# CARDIAC RHYTHM MANAGEMENT

## Product Performance Report

*Important Patient Management Information for Physicians*

2023

2nd Edition – Issue 89

Medtronic

# CRM Product Performance Report


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2023

2nd Edition

Issue 89


Cutoff date for this edition is 28 July 2023 for Lead Study data and 06 November 2023 for all other data, unless otherwise stated.

# Our Commitment to Quality

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

The third tenet of the mission is all about quality:

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

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

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

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

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

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

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

# Contact Information

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

## 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

## Editorial Staff

Editor

Carrie Schleis, *Vice President, CRM Quality*

## International Technical Centers

Europe, the Middle East and Africa (Heerlen NL)

Please contact local Medtronic Representative.

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

crdm.returnedproduct@medtronic.com

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Secura®
Secure®
SelectSecure®
Sensia®
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# Introduction

**For 40 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.**

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

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

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

**Survival Estimates**

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

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

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

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

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

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

## Introduction continued

### ICD Charge Times

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

### Customer Communications - Advisory Summaries

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

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

### Customer Communications - Performance Notes

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

### Customer Communications - Product Education Briefs

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

### How You Can Help

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

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

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

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

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

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

**Overview of Survival Analysis**

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

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

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

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

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

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

**Confidence Intervals**

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

**Survival Curves in the Product Performance Report**

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRTs, ICDs, and IPGs, and when the number entered is less than 50 for leads. The survival charts in the Product Performance Report show the effective sample size for

## Introduction continued

each year interval where Medtronic has experience. When the effective sample size reaches 100 for CRTs, ICDs, and IPGs or when the number entered reaches 50 for leads, the next data point is added to the survival curve.

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

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

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

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

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

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

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

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

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

**Categorization of Depleted and Malfunctioning Devices for Survival Analysis**

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

### Definition of Malfunction

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

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

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

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

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

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

Normal Battery Depletion – The condition when:

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

(a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings

Or

(b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information

Or

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

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

### Malfunction with Compromised Therapy Function

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

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

### Malfunction without Compromised Therapy Function

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

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

**Expanded Malfunction Detail**

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

Battery – Findings linked to the battery and its components

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

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

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

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

Software/Firmware – Findings linked to software or firmware function

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

**Returned Product Analysis Process**

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

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

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

**Statistical Methods for Survival Analysis**

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

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

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

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRT, ICD, and IPG devices. The survival charts in the

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

Product Performance Report show the effective sample size for each year interval where we have experience. When the effective sample size reaches 100, the next data point is added to the survival curve.

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

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

**Sample Size and How the Population and Population Samples Are Defined**

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

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

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

**Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion**

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

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

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

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

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

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

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

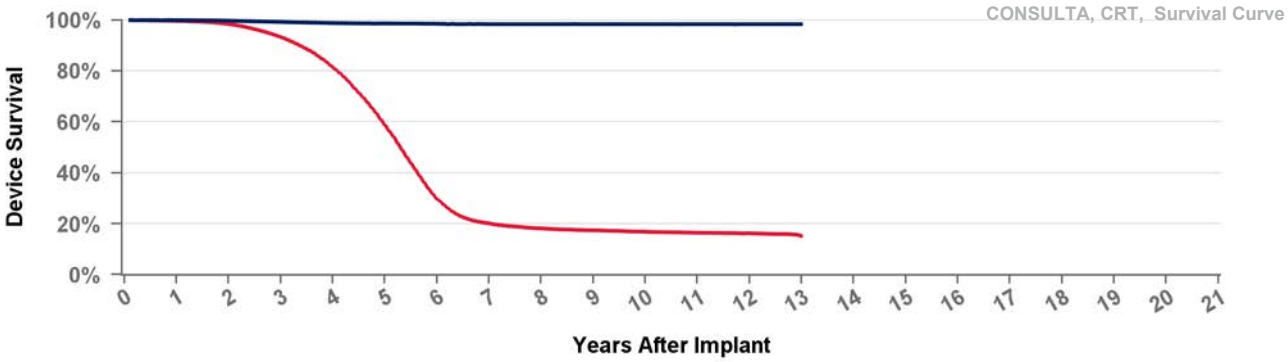
**Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service**

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

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

## D204TRM Consulta CRT-D

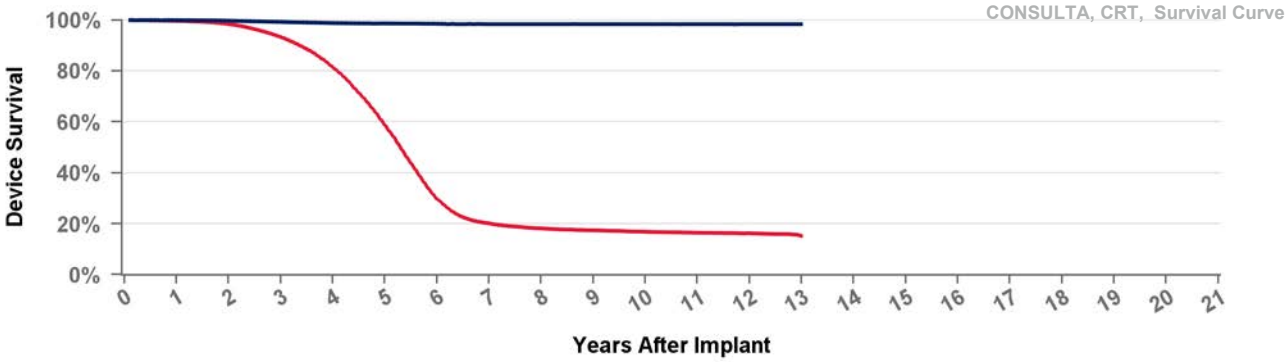
| | | | |
|---|---|---|---|
| **US Market Release** | 09Jan2012 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 2,048 | Battery | 1 |
| **Estimated Active USA Implants** | 259 | Electrical Component | 1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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.8% | 98.7% | 98.5% | 98.4% | 98.4% | 98.4% | 98.4% | 98.3% | 98.3% | 98.3% |
| Including NBD | 99.7% | 98.4% | 93.3% | 81.3% | 58.9% | 29.8% | 20.2% | 18.2% | 17.5% | 16.9% | 16.5% | 16.3% | 15.2% |
| Effective Sample Size | 56118 | 50205 | 42857 | 33041 | 19346 | 7437 | 4019 | 3271 | 2912 | 2636 | 2080 | 1400 | 122 |

## D214TRM Consulta CRT-D

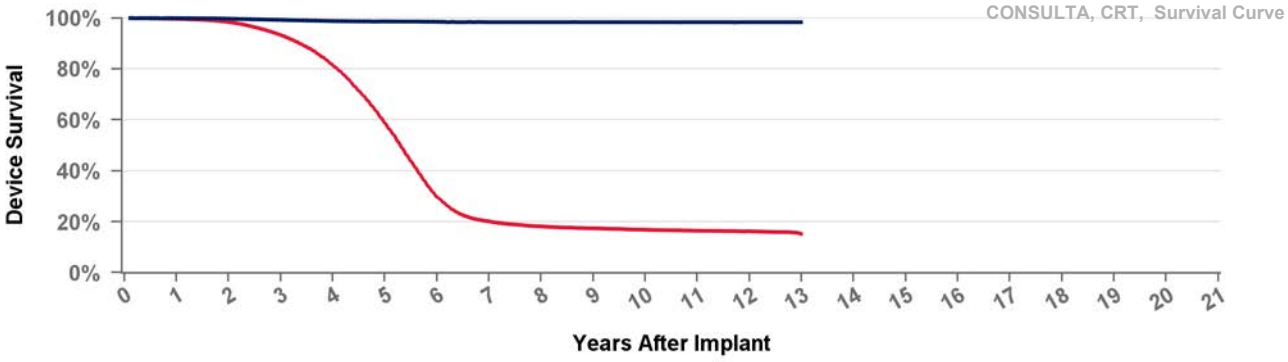
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 22Jul2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.8% | 98.7% | 98.5% | 98.4% | 98.4% | 98.4% | 98.4% | 98.3% | 98.3% | 98.3% |
| Including NBD | 99.7% | 98.4% | 93.3% | 81.3% | 58.9% | 29.8% | 20.2% | 18.2% | 17.5% | 16.9% | 16.5% | 16.3% | 15.2% |
| Effective Sample Size | 56118 | 50205 | 42857 | 33041 | 19346 | 7437 | 4019 | 3271 | 2912 | 2636 | 2080 | 1400 | 122 |

## D224TRK Consulta CRT-D

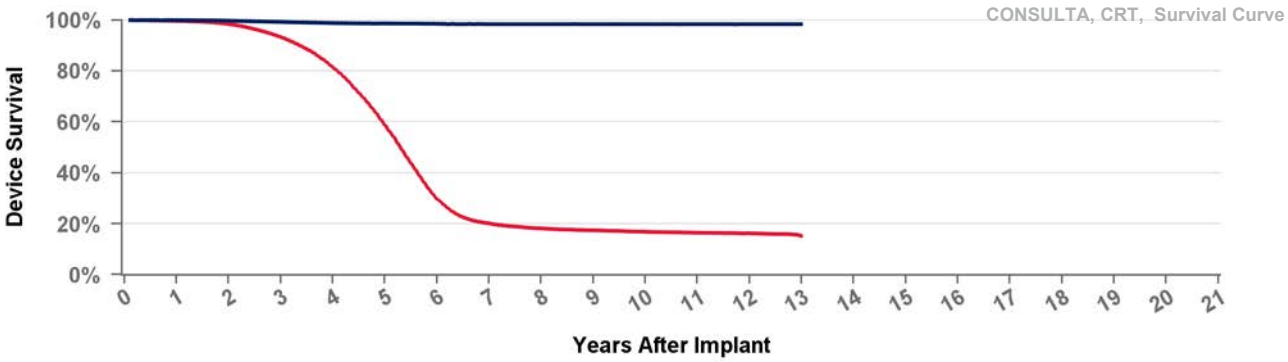
| | | | |
|---|---|---|---|
| **US Market Release** | 15Sep2008 | **Total Malfunctions (USA)** | **604** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **573** |
| **Registered USA Implants** | 65,130 | Battery | 2 |
| **Estimated Active USA Implants** | 5,026 | Electrical Component | 67 |
| **Normal Battery Depletions** | 18,955 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 496 |
| | | Software/Firmware | 6 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **31** |
| | | Battery | 5 |
| | | Electrical Component | 26 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.8% | 98.7% | 98.5% | 98.4% | 98.4% | 98.4% | 98.4% | 98.3% | 98.3% | 98.3% |
| Including NBD | 99.7% | 98.4% | 93.3% | 81.3% | 58.9% | 29.8% | 20.2% | 18.2% | 17.5% | 16.9% | 16.5% | 16.3% | 15.2% |
| Effective Sample Size | 56118 | 50205 | 42857 | 33041 | 19346 | 7437 | 4019 | 3271 | 2912 | 2636 | 2080 | 1400 | 122 |

## D234TRK Consulta CRT-D

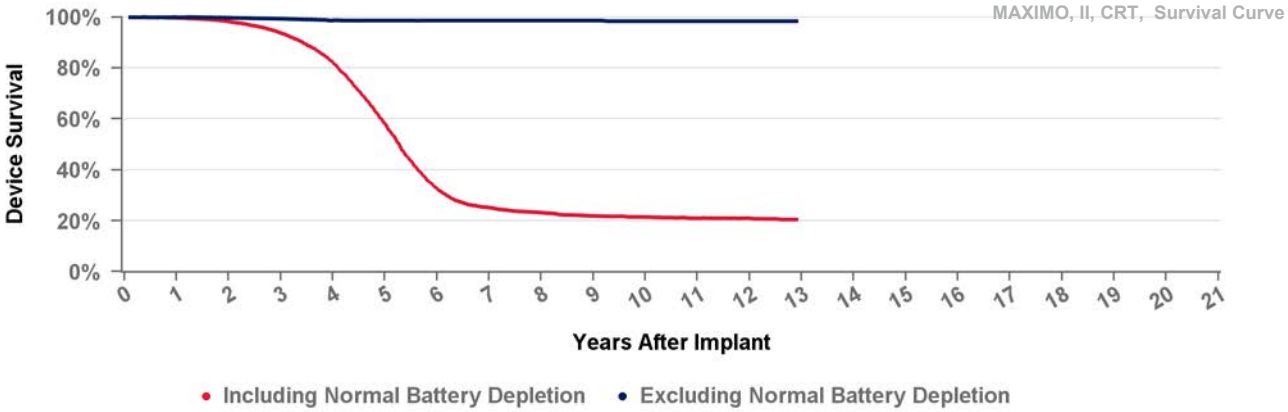
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.8% | 98.7% | 98.5% | 98.4% | 98.4% | 98.4% | 98.4% | 98.3% | 98.3% | 98.3% |
| Including NBD | 99.7% | 98.4% | 93.3% | 81.3% | 58.9% | 29.8% | 20.2% | 18.2% | 17.5% | 16.9% | 16.5% | 16.3% | 15.2% |
| Effective Sample Size | 56118 | 50205 | 42857 | 33041 | 19346 | 7437 | 4019 | 3271 | 2912 | 2636 | 2080 | 1400 | 122 |

## D264TRM Maximo II CRT-D

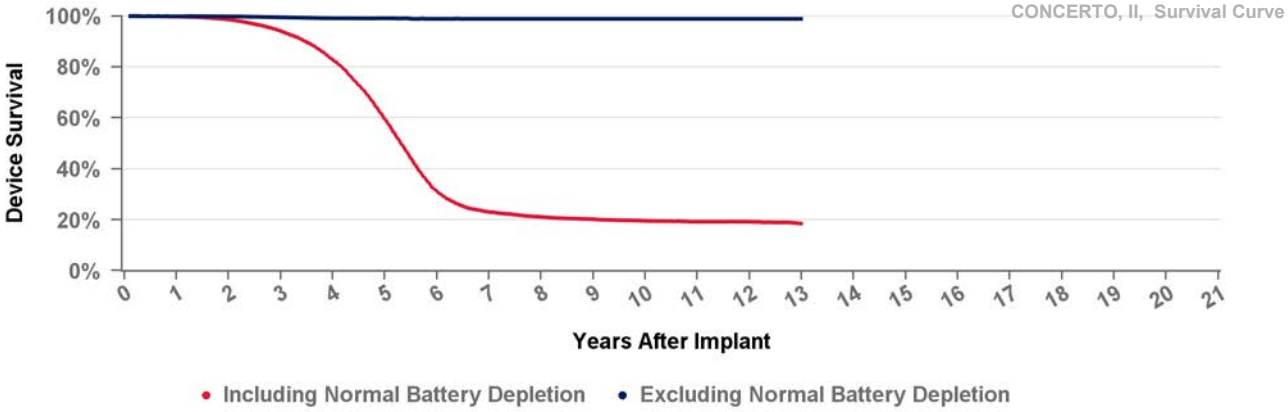
| | | | |
|---|---|---|---|
| **US Market Release** | 09Jan2012 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 22Jul2010 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 15 | Other | 1 |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised**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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.7% | 98.6% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% |
| Including NBD | 99.7% | 98.3% | 93.7% | 82.1% | 58.2% | 32.5% | 25.2% | 23.2% | 21.9% | 21.5% | 21.1% | 20.9% | 20.6% |
| Effective Sample Size | 12499 | 11085 | 9499 | 7256 | 3992 | 1658 | 1088 | 912 | 797 | 730 | 583 | 373 | 120 |

## D274TRK Concerto II CRT-D

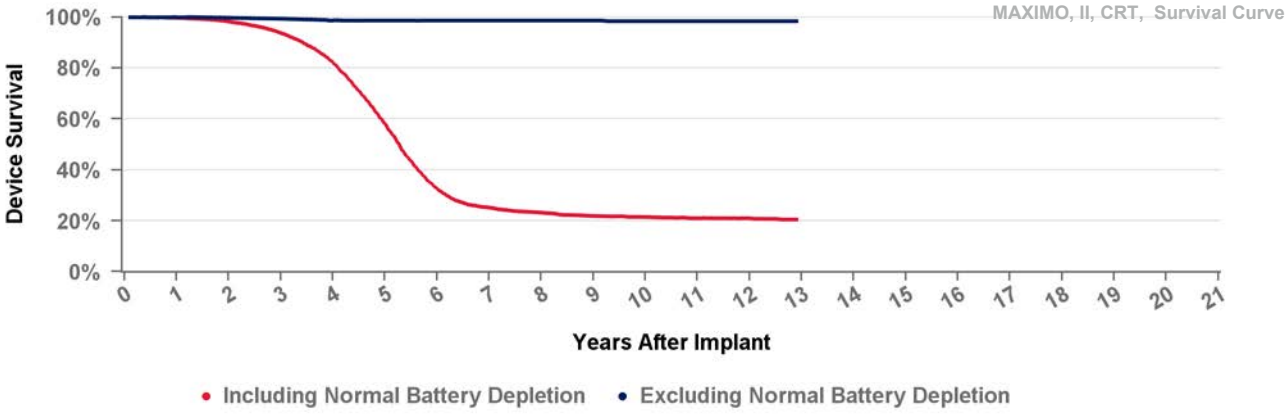
| | | | |
|---|---|---|---|
| **US Market Release** | 15Aug2009 | **Total Malfunctions (USA)** | **187** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **176** |
| **Registered USA Implants** | 30,190 | Battery | 1 |
| **Estimated Active USA Implants** | 2,595 | Electrical Component | 22 |
| **Normal Battery Depletions** | 8,021 | Possible Early Battery Depletion | 152 |
| | | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **11** |
| | | Battery | 1 |
| | | Electrical Component | 10 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.8% | 99.5% | 99.1% | 99.1% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% |
| Including NBD | 99.8% | 98.6% | 94.1% | 82.7% | 59.6% | 31.0% | 23.1% | 21.1% | 20.3% | 19.6% | 19.3% | 19.3% | 18.5% |
| Effective Sample Size | 25088 | 22503 | 19399 | 14878 | 8270 | 3133 | 1911 | 1580 | 1404 | 1281 | 1168 | 965 | 117 |

## D284TRK Maximo II CRT-D

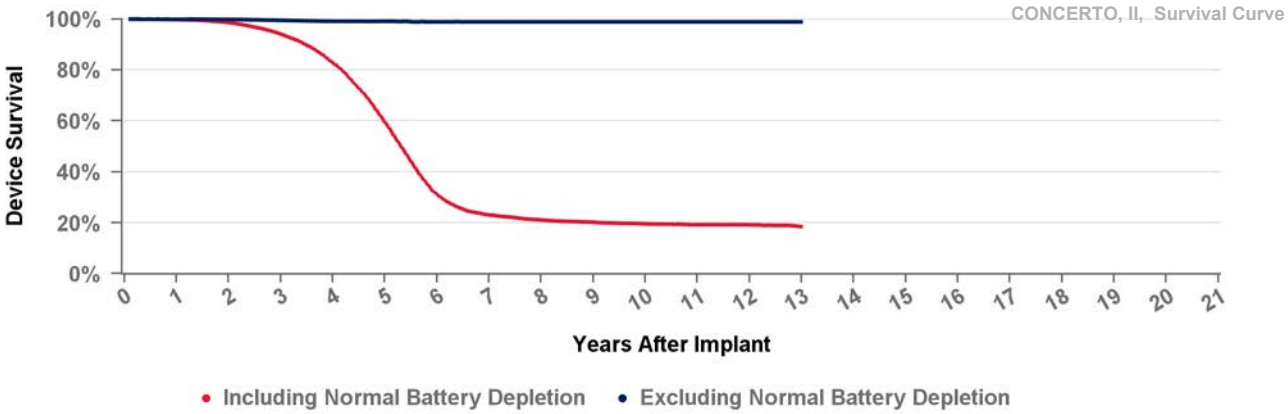
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **135** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **130** |
| **Registered USA Implants** | 14,990 | Electrical Component | 6 |
| **Estimated Active USA Implants** | 1,340 | Possible Early Battery Depletion | 124 |
| **Normal Battery Depletions** | 4,084 | **Therapy Function Compromised** | **5** |
| | | Electrical Component | 5 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.7% | 98.6% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% |
| Including NBD | 99.7% | 98.3% | 93.7% | 82.1% | 58.2% | 32.5% | 25.2% | 23.2% | 21.9% | 21.5% | 21.1% | 20.9% | 20.6% |
| Effective Sample Size | 12499 | 11085 | 9499 | 7256 | 3992 | 1658 | 1088 | 912 | 797 | 730 | 583 | 373 | 120 |

## D294TRK Concerto II CRT-D

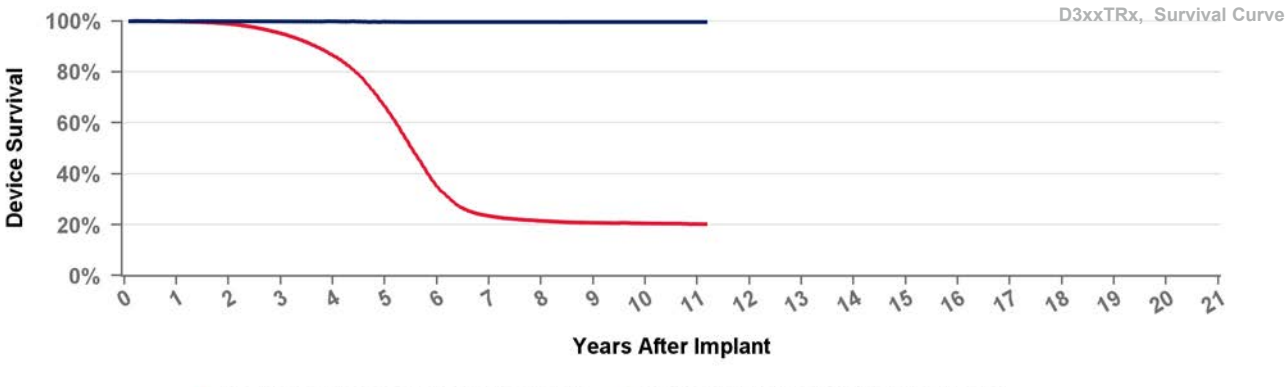
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Aug2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.8% | 99.5% | 99.1% | 99.1% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% |
| Including NBD | 99.8% | 98.6% | 94.1% | 82.7% | 59.6% | 31.0% | 23.1% | 21.1% | 20.3% | 19.6% | 19.3% | 19.3% | 18.5% |
| Effective Sample Size | 25088 | 22503 | 19399 | 14878 | 8270 | 3133 | 1911 | 1580 | 1404 | 1281 | 1168 | 965 | 117 |

## D314TRG Protecta XT CRT-D

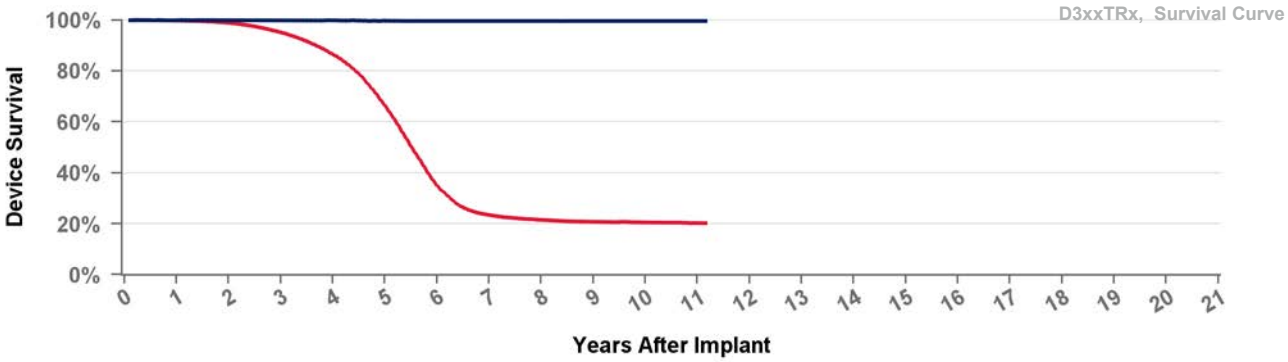
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **94** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **75** |
| **Registered USA Implants** | 41,865 | Battery | 8 |
| **Estimated Active USA Implants** | 4,685 | Electrical Component | 40 |
| **Normal Battery Depletions** | 10,517 | Possible Early Battery Depletion | 25 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **19** |
| | | Battery | 11 |
| | | Electrical Component | 8 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D314TRM Protecta XT CRT-D

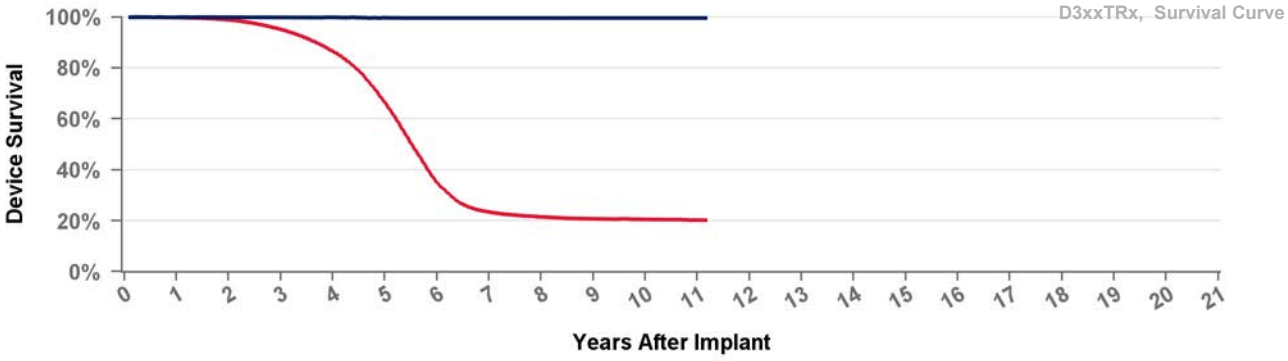
| | | | |
|---|---|---|---|
| **US Market Release** | 09Nov2011 | **Total Malfunctions (USA)** | **20** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 12,197 | Battery | 4 |
| **Estimated Active USA Implants** | 1,463 | Electrical Component | 8 |
| **Normal Battery Depletions** | 3,512 | Possible Early Battery Depletion | 5 |
| | | **Therapy Function Compromised** | **3** |
| | | Battery | 1 |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D334TRG Protecta CRT-D

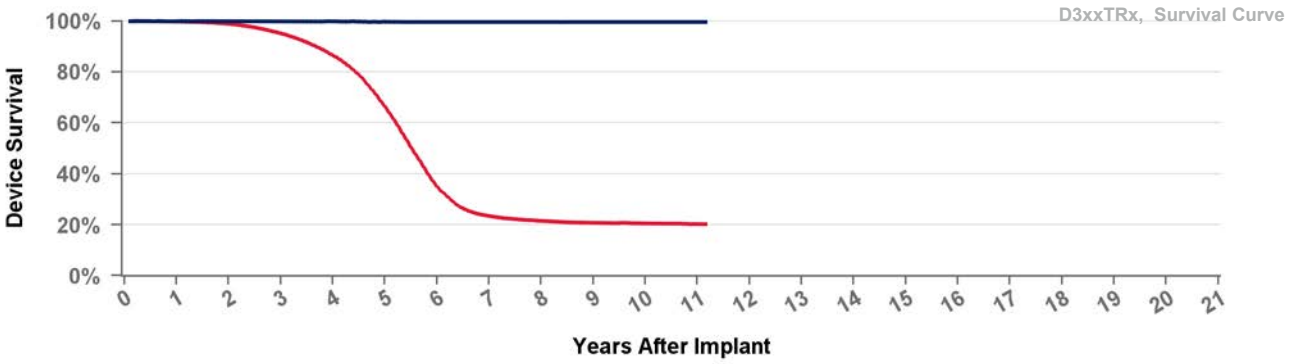
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **14** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **11** |
| **Registered USA Implants** | 8,103 | Electrical Component | 8 |
| **Estimated Active USA Implants** | 980 | Possible Early Battery Depletion | 3 |
| **Normal Battery Depletions** | 2,169 | **Therapy Function Compromised** | **3** |
| | | Battery | 1 |
| | | Electrical Component | 1 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D334TRM Protecta CRT-D

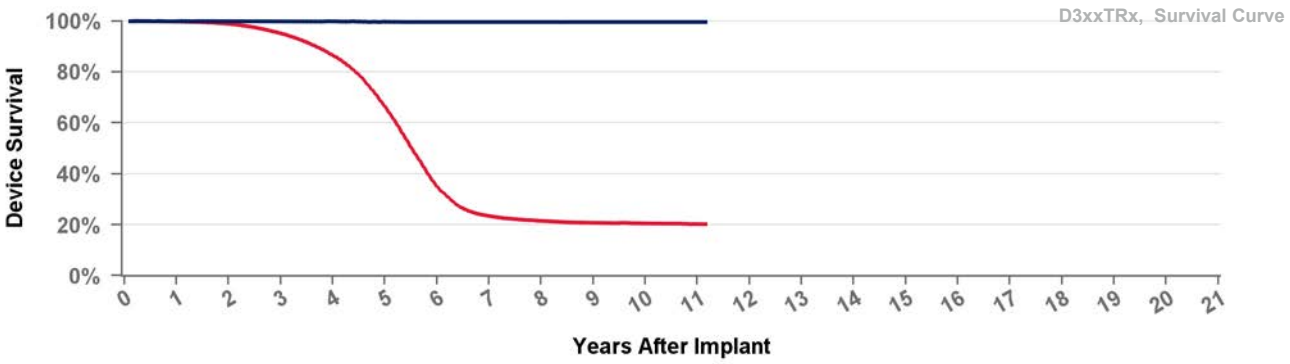
| | | | |
|---|---|---|---|
| **US Market Release** | 09Nov2011 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 1,785 | Battery | 3 |
| **Estimated Active USA Implants** | 248 | Electrical Component | 1 |
| **Normal Battery Depletions** | 572 | Possible Early Battery Depletion | 2 |
| | | **Therapy Function Compromised** | **2** |
| | | Battery | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D354TRG Protecta XT CRT-D

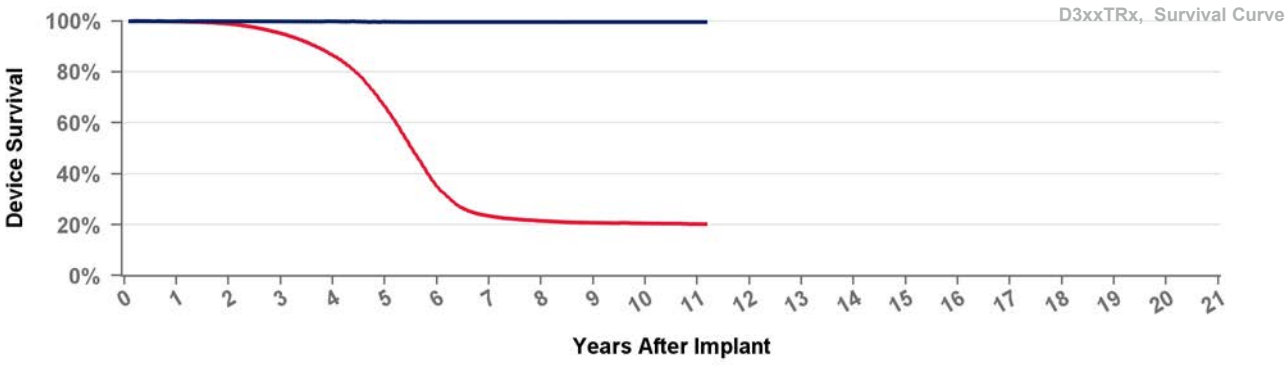
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 25Mar2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D354TRM Protecta XT CRT-D

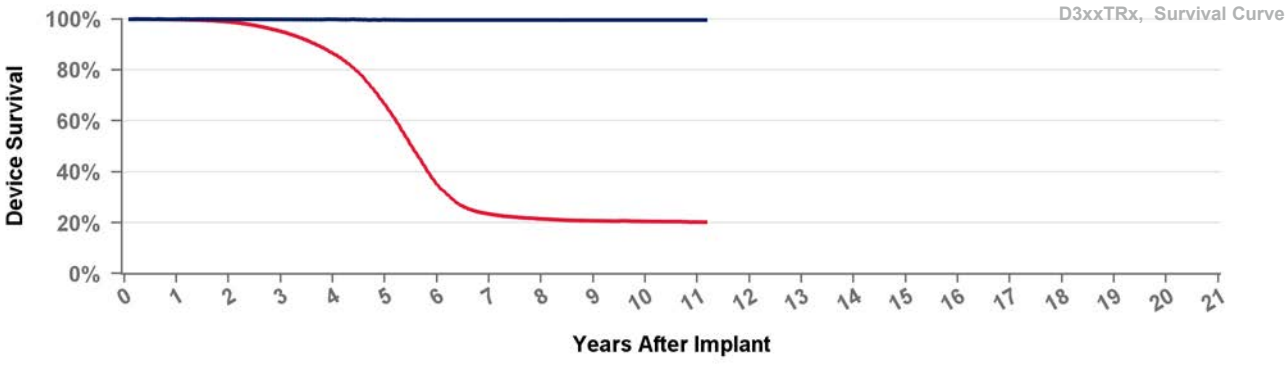
**US Market Release**
**CE Approval Date** 15Jul2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D364TRG Protecta CRT-D

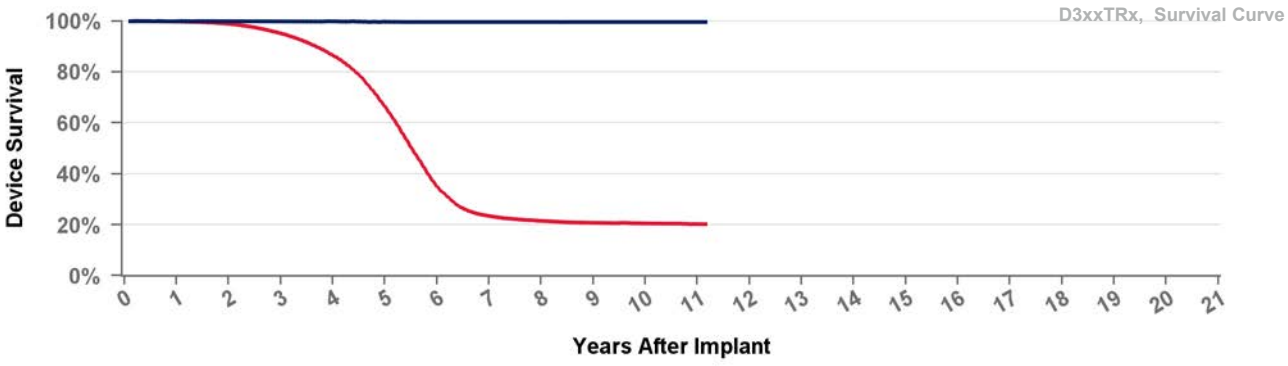
**US Market Release**
**CE Approval Date** 25Mar2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D364TRM Protecta CRT-D

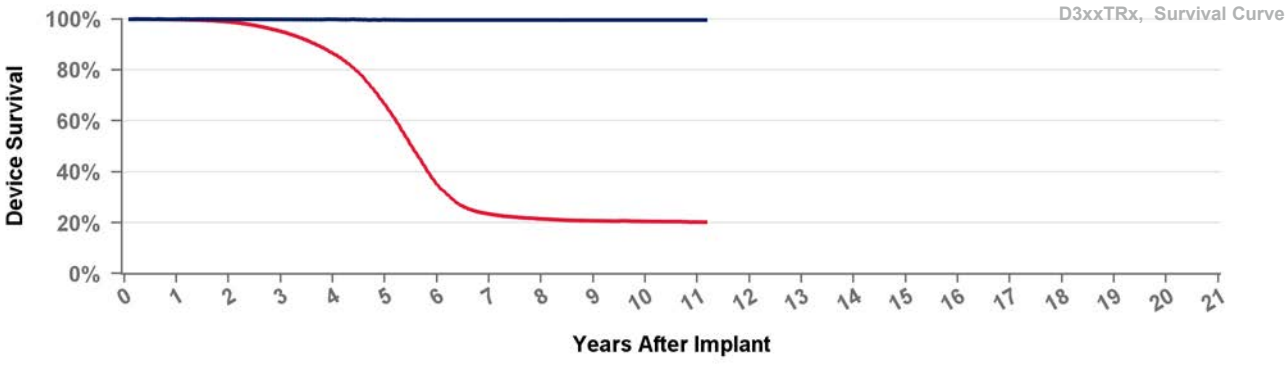
**US Market Release**
**CE Approval Date** 15Jul2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D384TRG Cardia CRT-D

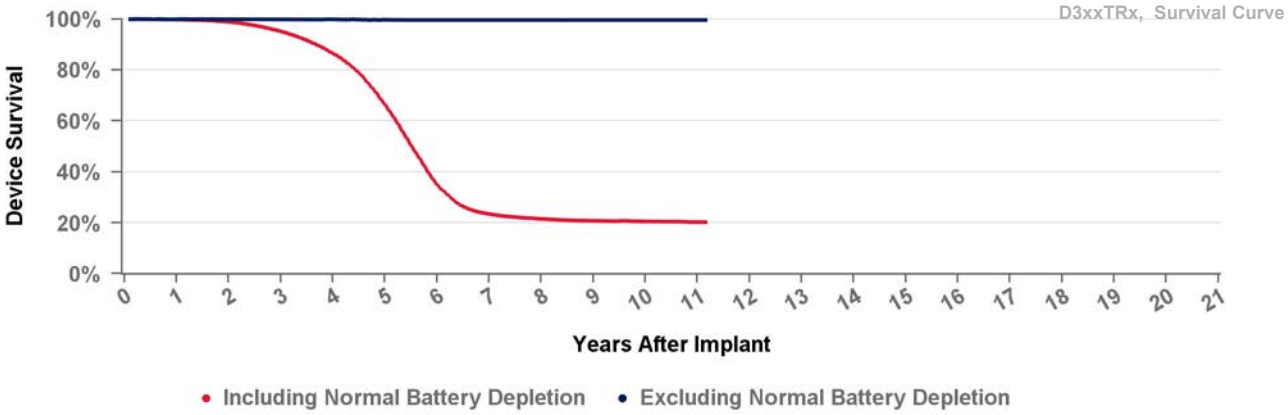
**US Market Release**
**CE Approval Date** 12Jan2011
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## D394TRG Egida CRT-D

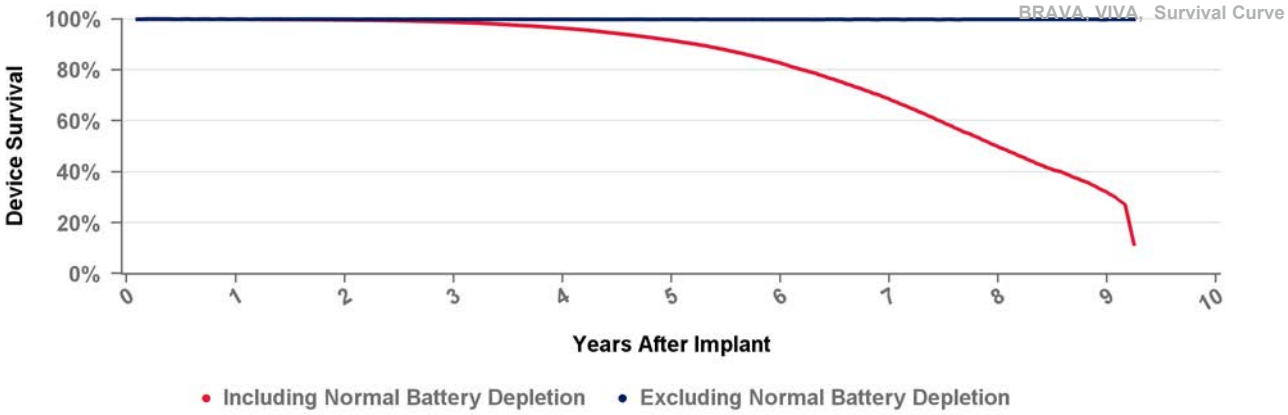
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 12Jan2011 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.6% | 35.1% | 23.5% | 21.5% | 20.8% | 20.6% | 20.3% | 20.3% |
| Effective Sample Size | 54159 | 48931 | 42283 | 33506 | 21031 | 8867 | 4841 | 4000 | 3578 | 3088 | 693 | 192 |

## DTBA1D1 Viva XT

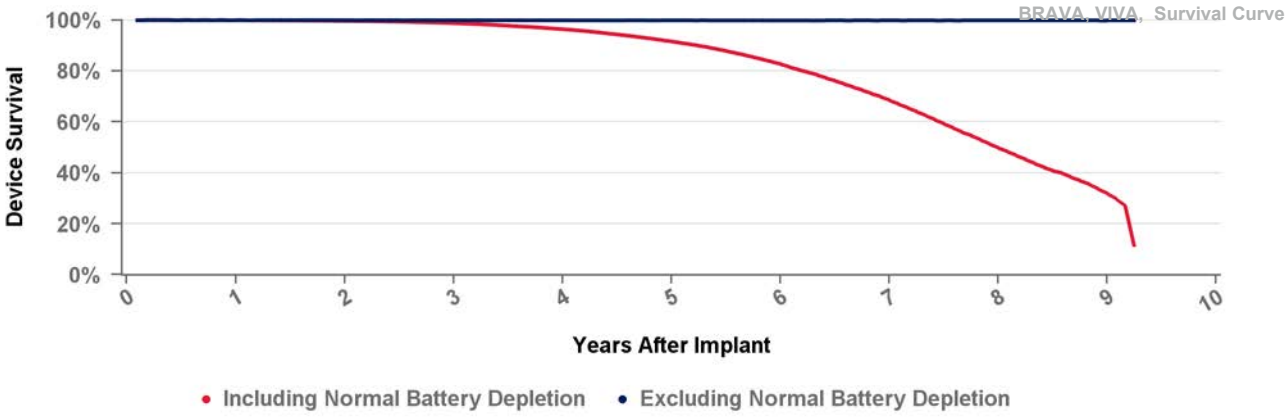
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **70** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **46** |
| **Registered USA Implants** | 110,569 | Battery | 10 |
| **Estimated Active USA Implants** | 31,345 | Electrical Component | 32 |
| **Normal Battery Depletions** | 13,926 | Possible Early Battery Depletion | 1 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **24** |
| | | Battery | 19 |
| | | Device-Related Current Pathway | 1 |
| | | Electrical Component | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBA1D4 Viva XT

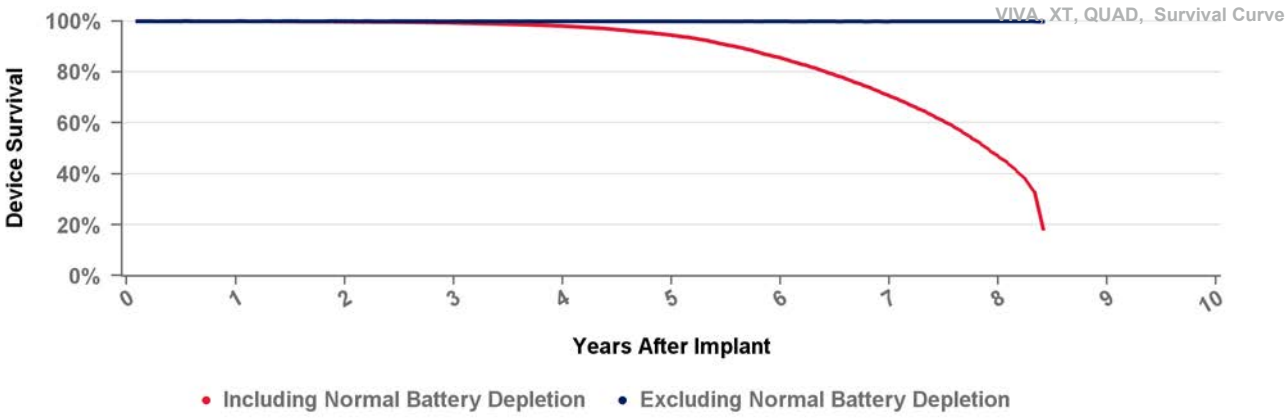
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **33** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **24** |
| **Registered USA Implants** | 37,782 | Battery | 6 |
| **Estimated Active USA Implants** | 9,801 | Electrical Component | 15 |
| **Normal Battery Depletions** | 6,142 | Possible Early Battery Depletion | 3 |
| | | **Therapy Function Compromised** | **9** |
| | | Battery | 6 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBA1Q1 Viva Quad XT

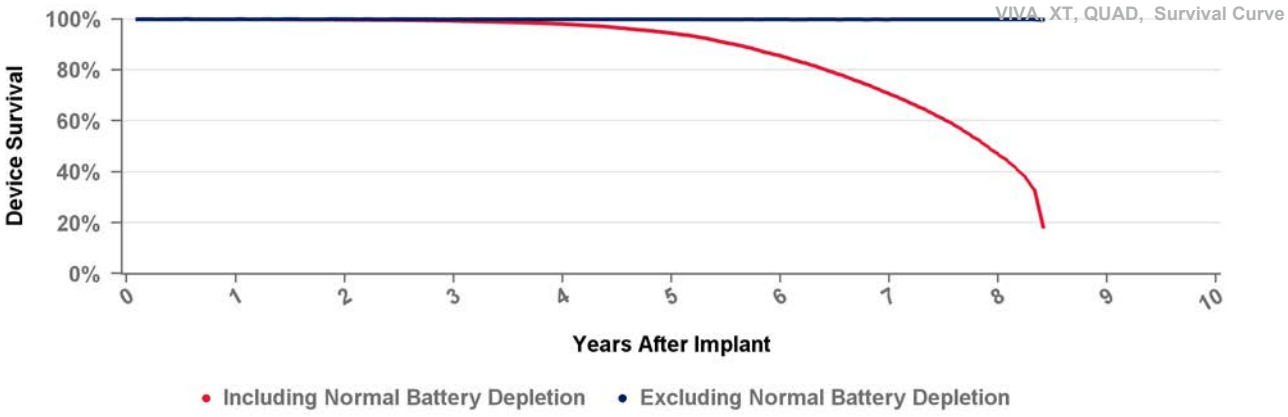
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **14** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 21,350 | Battery | 3 |
| **Estimated Active USA Implants** | 6,737 | Electrical Component | 4 |
| **Normal Battery Depletions** | 2,532 | Possible Early Battery Depletion | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **5** |
| | | Battery | 4 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTBA1QQ Viva Quad XT

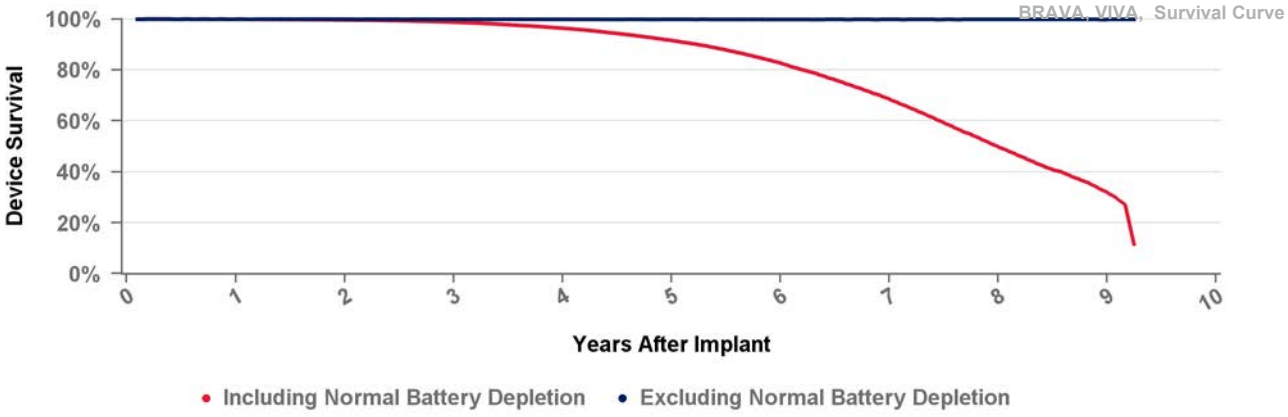
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **47** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **35** |
| **Registered USA Implants** | 53,405 | Battery | 11 |
| **Estimated Active USA Implants** | 18,073 | Electrical Component | 19 |
| **Normal Battery Depletions** | 7,570 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 3 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **12** |
| | | Battery | 9 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTBA2D1 Viva XT

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

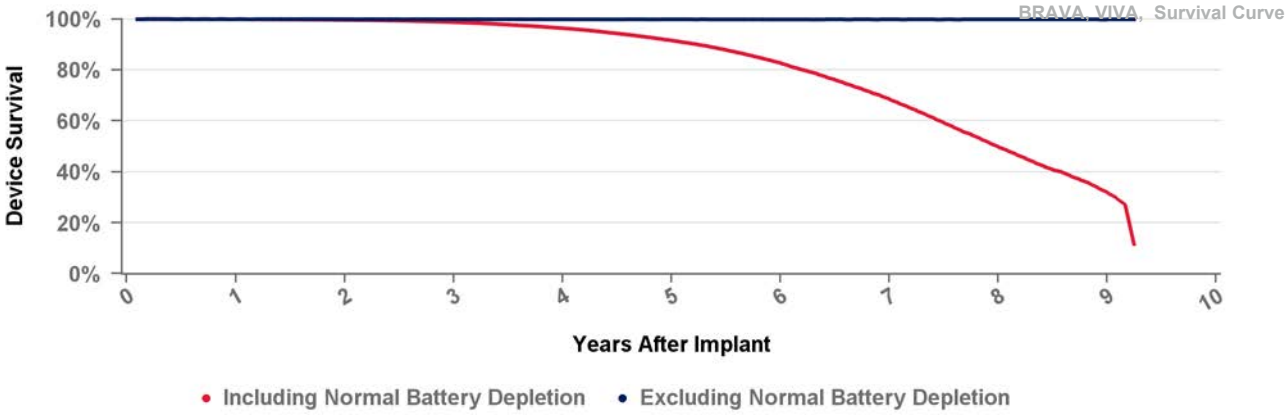



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBA2D4 Viva XT

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

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

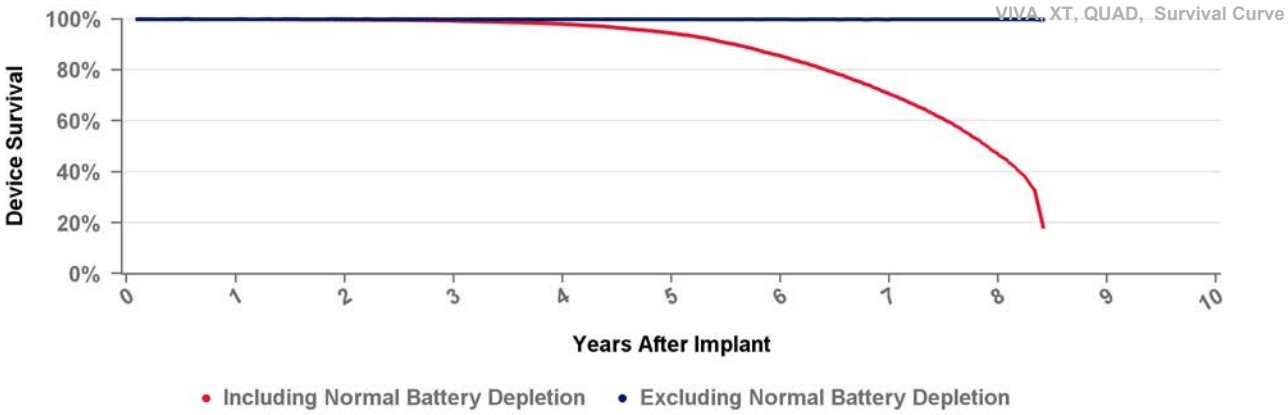



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBA2Q1 Viva Quad XT

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

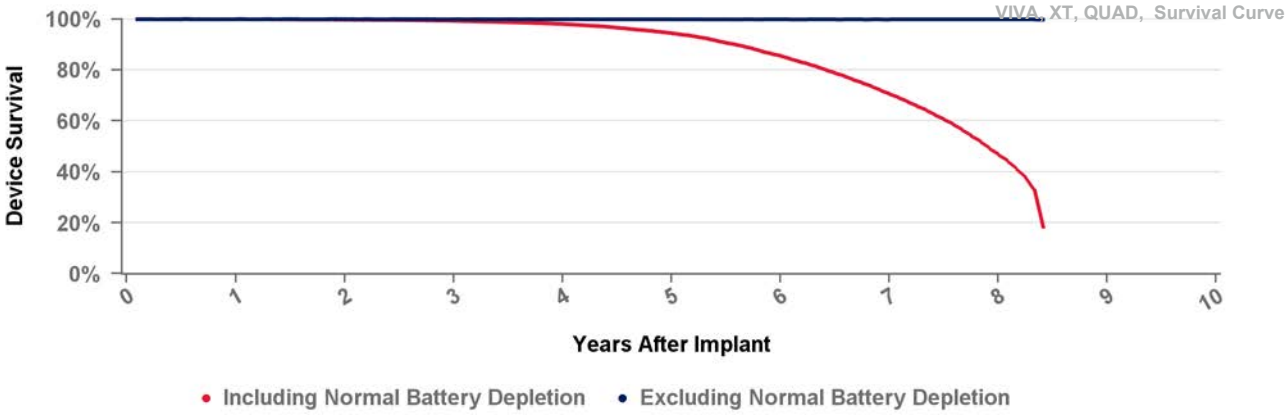
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTBA2QQ Viva Quad XT

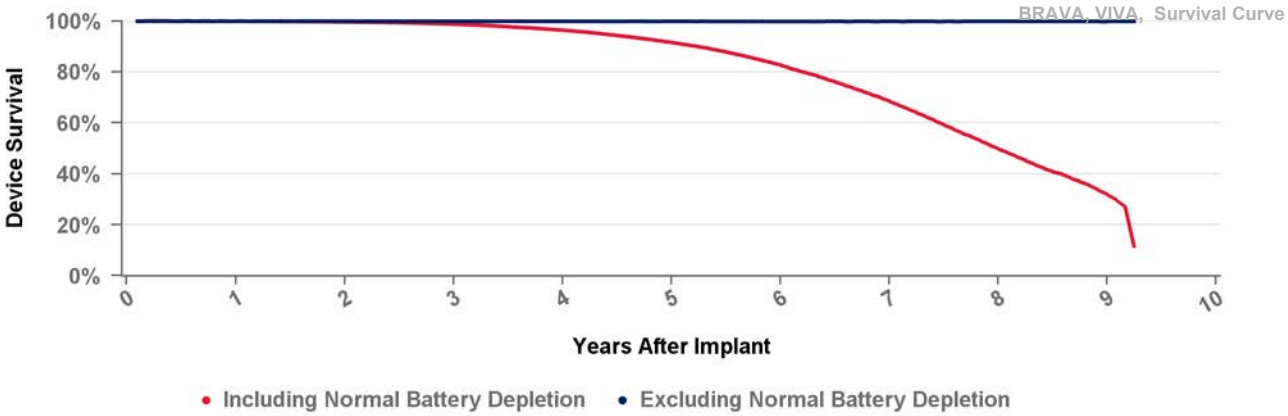
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 08Aug2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTBB1D1 Viva S

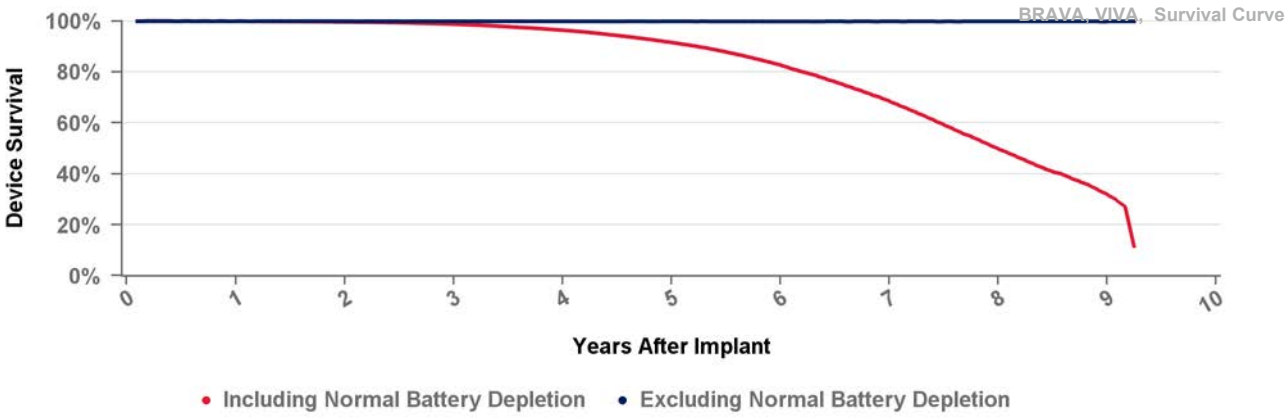
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **22** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 27,550 | Battery | 9 |
| **Estimated Active USA Implants** | 6,347 | Electrical Component | 5 |
| **Normal Battery Depletions** | 4,341 | Possible Early Battery Depletion | 2 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **5** |
| | | Battery | 4 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB1D4 Viva S

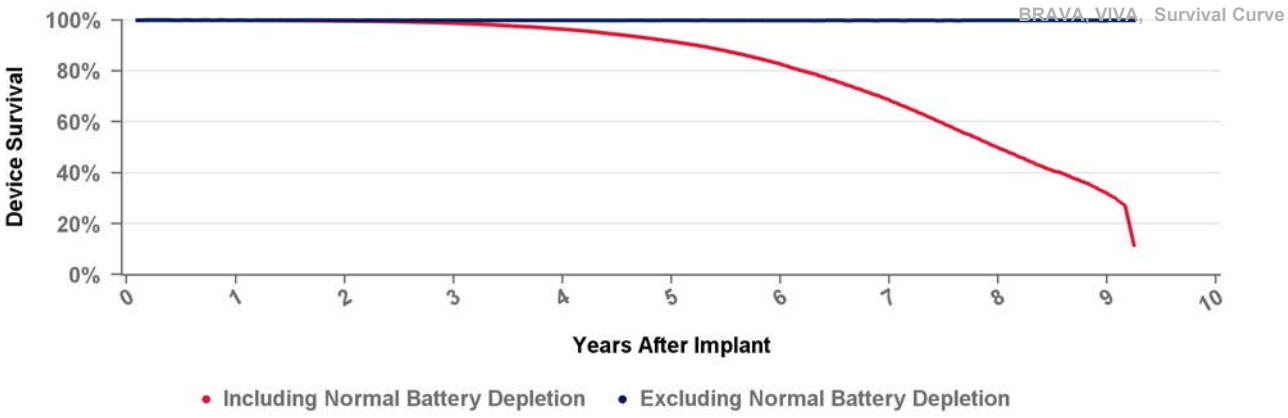
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 8,836 | Battery | 3 |
| **Estimated Active USA Implants** | 2,082 | Electrical Component | 2 |
| **Normal Battery Depletions** | 1,536 | Other | 1 |
| | | **Therapy Function Compromised** | **3** |
| | | Battery | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB1Q1 Viva Quad S

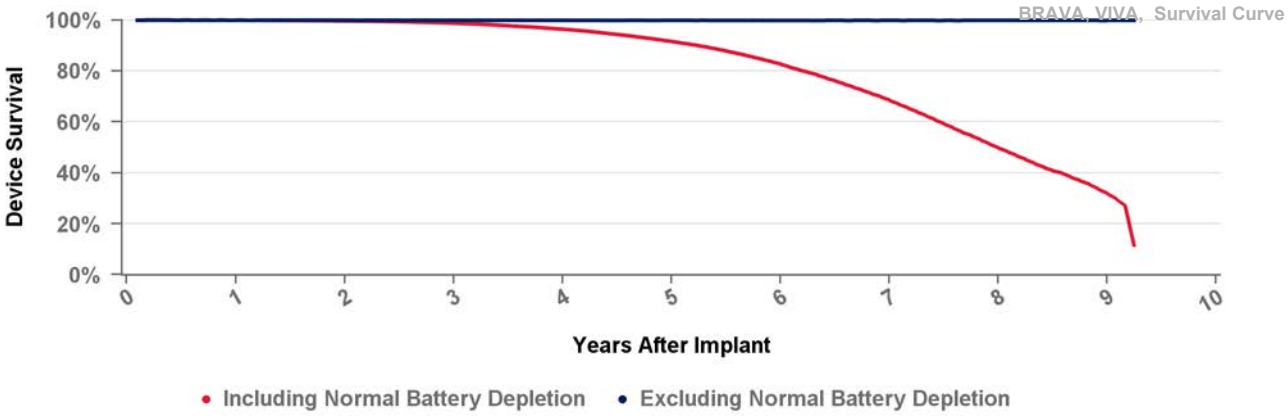
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 4,539 | Battery | 1 |
| **Estimated Active USA Implants** | 1,372 | Electrical Component | 1 |
| **Normal Battery Depletions** | 683 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB1QQ Viva Quad S

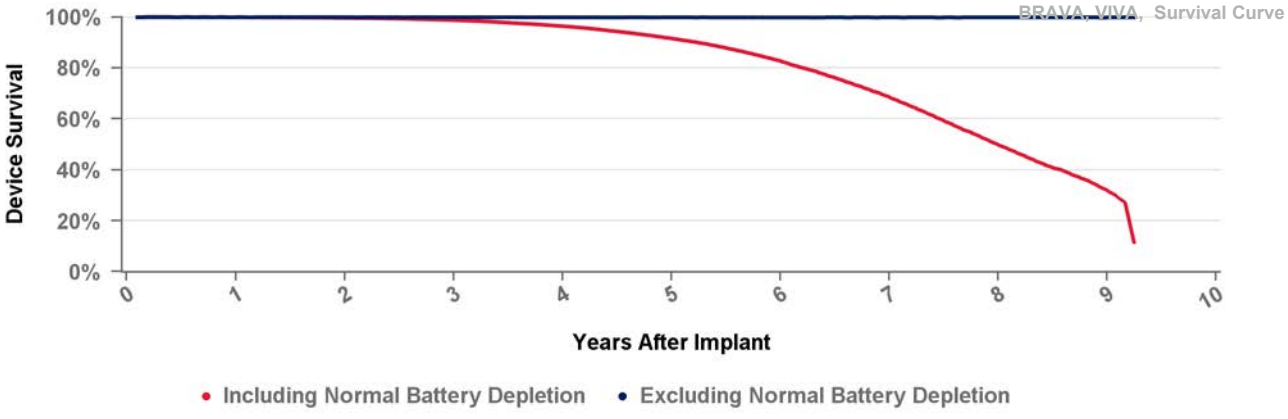
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **7** |
| **Registered USA Implants** | 9,869 | Battery | 1 |
| **Estimated Active USA Implants** | 3,125 | Electrical Component | 3 |
| **Normal Battery Depletions** | 1,704 | Possible Early Battery Depletion | 2 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **2** |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB2D1 Viva S

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

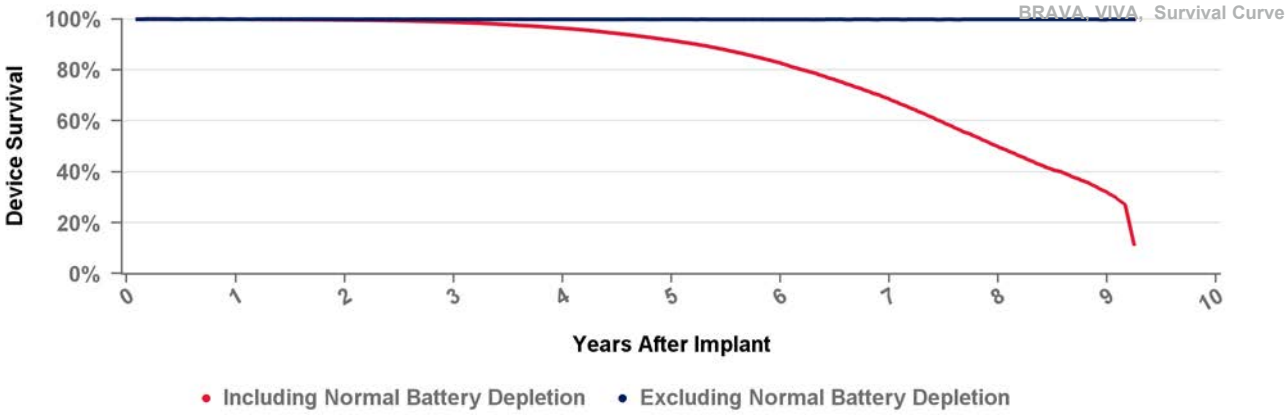



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB2D4 Viva S

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

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

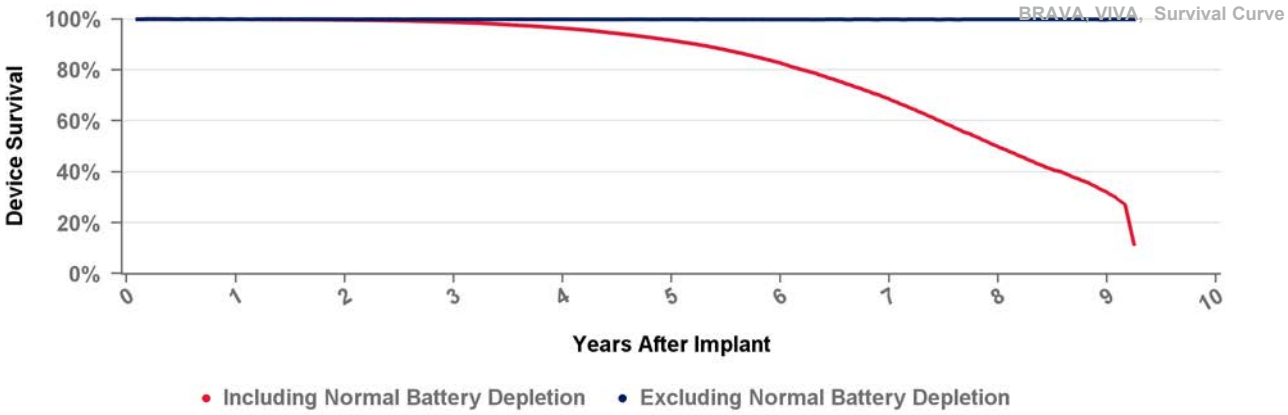



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBB2QQ Viva Quad S

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

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBC2D1 Brava

**US Market Release**

**CE Approval Date** 08Aug2012

**Registered USA Implants**

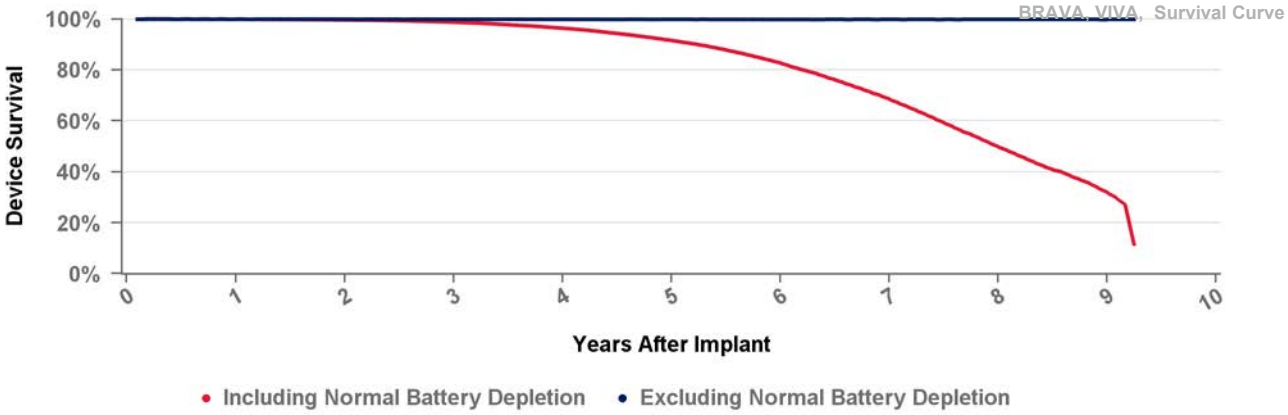
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBC2D4 Brava

**US Market Release**

**CE Approval Date** 08Aug2012

**Registered USA Implants**

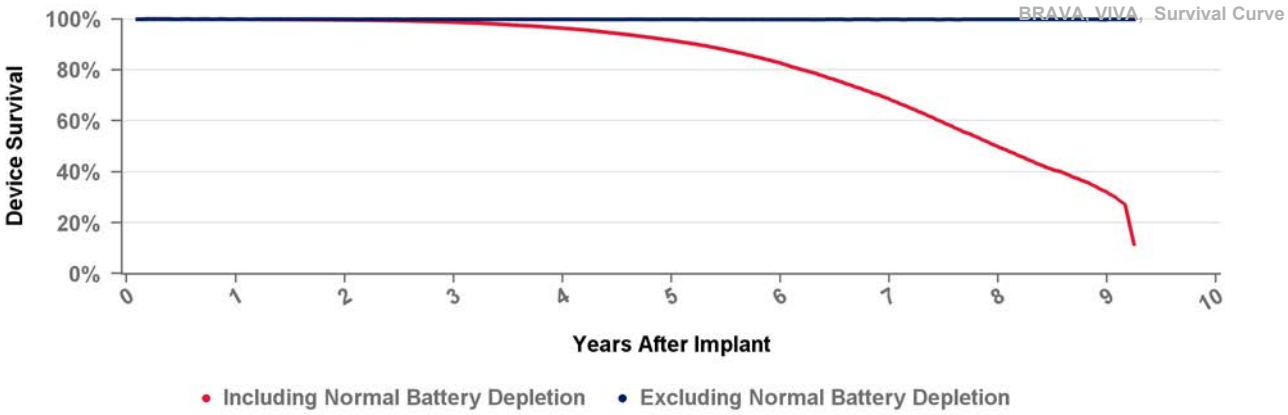
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

**Therapy Function Compromised**

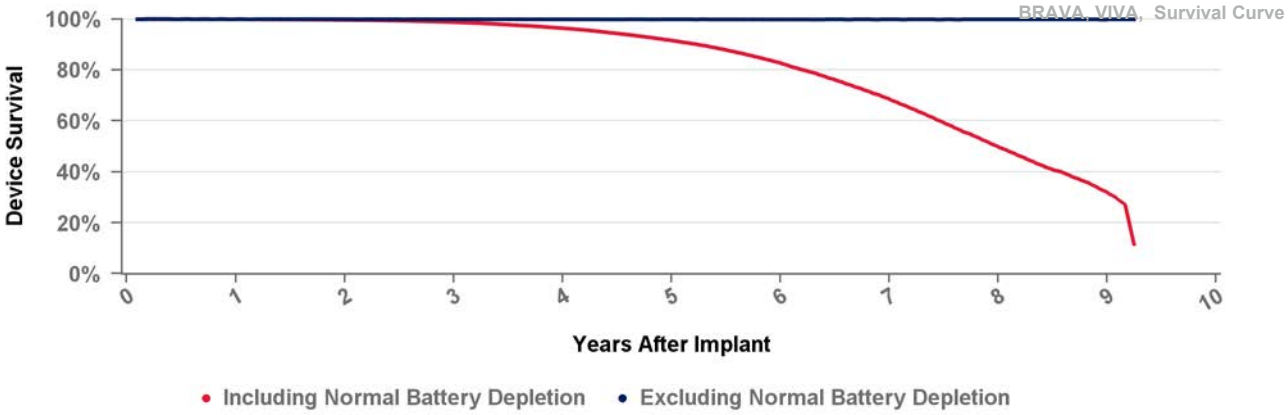



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBC2Q1 Brava Quad

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

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

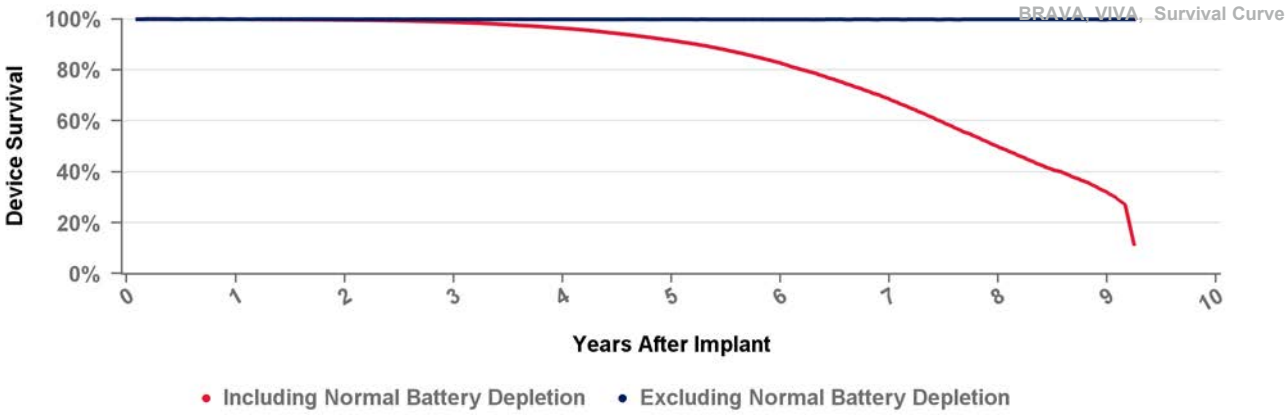



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBC2QQ Brava Quad

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

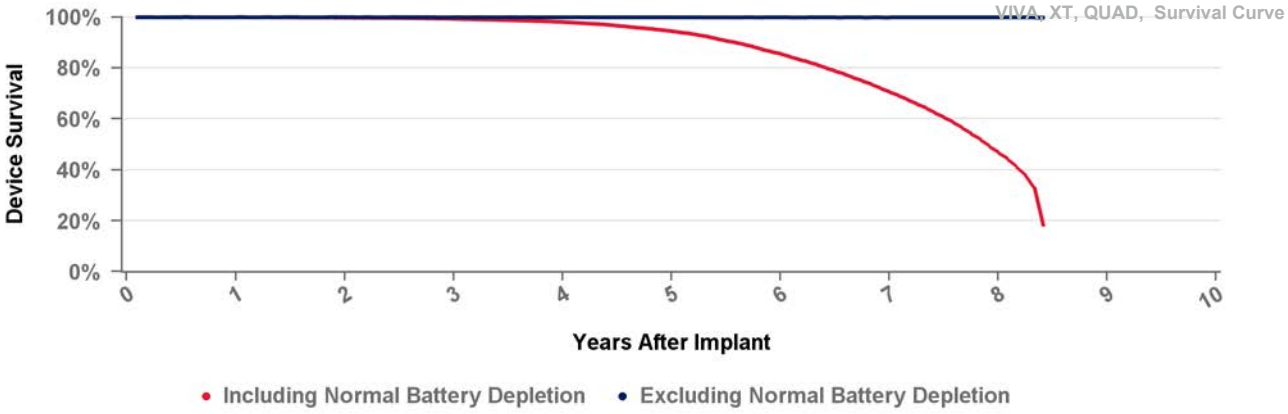
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 111 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.6% | 82.7% | 68.5% | 49.8% | 31.9% | 11.4% |
| Effective Sample Size | 86452 | 78598 | 71240 | 62984 | 53108 | 40787 | 25472 | 10097 | 1689 | 122 |

## DTBX1QQ Viva Quad C

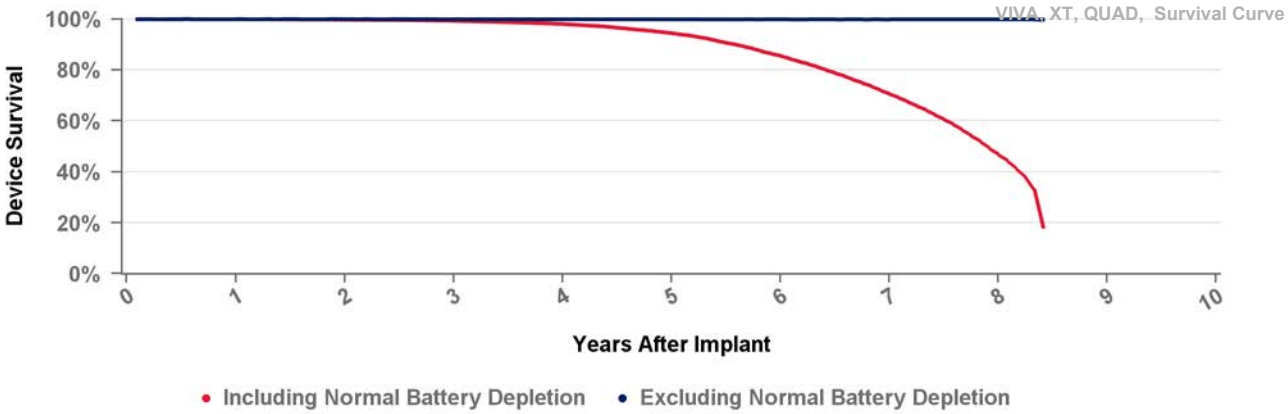
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 1,276 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 144 | **Therapy Function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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTBX2QQ Viva Quad C

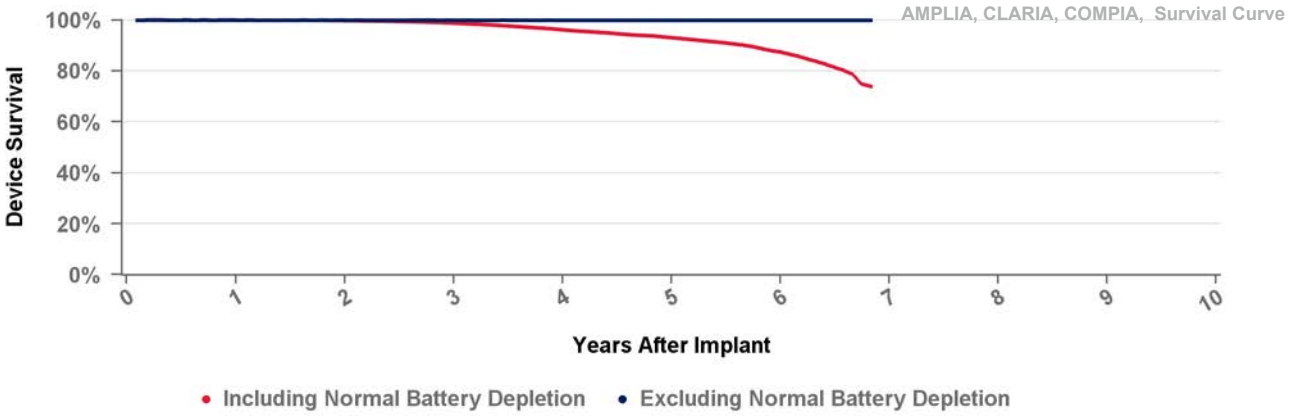
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 101 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 98.0% | 94.5% | 85.6% | 70.6% | 46.8% | 18.3% |
| Effective Sample Size | 33775 | 31347 | 28908 | 25957 | 22290 | 17402 | 11139 | 3093 | 188 |

## DTMA1D1 Claria MRI

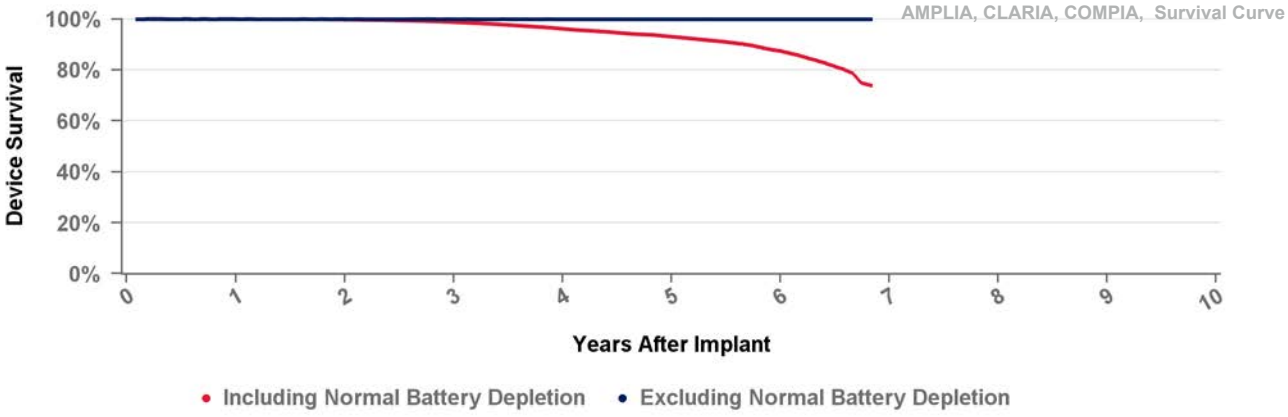
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **7** |
| **Registered USA Implants** | 19,106 | Battery | 4 |
| **Estimated Active USA Implants** | 14,451 | Electrical Component | 1 |
| **Normal Battery Depletions** | 372 | Electrical Interconnect | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMA1D4 Claria MRI

