CARDIAC RHYTHM MANAGEMENT

Product Performance Report

Important Patient Management Information for Physicians

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Medtronic

CRM Product Performance Report

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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.

US Technical Services Department

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Phone:

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Please contact local Medtronic Representative.

Australia-New Zealand

au.crdmtechservices@medtronic.com

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

Outside the United States:

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

Within the United States:

Your Medtronic representative or

CRM Returned Product Analysis Laboratory

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

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Introduction

For 41 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, insertable cardiac monitors (ICMs), 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.

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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.

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

In alignment with industry guidance, Medtronic CRM considers a device as having malfunctioned when the device is removed from service and the analysis shows that any parameter was outside the performance limits established by Medtronic while in service.

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:

(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.

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

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%.

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

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.

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.

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

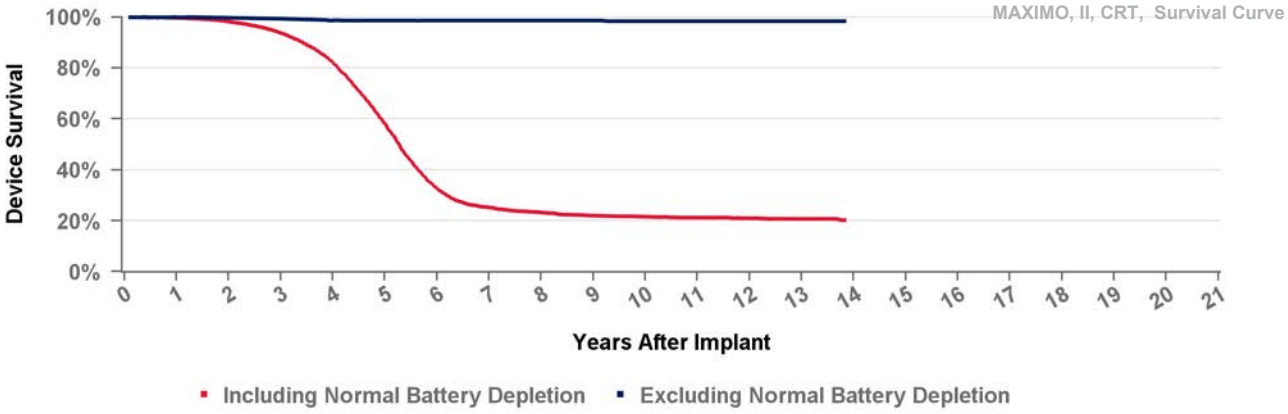
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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.

D284TRK Maximo II CRT-D

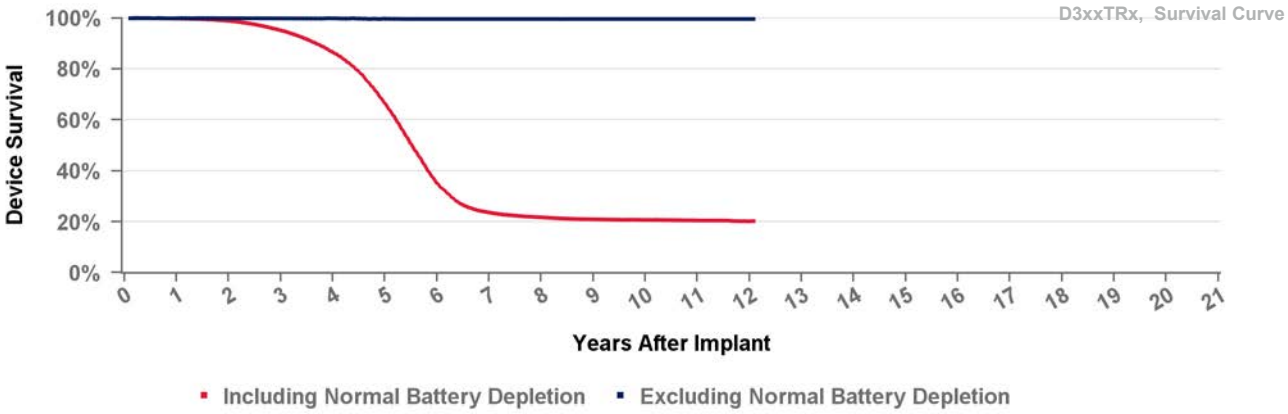
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**135**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**129**
Registered USA Implants	14,990	Electrical Component	5
Estimated Active USA Implants	1,327	Possible Early Battery Depletion	124
Normal Battery Depletions	4,084	**Therapy Function Compromised**	**6**
		Electrical Component	6



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 166 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%	98.5%
Including NBD	99.7%	98.2%	93.7%	82.1%	58.2%	32.5%	25.3%	23.3%	22.0%	21.6%	21.3%	21.0%	20.8%	20.4%
Effective Sample Size	12496	11082	9495	7252	3990	1660	1091	915	801	744	676	540	335	102

D314TRG Protecta XT CRT-D

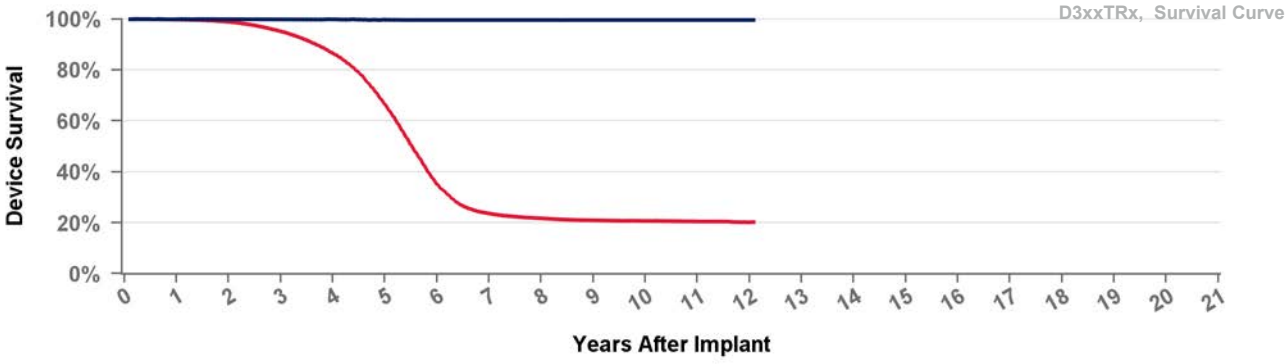
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**94**
CE Approval Date		**Therapy Function Not Compromised**	**75**
Registered USA Implants	41,864	Battery	8
Estimated Active USA Implants	4,649	Electrical Component	40
Normal Battery Depletions	10,523	Possible Early Battery Depletion	25
		Other	2
		Therapy Function Compromised	**19**
		Battery	11
		Electrical Component	8



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

D354TRG Protecta XT CRT-D

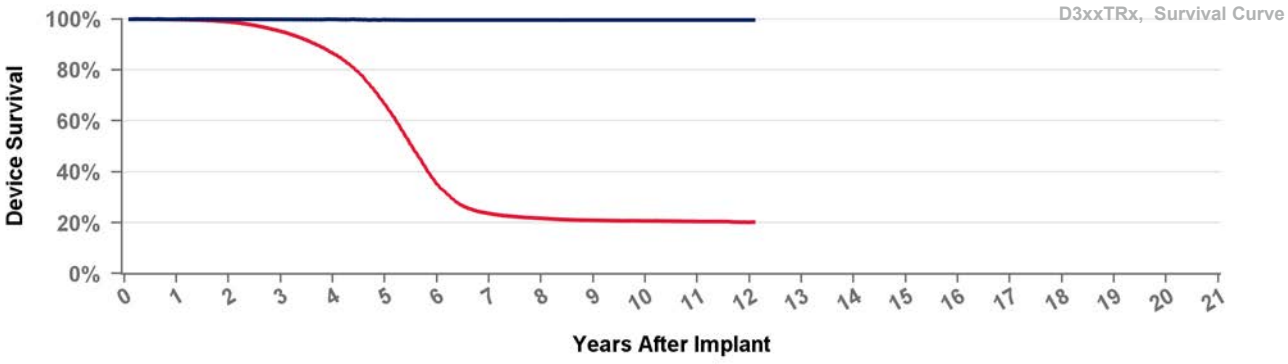
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	25Mar2010	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

D354TRM Protecta XT CRT-D

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



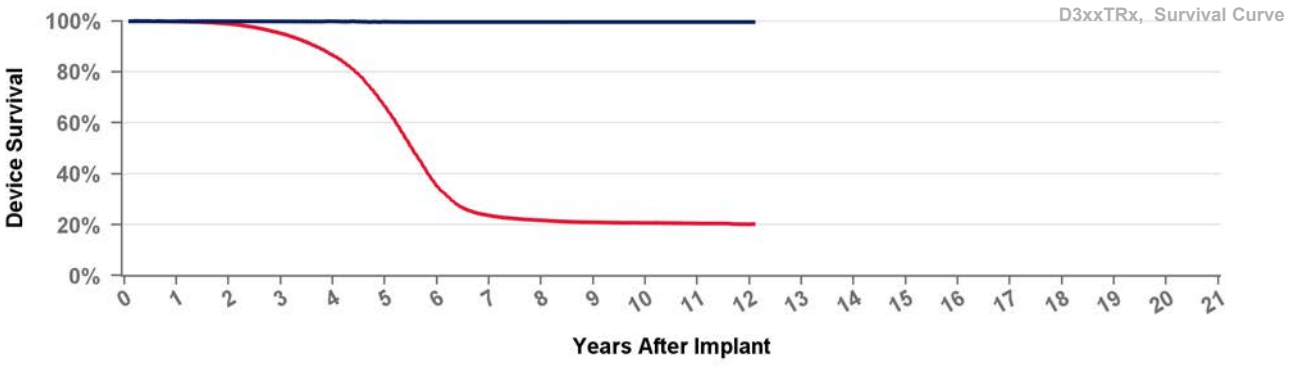
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

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



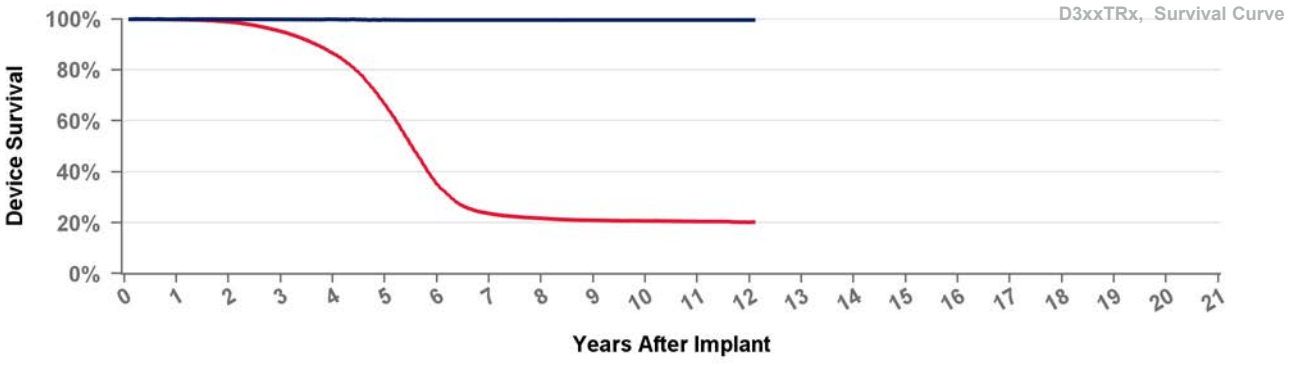
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

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

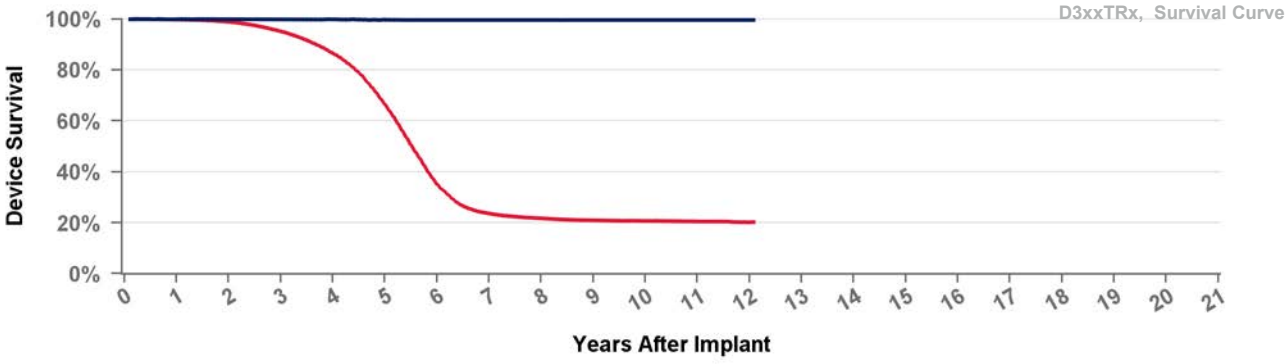
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

D394TRG Egida CRT-D

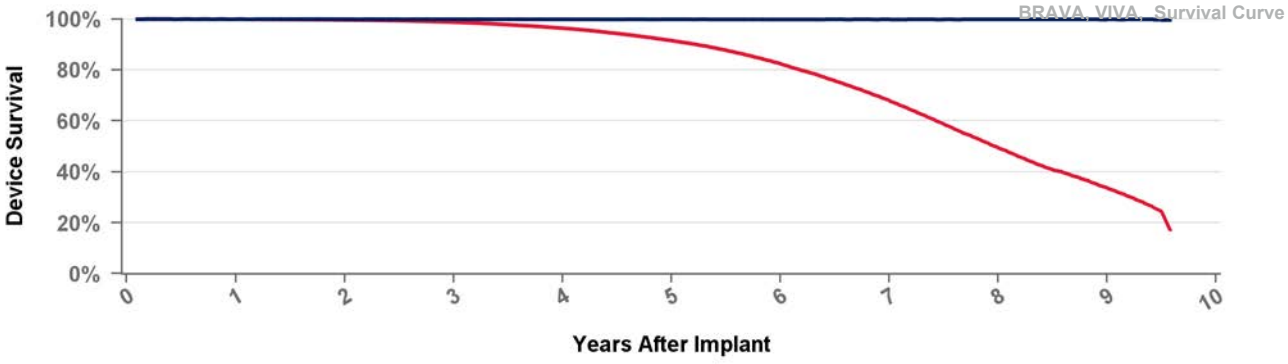
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.6%	99.6%
Including NBD	99.8%	98.9%	95.1%	86.5%	66.7%	35.3%	23.7%	21.7%	21.0%	20.8%	20.6%	20.2%	20.2%
Effective Sample Size	54152	48925	42274	33505	21046	8894	4881	4038	3623	3382	2917	526	291

DTBA1D1 Viva XT

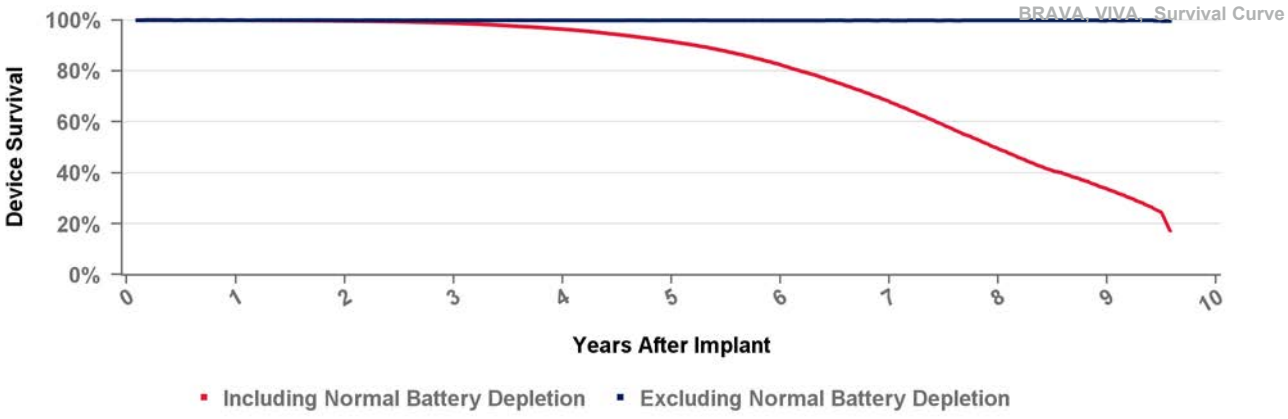
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**71**
CE Approval Date		**Therapy Function Not Compromised**	**46**
Registered USA Implants	56,946	Battery	10
Estimated Active USA Implants	14,182	Electrical Component	32
Normal Battery Depletions	16,168	Possible Early Battery Depletion	1
		Other	3
		Therapy Function Compromised	**25**
		Battery	19
		Device-Related Current Pathway	2
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBA1D4 Viva XT

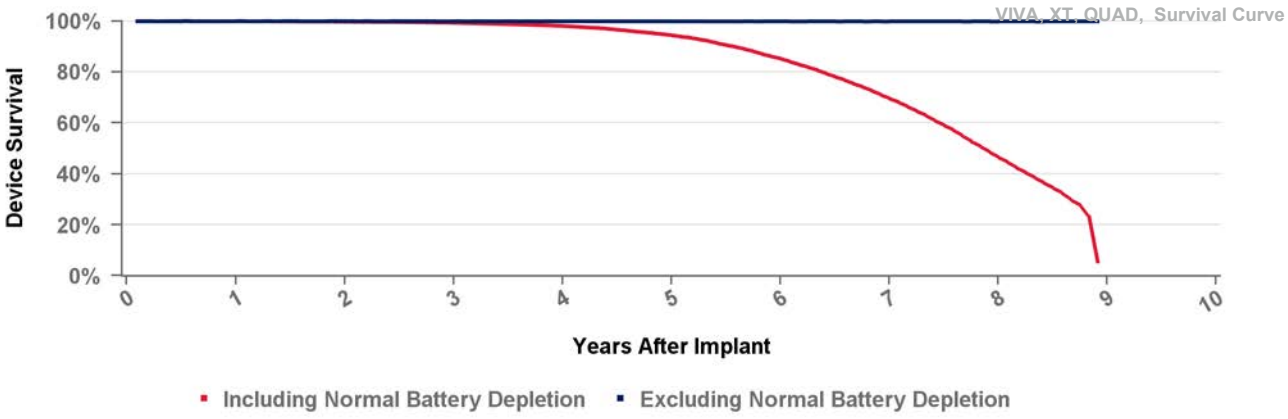
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**33**
CE Approval Date		**Therapy Function Not Compromised**	**24**
Registered USA Implants	19,628	Battery	6
Estimated Active USA Implants	4,752	Electrical Component	15
Normal Battery Depletions	6,823	Possible Early Battery Depletion	3
		Therapy Function Compromised	**9**
		Battery	6
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBA1Q1 Viva Quad XT

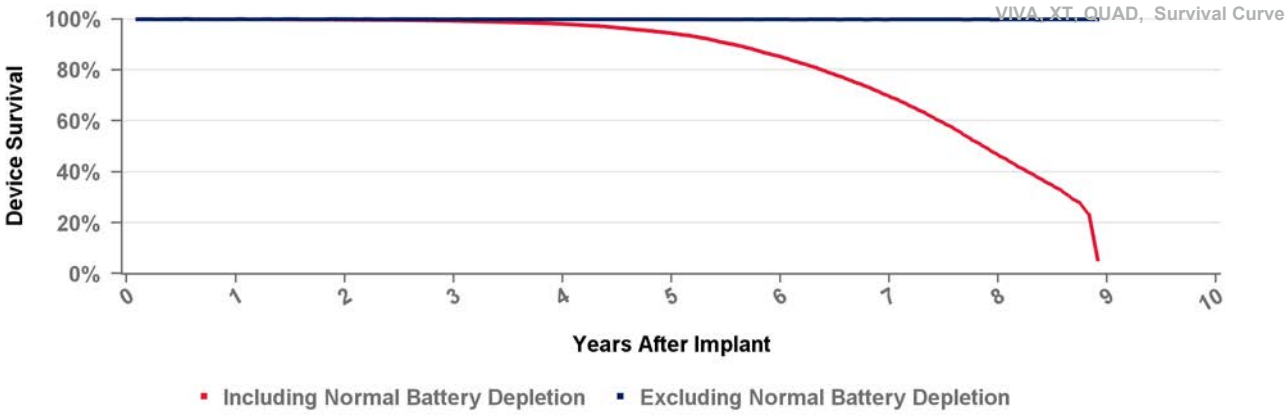
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	11,065	Battery	3
Estimated Active USA Implants	3,027	Electrical Component	4
Normal Battery Depletions	3,053	Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**5**
		Battery	4
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

DTBA1QQ Viva Quad XT

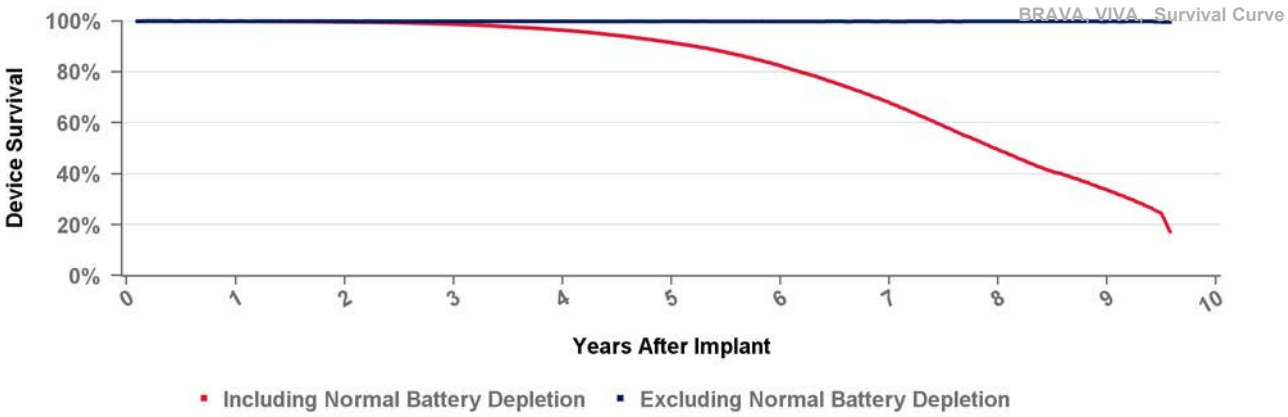
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**49**
CE Approval Date		**Therapy Function Not Compromised**	**37**
Registered USA Implants	27,415	Battery	12
Estimated Active USA Implants	7,621	Electrical Component	20
Normal Battery Depletions	9,459	Electrical Interconnect	1
		Possible Early Battery Depletion	3
		Other	1
		Therapy Function Compromised	**12**
		Battery	9
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

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			

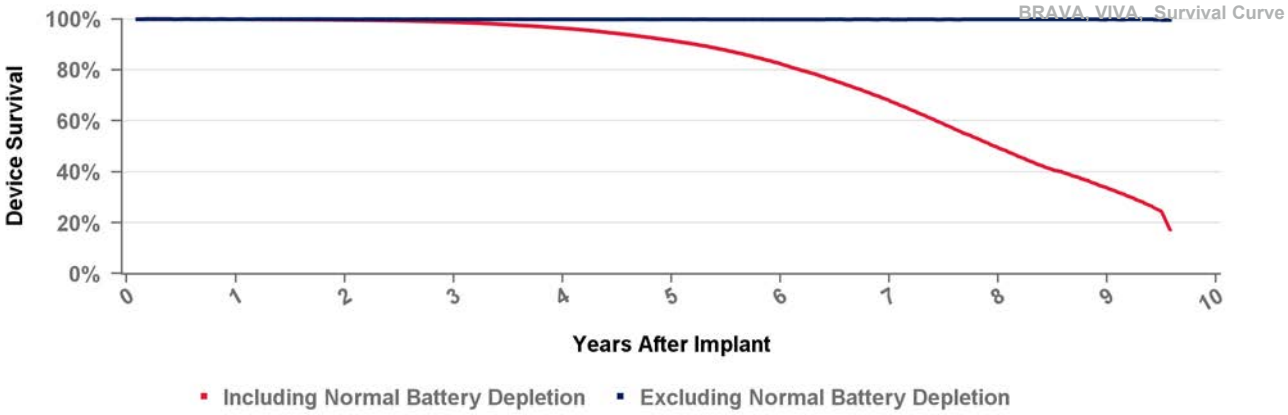


Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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

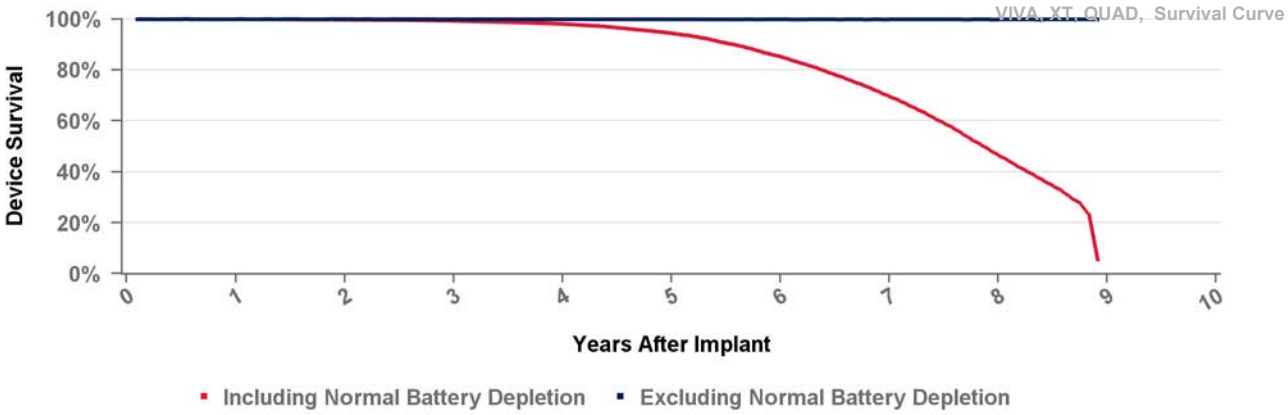


Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBA2Q1 Viva Quad XT

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

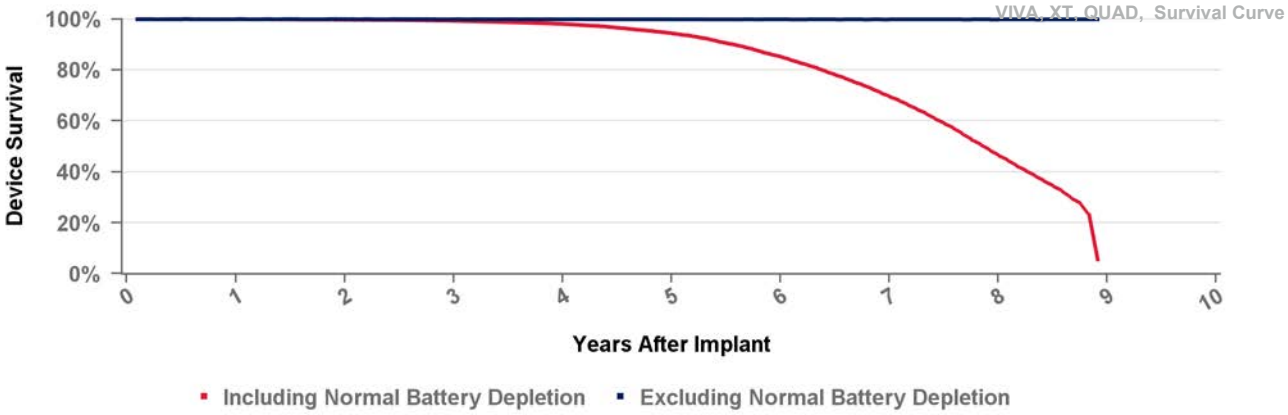
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

DTBA2QQ Viva Quad XT

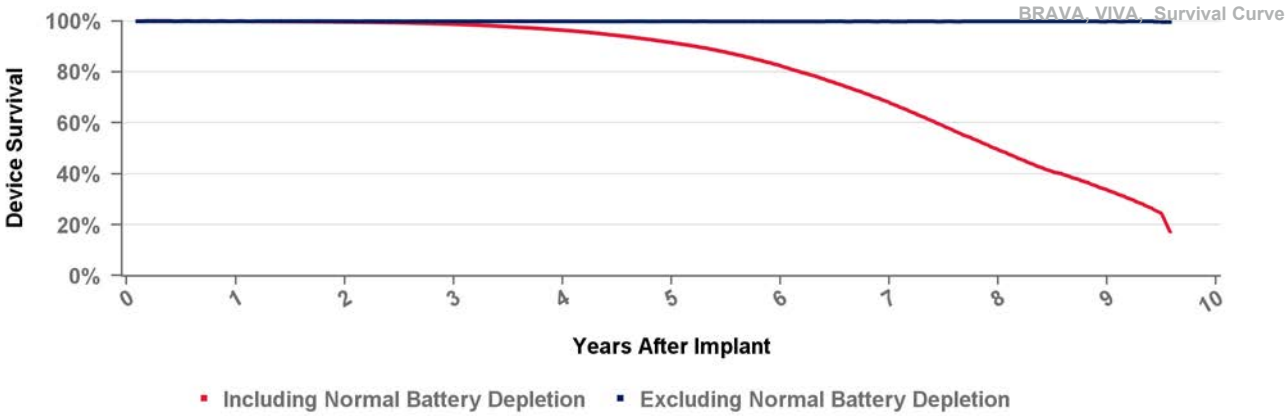
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	08Aug2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

DTBB1D1 Viva S

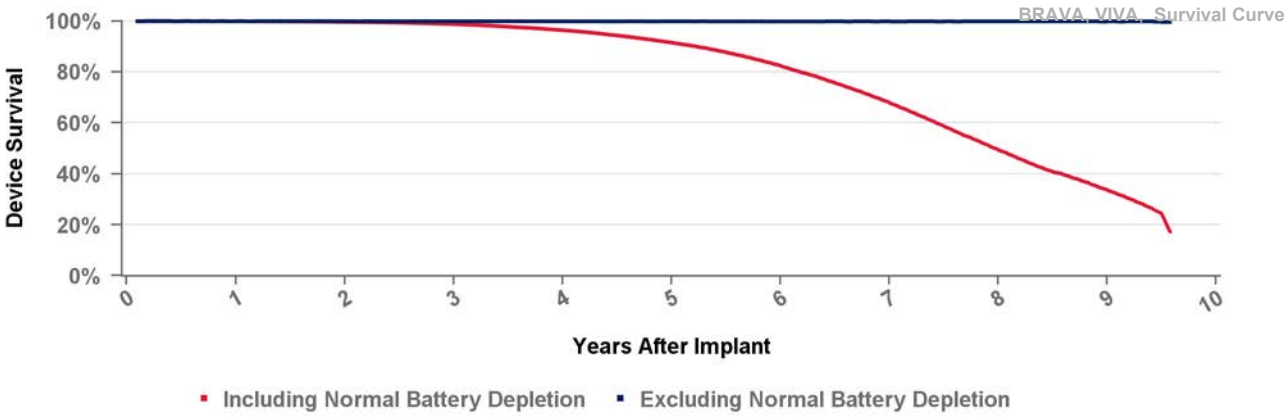
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**20**
Registered USA Implants	14,103	Battery	9
Estimated Active USA Implants	2,931	Electrical Component	8
Normal Battery Depletions	4,843	Possible Early Battery Depletion	2
		Other	1
		Therapy Function Compromised	**5**
		Battery	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%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBB1D4 Viva S

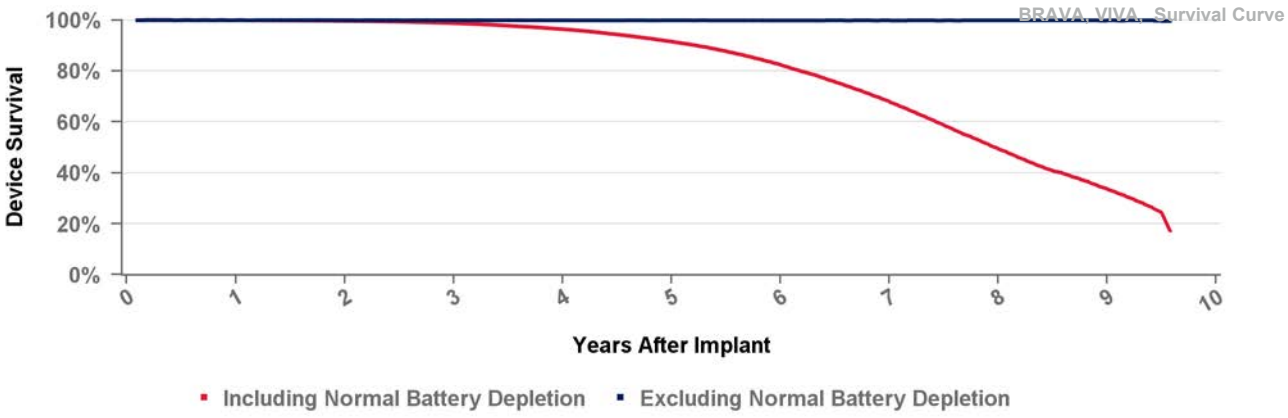
US Market Release	29Jan2013	**Total Malfunctions (USA)**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	4,637	Battery	3
Estimated Active USA Implants	1,096	Electrical Component	2
Normal Battery Depletions	1,633	Other	1
		Therapy Function Compromised	**3**
		Battery	3



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBB1Q1 Viva Quad S

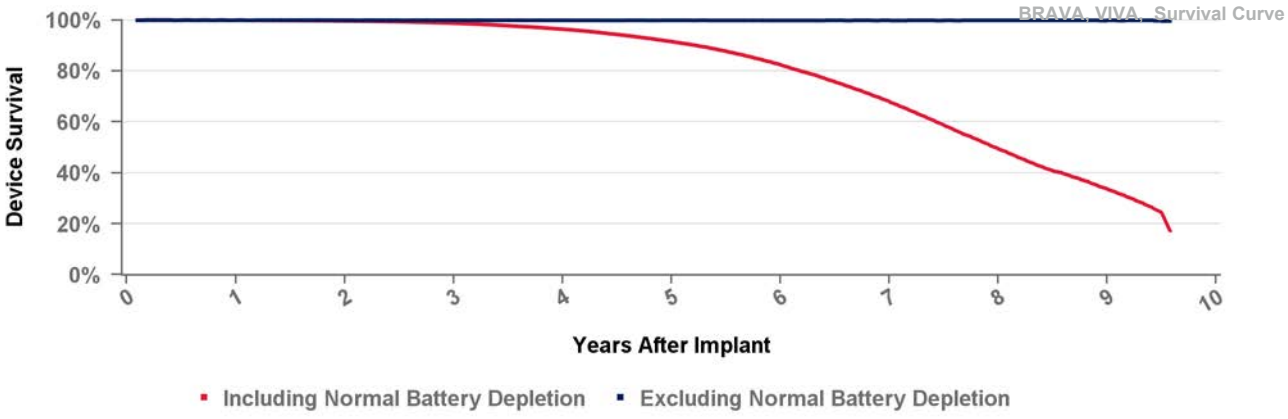
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,361	Battery	1
Estimated Active USA Implants	625	Electrical Component	1
Normal Battery Depletions	817	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBB1QQ Viva Quad S

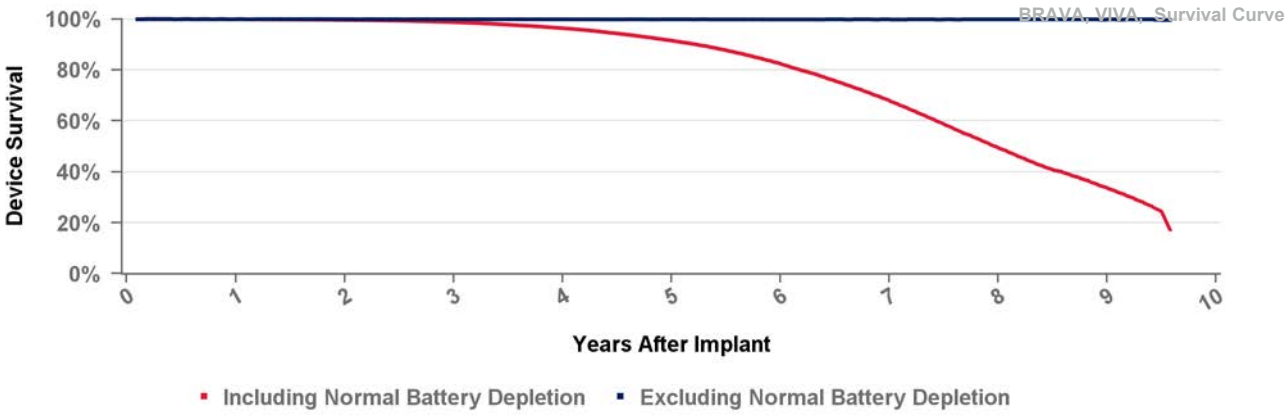
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**10**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	5,113	Battery	1
Estimated Active USA Implants	1,361	Electrical Component	4
Normal Battery Depletions	2,102	Possible Early Battery Depletion	2
		Other	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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			



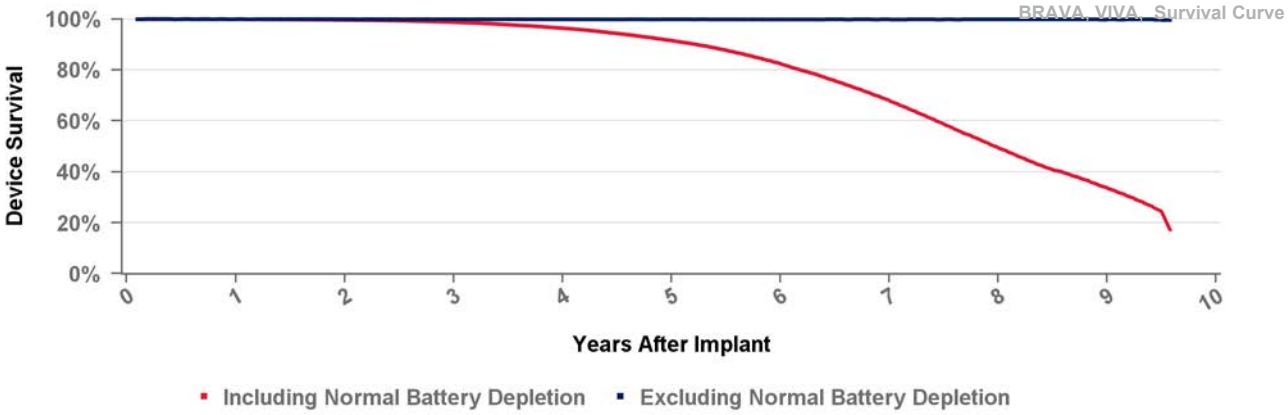
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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



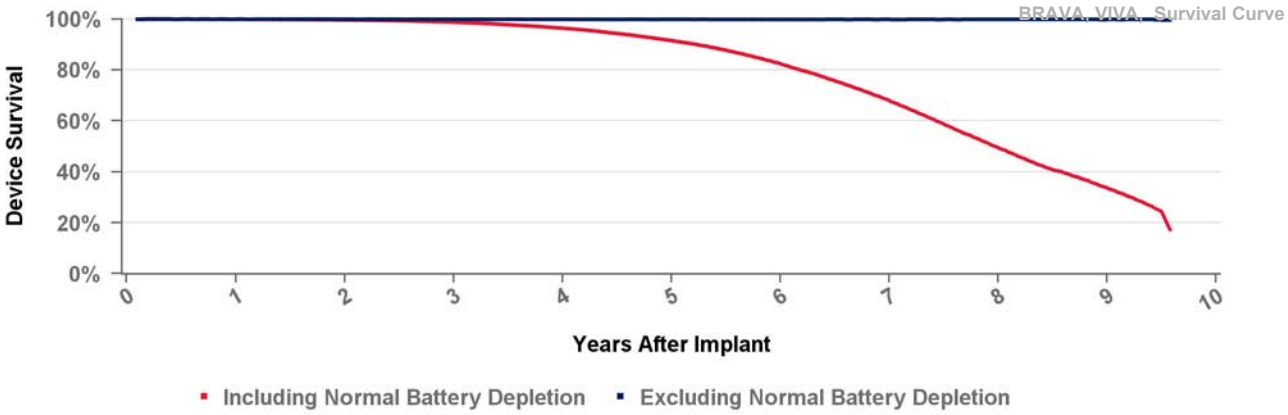
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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



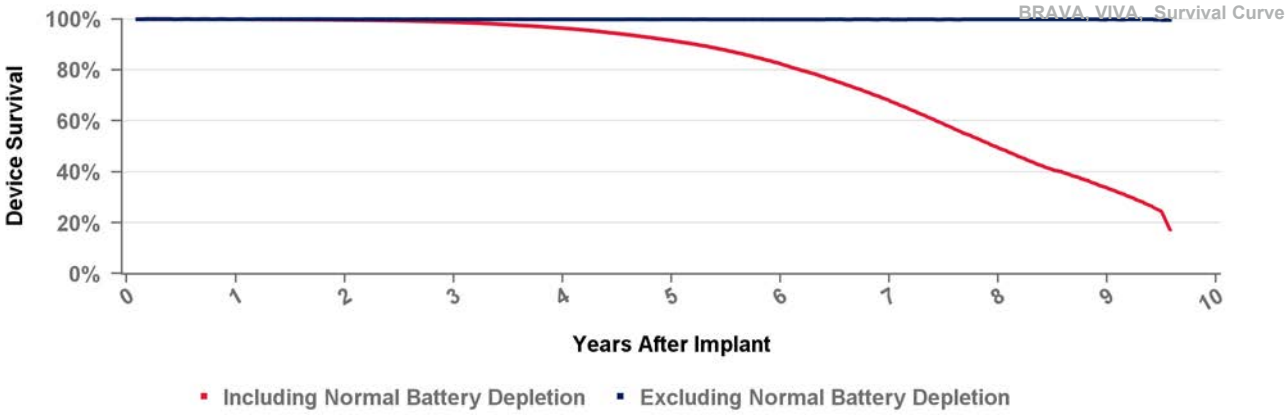
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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



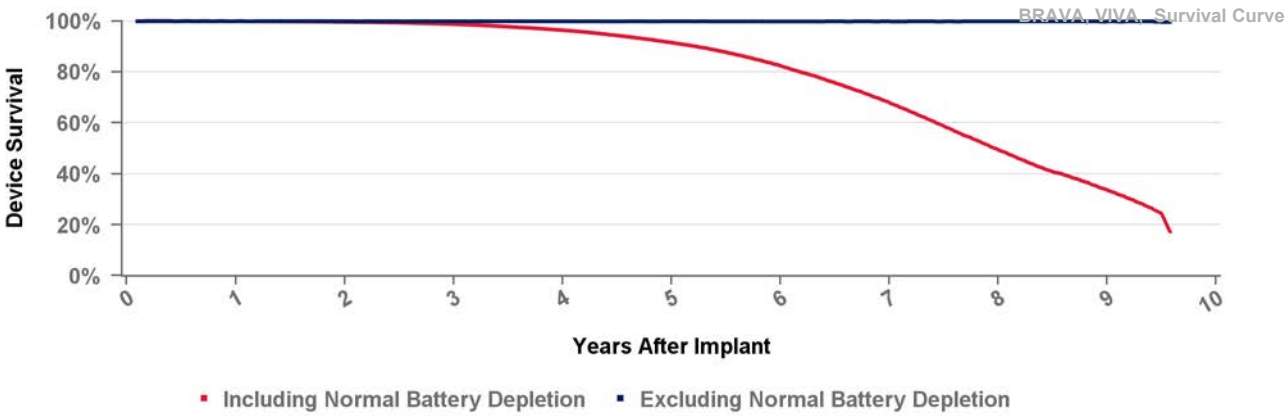
Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

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

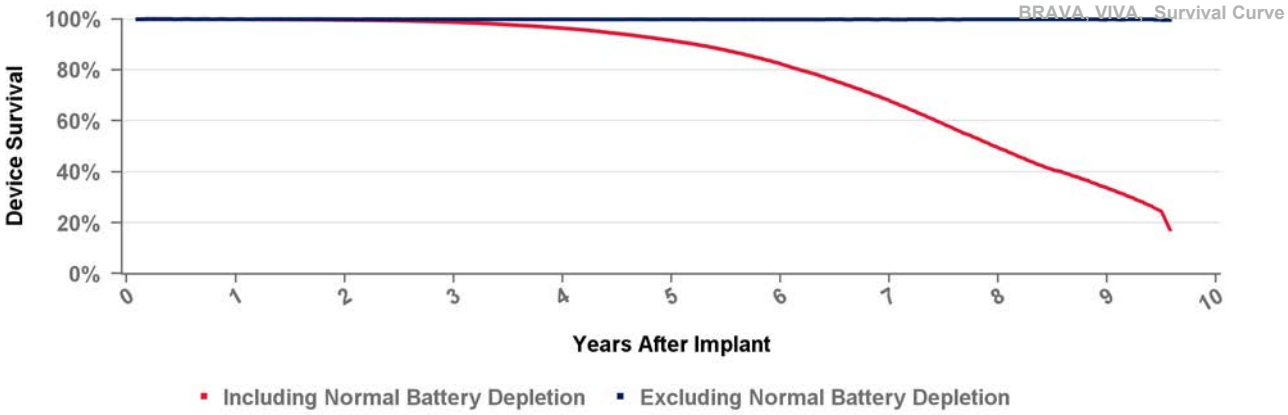
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBC2Q1 Brava Quad

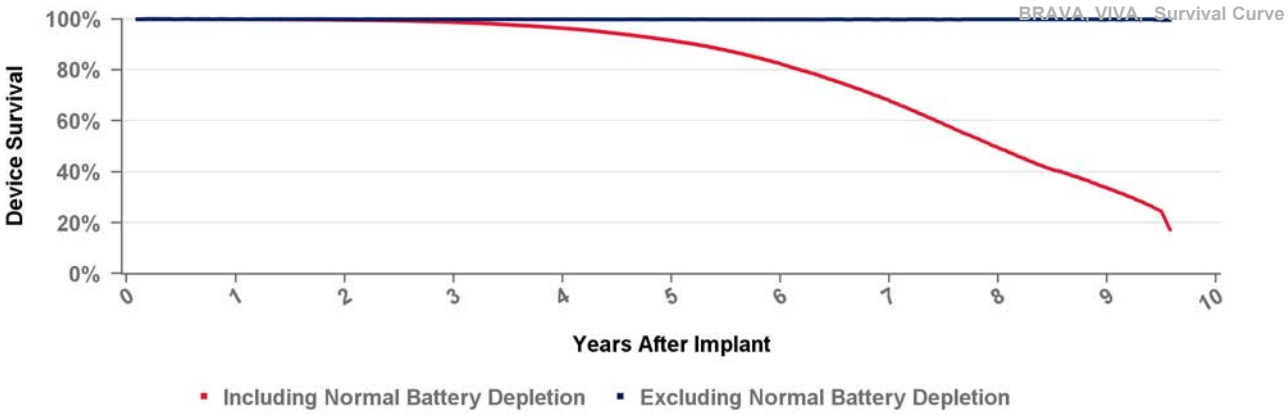
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Sep2013	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBC2QQ Brava Quad

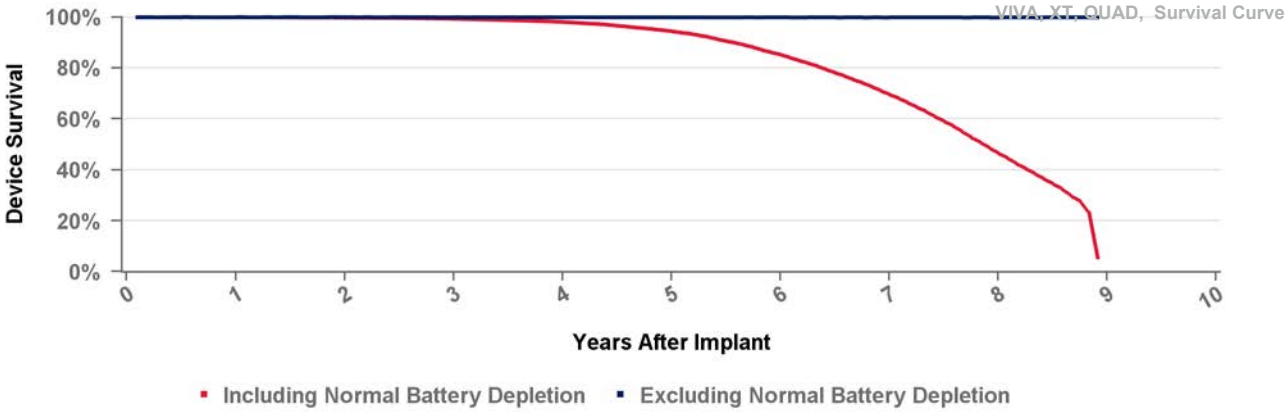
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	08Aug2012	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 115 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	98.8%	96.4%	91.5%	82.4%	67.9%	49.4%	33.7%	17.1%
Effective Sample Size	86422	78563	71228	62992	53097	41460	27946	13827	3595	112

DTBX1QQ Viva Quad C

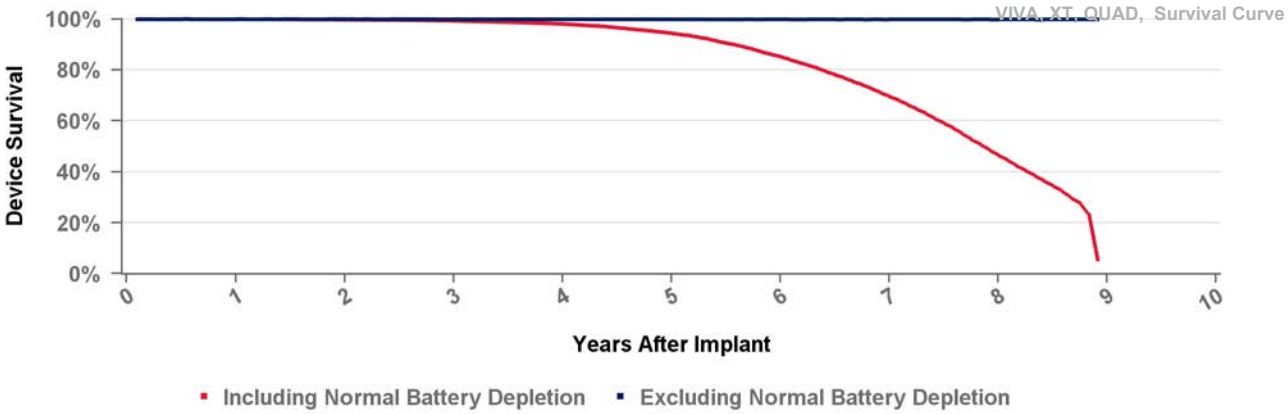
US Market Release	03Jul2014	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	638	Electrical Component	1
Estimated Active USA Implants	72	**Therapy Function Compromised**	**0**
Normal Battery Depletions	382		



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

DTBX2QQ Viva Quad C

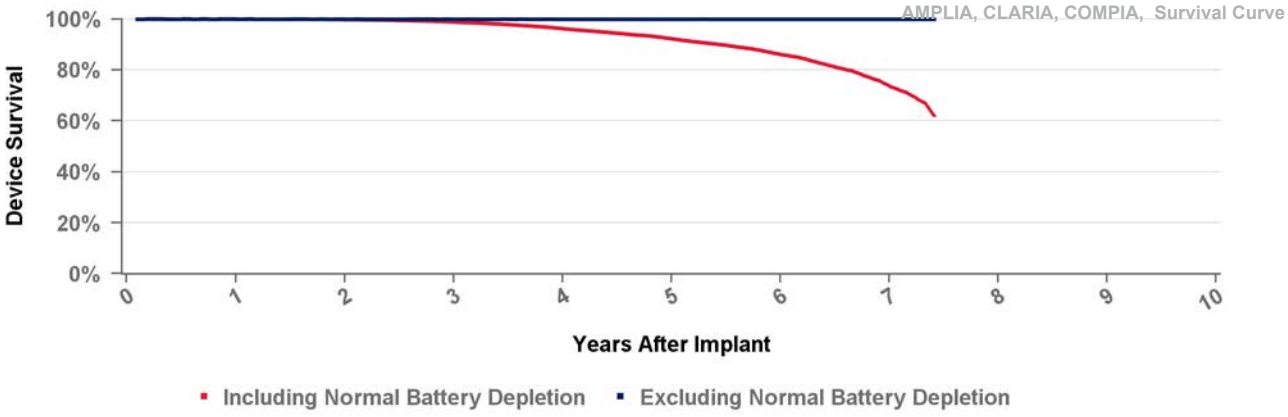
US Market Release	03Jul2014	**Total Malfunctions (USA)**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 107 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%	94.4%	85.3%	69.6%	46.5%	5.4%
Effective Sample Size	33764	31339	28906	25966	22290	17399	11717	5327	108

DTMA1D1 Claria MRI

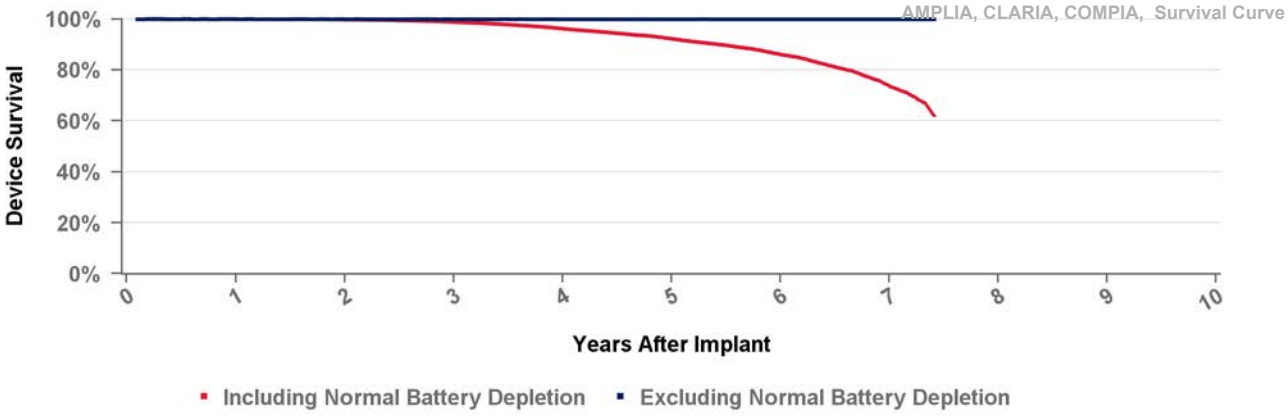
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**9**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	17,502	Battery	4
Estimated Active USA Implants	12,742	Electrical Component	1
Normal Battery Depletions	1,395	Electrical Interconnect	1
		Other	1
		Therapy Function Compromised	**2**
		Battery	1
		Electrical Component	1



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMA1D4 Claria MRI

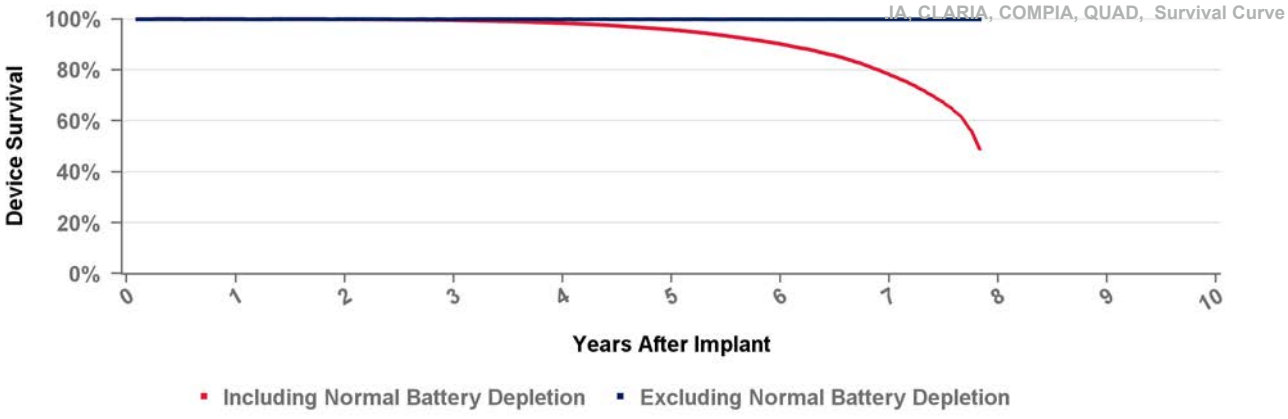
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**11**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	16,805	Battery	1
Estimated Active USA Implants	12,844	Electrical Component	4
Normal Battery Depletions	1,183	**Therapy Function Compromised**	**6**
		Battery	1
		Device-Related Current Pathway	2
		Electrical Component	2
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMA1Q1 Claria MRI

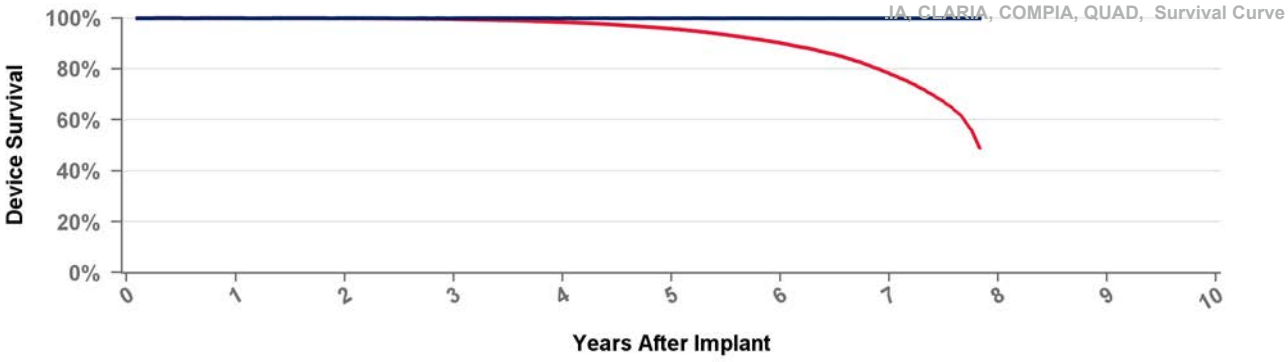
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	12,258	Battery	1
Estimated Active USA Implants	9,307	Electrical Interconnect	1
Normal Battery Depletions	735	Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMA1QQ Claria MRI

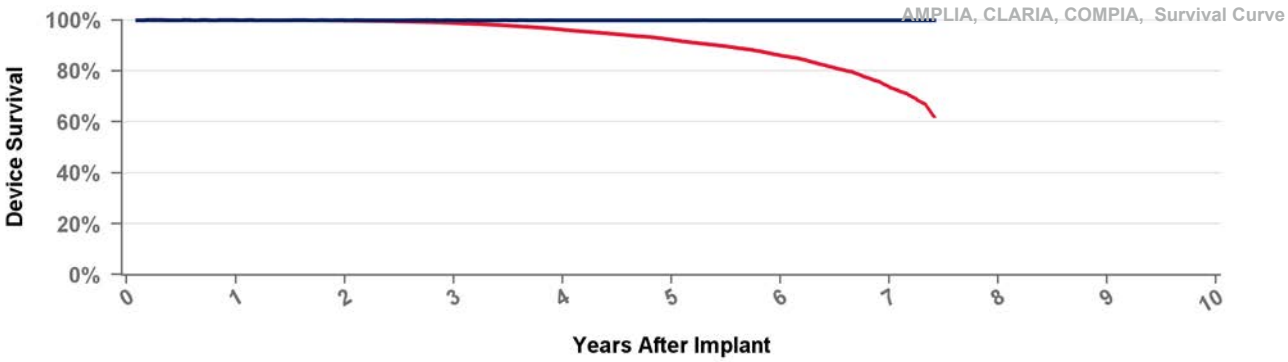
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**33**
CE Approval Date		**Therapy Function Not Compromised**	**21**
Registered USA Implants	76,356	Battery	2
Estimated Active USA Implants	61,034	Electrical Component	13
Normal Battery Depletions	4,425	Electrical Interconnect	1
		Possible Early Battery Depletion	1
		Software/Firmware	1
		Other	3
		Therapy Function Compromised	**12**
		Device-Related Current Pathway	5
		Electrical Component	7



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

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			

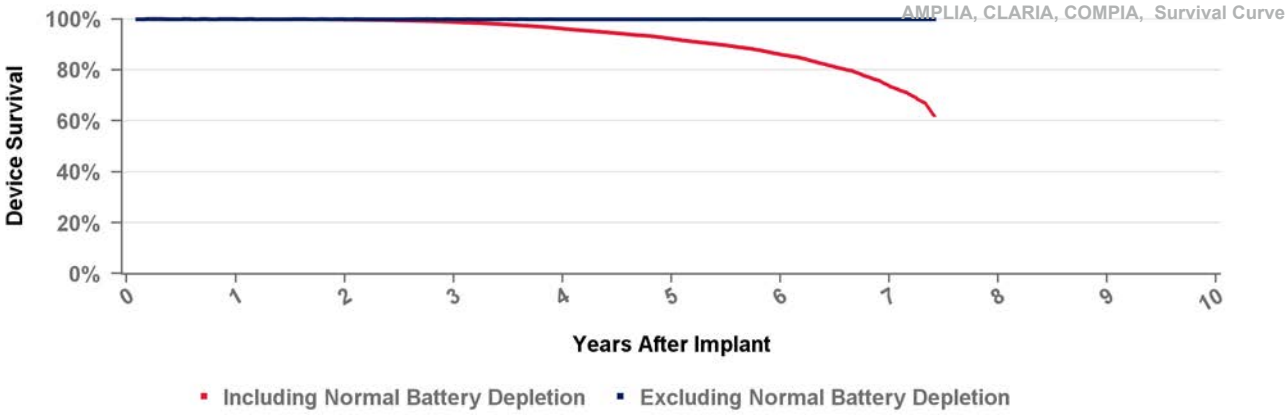


Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

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

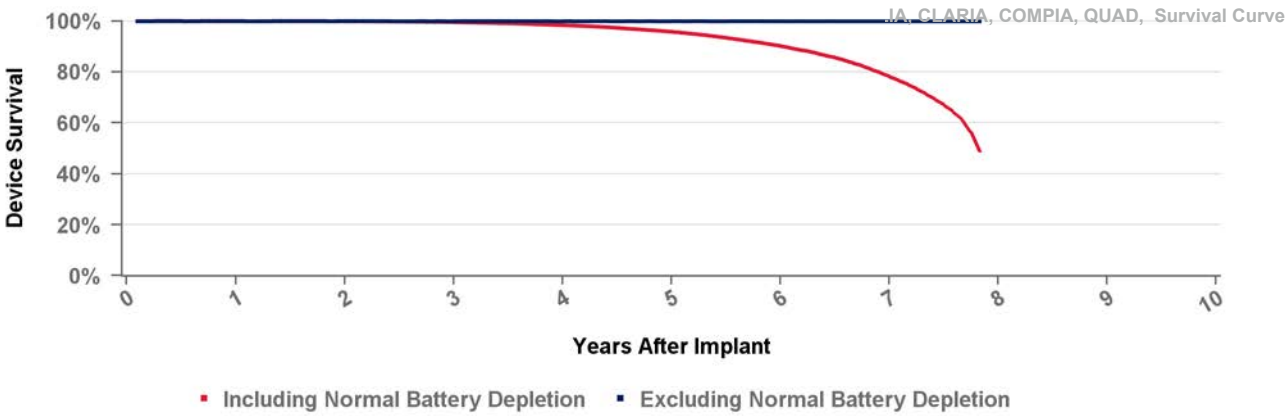


Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMA2Q1 Claria MRI

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

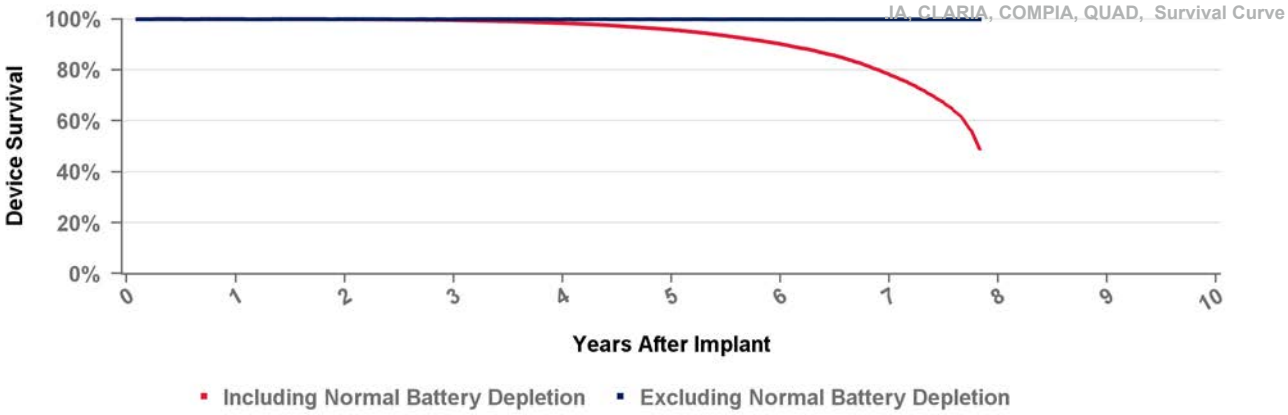
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMA2QQ Claria MRI

