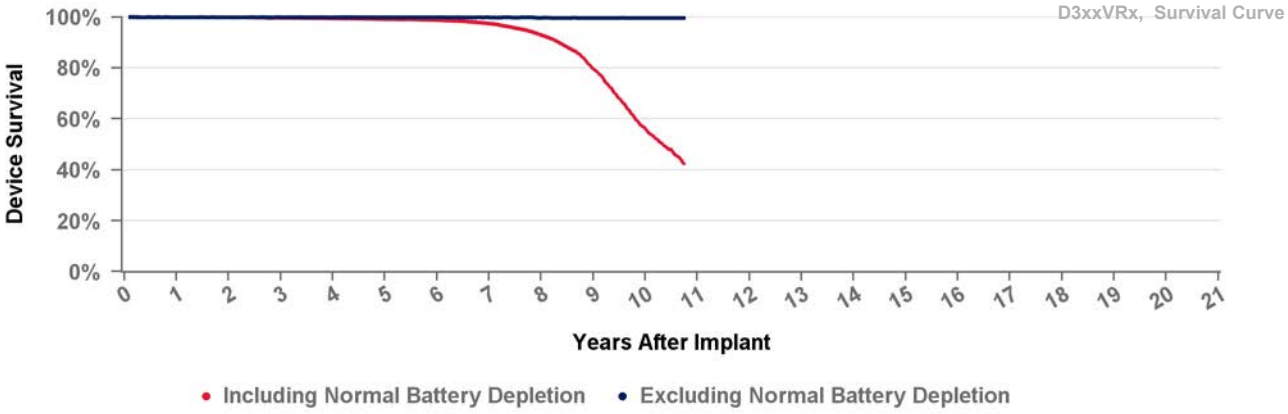
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	6,488	Battery	2
Estimated Active USA Implants	1,571	Electrical Component	4
Normal Battery Depletions	613	**Therapy Function Compromised**	**6**
		Battery	4
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D334VRM Protecta VR

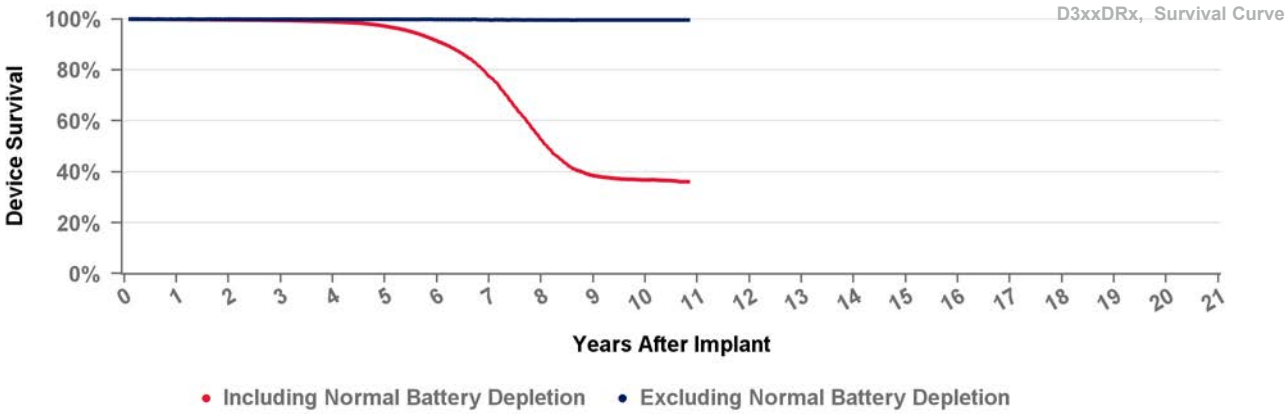
US Market Release	02May2012	**Total Malfunctions (USA)**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,167	Battery	1
Estimated Active USA Implants	579	Other	1
Normal Battery Depletions	208	**Therapy Function Compromised**	**2**
		Battery	2



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D354DRG Protecta XT DR

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	25Mar2010	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D354DRM Protecta XT DR

US Market Release

CE Approval Date 15Jul2010

Registered USA Implants

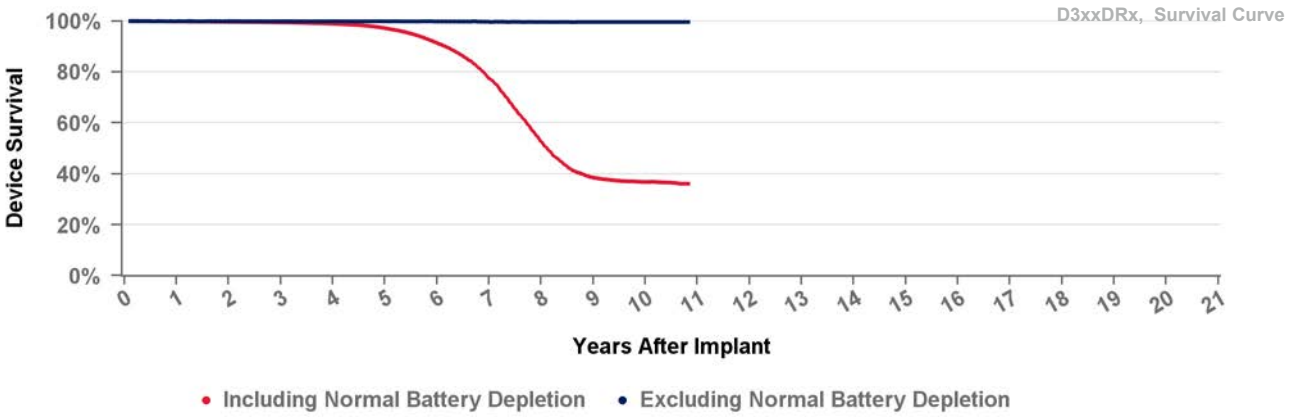
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D354VRG Protecta XT VR

US Market Release

CE Approval Date 25Mar2010

Registered USA Implants

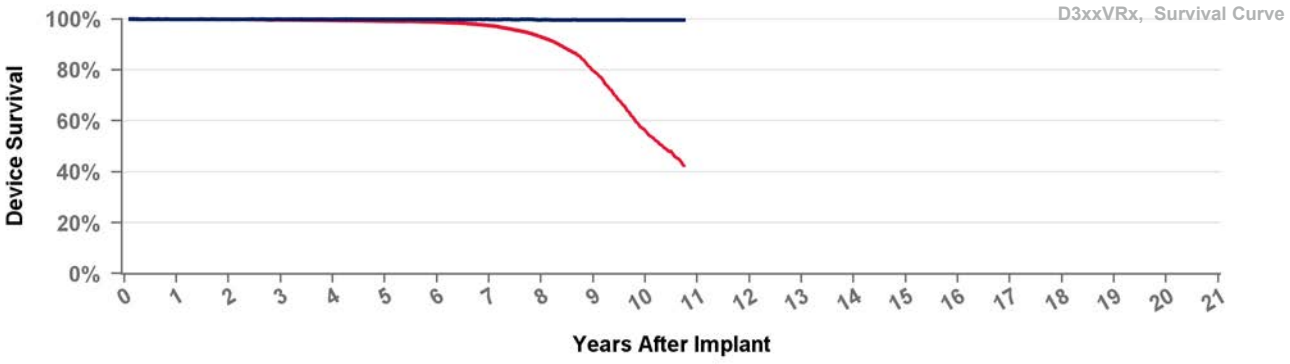
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

Therapy Function Compromised

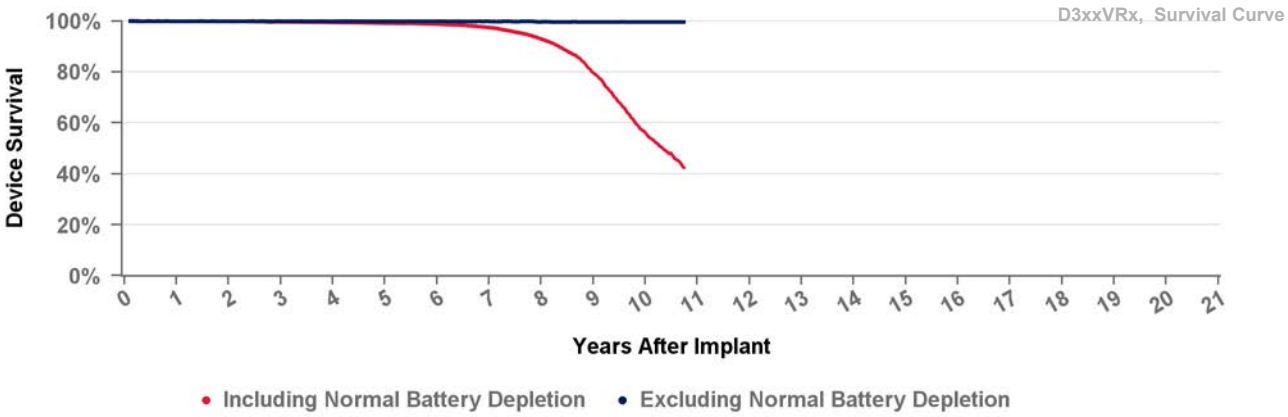


Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D354VRM Protecta XT VR

US Market Release
CE Approval Date 17Dec2010
Registered USA Implants 1
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

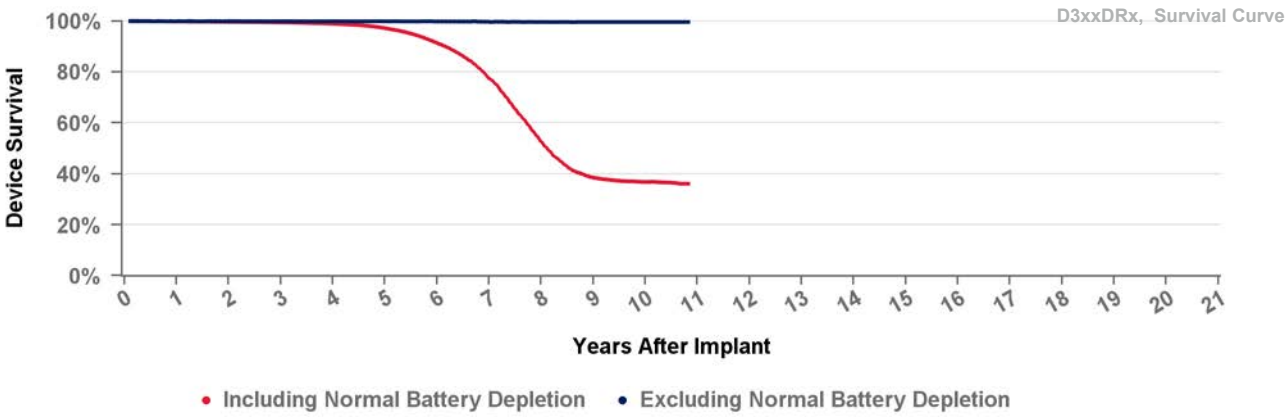


Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D364DRG Protecta DR

US Market Release
CE Approval Date 25Mar2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

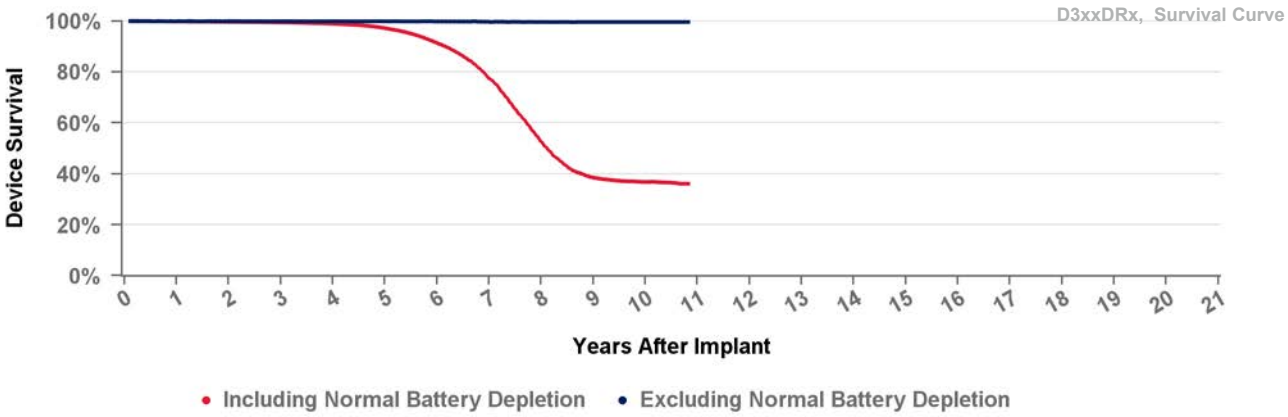


Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D364DRM Protecta DR

US Market Release
CE Approval Date 15Jul2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

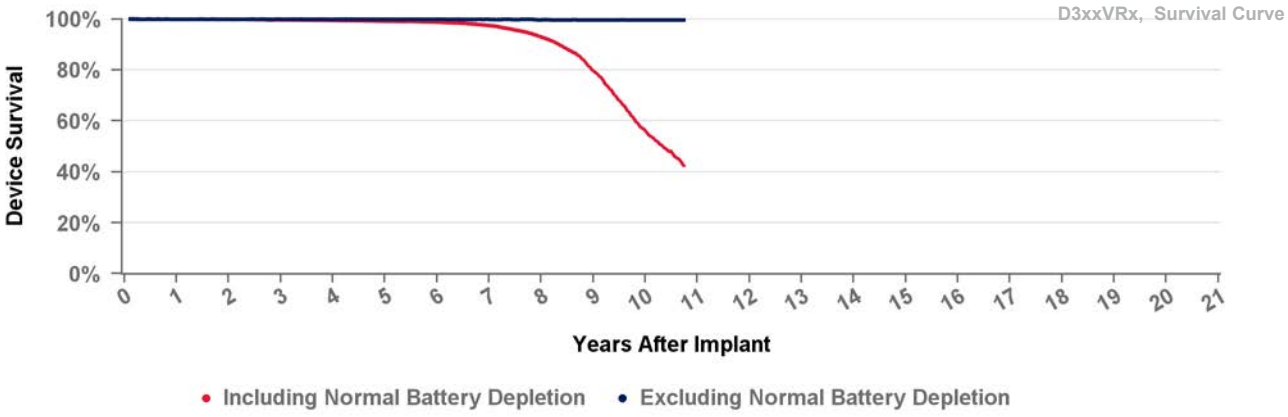


Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D364VRG Protecta VR

US Market Release
CE Approval Date 25Mar2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

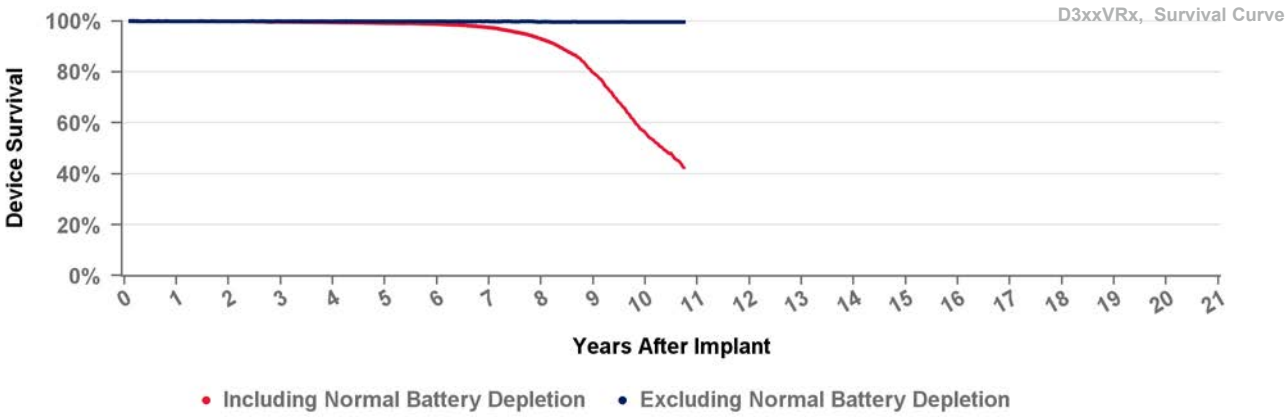


Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D364VRM Protecta VR

US Market Release
CE Approval Date 17Dec2010
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

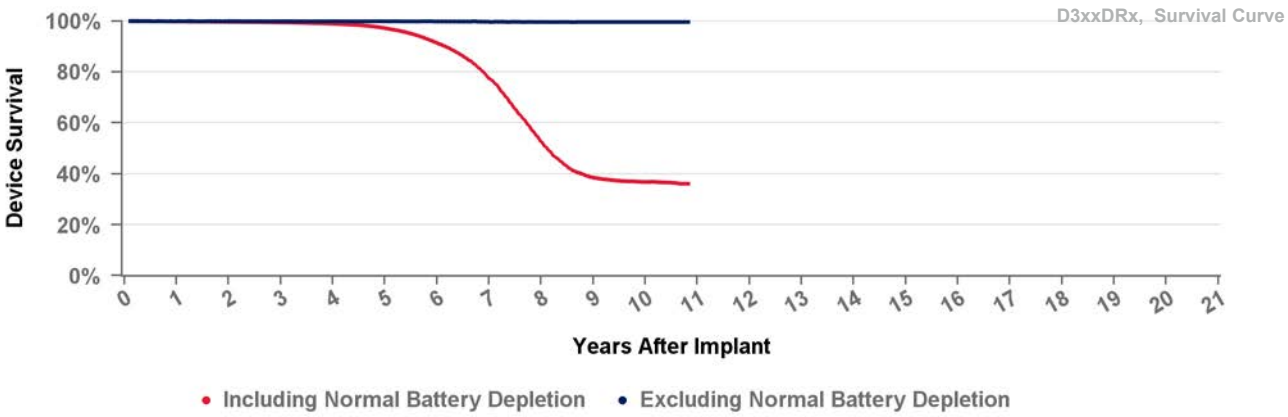


Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D384DRG Cardia DR

US Market Release
CE Approval Date 12Jan2011
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

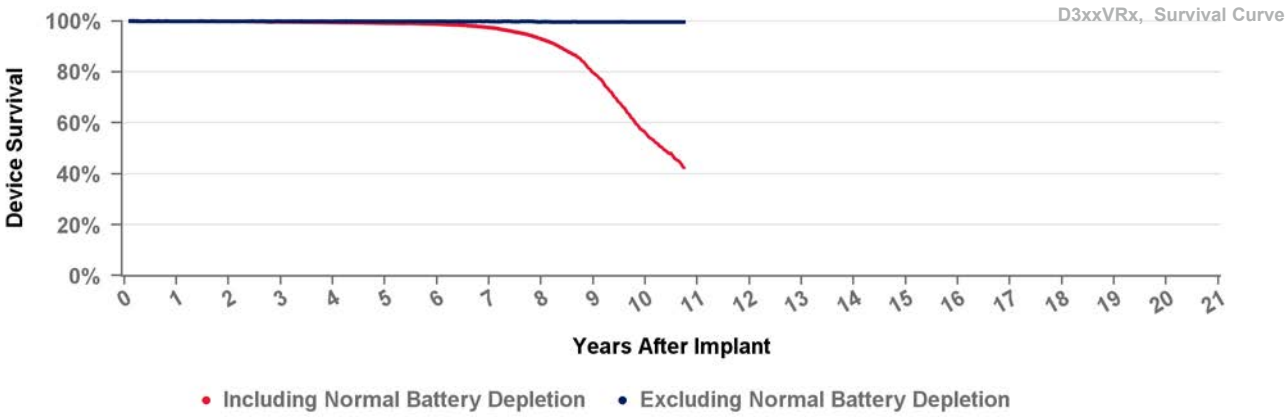


Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D384VRG Cardia VR

US Market Release
CE Approval Date 12Jan2011
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

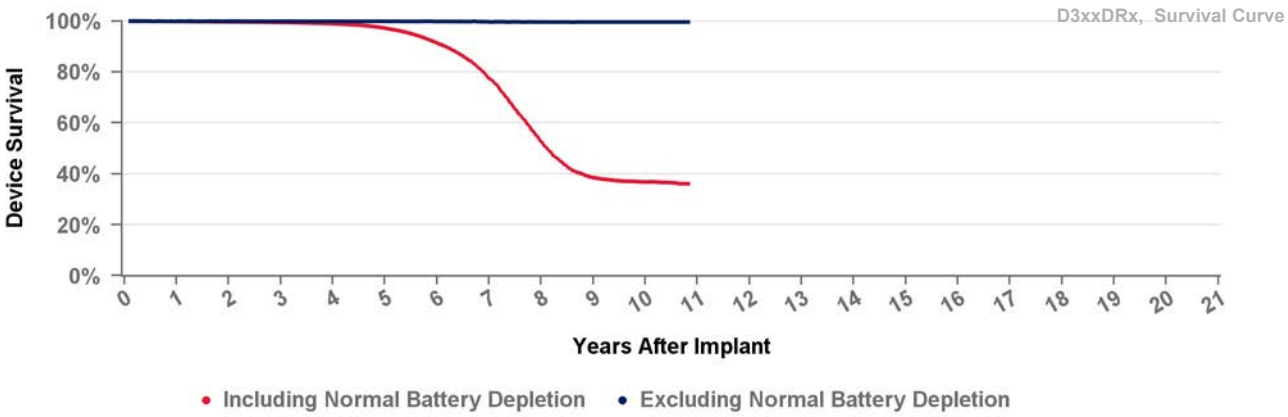


Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

D394DRG Egida DR

US Market Release
CE Approval Date 12Jan2011
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

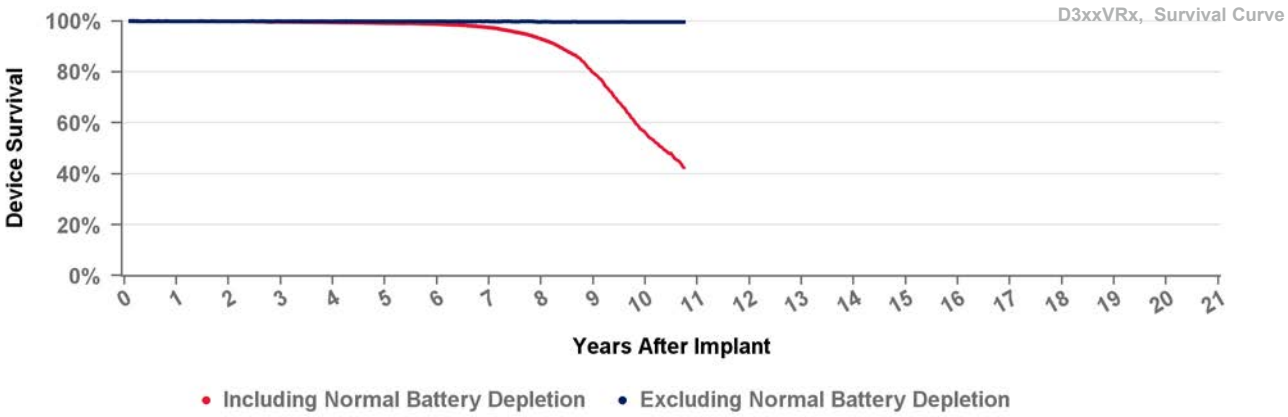
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.6%	52.7%	38.5%	36.8%	36.1%
Effective Sample Size	54185	50304	46254	42264	37896	31018	20414	9173	4976	3236	203

D394VRG Egida VR

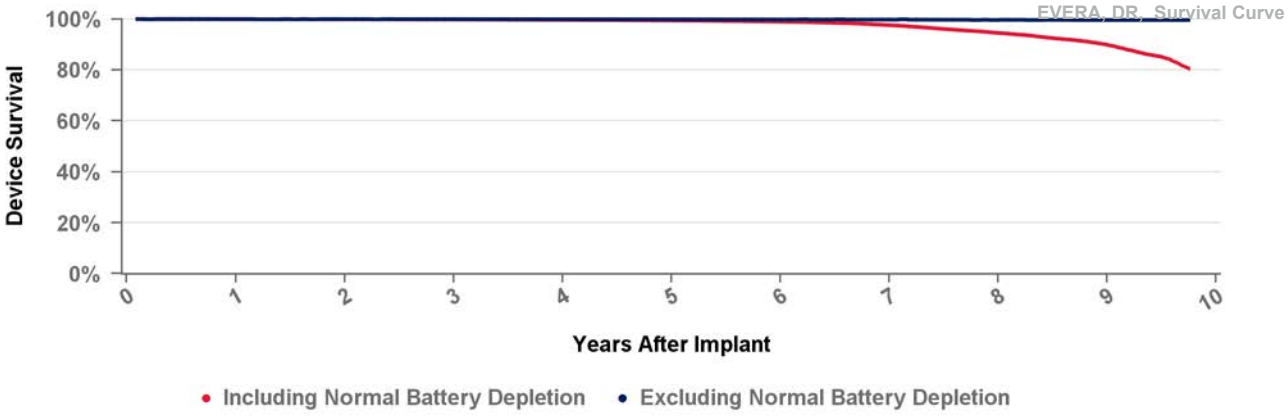
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.7%	56.1%	42.3%
Effective Sample Size	25800	23981	22240	20573	19020	17444	15679	12951	8052	2965	211

DDBB1D1 Evera XT

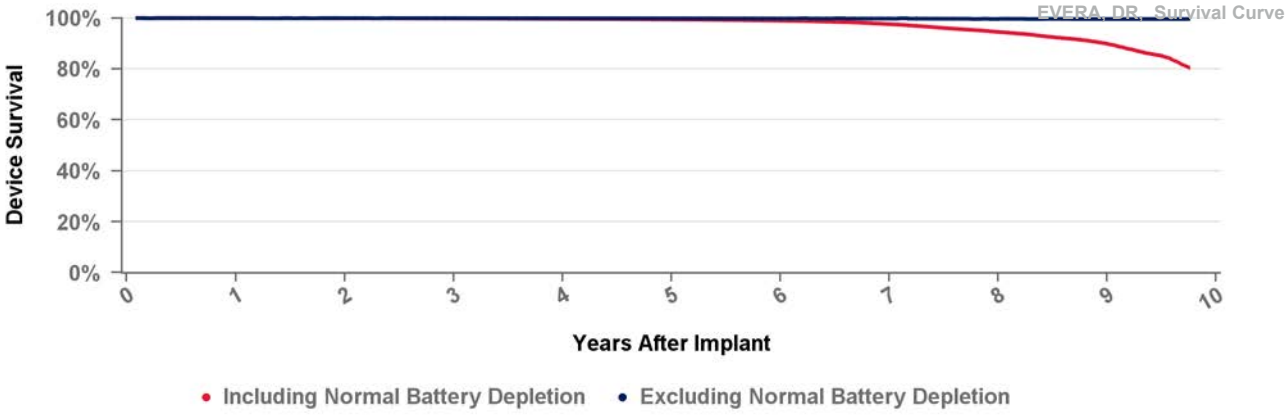
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**77**
CE Approval Date		**Therapy Function Not Compromised**	**45**
Registered USA Implants	82,205	Battery	28
Estimated Active USA Implants	44,220	Electrical Component	15
Normal Battery Depletions	1,638	Other	2
		Therapy Function Compromised	**32**
		Battery	29
		Electrical Component	1
		Electrical Interconnect	1
		Other	1



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDBB1D4 Evera XT

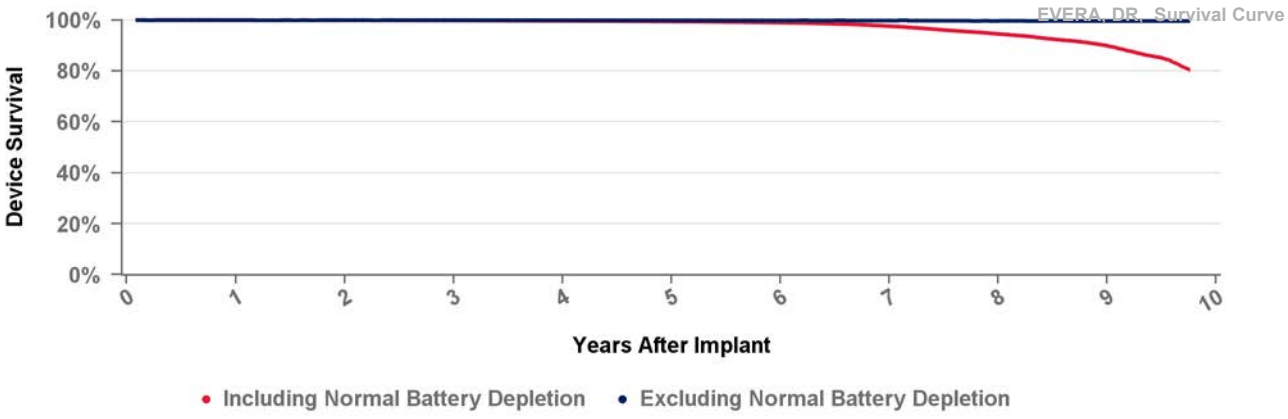
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**70**
CE Approval Date		**Therapy Function Not Compromised**	**41**
Registered USA Implants	59,385	Battery	30
Estimated Active USA Implants	32,699	Electrical Component	7
Normal Battery Depletions	1,203	Electrical Interconnect	2
		Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**29**
		Battery	22
		Device-Related Current Pathway	3
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDBB2D1 Evera XT

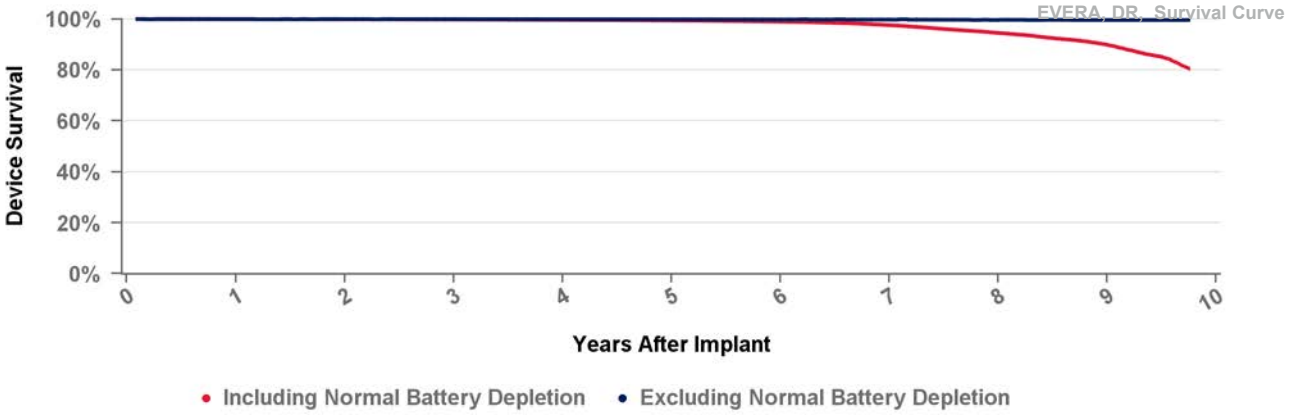
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDBB2D4 Evera XT

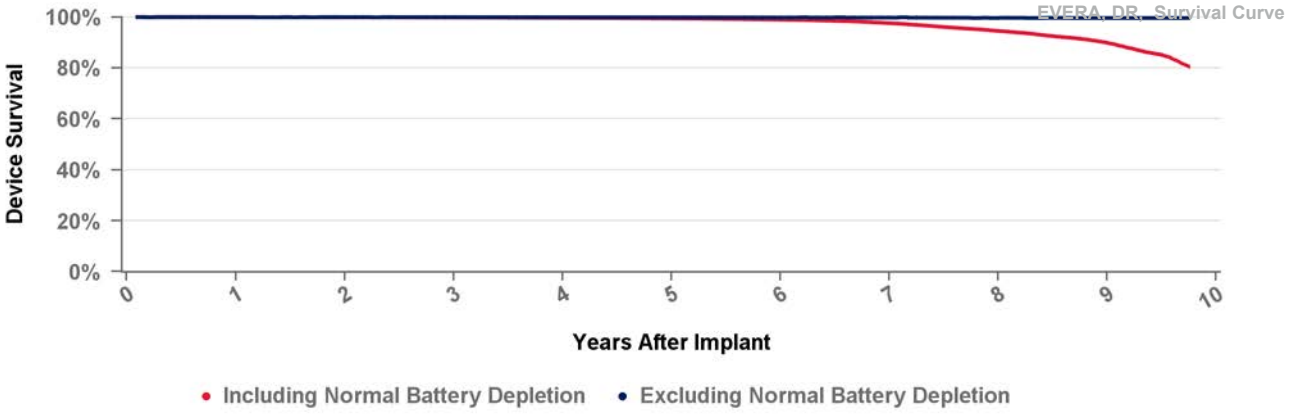
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDBC3D1 Evera S

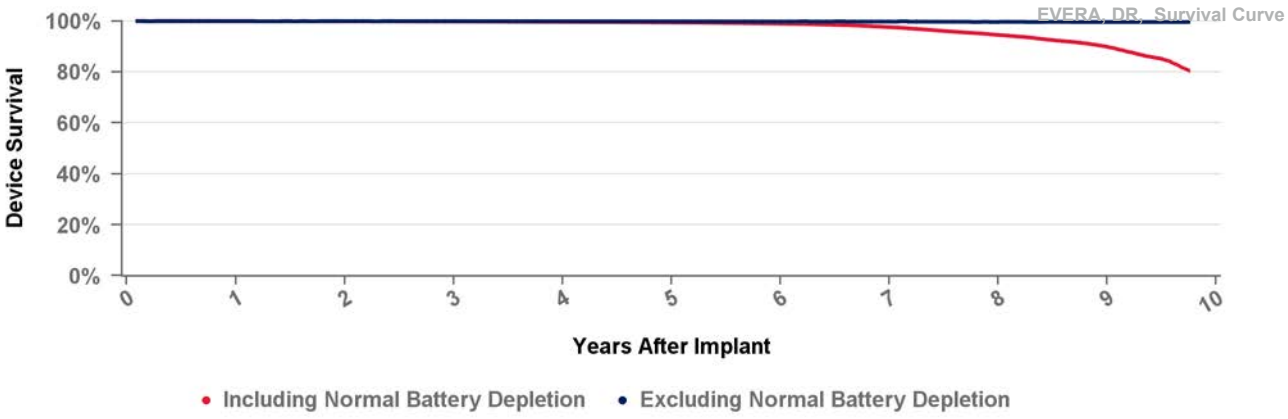
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**17**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**8**
Registered USA Implants	15,930	Battery	6
Estimated Active USA Implants	8,500	Electrical Component	2
Normal Battery Depletions	378	**Therapy Function Compromised**	**9**
		Battery	6
		Device-Related Current Pathway	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDBC3D4 Evera S

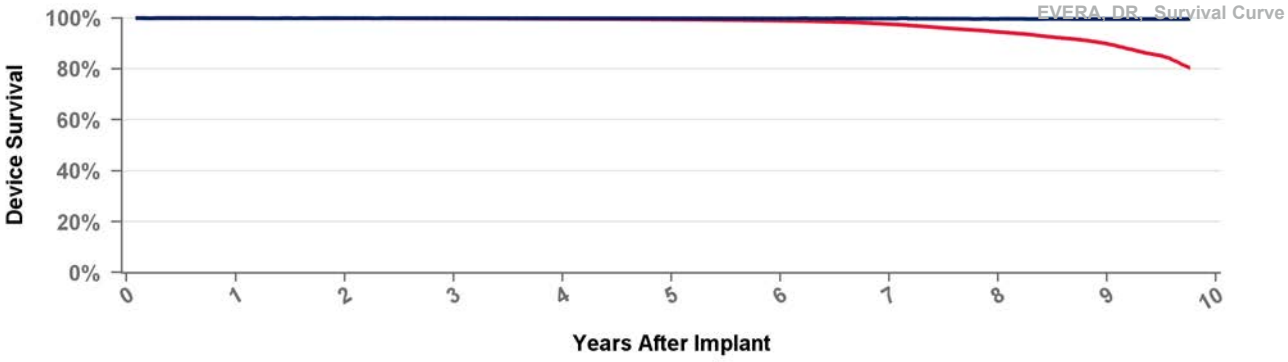
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**13**
CE Approval Date	17Dec2013	**Therapy Function Not Compromised**	**5**
Registered USA Implants	11,810	Battery	3
Estimated Active USA Implants	6,603	Electrical Component	2
Normal Battery Depletions	234	**Therapy Function Compromised**	**8**
		Battery	5
		Device-Related Current Pathway	1
		Electrical Component	1
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMB1D1 Evera MRI XT

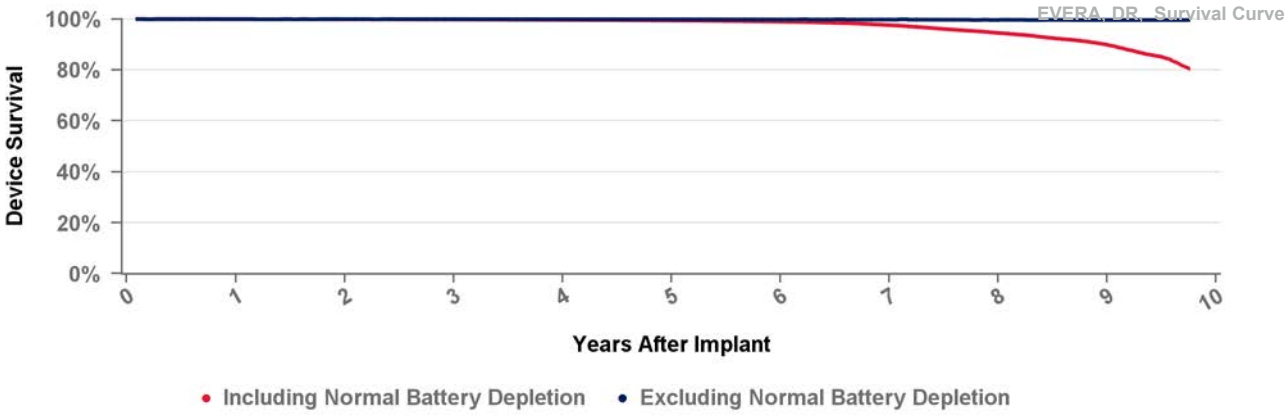
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**31**
CE Approval Date		**Therapy Function Not Compromised**	**18**
Registered USA Implants	45,186	Battery	9
Estimated Active USA Implants	35,763	Device-Related Current Pathway	1
Normal Battery Depletions	71	Electrical Component	6
		Electrical Interconnect	1
		Other	1
		Therapy Function Compromised	**13**
		Battery	5
		Device-Related Current Pathway	3
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMB1D4 Evera MRI XT

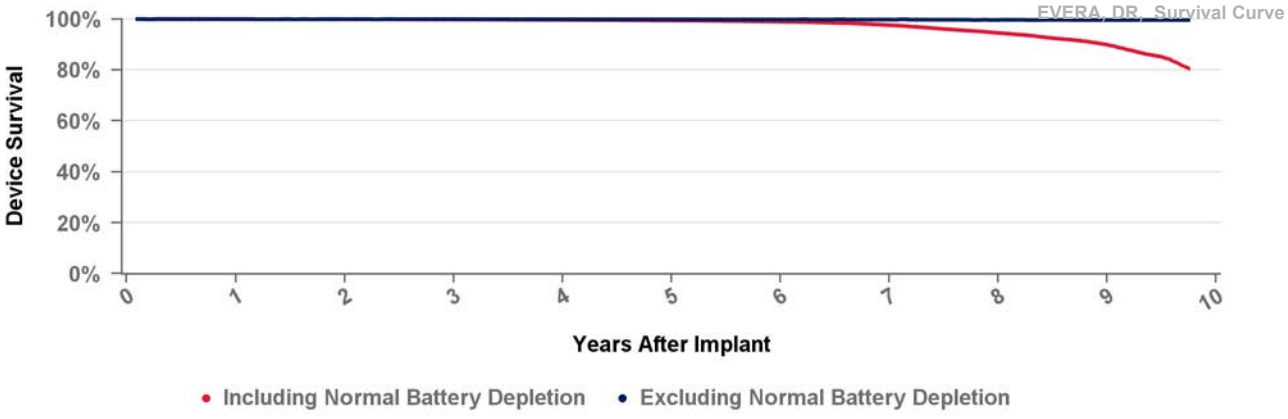
US Market Release	11Sep2015	**Total Malfunctions (USA)**	**80**
CE Approval Date		**Therapy Function Not Compromised**	**46**
Registered USA Implants	135,188	Battery	22
Estimated Active USA Implants	107,862	Electrical Component	20
Normal Battery Depletions	243	Electrical Interconnect	2
		Other	2
		Therapy Function Compromised	**34**
		Battery	22
		Device-Related Current Pathway	9
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMB2D1 Evera MRI XT

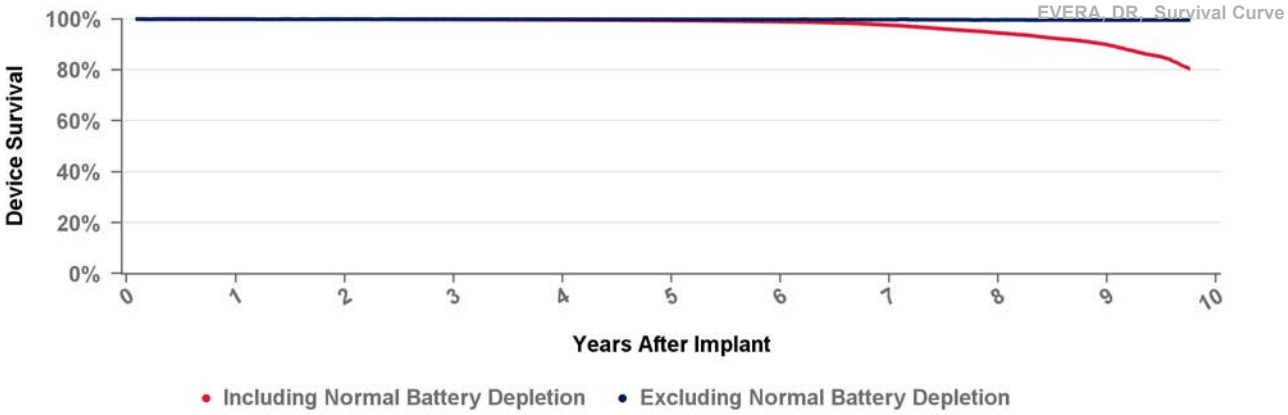
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMB2D4 Evera MRI XT

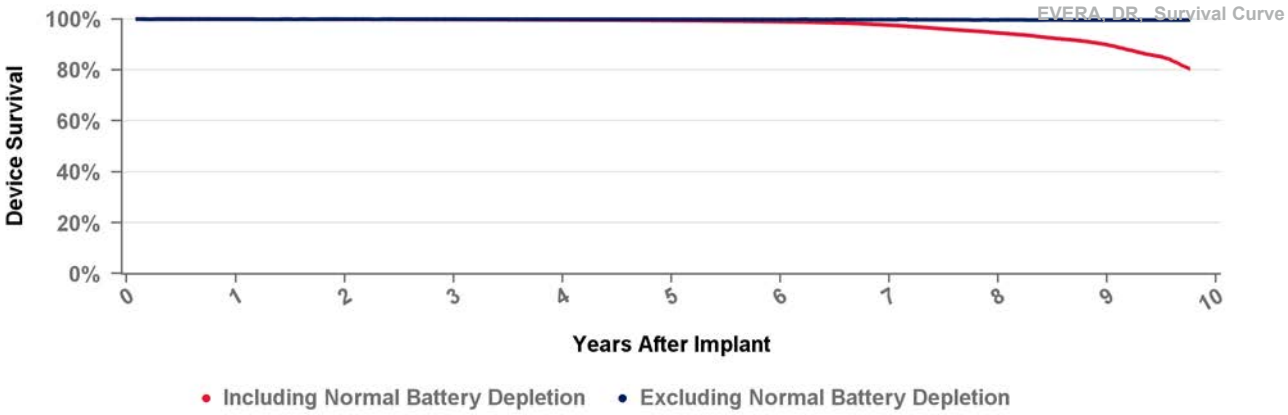
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMC3D1 Evera MRI S

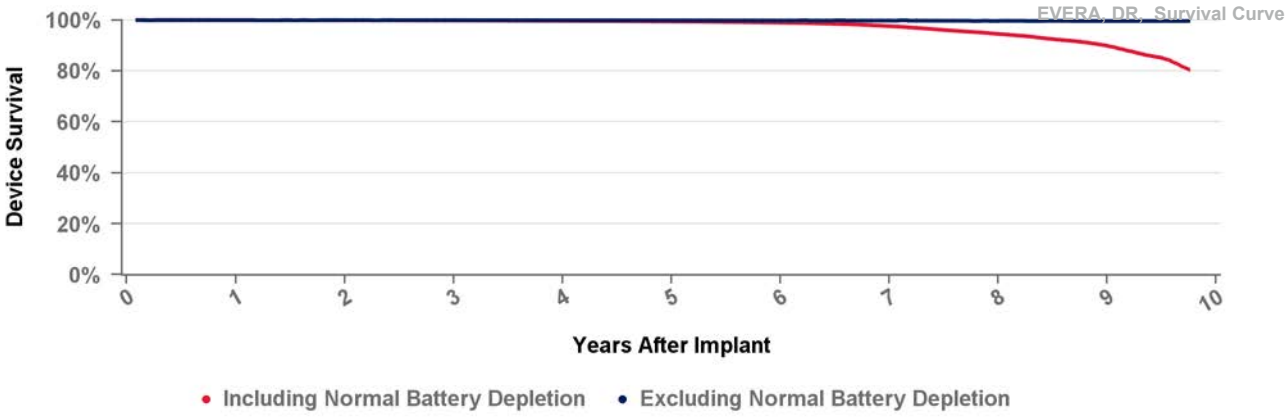
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**2**
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	**2**
Registered USA Implants	4,044	Battery	1
Estimated Active USA Implants	3,186	Electrical Component	1
Normal Battery Depletions	4	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMC3D4 Evera MRI

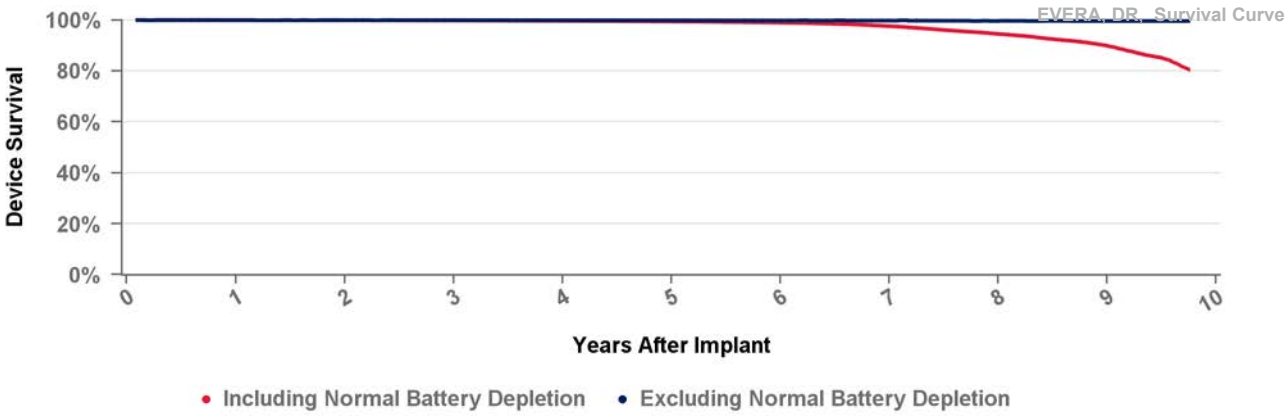
US Market Release	11Sep2015	**Total Malfunctions (USA)**	**6**
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	**3**
Registered USA Implants	9,061	Battery	2
Estimated Active USA Implants	7,194	Electrical Component	1
Normal Battery Depletions	14	**Therapy Function Compromised**	**3**
		Battery	1
		Device-Related Current Pathway	1
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMD3D1 Primo

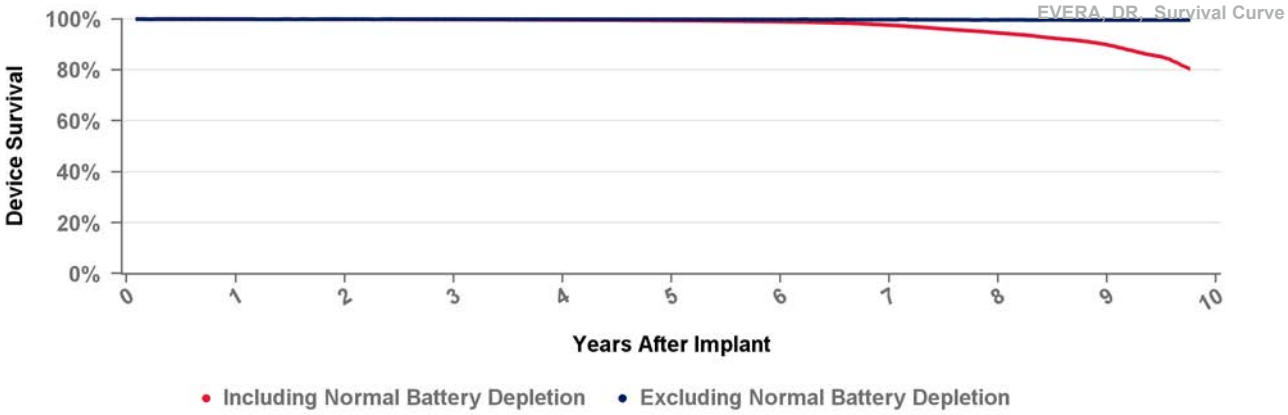
US Market Release	01Mar2018	**Total Malfunctions (USA)**	**1**
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	**1**
Registered USA Implants	384	Electrical Component	1
Estimated Active USA Implants	351	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDMD3D4 Primo

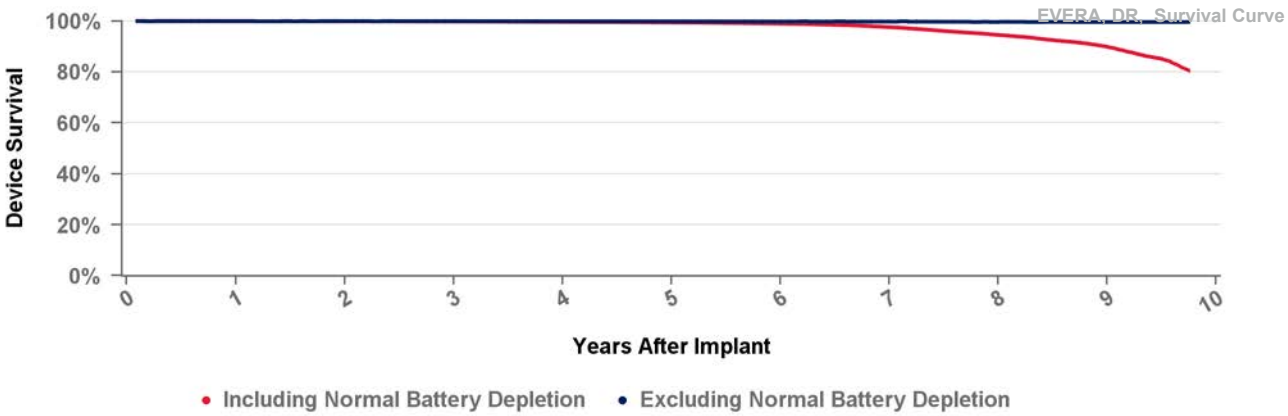
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	1,157		
Estimated Active USA Implants	1,070	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDME3D1 Mirro

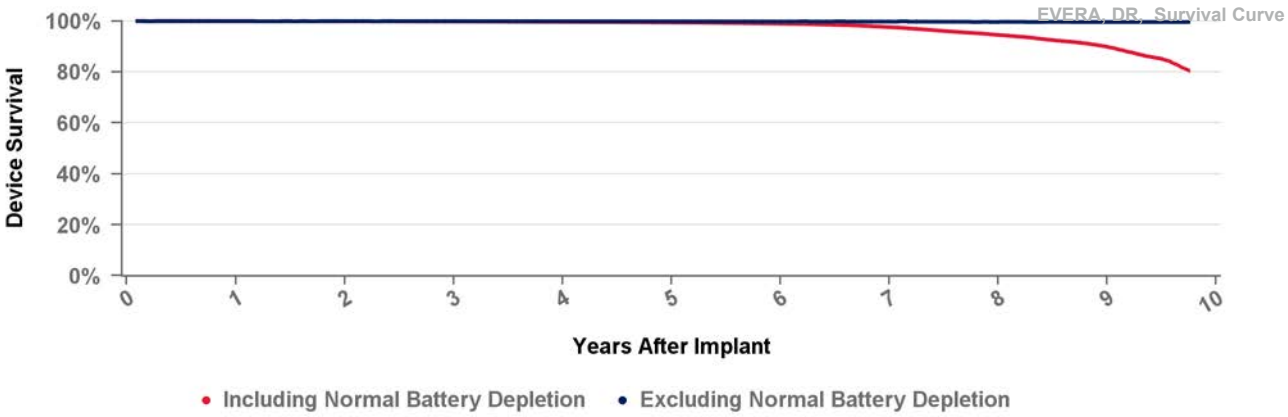
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDME3D4 Mirro

