# CARDIAC RHYTHM MANAGEMENT

## Product Performance Report

*Important Patient Management Information for Physicians*

2025

2nd Edition – Issue 93

Medtronic

# CRM Product Performance Report


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# Our Commitment to Quality

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

The third tenet of the mission is all about quality:

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

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

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

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

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

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

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

# Contact Information

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

## US Technical Services Department

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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Relia™
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Secura®
Secure®
SelectSecure®
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# Introduction

**For 42 years, Medtronic has monitored performance via both returned product analysis and multicenter clinical studies.**

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

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

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

**Survival Estimates**

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

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

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

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

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

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

## Introduction continued

### ICD Charge Times

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

### Customer Communications - Advisory Summaries

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

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

### Customer Communications - Performance Notes

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

### Customer Communications - Product Education Briefs

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

### How You Can Help

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

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

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

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

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

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

**Overview of Survival Analysis**

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

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

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

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

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

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

**Confidence Intervals**

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

**Survival Curves in the Product Performance Report**

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

## Introduction continued

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

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

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

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

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

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

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

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

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

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

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

### Definition of Malfunction

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

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

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

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

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

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

Normal Battery Depletion – The condition when:

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

Or

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

Or

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

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

### Malfunction with Compromised Therapy Function

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

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

### Malfunction without Compromised Therapy Function

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

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

**Expanded Malfunction Detail**

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

Battery – Findings linked to the battery and its components

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

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

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

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

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

Software/Firmware – Findings linked to software or firmware function

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

**Returned Product Analysis Process**

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

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

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

**Statistical Methods for Survival Analysis**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

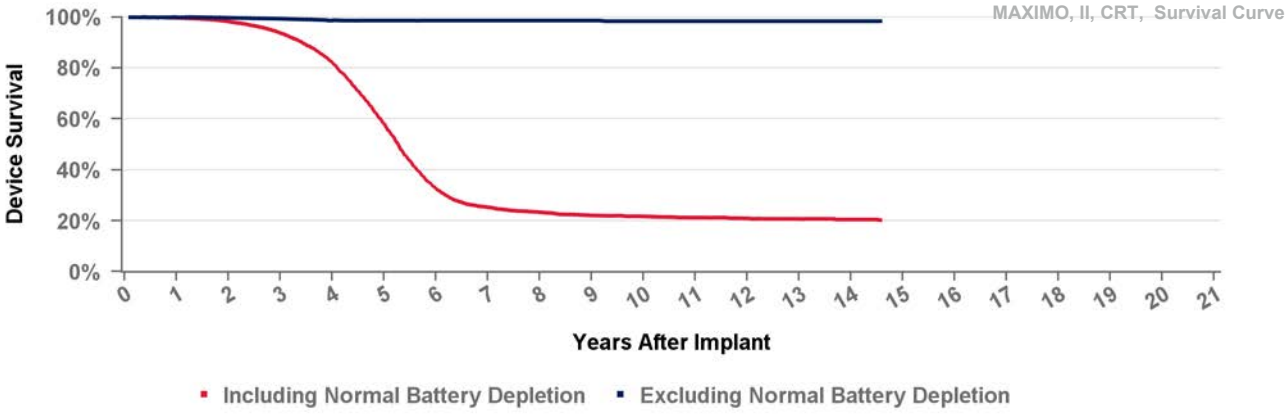
**Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service**

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

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

## D284TRK Maximo II CRT-D

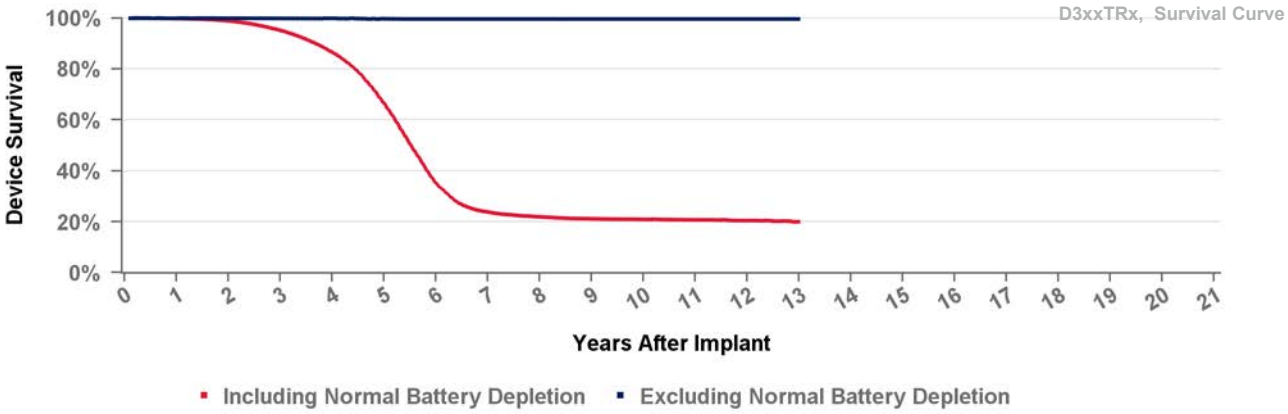
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **135** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **131** |
| **Registered USA Implants** | 14,990 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 1,317 | Possible Early Battery Depletion | 124 |
| **Normal Battery Depletions** | 4,085 | **Therapy Function Compromised** | **4** |
| | | Electrical Component | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 175 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.7% | 99.3% | 98.7% | 98.6% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% | 98.5% |
| Including NBD | 99.7% | 98.3% | 93.7% | 82.1% | 58.3% | 32.6% | 25.3% | 23.4% | 22.1% | 21.7% | 21.3% | 20.9% | 20.7% | 20.4% | 20.2% |
| Effective Sample Size | 12496 | 11085 | 9498 | 7256 | 3993 | 1663 | 1095 | 919 | 805 | 749 | 679 | 603 | 473 | 268 | 109 |

## D314TRG Protecta XT CRT-D

| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **94** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **75** |
| **Registered USA Implants** | 41,864 | Battery | 8 |
| **Estimated Active USA Implants** | 4,614 | Electrical Component | 40 |
| **Normal Battery Depletions** | 10,528 | Possible Early Battery Depletion | 25 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **19** |
| | | Battery | 11 |
| | | Electrical Component | 8 |

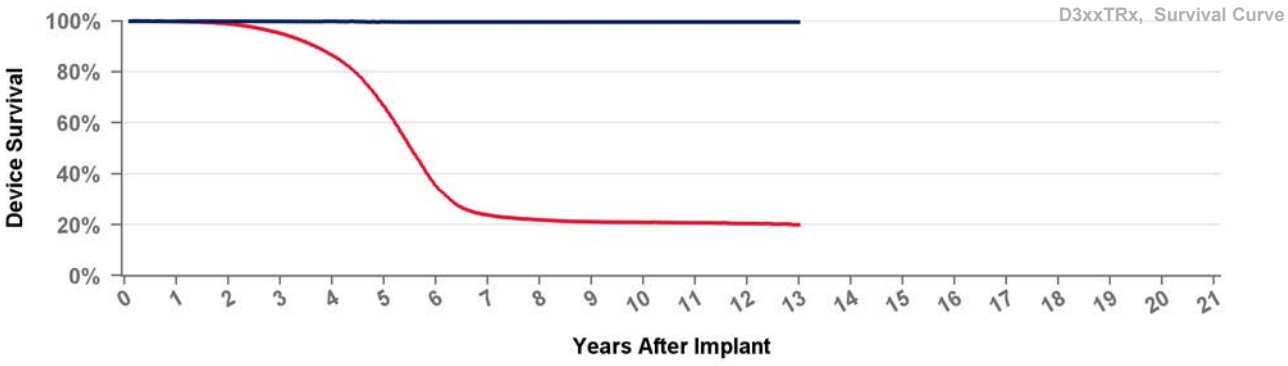



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

## D354TRG Protecta XT CRT-D

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

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

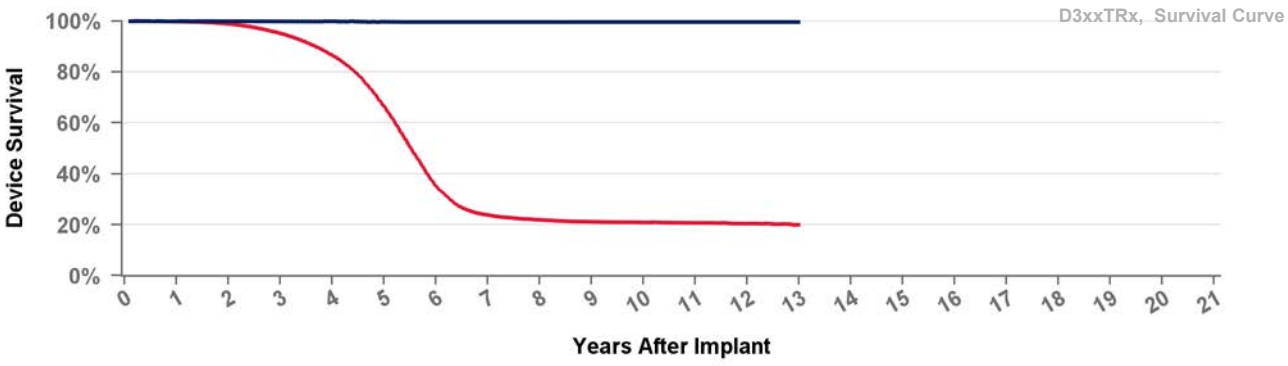



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

## 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**



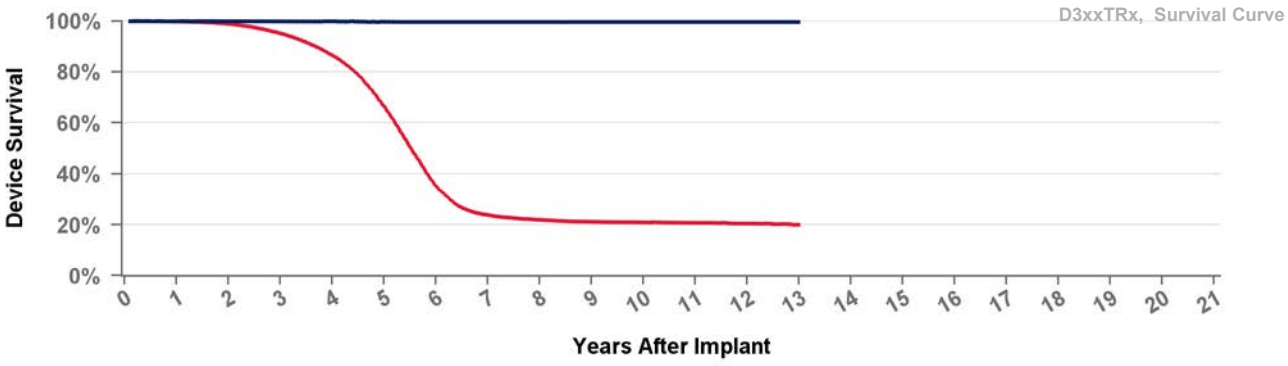

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

## D364TRG Protecta CRT-D

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

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

**Therapy Function Compromised**



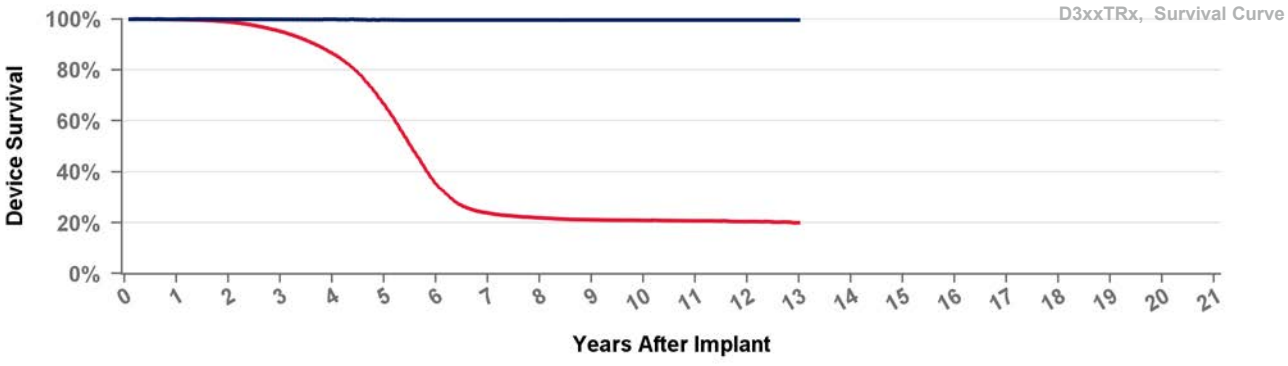

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

## D364TRM Protecta CRT-D

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

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

**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

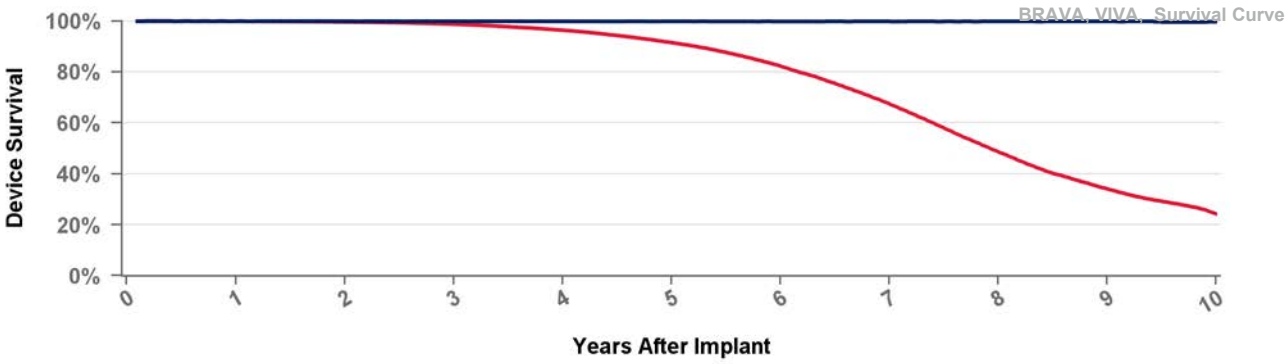
## D394TRG Egida CRT-D

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


| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 98.9% | 95.1% | 86.5% | 66.7% | 35.4% | 23.9% | 21.9% | 21.2% | 21.0% | 20.8% | 20.5% | 19.9% |
| Effective Sample Size | 54149 | 48922 | 42273 | 33505 | 21055 | 8922 | 4922 | 4076 | 3660 | 3424 | 3145 | 2653 | 299 |

## DTBA1D1 Viva XT

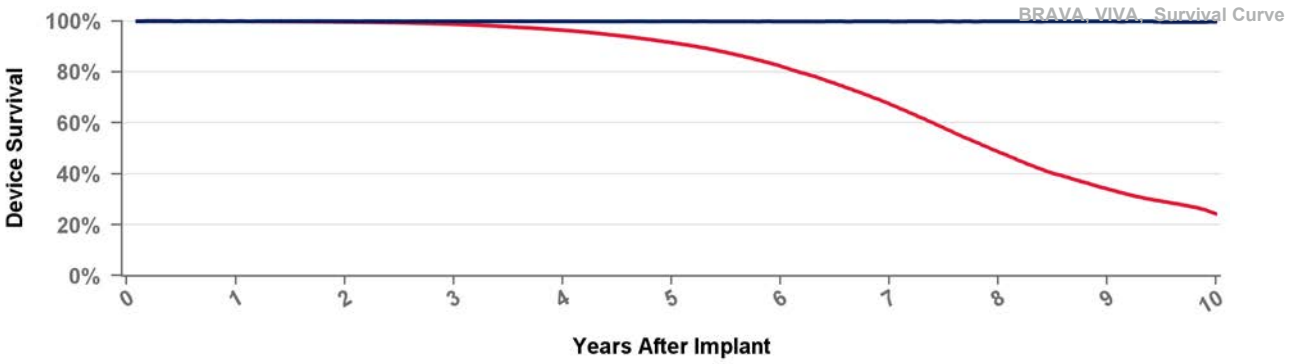
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **72** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **47** |
| **Registered USA Implants** | 56,949 | Battery | 10 |
| **Estimated Active USA Implants** | 12,720 | Electrical Component | 33 |
| **Normal Battery Depletions** | 17,233 | Possible Early Battery Depletion | 1 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **25** |
| | | Battery | 19 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBA1D4 Viva XT

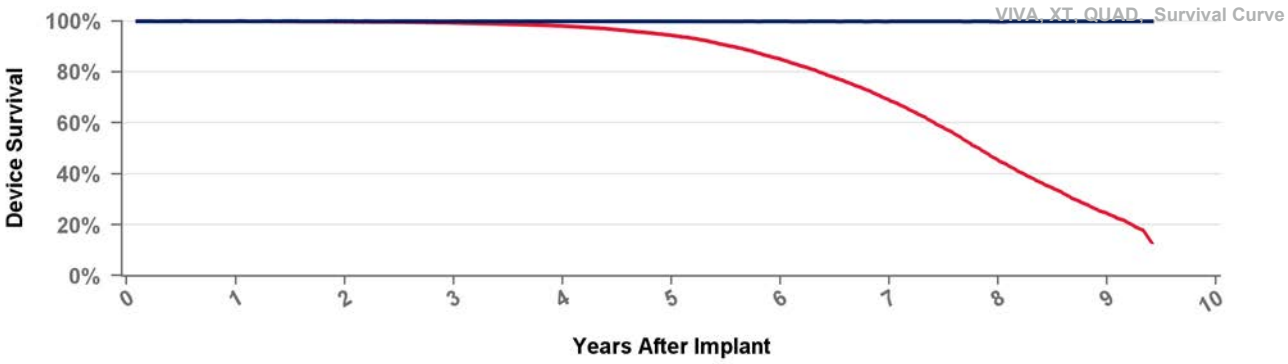
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **33** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **24** |
| **Registered USA Implants** | 19,629 | Battery | 6 |
| **Estimated Active USA Implants** | 4,355 | Electrical Component | 15 |
| **Normal Battery Depletions** | 7,051 | 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 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBA1Q1 Viva Quad XT

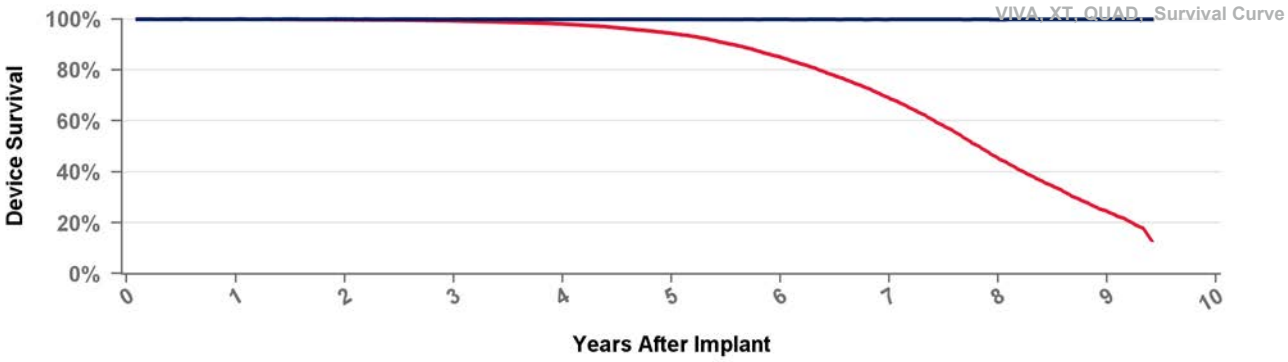
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **14** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 11,065 | Battery | 3 |
| **Estimated Active USA Implants** | 2,774 | Electrical Component | 4 |
| **Normal Battery Depletions** | 3,258 | 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 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTBA1QQ Viva Quad XT

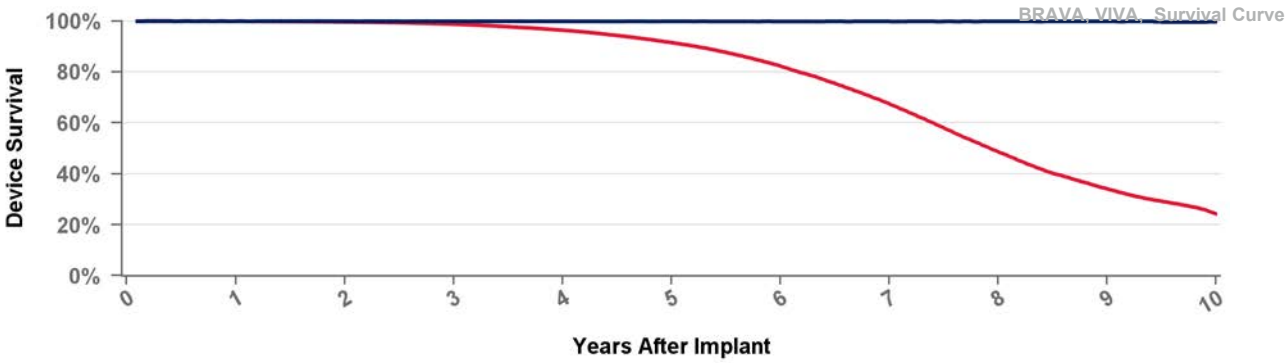
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **50** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **38** |
| **Registered USA Implants** | 27,416 | Battery | 13 |
| **Estimated Active USA Implants** | 6,790 | Electrical Component | 20 |
| **Normal Battery Depletions** | 10,199 | 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 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTBA2D1 Viva XT

| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 29Aug2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |

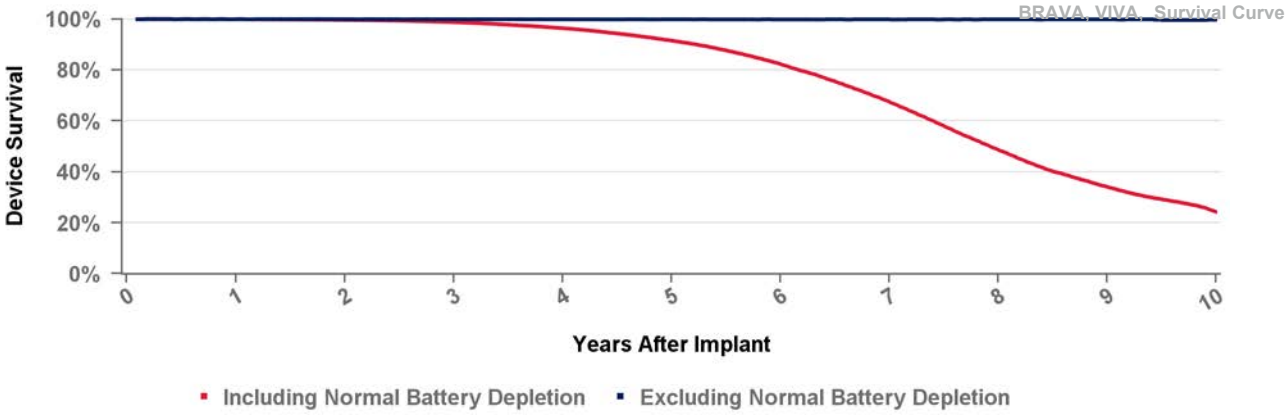



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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**

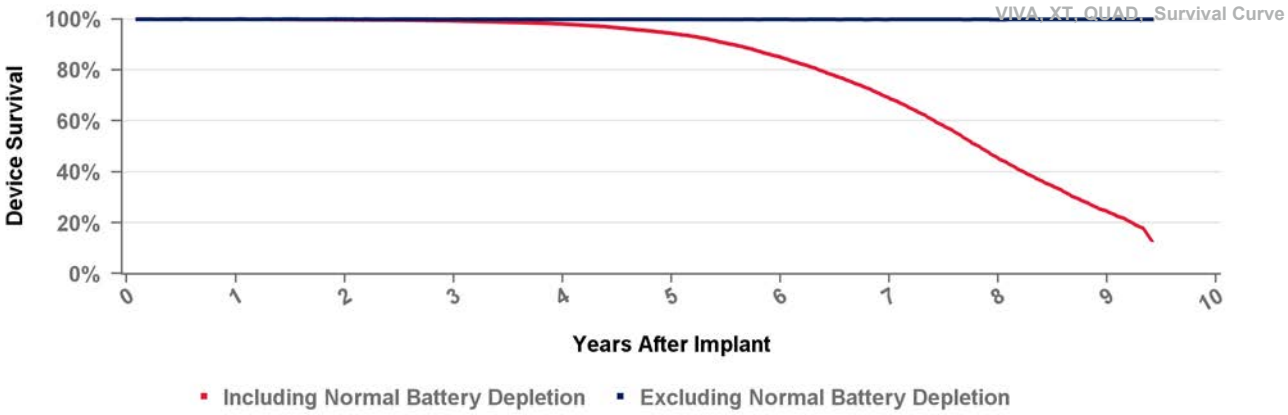



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBA2Q1 Viva Quad XT

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

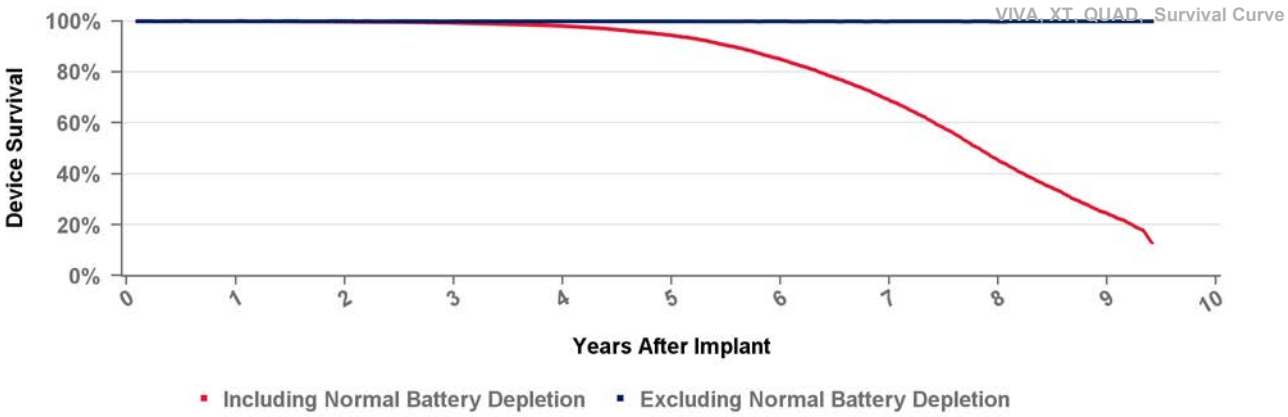
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTBA2QQ Viva Quad XT

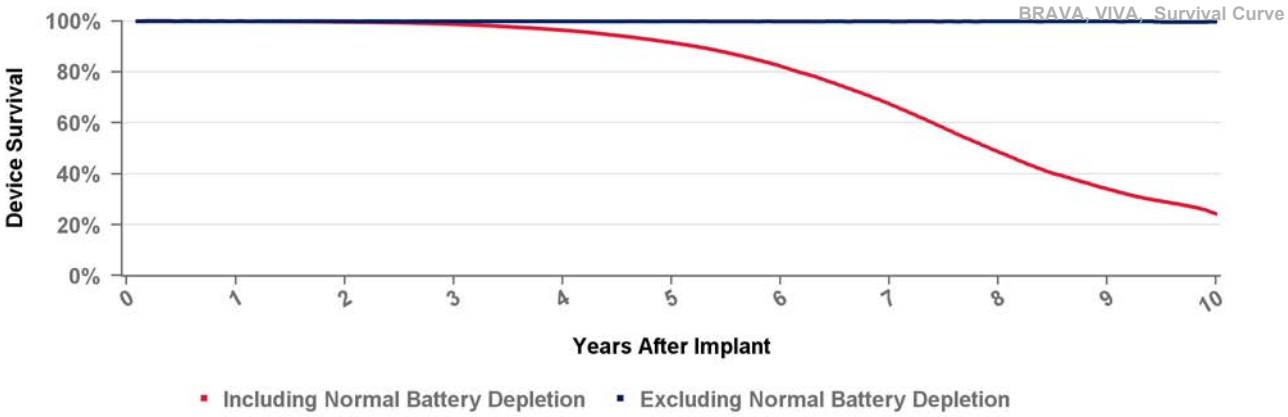
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 08Aug2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTBB1D1 Viva S

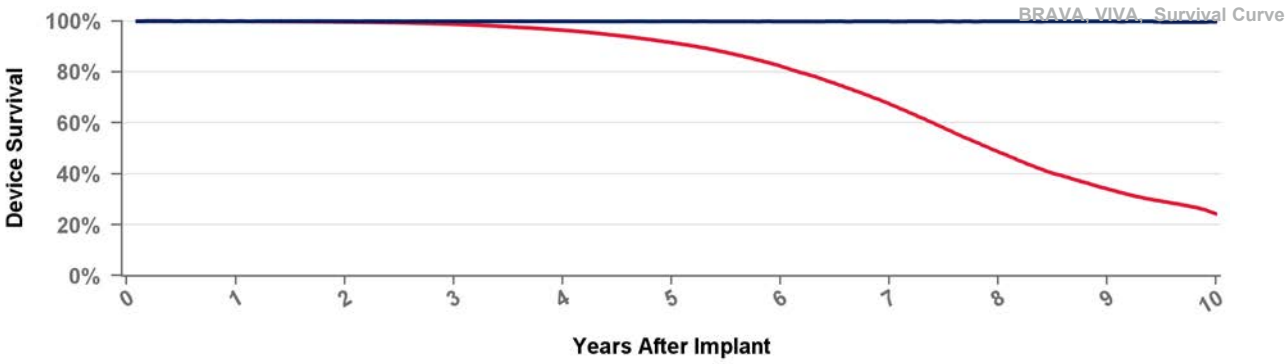
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **26** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **21** |
| **Registered USA Implants** | 14,104 | Battery | 9 |
| **Estimated Active USA Implants** | 2,706 | Electrical Component | 9 |
| **Normal Battery Depletions** | 5,034 | 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 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBB1D4 Viva S

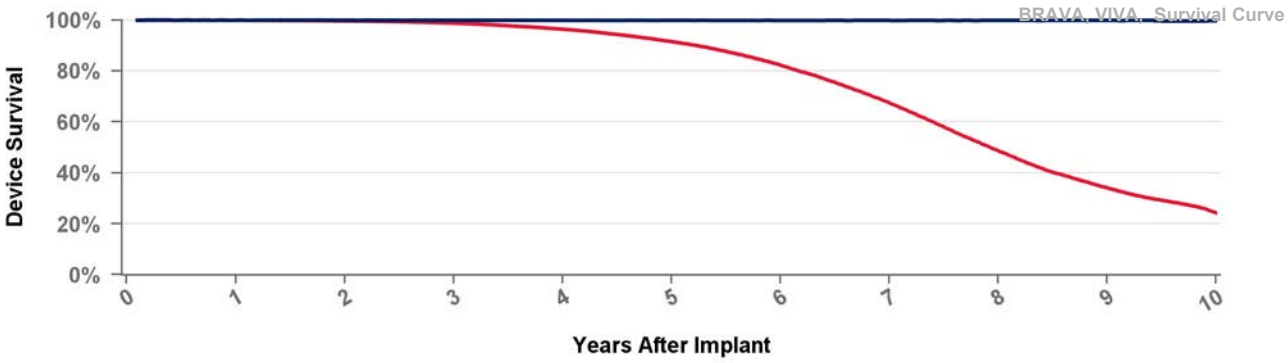
| | | | |
|---|---|---|---|
| **US Market Release** | 29Jan2013 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 4,637 | Battery | 3 |
| **Estimated Active USA Implants** | 1,001 | Electrical Component | 2 |
| **Normal Battery Depletions** | 1,680 | Other | 1 |
| | | **Therapy Function Compromised** | **3** |
| | | Battery | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBB1Q1 Viva Quad S

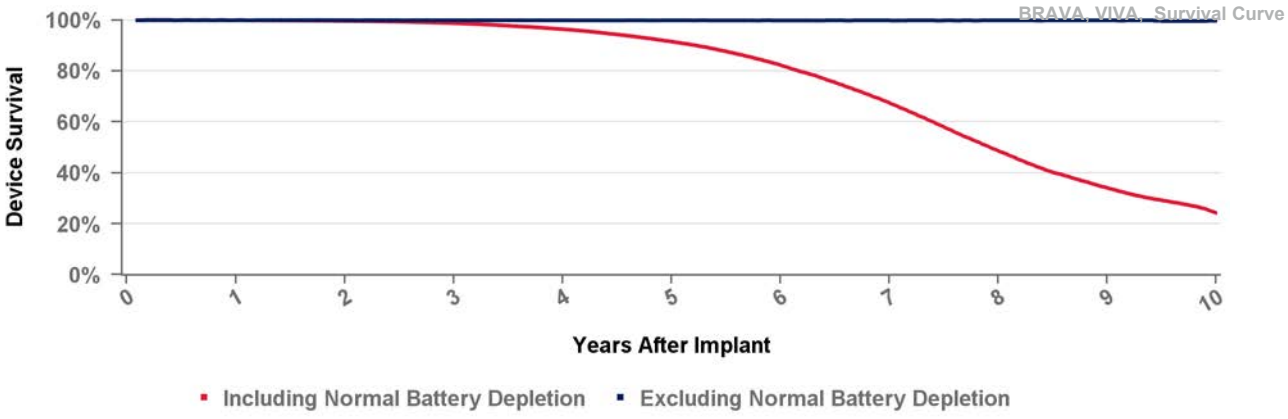
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 2,362 | Battery | 1 |
| **Estimated Active USA Implants** | 553 | Electrical Component | 2 |
| **Normal Battery Depletions** | 862 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBB1QQ Viva Quad S

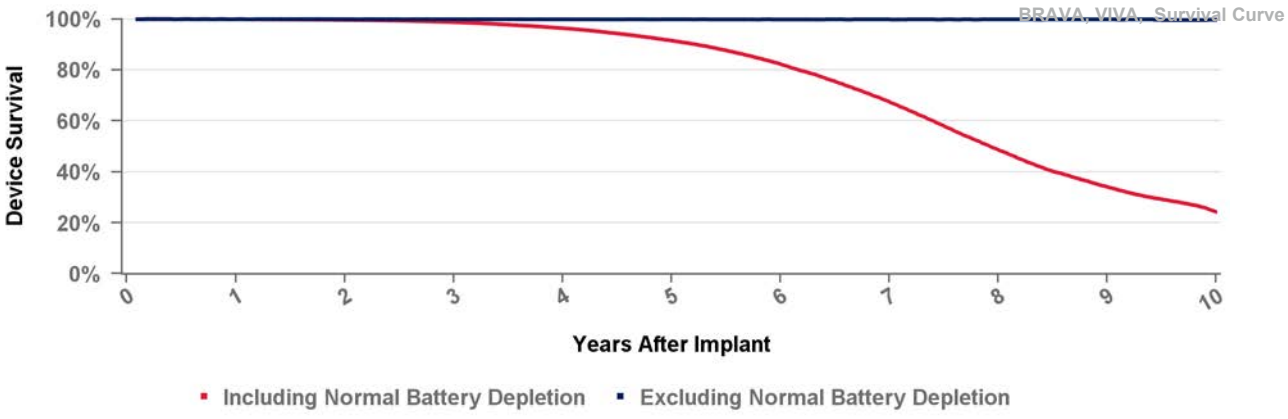
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **10** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 5,114 | Battery | 1 |
| **Estimated Active USA Implants** | 1,220 | Electrical Component | 4 |
| **Normal Battery Depletions** | 2,199 | 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 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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** | | | |



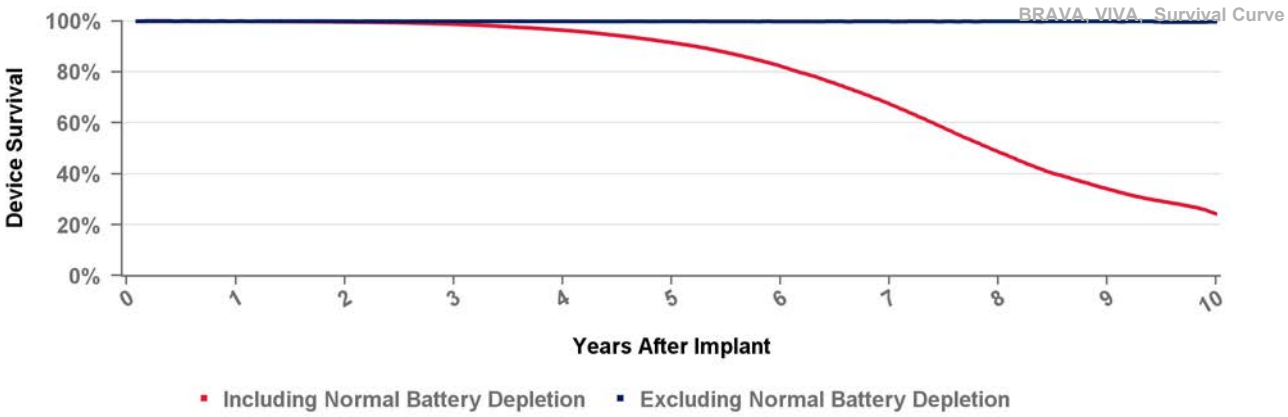

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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**



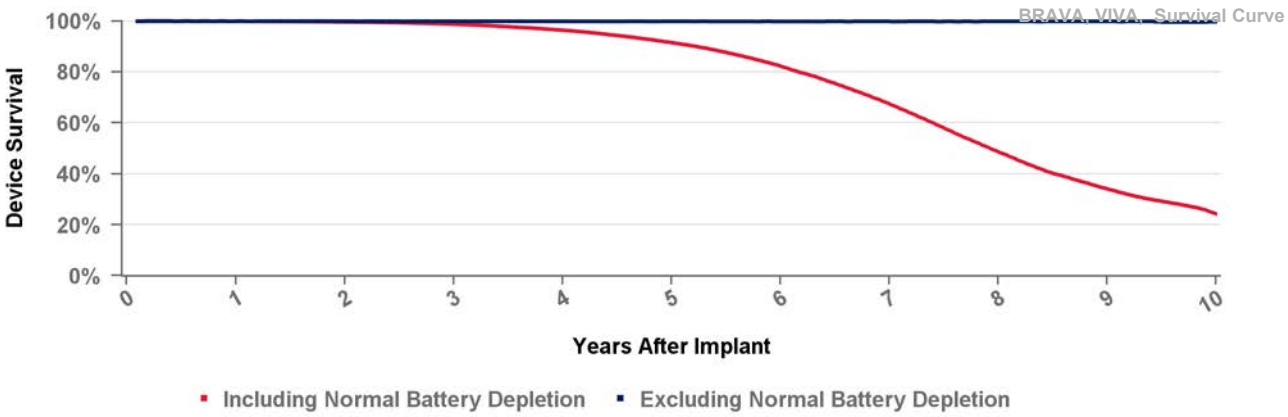

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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**



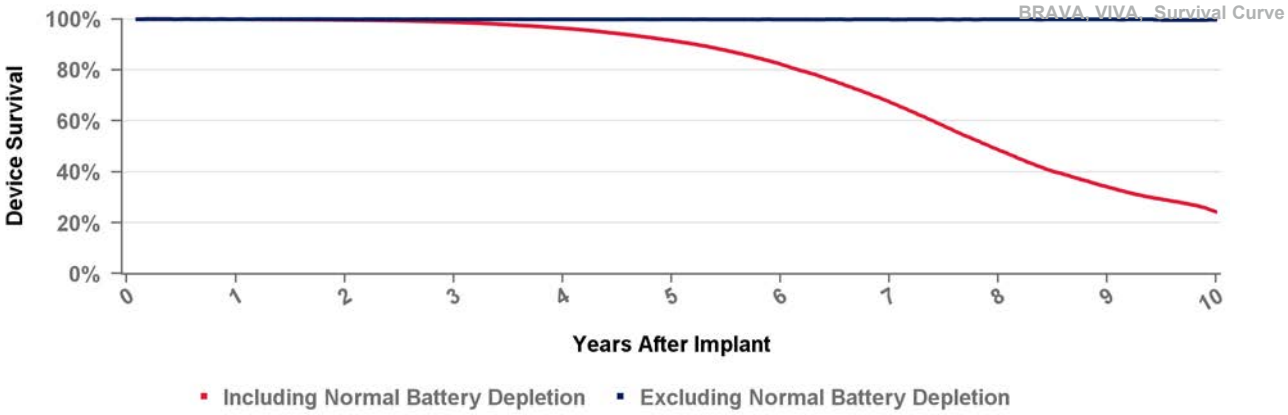

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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**



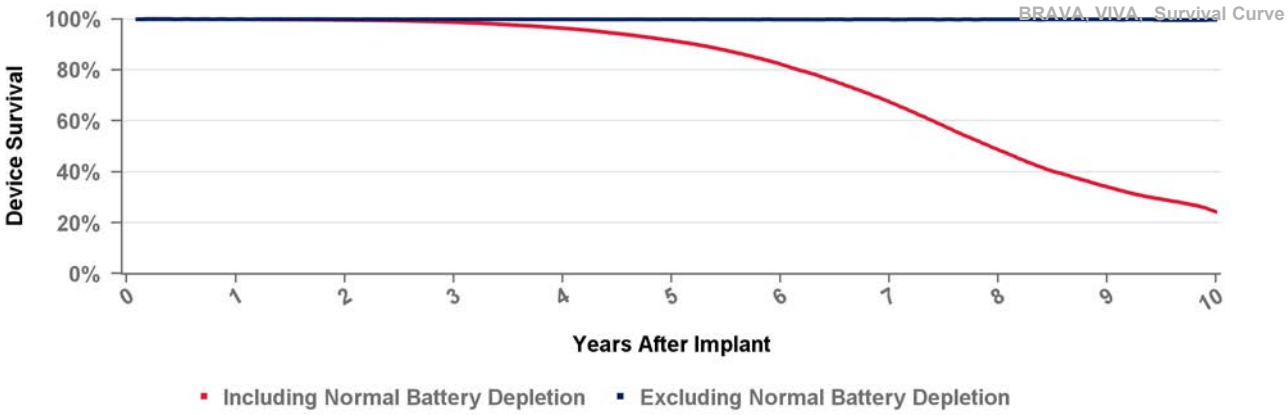

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## 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**

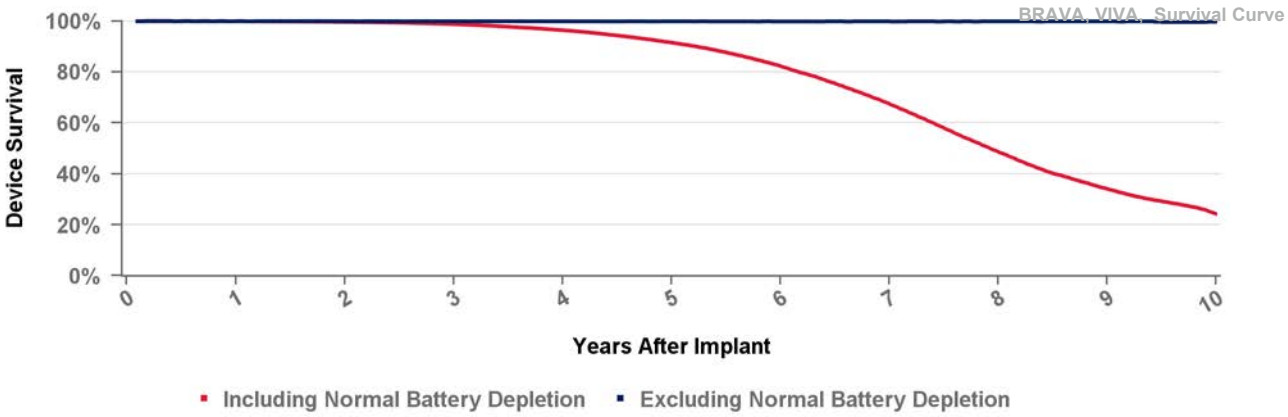
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBC2Q1 Brava Quad

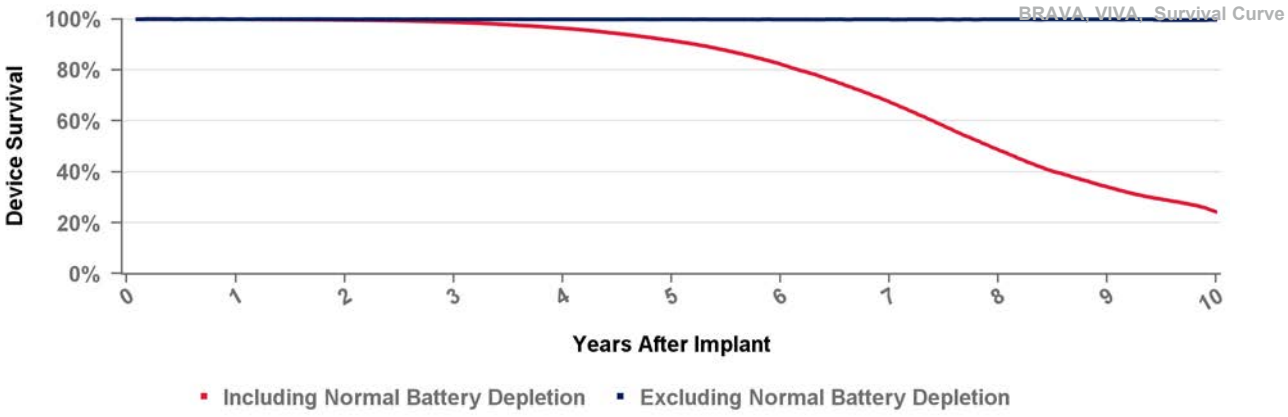
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 12Sep2013 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBC2QQ Brava Quad

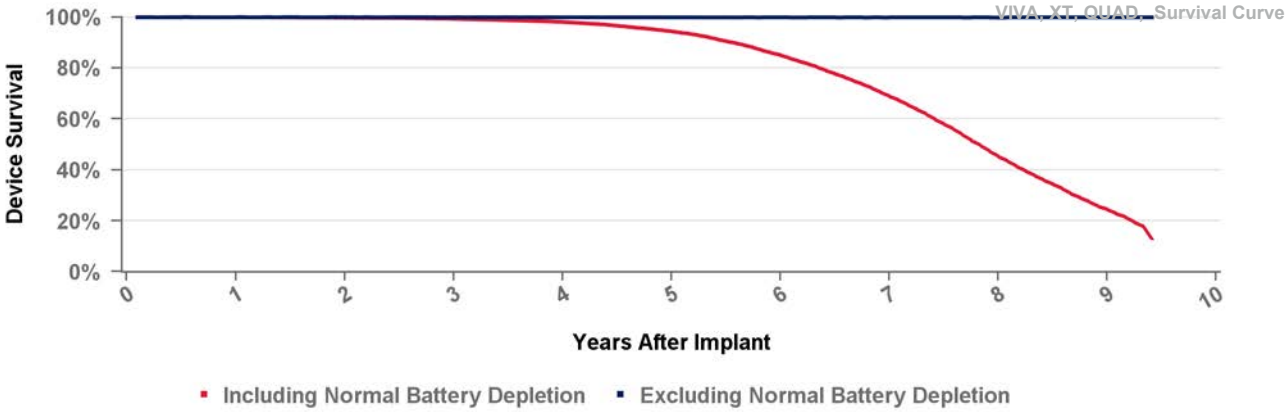
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 08Aug2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 120 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.8% | 99.7% |
| Including NBD | 99.9% | 99.7% | 98.8% | 96.4% | 91.5% | 82.3% | 67.5% | 48.6% | 34.1% | 24.2% |
| Effective Sample Size | 86432 | 78571 | 71240 | 63022 | 53143 | 41472 | 28408 | 15521 | 6337 | 256 |

## DTBX1QQ Viva Quad C

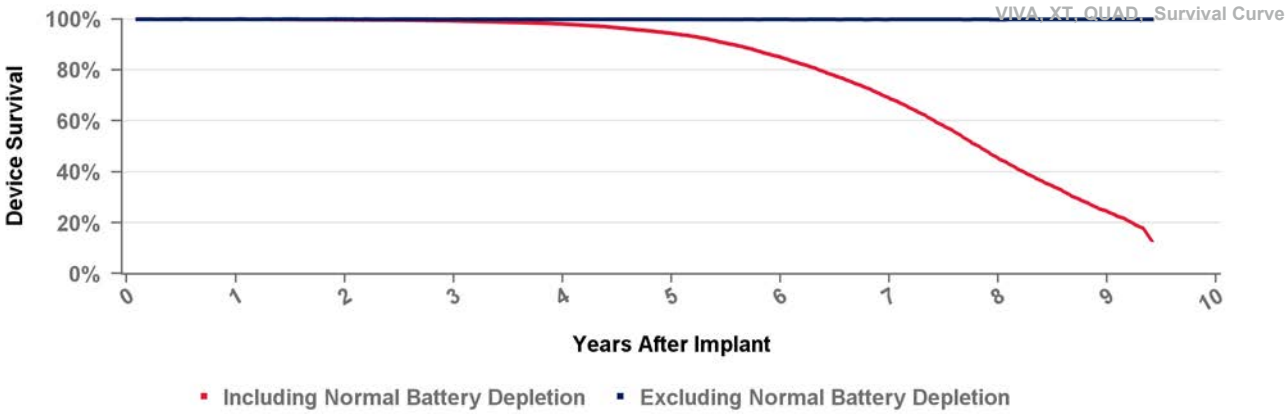
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 638 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 72 | **Therapy Function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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTBX2QQ Viva Quad C

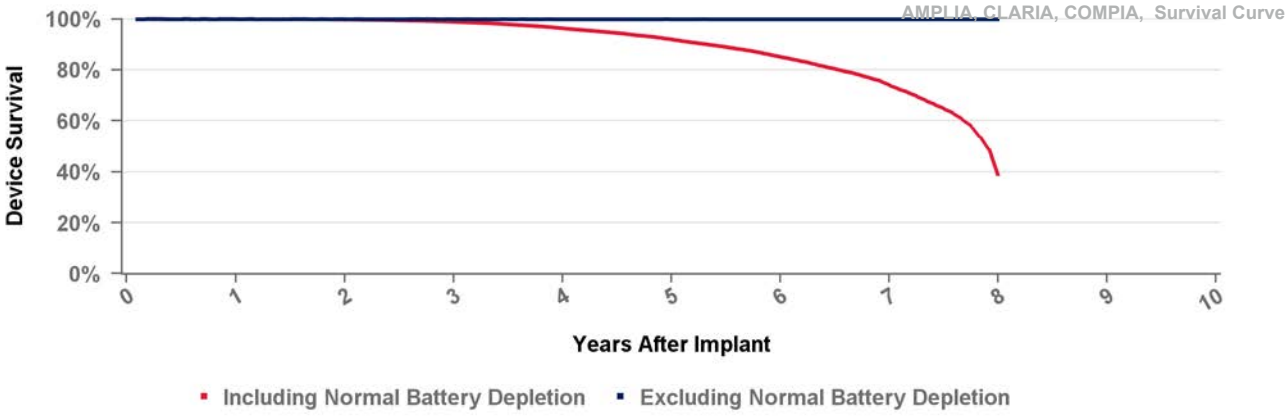
| | | | |
|---|---|---|---|
| **US Market Release** | 03Jul2014 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 113 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% | 99.8% | 99.3% | 98.1% | 94.4% | 85.0% | 68.9% | 45.2% | 24.5% | 12.9% |
| Effective Sample Size | 33765 | 31341 | 28909 | 25971 | 22289 | 17376 | 11664 | 5755 | 1457 | 198 |

## DTMA1D1 Claria MRI

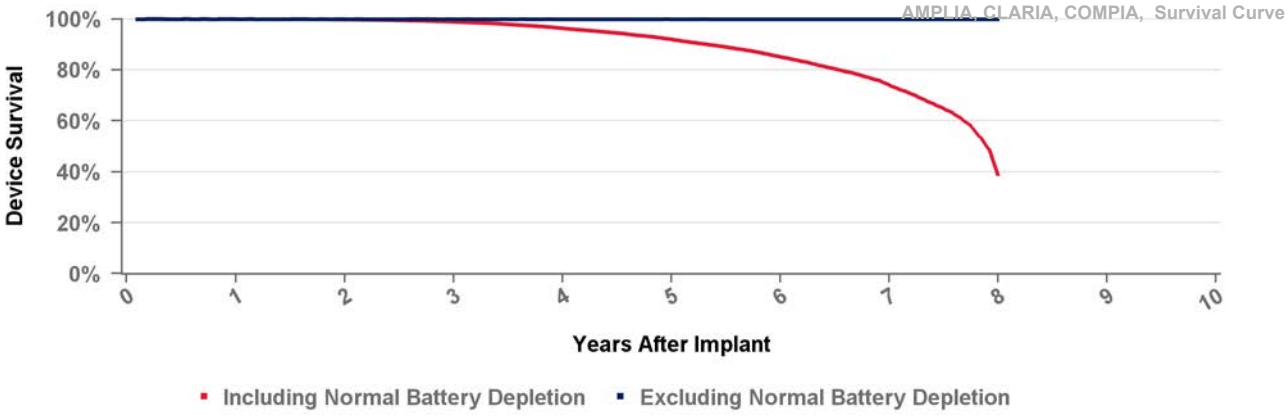
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **10** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 17,560 | Battery | 4 |
| **Estimated Active USA Implants** | 11,690 | Electrical Component | 2 |
| **Normal Battery Depletions** | 1,171 | Electrical Interconnect | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **2** |
| | | Battery | 1 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMA1D4 Claria MRI

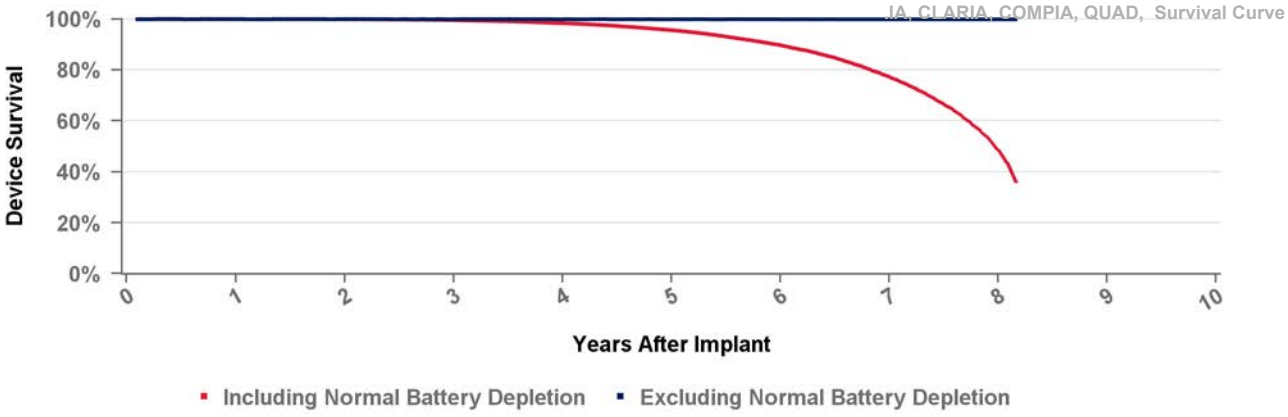
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **12** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 16,882 | Battery | 1 |
| **Estimated Active USA Implants** | 11,934 | Electrical Component | 5 |
| **Normal Battery Depletions** | 910 | **Therapy Function Compromised** | **6** |
| | | Battery | 1 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 2 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMA1Q1 Claria MRI

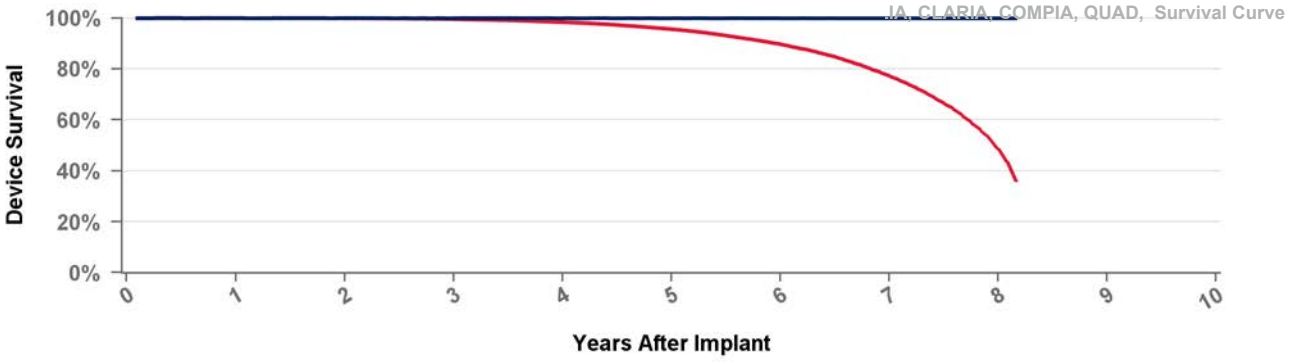
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 12,323 | Battery | 1 |
| **Estimated Active USA Implants** | 8,602 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 677 | Possible Early Battery Depletion | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMA1QQ Claria MRI

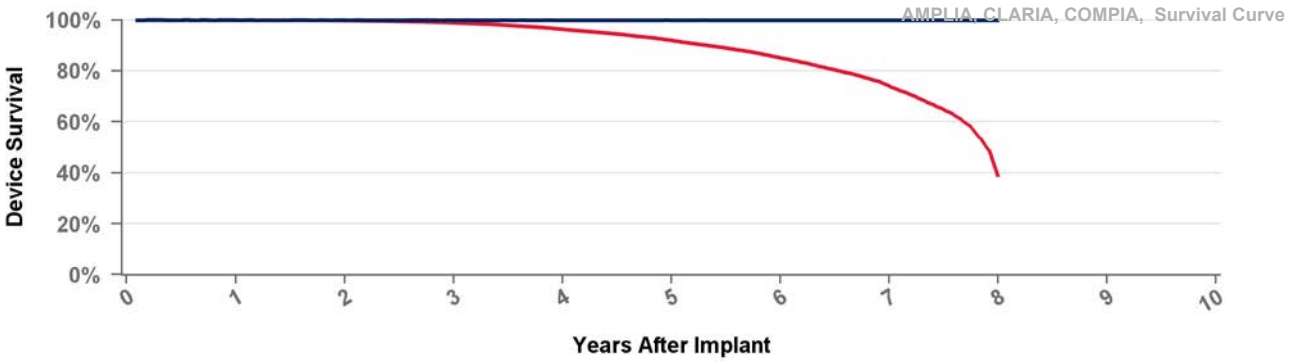
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **36** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **24** |
| **Registered USA Implants** | 76,594 | Battery | 2 |
| **Estimated Active USA Implants** | 56,393 | Electrical Component | 16 |
| **Normal Battery Depletions** | 4,126 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 1 |
| | | Software/Firmware | 1 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **12** |
| | | Device-Related Current Pathway | 5 |
| | | Electrical Component | 7 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMA2D1 Claria MRI

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



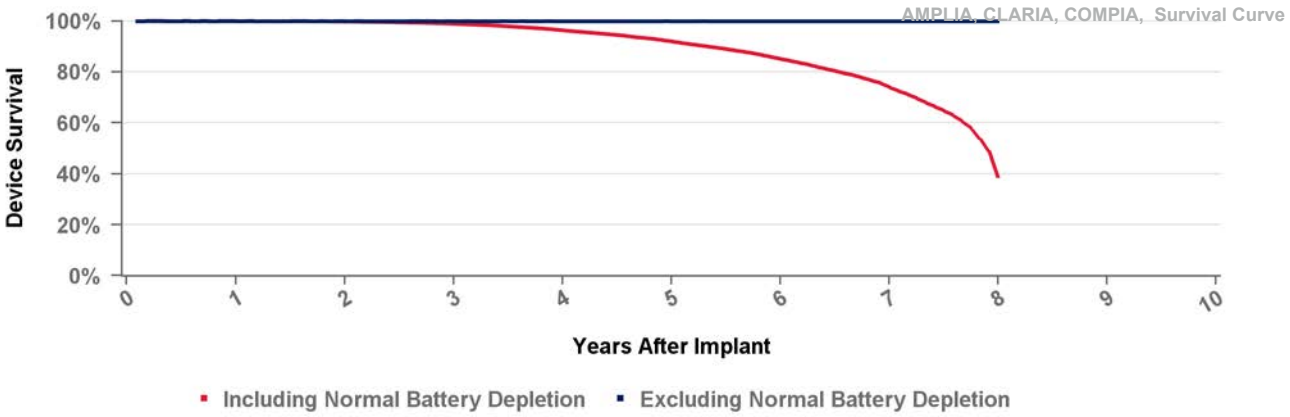

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMA2D4 Claria MRI

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

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

**Therapy Function Compromised**



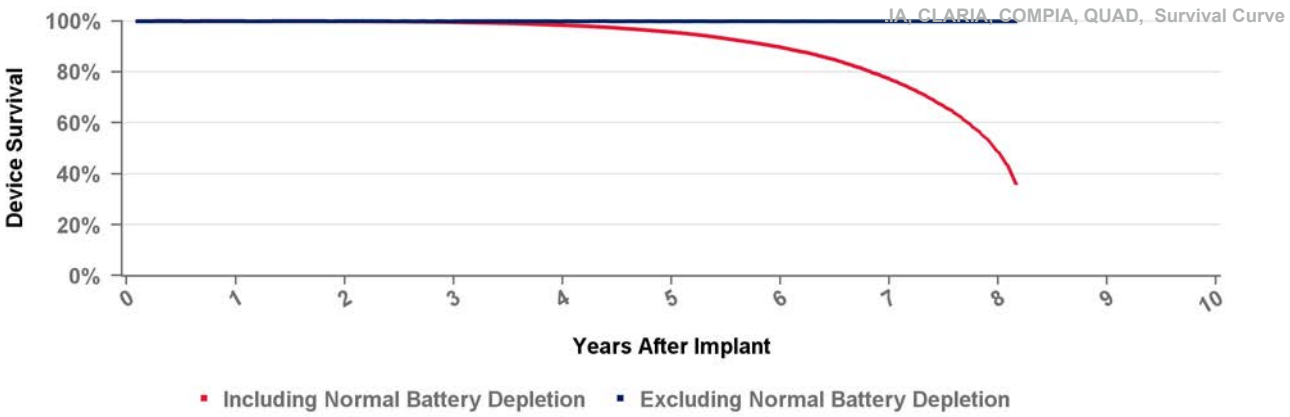

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## 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**

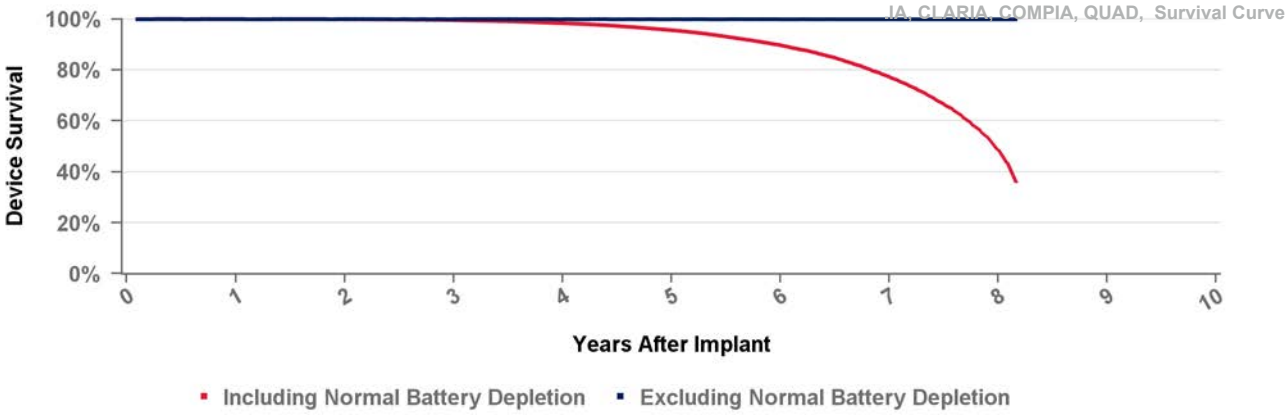
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMA2QQ Claria MRI

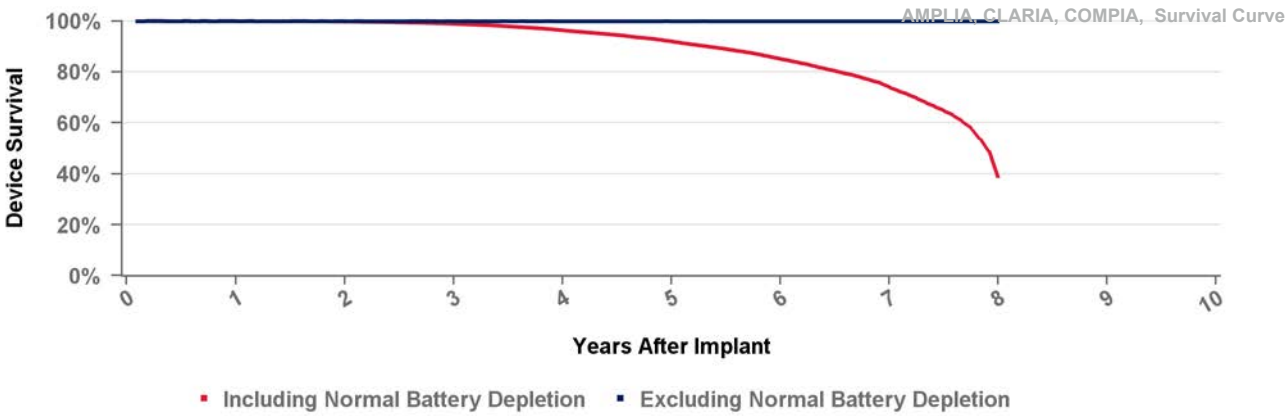
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Feb2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMB1D1 Amplia MRI

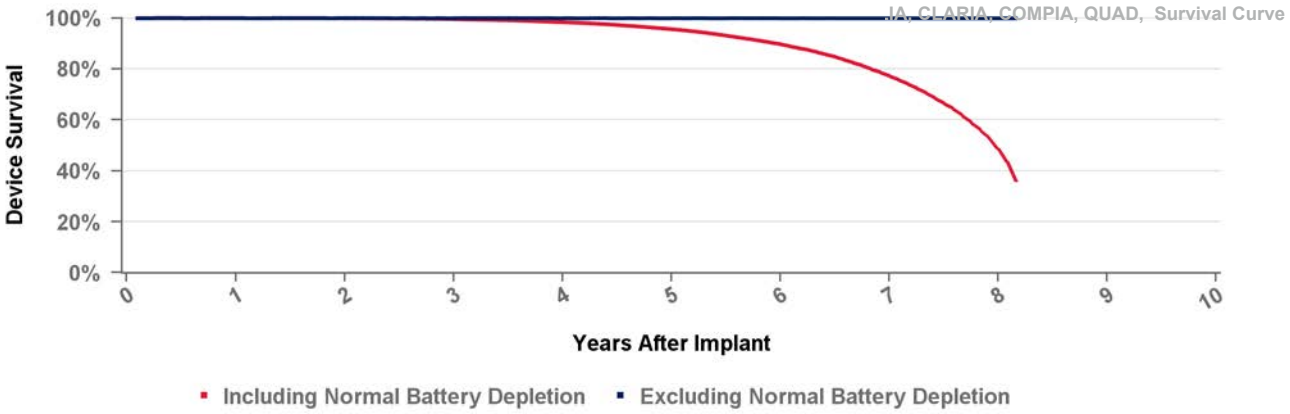
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **6** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 6,769 | Battery | 2 |
| **Estimated Active USA Implants** | 3,891 | Electrical Component | 2 |
| **Normal Battery Depletions** | 743 | Other | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMB1Q1 Amplia MRI

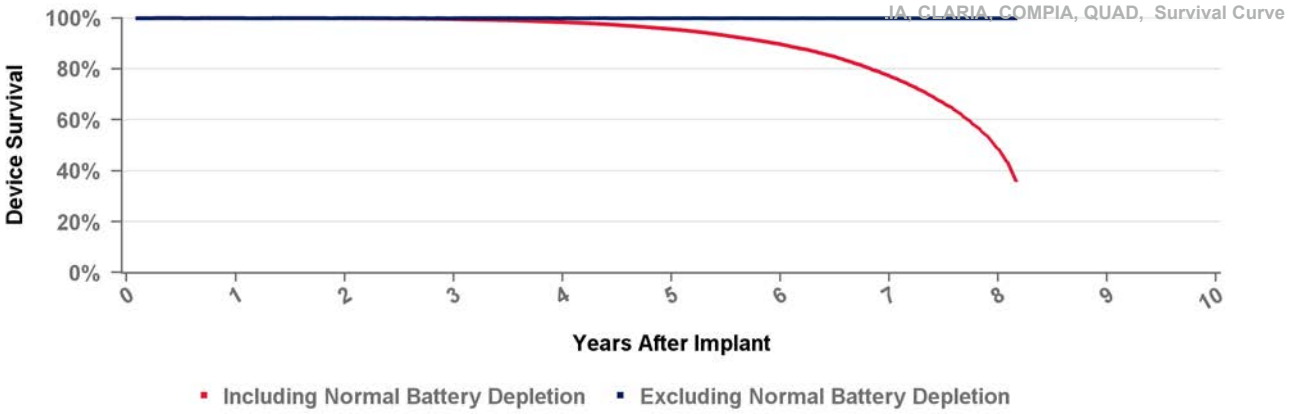
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 4,485 | Battery | 2 |
| **Estimated Active USA Implants** | 2,785 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 439 | Battery | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMB1QQ Amplia MRI

| | | | |
|---|---|---|---|
| **US Market Release** | 01Feb2016 | **Total Malfunctions (USA)** | **42** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **33** |
| **Registered USA Implants** | 31,999 | Battery | 14 |
| **Estimated Active USA Implants** | 16,302 | Electrical Component | 13 |
| **Normal Battery Depletions** | 6,003 | Possible Early Battery Depletion | 3 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **9** |
| | | Battery | 8 |
| | | Device-Related Current Pathway | 1 |

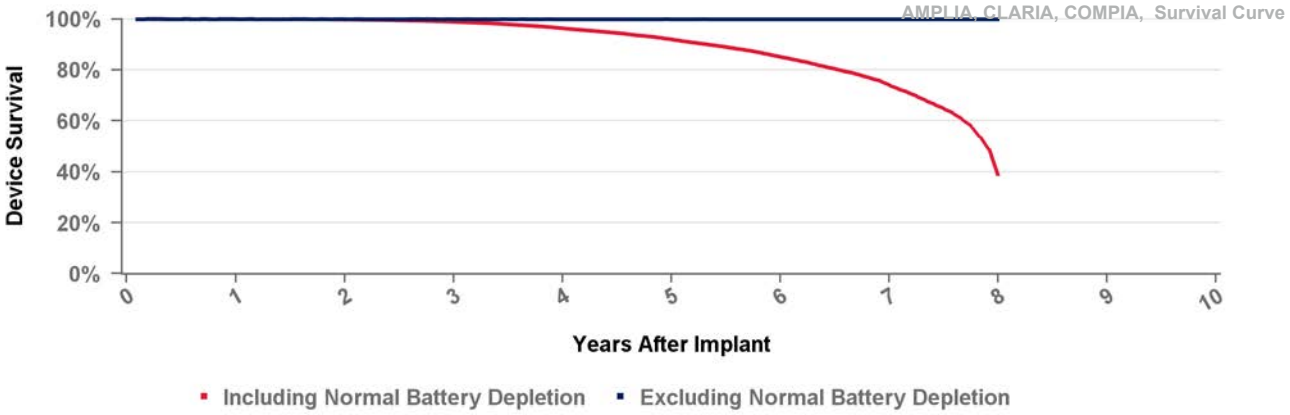



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMB2D1 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**