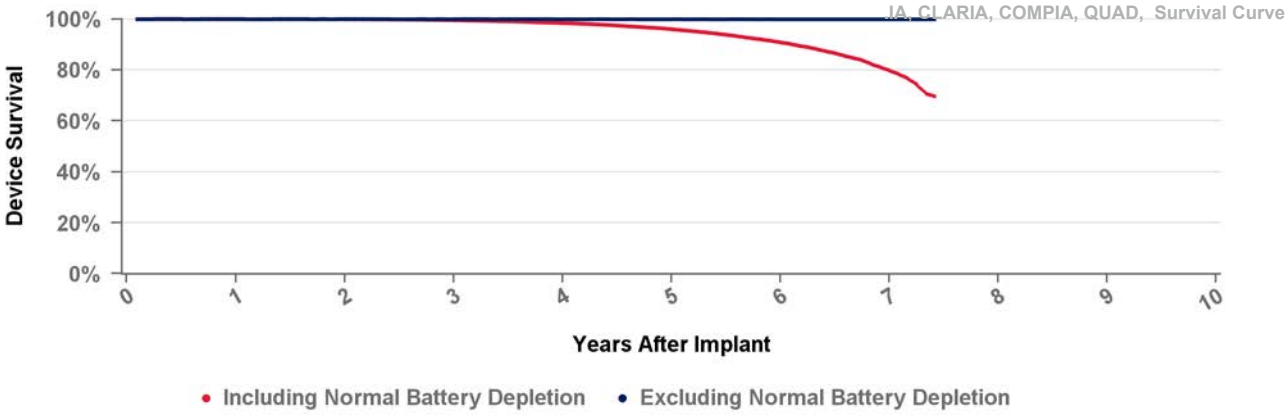
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **11** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 17,506 | Battery | 1 |
| **Estimated Active USA Implants** | 13,939 | Electrical Component | 4 |
| **Normal Battery Depletions** | 306 | **Therapy Function Compromised** | **6** |
| | | Battery | 1 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 2 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMA1Q1 Claria MRI

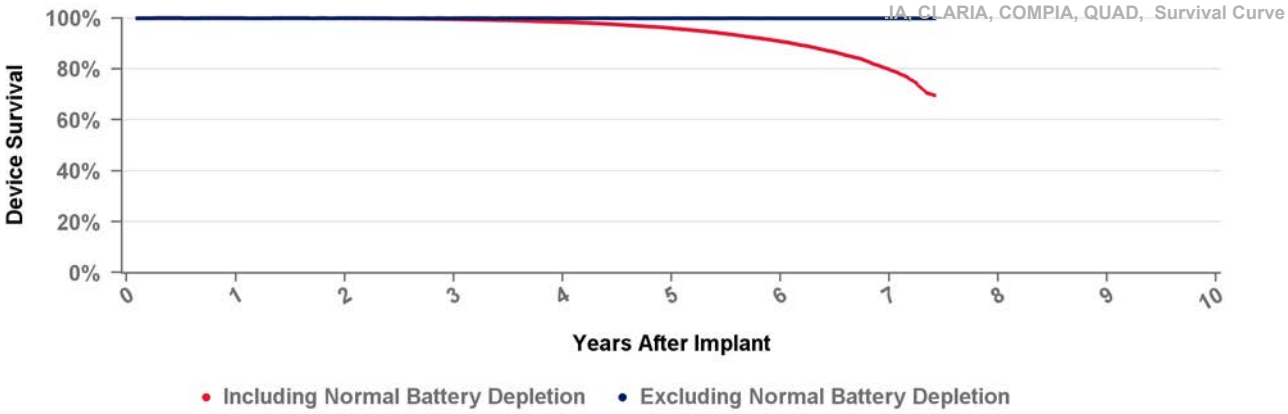
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 12,912 | Electrical Interconnect | 1 |
| **Estimated Active USA Implants** | 10,148 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 186 | Other | 1 |
| | | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMA1QQ Claria MRI

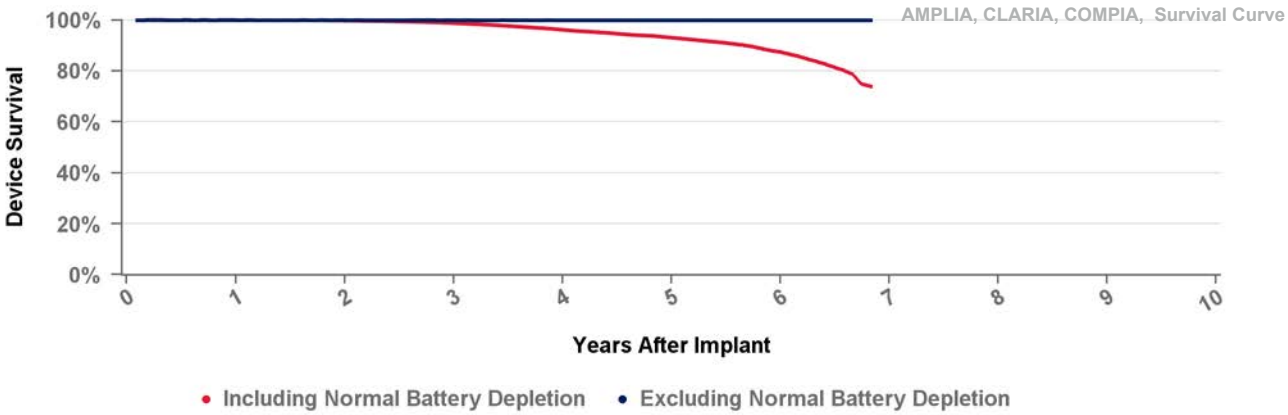
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **28** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **18** |
| **Registered USA Implants** | 81,766 | Battery | 1 |
| **Estimated Active USA Implants** | 67,903 | Electrical Component | 11 |
| **Normal Battery Depletions** | 1,011 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 1 |
| | | Software/Firmware | 1 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **10** |
| | | Device-Related Current Pathway | 4 |
| | | Electrical Component | 6 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMA2D1 Claria MRI

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

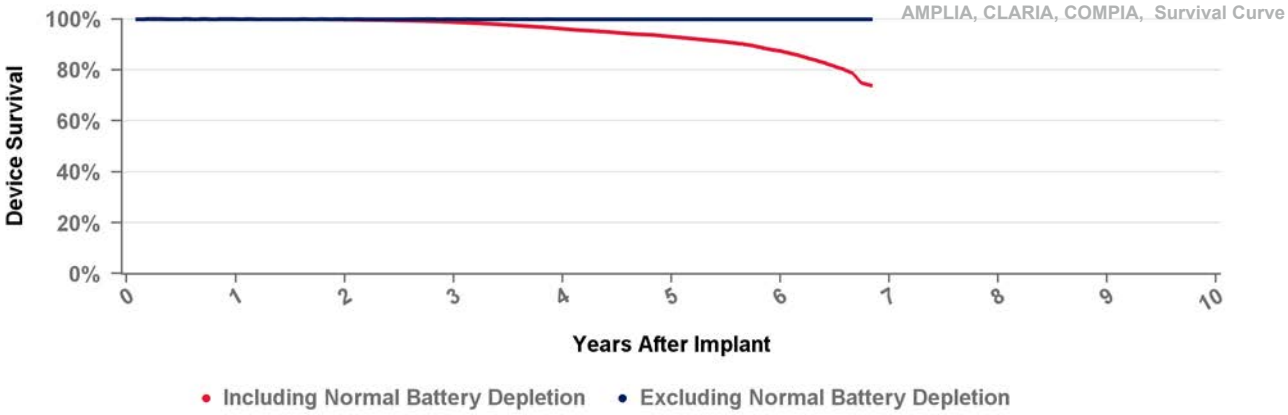



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMA2D4 Claria MRI

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

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

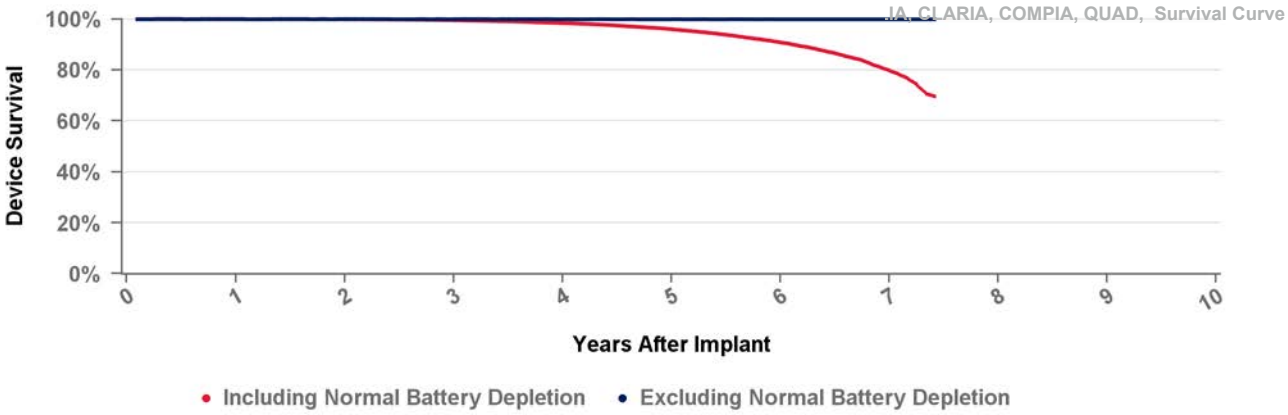



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMA2Q1 Claria MRI

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

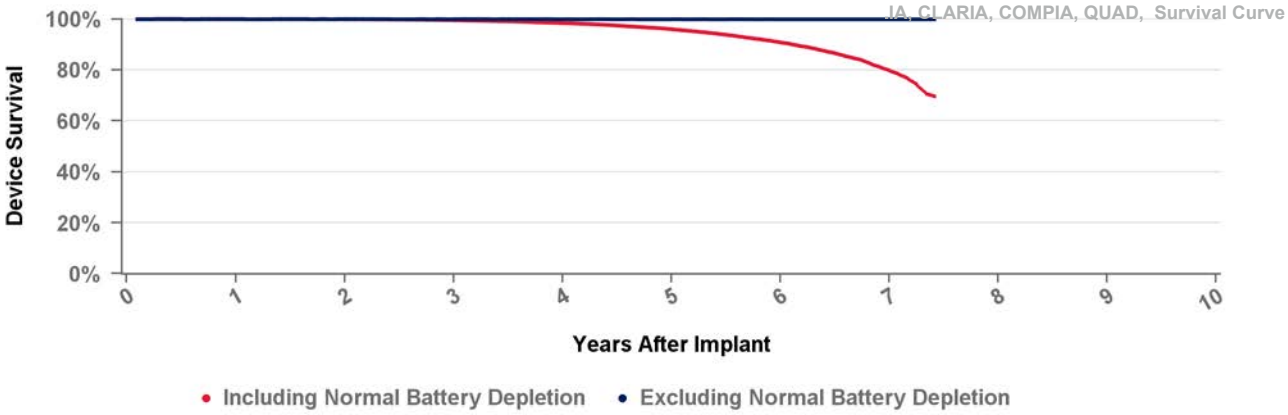
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMA2QQ Claria MRI

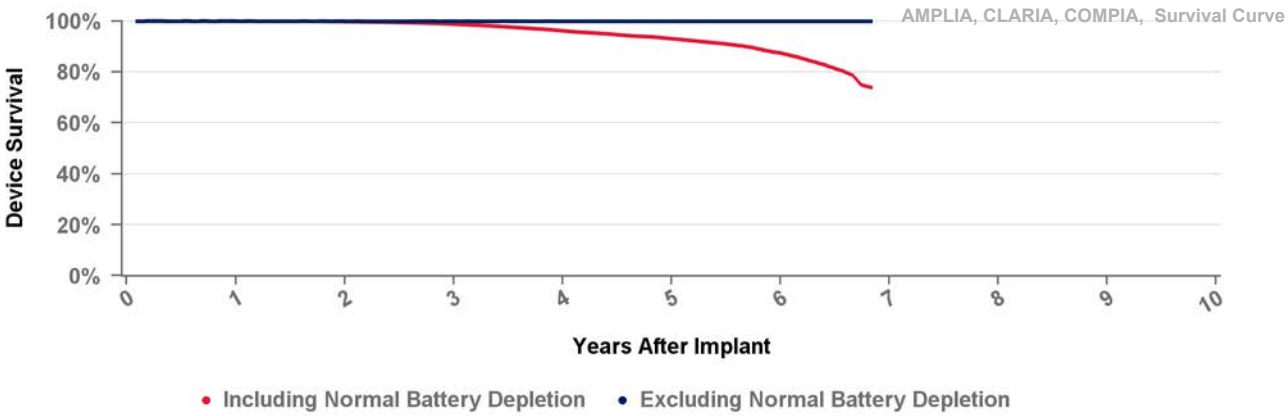
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Feb2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMB1D1 Amplia MRI

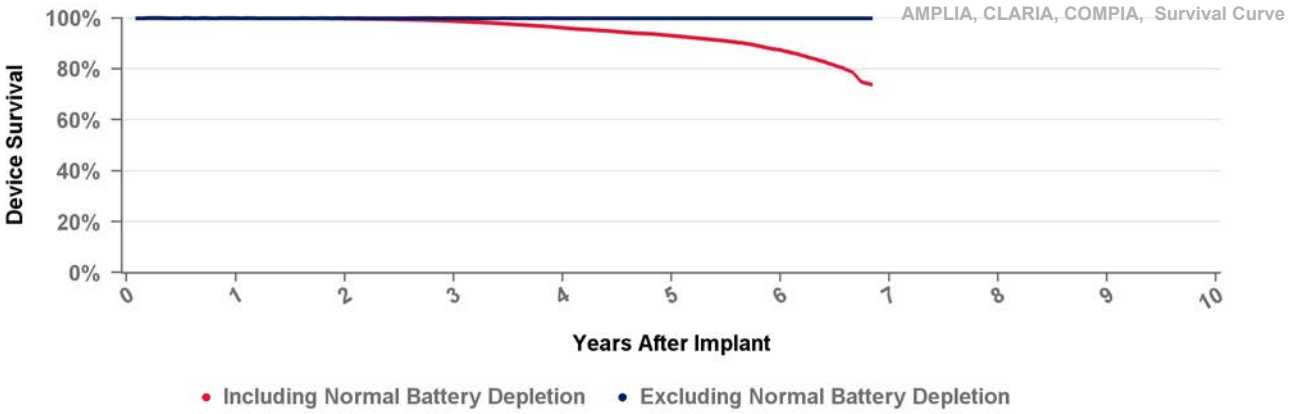
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **5** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 9,142 | Battery | 1 |
| **Estimated Active USA Implants** | 6,093 | Electrical Component | 2 |
| **Normal Battery Depletions** | 282 | Other | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMB1D4 Amplia MRI

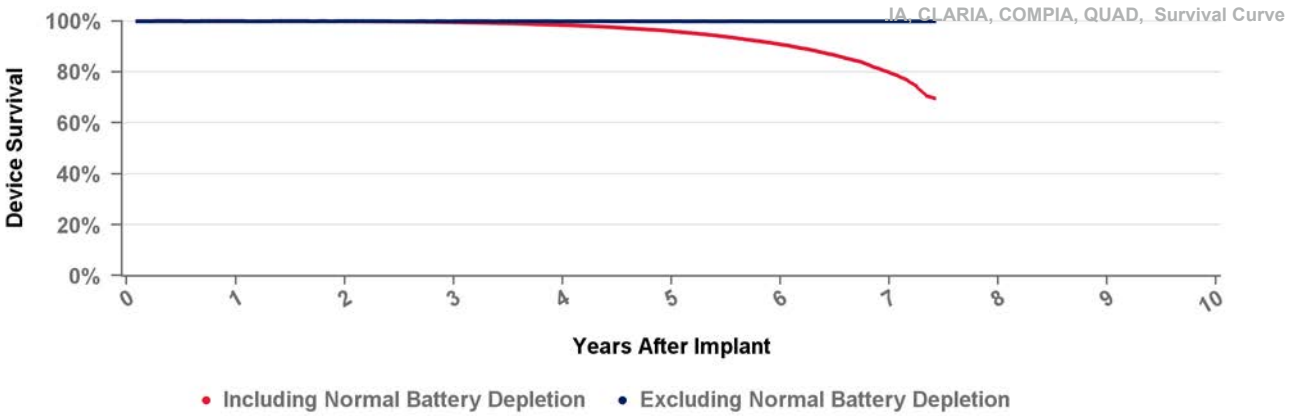
| | | | |
|---|---|---|---|
| **US Market Release** | 01Feb2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 9,770 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 6,027 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 416 | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMB1Q1 Amplia MRI

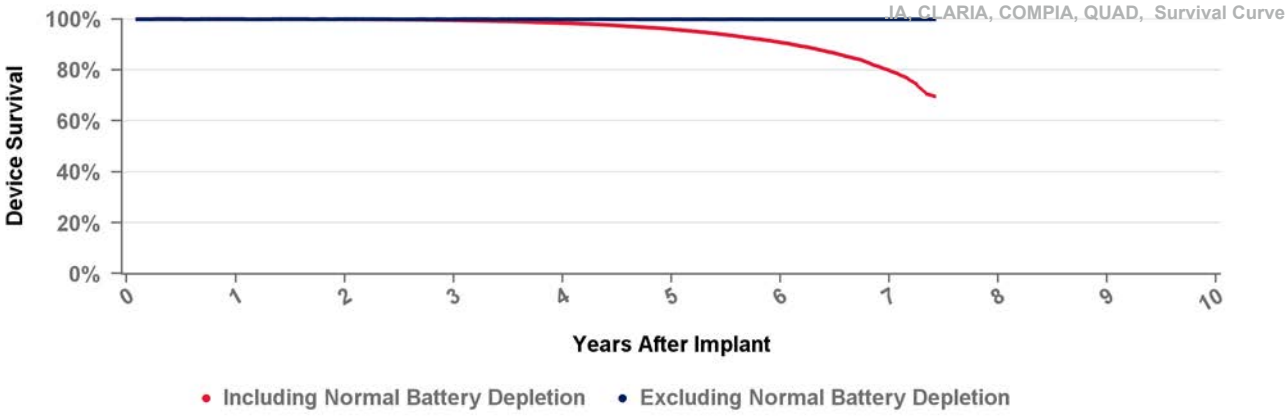
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 5,873 | Battery | 1 |
| **Estimated Active USA Implants** | 4,086 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 151 | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMB1QQ Amplia MRI

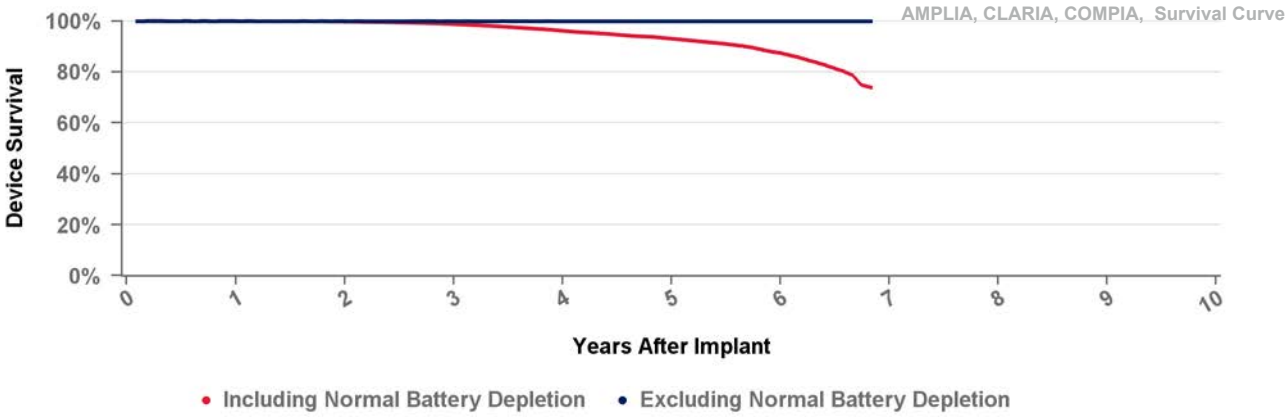
| | | | |
|---|---|---|---|
| **US Market Release** | 01Feb2016 | **Total Malfunctions (USA)** | **37** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **28** |
| **Registered USA Implants** | 49,187 | Battery | 12 |
| **Estimated Active USA Implants** | 31,780 | Electrical Component | 10 |
| **Normal Battery Depletions** | 2,188 | Possible Early Battery Depletion | 3 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **9** |
| | | Battery | 8 |
| | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMB2D1 Amplia MRI

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

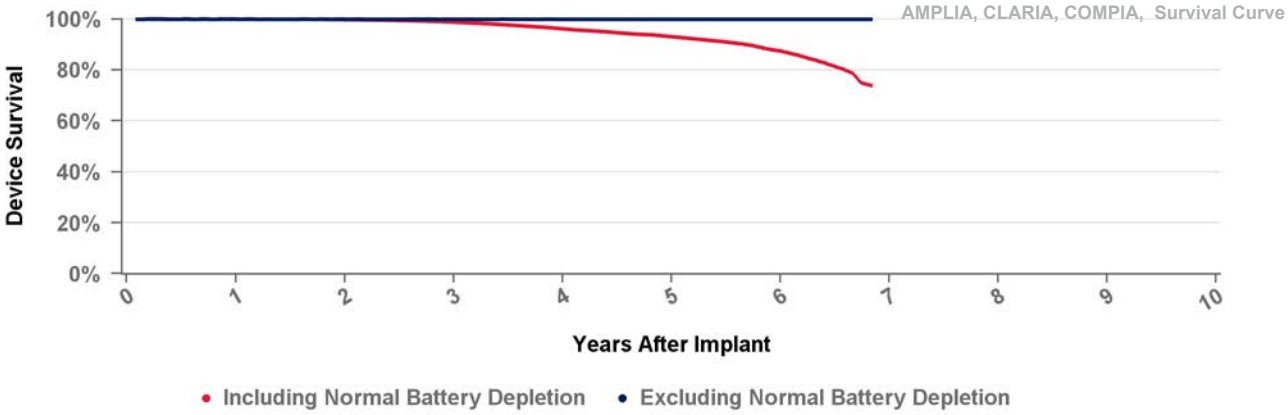



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMB2D4 Amplia MRI

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

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

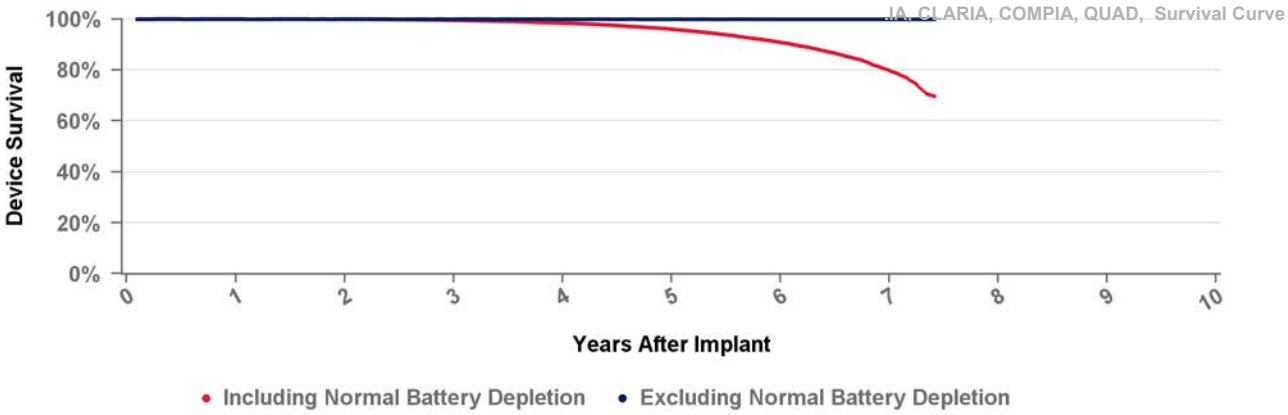



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMB2Q1 Amplia MRI

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

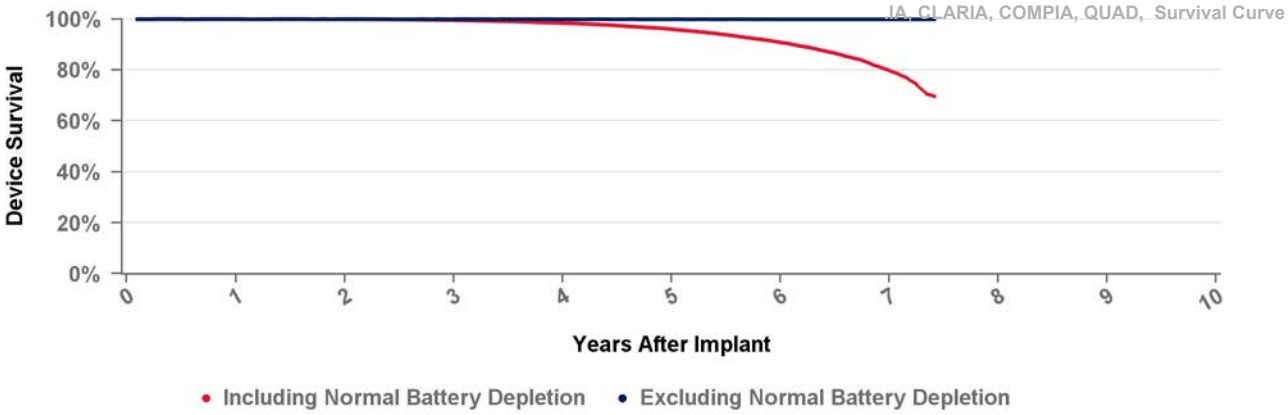
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMB2QQ Amplia MRI

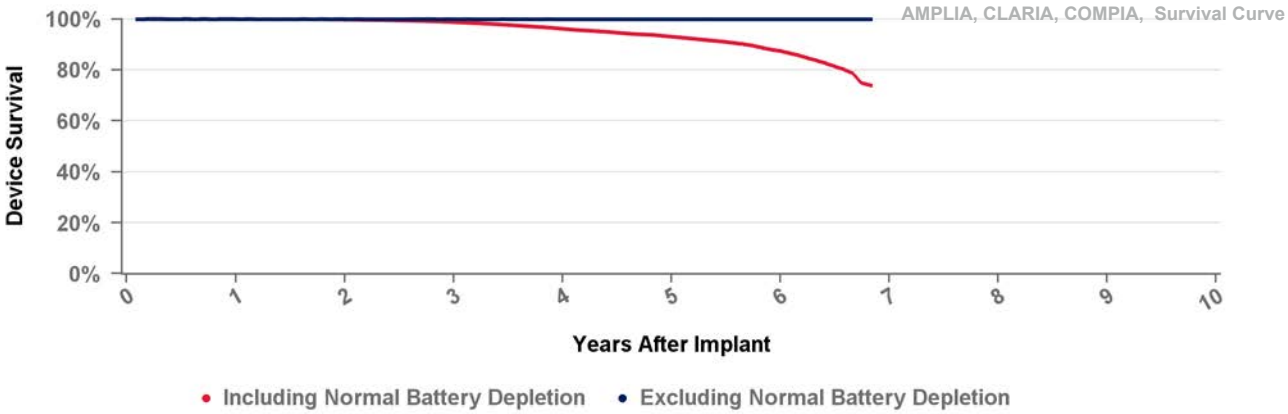
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Feb2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMC1D1 Compia MRI

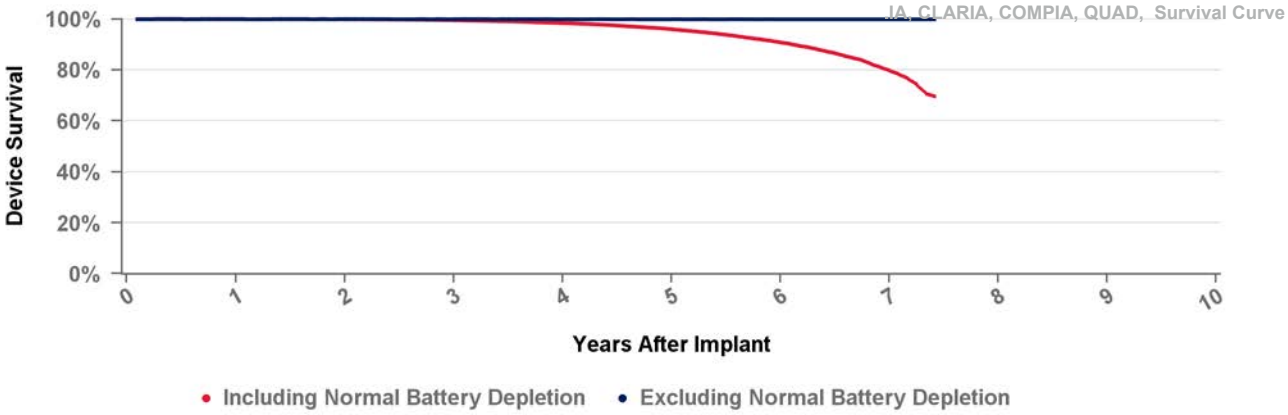
| | | | | |
|---|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | | **0** |
| **Registered USA Implants** | 1,371 | | | |
| **Estimated Active USA Implants** | 979 | **Therapy Function Compromised** | | **1** |
| **Normal Battery Depletions** | 42 | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMC1QQ Compia MRI

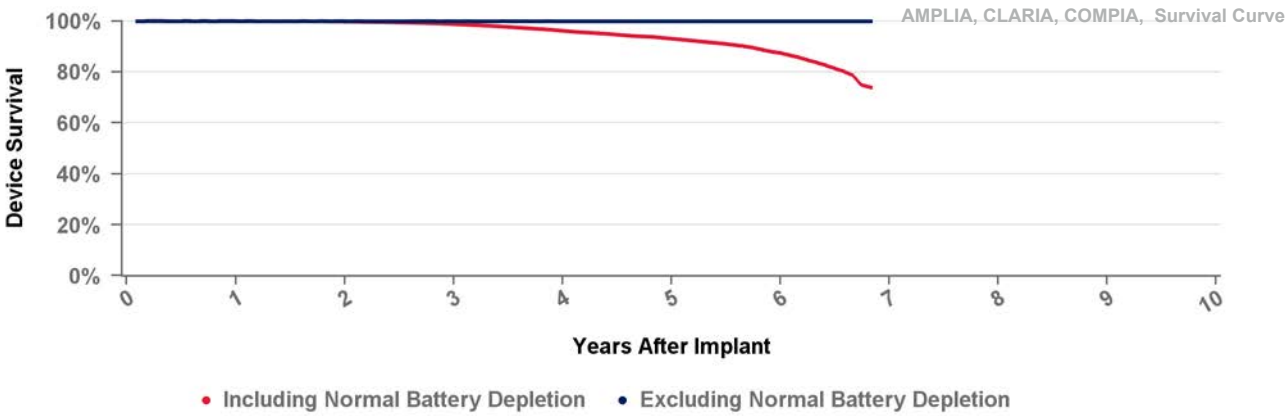
| | | | |
|---|---|---|---|
| **US Market Release** | 01Feb2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 6,438 | Battery | 1 |
| **Estimated Active USA Implants** | 4,531 | Electrical Component | 2 |
| **Normal Battery Depletions** | 313 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTMC2D1 Compia MRI

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

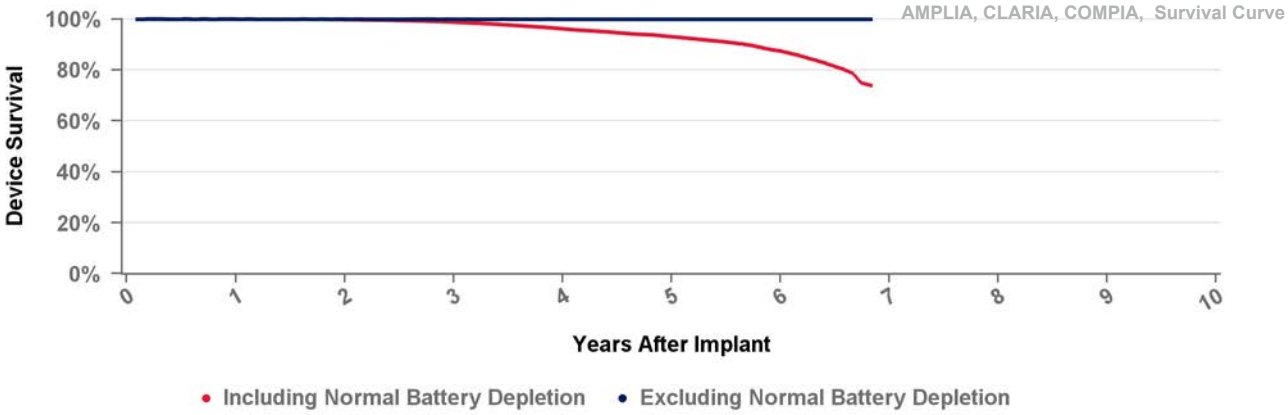



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMC2D4 Compia MRI

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

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

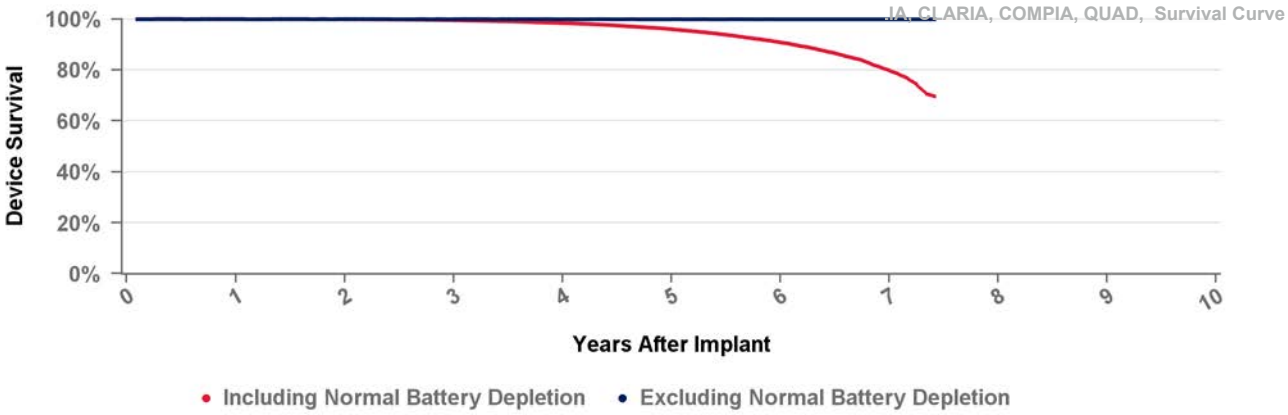



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 82 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 98.8% | 96.2% | 93.1% | 87.5% | 73.8% |
| Effective Sample Size | 38781 | 30076 | 23261 | 16152 | 9916 | 3626 | 141 |

## DTMC2QQ Compia MRI

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

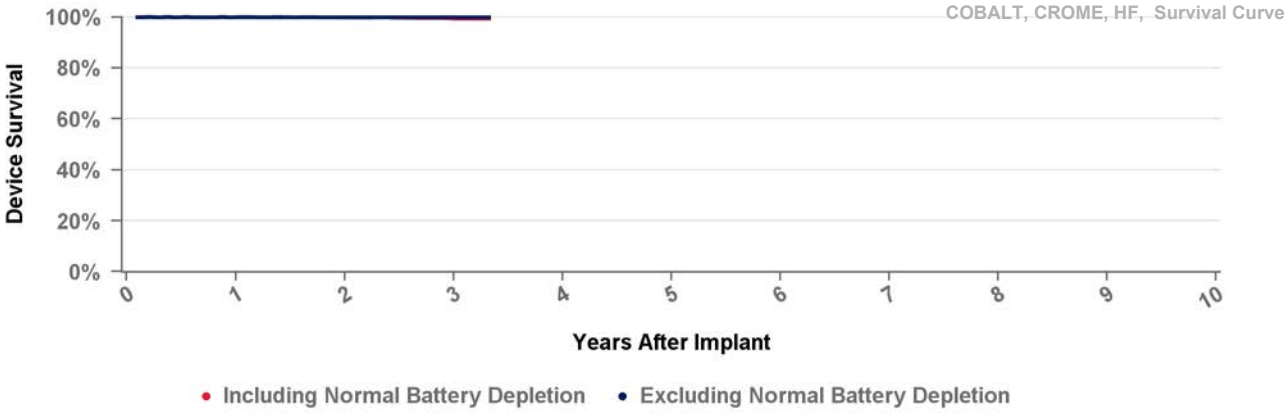
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.5% | 98.4% | 96.0% | 90.8% | 79.8% | 69.6% |
| Effective Sample Size | 108018 | 88495 | 72908 | 51737 | 31929 | 15717 | 3364 | 305 |

## DTPA2D1 Cobalt XT HF

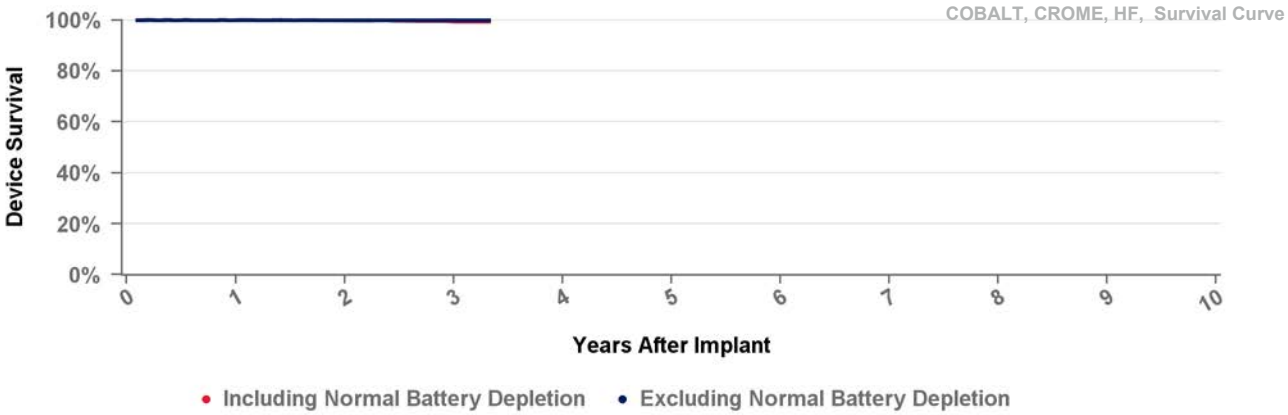
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 6,538 | Other | 1 |
| **Estimated Active USA Implants** | 6,237 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 4 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPA2D4 Cobalt XT HF

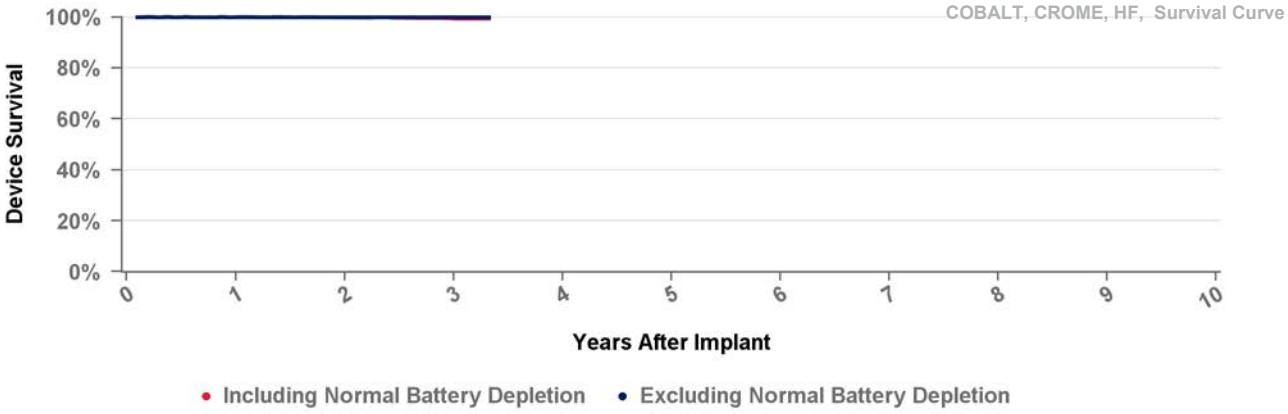
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 7,526 | Electrical Interconnect | 1 |
| **Estimated Active USA Implants** | 7,182 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 4 | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPA2Q1 Cobalt XT HF Quad

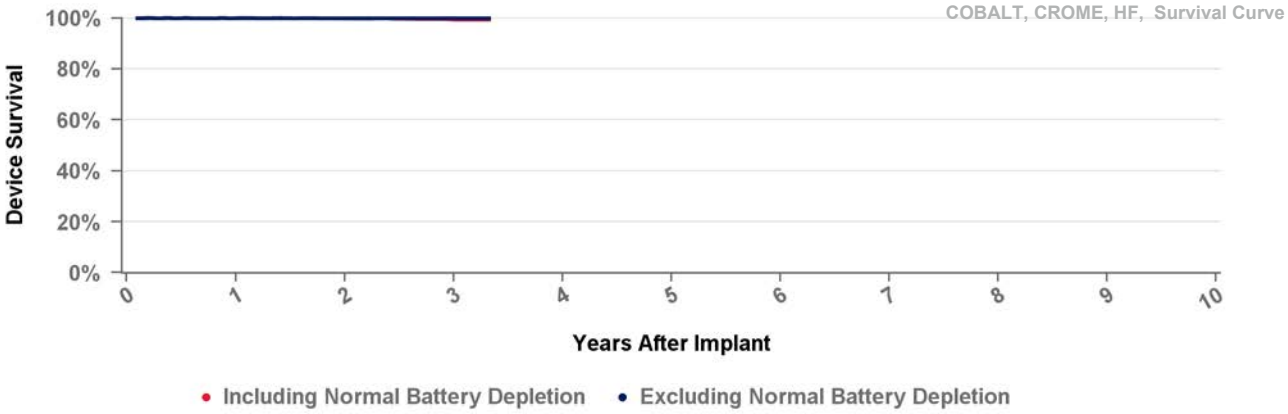
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 4,388 | Software/Firmware | 1 |
| **Estimated Active USA Implants** | 4,162 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 4 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPA2QQ Cobalt XT HF Quad

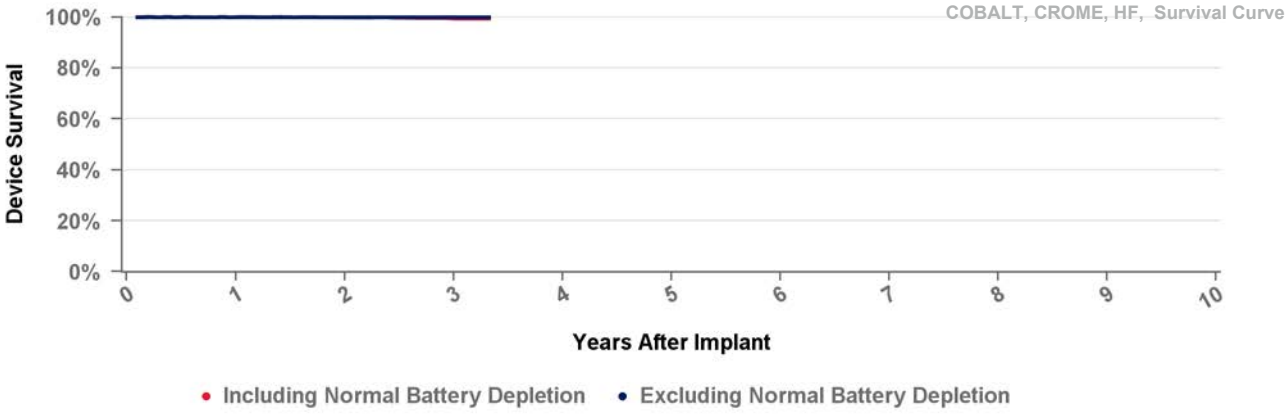
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 41,866 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 40,470 | Software/Firmware | 1 |
| **Normal Battery Depletions** | 4 | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPB2D1 Cobalt HF

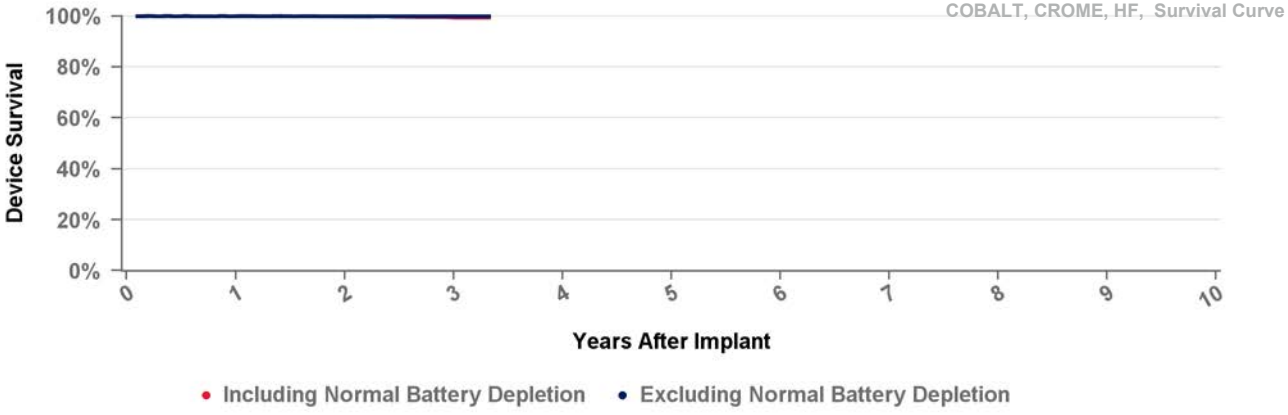
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 6,325 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 5,857 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | 6 | Electrical Component | 1 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPB2D4 Cobalt HF

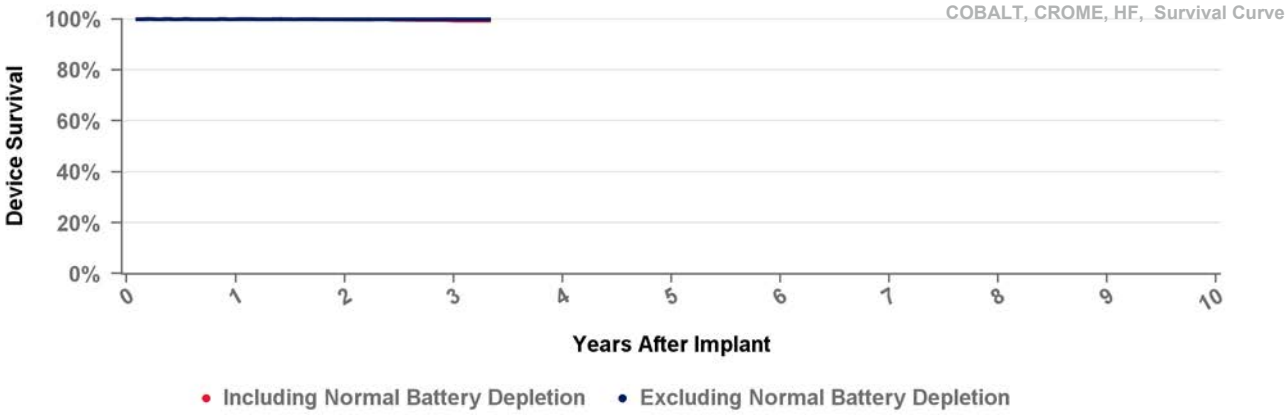
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **5** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 6,318 | Electrical Interconnect | 3 |
| **Estimated Active USA Implants** | 5,934 | Software/Firmware | 1 |
| **Normal Battery Depletions** | 4 | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPB2Q1 Cobalt HF Quad

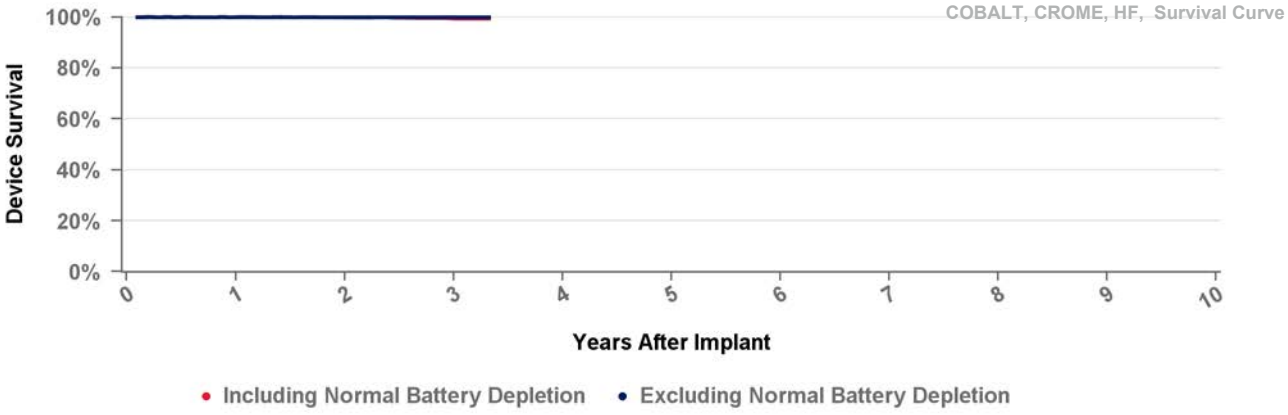
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4,178 | | |
| **Estimated Active USA Implants** | 3,878 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 2 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPB2QQ Cobalt HF Quad

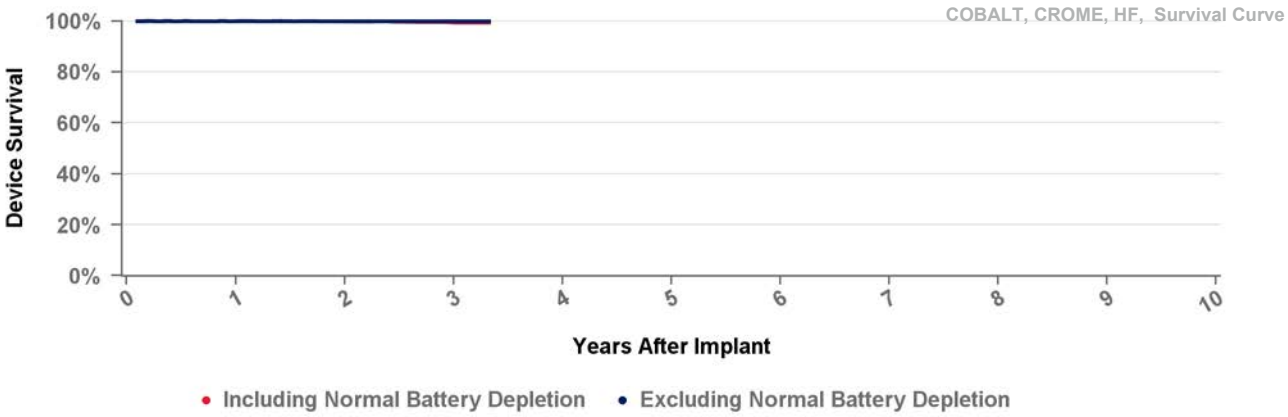
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 32,825 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 31,186 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 14 | Other | 1 |
| | | **Therapy Function Compromised** | **6** |
| | | Electrical Component | 3 |
| | | Electrical Interconnect | 3 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPC2D1 Crome HF

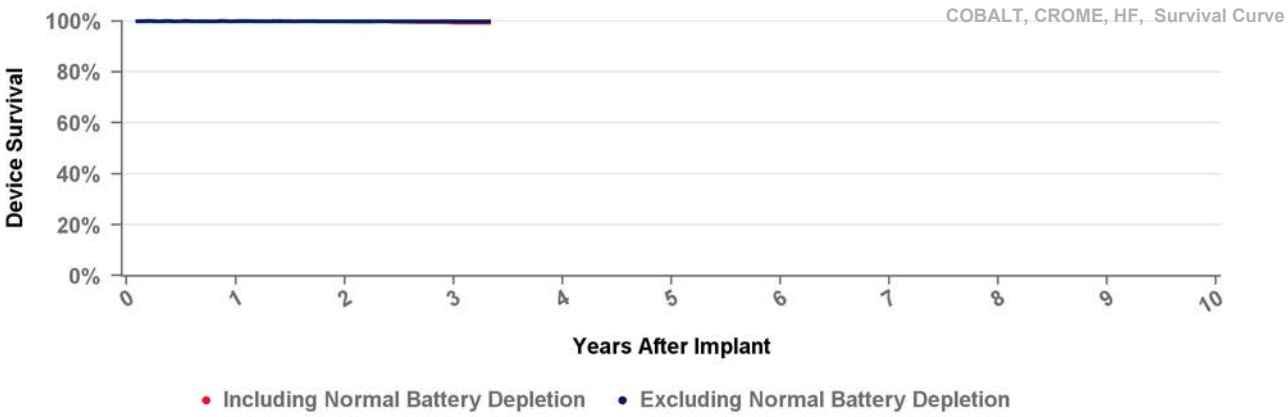
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 498 | | |
| **Estimated Active USA Implants** | 450 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPC2D4 Crome HF

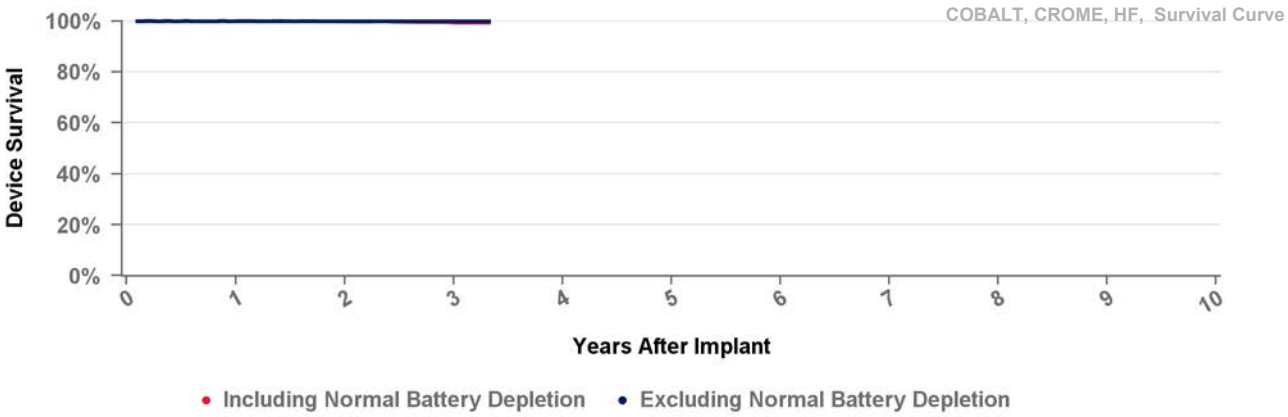
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 480 | | |
| **Estimated Active USA Implants** | 446 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 4 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPC2Q1 Crome HF Quad

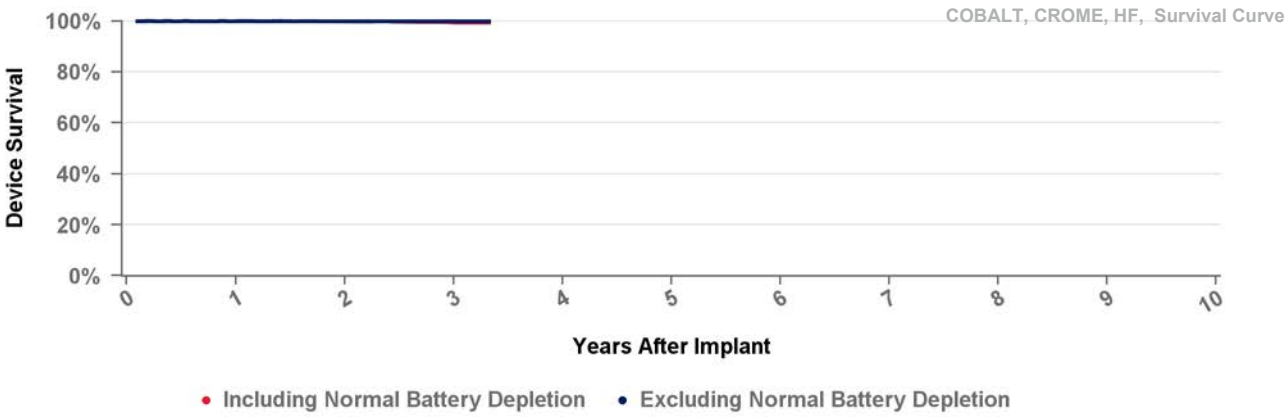
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 225 | | |
| **Estimated Active USA Implants** | 211 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## DTPC2QQ Crome HF Quad

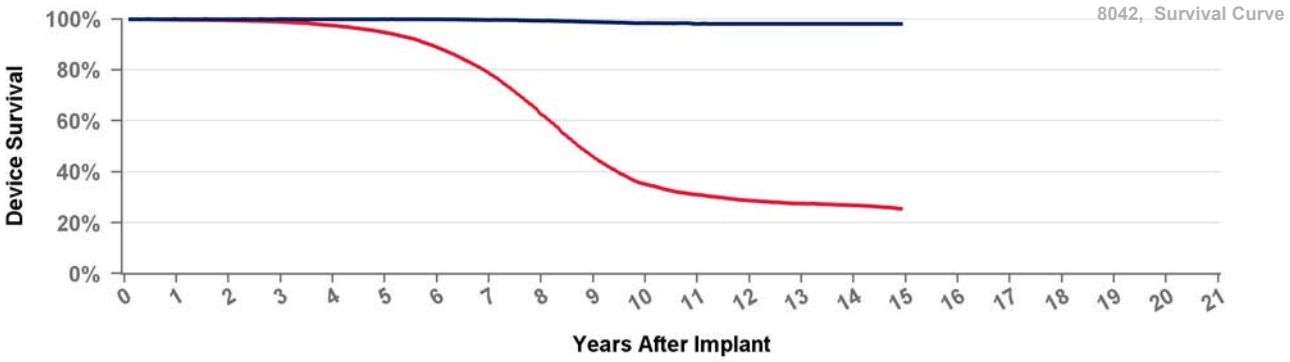
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,209 | | |
| **Estimated Active USA Implants** | 2,097 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 2 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 99.4% | 99.4% |
| Effective Sample Size | 32483 | 17430 | 1827 | 170 |

## 8042 InSync III

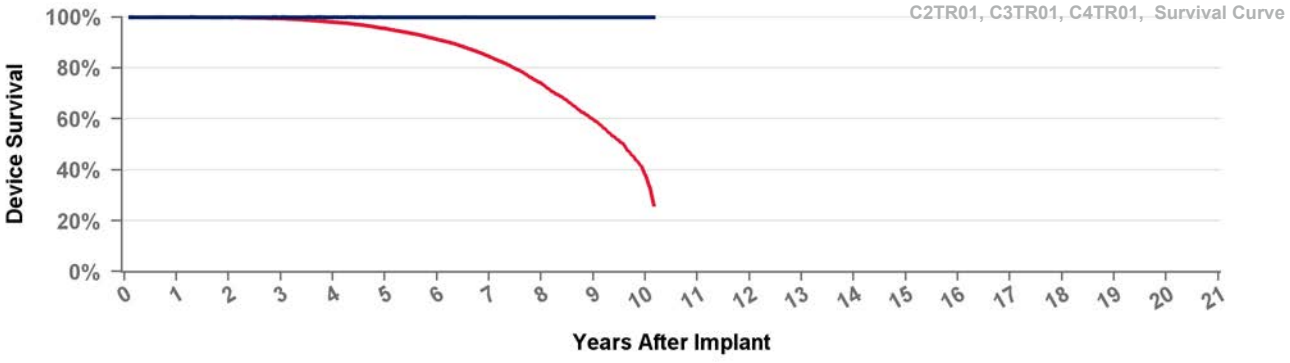
| | | | |
|---|---|---|---|
| **US Market Release** | 25Feb2003 | **Total Malfunctions (USA)** | **116** |
| **CE Approval Date** | 07Feb2001 | **Therapy Function Not Compromised** | **67** |
| **Registered USA Implants** | 39,276 | Battery | 55 |
| **Estimated Active USA Implants** | 1,871 | Electrical Component | 2 |
| **Normal Battery Depletions** | 5,251 | Electrical Interconnect | 3 |
| | | Possible Early Battery Depletion | 2 |
| | | Other | 5 |
| | | **Therapy Function Compromised** | **49** |
| | | Battery | 37 |
| | | Electrical Interconnect | 12 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 179 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.7% | 99.3% | 98.9% | 98.5% | 98.2% | 98.2% | 98.2% | 98.2% | 98.2% |
| Including NBD | 99.8% | 99.5% | 99.0% | 97.5% | 94.7% | 88.9% | 78.6% | 62.6% | 45.8% | 35.2% | 31.0% | 28.7% | 27.6% | 26.9% | 25.7% |
| Effective Sample Size | 30381 | 26391 | 22925 | 19730 | 16594 | 12739 | 9043 | 5910 | 3411 | 2145 | 1614 | 1276 | 1010 | 489 | 102 |

## C2TR01 Syncra CRT-P

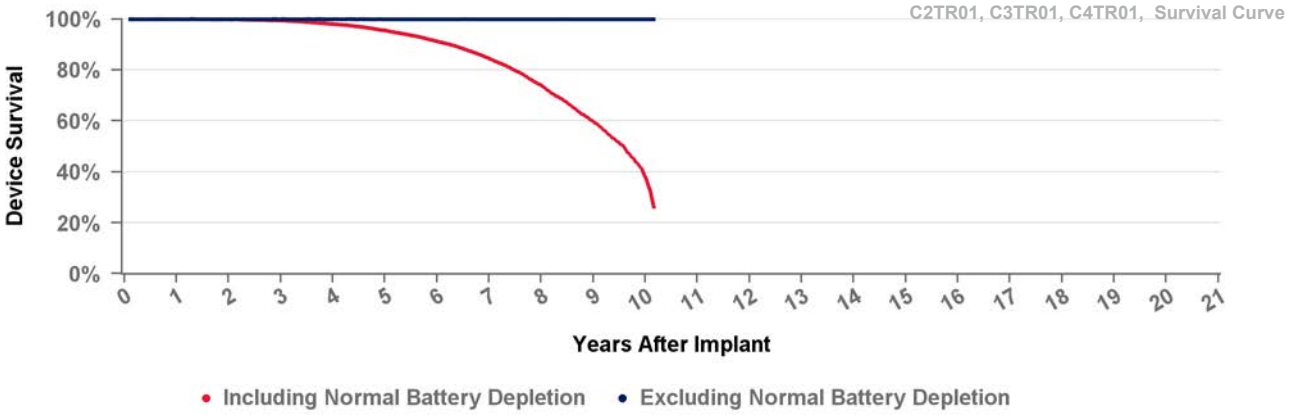
| | | | |
|---|---|---|---|
| **US Market Release** | 22Mar2011 | **Total Malfunctions (USA)** | **7** |
| **CE Approval Date** | 11May2010 | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 10,236 | Possible Early Battery Depletion | 5 |
| **Estimated Active USA Implants** | 2,304 | Other | 1 |
| **Normal Battery Depletions** | 939 | **Therapy Function Compromised** | **1** |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 122 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.2% | 84.5% | 74.0% | 59.6% | 38.1% | 26.1% |
| Effective Sample Size | 26187 | 23392 | 20953 | 18305 | 15669 | 13080 | 9989 | 6352 | 3141 | 474 | 146 |

## C3TR01 Consulta CRT-P

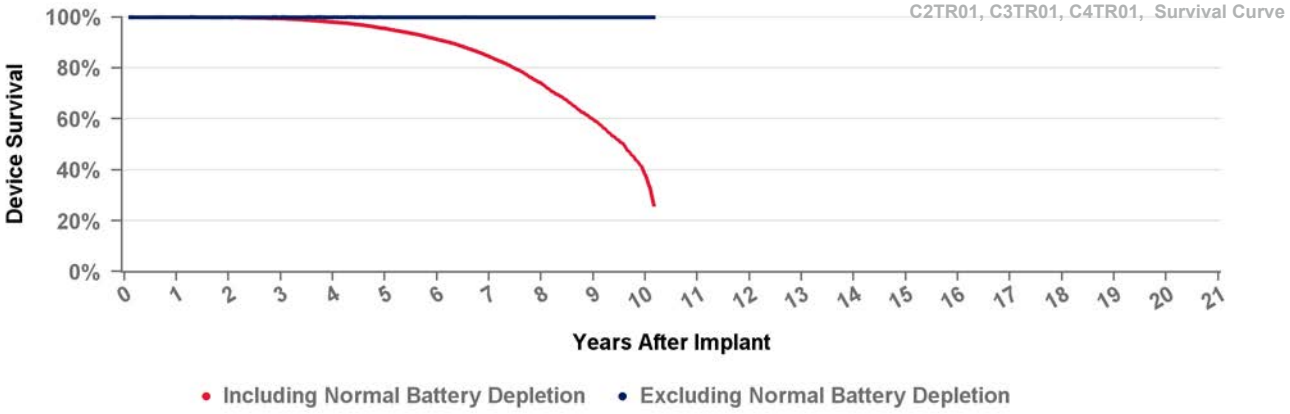
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 11May2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 122 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.2% | 84.5% | 74.0% | 59.6% | 38.1% | 26.1% |
| Effective Sample Size | 26187 | 23392 | 20953 | 18305 | 15669 | 13080 | 9989 | 6352 | 3141 | 474 | 146 |

## C4TR01 Consulta CRT-P

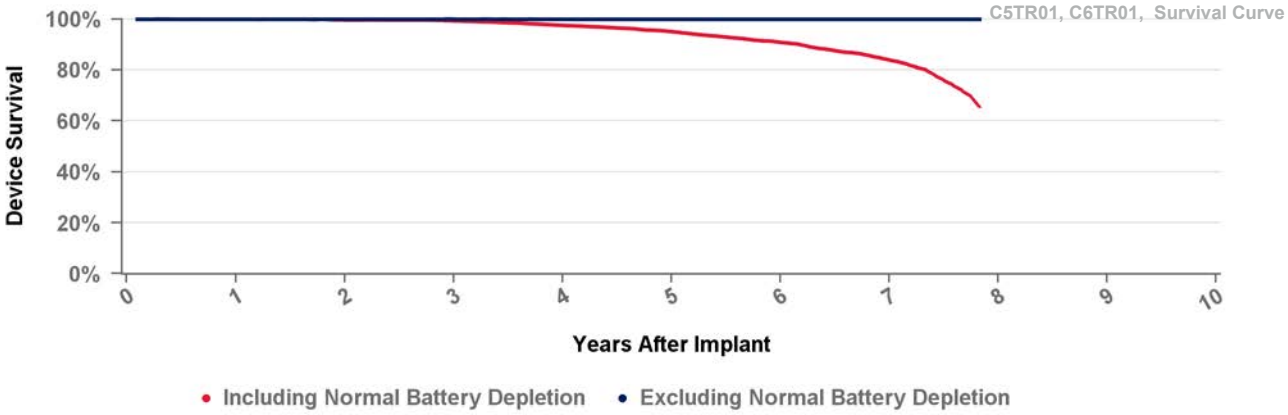
| | | | |
|---|---|---|---|
| **US Market Release** | 22Mar2011 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 23,407 | Possible Early Battery Depletion | 5 |
| **Estimated Active USA Implants** | 6,085 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | 2,101 | Electrical Component | 2 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 122 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.2% | 84.5% | 74.0% | 59.6% | 38.1% | 26.1% |
| Effective Sample Size | 26187 | 23392 | 20953 | 18305 | 15669 | 13080 | 9989 | 6352 | 3141 | 474 | 146 |

## C5TR01 Viva CRT-P

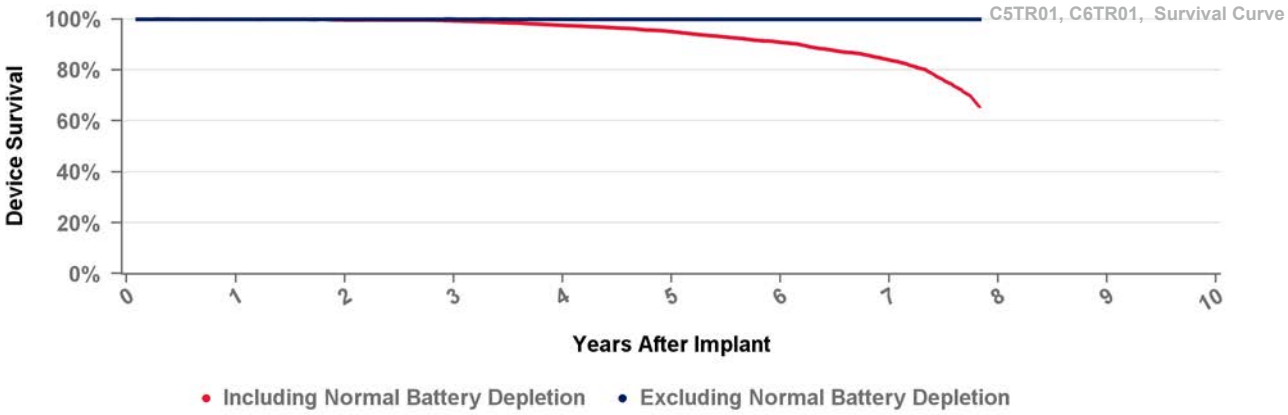
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 04Apr2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.3% | 97.5% | 95.1% | 90.9% | 83.9% | 65.6% |
| Effective Sample Size | 7369 | 6608 | 5922 | 5151 | 4410 | 3628 | 1757 | 126 |

## C6TR01 Viva CRT-P

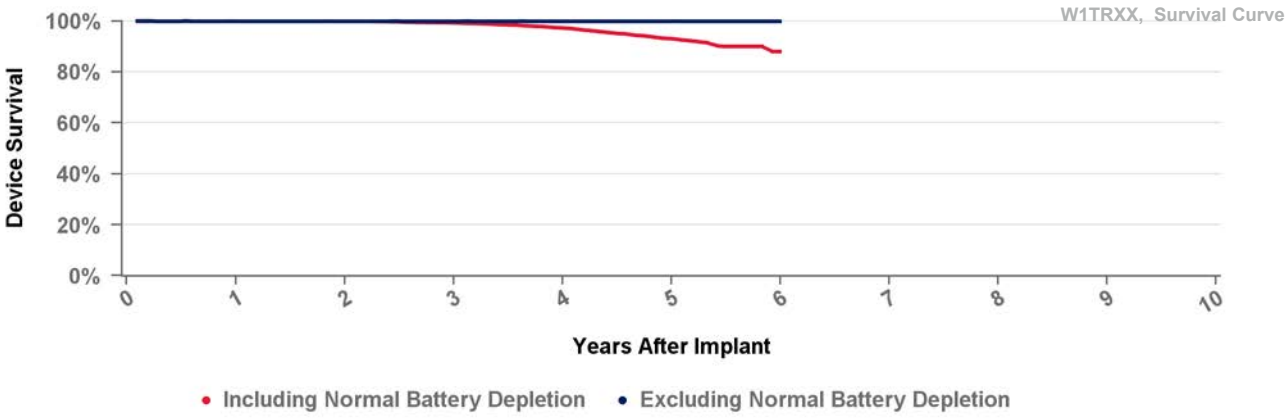
| | | | |
|---|---|---|---|
| **US Market Release** | 09Jul2014 | **Total Malfunctions (USA)** | **6** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 9,198 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 4,196 | Possible Early Battery Depletion | 5 |
| **Normal Battery Depletions** | 477 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.3% | 97.5% | 95.1% | 90.9% | 83.9% | 65.6% |
| Effective Sample Size | 7369 | 6608 | 5922 | 5151 | 4410 | 3628 | 1757 | 126 |

## W1TR01 Percepta CRTP MRI

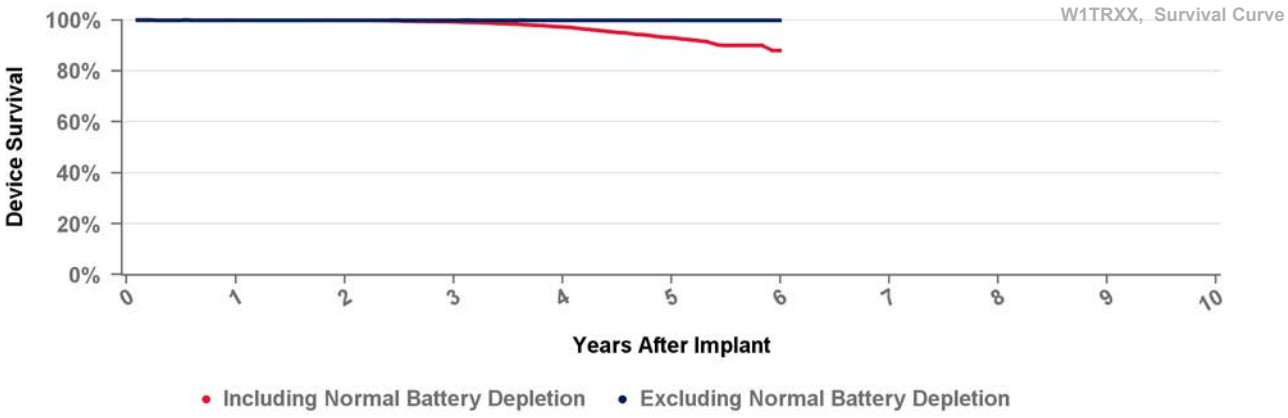
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **5** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 14,723 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 12,491 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 93 | Other | 1 |
| | | **Therapy Function Compromised** | **2** |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W1TR02 Serena CRTP MRI

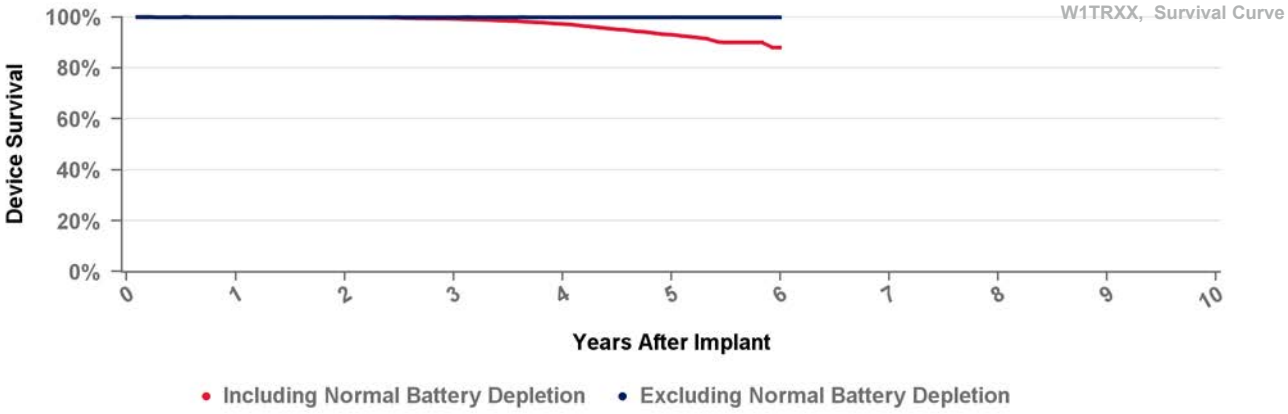
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 2,844 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 2,338 | Other | 1 |
| **Normal Battery Depletions** | 29 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W1TR03 Solara CRTP MRI

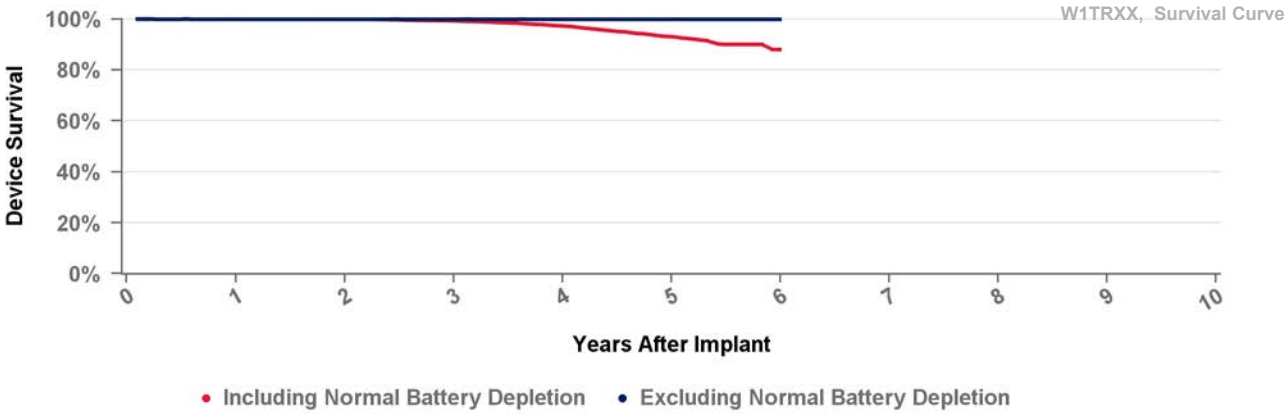
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 3,707 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 2,888 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 55 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W1TR04 Percepta CRTP MRI

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

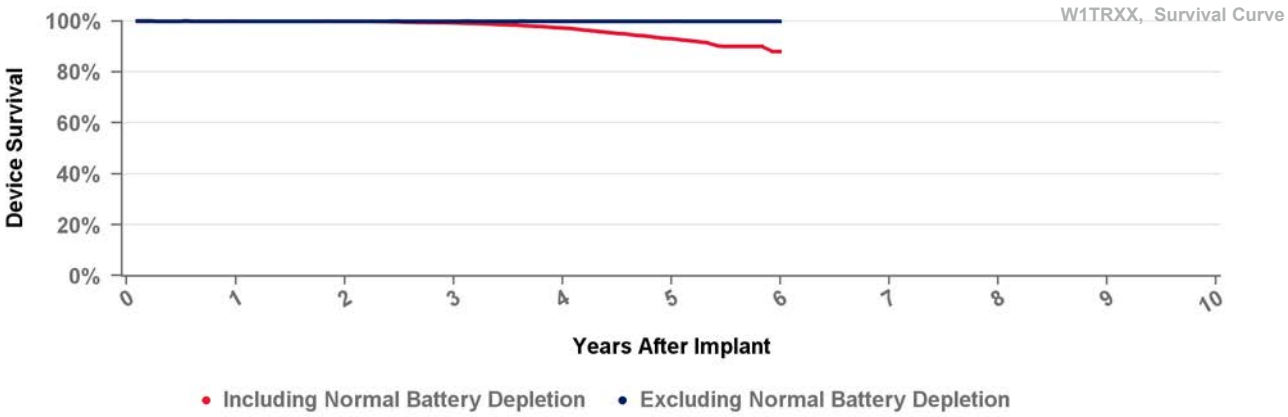



| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W1TR05 Serena CRTP MRI

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

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

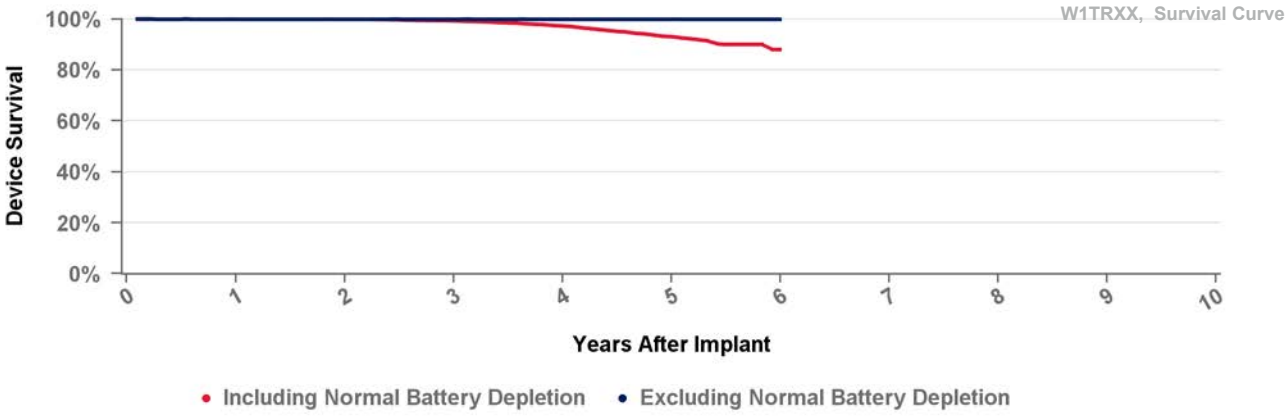



| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W1TR06 Solara CRTP MRI

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

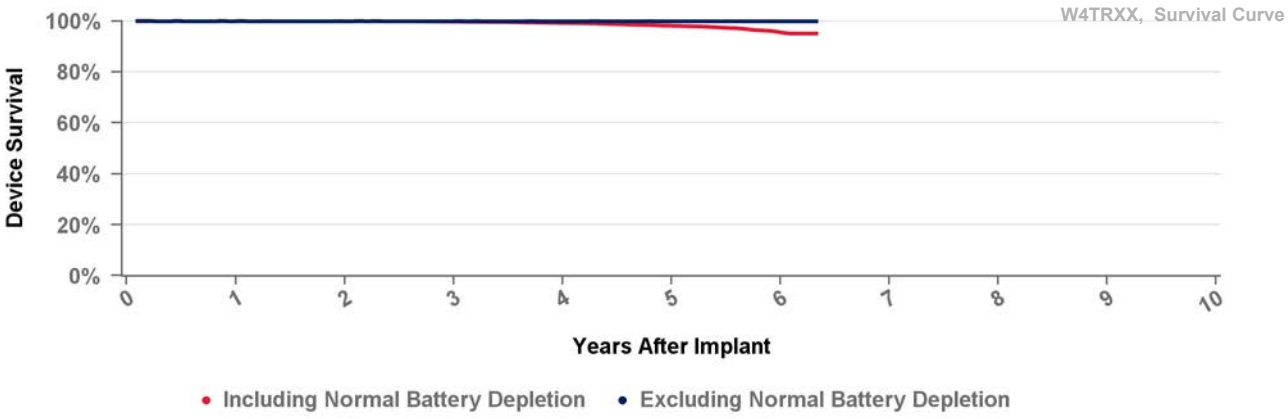
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 99.9% | 99.9% | 99.3% | 97.3% | 93.1% | 88.1% |
| Effective Sample Size | 15243 | 11140 | 7442 | 4310 | 1722 | 128 |

