CARDIAC RHYTHM MANAGEMENT

Product Performance Report

Important Patient Management Information for Physicians

2021

2nd Edition – Issue 85

Medtronic

CRM Product Performance Report

2021
2nd Edition
Issue 85

Cutoff date for this edition is 30 Jul 2021 for Lead Study data and 03 December 2021 for all other data, unless otherwise stated.

Our Commitment to Quality

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

The third tenet of the mission is all about quality:

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

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

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

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

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

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

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

Contact Information

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

US Technical Services Department

tshelp@medtronic.com

Phone:

1 (800) 723-4636 (Tachy)

1 (800) 505-4636 (Brady)

Fax:
1 (800) 824-2362

US Instrumental Technical Services

1 (800) 638-1991

International Technical Centers

Europe, the Middle East and Africa (Heerlen NL)
+31-45-566-8844
rs.mst-techserviceseurope@medtronic.com

Japan (Tokyo)

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
Email:
crdm.returnedproduct@medtronic.com

Editorial Staff

Trademarks of Medtronic

Introduction

For 38 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.

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

This Product Performance Report has been prepared in accordance with International Standard ISO 5841-2:2000(E). As Transcatheter Pacing Systems (TPS) combine the pacing functions of an IPG with the therapy delivery functions of an implantable lead into a single device implanted inside the heart, TPS is subject to complications similar to pacing leads and malfunctions or battery depletion events similar to an implanted pulse generator (IPG). The TPS performance report has been developed to align with these guidelines to the extent possible due to the unique difference between TPS compared to a typical implantable device or lead.

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

Survival Estimates

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

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

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

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

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

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

Introduction continued

ICD Charge Times

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

Customer Communications - Advisory Summaries

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

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

Customer Communications- Performance Notes

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

How You Can Help

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

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

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

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

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

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

Introduction continued

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 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 US returned product analysis data. These data are presented graphically and numerically.

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

Categorization of Depleted and Malfunctioning Devices for Survival Analysis

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

Definition of Malfunction

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

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

A device subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRM and 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 compromised while in the malfunction state.

Malfunction without Compromised Therapy Function

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

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

Expanded Malfunction Detail

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

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

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

Battery – Findings linked to the battery and its components

Software/Firmware – Findings linked to software or firmware function

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

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

Returned Product Analysis Process

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

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

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic 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%.

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 And Registrant Tracking (DART system with data from Returned Product Analysis.

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

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

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

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

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

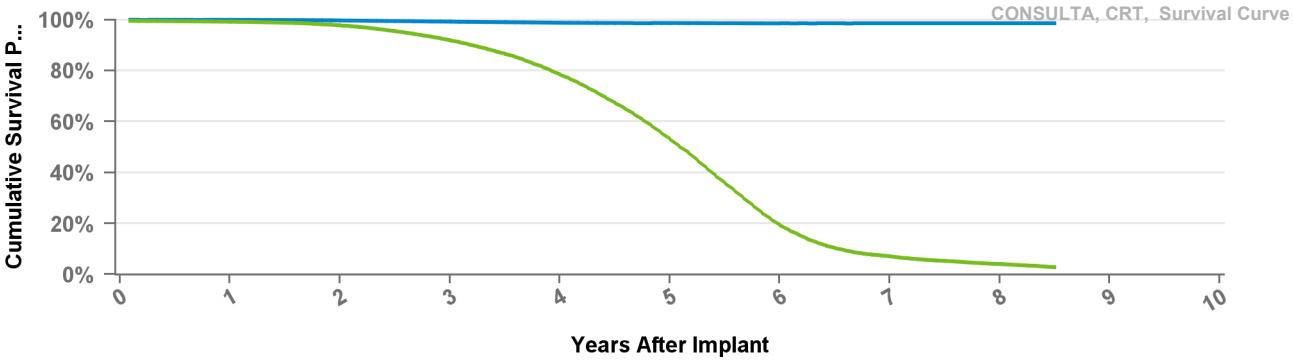
Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

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

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

D204TRM Consulta CRT-D

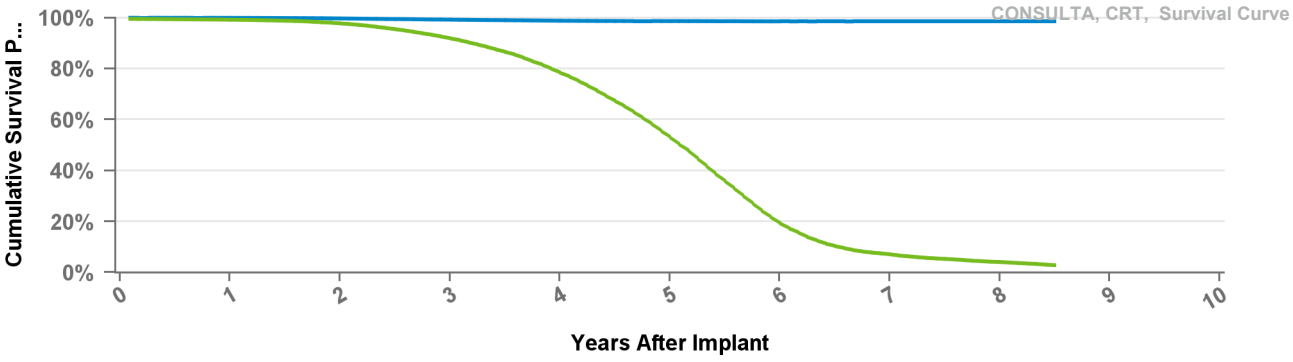
US Market Release	Jan-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	2,099	Battery Malfunction	1
Estimated Active USA Implants	273	Electrical Component	1
Normal Battery Depletions	723	Poss Early Battery Depltn	1
		Therapy Function Compromised	**0**



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.5%	98.5%	98.5%
Including NBD	99.2%	97.8%	91.9%	78.5%	53.1%	19.4%	7.1%	4.1%	2.8%
Effective Sample Size	56964	50970	43415	33008	17997	4874	1172	431	124

D214TRM Consulta CRT-D

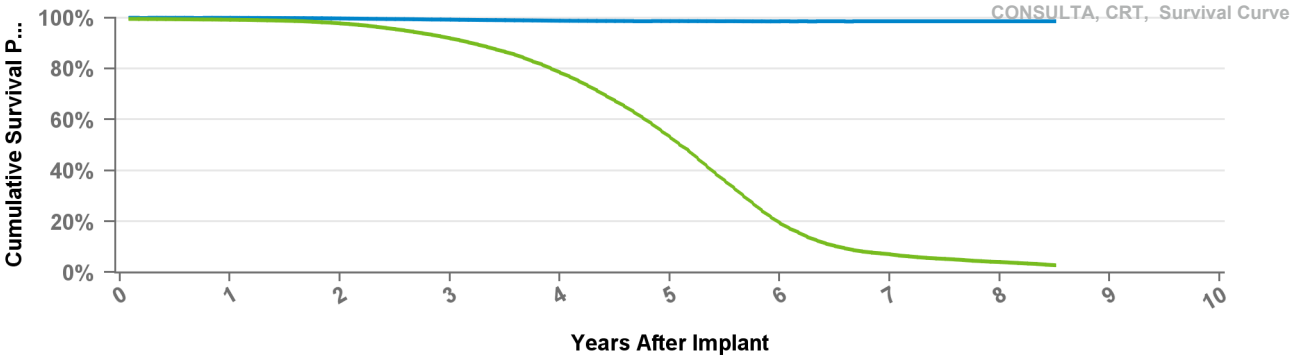
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.5%	98.5%	98.5%
Including NBD	99.2%	97.8%	91.9%	78.5%	53.1%	19.4%	7.1%	4.1%	2.8%
Effective Sample Size	56964	50970	43415	33008	17997	4874	1172	431	124

D224TRK Consulta CRT-D

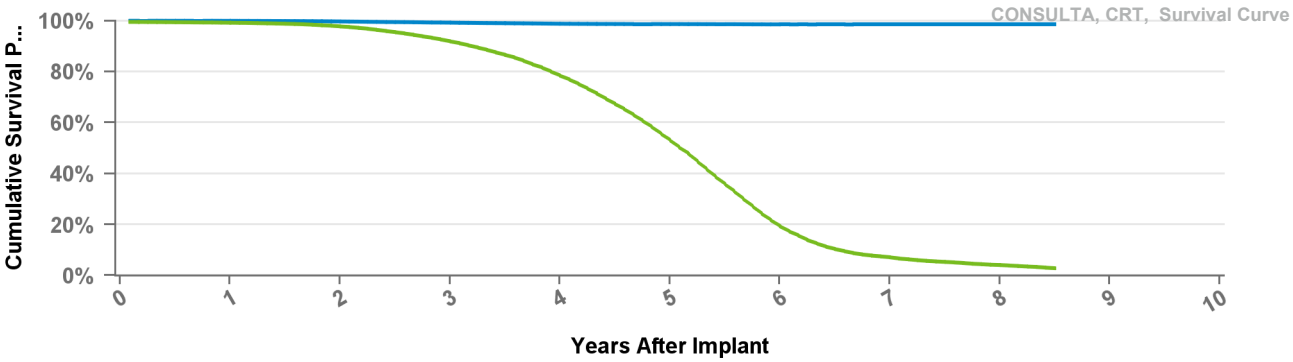
US Market Release	Sep-08	**Total Malfunctions**	**605**
CE Approval Date		**Therapy Function Not Compromised**	**574**
Registered USA Implants	66,033	Battery Malfunction	2
Estimated Active USA Implants	5,219	Electrical Component	67
Normal Battery Depletions	18,947	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	497
		Software Malfunction	6
		Therapy Function Compromised	**31**
		Battery Malfunction	5
		Electrical Component	26



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.5%	98.5%	98.5%
Including NBD	99.2%	97.8%	91.9%	78.5%	53.1%	19.4%	7.1%	4.1%	2.8%
Effective Sample Size	56964	50970	43415	33008	17997	4874	1172	431	124

D234TRK Consulta CRT-D

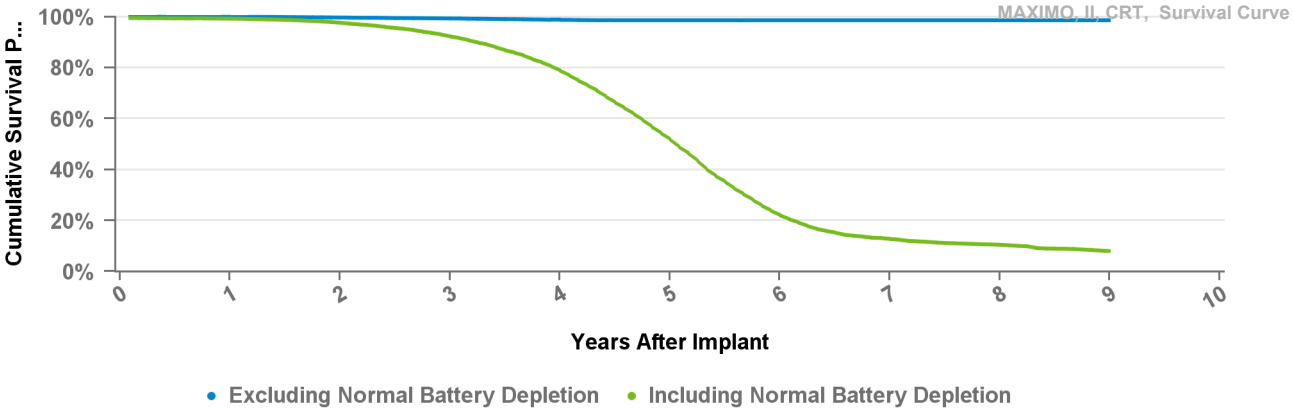
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.7%	98.6%	98.5%	98.5%	98.5%
Including NBD	99.2%	97.8%	91.9%	78.5%	53.1%	19.4%	7.1%	4.1%	2.8%
Effective Sample Size	56964	50970	43415	33008	17997	4874	1172	431	124

D264TRM Maximo II CRT-D

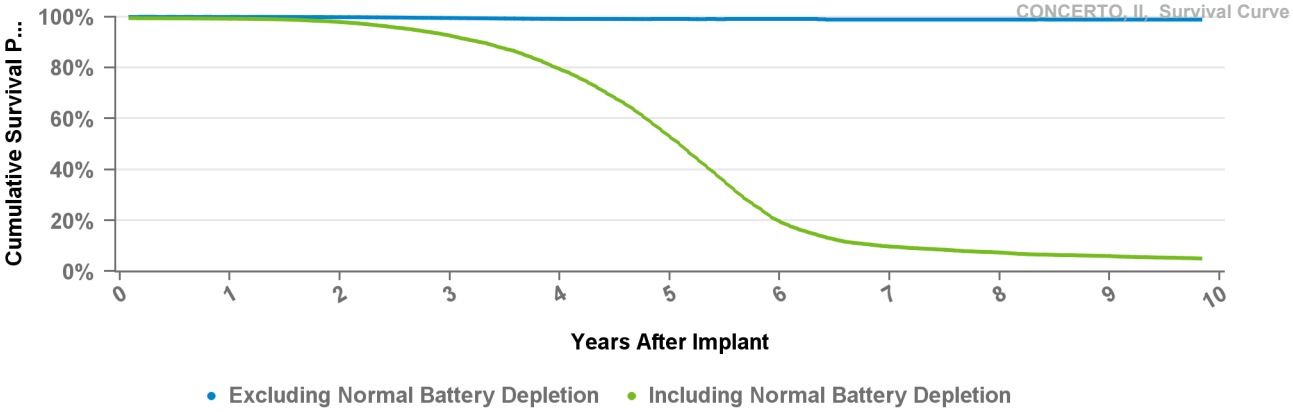
US Market Release	Jan-12	**Total Malfunctions**	**1**
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	**1**
Registered USA Implants	15	Other Malfunction	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.6%	98.6%	98.6%	98.6%	98.6%
Including NBD	99.3%	97.7%	92.3%	78.9%	51.9%	22.1%	12.8%	10.5%	8.0%
Effective Sample Size	12731	11289	9643	7242	3692	1103	477	314	107

D274TRK Concerto II CRT-D

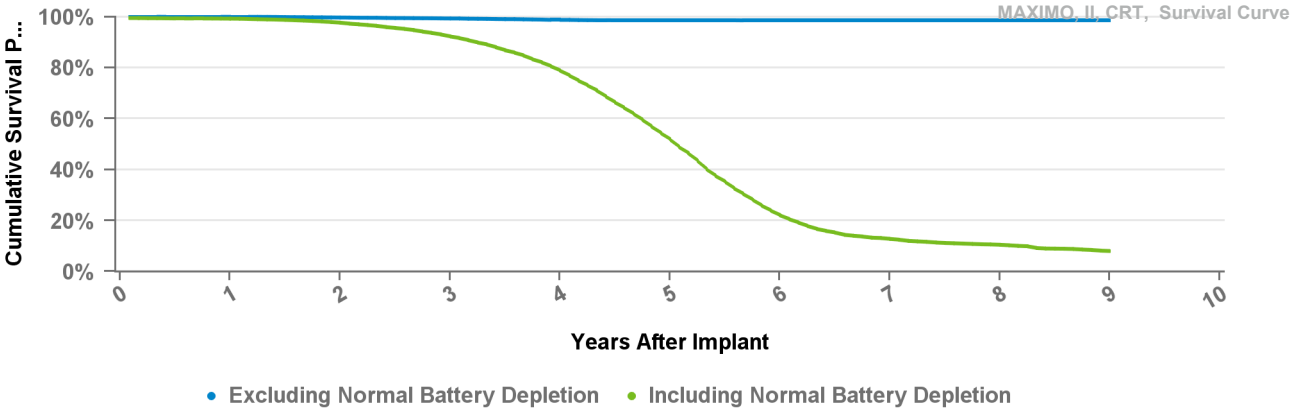
US Market Release	Aug-09	**Total Malfunctions**	**187**
CE Approval Date		**Therapy Function Not Compromised**	**176**
Registered USA Implants	30,191	Battery Malfunction	1
Estimated Active USA Implants	2,646	Electrical Component	22
Normal Battery Depletions	7,999	Poss Early Battery Depltn	152
		Software Malfunction	1
		Therapy Function Compromised	**11**
		Battery Malfunction	1
		Electrical Component	10



Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%	99.0%	99.0%	99.0%	98.9%	98.9%
Including NBD	99.2%	97.9%	92.6%	79.4%	52.8%	19.5%	9.8%	7.4%	6.0%	5.1%
Effective Sample Size	25004	22429	19256	14534	7460	1983	709	451	287	118

D284TRK Maximo II CRT-D

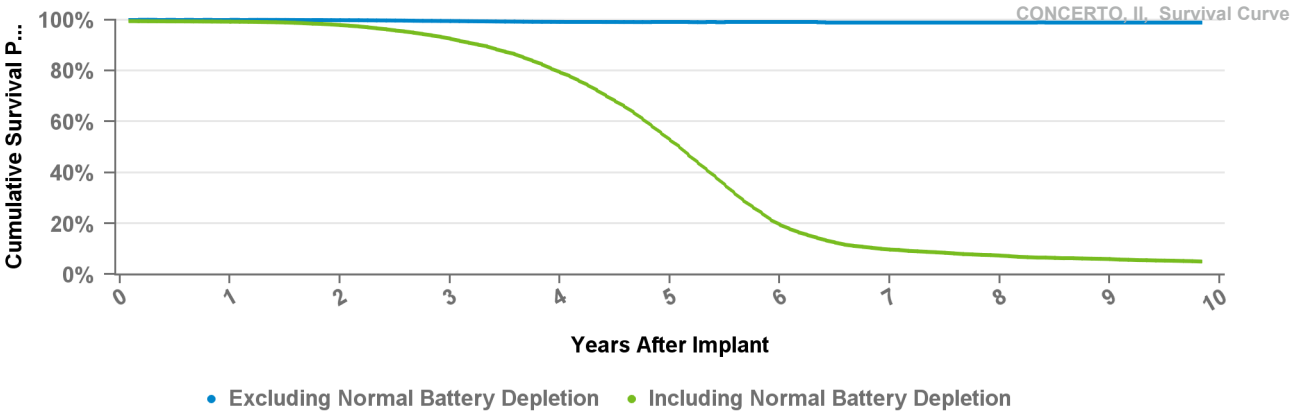
US Market Release	Sep-08	**Total Malfunctions**	**135**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**130**
Registered USA Implants	15,257	Electrical Component	6
Estimated Active USA Implants	1,411	Poss Early Battery Depltn	124
Normal Battery Depletions	4,081	**Therapy Function Compromised**	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	99.7%	99.3%	98.8%	98.6%	98.6%	98.6%	98.6%	98.6%
Including NBD	99.3%	97.7%	92.3%	78.9%	51.9%	22.1%	12.8%	10.5%	8.0%
Effective Sample Size	12731	11289	9643	7242	3692	1103	477	314	107

D294TRK Concerto II CRT-D

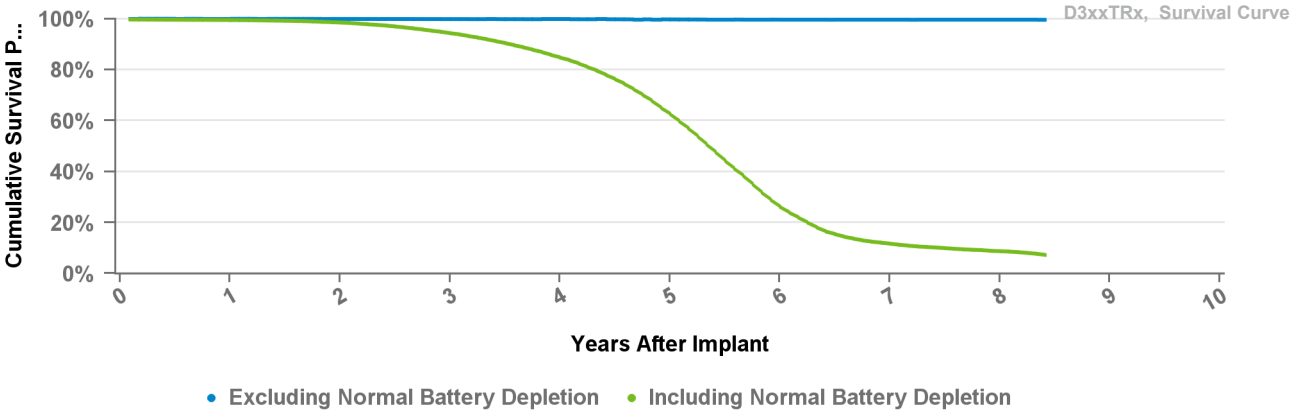
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%	99.0%	99.0%	99.0%	98.9%	98.9%
Including NBD	99.2%	97.9%	92.6%	79.4%	52.8%	19.5%	9.8%	7.4%	6.0%	5.1%
Effective Sample Size	25004	22429	19256	14534	7460	1983	709	451	287	118

D314TRG Protecta XT CRT-D

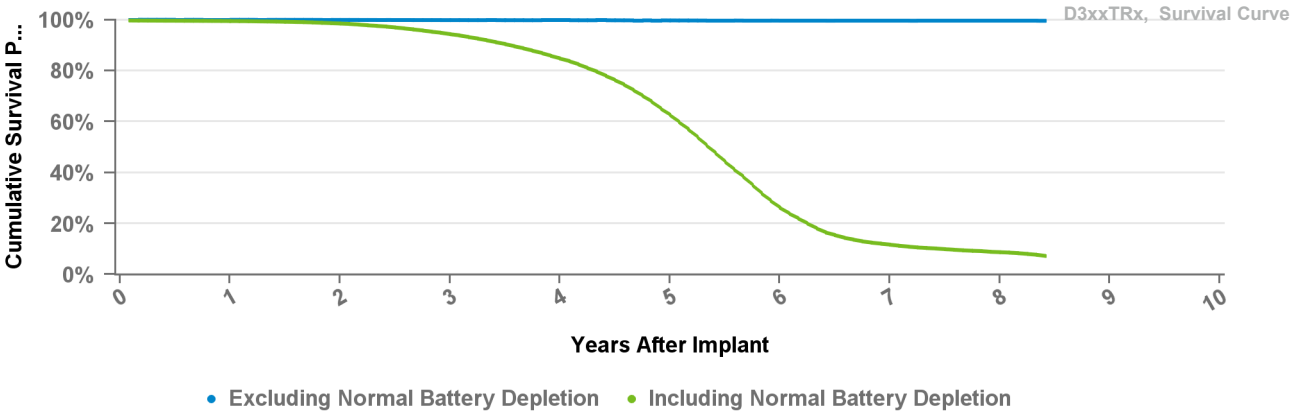
US Market Release	Mar-11	**Total Malfunctions**	**93**
CE Approval Date		**Therapy Function Not Compromised**	**74**
Registered USA Implants	42,541	Battery Malfunction	7
Estimated Active USA Implants	4,963	Electrical Component	40
Normal Battery Depletions	10,473	Other Malfunction	2
		Poss Early Battery Depltn	25
		Therapy Function Compromised	**19**
		Battery Malfunction	11
		Electrical Component	8



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D314TRM Protecta XT CRT-D

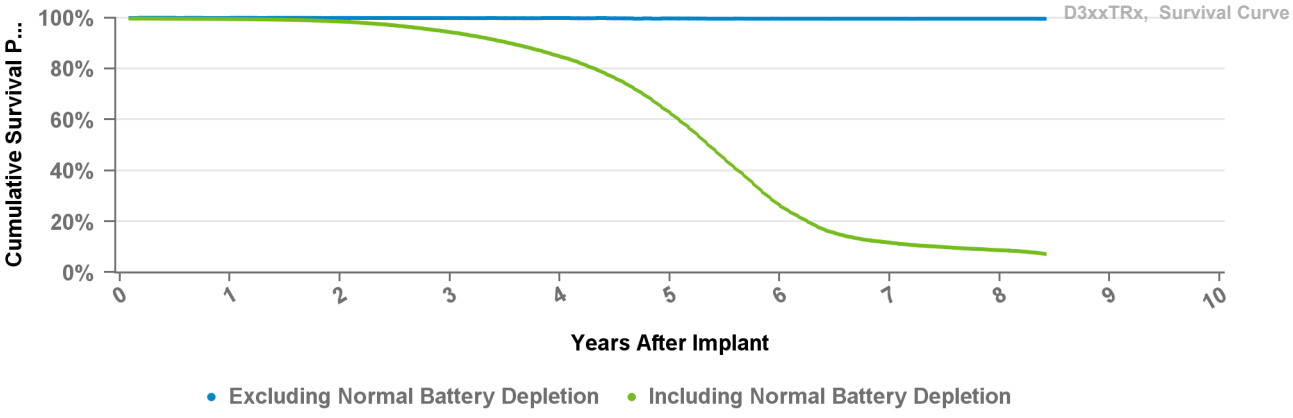
US Market Release	Nov-11	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**17**
Registered USA Implants	12,264	Battery Malfunction	4
Estimated Active USA Implants	1,515	Electrical Component	8
Normal Battery Depletions	3,496	Poss Early Battery Depltn	5
		Therapy Function Compromised	**3**
		Battery Malfunction	1
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D334TRG Protecta CRT-D

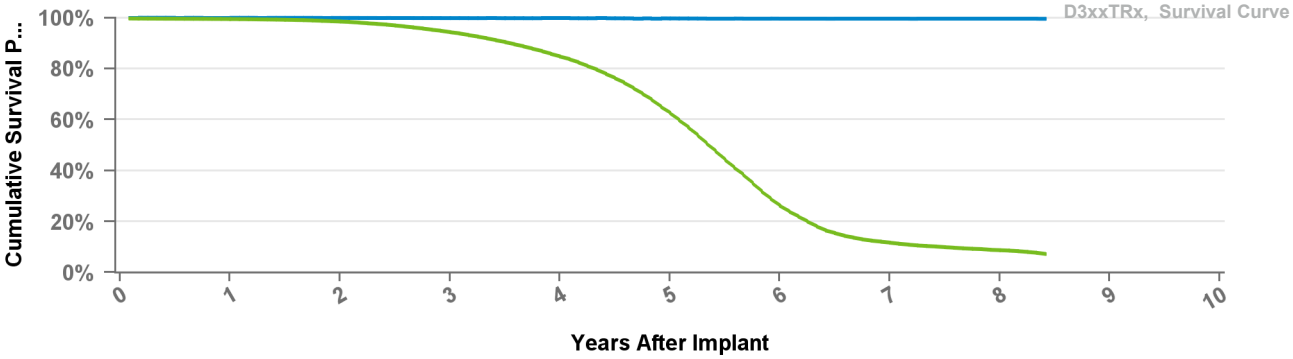
US Market Release	Mar-11	**Total Malfunctions**	**14**
CE Approval Date		**Therapy Function Not Compromised**	**11**
Registered USA Implants	8,103	Electrical Component	8
Estimated Active USA Implants	1,016	Poss Early Battery Depltn	3
Normal Battery Depletions	2,150	**Therapy Function Compromised**	**3**
		Battery Malfunction	1
		Electrical Component	1
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D334TRM Protecta CRT-D

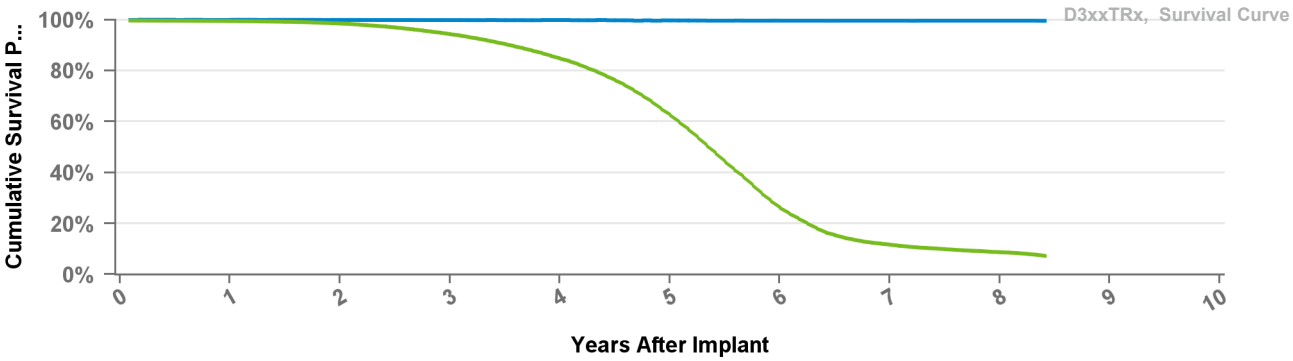
US Market Release	Nov-11	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	1,786	Battery Malfunction	3
Estimated Active USA Implants	258	Electrical Component	1
Normal Battery Depletions	568	Poss Early Battery Depltn	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D354TRG Protecta XT CRT-D

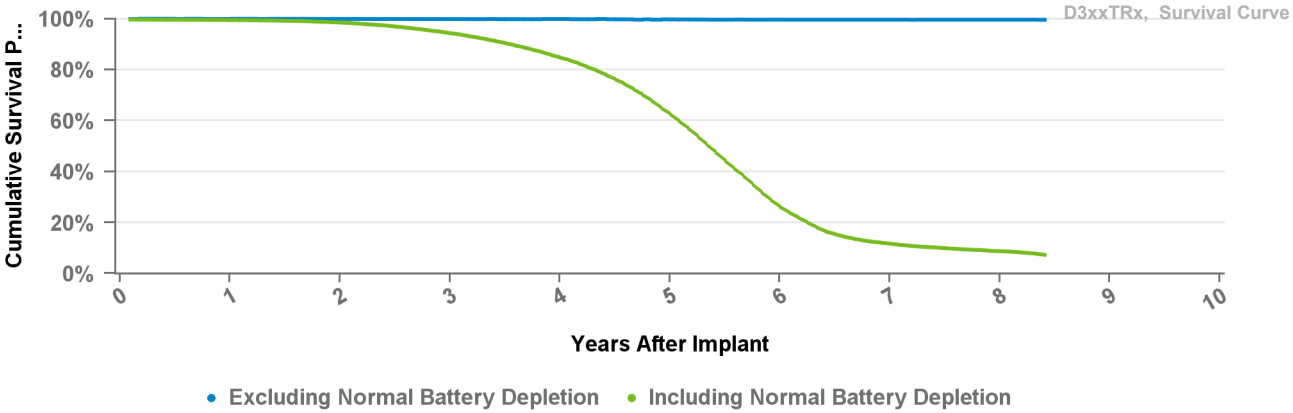
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D354TRM Protecta XT CRT-D

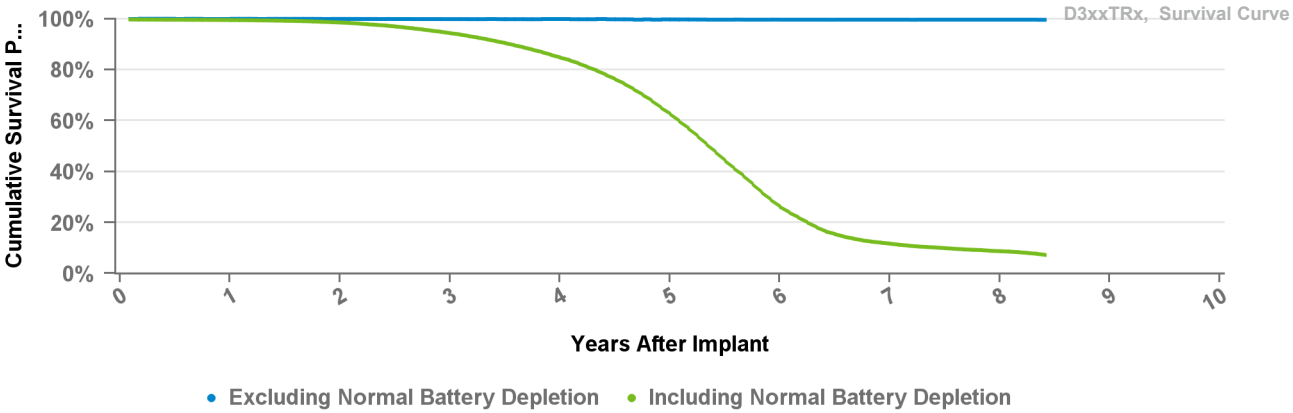
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D364TRG Protecta CRT-D

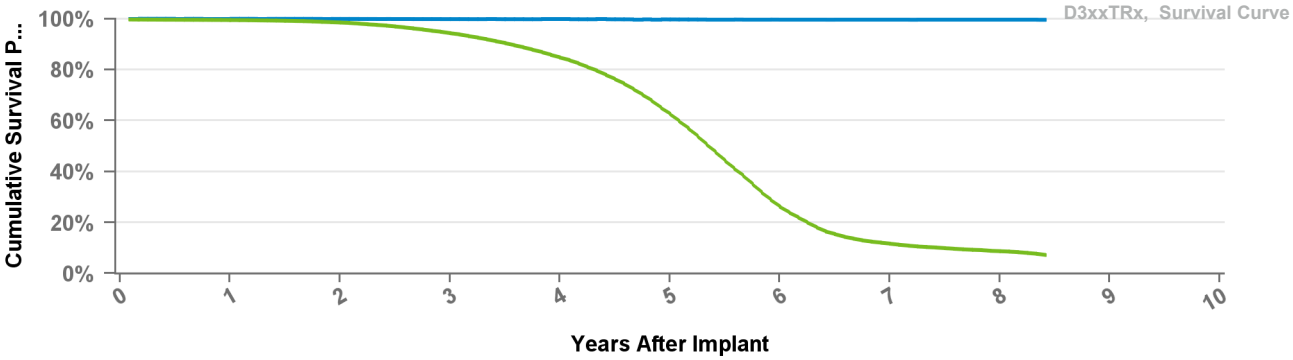
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D364TRM Protecta CRT-D

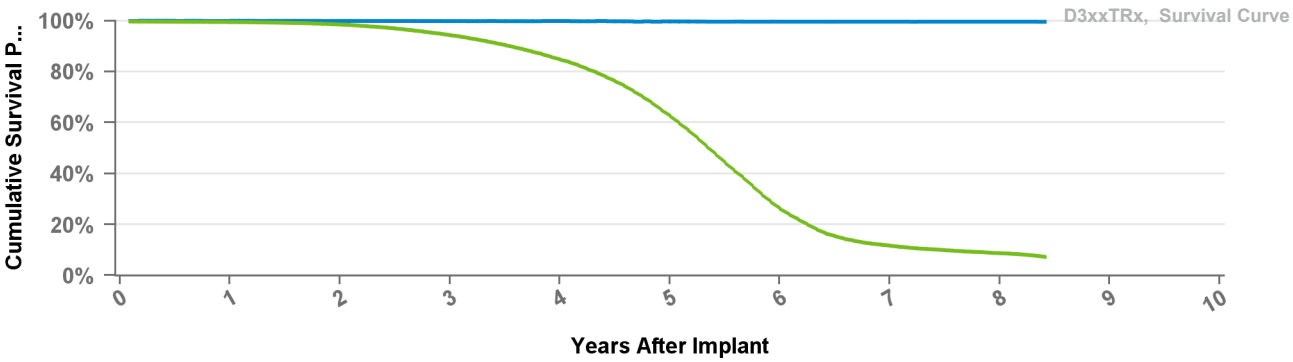
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D384TRG Cardia CRT-D

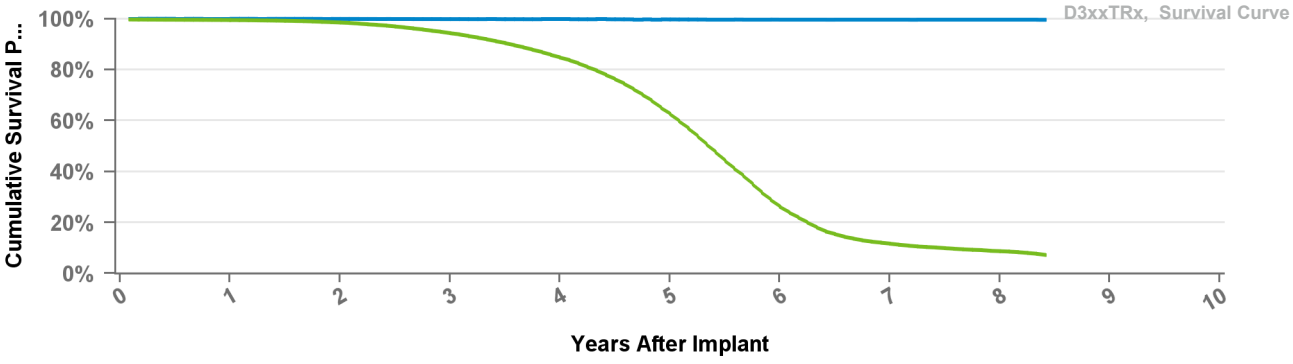
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

D394TRG Egida CRT-D

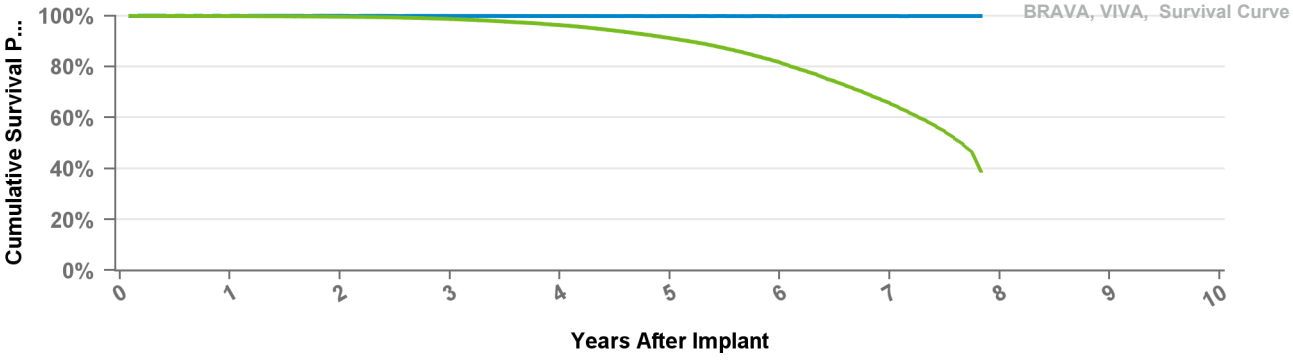
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.5%	98.5%	94.3%	84.8%	62.7%	26.2%	11.7%	8.7%	7.2%
Effective Sample Size	54902	49616	42817	33505	19691	6255	1918	784	201

DTBA1D1 Viva XT

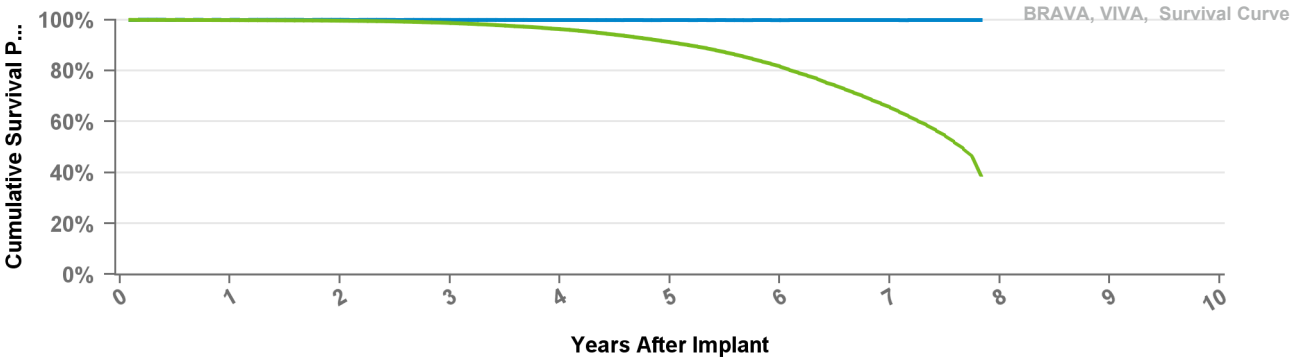
US Market Release	Jan-13	**Total Malfunctions**	**121**
CE Approval Date		**Therapy Function Not Compromised**	**84**
Registered USA Implants	111,001	Battery Malfunction	16
Estimated Active USA Implants	45,879	Electrical Component	61
Normal Battery Depletions	8,379	Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**37**
		Battery Malfunction	27
		Electrical Component	10



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBA1D4 Viva XT

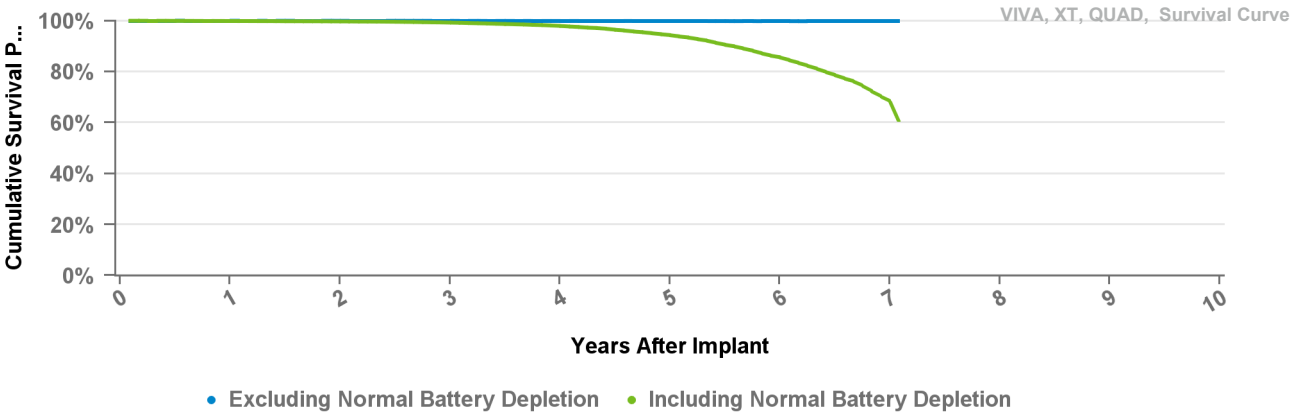
US Market Release	Jan-13	**Total Malfunctions**	**62**
CE Approval Date		**Therapy Function Not Compromised**	**48**
Registered USA Implants	38,932	Battery Malfunction	8
Estimated Active USA Implants	15,825	Electrical Component	34
Normal Battery Depletions	3,828	Poss Early Battery Depltn	6
		Therapy Function Compromised	**14**
		Battery Malfunction	8
		Electrical Component	6



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBA1Q1 Viva Quad XT

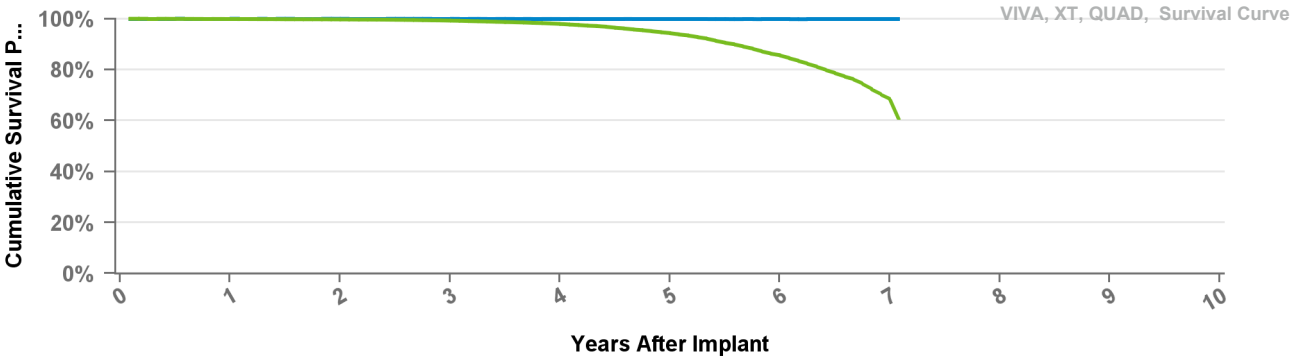
US Market Release	Jul-14	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	21,326	Battery Malfunction	4
Estimated Active USA Implants	10,307	Electrical Component	6
Normal Battery Depletions	1,142	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**6**
		Battery Malfunction	4
		Electrical Component	2



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTBA1QQ Viva Quad XT

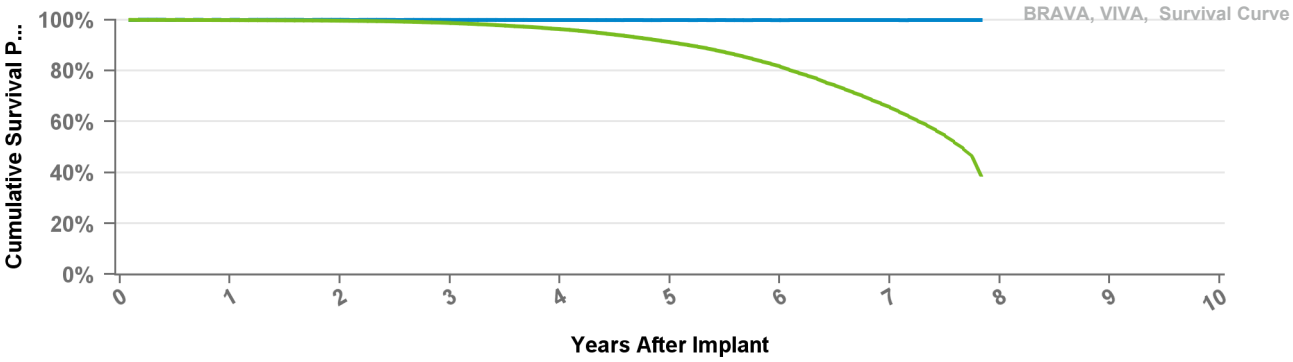
US Market Release	Jul-14	**Total Malfunctions**	**83**
CE Approval Date		**Therapy Function Not Compromised**	**63**
Registered USA Implants	53,719	Battery Malfunction	18
Estimated Active USA Implants	29,712	Electrical Component	34
Normal Battery Depletions	3,022	Electrical Interconnect	2
		Other Malfunction	3
		Poss Early Battery Depltn	6
		Therapy Function Compromised	**20**
		Battery Malfunction	16
		Electrical Component	4



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTBA2D1 Viva XT

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

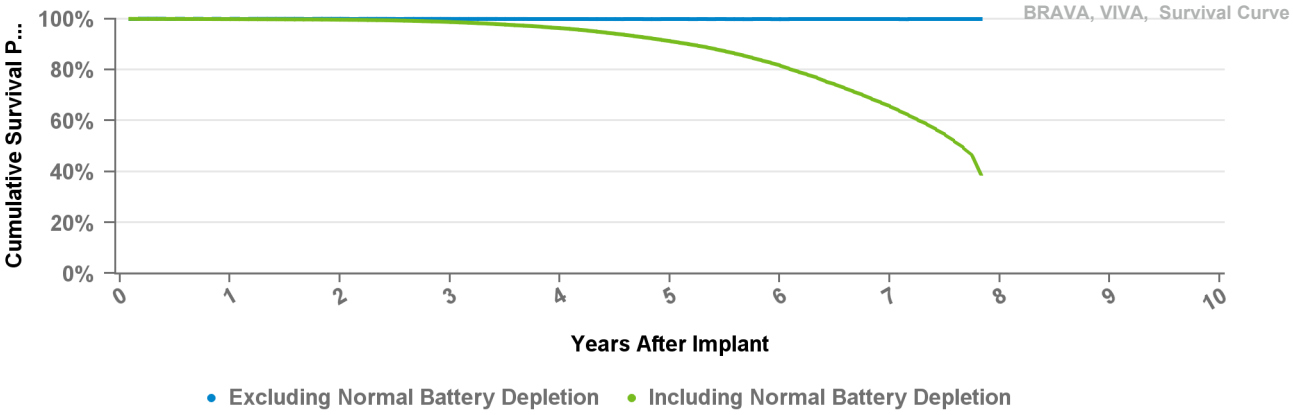


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBA2D4 Viva XT

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

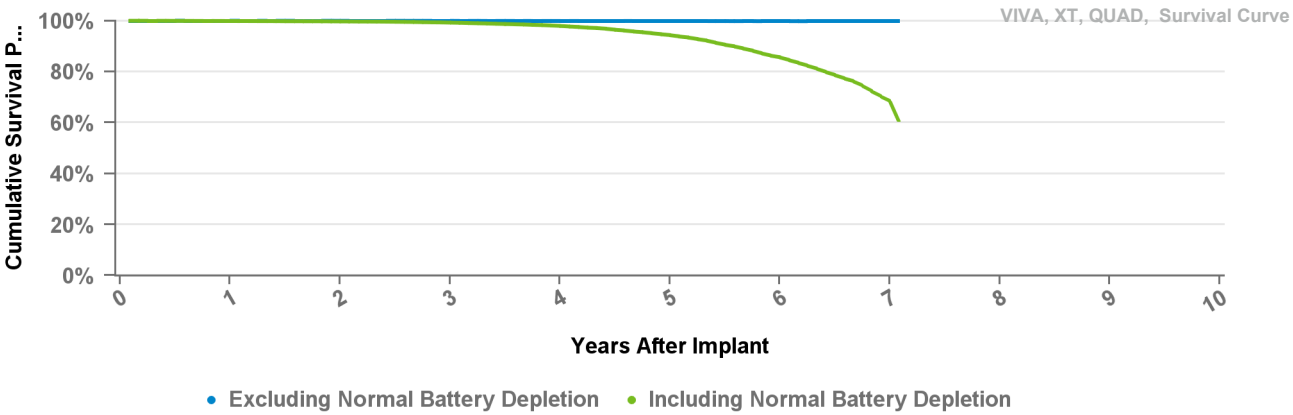


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBA2Q1 Viva Quad XT

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

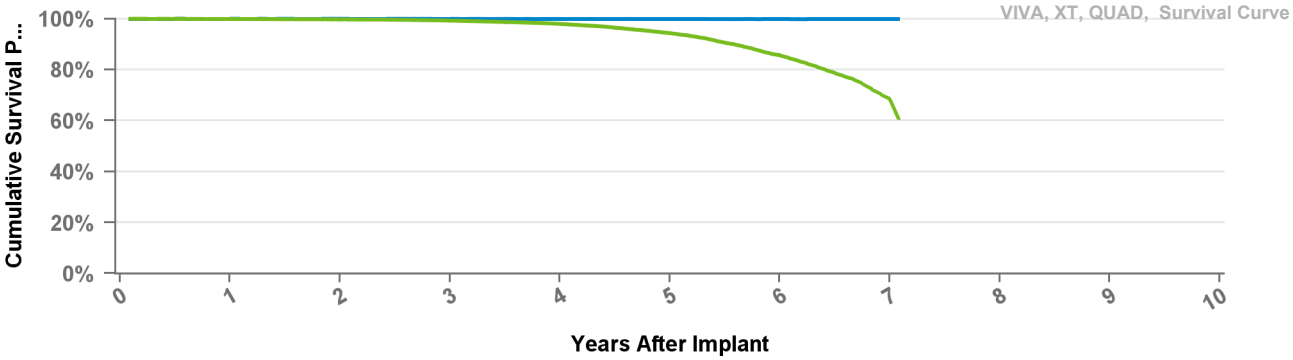
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTBA2QQ Viva Quad XT

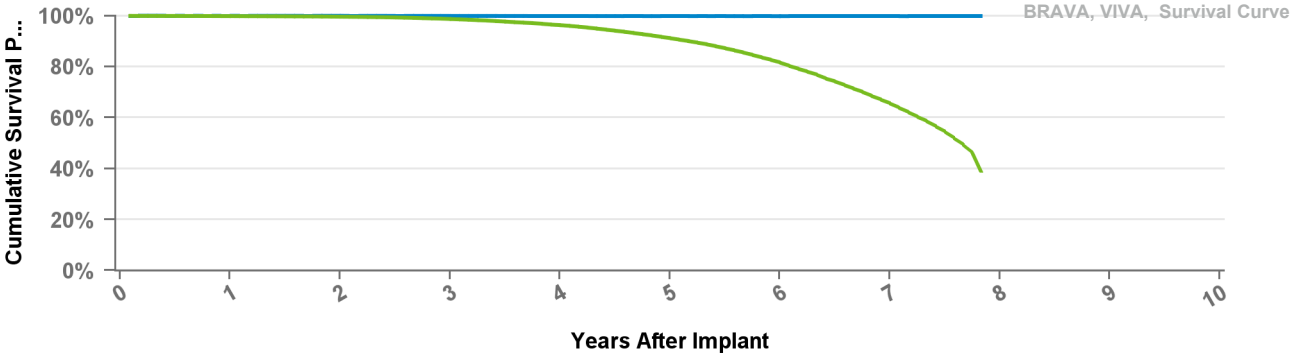
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTBB1D1 Viva S

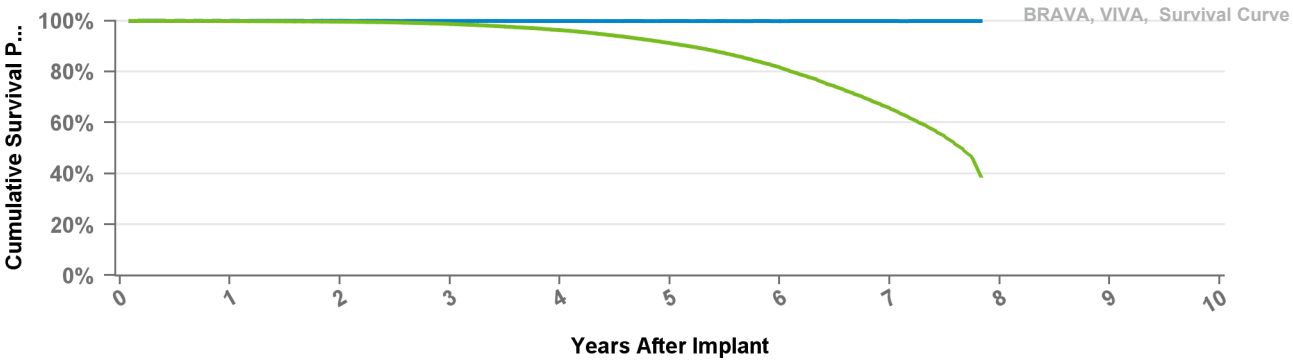
US Market Release	Jan-13	**Total Malfunctions**	**33**
CE Approval Date		**Therapy Function Not Compromised**	**25**
Registered USA Implants	27,550	Battery Malfunction	12
Estimated Active USA Implants	9,380	Electrical Component	7
Normal Battery Depletions	2,936	Other Malfunction	2
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**8**
		Battery Malfunction	6
		Electrical Component	2



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB1D4 Viva S

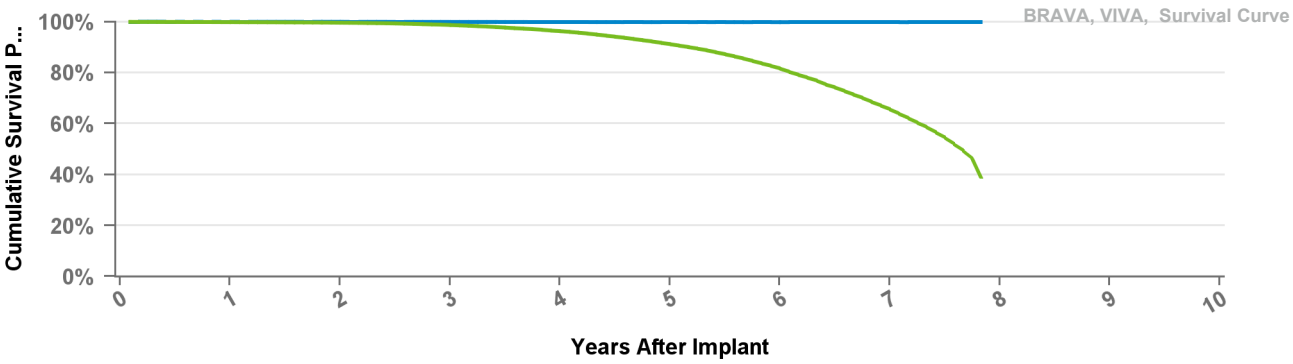
US Market Release	Jan-13	**Total Malfunctions**	**16**
CE Approval Date		**Therapy Function Not Compromised**	**10**
Registered USA Implants	8,818	Battery Malfunction	4
Estimated Active USA Implants	2,977	Electrical Component	4
Normal Battery Depletions	1,150	Other Malfunction	2
		Therapy Function Compromised	**6**
		Battery Malfunction	6



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB1Q1 Viva Quad S

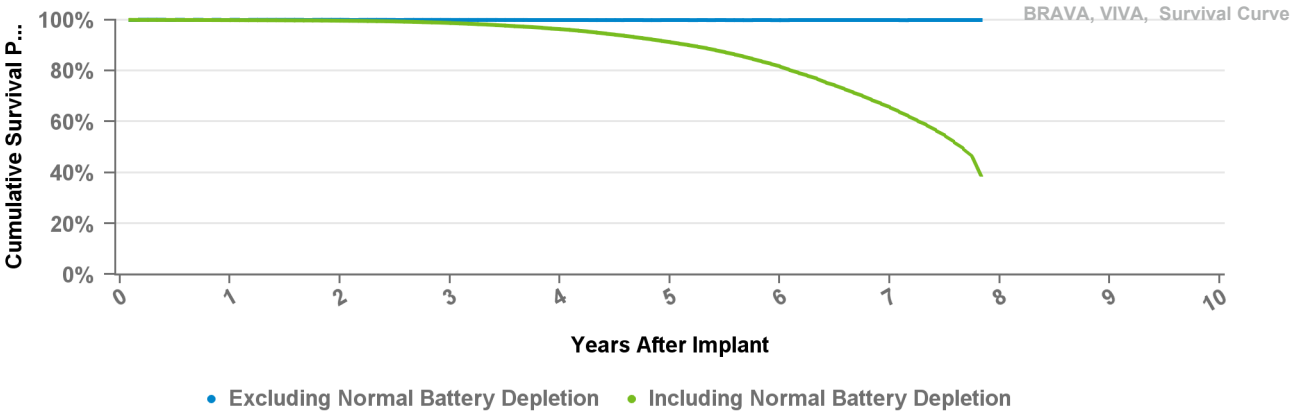
US Market Release	Jul-14	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	4,539	Electrical Component	2
Estimated Active USA Implants	2,098	**Therapy Function Compromised**	**0**
Normal Battery Depletions	321		



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB1QQ Viva Quad S

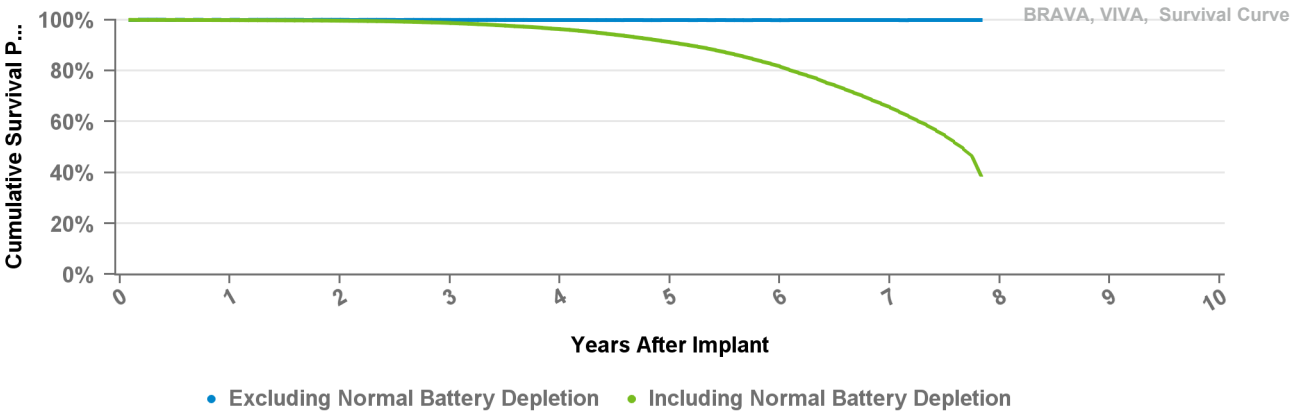
US Market Release	Jul-14	**Total Malfunctions**	**17**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	9,863	Battery Malfunction	2
Estimated Active USA Implants	5,165	Electrical Component	4
Normal Battery Depletions	680	Other Malfunction	3
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**4**
		Electrical Component	4



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB2D1 Viva S

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

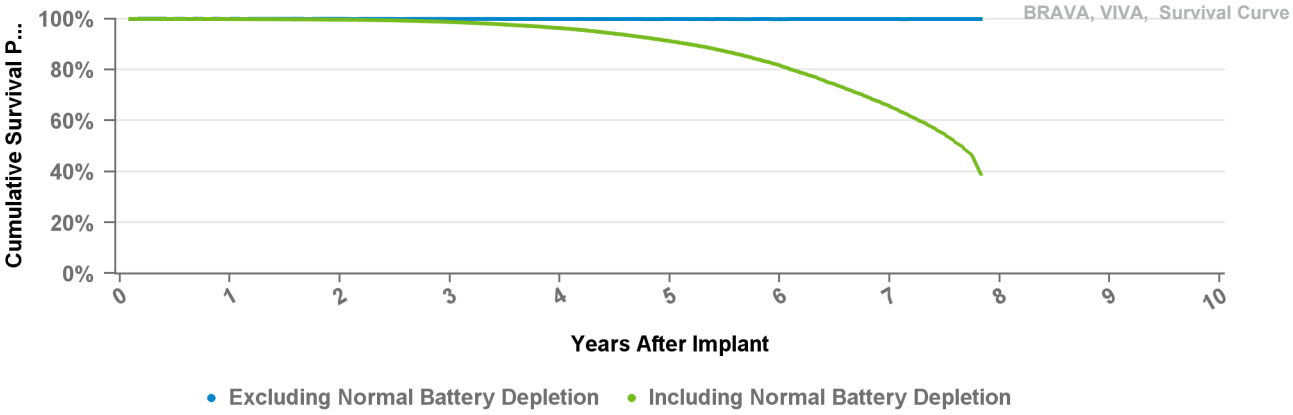


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB2D4 Viva S

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

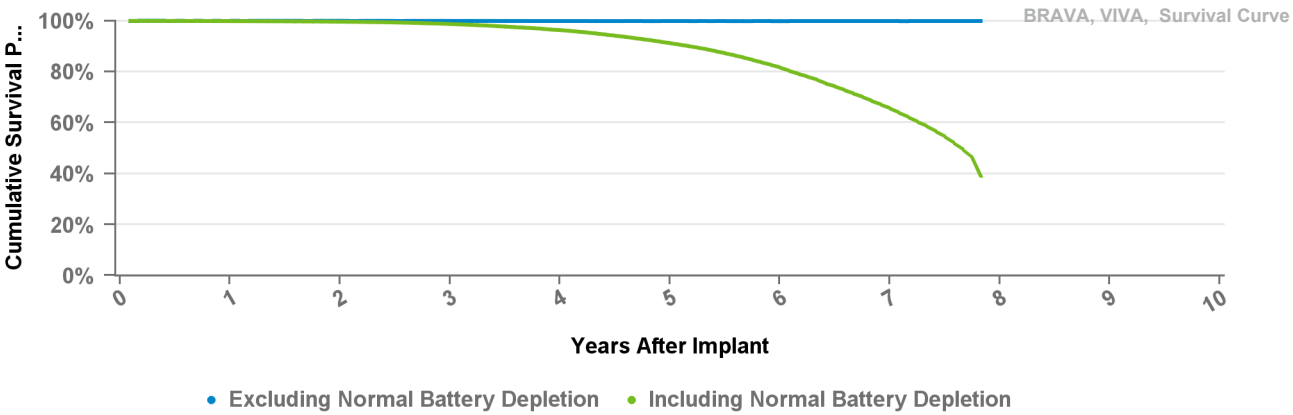


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBB2QQ Viva Quad S

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

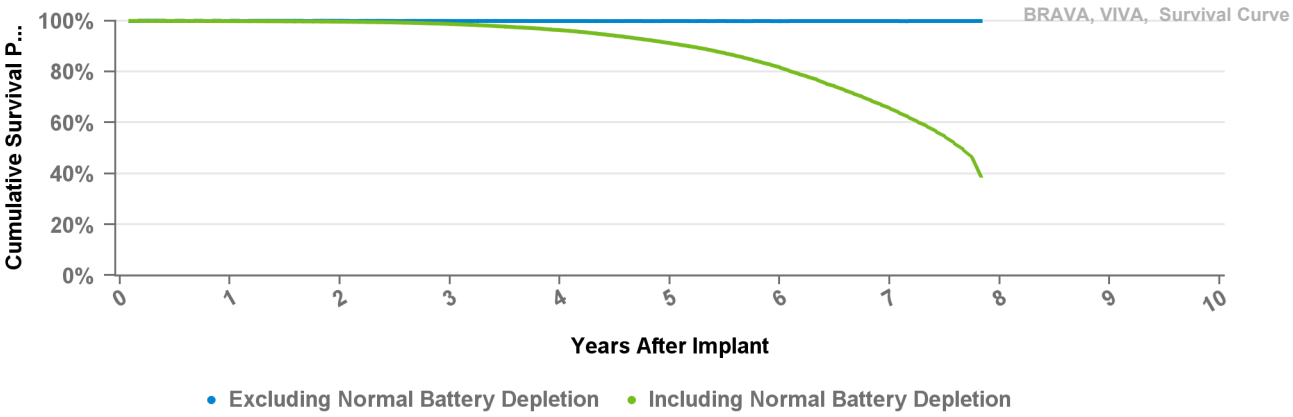


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBC2D1 Brava

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

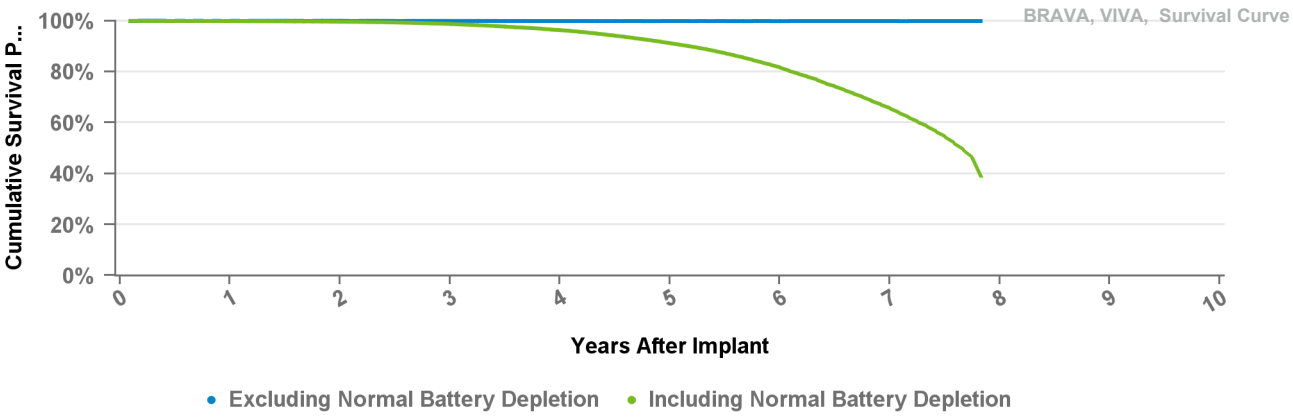


Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBC2D4 Brava

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

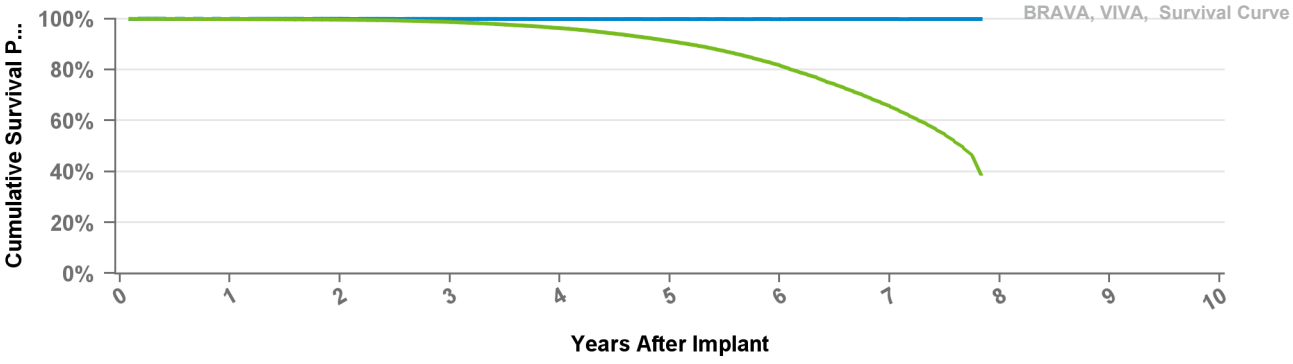
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBC2Q1 Brava Quad

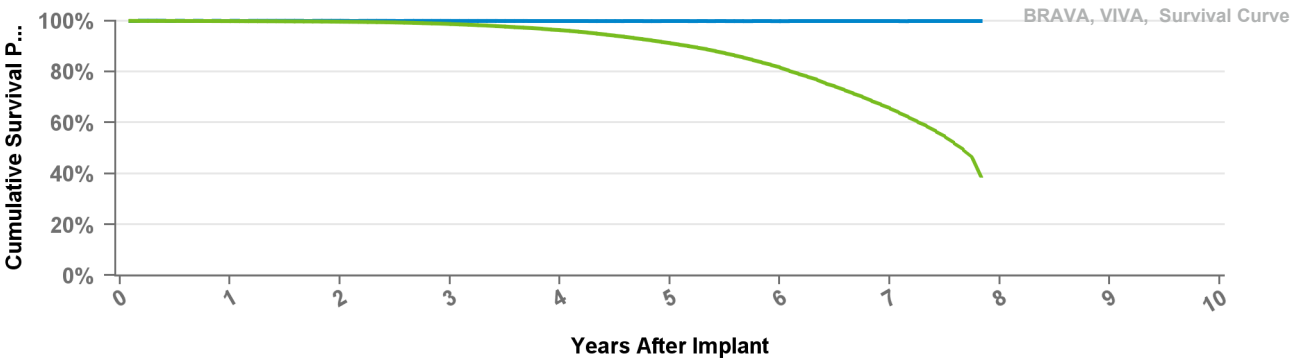
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-13	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBC2QQ Brava Quad

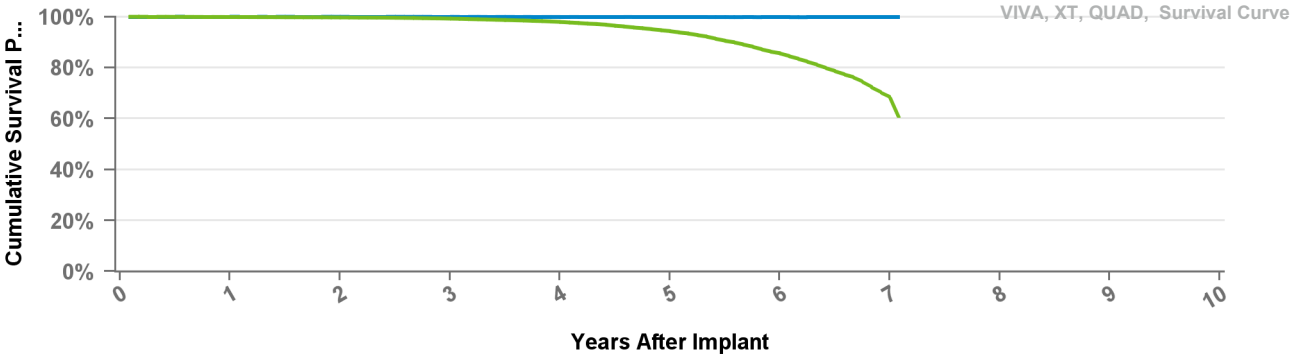
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-12	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	at 94 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.6%	98.7%	96.3%	91.2%	81.6%	65.6%	38.9%
Effective Sample Size	89302	80732	71638	60565	45922	27022	10924	626