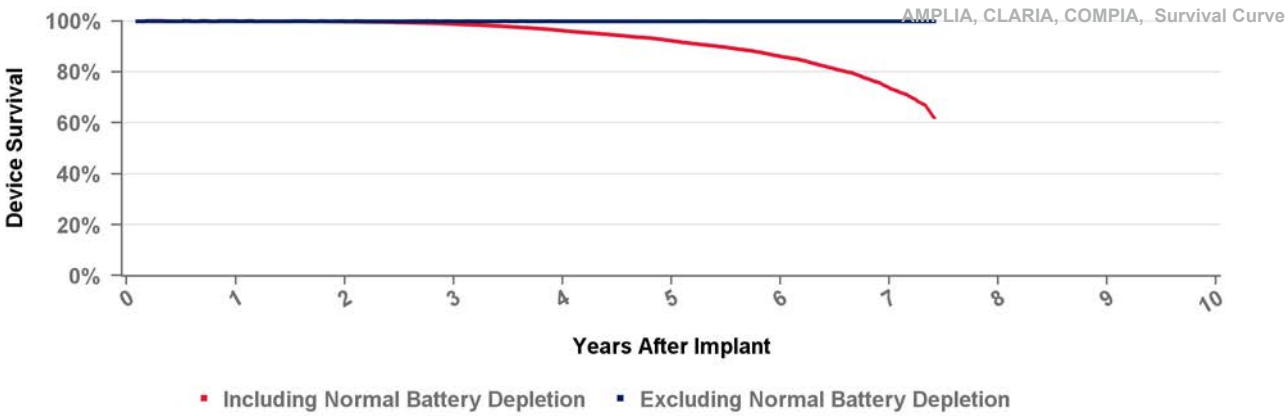
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMB1D1 Amplia MRI

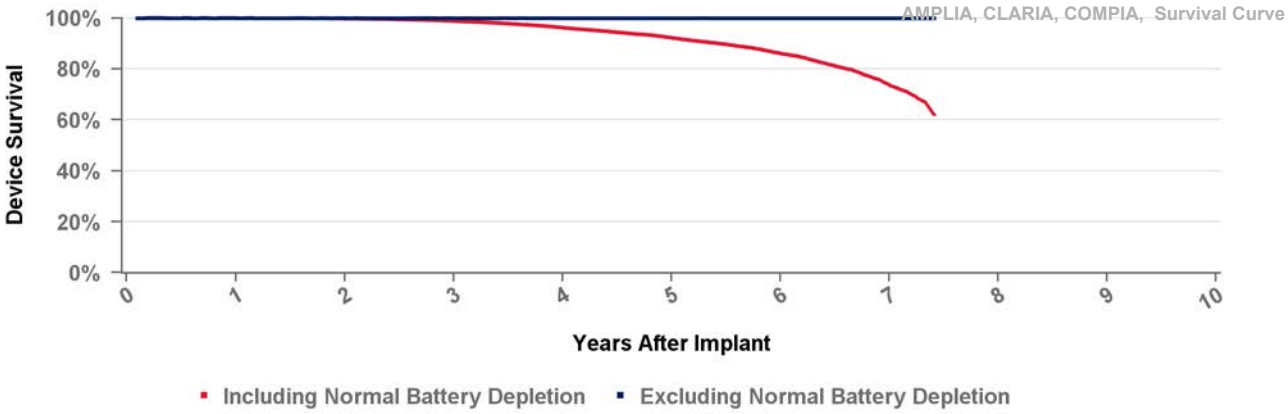
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	6,756	Battery	1
Estimated Active USA Implants	4,383	Electrical Component	2
Normal Battery Depletions	661	Other	1
		Therapy Function Compromised	**1**
		Battery	1



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMB1D4 Amplia MRI

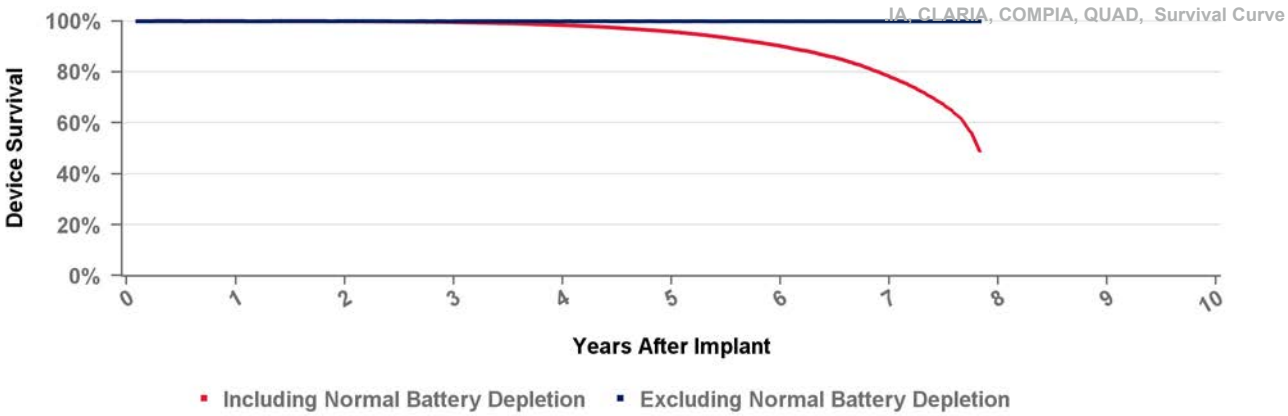
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	6,996	Electrical Component	2
Estimated Active USA Implants	4,228	**Therapy Function Compromised**	**1**
Normal Battery Depletions	810	Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMB1Q1 Amplia MRI

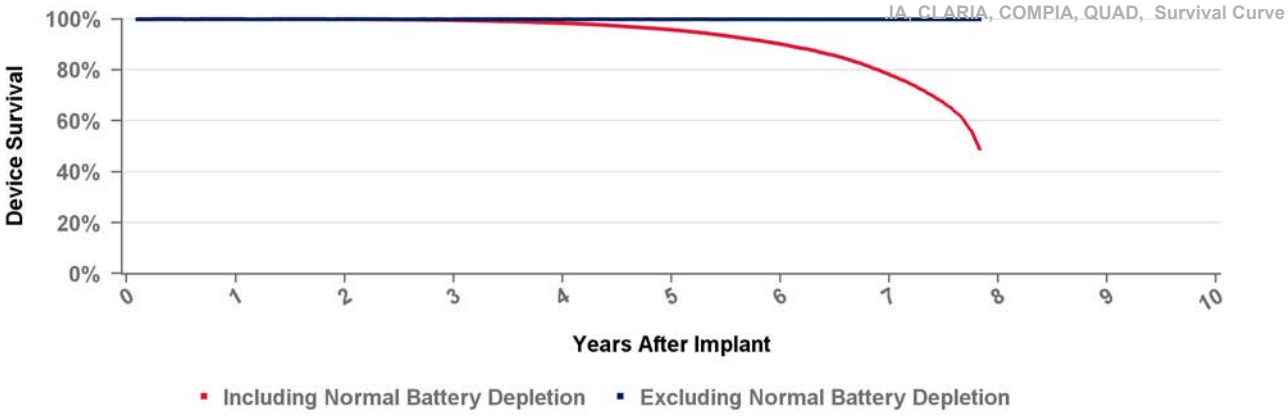
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,461	Battery	1
Estimated Active USA Implants	3,072	**Therapy Function Compromised**	**1**
Normal Battery Depletions	360	Battery	1



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMB1QQ Amplia MRI

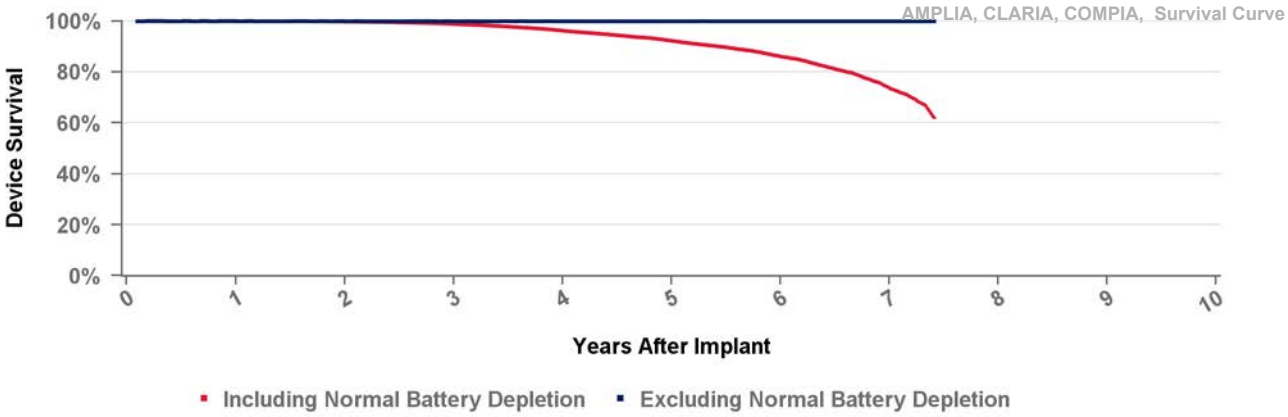
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**40**
CE Approval Date		**Therapy Function Not Compromised**	**31**
Registered USA Implants	31,985	Battery	13
Estimated Active USA Implants	19,229	Electrical Component	12
Normal Battery Depletions	4,367	Possible Early Battery Depletion	3
		Other	3
		Therapy Function Compromised	**9**
		Battery	8
		Device-Related Current Pathway	1



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

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			

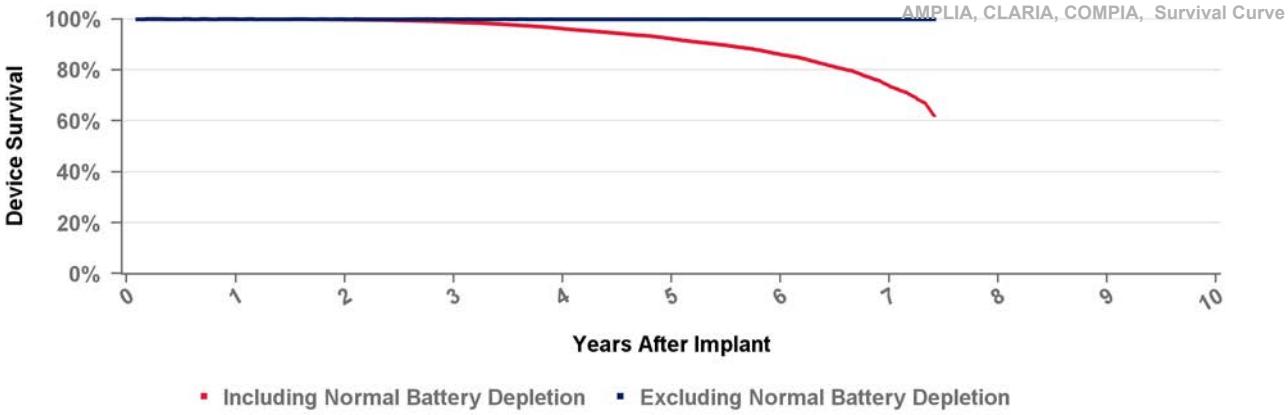


Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

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

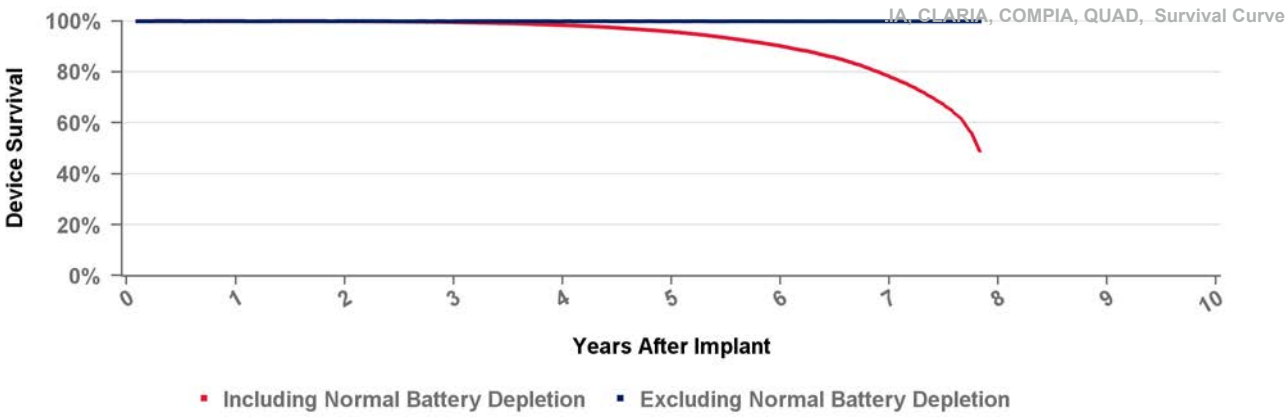


Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMB2Q1 Amplia MRI

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

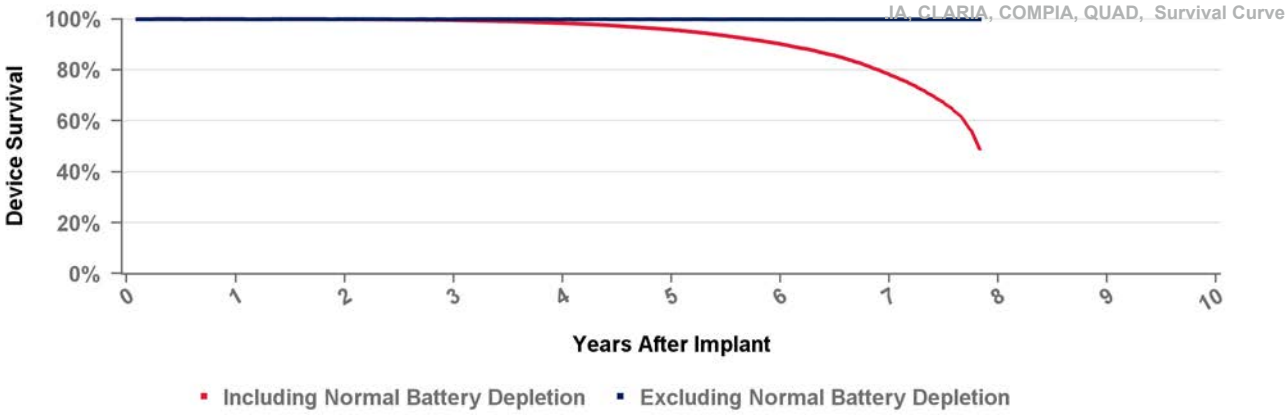
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMB2QQ Amplia MRI

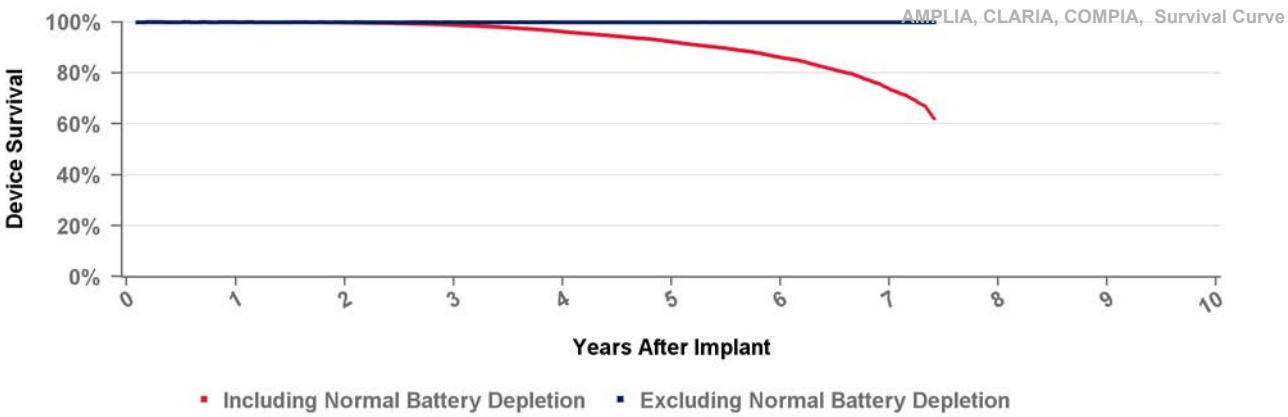
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMC1D1 Compia MRI

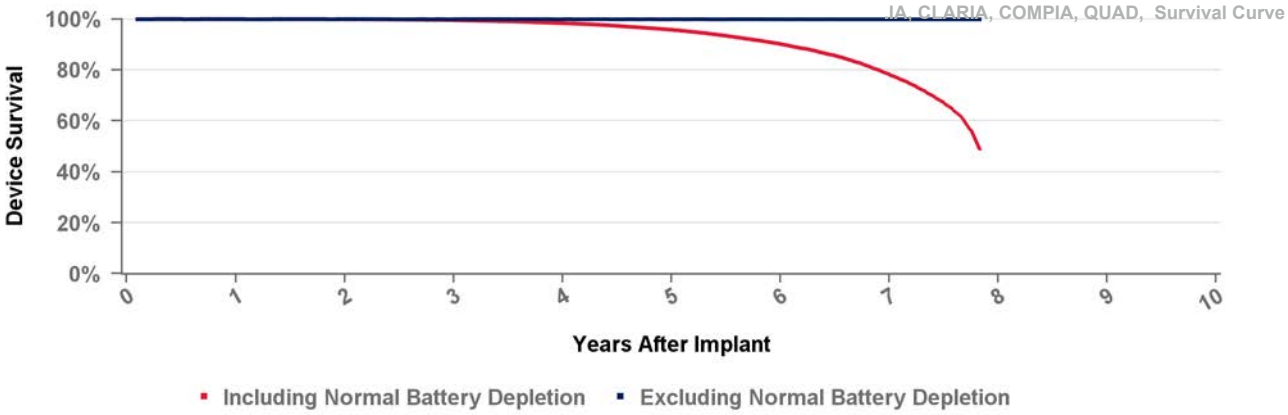
US Market Release	05Dec2016	**Total Malfunctions (USA)**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,139		
Estimated Active USA Implants	805	**Therapy Function Compromised**	**1**
Normal Battery Depletions	111	Device-Related Current Pathway	1



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMC1QQ Compia MRI

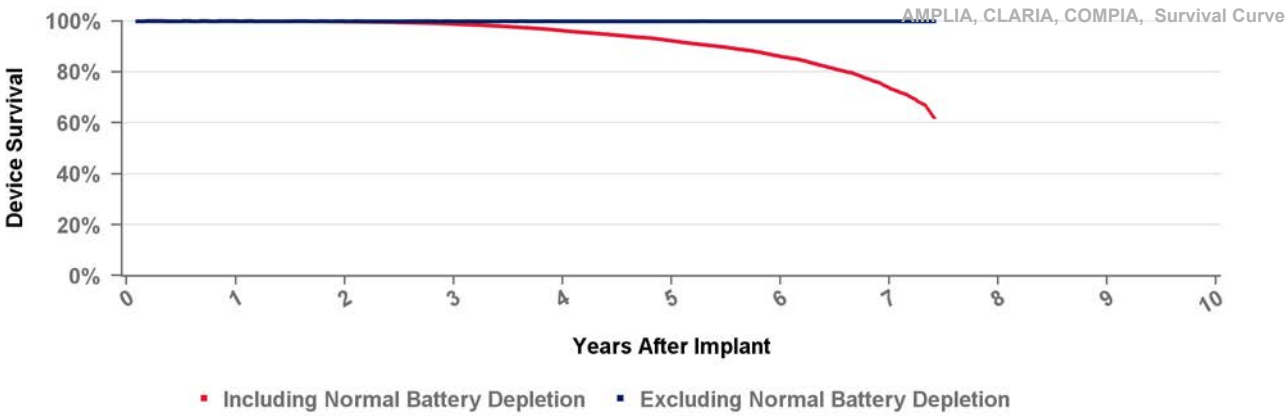
US Market Release	01Feb2016	**Total Malfunctions (USA)**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	5,008	Battery	2
Estimated Active USA Implants	3,389	Electrical Component	2
Normal Battery Depletions	703	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTMC2D1 Compia MRI

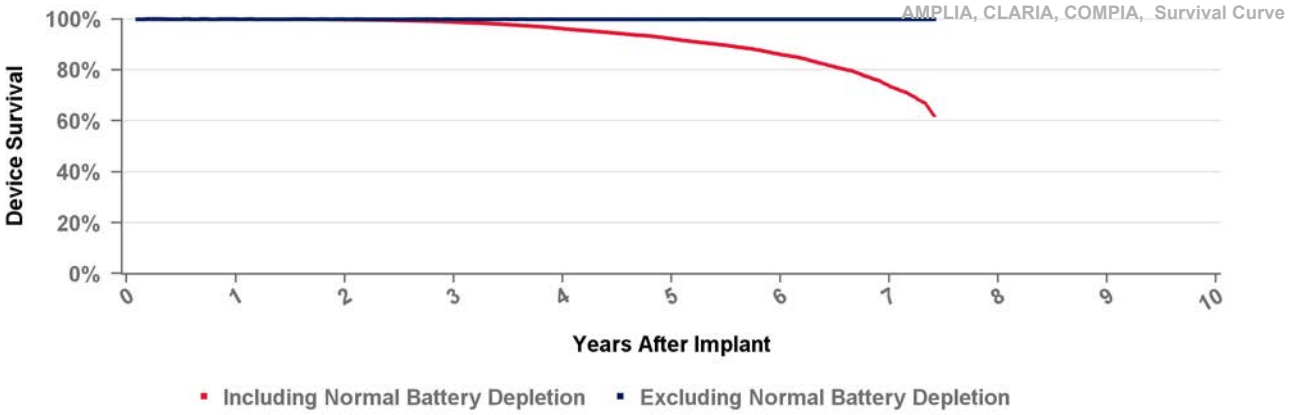
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	29Aug2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMC2D4 Compia MRI

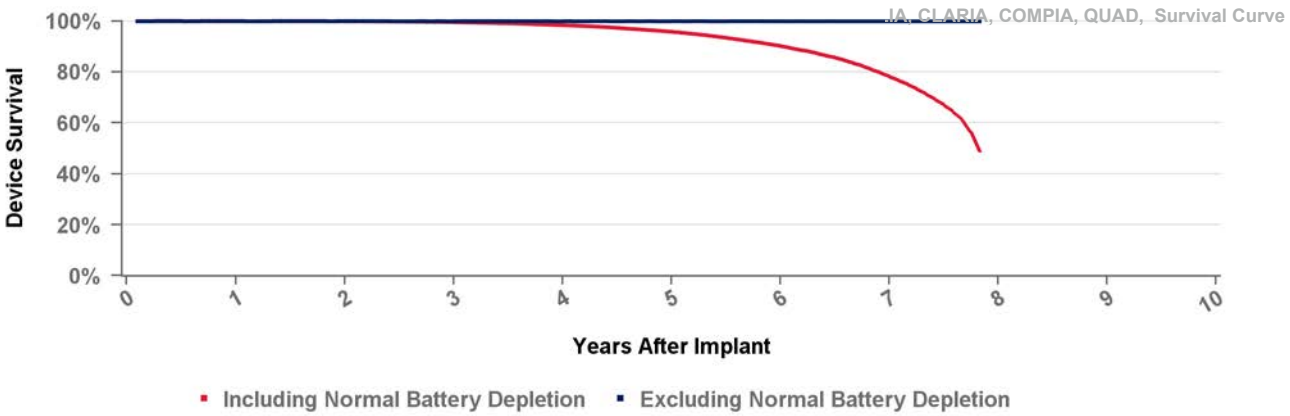
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.8%	96.2%	92.3%	86.1%	73.6%	62.1%
Effective Sample Size	42585	35869	27542	20918	14261	8220	2176	393

DTMC2QQ Compia MRI

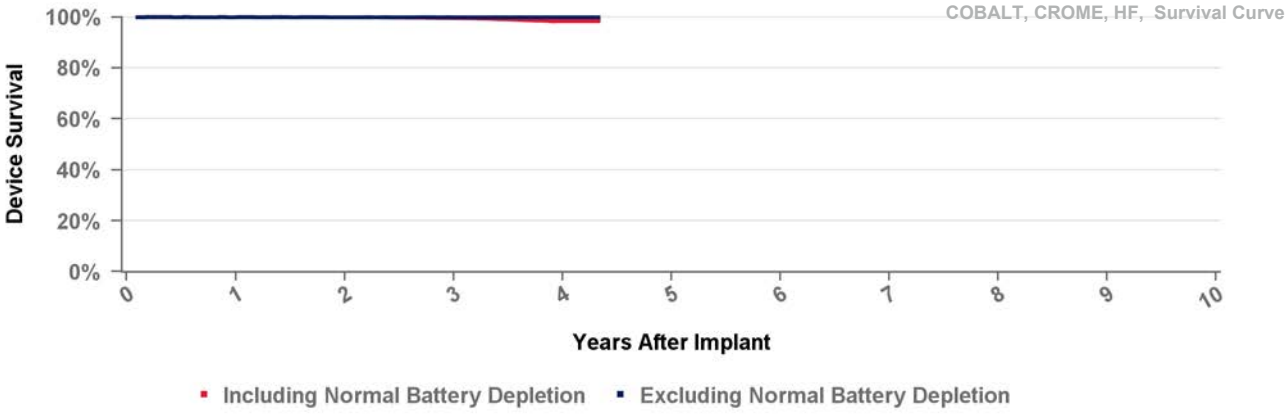
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Feb2016	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.4%	95.8%	90.2%	78.2%	49.0%
Effective Sample Size	114917	100747	82600	67393	46692	26834	10564	652

DTPA2D1 Cobalt XT HF

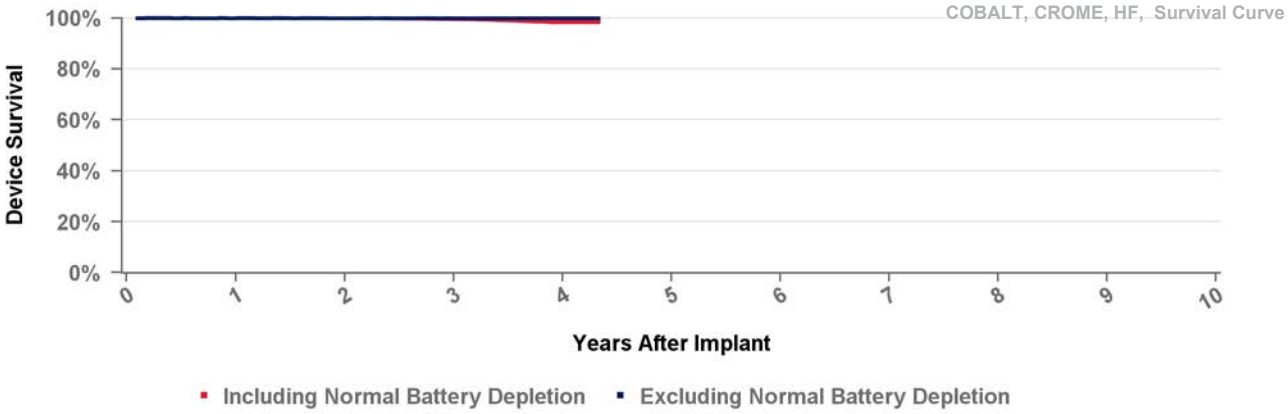
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6,112	Other	1
Estimated Active USA Implants	5,813	**Therapy Function Compromised**	**0**
Normal Battery Depletions	12		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPA2D4 Cobalt XT HF

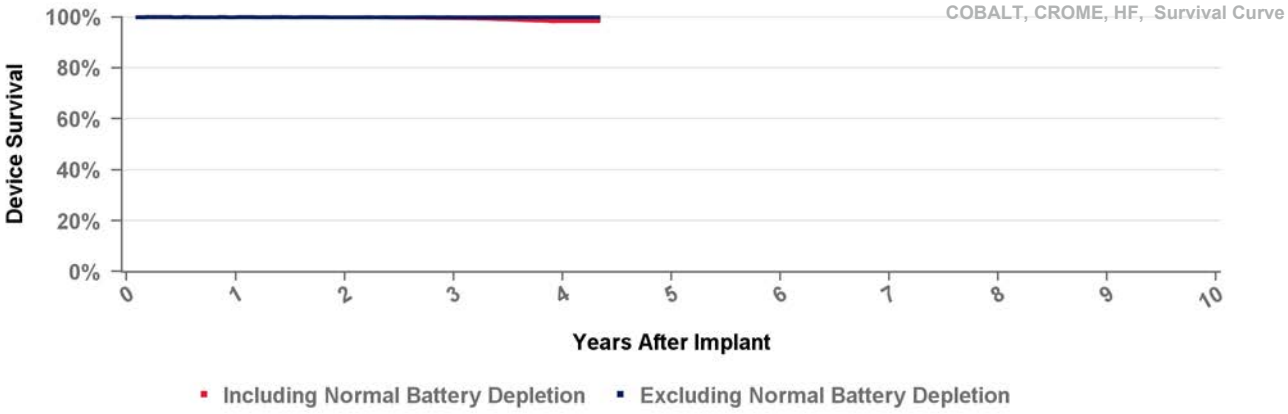
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**3**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**2**
Registered USA Implants	9,169	Electrical Component	1
Estimated Active USA Implants	8,772	Electrical Interconnect	1
Normal Battery Depletions	10	**Therapy Function Compromised**	**1**
		Electrical Interconnect	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPA2Q1 Cobalt XT HF Quad

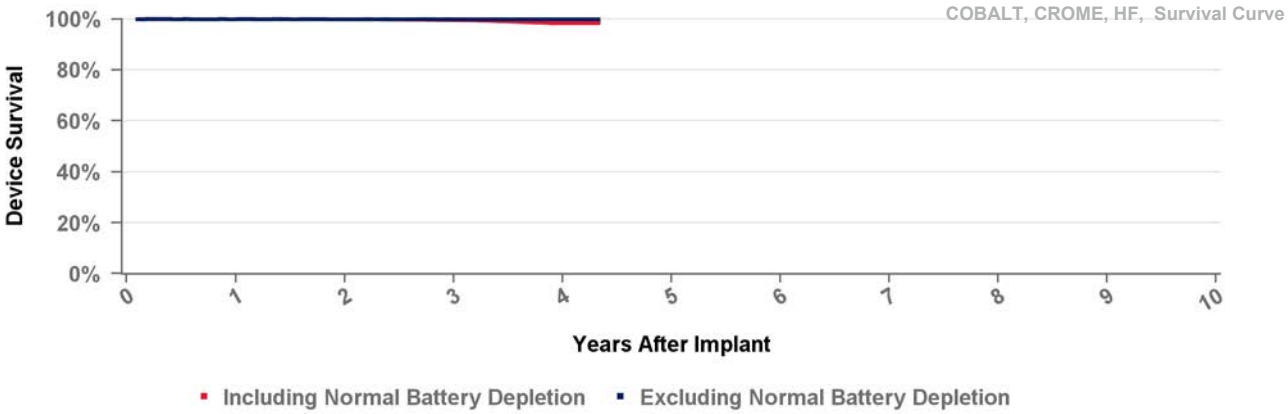
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,202	Software/Firmware	1
Estimated Active USA Implants	3,978	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPA2QQ Cobalt XT HF Quad

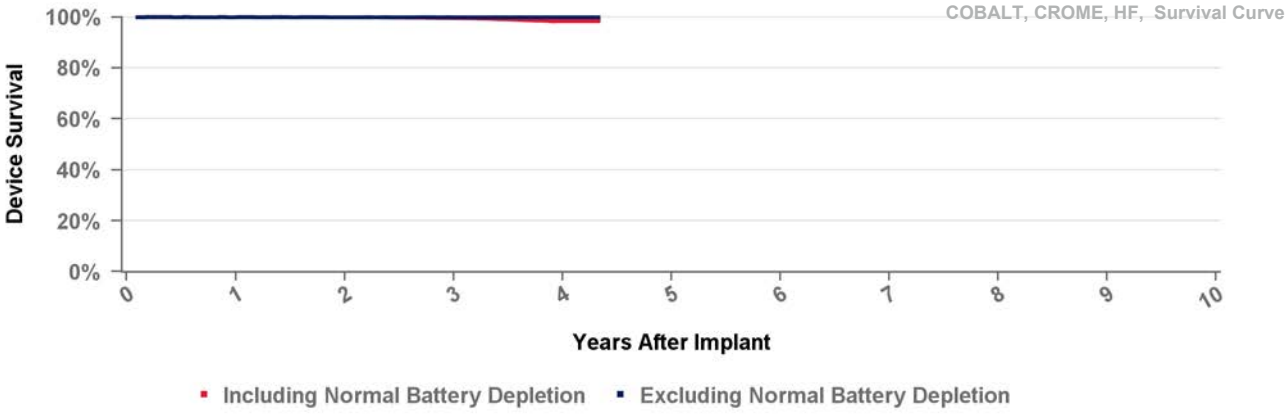
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**6**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**4**
Registered USA Implants	40,338	Electrical Component	3
Estimated Active USA Implants	38,767	Software/Firmware	1
Normal Battery Depletions	18	**Therapy Function Compromised**	**2**
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPB2D1 Cobalt HF

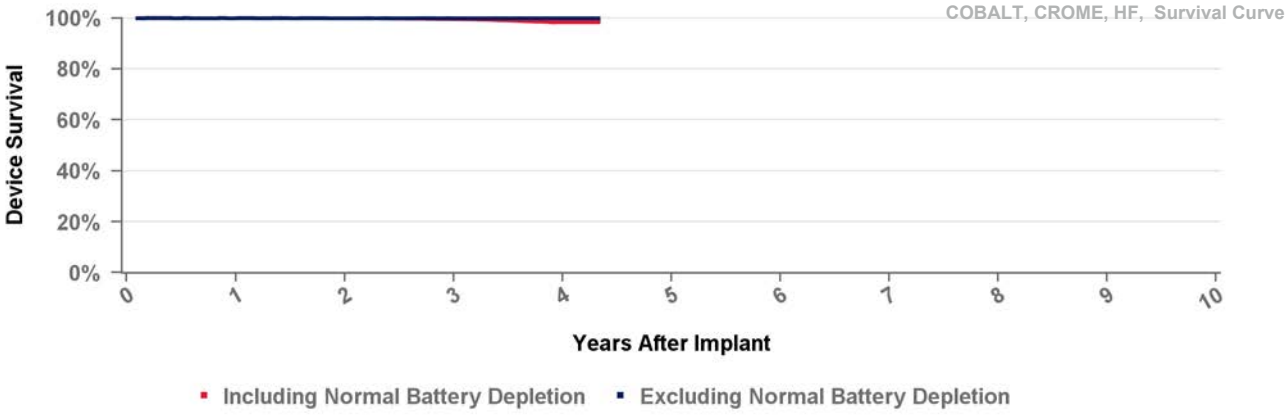
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**3**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,064	Electrical Component	1
Estimated Active USA Implants	3,710	**Therapy Function Compromised**	**2**
Normal Battery Depletions	30	Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPB2D4 Cobalt HF

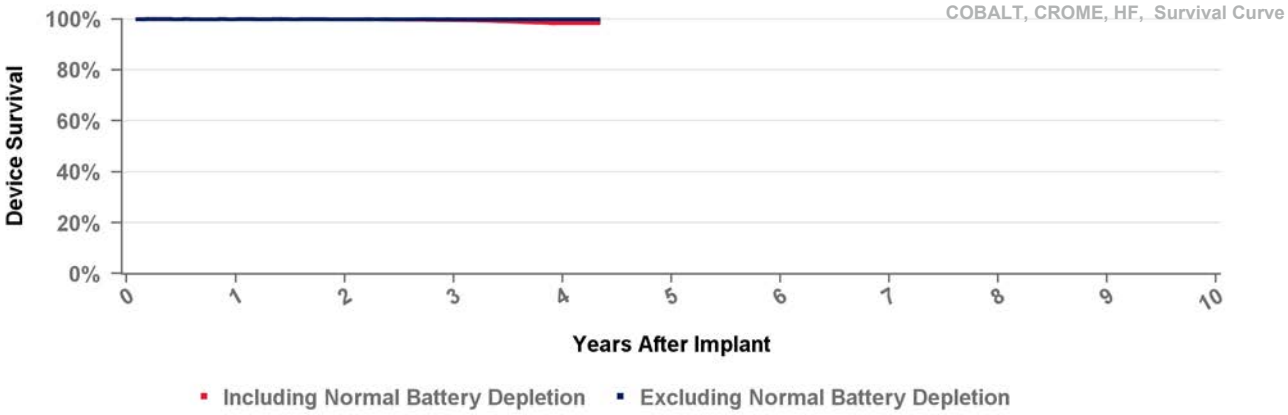
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**5**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**4**
Registered USA Implants	4,418	Electrical Interconnect	3
Estimated Active USA Implants	4,106	Software/Firmware	1
Normal Battery Depletions	22	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPB2Q1 Cobalt HF Quad

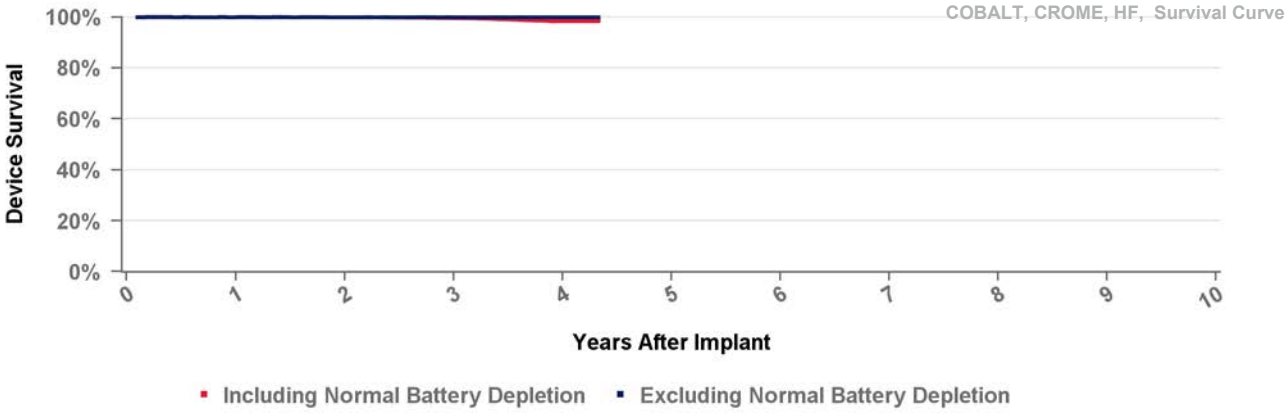
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	2,712		
Estimated Active USA Implants	2,490	**Therapy Function Compromised**	
Normal Battery Depletions	8		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPB2QQ Cobalt HF Quad

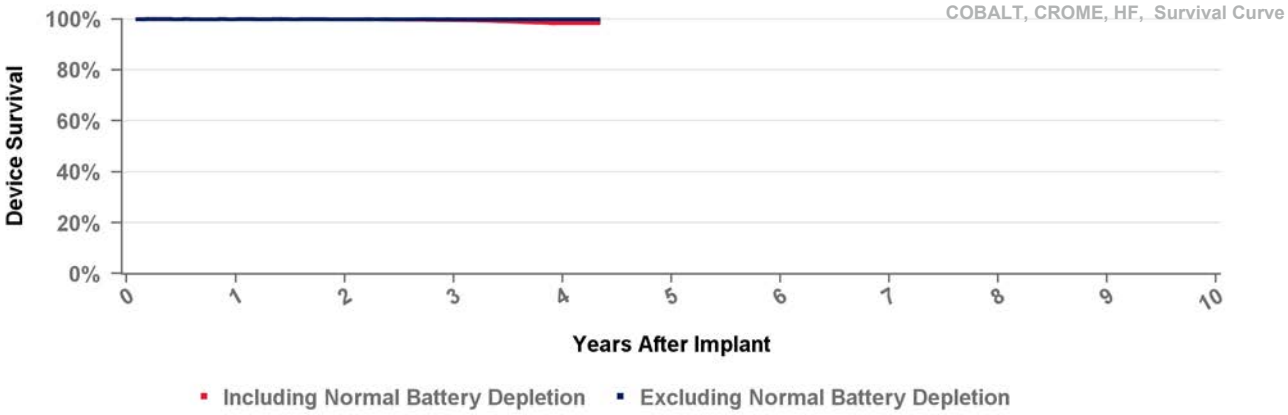
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**13**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**7**
Registered USA Implants	21,089	Electrical Component	5
Estimated Active USA Implants	19,811	Electrical Interconnect	1
Normal Battery Depletions	68	Other	1
		Therapy Function Compromised	**6**
		Electrical Component	3
		Electrical Interconnect	3



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPC2D1 Crome HF

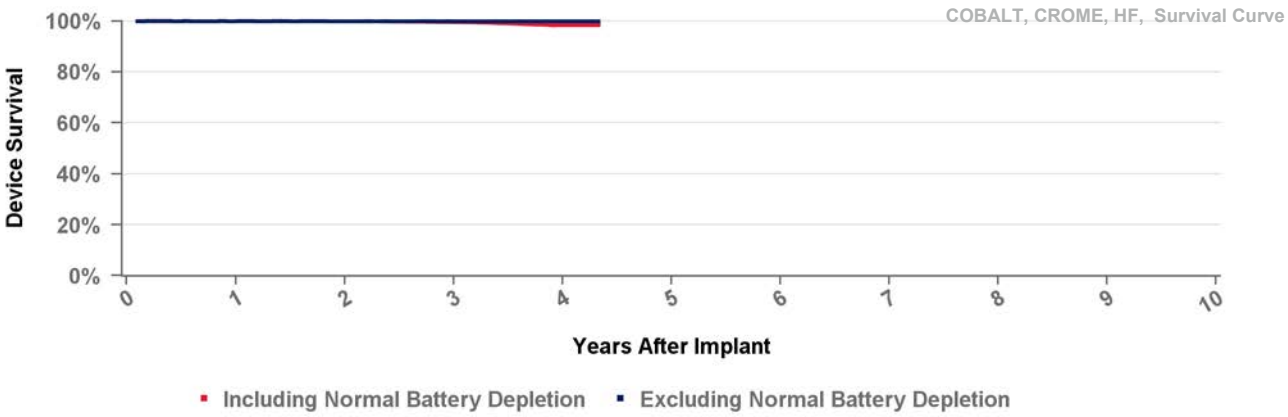
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	413		
Estimated Active USA Implants	381	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPC2D4 Crome HF

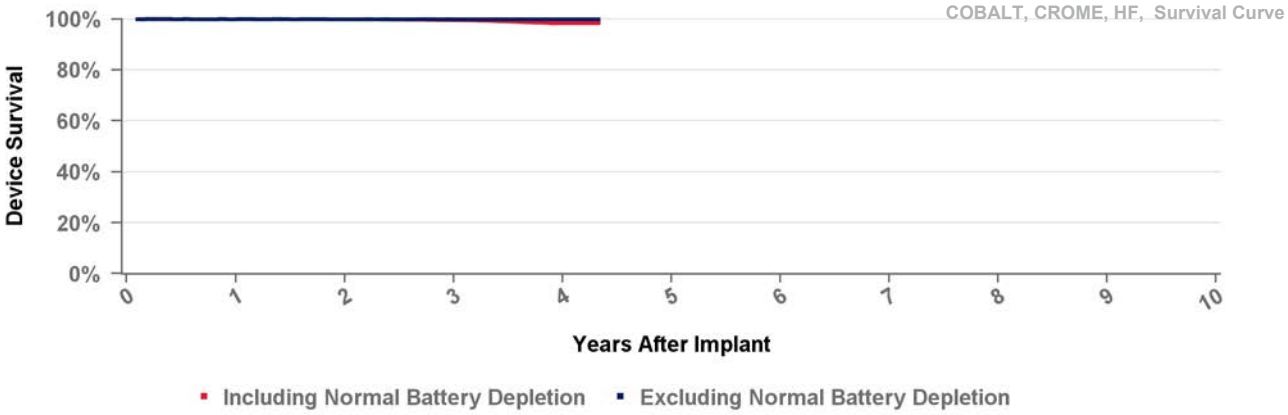
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	462		
Estimated Active USA Implants	433	**Therapy Function Compromised**	
Normal Battery Depletions	4		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPC2Q1 Crome HF Quad

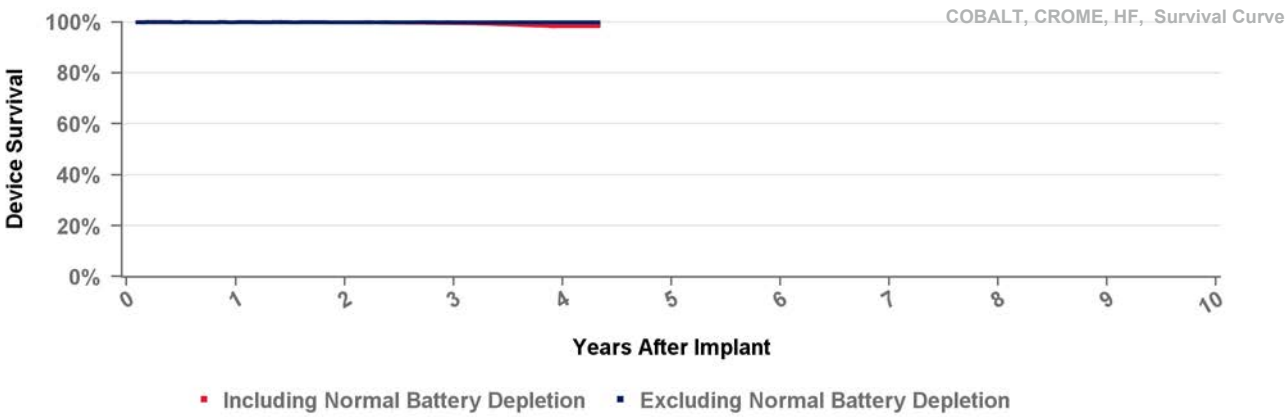
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	200		
Estimated Active USA Implants	188	**Therapy Function Compromised**	
Normal Battery Depletions	4		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

DTPC2QQ Crome HF Quad

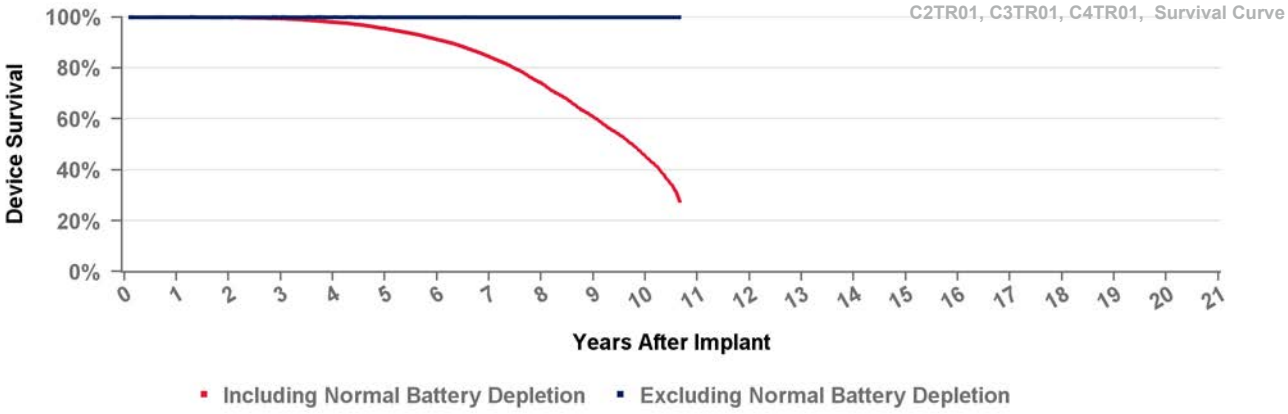
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,846	Electrical Component	1
Estimated Active USA Implants	1,743	**Therapy Function Compromised**	**0**
Normal Battery Depletions	8		



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.6%	98.3%	98.3%
Effective Sample Size	56949	31260	16772	1730	144

C2TR01 Syncra CRT-P

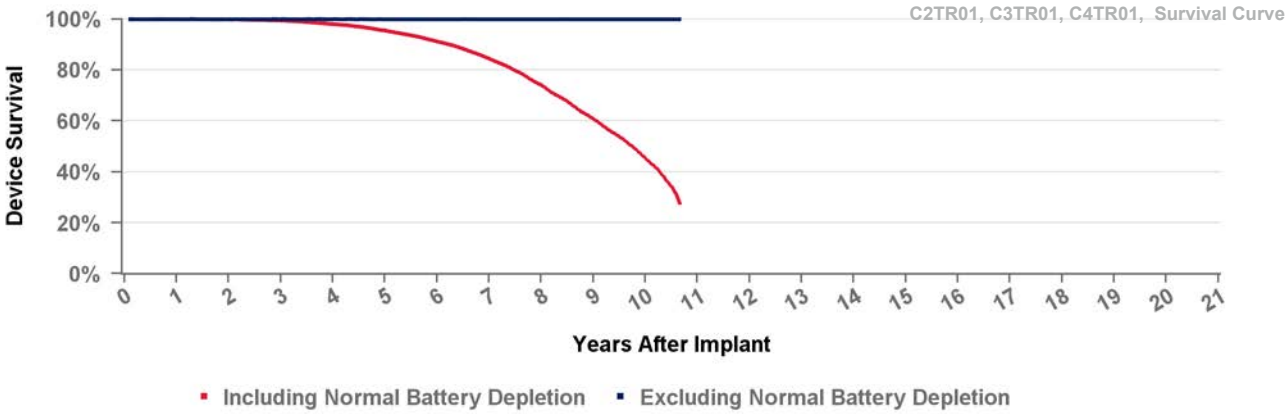
US Market Release	22Mar2011	**Total Malfunctions (USA)**	**7**
CE Approval Date	11May2010	**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,237	Possible Early Battery Depletion	5
Estimated Active USA Implants	2,114	Other	1
Normal Battery Depletions	1,008	**Therapy Function Compromised**	**1**
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	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%	84.4%	74.1%	60.7%	45.3%	27.6%
Effective Sample Size	26186	23391	20951	18300	15667	13090	10447	7237	4113	1577	132

C3TR01 Consulta CRT-P

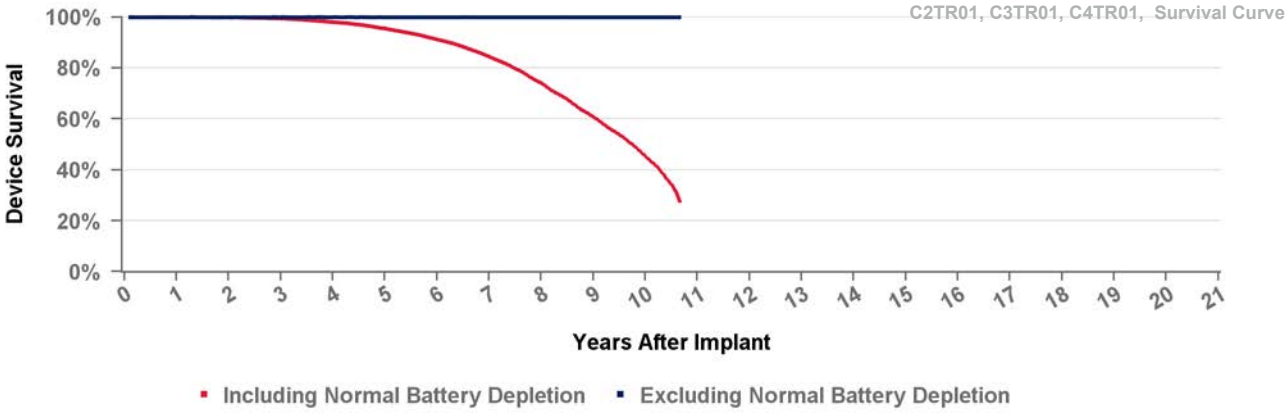
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	11May2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	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%	84.4%	74.1%	60.7%	45.3%	27.6%
Effective Sample Size	26186	23391	20951	18300	15667	13090	10447	7237	4113	1577	132

C4TR01 Consulta CRT-P

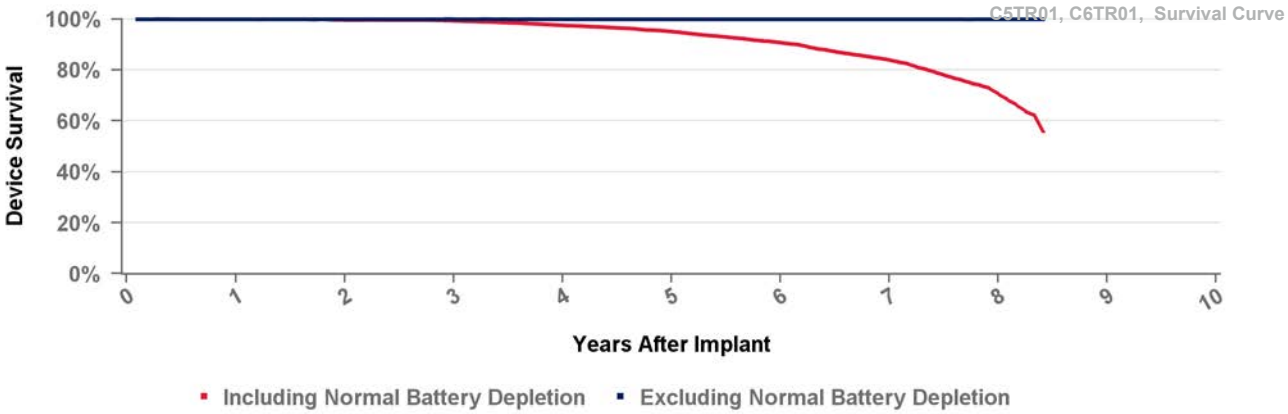
US Market Release	22Mar2011	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	23,406	Possible Early Battery Depletion	5
Estimated Active USA Implants	5,424	**Therapy Function Compromised**	**3**
Normal Battery Depletions	2,359	Electrical Component	2
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	10	at 128 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	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%	84.4%	74.1%	60.7%	45.3%	27.6%
Effective Sample Size	26186	23391	20951	18300	15667	13090	10447	7237	4113	1577	132

C5TR01 Viva CRT-P

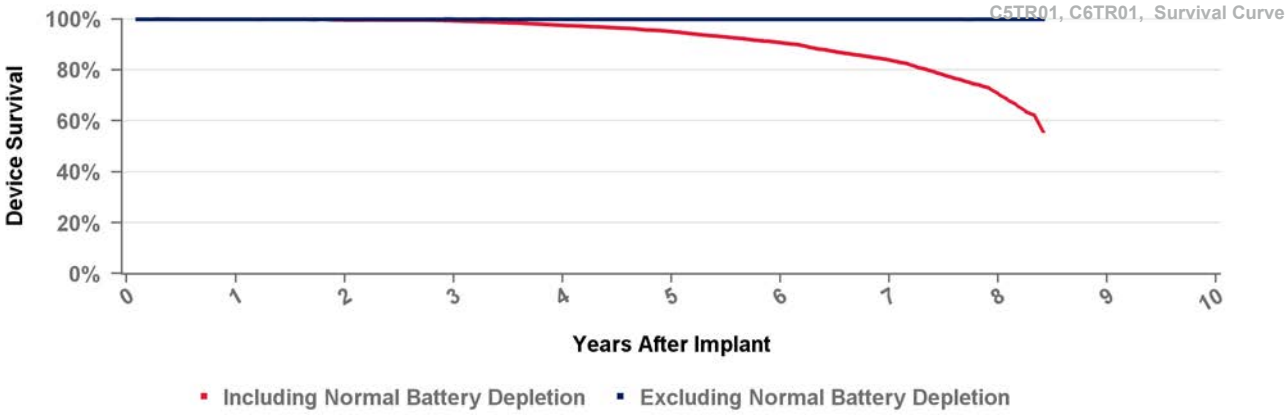
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	04Apr2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	97.5%	95.1%	90.7%	83.9%	70.6%	55.9%
Effective Sample Size	7363	6602	5917	5148	4409	3634	2861	1029	251

C6TR01 Viva CRT-P

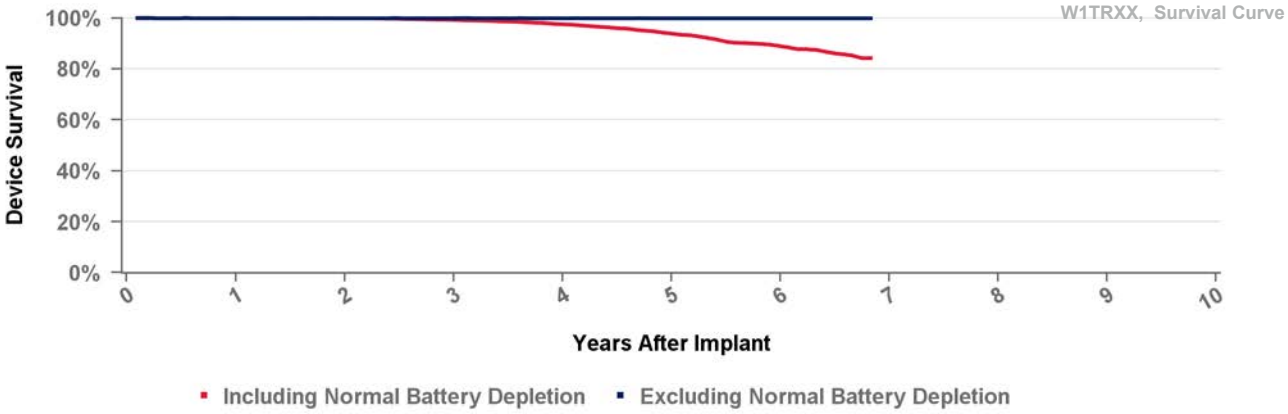
US Market Release	09Jul2014	**Total Malfunctions (USA)**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**8**
Registered USA Implants	9,202	Electrical Component	2
Estimated Active USA Implants	3,634	Possible Early Battery Depletion	6
Normal Battery Depletions	694	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	97.5%	95.1%	90.7%	83.9%	70.6%	55.9%
Effective Sample Size	7363	6602	5917	5148	4409	3634	2861	1029	251

W1TR01 Percepta CRTP MRI

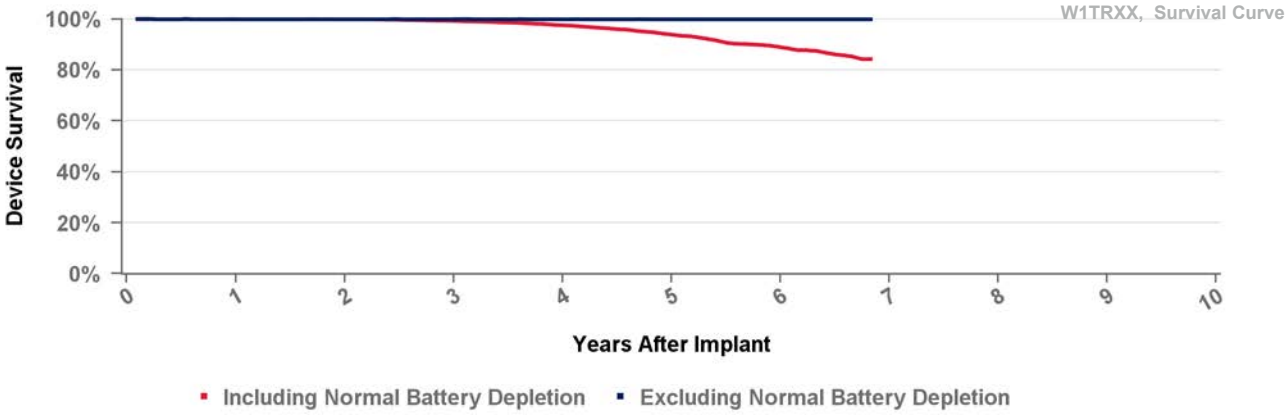
US Market Release	06May2017	**Total Malfunctions (USA)**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	18,071	Electrical Component	2
Estimated Active USA Implants	15,201	Possible Early Battery Depletion	1
Normal Battery Depletions	175	Other	1
		Therapy Function Compromised	**2**
		Electrical Component	2



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W1TR02 Serena CRTP MRI

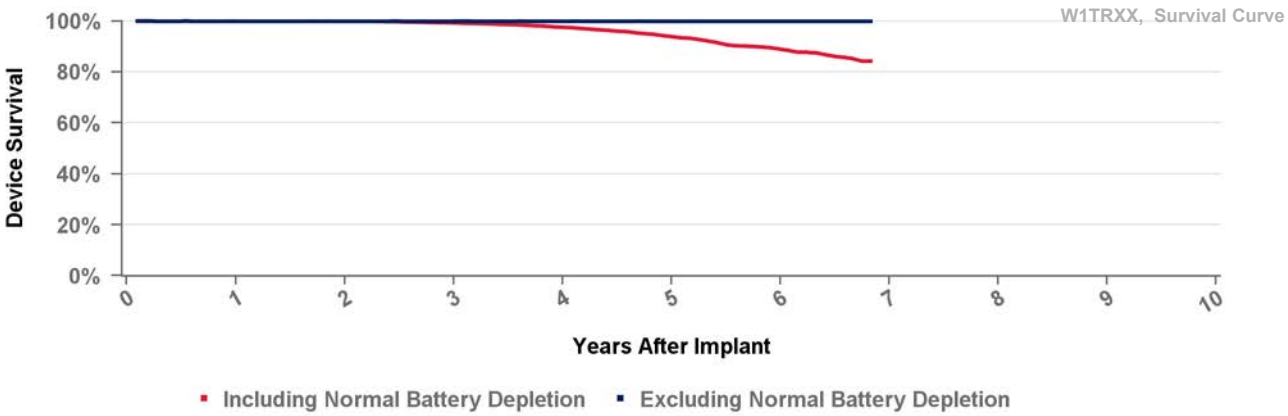
US Market Release	06May2017	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	3,251	Electrical Component	2
Estimated Active USA Implants	2,606	Other	1
Normal Battery Depletions	51	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W1TR03 Solara CRTP MRI

US Market Release	06May2017	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	4,044	Electrical Component	2
Estimated Active USA Implants	3,052	Possible Early Battery Depletion	1
Normal Battery Depletions	95	**Therapy Function Compromised**	**0**

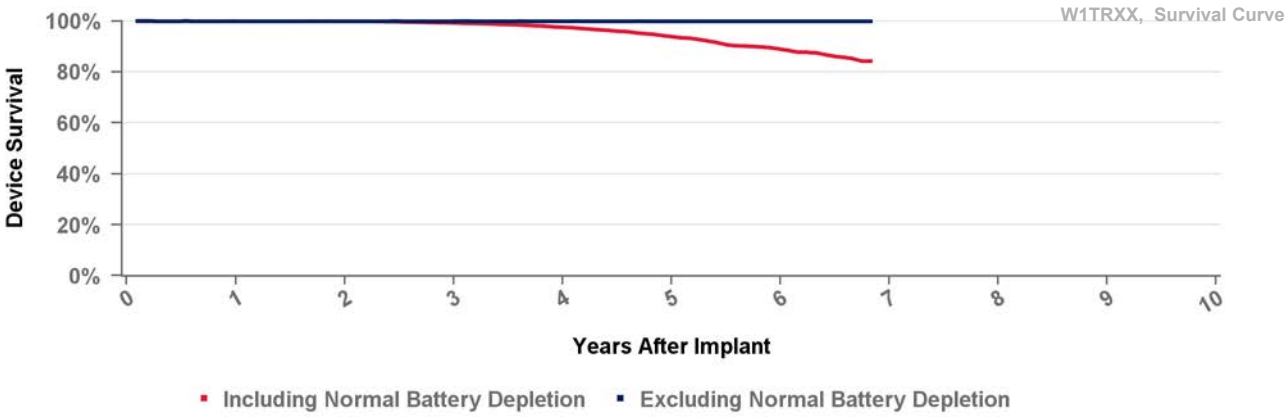


Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W1TR04 Percepta 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

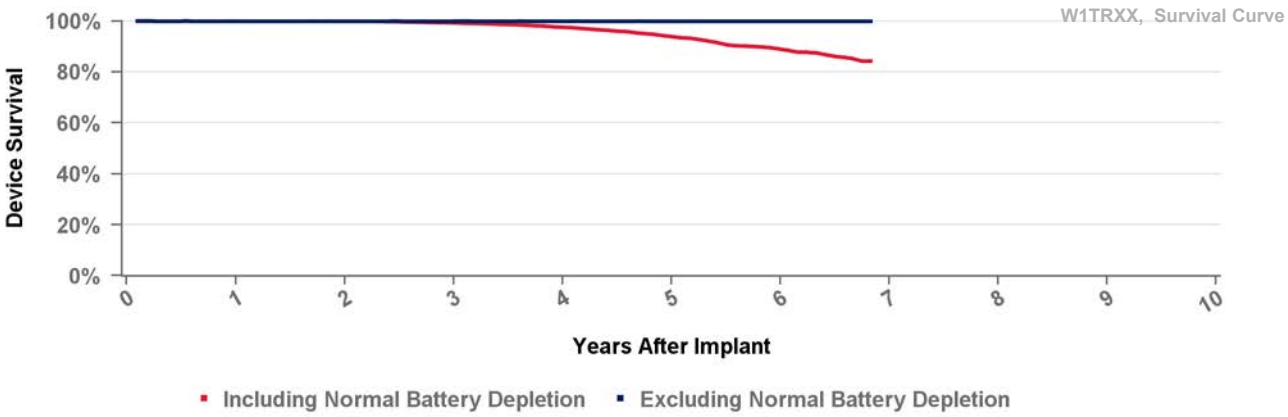


Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W1TR05 Serena CRTP MRI

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

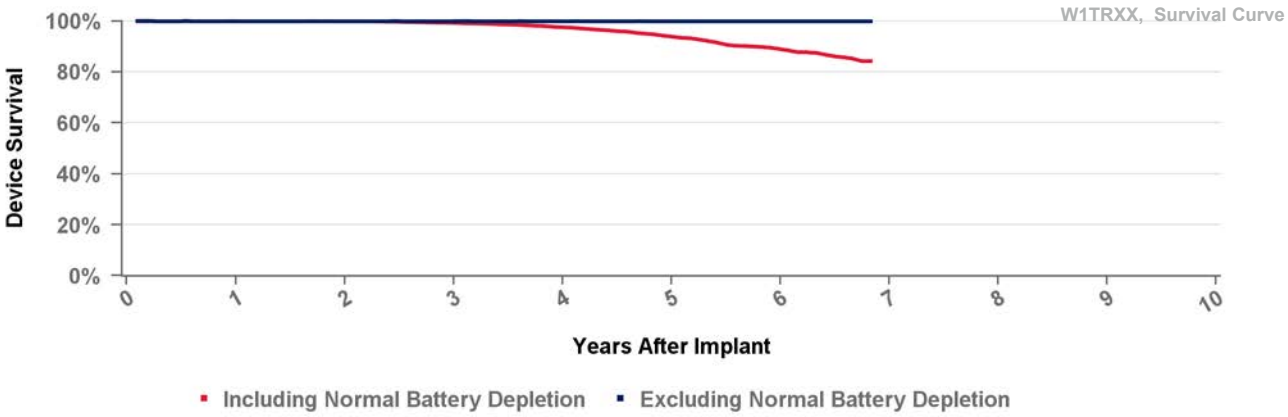
Total Malfunctions (USA)
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W1TR06 Solara CRTP MRI