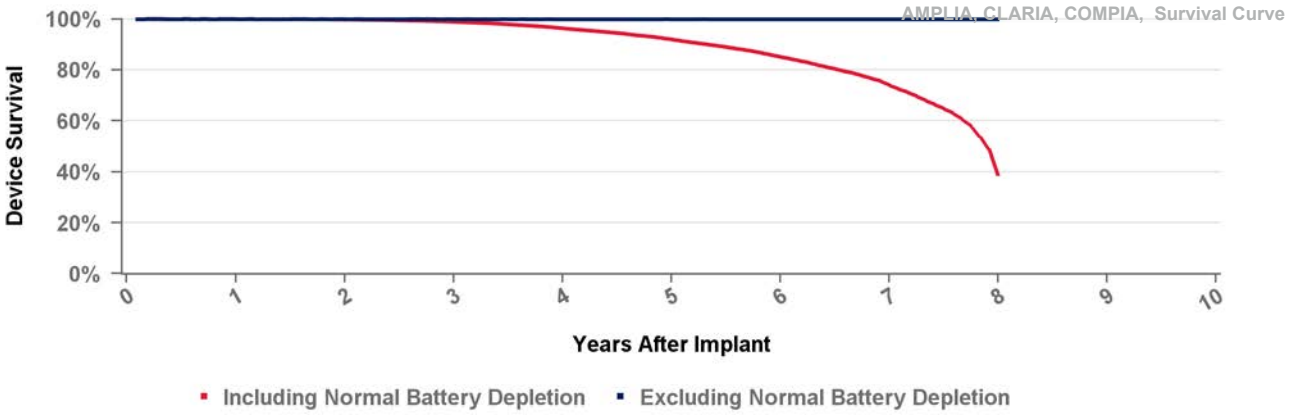



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMB2D4 Amplia MRI

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

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

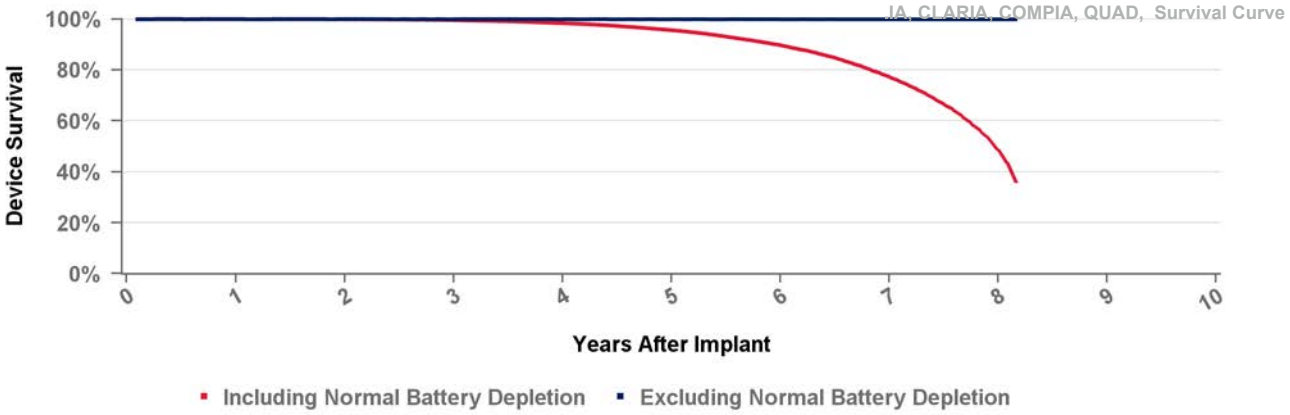



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## 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**

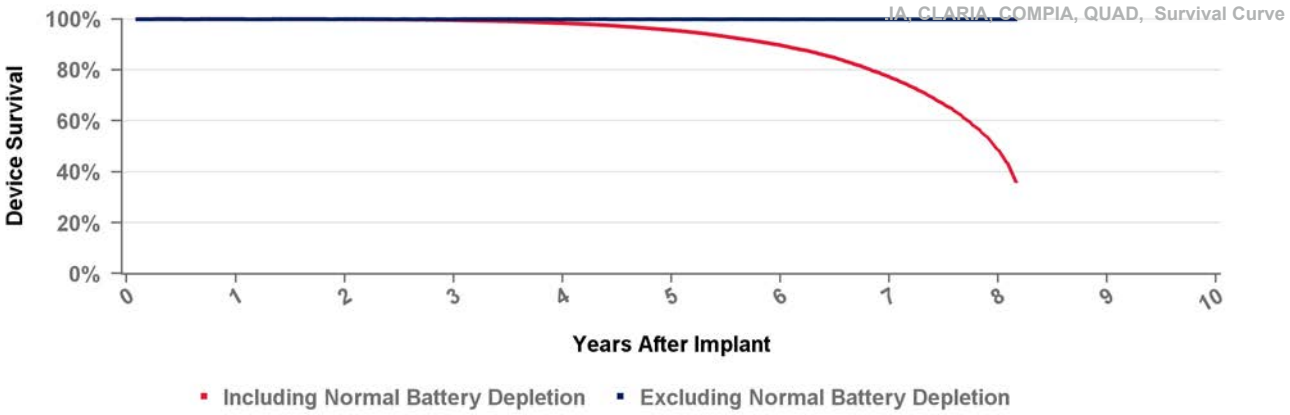



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMB2QQ Amplia MRI

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

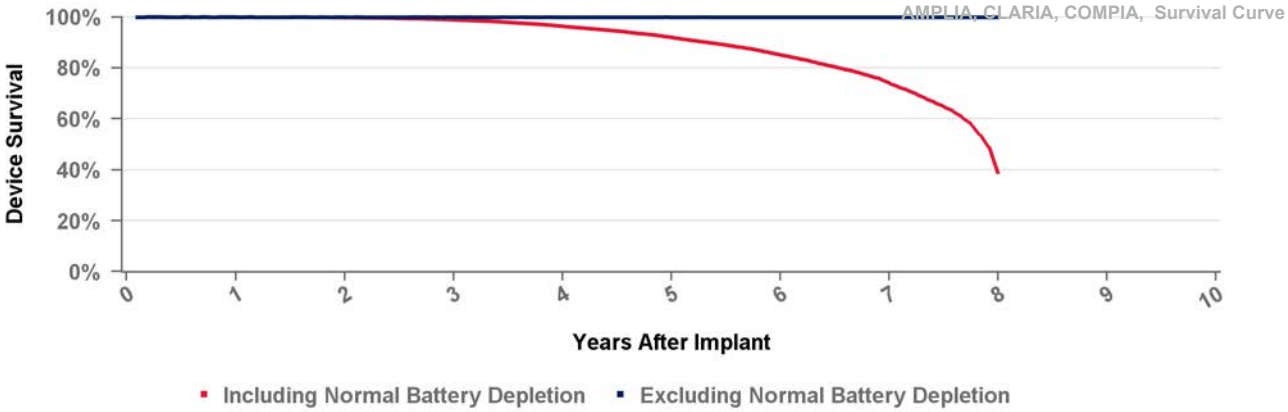
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMC1D1 Compia MRI

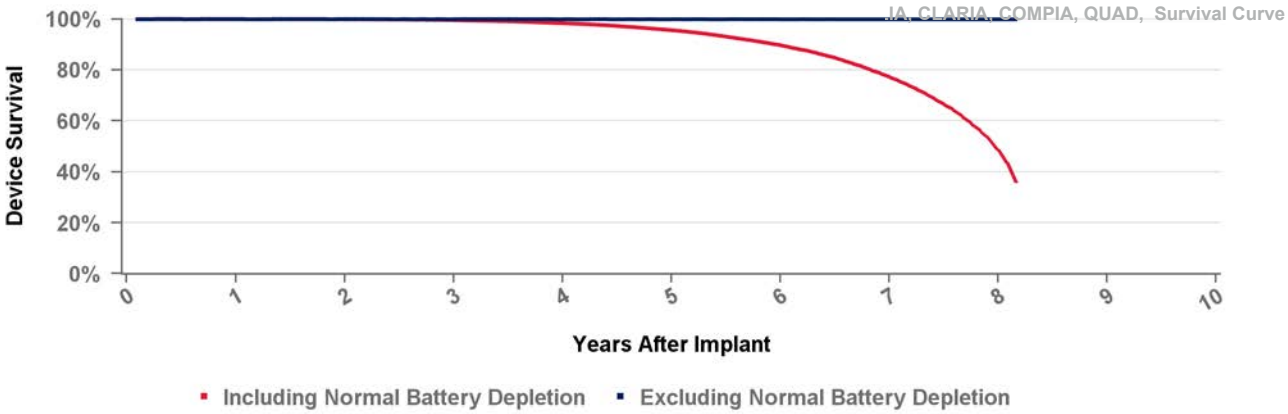
| | | | |
|---|---|---|---|
| **US Market Release** | 05Dec2016 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 1,142 | | |
| **Estimated Active USA Implants** | 725 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 119 | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMC1QQ Compia MRI

| | | | |
|---|---|---|---|
| **US Market Release** | 01Feb2016 | **Total Malfunctions (USA)** | **5** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 5,017 | Battery | 3 |
| **Estimated Active USA Implants** | 3,039 | Electrical Component | 2 |
| **Normal Battery Depletions** | 822 | **Therapy Function Compromised** | **0** |



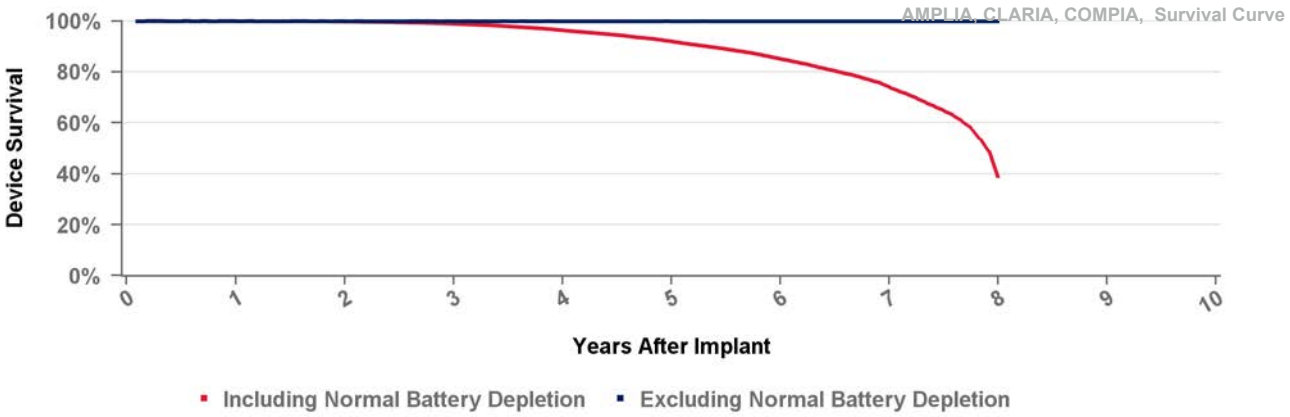

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTMC2D1 Compia 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**



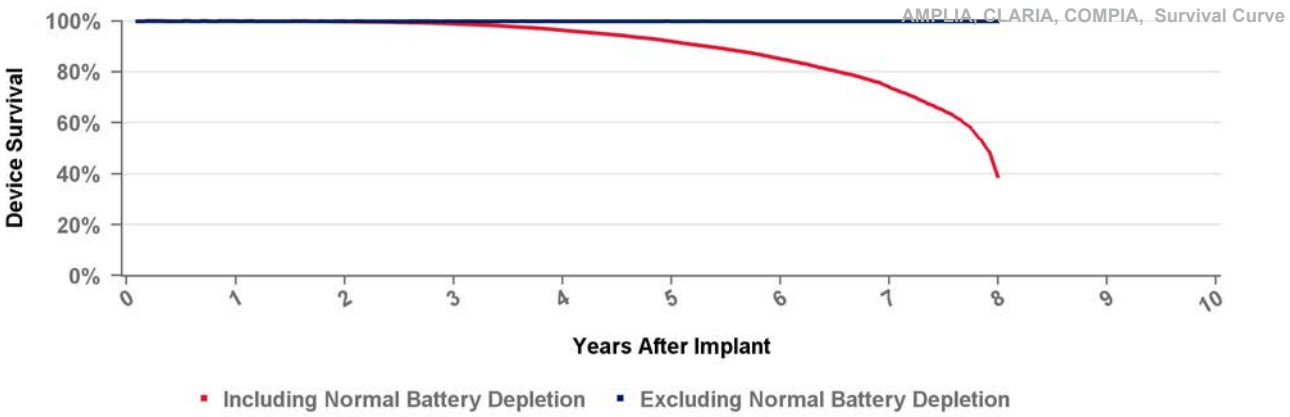

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## 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**

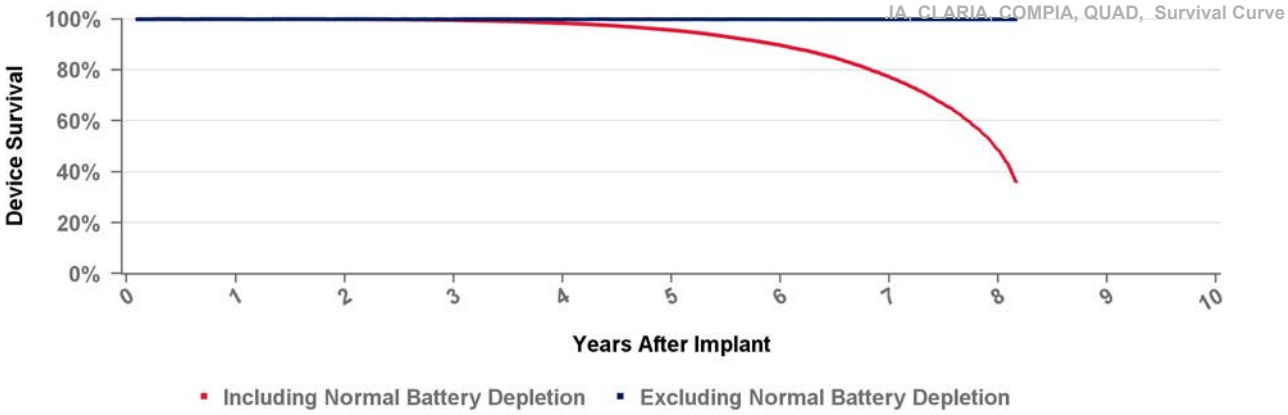
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.8% | 98.9% | 96.4% | 92.0% | 85.1% | 74.0% | 38.9% |
| Effective Sample Size | 43141 | 39388 | 32943 | 24768 | 18279 | 11786 | 5763 | 175 |

## DTMC2QQ Compia MRI

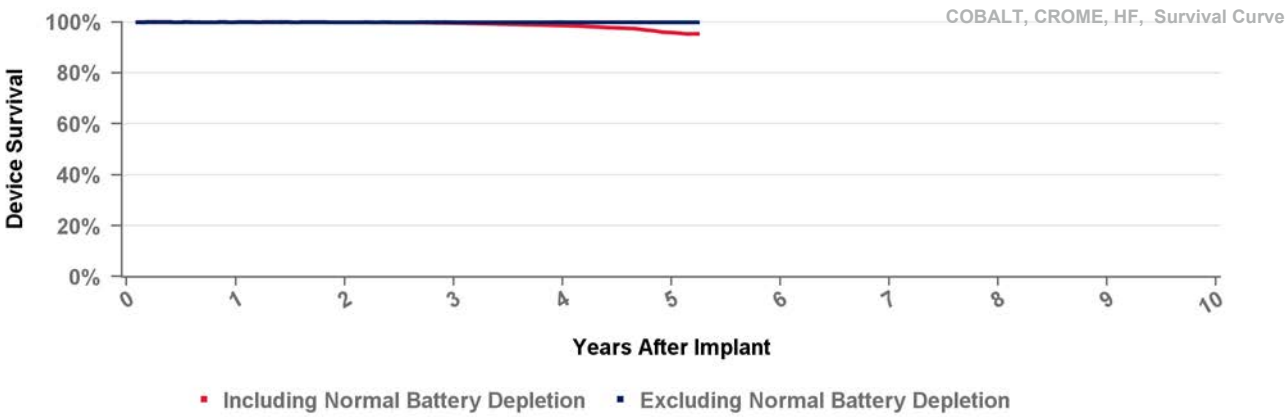
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Feb2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 98 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.4% | 95.6% | 89.7% | 77.2% | 48.8% | 36.1% |
| Effective Sample Size | 115300 | 106786 | 93827 | 75960 | 60590 | 39320 | 18632 | 2931 | 967 |

## DTPA2D1 Cobalt XT HF

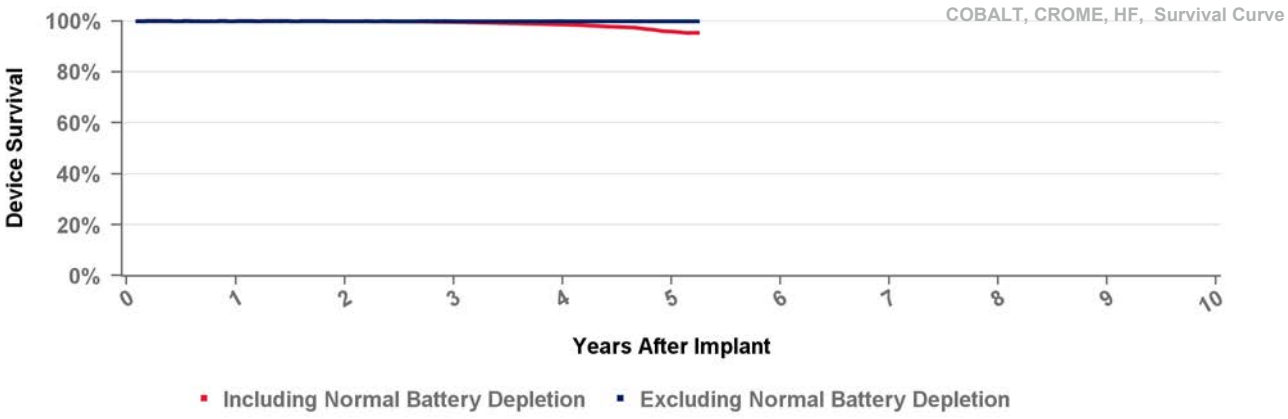
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 8,927 | Other | 1 |
| **Estimated Active USA Implants** | 8,351 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 23 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPA2D4 Cobalt XT HF

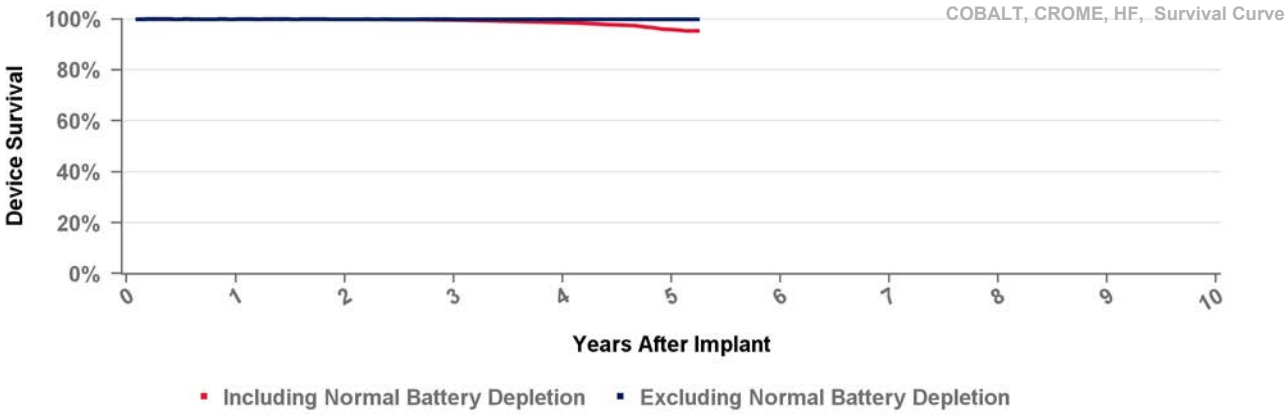
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 15,805 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 14,971 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 17 | **Therapy Function Compromised** | **2** |
| | | Electrical Component | 1 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPA2Q1 Cobalt XT HF Quad

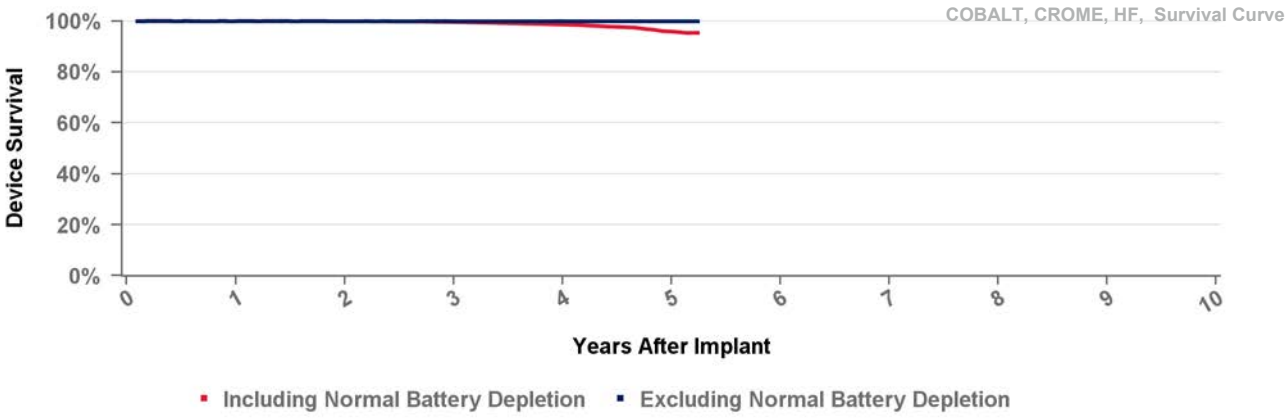
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 6,378 | Software/Firmware | 1 |
| **Estimated Active USA Implants** | 5,981 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 5 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPA2QQ Cobalt XT HF Quad

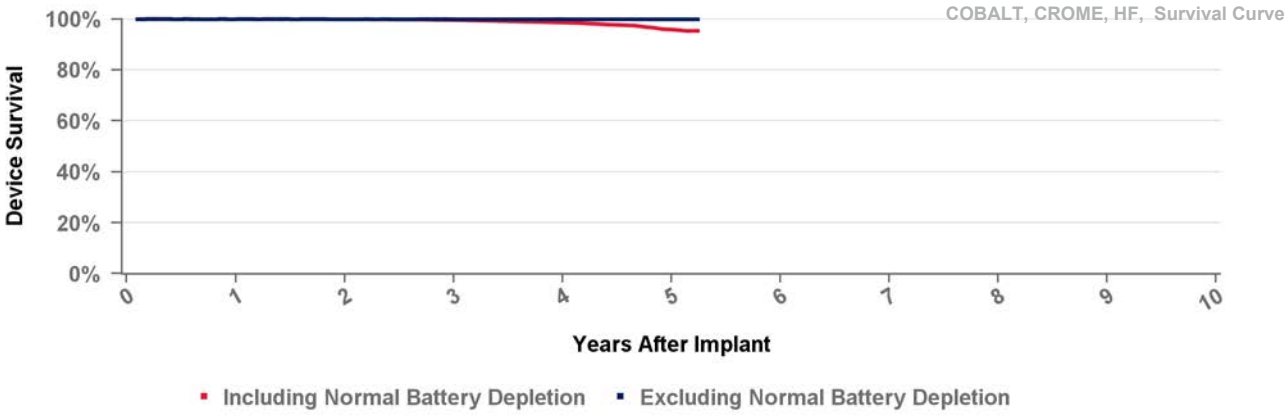
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **7** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 61,455 | Electrical Component | 4 |
| **Estimated Active USA Implants** | 58,489 | Software/Firmware | 1 |
| **Normal Battery Depletions** | 45 | **Therapy Function Compromised** | **2** |
| | | Electrical Component | 1 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPB2D1 Cobalt HF

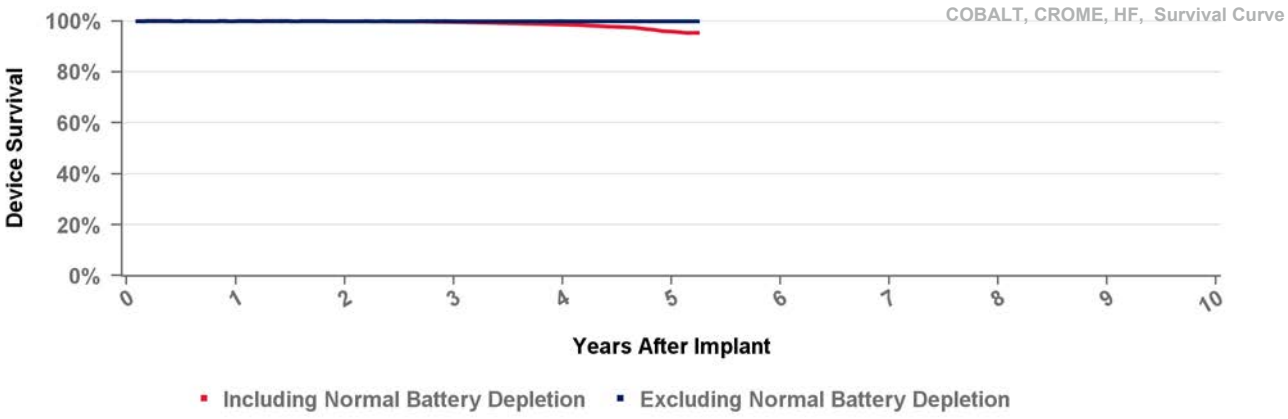
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 4,688 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 4,151 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | 42 | Electrical Component | 1 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPB2D4 Cobalt HF

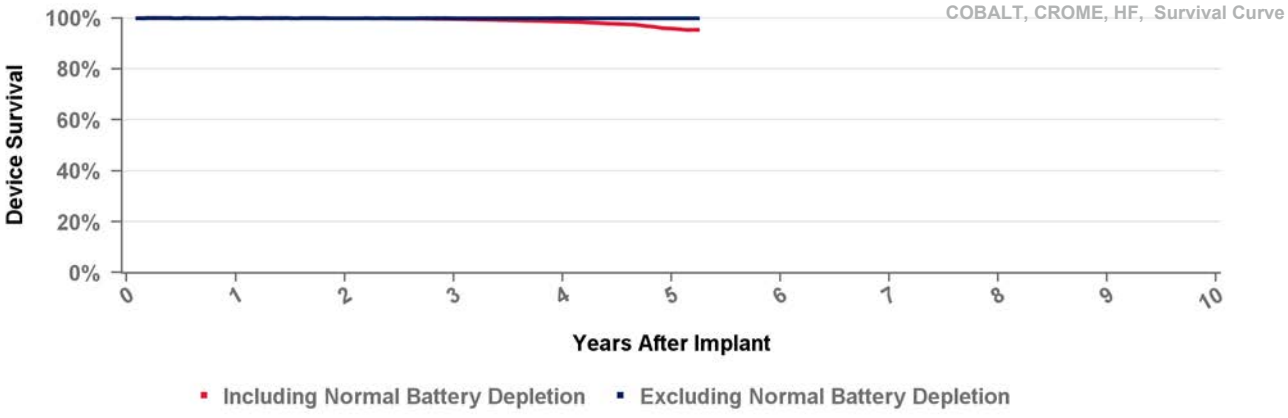
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **6** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 5,447 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 4,969 | Electrical Interconnect | 3 |
| **Normal Battery Depletions** | 25 | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPB2Q1 Cobalt HF Quad

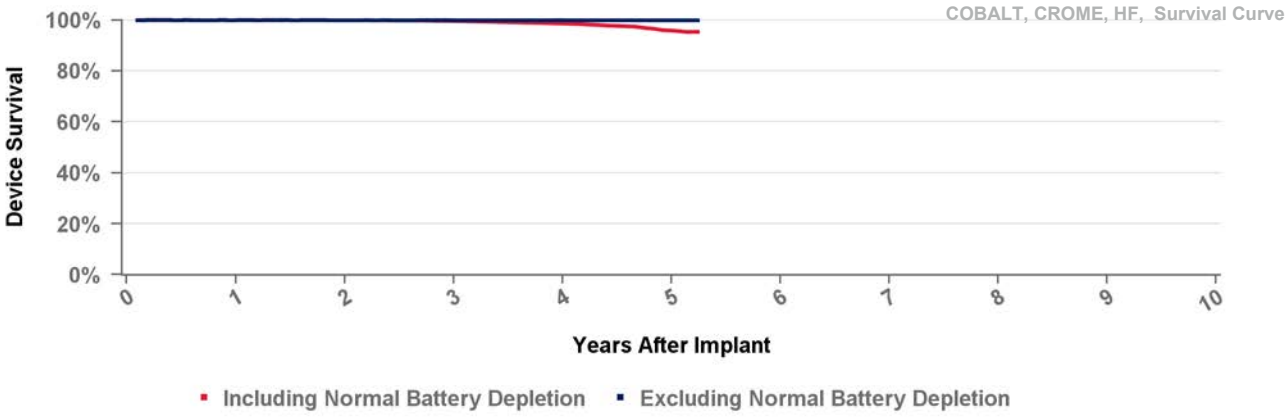
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 3,248 | | |
| **Estimated Active USA Implants** | 2,919 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 16 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPB2QQ Cobalt HF Quad

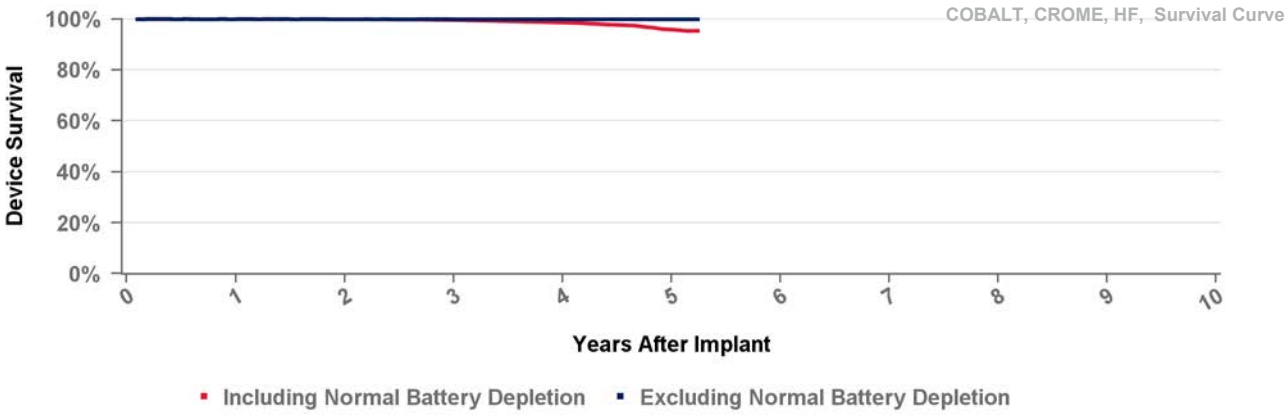
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **14** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 24,817 | Electrical Component | 6 |
| **Estimated Active USA Implants** | 22,880 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 100 | Other | 1 |
| | | **Therapy Function Compromised** | **6** |
| | | Electrical Component | 3 |
| | | Electrical Interconnect | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPC2D1 Crome HF

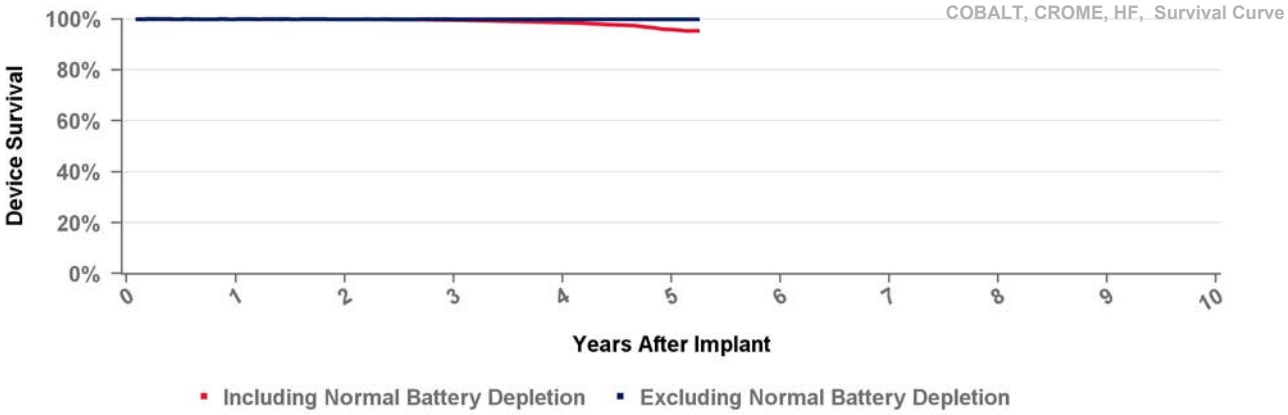
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 582 | | |
| **Estimated Active USA Implants** | 529 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 4 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPC2D4 Crome HF

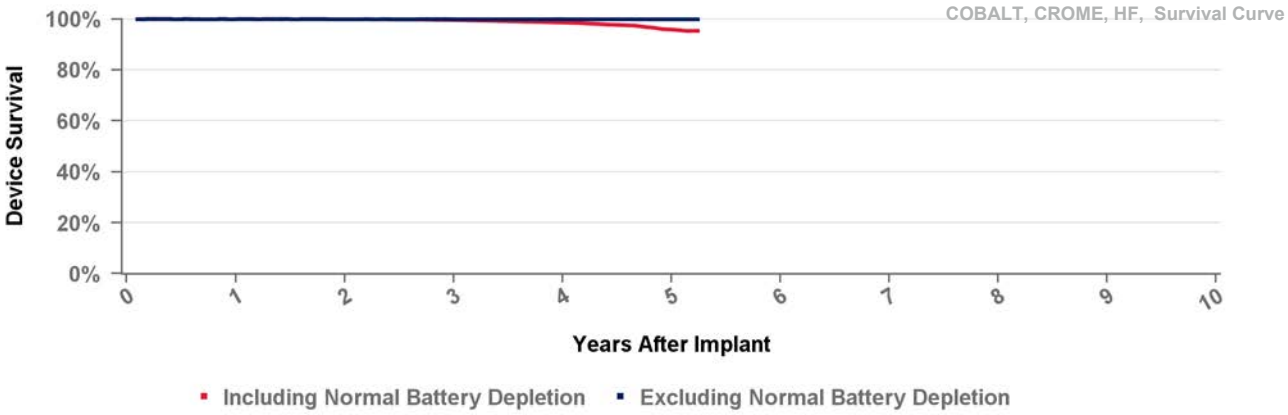
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 744 | | |
| **Estimated Active USA Implants** | 696 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 3 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPC2Q1 Crome HF Quad

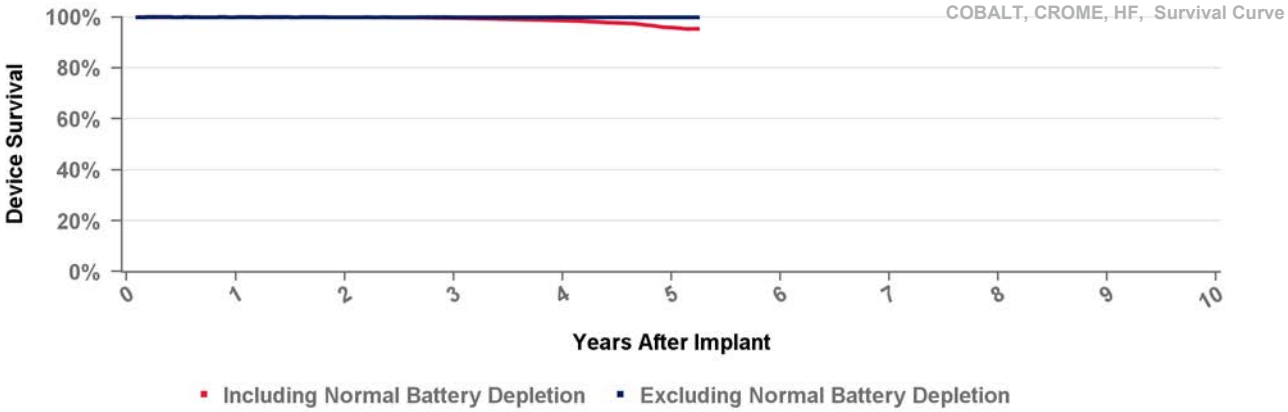
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 309 | | |
| **Estimated Active USA Implants** | 290 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 3 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## DTPC2QQ Crome HF Quad

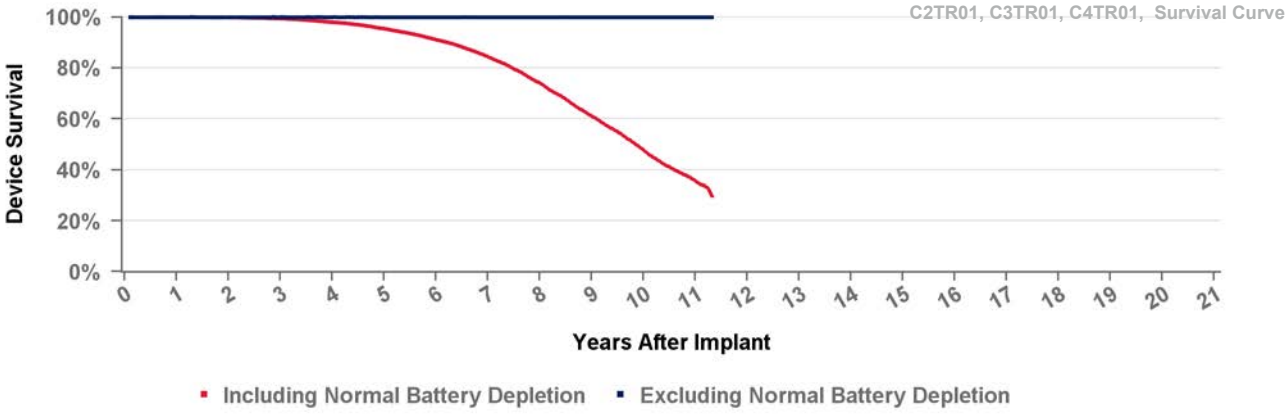
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 2,842 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 2,665 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 8 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.6% | 98.6% | 95.9% | 95.2% |
| Effective Sample Size | 92208 | 55170 | 30275 | 16153 | 1608 | 291 |

## C2TR01 Syncra CRT-P

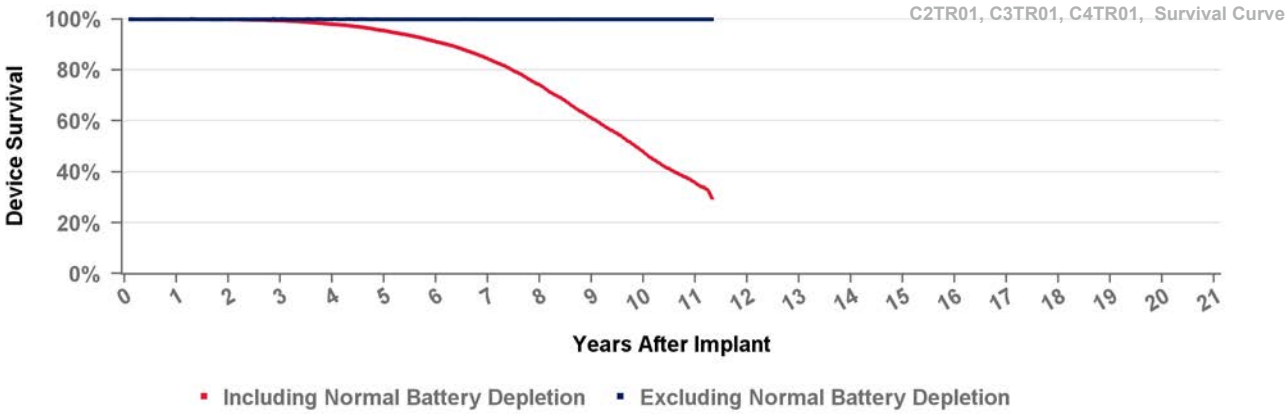
| | | | |
|---|---|---|---|
| **US Market Release** | 22Mar2011 | **Total Malfunctions (USA)** | **7** |
| **CE Approval Date** | 11May2010 | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 10,237 | Possible Early Battery Depletion | 5 |
| **Estimated Active USA Implants** | 1,997 | Other | 1 |
| **Normal Battery Depletions** | 1,050 | **Therapy Function Compromised** | **1** |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 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% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.1% | 84.4% | 74.1% | 61.1% | 47.8% | 35.7% | 29.6% |
| Effective Sample Size | 26194 | 23399 | 20959 | 18309 | 15684 | 13109 | 10483 | 7745 | 4975 | 2523 | 706 | 159 |

## C3TR01 Consulta CRT-P

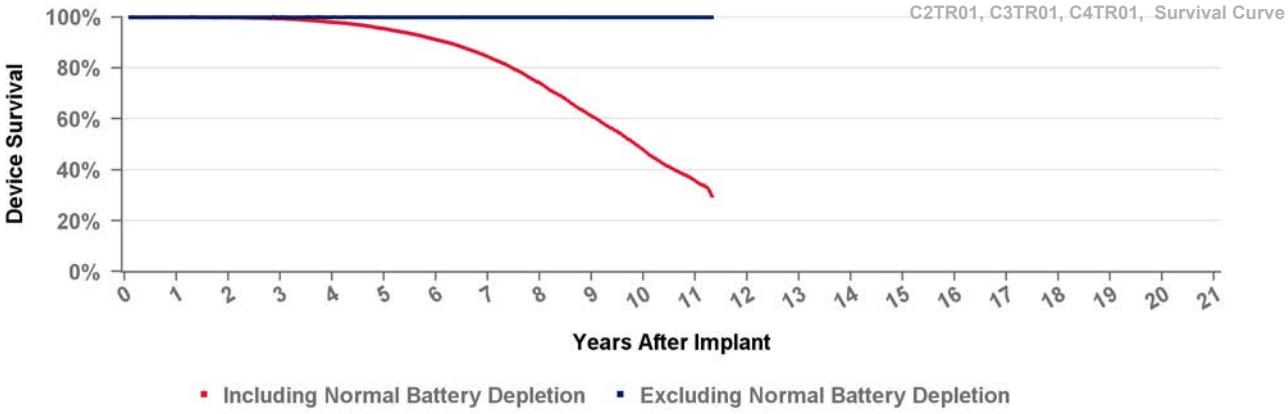
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 11May2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 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% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.1% | 84.4% | 74.1% | 61.1% | 47.8% | 35.7% | 29.6% |
| Effective Sample Size | 26194 | 23399 | 20959 | 18309 | 15684 | 13109 | 10483 | 7745 | 4975 | 2523 | 706 | 159 |

## C4TR01 Consulta CRT-P

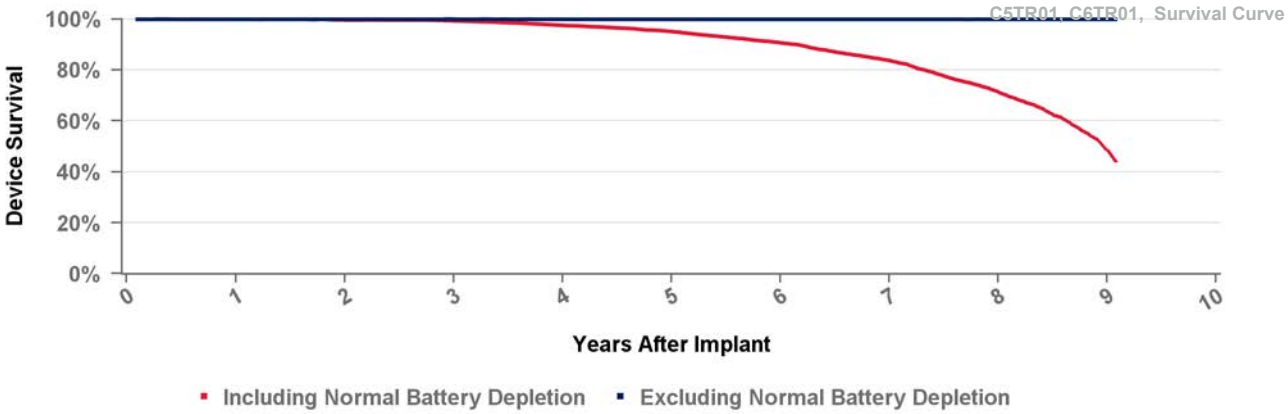
| | | | |
|---|---|---|---|
| **US Market Release** | 22Mar2011 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 23,406 | Possible Early Battery Depletion | 5 |
| **Estimated Active USA Implants** | 5,021 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | 2,548 | Electrical Component | 2 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 136 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% | 99.9% |
| Including NBD | 99.9% | 99.8% | 99.5% | 98.0% | 95.5% | 91.1% | 84.4% | 74.1% | 61.1% | 47.8% | 35.7% | 29.6% |
| Effective Sample Size | 26194 | 23399 | 20959 | 18309 | 15684 | 13109 | 10483 | 7745 | 4975 | 2523 | 706 | 159 |

## C5TR01 Viva CRT-P

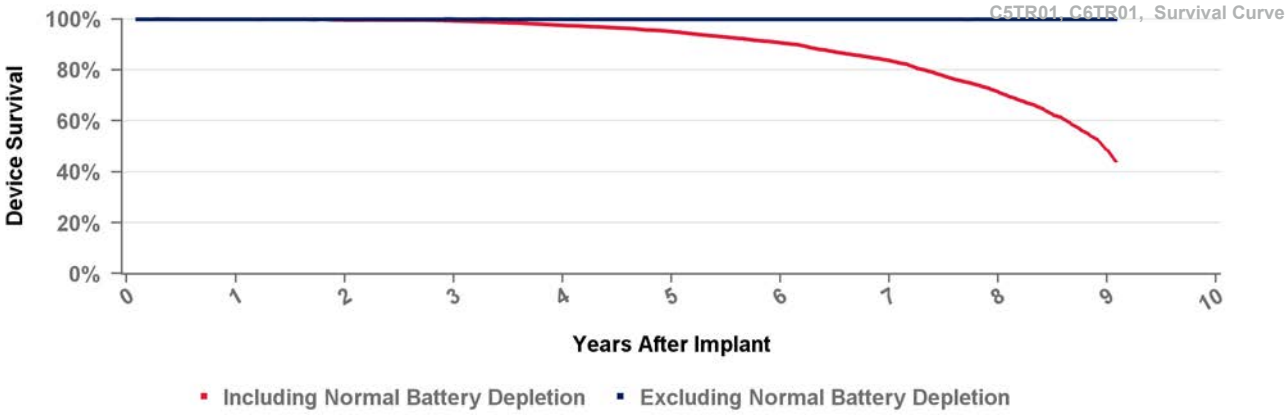
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 04Apr2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.3% | 97.5% | 95.1% | 90.7% | 83.7% | 71.3% | 48.7% | 44.2% |
| Effective Sample Size | 7364 | 6604 | 5921 | 5152 | 4414 | 3639 | 2871 | 2033 | 321 | 185 |

## C6TR01 Viva CRT-P

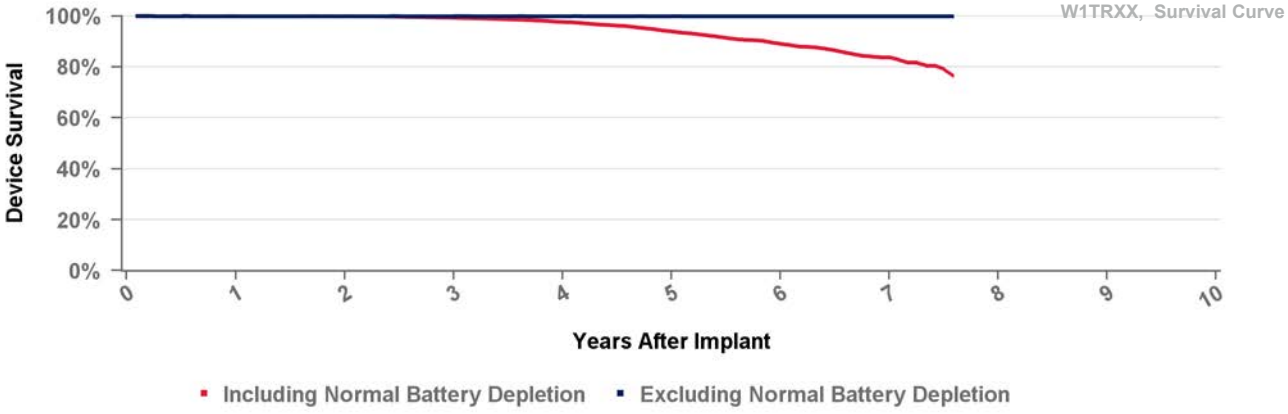
| | | | |
|---|---|---|---|
| **US Market Release** | 09Jul2014 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 9,202 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 3,098 | Possible Early Battery Depletion | 6 |
| **Normal Battery Depletions** | 906 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.3% | 97.5% | 95.1% | 90.7% | 83.7% | 71.3% | 48.7% | 44.2% |
| Effective Sample Size | 7364 | 6604 | 5921 | 5152 | 4414 | 3639 | 2871 | 2033 | 321 | 185 |

## W1TR01 Percepta CRTP MRI

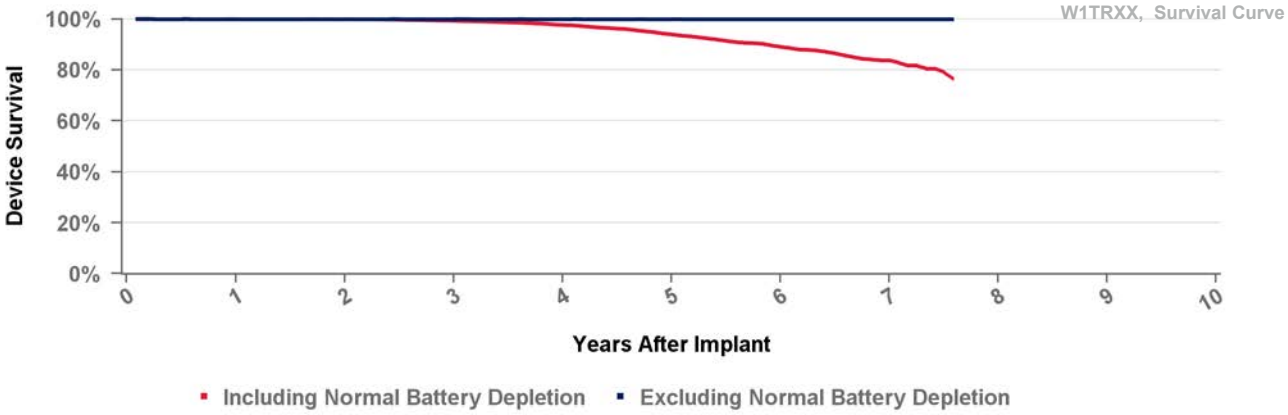
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **6** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 21,723 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 17,938 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 304 | Other | 1 |
| | | **Therapy Function Compromised** | **2** |
| | | Battery | 1 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| Effective Sample Size | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W1TR02 Serena CRTP MRI

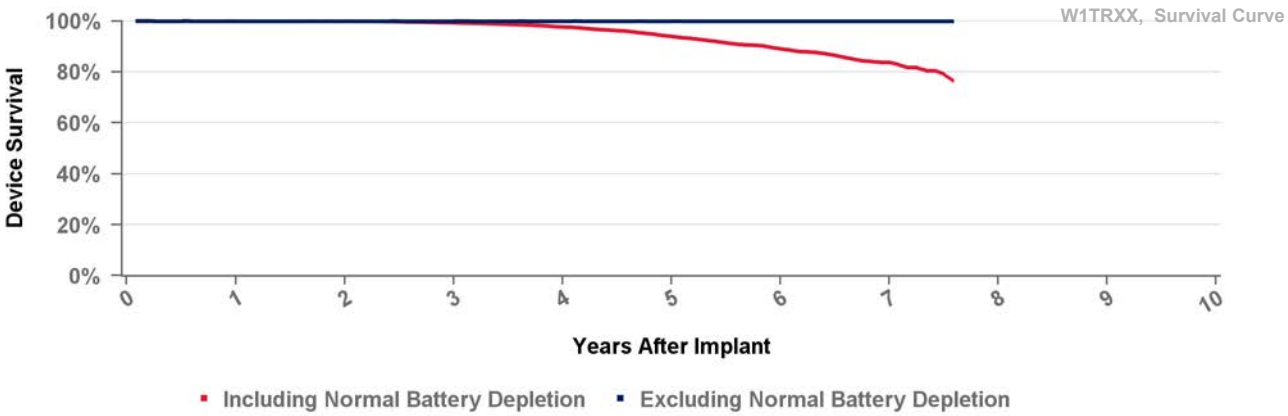
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 3,613 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 2,792 | Other | 1 |
| **Normal Battery Depletions** | 83 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| Effective Sample Size | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W1TR03 Solara CRTP MRI

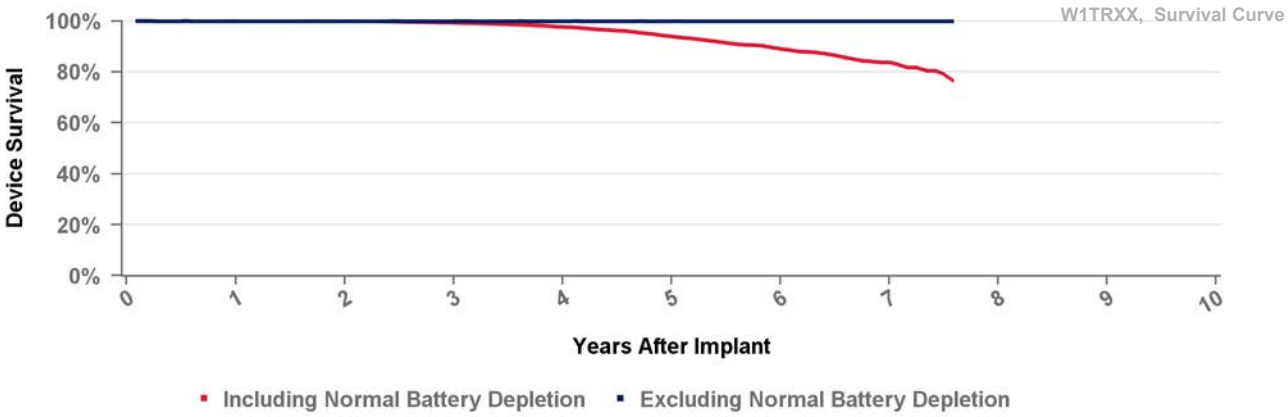
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 4,383 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 3,165 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 138 | **Therapy Function Compromised** | **0** |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| Effective Sample Size | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W1TR04 Percepta CRTP MRI

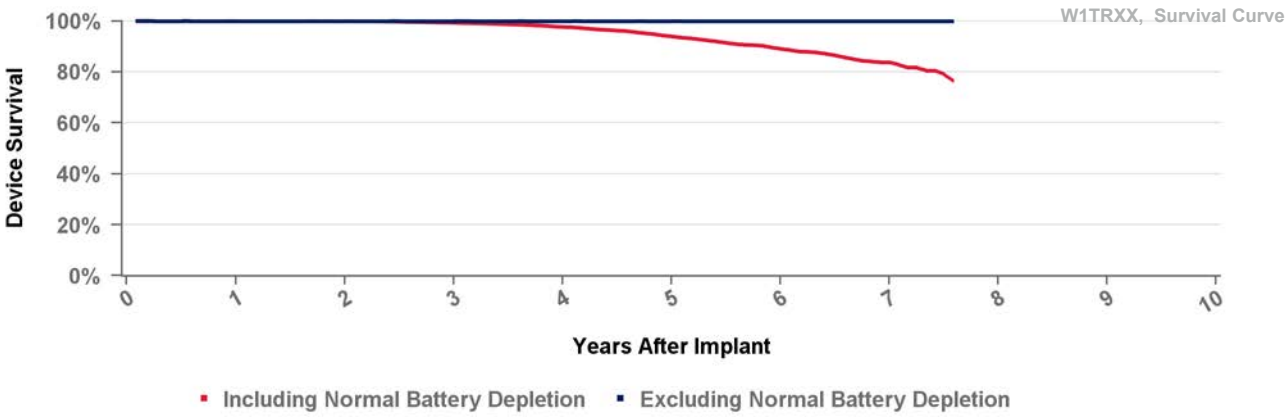
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Feb2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| **Excluding NBD** | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| **Including NBD** | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| **Effective Sample Size** | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W1TR05 Serena CRTP MRI

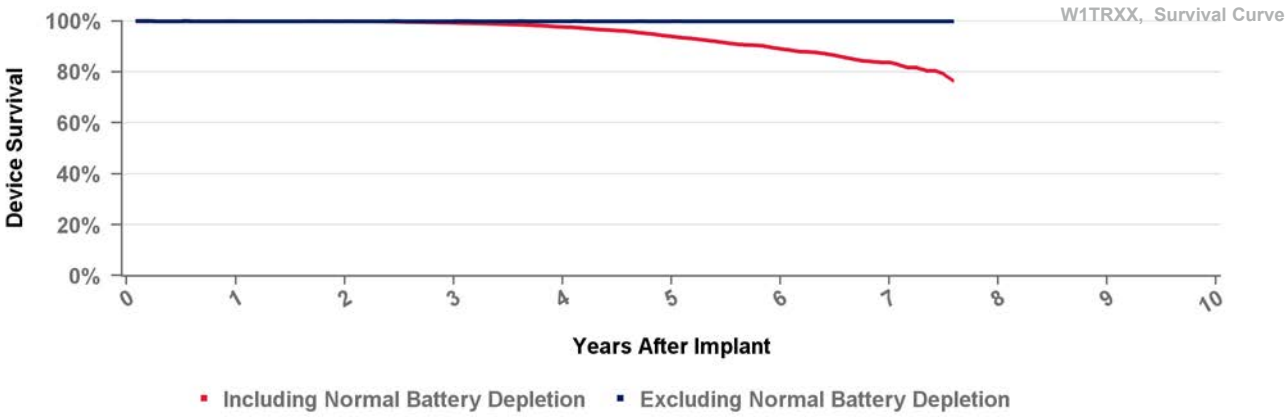
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Feb2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| **Excluding NBD** | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| **Including NBD** | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| **Effective Sample Size** | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W1TR06 Solara CRTP MRI

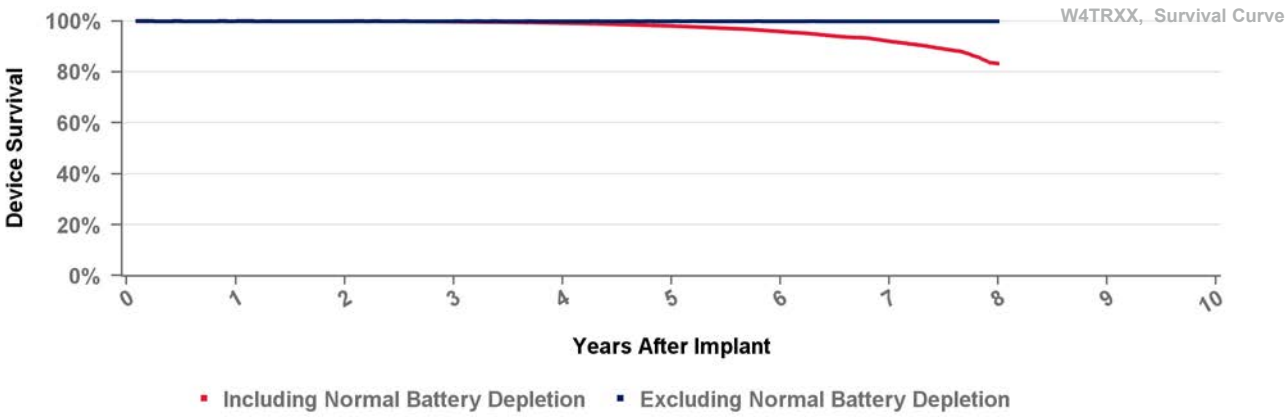
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Feb2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 99.9% | 99.3% | 97.7% | 94.0% | 89.1% | 83.8% | 76.5% |
| Effective Sample Size | 23388 | 18147 | 13543 | 9690 | 6048 | 3164 | 1020 | 119 |

## W4TR01 Percepta Quad CRTP MRI SureScan

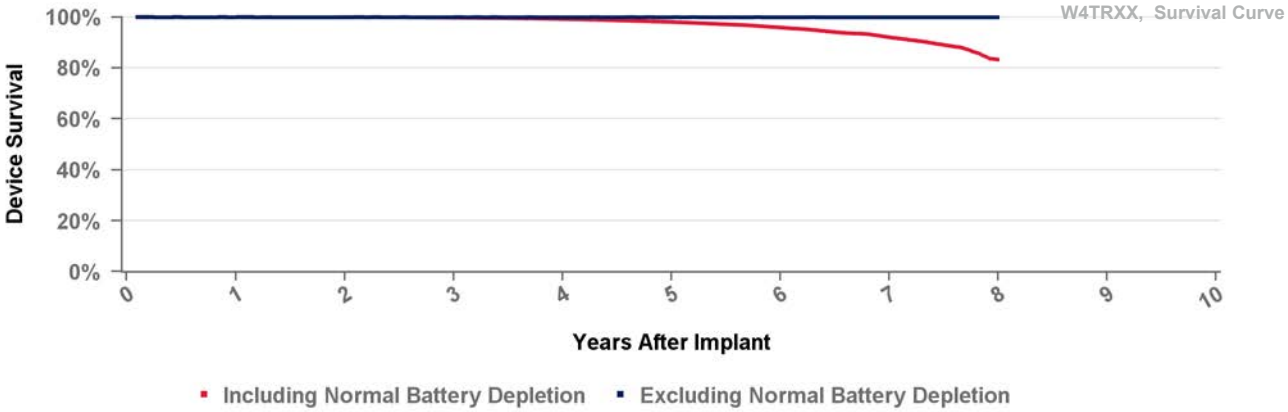
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **16** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **15** |
| **Registered USA Implants** | 72,088 | Electrical Component | 13 |
| **Estimated Active USA Implants** | 60,442 | Possible Early Battery Depletion | 1 |
| **Normal Battery Depletions** | 615 | Other | 1 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| Effective Sample Size | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## W4TR02 Serena Quad CRTP MRI SureScan

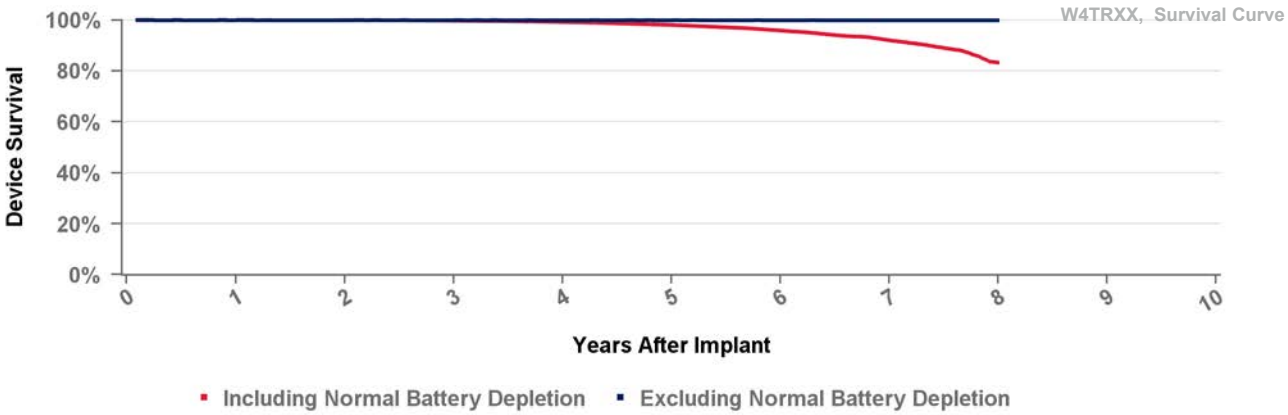
| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 9,539 | Electrical Component | 3 |
| **Estimated Active USA Implants** | 7,581 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 105 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| Effective Sample Size | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## W4TR03 Solara Quad CRTP MRI SureScan

| | | | |
|---|---|---|---|
| **US Market Release** | 06May2017 | **Total Malfunctions (USA)** | **7** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 11,182 | Electrical Component | 4 |
| **Estimated Active USA Implants** | 8,392 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | 165 | Electrical Component | 2 |
| | | Possible Early Battery Depletion | 1 |

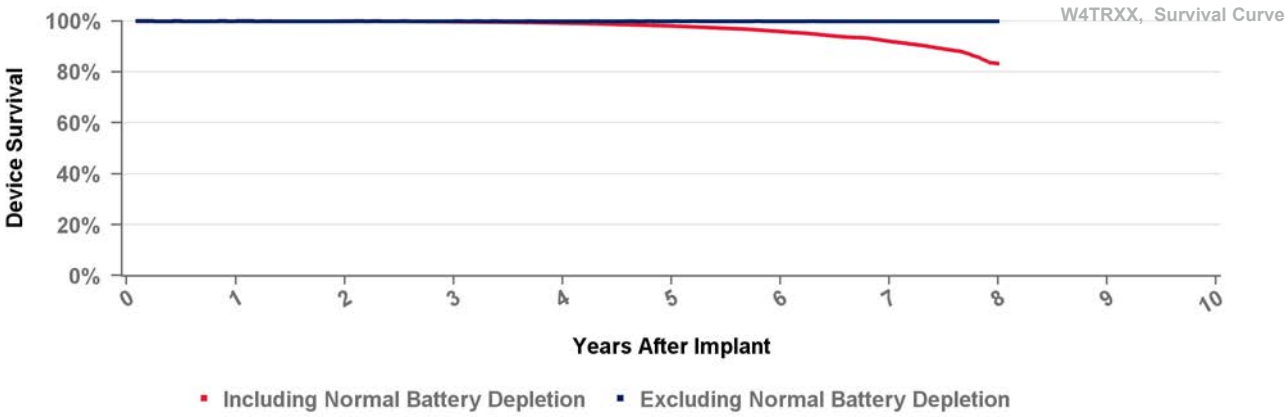



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| Effective Sample Size | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## W4TR04 Percepta Quad CRTP MRI SureScan

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

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

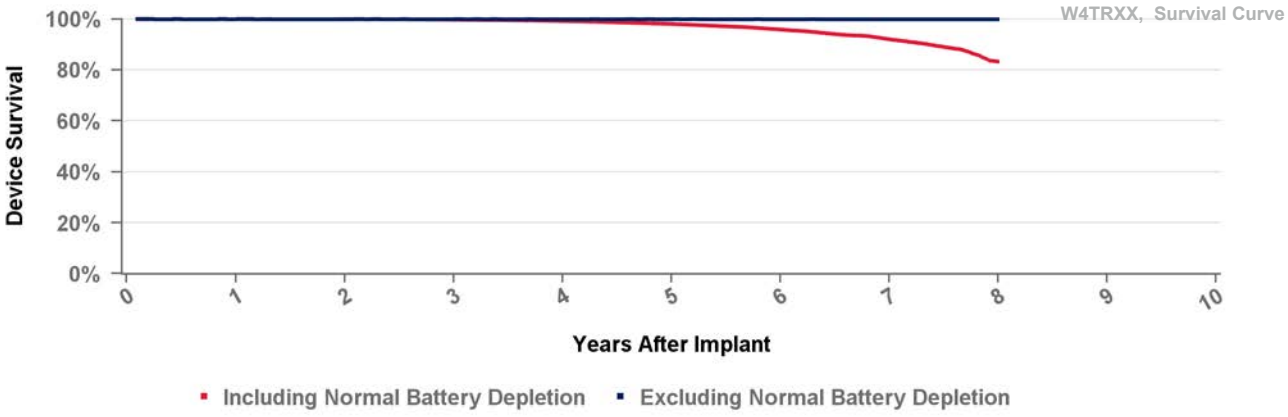



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| Effective Sample Size | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## W4TR05 Serena Quad CRTP MRI SureScan

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

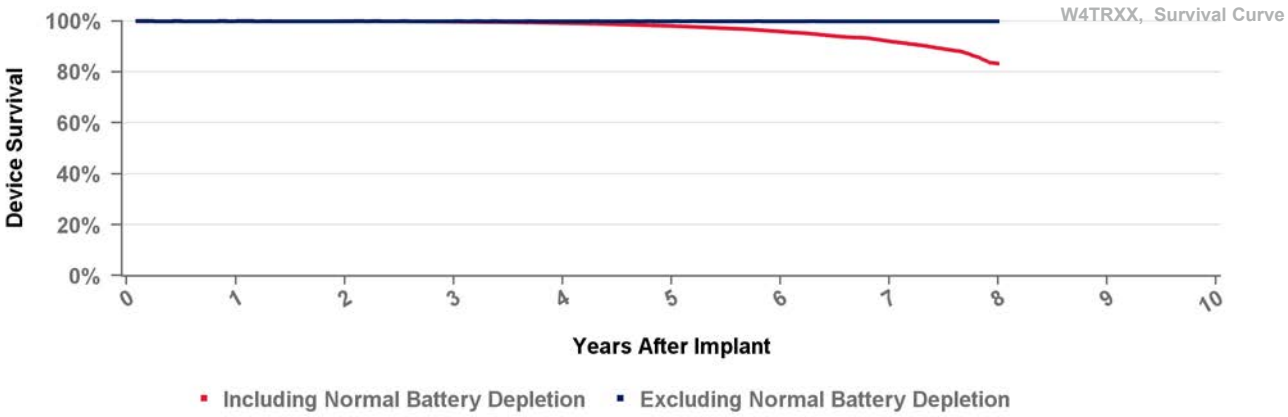
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| Including NBD | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| Effective Sample Size | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## W4TR06 Solara Quad CRTP 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** | | | |

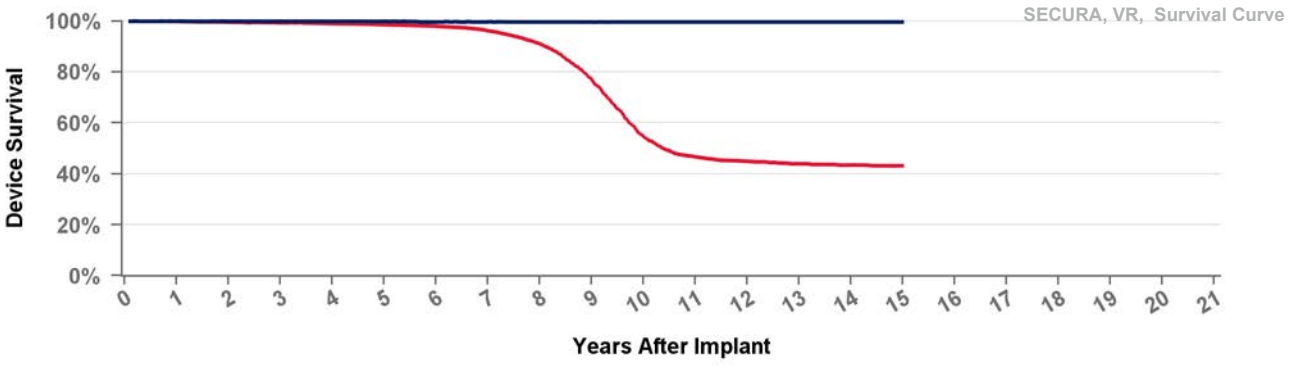



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| **Excluding NBD** | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% |
| **Including NBD** | 100.0% | 100.0% | 99.8% | 99.2% | 98.1% | 95.9% | 92.0% | 83.3% |
| **Effective Sample Size** | 74098 | 59409 | 46038 | 33901 | 22641 | 13437 | 5687 | 411 |

## D234VRC Secura VR

**US Market Release**
**CE Approval Date** 14Mar2008
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**

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

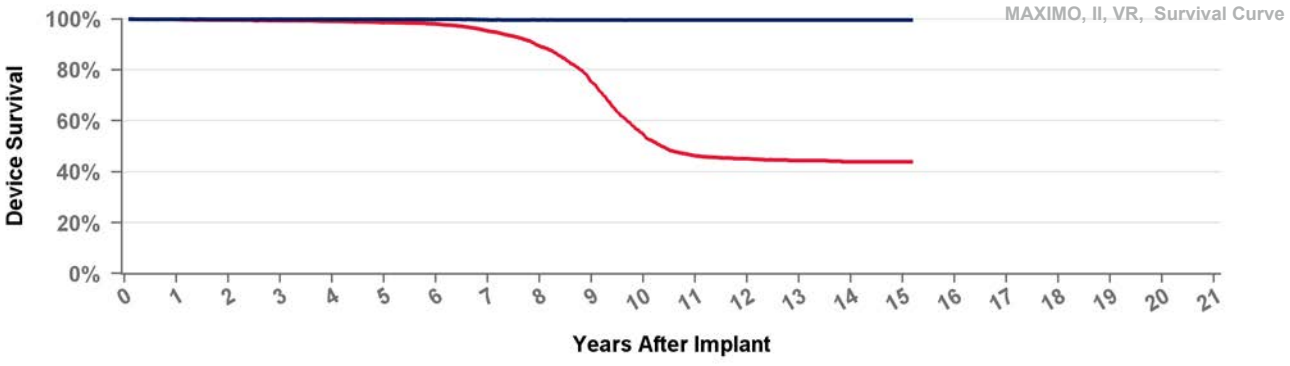



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 180 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.3% | 99.0% | 98.6% | 98.0% | 96.2% | 91.1% | 77.1% | 54.7% | 46.7% | 44.9% | 43.9% | 43.5% | 43.1% |
| Effective Sample Size | 17639 | 16329 | 15176 | 14071 | 12959 | 11845 | 10615 | 8589 | 5572 | 2908 | 2094 | 1674 | 1267 | 867 | 156 |