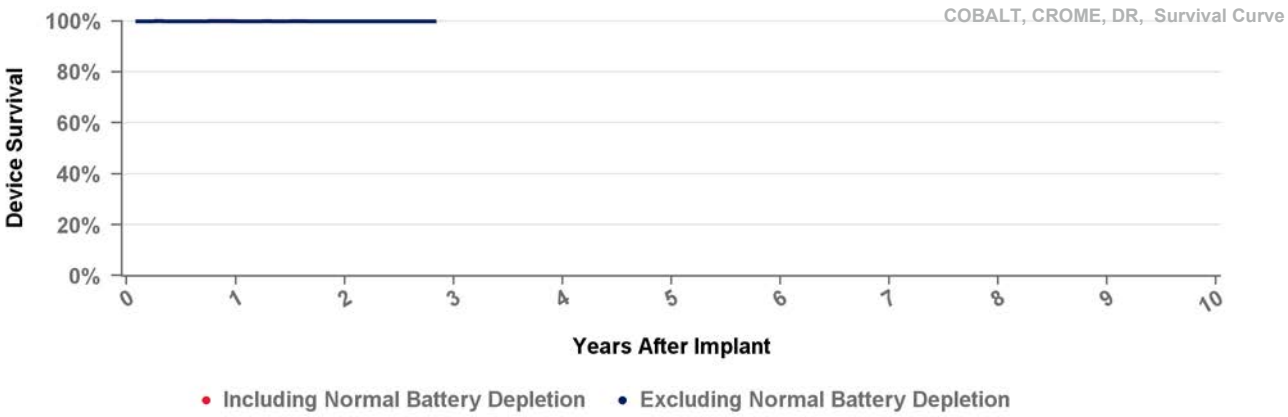
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	99.0%	97.6%	94.5%	89.9%	80.5%
Effective Sample Size	207323	184290	157385	126715	96304	68087	42931	23450	8504	236

DDPA2D1 Cobalt XT

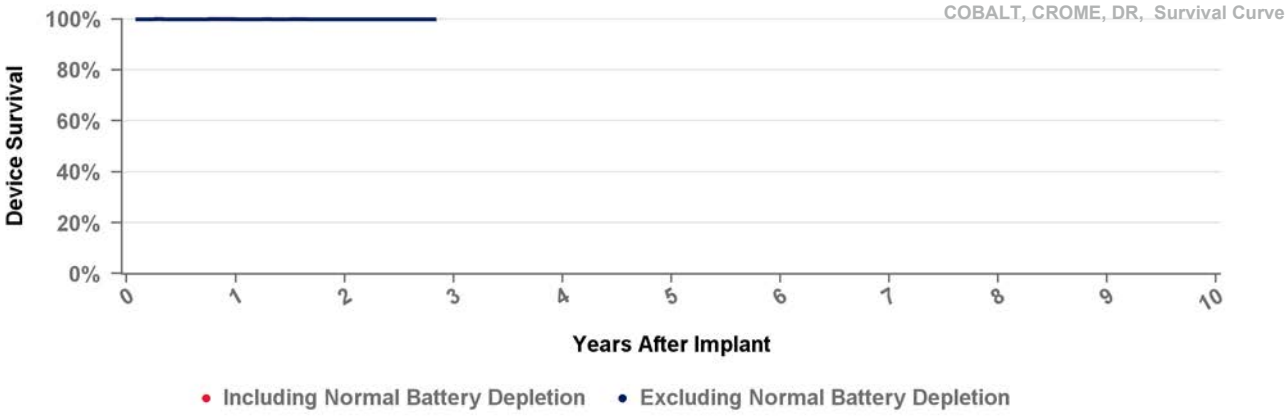
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	1,451		
Estimated Active USA Implants	1,401	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DDPA2D4 Cobalt XT

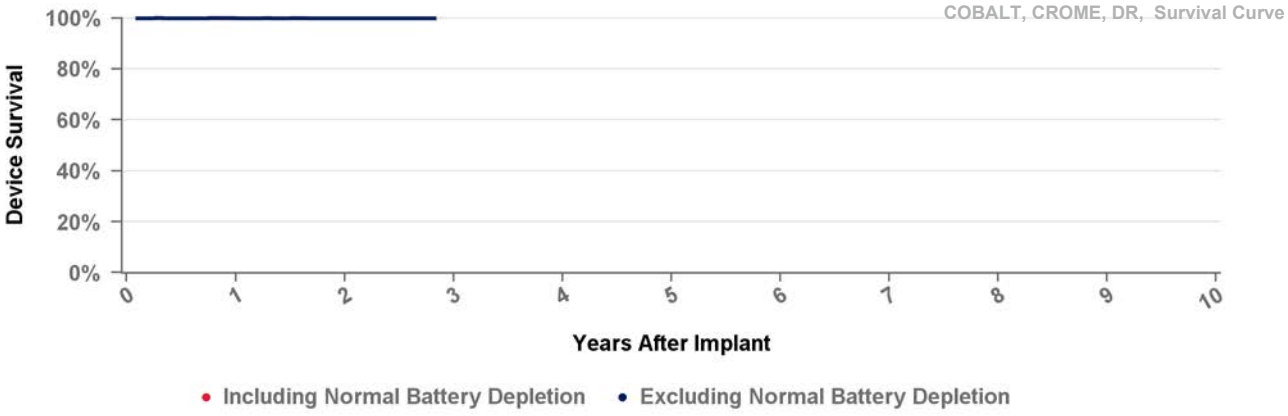
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	12,864		
Estimated Active USA Implants	12,425	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DDPB3D1 Cobalt

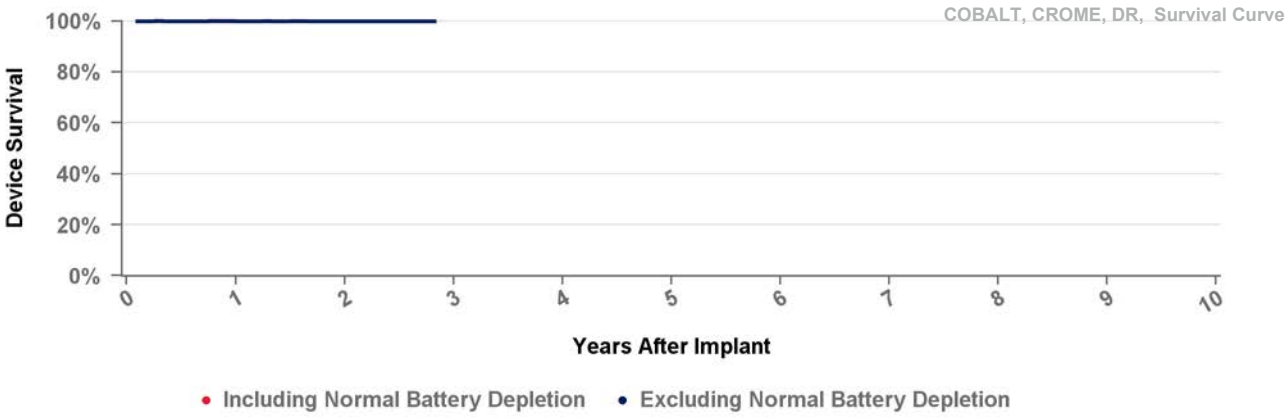
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**2**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,660	Battery	1
Estimated Active USA Implants	1,566	**Therapy Function Compromised**	**1**
Normal Battery Depletions		Device-Related Current Pathway	1



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DDPB3D4 Cobalt

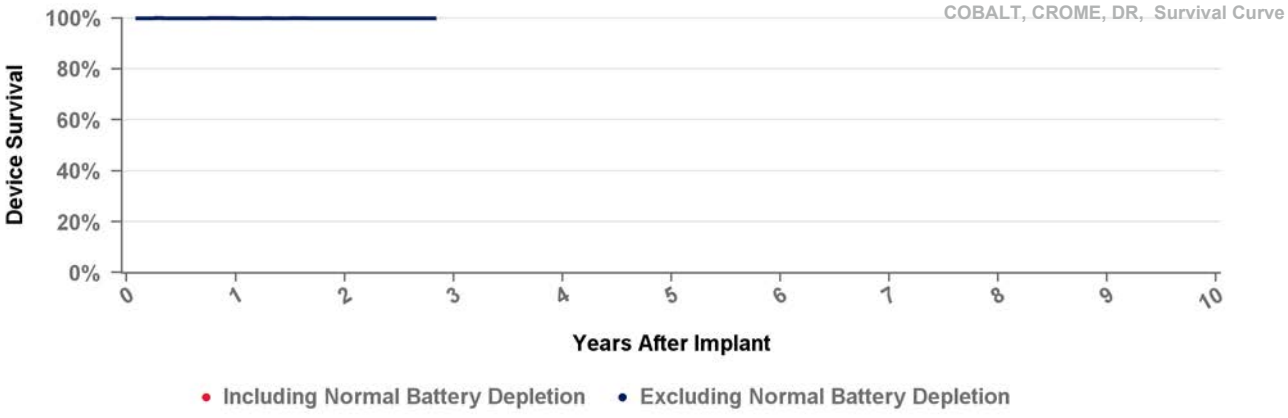
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**6**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**3**
Registered USA Implants	10,007	Electrical Component	1
Estimated Active USA Implants	9,485	Other	2
Normal Battery Depletions	1	**Therapy Function Compromised**	**3**
		Electrical Component	1
		Electrical Interconnect	2



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DDPC3D1 Crome

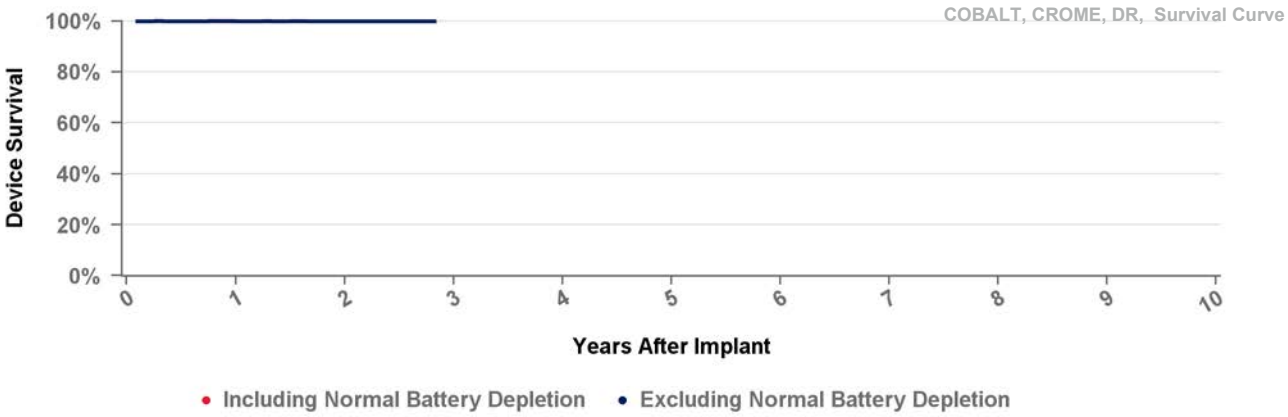
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	108		
Estimated Active USA Implants	100	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DDPC3D4 Crome

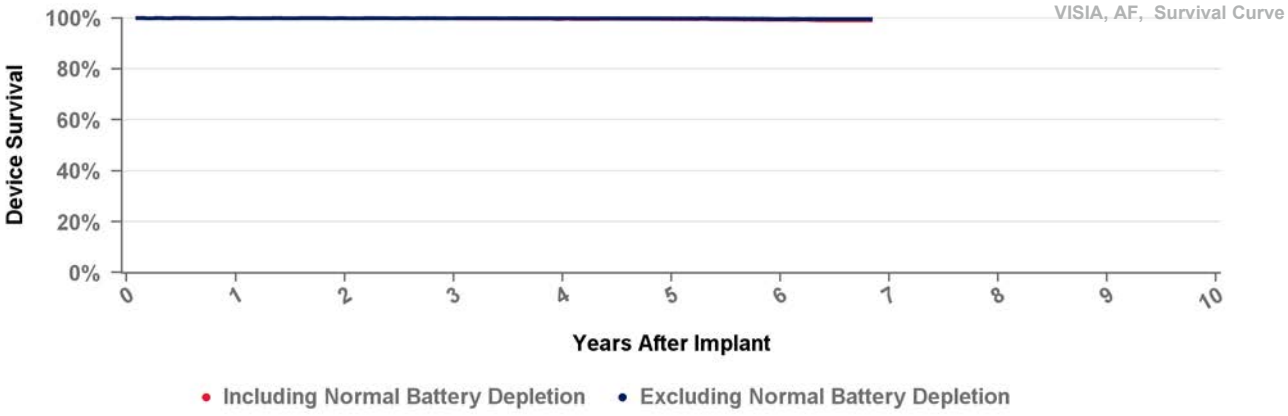
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	615		
Estimated Active USA Implants	580	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	15224	5370	179

DVAB1D1 Visia AF

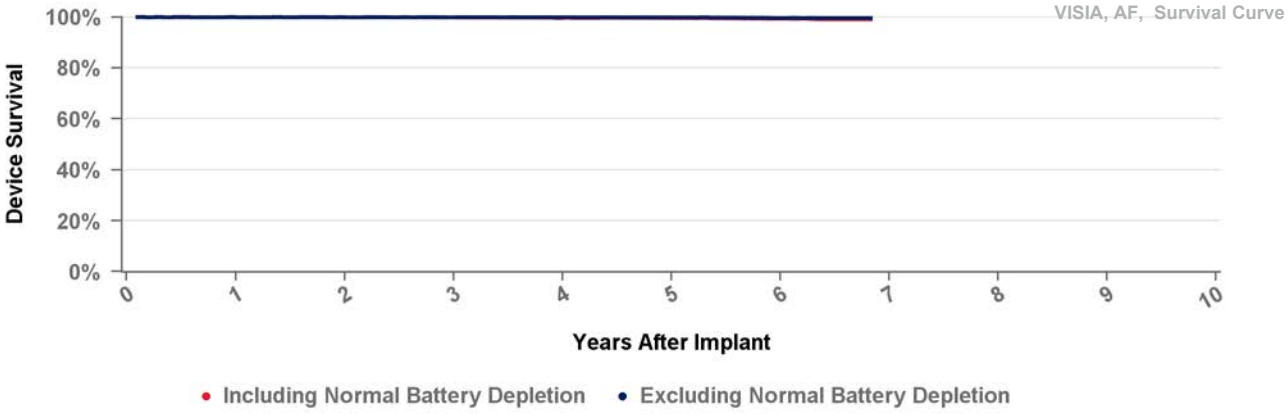
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	5,078	Battery	4
Estimated Active USA Implants	3,523	**Therapy Function Compromised**	**2**
Normal Battery Depletions	13	Battery	2



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVAB1D4 Visia AF

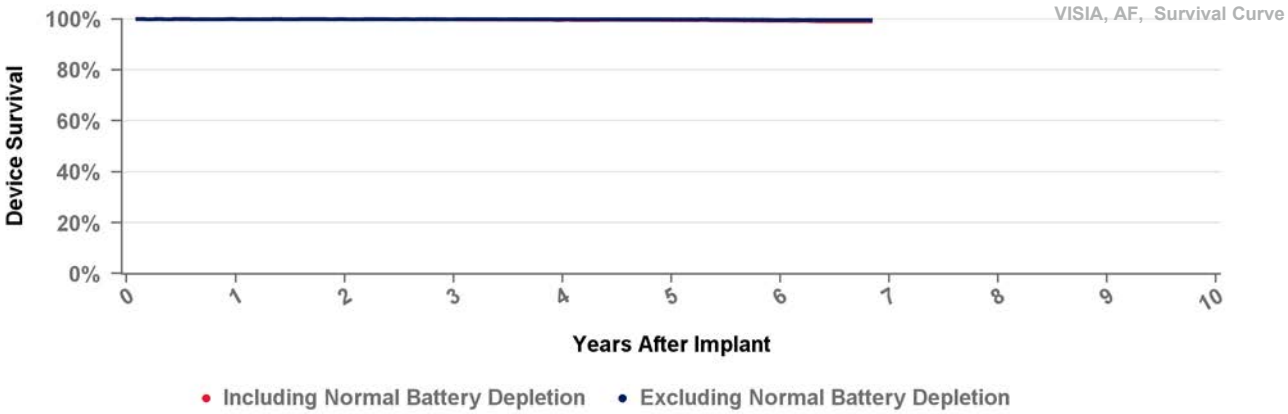
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	3,462	Battery	2
Estimated Active USA Implants	2,471	**Therapy Function Compromised**	**3**
Normal Battery Depletions		Battery	2
		Device-Related Current Pathway	1



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVAB2D1 Visia AF XT

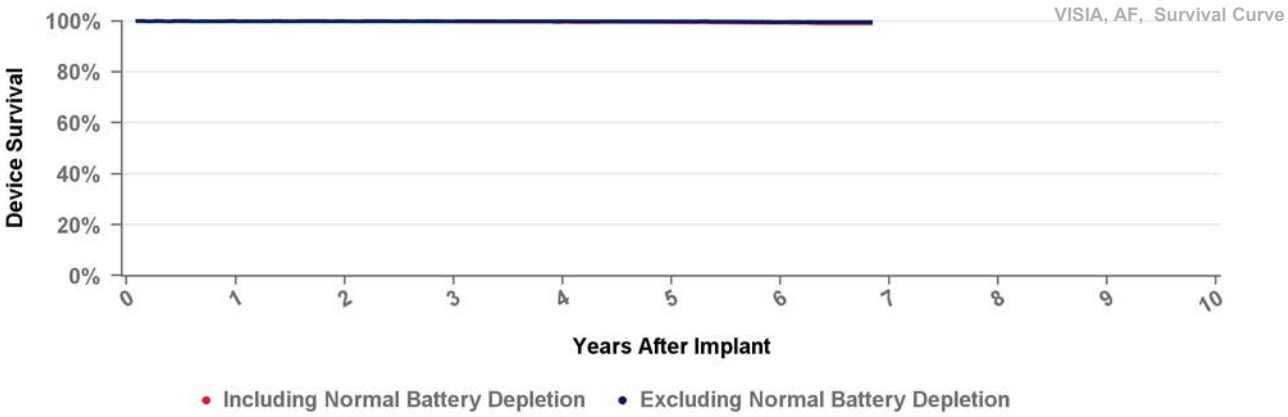
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVAC3D1 Visia AF S

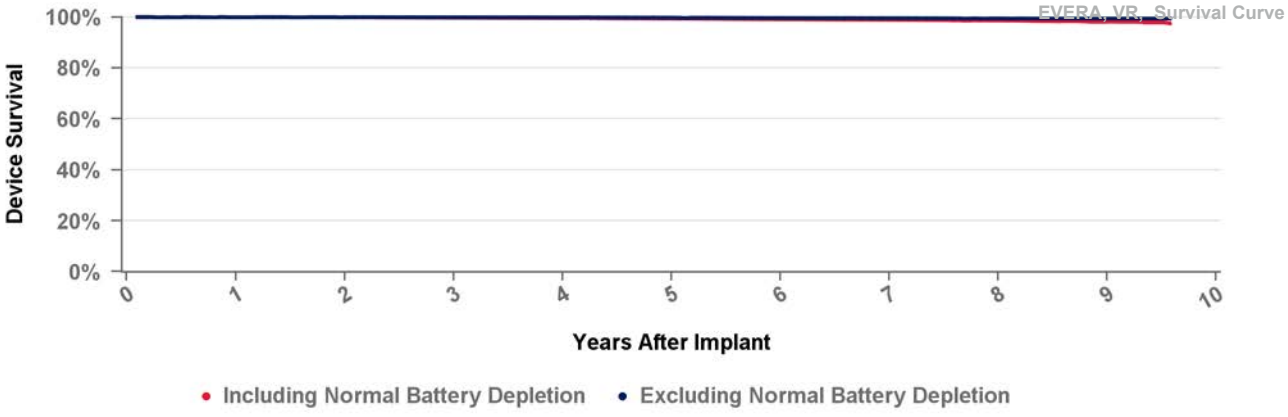
US Market Release	19Jan2016	**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVBB1D1 Evera XT

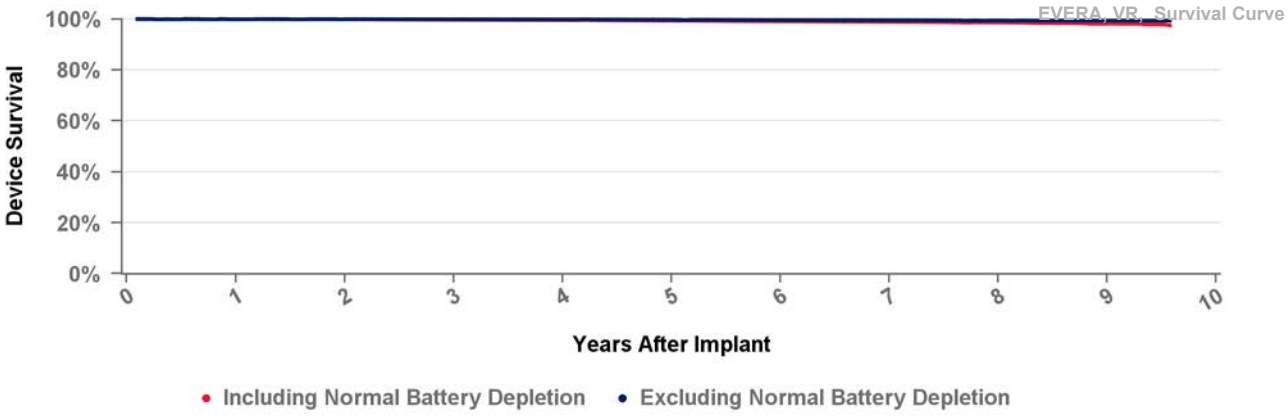
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**68**
CE Approval Date		**Therapy Function Not Compromised**	**48**
Registered USA Implants	32,233	Battery	41
Estimated Active USA Implants	18,439	Electrical Component	7
Normal Battery Depletions	62	**Therapy Function Compromised**	**20**
		Battery	16
		Device-Related Current Pathway	1
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVBB1D4 Evera XT

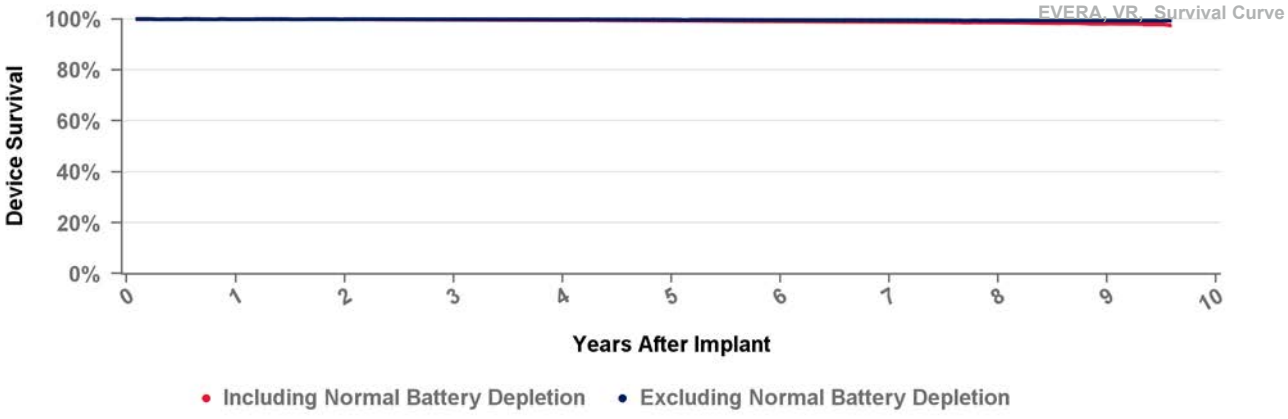
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**81**
CE Approval Date		**Therapy Function Not Compromised**	**51**
Registered USA Implants	43,927	Battery	36
Estimated Active USA Implants	27,133	Electrical Component	9
Normal Battery Depletions	104	Possible Early Battery Depletion	2
		Other	4
		Therapy Function Compromised	**30**
		Battery	25
		Device-Related Current Pathway	4
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVBB2D1 Evera XT

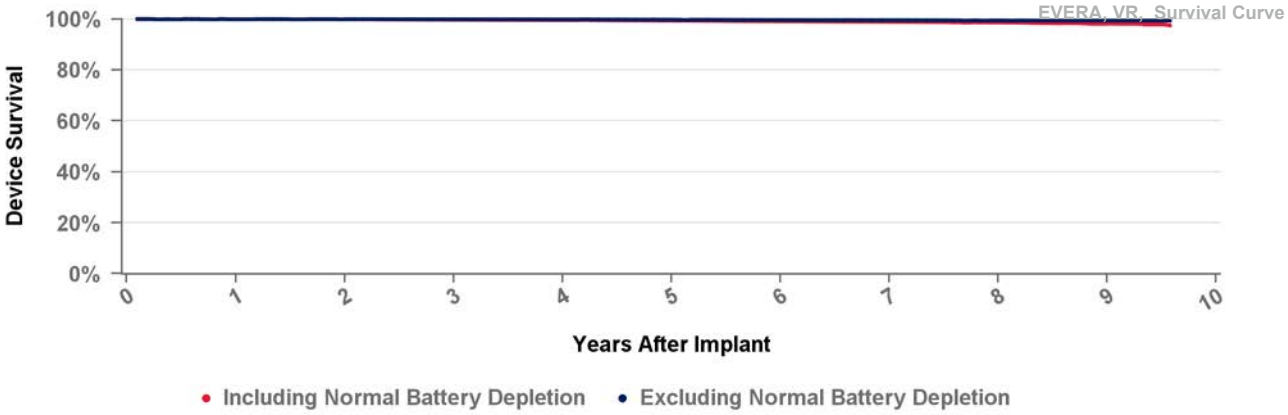
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVBB2D4 Evera XT

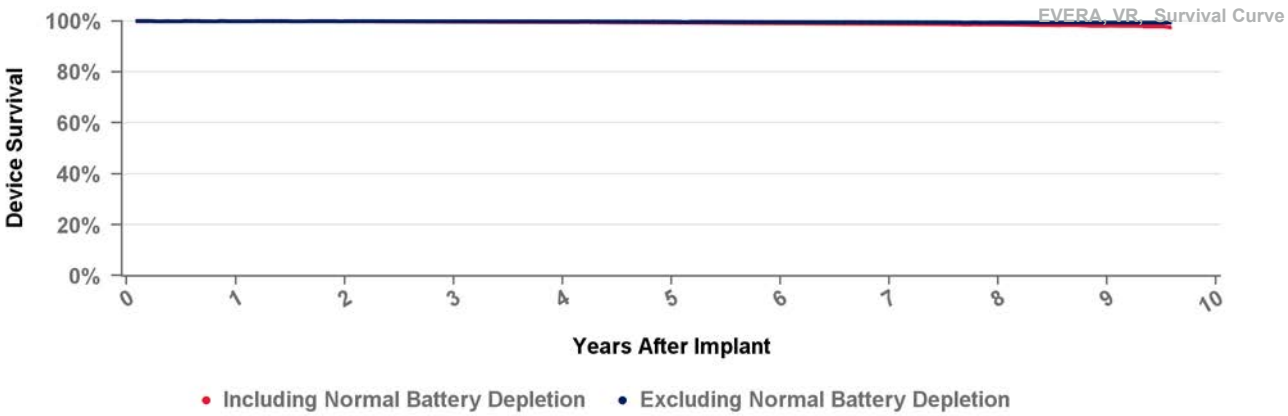
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVBC3D1 Evera S

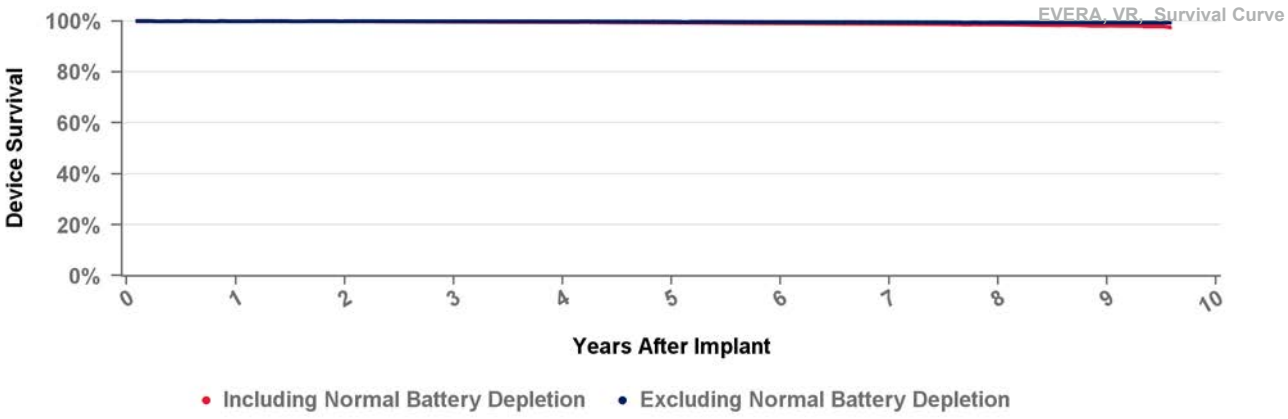
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**26**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**17**
Registered USA Implants	8,961	Battery	15
Estimated Active USA Implants	5,324	Electrical Component	2
Normal Battery Depletions	16	**Therapy Function Compromised**	**9**
		Battery	8
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVBC3D4 Evera S

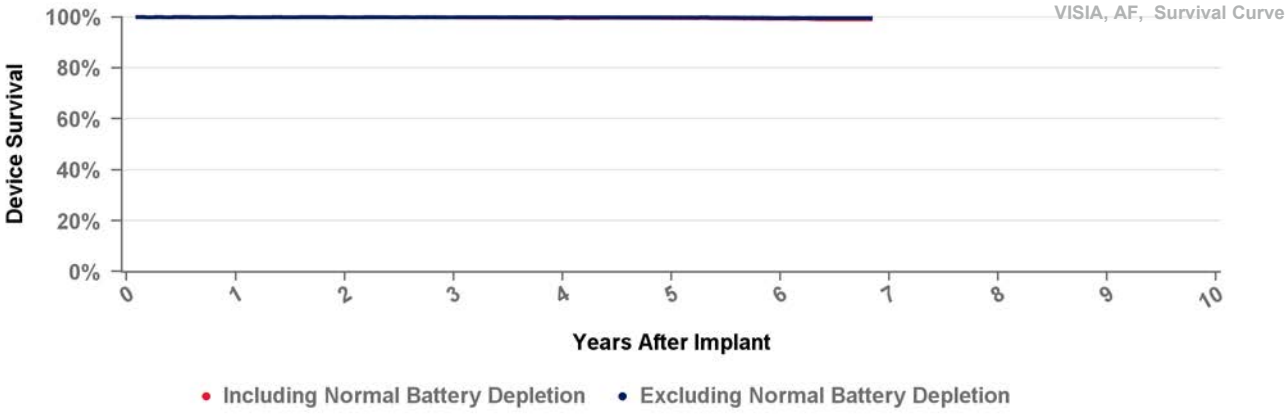
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**18**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**11**
Registered USA Implants	11,103	Battery	8
Estimated Active USA Implants	7,092	Electrical Component	3
Normal Battery Depletions	22	**Therapy Function Compromised**	**7**
		Battery	5
		Device-Related Current Pathway	2



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVFB1D1 Visia MRI AF

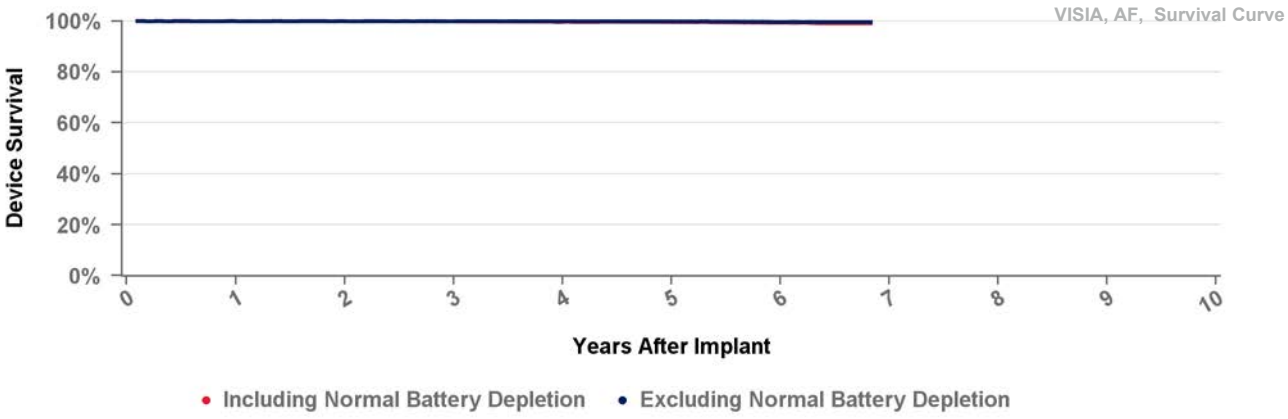
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**15**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	21,084	Battery	6
Estimated Active USA Implants	17,446	Electrical Component	2
Normal Battery Depletions	12	Other	1
		Therapy Function Compromised	**6**
		Battery	2
		Device-Related Current Pathway	2
		Electrical Component	2



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVFB1D4 Visia MRI AF

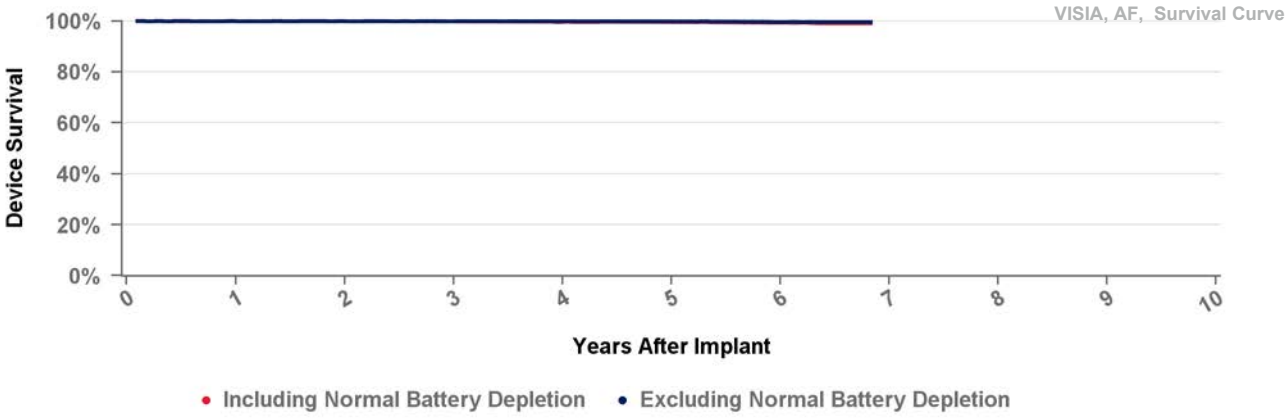
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**57**
CE Approval Date		**Therapy Function Not Compromised**	**34**
Registered USA Implants	69,711	Battery	26
Estimated Active USA Implants	56,790	Electrical Component	7
Normal Battery Depletions	19	Other	1
		Therapy Function Compromised	**23**
		Battery	13
		Device-Related Current Pathway	7
		Electrical Component	3



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVFB2D1 Visia MRI AF XT

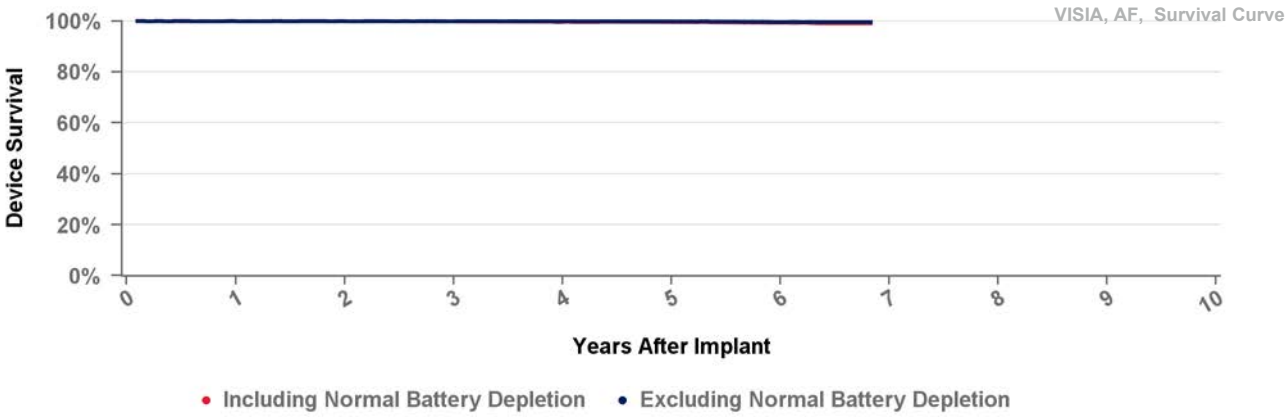
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVFB2D4 Visia MRI AF XT

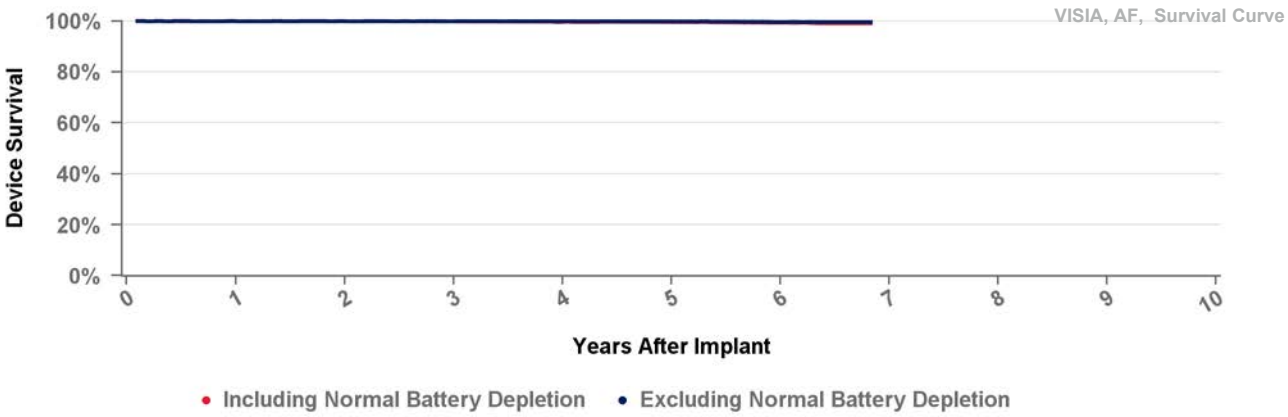
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVFC3D1 Visia MRI AF S

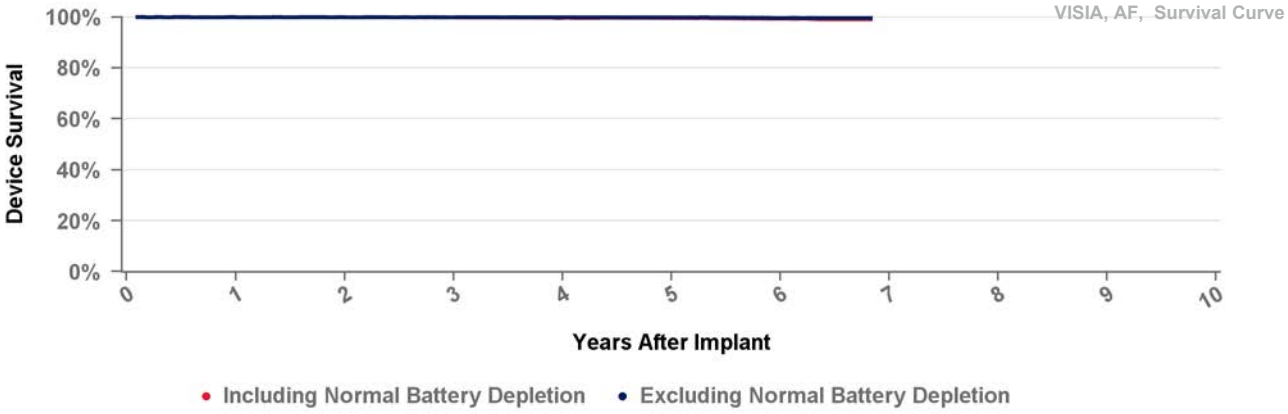
US Market Release	12Oct2016	**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants	1,692		
Estimated Active USA Implants	1,459	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVFC3D4 Visia MRI AF S

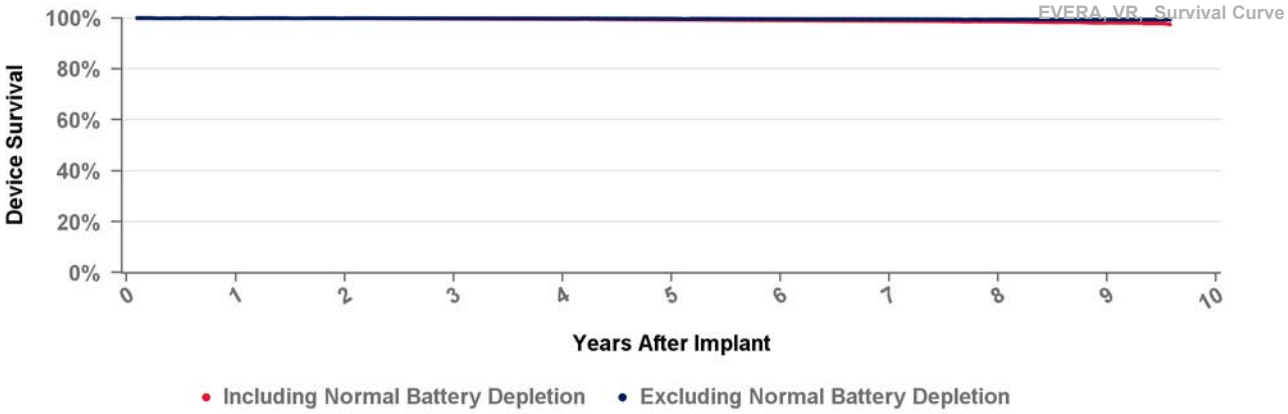
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**3**
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,009	Battery	3
Estimated Active USA Implants	3,423	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.3%	99.2%
Effective Sample Size	70861	60303	48126	34538	21237	8557	410

DVMB1D4 Evera MRI XT

US Market Release	11Sep2015	**Total Malfunctions (USA)**	**31**
CE Approval Date		**Therapy Function Not Compromised**	**15**
Registered USA Implants	20,550	Battery	11
Estimated Active USA Implants	14,198	Electrical Component	3
Normal Battery Depletions	14	Other	1
		Therapy Function Compromised	**16**
		Battery	13
		Device-Related Current Pathway	3

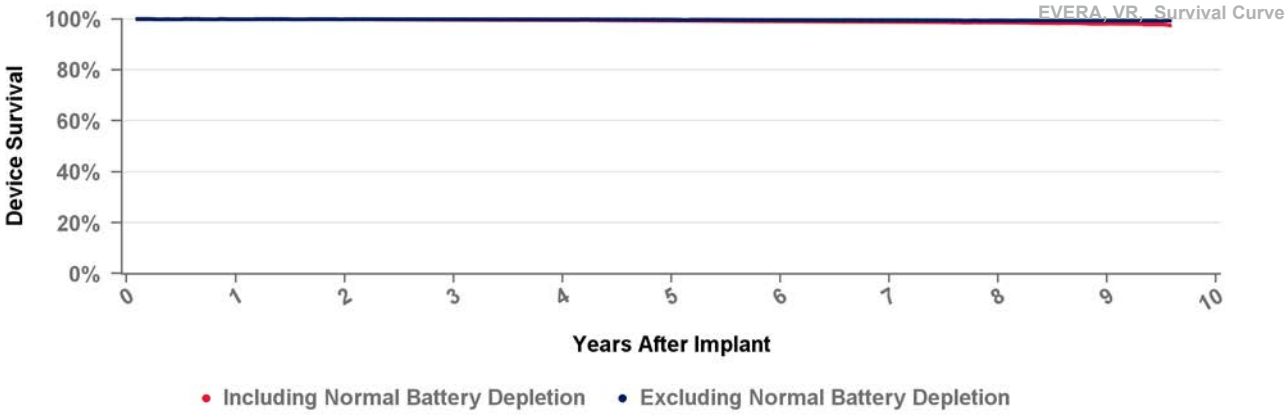


Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMB2D1 Evera MRI XT

US Market Release
CE Approval Date 05Sep2016
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

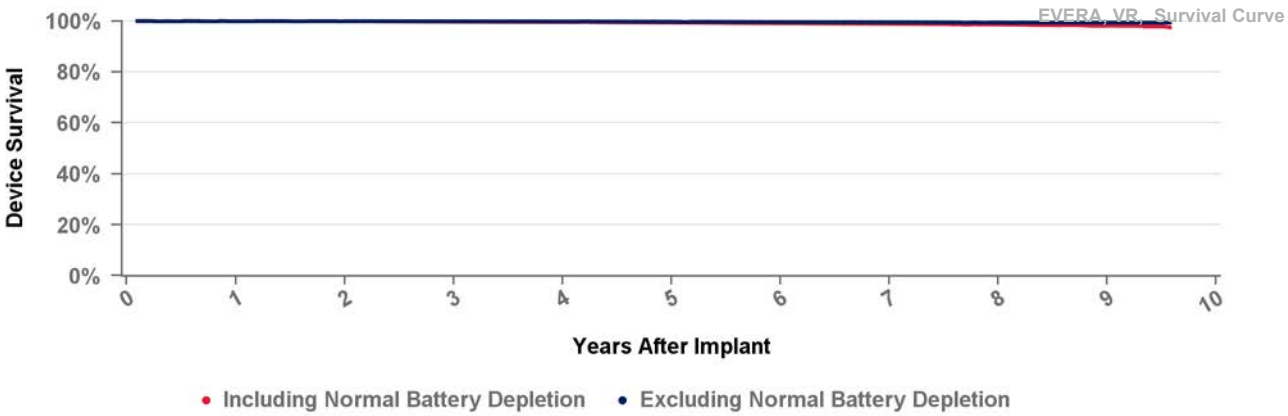


Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMB2D4 Evera MRI XT

US Market Release
CE Approval Date 31Mar2014
Registered USA Implants 2
Estimated Active USA Implants
Normal Battery Depletions

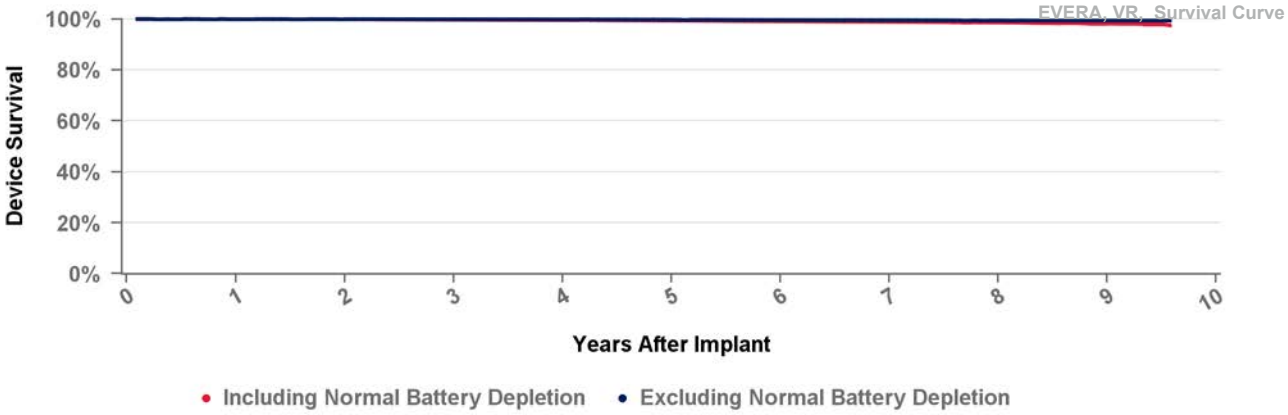
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMC3D1 Evera MRI S

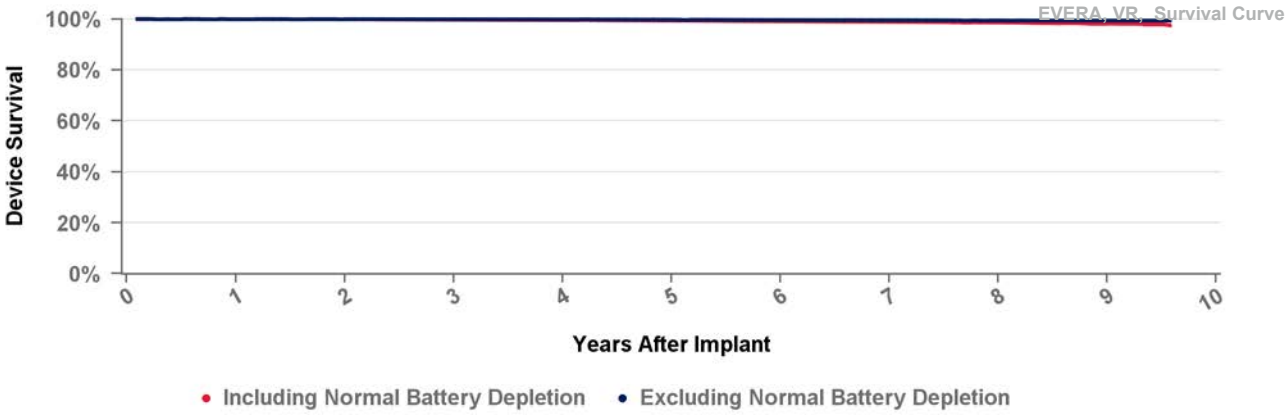
US Market Release	12Oct2016	**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMC3D4 Evera MRI S

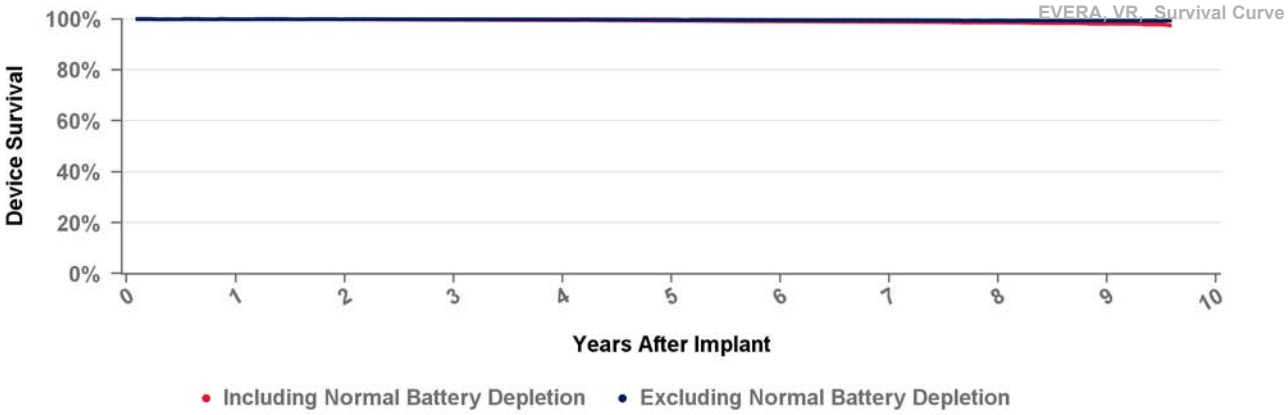
US Market Release	11Sep2015	**Total Malfunctions (USA)**	
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMD3D1 Primo

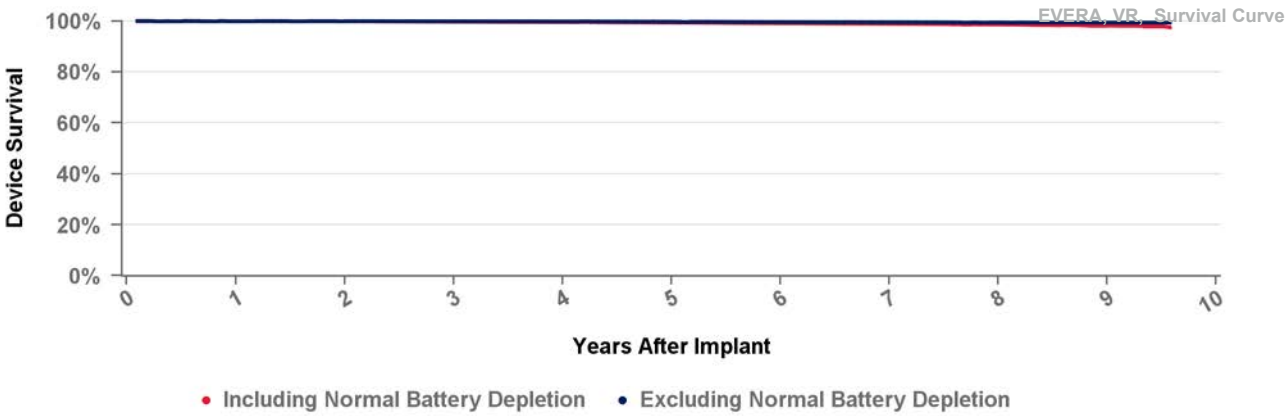
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	256		
Estimated Active USA Implants	234	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVMD3D4 Primo

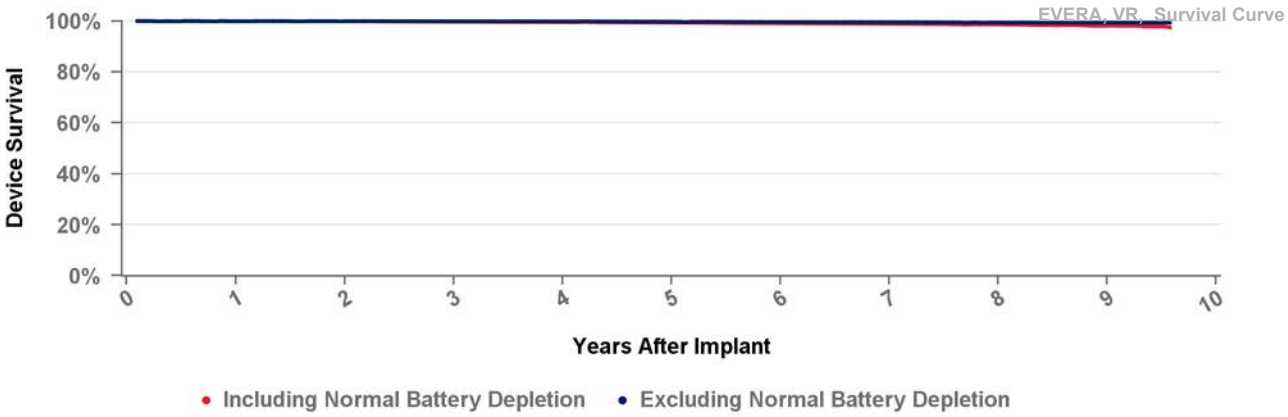
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	522		
Estimated Active USA Implants	486	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVME3D1 Mirro