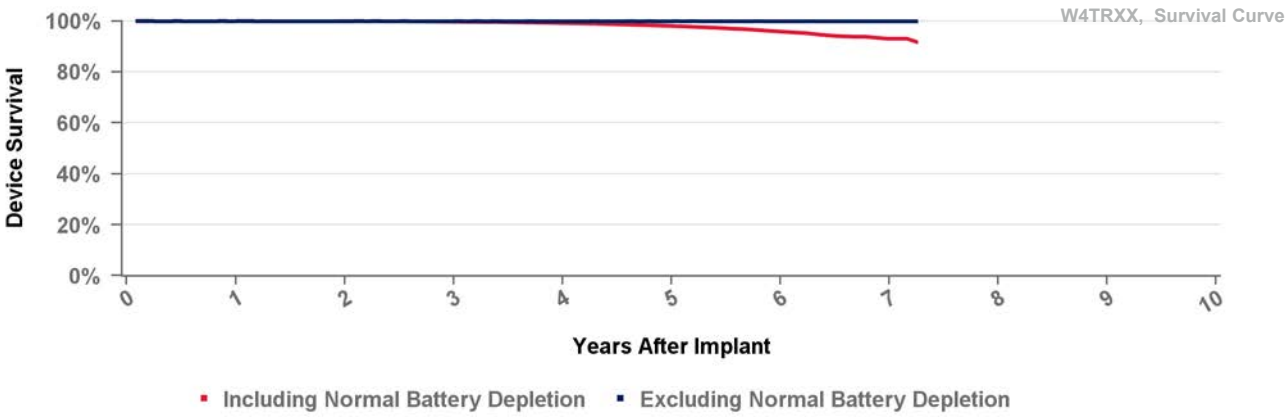
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	10Feb2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.3%	97.6%	93.9%	88.9%	84.2%
Effective Sample Size	19208	14409	10525	6913	3843	1480	168

W4TR01 Percepta Quad CRTP MRI SureScan

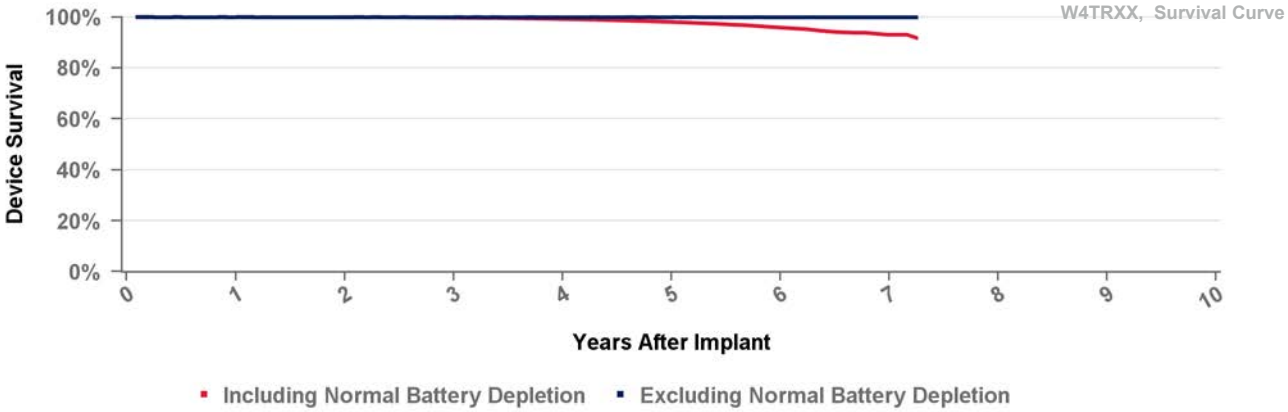
US Market Release	06May2017	**Total Malfunctions (USA)**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	61,482	Electrical Component	11
Estimated Active USA Implants	52,289	Possible Early Battery Depletion	1
Normal Battery Depletions	309	Other	1
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

W4TR02 Serena Quad CRTP MRI SureScan

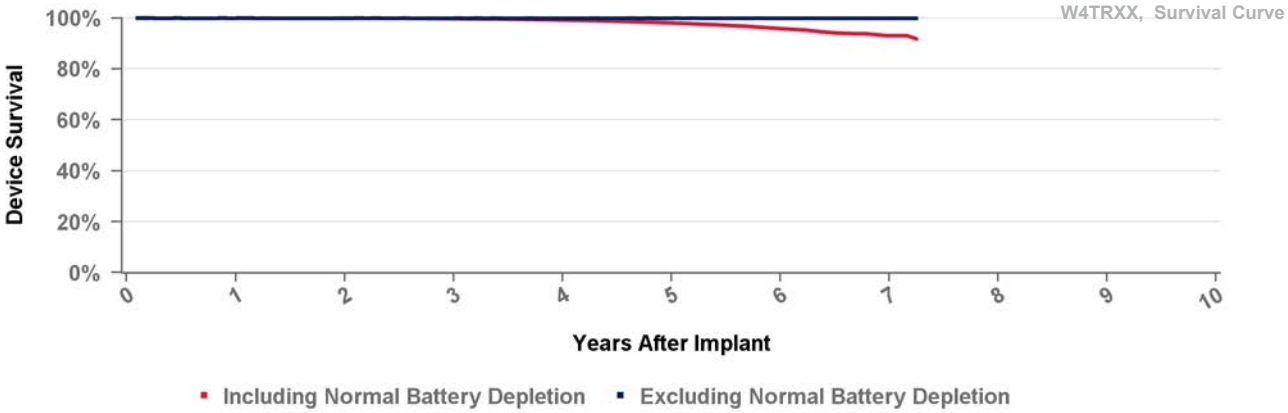
US Market Release	06May2017	**Total Malfunctions (USA)**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	8,547	Electrical Component	3
Estimated Active USA Implants	6,929	**Therapy Function Compromised**	**0**
Normal Battery Depletions	53		



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

W4TR03 Solara Quad CRTP MRI SureScan

US Market Release	06May2017	**Total Malfunctions (USA)**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	10,490	Electrical Component	3
Estimated Active USA Implants	8,155	**Therapy Function Compromised**	**3**
Normal Battery Depletions	76	Electrical Component	2
		Possible Early Battery Depletion	1

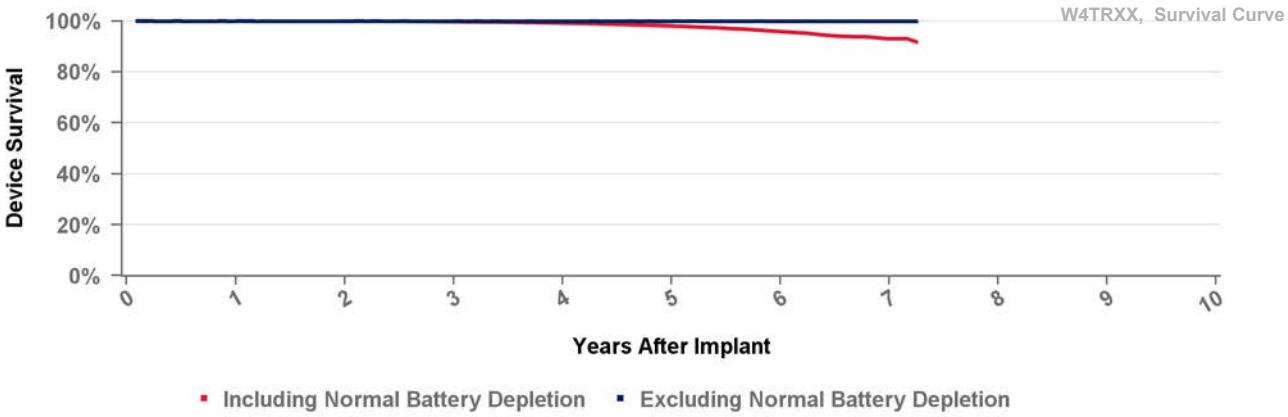


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

W4TR04 Percepta 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

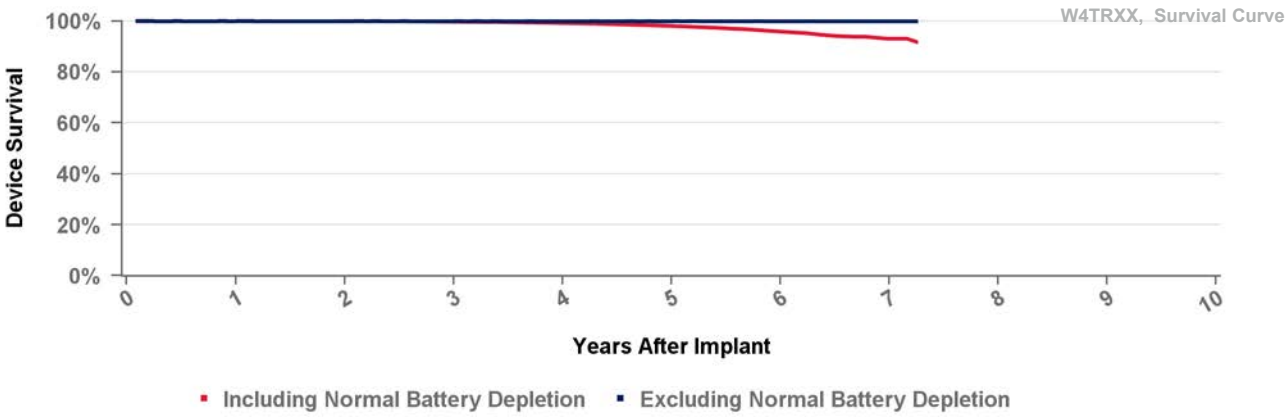


Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

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	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

W4TR06 Solara Quad CRTP MRI SureScan

US Market Release

CE Approval Date 10Feb2017

Registered USA Implants

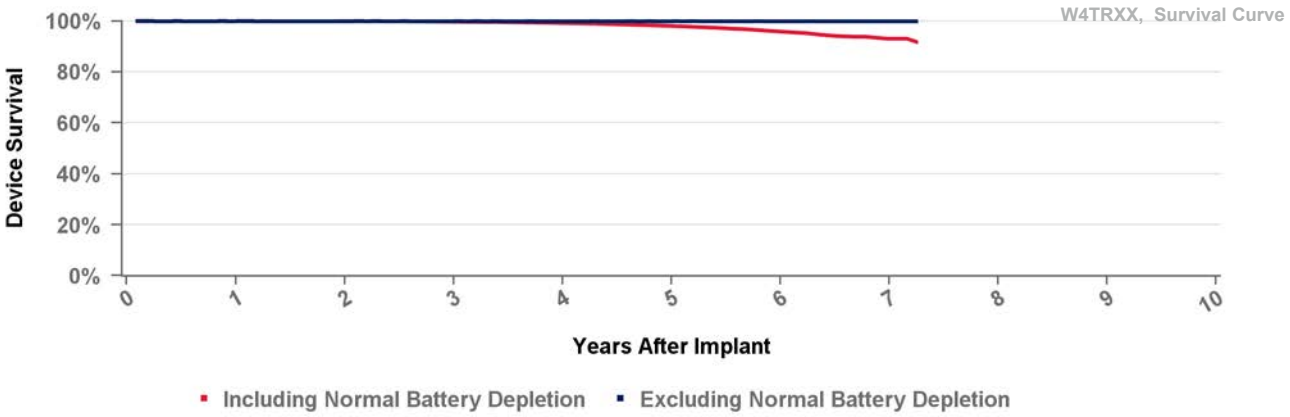
Estimated Active USA Implants

Normal Battery Depletions

Total Malfunctions (USA)

Therapy Function Not Compromised

Therapy Function Compromised



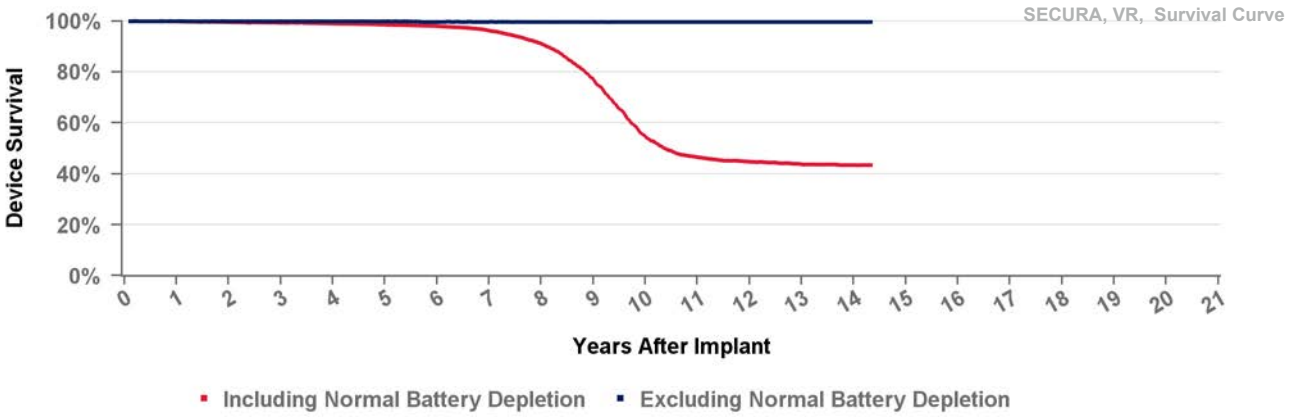
Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	100.0%	99.8%	99.2%	98.1%	95.9%	93.1%	91.7%
Effective Sample Size	62997	48587	35821	24357	14927	6906	1247	209

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



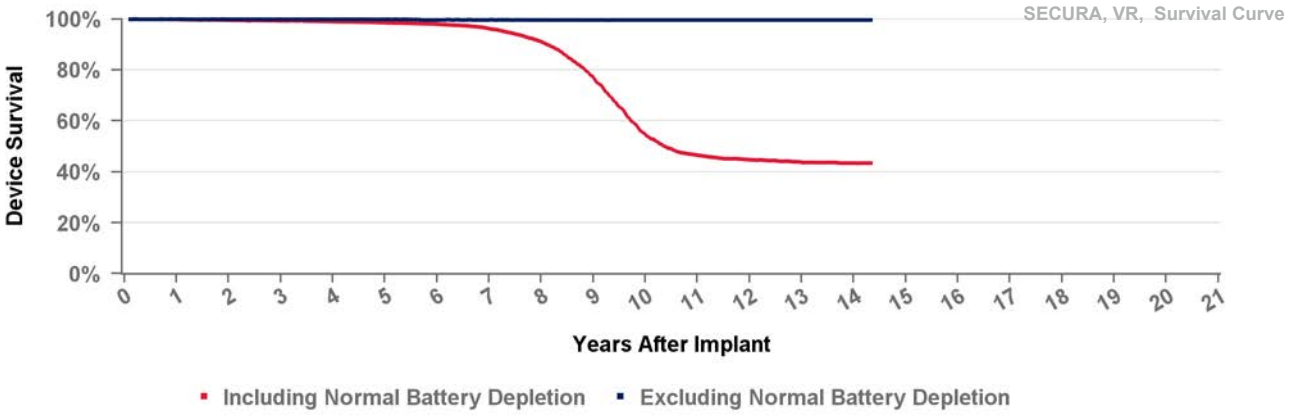
Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 172 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.6%	46.6%	44.8%	43.8%	43.5%	43.3%
Effective Sample Size	17637	16328	15175	14070	12958	11844	10615	8585	5566	2897	2072	1578	1144	425	150

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

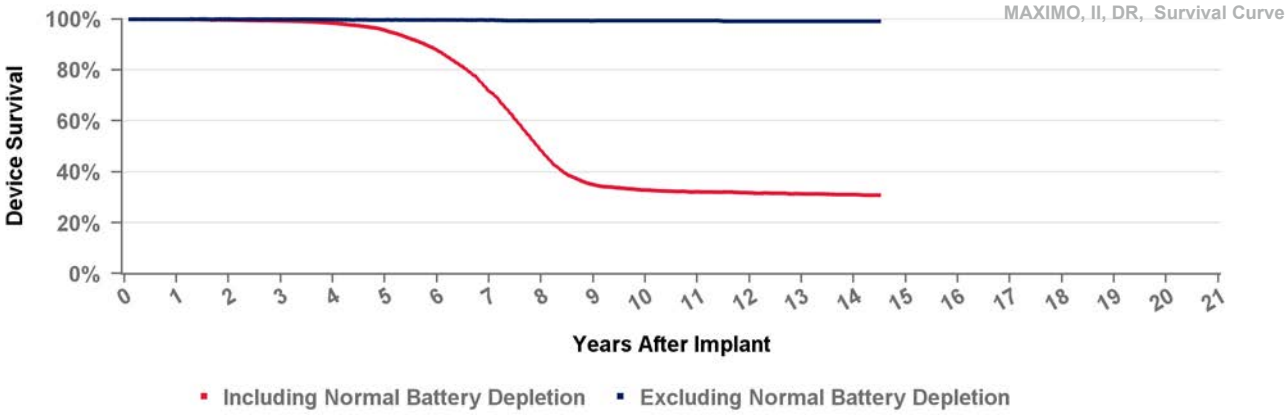
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 172 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%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	99.0%	98.6%	98.0%	96.2%	91.1%	77.0%	54.6%	46.6%	44.8%	43.8%	43.5%	43.3%
Effective Sample Size	17637	16328	15175	14070	12958	11844	10615	8585	5566	2897	2072	1578	1144	425	150

D264DRM Maximo II DR

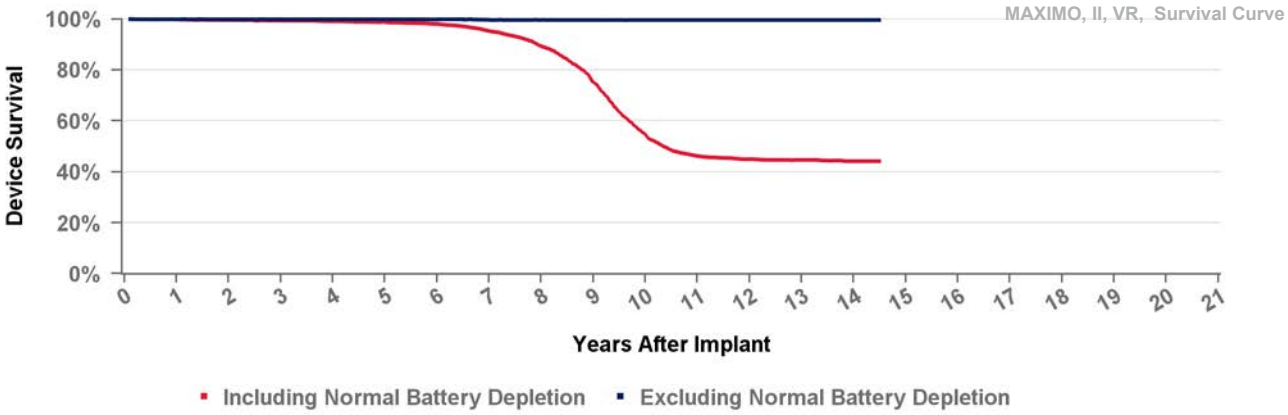
US Market Release	09Jan2012	**Total Malfunctions (USA)**	
CE Approval Date	22Jul2010	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 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%	99.2%
Including NBD	99.9%	99.6%	99.3%	98.4%	95.6%	87.7%	71.7%	48.4%	35.0%	32.9%	32.2%	31.8%	31.4%	31.1%	30.8%
Effective Sample Size	17236	15934	14783	13616	12097	9584	5993	2812	1730	1494	1356	1155	856	372	107

D264VRM Maximo II VR

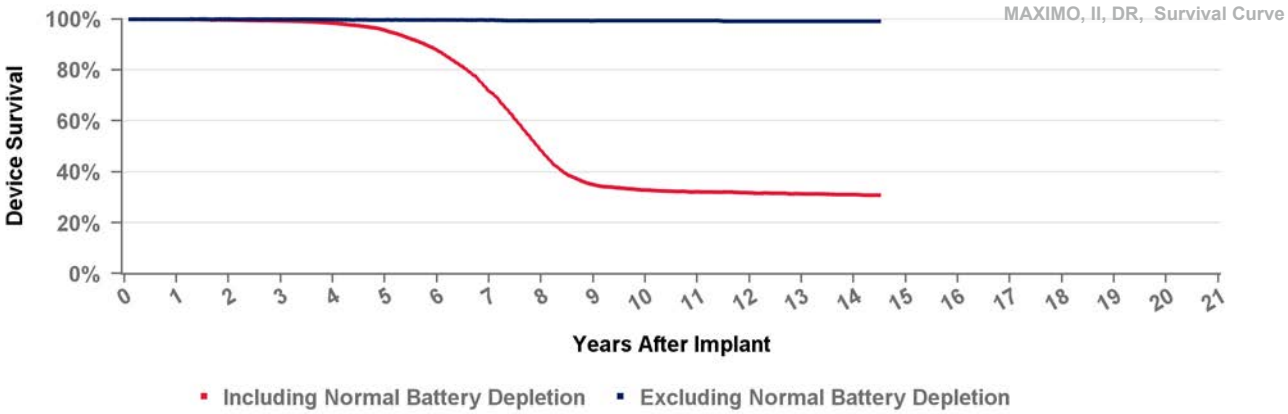
US Market Release	02May2012	**Total Malfunctions (USA)**	
CE Approval Date	17Dec2010	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 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%	99.6%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.3%	89.3%	75.3%	54.6%	46.2%	45.1%	44.6%	44.3%	44.3%
Effective Sample Size	10870	10122	9420	8721	8028	7335	6491	5259	3411	1860	1345	1077	777	356	138

D284DRG Maximo II DR

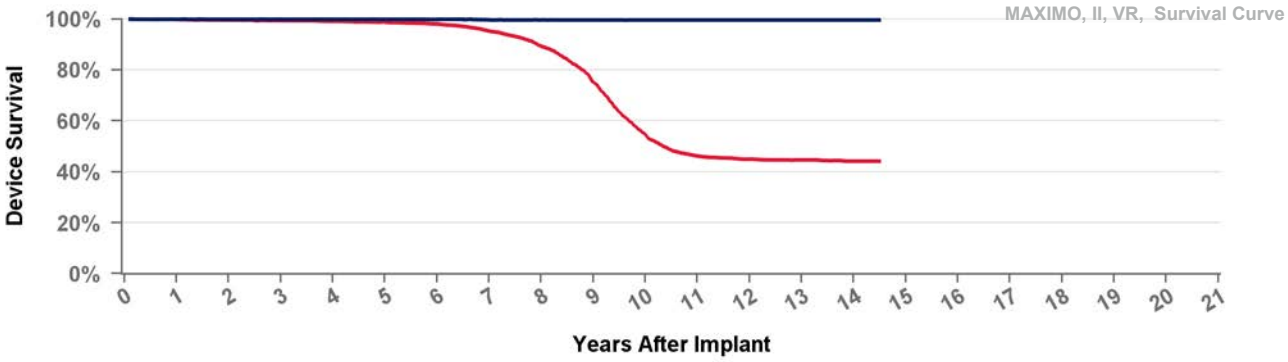
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**71**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**54**
Registered USA Implants	19,956	Battery	7
Estimated Active USA Implants	2,339	Electrical Component	15
Normal Battery Depletions	3,647	Possible Early Battery Depletion	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	14	at 174 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%	99.2%
Including NBD	99.9%	99.6%	99.3%	98.4%	95.6%	87.7%	71.7%	48.4%	35.0%	32.9%	32.2%	31.8%	31.4%	31.1%	30.8%
Effective Sample Size	17236	15934	14783	13616	12097	9584	5993	2812	1730	1494	1356	1155	856	372	107

D284VRC Maximo II VR

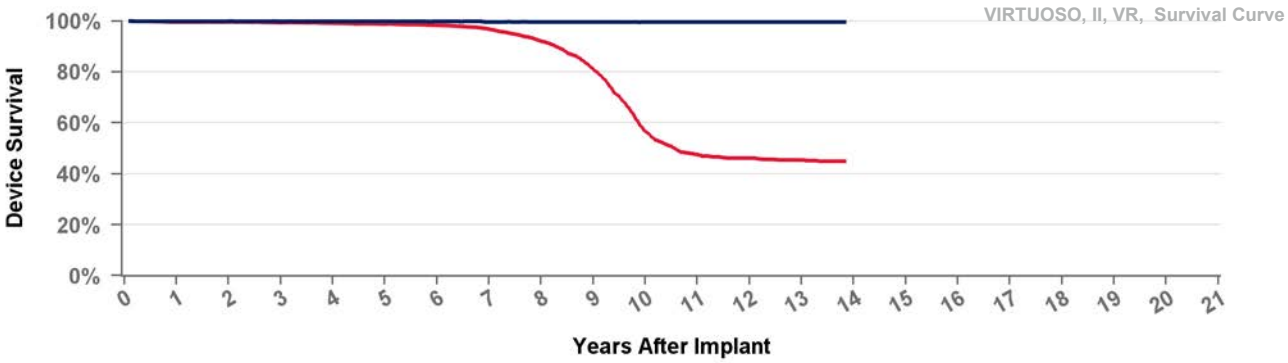
US Market Release	17Sep2008	**Total Malfunctions (USA)**	**32**
CE Approval Date	14Mar2008	**Therapy Function Not Compromised**	**22**
Registered USA Implants	12,860	Battery	10
Estimated Active USA Implants	2,063	Electrical Component	5
Normal Battery Depletions	1,623	Possible Early Battery Depletion	4
		Software/Firmware	3
		Therapy Function Compromised	**10**
		Battery	6
		Electrical Component	3
		Software/Firmware	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 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%	99.6%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.8%	98.1%	95.3%	89.3%	75.3%	54.6%	46.2%	45.1%	44.6%	44.3%	44.3%
Effective Sample Size	10870	10122	9420	8721	8028	7335	6491	5259	3411	1860	1345	1077	777	356	138

D294VRC Virtuoso II VR

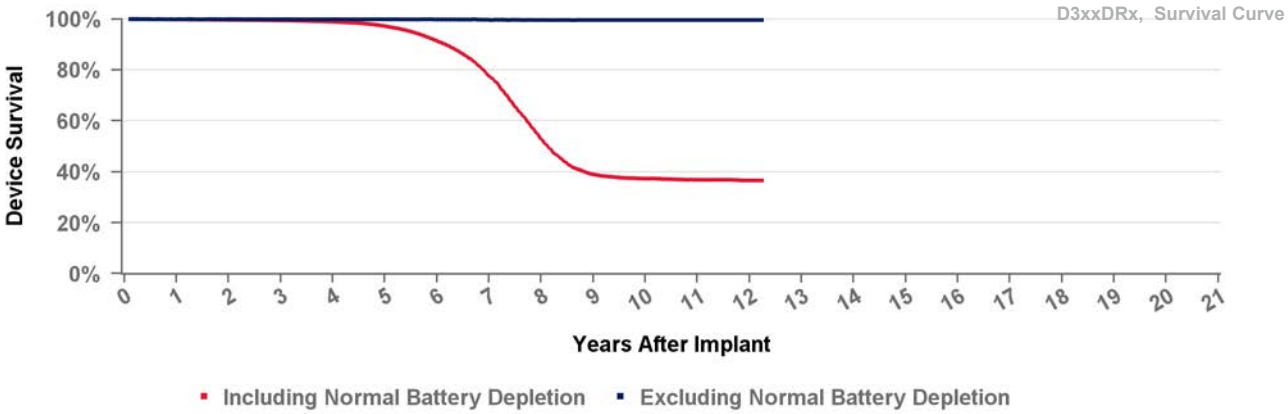
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	20Aug2008	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 166 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%	99.5%
Including NBD	99.7%	99.7%	99.4%	99.2%	98.8%	98.3%	96.8%	92.1%	80.9%	56.8%	47.5%	46.2%	45.5%	45.0%
Effective Sample Size	7677	7159	6652	6135	5662	5129	4570	3748	2499	1296	887	714	540	139

D314DRG Protecta XT DR

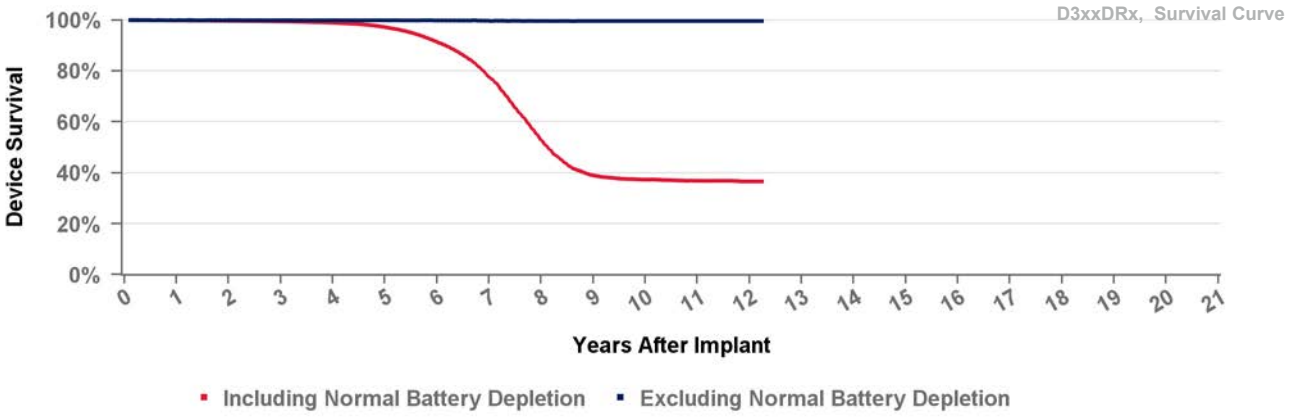
US Market Release	25Mar2011	**Total Malfunctions (USA)**	**77**
CE Approval Date		**Therapy Function Not Compromised**	**40**
Registered USA Implants	34,746	Battery	8
Estimated Active USA Implants	4,594	Electrical Component	26
Normal Battery Depletions	4,554	Electrical Interconnect	1
		Possible Early 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	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D314DRM Protecta XT DR

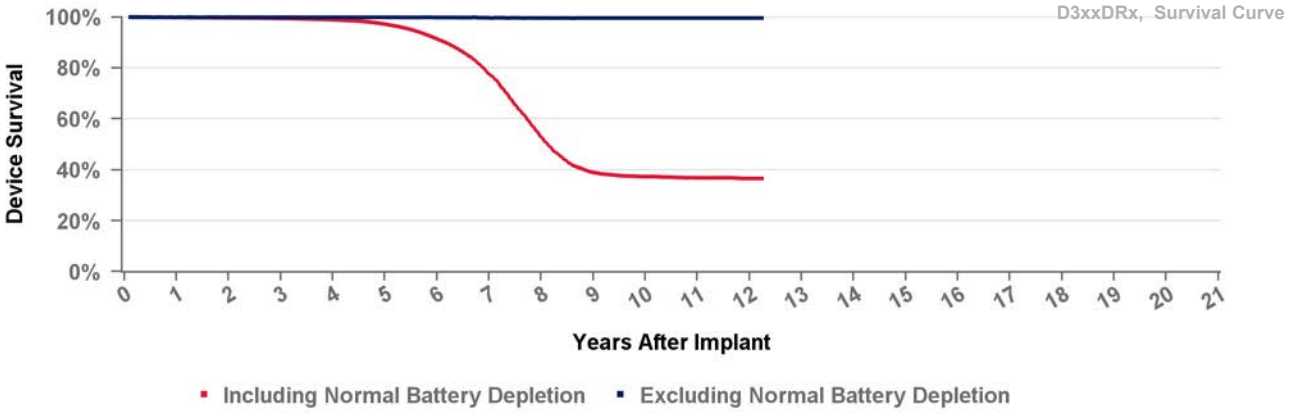
US Market Release	09Nov2011	**Total Malfunctions (USA)**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	13,914	Battery	3
Estimated Active USA Implants	2,180	Electrical Component	12
Normal Battery Depletions	1,928	Other	2
		Therapy Function Compromised	**8**
		Battery	7
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D354DRG Protecta XT DR

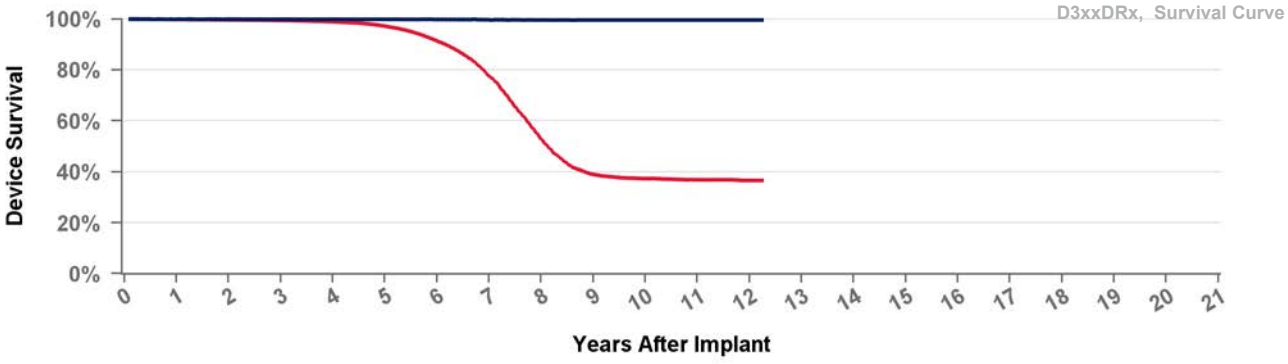
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	25Mar2010	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D354DRM Protecta XT DR

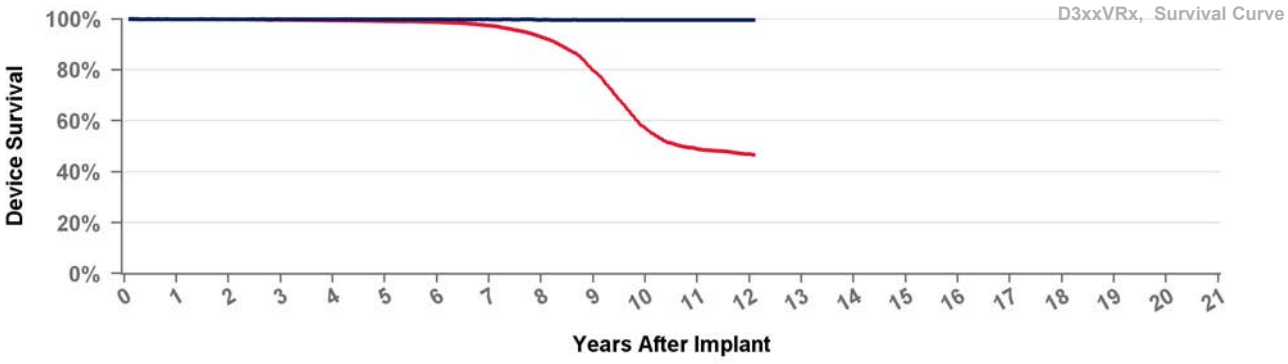
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	15Jul2010	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D354VRG Protecta XT VR

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



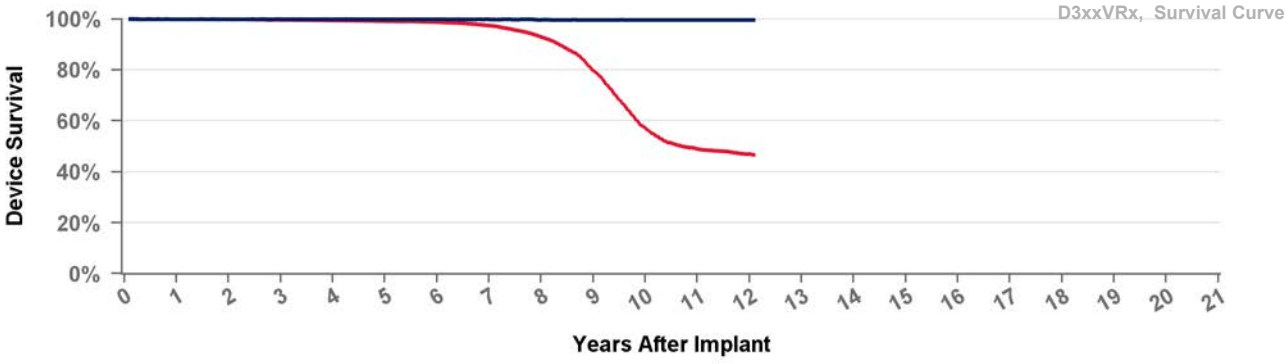
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

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



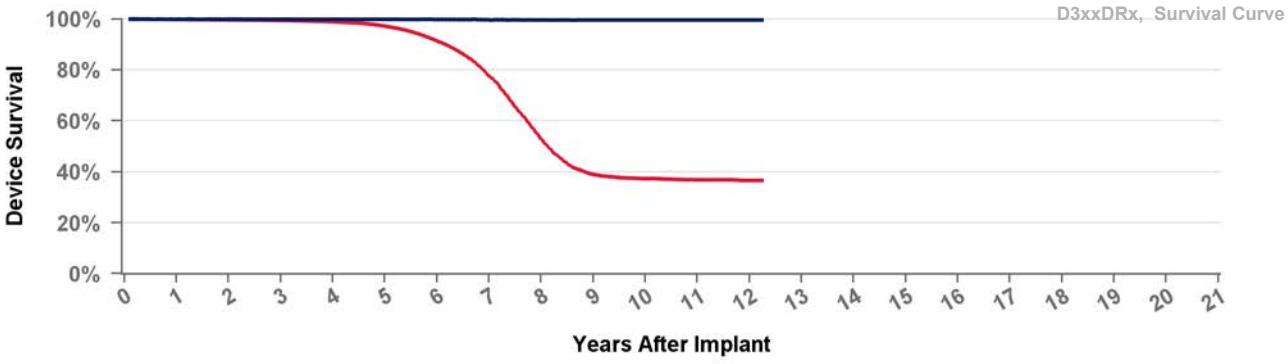
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

D364DRG Protecta DR

US Market Release
CE Approval Date 25Mar2010
Registered USA Implants 1
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions (USA)
Therapy Function Not Compromised

Therapy Function Compromised



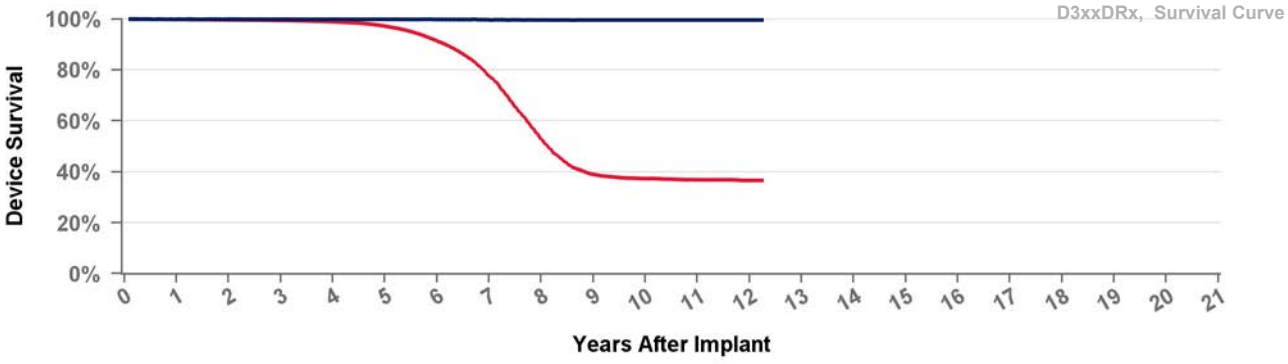
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

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



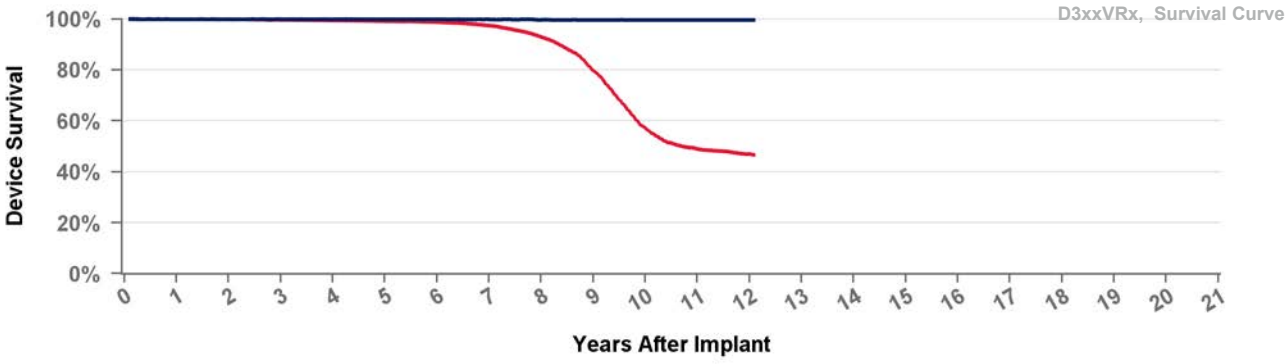
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

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



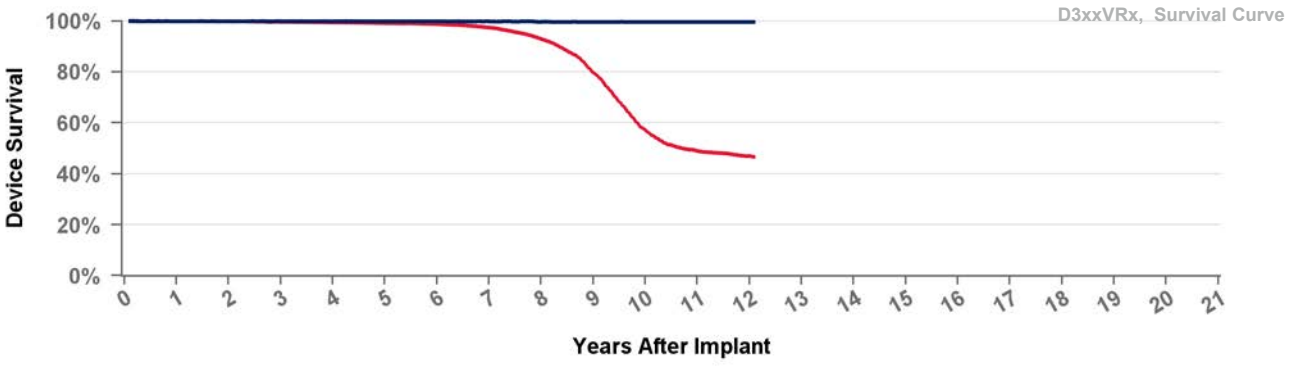
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

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



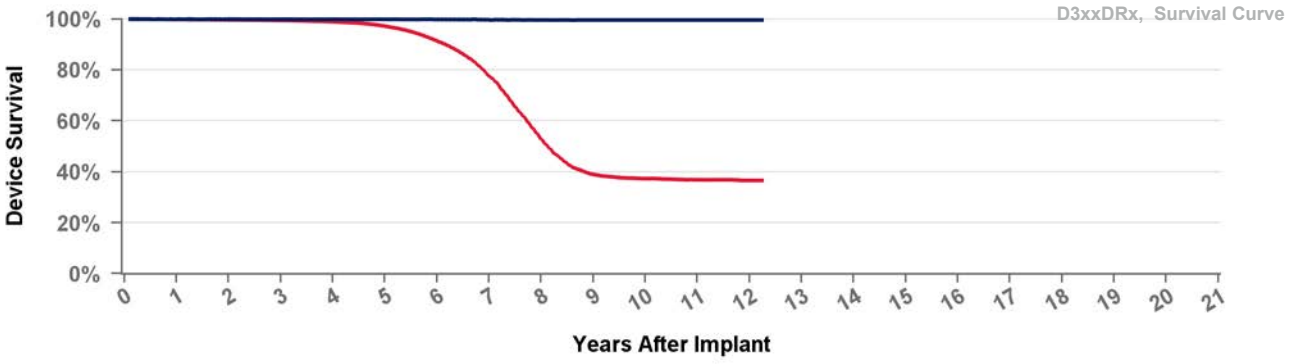
Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

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

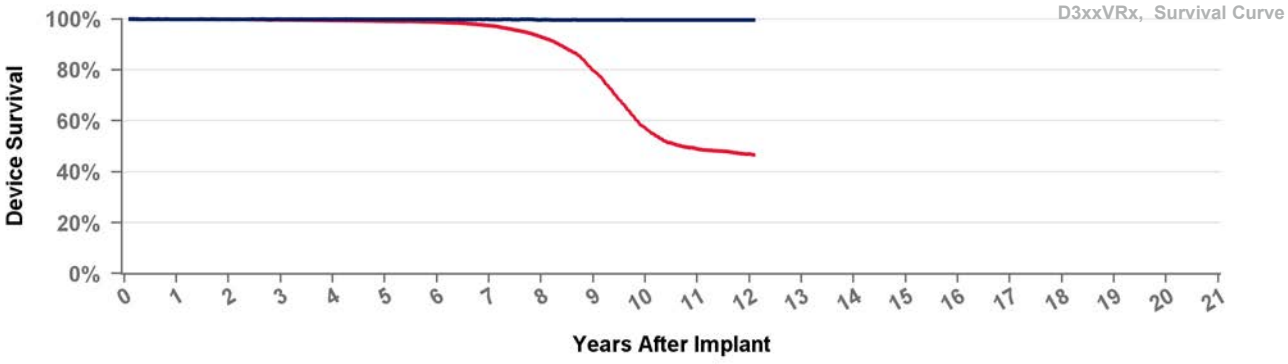
Therapy Function Compromised



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D384VRG Cardia VR

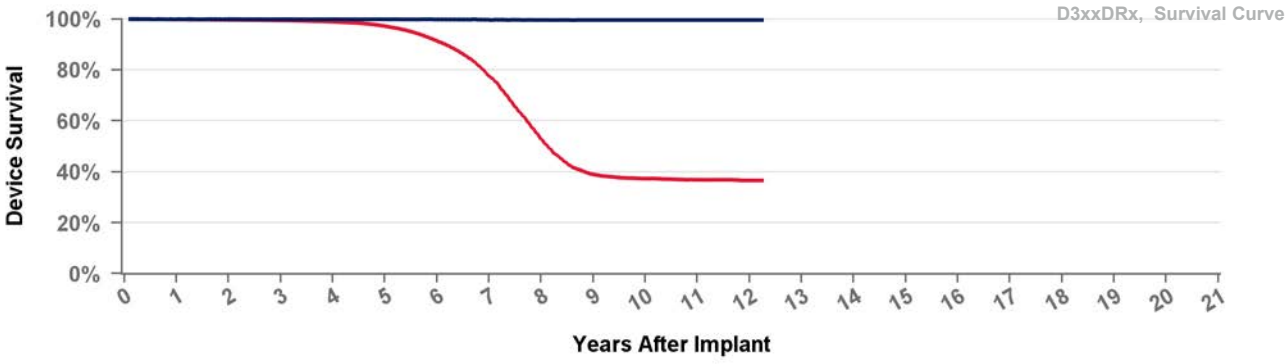
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

D394DRG Egida DR

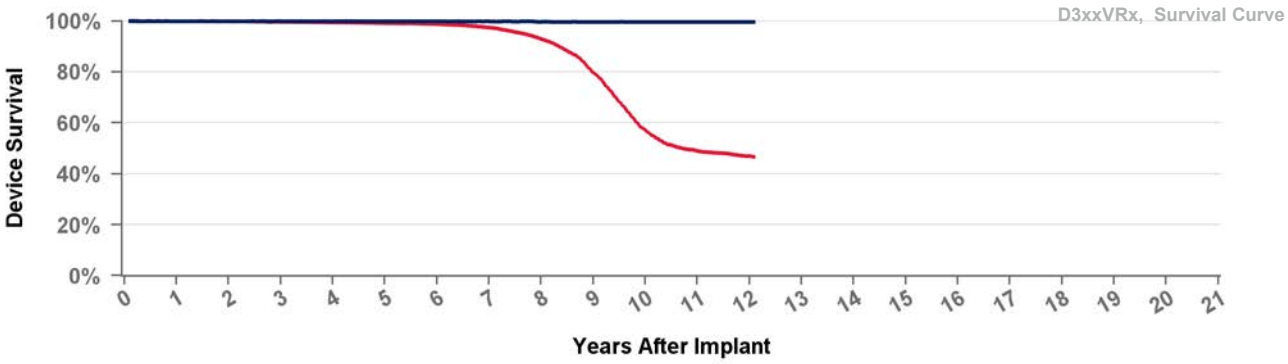
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 147 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%
Including NBD	99.8%	99.7%	99.5%	99.0%	97.2%	91.3%	77.7%	53.0%	39.0%	37.4%	36.9%	36.7%	36.7%
Effective Sample Size	54185	50301	46253	42262	37892	31014	20480	9398	5321	4618	3945	1133	266

D394VRG Egida VR

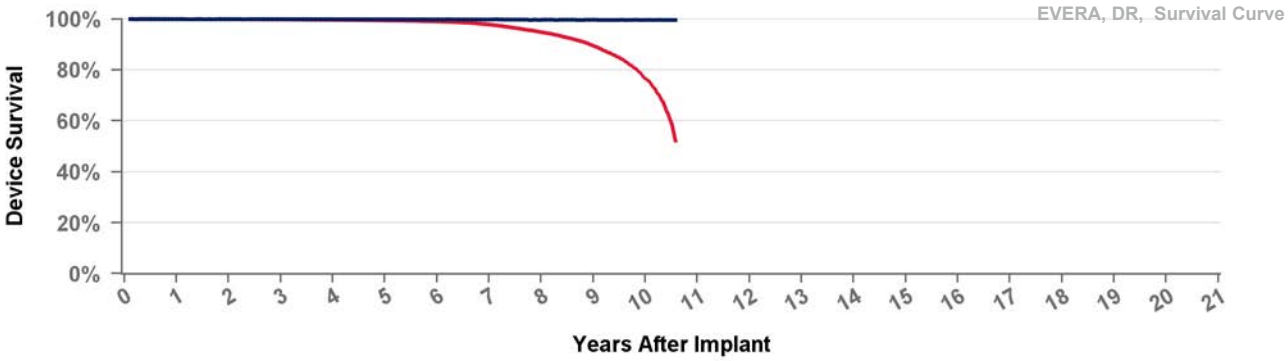
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	12Jan2011	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 145 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%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.7%	99.5%	99.2%	98.8%	97.4%	92.9%	79.8%	57.1%	48.9%	47.0%	46.6%
Effective Sample Size	25806	23987	22247	20577	19027	17454	15701	13107	8578	4306	2814	442	249

DDBB1D1 Evera XT

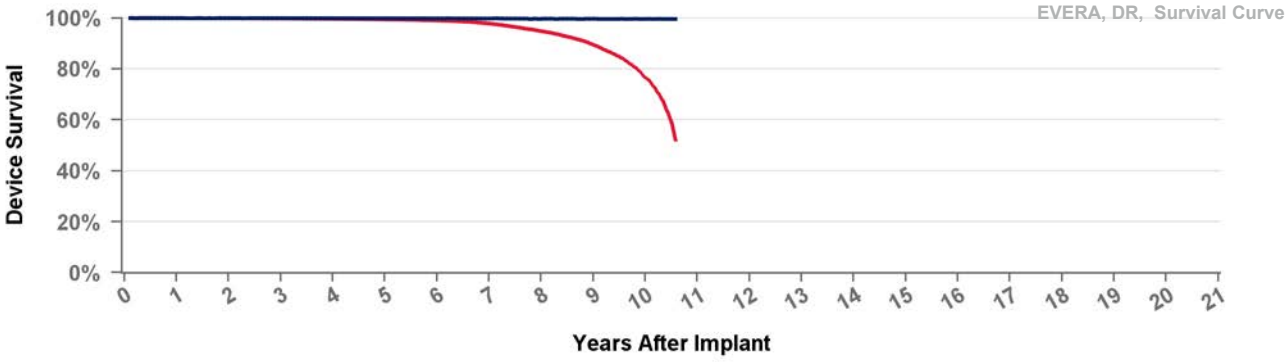
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**85**
CE Approval Date		**Therapy Function Not Compromised**	**50**
Registered USA Implants	43,050	Battery	31
Estimated Active USA Implants	19,681	Electrical Component	16
Normal Battery Depletions	3,582	Software/Firmware	1
		Other	2
		Therapy Function Compromised	**35**
		Battery	30
		Device-Related Current Pathway	1
		Electrical Component	2
		Electrical Interconnect	1
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDBB1D4 Evera XT

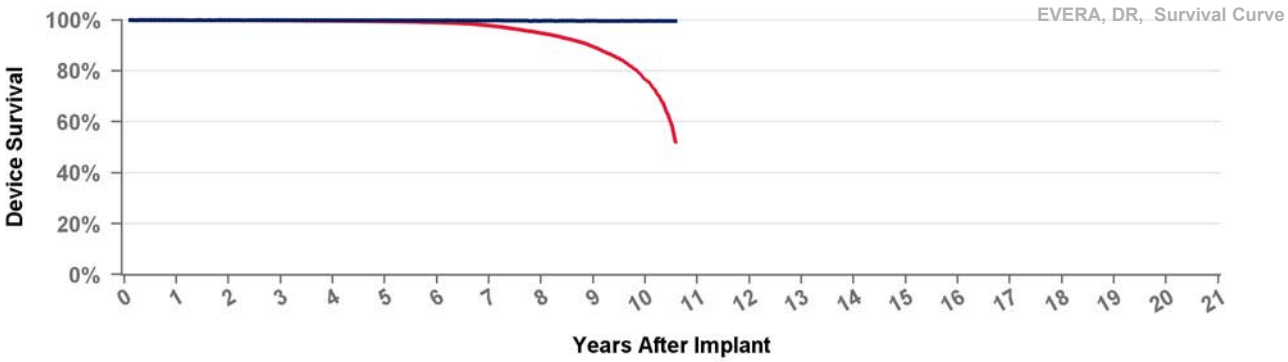
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**77**
CE Approval Date		**Therapy Function Not Compromised**	**47**
Registered USA Implants	30,217	Battery	34
Estimated Active USA Implants	13,094	Electrical Component	9
Normal Battery Depletions	3,073	Electrical Interconnect	2
		Possible Early Battery Depletion	1
		Other	1
		Therapy Function Compromised	**30**
		Battery	22
		Device-Related Current Pathway	4
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDBB2D1 Evera XT

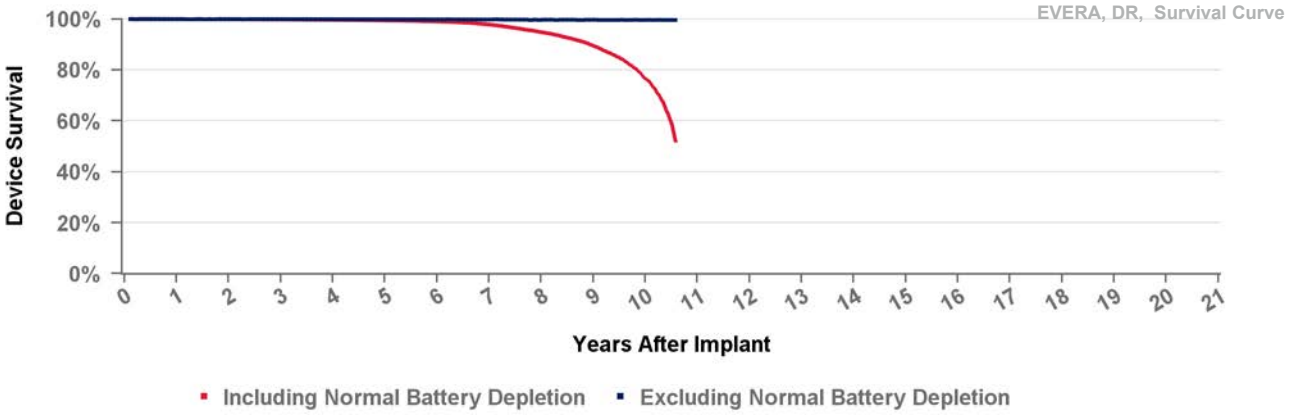
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDBB2D4 Evera XT

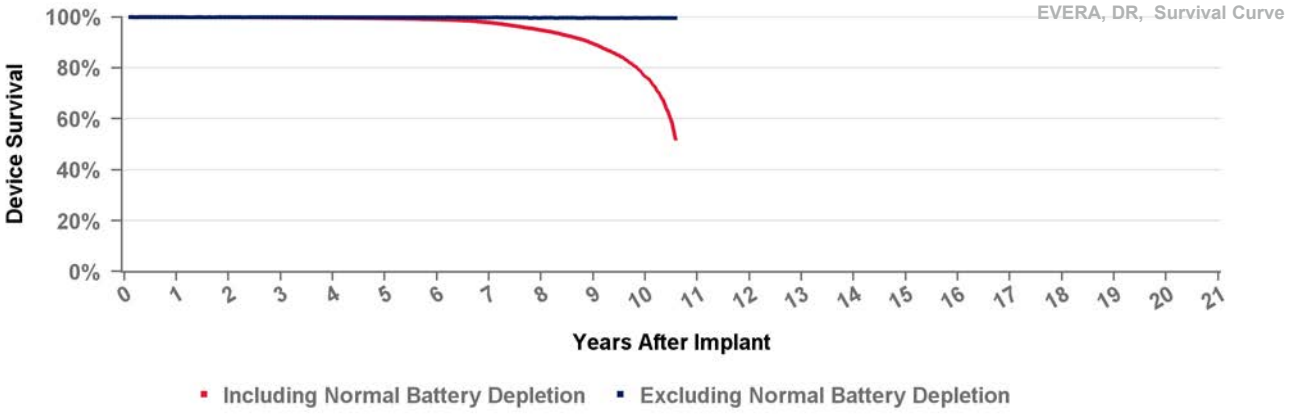
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDBC3D1 Evera S

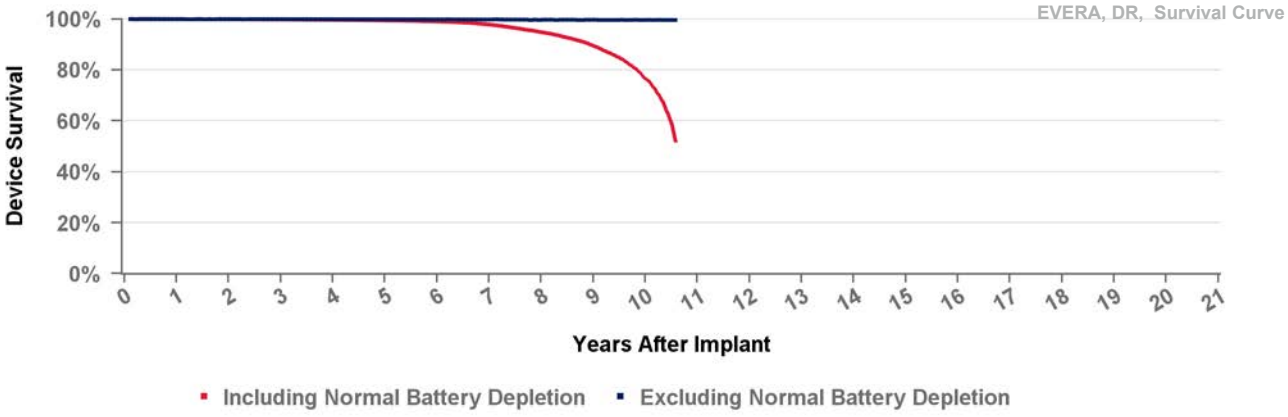
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**18**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**9**
Registered USA Implants	8,434	Battery	7
Estimated Active USA Implants	3,729	Electrical Component	2
Normal Battery Depletions	864	**Therapy Function Compromised**	**9**
		Battery	6
		Device-Related Current Pathway	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDBC3D4 Evera S

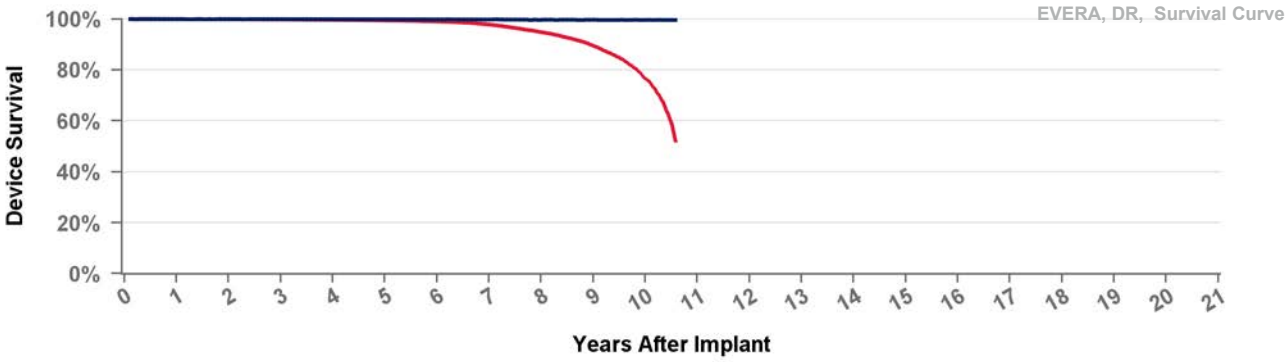
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**14**
CE Approval Date	17Dec2013	**Therapy Function Not Compromised**	**5**
Registered USA Implants	6,064	Battery	3
Estimated Active USA Implants	2,616	Electrical Component	2
Normal Battery Depletions	717	**Therapy Function Compromised**	**9**
		Battery	5
		Device-Related Current Pathway	2
		Electrical Component	1
		Possible Early Battery Depletion	1



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMB1D1 Evera MRI XT

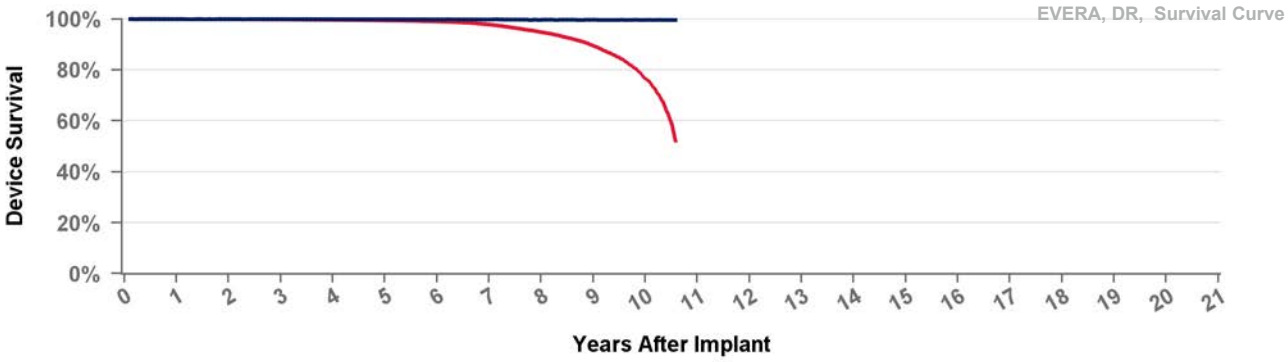
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**45**
CE Approval Date		**Therapy Function Not Compromised**	**26**
Registered USA Implants	37,266	Battery	13
Estimated Active USA Implants	28,807	Electrical Component	11
Normal Battery Depletions	256	Electrical Interconnect	1
		Other	1
		Therapy Function Compromised	**19**
		Battery	6
		Device-Related Current Pathway	5
		Electrical Component	8



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMB1D4 Evera MRI XT

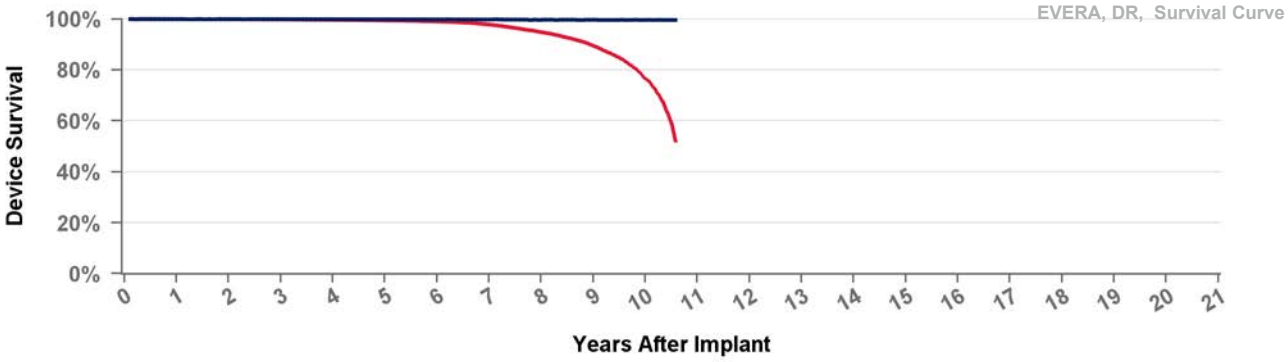
US Market Release	11Sep2015	**Total Malfunctions (USA)**	**104**
CE Approval Date		**Therapy Function Not Compromised**	**63**
Registered USA Implants	107,052	Battery	32
Estimated Active USA Implants	84,706	Electrical Component	24
Normal Battery Depletions	960	Electrical Interconnect	4
		Other	3
		Therapy Function Compromised	**41**
		Battery	24
		Device-Related Current Pathway	13
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMB2D1 Evera MRI XT