## D264VRM Maximo II VR

**US Market Release** 02May2012
**CE Approval Date** 17Dec2010
**Registered USA Implants**
**Estimated Active USA Implants**
**Normal Battery Depletions**

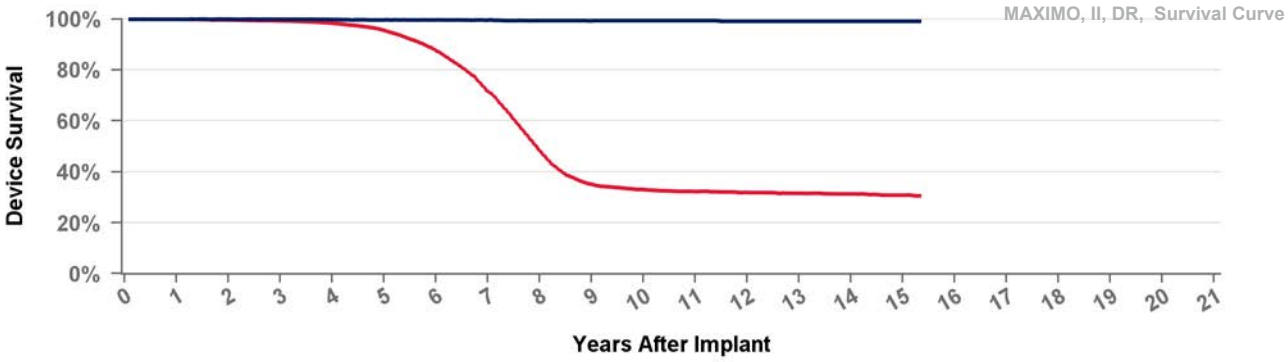
**Total Malfunctions (USA)**
**Therapy Function Not Compromised**
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 182 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.4% | 99.2% | 98.8% | 98.1% | 95.3% | 89.3% | 75.4% | 54.7% | 46.3% | 45.2% | 44.5% | 44.1% | 44.1% | 44.1% |
| Effective Sample Size | 10871 | 10123 | 9421 | 8722 | 8029 | 7339 | 6496 | 5265 | 3418 | 1866 | 1355 | 1108 | 884 | 591 | 185 | 112 |

## D284DRG Maximo II DR

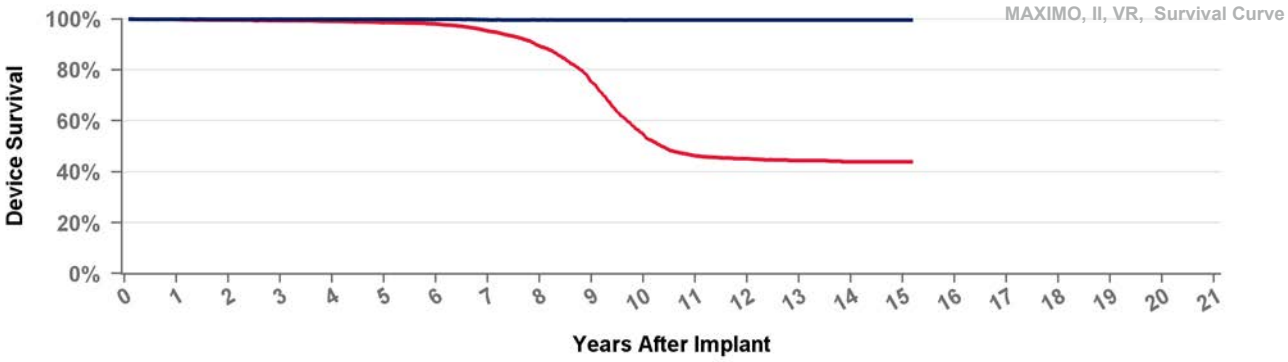
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **71** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **54** |
| **Registered USA Implants** | 19,956 | Battery | 7 |
| **Estimated Active USA Implants** | 2,319 | Electrical Component | 15 |
| **Normal Battery Depletions** | 3,651 | Possible Early Battery Depletion | 30 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **17** |
| | | Battery | 11 |
| | | Electrical Component | 5 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 184 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.7% | 99.7% | 99.5% | 99.3% | 99.3% | 99.3% | 99.3% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% |
| Including NBD | 99.9% | 99.6% | 99.3% | 98.4% | 95.5% | 87.6% | 71.7% | 48.5% | 35.1% | 33.0% | 32.3% | 31.9% | 31.6% | 31.4% | 30.9% | 30.6% |
| Effective Sample Size | 17236 | 15934 | 14783 | 13616 | 12097 | 9584 | 5994 | 2817 | 1734 | 1498 | 1379 | 1237 | 1051 | 760 | 276 | 108 |

## D284VRC Maximo II VR

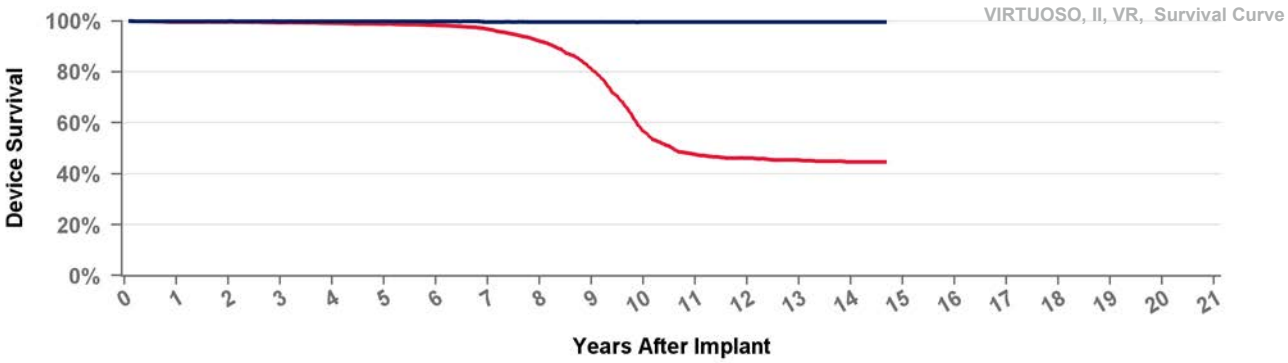
| | | | |
|---|---|---|---|
| **US Market Release** | 17Sep2008 | **Total Malfunctions (USA)** | **32** |
| **CE Approval Date** | 14Mar2008 | **Therapy Function Not Compromised** | **22** |
| **Registered USA Implants** | 12,861 | Battery | 10 |
| **Estimated Active USA Implants** | 2,045 | Electrical Component | 5 |
| **Normal Battery Depletions** | 1,629 | Possible Early Battery Depletion | 4 |
| | | Software/Firmware | 3 |
| | | **Therapy Function Compromised** | **10** |
| | | Battery | 6 |
| | | Electrical Component | 3 |
| | | Software/Firmware | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 182 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.6% | 99.4% | 99.2% | 98.8% | 98.1% | 95.3% | 89.3% | 75.4% | 54.7% | 46.3% | 45.2% | 44.5% | 44.1% | 44.1% | 44.1% |
| Effective Sample Size | 10871 | 10123 | 9421 | 8722 | 8029 | 7339 | 6496 | 5265 | 3418 | 1866 | 1355 | 1108 | 884 | 591 | 185 | 112 |

## D294VRC Virtuoso II VR

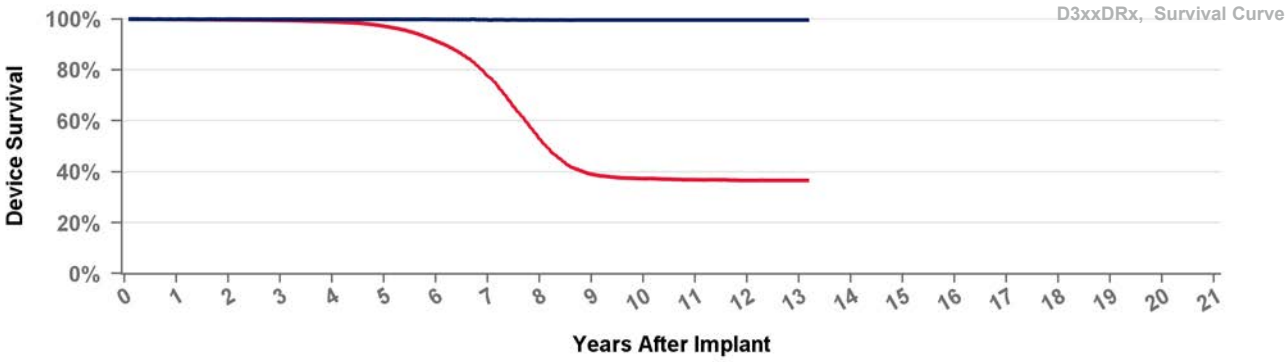
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Aug2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 176 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% | 99.5% |
| Including NBD | 99.7% | 99.7% | 99.4% | 99.2% | 98.8% | 98.3% | 96.8% | 92.1% | 81.0% | 56.8% | 47.6% | 46.3% | 45.4% | 44.7% | 44.7% |
| Effective Sample Size | 7677 | 7159 | 6652 | 6136 | 5663 | 5130 | 4573 | 3750 | 2502 | 1298 | 891 | 717 | 563 | 409 | 127 |

## D314DRG Protecta XT DR

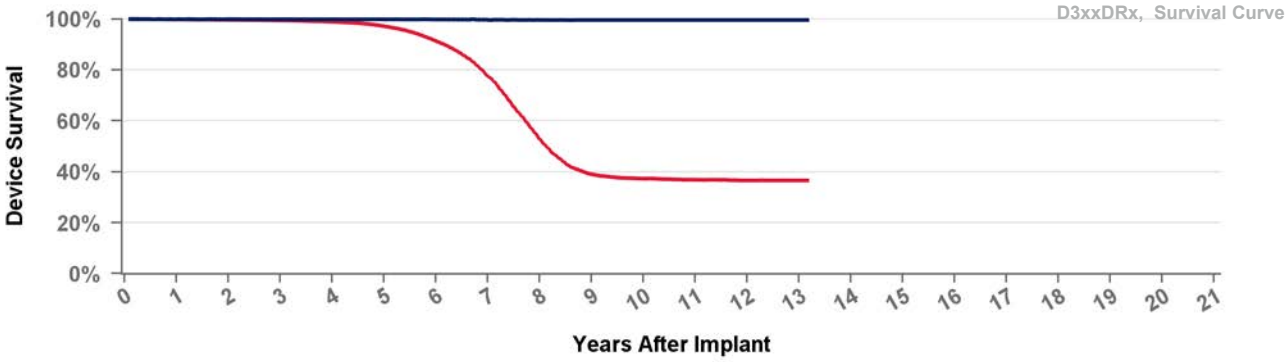
| | | | |
|---|---|---|---|
| **US Market Release** | 25Mar2011 | **Total Malfunctions (USA)** | **77** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **39** |
| **Registered USA Implants** | 34,746 | Battery | 8 |
| **Estimated Active USA Implants** | 4,557 | Electrical Component | 25 |
| **Normal Battery Depletions** | 4,561 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 4 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **38** |
| | | Battery | 30 |
| | | Electrical Component | 8 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D354DRG Protecta XT DR

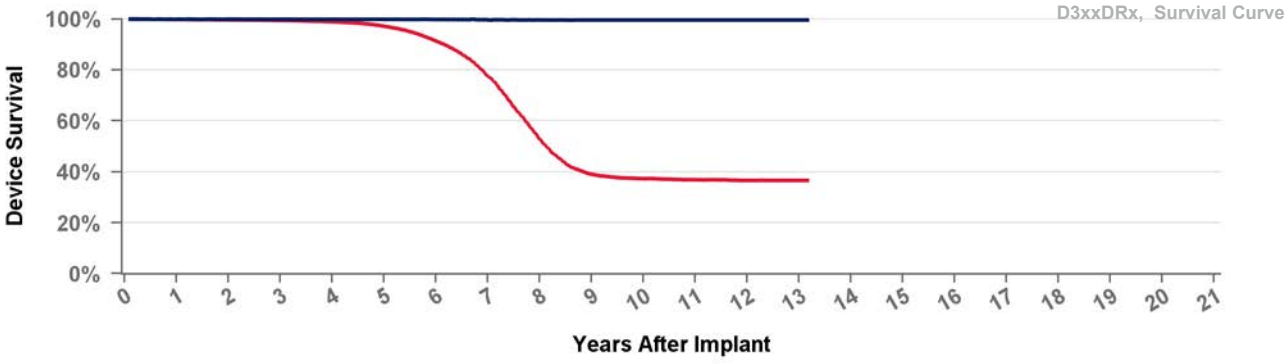
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 25Mar2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D354DRM Protecta XT DR

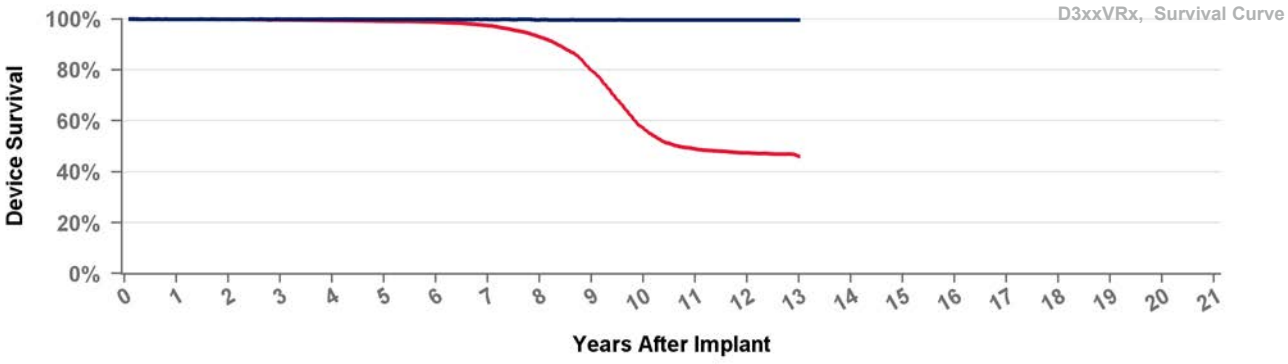
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 15Jul2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D354VRG Protecta XT VR

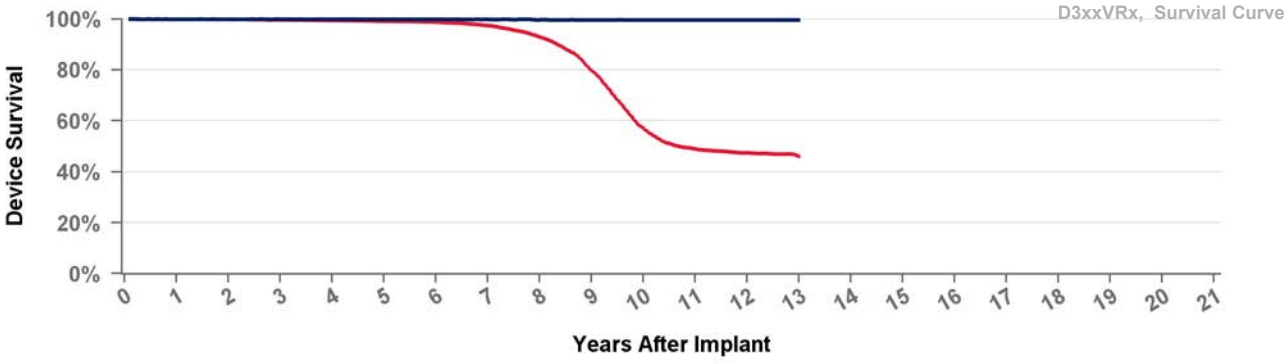
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 25Mar2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## D354VRM Protecta XT VR

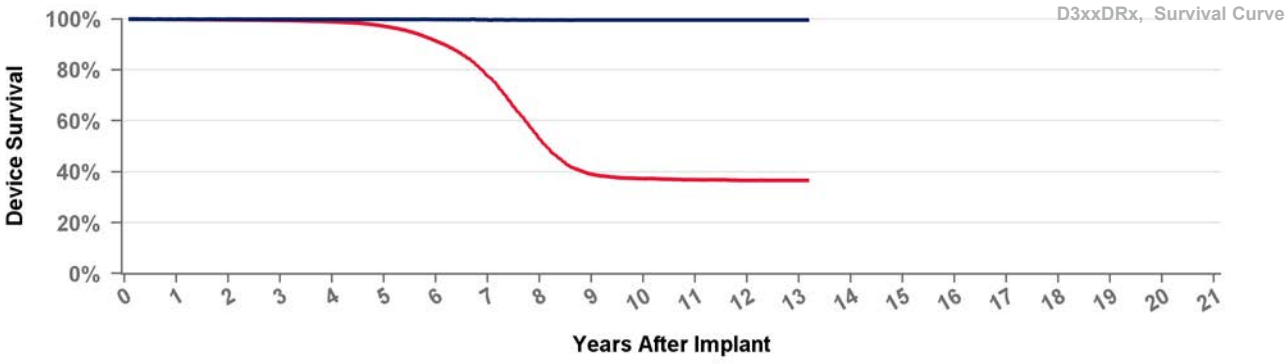
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## D364DRG Protecta DR

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



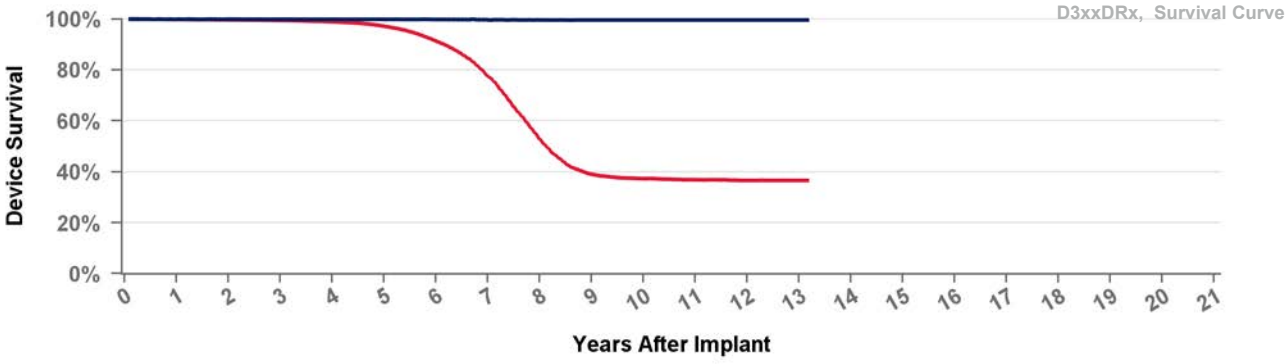

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D364DRM Protecta DR

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

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

**Therapy Function Compromised**



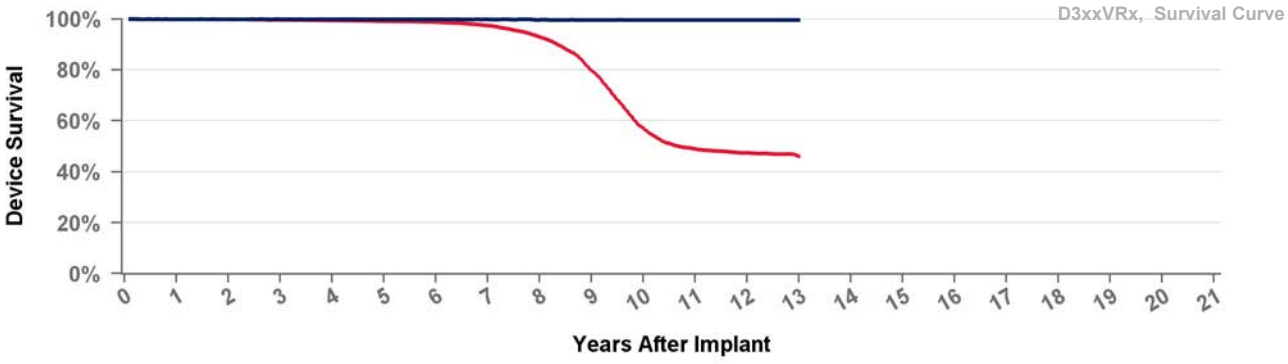

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D364VRG Protecta VR

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

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

**Therapy Function Compromised**

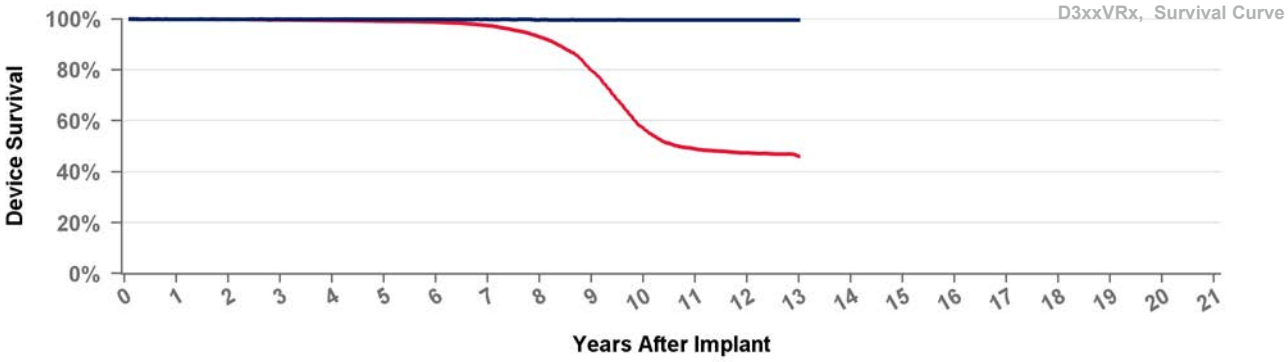



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## D364VRM Protecta VR

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

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

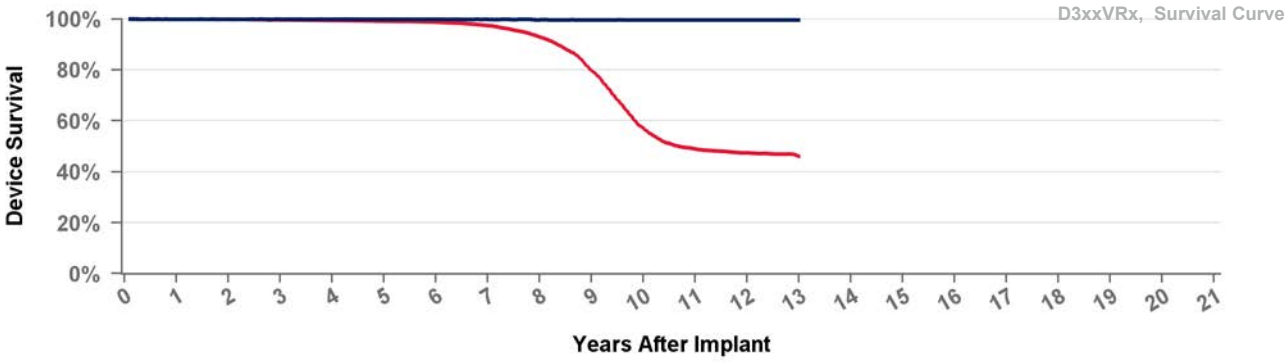



| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## D384VRG Cardia VR

**US Market Release**
**CE Approval Date** 12Jan2011
**Registered USA Implants** 1
**Estimated Active USA Implants**
**Normal Battery Depletions** 1

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



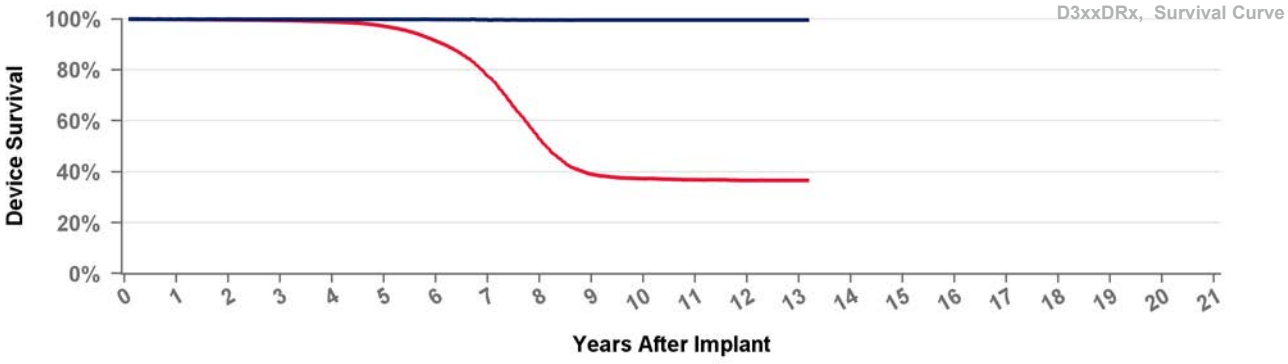

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## 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**



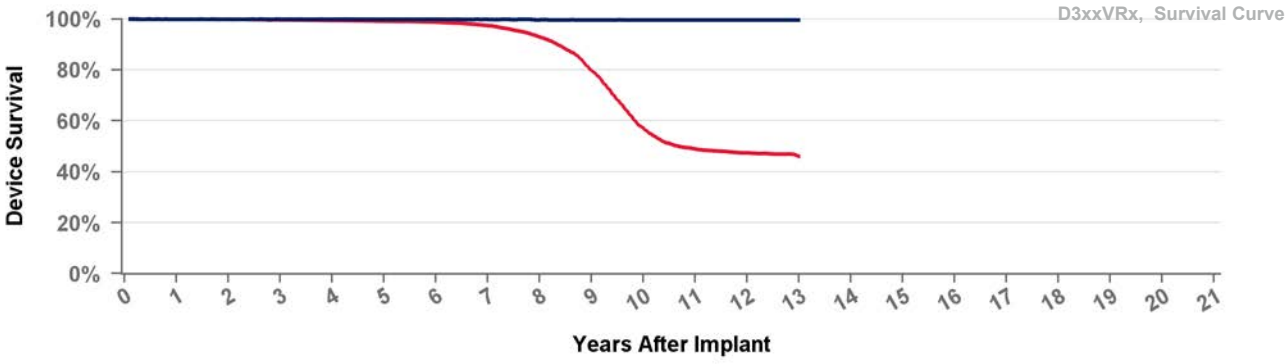

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 158 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% | 99.6% |
| Including NBD | 99.8% | 99.7% | 99.5% | 98.9% | 97.2% | 91.3% | 77.7% | 53.1% | 39.0% | 37.3% | 36.9% | 36.7% | 36.7% | 36.7% |
| Effective Sample Size | 54188 | 50303 | 46253 | 42262 | 37892 | 31012 | 20482 | 9427 | 5352 | 4652 | 4256 | 3639 | 882 | 303 |

## D394VRG Egida 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**

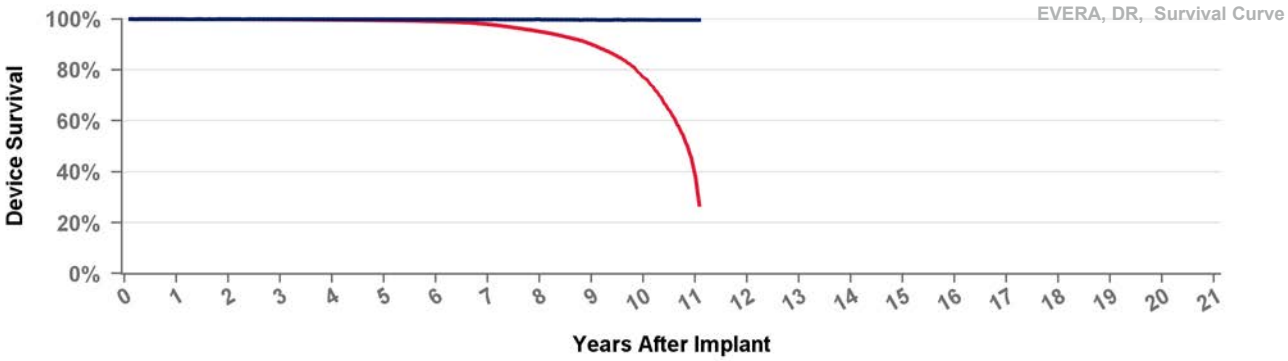
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 99.9% | 99.9% | 99.7% | 99.5% | 99.2% | 98.8% | 97.4% | 92.9% | 79.9% | 57.1% | 48.9% | 47.5% | 46.0% |
| Effective Sample Size | 25809 | 23990 | 22250 | 20580 | 19031 | 17462 | 15714 | 13132 | 8631 | 4395 | 3163 | 2413 | 166 |

## DDBB1D1 Evera XT

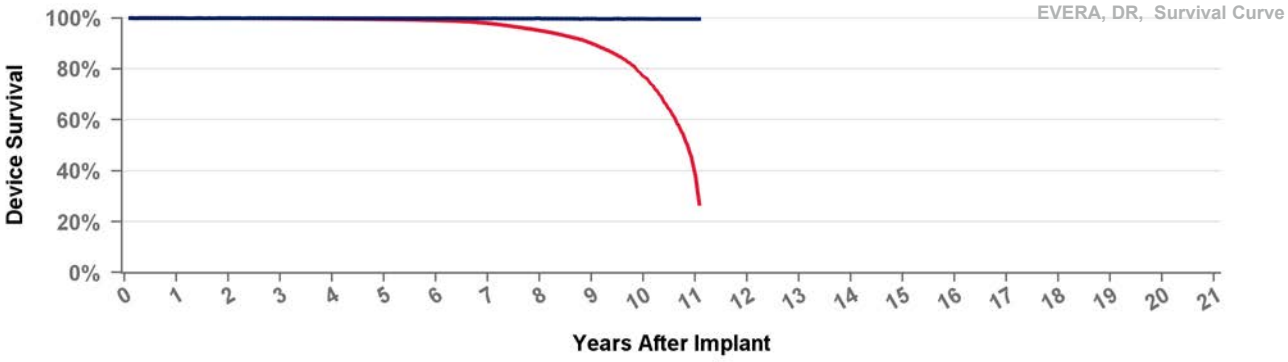
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **94** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **58** |
| **Registered USA Implants** | 43,053 | Battery | 36 |
| **Estimated Active USA Implants** | 16,652 | Electrical Component | 19 |
| **Normal Battery Depletions** | 5,461 | Software/Firmware | 1 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **36** |
| | | Battery | 31 |
| | | Device-Related Current Pathway | 1 |
| | | Electrical Component | 2 |
| | | Electrical Interconnect | 1 |
| | | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDBB1D4 Evera XT

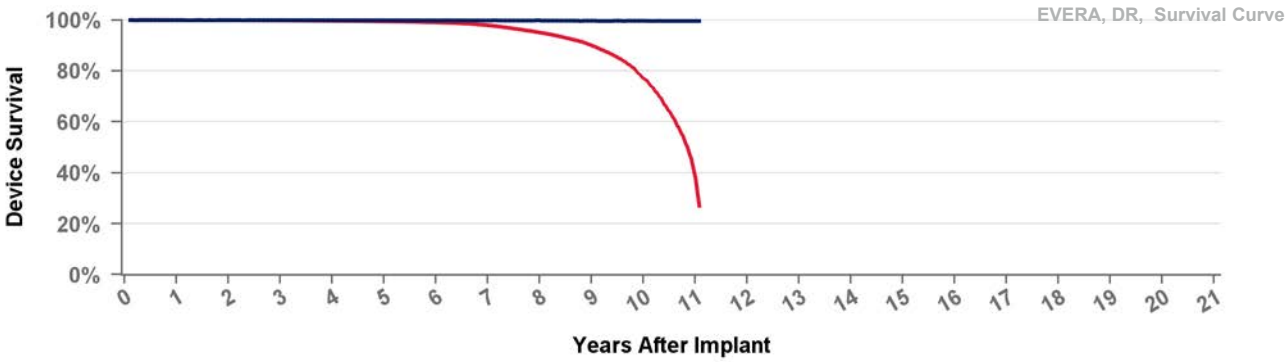
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **82** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **52** |
| **Registered USA Implants** | 30,222 | Battery | 37 |
| **Estimated Active USA Implants** | 10,254 | Electrical Component | 11 |
| **Normal Battery Depletions** | 4,944 | Electrical Interconnect | 2 |
| | | Possible Early Battery Depletion | 1 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **30** |
| | | Battery | 23 |
| | | Device-Related Current Pathway | 4 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDBB2D1 Evera XT

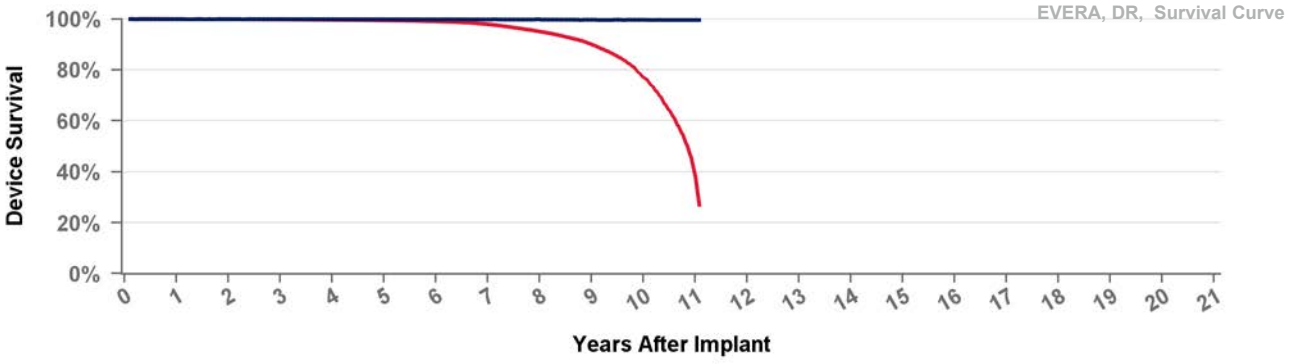
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDBB2D4 Evera XT

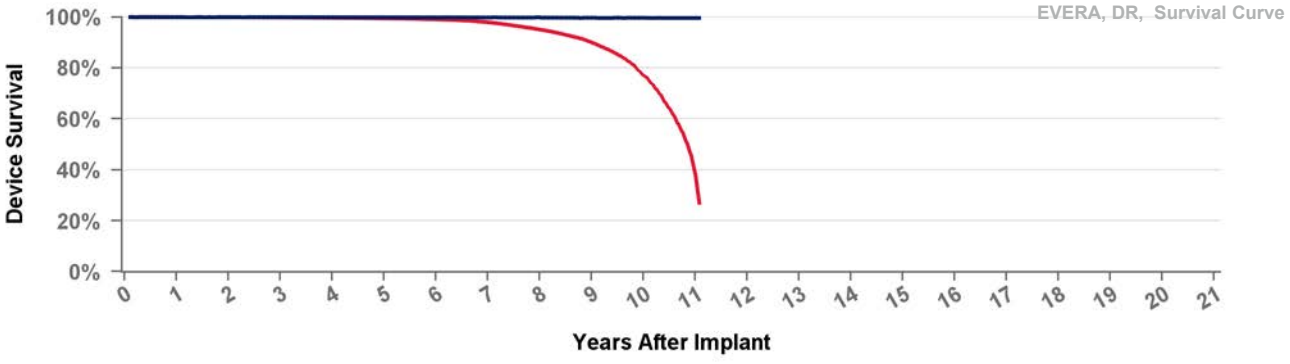
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDBC3D1 Evera S

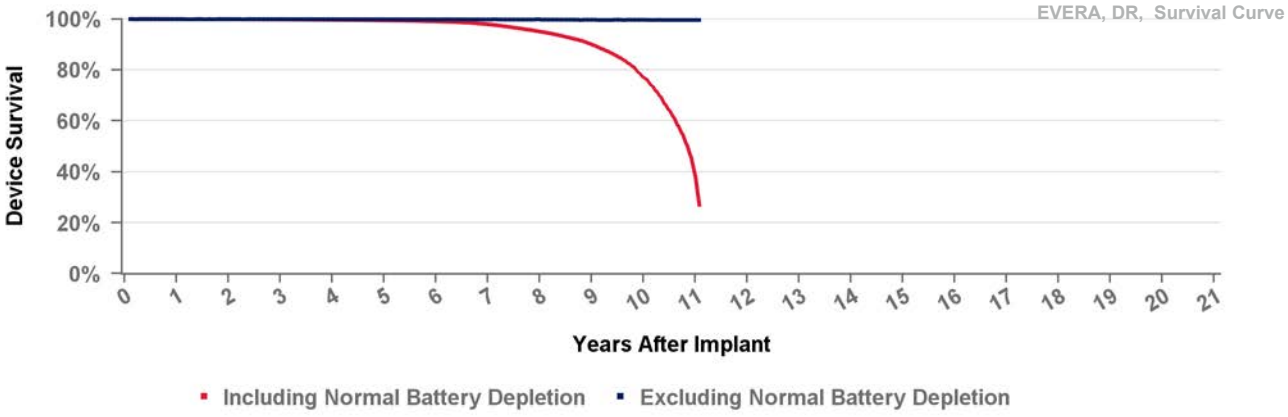
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **19** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **10** |
| **Registered USA Implants** | 8,435 | Battery | 7 |
| **Estimated Active USA Implants** | 3,173 | Electrical Component | 3 |
| **Normal Battery Depletions** | 1,234 | **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 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDBC3D4 Evera S

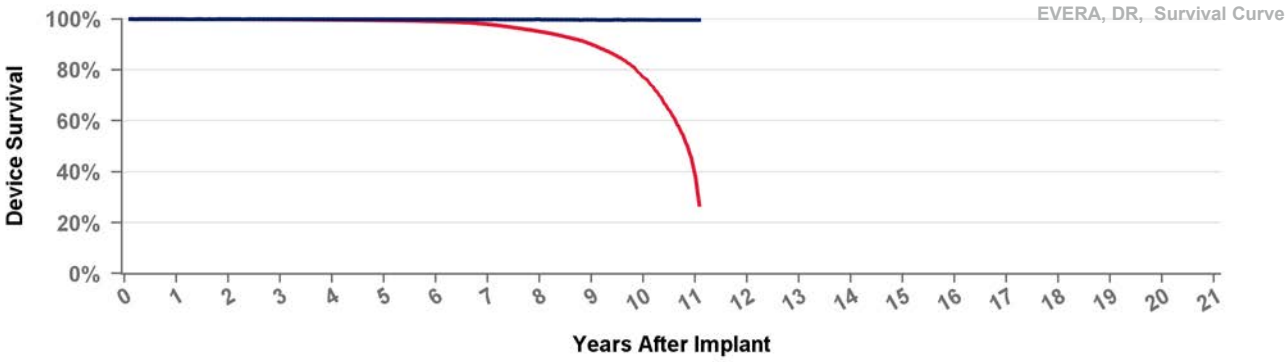
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **14** |
| **CE Approval Date** | 17Dec2013 | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 6,064 | Battery | 3 |
| **Estimated Active USA Implants** | 2,171 | Electrical Component | 2 |
| **Normal Battery Depletions** | 1,055 | **Therapy Function Compromised** | **9** |
| | | Battery | 5 |
| | | Device-Related Current Pathway | 2 |
| | | Electrical Component | 1 |
| | | Possible Early Battery Depletion | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMB1D1 Evera MRI XT

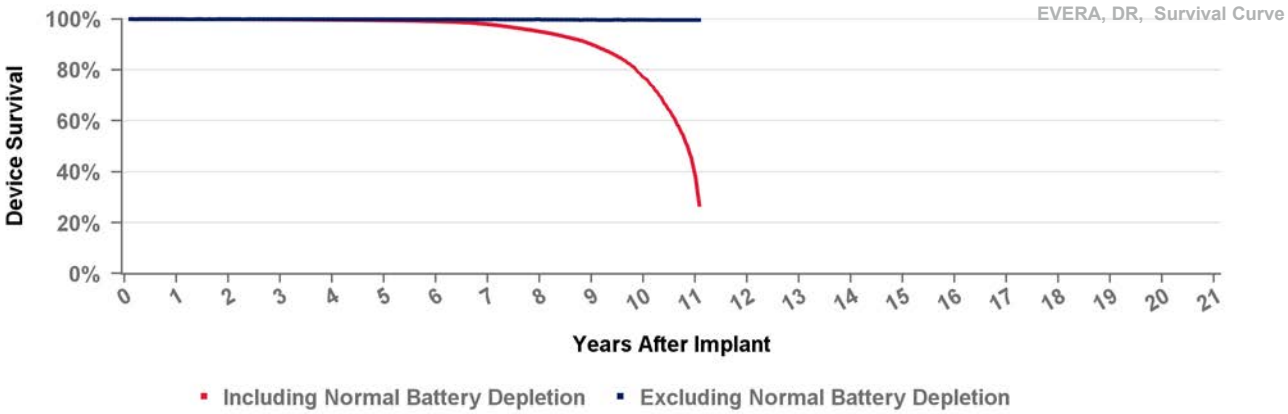
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **49** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **28** |
| **Registered USA Implants** | 37,362 | Battery | 14 |
| **Estimated Active USA Implants** | 27,724 | Electrical Component | 11 |
| **Normal Battery Depletions** | 388 | Electrical Interconnect | 1 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **21** |
| | | Battery | 7 |
| | | Device-Related Current Pathway | 5 |
| | | Electrical Component | 9 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMB1D4 Evera MRI XT

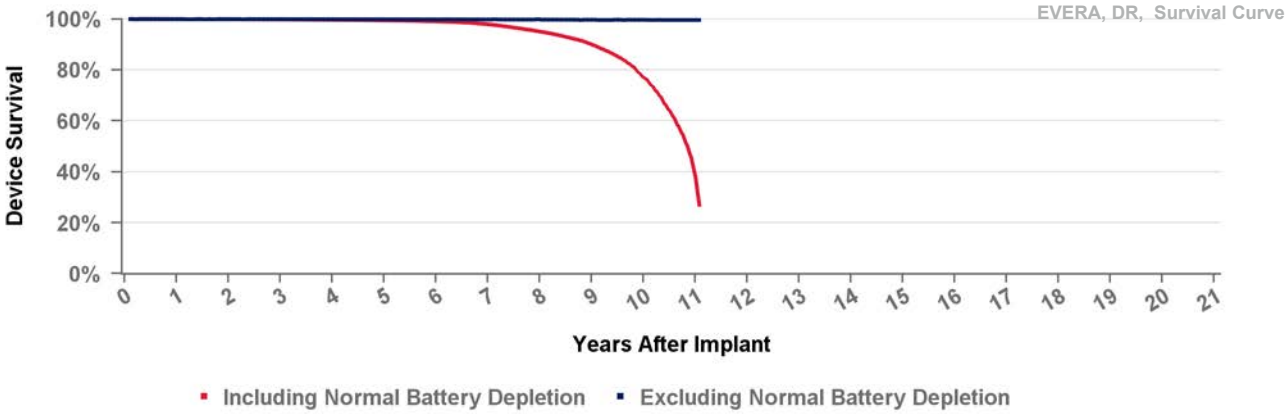
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **115** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **68** |
| **Registered USA Implants** | 107,264 | Battery | 37 |
| **Estimated Active USA Implants** | 81,425 | Electrical Component | 24 |
| **Normal Battery Depletions** | 1,640 | Electrical Interconnect | 4 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **47** |
| | | Battery | 25 |
| | | Device-Related Current Pathway | 16 |
| | | Electrical Component | 6 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMB2D1 Evera MRI XT

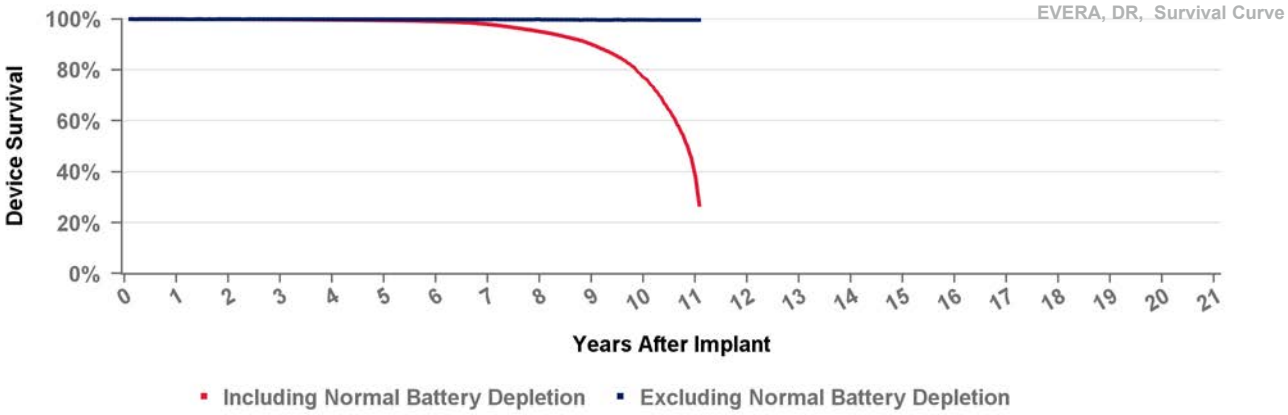
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMB2D4 Evera MRI XT

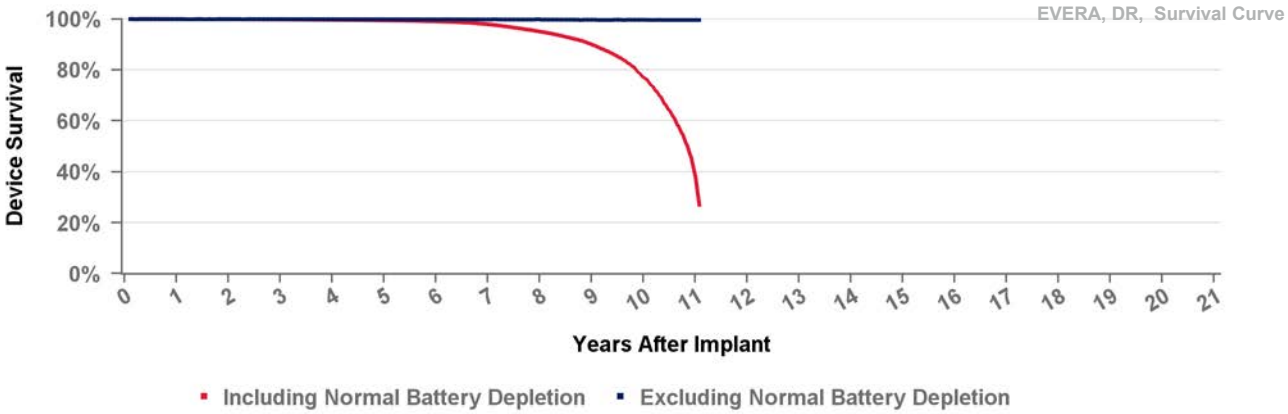
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMC3D1 Evera MRI S

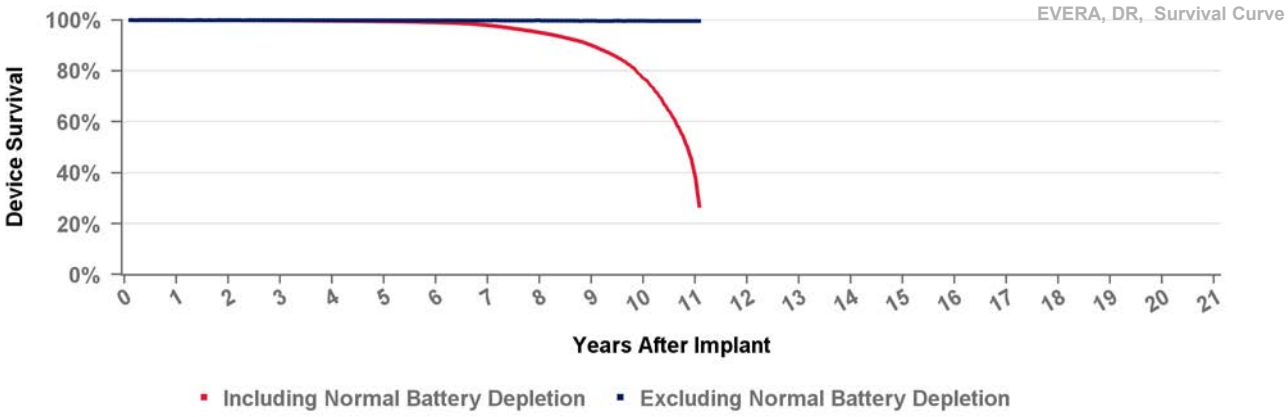
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **3** |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 3,379 | Battery | 1 |
| **Estimated Active USA Implants** | 2,493 | Electrical Component | 1 |
| **Normal Battery Depletions** | 54 | **Therapy Function Compromised** | **1** |
| | | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMC3D4 Evera MRI

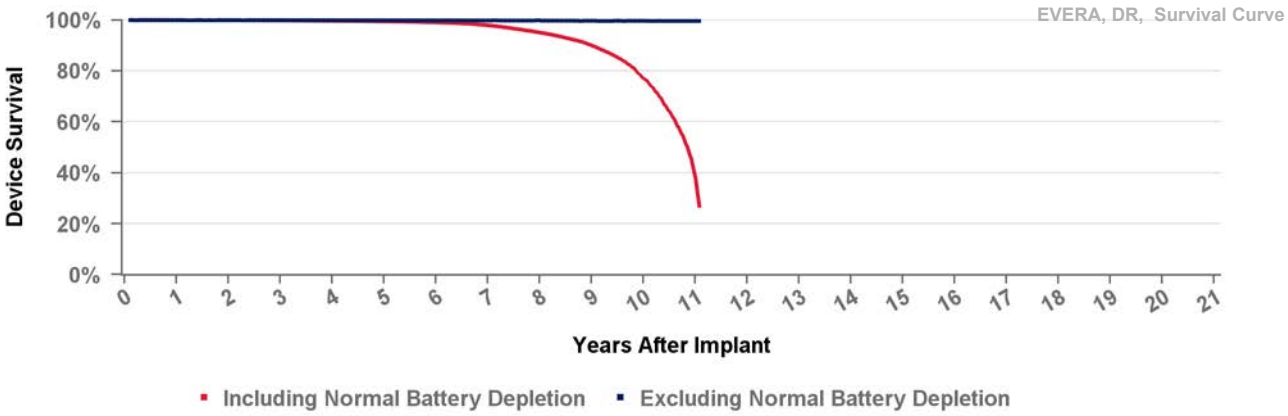
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **10** |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | **6** |
| **Registered USA Implants** | 7,186 | Battery | 5 |
| **Estimated Active USA Implants** | 5,340 | Electrical Component | 1 |
| **Normal Battery Depletions** | 143 | **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 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMD3D1 Primo

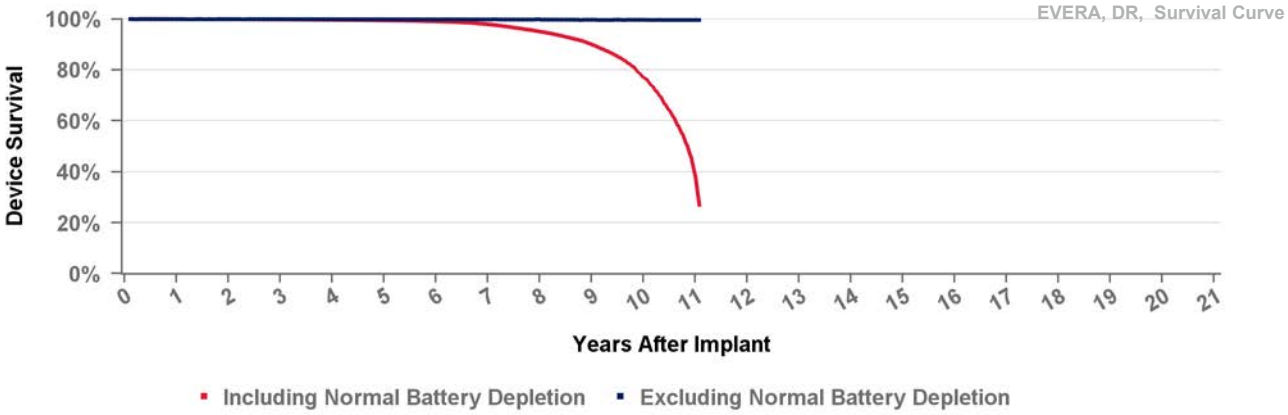
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 451 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 381 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDMD3D4 Primo

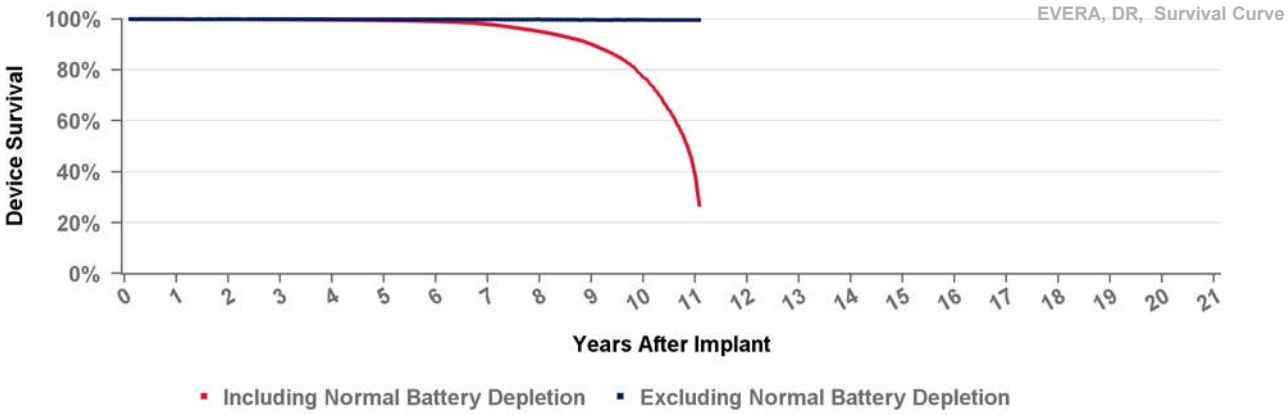
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,491 | | |
| **Estimated Active USA Implants** | 1,303 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 1 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDME3D1 Mirro

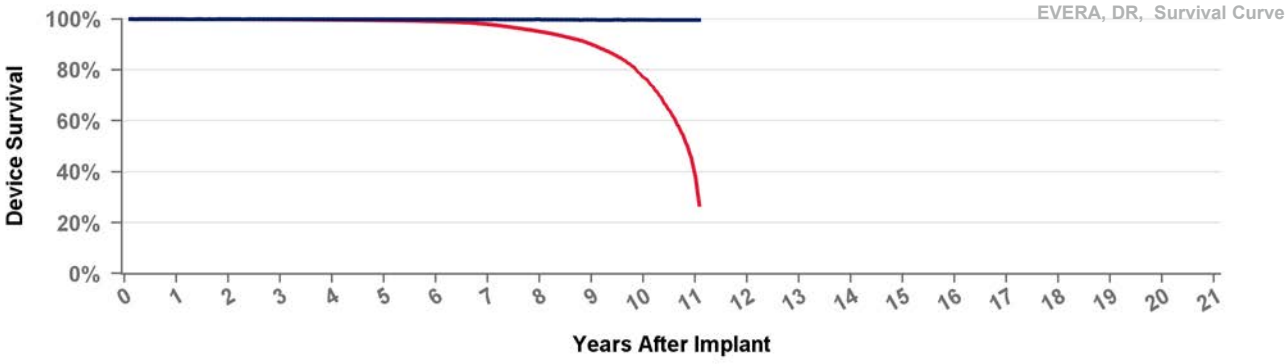
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDME3D4 Mirro

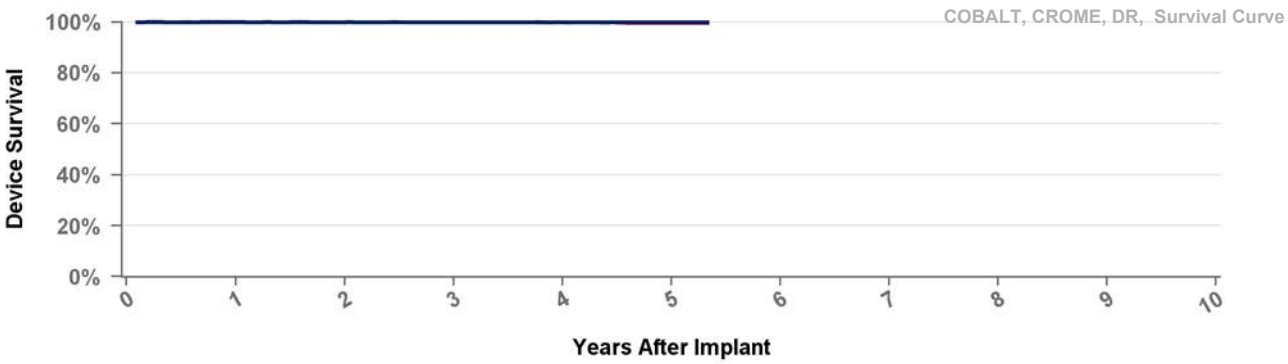
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 133 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% | 99.8% | 99.7% | 99.5% | 99.1% | 97.9% | 95.1% | 90.0% | 77.3% | 38.9% | 26.8% |
| Effective Sample Size | 218912 | 204367 | 186426 | 166279 | 147684 | 121991 | 93610 | 65617 | 39293 | 16492 | 1289 | 380 |

## DDPA2D1 Cobalt XT

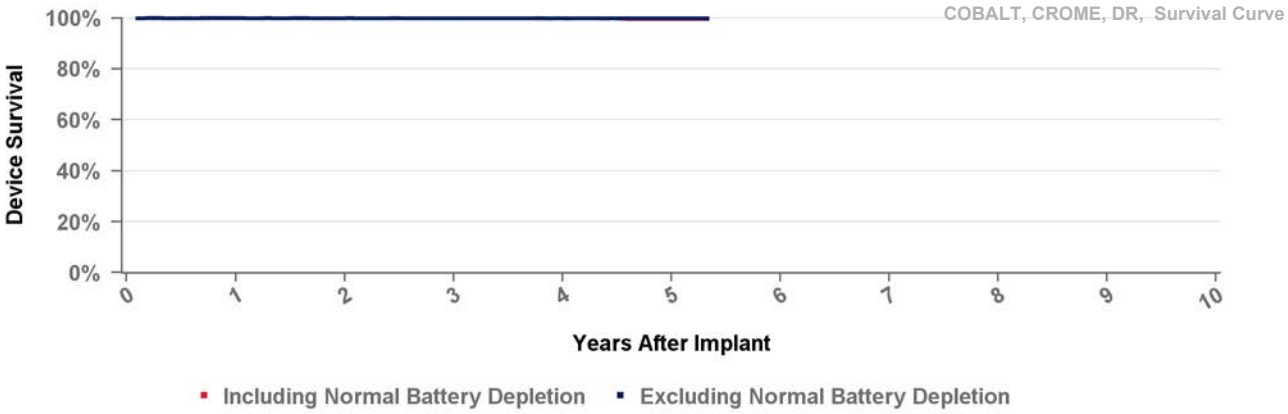
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 8,216 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 7,832 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 1 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DDPA2D4 Cobalt XT

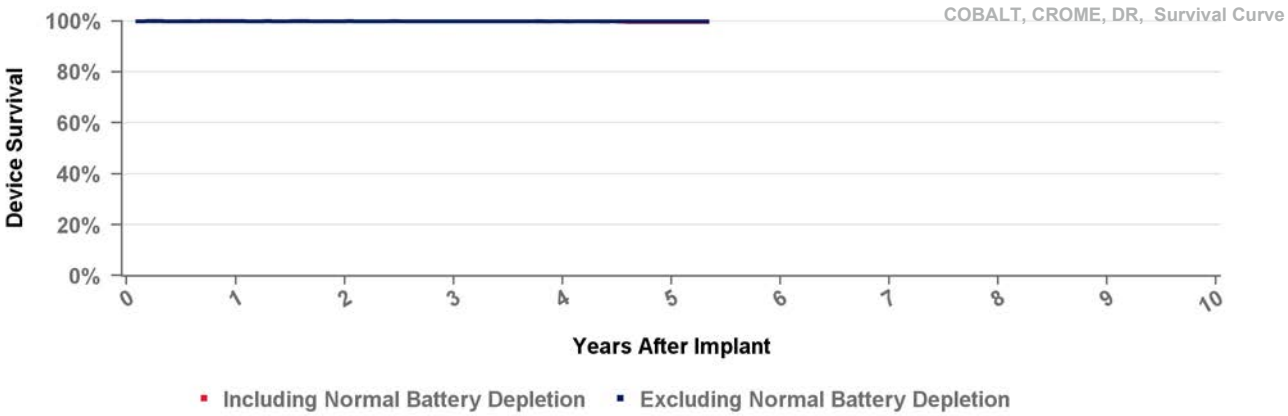
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **3** |
| **Registered USA Implants** | 52,900 | Electrical Component | 3 |
| **Estimated Active USA Implants** | 50,159 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 8 | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DDPB3D1 Cobalt

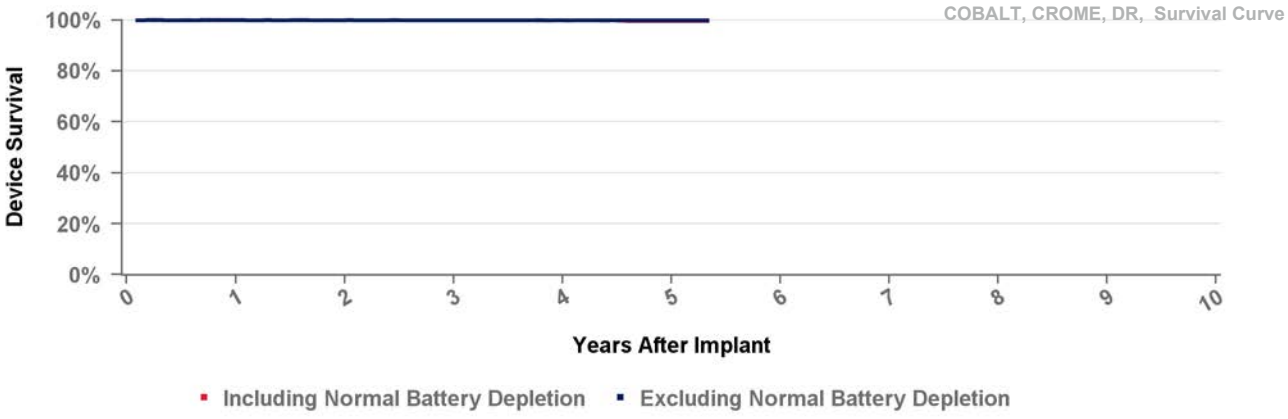
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 3,214 | Battery | 1 |
| **Estimated Active USA Implants** | 2,955 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 1 | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DDPB3D4 Cobalt

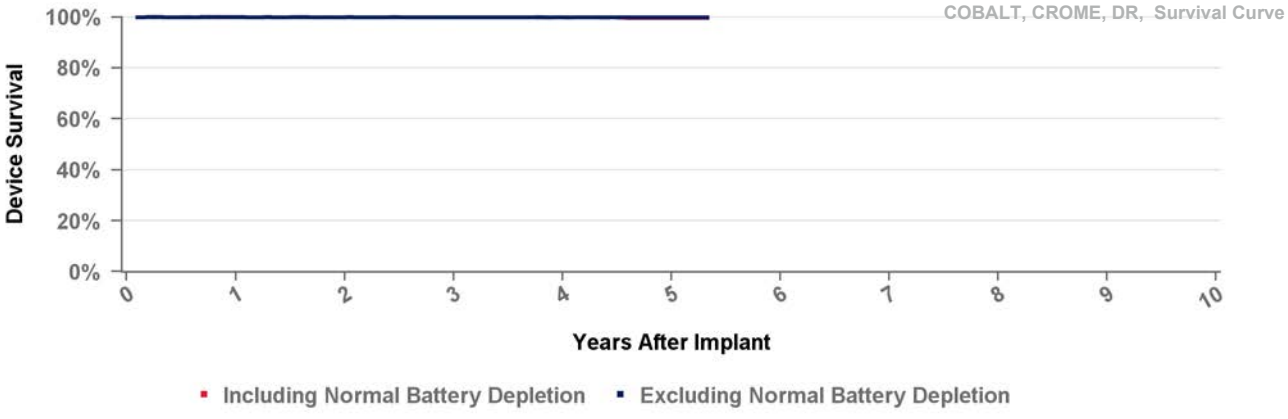
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **8** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **5** |
| **Registered USA Implants** | 17,449 | Battery | 1 |
| **Estimated Active USA Implants** | 16,016 | Electrical Component | 2 |
| **Normal Battery Depletions** | 4 | Other | 2 |
| | | **Therapy Function Compromised** | **3** |
| | | Electrical Component | 1 |
| | | Electrical Interconnect | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DDPC3D1 Crome

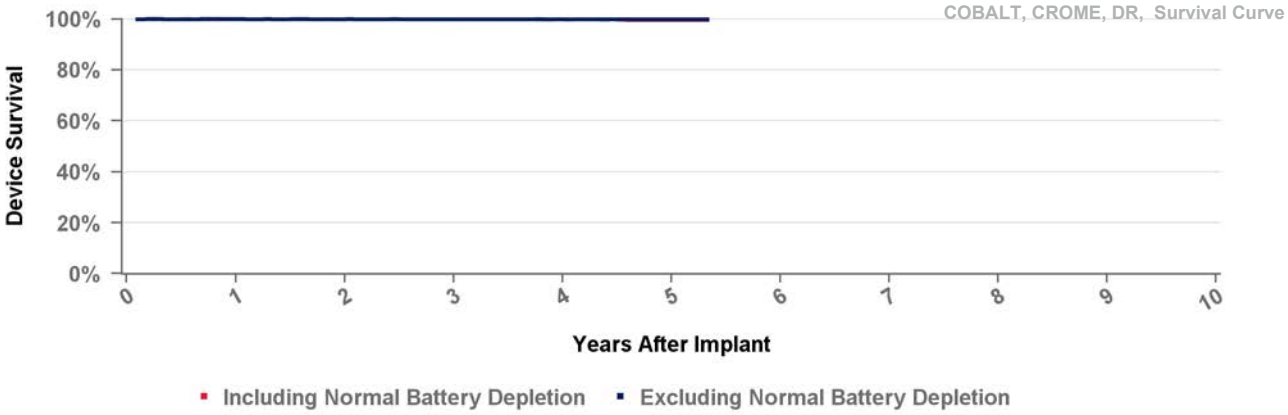
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 523 | | |
| **Estimated Active USA Implants** | 491 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DDPC3D4 Crome

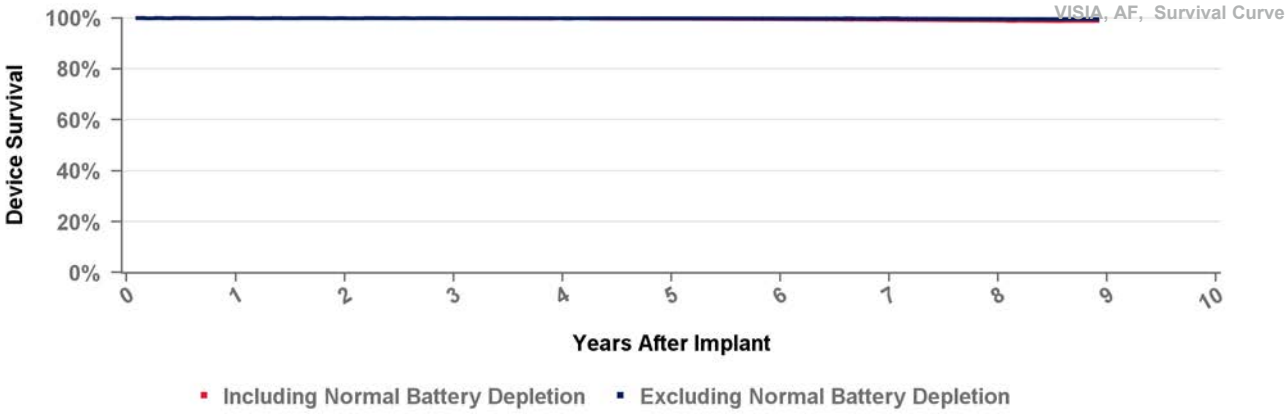
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,220 | | |
| **Estimated Active USA Implants** | 2,096 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.7% |
| Effective Sample Size | 55512 | 32174 | 17989 | 9852 | 1143 | 151 |

## DVAB1D1 Visia AF

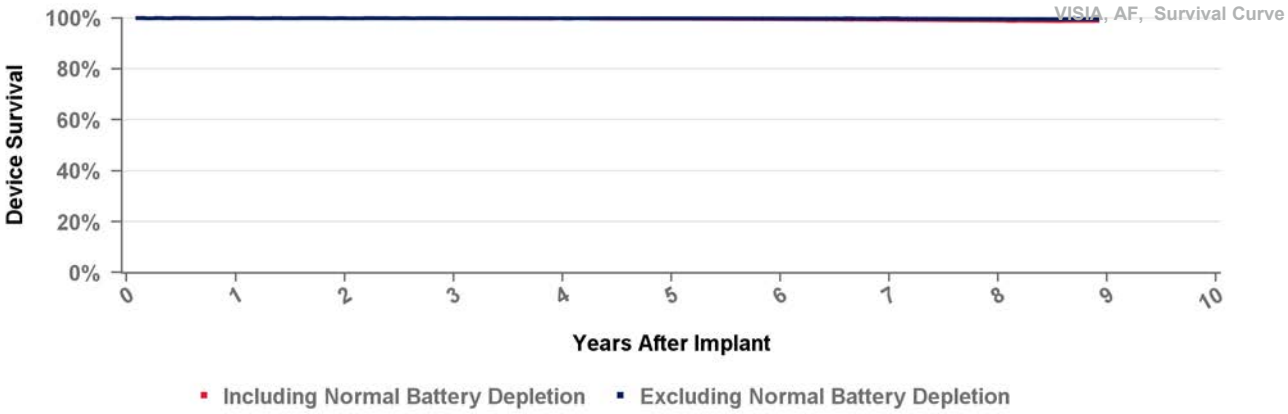
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **16** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **12** |
| **Registered USA Implants** | 3,051 | Battery | 11 |
| **Estimated Active USA Implants** | 2,005 | Electrical Component | 1 |
| **Normal Battery Depletions** | 15 | **Therapy Function Compromised** | **4** |
| | | Battery | 2 |
| | | Device-Related Current Pathway | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVAB1D4 Visia AF

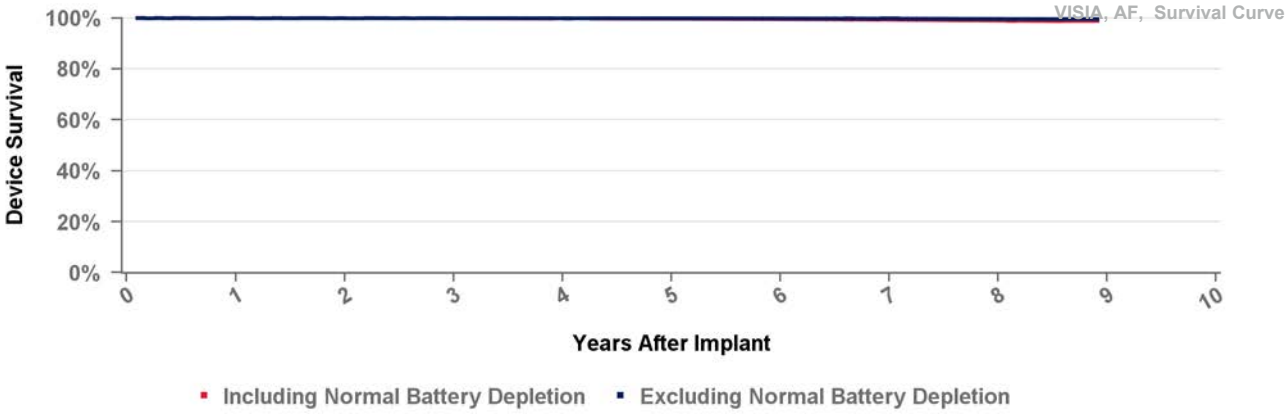
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 2,045 | Battery | 2 |
| **Estimated Active USA Implants** | 1,397 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | | Battery | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVAB2D1 Visia AF XT