DTBX1QQ Viva Quad C

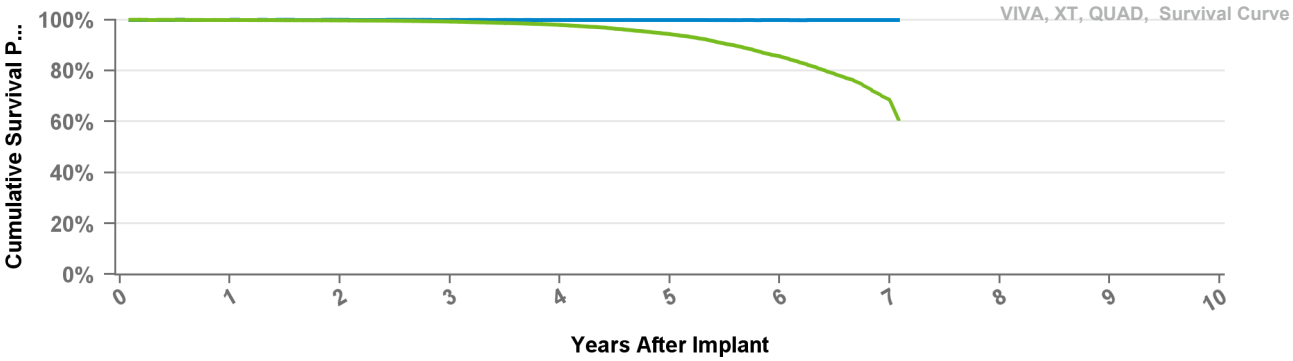
US Market Release	Jul-14	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**2**
Registered USA Implants	1,274	Electrical Component	2
Estimated Active USA Implants	178	**Therapy Function Compromised**	**0**
Normal Battery Depletions	360		



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTBX2QQ Viva Quad C

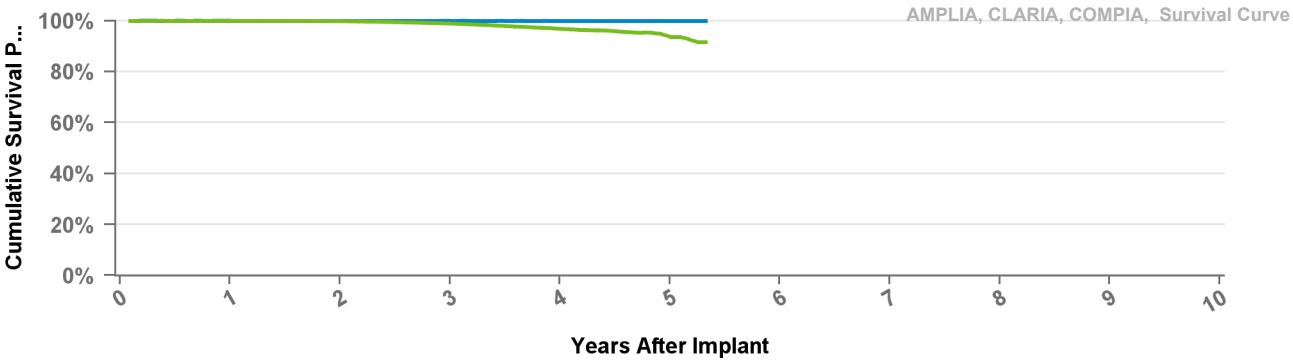
US Market Release	Jul-14	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	at 85 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.3%	98.0%	94.4%	85.6%	68.4%	60.9%
Effective Sample Size	34749	31991	29083	25510	20307	11040	877	336

DTMA1D1 Claria MRI

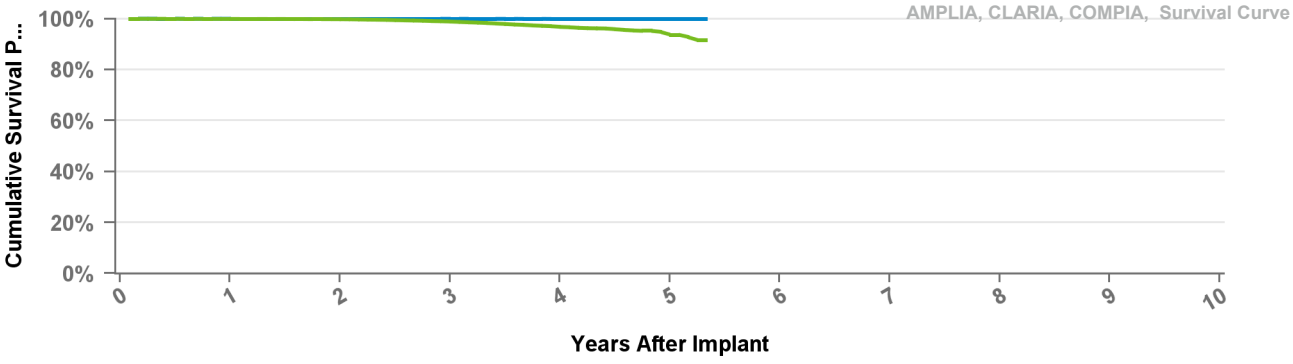
US Market Release	Dec-16	**Total Malfunctions**	**7**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	14,446	Battery Malfunction	2
Estimated Active USA Implants	11,367	Electrical Interconnect	1
Normal Battery Depletions	93	Other Malfunction	2
		Therapy Function Compromised	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMA1D4 Claria MRI

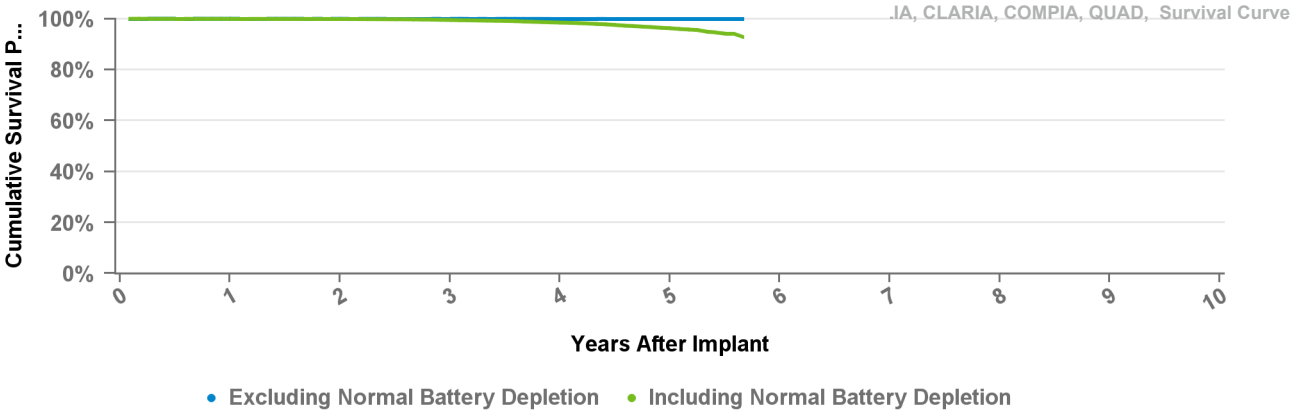
US Market Release	Dec-16	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	12,734	Electrical Component	3
Estimated Active USA Implants	10,462	**Therapy Function Compromised**	**1**
Normal Battery Depletions	72	Electrical Interconnect	1



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMA1Q1 Claria MRI

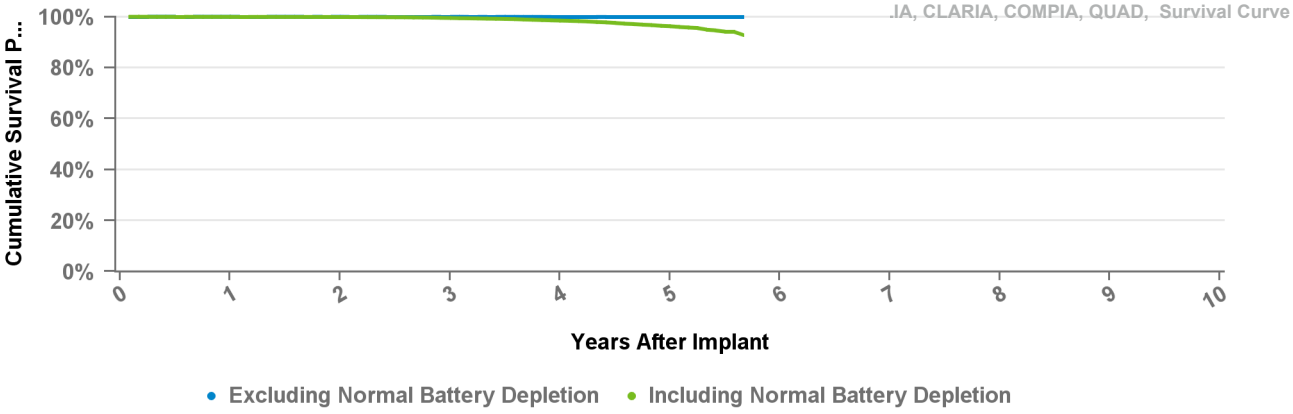
US Market Release	Dec-16	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	9,918	Electrical Interconnect	2
Estimated Active USA Implants	8,073	Other Malfunction	1
Normal Battery Depletions	19	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMA1QQ Claria MRI

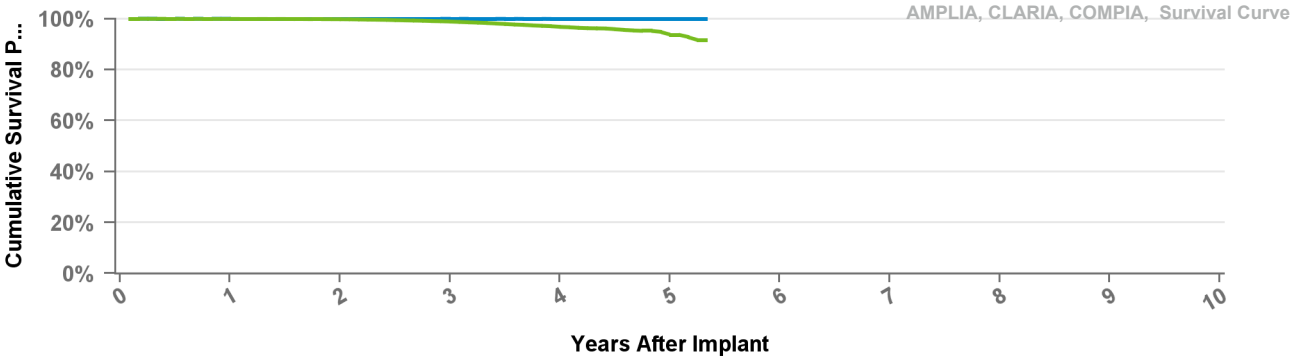
US Market Release	Dec-16	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**14**
Registered USA Implants	63,310	Electrical Component	8
Estimated Active USA Implants	54,486	Electrical Interconnect	1
Normal Battery Depletions	164	Other Malfunction	4
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**4**
		Electrical Component	4



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMA2D1 Claria MRI

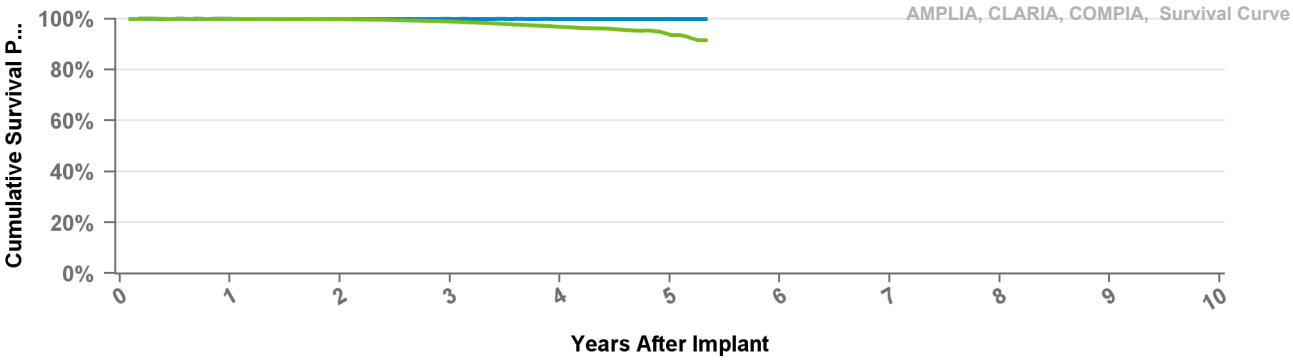
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMA2D4 Claria MRI

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

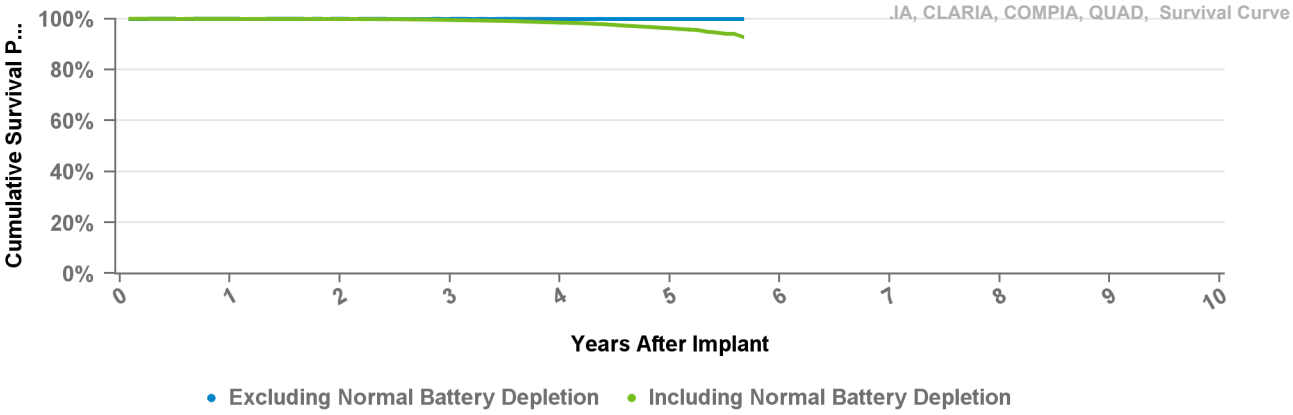


Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMA2Q1 Claria MRI

US Market Release
CE Approval Date Aug-16
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

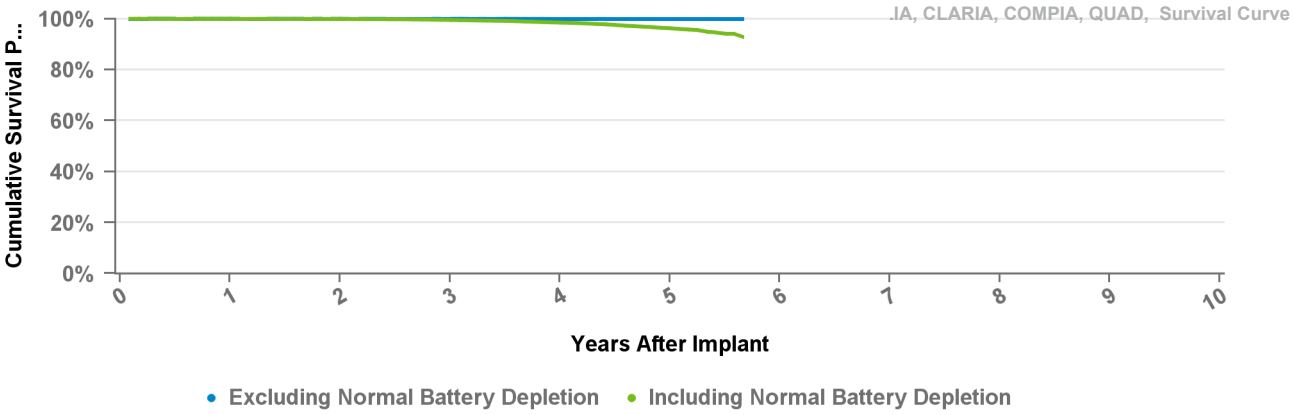


Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMA2QQ Claria MRI

US Market Release
CE Approval Date Feb-16
Registered USA Implants
Estimated Active USA Implants
Normal Battery Depletions

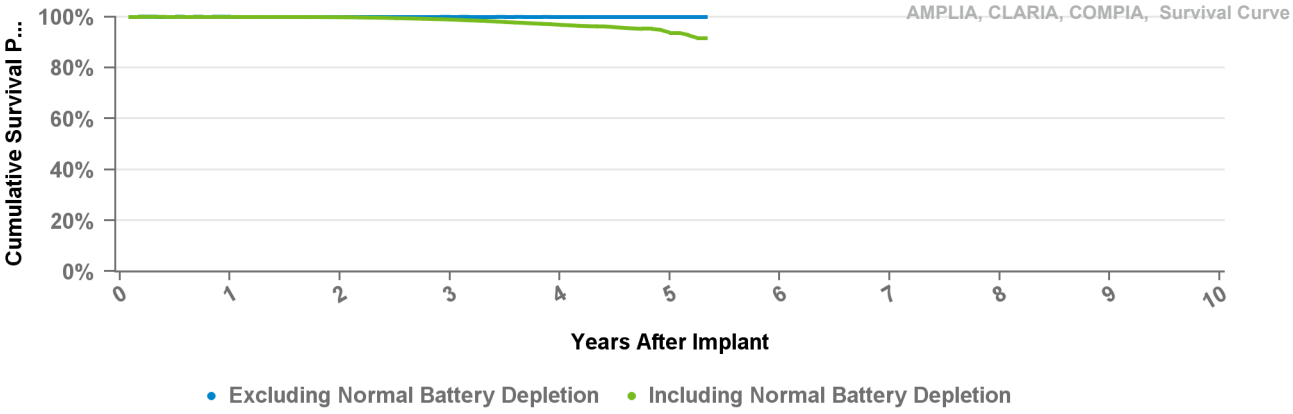
Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMB1D1 Amplia MRI

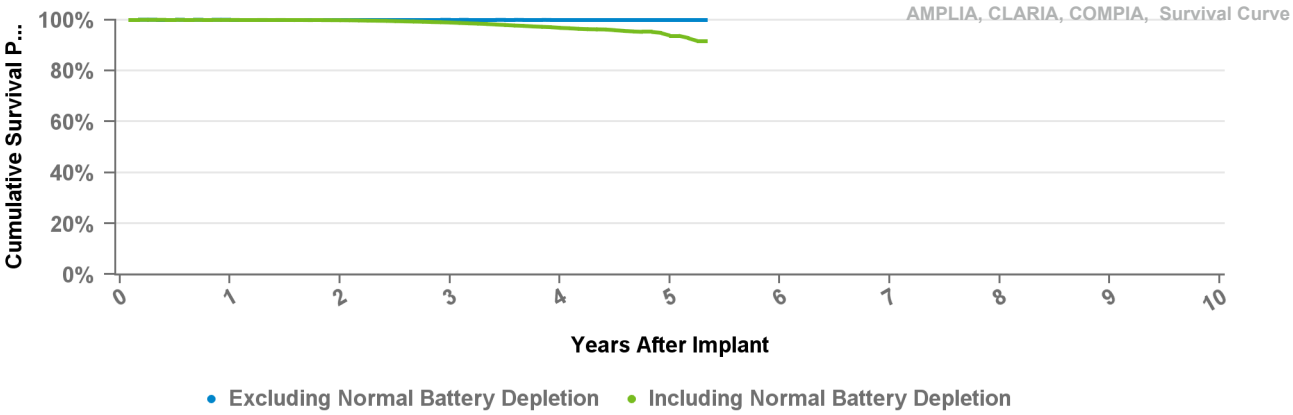
US Market Release	Dec-16	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	8,398	Battery Malfunction	2
Estimated Active USA Implants	6,164	Other Malfunction	1
Normal Battery Depletions	59	**Therapy Function Compromised**	**2**
		Battery Malfunction	2



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMB1D4 Amplia MRI

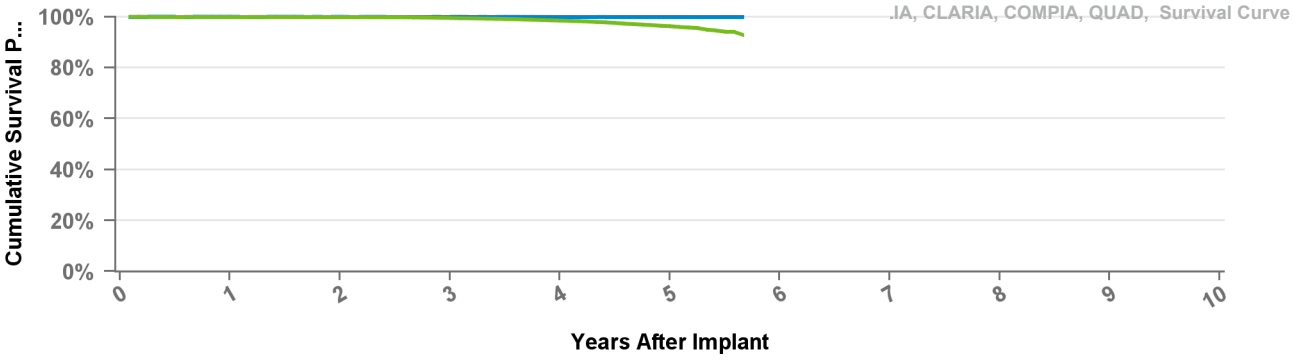
US Market Release	Feb-16	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**3**
Registered USA Implants	9,199	Electrical Component	3
Estimated Active USA Implants	6,477	**Therapy Function Compromised**	**2**
Normal Battery Depletions	126	Poss Early Battery Depltn	2



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMB1Q1 Amplia MRI

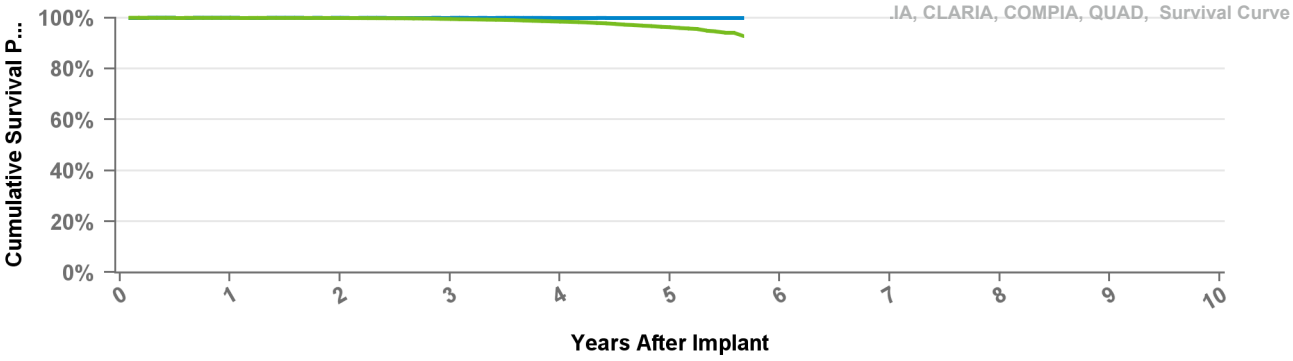
US Market Release	Dec-16	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	5,095		
Estimated Active USA Implants	3,805	**Therapy Function Compromised**	**2**
Normal Battery Depletions	31	Battery Malfunction	2



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMB1QQ Amplia MRI

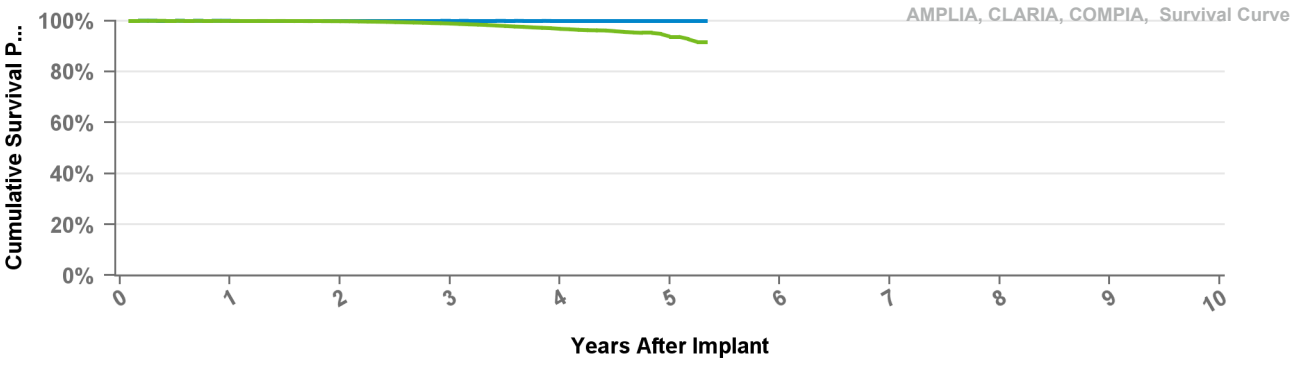
US Market Release	Feb-16	**Total Malfunctions**	**50**
CE Approval Date		**Therapy Function Not Compromised**	**38**
Registered USA Implants	46,864	Battery Malfunction	10
Estimated Active USA Implants	35,088	Electrical Component	16
Normal Battery Depletions	469	Other Malfunction	8
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**12**
		Battery Malfunction	12



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMB2D1 Amplia MRI

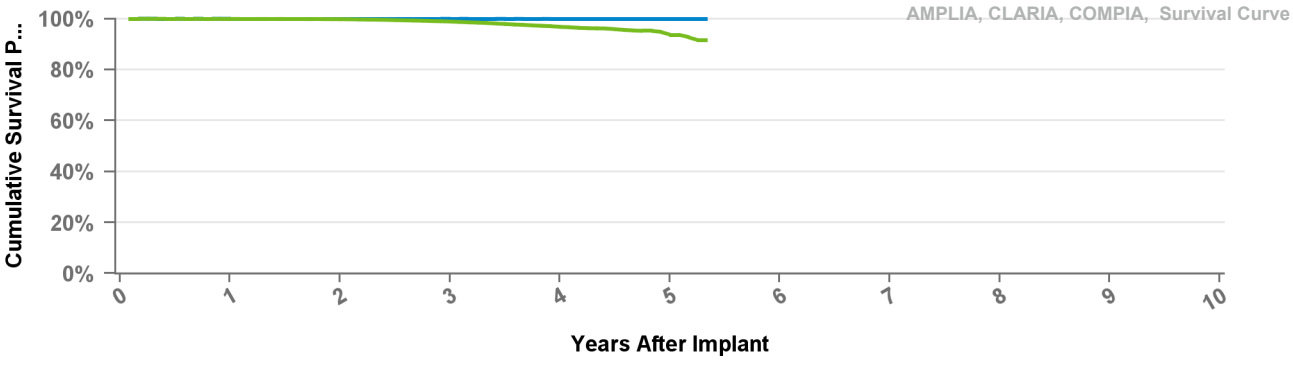
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMB2D4 Amplia MRI

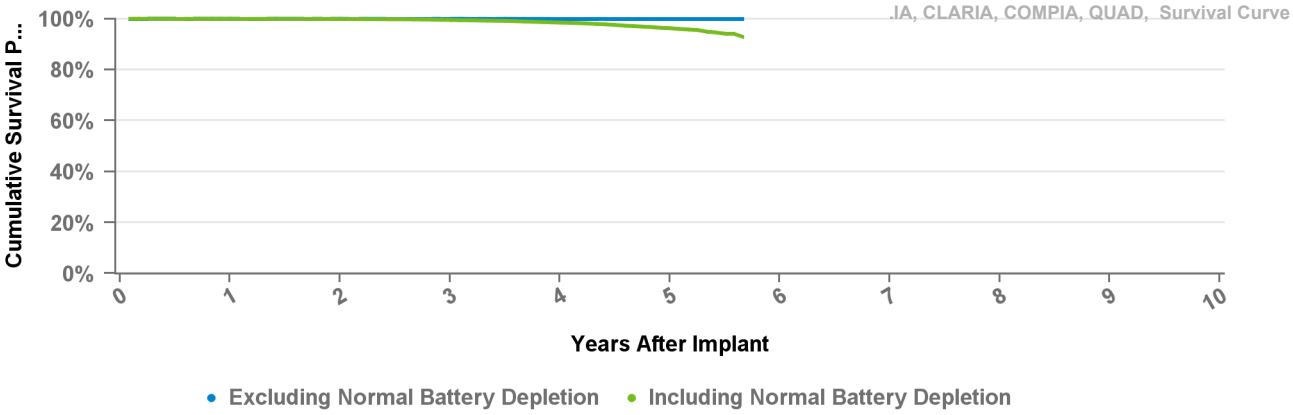
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMB2Q1 Amplia MRI

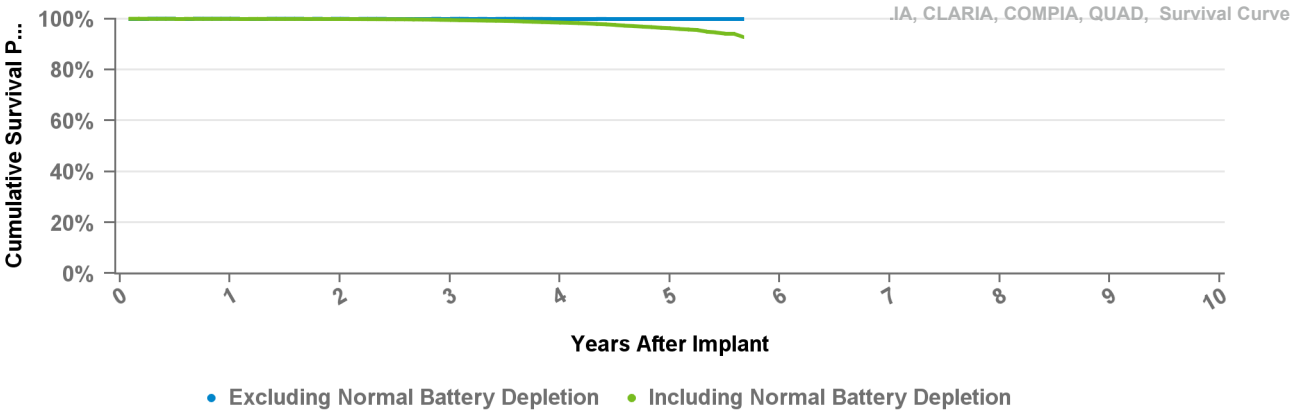
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMB2QQ Amplia MRI

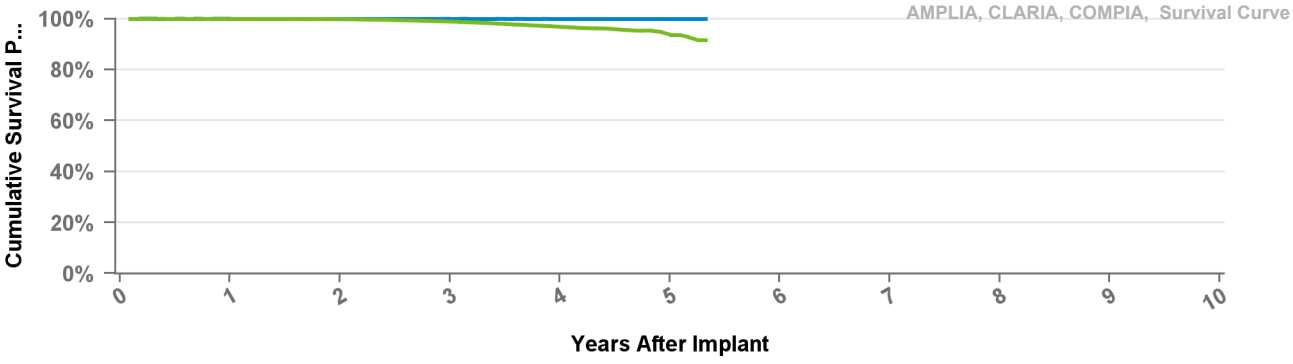
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMC1D1 Compia MRI

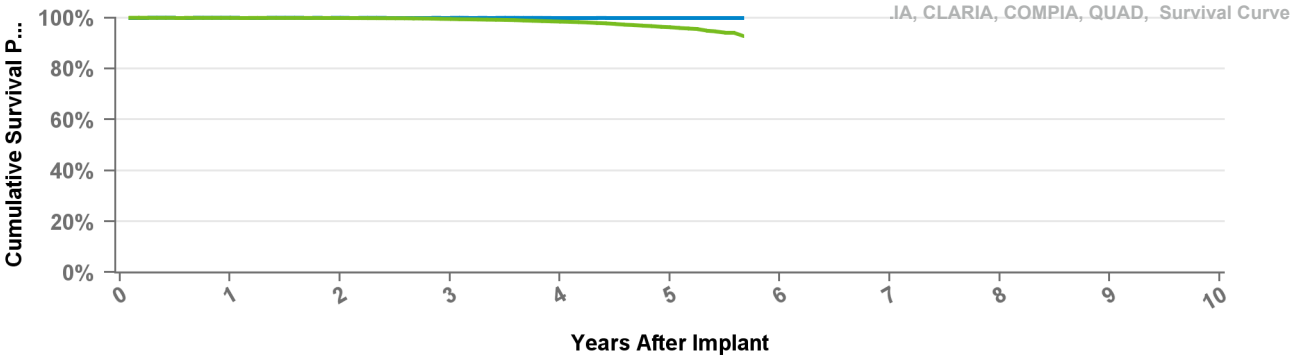
US Market Release	Dec-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	1,145		
Estimated Active USA Implants	885	**Therapy Function Compromised**	
Normal Battery Depletions	11		



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMC1QQ Compia MRI

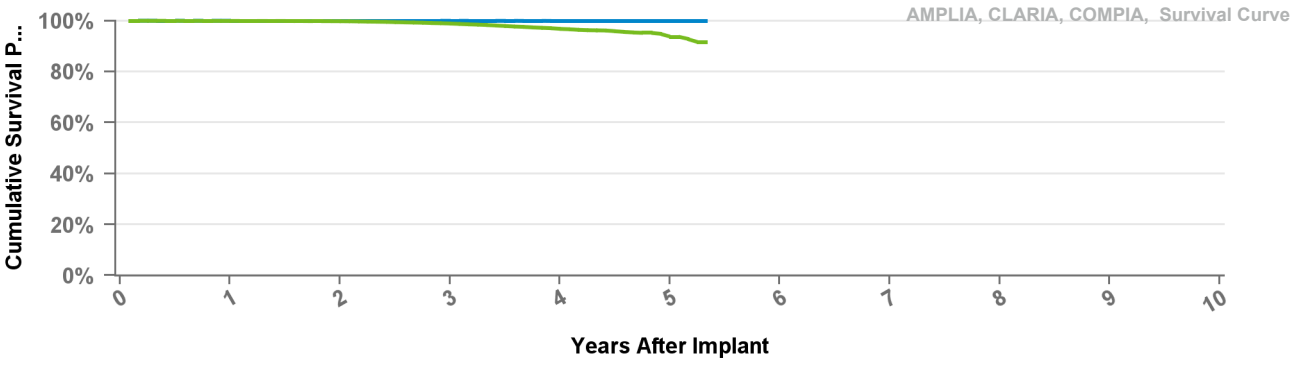
US Market Release	Feb-16	**Total Malfunctions**	**6**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	5,529	Battery Malfunction	2
Estimated Active USA Implants	4,292	Electrical Component	4
Normal Battery Depletions	63	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

DTMC2D1 Compia MRI

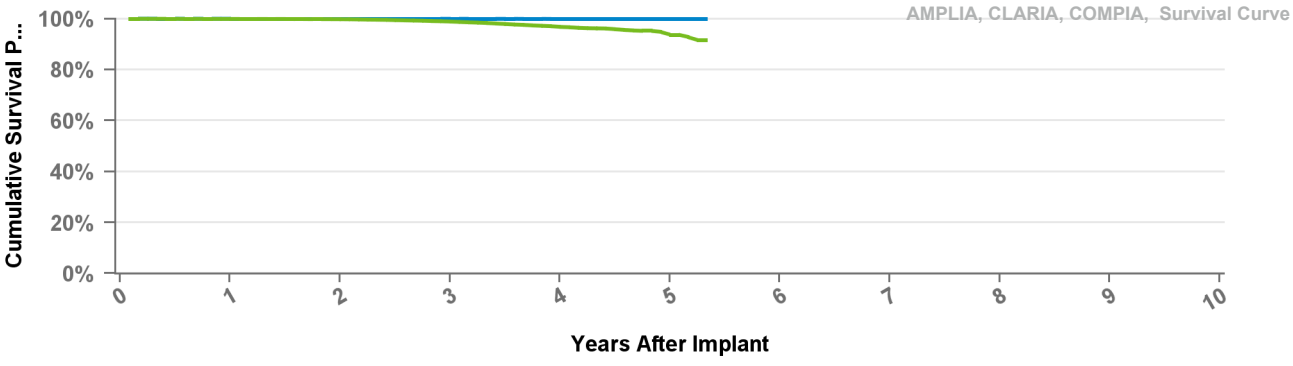
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMC2D4 Compia MRI

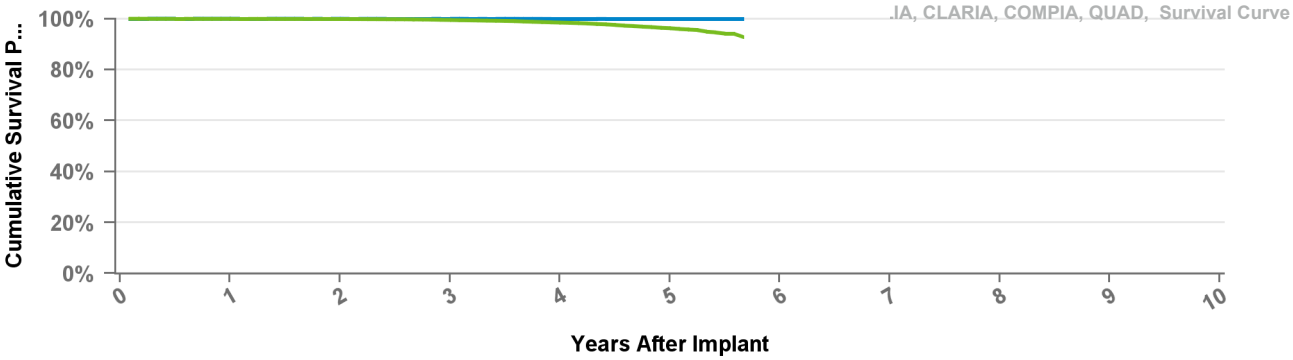
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	98.9%	96.8%	93.7%	91.6%
Effective Sample Size	28599	20323	12751	5278	505	155

DTMC2QQ Compia MRI

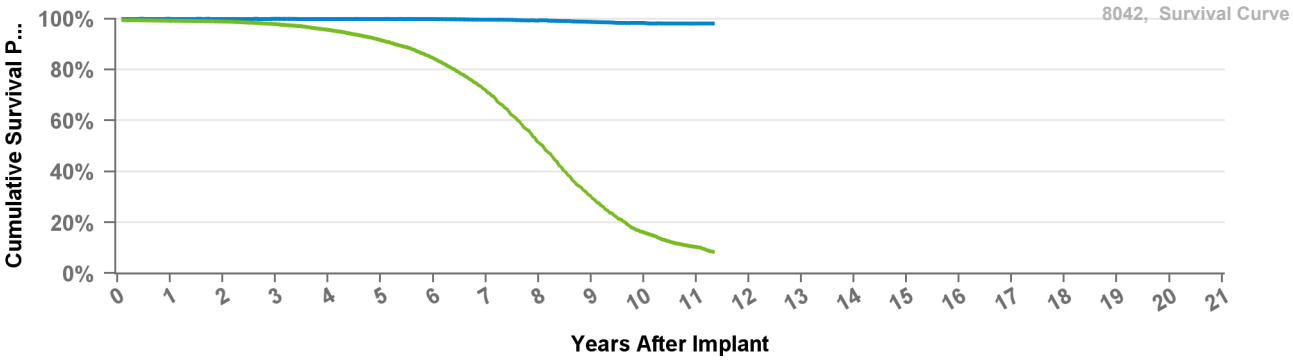
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-16	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 68 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.5%	98.5%	96.3%	92.7%
Effective Sample Size	84214	60626	38432	20463	6213	407

8042 InSync III

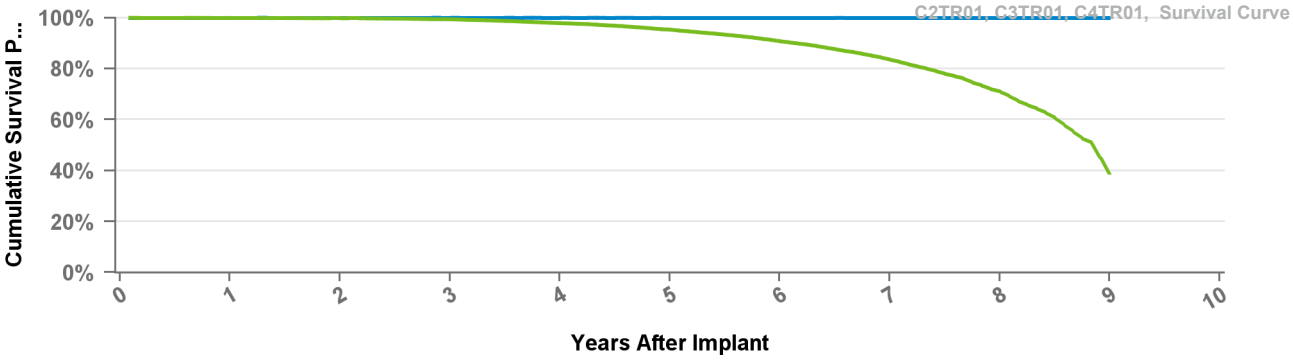
US Market Release	Feb-03	**Total Malfunctions**	**115**
CE Approval Date	Feb-01	**Therapy Function Not Compromised**	**66**
Registered USA Implants	39,497	Battery Malfunction	54
Estimated Active USA Implants	1,992	Electrical Component	2
Normal Battery Depletions	5,219	Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**49**
		Battery Malfunction	37
		Electrical Interconnect	12



Years	1	2	3	4	5	6	7	8	9	10	11	at 136 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.6%	99.3%	98.8%	98.3%	98.1%	98.1%
Including NBD	99.2%	98.9%	97.9%	95.7%	91.6%	84.5%	71.7%	51.5%	30.1%	16.1%	10.4%	8.5%
Effective Sample Size	30223	25748	21886	18450	15150	11270	7658	4520	2028	816	367	154

C2TR01 Syncra CRT-P

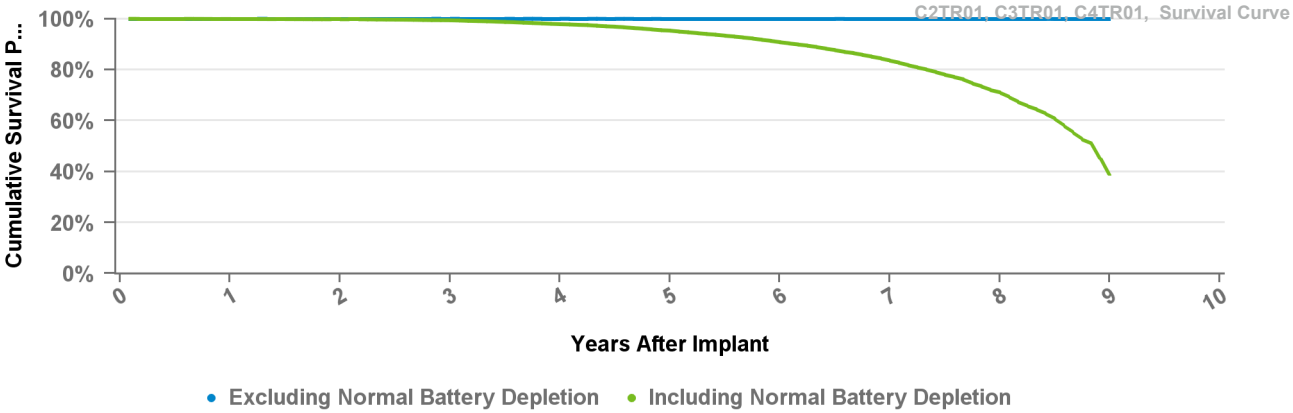
US Market Release	Mar-11	**Total Malfunctions**	**7**
CE Approval Date	May-10	**Therapy Function Not Compromised**	**6**
Registered USA Implants	10,235	Other Malfunction	1
Estimated Active USA Implants	2,917	Poss Early Battery Depltn	5
Normal Battery Depletions	708	**Therapy Function Compromised**	**1**
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	97.9%	95.3%	90.8%	83.6%	71.1%	39.0%
Effective Sample Size	26566	23698	21148	18334	14976	11285	7267	3089	227

C3TR01 Consulta CRT-P

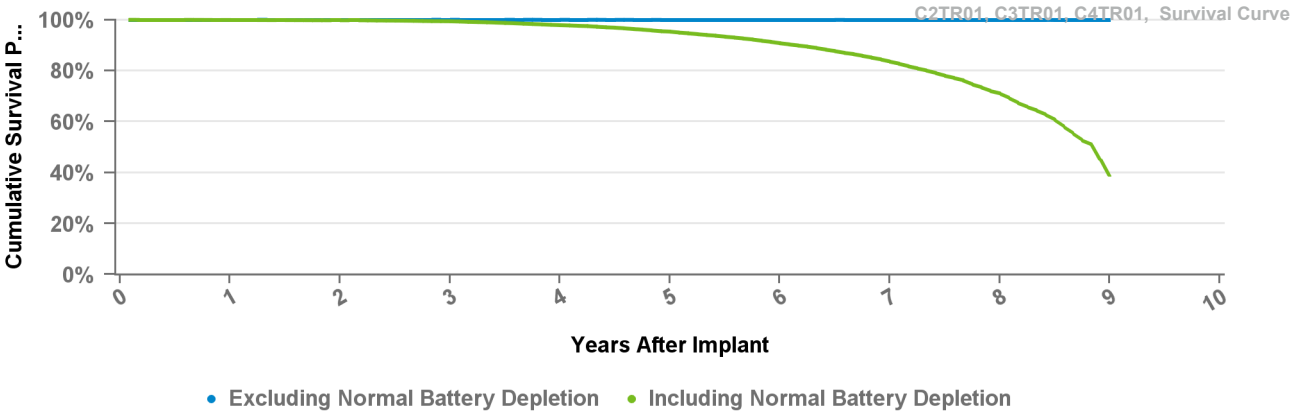
US Market Release		**Total Malfunctions**	
CE Approval Date	May-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	97.9%	95.3%	90.8%	83.6%	71.1%	39.0%
Effective Sample Size	26566	23698	21148	18334	14976	11285	7267	3089	227

C4TR01 Consulta CRT-P

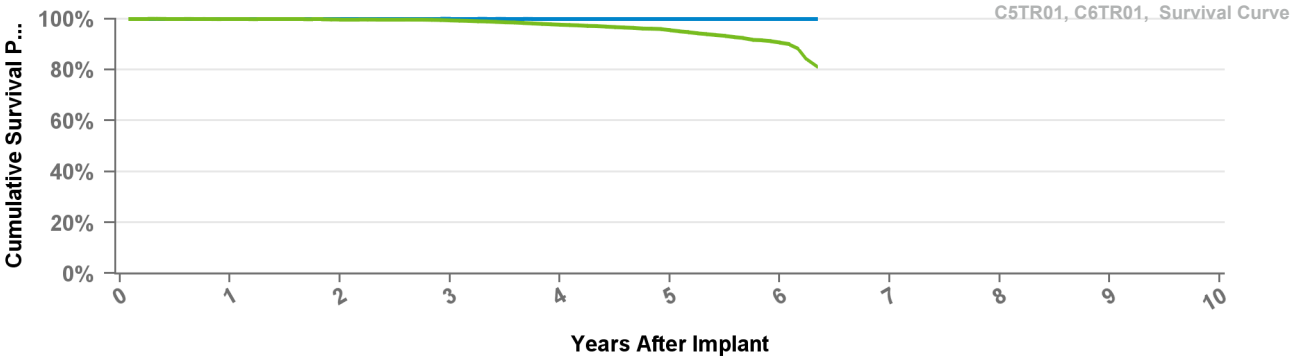
US Market Release	Mar-11	**Total Malfunctions**	**7**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	23,549	Poss Early Battery Depltn	5
Estimated Active USA Implants	8,100	**Therapy Function Compromised**	**2**
Normal Battery Depletions	1,433	Electrical Component	1
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.4%	97.9%	95.3%	90.8%	83.6%	71.1%	39.0%
Effective Sample Size	26566	23698	21148	18334	14976	11285	7267	3089	227

C5TR01 Viva CRT-P

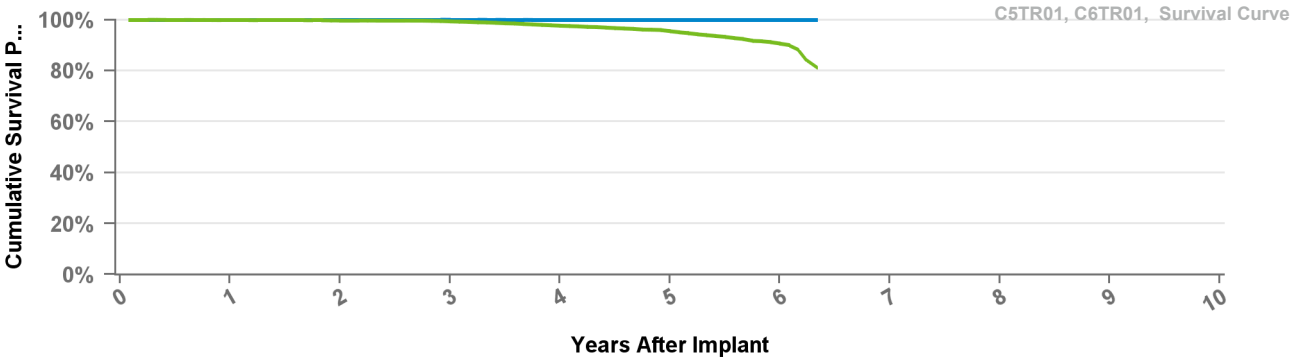
US Market Release		**Total Malfunctions**	
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.4%	97.6%	95.5%	90.6%	81.2%
Effective Sample Size	7593	6796	6080	5203	3107	807	145

C6TR01 Viva CRT-P

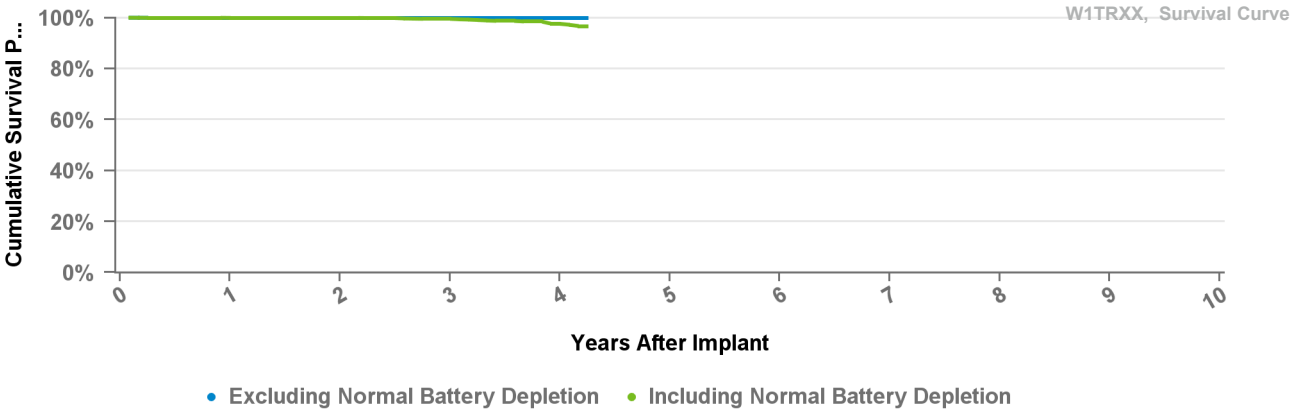
US Market Release	Jul-14	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**5**
Registered USA Implants	9,300	Poss Early Battery Depltn	5
Estimated Active USA Implants	5,224	**Therapy Function Compromised**	**0**
Normal Battery Depletions	197		



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.4%	97.6%	95.5%	90.6%	81.2%
Effective Sample Size	7593	6796	6080	5203	3107	807	145

W1TR01 Percepta CRTP MRI

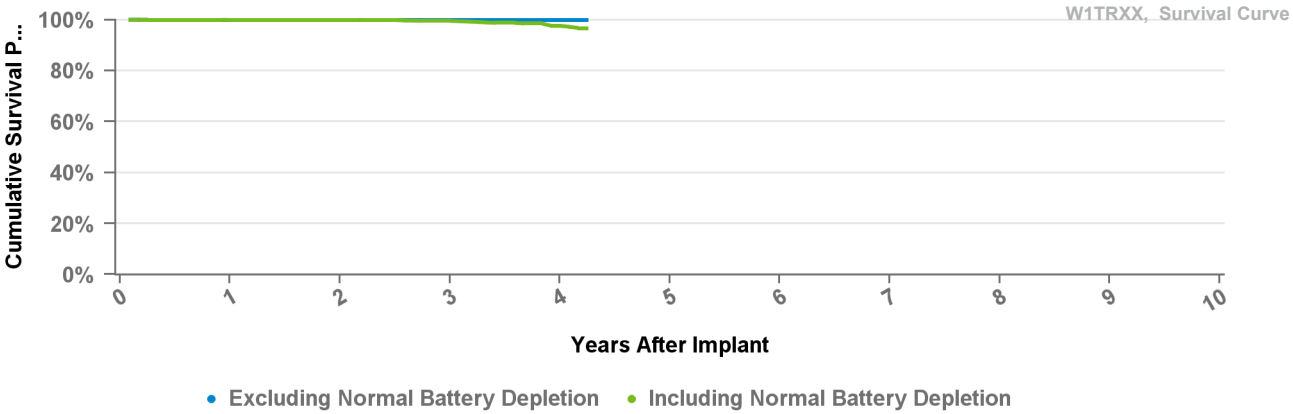
US Market Release	May-17	**Total Malfunctions**	**2**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	9,057	Other Malfunction	1
Estimated Active USA Implants	7,793	**Therapy Function Compromised**	**1**
Normal Battery Depletions	16	Electrical Component	1



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W1TR02 Serena CRTP MRI

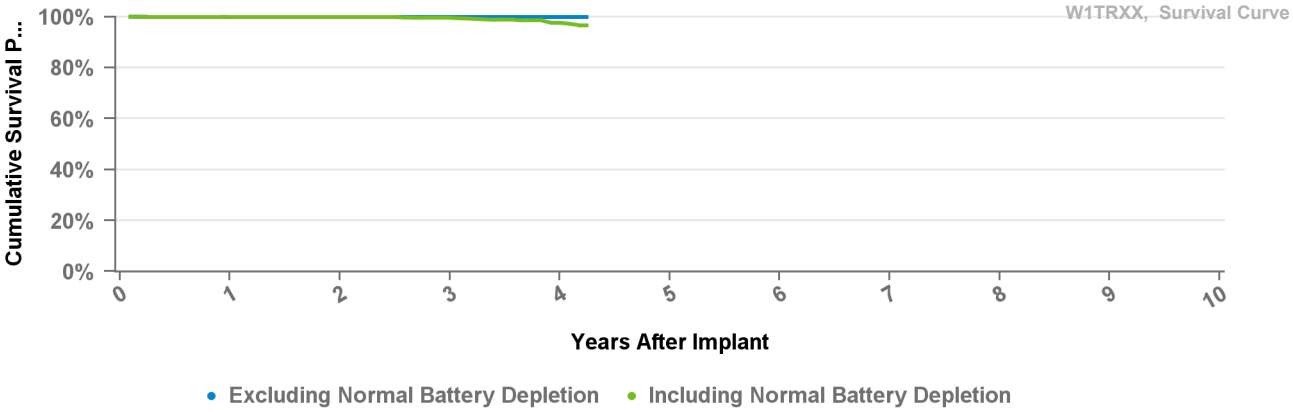
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,881	Other Malfunction	1
Estimated Active USA Implants	1,584	**Therapy Function Compromised**	**0**
Normal Battery Depletions	2		



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W1TR03 Solara CRTP MRI

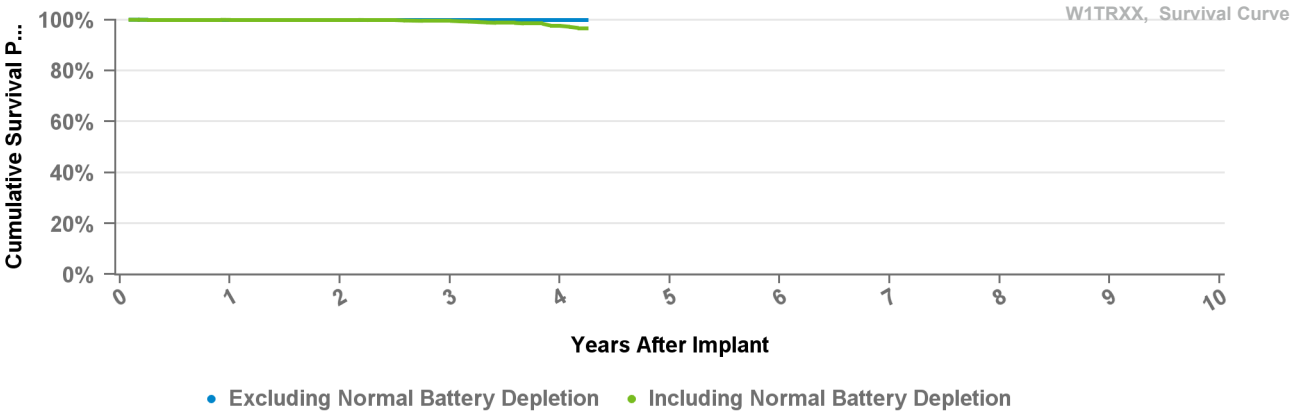
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,826	Electrical Component	1
Estimated Active USA Implants	2,301	**Therapy Function Compromised**	**0**
Normal Battery Depletions	5		



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W1TR04 Percepta CRTP MRI

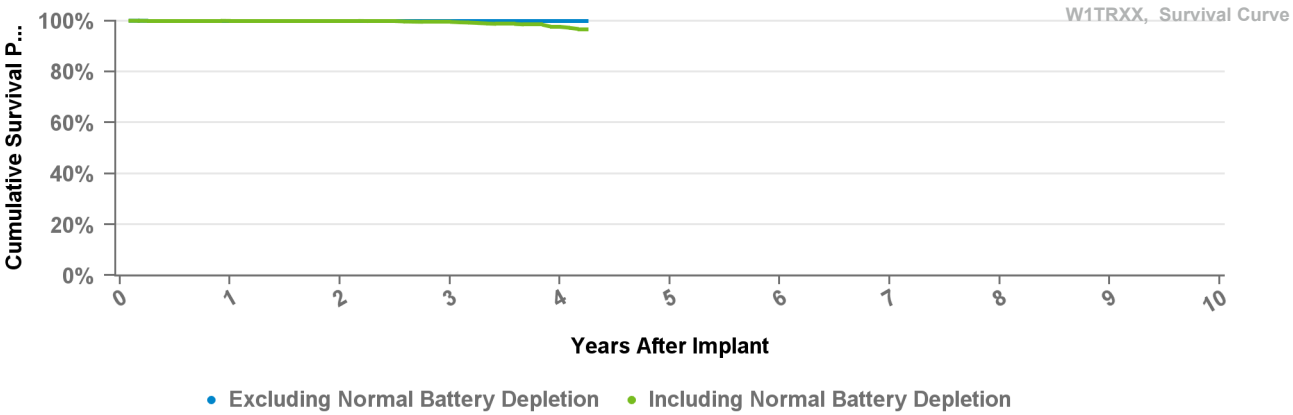
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W1TR05 Serena CRTP MRI

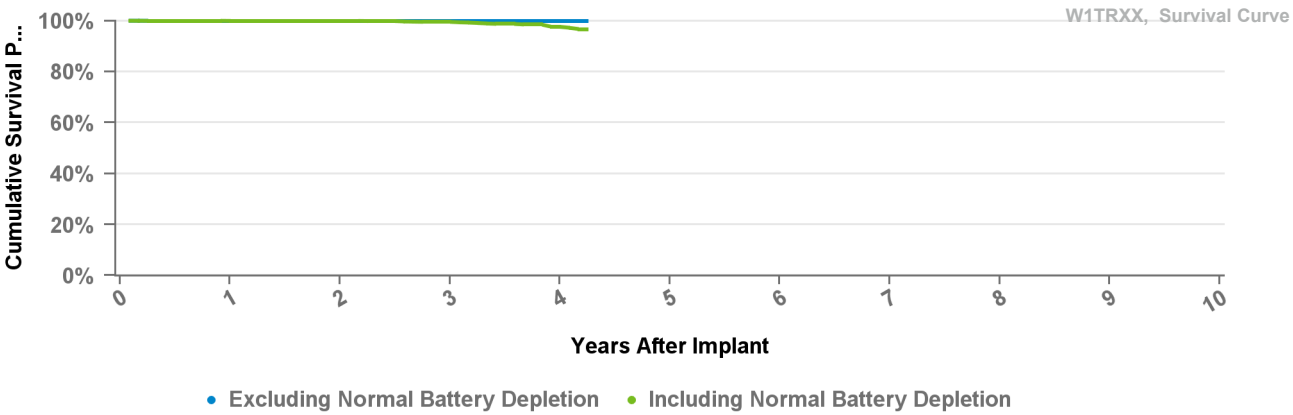
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W1TR06 Solara CRTP MRI

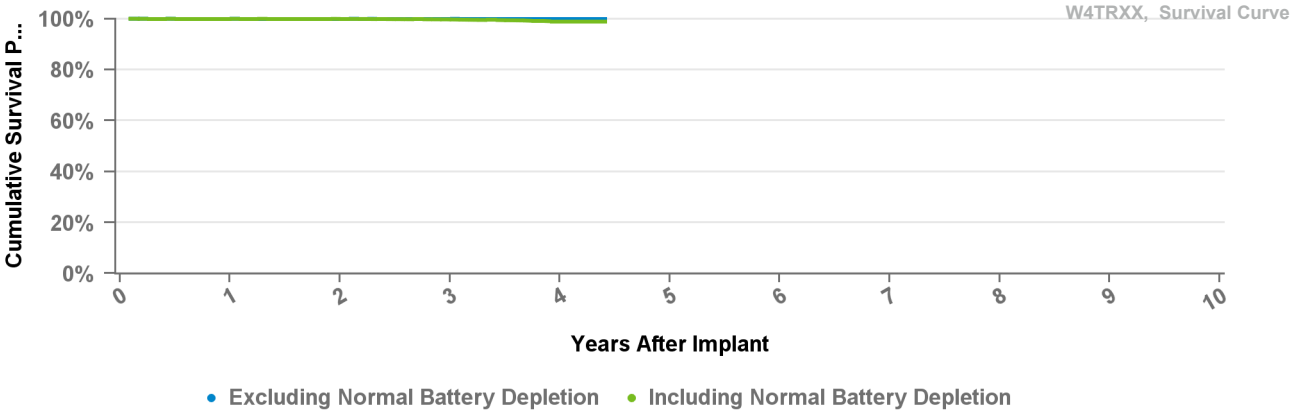
US Market Release		**Total Malfunctions**	
CE Approval Date	Feb-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	at 51 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.6%	97.6%	96.7%
Effective Sample Size	8854	5328	2364	331	126

W4TR01 Percepta Quad CRTP MRI SureScan

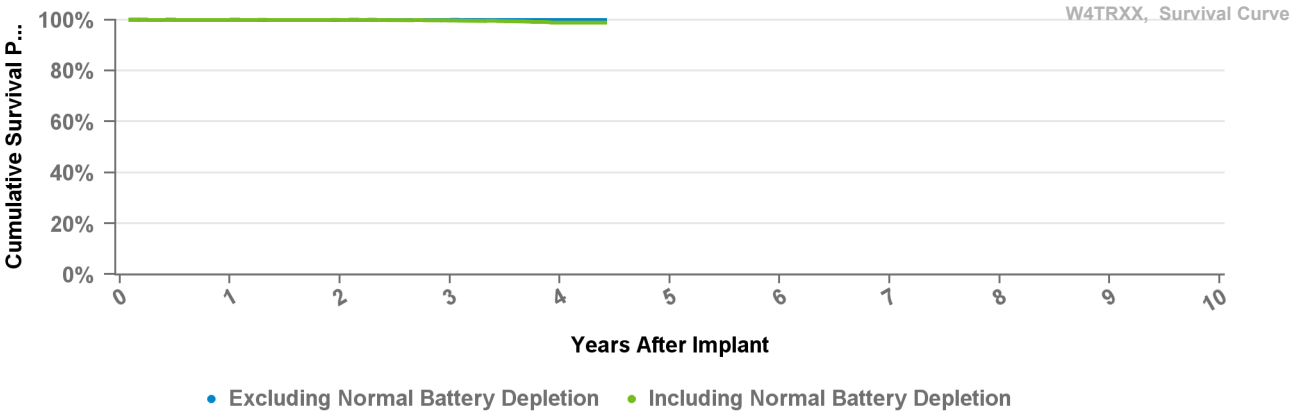
US Market Release	May-17	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	33,789	Electrical Component	3
Estimated Active USA Implants	28,942	Other Malfunction	1
Normal Battery Depletions	18	**Therapy Function Compromised**	**0**



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

W4TR02 Serena Quad CRTP MRI SureScan

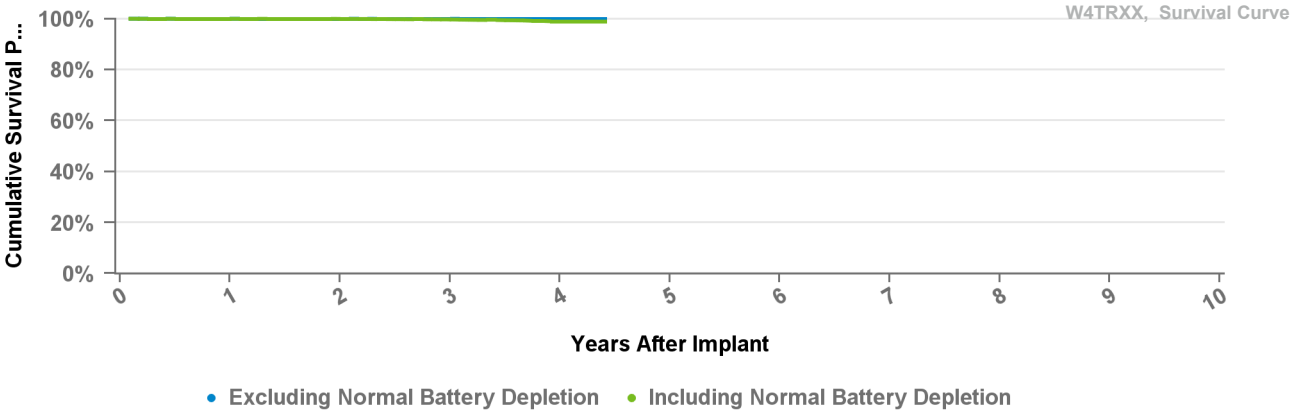
US Market Release	May-17	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	5,566	Electrical Component	1
Estimated Active USA Implants	4,651	**Therapy Function Compromised**	**0**
Normal Battery Depletions	7		



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

W4TR03 Solara Quad CRTP MRI SureScan

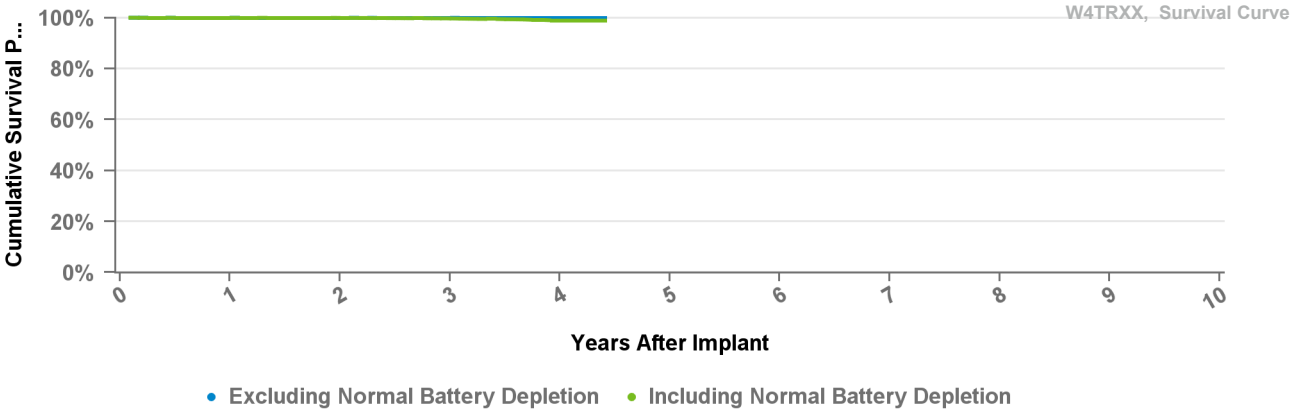
US Market Release	May-17	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	7,743		
Estimated Active USA Implants	6,260	**Therapy Function Compromised**	**3**
Normal Battery Depletions	10	Electrical Component	2
		Poss Early Battery Depltn	1



Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

W4TR04 Percepta Quad CRT-P MRI SureScan

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

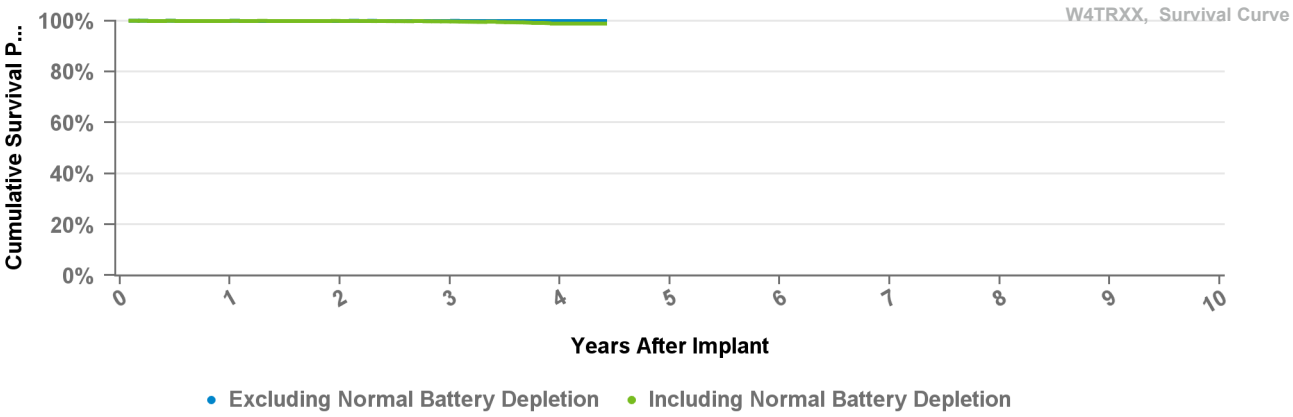


Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

W4TR05 Serena Quad CRTP MRI SureScan

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

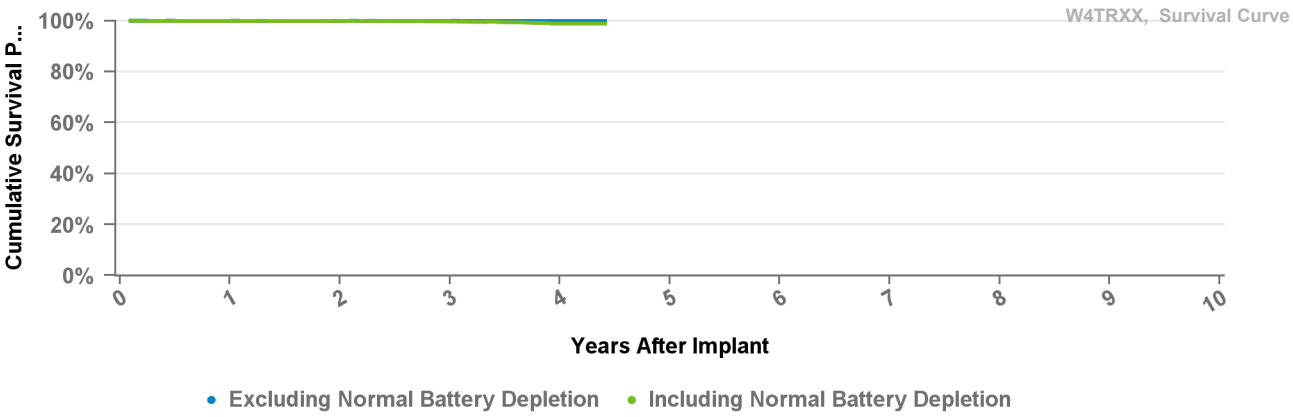


Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

W4TR06 Solara Quad CRTP MRI SureScan

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

Total Malfunctions
Therapy Function Not Compromised
Therapy Function Compromised

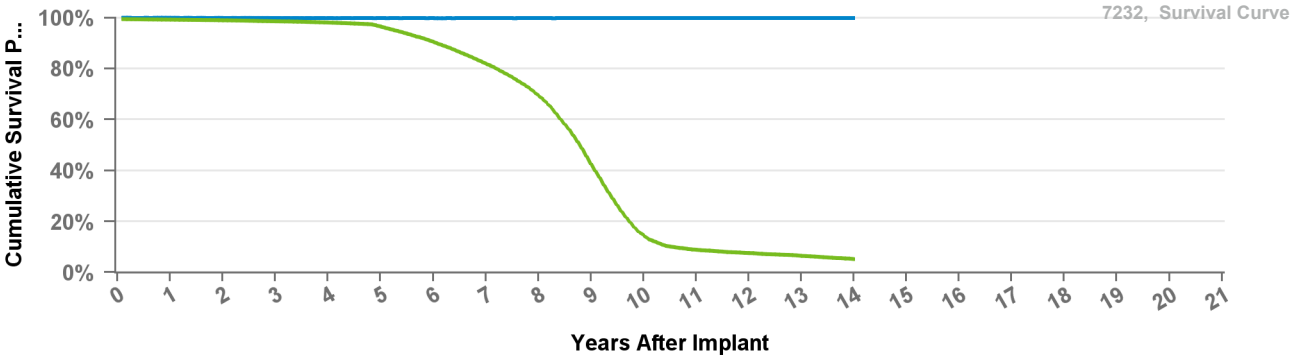


Years	1	2	3	4	at 53 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.7%	99.0%	99.0%
Effective Sample Size	30372	18753	9089	2188	230