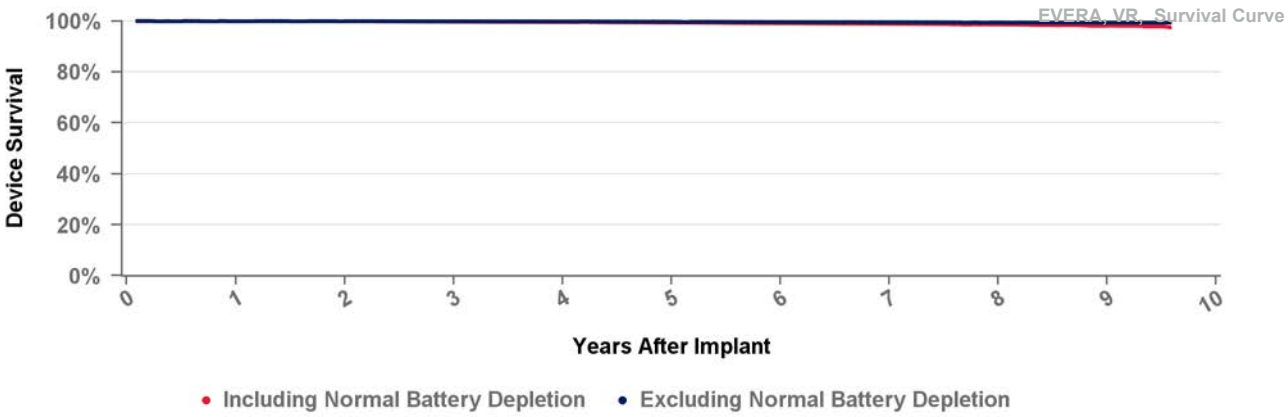
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVME3D4 Mirro

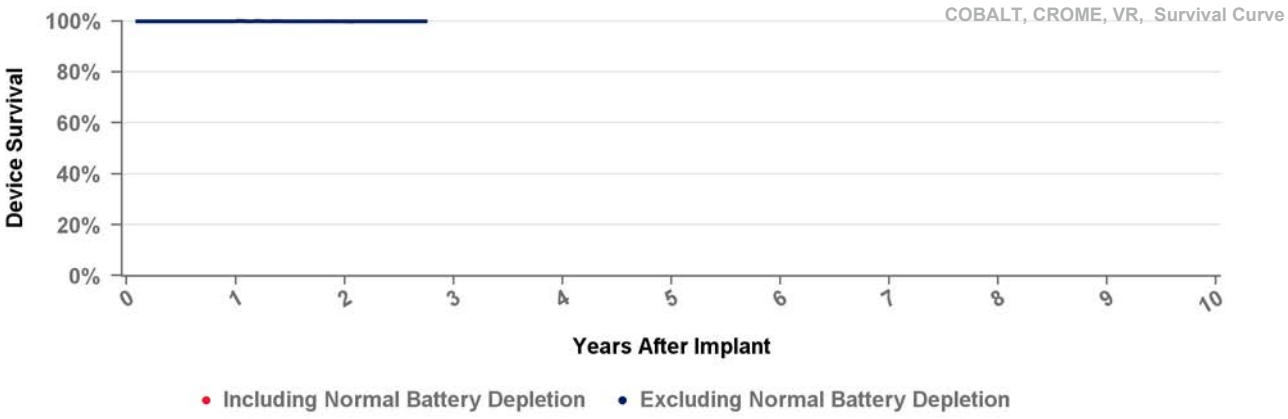
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.6%	99.6%	99.4%	99.4%	99.4%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.2%	97.5%
Effective Sample Size	52379	48741	45279	42174	39094	35860	29329	16096	5160	361

DVPA2D1 Cobalt XT

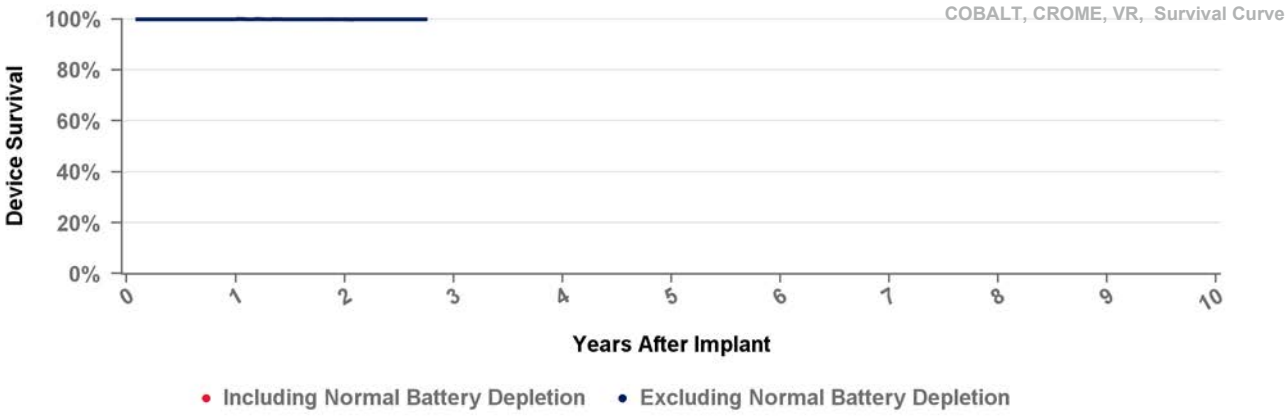
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	1,076		
Estimated Active USA Implants	1,036	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

DVPA2D4 Cobalt XT

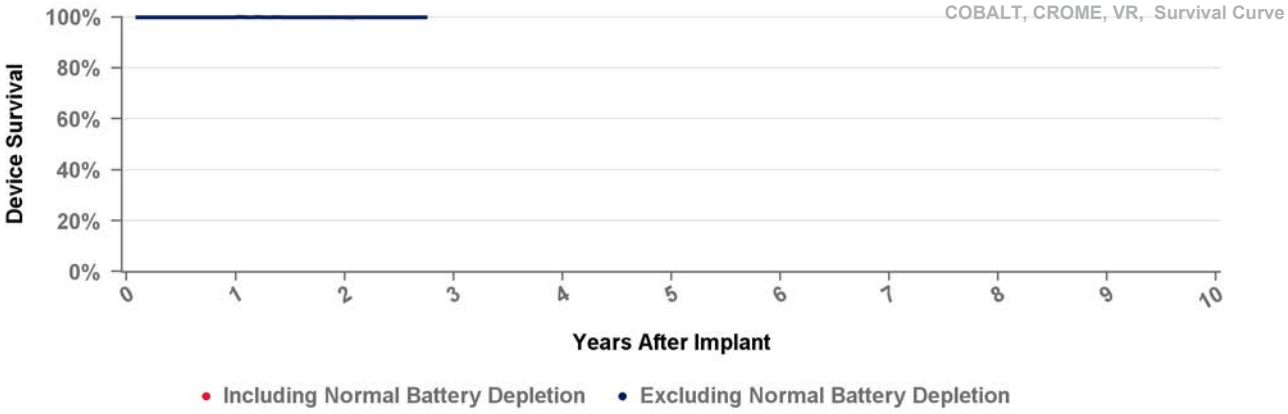
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**0**
Registered USA Implants	5,542		
Estimated Active USA Implants	5,337	**Therapy Function Compromised**	**1**
Normal Battery Depletions		Device-Related Current Pathway	1



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

DVPB3D1 Cobalt

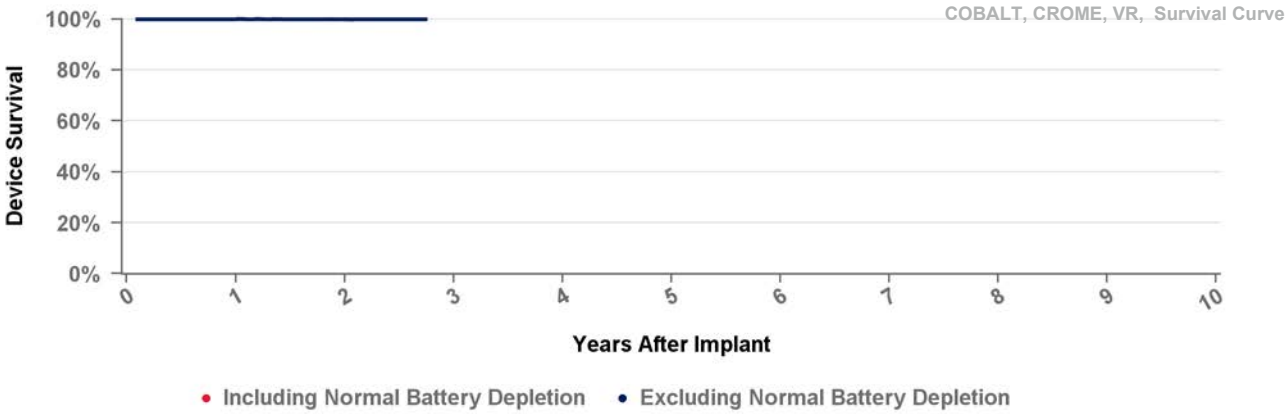
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**2**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,486		
Estimated Active USA Implants	1,403	**Therapy Function Compromised**	**2**
Normal Battery Depletions		Electrical Interconnect	2



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

DVPB3D4 Cobalt

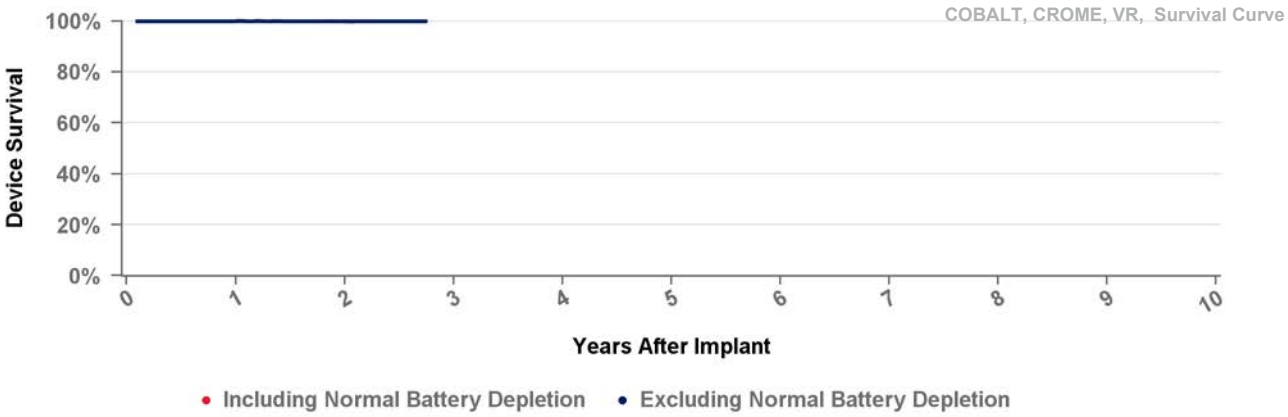
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**3**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**0**
Registered USA Implants	4,514		
Estimated Active USA Implants	4,279	**Therapy Function Compromised**	**3**
Normal Battery Depletions		Device-Related Current Pathway	2
		Electrical Interconnect	1



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

DVPC3D1 Crome

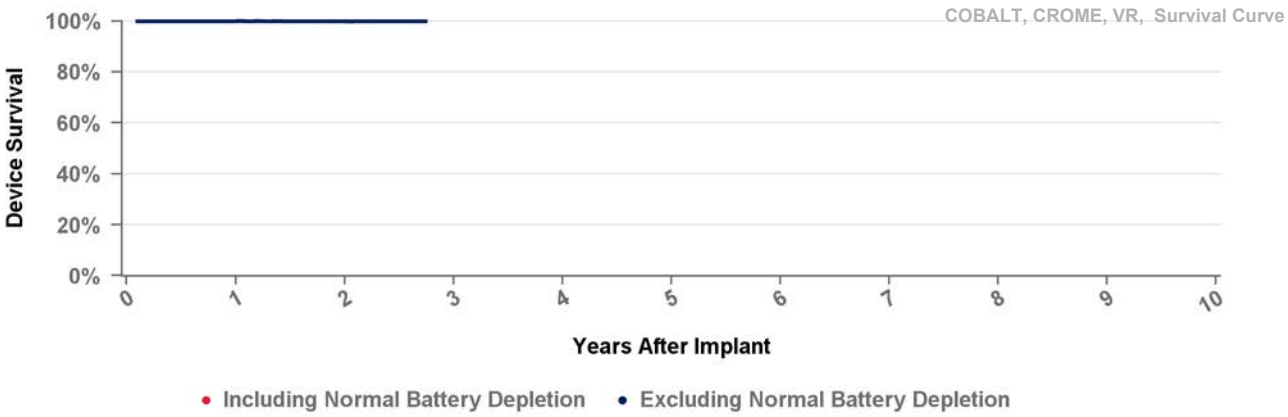
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	116		
Estimated Active USA Implants	110	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

DVPC3D4 Crome

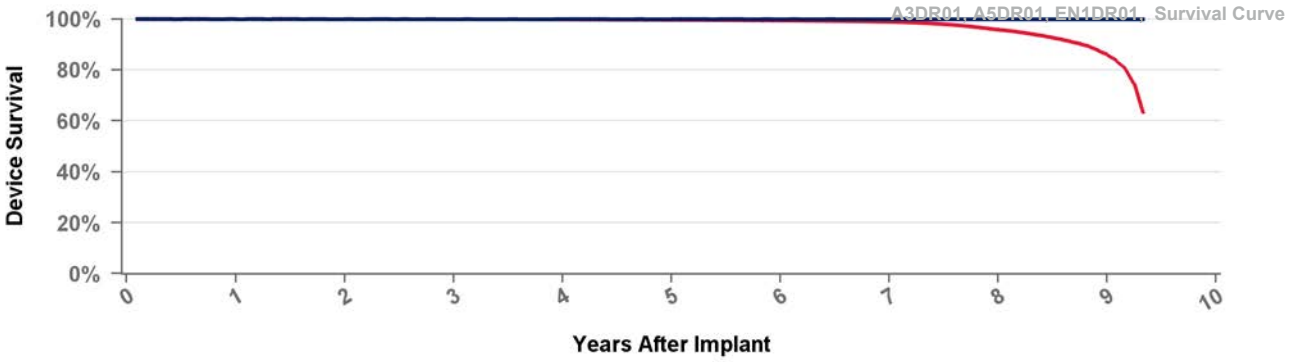
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	356		
Estimated Active USA Implants	336	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 33 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	100.0%	99.8%	99.8%
Effective Sample Size	8109	2816	192

A2DR01 Advisa DR MRI

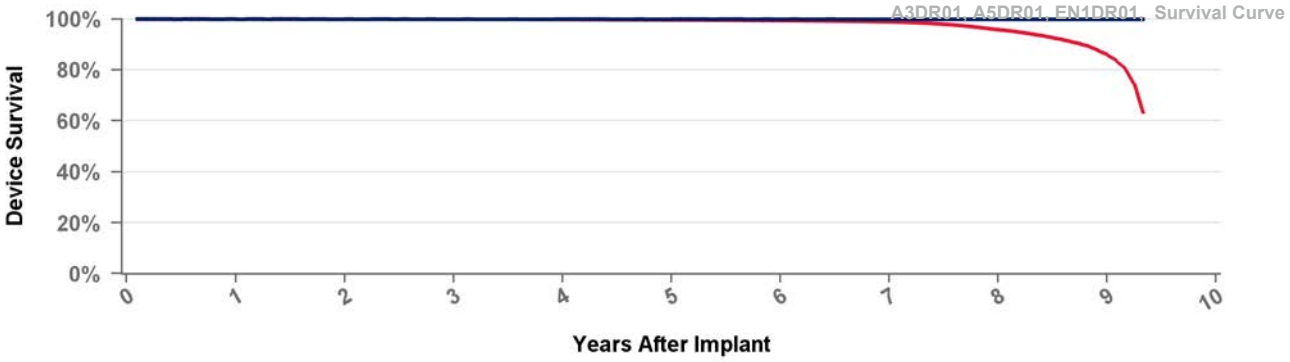
US Market Release	15Jan2013	**Total Malfunctions (USA)**	**74**
CE Approval Date		**Therapy Function Not Compromised**	**69**
Registered USA Implants	344,397	Battery	1
Estimated Active USA Implants	232,139	Electrical Component	34
Normal Battery Depletions	3,316	Electrical Interconnect	4
		Possible Early Battery Depletion	21
		Software/Firmware	6
		Other	3
		Therapy Function Compromised	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	95.8%	86.0%	63.3%
Effective Sample Size	308831	290800	273004	255344	234967	171787	103704	46529	8134	697

A3DR01 Advisa DR MRI

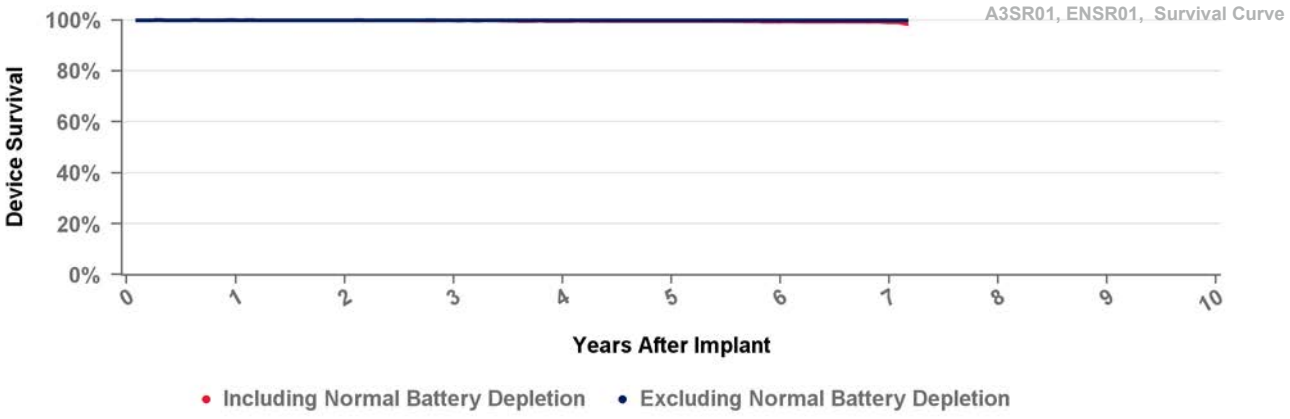
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Jun2009	**Therapy Function Not Compromised**	
Registered USA Implants	15		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	95.8%	86.0%	63.3%
Effective Sample Size	308831	290800	273004	255344	234967	171787	103704	46529	8134	697

A3SR01 Advisa SR MRI

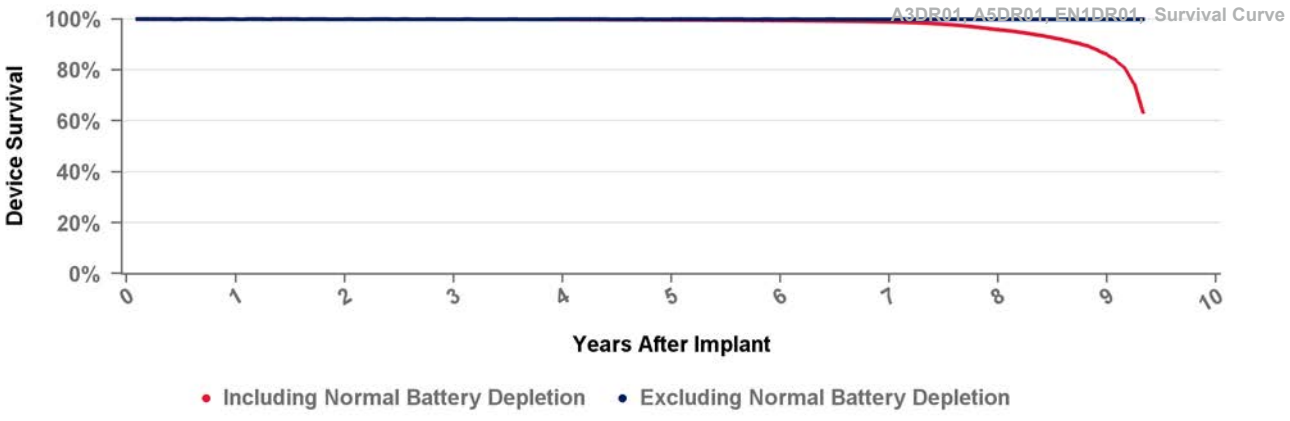
US Market Release	19Mar2015	**Total Malfunctions (USA)**	**9**
CE Approval Date	24Apr2014	**Therapy Function Not Compromised**	**8**
Registered USA Implants	28,081	Electrical Component	3
Estimated Active USA Implants	16,213	Electrical Interconnect	1
Normal Battery Depletions	42	Possible Early Battery Depletion	2
		Other	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	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%	99.6%	99.5%	99.1%	98.3%
Effective Sample Size	22074	19412	17178	14992	12767	7159	1157	249

A5DR01 Advisa DR

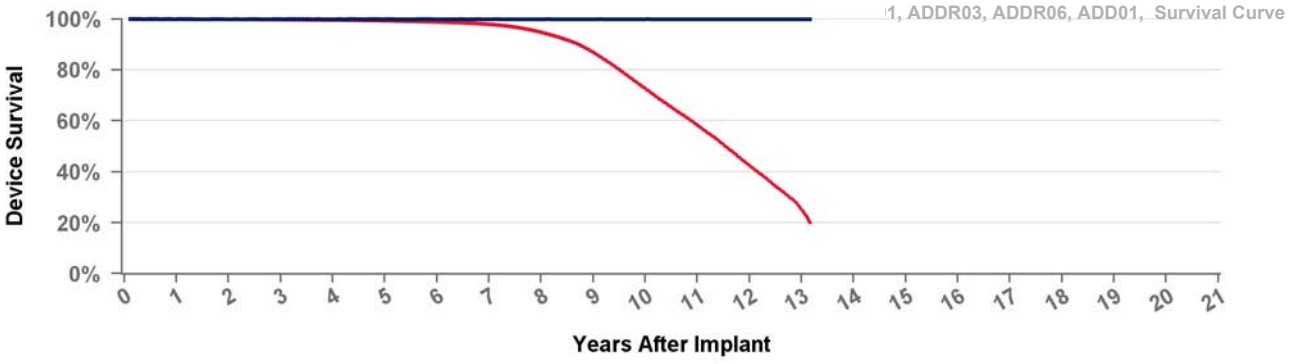
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Jun2009	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	95.8%	86.0%	63.3%
Effective Sample Size	308831	290800	273004	255344	234967	171787	103704	46529	8134	697

ADD01 Adapta D

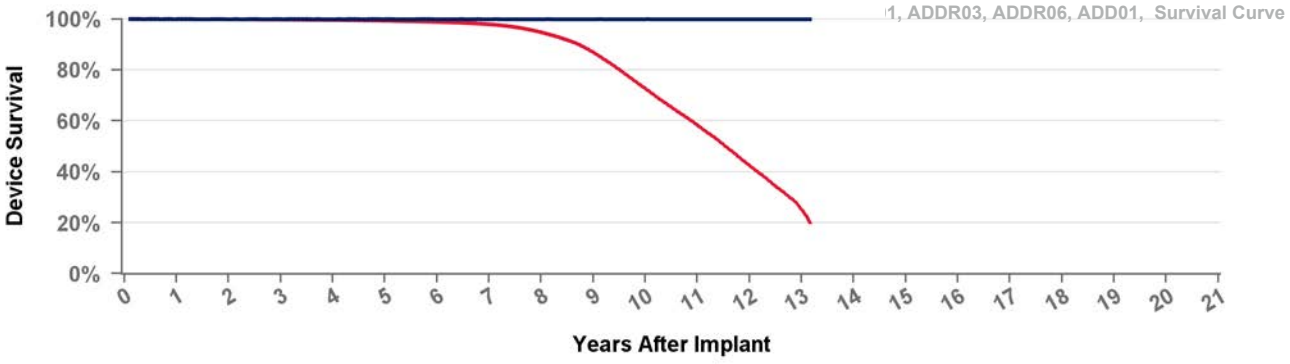
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

ADDR01 Adapta DR

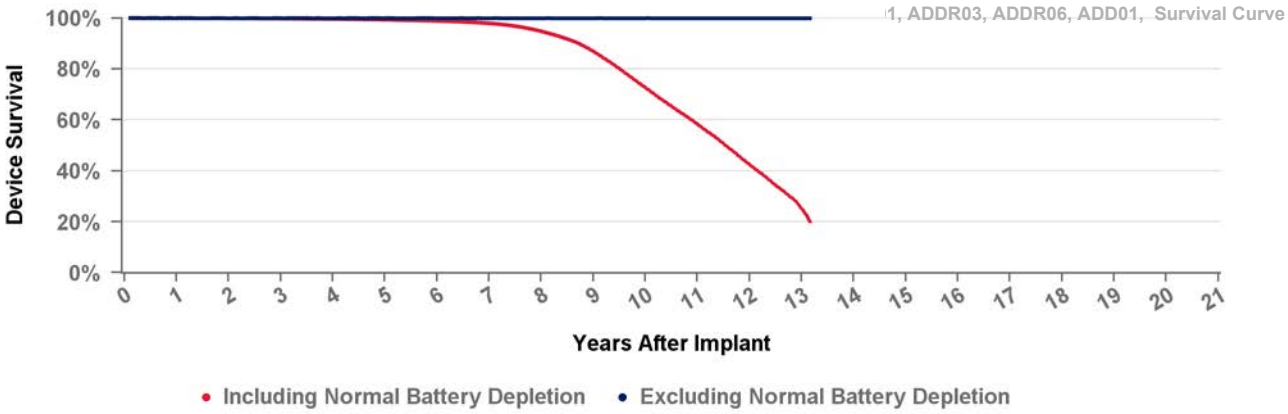
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**94**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**66**
Registered USA Implants	454,855	Electrical Component	58
Estimated Active USA Implants	134,118	Electrical Interconnect	1
Normal Battery Depletions	44,360	Possible Early Battery Depletion	6
		Other	1
		Therapy Function Compromised	**28**
		Electrical Component	23
		Electrical Interconnect	3
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

ADDR03 Adapta DR

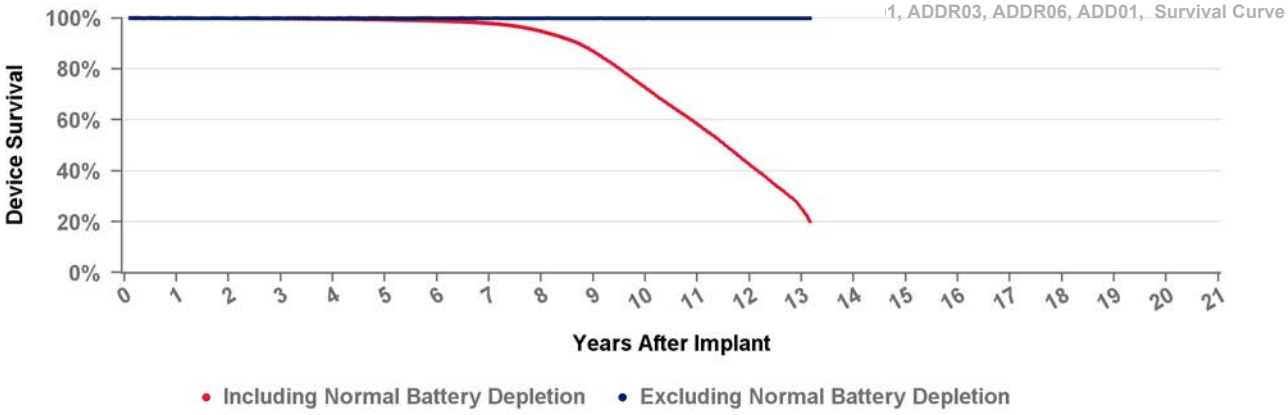
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**2**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,514	Electrical Component	1
Estimated Active USA Implants	1,377	**Therapy Function Compromised**	**1**
Normal Battery Depletions	555	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

ADDR06 Adapta DR

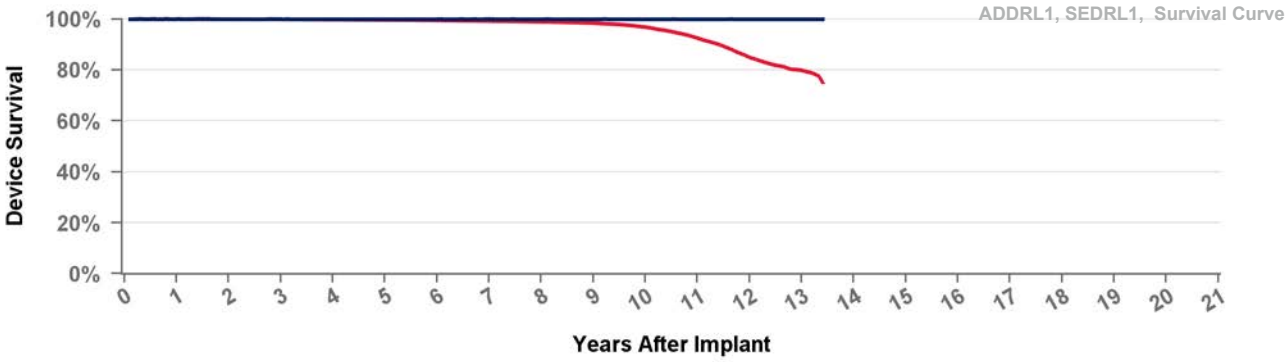
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**1**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,583	Electrical Component	1
Estimated Active USA Implants	886	**Therapy Function Compromised**	**0**
Normal Battery Depletions	410		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

ADDRL1 Adapta L DR

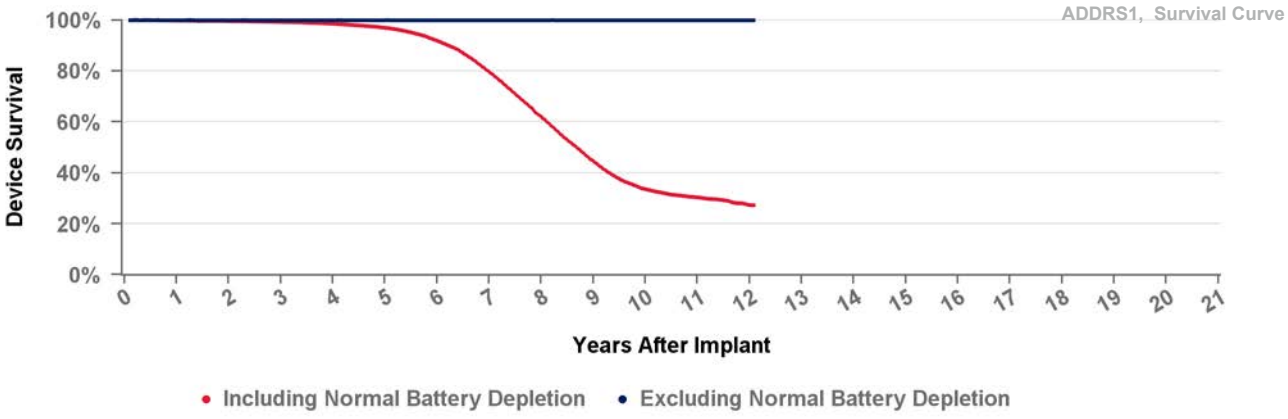
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**24**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**17**
Registered USA Implants	138,598	Electrical Component	13
Estimated Active USA Implants	70,524	Electrical Interconnect	1
Normal Battery Depletions	2,846	Possible Early Battery Depletion	2
		Software/Firmware	1
		Therapy Function Compromised	**7**
		Electrical Component	4
		Electrical Interconnect	1
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 161 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.4%	96.8%	92.5%	84.9%	79.9%	74.9%
Effective Sample Size	119815	112804	106035	99367	92042	83154	72394	60611	48119	35058	22227	11085	2591	122

ADDRS1 Adapta S DR

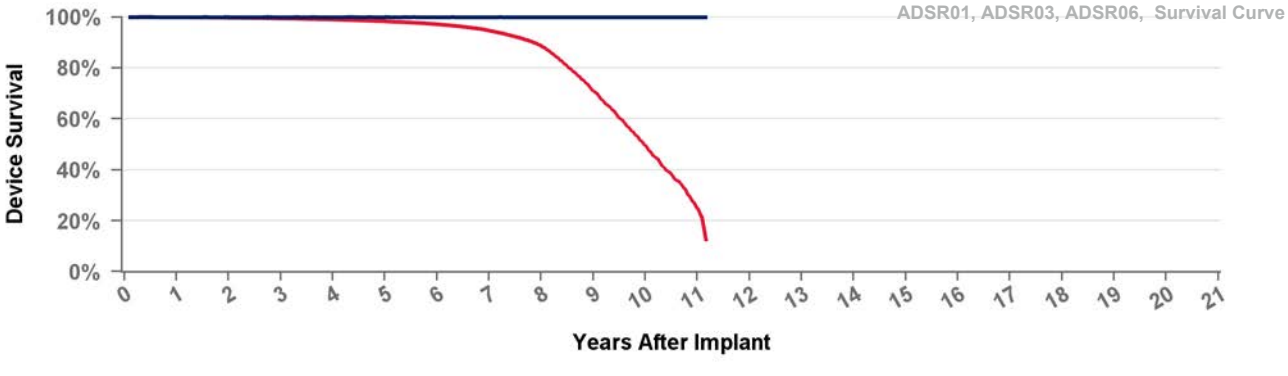
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**15**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**9**
Registered USA Implants	49,296	Electrical Component	5
Estimated Active USA Implants	10,609	Possible Early Battery Depletion	3
Normal Battery Depletions	6,260	Other	1
		Therapy Function Compromised	**6**
		Electrical Component	4
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.6%	99.3%	98.6%	97.0%	91.8%	79.6%	61.9%	44.5%	33.6%	30.4%	27.3%	27.3%
Effective Sample Size	40111	36075	32222	28623	25092	20704	14990	9288	4948	2349	1156	200	125

ADSR01 Adapta SR

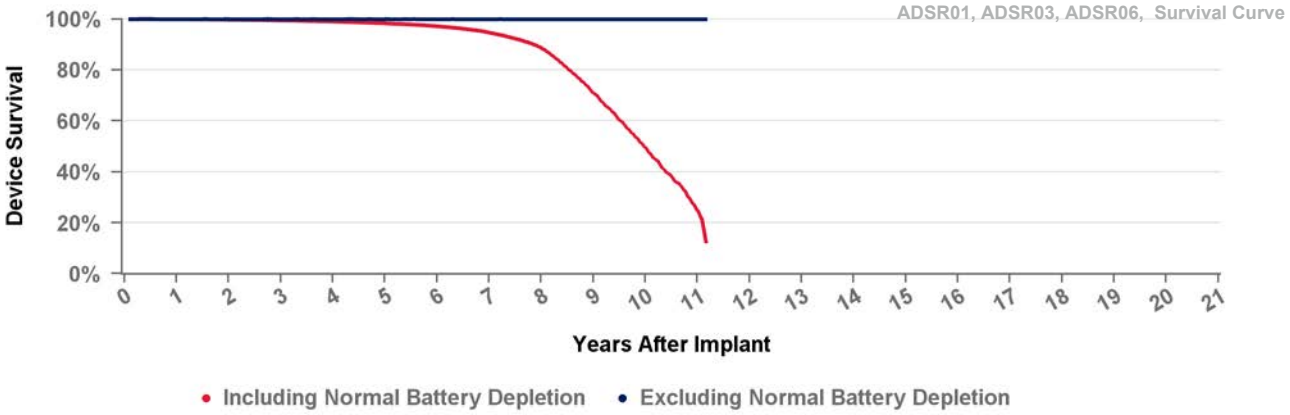
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**18**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**12**
Registered USA Implants	91,656	Electrical Component	7
Estimated Active USA Implants	20,710	Electrical Interconnect	1
Normal Battery Depletions	5,750	Possible Early Battery Depletion	4
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	99.0%	98.3%	97.2%	94.7%	88.6%	71.1%	49.7%	25.1%	12.5%
Effective Sample Size	72017	62921	54925	47766	40980	34684	28455	21008	11866	4863	619	119

ADSR03 Adapta SR

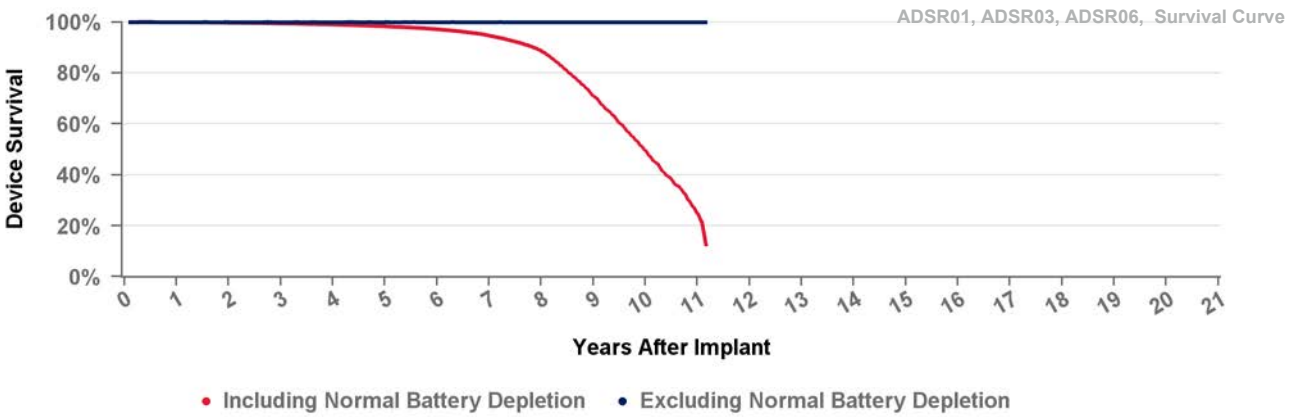
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	2,114		
Estimated Active USA Implants	455	**Therapy Function Compromised**	
Normal Battery Depletions	184		



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	99.0%	98.3%	97.2%	94.7%	88.6%	71.1%	49.7%	25.1%	12.5%
Effective Sample Size	72017	62921	54925	47766	40980	34684	28455	21008	11866	4863	619	119

ADSR06 Adapta SR

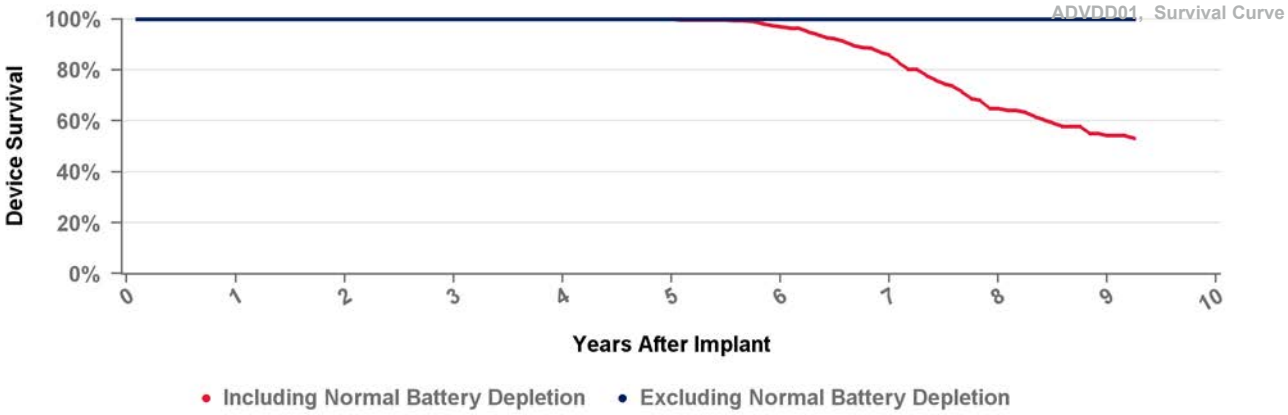
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**2**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,878	Electrical Component	2
Estimated Active USA Implants	627	**Therapy Function Compromised**	**0**
Normal Battery Depletions	255		



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	99.0%	98.3%	97.2%	94.7%	88.6%	71.1%	49.7%	25.1%	12.5%
Effective Sample Size	72017	62921	54925	47766	40980	34684	28455	21008	11866	4863	619	119

ADVDD01 Adapta VDD

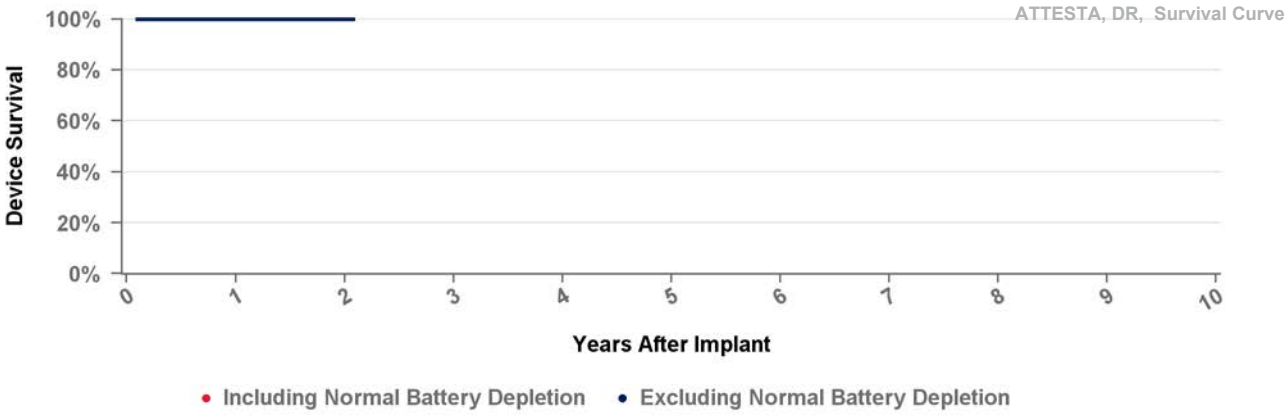
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	854		
Estimated Active USA Implants	222	**Therapy Function Compromised**	
Normal Battery Depletions	95		



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	100.0%	100.0%	100.0%	100.0%	100.0%	97.0%	85.8%	64.9%	54.2%	53.1%
Effective Sample Size	698	637	574	523	468	405	312	178	114	104

ATDR01 Attesta DR MRI

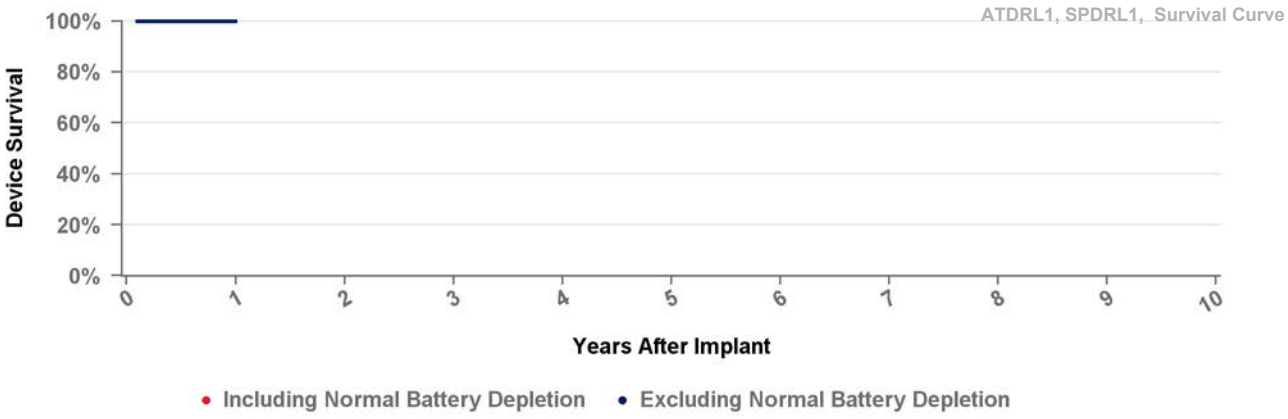
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1,359		
Estimated Active USA Implants	1,334	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 25 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	803	137	109

ATDRL1 Attesta L DR MRI

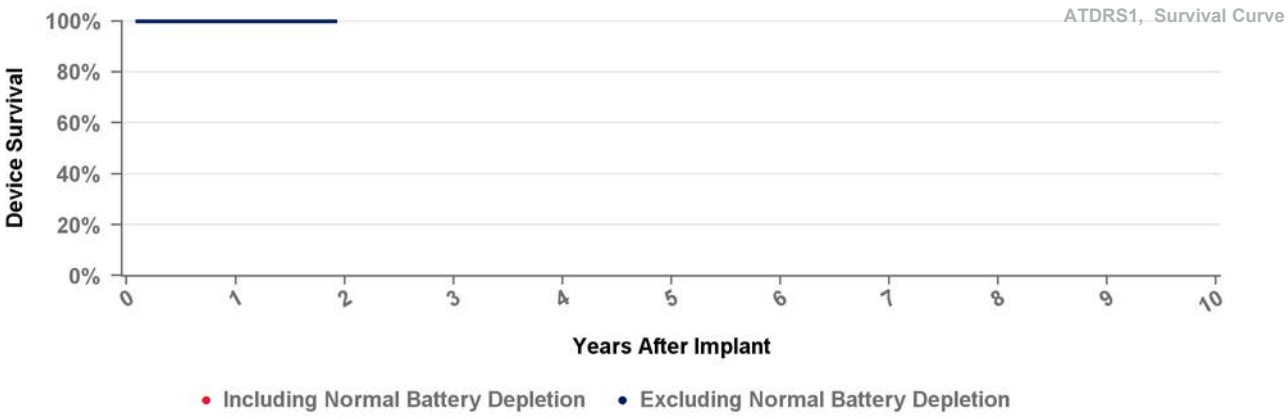
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	199		
Estimated Active USA Implants	193	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 12 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	109

ATDRS1 Attesta S DR MRI

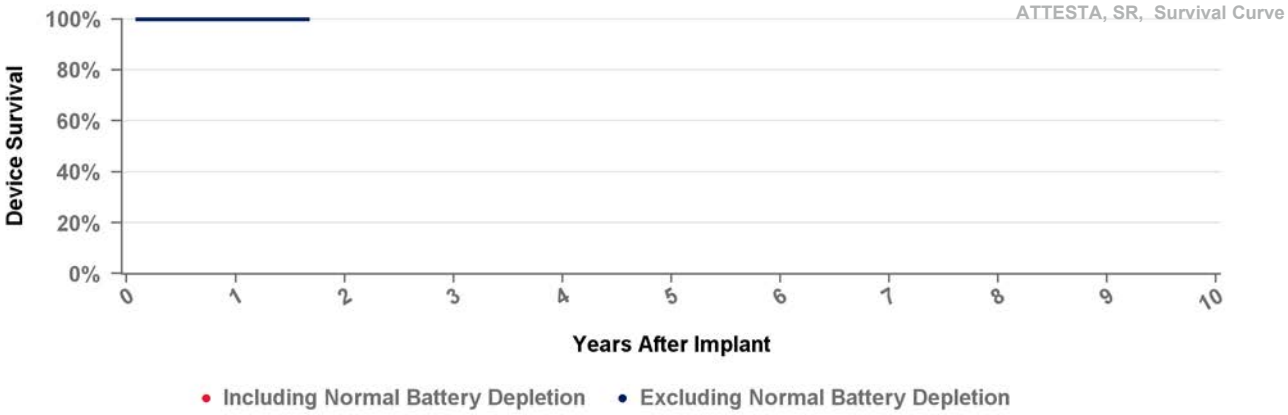
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	872		
Estimated Active USA Implants	817	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 23 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	441	110

ATSR01 Attesta SR MRI

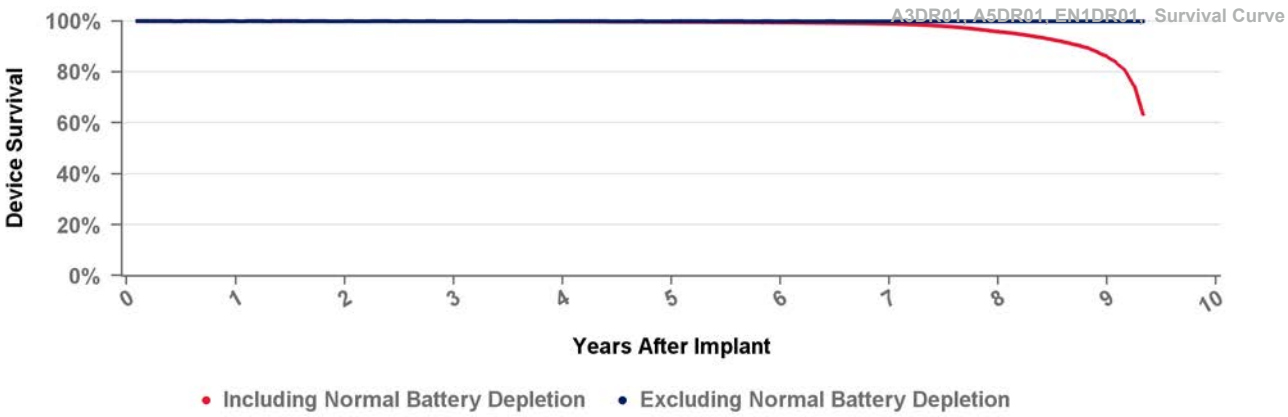
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	674		
Estimated Active USA Implants	549	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	at 20 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	300	114

EN1DR01 Ensura MRI

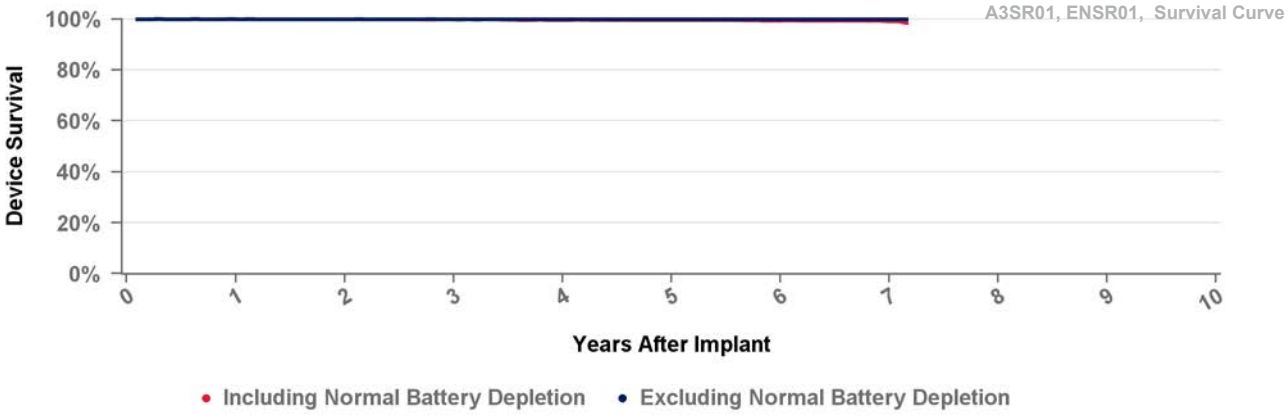
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	23Jun2010	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 112 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	95.8%	86.0%	63.3%
Effective Sample Size	308831	290800	273004	255344	234967	171787	103704	46529	8134	697

EN1SR01 Ensura SR MRI

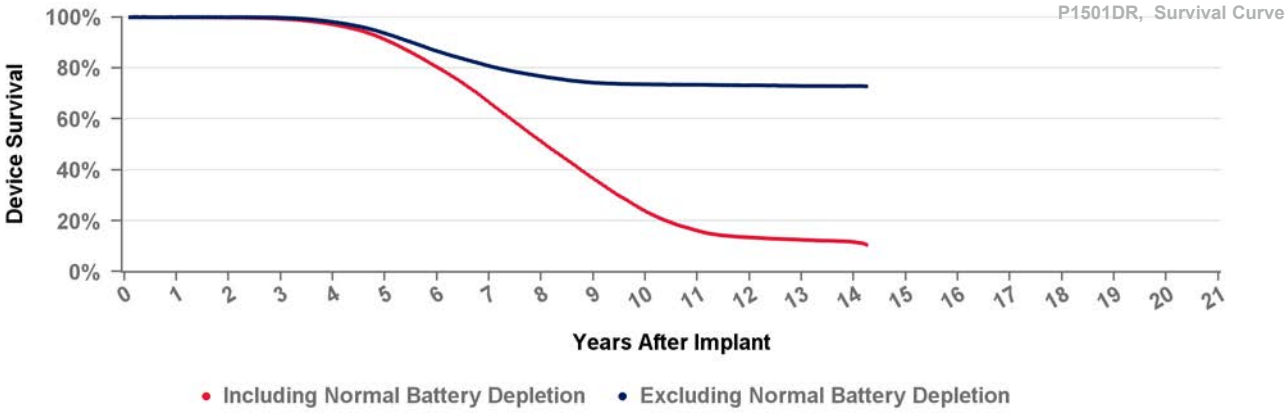
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	24Apr2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	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%	99.6%	99.5%	99.1%	98.3%
Effective Sample Size	22074	19412	17178	14992	12767	7159	1157	249