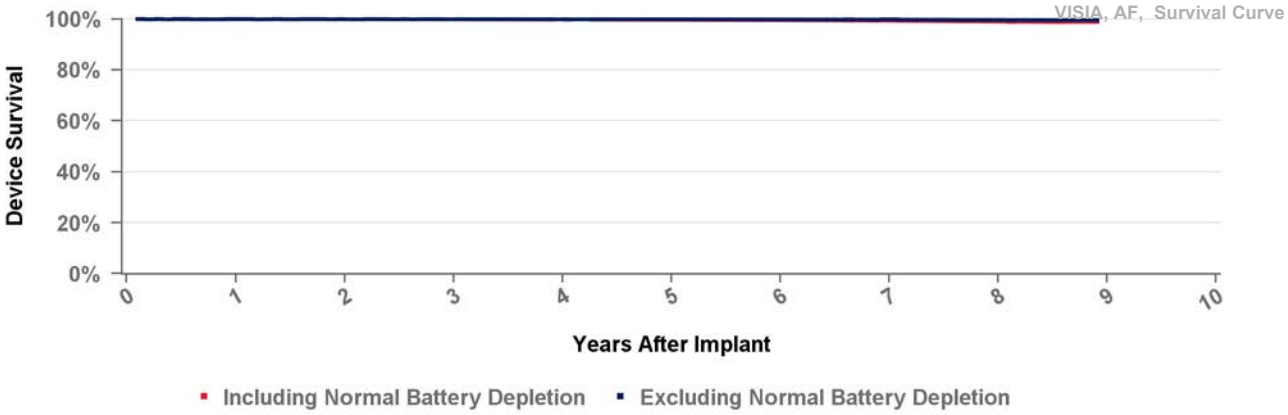
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVAC3D1 Visia AF S

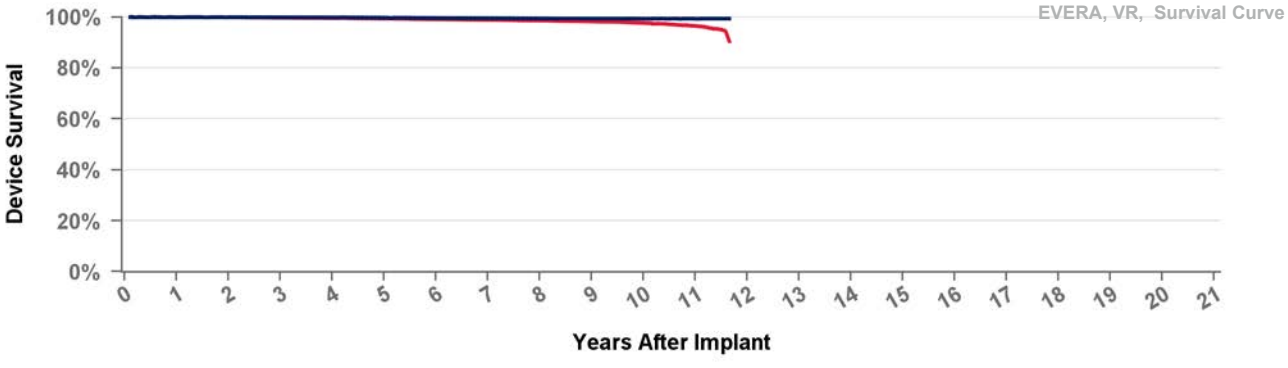
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVBB1D1 Evera XT

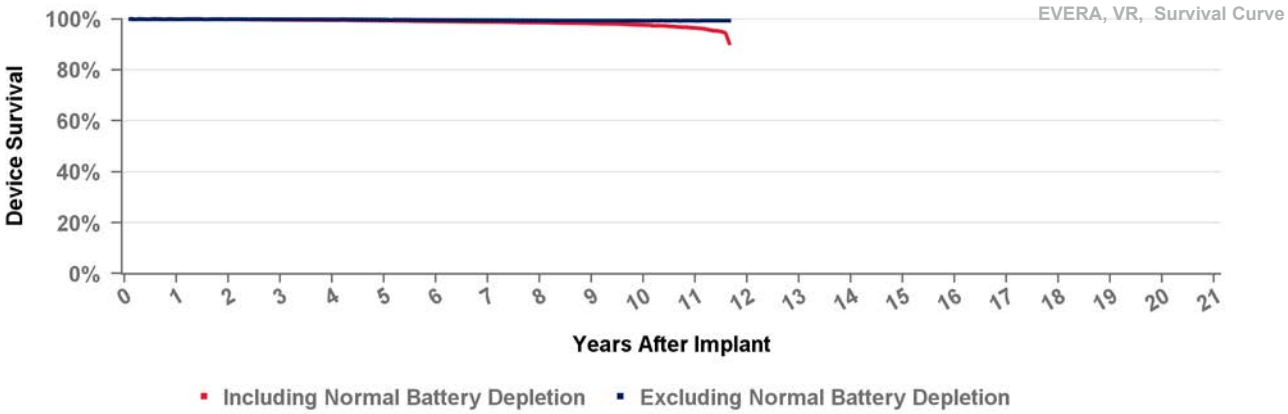
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **80** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **55** |
| **Registered USA Implants** | 16,113 | Battery | 48 |
| **Estimated Active USA Implants** | 8,338 | Electrical Component | 7 |
| **Normal Battery Depletions** | 174 | **Therapy Function Compromised** | **25** |
| | | Battery | 16 |
| | | Device-Related Current Pathway | 5 |
| | | Electrical Component | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVBB1D4 Evera XT

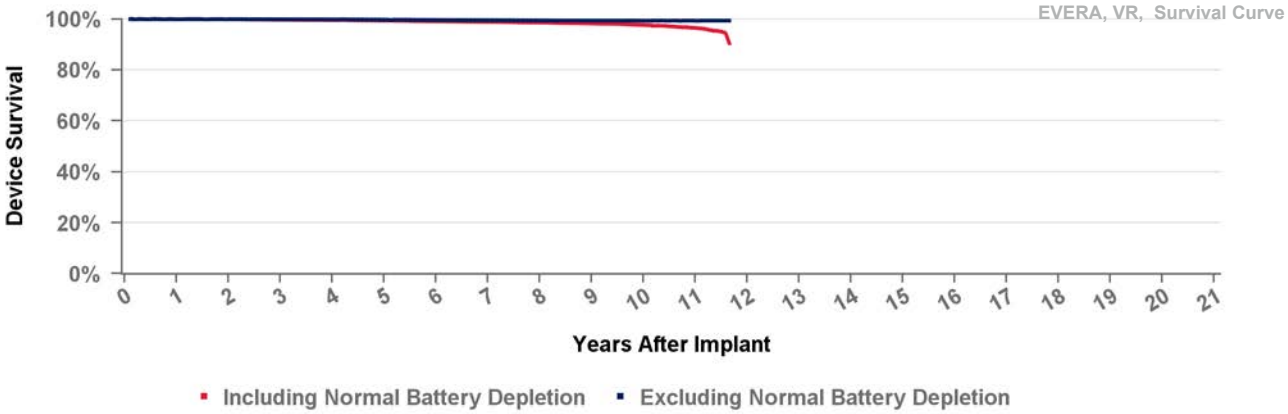
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **102** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **68** |
| **Registered USA Implants** | 21,954 | Battery | 52 |
| **Estimated Active USA Implants** | 12,337 | Electrical Component | 9 |
| **Normal Battery Depletions** | 284 | Possible Early Battery Depletion | 2 |
| | | Other | 5 |
| | | **Therapy Function Compromised** | **34** |
| | | Battery | 26 |
| | | Device-Related Current Pathway | 7 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVBB2D1 Evera XT

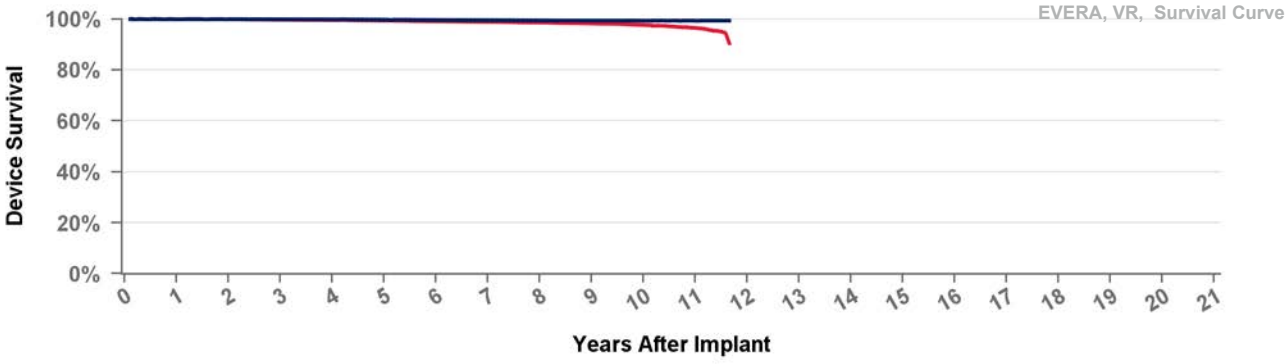
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVBB2D4 Evera XT

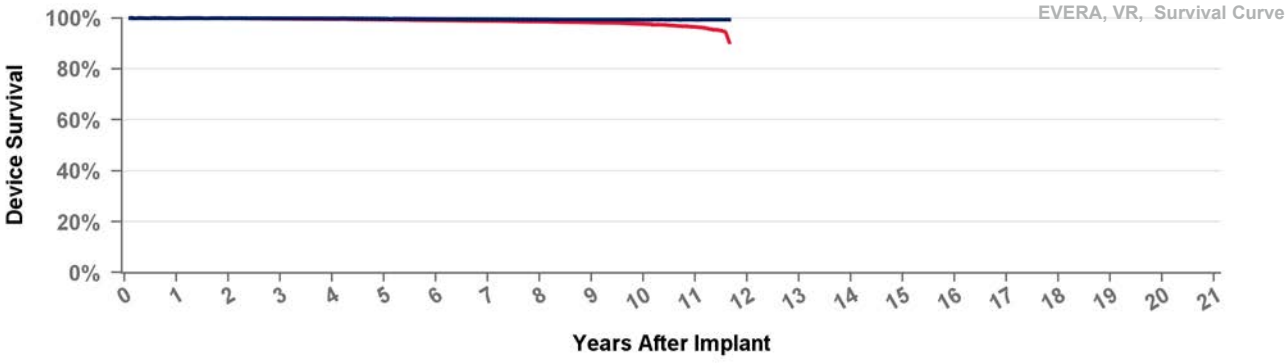
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVBC3D1 Evera S

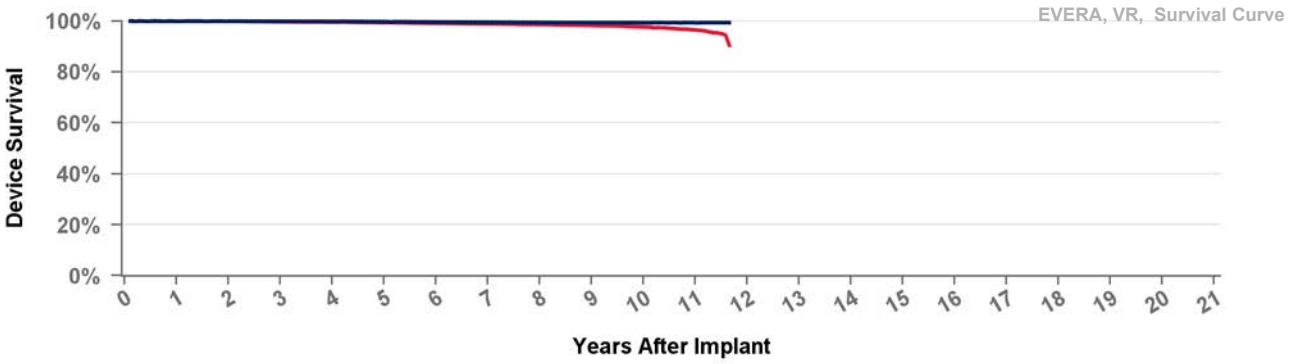
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **28** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **19** |
| **Registered USA Implants** | 4,643 | Battery | 17 |
| **Estimated Active USA Implants** | 2,526 | Electrical Component | 2 |
| **Normal Battery Depletions** | 48 | **Therapy Function Compromised** | **9** |
| | | Battery | 8 |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVBC3D4 Evera S

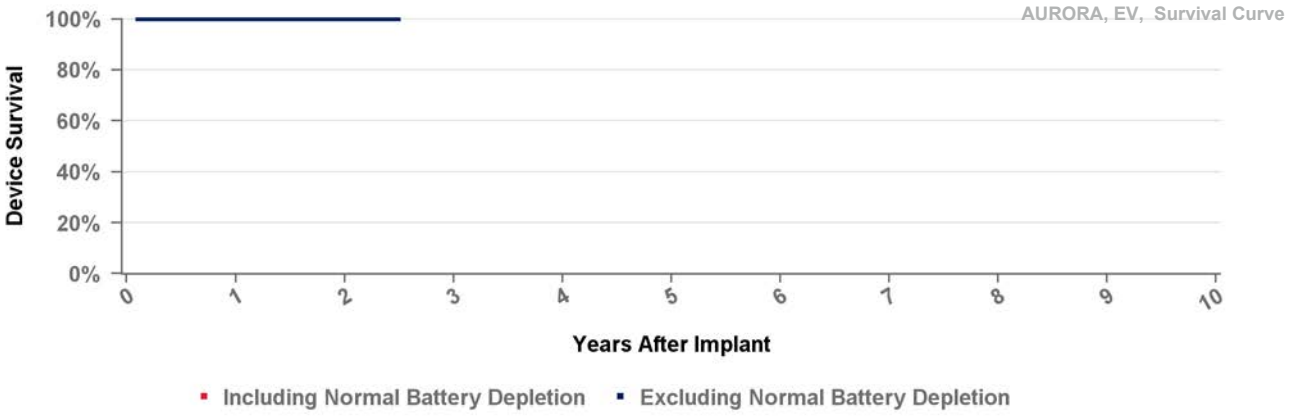
| | | | |
|---|---|---|---|
| **US Market Release** | 03Apr2013 | **Total Malfunctions (USA)** | **24** |
| **CE Approval Date** | 17Dec2012 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 5,623 | Battery | 14 |
| **Estimated Active USA Implants** | 3,261 | Electrical Component | 3 |
| **Normal Battery Depletions** | 50 | **Therapy Function Compromised** | **7** |
| | | Battery | 5 |
| | | Device-Related Current Pathway | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVEA3E4 Aurora EV-ICD

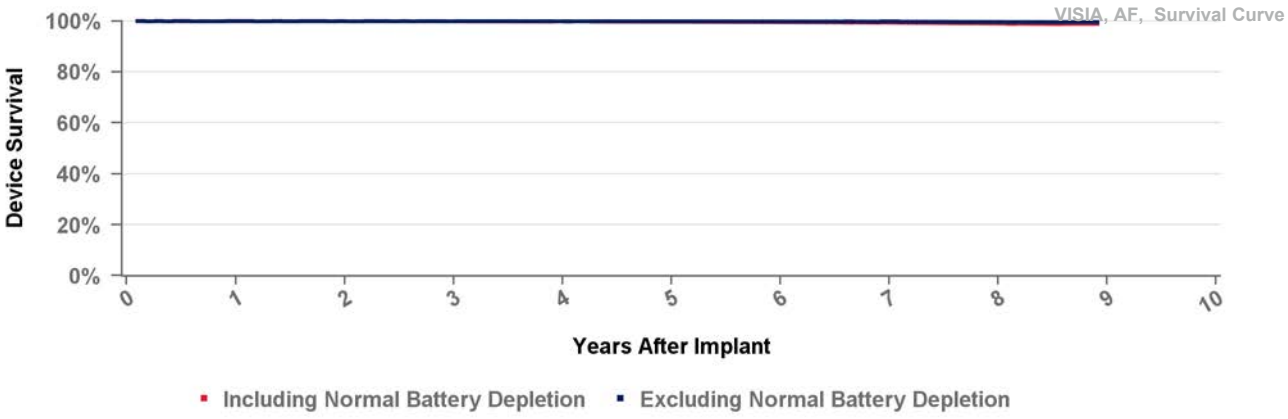
| | | | |
|---|---|---|---|
| **US Market Release** | 20Oct2023 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 17Feb2023 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 2,765 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 2,661 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | at 30 mo |
|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 984 | 124 | 104 |

## DVFB1D1 Visia MRI AF

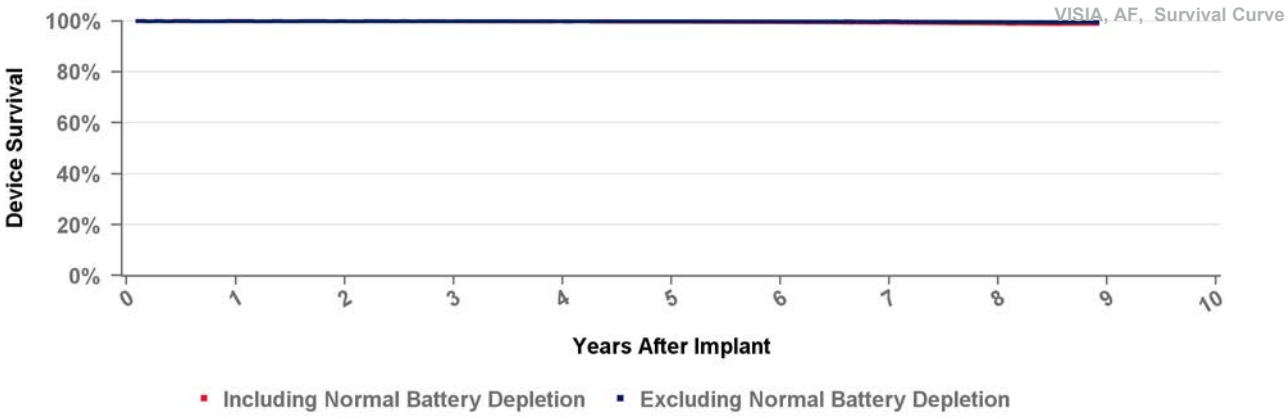
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **25** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 17,782 | Battery | 10 |
| **Estimated Active USA Implants** | 14,041 | Electrical Component | 6 |
| **Normal Battery Depletions** | 16 | Other | 1 |
| | | **Therapy Function Compromised** | **8** |
| | | Battery | 2 |
| | | Device-Related Current Pathway | 3 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVFB1D4 Visia MRI AF

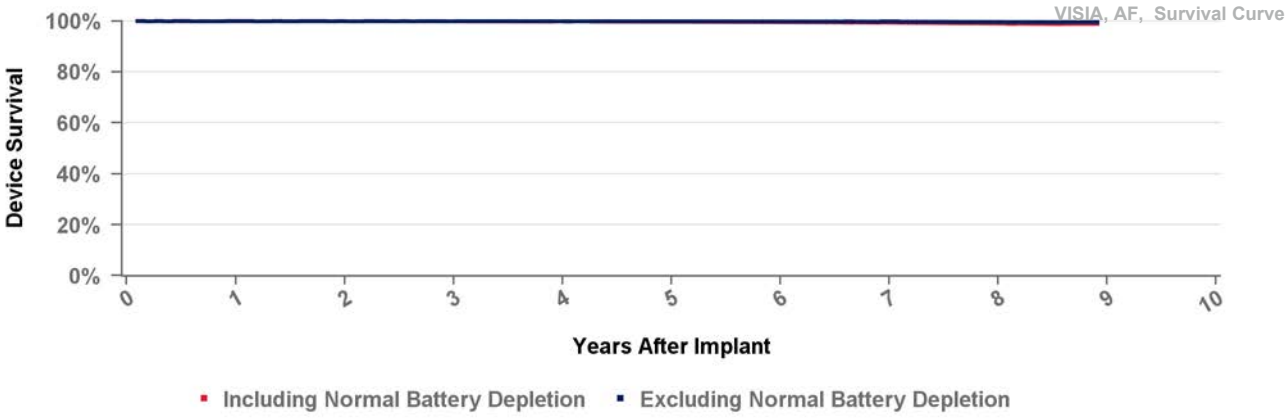
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **96** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **62** |
| **Registered USA Implants** | 57,296 | Battery | 50 |
| **Estimated Active USA Implants** | 45,213 | Electrical Component | 11 |
| **Normal Battery Depletions** | 53 | Other | 1 |
| | | **Therapy Function Compromised** | **34** |
| | | Battery | 16 |
| | | Device-Related Current Pathway | 15 |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVFB2D1 Visia MRI AF XT

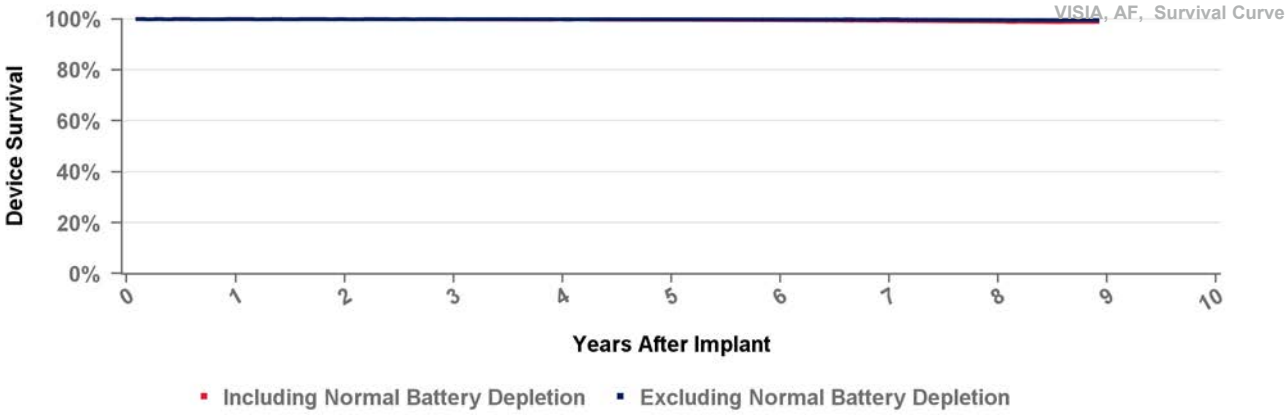
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVFB2D4 Visia MRI AF XT

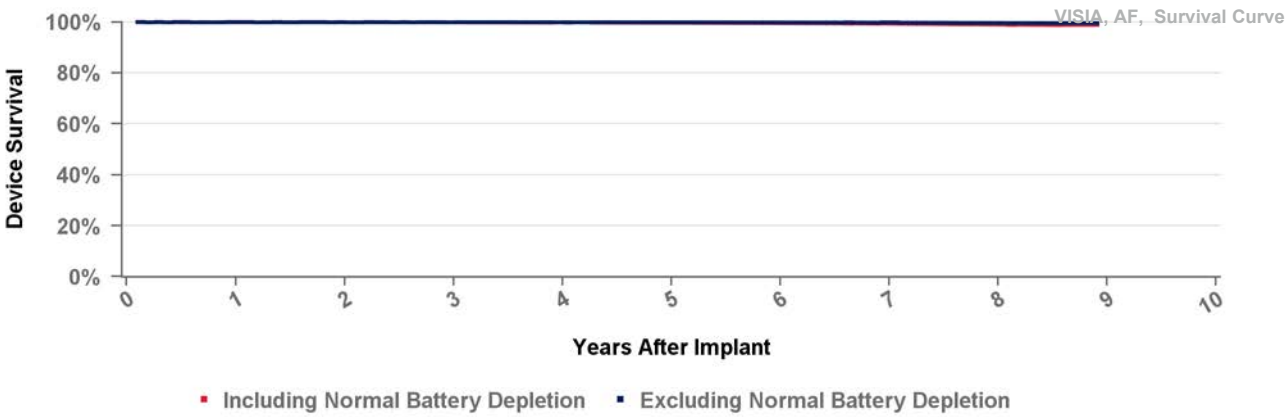
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVFC3D1 Visia MRI AF S

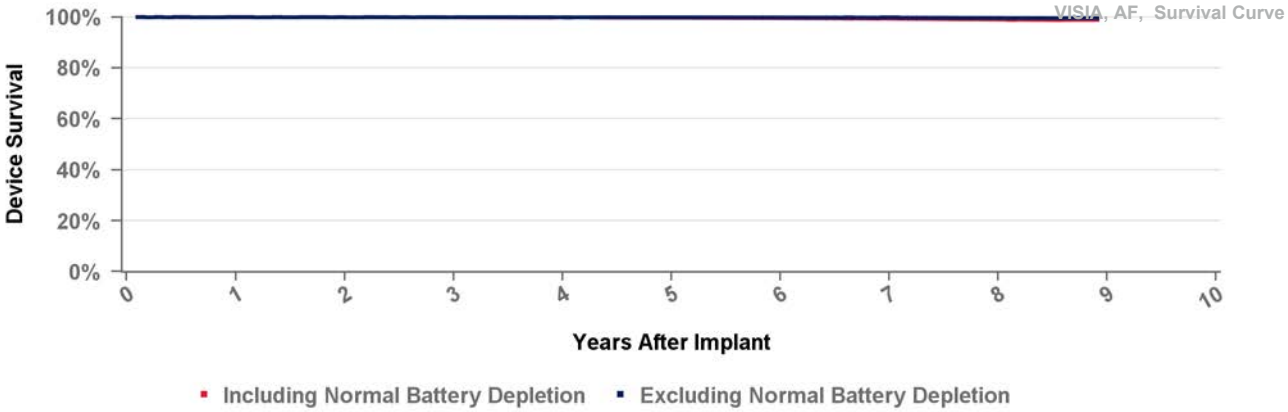
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 1,477 | Battery | 1 |
| **Estimated Active USA Implants** | 1,186 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVFC3D4 Visia MRI AF S

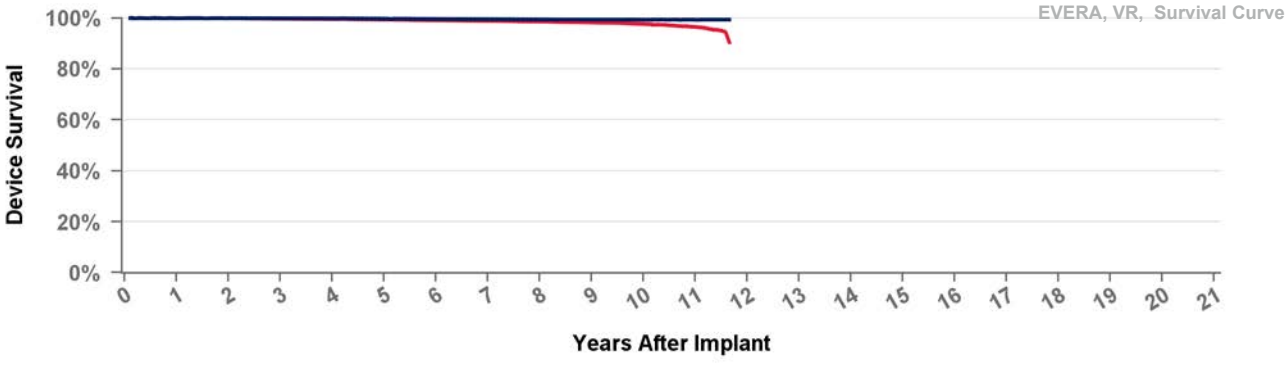
| | | | |
|---|---|---|---|
| **US Market Release** | 19Jan2016 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 19Oct2015 | **Therapy Function Not Compromised** | **4** |
| **Registered USA Implants** | 3,592 | Battery | 4 |
| **Estimated Active USA Implants** | 2,959 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 7 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 107 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.4% | 99.0% | 98.8% |
| Effective Sample Size | 76507 | 71635 | 64618 | 55414 | 47096 | 35528 | 22819 | 10781 | 578 |

## DVMB1D4 Evera MRI XT

| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | **40** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **20** |
| **Registered USA Implants** | 10,271 | Battery | 16 |
| **Estimated Active USA Implants** | 6,586 | Electrical Component | 3 |
| **Normal Battery Depletions** | 30 | Other | 1 |
| | | **Therapy Function Compromised** | **20** |
| | | Battery | 16 |
| | | Device-Related Current Pathway | 4 |



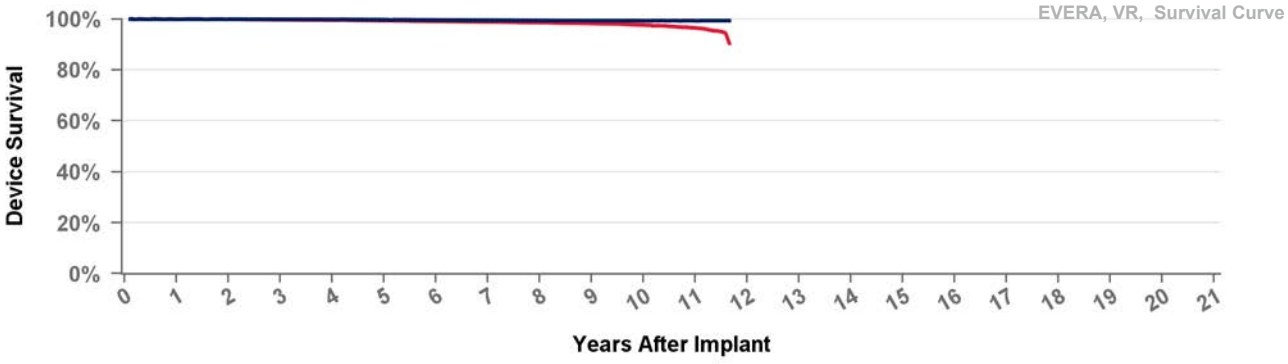

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## 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**



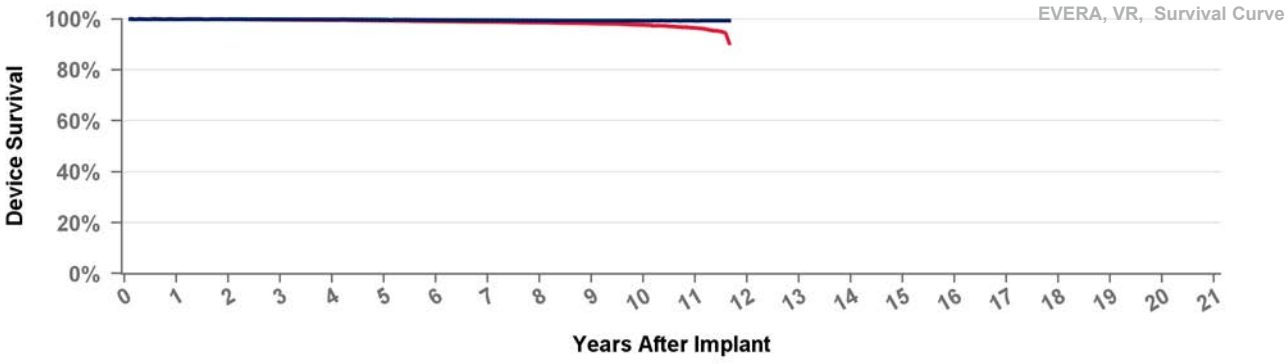

| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## 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**

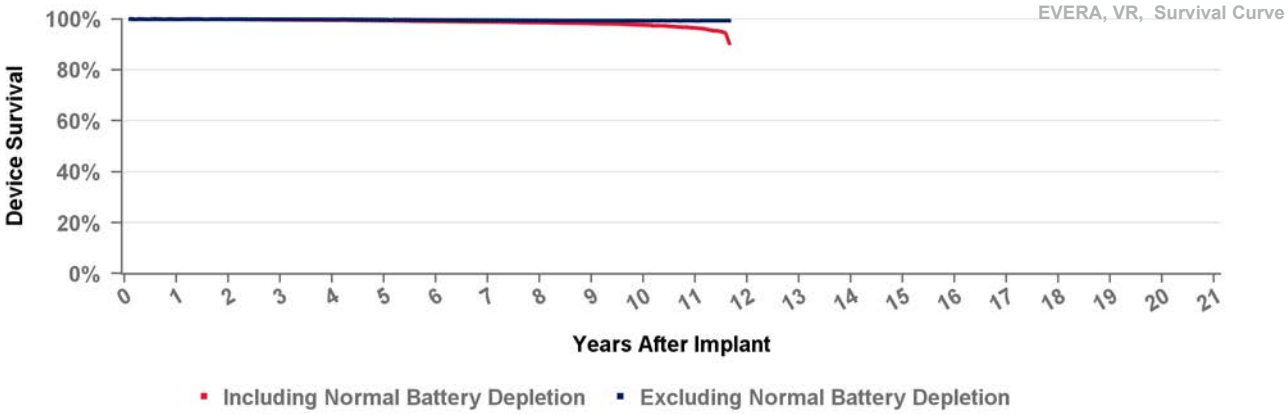
**Therapy Function Compromised**




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVMC3D1 Evera MRI S

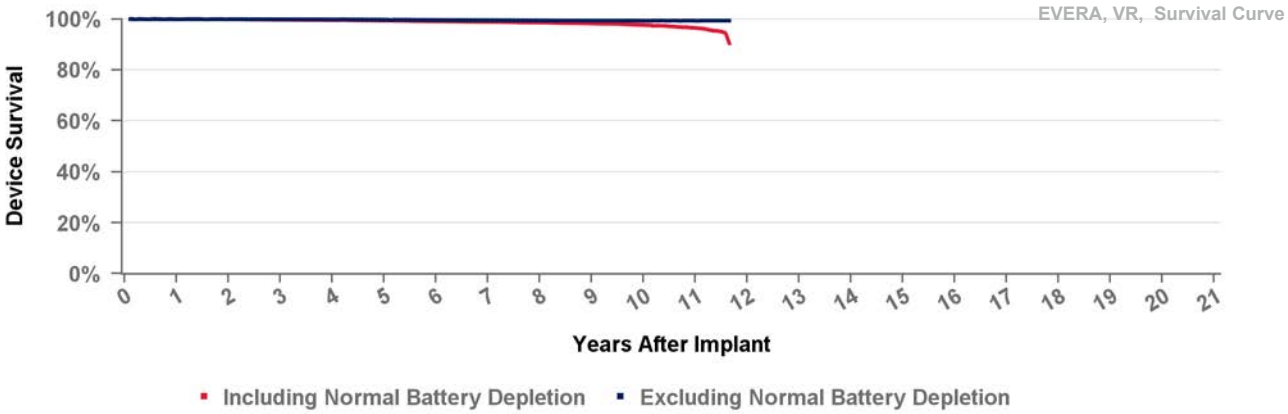
| | | | |
|---|---|---|---|
| **US Market Release** | 12Oct2016 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 05Sep2016 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVMC3D4 Evera MRI S

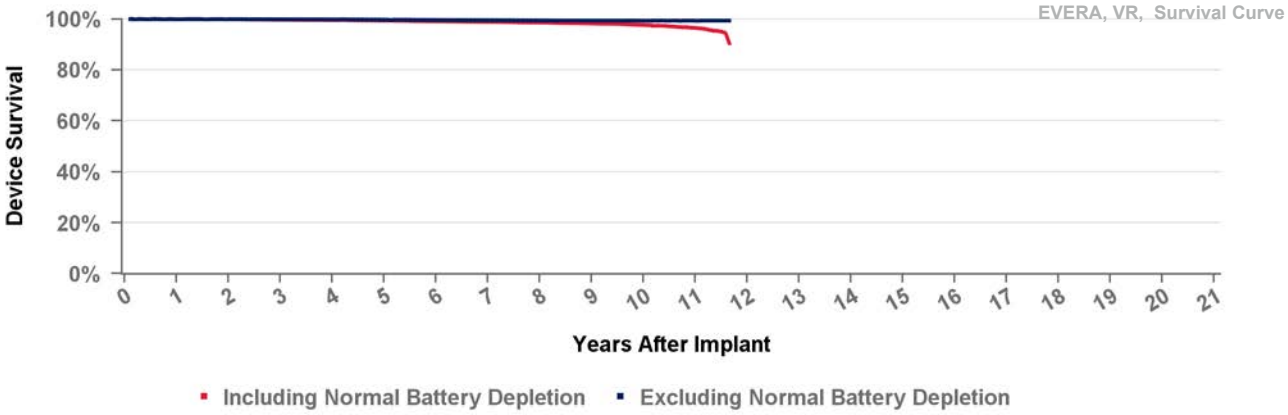
| | | | |
|---|---|---|---|
| **US Market Release** | 11Sep2015 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 31Mar2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVMD3D1 Primo

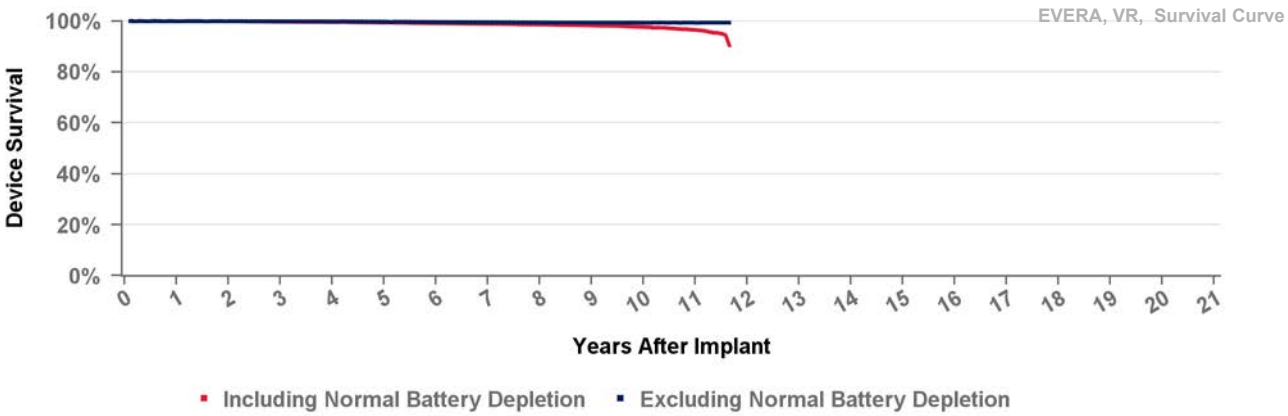
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 274 | | |
| **Estimated Active USA Implants** | 236 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVMD3D4 Primo

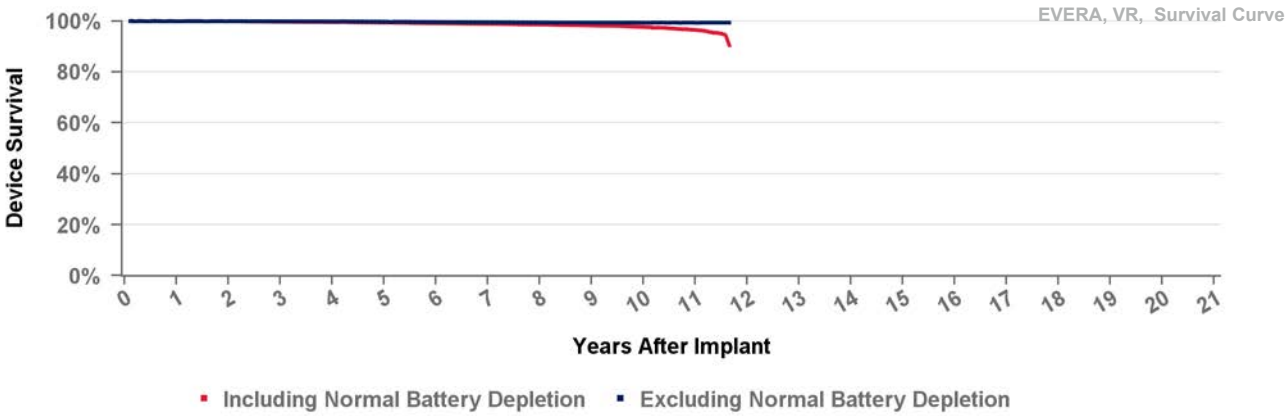
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 627 | | |
| **Estimated Active USA Implants** | 545 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVME3D1 Mirro

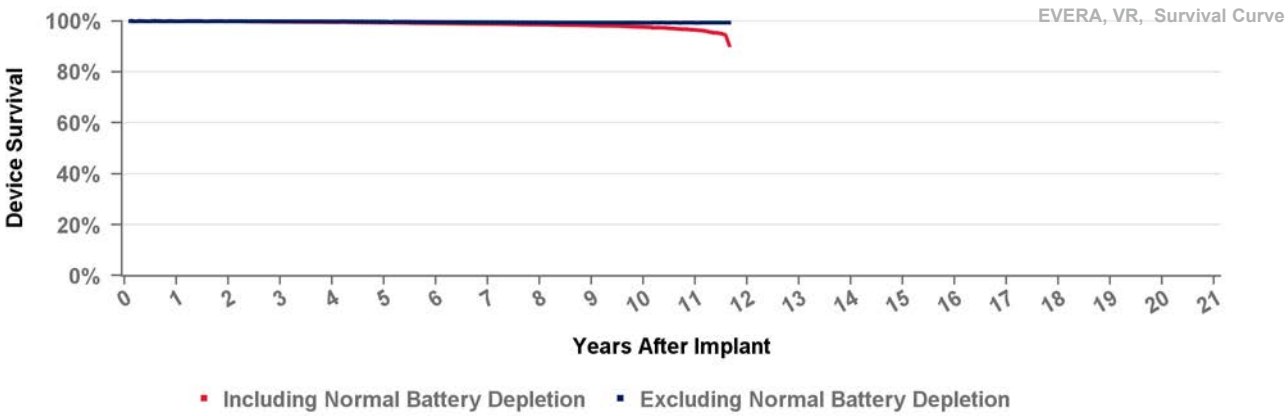
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVME3D4 Mirro

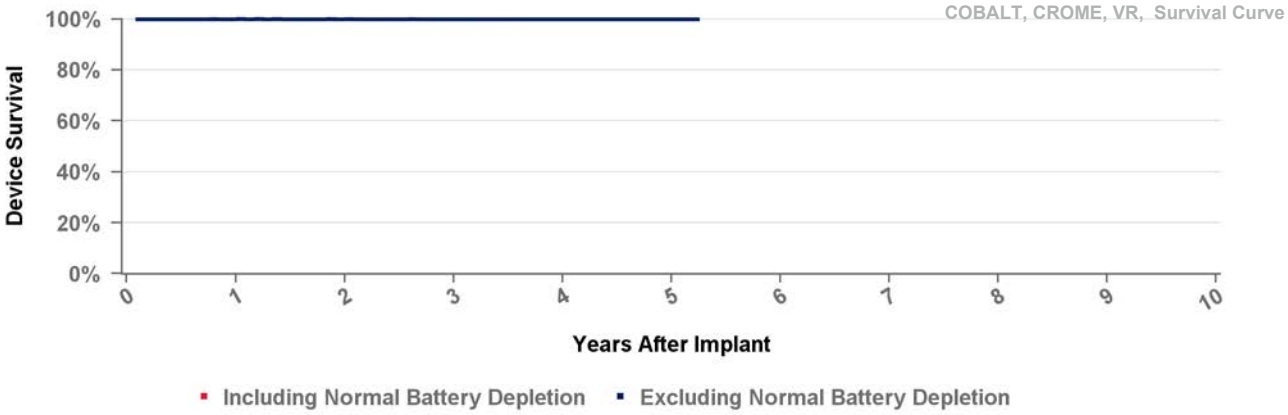
| | | | |
|---|---|---|---|
| **US Market Release** | 01Mar2018 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 10Nov2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.8% | 99.7% | 99.6% | 99.5% | 99.4% | 99.3% | 99.3% | 99.3% |
| Including NBD | 100.0% | 99.9% | 99.7% | 99.6% | 99.4% | 99.1% | 98.9% | 98.6% | 98.3% | 97.7% | 96.5% | 90.3% |
| Effective Sample Size | 52452 | 48926 | 45570 | 42496 | 39407 | 36227 | 33371 | 30859 | 27842 | 17627 | 6236 | 157 |

## DVPA2D1 Cobalt XT

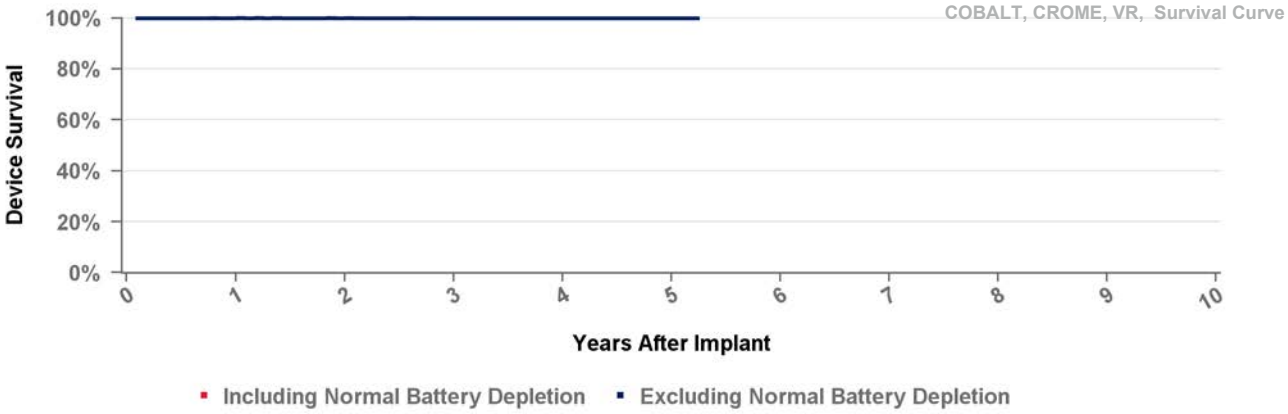
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,245 | | |
| **Estimated Active USA Implants** | 2,079 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 1 | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## DVPA2D4 Cobalt XT

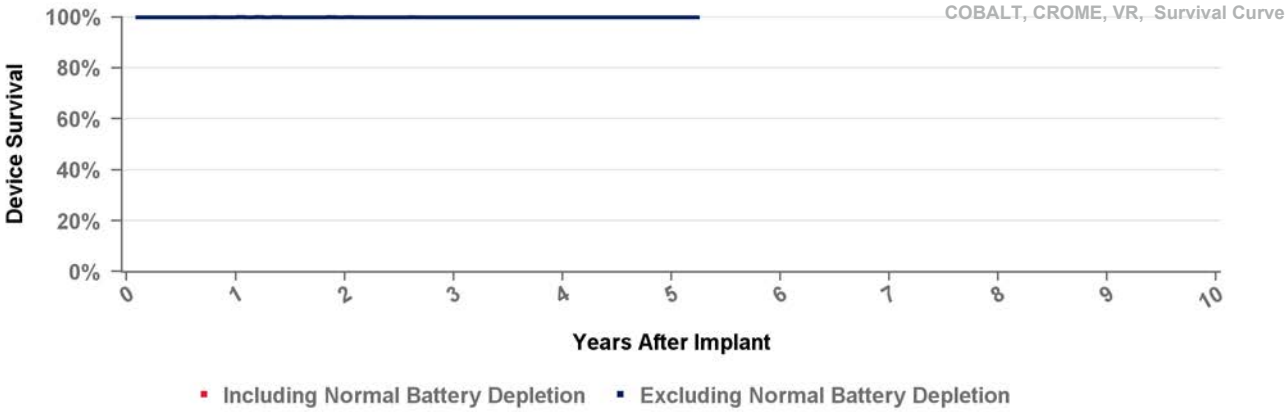
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 19,379 | Electrical Interconnect | 1 |
| **Estimated Active USA Implants** | 18,277 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 2 | Device-Related Current Pathway | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## DVPB3D1 Cobalt

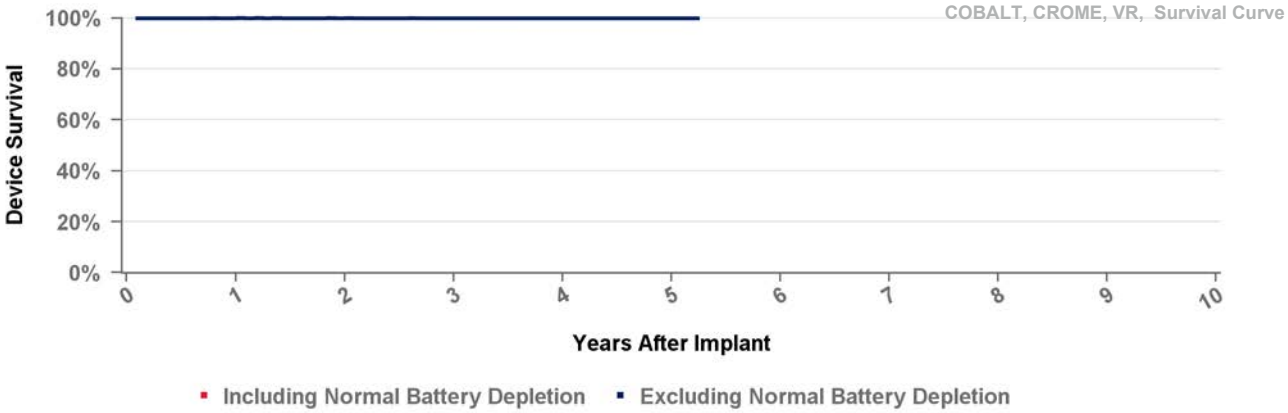
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **0** |
| **Registered USA Implants** | 1,790 | | |
| **Estimated Active USA Implants** | 1,600 | **Therapy Function Compromised** | **2** |
| **Normal Battery Depletions** | | Electrical Interconnect | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## DVPB3D4 Cobalt

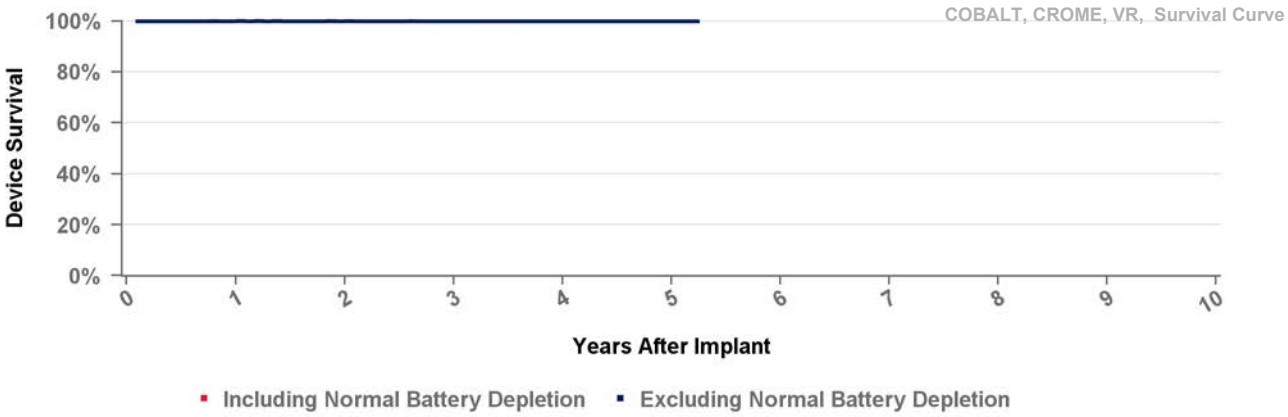
| | | | |
|---|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** | **4** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 7,245 | Other | 1 |
| **Estimated Active USA Implants** | 6,652 | **Therapy Function Compromised** | **3** |
| **Normal Battery Depletions** | 1 | Device-Related Current Pathway | 2 |
| | | Electrical Interconnect | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## DVPC3D1 Crome

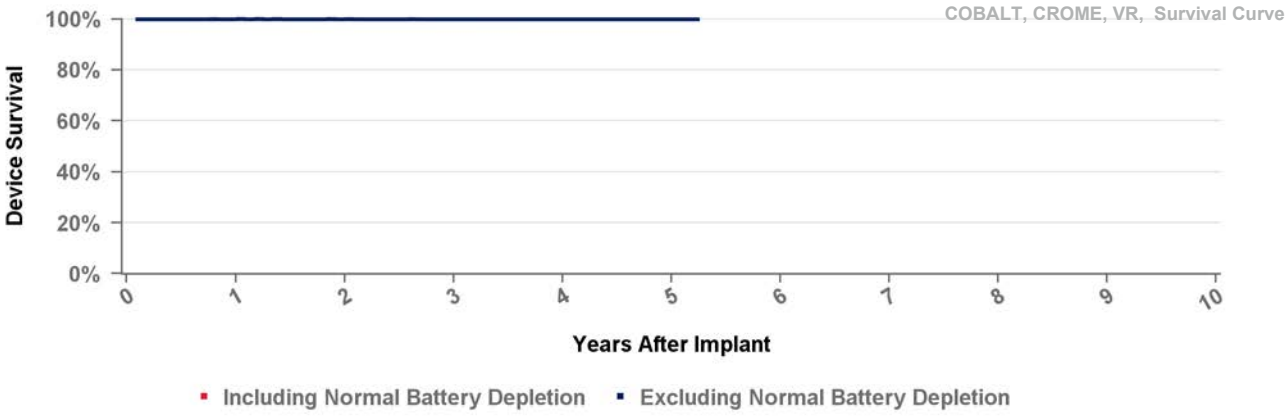
| | | |
|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** |
| **Registered USA Implants** | 170 | |
| **Estimated Active USA Implants** | 152 | **Therapy Function Compromised** |
| **Normal Battery Depletions** | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## DVPC3D4 Crome

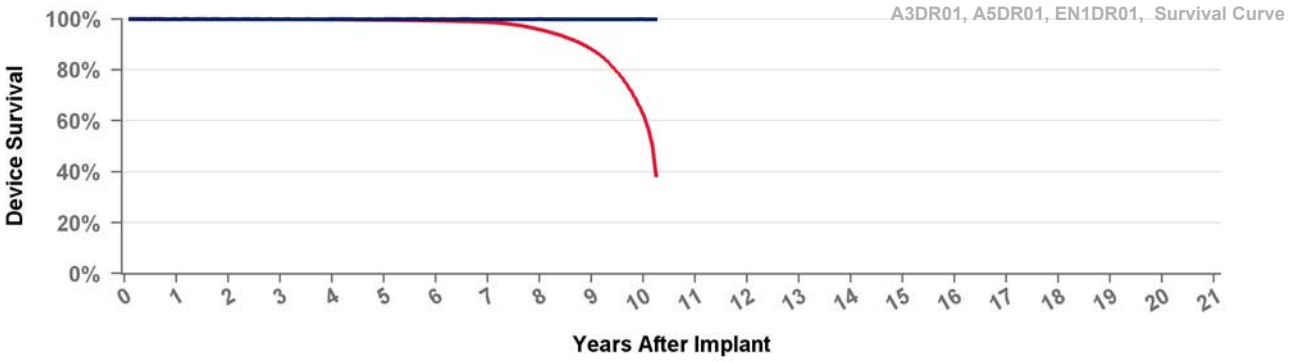
| | | |
|---|---|---|
| **US Market Release** | 23Apr2020 | **Total Malfunctions (USA)** |
| **CE Approval Date** | 18Dec2019 | **Therapy Function Not Compromised** |
| **Registered USA Implants** | 926 | |
| **Estimated Active USA Implants** | 869 | **Therapy Function Compromised** |
| **Normal Battery Depletions** | | |




| Years | 1 | 2 | 3 | 4 | 5 | at 63 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.9% | 99.9% | 99.9% |
| Effective Sample Size | 22552 | 14745 | 9174 | 5322 | 644 | 176 |

## A2DR01 Advisa DR MRI

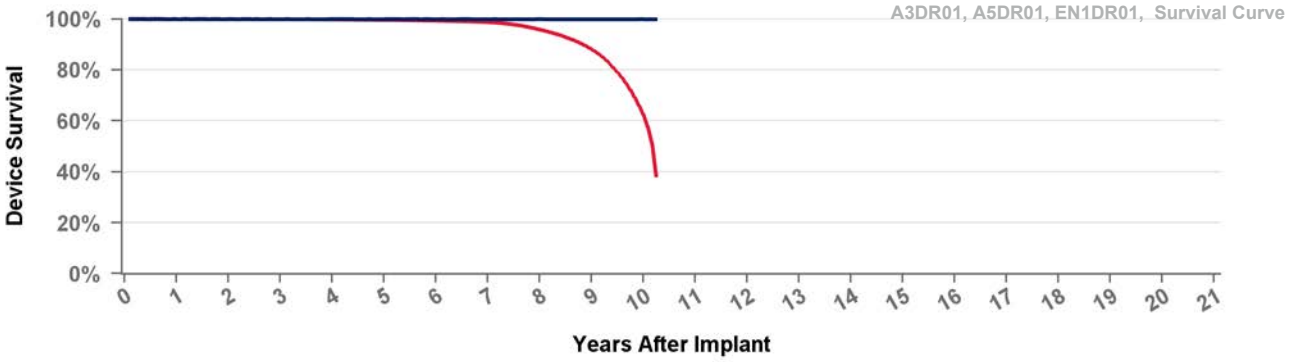
| | | | |
|---|---|---|---|
| **US Market Release** | 15Jan2013 | **Total Malfunctions (USA)** | **86** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **81** |
| **Registered USA Implants** | 344,448 | Battery | 1 |
| **Estimated Active USA Implants** | 181,791 | Electrical Component | 41 |
| **Normal Battery Depletions** | 18,717 | Electrical Interconnect | 4 |
| | | Possible Early Battery Depletion | 26 |
| | | Software/Firmware | 6 |
| | | Other | 3 |
| | | **Therapy Function Compromised** | **5** |
| | | Electrical Component | 5 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 123 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.8% | 95.8% | 88.1% | 62.7% | 38.4% |
| Effective Sample Size | 308316 | 290486 | 273758 | 257153 | 237772 | 216912 | 196453 | 158719 | 82763 | 16245 | 3383 |

## A3DR01 Advisa DR MRI

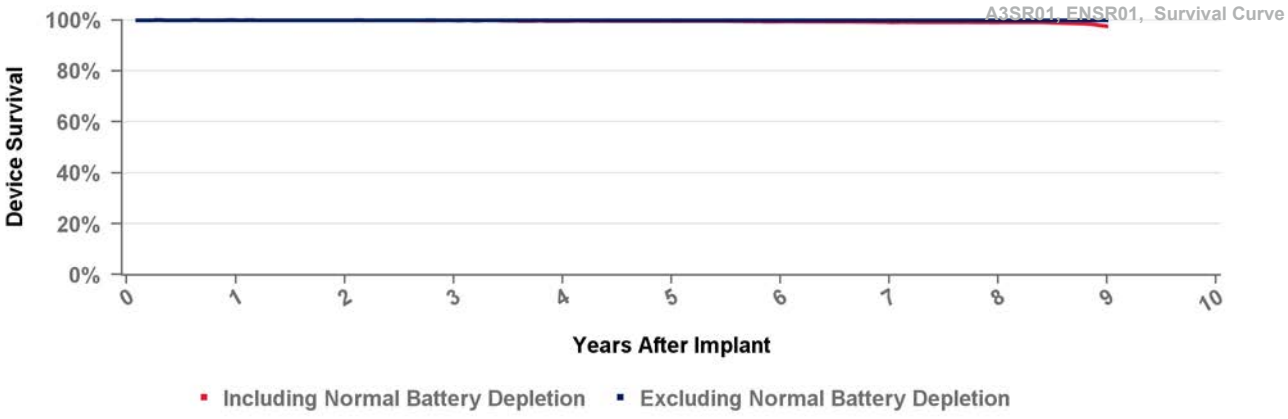
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Jun2009 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 26 | | |
| **Estimated Active USA Implants** | 3 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 5 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 123 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.8% | 95.8% | 88.1% | 62.7% | 38.4% |
| Effective Sample Size | 308316 | 290486 | 273758 | 257153 | 237772 | 216912 | 196453 | 158719 | 82763 | 16245 | 3383 |

## A3SR01 Advisa SR MRI

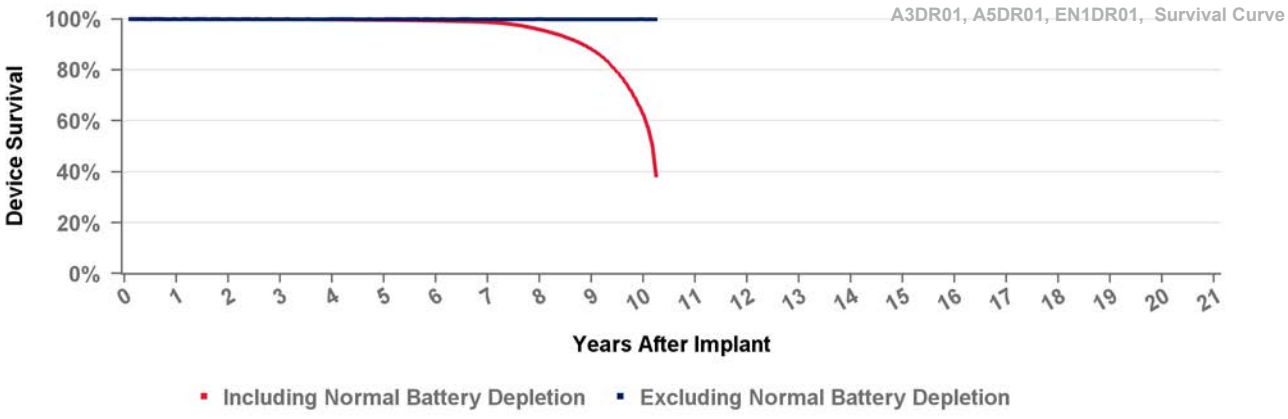
| | | | |
|---|---|---|---|
| **US Market Release** | 19Mar2015 | **Total Malfunctions (USA)** | **9** |
| **CE Approval Date** | 24Apr2014 | **Therapy Function Not Compromised** | **8** |
| **Registered USA Implants** | 28,083 | Electrical Component | 3 |
| **Estimated Active USA Implants** | 15,428 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 73 | Possible Early Battery Depletion | 2 |
| | | Other | 2 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.5% | 99.2% | 99.0% | 97.5% |
| Effective Sample Size | 22016 | 19373 | 17194 | 15015 | 12898 | 10981 | 9364 | 6442 | 401 |

## A5DR01 Advisa DR

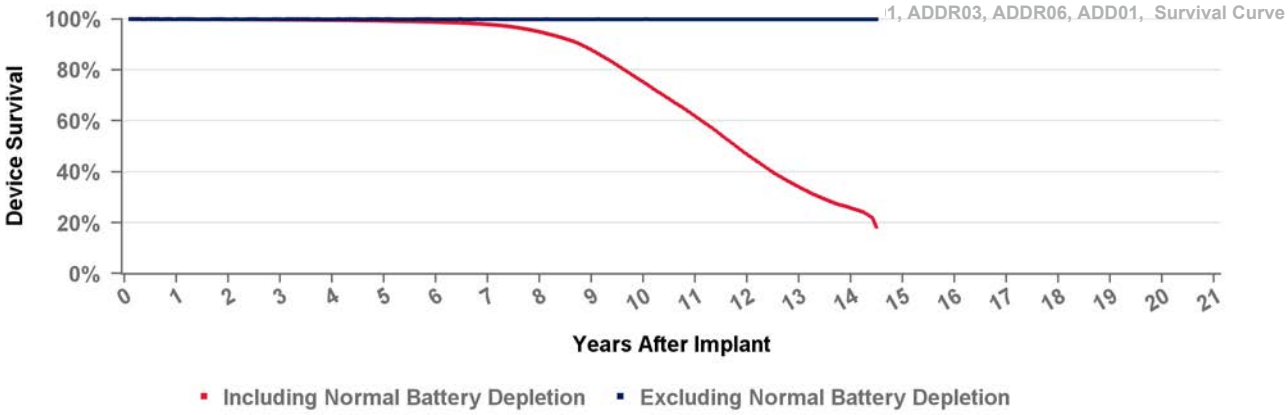
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Jun2009 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 123 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.8% | 95.8% | 88.1% | 62.7% | 38.4% |
| Effective Sample Size | 308316 | 290486 | 273758 | 257153 | 237772 | 216912 | 196453 | 158719 | 82763 | 16245 | 3383 |

## ADD01 Adapta D

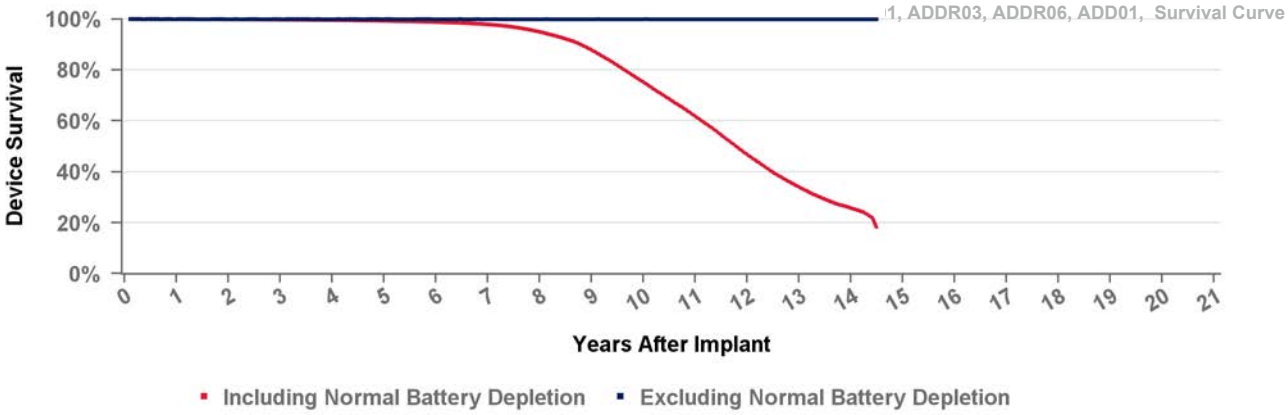
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## ADDR01 Adapta DR

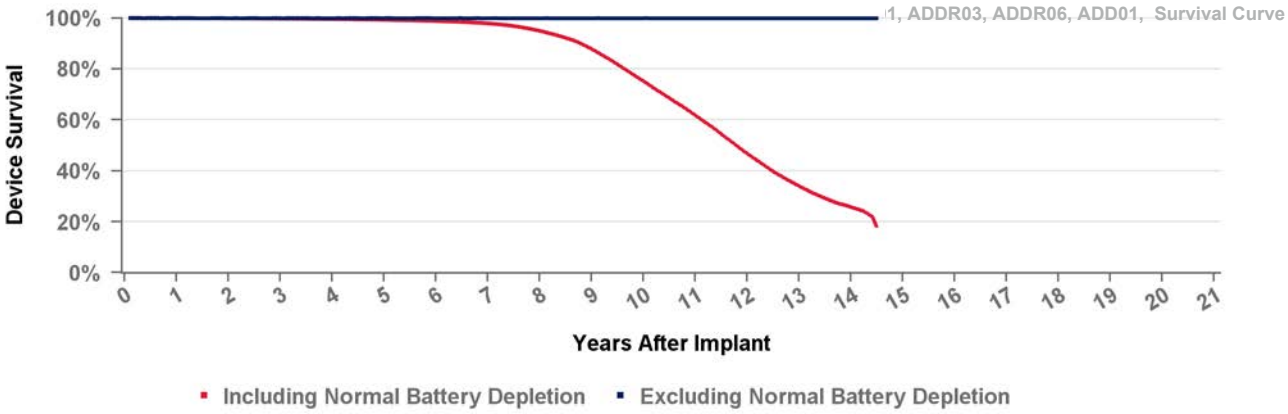
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **95** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **67** |
| **Registered USA Implants** | 454,889 | Electrical Component | 59 |
| **Estimated Active USA Implants** | 109,844 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 55,604 | 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 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## ADDR03 Adapta DR

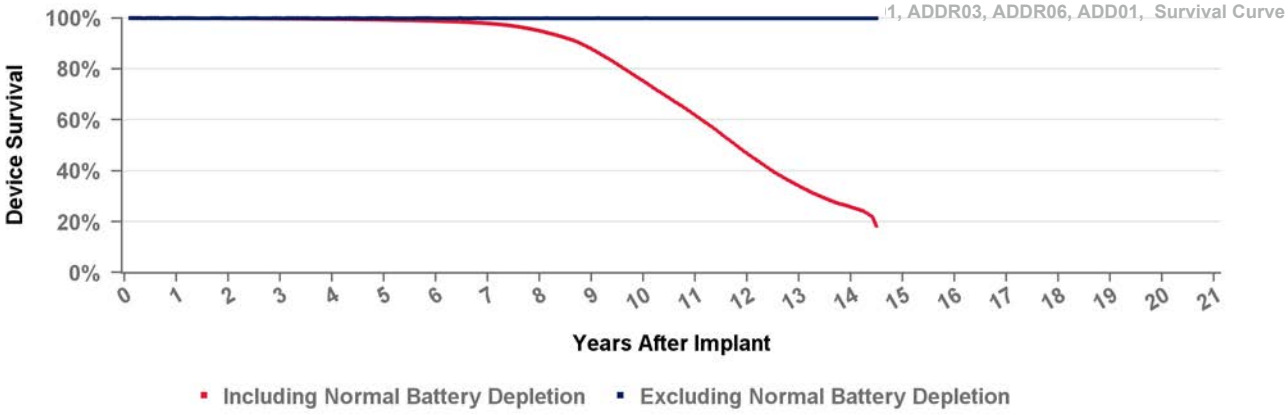
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 4,582 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 1,210 | **Therapy Function Compromised** | **1** |
| **Normal Battery Depletions** | 664 | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## ADDR06 Adapta DR

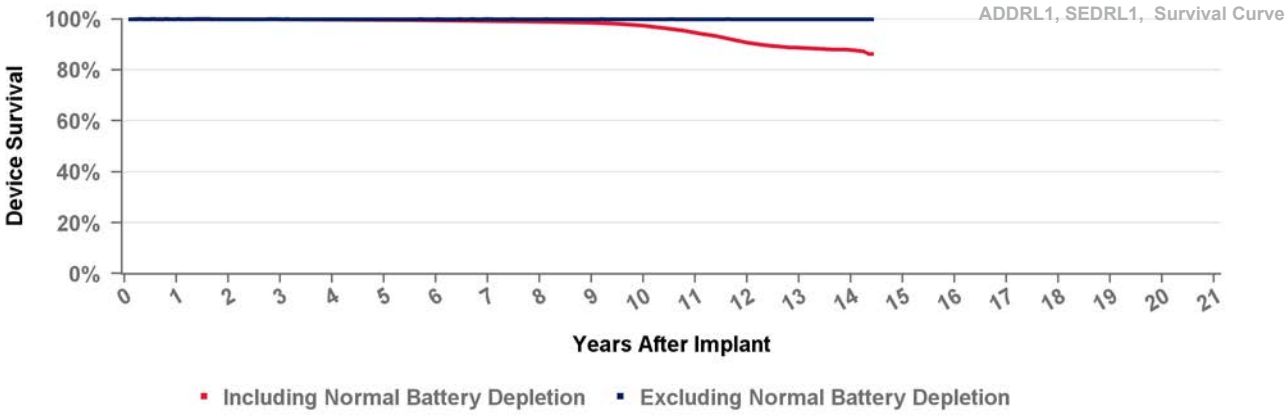
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 3,682 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 836 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 452 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## ADDRL1 Adapta L DR

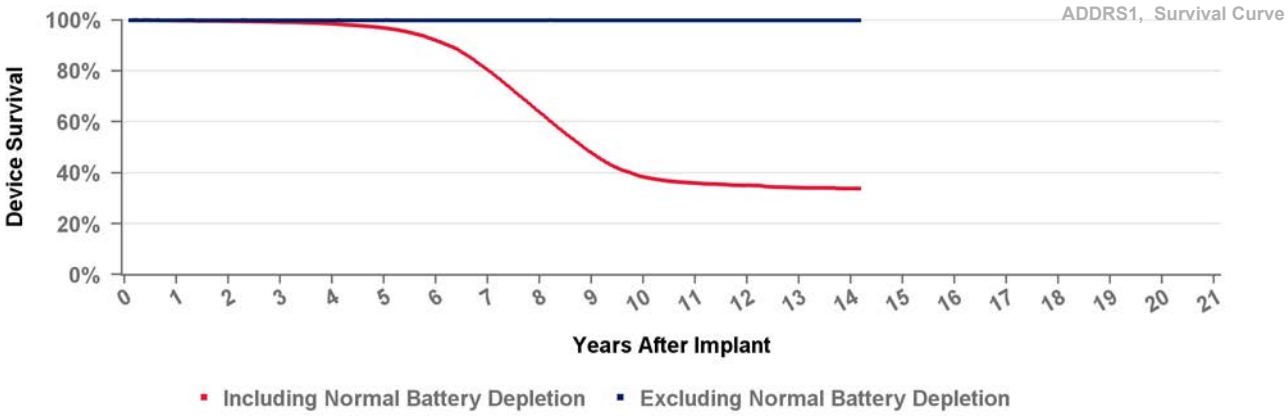
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **25** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 138,619 | Electrical Component | 13 |
| **Estimated Active USA Implants** | 60,210 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 2,943 | Possible Early Battery Depletion | 2 |
| | | Software/Firmware | 1 |
| | | **Therapy Function Compromised** | **8** |
| | | Electrical Component | 5 |
| | | Electrical Interconnect | 1 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 173 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% | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 99.0% | 98.5% | 97.4% | 94.6% | 90.7% | 88.7% | 87.9% | 86.3% |
| Effective Sample Size | 119669 | 112688 | 106043 | 99521 | 92209 | 84483 | 77120 | 70307 | 62002 | 51808 | 40102 | 26523 | 13871 | 3554 | 129 |