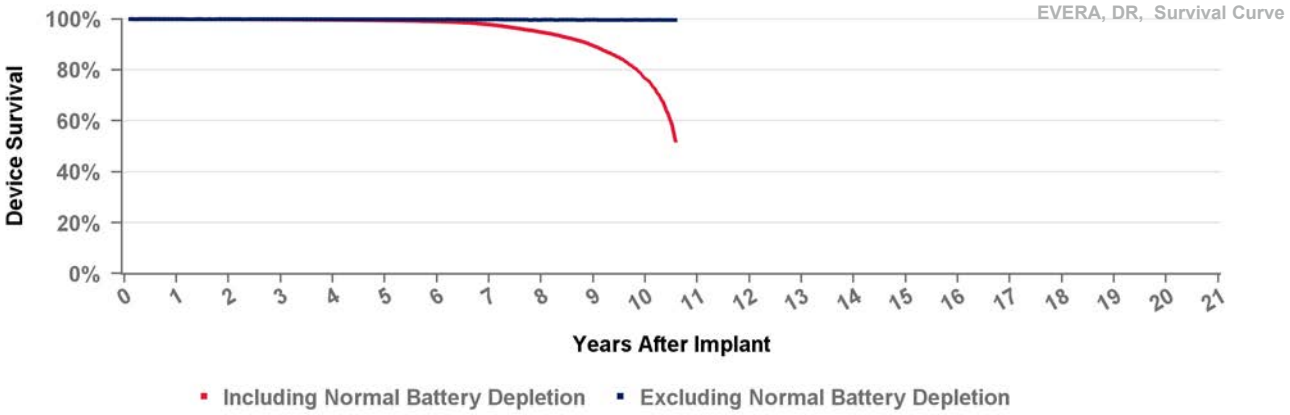
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMB2D4 Evera MRI XT

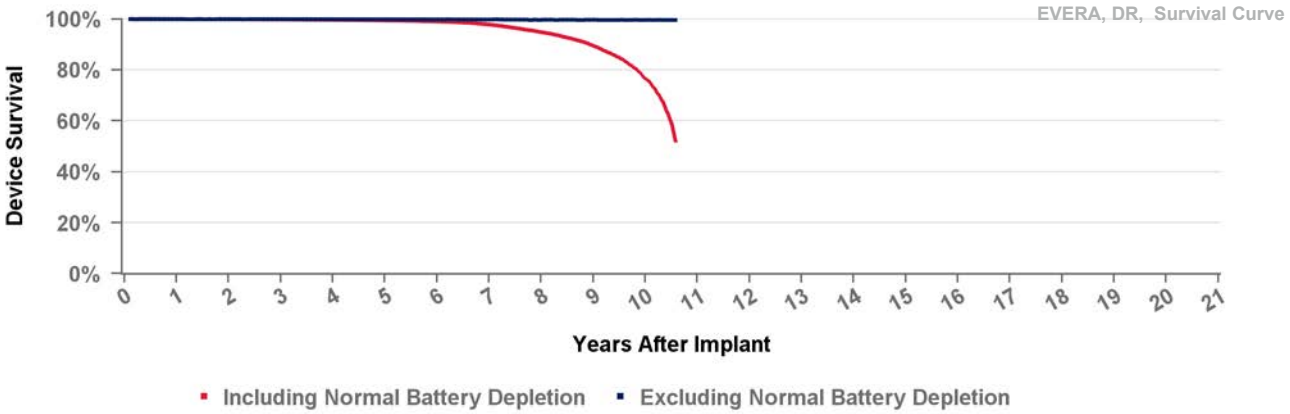
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMC3D1 Evera MRI S

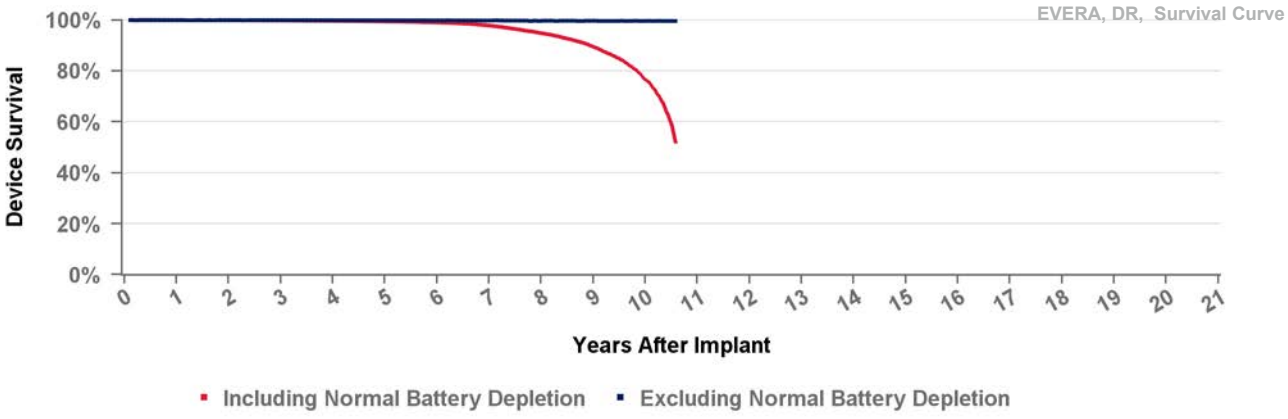
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**3**
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	**2**
Registered USA Implants	3,379	Battery	1
Estimated Active USA Implants	2,581	Electrical Component	1
Normal Battery Depletions	40	**Therapy Function Compromised**	**1**
		Device-Related Current Pathway	1



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMC3D4 Evera MRI

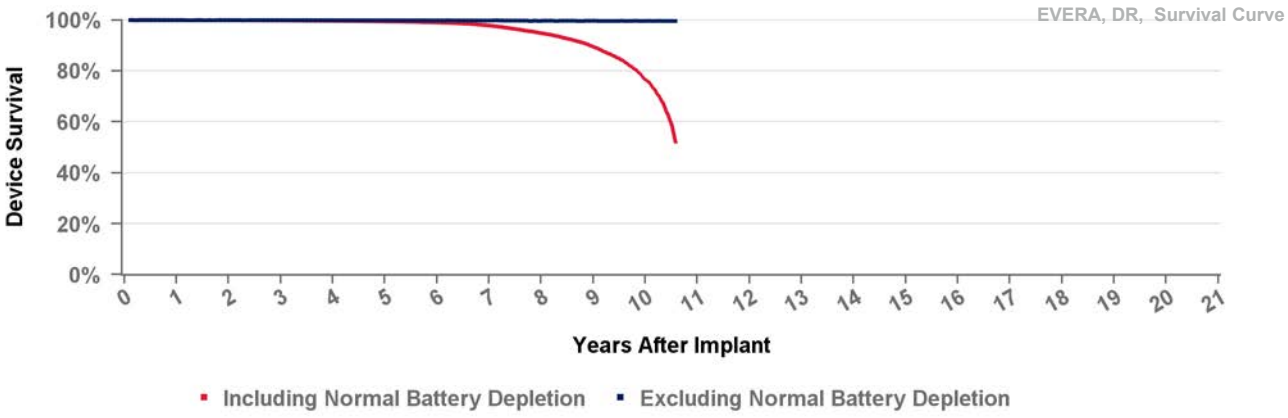
US Market Release	11Sep2015	**Total Malfunctions (USA)**	**9**
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	**5**
Registered USA Implants	7,178	Battery	4
Estimated Active USA Implants	5,591	Electrical Component	1
Normal Battery Depletions	66	**Therapy Function Compromised**	**4**
		Battery	1
		Device-Related Current Pathway	2
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMD3D1 Primo

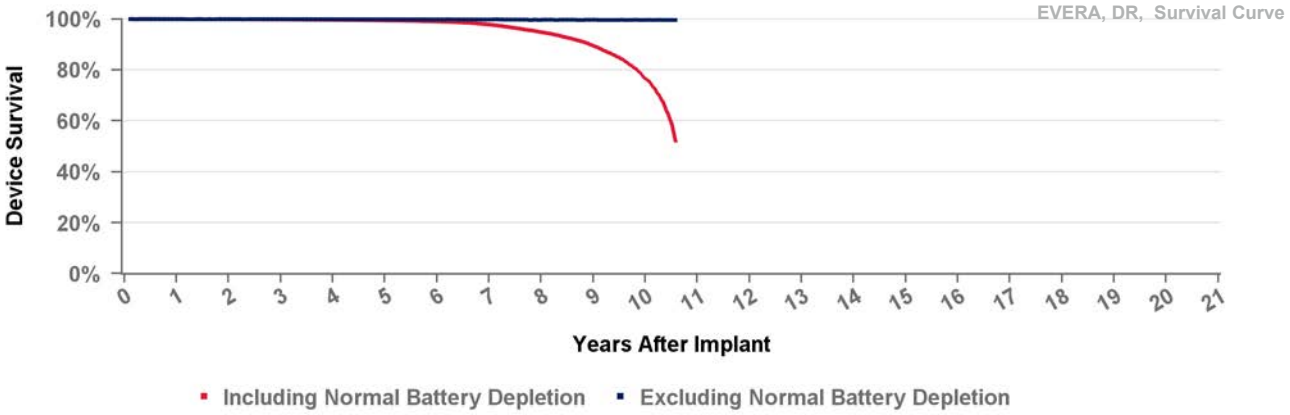
US Market Release	01Mar2018	**Total Malfunctions (USA)**	**1**
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	**1**
Registered USA Implants	449	Electrical Component	1
Estimated Active USA Implants	391	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDMD3D4 Primo

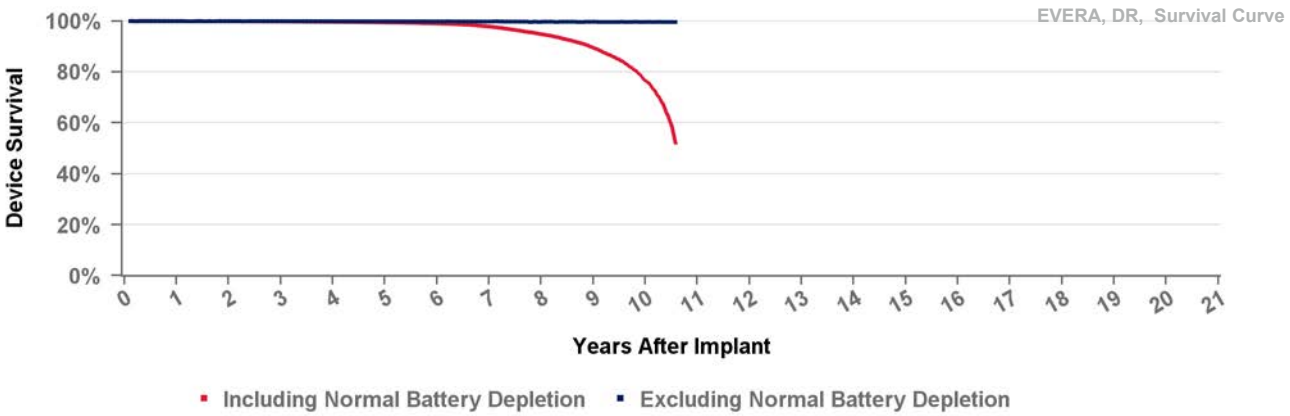
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	1,483		
Estimated Active USA Implants	1,331	**Therapy Function Compromised**	
Normal Battery Depletions	3		



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDME3D1 Mirro

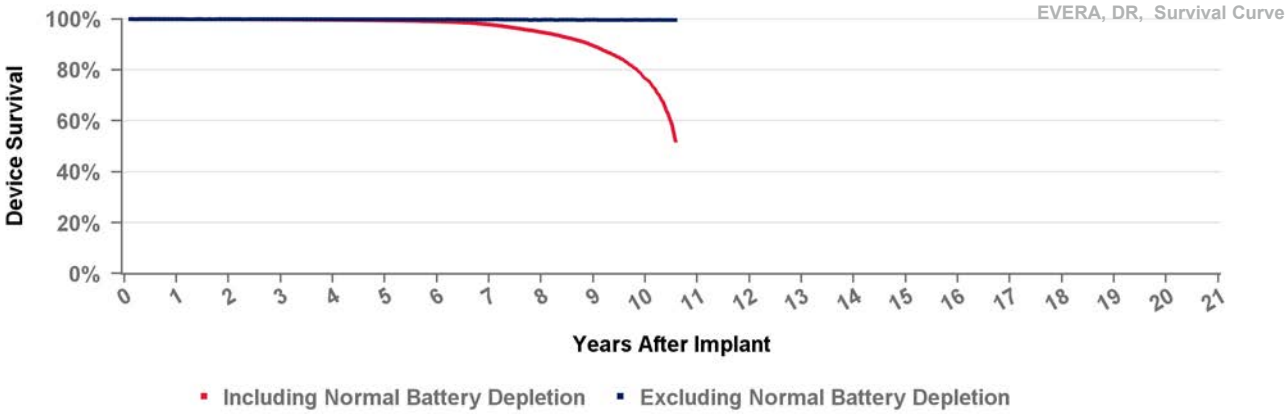
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDME3D4 Mirro

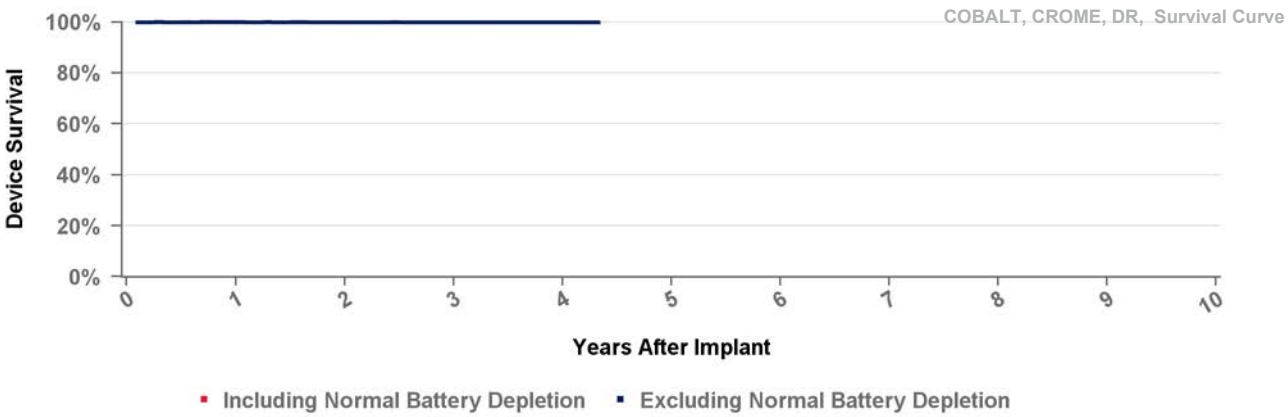
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 127 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.5%	99.1%	97.8%	94.8%	89.5%	76.7%	52.0%
Effective Sample Size	218225	198372	176480	156414	129273	100416	72513	46264	24723	8359	916

DDPA2D1 Cobalt XT

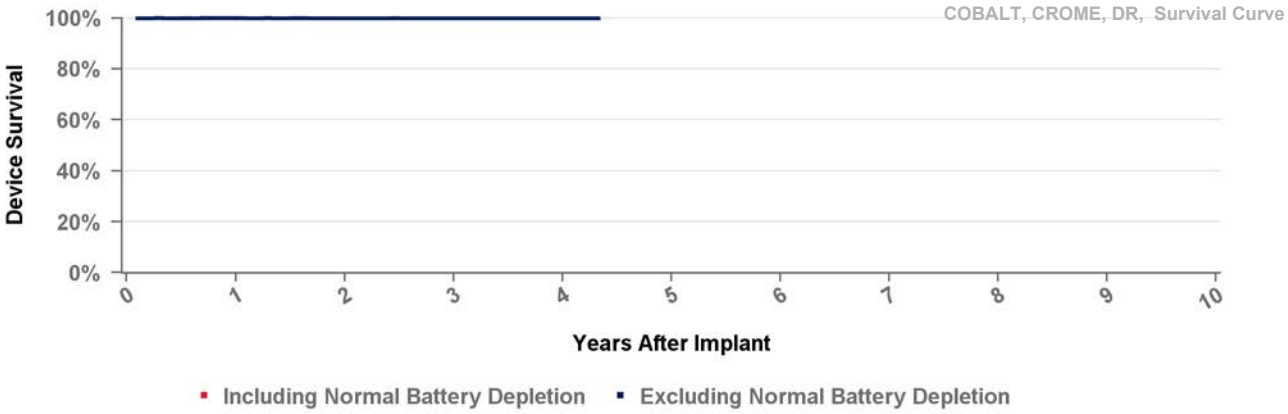
US Market Release	23Apr2020	**Total Malfunctions (USA)**		**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**		**1**
Registered USA Implants	4,729		Electrical Component	1
Estimated Active USA Implants	4,551	**Therapy Function Compromised**		**0**
Normal Battery Depletions				



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DDPA2D4 Cobalt XT

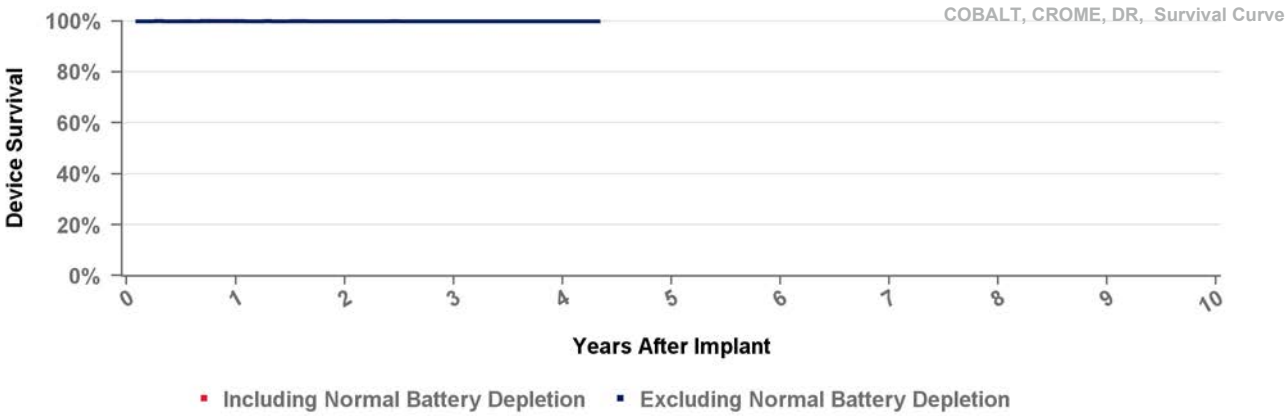
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**2**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	33,757	Electrical Component	1
Estimated Active USA Implants	32,291	**Therapy Function Compromised**	**1**
Normal Battery Depletions	5	Electrical Component	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DDPB3D1 Cobalt

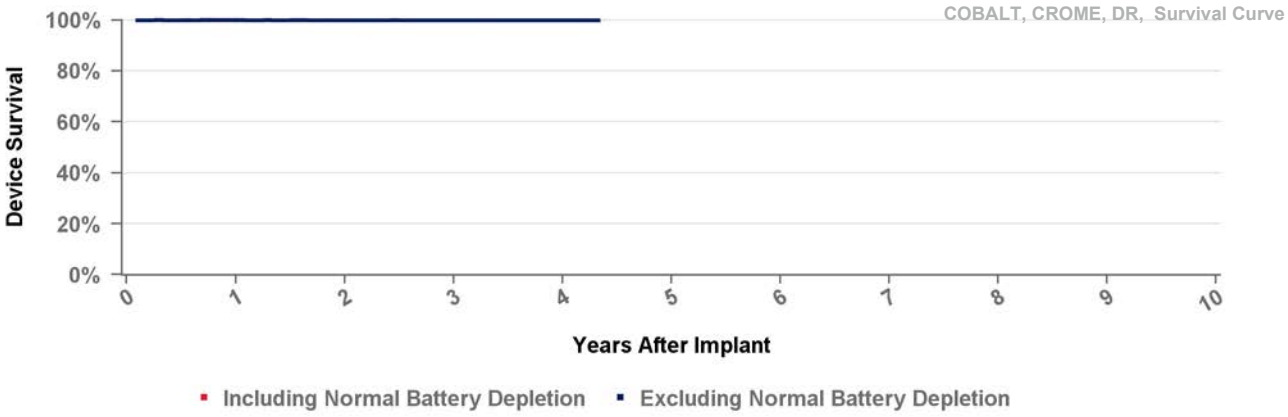
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**2**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,554	Battery	1
Estimated Active USA Implants	2,375	**Therapy Function Compromised**	**1**
Normal Battery Depletions		Device-Related Current Pathway	1



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DDPB3D4 Cobalt

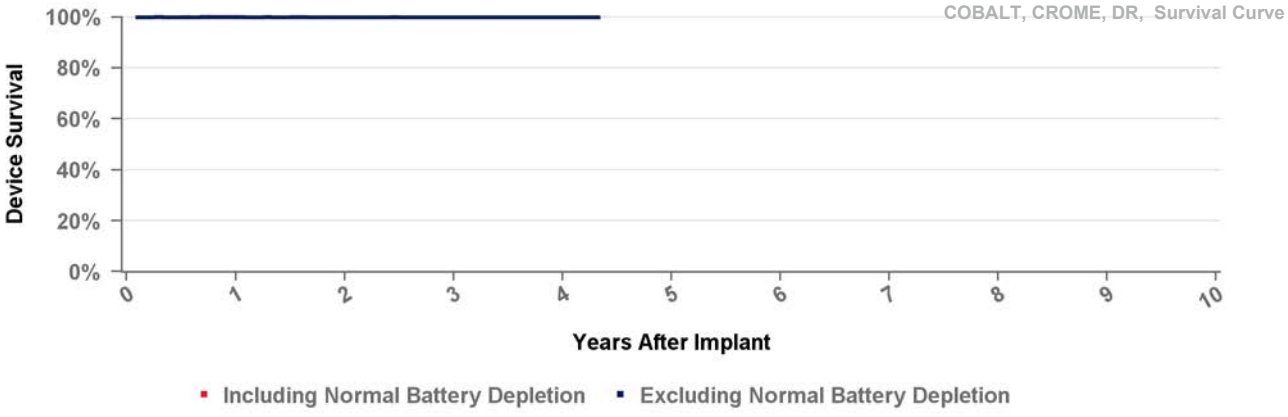
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**7**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**4**
Registered USA Implants	14,566	Battery	1
Estimated Active USA Implants	13,547	Electrical Component	1
Normal Battery Depletions	4	Other	2
		Therapy Function Compromised	**3**
		Electrical Component	1
		Electrical Interconnect	2



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DDPC3D1 Crome

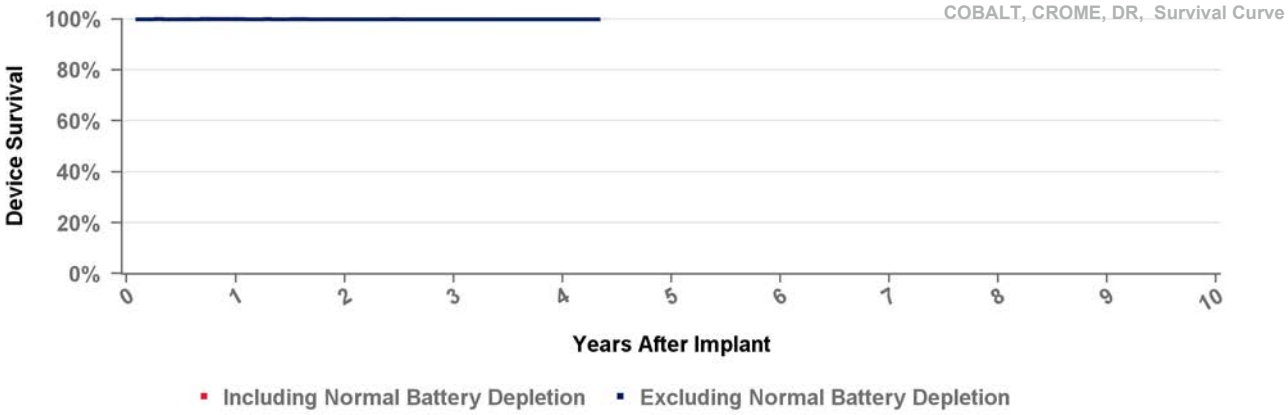
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	277		
Estimated Active USA Implants	254	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DDPC3D4 Crome

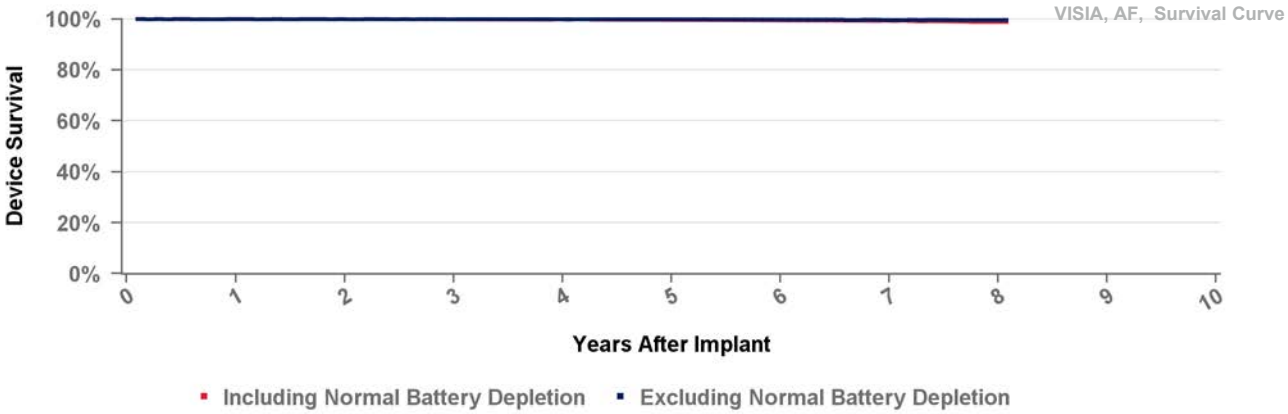
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	1,384		
Estimated Active USA Implants	1,303	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	33348	18605	10156	1167	154

DVAB1D1 Visia AF

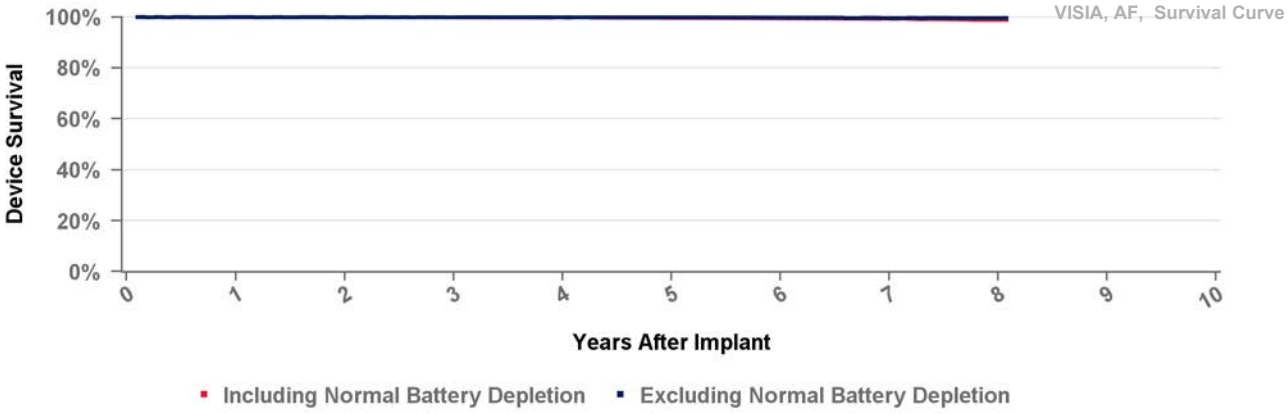
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**11**
CE Approval Date		**Therapy Function Not Compromised**	**7**
Registered USA Implants	3,051	Battery	7
Estimated Active USA Implants	2,042	**Therapy Function Compromised**	**4**
Normal Battery Depletions	15	Battery	2
		Device-Related Current Pathway	2



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVAB1D4 Visia AF

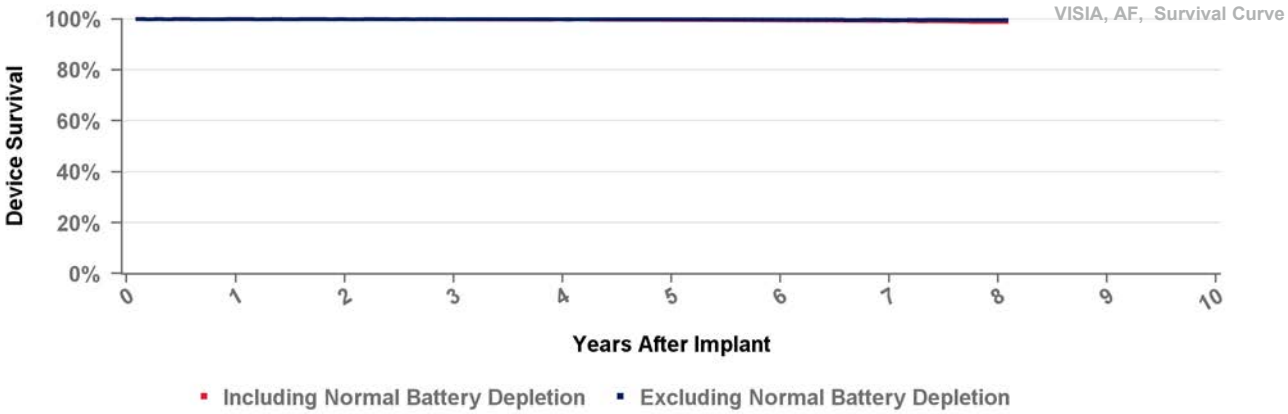
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,045	Battery	2
Estimated Active USA Implants	1,423	**Therapy Function Compromised**	**3**
Normal Battery Depletions		Battery	2
		Device-Related Current Pathway	1



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVAB2D1 Visia AF XT

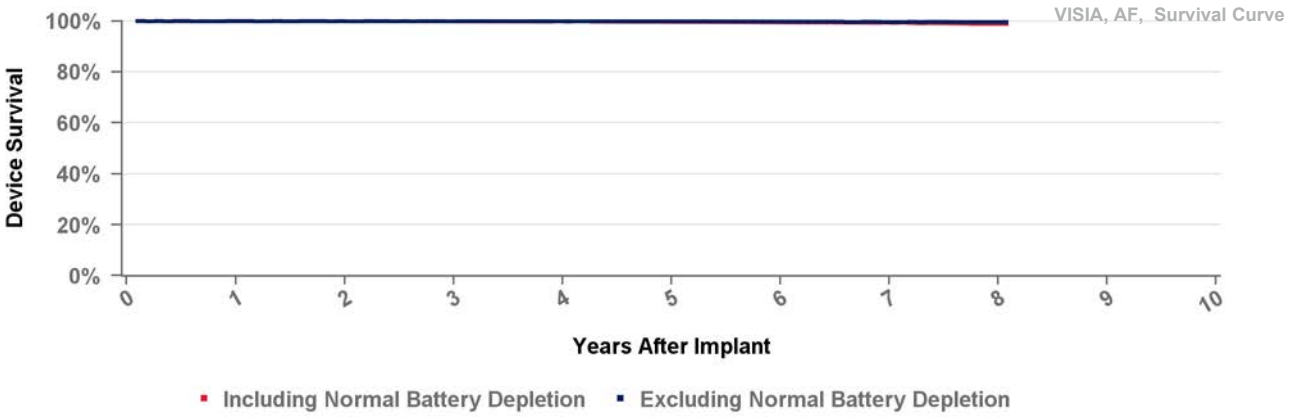
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVAC3D1 Visia AF S

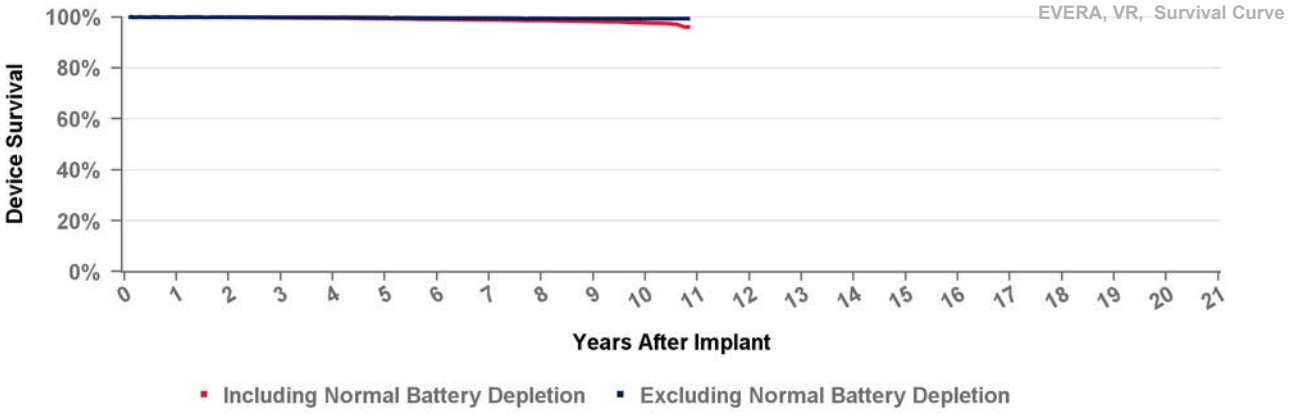
US Market Release	19Jan2016	**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVBB1D1 Evera XT

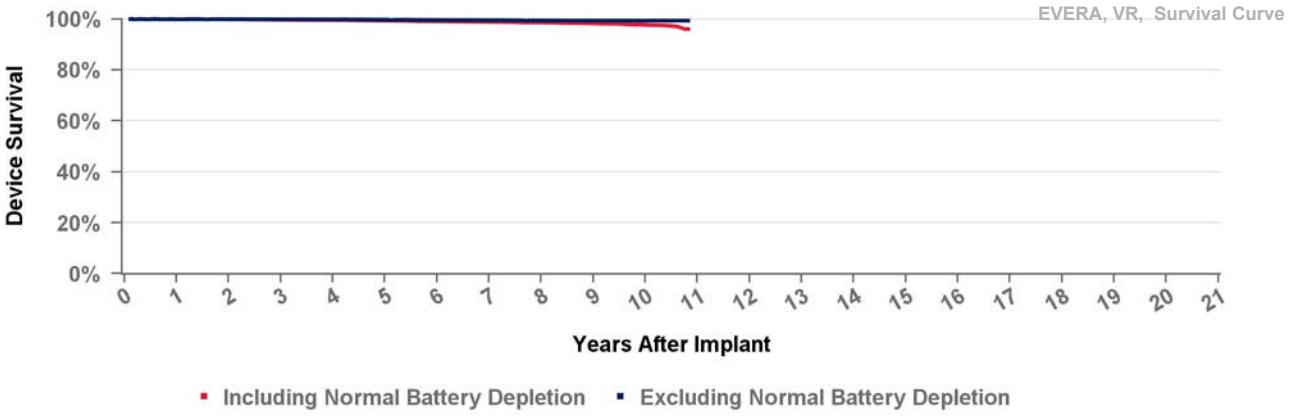
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**74**
CE Approval Date		**Therapy Function Not Compromised**	**52**
Registered USA Implants	16,113	Battery	45
Estimated Active USA Implants	8,751	Electrical Component	7
Normal Battery Depletions	92	**Therapy Function Compromised**	**22**
		Battery	16
		Device-Related Current Pathway	2
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVBB1D4 Evera XT

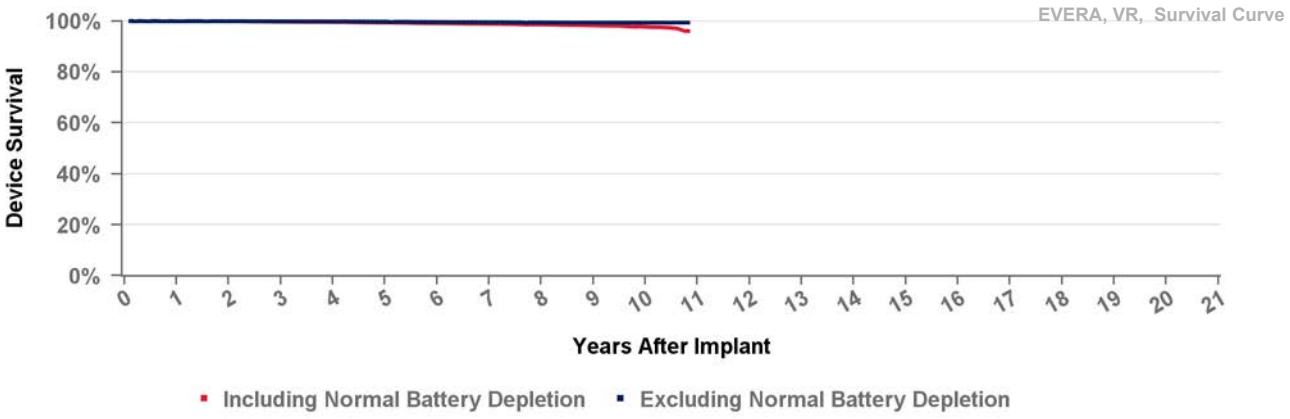
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**97**
CE Approval Date		**Therapy Function Not Compromised**	**65**
Registered USA Implants	21,952	Battery	49
Estimated Active USA Implants	12,921	Electrical Component	9
Normal Battery Depletions	170	Possible Early Battery Depletion	2
		Other	5
		Therapy Function Compromised	**32**
		Battery	26
		Device-Related Current Pathway	5
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVBB2D1 Evera XT

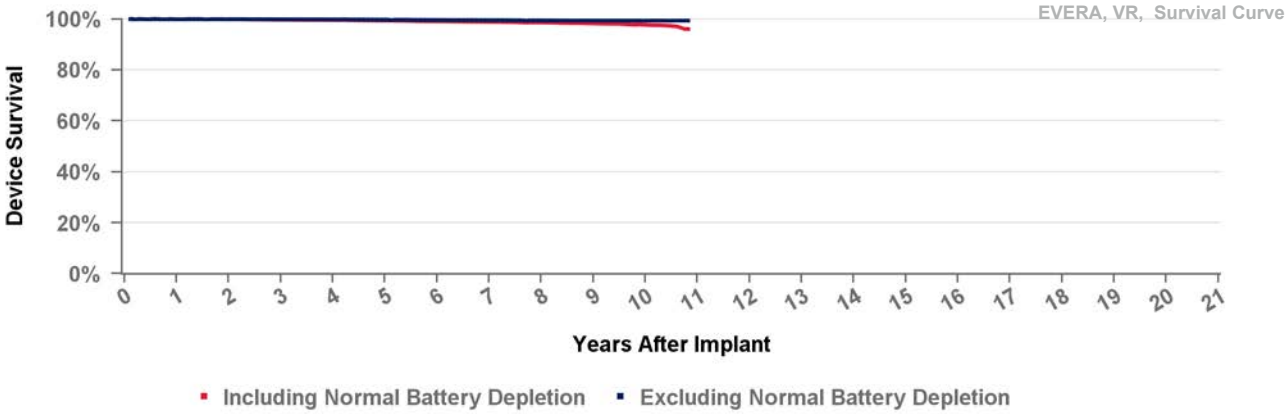
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVBB2D4 Evera XT

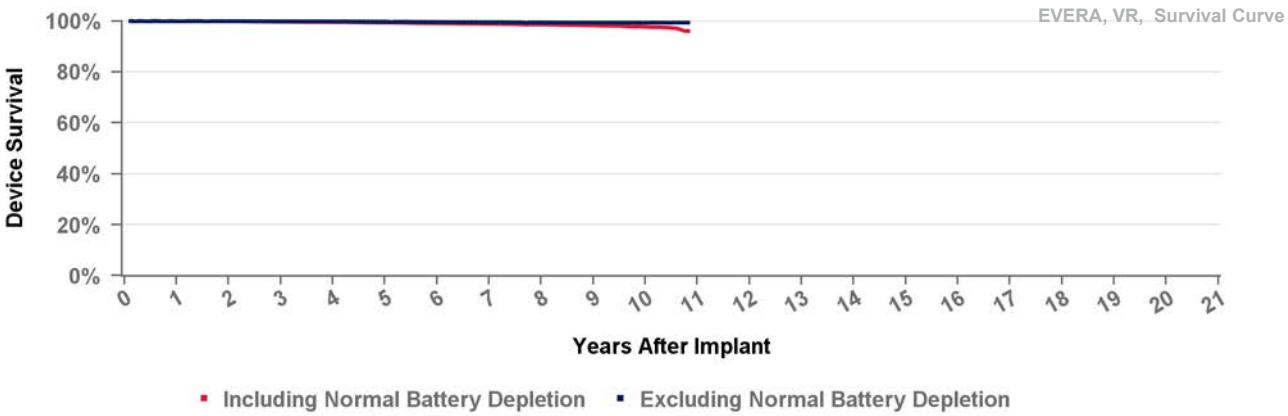
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVBC3D1 Evera S

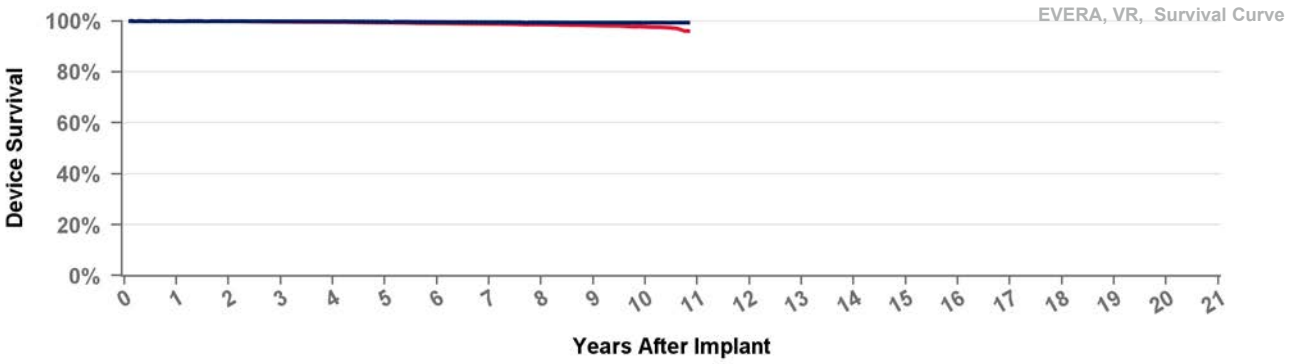
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**28**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**19**
Registered USA Implants	4,642	Battery	17
Estimated Active USA Implants	2,636	Electrical Component	2
Normal Battery Depletions	30	**Therapy Function Compromised**	**9**
		Battery	8
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVBC3D4 Evera S

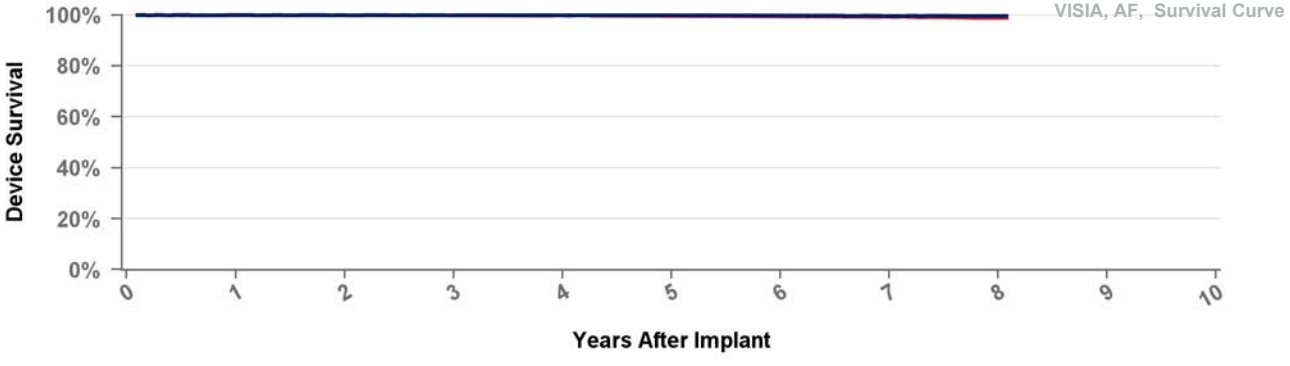
US Market Release	03Apr2013	**Total Malfunctions (USA)**	**22**
CE Approval Date	17Dec2012	**Therapy Function Not Compromised**	**15**
Registered USA Implants	5,623	Battery	12
Estimated Active USA Implants	3,430	Electrical Component	3
Normal Battery Depletions	32	**Therapy Function Compromised**	**7**
		Battery	5
		Device-Related Current Pathway	2



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVFB1D1 Visia MRI AF

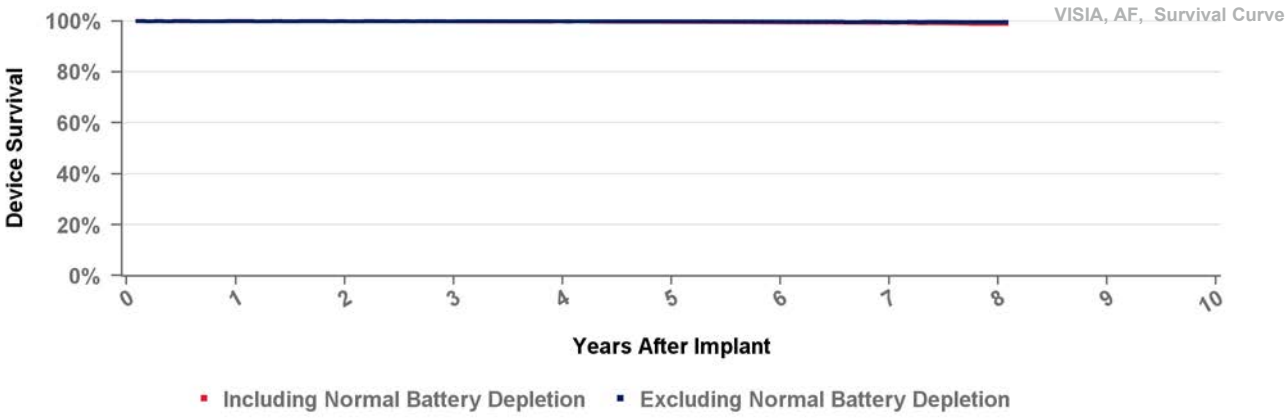
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**21**
CE Approval Date		**Therapy Function Not Compromised**	**12**
Registered USA Implants	17,756	Battery	8
Estimated Active USA Implants	14,389	Electrical Component	3
Normal Battery Depletions	25	Other	1
		Therapy Function Compromised	**9**
		Battery	2
		Device-Related Current Pathway	3
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVFB1D4 Visia MRI AF

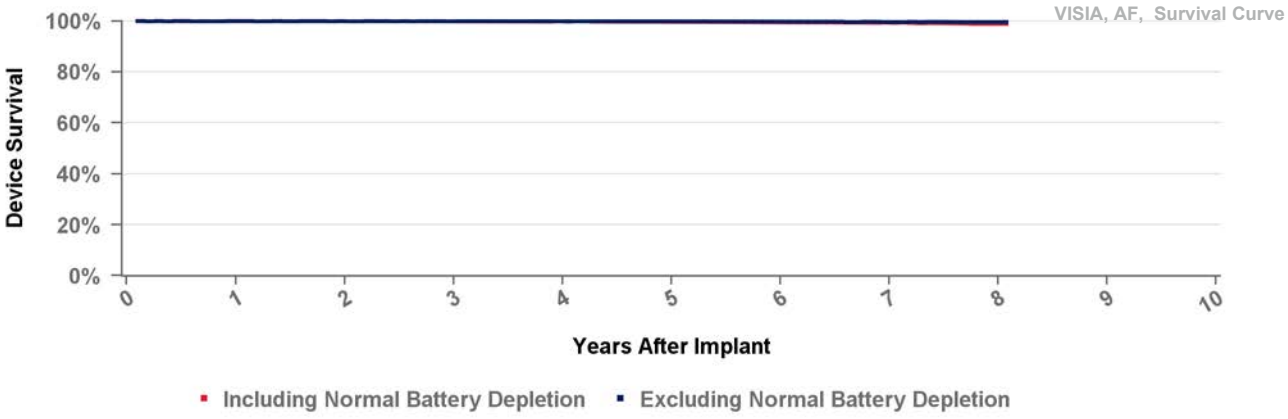
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**75**
CE Approval Date		**Therapy Function Not Compromised**	**46**
Registered USA Implants	57,174	Battery	36
Estimated Active USA Implants	46,175	Electrical Component	9
Normal Battery Depletions	63	Other	1
		Therapy Function Compromised	**29**
		Battery	14
		Device-Related Current Pathway	12
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVFB2D1 Visia MRI AF XT

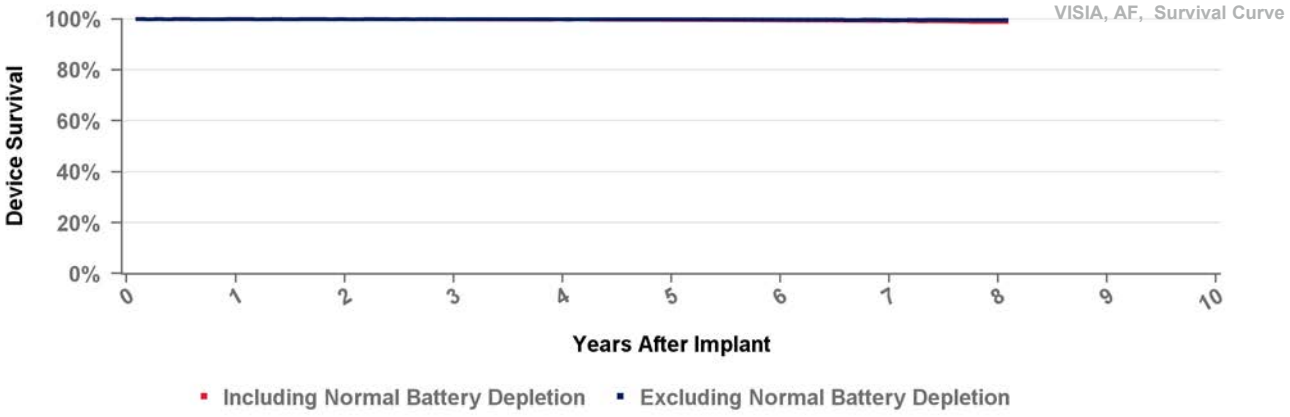
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVFB2D4 Visia MRI AF XT

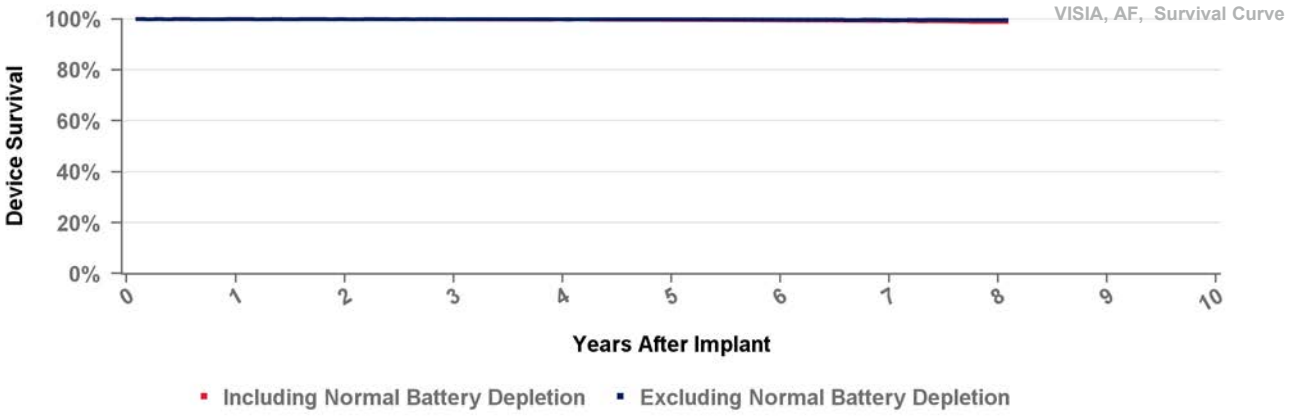
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVFC3D1 Visia MRI AF S

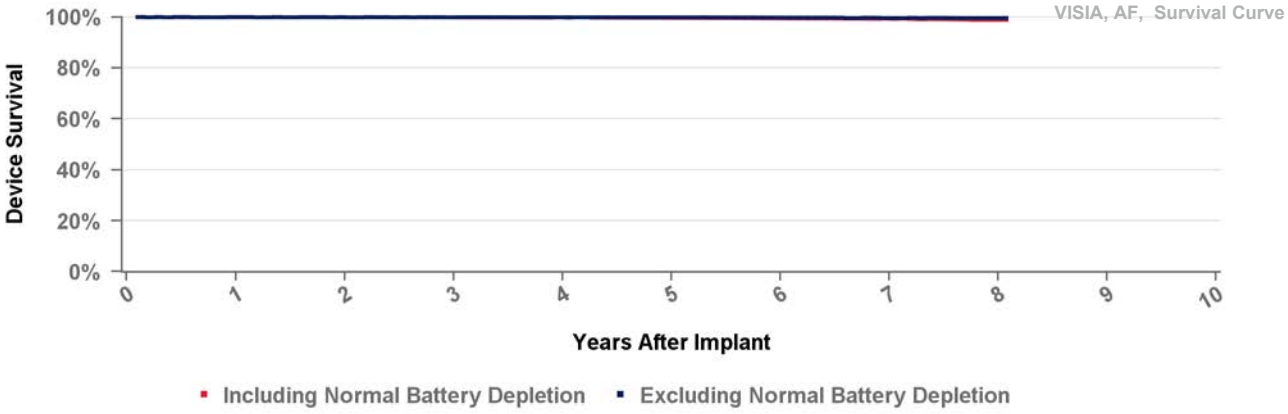
US Market Release	12Oct2016	**Total Malfunctions (USA)**	**1**
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,477	Battery	1
Estimated Active USA Implants	1,221	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVFC3D4 Visia MRI AF S

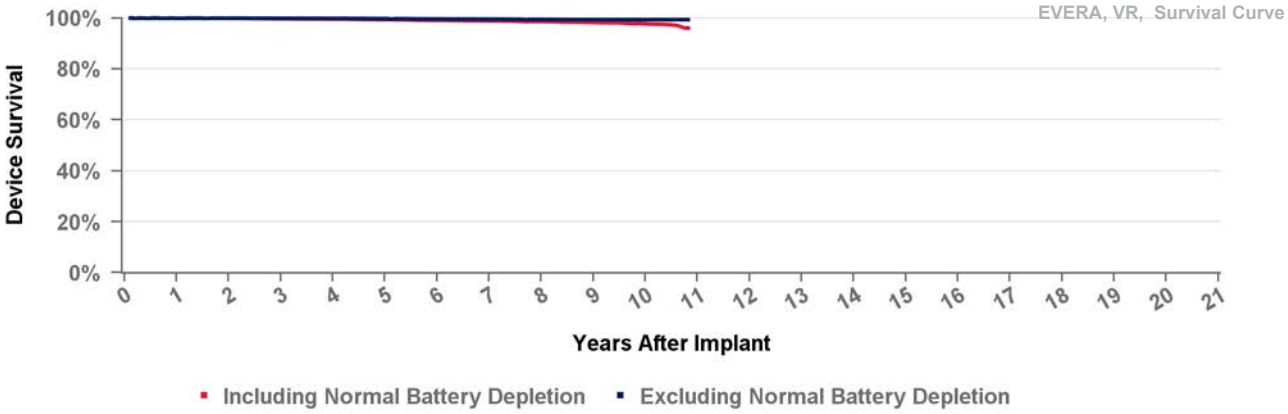
US Market Release	19Jan2016	**Total Malfunctions (USA)**	**4**
CE Approval Date	19Oct2015	**Therapy Function Not Compromised**	**4**
Registered USA Implants	3,587	Battery	4
Estimated Active USA Implants	3,014	**Therapy Function Compromised**	**0**
Normal Battery Depletions	9		



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	76404	68673	58504	49559	37571	24498	12154	877	180

DVMB1D4 Evera MRI XT

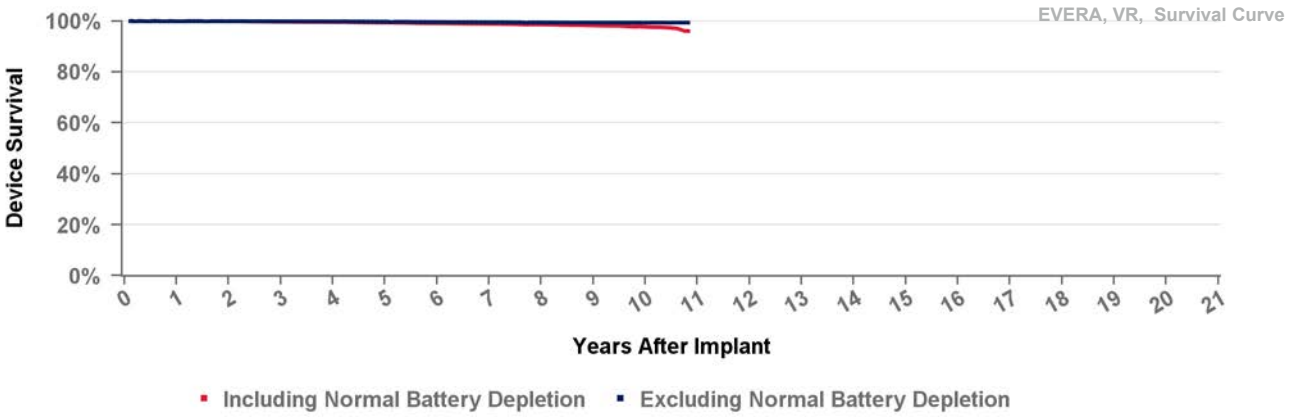
US Market Release	11Sep2015	**Total Malfunctions (USA)**	**35**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	10,270	Battery	13
Estimated Active USA Implants	6,775	Electrical Component	3
Normal Battery Depletions	20	Other	1
		Therapy Function Compromised	**18**
		Battery	14
		Device-Related Current Pathway	4



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMB2D1 Evera MRI XT

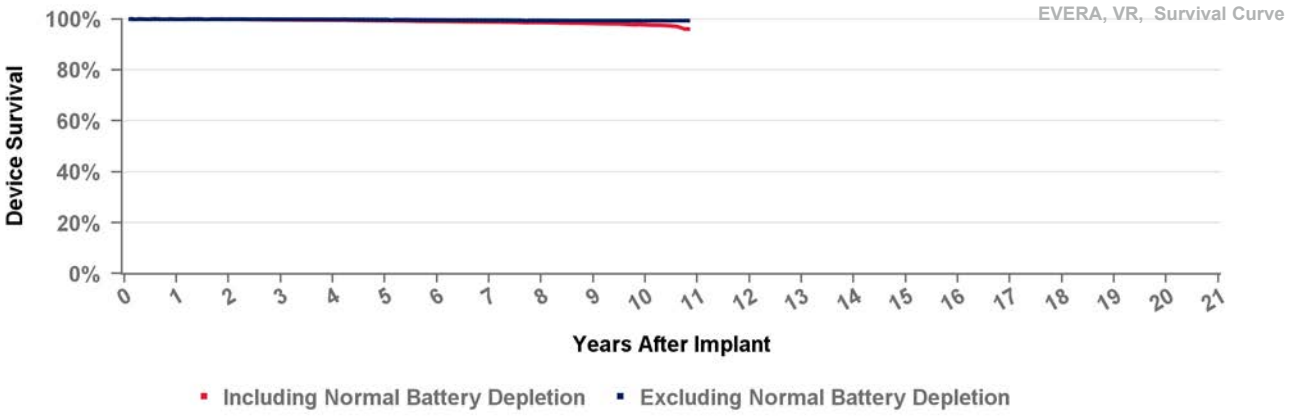
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMB2D4 Evera MRI XT

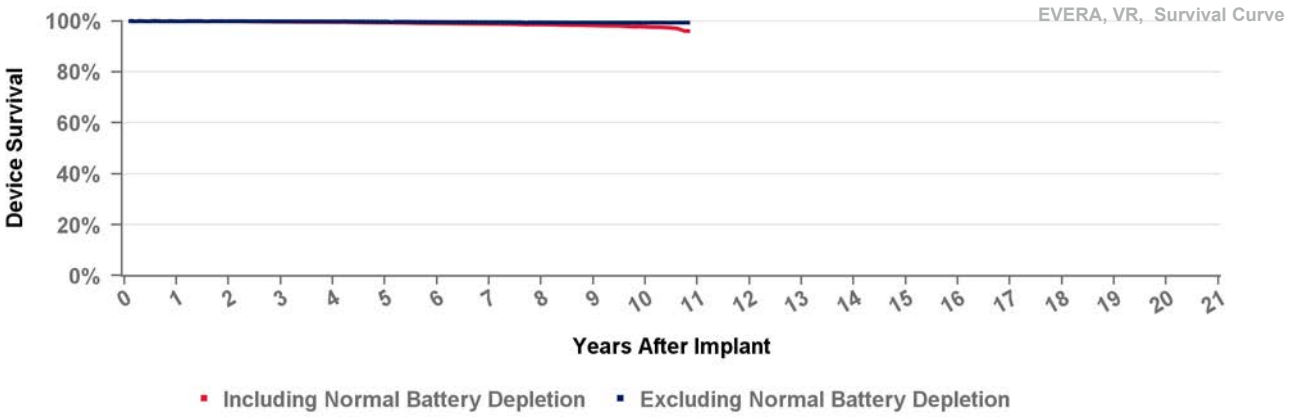
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMC3D1 Evera MRI S

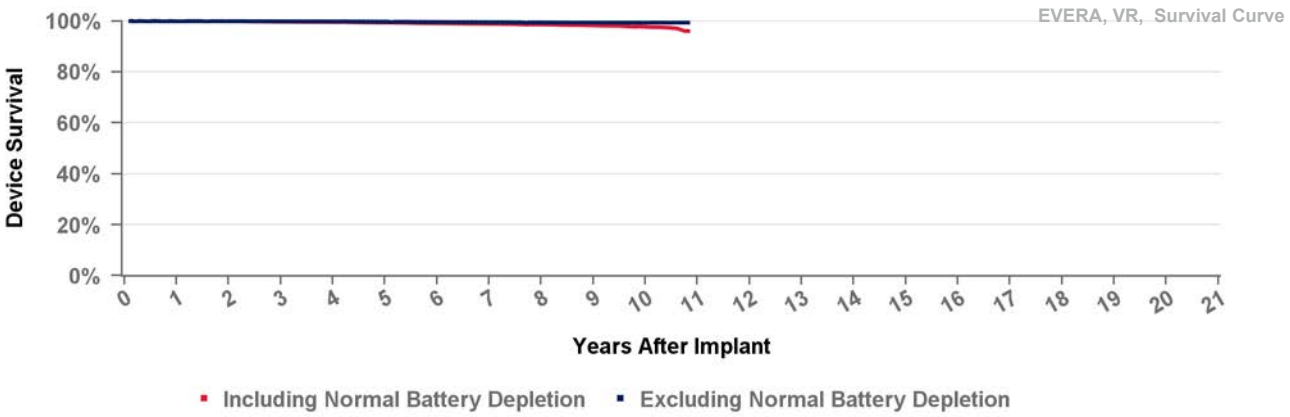
US Market Release	12Oct2016	**Total Malfunctions (USA)**	
CE Approval Date	05Sep2016	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMC3D4 Evera MRI S

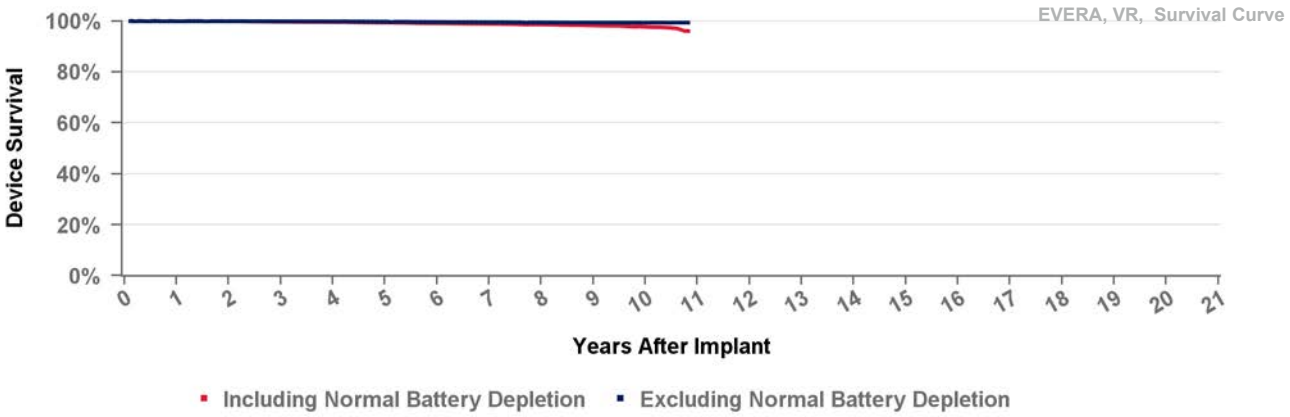
US Market Release	11Sep2015	**Total Malfunctions (USA)**	
CE Approval Date	31Mar2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMD3D1 Primo

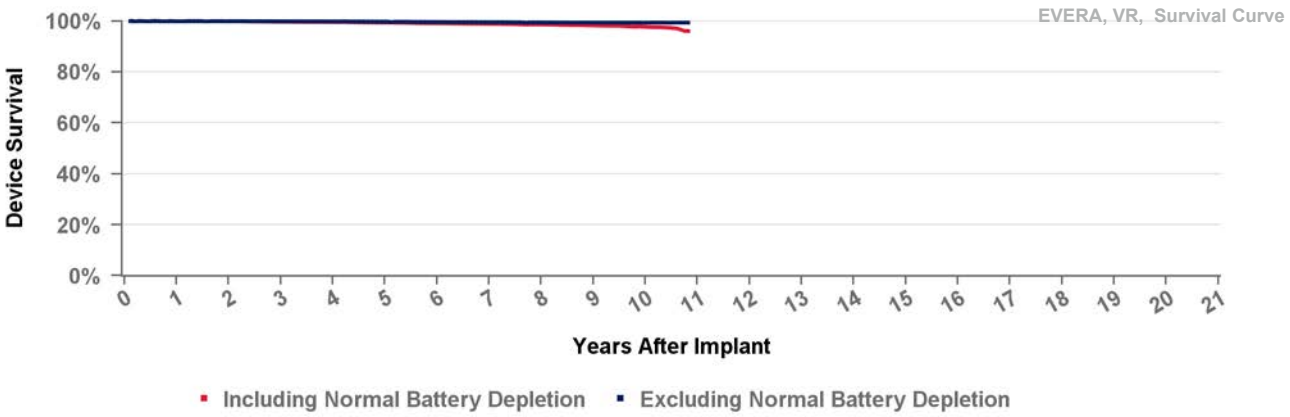
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	274		
Estimated Active USA Implants	242	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVMD3D4 Primo