7232Cx Maximo VR

US Market Release	Oct-03
CE Approval Date	Oct-03
Registered USA Implants	43,532
Estimated Active USA Implants	2,807
Normal Battery Depletions	10,325

Total Malfunctions	**72**
Therapy Function Not Compromised	**57**
Electrical Component	28
Other Malfunction	2
Poss Early Battery Depltn	25
Software Malfunction	2
Therapy Function Compromised	**15**
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	1

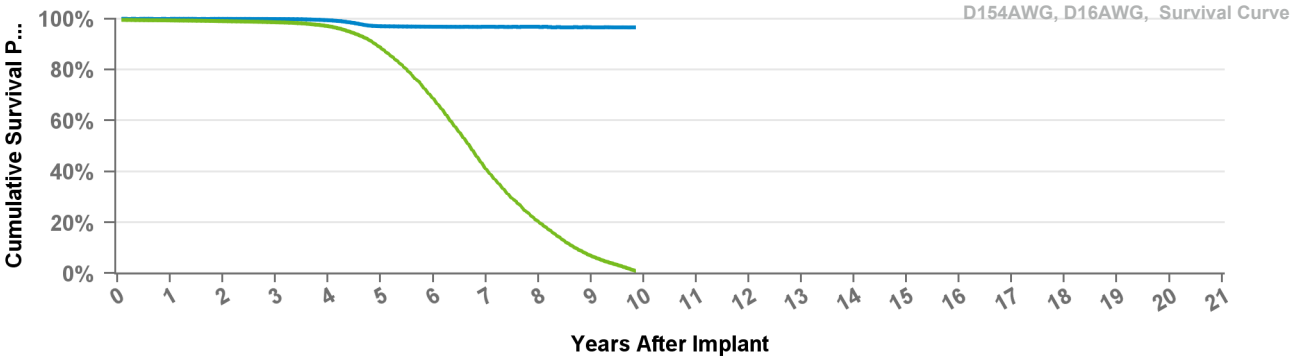


Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.3%	99.0%	98.6%	98.1%	96.5%	90.5%	81.9%	69.4%	42.8%	14.6%	8.9%	7.6%	6.5%	5.2%
Effective Sample Size	37883	33854	30119	26477	23219	20035	16769	13189	7447	2009	902	608	394	121

D164AWG Virtuoso DR

US Market Release	
CE Approval Date	Mar-06
Registered USA Implants	10
Estimated Active USA Implants	3
Normal Battery Depletions	4

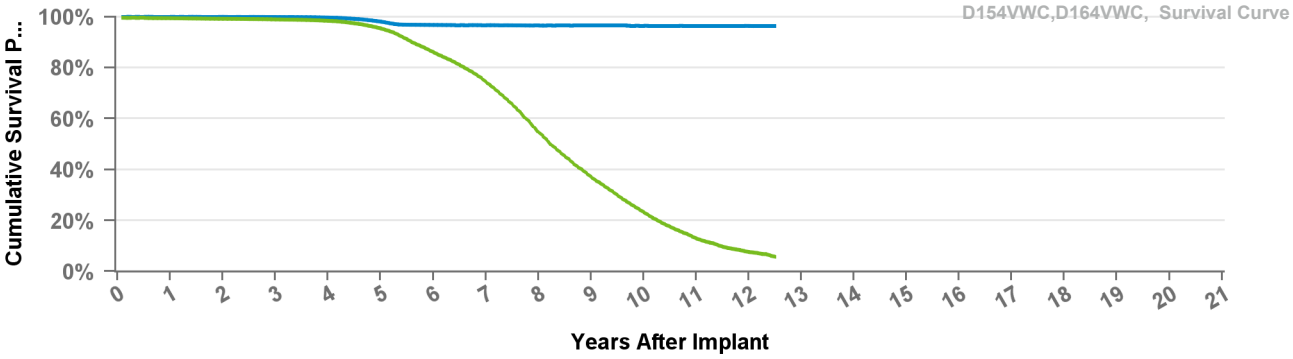
Total Malfunctions	
Therapy Function Not Compromised	
Therapy Function Compromised	



Years	1	2	3	4	5	6	7	8	9	at 118 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.1%	96.9%	96.8%	96.8%	96.7%	96.6%
Including NBD	99.4%	99.1%	98.6%	97.1%	88.6%	68.8%	41.2%	20.2%	6.9%	1.0%
Effective Sample Size	62960	57626	52323	47138	39512	28328	15171	6294	1681	192

D164VWC Virtuoso VR

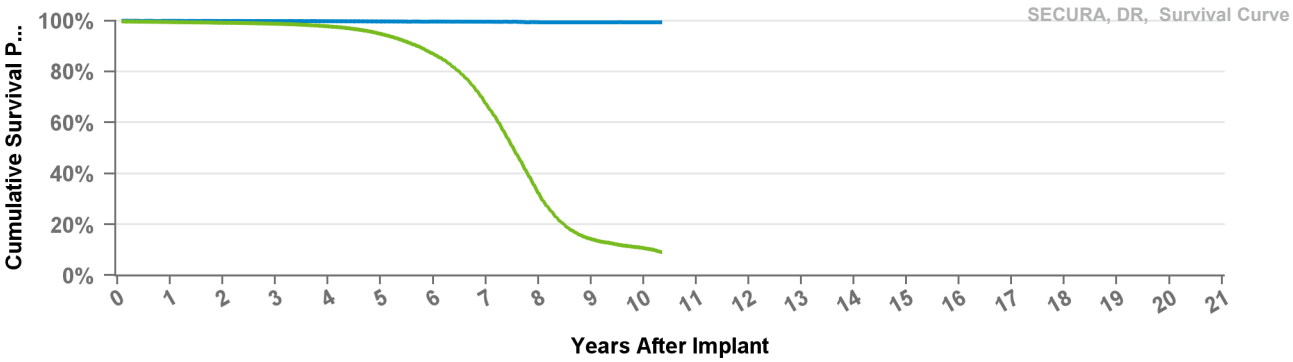
US Market Release		**Total Malfunctions**	**1**
CE Approval Date	Mar-06	**Therapy Function Not Compromised**	**1**
Registered USA Implants	6	Electrical Component	1
Estimated Active USA Implants	2	**Therapy Function Compromised**	**0**
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.1%	96.8%	96.7%	96.6%	96.5%	96.5%	96.4%	96.4%	96.3%
Including NBD	99.4%	99.2%	99.0%	98.4%	95.4%	86.1%	74.3%	54.8%	37.1%	23.2%	12.9%	7.6%	5.8%
Effective Sample Size	28321	25771	23406	21270	18848	15717	12637	8492	5095	2824	1323	546	101

D204DRM Secura DR

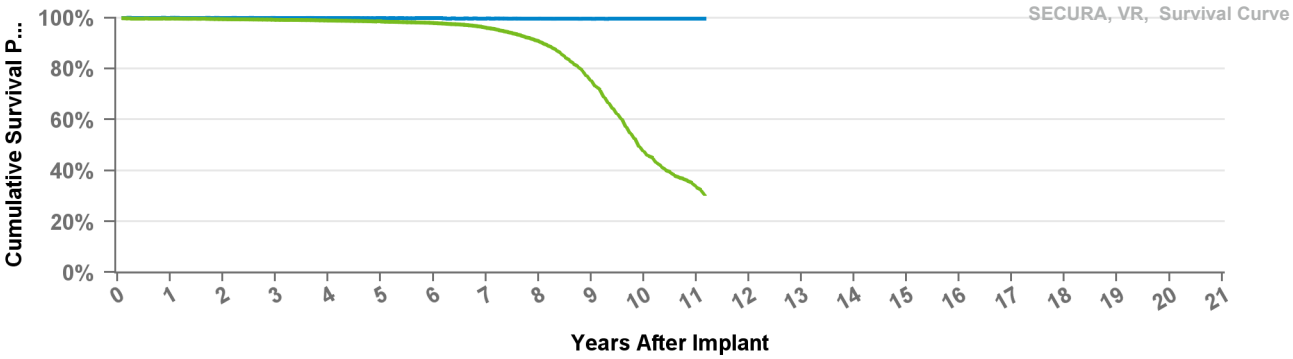
US Market Release	Jan-12	**Total Malfunctions**	**5**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,879	Other Malfunction	1
Estimated Active USA Implants	351	**Therapy Function Compromised**	**4**
Normal Battery Depletions	306	Battery Malfunction	2
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.8%	97.8%	94.8%	86.9%	67.6%	32.5%	14.3%	10.7%	9.1%
Effective Sample Size	44612	41239	38151	35020	31040	24835	15580	5443	1482	460	107

D204VRM Secura VR

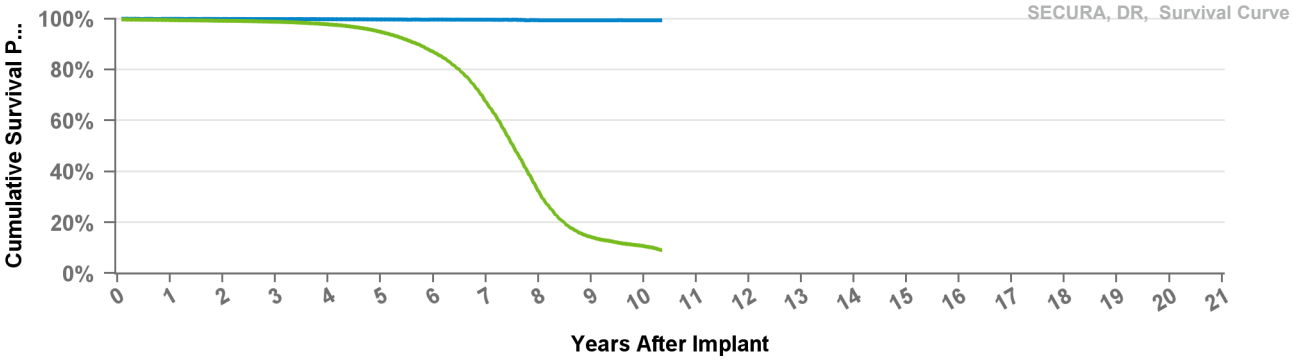
US Market Release	May-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	1,185	Electrical Component	1
Estimated Active USA Implants	469	**Therapy Function Compromised**	**2**
Normal Battery Depletions	31	Battery Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.2%	98.9%	98.5%	97.9%	96.0%	90.8%	75.5%	47.7%	33.5%	30.7%
Effective Sample Size	17922	16600	15435	14305	13116	11891	10537	8322	4716	1711	337	149

D214DRM Secura DR

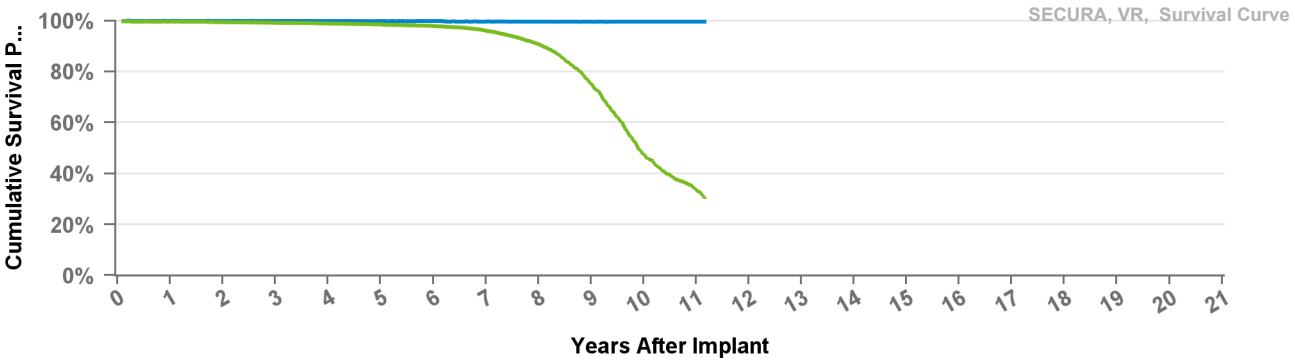
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.8%	97.8%	94.8%	86.9%	67.6%	32.5%	14.3%	10.7%	9.1%
Effective Sample Size	44612	41239	38151	35020	31040	24835	15580	5443	1482	460	107

D214VRM Secura VR

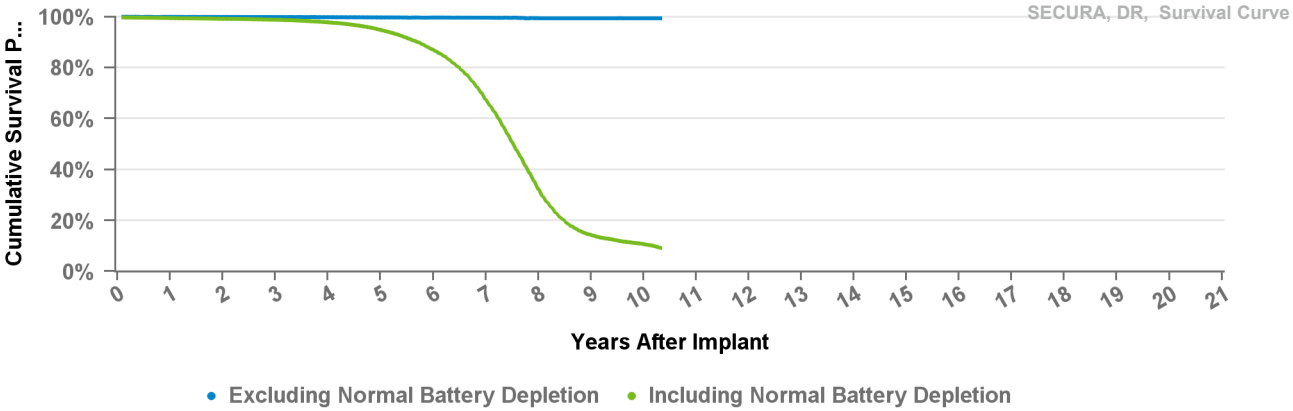
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.2%	98.9%	98.5%	97.9%	96.0%	90.8%	75.5%	47.7%	33.5%	30.7%
Effective Sample Size	17922	16600	15435	14305	13116	11891	10537	8322	4716	1711	337	149

D224DRG Secura DR

US Market Release	Sep-08	**Total Malfunctions**	**152**
CE Approval Date		**Therapy Function Not Compromised**	**115**
Registered USA Implants	49,933	Battery Malfunction	14
Estimated Active USA Implants	5,549	Electrical Component	38
Normal Battery Depletions	10,259	Other Malfunction	4
		Poss Early Battery Depltn	50
		Software Malfunction	9
		Therapy Function Compromised	**37**
		Battery Malfunction	21
		Electrical Component	13
		Other Malfunction	1
		Poss Early Battery Depltn	1
		Software Malfunction	1

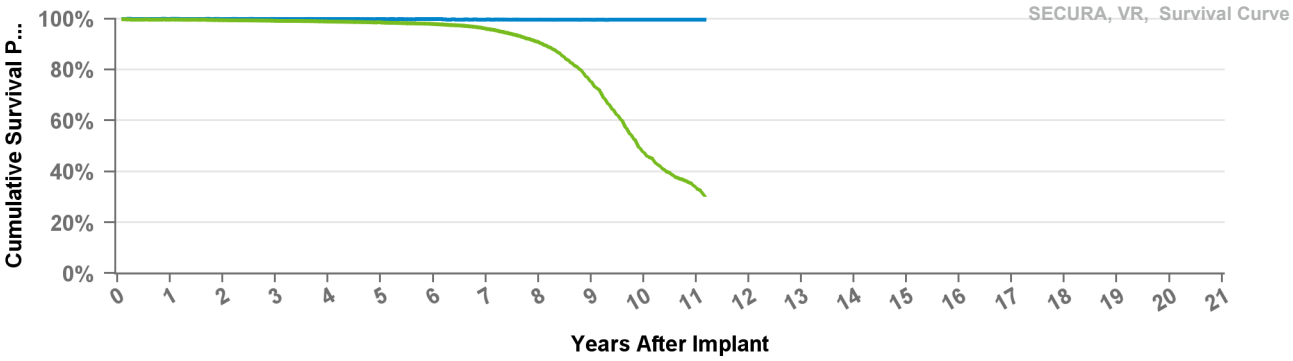


Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.8%	97.8%	94.8%	86.9%	67.6%	32.5%	14.3%	10.7%	9.1%
Effective Sample Size	44612	41239	38151	35020	31040	24835	15580	5443	1482	460	107

D224VRC Secura VR

US Market Release	Sep-08
CE Approval Date	
Registered USA Implants	20,064
Estimated Active USA Implants	3,403
Normal Battery Depletions	2,040

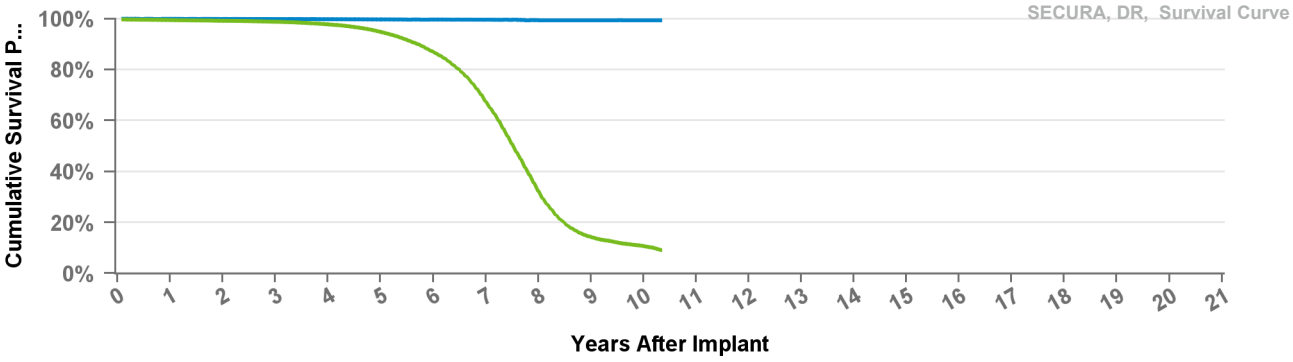
Total Malfunctions	**53**
Therapy Function Not Compromised	**35**
Battery Malfunction	14
Electrical Component	10
Other Malfunction	1
Poss Early Battery Depltn	8
Software Malfunction	2
Therapy Function Compromised	**18**
Battery Malfunction	10
Electrical Component	6
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.2%	98.9%	98.5%	97.9%	96.0%	90.8%	75.5%	47.7%	33.5%	30.7%
Effective Sample Size	17922	16600	15435	14305	13116	11891	10537	8322	4716	1711	337	149

D234DRG Secura DR

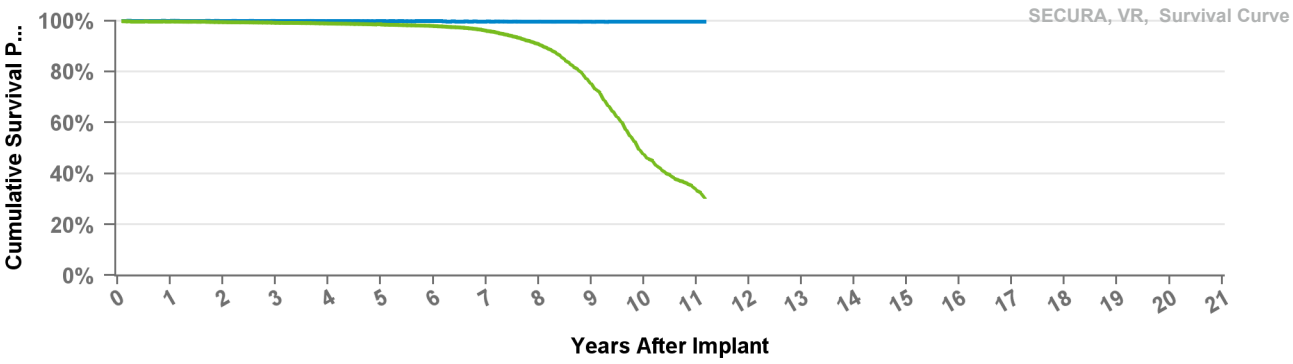
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.8%	97.8%	94.8%	86.9%	67.6%	32.5%	14.3%	10.7%	9.1%
Effective Sample Size	44612	41239	38151	35020	31040	24835	15580	5443	1482	460	107

D234VRC Secura VR

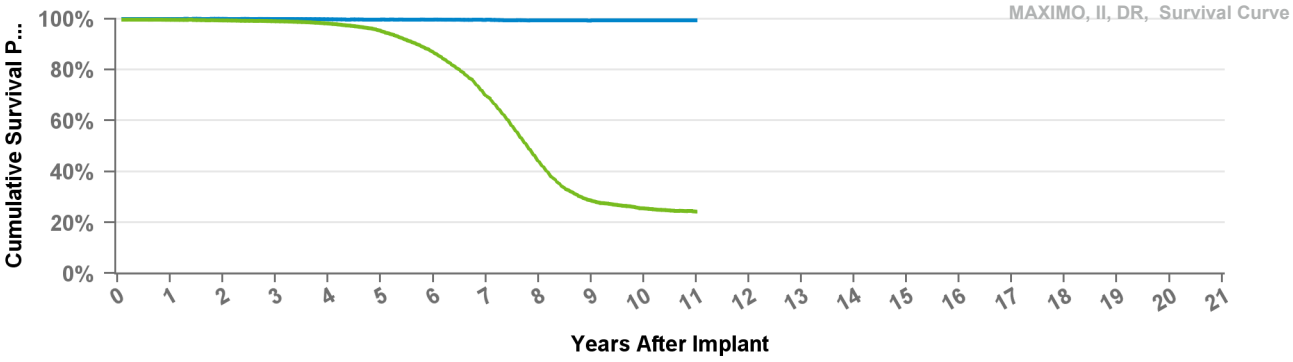
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.6%	99.6%	99.6%	99.6%
Including NBD	99.7%	99.5%	99.2%	98.9%	98.5%	97.9%	96.0%	90.8%	75.5%	47.7%	33.5%	30.7%
Effective Sample Size	17922	16600	15435	14305	13116	11891	10537	8322	4716	1711	337	149

D264DRM Maximo II DR

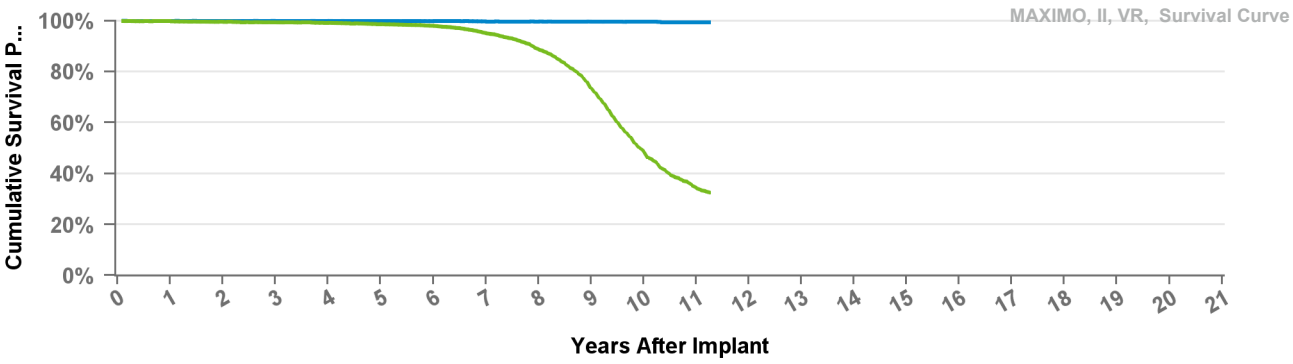
US Market Release	Jan-12	**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	7		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	2		



Years	1	2	3	4	5	6	7	8	9	10	at 132 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%
Including NBD	99.6%	99.3%	99.0%	98.1%	95.2%	86.7%	69.9%	44.2%	28.6%	25.6%	24.3%
Effective Sample Size	17289	15985	14848	13683	12143	9529	5790	2438	1163	680	129

D264VRM Maximo II VR

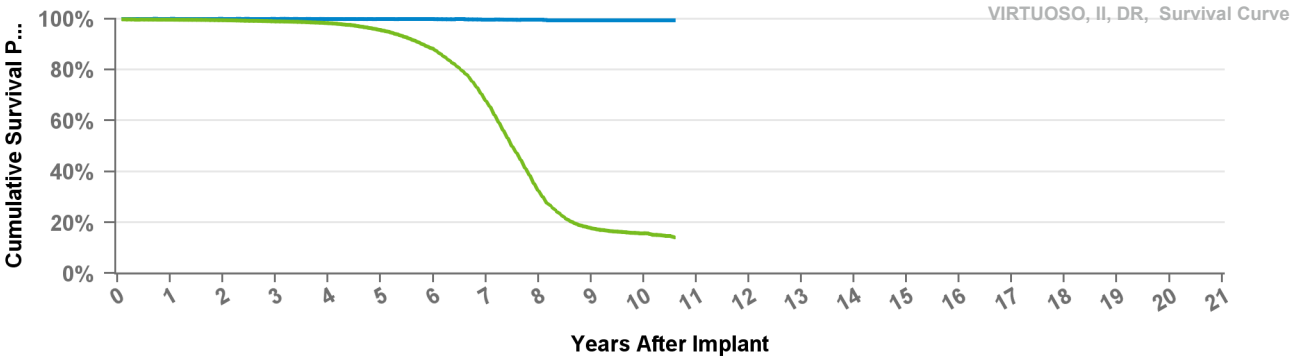
US Market Release	May-12	**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 135 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.5%	99.5%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.7%	98.0%	95.1%	88.7%	73.7%	48.7%	34.3%	32.5%
Effective Sample Size	11021	10259	9543	8817	8080	7319	6388	5055	2909	1092	256	118

D274DRG Virtuoso II DR

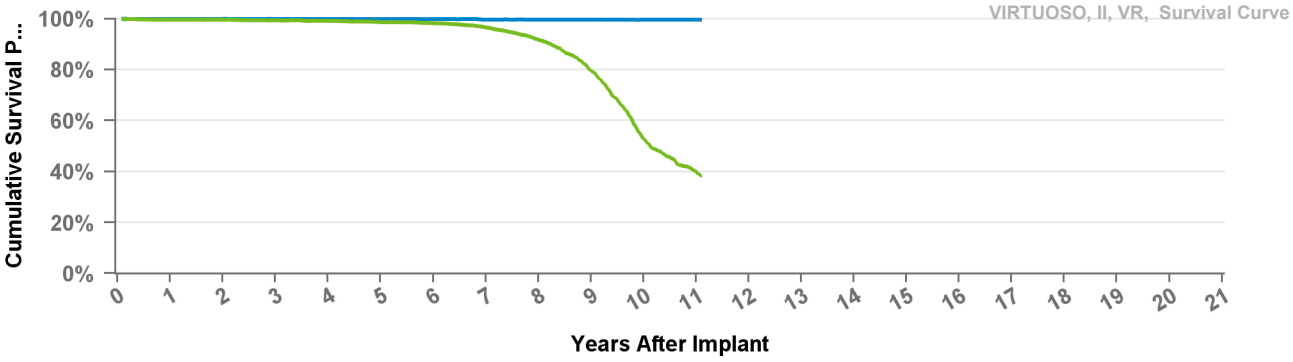
US Market Release	Aug-09	**Total Malfunctions**	**47**
CE Approval Date		**Therapy Function Not Compromised**	**29**
Registered USA Implants	22,240	Battery Malfunction	10
Estimated Active USA Implants	2,607	Electrical Component	11
Normal Battery Depletions	4,303	Poss Early Battery Depltn	7
		Software Malfunction	1
		Therapy Function Compromised	**18**
		Battery Malfunction	15
		Electrical Component	2
		Other Malfunction	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%	99.7%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.6%	99.4%	99.0%	98.3%	95.5%	88.1%	67.9%	32.6%	17.8%	15.8%	14.1%
Effective Sample Size	18988	17641	16340	14980	13161	10404	6454	2444	1002	639	191

D274VRC Virtuoso II VR

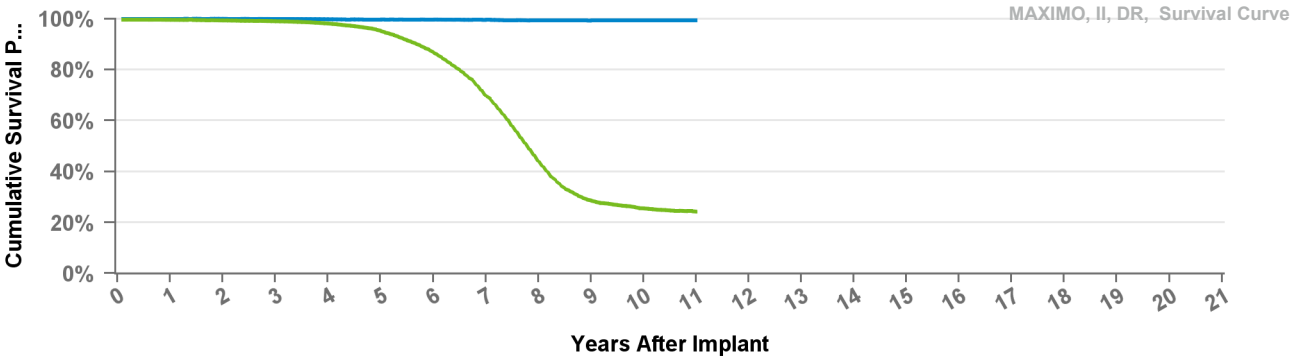
US Market Release	Aug-09	**Total Malfunctions**	**21**
CE Approval Date		**Therapy Function Not Compromised**	**13**
Registered USA Implants	9,130	Battery Malfunction	6
Estimated Active USA Implants	1,428	Electrical Component	4
Normal Battery Depletions	851	Poss Early Battery Depltn	2
		Software Malfunction	1
		Therapy Function Compromised	**8**
		Battery Malfunction	7
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 133 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%
Including NBD	99.6%	99.6%	99.3%	99.2%	98.7%	98.3%	96.6%	91.7%	79.7%	53.1%	39.8%	38.3%
Effective Sample Size	7627	7105	6608	6096	5618	5075	4486	3633	2345	1045	209	158

D284DRG Maximo II DR

US Market Release	Sep-08	**Total Malfunctions**	**71**
CE Approval Date	Mar-08	**Therapy Function Not Compromised**	**54**
Registered USA Implants	20,106	Battery Malfunction	7
Estimated Active USA Implants	2,459	Electrical Component	15
Normal Battery Depletions	3,609	Other Malfunction	2
		Poss Early Battery Depltn	30
		Therapy Function Compromised	**17**
		Battery Malfunction	11
		Electrical Component	5
		Poss Early Battery Depltn	1

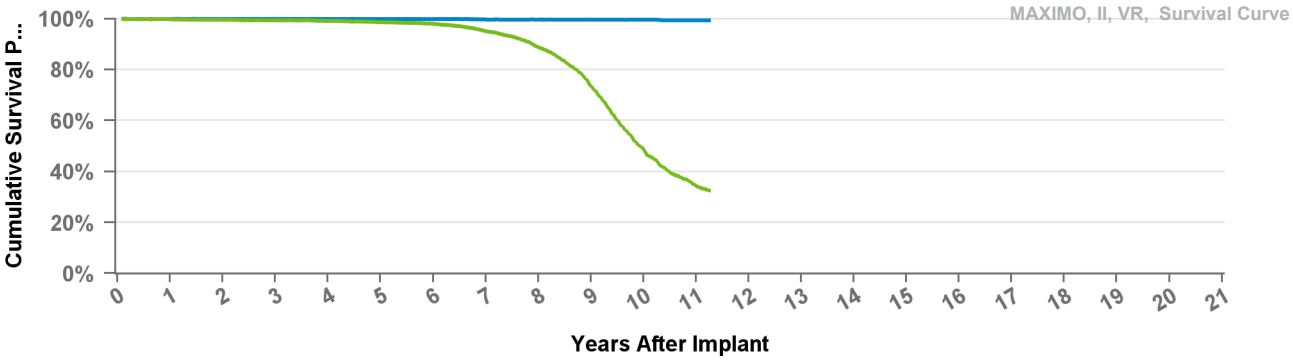


Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.5%	99.3%	99.3%	99.3%	99.3%
Including NBD	99.6%	99.3%	99.0%	98.1%	95.2%	86.7%	69.9%	44.2%	28.6%	25.6%	24.3%
Effective Sample Size	17289	15985	14848	13683	12143	9529	5790	2438	1163	680	129

D284VRC Maximo II VR

US Market Release	Sep-08
CE Approval Date	Mar-08
Registered USA Implants	13,040
Estimated Active USA Implants	2,432
Normal Battery Depletions	1,500

Total Malfunctions	**32**
Therapy Function Not Compromised	**23**
Battery Malfunction	10
Electrical Component	6
Poss Early Battery Depltn	4
Software Malfunction	3
Therapy Function Compromised	**9**
Battery Malfunction	6
Electrical Component	2
Software Malfunction	1

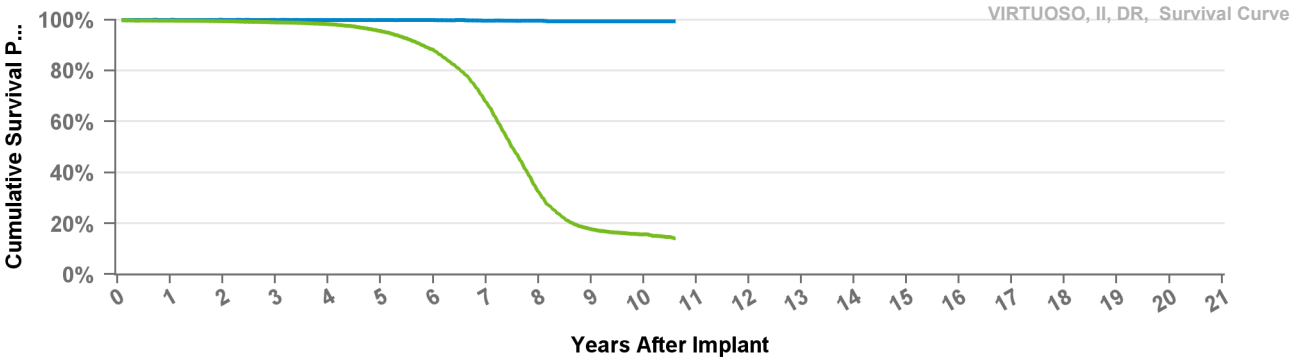


Years	1	2	3	4	5	6	7	8	9	10	11	at 135 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.7%	99.6%	99.6%	99.5%	99.5%
Including NBD	99.8%	99.6%	99.4%	99.2%	98.7%	98.0%	95.1%	88.7%	73.7%	48.7%	34.3%	32.5%
Effective Sample Size	11021	10259	9543	8817	8080	7319	6388	5055	2909	1092	256	118

D294DRG Virtuoso II DR

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

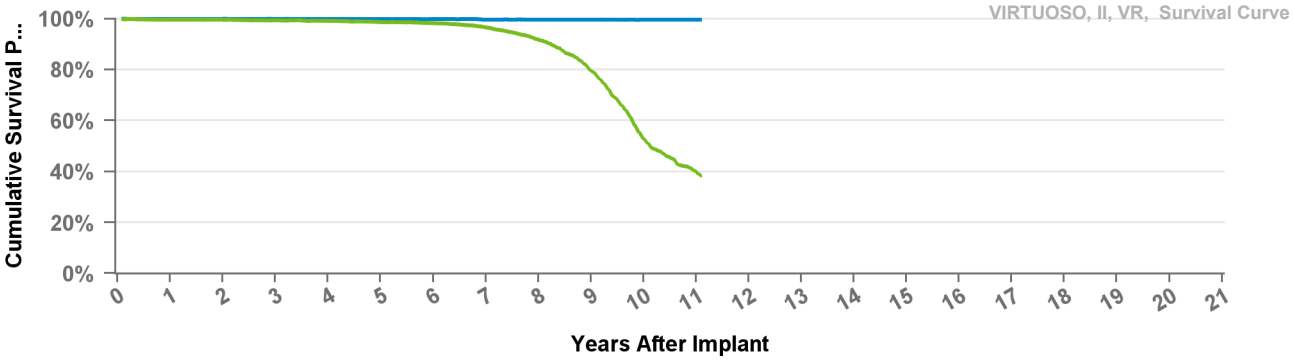
Total Malfunctions	
Therapy Function Not Compromised	
Therapy Function Compromised	



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%	99.7%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.6%	99.4%	99.0%	98.3%	95.5%	88.1%	67.9%	32.6%	17.8%	15.8%	14.1%
Effective Sample Size	18988	17641	16340	14980	13161	10404	6454	2444	1002	639	191

D294VRC Virtuoso II VR

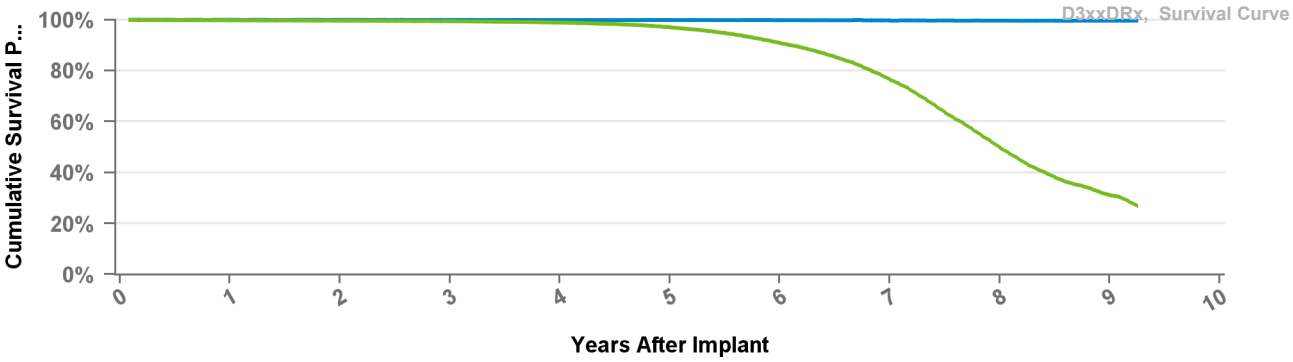
US Market Release		**Total Malfunctions**	
CE Approval Date	Aug-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 133 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%
Including NBD	99.6%	99.6%	99.3%	99.2%	98.7%	98.3%	96.6%	91.7%	79.7%	53.1%	39.8%	38.3%
Effective Sample Size	7627	7105	6608	6096	5618	5075	4486	3633	2345	1045	209	158

D314DRG Protecta XT DR

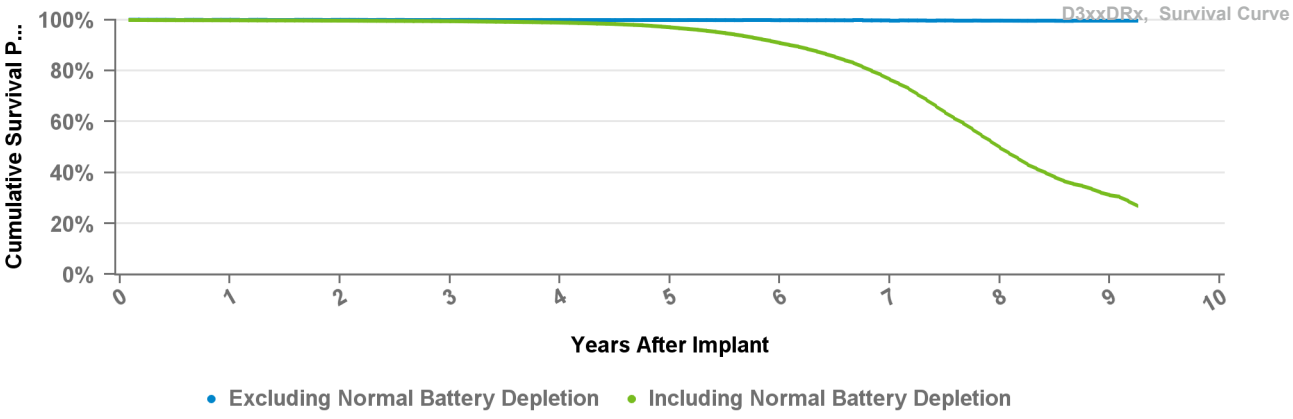
US Market Release	Mar-11	**Total Malfunctions**	**77**
CE Approval Date		**Therapy Function Not Compromised**	**40**
Registered USA Implants	34,865	Battery Malfunction	8
Estimated Active USA Implants	5,196	Electrical Component	26
Normal Battery Depletions	4,368	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	4
		Therapy Function Compromised	**37**
		Battery Malfunction	30
		Electrical Component	7



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D314DRM Protecta XT DR

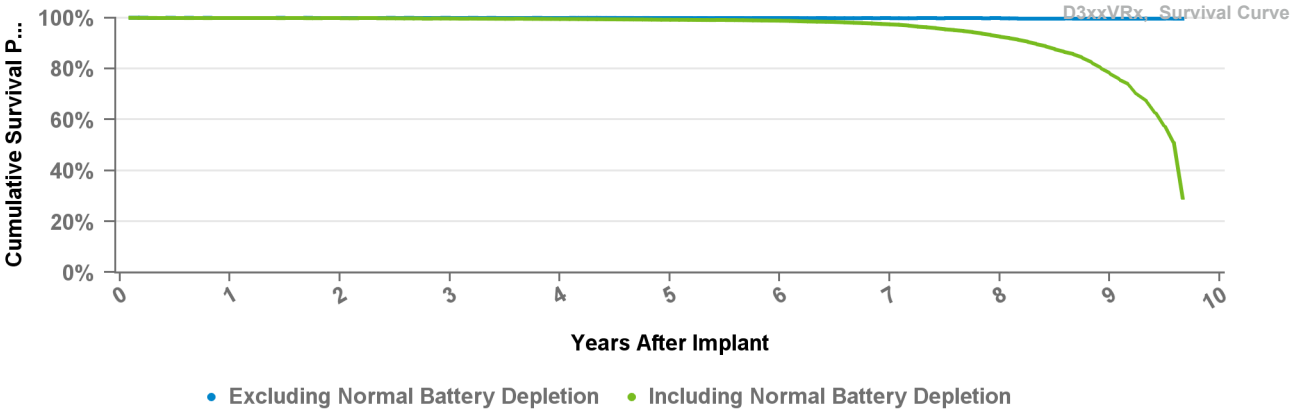
US Market Release	Nov-11	**Total Malfunctions**	**24**
CE Approval Date		**Therapy Function Not Compromised**	**16**
Registered USA Implants	13,931	Battery Malfunction	2
Estimated Active USA Implants	2,487	Electrical Component	12
Normal Battery Depletions	1,814	Other Malfunction	2
		Therapy Function Compromised	**8**
		Battery Malfunction	7
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D314VRG Protecta XT VR

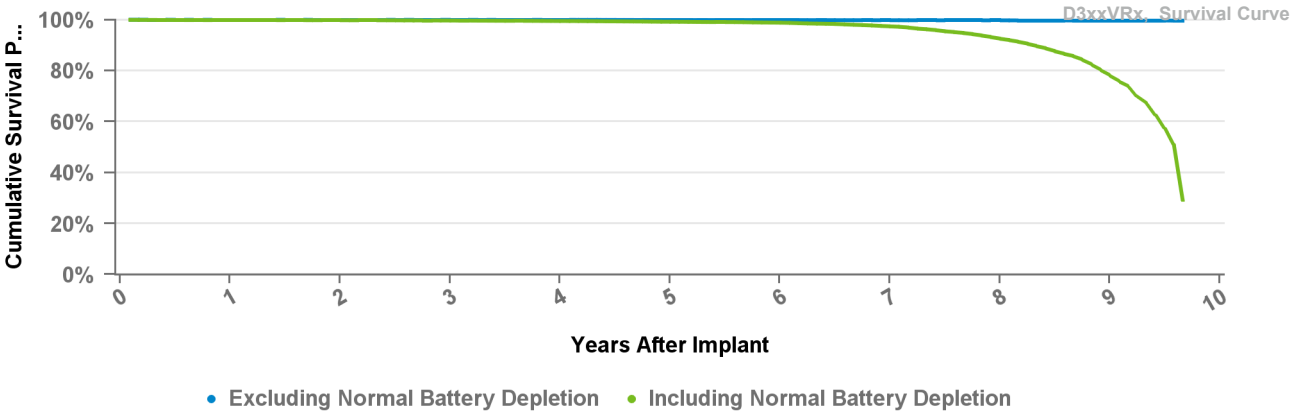
US Market Release	Mar-11	**Total Malfunctions**	**31**
CE Approval Date		**Therapy Function Not Compromised**	**21**
Registered USA Implants	14,234	Battery Malfunction	11
Estimated Active USA Implants	4,217	Electrical Component	9
Normal Battery Depletions	813	Other Malfunction	1
		Therapy Function Compromised	**10**
		Battery Malfunction	9
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D314VRM Protecta XT VR

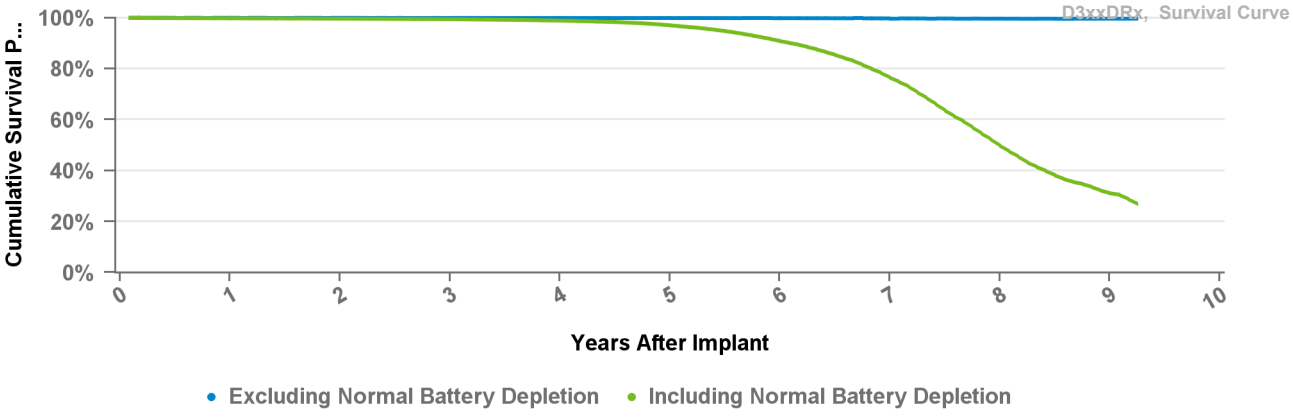
US Market Release	May-12	**Total Malfunctions**	**8**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	7,375	Battery Malfunction	1
Estimated Active USA Implants	3,051	Electrical Component	2
Normal Battery Depletions	265	Poss Early Battery Depltn	1
		Therapy Function Compromised	**4**
		Battery Malfunction	2
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D334DRG Protecta DR

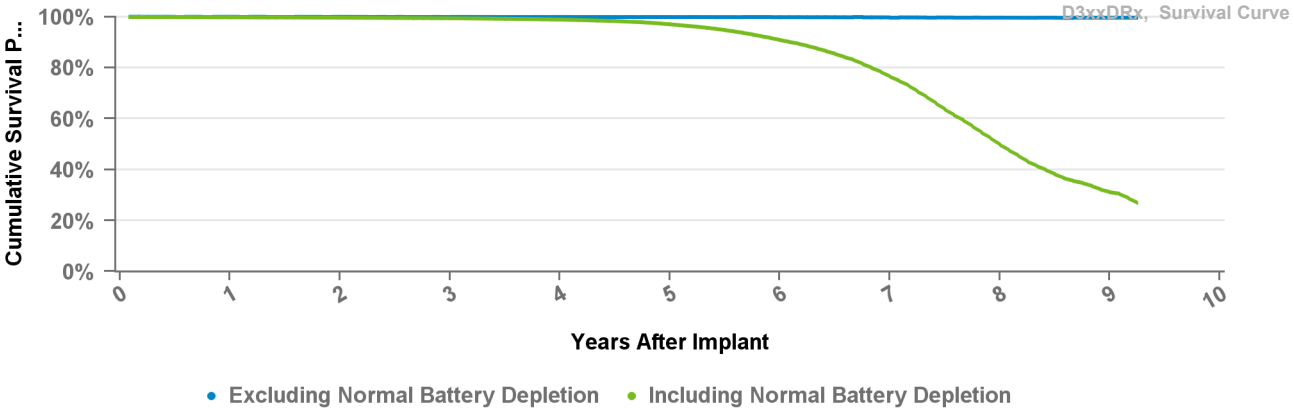
US Market Release	Mar-11	**Total Malfunctions**	**20**
CE Approval Date		**Therapy Function Not Compromised**	**9**
Registered USA Implants	10,694	Battery Malfunction	2
Estimated Active USA Implants	1,635	Electrical Component	6
Normal Battery Depletions	1,760	Poss Early Battery Depltn	1
		Therapy Function Compromised	**11**
		Battery Malfunction	8
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D334DRM Protecta DR

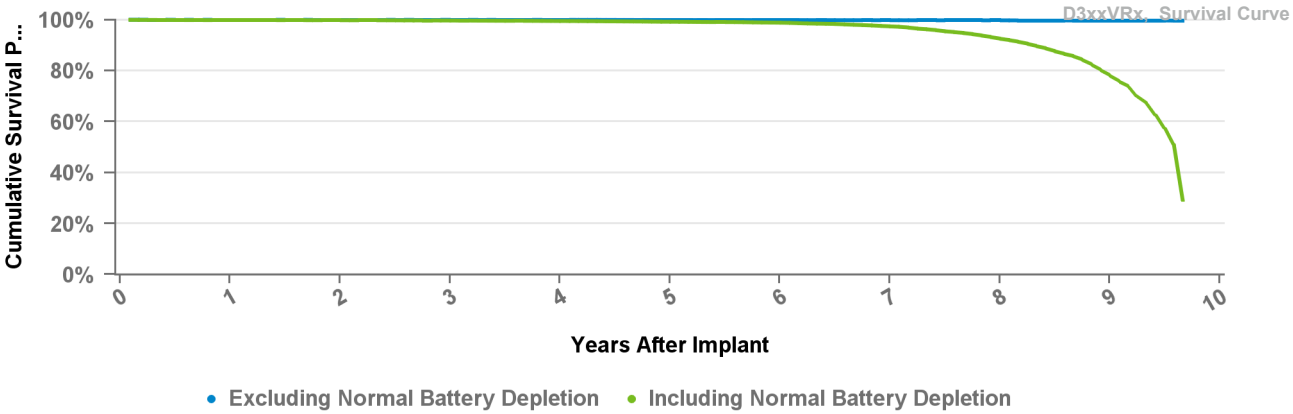
US Market Release	Nov-11	**Total Malfunctions**	**1**
CE Approval Date		**Therapy Function Not Compromised**	**0**
Registered USA Implants	2,994		
Estimated Active USA Implants	567	**Therapy Function Compromised**	**1**
Normal Battery Depletions	548	Battery Malfunction	1



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D334VRG Protecta VR

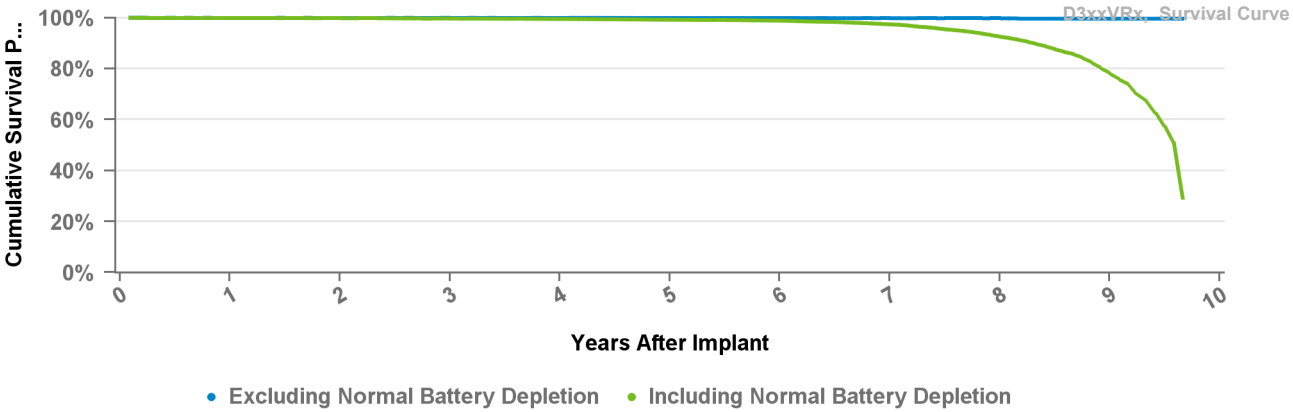
US Market Release	Mar-11	**Total Malfunctions**	**12**
CE Approval Date		**Therapy Function Not Compromised**	**6**
Registered USA Implants	6,486	Battery Malfunction	2
Estimated Active USA Implants	2,118	Electrical Component	4
Normal Battery Depletions	436	**Therapy Function Compromised**	**6**
		Battery Malfunction	4
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D334VRM Protecta VR

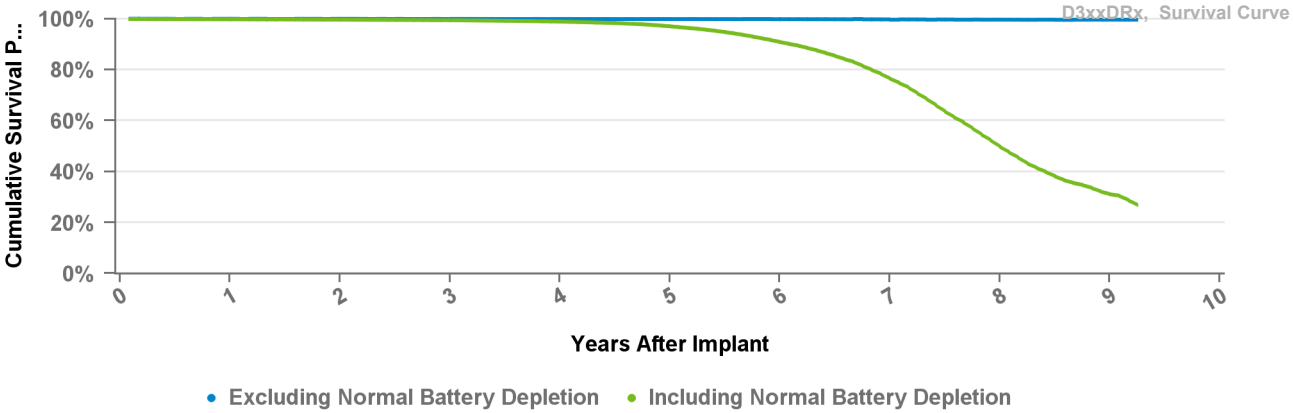
US Market Release	May-12	**Total Malfunctions**	**3**
CE Approval Date		**Therapy Function Not Compromised**	**1**
Registered USA Implants	2,165	Other Malfunction	1
Estimated Active USA Implants	935	**Therapy Function Compromised**	**2**
Normal Battery Depletions	95	Battery Malfunction	2



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D354DRG Protecta XT DR

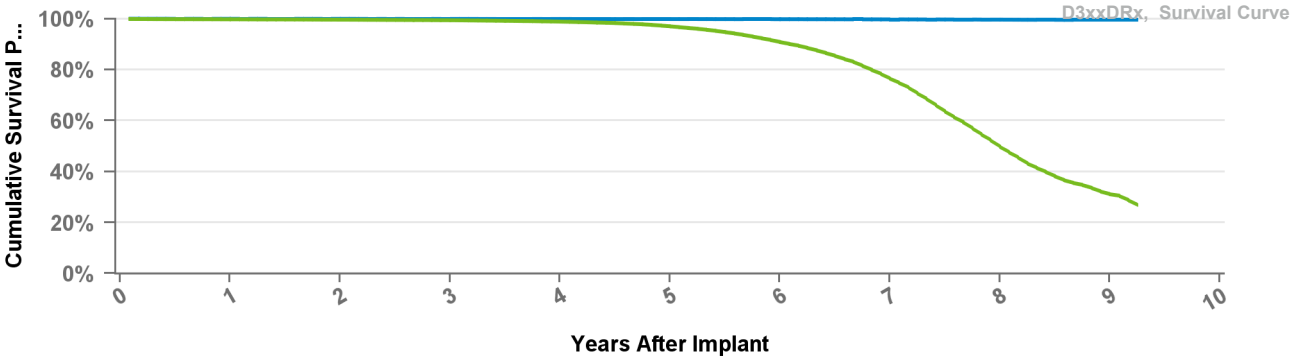
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	5		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D354DRM Protecta XT DR

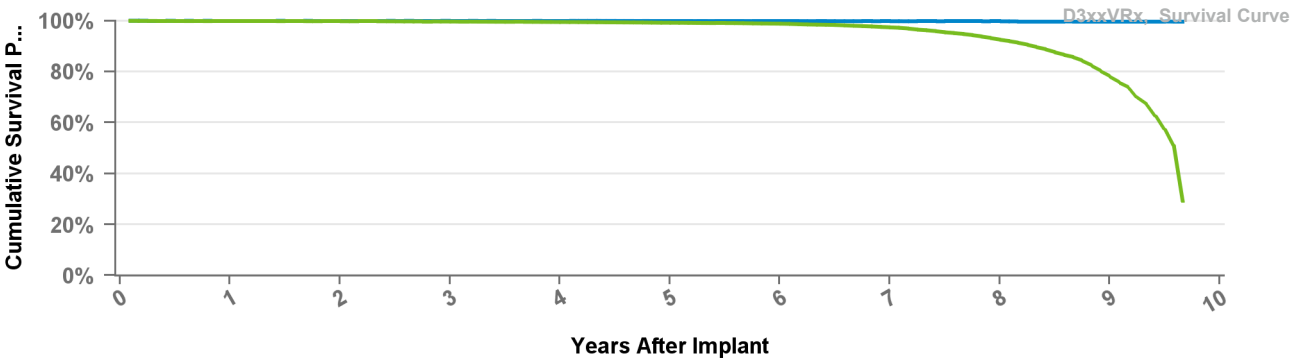
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D354VRG Protecta XT VR

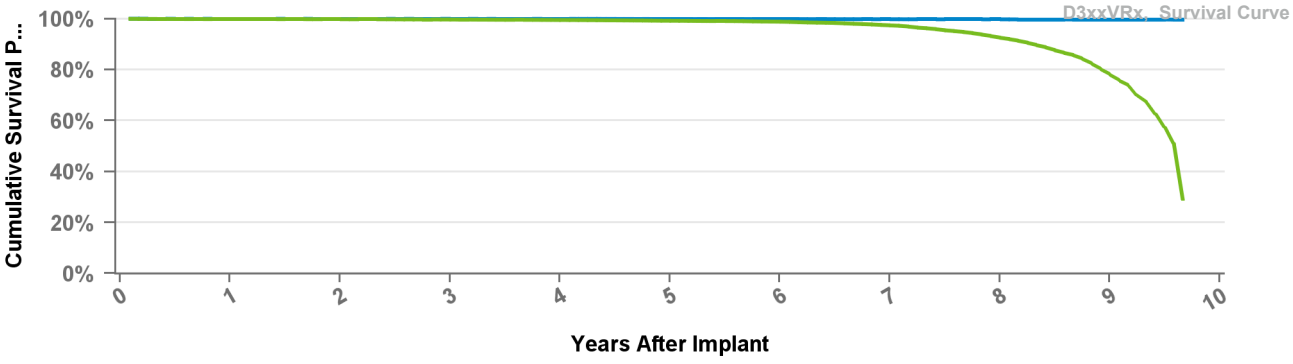
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D354VRM Protecta XT VR

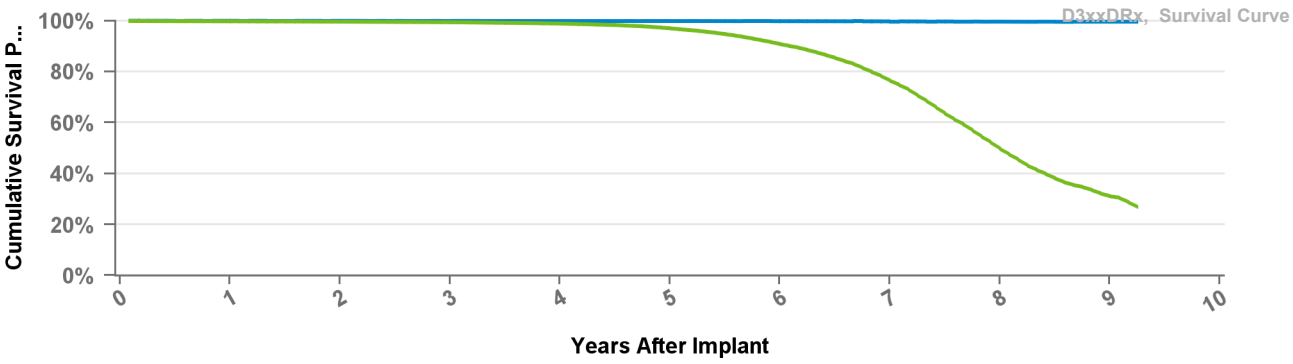
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D364DRG Protecta DR

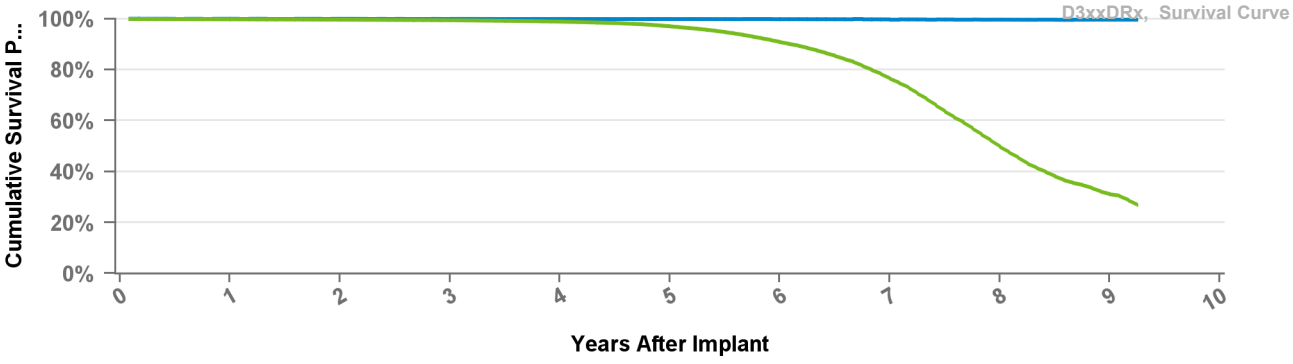
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D364DRM Protecta DR

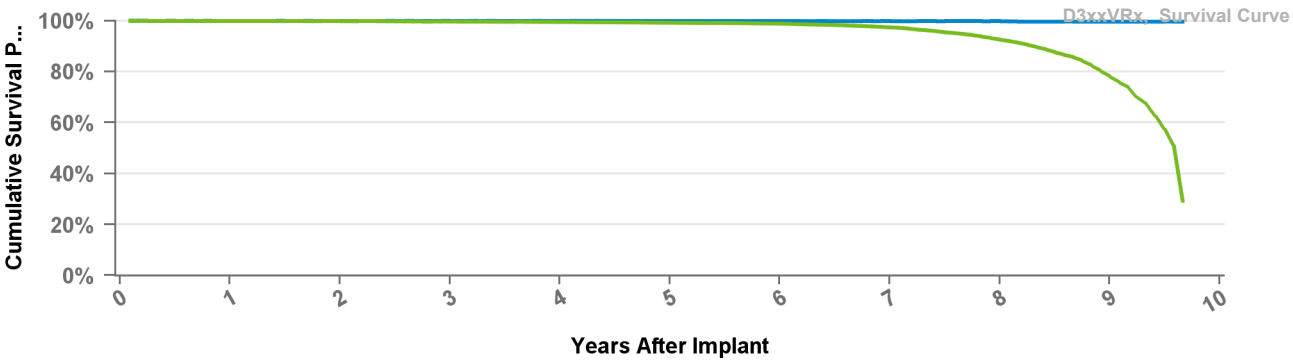
US Market Release		**Total Malfunctions**	
CE Approval Date	Jul-10	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D364VRG Protecta VR

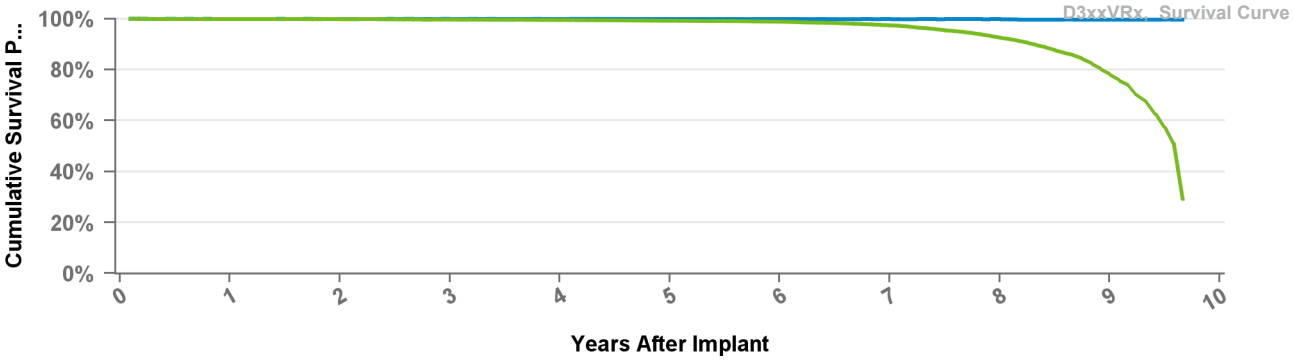
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-10	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D364VRM Protecta VR

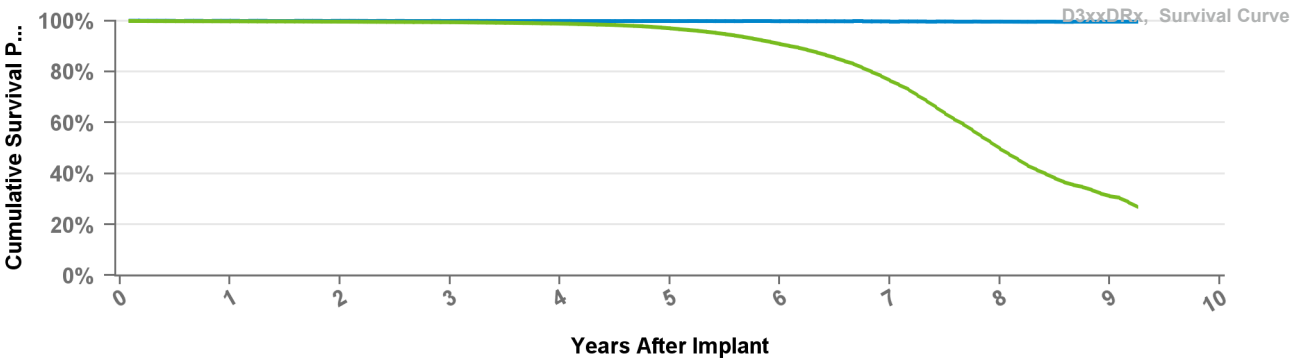
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-10	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D384DRG Cardia DR

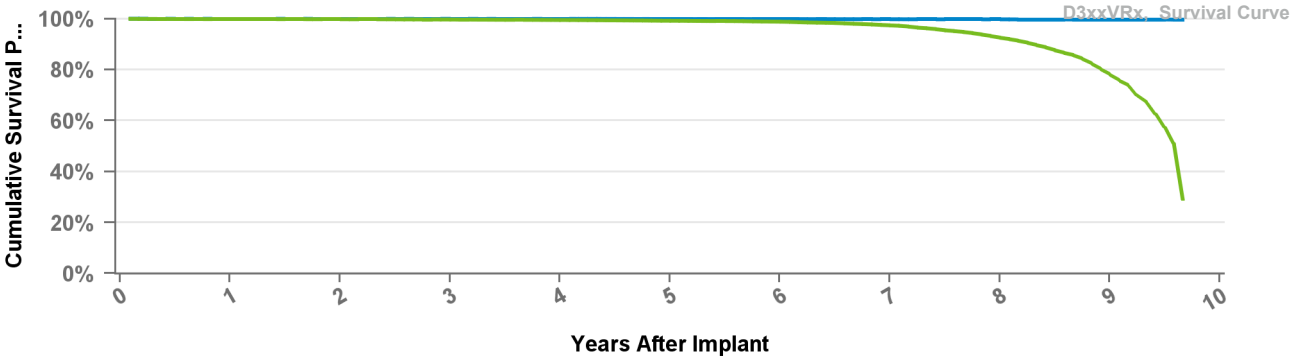
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D384VRG Cardia VR

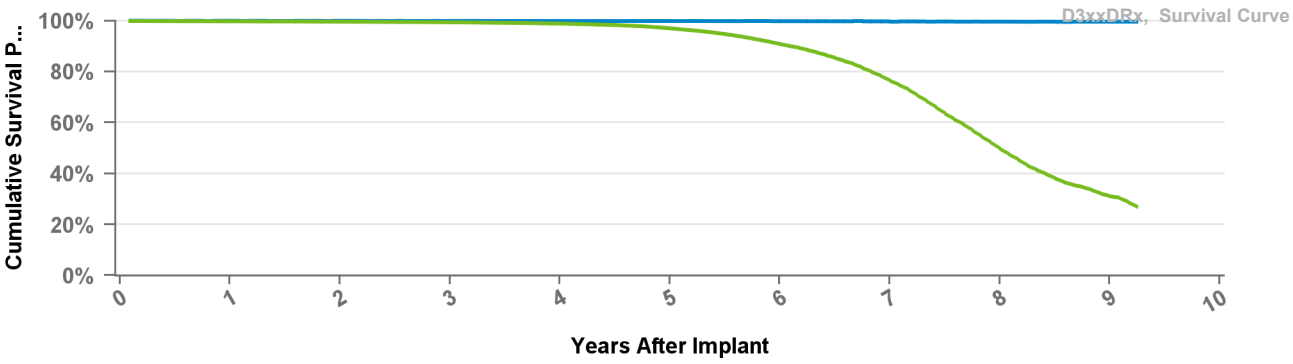
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