## W4TR01 Percepta Quad CRTP MRI SureScan

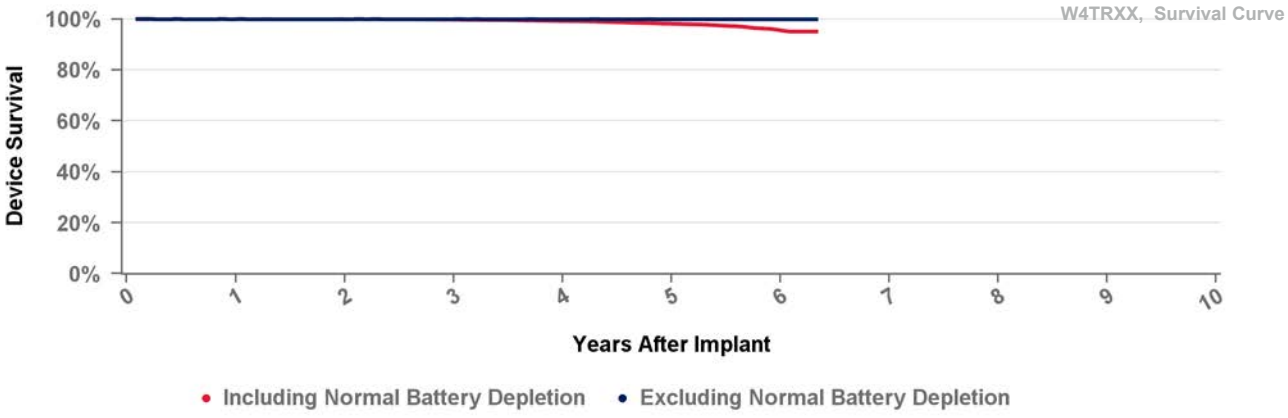
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **11** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **10** |
| **Registered USA Implants** | 52,784 | Electrical Component | 8 |
| **Estimated Active USA Implants** | 45,229 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 143 | Other | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## W4TR02 Serena Quad CRTP MRI SureScan

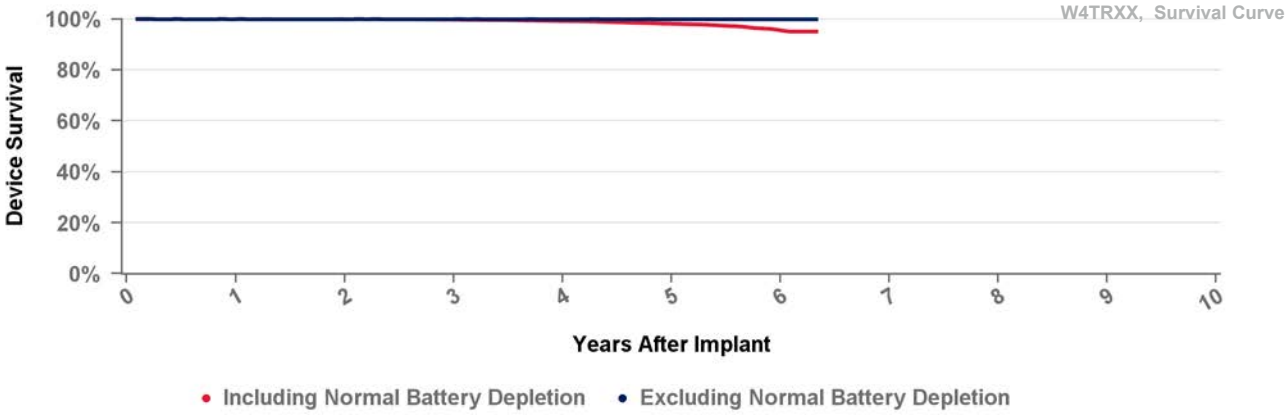
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 7,724 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 6,366 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 27 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## W4TR03 Solara Quad CRTP MRI SureScan

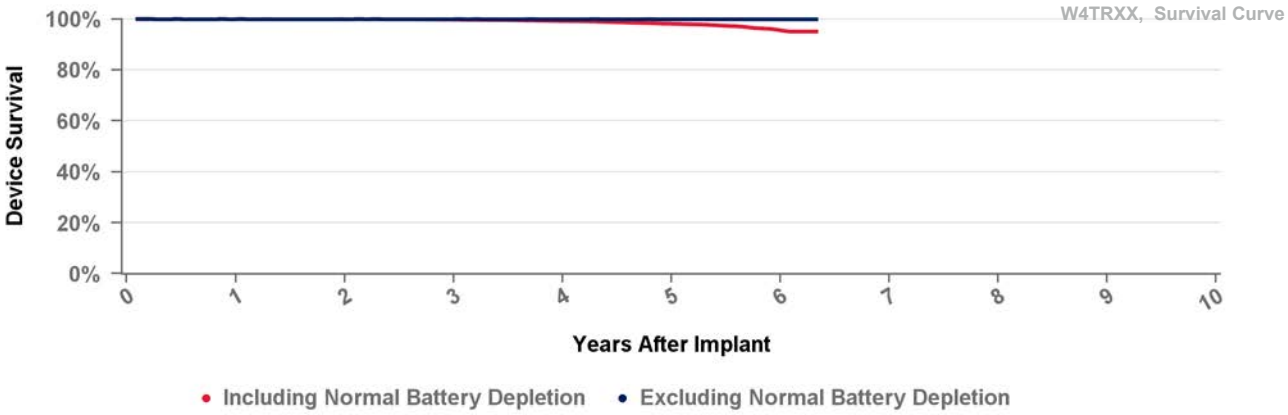
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 9,903 | | |
| **Estimated Active USA Implants** | 7,873 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | 36 | Electrical Component | 2 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## W4TR04 Percepta Quad CRT-P MRI SureScan

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

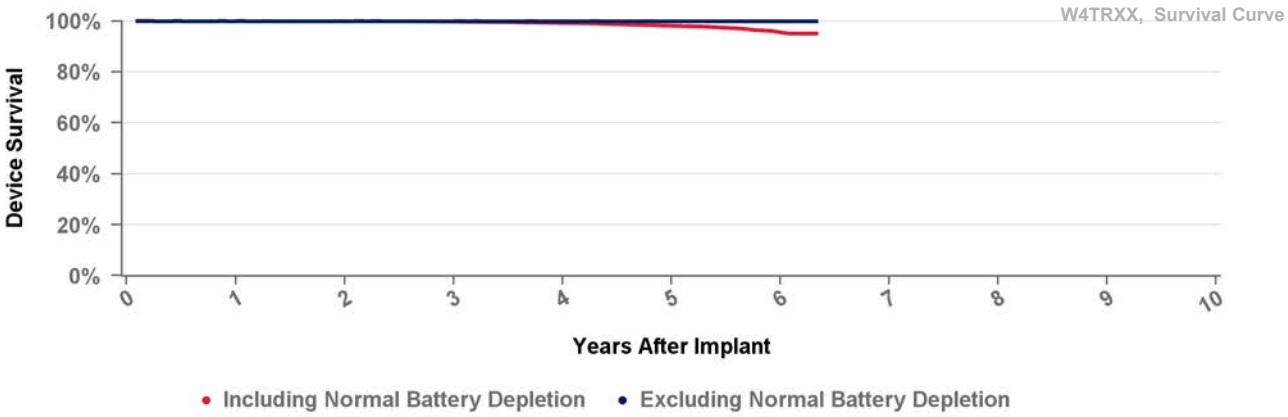



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## W4TR05 Serena Quad CRTP MRI SureScan

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

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

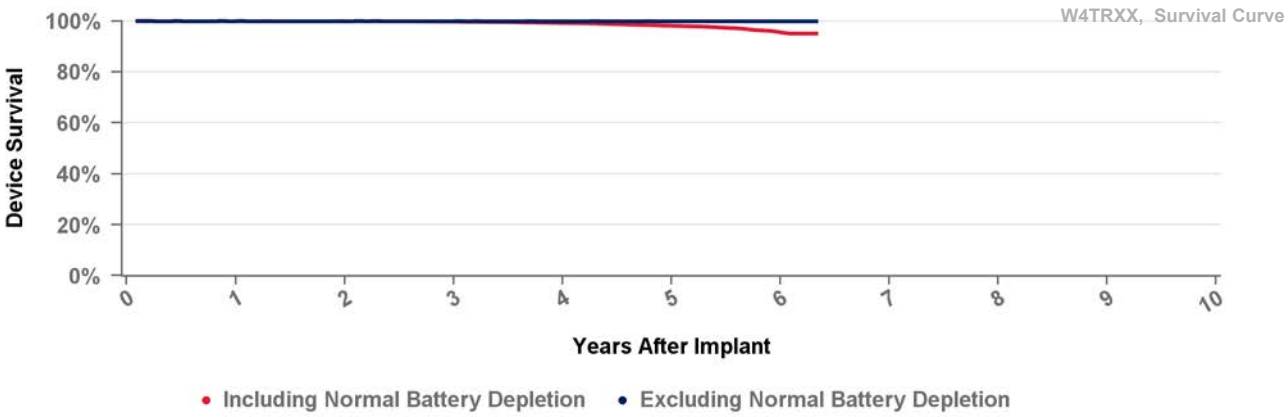



| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## W4TR06 Solara Quad CRTP MRI SureScan

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

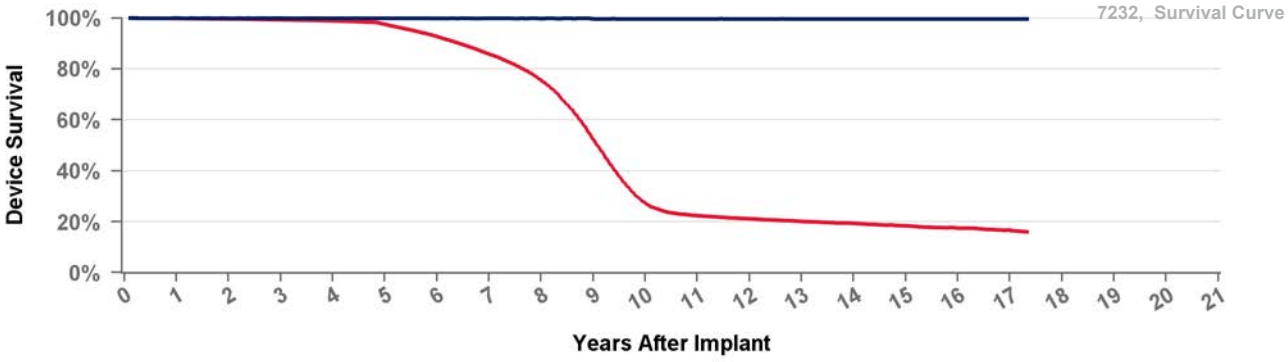
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 76 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.2% | 95.6% | 95.1% |
| Effective Sample Size | 51537 | 37746 | 25573 | 15839 | 7540 | 1521 | 128 |

## 7232Cx Maximo VR

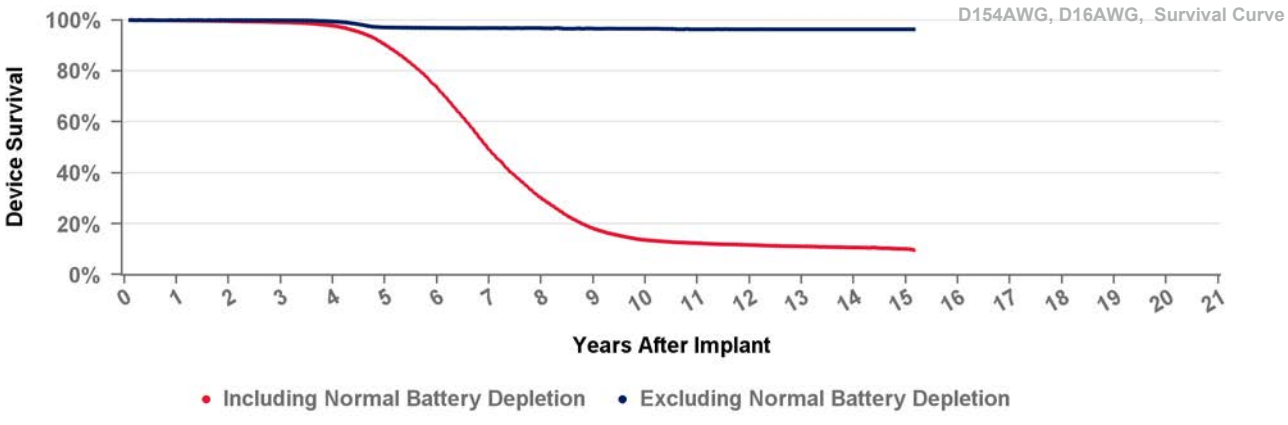
| | | | |
|---|---|---|---|
| **US Market Release** | 06Oct2003 | **Total Malfunctions (USA)** | **73** |
| **CE Approval Date** | 28Oct2003 | **Therapy Function Not Compromised** | **58** |
| **Registered USA Implants** | 43,623 | Electrical Component | 29 |
| **Estimated Active USA Implants** | 2,750 | Possible Early Battery Depletion | 25 |
| **Normal Battery Depletions** | 10,395 | Software/Firmware | 2 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **15** |
| | | Electrical Component | 12 |
| | | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 1 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 208 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.3% | 98.9% | 97.5% | 92.7% | 85.8% | 75.4% | 52.4% | 27.3% | 22.4% | 21.2% | 20.1% | 19.4% | 18.4% | 17.6% | 16.6% | 16.0% |
| Effective Sample Size | 38514 | 35189 | 31911 | 28429 | 25002 | 21613 | 18239 | 14653 | 9037 | 3706 | 2514 | 2013 | 1574 | 1226 | 932 | 645 | 308 | 113 |

## D164AWG Virtuoso DR

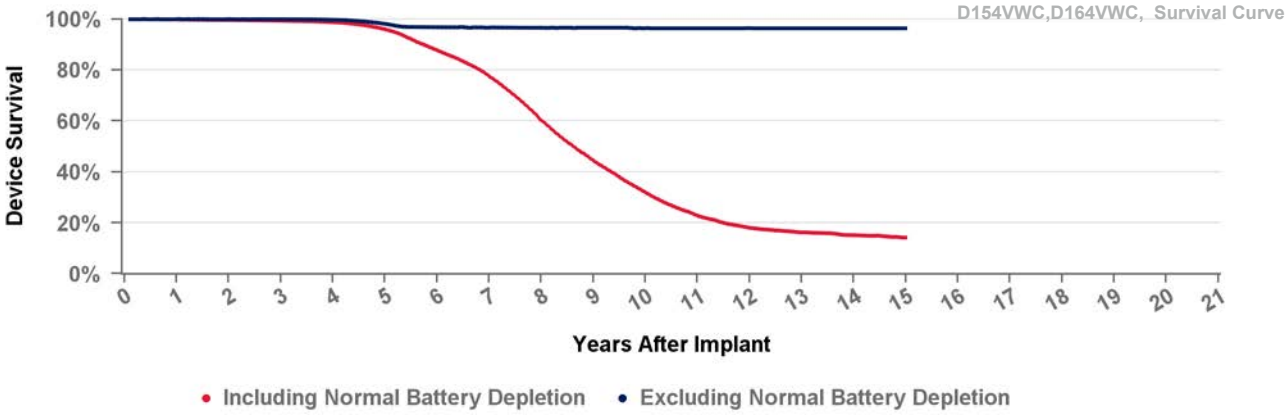
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07Mar2006 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 3 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 182 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.4% | 97.1% | 96.9% | 96.8% | 96.8% | 96.7% | 96.6% | 96.5% | 96.4% | 96.4% | 96.4% | 96.4% | 96.4% |
| Including NBD | 99.8% | 99.6% | 99.1% | 97.8% | 90.3% | 73.5% | 49.2% | 30.0% | 18.1% | 13.6% | 12.4% | 11.7% | 11.1% | 10.7% | 10.1% | 9.6% |
| Effective Sample Size | 63551 | 58491 | 53190 | 47920 | 40414 | 29771 | 17372 | 8914 | 4491 | 2854 | 2363 | 2018 | 1713 | 1408 | 362 | 128 |

## D164VWC Virtuoso VR

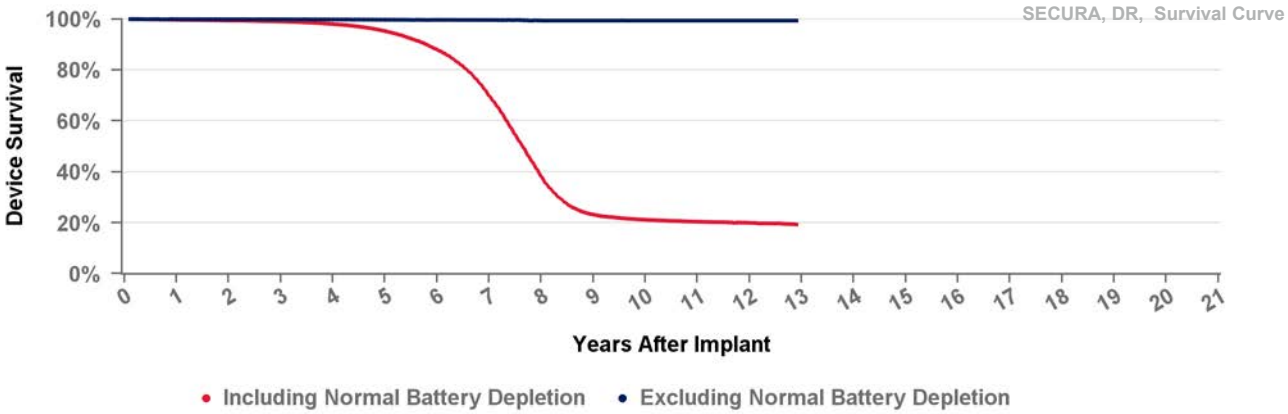
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07Mar2006 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 180 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.7% | 98.1% | 96.8% | 96.7% | 96.6% | 96.5% | 96.5% | 96.4% | 96.4% | 96.4% | 96.4% | 96.3% |
| Including NBD | 99.8% | 99.6% | 99.3% | 98.8% | 96.0% | 87.7% | 77.5% | 60.3% | 44.4% | 31.9% | 22.8% | 18.0% | 16.3% | 15.2% | 14.2% |
| Effective Sample Size | 28535 | 26124 | 23730 | 21531 | 19161 | 16195 | 13286 | 9329 | 6103 | 3950 | 2478 | 1605 | 1153 | 849 | 126 |

## D204DRM Secura DR

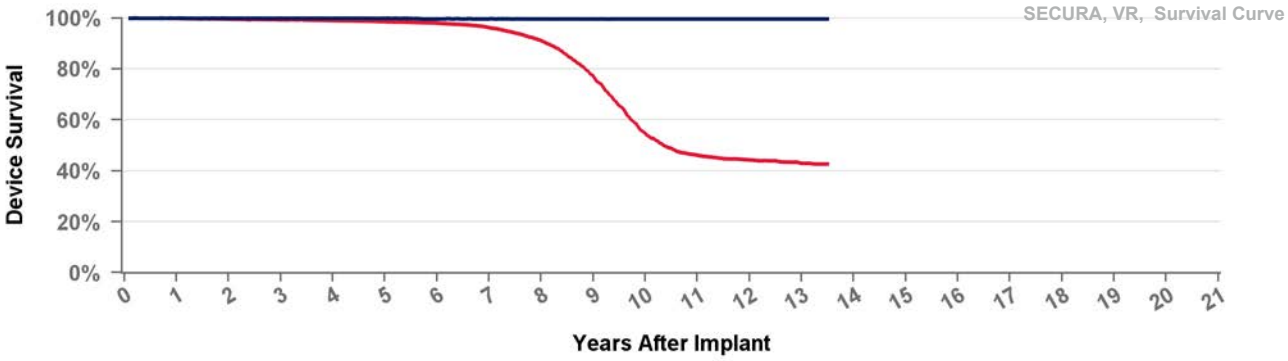
| | | | | |
|---|---|---|---|---|
| **US Market Release** | 09Jan2012 | **Total Malfunctions (USA)** | | **5** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | | **1** |
| **Registered USA Implants** | 1,850 | Other | | 1 |
| **Estimated Active USA Implants** | 315 | **Therapy Function Compromised** | | **4** |
| **Normal Battery Depletions** | 321 | Battery | | 2 |
| | | Electrical Component | | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% |
| Including NBD | 99.7% | 99.4% | 99.0% | 98.0% | 95.3% | 87.9% | 70.0% | 38.4% | 23.2% | 21.2% | 20.4% | 20.0% | 19.3% |
| Effective Sample Size | 44540 | 41185 | 38105 | 34983 | 31058 | 25091 | 16332 | 6719 | 3259 | 2658 | 2088 | 1503 | 193 |

## D204VRM Secura VR

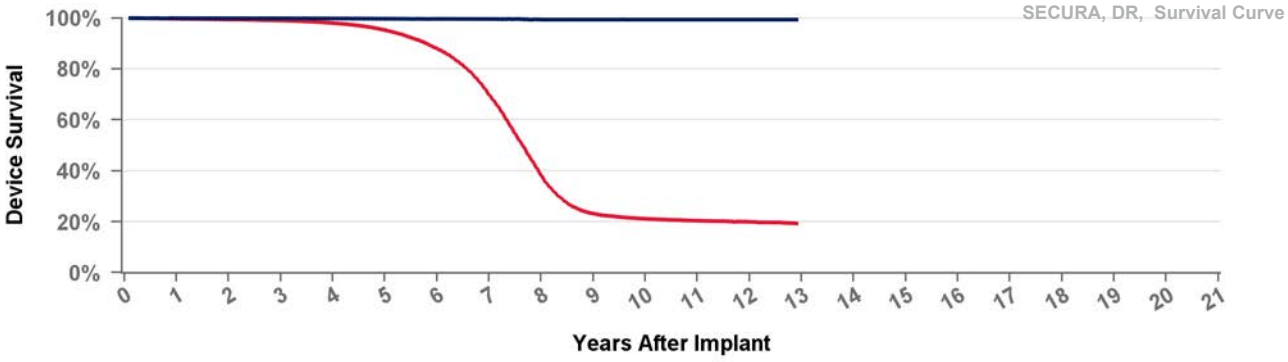
| | | | |
|---|---|---|---|
| **US Market Release** | 02May2012 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 1,152 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 292 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | 90 | Battery | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.3% | 99.0% | 98.6% | 98.0% | 96.2% | 91.1% | 77.1% | 54.5% | 46.1% | 44.3% | 42.9% | 42.6% |
| Effective Sample Size | 17640 | 16331 | 15178 | 14073 | 12961 | 11846 | 10616 | 8586 | 5565 | 2829 | 1791 | 1271 | 519 | 108 |

## D214DRM Secura DR

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% |
| Including NBD | 99.7% | 99.4% | 99.0% | 98.0% | 95.3% | 87.9% | 70.0% | 38.4% | 23.2% | 21.2% | 20.4% | 20.0% | 19.3% |
| Effective Sample Size | 44540 | 41185 | 38105 | 34983 | 31058 | 25091 | 16332 | 6719 | 3259 | 2658 | 2088 | 1503 | 193 |

## D214VRM Secura VR

**US Market Release**

**CE Approval Date** 17Dec2010

**Registered USA Implants**

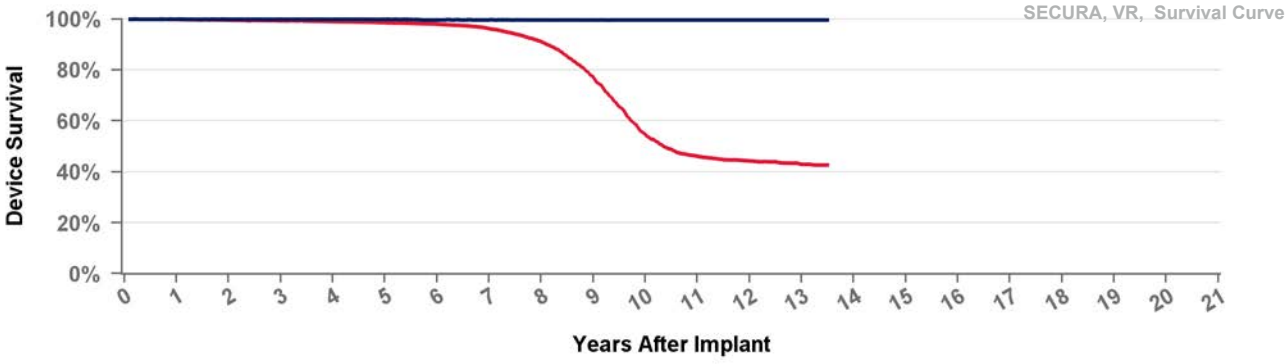
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

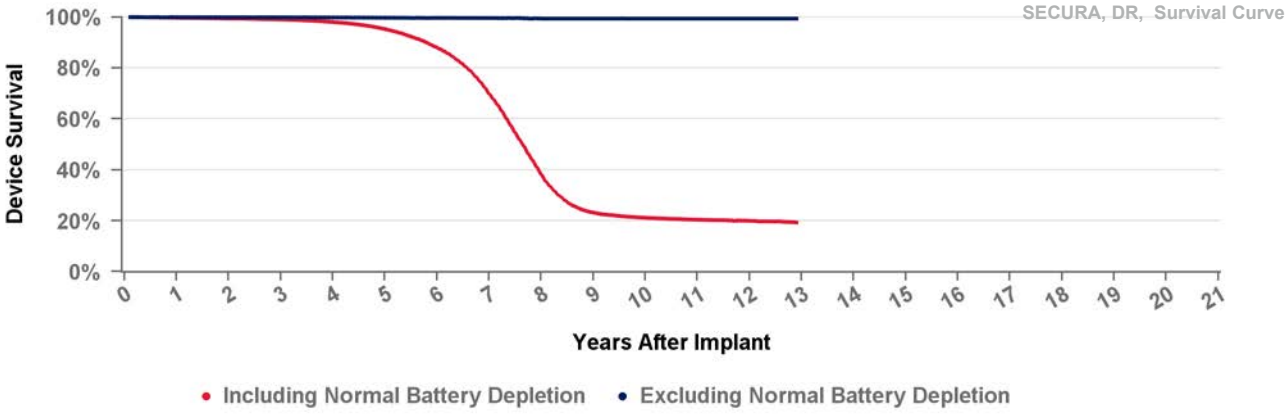
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.3% | 99.0% | 98.6% | 98.0% | 96.2% | 91.1% | 77.1% | 54.5% | 46.1% | 44.3% | 42.9% | 42.6% |
| Effective Sample Size | 17640 | 16331 | 15178 | 14073 | 12961 | 11846 | 10616 | 8586 | 5565 | 2829 | 1791 | 1271 | 519 | 108 |

## D224DRG Secura DR

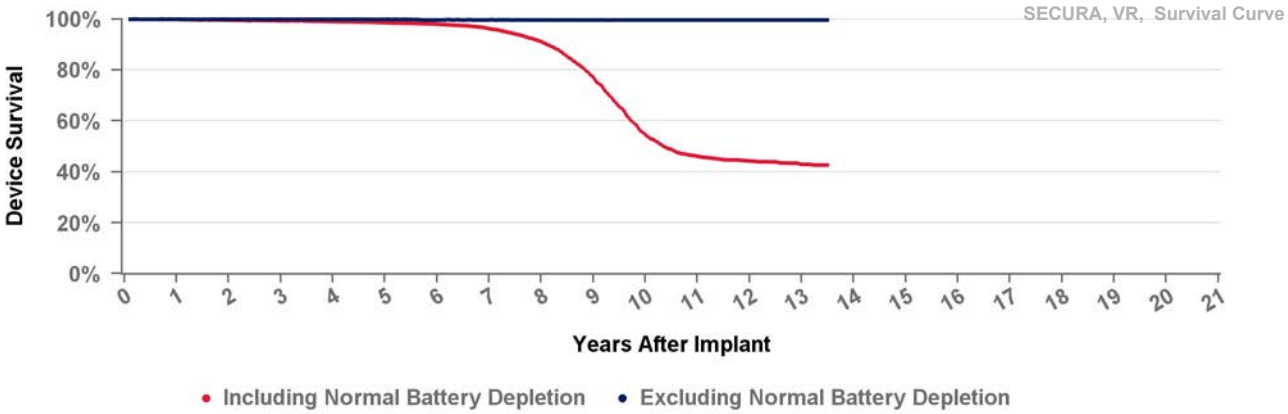
| | | | |
|---|---|---|---|
| **US Market Release** | 15Sep2008 | **Total Malfunctions (USA)** | **152** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **115** |
| **Registered USA Implants** | 49,639 | Battery | 14 |
| **Estimated Active USA Implants** | 5,377 | Electrical Component | 38 |
| **Normal Battery Depletions** | 10,323 | Possible Early Battery Depletion | 50 |
| | | Software/Firmware | 9 |
| | | Other | 4 |
| | | **Therapy Function Compromised** | **37** |
| | | Battery | 21 |
| | | Electrical Component | 13 |
| | | Possible Early Battery Depletion | 1 |
| | | Software/Firmware | 1 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% |
| Including NBD | 99.7% | 99.4% | 99.0% | 98.0% | 95.3% | 87.9% | 70.0% | 38.4% | 23.2% | 21.2% | 20.4% | 20.0% | 19.3% |
| Effective Sample Size | 44540 | 41185 | 38105 | 34983 | 31058 | 25091 | 16332 | 6719 | 3259 | 2658 | 2088 | 1503 | 193 |

## D224VRC Secura VR

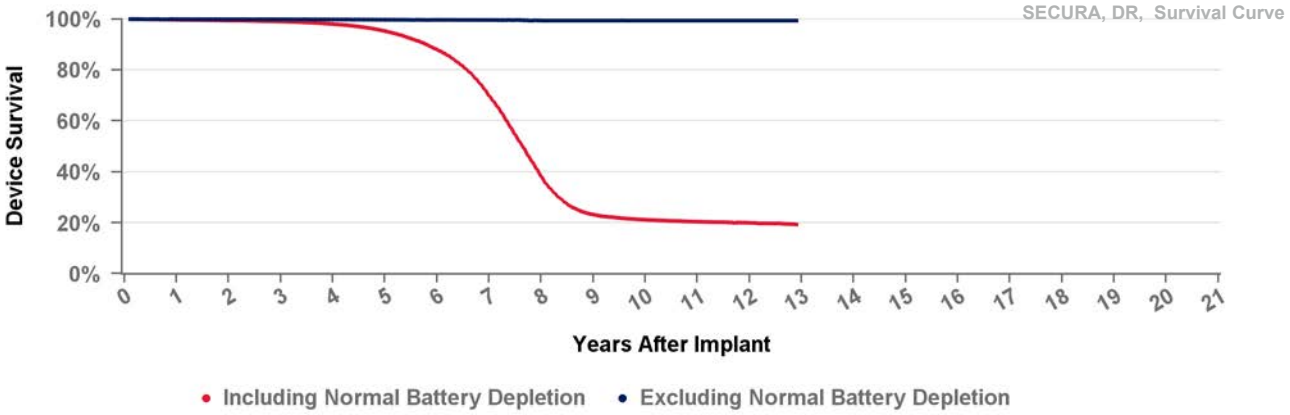
| | | | |
|---|---|---|---|
| **US Market Release** | 15Sep2008 | **Total Malfunctions (USA)** | **52** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **35** |
| **Registered USA Implants** | 19,673 | Battery | 14 |
| **Estimated Active USA Implants** | 2,963 | Electrical Component | 10 |
| **Normal Battery Depletions** | 2,152 | Possible Early Battery Depletion | 8 |
| | | Software/Firmware | 2 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **17** |
| | | Battery | 9 |
| | | Electrical Component | 6 |
| | | Possible Early Battery Depletion | 1 |
| | | Software/Firmware | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.3% | 99.0% | 98.6% | 98.0% | 96.2% | 91.1% | 77.1% | 54.5% | 46.1% | 44.3% | 42.9% | 42.6% |
| Effective Sample Size | 17640 | 16331 | 15178 | 14073 | 12961 | 11846 | 10616 | 8586 | 5565 | 2829 | 1791 | 1271 | 519 | 108 |

## D234DRG Secura DR

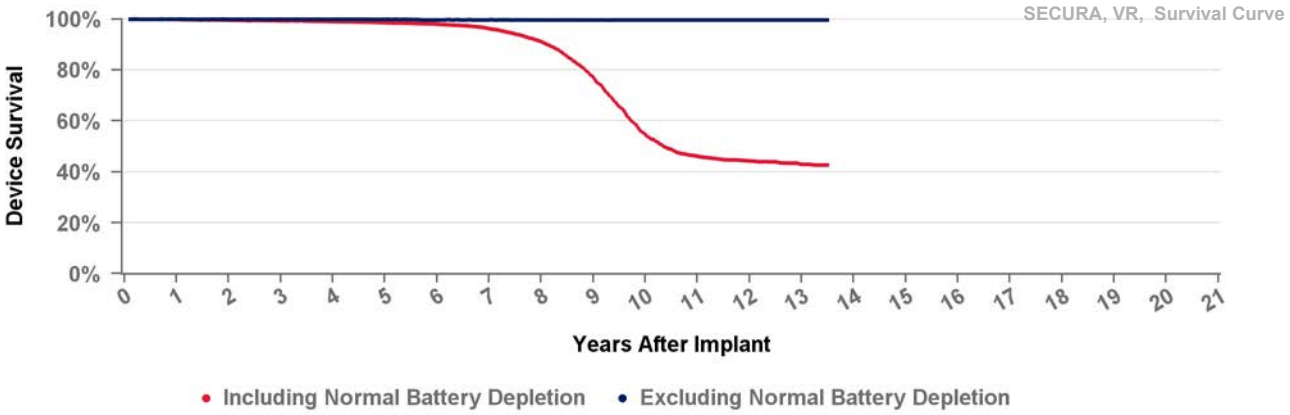
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 155 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% | 99.4% |
| Including NBD | 99.7% | 99.4% | 99.0% | 98.0% | 95.3% | 87.9% | 70.0% | 38.4% | 23.2% | 21.2% | 20.4% | 20.0% | 19.3% |
| Effective Sample Size | 44540 | 41185 | 38105 | 34983 | 31058 | 25091 | 16332 | 6719 | 3259 | 2658 | 2088 | 1503 | 193 |

## D234VRC Secura VR

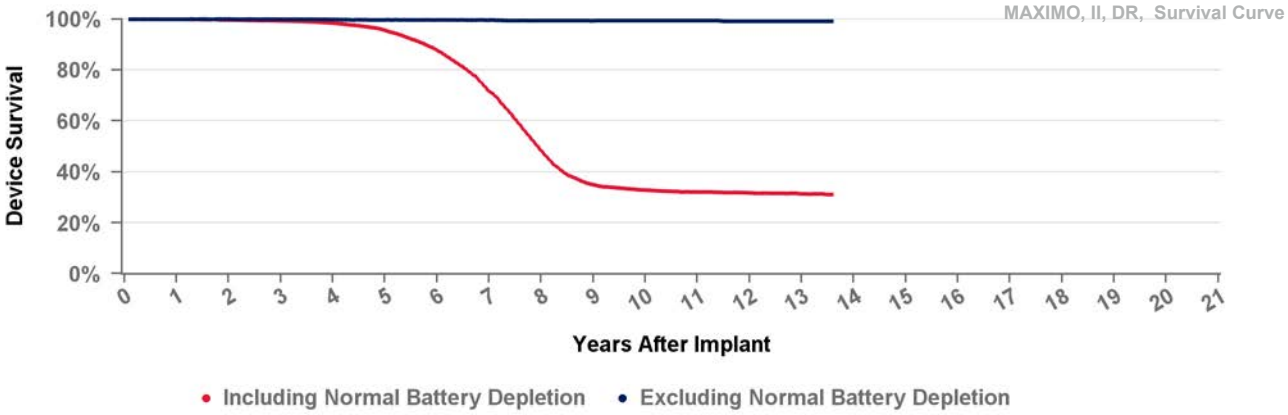
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.3% | 99.0% | 98.6% | 98.0% | 96.2% | 91.1% | 77.1% | 54.5% | 46.1% | 44.3% | 42.9% | 42.6% |
| Effective Sample Size | 17640 | 16331 | 15178 | 14073 | 12961 | 11846 | 10616 | 8586 | 5565 | 2829 | 1791 | 1271 | 519 | 108 |

## D264DRM Maximo II DR

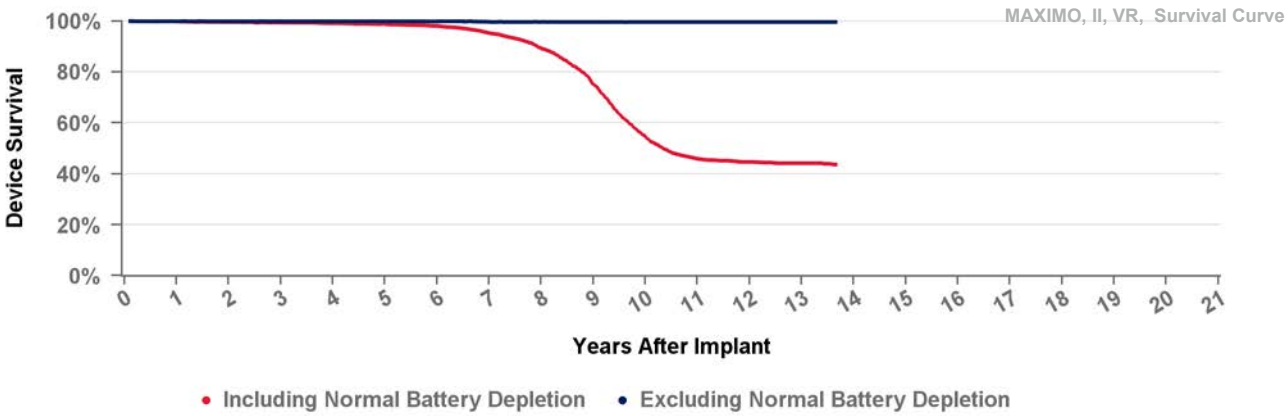
| | | | |
|---|---|---|---|
| **US Market Release** | 09Jan2012 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 22Jul2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 6 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 163 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.7% | 99.7% | 99.5% | 99.3% | 99.3% | 99.3% | 99.3% | 99.2% | 99.2% | 99.2% |
| Including NBD | 99.9% | 99.6% | 99.3% | 98.4% | 95.6% | 87.6% | 71.7% | 48.4% | 34.9% | 32.8% | 32.1% | 31.7% | 31.3% | 31.1% |
| Effective Sample Size | 17236 | 15934 | 14783 | 13616 | 12097 | 9583 | 5994 | 2813 | 1728 | 1473 | 1232 | 917 | 428 | 108 |

## D264VRM Maximo II VR

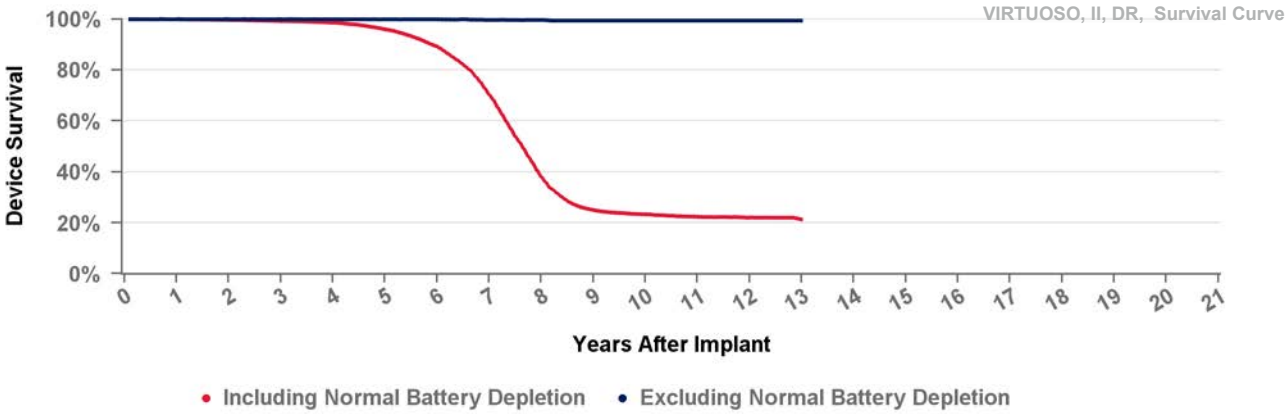
| | | | |
|---|---|---|---|
| **US Market Release** | 02May2012 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 164 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.4% | 99.2% | 98.8% | 98.1% | 95.3% | 89.2% | 75.3% | 54.6% | 45.9% | 44.7% | 44.3% | 43.8% |
| Effective Sample Size | 10873 | 10125 | 9423 | 8722 | 8029 | 7335 | 6489 | 5254 | 3408 | 1828 | 1208 | 861 | 433 | 103 |

## D274DRG Virtuoso II DR

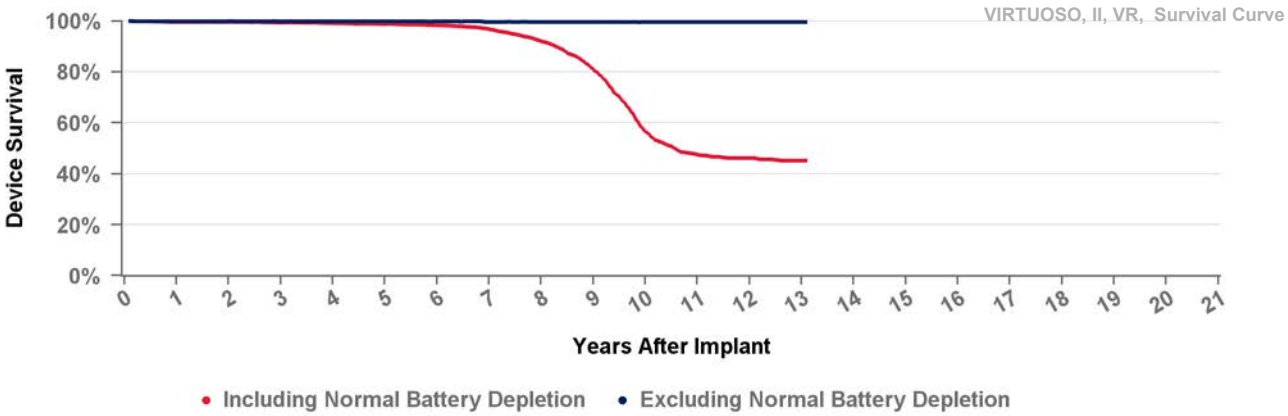
| | | | |
|---|---|---|---|
| **US Market Release** | 15Aug2009 | **Total Malfunctions (USA)** | **47** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **29** |
| **Registered USA Implants** | 22,251 | Battery | 10 |
| **Estimated Active USA Implants** | 2,561 | Electrical Component | 11 |
| **Normal Battery Depletions** | 4,322 | Possible Early Battery Depletion | 7 |
| | | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **18** |
| | | Battery | 15 |
| | | Electrical Component | 2 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| Including NBD | 99.9% | 99.7% | 99.2% | 98.6% | 96.0% | 89.2% | 70.5% | 38.2% | 25.0% | 23.4% | 22.4% | 22.1% | 21.3% |
| Effective Sample Size | 19000 | 17629 | 16324 | 14964 | 13153 | 10488 | 6731 | 2932 | 1546 | 1312 | 1177 | 978 | 102 |

## D274VRC Virtuoso II VR

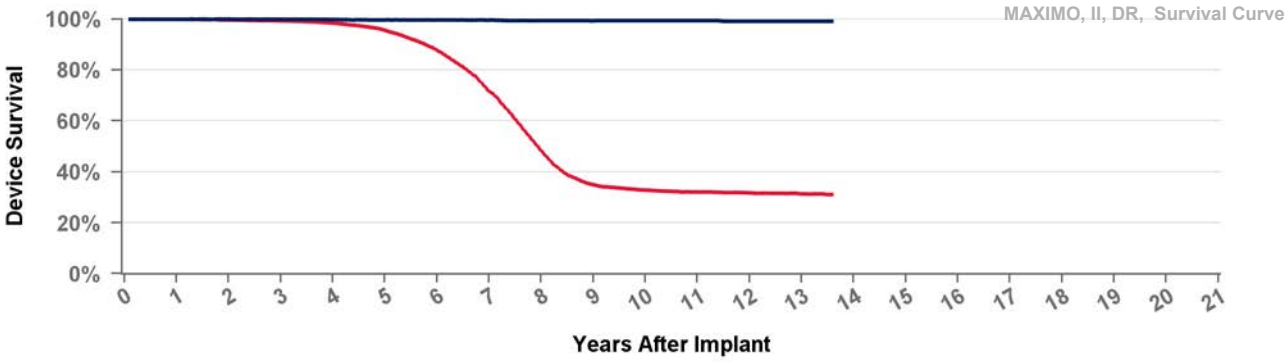
| | | | |
|---|---|---|---|
| **US Market Release** | 15Aug2009 | **Total Malfunctions (USA)** | **21** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **13** |
| **Registered USA Implants** | 9,131 | Battery | 6 |
| **Estimated Active USA Implants** | 1,351 | Electrical Component | 4 |
| **Normal Battery Depletions** | 887 | Possible Early Battery Depletion | 2 |
| | | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **8** |
| | | Battery | 7 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 157 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.7% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| Including NBD | 99.7% | 99.7% | 99.4% | 99.2% | 98.8% | 98.3% | 96.8% | 92.0% | 80.8% | 56.7% | 47.6% | 46.2% | 45.3% | 45.3% |
| Effective Sample Size | 7678 | 7160 | 6653 | 6136 | 5663 | 5130 | 4569 | 3747 | 2497 | 1295 | 885 | 687 | 182 | 130 |

## D284DRG Maximo II DR

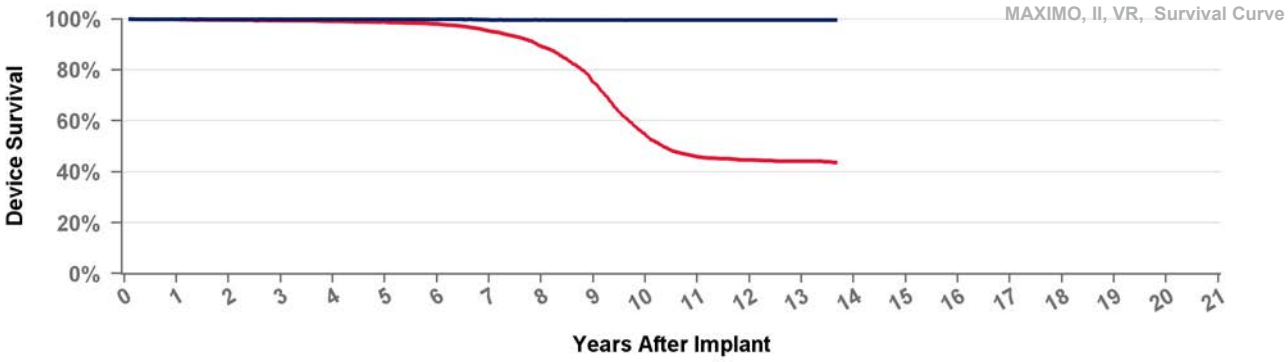
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **71** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **54** |
| **Registered USA Implants** | 19,956 | Battery | 7 |
| **Estimated Active USA Implants** | 2,363 | Electrical Component | 15 |
| **Normal Battery Depletions** | 3,640 | Possible Early Battery Depletion | 30 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **17** |
| | | Battery | 11 |
| | | Electrical Component | 5 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 163 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.7% | 99.7% | 99.5% | 99.3% | 99.3% | 99.3% | 99.3% | 99.2% | 99.2% | 99.2% |
| Including NBD | 99.9% | 99.6% | 99.3% | 98.4% | 95.6% | 87.6% | 71.7% | 48.4% | 34.9% | 32.8% | 32.1% | 31.7% | 31.3% | 31.1% |
| Effective Sample Size | 17236 | 15934 | 14783 | 13616 | 12097 | 9583 | 5994 | 2813 | 1728 | 1473 | 1232 | 917 | 428 | 108 |

## D284VRC Maximo II VR

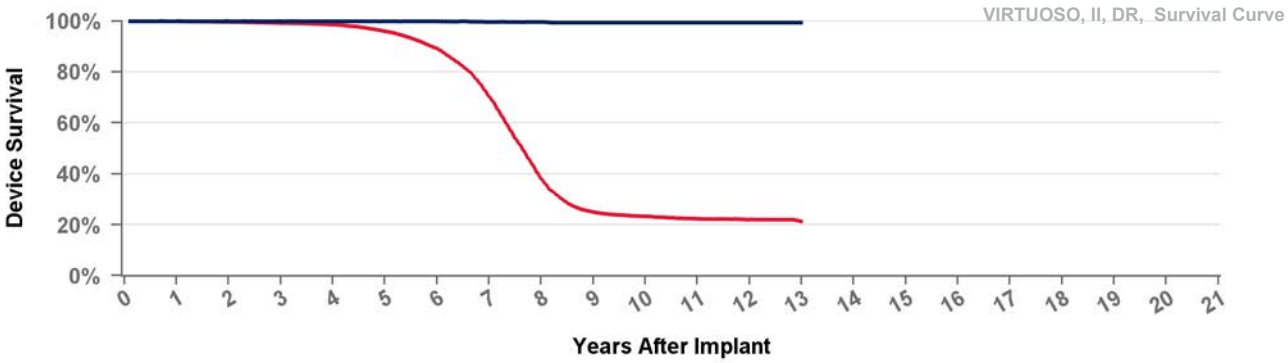
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **32** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **23** |
| **Registered USA Implants** | 12,861 | Battery | 10 |
| **Estimated Active USA Implants** | 2,097 | Electrical Component | 6 |
| **Normal Battery Depletions** | 1,612 | Possible Early Battery Depletion | 4 |
| | | Software/Firmware | 3 |
| | | **Therapy Function Compromised** | **9** |
| | | Battery | 6 |
| | | Electrical Component | 2 |
| | | Software/Firmware | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 164 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.4% | 99.2% | 98.8% | 98.1% | 95.3% | 89.2% | 75.3% | 54.6% | 45.9% | 44.7% | 44.3% | 43.8% |
| Effective Sample Size | 10873 | 10125 | 9423 | 8722 | 8029 | 7335 | 6489 | 5254 | 3408 | 1828 | 1208 | 861 | 433 | 103 |

## D294DRG Virtuoso II DR

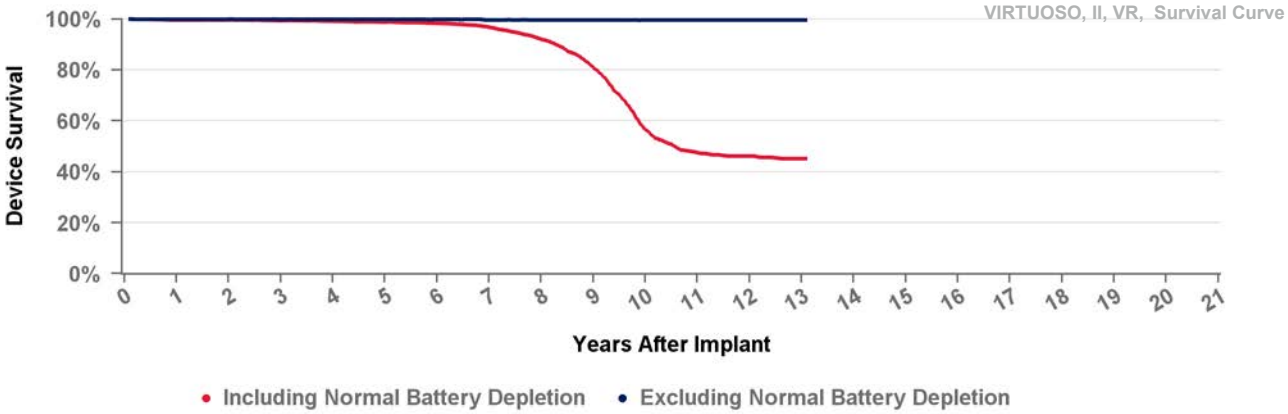
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Aug2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| Including NBD | 99.9% | 99.7% | 99.2% | 98.6% | 96.0% | 89.2% | 70.5% | 38.2% | 25.0% | 23.4% | 22.4% | 22.1% | 21.3% |
| Effective Sample Size | 19000 | 17629 | 16324 | 14964 | 13153 | 10488 | 6731 | 2932 | 1546 | 1312 | 1177 | 978 | 102 |

## D294VRC Virtuoso II VR

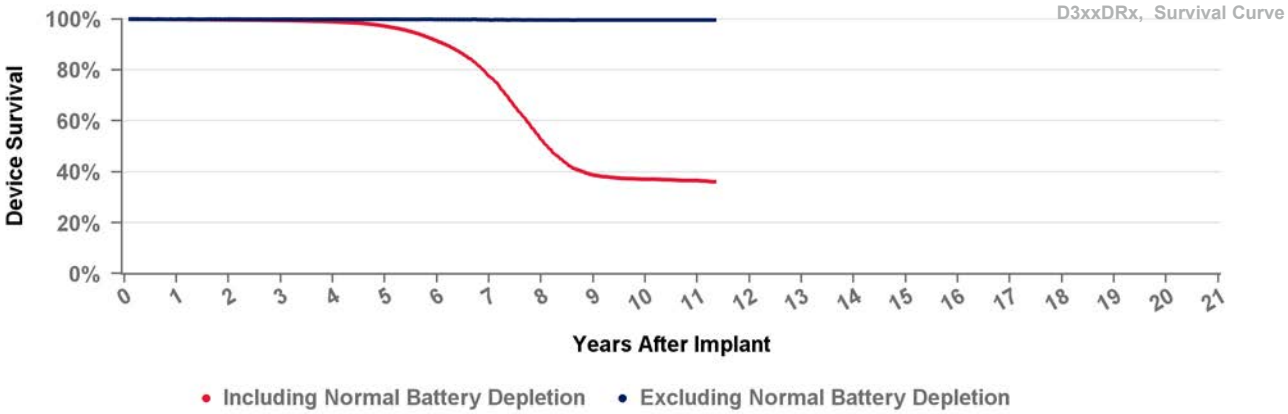
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Aug2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 157 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.7% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| Including NBD | 99.7% | 99.7% | 99.4% | 99.2% | 98.8% | 98.3% | 96.8% | 92.0% | 80.8% | 56.7% | 47.6% | 46.2% | 45.3% | 45.3% |
| Effective Sample Size | 7678 | 7160 | 6653 | 6136 | 5663 | 5130 | 4569 | 3747 | 2497 | 1295 | 885 | 687 | 182 | 130 |

## D314DRG Protecta XT DR

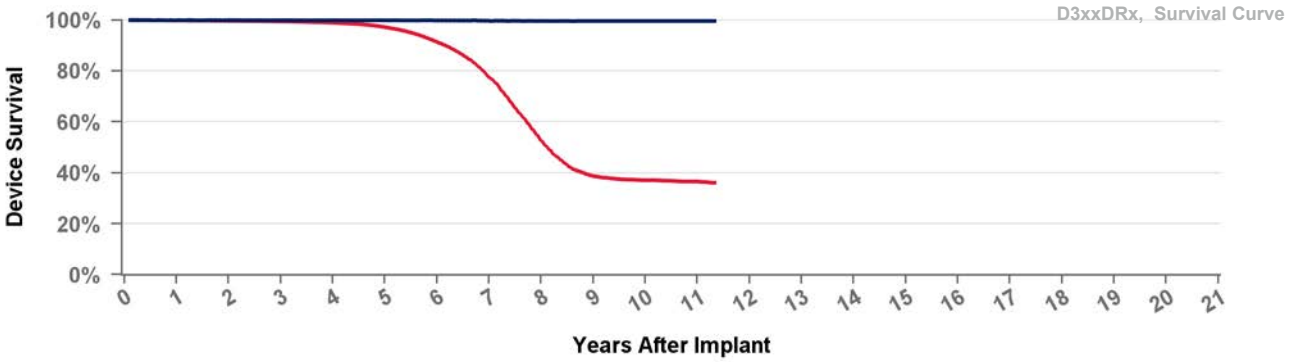
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **77** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **40** |
| **Registered USA Implants** | 34,745 | Battery | 8 |
| **Estimated Active USA Implants** | 4,672 | Electrical Component | 26 |
| **Normal Battery Depletions** | 4,544 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 4 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **37** |
| | | Battery | 30 |
| | | Electrical Component | 7 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D314DRM Protecta XT DR

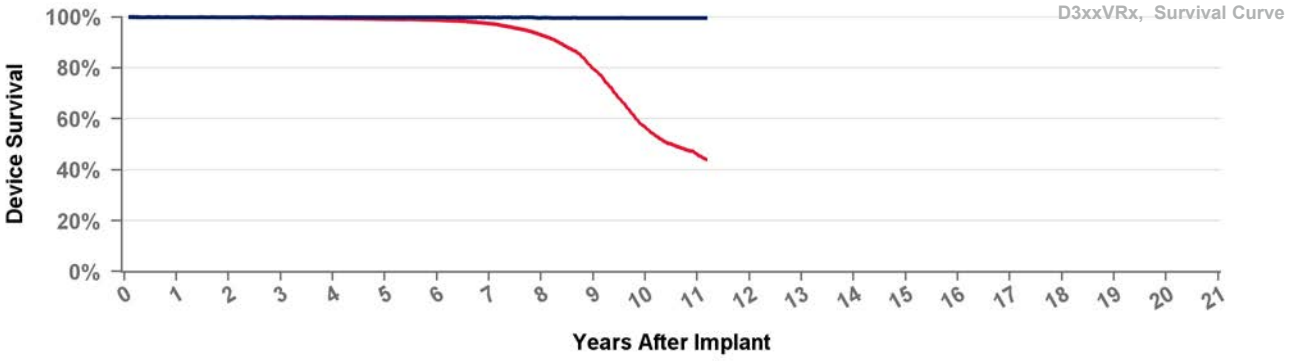
| | | | |
|---|---|---|---|
| **US Market Release** | 09Nov2011 | **Total Malfunctions (USA)** | **25** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 13,914 | Battery | 3 |
| **Estimated Active USA Implants** | 2,215 | Electrical Component | 12 |
| **Normal Battery Depletions** | 1,924 | Other | 2 |
| | | **Therapy Function Compromised** | **8** |
| | | Battery | 7 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D314VRG Protecta XT VR

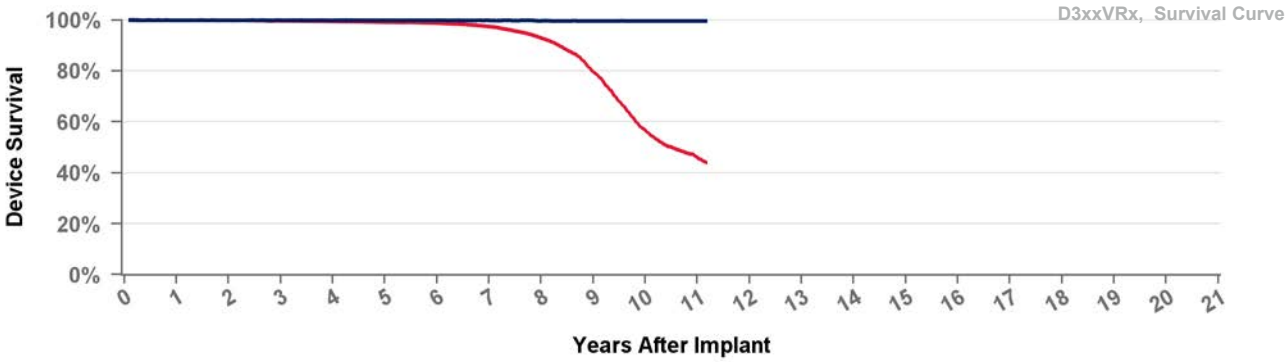
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **31** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **21** |
| **Registered USA Implants** | 14,092 | Battery | 11 |
| **Estimated Active USA Implants** | 2,807 | Electrical Component | 9 |
| **Normal Battery Depletions** | 1,218 | Other | 1 |
| | | **Therapy Function Compromised** | **10** |
| | | Battery | 9 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D314VRM Protecta XT VR

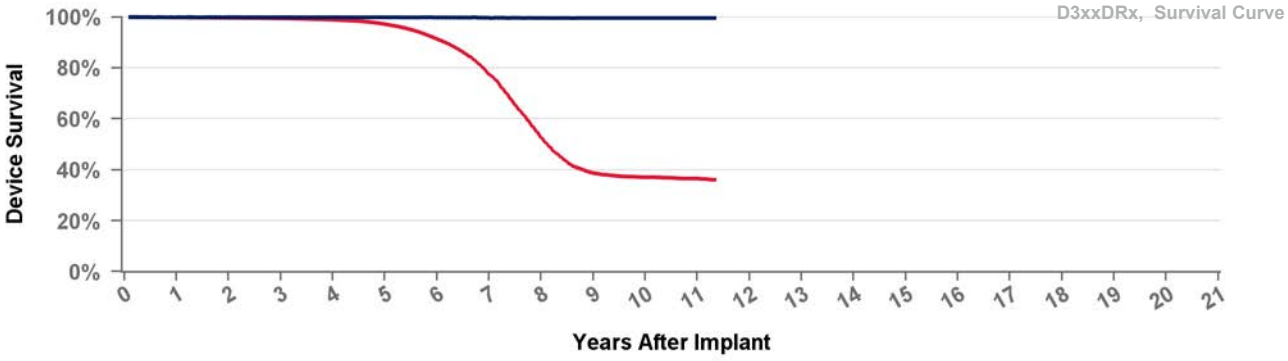
| | | | |
|---|---|---|---|
| **US Market Release** | 02May2012 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 7,334 | Battery | 1 |
| **Estimated Active USA Implants** | 1,660 | Electrical Component | 2 |
| **Normal Battery Depletions** | 708 | Possible Early Battery Depletion | 1 |
| | | **Therapy Function Compromised** | **4** |
| | | Battery | 2 |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D334DRG Protecta DR

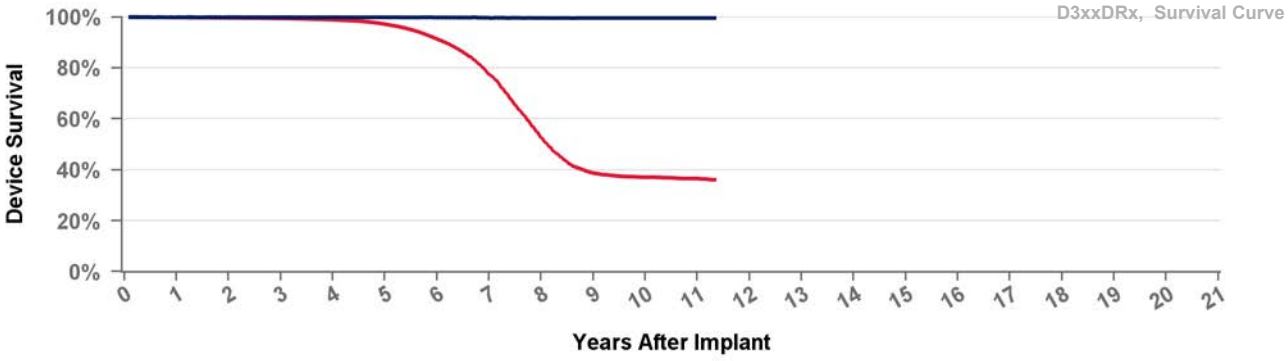
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **20** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 10,704 | Battery | 2 |
| **Estimated Active USA Implants** | 1,436 | Electrical Component | 6 |
| **Normal Battery Depletions** | 1,836 | Possible Early Battery Depletion | 1 |
| | | **Therapy Function Compromised** | **11** |
| | | Battery | 8 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D334DRM Protecta DR

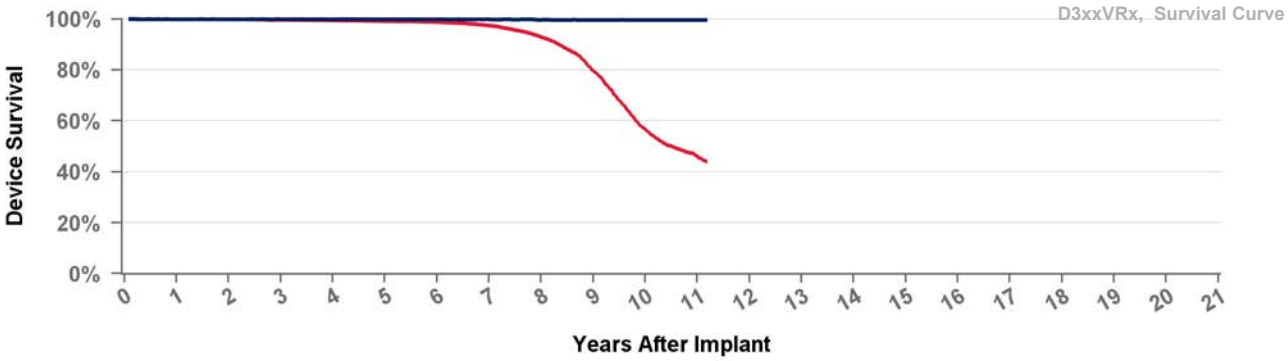
| | | | |
|---|---|---|---|
| **US Market Release** | 09Nov2011 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 2,997 | | |
| **Estimated Active USA Implants** | 500 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 577 | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D334VRG Protecta VR

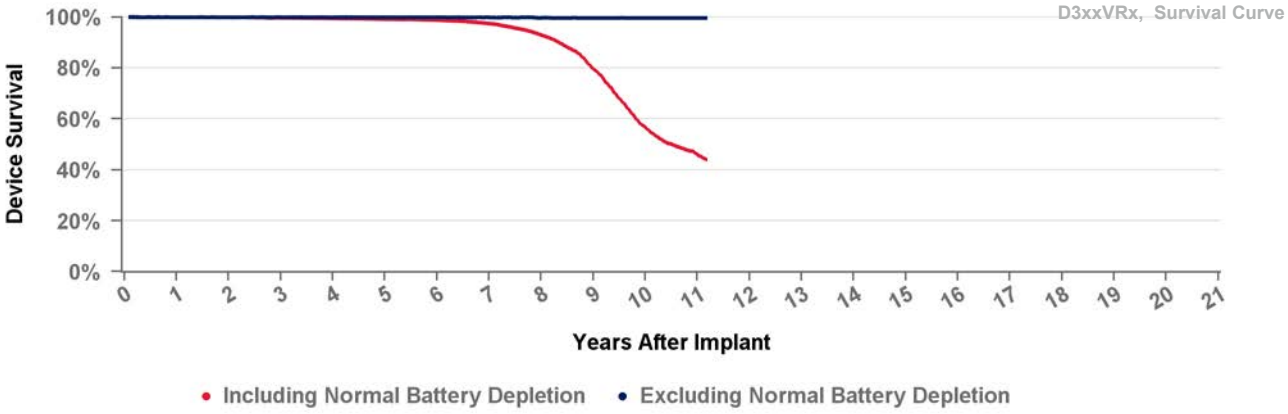
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **12** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 6,488 | Battery | 2 |
| **Estimated Active USA Implants** | 1,497 | Electrical Component | 4 |
| **Normal Battery Depletions** | 654 | **Therapy Function Compromised** | **6** |
| | | Battery | 4 |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D334VRM Protecta VR

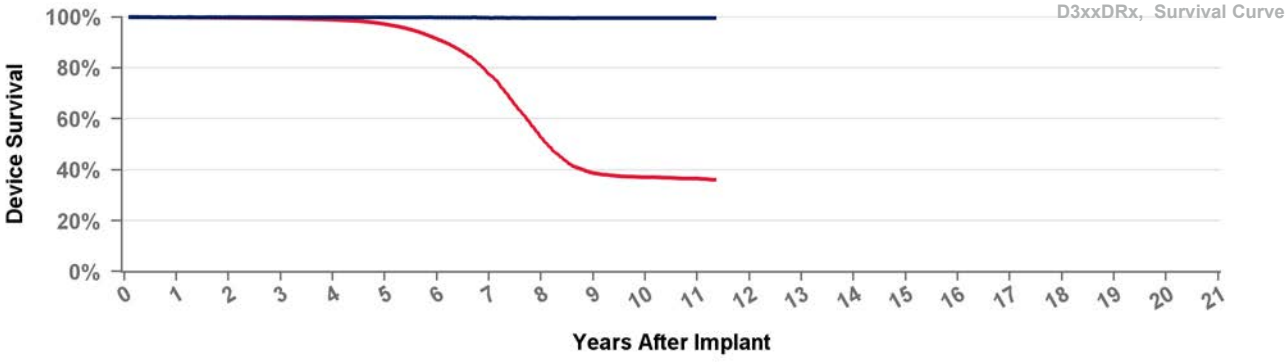
| | | | |
|---|---|---|---|
| **US Market Release** | 02May2012 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 2,167 | Battery | 1 |
| **Estimated Active USA Implants** | 539 | Other | 1 |
| **Normal Battery Depletions** | 234 | **Therapy Function Compromised** | **2** |
| | | Battery | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D354DRG Protecta XT DR

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D354DRM Protecta XT DR

**US Market Release**

**CE Approval Date** 15Jul2010

**Registered USA Implants**

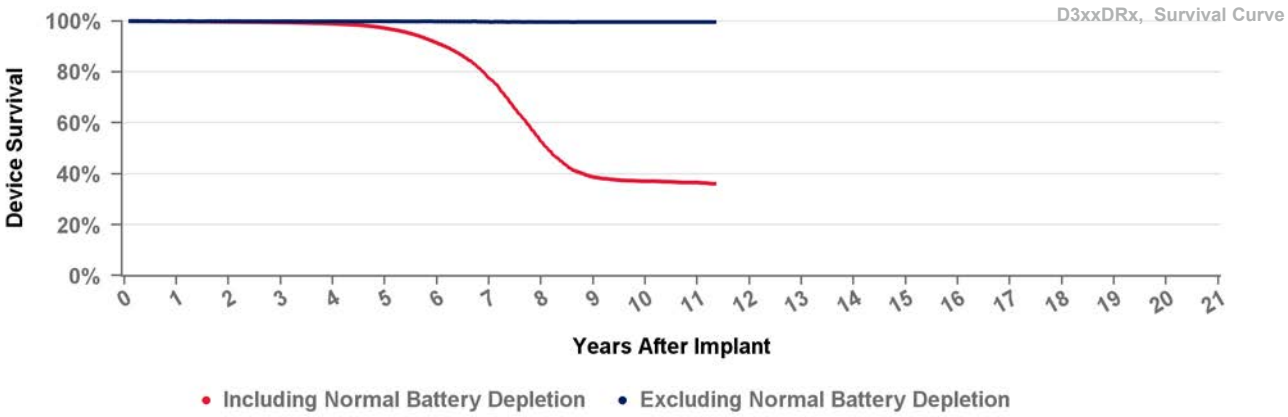
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D354VRG Protecta XT VR

**US Market Release**

**CE Approval Date** 25Mar2010

**Registered USA Implants**

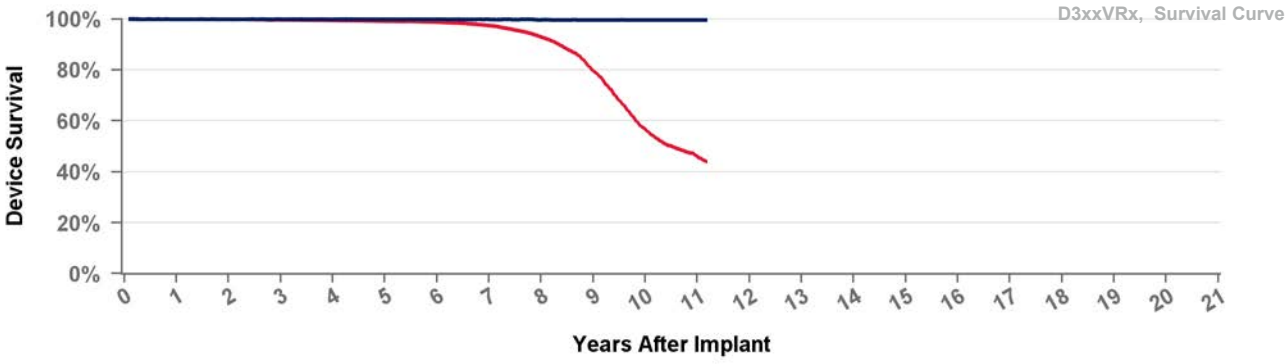
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

**Therapy Function Compromised**

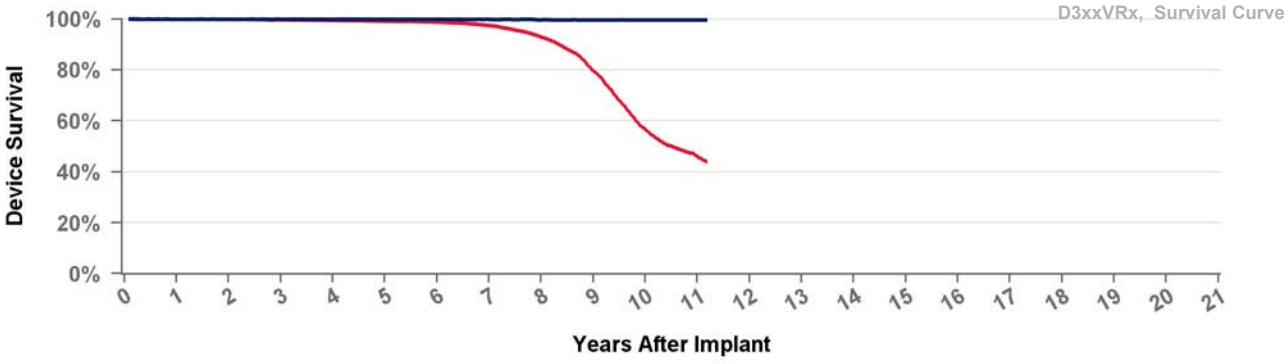



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D354VRM Protecta XT VR

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

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

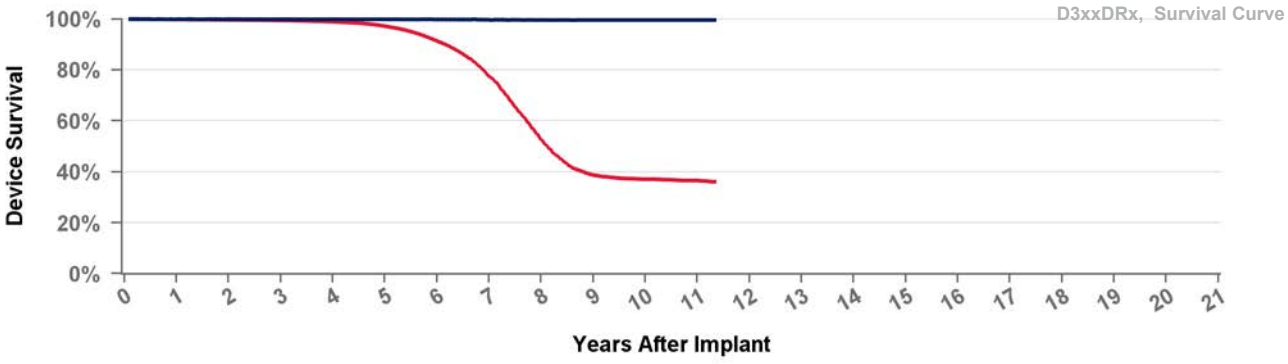



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D364DRG Protecta DR

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

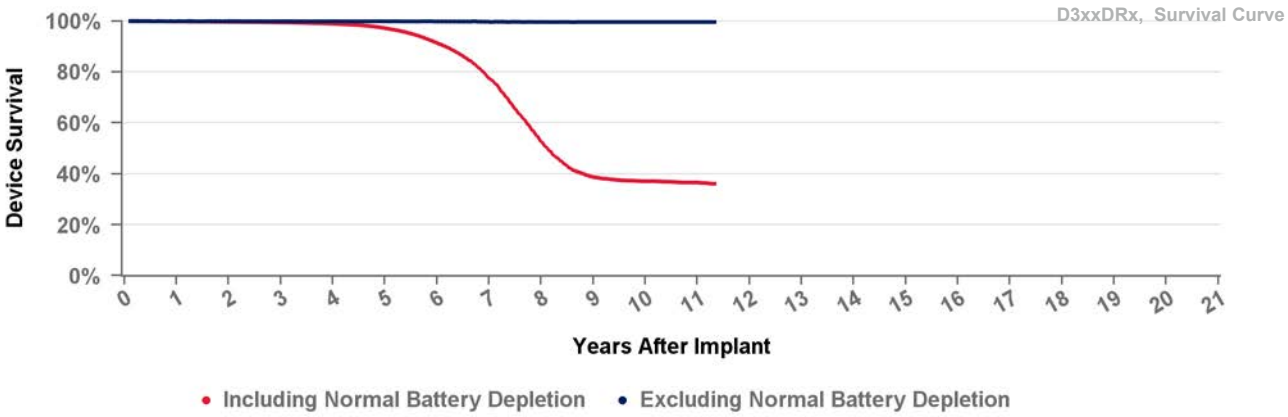
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D364DRM Protecta DR

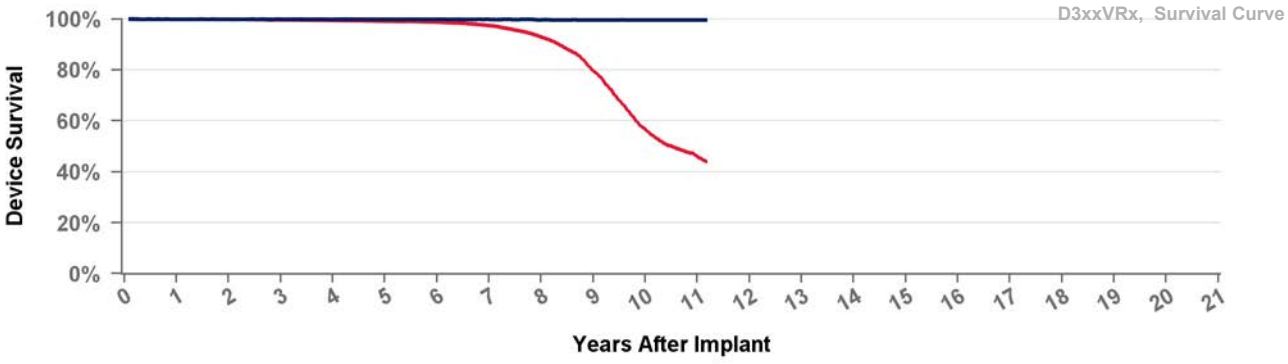
**US Market Release**
**CE Approval Date** 15Jul2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D364VRG Protecta VR

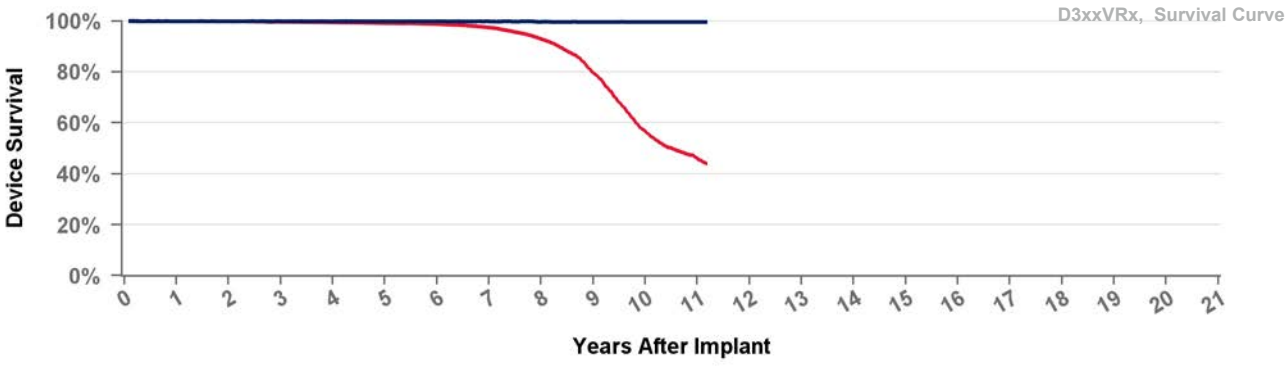
**US Market Release**
**CE Approval Date** 25Mar2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D364VRM Protecta VR

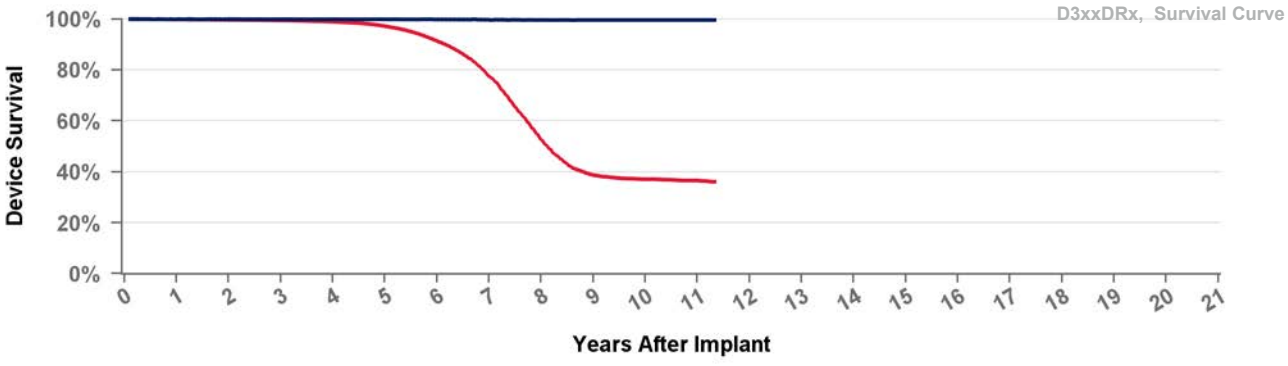
**US Market Release**
**CE Approval Date** 17Dec2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D384DRG Cardia DR