## ADDRS1 Adapta S DR

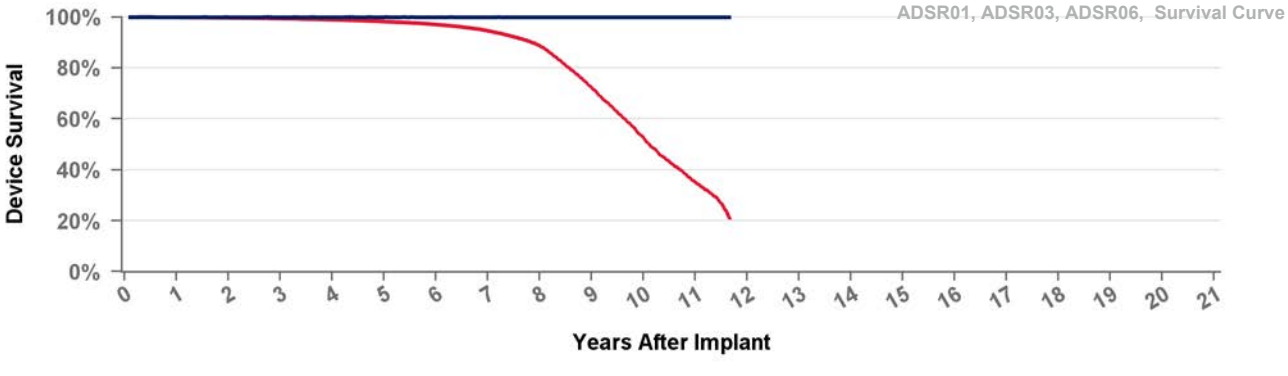
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **15** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **9** |
| **Registered USA Implants** | 49,319 | Electrical Component | 5 |
| **Estimated Active USA Implants** | 9,353 | Possible Early Battery Depletion | 3 |
| **Normal Battery Depletions** | 6,804 | Other | 1 |
| | | **Therapy Function Compromised** | **6** |
| | | Electrical Component | 4 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 170 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.8% | 99.6% | 99.2% | 98.5% | 96.9% | 92.0% | 80.3% | 63.7% | 47.9% | 38.4% | 36.0% | 35.0% | 34.2% | 33.9% | 33.9% |
| Effective Sample Size | 40122 | 36095 | 32382 | 29064 | 25858 | 21901 | 16771 | 11400 | 7122 | 4562 | 3313 | 2116 | 1162 | 247 | 110 |

## ADSR01 Adapta SR

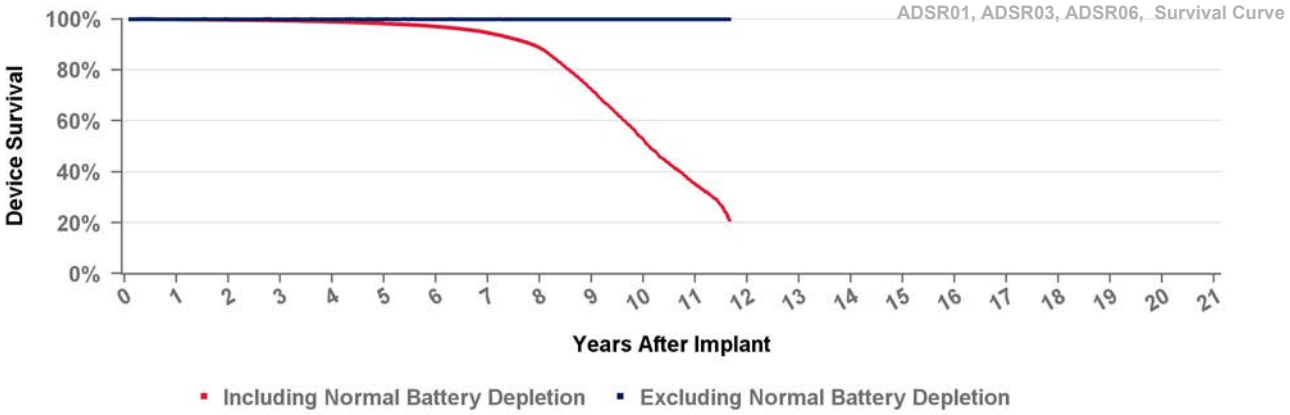
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **18** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **12** |
| **Registered USA Implants** | 91,665 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 18,108 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 6,804 | 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 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.4% | 99.0% | 98.2% | 97.1% | 94.6% | 88.7% | 72.2% | 52.6% | 35.1% | 21.1% |
| Effective Sample Size | 72052 | 62968 | 55144 | 48132 | 41294 | 34944 | 29017 | 22720 | 15220 | 8342 | 2785 | 335 |

## ADSR03 Adapta SR

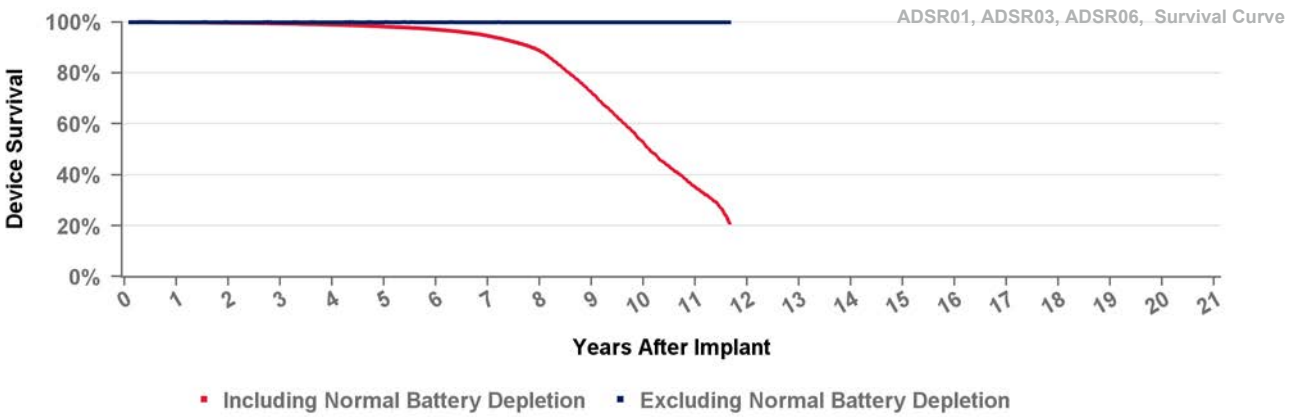
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2,133 | | |
| **Estimated Active USA Implants** | 411 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 213 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.4% | 99.0% | 98.2% | 97.1% | 94.6% | 88.7% | 72.2% | 52.6% | 35.1% | 21.1% |
| Effective Sample Size | 72052 | 62968 | 55144 | 48132 | 41294 | 34944 | 29017 | 22720 | 15220 | 8342 | 2785 | 335 |

## ADSR06 Adapta SR

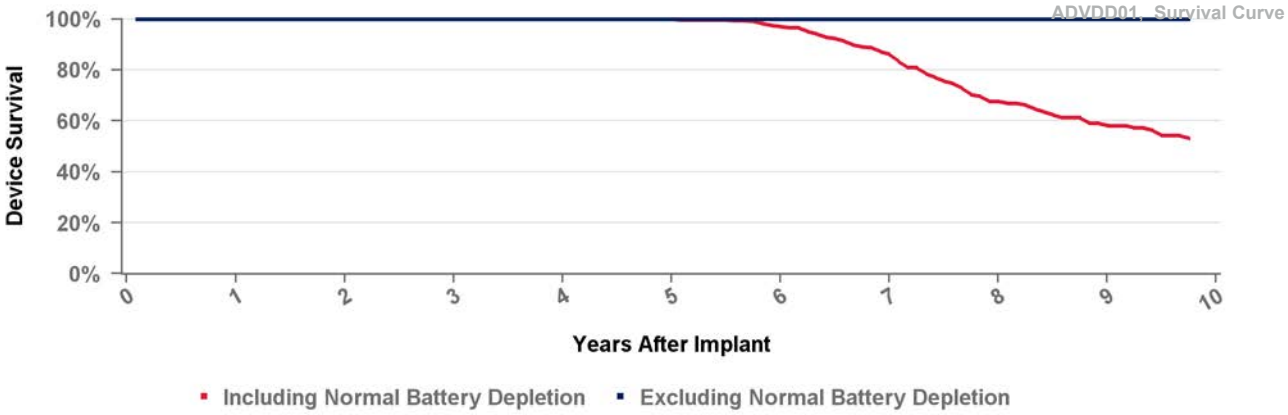
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **2** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **2** |
| **Registered USA Implants** | 2,922 | Electrical Component | 2 |
| **Estimated Active USA Implants** | 584 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 286 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.4% | 99.0% | 98.2% | 97.1% | 94.6% | 88.7% | 72.2% | 52.6% | 35.1% | 21.1% |
| Effective Sample Size | 72052 | 62968 | 55144 | 48132 | 41294 | 34944 | 29017 | 22720 | 15220 | 8342 | 2785 | 335 |

## ADVDD01 Adapta VDD

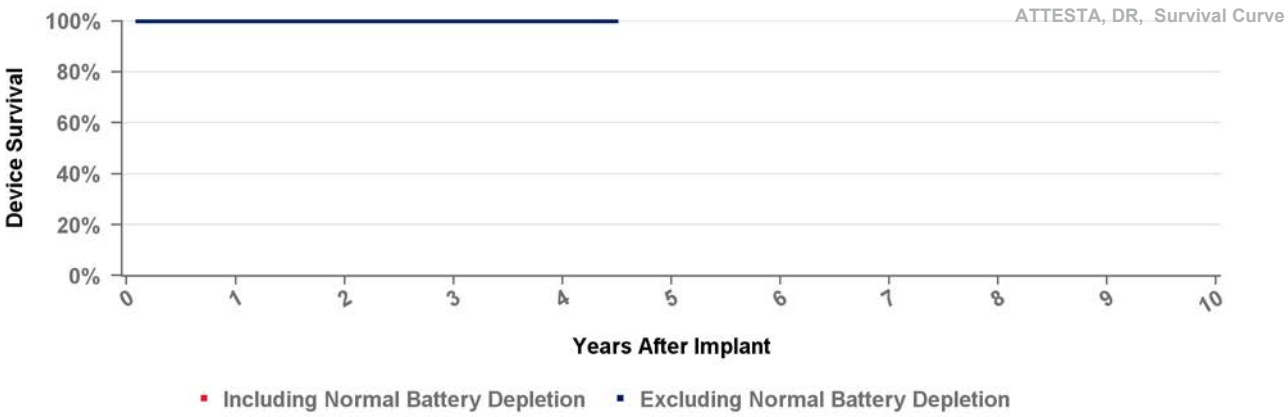
| | | |
|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** |
| **Registered USA Implants** | 858 | |
| **Estimated Active USA Implants** | 213 | **Therapy Function Compromised** |
| **Normal Battery Depletions** | 95 | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 117 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 97.0% | 86.1% | 67.6% | 58.2% | 53.1% |
| Effective Sample Size | 706 | 650 | 593 | 541 | 478 | 412 | 325 | 198 | 132 | 101 |

## ATDR01 Attesta DR MRI

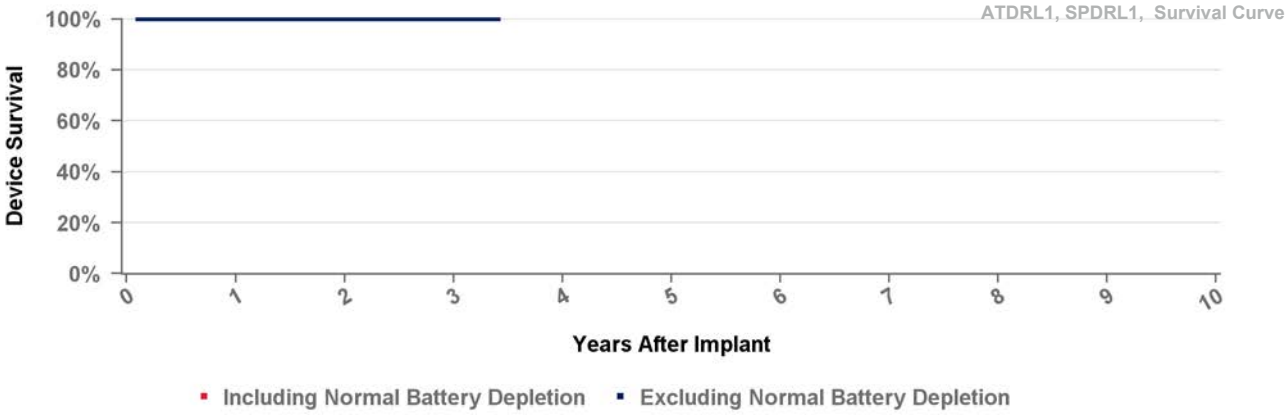
| | | |
|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** |
| **Registered USA Implants** | 2,285 | |
| **Estimated Active USA Implants** | 2,159 | **Therapy Function Compromised** |
| **Normal Battery Depletions** | | |




| Years | 1 | 2 | 3 | 4 | at 54 mo |
|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 2021 | 1615 | 999 | 371 | 102 |

## ATDRL1 Attesta L DR MRI

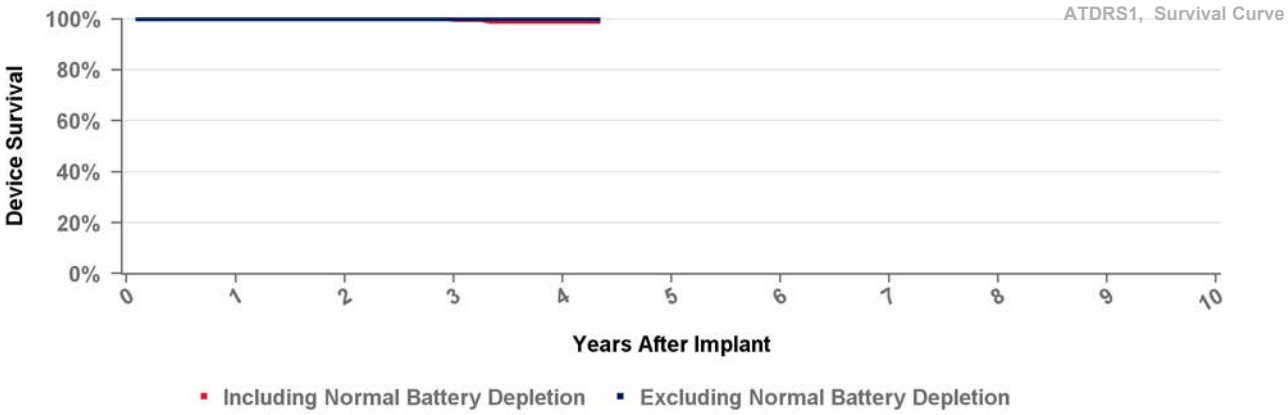
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 324 | | |
| **Estimated Active USA Implants** | 302 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | at 41 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 283 | 223 | 140 | 100 |

## ATDRS1 Attesta S DR MRI

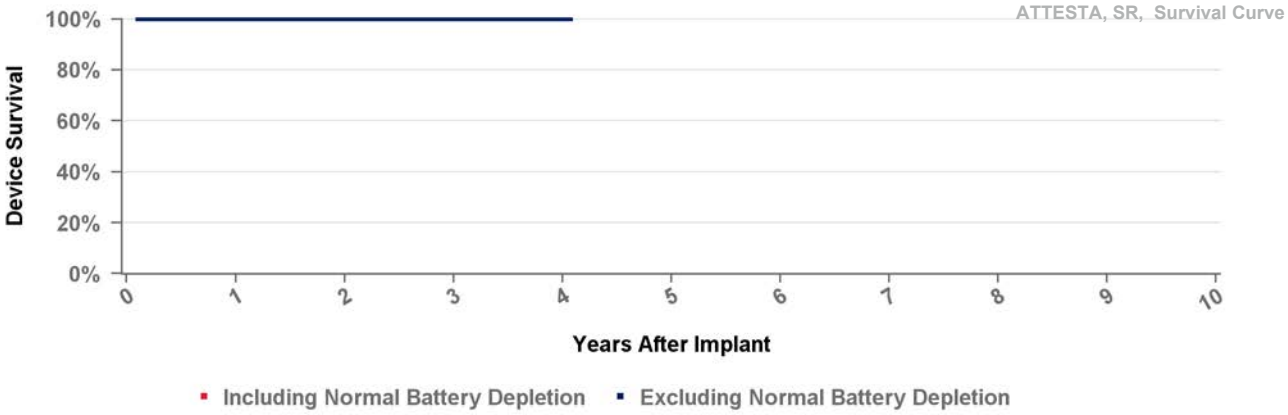
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,640 | | |
| **Estimated Active USA Implants** | 1,457 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 2 | | |




| Years | 1 | 2 | 3 | 4 | at 52 mo |
|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.7% | 98.8% | 98.8% |
| Effective Sample Size | 1302 | 940 | 612 | 225 | 119 |

## ATSR01 Attesta SR MRI

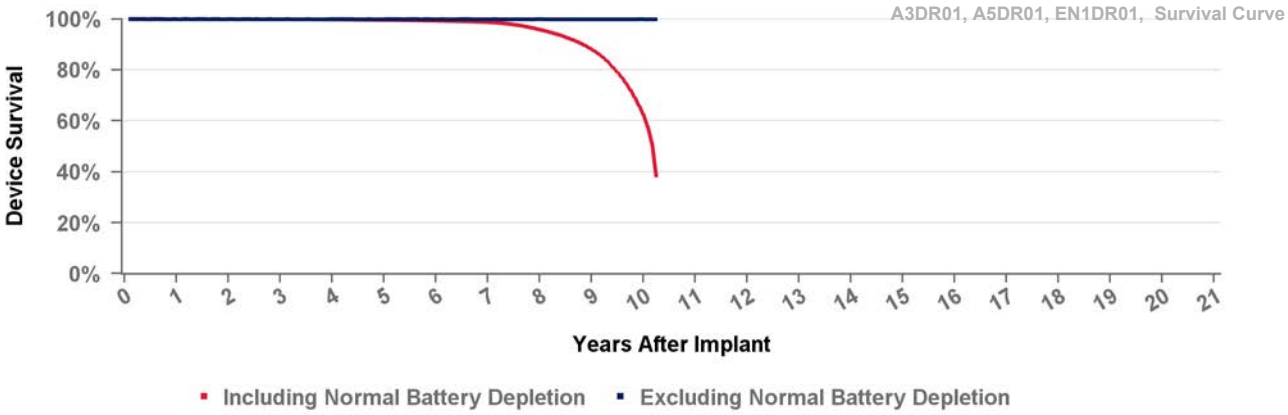
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1,421 | | |
| **Estimated Active USA Implants** | 1,060 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | 1 | | |




| Years | 1 | 2 | 3 | 4 | at 49 mo |
|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.8% | 99.8% | 99.8% | 99.8% | 99.8% |
| Effective Sample Size | 893 | 645 | 367 | 133 | 104 |

## EN1DR01 Ensura MRI

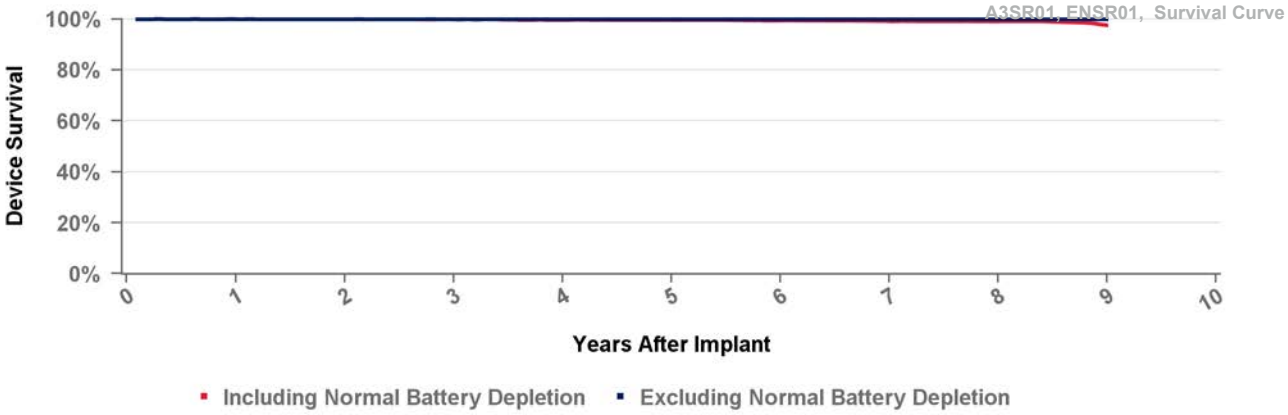
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 23Jun2010 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 6 | | |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 123 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 99.9% | 99.9% | 99.8% | 99.7% | 99.4% | 98.8% | 95.8% | 88.1% | 62.7% | 38.4% |
| Effective Sample Size | 308316 | 290486 | 273758 | 257153 | 237772 | 216912 | 196453 | 158719 | 82763 | 16245 | 3383 |

## EN1SR01 Ensura SR MRI

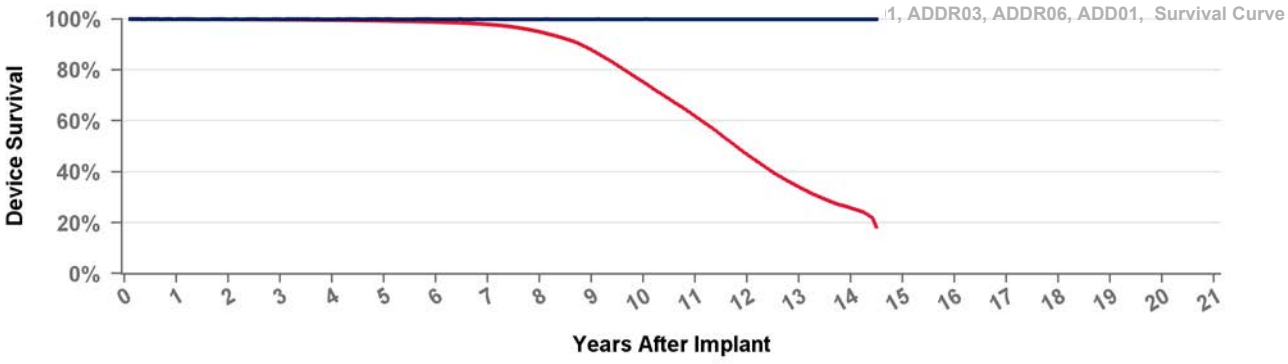
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 24Apr2014 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.7% | 99.6% | 99.5% | 99.2% | 99.0% | 97.5% |
| Effective Sample Size | 22016 | 19373 | 17194 | 15015 | 12898 | 10981 | 9364 | 6442 | 401 |

## RED01 Relia D

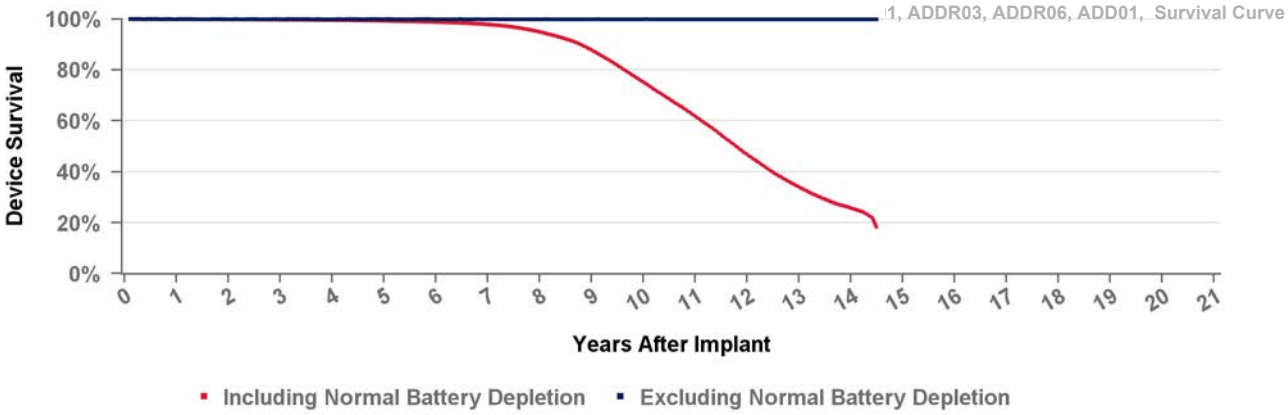
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 2 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## REDR01 Relia DR

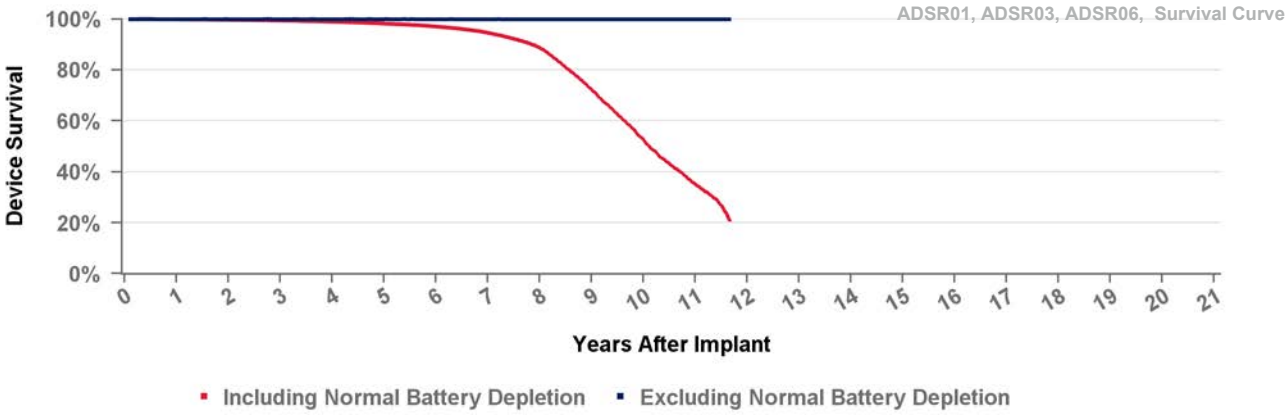
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 11 | | |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.3% | 98.8% | 97.9% | 95.0% | 87.8% | 75.2% | 61.8% | 46.8% | 34.0% | 25.8% | 18.3% |
| Effective Sample Size | 393221 | 365355 | 338873 | 313290 | 289596 | 265352 | 241242 | 213907 | 174832 | 129463 | 88825 | 50050 | 22658 | 6025 | 200 |

## RES01 Relia S

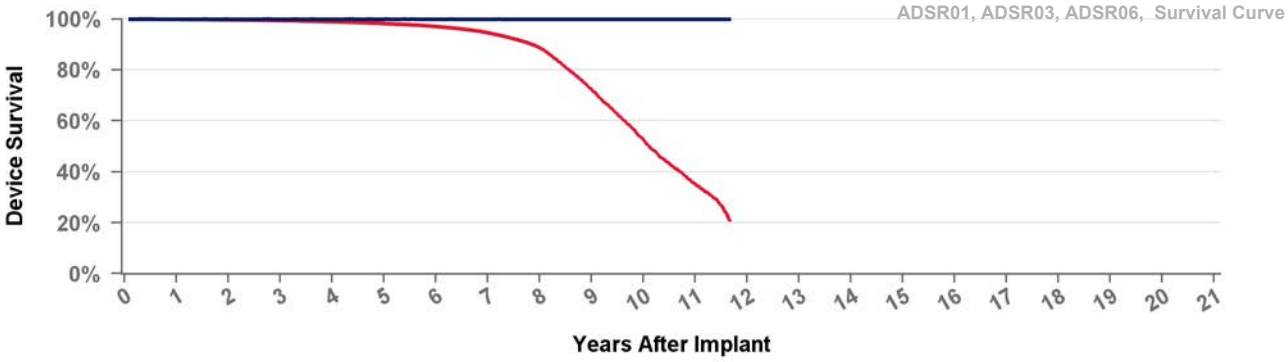
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.4% | 99.0% | 98.2% | 97.1% | 94.6% | 88.7% | 72.2% | 52.6% | 35.1% | 21.1% |
| Effective Sample Size | 72052 | 62968 | 55144 | 48132 | 41294 | 34944 | 29017 | 22720 | 15220 | 8342 | 2785 | 335 |

## RESR01 Relia SR

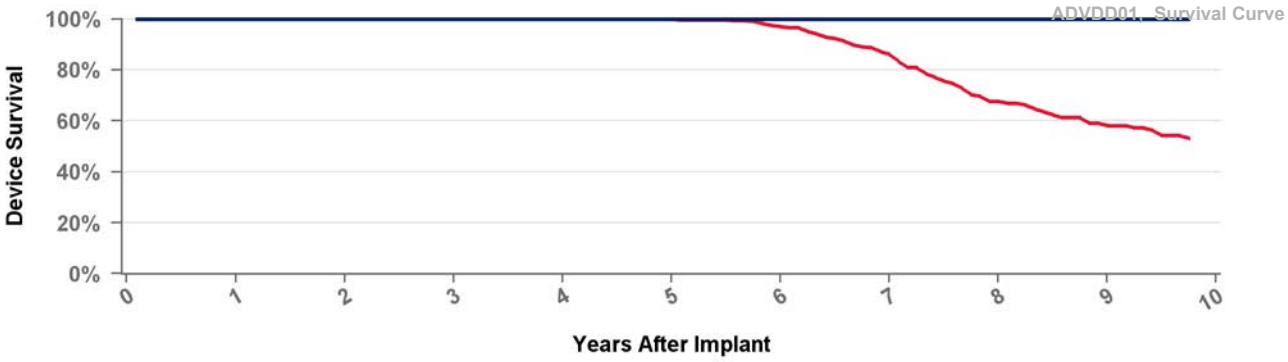
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 7 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.7% | 99.4% | 99.0% | 98.2% | 97.1% | 94.6% | 88.7% | 72.2% | 52.6% | 35.1% | 21.1% |
| Effective Sample Size | 72052 | 62968 | 55144 | 48132 | 41294 | 34944 | 29017 | 22720 | 15220 | 8342 | 2785 | 335 |

## REVDD01 Relia VDD

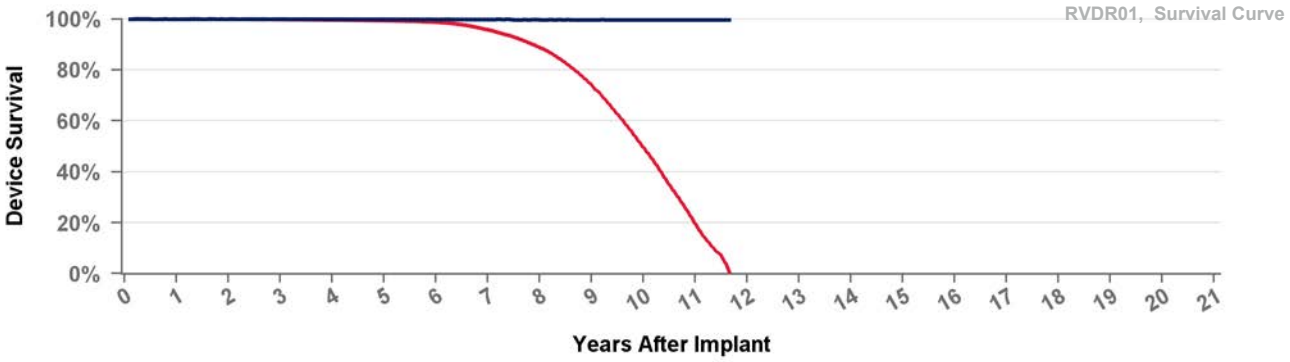
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 07May2008 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 117 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 97.0% | 86.1% | 67.6% | 58.2% | 53.1% |
| Effective Sample Size | 706 | 650 | 593 | 541 | 478 | 412 | 325 | 198 | 132 | 101 |

## RVDR01 Revo MRI SureScan

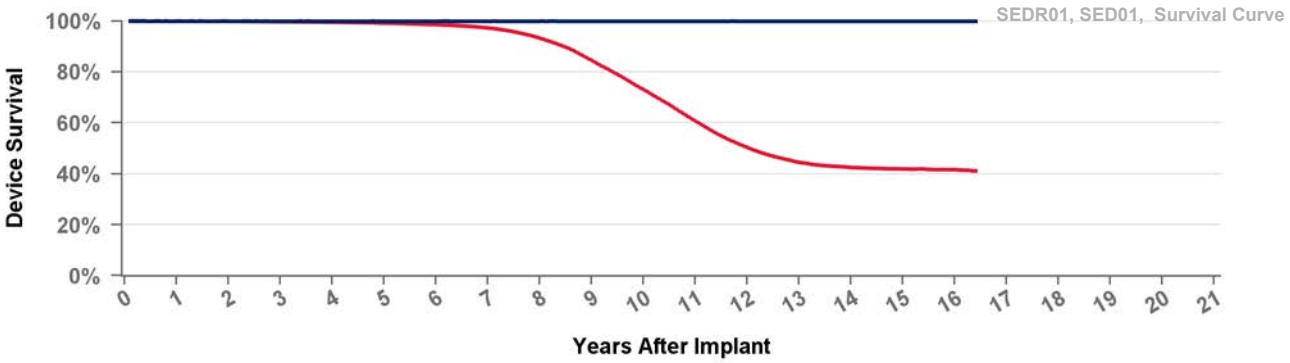
| | | | |
|---|---|---|---|
| **US Market Release** | 08Feb2011 | **Total Malfunctions (USA)** | **111** |
| **CE Approval Date** | | **Therapy Function Not Compromised** | **108** |
| **Registered USA Implants** | 69,117 | Battery | 1 |
| **Estimated Active USA Implants** | 13,584 | Electrical Component | 40 |
| **Normal Battery Depletions** | 12,242 | Electrical Interconnect | 1 |
| | | Possible Early Battery Depletion | 61 |
| | | Software/Firmware | 4 |
| | | Other | 1 |
| | | **Therapy Function Compromised** | **3** |
| | | Electrical Component | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 140 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.7% | 99.7% | 99.7% | 99.7% |
| Including NBD | 100.0% | 99.9% | 99.8% | 99.6% | 99.4% | 98.8% | 95.8% | 88.8% | 74.1% | 49.8% | 19.8% | 0.6% |
| Effective Sample Size | 59302 | 56150 | 53137 | 49977 | 46287 | 42272 | 37451 | 31329 | 22641 | 11906 | 3053 | 131 |

## SED01 Sensia D

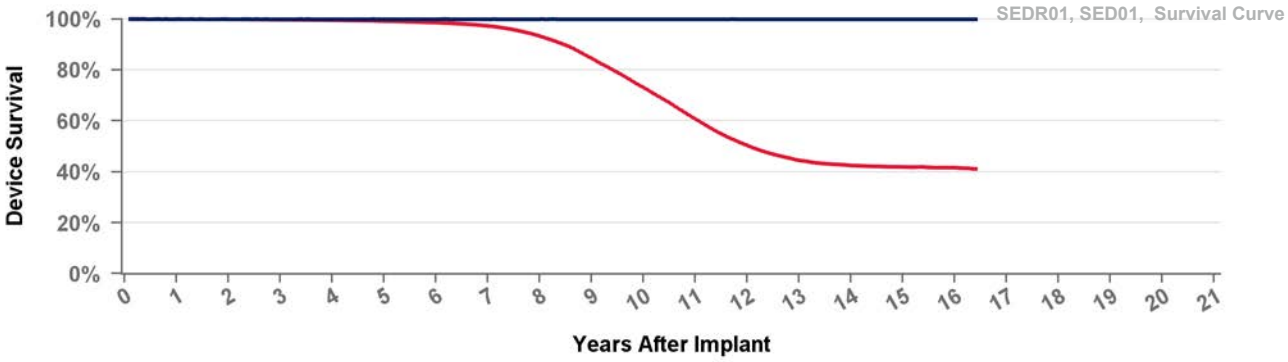
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 5 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 197 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.3% | 93.3% | 84.6% | 73.1% | 60.7% | 50.4% | 44.5% | 42.5% | 41.9% | 41.6% | 41.2% |
| Effective Sample Size | 120513 | 108986 | 98339 | 88705 | 79974 | 72182 | 64968 | 56762 | 46858 | 36316 | 25803 | 16987 | 11135 | 7383 | 4221 | 1404 | 302 |

## SEDR01 Sensia DR

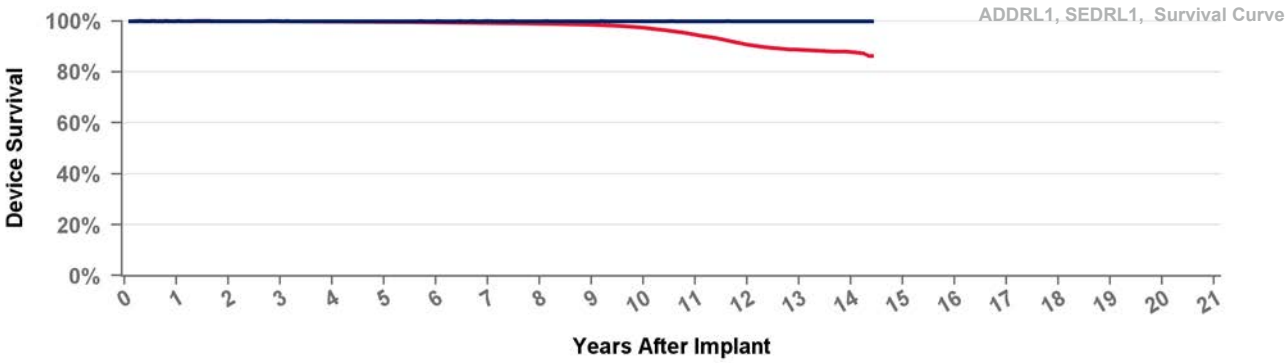
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **33** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **17** |
| **Registered USA Implants** | 149,412 | Electrical Component | 15 |
| **Estimated Active USA Implants** | 27,401 | Electrical Interconnect | 1 |
| **Normal Battery Depletions** | 17,726 | Other | 1 |
| | | **Therapy Function Compromised** | **16** |
| | | Electrical Component | 6 |
| | | Electrical Interconnect | 3 |
| | | Possible Early Battery Depletion | 1 |
| | | Other | 6 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 197 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.3% | 93.3% | 84.6% | 73.1% | 60.7% | 50.4% | 44.5% | 42.5% | 41.9% | 41.6% | 41.2% |
| Effective Sample Size | 120513 | 108986 | 98339 | 88705 | 79974 | 72182 | 64968 | 56762 | 46858 | 36316 | 25803 | 16987 | 11135 | 7383 | 4221 | 1404 | 302 |

## SEDRL1 Sensia L DR

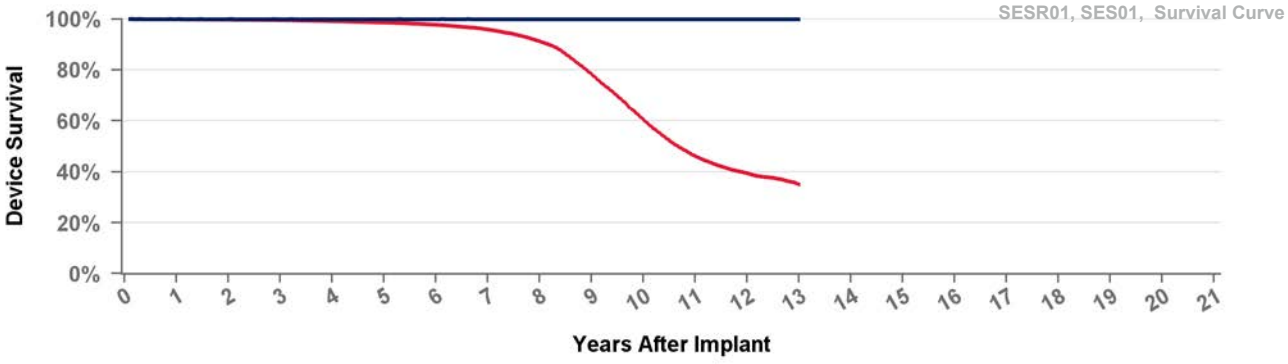
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 5 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 173 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% | 99.9% | 99.8% | 99.7% | 99.5% | 99.2% | 99.0% | 98.5% | 97.4% | 94.6% | 90.7% | 88.7% | 87.9% | 86.3% |
| Effective Sample Size | 119669 | 112688 | 106043 | 99521 | 92209 | 84483 | 77120 | 70307 | 62002 | 51808 | 40102 | 26523 | 13871 | 3554 | 129 |

## SES01 Sensia S

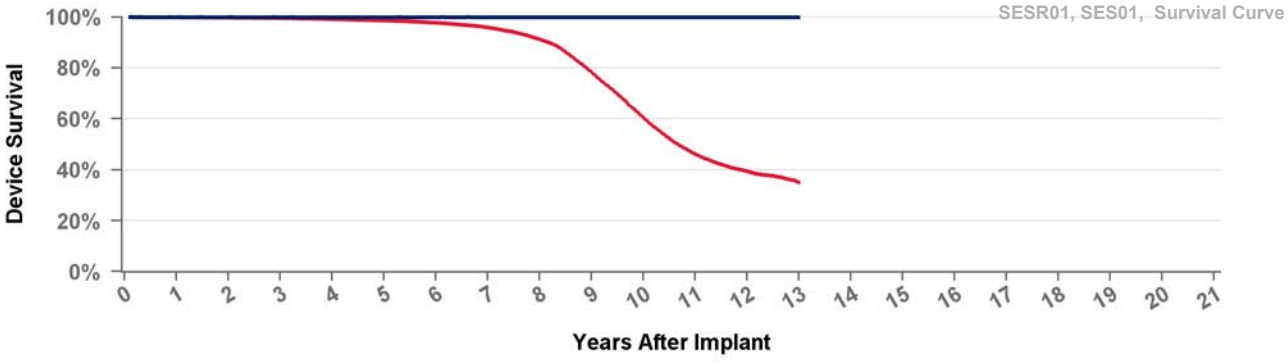
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 4 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.8% | 95.9% | 91.2% | 78.3% | 60.5% | 46.2% | 39.5% | 35.0% |
| Effective Sample Size | 85819 | 74448 | 64544 | 56005 | 48248 | 41092 | 34581 | 27809 | 20267 | 12747 | 6661 | 2943 | 295 |

## SESR01 Sensia SR

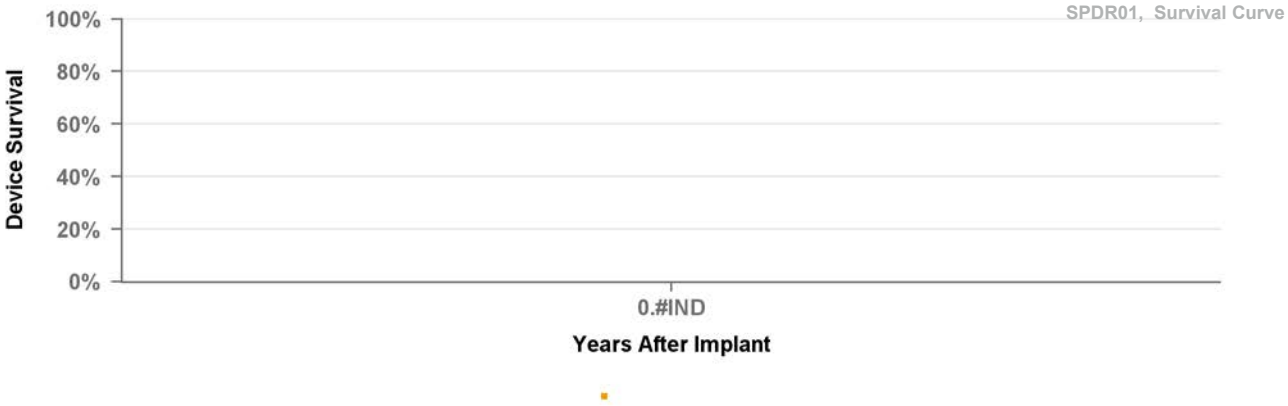
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **17** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **13** |
| **Registered USA Implants** | 117,371 | Electrical Component | 7 |
| **Estimated Active USA Implants** | 20,562 | Possible Early Battery Depletion | 4 |
| **Normal Battery Depletions** | 9,338 | 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 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.8% | 95.9% | 91.2% | 78.3% | 60.5% | 46.2% | 39.5% | 35.0% |
| Effective Sample Size | 85819 | 74448 | 64544 | 56005 | 48248 | 41092 | 34581 | 27809 | 20267 | 12747 | 6661 | 2943 | 295 |

## SPDR01 Sphera DR MRI

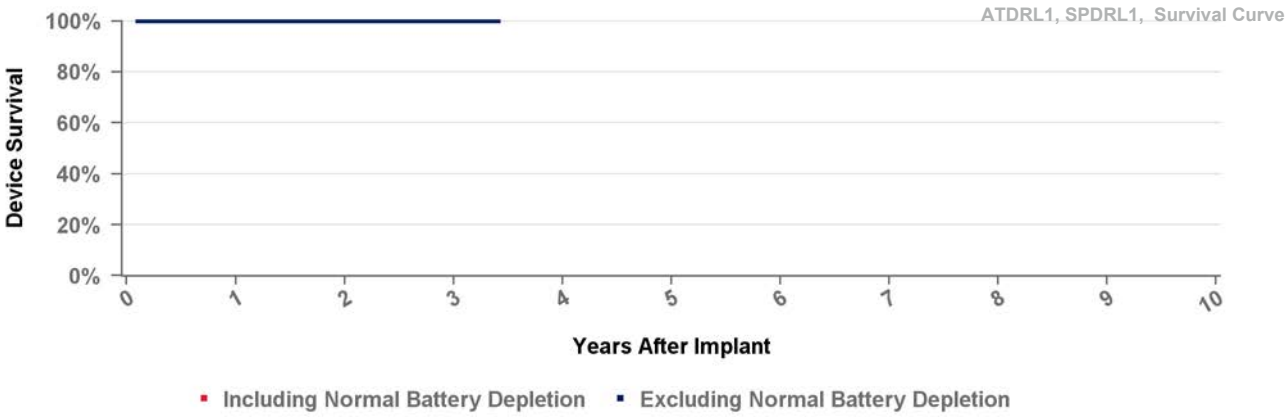
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




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

## SPDRL1 Sphera L DR MRI

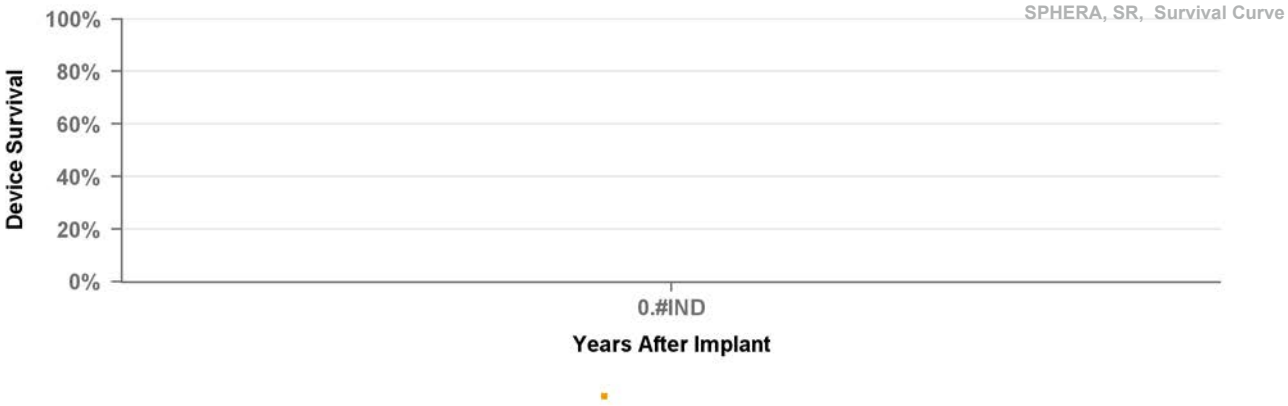
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal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




| Years | 1 | 2 | 3 | at 41 mo |
|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 100.0% | 100.0% |
| Effective Sample Size | 283 | 223 | 140 | 100 |

## SPSR01 Sphera SR MRI

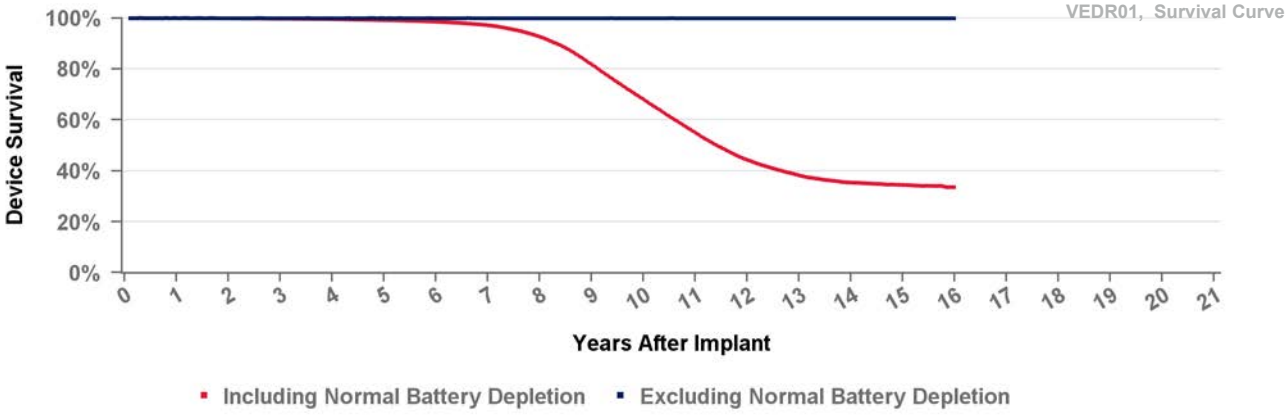
| | | | |
|---|---|---|---|
| **US Market Release** | 03Aug2017 | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 16Jun2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | 1 | **Therapy Function Compromised** | |
| **Normal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




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

## VEDR01 Versa DR

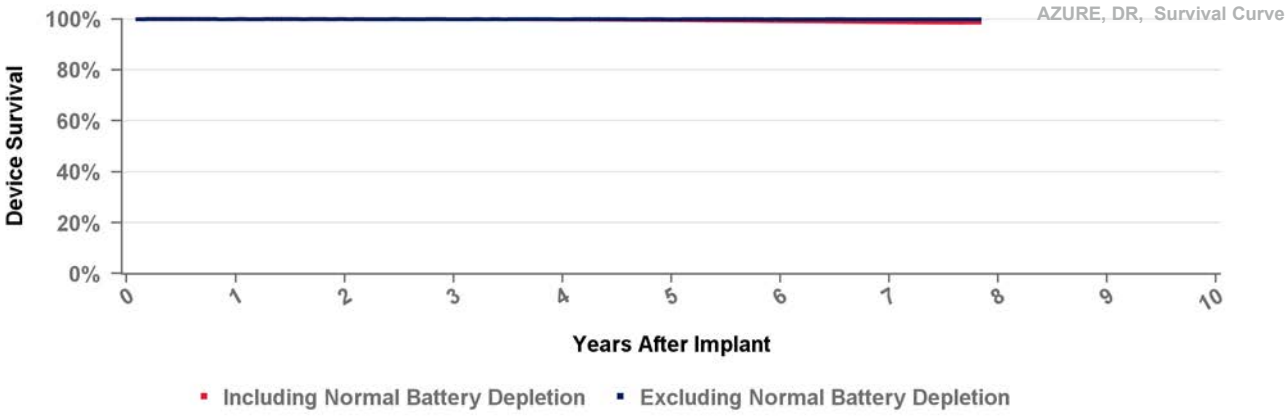
| | | | |
|---|---|---|---|
| **US Market Release** | 17Jul2006 | **Total Malfunctions (USA)** | **28** |
| **CE Approval Date** | 20Sep2005 | **Therapy Function Not Compromised** | **13** |
| **Registered USA Implants** | 118,958 | Electrical Component | 9 |
| **Estimated Active USA Implants** | 22,798 | Electrical Interconnect | 2 |
| **Normal Battery Depletions** | 15,354 | Possible Early Battery Depletion | 2 |
| | | **Therapy Function Compromised** | **15** |
| | | Electrical Component | 11 |
| | | Other | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 192 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 99.9% | 99.9% | 99.8% | 99.6% | 99.2% | 98.6% | 97.2% | 92.6% | 81.8% | 68.1% | 55.0% | 44.3% | 38.2% | 35.4% | 34.5% | 33.7% |
| Effective Sample Size | 98640 | 90151 | 82062 | 74679 | 67970 | 62039 | 55945 | 48007 | 36626 | 26273 | 17973 | 11414 | 7238 | 4326 | 2107 | 105 |

## W1DR01 Azure XT DR

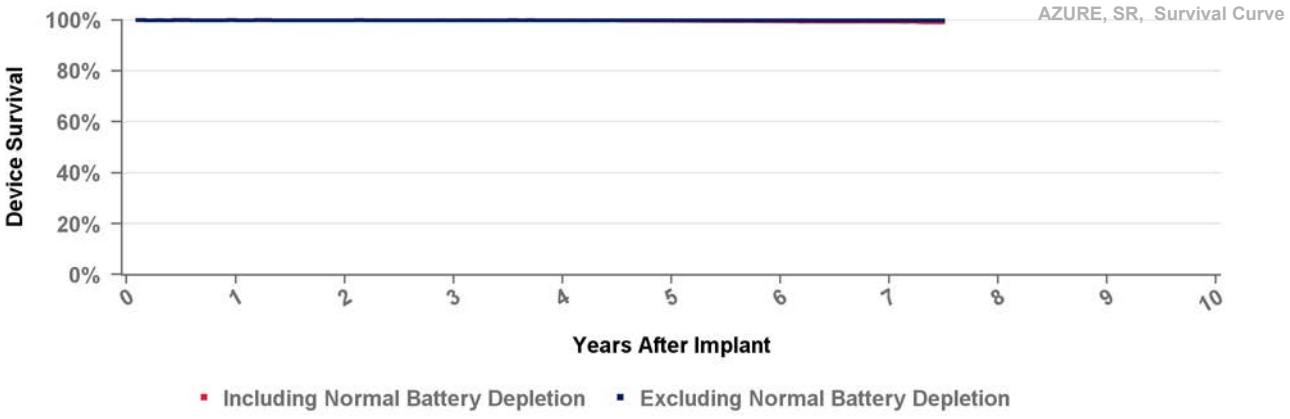
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **165** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **151** |
| **Registered USA Implants** | 878,312 | Battery | 4 |
| **Estimated Active USA Implants** | 788,377 | Electrical Component | 92 |
| **Normal Battery Depletions** | 1,130 | Possible Early Battery Depletion | 4 |
| | | Software/Firmware | 28 |
| | | Other | 23 |
| | | **Therapy Function Compromised** | **14** |
| | | Battery | 2 |
| | | Electrical Component | 12 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.6% | 99.2% | 98.8% | 98.5% |
| Effective Sample Size | 766662 | 603737 | 457784 | 332138 | 220192 | 129532 | 46915 | 725 |

## W1SR01 Azure XT SR

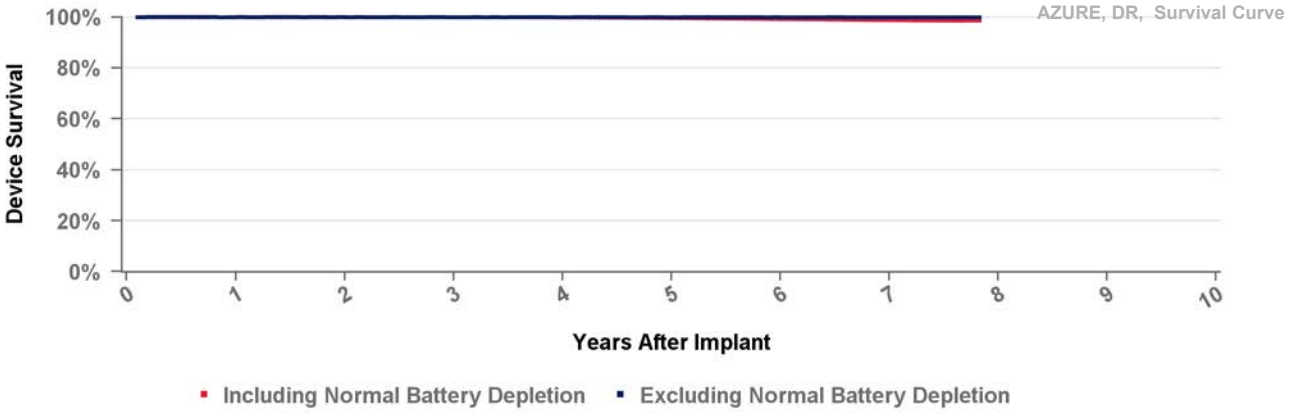
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **11** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **10** |
| **Registered USA Implants** | 67,106 | Battery | 1 |
| **Estimated Active USA Implants** | 55,586 | Electrical Component | 6 |
| **Normal Battery Depletions** | 49 | Software/Firmware | 1 |
| | | 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 | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% | 99.4% | 99.1% |
| Effective Sample Size | 63225 | 49810 | 38169 | 27775 | 18064 | 9967 | 2919 | 336 |

## W2DR01 Azure XT DR

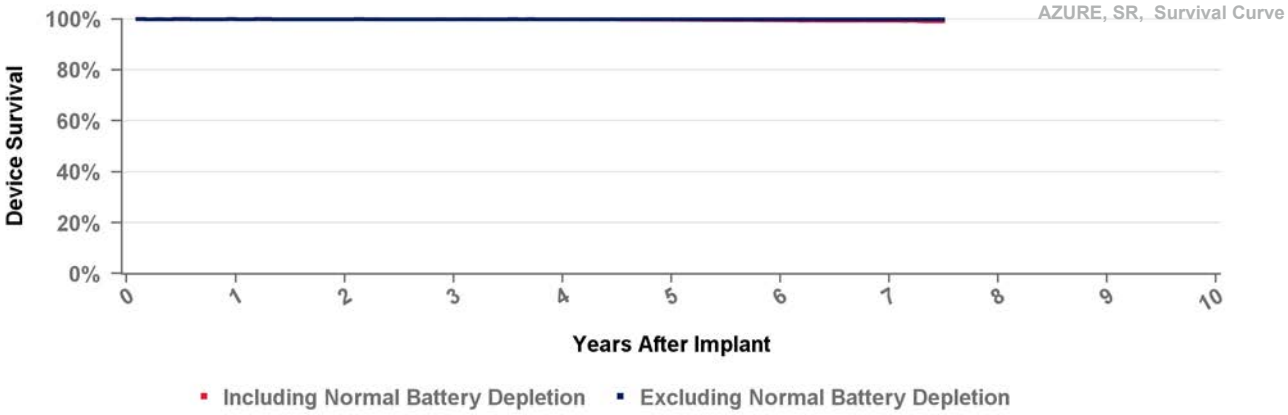
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 3 | | |
| **Estimated Active USA Implants** | 2 | **Therapy Function Compromised** | |
| **Normal Battery Depletions** | | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.6% | 99.2% | 98.8% | 98.5% |
| Effective Sample Size | 766662 | 603737 | 457784 | 332138 | 220192 | 129532 | 46915 | 725 |

## W2SR01 Azure XT SR

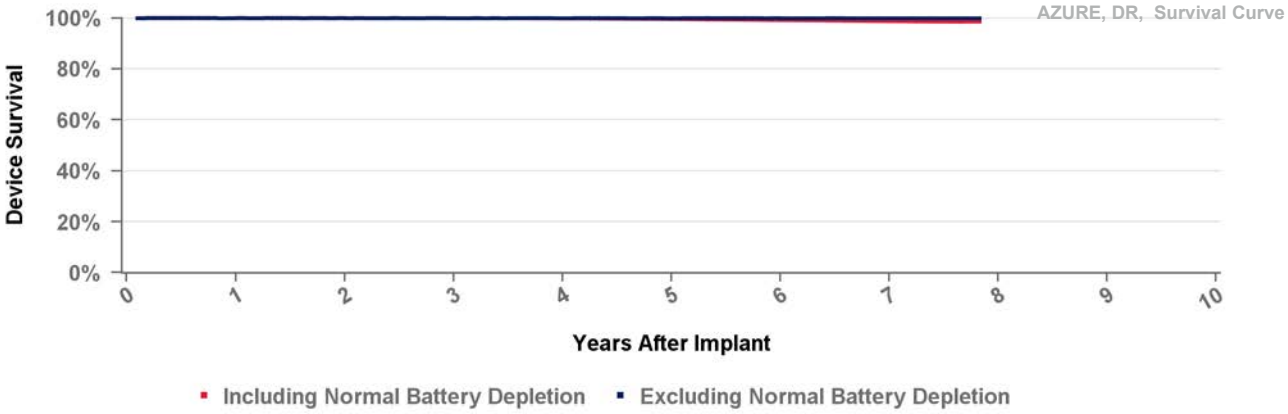
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% | 99.4% | 99.1% |
| Effective Sample Size | 63225 | 49810 | 38169 | 27775 | 18064 | 9967 | 2919 | 336 |

## W3DR01 Azure S DR

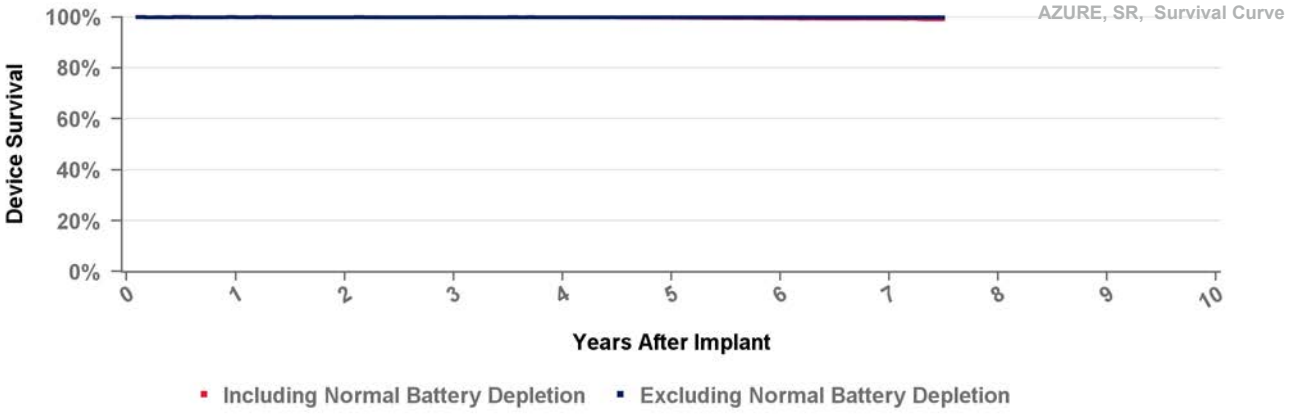
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **15** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **14** |
| **Registered USA Implants** | 70,168 | Electrical Component | 10 |
| **Estimated Active USA Implants** | 61,219 | Possible Early Battery Depletion | 2 |
| **Normal Battery Depletions** | 209 | Software/Firmware | 2 |
| | | **Therapy Function Compromised** | **1** |
| | | Electrical Component | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 mo |
|---|---|---|---|---|---|---|---|---|
| Excluding NBD | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |
| Including NBD | 100.0% | 100.0% | 99.9% | 99.8% | 99.6% | 99.2% | 98.8% | 98.5% |
| Effective Sample Size | 766662 | 603737 | 457784 | 332138 | 220192 | 129532 | 46915 | 725 |

## W3SR01 Azure S SR

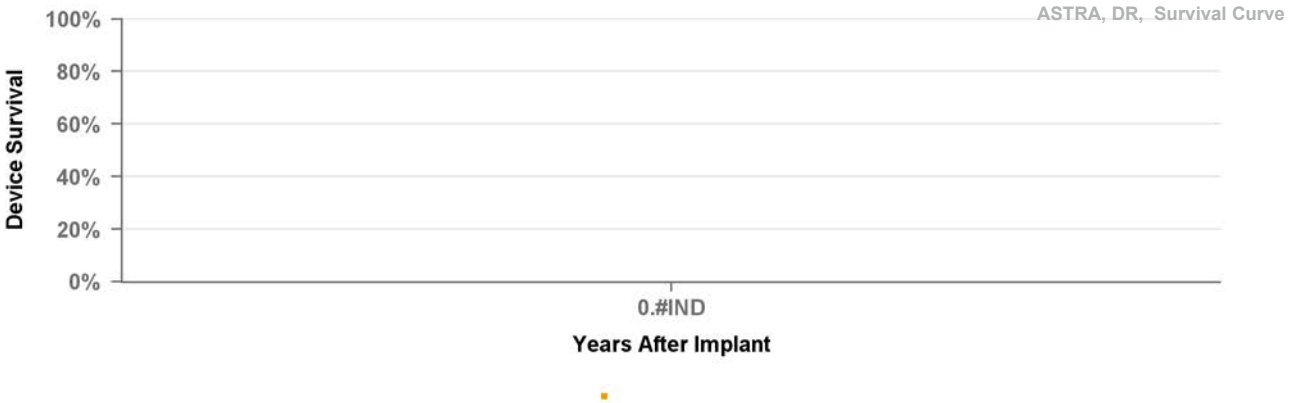
| | | | |
|---|---|---|---|
| **US Market Release** | 16Aug2017 | **Total Malfunctions (USA)** | **1** |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | **1** |
| **Registered USA Implants** | 14,332 | Electrical Component | 1 |
| **Estimated Active USA Implants** | 11,690 | **Therapy Function Compromised** | **0** |
| **Normal Battery Depletions** | 8 | | |




| 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 | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.5% | 99.4% | 99.1% |
| Effective Sample Size | 63225 | 49810 | 38169 | 27775 | 18064 | 9967 | 2919 | 336 |

## X2DR01 Astra XT DR MRI SureScan

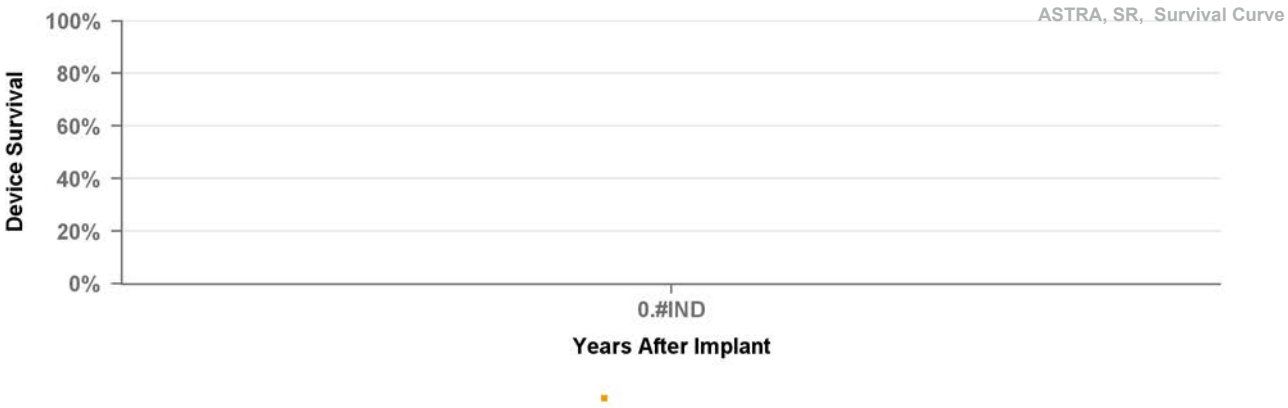
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | 1 | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




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

## X2SR01 Astra XT SR MRI SureScan

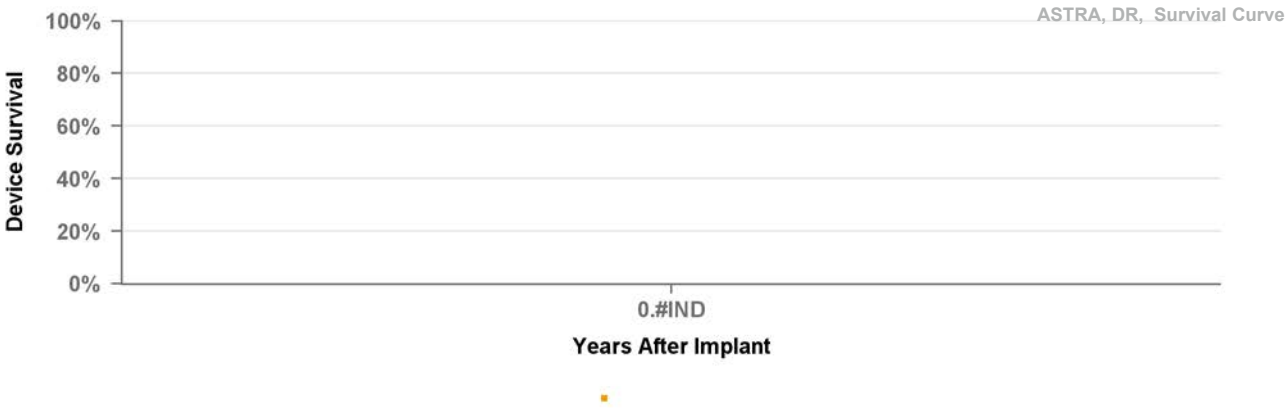
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




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

## X3DR01 Astra S DR

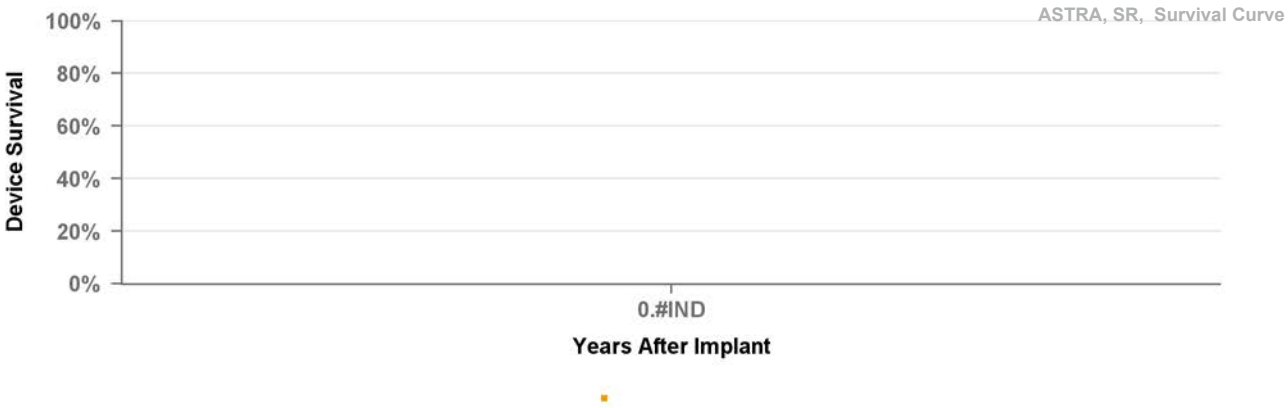
| | | | |
|---|---|---|---|
| **US Market Release** | | **Total Malfunctions (USA)** | |
| **CE Approval Date** | 02Mar2017 | **Therapy Function Not Compromised** | |
| **Registered USA Implants** | | | |
| **Estimated Active USA Implants** | | **Therapy Function Compromised** | |
| **Normal Battery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