D394DRG Egida DR

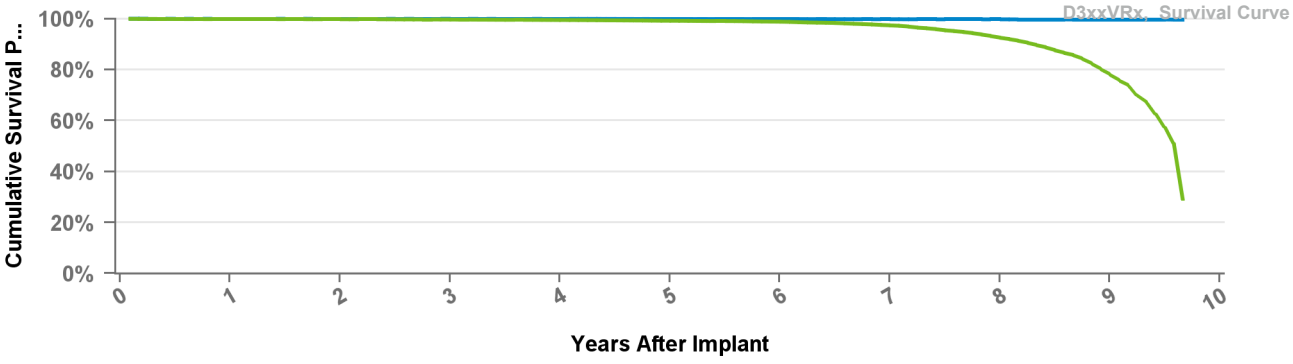
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 111 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.4%	98.9%	97.0%	90.9%	76.5%	49.8%	31.1%	26.9%
Effective Sample Size	54440	50564	46486	42366	37822	30488	19384	7683	1162	150

D394VRG Egida VR

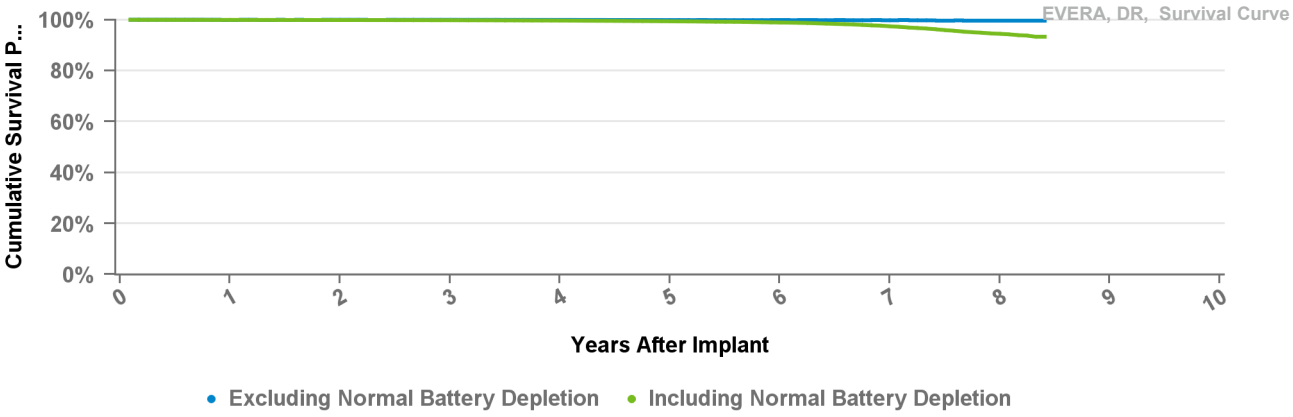
US Market Release		**Total Malfunctions**	
CE Approval Date	Jan-11	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	at 116 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	97.4%	92.6%	78.1%	29.0%
Effective Sample Size	25981	24155	22397	20680	19004	17293	15232	11621	3925	123

DDBB1D1 Evera XT

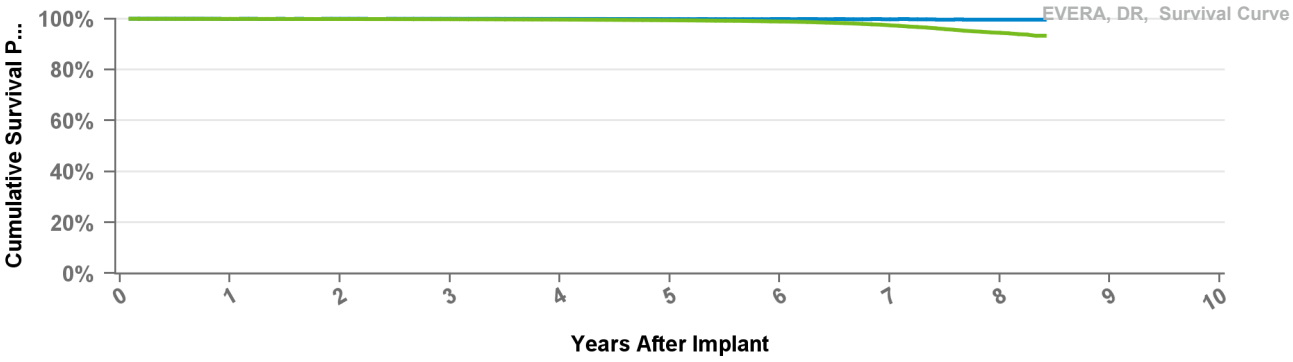
US Market Release	Apr-13	**Total Malfunctions**	**124**
CE Approval Date		**Therapy Function Not Compromised**	**64**
Registered USA Implants	82,182	Battery Malfunction	38
Estimated Active USA Implants	48,760	Electrical Component	22
Normal Battery Depletions	730	Other Malfunction	4
		Therapy Function Compromised	**60**
		Battery Malfunction	50
		Electrical Component	5
		Electrical Interconnect	2
		Other Malfunction	3



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDBB1D4 Evera XT

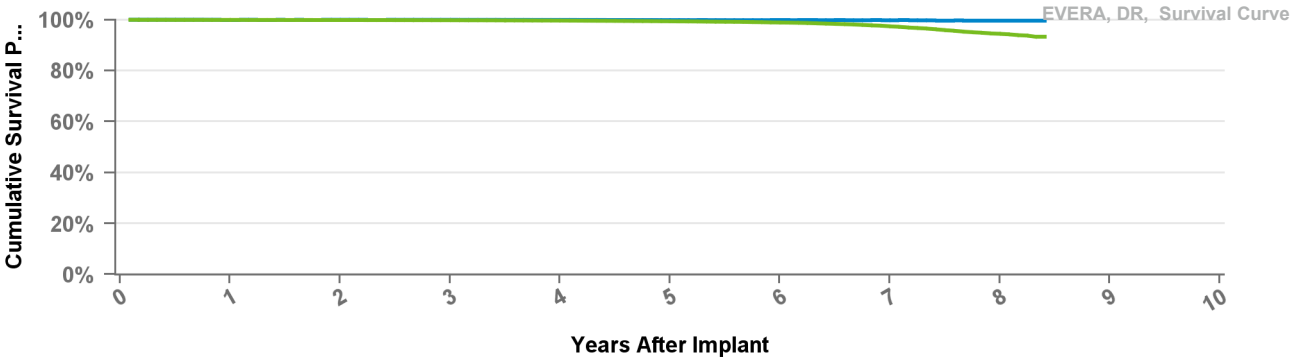
US Market Release	Apr-13	**Total Malfunctions**	**112**
CE Approval Date		**Therapy Function Not Compromised**	**70**
Registered USA Implants	59,823	Battery Malfunction	50
Estimated Active USA Implants	36,674	Electrical Component	14
Normal Battery Depletions	438	Electrical Interconnect	2
		Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**42**
		Battery Malfunction	32
		Electrical Component	10



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDBB2D1 Evera XT

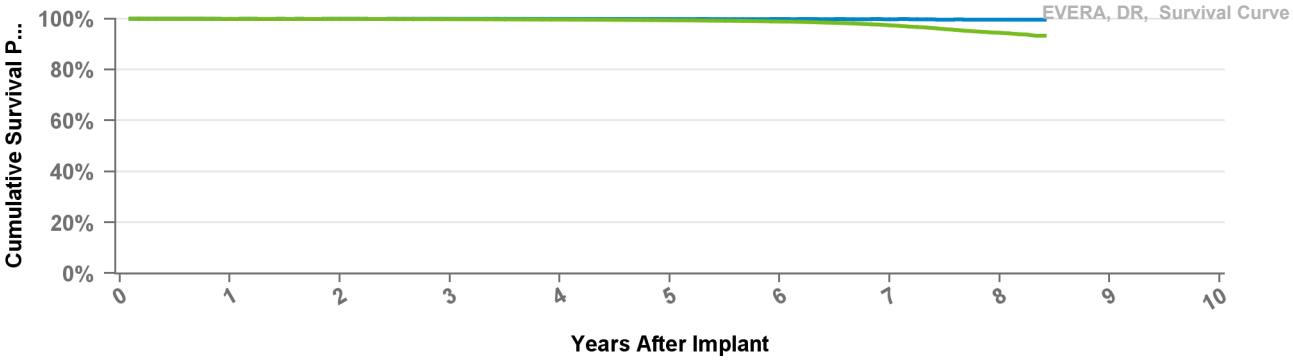
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDBB2D4 Evera XT

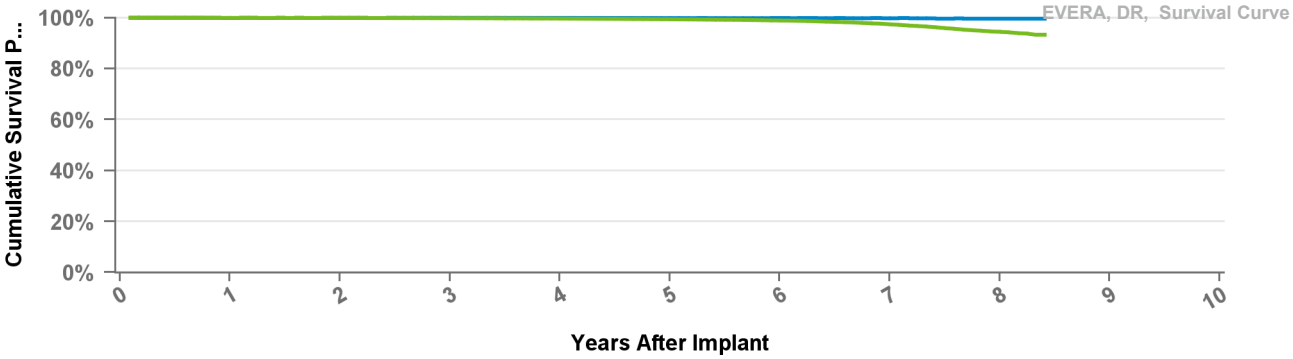
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDBC3D1 Evera S

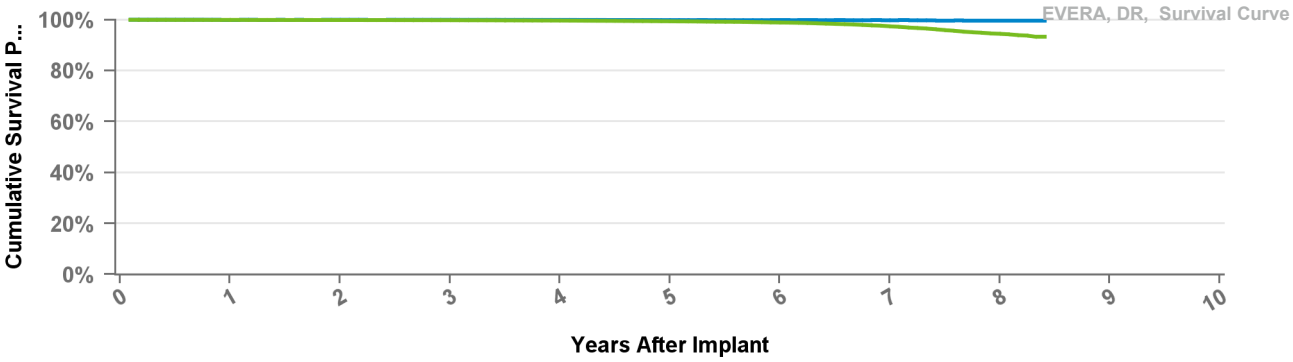
US Market Release	Apr-13	**Total Malfunctions**	**26**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**14**
Registered USA Implants	15,932	Battery Malfunction	10
Estimated Active USA Implants	9,510	Electrical Component	4
Normal Battery Depletions	165	**Therapy Function Compromised**	**12**
		Battery Malfunction	8
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDBC3D4 Evera S

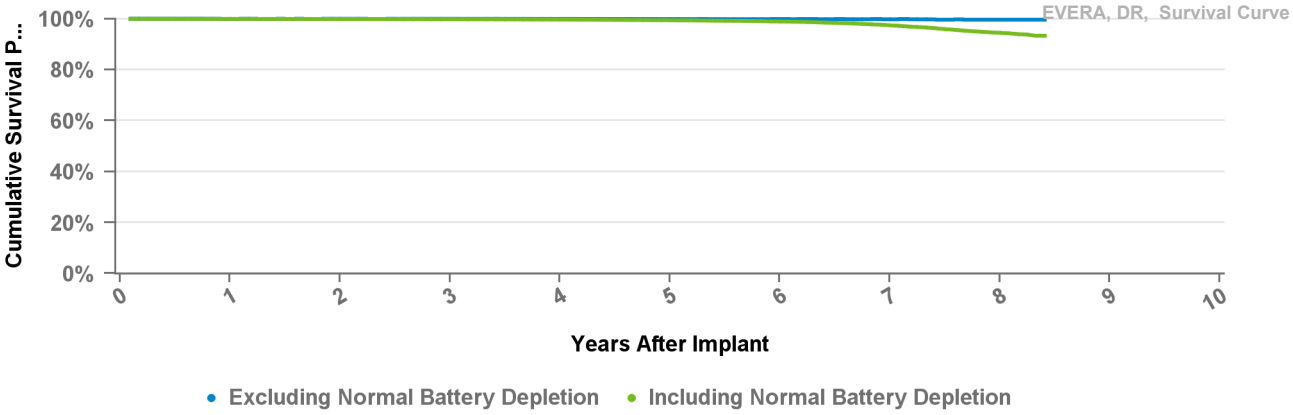
US Market Release	Apr-13	**Total Malfunctions**	**22**
CE Approval Date	Dec-13	**Therapy Function Not Compromised**	**8**
Registered USA Implants	11,787	Battery Malfunction	4
Estimated Active USA Implants	7,334	Electrical Component	4
Normal Battery Depletions	77	**Therapy Function Compromised**	**14**
		Battery Malfunction	10
		Electrical Component	2
		Poss Early Battery Depltn	2



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMB1D1 Evera MRI XT

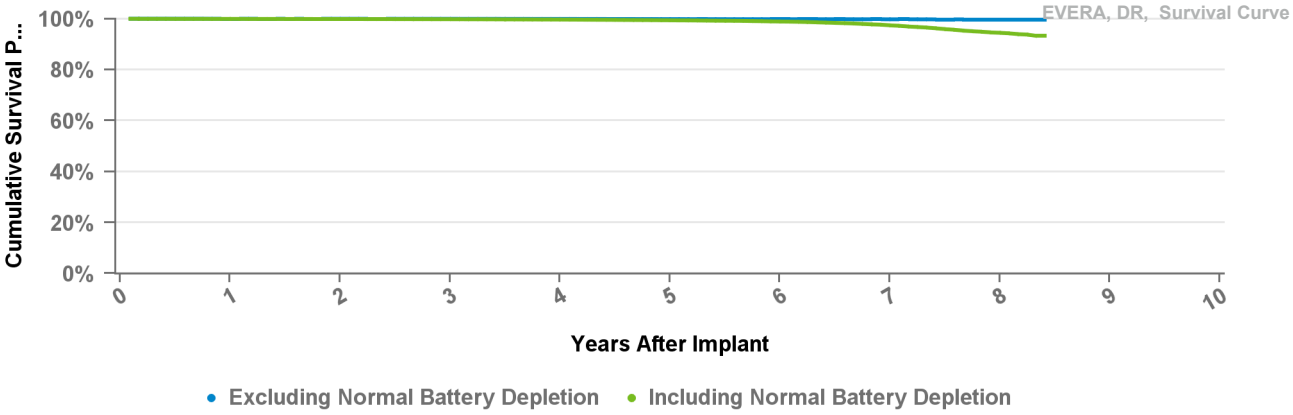
US Market Release	Oct-16	**Total Malfunctions**	**25**
CE Approval Date		**Therapy Function Not Compromised**	**18**
Registered USA Implants	41,790	Battery Malfunction	11
Estimated Active USA Implants	34,102	Electrical Component	3
Normal Battery Depletions	21	Electrical Interconnect	2
		Other Malfunction	2
		Therapy Function Compromised	**7**
		Battery Malfunction	4
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMB1D4 Evera MRI XT

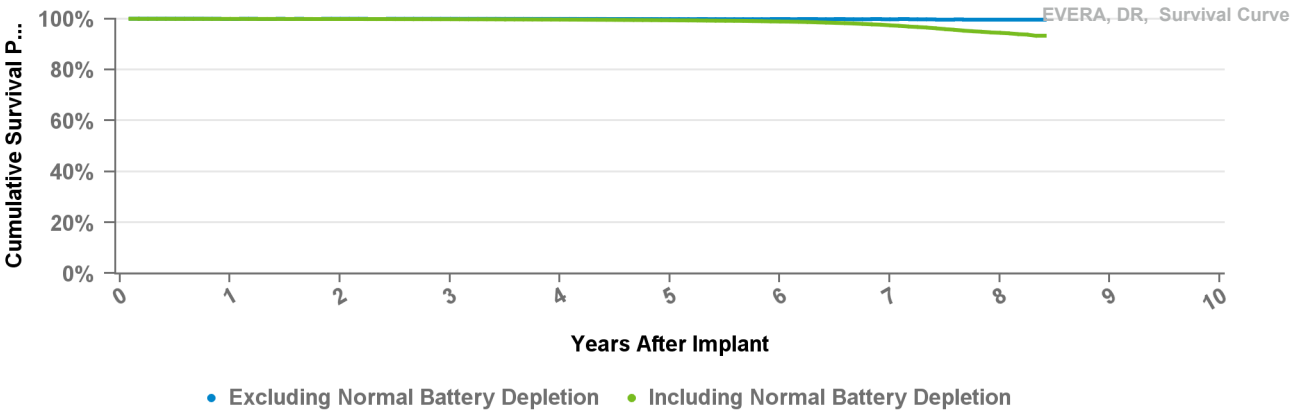
US Market Release	Sep-15	**Total Malfunctions**	**85**
CE Approval Date		**Therapy Function Not Compromised**	**53**
Registered USA Implants	120,306	Battery Malfunction	22
Estimated Active USA Implants	97,600	Electrical Component	25
Normal Battery Depletions	103	Electrical Interconnect	3
		Other Malfunction	3
		Therapy Function Compromised	**32**
		Battery Malfunction	28
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMB2D1 Evera MRI XT

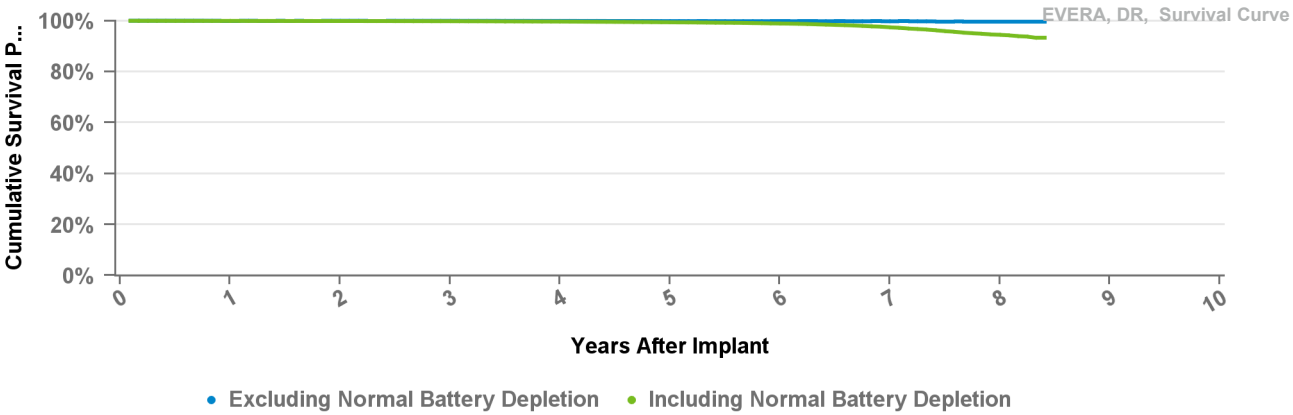
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMB2D4 Evera MRI XT

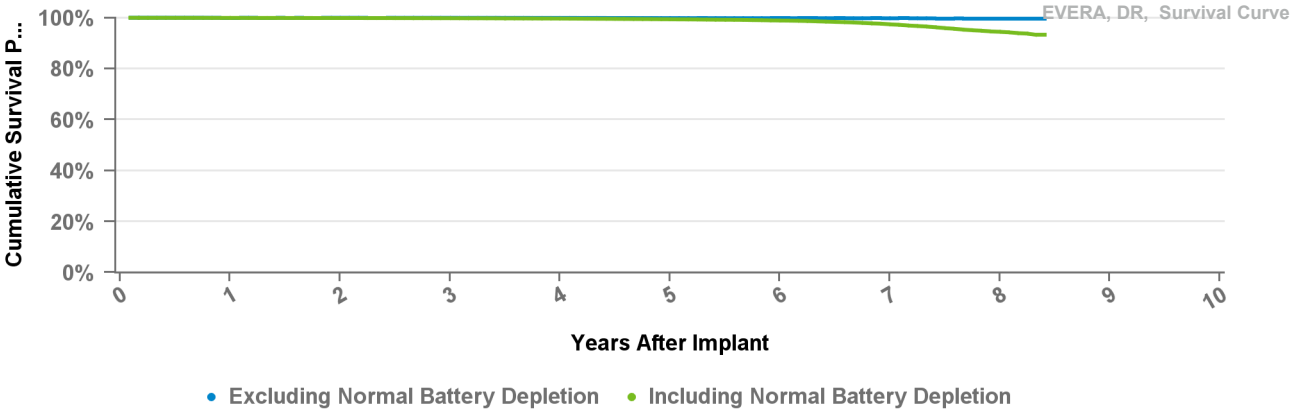
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMC3D1 Evera MRI S

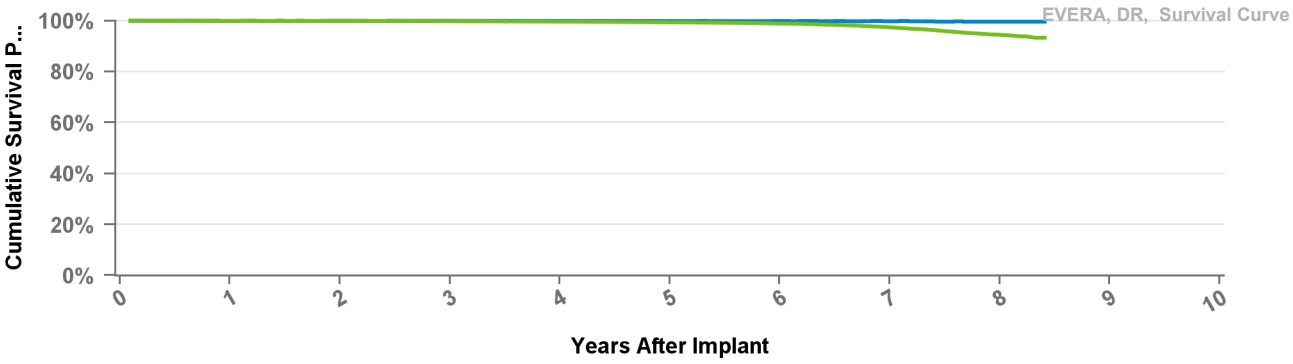
US Market Release	Oct-16	**Total Malfunctions**	**3**
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	**3**
Registered USA Implants	3,817	Battery Malfunction	2
Estimated Active USA Implants	3,130	Electrical Component	1
Normal Battery Depletions	2	**Therapy Function Compromised**	**0**



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMC3D4 Evera MRI

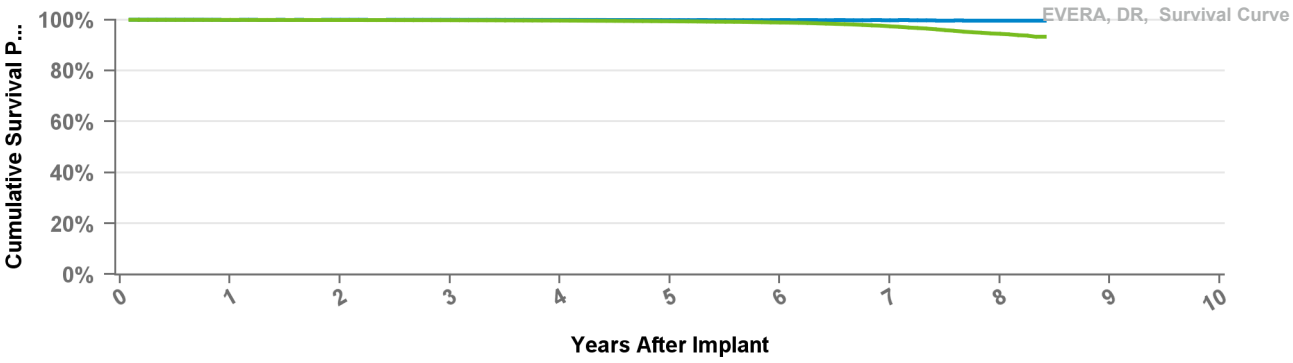
US Market Release	Sep-15	**Total Malfunctions**	**7**
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	**4**
Registered USA Implants	8,338	Battery Malfunction	2
Estimated Active USA Implants	6,789	Electrical Component	2
Normal Battery Depletions	4	**Therapy Function Compromised**	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMD3D1 Primo

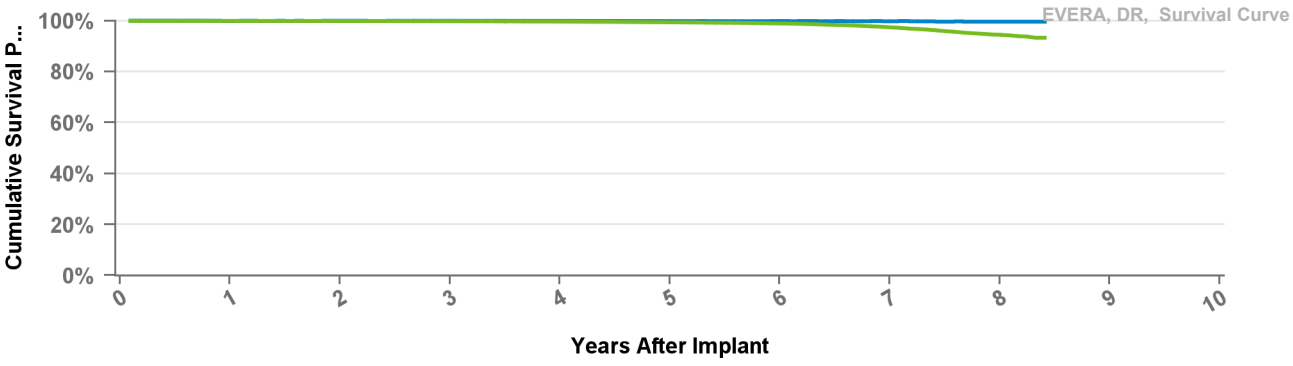
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	298		
Estimated Active USA Implants	274	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDMD3D4 Primo

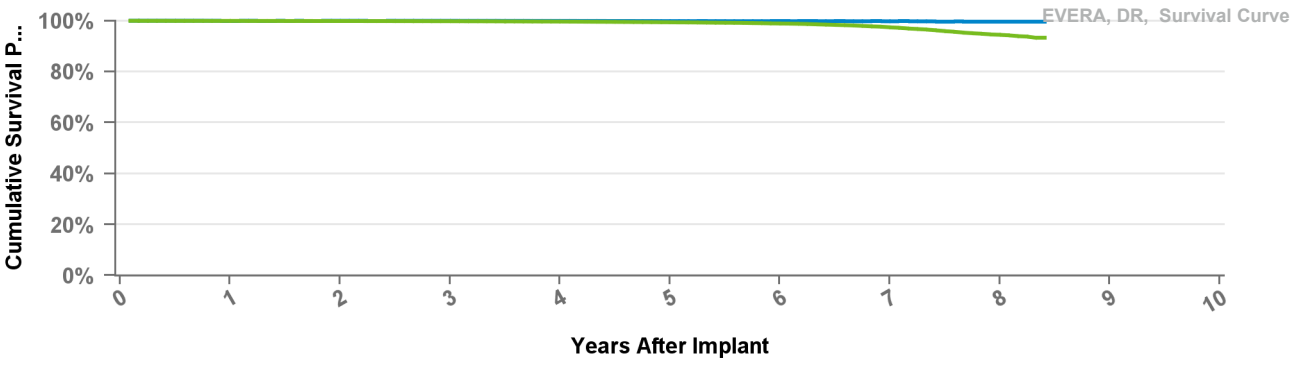
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	674		
Estimated Active USA Implants	629	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDME3D1 Mirro

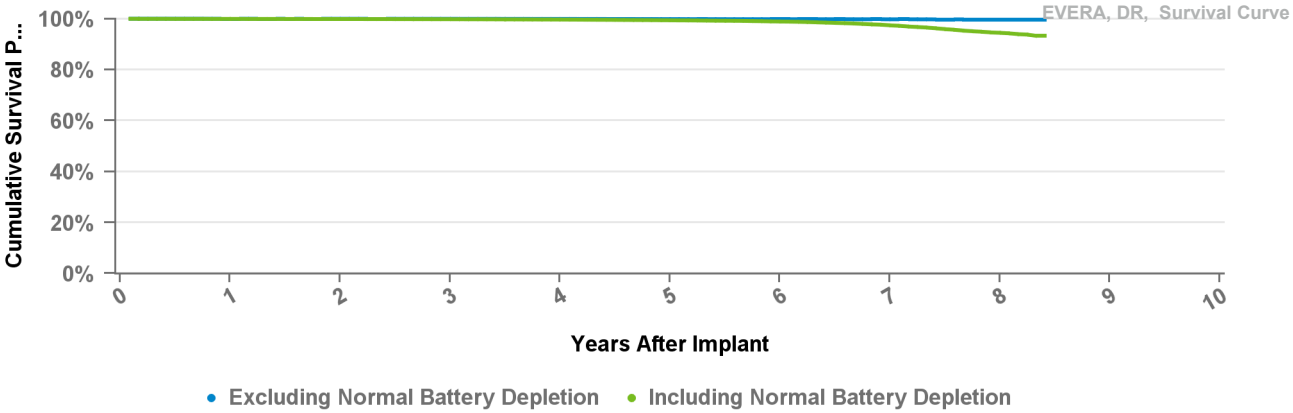
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DDME3D4 Mirro

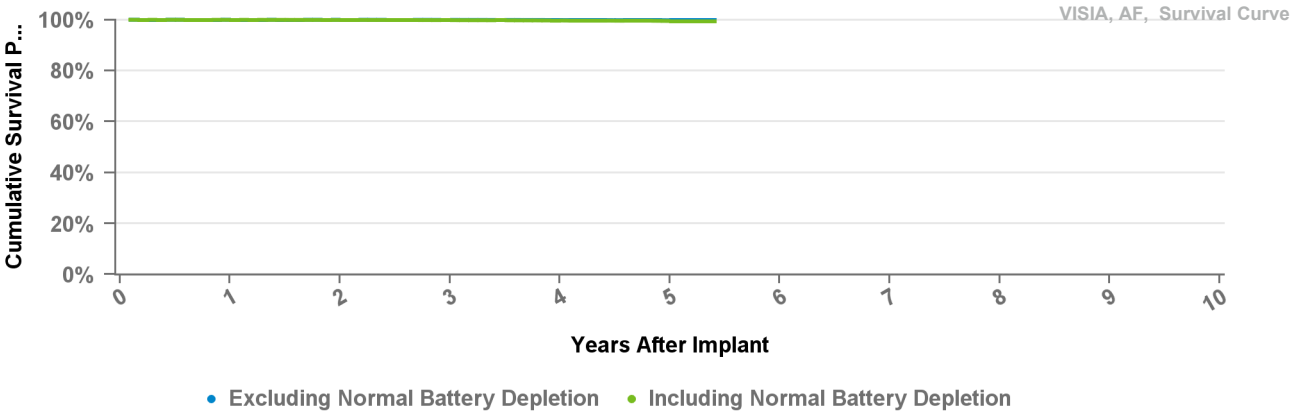
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 101 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.4%	98.9%	97.4%	94.5%	93.2%
Effective Sample Size	193720	160725	125788	92962	63066	38346	19541	4538	216

DVAB1D1 Visia AF

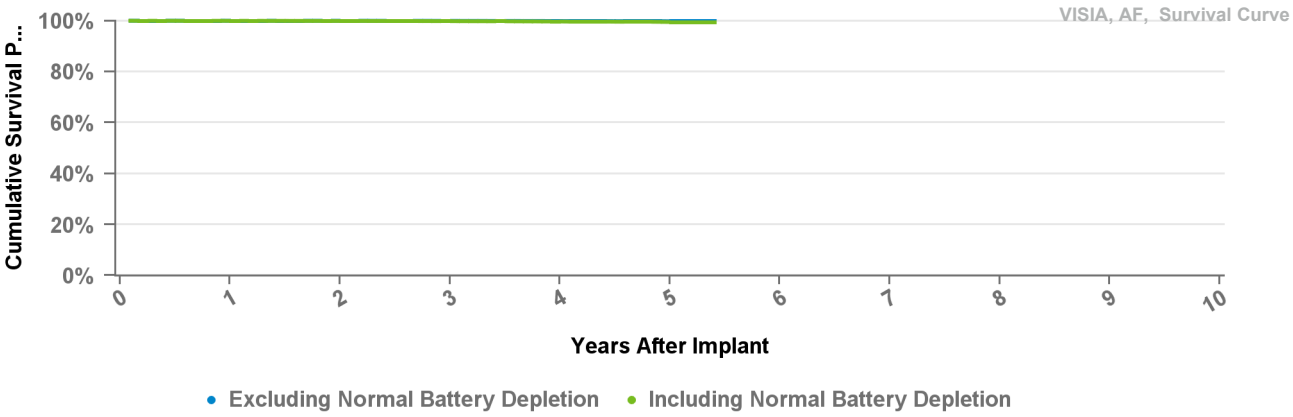
US Market Release	Jan-16	**Total Malfunctions**	**4**
CE Approval Date		**Therapy Function Not Compromised**	**4**
Registered USA Implants	5,054	Battery Malfunction	4
Estimated Active USA Implants	3,683	**Therapy Function Compromised**	**0**
Normal Battery Depletions	11		



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVAB1D4 Visia AF

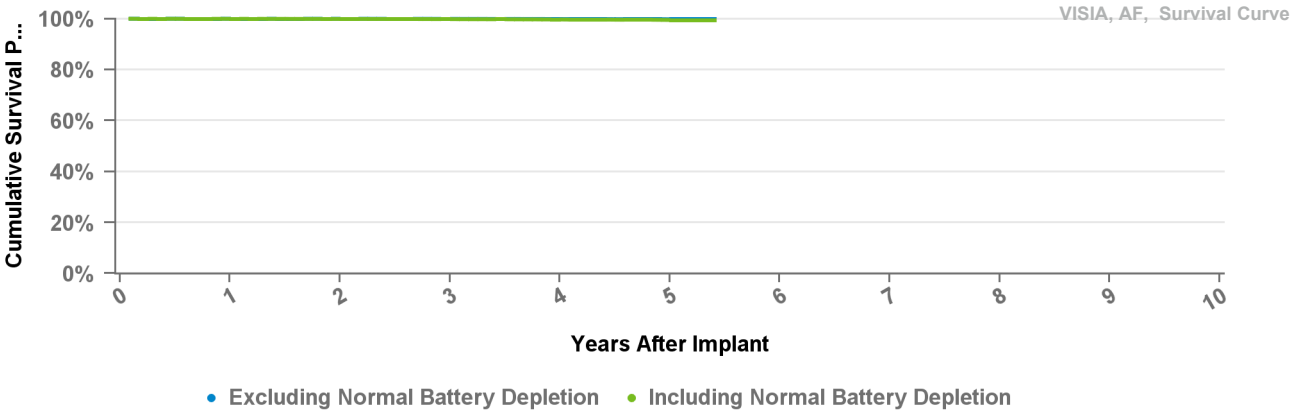
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date		**Therapy Function Not Compromised**	
Registered USA Implants	3,440		
Estimated Active USA Implants	2,558	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVAB2D1 Visia AF XT

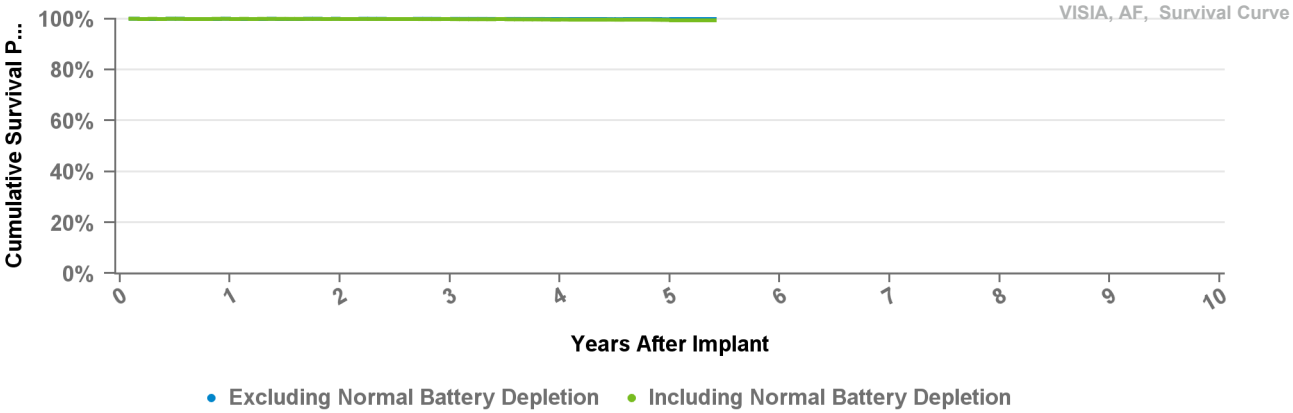
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVAC3D1 Visia AF S

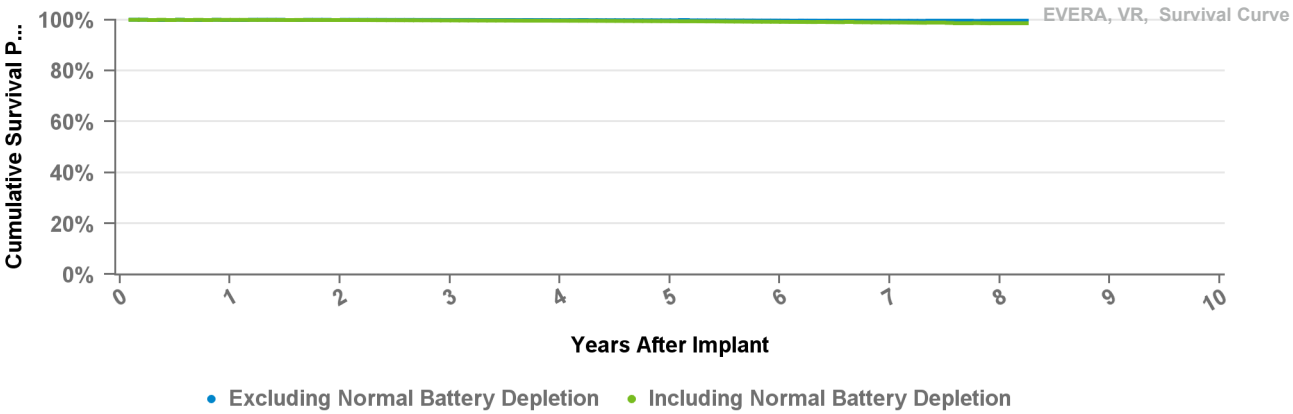
US Market Release	Jan-16	**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVBB1D1 Evera XT

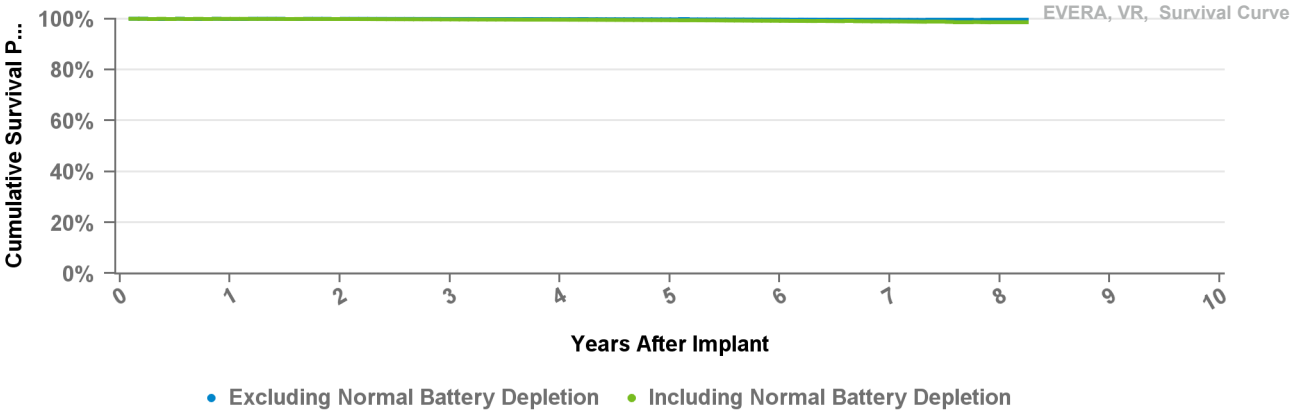
US Market Release	Apr-13	**Total Malfunctions**	**95**
CE Approval Date		**Therapy Function Not Compromised**	**69**
Registered USA Implants	32,229	Battery Malfunction	54
Estimated Active USA Implants	19,403	Electrical Component	15
Normal Battery Depletions	44	**Therapy Function Compromised**	**26**
		Battery Malfunction	22
		Electrical Component	4



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVBB1D4 Evera XT

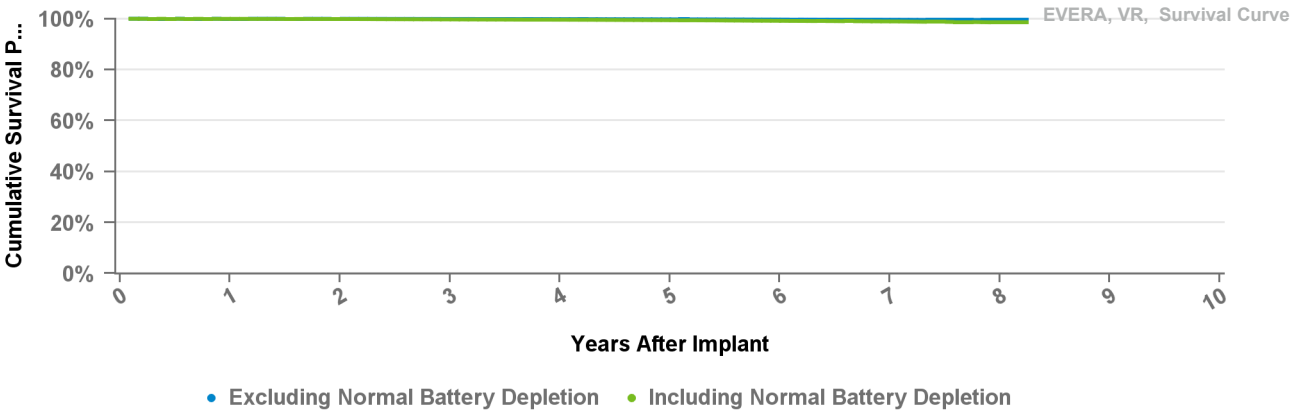
US Market Release	Apr-13	**Total Malfunctions**	**117**
CE Approval Date		**Therapy Function Not Compromised**	**79**
Registered USA Implants	44,763	Battery Malfunction	54
Estimated Active USA Implants	29,035	Electrical Component	14
Normal Battery Depletions	74	Other Malfunction	9
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**38**
		Battery Malfunction	36
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVBB2D1 Evera XT

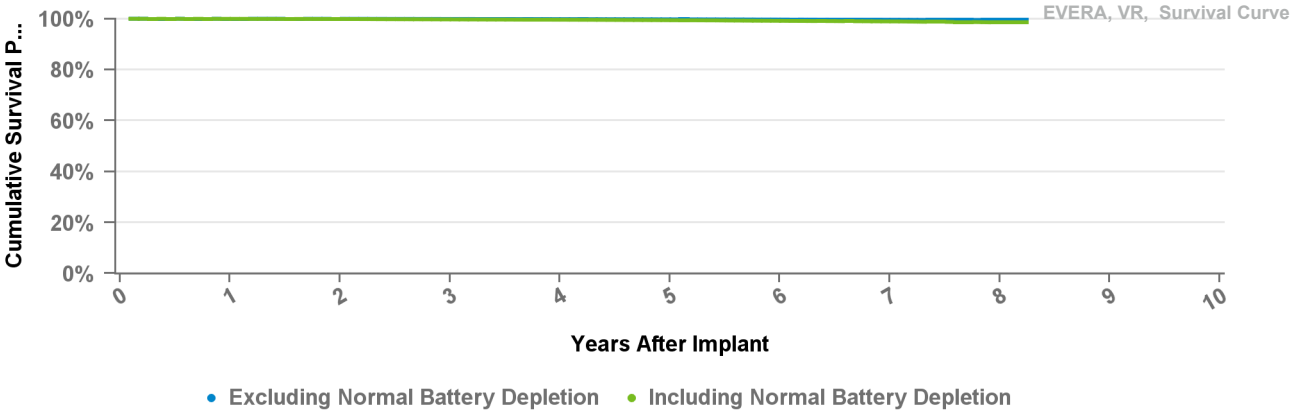
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVBB2D4 Evera XT

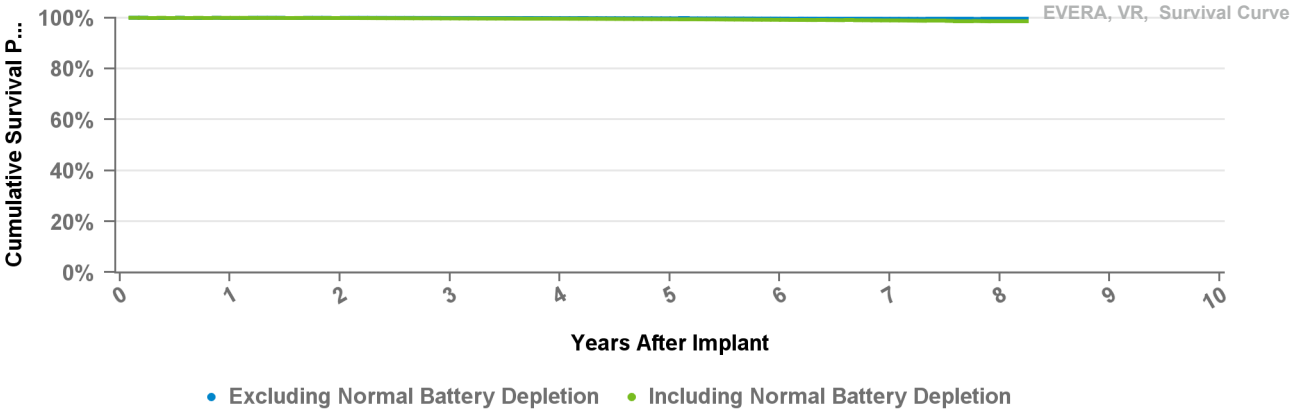
US Market Release		**Total Malfunctions**	
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVBC3D1 Evera S

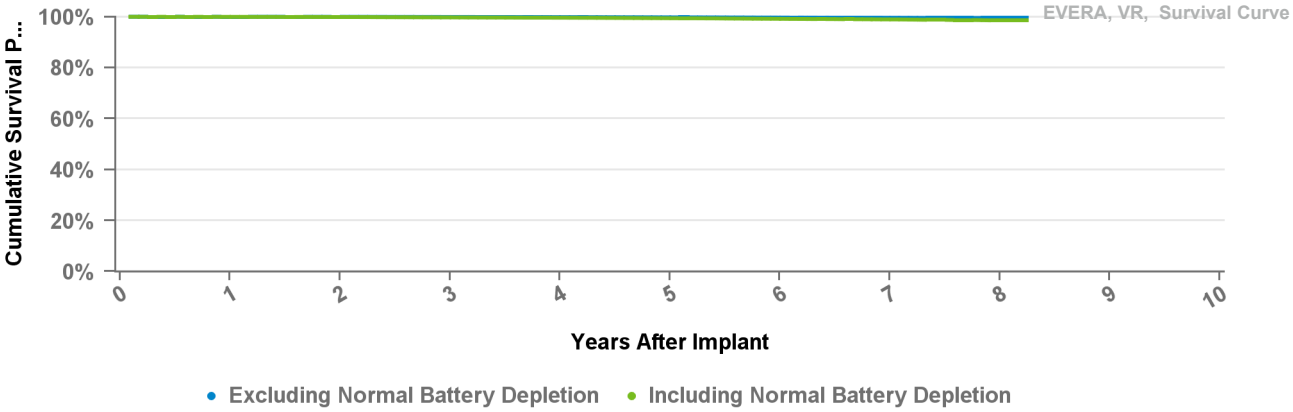
US Market Release	Apr-13	**Total Malfunctions**	**48**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**32**
Registered USA Implants	8,957	Battery Malfunction	28
Estimated Active USA Implants	5,609	Electrical Component	4
Normal Battery Depletions	12	**Therapy Function Compromised**	**16**
		Battery Malfunction	14
		Electrical Component	2



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVBC3D4 Evera S

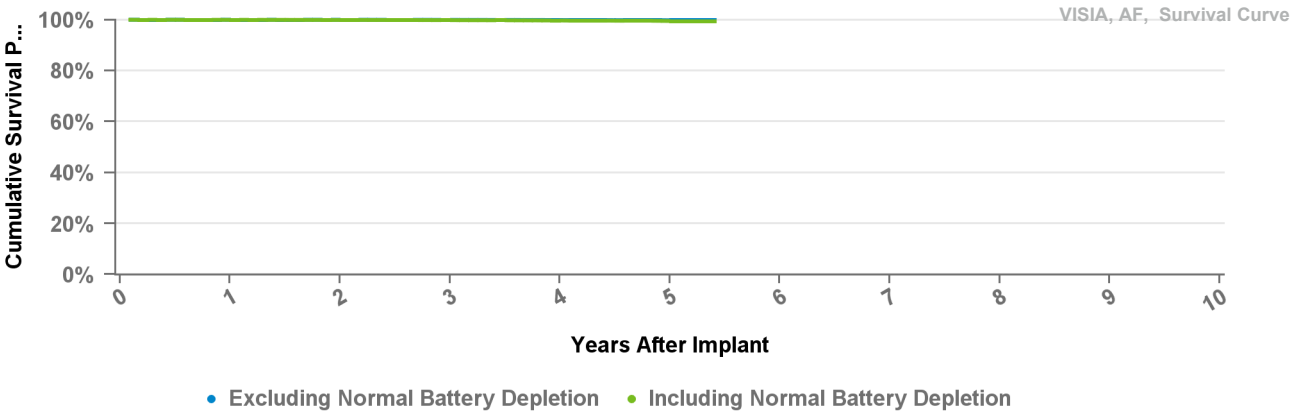
US Market Release	Apr-13	**Total Malfunctions**	**28**
CE Approval Date	Dec-12	**Therapy Function Not Compromised**	**18**
Registered USA Implants	11,079	Battery Malfunction	12
Estimated Active USA Implants	7,350	Electrical Component	6
Normal Battery Depletions	10	**Therapy Function Compromised**	**10**
		Battery Malfunction	10



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVFB1D1 Visia MRI AF

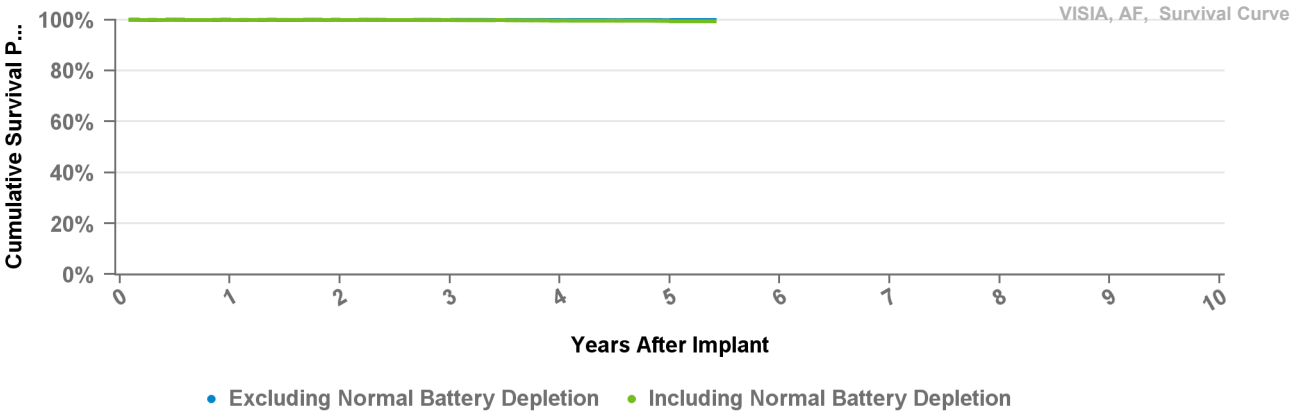
US Market Release	Oct-16	**Total Malfunctions**	**18**
CE Approval Date		**Therapy Function Not Compromised**	**15**
Registered USA Implants	18,960	Battery Malfunction	12
Estimated Active USA Implants	16,126	Electrical Component	1
Normal Battery Depletions	9	Other Malfunction	2
		Therapy Function Compromised	**3**
		Battery Malfunction	2
		Electrical Component	1



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVFB1D4 Visia MRI AF

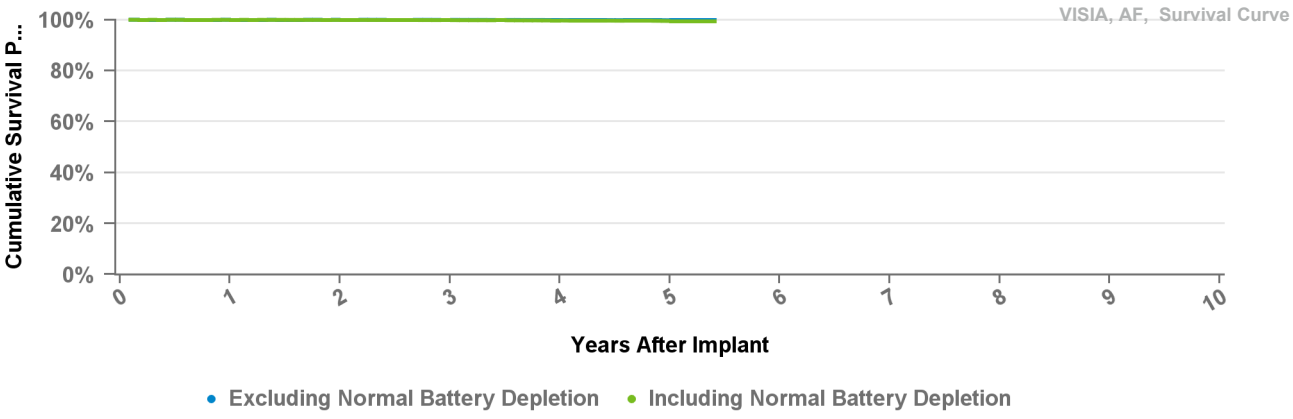
US Market Release	Jan-16	**Total Malfunctions**	**61**
CE Approval Date		**Therapy Function Not Compromised**	**43**
Registered USA Implants	61,465	Battery Malfunction	28
Estimated Active USA Implants	50,785	Electrical Component	12
Normal Battery Depletions	13	Other Malfunction	3
		Therapy Function Compromised	**18**
		Battery Malfunction	14
		Electrical Component	4



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVFB2D1 Visia MRI AF XT

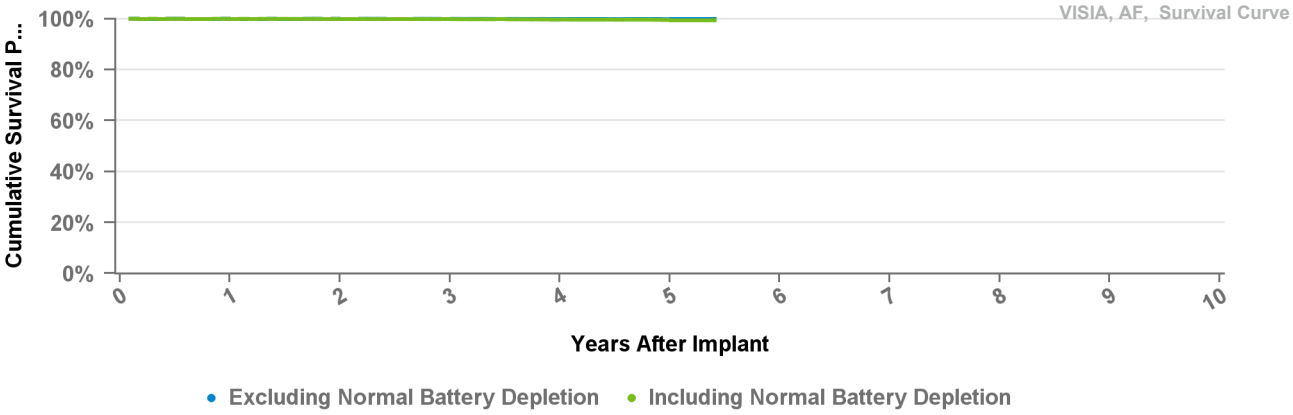
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVFB2D4 Visia MRI AF XT

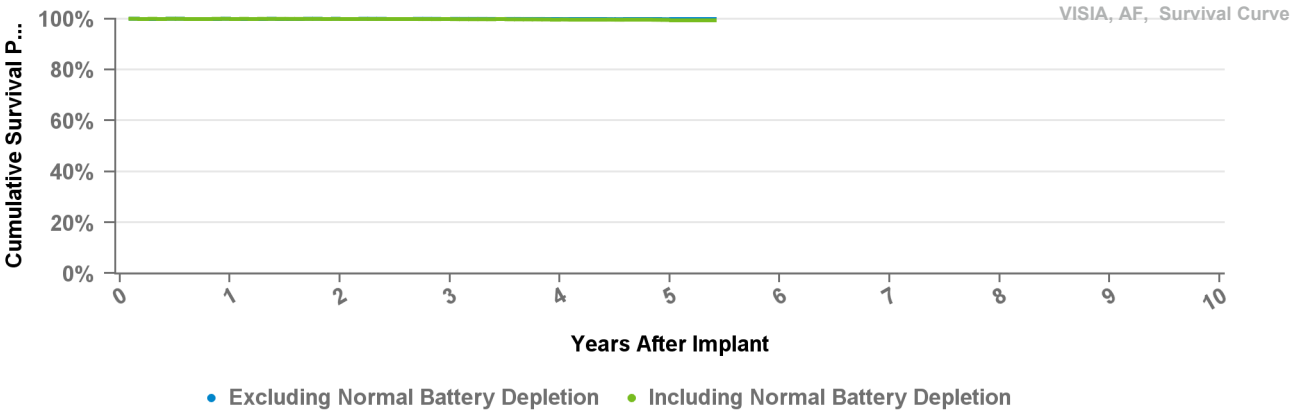
US Market Release		**Total Malfunctions**	
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVFC3D1 Visia MRI AF S

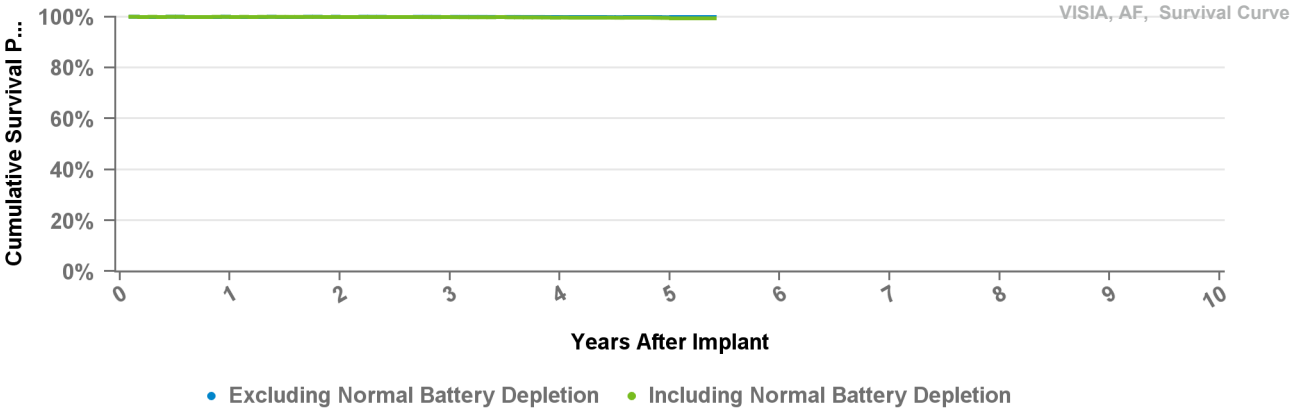
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants	1,602		
Estimated Active USA Implants	1,433	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVFC3D4 Visia MRI AF S

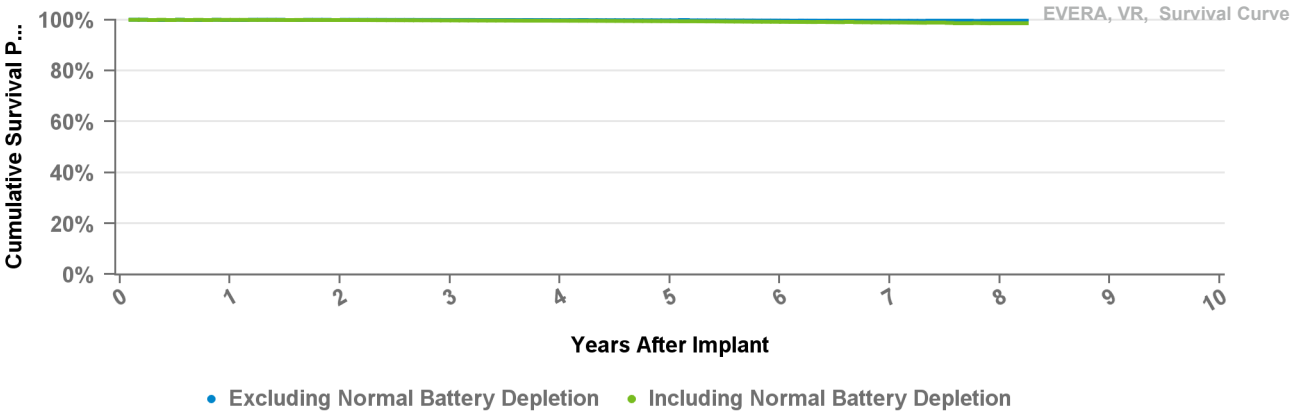
US Market Release	Jan-16	**Total Malfunctions**	**2**
CE Approval Date	Oct-15	**Therapy Function Not Compromised**	**2**
Registered USA Implants	3,364	Battery Malfunction	2
Estimated Active USA Implants	2,922	**Therapy Function Compromised**	**0**
Normal Battery Depletions	4		



Years	1	2	3	4	5	at 65 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%
Effective Sample Size	61324	46610	30951	16627	3845	393

DVMB1D4 Evera MRI XT

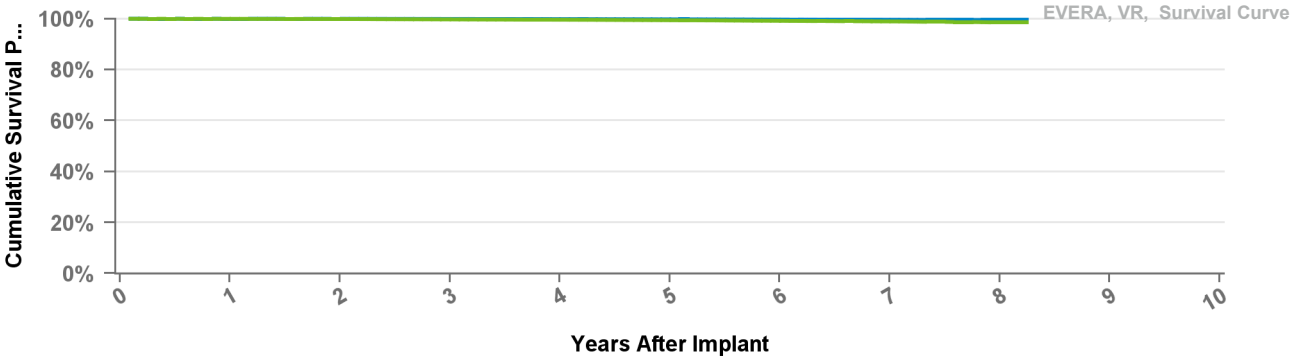
US Market Release	Sep-15	**Total Malfunctions**	**41**
CE Approval Date		**Therapy Function Not Compromised**	**21**
Registered USA Implants	21,209	Battery Malfunction	12
Estimated Active USA Implants	15,333	Electrical Component	6
Normal Battery Depletions	14	Other Malfunction	3
		Therapy Function Compromised	**20**
		Battery Malfunction	20



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMB2D1 Evera MRI XT

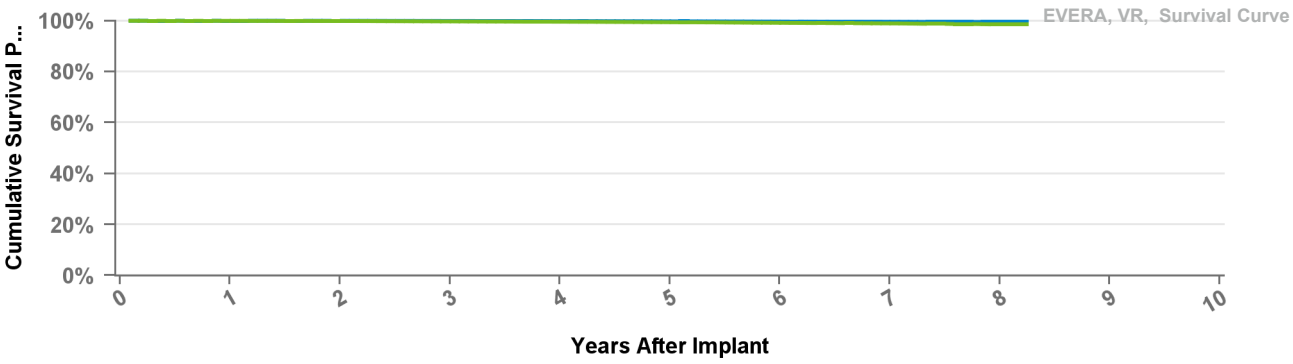
US Market Release		**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMB2D4 Evera MRI XT

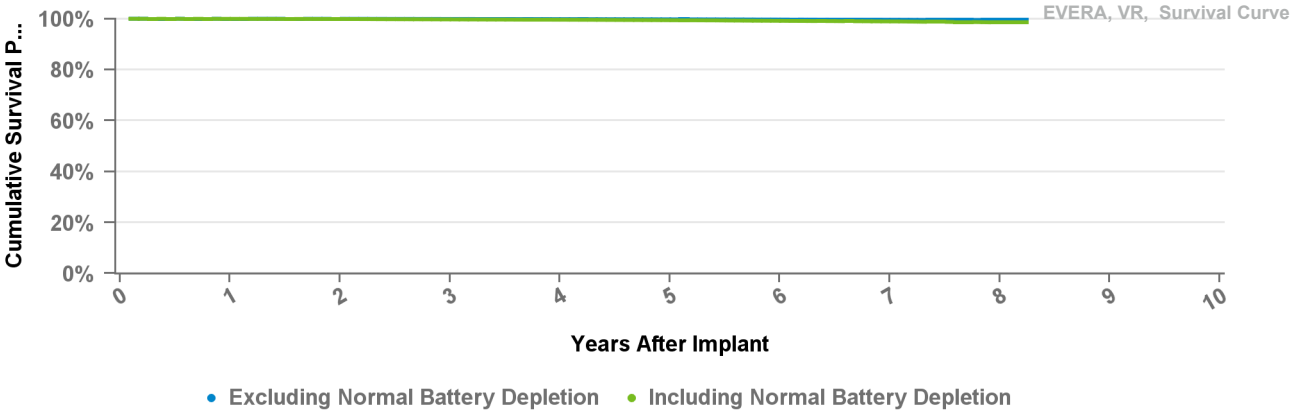
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMC3D1 Evera MRI S

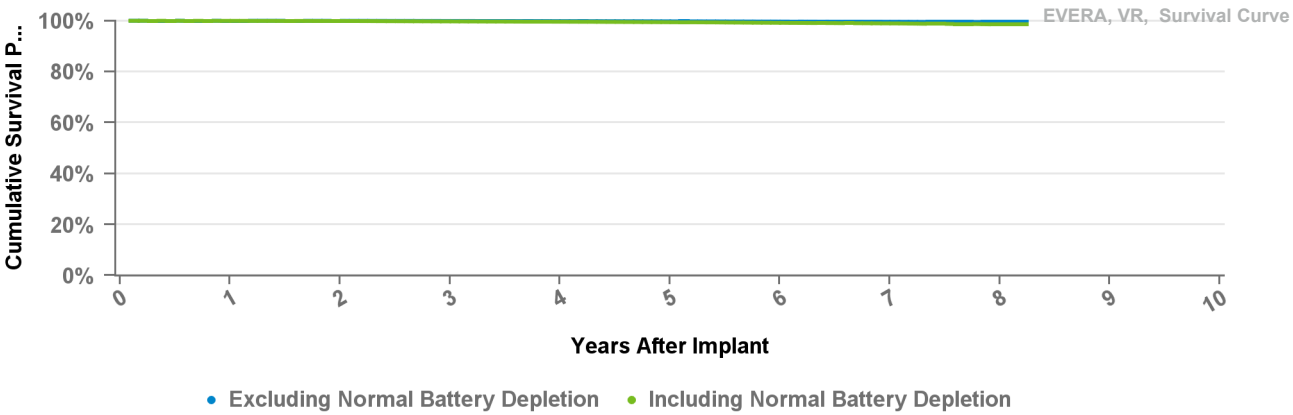
US Market Release	Oct-16	**Total Malfunctions**	
CE Approval Date	Sep-16	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMC3D4 Evera MRI S

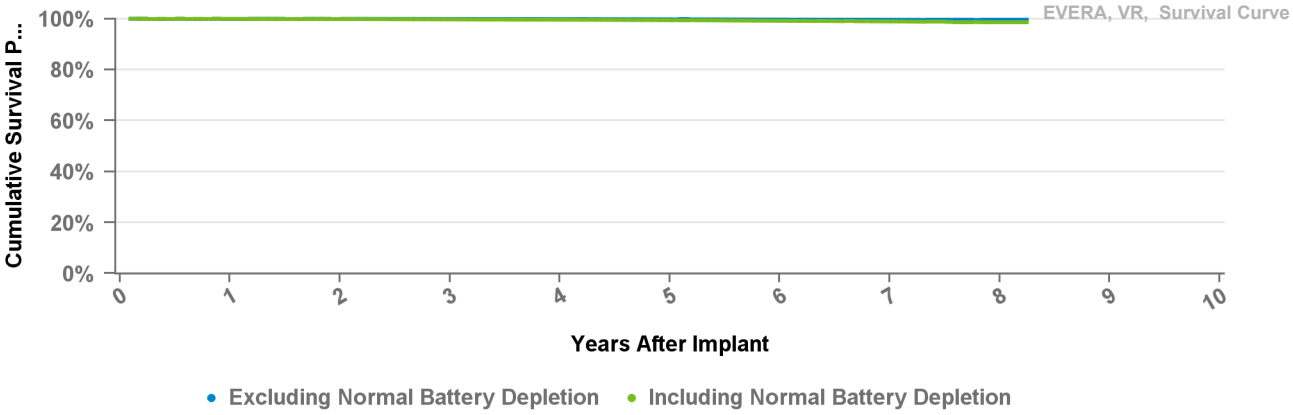
US Market Release	Sep-15	**Total Malfunctions**	
CE Approval Date	Mar-14	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants	4	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMD3D1 Primo