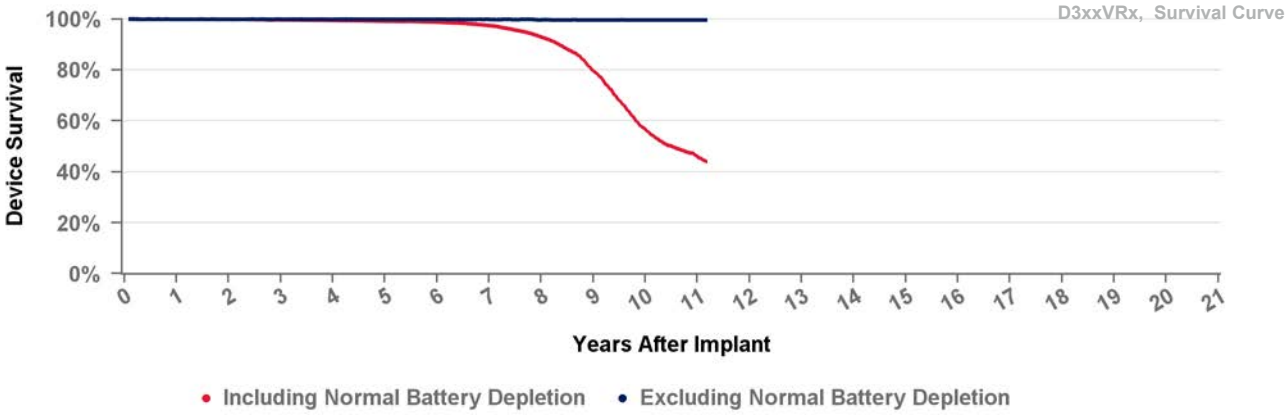
**US Market Release**
**CE Approval Date** 12Jan2011
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D384VRG Cardia VR

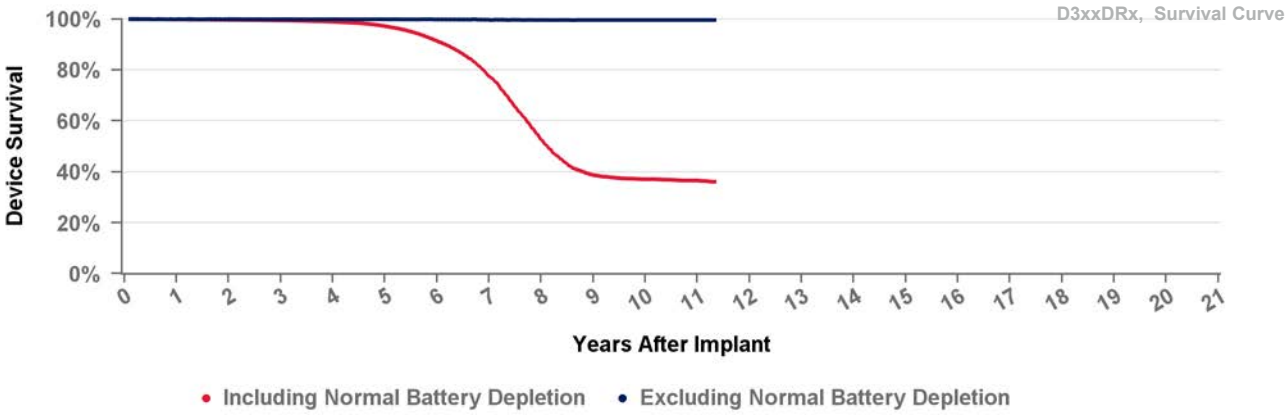
**US Market Release**
**CE Approval Date** 12Jan2011
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## D394DRG Egida DR

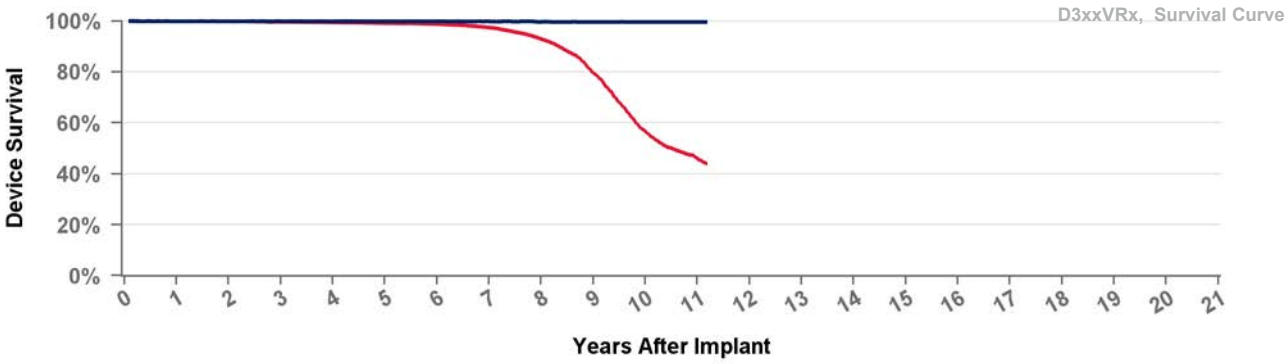
**US Market Release**
**CE Approval Date** 12Jan2011
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 99.0% | 97.2% | 91.3% | 77.6% | 52.8% | 38.7% | 37.1% | 36.5% | 36.2% |
| Effective Sample Size | 54184 | 50301 | 46252 | 42263 | 37893 | 31012 | 20451 | 9299 | 5158 | 4196 | 1292 | 127 |

## D394VRG Egida VR

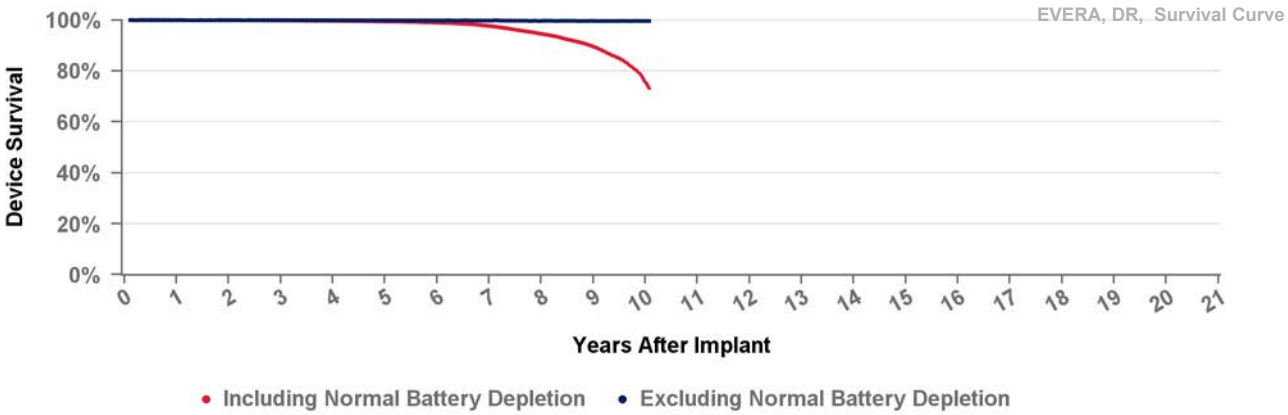
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 12Jan2011 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 134 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.7% | 56.6% | 45.9% | 44.0% |
| Effective Sample Size | 25804 | 23985 | 22243 | 20574 | 19021 | 17446 | 15686 | 13055 | 8322 | 3796 | 670 | 231 |

## DDBB1D1 Evera XT

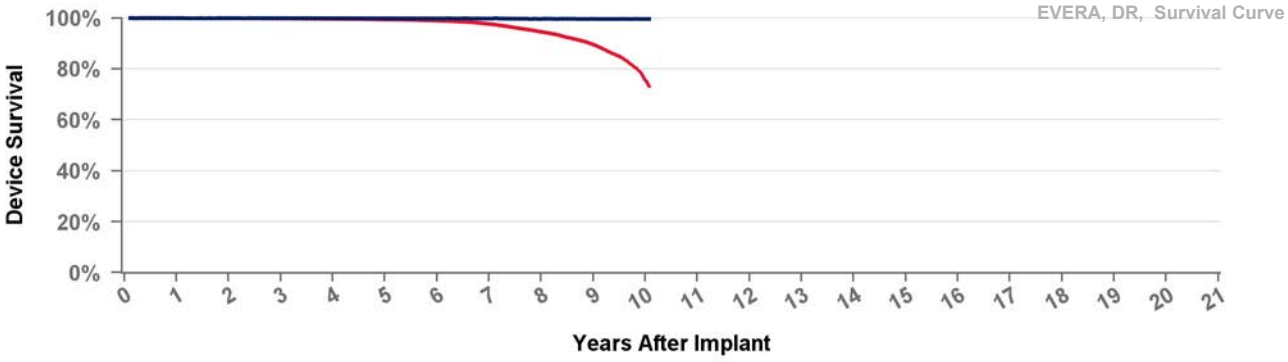
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **79** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **46** |
| **Registered USA Implants** | 82,211 | Battery | 28 |
| **Estimated Active USA Implants** | 42,056 | Electrical Component | 15 |
| **Normal Battery Depletions** | 2,200 | Software/Firmware | 1 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **33** |
| | | Battery | 29 |
| | | Electrical Component | 2 |
| | | Electrical Interconnect | 1 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDBB1D4 Evera XT

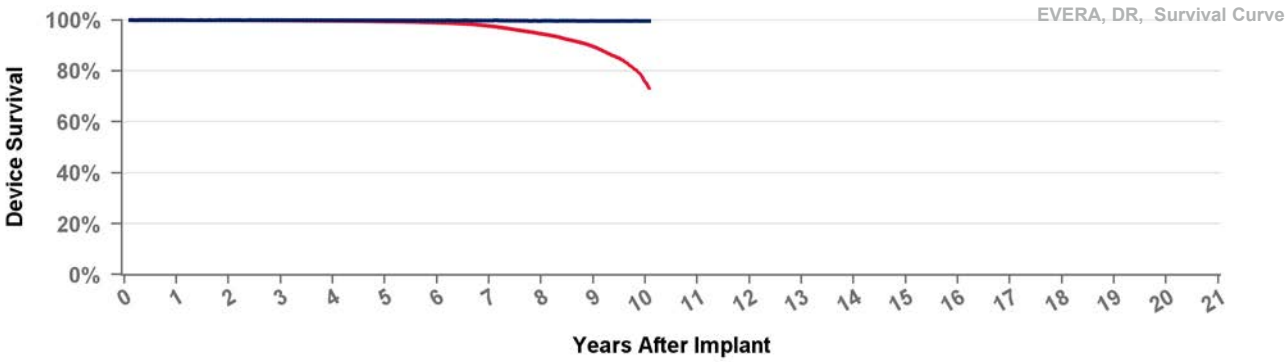
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **72** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **42** |
| **Registered USA Implants** | 59,387 | Battery | 31 |
| **Estimated Active USA Implants** | 30,735 | Electrical Component | 7 |
| **Normal Battery Depletions** | 1,668 | Electrical Interconnect | 2 |
| | | Possible Early Battery Depletion | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **30** |
| | | Battery | 22 |
| | | Device-Related Current Pathway | 4 |
| | | Electrical Component | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDBB2D1 Evera XT

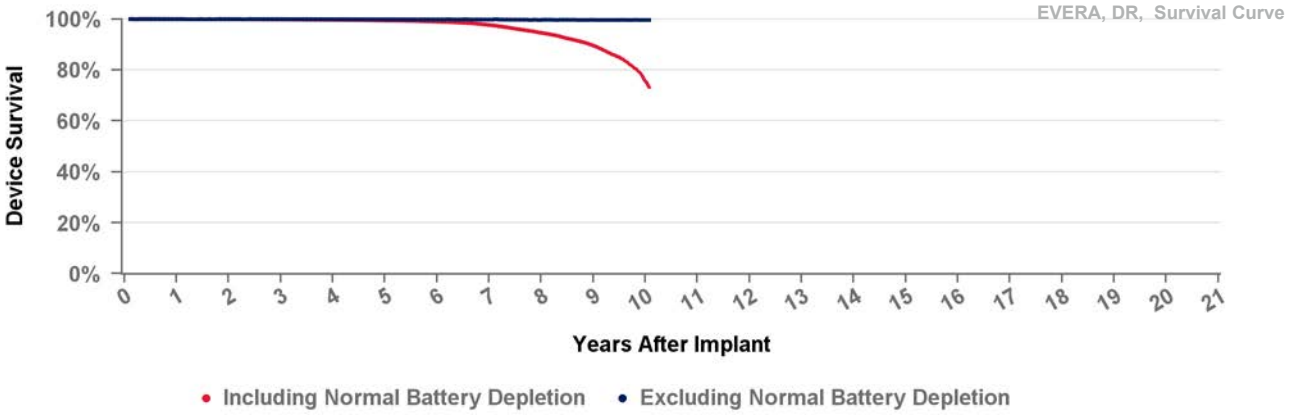
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDBB2D4 Evera XT

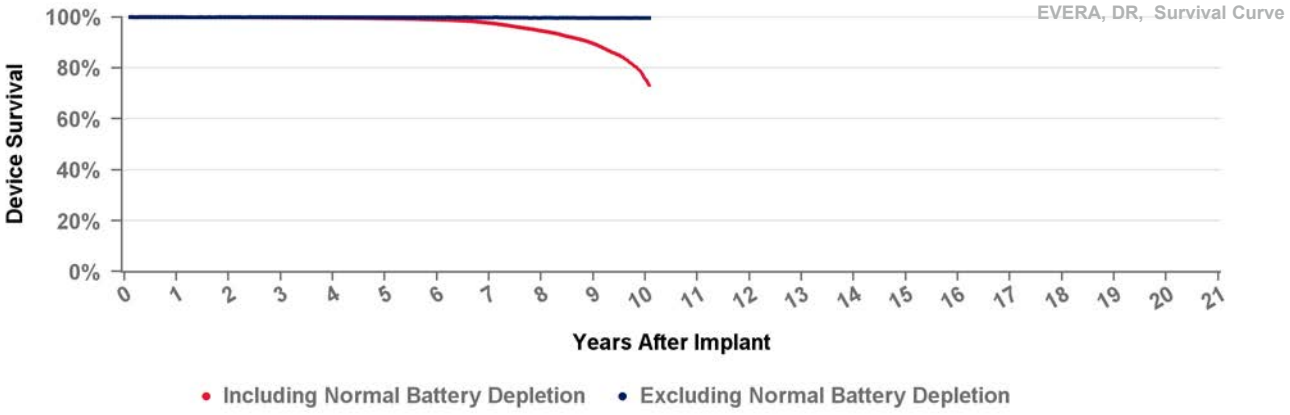
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDBC3D1 Evera S

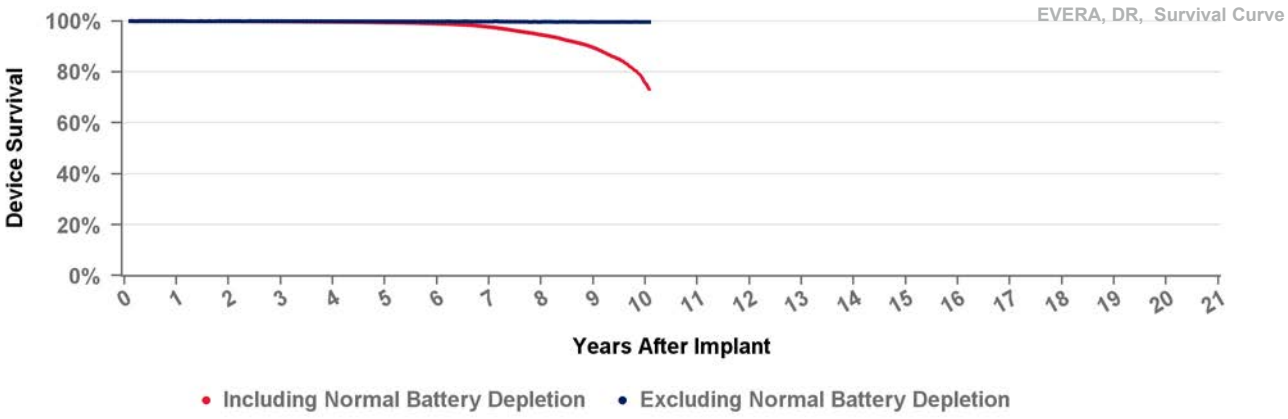
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **18** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 15,930 | Battery | 7 |
| **Estimated Active USA Implants** | 7,997 | Electrical Component | 2 |
| **Normal Battery Depletions** | 540 | **Therapy Function Compromised** | **9** |
| | | Battery | 6 |
| | | Device-Related Current Pathway | 1 |
| | | Electrical Component | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDBC3D4 Evera S

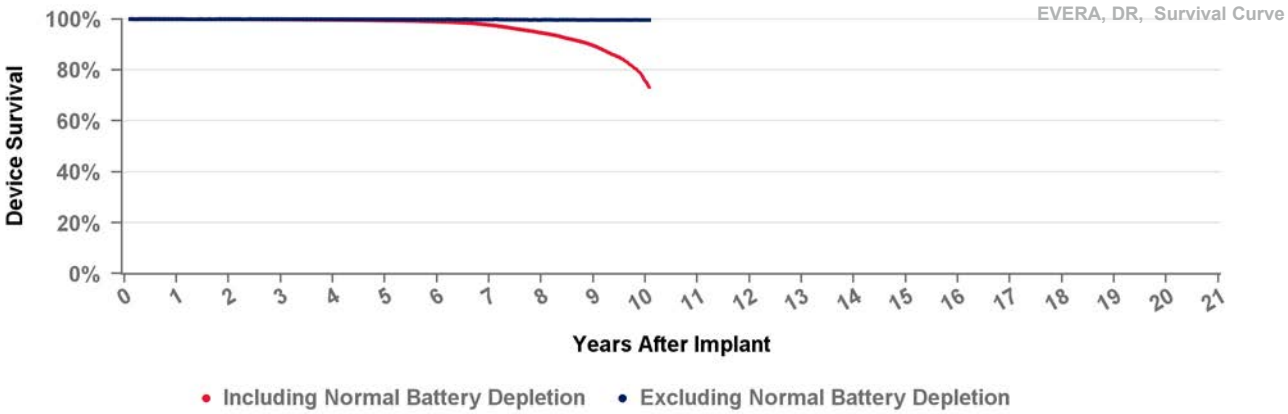
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **13** |
| **CE Approval Date** | 17Dec2013 | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 11,810 | Battery | 3 |
| **Estimated Active USA Implants** | 6,211 | Electrical Component | 2 |
| **Normal Battery Depletions** | 354 | **Therapy Function Compromised** | **8** |
| | | Battery | 5 |
| | | Device-Related Current Pathway | 1 |
| | | Electrical Component | 1 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMB1D1 Evera MRI XT

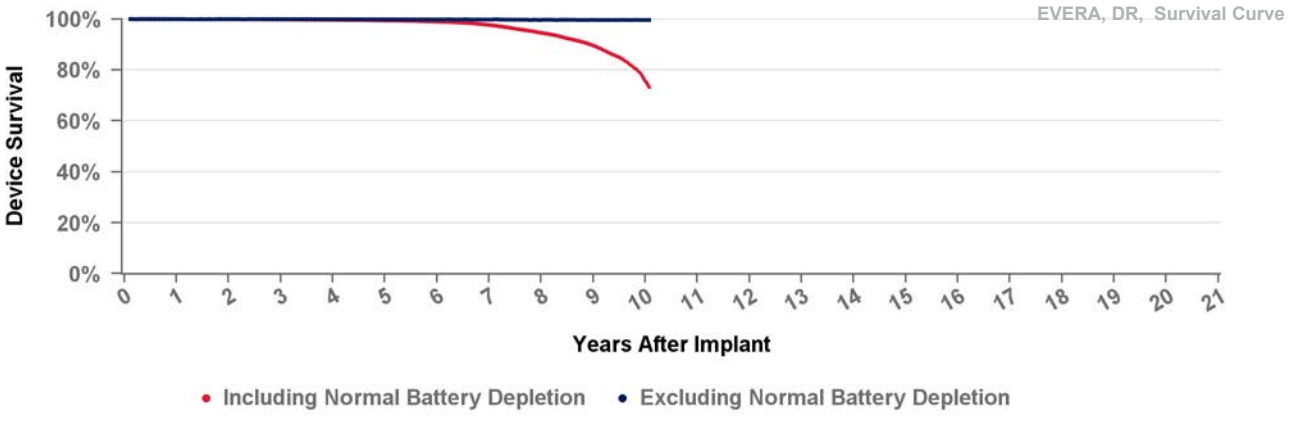
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **37** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **20** |
| **Registered USA Implants** | 45,768 | Battery | 12 |
| **Estimated Active USA Implants** | 35,757 | Electrical Component | 6 |
| **Normal Battery Depletions** | 89 | Electrical Interconnect | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **17** |
| | | Battery | 6 |
| | | Device-Related Current Pathway | 5 |
| | | Electrical Component | 6 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMB1D4 Evera MRI XT

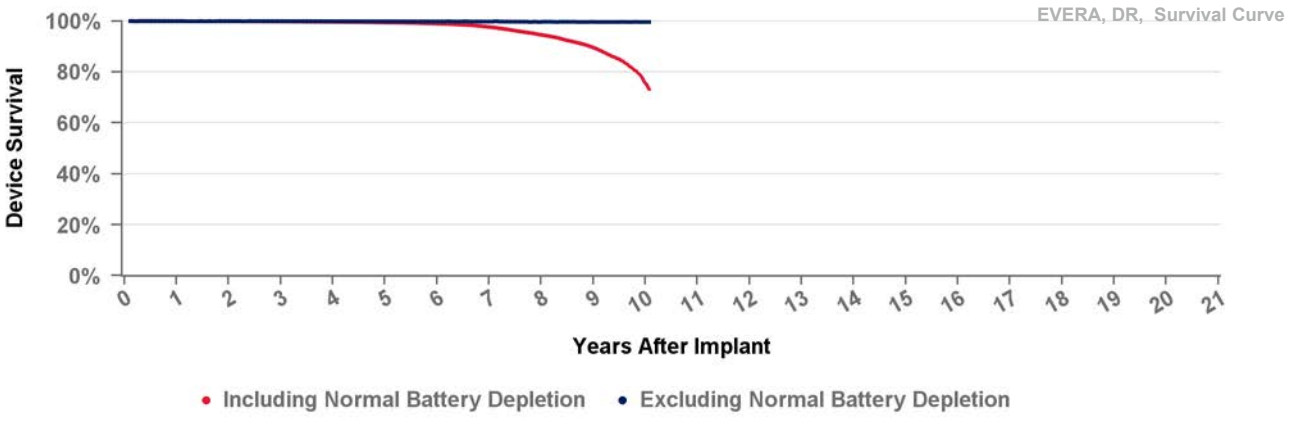
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **88** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **53** |
| **Registered USA Implants** | 137,457 | Battery | 24 |
| **Estimated Active USA Implants** | 108,425 | Electrical Component | 23 |
| **Normal Battery Depletions** | 371 | Electrical Interconnect | 4 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **35** |
| | | Battery | 23 |
| | | Device-Related Current Pathway | 9 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMB2D1 Evera MRI XT

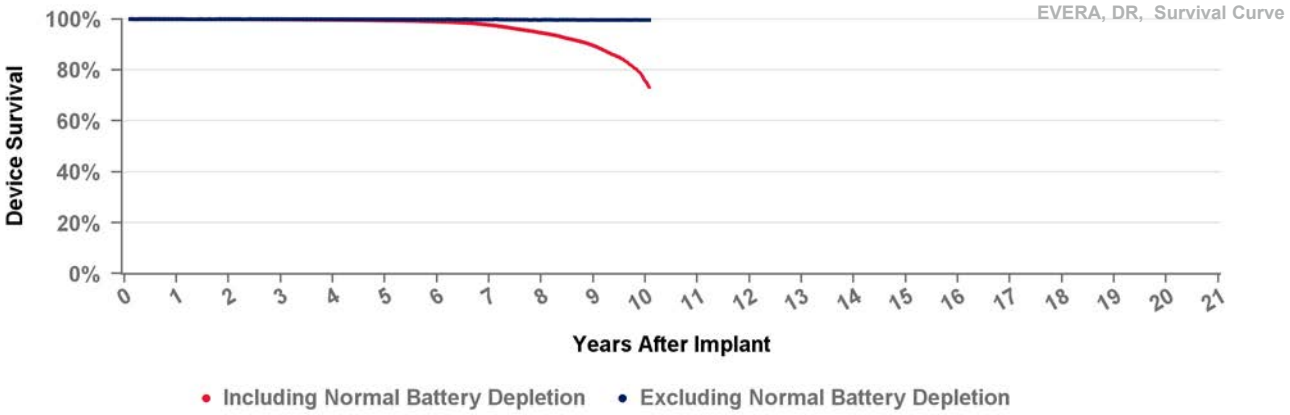
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMB2D4 Evera MRI XT

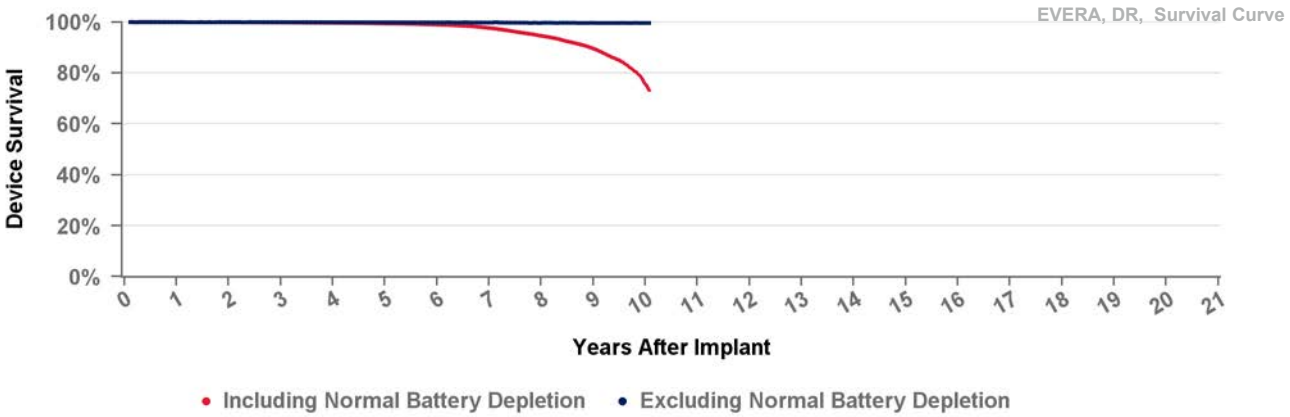
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMC3D1 Evera MRI S

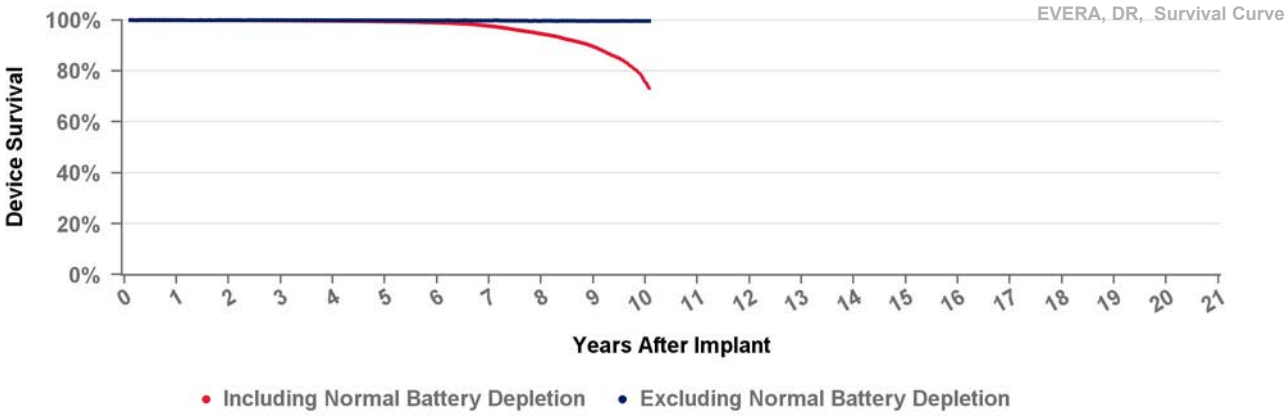
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 4,073 | Battery | 1 |
| **Estimated Active USA Implants** | 3,157 | Electrical Component | 1 |
| **Normal Battery Depletions** | 10 | Other | 1 |
| | | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMC3D4 Evera MRI

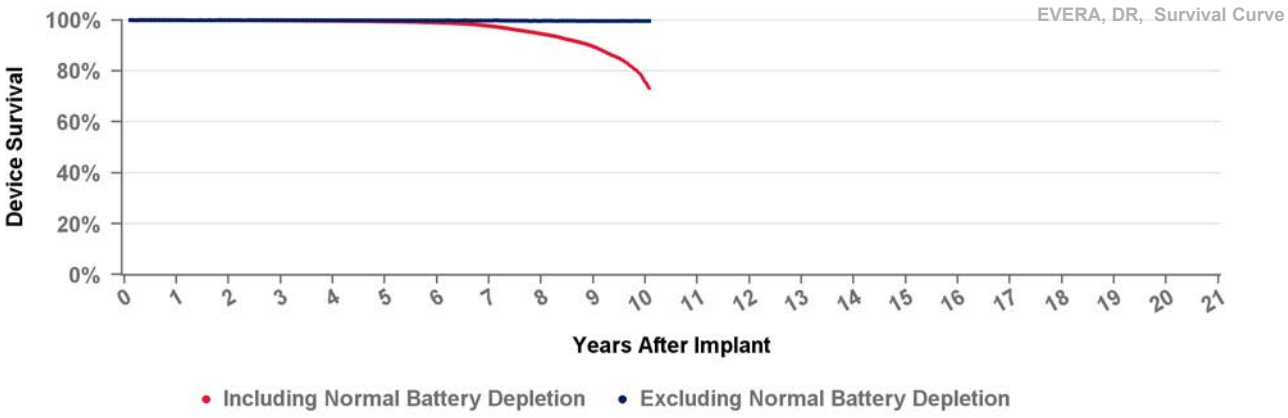
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 9,169 | Battery | 3 |
| **Estimated Active USA Implants** | 7,168 | Electrical Component | 1 |
| **Normal Battery Depletions** | 18 | **Therapy Function Compromised** | **4** |
| | | Battery | 1 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMD3D1 Primo

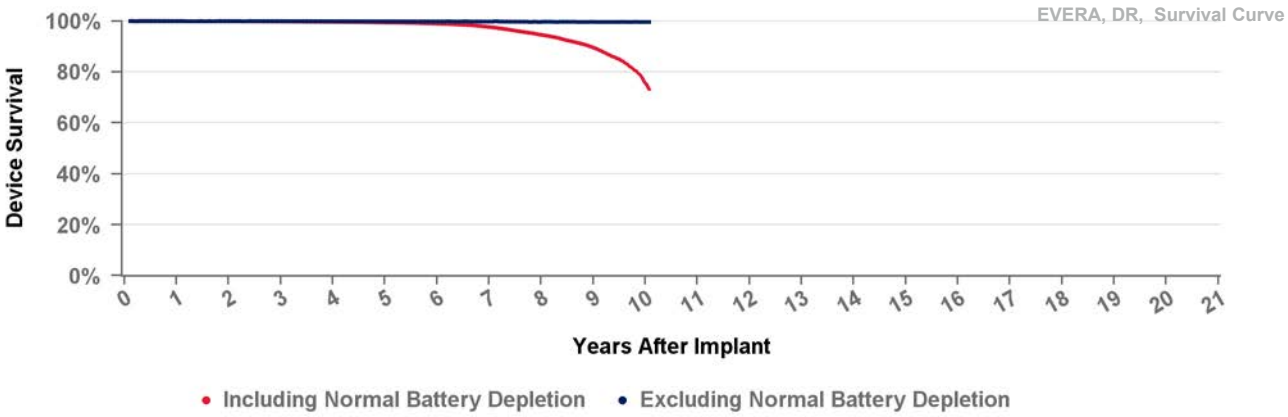
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 422 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 377 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDMD3D4 Primo

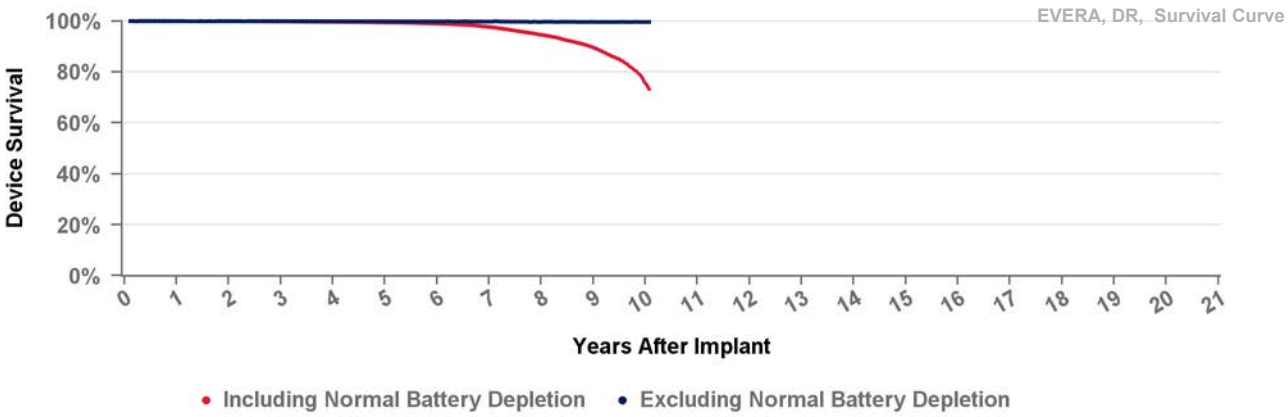
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,335 | | |
| **Estimated Active USA Implants** | 1,230 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 1 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDME3D1 Mirro

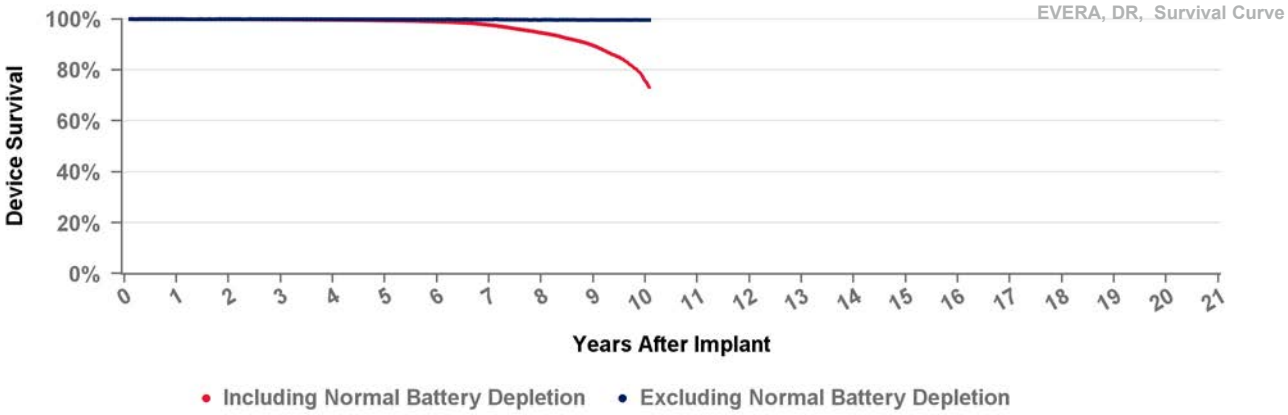
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDME3D4 Mirro

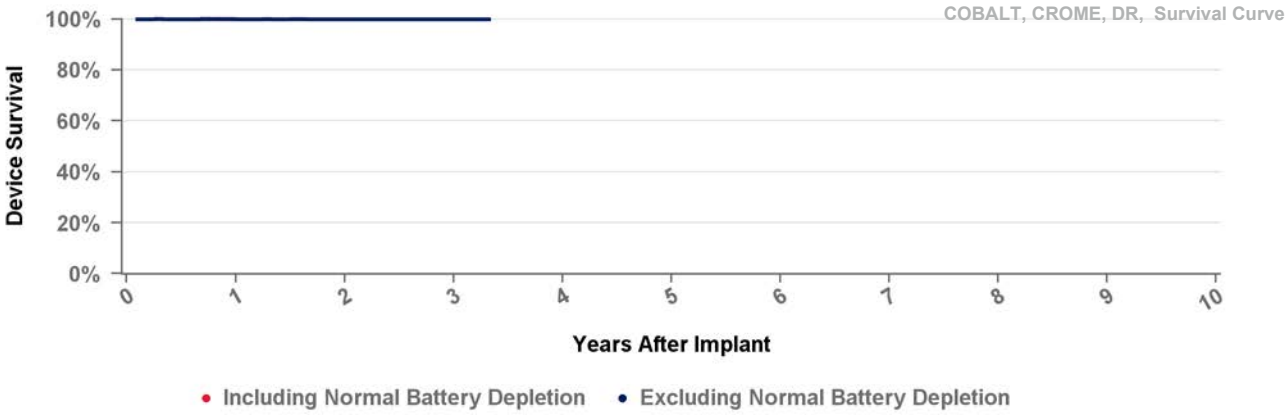
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 121 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.0% | 97.7% | 94.6% | 89.6% | 75.8% | 73.1% |
| Effective Sample Size | 212786 | 188891 | 167116 | 138203 | 107861 | 79132 | 52506 | 30455 | 14116 | 1518 | 763 |

## DDPA2D1 Cobalt XT

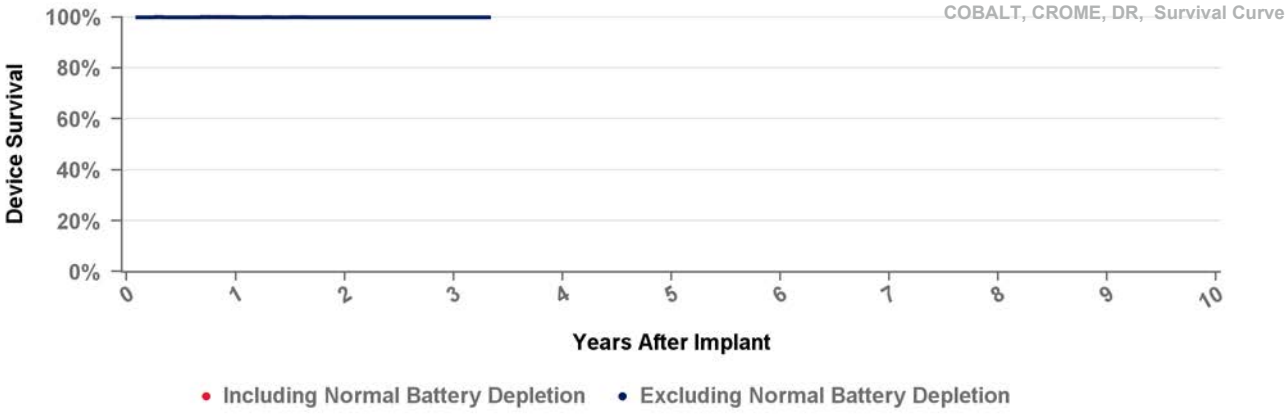
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4,173 | | |
| **Estimated Active USA Implants** | 3,996 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DDPA2D4 Cobalt XT

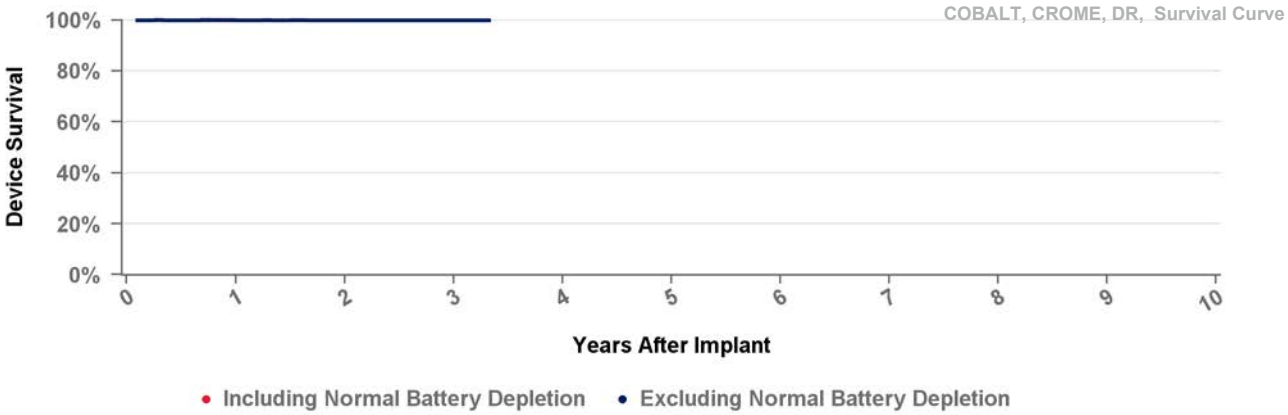
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 34,591 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 33,234 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 4 | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DDPB3D1 Cobalt

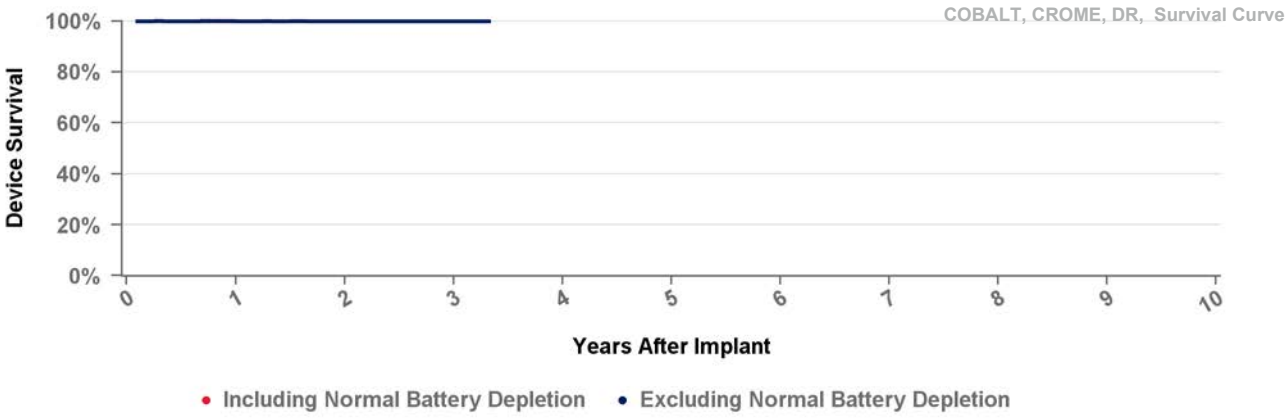
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 3,719 | Battery | 1 |
| **Estimated Active USA Implants** | 3,485 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DDPB3D4 Cobalt

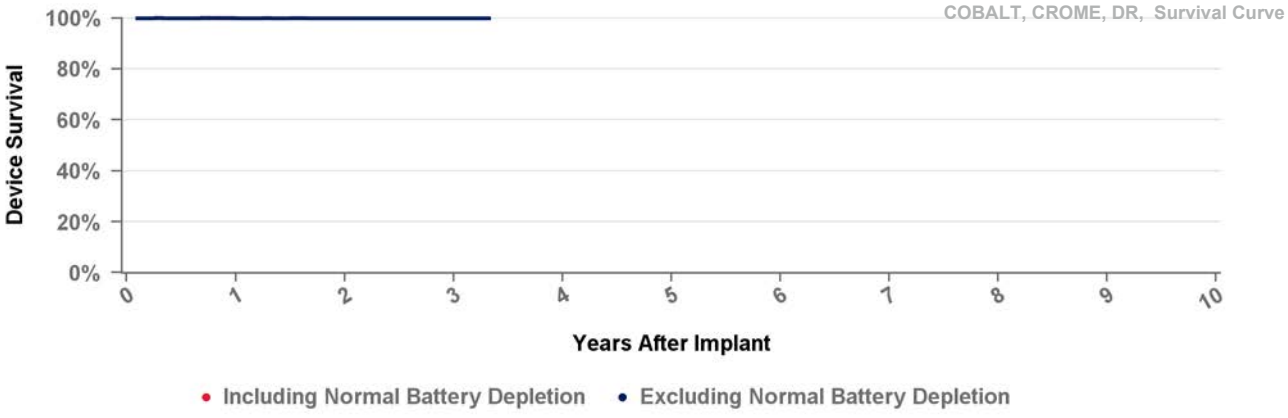
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **6** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 22,101 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 20,744 | Other | 2 |
| **Normal Battery Depletions** | 2 | **Therapy Function Compromised** | **3** |
| | | Electrical Component | 1 |
| | | Electrical Interconnect | 2 |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DDPC3D1 Crome

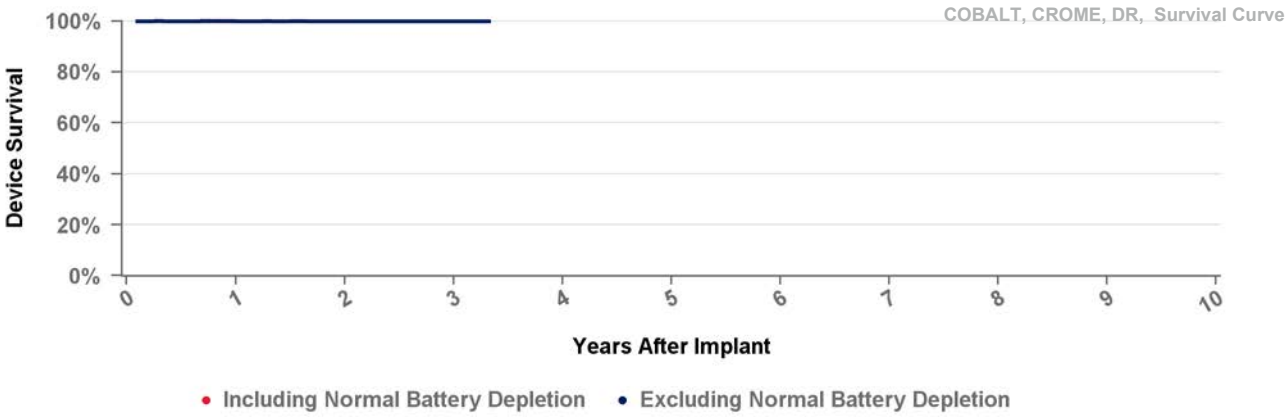
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 257 | | |
| **Estimated Active USA Implants** | 235 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DDPC3D4 Crome

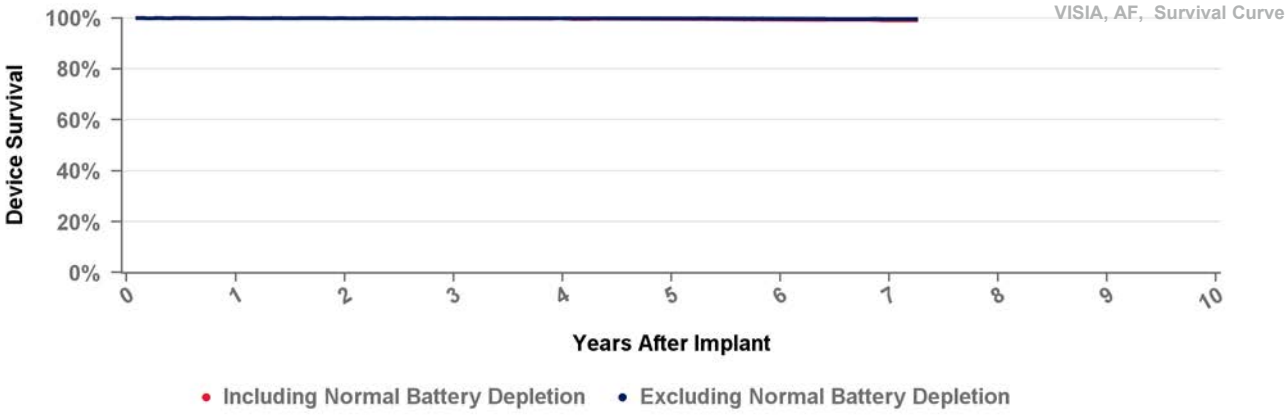
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,492 | | |
| **Estimated Active USA Implants** | 1,408 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 40 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 19386 | 10576 | 1202 | 153 |

## DVAB1D1 Visia AF

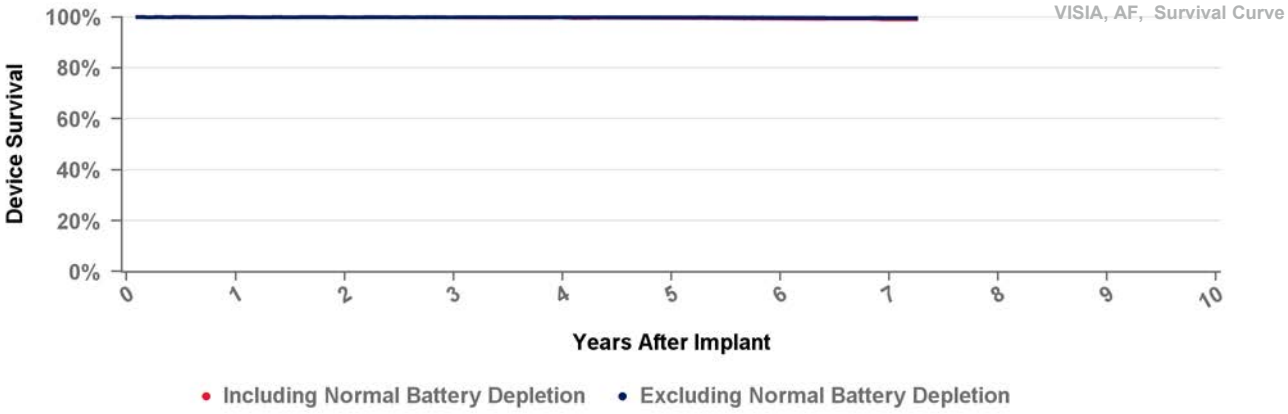
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **7** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 5,079 | Battery | 5 |
| **Estimated Active USA Implants** | 3,457 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | 13 | Battery | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVAB1D4 Visia AF

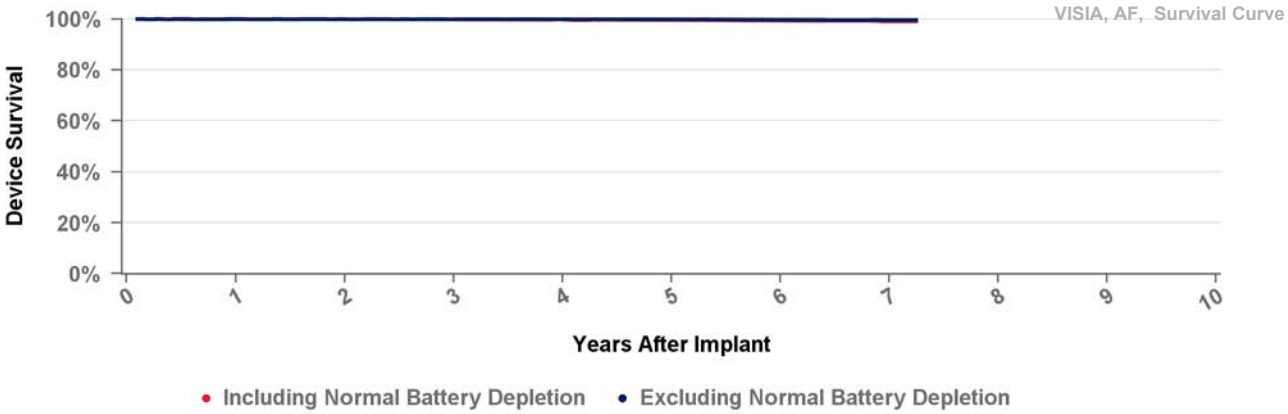
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **5** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 3,462 | Battery | 2 |
| **Estimated Active USA Implants** | 2,449 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | | Battery | 2 |
| | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVAB2D1 Visia AF XT

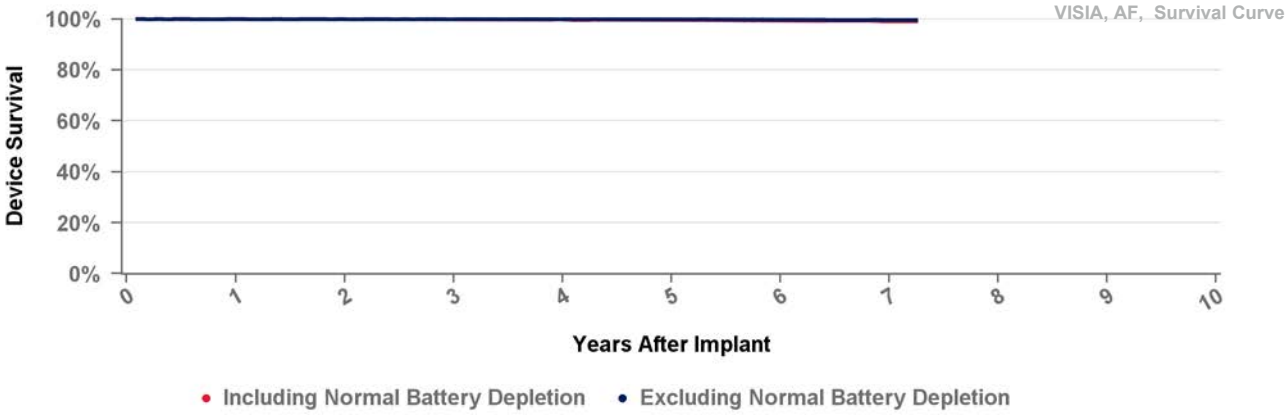
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVAC3D1 Visia AF S

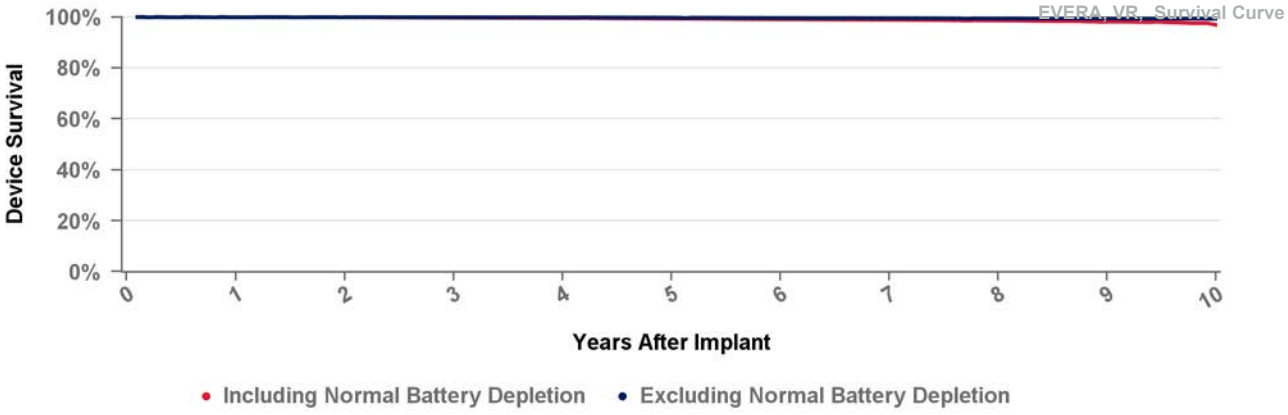
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVBB1D1 Evera XT

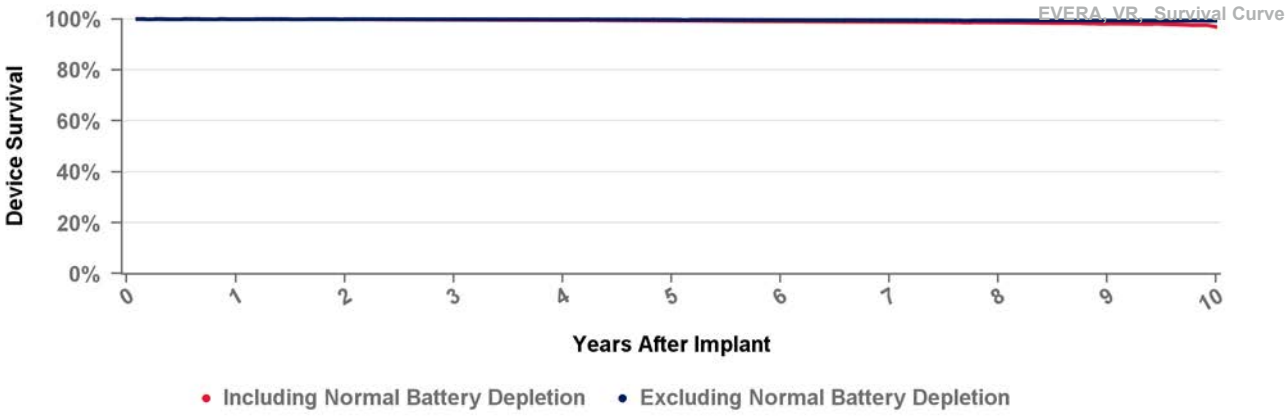
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **71** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **51** |
| **Registered USA Implants** | 32,233 | Battery | 44 |
| **Estimated Active USA Implants** | 18,111 | Electrical Component | 7 |
| **Normal Battery Depletions** | 70 | **Therapy Function Compromised** | **20** |
| | | Battery | 16 |
| | | Device-Related Current Pathway | 1 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVBB1D4 Evera XT

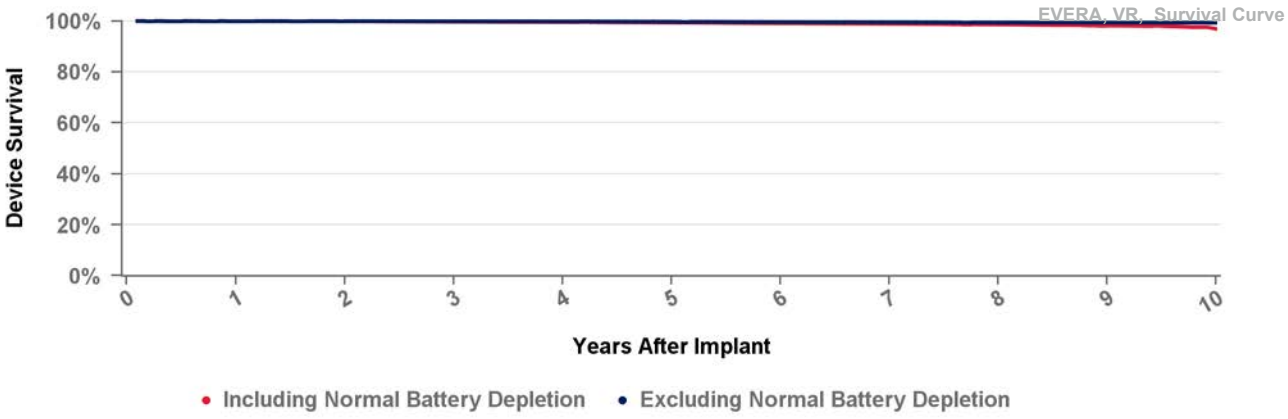
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **89** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **58** |
| **Registered USA Implants** | 43,927 | Battery | 43 |
| **Estimated Active USA Implants** | 26,720 | Electrical Component | 9 |
| **Normal Battery Depletions** | 120 | Possible Early Battery Depletion | 2 |
| | | Other | 4 |
| | | **Therapy Function Compromised** | **31** |
| | | Battery | 26 |
| | | Device-Related Current Pathway | 4 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVBB2D1 Evera XT

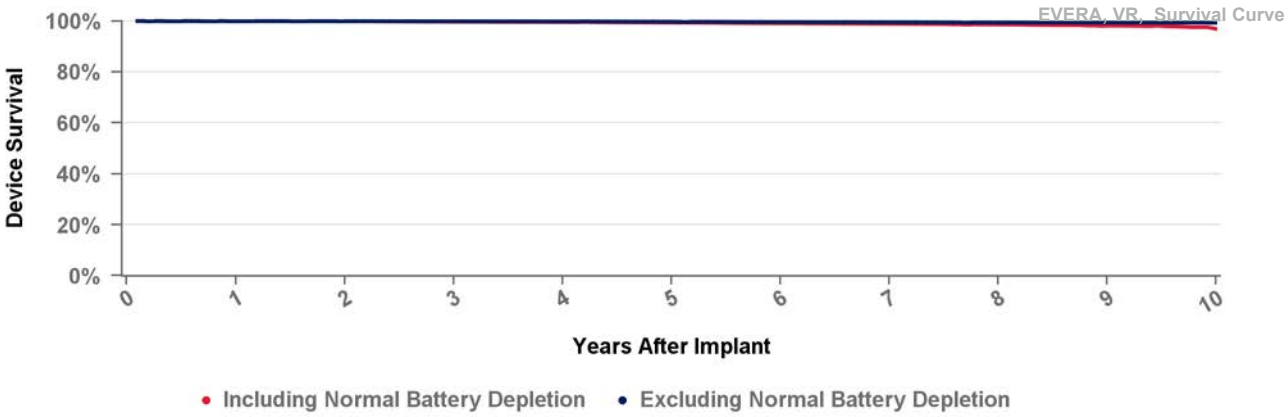
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVBB2D4 Evera XT

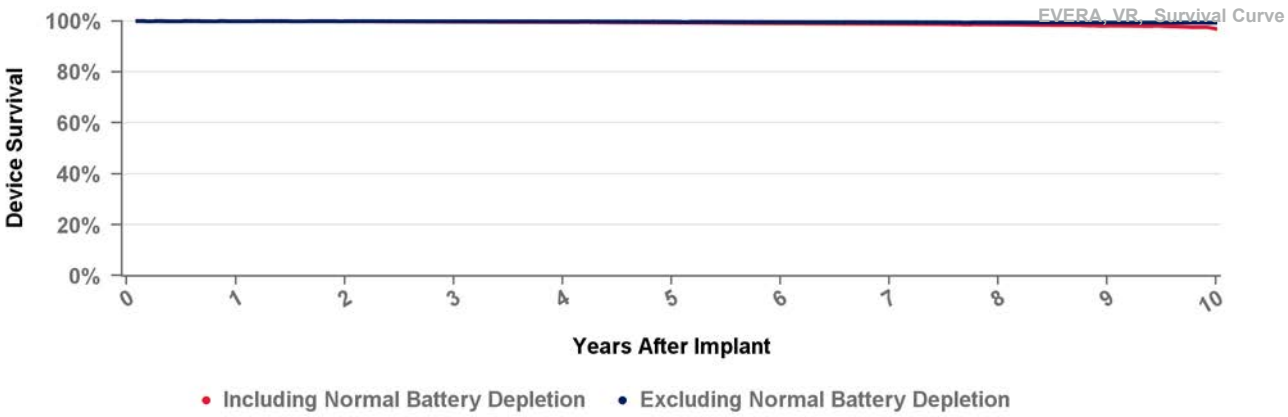
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVBC3D1 Evera S

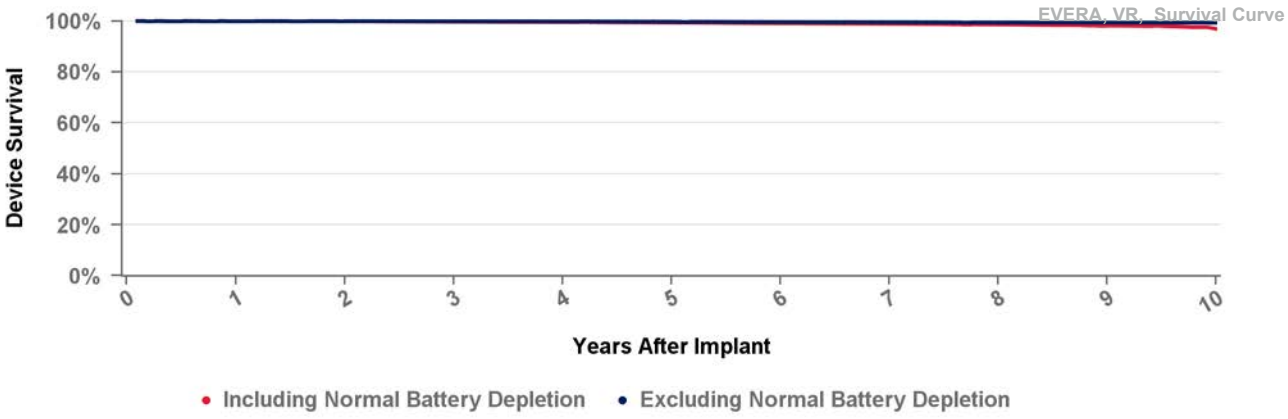
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **26** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 8,961 | Battery | 15 |
| **Estimated Active USA Implants** | 5,218 | Electrical Component | 2 |
| **Normal Battery Depletions** | 18 | **Therapy Function Compromised** | **9** |
| | | Battery | 8 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVBC3D4 Evera S

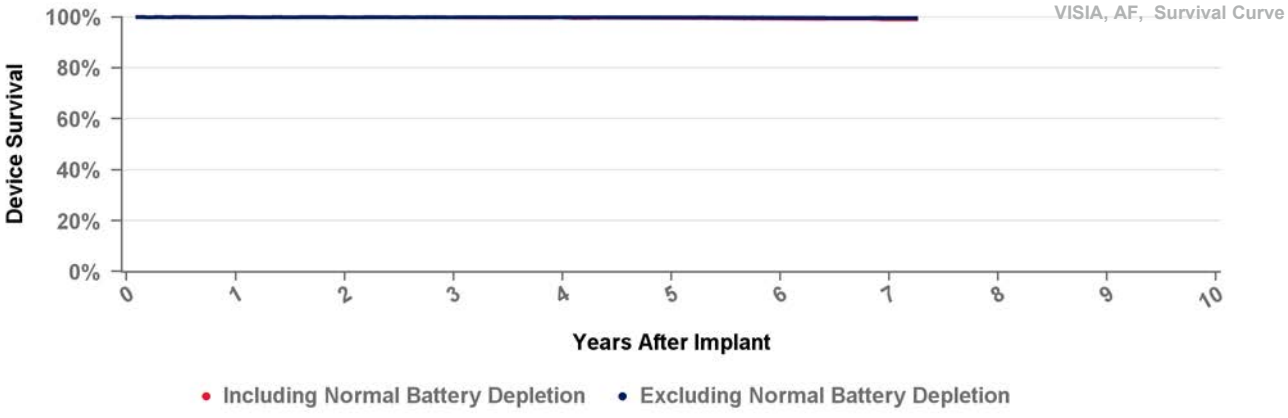
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **19** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **12** |
| **Registered USA Implants** | 11,103 | Battery | 9 |
| **Estimated Active USA Implants** | 6,988 | Electrical Component | 3 |
| **Normal Battery Depletions** | 24 | **Therapy Function Compromised** | **7** |
| | | Battery | 5 |
| | | Device-Related Current Pathway | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVFB1D1 Visia MRI AF

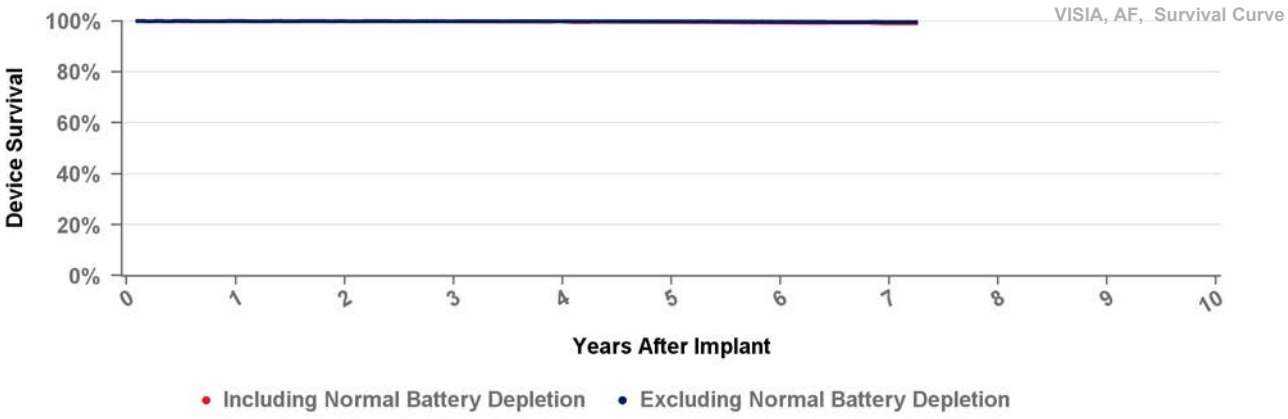
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **17** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **10** |
| **Registered USA Implants** | 21,301 | Battery | 6 |
| **Estimated Active USA Implants** | 17,422 | Electrical Component | 3 |
| **Normal Battery Depletions** | 12 | Other | 1 |
| | | **Therapy Function Compromised** | **7** |
| | | Battery | 2 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVFB1D4 Visia MRI AF

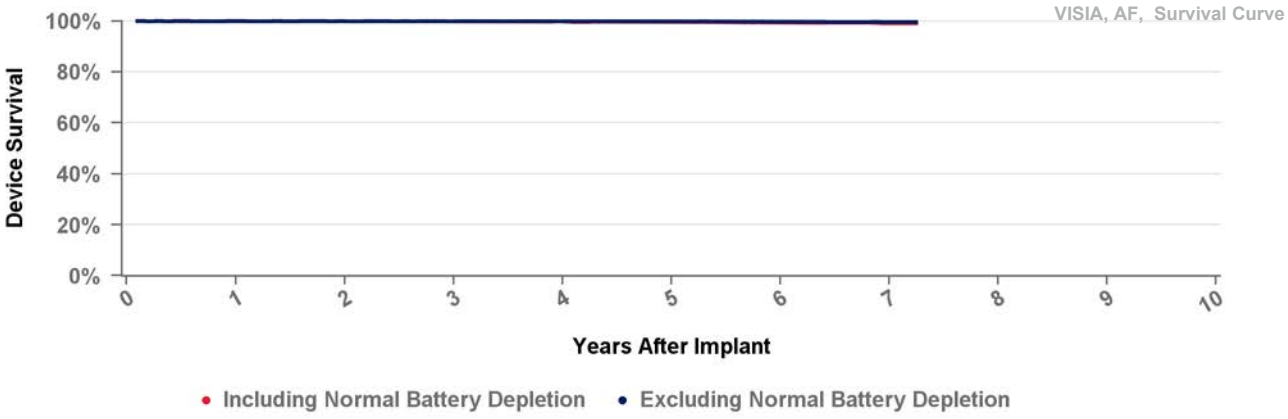
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **62** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **38** |
| **Registered USA Implants** | 70,944 | Battery | 29 |
| **Estimated Active USA Implants** | 57,264 | Electrical Component | 8 |
| **Normal Battery Depletions** | 24 | Other | 1 |
| | | **Therapy Function Compromised** | **24** |
| | | Battery | 14 |
| | | Device-Related Current Pathway | 7 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVFB2D1 Visia MRI AF XT

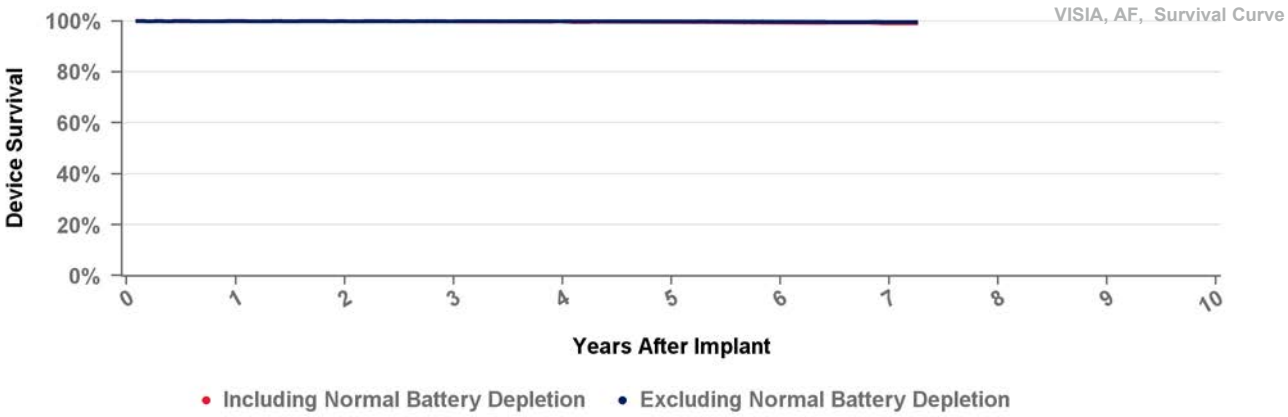
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVFB2D4 Visia MRI AF XT

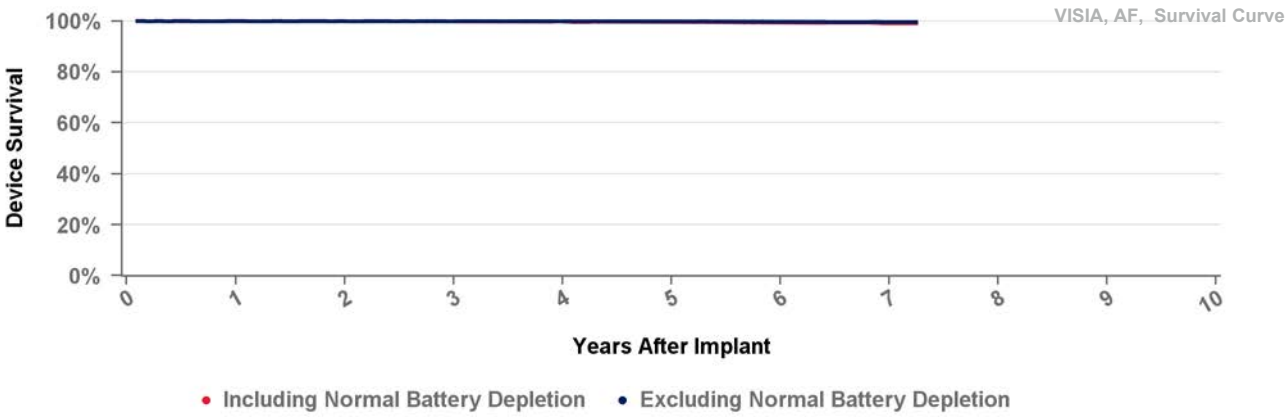
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVFC3D1 Visia MRI AF S

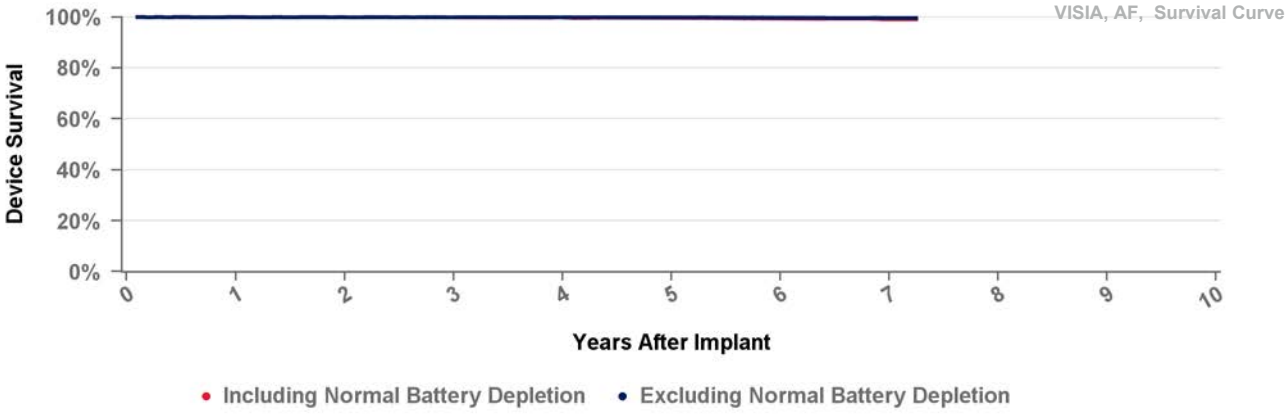
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,700 | | |
| **Estimated Active USA Implants** | 1,442 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVFC3D4 Visia MRI AF S

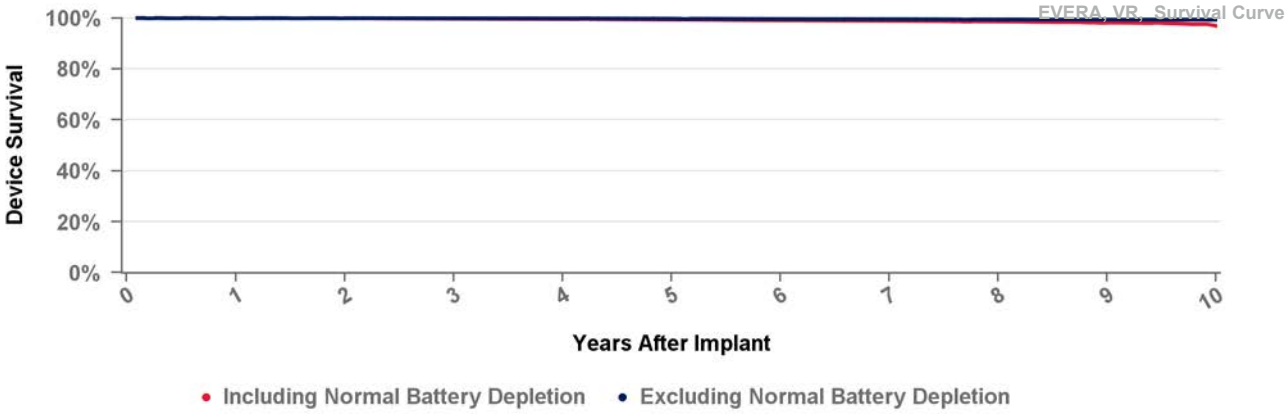
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 4,111 | Battery | 4 |
| **Estimated Active USA Implants** | 3,471 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 5 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 73922 | 63000 | 53111 | 40359 | 26873 | 14115 | 2503 | 475 |

## DVMB1D4 Evera MRI XT

| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **34** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **16** |
| **Registered USA Implants** | 20,552 | Battery | 12 |
| **Estimated Active USA Implants** | 13,967 | Electrical Component | 3 |
| **Normal Battery Depletions** | 14 | Other | 1 |
| | | **Therapy Function Compromised** | **18** |
| | | Battery | 14 |
| | | Device-Related Current Pathway | 4 |

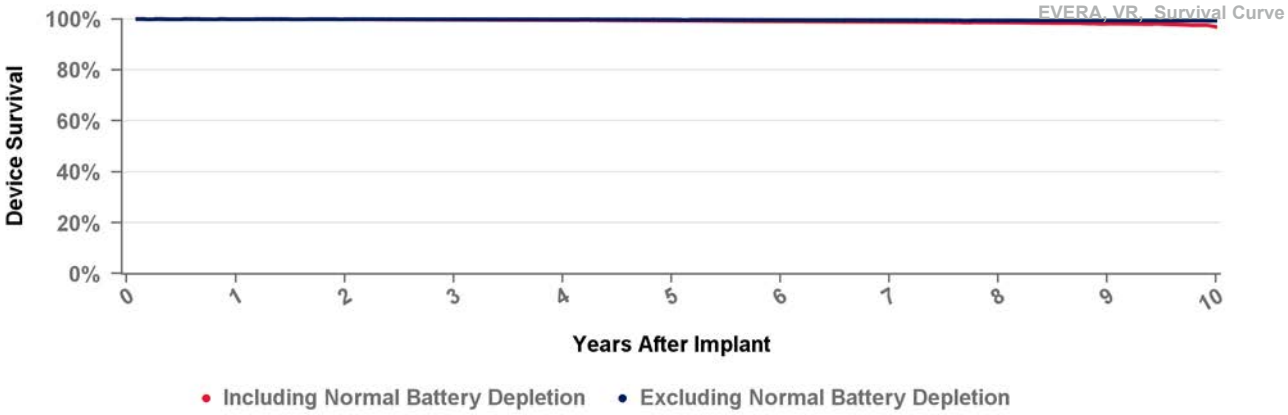



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMB2D1 Evera MRI XT

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

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

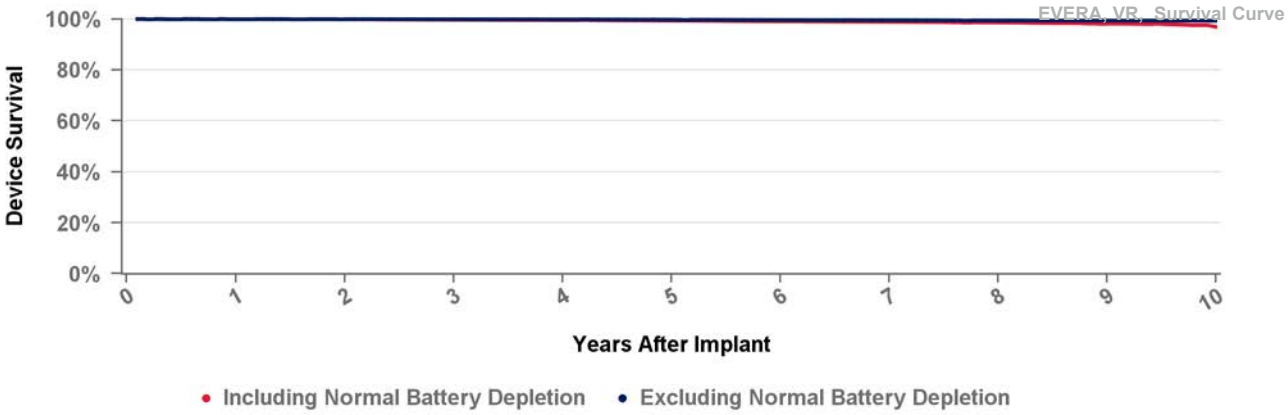



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMB2D4 Evera MRI XT

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

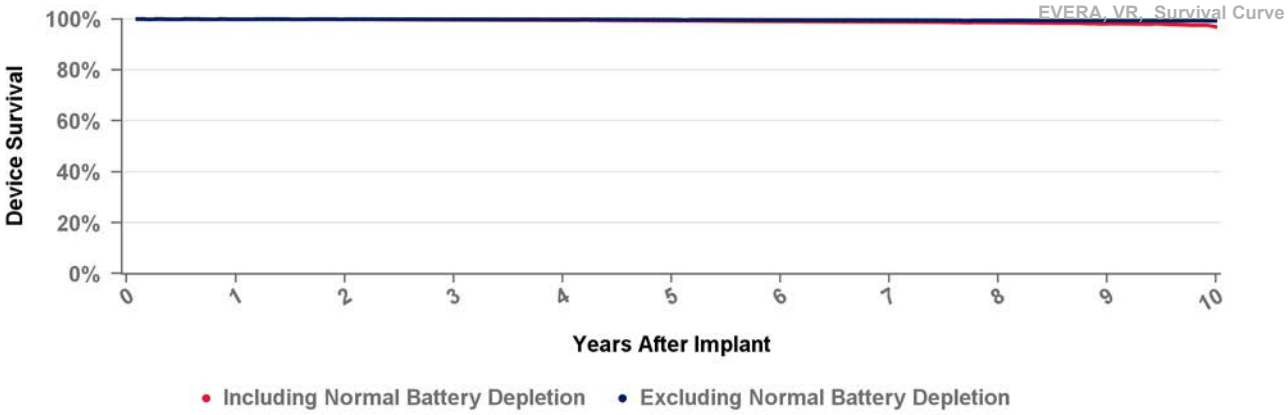
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMC3D1 Evera MRI S