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

## X3SR01 Astra S SR

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




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

# Method for Estimating Transcatheter Pacing Performance

**Micra TPS Performance Analysis**

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

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

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

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

**The CareLink™ Network**

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

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

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

### Definition of Qualifying Complication or Malfunction

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

## Methods for Estimating Transcatheter Pacing Performance continued

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

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

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

### Normal Battery Depletion

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

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

### Statistical and Data Analysis Methods

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

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

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

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

## Methods for Estimating Transcatheter Pacing Performance continued

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

### Definition of Analysis Dataset

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

**US Reports of Acute Observations**

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

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

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

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

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

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

**US Reports of the Day of Implant Observations**

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

## Methods for Estimating Transcatheter Pacing Performance continued

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

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

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

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

## MC1AVR1 Micra AV

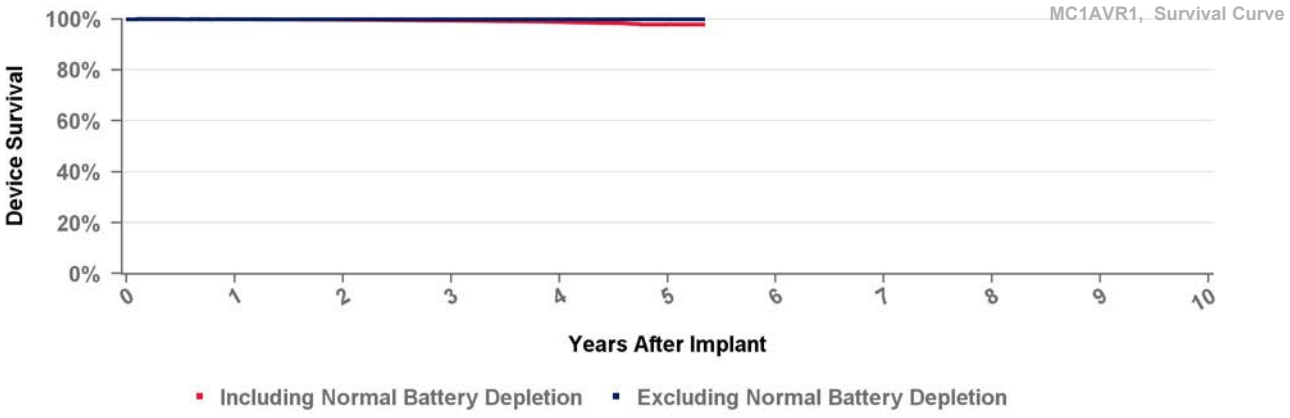
| | |
|---|---|
| **US Market Release** | 15Jan2020 |
| **CE Approval Date** | 31Mar2020 |
| **Registered USA Implants** | 52,263 |

### CareLink Population

| | |
|---|---|
| Enrolled | 35,576 |
| Active | 25,088 |
| Cumulative Follow-Up Months | 1,008,200 |
| Normal Battery Depletion | 160 |

### CareLink Qualifying Malfunctions/Complications

| | |
|---|---|
| Dislodgements | 3 |
| Elevated Pacing Threshold | 11 |
| Failure To Capture | 7 |
| Premature Battery Depletion | 8 |
| Tine Fracture | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | at 64 mo |
|---|---|---|---|---|---|---|
| Excluding NBD | 99.9% | 99.9% | 99.9% | 99.9% | 99.8% | 99.8% |
| Including NBD | 99.9% | 99.7% | 99.4% | 98.9% | 98.0% | 97.8% |
| Effective Sample Size | 30242 | 21501 | 11762 | 4902 | 1011 | 289 |

### *Acute Observations N = 52,263

| | |
|---|---|
| Cardiac Perforation | 13 |
| Dislodgement | 30 |
| Elevated Pacing Threshold | 90 |
| Failure to Capture | 47 |
| Failure To Sense | 122 |

### *Day of Implant Observations N = 52,263

| | |
|---|---|
| Cardiac Perforation | 272 |
| Dislodgement | 88 |
| Elevated Pacing Threshold | 144 |
| Failure to Capture | 84 |
| Failure to Sense | 39 |

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

[1]El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
[2]Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089
*Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

## MC1VR01 Micra VR

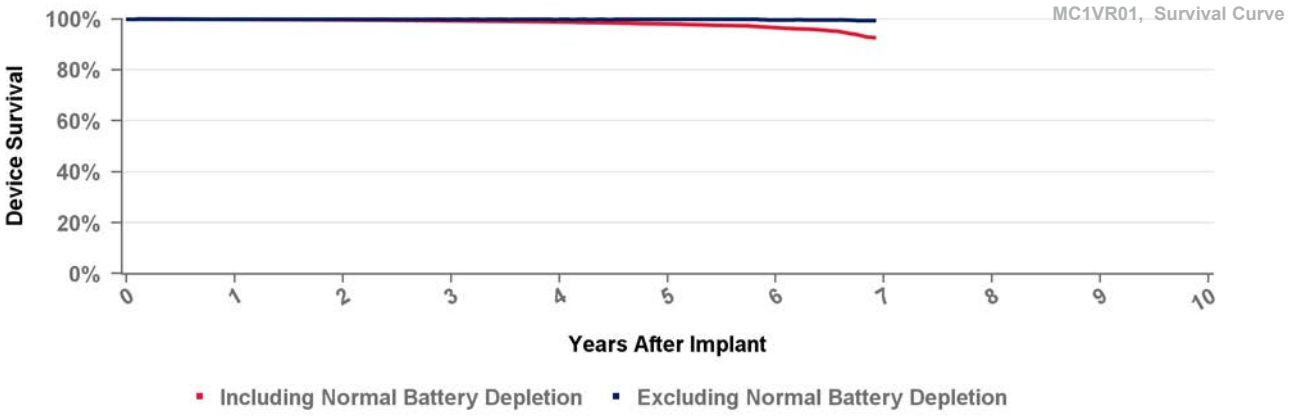
| | |
|---|---|
| **US Market Release** | 06Apr2016 |
| **CE Approval Date** | 14Apr2015 |
| **Registered USA Implants** | 72,365 |

### CareLink Population

| | |
|---|---|
| Enrolled | 47,513 |
| Active | 27,338 |
| Cumulative Follow-Up Months | 1,733,995 |
| Normal Battery Depletion | 440 |

### CareLink Qualifying Malfunctions/Complications

| | |
|---|---|
| Cardiac Perforation | 8 |
| Dislodgements | 1 |
| Elevated Pacing Threshold | 45 |
| Failure To Capture | 7 |
| Premature Battery Depletion | 17 |
| Tine Fracture | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 83 mo |
|---|---|---|---|---|---|---|---|
| Excluding NBD | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.7% | 99.5% |
| Including NBD | 99.9% | 99.7% | 99.3% | 98.9% | 98.1% | 96.6% | 92.7% |
| Effective Sample Size | 41895 | 32933 | 23123 | 14830 | 8282 | 3502 | 407 |

### *Acute Observations N = 72,365

| | |
|---|---|
| Cardiac Perforation | 21 |
| Dislodgement | 22 |
| Elevated Pacing Threshold | 167 |
| Failure to Capture | 83 |
| Failure To Sense | 19 |

### *Day of Implant Observations N = 72,365

| | |
|---|---|
| Cardiac Perforation | 291 |
| Dislodgement | 179 |
| Elevated Pacing Threshold | 273 |
| Failure to Capture | 136 |
| Failure to Sense | 72 |

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

[1]El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
[2]Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089
*Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

## MC2AVR1 Micra AV2

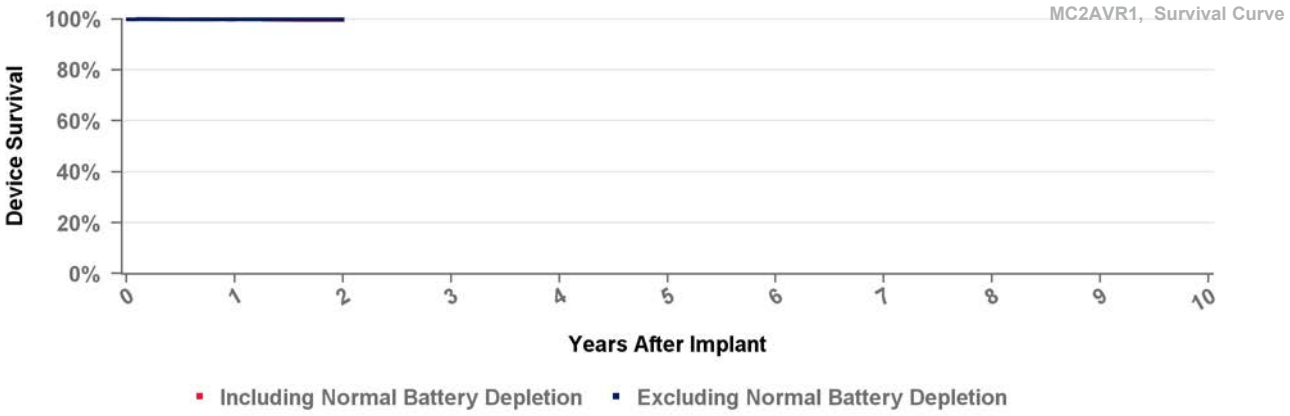
| | |
|---|---|
| **US Market Release** | 20Apr2023 |
| **CE Approval Date** | 04Jan2024 |
| **Registered USA Implants** | 43,232 |

### CareLink Population

| | |
|---|---|
| Enrolled | 25,533 |
| Active | 21,820 |
| Cumulative Follow-Up Months | 219,855 |
| Normal Battery Depletion | 22 |

### CareLink Qualifying Malfunctions/Complications

| | |
|---|---|
| Elevated Pacing Threshold | 13 |
| Failure To Capture | 5 |




| Years | 1 | at 24 mo |
|---|---|---|
| Excluding NBD | 99.9% | 99.9% |
| Including NBD | 99.8% | 99.7% |
| Effective Sample Size | 8377 | 506 |

### *Acute Observations N = 43,232

| | |
|---|---|
| Cardiac Perforation | 4 |
| Dislodgement | 12 |
| Elevated Pacing Threshold | 83 |
| Failure to Capture | 41 |
| Failure To Sense | 41 |

### *Day of Implant Observations N = 43,232

| | |
|---|---|
| Cardiac Perforation | 88 |
| Dislodgement | 66 |
| Elevated Pacing Threshold | 75 |
| Failure to Capture | 52 |
| Failure to Sense | 16 |

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

[1]El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
[2]Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089
*Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

## MC2VR01 Micra VR2

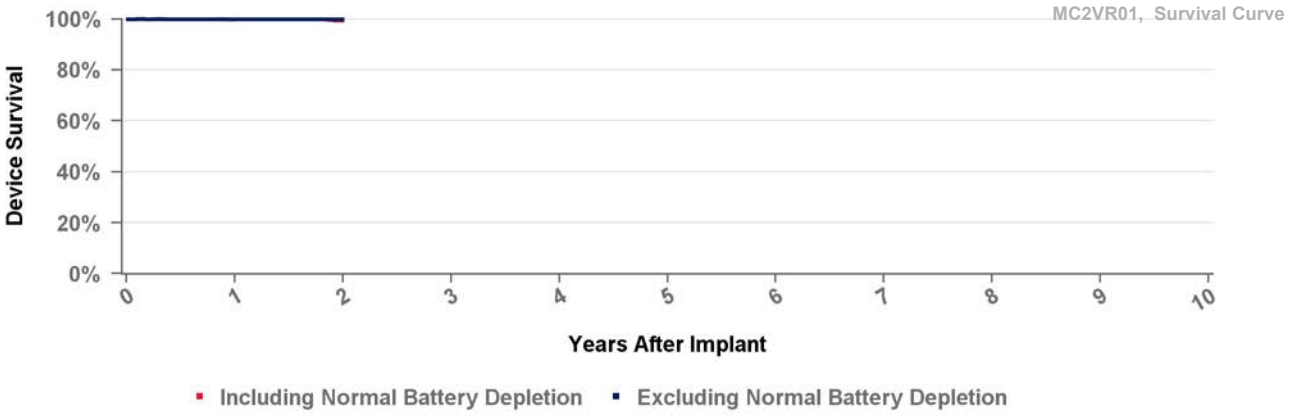
| | |
|---|---|
| **US Market Release** | 20Apr2023 |
| **CE Approval Date** | 04Jan2024 |
| **Registered USA Implants** | 15,040 |

### CareLink Population

| | |
|---|---|
| Enrolled | 8,465 |
| Active | 7,785 |
| Cumulative Follow-Up Months | 81,031 |
| Normal Battery Depletion | 7 |

### CareLink Qualifying Malfunctions/Complications

| | |
|---|---|
| Dislodgements | 1 |
| Elevated Pacing Threshold | 1 |
| Failure To Capture | 1 |
| Tine Fracture | 1 |




| Years | 1 | at 24 mo |
|---|---|---|
| Excluding NBD | 99.9% | 99.9% |
| Including NBD | 99.8% | 99.5% |
| Effective Sample Size | 3157 | 226 |

### *Acute Observations N = 15,040

| | |
|---|---|
| Cardiac Perforation | 1 |
| Dislodgement | 12 |
| Elevated Pacing Threshold | 34 |
| Failure to Capture | 22 |
| Failure To Sense | 7 |

### *Day of Implant Observations N = 15,040

| | |
|---|---|
| Cardiac Perforation | 15 |
| Dislodgement | 31 |
| Elevated Pacing Threshold | 38 |
| Failure to Capture | 41 |
| Failure to Sense | 5 |

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

[1]El-Chami et al. Heart Rhythm 2018 15(12): 1800-1807.
[2]Piccini et al. Heart Rhythm 2020 17(5 Supplement) D-PO02-089
*Data in these tables is sourced direct from the MDT complaint handling database summarizing observations reported to Medtronic relative to the registered US implant population.

# Method for Estimating Lead Performance

**Medtronic Cardiac Rhythm Management (CRM) has tracked lead survival for over 42 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 | 346,261 |
| Estimated Active USA Implants | 305,755 |
| Fixation Type | Fixed Screw |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 49 |
| Insulation Breach | 140 |
| Crimp/Weld/Bond | 0 |
| Other | 28 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 113 |
| Conductor Fracture | 6 |
| Extra Cardiac Stimulation | 13 |
| Failure to Capture | 839 |
| Failure to Sense | 136 |
| Impedance Out of Range | 95 |
| Insulation Breach | 2 |
| Lead Dislodgement | 1,102 |
| Oversensing | 173 |
| Unspecified Clinical Failure | 2 |

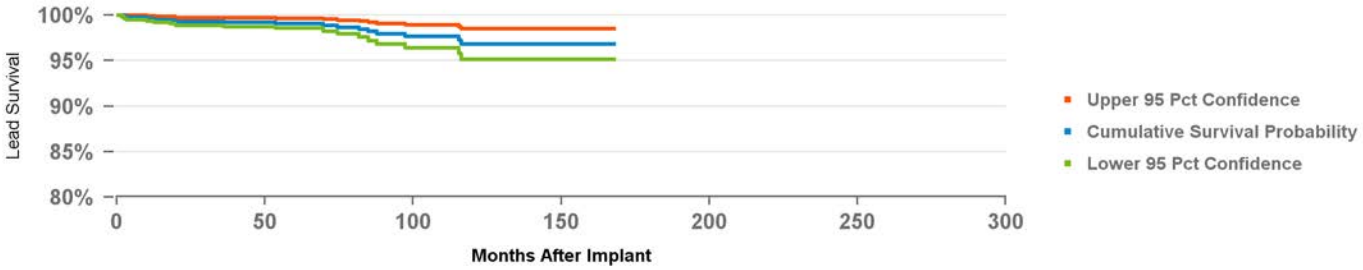
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,846 |
| Cumulative Months of Follow-Up | 101,289 |
| Number of Leads Active in Study | 592 |

### Qualifying Complications 21

| | | | |
|---|---|---|---|
| Cardiac Perforation | 1 | Impedance Out of Range | 2 |
| Conductor Fracture | 3 | Insulation (not further defined) | 1 |
| Extra Cardiac Stimulation | 1 | Lead Dislodgement | 5 |
| Failure to Capture | 4 | Oversensing | 1 |
| Failure to Sense | 3 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.3% | 99.3% | 99.2% | 99.1% | 98.9% | 98.4% | 97.9% | 97.6% | 96.8% | 96.8% | 96.8% | 96.8% | 96.8% |
| # | 1,591 | 1,297 | 1,023 | 797 | 630 | 503 | 400 | 338 | 277 | 223 | 198 | 158 | 98 | 58 |

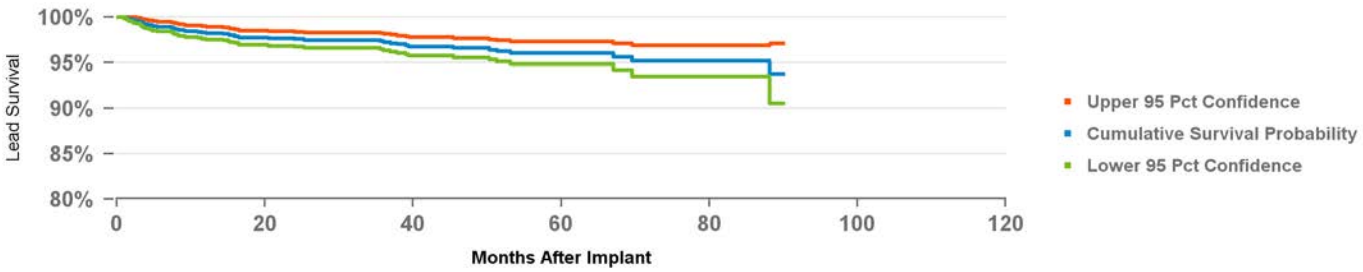
## His Bundle Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,504 |
| Cumulative Months of Follow-Up | 61,964 |
| Number of Leads Active in Study | 774 |

### Qualifying Complications 48

| | | | |
|---|---|---|---|
| Extra Cardiac Stimulation | 1 | Lead Dislodgement | 6 |
| Failure to Capture | 34 | Oversensing | 1 |
| Failure to Sense | 3 | Other | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 90 mo |
|---|---|---|---|---|---|---|---|---|
| % | 98.3% | 97.5% | 97.2% | 96.6% | 96.0% | 95.2% | 95.2% | 93.8% |
| # | 1,299 | 1,066 | 851 | 600 | 371 | 171 | 82 | 58 |

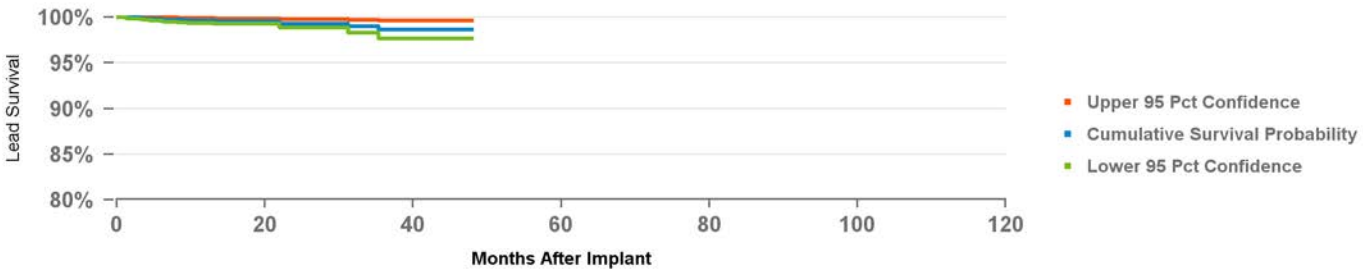
## Left Bundle Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,206 |
| Cumulative Months of Follow-Up | 43,475 |
| Number of Leads Active in Study | 1,734 |

### Qualifying Complications 13

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Lead Dislodgement | 5 |
| Failure to Capture | 7 | | |




| Years | 1 | 2 | 3 | at 48 mo |
|---|---|---|---|---|
| % | 99.6% | 99.3% | 98.7% | 98.7% |
| # | 1,726 | 661 | 268 | 82 |

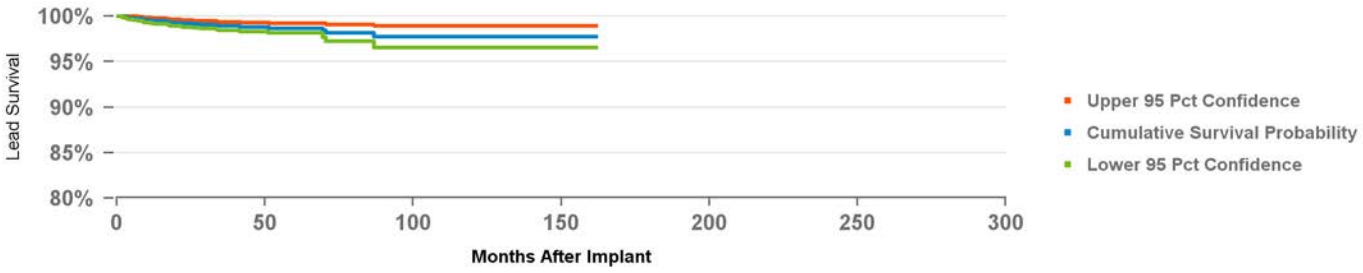
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,601 |
| Cumulative Months of Follow-Up | 111,318 |
| Number of Leads Active in Study | 1,374 |

### Qualifying Complications 27

| | | | |
|---|---|---|---|
| Failure to Capture | 14 | Impedance Out of Range | 2 |
| | | Lead Dislodgement | 9 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.2% | 98.9% | 98.8% | 98.7% | 98.1% | 98.1% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% |
| # | 2,275 | 1,901 | 1,261 | 788 | 533 | 341 | 258 | 208 | 166 | 125 | 113 | 92 | 59 | 50 |

# 4074 CapSure Sense

| | |
|---|---|
| US Market Release | 23Jun2002 |
| CE Approval | 01Feb2002 |
| Registered USA Implants | 161,779 |
| Estimated Active USA Implants | 79,200 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 17 |
| Insulation Breach | 65 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 39 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 4 |
| Failure to Capture | 207 |
| Failure to Sense | 19 |
| Impedance Out of Range | 19 |
| Lead Dislodgement | 220 |
| Oversensing | 9 |

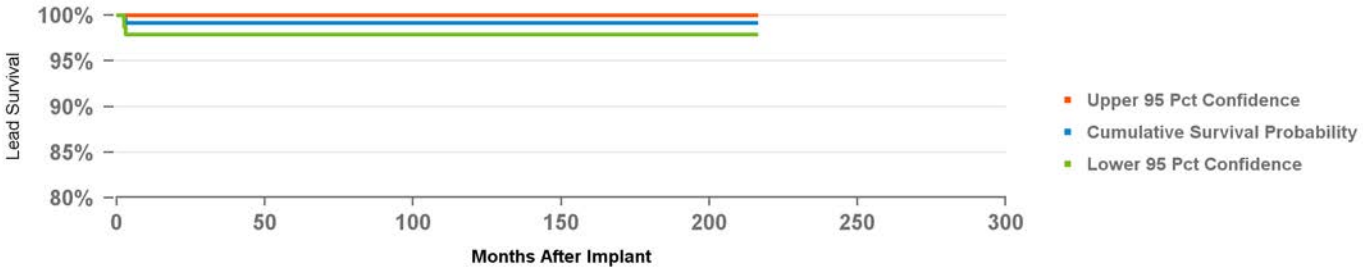
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 227 |
| Cumulative Months of Follow-Up | 30,343 |
| Number of Leads Active in Study | 38 |

### Qualifying Complications 2

| | | | |
|---|---|---|---|
| Failure to Sense | 1 | Lead Dislodgement | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 216 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% | 99.1% |
| # | 214 | 205 | 198 | 183 | 167 | 158 | 148 | 136 | 126 | 117 | 110 | 107 | 99 | 96 | 90 | 78 | 71 | 50 |

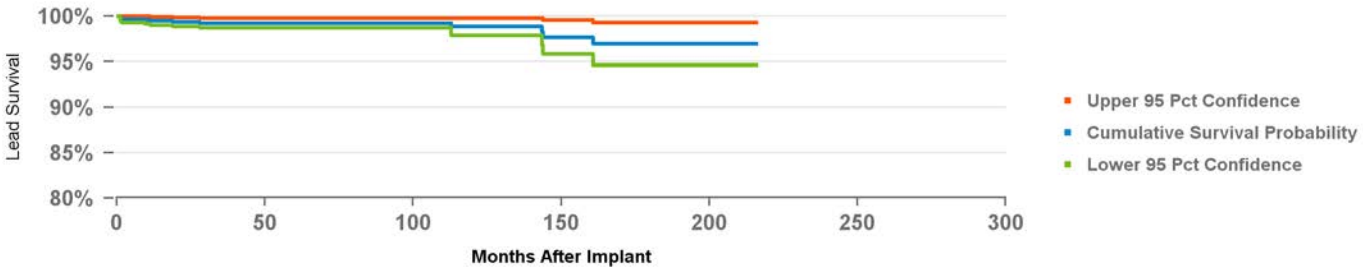
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,192 |
| Cumulative Months of Follow-Up | 83,011 |
| Number of Leads Active in Study | 83 |

### 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 | 17 | at 216 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 99.2% | 98.8% | 98.8% | 97.7% | 97.7% | 96.9% | 96.9% | 96.9% | 96.9% | 96.9% |
| # | 1,031 | 881 | 742 | 640 | 499 | 411 | 346 | 300 | 263 | 223 | 195 | 166 | 132 | 125 | 112 | 92 | 76 | 54 |

# 4076 CapSureFix Novus

| | |
|---|---|
| US Market Release | 25Feb2004 |
| CE Approval | 14Jun2004 |
| Registered USA Implants | 888,361 |
| Estimated Active USA Implants | 531,305 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 138 |
| Insulation Breach | 238 |
| Crimp/Weld/Bond | 2 |
| Other | 24 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 298 |
| Conductor Fracture | 11 |
| Extra Cardiac Stimulation | 30 |
| Failure to Capture | 503 |
| Failure to Sense | 345 |
| Impedance Out of Range | 96 |
| Insulation Breach | 2 |
| Lead Dislodgement | 1,067 |
| Oversensing | 198 |
| Unspecified Clinical Failure | 10 |

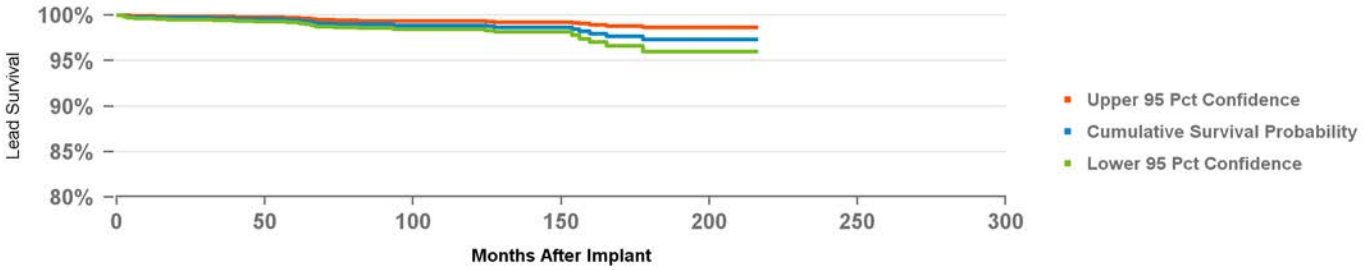
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 5,123 |
| Cumulative Months of Follow-Up | 312,607 |
| Number of Leads Active in Study | 1,461 |

### Qualifying Complications 39

| | | | |
|---|---|---|---|
| Cardiac Perforation | 2 | Insulation (not further defined) | 3 |
| Conductor Fracture | 3 | Lead Dislodgement | 14 |
| Failure to Capture | 9 | Oversensing | 2 |
| Failure to Sense | 3 | Other | 2 |
| | | Unspecified Clinical Failure | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | at 216 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.7% | 99.6% | 99.5% | 99.4% | 99.1% | 99.0% | 98.9% | 98.9% | 98.9% | 98.7% | 98.7% | 98.4% | 97.7% | 97.3% | 97.3% | 97.3% | 97.3% |
| # | 4,013 | 3,332 | 2,825 | 2,449 | 2,075 | 1,752 | 1,500 | 1,313 | 1,137 | 964 | 769 | 567 | 420 | 328 | 230 | 137 | 99 | 54 |

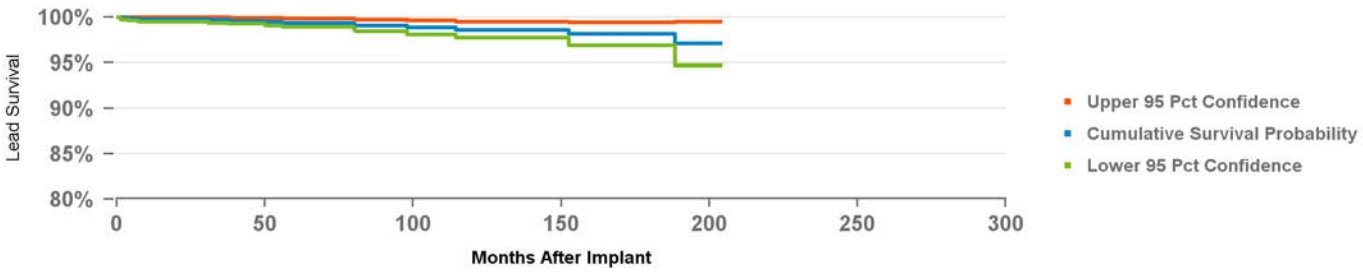
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,778 |
| Cumulative Months of Follow-Up | 124,770 |
| Number of Leads Active in Study | 195 |

### Qualifying Complications 14

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | at 204 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.7% | 99.7% | 99.6% | 99.4% | 99.4% | 99.0% | 99.0% | 98.8% | 98.6% | 98.6% | 98.6% | 98.1% | 98.1% | 98.1% | 97.1% | 97.1% |
| # | 1,462 | 1,313 | 1,169 | 1,010 | 817 | 706 | 576 | 495 | 435 | 374 | 316 | 245 | 206 | 173 | 134 | 84 | 60 |

# 4092 CapSure SP Novus

| | |
|---|---|
| US Market Release | 17Sep1998 |
| CE Approval | 15Apr1998 |
| Registered USA Implants | 186,245 |
| Estimated Active USA Implants | 35,752 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

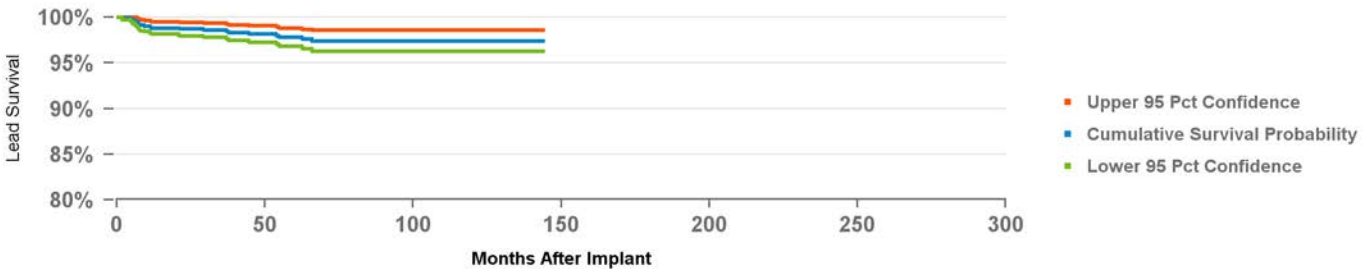
| | |
|---|---|
| Cardiac Perforation | 4 |
| Conductor Fracture | 4 |
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 35 |
| Impedance Out of Range | 2 |
| Insulation Breach | 1 |
| Lead Dislodgement | 35 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,202 |
| Cumulative Months of Follow-Up | 70,387 |
| Number of Leads Active in Study | 3 |

## Qualifying Complications 21

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 144 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.8% | 98.7% | 98.5% | 98.1% | 97.8% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% | 97.4% |
| # | 921 | 822 | 734 | 629 | 515 | 402 | 333 | 279 | 239 | 158 | 94 | 57 |

# 4574 CapSure Sense

| | |
|---|---|
| US Market Release | 23Jun2002 |
| CE Approval | 01Feb2002 |
| Registered USA Implants | 131,655 |
| Estimated Active USA Implants | 77,913 |
| Fixation Type | J-shape, tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

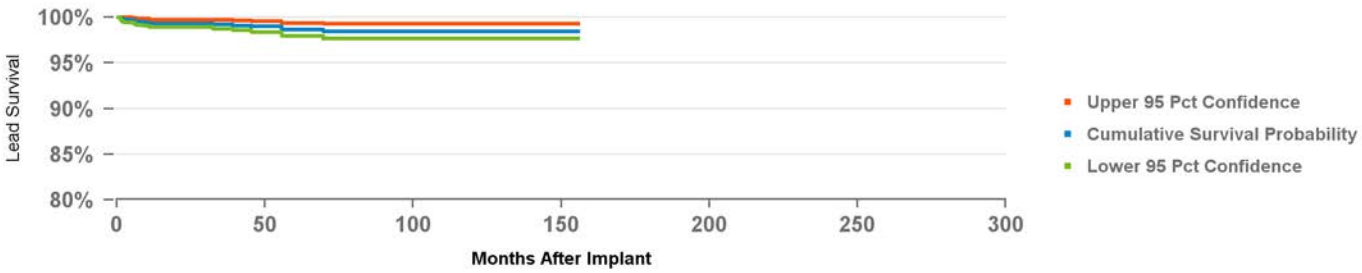
| | |
|---|---|
| Cardiac Perforation | 6 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 228 |
| Failure to Sense | 103 |
| Impedance Out of Range | 14 |
| Lead Dislodgement | 313 |
| Oversensing | 21 |
| Unspecified Clinical Failure | 4 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,782 |
| Cumulative Months of Follow-Up | 92,195 |
| Number of Leads Active in Study | 508 |

## Qualifying Complications 17

| | | | |
|---|---|---|---|
| Conductor Fracture | 2 | Lead Dislodgement | 7 |
| Failure to Capture | 8 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.3% | 99.3% | 99.2% | 99.0% | 98.6% | 98.4% | 98.4% | 98.4% | 98.4% | 98.4% | 98.4% | 98.4% | 98.4% |
| # | 1,437 | 1,140 | 919 | 716 | 562 | 474 | 399 | 338 | 271 | 201 | 146 | 102 | 61 |

# 4592 CapSure SP Novus

| | |
|---|---|
| US Market Release | 05Oct1998 |
| CE Approval | 15Apr1998 |
| Registered USA Implants | 89,802 |
| Estimated Active USA Implants | 19,517 |
| Fixation Type | J-shape, tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

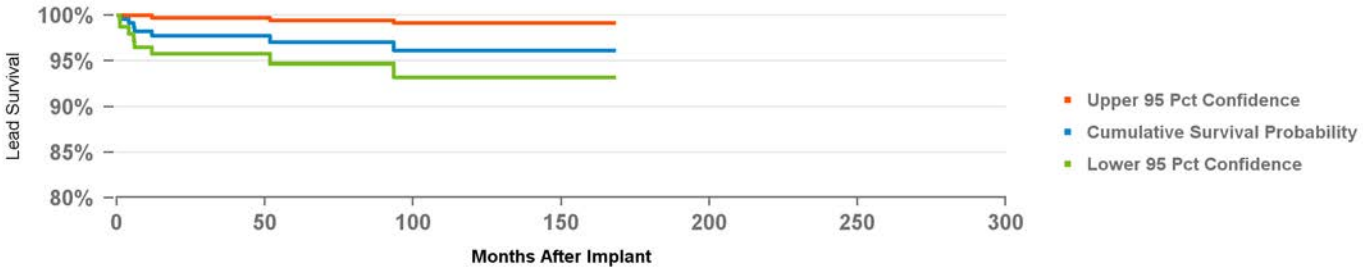
| | |
|---|---|
| Failure to Capture | 10 |
| Failure to Sense | 2 |
| Insulation Breach | 1 |
| Lead Dislodgement | 37 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 369 |
| Cumulative Months of Follow-Up | 23,344 |
| Number of Leads Active in Study | 21 |

## Qualifying Complications 9

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 97.7% | 97.7% | 97.7% | 97.7% | 97.0% | 97.0% | 97.0% | 96.1% | 96.1% | 96.1% | 96.1% | 96.1% | 96.1% | 96.1% |
| # | 204 | 182 | 167 | 158 | 134 | 126 | 110 | 106 | 99 | 89 | 82 | 78 | 60 | 52 |

# 5054 CapSure Z Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 05Jun1997 |
| Registered USA Implants | 100,060 |
| Estimated Active USA Implants | 18,103 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 16 |
| Insulation Breach | 48 |
| Crimp/Weld/Bond | 1 |
| Other | 0 |

### US Acute Lead Observations

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

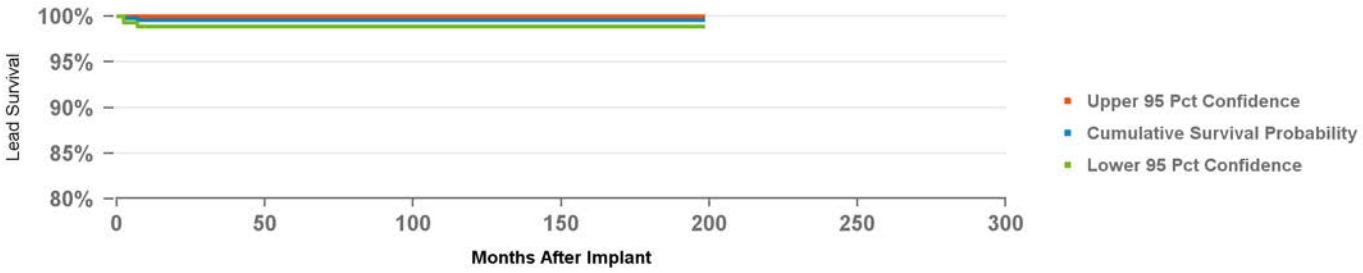
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 425 |
| Cumulative Months of Follow-Up | 42,516 |
| Number of Leads Active in Study | 1 |

### Qualifying Complications 3

| | | | |
|---|---|---|---|
| Failure to Capture | 2 | Lead Dislodgement | 1 |




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

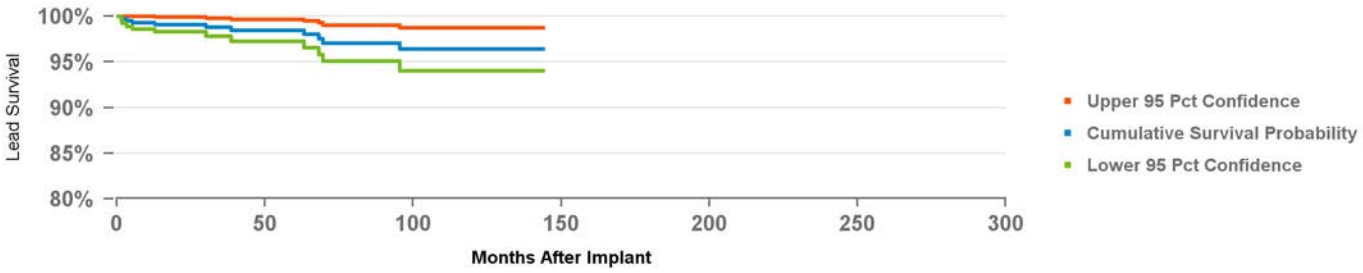
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 992 |
| Cumulative Months of Follow-Up | 35,958 |
| Number of Leads Active in Study | 5 |

### 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% |
| # | 473 | 390 | 303 | 263 | 229 | 191 | 166 | 143 | 113 | 94 | 73 | 55 |

# 5076 CapSureFix Novus

| | |
|---|---|
| US Market Release | 31Aug2000 |
| CE Approval | 12Aug1999 |
| Registered USA Implants | 3,588,001 |
| Estimated Active USA Implants | 2,075,632 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1,687 |
| Insulation Breach | 1,756 |
| Crimp/Weld/Bond | 4 |
| Other | 208 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 1,894 |
| Conductor Fracture | 41 |
| Extra Cardiac Stimulation | 119 |
| Failure to Capture | 3,083 |
| Failure to Sense | 1,917 |
| Impedance Out of Range | 576 |
| Insulation Breach | 17 |
| Lead Dislodgement | 6,006 |
| Oversensing | 1,112 |
| Unspecified Clinical Failure | 26 |

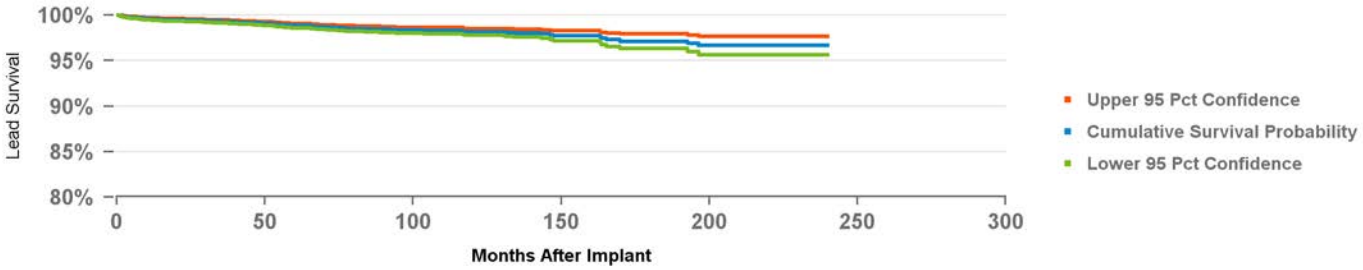
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 14,209 |
| Cumulative Months of Follow-Up | 735,050 |
| Number of Leads Active in Study | 4,549 |

### Qualifying Complications 136

| | | | |
|---|---|---|---|
| Cardiac Perforation | 2 | Impedance Out of Range | 13 |
| Conductor Fracture | 16 | Insulation (not further defined) | 3 |
| Extra Cardiac Stimulation | 3 | Lead Dislodgement | 51 |
| Failure to Capture | 21 | Oversensing | 4 |
| Failure to Sense | 13 | Other | 10 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | at 240 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.4% | 99.3% | 99.1% | 98.8% | 98.6% | 98.5% | 98.3% | 98.3% | 98.1% | 98.1% | 97.9% | 97.7% | 97.3% | 97.1% | 97.1% | 96.6% | 96.6% | 96.6% | 96.6% |
| # | 10,552 | 8,395 | 6,854 | 5,660 | 4,768 | 3,949 | 3,314 | 2,760 | 2,167 | 1,716 | 1,396 | 1,061 | 797 | 626 | 508 | 416 | 331 | 254 | 167 | 87 |

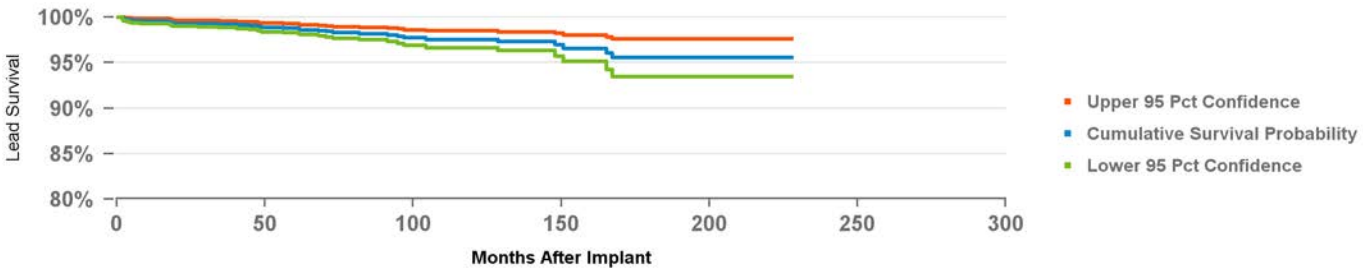
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,434 |
| Cumulative Months of Follow-Up | 177,514 |
| Number of Leads Active in Study | 440 |

### Qualifying Complications 41

| | | | |
|---|---|---|---|
| Cardiac Perforation | 1 | Impedance Out of Range | 6 |
| Conductor Fracture | 10 | Insulation (not further defined) | 1 |
| Failure to Capture | 13 | Lead Dislodgement | 5 |
| Failure to Sense | 1 | Oversensing | 2 |
| | | Other | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | at 228 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 98.9% | 98.8% | 98.4% | 98.2% | 97.9% | 97.5% | 97.5% | 97.3% | 97.3% | 96.5% | 95.5% | 95.5% | 95.5% | 95.5% | 95.5% | 95.5% |
| # | 2,278 | 1,965 | 1,675 | 1,410 | 1,182 | 953 | 758 | 628 | 540 | 470 | 391 | 301 | 220 | 179 | 148 | 125 | 98 | 75 | 52 |

# 5086MRI CapsureFix Novus MRI

| | |
|---|---|
| US Market Release | 08Feb2011 |
| CE Approval | 21Jan2009 |
| Registered USA Implants | 207,830 |
| Estimated Active USA Implants | 124,401 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 124 |
| Insulation Breach | 230 |
| Crimp/Weld/Bond | 0 |
| Other | 12 |

### US Acute Lead Observations

| | |
|---|---|
| Cardiac Perforation | 213 |
| 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 | 32 |

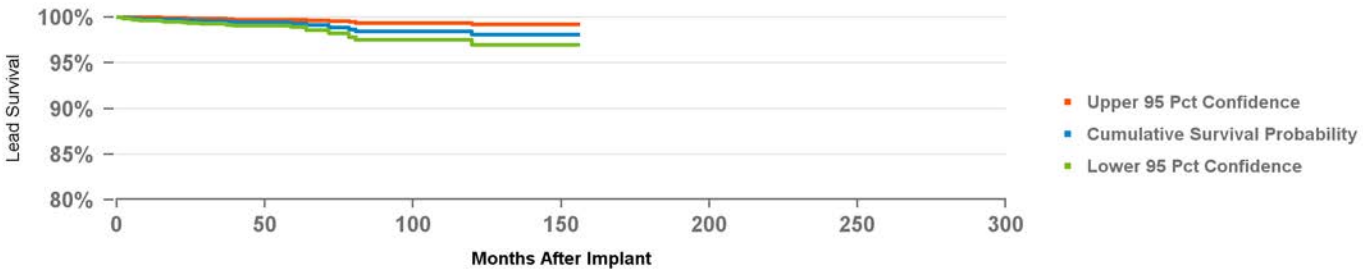
## Atrial Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,142 |
| Cumulative Months of Follow-Up | 149,577 |
| Number of Leads Active in Study | 1,250 |

### Qualifying Complications 21

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.8% | 99.6% | 99.6% | 99.4% | 99.3% | 98.9% | 98.4% | 98.4% | 98.4% | 98.1% | 98.1% | 98.1% | 98.1% |
| # | 2,528 | 2,202 | 1,878 | 1,460 | 766 | 453 | 398 | 354 | 320 | 296 | 230 | 141 | 64 |

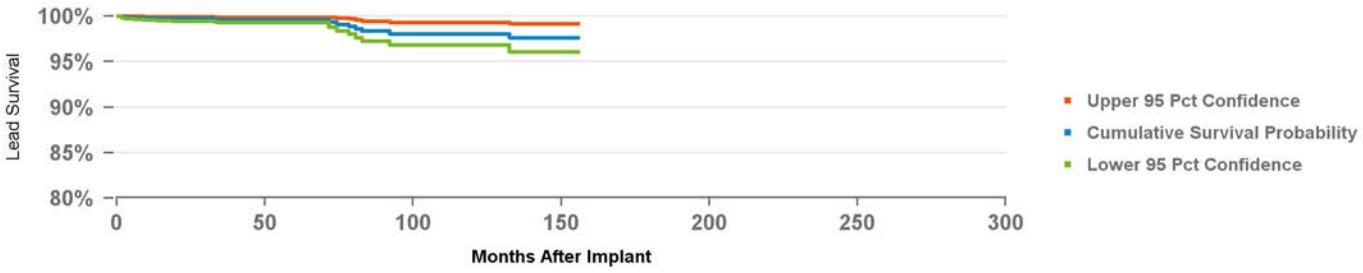
## Ventricular Placement

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,072 |
| Cumulative Months of Follow-Up | 146,399 |
| Number of Leads Active in Study | 1,231 |

### Qualifying Complications 21

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.7% | 99.6% | 99.6% | 99.6% | 99.3% | 98.3% | 98.0% | 98.0% | 98.0% | 98.0% | 97.6% | 97.6% |
| # | 2,525 | 2,182 | 1,850 | 1,425 | 734 | 422 | 374 | 331 | 300 | 277 | 212 | 131 | 62 |

# 5092 CapSure SP Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 25Sep1997 |
| Registered USA Implants | 141,709 |
| Estimated Active USA Implants | 28,840 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

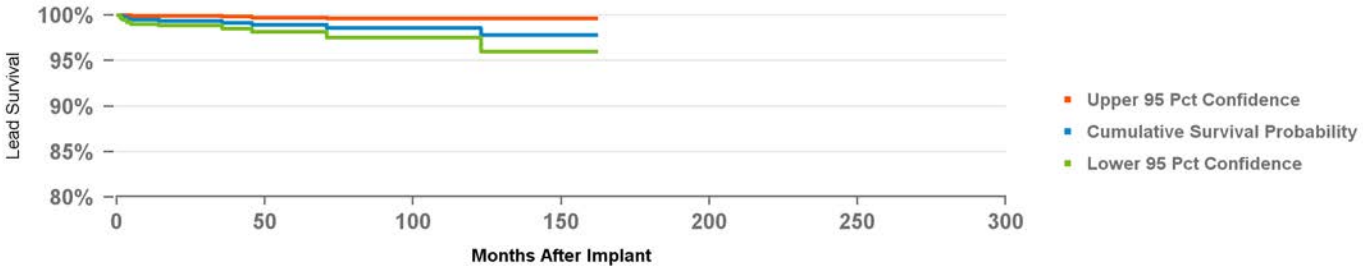
| | |
|---|---|
| Cardiac Perforation | 7 |
| Conductor Fracture | 3 |
| Extra Cardiac Stimulation | 3 |
| Failure to Capture | 49 |
| Failure to Sense | 7 |
| Impedance Out of Range | 1 |
| Insulation Breach | 3 |
| Lead Dislodgement | 72 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 8 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,218 |
| Cumulative Months of Follow-Up | 54,906 |
| Number of Leads Active in Study | 9 |

## Qualifying Complications 10

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.2% | 98.9% | 98.9% | 98.6% | 98.6% | 98.6% | 98.6% | 98.6% | 97.8% | 97.8% | 97.8% | 97.8% |
| # | 814 | 652 | 517 | 421 | 335 | 265 | 219 | 174 | 149 | 133 | 110 | 82 | 57 | 53 |

## 5554 CapSure Z Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 05Jun1997 |
| Registered USA Implants | 64,872 |
| Estimated Active USA Implants | 14,148 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 24 |
| Insulation Breach | 45 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

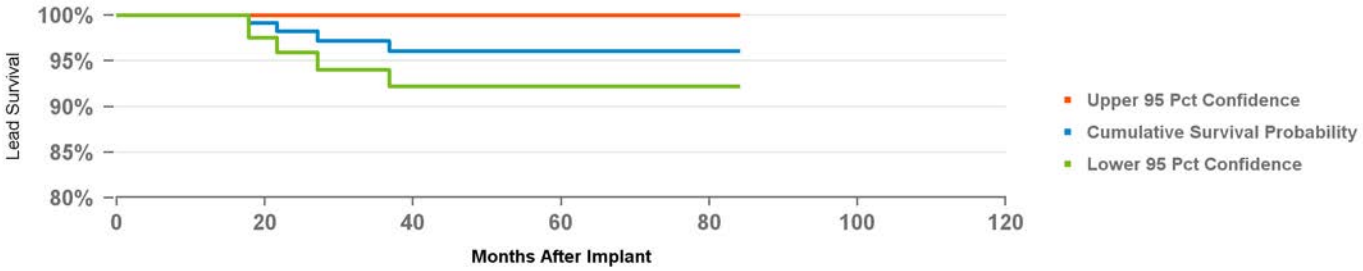
| | |
|---|---|
| Conductor Fracture | 1 |
| Failure to Capture | 31 |
| Failure to Sense | 2 |
| Impedance Out of Range | 1 |
| Lead Dislodgement | 39 |
| Unspecified Clinical Failure | 3 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 370 |
| Cumulative Months of Follow-Up | 9,603 |
| Number of Leads Active in Study | 6 |

### Qualifying Complications 5

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | at 84 mo |
|---|---|---|---|---|---|---|---|
| % | 100.0% | 98.2% | 97.2% | 96.0% | 96.0% | 96.0% | 96.0% |
| # | 141 | 107 | 84 | 77 | 63 | 55 | 55 |

# 5592 CapSure SP Novus

| | |
|---|---|
| US Market Release | 03Jun1998 |
| CE Approval | 25Sep1997 |
| Registered USA Implants | 37,336 |
| Estimated Active USA Implants | 9,725 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 8 |
| Insulation Breach | 7 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

## US Acute Lead Observations

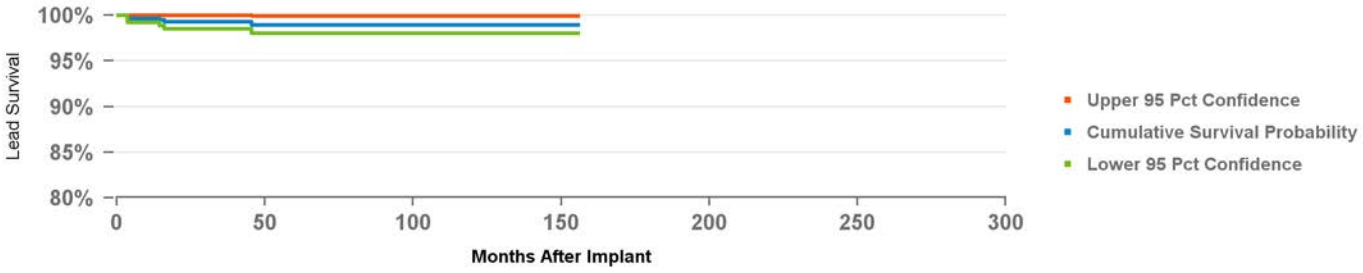
| | |
|---|---|
| Cardiac Perforation | 1 |
| Failure to Capture | 4 |
| Failure to Sense | 4 |
| Lead Dislodgement | 43 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 722 |
| Cumulative Months of Follow-Up | 40,006 |
| Number of Leads Active in Study | 21 |

## Qualifying Complications 5

| | | | |
|---|---|---|---|
| Failure to Capture | 3 | Lead Dislodgement | 2 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 156 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.3% | 99.3% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% | 98.9% |
| # | 523 | 432 | 351 | 299 | 249 | 197 | 169 | 154 | 132 | 118 | 103 | 72 | 52 |

# 5594 CapSure SP Novus

| | |
|---|---|
| US Market Release | 25Jun2001 |
| CE Approval | 23Mar2001 |
| Registered USA Implants | 17,612 |
| Estimated Active USA Implants | 5,414 |
| Fixation Type | Tines |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

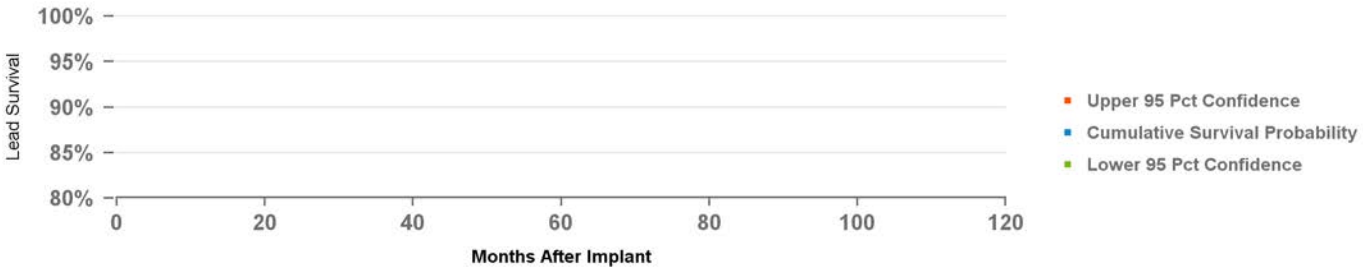
| | |
|---|---|
| Failure to Capture | 4 |
| Lead Dislodgement | 14 |
| Unspecified Clinical Failure | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 43 |
| Cumulative Months of Follow-Up | 4,827 |
| Number of Leads Active in Study | 8 |

## Qualifying Complications 3

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




| Years | at 0 mo |
|---|---|
| % | 100.0% |
| # | |

# 6721 Epicardial Patch

| | |
|---|---|
| US Market Release | 31Mar1994 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 3,434 |
| Estimated Active USA Implants | 854 |
| Fixation Type | Suture |
| Pace Sense Polarity | n/a |
| Steroid Indicator | None |

## US Returned Product Analysis

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

## US Acute Lead Observations

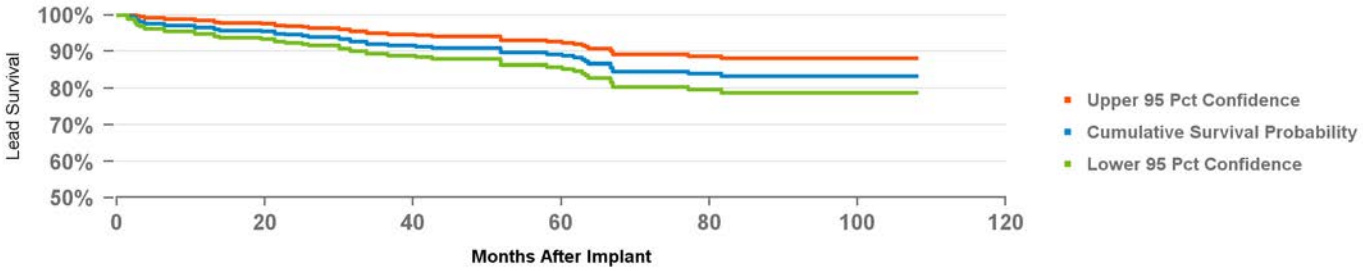
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Failure to Capture | 4 |
| Failure to Sense | 2 |
| Impedance Out of Range | 24 |
| Oversensing | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 417 |
| Cumulative Months of Follow-Up | 24,258 |
| Number of Leads Active in Study | 5 |

## Qualifying Complications 51

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| % | 96.6% | 94.6% | 92.1% | 91.0% | 89.3% | 84.7% | 83.3% | 83.3% | 83.3% |
| # | 347 | 319 | 274 | 221 | 190 | 136 | 102 | 66 | 58 |

# 6930 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 354 |
| Estimated Active USA Implants | 62 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

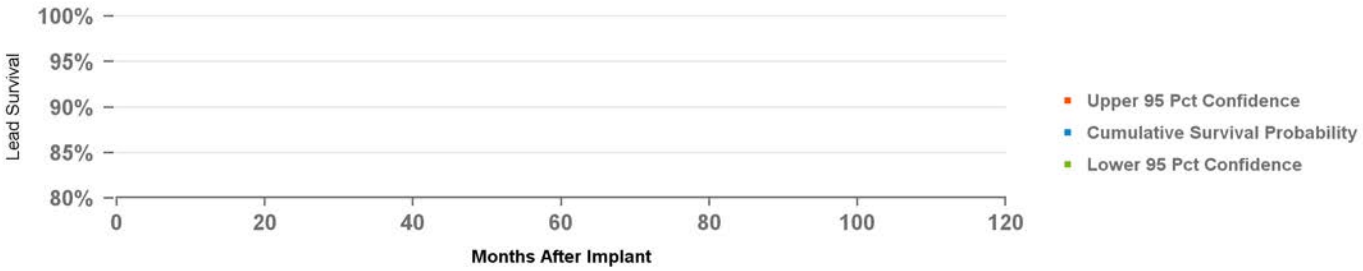
| | |
|---|---|
| Conductor Fracture | 5 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

## US Acute Lead Observations

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

## Product Surveillance Registry Results

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




| Years | at 0 mo |
|---|---|
| % | 100.0% |
| # | |

# 6931 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 8,081 |
| Estimated Active USA Implants | 1,138 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 672 |
| Insulation Breach | 1 |
| Crimp/Weld/Bond | 0 |
| Other | 5 |

## US Acute Lead Observations

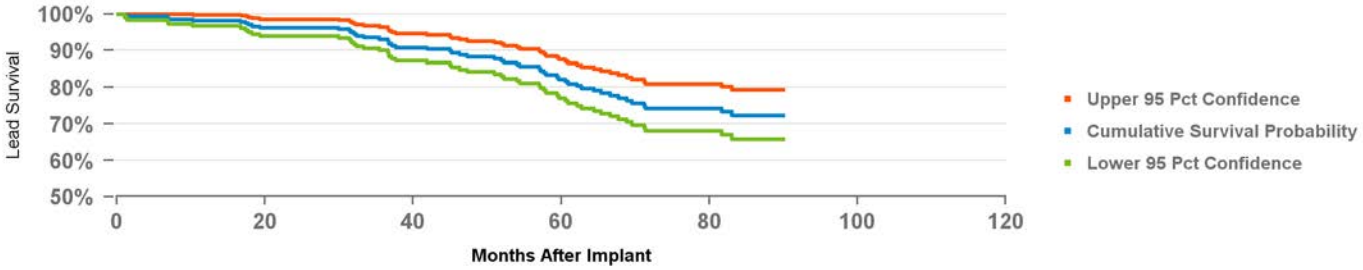
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Failure to Capture | 1 |
| Failure to Sense | 1 |
| Lead Dislodgement | 1 |
| Oversensing | 3 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 311 |
| Cumulative Months of Follow-Up | 18,202 |
| Number of Leads Active in Study | 5 |

## Qualifying Complications 59

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




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

# 6935 Sprint Quattro Secure S

| | |
|---|---|
| US Market Release | 01Nov2008 |
| CE Approval | 31Mar2008 |
| Registered USA Implants | 70,694 |
| Estimated Active USA Implants | 41,474 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 513 |
| Insulation Breach | 15 |
| Crimp/Weld/Bond | 0 |
| Other | 44 |

## US Acute Lead Observations

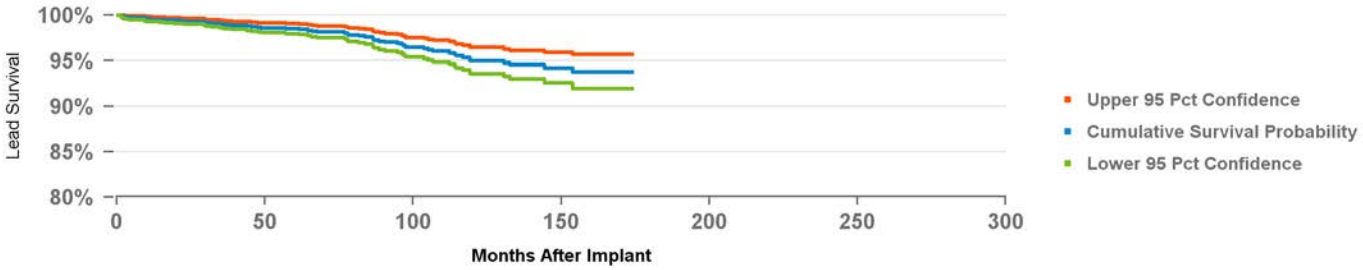
| | |
|---|---|
| Cardiac Perforation | 30 |
| Conductor Fracture | 3 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 46 |
| Failure to Sense | 16 |
| Impedance Out of Range | 38 |
| Insulation Breach | 1 |
| Lead Dislodgement | 71 |
| Oversensing | 71 |
| Unspecified Clinical Failure | 5 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 3,026 |
| Cumulative Months of Follow-Up | 179,916 |
| Number of Leads Active in Study | 452 |

## Qualifying Complications 69

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 174 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.0% | 98.6% | 98.5% | 98.1% | 97.6% | 96.9% | 96.0% | 95.0% | 94.8% | 94.5% | 93.8% | 93.8% | 93.8% |
| # | 2,509 | 2,074 | 1,697 | 1,379 | 1,177 | 1,024 | 860 | 718 | 623 | 518 | 428 | 319 | 177 | 95 | 64 |

# 6935M Sprint Quattro Secure S

| | |
|---|---|
| US Market Release | 02Aug2012 |
| CE Approval | 12Jul2012 |
| Registered USA Implants | 456,809 |
| Estimated Active USA Implants | 377,529 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/One Coil |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 959 |
| Insulation Breach | 41 |
| Crimp/Weld/Bond | 2 |
| Other | 106 |

## US Acute Lead Observations

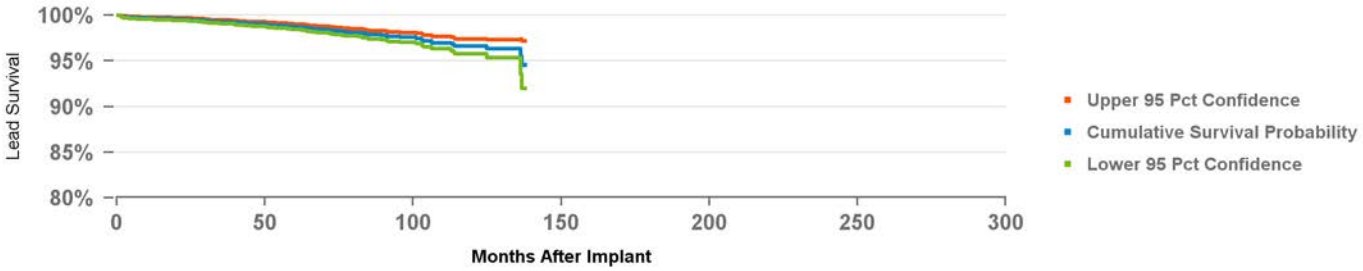
| | |
|---|---|
| Cardiac Perforation | 226 |
| Conductor Fracture | 24 |
| Extra Cardiac Stimulation | 36 |
| Failure to Capture | 583 |
| Failure to Sense | 198 |
| Impedance Out of Range | 164 |
| Insulation Breach | 3 |
| Lead Dislodgement | 744 |
| Oversensing | 441 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 10,117 |
| Cumulative Months of Follow-Up | 471,812 |
| Number of Leads Active in Study | 2,961 |

## Qualifying Complications 128

| | |
|---|---|
| Cardiac Perforation | 2 |
| Conductor Fracture | 59 |
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 15 |
| Failure to Sense | 1 |
| Impedance Out of Range | 11 |
| Insulation (not further defined) | 3 |
| Lead Dislodgement | 24 |
| Oversensing | 6 |
| Other | 5 |
| Unspecified Clinical Failure | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 138 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.6% | 99.5% | 99.3% | 99.0% | 98.7% | 98.3% | 97.9% | 97.6% | 97.0% | 96.6% | 96.3% | 94.6% |
| # | 8,384 | 6,260 | 4,879 | 3,972 | 3,318 | 2,701 | 2,138 | 1,590 | 919 | 498 | 205 | 78 |

# 6937A Transvene SVC-CS

| | |
|---|---|
| US Market Release | 06Apr2001 |
| CE Approval | |
| Registered USA Implants | 3,240 |
| Estimated Active USA Implants | 1,689 |
| Fixation Type | Passive |
| Pace Sense Polarity | One Coil |
| Steroid Indicator | None |

## US Returned Product Analysis

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

## US Acute Lead Observations

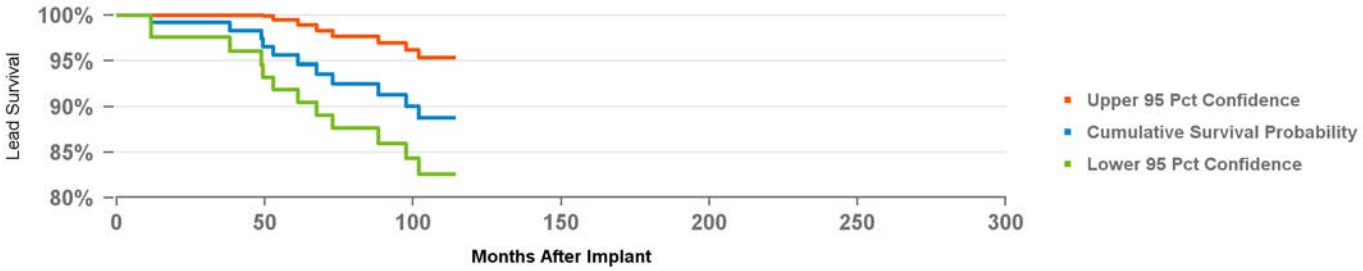
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 3 |
| Impedance Out of Range | 2 |
| Lead Dislodgement | 1 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 127 |
| Cumulative Months of Follow-Up | 14,635 |
| Number of Leads Active in Study | 7 |

## Qualifying Complications 16

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 mo |
|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 99.2% | 99.2% | 98.3% | 95.6% | 93.6% | 92.5% | 91.3% | 88.8% | 88.8% |
| # | 119 | 117 | 114 | 109 | 98 | 87 | 81 | 74 | 61 | 55 |

# 6944 Sprint Quattro

| | |
|---|---|
| US Market Release | 13Dec2000 |
| CE Approval | 05Nov1999 |
| Registered USA Implants | 44,865 |
| Estimated Active USA Implants | 11,649 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 242 |
| Insulation Breach | 4 |
| Crimp/Weld/Bond | 1 |
| Other | 4 |

## US Acute Lead Observations

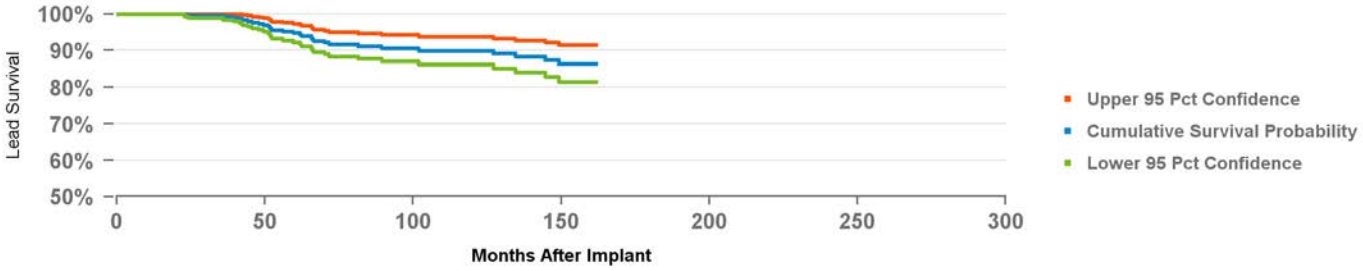
| | |
|---|---|
| Conductor Fracture | 2 |
| Failure to Capture | 17 |
| Failure to Sense | 3 |
| Impedance Out of Range | 10 |
| Lead Dislodgement | 24 |
| Oversensing | 18 |
| Unspecified Clinical Failure | 6 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 640 |
| Cumulative Months of Follow-Up | 39,432 |
| Number of Leads Active in Study | 46 |

## Qualifying Complications 34

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 162 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 100.0% | 99.8% | 99.2% | 97.3% | 94.8% | 91.7% | 91.1% | 90.6% | 89.9% | 89.9% | 89.1% | 88.3% | 86.3% | 86.3% |
| # | 502 | 418 | 352 | 290 | 228 | 192 | 165 | 148 | 135 | 118 | 111 | 95 | 70 | 59 |

## 6946M Sprint Quattro

| | |
|---|---|
| US Market Release | 05Jan2016 |
| CE Approval | 12Sep2013 |
| Registered USA Implants | 5,074 |
| Estimated Active USA Implants | 4,415 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 2 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

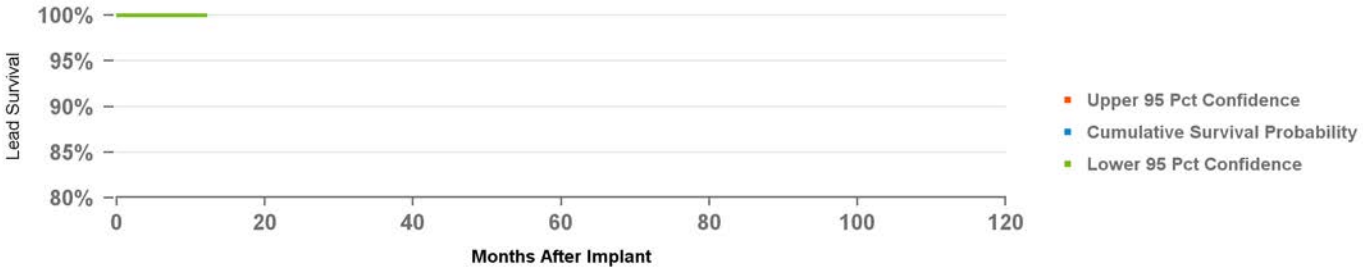
| | |
|---|---|
| Cardiac Perforation | 1 |
| Failure to Capture | 7 |
| Failure to Sense | 2 |
| Impedance Out of Range | 2 |
| Lead Dislodgement | 9 |
| Oversensing | 6 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 68 |
| Cumulative Months of Follow-Up | 2,684 |
| Number of Leads Active in Study | 37 |