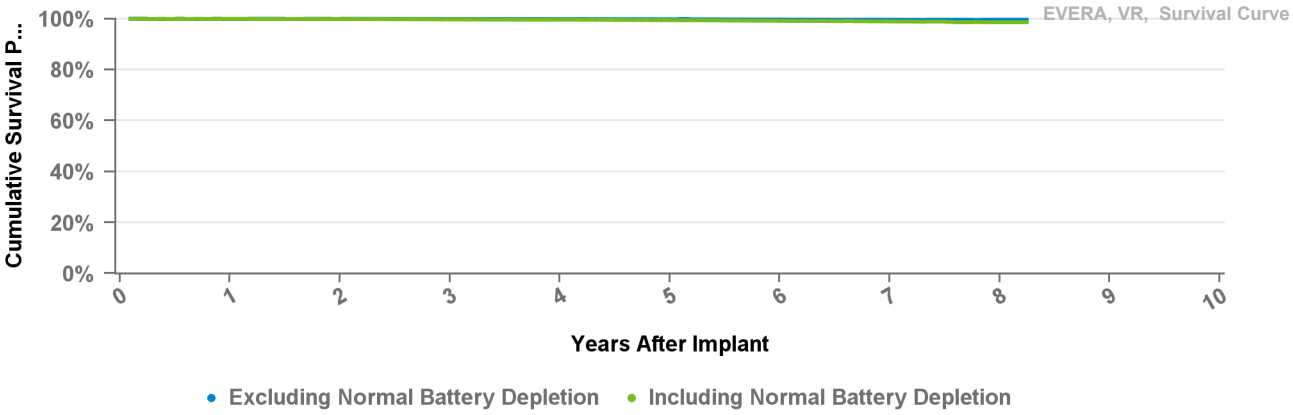
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	192		
Estimated Active USA Implants	179	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVMD3D4 Primo

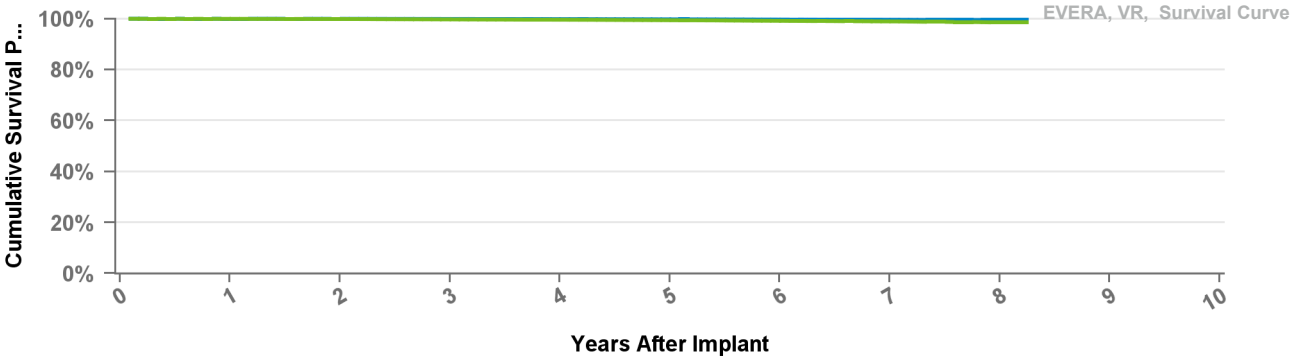
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants	333		
Estimated Active USA Implants	318	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVME3D1 Mirro

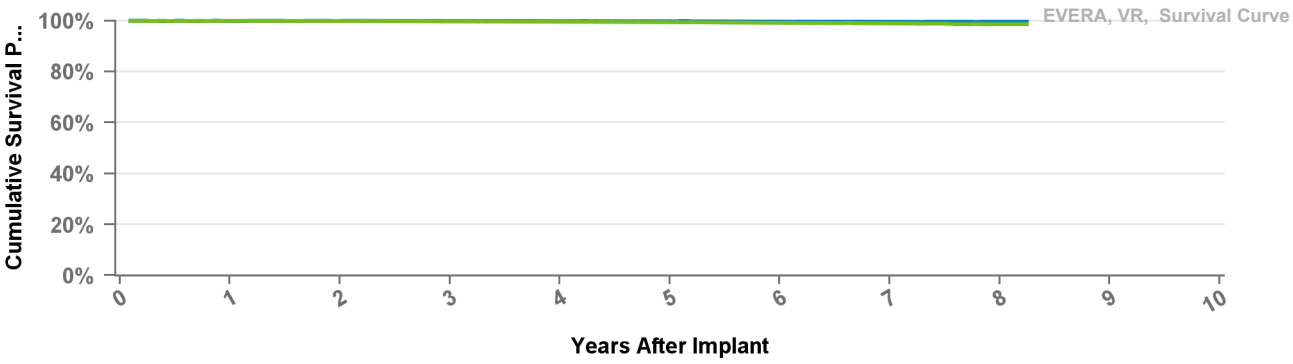
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

DVME3D4 Mirro

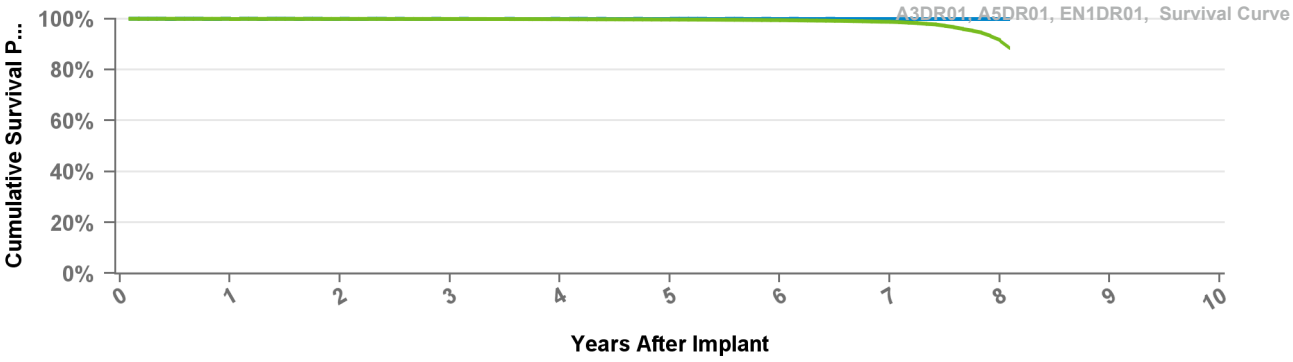
US Market Release	Mar-18	**Total Malfunctions**	
CE Approval Date	Nov-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.5%
Including NBD	100.0%	99.9%	99.7%	99.6%	99.4%	99.2%	99.0%	98.6%	98.6%
Effective Sample Size	53634	49794	46232	42875	38193	25984	12212	1951	190

A2DR01 Advisa DR MRI

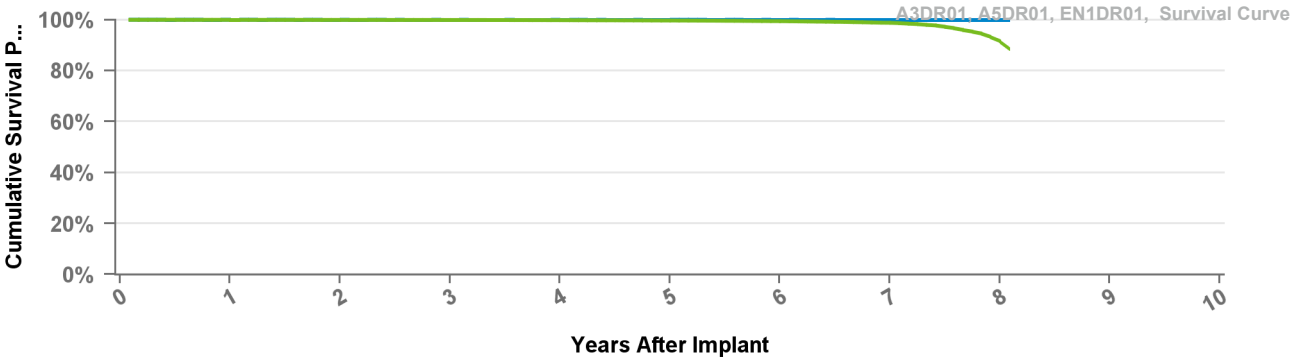
US Market Release	Jan-13	**Total Malfunctions**	**67**
CE Approval Date		**Therapy Function Not Compromised**	**62**
Registered USA Implants	347,982	Battery Malfunction	1
Estimated Active USA Implants	249,733	Electrical Component	34
Normal Battery Depletions	983	Electrical Interconnect	3
		Other Malfunction	2
		Poss Early Battery Depltn	19
		Software Malfunction	3
		Therapy Function Compromised	**5**
		Electrical Component	5



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	98.8%	91.5%	88.5%
Effective Sample Size	315311	295214	273644	235132	154445	85753	32542	2927	1312

A3DR01 Advisa DR MRI

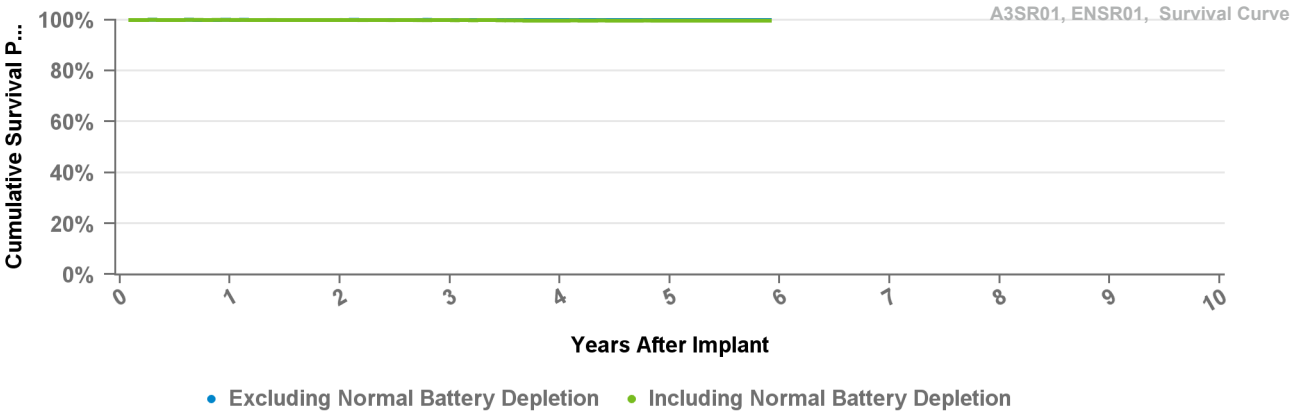
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	21		
Estimated Active USA Implants	10	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	98.8%	91.5%	88.5%
Effective Sample Size	315311	295214	273644	235132	154445	85753	32542	2927	1312

A3SR01 Advisa SR MRI

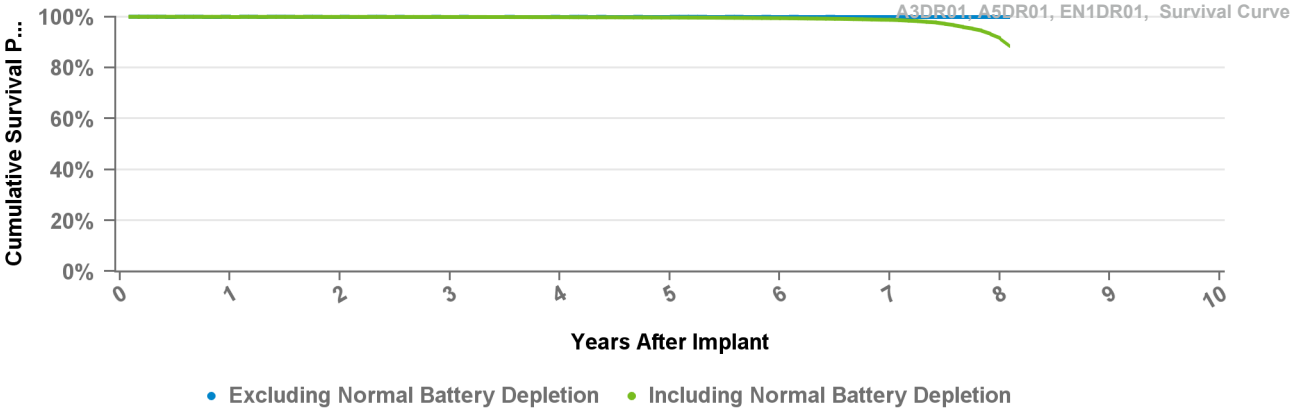
US Market Release	Mar-15	**Total Malfunctions**	**9**
CE Approval Date	Apr-14	**Therapy Function Not Compromised**	**8**
Registered USA Implants	28,669	Electrical Component	3
Estimated Active USA Implants	17,380	Electrical Interconnect	1
Normal Battery Depletions	23	Other Malfunction	2
		Poss Early Battery Depltn	2
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	4	5	at 71 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Effective Sample Size	23021	20141	17465	13236	5713	254

A5DR01 Advisa DR

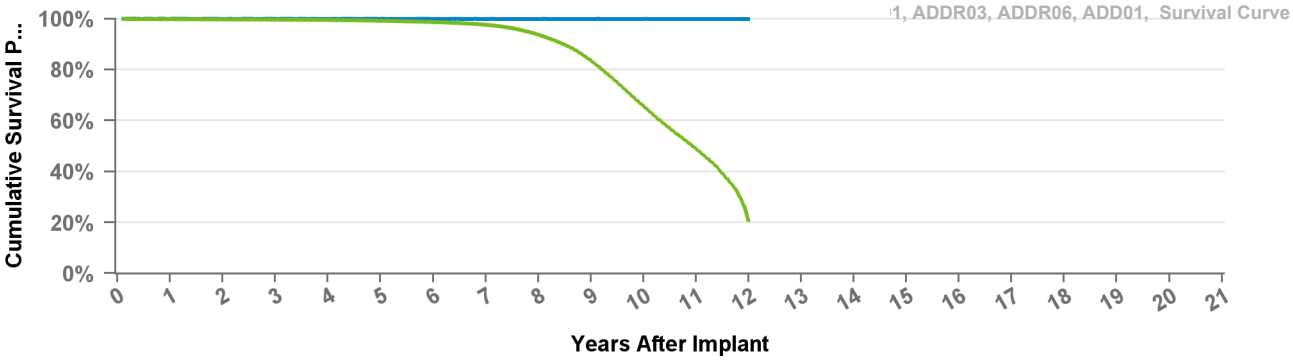
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-09	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	98.8%	91.5%	88.5%
Effective Sample Size	315311	295214	273644	235132	154445	85753	32542	2927	1312

ADD01 Adapta D

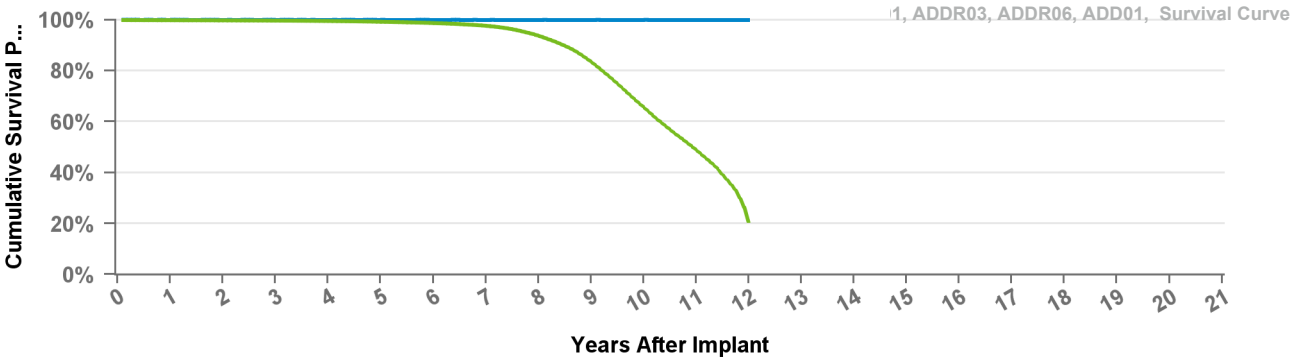
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

ADDR01 Adapta DR

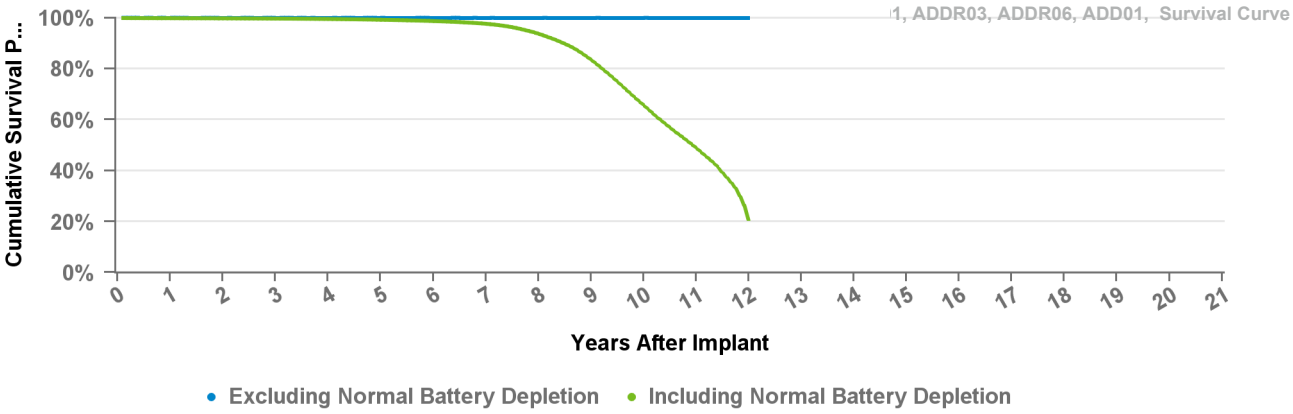
US Market Release	Jul-06	**Total Malfunctions**	**94**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**66**
Registered USA Implants	460,639	Electrical Component	57
Estimated Active USA Implants	157,263	Electrical Interconnect	1
Normal Battery Depletions	35,926	Other Malfunction	1
		Poss Early Battery Depltn	7
		Therapy Function Compromised	**28**
		Electrical Component	23
		Electrical Interconnect	3
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

ADDR03 Adapta DR

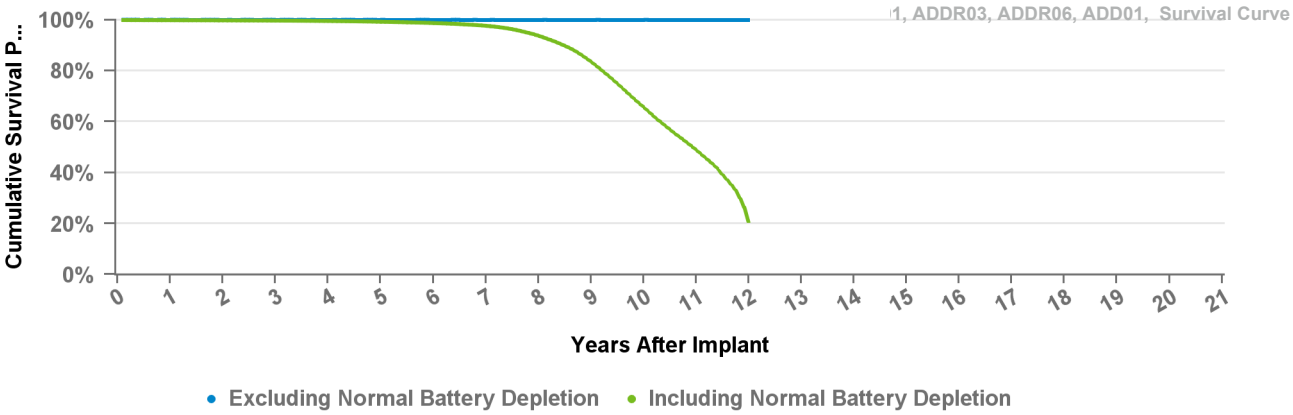
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	4,573	Electrical Component	1
Estimated Active USA Implants	1,563	**Therapy Function Compromised**	**1**
Normal Battery Depletions	472	Electrical Component	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

ADDR06 Adapta DR

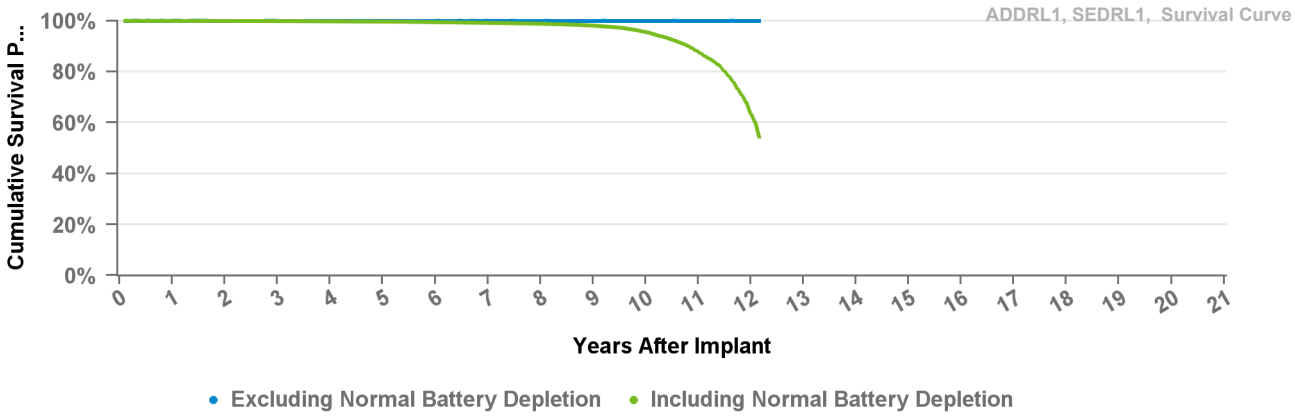
US Market Release	Jul-06	**Total Malfunctions**	**1**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**1**
Registered USA Implants	3,548	Electrical Component	1
Estimated Active USA Implants	954	**Therapy Function Compromised**	**0**
Normal Battery Depletions	374		



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

ADDRL1 Adapta L DR

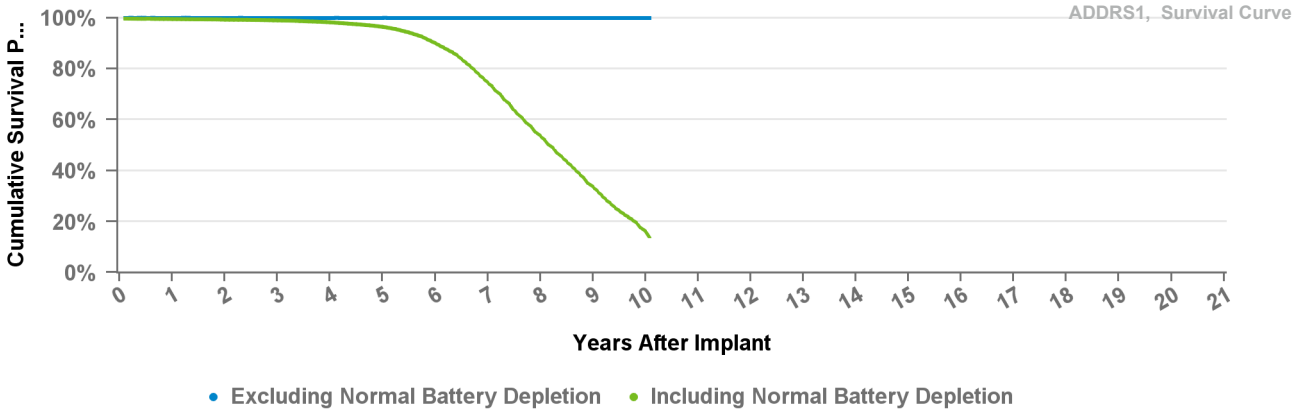
US Market Release	Jul-06	**Total Malfunctions**	**23**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**16**
Registered USA Implants	138,549	Electrical Component	13
Estimated Active USA Implants	74,915	Electrical Interconnect	1
Normal Battery Depletions	2,792	Poss Early Battery Depltn	2
		Therapy Function Compromised	**7**
		Electrical Component	4
		Electrical Interconnect	1
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 146 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%	99.9%	99.9%	99.8%	99.7%	99.5%	99.2%	98.8%	98.1%	95.6%	87.8%	63.7%	54.3%
Effective Sample Size	120582	113294	106248	97871	86738	74114	61053	46952	33592	21236	10639	1637	576

ADDRS1 Adapta S DR

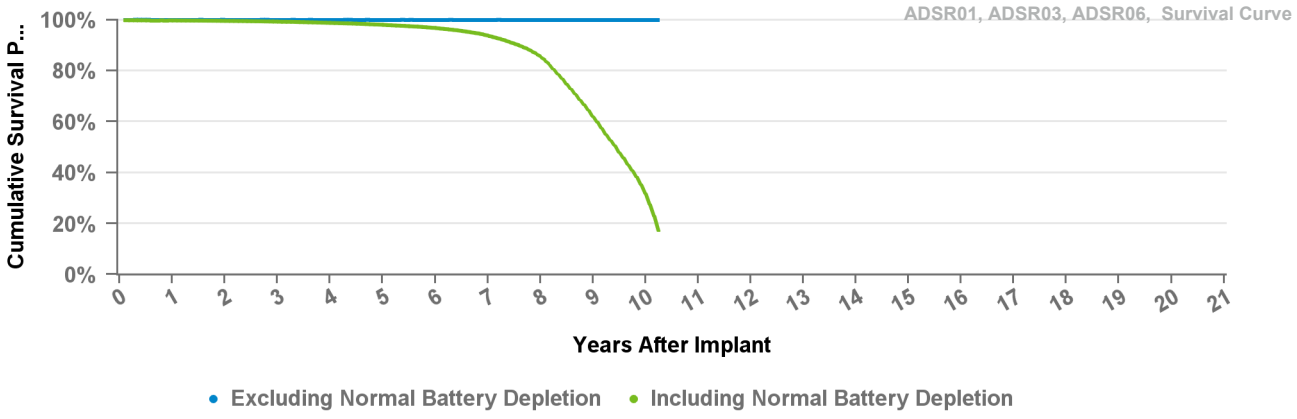
US Market Release	Jul-06	**Total Malfunctions**	**14**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**8**
Registered USA Implants	49,302	Electrical Component	5
Estimated Active USA Implants	12,141	Poss Early Battery Depltn	3
Normal Battery Depletions	5,679	**Therapy Function Compromised**	**6**
		Electrical Component	4
		Other Malfunction	2



Years	1	2	3	4	5	6	7	8	9	10	at 121 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.3%	99.0%	98.2%	96.4%	90.0%	74.4%	53.5%	33.5%	16.0%	13.9%
Effective Sample Size	40287	36018	32029	28159	24142	19165	12818	6601	2535	302	187

ADSR01 Adapta SR

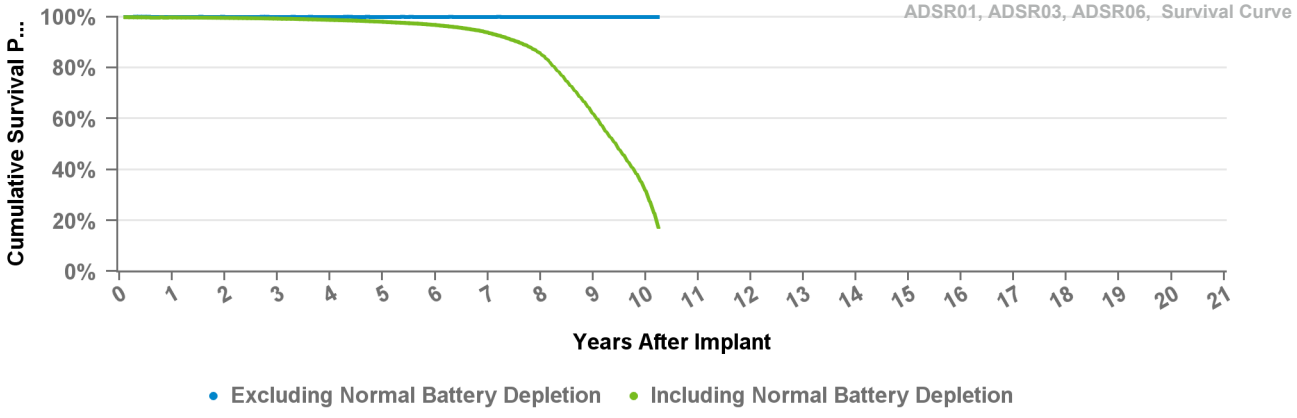
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**11**
Registered USA Implants	93,421	Electrical Component	6
Estimated Active USA Implants	23,843	Electrical Interconnect	1
Normal Battery Depletions	4,929	Poss Early Battery Depltn	4
		Therapy Function Compromised	**6**
		Electrical Component	5
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.5%	99.3%	98.8%	98.0%	96.8%	93.7%	85.5%	62.1%	31.9%	17.3%
Effective Sample Size	73380	63725	55433	47780	40414	33510	25454	16668	7724	1434	349

ADSR03 Adapta SR

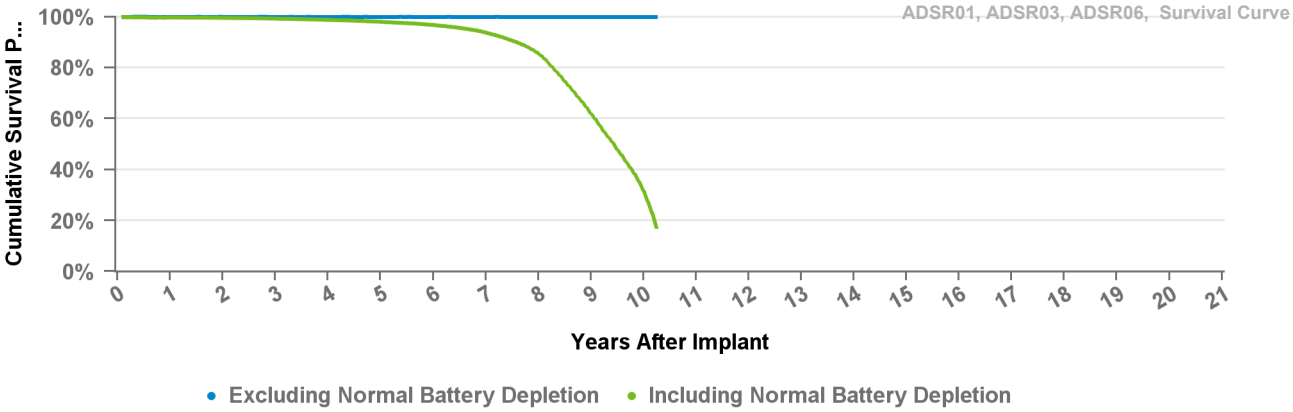
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	2,125		
Estimated Active USA Implants	509	**Therapy Function Compromised**	
Normal Battery Depletions	166		



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.5%	99.3%	98.8%	98.0%	96.8%	93.7%	85.5%	62.1%	31.9%	17.3%
Effective Sample Size	73380	63725	55433	47780	40414	33510	25454	16668	7724	1434	349

ADSR06 Adapta SR

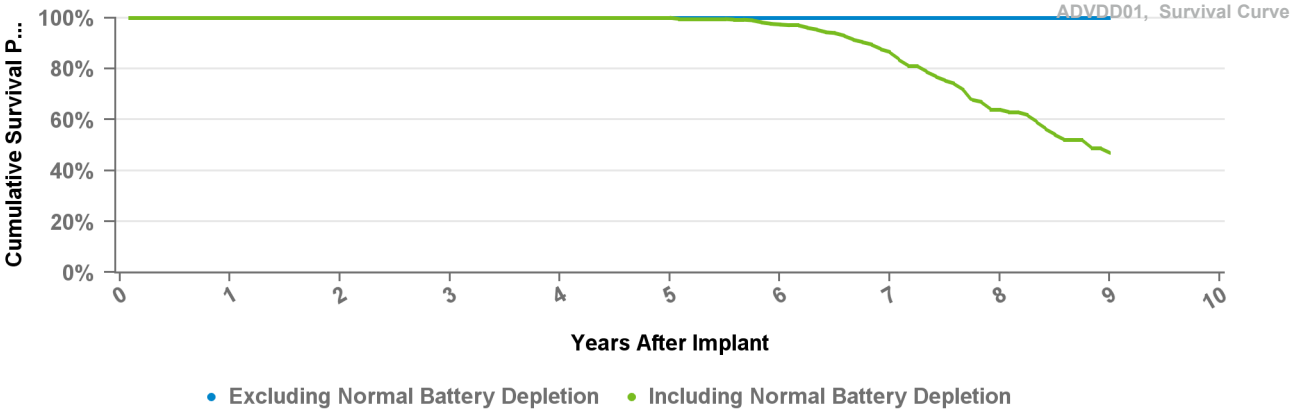
US Market Release	Jul-06	**Total Malfunctions**	**2**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**2**
Registered USA Implants	2,894	Electrical Component	2
Estimated Active USA Implants	687	**Therapy Function Compromised**	**0**
Normal Battery Depletions	236		



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.5%	99.3%	98.8%	98.0%	96.8%	93.7%	85.5%	62.1%	31.9%	17.3%
Effective Sample Size	73380	63725	55433	47780	40414	33510	25454	16668	7724	1434	349

ADVDD01 Adapta VDD

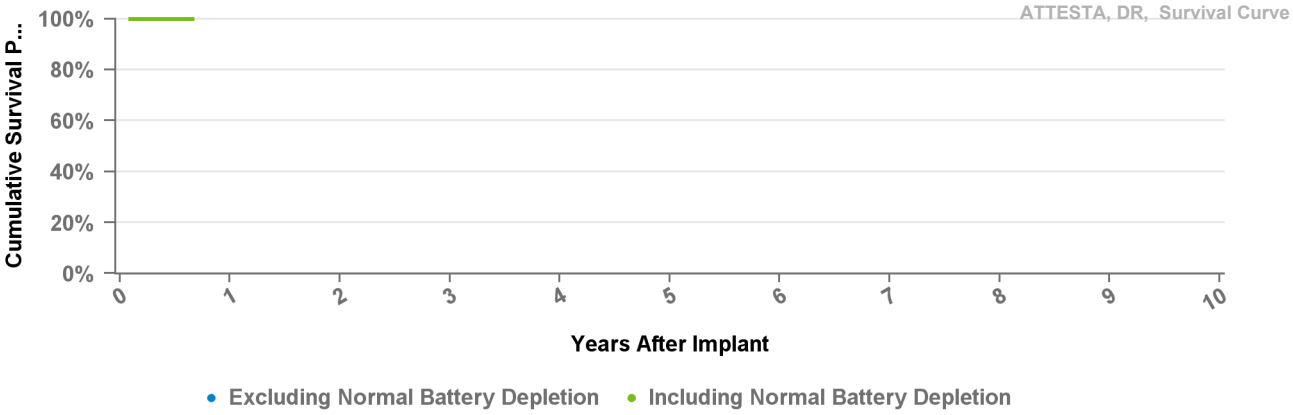
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	1,437		
Estimated Active USA Implants	507	**Therapy Function Compromised**	
Normal Battery Depletions	98		



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.3%	86.5%	63.9%	46.8%
Effective Sample Size	1221	1131	1031	921	819	708	520	266	102

ATDR01 Attesta DR MRI

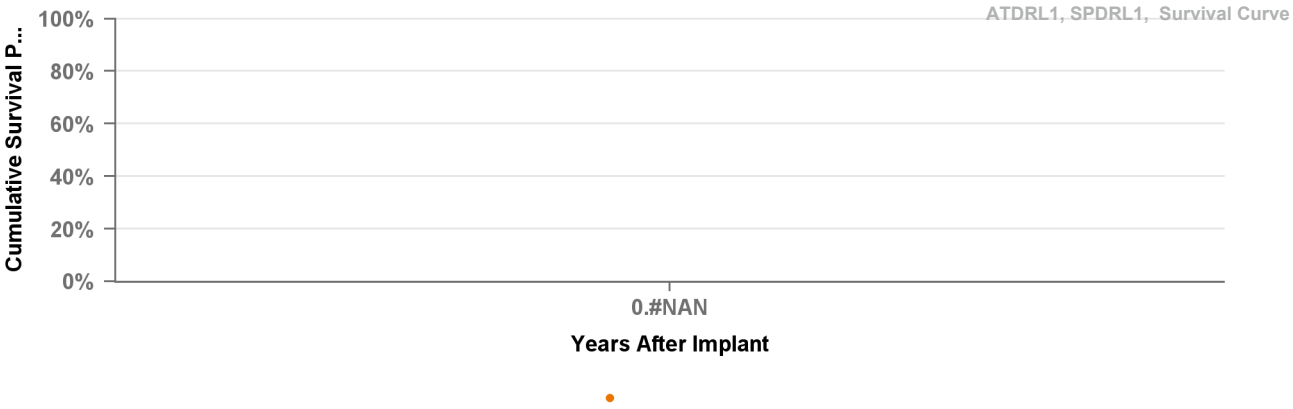
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	448		
Estimated Active USA Implants	443	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 8 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	108

ATDRL1 Attesta L DR MRI

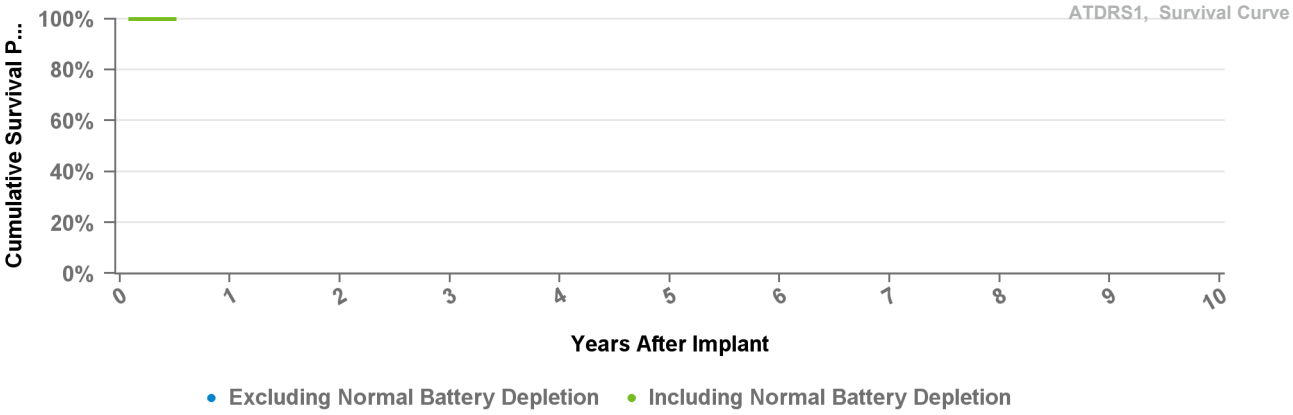
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	57		
Estimated Active USA Implants	55	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

ATDRS1 Attesta S DR MRI

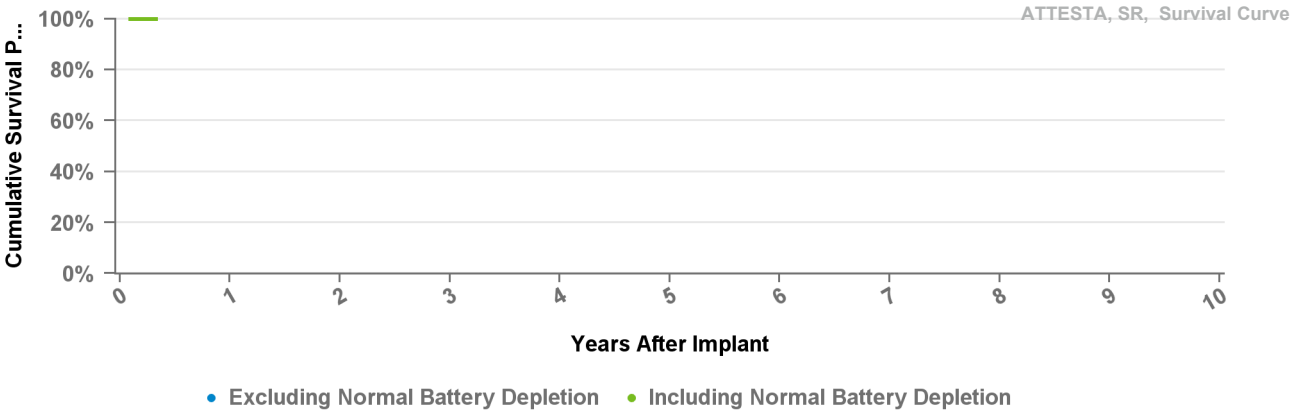
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	284		
Estimated Active USA Implants	276	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 6 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	113

ATSR01 Attesta SR MRI

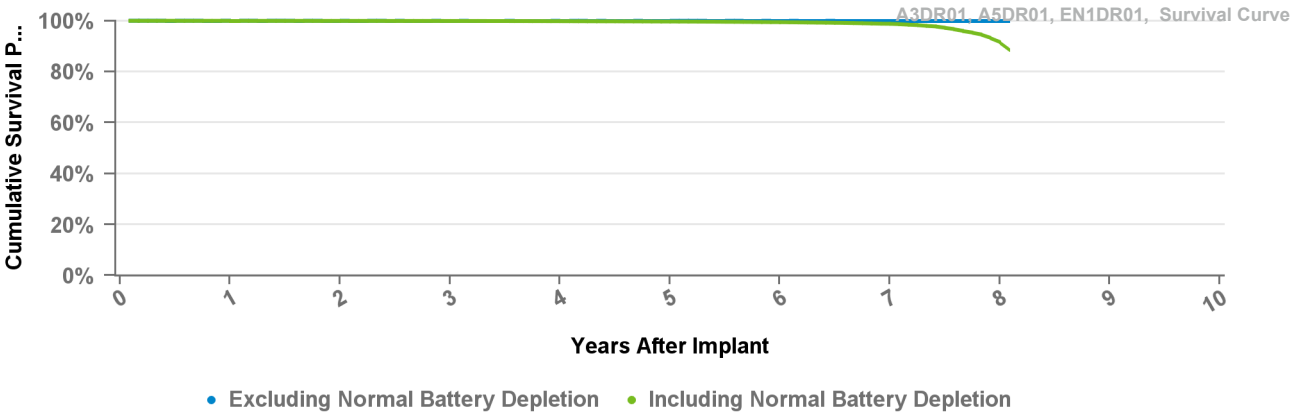
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	198		
Estimated Active USA Implants	175	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	at 4 mo
Excluding NBD	100.0%
Including NBD	100.0%
Effective Sample Size	104

EN1DR01 Ensura MRI

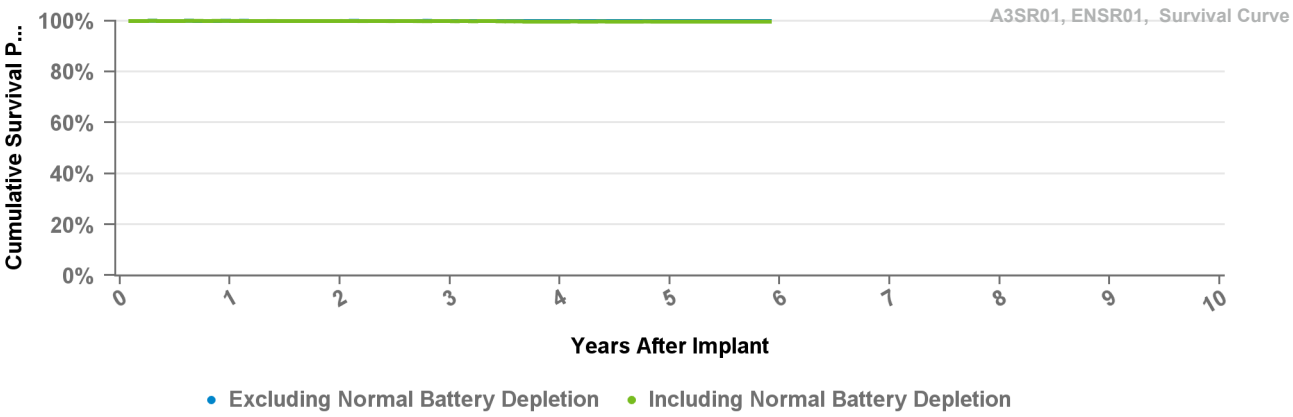
US Market Release		**Total Malfunctions**	
CE Approval Date	Jun-10	**Therapy Function Not Compromised**	
Registered USA Implants	18		
Estimated Active USA Implants	12	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	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%	98.8%	91.5%	88.5%
Effective Sample Size	315311	295214	273644	235132	154445	85753	32542	2927	1312

EN1SR01 Ensura SR MRI

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

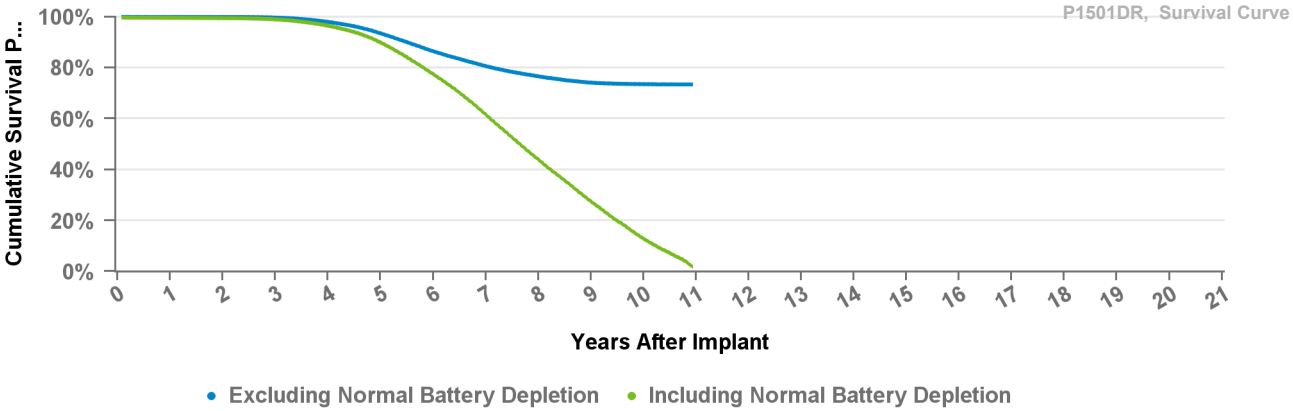


Years	1	2	3	4	5	at 71 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.7%	99.7%	99.7%
Effective Sample Size	23021	20141	17465	13236	5713	254

P1501DR EnRhythm DR

US Market Release	May-05
CE Approval Date	Aug-04
Registered USA Implants	110,024
Estimated Active USA Implants	7,981
Normal Battery Depletions	17,459

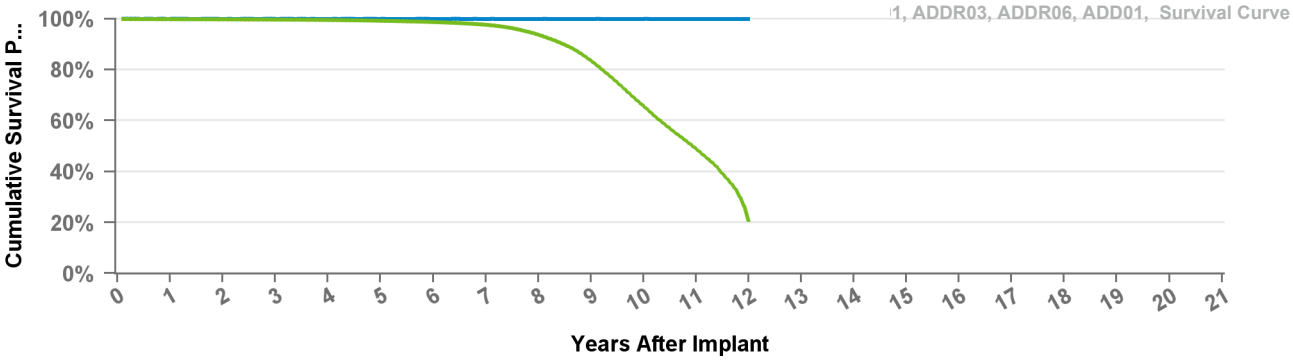
Total Malfunctions	**15,157**
Therapy Function Not Compromised	**15,102**
Battery Malfunction	14,971
Electrical Component	59
Electrical Interconnect	2
Other Malfunction	1
Poss Early Battery Depltn	69
Therapy Function Compromised	**55**
Battery Malfunction	6
Electrical Component	38
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2



Years	1	2	3	4	5	6	7	8	9	10	at 131 mo
Excluding NBD	99.9%	99.9%	99.7%	98.0%	93.5%	86.4%	80.6%	76.6%	74.1%	73.5%	73.4%
Including NBD	99.6%	99.5%	98.9%	96.5%	89.8%	77.4%	61.5%	43.9%	27.4%	12.8%	1.9%
Effective Sample Size	94528	87956	81455	73767	63481	49609	35351	21957	11596	4376	350

RED01 Relia D

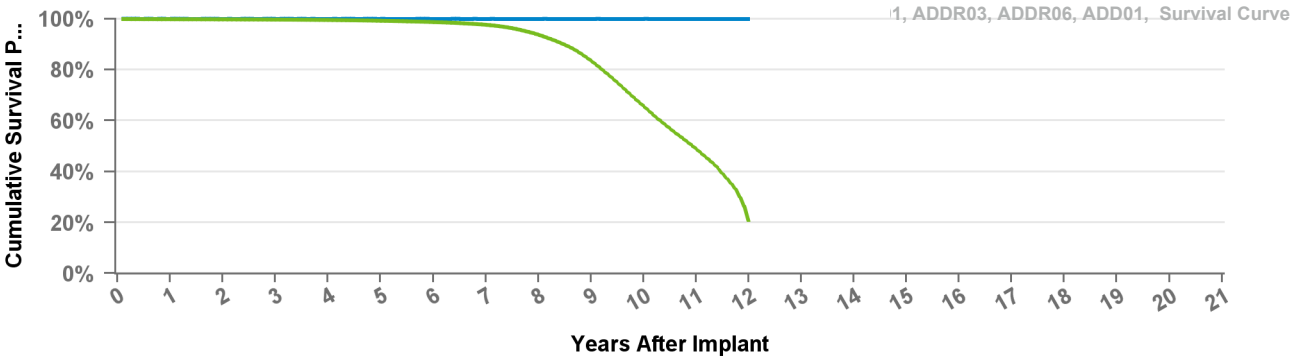
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

REDR01 Relia DR

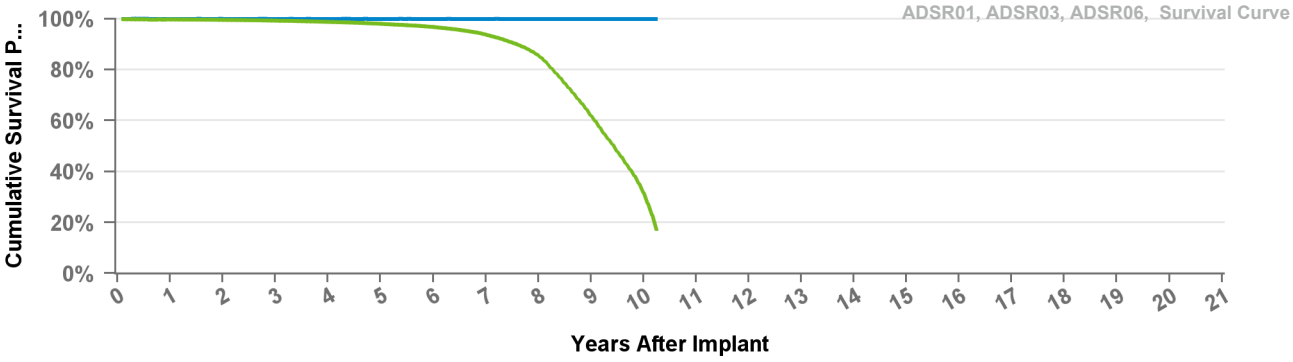
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	11		
Estimated Active USA Implants	5	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 144 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	99.8%	99.8%	99.7%	99.5%	99.2%	98.7%	97.6%	93.7%	83.5%	65.6%	48.9%	20.7%
Effective Sample Size	399965	371113	343729	314871	283499	250242	216147	173232	120282	66650	27697	1540

RES01 Relia S

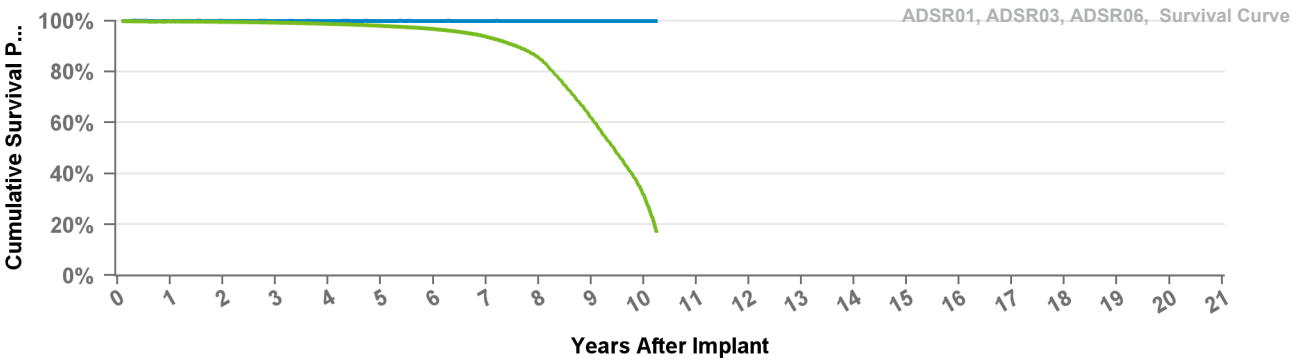
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	3		
Estimated Active USA Implants	2	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.5%	99.3%	98.8%	98.0%	96.8%	93.7%	85.5%	62.1%	31.9%	17.3%
Effective Sample Size	73380	63725	55433	47780	40414	33510	25454	16668	7724	1434	349

RESR01 Relia SR

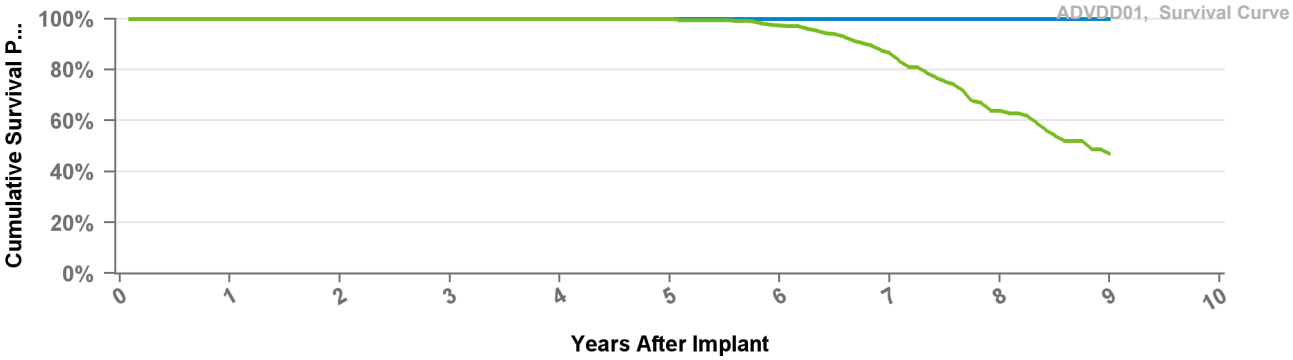
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.5%	99.3%	98.8%	98.0%	96.8%	93.7%	85.5%	62.1%	31.9%	17.3%
Effective Sample Size	73380	63725	55433	47780	40414	33510	25454	16668	7724	1434	349

REVDD01 Relia VDD

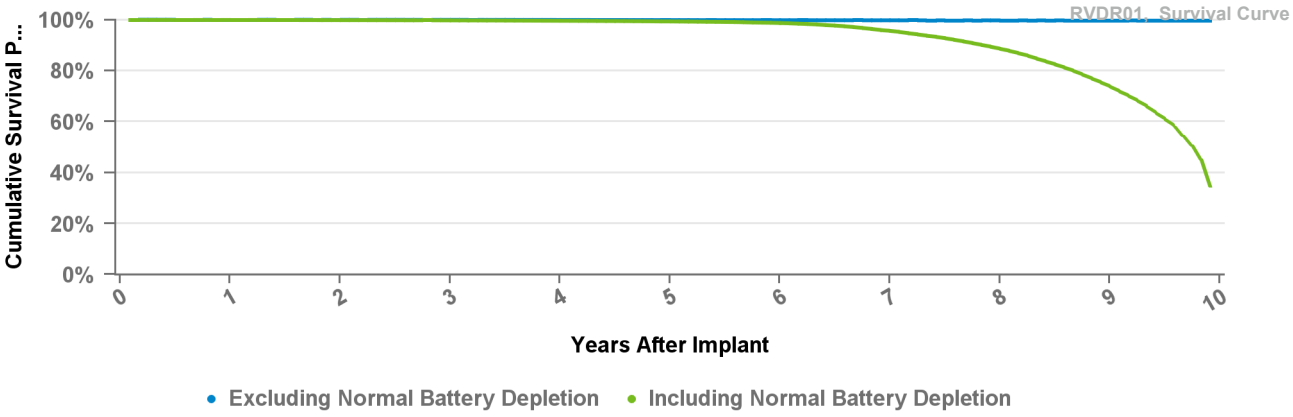
US Market Release		**Total Malfunctions**	
CE Approval Date	May-08	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	97.3%	86.5%	63.9%	46.8%
Effective Sample Size	1221	1131	1031	921	819	708	520	266	102

RVDR01 Revo MRI SureScan

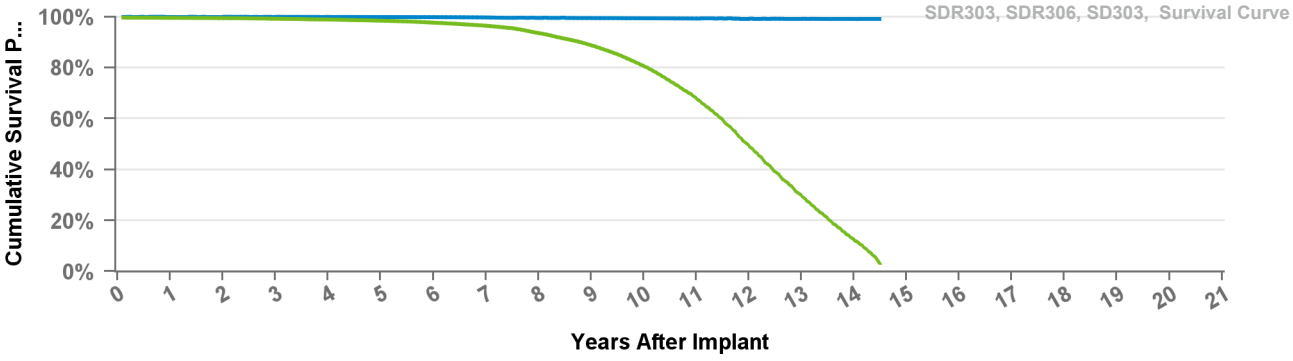
US Market Release	Feb-11	**Total Malfunctions**	**110**
CE Approval Date		**Therapy Function Not Compromised**	**107**
Registered USA Implants	69,186	Battery Malfunction	1
Estimated Active USA Implants	27,786	Electrical Component	40
Normal Battery Depletions	6,126	Electrical Interconnect	1
		Other Malfunction	1
		Poss Early Battery Depltn	60
		Software Malfunction	4
		Therapy Function Compromised	**3**
		Electrical Component	3



Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%
Including NBD	99.9%	99.9%	99.8%	99.6%	99.3%	98.7%	95.7%	88.6%	73.8%	34.6%
Effective Sample Size	59525	56205	53121	49707	45825	41683	36665	29613	15578	755

SD303 Sigma 300 D

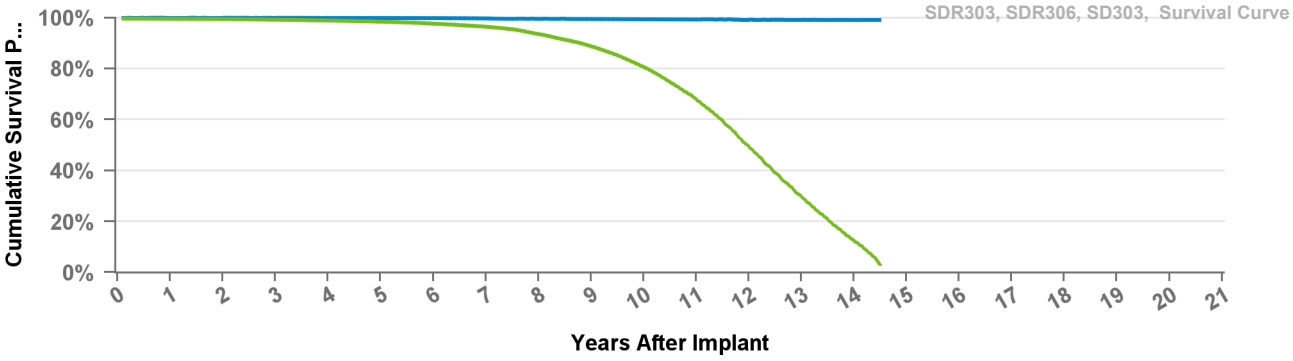
US Market Release	Aug-99	**Total Malfunctions**	**2**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**0**
Registered USA Implants	123		
Estimated Active USA Implants	17	**Therapy Function Compromised**	**2**
Normal Battery Depletions	8	Electrical Interconnect	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.2%	99.1%	99.1%
Including NBD	99.6%	99.5%	99.2%	98.9%	98.5%	97.7%	96.5%	93.6%	88.8%	80.7%	67.9%	49.4%	29.8%	12.4%	3.3%
Effective Sample Size	86582	76435	67282	58910	51340	44585	38180	32396	27123	21688	16073	9276	4031	1136	169

SDR303 Sigma 300 DR

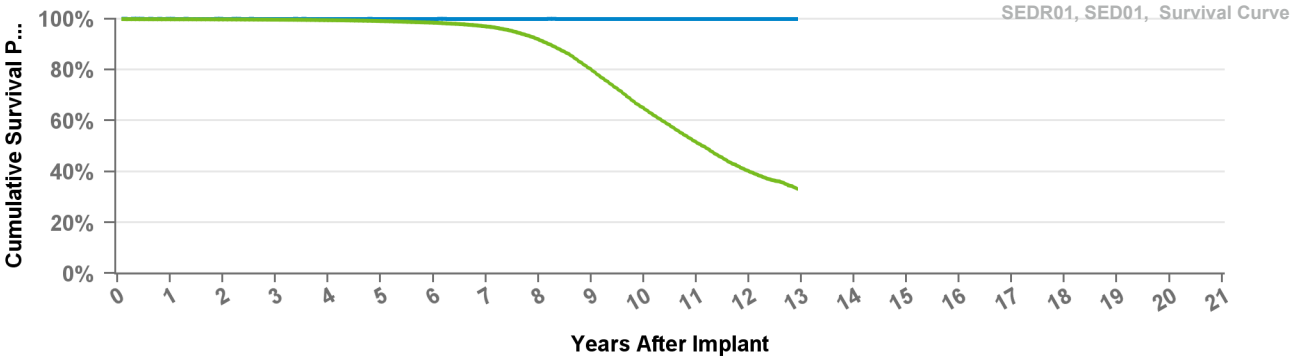
US Market Release	Aug-99	**Total Malfunctions**	**288**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**62**
Registered USA Implants	104,647	Electrical Component	9
Estimated Active USA Implants	5,121	Electrical Interconnect	51
Normal Battery Depletions	11,206	Other Malfunction	1
		Poss Early Battery Depltn	1
		Therapy Function Compromised	**226**
		Electrical Component	7
		Electrical Interconnect	218
		Other Malfunction	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.2%	99.1%	99.1%
Including NBD	99.6%	99.5%	99.2%	98.9%	98.5%	97.7%	96.5%	93.6%	88.8%	80.7%	67.9%	49.4%	29.8%	12.4%	3.3%
Effective Sample Size	86582	76435	67282	58910	51340	44585	38180	32396	27123	21688	16073	9276	4031	1136	169

SED01 Sensia D

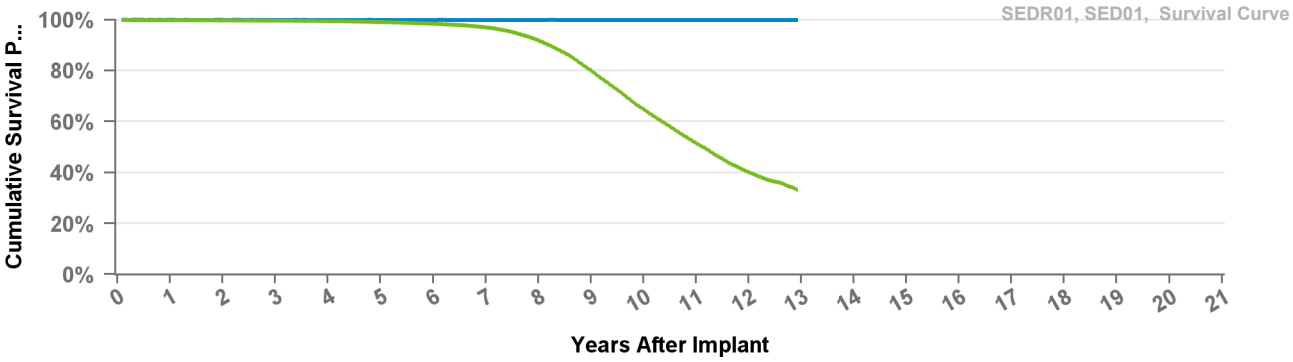
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	9		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions	1		



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 155 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.6%	99.4%	99.1%	98.4%	97.0%	91.8%	80.1%	64.9%	51.5%	40.1%	33.2%
Effective Sample Size	121522	109942	99322	89708	80886	71319	60416	47467	32559	19299	9743	3529	173

SEDR01 Sensia DR

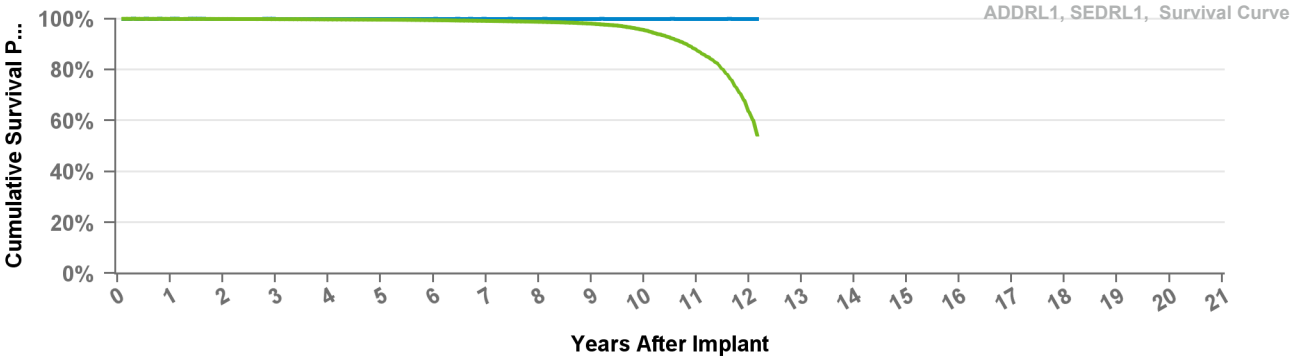
US Market Release	Jul-06	**Total Malfunctions**	**32**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**17**
Registered USA Implants	149,371	Electrical Component	15
Estimated Active USA Implants	37,260	Electrical Interconnect	1
Normal Battery Depletions	12,355	Other Malfunction	1
		Therapy Function Compromised	**15**
		Electrical Component	6
		Electrical Interconnect	3
		Other Malfunction	5
		Poss Early Battery Depltn	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 155 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.6%	99.4%	99.1%	98.4%	97.0%	91.8%	80.1%	64.9%	51.5%	40.1%	33.2%
Effective Sample Size	121522	109942	99322	89708	80886	71319	60416	47467	32559	19299	9743	3529	173

SEDRL1 Sensia L DR

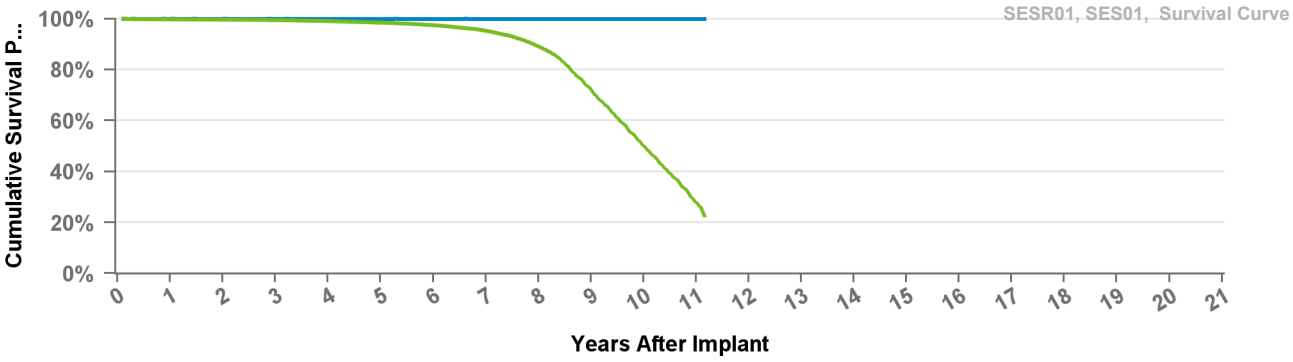
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	6		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 146 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%	99.9%	99.9%	99.8%	99.7%	99.5%	99.2%	98.8%	98.1%	95.6%	87.8%	63.7%	54.3%
Effective Sample Size	120582	113294	106248	97871	86738	74114	61053	46952	33592	21236	10639	1637	576

SES01 Sensia S

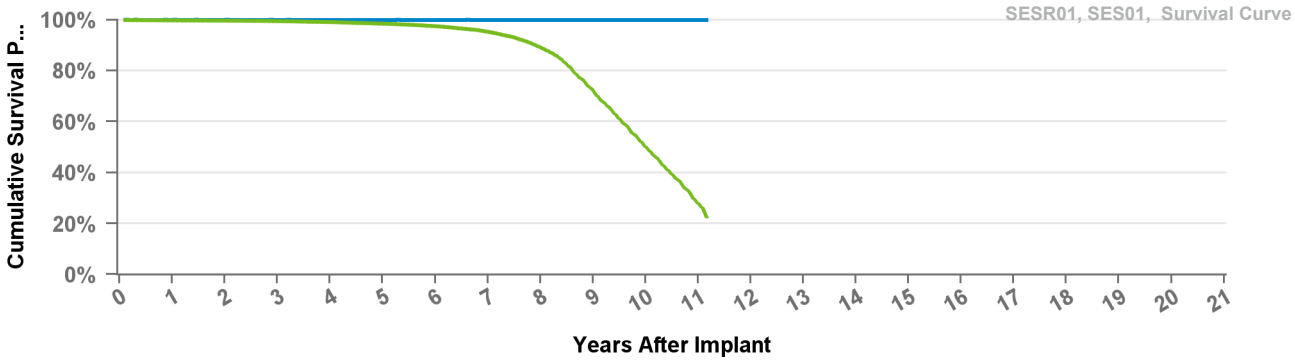
US Market Release	Jul-06	**Total Malfunctions**	
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	
Registered USA Implants	10		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.5%	95.3%	89.1%	72.2%	50.3%	28.0%	22.6%
Effective Sample Size	86067	74595	64560	55415	47105	39063	30684	21701	12408	5066	729	308