P1501DR EnRhythm DR

US Market Release	05May2005	**Total Malfunctions (USA)**	**15,167**
CE Approval Date	13Aug2004	**Therapy Function Not Compromised**	**15,112**
Registered USA Implants	109,982	Battery	14,981
Estimated Active USA Implants	7,734	Electrical Component	59
Normal Battery Depletions	17,528	Electrical Interconnect	2
		Possible Early Battery Depletion	69
		Other	1
		Therapy Function Compromised	**55**
		Battery	6
		Electrical Component	38
		Electrical Interconnect	4
		Possible Early Battery Depletion	2
		Other	5

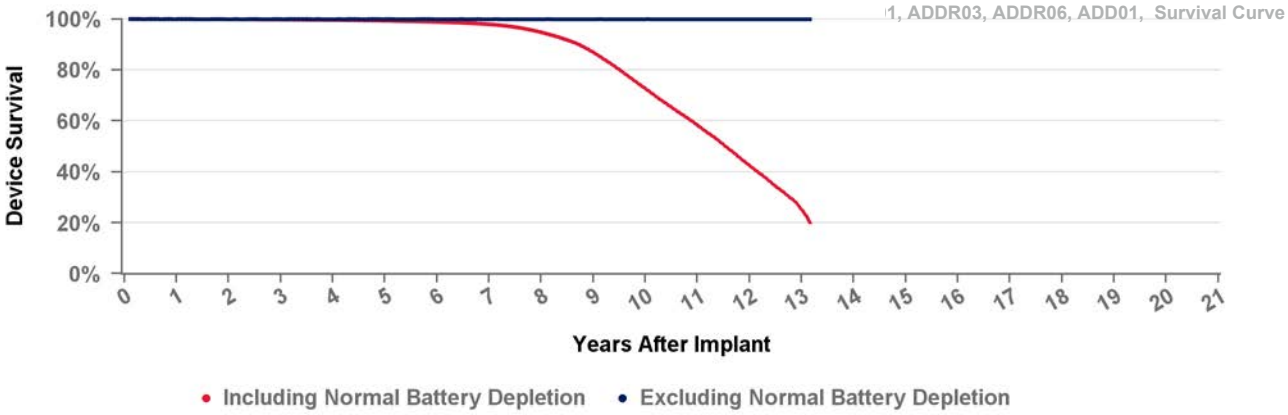


Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 171 mo
Excluding NBD	100.0%	100.0%	99.7%	98.1%	93.6%	86.6%	80.8%	76.7%	74.2%	73.6%	73.4%	73.2%	72.9%	72.8%	72.8%
Including NBD	99.9%	99.8%	99.3%	97.1%	91.1%	80.3%	66.5%	51.1%	36.5%	23.7%	16.1%	13.5%	12.5%	11.7%	10.5%
Effective Sample Size	94971	88746	82392	74746	64541	51278	37787	25048	15163	8307	4688	3074	1713	482	185

RED01 Relia D

US Market Release
CE Approval Date 07May2008
Registered USA Implants 1
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

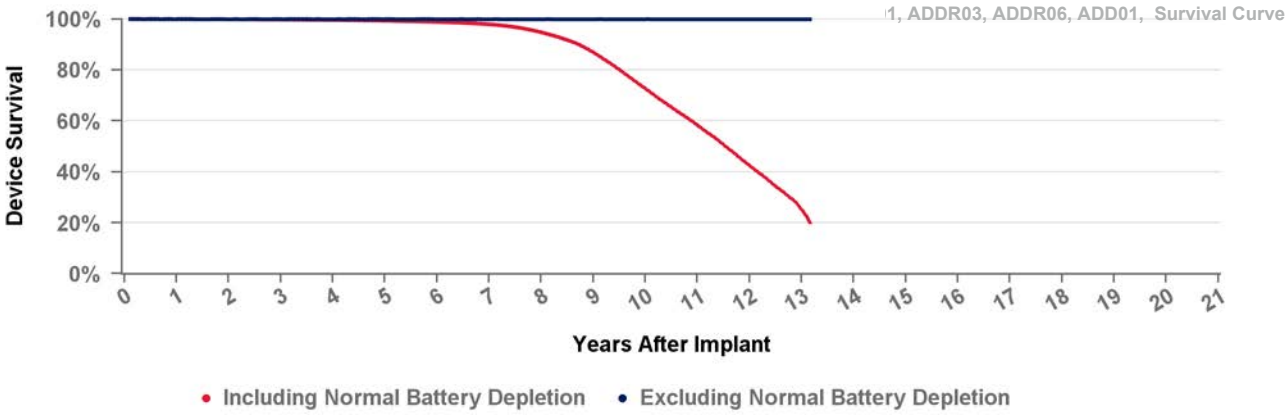


Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

REDR01 Relia DR

US Market Release
CE Approval Date 07May2008
Registered USA Implants 6
Estimated Active USA Implants 2
Normal Battery Depletions 1

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

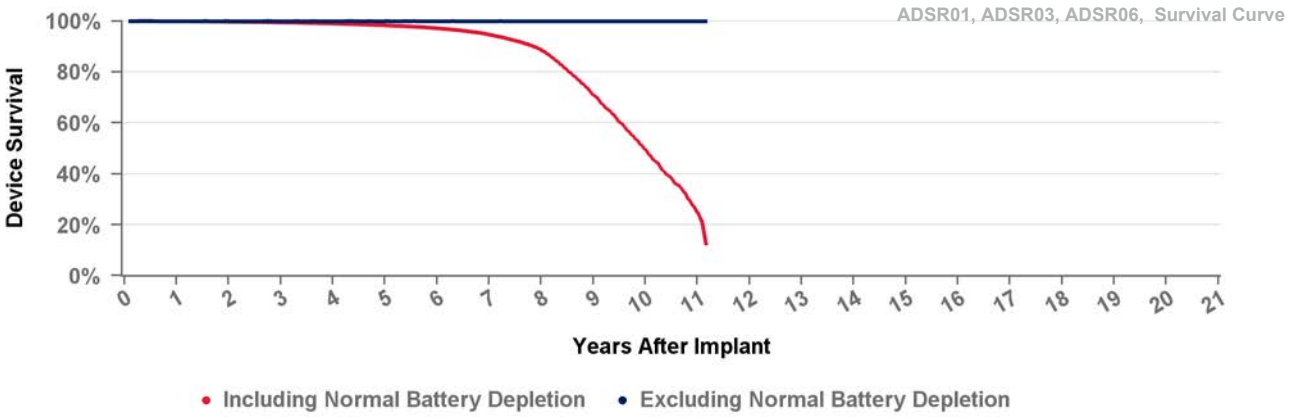


Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 158 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.4%	98.9%	97.9%	94.8%	86.9%	72.6%	58.2%	42.4%	25.4%	20.0%
Effective Sample Size	393192	365260	338498	312352	287457	260389	230174	194921	148759	97490	55392	24041	3647	1238

RES01 Relia S

US Market Release
CE Approval Date 07May2008
Registered USA Implants 1
Estimated Active USA Implants 1
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised

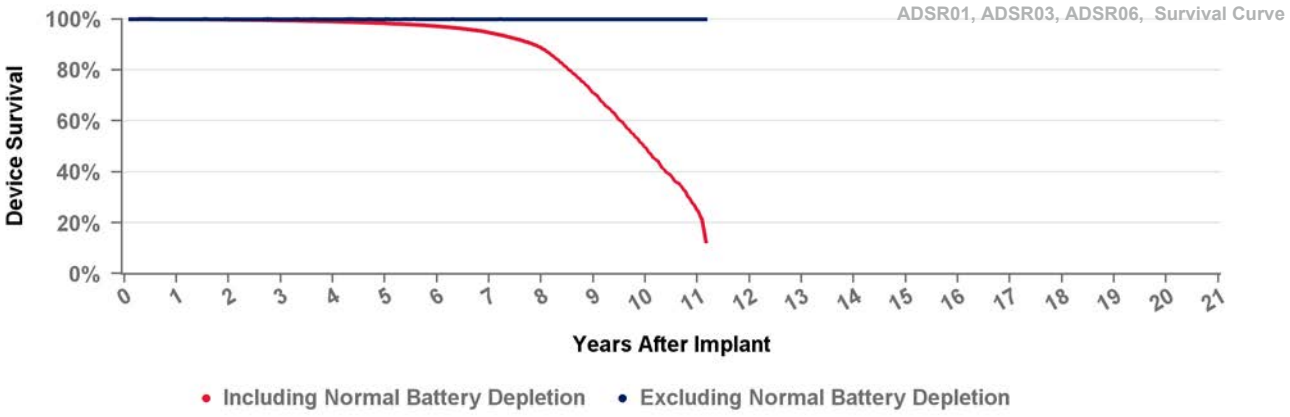


Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	99.0%	98.3%	97.2%	94.7%	88.6%	71.1%	49.7%	25.1%	12.5%
Effective Sample Size	72017	62921	54925	47766	40980	34684	28455	21008	11866	4863	619	119

RESR01 Relia SR

US Market Release
CE Approval Date 07May2008
Registered USA Implants 6
Estimated Active USA Implants
Normal Battery Depletions

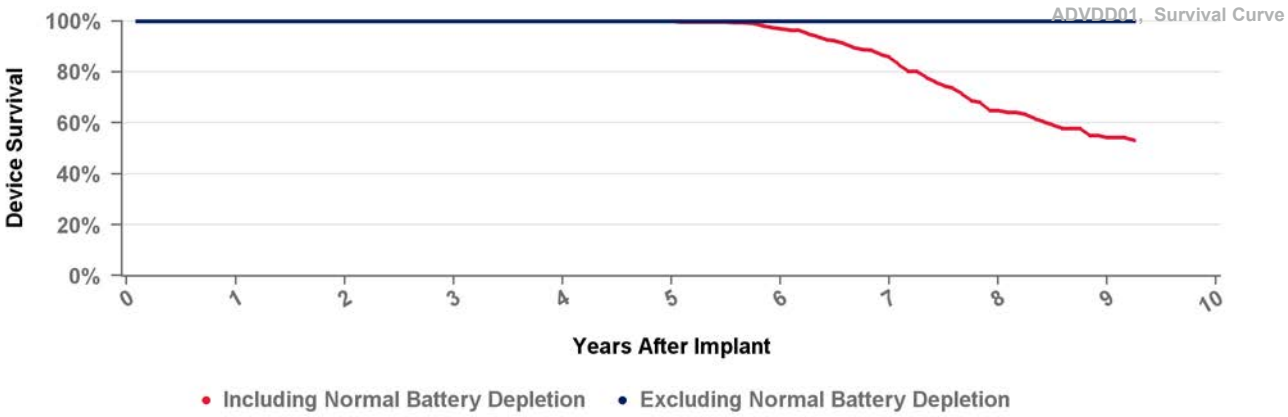
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.7%	99.5%	99.0%	98.3%	97.2%	94.7%	88.6%	71.1%	49.7%	25.1%	12.5%
Effective Sample Size	72017	62921	54925	47766	40980	34684	28455	21008	11866	4863	619	119

REVDD01 Relia VDD

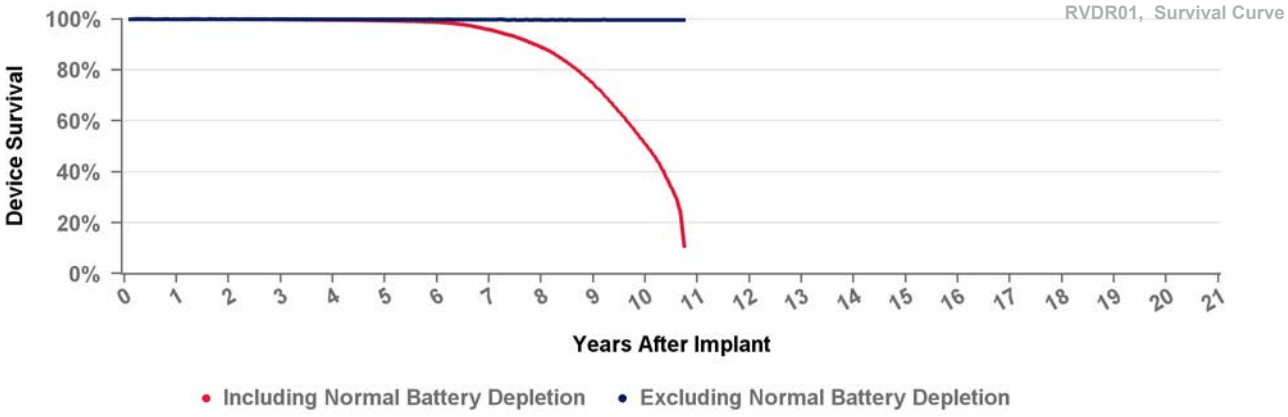
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.0%	85.8%	64.9%	54.2%	53.1%
Effective Sample Size	698	637	574	523	468	405	312	178	114	104

RVDR01 Revo MRI SureScan

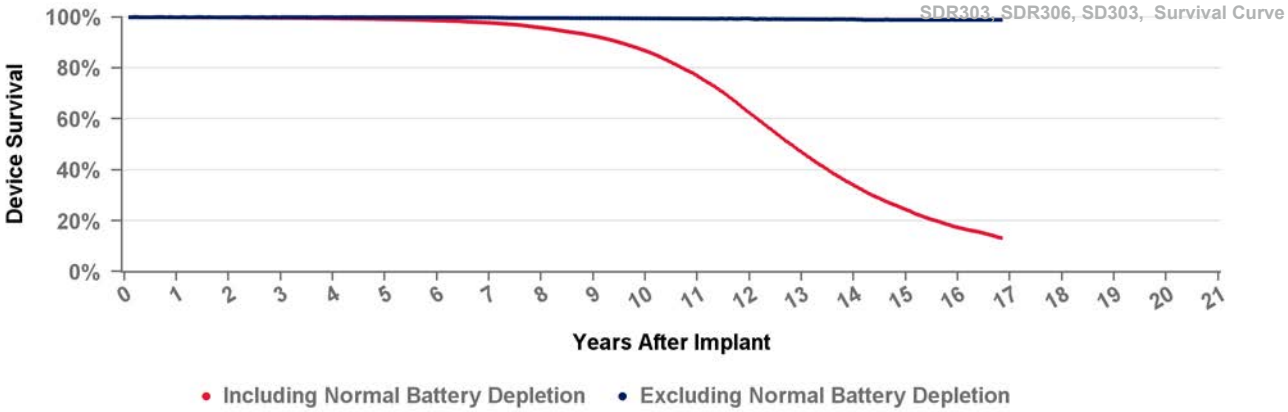
US Market Release	08Feb2011	**Total Malfunctions (USA)**	**111**
CE Approval Date		**Therapy Function Not Compromised**	**108**
Registered USA Implants	69,108	Battery	1
Estimated Active USA Implants	18,418	Electrical Component	40
Normal Battery Depletions	9,812	Electrical Interconnect	1
		Possible Early Battery Depletion	61
		Software/Firmware	4
		Other	1
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	10	at 129 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.4%	98.8%	95.9%	88.9%	74.5%	51.1%	10.7%
Effective Sample Size	59299	56139	53123	49954	46250	42232	37390	30794	21897	10469	450

SD303 Sigma 300 D

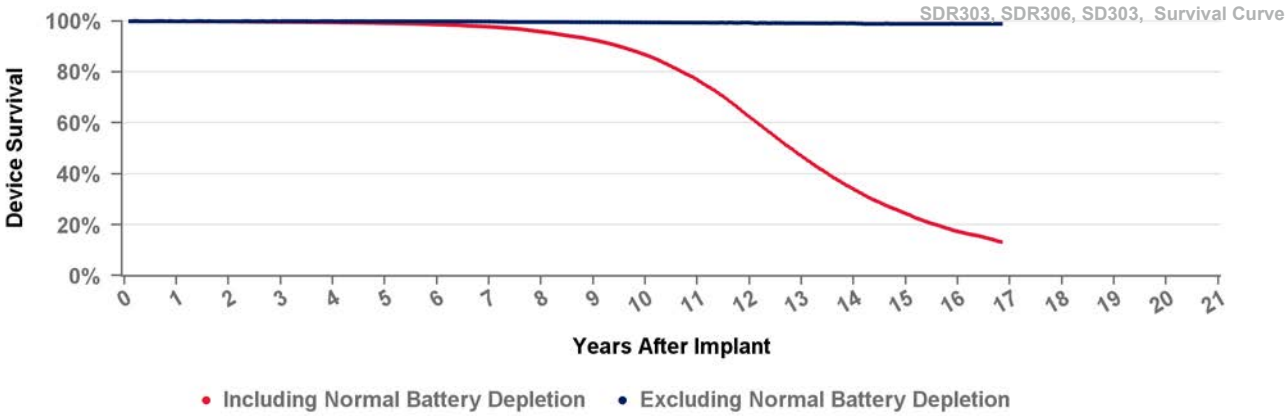
US Market Release	26Aug1999	**Total Malfunctions (USA)**	**2**
CE Approval Date	17Dec1998	**Therapy Function Not Compromised**	**0**
Registered USA Implants	124		
Estimated Active USA Implants	18	**Therapy Function Compromised**	**2**
Normal Battery Depletions	7	Electrical Interconnect	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 202 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.6%	99.5%	99.5%	99.3%	99.3%	99.2%	99.0%	99.0%	99.0%	99.0%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.6%	97.8%	95.8%	92.6%	86.7%	76.8%	62.2%	46.9%	33.9%	24.4%	17.4%	13.2%
Effective Sample Size	86426	77420	69084	61256	53949	47361	41017	35248	29917	24487	18928	12549	7104	3690	1879	806	137

SDR303 Sigma 300 DR

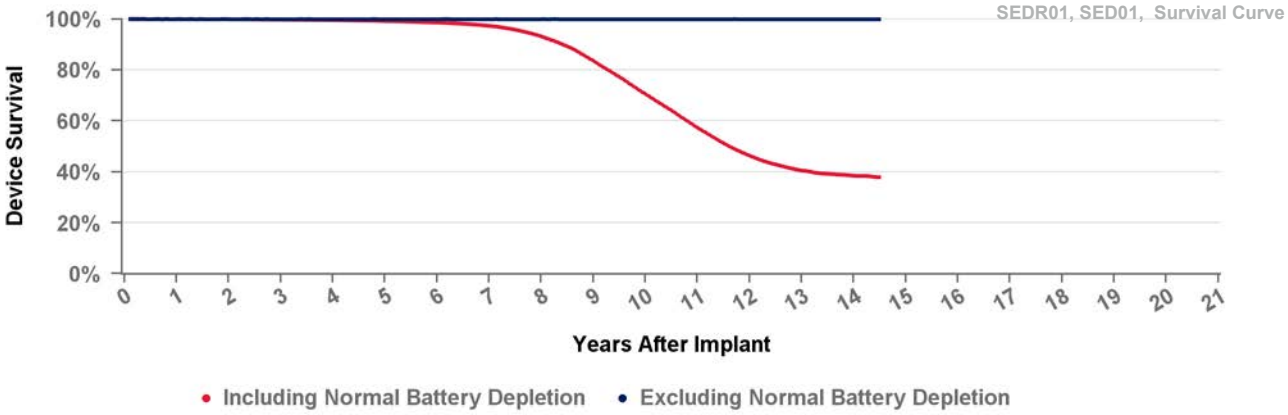
US Market Release	26Aug1999	**Total Malfunctions (USA)**	**288**
CE Approval Date	17Dec1998	**Therapy Function Not Compromised**	**62**
Registered USA Implants	105,692	Electrical Component	9
Estimated Active USA Implants	4,847	Electrical Interconnect	51
Normal Battery Depletions	11,359	Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**226**
		Electrical Component	7
		Electrical Interconnect	218
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 202 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.6%	99.5%	99.5%	99.3%	99.3%	99.2%	99.0%	99.0%	99.0%	99.0%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.6%	97.8%	95.8%	92.6%	86.7%	76.8%	62.2%	46.9%	33.9%	24.4%	17.4%	13.2%
Effective Sample Size	86426	77420	69084	61256	53949	47361	41017	35248	29917	24487	18928	12549	7104	3690	1879	806	137

SED01 Sensia D

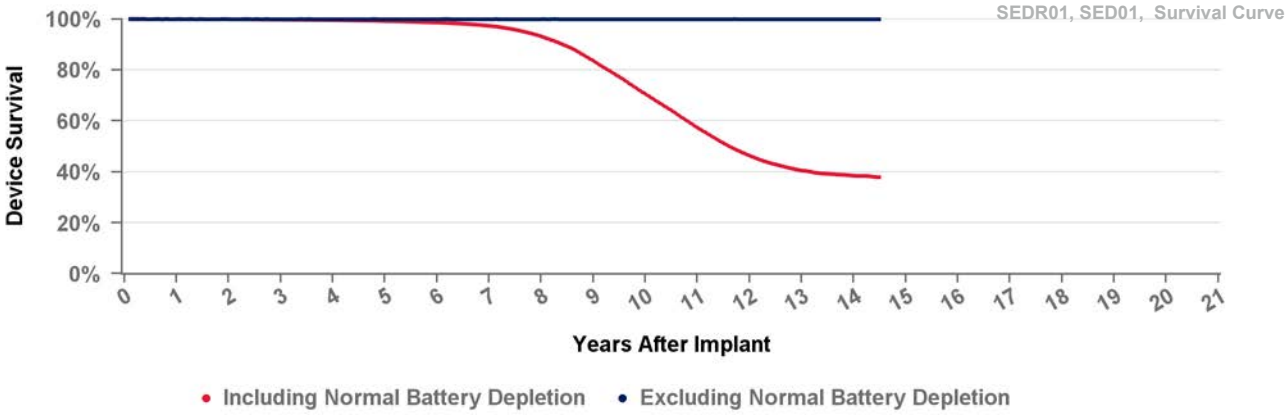
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.2%	98.6%	97.3%	93.1%	83.6%	70.6%	57.3%	46.3%	40.5%	38.5%	38.0%
Effective Sample Size	120565	109036	98383	88750	80019	72208	64483	53251	39611	26729	16318	8933	4314	1350	171

SEDR01 Sensia DR

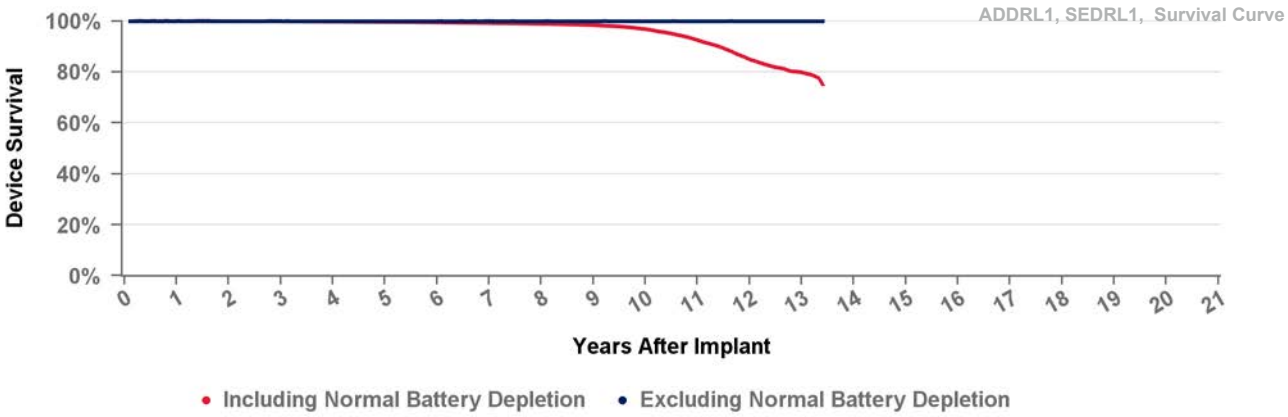
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**33**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,395	Electrical Component	15
Estimated Active USA Implants	32,313	Electrical Interconnect	1
Normal Battery Depletions	14,823	Other	1
		Therapy Function Compromised	**16**
		Electrical Component	6
		Electrical Interconnect	3
		Possible Early Battery Depletion	1
		Other	6



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.2%	98.6%	97.3%	93.1%	83.6%	70.6%	57.3%	46.3%	40.5%	38.5%	38.0%
Effective Sample Size	120565	109036	98383	88750	80019	72208	64483	53251	39611	26729	16318	8933	4314	1350	171

SEDRL1 Sensia L DR

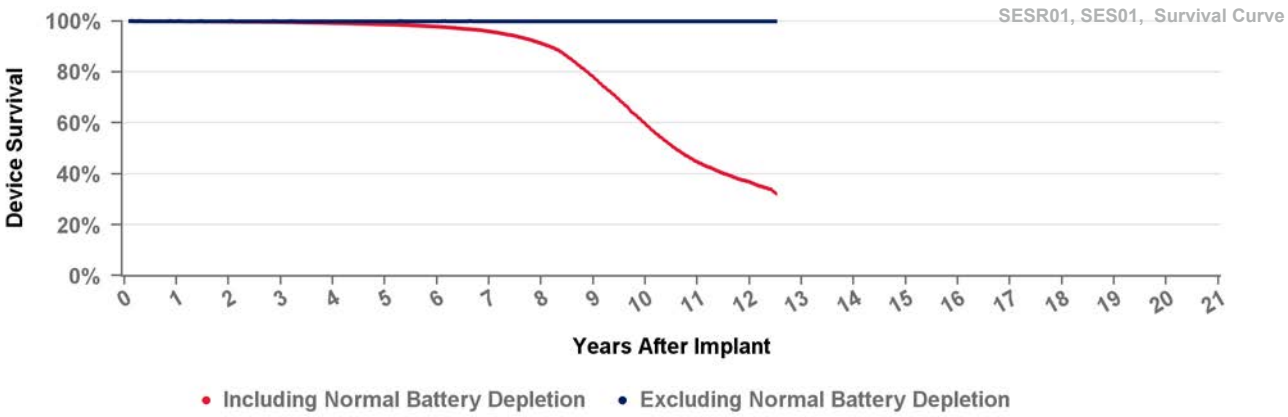
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 161 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.4%	96.8%	92.5%	84.9%	79.9%	74.9%
Effective Sample Size	119815	112804	106035	99367	92042	83154	72394	60611	48119	35058	22227	11085	2591	122

SES01 Sensia S

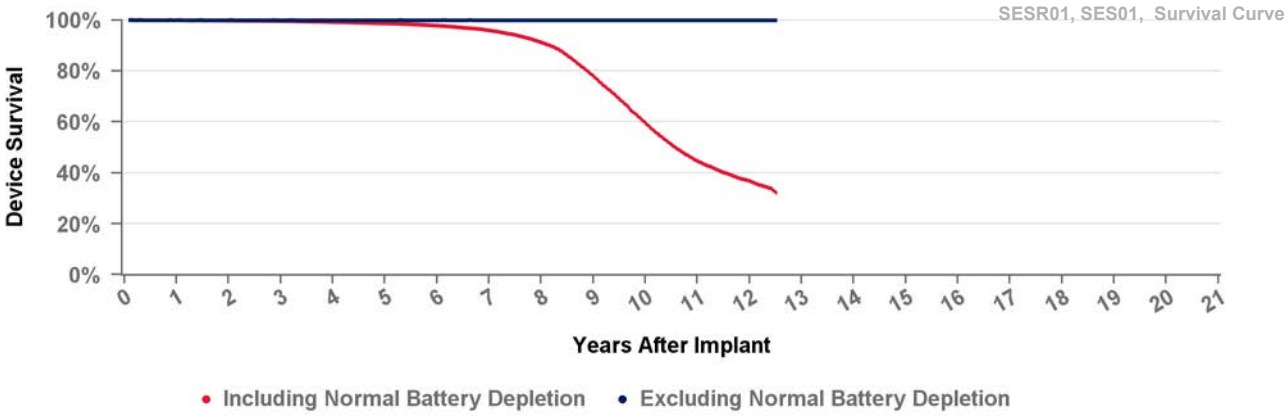
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.7%	97.8%	95.9%	91.2%	78.0%	59.5%	44.6%	36.8%	32.2%
Effective Sample Size	85840	74466	64562	56008	48243	41054	34461	26589	17142	9110	4005	1100	106

SESR01 Sensia SR

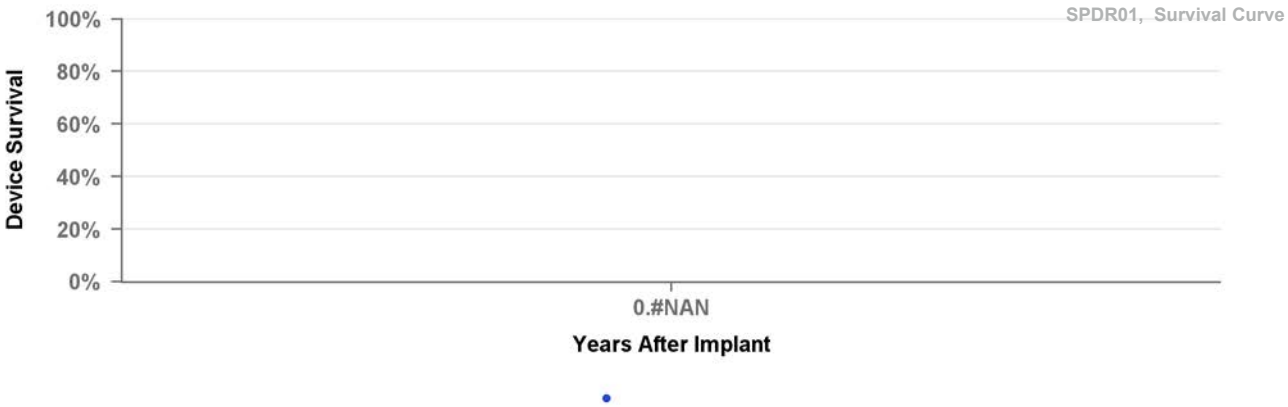
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**17**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**13**
Registered USA Implants	117,367	Electrical Component	7
Estimated Active USA Implants	23,273	Possible Early Battery Depletion	4
Normal Battery Depletions	7,945	Other	2
		Therapy Function Compromised	**4**
		Electrical Component	3
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.6%	99.2%	98.7%	97.8%	95.9%	91.2%	78.0%	59.5%	44.6%	36.8%	32.2%
Effective Sample Size	85840	74466	64562	56008	48243	41054	34461	26589	17142	9110	4005	1100	106

SPDR01 Sphera DR MRI

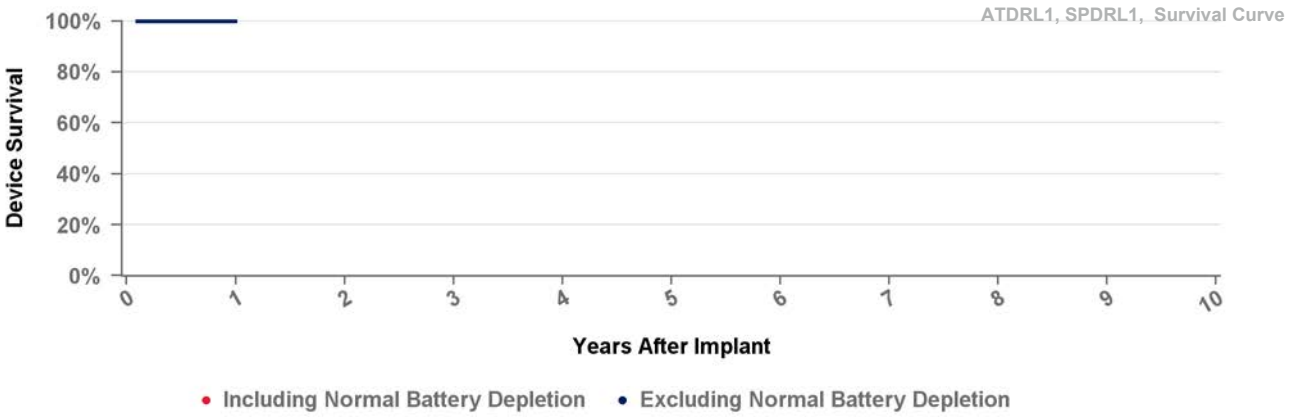
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPDRL1 Sphera L DR MRI

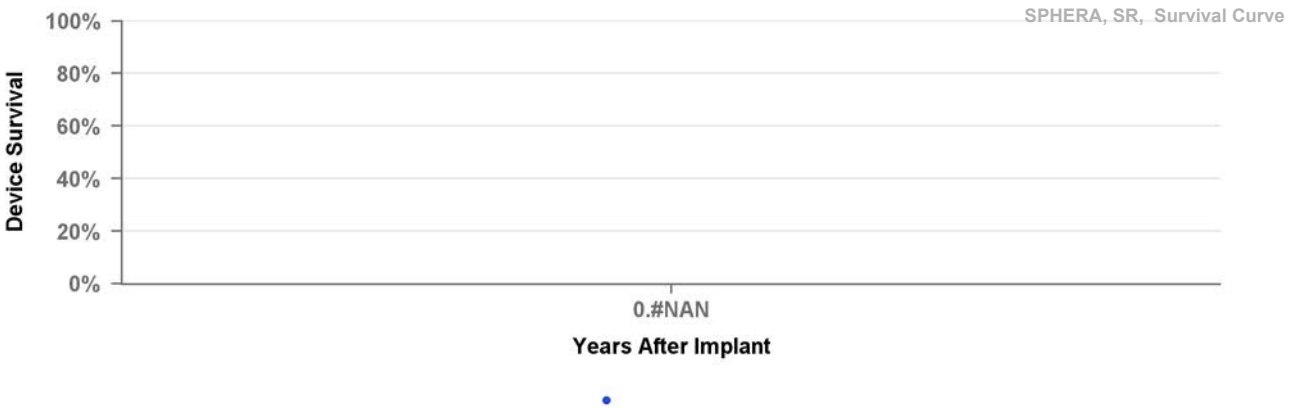
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 12 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	109

SPSR01 Sphera SR MRI

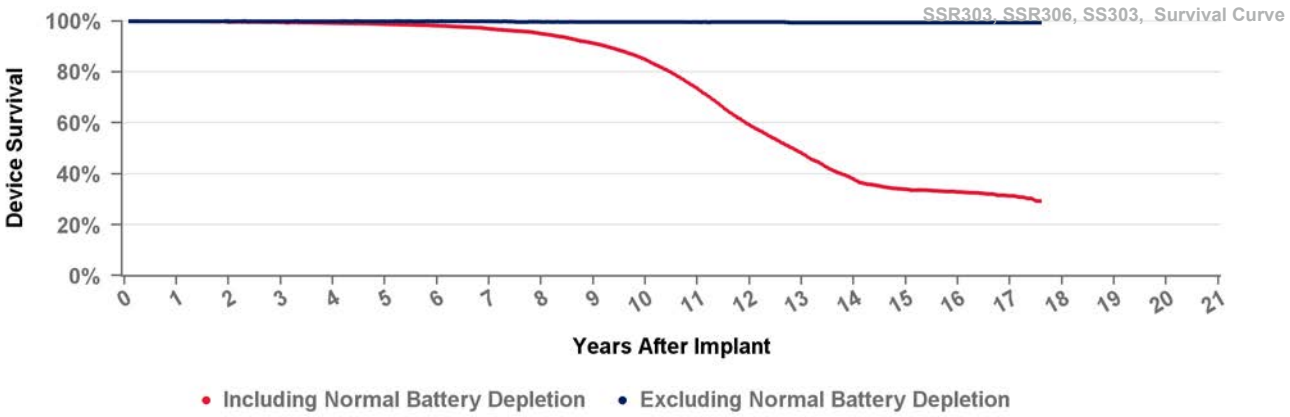
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SS303 Sigma 300 S

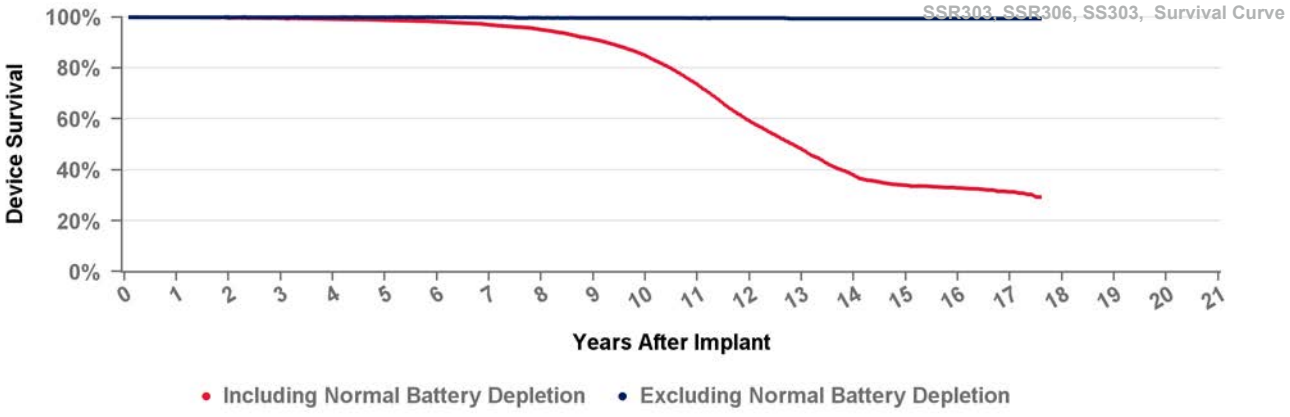
US Market Release	15Sep1999	**Total Malfunctions (USA)**	
CE Approval Date	17Dec1998	**Therapy Function Not Compromised**	
Registered USA Implants	165		
Estimated Active USA Implants	12	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	at 211 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.7%	99.7%	99.6%	99.6%	99.5%	99.5%	99.5%	99.5%	99.5%	99.4%	99.4%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.8%	98.2%	97.0%	95.0%	91.2%	84.9%	73.4%	59.1%	48.1%	37.9%	34.0%	32.9%	31.4%	29.2%
Effective Sample Size	39859	33379	27865	23284	19400	16069	13265	10926	8872	7003	5089	3263	2032	1190	788	548	249	108

SSR303 Sigma 300 SR

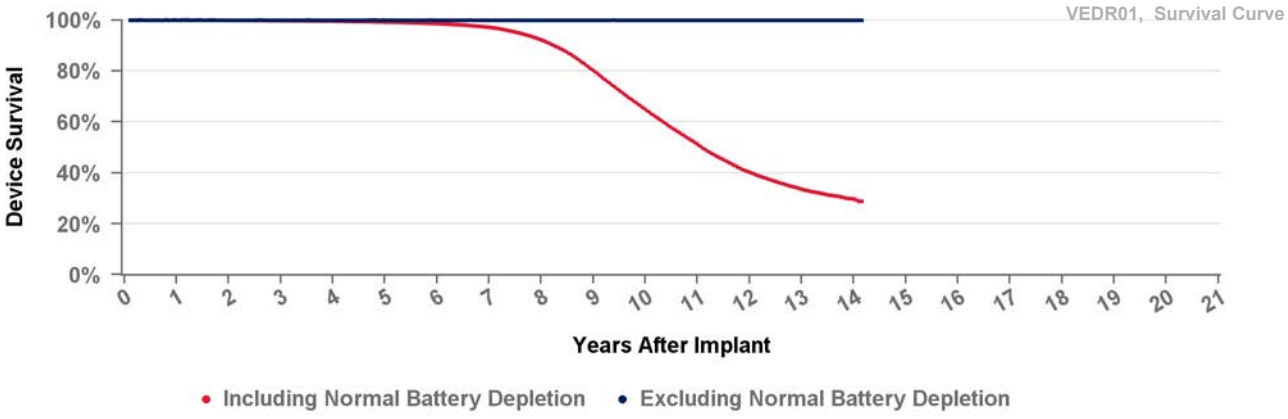
US Market Release	30Aug1999	**Total Malfunctions (USA)**	**58**
CE Approval Date	17Dec1998	**Therapy Function Not Compromised**	**12**
Registered USA Implants	51,767	Electrical Interconnect	10
Estimated Active USA Implants	1,810	Software/Firmware	1
Normal Battery Depletions	3,118	Other	1
		Therapy Function Compromised	**46**
		Electrical Component	3
		Electrical Interconnect	43



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	at 211 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.7%	99.7%	99.6%	99.6%	99.5%	99.5%	99.5%	99.5%	99.5%	99.4%	99.4%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.8%	98.2%	97.0%	95.0%	91.2%	84.9%	73.4%	59.1%	48.1%	37.9%	34.0%	32.9%	31.4%	29.2%
Effective Sample Size	39859	33379	27865	23284	19400	16069	13265	10926	8872	7003	5089	3263	2032	1190	788	548	249	108

VEDR01 Versa DR

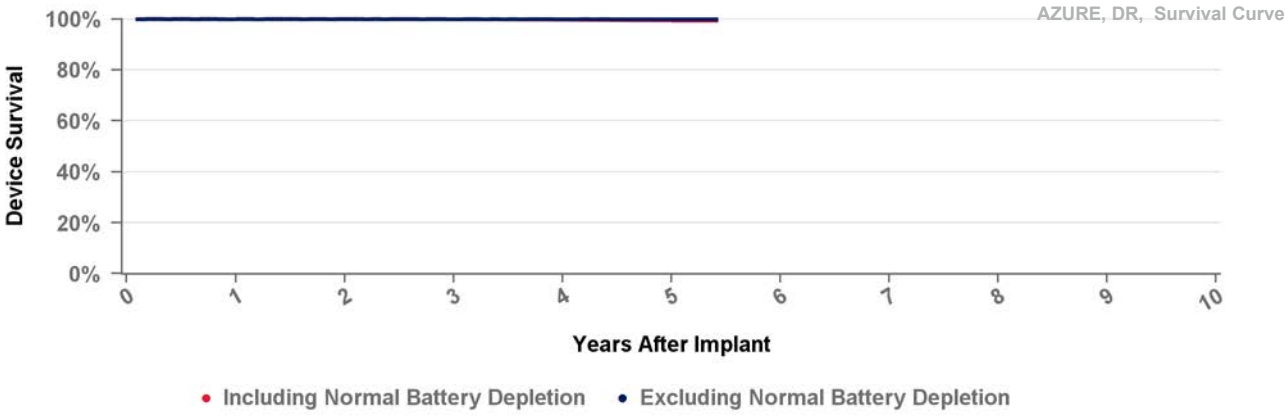
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**25**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**11**
Registered USA Implants	118,951	Electrical Component	7
Estimated Active USA Implants	26,783	Electrical Interconnect	2
Normal Battery Depletions	13,214	Possible Early Battery Depletion	2
		Therapy Function Compromised	**14**
		Electrical Component	10
		Other	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 170 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.2%	98.6%	97.1%	92.2%	80.1%	64.9%	51.2%	40.2%	33.5%	29.7%	28.9%
Effective Sample Size	98697	90201	82109	74730	67698	60386	52144	43029	31141	20111	11776	6085	2644	418	110

W1DR01 Azure XT DR

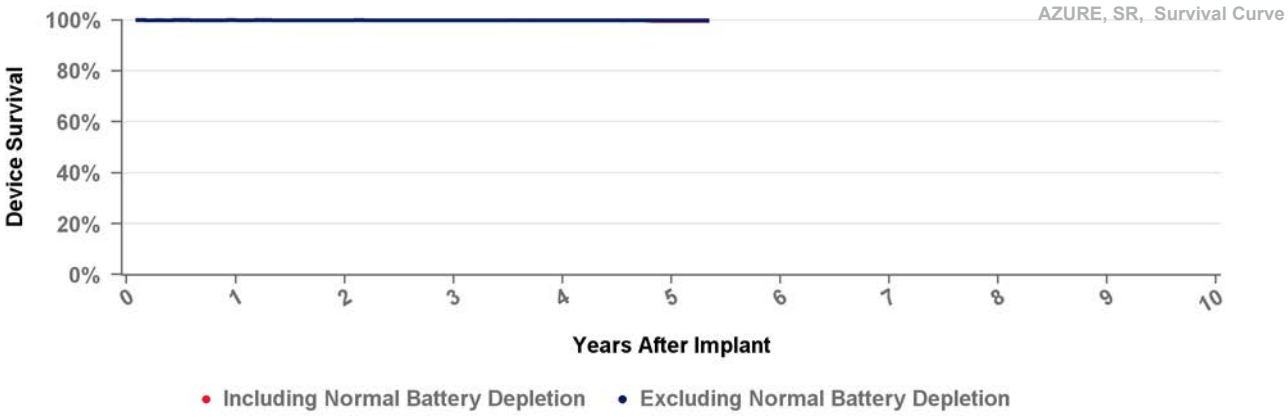
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**99**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**86**
Registered USA Implants	556,721	Battery	2
Estimated Active USA Implants	502,775	Electrical Component	45
Normal Battery Depletions	223	Possible Early Battery Depletion	1
		Software/Firmware	19
		Other	19
		Therapy Function Compromised	**13**
		Battery	2
		Electrical Component	11



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.5%
Effective Sample Size	428893	295376	183341	92198	16074	224

W1SR01 Azure XT SR

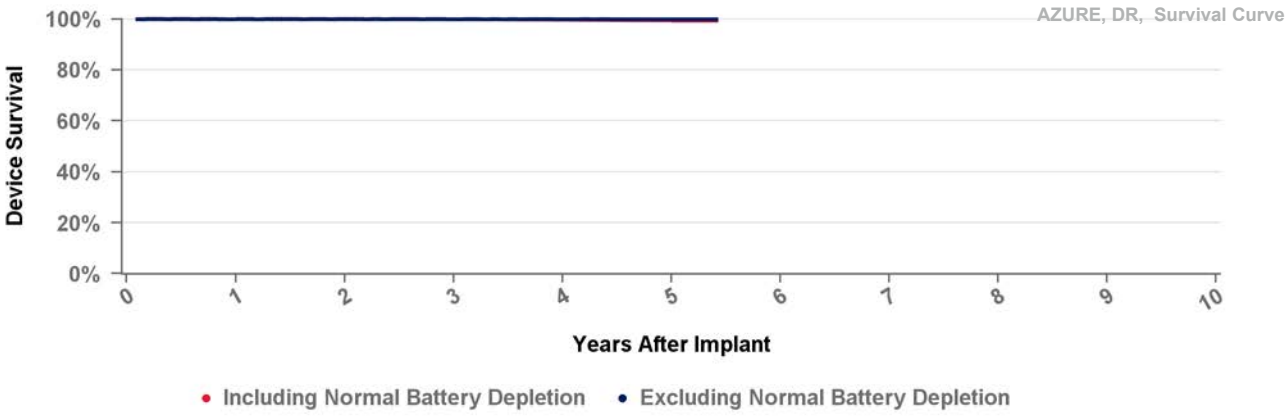
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**8**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**7**
Registered USA Implants	45,237	Battery	1
Estimated Active USA Implants	37,487	Electrical Component	3
Normal Battery Depletions	10	Software/Firmware	1
		Other	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 64 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%	99.7%	99.7%
Effective Sample Size	38267	26220	15605	7428	1260	115

W2DR01 Azure XT DR

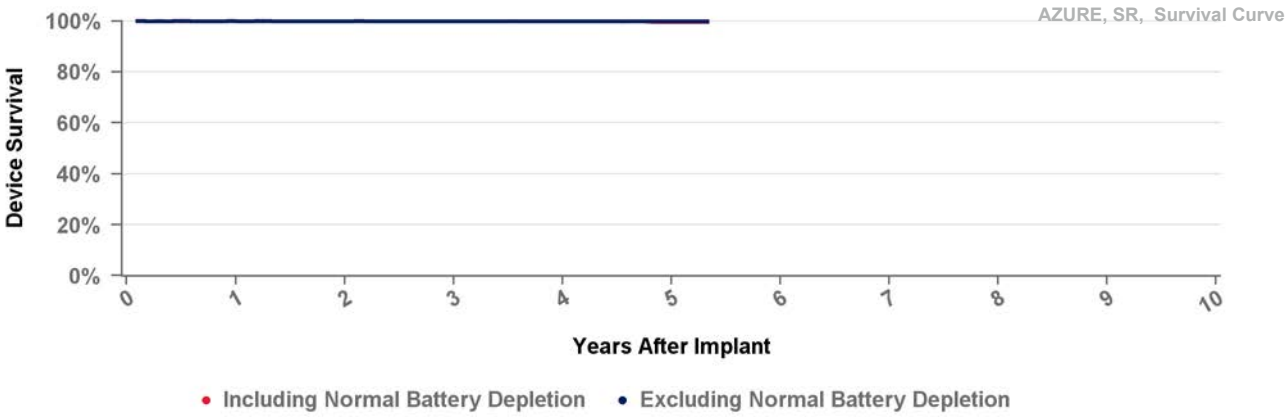
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.5%
Effective Sample Size	428893	295376	183341	92198	16074	224

W2SR01 Azure XT SR

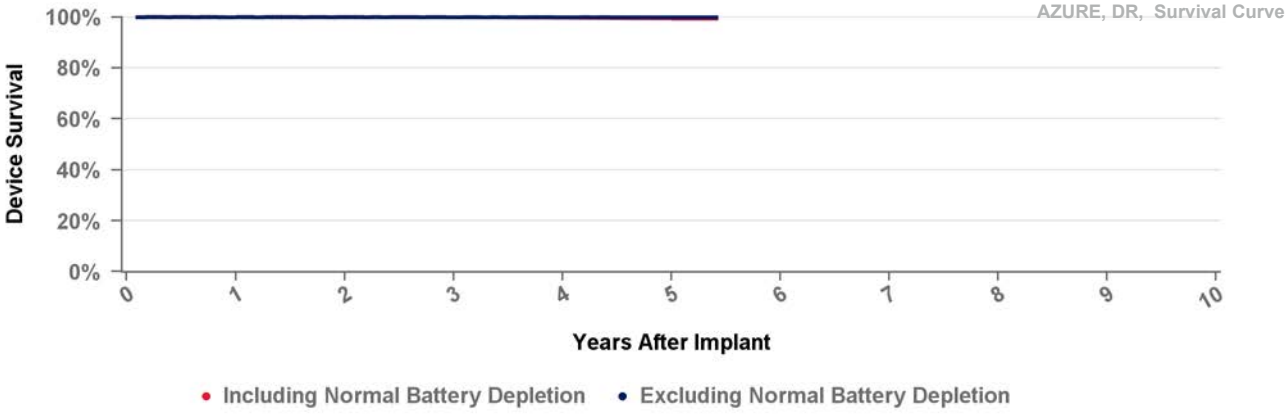
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 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%	99.7%	99.7%
Effective Sample Size	38267	26220	15605	7428	1260	115

W3DR01 Azure S DR

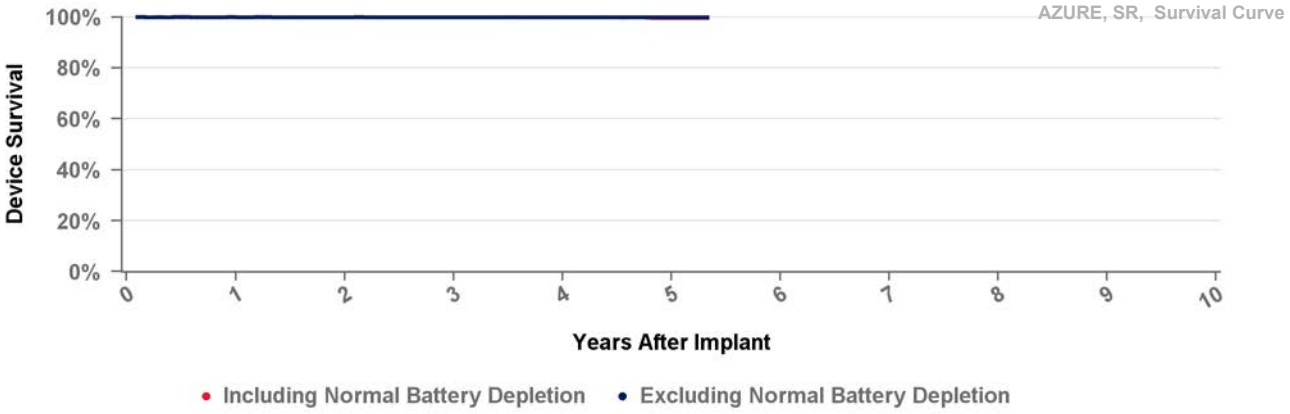
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**8**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**7**
Registered USA Implants	53,930	Electrical Component	6
Estimated Active USA Implants	47,936	Software/Firmware	1
Normal Battery Depletions	44	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.5%
Effective Sample Size	428893	295376	183341	92198	16074	224

W3SR01 Azure S SR

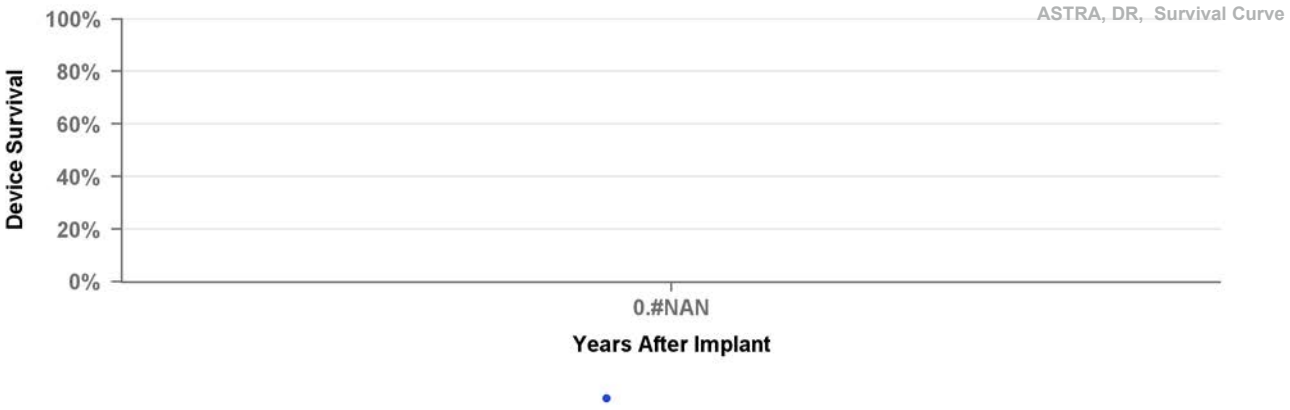
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**1**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**1**
Registered USA Implants	10,717	Electrical Component	1
Estimated Active USA Implants	8,920	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 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%	99.7%	99.7%
Effective Sample Size	38267	26220	15605	7428	1260	115

X2DR01 Astra XT DR MRI SureScan

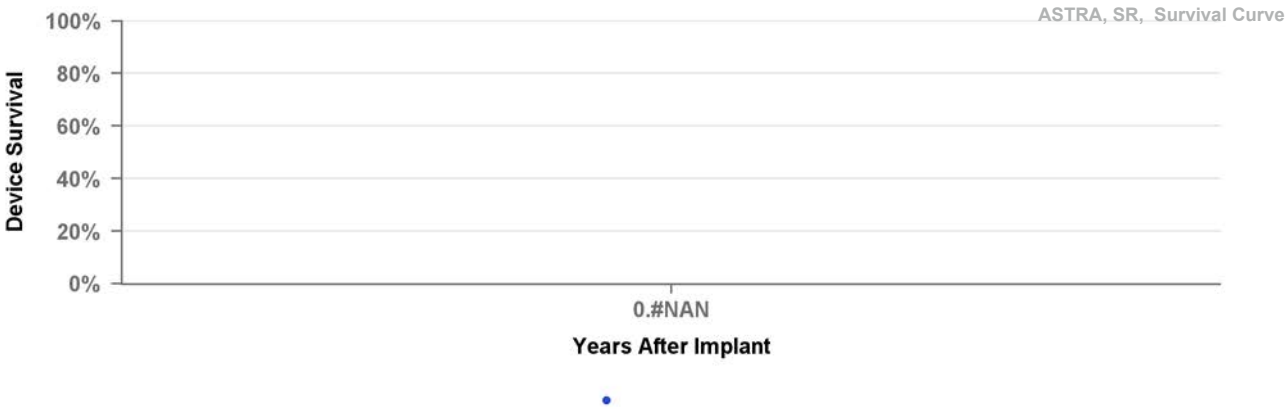
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

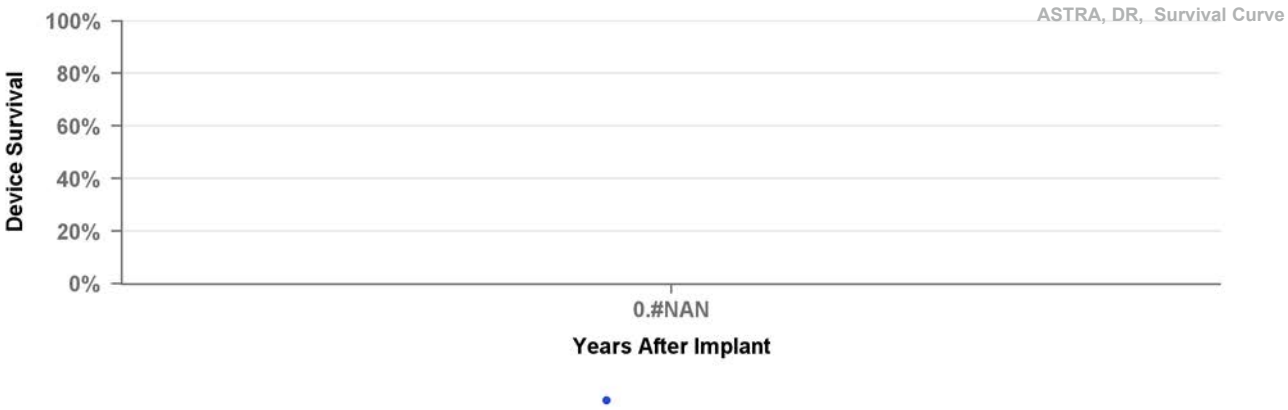
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3DR01 Astra S DR

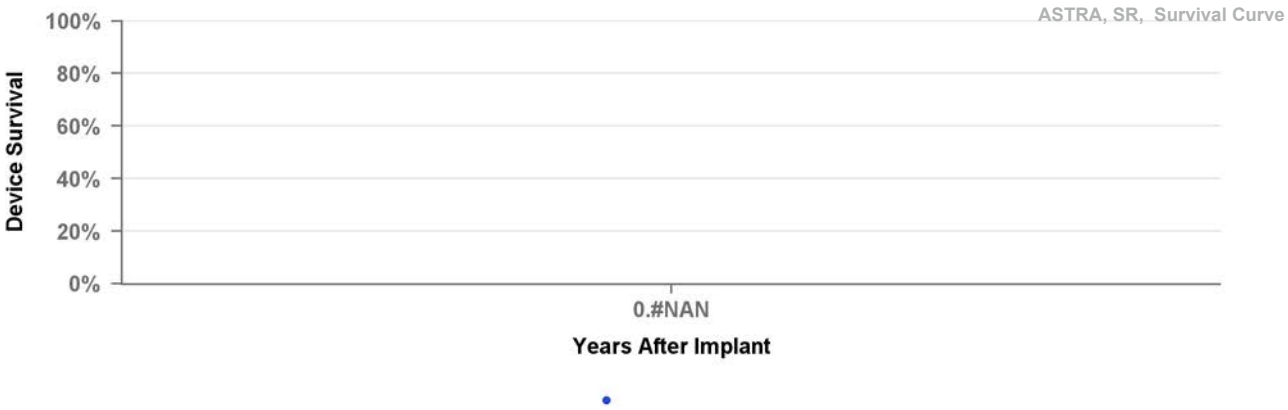
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3SR01 Astra S SR

US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**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 Transcatheter Pacing Performance

Micra TPS Performance Analysis

Transcatheter pacing systems (TPS) combine the pacing functions of an IPG with the therapy delivery functions of an implantable lead into a single device implanted inside the heart. Therefore, TPS is subject to complications similar to pacing leads (e.g. cardiac perforation) and malfunctions or battery depletion events similar to an implanted pulse generator (IPG). Although both transvenous systems and Micra IPG experience similar system level major complications, Micra has been shown to reduce the likelihood of major complications at a system level in post-approval registry data.