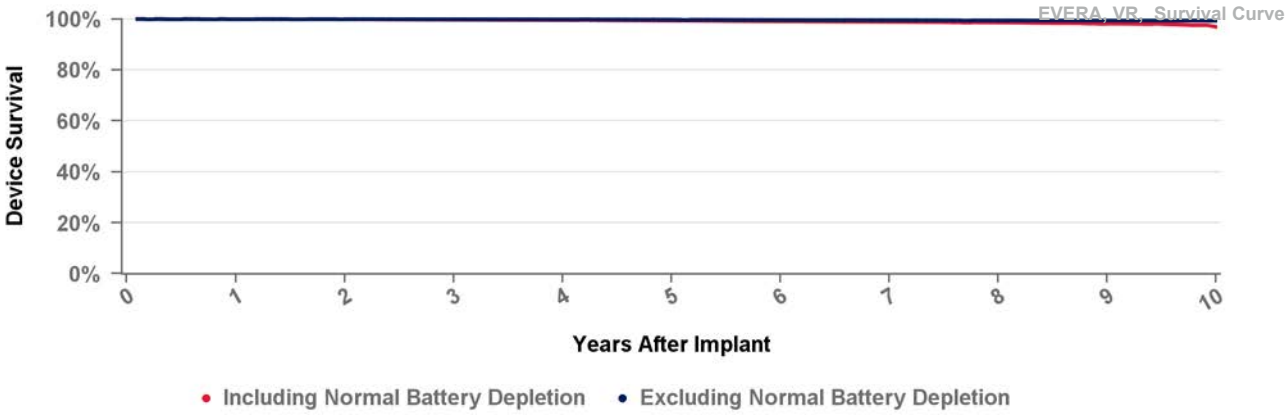
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMC3D4 Evera MRI S

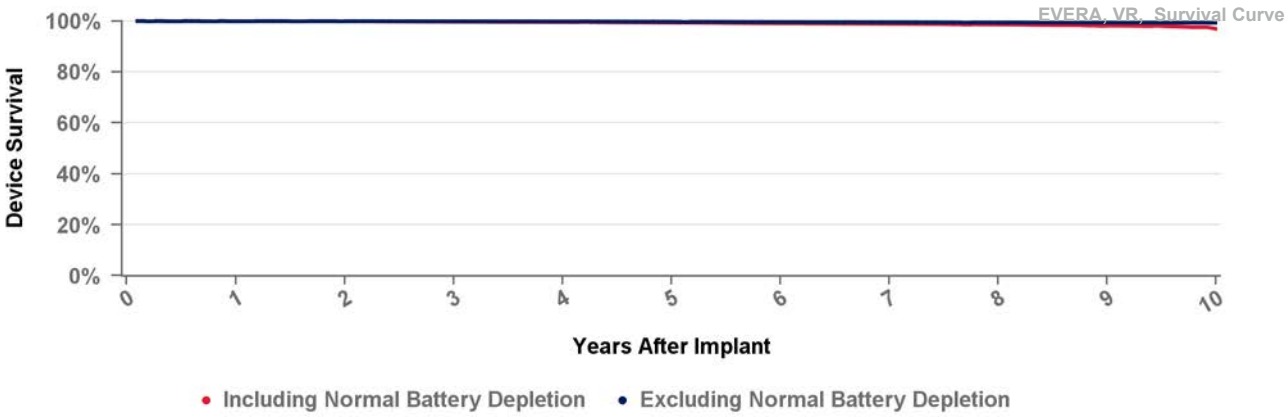
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMD3D1 Primo

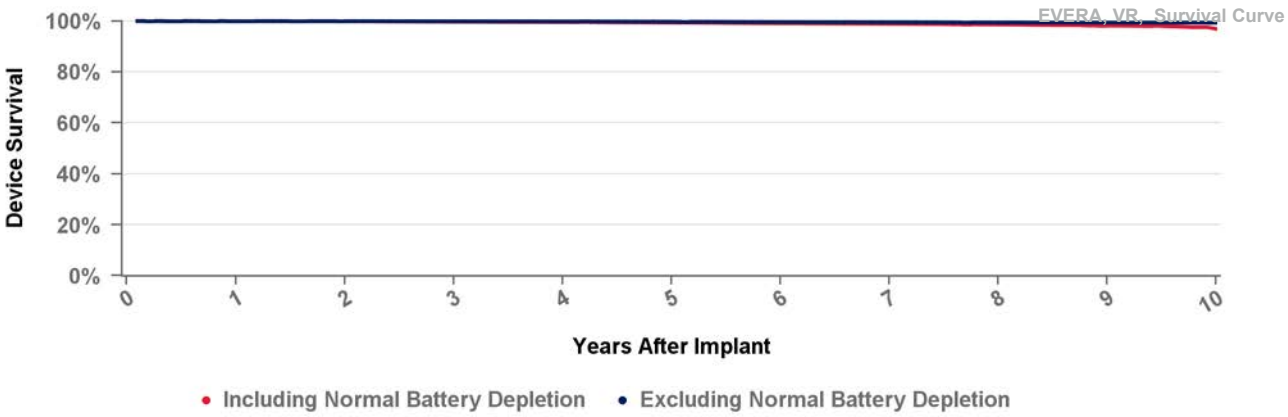
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 266 | | |
| **Estimated Active USA Implants** | 240 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVMD3D4 Primo

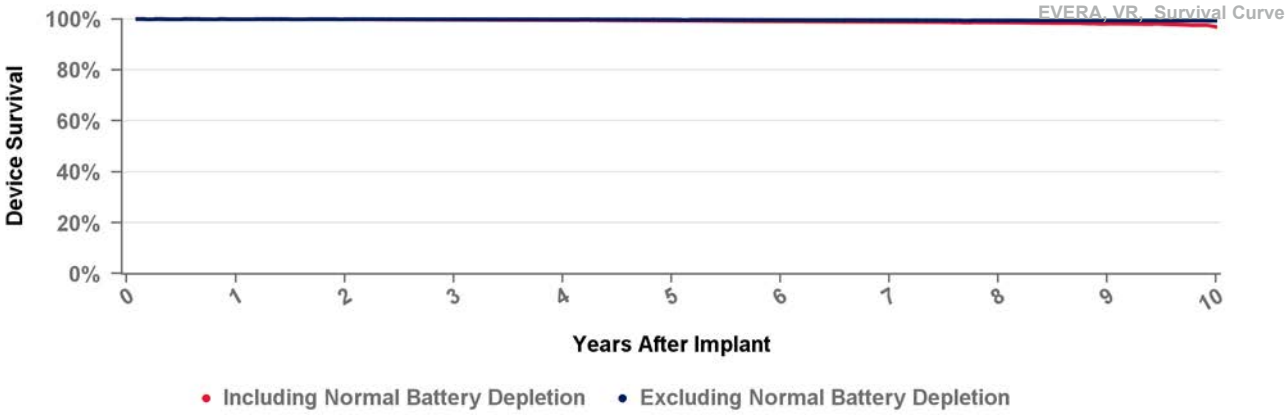
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 569 | | |
| **Estimated Active USA Implants** | 526 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVME3D1 Mirro

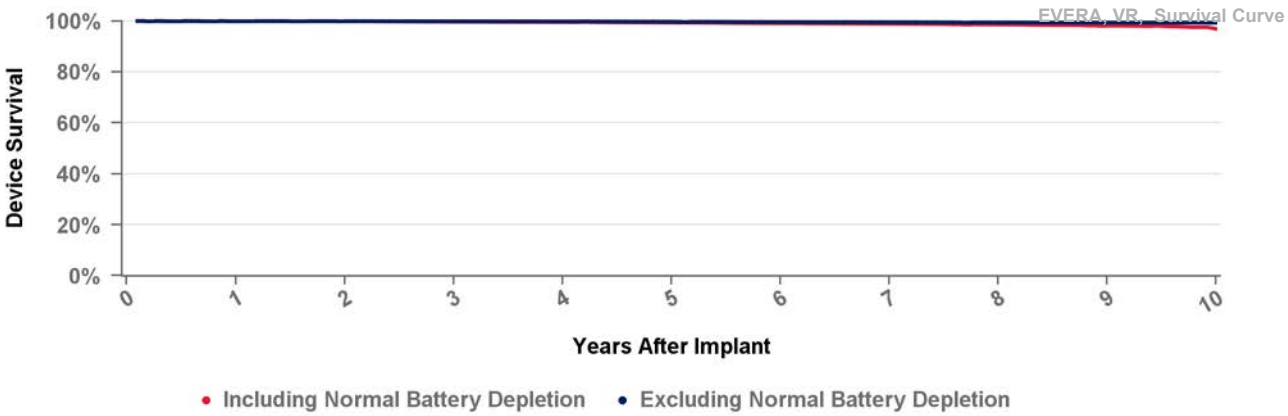
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVME3D4 Mirro

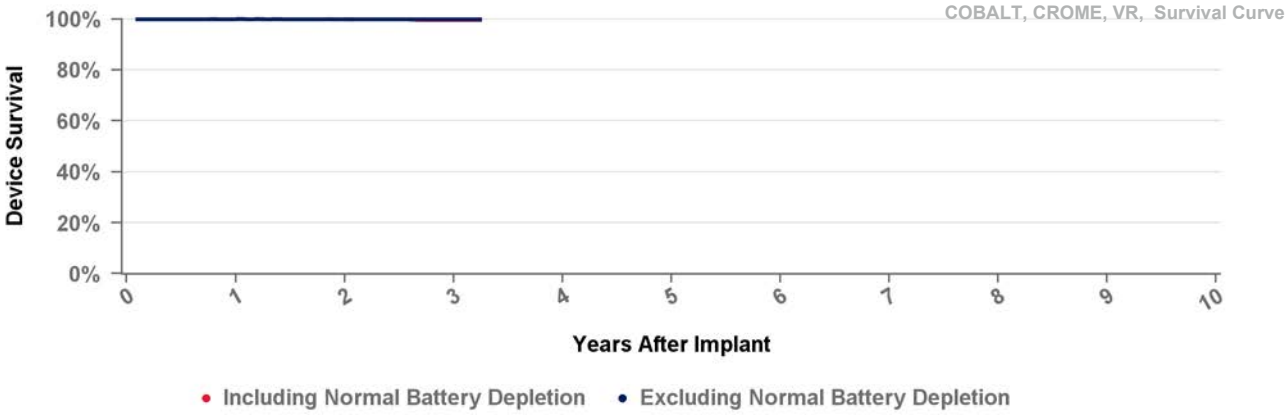
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.6% | 99.6% | 99.5% | 99.4% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.7% | 98.2% | 96.9% |
| Effective Sample Size | 52410 | 48789 | 45352 | 42218 | 39145 | 35975 | 32330 | 21288 | 9285 | 256 |

## DVPA2D1 Cobalt XT

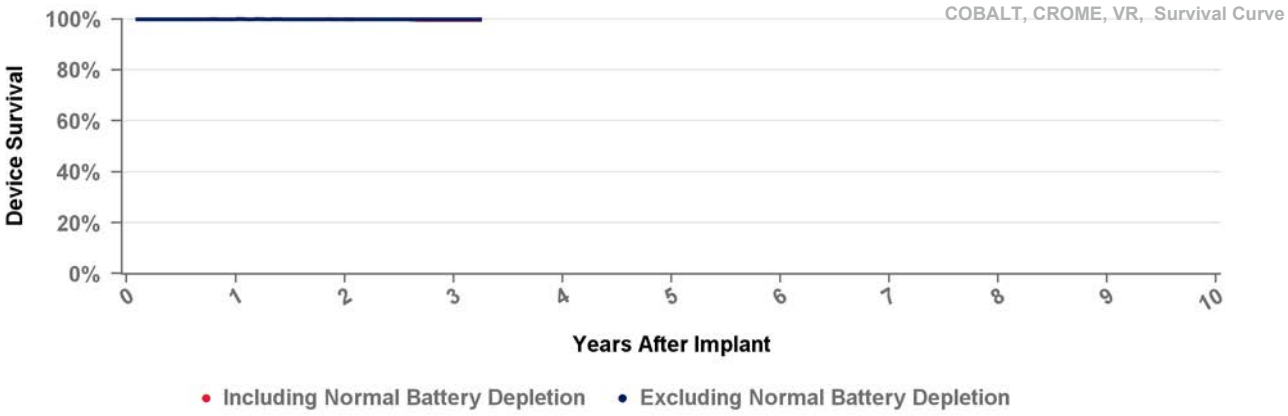
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,510 | | |
| **Estimated Active USA Implants** | 2,382 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 2 | | |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## DVPA2D4 Cobalt XT

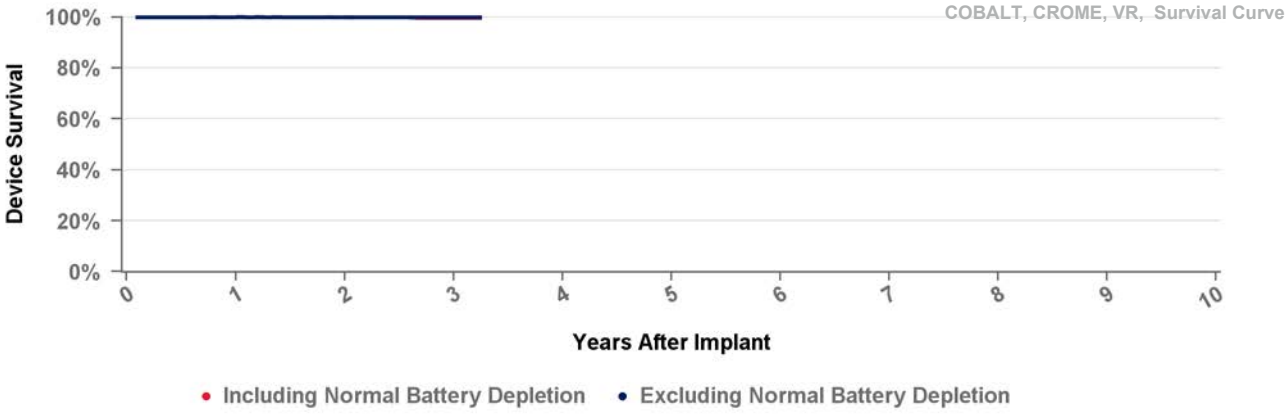
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 14,671 | | |
| **Estimated Active USA Implants** | 14,048 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## DVPB3D1 Cobalt

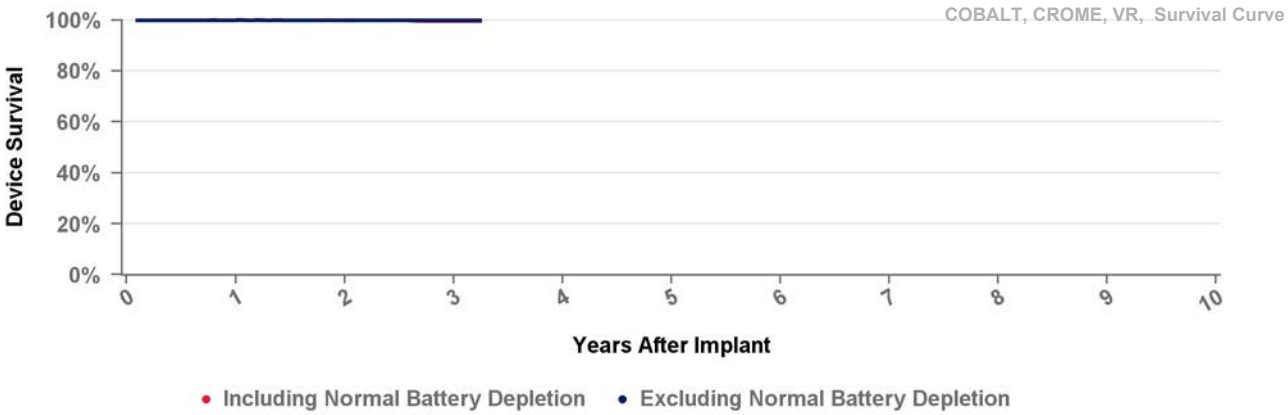
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 3,078 | | |
| **Estimated Active USA Implants** | 2,860 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | | Electrical Interconnect | 2 |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## DVPB3D4 Cobalt

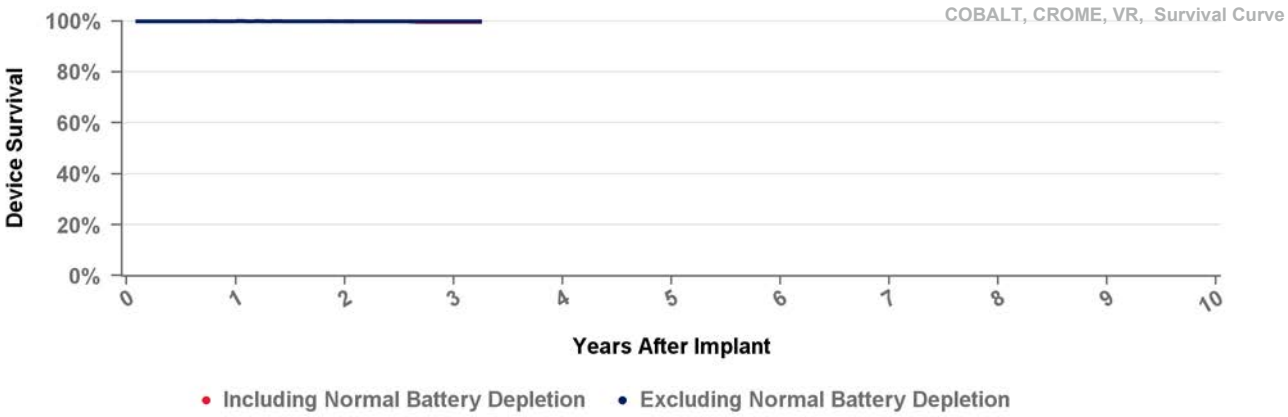
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 9,804 | Other | 1 |
| **Estimated Active USA Implants** | 9,217 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | | Device-Related Current Pathway | 2 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## DVPC3D1 Crome

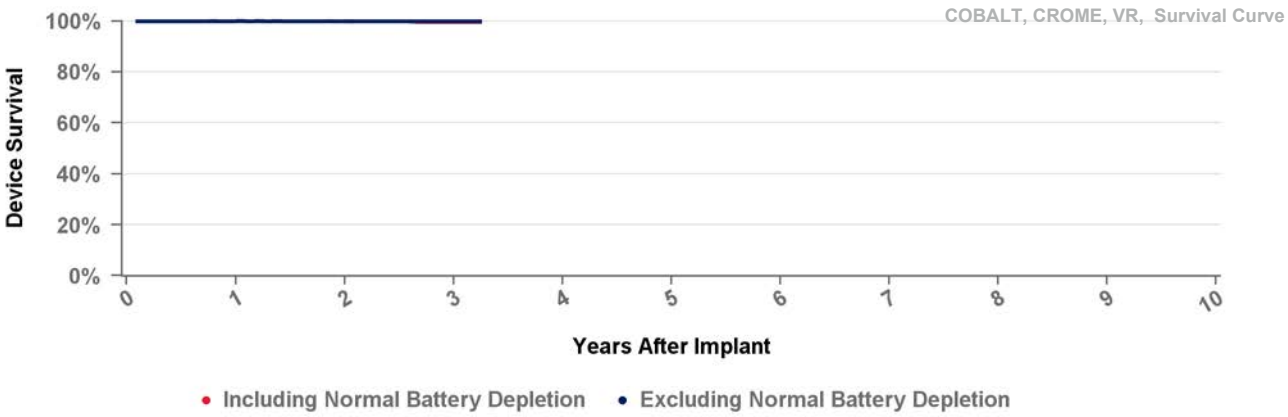
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 254 | | |
| **Estimated Active USA Implants** | 240 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## DVPC3D4 Crome

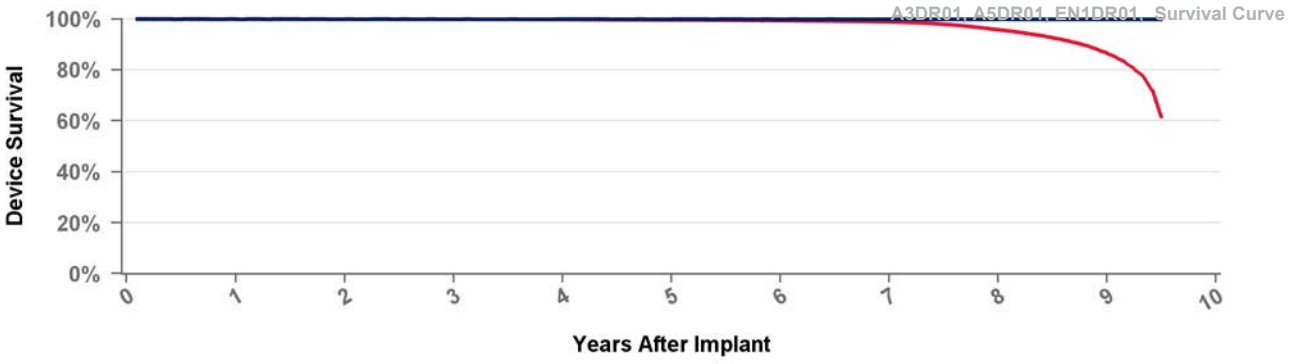
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 811 | | |
| **Estimated Active USA Implants** | 761 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 39 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.7% |
| Effective Sample Size | 9986 | 5740 | 669 | 177 |

## A2DR01 Advisa DR MRI

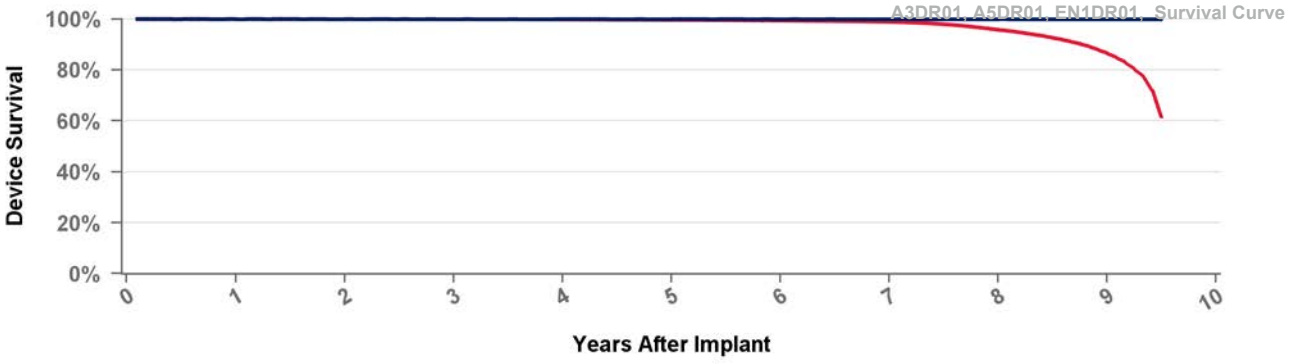
| | | | |
|---|---|---|---|
| **US Market Release** | 15Jan2013 | **Total Malfunctions (USA)** | **75** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **70** |
| **Registered USA Implants** | 344,410 | Battery | 1 |
| **Estimated Active USA Implants** | 224,819 | Electrical Component | 35 |
| **Normal Battery Depletions** | 5,168 | Electrical Interconnect | 4 |
| | | Possible Early Battery Depletion | 21 |
| | | Software/Firmware | 6 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **5** |
| | | Electrical Component | 5 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.9% | 95.8% | 86.5% | 61.6% |
| Effective Sample Size | 308694 | 290819 | 273543 | 256306 | 236935 | 201097 | 129775 | 66515 | 17042 | 1608 |

## A3DR01 Advisa DR MRI

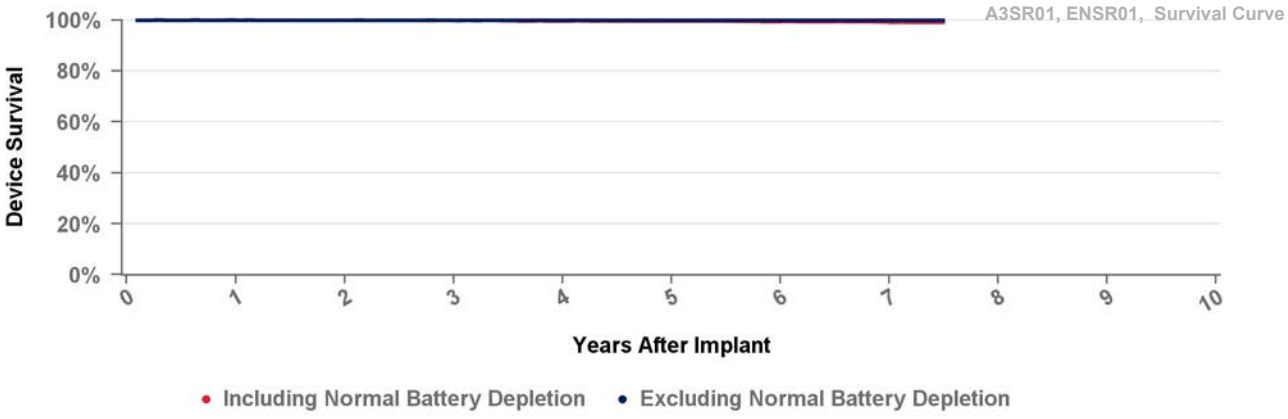
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Jun2009 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 19 | | |
| **Estimated Active USA Implants** | 3 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 3 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.9% | 95.8% | 86.5% | 61.6% |
| Effective Sample Size | 308694 | 290819 | 273543 | 256306 | 236935 | 201097 | 129775 | 66515 | 17042 | 1608 |

## A3SR01 Advisa SR MRI

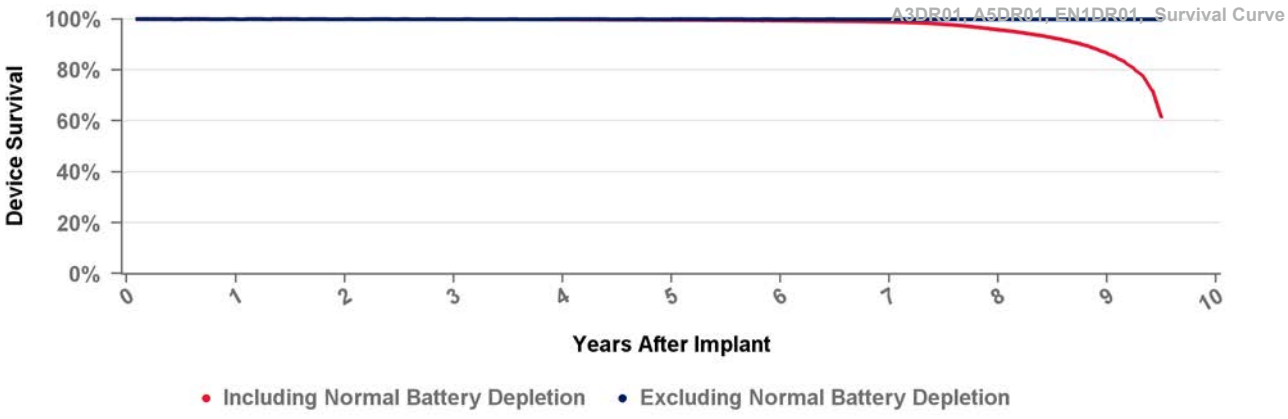
| | | | |
|---|---|---|---|
| **US Market Release** | 19Mar2015 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | 24Apr2014 | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 28,081 | Electrical Component | 3 |
| **Estimated Active USA Implants** | 16,033 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 45 | Possible Early Battery Depletion | 2 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.5% | 99.2% | 99.2% |
| Effective Sample Size | 22054 | 19406 | 17207 | 15022 | 12897 | 9606 | 3250 | 417 |

## A5DR01 Advisa DR

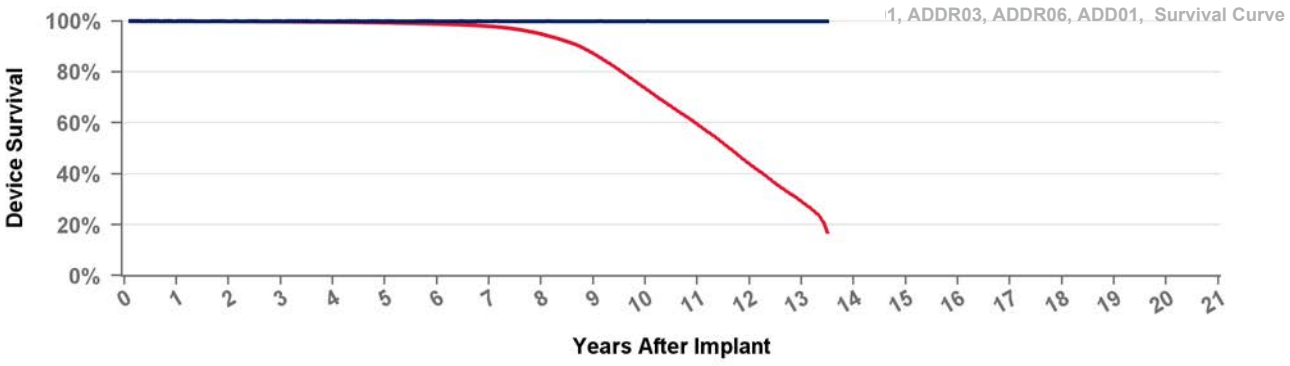
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Jun2009 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.9% | 95.8% | 86.5% | 61.6% |
| Effective Sample Size | 308694 | 290819 | 273543 | 256306 | 236935 | 201097 | 129775 | 66515 | 17042 | 1608 |

## ADD01 Adapta D

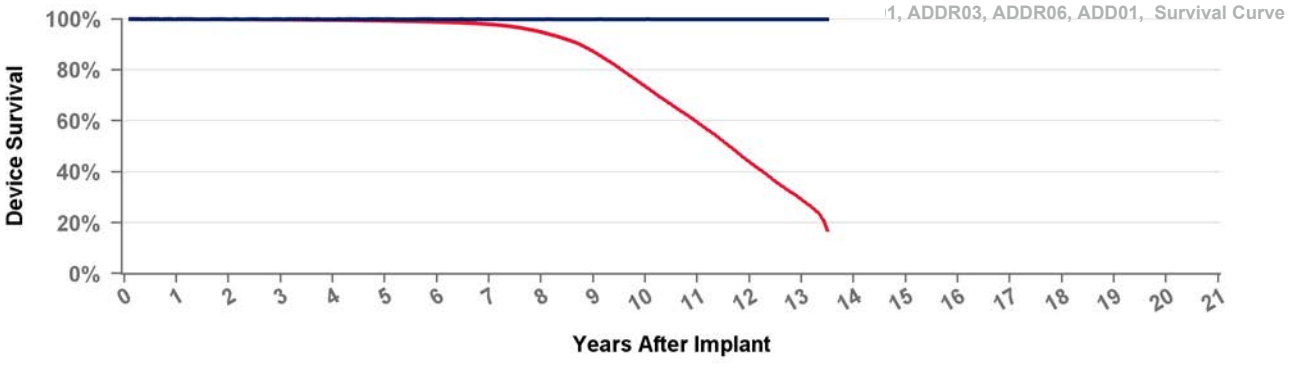
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## ADDR01 Adapta DR

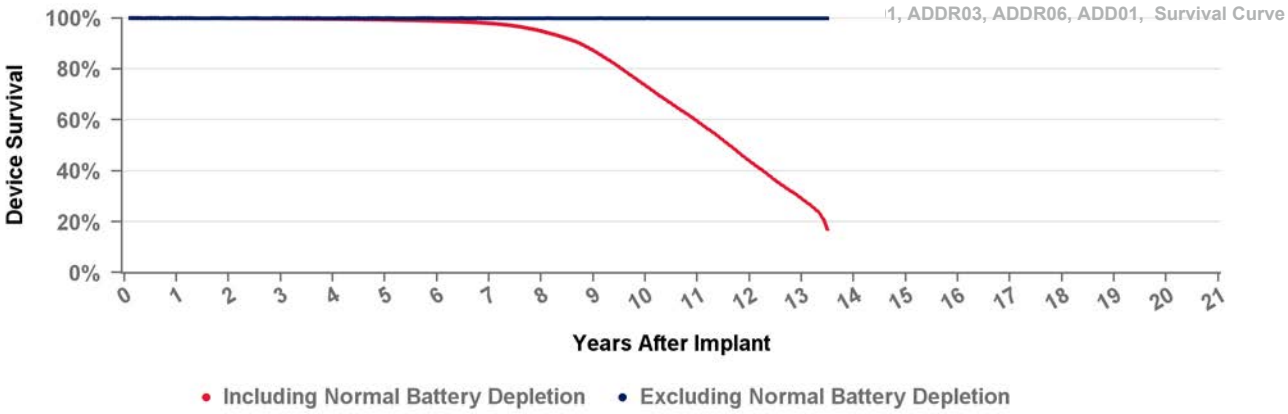
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **94** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **66** |
| **Registered USA Implants** | 454,869 | Electrical Component | 58 |
| **Estimated Active USA Implants** | 128,123 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 47,233 | Possible Early Battery Depletion | 6 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **28** |
| | | Electrical Component | 23 |
| | | Electrical Interconnect | 3 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## ADDR03 Adapta DR

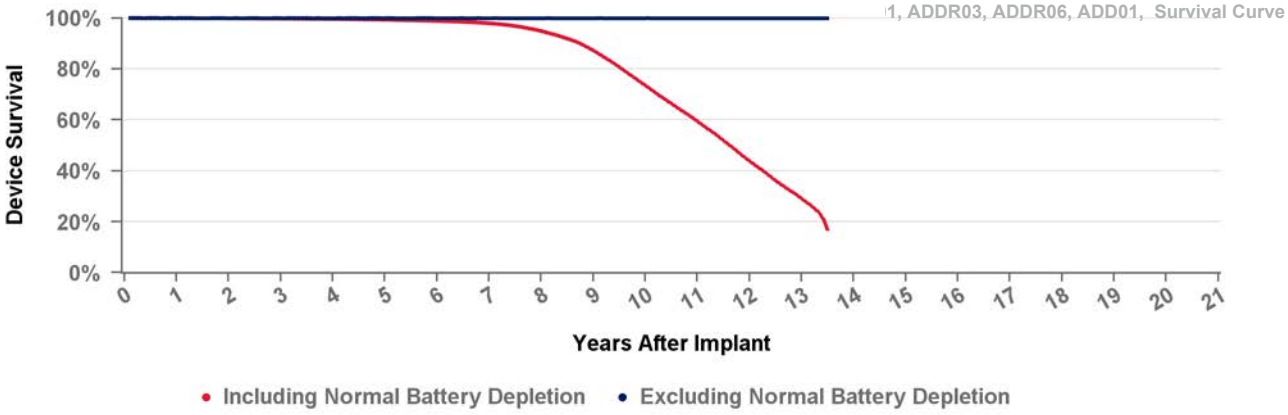
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 4,536 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 1,339 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 576 | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## ADDR06 Adapta DR

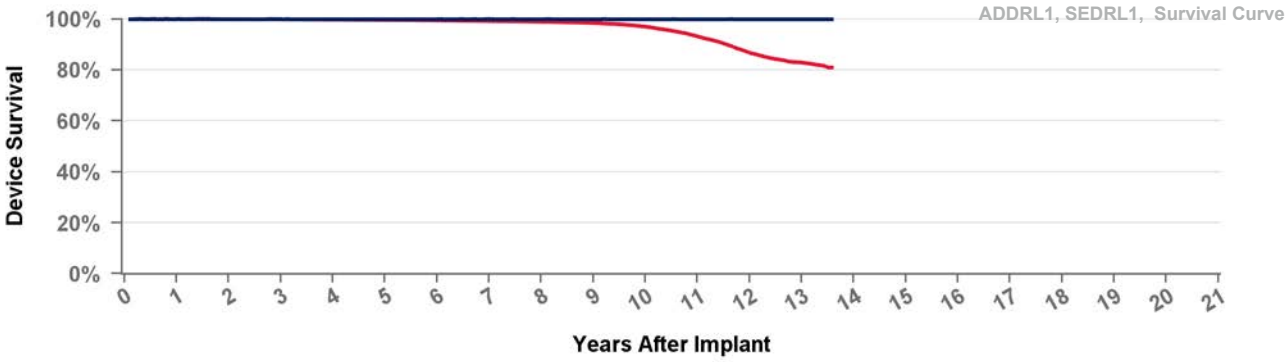
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 3,607 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 874 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 419 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## ADDRL1 Adapta L DR

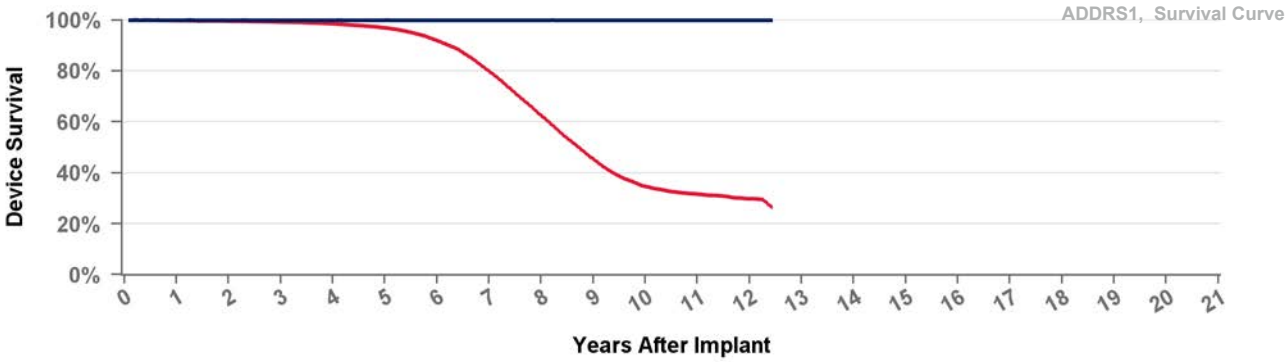
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **24** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 138,603 | Electrical Component | 13 |
| **Estimated Active USA Implants** | 68,781 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 2,862 | Possible Early Battery Depletion | 2 |
| | | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **7** |
| | | Electrical Component | 4 |
| | | Electrical Interconnect | 1 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 163 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 98.9% | 98.5% | 97.0% | 93.2% | 86.7% | 82.9% | 81.0% |
| Effective Sample Size | 119802 | 112808 | 106115 | 99459 | 92141 | 84246 | 74731 | 63708 | 52209 | 39095 | 25913 | 13841 | 4671 | 446 |

## ADDRS1 Adapta S DR

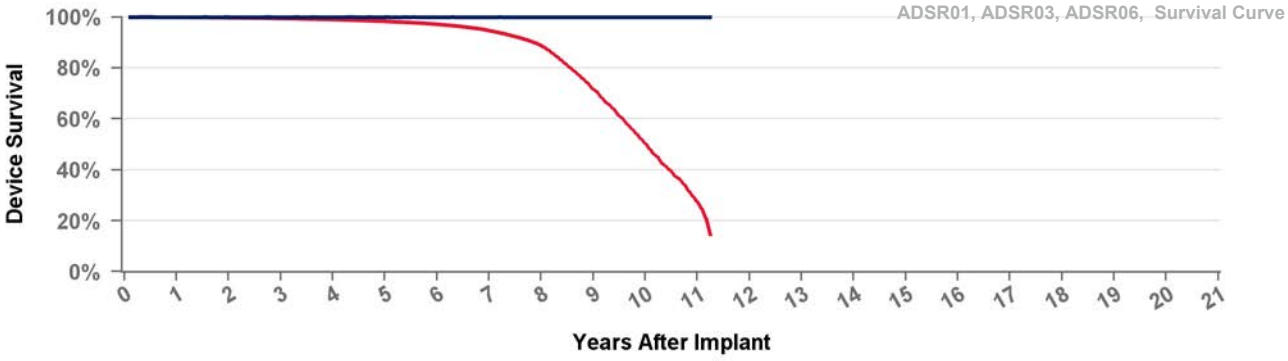
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **15** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 49,301 | Electrical Component | 5 |
| **Estimated Active USA Implants** | 10,261 | Possible Early Battery Depletion | 3 |
| **Normal Battery Depletions** | 6,411 | Other | 1 |
| | | **Therapy Function Compromised** | **6** |
| | | Electrical Component | 4 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 149 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.8% | 99.6% | 99.3% | 98.6% | 96.9% | 91.9% | 79.8% | 62.4% | 45.4% | 34.7% | 31.7% | 29.8% | 26.5% |
| Effective Sample Size | 40111 | 36089 | 32321 | 28769 | 25335 | 21093 | 15478 | 9837 | 5483 | 2752 | 1525 | 504 | 145 |

## ADSR01 Adapta SR

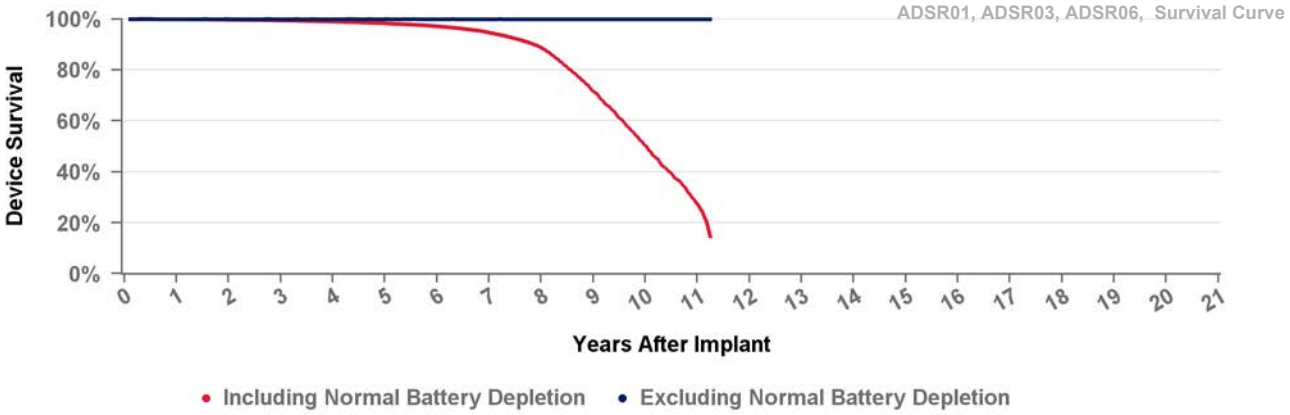
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **18** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **12** |
| **Registered USA Implants** | 91,659 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 20,032 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 6,021 | Possible Early Battery Depletion | 4 |
| | | **Therapy Function Compromised** | **6** |
| | | Electrical Component | 5 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 135 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.0% | 98.3% | 97.2% | 94.7% | 88.7% | 71.7% | 50.5% | 27.5% | 14.6% |
| Effective Sample Size | 72024 | 62938 | 55043 | 47920 | 41117 | 34801 | 28762 | 21871 | 12930 | 5487 | 876 | 116 |

## ADSR03 Adapta SR

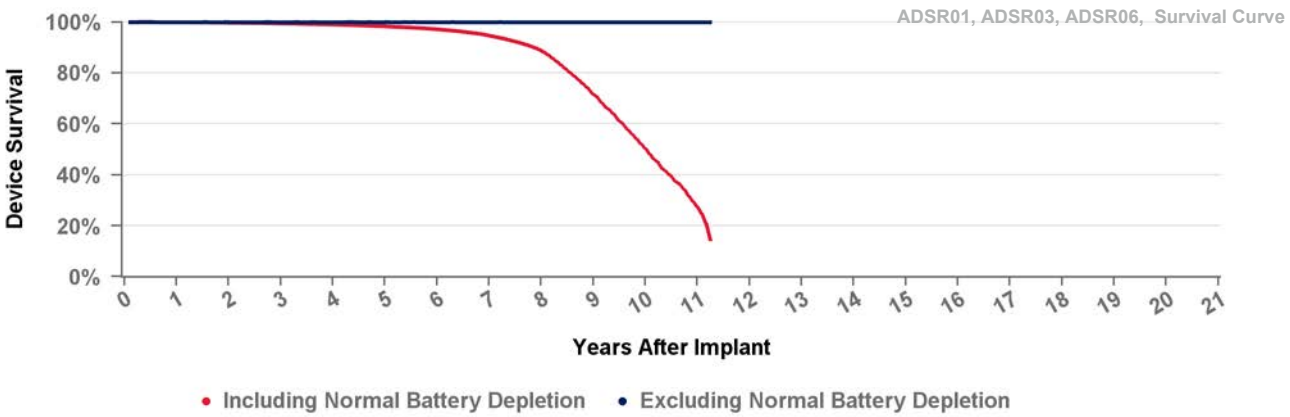
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,116 | | |
| **Estimated Active USA Implants** | 444 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 193 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 135 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.0% | 98.3% | 97.2% | 94.7% | 88.7% | 71.7% | 50.5% | 27.5% | 14.6% |
| Effective Sample Size | 72024 | 62938 | 55043 | 47920 | 41117 | 34801 | 28762 | 21871 | 12930 | 5487 | 876 | 116 |

## ADSR06 Adapta SR

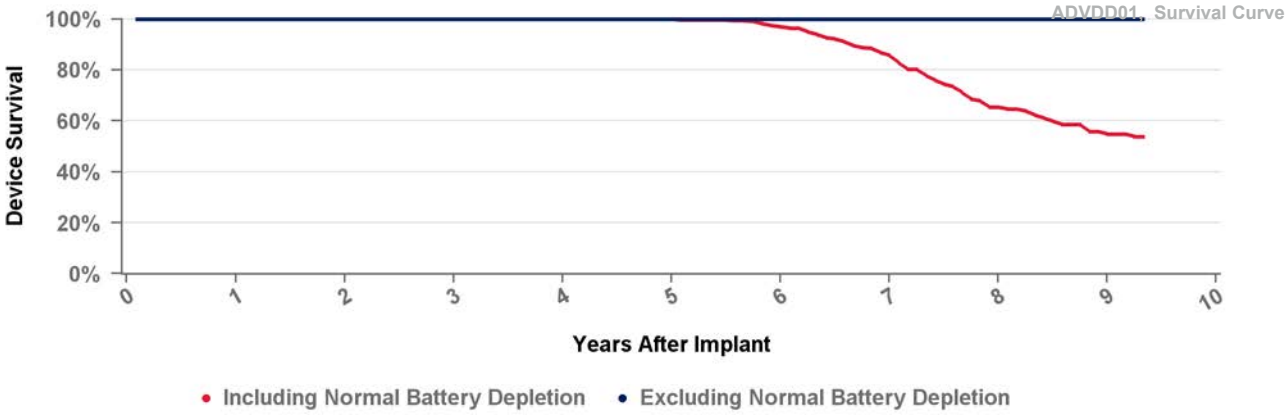
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 2,891 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 612 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 265 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 135 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.0% | 98.3% | 97.2% | 94.7% | 88.7% | 71.7% | 50.5% | 27.5% | 14.6% |
| Effective Sample Size | 72024 | 62938 | 55043 | 47920 | 41117 | 34801 | 28762 | 21871 | 12930 | 5487 | 876 | 116 |

## ADVDD01 Adapta VDD

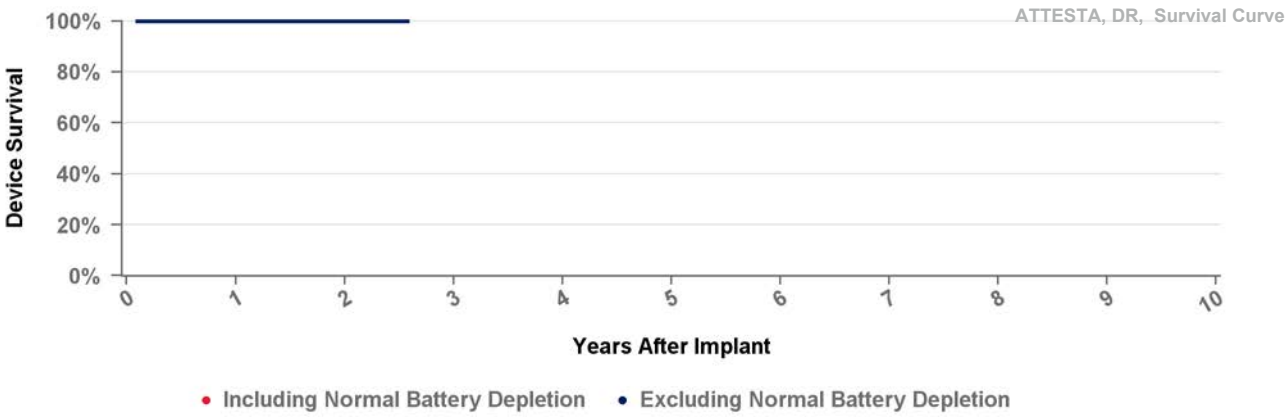
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 855 | | |
| **Estimated Active USA Implants** | 218 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 95 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 112 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 97.0% | 85.7% | 65.4% | 54.9% | 53.8% |
| Effective Sample Size | 703 | 643 | 579 | 522 | 466 | 404 | 311 | 182 | 115 | 101 |

## ATDR01 Attesta DR MRI

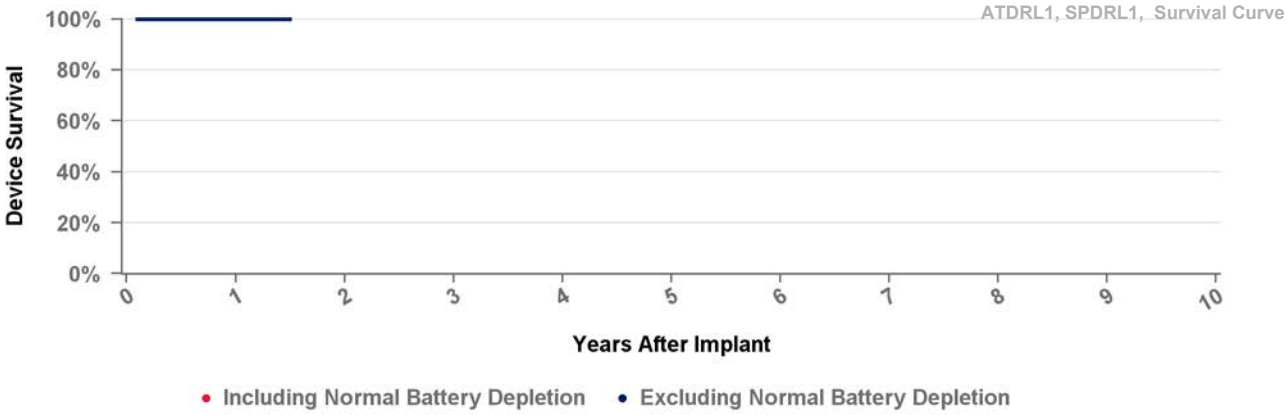
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,687 | | |
| **Estimated Active USA Implants** | 1,644 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | at 31 mo |
|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 1058 | 414 | 104 |

## ATDRL1 Attesta L DR MRI

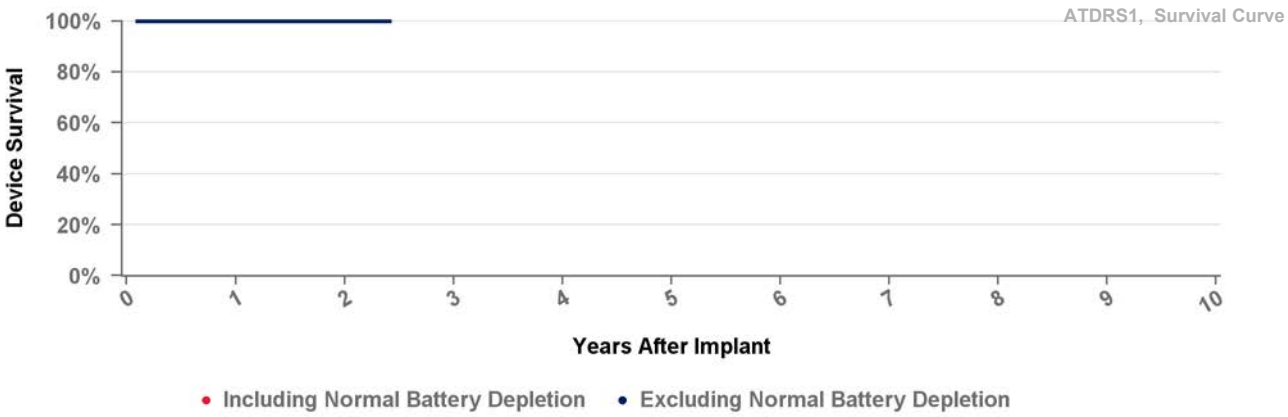
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 238 | | |
| **Estimated Active USA Implants** | 231 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | at 18 mo |
|---|---|---|
| Excluding NBD | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% |
| Effective Sample Size | 159 | 106 |

## ATDRS1 Attesta S DR MRI

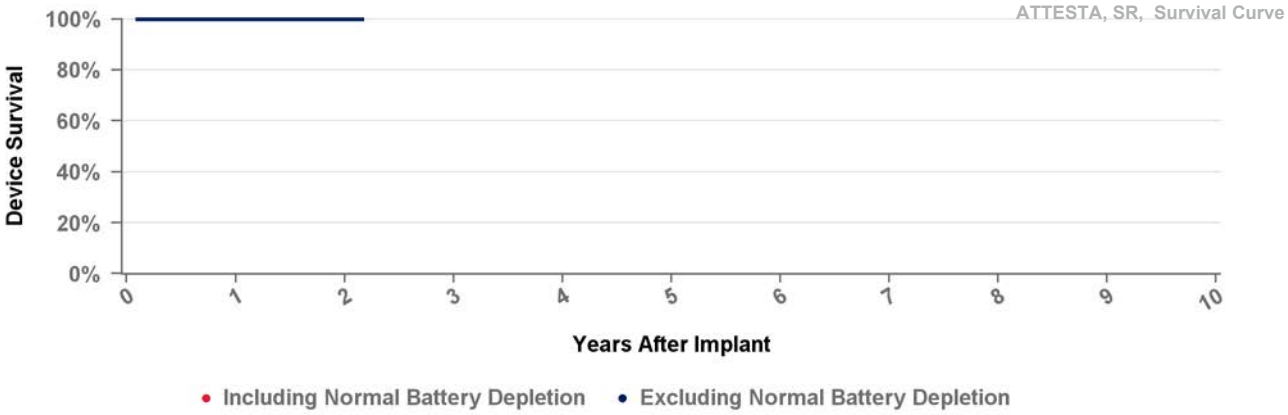
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,028 | | |
| **Estimated Active USA Implants** | 958 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | at 29 mo |
|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 652 | 242 | 105 |

## ATSR01 Attesta SR MRI

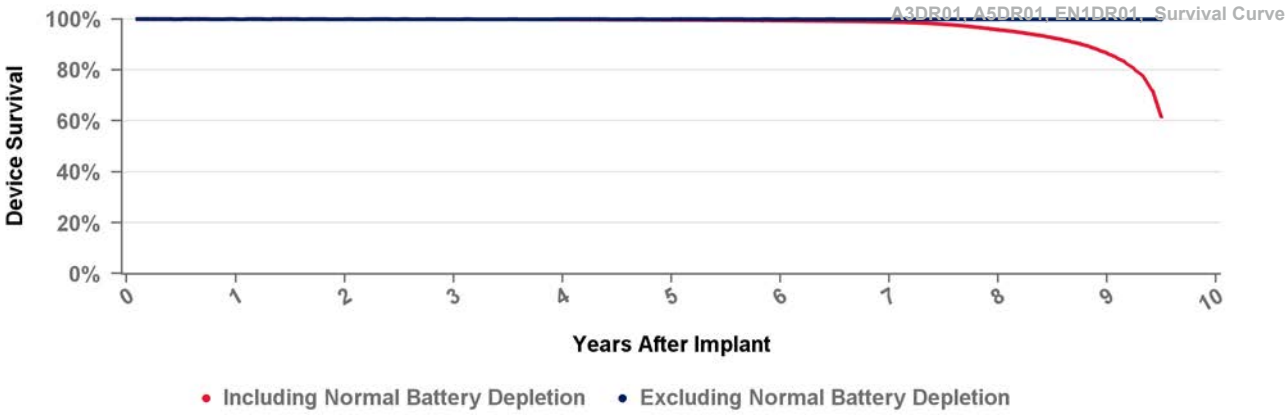
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 866 | | |
| **Estimated Active USA Implants** | 674 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | at 26 mo |
|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 408 | 158 | 110 |

## EN1DR01 Ensura MRI

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.9% | 95.8% | 86.5% | 61.6% |
| Effective Sample Size | 308694 | 290819 | 273543 | 256306 | 236935 | 201097 | 129775 | 66515 | 17042 | 1608 |

## EN1SR01 Ensura SR MRI

**US Market Release**

**CE Approval Date** 24Apr2014

**Registered USA Implants**

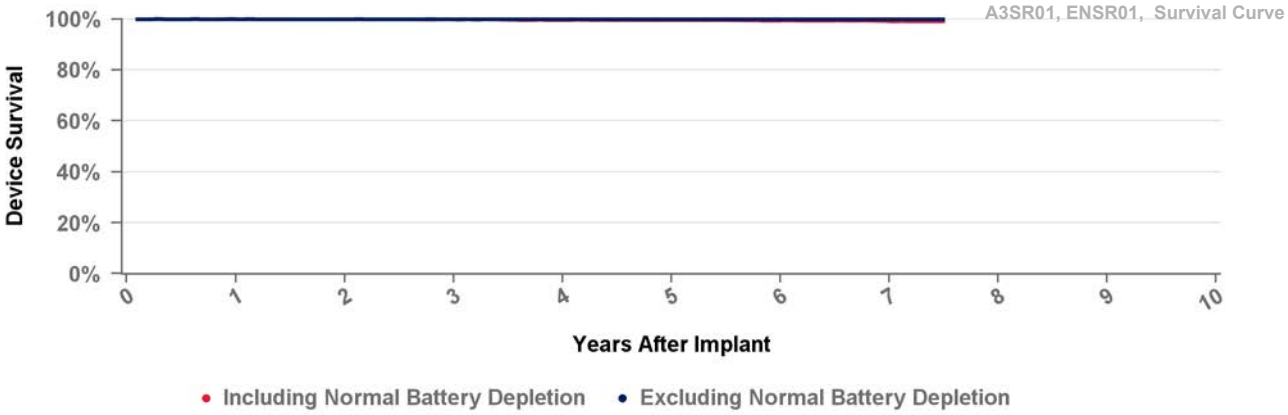
**Estimated Active USA Implants**

**Normal Battery Depletions**

**Total Malfunctions (USA)**

**Therapy Function Not Compromised**

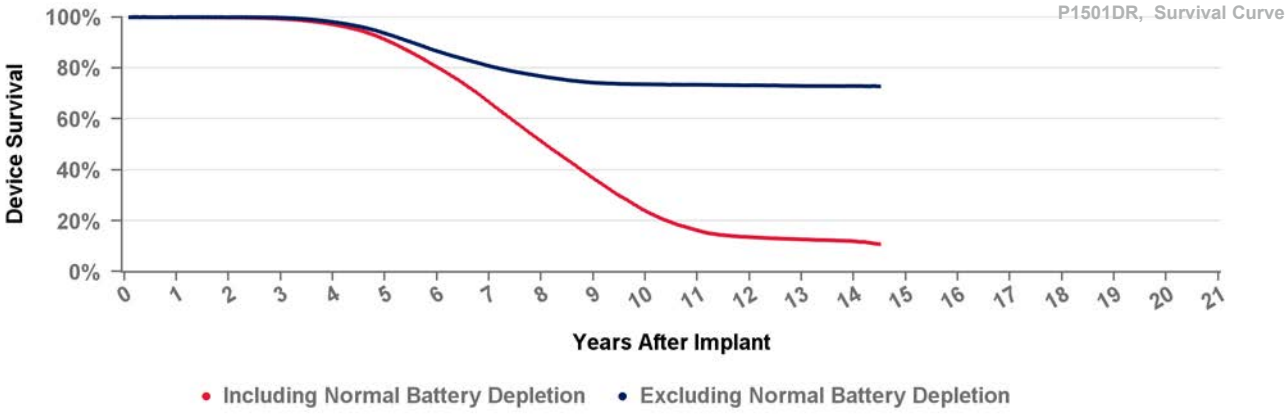
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.5% | 99.2% | 99.2% |
| Effective Sample Size | 22054 | 19406 | 17207 | 15022 | 12897 | 9606 | 3250 | 417 |

## P1501DR EnRhythm DR

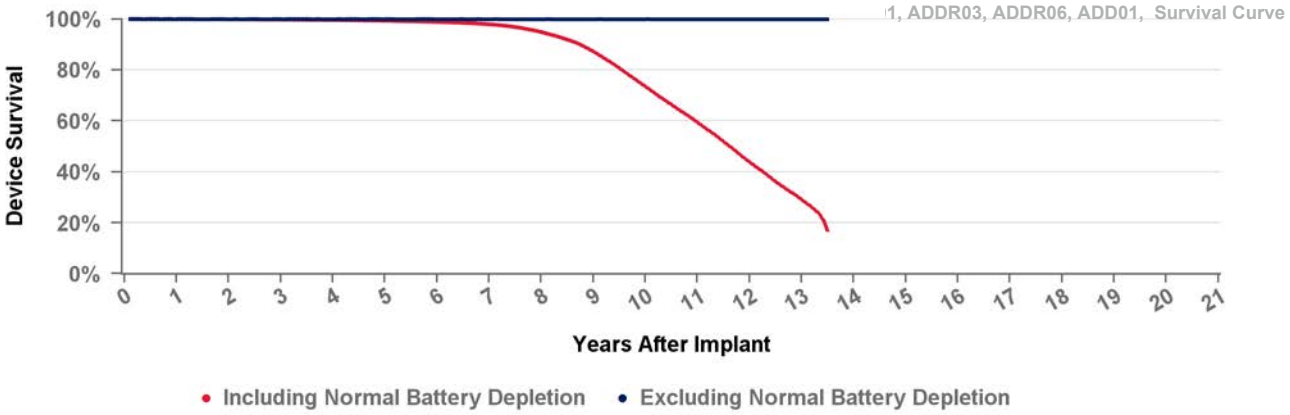
| | | | |
|---|---|---|---|
| **US Market Release** | 05May2005 | **Total Malfunctions (USA)** | **15,168** |
| **CE Approval Date** | 13Aug2004 | **Therapy Function Not Compromised** | **15,113** |
| **Registered USA Implants** | 109,982 | Battery | 14,982 |
| **Estimated Active USA Implants** | 7,702 | Electrical Component | 59 |
| **Normal Battery Depletions** | 17,538 | Electrical Interconnect | 2 |
| | | Possible Early Battery Depletion | 69 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **55** |
| | | Battery | 6 |
| | | Electrical Component | 38 |
| | | Electrical Interconnect | 4 |
| | | Possible Early Battery Depletion | 2 |
| | | Other | 5 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.7% | 98.1% | 93.6% | 86.6% | 80.8% | 76.7% | 74.2% | 73.6% | 73.4% | 73.3% | 73.0% | 72.9% | 72.8% |
| Including NBD | 99.9% | 99.8% | 99.3% | 97.1% | 91.1% | 80.3% | 66.5% | 51.2% | 36.6% | 23.8% | 16.2% | 13.6% | 12.7% | 12.0% | 10.8% |
| Effective Sample Size | 94969 | 88744 | 82391 | 74749 | 64545 | 51290 | 37804 | 25073 | 15196 | 8340 | 4733 | 3146 | 2037 | 796 | 155 |

## RED01 Relia D

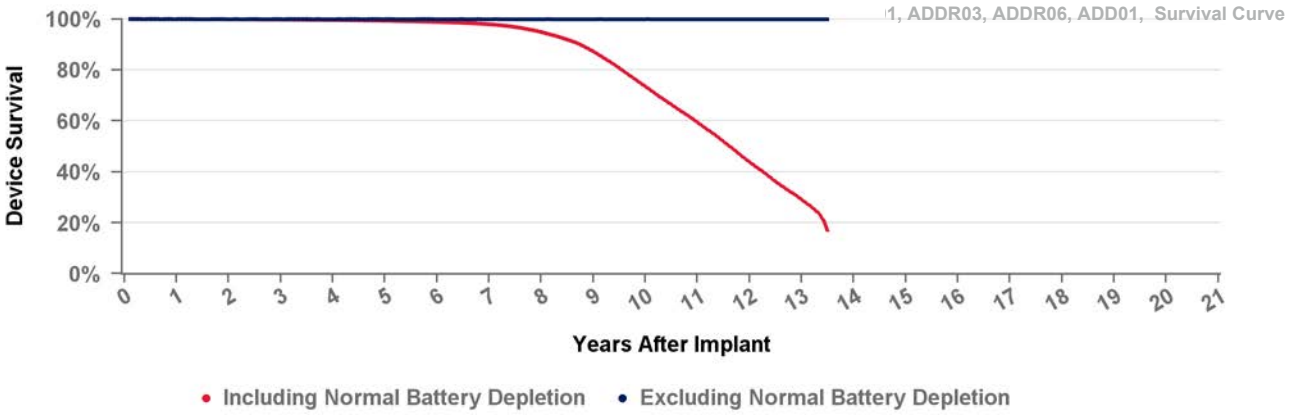
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## REDR01 Relia DR

| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 6 | | |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 1 | | |

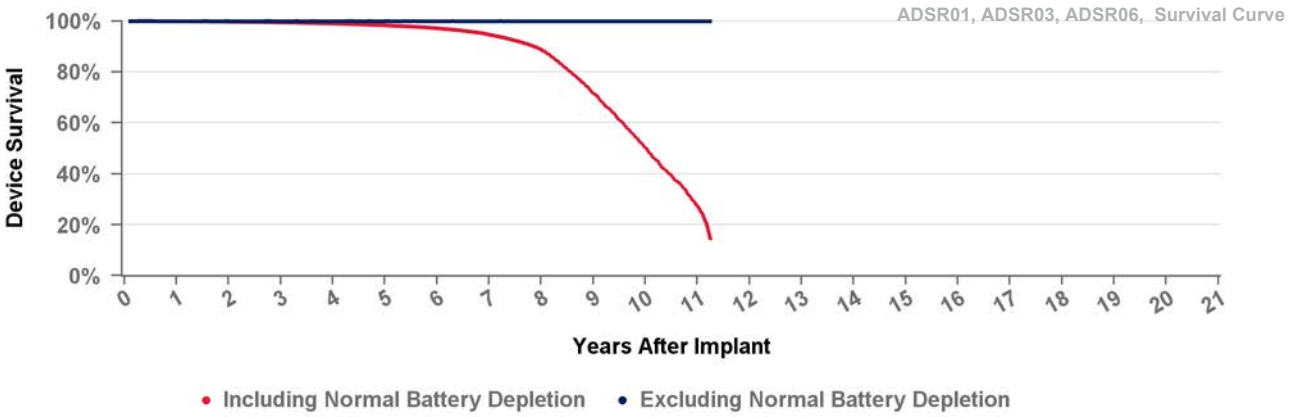



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.4% | 98.9% | 97.9% | 94.9% | 87.2% | 73.5% | 59.4% | 43.8% | 29.0% | 17.1% |
| Effective Sample Size | 393196 | 365311 | 338692 | 312687 | 288595 | 263716 | 235296 | 200861 | 157429 | 106364 | 63561 | 29901 | 8351 | 732 |

## RES01 Relia S

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

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

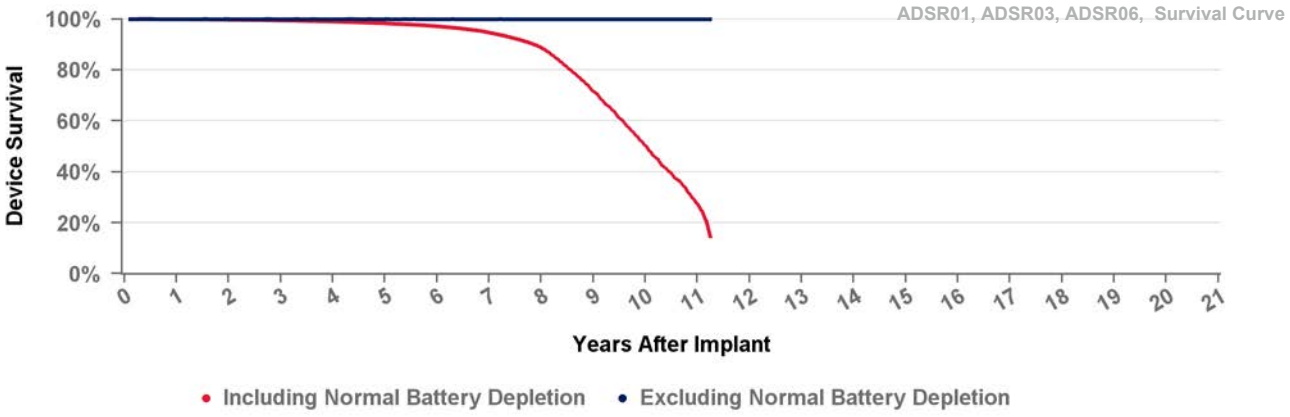



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 135 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.0% | 98.3% | 97.2% | 94.7% | 88.7% | 71.7% | 50.5% | 27.5% | 14.6% |
| Effective Sample Size | 72024 | 62938 | 55043 | 47920 | 41117 | 34801 | 28762 | 21871 | 12930 | 5487 | 876 | 116 |

## RESR01 Relia SR

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

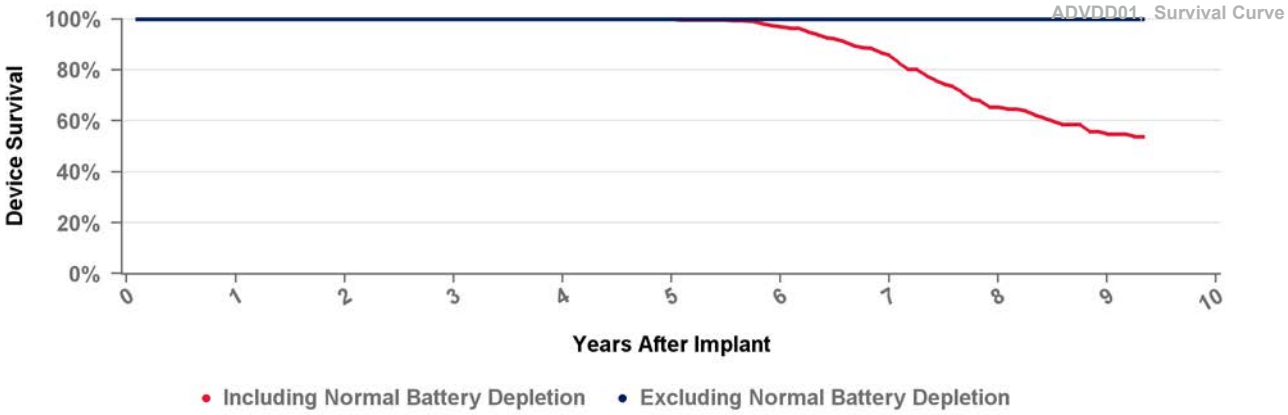
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 135 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.0% | 98.3% | 97.2% | 94.7% | 88.7% | 71.7% | 50.5% | 27.5% | 14.6% |
| Effective Sample Size | 72024 | 62938 | 55043 | 47920 | 41117 | 34801 | 28762 | 21871 | 12930 | 5487 | 876 | 116 |

## REVDD01 Relia VDD

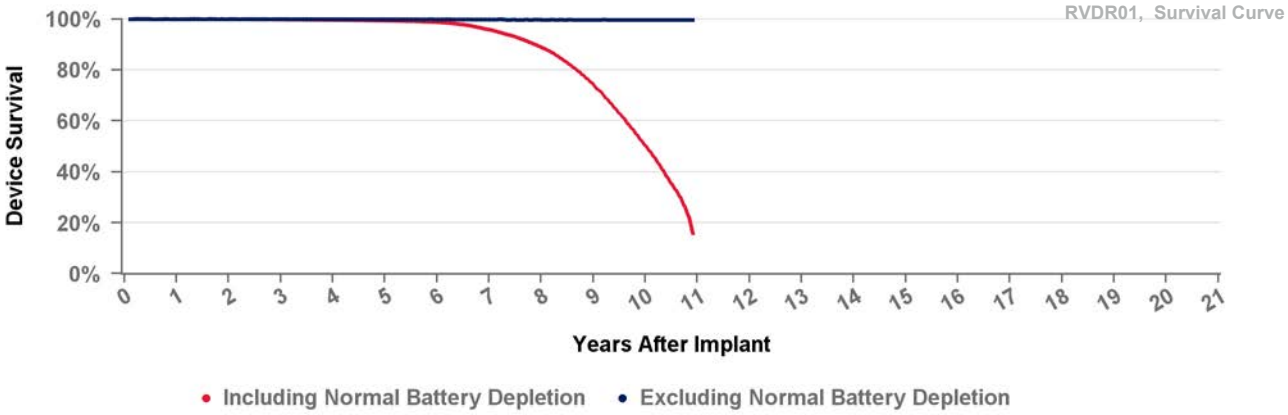
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 112 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 97.0% | 85.7% | 65.4% | 54.9% | 53.8% |
| Effective Sample Size | 703 | 643 | 579 | 522 | 466 | 404 | 311 | 182 | 115 | 101 |

## RVDR01 Revo MRI SureScan

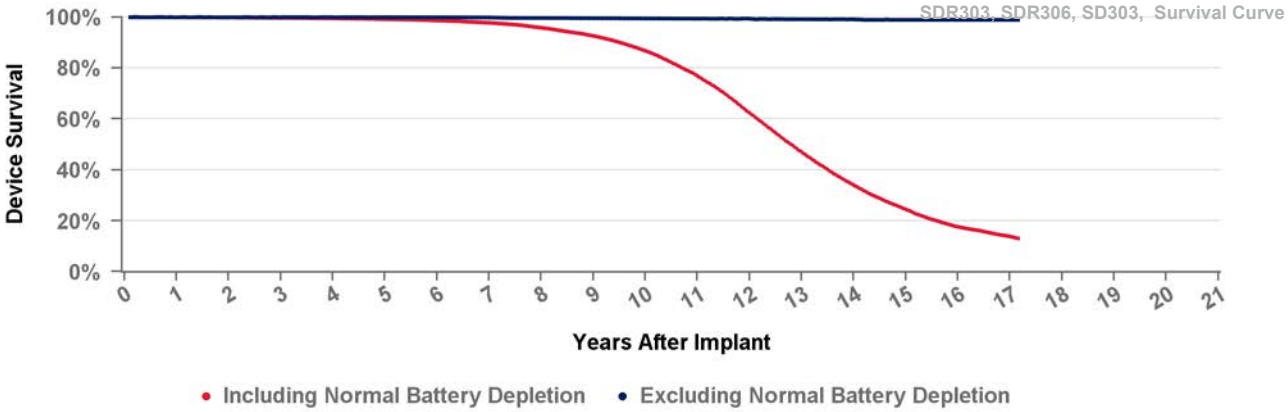
| | | | |
|---|---|---|---|
| **US Market Release** | 08Feb2011 | **Total Malfunctions (USA)** | **111** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **108** |
| **Registered USA Implants** | 69,111 | Battery | 1 |
| **Estimated Active USA Implants** | 16,421 | Electrical Component | 40 |
| **Normal Battery Depletions** | 10,830 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 61 |
| | | Software/Firmware | 4 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **3** |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 131 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.8% | 99.7% | 99.4% | 98.8% | 95.9% | 88.9% | 74.3% | 50.4% | 15.7% |
| Effective Sample Size | 59304 | 56143 | 53128 | 49961 | 46262 | 42242 | 37409 | 30948 | 22048 | 11388 | 934 |

## SD303 Sigma 300 D

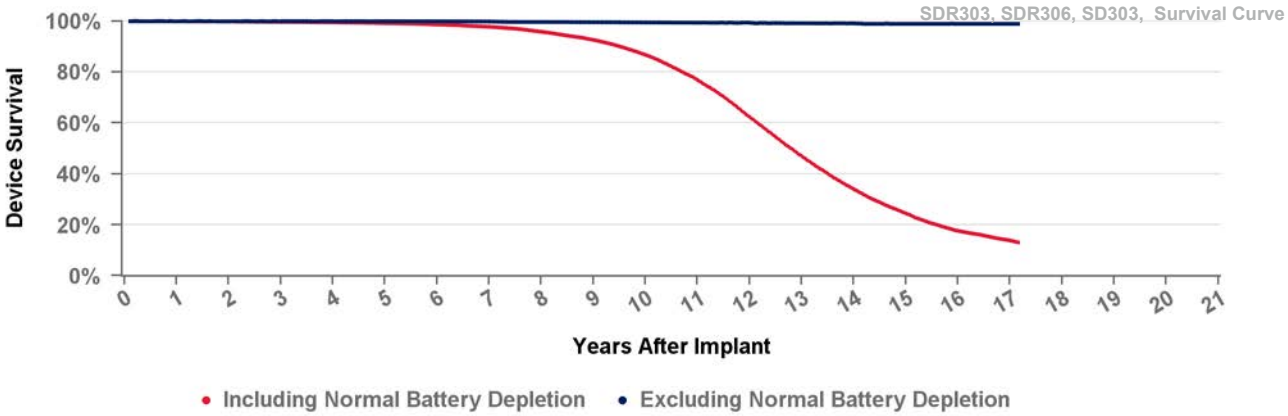
| | | | |
|---|---|---|---|
| **US Market Release** | 26Aug1999 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 17Dec1998 | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 124 | | |
| **Estimated Active USA Implants** | 18 | **Therapy Function Compromised**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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 206 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.6% | 99.5% | 99.5% | 99.3% | 99.3% | 99.2% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% |
| Including NBD | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 98.6% | 97.7% | 95.8% | 92.6% | 86.7% | 76.8% | 62.2% | 47.0% | 34.0% | 24.5% | 17.6% | 13.8% | 13.0% |
| Effective Sample Size | 86426 | 77419 | 69083 | 61255 | 53949 | 47362 | 41019 | 35253 | 29923 | 24493 | 18934 | 12556 | 7115 | 3701 | 1886 | 951 | 232 | 125 |

## SDR303 Sigma 300 DR

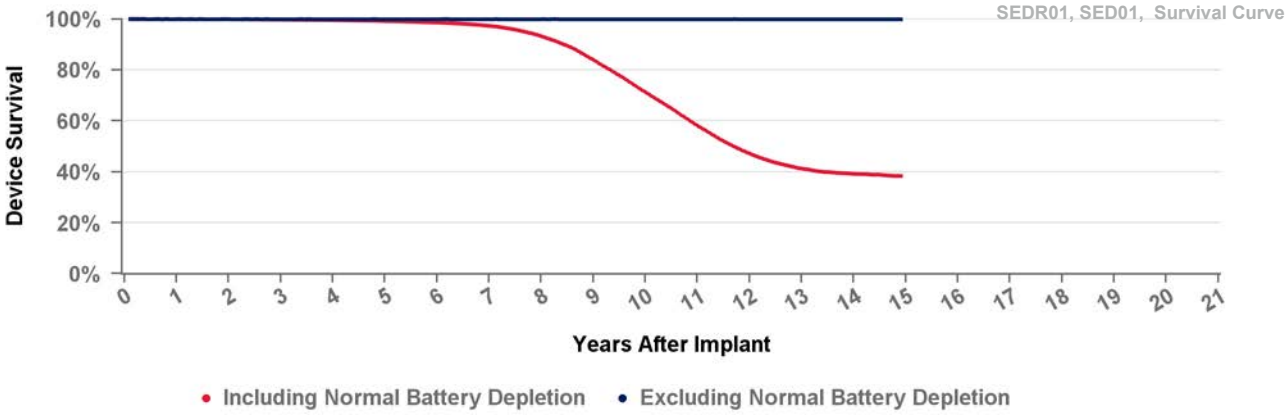
| | | | |
|---|---|---|---|
| **US Market Release** | 26Aug1999 | **Total Malfunctions (USA)** | **288** |
| **CE Approval Date** | 17Dec1998 | **Therapy Function Not Compromised** | **62** |
| **Registered USA Implants** | 105,692 | Electrical Component | 9 |
| **Estimated Active USA Implants** | 4,822 | Electrical Interconnect | 51 |
| **Normal Battery Depletions** | 11,378 | Possible Early Battery Depletion | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **226** |
| | | Electrical Component | 7 |
| | | Electrical Interconnect | 218 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 206 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.6% | 99.5% | 99.5% | 99.3% | 99.3% | 99.2% | 99.0% | 99.0% | 99.0% | 99.0% | 99.0% |
| Including NBD | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 98.6% | 97.7% | 95.8% | 92.6% | 86.7% | 76.8% | 62.2% | 47.0% | 34.0% | 24.5% | 17.6% | 13.8% | 13.0% |
| Effective Sample Size | 86426 | 77419 | 69083 | 61255 | 53949 | 47362 | 41019 | 35253 | 29923 | 24493 | 18934 | 12556 | 7115 | 3701 | 1886 | 951 | 232 | 125 |