SESR01 Sensia SR

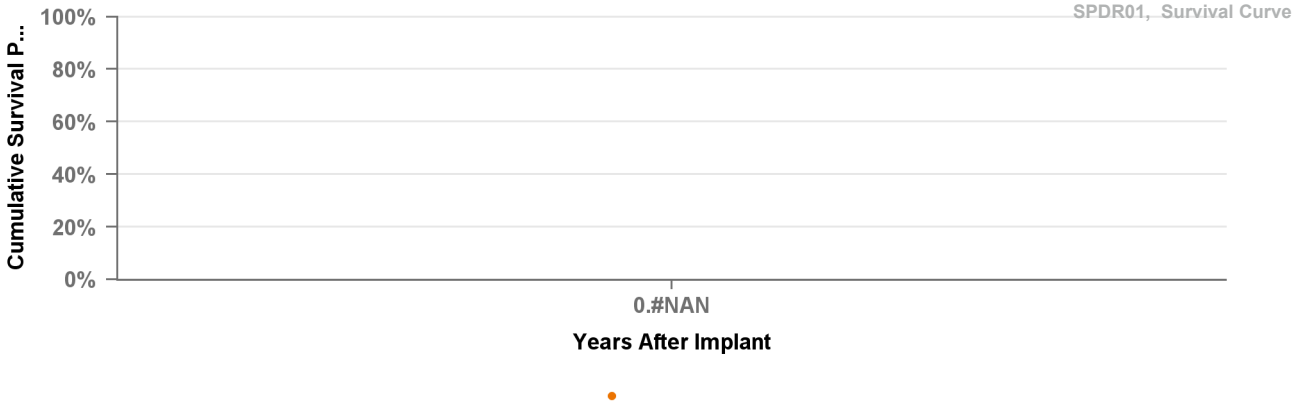
US Market Release	Jul-06	**Total Malfunctions**	**17**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**13**
Registered USA Implants	117,298	Electrical Component	7
Estimated Active USA Implants	26,140	Other Malfunction	2
Normal Battery Depletions	6,764	Poss Early Battery Depltn	4
		Therapy Function Compromised	**4**
		Electrical Component	3
		Electrical Interconnect	1



Years	1	2	3	4	5	6	7	8	9	10	11	at 134 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.5%	99.1%	98.5%	97.5%	95.3%	89.1%	72.2%	50.3%	28.0%	22.6%
Effective Sample Size	86067	74595	64560	55415	47105	39063	30684	21701	12408	5066	729	308

SPDR01 Sphera DR MRI

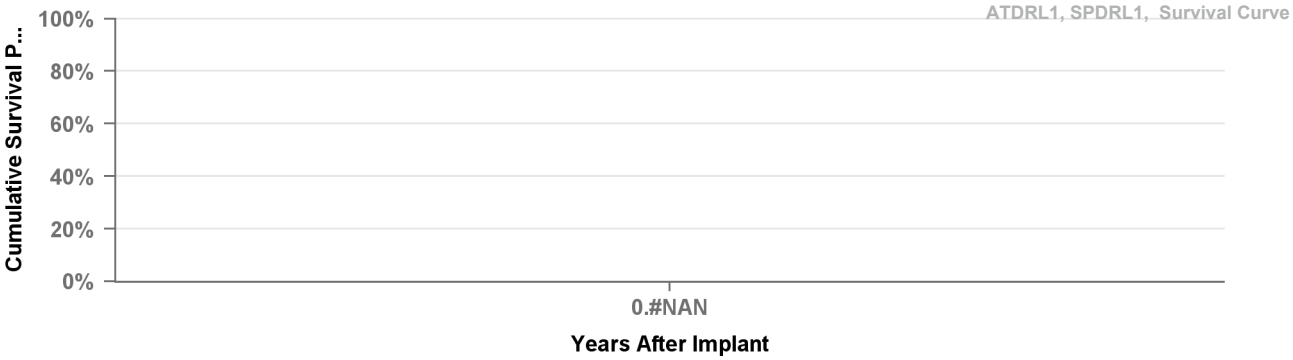
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants	1		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPDRL1 Sphera L DR MRI

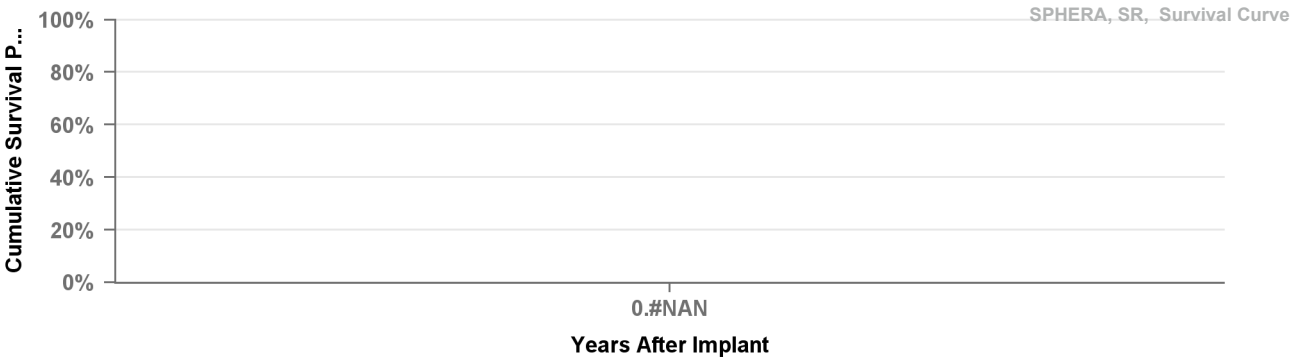
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SPSR01 Sphera SR MRI

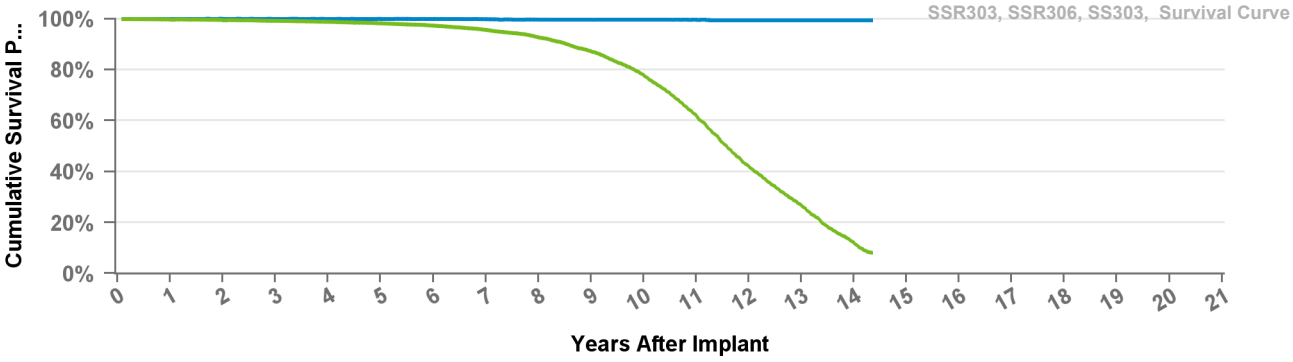
US Market Release	Aug-17	**Total Malfunctions**	
CE Approval Date	Jun-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

SS303 Sigma 300 S

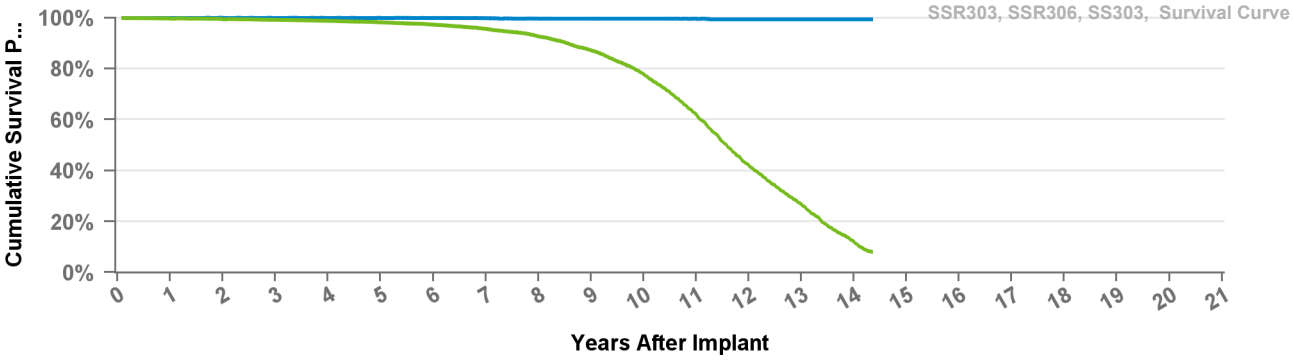
US Market Release	Sep-99	**Total Malfunctions**	
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	
Registered USA Implants	248		
Estimated Active USA Implants	36	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 172 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%	99.6%	99.5%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.7%	99.5%	99.2%	98.8%	98.2%	97.3%	95.6%	92.6%	87.2%	77.8%	62.0%	42.0%	26.7%	12.0%	8.1%
Effective Sample Size	40287	33065	27157	22368	18400	15047	12239	9922	7904	5967	3914	2028	938	277	103

SSR303 Sigma 300 SR

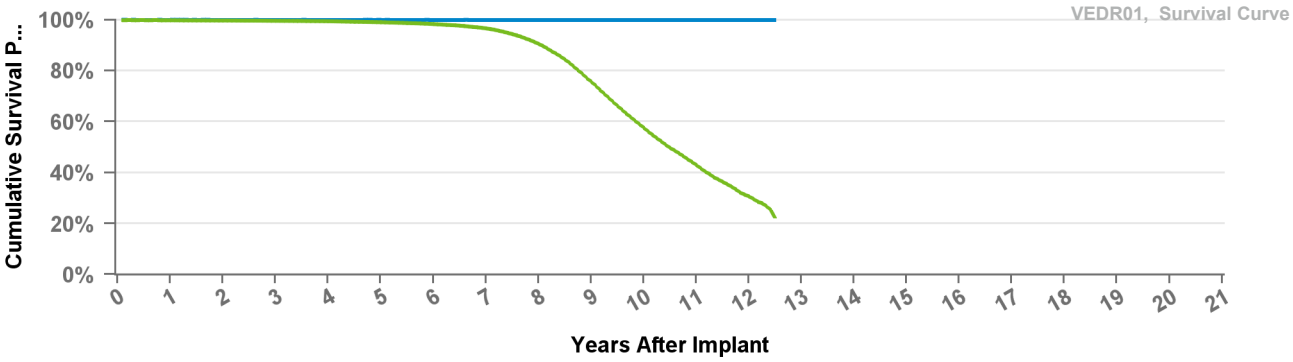
US Market Release	Aug-99	**Total Malfunctions**	**58**
CE Approval Date	Dec-98	**Therapy Function Not Compromised**	**11**
Registered USA Implants	51,296	Electrical Interconnect	10
Estimated Active USA Implants	1,894	Other Malfunction	1
Normal Battery Depletions	3,071	**Therapy Function Compromised**	**47**
		Electrical Component	3
		Electrical Interconnect	44



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 172 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%	99.6%	99.5%	99.5%	99.5%	99.5%	99.5%
Including NBD	99.7%	99.5%	99.2%	98.8%	98.2%	97.3%	95.6%	92.6%	87.2%	77.8%	62.0%	42.0%	26.7%	12.0%	8.1%
Effective Sample Size	40287	33065	27157	22368	18400	15047	12239	9922	7904	5967	3914	2028	938	277	103

VEDR01 Versa DR

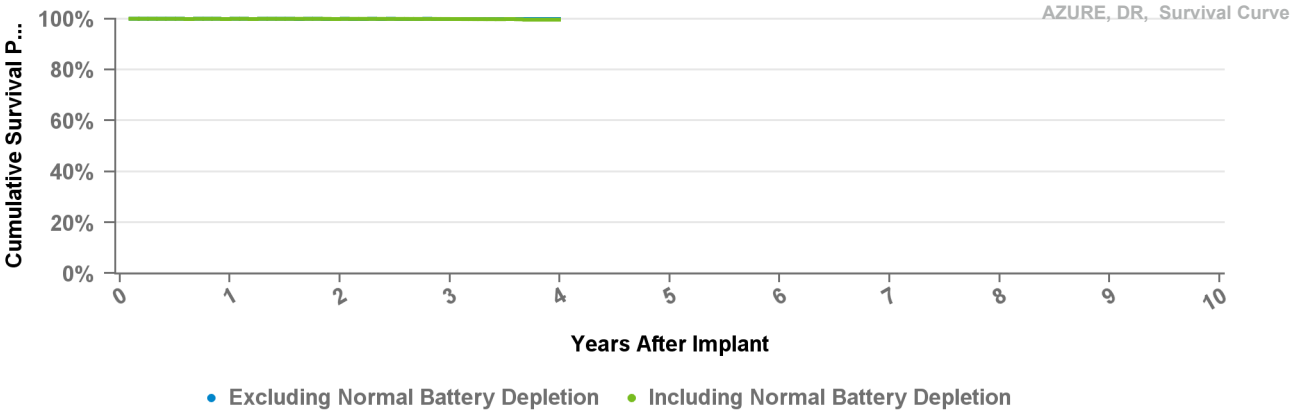
US Market Release	Jul-06	**Total Malfunctions**	**25**
CE Approval Date	Sep-05	**Therapy Function Not Compromised**	**11**
Registered USA Implants	118,831	Electrical Component	7
Estimated Active USA Implants	30,610	Electrical Interconnect	2
Normal Battery Depletions	11,355	Poss Early Battery Depltn	2
		Therapy Function Compromised	**14**
		Electrical Component	10
		Other Malfunction	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.6%	99.4%	99.0%	98.3%	96.6%	90.5%	75.7%	57.6%	42.9%	30.7%	22.6%
Effective Sample Size	99229	90636	82500	74378	65636	57554	49208	39010	25862	14169	6477	1694	226

W1DR01 Azure XT DR

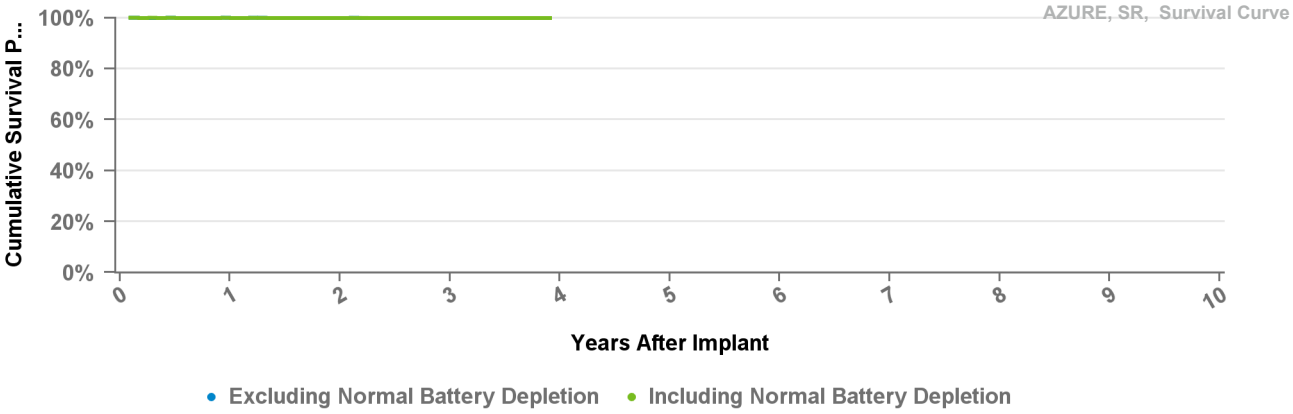
US Market Release	Aug-17	**Total Malfunctions**	**70**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**60**
Registered USA Implants	382,581	Battery Malfunction	3
Estimated Active USA Implants	344,948	Electrical Component	28
Normal Battery Depletions	41	Other Malfunction	23
		Poss Early Battery Depltn	1
		Software Malfunction	5
		Therapy Function Compromised	**10**
		Electrical Component	10



Years	1	2	3	at 48 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.7%
Effective Sample Size	264137	155258	59063	247

W1SR01 Azure XT SR

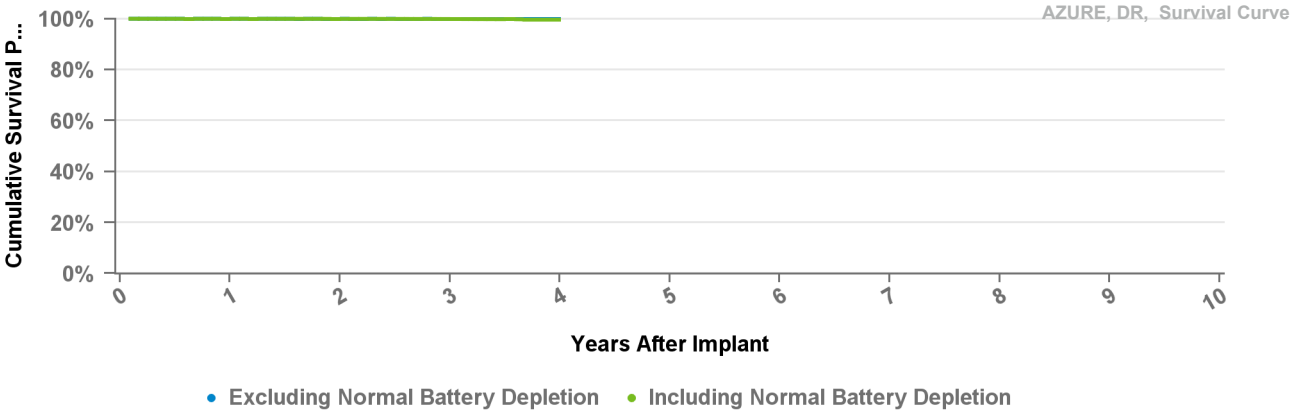
US Market Release	Aug-17	**Total Malfunctions**	**9**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**8**
Registered USA Implants	32,685	Battery Malfunction	1
Estimated Active USA Implants	26,897	Electrical Component	3
Normal Battery Depletions	3	Other Malfunction	4
		Therapy Function Compromised	**1**
		Electrical Component	1



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	24229	13310	4698	108

W2DR01 Azure XT DR

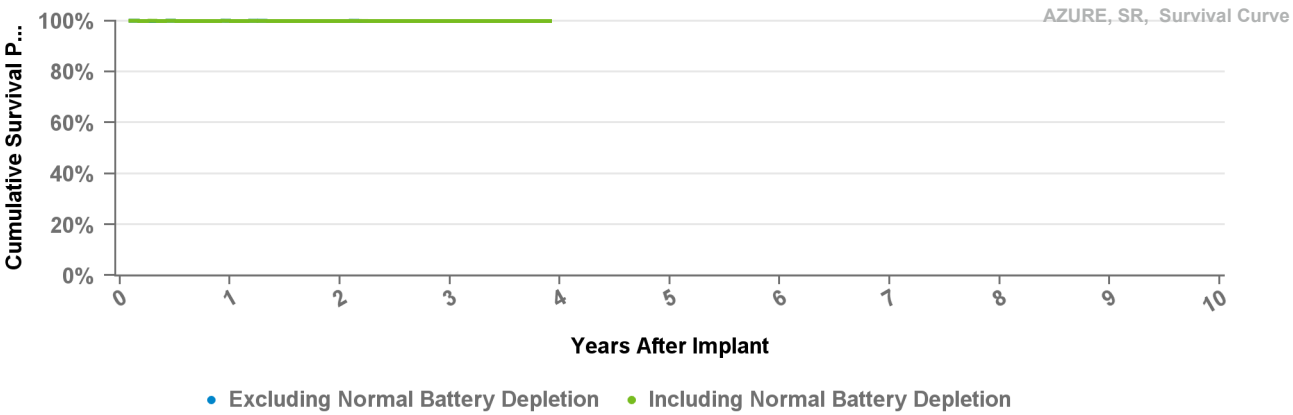
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	2		
Estimated Active USA Implants	1	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 48 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.7%
Effective Sample Size	264137	155258	59063	247

W2SR01 Azure XT SR

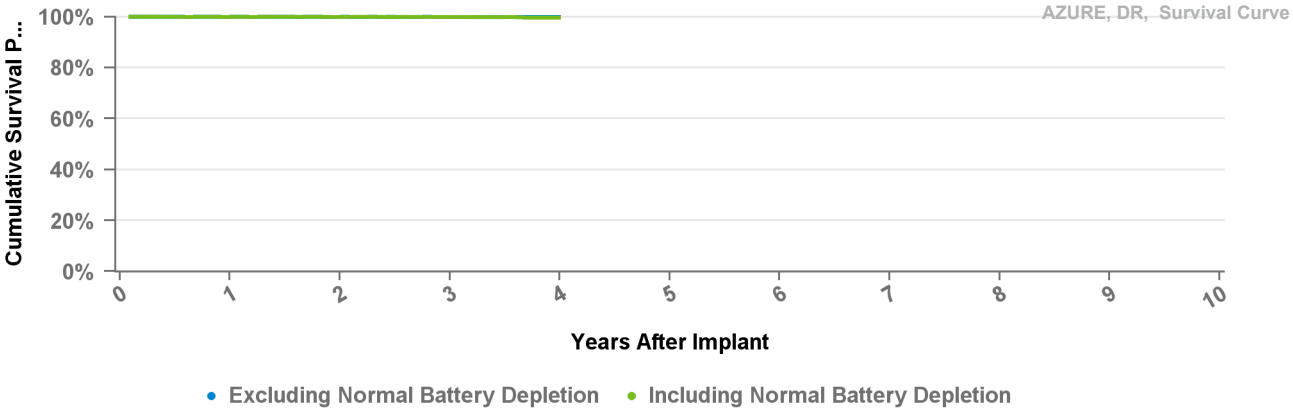
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	24229	13310	4698	108

W3DR01 Azure S DR

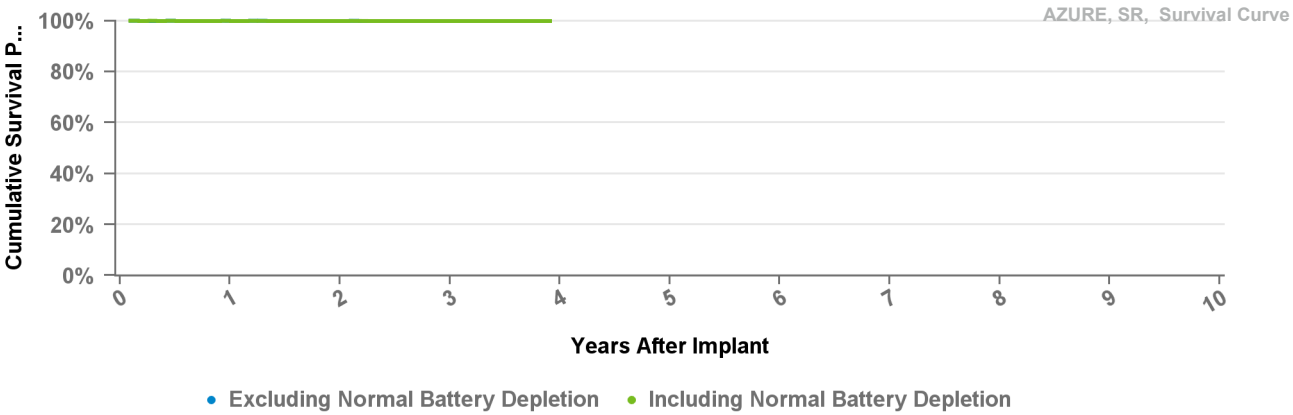
US Market Release	Aug-17	**Total Malfunctions**	**6**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**5**
Registered USA Implants	42,101	Electrical Component	4
Estimated Active USA Implants	37,623	Software Malfunction	1
Normal Battery Depletions	8	**Therapy Function Compromised**	**1**
		Electrical Component	1



Years	1	2	3	at 48 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.7%
Effective Sample Size	264137	155258	59063	247

W3SR01 Azure S SR

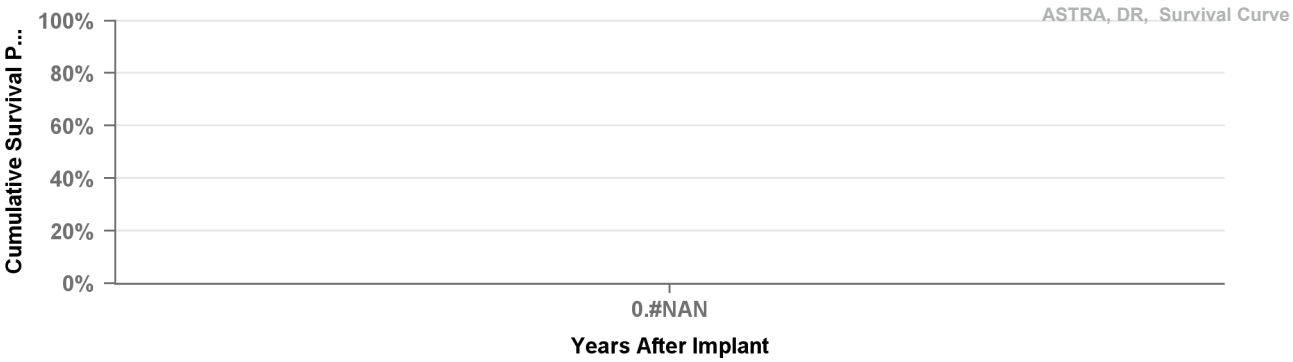
US Market Release	Aug-17	**Total Malfunctions**	**1**
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	**1**
Registered USA Implants	7,865	Electrical Component	1
Estimated Active USA Implants	6,511	**Therapy Function Compromised**	**0**
Normal Battery Depletions			



Years	1	2	3	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%
Effective Sample Size	24229	13310	4698	108

X2DR01 Astra XT DR MRI SureScan

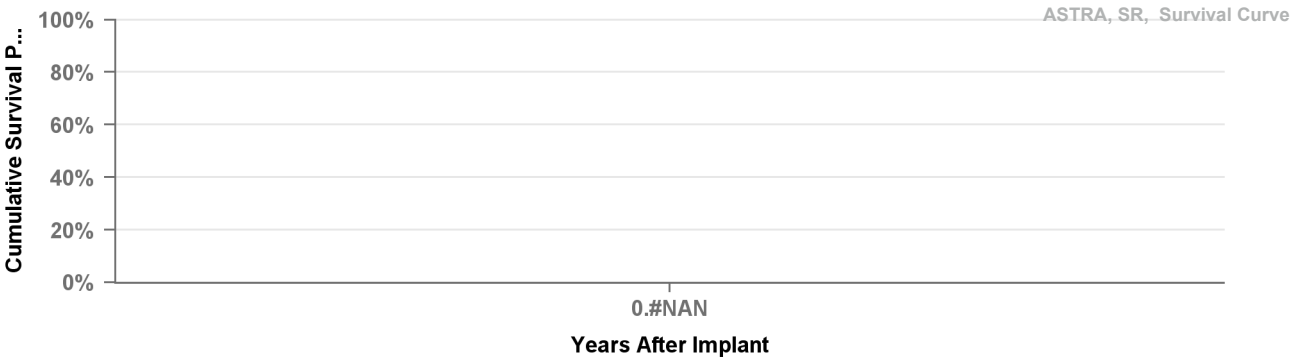
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants	4		
Estimated Active USA Implants	3	**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X2SR01 Astra XT SR MRI SureScan

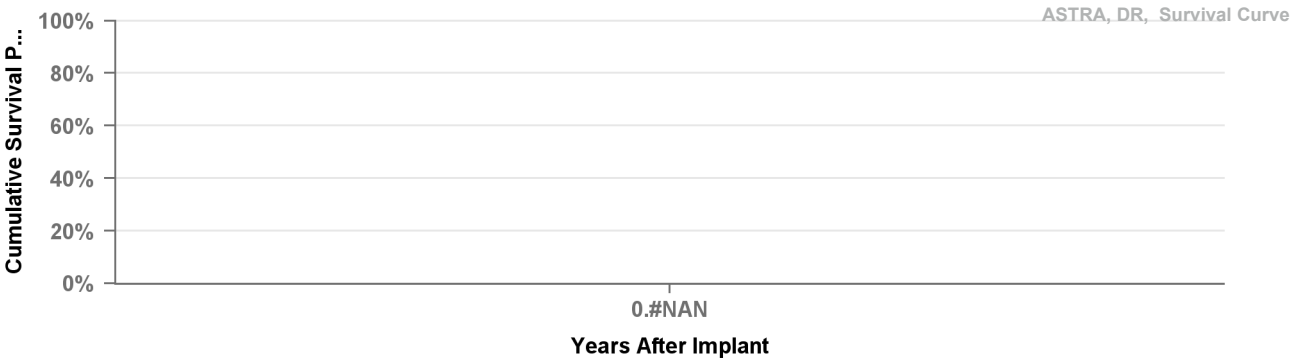
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3DR01 Astra S DR

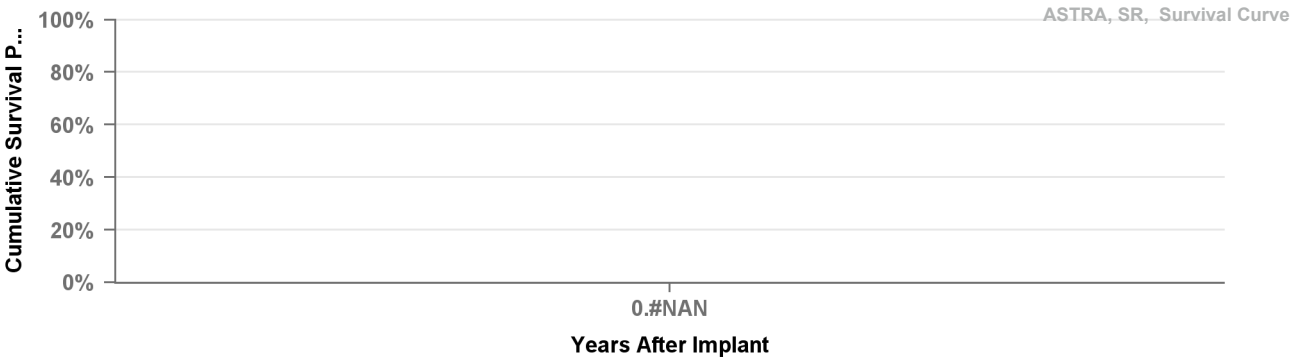
US Market Release		**Total Malfunctions**	
CE Approval Date	Mar-17	**Therapy Function Not Compromised**	
Registered USA Implants			
Estimated Active USA Implants		**Therapy Function Compromised**	
Normal Battery Depletions			



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

X3SR01 Astra S SR

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



Years	
Excluding NBD	
Including NBD	
Effective Sample Size	

Methods for Estimating Transcatheter Pacing Performance

Micra TPS Performance Analysis

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

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

Shortfalls of using returned products to Estimate Micra TPS Performance

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

The CareLink™ Network

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

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

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

Definition of Qualifying Complication or Malfunction

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

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

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

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

Normal Battery Depletion

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

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

Statistical and Data Analysis Methods

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

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

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.

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

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

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:

1. Cardiac Perforation
2. Dislodgement
3. Failure to Capture
4. Failure to Sense
5. 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."

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:

1. Cardiac Perforation
2. Dislodgement
3. Failure to Capture
4. Failure to Sense
5. Elevated Pacing Threshold

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

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

MC1VR01 Micra VR

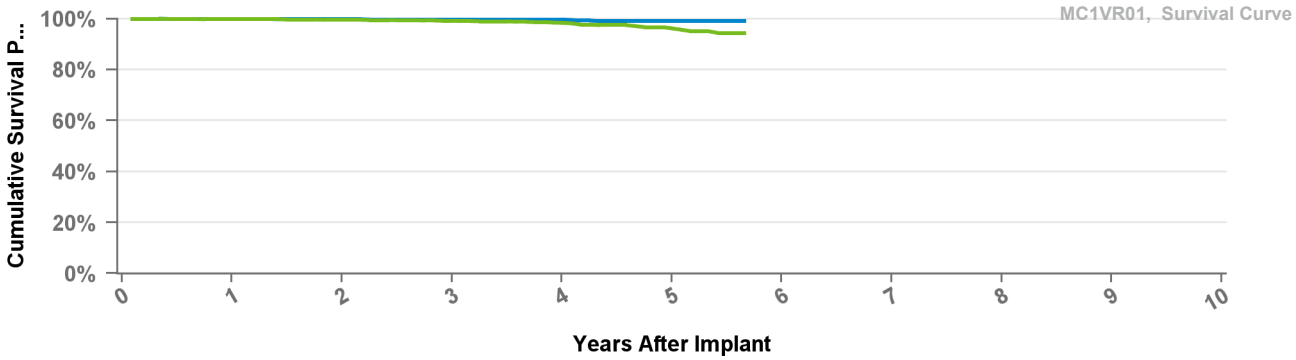
US Market Release	Apr-16
CE Approval Date	Apr-15
Registered USA Implants	51,561

CareLink Population

Enrolled	28,942
Active	24,484
Cumulative Follow-Up Months	559,098
Normal Battery Depletions	72

CareLink Qualifying Malfunctions/Complications

Cardiac Perforation	7
Dislodgements	1
Elevated Pacing Threshold	31
Failure to Capture	7
Premature Battery Depletion	8



Years	1	2	3	4	5	at 68 mo
Excluding NBD	99.9%	99.8%	99.7%	99.7%	99.1%	99.1%
Including NBD	99.8%	99.6%	99.2%	98.4%	96.2%	94.4%
Effective Sample Size	18978	9883	3805	827	199	109

***Acute Observations (N = 51,561)**

Cardiac Perforation	16
Dislodgement	13
Elevated Pacing Threshold	126
Failure to Capture	46
Failure to Sense	8

***Day of Implant Observations (N = 51,561)**

Cardiac Perforation	233
Dislodgement	110
Elevated Pacing Threshold	191
Failure to Capture	76
Failure to Sense	57

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

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

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

MC1AVR1 Micra AV

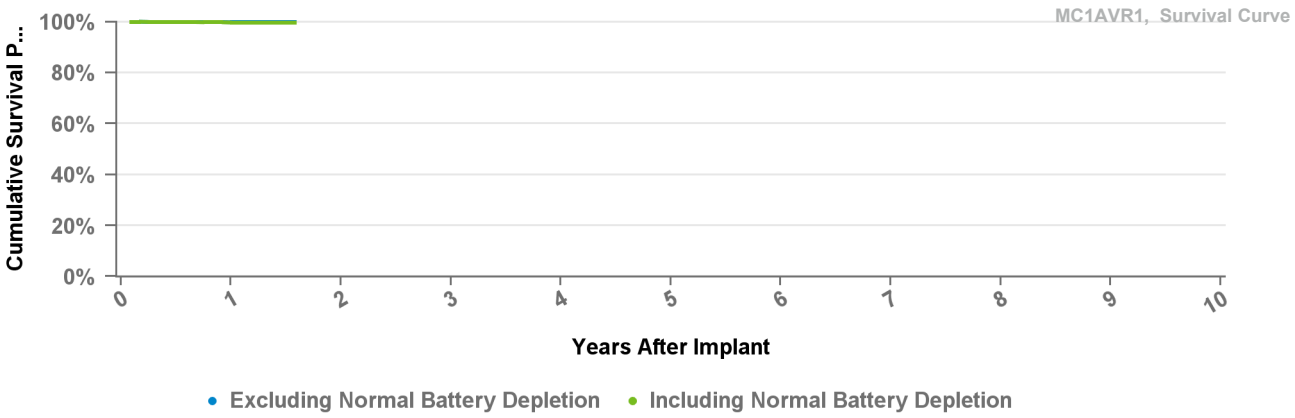
US Market Release	Jan-20
CE Approval Date	Mar-20
Registered USA Implants	18,733

CareLink Population

Enrolled	8,655
Active	8,301
Cumulative Follow-Up Months	65,827
Normal Battery Depletions	3

CareLink Qualifying Malfunctions/Complications

Dislodgements	1
Elevated Pacing Threshold	5
Failure to Capture	3



Years	1	at 19 mo
Excluding NBD	99.8%	99.8%
Including NBD	99.7%	99.7%
Effective Sample Size	1927	106

***Acute Observations (N = 18,733)**

Cardiac Perforation	6
Dislodgement	9
Elevated Pacing Threshold	25
Failure to Capture	11
Failure to Sense	59

***Day of Implant Observations (N = 18,733)**

Cardiac Perforation	123
Dislodgement	26
Elevated Pacing Threshold	51
Failure to Capture	33
Failure to Sense	15

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

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

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

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm Management (CRM) has tracked lead survival for over 38 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.

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 is presented in four categories. The lead reporting categories are:

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

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

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

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

Method for Estimating Lead Performance continued

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

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

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

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

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

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

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

Estimated Number of Implanted and Active Leads in the United States

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

Footnotes:

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

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

3830 SelectSecure

US Market Release	03Aug2005
CE Approval	31Jan2003
Registered USA Implants	99,929
Estimated Active USA Implants	77,293
Fixation Type	Fixed Screw
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	29
Crimp Weld Bond	
Insulation Breach	53
Other	8

US Acute Lead Observations

Cardiac Perforation	34
Conductor Fracture	3
Failure To Capture	317
Failure To Sense	28
Impedance Out of Range	8
Insulation Breach	1
Lead Dislodgement	368
Oversensing	78
Extra Cardiac Stimulation	8
Unspecified Clinical Failure	2

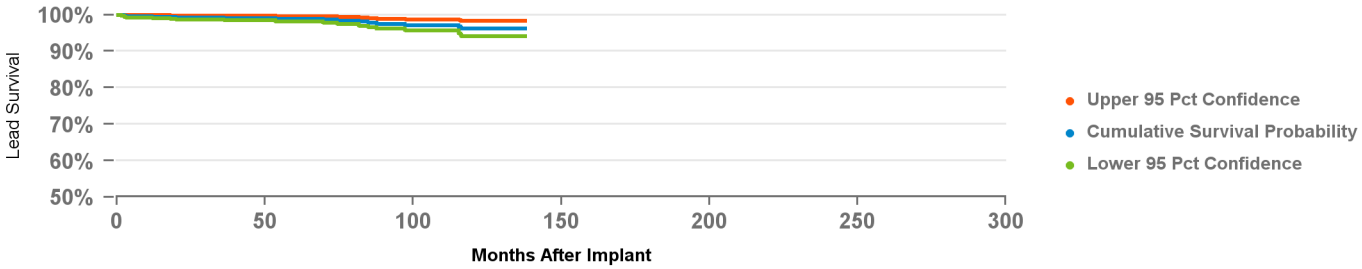
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,418
Number of Leads Active in Study	640
Cumulative Months of Follow-Up	69,373

Qualifying Complications 19

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



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.5%	99.2%	99.2%	99.1%	98.9%	98.7%	98.1%	97.5%	97.2%	96.2%	96.2%	96.2%
#	1,070	847	703	566	463	398	338	287	237	160	71	53

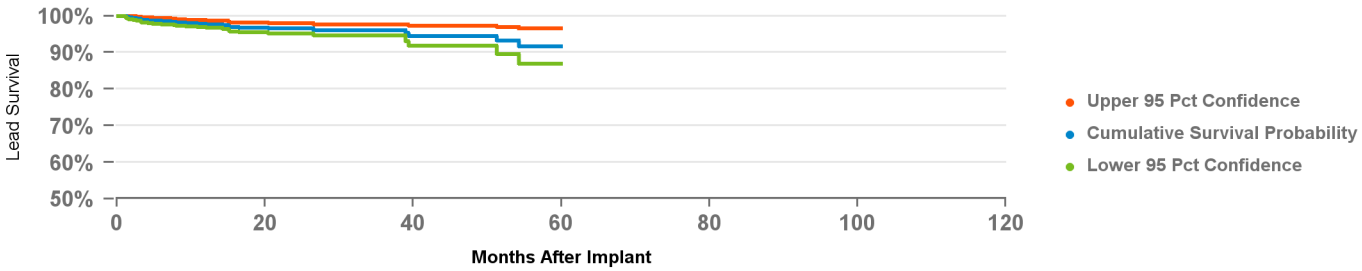
His Bundle Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,143
Number of Leads Active in Study	903
Cumulative Months of Follow-Up	20,012

Qualifying Complications 31

Failure to Capture	23
Failure to Sense	2
Lead Dislodgement	2
Other	3
Oversensing	1



Years	1	2	3	4	at 60 mo
%	97.9%	96.5%	96.1%	94.5%	91.6%
#	671	300	139	84	50

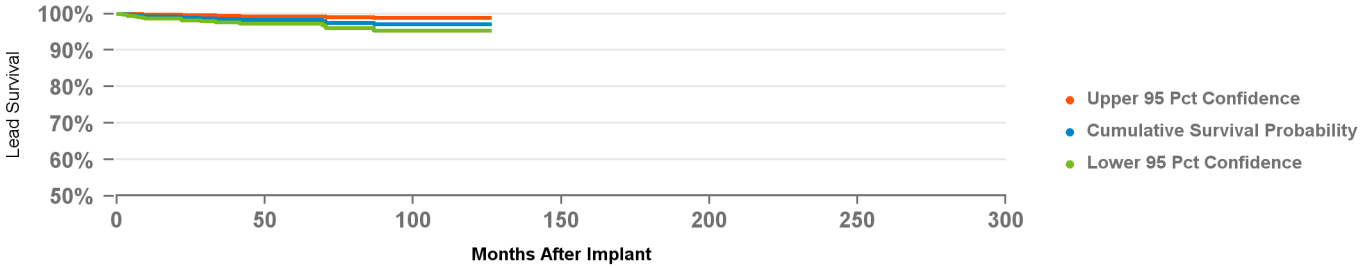
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,454
Number of Leads Active in Study	877
Cumulative Months of Follow-Up	49,094

Qualifying Complications 16

Failure to Capture	9
Impedance Out of Range	1
Lead Dislodgement	5
Other	1



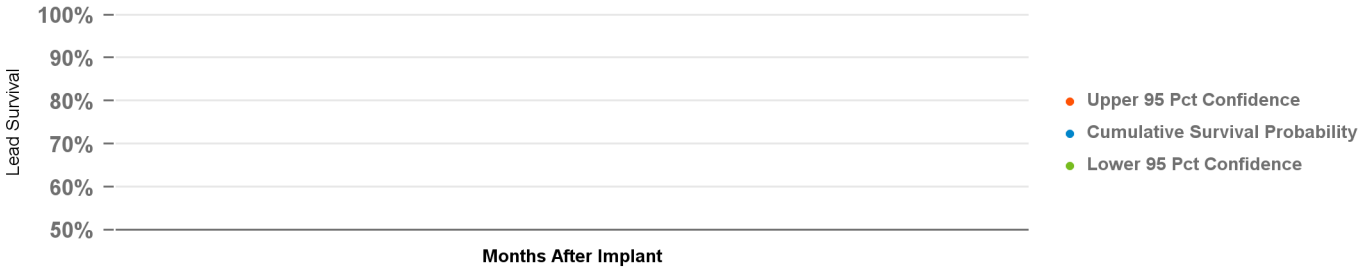
Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.2%	98.9%	98.5%	98.3%	98.3%	97.5%	97.5%	97.0%	97.0%	97.0%	97.0%
#	920	623	496	368	300	245	205	162	132	85	54

4073 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	771
Estimated Active USA Implants	141
Fixation Type	Tines
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations



Years	at mo
%	
#	

4074 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	147,071
Estimated Active USA Implants	67,502
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	
Insulation Breach	50
Other	

US Acute Lead Observations

Cardiac Perforation	29
Conductor Fracture	2
Failure To Capture	148
Failure To Sense	9
Impedance Out of Range	4
Lead Dislodgement	182
Oversensing	7
Extra Cardiac Stimulation	3

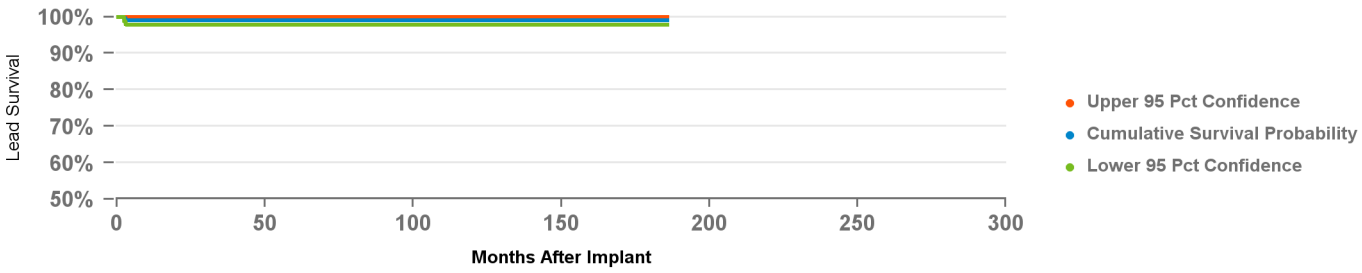
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	227
Number of Leads Active in Study	90
Cumulative Months of Follow-Up	27,251

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	at 186 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%
#	214	205	198	183	167	158	148	136	126	117	109	103	94	84	57	52

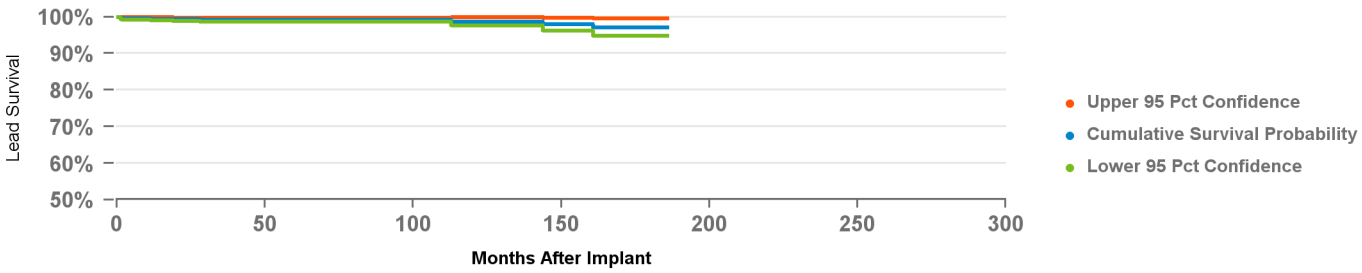
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,188
Number of Leads Active in Study	263
Cumulative Months of Follow-Up	74,402

Qualifying Complications 11

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.4%	99.3%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.7%	98.7%	98.0%	98.0%	97.2%	97.2%	97.2%
#	1,017	859	707	596	467	380	323	269	218	173	151	138	119	103	66	55

4076 CapSureFix Novus

US Market Release	25Feb2004
CE Approval	14Jun2004
Registered USA Implants	729,812
Estimated Active USA Implants	397,689
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	115
Crimp Weld Bond	1
Insulation Breach	186
Other	22

US Acute Lead Observations

Cardiac Perforation	192
Conductor Fracture	10
Failure To Capture	266
Failure To Sense	115
Impedance Out of Range	44
Insulation Breach	1
Lead Dislodgement	713
Oversensing	94
Extra Cardiac Stimulation	25
Unspecified Clinical Failure	10

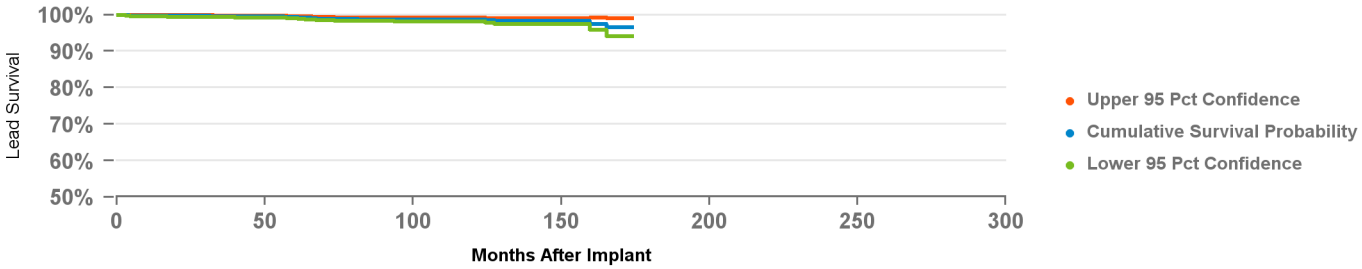
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,115
Number of Leads Active in Study	1,503
Cumulative Months of Follow-Up	235,332

Qualifying Complications 33

Cardiac Perforation	3	Lead Dislodgement	9
Conductor Fracture	2	Other	3
Failure to Capture	10	Oversensing	1
Failure to Sense	3	Insulation (not further defined)	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	99.8%	99.7%	99.6%	99.5%	99.3%	98.9%	98.8%	98.7%	98.7%	98.7%	98.3%	98.3%	98.3%	96.5%	96.5%
#	3,128	2,691	2,317	2,050	1,756	1,502	1,277	992	751	594	417	229	153	83	53

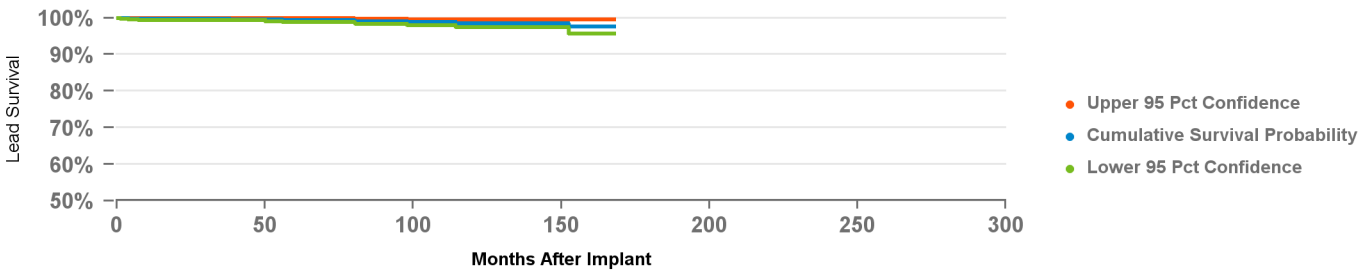
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,713
Number of Leads Active in Study	408
Cumulative Months of Follow-Up	106,524

Qualifying Complications 13

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.7%	99.7%	99.7%	99.6%	99.4%	99.4%	99.0%	99.0%	98.8%	98.5%	98.5%	98.5%	97.6%	97.6%
#	1,393	1,227	1,063	903	731	640	528	424	358	295	233	138	104	63

4092 CapSure SP Novus

US Market Release	17Sep1998
CE Approval	15Apr1998
Registered USA Implants	186,423
Estimated Active USA Implants	38,101
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	19
Crimp Weld Bond	
Insulation Breach	93
Other	

US Acute Lead Observations

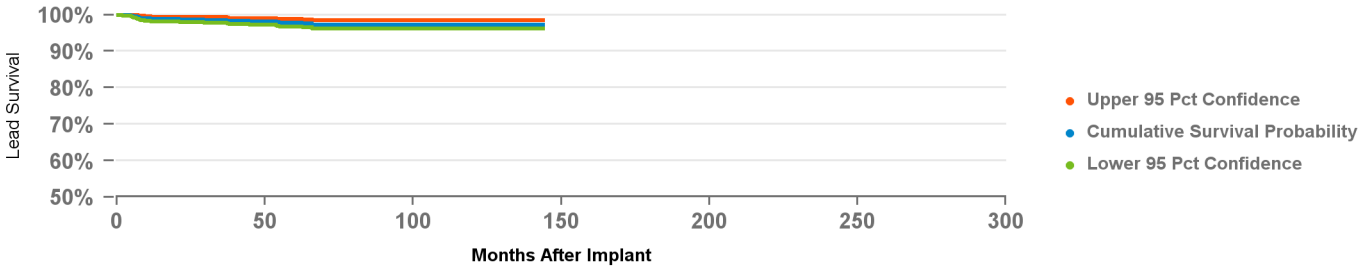
Cardiac Perforation	4
Conductor Fracture	4
Failure To Capture	35
Impedance Out of Range	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	1
Extra Cardiac Stimulation	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,201
Number of Leads Active in Study	25
Cumulative Months of Follow-Up	69,703

Qualifying Complications 21

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



Years	1	2	3	4	5	6	7	8	9	10	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	277	237	156	91	53

4574 CapSure Sense

US Market Release	23Jun2002
CE Approval	01Feb2002
Registered USA Implants	105,390
Estimated Active USA Implants	55,493
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	11
Crimp Weld Bond	
Insulation Breach	22
Other	

US Acute Lead Observations

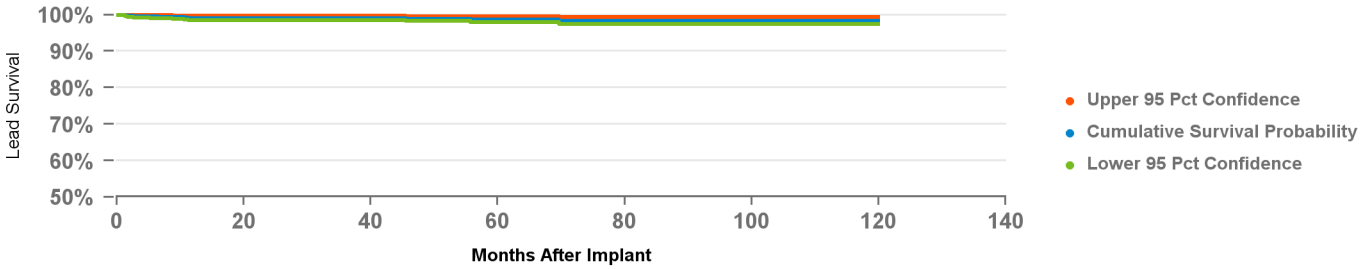
Cardiac Perforation	1
Conductor Fracture	1
Failure To Capture	98
Failure To Sense	46
Impedance Out of Range	7
Lead Dislodgement	221
Oversensing	13
Extra Cardiac Stimulation	1
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,420
Number of Leads Active in Study	676
Cumulative Months of Follow-Up	60,314

Qualifying Complications 13

Conductor Fracture	2	Lead Dislodgement	7
Failure to Capture	4		



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.1%	99.1%	99.1%	98.9%	98.7%	98.4%	98.4%	98.4%	98.4%	98.4%
#	1,026	812	662	516	407	312	230	177	103	59

4592 CapSure SP Novus

US Market Release	05Oct1998
CE Approval	15Apr1998
Registered USA Implants	89,022
Estimated Active USA Implants	20,359
Fixation Type	J-shape, tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp Weld Bond	
Insulation Breach	32
Other	

US Acute Lead Observations

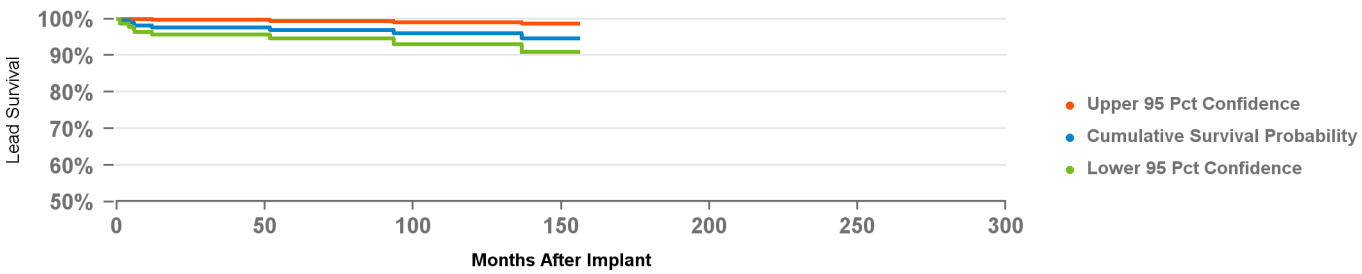
Failure To Capture	10
Failure To Sense	2
Insulation Breach	1
Lead Dislodgement	37
Oversensing	2
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	363
Number of Leads Active in Study	37
Cumulative Months of Follow-Up	21,695

Qualifying Complications 9

Failure to Capture	5	Lead Dislodgement	2
Failure to Sense	1	Other	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	97.7%	97.7%	97.7%	97.7%	97.0%	97.0%	97.0%	96.1%	96.1%	96.1%	96.1%	94.7%	94.7%
#	202	180	165	156	132	124	108	103	95	82	76	70	51

5054 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	98,933
Estimated Active USA Implants	19,049
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	16
Crimp Weld Bond	1
Insulation Breach	43
Other	

US Acute Lead Observations

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

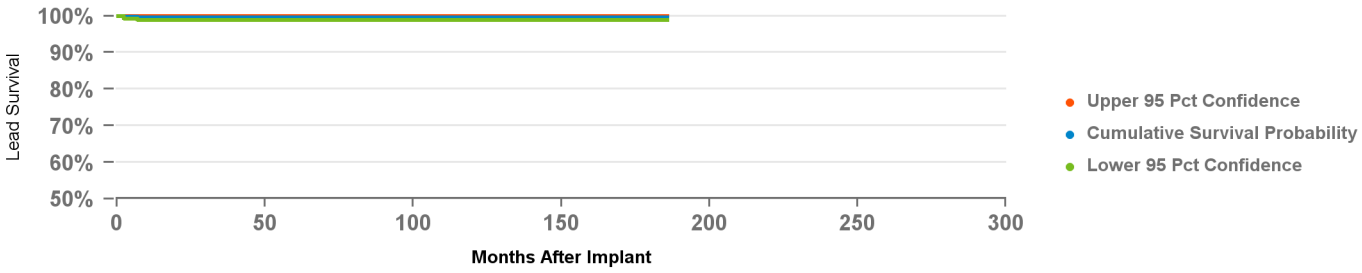
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	426
Number of Leads Active in Study	41
Cumulative Months of Follow-Up	41,161

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	at 186 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%
#	411	391	358	322	289	252	219	186	153	129	108	93	75	65	56	53

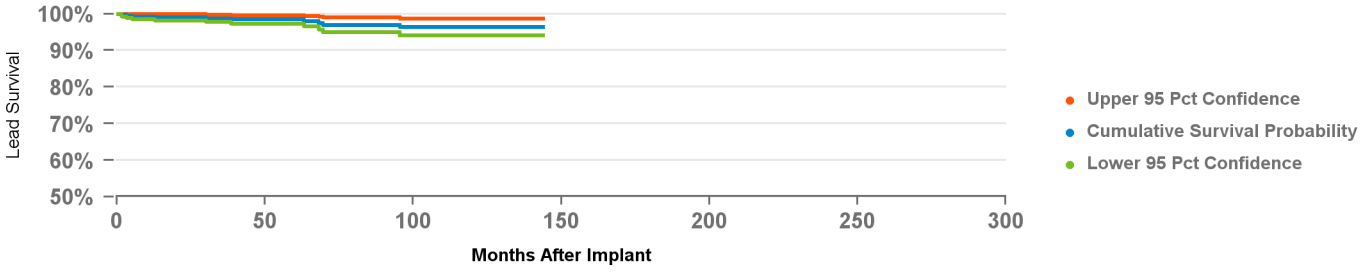
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	989
Number of Leads Active in Study	27
Cumulative Months of Follow-Up	34,889

Qualifying Complications 11

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



Years	1	2	3	4	5	6	7	8	9	10	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	263	229	191	167	142	110	91	69	51

5076 CapSureFix Novus

US Market Release	31Aug2000
CE Approval	12Aug1999
Registered USA Implants	2,968,831
Estimated Active USA Implants	1,581,352
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,273
Crimp Weld Bond	1
Insulation Breach	1,375
Other	190

US Acute Lead Observations

Cardiac Perforation	1,367
Conductor Fracture	27
Failure To Capture	1,795
Failure To Sense	795
Impedance Out of Range	266
Insulation Breach	11
Lead Dislodgement	4,365
Oversensing	595
Extra Cardiac Stimulation	100
Unspecified Clinical Failure	26

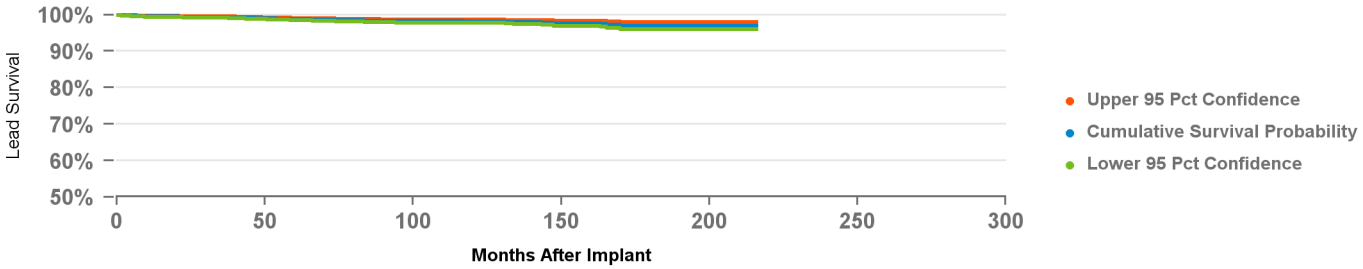
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	10,619
Number of Leads Active in Study	4,416
Cumulative Months of Follow-Up	497,965

Qualifying Complications 95

Cardiac Perforation	2	Impedance Out of Range	7
Conductor Fracture	11	Lead Dislodgement	34
Extra Cardiac Stimulation	3	Other	6
Failure to Capture	15	Oversensing	5
Failure to Sense	9	Insulation (not further defined)	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	at 216 mo
%	99.6%	99.5%	99.3%	99.1%	98.8%	98.7%	98.4%	98.3%	98.3%	98.2%	98.1%	97.8%	97.7%	97.3%	97.0%	97.0%	97.0%	97.0%
#	7,143	5,928	4,940	4,123	3,314	2,617	2,176	1,699	1,358	1,114	897	705	560	425	290	186	117	60

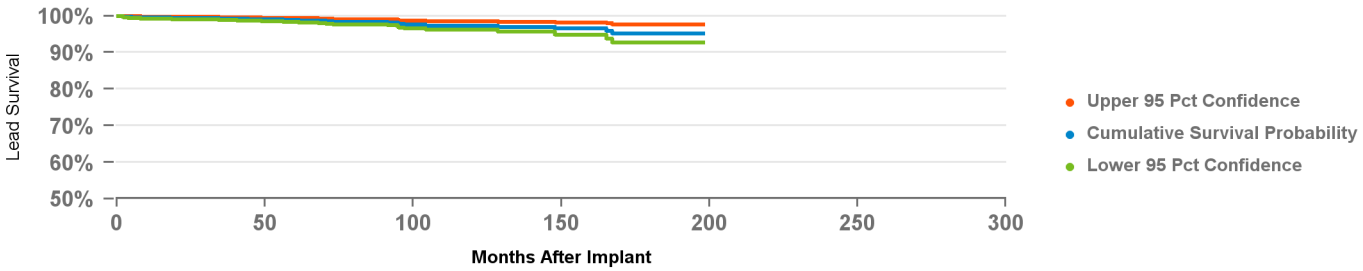
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,230
Number of Leads Active in Study	914
Cumulative Months of Follow-Up	141,203

Qualifying Complications 33

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



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	at 198 mo
%	99.5%	99.3%	99.2%	99.1%	98.9%	98.5%	98.4%	97.8%	97.3%	97.3%	97.0%	97.0%	96.5%	95.1%	95.1%	95.1%	95.1%
#	2,086	1,662	1,295	1,029	876	745	621	474	387	341	272	215	161	133	102	72	60

5086MRI CapsureFix Novus MRI

US Market Release	08Feb2011
CE Approval	21Jan2009
Registered USA Implants	208,678
Estimated Active USA Implants	132,066
Fixation Type	Active Screw In
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	98
Crimp Weld Bond	
Insulation Breach	176
Other	11

US Acute Lead Observations

Cardiac Perforation	213
Conductor Fracture	2
Failure To Capture	143
Failure To Sense	28
Impedance Out of Range	9
Insulation Breach	1
Lead Dislodgement	310
Oversensing	31
Extra Cardiac Stimulation	18

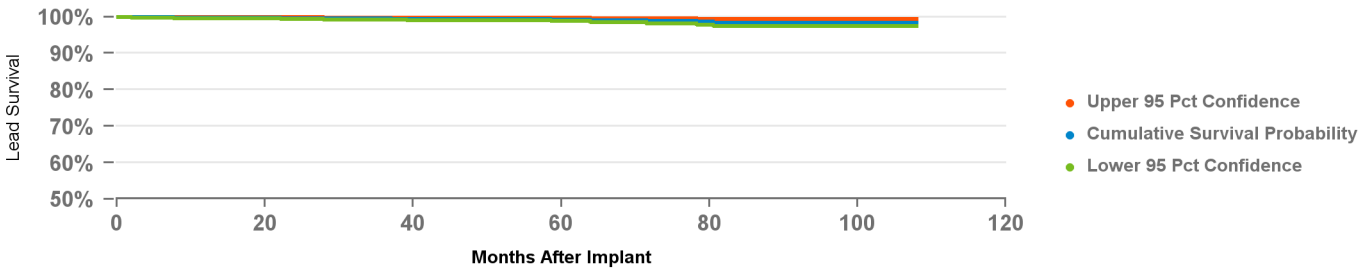
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,124
Number of Leads Active in Study	1,418
Cumulative Months of Follow-Up	136,717

Qualifying Complications 20

Conductor Fracture	3
Failure to Capture	3
Lead Dislodgement	11
Other	1
Oversensing	2



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.8%	99.6%	99.6%	99.4%	99.3%	98.9%	98.4%	98.4%	98.4%
#	2,533	2,206	1,882	1,465	763	439	359	259	100

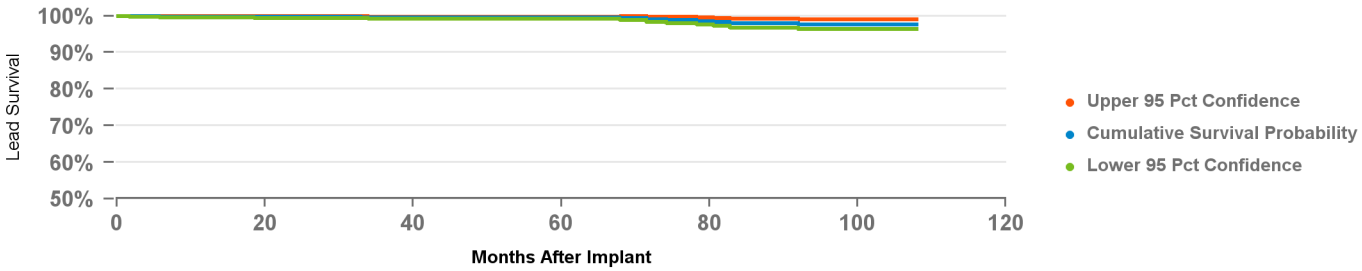
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	3,063
Number of Leads Active in Study	1,401
Cumulative Months of Follow-Up	134,823

Qualifying Complications 20

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



Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.7%	99.7%	99.6%	99.6%	99.6%	99.1%	98.0%	97.7%	97.7%
#	2,530	2,186	1,854	1,432	736	412	345	248	97

5092 CapSure SP Novus

US Market Release	03Jun1998
CE Approval	25Sep1997
Registered USA Implants	140,298
Estimated Active USA Implants	30,206
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	25
Crimp Weld Bond	
Insulation Breach	69
Other	1

US Acute Lead Observations

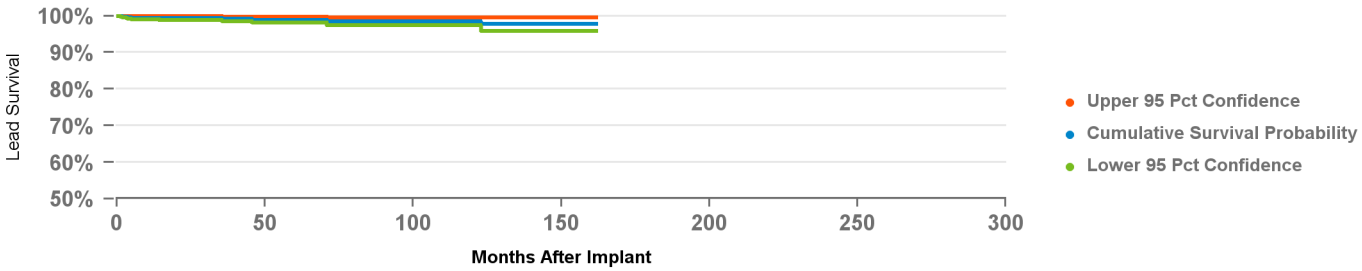
Cardiac Perforation	7
Conductor Fracture	3
Failure To Capture	49
Failure To Sense	7
Impedance Out of Range	1
Insulation Breach	3
Lead Dislodgement	72
Oversensing	1
Extra Cardiac Stimulation	3
Unspecified Clinical Failure	8

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,214
Number of Leads Active in Study	27
Cumulative Months of Follow-Up	53,982

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	334	263	217	171	145	129	106	80	56	52

5554 CapSure Z Novus

US Market Release	03Jun1998
CE Approval	05Jun1997
Registered USA Implants	64,483
Estimated Active USA Implants	14,774
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	22
Crimp Weld Bond	
Insulation Breach	39
Other	

US Acute Lead Observations

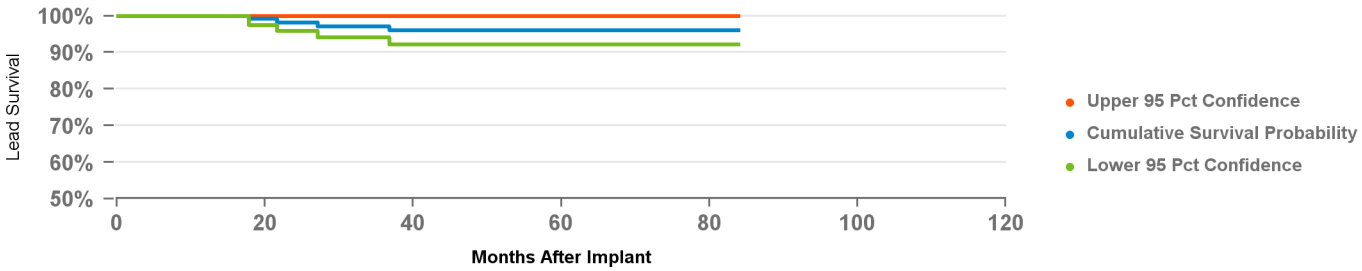
Conductor Fracture	1
Failure To Capture	31
Failure To Sense	2
Impedance Out of Range	1
Lead Dislodgement	38
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	366
Number of Leads Active in Study	10
Cumulative Months of Follow-Up	9,236

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
%	100.0%	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	36,953
Estimated Active USA Implants	10,164
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	7
Other	

US Acute Lead Observations

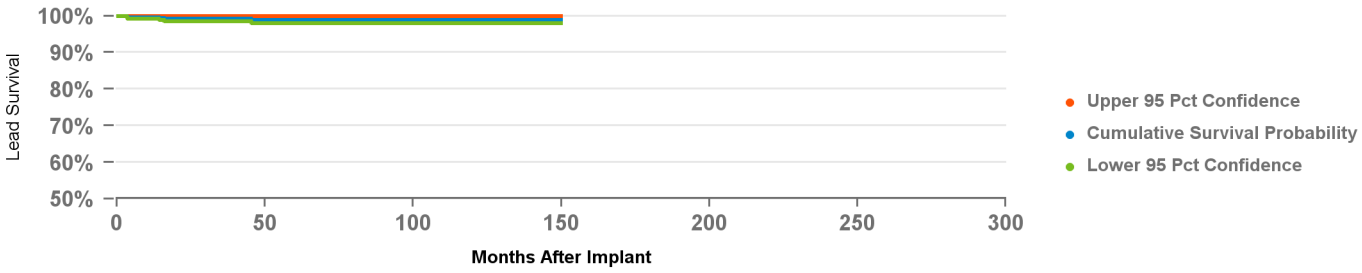
Cardiac Perforation	1
Failure To Capture	4
Failure To Sense	3
Lead Dislodgement	43
Oversensing	1
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	719
Number of Leads Active in Study	41
Cumulative Months of Follow-Up	38,516

Qualifying Complications 5

Failure to Capture	3	Lead Dislodgement	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 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	167	142	121	108	95	69	57

5594 CapSure SP Novus

US Market Release	25Jun2001
CE Approval	23Mar2001
Registered USA Implants	17,599
Estimated Active USA Implants	5,723
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	
Insulation Breach	17
Other	