The performance report information is determined from the analysis of Medtronic Cardiac Rhythm Management (CRM) United States registration, complaint and CareLink™ network data.

Shortfalls of using returned products to Estimate Micra TPS Performance

Micra TPS devices 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 failure mechanisms, this data cannot be used by itself for determining the survival probability because only a small fraction of Micra devices are explanted and returned to Medtronic for analysis. Some devices are programmed off due to an adverse event, however, they are often not retrieved/ explanted. The devices that are retrieved and returned cannot be assumed to be statistically representative of the performance of the total population for a given model. For this same reason, devices that meet their expected longevity are also not expected to be returned to Medtronic CRM.

The CareLink™ Network

To account for the shortfalls of returned product analysis, a study of de-identified product data on the Medtronic CareLink™ network is used. The number of devices enrolled and transmitting actively enables a population large enough to give a representative volume of normal battery depletions and to provide insight into the complications that may occur after the device was successfully implanted. As the intent of the product performance report is to provide visibility to long-term device performance, the devices reviewed from the CareLink™ Network have been implanted for at least 30 days.

Categorization of Micra TPS Qualifying Complications or Malfunctions for Survival Analysis on CareLink™

For survival estimation, complication and premature battery depletion data from Medtronic's Complaint Handling System is adjudicated and subsequently cross-referenced with an assessment of device performance from the Medtronic CareLink™ network to categorize if the device is 1) functioning normally, 2) has reached normal battery depletion, or 3) has experienced a qualifying malfunction or complication. This categorization is combined with the CareLink™ data for the total number of implants and implant durations to create survival estimates for the likelihood of experiencing a qualifying complication or malfunction, and normal battery depletion. Ultimately, the data is summarized in two survival curves, one with only qualifying complications or malfunctions and the other including normal battery depletion.

Definition of Qualifying Complication or Malfunction

A longevity analysis is completed for all de-identified devices followed on CareLink™ that have reached the Recommended Replacement Time (RRT), to identify devices that experienced possible early battery depletion. These are findings where the actual reported implant time is less than 80% of the expected longevity calculated using the available device diagnostic information.

Methods for Estimating Transcatheter Pacing Performance continued

Additionally, all reported Micra TPS complaints are adjudicated by subject matter experts and medical safety personnel for inclusion as a product performance event given available information. These product performance events are then cross-referenced with the CareLink™ population for inclusion in the survival analysis.

Product Performance events include, but are not limited to, these that occur 30 days after the implant procedure:

- Premature Battery Depletion
- Cardiac Perforation
- Dislodgement
- Failure to Capture
- Elevated Pacing Threshold

Normal Battery Depletion

A longevity analysis is completed for all devices followed on CareLink™ that are at or within 6 months of RRT to identify devices were taken out of service due to normal battery depletion. The population that is within six months of RRT is assessed against the expected longevity of the product. Normal Battery Depletion is defined as the condition when the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device diagnostic information.

Medtronic CRM 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. 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.

Statistical and Data Analysis Methods

The performance 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 a chronic device-related complication.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. Of the several different statistical methods available for survival analysis, PPR survival analysis is estimated using the Standard Actuarial Method, with suspensions assumed distributed evenly within the intervals (Cutler-Ederer Method), and incorporated data from these retrospectively enrolled devices. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

The survival estimates is the probability that a device is free of a product performance event or normal battery depletion at a given time point. For example, if a survival probability is 95% after 5 years of service, then the device has a 5% chance of experiencing a related complication or battery depletion in the first 5 years following implant.

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 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.

Methods for Estimating Transcatheter Pacing Performance continued

Because the de-identified information pulled from the CareLink™ network allows for assessment of all devices that were taken out of service there are no adjustments done for underreporting of malfunctions or battery depletion.

Definition of Analysis Dataset

To be included in the US survival analysis dataset, the product must have been successfully implanted and on the CareLink™ network for at least 30 days.

US Reports of Acute Observations

In the first weeks following implantation, physiologic responses and performance can vary until long-term stability is attained. Acute 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 performance stabilizes. It is for this reason that the CareLink™ analysis, which is intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

Acute performance information, defined as the first month after implant, but not including the day of the implant procedure, is included in our reporting. The source of this information is the Medtronic complaint handling system database that includes events reported to Medtronic. This information is summarized in tables titled "Acute 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 Observation categories. The categories are:

- Cardiac Perforation
- Dislodgement
- Failure to Capture
- Failure to Sense
- Elevated Pacing Threshold

Although multiple observations are possible for any given Micra, only one observation is reported per device. The observation reported is the observation highest on the list. For example, if an Event Report includes observations for both Cardiac Perforation and Elevated Pacing Thresholds, Cardiac Perforation is reported.

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

US Reports of the Day of Implant Observations

Due to the procedural differences with Micra products compared to transvenous leads and IPGs, information about the clinical experience on the day of implant is included in our reporting. The source of this information is the Medtronic complaint handling system database that includes events reported to Medtronic which may be related to either the Micra device or the delivery system. The information is summarized in tables titled "Day of Implant Observations."

Methods for Estimating Transcatheter Pacing Performance continued

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 Day of Implant Observation categories. The categories are:

- Cardiac Perforation
- Dislodgement
- Failure to Capture
- Failure to Sense
- Elevated Pacing Threshold

Although multiple observations are possible for any given Micra, only one observation is reported per device. The observation reported is the observation highest on the list. For example, if an Event Report includes observations for both Cardiac Perforation and Elevated Pacing Thresholds, Cardiac Perforation is reported.

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

MC1VR01 Micra VR

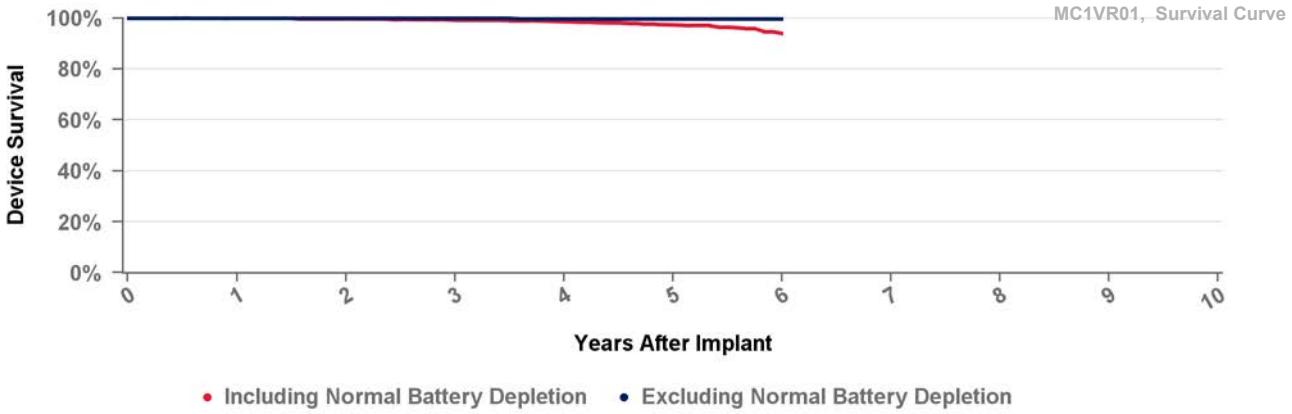
US Market Release	06Apr2016
CE Approval Date	14Apr2015
Registered USA Implants	66,212

CareLink Population

Enrolled	35,749
Active	25,644
Cumulative Follow-Up Months	891,607
Normal Battery Depletions	159

CareLink Qualifying Malfunctions/Complications

Cardiac Perforation	7
Dislodgements	2
Elevated Pacing Threshold	36
Failure to Capture	7
Premature Battery Depletion	10



Years	1	2	3	4	5	at 72 mo
Excluding NBD	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.2%	98.6%	97.3%	93.9%
Effective Sample Size	26777	14974	9926	4349	1241	148

***Acute Observations (N = 66,212)**

Cardiac Perforation	20
Dislodgement	21
Elevated Pacing Threshold	146
Failure to Capture	71
Failure to Sense	12

***Day of Implant Observations (N = 66,212)**

Cardiac Perforation	271
Dislodgement	152
Elevated Pacing Threshold	235
Failure to Capture	108
Failure to Sense	69

The rate of perforation for commercially released Micra VR devices continues to perform acceptably within levels observed within the post-approval clinical study registry. Overall, clinical studies have demonstrated a reduction in the risk of major complications of 63% through 12 months[1] and 57% through 36 months[2] relative to transvenous pacing systems.

1. El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
2. Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089

* Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

MC1AVR1 Micra AV

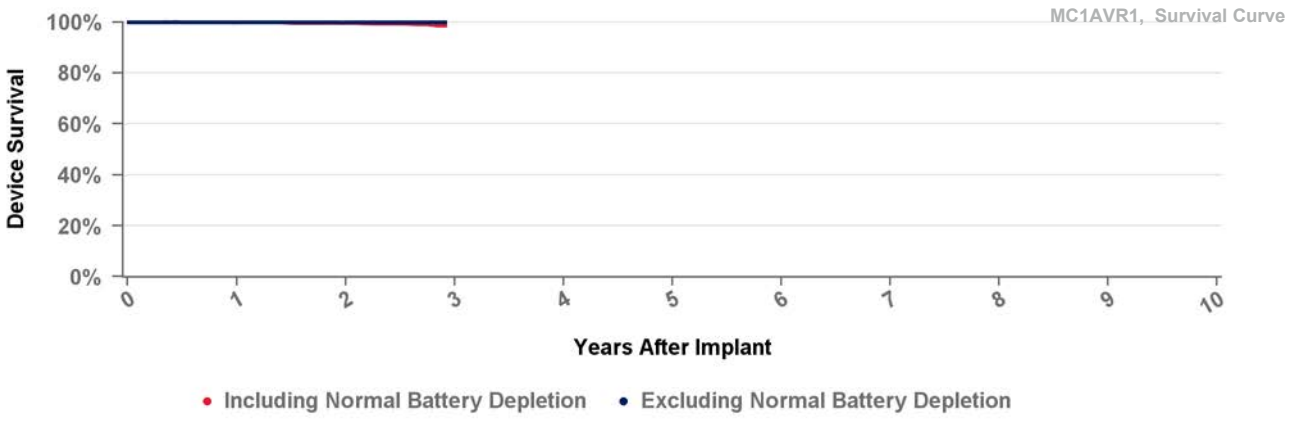
US Market Release	15Jan2020
CE Approval Date	31Mar2020
Registered USA Implants	39,372

CareLink Population

Enrolled	18,950
Active	16,270
Cumulative Follow-Up Months	256,631
Normal Battery Depletions	24

CareLink Qualifying Malfunctions/Complications

Dislodgements	2
Elevated Pacing Threshold	8
Failure to Capture	4
Premature Battery Depletion	4



Years	1	2	at 35 mo
Excluding NBD	99.9%	99.8%	99.8%
Including NBD	99.8%	99.6%	98.7%
Effective Sample Size	10208	3213	187

***Acute Observations (N = 39,372)**

Cardiac Perforation	13
Dislodgement	20
Elevated Pacing Threshold	68
Failure to Capture	28
Failure to Sense	99

***Day of Implant Observations (N = 39,372)**

Cardiac Perforation	223
Dislodgement	66
Elevated Pacing Threshold	107
Failure to Capture	61
Failure to Sense	31

The rate of perforation for commercially released Micra AV devices continues to perform acceptably within levels observed within the post-approval clinical study registry. Overall, predicate clinical studies for Micra VR have demonstrated a reduction in the risk of major complications of 63% through 12 months[1] and 57% through 36 months[2] relative to transvenous pacing systems.

1. El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
2. Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089

* Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm Management (CRM) has tracked lead survival for over 39 years with its multicenter, global chronic lead studies.

Leads Performance Analysis

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

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

Shortfalls Of Using Returned Product And Complaints To Estimate Lead Performance

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

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

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

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

PAN Registry

Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study since 1983 and has evaluated the performance of more than 131,000 leads, with data reported from countries around the world. Throughout this time period, Medtronic has continually worked to adapt systems and processes to more effectively monitor product performance following market release. The following summarizes current registry requirements.

Method for Estimating Lead Performance continued

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

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

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

Patients are eligible for enrollment if:

- Patient is intended to be implanted or has been implanted with 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 required 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.

Method for Estimating Lead Performance continued

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the number of leads entering an interval is less than 50 leads. When the number of leads entering an interval reaches 50, the next data point is added to the survival curve. For those lead models that do not have sufficient sample size, a survival curve will not be presented.

Definition of Analysis Dataset

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

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

Criteria for Model Inclusion

Survival probabilities and the associated study 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 CRM 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 are 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 CRM and found, through analysis, to actually have performed outside the performance limits established by Medtronic.

Method for Estimating Lead Performance continued

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.

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:

- Cardiac Perforation
- Conductor Fracture
- Lead Dislodgement
- Failure to Capture
- Oversensing
- Failure to Sense
- Insulation Breach
- Impedance Abnormal
- Extracardiac Stimulation
- 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.

Method for Estimating Lead Performance continued

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 Registration Tracking Application (DTrak).

Footnotes:

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

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

3830 SelectSecure

US Market Release	03Aug2005
CE Approval	31Jan2003
Registered USA Implants	153,960
Estimated Active USA Implants	127,406
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	35
Insulation Breach	72
Crimp/Weld/Bond	0
Other	13

US Acute Lead Observations

Cardiac Perforation	50
Conductor Fracture	5
Extra Cardiac Stimulation	9
Failure to Capture	455
Failure to Sense	54
Impedance Out of Range	26
Insulation Breach	2
Lead Dislodgement	543
Oversensing	93
Unspecified Clinical Failure	2

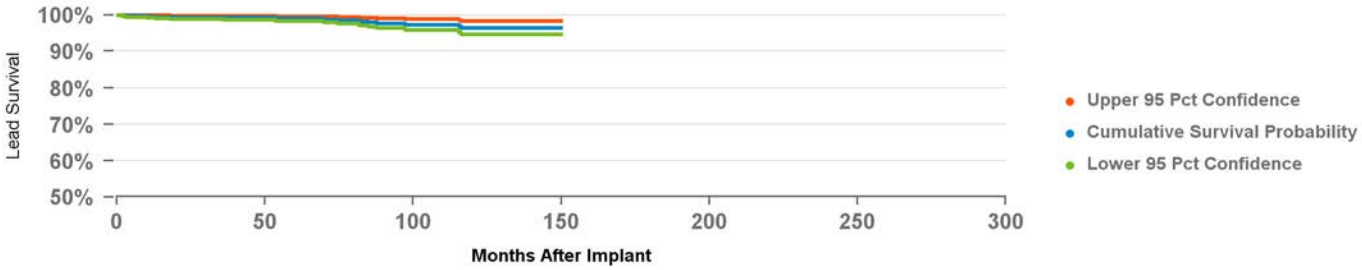
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,679
Number of Leads Active in Study	775
Cumulative Months of Follow-Up	80,081

Qualifying Complications 19

Cardiac Perforation	1	Impedance Out of Range	2
Conductor Fracture	3	Insulation (not further defined)	1
Extra Cardiac Stimulation	1	Lead Dislodgement	4
Failure to Capture	4	Other	0
Failure to Sense	3		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	99.3%	99.1%	99.0%	98.7%	98.2%	97.6%	97.3%	96.4%	96.4%	96.4%	96.4%
#	1,241	986	798	619	503	416	354	307	255	212	161	93	60

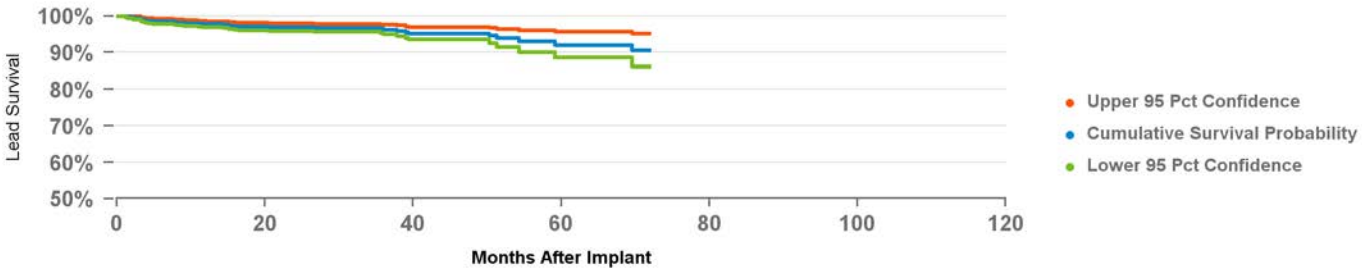
His Bundle Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,387
Number of Leads Active in Study	985
Cumulative Months of Follow-Up	34,621

Qualifying Complications 46

Failure to Capture	35	Impedance Out of Range	0
Failure to Sense	3	Lead Dislodgement	4
		Oversensing	1
		Other	2
		Unspecified Clinical Failure	1



Years	1	2	3	4	5	at 72 mo
%	97.8%	96.9%	96.2%	95.2%	92.1%	90.6%
#	1,008	659	355	168	91	53

Ventricular Placement

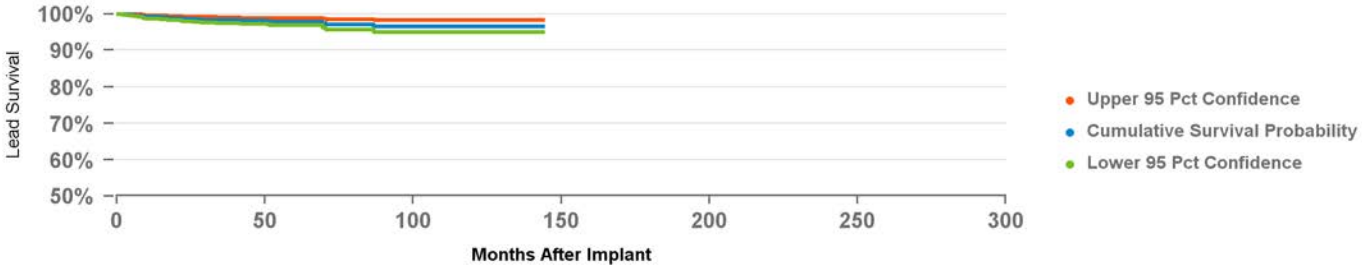
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,393
Number of Leads Active in Study	1,651
Cumulative Months of Follow-Up	65,296

Qualifying Complications

Failure to Capture	14	Impedance Out of Range	2
		Lead Dislodgement	8
		Other	1

25



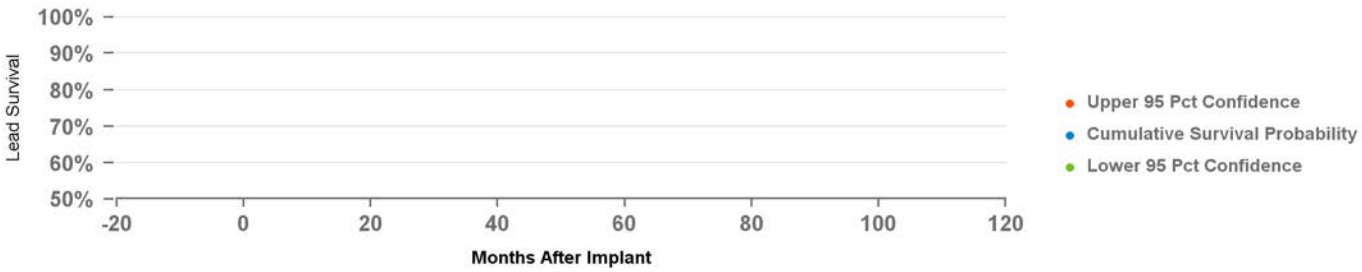
Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.1%	98.7%	98.3%	98.1%	97.8%	97.1%	97.1%	96.7%	96.7%	96.7%	96.7%	96.7%
#	1,334	905	616	420	334	262	219	182	146	116	87	50

4073 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	769
Estimated Active USA Implants	132
Fixation Type	Tines
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations



Years	at mo
%	
#	

4074 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	150,312
Estimated Active USA Implants	70,608
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Insulation Breach	55
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

Cardiac Perforation	32
Conductor Fracture	2
Extra Cardiac Stimulation	3
Failure to Capture	171
Failure to Sense	12
Impedance Out of Range	6
Lead Dislodgement	201
Oversensing	8

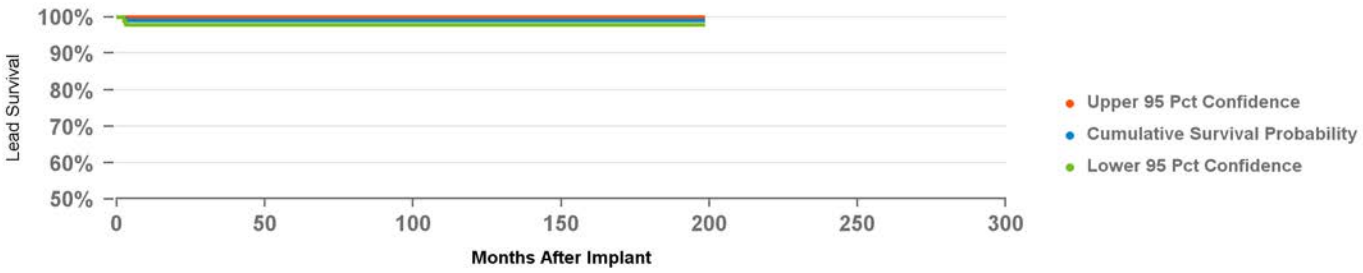
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Number of Leads Active in Study	68
Cumulative Months of Follow-Up	28,700

Qualifying Complications 2

Failure to Capture	0
Failure to Sense	1
Impedance Out of Range	0
Lead Dislodgement	1
Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 198 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	214	205	198	183	167	158	148	136	126	117	110	107	98	92	88	62	54

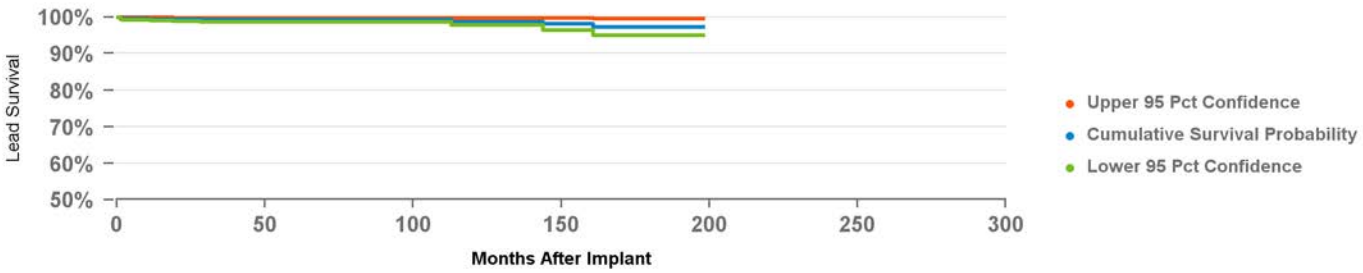
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,191
Number of Leads Active in Study	195
Cumulative Months of Follow-Up	78,251

Qualifying Complications 11

Conductor Fracture	1
Failure to Capture	3
Impedance Out of Range	2
Insulation (not further defined)	2
Lead Dislodgement	2
Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 198 mo
%	99.4%	99.3%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.8%	98.8%	98.1%	98.1%	97.3%	97.3%	97.3%	97.3%
#	1,029	876	730	616	476	390	330	291	243	190	161	141	121	116	108	68	56

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	777,799
Estimated Active USA Implants	439,266
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	125
Insulation Breach	206
Crimp/Weld/Bond	1
Other	22

US Acute Lead Observations

Cardiac Perforation	234
Conductor Fracture	11
Extra Cardiac Stimulation	28
Failure to Capture	337
Failure to Sense	185
Impedance Out of Range	64
Insulation Breach	2
Lead Dislodgement	827
Oversensing	119
Unspecified Clinical Failure	10

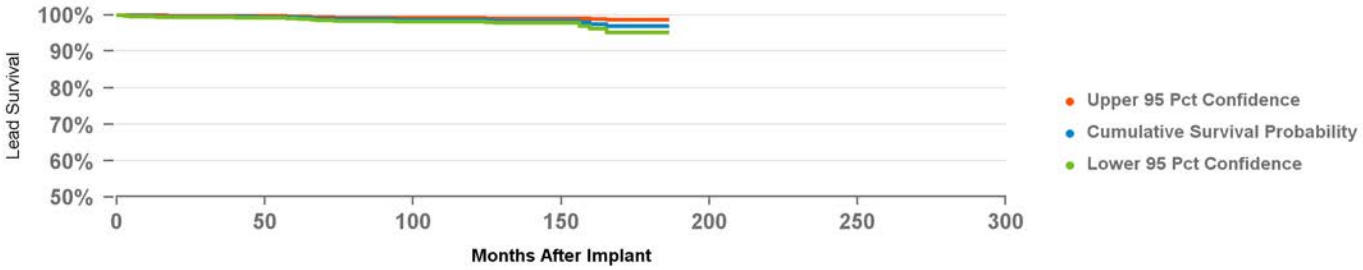
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,529
Number of Leads Active in Study	1,626
Cumulative Months of Follow-Up	263,099

Qualifying Complications 37

Cardiac Perforation	2	Impedance Out of Range	0
Conductor Fracture	3	Insulation (not further defined)	3
Failure to Capture	10	Lead Dislodgement	12
Failure to Sense	3	Oversensing	2
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.7%	99.6%	99.6%	99.5%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.4%	98.4%	98.4%	96.9%	96.9%	96.9%
#	3,318	2,910	2,527	2,165	1,850	1,604	1,412	1,203	974	725	546	391	243	152	99	76

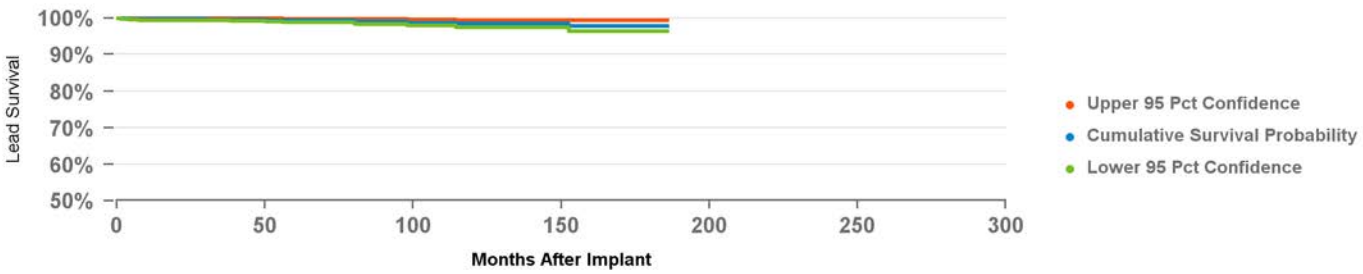
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,746
Number of Leads Active in Study	366
Cumulative Months of Follow-Up	114,067

Qualifying Complications 14

Conductor Fracture	1	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Lead Dislodgement	1
Failure to Capture	6	Other	2
Failure to Sense	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.7%	99.7%	99.7%	99.6%	99.3%	99.3%	99.0%	99.0%	98.8%	98.5%	98.5%	98.5%	97.9%	97.9%	97.9%	97.9%
#	1,427	1,271	1,125	943	753	657	551	472	391	322	266	209	148	104	69	53

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	186,233
Estimated Active USA Implants	36,641
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	20
Insulation Breach	98
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

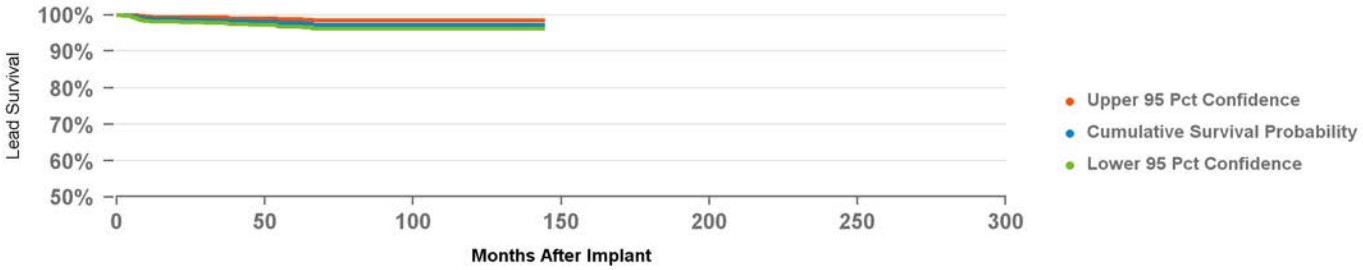
Cardiac Perforation	4
Conductor Fracture	4
Extra Cardiac Stimulation	1
Failure to Capture	35
Impedance Out of Range	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,201
Number of Leads Active in Study	15
Cumulative Months of Follow-Up	70,037

Qualifying Complications 21

Conductor Fracture	3	Impedance Out of Range	1
Extra Cardiac Stimulation	1	Lead Dislodgement	4
Failure to Capture	12	Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	98.8%	98.7%	98.5%	98.1%	97.8%	97.4%	97.4%	97.4%	97.4%	97.4%	97.4%	97.4%
#	921	822	734	629	515	402	333	279	238	157	93	56

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	113,050
Estimated Active USA Implants	61,892
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Insulation Breach	25
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

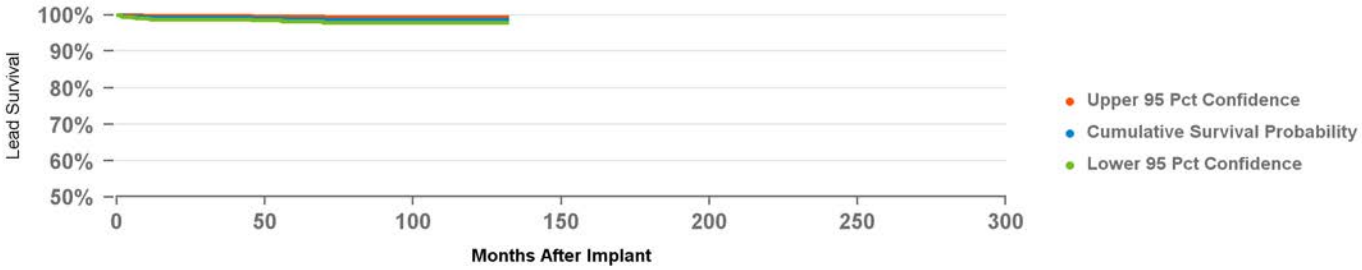
Cardiac Perforation	3
Conductor Fracture	1
Extra Cardiac Stimulation	1
Failure to Capture	130
Failure to Sense	64
Impedance Out of Range	9
Lead Dislodgement	254
Oversensing	16
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,635
Number of Leads Active in Study	751
Cumulative Months of Follow-Up	71,437

Qualifying Complications 13

Conductor Fracture	2	Impedance Out of Range	0
Failure to Capture	4	Lead Dislodgement	7
		Other	0



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.2%	99.2%	99.2%	99.1%	98.9%	98.6%	98.6%	98.6%	98.6%	98.6%	98.6%
#	1,180	892	736	592	467	390	322	231	170	111	61

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	89,797
Estimated Active USA Implants	19,945
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Insulation Breach	33
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

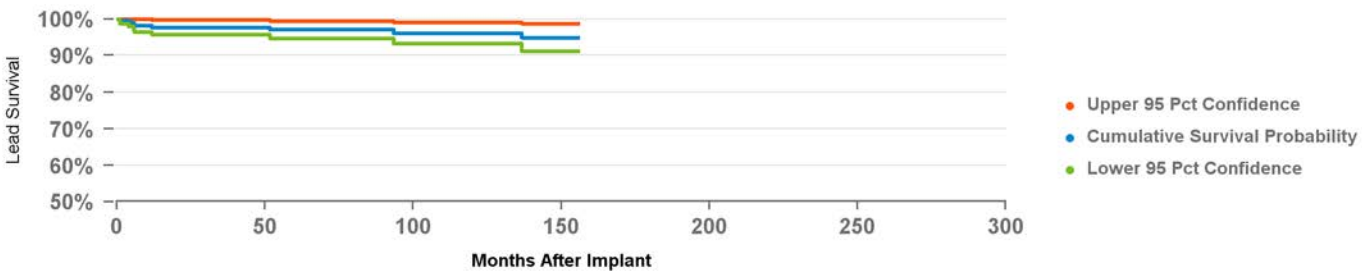
Failure to Capture	10
Failure to Sense	2
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	365
Number of Leads Active in Study	32
Cumulative Months of Follow-Up	22,424

Qualifying Complications 10

Failure to Capture	5	Impedance Out of Range	0
Failure to Sense	1	Lead Dislodgement	3
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	97.7%	97.7%	97.7%	97.7%	97.0%	97.0%	97.0%	96.1%	96.1%	96.1%	96.1%	94.8%	94.8%
#	203	181	166	157	134	125	109	105	98	87	82	74	55

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	100,057
Estimated Active USA Implants	18,608
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Insulation Breach	45
Crimp/Weld/Bond	1
Other	0

US Acute Lead Observations

Cardiac Perforation	2
Conductor Fracture	2
Failure to Capture	23
Impedance Out of Range	4
Insulation Breach	1
Lead Dislodgement	30
Unspecified Clinical Failure	9

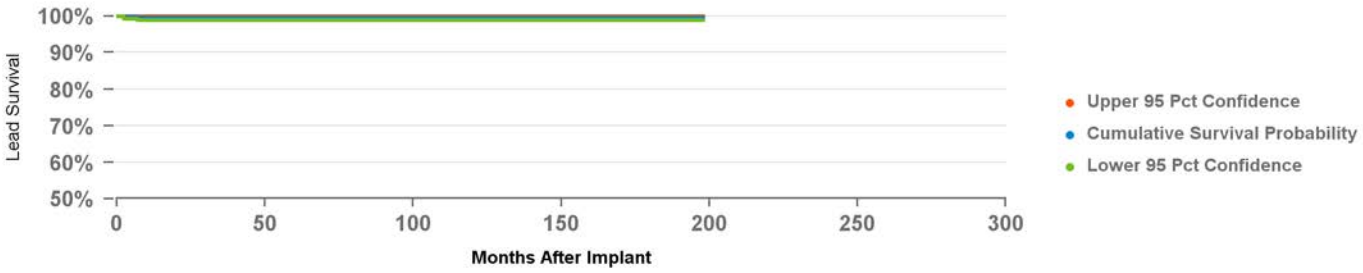
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Number of Leads Active in Study	33
Cumulative Months of Follow-Up	41,851

Qualifying Complications 3

Failure to Capture	2	Impedance Out of Range	0
		Lead Dislodgement	1
		Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 198 mo
%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%
#	411	391	358	322	289	252	219	186	153	129	108	93	75	65	59	52	51

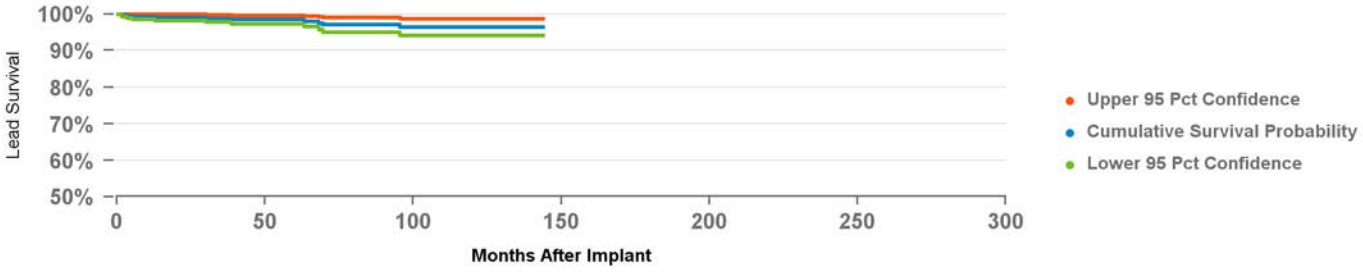
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	989
Number of Leads Active in Study	18
Cumulative Months of Follow-Up	35,298

Qualifying Complications 13

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



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.3%	99.1%	98.8%	98.4%	98.4%	97.0%	97.0%	96.4%	96.4%	96.4%	96.4%	96.4%
#	474	391	304	264	230	191	167	143	112	92	71	52

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	3,204,116
Estimated Active USA Implants	1,770,880
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,415
Insulation Breach	1,524
Crimp/Weld/Bond	3
Other	199

US Acute Lead Observations

Cardiac Perforation	1,544
Conductor Fracture	31
Extra Cardiac Stimulation	110
Failure to Capture	2,245
Failure to Sense	1,124
Impedance Out of Range	367
Insulation Breach	15
Lead Dislodgement	4,925
Oversensing	724
Unspecified Clinical Failure	26

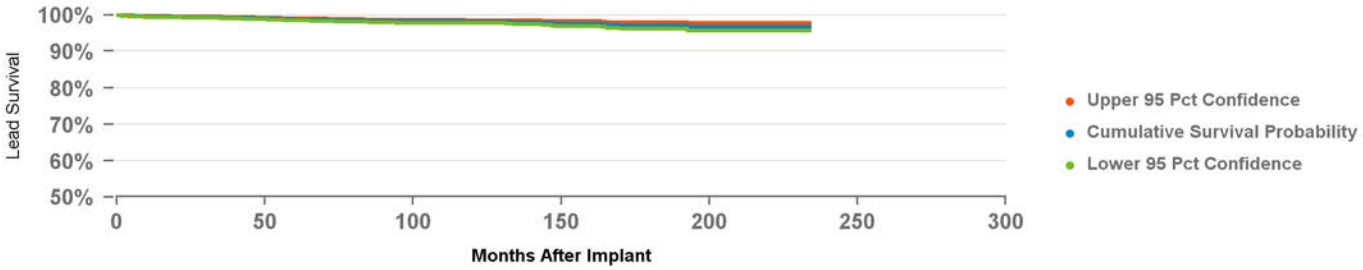
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	12,432
Number of Leads Active in Study	5,235
Cumulative Months of Follow-Up	578,296

Qualifying Complications 108

Cardiac Perforation	2	Impedance Out of Range	11
Conductor Fracture	13	Insulation (not further defined)	3
Extra Cardiac Stimulation	3	Lead Dislodgement	39
Failure to Capture	17	Oversensing	3
Failure to Sense	9	Other	8



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	at 234 mo
%	99.6%	99.4%	99.3%	99.1%	98.8%	98.6%	98.4%	98.3%	98.3%	98.2%	98.1%	97.9%	97.6%	97.3%	97.1%	97.1%	96.7%	96.7%	96.7%	96.7%
#	7,992	6,675	5,634	4,679	3,944	3,219	2,531	2,055	1,681	1,293	1,045	833	632	501	395	295	193	123	70	53

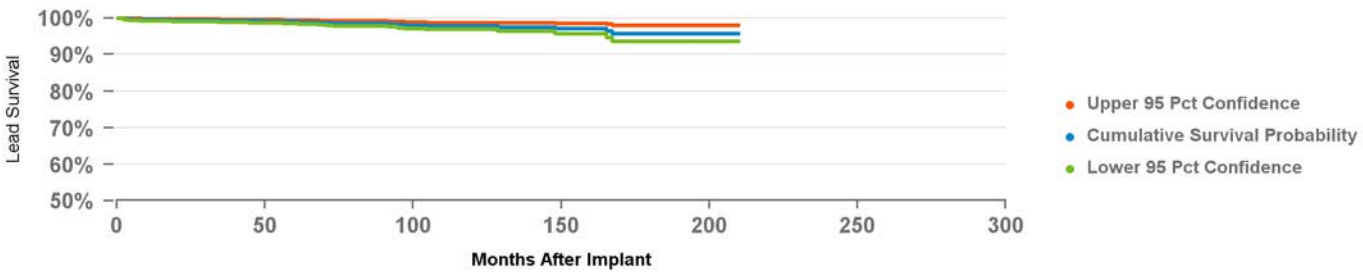
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,355
Number of Leads Active in Study	799
Cumulative Months of Follow-Up	156,992

Qualifying Complications 32

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	6	Lead Dislodgement	5
Failure to Capture	12	Oversensing	1
Failure to Sense	1	Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	at 210 mo
%	99.6%	99.4%	99.3%	99.1%	99.0%	98.6%	98.5%	98.2%	97.8%	97.8%	97.5%	97.5%	97.0%	95.8%	95.8%	95.8%	95.8%	95.8%
#	2,197	1,837	1,507	1,173	954	798	668	562	470	381	312	248	178	145	125	104	72	59

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	207,785
Estimated Active USA Implants	128,533
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	112
Insulation Breach	199
Crimp/Weld/Bond	0
Other	11

US Acute Lead Observations

Cardiac Perforation	212
Conductor Fracture	4
Extra Cardiac Stimulation	18
Failure to Capture	144
Failure to Sense	27
Impedance Out of Range	9
Insulation Breach	2
Lead Dislodgement	312
Oversensing	31

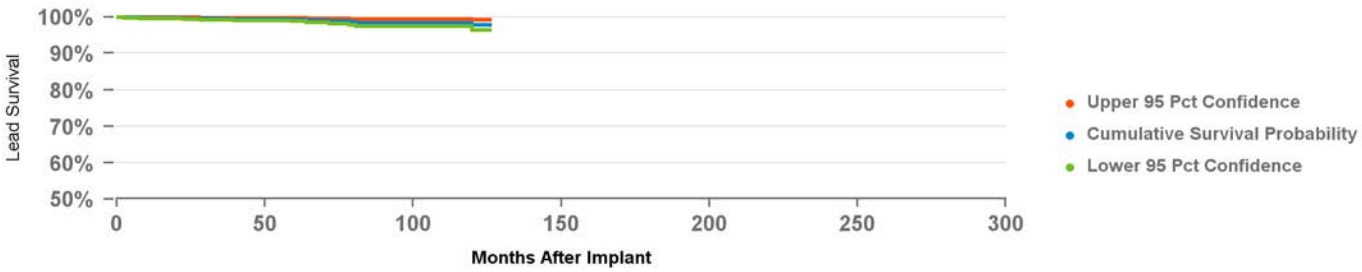
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,136
Number of Leads Active in Study	1,349
Cumulative Months of Follow-Up	142,455

Qualifying Complications 21

Conductor Fracture	3	Impedance Out of Range	0
Failure to Capture	3	Lead Dislodgement	12
		Oversensing	2
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.8%	99.6%	99.6%	99.4%	99.3%	98.9%	98.4%	98.4%	98.4%	97.8%	97.8%
#	2,528	2,201	1,878	1,462	765	450	389	339	280	168	97

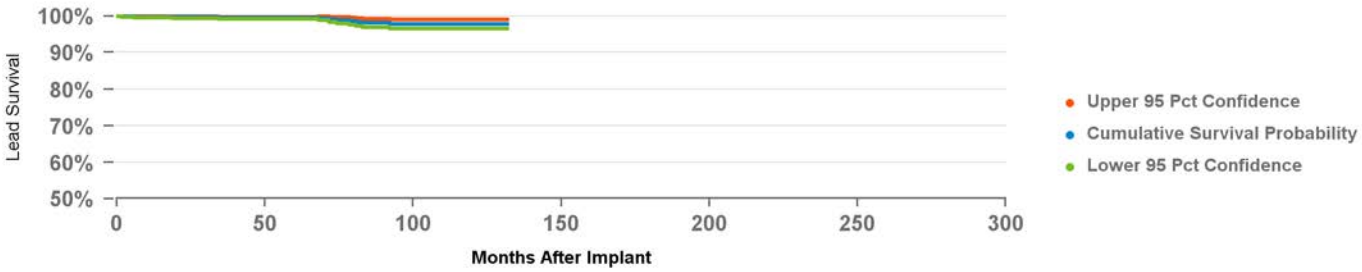
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,070
Number of Leads Active in Study	1,326
Cumulative Months of Follow-Up	140,297

Qualifying Complications 22

Conductor Fracture	4	Impedance Out of Range	2
Failure to Capture	9	Lead Dislodgement	3
Failure to Sense	1	Oversensing	2
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.7%	99.7%	99.6%	99.6%	99.6%	99.1%	98.1%	97.8%	97.8%	97.8%	97.8%
#	2,527	2,183	1,851	1,428	735	421	371	322	269	166	50

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	141,700
Estimated Active USA Implants	29,515
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	27
Insulation Breach	71
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

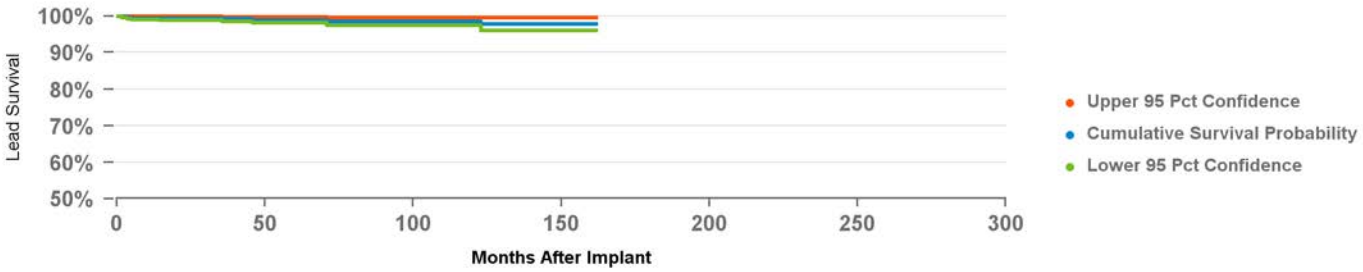
Cardiac Perforation	7
Conductor Fracture	3
Extra Cardiac Stimulation	3
Failure to Capture	49
Failure to Sense	7
Impedance Out of Range	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified Clinical Failure	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,216
Number of Leads Active in Study	21
Cumulative Months of Follow-Up	54,448

Qualifying Complications 10

Extra Cardiac Stimulation	1	Impedance Out of Range	1
Failure to Capture	3	Lead Dislodgement	5
		Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.5%	99.3%	99.2%	98.9%	98.9%	98.6%	98.6%	98.6%	98.6%	98.6%	97.8%	97.8%	97.8%	97.8%
#	814	652	517	421	335	264	218	173	149	131	109	81	56	52

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,866
Estimated Active USA Implants	14,456
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	24
Insulation Breach	42
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

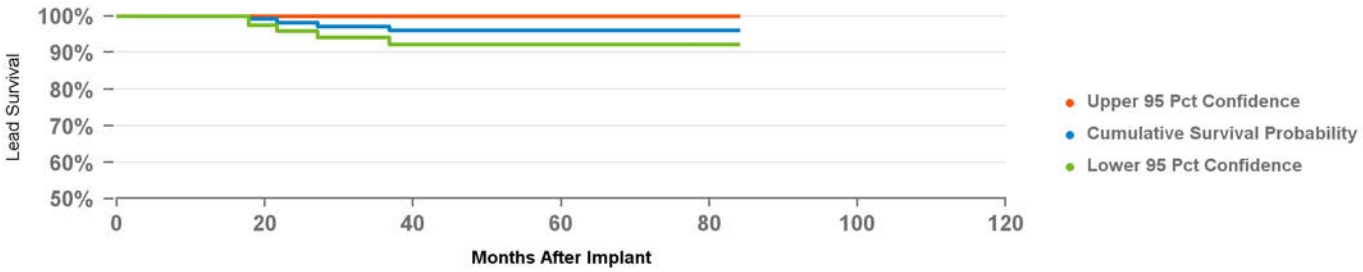
Conductor Fracture	1
Failure to Capture	31
Failure to Sense	2
Impedance Out of Range	1
Lead Dislodgement	39
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	367
Number of Leads Active in Study	7
Cumulative Months of Follow-Up	9,386