## SED01 Sensia D

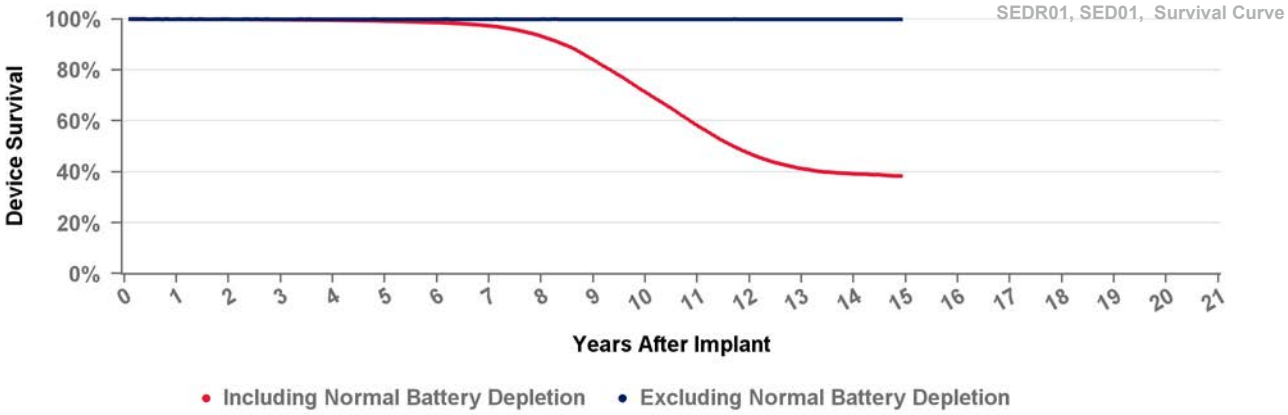
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 5 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 179 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.3% | 93.2% | 84.0% | 71.3% | 58.1% | 47.2% | 41.3% | 39.2% | 38.5% |
| Effective Sample Size | 120560 | 109033 | 98382 | 88748 | 80022 | 72221 | 64926 | 54917 | 41774 | 28948 | 18360 | 10649 | 5778 | 2580 | 168 |

## SEDR01 Sensia DR

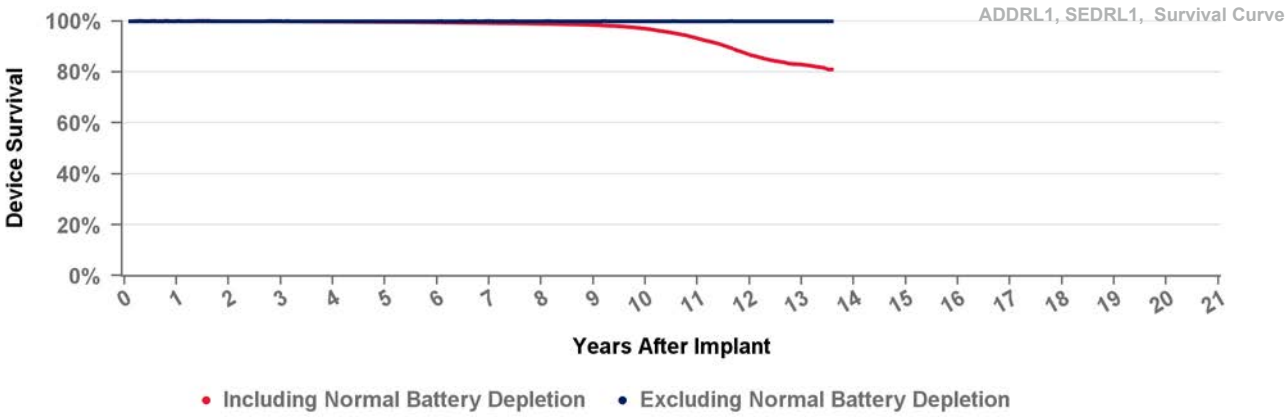
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **33** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 149,401 | Electrical Component | 15 |
| **Estimated Active USA Implants** | 31,023 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 15,622 | Other | 1 |
| | | **Therapy Function Compromised** | **16** |
| | | Electrical Component | 6 |
| | | Electrical Interconnect | 3 |
| | | Possible Early Battery Depletion | 1 |
| | | Other | 6 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 179 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.3% | 93.2% | 84.0% | 71.3% | 58.1% | 47.2% | 41.3% | 39.2% | 38.5% |
| Effective Sample Size | 120560 | 109033 | 98382 | 88748 | 80022 | 72221 | 64926 | 54917 | 41774 | 28948 | 18360 | 10649 | 5778 | 2580 | 168 |

## SEDRL1 Sensia L DR

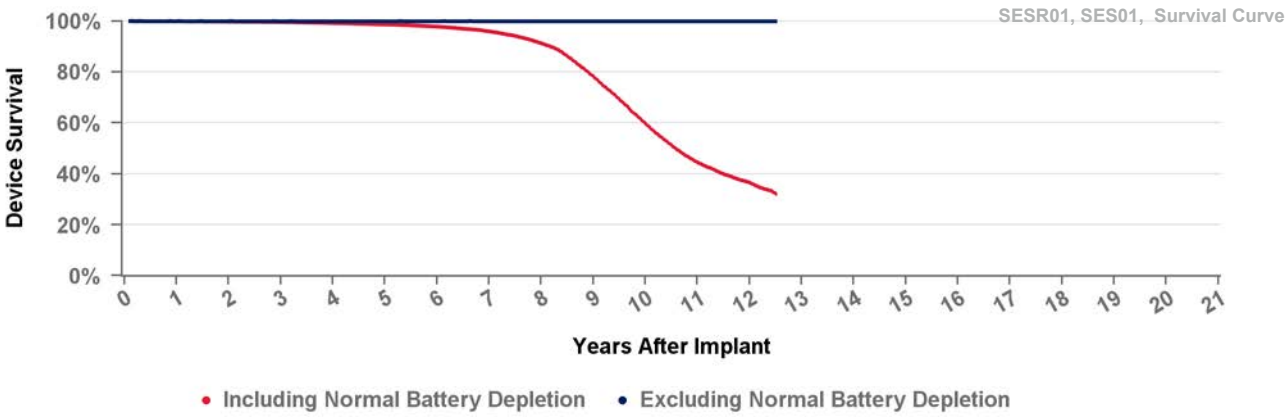
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 163 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 98.9% | 98.5% | 97.0% | 93.2% | 86.7% | 82.9% | 81.0% |
| Effective Sample Size | 119802 | 112808 | 106115 | 99459 | 92141 | 84246 | 74731 | 63708 | 52209 | 39095 | 25913 | 13841 | 4671 | 446 |

## SES01 Sensia S

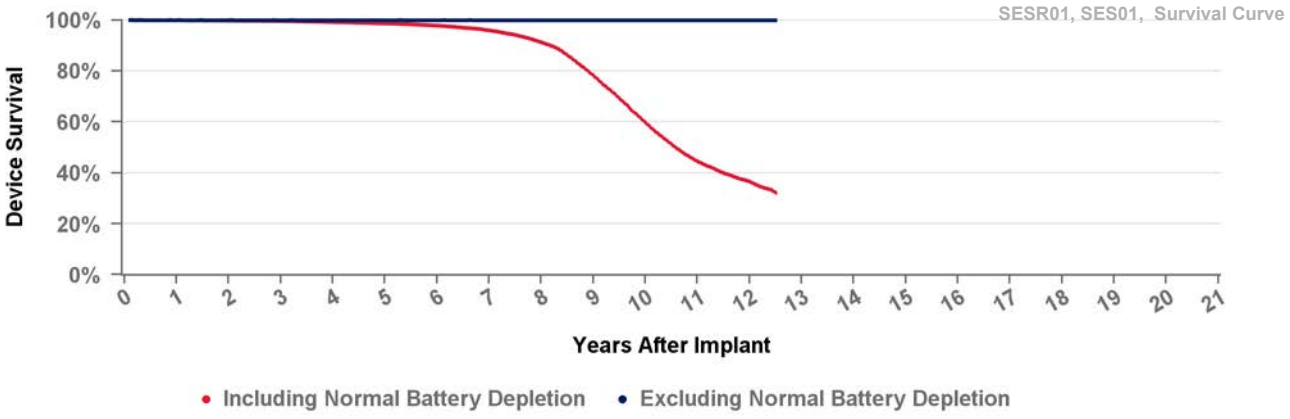
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.8% | 99.6% | 99.2% | 98.7% | 97.8% | 95.9% | 91.2% | 78.2% | 59.7% | 44.5% | 36.6% | 32.1% |
| Effective Sample Size | 85835 | 74463 | 64559 | 56014 | 48248 | 41086 | 34591 | 27300 | 18152 | 9821 | 4351 | 1307 | 139 |

## SESR01 Sensia SR

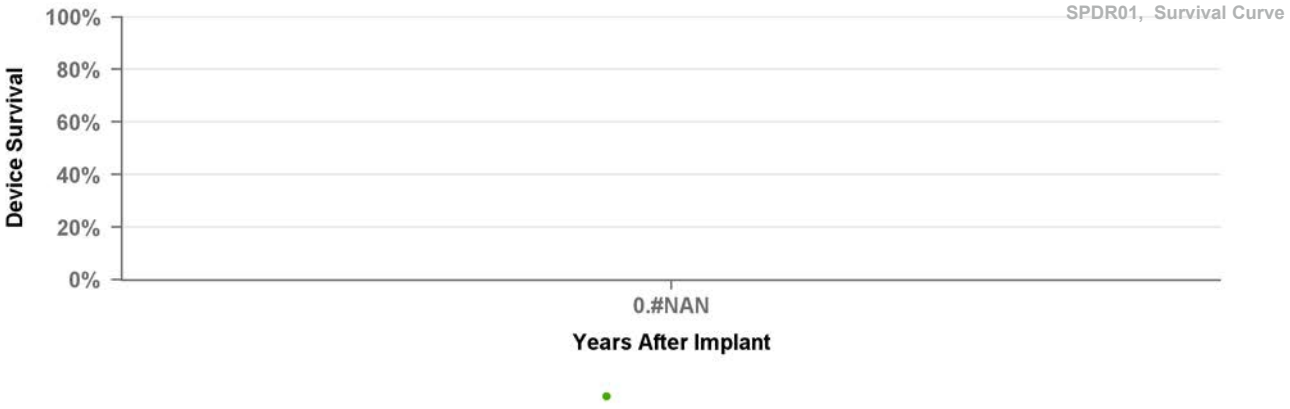
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **17** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **13** |
| **Registered USA Implants** | 117,369 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 22,566 | Possible Early Battery Depletion | 4 |
| **Normal Battery Depletions** | 8,294 | Other | 2 |
| | | **Therapy Function Compromised** | **4** |
| | | Electrical Component | 3 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.8% | 99.6% | 99.2% | 98.7% | 97.8% | 95.9% | 91.2% | 78.2% | 59.7% | 44.5% | 36.6% | 32.1% |
| Effective Sample Size | 85835 | 74463 | 64559 | 56014 | 48248 | 41086 | 34591 | 27300 | 18152 | 9821 | 4351 | 1307 | 139 |

## SPDR01 Sphera DR MRI

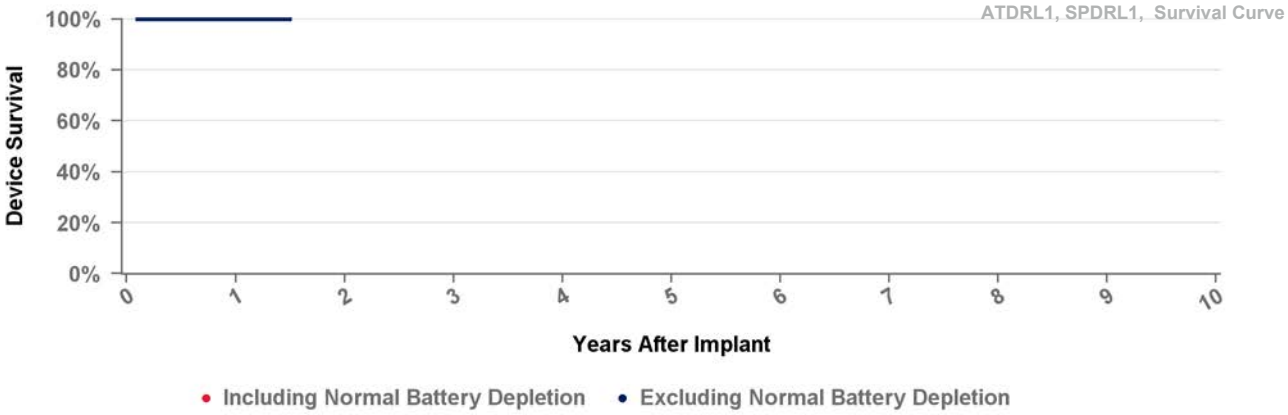
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | |
|---|---|
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

## SPDRL1 Sphera L DR MRI

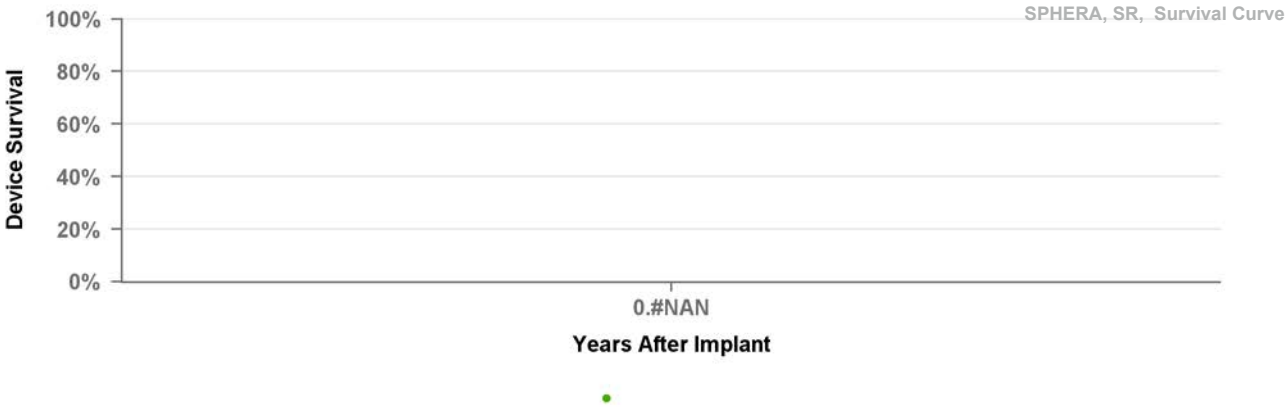
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | at 18 mo |
|---|---|---|
| Excluding NBD | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% |
| Effective Sample Size | 159 | 106 |

## SPSR01 Sphera SR MRI

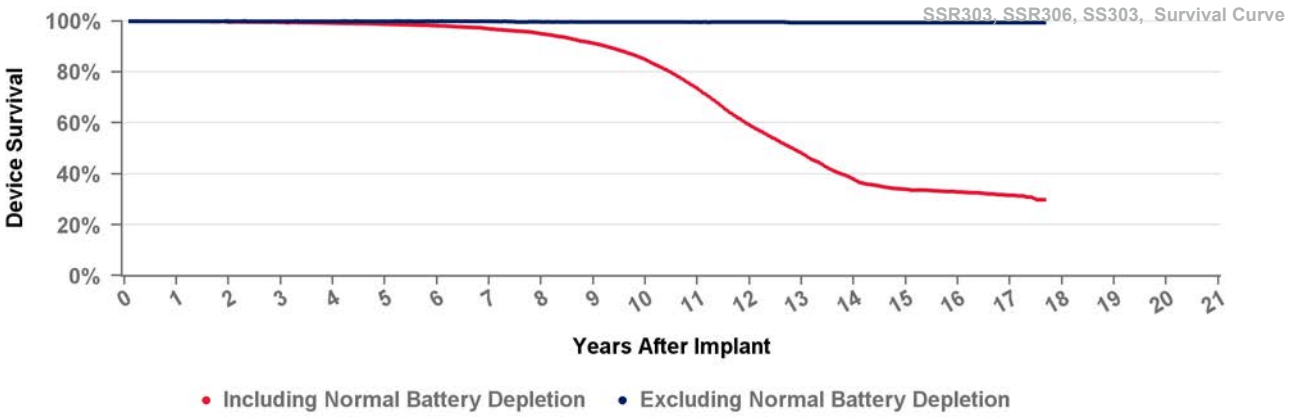
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | |
|---|---|
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

## SS303 Sigma 300 S

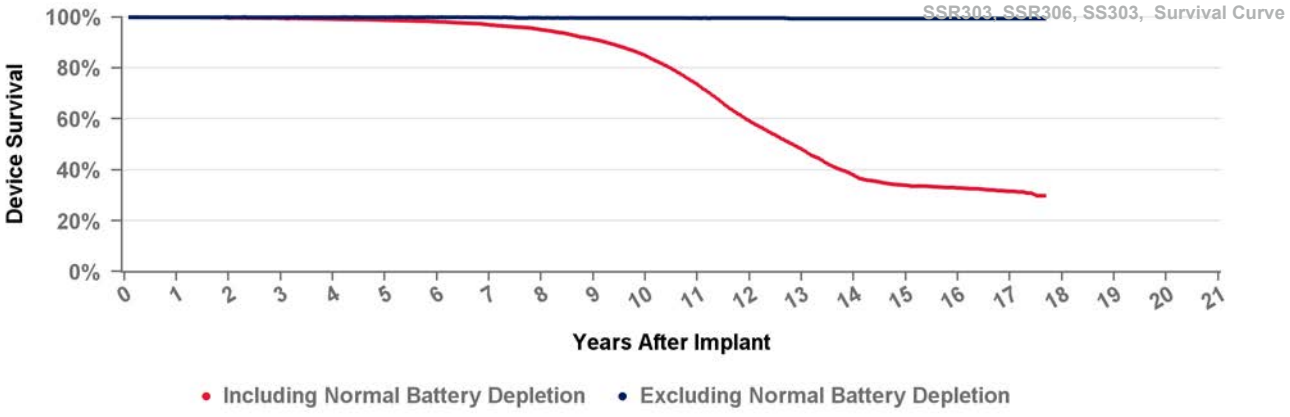
| | | | |
|---|---|---|---|
| **US Market Release** | 15Sep1999 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec1998 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 165 | | |
| **Estimated Active USA Implants** | 12 | **Therapy Function Compromised** | |
|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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 212 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.7% | 99.7% | 99.6% | 99.6% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.4% | 99.4% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 98.2% | 97.0% | 95.0% | 91.2% | 84.8% | 73.4% | 59.1% | 48.1% | 37.9% | 34.0% | 32.9% | 31.6% | 29.9% |
| Effective Sample Size | 39857 | 33377 | 27863 | 23281 | 19397 | 16067 | 13264 | 10926 | 8873 | 7005 | 5091 | 3263 | 2032 | 1190 | 788 | 575 | 340 | 110 |

## SSR303 Sigma 300 SR

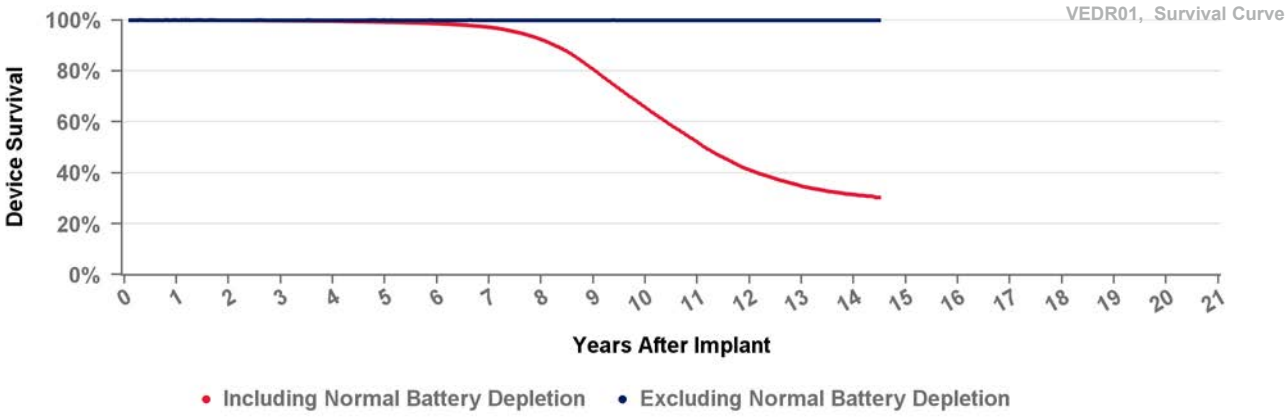
| | | | |
|---|---|---|---|
| **US Market Release** | 30Aug1999 | **Total Malfunctions (USA)** | **58** |
| **CE Approval Date** | 17Dec1998 | **Therapy Function Not Compromised** | **12** |
| **Registered USA Implants** | 51,767 | Electrical Interconnect | 10 |
| **Estimated Active USA Implants** | 1,807 | Software/Firmware | 1 |
| **Normal Battery Depletions** | 3,121 | Other | 1 |
| | | **Therapy Function Compromised** | **46** |
| | | Electrical Component | 3 |
| | | Electrical Interconnect | 43 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 212 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.7% | 99.7% | 99.6% | 99.6% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.4% | 99.4% |
| Including NBD | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 98.2% | 97.0% | 95.0% | 91.2% | 84.8% | 73.4% | 59.1% | 48.1% | 37.9% | 34.0% | 32.9% | 31.6% | 29.9% |
| Effective Sample Size | 39857 | 33377 | 27863 | 23281 | 19397 | 16067 | 13264 | 10926 | 8873 | 7005 | 5091 | 3263 | 2032 | 1190 | 788 | 575 | 340 | 110 |

## VEDR01 Versa DR

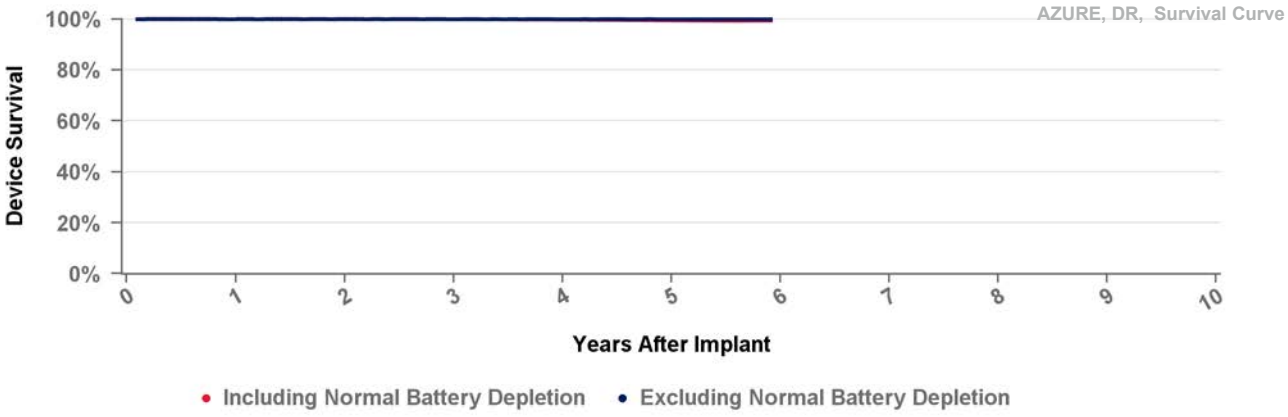
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **25** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **11** |
| **Registered USA Implants** | 118,952 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 25,736 | Electrical Interconnect | 2 |
| **Normal Battery Depletions** | 13,789 | Possible Early Battery Depletion | 2 |
| | | **Therapy Function Compromised** | **14** |
| | | Electrical Component | 10 |
| | | Other | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.2% | 92.3% | 80.6% | 65.6% | 52.0% | 41.1% | 34.7% | 31.5% | 30.5% |
| Effective Sample Size | 98680 | 90185 | 82094 | 74713 | 67947 | 61263 | 53347 | 44159 | 32486 | 21650 | 13238 | 7273 | 3678 | 1228 | 248 |

## W1DR01 Azure XT DR

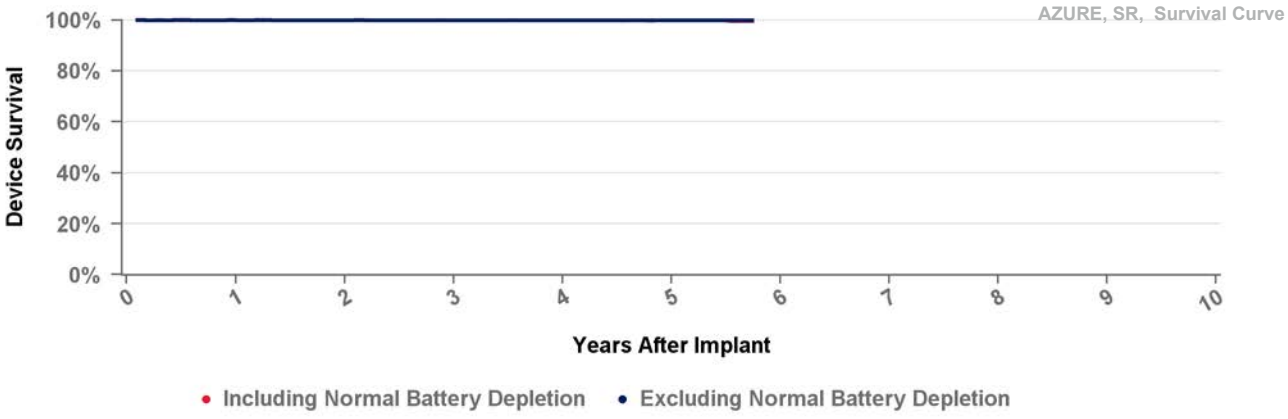
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **112** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **99** |
| **Registered USA Implants** | 623,926 | Battery | 3 |
| **Estimated Active USA Implants** | 562,890 | Electrical Component | 54 |
| **Normal Battery Depletions** | 339 | Possible Early Battery Depletion | 2 |
| | | Software/Firmware | 20 |
| | | Other | 20 |
| | | **Therapy Function Compromised** | **13** |
| | | Battery | 2 |
| | | Electrical Component | 11 |




| 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 | 100.0% | 100.0% | 99.9% | 99.8% | 99.5% | 99.3% |
| Effective Sample Size | 491226 | 352544 | 232747 | 136943 | 49863 | 112 |

## W1SR01 Azure XT SR

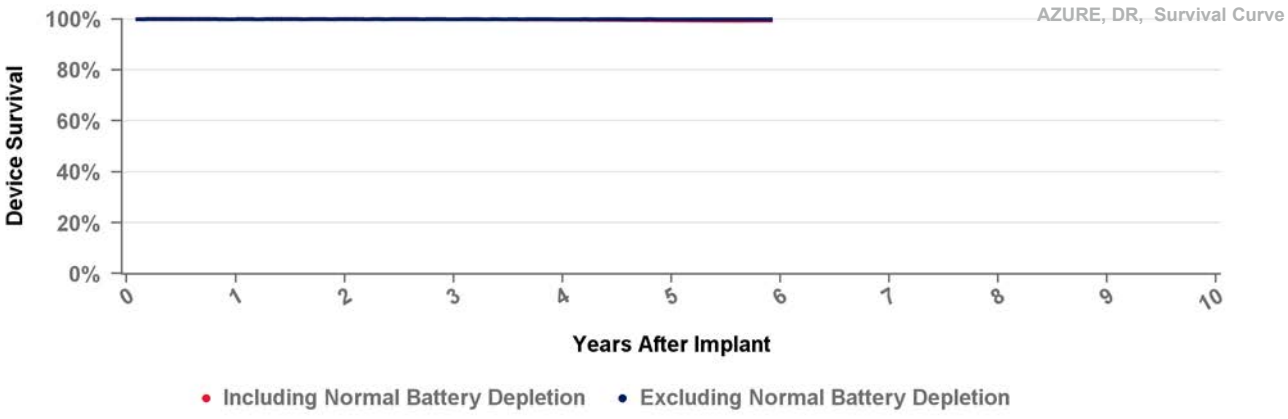
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 50,025 | Battery | 1 |
| **Estimated Active USA Implants** | 41,455 | Electrical Component | 4 |
| **Normal Battery Depletions** | 13 | Software/Firmware | 1 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 69 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% |
| Effective Sample Size | 43364 | 30988 | 20185 | 11384 | 3919 | 246 |

## W2DR01 Azure XT DR

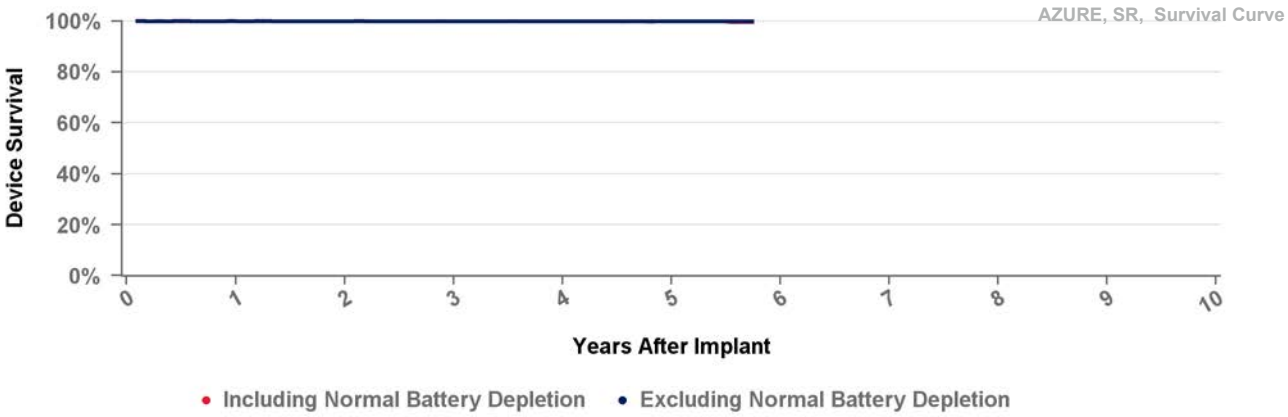
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | at 71 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.5% | 99.3% |
| Effective Sample Size | 491226 | 352544 | 232747 | 136943 | 49863 | 112 |

## W2SR01 Azure XT SR

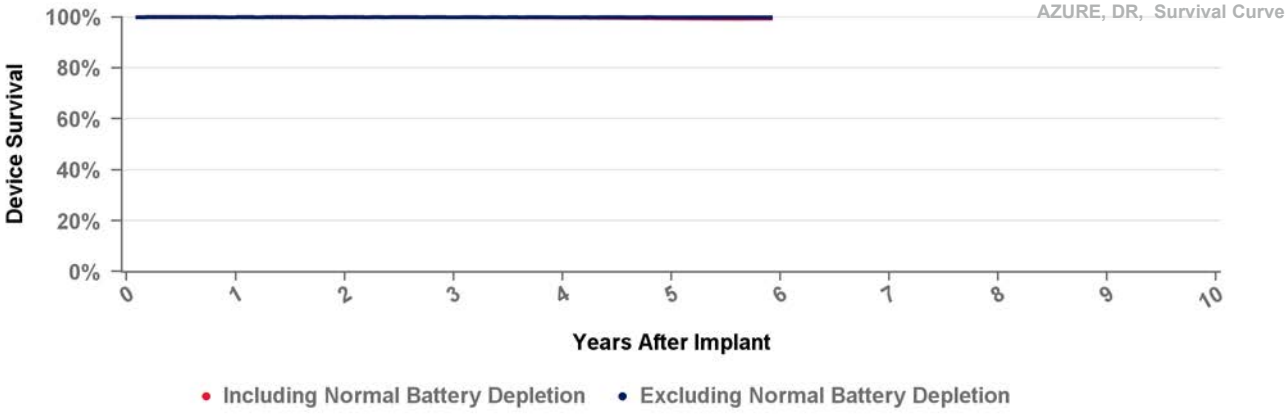
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | at 69 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% |
| Effective Sample Size | 43364 | 30988 | 20185 | 11384 | 3919 | 246 |

## W3DR01 Azure S DR

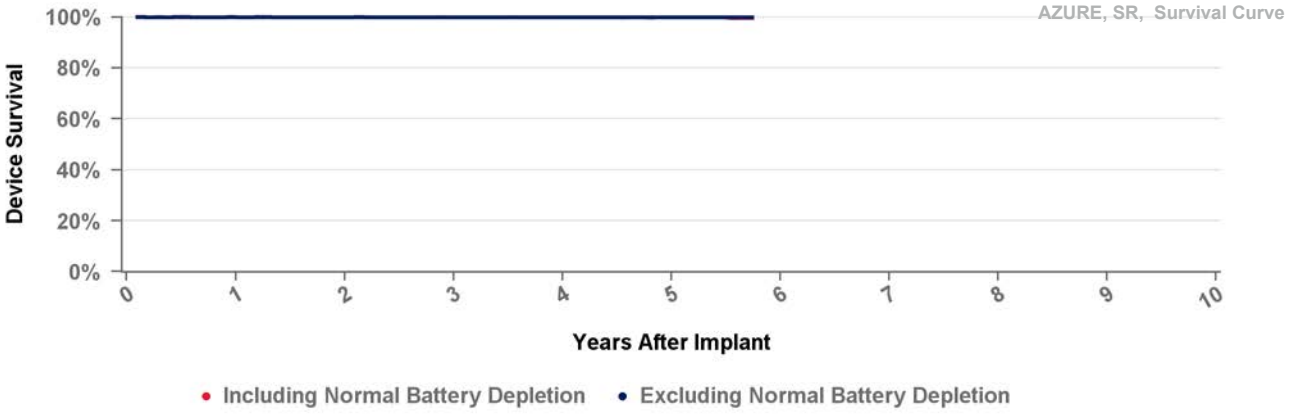
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 57,921 | Electrical Component | 6 |
| **Estimated Active USA Implants** | 51,269 | Software/Firmware | 2 |
| **Normal Battery Depletions** | 64 | **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 | 100.0% | 100.0% | 99.9% | 99.8% | 99.5% | 99.3% |
| Effective Sample Size | 491226 | 352544 | 232747 | 136943 | 49863 | 112 |

## W3SR01 Azure S SR

| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 11,566 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 9,618 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 69 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% |
| Effective Sample Size | 43364 | 30988 | 20185 | 11384 | 3919 | 246 |

## X2DR01 Astra XT DR MRI SureScan

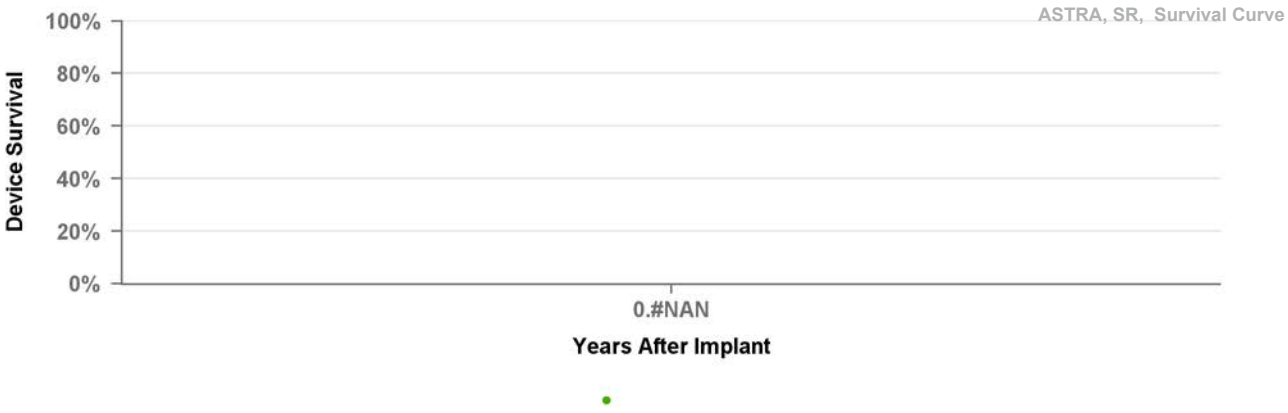
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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


| Years | |
|---|---|
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

## X2SR01 Astra XT SR MRI SureScan

**US Market Release**
**CE Approval Date** 02Mar2017
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**

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

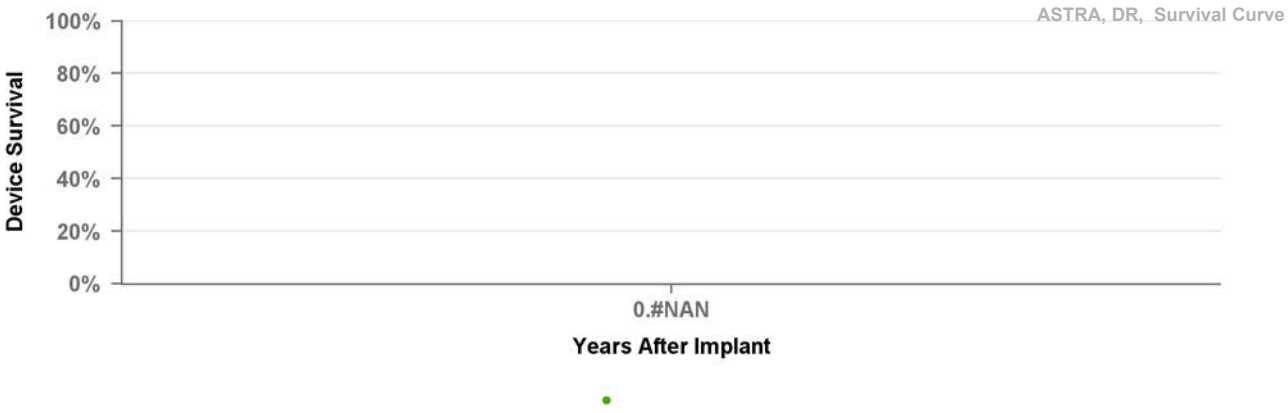



| | |
|---|---|
| Years | |
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

## X3DR01 Astra S DR

**US Market Release**
**CE Approval Date** 02Mar2017
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**

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




| | |
|---|---|
| Years | |
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

## X3SR01 Astra S SR

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


| | |
|---|---|
| Years | |
| Excluding NBD | |
| Including NBD | |
| Effective Sample Size | |

# Method for Estimating Transcatheter Pacing Performance

**Micra TPS Performance Analysis**

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

The performance report information is determined from the analysis of Medtronic Cardiac Rhythm Management (CRM) United States registration, complaint and CareLink™ network data. A TPS model or model family will be included in this report when it has accumulated at least 10,000 implant months and will remain in the report as long as at least 500 devices remain active in the CareLink™ population.

**Shortfalls of using returned products to Estimate Micra TPS Performance**

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

**The CareLink™ Network**

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

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

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

### Definition of Qualifying Complication or Malfunction

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

## Methods for Estimating Transcatheter Pacing Performance continued

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

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

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

### Normal Battery Depletion

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

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

### Statistical and Data Analysis Methods

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

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

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

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

## Methods for Estimating Transcatheter Pacing Performance continued

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

### Definition of Analysis Dataset

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

**US Reports of Acute Observations**

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

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

Each Event Report received by Medtronic's complaint handling system is assigned one or more Reason for Report codes based on the information received. The Reason for Report codes have been grouped into Acute Observation categories. The categories are:

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

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

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

### US Reports of the Day of Implant Observations

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

## Methods for Estimating Transcatheter Pacing Performance continued

Each Event Report received by Medtronic's complaint handling system is assigned one or more Reason for Report codes based on the information received. The Reason for Report codes have been grouped into Day of Implant Observation categories. The categories are:

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

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

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

# MC1VR01 Micra VR

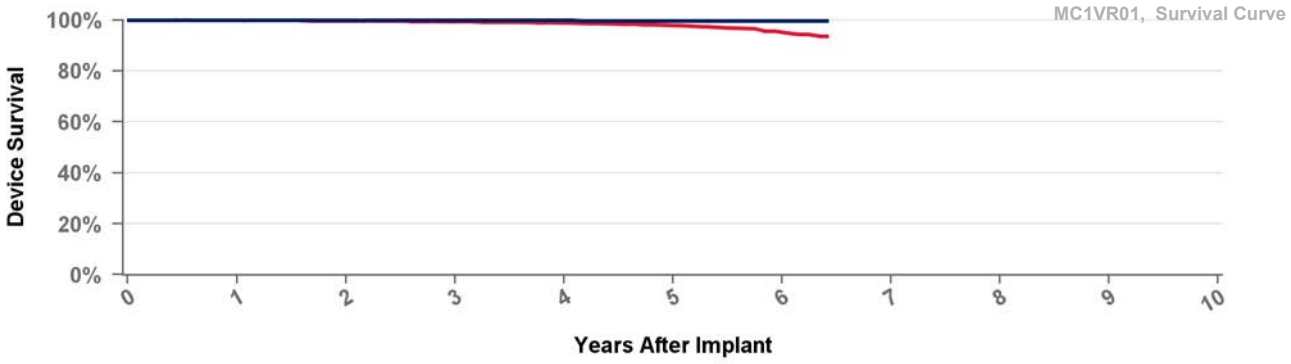
| | |
|---|---|
| **US Market Release** | 06Apr2016 |
| **CE Approval Date** | 14Apr2015 |
| **Registered USA Implants** | 70,177 |

**CareLink Population**

| | |
|---|---|
| Enrolled | 43,159 |
| Active | 30,856 |
| Cumulative Follow-Up Months | 1,166,218 |
| Normal Battery Depletions | 210 |

**CareLink Qualifying Malfunctions/Complications**

| | |
|---|---|
| Cardiac Perforation | 7 |
| Dislodgements | 2 |
| Elevated Pacing Threshold | 38 |
| Failure to Capture | 7 |
| Premature Battery Depletion | 11 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 77 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.7% | 99.3% | 98.9% | 97.9% | 95.2% | 93.7% |
| Effective Sample Size | 33311 | 22381 | 13628 | 7081 | 2599 | 455 | 128 |

***Acute Observations (N = 70,177)**

| | |
|---|---|
| Cardiac Perforation | 21 |
| Dislodgement | 21 |
| Elevated Pacing Threshold | 156 |
| Failure to Capture | 76 |
| Failure to Sense | 15 |

***Day of Implant Observations (N = 70,177)**

| | |
|---|---|
| Cardiac Perforation | 284 |
| Dislodgement | 163 |
| Elevated Pacing Threshold | 250 |
| Failure to Capture | 120 |
| Failure to Sense | 71 |

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


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


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

## MC1AVR1 Micra AV

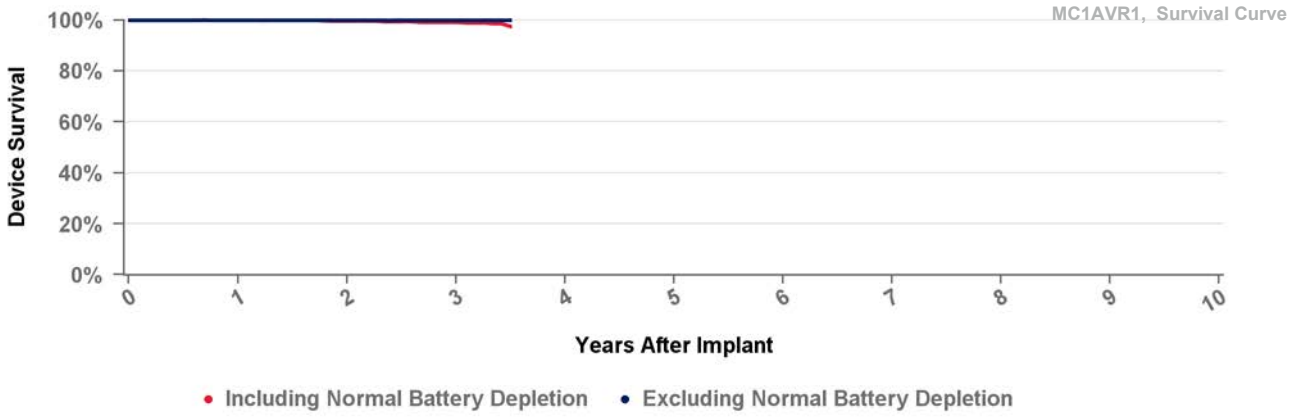
| | |
|---|---|
| **US Market Release** | 15Jan2020 |
| **CE Approval Date** | 31Mar2020 |
| **Registered USA Implants** | 45,911 |

**CareLink Population**

| | |
|---|---|
| Enrolled | 26,855 |
| Active | 22,885 |
| Cumulative Follow-Up Months | 414,692 |
| Normal Battery Depletions | 41 |

**CareLink Qualifying Malfunctions/Complications**

| | |
|---|---|
| Dislodgements | 3 |
| Elevated Pacing Threshold | 9 |
| Failure to Capture | 5 |
| Premature Battery Depletion | 6 |




| Years | 1 | 2 | 3 | at 42 mo |
|---|---|---|---|---|
| Excluding NBD | 99.9% | 99.9% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.1% | 97.4% |
| Effective Sample Size | 15827 | 6552 | 1245 | 109 |

***Acute Observations (N = 45,911)**

| | |
|---|---|
| Cardiac Perforation | 13 |
| Dislodgement | 27 |
| Elevated Pacing Threshold | 83 |
| Failure to Capture | 35 |
| Failure to Sense | 108 |

***Day of Implant Observations (N = 45,911)**

| | |
|---|---|
| Cardiac Perforation | 248 |
| Dislodgement | 76 |
| Elevated Pacing Threshold | 128 |
| Failure to Capture | 67 |
| Failure to Sense | 35 |

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 40 years with its multicenter, global chronic lead studies.**

### Leads Performance Analysis

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

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

### Shortfalls Of Using Returned Product And Complaints To Estimate Lead Performance

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

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

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

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

### PAN Registry

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

## Method for Estimating Lead Performance continued

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

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

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

Patients are eligible for enrollment if:

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

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

**Lead Complications**

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

## Method for Estimating Lead Performance continued

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

Product performance events include, but are not limited to:

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

**Data Analysis Methods**

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

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

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

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

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

## Method for Estimating Lead Performance continued

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

**Definition of Analysis Dataset**

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

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

**Criteria for Model Inclusion**

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

**Returned Product Analysis Results**

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

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

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

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

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

## Method for Estimating Lead Performance continued

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

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

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

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

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

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

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

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

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

## Method for Estimating Lead Performance continued

**Estimated Number of Implanted and Active Leads in the United States**

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

Footnotes:

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

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

# 3830 SelectSecure

| | |
|---|---|
| US Market Release | 03Aug2005 |
| CE Approval | 31Jan2003 |
| Registered USA Implants | 184,124 |
| Estimated Active USA Implants | 155,562 |
| Fixation Type | Fixed Screw |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 36 |
| Insulation Breach | 82 |
| Crimp/Weld/Bond | 0 |
| Other | 13 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 62 |
| Conductor Fracture | 5 |
| Extra Cardiac Stimulation | 10 |
| Failure to Capture | 530 |
| Failure to Sense | 74 |
| Impedance Out of Range | 39 |
| Insulation Breach | 2 |
| Lead Dislodgement | 635 |
| Oversensing | 106 |
| Unspecified Clinical Failure | 2 |

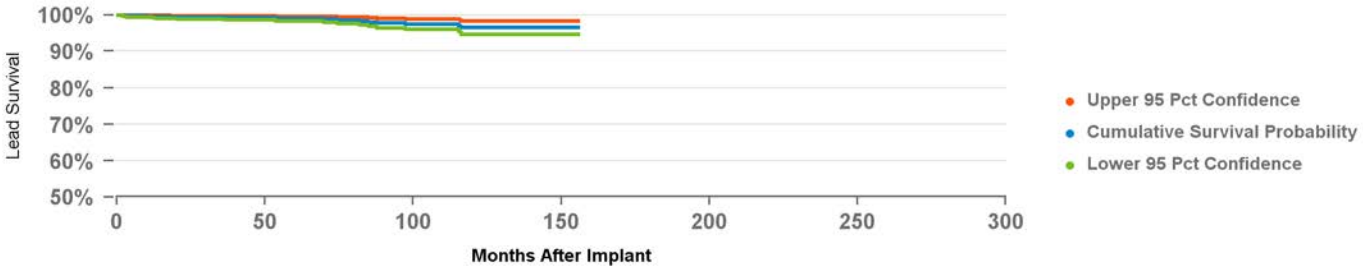
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,774 |
| Number of Leads Active in Study | 756 |
| Cumulative Months of Follow-Up | 84,591 |

### Qualifying Complications 19

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.3% | 99.3% | 99.2% | 99.0% | 98.8% | 98.3% | 97.7% | 97.4% | 96.6% | 96.6% | 96.6% | 96.6% |
| # | 1,308 | 1,032 | 833 | 649 | 517 | 436 | 357 | 313 | 263 | 213 | 186 | 126 | 59 |

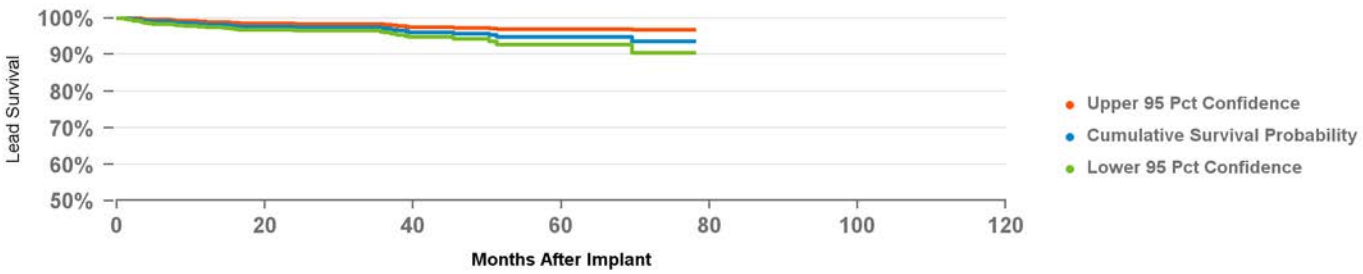
## His Bundle Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,435 |
| Number of Leads Active in Study | 953 |
| Cumulative Months of Follow-Up | 40,363 |

### Qualifying Complications 40

| | | | |
|---|---|---|---|
| Failure to Capture | 30 | Impedance Out of Range | 0 |
| Failure to Sense | 3 | Lead Dislodgement | 4 |
| | | Oversensing | 1 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 78 mo |
|---|---|---|---|---|---|---|---|
| % | 98.3% | 97.5% | 97.1% | 95.8% | 94.8% | 93.6% | 93.6% |
| # | 1,092 | 773 | 479 | 240 | 106 | 64 | 51 |

## Ventricular Placement

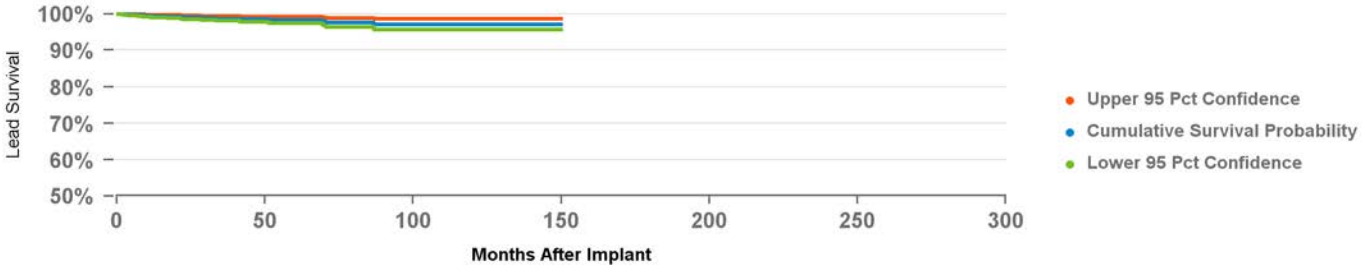
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,524 |
| Number of Leads Active in Study | 1,695 |
| Cumulative Months of Follow-Up | 73,178 |

### Qualifying Complications

| | | | |
|---|---|---|---|
| Failure to Capture | 11 | Impedance Out of Range | 2 |
| | | Lead Dislodgement | 8 |
| | | Other | 1 |

**22**



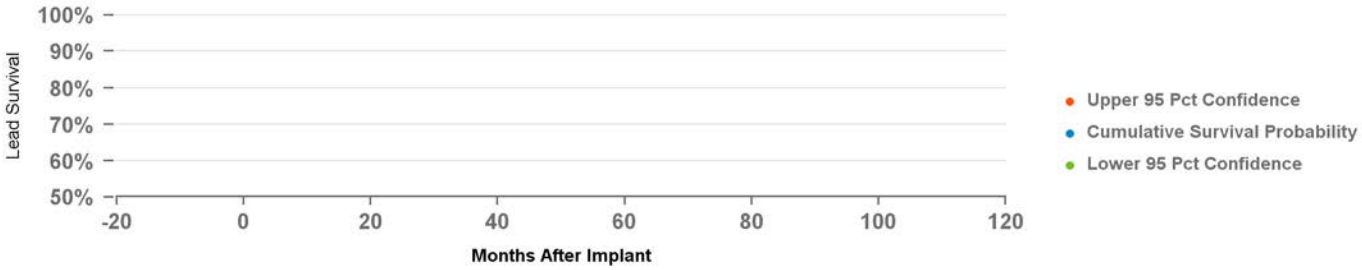

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.4% | 99.1% | 98.7% | 98.6% | 98.3% | 97.6% | 97.6% | 97.2% | 97.2% | 97.2% | 97.2% | 97.2% | 97.2% |
| # | 1,534 | 1,002 | 717 | 455 | 350 | 272 | 221 | 186 | 154 | 116 | 100 | 74 | 50 |

## 4073 CapSure Sense

| | |
|---|---|
| US Market Release | 23Jun2002 |
| CE Approval | 01Feb2002 |
| Registered USA Implants | 769 |
| Estimated Active USA Implants | 131 |
| 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 | 152,971 |
| Estimated Active USA Implants | 72,703 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 14 |
| Insulation Breach | 57 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 33 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 3 |
| Failure to Capture | 183 |
| Failure to Sense | 15 |
| Impedance Out of Range | 6 |
| Lead Dislodgement | 204 |
| Oversensing | 8 |

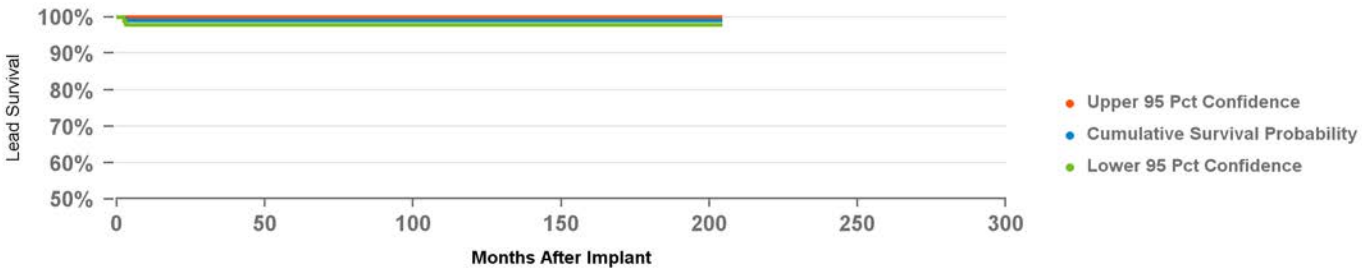
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 227 |
| Number of Leads Active in Study | 61 |
| Cumulative Months of Follow-Up | 29,196 |

### Qualifying Complications 2

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 204 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% |
| # | 214 | 205 | 198 | 183 | 167 | 158 | 148 | 136 | 126 | 117 | 110 | 107 | 98 | 94 | 88 | 73 | 51 |

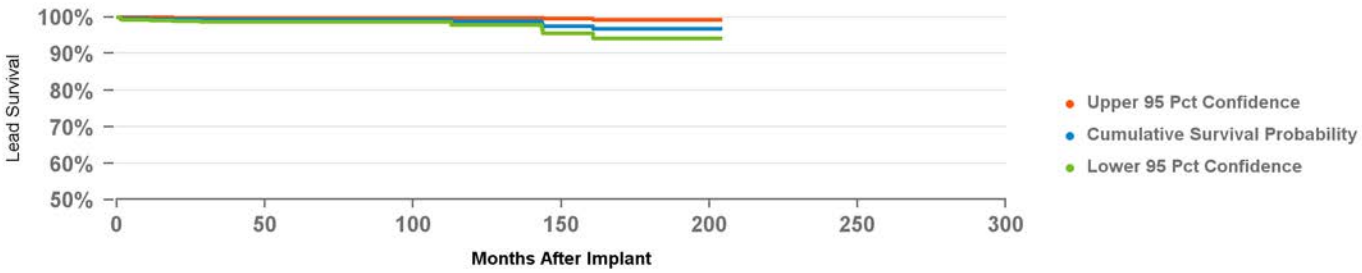
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,193 |
| Number of Leads Active in Study | 167 |
| Cumulative Months of Follow-Up | 79,817 |

### Qualifying Complications 12

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Impedance Out of Range | 2 |
| Failure to Capture | 4 | Insulation (not further defined) | 2 |
| | | Lead Dislodgement | 2 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 204 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 98.8% | 98.8% | 97.5% | 97.5% | 96.7% | 96.7% | 96.7% | 96.7% |
| # | 1,029 | 878 | 737 | 624 | 481 | 393 | 337 | 294 | 252 | 203 | 171 | 151 | 121 | 117 | 111 | 84 | 52 |

# 4076 CapSureFix Novus

| | |
|---|---|
| US Market Release | 25Feb2004 |
| CE Approval | 14Jun2004 |
| Registered USA Implants | 801,663 |
| Estimated Active USA Implants | 459,590 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 130 |
| Insulation Breach | 217 |
| Crimp/Weld/Bond | 2 |
| Other | 23 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 245 |
| Conductor Fracture | 11 |
| Extra Cardiac Stimulation | 27 |
| Failure to Capture | 370 |
| Failure to Sense | 258 |
| Impedance Out of Range | 68 |
| Insulation Breach | 2 |
| Lead Dislodgement | 875 |
| Oversensing | 140 |
| Unspecified Clinical Failure | 10 |

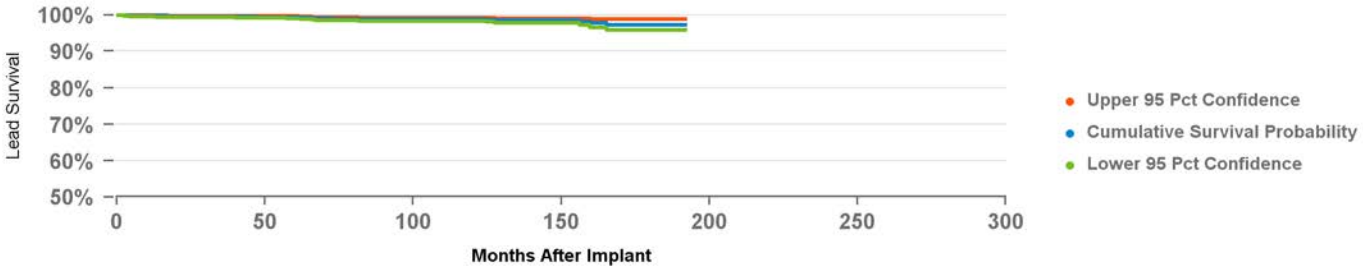
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 4,720 |
| Number of Leads Active in Study | 1,682 |
| Cumulative Months of Follow-Up | 271,871 |

### Qualifying Complications 36

| | | | |
|---|---|---|---|
| Cardiac Perforation | 2 | Impedance Out of Range | 0 |
| Conductor Fracture | 3 | Insulation (not further defined) | 3 |
| Failure to Capture | 9 | Lead Dislodgement | 12 |
| Failure to Sense | 3 | Oversensing | 2 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 192 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.6% | 99.6% | 99.5% | 99.4% | 99.0% | 98.9% | 98.8% | 98.8% | 98.8% | 98.5% | 98.5% | 98.5% | 97.3% | 97.3% | 97.3% |
| # | 3,400 | 2,963 | 2,583 | 2,216 | 1,879 | 1,628 | 1,433 | 1,230 | 1,022 | 787 | 576 | 426 | 301 | 184 | 118 | 64 |

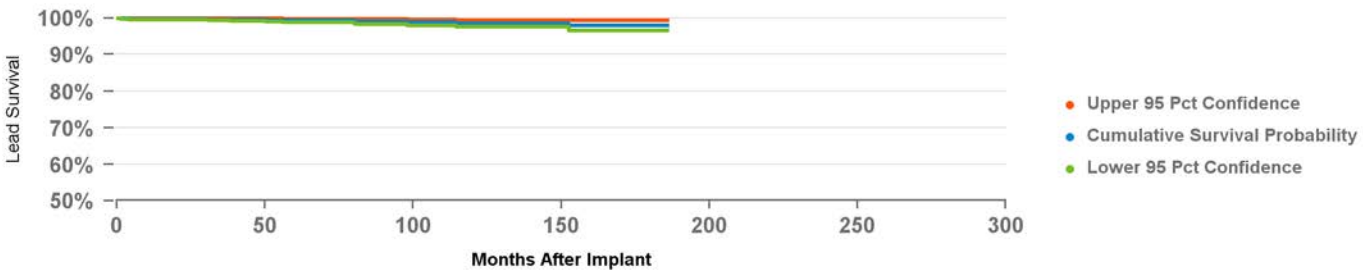
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,760 |
| Number of Leads Active in Study | 351 |
| Cumulative Months of Follow-Up | 116,900 |

### Qualifying Complications 14

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 186 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.7% | 99.7% | 99.6% | 99.3% | 99.3% | 99.0% | 99.0% | 98.8% | 98.5% | 98.5% | 98.5% | 98.0% | 98.0% | 98.0% | 98.0% |
| # | 1,443 | 1,286 | 1,136 | 963 | 769 | 666 | 558 | 481 | 413 | 327 | 275 | 221 | 172 | 115 | 82 | 69 |

# 4092 CapSure SP Novus

| | |
|---|---|
| US Market Release | 17Sep1998 |
| CE Approval | 15Apr1998 |
| Registered USA Implants | 186,236 |
| Estimated Active USA Implants | 36,444 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 21 |
| Insulation Breach | 99 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

## US Acute Lead Observations

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

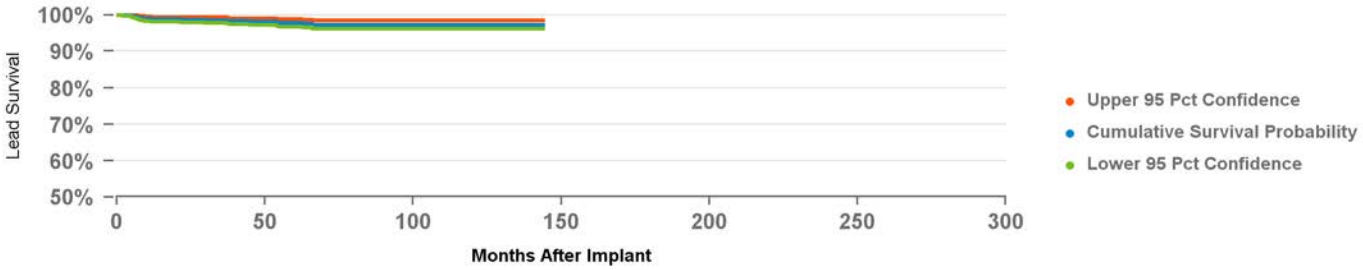
## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,202 |
| Number of Leads Active in Study | 13 |
| Cumulative Months of Follow-Up | 70,144 |

## Qualifying Complications

**21**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 144 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.8% | 98.7% | 98.5% | 98.1% | 97.8% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% |
| # | 921 | 822 | 734 | 629 | 515 | 402 | 333 | 279 | 239 | 157 | 93 | 57 |

## 4574 CapSure Sense

| | |
|---|---|
| US Market Release | 23Jun2002 |
| CE Approval | 01Feb2002 |
| Registered USA Implants | 116,713 |
| Estimated Active USA Implants | 65,087 |
| Fixation Type | J-shape, tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 14 |
| Insulation Breach | 25 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 4 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 146 |
| Failure to Sense | 80 |
| Impedance Out of Range | 10 |
| Lead Dislodgement | 267 |
| Oversensing | 16 |
| Unspecified Clinical Failure | 4 |

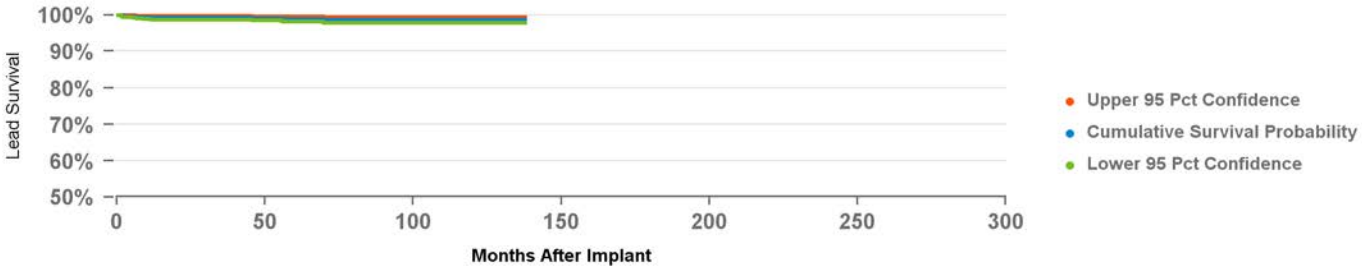
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,700 |
| Number of Leads Active in Study | 713 |
| Cumulative Months of Follow-Up | 76,336 |

### Qualifying Complications

**14**

| | | | |
|---|---|---|---|
| Conductor Fracture | 2 | Impedance Out of Range | 0 |
| Failure to Capture | 5 | Lead Dislodgement | 7 |
| | | Other | 0 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 138 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 99.2% | 99.2% | 99.1% | 98.9% | 98.6% | 98.6% | 98.6% | 98.6% | 98.6% | 98.6% | 98.6% |
| # | 1,236 | 943 | 761 | 617 | 491 | 407 | 345 | 268 | 201 | 141 | 83 | 61 |

## 4592 CapSure SP Novus

| | |
|---|---|
| US Market Release | 05Oct1998 |
| CE Approval | 15Apr1998 |
| Registered USA Implants | 89,798 |
| Estimated Active USA Implants | 19,854 |
| Fixation Type | J-shape, tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

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

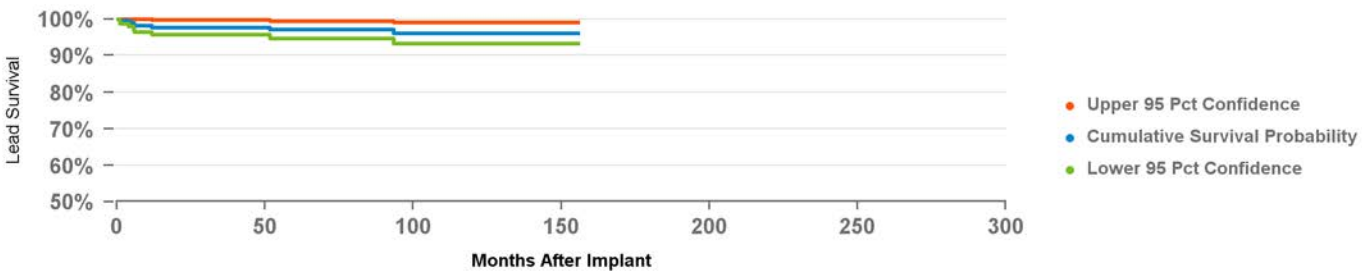
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 366 |
| Number of Leads Active in Study | 27 |
| Cumulative Months of Follow-Up | 22,549 |

### Qualifying Complications

**9**

| | | | |
|---|---|---|---|
| Failure to Capture | 4 | Impedance Out of Range | 0 |
| Failure to Sense | 1 | Lead Dislodgement | 3 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 97.7% | 97.7% | 97.7% | 97.7% | 97.0% | 97.0% | 97.0% | 96.1% | 96.1% | 96.1% | 96.1% | 96.1% | 96.1% |
| # | 203 | 181 | 166 | 157 | 133 | 125 | 108 | 104 | 97 | 86 | 81 | 75 | 56 |

# 5054 CapSure Z Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 05Jun1997 |
| Registered USA Implants | 100,058 |
| Estimated Active USA Implants | 18,503 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 16 |
| Insulation Breach | 46 |
| Crimp/Weld/Bond | 1 |
| Other | 0 |

### US Acute Lead Observations

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

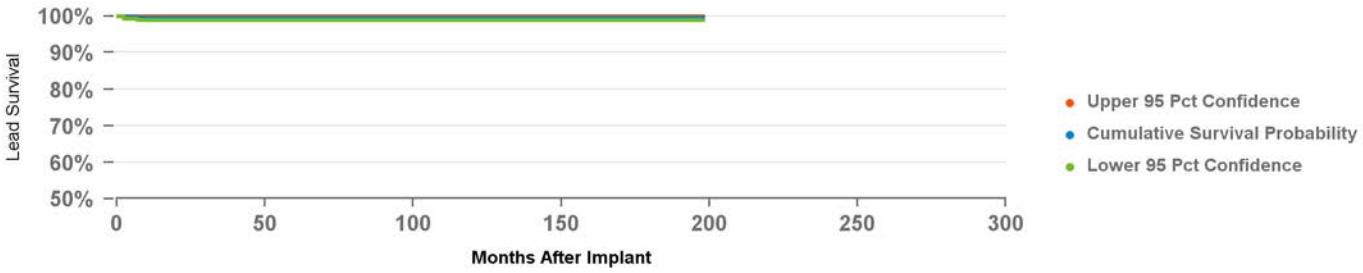
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 425 |
| Number of Leads Active in Study | 28 |
| Cumulative Months of Follow-Up | 41,984 |

### Qualifying Complications 3

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 198 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| # | 411 | 391 | 358 | 322 | 289 | 252 | 219 | 185 | 152 | 128 | 107 | 92 | 74 | 64 | 58 | 51 | 50 |

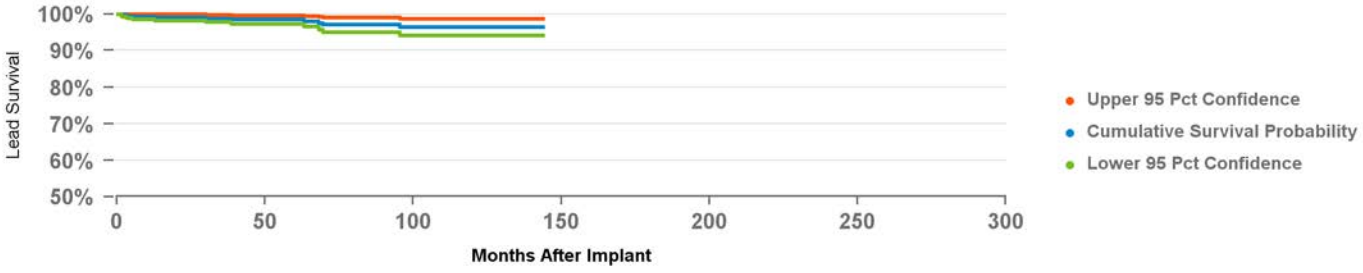
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 991 |
| Number of Leads Active in Study | 18 |
| Cumulative Months of Follow-Up | 35,502 |

### Qualifying Complications 13

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 144 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.3% | 99.1% | 98.8% | 98.4% | 98.4% | 97.0% | 97.0% | 96.4% | 96.4% | 96.4% | 96.4% | 96.4% |
| # | 474 | 391 | 304 | 264 | 230 | 192 | 167 | 144 | 113 | 93 | 72 | 54 |

# 5076 CapSureFix Novus

| | |
|---|---|
| US Market Release | 31Aug2000 |
| CE Approval | 12Aug1999 |
| Registered USA Implants | 3,285,505 |
| Estimated Active USA Implants | 1,836,408 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1,465 |
| Insulation Breach | 1,574 |
| Crimp/Weld/Bond | 4 |
| Other | 205 |

## US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 1,621 |
| Conductor Fracture | 32 |
| Extra Cardiac Stimulation | 114 |
| Failure to Capture | 2,387 |
| Failure to Sense | 1,452 |
| Impedance Out of Range | 400 |
| Insulation Breach | 15 |
| Lead Dislodgement | 5,159 |
| Oversensing | 800 |
| Unspecified Clinical Failure | 26 |

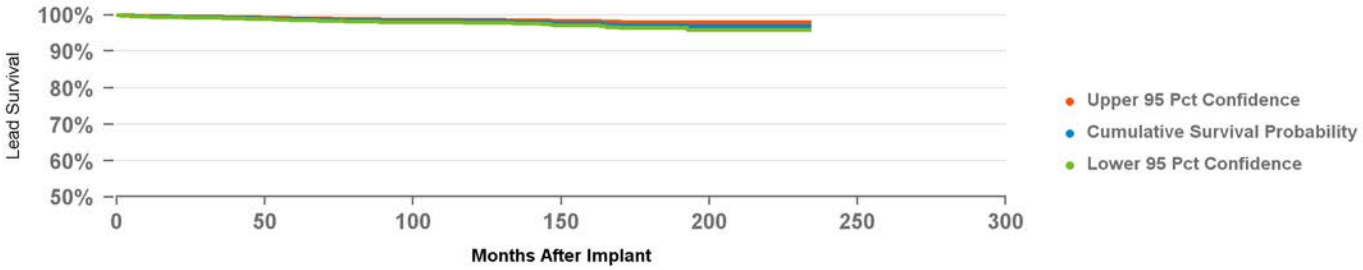
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 13,115 |
| Number of Leads Active in Study | 5,396 |
| Cumulative Months of Follow-Up | 608,439 |

### Qualifying Complications 111

| | | | |
|---|---|---|---|
| Cardiac Perforation | 2 | Impedance Out of Range | 11 |
| Conductor Fracture | 13 | Insulation (not further defined) | 3 |
| Extra Cardiac Stimulation | 3 | Lead Dislodgement | 41 |
| Failure to Capture | 17 | Oversensing | 3 |
| Failure to Sense | 10 | Other | 8 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | at 234 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.5% | 99.3% | 99.1% | 98.8% | 98.7% | 98.5% | 98.3% | 98.3% | 98.3% | 98.2% | 98.0% | 97.7% | 97.4% | 97.2% | 97.2% | 96.9% | 96.9% | 96.9% | 96.9% |
| # | 8,441 | 6,914 | 5,877 | 4,888 | 4,079 | 3,412 | 2,727 | 2,173 | 1,773 | 1,382 | 1,086 | 874 | 673 | 521 | 420 | 335 | 223 | 142 | 84 | 65 |

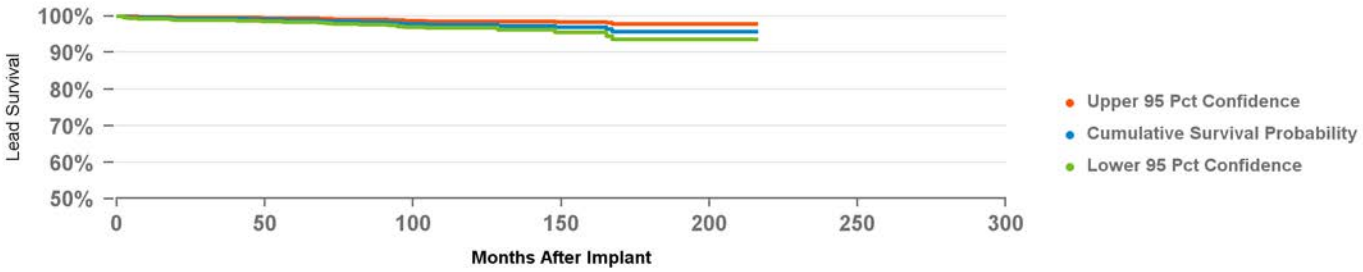
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,387 |
| Number of Leads Active in Study | 749 |
| Cumulative Months of Follow-Up | 162,124 |

### Qualifying Complications 35

| | | | |
|---|---|---|---|
| Cardiac Perforation | 1 | Impedance Out of Range | 4 |
| Conductor Fracture | 7 | Insulation (not further defined) | 1 |
| Failure to Capture | 13 | Lead Dislodgement | 5 |
| Failure to Sense | 1 | Oversensing | 1 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 216 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 99.1% | 98.9% | 98.6% | 98.3% | 98.0% | 97.6% | 97.6% | 97.3% | 97.3% | 96.9% | 95.7% | 95.7% | 95.7% | 95.7% | 95.7% |
| # | 2,222 | 1,886 | 1,560 | 1,244 | 996 | 827 | 688 | 579 | 498 | 405 | 325 | 257 | 186 | 152 | 128 | 109 | 77 | 55 |

# 5086MRI CapsureFix Novus MRI

| | |
|---|---|
| US Market Release | 08Feb2011 |
| CE Approval | 21Jan2009 |
| Registered USA Implants | 207,801 |
| Estimated Active USA Implants | 127,629 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 112 |
| Insulation Breach | 206 |
| Crimp/Weld/Bond | 0 |
| Other | 12 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 212 |
| Conductor Fracture | 4 |
| Extra Cardiac Stimulation | 18 |
| Failure to Capture | 144 |
| Failure to Sense | 29 |
| Impedance Out of Range | 9 |
| Insulation Breach | 2 |
| Lead Dislodgement | 312 |
| Oversensing | 31 |

## Atrial Placement

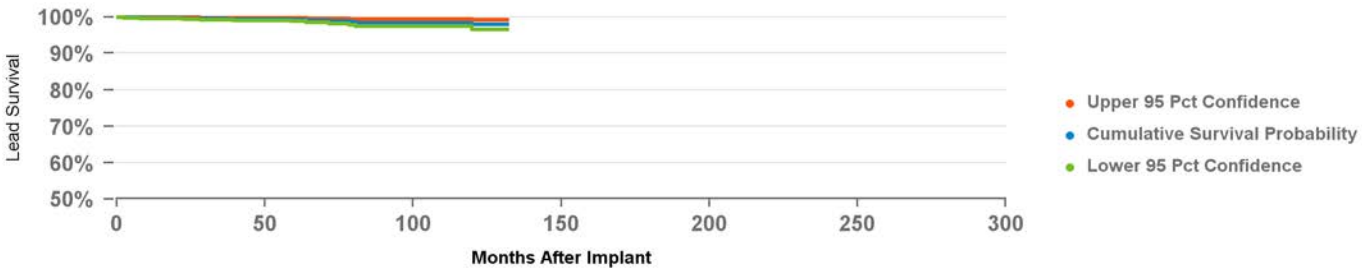
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,139 |
| Number of Leads Active in Study | 1,332 |
| Cumulative Months of Follow-Up | 144,064 |

### Qualifying Complications

21

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 132 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.8% | 99.6% | 99.6% | 99.4% | 99.3% | 98.9% | 98.4% | 98.4% | 98.4% | 97.9% | 97.9% |
| # | 2,529 | 2,202 | 1,879 | 1,463 | 767 | 452 | 395 | 346 | 299 | 207 | 90 |

## Ventricular Placement

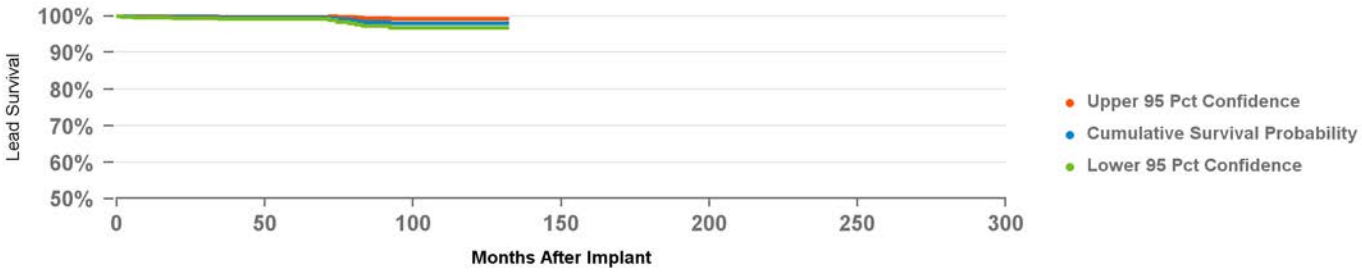
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,073 |
| Number of Leads Active in Study | 1,312 |
| Cumulative Months of Follow-Up | 141,807 |