US Acute Lead Observations

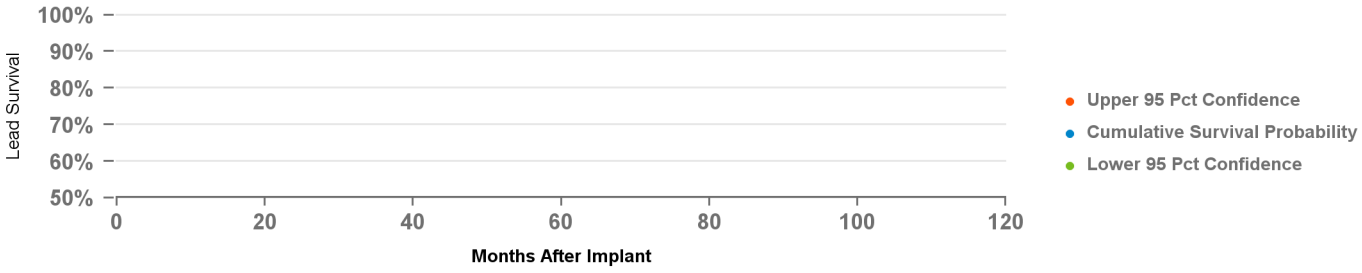
Failure To Capture	4
Lead Dislodgement	14
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	42
Number of Leads Active in Study	12
Cumulative Months of Follow-Up	4,189

Qualifying Complications 3

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



Years	at 0 mo
%	100.0%
#	

6721 Epicardial Patch

US Market Release	31Mar1994
CE Approval	01Jan1993
Registered USA Implants	3,325
Estimated Active USA Implants	857
Fixation Type	Suture
Pace Sense Polarity	n/a
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	15
Crimp Weld Bond	
Insulation Breach	1
Other	

US Acute Lead Observations

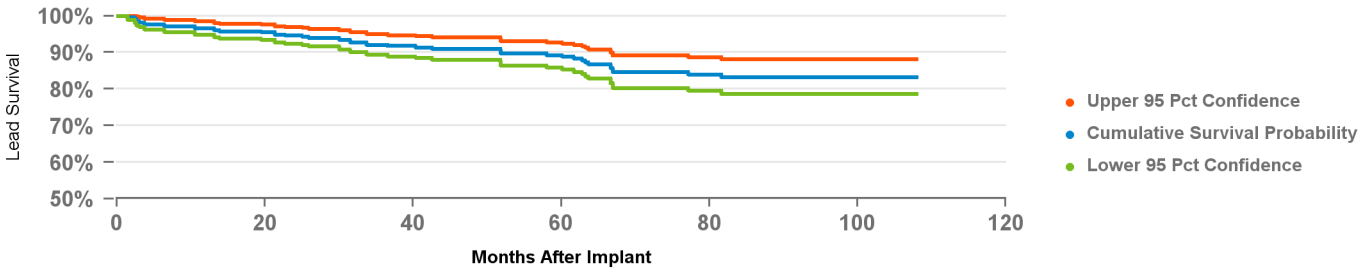
Cardiac Perforation	1
Conductor Fracture	2
Failure To Capture	3
Failure To Sense	1
Impedance Out of Range	20
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	417
Number of Leads Active in Study	7
Cumulative Months of Follow-Up	24,038

Qualifying Complications 47

Conductor Fracture	21
Failure to Capture	8
Impedance Out of Range	4
Other	12
Insulation (not further defined)	2



Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.6%	94.6%	92.1%	91.0%	89.3%	84.6%	83.2%	83.2%	83.2%
#	348	319	274	220	186	133	100	64	56

6930 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	354
Estimated Active USA Implants	66
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

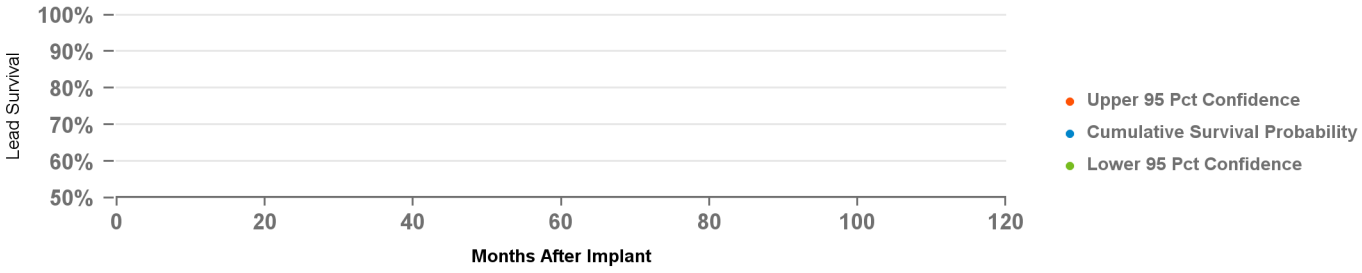
Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Number of Leads Active in Study	1
Cumulative Months of Follow-Up	310



Years	at 0 mo
%	100.0%
#	

6931 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	8,066
Estimated Active USA Implants	1,234
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	659
Crimp Weld Bond	
Insulation Breach	1
Other	5

US Acute Lead Observations

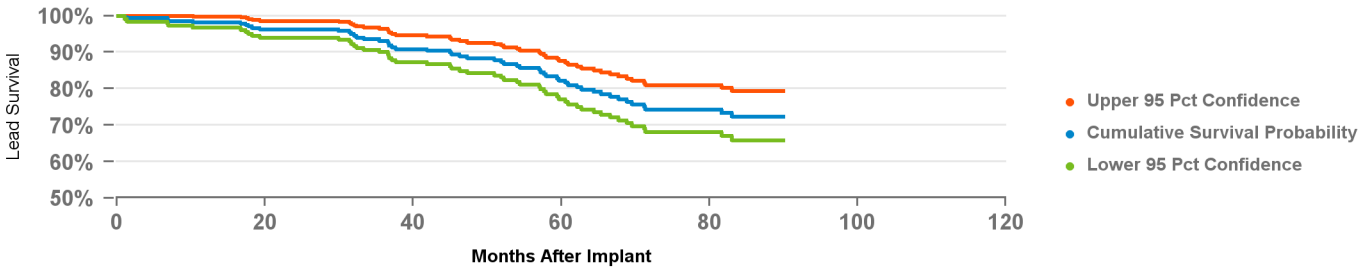
Cardiac Perforation	1
Conductor Fracture	2
Failure To Capture	1
Failure To Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	310
Number of Leads Active in Study	11
Cumulative Months of Follow-Up	17,863

Qualifying Complications 58

Conductor Fracture	35	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	69	55

6935 Sprint Quattro Secure S

US Market Release	01Nov2008
CE Approval	31Mar2008
Registered USA Implants	64,170
Estimated Active USA Implants	37,391
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	414
Crimp Weld Bond	
Insulation Breach	12
Other	42

US Acute Lead Observations

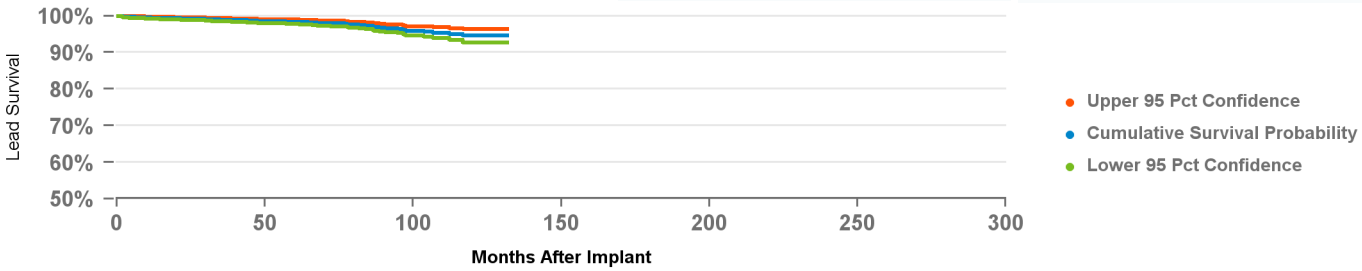
Cardiac Perforation	26
Conductor Fracture	4
Failure To Capture	28
Failure To Sense	14
Impedance Out of Range	26
Insulation Breach	1
Lead Dislodgement	65
Oversensing	63
Extra Cardiac Stimulation	1
Unspecified Clinical Failure	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,817
Number of Leads Active in Study	810
Cumulative Months of Follow-Up	145,962

Qualifying Complications 58

Cardiac Perforation	1	Impedance Out of Range	7
Conductor Fracture	21	Lead Dislodgement	7
Extra Cardiac Stimulation	1	Other	4
Failure to Capture	7	Oversensing	8
Failure to Sense	1	Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	99.2%	98.9%	98.6%	98.4%	97.9%	97.3%	96.4%	95.4%	94.6%	94.6%
#	2,314	1,908	1,566	1,259	1,060	912	751	549	321	191	77

6935M Sprint Quattro Secure S

US Market Release	02Aug2012
CE Approval	12Jul2012
Registered USA Implants	299,768
Estimated Active USA Implants	242,583
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/One Coil
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	521
Crimp Weld Bond	1
Insulation Breach	28
Other	76

US Acute Lead Observations

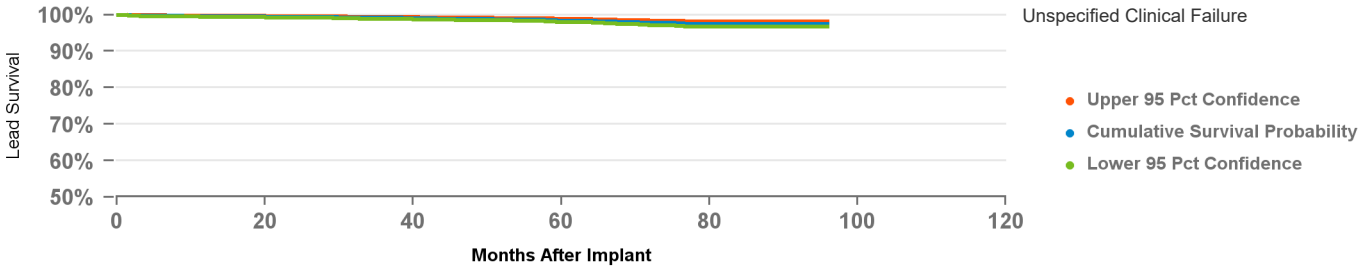
Cardiac Perforation	141
Conductor Fracture	16
Failure To Capture	291
Failure To Sense	91
Impedance Out of Range	85
Insulation Breach	2
Lead Dislodgement	506
Oversensing	259
Extra Cardiac Stimulation	26

Product Surveillance Registry Results

Number of Leads Enrolled in Study	7,355
Number of Leads Active in Study	4,056
Cumulative Months of Follow-Up	274,486

Qualifying Complications 82

Cardiac Perforation	2	Impedance Out of Range	7
Conductor Fracture	27	Lead Dislodgement	17
Extra Cardiac Stimulation	1	Other	2
Failure to Capture	16	Oversensing	5
Failure to Sense	1	Insulation (not further defined)	3
		Unspecified Clinical Failure	1



Years	1	2	3	4	5	6	7	at 96 mo
%	99.6%	99.5%	99.2%	98.9%	98.4%	97.7%	97.5%	97.5%
#	5,712	4,615	3,625	2,768	1,746	867	353	52

6937A Transvene SVC-CS

US Market Release	06Apr2001
CE Approval	
Registered USA Implants	2,827
Estimated Active USA Implants	1,427
Fixation Type	Passive
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

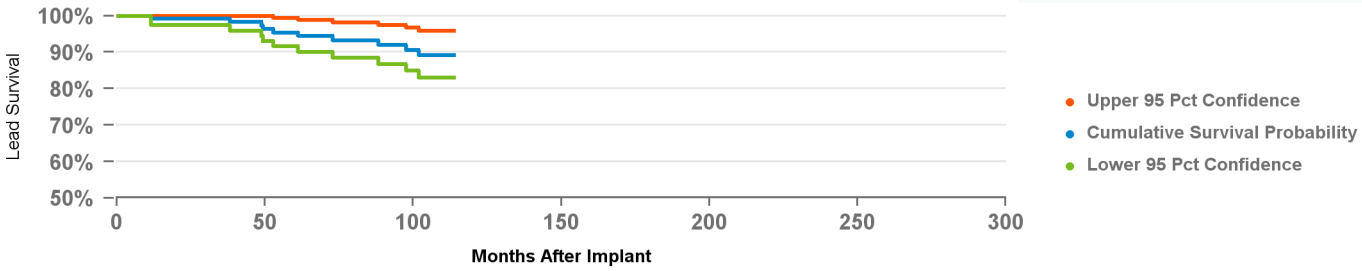
Conductor Fracture	3
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	123
Number of Leads Active in Study	8
Cumulative Months of Follow-Up	13,932

Qualifying Complications 14

Conductor Fracture	5	Impedance Out of Range	1
		Lead Dislodgement	1
		Other	1
		Insulation (not further defined)	2
		Unspecified Clinical Failure	4



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.1%	99.1%	99.1%	98.3%	95.4%	94.4%	93.3%	92.0%	89.2%	89.2%
#	116	114	111	105	93	82	76	69	56	51

6944 Sprint Quattro

US Market Release	13Dec2000
CE Approval	05Nov1999
Registered USA Implants	44,815
Estimated Active USA Implants	12,358
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	223
Crimp Weld Bond	1
Insulation Breach	5
Other	4

US Acute Lead Observations

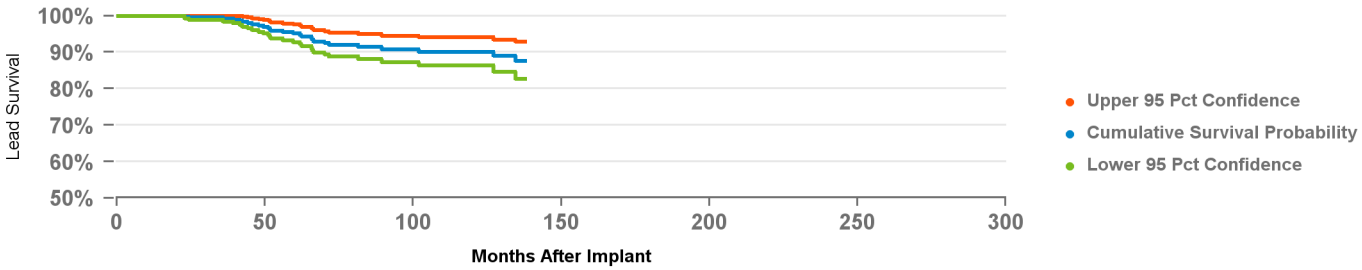
Conductor Fracture	2
Failure To Capture	17
Failure To Sense	3
Impedance Out of Range	10
Lead Dislodgement	24
Oversensing	18
Unspecified Clinical Failure	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	626
Number of Leads Active in Study	104
Cumulative Months of Follow-Up	35,894

Qualifying Complications 30

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



Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	100.0%	99.8%	99.2%	97.3%	95.1%	92.0%	91.4%	90.8%	90.1%	90.1%	89.0%	87.6%
#	501	416	351	289	228	188	158	135	116	92	69	57

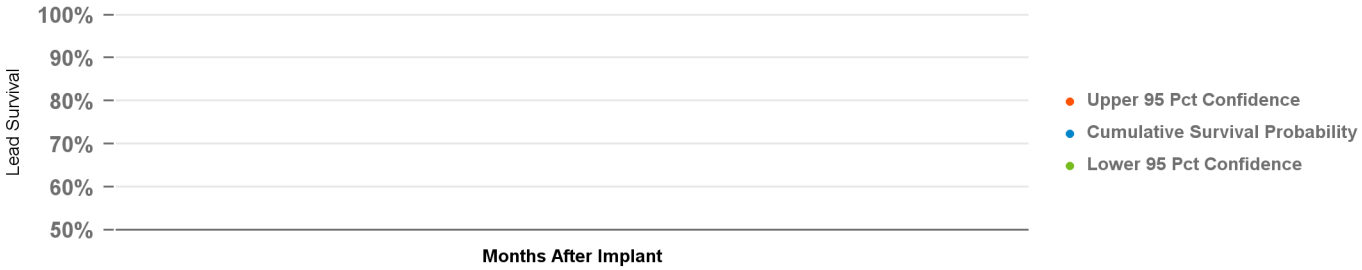
6946M Sprint Quattro

US Market Release	05Jan2016
CE Approval	12Sep2013
Registered USA Implants	2,996
Estimated Active USA Implants	2,573
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

US Acute Lead Observations

Cardiac Perforation	1
Failure To Capture	3
Lead Dislodgement	5
Oversensing	6



Years	at mo
%	
#	

6947 Sprint Quattro Secure

US Market Release	12Nov2001
CE Approval	04Oct2001
Registered USA Implants	376,244
Estimated Active USA Implants	130,377
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	1,315
Crimp Weld Bond	4
Insulation Breach	99
Other	193

US Acute Lead Observations

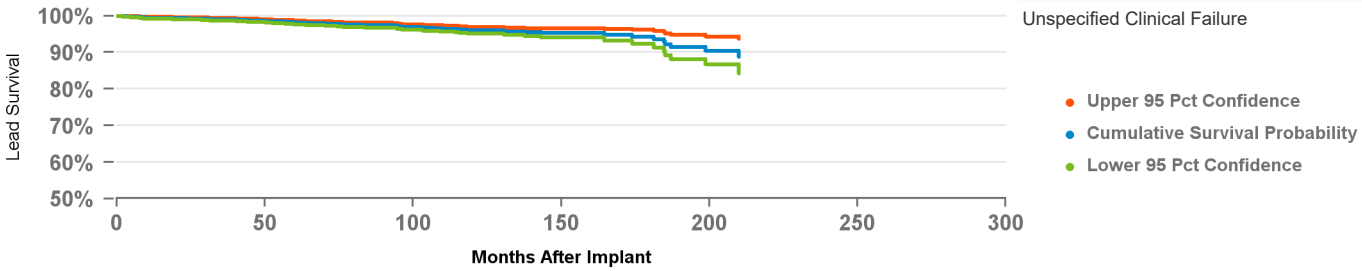
Cardiac Perforation	29
Conductor Fracture	26
Failure To Capture	82
Failure To Sense	34
Impedance Out of Range	61
Insulation Breach	4
Lead Dislodgement	124
Oversensing	140
Extra Cardiac Stimulation	2
Unspecified Clinical Failure	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4,493
Number of Leads Active in Study	852
Cumulative Months of Follow-Up	275,853

Qualifying Complications 93

Conductor Fracture	34
Failure to Capture	8
Failure to Sense	2
Impedance Out of Range	13
Lead Dislodgement	5
Other	4
Oversensing	19
Insulation (not further defined)	5
Unspecified Clinical Failure	3



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%	99.0%	98.7%	98.2%	97.9%	97.5%	97.1%	96.7%	96.1%	95.8%	95.3%	95.3%	94.8%	94.2%	91.4%	90.5%	88.9%
#	3,285	2,886	2,530	2,240	2,000	1,750	1,501	1,316	1,126	872	613	361	241	174	143	117	75	56

6947M Sprint Quattro Secure

US Market Release	13Feb2012
CE Approval	12Mar2010
Registered USA Implants	128,828
Estimated Active USA Implants	89,554
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	208
Crimp Weld Bond	
Insulation Breach	13
Other	33

US Acute Lead Observations

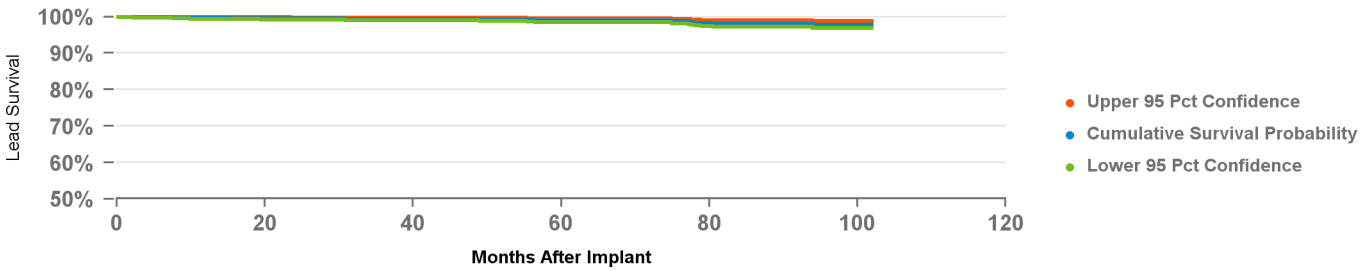
Cardiac Perforation	39
Conductor Fracture	14
Failure To Capture	106
Failure To Sense	40
Impedance Out of Range	31
Lead Dislodgement	224
Oversensing	79
Extra Cardiac Stimulation	12

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,215
Number of Leads Active in Study	781
Cumulative Months of Follow-Up	111,865

Qualifying Complications 22

Conductor Fracture	11	Lead Dislodgement	1
Failure to Capture	4	Other	1
Failure to Sense	3	Oversensing	2



Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.7%	99.5%	99.4%	99.4%	99.0%	99.0%	98.1%	97.9%	97.9%
#	1,766	1,491	1,317	1,115	940	752	603	308	140

6948 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	10,351
Estimated Active USA Implants	1,706
Fixation Type	Tines
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	214
Crimp Weld Bond	
Insulation Breach	3
Other	4

US Acute Lead Observations

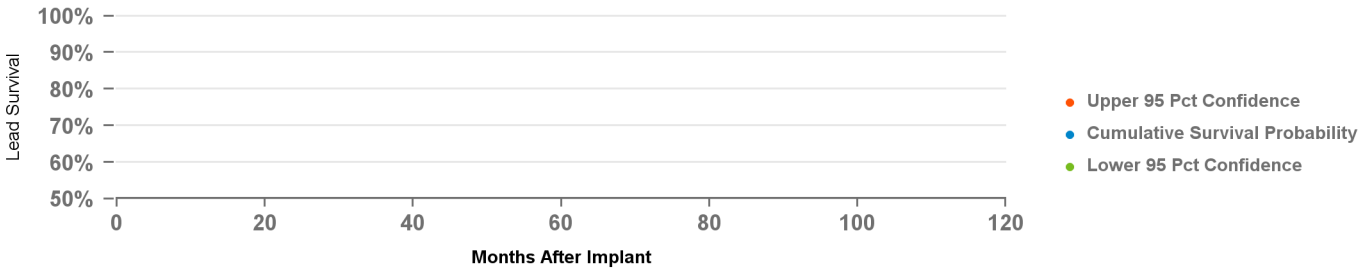
Conductor Fracture	2
Failure To Capture	7
Lead Dislodgement	7
Oversensing	1
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	39
Number of Leads Active in Study	2
Cumulative Months of Follow-Up	2,259

Qualifying Complications 5

Conductor Fracture	4	Impedance Out of Range	1



Years	at 0 mo
%	100.0%
#	

6949 Sprint Fidelis

US Market Release	02Sep2004
CE Approval	
Registered USA Implants	186,295
Estimated Active USA Implants	25,513
Fixation Type	Active Screw In
Pace Sense Polarity	True Bipolar/Two Coils
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8,083
Crimp Weld Bond	3
Insulation Breach	37
Other	107

US Acute Lead Observations

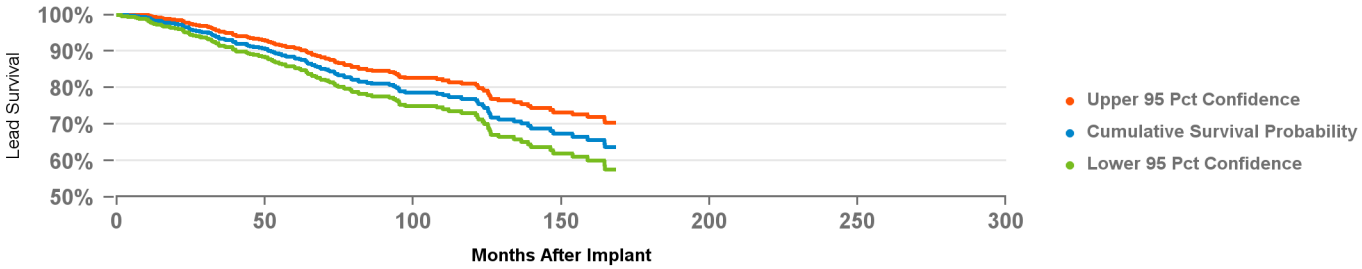
Cardiac Perforation	10
Conductor Fracture	51
Failure To Capture	32
Failure To Sense	19
Impedance Out of Range	19
Insulation Breach	5
Lead Dislodgement	22
Oversensing	36
Unspecified Clinical Failure	24

Product Surveillance Registry Results

Number of Leads Enrolled in Study	982
Number of Leads Active in Study	58
Cumulative Months of Follow-Up	56,762

Qualifying Complications 132

Conductor Fracture	76
Failure to Capture	5
Failure to Sense	6
Impedance Out of Range	19
Lead Dislodgement	1
Other	2
Oversensing	21
Insulation (not further defined)	2



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	98.6%	96.5%	93.4%	91.0%	88.2%	84.5%	81.6%	79.1%	78.3%	77.0%	71.3%	68.8%	66.6%	63.7%
#	719	626	532	458	392	344	282	236	188	153	126	97	79	51

6996 Sub-Q Lead

US Market Release	11Jun2001
CE Approval	19Dec1997
Registered USA Implants	5,451
Estimated Active USA Implants	2,400
Fixation Type	Suture on Anchor Sleeve
Pace Sense Polarity	One Coil
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	35
Crimp Weld Bond	
Insulation Breach	
Other	

US Acute Lead Observations

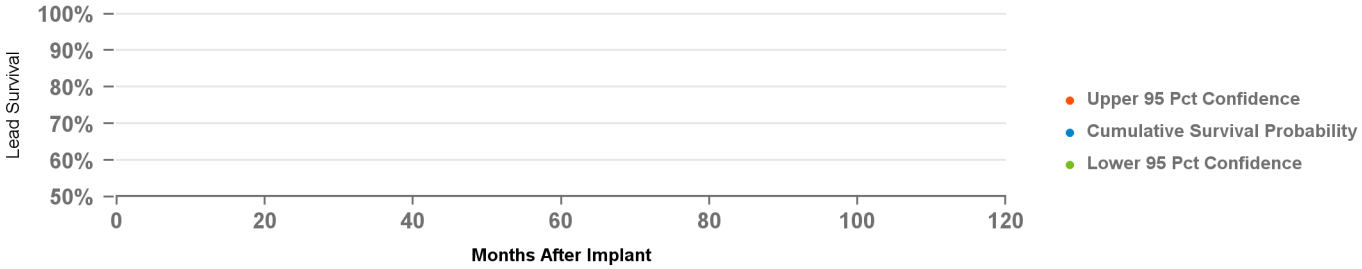
Cardiac Perforation	1
Failure To Capture	1
Impedance Out of Range	15
Insulation Breach	1
Lead Dislodgement	2
Oversensing	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	53
Number of Leads Active in Study	6
Cumulative Months of Follow-Up	2,413

Qualifying Complications 3

Conductor Fracture	1
Impedance Out of Range	2



Years	at 0 mo
%	100.0%
#	

2187 Attain LV

US Market Release	28Aug2001
CE Approval	
Registered USA Implants	11,954
Estimated Active USA Implants	1,027
Fixation Type	Distal Continous Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	1
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

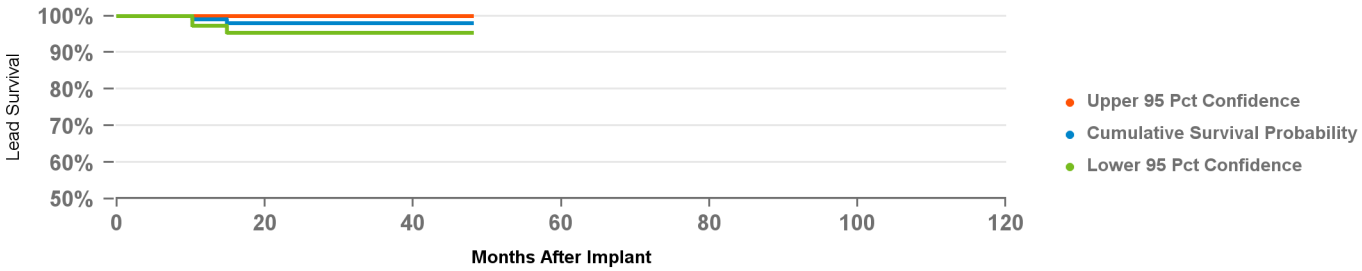
Failure To Capture	3
Failure To Sense	1
Lead Dislodgement	9
Extra Cardiac Stimulation	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	140
Number of Leads Active in Study	6
Cumulative Months of Follow-Up	7,063

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	100,575
Estimated Active USA Implants	12,755
Fixation Type	Double Curve
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	89
Crimp Weld Bond	
Insulation Breach	31
Other	12

US Acute Lead Observations

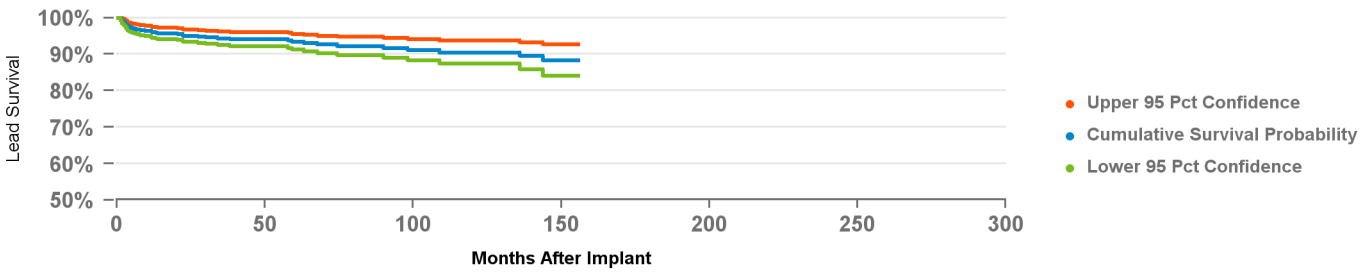
Failure To Capture	11
Lead Dislodgement	45
Oversensing	1
Extra Cardiac Stimulation	18
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	805
Number of Leads Active in Study	44
Cumulative Months of Follow-Up	41,645

Qualifying Complications 49

Conductor Fracture	1	Impedance Out of Range	2
Extra Cardiac Stimulation	10	Lead Dislodgement	14
Failure to Capture	19	Unspecified Clinical Failure	3



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	96.0%	95.1%	94.4%	94.1%	93.4%	92.6%	92.2%	91.7%	91.2%	90.5%	90.5%	88.3%	88.3%
#	569	444	375	304	252	228	193	171	139	118	96	76	56

4194 Attain OTW

US Market Release	24Aug2004
CE Approval	14Jul2003
Registered USA Implants	115,028
Estimated Active USA Implants	30,182
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	46
Crimp Weld Bond	
Insulation Breach	162
Other	2

US Acute Lead Observations

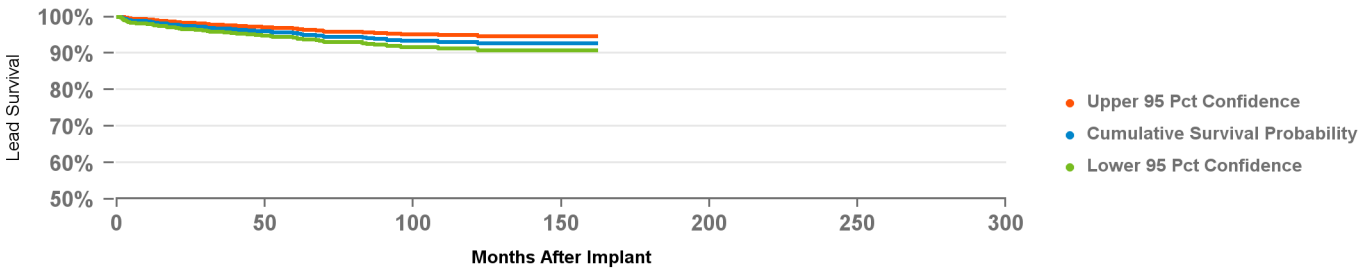
Cardiac Perforation	2
Conductor Fracture	2
Failure To Capture	42
Impedance Out of Range	9
Lead Dislodgement	153
Oversensing	2
Extra Cardiac Stimulation	49
Unspecified Clinical Failure	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,647
Number of Leads Active in Study	250
Cumulative Months of Follow-Up	93,896

Qualifying Complications 67

Conductor Fracture	2	Lead Dislodgement	30
Extra Cardiac Stimulation	11	Insulation (not further defined)	2
Failure to Capture	21	Insulation (ESC)	1



Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 162 mo
%	98.6%	97.4%	96.7%	96.1%	95.6%	94.4%	94.3%	93.4%	93.4%	93.1%	92.7%	92.7%	92.7%	92.7%
#	1,238	1,046	898	769	695	614	494	390	311	251	175	108	73	59

4195 Attain StarFix

US Market Release	15Aug2008
CE Approval	13May2005
Registered USA Implants	17,450
Estimated Active USA Implants	6,566
Fixation Type	Deployable Lobe Fixation
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp Weld Bond	
Insulation Breach	3
Other	2

US Acute Lead Observations

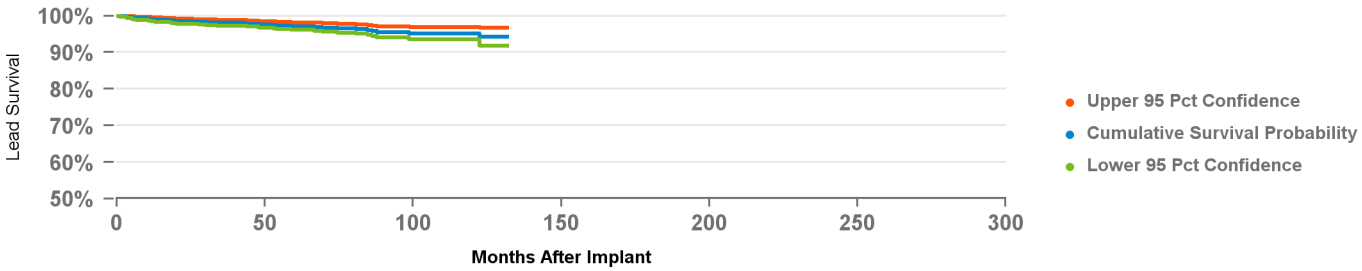
Failure To Capture	21
Impedance Out of Range	4
Lead Dislodgement	30
Extra Cardiac Stimulation	30
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,486
Number of Leads Active in Study	256
Cumulative Months of Follow-Up	82,057

Qualifying Complications 41

Conductor Fracture	4	Impedance Out of Range	2
Extra Cardiac Stimulation	16	Lead Dislodgement	5
Failure to Capture	8	Other	1
		Insulation (not further defined)	5



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.1%	98.5%	98.1%	97.6%	97.2%	96.8%	96.4%	95.6%	95.2%	95.2%	94.3%
#	1,243	1,072	924	746	614	502	391	275	187	114	54

4196 Attain Ability

US Market Release	15May2009
CE Approval	24Jul2007
Registered USA Implants	69,891
Estimated Active USA Implants	29,386
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	26
Crimp Weld Bond	
Insulation Breach	2
Other	9

US Acute Lead Observations

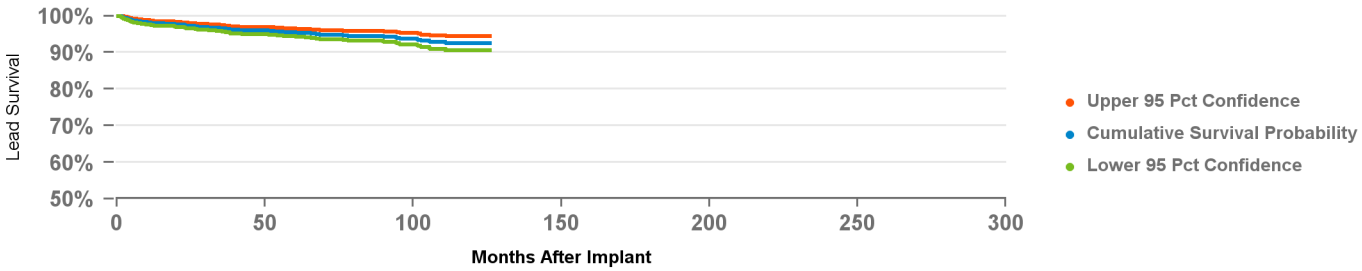
Cardiac Perforation	3
Conductor Fracture	2
Failure To Capture	64
Failure To Sense	1
Impedance Out of Range	10
Insulation Breach	1
Lead Dislodgement	224
Oversensing	1
Extra Cardiac Stimulation	95
Unspecified Clinical Failure	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,309
Number of Leads Active in Study	342
Cumulative Months of Follow-Up	110,819

Qualifying Complications 89

Conductor Fracture	3
Extra Cardiac Stimulation	16
Failure to Capture	40
Impedance Out of Range	2
Lead Dislodgement	23
Other	4
Insulation (not further defined)	1



Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	98.0%	97.3%	96.6%	96.0%	95.5%	94.8%	94.5%	93.8%	92.8%	92.5%	92.5%
#	1,878	1,489	1,181	952	765	608	464	357	267	162	99

4296 Attain Ability Plus

US Market Release	01Apr2011
CE Approval	18Dec2009
Registered USA Implants	34,950
Estimated Active USA Implants	17,770
Fixation Type	Double Curve
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp Weld Bond	2
Insulation Breach	
Other	4

US Acute Lead Observations

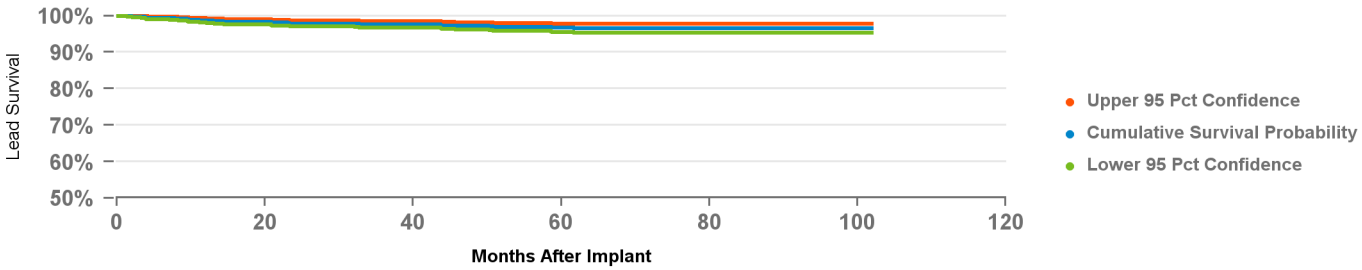
Cardiac Perforation	2
Conductor Fracture	1
Failure To Capture	32
Impedance Out of Range	11
Insulation Breach	4
Lead Dislodgement	118
Extra Cardiac Stimulation	61

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,462
Number of Leads Active in Study	361
Cumulative Months of Follow-Up	67,772

Qualifying Complications 35

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



Years	1	2	3	4	5	6	7	8	at 102 mo
%	98.7%	97.9%	97.7%	97.2%	96.7%	96.5%	96.5%	96.5%	96.5%
#	1,155	930	760	634	531	447	331	151	89

4298 Attain Performa

US Market Release	01Aug2014
CE Approval	01Jan2013
Registered USA Implants	98,276
Estimated Active USA Implants	75,521
Fixation Type	Double Curve
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	
Other	22

US Acute Lead Observations

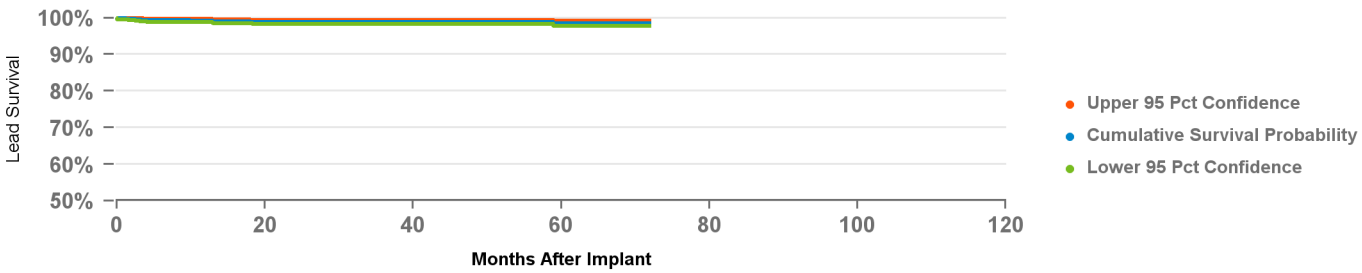
Cardiac Perforation	7
Conductor Fracture	1
Failure To Capture	118
Failure To Sense	1
Impedance Out of Range	35
Lead Dislodgement	208
Extra Cardiac Stimulation	204

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,149
Number of Leads Active in Study	1,167
Cumulative Months of Follow-Up	76,884

Qualifying Complications 22

Extra Cardiac Stimulation	4	Lead Dislodgement	13
Failure to Capture	2	Other	3



Years	1	2	3	4	5	at 72 mo
%	99.3%	98.9%	98.8%	98.8%	98.6%	98.6%
#	1,795	1,400	984	687	419	122

4396 Attain Ability Straight

US Market Release	31Mar2011
CE Approval	18Dec2009
Registered USA Implants	8,354
Estimated Active USA Implants	4,480
Fixation Type	Tines
Pace Sense Polarity	Dual Electrodes
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp Weld Bond	
Insulation Breach	1
Other	

US Acute Lead Observations

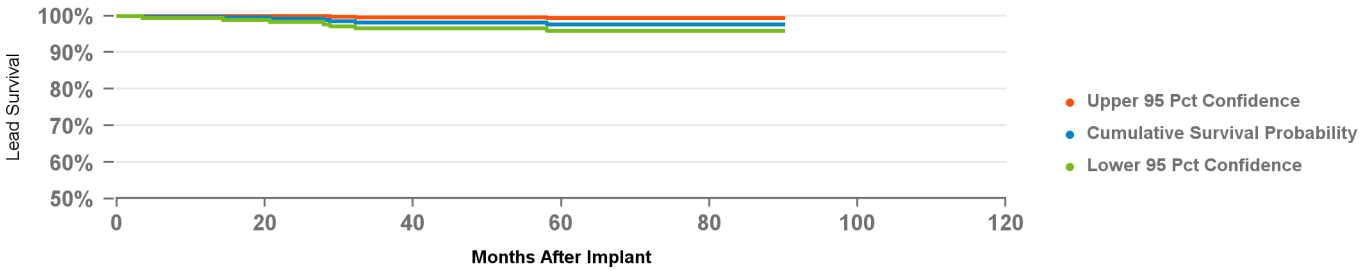
Cardiac Perforation	1
Conductor Fracture	2
Failure To Capture	11
Lead Dislodgement	35
Extra Cardiac Stimulation	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	473
Number of Leads Active in Study	134
Cumulative Months of Follow-Up	22,234

Qualifying Complications 9

Extra Cardiac Stimulation	1	Lead Dislodgement	3
Failure to Capture	4	Insulation (not further defined)	1



Years	1	2	3	4	5	6	7	at 90 mo
%	99.8%	99.2%	98.1%	98.1%	97.6%	97.6%	97.6%	97.6%
#	374	300	260	223	182	137	89	71

4398 Attain Performa Straight

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	32,639
Estimated Active USA Implants	26,092
Fixation Type	Tines
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp Weld Bond	
Insulation Breach	
Other	6

US Acute Lead Observations

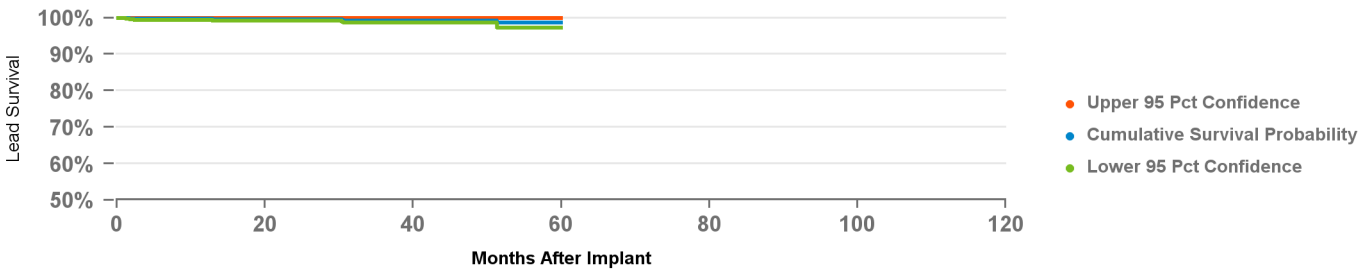
Cardiac Perforation	6
Failure To Capture	50
Impedance Out of Range	8
Lead Dislodgement	37
Extra Cardiac Stimulation	88

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,603
Number of Leads Active in Study	1,110
Cumulative Months of Follow-Up	38,360

Qualifying Complications 9

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



Years	1	2	3	4	at 60 mo
%	99.7%	99.6%	99.2%	99.2%	98.6%
#	1,114	720	385	189	94

4598 Attain Performa S

US Market Release	10Dec2014
CE Approval	01Jan2013
Registered USA Implants	59,127
Estimated Active USA Implants	47,461
Fixation Type	S-shape
Pace Sense Polarity	Quad Pole
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp Weld Bond	
Insulation Breach	
Other	8

US Acute Lead Observations

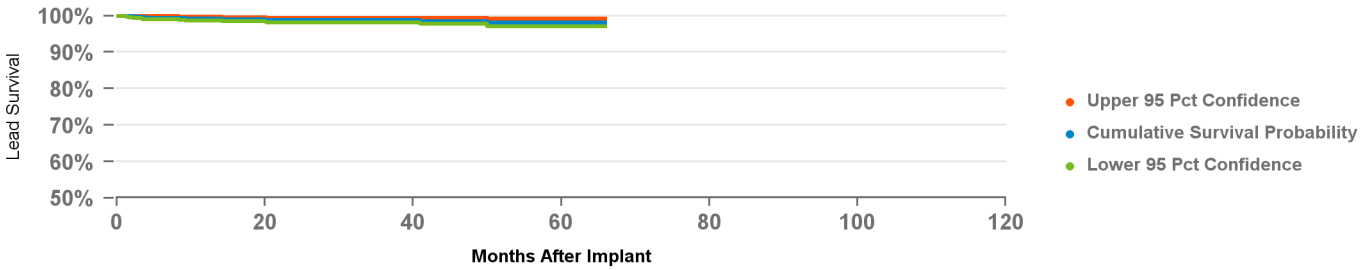
Cardiac Perforation	9
Conductor Fracture	1
Failure To Capture	65
Impedance Out of Range	21
Lead Dislodgement	66
Oversensing	1
Extra Cardiac Stimulation	105

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,286
Number of Leads Active in Study	727
Cumulative Months of Follow-Up	41,359

Qualifying Complications 15

Extra Cardiac Stimulation	3
Failure to Sense	1
Lead Dislodgement	11



Years	1	2	3	4	5	at 66 mo
%	99.2%	98.8%	98.8%	98.6%	98.2%	98.2%
#	1,063	814	503	299	148	73

4798 Attain Stability

US Market Release	17Apr2017
CE Approval	
Registered USA Implants	20,441
Estimated Active USA Implants	19,255
Fixation Type	
Pace Sense Polarity	
Steroid Indicator	

US Returned Product Analysis

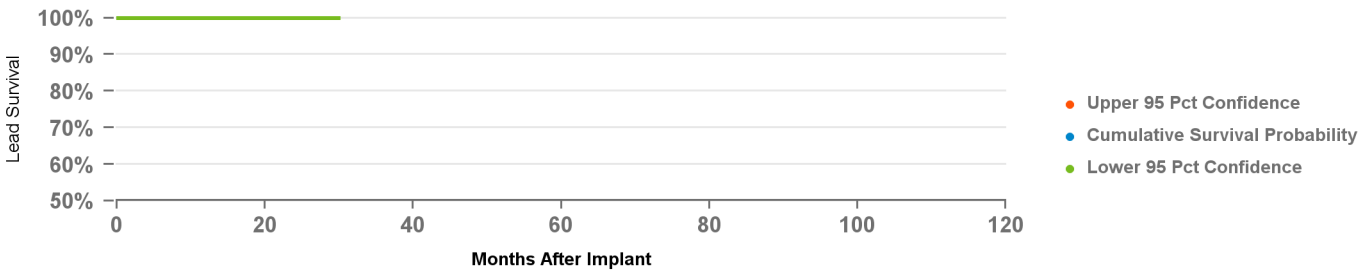
Conductor Fracture	
Crimp Weld Bond	
Insulation Breach	
Other	4

US Acute Lead Observations

Cardiac Perforation	4
Conductor Fracture	1
Failure To Capture	32
Impedance Out of Range	15
Lead Dislodgement	62
Oversensing	1
Extra Cardiac Stimulation	44

Product Surveillance Registry Results

Number of Leads Enrolled in Study	482
Number of Leads Active in Study	412
Cumulative Months of Follow-Up	5,472



Years	1	2	at 30 mo
%	100.0%	100.0%	100.0%
#	176	96	69

4965 CapSure Epi

US Market Release	06Sep1996
CE Approval	01Jan1993
Registered USA Implants	23,687
Estimated Active USA Implants	7,124
Fixation Type	Suture
Pace Sense Polarity	Unipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	291
Crimp Weld Bond	1
Insulation Breach	63
Other	

US Acute Lead Observations

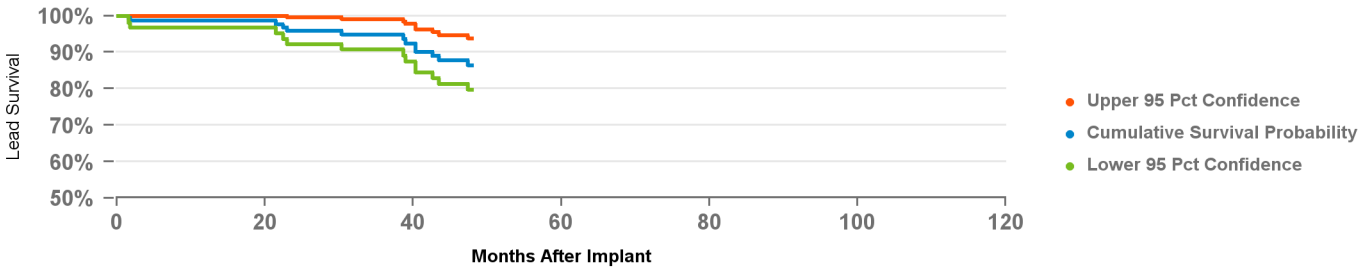
Cardiac Perforation	1
Conductor Fracture	1
Failure To Capture	10
Failure To Sense	7
Impedance Out of Range	19
Oversensing	2
Unspecified Clinical Failure	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	235
Number of Leads Active in Study	5
Cumulative Months of Follow-Up	7,451

Qualifying Complications 17

Conductor Fracture	10
Failure to Capture	3
Failure to Sense	1
Oversensing	2
Insulation (not further defined)	1



Years	1	2	3	at 48 mo
%	98.6%	95.8%	94.8%	86.4%
#	119	101	83	61

4968 CapSure Epi

US Market Release	16Sep1999
CE Approval	21Apr1998
Registered USA Implants	55,479
Estimated Active USA Implants	30,029
Fixation Type	Suture
Pace Sense Polarity	Bipolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	125
Crimp Weld Bond	
Insulation Breach	67
Other	1

US Acute Lead Observations

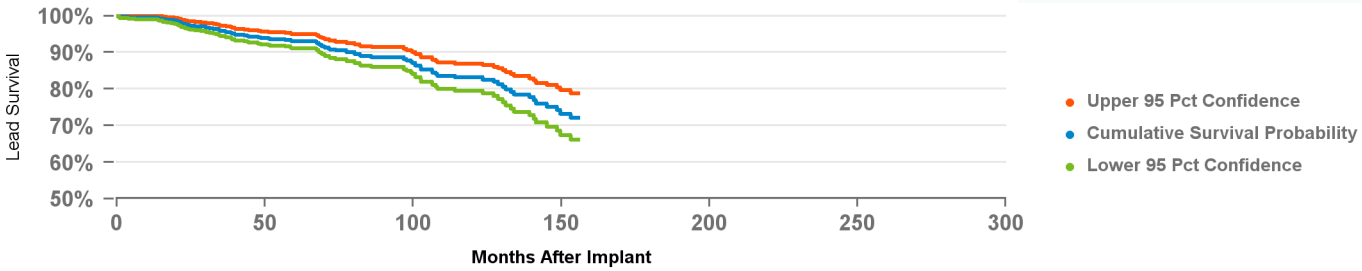
Cardiac Perforation	1
Conductor Fracture	4
Failure To Capture	68
Failure To Sense	8
Impedance Out of Range	14
Insulation Breach	1
Lead Dislodgement	7
Oversensing	29
Extra Cardiac Stimulation	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,034
Number of Leads Active in Study	191
Cumulative Months of Follow-Up	64,046

Qualifying Complications 101

Conductor Fracture	28
Extra Cardiac Stimulation	2
Failure to Capture	31
Failure to Sense	3
Impedance Out of Range	5
Lead Dislodgement	1
Other	2
Oversensing	25
Insulation (not further defined)	4



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.5%	97.5%	95.9%	94.2%	93.1%	90.8%	89.0%	88.8%	84.0%	83.2%	80.0%	76.1%	72.2%
#	807	723	646	545	476	389	327	279	202	152	112	86	59

5071 Screw-in

US Market Release	03Dec1992
CE Approval	01Jan1993
Registered USA Implants	55,857
Estimated Active USA Implants	12,186
Fixation Type	Fixed Screw
Pace Sense Polarity	Unipolar
Steroid Indicator	None

US Returned Product Analysis

Conductor Fracture	30
Crimp Weld Bond	
Insulation Breach	2
Other	1

US Acute Lead Observations

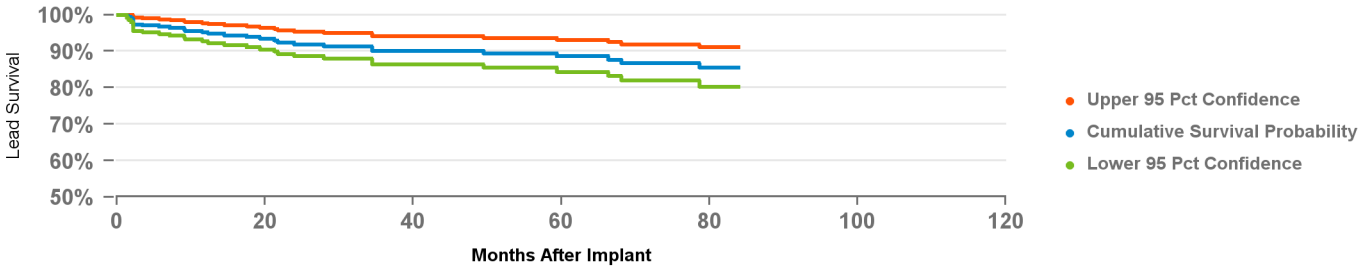
Cardiac Perforation	1
Failure To Capture	96
Failure To Sense	3
Impedance Out of Range	11
Lead Dislodgement	2
Oversensing	1
Extra Cardiac Stimulation	6
Unspecified Clinical Failure	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	458
Number of Leads Active in Study	84
Cumulative Months of Follow-Up	15,596

Qualifying Complications 34

Conductor Fracture	4	Impedance Out of Range	1
Extra Cardiac Stimulation	1	Lead Dislodgement	2
Failure to Capture	21	Other	1
Failure to Sense	2	Oversensing	2



Years	1	2	3	4	5	6	at 84 mo
%	95.2%	91.9%	90.2%	90.2%	88.6%	86.8%	85.5%
#	229	176	148	129	104	85	58

5038 CapSure VDD-2

US Market Release	10Sep1998
CE Approval	15Apr1997
Registered USA Implants	10,449
Estimated Active USA Implants	2,632
Fixation Type	Tines
Pace Sense Polarity	Quadripolar
Steroid Indicator	Yes

US Returned Product Analysis

Conductor Fracture	8
Crimp Weld Bond	
Insulation Breach	2
Other	

US Acute Lead Observations

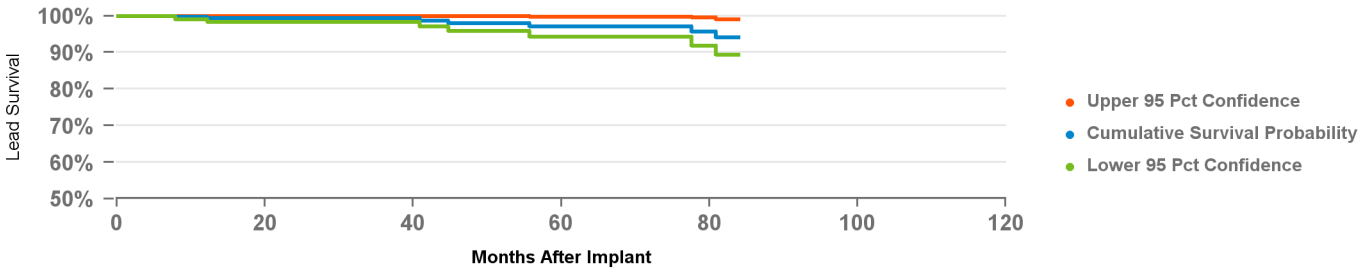
Failure To Capture	3
Failure To Sense	3
Lead Dislodgement	7
Oversensing	1
Extra Cardiac Stimulation	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	568
Number of Leads Active in Study	2
Cumulative Months of Follow-Up	15,862

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

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 CR 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.

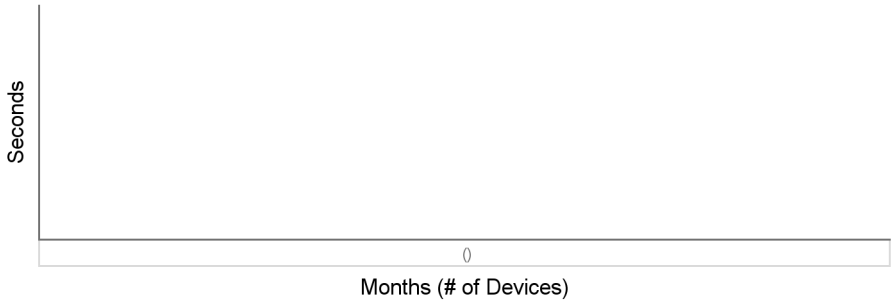
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available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

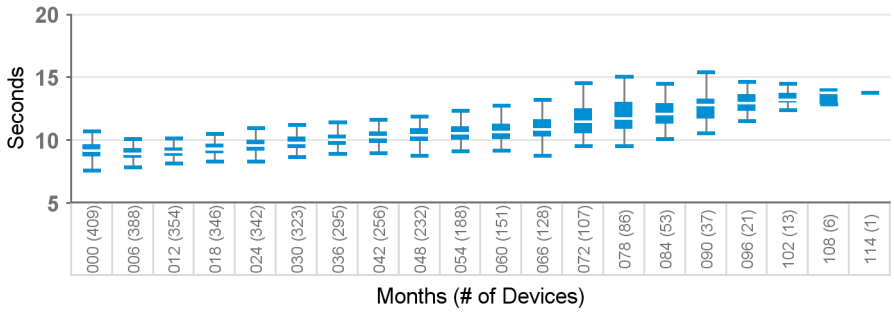
7232

Model Number	Brand
7232Cx	Maximo VR



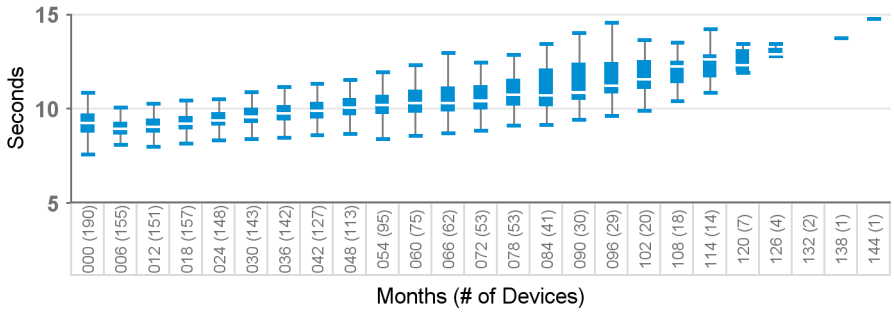
D154AWG, D164AWG

Model Number	Brand
D164AWG	Virtuoso DR



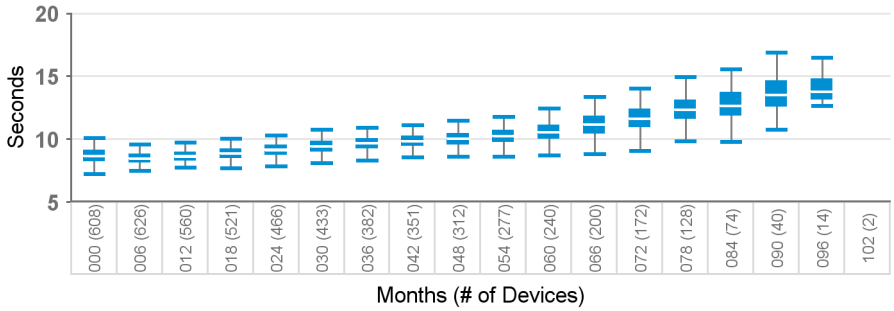
D154VWC, D164VWC

Model Number	Brand
D164VWC	Virtuoso VR



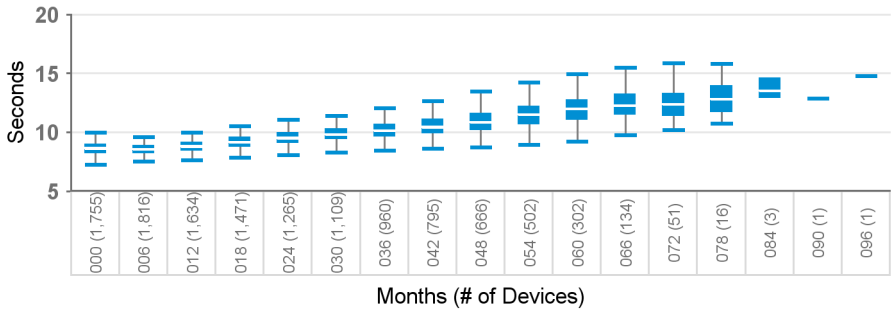
D204DRM, D214DRM, D224DRG, D234DRG

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



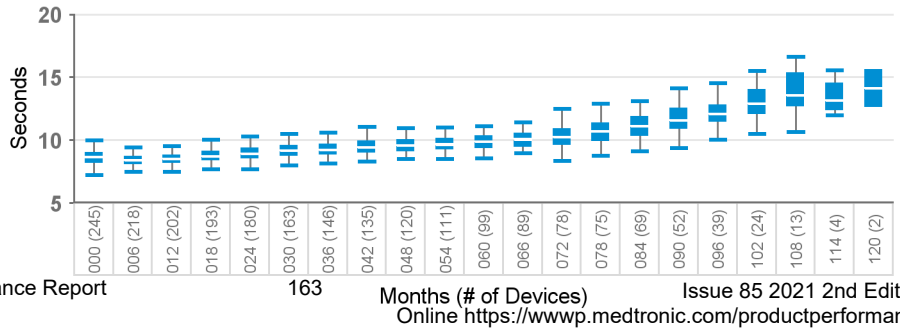
D204TRM, D214TRM, D224TRK, D234TRK

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



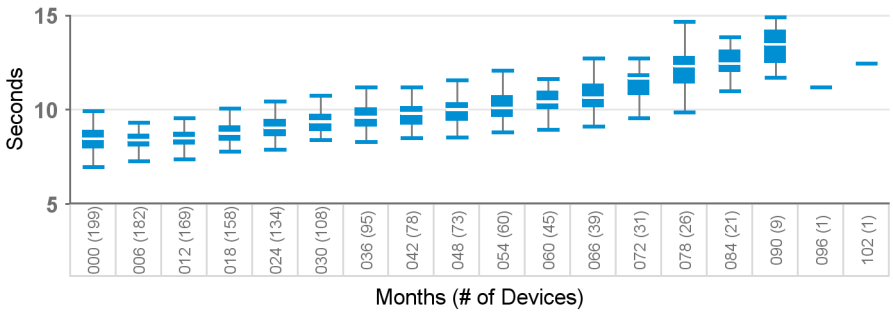
D204VRM, D214VRM, D224VRC, D234VRC

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



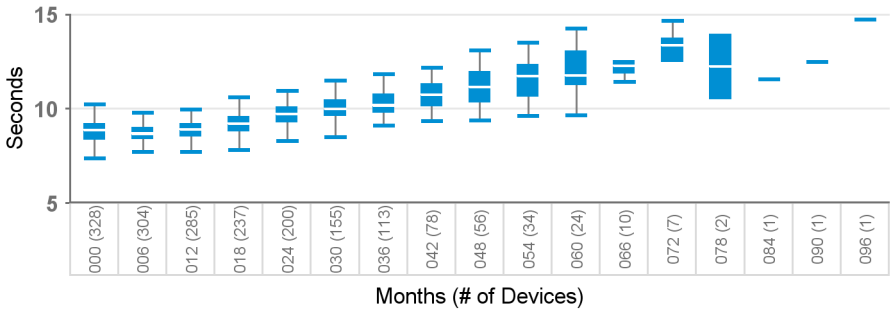
D264DRG, D284DRG, D384DRx, D394DRx

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



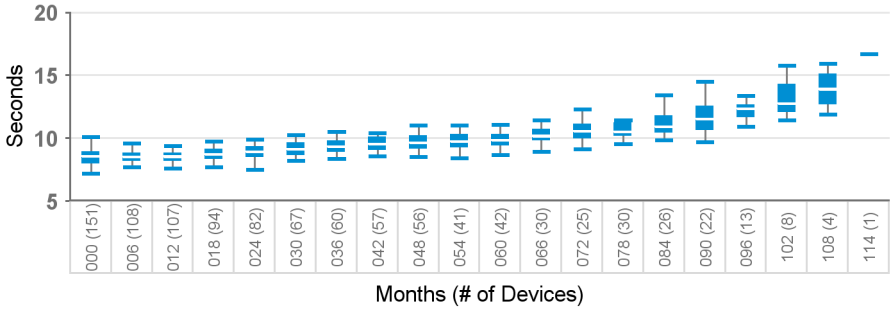
D264TRM, D284TRK, D384TRx, D394TRx

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



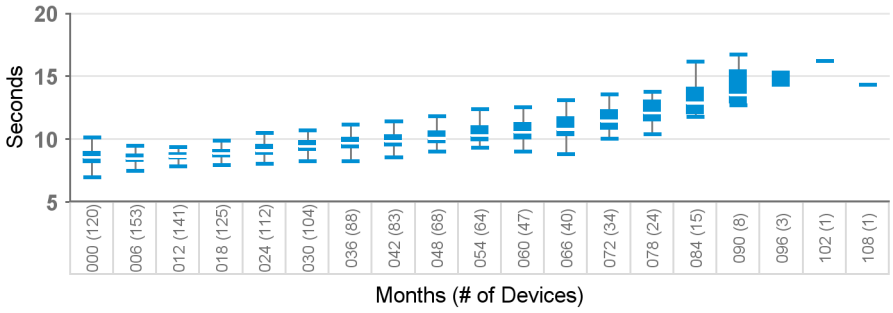
D264VRM, D284VRC, D384VRx, D394VRx

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



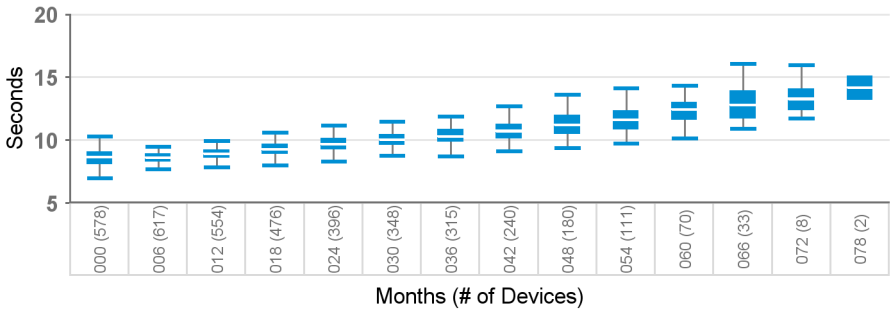
D274DRG, D294DRG

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



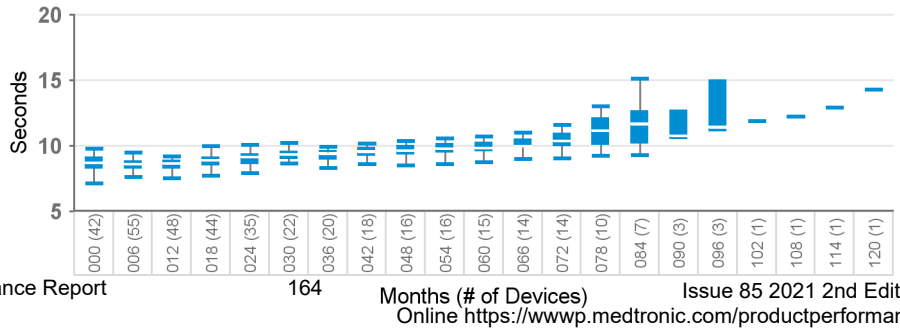
D274TRK, D294TRK

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



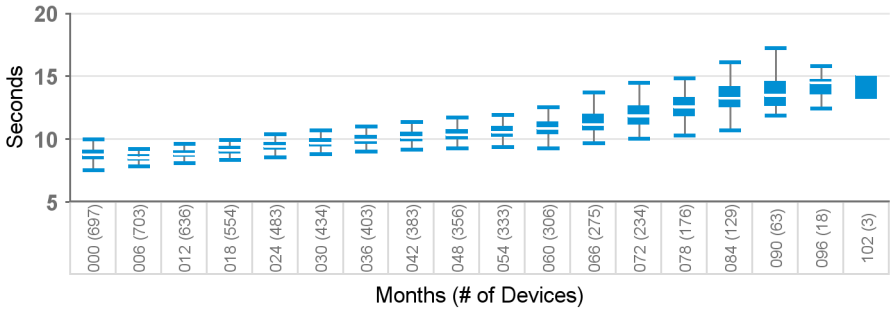
D274VRC, D294VRC

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



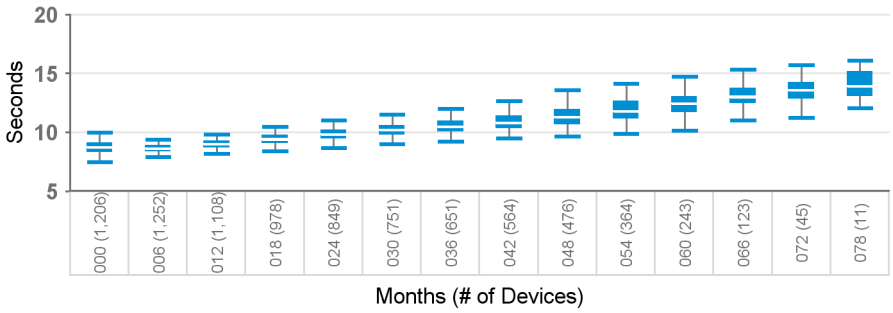
D314DRx

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



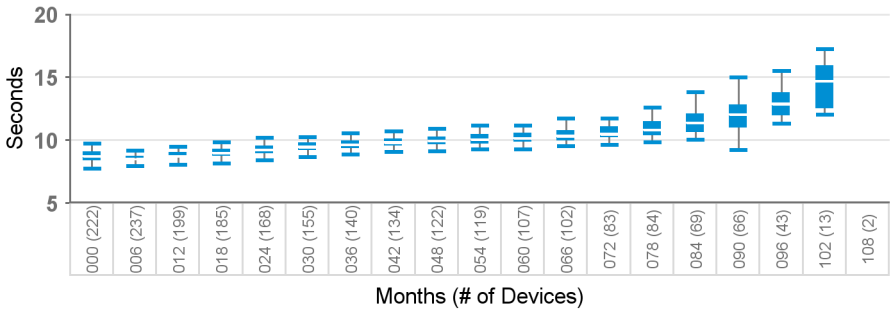
D314TRx

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



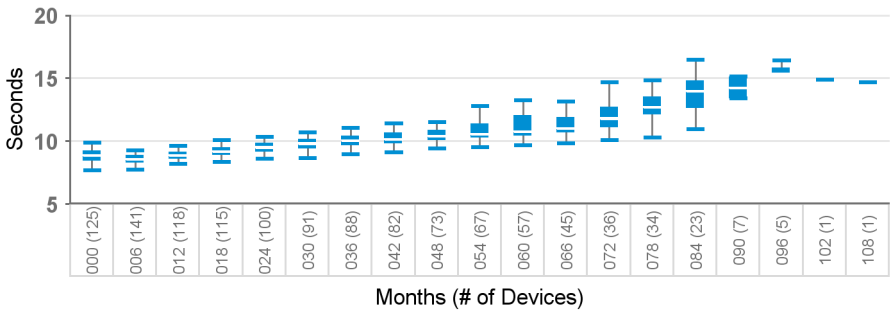
D314VRx

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



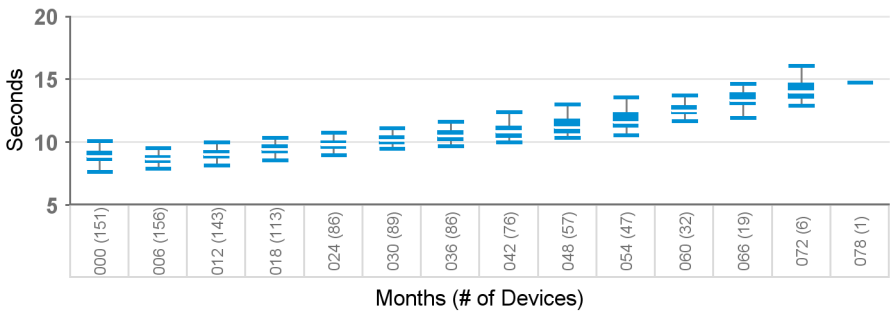
D334DRx, D364DRx

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



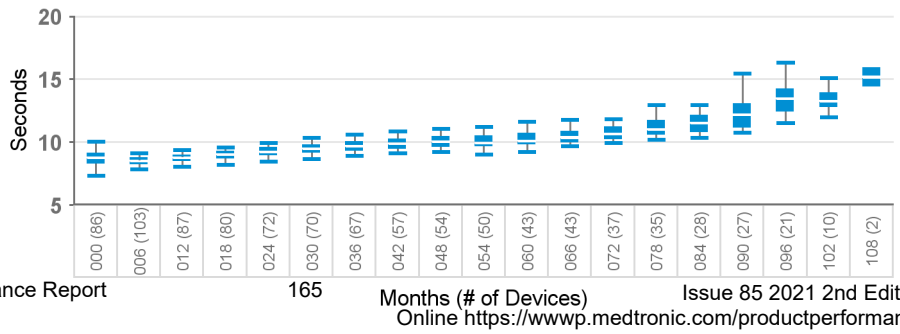
D334TRx, D364TRx

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



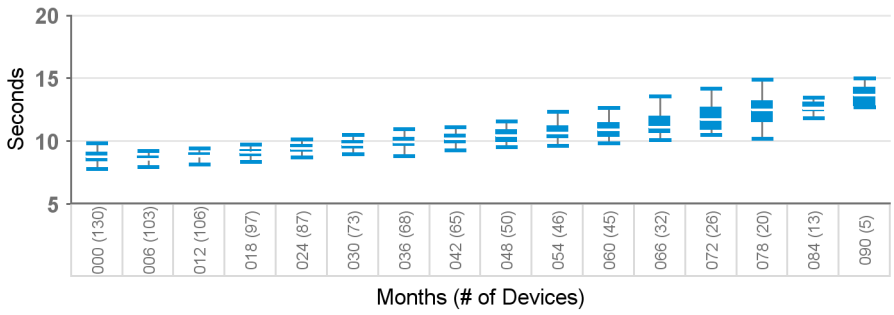
D334VRx, D364VRx

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



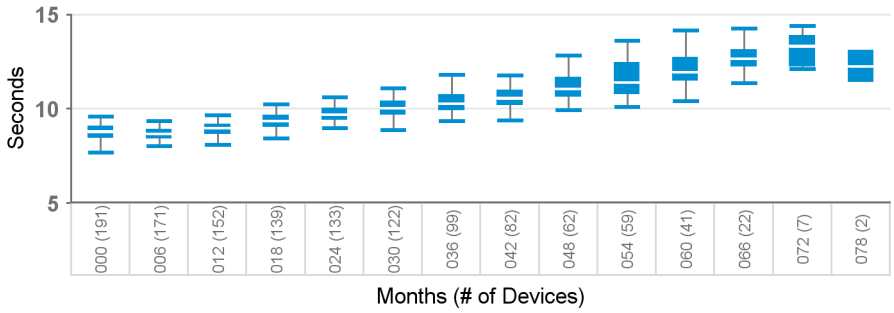
D354DRx

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



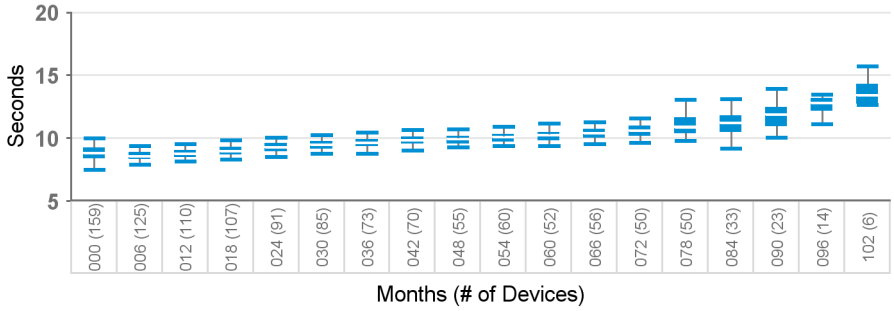
D354TRx

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



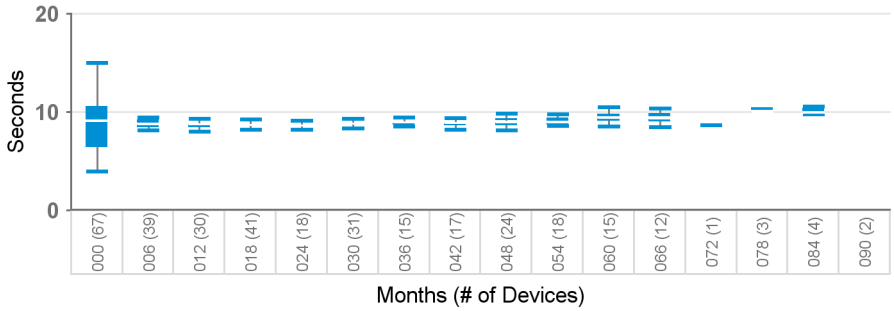
D354VRx

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



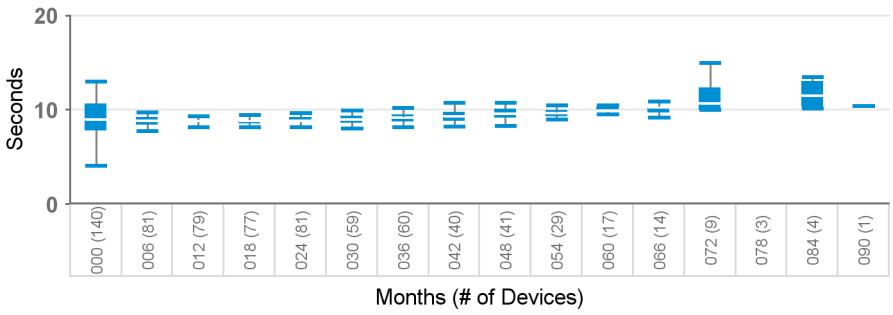
DDxxxxx, DR

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



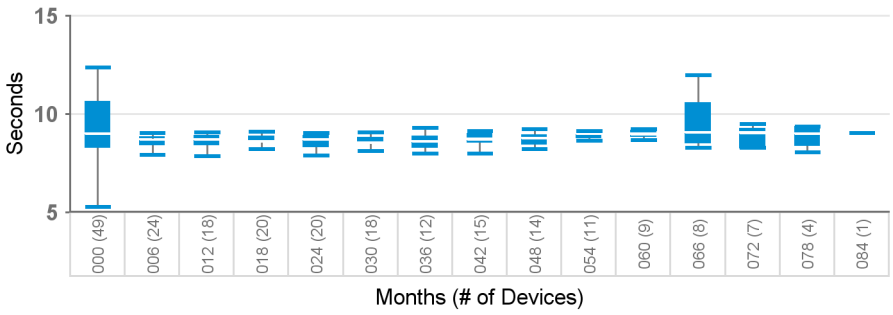
DTxxxxx, CRT-D

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



DVxxxxx, VR

Model Number	Brand
DVAB1D1	Visia AF
DVAB1D4	Visia AF
DVAB2D1	Visia AF XT
DVAC3D1	Visia AF S
DVBB1D1	Evera XT
DVBB1D4	Evera XT
DVBB2D1	Evera XT
DVBB2D4	Evera XT
DVBC3D1	Evera S
DVBC3D4	Evera S
DVFB1D1	Visia MRI AF
DVFB1D4	Visia MRI AF
DVFB2D1	Visia MRI AF XT
DVFB2D4	Visia MRI AF XT
DVFC3D1	Visia MRI AF S
DVFC3D4	Visia MRI AF S
DVMB1D4	Evera MRI XT
DVMB2D1	Evera MRI XT
DVMB2D4	Evera MRI XT
DVMC3D1	Evera MRI S
DVMC3D4	Evera MRI S
DVMD3D1	Primo
DVMD3D4	Primo
DVME3D1	Mirro
DVME3D4	Mirro



Procedure Education Brief: Micra TPS Implant

Micra TPS devices

Original Date of Communication: November 2021

Overview

This Medtronic Procedure Education Brief provides a reminder of specific implant procedure safety recommendations included in the current labeling for Micra™ VR and Micra™ AV Transcatheter Pacing System (TPS) specifically from the Micra Instructions for Use (IFU) and the Micra implanter training program. Following instructions provided in the IFU and implanter training can reduce the risk of cardiac perforation, especially considerations for delivery system steering, repositioning the device, and patient selection.