Qualifying Complications 5

Failure to Capture	2	Impedance Out of Range	1
		Lead Dislodgement	1
		Oversensing	1
		Other	0



Years	1	2	3	4	5	6	at 84 mo
%	#####	98.2%	97.2%	96.0%	96.0%	96.0%	96.0%
#	141	107	84	77	63	55	55

5592 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	37,334
Estimated Active USA Implants	9,992
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Insulation Breach	7
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

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

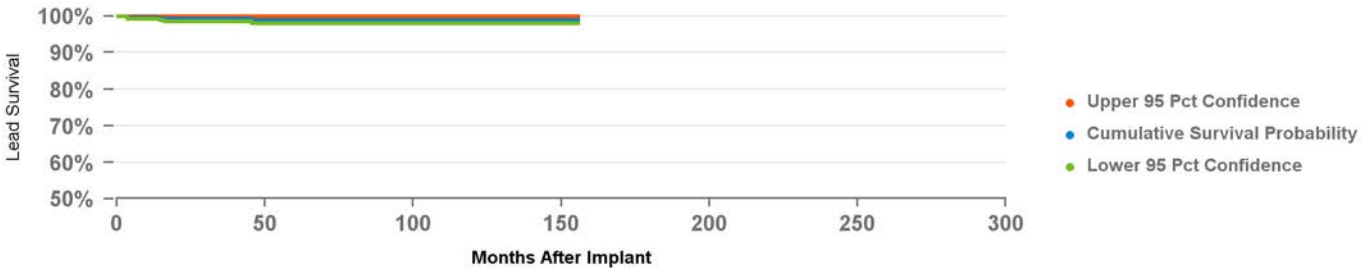
Product Surveillance Registry Results

Number of Leads Enrolled in Study	721
Number of Leads Active in Study	38
Cumulative Months of Follow-Up	39,165

Qualifying Complications

5

Failure to Capture	3
Impedance Out of Range	0
Lead Dislodgement	2
Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.6%	99.3%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	523	432	351	299	249	197	169	154	126	111	97	69	51

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,611
Estimated Active USA Implants	5,581
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Insulation Breach	18
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

Failure to Capture	4
Lead Dislodgement	14
Unspecified Clinical Failure	2

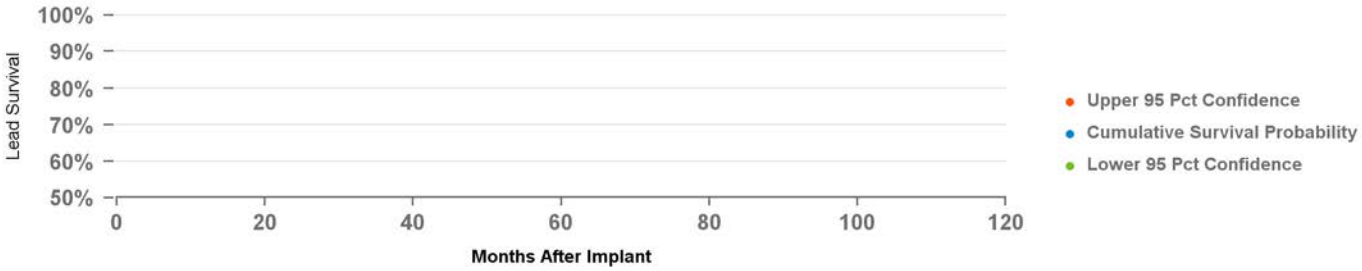
Product Surveillance Registry Results

Number of Leads Enrolled in Study	43
Number of Leads Active in Study	12
Cumulative Months of Follow-Up	4,510

Qualifying Complications

3

Conductor Fracture	1
Failure to Capture	0
Impedance Out of Range	0
Insulation (not further defined)	1
Oversensing	1
Other	0



Years	at 0 mo
%	#####
#	

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,397
Estimated Active USA Implants	855
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	2
Failure to Capture	3
Failure to Sense	2
Impedance Out of Range	20
Oversensing	1

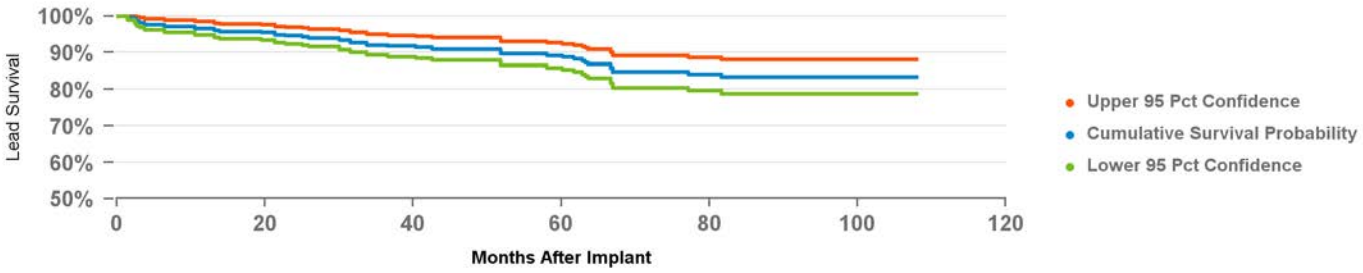
Product Surveillance Registry Results

Number of Leads Enrolled in Study	418
Number of Leads Active in Study	7
Cumulative Months of Follow-Up	24,190

Qualifying Complications

51

Conductor Fracture	21
Failure to Capture	8
Impedance Out of Range	4
Insulation (not further defined)	2
Other	16



Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.6%	92.1%	91.0%	89.3%	84.7%	83.3%	83.3%	83.3%
#	348	320	274	222	190	135	100	65	56

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	64
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

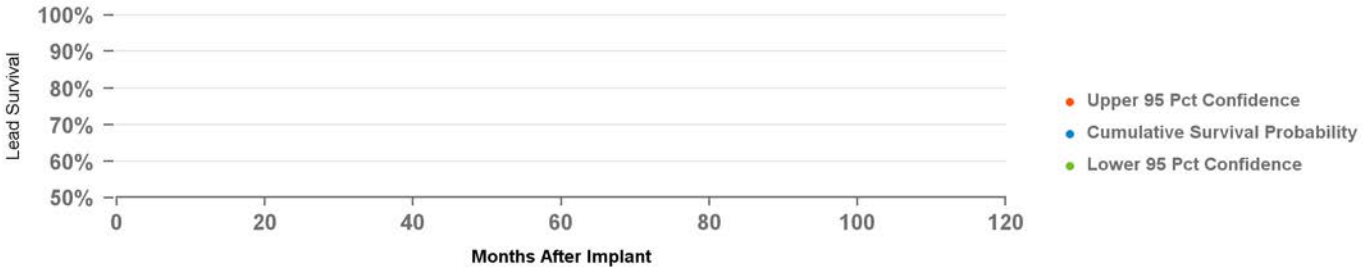
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Number of Leads Active in Study	1
Cumulative Months of Follow-Up	329

Qualifying Complications

Failure to Capture	0
Impedance Out of Range	0
Other	0



Years	at 0 mo
%	#####
#	

6931 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	8,081
Estimated Active USA Implants	1,195
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	667
Insulation Breach	1
Crimp/Weld/Bond	0
Other	5

US Acute Lead Observations

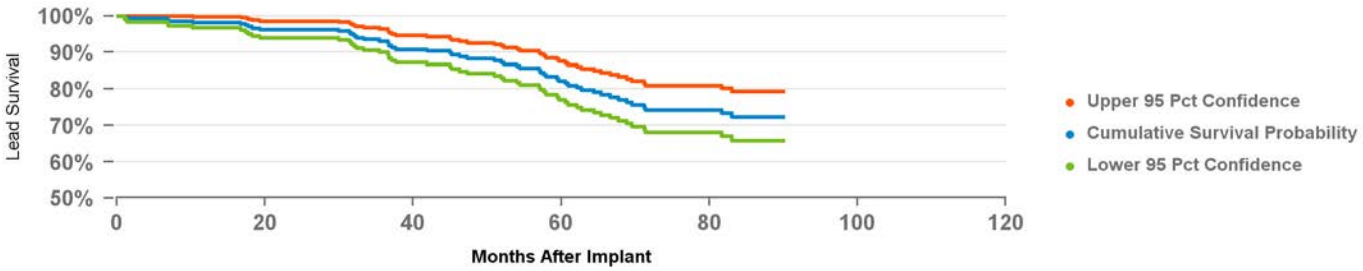
Cardiac Perforation	1
Conductor Fracture	2
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	311
Number of Leads Active in Study	10
Cumulative Months of Follow-Up	17,976

Qualifying Complications 58

Conductor Fracture	35
Failure to Capture	3
Failure to Sense	1
Impedance Out of Range	10
Lead Dislodgement	2
Oversensing	7
Other	0



Years	1	2	3	4	5	6	7	at 90 mo
%	98.2%	96.2%	93.1%	88.3%	82.2%	74.3%	72.3%	72.3%
#	261	232	204	166	137	104	70	55

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	66,206
Estimated Active USA Implants	38,677
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	456
Insulation Breach	13
Crimp/Weld/Bond	0
Other	44

US Acute Lead Observations

Cardiac Perforation	29
Conductor Fracture	4
Extra Cardiac Stimulation	2
Failure to Capture	32
Failure to Sense	15
Impedance Out of Range	28
Insulation Breach	1
Lead Dislodgement	68
Oversensing	65
Unspecified Clinical Failure	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,933
Number of Leads Active in Study	752
Cumulative Months of Follow-Up	160,037

Qualifying Complications 66

Cardiac Perforation	1	Impedance Out of Range	8
Conductor Fracture	24	Lead Dislodgement	8
Extra Cardiac Stimulation	1	Oversensing	9
Failure to Capture	8	Other	5
Failure to Sense	1	Unspecified Clinical Failure	1

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.5%	99.3%	98.9%	98.6%	98.5%	98.0%	97.4%	96.6%	95.7%	94.6%	94.2%	93.7%	92.8%
#	2,376	1,961	1,613	1,318	1,111	953	797	666	544	365	198	104	64

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	353,907
Estimated Active USA Implants	289,642
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	683
Insulation Breach	33
Crimp/Weld/Bond	1
Other	94

US Acute Lead Observations

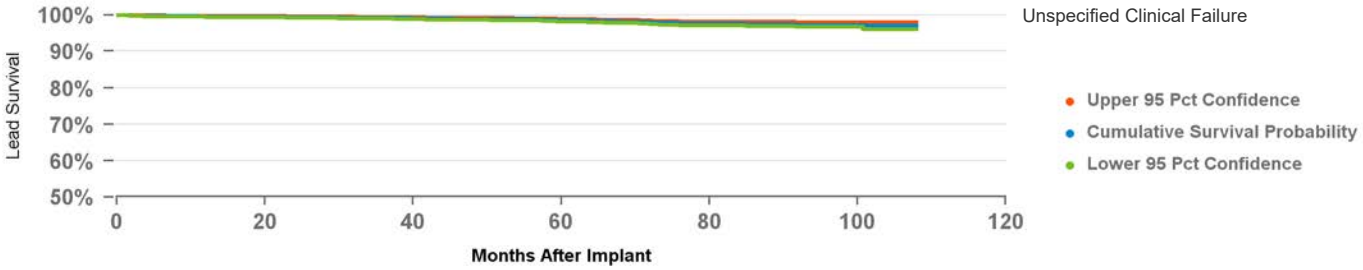
Cardiac Perforation	167
Conductor Fracture	19
Extra Cardiac Stimulation	30
Failure to Capture	381
Failure to Sense	129
Impedance Out of Range	110
Insulation Breach	3
Lead Dislodgement	596
Oversensing	308

Product Surveillance Registry Results

Number of Leads Enrolled in Study	8,680
Number of Leads Active in Study	4,489
Cumulative Months of Follow-Up	345,426

Qualifying Complications 98

Cardiac Perforation	2	Impedance Out of Range	9
Conductor Fracture	37	Insulation (not further defined)	3
Extra Cardiac Stimulation	1	Lead Dislodgement	18
Failure to Capture	19	Oversensing	5
Failure to Sense	1	Other	2
		Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.6%	99.5%	99.2%	98.9%	98.6%	98.0%	97.6%	97.4%	97.0%
#	6,401	5,132	4,191	3,350	2,673	1,810	1,006	439	132

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	2,999
Estimated Active USA Implants	1,553
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

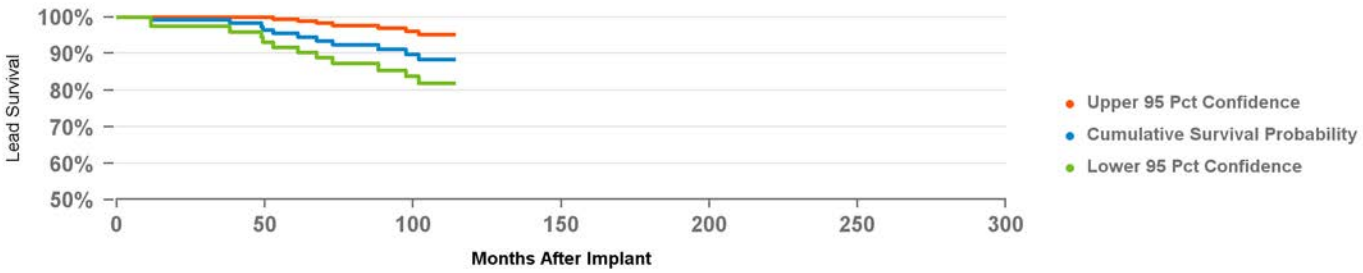
Conductor Fracture	3
Lead Dislodgement	1
Oversensing	2
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	124
Number of Leads Active in Study	6
Cumulative Months of Follow-Up	14,124

Qualifying Complications 16

Conductor Fracture	6	Impedance Out of Range	2
Failure to Capture	0	Insulation (not further defined)	2
		Lead Dislodgement	1
		Other	1
		Unspecified Clinical Failure	4



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.2%	99.2%	99.2%	98.3%	95.5%	93.4%	92.3%	91.0%	88.4%	88.4%
#	117	115	112	107	95	83	76	70	57	52

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,861
Estimated Active USA Implants	12,095
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	229
Insulation Breach	4
Crimp/Weld/Bond	1
Other	4

US Acute Lead Observations

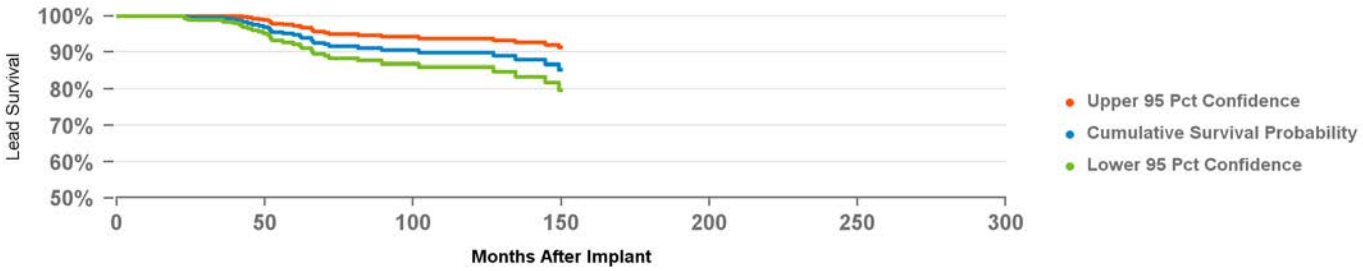
Conductor Fracture	2
Failure to Capture	17
Failure to Sense	3
Impedance Out of Range	10
Lead Dislodgement	24
Oversensing	18
Unspecified Clinical Failure	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	634
Number of Leads Active in Study	87
Cumulative Months of Follow-Up	37,464

Qualifying Complications 34

Conductor Fracture	17
Failure to Capture	4
Failure to Sense	1
Impedance Out of Range	7
Oversensing	3
Other	1
Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	#####	99.8%	99.2%	97.3%	94.8%	91.7%	91.1%	90.5%	89.9%	89.9%	89.0%	87.9%	85.2%
#	502	418	352	290	227	191	164	144	129	110	93	72	55

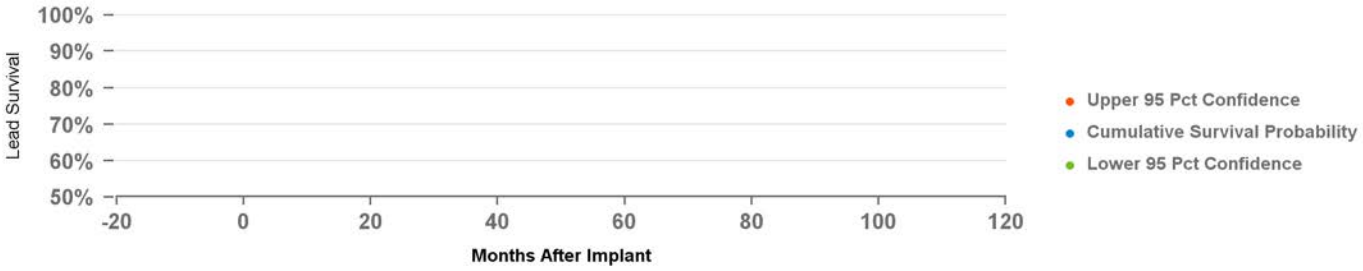
6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	3,728
Estimated Active USA Implants	3,227
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations

Cardiac Perforation	1
Failure to Capture	3
Failure to Sense	1
Lead Dislodgement	7
Oversensing	6



Years	at mo
%	
#	

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	375,372
Estimated Active USA Implants	126,901
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,372
Insulation Breach	103
Crimp/Weld/Bond	4
Other	197

US Acute Lead Observations

Cardiac Perforation	29
Conductor Fracture	26
Extra Cardiac Stimulation	2
Failure to Capture	82
Failure to Sense	36
Impedance Out of Range	61
Insulation Breach	4
Lead Dislodgement	124
Oversensing	141
Unspecified Clinical Failure	20

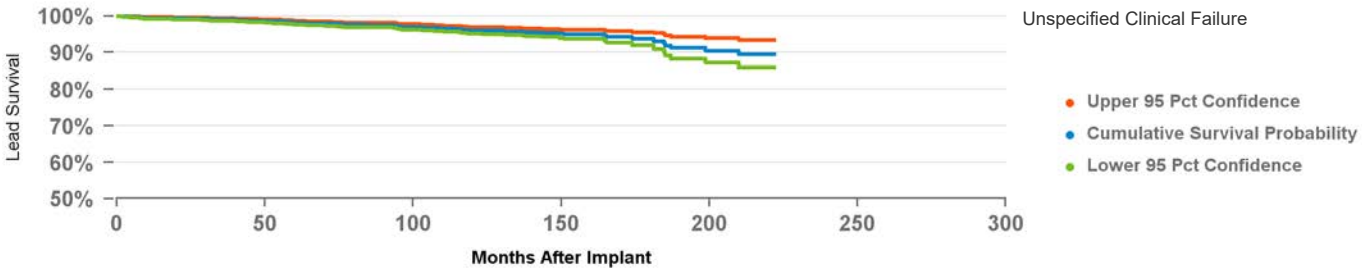
Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,553
Number of Leads Active in Study	703
Cumulative Months of Follow-Up	290,162

Qualifying Complications

102

Cardiac Perforation	1
Conductor Fracture	38
Failure to Capture	8
Failure to Sense	2
Impedance Out of Range	13
Insulation (not further defined)	6
Lead Dislodgement	5
Oversensing	21
Other	5
Unspecified Clinical Failure	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	at 222 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	97.9%	97.5%	97.1%	96.7%	96.1%	95.8%	95.3%	95.0%	94.2%	93.7%	91.2%	90.5%	89.6%	89.6%
#	3,293	2,896	2,541	2,248	2,017	1,773	1,525	1,364	1,209	1,019	812	585	378	240	159	133	112	82	67

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	134,053
Estimated Active USA Implants	92,621
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	240
Insulation Breach	15
Crimp/Weld/Bond	1
Other	37

US Acute Lead Observations

Cardiac Perforation	39
Conductor Fracture	15
Extra Cardiac Stimulation	12
Failure to Capture	116
Failure to Sense	42
Impedance Out of Range	35
Insulation Breach	1
Lead Dislodgement	236
Oversensing	80

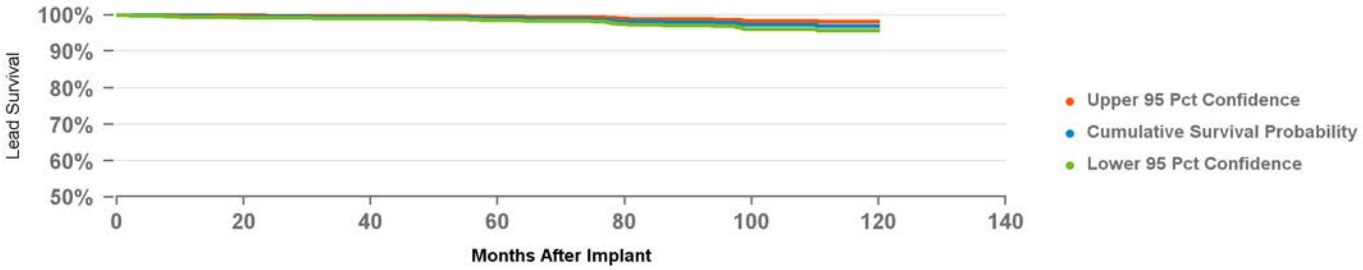
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,332
Number of Leads Active in Study	722
Cumulative Months of Follow-Up	124,607

Qualifying Complications

28

Conductor Fracture	15
Failure to Capture	4
Failure to Sense	4
Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	2
Other	1



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.7%	99.5%	99.4%	99.4%	99.0%	98.9%	98.1%	97.8%	97.2%	97.0%
#	1,806	1,525	1,352	1,143	985	823	676	543	392	104

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,381
Estimated Active USA Implants	1,662
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	218
Insulation Breach	3
Crimp/Weld/Bond	0
Other	6

US Acute Lead Observations

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

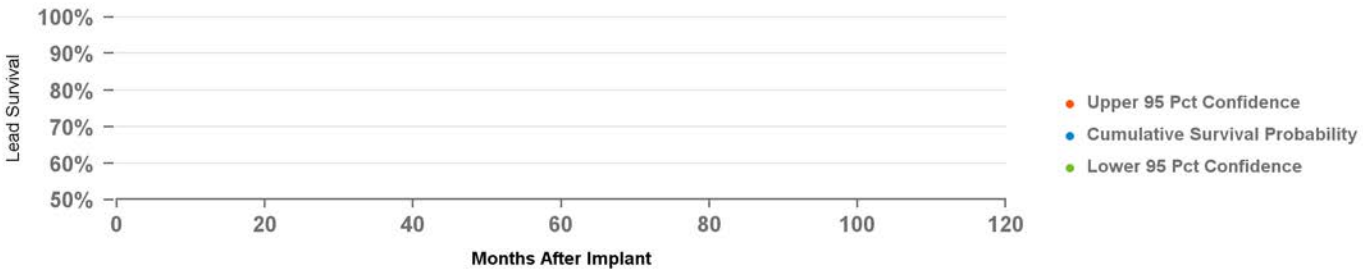
Product Surveillance Registry Results

Number of Leads Enrolled in Study	40
Number of Leads Active in Study	3
Cumulative Months of Follow-Up	2,280

Qualifying Complications

5

Conductor Fracture	4
Failure to Capture	0
Impedance Out of Range	1
Other	0



Years	at 0 mo
%	#####
#	

6949 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	186,212
Estimated Active USA Implants	24,613
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8,146
Insulation Breach	37
Crimp/Weld/Bond	3
Other	119

US Acute Lead Observations

Cardiac Perforation	10
Conductor Fracture	51
Failure to Capture	31
Failure to Sense	19
Impedance Out of Range	20
Insulation Breach	5
Lead Dislodgement	22
Oversensing	37
Unspecified Clinical Failure	24

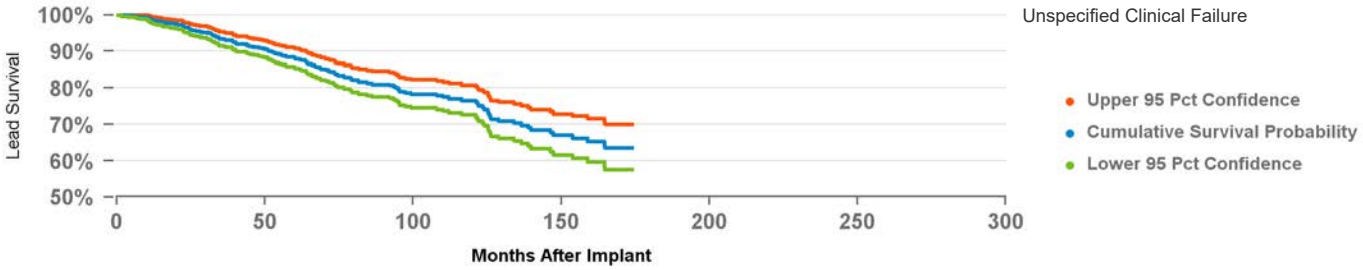
Product Surveillance Registry Results

Number of Leads Enrolled in Study	984
Number of Leads Active in Study	42
Cumulative Months of Follow-Up	57,425

Qualifying Complications

135

Conductor Fracture	77
Failure to Capture	5
Failure to Sense	6
Impedance Out of Range	19
Insulation (not further defined)	2
Lead Dislodgement	1
Oversensing	21
Other	3
Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	98.6%	96.5%	93.4%	91.0%	88.2%	84.5%	81.6%	79.0%	78.0%	76.6%	70.9%	68.5%	66.2%	63.5%	63.5%
#	719	626	532	458	392	343	281	236	187	152	125	96	79	65	55

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	5,632
Estimated Active USA Implants	2,520
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	37
Insulation Breach	0
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

Cardiac Perforation	1
Failure to Capture	1
Impedance Out of Range	17
Insulation Breach	1
Lead Dislodgement	2
Oversensing	1

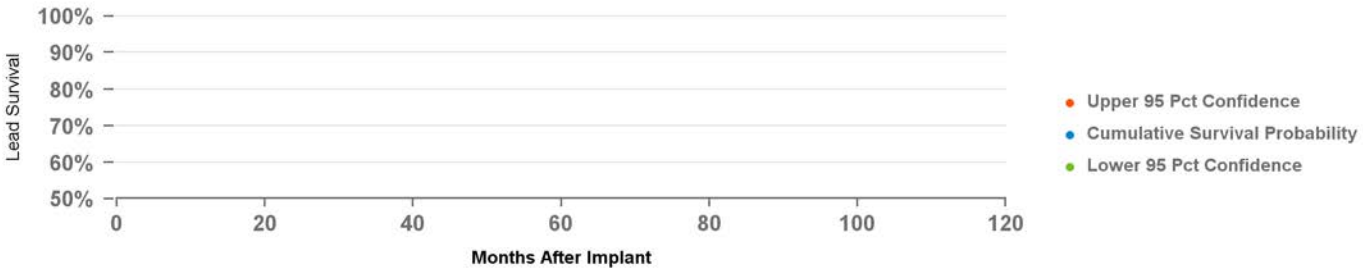
Product Surveillance Registry Results

Number of Leads Enrolled in Study	54
Number of Leads Active in Study	5
Cumulative Months of Follow-Up	2,501

Qualifying Complications

3

Conductor Fracture	1
Failure to Capture	0
Impedance Out of Range	2
Other	0



Years	at 0 mo
%	#####
#	

2187 Attain LV

US Market Release	28Aug2001
CE Approval	
Registered USA Implants	11,921
Estimated Active USA Implants	990
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	1
Insulation Breach	3
Crimp/Weld/Bond	0
Other	3

US Acute Lead Observations

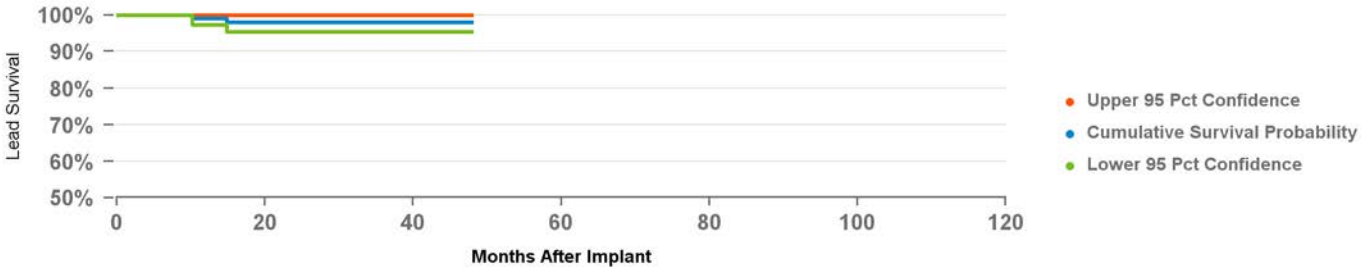
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	1
Lead Dislodgement	9

Product Surveillance Registry Results

Number of Leads Enrolled in Study	140
Number of Leads Active in Study	5
Cumulative Months of Follow-Up	7,156

Qualifying Complications 3

Failure to Capture	3	Impedance Out of Range	0
		Other	0



Years	1	2	3	at 48 mo
%	99.1%	98.0%	98.0%	98.0%
#	101	85	65	52

4193 Attain OTW

US Market Release	03May2002
CE Approval	22Dec2000
Registered USA Implants	100,664
Estimated Active USA Implants	12,387
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	91
Insulation Breach	31
Crimp/Weld/Bond	0
Other	15

US Acute Lead Observations

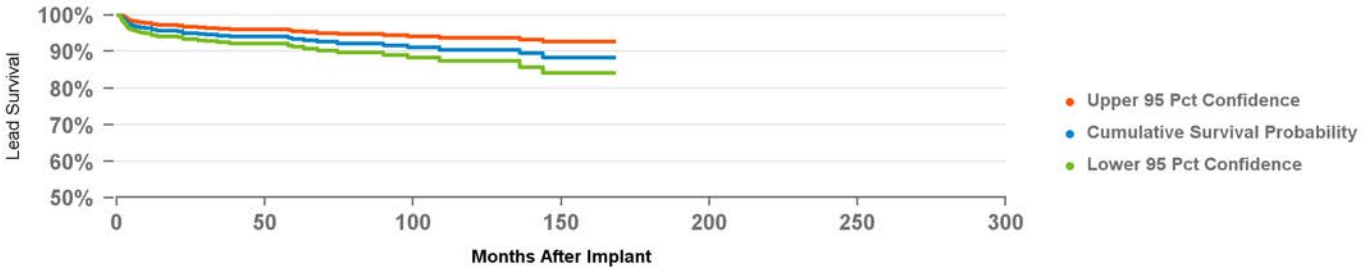
Extra Cardiac Stimulation	18
Failure to Capture	11
Lead Dislodgement	45
Oversensing	1
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	805
Number of Leads Active in Study	32
Cumulative Months of Follow-Up	42,295

Qualifying Complications 51

Conductor Fracture	1	Impedance Out of Range	2
Extra Cardiac Stimulation	10	Lead Dislodgement	15
Failure to Capture	20	Other	0
		Unspecified Clinical Failure	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	96.0%	95.1%	94.4%	94.1%	93.4%	92.6%	92.2%	91.7%	91.2%	90.5%	90.5%	88.4%	88.4%	88.4%
#	569	444	376	304	252	228	193	171	139	118	97	78	62	50

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	114,261
Estimated Active USA Implants	29,033
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	48
Insulation Breach	164
Crimp/Weld/Bond	0
Other	2

US Acute Lead Observations

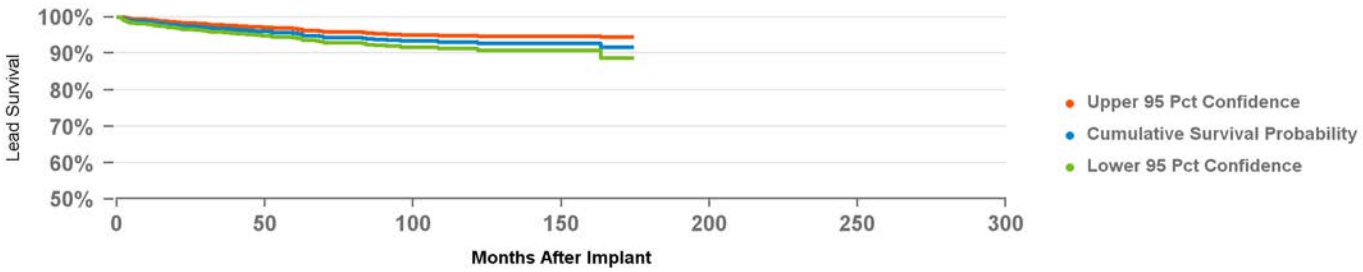
Cardiac Perforation	2
Conductor Fracture	2
Extra Cardiac Stimulation	49
Failure to Capture	42
Impedance Out of Range	9
Lead Dislodgement	153
Oversensing	2
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,654
Number of Leads Active in Study	210
Cumulative Months of Follow-Up	97,689

Qualifying Complications 68

Conductor Fracture	2	Impedance Out of Range	0
Extra Cardiac Stimulation	11	Insulation (ESC)	1
Failure to Capture	22	Insulation (not further defined)	2
		Lead Dislodgement	30
		Other	0



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	98.6%	97.4%	96.7%	96.1%	95.6%	94.3%	94.1%	93.3%	93.3%	93.1%	92.7%	92.7%	92.7%	91.6%	91.6%
#	1,239	1,047	899	771	699	617	505	425	350	283	221	149	103	68	50

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,443
Estimated Active USA Implants	6,362
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Insulation Breach	3
Crimp/Weld/Bond	0
Other	2

US Acute Lead Observations

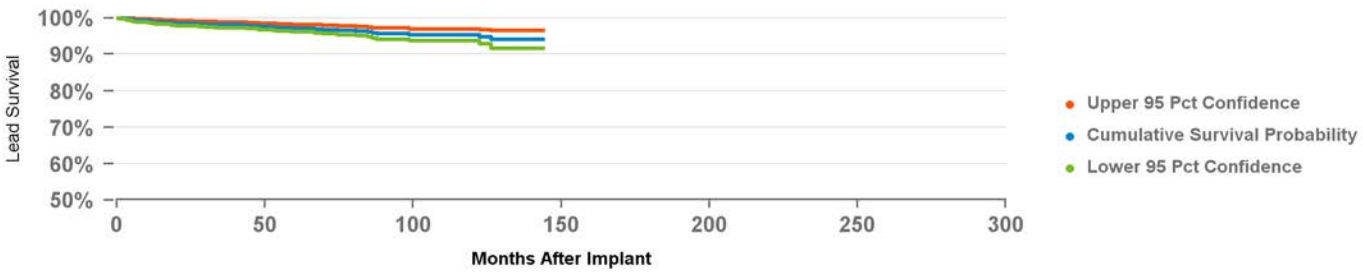
Extra Cardiac Stimulation	30
Failure to Capture	21
Impedance Out of Range	4
Lead Dislodgement	30
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,486
Number of Leads Active in Study	178
Cumulative Months of Follow-Up	85,871

Qualifying Complications 43

Conductor Fracture	4	Impedance Out of Range	2
Extra Cardiac Stimulation	18	Insulation (not further defined)	5
Failure to Capture	8	Lead Dislodgement	5
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.1%	98.5%	98.1%	97.6%	97.2%	96.8%	96.4%	95.7%	95.4%	95.4%	94.1%	94.1%
#	1,243	1,072	924	747	621	509	412	317	243	173	111	67

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	68,727
Estimated Active USA Implants	27,947
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	26
Insulation Breach	2
Crimp/Weld/Bond	0
Other	9

US Acute Lead Observations

Cardiac Perforation	3
Conductor Fracture	2
Extra Cardiac Stimulation	98
Failure to Capture	66
Failure to Sense	1
Impedance Out of Range	12
Insulation Breach	1
Lead Dislodgement	228
Oversensing	1
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,318
Number of Leads Active in Study	255
Cumulative Months of Follow-Up	116,139

Qualifying Complications 92

Conductor Fracture	3	Impedance Out of Range	2
Extra Cardiac Stimulation	17	Insulation (not further defined)	1
Failure to Capture	42	Lead Dislodgement	23
		Other	4

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	98.0%	97.3%	96.6%	95.9%	95.5%	94.8%	94.5%	93.8%	93.0%	92.6%	92.6%	92.1%
#	1,884	1,495	1,188	960	786	619	487	395	314	232	165	67

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	35,061
Estimated Active USA Implants	17,403
Fixation Type	Double Curve
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

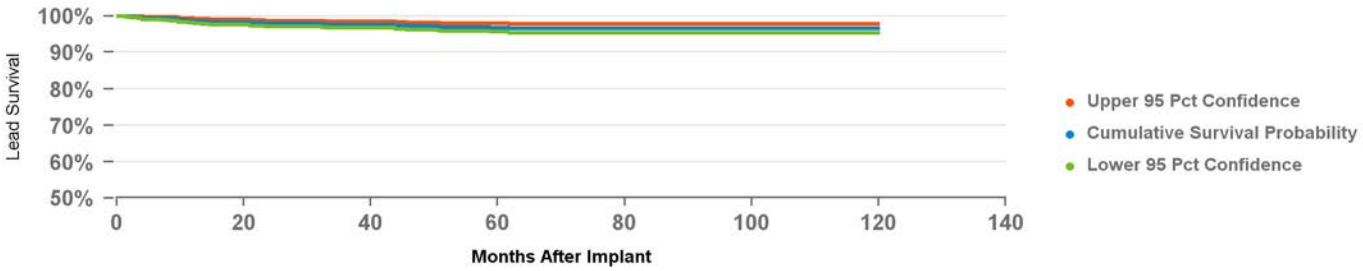
Cardiac Perforation	2
Conductor Fracture	1
Extra Cardiac Stimulation	63
Failure to Capture	35
Impedance Out of Range	11
Insulation Breach	4
Lead Dislodgement	119

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,466
Number of Leads Active in Study	291
Cumulative Months of Follow-Up	73,909

Qualifying Complications 35

Extra Cardiac Stimulation	12	Impedance Out of Range	0
Failure to Capture	9	Lead Dislodgement	13
		Other	1



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	98.7%	97.9%	97.7%	97.2%	96.8%	96.6%	96.6%	96.6%	96.6%	96.6%
#	1,160	937	769	651	544	460	393	308	192	62

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	110,907
Estimated Active USA Implants	85,582
Fixation Type	Double Curve
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

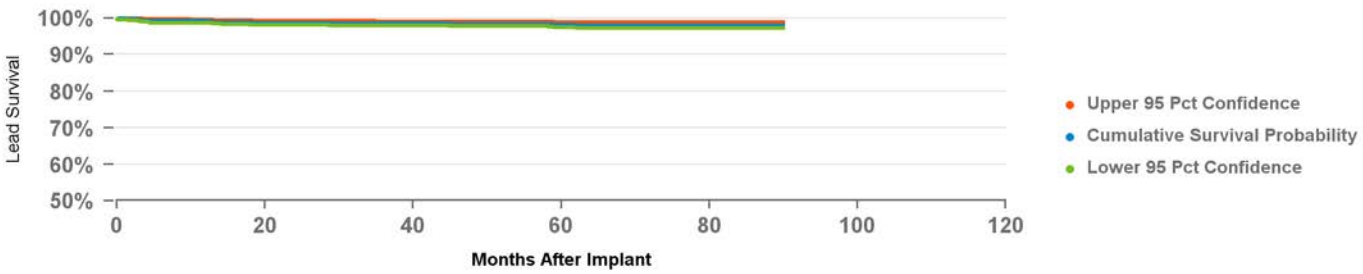
Cardiac Perforation	7
Conductor Fracture	1
Extra Cardiac Stimulation	223
Failure to Capture	143
Failure to Sense	1
Impedance Out of Range	40
Lead Dislodgement	236

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,218
Number of Leads Active in Study	995
Cumulative Months of Follow-Up	96,533

Qualifying Complications 30

Extra Cardiac Stimulation	5	Impedance Out of Range	0
Failure to Capture	7	Lead Dislodgement	15
		Other	3



Years	1	2	3	4	5	6	7	at 90 mo
%	99.2%	98.7%	98.5%	98.4%	98.1%	98.0%	98.0%	98.0%
#	1,848	1,574	1,312	938	693	440	202	93

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	8,302
Estimated Active USA Implants	4,350
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

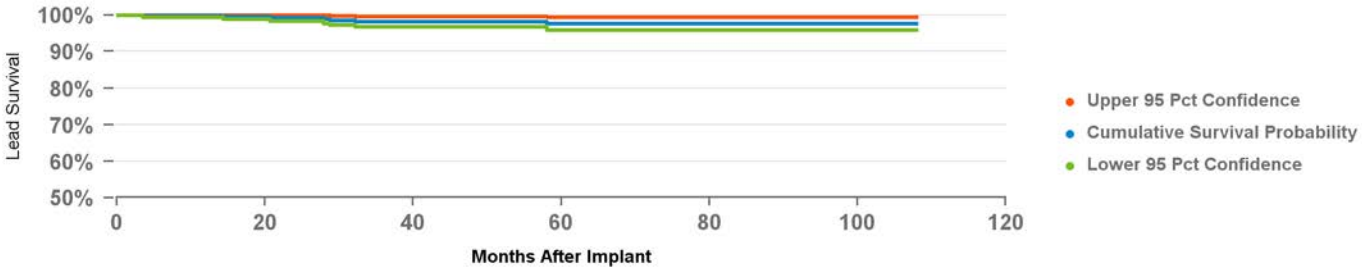
Cardiac Perforation	1
Conductor Fracture	2
Extra Cardiac Stimulation	21
Failure to Capture	12
Lead Dislodgement	35

Product Surveillance Registry Results

Number of Leads Enrolled in Study	482
Number of Leads Active in Study	115
Cumulative Months of Follow-Up	24,391

Qualifying Complications 10

Extra Cardiac Stimulation	1
Failure to Capture	4
Impedance Out of Range	0
Insulation (not further defined)	1
Lead Dislodgement	4
Other	0



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.8%	99.2%	98.2%	98.2%	97.7%	97.7%	97.7%	97.7%	97.7%
#	380	304	265	229	194	151	115	89	55

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	37,966
Estimated Active USA Implants	30,379
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Insulation Breach	0
Crimp/Weld/Bond	0
Other	7

US Acute Lead Observations

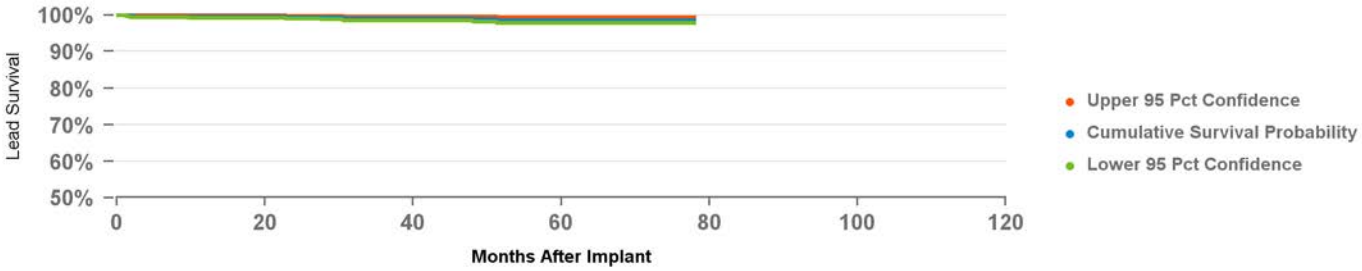
Cardiac Perforation	7
Extra Cardiac Stimulation	99
Failure to Capture	70
Impedance Out of Range	11
Lead Dislodgement	41

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,937
Number of Leads Active in Study	1,188
Cumulative Months of Follow-Up	57,784

Qualifying Complications 15

Extra Cardiac Stimulation	1
Failure to Capture	7
Impedance Out of Range	1
Lead Dislodgement	6
Other	0



Years	1	2	3	4	5	6	at 78 mo
%	99.6%	99.4%	99.1%	99.1%	98.6%	98.6%	98.6%
#	1,401	1,048	739	435	215	100	58

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	69,589
Estimated Active USA Implants	56,272
Fixation Type	S-shape
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Insulation Breach	0
Crimp/Weld/Bond	0
Other	11

US Acute Lead Observations

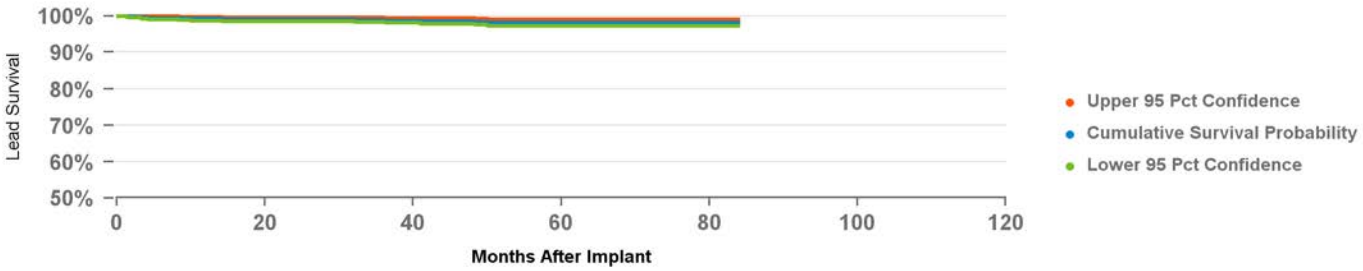
Cardiac Perforation	10
Conductor Fracture	2
Extra Cardiac Stimulation	121
Failure to Capture	83
Impedance Out of Range	29
Lead Dislodgement	80
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,347
Number of Leads Active in Study	624
Cumulative Months of Follow-Up	54,112

Qualifying Complications 17

Extra Cardiac Stimulation	3	Impedance Out of Range	0
Failure to Capture	2	Lead Dislodgement	11
Failure to Sense	1	Other	0



Years	1	2	3	4	5	6	at 84 mo
%	99.2%	99.0%	98.9%	98.6%	98.2%	98.2%	98.2%
#	1,111	935	764	536	312	161	56

4798 Attain Stability

US Market Release	17Apr2017
CE Approval	01May2020
Registered USA Implants	37,187
Estimated Active USA Implants	34,936
Fixation Type	Non-electrically Active Side Fixation
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1
Insulation Breach	0
Crimp/Weld/Bond	0
Other	9

US Acute Lead Observations

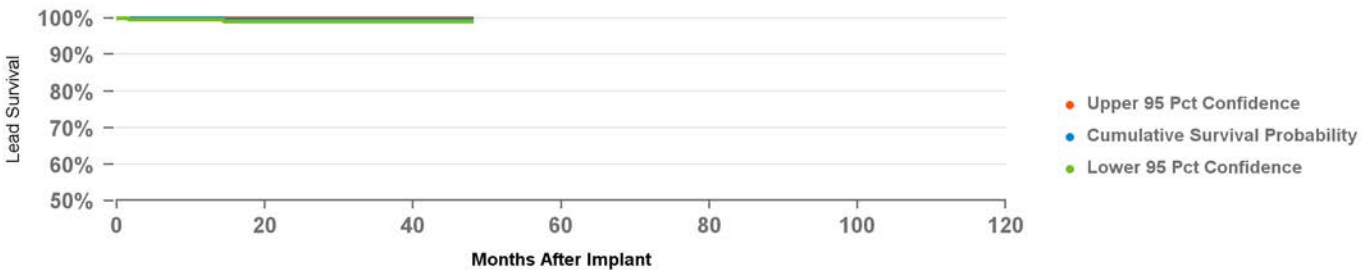
Cardiac Perforation	6
Conductor Fracture	2
Extra Cardiac Stimulation	73
Failure to Capture	68
Impedance Out of Range	27
Lead Dislodgement	86
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	985
Number of Leads Active in Study	757
Cumulative Months of Follow-Up	14,520

Qualifying Complications 3

Conductor Fracture	1	Impedance Out of Range	0
Extra Cardiac Stimulation	1	Lead Dislodgement	1
Failure to Capture	0	Other	0



Years	1	2	3	at 48 mo
%	99.9%	99.6%	99.6%	99.6%
#	463	221	116	61

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	24,151
Estimated Active USA Implants	6,970
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	295
Insulation Breach	64
Crimp/Weld/Bond	1
Other	0

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	1
Failure to Capture	11
Failure to Sense	7
Impedance Out of Range	21
Oversensing	2
Unspecified Clinical Failure	3

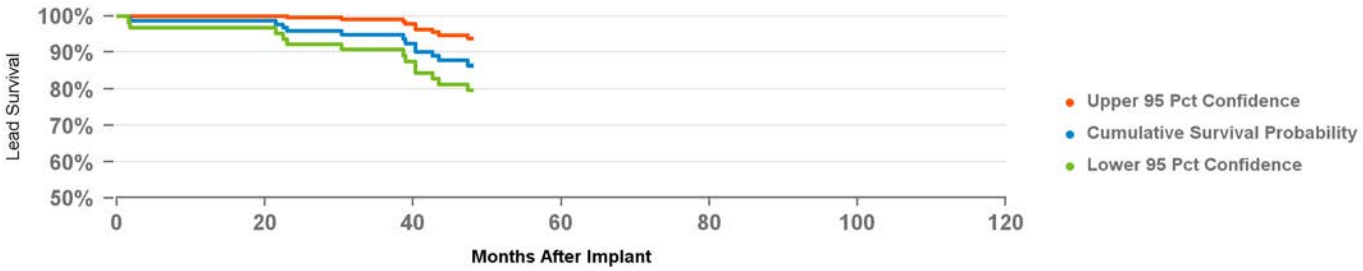
Product Surveillance Registry Results

Number of Leads Enrolled in Study	234
Number of Leads Active in Study	4
Cumulative Months of Follow-Up	7,525

Qualifying Complications

17

Conductor Fracture	10
Failure to Capture	3
Failure to Sense	1
Impedance Out of Range	0
Insulation (not further defined)	1
Oversensing	2
Other	0



Years	1	2	3	at 48 mo
%	98.6%	95.8%	94.8%	86.4%
#	119	101	83	61

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	60,048
Estimated Active USA Implants	32,808
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	135
Insulation Breach	71
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

Cardiac Perforation	1
Conductor Fracture	4
Extra Cardiac Stimulation	7
Failure to Capture	84
Failure to Sense	9
Impedance Out of Range	20
Insulation Breach	1
Lead Dislodgement	7
Oversensing	30

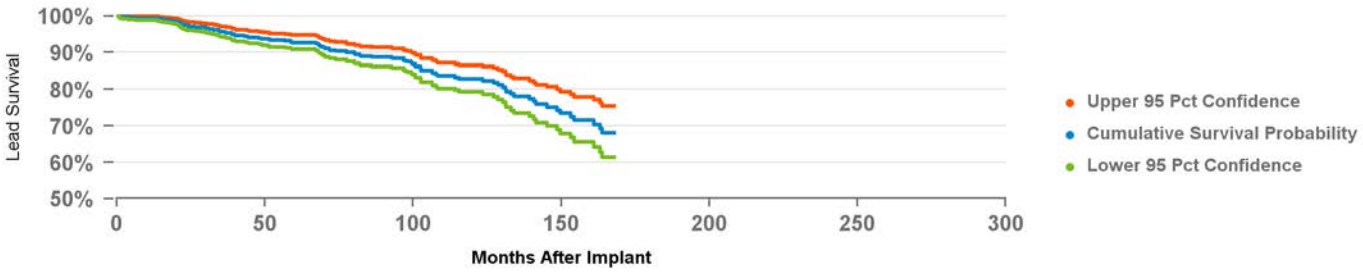
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,053
Number of Leads Active in Study	185
Cumulative Months of Follow-Up	67,181

Qualifying Complications

108

Conductor Fracture	30
Extra Cardiac Stimulation	2
Failure to Capture	34
Failure to Sense	3
Impedance Out of Range	5
Insulation (not further defined)	4
Lead Dislodgement	1
Oversensing	26
Other	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.4%	97.3%	95.7%	94.0%	92.8%	90.7%	89.0%	88.5%	84.1%	82.9%	79.4%	76.0%	71.6%	68.1%
#	817	732	655	563	495	416	357	295	218	176	127	97	67	53

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	56,908
Estimated Active USA Implants	12,368
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	31
Insulation Breach	2
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

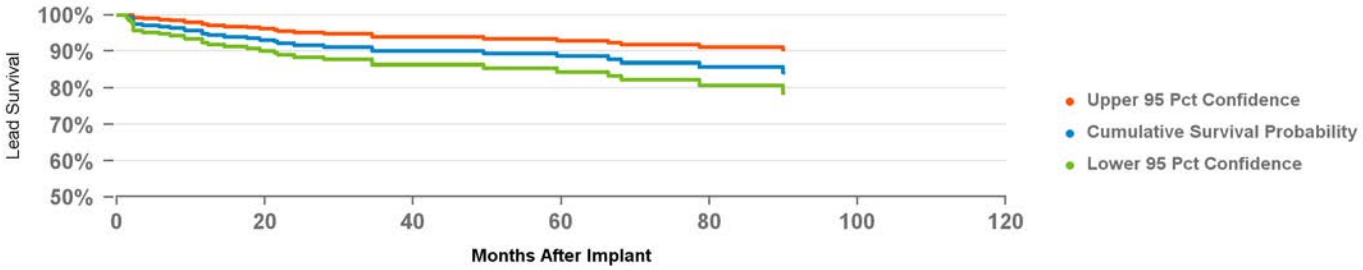
Cardiac Perforation	1
Extra Cardiac Stimulation	6
Failure to Capture	102
Failure to Sense	4
Impedance Out of Range	13
Lead Dislodgement	2
Oversensing	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	468
Number of Leads Active in Study	70
Cumulative Months of Follow-Up	16,870