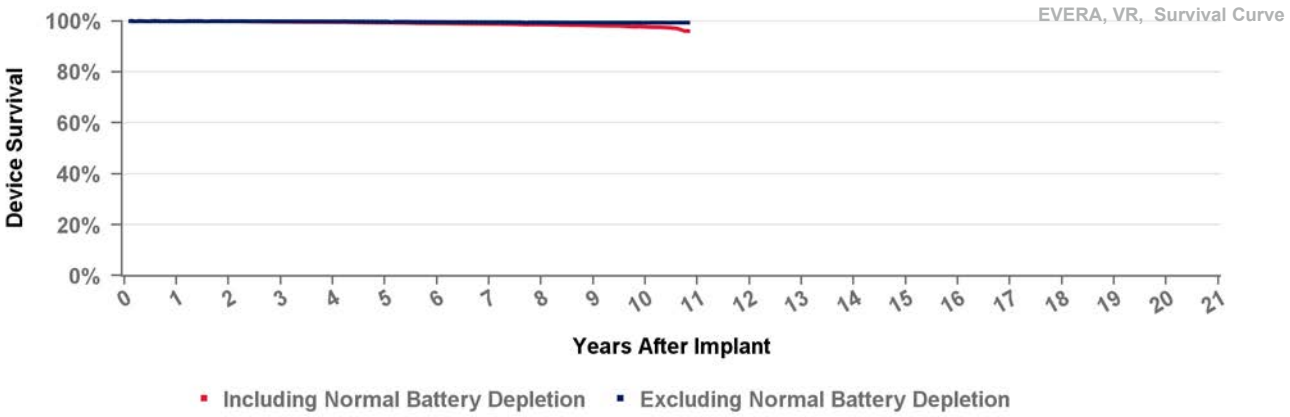
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants	624		
Estimated Active USA Implants	562	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVME3D1 Mirro

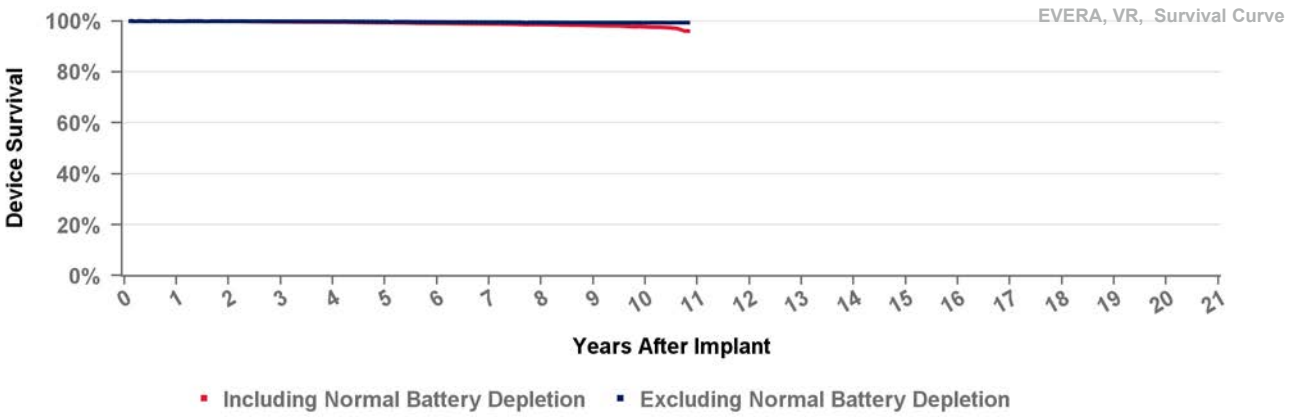
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVME3D4 Mirro

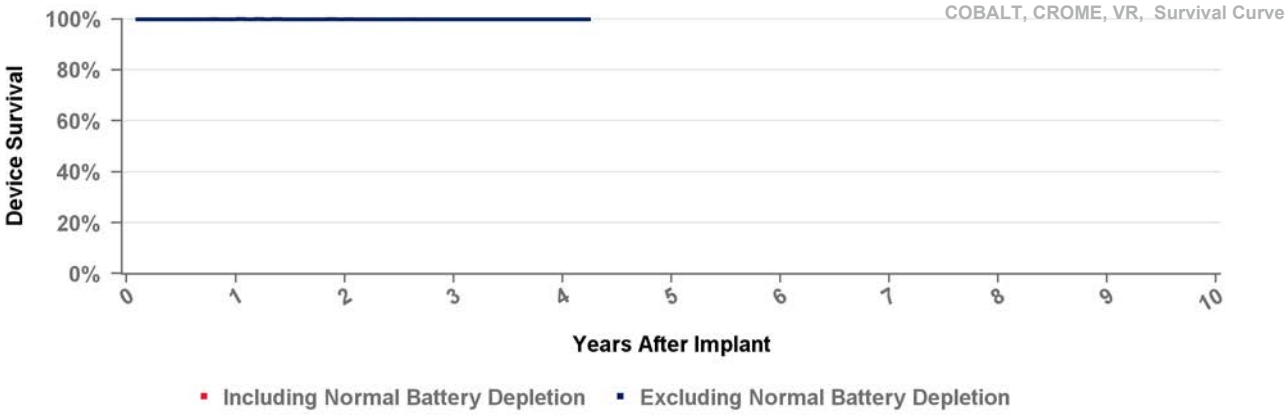
US Market Release	01Mar2018	**Total Malfunctions (USA)**	
CE Approval Date	10Nov2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.1%	98.9%	98.7%	98.3%	97.8%	96.1%
Effective Sample Size	52428	48822	45453	42319	39231	36059	33207	30001	19453	7802	218

DVPA2D1 Cobalt XT

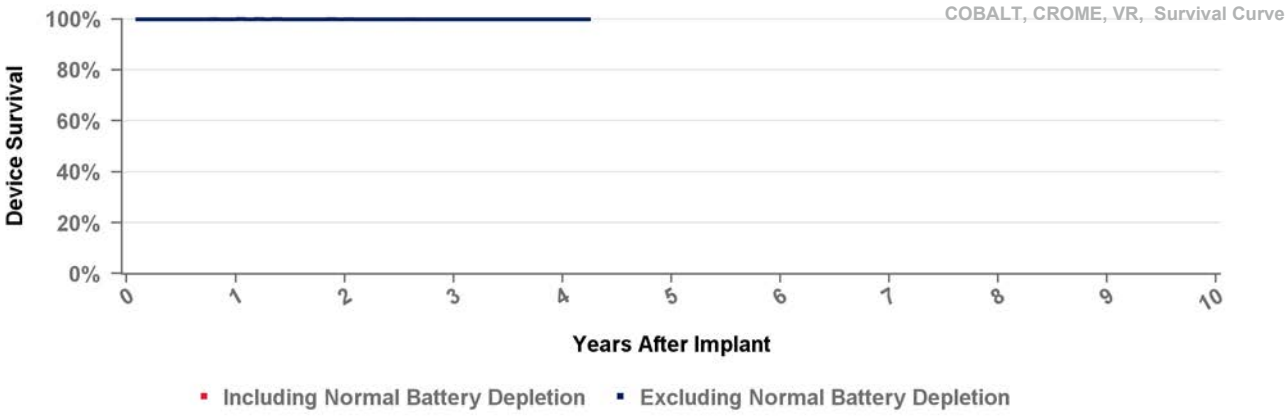
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	1,680		
Estimated Active USA Implants	1,578	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

DVPA2D4 Cobalt XT

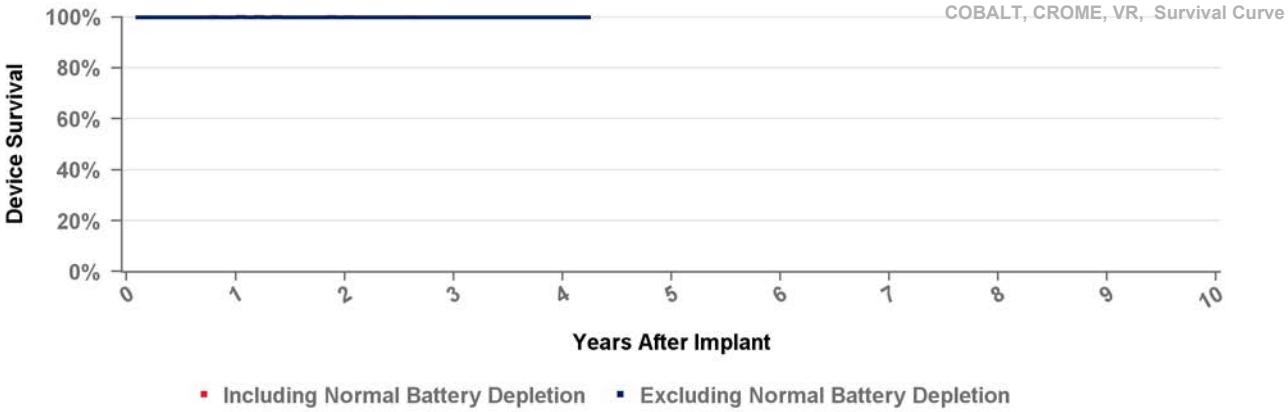
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**1**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**0**
Registered USA Implants	13,110		
Estimated Active USA Implants	12,478	**Therapy Function Compromised**	**1**
Normal Battery Depletions		Device-Related Current Pathway	1



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

DVPB3D1 Cobalt

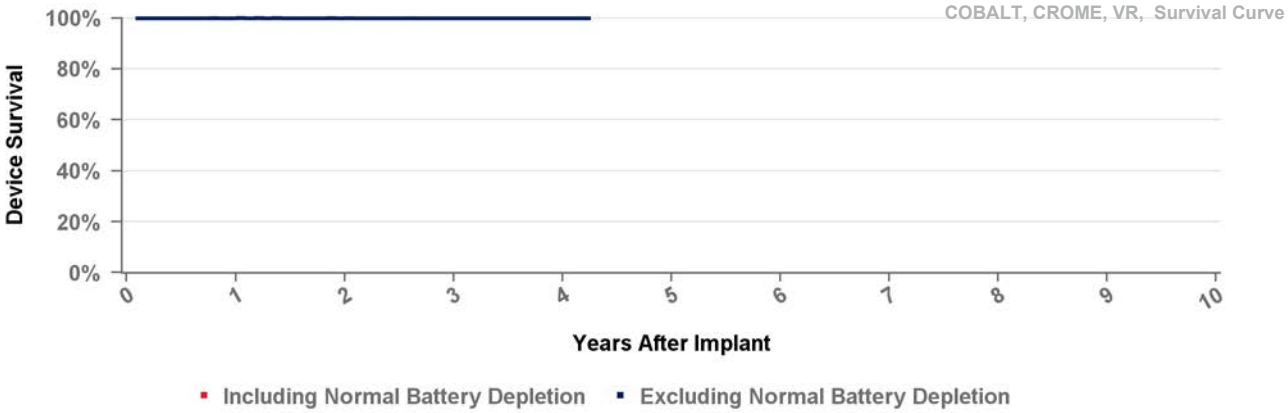
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**2**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**0**
Registered USA Implants	1,653		
Estimated Active USA Implants	1,504	**Therapy Function Compromised**	**2**
Normal Battery Depletions		Electrical Interconnect	2



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

DVPB3D4 Cobalt

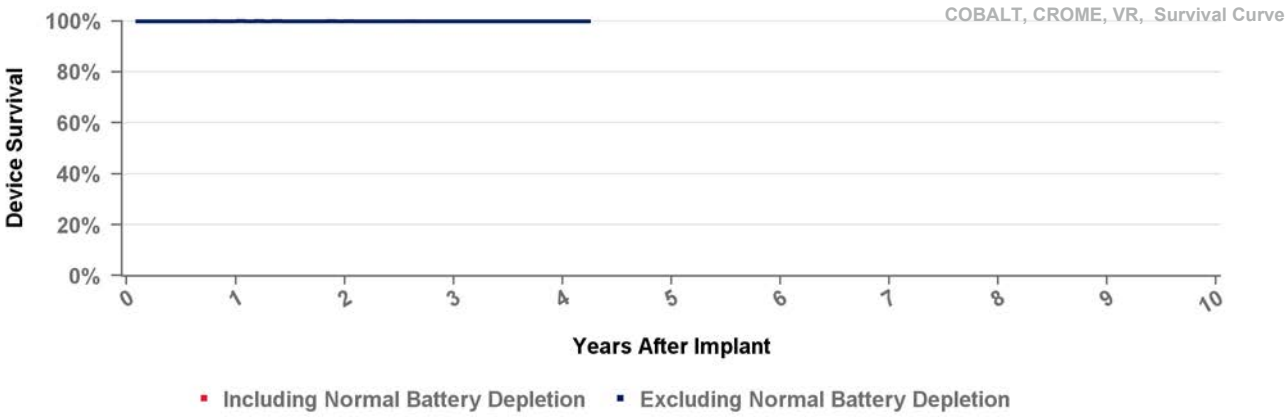
US Market Release	23Apr2020	**Total Malfunctions (USA)**	**4**
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6,197	Other	1
Estimated Active USA Implants	5,755	**Therapy Function Compromised**	**3**
Normal Battery Depletions	2	Device-Related Current Pathway	2
		Electrical Interconnect	1



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

DVPC3D1 Crome

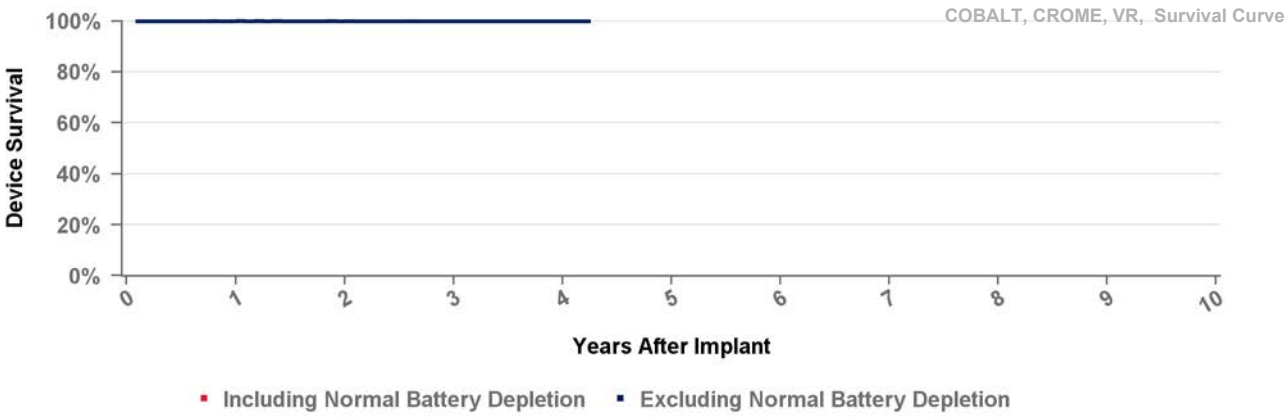
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	140		
Estimated Active USA Implants	128	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

DVPC3D4 Crome

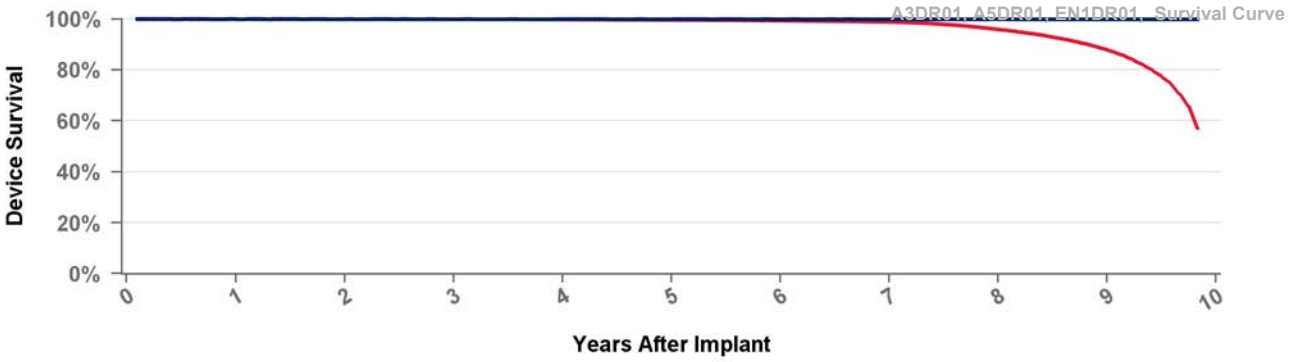
US Market Release	23Apr2020	**Total Malfunctions (USA)**	
CE Approval Date	18Dec2019	**Therapy Function Not Compromised**	
Registered USA Implants	631		
Estimated Active USA Implants	591	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	15363	9527	5508	651	176

A2DR01 Advisa DR MRI

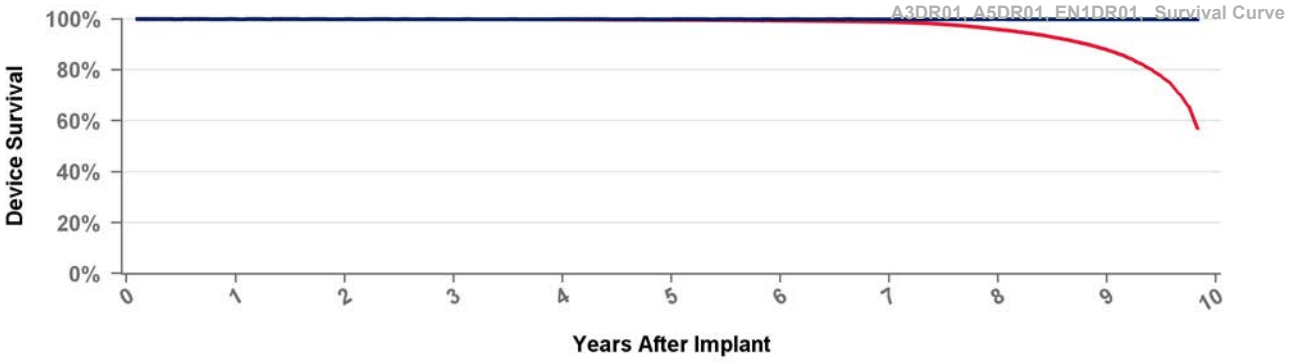
US Market Release	15Jan2013	**Total Malfunctions (USA)**	**84**
CE Approval Date		**Therapy Function Not Compromised**	**79**
Registered USA Implants	344,430	Battery	1
Estimated Active USA Implants	206,040	Electrical Component	40
Normal Battery Depletions	10,341	Electrical Interconnect	4
		Possible Early Battery Depletion	25
		Software/Firmware	6
		Other	3
		Therapy Function Compromised	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	9	at 118 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%	98.8%	95.9%	87.9%	57.1%
Effective Sample Size	308384	290536	273794	257049	237637	216768	182503	109966	45804	3338

A3DR01 Advisa DR MRI

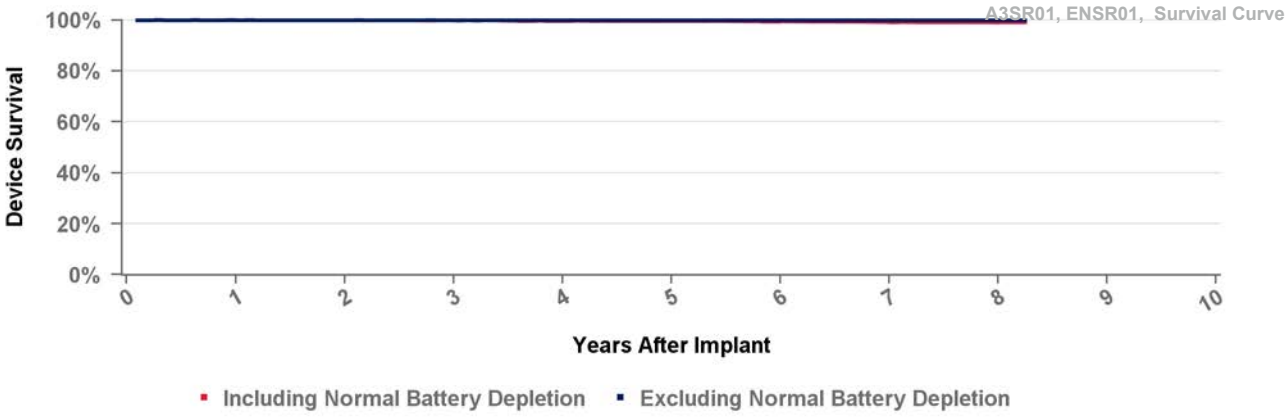
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Jun2009	**Therapy Function Not Compromised**	
Registered USA Implants	23		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	4		



Years	1	2	3	4	5	6	7	8	9	at 118 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%	98.8%	95.9%	87.9%	57.1%
Effective Sample Size	308384	290536	273794	257049	237637	216768	182503	109966	45804	3338

A3SR01 Advisa SR MRI

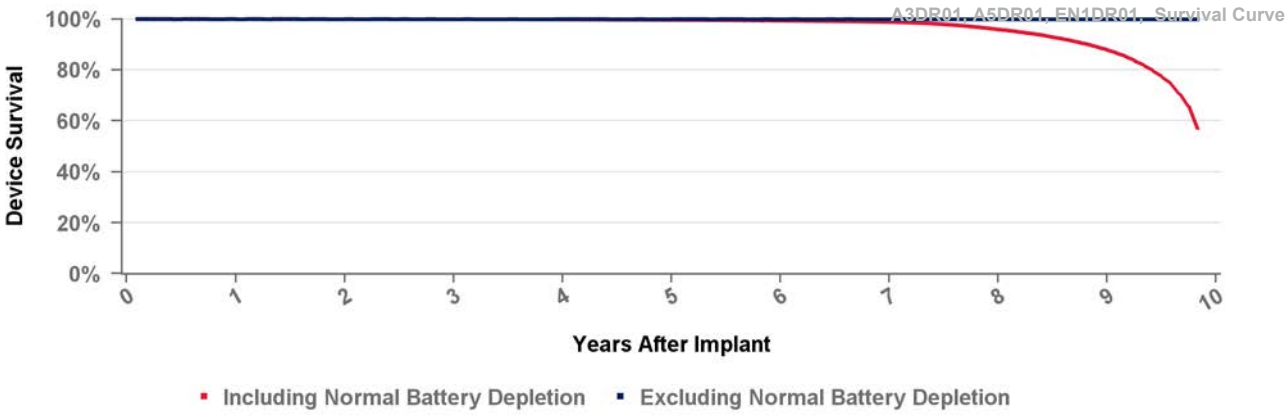
US Market Release	19Mar2015	**Total Malfunctions (USA)**	**9**
CE Approval Date	24Apr2014	**Therapy Function Not Compromised**	**8**
Registered USA Implants	28,082	Electrical Component	3
Estimated Active USA Implants	15,729	Electrical Interconnect	1
Normal Battery Depletions	57	Possible Early Battery Depletion	2
		Other	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%	99.0%	99.0%
Effective Sample Size	22025	19382	17201	15020	12895	10984	7908	1730	268

A5DR01 Advisa DR

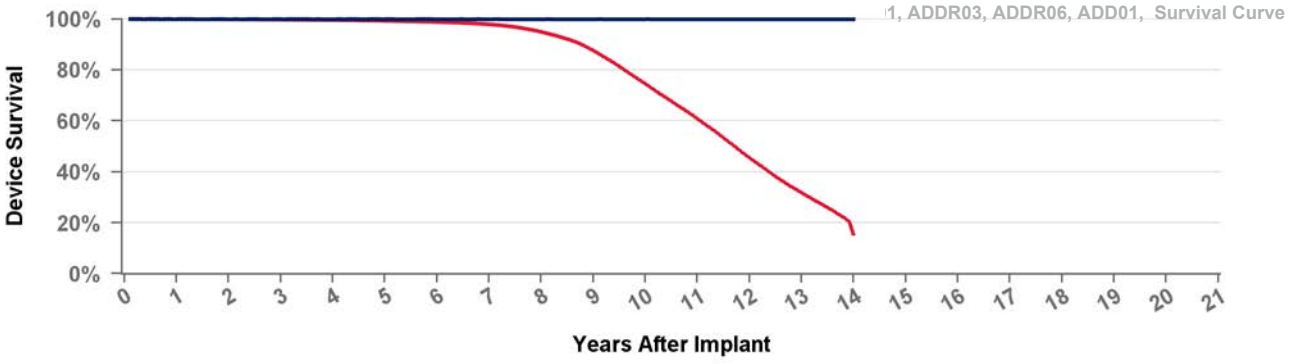
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Jun2009	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 118 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%	98.8%	95.9%	87.9%	57.1%
Effective Sample Size	308384	290536	273794	257049	237637	216768	182503	109966	45804	3338

ADD01 Adapta D

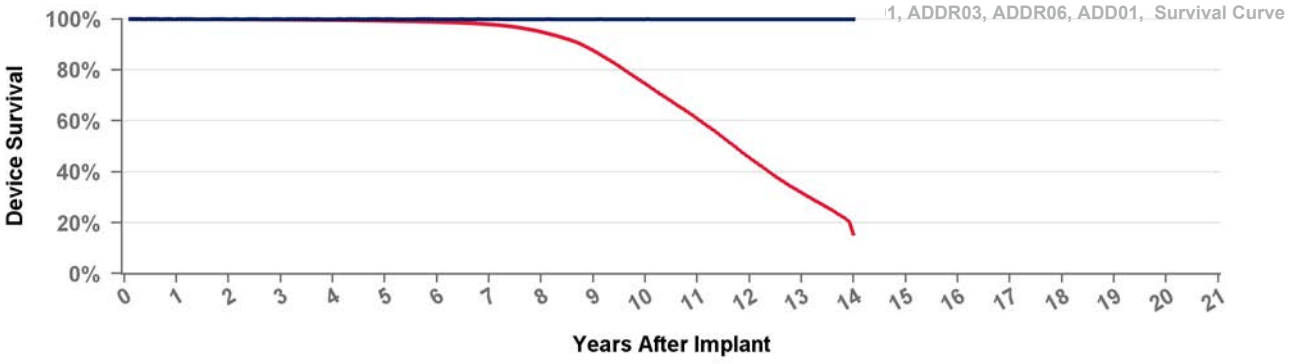
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

ADDR01 Adapta DR

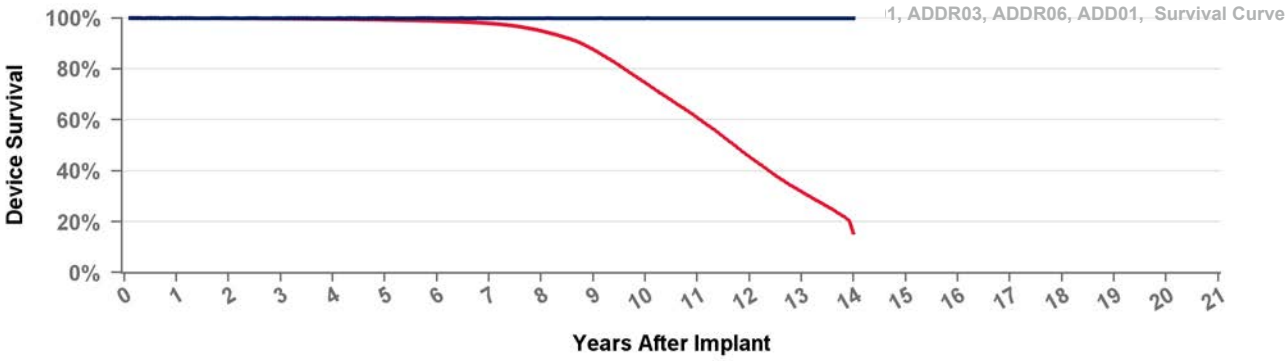
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**94**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**66**
Registered USA Implants	454,879	Electrical Component	58
Estimated Active USA Implants	117,929	Electrical Interconnect	1
Normal Battery Depletions	51,962	Possible Early 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 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

ADDR03 Adapta DR

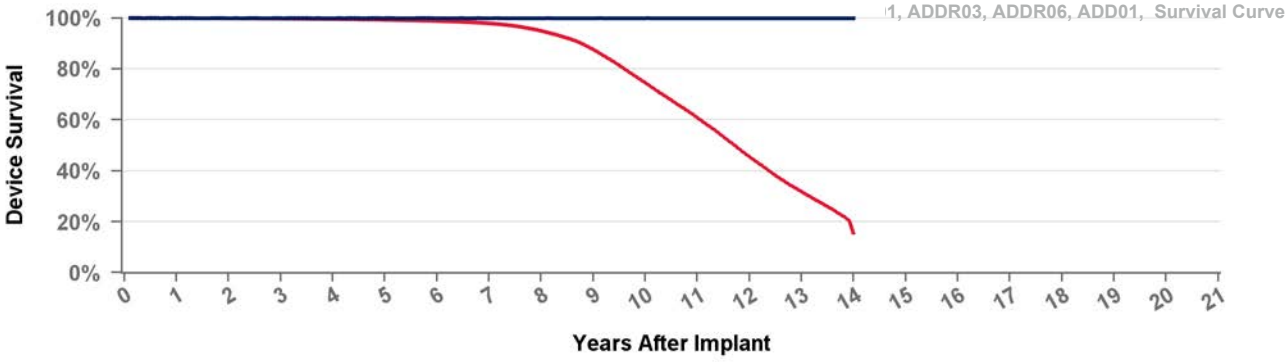
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**2**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,565	Electrical Component	1
Estimated Active USA Implants	1,272	**Therapy Function Compromised**	**1**
Normal Battery Depletions	630	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

ADDR06 Adapta DR

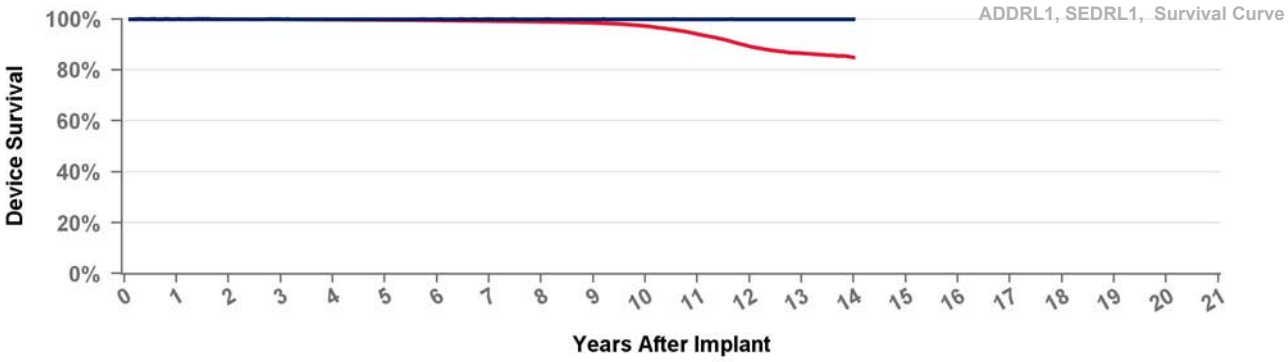
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**1**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,641	Electrical Component	1
Estimated Active USA Implants	849	**Therapy Function Compromised**	**0**
Normal Battery Depletions	432		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

ADDRL1 Adapta L DR

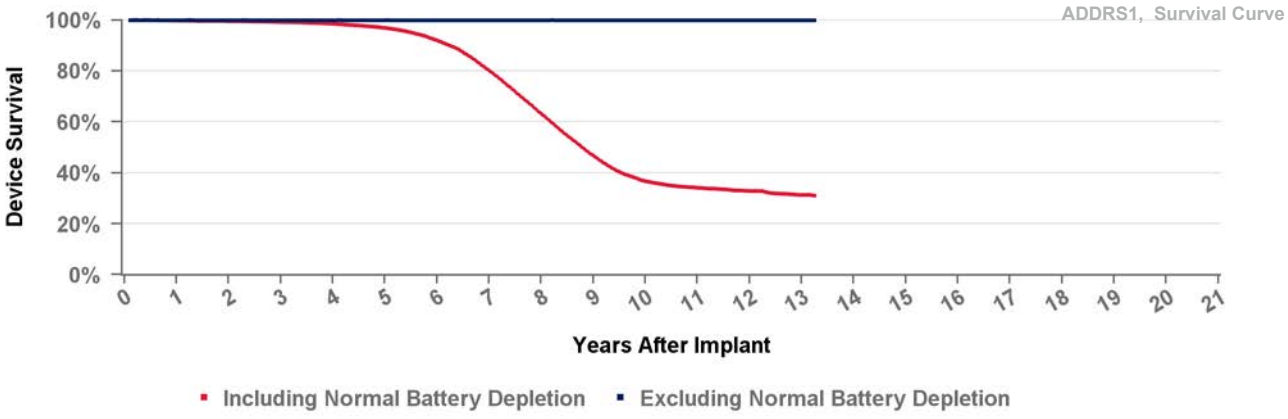
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**25**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**17**
Registered USA Implants	138,605	Electrical Component	13
Estimated Active USA Implants	64,630	Electrical Interconnect	1
Normal Battery Depletions	2,889	Possible Early Battery Depletion	2
		Software/Firmware	1
		Therapy Function Compromised	**8**
		Electrical Component	5
		Electrical Interconnect	1
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.0%	98.5%	97.2%	94.1%	89.2%	86.6%	84.9%
Effective Sample Size	119685	112697	106052	99500	92186	84456	76957	68062	57703	46414	32989	19845	8659	457

ADDRS1 Adapta S DR

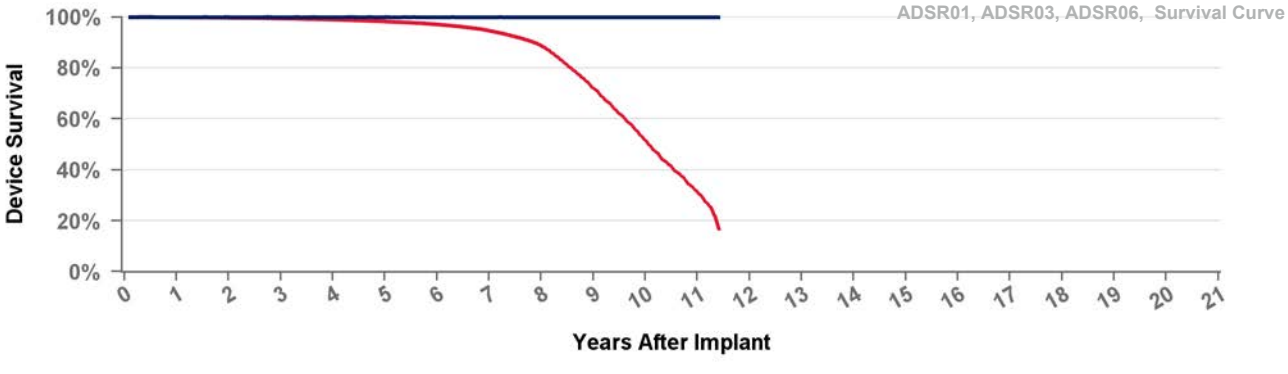
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**15**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**9**
Registered USA Implants	49,311	Electrical Component	5
Estimated Active USA Implants	9,722	Possible Early Battery Depletion	3
Normal Battery Depletions	6,646	Other	1
		Therapy Function Compromised	**6**
		Electrical Component	4
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 159 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	99.8%	99.6%	99.2%	98.5%	96.9%	92.0%	80.1%	63.1%	46.8%	36.7%	34.1%	32.9%	31.3%	31.1%
Effective Sample Size	40117	36090	32378	29007	25636	21621	16274	10707	6377	3743	2299	1282	325	125

ADSR01 Adapta SR

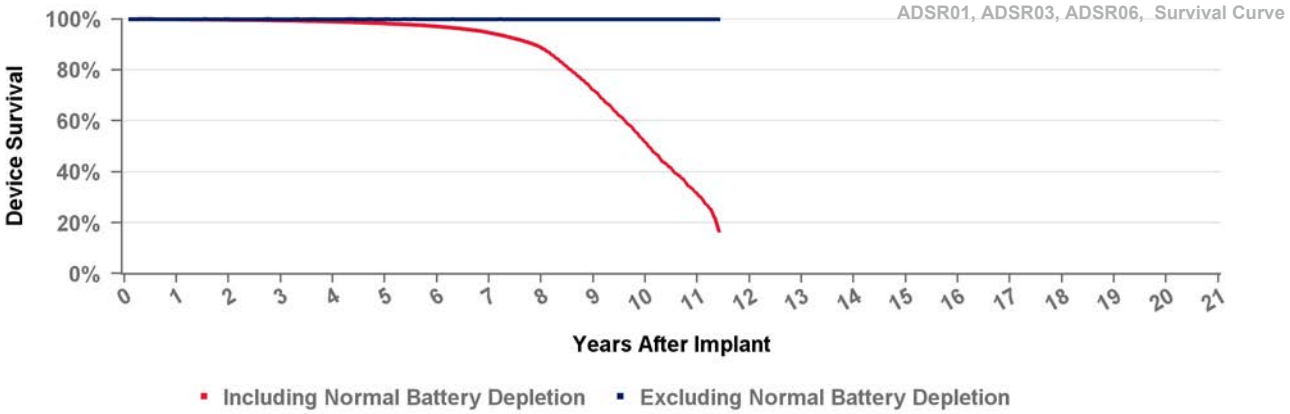
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**18**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**12**
Registered USA Implants	91,662	Electrical Component	7
Estimated Active USA Implants	18,928	Electrical Interconnect	1
Normal Battery Depletions	6,477	Possible Early Battery 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 137 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%	99.4%	99.0%	98.3%	97.1%	94.6%	88.7%	72.1%	51.7%	31.1%	16.8%
Effective Sample Size	72032	62950	55120	48082	41254	34912	28987	22404	14621	6795	1577	169

ADSR03 Adapta SR

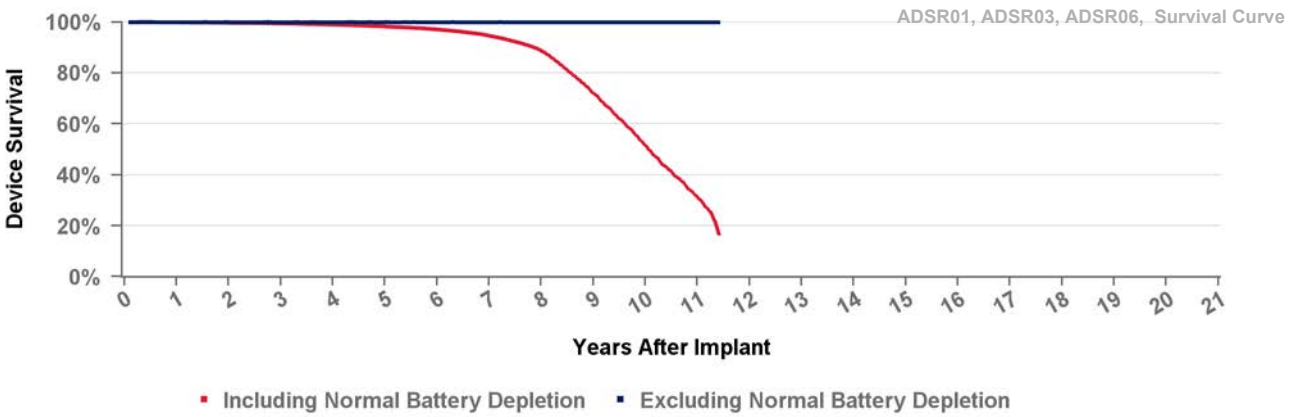
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	2,124		
Estimated Active USA Implants	423	**Therapy Function Compromised**	
Normal Battery Depletions	203		



Years	1	2	3	4	5	6	7	8	9	10	11	at 137 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%	99.4%	99.0%	98.3%	97.1%	94.6%	88.7%	72.1%	51.7%	31.1%	16.8%
Effective Sample Size	72032	62950	55120	48082	41254	34912	28987	22404	14621	6795	1577	169

ADSR06 Adapta SR

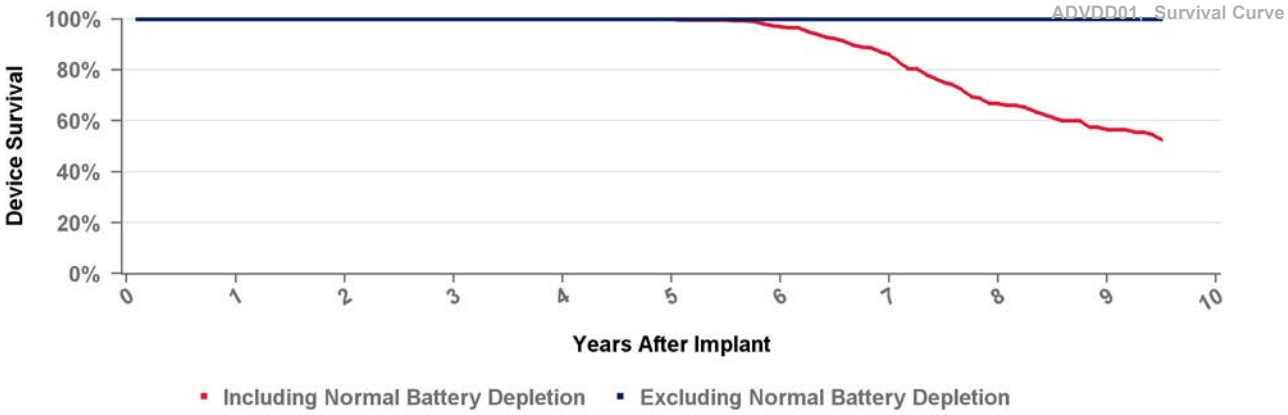
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**2**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,908	Electrical Component	2
Estimated Active USA Implants	594	**Therapy Function Compromised**	**0**
Normal Battery Depletions	277		



Years	1	2	3	4	5	6	7	8	9	10	11	at 137 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%	99.4%	99.0%	98.3%	97.1%	94.6%	88.7%	72.1%	51.7%	31.1%	16.8%
Effective Sample Size	72032	62950	55120	48082	41254	34912	28987	22404	14621	6795	1577	169

ADVDD01 Adapta VDD

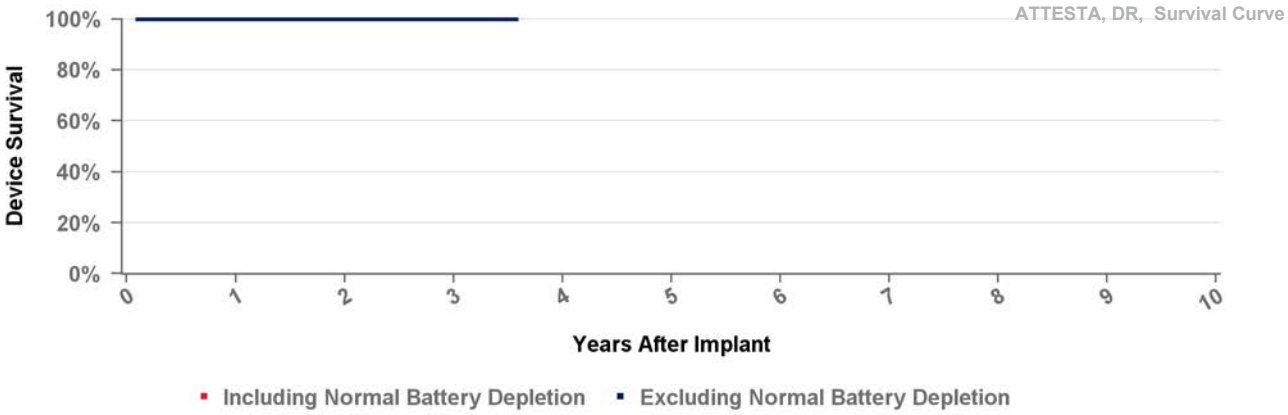
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	856		
Estimated Active USA Implants	214	**Therapy Function Compromised**	
Normal Battery Depletions	95		



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.0%	86.0%	66.8%	56.6%	52.5%
Effective Sample Size	705	648	588	532	471	410	318	186	127	104

ATDR01 Attesta DR MRI

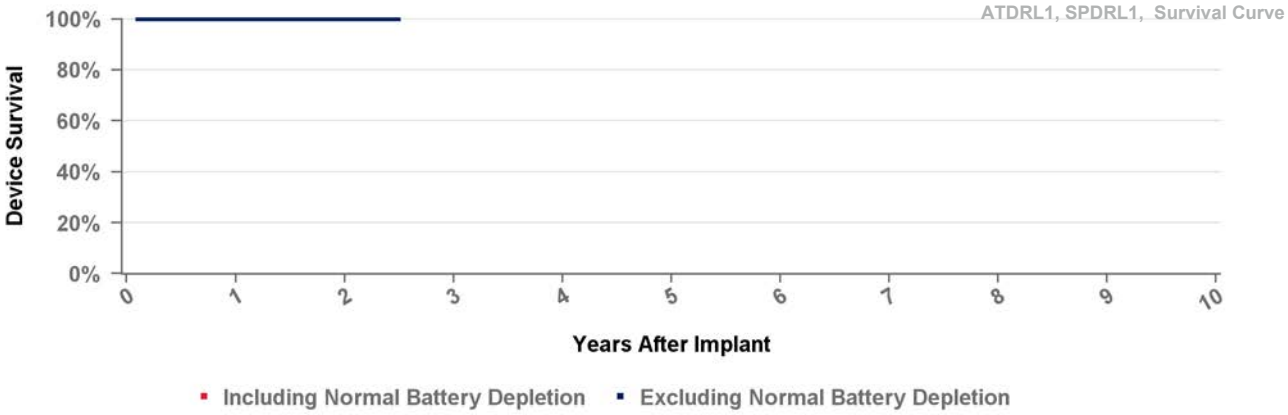
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	2,093		
Estimated Active USA Implants	2,003	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 43 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	1666	1039	405	100

ATDRL1 Attesta L DR MRI

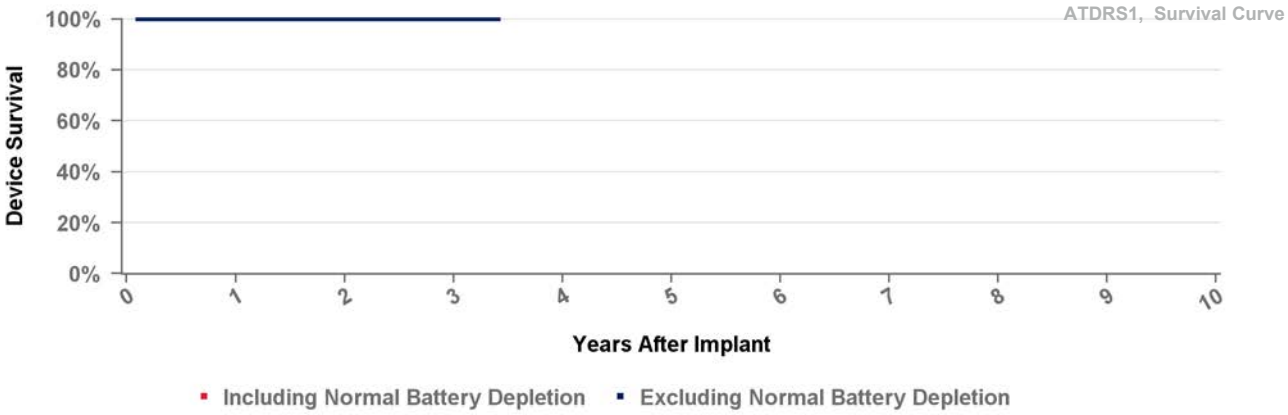
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	295		
Estimated Active USA Implants	286	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	234	150	100

ATDRS1 Attesta S DR MRI

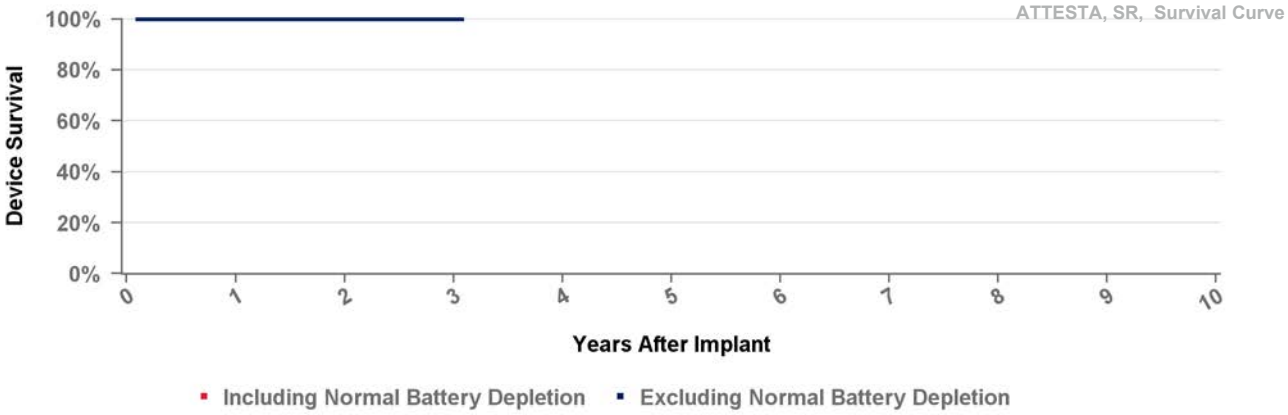
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1,362		
Estimated Active USA Implants	1,250	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	982	623	239	101

ATSR01 Attesta SR MRI

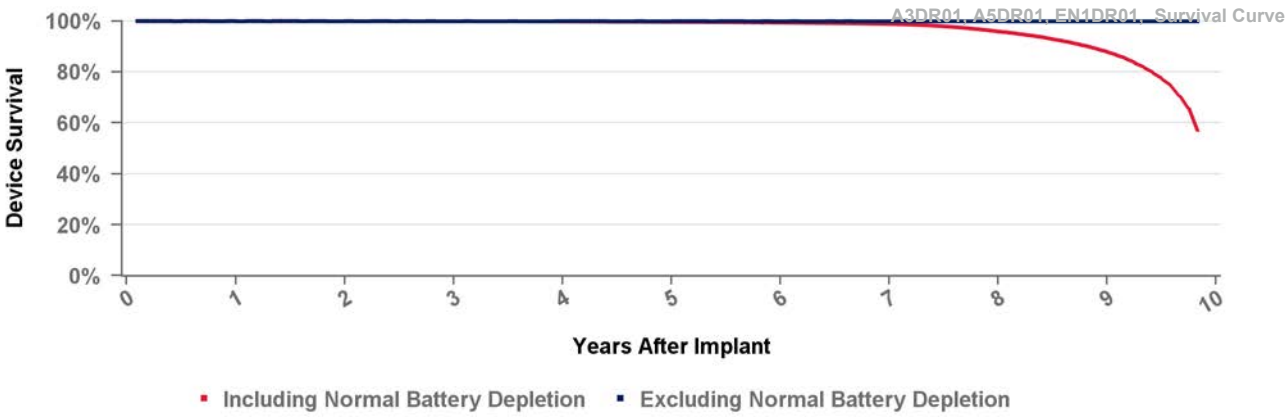
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1,183		
Estimated Active USA Implants	893	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 37 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	681	392	146	116

EN1DR01 Ensura MRI

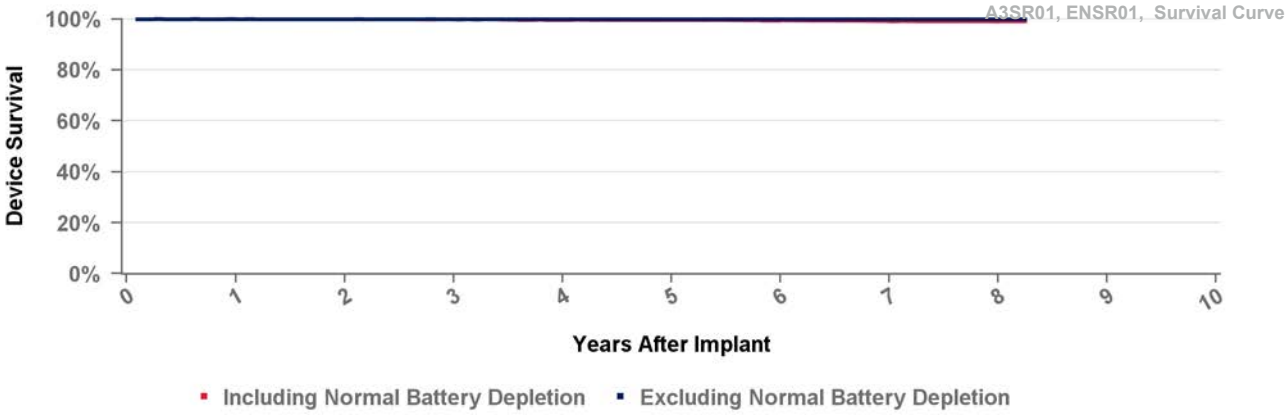
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	23Jun2010	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 118 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%	98.8%	95.9%	87.9%	57.1%
Effective Sample Size	308384	290536	273794	257049	237637	216768	182503	109966	45804	3338

EN1SR01 Ensura SR MRI

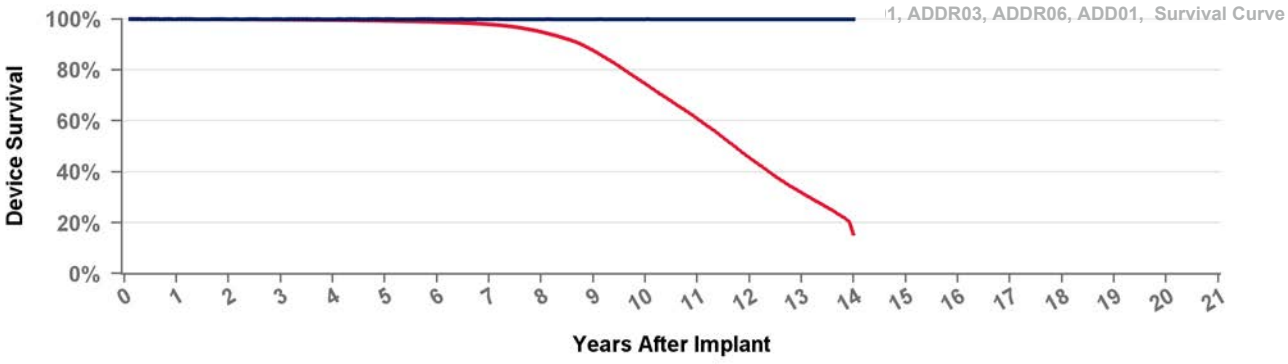
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	24Apr2014	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.2%	99.0%	99.0%
Effective Sample Size	22025	19382	17201	15020	12895	10984	7908	1730	268

RED01 Relia D

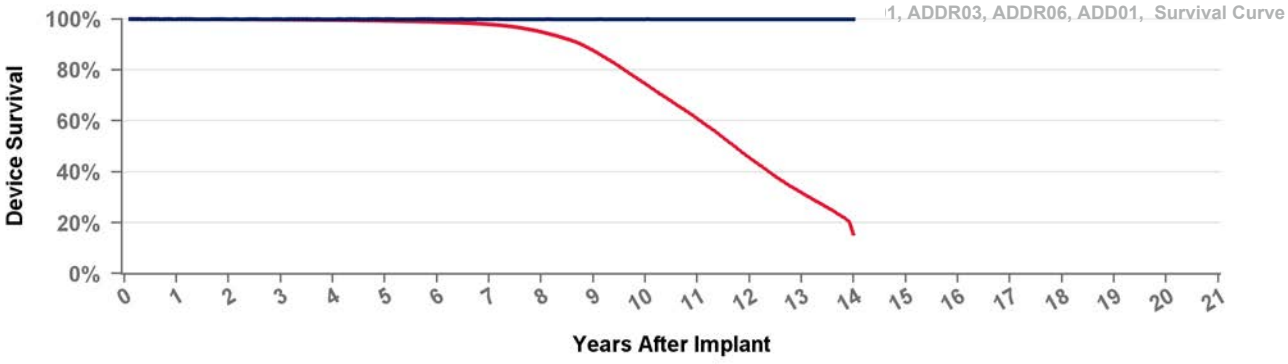
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

REDR01 Relia DR

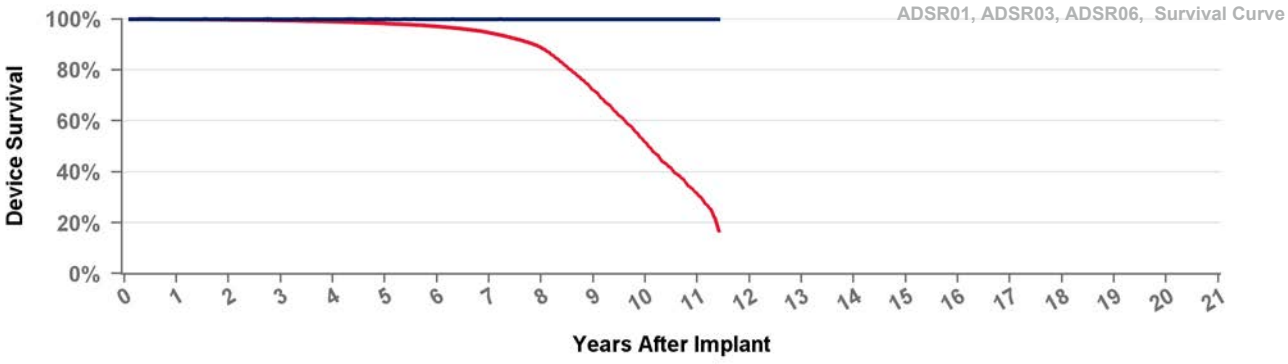
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants	11		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.3%	98.8%	97.9%	94.9%	87.6%	74.5%	60.7%	45.4%	31.7%	15.4%
Effective Sample Size	393167	365261	338800	313064	289162	264932	240345	209077	167005	120676	76751	40118	14946	465

RES01 Relia S

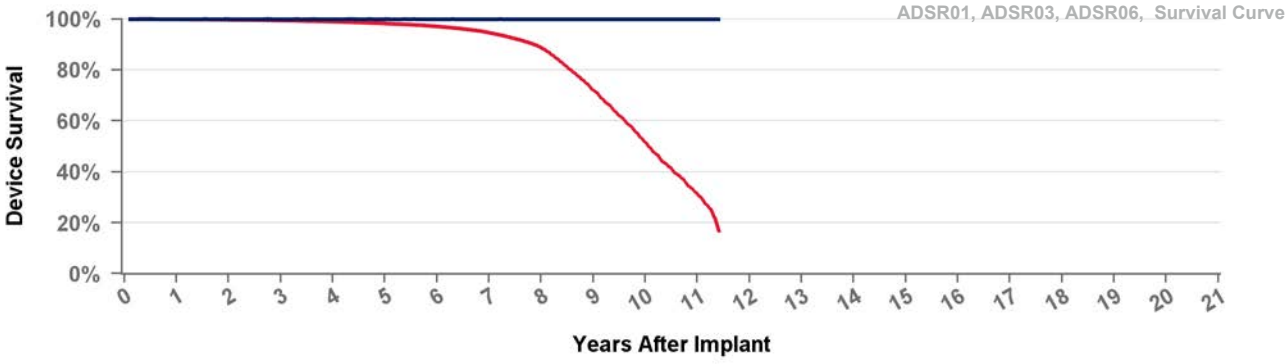
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 137 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%	99.4%	99.0%	98.3%	97.1%	94.6%	88.7%	72.1%	51.7%	31.1%	16.8%
Effective Sample Size	72032	62950	55120	48082	41254	34912	28987	22404	14621	6795	1577	169

RESR01 Relia SR

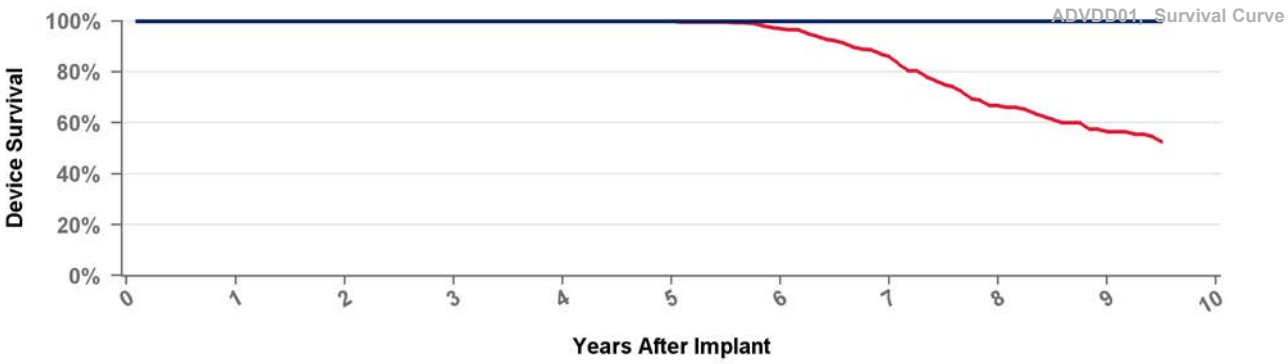
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	at 137 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%	99.4%	99.0%	98.3%	97.1%	94.6%	88.7%	72.1%	51.7%	31.1%	16.8%
Effective Sample Size	72032	62950	55120	48082	41254	34912	28987	22404	14621	6795	1577	169

REVDD01 Relia VDD

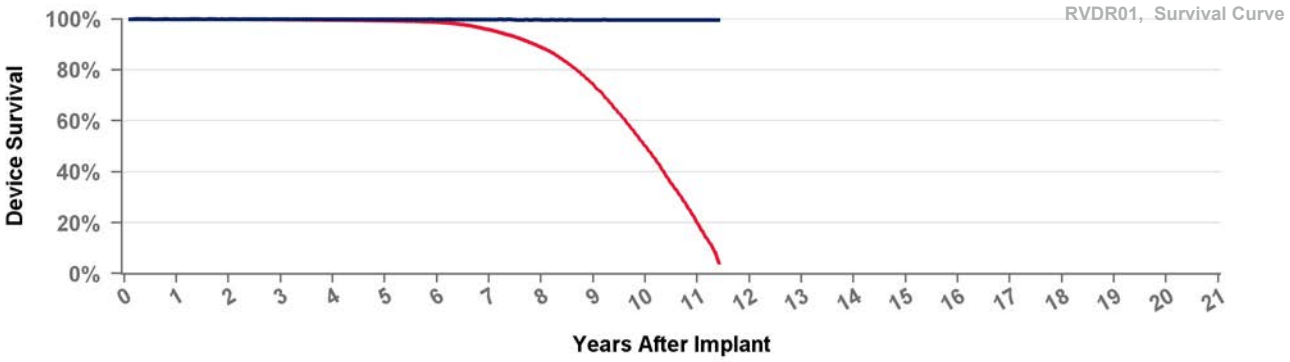
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	07May2008	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.0%	86.0%	66.8%	56.6%	52.5%
Effective Sample Size	705	648	588	532	471	410	318	186	127	104

RVDR01 Revo MRI SureScan

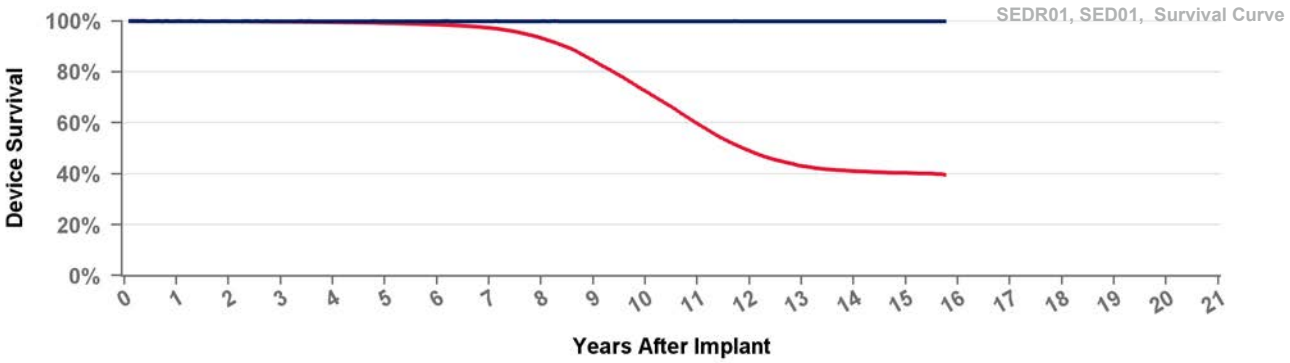
US Market Release	08Feb2011	**Total Malfunctions (USA)**	**111**
CE Approval Date		**Therapy Function Not Compromised**	**108**
Registered USA Implants	69,114	Battery	1
Estimated Active USA Implants	14,329	Electrical Component	40
Normal Battery Depletions	11,871	Electrical Interconnect	1
		Possible Early 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	11	at 137 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%	99.7%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.4%	98.8%	95.8%	88.8%	74.2%	50.2%	20.0%	4.3%
Effective Sample Size	59303	56149	53135	49973	46276	42262	37432	31261	22363	11778	2892	297

SED01 Sensia D

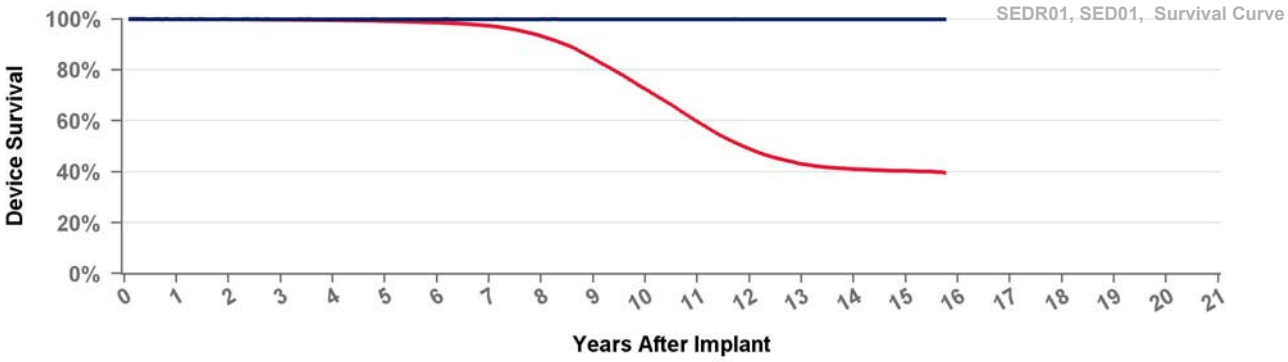
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 189 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%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.2%	98.6%	97.3%	93.3%	84.5%	72.5%	59.6%	49.0%	43.1%	41.1%	40.4%	39.6%
Effective Sample Size	120524	108996	98345	88712	79982	72189	64963	56692	45152	33154	22176	14008	8697	5116	2228	227