Micra IFU and Implant Procedure Training

The Micra IFU is available on the Medtronic electronic manuals website (https://manuals.medtronic.com/manuals/main/region). Implanter training material for implanters who have attended training, and been certified to implant Micra TPS, can be found on the Medtronic Academy website (https://www.medtronicacademy.com/products/micra-transcatheter-pacing-systems-overview-and-training). These instructional materials provide recommendations that limit implant complications such as:

- patient selection considerations to minimize perforation risk
- steering the delivery system with the use of fluoroscopy
- identifying implant location at the right ventricular septum with the use of contrast-enhanced fluoroscopy
- confirming position on the septum with contrast-enhanced fluoroscopy prior to deployment
- considerations for repositioning the device
- ensuring attending staff are prepared to manage pericardial effusion and tamponade, including immediate access to echocardiography equipment and availability of a pericardiocentesis kit
- recognizing clinical signs and symptoms of pericardial effusion and tamponade in order to minimize clinical response time
- preparedness for cardiac surgical intervention

Micra Safety and Effectiveness Data

On 17 November 2021, the US FDA posted a Letter to Healthcare Providers (*Leadless Pacing Systems: Risk of Major Complications Related to Cardiac Perforation During Implantation - Letter to Health Care Providers*) reminding physicians about the rare but possible risk of cardiac perforations associated with leadless pacemaker implantation. They reiterated the specific recommendations from Medtronic Micra implant training and IFU (reviewed above). This communication can be found here: https:/www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers.

While regulatory agencies and Micra implanters are aware that cardiac perforation is a known risk, the FDA Letter to Healthcare Providers included data for which implanters may be seeking additional context. The letter indicated that risk of cardiac perforation between transvenous pacing implants and Micra implants are similar, and that Micra implant complication rates are within expectations. The letter also indicated that in some scenarios, when a perforation occurs with a Micra implant procedure, the severity of the perforation complications can be higher than when a perforation occurs with a transvenous implant procedure.

Data from our Global Complaint Handling database suggests that the Micra rate of perforation is 0.6% and the rate of perforation related death is 0.13% out of over 100,000 implants worldwide. The Micra real-world perforation rate is in-line with, or lower than, the perforation rate observed in pre-market or post-market clinical studies[1].

Since Micra received pre-market approval in 2016, Medtronic has continuously monitored its safety and effectiveness. Multiple studies have shown that Micra has a high rate of implant success (exceeding 99%)[2,3]. Additionally, in the global Micra Investigational Device Exemption (IDE) Trial, Micra has been shown to reduce the risk for major complications compared to transvenous implants (through 12-months) by 48%[2], and in the global Micra Post Approval Registry by 63%[3].

Medtronic is further assessing the outcomes of Micra in the Micra Coverage with Evidence Development (CED) Study, which is a continuously enrolling, observational, cohort study evaluating complications, utilization, and outcomes of Micra.

Recent publications from the Micra CED Study in July 2021[4] and November 2021[5] based on 5,746 Micra patients and 9,622 with contemporaneously implanted transvenous single-chamber pacing patients show that at time of implant, Micra patients tend to be sicker than the transvenous single-chamber pacemaker population. Micra patients have a higher comorbidity burden as measured by the Charlson comorbidity index (5.1 vs 4.6, P<0.001) and a higher rate of end stage renal disease (12.0% vs 2.3%, P<0.001)[4]. Acute and longer-term outcomes reported in these publications are shown in the table below.

Measure	Unadjusted Results (Micra vs Transvenous-VVI)	Results Adjusted for Patient Medical History (Micra vs Transvenous-VVI)
Acute (30-day) device-related complications including dislodgement, infection, pocket complications[4]	1.4% vs 2.6% (P<0.001)	1.4% vs 2.5% (P<0.001)
Total acute (30-day) complications[4]	8.4% vs 7.3%(P=0.02)	7.7% vs 7.4% (P=0.49)
Cardiac perforation/effusion[4]	0.8% vs 0.4% (P<0.001)	0.8% vs 0.4% (P<0.001)
30-day all-cause mortality[5]	4.4% vs 3.8% (P=0.10)	4.0% vs 4.4% (P=0.60)
2-year reintervention rate[5]	3.0% vs 4.8% (P=0.006)	3.1% vs 4.9% (P=0.003)
2-year chronic complications[5]	4.9% vs 6.5% (P<0.001)	4.6% vs 6.5% (P<0.001)
2-year all-cause mortality[5]	34.0% vs 31.6% (P=0.002)	31.4% vs 32.5% (P=0.37)

Medtronic monitors and evaluates product performance and publishes device performance data on our product performance website http://productperformance.medtronic.com. In addition, Medtronic continues to collaborate with physicians and regulatory agencies to improve patient outcomes and clinical experience as part of our dedication to patient safety and product effectiveness.

---

[1] Micra IDE: 1.8% (13/726), Micra post-approval registry 0.8% (15/1811), Micra Coverage with Evidence Development 0.8% (47/5746)

[2] Reynolds et al. NEJM 2016; 374(6): 533-541.

[3] El-Chami et al. Heart Rhythm 2018; 15(12): 1800-1807.

[4] Piccini et al. JAMA Cardiology 2021; 6(10): 1187-1195.

[5] El-Chami et al. EHJ 2021; ePub ahead of print

Software Update - SmartSync Error Message on Device Interrogation

CareLink SmartSync™ Device Manager supporting Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: October 2021

STATUS UPDATE - NOVEMBER 2021

Through 09 November 2021, Medtronic has confirmed 23 reports of a software interrogation failure due to this issue out of approximately 56,500 devices distributed worldwide (0.041%). No permanent patient harms have occurred.

ORIGINAL COMMUNICATION - OCTOBER 2021

This communication provides notice of **a software update for CareLink SmartSync™ Device Managers (SmartSync)** to correct the potential for a small number of SmartSync interrogation sessions, or CareLink network transmissions to fail due to a software error. The issue described below can only occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds) when the current session data includes diagnostic episodes with a specific type of VT/VF therapy sequences.

Please install **application software D00U005 version 5.0.0** (or higher) on all SmartSync tablets in your facility. This software update ensures SmartSync tablets will interrogate all episode and data types for all programmer sessions. No programming or reprogramming of devices is required.

ISSUE DETAILS

With prior software versions, a small number of SmartSync interrogation sessions, or CareLink network transmissions may fail for Cobalt or Crome devices when the current session diagnostic data includes any VT/VF episode type with multiple therapy sequences and three or more data recording suspensions. For these specific episodes, the software is unable to decode and process the data. SmartSync will display a message indicating an "Unexpected error occurred", and the application software requires restarting. Within CareLink, the current transmission processing may fail, and the information will not be viewable. For both of these scenarios Medtronic Technical Services can assist clinicians with retrieving stored device information for the failed transmission.

Through 24 Sep 2021, Medtronic has confirmed 22 reports of a software interrogation failure due to this issue out of approximately 48,700 devices distributed worldwide (0.045%). No permanent patient harms have occurred.

No device operations are affected by the software error. All device features and therapies continue to operate as programmed. Risks associated with an interrogation failure are potential for unnecessary device replacement, and/or delays in patient care due to missed Care Alerts, or inability to access stored device

diagnostic information until a SmartSync tablet with the updated software is located, and a new session can be established.

The SmartSync software release D00U005 version 5.0.0 is available for immediate download on to all tablets. (Software availability varies by geography.) A CareLink software update is anticipated to be released in mid-2022.

PATIENT MANAGEMENT RECOMMENDATIONS

We realize that each patient requires unique clinical considerations. Medtronic recommends physicians follow normal clinical practices given these devices will continue to operate as programmed:

- If a failure to interrogate a Cobalt or Crome device occurs with a SmartSync programmer, confirm that the SmartSync application software has been updated to D00U005 version 5.0.0 (or higher). Contact your Medtronic representative or Tachy Technical Services at 800-723-4636 for assistance with retrieving the session data.

  Note: Cobalt and Crome devices are only supported by the SmartSync programmer; these devices are not supported by the Model 2090 and Encore programmers.

- If a CareLink transmission is attempted, but the transmission is not viewable on the CareLink network (i.e., the transmission is missing from the transmission list for the patient), contact Medtronic Technical Services at 800-723-4636 for assistance. This team can help with retrieving the transmission data and/or provide additional troubleshooting guidance that may be needed. Missing transmissions can occur due to connectivity or other issues and may be unrelated to the software decode error described in this letter.

LINQ II - Brady, Pause and PVC Detections Disabled Following Electrical Reset SN 08-Sep-2021

LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

STATUS UPDATE – NOVEMBER 2021

Medtronic implemented a manufacturing update to all newly manufactured LINQ II ICMs released into distribution to prevent a partial electrical reset from disabling Brady, Pause and PVC event detection.

Updated LINQ II ICMs can be identified, before being implanted, by the GTIN that is printed under the barcode on the box. The new U.S. LINQ II GTIN ends with "002."

As a reminder, unused LINQ II devices manufactured prior to June 2021 were requested to be returned to Medtronic per the Original advisory (dated June 2021) – these devices cannot be updated in the field and will continue to be susceptible to the issue.

ORIGINAL COMMUNICATION – JUNE 2021

This notice is to inform you that LINQ II insertable cardiac monitors (ICMs) that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause and PVC events to clinicians. Medtronic estimates that 0.21% of LINQ II ICMs have experienced a partial electrical reset resulting in the inability to detect Brady, Pause and PVC events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady, Pause and PVC episode types will not be reported to the clinician.

- A correction for currently implanted LINQ II ICMs is not available.
- We are requesting that hospitals quarantine all LINQ II ICMs on hospital shelves. Physicians should cease implanting any remaining LINQ II ICMs that may remain in shelf stock and return any unused product to Medtronic.
- There will be an update for future manufactured LINQ II ICMs, which is anticipated to be available in the U.S. July 2021.

This letter contains a description of the information known to date and patient management recommendations.

ISSUE DESCRIPTION

Medtronic has identified that LINQ II ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady, Pause, and PVC events. A partial electrical reset is normal behavior that can occur when the device detects a possible issue with the device software. However, an error in the partial electrical reset implementation is causing this unintended behavior.

All LINQ II ICM devices currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 37 complaints related to an electrical reset. The projected rate of a LINQ II ICM experiencing a partial electrical reset that results in the inability to detect Brady, Pause, and PVC events is 0.73% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady, Pause, and/or PVC events, and an explant procedure.

If a partial electrical reset occurs, CareLink™ and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady, Pause, and PVC events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing and mark symptoms.

Tachy and AT/AF detections are not affected by a partial electrical reset.

HOSPITAL RISK MANAGER ACTIONS (U.S. CUSTOMERS ONLY)

Medtronic is requesting customers with affected product on hand to take the following actions:

1. Identify and quarantine all unused affected Medtronic LINQ II ICMs.
2. Return all unused affected product in your inventory to Medtronic. Contact Medtronic Customer Service at 1-800-848-9300 to initiate a product return. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
3. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).
4. Complete the enclosed Confirmation Form and email to RS.CFQFCA@medtronic.com

PATIENT MANAGEMENT RECOMMENDATIONS

If an electrical reset has never occurred, all detection criteria are being monitored and recorded as programmed. Continue with normal follow-up per local clinic protocols for these patients.

Identifying if an electrical reset has occurred:

For patients who are actively followed on CareLink in the U.S: During our investigation of this issue, we identified patients whose device showed evidence of a partial electrical reset as of 10 May 2021. For those clinicians with identified patients, a supplemental letter was provided. If you have not received a supplemental letter, then none of your patients who are actively transmitting on CareLink were identified as having a recorded electrical reset event during our investigation.

All patients, including those on CareLink, should be carefully monitored for reports of an electrical reset condition. Follow instructions below.

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. **Note:** Once cleared, electrical reset notifications are no longer accessible.

- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady, Pause or PVC events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

Patients with a confirmed partial electrical reset:

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady, Pause, or PVC events, device replacement may be appropriate. Consider the following before device replacement:
    - It is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue.
    - If replacement is desirable, consider Reveal LINQ with TruRhythm™ or alternative ICM. While Reveal LINQ devices are also are susceptible to this issue (see correction notice, Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems Brady & Pause Detections Disabled Following Partial Electrical Reset), the observed rate is 0.049% for Reveal LINQ with TruRhythm ICMs compared to 0.21% for LINQ II ICMs.

      Note: Implanted Reveal LINQ with TruRhythm ICMs have the ability to receive a future software update to correct this issue, which will be implemented via the Model 2090 and Encore™ programmers, and is anticipated to be available in the U.S. late calendar year 2021.

    - Future manufactured LINQ II devices will have a correction for this issue implemented during manufacturing pending regulatory approval of the corrective fix, but initial supply may be limited.

- As a reminder, per the LINQ II ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

Reveal LINQ with TruRhythm - Brady & Pause Detections Disabled Following Electrical Reset

Reveal LINQ with TruRhythm Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

STATUS UPDATE - NOVEMBER 2021

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

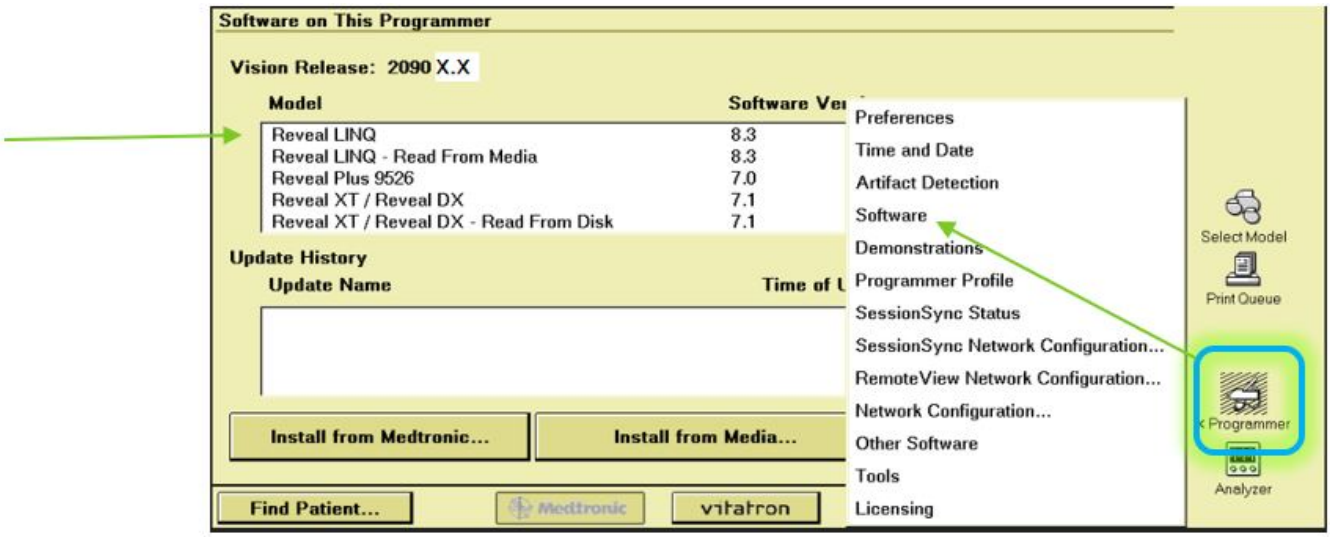
Software Update Available

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)?

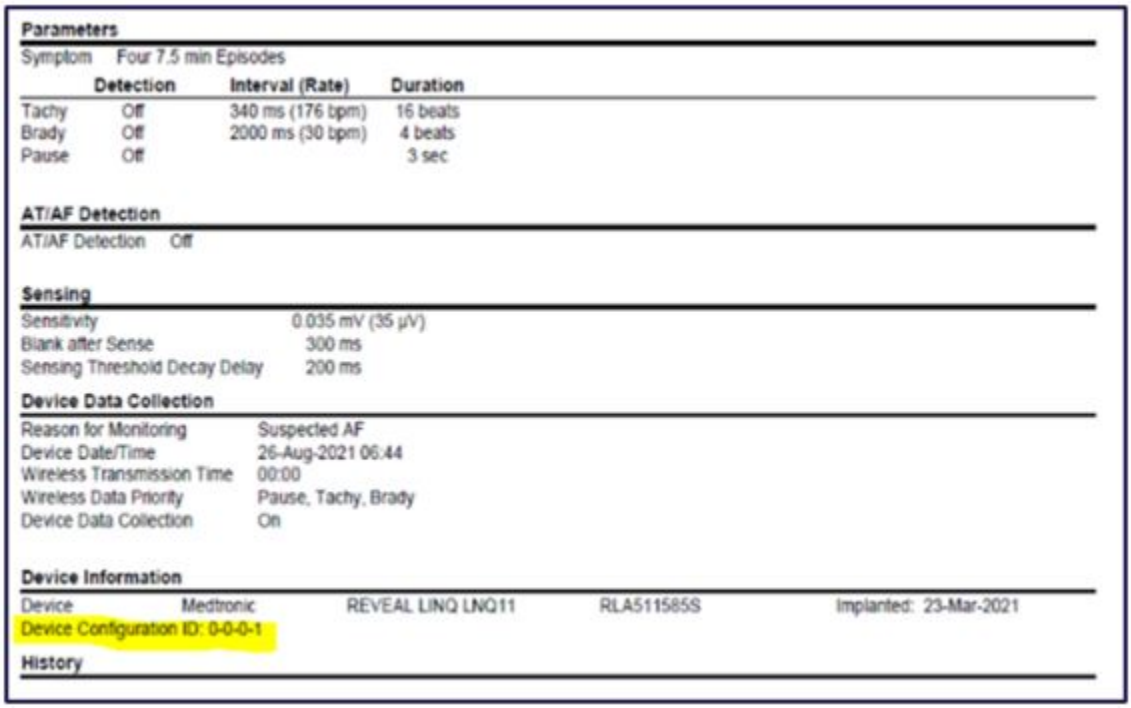
From the Find Patient screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.



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.



Parameters

Symptom Four 7.5 min Episodes

	Detection	Interval (Rate)	Duration
Tachy	Off	340 ms (176 bpm)	16 beats
Brady	Off	2000 ms (30 bpm)	4 beats
Pause	Off		3 sec

AT/AF Detection

AT/AF Detection Off

Sensing

Sensitivity	0.035 mV (35 µV)
Blank after Sense	300 ms
Sensing Threshold Decay Delay	200 ms

Device Data Collection

Reason for Monitoring	Suspected AF
Device Date/Time	26-Aug-2021 06:44
Wireless Transmission Time	00:00
Wireless Data Priority	Pause, Tachy, Brady
Device Data Collection	On

Device Information

Device Medtronic REVEAL LINQ LNQ11 RLA511585S Implanted: 23-Mar-2021

Device Configuration ID: 0-0-0-1

History

SmartSync Longevity Estimation Software Error

Percepta MRI, Serena MRI and Solara MRI CRT-P devices

Original Date of Communication: April 2021

STATUS UPDATE – NOVEMBER 2021

Through 8th November 2021, Medtronic has received 6 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue.

This advisory has been addressed through release of new software to correct the longevity estimation error. Software updates are now available for SmartSync to correct this programmer display issue (Percepta™ /Serena™/ Solara™, D00U004, version 4.0 or higher). Clinicians may update their SmartSync App by connecting their tablet to the internet and accepting the update. Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel may assist with updating SmartSync tablets in your account. Refer to the original communication (below) for additional details.

ORIGINAL COMMUNICATION - APRIL 2021

This notice provides information on the availability of a software update for CareLink SmartSync™ Device Managers (SmartSync) supporting Medtronic Percepta™, Serena™, Solara™ cardiac resynchronization therapy pacemakers (CRT-P). This update addresses a SmartSync software issue that results in an overestimation in the displayed longevity of these devices during an approximate 6-month window of time before the device triggers its Recommended Replacement Time (RRT).

Through 09 March 2021, Medtronic has received four (4) complaints due to this issue. No adverse events or permanent patient harm have been reported related to this issue. If the software update is not applied to SmartSync, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention. Battery performance is not affected by this programmer display error. RRT will alert appropriately, and if patients are followed per standard clinical practice, the risk to patients is minimal.

The SmartSync software application uses measured battery voltage to detect when the device is within approximately 6 months of its RRT voltage threshold. It is during this period prior to RRT that the software incorrectly calculates remaining longevity due to an error in the software algorithm.

An overestimation error only occurs when the device is interrogated with SmartSync and the device is within approximately 6 months of its RRT indicator. Correct remaining longevity estimates will be reported through interrogations done via a Model 2090 or Encore programmer, and through CareLink remote monitoring transmissions. Note, other devices supported by SmartSync are not affected by this error.

Software updates are now available for SmartSync to correct this programmer display issue (Percepta™ /Serena™/ Solara™, D00U004, version 4.0). Clinicians may update their SmartSync App by connecting their tablet to the internet and accepting the update. Based on your facility's needs and accessibility, once the software is available, a Medtronic Representative or authorized personnel may assist with updating SmartSync tablets in your account.

Once updated, SmartSync longevity estimates for these devices will no longer be affected by this issue. No change in patient management is necessary. There is no need to schedule patients to come in before their next regularly scheduled follow-up visit. The patient's device does not require an update.

Unipolar Longevity Estimation Software Error

Azure/Astra DR and SR Pacemakers and Percepta/Serena/Solara CRT-Ps

Original Date of Communication: April 2021

STATUS UPDATE – NOVEMBER 2021

Through 9th November 2021, Medtronic has received 18 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue.

This advisory has been addressed through release of new software to correct the longevity estimation error. Software updates are now available for Medtronic model 2090, Model 29901 Encore programmers, and SmartSync to correct this programmer display issue (see Table 1 below).

Medtronic 2090 and Encore Programmer Software Update	Medtronic SmartSync Software Update
Azure™/Astra™ (SW030) v 8.2 Percepta™/Serena™/ Solara™ (SW040) v 8.4	Azure™/Astra™ (D00U003) v 4.0 Percepta™/Serena™/ Solara™ (D00U004) v 4.0

Table 1: Software updates by device family and programmer

Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will assist with installing software on programmers in your account. Until all SmartSync and Model 2090 and Encore programmers are updated to the version of software indicated in the table (or higher), a difference in longevity estimates may be displayed between programmers and the CareLink network due to this software error. Refer to the original communication (below) for additional details.

ORIGINAL COMMUNICATION - April 2021

This notice is to inform you of the availability of software updates to address a potential inaccurate longevity estimate that may occur with the Azure™ and Astra™ family of pacemakers (IPGs) and the Percepta™, Serena™, Solara™ family of cardiac resynchronization therapy pacemakers (CRT-Ps). A longevity estimation error may occur in the early years of device life when a unipolar pacing vector is programmed in the right atrial (RA) lead and/or the right ventricular (RV) lead. No other device features or therapies are impacted. For devices programmed to bipolar pacing in both the RA and RV chambers, the longevity estimates are not affected by this issue.

Through 05 March 2021, Medtronic has received 13 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue. If the software update is not applied to the programmer, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention. Battery performance is not affected by this programmer display error. RRT will alert appropriately, and if patients are followed per standard clinical practice, the risk to patients is minimal.

The longevity estimation error associated with unipolar pacing configurations occurs only in the first half of the device life (prior to 50% depletion of the battery). During this phase, the estimator algorithm utilizes lead impedance as an input. When a unipolar pacing configuration is programmed, the algorithm incorrectly uses the bipolar lead impedance as input (rather than the appropriate unipolar pacing lead impedance). As a result, the algorithm will over-estimate the remaining longevity during this phase. At all times, RRT, Elective Replacement Indication, and End of Service will accurately display on programmers – even if the software update has not yet been installed.

Software updates are now available for Medtronic model 2090, Model 29901 Encore programmers, and SmartSync to correct this programmer display issue (see Table 1 below).

Medtronic 2090 and Encore Programmer Software Update	Medtronic SmartSync Software Update
Azure™/Astra™ (SW030) v 8.2 Percepta™/Serena™/ Solara™ (SW040) v 8.4	Azure™/Astra™ (D00U003) v 4.0 Percepta™/Serena™/ Solara™ (D00U004) v 4.0

Table 1: Software updates by device family and programmer

As of 26 March 2021, Medtronic CareLink network has been updated and will display correct longevity estimates for devices affected by this issue. Azure IPG and Percepta/Serena/Solara CRT-P patients remotely monitored via the MyCareLink Heart™ mobile app will automatically receive an updated longevity estimate on their mobile app with their next scheduled transmission or within 92 days of their last longevity update, whichever occurs first.

No change in patient management is necessary. Per labeling, the RRT notification can be used to identify when device replacement should be scheduled. There is no need to schedule patients to come in before their next regularly scheduled follow-up visit. The corrective fix for this error is implemented in programmers and the CareLink network. The patient's implanted device does not require an update.

Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will assist with installing software on programmers in your account. Until all SmartSync and Model 2090 and Encore programmers are updated, a difference in longevity estimates may be displayed between programmers and the CareLink network due to this software error.

Potential for Shortened RRT-to-EOS in Subset of ICDs and CRT-Ds

Subset of ICDs and CRT-Ds

Original Date of Communication: February 2021

STATUS UPDATE – NOVEMBER 2021

As of 4 November 2021, approximately 299,440 devices susceptible to this issue are estimated to still be active worldwide. Observed rate of occurrence is 0.10% 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.

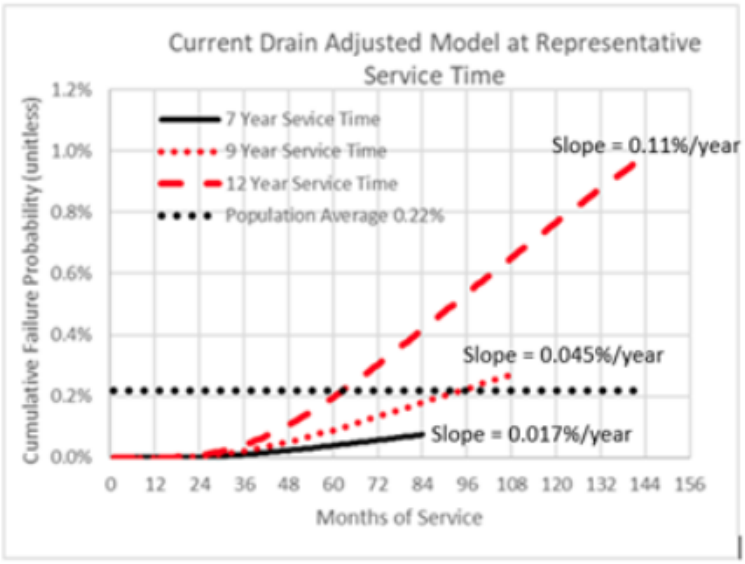
Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/

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.

Device Programming Information - Setting VF ATP During Charging Therapy

Cobalt™ XT, Cobalt and Crome™ ICDs and CRT-Ds

Original Date of Communication: September 2020

STATUS UPDATE – NOVEMBER 2021

As of 08-Nov-2021, Medtronic has received 11 complaints (out of 56,552 devices sold worldwide) related to this issue. No serious adverse events have been reported.

ORIGINAL COMMUNICATION - SEPTEMBER 2020

This communication provides information about the programming of *Ventricular Fibrillation Antitachycardia Pacing (VF ATP) During Charging.* When enabled, *VF ATP During Charging* allows the device to simultaneously deliver ATP therapy while charging to deliver a high-voltage VF therapy, if needed.

For Cobalt and Crome ICD and CRT-D devices, clinicians should confirm that the VF ATP parameterhas been set to the desired value. Depending on pre-implant programming sequences, the VF ATP parametermay not be automatically enabled and may require manual programming (see Image 1 below). In prior generations of Medtronic devices, the VF ATP parameter was automatically enabled with all VF therapies.

As of 21-Sept-2020, Medtronic has received one (1) complaint (out of 3,237 devices sold worldwide) related to this issue. No serious adverse events have been reported.

These devices will deliver all programmed high-voltage therapies as expected, regardless of the VF ATP parameter setting. Likewise, all device functions will operate as programmed. If the VF ATP is not enabled, there is risk for a high-voltage therapy to be applied for a Fast VT arrhythmia in the VF detection zone, which could have been treated with ATP During Charging.

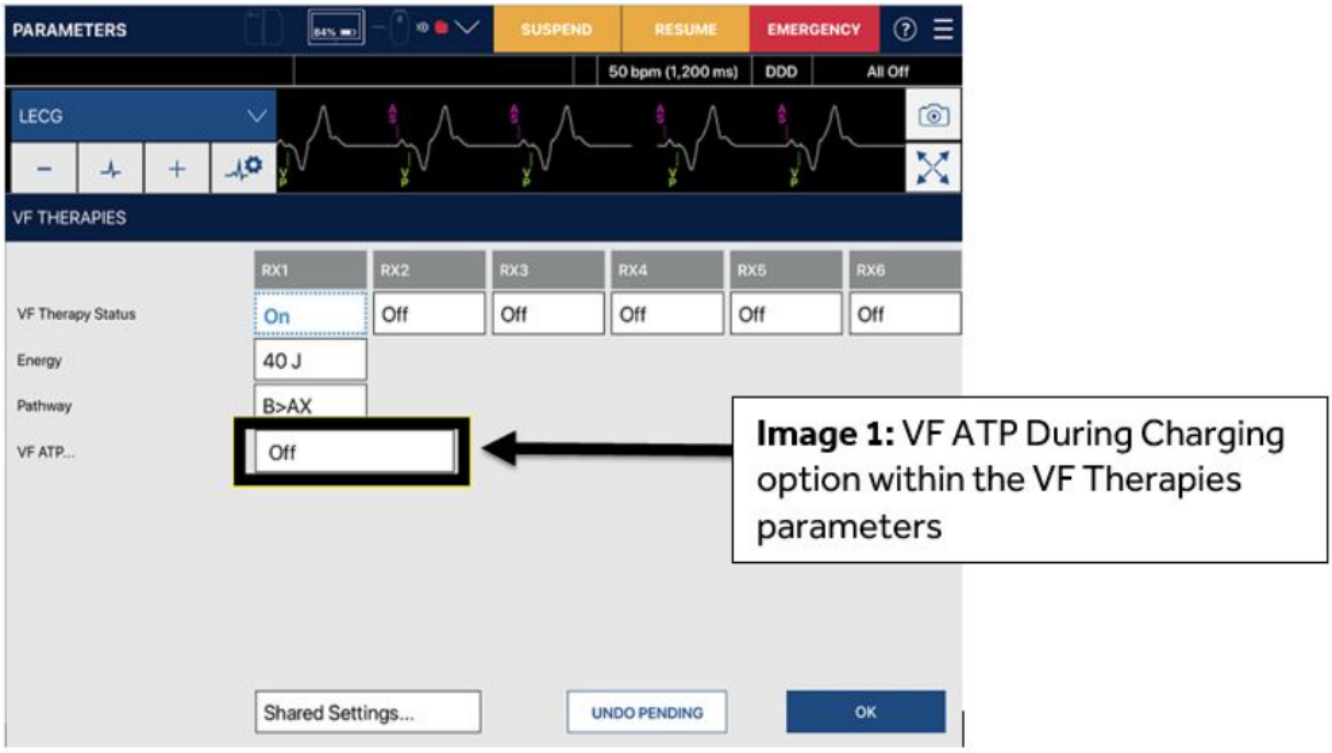


Image 1: VF ATP During Charging option within the VF Therapies parameters

Clinician Actions

We realize that each patient requires unique clinical considerations. With deference to those considerations, Medtronic recommends physicians follow normal clinical practices, including:

- At implant, as described in labeling, confirm the appropriate selection has been programmed for the VF ATP parameter.
- At routine follow-up, confirm that the VF ATP parameter is programmed to the desired setting for each patient.

CFx Longevity Estimator Software Error - Software Updates Available June 2020

Subset of IPG, ICD, CRT-P, CRT-D, and Micra TPS devices - June 2020

Original Date of Communication: June 2020

STATUS UPDATE – NOVEMBER 2021

This advisory has been addressed through release of several new software updates. The complete list of software applications available are listed in the table below. Medtronic representatives will work with local clinic and hospital staff to update programmers. Once a programmer has been updated with the version of software indicated in the table (or higher), the correct longevity estimate for the affected devices will be displayed.

Note that as of September 2020 the Medtronic CareLink Network was updated for this advisory. All longevity estimates displayed on CareLink reflect accurate estimates (based on programmed settings and use conditions recorded by the device).

Phase 1 – June 2020	Phase 2 – January 2021
Azure™/Astra™ (SW030) v 8.1	Viva™/Brava™/ Evera (SW016) v8.4
Serena™/ Solara™/ Percepta™ (SW040) v 8.3	Evera™ MRI/ Primo™ MRI/ Mirro™ MRI(SW033) v8.5
Visia AF™/ Visia AF™ MRI (SW035) v 8.2	Micra™ VR TPS (SW033) v8.2
Claria™/ Amplia™/ Compia™ (SW034) v 8.4 (US Only)	Claria™/ Amplia™/ Compia™ (SW034) v 8.5

Table 1: Device family updates by phases

Note: The availability of software releases is specific to countries that follow FDA and CE Mark approvals. Release timing may differ for other geographies. Check with your local Medtronic representative.

As of November 8, 2021, there have been 746 total complaints received related to the software displaying a lower-than-expected longevity estimate. Within the 746 complaints reported, no patient harm was reported and 19 devices were prematurely explanted after observing an inaccurate longevity estimate.

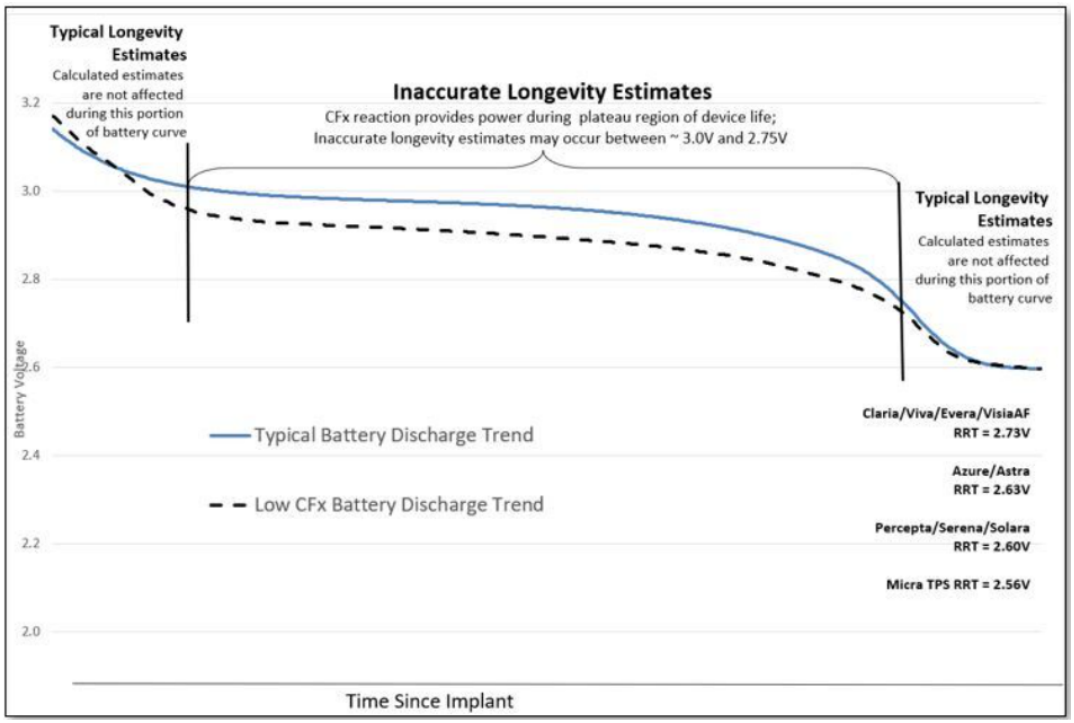
ORIGINAL COMMUNICATION - JUNE 2020

In October 2019, Medtronic identified the potential for Medtronic programmer and remote monitoring software applications to display an inaccurate remaining longevity estimate for a subset of implanted cardiac device models. This issue does not impact device functionality. Furthermore, the Recommended Replacement Time (RRT) remains an accurate indicator for device replacement.

Through September 18, 2019 there have been three (3) reported complaints and there have been no (0) serious adverse events or deaths.

The inaccurate longevity estimation is limited to a well-defined subset of devices manufactured between October 2018 and April 2019, and only occurs in the middle (plateau) phase of the device life, as illustrated in the graph below. Approximately 53,100 devices worldwide, out of 1.23 million distributed or sold from the identified device families, are susceptible to displaying inaccurate longevity.

The cause of the inaccurate longevity estimate is a slightly lower-than-typical discharge voltage during the plateau phase of the battery depletion curve (dashed line), compared to a typical voltage plateau (solid line), as illustrated in the graph below. During this plateau period, the Carbon Monofluoride (CFx) in the battery cathode is powering the device. Note, longevity estimates early after implantation and later in the device life are unaffected, as shown below. The battery remains within operating specifications.



The Independent Physician Quality Panel recommends routine follow up in accordance with standard practice for these devices, as RRT function is normal and the battery longevity is unaffected. There is no need to schedule patients to come in outside of their planned, scheduled visits due to this issue.The corrective fix is implemented in programmers, CareLink, and other systems which display device longevity. The patient's device does not require an update. Follow the steps below as applicable to your clinic or hospital. A local Medtronic Representative can assist in updating Model 2090/Encore programmers and SmartSync Device Managers in your facilities.

- Model 2090 and Encore™ Programmers

  These programmers will require new software to be installed to correct the displayed longevity estimator error. The software applications and version are listed in Table 1 above and can be installed via Medtronic Software Distribution Network (SDN) or via secure USB.

- SmartSync™ Device Managers

  These tablet-based programmers will require a software update to be installed via the internet - refer to Appendix A (below) for detailed instructions on how to download and install the updated application software.

Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions. Based on your facility's needs and accessibility, Medtronic Representative or authorized personnel will work with your facility as requested to complete the updates. Customers with Paceart systems should contact their support team to ensure the latest device update is applied.

Note: Once a programmer is updated, the correct longevity estimate will display at the patient's next regularly scheduled clinic visit. Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, a difference in longevity estimates between programmers and CareLink Network-displayed longevitymay be observed.

APPENDIX A – UPDATING SMARTSYNC™ DEVICE MANAGER

Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, you may observe a difference in longevity estimates between these programmers and CareLink-displayed longevity.

Updating Medtronic SmartSync™ Device Managers:

1) Connect tablet to internet and open the SmartSync App

- The SmartSync App automatically checks for available updates each time it is opened.

2) If your tablet does not contain the most recent software, you will automatically receive a notification that a new version of the SmartSync App is available (3.2.01):

- If pop-up messages appear with the option to "cancel" or to "update", select "update".
  - **Medtronic Managed Tablets:** If the App closes, find the Medtronic App Catalog, and select **"Install"** to initiate the download.
  - **Customer Owned Tablets:** If the App closes, navigate to the AirWatch App Catalog or App Store and **select "Install" t**o initiate the download.
- If you do not receive a notification that a new version of the SmartSync App is available, skip to Step 3.

3) Once you confirm the newest version of the SmartSync App is on your tablet, re-open the SmartSync App.

- The app will automatically provide pop-up notifications informing you if there are new versions of device software applications that must be installed (see table below).
  - Select CONTINUE for each pop-up window that appears. If you do not receive any pop-up notifications when you open the SmartSync App, then your tablet contains the most recent versions of all available software.

Device Family	SmartSync Application SW Version
Azure™/Astra™ DR and SR	D00U003, Version 3.2.02
Percepta™/Serena™/Solara™	D00U004, Version 3.2.02

SmartSync Device Manager Telemetry Issue – Software Updates Available June 2020

Azure™ pacemakers, and Percepta™, Serena™, Solara™ CRT-pacemakers

Original Date of Communication: June 2020

STATUS UPDATE – NOVEMBER 2021

As of 8 November 2021, Medtronic has received thirty-six (36) complaints due to this issue. No adverse events or patient harm have been reported.

This advisory has been addressed through release of new software. As described in the original advisory communication (June 2020), updates are available for the CareLink SmartSync Device Manager to address this issue. The SmartSync Device Manager software version 3.2.01 (or higher) can be obtained by connecting the tablet to the internet and accepting all application updates if/when prompted. A local Medtronic Representative can assist or advise your staff on the SmartSync update process as needed.

ORIGINAL COMMUNICATION – JUNE 2020

This communication provides notice on software updates available for CareLink SmartSync™ Device Managers supporting Medtronic Azure™ pacemakers, and Percepta™, Serena™, Solara™ cardiac resynchronization therapy pacemakers (CRT-P).

This update addresses a rare communication sequence during the first device interrogation with a SmartSync Device Manager that may result in the temporary suspension of some device features (i.e., battery measurements, Capture Management™, Atrial Lead Position Check™, EffectivCRT™ algorithms, and AdaptivCRT™). This rare interaction results in temporary suspension of automatic threshold testing and output adjustments, and suspension of auto-optimization of CRT therapy. The issue is unlikely to result in clinical impact to the patient, and features are restored upon next programmer device interrogation or presence of a magnet.

As of 8 May 2020, Medtronic has received sixteen (16) complaints due to this issue. The predicted rate of occurrence for this issue is 0.03% on first interrogation of an Azure, Percepta, Serena, or Solara device with a SmartSync programmer. No adverse events or patient harm have been reported. Based on consultation with the Independent Physician Quality Panel and considering that the issue is unlikely to result in clinical impact to the patient, routine patient follow-up in accordance with standard practice is recommended.

Updates are available for the CareLink SmartSync Device Manager to address this issue. The SmartSync Device Manager software version 3.2.01 update can be obtained by connecting the tablet to the internet and requesting all application downloads. The software update will modify the SmartSync Device Manager to prevent this issue from occurring; no patient actions are required.

A local Medtronic Representative can assist or advise your staff on the SmartSync update process as needed.

Azure S DR Atrial Lead Position Check (ALPC) Incorrectly Enabled – Software Update Available June 2020

Subset of Azure™ S DR pacemakers

Original Date of Communication: June 2020

STATUS UPDATE – NOVEMBER 2021

As of 8 Nov 2021, there have been eight (8) complaints reported due to the ALPC feature being enabled and over 45,000 devices distributed. No serious adverse events or patient harm have been reported.

This advisory has been addressed through release of new software to correct for the issue. Software application SW030 version 8.1 (or higher) must be installed on Model 2090 and Encore programmers to correct for this issue. Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel may assist with updating programmers in your account. Refer to the original communication (below) for additional details.

ORIGINAL COMMUNICATION – JUNE 2020

This communication provides notice on a software update available for a subset of Azure™ S DR pacemakers manufactured prior to February 2020 to addresses an issue in which the Atrial Lead Position Check (ALPC) was incorrectly enabled in a subset of this device model. ALPC is intended to operate as an optional feature in device models that offer atrial anti-tachy pacing therapies (ATP). Model Azure S DR does not offer atrial ATP. This update will ensure that ALPC is inactivated in all Azure S DR devices. Device therapies and battery performance are not affected by this issue.

As of 11 May 2020, there have been seven (7) complaints reported due to the ALPC feature being enabled and over 45,000 devices distributed. ALPC has the potential to pace at the programmed pacing rate for approximately 5 minutes at high output during its nightly assessment. No serious adverse events or patient harm have been reported.

Currently, updates are available for CareLink SmartSync™ Device Manager for this issue. The SmartSync Device Manager may receive software version 3.2.01 update by connecting the tablet to the internet. As of 4 June 2020, software application SW030 version 8.1 will be available via Medtronic Software Distribution Network (SDN) for Model 2090 and Encore programmers. In mid-June 2020, software application SW030 version 8.1will be available via secure USB for Model 2090 and Encore programmers.

Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions. Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel will assist with installing software on programmers in your account. Once a programmer is updated, the ALPC feature will be automatically inactivated at the patient's next regularly scheduled interrogation if the device is in scope of this issue. There is no need to schedule patients to come in outside of their planned, scheduled visits due to this issue.

Potential for Partial Reset During Programmer Interrogation

Claria MRI, Amplia MRI, Compia MRI and CRT-Ds

Original Date of Communication: March 2020

Model
CareLink™ 2090 Programmer with Software Application SW034 versions 8.3 and 8.4
CareLink™ 29901 Programmer with Software Application SW034 versions 8.3 and 8.4

STATUS UPDATE – NOVEMBER 2021

Medtronic has identified two versions of software that are susceptible to the one-time partial reset during programming interrogation – software applications SW034 version 8.3 and version 8.4. As documented in the original communication (March 2020), the risk for a partial reset on first interrogation with a programmer is approximately 2%. As of November 8, 2021, there are 448 complaints received due to this issue and zero (0) adverse events reported.

This advisory has been addressed through release of new software to correct for the issue. Software application SW034 version 8.5 (or higher) must be installed on Model 2090 and Encore programmers to correct for this issue. Based on your facility's needs and accessibility, a Medtronic Representative or authorized personnel may assist with updating programmers in your account. Refer to the original communication (below) for additional details.

ORIGINAL COMMUNICATION - MARCH 2020

This notice provides information regarding the potential for a one-time loss of diagnostic information due to a partial electrical reset that may occur for patients implanted with a Medtronic ClariaMRI, Amplia MRI or Compia MRI Cardiac Resynchronization Defibrillator (CRT-D). Based on data available as of March 2020, the calculated occurrence rate of this one-time partial reset is approximately 2%. **Device therapy and programmed settings are not affected by a partial electrical reset.**

A patient with a Claria MRI, Amplia MRI, or Compia MRI may experience a partial electrical reset when the patient has their device interrogated with a programmer that has been updated to software application SW034 version 8.3, and it is the **first** interrogation with this new software.

Background Information

Medtronic analysis identified that the 2% risk for a partial electric reset during the interrogation process is due to an uncommon scenario when a software update is installed simultaneously with routine critical memory scans. Should a reset occur, the clinician will be prompted to "Clear" the reset condition on the programmer (guidance to clear a partial reset is documented in the Instructions for Use for the above-named devices). When the "Clear" option is selected, the programmer will automatically interrogate the device again, and will successfully write the software enhancement to the device memory. Importantly, 98% of download attempts will successfully complete without an electrical reset. **Once the software update has been successfully installed into the device, the potential for a future partial reset due to this interaction no longer exists.**

Additional Details

As documented in the Instructions for Use, a partial electrical reset will result in the loss of stored diagnostic information and episodes. The device longevity estimator will show an "initializing" status for the next seven (7) days, and Recommended Replacement Time (RRT) status will continue to function as normal. Device programmed parameters, and all functions including detection and therapies are maintained. All Claria MRI, Amplia MRI and Compia MRI CRT-D devices are updated with the new software when interrogated for the first time by a programmer with software application SW034 version 8.3.

Medtronic recommends continued routine management of your patients. We recognize that a one-time loss of stored device information may limit your ability to assess your patient's clinical status – particularly when an audible alert, symptoms or VF shock delivery has been reported. Please work with your Medtronic Representative to identify data management options that may be available to your clinic.

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

STATUS UPDATE – NOVEMBER 2021

As of 8 November 2021, there have been a total of 21 confirmed events worldwide associated with this failure mode. No additional deaths, beyond the two deaths previously disclosed*, have been reported. Confirmed events included reports of no output, premature depletion and electrical reset that reverted to VVI 65 operation. The range of events have occurred between 2 and 28 months post-implant.

Medtronic's ongoing monitoring of these failures have allowed us to improve long-term modeling projections for future device failures. The overall projected lifetime rate of occurrence for the remaining active devices manufactured with the original low voltage capacitor is projected to be 0.026%.

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

Dual Chamber IPG Circuit Error

Adapta, Versa, Sensia, Relia, Attesta, Sphera, and Vitatron A, E, G, Q series

Original Date of Advisory: January 2019

STATUS UPDATE – NOVEMBER 2021

- In September 2019 Medtronic released several software updates to correct for this issue. These software applications are:
  - For Adapta/Versa/Sensia IPGs - Software model SW003 v8.2
  - For Relia IPGs - SW010 v8.2
  - For Attesta/Sphera IPGs - SW043 v8.2
  - For Vitatron IPGs – VSF20 v8.2 and FSF21 v8.2
- Once a device is interrogated by a programmer with the updated software, any pacemaker programmed to a non-susceptible pacing mode, specifically to avoid a circuit error, may be reprogrammed to any pacing mode.
- Once a device is updated (update is installed onto devices via interrogation by a programmer with one of the above software applications), if the circuit error were to occur, the pacing cycle will automatically reset; this may be observed as a single dropped beat.
- As of November 8, 2021, 87,000 devices remain active out of an original population of 156,957 devices worldwide.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
156,957 Worldwide	**37** Worldwide	**87,000** Worldwide	**0.02%** Worldwide

ORIGINAL COMMUNICATION - JANUARY 2019

Product

A subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names Adapta™, Versa™, Sensia™, Relia™, Attesta™, Sphera™, and Vitatron™ A, E, G, Q series may experience a circuit error that affects device functionality. Please note that not all devices within these brand names are affected by this recall. You may use the "Search for Information by Serial Number" tool on home page of this web site to determine if a specific device is affected.

Advisory

Devices in the affected subset, when programmed to a dual chamber mode with atrial-sensing, may experience a circuit error that affects device functionality. See Table 1 for modes that are susceptible to this circuit error. For this error to occur, a unique combination of events must take place while the device is processing an atrial-sensed event. If this error occurs, the device will be unable to provide pacing until a ventricular-sensed event (VS) is detected. Once a VS is detected, normal pacing functionality is restored immediately. If a VS is not detected, the device will withhold both atrial and ventricular pacing. In addition, until a VS is detected, the device will be unable to initiate a session with a programmer, initiate a session with a CareLink™ remote monitor, or respond to a magnet. Single chamber and dual chamber pacing modes that do not sense atrial activity are not susceptible to this circuit error (see Table 1).

Table 1: Identification of modes susceptible/not susceptible to circuit error

Modes susceptible to circuit error	Modes NOT susceptible to circuit error
DDD, DDDR	VVI, VVIR
DDI, DDIR	DVI, DVIR
VDD	AAI, AAIR
ADI, ADIR	VOO, VOOR
VDI, VDIR	AOO, AOOR
ODO	DOO, DOOR
OAO	OVO
MVP - when operating in DDD, DDDR, DDI or DDIR mode	VVT, AAT

Through 4 January 2019, Medtronic is aware of four (4) reported occurrences in two (2) patients where a pause in pacing therapy was clinicallyapparent due to this circuit error. These reported events occurred in three (3) devices from a total of 156,957devices sold worldwide. No deaths have been reported as a result of this issue.

Patient risk is determined by the patient's underlying cardiac rhythm and whether the device is in a susceptible pacing mode as described above. Through our analysis of this issue, Medtronic estimates that on average, a device in a susceptible pacing mode has a 2.8% chance per month of experiencing a pacing pause of 1.5 seconds or longer. Risk is minimized in patients who have an escape rhythm adequate to prevent syncope during a loss of ventricular pacing, since a VS restores full device functionality. No risk of a pause due to this circuit error exists for patients programmed to a non-susceptible pacing mode.

The root cause for this issue is related to a design change to an integrated circuit in a subset of devices that were distributed between 10 March 2017 and 7 January 2019.

Medtronic is developing a software update that can be installed into affected devices to correct this issue. Medtronic estimates submission of this software update to regulatory agencies by the 2nd half of 2019. Upon subsequent regulatory approval, Medtronic will notify customers of its availability. Until that time, Medtronic is providing the patient management recommendations described below and depicted in Appendix A.

Patient Management Recommendations

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), **Medtronic recommends programming to a non-susceptible pacing mode as the primary mitigation for patients implanted with an affected device until the software update has been installed.** Specific patient risk assessment and programming recommendations are outlined below and provided in Appendix A.

• For patients whose device is programmed to a non-susceptible mode (see Table 1), no action is needed at this time. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode and are continually in persistent atrial fibrillation, reprogramming the device to the non-susceptible VVI or VVIR mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

• For patients whose device is programmed to a susceptible mode and either: have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs, programming to a non-susceptible mode is recommended to eliminate risk due to this issue until the software update has been installed. Continue routine clinical monitoring.

• For patients who do not tolerate programming to a non-susceptible pacing mode and either: have no underlying ventricular escape rhythm; or are at risk for a symptomatic pause until a ventricular escape beat occurs, continue clinical monitoring in a susceptible mode until the software update is available, or consider device replacement.

  o The estimated per patient mortality risk due to this issue is 0.021% when programmed to a susceptible pacing

mode over the estimated time until the software update becomes available. This risk is comparable to the Medtronic estimated per-patient mortality risk associated with a device replacement (0.027%) *.

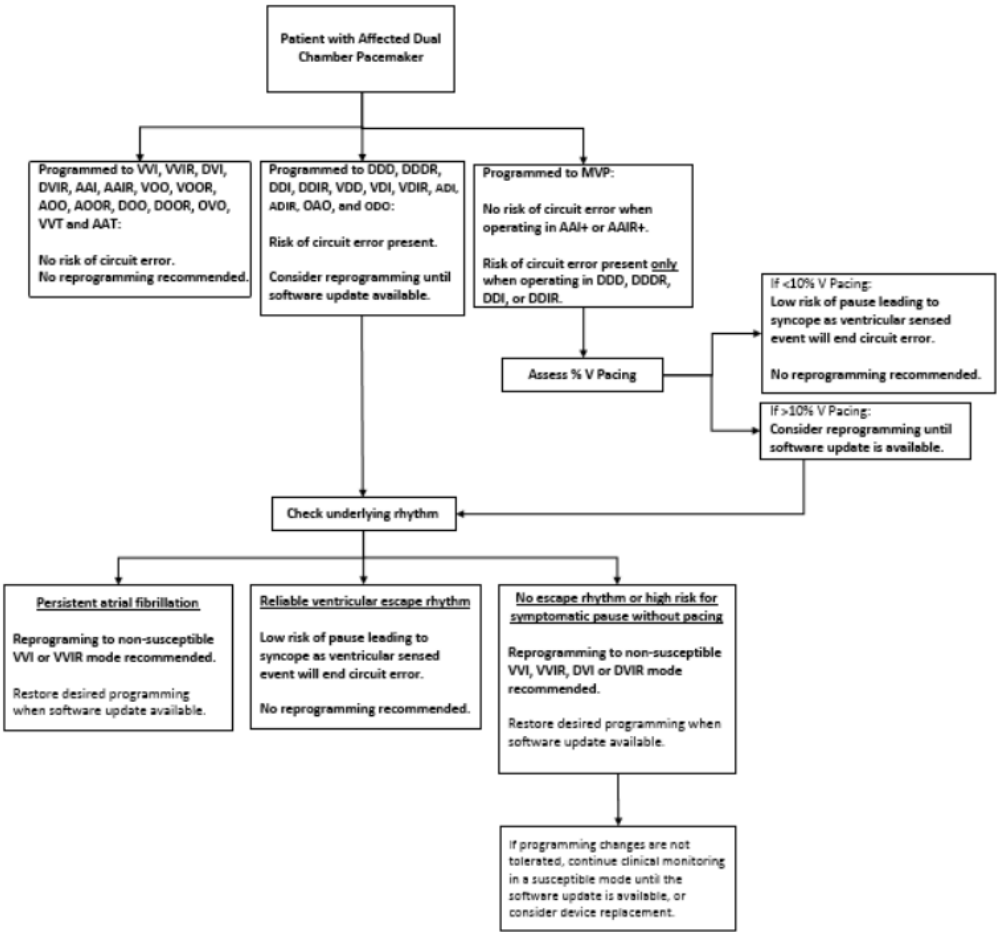
o If a patient reports symptoms consistent with a pacing pause, and you would like assistance assessing whether a patient had a pause due to this issue, contact your Medtronic representative.

• Advise patients remaining in a susceptible mode to seek immediate medical attention if they experience new or unexpected symptoms consistent with a pacing pause.

• Other than reprogramming to a non-susceptible pacing mode, no additional programming options have been identified to mitigate this issue.

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

Appendix A: Programming decision flow chart



Potential Loss of Device Functionality Lower Risk Subset

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

Original Date of Advisory: March 2018

STATUS UPDATE - NOVEMBER 2021

Within the 752 lower-risk devices, there have been zero confirmed failures (0%) through November 8, 2021. An estimated 390 devices remain active

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
752 Worldwide (all in USA, Puerto Rico or US Virgin Islands.)	**0**	**390**	**0%** Worldwide

ORIGINAL COMMUNICATION - MARCH 2018

Product

In January 2018, Medtronic completed notification to physicians about a subset of 48 Medtronic Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs) underwent a specific sequence of manufacturing processes that could result in an unexpected loss of device functionality, including high-voltage therapy.

Within this Lower-Risk Subset of 752 devices, if the device delivered the maximum number of shocks until battery depletion, we estimate 0.5% of these devices would experience arcing during high voltage charging, with failure occurring within the first two (2) high-voltage charges in 0.18% of the devices. See table below for comparison of device subsets.

Through 8 March 2018, there have been zero (0) complaints related to internal arcing in these 752 devices. While the risk for failure is lower in this group of devices, it is not possible to identify which of these 752 devices may fail or when they may fail. Successful delivery of previous high-voltage therapy does not ensure future performance.

You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ to determine if a specific device is affected.

Table – Device Subsets

January 2018 48 Implanted Higher-Risk Devices	**March 2018 752 Lower-Risk Devices**
One field failure has been observed with no deaths reported 7.7% of these devices are projected to fail during the first two high-voltage charges	No field failures have been observed 0.18% of these devices are projected to fail during the first two high-voltage charges
Medtronic communicated a recommendation to strongly consider prophylactic replacement in these devices.	Patient management recommendations follow below.

Patient Management Recommendations – Lower Risk Subset

We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic provides the following recommendations to physicians for patients who have been implanted with one of the identified devices:

- Prophylactic device replacement should be considered for patients at higher risk, including patients whose clinical history indicates prior need for high-voltage therapy and/or for pacemaker-dependent patients.
- Physicians should carefully weigh the risks and benefits of device replacement. The estimated per patient risk for mortality due to this issue is 0.02% to 0.04% considering the risk of device failure and the likelihood of a patient requiring high voltage therapy. This is comparable to the estimated per patient mortality risk of complications associated with a device replacement (0.04%)[i],[ii].
- For patients in whom it is determined that replacement is not warranted:
    - Consider programming changes to reduce the potential for high-voltage charges associated with arrhythmia detection and therapies, such as enabling ATP before charging for fast ventricular rhythms or programming a separate fast VT via VF zone with ATP. For assistance with patient-specific programming needs, contact Medtronic Technical Services at 800-723-4636.
    - -Continue three-month in-clinic or remote follow-ups to verify device functionality. Inability to interrogate a device or a failed remote monitoring transmission may be an indication that internal arcing has occurred. Devices that have failed will not send an alert as telemetry and all device functionality is immediately lost if internal arcing occurs.
    - Advise patients to seek medical attention immediately if they experience new or unexpected symptoms suspicious for a ventricular arrhythmia.

- Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; MRCS: MDT2260884, Version 2.0, 11/02/2015.
- Birnie, D et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm, Volume 5, Issue 3, Pages 387-390.

Potential Rapid Battery Depletion Due To Circuit Component

Viva™ CRT-D and Evera™ ICD

Original Date of Advisory: August 2016

STATUS UPDATE - NOVEMBER 2021

Within the 78 devices, there have been 10 confirmed failures (13%) through November 8, 2021. Medtronic modeling predicts an additional three (3) failures may occur in the remaining active population. An estimated 21 devices remain active.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
78 Worldwide	**10** Worldwide	**21** Worldwide	**13%** Worldwide

ORIGINAL COMMUNICATION - AUGUST 2016

Product

A specific subset of 78 Viva CRT-D and Evera ICD may experience rapid battery depletion due to a low resistance path developing within a circuit component. You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance to determine if a specific device is affected.

Advisory

Devices in the affected population may experience rapid battery depletion due to a low resistance path developing within a circuit component. This is not related to a failure within the battery.

Development of a low resistance path in the circuit component in some cases has been reported to cause battery depletion in seven (7) days or less and may present clinically during a patient follow-up visit as:

- One or more electrical resets, which will display as an observation on the programmer.
- No pacing or defibrillation therapy output.
- No telemetry.
- Programmer screen display of "SERIOUS DEVICE MEMORY FAILURE."

Patient audible alerts and CareAlerts™ may not reliably notify the patient or clinician, due to this issue.

Reported complications have included shortness of breath, pocket heating, low heart rate, and early device explant.

Patient Management Recommendations

We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following options for managing patients implanted with an affected device:

Advise patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness) or if the audible patient alert sounds.

For pacemaker-dependent patients or those at a higher risk of Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF):

- Physicians should consider device replacement.

For patients where the physician does not believe device explant is the best course of action, Medtronic offers these additional options:

- Program the audible alerts for "Low Battery Voltage RRT" to "On-High". It is possible that alerts may not sound if the battery is depleted. Therefore physicians should also consider one of the following:
  - Provide a handheld magnet to patients to frequently check device status.
    - Requires one or more audible alerts be programmed ON.
    - Device operation may be monitored frequently (e.g., daily) by patients placing the magnet over the device for **1-2 seconds and then removing the magnet.** If the device is functional, a steady tone will sound for approximately 10 seconds. If no tone or an oscillating high/low tone is heard, advise patients to seek care immediately.
  - Prescribe either a CareLink™ transmission be performed by the patient, or a maintenance transmission by the clinic, on a more frequent basis (e.g., weekly or daily) based on the unique patient considerations. The clinic should review these transmissions upon receipt.
    - If the transmission is unsuccessful the patient should be brought into the clinic for immediate follow-up as this may be an indication that the device battery has depleted to a level where it can no longer support telemetry.
    - Review transmissions for any signs of this issue (e.g., one or more electrical resets, or notification that a device alert has occurred).
    - Each transmission will decrease battery longevity by approximately one day

Potential Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

STATUS UPDATE - NOVEMBER 2021

As of November 8, 2021, of the initial implant population of 205,600 in the United States, approximately 28,000 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 63.6% (+6.7/-6.0%) at 168 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)	**7,303** Worldwide (**5,221** United States)	**39,000** Worldwide (**28,000** United States)

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 fractures1. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks.

- **If a Fidelis lead fracture of any type has occurred,we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred. This data is available at https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/sprint-fidelis-11-2015-update.html
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Footnotes:

1: Swerdlow C, Gunderson, B, et al."Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRM Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

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

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

Mailer kits can be obtained by contacting the Returned Product Lab.

CRM Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

For questions related to returning explanted product from outside the United States, please contact your local Medtronic Representative.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

medtronic.com

Medtronic