Qualifying Complications 36

Conductor Fracture	4	Impedance Out of Range	1
Extra Cardiac Stimulation	1	Lead Dislodgement	3
Failure to Capture	22	Oversensing	2
Failure to Sense	2	Other	1



Years	1	2	3	4	5	6	7	at 90 mo
%	94.9%	91.7%	90.0%	90.0%	88.6%	86.9%	85.8%	84.3%
#	230	185	156	139	119	90	70	55

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	9,612
Estimated Active USA Implants	2,198
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Insulation Breach	3
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

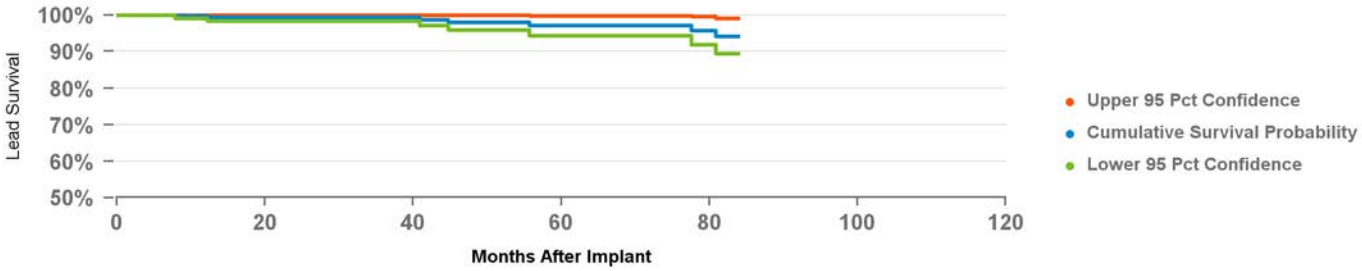
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	2
Lead Dislodgement	7
Oversensing	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	570
Number of Leads Active in Study	4
Cumulative Months of Follow-Up	15,886

Qualifying Complications 8

Conductor Fracture	3	Impedance Out of Range	0
Failure to Capture	2	Other	0
Failure to Sense	3		



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.3%	99.3%	97.9%	97.1%	97.1%	94.1%
#	288	218	160	132	105	78	56

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

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

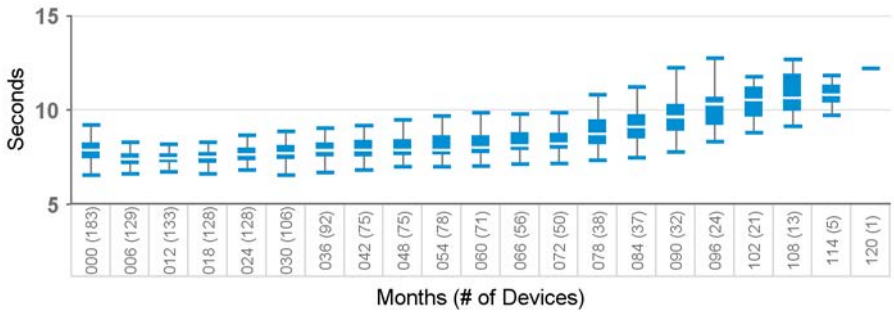
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

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

ICD and CRT-D Charge Time Performance

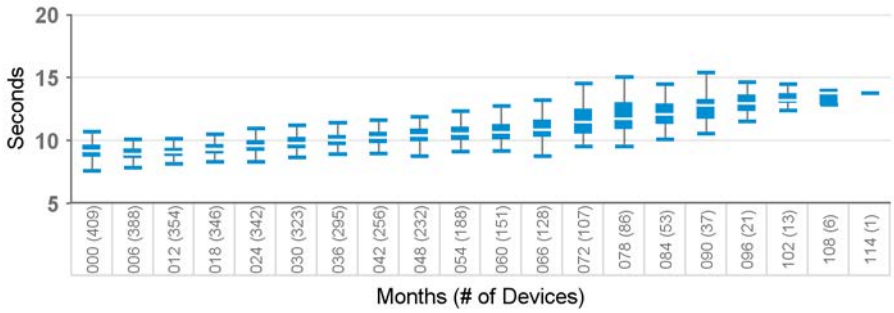
7232

Model Number	Brand
7232Cx	Maximo VR



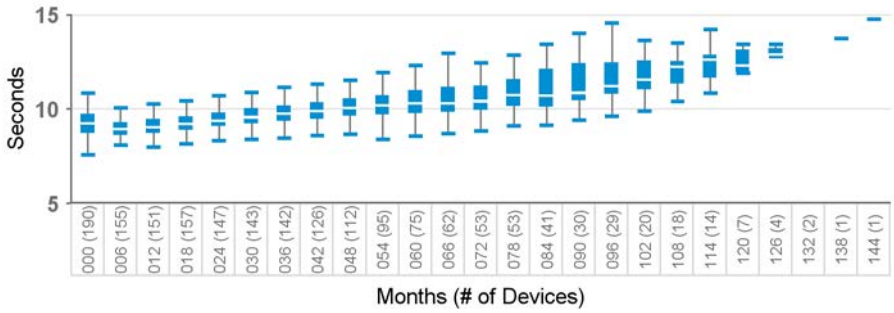
D154AWG, D164AWG

Model Number	Brand
D164AWG	Virtuoso DR



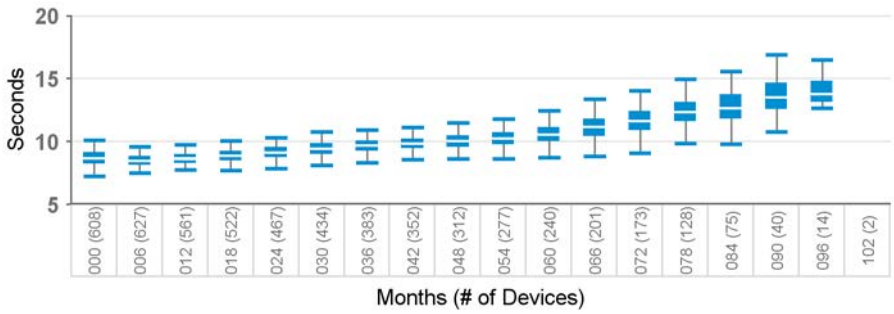
D154VWC, D164VWC

Model Number	Brand
D164VWC	Virtuoso VR



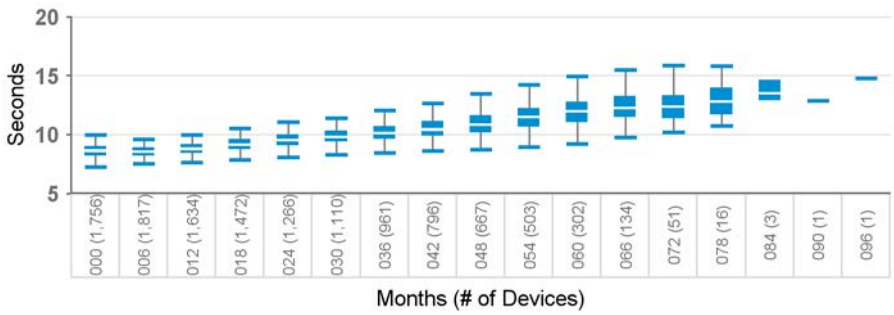
D204DRM, D214DRM, D224DRG, D234DRG

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



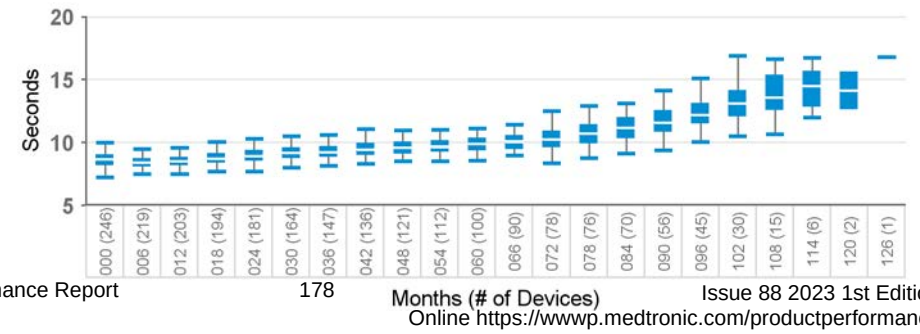
D204TRM, D214TRM, D224TRK, D234TRK

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



D204VRM, D214VRM, D224VRC, D234VRC

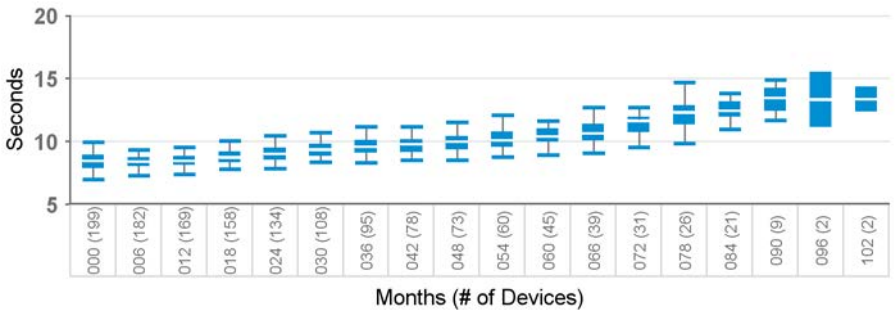
Model Number	Brand
D204VRM	Secura VR
D214VRM	Secura VR
D224VRC	Secura VR
D234VRC	Secura VR



ICD and CRT-D Charge Time Performance

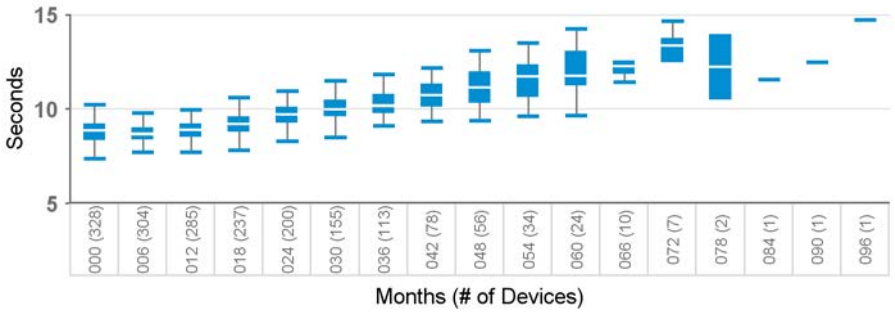
D264DRG, D284DRG, D384DRx, D394DRx

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



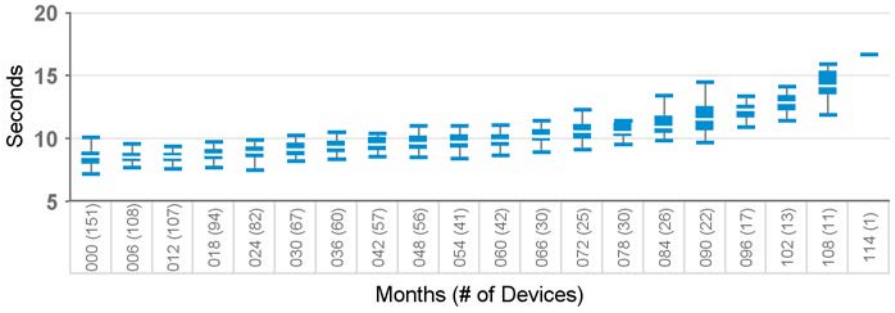
D264TRM, D284TRK, D384TRx, D394TRx

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



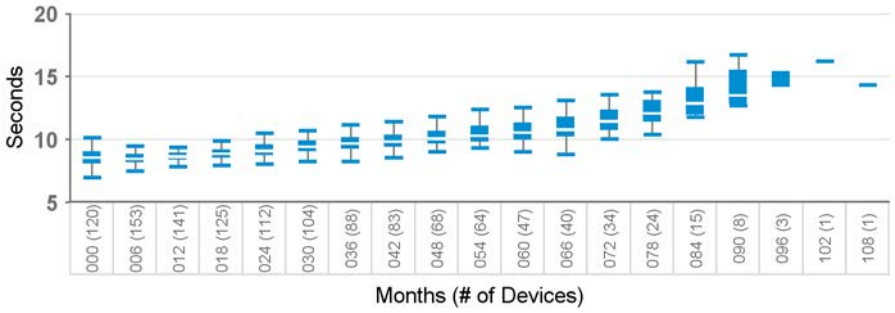
D264VRM, D284VRC, D384VRx, D394VRx

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



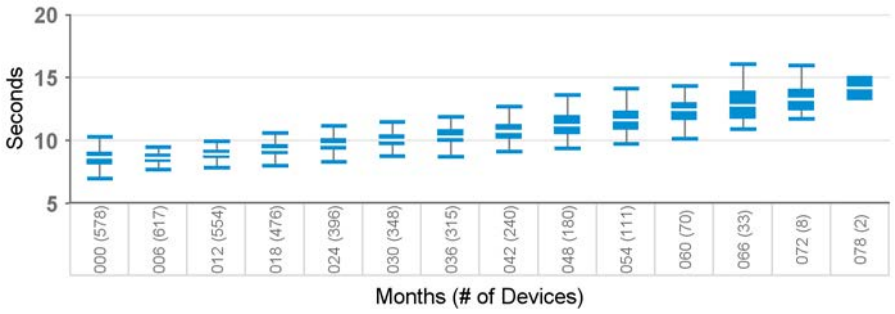
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



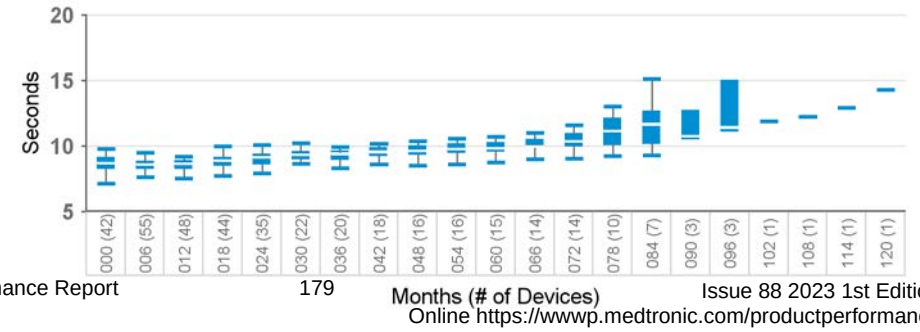
D274TRK, D294TRK

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



D274VRC, D294VRC

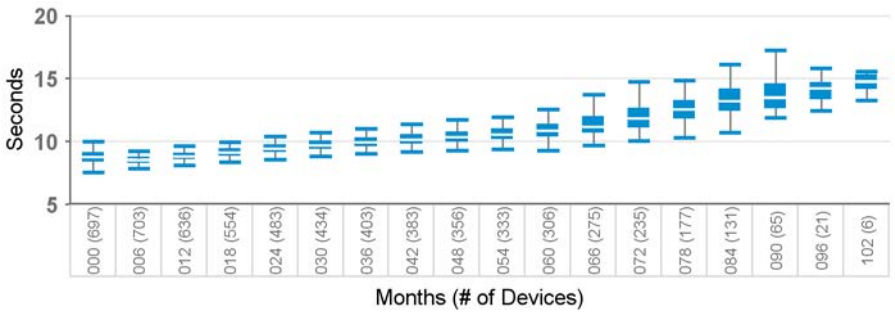
Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



ICD and CRT-D Charge Time Performance

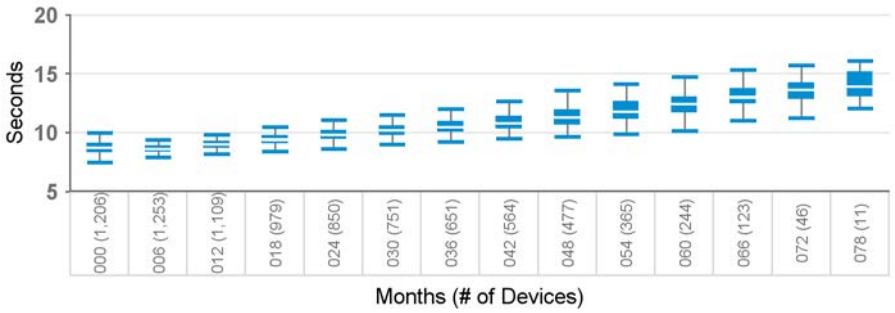
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



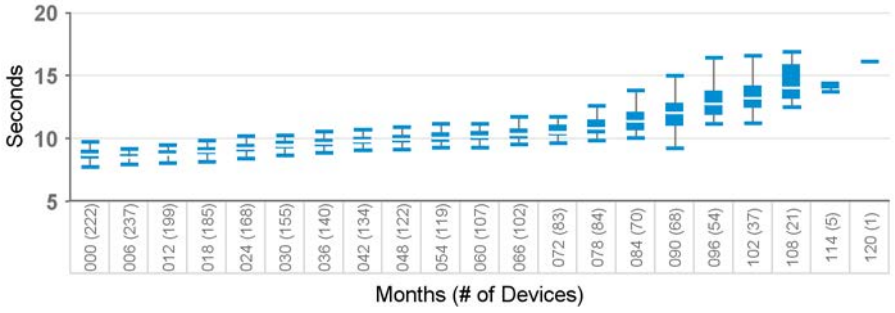
D314TRx

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



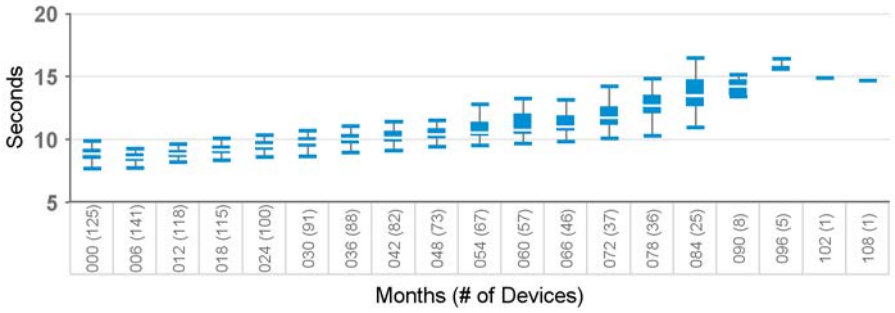
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



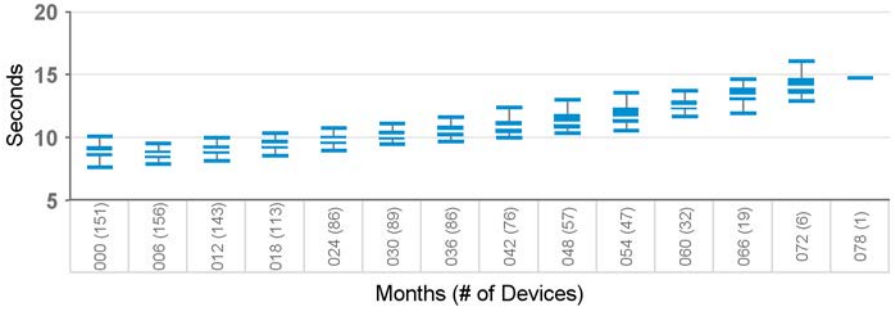
D334DRx, D364DRx

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



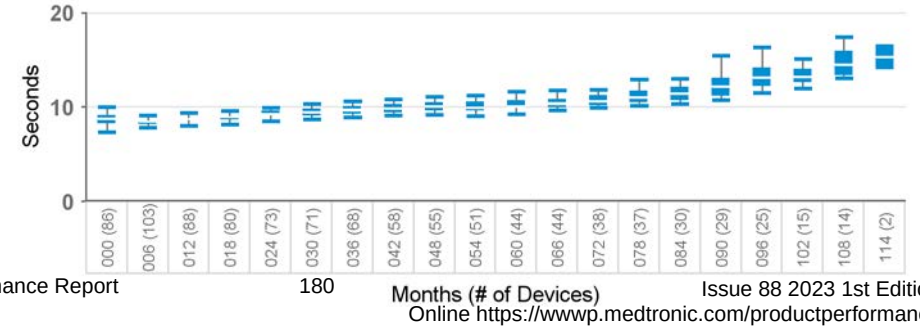
D334TRx, D364TRx

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



D334VRx, D364VRx

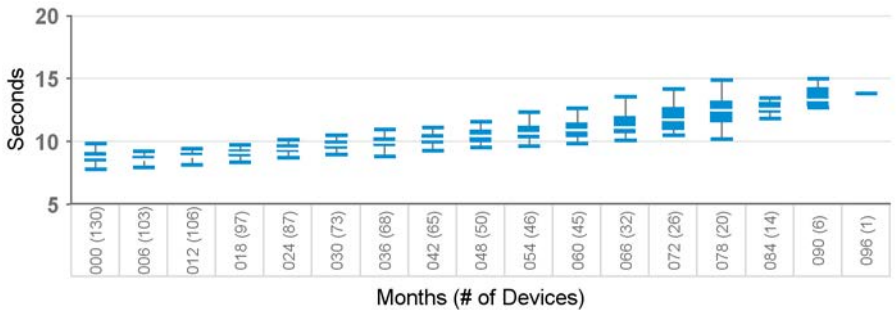
Model Number	Brand
D334VRG	Protecta VR
D334VRM	Protecta VR
D364VRG	Protecta VR
D364VRM	Protecta VR



ICD and CRT-D Charge Time Performance

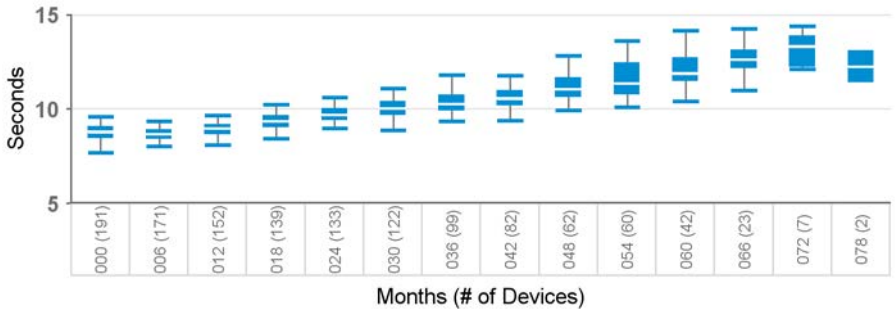
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



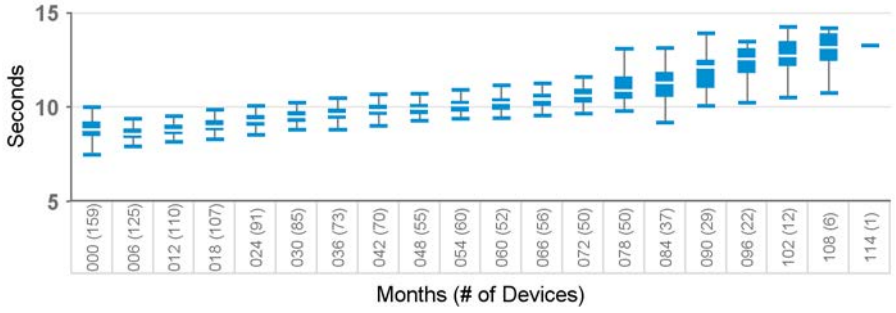
D354TRx

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



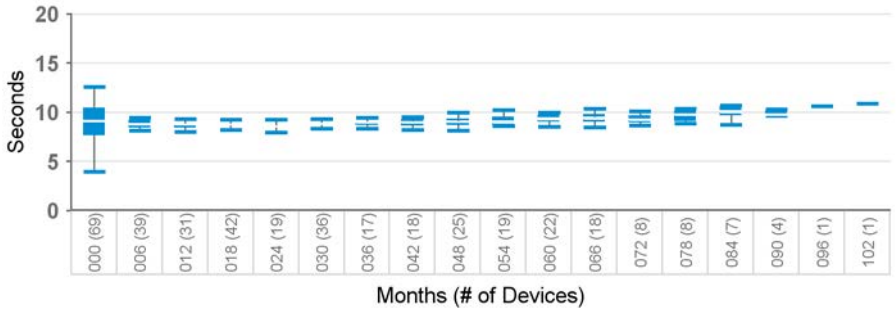
D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



DDxxxxx, DR

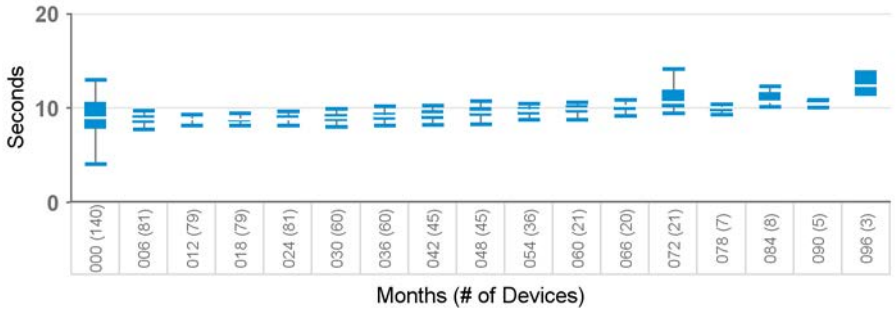
Model Number	Brand
DDBB1D1	Evera XT
DDBB1D4	Evera XT
DDBB2D1	Evera XT
DDBB2D4	Evera XT
DDBC3D1	Evera S
DDBC3D4	Evera S
DDMB1D1	Evera MRI XT
DDMB1D4	Evera MRI XT
DDMB2D1	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D1	Evera MRI S
DDMC3D4	Evera MRI
DDMD3D1	Primo
DDMD3D4	Primo
DDME3D1	Mirro
DDME3D4	Mirro



ICD and CRT-D Charge Time Performance

DTxxxxx, CRT-D

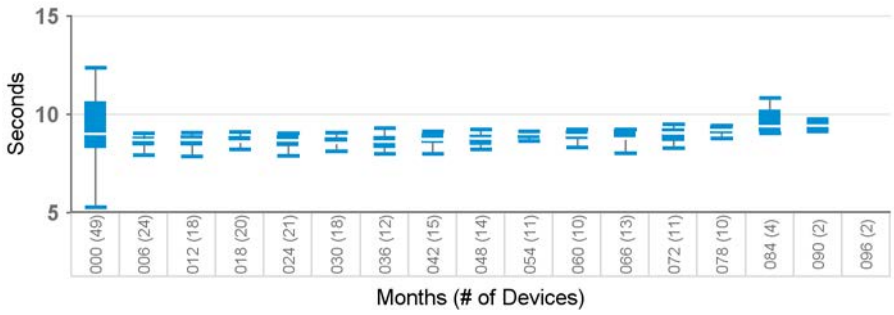
Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava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



ICD and CRT-D Charge Time Performance

DVxxxxx, VR

Model Number	Brand
DVAB1D1	Visia AF
DVAB1D4	Visia AF
DVAB2D1	Visia AF XT
DVAC3D1	Visia AF S
DVBB1D1	Evera XT
DVBB1D4	Evera XT
DVBB2D1	Evera XT
DVBB2D4	Evera XT
DVBC3D1	Evera S
DVBC3D4	Evera S
DVFB1D1	Visia MRI AF
DVFB1D4	Visia MRI AF
DVFB2D1	Visia MRI AF XT
DVFB2D4	Visia MRI AF XT
DVFC3D1	Visia MRI AF S
DVFC3D4	Visia MRI AF S
DVMB1D4	Evera MRI XT
DVMB2D1	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D1	Evera MRI S
DVMC3D4	Evera MRI S
DVMD3D1	Primo
DVMD3D4	Primo
DVME3D1	Mirro
DVME3D4	Mirro



Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

Cobalt™ XT, Cobalt and Crome™ ICDs and CRT-Ds

Original Date of Communication: May 2023

ORIGINAL COMMUNICATION - MAY 2023

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

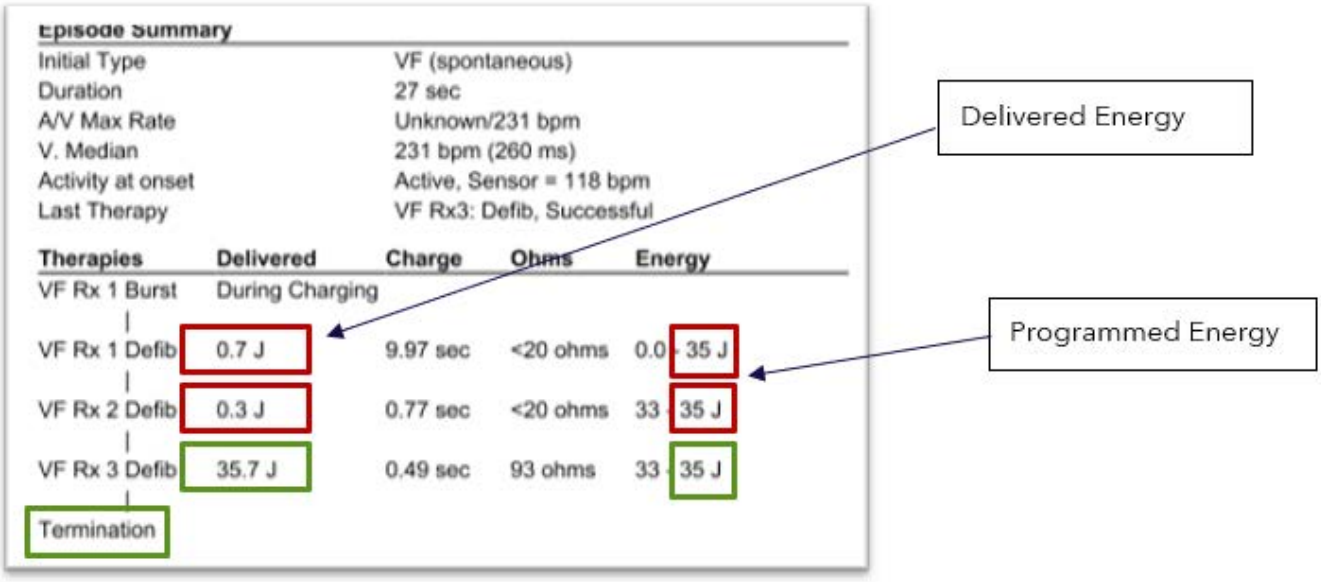
A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

PATIENT MANAGEMENT RECOMMENDATIONS:

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).



Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

ISSUE DETAILS:

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm.

Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming

Population		Projected event rate (one or more reduced- or no-energy HV therapies in an episode)	Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia
Glassed feedthrough devices with current field programming (~816,000 devices)	Overall Population of Devices	**0.02% @ 5 years***	**0.004% @ 5 years***
	For Patients with History of HV Therapy	**0.48% @ 5 years***	**0.08% @ 5 years***
Glassed feedthrough devices after all HV pathways reprogrammed B>AX	Overall Population of Devices	**0.005% @ 9 years****	**0.001% @ 9 years****
	For Patients with History of HV Therapy	**0.04% @ 9 years****	**0.01% @ 9 years****
Historical devices dating back to 2012 (~651,000 devices)	Overall Population of Devices	**0.006% @ 9years****	**0.001% @ 9years****
	For Patients with History of HV Therapy	**0.05% @ 9 years****	**0.01% @ 9 years****

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device.**Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP

events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Cobalt/Crome ICD and CRT-D devices:

Identifying SCP events during high voltage (HV) therapy delivery: When an SCP event has occurred, the device will issue an RV Defibrillation Lead Impedance CareAlert. Audible and wireless alerts are issued, if enabled. These devices are shipped with alerts enabled and are nominally active once implant detection completes.

A CareAlert will occur simultaneous with HV therapy delivery and will specifically report "RV Defib Lead Impedance 0 Ω" with the same time stamp as the therapy delivery. The alert condition is displayed in the CareAlert Events log (Data >> CareAlert Events). The Quick Look Observations will also display "Alert: RV defib lead impedance warning on Mmm/DD/YYYY." SCP events are not reflected in the long-term lead impedance trends.

Following an SCP event in devices with both the SVC Coil and Active Can enabled, the device will turn off the SVC coil. If the SCP event is caused by a lead integrity issue involving the SVC coil, turning off the SVC coil can allow any subsequent shocks to be delivered using the RV Coil -to- Active Can vector. The programmed therapy parameters will indicate the SVC Coil has been automatically disabled. The SVC coil will remain off until it is turned back on by the clinician.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

Claria, Amplia, Compia, Viva, Brava, Visia AF, Evera, Primo, Mirro ICDs & CRT-Ds

Original Date of Communication: May 2023

ORIGINAL COMMUNICATION - MAY 2023

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

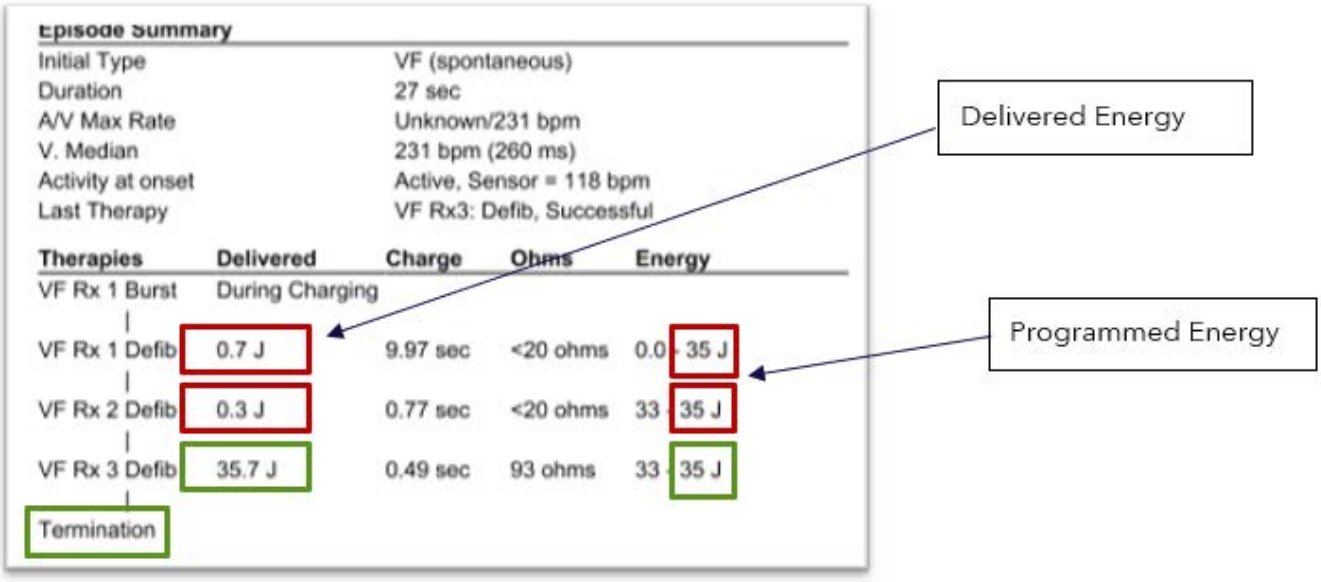
A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

PATIENT MANAGEMENT RECOMMENDATIONS:

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).



Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

ISSUE DETAILS:

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm. Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming

Population		Projected event rate (one or more reduced- or no-energy HV therapies in an episode)	Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia
Glassed feedthrough devices with current field programming (~816,000 devices)	Overall Population of Devices	**0.02% @ 5 years***	**0.004% @ 5 years***
	For Patients with History of HV Therapy	**0.48% @ 5 years***	**0.08% @ 5 years***
Glassed feedthrough devices after all HV pathways reprogrammed B>AX	Overall Population of Devices	**0.005% @ 9 years****	**0.001% @ 9 years****
	For Patients with History of HV Therapy	**0.04% @ 9 years****	**0.01% @ 9 years****
Historical devices dating back to 2012 (~651,000 devices)	Overall Population of Devices	**0.006% @ 9years****	**0.001% @ 9years****
	For Patients with History of HV Therapy	**0.05% @ 9 years****	**0.01% @ 9 years****

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device.**Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP

events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Evera/Visia AF/Primo/Mirro ICDs and Viva/Brava/Claria/Amplia/Compia CRT-D devices:

> Identifying SCP events: For episodes in which a high voltage therapy was delivered, if there is a significantly reduced-energy or no-energy shock delivered, the device may have experienced an SCP event. In each stored episode, delivered energy is displayed in the Episode Text and on the Interval Plot. If an SCP event occurred, this text may indicate that a lower energy was delivered and <20 ohm impedance value. Note: there is currently no available SCP alert in this family of devices.
>
> Clinicians can consider enabling the device audible alert and/or CareAlert for "Number of Shocks Delivered in an Episode," with "N = 1." Turning this alert "ON" may help ensure the patient and/or clinic is made aware when a HV therapy is delivered by the device.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

Product Education Brief: Alert Threshold for Lead Impedances

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

Original Date of Communication: April 2023

Overview

This Product Education Brief describes a lead impedance alert behavior in Medtronic Azure™, Astra™, Percepta™, Serena™, and Solara™ devices that may be observed when the pacing lead impedance displayed is slightly above the programmed lower alert threshold.

Details regarding CareAlerts and impedance measurements

In Azure, Astra, Percepta, Serena, and Solara devices, a CareAlert may be triggered when the lead impedance displayed is slightly above the programmed lower alert threshold.
See Figure 1 and 2 for an example case where the lower threshold for a lead impedance alert is programmed at 200 ohms. In the Lead Impedance Trend (Figure 1) the precise measured impedance value is 209 ohms; and yet in the CareAlert display (Figure 2) an alert was triggered indicating the impedance crossed the 200 ohm impedance threshold, and suggesting the impedance is 190 ohms. This scenario can happen due to the range of impedance values used for alert monitoring. In this scenario, the devices are functioning within design specifications and tolerances.

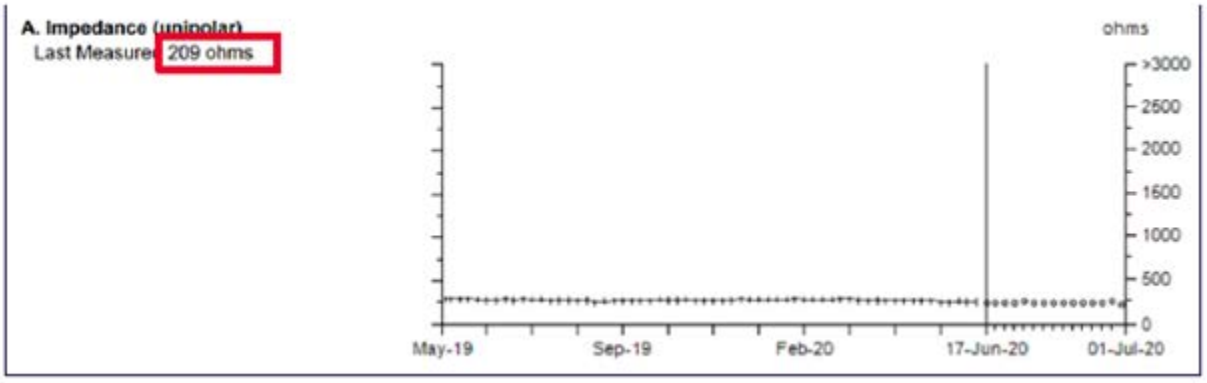

Figure 1– Lead Impedance Trend showing precise impedance values over time

Date/Time	Event	Threshold
01-Jul-2020 03:00:00	*A. Unipolar lead impedanc	190 ohms. 200 ohms

Figure 2– CareAlert triggered showing 190 ohms impedance value with a 200ohm alert threshold

While most leads are programmed to pace bipolar, every night the device will assess all lead impedance vectors at 1:00am. Unipolar measurements tend to be lower than bipolar measurements in the same system. Therefore, the nightly unipolar lead impedance measurement will likely be closer to the programmed lower alert threshold than the bipolar measurement.

The impedance value range for alerts is never higher than the measured impedance, so all impedance values that are below the programmed threshold will generate an alert as programmed.

Patient Management

Clinicians should continue to follow patients per their standard clinical practice when a CareAlert triggers for lead impedances. Impedance alerts are designed to prompt the clinician to review impedances in the Lead Impedance Trend Log. The Lead Impedance Trend records precise lead impedance measurements over time. These historic impedance measurements provide evidence as to whether the impedance is stable and functioning as designed (albeit near the programmed threshold); or unstable and necessitating further assessment and/or close monitoring. Note: If impedance values reported in the Lead Impedance Trend indicate impedances are below the programmed lower threshold, then the lead should be assessed for possible insulation breach per standard clinical practice.

Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event (2022)

Cobalt™ XT, Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: June 2022

STATUS UPDATE - MAY 2023

As of 10 August 2022, a software release is now available for CareLink™ SmartSync™ Device Managers (SmartSync). Once a SmartSync tablet has been updated with software application D00U005 version 7.1.1 (or higher), the programmer will deploy a device update to Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) to prevent the potential for an intermittent, second-phase Short Circuit Protection (SCP) event during high-voltage (HV) therapy delivery. This software update was previously announced as part of an advisory communication Medtronic issued in June 2022 (see original communication posted below).

Through 11 April 2023, Medtronic has confirmed 95 devices, out of approximately 128,600 devices distributed worldwide (observed rate 0.07%) have experienced a second-phase SCP event. For all 95 devices, ~79% of the programmed shock energy was delivered. There has been no cases reported for device programmed B>AX per the original communication and that have received the August 2022 software update that corrects for this issue when programmed B>AX. This rate remains within the projected rate expected to occur within 24 months for devices without the software update installed.

Medtronic representatives are available to work with clinicians to ensure all SmartSync tablets in their facility(s) are updated with application software D00U005 version 7.1.1 (or higher). The software can be installed by connecting each SmartSync tablet to the internet, opening the SmartSync App and accepting the on-screen prompts.

As disclosed in the June 2022 patient management recommendations, patients will require an in-clinic visit for the update to be installed into their device via interrogation with an updated SmartSync tablet. Once installed, the update will allow devices to deliver the full programmed shock energy. Programming B>AX pathway and Active Can enabled is still required. On-screen messaging will reinforce these programming recommendations. Additionally, this programming mitigates the theoretical risk for proarrhythmia if a low-level current pathway develops in the HV circuitry.

Clinicians can identify if a patient's device has successfully received the update by viewing the displayed Configuration ID and confirming the first number in the sequence is as indicated below:

- 11-1-0 or higher for Cobalt/Crome VR devices
- 10-1-0 or higher for Cobalt/Crome DR and CRT-D devices

The Device Configuration ID can be found under the "Device Information" section of the SmartSync Parameters Report, or for CareLink patients, under the Transmission Details page by selecting <More Reports > 'Parameters.'

ORIGINAL COMMUNICATION - JUNE 2022

This communication provides notice of the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Through 03 June 2022, Medtronic has identified 27 devices (0.03% of devices distributed worldwide) that have experienced a reduced-energy shock, which is accompanied by a Short Circuit Protection (SCP) alert. Medtronic has not received any reports of permanent harm or death due to this issue. Medtronic has submitted a device software update to address this issue and anticipates it will be available for download into implanted devices <beginning third/fourth quarter of calendar year 2022>, pending regulatory approvals.

ISSUE SUMMARY:

Short Circuit Protection (SCP) alerts trigger during HV therapy during the first- or second-phase of the HV biphasic waveform delivery. This communication focuses on second-phase SCP events that are the result of a secondary, low-level current pathway detected in the HV circuitry.

- A second-phase SCP event **will deliver approximately 79%** of programmed energy as a monophasic waveform.
- **Defibrillation efficacy is reduced by ~1%**for this type of SCP event when HV therapy is programmed to 40J, considering cumulative success across the full series of shocks (Rx1 through Rx6).

Based on analysis of peer-reviewed literature as well as CareLink data on shock efficacy from more than 279,000 episodes*, termination success rates for 32J (~79% of 40J), monophasic shocks versus 40J biphasic shocks are estimated in Table 1. Termination success may vary depending on individual patient risk factors and medication use.

TABLE 1

	Normal Operation (40J, Biphasic delivery)	Second-phase SCP (32J, Monophasic delivery)
Estimated First Shock Success* (in VF Zone)	89%	85%
Estimated Cumulative Success Shocks 1-6*	99%	98%

*Medtronic data on file; May 2022.

- While 0.03% has been observed to date, Medtronic projects 0.18%** of the ~80,000 distributed devices may experience a second-phase SCP event within 24 months of service life, when considering the probability for these SCP events increases over time, and the likelihood a patient will need HV therapy during that time.

- For the population of patients who received HV therapy, the observed rate was 0.77%. When projecting for this population, the chance of encountering a second-phase SCP event is ~5.0%** at 24 months.

**The above projections are based on calculations without the planned device software update. Once installed, this update, in addition to the programming recommendations, will resolve occurrences of second-phase SCP events.

Potential harms related to a second-phase SCP event include failure to terminate the arrhythmia due to reduced-delivered-energy, a theoretical risk of proarrhythmia, and complications associated with device replacement, including unnecessary lead replacement due to misinterpretation of the SCP alert.

- **While not observed clinically**, Medtronic estimates the risk for proarrhythmia is 0.002% in the AX>B configuration, and improbable in the B>AX configuration (less than 0.00004%), with Active Can pathway enabled. These risks may be higher when Active Can is disabled.
- The overall risk for **patient mortality due to this issue is estimated to be 0.002%** at 24 months when combining the likelihood a patient will need therapy with the probability an arrhythmia fails to terminate after six sequences of 32J monophasic shocks.
    - Comparatively, the risk of **patient mortality due to complications associated with device replacement is 0.032% - 0.043%**[1,2,3]

PATIENT MANAGEMENT RECOMMENDATIONS AND CONSIDERATIONS:

SCP events are evident to the patient and clinician. Devices will issue an audible tone and, for patients enrolled in CareLink, a wireless CareAlert will report *RV Defib lead impedance 0 ohms*.

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends:

- **Prophylactic device replacement is NOT recommended.**
- Remote monitoring with normal frequency of follow-up per clinic protocol, with patients' next follow-up scheduled in-clinic to allow for device reprogramming (if necessary):
    - **Programming all HV therapies to 40J with a B>AX pathway and Active Can/SVC Coil set with Active Can enabled across all therapy zones.**
- Contact Medtronic Technical Services (1-800-723-4636) or your local representative if an *RV Defib Lead Impedance Alert* reporting zero (0) ohms is observed – as this is an indicator that an SCP event was detected during HV therapy.
    - Importantly, if the delivered energy during the episode is ~79% of the programmed energy AND the SCP alert indicates an RV Defib Lead impedance alert reporting exactly zero (0) ohms, this is an indication of a second-phase SCP event (as described in this letter) and not a lead issue.

- Consider device replacement only after observing and confirming the cause of an SCP event with a Medtronic representative, with the understanding a device has an ~81% probability of delivering subsequent reduced-energy shocks, and with the understanding an update for implanted devices is anticipated to be available beginning <third quarter/fourth quarter> of calendar year 2022.
  Note: The software update will require an additional in-clinic follow-up in order for it to be installed into a patient's device. The update will ensure the full shock energy is delivered in the presence of a secondary, low-level current pathway in the HV circuitry.
- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.

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[1] Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.

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

[3] Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

Software Update Available to Correct Potential for SmartSync Telemetry Error

CareLink SmartSync™ Device Manager supporting Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: April 2022

STATUS UPDATE - MAY 2023

As of 19 April 2023, Medtronic has received 210 reports of the SmartSync Telemetry Error in Cobalt and Crome devices. No serious adverse events or permanent harms have been reported.

ORIGINAL COMMUNICATION – APRIL 2022

Medtronic is notifying health care professionals of **a software update for CareLink SmartSync™ Device Managers** (SmartSync) that will address a telemetry error that may occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Specifically, **software application D00U005 version 6.0.3 will deploy an update** to implanted devices that will correct the potential for temporary suspension of some device features (details below) due to a telemetry error involving inductive (non-Bluetooth) telemetry. As of 22 March 2022, 0.3% of devices have experienced this issue. No serious adverse events or permanent harms have been reported due to this error.

Medtronic representatives will work with you to ensure all SmartSync tablets in your facility are updated with application software D00U005 version 6.0.3 or higher. Once the software has been installed on a tablet, a patient's device will automatically receive an update (to prevent the telemetry error) during their next SmartSync session.

Details:

Some Cobalt and Crome devices may encounter a persistent "session-active" flag following the use of inductive telemetry. The persistent session-active flag is the result of a telemetry connection error that can occur when intermittent or disrupted signals manifest while communicating with the device at the end of the telemetry session. Inductive telemetry with a Cobalt/Crome device typically occurs during device interrogation with a CareLink Express™ Mobile reader head. A persistent session-active flag will result in temporary suspension of the following features (if available in the device) until the flag is cleared:

- Battery voltage measurements
- Capture Management™

- Atrial Lead Position Check™
- AdaptivCRT™, EffectivCRT™ diagnostic, and EffectivCRT™ During AF
- Wavelet™ template management
- Battery conditioning charges

Potential risks include loss of pacing or inadequate CRT support, and/or loss of Recommended Replacement Time (RRT) indicator.

When battery measurements are suspended for more than seven days, the longevity estimator cannot calculate a value and the estimator will display a grey bar with "???." Longevity estimates will be unavailable for approximately 82 weeks. A device that experiences a persistent session-active flag can be manually cleared via a specific sequence of steps, using a non-Bluetooth SmartSync telemetry session. Contact Medtronic Technical Services at 800-723-4636 for further instruction. After the persistent flag is manually cleared, the above features will automatically be restored. Remaining longevity estimates will resume approximately 82 weeks after the date the flag is cleared. The issue is unlikely to result in clinical impact to the patient given the features listed above can be restored with an in-clinic SmartSync programmer session.

Devices manufactured after July 2021 have already received the software update and are not susceptible to the described behavior. Refer to Appendix A (below) for details on how to identify which Cobalt/Crome devices have already received the update.

Patient Management Recommendations:

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends continuing normal follow-up frequency per local clinic protocol.

Once the software is installed on a SmartSync tablet, please follow these recommendations:

- **Patients routinely seen in the clinic** will automatically receive the update during their next interrogation using an updated SmartSync tablet (D00U005 version 6.0.3 or higher). No additional programming of the device is required.
- **Patients followed remotely who do not have regularly scheduled in-clinic sessions**should have their next follow-up session conducted in clinic using an updated SmartSync tablet (D00U005 version 6.0.3 or higher). No additional programming of the device is required.

Note: If a patient's device displays a grey longevity estimator bar with "???," the device may have a persistent session-active flag. Contact Medtronic Technical Services at 800-723-4636 for assistance.

APPENDIX A

How to Confirm a Patient's Device Has Received the Update?

Each device will display a Device Configuration ID after interrogation by an updated SmartSync tablet, or after transmitting to CareLink. The Device Configuration ID can be found via the Parameters Report as noted below:

For SmartSync – the following is available from the Parameters Report PDF file.

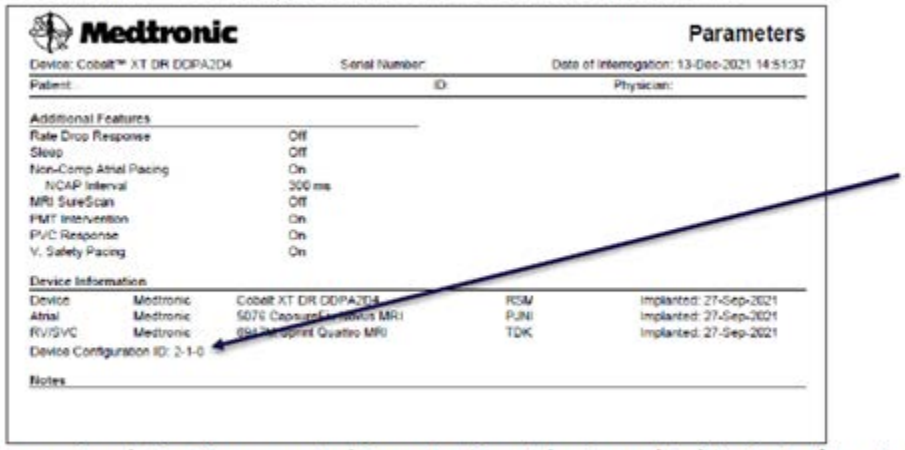


Image: Sample SmartSync-generated Parameters Report showing updated Device Configuration ID.

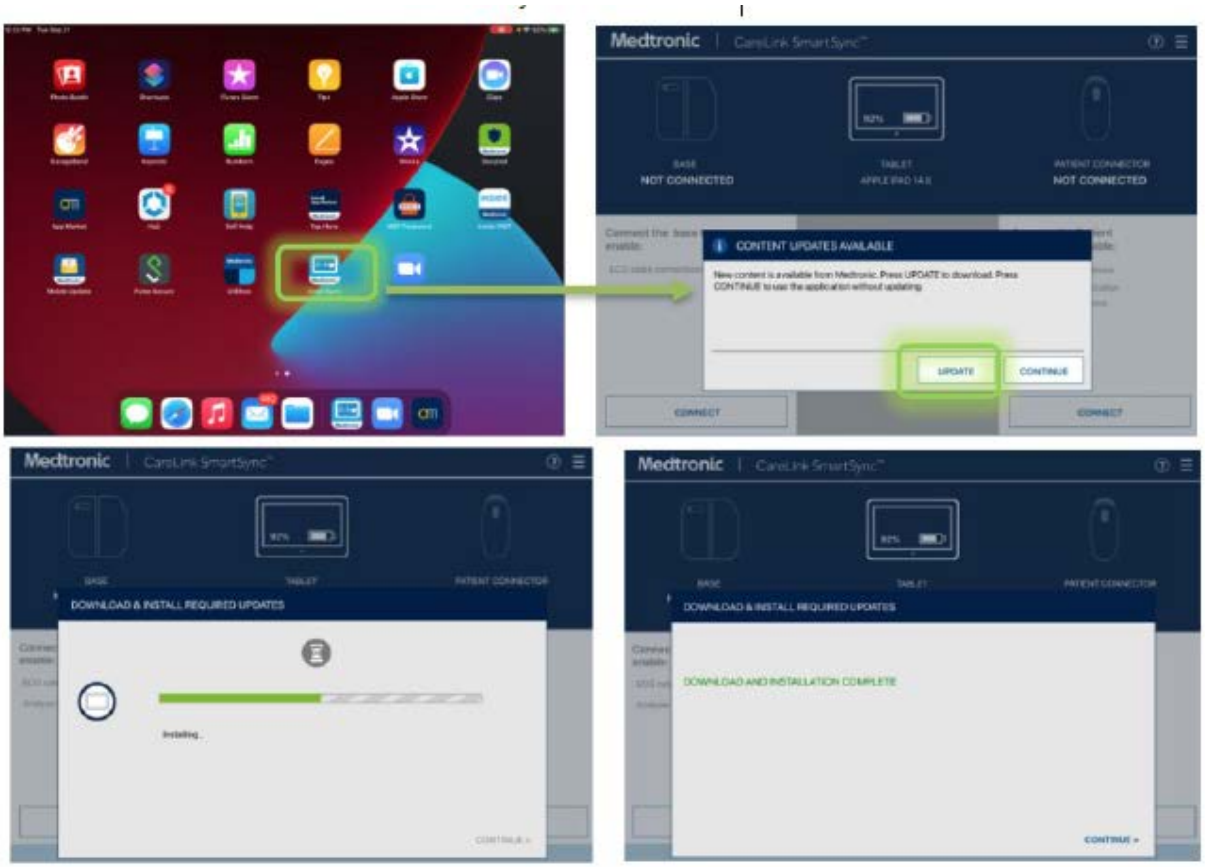
For CareLink – the following is available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'

Image: Sample CareLink Parameters Report showing updated Device Configuration ID.