SEDR01 Sensia DR

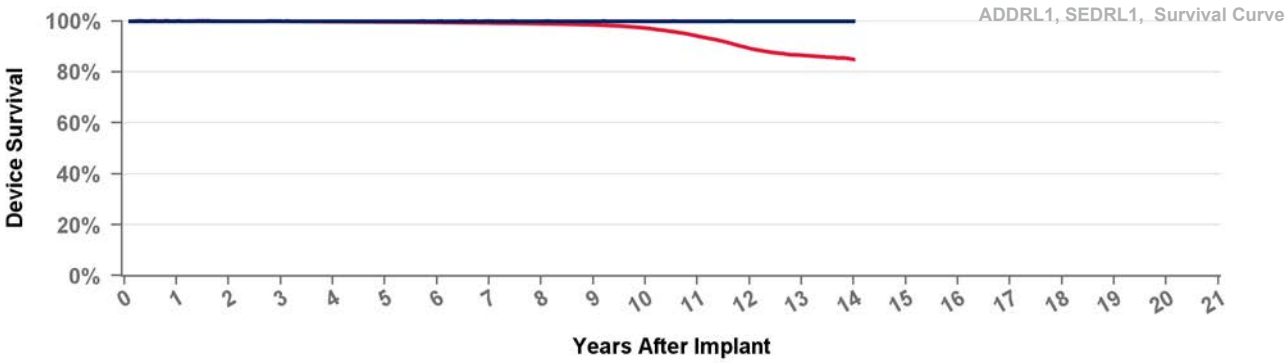
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**33**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,406	Electrical Component	15
Estimated Active USA Implants	28,923	Electrical Interconnect	1
Normal Battery Depletions	16,824	Other	1
		Therapy 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	15	at 189 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%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.2%	98.6%	97.3%	93.3%	84.5%	72.5%	59.6%	49.0%	43.1%	41.1%	40.4%	39.6%
Effective Sample Size	120524	108996	98345	88712	79982	72189	64963	56692	45152	33154	22176	14008	8697	5116	2228	227

SEDRL1 Sensia L DR

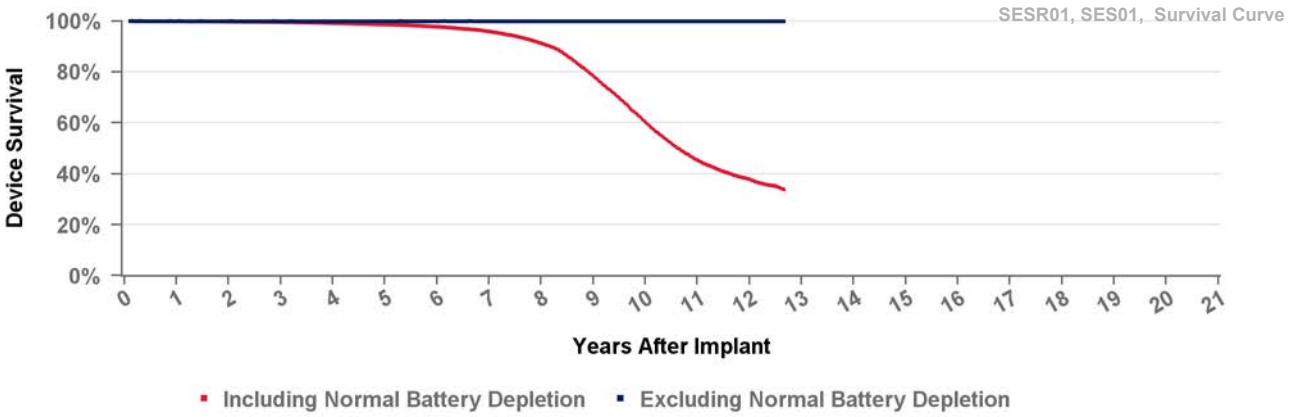
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 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%	99.0%	98.5%	97.2%	94.1%	89.2%	86.6%	84.9%
Effective Sample Size	119685	112697	106052	99500	92186	84456	76957	68062	57703	46414	32989	19845	8659	457

SES01 Sensia S

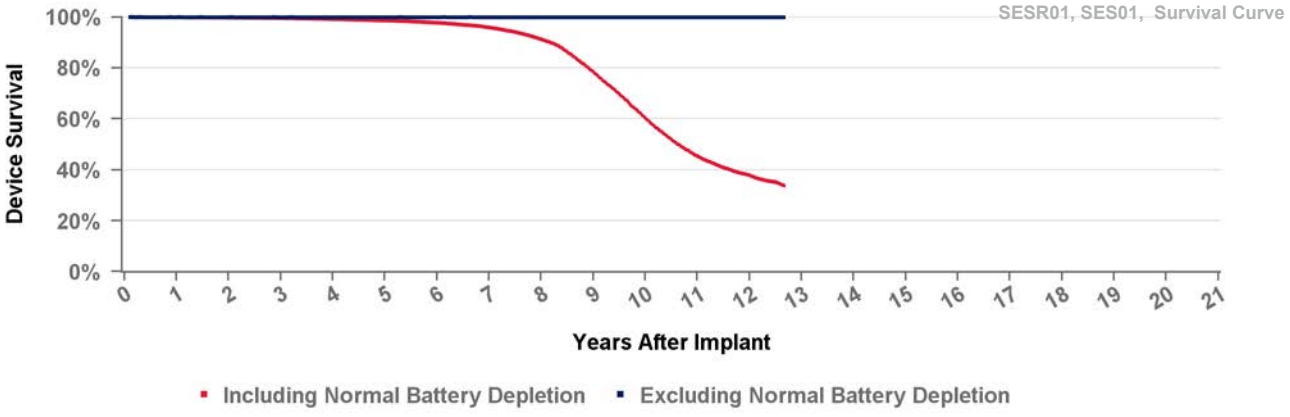
US Market Release	17Jul2006	**Total Malfunctions (USA)**	
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 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%	98.6%	97.8%	95.9%	91.2%	78.4%	60.2%	45.3%	37.8%	33.7%
Effective Sample Size	85820	74447	64542	56003	48244	41081	34577	27777	19746	11349	5317	1928	278

SESR01 Sensia SR

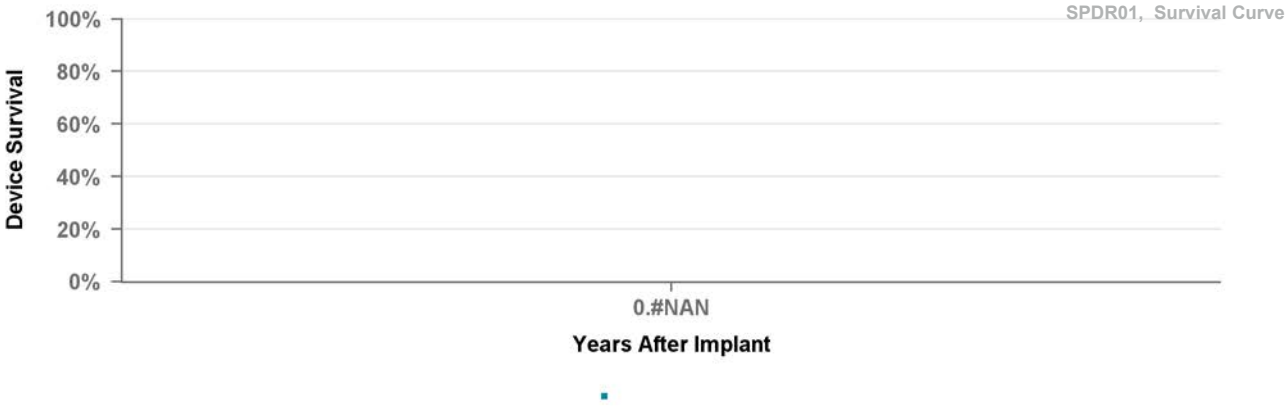
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**17**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**13**
Registered USA Implants	117,372	Electrical Component	7
Estimated Active USA Implants	21,421	Possible Early Battery Depletion	4
Normal Battery Depletions	8,890	Other	2
		Therapy Function Compromised	**4**
		Electrical Component	3
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 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%	98.6%	97.8%	95.9%	91.2%	78.4%	60.2%	45.3%	37.8%	33.7%
Effective Sample Size	85820	74447	64542	56003	48244	41081	34577	27777	19746	11349	5317	1928	278

SPDR01 Sphera DR MRI

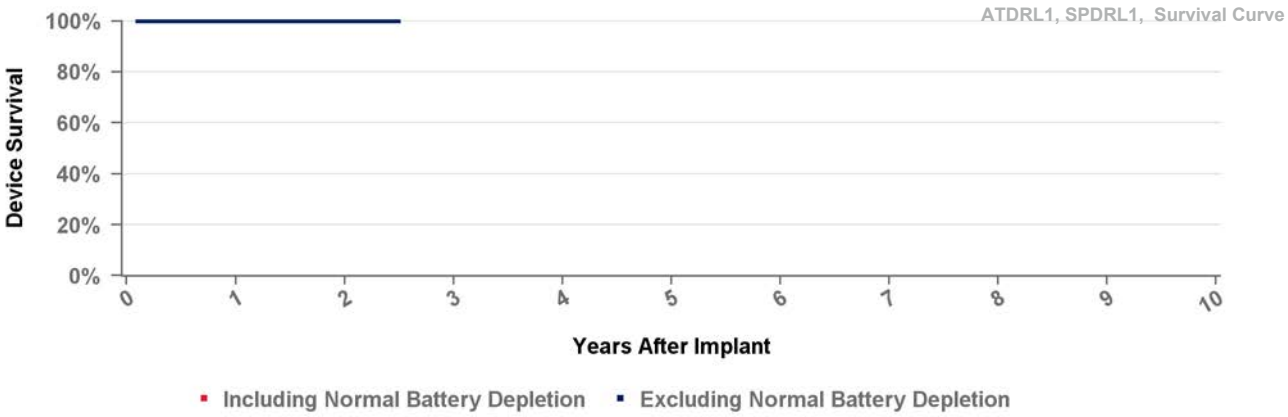
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPDRL1 Sphera L DR MRI

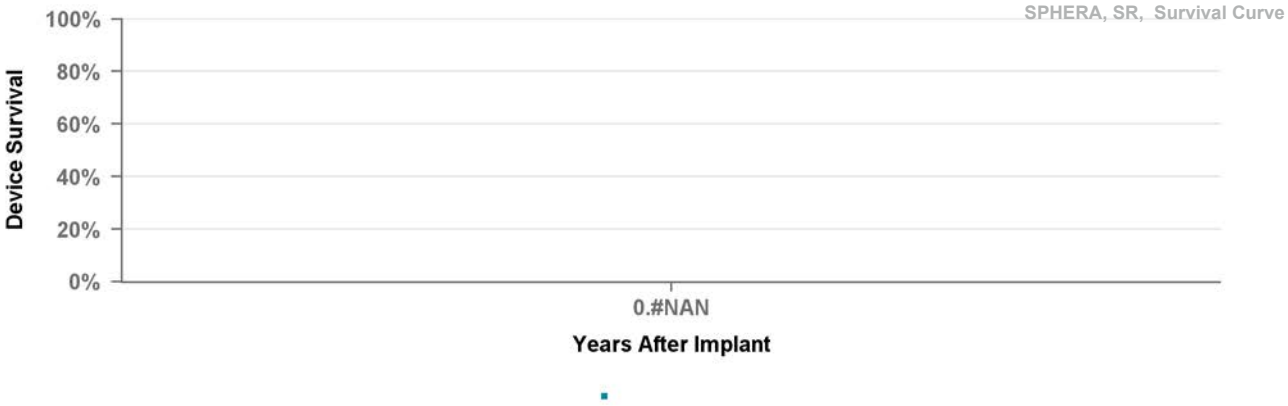
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	at 30 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%
Effective Sample Size	234	150	100

SPSR01 Sphera SR MRI

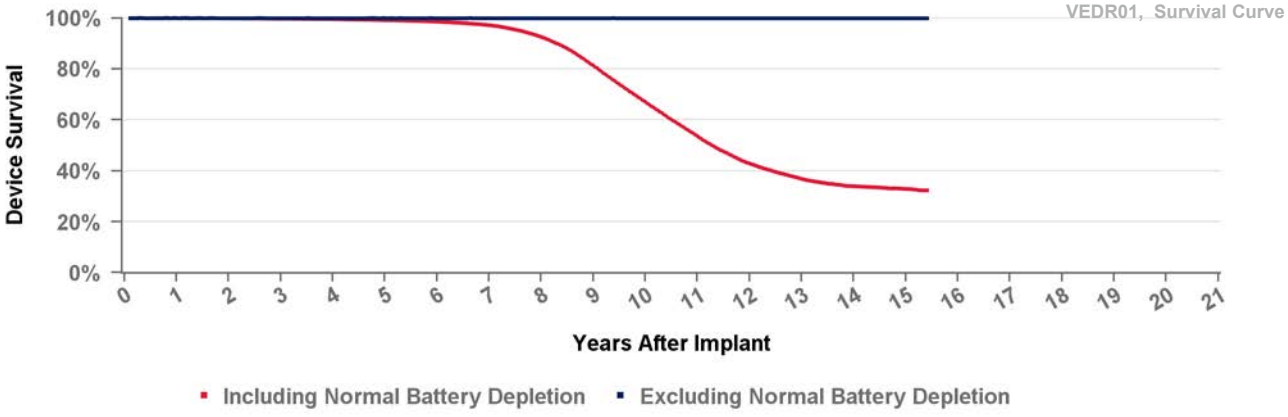
US Market Release	03Aug2017	**Total Malfunctions (USA)**	
CE Approval Date	16Jun2017	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

VEDR01 Versa DR

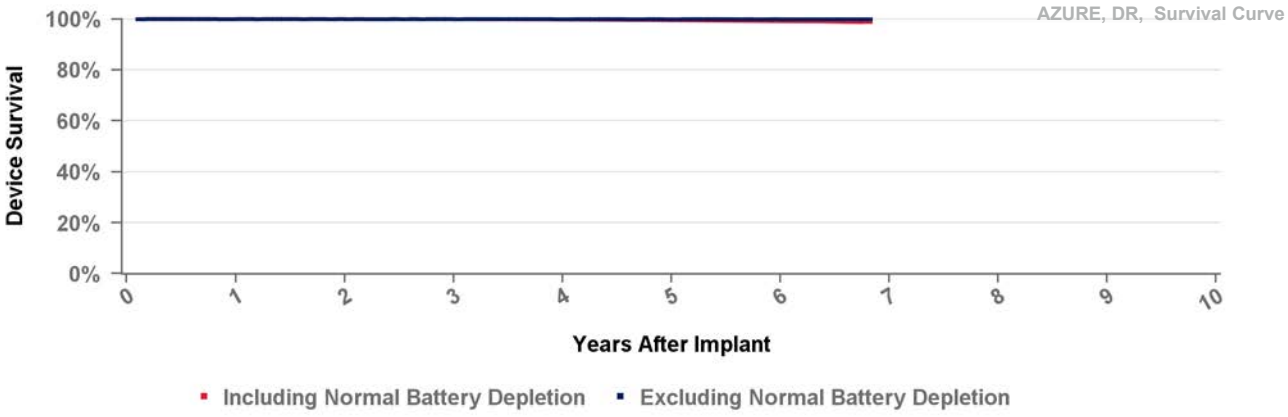
US Market Release	17Jul2006	**Total Malfunctions (USA)**	**26**
CE Approval Date	20Sep2005	**Therapy Function Not Compromised**	**11**
Registered USA Implants	118,955	Electrical Component	7
Estimated Active USA Implants	24,021	Electrical Interconnect	2
Normal Battery Depletions	14,699	Possible Early Battery Depletion	2
		Therapy Function Compromised	**15**
		Electrical Component	11
		Other	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 185 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%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.2%	98.6%	97.2%	92.5%	81.3%	67.0%	53.6%	42.9%	36.8%	34.0%	32.9%	32.4%
Effective Sample Size	98650	90156	82067	74685	67978	62015	55278	46203	34735	24253	15839	9664	5679	2976	912	125

W1DR01 Azure XT DR

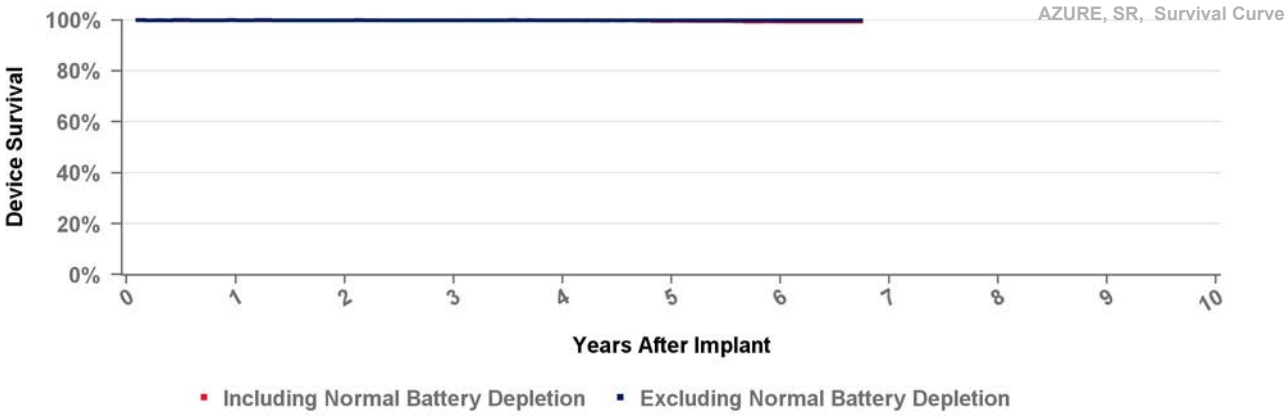
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**150**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**137**
Registered USA Implants	738,134	Battery	4
Estimated Active USA Implants	666,274	Electrical Component	84
Normal Battery Depletions	634	Possible Early Battery Depletion	5
		Software/Firmware	22
		Other	22
		Therapy Function Compromised	**13**
		Battery	2
		Electrical Component	11



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.2%	98.8%
Effective Sample Size	625708	471555	340627	226084	132936	48209	937

W1SR01 Azure XT SR

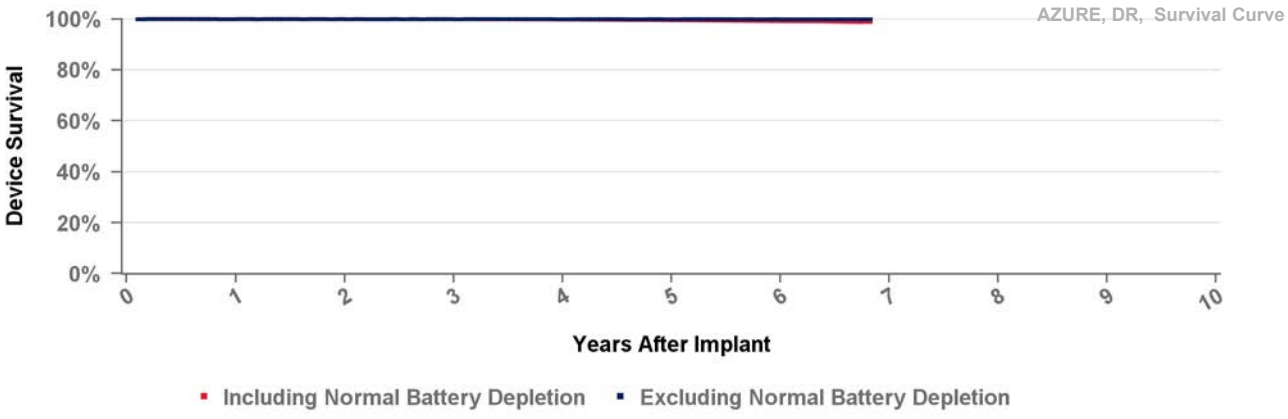
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**11**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**10**
Registered USA Implants	57,825	Battery	1
Estimated Active USA Implants	48,145	Electrical Component	6
Normal Battery Depletions	29	Software/Firmware	1
		Other	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	53593	40605	29489	19415	10997	3781	227

W2DR01 Azure XT DR

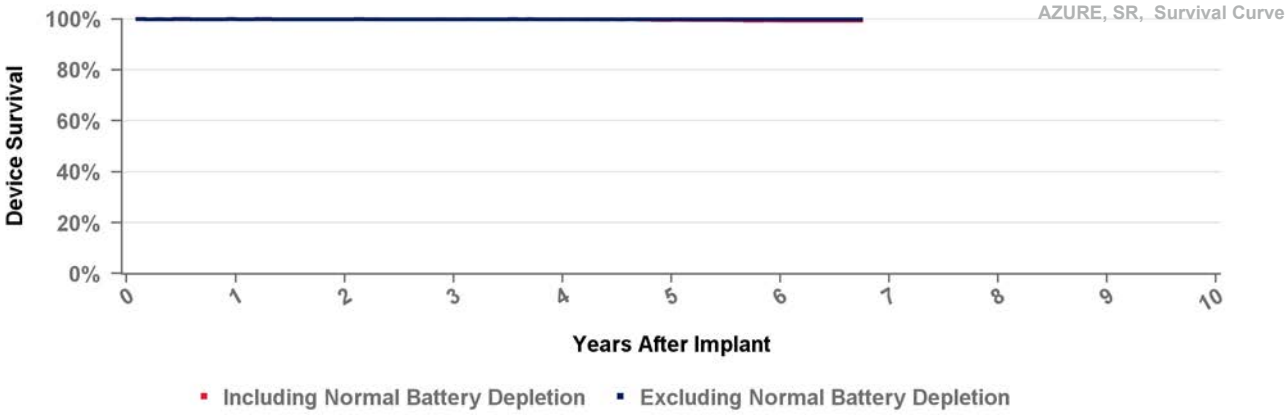
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.2%	98.8%
Effective Sample Size	625708	471555	340627	226084	132936	48209	937

W2SR01 Azure XT SR

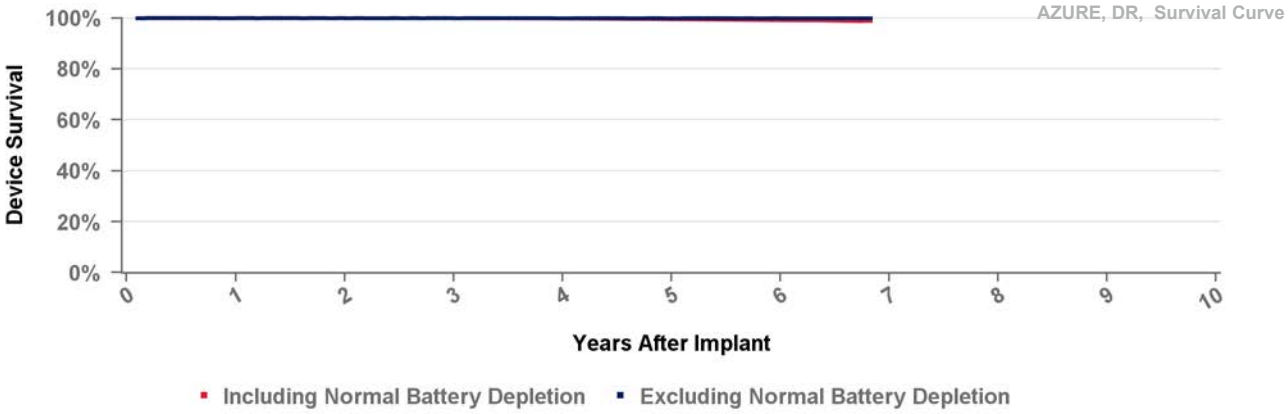
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	53593	40605	29489	19415	10997	3781	227

W3DR01 Azure S DR

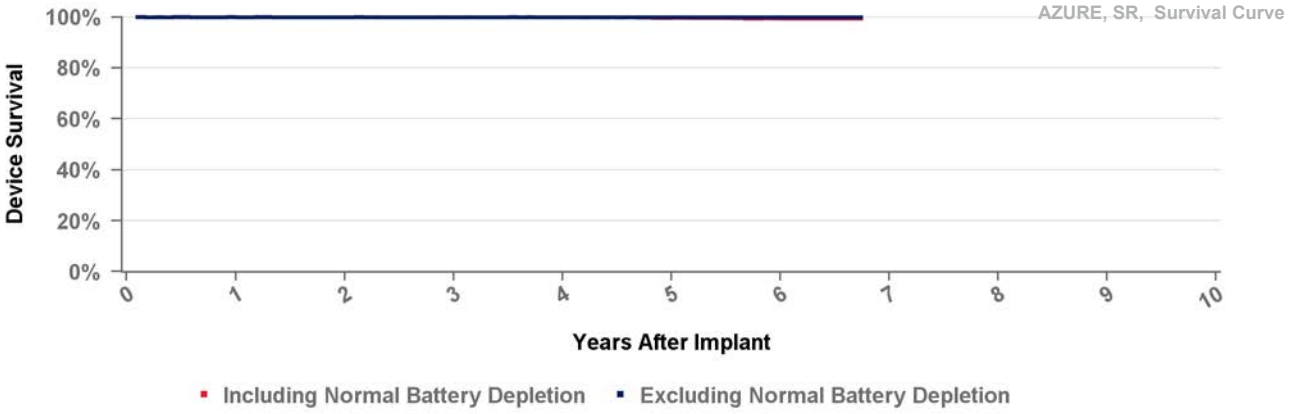
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**14**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**13**
Registered USA Implants	63,131	Electrical Component	10
Estimated Active USA Implants	55,500	Possible Early Battery Depletion	1
Normal Battery Depletions	136	Software/Firmware	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	6	at 82 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	99.2%	98.8%
Effective Sample Size	625708	471555	340627	226084	132936	48209	937

W3SR01 Azure S SR

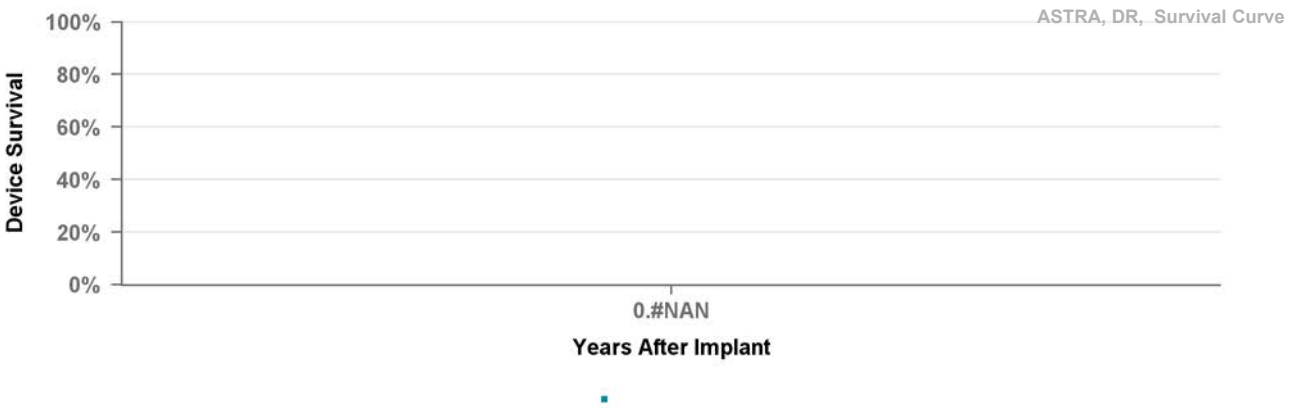
US Market Release	16Aug2017	**Total Malfunctions (USA)**	**1**
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	**1**
Registered USA Implants	13,059	Electrical Component	1
Estimated Active USA Implants	10,792	**Therapy Function Compromised**	**0**
Normal Battery Depletions	6		



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%	99.7%	99.4%	99.4%
Effective Sample Size	53593	40605	29489	19415	10997	3781	227

X2DR01 Astra XT DR MRI SureScan

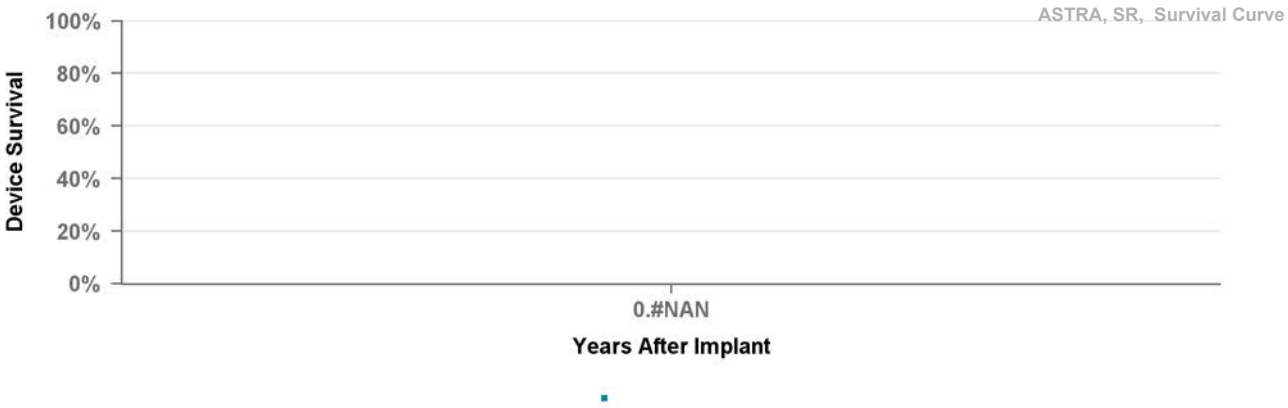
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

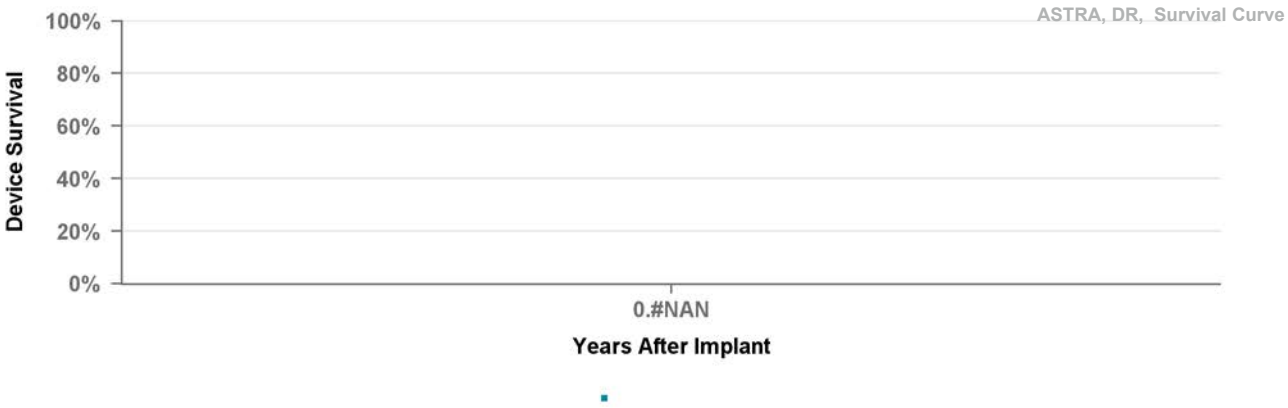
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3DR01 Astra S DR

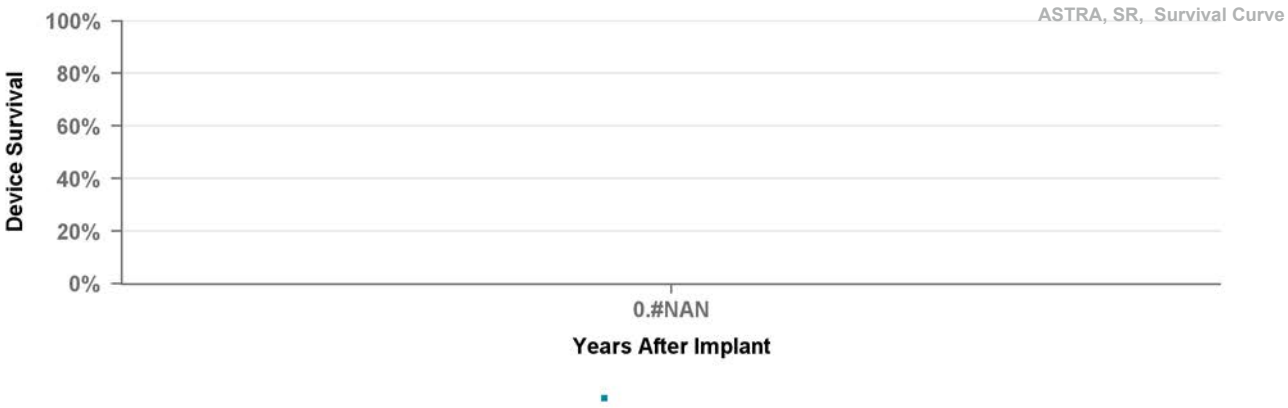
US Market Release		**Total Malfunctions (USA)**	
CE Approval Date	02Mar2017	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



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. A TPS 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 in the CareLink™ population.

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
- Tine Fracture

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 estimate 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.

MC1AVR1 Micra AV

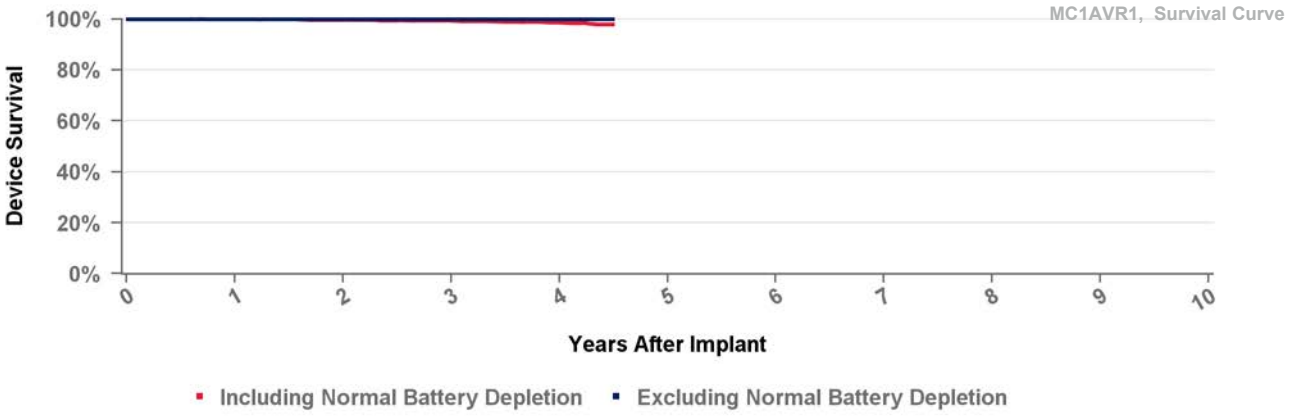
US Market Release	15Jan2020
CE Approval Date	31Mar2020
Registered USA Implants	51,498

CareLink Population

Enrolled	33,338
Active	25,894
Cumulative Follow-Up Months	709,116
Normal Battery Depletion	102

CareLink Qualifying Malfunctions/Complications

Dislodgements	3
Elevated Pacing Threshold	10
Failure To Capture	7
Premature Battery Depletion	7
Tine Fracture	1



Years	1	2	3	4	at 54 mo
Excluding NBD	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.3%	98.6%	97.9%
Effective Sample Size	24997	13567	5726	1154	109

*Acute Observations N = 51,498

Cardiac Perforation	13
Dislodgement	30
Elevated Pacing Threshold	89
Failure to Capture	46
Failure To Sense	121

*Day of Implant Observations N = 51,498

Cardiac Perforation	268
Dislodgement	86
Elevated Pacing Threshold	143
Failure to Capture	84
Failure to Sense	38

The rate of perforation for commercially released Micra 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.

MC1VR01 Micra VR

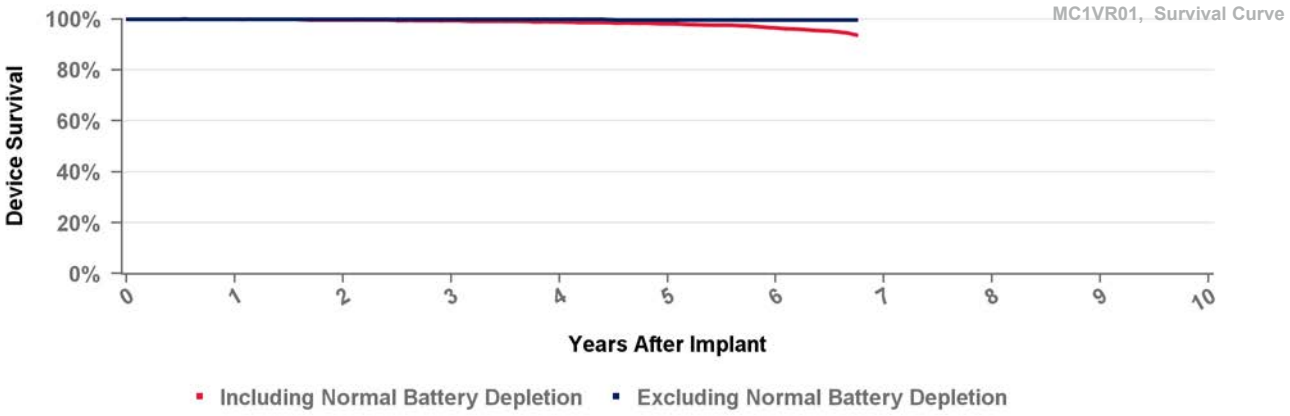
US Market Release	06Apr2016
CE Approval Date	14Apr2015
Registered USA Implants	71,898

CareLink Population

Enrolled	47,296
Active	30,494
Cumulative Follow-Up Months	1,510,074
Normal Battery Depletion	327

CareLink Qualifying Malfunctions/Complications

Cardiac Perforation	8
Dislodgements	1
Elevated Pacing Threshold	43
Failure To Capture	7
Premature Battery Depletion	13
Tine Fracture	1



Years	1	2	3	4	5	6	at 81 mo
Excluding NBD	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.7%	99.3%	98.9%	98.1%	96.5%	93.6%
Effective Sample Size	39558	28471	18937	11438	5786	1924	366

***Acute Observations N = 71,898**

Cardiac Perforation	21
Dislodgement	22
Elevated Pacing Threshold	165
Failure to Capture	83
Failure To Sense	19

***Day of Implant Observations N = 71,898**

Cardiac Perforation	291
Dislodgement	178
Elevated Pacing Threshold	268
Failure to Capture	131
Failure to Sense	72

The rate of perforation for commercially released Micra 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.

MC2AVR1 Micra AV2

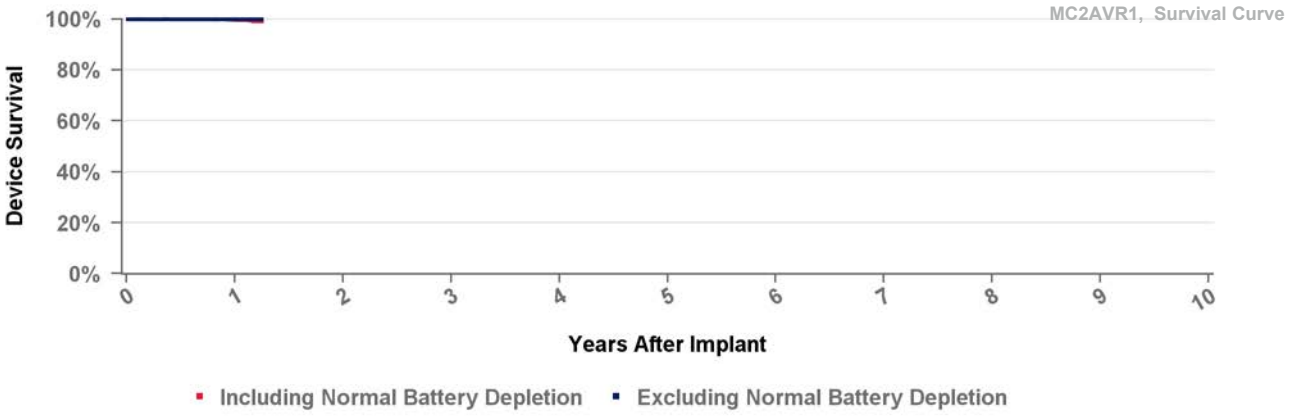
US Market Release	20Apr2023
CE Approval Date	04Jan2024
Registered USA Implants	17,387

CareLink Population

Enrolled	8,027
Active	7,666
Cumulative Follow-Up Months	46,966
Normal Battery Depletion	5

CareLink Qualifying Malfunctions/Complications

Elevated Pacing Threshold	4
Failure To Capture	1



Years	1	at 15 mo
Excluding NBD	99.9%	99.9%
Including NBD	99.7%	99.2%
Effective Sample Size	760	126

*Acute Observations N = 17,387

Cardiac Perforation	2
Dislodgement	5
Elevated Pacing Threshold	26
Failure to Capture	16
Failure To Sense	23

*Day of Implant Observations N = 17,387

Cardiac Perforation	31
Dislodgement	28
Elevated Pacing Threshold	32
Failure to Capture	24
Failure to Sense	11

The rate of perforation for commercially released Micra 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.

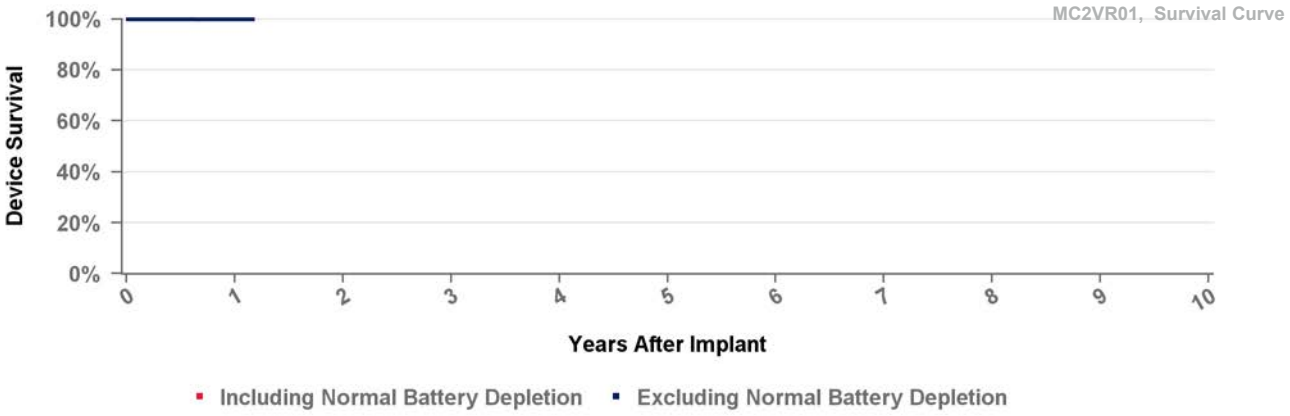
MC2VR01 Micra VR2

US Market Release	20Apr2023
CE Approval Date	04Jan2024
Registered USA Implants	6,428

CareLink Population

Enrolled	2,992
Active	2,879
Cumulative Follow-Up Months	17,451
Normal Battery Depletion	2

CareLink Qualifying Malfunctions/Complications



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.8%	99.8%
Effective Sample Size	290	115

*Acute Observations N = 6,428

Dislodgement	3
Elevated Pacing Threshold	14
Failure to Capture	8
Failure To Sense	5

*Day of Implant Observations N = 6,428

Cardiac Perforation	7
Dislodgement	10
Elevated Pacing Threshold	20
Failure to Capture	13
Failure to Sense	4

The rate of perforation for commercially released Micra 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 41 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	259,709
Estimated Active USA Implants	225,918
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	41
Insulation Breach	111
Crimp/Weld/Bond	0
Other	23

US Acute Lead Observations

Cardiac Perforation	86
Conductor Fracture	5
Extra Cardiac Stimulation	12
Failure to Capture	664
Failure to Sense	103
Impedance Out of Range	61
Insulation Breach	2
Lead Dislodgement	855
Oversensing	133
Unspecified Clinical Failure	2

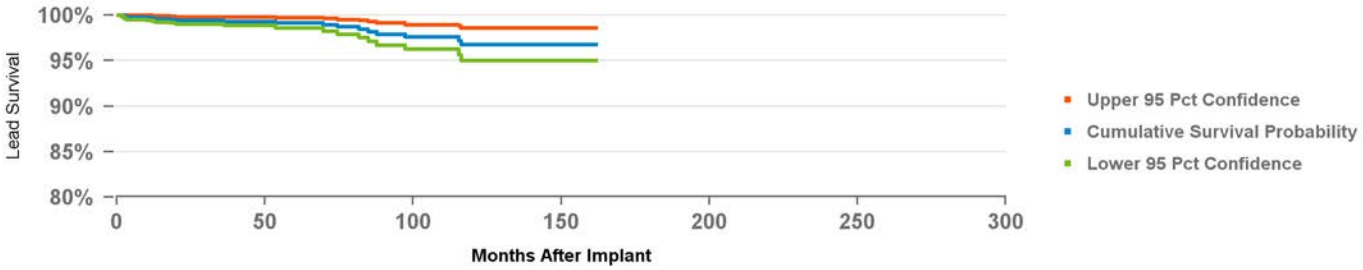
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,841
Cumulative Months of Follow-Up	93,107
Number of Leads Active in Study	667

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		
Failure to Sense	3		



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	99.6%	99.4%	99.4%	99.3%	99.1%	98.9%	98.4%	97.9%	97.6%	96.7%	96.7%	96.7%	96.7%	96.7%
#	1,488	1,145	933	704	568	456	378	320	272	220	192	156	85	62

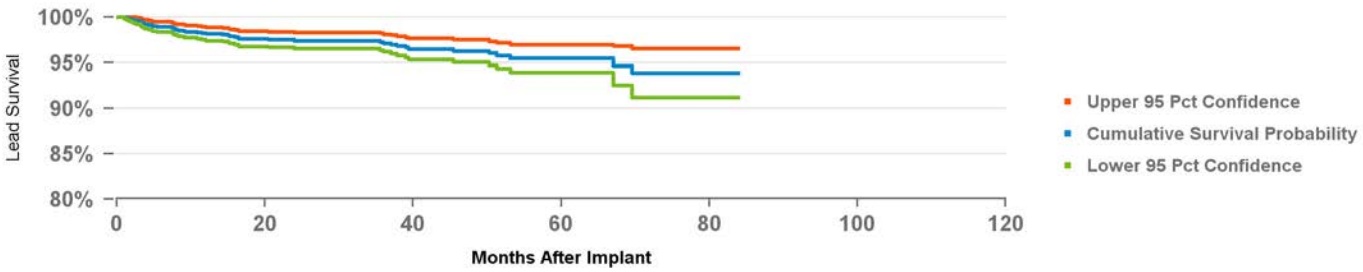
His Bundle Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,506
Cumulative Months of Follow-Up	51,303
Number of Leads Active in Study	916

Qualifying Complications 46

Extra Cardiac Stimulation	1	Lead Dislodgement	5
Failure to Capture	33	Oversensing	1
Failure to Sense	3	Other	3



Years	1	2	3	4	5	6	at 84 mo
%	98.2%	97.4%	97.1%	96.3%	95.4%	93.8%	93.8%
#	1,215	955	670	418	208	96	54

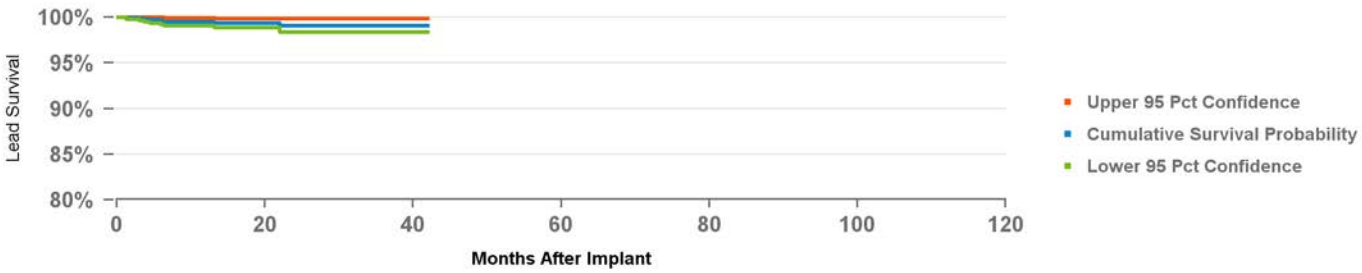
Left Bundle Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,154
Cumulative Months of Follow-Up	21,713
Number of Leads Active in Study	1,926

Qualifying Complications 8

Failure to Capture	3	Impedance Out of Range	1
		Lead Dislodgement	4



Years	1	2	3	at 42 mo
%	99.5%	99.1%	99.1%	99.1%
#	804	309	122	69

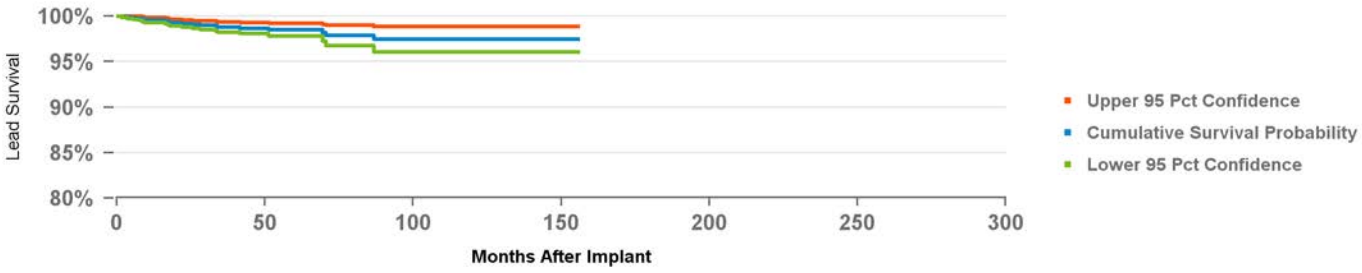
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,602
Cumulative Months of Follow-Up	93,014
Number of Leads Active in Study	1,551

Qualifying Complications 25

Failure to Capture	13	Impedance Out of Range	2
		Lead Dislodgement	8
		Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	99.2%	98.8%	98.7%	98.5%	97.8%	97.8%	97.4%	97.4%	97.4%	97.4%	97.4%	97.4%
#	2,107	1,377	919	602	402	298	240	191	162	125	106	89	52

4074 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	157,705
Estimated Active USA Implants	76,257
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Insulation Breach	63
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

Cardiac Perforation	36
Conductor Fracture	2
Extra Cardiac Stimulation	4
Failure to Capture	196
Failure to Sense	19
Impedance Out of Range	14
Lead Dislodgement	213
Oversensing	9

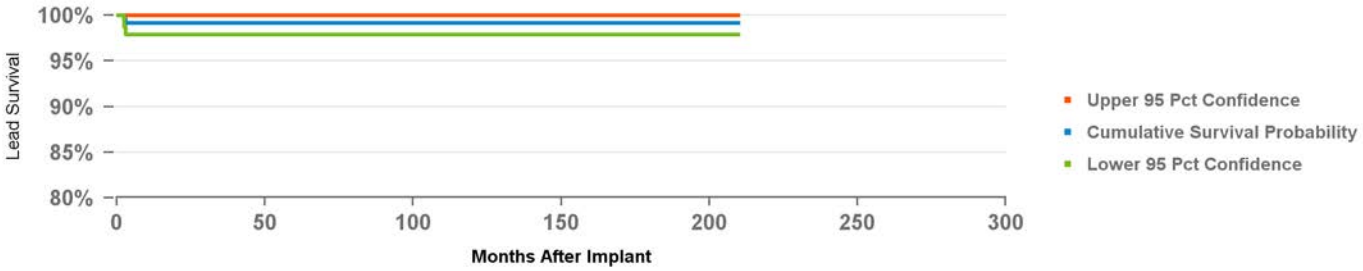
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Cumulative Months of Follow-Up	29,664
Number of Leads Active in Study	56

Qualifying Complications 2

Failure to Sense	1
Lead Dislodgement	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	at 210 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%	99.1%
#	214	205	198	183	167	158	148	136	126	117	110	107	99	95	88	77	59	52

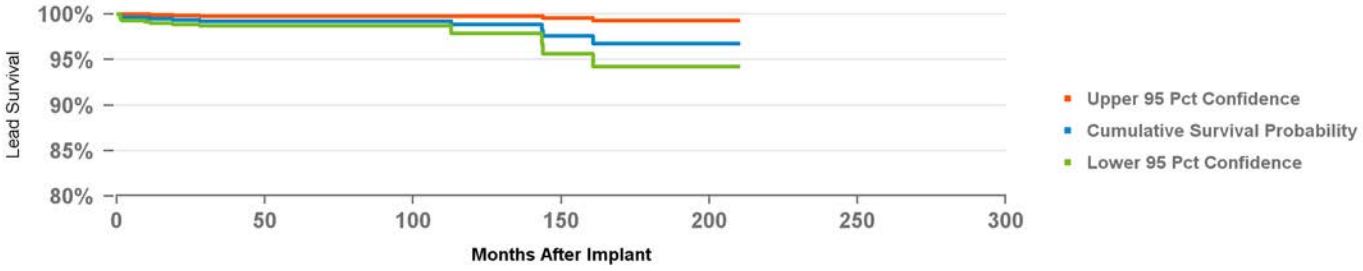
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,192
Cumulative Months of Follow-Up	81,246
Number of Leads Active in Study	142

Qualifying Complications 12

Conductor Fracture	1
Failure to Capture	4
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	17	at 210 mo
%	99.5%	99.3%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.8%	98.8%	97.6%	97.6%	96.8%	96.8%	96.8%	96.8%	96.8%
#	1,030	879	738	635	493	399	339	298	258	219	182	154	126	118	111	90	62	51

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	845,596
Estimated Active USA Implants	496,060
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	134
Insulation Breach	231
Crimp/Weld/Bond	2
Other	23

US Acute Lead Observations

Cardiac Perforation	284
Conductor Fracture	11
Extra Cardiac Stimulation	28
Failure to Capture	435
Failure to Sense	306
Impedance Out of Range	77
Insulation Breach	2
Lead Dislodgement	966
Oversensing	171
Unspecified Clinical Failure	10

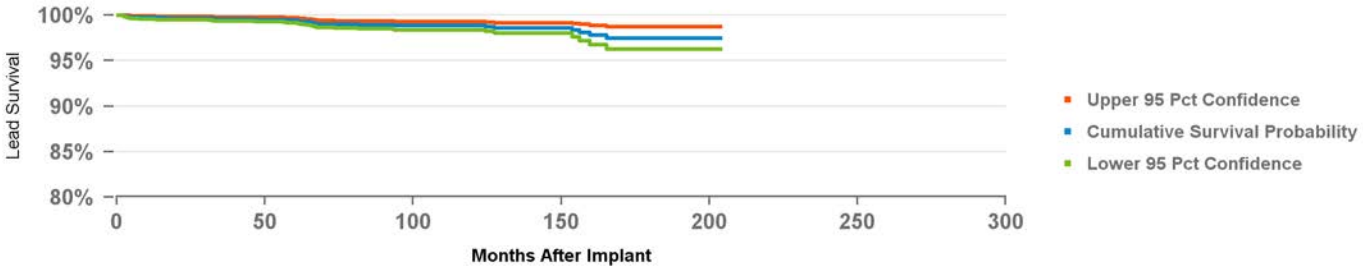
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	5,106
Cumulative Months of Follow-Up	292,446
Number of Leads Active in Study	1,742

Qualifying Complications 38

Cardiac Perforation	2	Insulation (not further defined)	3
Conductor Fracture	3	Lead Dislodgement	14
Failure to Capture	9	Oversensing	2
Failure to Sense	3	Other	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 204 mo
%	99.7%	99.6%	99.6%	99.5%	99.4%	99.0%	98.9%	98.8%	98.8%	98.8%	98.6%	98.6%	98.3%	97.4%	97.4%	97.4%	97.4%
#	3,673	3,098	2,694	2,351	1,963	1,678	1,475	1,283	1,095	907	681	493	379	260	163	109	60

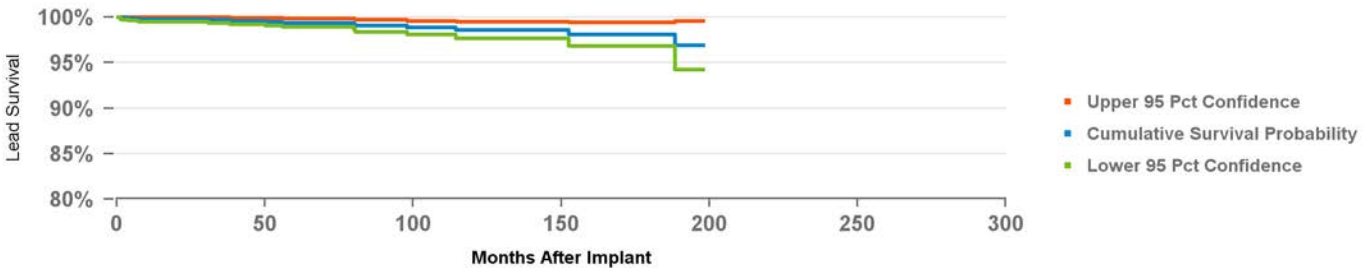
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,778
Cumulative Months of Follow-Up	121,366
Number of Leads Active in Study	279

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	16	at 198 mo
%	99.7%	99.7%	99.7%	99.6%	99.4%	99.4%	99.0%	99.0%	98.8%	98.6%	98.6%	98.6%	98.1%	98.1%	98.1%	96.9%	96.9%
#	1,455	1,305	1,156	994	799	688	568	489	428	363	290	234	198	148	100	70	53

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	186,243
Estimated Active USA Implants	36,083
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	21
Insulation Breach	101
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

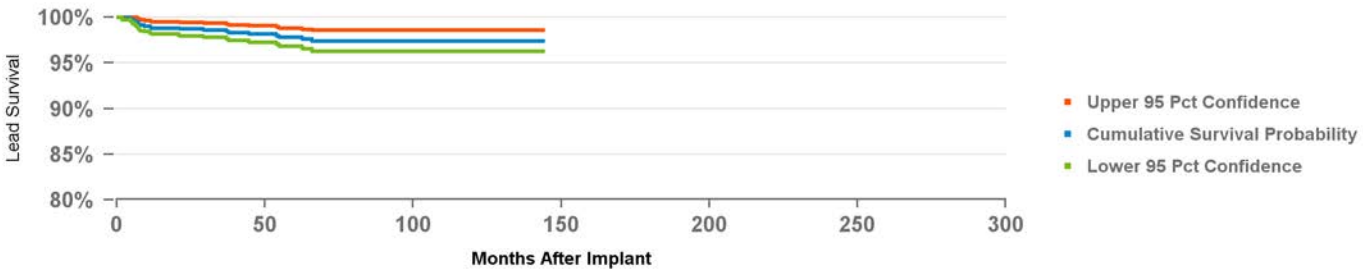
Cardiac Perforation	4
Conductor Fracture	4
Extra Cardiac Stimulation	1
Failure to Capture	35
Impedance Out of Range	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,202
Cumulative Months of Follow-Up	70,291
Number of Leads Active in Study	8

Qualifying Complications 21

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



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	239	158	93	57

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	124,110
Estimated Active USA Implants	71,424
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	14
Insulation Breach	26
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

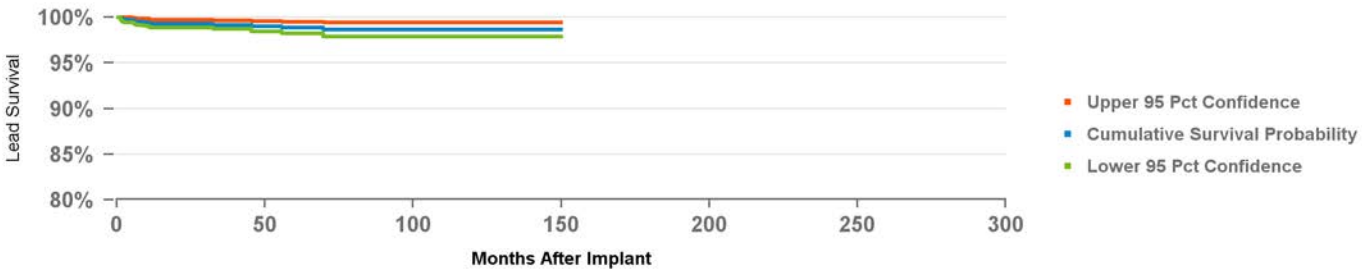
Cardiac Perforation	4
Conductor Fracture	1
Extra Cardiac Stimulation	1
Failure to Capture	187
Failure to Sense	91
Impedance Out of Range	12
Lead Dislodgement	290
Oversensing	18
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,777
Cumulative Months of Follow-Up	84,545
Number of Leads Active in Study	653

Qualifying Complications 15

Conductor Fracture	2	Lead Dislodgement	7
Failure to Capture	6		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.3%	99.3%	99.2%	99.0%	98.8%	98.6%	98.6%	98.6%	98.6%	98.6%	98.6%	98.6%	98.6%
#	1,365	1,048	819	651	528	450	377	310	240	169	115	65	51

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	89,801
Estimated Active USA Implants	19,678
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	17
Insulation Breach	34
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

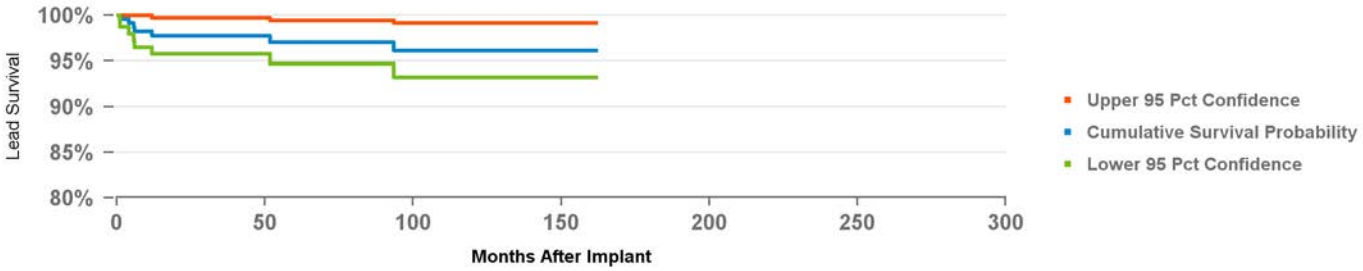
Failure to Capture	10
Failure to Sense	2
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	369
Cumulative Months of Follow-Up	23,033
Number of Leads Active in Study	26

Qualifying Complications 9

Failure to Capture	4	Lead Dislodgement	3
Failure to Sense	1	Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	97.7%	97.7%	97.7%	97.7%	97.0%	97.0%	97.0%	96.1%	96.1%	96.1%	96.1%	96.1%	96.1%	96.1%
#	204	182	167	158	134	126	110	105	99	88	82	78	60	51

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	100,058
Estimated Active USA Implants	18,278
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Insulation Breach	47
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

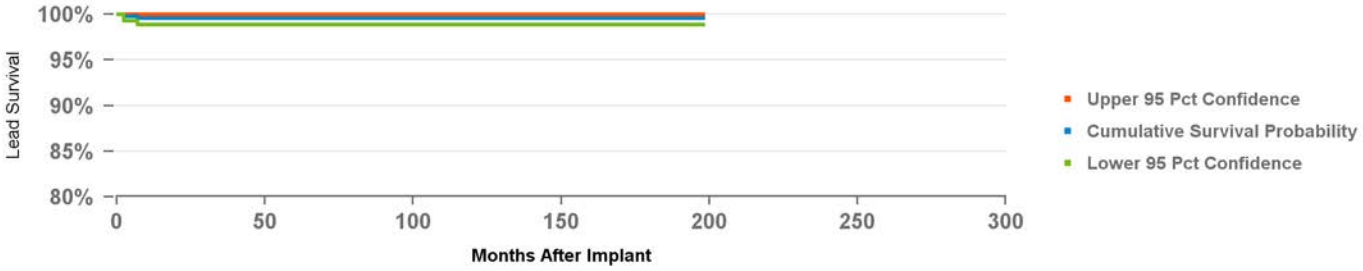
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	425
Cumulative Months of Follow-Up	42,354
Number of Leads Active in Study	18

Qualifying Complications 3

Failure to Capture	2	Lead Dislodgement	1



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	185	152	128	107	92	74	64	58	51	50

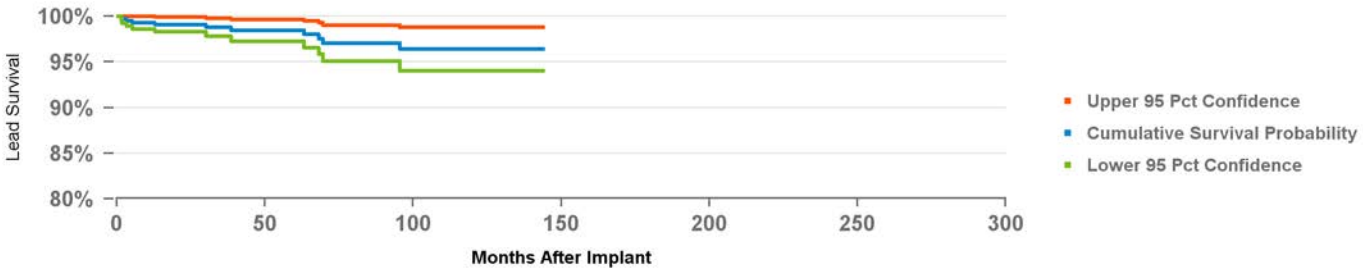
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	992
Cumulative Months of Follow-Up	35,826
Number of Leads Active in Study	13