### Qualifying Complications

21

| | | | |
|---|---|---|---|
| Conductor Fracture | 4 | Impedance Out of Range | 2 |
| Failure to Capture | 8 | Lead Dislodgement | 3 |
| Failure to Sense | 1 | Oversensing | 2 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 132 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.3% | 98.3% | 98.0% | 98.0% | 98.0% | 98.0% |
| # | 2,528 | 2,184 | 1,852 | 1,429 | 736 | 423 | 375 | 328 | 285 | 203 | 92 |

## 5092 CapSure SP Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 25Sep1997 |
| Registered USA Implants | 141,703 |
| Estimated Active USA Implants | 29,378 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 27 |
| Insulation Breach | 72 |
| Crimp/Weld/Bond | 0 |
| Other | 1 |

### US Acute Lead Observations

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

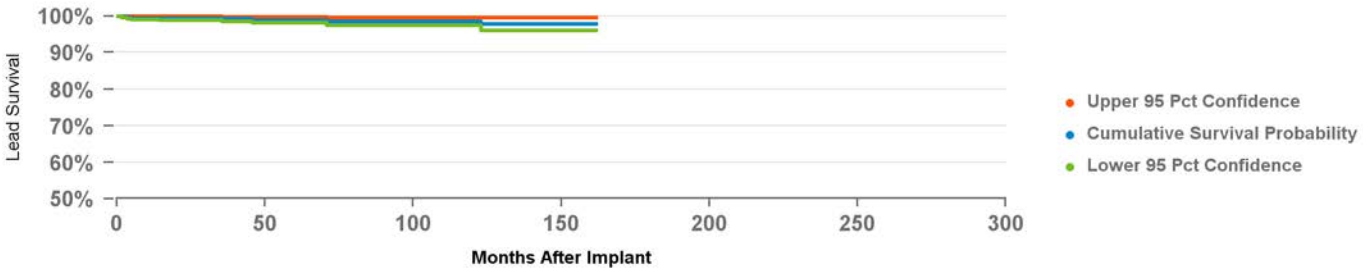
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,216 |
| Number of Leads Active in Study | 16 |
| Cumulative Months of Follow-Up | 54,564 |

### Qualifying Complications

**10**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 98.9% | 98.9% | 98.6% | 98.6% | 98.6% | 98.6% | 98.6% | 97.8% | 97.8% | 97.8% | 97.8% |
| # | 814 | 652 | 517 | 421 | 335 | 265 | 218 | 173 | 149 | 133 | 109 | 81 | 56 | 52 |

## 5554 CapSure Z Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 05Jun1997 |
| Registered USA Implants | 64,867 |
| Estimated Active USA Implants | 14,396 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 24 |
| Insulation Breach | 43 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

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

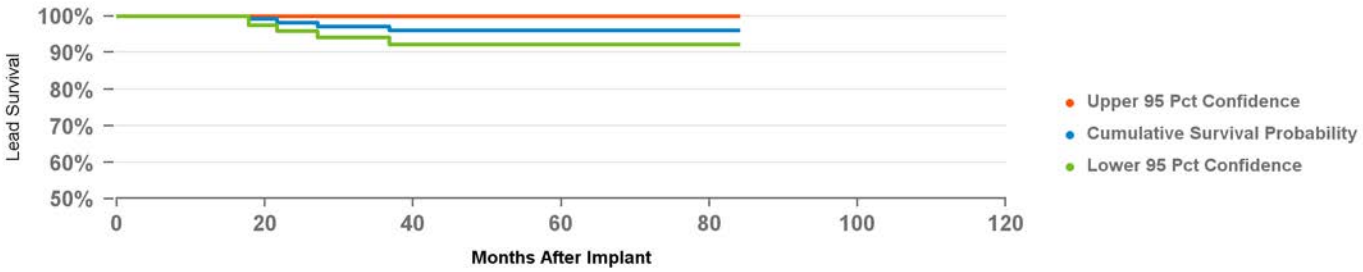
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 369 |
| Number of Leads Active in Study | 9 |
| Cumulative Months of Follow-Up | 9,403 |

### Qualifying Complications

**5**

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




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

## 5592 CapSure SP Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 25Sep1997 |
| Registered USA Implants | 37,335 |
| Estimated Active USA Implants | 9,926 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

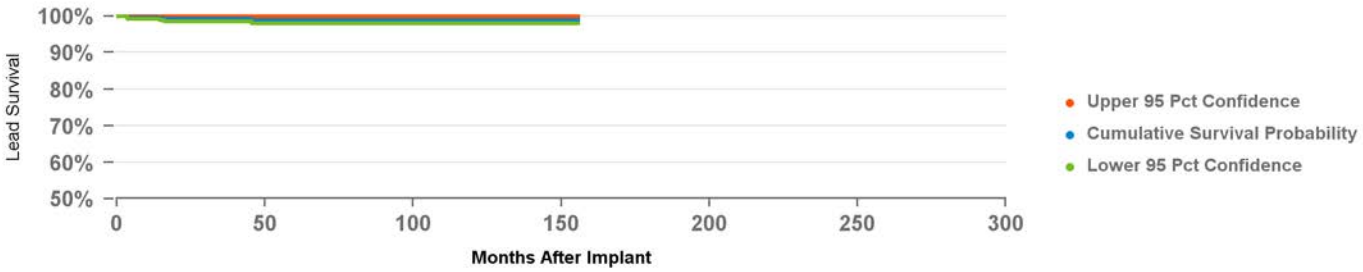
| | |
|---|---|
| Cardiac Perforation | 1 |
| Failure to Capture | 4 |
| Failure to Sense | 3 |
| Lead Dislodgement | 43 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 1 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 722 |
| Number of Leads Active in Study | 36 |
| Cumulative Months of Follow-Up | 39,413 |

### Qualifying Complications 5

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.3% | 99.3% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% |
| # | 523 | 432 | 351 | 299 | 249 | 197 | 169 | 154 | 131 | 111 | 97 | 69 | 51 |

## 5594 CapSure SP Novus

| | |
|---|---|
| US Market Release | 25Jun2001 |
| CE Approval | 23Mar2001 |
| Registered USA Implants | 17,611 |
| Estimated Active USA Implants | 5,542 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

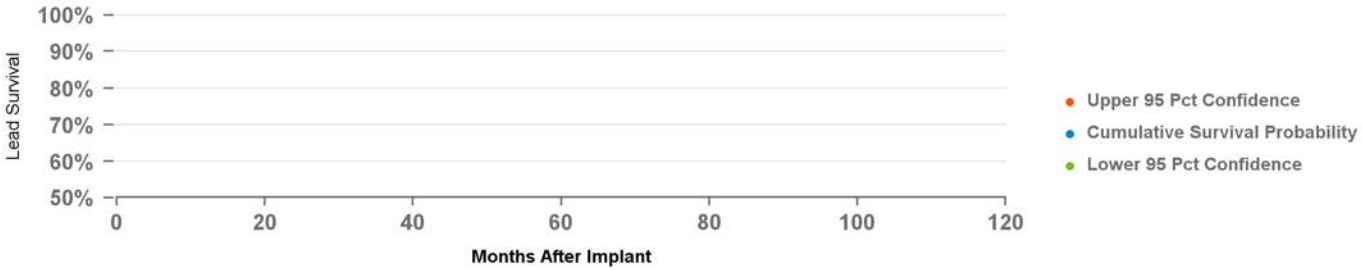
| | |
|---|---|
| Failure to Capture | 4 |
| Lead Dislodgement | 14 |
| Unspecified Clinical Failure | 2 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 43 |
| Number of Leads Active in Study | 12 |
| Cumulative Months of Follow-Up | 4,574 |

### Qualifying Complications 3

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




| Years | at 0 mo |
|---|---|
| % | ##### |
| # | |

## 6721 Epicardial Patch

| | |
|---|---|
| US Market Release | 31Mar1994 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 3,408 |
| Estimated Active USA Implants | 862 |
| Fixation Type | Suture |
| Pace Sense Polarity | n/a |
| Steroid Indicator | None |

### US Returned Product Analysis

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

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Failure to Capture | 4 |
| Failure to Sense | 2 |
| Impedance Out of Range | 22 |
| Oversensing | 1 |

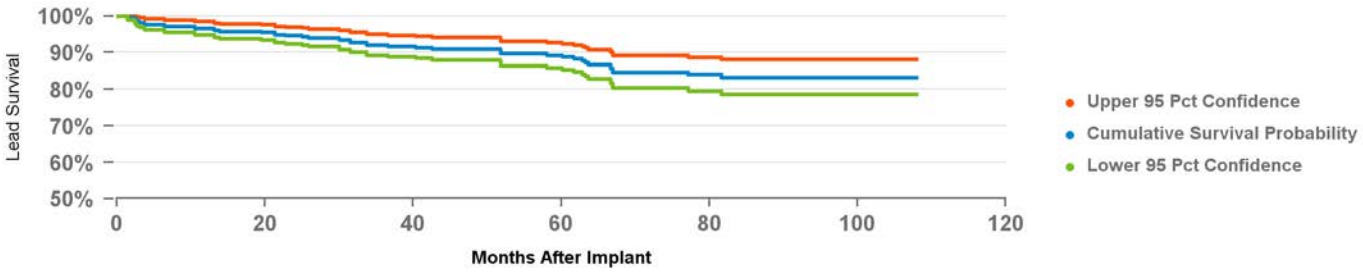
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 417 |
| Number of Leads Active in Study | 6 |
| Cumulative Months of Follow-Up | 24,142 |

### Qualifying Complications

**51**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| % | 96.6% | 94.6% | 92.1% | 91.0% | 89.3% | 84.7% | 83.3% | 83.3% | 83.3% |
| # | 347 | 319 | 273 | 221 | 190 | 134 | 101 | 65 | 57 |

## 6930 Sprint Fidelis

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

### US Returned Product Analysis

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

### US Acute Lead Observations

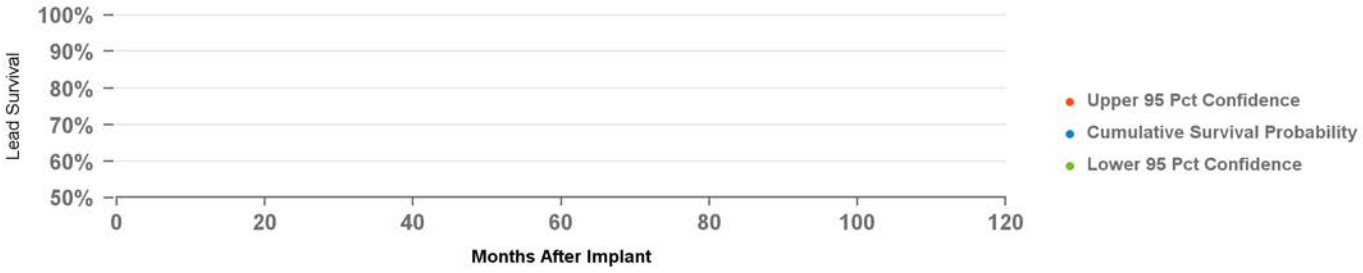
| | |
|---|---|
| Unspecified Clinical Failure | 1 |

### Product Surveillance Registry Results

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

### Qualifying Complications

| | |
|---|---|
| Failure to Capture | 0 |
| Impedance Out of Range | 0 |
| Other | 0 |




| Years | at 0 mo |
|---|---|
| % | ##### |
| # | |

# 6931 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 8,081 |
| Estimated Active USA Implants | 1,182 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 668 |
| Insulation Breach | 1 |
| Crimp/Weld/Bond | 0 |
| Other | 5 |

## US Acute Lead Observations

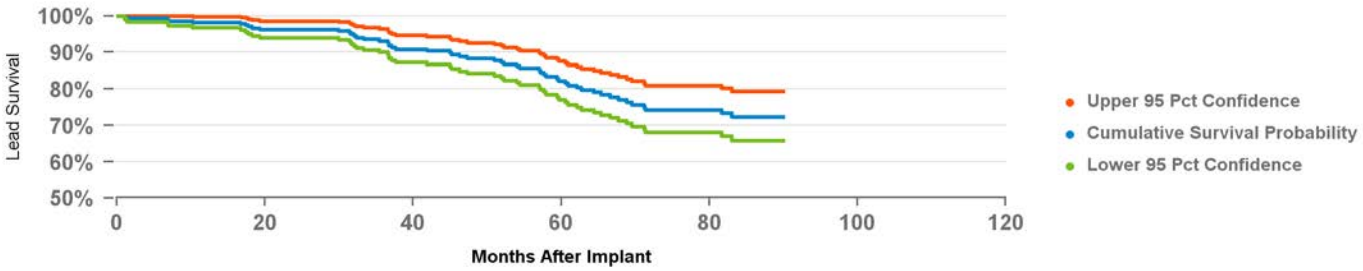
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Failure to Capture | 1 |
| Failure to Sense | 1 |
| Lead Dislodgement | 1 |
| Oversensing | 3 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 311 |
| Number of Leads Active in Study | 9 |
| Cumulative Months of Follow-Up | 18,038 |

## Qualifying Complications 59

| | |
|---|---|
| Conductor Fracture | 36 |
| Failure to Capture | 3 |
| Failure to Sense | 1 |
| Impedance Out of Range | 10 |
| Lead Dislodgement | 2 |
| Oversensing | 7 |
| Other | 0 |




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

# 6935 Sprint Quattro Secure S

| | |
|---|---|
| US Market Release | 01Nov2008 |
| CE Approval | 31Mar2008 |
| Registered USA Implants | 67,061 |
| Estimated Active USA Implants | 39,156 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 470 |
| Insulation Breach | 13 |
| Crimp/Weld/Bond | 0 |
| Other | 44 |

## US Acute Lead Observations

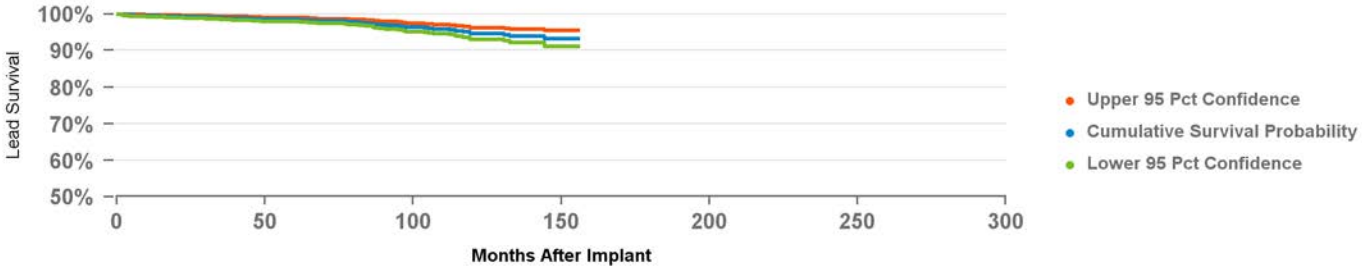
| | |
|---|---|
| Cardiac Perforation | 29 |
| Conductor Fracture | 3 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 35 |
| Failure to Sense | 15 |
| Impedance Out of Range | 28 |
| Insulation Breach | 1 |
| Lead Dislodgement | 68 |
| Oversensing | 67 |
| Unspecified Clinical Failure | 5 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,977 |
| Number of Leads Active in Study | 720 |
| Cumulative Months of Follow-Up | 164,563 |

## Qualifying Complications 67

| | | | |
|---|---|---|---|
| Cardiac Perforation | 1 | Impedance Out of Range | 9 |
| Conductor Fracture | 24 | Lead Dislodgement | 8 |
| Extra Cardiac Stimulation | 1 | Oversensing | 9 |
| Failure to Capture | 7 | Other | 6 |
| Failure to Sense | 1 | Unspecified Clinical Failure | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 98.9% | 98.6% | 98.5% | 98.1% | 97.5% | 96.8% | 95.9% | 94.7% | 94.3% | 93.9% | 93.3% |
| # | 2,415 | 1,976 | 1,626 | 1,330 | 1,125 | 968 | 807 | 678 | 571 | 432 | 248 | 143 | 57 |

## 6935M Sprint Quattro Secure S

| | |
|---|---|
| US Market Release | 02Aug2012 |
| CE Approval | 12Jul2012 |
| Registered USA Implants | 373,555 |
| Estimated Active USA Implants | 306,381 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 735 |
| Insulation Breach | 35 |
| Crimp/Weld/Bond | 1 |
| Other | 99 |

### US Acute Lead Observations

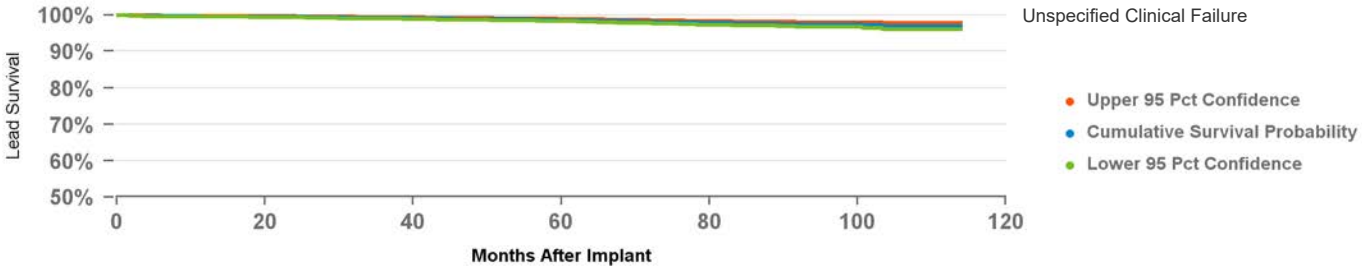
| | |
|---|---|
| Cardiac Perforation | 183 |
| Conductor Fracture | 21 |
| Extra Cardiac Stimulation | 31 |
| Failure to Capture | 422 |
| Failure to Sense | 146 |
| Impedance Out of Range | 126 |
| Insulation Breach | 3 |
| Lead Dislodgement | 633 |
| Oversensing | 327 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 9,312 |
| Number of Leads Active in Study | 4,439 |
| Cumulative Months of Follow-Up | 371,545 |

### Qualifying Complications 102

| | |
|---|---|
| Cardiac Perforation | 2 |
| Conductor Fracture | 43 |
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 15 |
| Failure to Sense | 1 |
| Impedance Out of Range | 9 |
| Insulation (not further defined) | 3 |
| Lead Dislodgement | 19 |
| Oversensing | 5 |
| Other | 3 |
| Unspecified Clinical Failure | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.5% | 99.2% | 98.9% | 98.6% | 98.2% | 97.7% | 97.4% | 97.0% | 97.0% |
| # | 6,732 | 5,312 | 4,334 | 3,508 | 2,833 | 2,131 | 1,302 | 634 | 259 | 139 |

## 6937A Transvene SVC-CS

| | |
|---|---|
| US Market Release | 06Apr2001 |
| CE Approval | |
| Registered USA Implants | 3,044 |
| Estimated Active USA Implants | 1,577 |
| Fixation Type | Passive |
| Pace Sense Polarity | One Coil |
| Steroid Indicator | None |

### US Returned Product Analysis

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

### US Acute Lead Observations

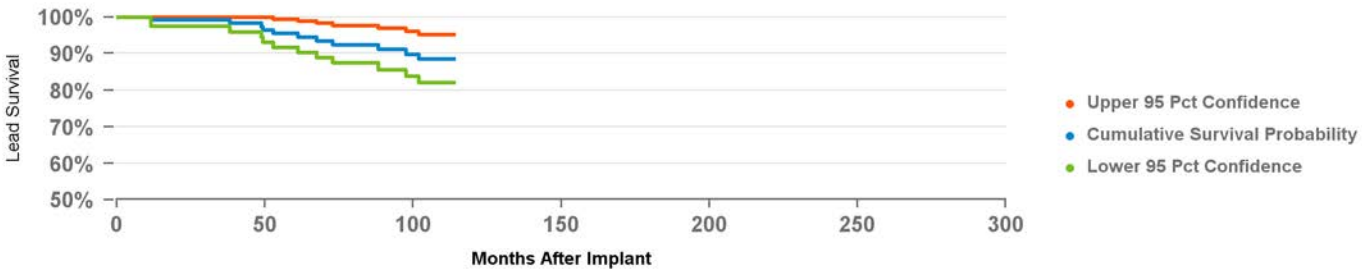
| | |
|---|---|
| Conductor Fracture | 3 |
| Impedance Out of Range | 2 |
| Lead Dislodgement | 1 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 2 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 125 |
| Number of Leads Active in Study | 7 |
| Cumulative Months of Follow-Up | 14,232 |

### Qualifying Complications 16

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 99.2% | 99.2% | 98.3% | 95.5% | 93.5% | 92.4% | 91.1% | 88.4% | 88.4% |
| # | 117 | 115 | 112 | 107 | 96 | 84 | 77 | 70 | 58 | 53 |

## 6944 Sprint Quattro

| | |
|---|---|
| US Market Release | 13Dec2000 |
| CE Approval | 05Nov1999 |
| Registered USA Implants | 44,864 |
| Estimated Active USA Implants | 11,989 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 233 |
| Insulation Breach | 4 |
| Crimp/Weld/Bond | 1 |
| Other | 4 |

### US Acute Lead Observations

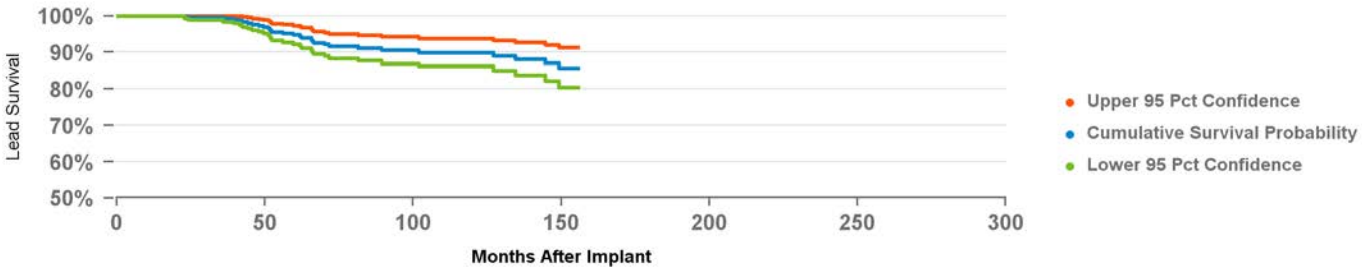
| | |
|---|---|
| Conductor Fracture | 2 |
| Failure to Capture | 17 |
| Failure to Sense | 3 |
| Impedance Out of Range | 10 |
| Lead Dislodgement | 24 |
| Oversensing | 18 |
| Unspecified Clinical Failure | 6 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 638 |
| Number of Leads Active in Study | 81 |
| Cumulative Months of Follow-Up | 38,025 |

### Qualifying Complications 34

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | ##### | 99.8% | 99.2% | 97.3% | 94.8% | 91.7% | 91.1% | 90.6% | 89.9% | 89.9% | 89.0% | 88.1% | 85.7% |
| # | 502 | 418 | 352 | 290 | 228 | 191 | 165 | 145 | 132 | 115 | 101 | 79 | 53 |

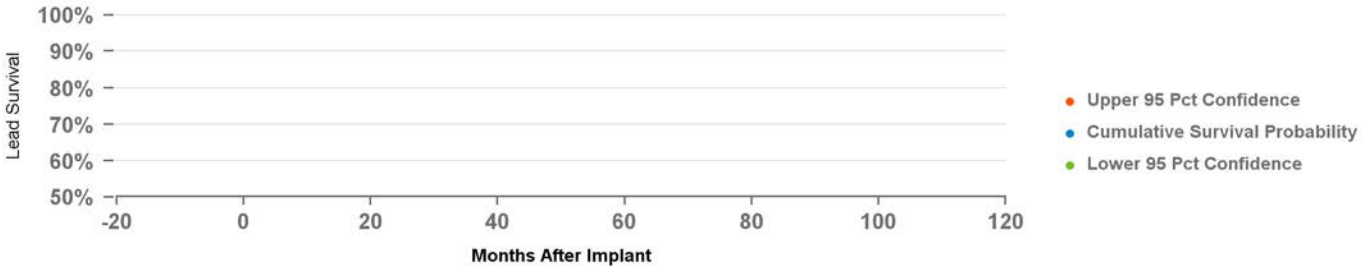
## 6946M Sprint Quattro

| | |
|---|---|
| US Market Release | 05Jan2016 |
| CE Approval | 12Sep2013 |
| Registered USA Implants | 3,992 |
| Estimated Active USA Implants | 3,456 |
| 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 | 4 |
| Failure to Sense | 2 |
| Lead Dislodgement | 7 |
| Oversensing | 6 |




| Years | at mo |
|---|---|
| % | |
| # | |

# 6947 Sprint Quattro Secure

| | |
|---|---|
| US Market Release | 12Nov2001 |
| CE Approval | 04Oct2001 |
| Registered USA Implants | 375,502 |
| Estimated Active USA Implants | 126,103 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1,398 |
| Insulation Breach | 103 |
| Crimp/Weld/Bond | 4 |
| Other | 197 |

## US Acute Lead Observations

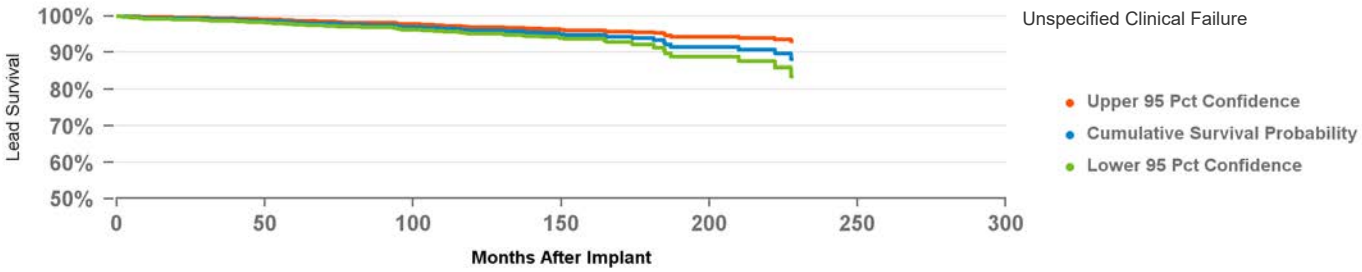
| | |
|---|---|
| Cardiac Perforation | 29 |
| Conductor Fracture | 26 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 83 |
| Failure to Sense | 36 |
| Impedance Out of Range | 61 |
| Insulation Breach | 4 |
| Lead Dislodgement | 124 |
| Oversensing | 141 |
| Unspecified Clinical Failure | 20 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 4,568 |
| Number of Leads Active in Study | 618 |
| Cumulative Months of Follow-Up | 294,892 |

## Qualifying Complications 102

| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 39 |
| Failure to Capture | 8 |
| Failure to Sense | 2 |
| Impedance Out of Range | 13 |
| Insulation (not further defined) | 6 |
| Lead Dislodgement | 5 |
| Oversensing | 21 |
| Other | 4 |
| Unspecified Clinical Failure | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | at 228 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.0% | 98.7% | 98.2% | 97.9% | 97.5% | 97.1% | 96.7% | 96.1% | 95.8% | 95.4% | 94.9% | 94.3% | 93.9% | 91.5% | 91.5% | 90.7% | 88.2% |
| # | 3,297 | 2,899 | 2,546 | 2,255 | 2,022 | 1,782 | 1,533 | 1,372 | 1,223 | 1,049 | 861 | 638 | 456 | 280 | 177 | 139 | 117 | 98 | 59 |

## 6947M Sprint Quattro Secure

| | |
|---|---|
| US Market Release | 13Feb2012 |
| CE Approval | 12Mar2010 |
| Registered USA Implants | 135,943 |
| Estimated Active USA Implants | 93,778 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 248 |
| Insulation Breach | 15 |
| Crimp/Weld/Bond | 1 |
| Other | 37 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 40 |
| Conductor Fracture | 15 |
| Extra Cardiac Stimulation | 12 |
| Failure to Capture | 117 |
| Failure to Sense | 46 |
| Impedance Out of Range | 37 |
| Insulation Breach | 1 |
| Lead Dislodgement | 238 |
| Oversensing | 85 |

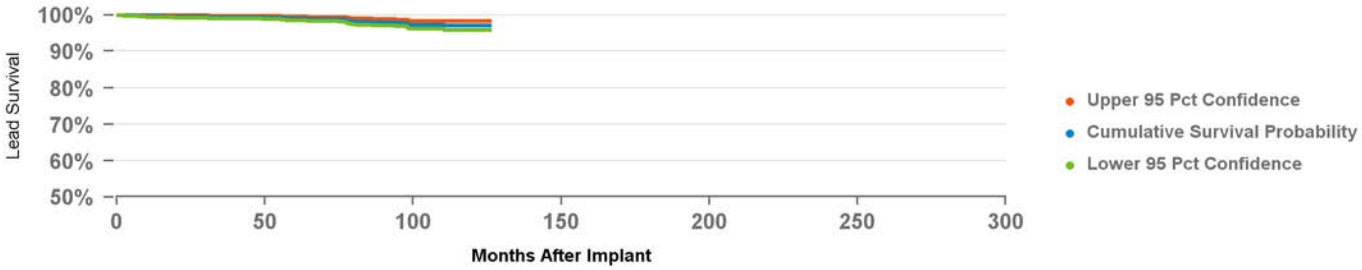
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,378 |
| Number of Leads Active in Study | 693 |
| Cumulative Months of Follow-Up | 128,937 |

### Qualifying Complications

**28**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 126 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.5% | 99.4% | 99.4% | 99.0% | 98.9% | 98.1% | 97.8% | 97.3% | 97.1% | 97.1% |
| # | 1,834 | 1,547 | 1,363 | 1,157 | 1,002 | 838 | 697 | 575 | 453 | 222 | 94 |

## 6948 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 10,381 |
| Estimated Active USA Implants | 1,650 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

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

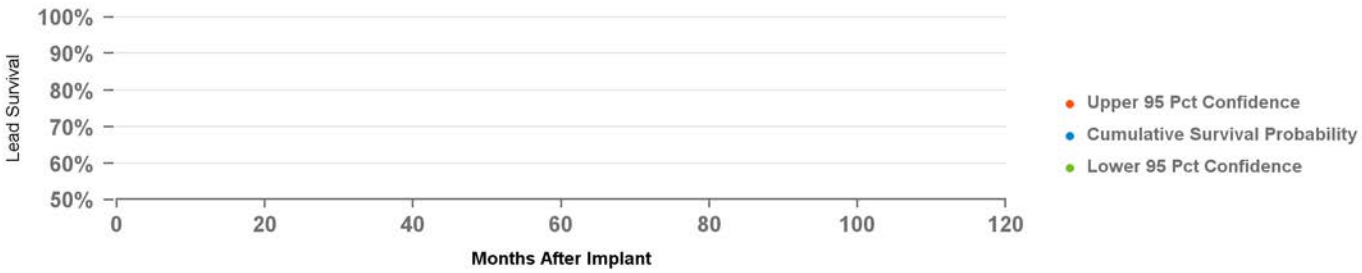
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 40 |
| Number of Leads Active in Study | 3 |
| Cumulative Months of Follow-Up | 2,301 |

### Qualifying Complications

**5**

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




| Years | at 0 mo |
|---|---|
| % | ##### |
| # | |

## 6949 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 186,212 |
| Estimated Active USA Implants | 24,351 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 8,157 |
| Insulation Breach | 37 |
| Crimp/Weld/Bond | 3 |
| Other | 119 |

### US Acute Lead Observations

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

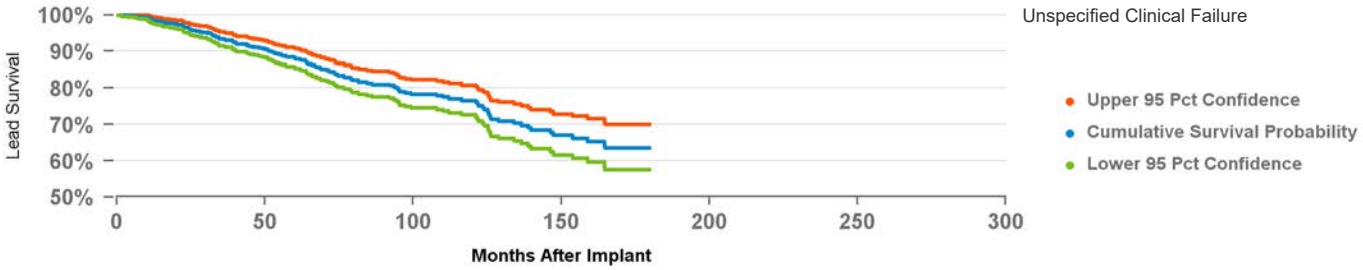
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 986 |
| Number of Leads Active in Study | 35 |
| Cumulative Months of Follow-Up | 57,726 |

### Qualifying Complications

**135**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 180 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.6% | 96.5% | 93.4% | 91.0% | 88.2% | 84.5% | 81.6% | 79.0% | 78.0% | 76.6% | 70.9% | 68.5% | 66.2% | 63.5% | 63.5% |
| # | 719 | 626 | 532 | 458 | 392 | 343 | 281 | 236 | 187 | 152 | 125 | 96 | 79 | 65 | 54 |

## 6996 Sub-Q Lead

| | |
|---|---|
| US Market Release | 11Jun2001 |
| CE Approval | 19Dec1997 |
| Registered USA Implants | 5,694 |
| Estimated Active USA Implants | 2,558 |
| Fixation Type | Suture on Anchor Sleeve |
| Pace Sense Polarity | One Coil |
| Steroid Indicator | None |

### US Returned Product Analysis

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

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 1 |
| Failure to Capture | 1 |
| Impedance Out of Range | 18 |
| Insulation Breach | 1 |
| Lead Dislodgement | 3 |
| Oversensing | 1 |

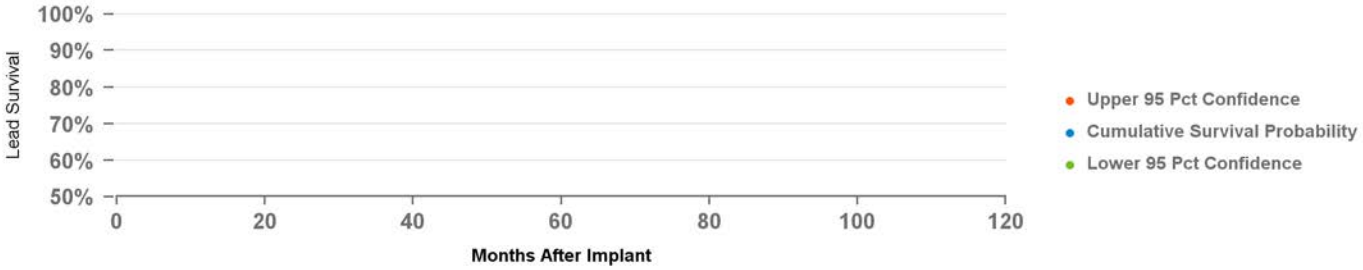
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 55 |
| Number of Leads Active in Study | 4 |
| Cumulative Months of Follow-Up | 2,554 |

### Qualifying Complications

**4**

| | |
|---|---|
| Conductor Fracture | 1 |
| Failure to Capture | 0 |
| Impedance Out of Range | 3 |
| Other | 0 |




| Years | at 0 mo |
|---|---|
| % | ##### |
| # | |

## 2187 Attain LV

| | |
|---|---|
| US Market Release | 28Aug2001 |
| CE Approval | |
| Registered USA Implants | 11,921 |
| Estimated Active USA Implants | 986 |
| Fixation Type | Distal Continous Curve |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | None |

### US Returned Product Analysis

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

### US Acute Lead Observations

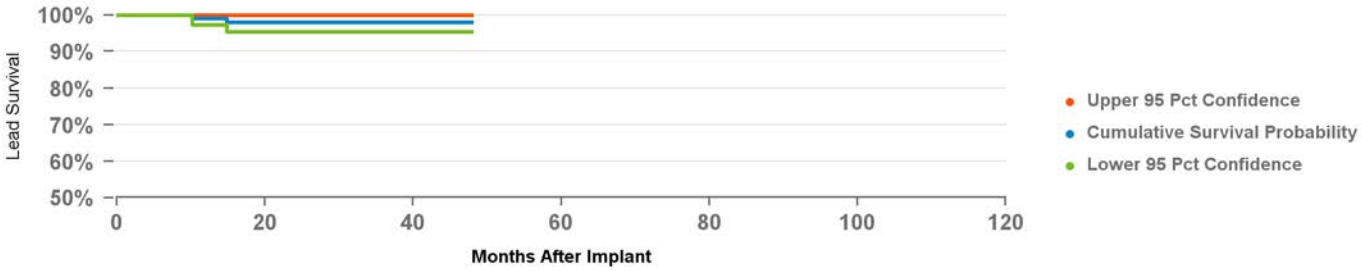
| | |
|---|---|
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 3 |
| Failure to Sense | 1 |
| Lead Dislodgement | 9 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 140 |
| Number of Leads Active in Study | 5 |
| Cumulative Months of Follow-Up | 7,196 |

### Qualifying Complications 3

| | | | |
|---|---|---|---|
| Failure to Capture | 3 | Impedance Out of Range | 0 |
| | | Other | 0 |




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

## 4193 Attain OTW

| | |
|---|---|
| US Market Release | 03May2002 |
| CE Approval | 22Dec2000 |
| Registered USA Implants | 100,664 |
| Estimated Active USA Implants | 12,282 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

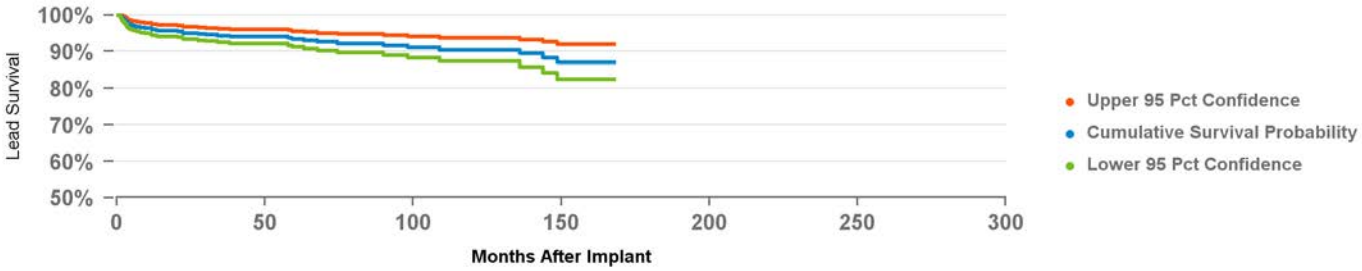
| | |
|---|---|
| Extra Cardiac Stimulation | 18 |
| Failure to Capture | 11 |
| Lead Dislodgement | 45 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 2 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 805 |
| Number of Leads Active in Study | 25 |
| Cumulative Months of Follow-Up | 42,382 |

### Qualifying Complications 52

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Impedance Out of Range | 2 |
| Extra Cardiac Stimulation | 10 | Lead Dislodgement | 16 |
| Failure to Capture | 20 | Other | 0 |
| | | Unspecified Clinical Failure | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 96.0% | 95.1% | 94.4% | 94.1% | 93.4% | 92.6% | 92.2% | 91.7% | 91.2% | 90.5% | 90.5% | 88.4% | 87.2% | 87.2% |
| # | 569 | 444 | 376 | 304 | 252 | 228 | 193 | 171 | 139 | 118 | 97 | 78 | 62 | 50 |

## 4194 Attain OTW

| | |
|---|---|
| US Market Release | 24Aug2004 |
| CE Approval | 14Jul2003 |
| Registered USA Implants | 114,259 |
| Estimated Active USA Implants | 28,808 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 48 |
| Insulation Breach | 165 |
| Crimp/Weld/Bond | 0 |
| Other | 2 |

### US Acute Lead Observations

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

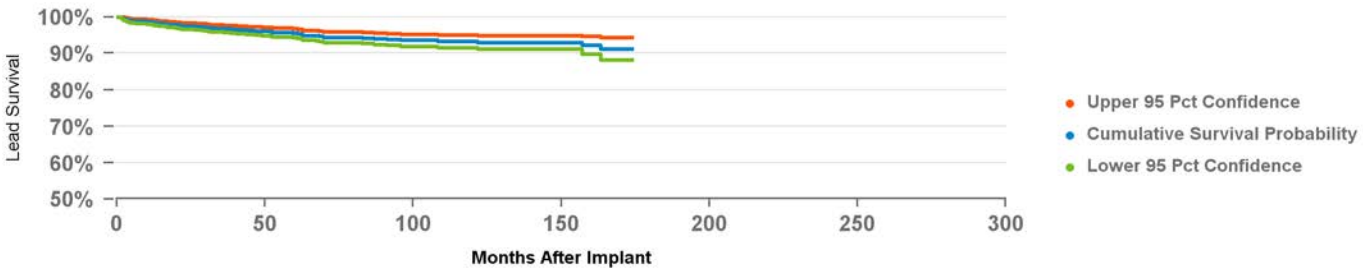
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,655 |
| Number of Leads Active in Study | 186 |
| Cumulative Months of Follow-Up | 98,854 |

### Qualifying Complications

**68**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.6% | 97.4% | 96.7% | 96.1% | 95.6% | 94.3% | 94.1% | 93.5% | 93.5% | 93.3% | 92.9% | 92.9% | 92.9% | 91.1% | 91.1% |
| # | 1,238 | 1,046 | 898 | 770 | 698 | 616 | 505 | 428 | 358 | 296 | 231 | 161 | 115 | 78 | 60 |

## 4195 Attain StarFix

| | |
|---|---|
| US Market Release | 15Aug2008 |
| CE Approval | 13May2005 |
| Registered USA Implants | 17,444 |
| Estimated Active USA Implants | 6,301 |
| Fixation Type | Deployable Lobe Fixation |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

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

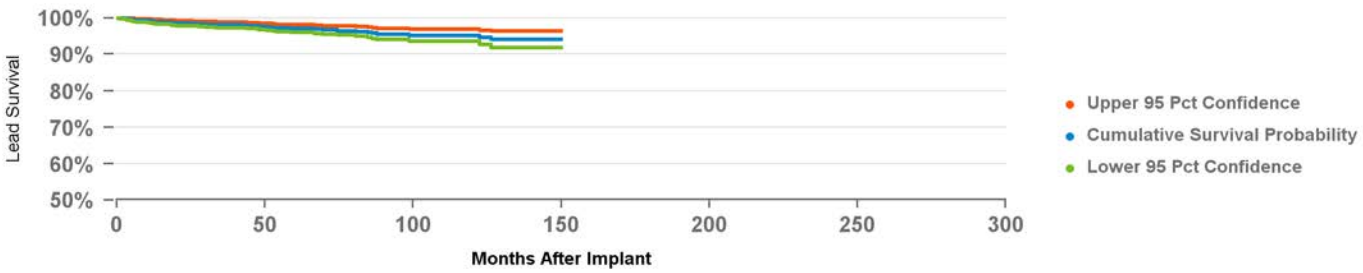
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,486 |
| Number of Leads Active in Study | 150 |
| Cumulative Months of Follow-Up | 86,820 |

### Qualifying Complications

**44**

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.1% | 98.5% | 98.1% | 97.6% | 97.0% | 96.7% | 96.3% | 95.5% | 95.2% | 95.2% | 94.0% | 94.0% | 94.0% |
| # | 1,243 | 1,072 | 924 | 747 | 620 | 509 | 412 | 319 | 250 | 190 | 126 | 80 | 54 |

# 4196 Attain Ability

| | |
|---|---|
| US Market Release | 15May2009 |
| CE Approval | 24Jul2007 |
| Registered USA Implants | 68,859 |
| Estimated Active USA Implants | 27,862 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

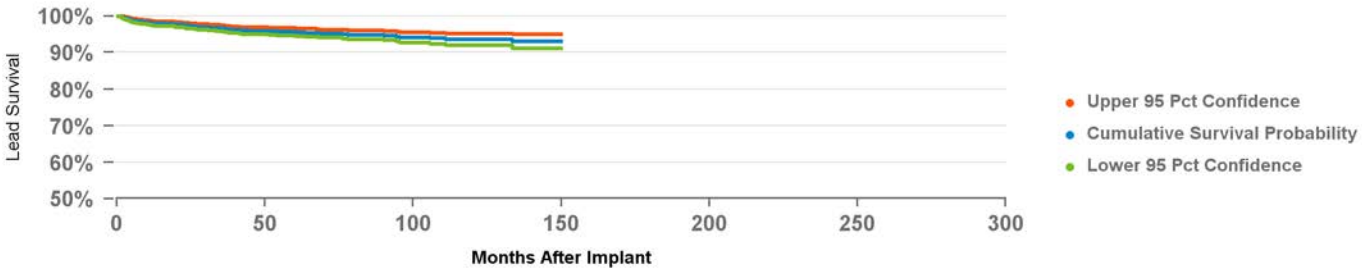
| | |
|---|---|
| Cardiac Perforation | 3 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 98 |
| Failure to Capture | 66 |
| Failure to Sense | 1 |
| Impedance Out of Range | 12 |
| Insulation Breach | 1 |
| Lead Dislodgement | 228 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,319 |
| Number of Leads Active in Study | 233 |
| Cumulative Months of Follow-Up | 117,864 |

## Qualifying Complications 87

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.0% | 97.3% | 96.6% | 95.9% | 95.7% | 95.2% | 94.8% | 94.2% | 93.9% | 93.6% | 93.6% | 93.1% | 93.1% |
| # | 1,884 | 1,494 | 1,189 | 960 | 788 | 632 | 491 | 407 | 328 | 248 | 187 | 109 | 62 |

## 4296 Attain Ability Plus

| | |
|---|---|
| US Market Release | 01Apr2011 |
| CE Approval | 18Dec2009 |
| Registered USA Implants | 35,126 |
| Estimated Active USA Implants | 17,320 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Dual Electrodes |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 2 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 63 |
| Failure to Capture | 36 |
| Impedance Out of Range | 11 |
| Insulation Breach | 4 |
| Lead Dislodgement | 119 |

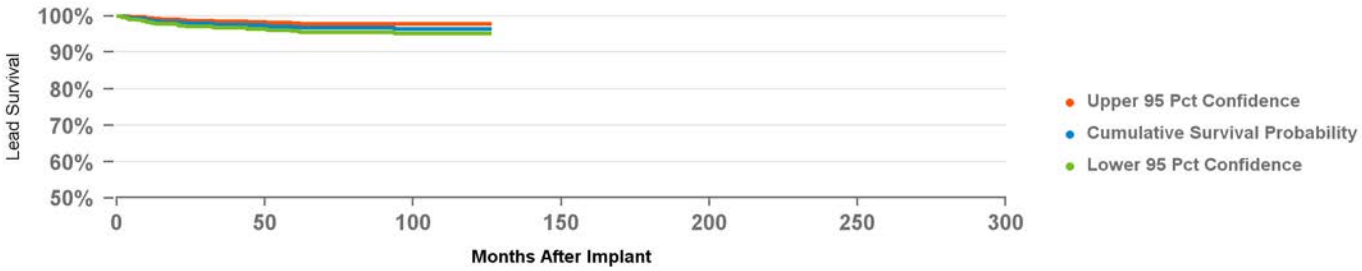
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,470 |
| Number of Leads Active in Study | 264 |
| Cumulative Months of Follow-Up | 75,878 |

### Qualifying Complications

35

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 126 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.7% | 97.9% | 97.7% | 97.4% | 96.9% | 96.7% | 96.7% | 96.4% | 96.4% | 96.4% | 96.4% |
| # | 1,162 | 939 | 772 | 655 | 550 | 465 | 400 | 321 | 236 | 115 | 64 |

## 4298 Attain Performa

| | |
|---|---|
| US Market Release | 01Aug2014 |
| CE Approval | 01Jan2013 |
| Registered USA Implants | 115,228 |
| Estimated Active USA Implants | 88,967 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 7 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 228 |
| Failure to Capture | 151 |
| Failure to Sense | 1 |
| Impedance Out of Range | 42 |
| Lead Dislodgement | 248 |

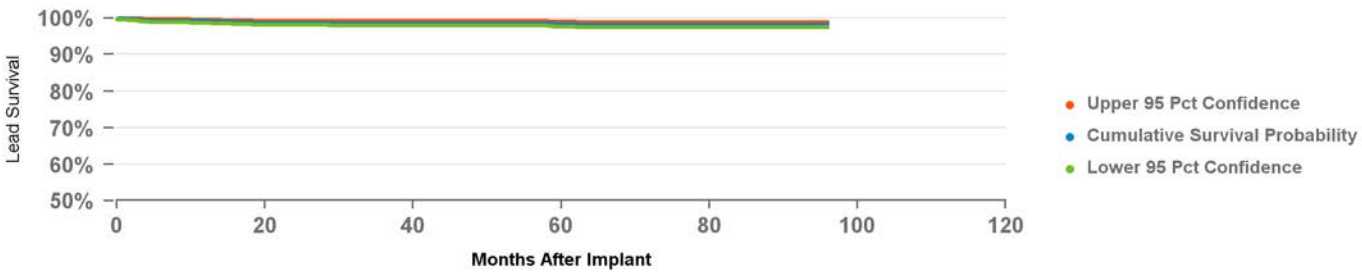
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,244 |
| Number of Leads Active in Study | 886 |
| Cumulative Months of Follow-Up | 102,599 |

### Qualifying Complications

28

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 98.7% | 98.6% | 98.6% | 98.3% | 98.2% | 98.2% | 98.2% |
| # | 1,868 | 1,580 | 1,351 | 1,043 | 751 | 516 | 300 | 85 |

## 4396 Attain Ability Straight

| | |
|---|---|
| US Market Release | 31Mar2011 |
| CE Approval | 18Dec2009 |
| Registered USA Implants | 8,366 |
| Estimated Active USA Implants | 4,363 |
| Fixation Type | Tines |
| Pace Sense Polarity | Dual Electrodes |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

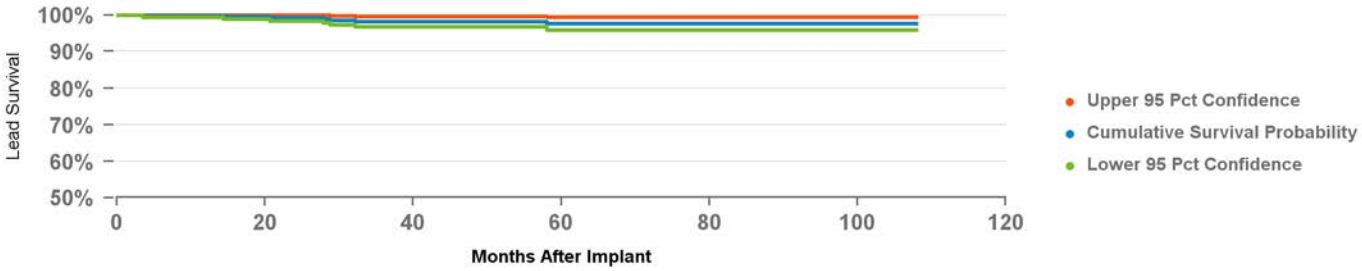
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 21 |
| Failure to Capture | 13 |
| Lead Dislodgement | 35 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 483 |
| Number of Leads Active in Study | 99 |
| Cumulative Months of Follow-Up | 25,054 |

### Qualifying Complications 10

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| % | 99.8% | 99.2% | 98.2% | 98.2% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% |
| # | 381 | 306 | 266 | 231 | 195 | 152 | 120 | 100 | 71 |

## 4398 Attain Performa Straight

| | |
|---|---|
| US Market Release | 10Dec2014 |
| CE Approval | 01Jan2013 |
| Registered USA Implants | 39,620 |
| Estimated Active USA Implants | 31,643 |
| Fixation Type | Tines |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

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

### US Acute Lead Observations

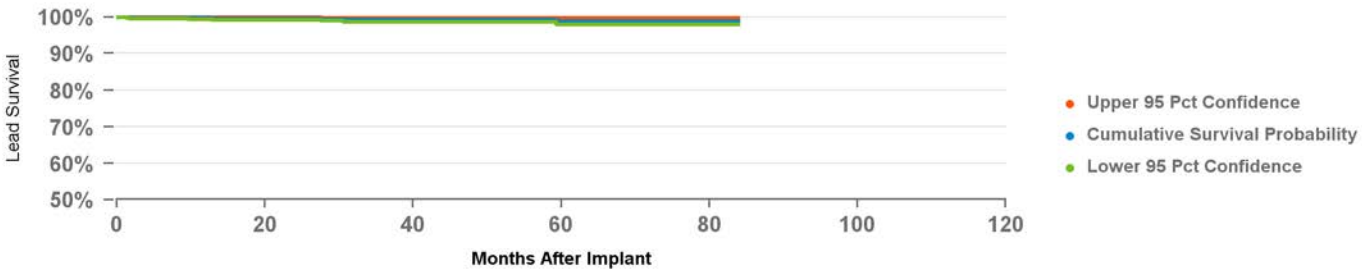
| | |
|---|---|
| Cardiac Perforation | 8 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 105 |
| Failure to Capture | 76 |
| Impedance Out of Range | 12 |
| Lead Dislodgement | 41 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,031 |
| Number of Leads Active in Study | 1,179 |
| Cumulative Months of Follow-Up | 64,512 |

### Qualifying Complications 13

| | |
|---|---|
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 4 |
| Impedance Out of Range | 1 |
| Lead Dislodgement | 7 |
| Other | 0 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 84 mo |
|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.5% | 99.2% | 99.2% | 98.9% | 98.9% | 98.9% |
| # | 1,499 | 1,143 | 836 | 542 | 281 | 129 | 54 |

## 4598 Attain Performa S

| | |
|---|---|
| US Market Release | 10Dec2014 |
| CE Approval | 01Jan2013 |
| Registered USA Implants | 73,022 |
| Estimated Active USA Implants | 59,049 |
| Fixation Type | S-shape |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 6 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 12 |

### US Acute Lead Observations

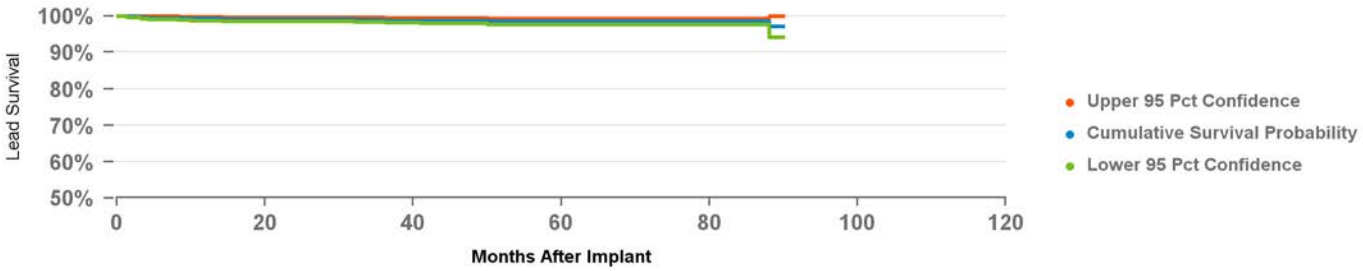
| | |
|---|---|
| Cardiac Perforation | 11 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 130 |
| Failure to Capture | 92 |
| Impedance Out of Range | 33 |
| Lead Dislodgement | 82 |
| Oversensing | 1 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,364 |
| Number of Leads Active in Study | 560 |
| Cumulative Months of Follow-Up | 57,890 |

### Qualifying Complications 17

| | | | |
|---|---|---|---|
| Extra Cardiac Stimulation | 3 | Impedance Out of Range | 0 |
| Failure to Capture | 1 | Lead Dislodgement | 12 |
| Failure to Sense | 1 | Other | 0 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 99.0% | 98.9% | 98.6% | 98.5% | 98.5% | 98.5% | 97.0% |
| # | 1,126 | 950 | 782 | 602 | 383 | 220 | 105 | 55 |

## 4798 Attain Stability Quad

| | |
|---|---|
| US Market Release | 03Jun2019 |
| CE Approval | 24Apr2017 |
| Registered USA Implants | 43,449 |
| Estimated Active USA Implants | 40,722 |
| | Non-electrically Active |
| Fixation Type | Side Fixation |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 14 |

### US Acute Lead Observations

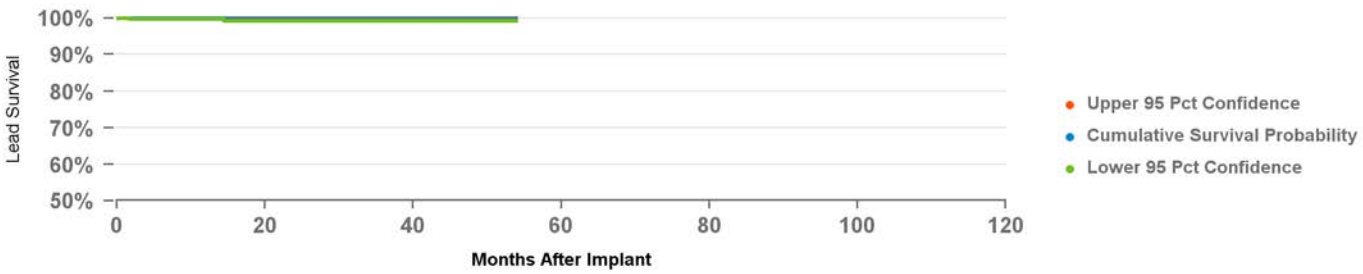
| | |
|---|---|
| Cardiac Perforation | 7 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 78 |
| Failure to Capture | 80 |
| Impedance Out of Range | 30 |
| Lead Dislodgement | 92 |
| Oversensing | 1 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,190 |
| Number of Leads Active in Study | 872 |
| Cumulative Months of Follow-Up | 18,836 |

### Qualifying Complications 3

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Impedance Out of Range | 0 |
| Extra Cardiac Stimulation | 1 | Lead Dislodgement | 1 |
| Failure to Capture | 0 | Other | 0 |




| Years | 1 | 2 | 3 | 4 | at 54 mo |
|---|---|---|---|---|---|
| % | 99.9% | 99.7% | 99.7% | 99.7% | 99.7% |
| # | 597 | 314 | 142 | 74 | 62 |

## 4965 CapSure Epi

| | |
|---|---|
| US Market Release | 06Sep1996 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 24,219 |
| Estimated Active USA Implants | 6,901 |
| Fixation Type | Suture |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 296 |
| Insulation Breach | 64 |
| Crimp/Weld/Bond | 1 |
| Other | 0 |

### US Acute Lead Observations

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

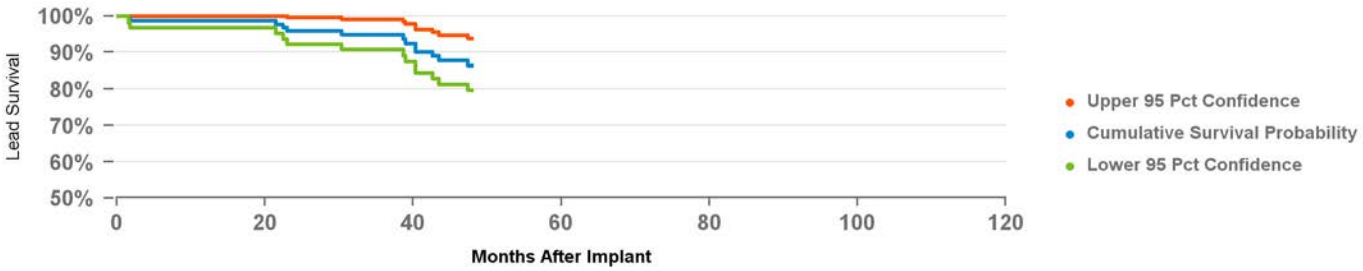
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 234 |
| Number of Leads Active in Study | 3 |
| Cumulative Months of Follow-Up | 7,569 |

### Qualifying Complications

**17**

| | |
|---|---|
| Conductor Fracture | 10 |
| Failure to Capture | 3 |
| Failure to Sense | 1 |
| Impedance Out of Range | 0 |
| Insulation (not further defined) | 1 |
| Oversensing | 2 |
| Other | 0 |




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

## 4968 CapSure Epi

| | |
|---|---|
| US Market Release | 16Sep1999 |
| CE Approval | 21Apr1998 |
| Registered USA Implants | 61,419 |
| Estimated Active USA Implants | 33,596 |
| Fixation Type | Suture |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 141 |
| Insulation Breach | 79 |
| Crimp/Weld/Bond | 0 |
| Other | 1 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 4 |
| Extra Cardiac Stimulation | 7 |
| Failure to Capture | 88 |
| Failure to Sense | 11 |
| Impedance Out of Range | 21 |
| Insulation Breach | 1 |
| Lead Dislodgement | 8 |
| Oversensing | 31 |

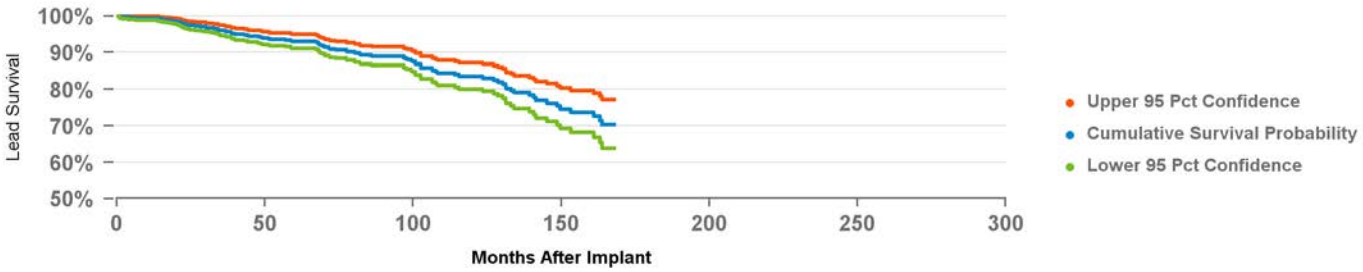
### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,050 |
| Number of Leads Active in Study | 176 |
| Cumulative Months of Follow-Up | 68,092 |

### Qualifying Complications

**104**

| | |
|---|---|
| Conductor Fracture | 31 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 29 |
| Failure to Sense | 3 |
| Impedance Out of Range | 5 |
| Insulation (not further defined) | 4 |
| Lead Dislodgement | 1 |
| Oversensing | 26 |
| Other | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.4% | 97.5% | 96.0% | 94.3% | 93.1% | 91.0% | 89.4% | 89.1% | 84.8% | 83.6% | 80.3% | 77.0% | 73.7% | 70.3% |
| # | 821 | 736 | 657 | 566 | 502 | 424 | 366 | 302 | 222 | 180 | 138 | 103 | 71 | 54 |

## 5071 Screw-in

| | |
|---|---|
| US Market Release | 03Dec1992 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 57,216 |
| Estimated Active USA Implants | 12,453 |
| Fixation Type | Fixed Screw |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | None |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 32 |
| Insulation Breach | 2 |
| Crimp/Weld/Bond | 0 |
| Other | 1 |

### US Acute Lead Observations

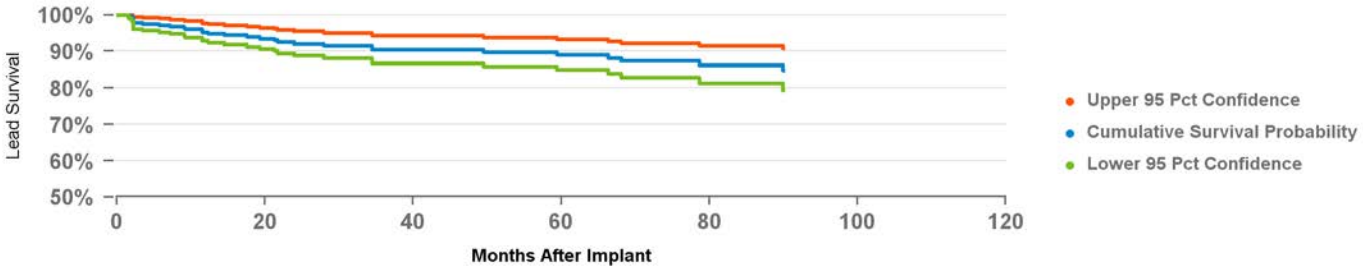
| | |
|---|---|
| Cardiac Perforation | 2 |
| Extra Cardiac Stimulation | 6 |
| Failure to Capture | 108 |
| Failure to Sense | 4 |
| Impedance Out of Range | 14 |
| Lead Dislodgement | 2 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 1 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 470 |
| Number of Leads Active in Study | 64 |
| Cumulative Months of Follow-Up | 17,254 |

### Qualifying Complications 37

| | | | |
|---|---|---|---|
| Conductor Fracture | 5 | Impedance Out of Range | 3 |
| Extra Cardiac Stimulation | 1 | Lead Dislodgement | 3 |
| Failure to Capture | 20 | Oversensing | 2 |
| Failure to Sense | 2 | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| % | 95.2% | 92.1% | 90.4% | 90.4% | 89.0% | 87.4% | 86.3% | 84.8% |
| # | 235 | 184 | 158 | 142 | 121 | 93 | 72 | 59 |

# 5038 CapSure VDD-2

| | |
|---|---|
| US Market Release | 10Sep1998 |
| CE Approval | 15Apr1997 |
| Registered USA Implants | 9,635 |
| Estimated Active USA Implants | 2,208 |
| Fixation Type | Tines |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 8 |
| Insulation Breach | 3 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

## US Acute Lead Observations

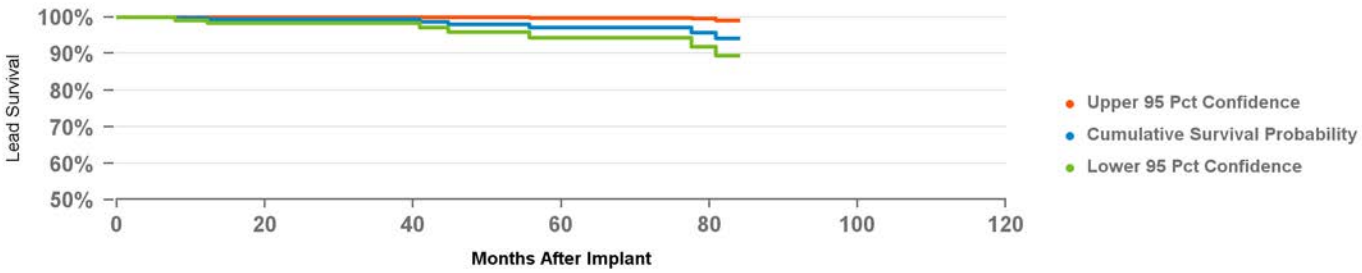
| | |
|---|---|
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 3 |
| Failure to Sense | 2 |
| Lead Dislodgement | 7 |
| Oversensing | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 570 |
| Number of Leads Active in Study | 3 |
| Cumulative Months of Follow-Up | 15,889 |

## Qualifying Complications 8

| | | | |
|---|---|---|---|
| Conductor Fracture | 3 | Impedance Out of Range | 0 |
| Failure to Capture | 2 | Other | 0 |
| Failure to Sense | 3 | | |




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

# ICD and CRT-D Charge Time Performance

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

**Introduction**

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

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

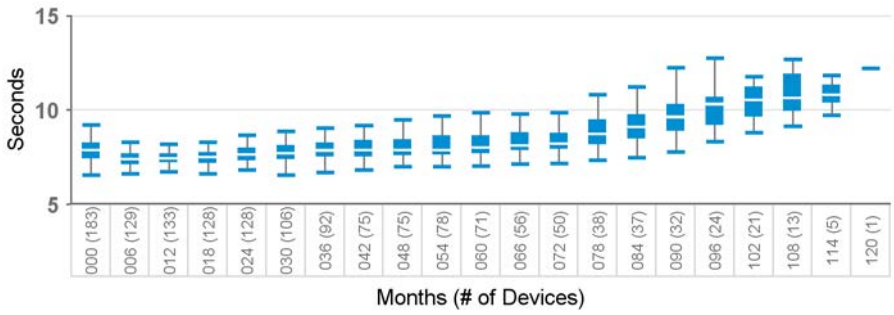
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

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

# ICD and CRT-D Charge Time Performance

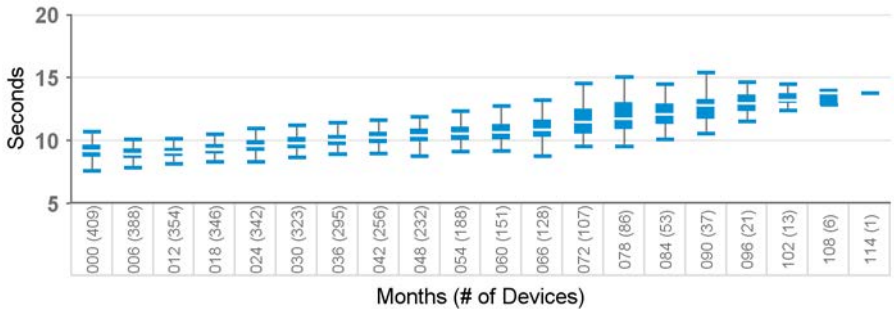
## 7232

| Model Number | Brand |
|---|---|
| 7232Cx | Maximo VR |



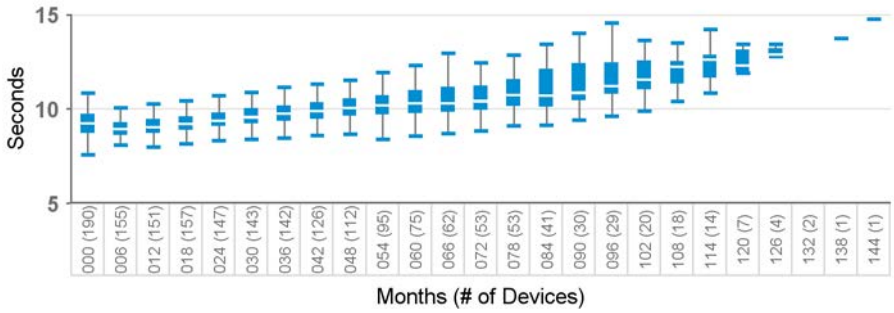

## D154AWG, D164AWG

| Model Number | Brand |
|---|---|
| D164AWG | Virtuoso DR |



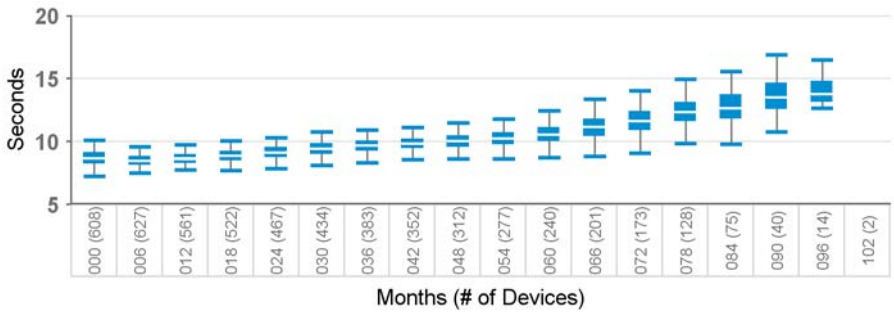

## D154VWC, D164VWC

| Model Number | Brand |
|---|---|
| D164VWC | Virtuoso VR |



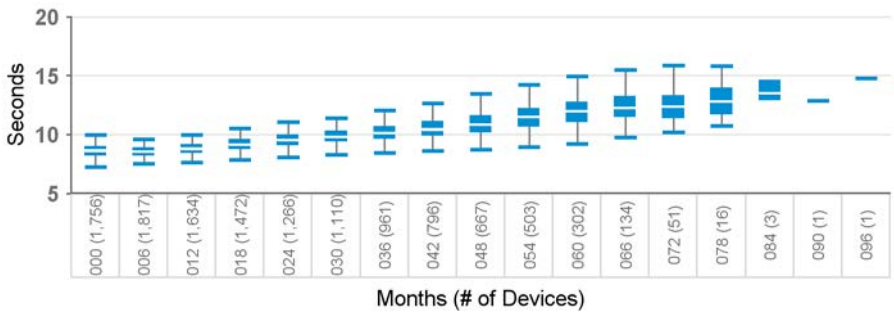

## D204DRM, D214DRM, D224DRG, D234DRG

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



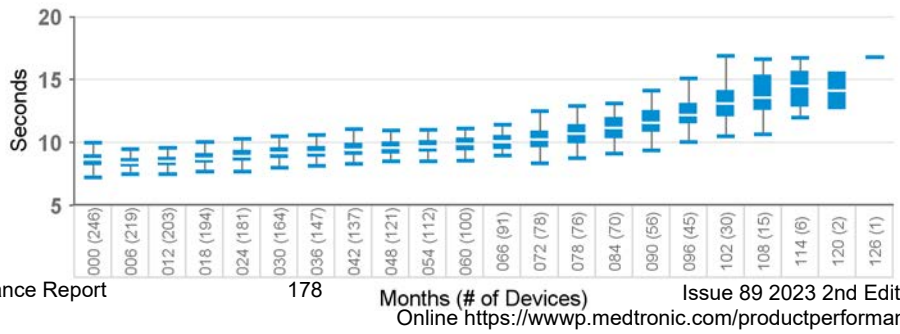

## D204TRM, D214TRM, D224TRK, D234TRK

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




## D204VRM, D214VRM, D224VRC, D234VRC

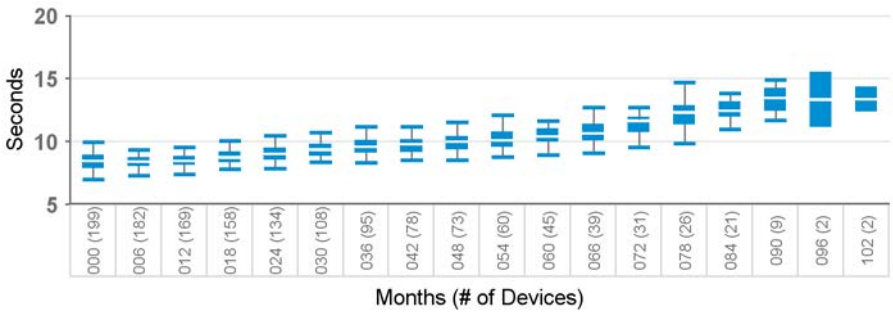
| Model Number | Brand |
|---|---|
| D204VRM | Secura VR |
| D214VRM | Secura VR |
| D224VRC | Secura VR |
| D234VRC | Secura VR |



# ICD and CRT-D Charge Time Performance

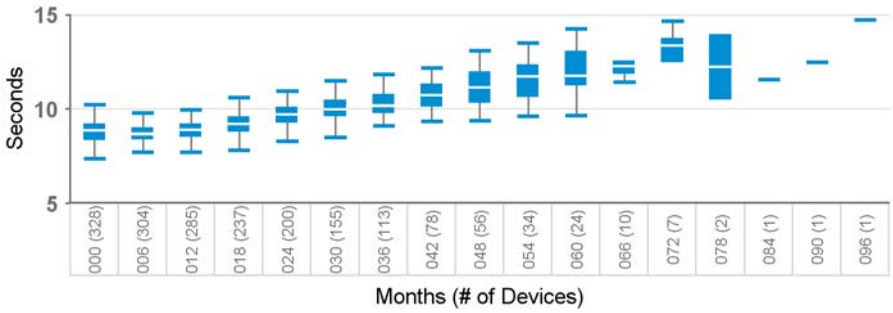
## D264DRG, D284DRG, D384DRx, D394DRx

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



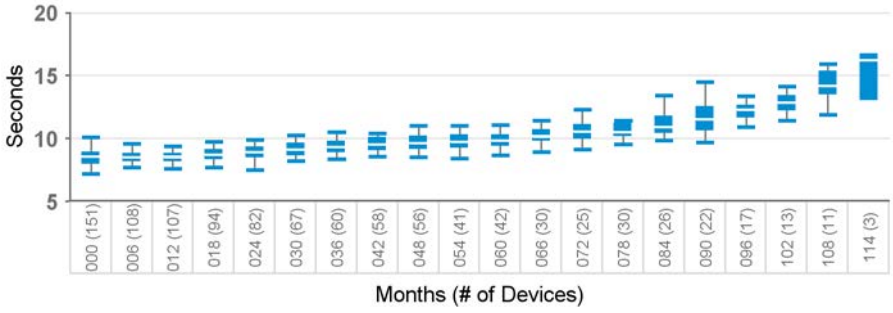

## D264TRM, D284TRK, D384TRx, D394TRx

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



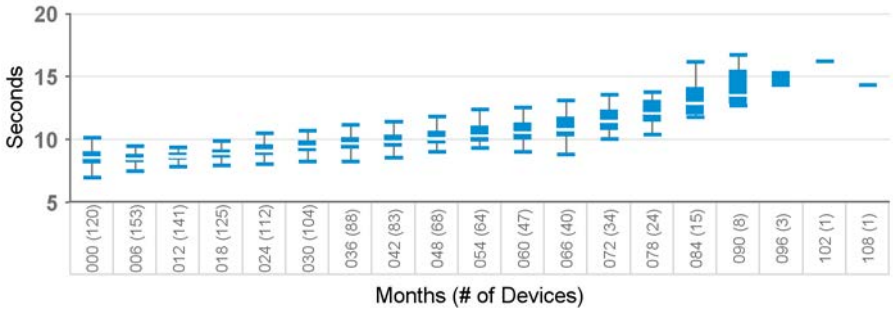

## D264VRM, D284VRC, D384VRx, D394VRx

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



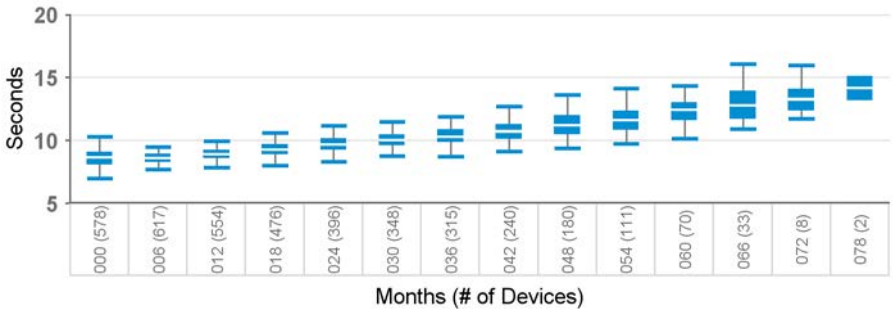

## D274DRG, D294DRG

| Model Number | Brand |
|---|---|
| D274DRG | Virtuoso II DR |
| D294DRG | Virtuoso II DR |



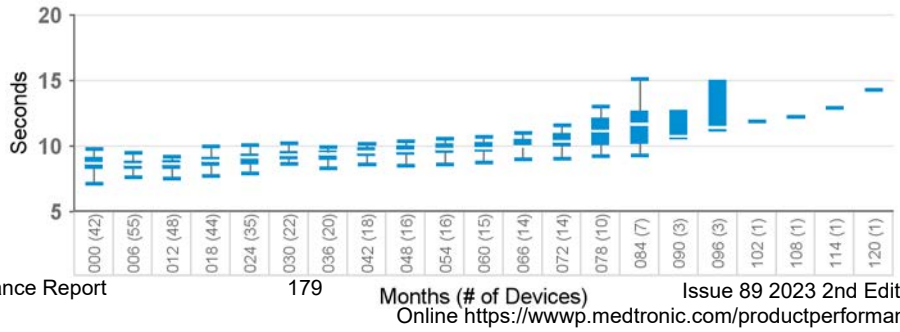

## D274TRK, D294TRK

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




## D274VRC, D294VRC

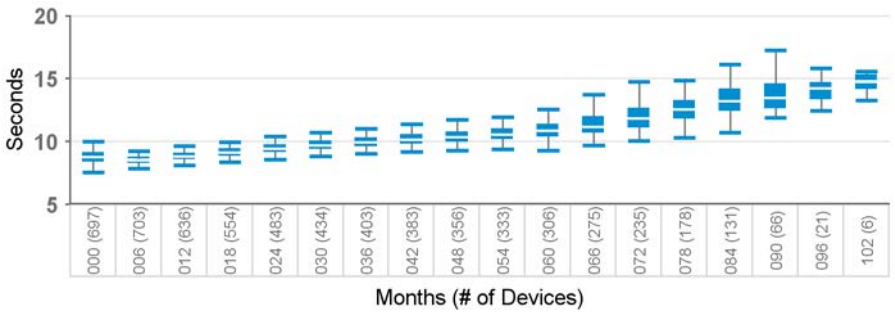
| Model Number | Brand |
|---|---|
| D274VRC | Virtuoso II VR |
| D294VRC | Virtuoso II VR |



# ICD and CRT-D Charge Time Performance

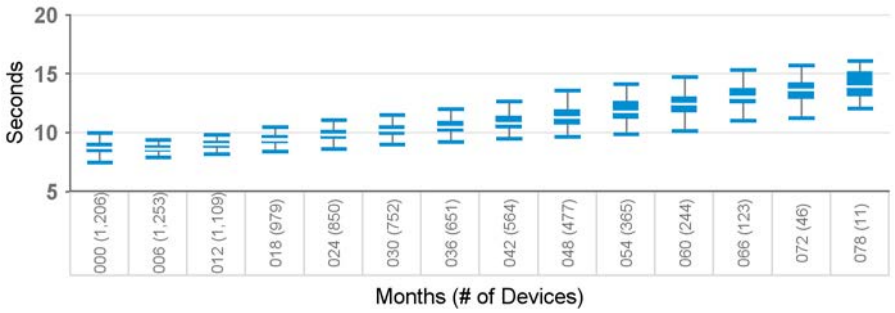
## D314DRx

| Model Number | Brand |
|---|---|
| D314DRG | Protecta XT DR |
| D314DRM | Protecta XT DR |



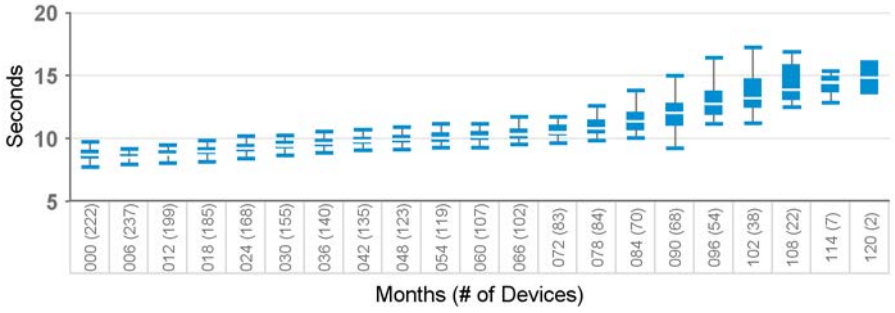

## D314TRx

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



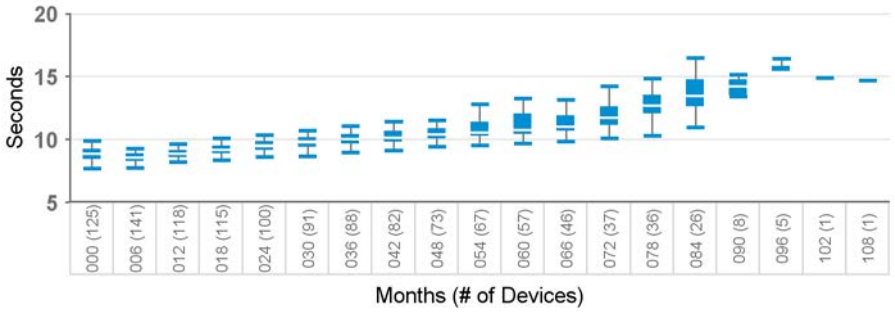

## D314VRx

| Model Number | Brand |
|---|---|
| D314VRG | Protecta XT VR |
| D314VRM | Protecta XT VR |



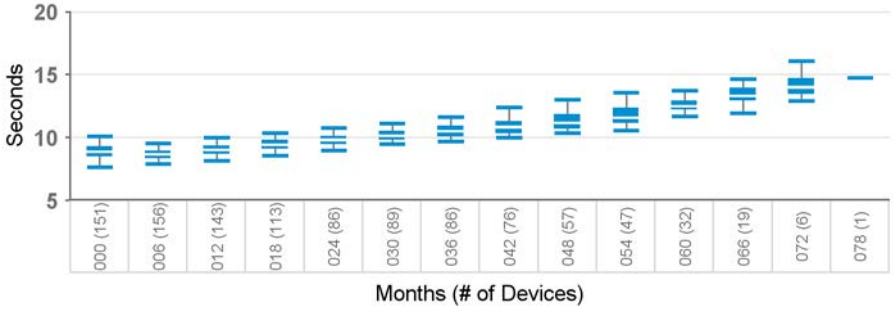

## D334DRx, D364DRx

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



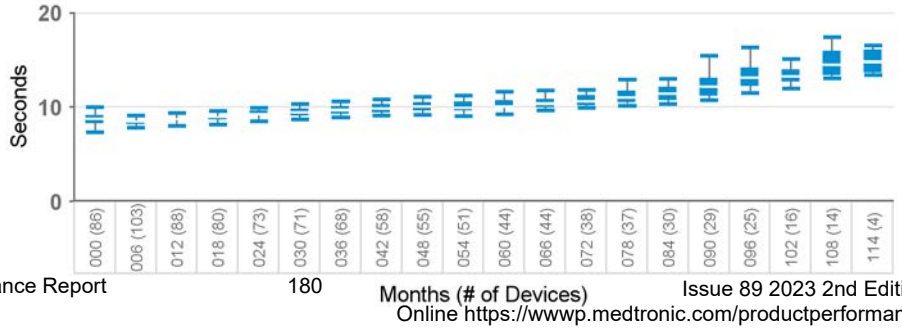

## D334TRx, D364TRx

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




## D334VRx, D364VRx

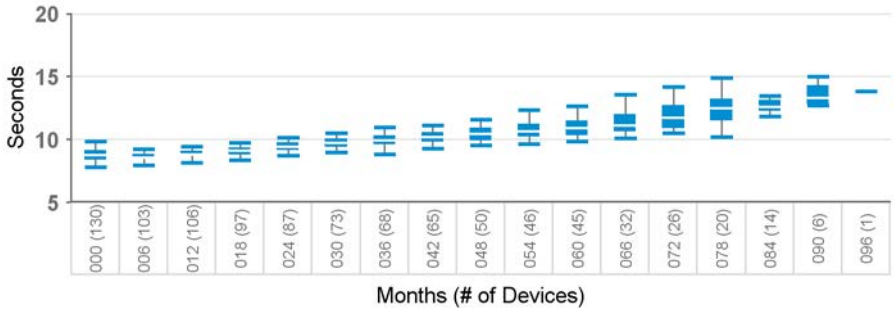
| Model Number | Brand |
|---|---|
| D334VRG | Protecta VR |
| D334VRM | Protecta VR |
| D364VRG | Protecta VR |
| D364VRM | Protecta VR |



# ICD and CRT-D Charge Time Performance

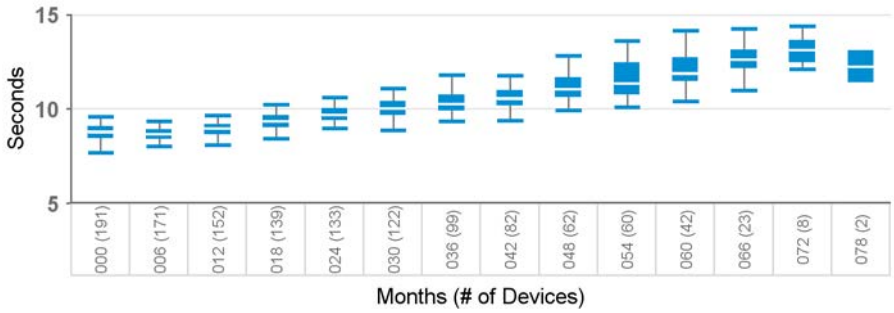
## D354DRx

| Model Number | Brand |
|---|---|
| D354DRG | Protecta XT DR |
| D354DRM | Protecta XT DR |



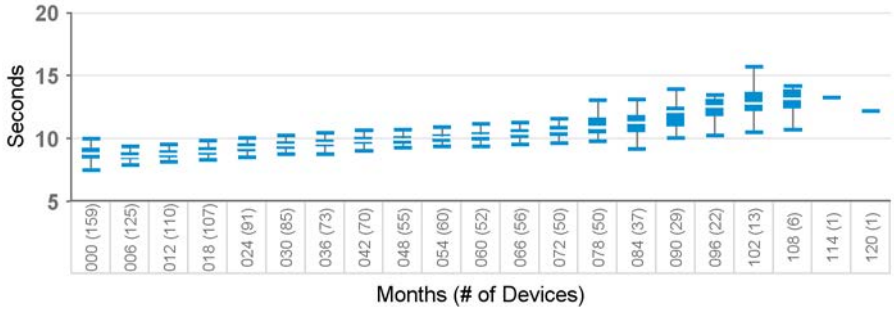

## D354TRx

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



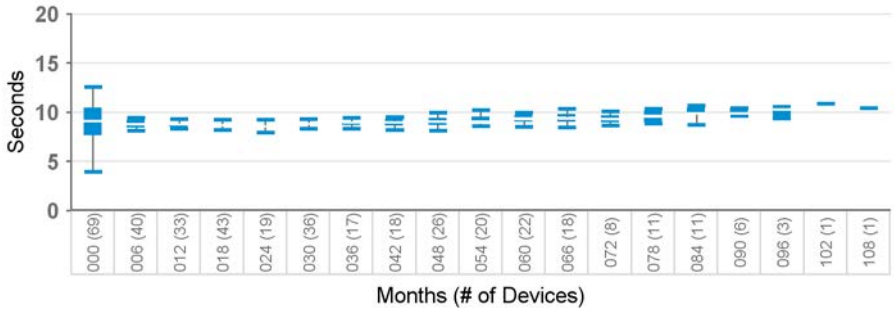

## D354VRx

| Model Number | Brand |
|---|---|
| D354VRG | Protecta XT VR |
| D354VRM | Protecta XT VR |




## DDxxxxx, DR

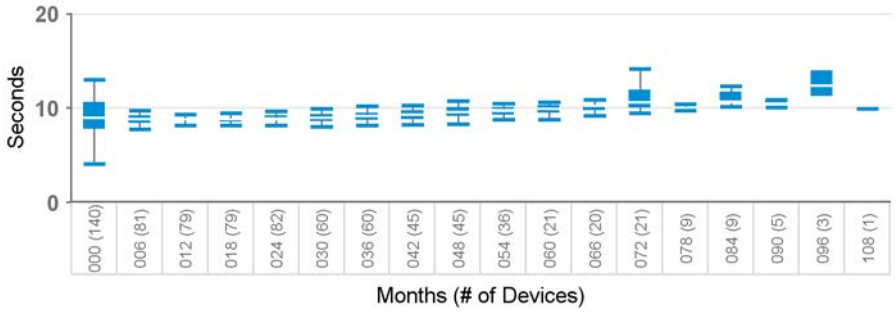
| Model Number | Brand |
|---|---|
| DDBB1D1 | Evera XT |
| DDBB1D4 | Evera XT |
| DDBB2D1 | Evera XT |
| DDBB2D4 | Evera XT |
| DDBC3D1 | Evera S |
| DDBC3D4 | Evera S |
| DDMB1D1 | Evera MRI XT |
| DDMB1D4 | Evera MRI XT |
| DDMB2D1 | Evera MRI XT |
| DDMB2D4 | Evera MRI XT |
| DDMC3D1 | Evera MRI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



# ICD and CRT-D Charge Time Performance

## DTxxxxx, CRT-D

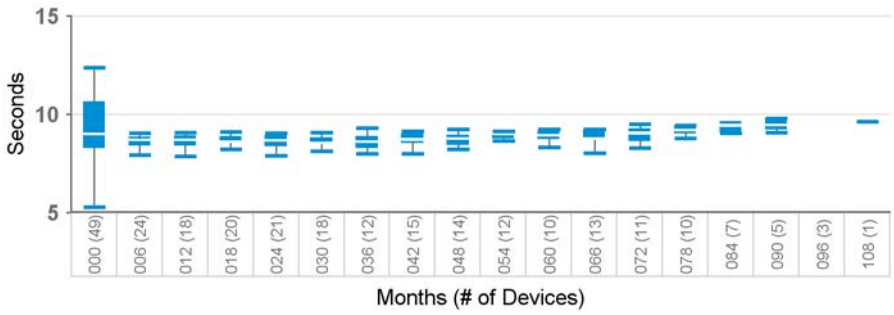
| Model Number | Brand |
|---|---|
| DTBA1D1 | Viva XT |
| DTBA1D4 | Viva XT |
| DTBA1Q1 | Viva Quad XT |
| DTBA1QQ | Viva Quad XT |
| DTBA2D1 | Viva XT |
| DTBA2D4 | Viva XT |
| DTBA2Q1 | Viva Quad XT |
| DTBA2QQ | Viva Quad XT |
| DTBB1D1 | Viva S |
| DTBB1D4 | Viva S |
| DTBB1Q1 | Viva Quad S |
|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



# ICD and CRT-D Charge Time Performance

## DVxxxxx, VR

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



# LINQ II ICM Potential for Amplified Noise

## LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: November 2023

**ORIGINAL COMMUNICATION - NOVEMBER 2023**

This notice is to inform risk managers/healthcare professionals that a population of LINQ II ICMs underwent a manufacturing process that may allow for moisture to impact electrode performance. This may create the potential for amplified noise and/or overall signal reduction of the ICM, which may interfere with intended recordings of heart rhythms. This noise pattern is different from occasional noise due to device position/migration, patient activity, or external electromagnetic interference.