How do I update my SmartSync™ application software for the issue described in the April/May 2022 communication?

On any tablet, you can update to the most recent version for all applications resident on that tablet by simply connecting to the internet and either automatically discover if new software is available by launching the SmartSync App (see images below), OR manually discover if new software is available by navigating to the Software Information

screen and perform "Check for Updates." Contact your local Medtronic representative or Medtronic Technical Services at 800-638-1991 if you need assistance.



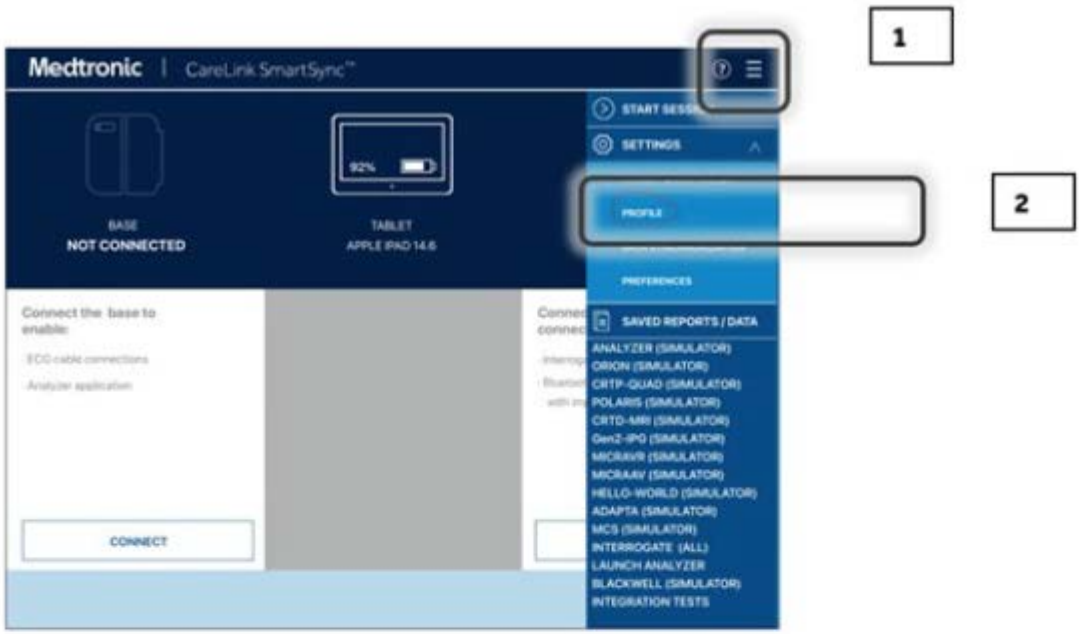
How do I confirm if a SmartSync tablet has already been installed with the updated software?

On any tablet, you can confirm the application software version for any device family by:

1. Selecting the MENU in the upper right corner of the SmartSync App [1]
2. Selecting PROFILE [2]
3. Selecting the SOFTWARE tab and scrolling through the SOFTWARE INFO list [3]

If the software update for this issue has already been installed, you will see the following versions listed:

- The Common/Platform application version is 3.6.4 (or higher)
- is 6.0.3 (or higher)



3 - Updated application versions

A Subset of LINQ II ICMs Susceptible to Moisture Ingress

LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: January 2022

Medtronic has identified eight (8) LINQ II Insertable Cardiac Monitors (ICMs) distributed worldwide that may experience a loss of functionality. Medtronic has provided a communication to the eight healthcare professionals following a patient implanted with one of these ICMs.

Issue Description:

Medtronic has identified eight (8) LINQ II ICMs that may be susceptible to moisture ingress that could cause a loss of functionality prior to the recommended replacement time (RRT). Loss of functionality could result in the ICM failing to transmit and collect data. Potential harms include those associated with the risk of a delayed medical intervention, a missed diagnosis, or an explant procedure. Through 05-JAN-2022 there have been zero (0) complaints or harms reported as a result of this issue.

Serial Number	GTIN
RLB035341G	00763000060374
RLB051224G	00763000060374
RLB059666G	00763000060374
RLB061064G	00763000060374
RLB061812G	00763000060381
RLB066367G	00763000060374
RLB091638G	00763000060374
RLB122769G	00763000554002

Patient Management Recommendations:

- For patients that are monitored on CareLink, LINQ II ICMs are designed to transmit nightly. When a transmission is not sent for 14 consecutive nights, the ICM will appear on the Disconnected Monitor list. If the ICM appears on this list, please contact Medtronic Technical Services for further assistance by calling < U.S. 1-800-929-4043>.
- Disconnected Monitors can be viewed from the Medtronic CareLink Network home page, under "Manage My Patient Views."
- For patients not on CareLink, where more frequent in-clinic office visits are not an acceptable option for monitoring the patient, ICM replacement may be appropriate. Also consider whether enrolling the patient on CareLink is an option. Contact Medtronic Technical Services for assistance by calling < U.S. 1-800-929-4043>.

Procedure Education Brief: Micra TPS Implant

Micra TPS devices

Original Date of Communication: November 2021

Overview

This Medtronic Procedure Education Brief provides a reminder of specific implant procedure safety recommendations included in the current labeling for Micra™ VR and Micra™ AV Transcatheter Pacing System (TPS) specifically from the Micra Instructions for Use (IFU) and the Micra implanter training program. Following instructions provided in the IFU and implanter training can reduce the risk of cardiac perforation, especially considerations for delivery system steering, repositioning the device, and patient selection.

Micra IFU and Implant Procedure Training

The Micra IFU is available on the Medtronic electronic manuals website (https://manuals.medtronic.com/manuals/main/region). Implanter training material for implanters who have attended training, and been certified to implant Micra TPS, can be found on the Medtronic Academy website (https://www.medtronicacademy.com/products/micra-transcatheter-pacing-systems-overview-and-training). These instructional materials provide recommendations that limit implant complications such as:

- patient selection considerations to minimize perforation risk
- steering the delivery system with the use of fluoroscopy
- identifying implant location at the right ventricular septum with the use of contrast-enhanced fluoroscopy
- confirming position on the septum with contrast-enhanced fluoroscopy prior to deployment
- considerations for repositioning the device
- ensuring attending staff are prepared to manage pericardial effusion and tamponade, including immediate access to echocardiography equipment and availability of a pericardiocentesis kit
- recognizing clinical signs and symptoms of pericardial effusion and tamponade in order to minimize clinical response time
- preparedness for cardiac surgical intervention

Micra Safety and Effectiveness Data

On 17 November 2021, the US FDA posted a Letter to Healthcare Providers (*Leadless Pacing Systems: Risk of Major Complications Related to Cardiac Perforation During Implantation - Letter to Health Care Providers*) reminding physicians about the rare but possible risk of cardiac perforations associated with leadless pacemaker implantation. They reiterated the specific recommendations from Medtronic Micra implant training and IFU (reviewed above). This communication can be found here: https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers.

While regulatory agencies and Micra implanters are aware that cardiac perforation is a known risk, the FDA Letter to Healthcare Providers included data for which implanters may be seeking additional context. The letter indicated that risk of cardiac perforation between transvenous pacing implants and Micra implants are similar, and that Micra implant complication rates are within expectations. The letter also indicated that in some scenarios, when a perforation occurs with a Micra implant procedure, the severity of the perforation complications can be higher than when a perforation occurs with a transvenous implant procedure.

Data from our Global Complaint Handling database suggests that the Micra rate of perforation is 0.6% and the rate of perforation related death is 0.13% out of over 100,000 implants worldwide. The Micra real-world perforation rate is in-line with, or lower than, the perforation rate observed in pre-market or post-market clinical studies[1].

Since Micra received pre-market approval in 2016, Medtronic has continuously monitored its safety and effectiveness. Multiple studies have shown that Micra has a high rate of implant success (exceeding 99%)[2,3]. Additionally, in the global Micra Investigational Device Exemption (IDE) Trial, Micra has been shown to reduce the risk for major complications compared to transvenous implants (through 12-months) by 48%[2], and in the global Micra Post Approval Registry by 63%[3].

Medtronic is further assessing the outcomes of Micra in the Micra Coverage with Evidence Development (CED) Study, which is a continuously enrolling, observational, cohort study evaluating complications, utilization, and outcomes of Micra.

Recent publications from the Micra CED Study in July 2021[4] and November 2021[5] based on 5,746 Micra patients and 9,622 with contemporaneously implanted transvenous single-chamber pacing patients show that at time of implant, Micra patients tend to be sicker than the transvenous single-chamber pacemaker population. Micra patients have a higher comorbidity burden as measured by the Charlson comorbidity index (5.1 vs 4.6, P<0.001) and a higher rate of end stage renal disease (12.0% vs 2.3%, P<0.001)[4]. Acute and longer-term outcomes reported in these publications are shown in the table below.

Measure	Unadjusted Results (Micra vs Transvenous-VVI)	Results Adjusted for Patient Medical History (Micra vs Transvenous-VVI)
Acute (30-day) device-related complications including dislodgement, infection, pocket complications[4]	1.4% vs 2.6% (P<0.001)	1.4% vs 2.5% (P<0.001)
Total acute (30-day) complications[4]	8.4% vs 7.3%(P=0.02)	7.7% vs 7.4% (P=0.49)
Cardiac perforation/effusion[4]	0.8% vs 0.4% (P<0.001)	0.8% vs 0.4% (P<0.001)
30-day all-cause mortality[5]	4.4% vs 3.8% (P=0.10)	4.0% vs 4.4% (P=0.60)

2-year reintervention rate[5]	3.0% vs 4.8% (P=0.006)	3.1% vs 4.9% (P=0.003)
2-year chronic complications[5]	4.9% vs 6.5% (P<0.001)	4.6% vs 6.5% (P<0.001)
2-year all-cause mortality[5]	34.0% vs 31.6% (P=0.002)	31.4% vs 32.5% (P=0.37)

Medtronic monitors and evaluates product performance and publishes device performance data on our product performance website http://productperformance.medtronic.com. In addition, Medtronic continues to collaborate with physicians and regulatory agencies to improve patient outcomes and clinical experience as part of our dedication to patient safety and product effectiveness.

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[1] Micra IDE: 1.8% (13/726), Micra post-approval registry 0.8% (15/1811), Micra Coverage with Evidence Development 0.8% (47/5746)

[2] Reynolds et al. *NEJM* 2016; 374(6): 533-541.

[3] El-Chami et al. *Heart Rhythm* 2018; 15(12): 1800-1807.

[4] Piccini et al. *JAMA Cardiology* 2021; 6(10): 1187-1195.

[5] El-Chami et al. *EHJ* 2021; ePub ahead of print

Software Update - SmartSync Error Message on Device Interrogation

CareLink SmartSync™ Device Manager supporting Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: October 2021

STATUS UPDATE - MAY 2023

Through 11 April 2023, Medtronic has confirmed 31 reports of a software interrogation failure due to this issue out of approximately 128,467 devices distributed worldwide (0.024%). No permanent patient harms have occurred.

ORIGINAL COMMUNICATION - OCTOBER 2021

This communication provides notice of **a software update for CareLink SmartSync™ Device Managers (SmartSync)** to correct the potential for a small number of SmartSync interrogation sessions, or CareLink network transmissions to fail due to a software error. The issue described below can only occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds) when the *current* session data includes diagnostic episodes with a specific type of VT/VF therapy sequences.

Please install **application software D00U005 version 5.0.0** (or higher) on all SmartSync tablets in your facility. This software update ensures SmartSync tablets will interrogate all episode and data types for all programmer sessions. No programming or reprogramming of devices is required.

ISSUE DETAILS

With prior software versions, a small number of SmartSync interrogation sessions, or CareLink network transmissions may fail for Cobalt or Crome devices when the *current* session diagnostic data includes any VT/VF episode type with multiple therapy sequences and three or more data recording suspensions. For these specific episodes, the software is unable to decode and process the data. SmartSync will display a message indicating an "Unexpected error occurred", and the application software requires restarting. Within CareLink, the current transmission processing may fail, and the information will not be viewable. For both of these scenarios Medtronic Technical Services can assist clinicians with retrieving stored device information for the failed transmission.

Through 24 Sep 2021, Medtronic has confirmed 22 reports of a software interrogation failure due to this issue out of approximately 48,700 devices distributed worldwide (0.045%). No permanent patient harms have occurred.

No device operations are affected by the software error. All device features and therapies continue to operate as programmed. Risks associated with an interrogation failure are potential for unnecessary device replacement, and/or

delays in patient care due to missed Care Alerts, or inability to access stored device diagnostic information until a SmartSync tablet with the updated software is located, and a new session can be established.

The SmartSync software release D00U005 version 5.0.0 is available for immediate download on to all tablets. (Software availability varies by geography.) A CareLink software update is anticipated to be released in mid-2022.

PATIENT MANAGEMENT RECOMMENDATIONS

We realize that each patient requires unique clinical considerations. Medtronic recommends physicians follow normal clinical practices given these devices will continue to operate as programmed:

- If a failure to interrogate a Cobalt or Crome device occurs with a SmartSync programmer, confirm that the SmartSync application software has been updated to D00U005 version 5.0.0 (or higher). Contact your Medtronic representative or Tachy Technical Services at 800-723-4636 for assistance with retrieving the session data.

  Note: Cobalt and Crome devices are only supported by the SmartSync programmer; these devices are not supported by the Model 2090 and Encore programmers.

- If a CareLink transmission is attempted, but the transmission is not viewable on the CareLink network (i.e., the transmission is missing from the transmission list for the patient), contact Medtronic Technical Services at 800-723-4636 for assistance. This team can help with retrieving the transmission data and/or provide additional troubleshooting guidance that may be needed. Missing transmissions can occur due to connectivity or other issues and may be unrelated to the software decode error described in this letter.

LINQ II - Brady, Pause and PVC Detections Disabled Following Electrical Reset

LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

STATUS UPDATE - MAY 2023

Medtronic implemented a manufacturing update to all newly manufactured LINQ II ICMs released into distribution to prevent a partial electrical reset from disabling Brady, Pause and PVC event detection.

Updated LINQ II ICMs can be identified, before being implanted, by the GTIN that is printed under the barcode on the box. The new U.S. LINQ II GTIN ends with "002."

As a reminder, unused LINQ II devices manufactured prior to June 2021 were requested to be returned to Medtronic per the Original advisory (dated June 2021) – these devices cannot be updated in the field and will continue to be susceptible to the issue.

ORIGINAL COMMUNICATION - JUNE 2021

This notice is to inform you that LINQ II insertable cardiac monitors (ICMs) that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause and PVC events to clinicians. Medtronic estimates that 0.21% of LINQ II ICMs have experienced a partial electrical reset resulting in the inability to detect Brady, Pause and PVC events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady, Pause and PVC episode types will not be reported to the clinician.

- A correction for currently implanted LINQ II ICMs is not available.
- We are requesting that hospitals quarantine all LINQ II ICMs on hospital shelves. Physicians should cease implanting any remaining LINQ II ICMs that may remain in shelf stock and return any unused product to Medtronic.
- There will be an update for future manufactured LINQ II ICMs, which is anticipated to be available in the U.S. July 2021.

This letter contains a description of the information known to date and patient management recommendations.

ISSUE DESCRIPTION

Medtronic has identified that LINQ II ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause, and PVC events. A partial electrical reset is normal behavior that can occur when the device detects a possible issue with the device software. However, an error in the partial electrical reset implementation is causing this unintended behavior.

All LINQ II ICM devices currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 37 complaints related to an electrical reset. The projected rate of a LINQ II ICM experiencing a partial electrical reset that results in the inability to detect Brady, Pause, and PVC events is 0.73% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady, Pause, and/or PVC events, and an explant procedure.

If a partial electrical reset occurs, CareLink™ and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady, Pause, and PVC events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing and mark symptoms.

Tachy and AT/AF detections are not affected by a partial electrical reset.

HOSPITAL RISK MANAGER ACTIONS (U.S. CUSTOMERS ONLY)

Medtronic is requesting customers with affected product on hand to take the following actions:

1. Identify and quarantine all unused affected Medtronic LINQ II ICMs.
2. Return all unused affected product in your inventory to Medtronic. Contact Medtronic Customer Service at 1-800-848-9300 to initiate a product return. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
3. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).
4. Complete the enclosed Confirmation Form and email to RS.CFQFCA@medtronic.com

PATIENT MANAGEMENT RECOMMENDATIONS

If an electrical reset has never occurred, all detection criteria are being monitored and recorded as programmed. Continue with normal follow-up per local clinic protocols for these patients.

Identifying if an electrical reset has occurred:

For patients who are actively followed on CareLink in the U.S: During our investigation of this issue, we identified patients whose device showed evidence of a partial electrical reset as of 10 May 2021. For those clinicians with identified patients, a supplemental letter was provided. If you have not received a supplemental letter, then none of your patients who are actively transmitting on CareLink were identified as having a recorded electrical reset event during our investigation.

All patients, including those on CareLink, should be carefully monitored for reports of an electrical reset condition. Follow instructions below.

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. **Note**: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady, Pause or PVC events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

Patients with a confirmed partial electrical reset:

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady, Pause, or PVC events, device replacement may be appropriate. Consider the following before device replacement:
    - It is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue.
    - If replacement is desirable, consider Reveal LINQ with TruRhythm™ or alternative ICM. While Reveal LINQ devices are also are susceptible to this issue (see correction notice, *Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems Brady & Pause Detections Disabled Following Partial Electrical Reset*), the observed rate is 0.049% for Reveal LINQ with TruRhythm ICMs compared to 0.21% for LINQ II ICMs.

      Note: Implanted Reveal LINQ with TruRhythm ICMs have the ability to receive a future

software update to correct this issue, which will be implemented via the Model 2090 and Encore™ programmers, and is anticipated to be available in the U.S. late calendar year 2021.

- Future manufactured LINQ II devices will have a correction for this issue implemented during manufacturing pending regulatory approval of the corrective fix, but initial supply may be limited.

- As a reminder, per the LINQ II ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

Reveal LINQ with TruRhythm - Brady & Pause Detections Disabled Following Electrical Reset

Reveal LINQ with TruRhythm Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

STATUS UPDATE - MAY 2023

This advisory is being addressed via a software update. Medtronic CareLink (2090) and Encore (29901) Programmer software, SW026 version 8.3, is available to correct a low rate of occurrence issue with Reveal LINQ ICMs (0.049%) where Brady and Pause detections are disabled following a partial electrical reset.

Reveal LINQ ICMs that are interrogated in-office with an updated 2090 or Encore programmer are no longer susceptible to this issue. This corrective fix to the device cannot be delivered with the Reveal LINQ™ Mobile Manager (LMM). Until the update is installed, future partial electrical resets may disable Brady and/or Pause detections as described in the June 2021 communication.

Note: The immediate availability of the software release is specific to countries that follow FDA approval, or that do not require software to be regulated. Release timing may differ for other geographies including those that require CE Mark approval. Check with your local Medtronic representative to determine if the software update is available in your region.

Please work with your local Medtronic Representative to update all 2090 and Encore device programmers. In addition, Medtronic requests you follow the below patient management recommendations:

Patient Management Recommendations:

- Reveal LINQ ICMs with a confirmed partial electrical reset will receive the corrective fix for this issue immediately by the device clinician completing the following steps:
    1. Interrogate the ICM with an updated 2090 or Encore programmer (software application SW026 version 8.3). The corrective fix is automatically installed during initial interrogation. To confirm an ICM has successfully received the update, refer to Appendix A.
    2. Per the Instructions for Use (IFU), following any electrical reset, verify ICM parameters are set appropriately for the patient and reprogram if necessary.
- For Reveal LINQ ICMs that have not experienced a partial electrical reset, an update will occur during the next in-clinic visit in which an updated Model 2090 or Encore programmer installed with software application SW026 version 8.3 (or higher) is used to interrogate the ICM. Partial electrical resets will disable Brady and/or Pause detections as described in the June 2021 communication until the update is installed on to the patient's ICM.

- For patients who are actively followed on CareLink, continue routine monitoring for CareAlerts and verify notification settings for electrical resets.
- Per the IFU, notify your Medtronic representative if an electrical reset occurs. If a partial electrical reset is confirmed, the patient's ICM will require reprogramming.
- During the programmer session, the corrective fix will be installed automatically.

ORIGINAL COMMUNICATION - JUNE 2021

This notice is to inform you that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events to clinicians. Medtronic estimates that 0.049% of Reveal LINQ with TruRhythm ICMs have experienced a partial electrical reset resulting in the inability to detect Brady and Pause events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady and Pause episode types will not be reported to the clinician.

- Currently implanted/distributed Reveal LINQ with TruRhythm ICMs will receive a future software update to correct this issue delivered via the Model 2090 and Encore™ programmers. The corrective fix is anticipated to be available late calendar year 2021 (U.S.). Availability of the software will be communicated once Medtronic has obtained the necessary regulatory approvals.
- There will be an update for future manufactured Reveal LINQ with TruRhythm ICMs, which is anticipated to be available in the U.S. October 2021. Medtronic will inform physicians once this manufacturing update is implemented into newly manufactured Reveal LINQ with TruRhythm ICMs.

ISSUE DESCRIPTION

Medtronic has identified that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events. A partial electrical reset is normal behavior that can occur when the device detects a possible issue with the device software. However, an error in the partial electrical reset implementation is causing this unintended behavior.

All Reveal LINQ with TruRhythm ICMs currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 87 complaints related to an electrical reset. The projected rate of a Reveal LINQ with TruRhythm ICM experiencing a partial electrical reset that results in the inability to detect Brady and Pause events is 0.056% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady and Pause events, and an explant procedure.

If a partial electrical reset occurs, CareLink™, Model 2090 and Encore programmer software and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady and Pause

events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing, and mark symptoms.

Tachy and AT/AF detections are not affected by a partial electrical reset.

HOSPITAL RISK MANAGER ACTIONS (U.S. CUSTOMERS ONLY)

1. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).
2. Complete the enclosed Confirmation Form and email to RS.CFQFCA@medtronic.com

PATIENT MANAGEMENT RECOMMENDATIONS

If an electrical reset has never occurred, all detection criteria are being monitored and recorded as programmed. Continue with normal follow-up per local clinic protocols for these patients.

Identifying if an electrical reset has occurred:

For patients who are actively followed on CareLink in the U.S: During our investigation of this issue, we identified patients whose device showed evidence of a partial electrical reset as of 10 May 2021. For those clinicians with identified patients, a supplemental letter was provided. If you have not received a supplemental letter, then none of your patients who are actively transmitting on CareLink were identified as having a recorded electrical reset event during our investigation.

All patients, including those on CareLink, should be carefully monitored for reports of an electrical reset condition. Follow instructions below.

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. Note: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady or Pause events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

Patients with a confirmed partial electrical reset:

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady or Pause events, it is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue. If patients require monitoring for Brady and/or Pause events, and it is not acceptable to wait for the software update to become available (see details below), consider device replacement. Recognize that exposure to EMI could introduce this issue for new device implants that occur before the manufacturing update is implemented anticipated in the U.S. in October 2021.
- As a reminder, per the Reveal LINQ with TruRhythm ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

FUTURE SOFTWARE UPDATE AVAILABILITY

Medtronic is developing a programmer-delivered software update to correct this issue for Reveal LINQ with TruRhythm ICMs currently implanted or in distribution. Anticipated availability in the U.S. is late calendar year 2021; Medtronic representatives will inform you of the availability and work with you to install the software onto clinic and hospital 2090 and Encore programmers. LMM application software will be unable to deliver the software update for this issue. In order for patients with Reveal LINQ with TruRhythm ICMs to receive the update, the device will need to be interrogated with an updated 2090 or Encore programmer.

APPENDIX A

Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

Brady & Pause Detections Disabled Following Partial Electrical Reset

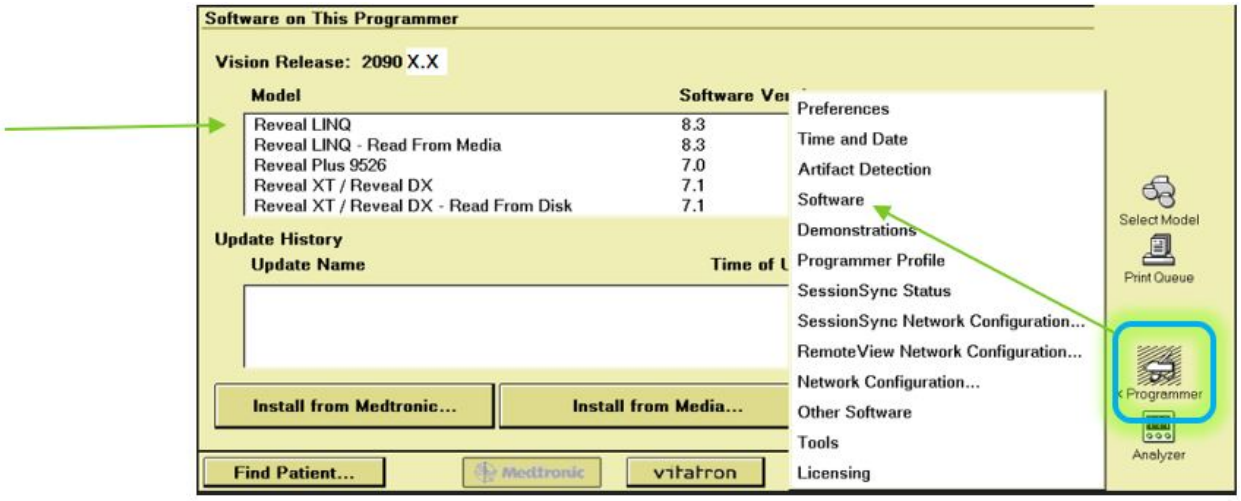
Software Update Available

How do I update my Model 2090 and Encore programmers with the Reveal LINQ with TruRhythm software described in the November 2021 communication)?

Software update SW026 version 8.3 can be installed onto all Model 2090 or Encore programmers through either the Medtronic Software Distribution Network (SDN) or via a USB. Medtronic representatives will work with you to install the software.

How do I confirm if a Model 2090 or Encore programmer has already been installed with the updated software (SW026 v8.3)?

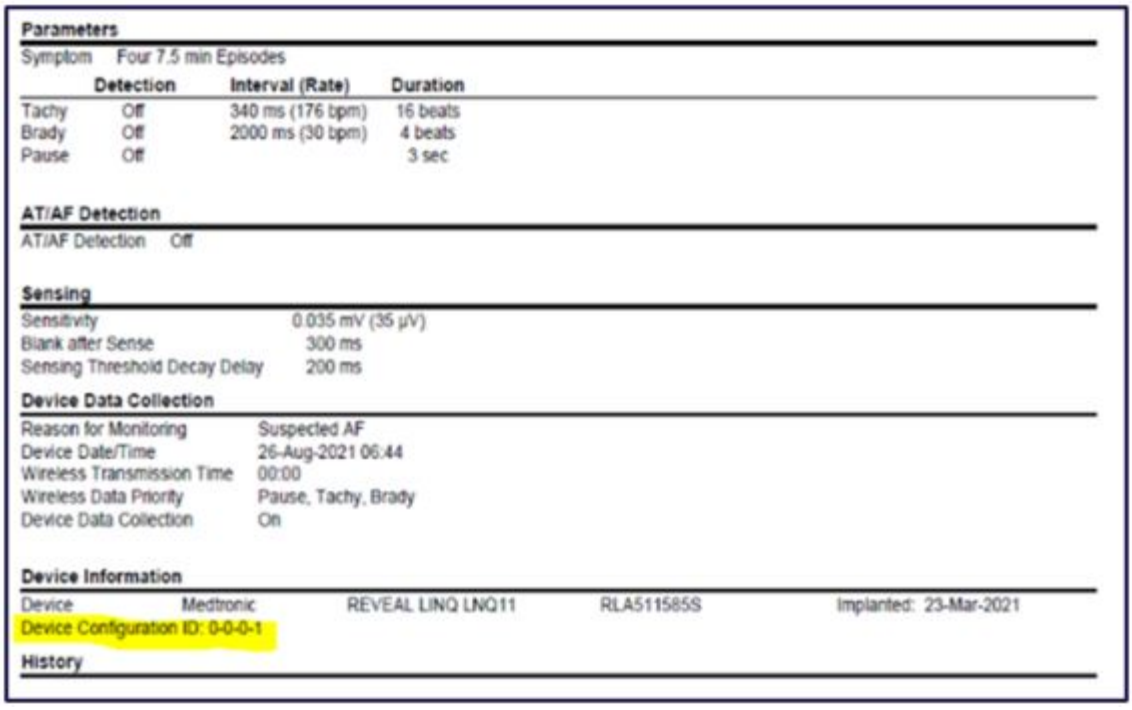
From the *Find Patient* screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.



How do I confirm if a patient's Reveal LINQ ICM has received the software update?

Clinicians can confirm if a patient's ICM has received the software update by verifying the Device Configuration ID via a 2090 or Encore programmer (LMM will not display the Configuration ID). To locate the Device Configuration ID, enter a follow-up session and Print the Parameters Report. All Reveal LINQ ICMs that have received the software update will have their Configuration ID ending in a "1" (e.g. X-X-X-1).

NOTE: The Reveal LINQ Device Configuration ID can be viewed on CareLink beginning January 2022 after a manual transmission is completed by the patient.



Unipolar Longevity Estimation Software Error

Azure/Astra DR and SR Pacemakers and Percepta/Serena/Solara CRT-Ps

Original Date of Communication: April 2021

STATUS UPDATE - MAY 2023

Through 19 April 2023, Medtronic has received 34 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue.

ORIGINAL COMMUNICATION - APRIL 2021

This notice is to inform you of the availability of software updates to address a potential inaccurate longevity estimate that may occur with the Azure™ and Astra™ family of pacemakers (IPGs) and the Percepta™, Serena™, Solara™ family of cardiac resynchronization therapy pacemakers (CRT-Ps). A longevity estimation error may occur in the early years of device life when a unipolar pacing vector is programmed in the right atrial (RA) lead and/or the right ventricular (RV) lead. No other device features or therapies are impacted. For devices programmed to bipolar pacing in both the RA and RV chambers, the longevity estimates are not affected by this issue.

Through 05 March 2021, Medtronic has received 13 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue. If the software update is not applied to the programmer, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention. Battery performance is not affected by this programmer display error. RRT will alert appropriately, and if patients are followed per standard clinical practice, the risk to patients is minimal.

The longevity estimation error associated with unipolar pacing configurations occurs only in the first half of the device life (prior to 50% depletion of the battery). During this phase, the estimator algorithm utilizes lead impedance as an input. When a unipolar pacing configuration is programmed, the algorithm incorrectly uses the bipolar lead impedance as input (rather than the appropriate unipolar pacing lead impedance). As a result, the algorithm will over-estimate the remaining longevity during this phase. At all times, RRT, Elective Replacement Indication, and End of Service will accurately display on programmers – even if the software update has not yet been installed.

Software updates are now available for Medtronic model 2090, Model 29901 Encore programmers, and SmartSync to correct this programmer display issue (see Table 1 below).

Medtronic 2090 and Encore Programmer Software Update	Medtronic SmartSync Software Update
Azure™/Astra™ (SW030) v 8.2 Percepta™/Serena™/ Solara™ (SW040) v 8.4	Azure™/Astra™ (D00U003) v 4.0 Percepta™/Serena™/ Solara™ (D00U004) v 4.0

Table 1: Software updates by device family and programmer

As of 26 March 2021, Medtronic CareLink network has been updated and will display correct longevity estimates for devices affected by this issue. Azure IPG and Percepta/Serena/Solara CRT-P patients remotely monitored via the MyCareLink Heart™ mobile app will automatically receive an updated longevity estimate on their mobile app with their next scheduled transmission or within 92 days of their last longevity update, whichever occurs first.

No change in patient management is necessary. Per labeling, the RRT notification can be used to identify when device replacement should be scheduled. There is no need to schedule patients to come in before their next regularly scheduled follow-up visit. The corrective fix for this error is implemented in programmers and the CareLink network. The patient's implanted device does not require an update.

Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will assist with installing software on programmers in your account. Until all SmartSync and Model 2090 and Encore programmers are updated, a difference in longevity estimates may be displayed between programmers and the CareLink network due to this software error.

Potential for Shortened RRT-to-EOS in Subset of ICDs and CRT-Ds

Subset of ICDs and CRT-Ds

Original Date of Communication: February 2021

STATUS UPDATE - MAY 2023

As of 11 April 2023, approximately 215,027 devices susceptible to this issue are estimated to still be active worldwide. Observed rate of occurrence is 0.14% and projected rate for the affected population of devices remains 0.22%. Devices with higher pacing outputs and high pacing percentages (e.g., CRT-D devices) have the lowest probability of occurrence (refer to Appendix A of the original communication for further details – see below). No permanent patient harms have been reported due to this issue.

ORIGINAL COMMUNICATION – FEBRUARY 2021

In February 2021, Medtronic informed physicians of a potential issue for a subset of Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds). Medtronic has identified that a small percentage of implanted cardiac devices, from a well-defined subset, may experience a shortened Recommended Replacement Time (RRT) to End of Service (EOS) interval following an earlier-than-expected RRT observation. The subset of ICDs and CRT-Ds affected by this issue were last implanted in February 2019 and manufactured with a specific battery design that is no longer being distributed.

We have received no reports of permanent harm to patients as a result of this issue.

Approximately 339,900 devices susceptible to this issue are estimated to still be active worldwide. Through 4 January 2021, confirmed events (observed rate 0.07%) have involved a rapid drop in battery voltage ranging from days to months, with unexpected RRT as one of the primary reported observations. For those devices in which RRT triggered earlier than expected, the median time from RRT to the EOS observation was 14 days. In a small number of the cases, no output/no telemetry was reported prior to device replacement. Medtronic projects approximately 0.22% of the affected device population may experience this issue during their service life.

The rapid depletion is caused by a latent shorting mechanism involving lithium plating, resulting from a thermal gradient between the anode and cathode components of the battery. **Devices with higher pacing outputs and high pacing percentages (e.g. CRT-D devices) have the lowest probability of occurrence (refer to Appendix A – see below)**. Conversely, devices with low current drain (evidenced by a longer overall service time from implant to RRT) have a higher probability of experiencing this issue. Importantly, the probability of this issue developing is constant after approximately three years of service time.

Patient Management Guidance

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic **recommends** the following:

- **Continue normal follow-up per local clinical protocol.**
    - Recognize that patients who require significant pacing support and high voltage therapy have the lowest risk for this issue - See Appendix A for additional details.
    - Where possible, take advantage of the CareLink™ home monitoring system and the wireless low battery voltage CareAlert.
    - The low battery voltage audible alert is shipped On with high-urgency tones; Remind patients to contact their clinic if they hear an audible alert, particularly since patients may be opting to delay clinic visits due to COVID-19 guidance.
    - Inform a Medtronic Representative of any unexpected device behaviors.
    - Be aware that the inability to interrogate the device, or to transmit data, may be an indicator that the device has experienced this issue.
- **If unexpected RRT is observed, prompt replacement of the device should occur commensurate with the underlying clinical situation of the patient:**
    - For non-pacing dependent patients or for primary prevention ICD patients, replacement within 1 week of an unexpected RRT notification is recommended.
    - For pacing dependent patients, immediate replacement is recommended following an unexpected RRT notification.

    Note: For all patients, this issue can also manifest as an unexpected change in the remaining longevity estimate that cannot be attributed to programming changes, or changes in use conditions.

Medtronic medical staff in consultation with the IPQP **recommends against prophylactic replacement** due to the low rate of occurrence and the low potential for permanent harm when prompt replacement occurs in response to an unexpected RRT.

Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/

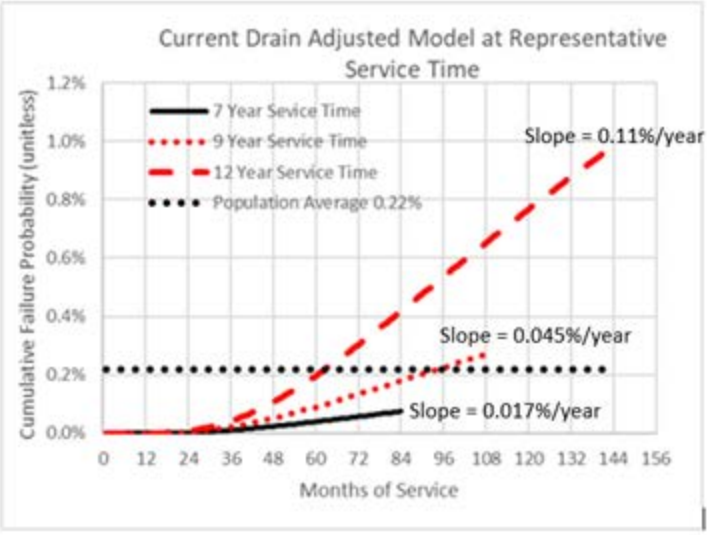
APPENDIX A

The table below provides a comparison of sample use conditions and their associated, projected service time (Implant to Recommended Replacement Time), along with their cumulative and per-year risk of encountering rapid depletion due to a latent shorting mechanism in the battery. Devices with higher pacing outputs and high pacing percentages have the lowest probability of occurrence. There have been no reports of permanent harm to patients as a result of this issue.

Probability (Risk per Year) of Rapid Depletion due to this Issue as a Function of Service Time

Projected Service Time * (based on sample programmed settings and use conditions)	Projected Risk per Year & Total Cumulative Risk at end of service time++	Notes/Example
12-year service time	0.11% per year, 0.98% cumulative	VR ICD patient with 0% pacing and no shocks delivered
10.25-year service time	0.070% per year, 0.50% cumulative	VR ICD patient with 50% pacing history and two (2) or fewer shocks per year
9-year service time	0.045% per year, 0.27% cumulative	DR ICD patient with little-to-no pacing history (e.g. 10%AP, 25%VP, and two (2) or fewer shocks per year)
8.25-year service time	0.033% per year, 0.18% cumulative	DR ICD patient with complete heart block (10% AP and 100% VP, and two (2) or fewer shocks per year)
7-year service time	0.017% per year, 0.075% cumulative	CRT-D patient with 15% AP, 90% RVP, 100% LVP, and two (2) or fewer shocks per year
* Assumes current drain remains stable throughout life of device (i.e. No change in remaining longevity due to reprogramming or changes in use conditions)	++ Per annum risk of issue becomes constant after approximately 3 years of service time. Cumulative risk = early risk plus annual risk over the projected service time.	A output = 1.5V, 0.4ms, 500 ohms RV output = 2.0V, 0.4ms, 500 ohms LV output = 2.5V, 0.4ms, 500 ohms Average pacing rate = 75 bpm

Customer Communications



Cumulative Probability is the expected risk for a device to experience this issue between implant and end of service. When risk is evaluated for a device that has reached a service life beyond 3 years, the remaining risk can be estimated based on the yearly risk value shown.

The Population Average (0.22%) is the cumulative probability for the full subset of devices susceptible to this issue. This value takes into account expected longevity and patient mortality. Not all devices with projected service time of 12 years will be in service all 12 years.

Key Points:
Slope of the curve reflects the risk per year based on sample service times of 7, 9, and 12 years.

Slope (risk per year) is constant after approximately 3 years of service time.

SmartSync Device Manager Telemetry Issue – Software Updates Available June 2020

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

Original Date of Communication: June 2020

STATUS UPDATE - MAY 2023

As of 11 April 2023, Medtronic has received forty-two (42) complaints due to this issue. No adverse events or patient harm have been reported.

ORIGINAL COMMUNICATION - JUNE 2020

This communication provides notice on software updates available for CareLink SmartSync™ Device Managers supporting Medtronic Azure™ pacemakers, and Percepta™, Serena™, Solara™ cardiac resynchronization therapy pacemakers (CRT-P).

This update addresses a rare communication sequence during the first device interrogation with a SmartSync Device Manager that may result in the temporary suspension of some device features (i.e., battery measurements, Capture Management™, Atrial Lead Position Check™, EffectivCRT™ algorithms, and AdaptivCRT™).This rare interaction results in temporary suspension of automatic threshold testing and output adjustments, and suspension of auto-optimization of CRT therapy. The issue is unlikely to result in clinical impact to the patient, and features are restored upon next programmer device interrogation or presence of a magnet.

As of 8 May 2020, Medtronic has received sixteen (16) complaints due to this issue. The predicted rate of occurrence for this issue is 0.03% on first interrogation of an Azure, Percepta, Serena, or Solara device with a SmartSync programmer. No adverse events or patient harm have been reported. Based on consultation with the Independent Physician Quality Panel and considering that the issue is unlikely to result in clinical impact to the patient, routine patient follow-up in accordance with standard practice is recommended.

Updates are available for the CareLink SmartSync Device Manager to address this issue. The SmartSync Device Manager software version 3.2.01 update can be obtained by connecting the tablet to the internet and requesting all application downloads. The software update will modify the SmartSync Device Manager to prevent this issue from occurring; no patient actions are required.

A local Medtronic Representative can assist or advise your staff on the SmartSync update process as needed.

CFx Longevity Estimator Software Error - Software Updates Available June 2020

Subset of IPG, ICD, CRT-P, CRT-D, and Micra TPS devices - June 2020

Original Date of Communication: June 2020

STATUS UPDATE - MAY 2023

This advisory has been addressed through release of several new software updates. The complete list of software applications available are listed in the table below. Medtronic representatives will work with local clinic and hospital staff to update programmers. Once a programmer has been updated with the version of software indicated in the table (or higher), the correct longevity estimate for the affected devices will be displayed.

Note that as of September 2020 the Medtronic CareLink Network was updated for this advisory. All longevity estimates displayed on CareLink reflect accurate estimates (based on programmed settings and use conditions recorded by the device).

Phase 1 – June 2020	Phase 2 – January 2021
Azure™/Astra™ (SW030) v 8.1	Viva™/Brava™/ Evera (SW016) v8.4
Serena™/ Solara™/ Percepta™ (SW040) v 8.3	Evera™ MRI/ Primo™ MRI/ Mirro™ MRI(SW033) v8.5
Visia AF™/ Visia AF™ MRI (SW035) v 8.2	Micra™ VR TPS (SW033) v8.2
Claria™/ Amplia™/ Compia™ (SW034) v 8.4 (US Only)	Claria™/ Amplia™/ Compia™ (SW034) v 8.5

Table 1: Device family updates by phases

Note: The availability of software releases is specific to countries that follow FDA and CE Mark approvals. Release timing may differ for other geographies. Check with your local Medtronic representative.

As of April 11, 2023, there have been 823 total complaints received related to the software displaying a lower-than-expected longevity estimate. Within the 823 complaints reported, no patient harm was reported, and 25 devices were prematurely explanted after observing an inaccurate longevity estimate.

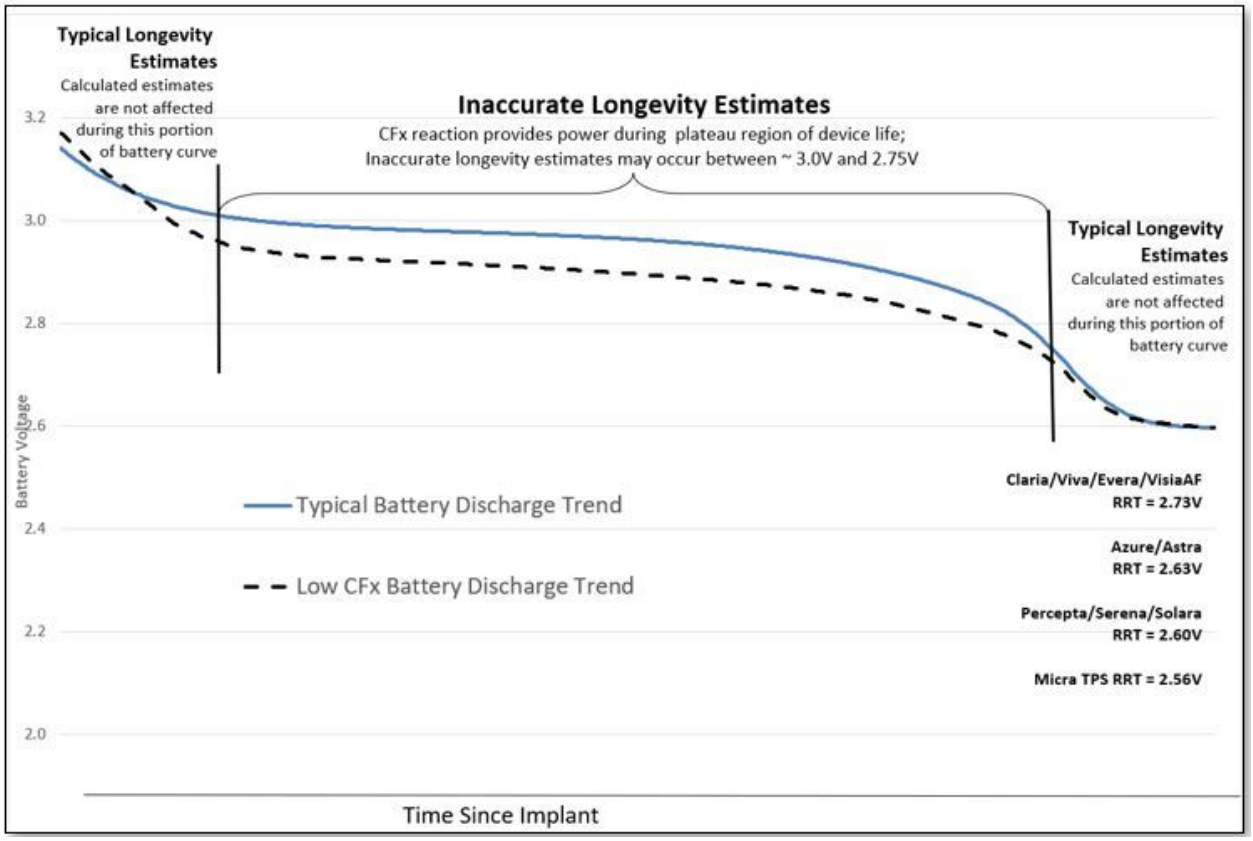
ORIGINAL COMMUNICATION - JUNE 2020

In October 2019, Medtronic identified the potential for Medtronic programmer and remote monitoring software applications to display an inaccurate remaining longevity estimate for a subset of implanted cardiac device models. This issue does not impact device functionality. Furthermore, the Recommended Replacement Time (RRT) remains an accurate indicator for device replacement.

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

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

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



The Independent Physician Quality Panel recommends routine follow up in accordance with standard practice for these devices, as RRT function is normal and the battery longevity is unaffected. There is no need to schedule patients to come in outside of their planned, scheduled visits due to this issue. The corrective fix is implemented in programmers, CareLink, and other systems which display device longevity. The patient's device does not require an update. Follow the steps below as applicable to your clinic or hospital. A local Medtronic Representative can assist in updating Model 2090/Encore programmers and SmartSync Device Managers in your facilities.

- Model 2090 and Encore™ Programmers

  These programmers will require new software to be installed to correct the displayed longevity estimator error. The software applications and version are listed in Table 1 above and can be installed via Medtronic Software Distribution Network (SDN) or via secure USB.

- SmartSync™ Device Managers

  These tablet-based programmers will require a software update to be installed via the internet - refer to Appendix A (below) for detailed instructions on how to download and install the updated application software.

Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions. Based on your facility's needs and accessibility, Medtronic Representative or authorized personnel will work with your facility as requested to complete the updates. Customers with Paceart systems should contact their support team to ensure the latest device update is applied.

Note: Once a programmer is updated, the correct longevity estimate will display at the patient's next regularly scheduled clinic visit. Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, a difference in longevity estimates between programmers and CareLink Network-displayed longevity may be observed.

APPENDIX A – UPDATING SMARTSYNC™ DEVICE MANAGER

Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, you may observe a difference in longevity estimates between these programmers and CareLink-displayed longevity.

Updating Medtronic SmartSync™ Device Managers:

1) Connect tablet to internet and open the SmartSync App

- The SmartSync App automatically checks for available updates each time it is opened.

2) If your tablet does not contain the most recent software, you will automatically receive a notification that a new version of the SmartSync App is available (3.2.01):

- If pop-up messages appear with the option to "cancel" or to "update", **select "update**".

- **Medtronic Managed Tablets:** If the App closes, find the Medtronic App Catalog, and **select** "**Install**" to initiate the download.
- **Customer Owned Tablets:** If the App closes, navigate to the AirWatch App Catalog or App Store and **select** "**Install"** to initiate the download.

- If you do not receive a notification that a new version of the SmartSync App is available, skip to Step 3.

3) Once you confirm the newest version of the SmartSync App is on your tablet, re-open the SmartSync App.

- The app will automatically provide pop-up notifications informing you if there are new versions of *device* software applications that must be installed (see table below).
  - Select CONTINUE for each pop-up window that appears. If you do not receive any pop-up notifications when you open the SmartSync App, then your tablet contains the most recent versions of all available software.

Device Family	SmartSync Application SW Version
Azure™/Astra™ DR and SR	D00U003, Version 3.2.02
Percepta™/Serena™/Solara™	D00U004, Version 3.2.02

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

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

Original Date of Communication: May 2019

STATUS UPDATE - MAY 2023

As of 11 April 2023, there have been a total of 29 confirmed events worldwide associated with this failure mode. No additional deaths, beyond the two deaths previously disclosed*, have been reported since the October 2020 update. Confirmed events included reports of no output, premature depletion and electrical reset that reverted to VVI 65 operation. The range of events have occurred between 2 and 53 months post-implant.

Medtronic's ongoing monitoring of these failures have allowed us to improve long-term modeling projections for future device failures. The overall projected lifetime rate of occurrence for the remaining active devices manufactured with the original low voltage capacitor is projected to be 0.025%.

All products in distribution are unaffected. The specific low voltage capacitor susceptible to this issue was last used in manufacturing 01 June 2019. Patient management recommendations remain unchanged from the original posting (refer to the May 2019 text below).

*Assessment for cause of death determined loss of pacing therapy could not be ruled out as a contributing factor.

ORIGINAL COMMUNICATION - MAY 2019

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

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

As of April 26, 2019, three complaints out of ~266,700 devices distributed worldwide since February 2017, have been received that included a no output /no telemetry scenario resulting from rapid battery depletion. Battery depletion due to this issue can range from several days to several weeks. One of these reported events contributed to a patient

death. The three confirmed failures occurred within 9 months post implant. The projected rate for this issue is 0.0028%, with the most susceptible period for a leakage pathway to develop in the capacitor being the first 12 months post implant.

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

Contact Medtronic Technical Services if you have concerns on a specific patient.

Brady Technical Services |rs.techservices@medtronic.com| 800-505-4636

Potential Loss of Device Functionality Lower Risk Subset

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

Original Date of Communication: March 2018

STATUS UPDATE - MAY 2023

Within the 752 lower-risk devices, there have been zero confirmed failures (0%) through April 11, 2023. An estimated 367 devices remain active. Due to low estimated remaining active population, this advisory will be removed at our next semi-annual publish of this product performance website.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
752 Worldwide (all in USA, Puerto Rico or US Virgin Islands.)	**0**	**367**	**0%** Worldwide

ORIGINAL COMMUNICATION - MARCH 2018

Product

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

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

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

You may use the "Search for Information by Serial Number" tool on home page of this web site to determine if a specific device is affected.

Table – Device Subsets

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

Patient Management Recommendations – Lower Risk Subset

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

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

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

[i]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; MRCS: MDT2260884, Version 2.0, 11/02/2015.
[ii]Birnie, D et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm, Volume 5, Issue 3, Pages 387-390.

Potential Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Communication: October 2007

STATUS UPDATE - MAY 2023

As of April 11, 2023, of the initial implant population of 205,600 in the United States, approximately 28,000 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 63.5% (+6.6/-6.0%) at 174 months. As the implanted population ages and the sample size increases for each time interval, the accuracy of the estimated survival probability will increase as shown by tighter confidence intervals.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population
279,500 Worldwide (**205,600** United States)	**7,324** Worldwide **(5,256** United States)	**38,000** Worldwide (**28,000** United States)

ORIGINAL COMMUNICATION - 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 here.
    - 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]

Footnotes:

1: Swerdlow C, Gunderson, B, et al."Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRM 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.

CRM Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

For questions related to returning explanted product from outside the United States, please contact your local Medtronic Representative.

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