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	192	167	144	114	94	72	54

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	3,442,082
Estimated Active USA Implants	1,961,260
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,571
Insulation Breach	1,666
Crimp/Weld/Bond	4
Other	206

US Acute Lead Observations

Cardiac Perforation	1,746
Conductor Fracture	35
Extra Cardiac Stimulation	115
Failure to Capture	2,722
Failure to Sense	1,723
Impedance Out of Range	468
Insulation Breach	16
Lead Dislodgement	5,589
Oversensing	976
Unspecified Clinical Failure	26

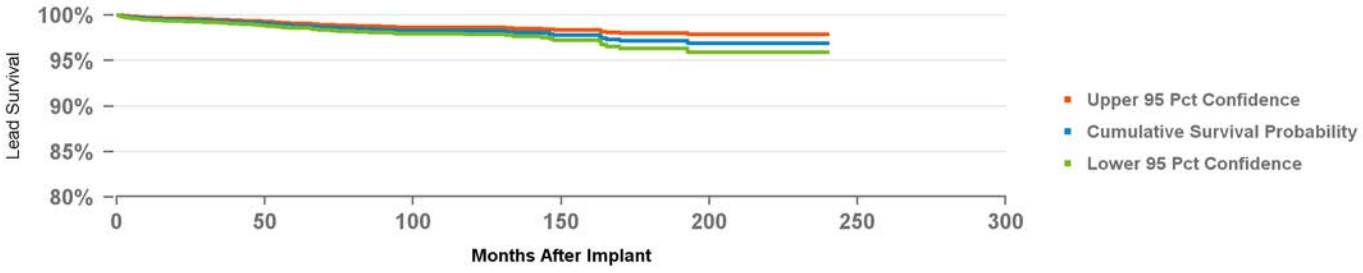
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	14,182
Cumulative Months of Follow-Up	673,573
Number of Leads Active in Study	5,402

Qualifying Complications 123

Cardiac Perforation	2	Impedance Out of Range	13
Conductor Fracture	13	Insulation (not further defined)	3
Extra Cardiac Stimulation	3	Lead Dislodgement	47
Failure to Capture	18	Oversensing	3
Failure to Sense	12	Other	9



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	at 240 mo
%	99.6%	99.4%	99.3%	99.1%	98.8%	98.6%	98.4%	98.3%	98.3%	98.2%	98.2%	98.0%	97.8%	97.3%	97.1%	97.1%	96.9%	96.9%	96.9%	96.9%
#	9,581	7,580	6,305	5,300	4,416	3,686	3,096	2,458	1,948	1,579	1,236	953	748	577	458	381	291	200	118	68

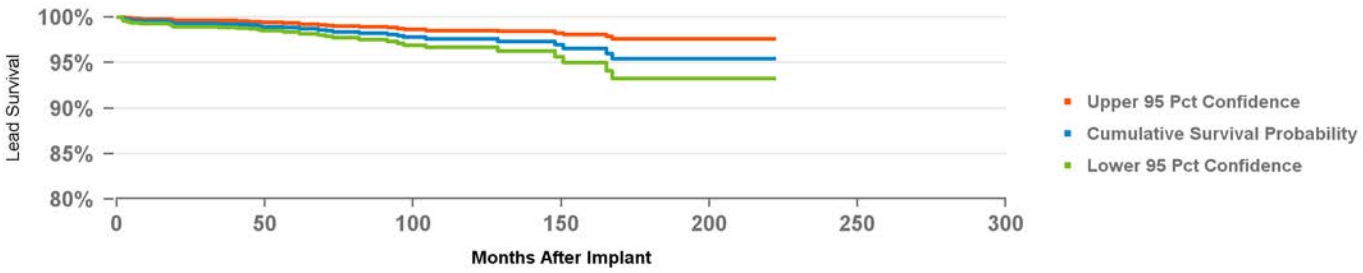
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,431
Cumulative Months of Follow-Up	170,887
Number of Leads Active in Study	578

Qualifying Complications 38

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	9	Insulation (not further defined)	1
Failure to Capture	13	Lead Dislodgement	5
Failure to Sense	1	Oversensing	2
		Other	2



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%	99.2%	99.0%	98.9%	98.5%	98.2%	97.9%	97.6%	97.6%	97.3%	97.3%	96.5%	95.4%	95.4%	95.4%	95.4%	95.4%	95.4%
#	2,256	1,929	1,627	1,343	1,108	883	724	605	527	456	353	279	207	167	138	118	90	66	57

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	207,819
Estimated Active USA Implants	125,891
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	119
Insulation Breach	216
Crimp/Weld/Bond	0
Other	12

US Acute Lead Observations

Cardiac Perforation	214
Conductor Fracture	4
Extra Cardiac Stimulation	18
Failure to Capture	144
Failure to Sense	29
Impedance Out of Range	9
Insulation Breach	2
Lead Dislodgement	311
Oversensing	31

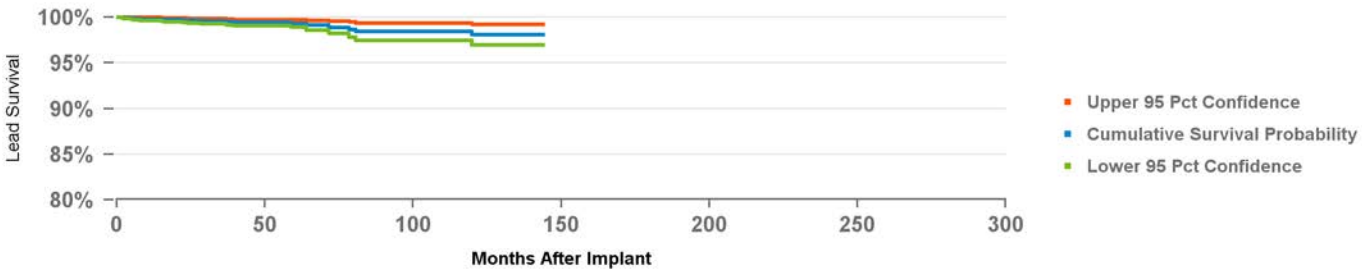
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,142
Cumulative Months of Follow-Up	147,112
Number of Leads Active in Study	1,288

Qualifying Complications 21

Conductor Fracture	3	Lead Dislodgement	12
Failure to Capture	3	Oversensing	2
		Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.8%	99.6%	99.6%	99.4%	99.3%	98.9%	98.4%	98.4%	98.4%	98.1%	98.1%	98.1%
#	2,528	2,202	1,877	1,460	766	452	397	352	317	281	169	68

Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,073
Cumulative Months of Follow-Up	144,430
Number of Leads Active in Study	1,268

Qualifying Complications 20

Conductor Fracture	3	Impedance Out of Range	2
Failure to Capture	8	Lead Dislodgement	3
Failure to Sense	1	Oversensing	2
		Other	1

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.7%	99.7%	99.6%	99.6%	99.6%	99.3%	98.3%	98.0%	98.0%	98.0%	98.0%	97.4%
#	2,526	2,183	1,850	1,426	735	423	375	332	300	266	162	65

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	141,706
Estimated Active USA Implants	29,054
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	28
Insulation Breach	73
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

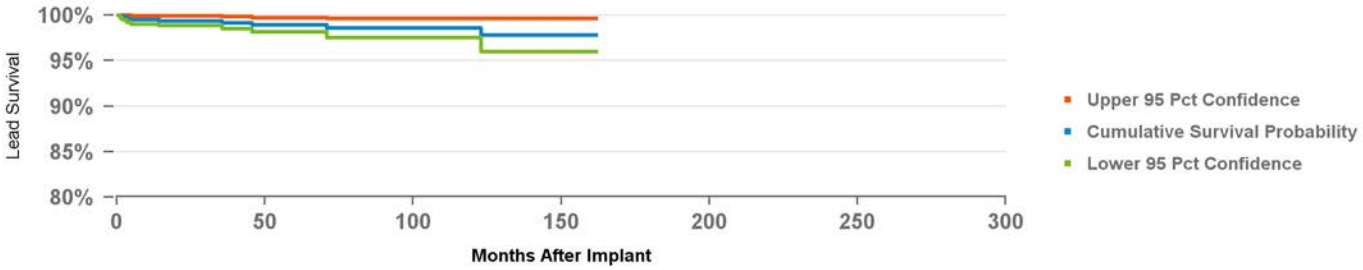
Cardiac Perforation	7
Conductor Fracture	3
Extra Cardiac Stimulation	3
Failure to Capture	49
Failure to Sense	7
Impedance Out of Range	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Unspecified Clinical Failure	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,218
Cumulative Months of Follow-Up	54,736
Number of Leads Active in Study	13

Qualifying Complications 10

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	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	265	219	173	149	133	110	81	57	53

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,868
Estimated Active USA Implants	14,258
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	24
Insulation Breach	44
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

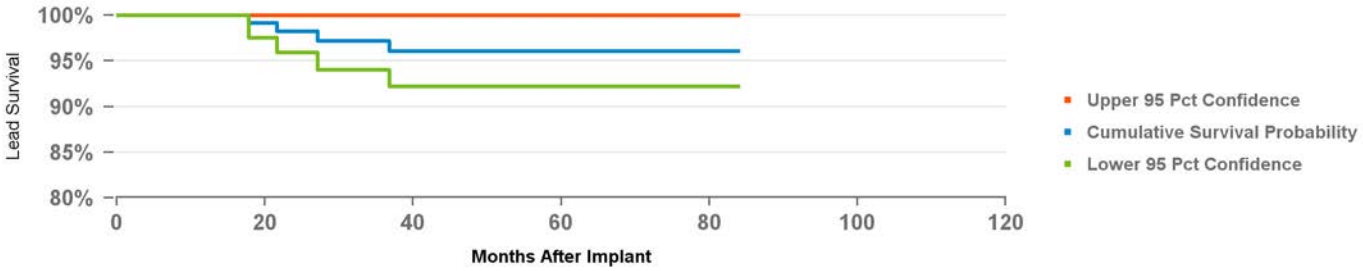
Conductor Fracture	1
Failure to Capture	31
Failure to Sense	2
Impedance Out of Range	1
Lead Dislodgement	39
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	370
Cumulative Months of Follow-Up	9,500
Number of Leads Active in Study	9

Qualifying Complications 5

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



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	37,335
Estimated Active USA Implants	9,806
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

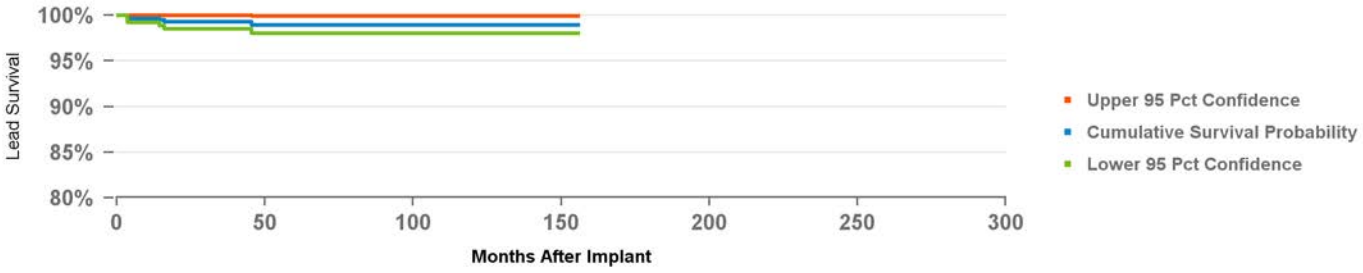
Cardiac Perforation	1
Failure to Capture	4
Failure to Sense	3
Lead Dislodgement	43
Oversensing	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	722
Cumulative Months of Follow-Up	39,777
Number of Leads Active in Study	27

Qualifying Complications 5

Failure to Capture	3	Lead Dislodgement	2



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	132	118	100	71	51

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,612
Estimated Active USA Implants	5,469
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

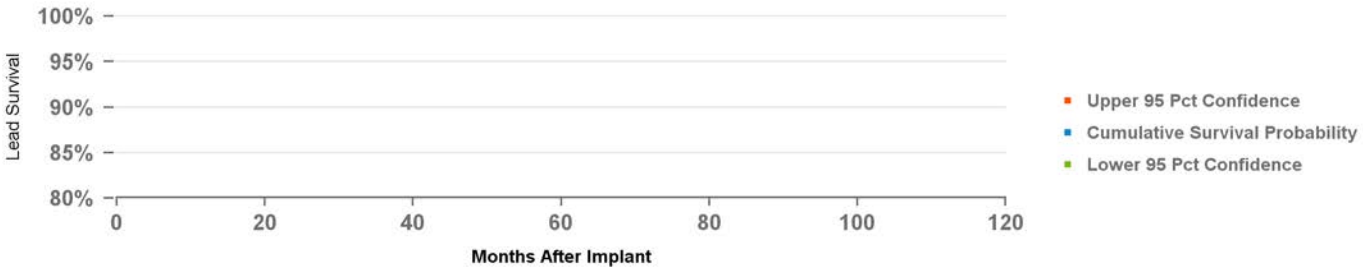
Failure to Capture	4
Lead Dislodgement	14
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	43
Cumulative Months of Follow-Up	4,691
Number of Leads Active in Study	11

Qualifying Complications 3

Conductor Fracture	1	Insulation (not further defined)	1
		Oversensing	1



Years	at 0 mo
%	#####
#	

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,428
Estimated Active USA Implants	863
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

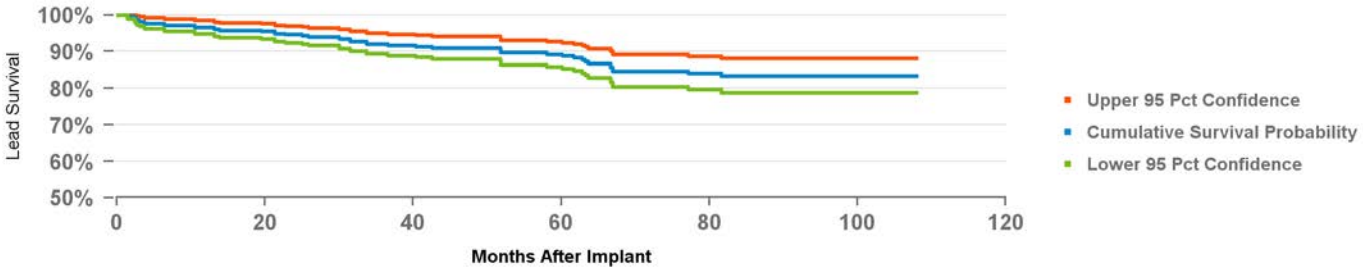
Cardiac Perforation	1
Conductor Fracture	2
Failure to Capture	4
Failure to Sense	2
Impedance Out of Range	24
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	417
Cumulative Months of Follow-Up	24,217
Number of Leads Active in Study	5

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%
#	347	319	274	221	190	136	102	66	57

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	63
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

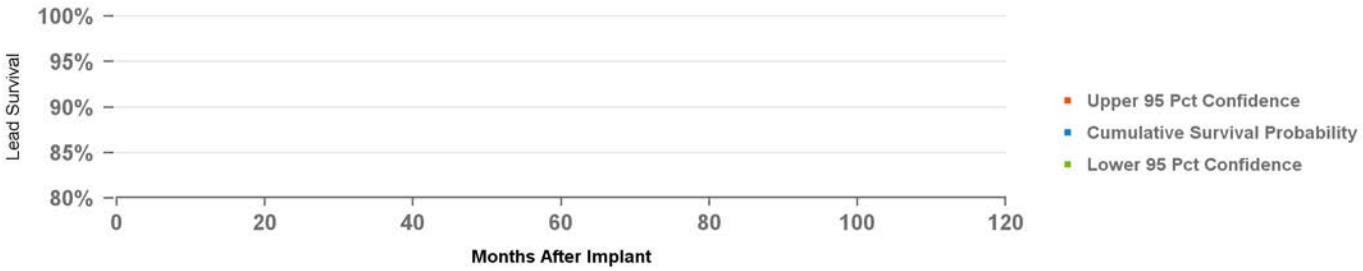
Conductor Fracture	5
Insulation Breach	0
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	332
Number of Leads Active in Study	



Years	at 0 mo
%	#####
#	

6931 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	8,081
Estimated Active USA Implants	1,161
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	670
Insulation Breach	1
Crimp/Weld/Bond	0
Other	5

US Acute Lead Observations

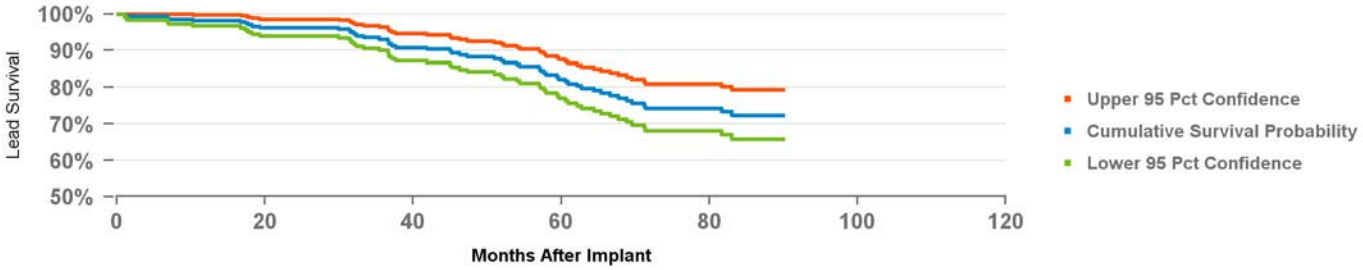
Cardiac Perforation	1
Conductor Fracture	2
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	311
Cumulative Months of Follow-Up	18,133
Number of Leads Active in Study	7

Qualifying Complications 59

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



Years	1	2	3	4	5	6	7	at 90 mo
%	98.2%	96.2%	93.1%	88.3%	82.2%	74.3%	72.3%	72.3%
#	261	232	204	166	137	104	70	56

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	68,869
Estimated Active USA Implants	40,278
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	492
Insulation Breach	14
Crimp/Weld/Bond	0
Other	44

US Acute Lead Observations

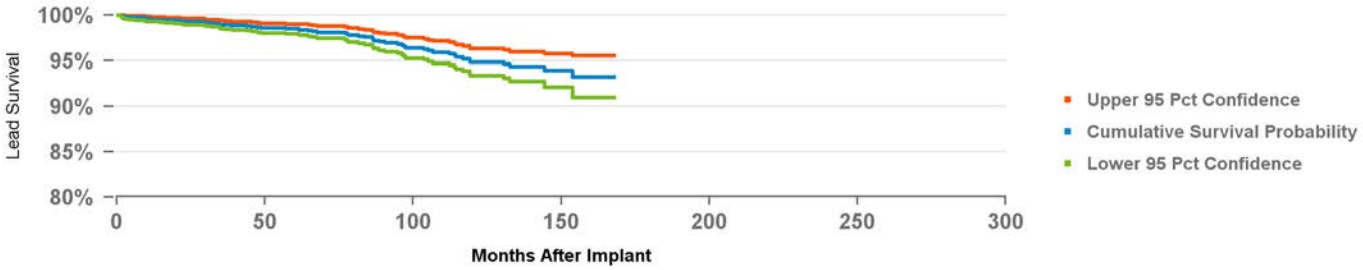
Cardiac Perforation	30
Conductor Fracture	3
Extra Cardiac Stimulation	2
Failure to Capture	42
Failure to Sense	16
Impedance Out of Range	34
Insulation Breach	1
Lead Dislodgement	68
Oversensing	70
Unspecified Clinical Failure	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,023
Cumulative Months of Follow-Up	172,950
Number of Leads Active in Study	608

Qualifying Complications 69

Cardiac Perforation	1	Impedance Out of Range	8
Conductor Fracture	26	Lead Dislodgement	8
Extra Cardiac Stimulation	1	Oversensing	9
Failure to Capture	8	Other	6
Failure to Sense	1	Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.5%	99.3%	98.9%	98.6%	98.5%	98.1%	97.5%	96.8%	95.9%	94.8%	94.6%	94.3%	93.2%	93.2%
#	2,476	2,022	1,657	1,352	1,152	997	832	702	601	496	376	223	118	51

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	414,235
Estimated Active USA Implants	341,226
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	844
Insulation Breach	37
Crimp/Weld/Bond	2
Other	104

US Acute Lead Observations

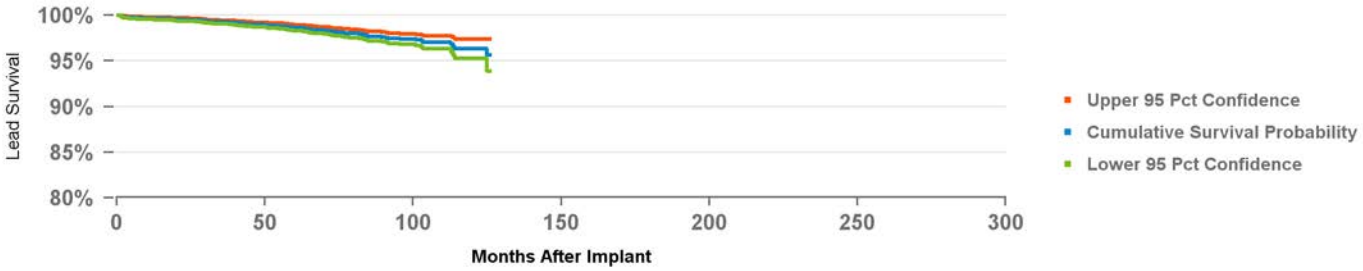
Cardiac Perforation	210
Conductor Fracture	22
Extra Cardiac Stimulation	34
Failure to Capture	496
Failure to Sense	177
Impedance Out of Range	147
Insulation Breach	3
Lead Dislodgement	694
Oversensing	378

Product Surveillance Registry Results

Number of Leads Enrolled in Study	10,085
Cumulative Months of Follow-Up	424,941
Number of Leads Active in Study	4,231

Qualifying Complications 119

Cardiac Perforation	2	Impedance Out of Range	10
Conductor Fracture	54	Insulation (not further defined)	3
Extra Cardiac Stimulation	1	Lead Dislodgement	23
Failure to Capture	14	Oversensing	5
Failure to Sense	1	Other	5
		Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.6%	99.5%	99.2%	99.0%	98.6%	98.2%	97.8%	97.4%	97.0%	96.3%	95.6%
#	7,654	5,730	4,571	3,762	3,092	2,475	1,865	1,116	563	234	115

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	3,126
Estimated Active USA Implants	1,611
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

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

US Acute Lead Observations

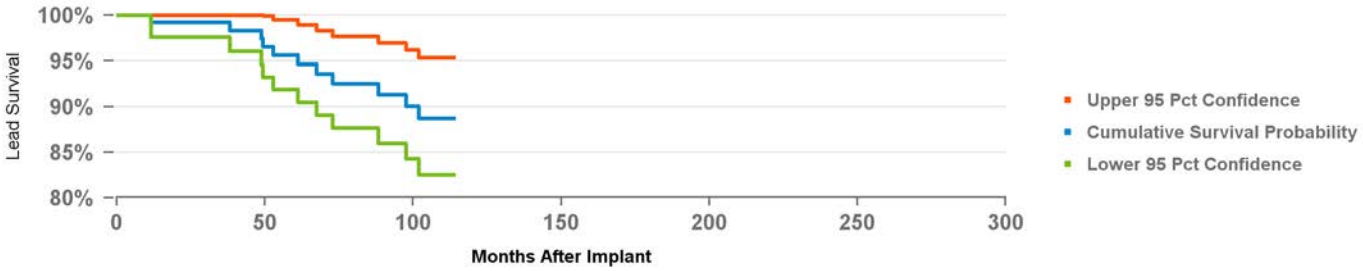
Cardiac Perforation	1
Conductor Fracture	3
Impedance Out of Range	2
Lead Dislodgement	1
Oversensing	2
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	127
Cumulative Months of Follow-Up	14,560
Number of Leads Active in Study	8

Qualifying Complications 16

Conductor Fracture	6
Impedance Out of Range	2
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%	95.6%	93.6%	92.5%	91.3%	88.7%	88.7%
#	119	117	114	109	98	87	79	73	60	54

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,865
Estimated Active USA Implants	11,792
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	237
Insulation Breach	4
Crimp/Weld/Bond	1
Other	4

US Acute Lead Observations

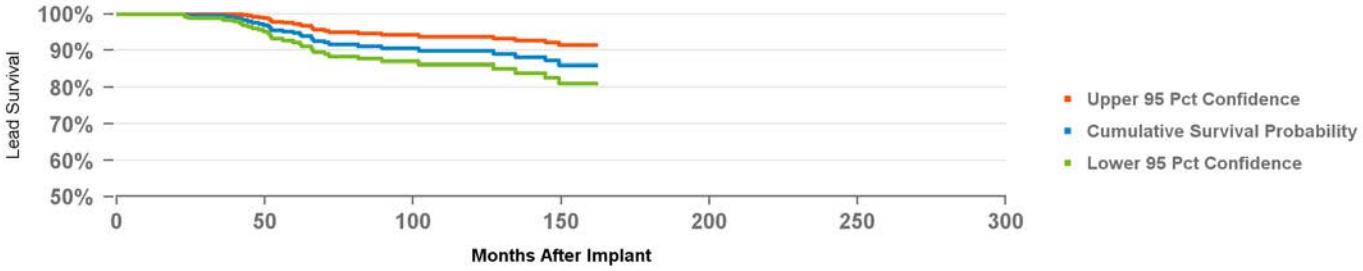
Conductor Fracture	2
Failure to Capture	17
Failure to Sense	3
Impedance Out of Range	10
Lead Dislodgement	24
Oversensing	18
Unspecified Clinical Failure	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	640
Cumulative Months of Follow-Up	38,786
Number of Leads Active in Study	63

Qualifying Complications 34

Conductor Fracture	18
Failure to Capture	4
Failure to Sense	1
Impedance Out of Range	6
Oversensing	3
Other	1
Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	#####	99.8%	99.2%	97.3%	94.8%	91.7%	91.1%	90.6%	89.9%	89.9%	89.1%	88.2%	86.1%	86.1%
#	502	418	352	290	228	192	165	147	132	118	106	91	62	54

6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	4,556
Estimated Active USA Implants	3,959
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

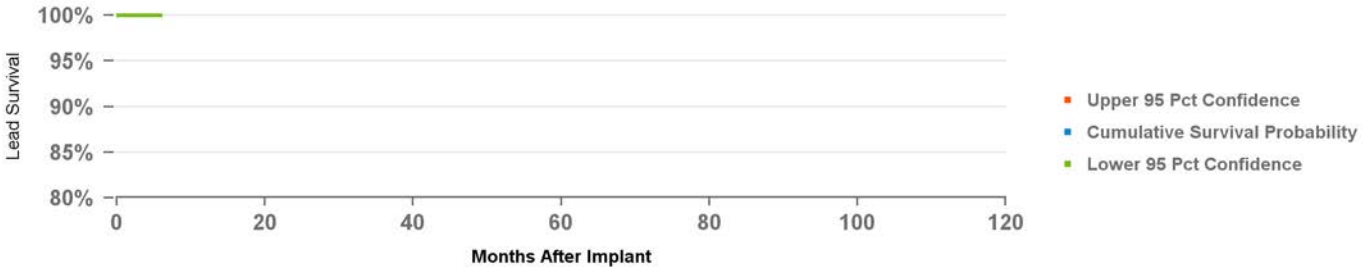
Cardiac Perforation	1
Failure to Capture	6
Failure to Sense	2
Impedance Out of Range	1
Lead Dislodgement	9
Oversensing	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	62
Cumulative Months of Follow-Up	2,286
Number of Leads Active in Study	35

Qualifying Complications 1

Conductor Fracture	1



Years	at 6 mo
%	#####
#	57

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	375,691
Estimated Active USA Implants	124,606
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,426
Insulation Breach	103
Crimp/Weld/Bond	4
Other	197

US Acute Lead Observations

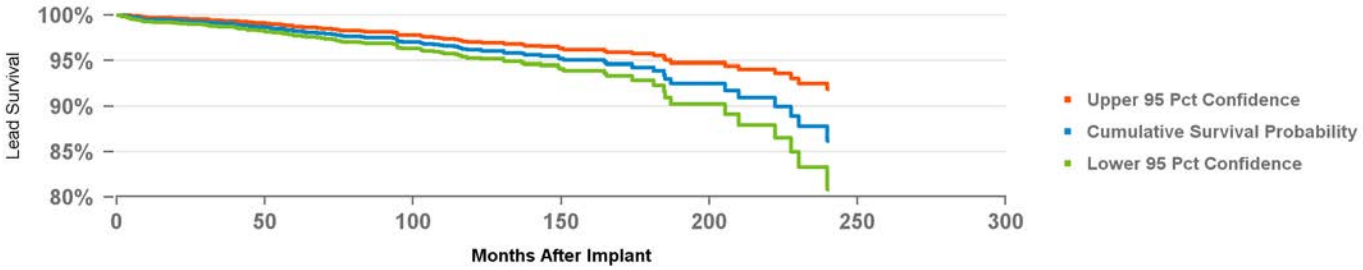
Cardiac Perforation	29
Conductor Fracture	26
Extra Cardiac Stimulation	2
Failure to Capture	83
Failure to Sense	36
Impedance Out of Range	61
Insulation Breach	4
Lead Dislodgement	125
Oversensing	141
Unspecified Clinical Failure	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,600
Cumulative Months of Follow-Up	302,679
Number of Leads Active in Study	529

Qualifying Complications 105

Cardiac Perforation	1	Impedance Out of Range	13
Conductor Fracture	42	Insulation (not further defined)	6
Failure to Capture	8	Lead Dislodgement	5
Failure to Sense	2	Oversensing	21
		Other	4
		Unspecified Clinical Failure	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	at 240 mo
%	99.5%	99.3%	99.0%	98.7%	98.2%	97.9%	97.5%	97.1%	96.7%	96.1%	95.9%	95.5%	95.0%	94.6%	94.3%	92.5%	92.5%	91.0%	88.9%	86.2%
#	3,307	2,907	2,552	2,262	2,027	1,788	1,545	1,385	1,239	1,085	911	720	561	399	241	159	122	109	82	50

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	139,606
Estimated Active USA Implants	96,001
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	264
Insulation Breach	15
Crimp/Weld/Bond	1
Other	37

US Acute Lead Observations

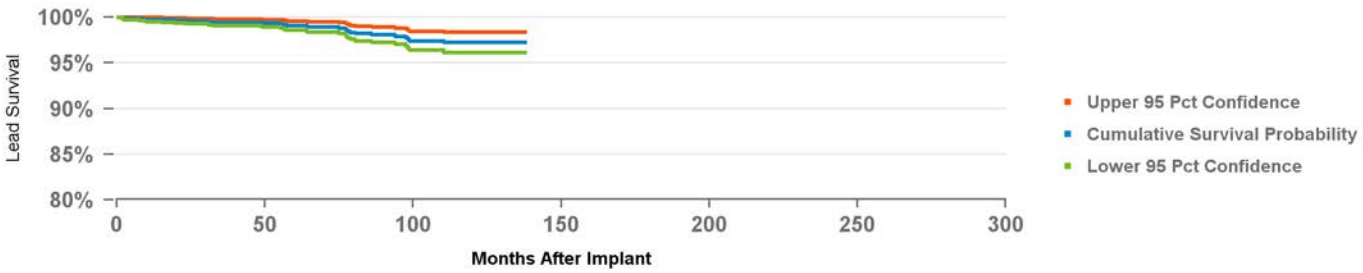
Cardiac Perforation	40
Conductor Fracture	15
Extra Cardiac Stimulation	12
Failure to Capture	127
Failure to Sense	49
Impedance Out of Range	36
Insulation Breach	1
Lead Dislodgement	243
Oversensing	88

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,444
Cumulative Months of Follow-Up	137,100
Number of Leads Active in Study	613

Qualifying Complications 28

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



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.7%	99.5%	99.4%	99.4%	99.0%	98.9%	98.2%	97.9%	97.4%	97.2%	97.2%	97.2%
#	1,888	1,579	1,375	1,169	1,014	854	724	612	506	391	216	98

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,381
Estimated Active USA Implants	1,634
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

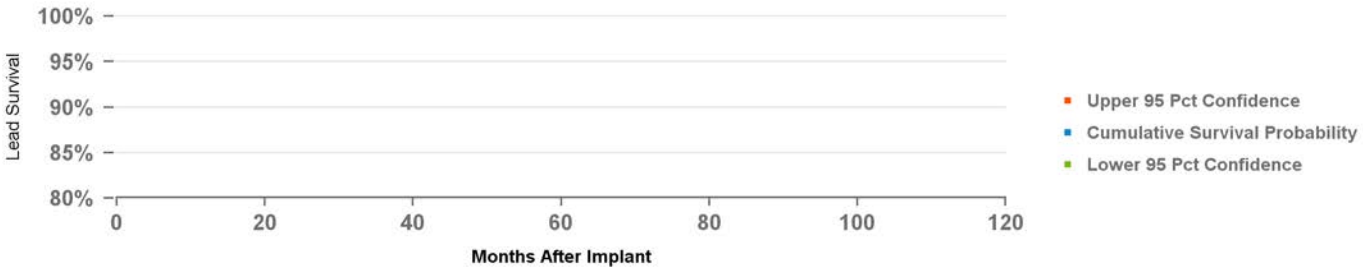
Conductor Fracture	2
Failure to Capture	7
Lead Dislodgement	7
Oversensing	1
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	40
Cumulative Months of Follow-Up	2,326
Number of Leads Active in Study	2

Qualifying Complications 5

Conductor Fracture	4	Impedance Out of Range	1



Years	at 0 mo
%	#####
#	

6949 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	186,211
Estimated Active USA Implants	23,933
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8,180
Insulation Breach	37
Crimp/Weld/Bond	3
Other	119

US Acute Lead Observations

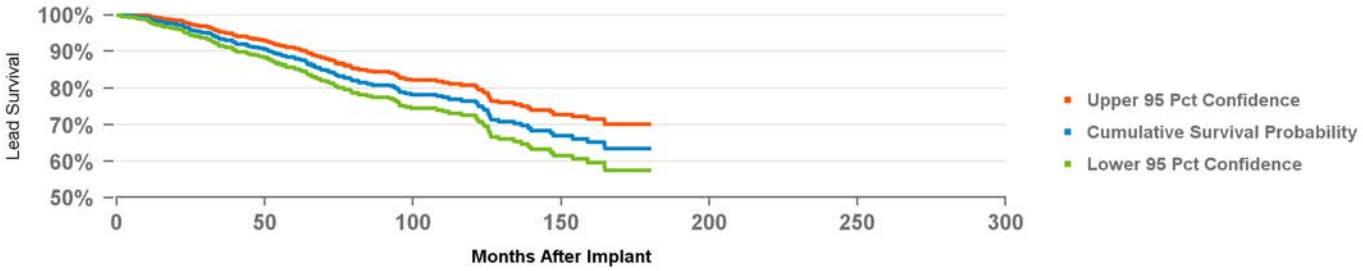
Cardiac Perforation	10
Conductor Fracture	52
Failure to Capture	31
Failure to Sense	19
Impedance Out of Range	20
Insulation Breach	5
Lead Dislodgement	22
Oversensing	37
Unspecified Clinical Failure	24

Product Surveillance Registry Results

Number of Leads Enrolled in Study	986
Cumulative Months of Follow-Up	58,066
Number of Leads Active in Study	28

Qualifying Complications 136

Conductor Fracture	78
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 180 mo
%	98.6%	96.5%	93.4%	91.0%	88.2%	84.5%	81.6%	79.0%	78.0%	76.6%	71.0%	68.5%	66.2%	63.5%	63.5%
#	719	626	532	458	392	343	281	236	187	153	125	96	79	65	55

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	5,809
Estimated Active USA Implants	2,626
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	39
Insulation Breach	0
Crimp/Weld/Bond	0
Other	0

US Acute Lead Observations

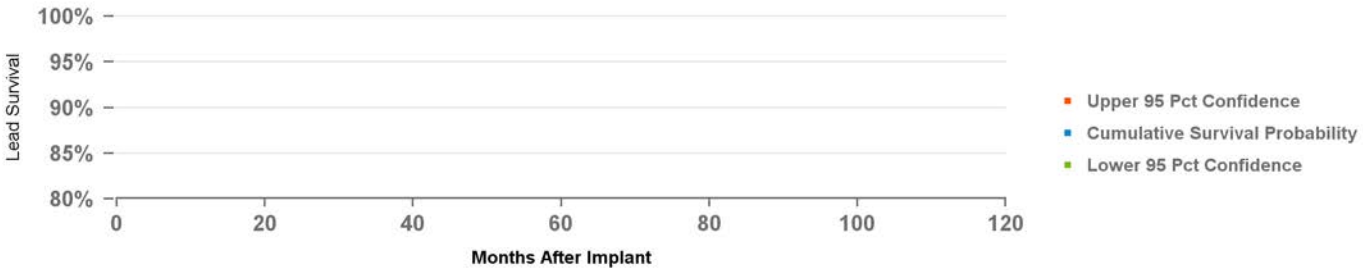
Cardiac Perforation	1
Failure to Capture	1
Impedance Out of Range	19
Insulation Breach	1
Lead Dislodgement	3
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	56
Cumulative Months of Follow-Up	2,599
Number of Leads Active in Study	4

Qualifying Complications 4

Conductor Fracture	1	Impedance Out of Range	3



Years	at 0 mo
%	#####
#	

2187 Attain LV

US Market Release	28Aug2001
CE Approval	
Registered USA Implants	11,921
Estimated Active USA Implants	977
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

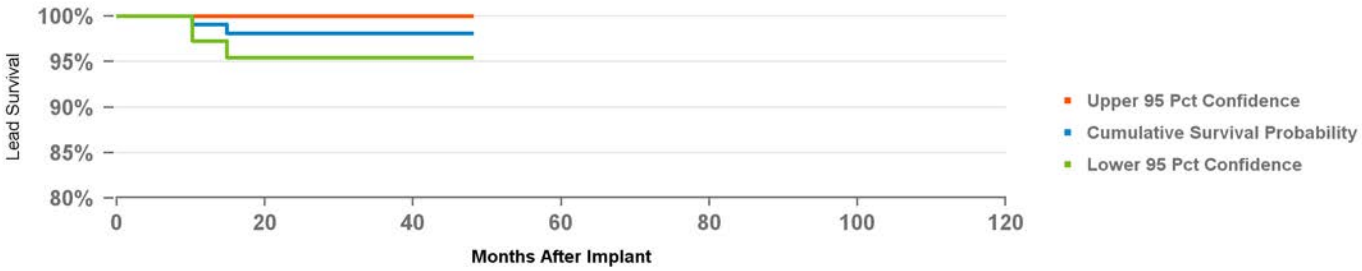
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	1
Lead Dislodgement	9

Product Surveillance Registry Results

Number of Leads Enrolled in Study	140
Cumulative Months of Follow-Up	7,260
Number of Leads Active in Study	4

Qualifying Complications 3

Failure to Capture	3



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	100,665
Estimated Active USA Implants	12,101
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

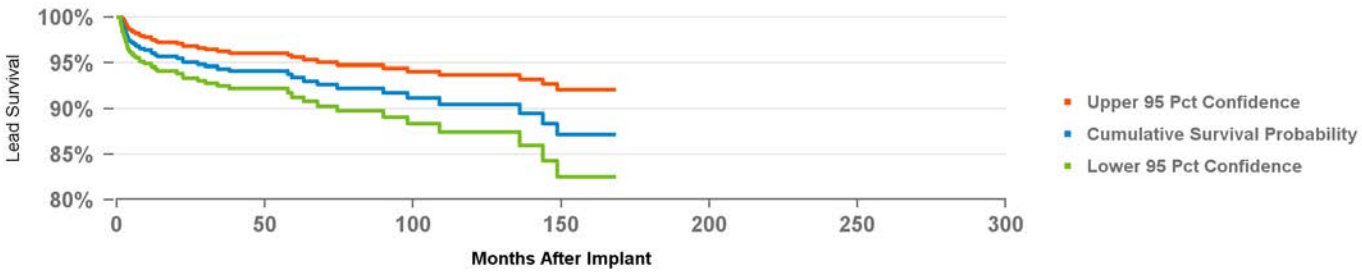
Extra Cardiac Stimulation	18
Failure to Capture	11
Lead Dislodgement	46
Oversensing	1
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	805
Cumulative Months of Follow-Up	42,652
Number of Leads Active in Study	18

Qualifying Complications 52

Conductor Fracture	1	Impedance Out of Range	2
Extra Cardiac Stimulation	10	Lead Dislodgement	16
Failure to Capture	20	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%	87.2%	87.2%
#	569	444	376	304	252	228	193	171	139	118	97	78	63	51

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	114,258
Estimated Active USA Implants	28,425
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	48
Insulation Breach	167
Crimp/Weld/Bond	0
Other	2

US Acute Lead Observations

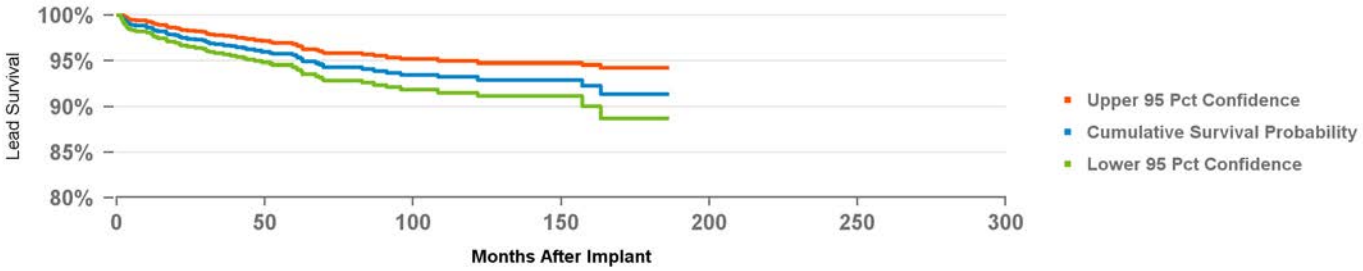
Cardiac Perforation	2
Conductor Fracture	3
Extra Cardiac Stimulation	49
Failure to Capture	42
Impedance Out of Range	9
Lead Dislodgement	153
Oversensing	2
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,654
Cumulative Months of Follow-Up	100,787
Number of Leads Active in Study	144

Qualifying Complications 68

Conductor Fracture	2	Insulation (ESC)	1
Extra Cardiac Stimulation	11	Insulation (not further defined)	2
Failure to Capture	22	Lead Dislodgement	30



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	98.6%	97.4%	96.7%	96.1%	95.6%	94.3%	94.1%	93.5%	93.5%	93.3%	93.0%	93.0%	93.0%	91.4%	91.4%	91.4%
#	1,238	1,045	897	769	697	616	505	429	367	315	257	188	139	94	62	55

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,445
Estimated Active USA Implants	6,185
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

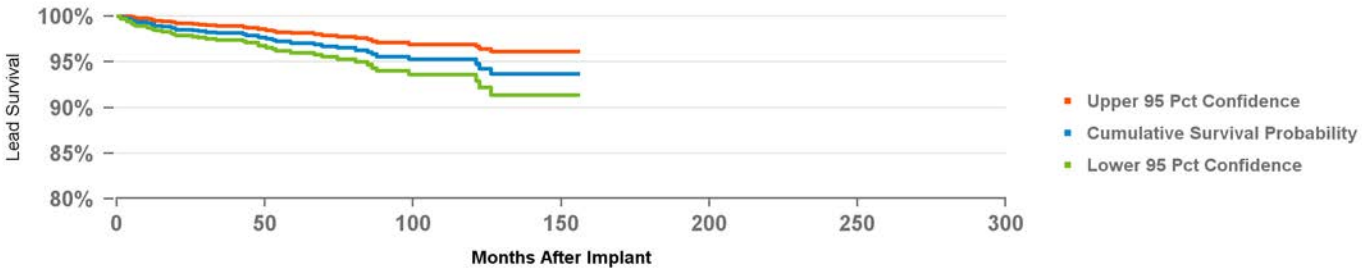
Extra Cardiac Stimulation	30
Failure to Capture	21
Impedance Out of Range	4
Lead Dislodgement	30
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,486
Cumulative Months of Follow-Up	88,590
Number of Leads Active in Study	121

Qualifying Complications 45

Conductor Fracture	4
Extra Cardiac Stimulation	18
Failure to Capture	9
Impedance Out of Range	2
Insulation (not further defined)	6
Lead Dislodgement	5
Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.1%	98.5%	98.1%	97.6%	97.0%	96.7%	96.3%	95.6%	95.3%	95.3%	93.7%	93.7%	93.7%
#	1,243	1,072	924	747	620	510	416	322	262	205	158	103	69

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	69,108
Estimated Active USA Implants	27,677
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	28
Insulation Breach	2
Crimp/Weld/Bond	0
Other	9

US Acute Lead Observations

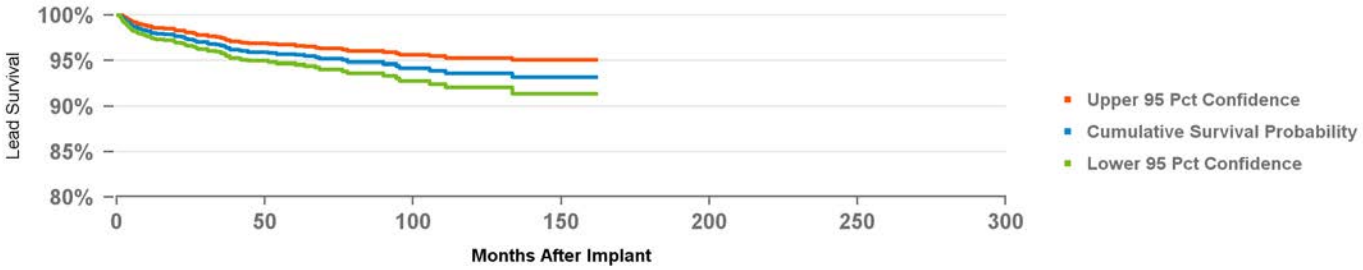
Cardiac Perforation	3
Conductor Fracture	2
Extra Cardiac Stimulation	99
Failure to Capture	67
Failure to Sense	1
Impedance Out of Range	12
Insulation Breach	1
Lead Dislodgement	229
Oversensing	1
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,324
Cumulative Months of Follow-Up	121,001
Number of Leads Active in Study	192

Qualifying Complications 87

Conductor Fracture	3	Impedance Out of Range	2
Extra Cardiac Stimulation	17	Insulation (not further defined)	1
Failure to Capture	37	Lead Dislodgement	23
		Other	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	98.0%	97.3%	96.6%	95.9%	95.7%	95.2%	94.9%	94.2%	93.9%	93.7%	93.7%	93.2%	93.2%	93.2%
#	1,891	1,501	1,194	967	794	639	505	414	350	274	211	152	85	52

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	35,255
Estimated Active USA Implants	17,177
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

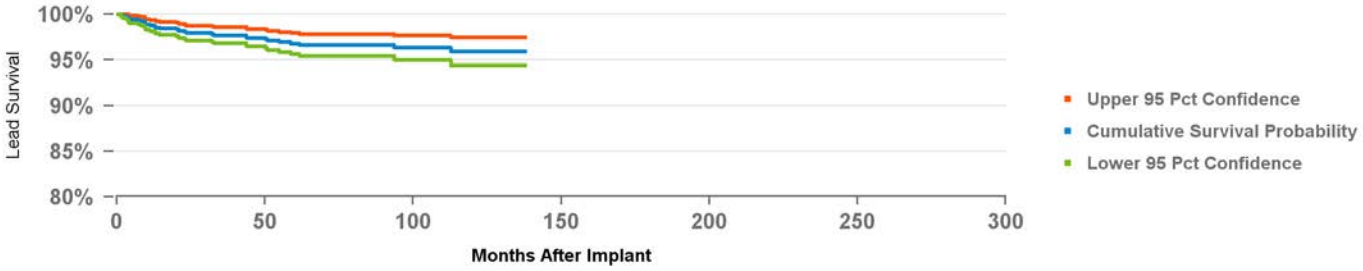
Cardiac Perforation	2
Conductor Fracture	1
Extra Cardiac Stimulation	65
Failure to Capture	37
Impedance Out of Range	11
Insulation Breach	4
Lead Dislodgement	120

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,473
Cumulative Months of Follow-Up	78,911
Number of Leads Active in Study	213

Qualifying Complications 37

Conductor Fracture	1	Lead Dislodgement	13
Extra Cardiac Stimulation	12	Other	2
Failure to Capture	9		



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	98.7%	97.9%	97.7%	97.4%	96.8%	96.6%	96.6%	96.3%	96.3%	95.9%	95.9%	95.9%
#	1,163	940	775	658	552	473	404	329	278	198	102	56

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	123,082
Estimated Active USA Implants	94,914
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

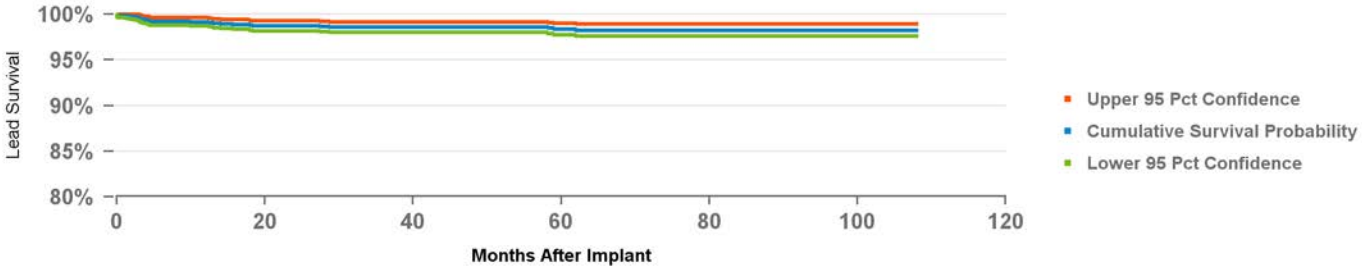
Cardiac Perforation	7
Conductor Fracture	1
Extra Cardiac Stimulation	244
Failure to Capture	172
Failure to Sense	1
Impedance Out of Range	46
Lead Dislodgement	265

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,271
Cumulative Months of Follow-Up	112,894
Number of Leads Active in Study	617

Qualifying Complications 29

Extra Cardiac Stimulation	5	Lead Dislodgement	16
Failure to Capture	5	Other	3



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.1%	98.7%	98.6%	98.6%	98.4%	98.2%	98.2%	98.2%	98.2%
#	1,893	1,612	1,372	1,155	887	654	450	249	77

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	8,462
Estimated Active USA Implants	4,389
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

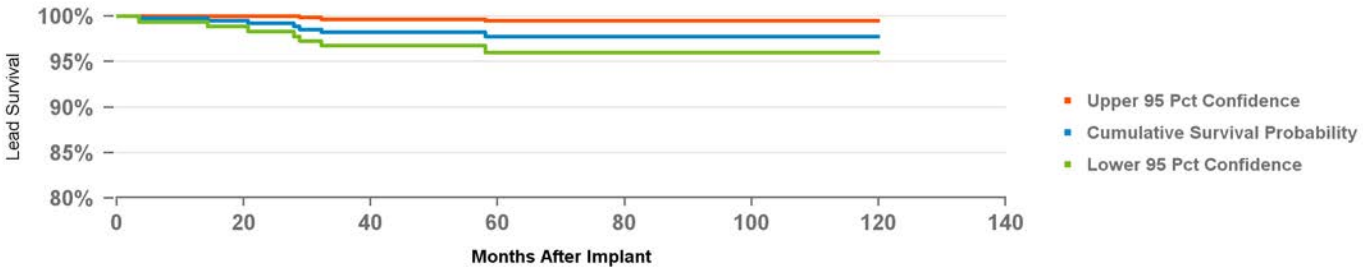
Cardiac Perforation	1
Conductor Fracture	2
Extra Cardiac Stimulation	21
Failure to Capture	14
Lead Dislodgement	35

Product Surveillance Registry Results

Number of Leads Enrolled in Study	486
Cumulative Months of Follow-Up	26,299
Number of Leads Active in Study	81

Qualifying Complications 10

Extra Cardiac Stimulation	1	Insulation (not further defined)	1
Failure to Capture	4	Lead Dislodgement	4



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.8%	99.2%	98.2%	98.2%	97.7%	97.7%	97.7%	97.7%	97.7%	97.7%
#	386	308	271	234	197	158	125	106	91	54

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	42,676
Estimated Active USA Implants	33,971
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

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

US Acute Lead Observations

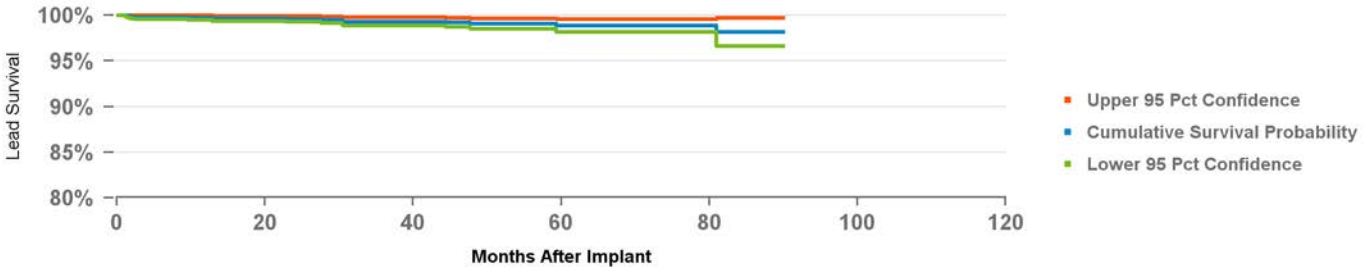
Cardiac Perforation	8
Conductor Fracture	1
Extra Cardiac Stimulation	111
Failure to Capture	81
Impedance Out of Range	13
Lead Dislodgement	44

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,132
Cumulative Months of Follow-Up	78,542
Number of Leads Active in Study	1,101

Qualifying Complications 17

Extra Cardiac Stimulation	1	Impedance Out of Range	1
Failure to Capture	7	Lead Dislodgement	8



Years	1	2	3	4	5	6	7	at 90 mo
%	99.7%	99.6%	99.3%	99.0%	98.8%	98.8%	98.1%	98.1%
#	1,678	1,315	995	725	467	239	108	65

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	79,543
Estimated Active USA Implants	64,273
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	15

US Acute Lead Observations

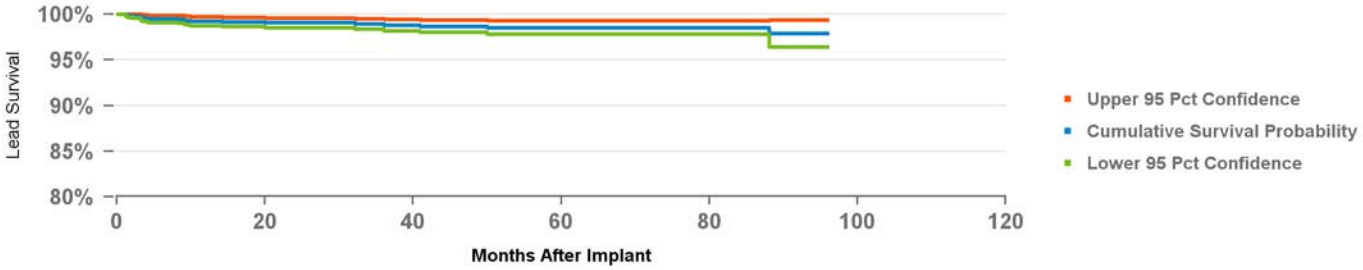
Cardiac Perforation	11
Conductor Fracture	2
Extra Cardiac Stimulation	144
Failure to Capture	109
Impedance Out of Range	36
Lead Dislodgement	90
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,384
Cumulative Months of Follow-Up	64,646
Number of Leads Active in Study	412

Qualifying Complications 17

Extra Cardiac Stimulation	3
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	12



Years	1	2	3	4	5	6	7	at 96 mo
%	99.2%	99.0%	98.9%	98.7%	98.5%	98.5%	98.5%	97.9%
#	1,160	975	802	673	518	322	183	86

4798 Attain Stability Quad

US Market Release	03Jun2019
CE Approval	24Apr2017
Registered USA Implants	56,731
Estimated Active USA Implants	52,807
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	15

US Acute Lead Observations

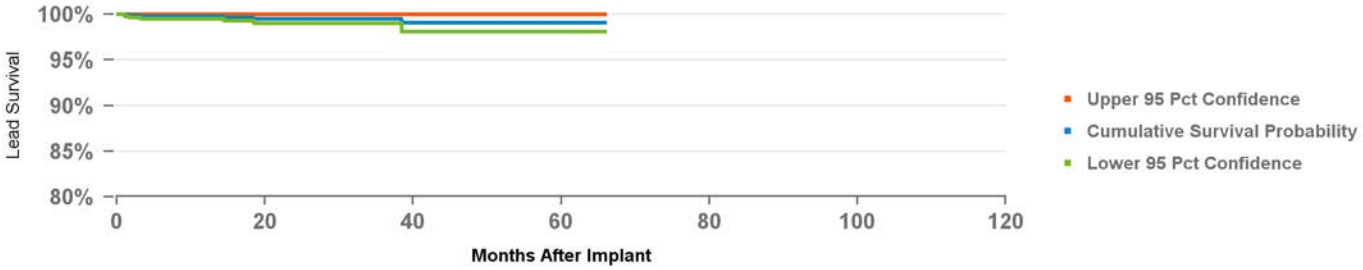
Cardiac Perforation	9
Conductor Fracture	2
Extra Cardiac Stimulation	104
Failure to Capture	125
Impedance Out of Range	42
Lead Dislodgement	113
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,482
Cumulative Months of Follow-Up	29,681
Number of Leads Active in Study	993

Qualifying Complications 8

Conductor Fracture	1
Extra Cardiac Stimulation	2
Failure to Capture	3
Lead Dislodgement	2



Years	1	2	3	4	5	at 66 mo
%	99.8%	99.5%	99.5%	99.1%	99.1%	99.1%
#	912	481	266	128	66	54

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	24,337
Estimated Active USA Implants	6,829
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	301
Insulation Breach	64
Crimp/Weld/Bond	1
Other	0

US Acute Lead Observations

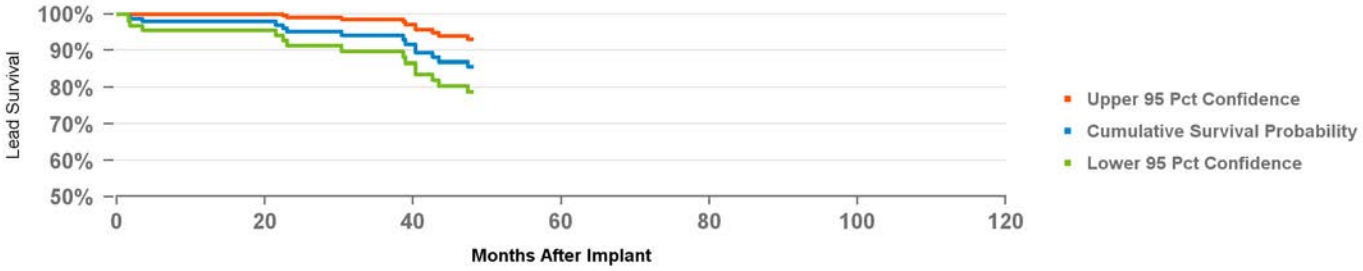
Cardiac Perforation	1
Conductor Fracture	1
Failure to Capture	11
Failure to Sense	8
Impedance Out of Range	21
Oversensing	2
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	234
Cumulative Months of Follow-Up	7,507
Number of Leads Active in Study	3

Qualifying Complications 18

Conductor Fracture	10
Failure to Capture	4
Failure to Sense	1
Insulation (not further defined)	1
Oversensing	2



Years	1	2	3	at 48 mo
%	97.9%	95.1%	94.0%	85.6%
#	118	100	82	60

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	64,526
Estimated Active USA Implants	35,330
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	154
Insulation Breach	95
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

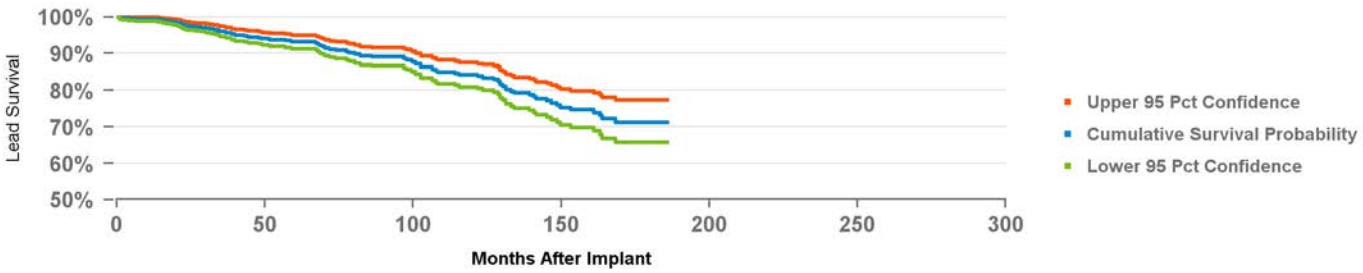
Cardiac Perforation	1
Conductor Fracture	4
Extra Cardiac Stimulation	7
Failure to Capture	104
Failure to Sense	14
Impedance Out of Range	22
Insulation Breach	1
Lead Dislodgement	8
Oversensing	33

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,055
Cumulative Months of Follow-Up	72,922
Number of Leads Active in Study	191

Qualifying Complications 109

Conductor Fracture	34	Impedance Out of Range	5
Extra Cardiac Stimulation	2	Insulation (not further defined)	6
Failure to Capture	29	Lead Dislodgement	1
Failure to Sense	3	Oversensing	26
		Other	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.4%	97.5%	96.0%	94.4%	93.2%	91.1%	89.4%	89.2%	85.3%	84.3%	80.3%	77.7%	74.7%	72.3%	71.3%	71.3%
#	827	746	667	579	512	442	390	335	259	205	171	140	105	77	62	53

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	57,782
Estimated Active USA Implants	12,528
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	35
Insulation Breach	2
Crimp/Weld/Bond	0
Other	1

US Acute Lead Observations

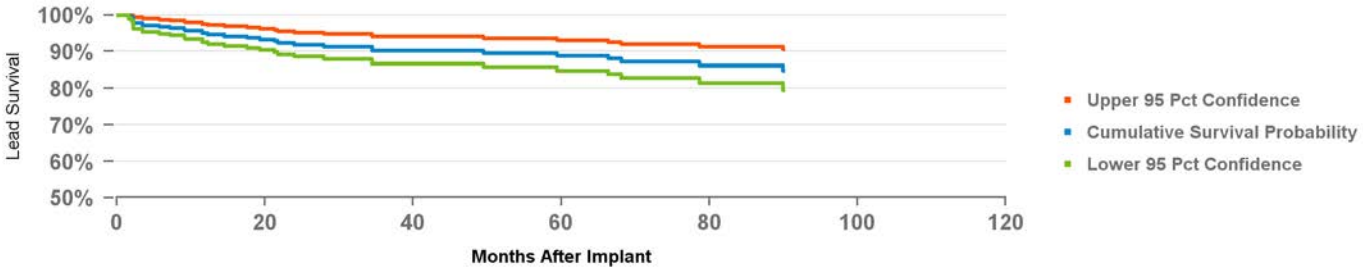
Cardiac Perforation	2
Extra Cardiac Stimulation	6
Failure to Capture	117
Failure to Sense	4
Impedance Out of Range	14
Lead Dislodgement	4
Oversensing	2
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	473
Cumulative Months of Follow-Up	17,847
Number of Leads Active in Study	47

Qualifying Complications 38

Conductor Fracture	5	Impedance Out of Range	3
Extra Cardiac Stimulation	1	Lead Dislodgement	3
Failure to Capture	21	Oversensing	2
Failure to Sense	2	Other	1



Years	1	2	3	4	5	6	7	at 90 mo
%	95.0%	91.9%	90.3%	90.3%	88.9%	87.3%	86.3%	84.9%
#	237	192	160	142	121	96	75	60

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	9,657
Estimated Active USA Implants	2,205
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

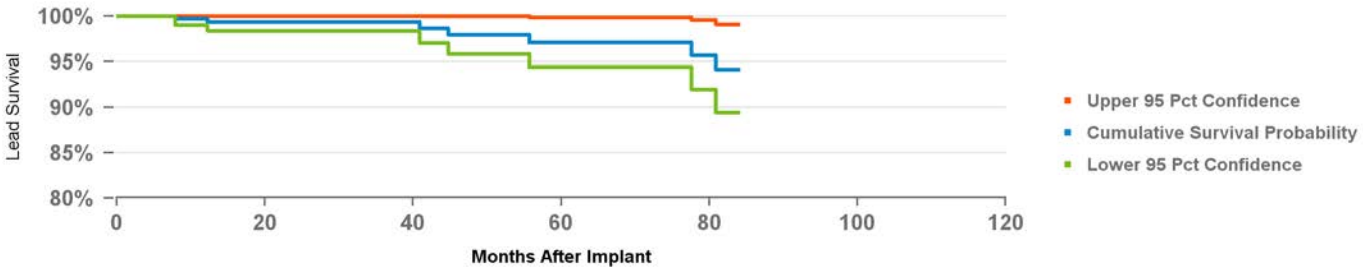
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	2
Lead Dislodgement	7
Oversensing	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	570
Cumulative Months of Follow-Up	15,946
Number of Leads Active in Study	3

Qualifying Complications 8

Conductor Fracture	3
Failure to Capture	2
Failure to Sense	3



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.3%	99.3%	97.9%	97.1%	97.1%	94.1%
#	288	218	160	132	105	78	56

Method for Estimating Insertable Cardiac Monitor Performance

Insertable Cardiac Monitor (ICM) Performance Analysis

The Reveal LINQ™ and LINQ II™ ICMs are small, leadless devices that are inserted under the skin, in the chest that records subcutaneous ECG. These ICMs can be subject to malfunctions, similar to other implanted devices.

The performance report information is determined from the analysis of available complaint and available CareLink™ network data. An ICM model 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 in the CareLink™ population.