As of 25 August 2023, Medtronic has analyzed and confirmed 7 returned devices that have exhibited these characteristics, with zero (0) reports of serious harm due to this issue. The potential for this behavior is limited to a population of 30,074 devices manufactured prior to September 2022. A small number of potentially unused LINQ II devices manufactured before September 2022 were requested to be returned to Medtronic. Based on an analysis of this specific population transmitting on CareLink, Medtronic estimates this issue has the potential to occur in 1.26% of these devices over a period of 4.5 years. If this occurs, potential harms include delayed medical intervention, missed diagnosis, and/or early device replacement.

**PATIENT MANAGEMENT RECOMMENDATIONS:**

In consultation with our Independent Physician Quality Panel (IPQP), Medtronic emphasizes continued care of patients implanted with an ICM in scope of this communication as per the existing device labeling.

- Encourage enrollment in and regular transmissions to CareLink.
    - Medtronic will apply recurring algorithmic searches on CareLink for the noise pattern and notify the clinician if present. The information used to identify this pattern is not visible to the clinician through CareLink. No further action is required for patients regularly transmitting to CareLink.
- For patients not followed in CareLink:
    - Consider whether enrolling in CareLink is an option, per HRS/EHRA/APHRS/LAHRS guidance.[1] Ongoing CareLink monitoring will reduce the potential for episodes caused by amplified noise to overwrite true episodes before they are reviewed.
    - If noise interferes with the ability to assess the patient's rhythm or reason for monitoring, contact Medtronic Technical Services for assistance (dxhelp@medtronic.com or 1-800-929-4043).
- If the ICM is no longer in use, no further action is necessary.

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

# Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

## Cobalt™ XT, Cobalt and Crome™ ICDs and CRT-Ds

Original Date of Communication: May 2023

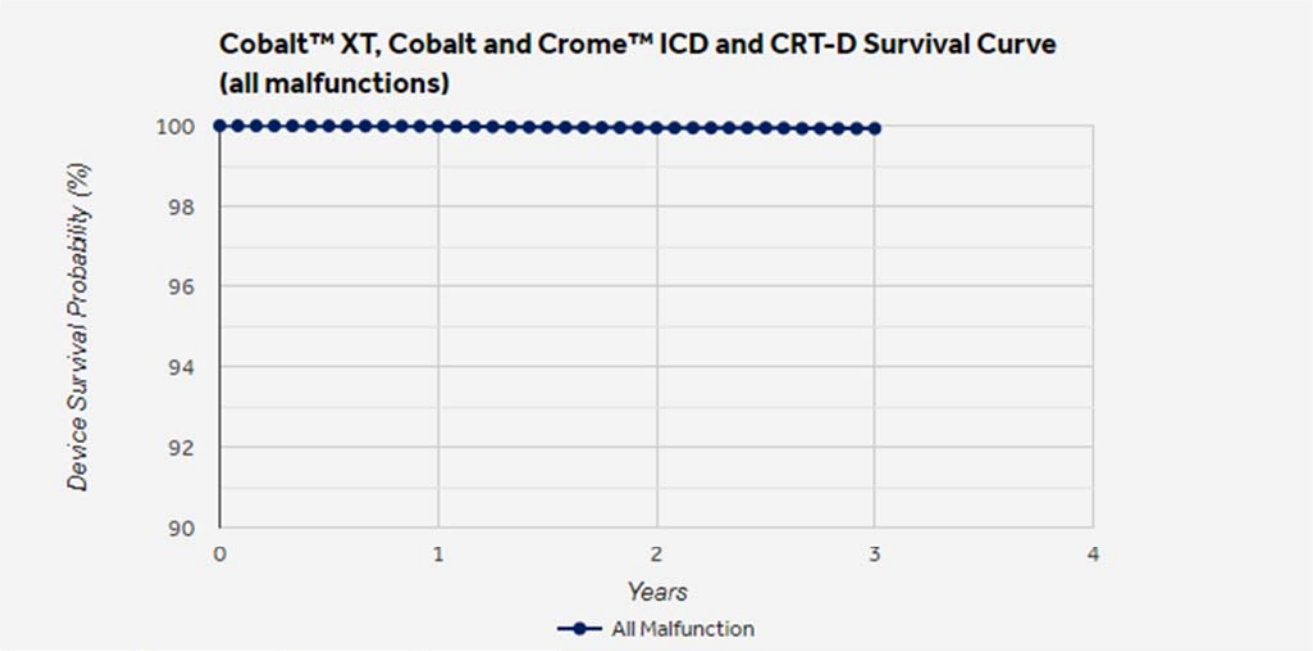
**Devices managed with an updated SmartSync tablet (device application software 8.1.0 or higher) are no longer in scope of the May 2023 communication.**

**STATUS UPDATE - NOVEMBER 2023**

As of 14 November 2023, Medtronic has identified 32 devices (representing 0.003% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the patient management recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

Medtronic is releasing a software update that aligns SmartSync tablets with the programming recommendations. This update is available in the United States and Europe and will be made available in other geographies and on other programming platforms pending regulatory approvals. Devices managed with an updated SmartSync tablet (device application software 8.1.0 or higher) are no longer in scope of the May 2023 communication.

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




| | 1 yr | 2 yr | 3 yr |
|---|---|---|---|
| % | 100.0% | 99.9% | 99.9% |
| # | 64,331 | 36,670 | 4,763 |

**ORIGINAL COMMUNICATION - MAY 2023**

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

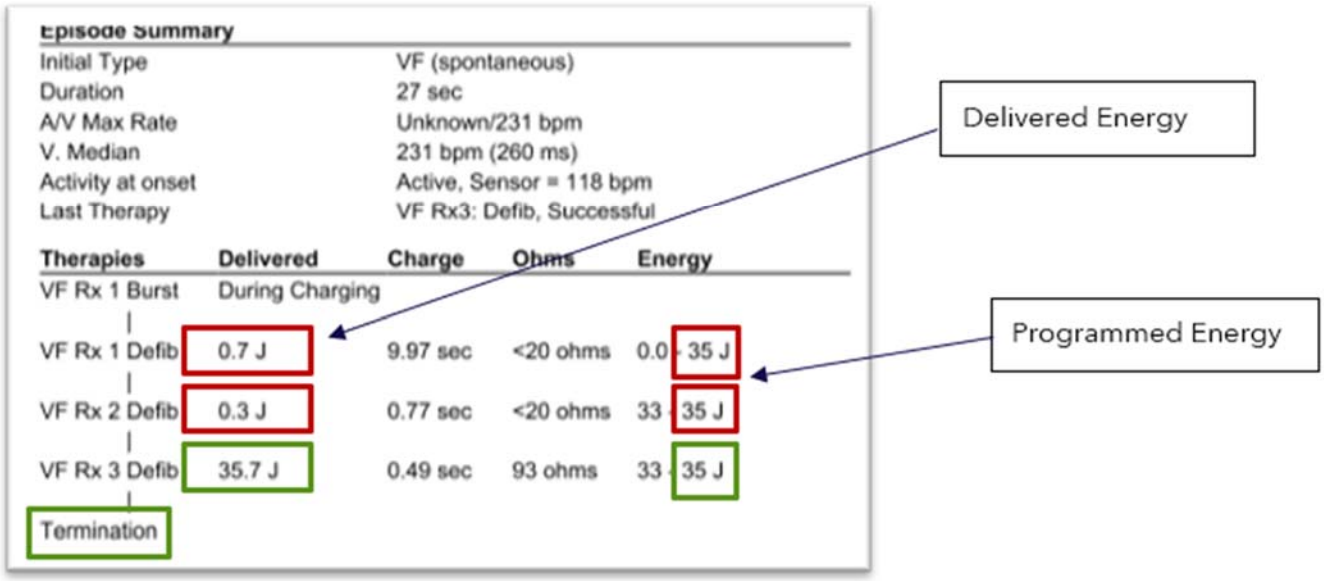
A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

**PATIENT MANAGEMENT RECOMMENDATIONS:**

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).




Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

**ISSUE DETAILS:**

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

**RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:**

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm.

Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

**TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming**

| Population | | Projected event rate (one or more reduced- or no-energy HV therapies in an episode) | Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia |
|---|---|---|---|
| **Glassed feedthrough devices with current field programming (~816,000 devices)** | Overall Population of Devices | **0.02% @ 5 years*** | **0.004% @ 5 years*** |
| | For Patients with History of HV Therapy | **0.48% @ 5 years*** | **0.08% @ 5 years*** |
| **Glassed feedthrough devices after all HV pathways reprogrammed B>AX** | Overall Population of Devices | **0.005% @ 9 years**** | **0.001% @ 9 years**** |
| | For Patients with History of HV Therapy | **0.04% @ 9 years**** | **0.01% @ 9 years**** |
| **Historical devices dating back to 2012 (~651,000 devices)** | Overall Population of Devices | **0.006% @ 9years**** | **0.001% @ 9years**** |
| | For Patients with History of HV Therapy | **0.05% @ 9 years**** | **0.01% @ 9 years**** |

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

**APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)**

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device. **Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Cobalt/Crome ICD and CRT-D devices:

Identifying SCP events during high voltage (HV) therapy delivery: When an SCP event has occurred, the device will issue an RV Defibrillation Lead Impedance CareAlert. Audible and wireless alerts are issued, if enabled. These devices are shipped with alerts enabled and are nominally active once implant detection completes.

A CareAlert will occur simultaneous with HV therapy delivery and will specifically report "RV Defib Lead Impedance 0 Ω" with the same time stamp as the therapy delivery. The alert condition is displayed in the CareAlert Events log (Data >> CareAlert Events). The Quick Look Observations will also display "Alert: RV defib lead impedance warning on Mmm/DD/YYYY." SCP events are not reflected in the long-term lead impedance trends.

Following an SCP event in devices with both the SVC Coil and Active Can enabled, the device will turn off the SVC coil. If the SCP event is caused by a lead integrity issue involving the SVC coil, turning off the SVC coil can allow any subsequent shocks to be delivered using the RV Coil -to- Active Can vector. The programmed therapy parameters will indicate the SVC Coil has been automatically disabled. The SVC coil will remain off until it is turned back on by the clinician.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

# Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

## Claria, Amplia, Compia, Viva, Brava, Visia AF, Evera, Primo, Mirro ICDs & CRT-Ds

Original Date of Communication: May 2023

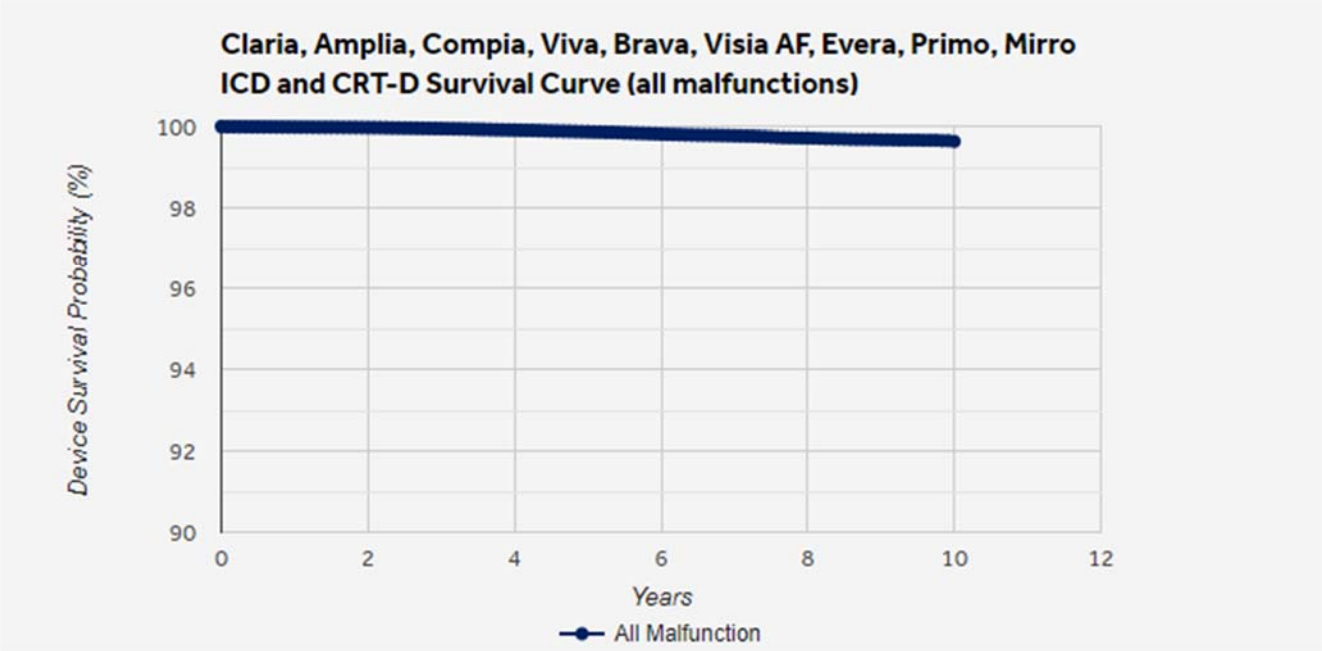
**Devices managed with an updated SmartSync tablet (device application software 2.1.0 or higher) are no longer in scope of the May 2023 communication.**

**STATUS UPDATE - NOVEMBER 2023**

As of 14 November 2023, Medtronic has identified 32 devices (representing 0.003% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

Medtronic is releasing a software update that aligns SmartSync tablets with the programming recommendations. This update is available in the United States and Europe and will be made available in other geographies, and on other programming platforms, pending regulatory approvals. Devices managed with an updated SmartSync tablet (device application software 2.1.0 or higher) are no longer in scope of the May 2023 communication.

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




| | 1 yr | 2 yr | 3 yr | 4 yr | 5 yr | 6 yr | 7 yr | 8 yr | 9 yr | 10 yr |
|---|---|---|---|---|---|---|---|---|---|---|
| % | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.6% |
| # | 609,368 | 534,059 | 468,269 | 386,303 | 301,458 | 219,357 | 141,219 | 78,170 | 35,459 | 6,890 |

**ORIGINAL COMMUNICATION - MAY 2023**

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

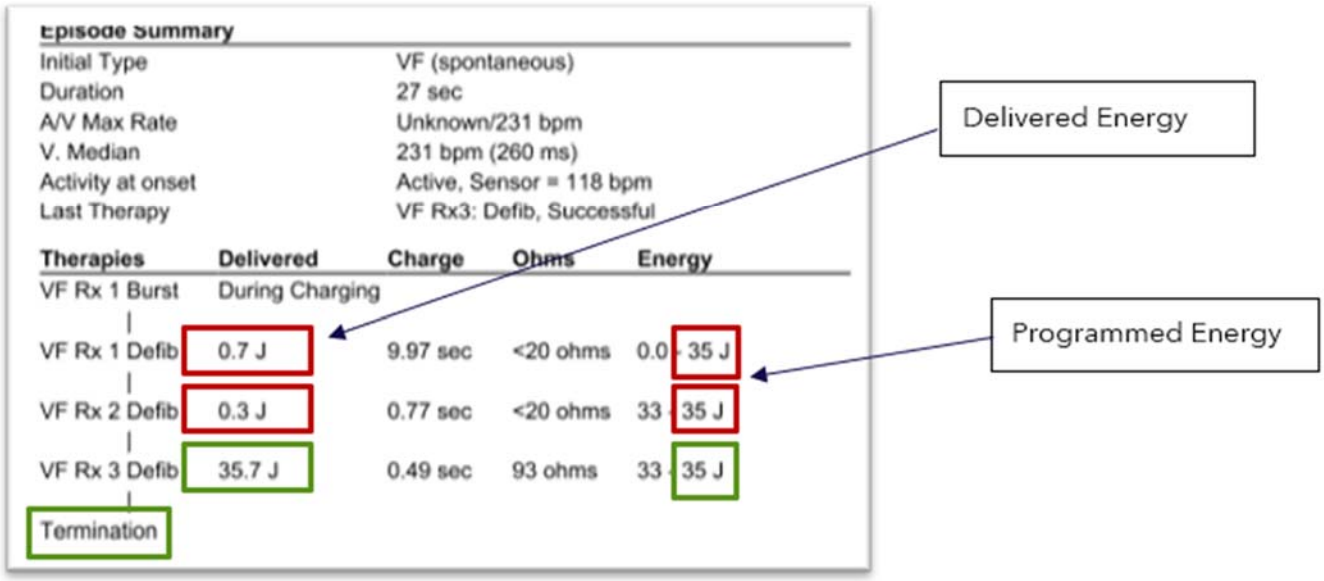
A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

**PATIENT MANAGEMENT RECOMMENDATIONS:**

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).




Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

**ISSUE DETAILS:**

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

**RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:**

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm. Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

**TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming**

| Population | | Projected event rate (one or more reduced- or no-energy HV therapies in an episode) | Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia |
|---|---|---|---|
| **Glassed feedthrough devices with current field programming (~816,000 devices)** | Overall Population of Devices | **0.02% @ 5 years*** | **0.004% @ 5 years*** |
| | For Patients with History of HV Therapy | **0.48% @ 5 years*** | **0.08% @ 5 years*** |
| **Glassed feedthrough devices after all HV pathways reprogrammed B>AX** | Overall Population of Devices | **0.005% @ 9 years**** | **0.001% @ 9 years**** |
| | For Patients with History of HV Therapy | **0.04% @ 9 years**** | **0.01% @ 9 years**** |
| **Historical devices dating back to 2012 (~651,000 devices)** | Overall Population of Devices | **0.006% @ 9years**** | **0.001% @ 9years**** |
| | For Patients with History of HV Therapy | **0.05% @ 9 years**** | **0.01% @ 9 years**** |

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

**APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)**

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device. **Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Evera/Visia AF/Primo/Mirro ICDs and Viva/Brava/Claria/Amplia/Compia CRT-D devices:

> Identifying SCP events: For episodes in which a high voltage therapy was delivered, if there is a significantly reduced-energy or no-energy shock delivered, the device may have experienced an SCP event. In each stored episode, delivered energy is displayed in the Episode Text and on the Interval Plot. If an SCP event occurred, this text may indicate that a lower energy was delivered and <20 ohm impedance value. Note: there is currently no available SCP alert in this family of devices.
>
> Clinicians can consider enabling the device audible alert and/or CareAlert for "Number of Shocks Delivered in an Episode," with "N = 1." Turning this alert "ON" may help ensure the patient and/or clinic is made aware when a HV therapy is delivered by the device.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

# Product Education Brief: Alert Threshold for Lead Impedances

## Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ CRT-P

Original Date of Communication: April 2023

**Overview**

This Product Education Brief describes a lead impedance alert behavior in Medtronic Azure™, Astra™, Percepta™, Serena™, and Solara™ devices that may be observed when the pacing lead impedance displayed is slightly above the programmed lower alert threshold.

**Details regarding CareAlerts and impedance measurements**

In Azure, Astra, Percepta, Serena, and Solara devices, a CareAlert may be triggered when the lead impedance displayed is slightly above the programmed lower alert threshold.
See Figure 1 and 2 for an example case where the lower threshold for a lead impedance alert is programmed at 200 ohms. In the Lead Impedance Trend (Figure 1) the precise measured impedance value is 209 ohms; and yet in the CareAlert display (Figure 2) an alert was triggered indicating the impedance crossed the 200 ohm impedance threshold, and suggesting the impedance is 190 ohms. This scenario can happen due to the range of impedance values used for alert monitoring. In this scenario, the devices are functioning within design specifications and tolerances.

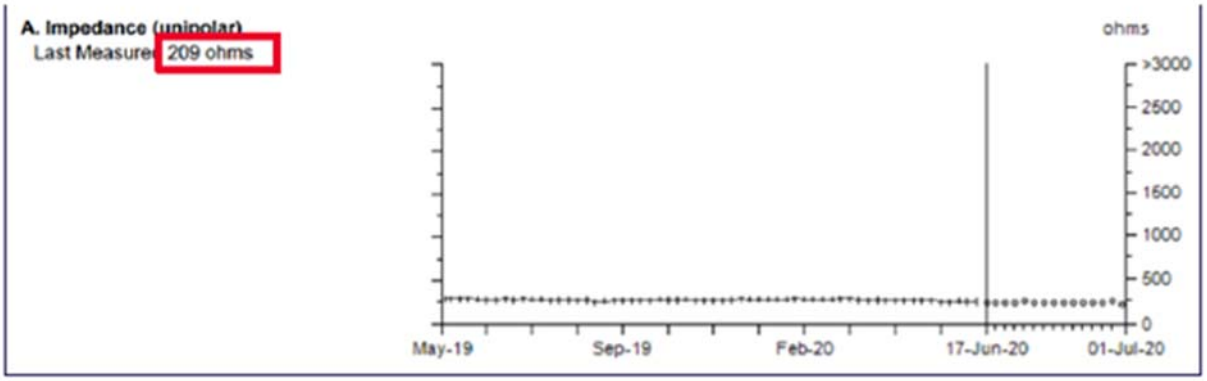


**Figure 1**– Lead Impedance Trend showing precise impedance values over time

| Date/Time | Event | Threshold |
|---|---|---|
| 01-Jul-2020 03:00:00 | *A. Unipolar lead impedanc | 190 ohms. 200 ohms |

**Figure 2**– CareAlert triggered showing 190 ohms impedance value with a 200ohm alert threshold

While most leads are programmed to pace bipolar, every night the device will assess all lead impedance vectors. Unipolar measurements tend to be lower than bipolar measurements in the same system. Therefore, the nightly unipolar lead impedance measurement will likely be closer to the programmed lower alert threshold than the bipolar measurement.

The impedance value range for alerts is never higher than the measured impedance, so all impedance values that are below the programmed threshold will generate an alert as programmed.

**Patient Management**

Clinicians should continue to follow patients per their standard clinical practice when a CareAlert triggers for lead impedances. Impedance alerts are designed to prompt the clinician to review impedances in the Lead Impedance Trend Log. The Lead Impedance Trend records precise lead impedance measurements over time. These historic impedance measurements provide evidence as to whether the impedance is stable and functioning as designed (albeit near the programmed threshold); or unstable and necessitating further assessment and/or close monitoring. Note: If impedance values reported in the Lead Impedance Trend indicate impedances are below the programmed lower threshold, then the lead should be assessed for possible insulation breach per standard clinical practice.

# Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event (2022)

## Cobalt™ XT, Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: June 2022

**STATUS UPDATE - NOVEMBER 2023**

As of 10 August 2022, a software release is now available for CareLink™ SmartSync™ Device Managers (SmartSync). Once a SmartSync tablet has been updated with software application D00U005 version 7.1.1 (or higher), the programmer will deploy a device update to Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) to prevent the potential for an intermittent, second-phase Short Circuit Protection (SCP) event during high-voltage (HV) therapy delivery. This software update was previously announced as part of an advisory communication Medtronic issued in June 2022 (see original communication posted below).

Through 14 November 2023, Medtronic has confirmed 128 devices (representing 0.08% of devices distributed worldwide) have experienced a second-phase SCP event. In all events, ~79% of the programmed shock energy was delivered. No events have occurred in devices programmed B>AX that have the August 2022 software update. No permanent harms or deaths have been directly attributed to this issue.

Medtronic representatives are available to work with clinicians to ensure all SmartSync tablets in their facility(s) are updated with application software D00U005 version 7.1.1 (or higher). The software can be installed by connecting each SmartSync tablet to the internet, opening the SmartSync App and accepting the on-screen prompts.

As disclosed in the June 2022 patient management recommendations, patients will require an in-clinic visit for the update to be installed into their device via interrogation with an updated SmartSync tablet. Once installed, the update will allow devices to deliver the full programmed shock energy. Programming B>AX pathway and Active Can enabled is still required. On-screen messaging will reinforce these programming recommendations.

Clinicians can identify if a patient's device has successfully received the update by viewing the displayed Configuration ID and confirming the first number in the sequence is as indicated below:

- 11-1-0 or higher for Cobalt/Crome VR devices
- 10-1-0 or higher for Cobalt/Crome DR and CRT-D devices

The Device Configuration ID can be found under the "Device Information" section of the SmartSync Parameters Report, or for CareLink patients, under the Transmission Details page by selecting <More Reports > 'Parameters.'

**ORIGINAL COMMUNICATION - JUNE 2022**

This communication provides notice of the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Through 03 June 2022, Medtronic has identified 27 devices (0.03% of devices distributed worldwide) that have experienced a reduced-energy shock, which is accompanied by a Short Circuit Protection (SCP) alert. Medtronic has not received any reports of permanent harm or death due to this issue. Medtronic has submitted a device software update to address this issue and anticipates it will be available for download into implanted devices <beginning third/fourth quarter of calendar year 2022>, pending regulatory approvals.

**ISSUE SUMMARY:**

Short Circuit Protection (SCP) alerts trigger during HV therapy during the first- or second-phase of the HV biphasic waveform delivery. This communication focuses on second-phase SCP events that are the result of a secondary, low-level current pathway detected in the HV circuitry.

- A second-phase SCP event **will deliver approximately 79%** of programmed energy as a monophasic waveform.
- **Defibrillation efficacy is reduced by ~1%**for this type of SCP event when HV therapy is programmed to 40J, considering cumulative success across the full series of shocks (Rx1 through Rx6).

Based on analysis of peer-reviewed literature as well as CareLink data on shock efficacy from more than 279,000 episodes*, termination success rates for 32J (~79% of 40J), monophasic shocks versus 40J biphasic shocks are estimated in Table 1. Termination success may vary depending on individual patient risk factors and medication use.

**TABLE 1**

| | Normal Operation (40J, Biphasic delivery) | Second-phase SCP (32J, Monophasic delivery) |
|---|---|---|
| **Estimated First Shock Success* (in VF Zone)** | 89% | 85% |
| **Estimated Cumulative Success Shocks 1-6*** | 99% | 98% |

*Medtronic data on file; May 2022.

- While 0.03% has been observed to date, Medtronic projects 0.18%** of the ~80,000 distributed devices may experience a second-phase SCP event within 24 months of service life, when considering the probability for these SCP events increases over time, and the likelihood a patient will need HV therapy during that time.
    - For the population of patients who received HV therapy, the observed rate was 0.77%. When projecting for this population, the chance of encountering a second-phase SCP event is ~5.0%** at 24 months.

**The above projections are based on calculations without the planned device software update. Once installed, this update, in addition to the programming recommendations, will resolve occurrences of second-phase SCP events.

Potential harms related to a second-phase SCP event include failure to terminate the arrhythmia due to reduced-delivered-energy, a theoretical risk of proarrhythmia, and complications associated with device replacement, including unnecessary lead replacement due to misinterpretation of the SCP alert.

- **While not observed clinically**, Medtronic estimates the risk for proarrhythmia is 0.002% in the AX>B configuration, and improbable in the B>AX configuration (less than 0.00004%), with Active Can pathway enabled. These risks may be higher when Active Can is disabled.
- The overall risk for **patient mortality due to this issue is estimated to be 0.002%** at 24 months when combining the likelihood a patient will need therapy with the probability an arrhythmia fails to terminate after six sequences of 32J monophasic shocks.
    - Comparatively, the risk of **patient mortality due to complications associated with device replacement is 0.032% - 0.043%**[1,2,3]

**PATIENT MANAGEMENT RECOMMENDATIONS AND CONSIDERATIONS:**

**SCP events are evident to the patient and clinician. Devices will issue an audible tone and, for patients enrolled in CareLink, a wireless CareAlert will report *RV Defib lead impedance 0 ohms*.**

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends:

- **Prophylactic device replacement is NOT recommended.**
- Remote monitoring with normal frequency of follow-up per clinic protocol, with patients' next follow-up scheduled in-clinic to allow for device reprogramming (if necessary):
    - **Programming all HV therapies to 40J with a B>AX pathway and Active Can/SVC Coil set with Active Can enabled across all therapy zones.**
- Contact Medtronic Technical Services (1-800-723-4636) or your local representative if an *RV Defib Lead Impedance Alert* reporting zero (0) ohms is observed – as this is an indicator that an SCP event was detected during HV therapy.
    - Importantly, if the delivered energy during the episode is ~79% of the programmed energy AND the SCP alert indicates an RV Defib Lead impedance alert reporting exactly zero (0) ohms, this is an indication of a second-phase SCP event (as described in this letter) and not a lead issue.
    - Consider device replacement only after observing and confirming the cause of an SCP event with a Medtronic representative, with the understanding a device has an ~81% probability of delivering subsequent reduced-energy shocks, and with the understanding an update for implanted devices is anticipated to be available beginning <third quarter/fourth quarter> of calendar year 2022.

Note: The software update will require an additional in-clinic follow-up in order for it to be installed into a patient's device. The update will ensure the full shock energy is delivered in the presence of a secondary, low-level current pathway in the HV circuitry.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.

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[1] Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.

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

[3] Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

# Software Update Available to Correct Potential for SmartSync Telemetry Error

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

Original Date of Communication: April 2022

**STATUS UPDATE - NOVEMBER 2023**

As of 26 October 2023, Medtronic has received 215 reports of the SmartSync Telemetry Error in Cobalt and Crome devices. No serious adverse events or permanent harms have been reported.

**ORIGINAL COMMUNICATION – APRIL 2022**

Medtronic is notifying health care professionals of **a software update for CareLink SmartSync™ Device Managers** (SmartSync) that will address a telemetry error that may occur with Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Specifically, **software application D00U005 version 6.0.3 will deploy an update** to implanted devices that will correct the potential for temporary suspension of some device features (details below) due to a telemetry error involving inductive (non-Bluetooth) telemetry. As of 22 March 2022, 0.3% of devices have experienced this issue. No serious adverse events or permanent harms have been reported due to this error.

Medtronic representatives will work with you to ensure all SmartSync tablets in your facility are updated with application software D00U005 version 6.0.3 or higher. Once the software has been installed on a tablet, a patient's device will automatically receive an update (to prevent the telemetry error) during their next SmartSync session.

**Details:**

Some Cobalt and Crome devices may encounter a persistent "session-active" flag following the use of inductive telemetry. The persistent session-active flag is the result of a telemetry connection error that can occur when intermittent or disrupted signals manifest while communicating with the device at the end of the telemetry session. Inductive telemetry with a Cobalt/Crome device typically occurs during device interrogation with a CareLink Express™ Mobile reader head. A persistent session-active flag will result in temporary suspension of the following features (if available in the device) until the flag is cleared:

- Battery voltage measurements
- Capture Management™

- Atrial Lead Position Check™
- AdaptivCRT™, EffectivCRT™ diagnostic, and EffectivCRT™ During AF
- Wavelet™ template management
- Battery conditioning charges

Potential risks include loss of pacing or inadequate CRT support, and/or loss of Recommended Replacement Time (RRT) indicator.

When battery measurements are suspended for more than seven days, the longevity estimator cannot calculate a value and the estimator will display a grey bar with "???." Longevity estimates will be unavailable for approximately 82 weeks. A device that experiences a persistent session-active flag can be manually cleared via a specific sequence of steps, using a non-Bluetooth SmartSync telemetry session. Contact Medtronic Technical Services at 800-723-4636 for further instruction. After the persistent flag is manually cleared, the above features will automatically be restored. Remaining longevity estimates will resume approximately 82 weeks after the date the flag is cleared. The issue is unlikely to result in clinical impact to the patient given the features listed above can be restored with an in-clinic SmartSync programmer session.

**Devices manufactured after July 2021 have already received the software update and are not susceptible to the described behavior.** Refer to Appendix A (below) for details on how to identify which Cobalt/Crome devices have already received the update.

**Patient Management Recommendations:**

We realize that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends continuing normal follow-up frequency per local clinic protocol.

Once the software is installed on a SmartSync tablet, please follow these recommendations:

- **Patients routinely seen in the clinic** will automatically receive the update during their next interrogation using an updated SmartSync tablet (D00U005 version 6.0.3 or higher). No additional programming of the device is required.
- **Patients followed remotely who do not have regularly scheduled in-clinic sessions**should have their next follow-up session conducted in clinic using an updated SmartSync tablet (D00U005 version 6.0.3 or higher). No additional programming of the device is required.

Note: If a patient's device displays a grey longevity estimator bar with "???," the device may have a persistent session-active flag. Contact Medtronic Technical Services at 800-723-4636 for assistance.

**APPENDIX A**

**How to Confirm a Patient's Device Has Received the Update?**

Each device will display a Device Configuration ID after interrogation by an updated SmartSync tablet, or after transmitting to CareLink. The Device Configuration ID can be found via the Parameters Report as noted below:

**For SmartSync** - the following is available from the Parameters Report PDF file.

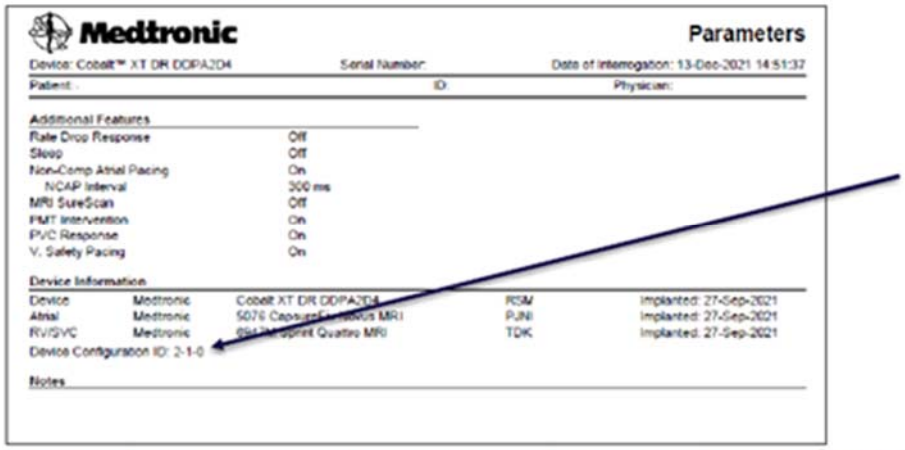



Image: Sample SmartSync-generated Parameters Report showing updated Device Configuration ID.

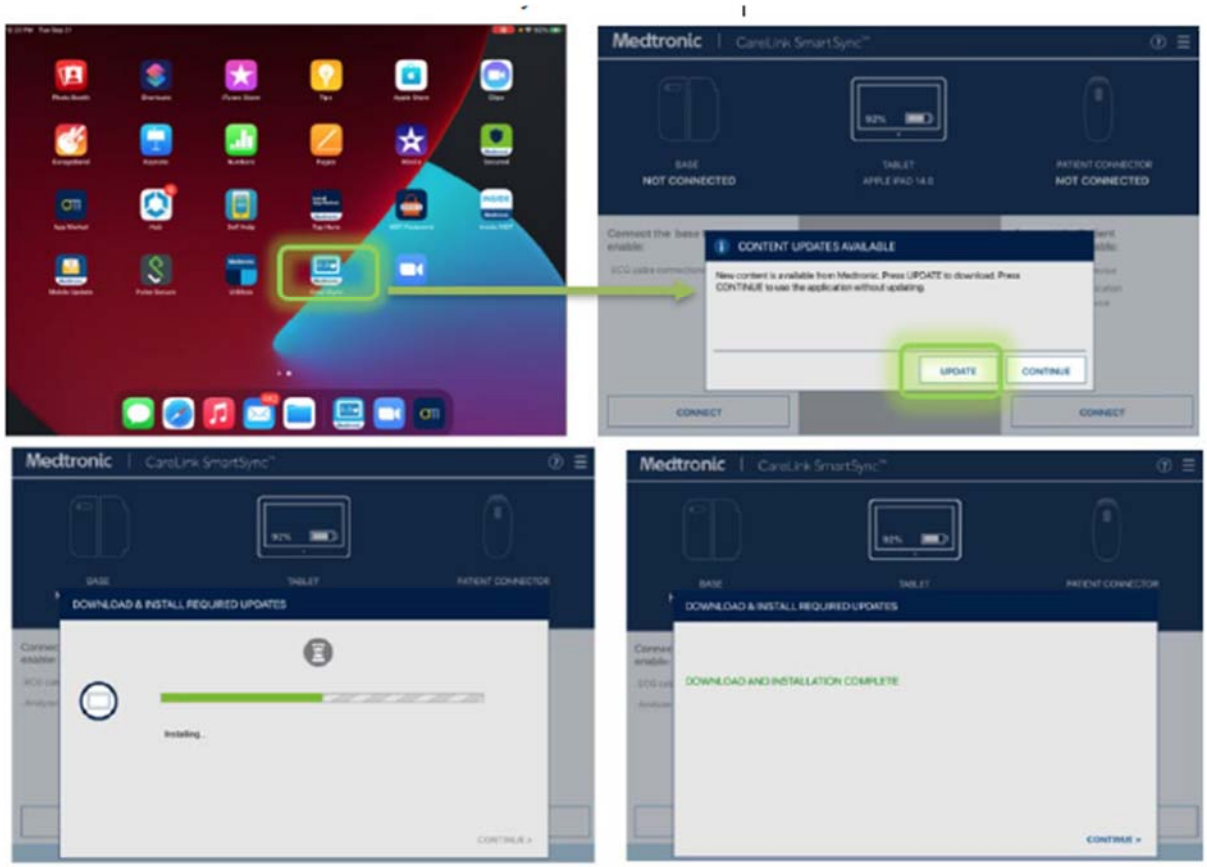
**For CareLink** - the following is available from the Transmission Details page by selecting 'More Reports' > 'Parameters.'


Image: Sample CareLink Parameters Report showing updated Device Configuration ID.

**How do I update my SmartSync™ application software for the issue described in the April/May 2022 communication?**

On any tablet, you can update to the most recent version for all applications resident on that tablet by simply connecting to the internet and either automatically discover if new software is available by launching the SmartSync App (see images below), OR manually discover if new software is available by navigating to the Software Information

screen and perform "Check for Updates." Contact your local Medtronic representative or Medtronic Technical Services at 800-638-1991 if you need assistance.



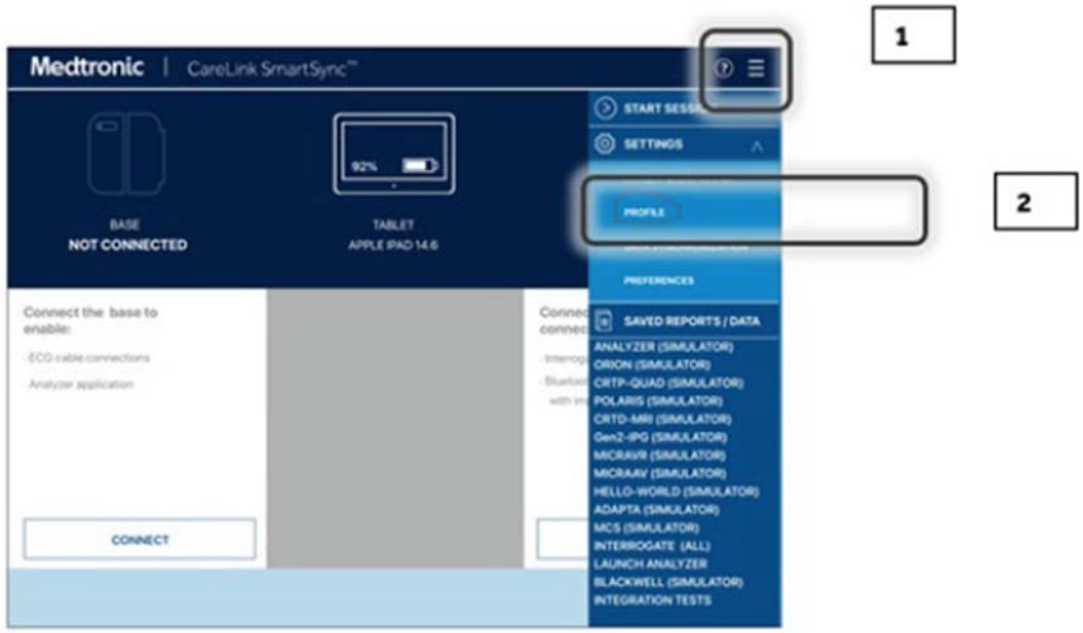

**How do I confirm if a SmartSync tablet has already been installed with the updated software?**
On any tablet, you can confirm the application software version for any device family by:

1. Selecting the MENU in the upper right corner of the SmartSync App [1]
2. Selecting PROFILE [2]
3. Selecting the SOFTWARE tab and scrolling through the SOFTWARE INFO list [3]

If the software update for this issue has already been installed, you will see the following versions listed:

- The Common/Platform application version is 3.6.4 (or higher)
- is 6.0.3 (or higher)

# Customer Communications





**3 - Updated application versions**

# Procedure Education Brief: Micra TPS Implant

## Micra TPS devices

Original Date of Communication: November 2021

**Overview**

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

**Micra IFU and Implant Procedure Training**

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

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

**Micra Safety and Effectiveness Data**

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

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**<br><br>**(Micra vs Transvenous-VVI)** | **Results Adjusted for Patient Medical History**<br><br>**(Micra vs Transvenous-VVI)** |
|---|---|---|
| Acute (30-day) device-related complications including dislodgement, infection, pocket complications[4] | 1.4% vs 2.6% (P<0.001) | 1.4% vs 2.5% (P<0.001) |
| Total acute (30-day) complications[4] | 8.4% vs 7.3%(P=0.02) | 7.7% vs 7.4% (P=0.49) |
| Cardiac perforation/effusion[4] | 0.8% vs 0.4% (P<0.001) | 0.8% vs 0.4% (P<0.001) |
| 30-day all-cause mortality[5] | 4.4% vs 3.8% (P=0.10) | 4.0% vs 4.4% (P=0.60) |

| | | |
|---|---|---|
| 2-year reintervention rate[5] | 3.0% vs 4.8% (P=0.006) | 3.1% vs 4.9% (P=0.003) |
| 2-year chronic complications[5] | 4.9% vs 6.5% (P<0.001) | 4.6% vs 6.5% (P<0.001) |
| 2-year all-cause mortality[5] | 34.0% vs 31.6% (P=0.002) | 31.4% vs 32.5% (P=0.37) |

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

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

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

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

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

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

# LINQ II - Brady, Pause and PVC Detections Disabled Following Electrical Reset

## LINQ II Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

**STATUS UPDATE - NOVEMBER 2023**

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

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

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

**ORIGINAL COMMUNICATION - JUNE 2021**

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

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

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

**ISSUE DESCRIPTION**

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

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

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

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

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

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

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

**PATIENT MANAGEMENT RECOMMENDATIONS**

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

**Identifying if an electrical reset has occurred:**

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

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

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. **Note**: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady, Pause or PVC events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

**Patients with a confirmed partial electrical reset:**

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

      **Note**: Implanted Reveal LINQ with TruRhythm ICMs have the ability to receive a future

software update to correct this issue, which will be implemented via the Model 2090 and Encore™ programmers, and is anticipated to be available in the U.S. late calendar year 2021.

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

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

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

## Reveal LINQ with TruRhythm Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

**STATUS UPDATE - NOVEMBER 2023**

This advisory is being addressed via a software update. Medtronic CareLink (2090) and Encore (29901) Programmer software, SW026 version 8.3, is available to correct a low rate of occurrence issue with Reveal LINQ ICMs (0.049%) where Brady and Pause detections are disabled following a partial electrical reset.

Reveal LINQ ICMs that are interrogated in-office with an updated 2090 or Encore programmer are no longer susceptible to this issue. This corrective fix to the device cannot be delivered with the Reveal LINQ™ Mobile Manager (LMM). Until the update is installed, future partial electrical resets may disable Brady and/or Pause detections as described in the June 2021 communication.

Note: The immediate availability of the software release is specific to countries that follow FDA approval, or that do not require software to be regulated. Release timing may differ for other geographies including those that require CE Mark approval. Check with your local Medtronic representative to determine if the software update is available in your region.

Please work with your local Medtronic Representative to update all 2090 and Encore device programmers. In addition, Medtronic requests you follow the below patient management recommendations:

**Patient Management Recommendations:**

- Reveal LINQ ICMs with a confirmed partial electrical reset will receive the corrective fix for this issue immediately by the device clinician completing the following steps:
    1. Interrogate the ICM with an updated 2090 or Encore programmer (software application SW026 version 8.3). The corrective fix is automatically installed during initial interrogation. To confirm an ICM has successfully received the update, refer to Appendix A.
    2. Per the Instructions for Use (IFU), following any electrical reset, verify ICM parameters are set appropriately for the patient and reprogram if necessary.
- For Reveal LINQ ICMs that have not experienced a partial electrical reset, an update will occur during the next in-clinic visit in which an updated Model 2090 or Encore programmer installed with software application SW026 version 8.3 (or higher) is used to interrogate the ICM. Partial electrical resets will disable Brady and/or Pause detections as described in the June 2021 communication until the update is installed on to the patient's ICM.

- For patients who are actively followed on CareLink, continue routine monitoring for CareAlerts and verify notification settings for electrical resets.
- Per the IFU, notify your Medtronic representative if an electrical reset occurs. If a partial electrical reset is confirmed, the patient's ICM will require reprogramming.
- During the programmer session, the corrective fix will be installed automatically.

**ORIGINAL COMMUNICATION - JUNE 2021**

This notice is to inform you that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events to clinicians. Medtronic estimates that 0.049% of Reveal LINQ with TruRhythm ICMs have experienced a partial electrical reset resulting in the inability to detect Brady and Pause events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady and Pause episode types will not be reported to the clinician.

- Currently implanted/distributed Reveal LINQ with TruRhythm ICMs will receive a future software update to correct this issue delivered via the Model 2090 and Encore™ programmers. The corrective fix is anticipated to be available late calendar year 2021 (U.S.). Availability of the software will be communicated once Medtronic has obtained the necessary regulatory approvals.
- There will be an update for future manufactured Reveal LINQ with TruRhythm ICMs, which is anticipated to be available in the U.S. October 2021. Medtronic will inform physicians once this manufacturing update is implemented into newly manufactured Reveal LINQ with TruRhythm ICMs.

**ISSUE DESCRIPTION**

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

All Reveal LINQ with TruRhythm ICMs currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 87 complaints related to an electrical reset. The projected rate of a Reveal LINQ with TruRhythm ICM experiencing a partial electrical reset that results in the inability to detect Brady and Pause events is 0.056% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady and Pause events, and an explant procedure.

If a partial electrical reset occurs, CareLink™, Model 2090 and Encore programmer software and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady and Pause

events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing, and mark symptoms.

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

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

1. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).
2. Complete the enclosed Confirmation Form and email to RS.CFQFCA@medtronic.com

**PATIENT MANAGEMENT RECOMMENDATIONS**

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

**Identifying if an electrical reset has occurred:**

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

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

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. Note: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady or Pause events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

**Patients with a confirmed partial electrical reset:**

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady or Pause events, it is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue. If patients require monitoring for Brady and/or Pause events, and it is not acceptable to wait for the software update to become available (see details below), consider device replacement. Recognize that exposure to EMI could introduce this issue for new device implants that occur before the manufacturing update is implemented anticipated in the U.S. in October 2021.
- As a reminder, per the Reveal LINQ with TruRhythm ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

**FUTURE SOFTWARE UPDATE AVAILABILITY**

Medtronic is developing a programmer-delivered software update to correct this issue for Reveal LINQ with TruRhythm ICMs currently implanted or in distribution. Anticipated availability in the U.S. is late calendar year 2021; Medtronic representatives will inform you of the availability and work with you to install the software onto clinic and hospital 2090 and Encore programmers. LMM application software will be unable to deliver the software update for this issue. In order for patients with Reveal LINQ with TruRhythm ICMs to receive the update, the device will need to be interrogated with an updated 2090 or Encore programmer.

**APPENDIX A**

**Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems**

Brady & Pause Detections Disabled Following Partial Electrical Reset

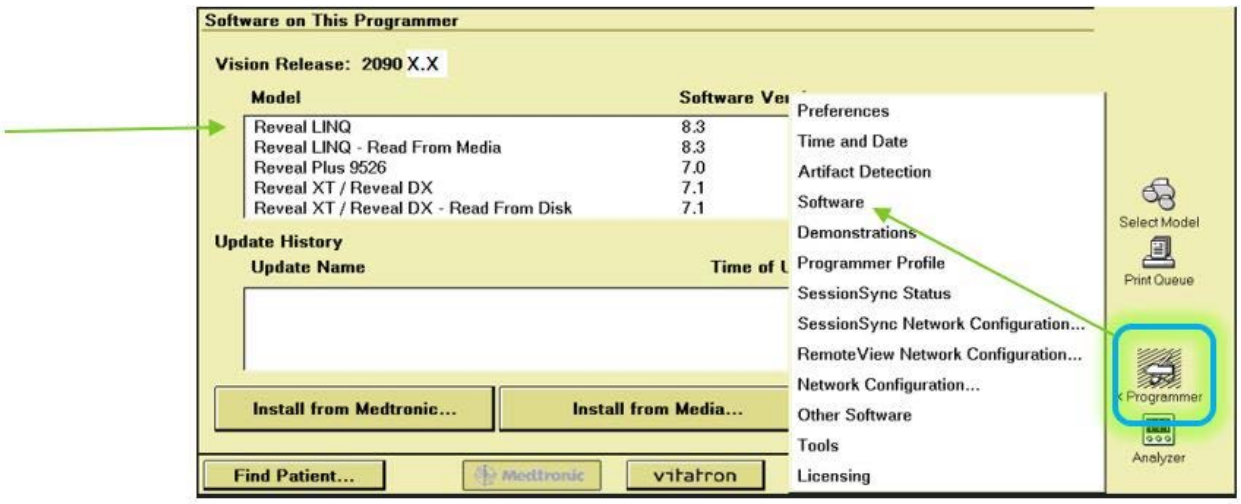
Software Update Available

**How do I update my Model 2090 and Encore programmers with the Reveal LINQ with TruRhythm software described in the November 2021 communication)?**

Software update SW026 version 8.3 can be installed onto all Model 2090 or Encore programmers through either the Medtronic Software Distribution Network (SDN) or via a USB. Medtronic representatives will work with you to install the software.

**How do I confirm if a Model 2090 or Encore programmer has already been installed with the updated software (SW026 v8.3)?**

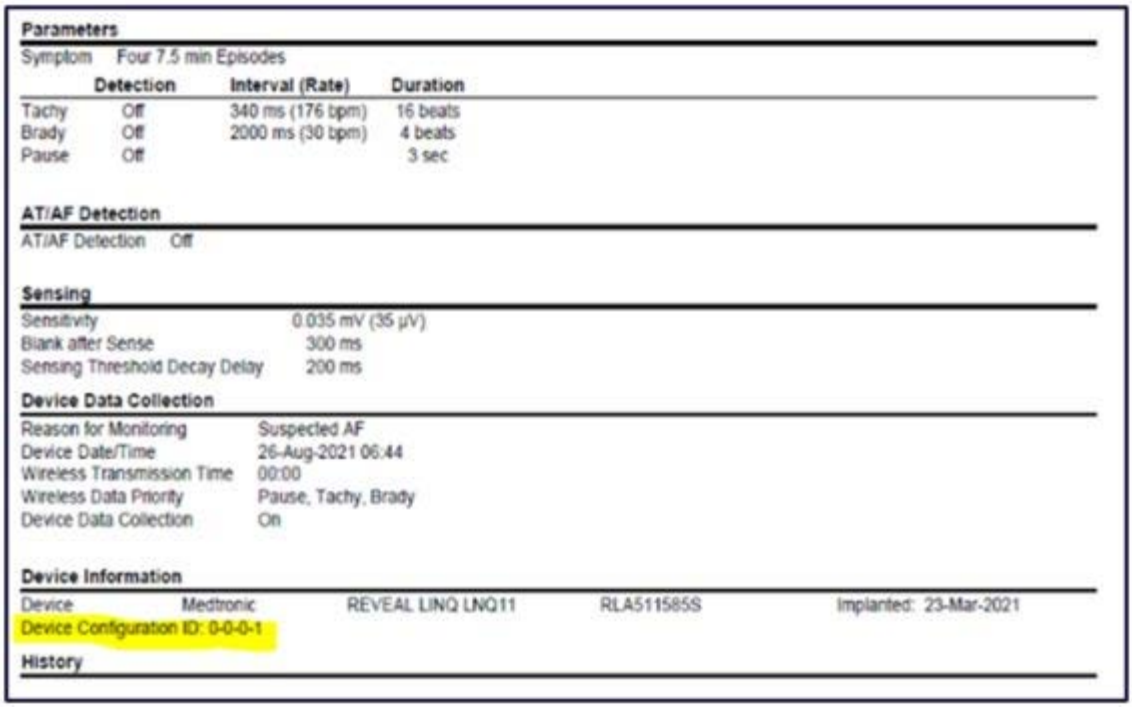
From the *Find Patient* screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.




**How do I confirm if a patient's Reveal LINQ ICM has received the software update?**

Clinicians can confirm if a patient's ICM has received the software update by verifying the Device Configuration ID via a 2090 or Encore programmer (LMM will not display the Configuration ID). To locate the Device Configuration ID, enter a follow-up session and Print the Parameters Report. All Reveal LINQ ICMs that have received the software update will have their Configuration ID ending in a "1" (e.g. X-X-X-1).

**NOTE**: The Reveal LINQ Device Configuration ID can be viewed on CareLink beginning January 2022 after a manual transmission is completed by the patient.



# Unipolar Longevity Estimation Software Error

## Azure/Astra DR and SR Pacemakers and Percepta/Serena/Solara CRT-Ps

Original Date of Communication: April 2021

**STATUS UPDATE - NOVEMBER 2023**

Through 26 October 2023, Medtronic has received 34 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue.

**ORIGINAL COMMUNICATION - APRIL 2021**

This notice is to inform you of the availability of software updates to address a potential inaccurate longevity estimate that may occur with the Azure™ and Astra™ family of pacemakers (IPGs) and the Percepta™, Serena™, Solara™ family of cardiac resynchronization therapy pacemakers (CRT-Ps). A longevity estimation error may occur in the early years of device life when a unipolar pacing vector is programmed in the right atrial (RA) lead and/or the right ventricular (RV) lead. No other device features or therapies are impacted. For devices programmed to bipolar pacing in both the RA and RV chambers, the longevity estimates are not affected by this issue.

Through 05 March 2021, Medtronic has received 13 complaints from clinicians related to this issue. No permanent patient harms have been reported due to this issue. If the software update is not applied to the programmer, confusion regarding device longevity could lead to a missed RRT alert and a potential delayed intervention. Battery performance is not affected by this programmer display error. RRT will alert appropriately, and if patients are followed per standard clinical practice, the risk to patients is minimal.

The longevity estimation error associated with unipolar pacing configurations occurs only in the first half of the device life (prior to 50% depletion of the battery). During this phase, the estimator algorithm utilizes lead impedance as an input. When a unipolar pacing configuration is programmed, the algorithm incorrectly uses the bipolar lead impedance as input (rather than the appropriate unipolar pacing lead impedance). As a result, the algorithm will over-estimate the remaining longevity during this phase. At all times, RRT, Elective Replacement Indication, and End of Service will accurately display on programmers – even if the software update has not yet been installed.

**Software updates are now available for Medtronic model 2090, Model 29901 Encore programmers, and SmartSync to correct this programmer display issue (see Table 1 below).**

| Medtronic 2090 and Encore Programmer Software Update | Medtronic SmartSync Software Update |
|---|---|
| Azure™/Astra™ (SW030) v 8.2<br>Percepta™/Serena™/ Solara™ (SW040) v 8.4 | Azure™/Astra™ (D00U003) v 4.0<br>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 2023**

As of 11 October 2023, approximately 187,728 devices susceptible to this issue are estimated to still be active worldwide. Observed rate of occurrence is 0.15% 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.

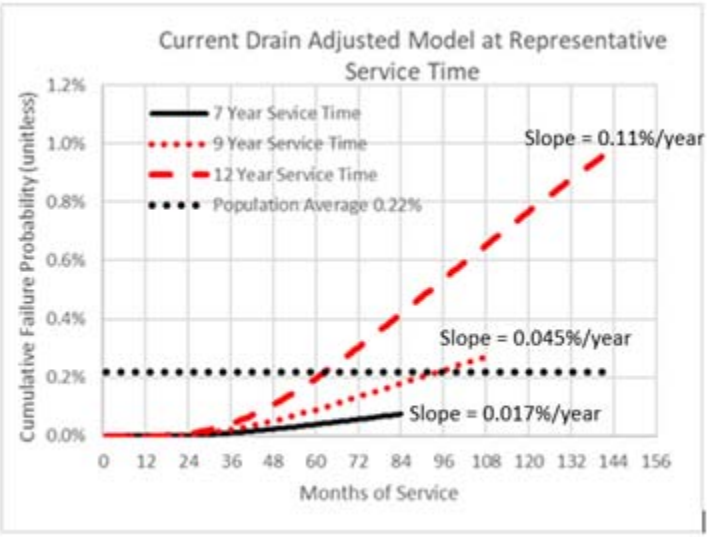
Patients and clinicians may determine if a specific device is affected by looking up the serial number on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance/

**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<br>RV output = 2.0V, 0.4ms, 500 ohms<br>LV output = 2.5V, 0.4ms, 500 ohms<br>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.

# 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 2023**

This advisory has been addressed through release of several new software updates. The complete list of software applications available are listed in the table below. Medtronic representatives will work with local clinic and hospital staff to update programmers. Once a programmer has been updated with the version of software indicated in the table (or higher), the correct longevity estimate for the affected devices will be displayed.

Note that as of September 2020 the Medtronic CareLink Network was updated for this advisory. All longevity estimates displayed on CareLink reflect accurate estimates (based on programmed settings and use conditions recorded by the device).

| Phase 1 – June 2020 | Phase 2 – January 2021 |
|---|---|
| Azure™/Astra™ (SW030) v 8.1 | Viva™/Brava™/ Evera (SW016) v8.4 |
| Serena™/ Solara™/ Percepta™ (SW040) v 8.3 | Evera™ MRI/ Primo™ MRI/ Mirro™ MRI(SW033) v8.5 |
| Visia AF™/ Visia AF™ MRI (SW035) v 8.2 | Micra™ VR TPS (SW033) v8.2 |
| Claria™/ Amplia™/ Compia™ (SW034) v 8.4 (US Only) | Claria™/ Amplia™/ Compia™ (SW034) v 8.5 |

**Table 1:**Device family updates by phases

Note: The availability of software releases is specific to countries that follow FDA and CE Mark approvals. Release timing may differ for other geographies. Check with your local Medtronic representative.

As of October 11, 2023, there have been 826 total complaints received related to the software displaying a lower-than-expected longevity estimate. Within the 826 complaints reported, no patient harm was reported, and 25 devices were prematurely explanted after observing an inaccurate longevity estimate.

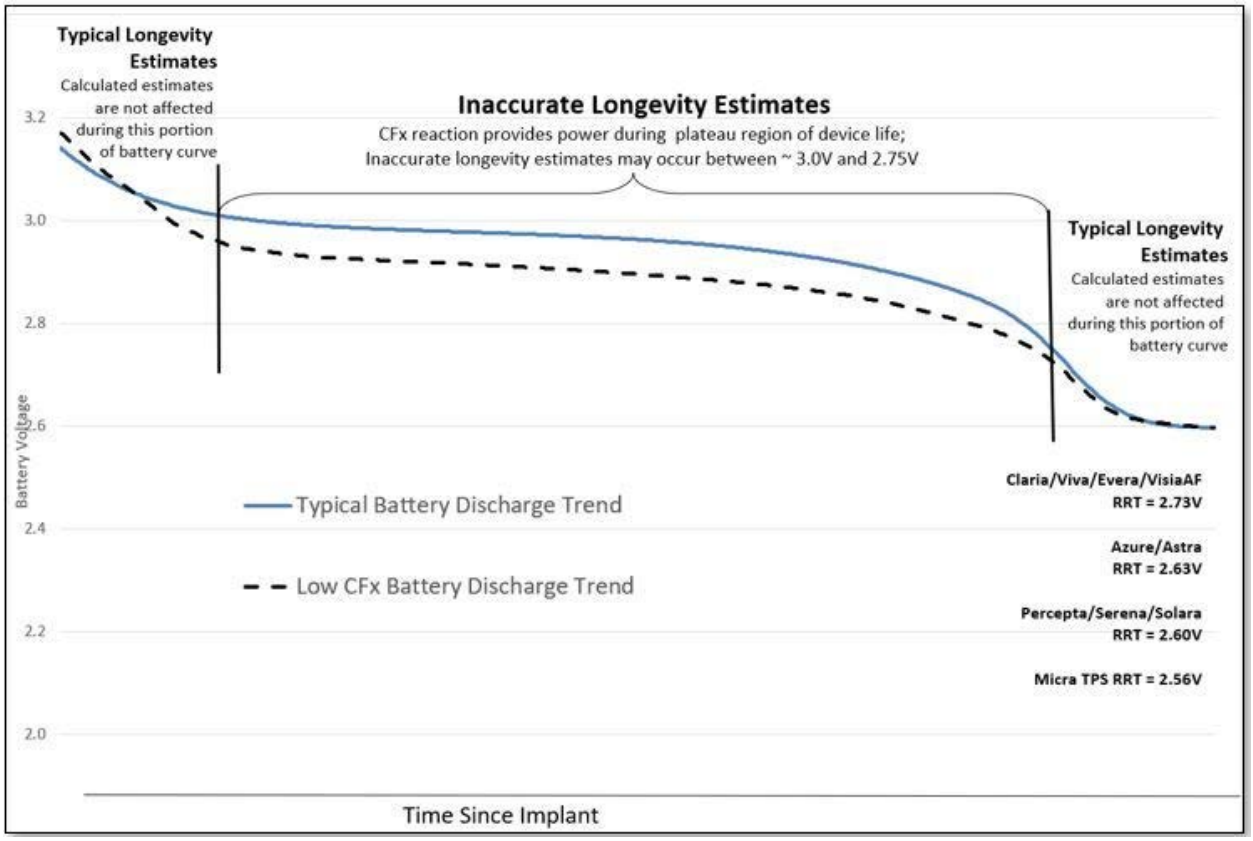
**ORIGINAL COMMUNICATION - JUNE 2020**

In October 2019, Medtronic identified the potential for Medtronic programmer and remote monitoring software applications to display an inaccurate remaining longevity estimate for a subset of implanted cardiac device models. This issue does not impact device functionality. Furthermore, the Recommended Replacement Time (RRT) remains an accurate indicator for device replacement.

Through September 18, 2019 there have been three (3) reported complaints and there have been no (0) serious adverse events or deaths.

The inaccurate longevity estimation is limited to a well-defined subset of devices manufactured between October 2018 and April 2019, and only occurs in the middle (plateau) phase of the device life, as illustrated in the graph below. Approximately 53,100 devices worldwide, out of 1.23 million distributed or sold from the identified device families, are susceptible to displaying inaccurate longevity.

The cause of the inaccurate longevity estimate is a slightly lower-than-typical discharge voltage during the plateau phase of the battery depletion curve (dashed line), compared to a typical voltage plateau (solid line), as illustrated in the graph below. During this plateau period, the Carbon Monofluoride (CFx) in the battery cathode is powering the device. Note, longevity estimates early after implantation and later in the device life are unaffected, as shown below. The battery remains within operating specifications.



The Independent Physician Quality Panel recommends routine follow up in accordance with standard practice for these devices, as RRT function is normal and the battery longevity is unaffected. There is no need to schedule patients to come in outside of their planned, scheduled visits due to this issue. The corrective fix is implemented in programmers, CareLink, and other systems which display device longevity. The patient's device does not require an update. Follow the steps below as applicable to your clinic or hospital. A local Medtronic Representative can assist in updating Model 2090/Encore programmers and SmartSync Device Managers in your facilities.

- Model 2090 and Encore™ Programmers

  These programmers will require new software to be installed to correct the displayed longevity estimator error. The software applications and version are listed in Table 1 above and can be installed via Medtronic Software Distribution Network (SDN) or via secure USB.

- SmartSync™ Device Managers

  These tablet-based programmers will require a software update to be installed via the internet - refer to Appendix A (below) for detailed instructions on how to download and install the updated application software.

Completion of programmer updates may be delayed due to COVID 19 pandemic-related facility restrictions. Based on your facility's needs and accessibility, Medtronic Representative or authorized personnel will work with your facility as requested to complete the updates. Customers with Paceart systems should contact their support team to ensure the latest device update is applied.

Note: Once a programmer is updated, the correct longevity estimate will display at the patient's next regularly scheduled clinic visit. Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, a difference in longevity estimates between programmers and CareLink Network-displayed longevity may be observed**.**

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APPENDIX A – UPDATING SMARTSYNC™ DEVICE MANAGER

Until all SmartSync Device Managers and Model 2090 and Encore programmers are updated, you may observe a difference in longevity estimates between these programmers and CareLink-displayed longevity.

**Updating Medtronic SmartSync™ Device Managers:**

1) Connect tablet to internet and open the SmartSync App

- The SmartSync App automatically checks for available updates each time it is opened.

2) If your tablet does not contain the most recent software, you will automatically receive a notification that a new version of the SmartSync App is available (3.2.01):

- If pop-up messages appear with the option to "cancel" or to "update", **select "update**".

- **Medtronic Managed Tablets:** If the App closes, find the Medtronic App Catalog, and **select** "**Install**" to initiate the download.
- **Customer Owned Tablets:** If the App closes, navigate to the AirWatch App Catalog or App Store and **select** "**Install"** to initiate the download.

- If you do not receive a notification that a new version of the SmartSync App is available, skip to Step 3.

3) Once you confirm the newest version of the SmartSync App is on your tablet, re-open the SmartSync App.

- The app will automatically provide pop-up notifications informing you if there are new versions of *device* software applications that must be installed (see table below).
  - Select CONTINUE for each pop-up window that appears. If you do not receive any pop-up notifications when you open the SmartSync App, then your tablet contains the most recent versions of all available software.

| Device Family | SmartSync Application SW Version |
|---|---|
| Azure™/Astra™ DR and SR | D00U003, Version 3.2.02 |
| Percepta™/Serena™/Solara™ | D00U004, Version 3.2.02 |

# Performance Note: Potential for no output/no telemetry condition in subset of IPG and CRT-P products due to ceramic capacitor leakage pathway

## Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ CRT-P

Original Date of Communication: May 2019

**STATUS UPDATE - NOVEMBER 2023**

As of 11 October 2023, there have been a total of 29 confirmed events worldwide associated with this failure mode. No additional deaths, beyond the two deaths previously disclosed*, have been reported since the October 2020 update. Confirmed events included reports of no output, premature depletion and electrical reset that reverted to VVI 65 operation. The range of events have occurred between 2 and 53 months post-implant.

Medtronic's ongoing monitoring of these failures have allowed us to improve long-term modeling projections for future device failures. The overall projected lifetime rate of occurrence for the remaining active devices manufactured with the original low voltage capacitor is projected to be 0.025%.

All products in distribution are unaffected. The specific low voltage capacitor susceptible to this issue was last used in manufacturing 01 June 2019. Patient management recommendations remain unchanged from the original posting (refer to the May 2019 text below).

*Assessment for cause of death determined loss of pacing therapy could not be ruled out as a contributing factor.

**ORIGINAL COMMUNICATION - MAY 2019**

Medtronic has identified a rare but potentially serious failure mode in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor. These devices continue to perform within reliability projections.

While inherently very reliable, a known failure mode of these capacitors is the potential for internal cracking that can be caused by thermal-mechanical stress during manufacturing. Under rare conditions, internal cracking within a capacitor may result in the development of a leakage pathway, causing high current drain and leading to rapid battery depletion. While the issue presents as rapid battery depletion, this is not a battery performance issue.

As of April 26, 2019, three complaints out of ~266,700 devices distributed worldwide since February 2017, have been received that included a no output /no telemetry scenario resulting from rapid battery depletion. Battery depletion due to this issue can range from several days to several weeks. One of these reported events contributed to a patient

death. The three confirmed failures occurred within 9 months post implant. The projected rate for this issue is 0.0028%, with the most susceptible period for a leakage pathway to develop in the capacitor being the first 12 months post implant.

Based on the low predicted rate of failure and the recent implementation of process and component enhancements, Medtronic expects few, if any, additional events to occur. Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend device replacement. Physicians should continue normal patient follow-up in accordance with standard practice, and where possible, continue to utilize the low battery voltage wireless CareAlert™ (shipped ON), together with remote monitoring via CareLink™ home monitor or the MyCareLink Heart™ mobile app. Per the instructions for use, at each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Pay attention to any unexpected changes in remaining longevity estimates or the inability to interrogate the device and/or transmit data.

Contact Medtronic Technical Services if you have concerns on a specific patient.

Brady Technical Services |rs.techservices@medtronic.com| 800-505-4636

# Potential Conductor Wire Fracture

## 6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Communication: October 2007

**STATUS UPDATE - NOVEMBER 2023**

As of October 11, 2023, of the initial implant population of 205,600 in the United States, approximately 27,000 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 63.5% (+6.6/-6.0%) at 180 months. As the implanted population ages and the sample size increases for each time interval, the accuracy of the estimated survival probability will increase as shown by tighter confidence intervals.

| Initial Affected Population | Number of Confirmed Advisory Related Events | Estimated Remaining Active Population |
|---|---|---|
| **279,500** Worldwide (**205,600** United States) | **7,327** Worldwide **(5,259** United States) | **37,000** Worldwide (**27,000** United States) |

**ORIGINAL COMMUNICATION - OCTOBER 2007**

PRODUCT

All Model 6930, 6931, 6948, and 6949 implantable defibrillation leads

ADVISORY

There are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. These two locations account for approximately 90% of the chronic fractures identified in Returned Product Analysis (RPA). The remaining 10% of chronic fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

PATIENT MANAGEMENT RECOMMENDATIONS (UPDATED APRIL 2011)

The Lead Integrity Alert (LIA) provides three days advance notice prior to inappropriate therapy to 76% of patients with lead fractures[1]. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks.

- **If a Fidelis lead fracture of any type has occurred, we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred. This data is available here.
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Footnotes:

1: Swerdlow C, Gunderson, B, et al."Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

# Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRM Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

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

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

Mailer kits can be obtained by contacting the Returned Product Lab.


CRM Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

For questions related to returning explanted product from outside the United States, please contact your local Medtronic Representative.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

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