### Qualifying Complications 1

| | |
|---|---|
| Conductor Fracture | 1 |




| Years | at 12 mo |
|---|---|
| % | 100.0% |
| # | 56 |

# 6947 Sprint Quattro Secure

| | |
|---|---|
| US Market Release | 12Nov2001 |
| CE Approval | 04Oct2001 |
| Registered USA Implants | 375,859 |
| Estimated Active USA Implants | 123,350 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1,451 |
| Insulation Breach | 104 |
| Crimp/Weld/Bond | 4 |
| Other | 199 |

## US Acute Lead Observations

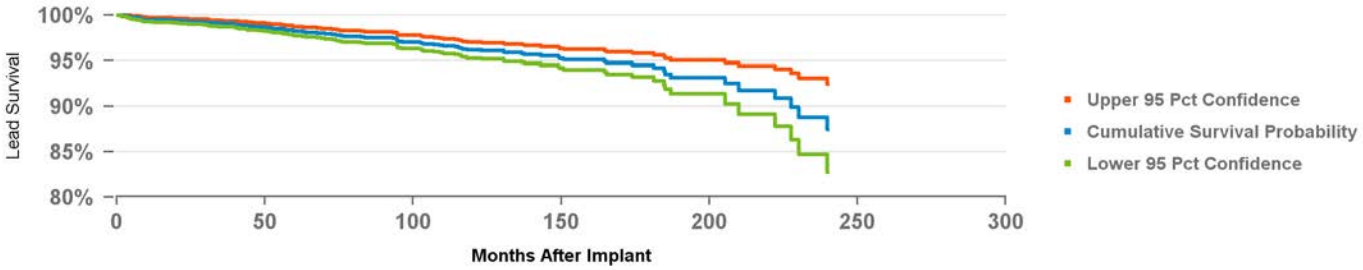
| | |
|---|---|
| Cardiac Perforation | 29 |
| Conductor Fracture | 26 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 83 |
| Failure to Sense | 36 |
| Impedance Out of Range | 61 |
| Insulation Breach | 4 |
| Lead Dislodgement | 124 |
| Oversensing | 142 |
| Unspecified Clinical Failure | 20 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 4,600 |
| Cumulative Months of Follow-Up | 308,305 |
| Number of Leads Active in Study | 379 |

## Qualifying Complications 105

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | at 240 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.5% | 99.3% | 99.0% | 98.7% | 98.2% | 97.9% | 97.5% | 97.1% | 96.7% | 96.2% | 95.9% | 95.5% | 95.1% | 94.7% | 94.5% | 93.2% | 93.2% | 91.8% | 89.9% | 87.5% |
| # | 3,310 | 2,912 | 2,556 | 2,263 | 2,032 | 1,793 | 1,548 | 1,390 | 1,246 | 1,096 | 933 | 755 | 621 | 472 | 336 | 216 | 141 | 111 | 89 | 63 |

# 6947M Sprint Quattro Secure

| | |
|---|---|
| US Market Release | 13Feb2012 |
| CE Approval | 12Mar2010 |
| Registered USA Implants | 142,494 |
| Estimated Active USA Implants | 97,568 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 281 |
| Insulation Breach | 15 |
| Crimp/Weld/Bond | 1 |
| Other | 38 |

## US Acute Lead Observations

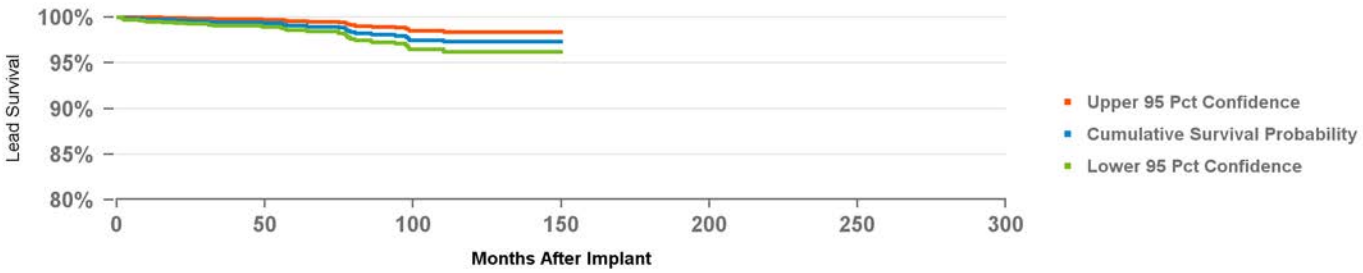
| | |
|---|---|
| Cardiac Perforation | 41 |
| Conductor Fracture | 16 |
| Extra Cardiac Stimulation | 12 |
| Failure to Capture | 131 |
| Failure to Sense | 50 |
| Impedance Out of Range | 42 |
| Insulation Breach | 1 |
| Lead Dislodgement | 245 |
| Oversensing | 92 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,445 |
| Cumulative Months of Follow-Up | 144,058 |
| Number of Leads Active in Study | 455 |

## Qualifying Complications 28

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | at 150 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.5% | 99.4% | 99.4% | 99.0% | 98.9% | 98.2% | 97.9% | 97.5% | 97.3% | 97.3% | 97.3% | 97.3% |
| # | 1,940 | 1,614 | 1,403 | 1,182 | 1,024 | 868 | 744 | 639 | 540 | 433 | 338 | 167 | 67 |

# 6948 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 10,381 |
| Estimated Active USA Implants | 1,611 |
| Fixation Type | Tines |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 219 |
| Insulation Breach | 3 |
| Crimp/Weld/Bond | 0 |
| Other | 6 |

## US Acute Lead Observations

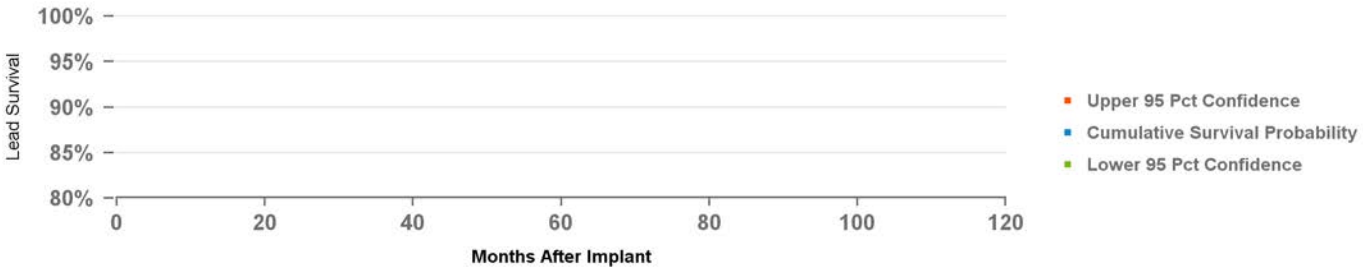
| | |
|---|---|
| Conductor Fracture | 2 |
| Failure to Capture | 7 |
| Lead Dislodgement | 7 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 3 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 40 |
| Cumulative Months of Follow-Up | 2,347 |
| Number of Leads Active in Study | 1 |

## Qualifying Complications 5

| | | | |
|---|---|---|---|
| Conductor Fracture | 4 | Impedance Out of Range | 1 |




| Years | at 0 mo |
|---|---|
| % | 100.0% |
| # | |

# 6949 Sprint Fidelis

| | |
|---|---|
| US Market Release | 02Sep2004 |
| CE Approval | |
| Registered USA Implants | 186,211 |
| Estimated Active USA Implants | 23,610 |
| Fixation Type | Active Screw In |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 8,187 |
| Insulation Breach | 37 |
| Crimp/Weld/Bond | 3 |
| Other | 119 |

## US Acute Lead Observations

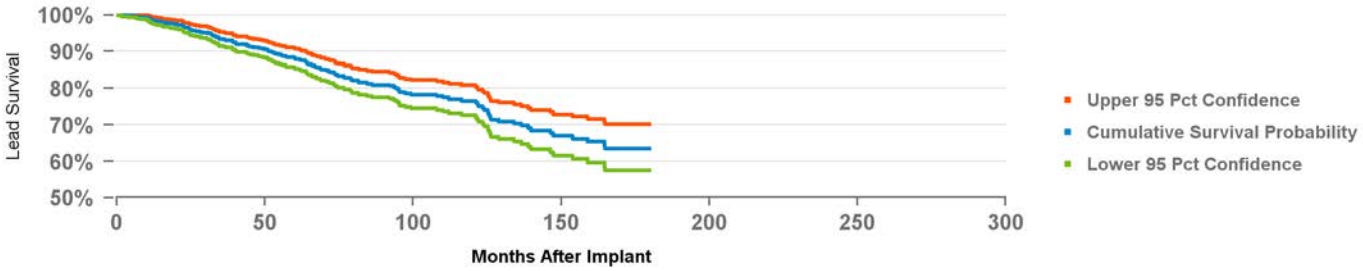
| | |
|---|---|
| Cardiac Perforation | 10 |
| Conductor Fracture | 53 |
| Failure to Capture | 31 |
| Failure to Sense | 19 |
| Impedance Out of Range | 20 |
| Insulation Breach | 5 |
| Lead Dislodgement | 22 |
| Oversensing | 37 |
| Unspecified Clinical Failure | 24 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 986 |
| Cumulative Months of Follow-Up | 58,377 |
| Number of Leads Active in Study | 26 |

## Qualifying Complications 136

| | |
|---|---|
| Conductor Fracture | 78 |
| Failure to Capture | 5 |
| Failure to Sense | 6 |
| Impedance Out of Range | 19 |
| Insulation (not further defined) | 2 |
| Lead Dislodgement | 1 |
| Oversensing | 21 |
| Other | 3 |
| Unspecified Clinical Failure | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | at 180 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.6% | 96.5% | 93.4% | 91.0% | 88.2% | 84.5% | 81.6% | 79.0% | 78.0% | 76.6% | 71.0% | 68.5% | 66.3% | 63.5% | 63.5% |
| # | 719 | 626 | 532 | 458 | 392 | 343 | 281 | 236 | 187 | 153 | 126 | 96 | 79 | 65 | 55 |

# 6996 Sub-Q Lead

| | |
|---|---|
| US Market Release | 11Jun2001 |
| CE Approval | 19Dec1997 |
| Registered USA Implants | 5,913 |
| Estimated Active USA Implants | 2,692 |
| Fixation Type | Suture on Anchor Sleeve |
| Pace Sense Polarity | One Coil |
| Steroid Indicator | None |

## US Returned Product Analysis

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

## US Acute Lead Observations

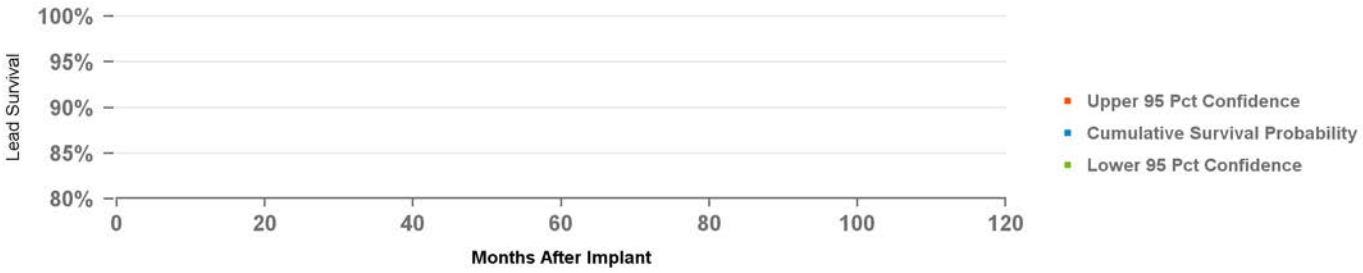
| | |
|---|---|
| Cardiac Perforation | 1 |
| Failure to Capture | 1 |
| Impedance Out of Range | 19 |
| Insulation Breach | 1 |
| Lead Dislodgement | 3 |
| Oversensing | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 56 |
| Cumulative Months of Follow-Up | 2,637 |
| Number of Leads Active in Study | 3 |

## Qualifying Complications 4

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Impedance Out of Range | 3 |




| Years | at 0 mo |
|---|---|
| % | 100.0% |
| # | |

## EV2401 Epsila EV

| | |
|---|---|
| US Market Release | 20Oct2023 |
| CE Approval | 17Feb2023 |
| Registered USA Implants | 2,906 |
| Estimated Active USA Implants | 2,781 |
| Fixation Type | Shaped passive fixation |
| Pace Sense Polarity | True Bipolar/Two Coils |
| Steroid Indicator | None |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 3 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

### US Acute Lead Observations

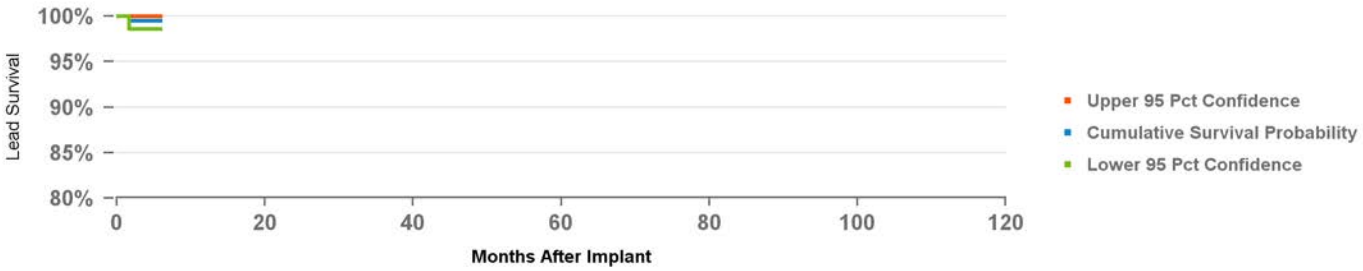
| | |
|---|---|
| Failure to Capture | 1 |
| Failure to Sense | 7 |
| Impedance Out of Range | 31 |
| Lead Dislodgement | 20 |
| Oversensing | 66 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 556 |
| Cumulative Months of Follow-Up | 1,151 |
| Number of Leads Active in Study | 542 |

### Qualifying Complications 1

| | |
|---|---|
| Lead Dislodgement | 1 |




| Years | at 6 mo |
|---|---|
| % | 99.5% |
| # | 81 |

## 2187 Attain LV

| | |
|---|---|
| US Market Release | 28Aug2001 |
| CE Approval | |
| Registered USA Implants | 11,921 |
| Estimated Active USA Implants | 971 |
| Fixation Type | Distal Continous Curve |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | None |

### US Returned Product Analysis

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

### US Acute Lead Observations

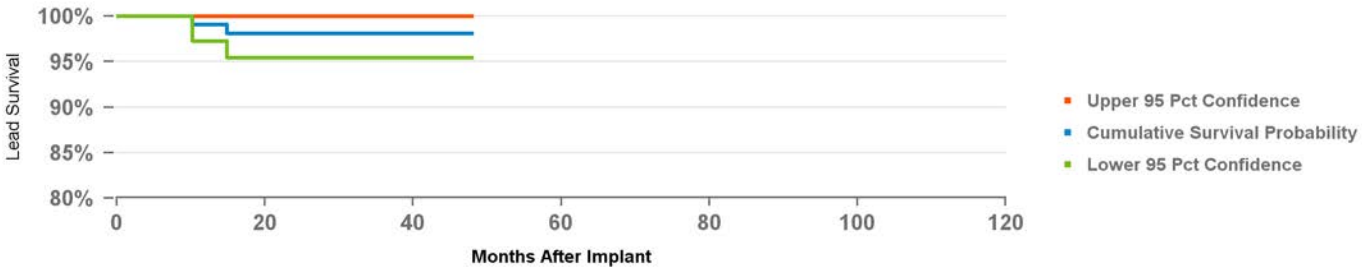
| | |
|---|---|
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 3 |
| Failure to Sense | 1 |
| Lead Dislodgement | 9 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 140 |
| Cumulative Months of Follow-Up | 7,300 |
| Number of Leads Active in Study | 4 |

### Qualifying Complications 3

| | |
|---|---|
| Failure to Capture | 3 |




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

## 4193 Attain OTW

| | |
|---|---|
| US Market Release | 03May2002 |
| CE Approval | 22Dec2000 |
| Registered USA Implants | 100,665 |
| Estimated Active USA Implants | 11,989 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

### US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 92 |
| Insulation Breach | 31 |
| Crimp/Weld/Bond | 0 |
| Other | 15 |

### US Acute Lead Observations

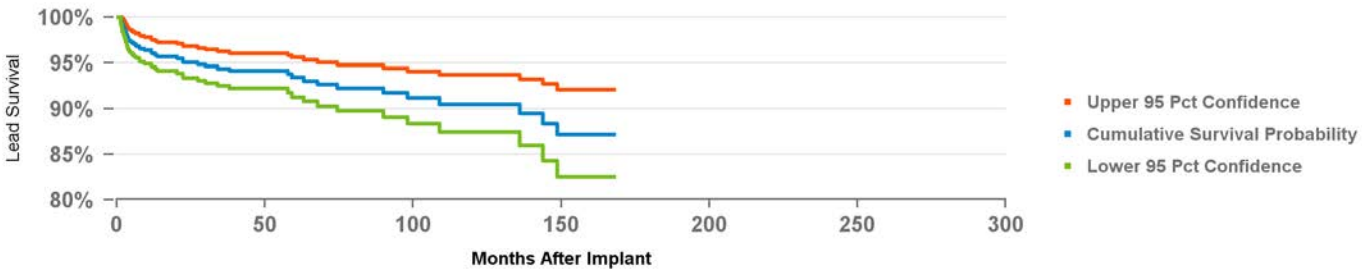
| | |
|---|---|
| Extra Cardiac Stimulation | 18 |
| Failure to Capture | 11 |
| Lead Dislodgement | 45 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 2 |

### Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 805 |
| Cumulative Months of Follow-Up | 42,838 |
| Number of Leads Active in Study | 16 |

### Qualifying Complications 52

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Impedance Out of Range | 2 |
| Extra Cardiac Stimulation | 10 | Lead Dislodgement | 16 |
| Failure to Capture | 20 | Unspecified Clinical Failure | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 96.0% | 95.1% | 94.4% | 94.1% | 93.4% | 92.6% | 92.2% | 91.7% | 91.2% | 90.5% | 90.5% | 88.4% | 87.2% | 87.2% |
| # | 569 | 444 | 376 | 304 | 252 | 228 | 193 | 171 | 139 | 118 | 97 | 78 | 63 | 51 |

# 4194 Attain OTW

| | |
|---|---|
| US Market Release | 24Aug2004 |
| CE Approval | 14Jul2003 |
| Registered USA Implants | 114,259 |
| Estimated Active USA Implants | 28,111 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

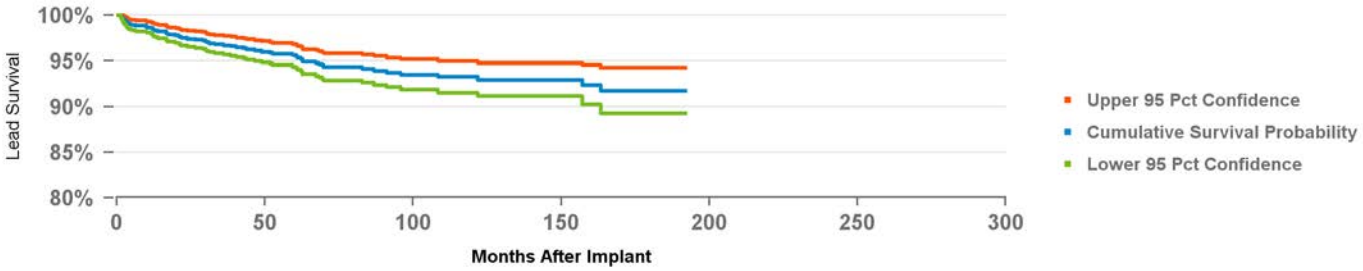
| | |
|---|---|
| Cardiac Perforation | 2 |
| Conductor Fracture | 3 |
| Extra Cardiac Stimulation | 49 |
| Failure to Capture | 43 |
| Impedance Out of Range | 9 |
| Lead Dislodgement | 153 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 4 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,654 |
| Cumulative Months of Follow-Up | 102,365 |
| Number of Leads Active in Study | 110 |

## Qualifying Complications 69

| | | | |
|---|---|---|---|
| Conductor Fracture | 2 | Insulation (ESC) | 1 |
| Extra Cardiac Stimulation | 12 | Insulation (not further defined) | 2 |
| Failure to Capture | 22 | Lead Dislodgement | 30 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 192 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.6% | 97.4% | 96.7% | 96.1% | 95.6% | 94.3% | 94.1% | 93.5% | 93.5% | 93.3% | 93.0% | 93.0% | 93.0% | 91.7% | 91.7% | 91.7% |
| # | 1,238 | 1,046 | 897 | 769 | 697 | 616 | 506 | 430 | 370 | 323 | 269 | 201 | 160 | 113 | 74 | 53 |

# 4195 Attain StarFix

| | |
|---|---|
| US Market Release | 15Aug2008 |
| CE Approval | 13May2005 |
| Registered USA Implants | 17,447 |
| Estimated Active USA Implants | 6,098 |
| Fixation Type | Deployable Lobe Fixation |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

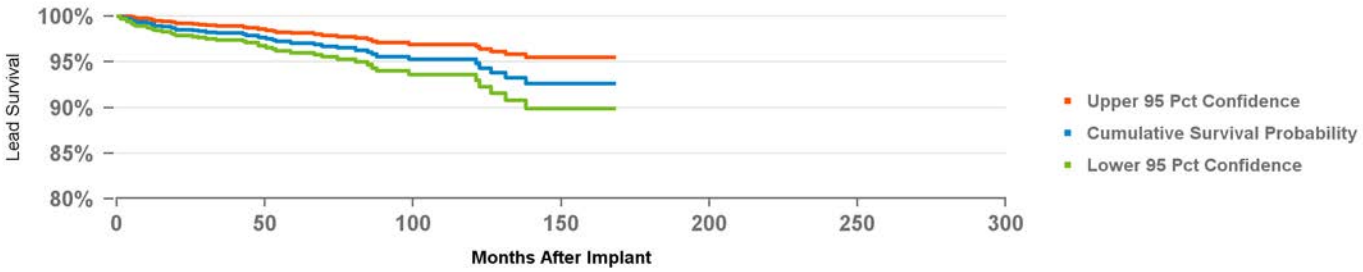
| | |
|---|---|
| Extra Cardiac Stimulation | 30 |
| Failure to Capture | 21 |
| Impedance Out of Range | 4 |
| Lead Dislodgement | 30 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,486 |
| Cumulative Months of Follow-Up | 89,945 |
| Number of Leads Active in Study | 97 |

## Qualifying Complications 47

| | |
|---|---|
| Conductor Fracture | 4 |
| Extra Cardiac Stimulation | 18 |
| Failure to Capture | 10 |
| Impedance Out of Range | 3 |
| Insulation (not further defined) | 6 |
| Lead Dislodgement | 5 |
| Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.1% | 98.5% | 98.1% | 97.6% | 97.0% | 96.7% | 96.3% | 95.6% | 95.3% | 95.3% | 93.3% | 92.7% | 92.7% | 92.7% |
| # | 1,243 | 1,072 | 924 | 747 | 620 | 510 | 416 | 325 | 265 | 214 | 169 | 123 | 88 | 55 |

# 4196 Attain Ability

| | |
|---|---|
| US Market Release | 15May2009 |
| CE Approval | 24Jul2007 |
| Registered USA Implants | 69,356 |
| Estimated Active USA Implants | 27,571 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

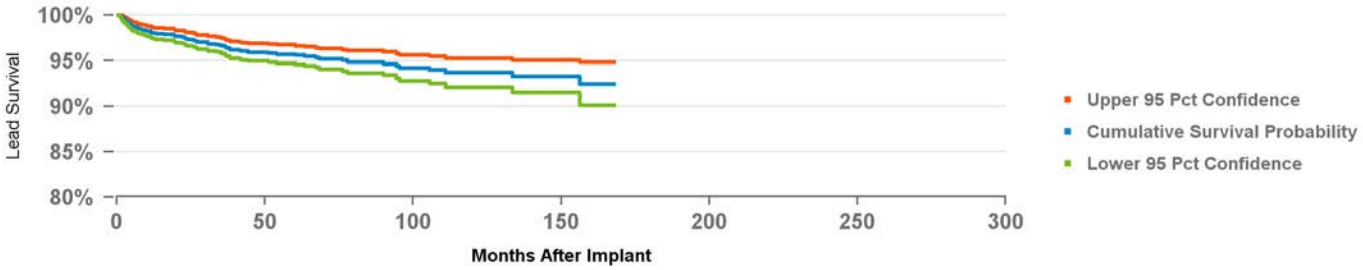
| | |
|---|---|
| Cardiac Perforation | 3 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 100 |
| Failure to Capture | 68 |
| Failure to Sense | 1 |
| Impedance Out of Range | 12 |
| Insulation Breach | 1 |
| Lead Dislodgement | 229 |
| Oversensing | 1 |
| Unspecified Clinical Failure | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,325 |
| Cumulative Months of Follow-Up | 123,086 |
| Number of Leads Active in Study | 146 |

## Qualifying Complications 88

| | | | |
|---|---|---|---|
| Conductor Fracture | 3 | Impedance Out of Range | 2 |
| Extra Cardiac Stimulation | 17 | Insulation (not further defined) | 1 |
| Failure to Capture | 37 | Lead Dislodgement | 24 |
| | | Other | 4 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | at 168 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.0% | 97.3% | 96.6% | 95.9% | 95.7% | 95.2% | 94.9% | 94.2% | 94.0% | 93.7% | 93.7% | 93.3% | 93.3% | 92.5% |
| # | 1,891 | 1,503 | 1,197 | 968 | 798 | 642 | 508 | 422 | 352 | 290 | 231 | 170 | 116 | 67 |

# 4296 Attain Ability Plus

| | |
|---|---|
| US Market Release | 01Apr2011 |
| CE Approval | 18Dec2009 |
| Registered USA Implants | 35,383 |
| Estimated Active USA Implants | 17,050 |
| Fixation Type | Double Curve |
| Pace Sense Polarity | Dual Electrodes |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

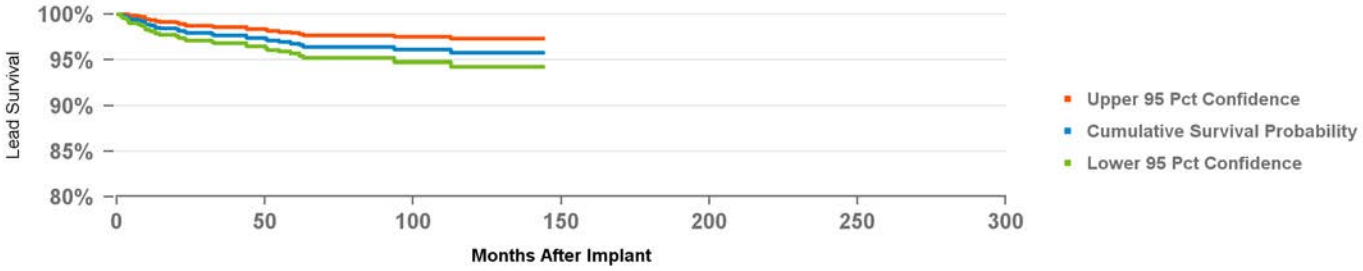
| | |
|---|---|
| Cardiac Perforation | 2 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 65 |
| Failure to Capture | 40 |
| Impedance Out of Range | 11 |
| Insulation Breach | 4 |
| Lead Dislodgement | 120 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,473 |
| Cumulative Months of Follow-Up | 81,242 |
| Number of Leads Active in Study | 159 |

## Qualifying Complications 38

| | | | |
|---|---|---|---|
| Conductor Fracture | 1 | Lead Dislodgement | 14 |
| Extra Cardiac Stimulation | 12 | Other | 2 |
| Failure to Capture | 9 | | |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | at 144 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 98.7% | 97.9% | 97.7% | 97.4% | 96.8% | 96.4% | 96.4% | 96.1% | 96.1% | 95.8% | 95.8% | 95.8% |
| # | 1,164 | 942 | 777 | 661 | 557 | 475 | 410 | 331 | 285 | 232 | 172 | 71 |

# 4396 Attain Ability Straight

| | |
|---|---|
| US Market Release | 31Mar2011 |
| CE Approval | 18Dec2009 |
| Registered USA Implants | 8,526 |
| Estimated Active USA Implants | 4,393 |
| Fixation Type | Tines |
| Pace Sense Polarity | Dual Electrodes |
| Steroid Indicator | Yes |

## US Returned Product Analysis

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

## US Acute Lead Observations

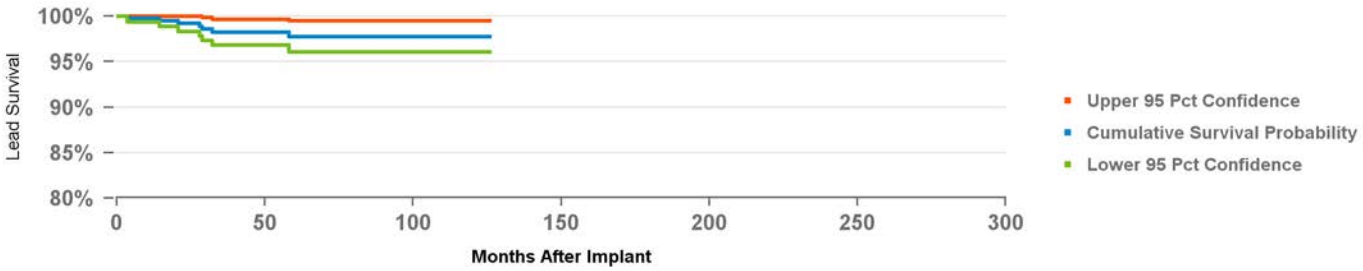
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 21 |
| Failure to Capture | 14 |
| Lead Dislodgement | 35 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 485 |
| Cumulative Months of Follow-Up | 27,157 |
| Number of Leads Active in Study | 62 |

## Qualifying Complications 10

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | at 126 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.8% | 99.2% | 98.2% | 98.2% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% | 97.7% |
| # | 386 | 312 | 273 | 238 | 198 | 158 | 128 | 110 | 95 | 68 | 55 |

# 4398 Attain Performa Straight

| | |
|---|---|
| US Market Release | 10Dec2014 |
| CE Approval | 01Jan2013 |
| Registered USA Implants | 45,390 |
| Estimated Active USA Implants | 35,980 |
| 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 | 8 |

## US Acute Lead Observations

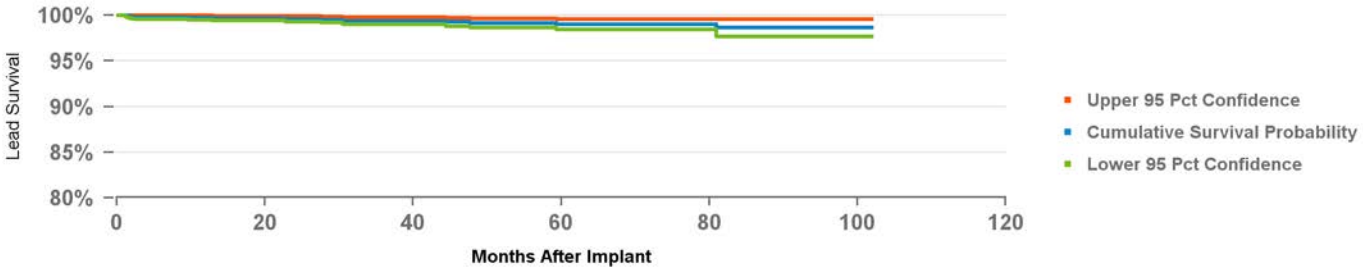
| | |
|---|---|
| Cardiac Perforation | 8 |
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 117 |
| Failure to Capture | 91 |
| Impedance Out of Range | 18 |
| Lead Dislodgement | 47 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 2,140 |
| Cumulative Months of Follow-Up | 91,852 |
| Number of Leads Active in Study | 937 |

## Qualifying Complications 17

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 102 mo |
|---|---|---|---|---|---|---|---|---|---|
| % | 99.7% | 99.6% | 99.3% | 99.1% | 99.0% | 99.0% | 98.6% | 98.6% | 98.6% |
| # | 1,792 | 1,458 | 1,155 | 869 | 635 | 419 | 218 | 88 | 56 |

# 4598 Attain Performa S

| | |
|---|---|
| US Market Release | 10Dec2014 |
| CE Approval | 01Jan2013 |
| Registered USA Implants | 85,774 |
| Estimated Active USA Implants | 69,201 |
| Fixation Type | S-shape |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 7 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 15 |

## US Acute Lead Observations

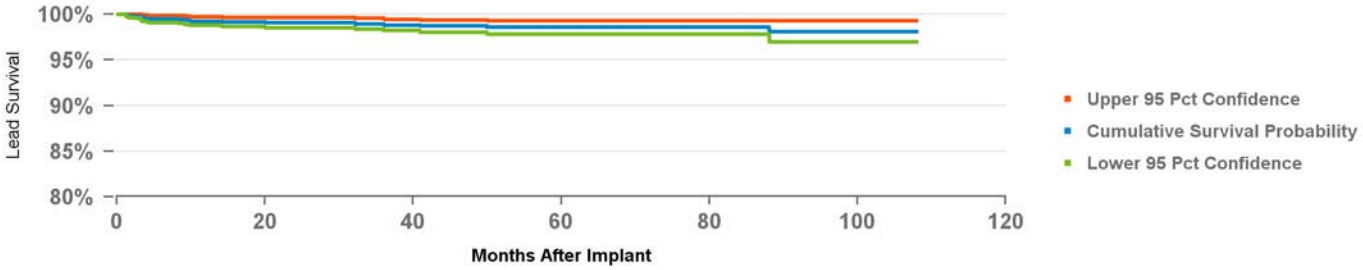
| | |
|---|---|
| Cardiac Perforation | 12 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 151 |
| Failure to Capture | 117 |
| Impedance Out of Range | 44 |
| Lead Dislodgement | 99 |
| Oversensing | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,391 |
| Cumulative Months of Follow-Up | 69,188 |
| Number of Leads Active in Study | 336 |

## Qualifying Complications 17

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




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 108 mo |
|---|---|---|---|---|---|---|---|---|---|
| % | 99.2% | 99.0% | 98.9% | 98.7% | 98.5% | 98.5% | 98.5% | 98.1% | 98.1% |
| # | 1,173 | 983 | 818 | 688 | 563 | 412 | 245 | 148 | 58 |

# 4798 Attain Stability Quad

| | |
|---|---|
| US Market Release | 03Jun2019 |
| CE Approval | 24Apr2017 |
| Registered USA Implants | 70,653 |
| Estimated Active USA Implants | 65,350 |
| Fixation Type | Non-electrically Active Side Fixation |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 1 |
| Insulation Breach | 0 |
| Crimp/Weld/Bond | 0 |
| Other | 17 |

## US Acute Lead Observations

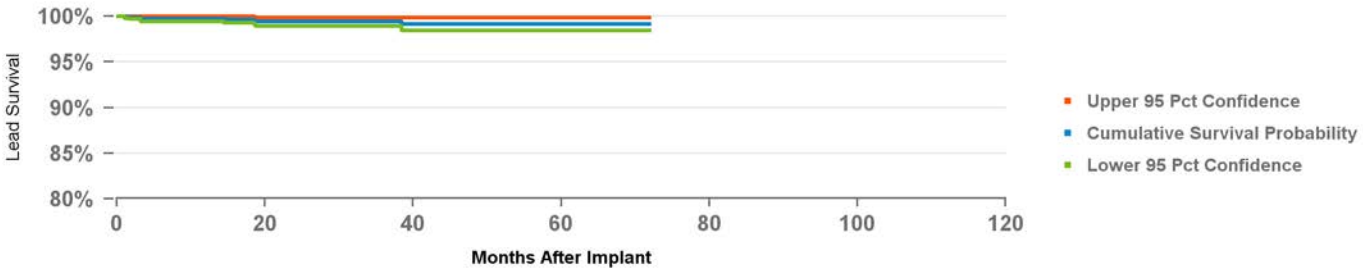
| | |
|---|---|
| Cardiac Perforation | 10 |
| Conductor Fracture | 2 |
| Extra Cardiac Stimulation | 127 |
| Failure to Capture | 159 |
| Impedance Out of Range | 55 |
| Lead Dislodgement | 135 |
| Oversensing | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,519 |
| Cumulative Months of Follow-Up | 40,553 |
| Number of Leads Active in Study | 886 |

## Qualifying Complications 10

| | |
|---|---|
| Conductor Fracture | 1 |
| Extra Cardiac Stimulation | 2 |
| Failure to Capture | 4 |
| Lead Dislodgement | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | at 72 mo |
|---|---|---|---|---|---|---|
| % | 99.7% | 99.4% | 99.4% | 99.1% | 99.1% | 99.1% |
| # | 1,199 | 708 | 406 | 249 | 106 | 50 |

# 4965 CapSure Epi

| | |
|---|---|
| US Market Release | 06Sep1996 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 24,421 |
| Estimated Active USA Implants | 6,699 |
| Fixation Type | Suture |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 305 |
| Insulation Breach | 66 |
| Crimp/Weld/Bond | 1 |
| Other | 0 |

## US Acute Lead Observations

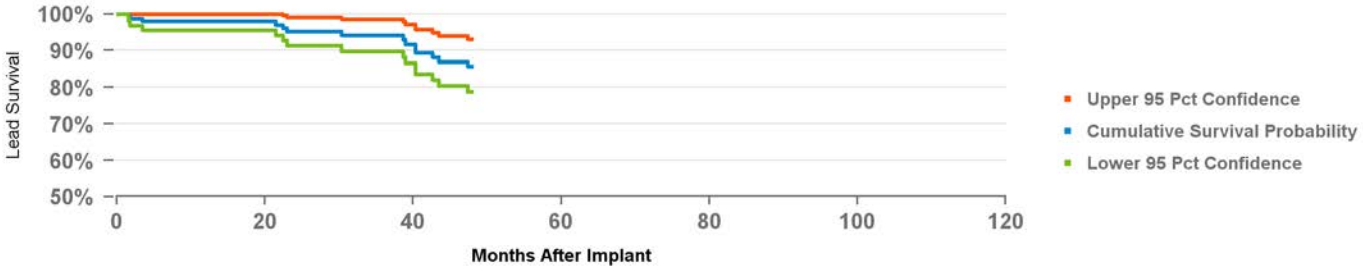
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 1 |
| Failure to Capture | 13 |
| Failure to Sense | 8 |
| Impedance Out of Range | 21 |
| Oversensing | 3 |
| Unspecified Clinical Failure | 3 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 234 |
| Cumulative Months of Follow-Up | 7,538 |
| Number of Leads Active in Study | 3 |

## Qualifying Complications 18

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




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

# 4968 CapSure Epi

| | |
|---|---|
| US Market Release | 16Sep1999 |
| CE Approval | 21Apr1998 |
| Registered USA Implants | 67,463 |
| Estimated Active USA Implants | 36,983 |
| Fixation Type | Suture |
| Pace Sense Polarity | Bipolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 160 |
| Insulation Breach | 101 |
| Crimp/Weld/Bond | 0 |
| Other | 1 |

## US Acute Lead Observations

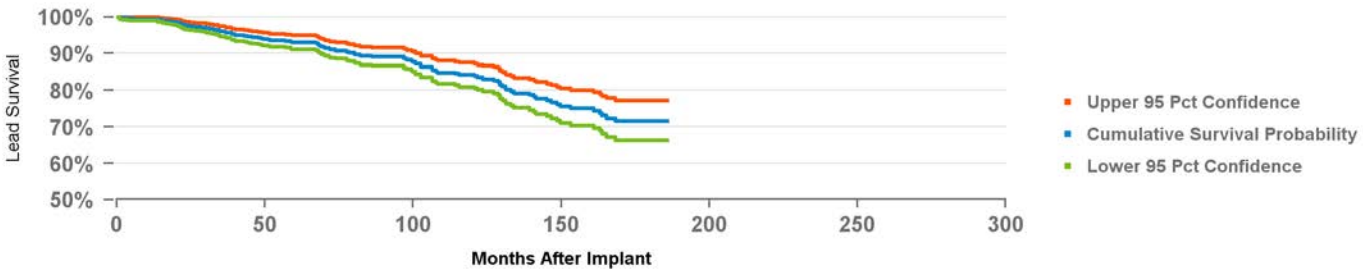
| | |
|---|---|
| Cardiac Perforation | 1 |
| Conductor Fracture | 4 |
| Extra Cardiac Stimulation | 7 |
| Failure to Capture | 114 |
| Failure to Sense | 15 |
| Impedance Out of Range | 23 |
| Insulation Breach | 1 |
| Lead Dislodgement | 8 |
| Oversensing | 35 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 1,058 |
| Cumulative Months of Follow-Up | 75,374 |
| Number of Leads Active in Study | 167 |

## Qualifying Complications 113

| | | | |
|---|---|---|---|
| Conductor Fracture | 36 | Impedance Out of Range | 5 |
| Extra Cardiac Stimulation | 2 | Insulation (not further defined) | 6 |
| Failure to Capture | 30 | Lead Dislodgement | 1 |
| Failure to Sense | 3 | Oversensing | 27 |
| | | Other | 3 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | at 186 mo |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| % | 99.4% | 97.6% | 96.1% | 94.2% | 93.1% | 91.1% | 89.4% | 89.2% | 85.2% | 84.2% | 80.2% | 77.8% | 75.1% | 72.4% | 71.6% | 71.6% |
| # | 827 | 751 | 673 | 583 | 519 | 450 | 403 | 346 | 274 | 233 | 181 | 156 | 126 | 95 | 72 | 57 |

# 5071 Screw-in

| | |
|---|---|
| US Market Release | 03Dec1992 |
| CE Approval | 01Jan1993 |
| Registered USA Implants | 58,275 |
| Estimated Active USA Implants | 12,635 |
| Fixation Type | Fixed Screw |
| Pace Sense Polarity | Unipolar |
| Steroid Indicator | None |

## US Returned Product Analysis

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

## US Acute Lead Observations

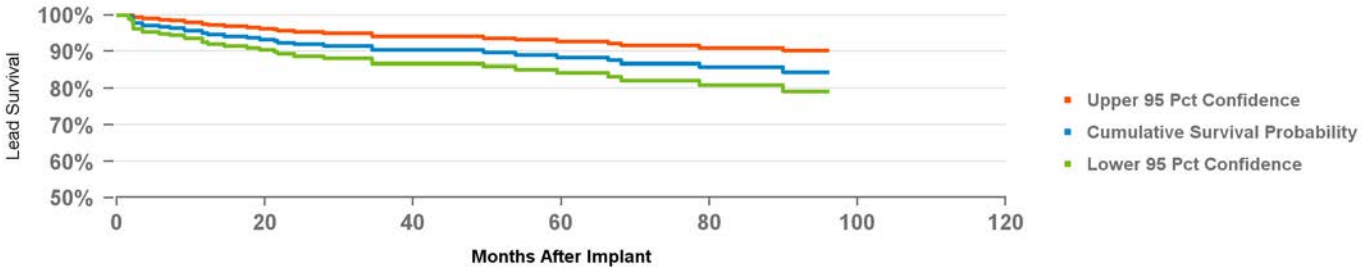
| | |
|---|---|
| Cardiac Perforation | 3 |
| Extra Cardiac Stimulation | 6 |
| Failure to Capture | 132 |
| Failure to Sense | 4 |
| Impedance Out of Range | 16 |
| Lead Dislodgement | 6 |
| Oversensing | 2 |
| Unspecified Clinical Failure | 1 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 474 |
| Cumulative Months of Follow-Up | 18,400 |
| Number of Leads Active in Study | 42 |

## Qualifying Complications 39

| | | | |
|---|---|---|---|
| Conductor Fracture | 6 | Impedance Out of Range | 3 |
| Extra Cardiac Stimulation | 1 | Lead Dislodgement | 3 |
| Failure to Capture | 21 | Oversensing | 2 |
| Failure to Sense | 2 | Other | 1 |




| Years | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 96 mo |
|---|---|---|---|---|---|---|---|---|
| % | 95.0% | 92.0% | 90.4% | 90.4% | 88.4% | 86.8% | 85.8% | 84.5% |
| # | 238 | 193 | 164 | 145 | 125 | 98 | 79 | 50 |

# 5038 CapSure VDD-2

| | |
|---|---|
| US Market Release | 10Sep1998 |
| CE Approval | 15Apr1997 |
| Registered USA Implants | 9,674 |
| Estimated Active USA Implants | 2,201 |
| Fixation Type | Tines |
| Pace Sense Polarity | Quadripolar |
| Steroid Indicator | Yes |

## US Returned Product Analysis

| | |
|---|---|
| Conductor Fracture | 8 |
| Insulation Breach | 3 |
| Crimp/Weld/Bond | 0 |
| Other | 0 |

## US Acute Lead Observations

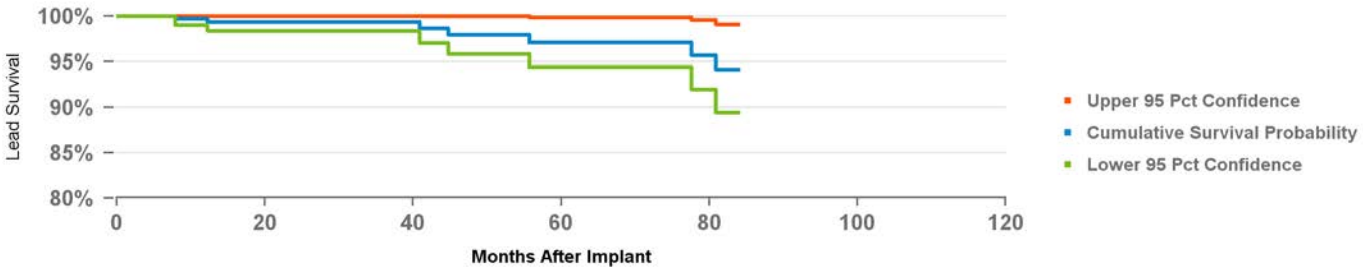
| | |
|---|---|
| Extra Cardiac Stimulation | 1 |
| Failure to Capture | 3 |
| Failure to Sense | 2 |
| Lead Dislodgement | 7 |
| Oversensing | 2 |

## Product Surveillance Registry Results

| | |
|---|---|
| Number of Leads Enrolled in Study | 570 |
| Cumulative Months of Follow-Up | 15,955 |
| Number of Leads Active in Study | 2 |

## Qualifying Complications 8

| | |
|---|---|
| Conductor Fracture | 3 |
| Failure to Capture | 2 |
| Failure to Sense | 3 |




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

# Method for Estimating Insertable Cardiac Monitor Performance

**Insertable Cardiac Monitor (ICM) Performance Analysis**

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

The performance report information is determined from the analysis of available complaint and available CareLink™ network data. An ICM model will be included in this report when it has accumulated at least 10,000 implant months and will remain in the report as long as at least 500 devices remain active in the CareLink™ population.

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

ICMs returned to Medtronic are analyzed to determine whether or not they meet performance limits established by Medtronic. Although returned product analyses are valuable for gaining insight into failure mechanisms, this data can be limited in determining the survival probability as not all ICMs are returned to Medtronic for analysis. As ICMs are diagnostic devices, it is possible for a device not to be returned after meeting the device designated longevity or the patient receiving a diagnosis of their condition.

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

### Qualifying Complication or Malfunctions

All reported ICM complaints are adjudicated by subject matter experts for inclusion as a product performance event given available information. These product performance events are then cross-referenced with the CareLink™ population for inclusion in the survival analysis.

Product Performance events include, but are not limited to:

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

**The CareLink™ Network**

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

### Statistical and Data Analysis Methods

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

## Method for Estimating Insertable Cardiac Monitor Performance continued

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

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

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

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

### Definition of Analysis Dataset

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

# LNQ22 LINQ II

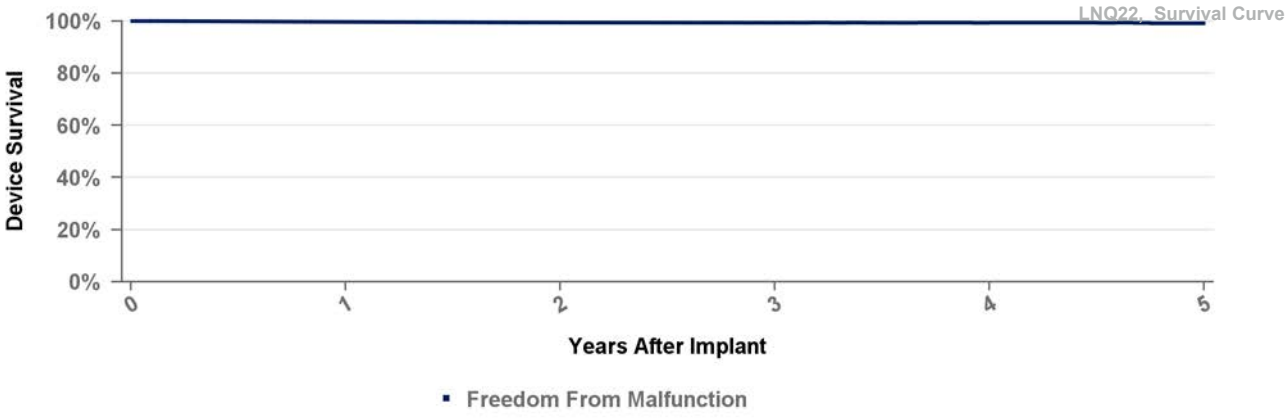
| | |
|---|---|
| **US Market Release** | 03Jul2020 |
| **CE Approval Date** | 05Nov2019 |
| **Serial Number Prefix** | RLB |
| **Mass** | 3.4 g |
| **Volume** | 1.4 cc |
| **Estimated Longevity** | 4.5 years |

### CareLink Population

| | |
|---|---|
| Enrolled | 422,883 |
| Active | 321,146 |
| Cumulative Follow-Up Months | 8,128,435 |

### Qualifying Malfunctions/Complications

| | |
|---|---|
| Amplified Noise due to moisture (FA1368) | 1,371 |
| Electrical Component | 10 |
| Other | 28 |
| Premature Battery Depletion | 327 |
| Software/Firmware | 107 |




| Years | 1 | 2 | 3 | 4 | at 60 mo |
|---|---|---|---|---|---|
| Freedom From Malfunction | 99.7% | 99.4% | 99.4% | 99.3% | 99.3% |
| Effective Sample Size | 266333 | 149150 | 64216 | 16870 | 838 |

# 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.

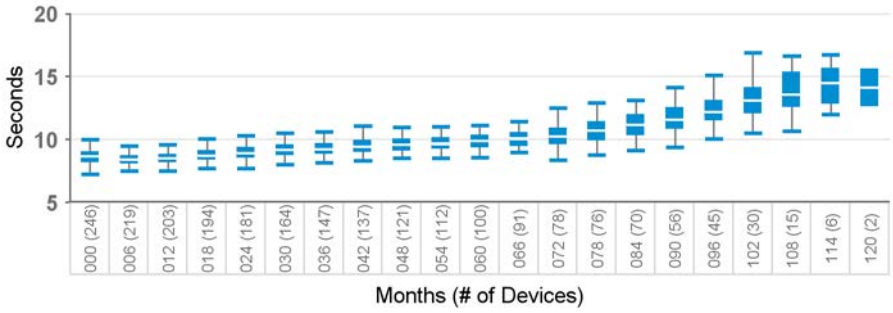
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

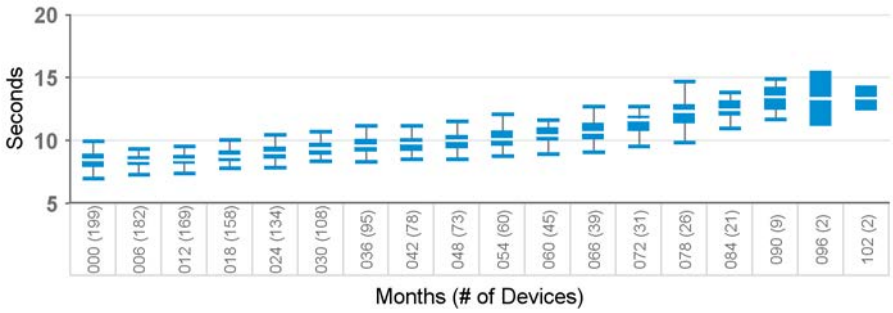
## D204VRM, D214VRM, D224VRC, D234VRC

| Model Number | Brand |
|---|---|
| D234VRC | Secura VR |



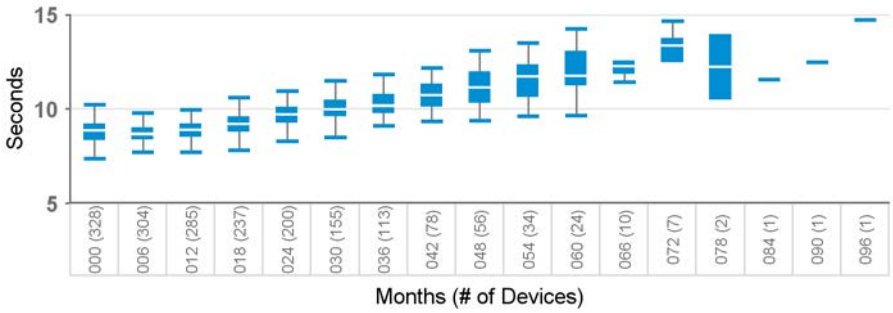

## D264DRG, D284DRG, D384DRx, D394DRx

| Model Number | Brand |
|---|---|
| D284DRG | Maximo II DR |
| D394DRG | Egida DR |



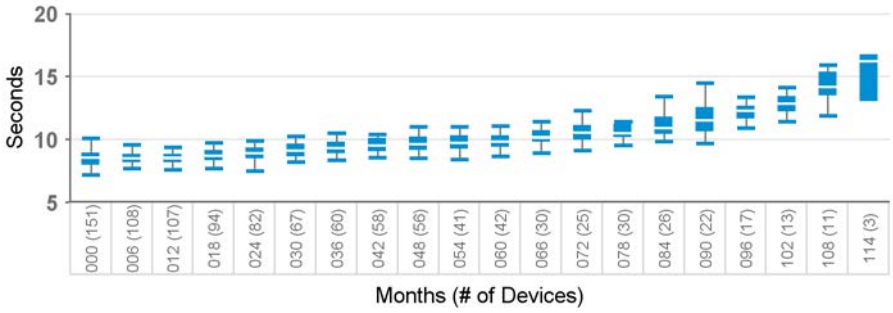

## D264TRM, D284TRK, D384TRx, D394TRx

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



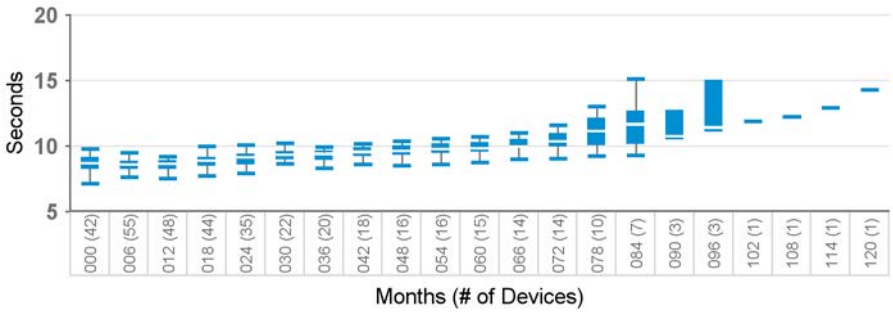

## D264VRM, D284VRC, D384VRx, D394VRx

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



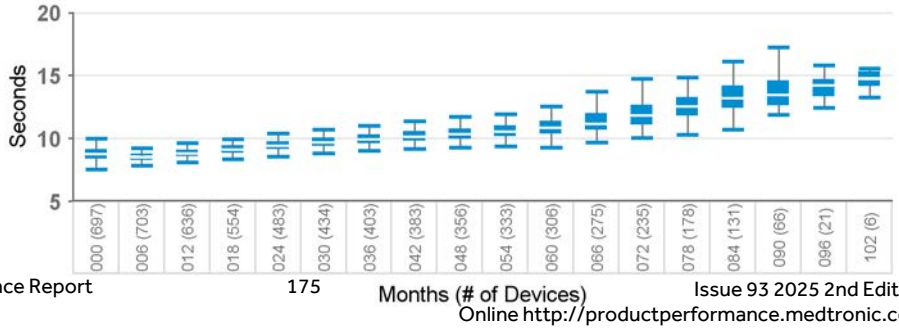

## D274VRC, D294VRC

| Model Number | Brand |
|---|---|
| D294VRC | Virtuoso II VR |




## D314DRx

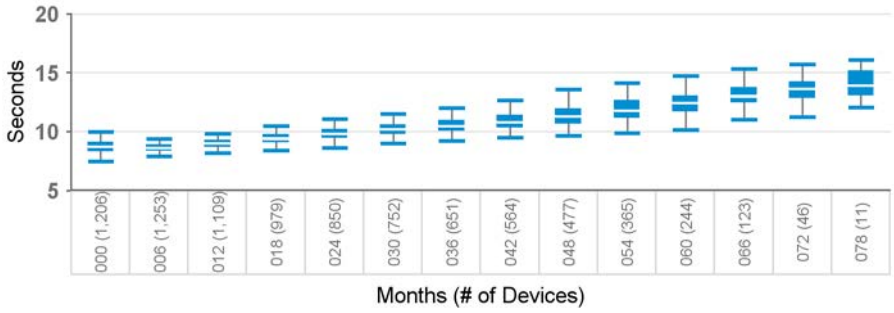
| Model Number | Brand |
|---|---|
| D314DRG | Protecta XT DR |



# ICD and CRT-D Charge Time Performance

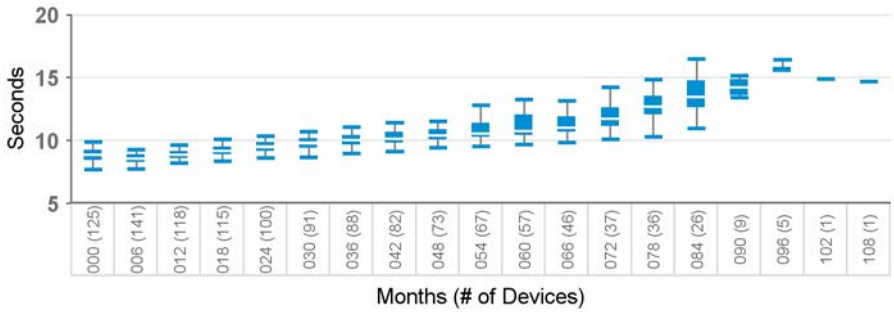
## D314TRx

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



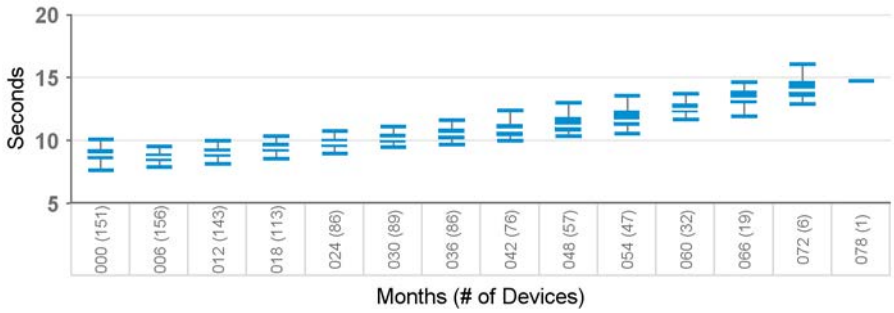

## D334DRx, D364DRx

| Model Number | Brand |
|---|---|
| D364DRG | Protecta DR |
| D364DRM | Protecta DR |



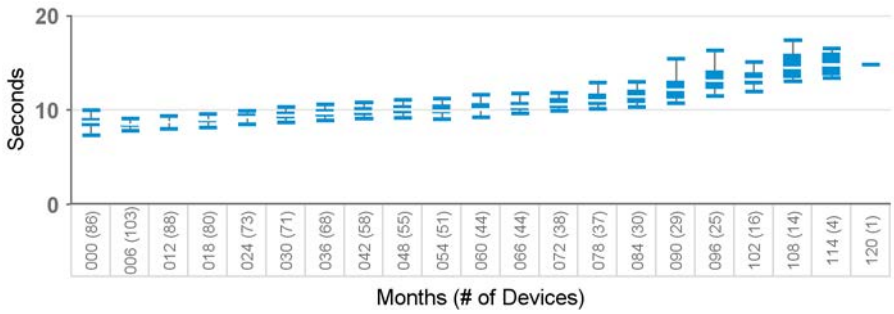

## D334TRx, D364TRx

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



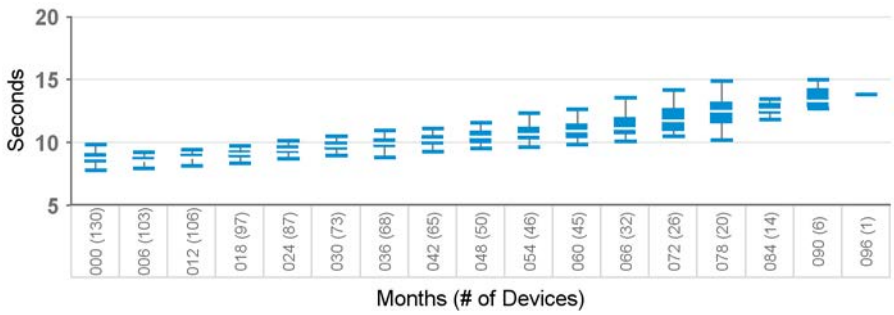

## D334VRx, D364VRx

| Model Number | Brand |
|---|---|
| D364VRG | Protecta VR |
| D364VRM | Protecta VR |



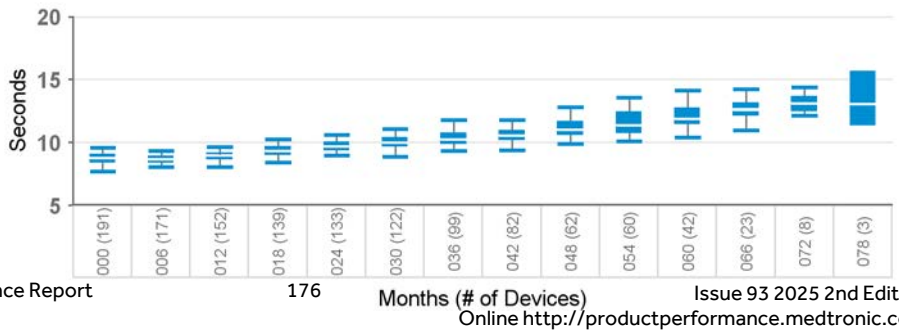

## D354DRx

| Model Number | Brand |
|---|---|
| D354DRG | Protecta XT DR |
| D354DRM | Protecta XT DR |




## D354TRx

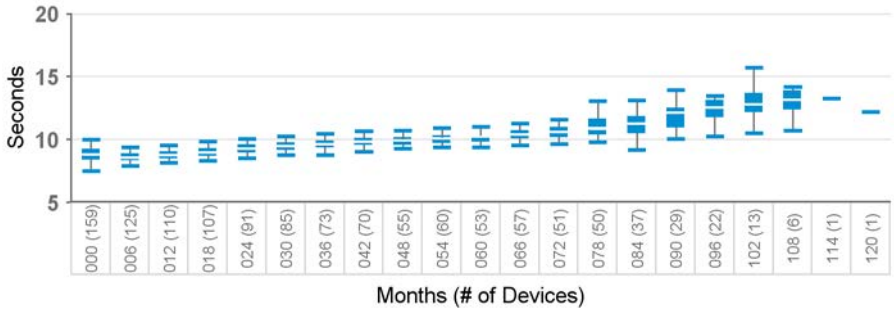
| Model Number | Brand |
|---|---|
| D354TRG | Protecta XT CRT-D |
| D354TRM | Protecta XT CRT-D |



# ICD and CRT-D Charge Time Performance

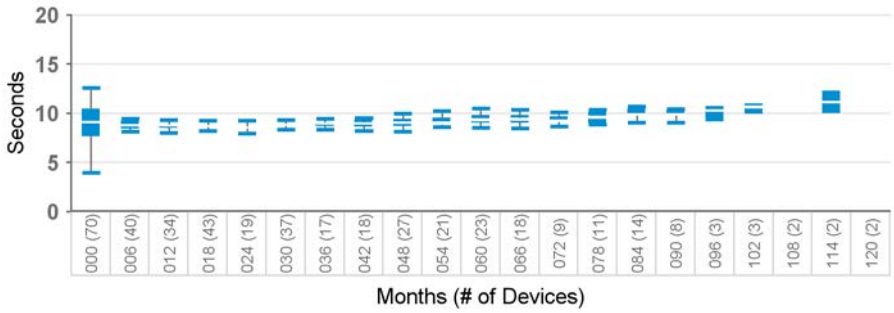
## D354VRx

| Model Number | Brand |
|---|---|
| D354VRG | Protecta XT VR |
| D354VRM | Protecta XT VR |




## DDxxxxx, DR

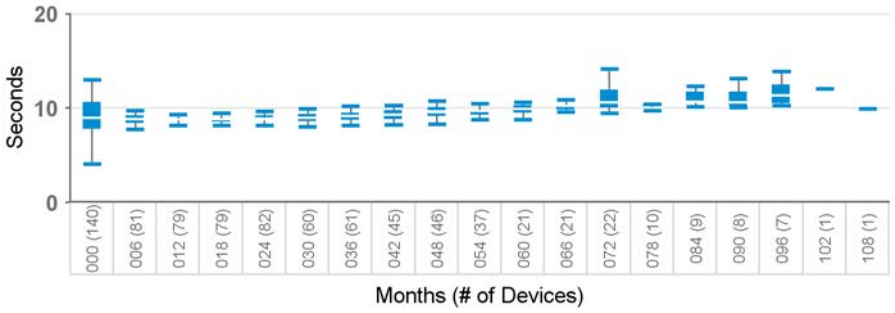
| Model Number | Brand |
|---|---|
| DDBB1D1 | Evera XT |
| DDBB1D4 | Evera XT |
| DDBB2D1 | Evera XT |
| DDBB2D4 | Evera XT |
| DDBC3D1 | Evera S |
| DDBC3D4 | Evera S |
| DDMB1D1 | Evera MRI XT |
| DDMB1D4 | Evera MRI XT |
| DDMB2D1 | Evera MRI XT |
| DDMB2D4 | Evera MRI XT |
| DDMC3D1 | Evera MRI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



# ICD and CRT-D Charge Time Performance

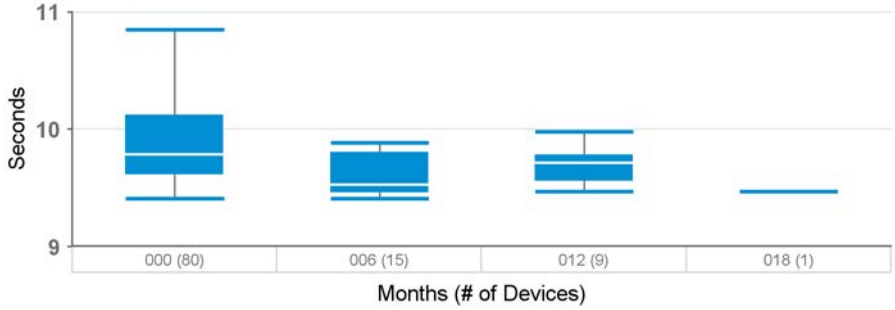
## DTxxxxx, CRT-D

| Model Number | Brand |
|---|---|
| DTBA1D1 | Viva XT |
| DTBA1D4 | Viva XT |
| DTBA1Q1 | Viva Quad XT |
| DTBA1QQ | Viva Quad XT |
| DTBA2D1 | Viva XT |
| DTBA2D4 | Viva XT |
| DTBA2Q1 | Viva Quad XT |
| DTBA2QQ | Viva Quad XT |
| DTBB1D1 | Viva S |
| DTBB1D4 | Viva S |
| DTBB1Q1 | Viva Quad S |
| DTBB1QQ | Viva Quad S |
| DTBB2D1 | Viva S |
| DTBB2D4 | Viva S |
| DTBB2QQ | Viva Quad S |
| DTBC2D1 | Brava |
| DTBC2D4 | Brava |
| DTBC2Q1 | Brava Quad |
| DTBC2QQ | Brava Quad |
| DTBX1QQ | Viva Quad C |
| DTBX2QQ | Viva Quad C |
| DTMA1D1 | Claria MRI |
| DTMA1D4 | Claria MRI |
| DTMA1Q1 | Claria MRI |
| DTMA1QQ | Claria MRI |
| DTMA2D1 | Claria MRI |
| DTMA2D4 | Claria MRI |
| DTMA2Q1 | Claria MRI |
| DTMA2QQ | Claria MRI |
| DTMB1D1 | Amplia MRI |
| 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 |




## DVEA3E4, DVEX2E4, DVEX3E4

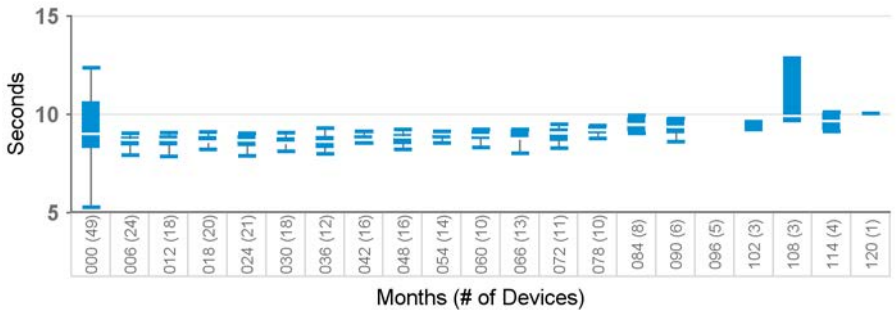
| Model Number | Brand |
|---|---|
| DVEA3E4 | Aurora EV-ICD |



# ICD and CRT-D Charge Time Performance

## DVxxxxx, VR

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



# Potential for Suspension of Dynamic Sensing Algorithm

## Aurora EV-ICD™ (DVEA3E4) and Clinical EV-ICD (DVEX3E4)

Original Date of Communication: October 2025

- The manufacturing change and SmartSync release mentioned below are based on regulatory approvals. Check with your Medtronic Representative for approval status in your geography.
- The serial number look up does not identify devices that have been updated via SmartSync. A CareLink report is available to assist with identifying devices that require the update, contact your Medtronic representative to obtain a copy of this report.

**ORIGINAL COMMUNICATION - OCTOBER 2025**

In a subset of Aurora EV-ICD™ (DVEA3E4) and Clinical EV-ICD (DVEX3E4) devices, there is a potential for delayed time to high-voltage therapy should a rare sequence of events occur. **A device update via CareLink™ SmartSync™ Device manager is available to eliminate this potential delay.** Through 2 October 2025, six (6) events (delay of 2-17 seconds) were observed among approximately 4,900 implanted devices worldwide (~0.12%). Five of the six devices experienced this behavior during a controlled defibrillation threshold test. While not observed clinically, a delay in HV therapy may impact defibrillation efficacy. There have been **zero** reports of permanent harm or death due to this behavior.

The root cause of this behavior is related to the EV-ICD dynamic sensing algorithm becoming static if a charge-end occurs while the device is processing a sensed event. This will set the sensitivity to 53% of the prior R-wave amplitude. A subsequent R-wave amplitude that exceeds the static 53% level will restore automatic sensitivity operation and allow R-wave synchronization for therapy delivery. See Appendix A for additional details.

Medtronic has implemented manufacturing changes, and devices manufactured with this update are not susceptible to this delay. In previously distributed devices, a device interrogation with the CareLink™ SmartSync™ Aurora EV-ICD™ application (D00U025) on CareLink SmartSync Device Managers will resolve the potential for this behavior (see Appendix B).

Individual devices susceptible to this behavior can be identified via search/look-up on the Medtronic Product Performance Report Website (productperformance.medtronic.com).

**PATIENT MANAGEMENT RECOMMENDATIONS FOR PREVIOUSLY DISTRIBUTED DEVICES:**

Medtronic acknowledges that each patient requires unique clinical considerations. Based on internal investigation and consultation with our Independent Physician Quality Panel, Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
- Schedule an **in-clinic SmartSync interrogation** to receive the software update, with the intent for all patients to receive the update within **the next 3-6 months.**

For patients remotely followed via CareLink, your Medtronic representative can provide a report to assist with identifying patients that require this in-person update. You may contact your local representative to obtain an updated copy of the report at any time.