Using returned product data and CareLink™ to Estimate Insertable Cardiac Monitor Performance

ICMs 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 can be limited in determining the survival probability as not all ICMs are returned to Medtronic for analysis. As ICMs are diagnostic devices, it is possible for a device not to be returned after meeting the device designated longevity or the patient receiving a diagnosis of their condition.

For certain malfunctions relating to oversensing for LINQ II™, CareLink™ Network data is leveraged. This data is related to FA1368: LINQ II™ Insertable Cardiac Monitoring Systems (LNQ22) with Potential for Amplified Noise.

Qualifying Complication or Malfunctions

All reported ICM complaints are adjudicated by subject matter experts 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:

- Amplified Noise due to moisture (FA1368) – this only affects LINQ II™
- Premature Battery Depletion
- Electrical Component
- Software/Firmware
- Other

The CareLink™ Network

As noted previously, the CareLink™ Network is leveraged for data related to FA1368, in addition to determining the inclusion of product performance events in the survival analysis.

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.

Method for Estimating Insertable Cardiac Monitor Performance continued

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 estimate is the probability that a device 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 device has a 5% chance of experiencing a related complication 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.

Because the 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.

Definition of Analysis Dataset

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

LNQ22 LINQ II

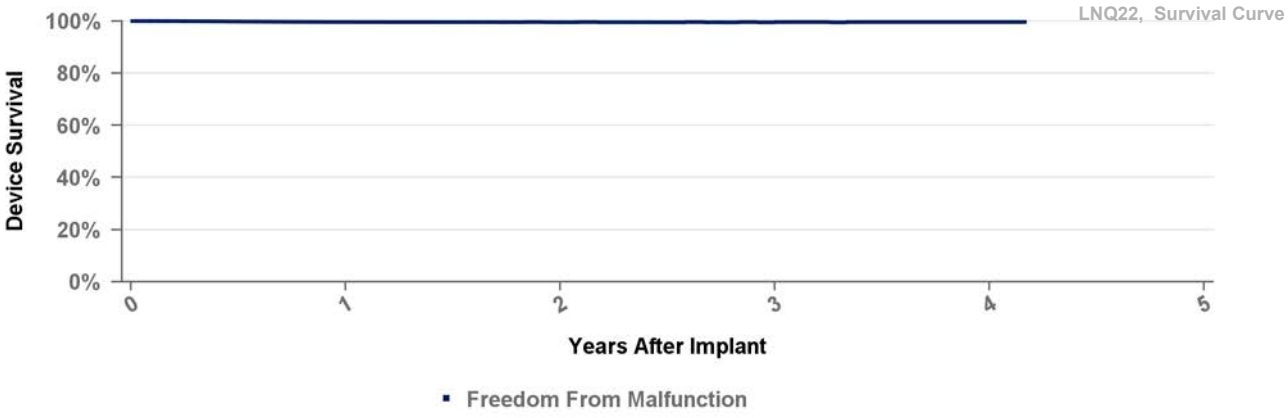
US Market Release	03Jul2020
CE Approval Date	05Nov2019
Serial Number Prefix	RLB
Mass	3.4 g
Volume	1.4 cc
Estimated Longevity	4.5 years

CareLink Population

Enrolled	308,758
Active	250,171
Cumulative Follow-Up Months	4,748,277

Qualifying Malfunctions/Complications

Amplified Noise due to moisture (FA1368)	920
Electrical Component	7
Other	23
Premature Battery Depletion	87
Software/Firmware	90



Years	1	2	3	4	at 50 mo
Freedom From Malfunction	99.6%	99.6%	99.5%	99.5%	99.5%
Effective Sample Size	170514	73619	19800	1140	147

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.

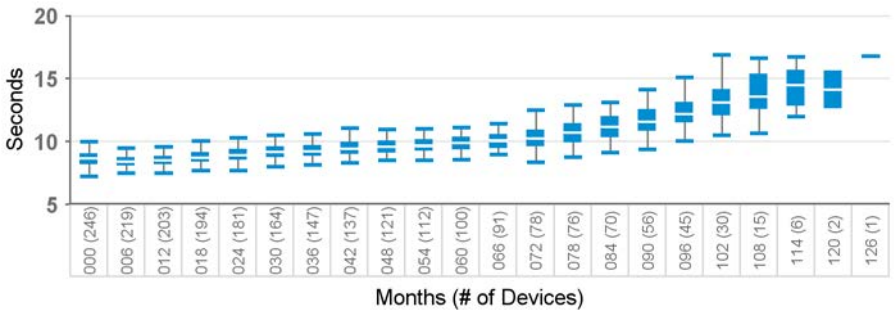
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

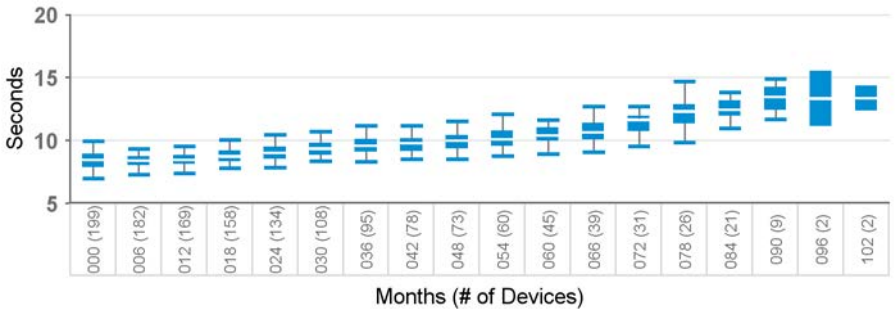
D204VRM, D214VRM, D224VRC, D234VRC

Model Number	Brand
D214VRM	Secura VR
D234VRC	Secura VR



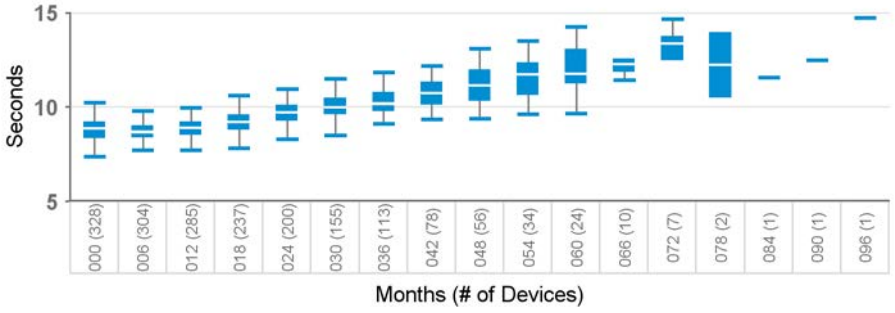
D264DRG, D284DRG, D384DRx, D394DRx

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



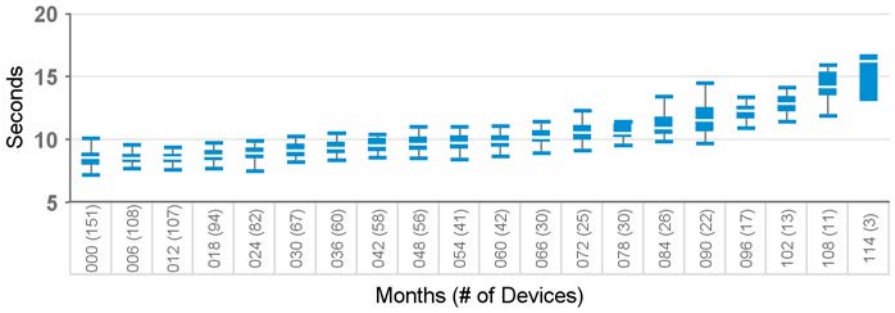
D264TRM, D284TRK, D384TRx, D394TRx

Model Number	Brand
D284TRK	Maximo II CRT-D
D394TRG	Egida CRT-D



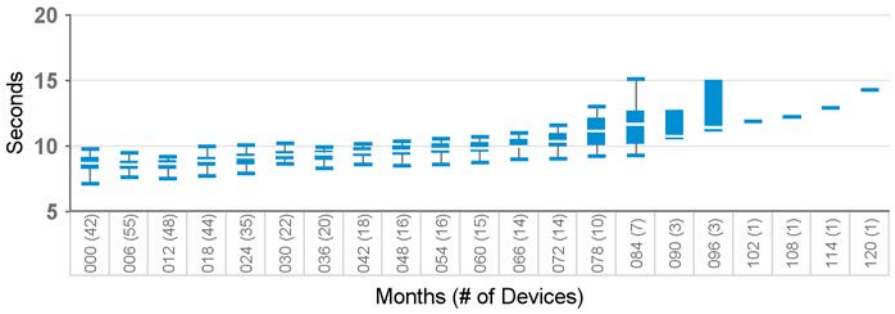
D264VRM, D284VRC, D384VRx, D394VRx

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



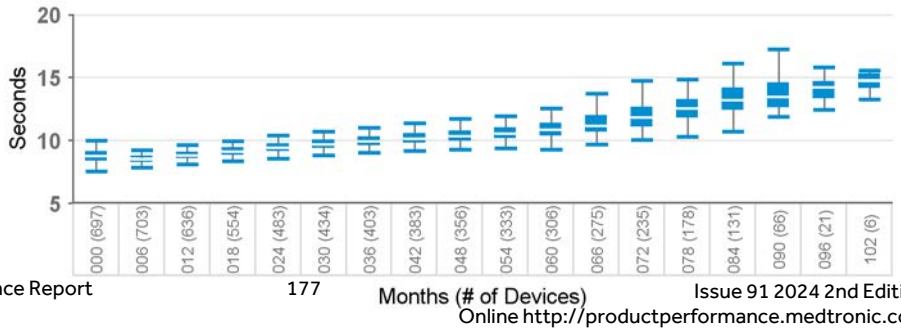
D274VRC, D294VRC

Model Number	Brand
D294VRC	Virtuoso II VR



D314DRx

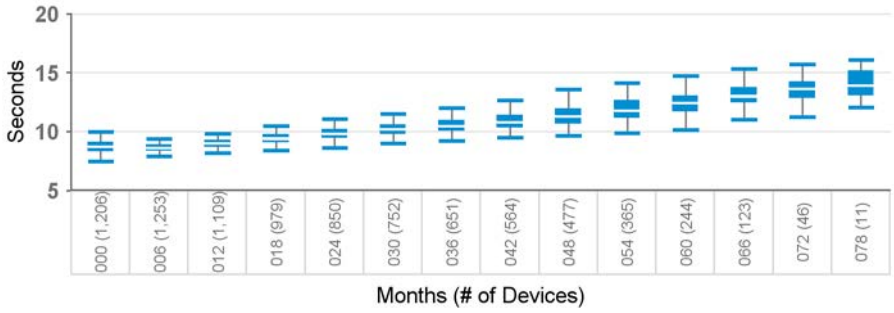
Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



ICD and CRT-D Charge Time Performance

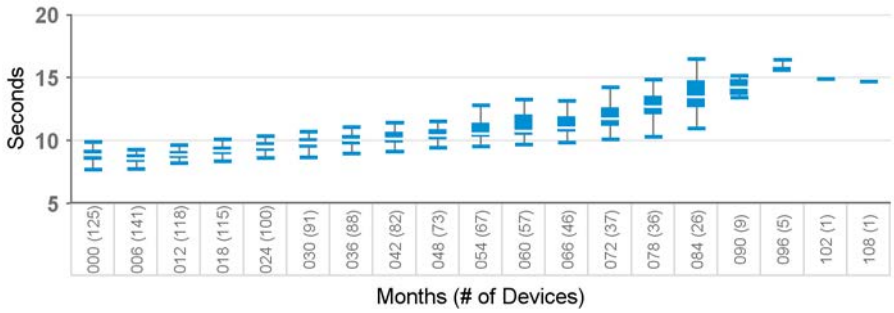
D314TRx

Model Number	Brand
D314TRG	Protecta XT CRT-D



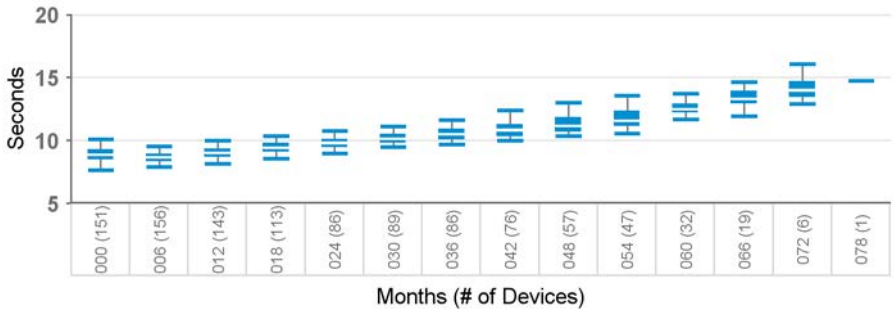
D334DRx, D364DRx

Model Number	Brand
D364DRG	Protecta DR
D364DRM	Protecta DR



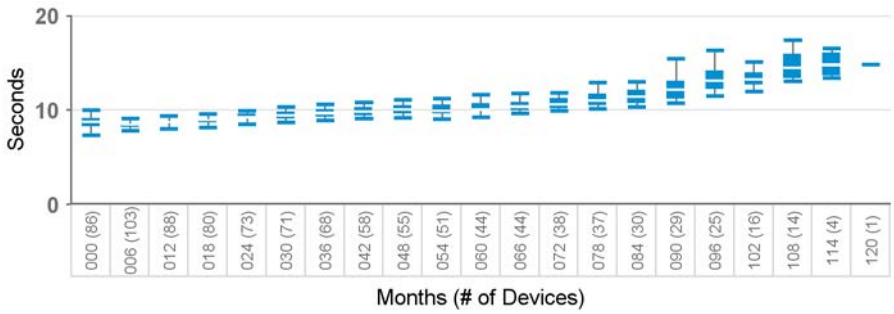
D334TRx, D364TRx

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



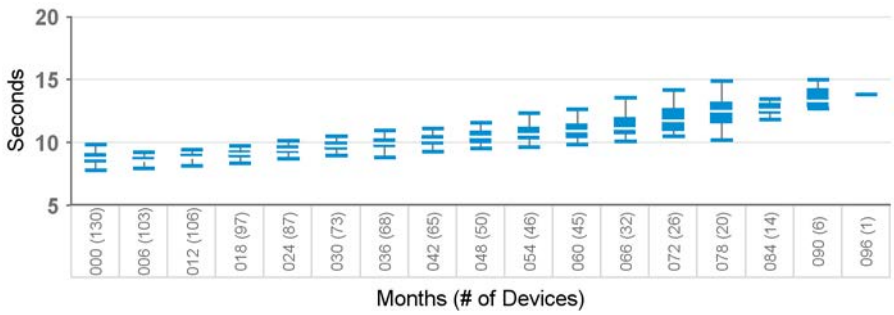
D334VRx, D364VRx

Model Number	Brand
D364VRG	Protecta VR
D364VRM	Protecta VR



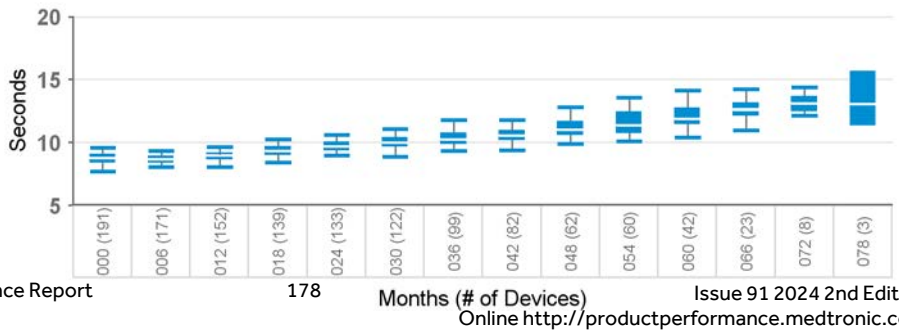
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



D354TRx

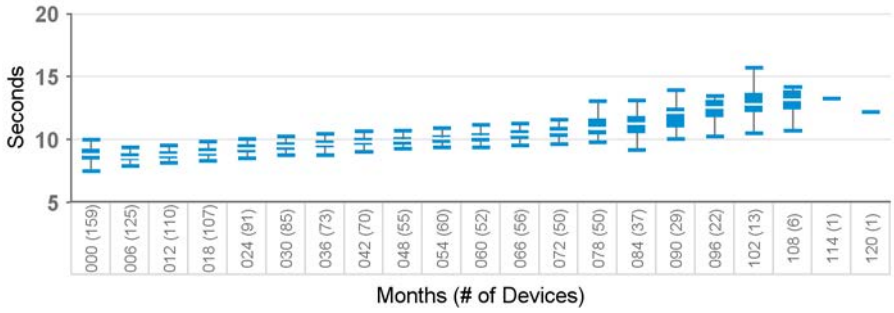
Model Number	Brand
D354TRG	Protecta XT CRT-D
D354TRM	Protecta XT CRT-D



ICD and CRT-D Charge Time Performance

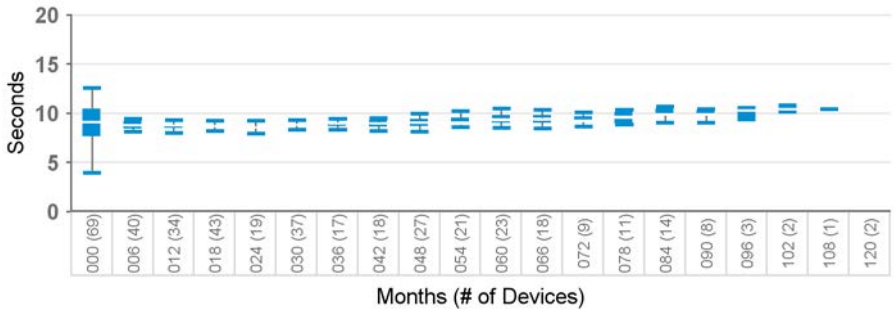
D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



DDxxxxx, DR

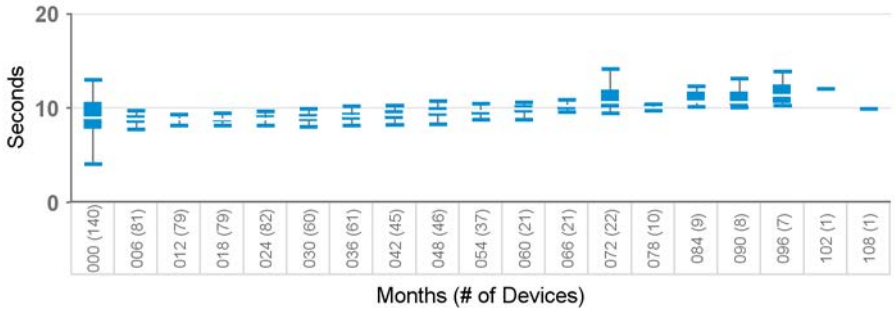
Model Number	Brand
DDBB1D1	Evera XT
DDBB1D4	Evera XT
DDBB2D1	Evera XT
DDBB2D4	Evera XT
DDBC3D1	Evera S
DDBC3D4	Evera S
DDMB1D1	Evera MRI XT
DDMB1D4	Evera MRI XT
DDMB2D1	Evera MRI XT
DDMB2D4	Evera MRI XT
DDMC3D1	Evera MRI S
DDMC3D4	Evera MRI
DDMD3D1	Primo
DDMD3D4	Primo
DDME3D1	Mirro
DDME3D4	Mirro



ICD and CRT-D Charge Time Performance

DTxxxxx, CRT-D

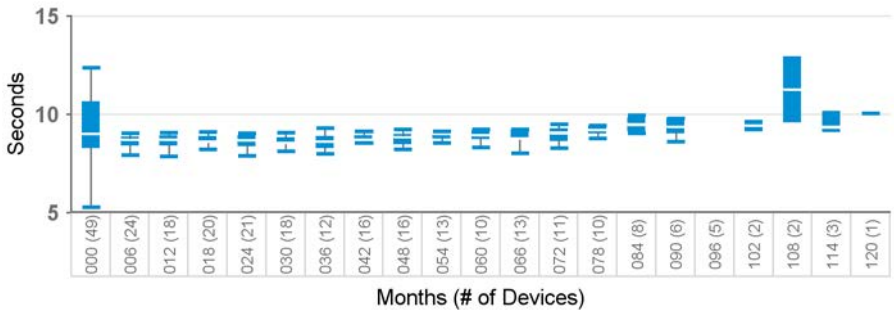
Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava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



Potential for Autonomous Cursor Motion

CareLink™ 2090 Programmer

Original Date of Communication: July 2024

STATUS UPDATE – OCTOBER 2024

As of 16 October 2024, Medtronic has 379 reports of autonomous cursor behavior including reports identified during the software update. There are no additional reports of unintended therapy delivered. There have been no reports of permanent harm or death associated with this behavior.

ORIGINAL COMMUNICATION - JULY 2024

Medtronic CareLink™ 2090 programmers with serial number prefixes PKK0 and PKK1 have the potential for autonomous cursor motion when Finger Touchscreen capability is enabled by software version 3.2 or higher. Through 11 June 2024, Medtronic has received 23 reports of autonomous cursor behavior, with 2 reports of unintended therapy delivered when the programmer was not under the control of trained personnel during a patient session. There have been no reports of permanent harm or death associated with this behavior.

If a programmer is unattended while in an active patient device session, a risk to patients may exist if an autonomous cursor motion engages in unintended programming. Medtronic estimates that 1.0% of Model 2090 programmers with serial number prefixes PKK0 or PKK1 could display this behavior when updated to software version 3.2 or higher.

INSTRUMENT MANAGEMENT RECOMMENDATIONS:

Software updates are necessary to maintain proper programmer function. Medtronic representatives will assist in performing the software update on all Medtronic CareLink™ 2090 programmers and assess proper function. Medtronic representatives will assist with returning programmers needing repair or replacement.

LINQ II ICM Potential for Amplified Noise June 2024

LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2024

STATUS UPDATE – OCTOBER 2024

As of 30 September 2024, Medtronic has identified 889 (1.37%) devices that have exhibited these characteristics, with zero (0) reports of serious harm. Medtronic estimates the projected rate of this issue to be 3.4% at 2 years or 8.7% at 4.5 years for the identified subset, and patient management recommendations are unchanged.

ORIGINAL COMMUNICATION – JUNE 2024

In November 2023, Medtronic communicated that a specific subset of LINQ II insertable cardiac monitors (ICMs) underwent a manufacturing process that may allow for moisture to impact electrode performance and create the potential for amplified noise and/or overall signal reduction of the ICM. This noise pattern is different from occasional noise due to device position/migration, patient activity, or external electromagnetic interference.

During continued investigation, Medtronic identified additional devices that have the potential for amplified noise. The identified subset now includes 64,700 total devices. Based on CareLink analysis and reported complaints as of 01 May 2024, 553 (0.85%) devices have exhibited these characteristics, with zero (0) reports of serious harm. Medtronic estimates the projected rate of this issue to be 2.9% at 2 years or 6.2% at 4.5 years for the identified subset. If an amplified noise pattern occurs, potential harms include missed/delayed diagnosis, delayed medical intervention, and early device replacement. **Medtronic recently implemented manufacturing changes to address this issue**. Overall LINQ II freedom from malfunction, including this issue, is projected to be 98.51% at 4.5 years.

PATIENT MANAGEMENT RECOMMENDATIONS:

In consultation with our Independent Physician Quality Panel (IPQP), Medtronic emphasizes continued care of patients implanted with an ICM per the existing device labeling. These recommendations are reflective of the November 2023 communication.

- Please encourage enrollment in and regular transmissions to CareLink.
    - Medtronic will continue to apply recurring algorithmic searches on CareLink for the specific amplified noise pattern and notify the clinician if present. No further action is required for patients regularly transmitting to CareLink.
- For patients not followed in CareLink:
    - Consider whether enrolling in CareLink is an option, per HRS/EHRA/APHRS/LAHRS guidance.[1] CareLink monitoring will reduce the potential for episodes caused by amplified noise to overwrite true episodes before they are reviewed.

    - If noise interferes with the ability to assess the patient's rhythm or reason for monitoring, contact Medtronic Technical Services for assistance (dxhelp@medtronic.com or 1-800-929-4043).
- If the ICM is no longer in use, no further action is necessary.

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[1]Ferrick A, et. al. (2023). 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, 20(9), e92-e144.

SOFTWARE UPDATE AVAILABLE - 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

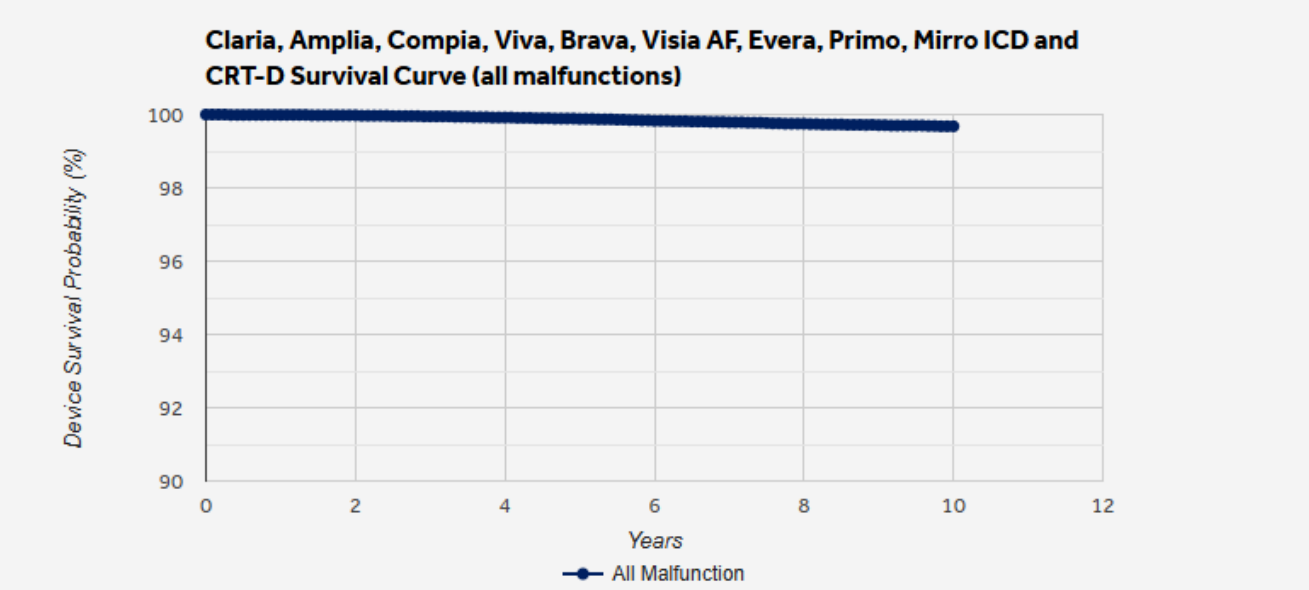
Devices managed with an updated programming system are no longer in scope of the May 2023 communication.

STATUS UPDATE – OCTOBER 2024

As of 18 October 2024, Medtronic has identified 38 devices (representing 0.0034% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

Medtronic has released a software update that aligns programming systems with the programming recommendations in most geographies. Devices managed with an updated programming system are no longer in scope of the May 2023 communication.

The overall reliability of these devices remains high. The graph below shows device survival probability inclusive of all confirmed malfunctions.



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
#	633,729	573,563	503,212	441,389	362,667	278,919	196,995	123,186	69,217	31,630

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.

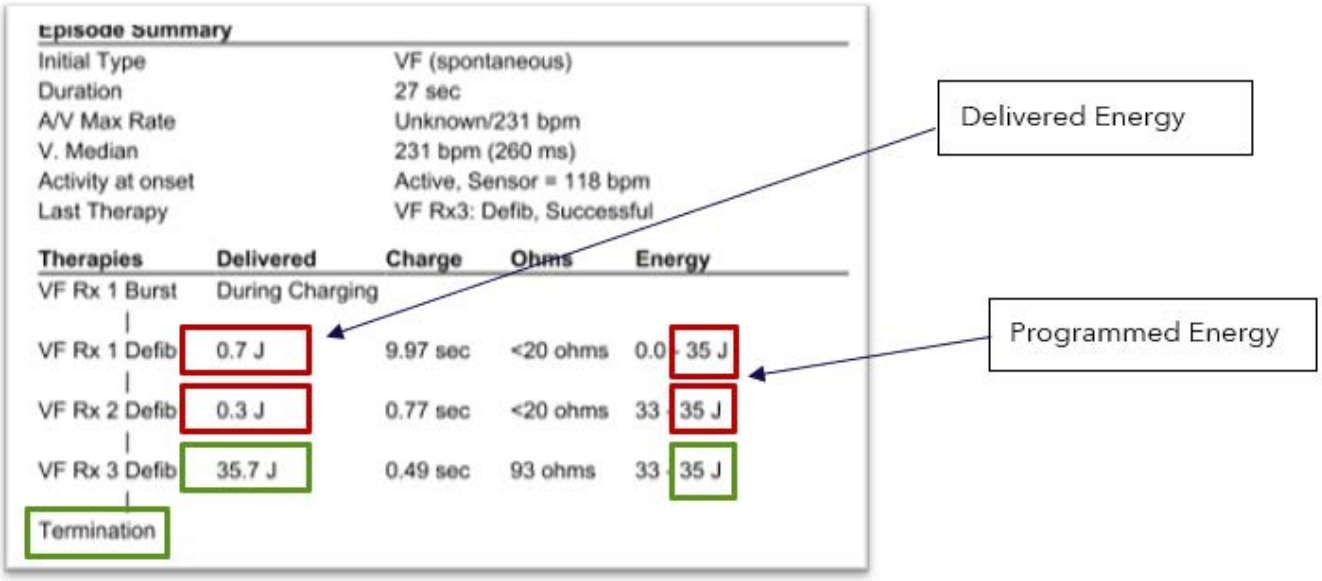
Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed**

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.

SOFTWARE UPDATE AVAILABLE - 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

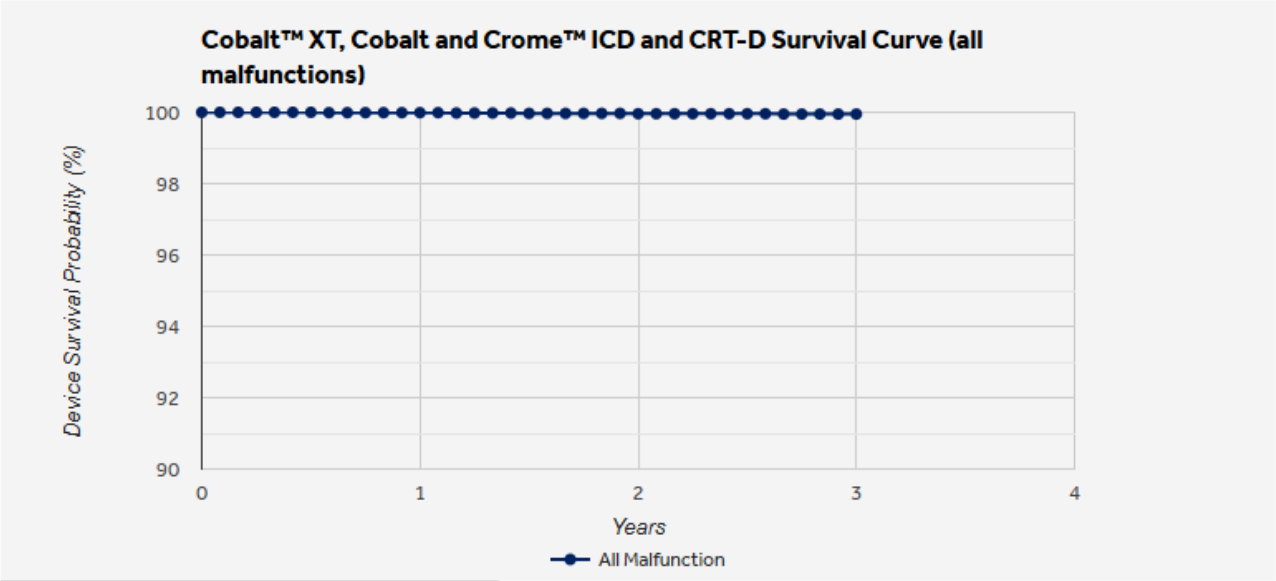
Devices managed with an updated programming system are no longer in scope of the May 2023 communication.

STATUS UPDATE - OCTOBER 2024

As of 18 October 2024, Medtronic has identified 38 devices (representing 0.0034% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the patient management recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

Medtronic has released a software update that aligns programming systems with the programming recommendations in most geographies. Devices managed with an updated programming system are no longer in scope of the May 2023 communication.

The overall reliability of these devices remains high. The graph below shows device survival probability inclusive of all confirmed malfunctions.



	1 yr	2 yr	3 yr
%	100.0%	100.0%	99.9%
#	109,330	63,000	35,691

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.

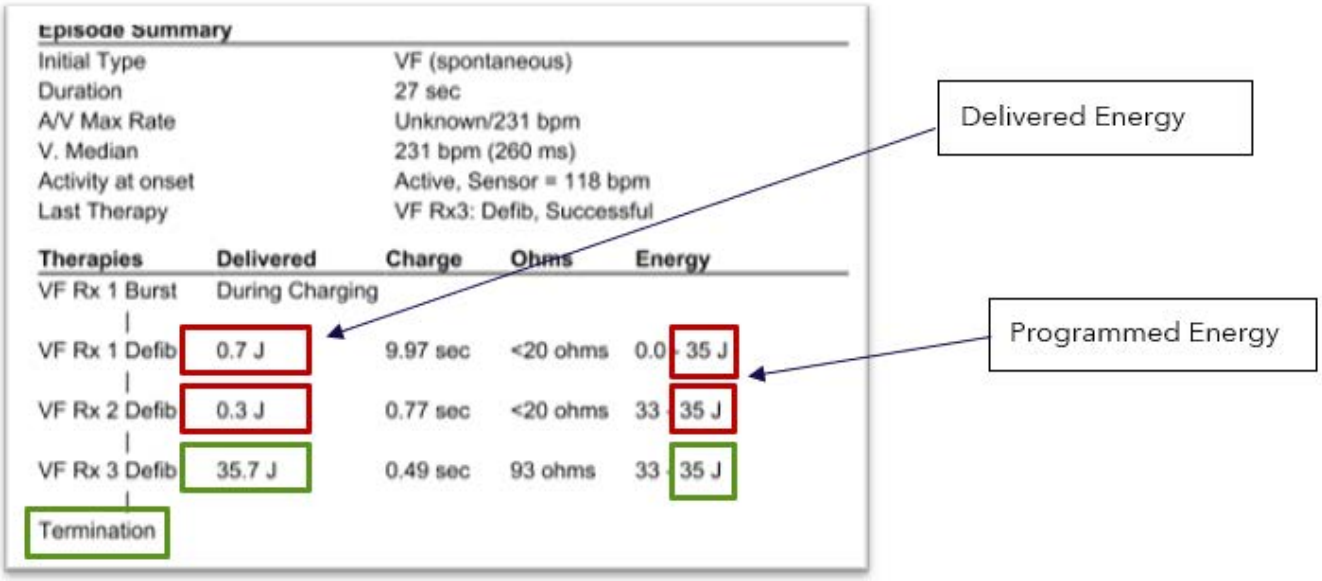
Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed**

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.

SOFTWARE UPDATE AVAILABLE - 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 - OCTOBER 2024

Manufacturing updates may increase device programming options. Contact Medtronic Technical Services for details.

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 21 October 2024, Medtronic has confirmed 152 devices (representing 0.08% of devices distributed worldwide) have experienced a second-phase SCP event. In all events, ~79% of the programmed shock energy was delivered. No events have occurred in devices programmed B>AX that have the August 2022 software update. No permanent harms or deaths have been directly attributed to this issue.

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.

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 - OCTOBER 2024

As of 29 October 2024, Medtronic has received 219 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.

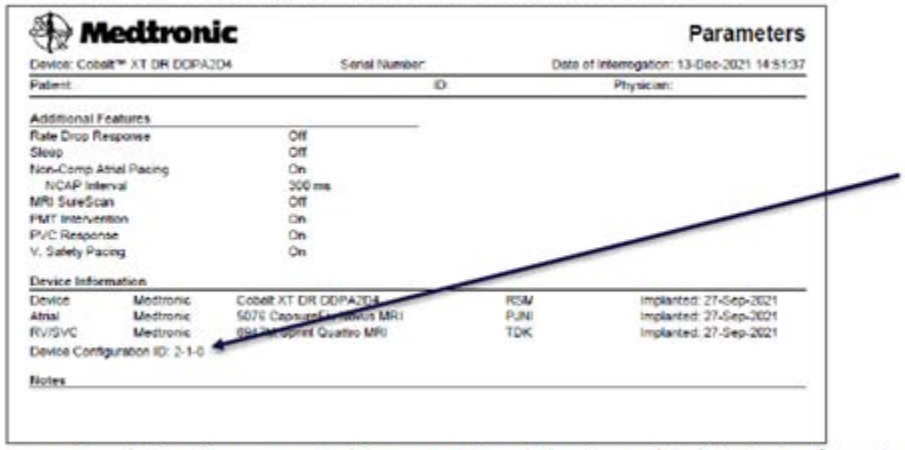


Image: Sample SmartSync-generated Parameters Report showing updated Device Configuration ID.

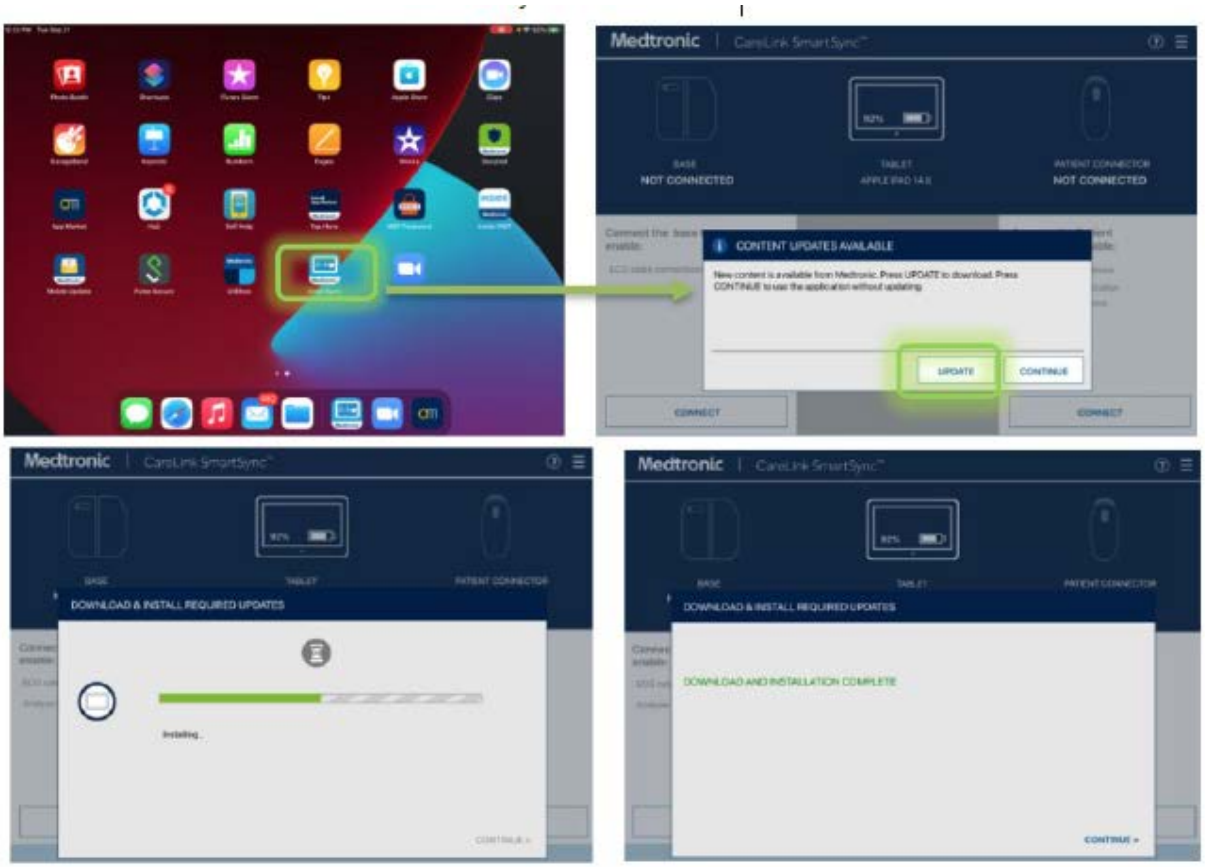
For CareLink – the following is available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'

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?

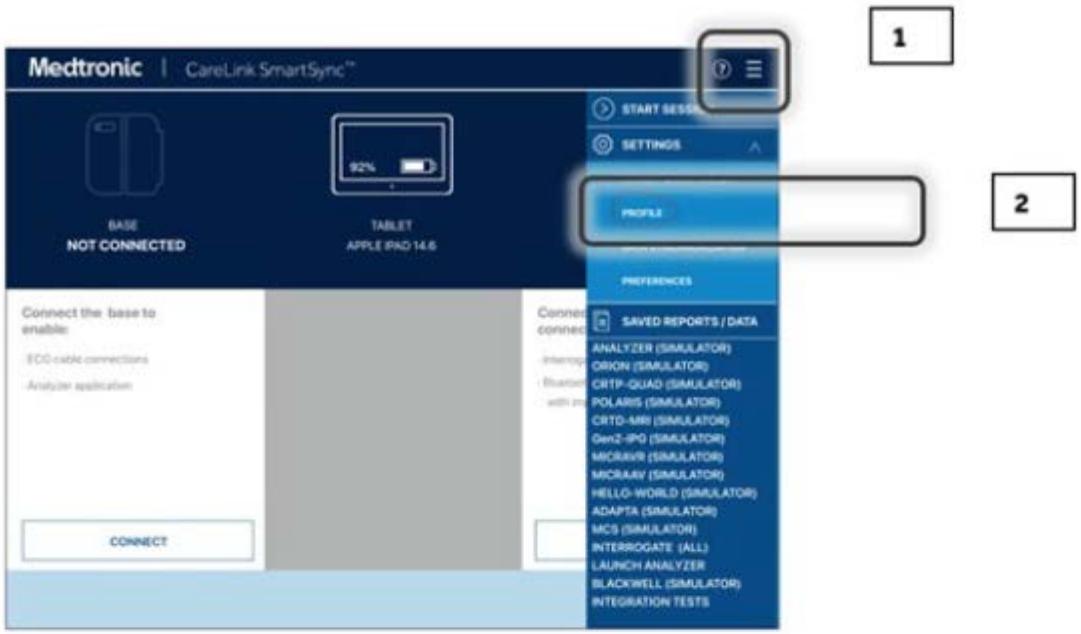
On any tablet, you can confirm the application software version for any device family by:

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)

Customer Communications



3 - Updated application versions

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 - OCTOBER 2024

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

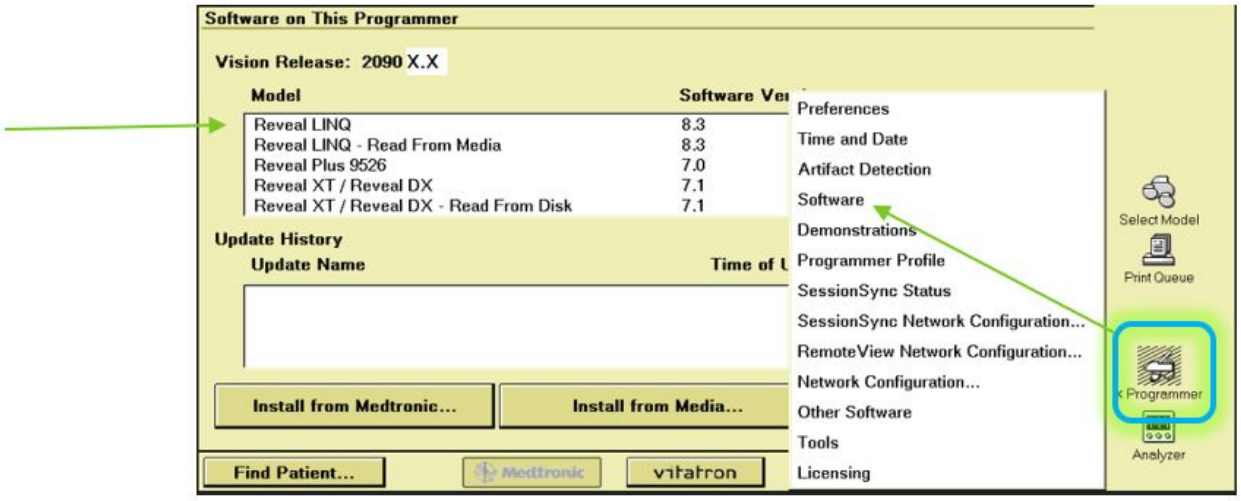
Software Update Available

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)?

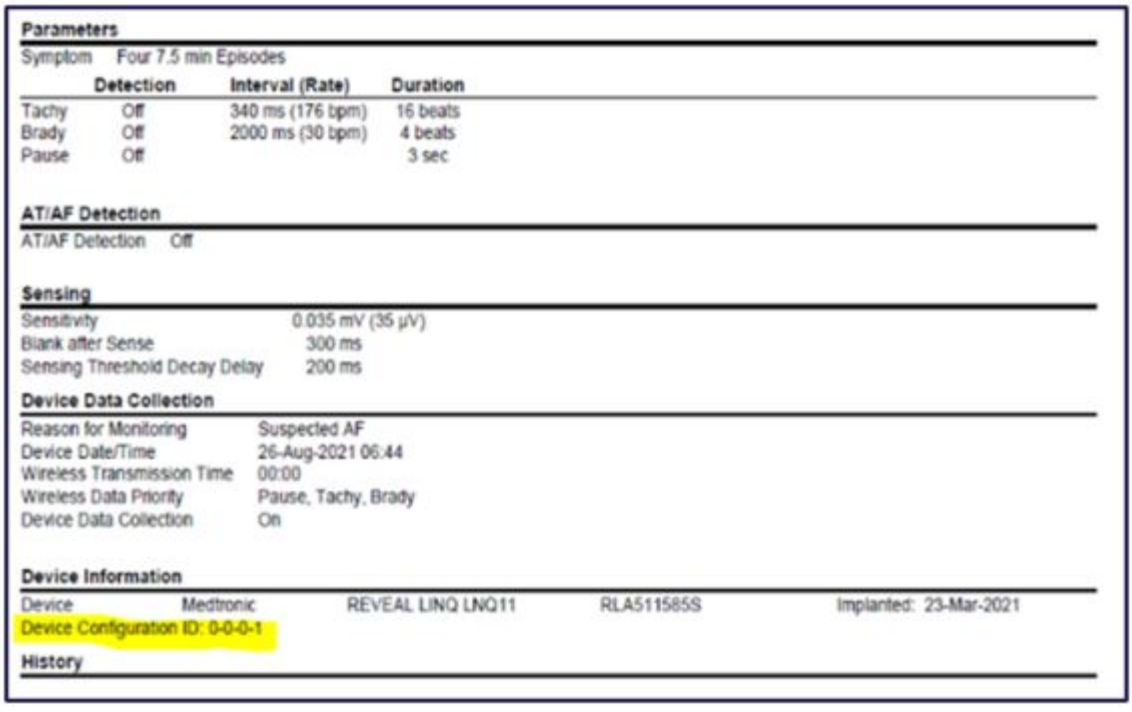
From the *Find Patient* screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.



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.



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 - OCTOBER 2024

Medtronic released a software update in August 2023 to address this issue in LINQ II ICMs manufactured from July 2020 to June 2021. The update is available through SmartSync App 3.12.4 or higher.

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.

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 - OCTOBER 2024

As of 15 October 2024, approximately 141,378 devices susceptible to this issue are estimated to still be active worldwide. Observed rate of occurrence is 0.16% 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.

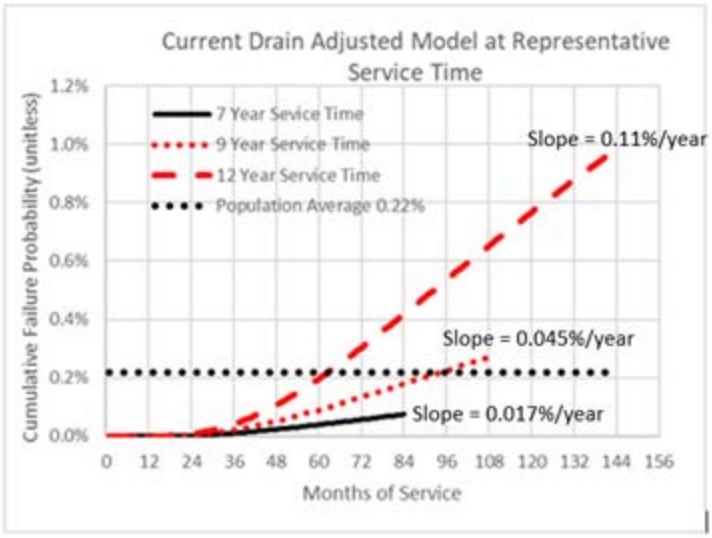
Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/

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



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.

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 - OCTOBER 2024

As of 15 October 2024, there have been a total of 32 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.

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 Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Communication: October 2007

STATUS UPDATE - OCTOBER 2024

As of October 15, 2024, of the initial implant population of 205,600 in the United States, approximately 26,800 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 63.5% (+6.6/-6.0%) at 180 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)	**7,334** Worldwide **(5,266** United States)	**36,600** Worldwide (**26,800** 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.
    - 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.

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.

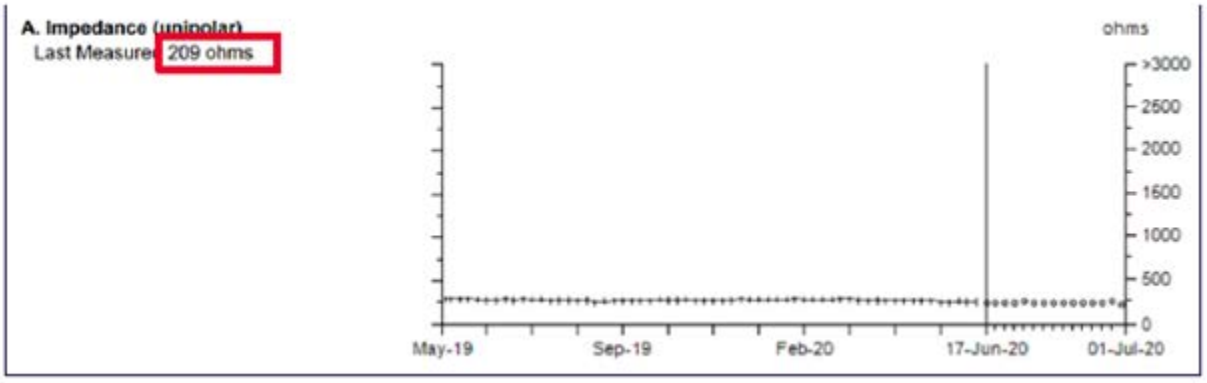


Figure 1– Lead Impedance Trend showing precise impedance values over time

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. 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.

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. 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

Legacy Models

Medtronic, at its discretion, may stop providing updated performance information on models in alignment with the inclusion criteria defined in the methods for estimating. Listed below are the final product performance reports for legacy models.

GENERATORS

Cardiac Resynchronization Therapy (CRT) Defibrillators

Product Name	Model	Final Issue
Cardia CRT-D	D384TRG	2023 2nd Edition (Issue 89)
Concerto CRT-D	C154DWK	2016 1st Edition (Issue 74)
Concerto CRT-D	C164AWK	2016 1st Edition (Issue 74)
Concerto CRT-D	C174AWK	2016 1st Edition (Issue 74)
Concerto II CRT-D	D274TRK	2023 2nd Edition (Issue 89)
Concerto II CRT-D	D294TRK	2023 2nd Edition (Issue 89)
Consulta CRT-D	D204TRM	2023 2nd Edition (Issue 89)
Consulta CRT-D	D214TRM	2023 2nd Edition (Issue 89)
Consulta CRT-D	D224TRK	2024 2nd Edition (Issue 91)
Consulta CRT-D	D234TRK	2023 2nd Edition (Issue 89)
InSync II Marquis	7289	2012 1st Edition (Issue 66)
InSync Maximo	7303	2012 1st Edition (Issue 66)
InSync Maximo	7304	2016 1st Edition (Issue 74)
InSync Sentry	7297	2012 1st Edition (Issue 66)
InSync Sentry	7299	2016 1st Edition (Issue 74)
Maximo II CRT-D	D264TRM	2023 2nd Edition (Issue 89)
Protecta CRT-D	D334TRG	2023 2nd Edition (Issue 89)
Protecta CRT-D	D334TRM	2023 2nd Edition (Issue 89)
Protecta XT CRT-D	D314TRM	2023 2nd Edition (Issue 89)

Cardiac Resynchronization Therapy (CRT) Pacemakers

Product Name	Model	Final Issue
InSync	8040	2016 1st Edition (Issue 74)
InSync III	8042	2023 2nd Edition (Issue 89)

Implantable Cardioverter Defibrillators (ICDs)

Product Name	Model	Final Issue
Entrust AT	D153ATG	2019 2nd Edition (Issue 81)
Entrust AT	D154ATG	2019 2nd Edition (Issue 81)
Entrust DR	D153DRG	2019 2nd Edition (Issue 81)
Entrust DR	D154DRG	2019 2nd Edition (Issue 81)
Entrust Escudo	D144DRG	2019 2nd Edition (Issue 81)

Product Name	Model	Final Issue
Entrust Escudo	D144VRC	2019 2nd Edition (Issue 81)
Entrust VR	D153VRC	2019 2nd Edition (Issue 81)
Entrust VR	D154VRC	2019 2nd Edition (Issue 81)
GEM	7227B	2011 1st Edition (Issue 64)
GEM	7227Cx	2011 1st Edition (Issue 64)
GEM	7227D	2011 1st Edition (Issue 64)
GEM	7227E	2011 1st Edition (Issue 64)
GEM DR	7271	2011 1st Edition (Issue 64)
GEM III DR	7275	2012 1st Edition (Issue 66)
GEM III VR	7231Cx	2016 1st Edition (Issue 74)
Intrinsic	7288	2016 1st Edition (Issue 74)
Marquis DR	7274	2016 1st Edition (Issue 74)
Marquis VR	7230B	2019 2nd Edition (Issue 81)
Marquis VR	7230Cx	2019 2nd Edition (Issue 81)
Marquis VR	7230E	2019 2nd Edition (Issue 81)
Maximo DR	7278	2017 1st Edition (Issue 76)
Maximo VR	7232B	2019 2nd Edition (Issue 81)
Maximo VR	7232Cx	2023 2nd Edition (Issue 89)
Maximo VR	7232E	2019 2nd Edition (Issue 81)
Onyx	7290Cx	2013 1st Edition (Issue 68)
Protecta DR	D334DRG	2023 2nd Edition (Issue 89)
Protecta DR	D334DRM	2023 2nd Edition (Issue 89)
Protecta VR	D334VRG	2023 2nd Edition (Issue 89)
Protecta VR	D334VRM	2023 2nd Edition (Issue 89)
Protecta XT VR	D314VRG	2024 2nd Edition (Issue 91)
Protecta XT VR	D314VRM	2024 2nd Edition (Issue 91)
Secura DR	D204DRM	2023 2nd Edition (Issue 89)
Secura DR	D214DRM	2023 2nd Edition (Issue 89)
Secura DR	D224DRG	2024 2nd Edition (Issue 91)
Secura DR	D234DRG	2023 2nd Edition (Issue 89)
Secura VR	D204VRM	2023 2nd Edition (Issue 89)
Secura VR	D224VRC	2023 2nd Edition (Issue 89)
Virtuoso DR	D154AWG	2019 2nd Edition (Issue 81)
Virtuoso DR	D164AWG	2023 2nd Edition (Issue 89)
Virtuoso II DR	D274DRG	2023 2nd Edition (Issue 89)
Virtuoso II DR	D294DRG	2023 2nd Edition (Issue 89)
Virtuoso II VR	D274VRC	2023 2nd Edition (Issue 89)
Virtuoso VR	D154VWC	2019 2nd Edition (Issue 81)
Virtuoso VR	D164VWC	2023 2nd Edition (Issue 89)

Implantable Pulse Generators (IPGs)

Product Name	Model	Final Issue
Advisa DR	A4DR01	2019 1st Edition (Issue 80)
AT500	AT501	2013 1st Edition (Issue 68)
EnPulse	E2D01	2017 2nd Edition (Issue 77)
EnPulse	E2D03	2017 2nd Edition (Issue 77)
EnPulse DR	E1DR01	2017 2nd Edition (Issue 77)
EnPulse DR	E1DR03	2017 2nd Edition (Issue 77)
EnPulse DR	E1DR06	2017 2nd Edition (Issue 77)
EnPulse DR	E1DR21	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR01	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR03	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR06	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR21	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR31	2017 2nd Edition (Issue 77)
EnPulse DR	E2DR33	2017 2nd Edition (Issue 77)
EnPulse SR	E2SR01	2017 2nd Edition (Issue 77)
EnPulse SR	E2SR03	2017 2nd Edition (Issue 77)
EnPulse SR	E2SR06	2017 2nd Edition (Issue 77)
EnPulse VDD	E2VDD01	2017 2nd Edition (Issue 77)
EnRhythm DR	P1501DR	2023 2nd Edition (Issue 89)
EnRhythm MRI	EMDR01	2017 1st Edition (Issue 76)
Kappa 400 DR	KDR401	2017 1st Edition (Issue 76)
Kappa 400 DR	KDR403	2017 1st Edition (Issue 76)
Kappa 400 SR	KSR401	2017 1st Edition (Issue 76)
Kappa 400 SR	KSR403	2017 1st Edition (Issue 76)
Kappa 600 DR	KDR601	2012 1st Edition (Issue 66)
Kappa 600 DR	KDR603	2012 1st Edition (Issue 66)
Kappa 600 DR	KDR606	2012 1st Edition (Issue 66)
Kappa 600 DR	KDR651	2012 1st Edition (Issue 66)
Kappa 600 DR	KDR653	2012 1st Edition (Issue 66)
Kappa 700 DR	KD700	2017 1st Edition (Issue 76)
Kappa 700 DR	KD701	2017 1st Edition (Issue 76)
Kappa 700 DR	KD703	2017 1st Edition (Issue 76)
Kappa 700 DR	KD706	2017 1st Edition (Issue 76)
Kappa 700 DR	KDR700	2017 1st Edition (Issue 76)
Kappa 700 DR	KDR701	2017 1st Edition (Issue 76)
Kappa 700 DR	KDR703	2017 1st Edition (Issue 76)
Kappa 700 DR	KDR706	2017 1st Edition (Issue 76)
Kappa 700 DR	KDR721	2017 1st Edition (Issue 76)
Kappa 700 SR	KSR700	2016 2nd Edition (Issue 75)
Kappa 700 SR	KSR701	2017 1st Edition (Issue 76)
Kappa 700 SR	KSR703	2017 1st Edition (Issue 76)
Kappa 700 SR	KSR706	2017 1st Edition (Issue 76)

Product Name	Model	Final Issue
Kappa 700 VDD	KVDD701	2012 2nd Edition (Issue 67)
Kappa 800 DR	KDR801	2013 1st Edition (Issue 68)
Kappa 800 DR	KDR803	2013 1st Edition (Issue 68)
Kappa 900 D	KD901	2017 1st Edition (Issue 76)
Kappa 900 D	KD903	2017 1st Edition (Issue 76)
Kappa 900 D	KD906	2017 1st Edition (Issue 76)
Kappa 900 DR	KDR901	2017 1st Edition (Issue 76)
Kappa 900 DR	KDR903	2017 1st Edition (Issue 76)
Kappa 900 DR	KDR906	2017 1st Edition (Issue 76)
Kappa 900 DR	KDR921	2017 1st Edition (Issue 76)
Kappa 900 SR	KSR901	2017 1st Edition (Issue 76)
Kappa 900 SR	KSR903	2017 1st Edition (Issue 76)
Kappa 900 SR	KSR906	2017 1st Edition (Issue 76)
Kappa 900 VDD	KVDD901	2017 1st Edition (Issue 76)
Legend II	8424	2012 1st Edition (Issue 66)
Legend II	8426	2012 1st Edition (Issue 66)
Legend II	8427	2012 1st Edition (Issue 66)
Minix	8340	2012 1st Edition (Issue 66)
Minix	8341	2012 1st Edition (Issue 66)
Minix	8341M	2012 1st Edition (Issue 66)
Minix	8342	2012 1st Edition (Issue 66)
Minix ST	8330	2012 1st Edition (Issue 66)
Minix ST	8331	2012 1st Edition (Issue 66)
Minix ST	8331M	2012 1st Edition (Issue 66)
Minuet	7107	2012 1st Edition (Issue 66)
Minuet	7108	2012 1st Edition (Issue 66)
Preva DR	7088	2012 1st Edition (Issue 66)
Preva DR	7089	2012 1st Edition (Issue 66)
Preva SR	8088	2012 1st Edition (Issue 66)
Preva SR	8089	2012 1st Edition (Issue 66)
Prevail S	8085	2012 1st Edition (Issue 66)
Prevail S	8086	2012 1st Edition (Issue 66)
Prodigy DR	7860	2012 1st Edition (Issue 66)
Prodigy DR	7861	2012 1st Edition (Issue 66)
Prodigy DR	7862	2012 1st Edition (Issue 66)
Prodigy SR	8158	2013 1st Edition (Issue 68)
Prodigy SR	8160	2013 1st Edition (Issue 68)
Prodigy SR	8161	2013 1st Edition (Issue 68)
Prodigy SR	8162	2013 1st Edition (Issue 68)
Sigma 100 S	SS103	2017 2nd Edition (Issue 77)
Sigma 100 S	SS106	2017 2nd Edition (Issue 77)
Sigma 200 D	SD203	2017 2nd Edition (Issue 77)

Implantable Pulse Generators (IPGs) continued

Product Name	Model	Final Issue
Sigma 200 DR	SDR203	2017 2nd Edition (Issue 77)
Sigma 200 S	SS203	2017 2nd Edition (Issue 77)
Sigma 200 SR	SSR203	2017 2nd Edition (Issue 77)
Sigma 300 D	SD303	2023 2nd Edition (Issue 89)
Sigma 300 DR	SDR303	2023 2nd Edition (Issue 89)
Sigma 300 DR	SDR306	2019 2nd Edition (Issue 81)
Sigma 300 S	SS303	2023 2nd Edition (Issue 89)
Sigma 300 SR	SSR303	2023 2nd Edition (Issue 89)
Sigma 300 SR	SSR306	2019 2nd Edition (Issue 81)
Sigma 300 VDD	SVDD303	2019 2nd Edition (Issue 81)
Thera-i DR	7960i	2012 1st Edition (Issue 66)
Thera-i DR	7961i	2012 1st Edition (Issue 66)
Thera-i DR	7962i	2012 1st Edition (Issue 66)
Thera-i SR	8960i	2012 1st Edition (Issue 66)
Thera-i SR	8961i	2012 1st Edition (Issue 66)
Thera-i SR	8962i	2012 1st Edition (Issue 66)
Thera-i VDD	8968i	2012 1st Edition (Issue 66)

LEADS

Pacing Leads

Product Name	Model	Final Issue
CapSure Sense	4073	2023 2nd Edition (Issue 89)
CapSure SP	4023	2012 2nd Edition (Issue 67)
CapSure SP	4024	2016 1st Edition (Issue 74)
CapSure SP	4523	2012 2nd Edition (Issue 67)
CapSure SP	4524	2016 1st Edition (Issue 74)
CapSure SP	5023	2012 2nd Edition (Issue 67)
CapSure SP	5023M	2012 2nd Edition (Issue 67)
CapSure SP	5024	2013 1st Edition (Issue 68)
CapSure SP	5024M	2013 1st Edition (Issue 68)
CapSure SP	5524	2013 1st Edition (Issue 68)
CapSure SP	5524M	2013 1st Edition (Issue 68)
CapSure Z	4033	2012 2nd Edition (Issue 67)
CapSure Z	4533	2012 2nd Edition (Issue 67)
CapSure Z	5033	2016 1st Edition (Issue 74)
CapSure Z	5034	2016 1st Edition (Issue 74)
CapSure Z	5534	2016 1st Edition (Issue 74)
CapSureFix	4067	2012 2nd Edition (Issue 67)
CapSureFix	4068	2016 1st Edition (Issue 74)

Pacing Leads continued

Product Name	Model	Final Issue
CapSureFix	4568	2017 2nd Edition (Issue 77)
CapSureFix	5068	2017 1st Edition (Issue 76)
CapSureFix	5568	2016 1st Edition (Issue 74)
CapSureFix	6940	2018 1st Edition (Issue 78)
Screw-In	4558M	2016 1st Edition (Issue 74)
SureFix	5072	2018 1st Edition (Issue 78)

Defibrillation Leads

Product Name	Model	Final Issue
Epicardial Patch	6921	2013 1st Edition (Issue 68)
Sprint	6932	2016 1st Edition (Issue 74)
Sprint	6942	2017 1st Edition (Issue 76)
Sprint	6943	2017 2nd Edition (Issue 77)
Sprint	6945	2017 2nd Edition (Issue 77)
Sub-Q	6999	2012 1st Edition (Issue 66)
Sub-Q Patch	6939	2012 1st Edition (Issue 66)
SVC/CS	6963	2013 1st Edition (Issue 68)
Transvene	6936	2013 1st Edition (Issue 68)
Transvene	6966	2013 1st Edition (Issue 68)
Transvene SVC	6937	2016 1st Edition (Issue 74)
Transvene SVC-CS	6933	2016 1st Edition (Issue 74)

Left Heart Pacing Leads

Product Name	Model	Final Issue
Attain CS	2188	2012 2nd Edition (Issue 67)

Epicardial/Myocardial Pacing Leads

Product Name	Model	Final Issue
Spectraflex	4951	2013 1st Edition (Issue 68)
Spectraflex	4951M	2013 1st Edition (Issue 68)

VDD Single Pass Pacing Leads

Product Name	Model	Final Issue
CapSure VDD	5032	2016 1st Edition (Issue 74)

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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