**APPENDIX A**

**TECHNICAL DETAILS**

The Aurora EV-ICD dynamic sensing algorithm is unique due to the implant location within the substernal space. Figure 1 below illustrates how the device sets sensitivity beat-by-beat based on R-wave measurement of the rectified and filtered EGM.

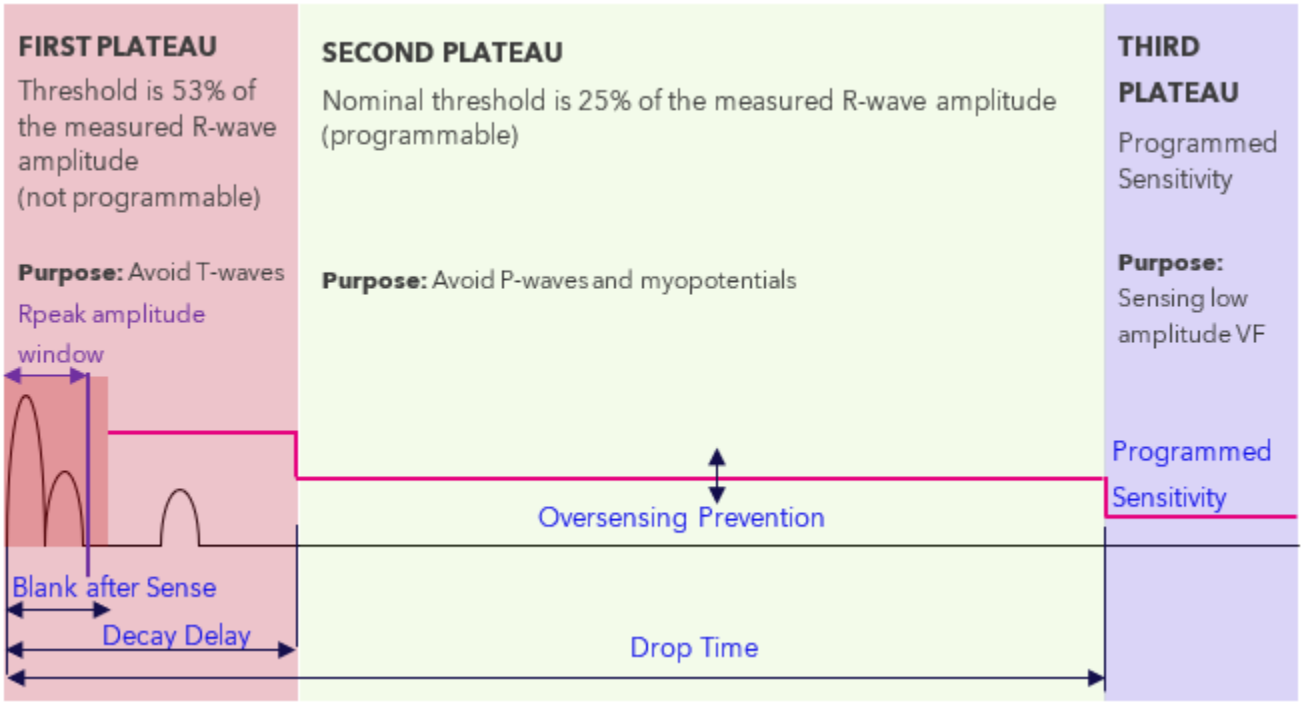



Figure 1 - Operation of Sensing Thresholds - The first plateau duration ("Decay Delay") is nominally 360 ms, the second plateau duration ("Drop Time") is nominally 1500 ms, and the third plateau lasts until another sensed beat. R-wave amplitude measurements take place during "Rpeak amplitude window" shown above, nominally 128.75 ms (not programmable).

The dynamic sensing algorithm may become suspended at the first plateau if the following sequence of events occurs:

1. Charge-end occurs within 128.75ms of the prior sensed beat, thus interrupting the in-progress R-wave measurement-***suspension of the dynamic sensing algorithm occurs and the sensitivity plateau becomes static at 53%.***
2. The sensitivity plateau will remain at 53% until a subsequent **R-wave amplitude exceeds this value**. In the case of a significant drop in R-wave amplitudes, delay in HV therapy delivery can occur.

While not observed clinically, a delay in HV therapy may impact defibrillation efficacy and result in harm related to failure to terminate an arrhythmia.

This behavior **applies only to non-committed shocks**. This includes cardioversion (CV) therapies in the ventricular tachycardia (VT), fast ventricular tachycardia (FVT) zones, and the first shock in the ventricular fibrillation (VF) zone.

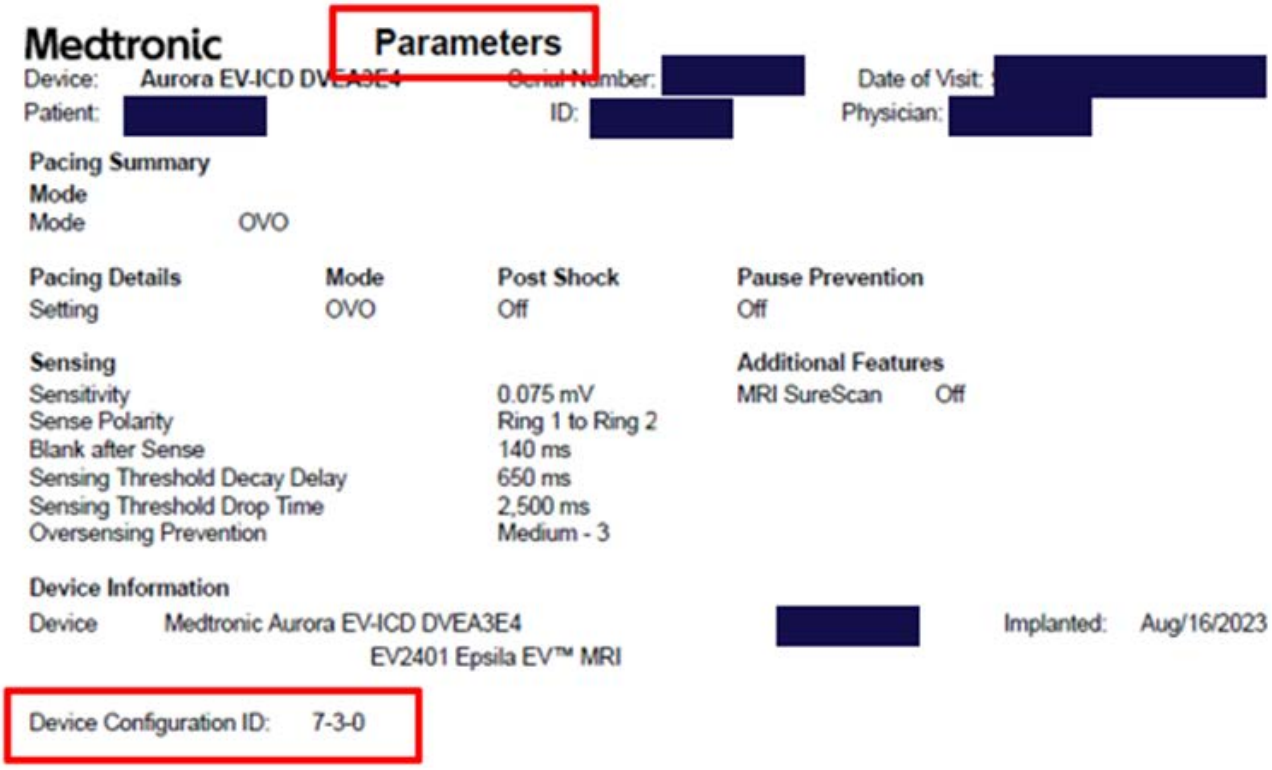
A Medtronic white paper, *Suspension of the Dynamic Sensing Algorithm: Determining the Potential Occurrence, Duration, and Patient Impacts of Delays to Therapy*, with additional technical details is available from your Medtronic representative if desired.

**APPENDIX B**

To identify if a patient's device has successfully received the update, view the displayed Configuration ID and confirm the first number in the sequence as indicated below:

- Clinical device (DVEX3E4) configuration ID is 6-1-0 or greater
- Aurora EV-ICD (DVEA3E4) is 7-3-0 or greater

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 'Parameters.' The Configuration ID is also included on the CareLink patient report that is available upon request. Note that devices that have successfully received the update will not be removed from the serial number lookup on the Medtronic Product Performance Report Website and will remain listed as in scope, therefore checking the configuration ID is required.



Medtronic

Parameters

Device: Aurora EV-ICD DVEA3E4 Serial Number: [redacted] Date of Visit: [redacted]

Patient: [redacted] ID: [redacted] Physician: [redacted]

**Pacing Summary**

**Mode**

Mode OVO

| Pacing Details | Mode | Post Shock | Pause Prevention |
|---|---|---|---|
| Setting | OVO | Off | Off |

**Sensing**

| | |
|---|---|
| Sensitivity | 0.075 mV |
| Sense Polarity | Ring 1 to Ring 2 |
| Blank after Sense | 140 ms |
| Sensing Threshold Decay Delay | 650 ms |
| Sensing Threshold Drop Time | 2,500 ms |
| Oversensing Prevention | Medium - 3 |

**Additional Features**

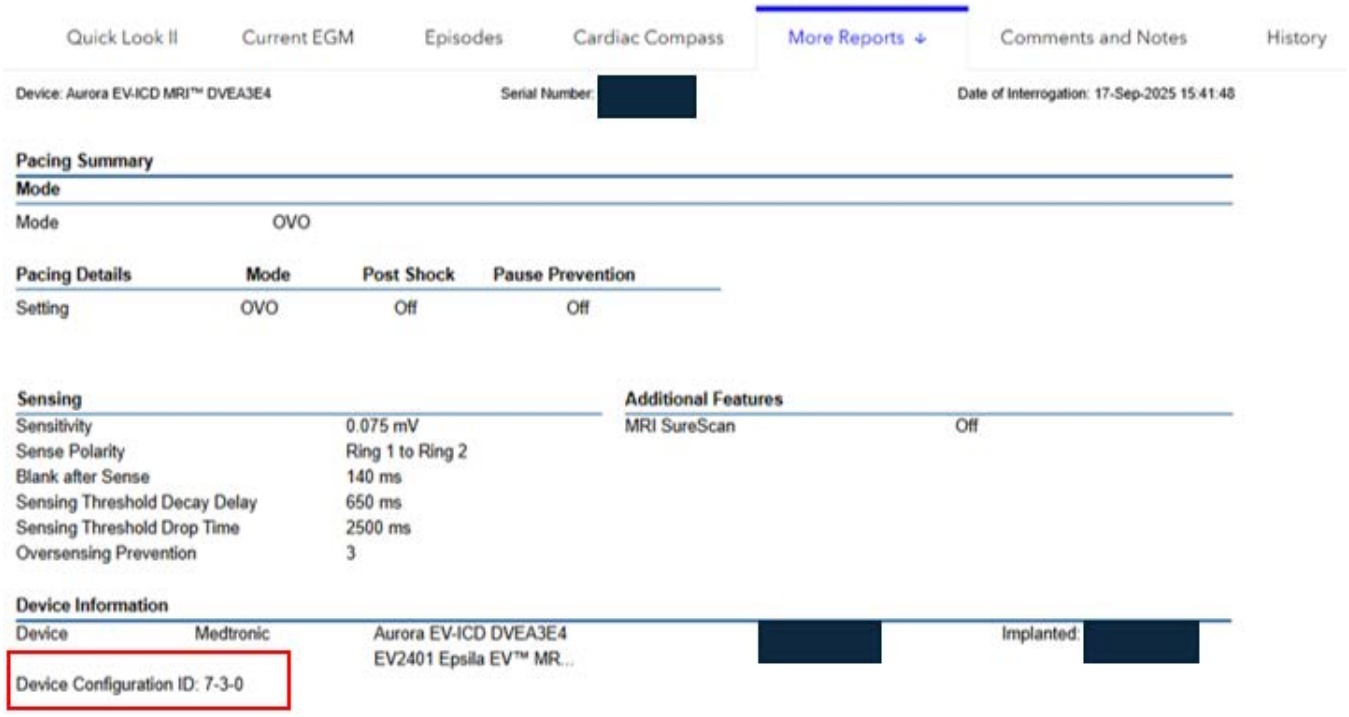
MRI SureScan Off

**Device Information**

Device Medtronic Aurora EV-ICD DVEA3E4 [redacted] Implanted: Aug/16/2023

EV2401 Epsila EV™ MRI

Device Configuration ID: 7-3-0


Quick Look II | Current EGM | Episodes | Cardiac Compass | More Reports | Comments and Notes | History

Device: Aurora EV-ICD MRI™ DVEA3E4 Serial Number: [redacted] Date of Interrogation: 17-Sep-2025 15:41:48

**Pacing Summary**

**Mode**

| Mode | OVO |
|---|---|

| Pacing Details | Mode | Post Shock | Pause Prevention |
|---|---|---|---|
| Setting | OVO | Off | Off |

**Sensing**

| | |
|---|---|
| Sensitivity | 0.075 mV |
| Sense Polarity | Ring 1 to Ring 2 |
| Blank after Sense | 140 ms |
| Sensing Threshold Decay Delay | 650 ms |
| Sensing Threshold Drop Time | 2500 ms |
| Oversensing Prevention | 3 |

**Additional Features**

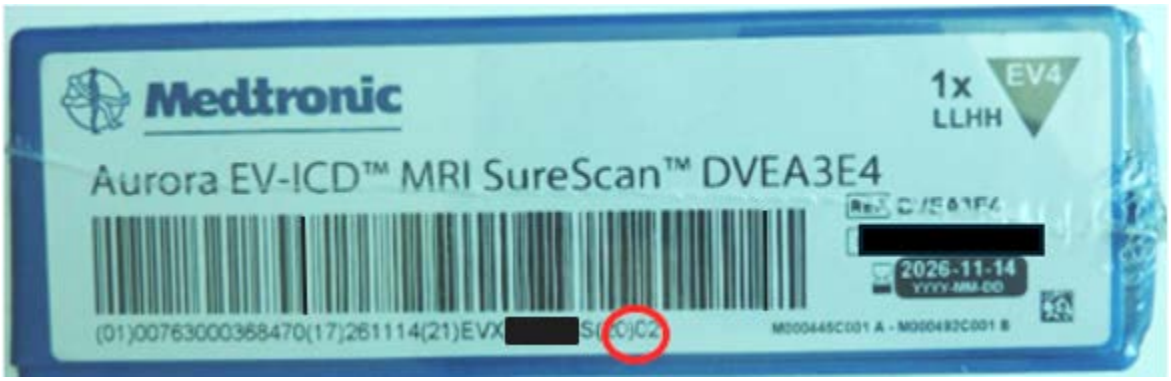
| | |
|---|---|
| MRI SureScan | Off |

**Device Information**

| | | | | |
|---|---|---|---|---|
| Device | Medtronic | Aurora EV-ICD DVEA3E4 EV2401 Epsila EV™ MR... | [redacted] | Implanted: [redacted] |

Device Configuration ID: 7-3-0

To identify if a device was manufactured with the update, look for version 02 or higher listed underneath the barcode:



# Potential for Autonomous Cursor Motion

## CareLink™ 2090 Programmer

Original Date of Communication: July 2024

**STATUS UPDATE – OCTOBER 2025**

As of 09 October 2025, Medtronic has 643 reports of autonomous cursor behavior including reports identified during the software update, including five reports of unintended therapy delivered. There have been no reports of permanent harm or death associated with this behavior.

**ORIGINAL COMMUNICATION - JULY 2024**

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

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

**INSTRUMENT MANAGEMENT RECOMMENDATIONS:**

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

# LINQ II ICM Potential for Amplified Noise June 2024

## LINQ II™ Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2024

**STATUS UPDATE – OCTOBER 2025**

As of 15 October 2025, Medtronic has identified 1,371 (2.12%) devices that have exhibited these characteristics, with zero (0) reports of serious harm. Medtronic estimates the projected rate of this issue to be 3.4% at 2 years or 8.7% at 4.5 years for the identified subset, and patient management recommendations are unchanged.

**ORIGINAL COMMUNICATION – JUNE 2024**

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

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

**PATIENT MANAGEMENT RECOMMENDATIONS:**

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

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

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

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

# SOFTWARE UPDATE AVAILABLE - Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

## Claria, Amplia, Compia, Viva, Brava, Visia AF, Evera, Primo, Mirro ICDs/CRT-Ds

Original Date of Communication: May 2023

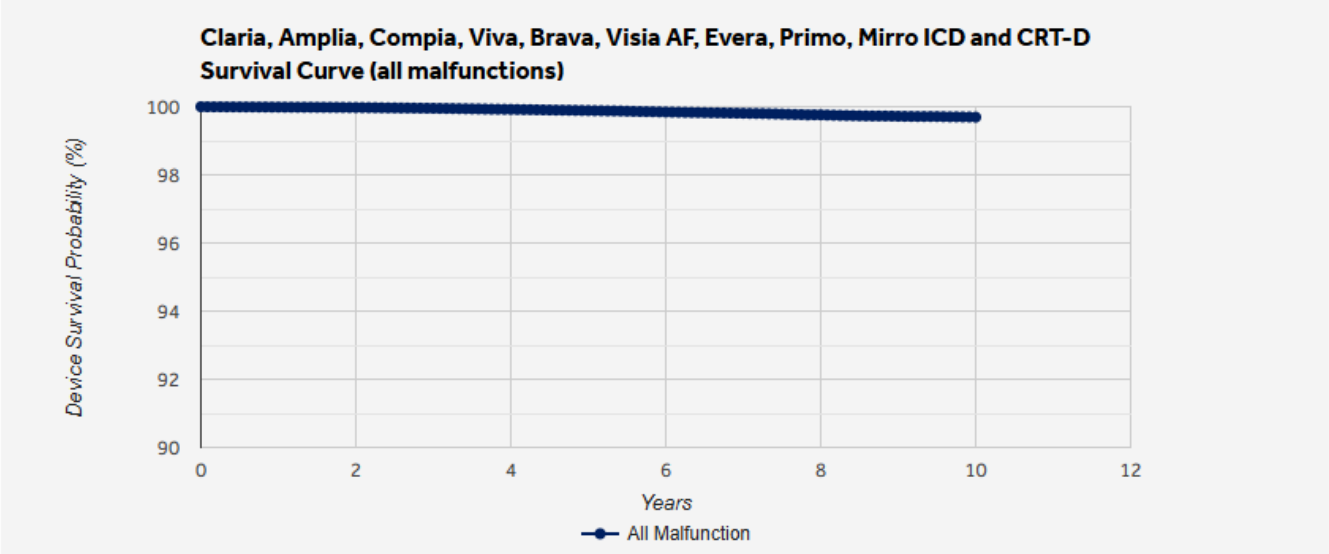
**Devices managed with an updated programming system are no longer in scope of the May 2023 communication.**

**STATUS UPDATE – OCTOBER 2025**

As of 07 October 2025, Medtronic has identified 42 devices (representing 0.0033% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

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

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




| | 1 yr | 2 yr | 3 yr | 4 yr | 5 yr | 6 yr | 7 yr | 8 yr | 9 yr | 10 yr |
|---|---|---|---|---|---|---|---|---|---|---|
| % | 100.0% | 100.0% | 100.0% | 99.9% | 99.9% | 99.8% | 99.8% | 99.8% | 99.7% | 99.7% |
| # | 639,738 | 596,998 | 540,531 | 473,740 | 413,053 | 333,326 | 249,327 | 170,794 | 107,162 | 60,069 |

**ORIGINAL COMMUNICATION - MAY 2023**

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

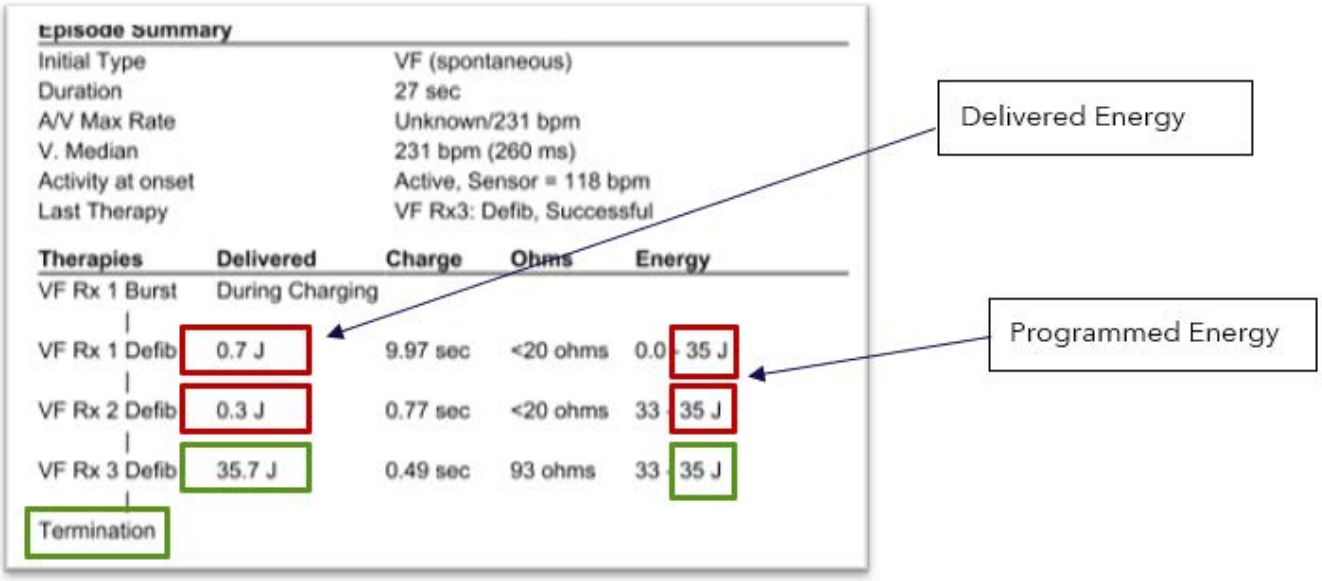
A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

**PATIENT MANAGEMENT RECOMMENDATIONS:**

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).




Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

**ISSUE DETAILS:**

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

**RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:**

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm. Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

**TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming**

| Population | | Projected event rate (one or more reduced- or no-energy HV therapies in an episode) | Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia |
|---|---|---|---|
| **Glassed feedthrough devices with current field programming (~816,000 devices)** | Overall Population of Devices | **0.02% @ 5 years*** | **0.004% @ 5 years*** |
| | For Patients with History of HV Therapy | **0.48% @ 5 years*** | **0.08% @ 5 years*** |
| **Glassed feedthrough devices after all HV pathways reprogrammed B>AX** | Overall Population of Devices | **0.005% @ 9 years**** | **0.001% @ 9 years**** |
| | For Patients with History of HV Therapy | **0.04% @ 9 years**** | **0.01% @ 9 years**** |
| **Historical devices dating back to 2012 (~651,000 devices)** | Overall Population of Devices | **0.006% @ 9years**** | **0.001% @ 9years**** |
| | For Patients with History of HV Therapy | **0.05% @ 9 years**** | **0.01% @ 9 years**** |

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

**APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)**

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device. **Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Evera/Visia AF/Primo/Mirro ICDs and Viva/Brava/Claria/Amplia/Compia CRT-D devices:

> Identifying SCP events: For episodes in which a high voltage therapy was delivered, if there is a significantly reduced-energy or no-energy shock delivered, the device may have experienced an SCP event. In each stored episode, delivered energy is displayed in the Episode Text and on the Interval Plot. If an SCP event occurred, this text may indicate that a lower energy was delivered and <20 ohm impedance value. Note: there is currently no available SCP alert in this family of devices.
>
> Clinicians can consider enabling the device audible alert and/or CareAlert for "Number of Shocks Delivered in an Episode," with "N = 1." Turning this alert "ON" may help ensure the patient and/or clinic is made aware when a HV therapy is delivered by the device.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

# SOFTWARE UPDATE AVAILABLE - Increased Potential for Reduced Energy or No Energy Delivered During HV Therapy When Programmed AX>B (2023)

## Cobalt™ XT, Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: May 2023

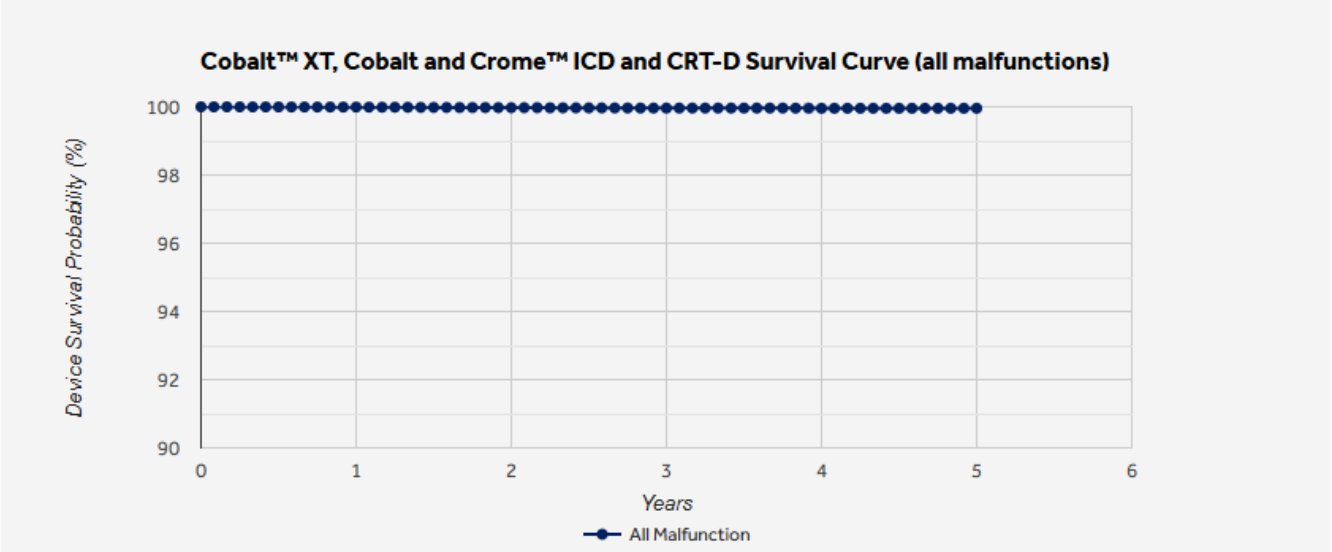
**Devices managed with an updated programming system are no longer in scope of the May 2023 communication.**

**STATUS UPDATE - OCTOBER 2025**

As of 07 October 2025, Medtronic has identified 42 devices (representing 0.0033% of devices distributed worldwide) that experienced the issue described in the communication. No permanent harms or deaths have been attributed to this issue. When programmed B>AX, the occurrence rate remains in line with the historic non-advisory population as described in the original communication. To support the patient management recommendations in the May 2023 communication, Medtronic reviewed more than 680,000 shock events that occurred in over 228,000 unique devices.

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

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




| | 1 yr | 2 yr | 3 yr | 4 yr | 5 yr |
|---|---|---|---|---|---|
| % | 99.99% | 99.97% | 99.96% | 99.96% | 99.96% |
| # | 170,842 | 104,106 | 59,901 | 33,436 | 3,815 |

**ORIGINAL COMMUNICATION - MAY 2023**

This communication advises physicians of a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds. Through 10 April 2023, Medtronic has identified 27 devices from approximately 816,000 devices (representing 0.003%) distributed worldwide that have experienced a reduced- or no-energy HV therapy due to the issue described in this letter. There have been no deaths due to this issue in the glassed feedthrough device population.

With current field programming, devices with a glassed feedthrough may experience increased potential (projected to be 0.02% at 5 years) for reduced- or no-energy output during HV therapy. In some cases, a persistent 50% drop in all pacing lead impedances may be displayed; lead function, however, is not affected. See Issue Details below for further information on root cause, projected rates, risks, and potential harms.

A broader analysis was conducted to determine the incidence of device related reduced- or no-energy HV therapy events outside of the above population, with implants dating back to 2012. Using these historical observed events, projected rates for this population of devices is 0.002% at five (5) years and 0.006% at nine (9) years. This analysis identified two deaths from the historical population in which there was evidence suggesting a device-related reduced- or no-energy HV therapy occurred.

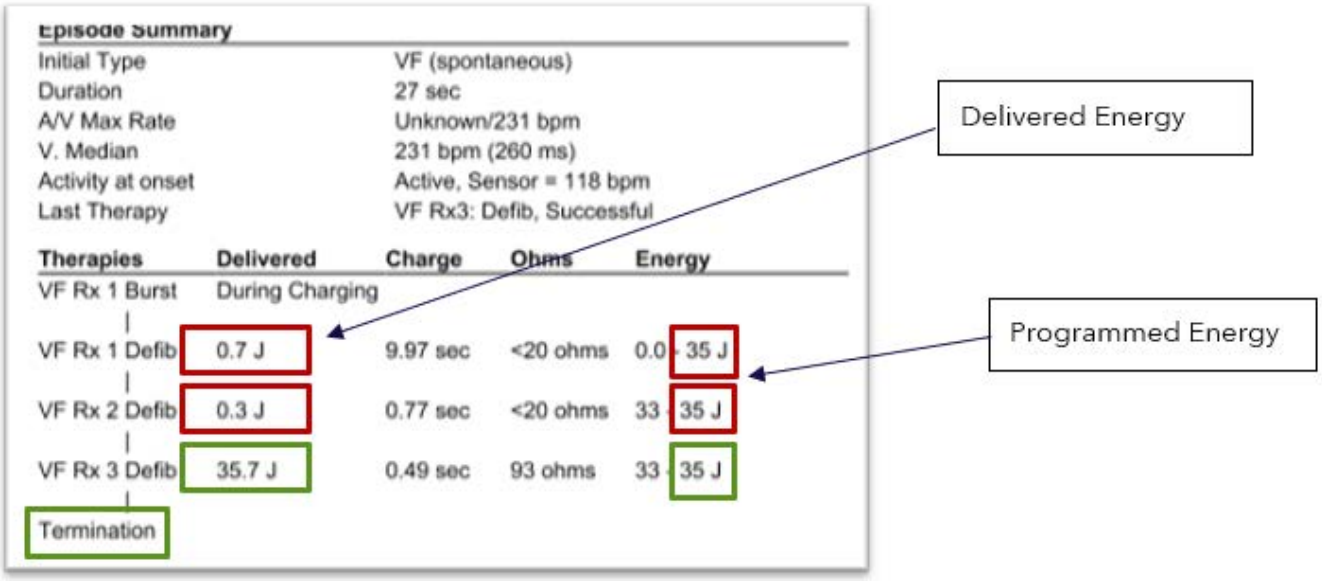
Should this issue occur, pacing, sensing, episode detection, anti-tachycardia pacing (ATP) therapies, battery longevity, and telemetry remain functional. **When devices in the glassed feedthrough population are programmed**

**exclusively in the B>AX configuration, the potential for a reduced- or no-energy HV therapy is 0.002% at five (5) years and 0.005% at nine (9) years, comparable to historical device performance.**

**PATIENT MANAGEMENT RECOMMENDATIONS:**

Medtronic recognizes that each patient requires unique clinical considerations. Based on internal investigation and external consultation with our Independent Physician Quality Panel (IPQP), Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
    - The risk of mortality for patients after reprogramming is 0.001% at 9 years and is less than the risk of patient mortality due to complications associated with device replacement (0.032% - 0.043%[1,2,3]).
- **Program all HV therapy pathways B>AX in all therapy zones to minimize the risk for this issue.**
    - Note: Using "Get Medtronic Nominals" **will require manual reprogramming of Rx5 and Rx6 to B>AX** for all ventricular therapies.
    - For patients remotely followed via CareLink, your Medtronic representative will provide a report to assist with identifying patients who may have one or more HV therapy pathways programmed AX>B. You may contact your local representative to obtain an updated copy of the report at any time.
- **Prioritize reprogramming patients who have both a history of HV therapy and Rx1 programmed AX>B.**
    - Rx1 provides the greatest statistical likelihood to resolve an arrhythmia, and therefore it is important to minimize risk of a reduced- or no-energy HV therapy in the first sequence.
- **For remaining patients with AX>B programming in any HV therapy sequence, schedule the next follow-up for in-clinic reprogramming, with the appropriate discretion**, to minimize potential for reduced- or no-energy HV therapies to occur.
- Per standard practice, check tachyarrhythmia episodes to determine effectiveness of therapies that have been delivered.
    - Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.
    - Verify delivered energy is consistent with programmed energy in the Episode Summary. Note: The image below highlights an episode experiencing intermittent reduced HV therapies (red boxes).




Example screen illustrating reduced-energy shocks for an Evera XT DR device.

- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- **Contact Medtronic Technical Services (1-800-929-4043) or your local representative if one of the following is observed as these may be an indication of either a device or lead-related issue:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.

**ISSUE DETAILS:**

There is an increased potential for a reduced- or no-energy HV therapy in the AX>B configuration when all the following conditions are met:

- The device has a glassed feedthrough (manufactured after July 2017).
- There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
- An unintended current pathway forms within the void created by the insulation separation, capable of conducting high levels of current during HV therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger (see Appendix A). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. SCP events may also be lead related; for both lead-related and device-related unintended current pathways, the defibrillation waveform is truncated early in the energy delivery sequence, resulting in reduced or no energy being delivered (~0-12J).

**RATES OF OCCURRENCE FOR DEVICE-RELATED REDUCED- or NO-ENERGY HV THERAPY:**

Through 10 April 2023, 27 devices with glassed feedthroughs have been identified as experiencing a reduced or no-energy HV therapy (0.003% out of 816,000 distributed devices). Of these, 26 were in devices with an AX>B delivered pathway. Based on an analysis of patients with a glassed feedthrough device and with a history of HV therapy, the observed rate for this issue is 0.03%. See Table 1 below for projected rates of occurrence and risk for harm.

Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the reduced- or no-energy HV therapy is erroneously attributed to a lead failure.

**TABLE 1: Comparison of projected event rates and risk of catastrophic harm, with and without reprogramming**

| Population | | Projected event rate (one or more reduced- or no-energy HV therapies in an episode) | Mortality risk of this issue, considering the probability a sequence of six HV therapies fails to terminate an arrhythmia |
|---|---|---|---|
| **Glassed feedthrough devices with current field programming (~816,000 devices)** | Overall Population of Devices | **0.02% @ 5 years*** | **0.004% @ 5 years*** |
| | For Patients with History of HV Therapy | **0.48% @ 5 years*** | **0.08% @ 5 years*** |
| **Glassed feedthrough devices after all HV pathways reprogrammed B>AX** | Overall Population of Devices | **0.005% @ 9 years**** | **0.001% @ 9 years**** |
| | For Patients with History of HV Therapy | **0.04% @ 9 years**** | **0.01% @ 9 years**** |
| **Historical devices dating back to 2012 (~651,000 devices)** | Overall Population of Devices | **0.006% @ 9years**** | **0.001% @ 9years**** |
| | For Patients with History of HV Therapy | **0.05% @ 9 years**** | **0.01% @ 9 years**** |

* A timeframe of 5 years is used for this projection given the average implant duration of the devices in scope of this communication is approximately 4 years and allowing for adequate time for reprogramming.

** A time frame of 9 years is used based on the weighted average for device longevity for ICDs and CRTDs.

Medtronic is updating Instructions for Use, HV therapy nominals and the programmer interfaces for these device models to be consistent with information in this letter. Medtronic will release additional information once the necessary regulatory approvals have been received, as applicable in the local region.

**APPENDIX A – ADDITIONAL DETAILS ON SHORT CIRCUIT PROTECTION (SCP)**

Short Circuit Protection (SCP) is a safety feature that can only occur during high voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device. **Contact Medtronic for additional guidance if you believe an SCP event occurred.**

Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., feedthrough), thereby minimizing the potential for an SCP event. Comparing the programmed energy to the delivered energy in the Episode Text for a treated episode can be used to identify SCP events. The lead impedance in the Episode Text will also display <20 ohms. Refer to the sections below on how to identify if an SCP event has occurred.

For Cobalt/Crome ICD and CRT-D devices:

Identifying SCP events during high voltage (HV) therapy delivery: When an SCP event has occurred, the device will issue an RV Defibrillation Lead Impedance CareAlert. Audible and wireless alerts are issued, if enabled. These devices are shipped with alerts enabled and are nominally active once implant detection completes.

A CareAlert will occur simultaneous with HV therapy delivery and will specifically report "RV Defib Lead Impedance 0 Ω" with the same time stamp as the therapy delivery. The alert condition is displayed in the CareAlert Events log (Data >> CareAlert Events). The Quick Look Observations will also display "Alert: RV defib lead impedance warning on Mmm/DD/YYYY." SCP events are not reflected in the long-term lead impedance trends.

Following an SCP event in devices with both the SVC Coil and Active Can enabled, the device will turn off the SVC coil. If the SCP event is caused by a lead integrity issue involving the SVC coil, turning off the SVC coil can allow any subsequent shocks to be delivered using the RV Coil -to- Active Can vector. The programmed therapy parameters will indicate the SVC Coil has been automatically disabled. The SVC coil will remain off until it is turned back on by the clinician.

If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the Last High Voltage Therapy section on the Battery and Lead Measurement screen of the programmer.

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[1]Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2]Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3]Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

# SOFTWARE UPDATE AVAILABLE - Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event (2022)

## Cobalt™ XT, Cobalt™ and Crome™ ICDs and CRT-Ds

Original Date of Communication: June 2022

**STATUS UPDATE - OCTOBER 2025**

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

As of 10 August 2022, a software release is now available for CareLink™ SmartSync™ Device Managers (SmartSync). Once a SmartSync tablet has been updated with software application D00U005 version 7.1.1 (or higher), the programmer will deploy a device update to Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) to prevent the potential for an intermittent, second-phase Short Circuit Protection (SCP) event during high-voltage (HV) therapy delivery. This software update was previously announced as part of an advisory communication Medtronic issued in June 2022 (see original communication posted below).

Through 08 October 2025, Medtronic has confirmed 161 devices (representing 0.09% 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.

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

## Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

**STATUS UPDATE - OCTOBER 2025**

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 where Brady and Pause detections are disabled following a partial electrical reset.

Reveal LINQ ICMs that are interrogated in-office with an updated 2090 or Encore programmer are no longer susceptible to this issue. This corrective fix to the device cannot be delivered with the Reveal LINQ™ Mobile Manager (LMM). Until the update is installed, future partial electrical resets may disable Brady and/or Pause detections as described in the June 2021 communication.

Note: The immediate availability of the software release is specific to countries that follow FDA approval, or that do not require software to be regulated. Release timing may differ for other geographies including those that require CE Mark approval. Check with your local Medtronic representative to determine if the software update is available in your region.

Please work with your local Medtronic Representative to update all 2090 and Encore device programmers. In addition, Medtronic requests you follow the below patient management recommendations:

**Patient Management Recommendations:**

- Reveal LINQ ICMs with a confirmed partial electrical reset will receive the corrective fix for this issue immediately by the device clinician completing the following steps:
    1. Interrogate the ICM with an updated 2090 or Encore programmer (software application SW026 version 8.3). The corrective fix is automatically installed during initial interrogation. To confirm an ICM has successfully received the update, refer to Appendix A.
    2. Per the Instructions for Use (IFU), following any electrical reset, verify ICM parameters are set appropriately for the patient and reprogram if necessary.
- For Reveal LINQ ICMs that have not experienced a partial electrical reset, an update will occur during the next in-clinic visit in which an updated Model 2090 or Encore programmer installed with software application SW026 version 8.3 (or higher) is used to interrogate the ICM. Partial electrical resets will disable Brady and/or Pause detections as described in the June 2021 communication until the update is installed on to the patient's ICM.

- For patients who are actively followed on CareLink, continue routine monitoring for CareAlerts and verify notification settings for electrical resets.
- Per the IFU, notify your Medtronic representative if an electrical reset occurs. If a partial electrical reset is confirmed, the patient's ICM will require reprogramming.
- During the programmer session, the corrective fix will be installed automatically.

**ORIGINAL COMMUNICATION - JUNE 2021**

This notice is to inform you that Reveal LINQ with TruRhythm ICMs that undergo a partial electrical reset appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events to clinicians. Medtronic estimates that 0.049% of Reveal LINQ with TruRhythm ICMs have experienced a partial electrical reset resulting in the inability to detect Brady and Pause events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue. After a partial electrical reset, these Brady and Pause episode types will not be reported to the clinician.

- Currently implanted/distributed Reveal LINQ with TruRhythm ICMs will receive a future software update to correct this issue delivered via the Model 2090 and Encore™ programmers. The corrective fix is anticipated to be available late calendar year 2021 (U.S.). Availability of the software will be communicated once Medtronic has obtained the necessary regulatory approvals.
- There will be an update for future manufactured Reveal LINQ with TruRhythm ICMs, which is anticipated to be available in the U.S. October 2021. Medtronic will inform physicians once this manufacturing update is implemented into newly manufactured Reveal LINQ with TruRhythm ICMs.

**ISSUE DESCRIPTION**

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

All Reveal LINQ with TruRhythm ICMs currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 87 complaints related to an electrical reset. The projected rate of a Reveal LINQ with TruRhythm ICM experiencing a partial electrical reset that results in the inability to detect Brady and Pause events is 0.056% at 36 months. Complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery. Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady and Pause events, and an explant procedure.

If a partial electrical reset occurs, CareLink™, Model 2090 and Encore programmer software and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady and Pause

events will not be automatically collected. The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing, and mark symptoms.

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

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

1. Please share this notification with the Cardiology and cardiac monitoring departments, Pacemaker/Device Clinic leadership, and physicians who implant or manage patients with LINQ II insertable cardiac monitors (ICMs).
2. Complete the enclosed Confirmation Form and email to RS.CFQFCA@medtronic.com

**PATIENT MANAGEMENT RECOMMENDATIONS**

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

**Identifying if an electrical reset has occurred:**

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

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

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. Note: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady or Pause events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

**Patients with a confirmed partial electrical reset:**

- Medtronic medical staff, in consultation with our Independent Physician Quality Panel, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
- When monitoring for Brady or Pause events, it is important to note that the Patient Assistant (Patient Activator) will continue to manually mark symptoms even after a partial electrical reset. Patient-activated recordings are not impacted by this issue. If patients require monitoring for Brady and/or Pause events, and it is not acceptable to wait for the software update to become available (see details below), consider device replacement. Recognize that exposure to EMI could introduce this issue for new device implants that occur before the manufacturing update is implemented anticipated in the U.S. in October 2021.
- As a reminder, per the Reveal LINQ with TruRhythm ICM's Instructions for Use, contact Medtronic anytime an electrical reset occurs.

**FUTURE SOFTWARE UPDATE AVAILABILITY**

Medtronic is developing a programmer-delivered software update to correct this issue for Reveal LINQ with TruRhythm ICMs currently implanted or in distribution. Anticipated availability in the U.S. is late calendar year 2021; Medtronic representatives will inform you of the availability and work with you to install the software onto clinic and hospital 2090 and Encore programmers. LMM application software will be unable to deliver the software update for this issue. In order for patients with Reveal LINQ with TruRhythm ICMs to receive the update, the device will need to be interrogated with an updated 2090 or Encore programmer.

**APPENDIX A**

**Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitoring Systems**

Brady & Pause Detections Disabled Following Partial Electrical Reset

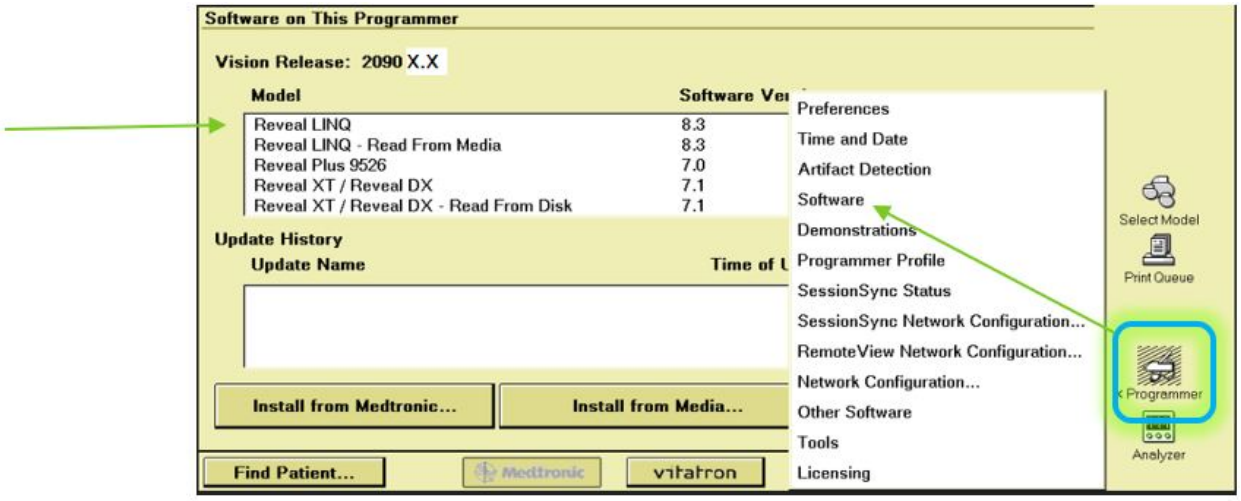
Software Update Available

**How do I update my Model 2090 and Encore programmers with the Reveal LINQ with TruRhythm software described in the November 2021 communication)?**

Software update SW026 version 8.3 can be installed onto all Model 2090 or Encore programmers through either the Medtronic Software Distribution Network (SDN) or via a USB. Medtronic representatives will work with you to install the software.

**How do I confirm if a Model 2090 or Encore programmer has already been installed with the updated software (SW026 v8.3)?**

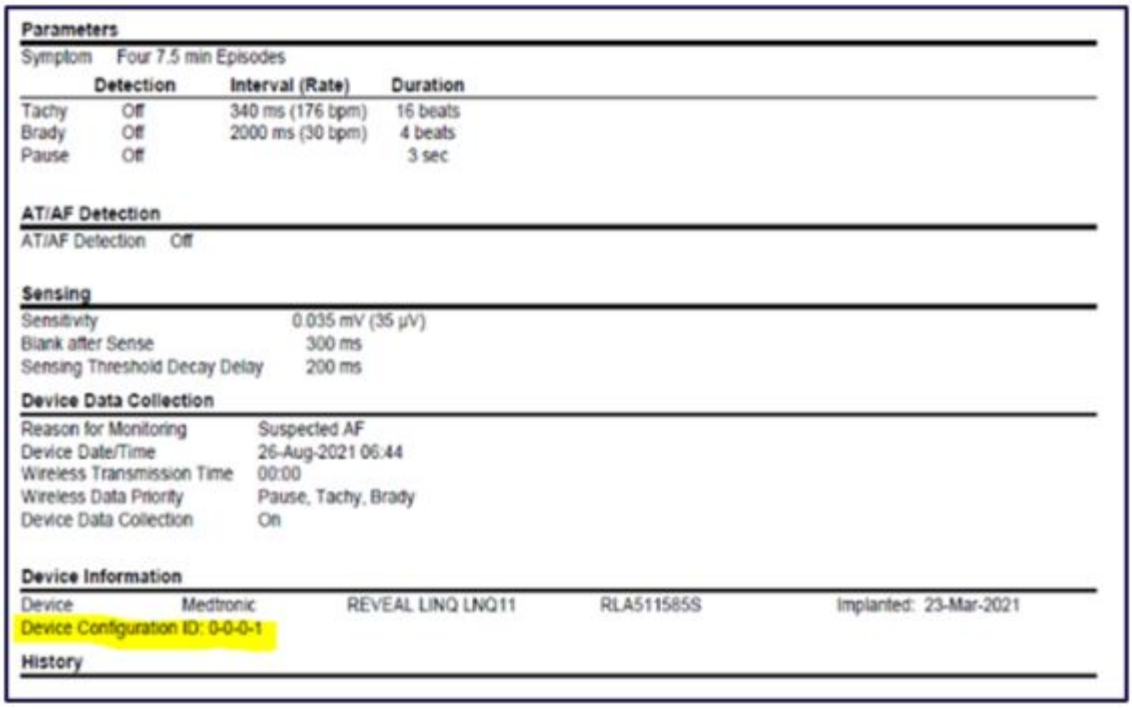
From the *Find Patient* screen on the programmer, Tap the Programmer Icon, select "Software," and scroll through the list of installed applications to find Reveal LINQ Software Version 8.3.




**How do I confirm if a patient's Reveal LINQ ICM has received the software update?**

Clinicians can confirm if a patient's ICM has received the software update by verifying the Device Configuration ID via a 2090 or Encore programmer (LMM will not display the Configuration ID). To locate the Device Configuration ID, enter a follow-up session and Print the Parameters Report. All Reveal LINQ ICMs that have received the software update will have their Configuration ID ending in a "1" (e.g. X-X-X-1).

**NOTE**: The Reveal LINQ Device Configuration ID can be viewed on CareLink beginning January 2022 after a manual transmission is completed by the patient.



# LINQ II - Brady, Pause and PVC Detections Disabled Following Electrical Reset

## LINQ II™ Insertable Cardiac Monitoring Systems

Original Date of Communication: June 2021

**STATUS UPDATE - OCTOBER 2025**

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

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

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

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

**ORIGINAL COMMUNICATION - JUNE 2021**

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

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

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

**ISSUE DESCRIPTION**

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

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

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

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

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

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

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

**PATIENT MANAGEMENT RECOMMENDATIONS**

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

**Identifying if an electrical reset has occurred:**

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

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

- **During in person or remote follow-up:** If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message. Actively monitor for these notifications at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. **Note**: Once cleared, electrical reset notifications are no longer accessible.
- **Retroactively:** Review the Brady lifetime episode counter from the most recent session report (CareLink or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady, Pause or PVC events. Review the Brady lifetime episode counter:
    - If the lifetime count for Brady is non-zero, a partial electrical reset has **not** occurred.
    - If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset **may** have occurred. Contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com (U.S.) OR calling 1-800-929-4043 (U.S.).

**Patients with a confirmed partial electrical reset:**

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

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

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

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

# Potential for Shortened RRT-to-EOS in Subset of ICDs and CRT-Ds

## Subset of ICDs and CRT-Ds

Original Date of Communication: February 2021

**STATUS UPDATE - OCTOBER 2025**

As of 07 October 2025, approximately 104,163 devices susceptible to this issue are estimated to still be active worldwide. Observed rate of occurrence is 0.18% 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: productperformance.medtronic.com

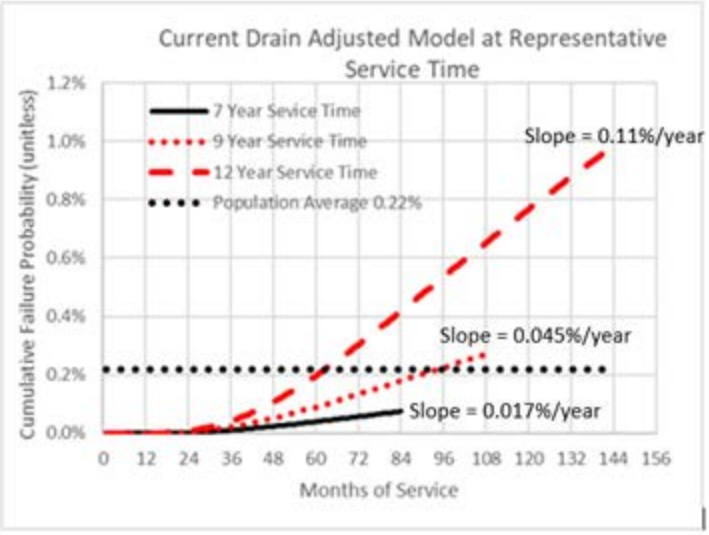
**APPENDIX A**

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 |

# Customer Communications




Cumulative Probability is the expected risk for a device to experience this issue between implant and end of service. When risk is evaluated for a device that has reached a service life beyond 3 years, the remaining risk can be estimated based on the yearly risk value shown.

The Population Average (0.22%) is the cumulative probability for the full subset of devices susceptible to this issue. This value takes into account expected longevity and patient mortality. Not all devices with projected service time of 12 years will be in service all 12 years.

Key Points:
Slope of the curve reflects the risk per year based on sample service times of 7, 9, and 12 years.

Slope (risk per year) is constant after approximately 3 years of service time.

# Performance Note: Potential for no output/no telemetry condition in subset of IPG and CRT-P products due to ceramic capacitor leakage pathway

## Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ CRT-P

Original Date of Communication: May 2019

**STATUS UPDATE - OCTOBER 2025**

As of 07 October 2025, there have been a total of 33 confirmed events worldwide associated with this failure mode (representing 0.010% of affected devices distributed worldwide). No additional deaths, beyond the two deaths previously disclosed*, have been reported since the October 2020 update. Confirmed events included reports of no output, premature depletion and electrical reset that reverted to VVI 65 operation.

Medtronic's ongoing monitoring of these failures have allowed us to improve long-term modeling projections for future device failures. The overall projected lifetime rate of occurrence for the remaining active devices manufactured with the original low voltage capacitor is projected to be 0.025%.

All products in distribution are unaffected. The specific low voltage capacitor susceptible to this issue was last used in manufacturing 01 June 2019. Patient management recommendations remain unchanged from the original posting (refer to the May 2019 text below).

*Assessment for cause of death determined loss of pacing therapy could not be ruled out as a contributing factor.

**ORIGINAL COMMUNICATION - MAY 2019**

Medtronic has identified a rare but potentially serious failure mode in a population of Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ cardiac resynchronization therapy pacemakers (CRT-P), manufactured with a specific multilayer ceramic capacitor. These devices continue to perform within reliability projections.

While inherently very reliable, a known failure mode of these capacitors is the potential for internal cracking that can be caused by thermal-mechanical stress during manufacturing. Under rare conditions, internal cracking within a capacitor may result in the development of a leakage pathway, causing high current drain and leading to rapid battery depletion. While the issue presents as rapid battery depletion, this is not a battery performance issue.

As of April 26, 2019, three complaints out of ~266,700 devices distributed worldwide since February 2017, have been received that included a no output /no telemetry scenario resulting from rapid battery depletion. Battery depletion due to this issue can range from several days to several weeks. One of these reported events contributed to a patient

death. The three confirmed failures occurred within 9 months post implant. The projected rate for this issue is 0.0028%, with the most susceptible period for a leakage pathway to develop in the capacitor being the first 12 months post implant.

Based on the low predicted rate of failure and the recent implementation of process and component enhancements, Medtronic expects few, if any, additional events to occur. Medtronic, in consultation with our Independent Physician Quality Panel, does not recommend device replacement. Physicians should continue normal patient follow-up in accordance with standard practice, and where possible, continue to utilize the low battery voltage wireless CareAlert™ (shipped ON), together with remote monitoring via CareLink™ home monitor or the MyCareLink Heart™ mobile app. Per the instructions for use, at each follow-up, verify the status of the implanted system as well as the clinical effectiveness of the device. Pay attention to any unexpected changes in remaining longevity estimates or the inability to interrogate the device and/or transmit data.

Contact Medtronic Technical Services if you have concerns on a specific patient.

Brady Technical Services |rs.techservices@medtronic.com| 800-505-4636

# Potential Conductor Wire Fracture

## 6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Communication: October 2007

**STATUS UPDATE - OCTOBER 2025**

As of October 8, 2025, of the initial implant population of 205,600 in the United States, approximately 26,500 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) | **7,341** Worldwide **(5,273** United States) | **36,100** Worldwide (**26,500** United States) |

**ORIGINAL COMMUNICATION - OCTOBER 2007**

PRODUCT

All Model 6930, 6931, 6948, and 6949 implantable defibrillation leads

ADVISORY

There are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. These two locations account for approximately 90% of the chronic fractures identified in Returned Product Analysis (RPA). The remaining 10% of chronic fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

PATIENT MANAGEMENT RECOMMENDATIONS (UPDATED APRIL 2011)

The Lead Integrity Alert (LIA) provides three days advance notice prior to inappropriate therapy to 76% of patients with lead fractures[1]. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks.

- **If a Fidelis lead fracture of any type has occurred, we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
    - Leave a properly performing lead intact.
    - Implant a new ICD lead without extraction of the existing lead.
    - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred.
    - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Footnotes:

1: Swerdlow C, Gunderson, B, et al."Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads", Circulation, November 2008, 118: 2122-2129.

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

# Product Education Brief: Micra Leadless Pacemaker - How to Prepare for Implant

## Micra™ AV2/VR2 TPS devices

Original Date of Communication: November 2025

**Overview**

This Product Education Brief re-enforces the instructions to program the real time clock (step 3 of the IFU below) along with completing other preparations before implanting a Micra device.

**Applicable Product**

Micra™ VR2 (MC2VR01), Micra™ AV2 (MC2AVR1)

**Background on Micra device clock**

The Micra devices initiate a date and time stamp at implant in order to trend data collected from the patient starting with the implant. If the internal Micra clock is not set before implant to match the geographic date and time of the implant location, data collection will proceed, but the associated time stamps on the data may not be as expected.

**Preparing for Implant**

The Micra instructions for use (IFU) describes the process of preparing a Micra device for implant prior to opening the sterile package and the order of operation should be followed. The Micra AV2/VR2 preparation steps are shown below.

### 4.1.5 How to prepare the device for implant

Before opening the sterile package, perform the following steps to prepare the device for implant:

1. Interrogate the device and create an Initial Interrogation Report.

   **Caution:** If the implantable device app reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.
2. Check the Initial Interrogation Report to confirm that the battery voltage is at least 2.93 V.
   If the battery voltage is below 2.93 V contact a Medtronic representative.

   **Note:** The device automatically measures the battery voltage once a day at 02:30. The automatic daily measurement of battery voltage is displayed on the Battery and Device Measurements screen. Battery voltage measurements can temporarily be impacted by cold temperatures.
3. Set the internal clock of the device
4. Program the therapy and pacing parameters to values appropriate for the patient.

   **Note:** Do not enable a pacing feature that affects the pacing rate before implanting the device. Taking this action can cause a pacing rate that is faster than expected.

   **Note:** Patient information typically is entered at the time of initial implant, and it can be revised at any time. If the patient has another active device implanted at the time of Micra AV2 implant, update patient information **Other Active Device** to **Yes** at the time of Micra AV2 implant. This parameter should be updated as necessary to indicate the presence or absence of another active device.
5. Program the device to the **Device Off** mode to prepare it for the implant.

If you have questions regarding this education brief, please contact Medtronic Technical Services.

# Product Education Brief: Boston Scientific Lead Advisory

## Medtronic ICDs and CRT-Ds

Original Date of Communication: October 2025

**Applicable Product:**

Single coil (SC) and dual coil (DC) RELIANCE™ G/SG defibrillation leads manufactured by Boston Scientific Corporation (BSC) from 2002 to 2021 with GORE™ expanded polytetrafluoroethylene (ePTFE) coil treatment connected to Medtronic ICD/CRT-D systems

**Executive Summary**

- Medtronic devices are NOT at risk of a BSC Code-1005 equivalent fault and its associated constraints on high-voltage therapy delivery, irrespective of shock polarity.
- Medtronic does not recommend reprogramming high voltage therapy polarity of Medtronic devices connected to recalled BSC leads.
- The BSC recommendation to consider lead replacement also applies to leads attached to Medtronic devices.

**Content**

This Product Education Brief leverages information in published literature, BSC's July 2025 Field Correction Action (FCA) letter*, and Medtronic data analysis to date to review:

- Reason for the advisory on BSC GORE™ ePTFE RELIANCE™ defibrillation leads
- BSC risk-mitigation recommendations for BSC devices
- Comparison of Medtronic device behavior to BSC device behavior when attached to BSC leads on advisory
- Therapy efficacy/success analysis on Medtronic devices with BSC ePTFE leads
- Medtronic position on the BSC advisory and Medtronic devices
    - Medtronic labeling for therapy polarity remains appropriate for Medtronic devices with BSC advisory leads

**Reason for BSC Recall of ePTFE RELIANCE leads***

The association of calcified defibrillation lead coil(s) with a pattern of gradually rising Low Voltage Shock Impedance (LVSI) measurements has been reported to BSC and described in several publications (listed in the BSC advisory letter*). The chronic calcification process originates in the ePTFE membrane coating the defibrillation coils. This calcification phenomenon can biologically encapsulate and electrically insulate the defibrillation lead coil(s), thus potentially reducing the amount of energy delivered and increasing the chances of unsuccessful defibrillation of

ventricular tachyarrhythmias. The BSC advisory letter did not provide mitigations to reduce the likelihood of lead calcification. At the time of the advisory letter, FDA disclosed that BSC reported 16 patient deaths, and 386 serious patient injuries related to the lead.

**BSC's Risk Mitigation for BSC Devices**

The July 2025 BSC advisory letter provides the following risk mitigation recommendations for BSC leads attached to BSC devices:

*"If an ePTFE lead is experiencing a gradually rising LVSI that exceeds 90Ω for a SC or 70Ω for a DC lead [on a BSC device], the risk of compromised shock efficacy can be mitigated by programming all shocks to maximum energy and shock polarity to Initial (RV-) in those patients whose [BSC] devices are not already programmed in this manner. For ePTFE leads with a gradually rising LVSI, there is a 4.5x higher likelihood of generating a EC-1005 in Reversed (RV+) polarity compared to Initial (RV-) polarity [on a BSC device]"**

Code-1005 indicates that a high-voltage energy delivery may have been truncated. Important points regarding the BSC recommendations:

1. Medtronic devices are at ZERO risk of a Code-1005 equivalent fault and its associated constraints on high voltage therapy delivery, irrespective of shock polarity (see next section for details).
2. The BSC shock-polarity recommendation reduces, but does not eliminate, the potential for triggering Code-1005 in leads with gradually rising impedances.
3. For BSC leads demonstrating LVSI ≥ 150ohms, consider lead replacement.

**BSC Code-1005 functionality is unique to BSC devices**

With respect to the behavior described in the July 2025 BSC advisory, conditions that contribute to Code-1005 include the following:

- As impedance rises in a calcified lead, the pulse width of a high-voltage shock waveform will extend. This is true of all fixed-tilt waveform systems.†
- The BSC first-phase shock delivery in a biphasic waveform is limited to a 20ms pulse width. If the first phase of a BSC shock is not completed within 20ms, the *"...bi-phasic waveform is truncated and a monophasic shock is delivered, potentially reducing shock efficacy."**

The shock-polarity recommendations in the BSC advisory letter provide a path to temporarily reduce the risk of triggering Code-1005 in the BSC system. The statement, *"4.5x higher likelihood of generating a Code-1005 in Reversed (RV+) polarity compared to Initial (RV-) polarity"** is not applicable to Medtronic devices.

**Medtronic High Voltage Delivery**

Differences in Medtronic device design are not accounted for in the BSC advisory recommendation. Specifically:

1. Medtronic devices use a 50% first-phase tilt (versus a 60% first phase tilt in BSC devices).
    - This means the first phase of energy delivery needs to unload a lower percentage of total energy in Medtronic devices before the first-phase waveform timeout is reached than in the BSC system.

2. Medtronic devices allow a 25.25ms pulse width for the first phase of waveform delivery. Due to differences in tilt and capacitance in Medtronic devices, waveform timeout will not typically occur until high-voltage impedances exceed ~200-250ohms.
    - Per the BSC advisory letter, *"If HVSI exceeds 145 ohms, BSC defibrillators, by design, limit shock duration of the first shock phase to 20ms. If this occurs, the shock's bi-phasic waveform is truncated and a monophasic shock is delivered, potentially reducing shock efficacy".*†

3. In Medtronic devices, if the entire first-phase energy has not been delivered within 25.25ms, the system will proceed to the second phase of energy delivery at the current voltage and deliver in the opposite polarity.
    - The BSC devices will truncate energy delivery at 20ms, resulting in a monophasic, truncated energy delivery when BSC Code-1005 conditions are met.

For these reasons, the BSC advisory polarity programming recommendations are not applicable to Medtronic devices.

**Therapy Efficacy Analysis - Medtronic Devices with BSC ePTFE leads**

Medtronic analyzed high-voltage events with BSC ePTFE leads attached to Medtronic devices in CareLink data. Every shock was assessed by Medtronic subject-matter experts for high-voltage pulse width, high-voltage impedance, and total voltage delivered to determine whether the device performed as expected. Leads with atypical performance were manually adjudicated for first shock success and episode success.

The manual adjudication of each therapy shows that Medtronic devices successfully delivered full-energy, biphasic, high-voltage therapies with BSC ePTFE leads in the Medtronic nominal/recommended B>AX polarity for all therapies regardless of the LVSI. Image 1 below demonstrates that Medtronic therapy success rates for these events are consistent with historical, expected performance. Of note, when coil impedances rose above the 70/90 ohm normal range, Medtronic observed an increased potential for abnormal therapy pulse widths. Medtronic devices will not truncate therapy due to an abnormal pulse width, but the abnormal pulse width signals that the lead may be compromised and may not perform as expected.

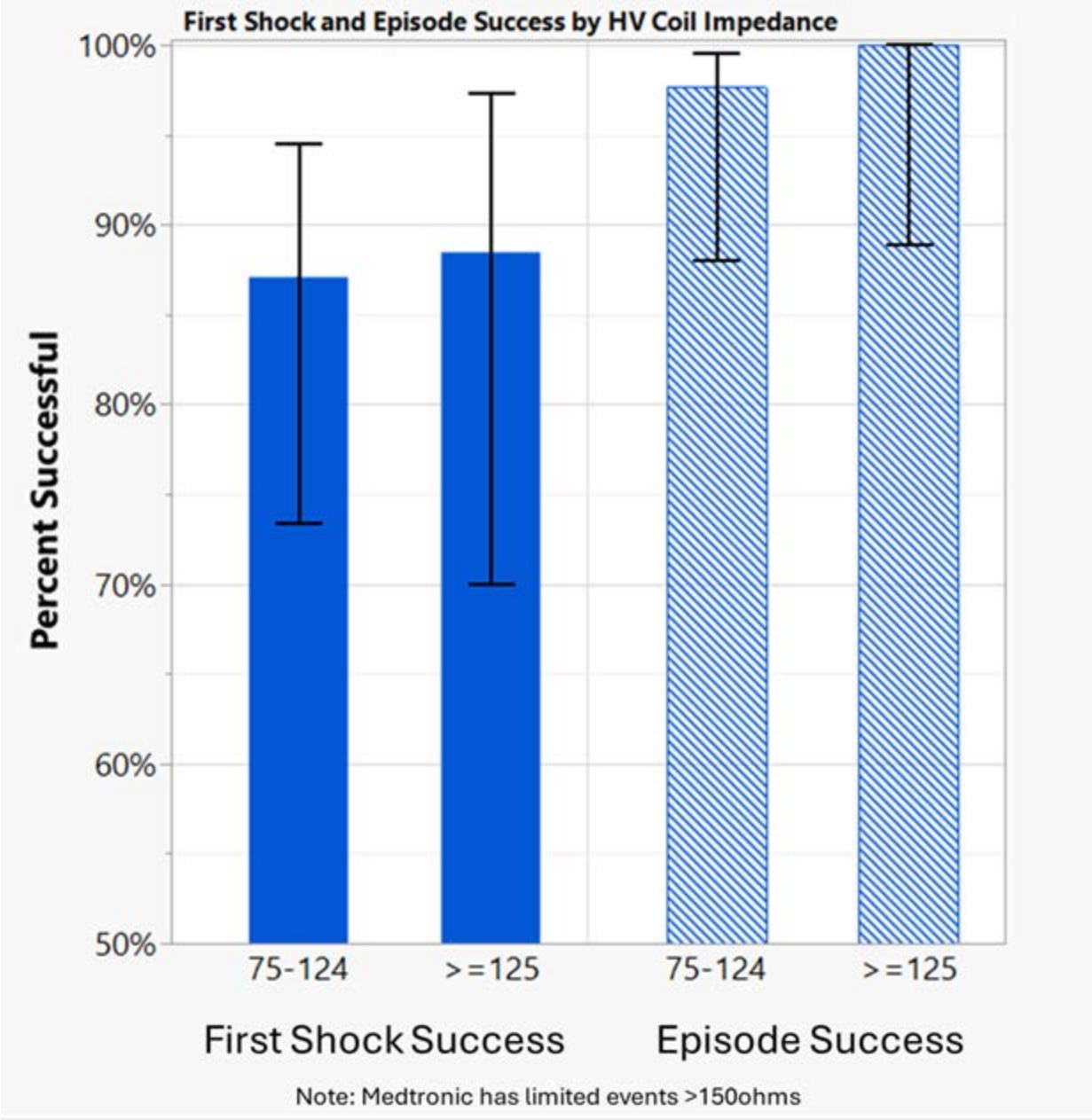



**Image 1:**First shock and episode success rates in B>AX polarity for Medtronic devices attached to ePTFE BSC single and dual coil leads with evidence of coil calcification

**Summary - Medtronic position regarding BSC recalled leads connected to Medtronic devices**

- **Medtronic devices are NOT at risk of a BSC Code-1005 equivalent fault and its associated constraints on high-voltage therapy delivery, irrespective of shock polarity.**
    - This difference in risk is due to a combination of Medtronic waveform tilt, capacitance, leading edge voltage, and algorithms controlling high-voltage shock delivery.

  - In Medtronic devices, first shock and episodic success remains consistent with historical performance across HVSI impedance ranges described in the BSC communication with the nominal/recommended polarity.

- **Medtronic does not recommend reprogramming high voltage therapy polarity** of Medtronic devices connected to recalled BSC leads. Medtronic devices that include labeling recommendations for shock polarity will display a pop-up warning if a non-nominal polarity setting is selected. These devices should not be reprogrammed in an attempt to replicate the recommended programming for BSC devices, as data does not support this action in Medtronic devices.
  - Medtronic therapy success (Image 1 above) is not limited by the shock polarity bias described in the BSC advisory letter when attached to BSC calcified leads.

- Table 1 of the BSC advisory includes lead-replacement considerations under defined conditions. **This BSC recommendation also applies to leads attached to Medtronic devices.**
  - When coil impedances rise above the 70/90 ohm normal range, there is increased potential for abnormal pulse widths. Abnormal pulse widths signal that the lead may not perform as expected.
    - In BSC devices, "HV impedance > 145 Ohms can alter the waveform of defibrillation and result in ineffective monophasic shocks."†
    - "Endotak Reliance defibrillation leads appear to be prone to shocking coil and/or distal pacing electrode calcification. The resulting high impedances may compromise defibrillation and pacing therapy."‡

Though Medtronic devices will not truncate therapy due to an abnormal pulse width in any polarity, ePTFE leads with rising impedances should be considered at risk for ineffective therapy.

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*Boston Scientific, *Management of Potentially Calcified ePTFE Defibrillation Lead Coil(s) Using 28-Day Averaged LVSI*, published July 2025

†Koneru, Jayanthi N. et al. PO-06-203 *Implantable Cardioverter Defibrillator Failure Due to High-Voltage Impedance Abnormality Causing Monophasic Shocks and Defibrillation Failure. Heart Rhythm*, Volume 22, Issue 4, S722 - S723.

‡Hauser, Robert G., et al. *High shocking and pacing impedances due to defibrillation lead calcification. Journal of Interventional Cardiac Electrophysiology*, (2020) 58:253–259, Published online: 18 December 2019

# Product Education Brief: Daily Restarts of SmartSync iPad Tablets

## CareLink SmartSync™ Device Manager Application and Pacing System Analyzer (PSA)

Original Date of Communication: March 2025

**Overview**

This Product Education Brief emphasizes the recommendation to **restart tablets daily as part of SmartSync management.** This may be completed by powering the tablet off between uses. Daily tablet restarts facilitate optimal SmartSync App performance. Tablets should also be restarted upon receipt of a "low tablet resources" pop-up, as indicated in the pop-up text.

**Impacts of Restarting the SmartSync Tablet**

Restarting the tablet clears the RAM (random-access memory) and closes any running apps, which improves overall tablet performance. When RAM is not cleared, or when other apps run concurrently with the SmartSync app, the following behavior may be observed:

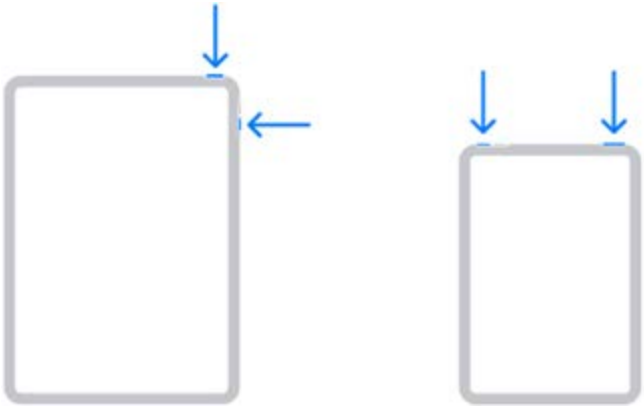
- Unexpected app closures*
- App unresponsiveness*
- System error messages as a result of limited available system memory

Should any of the above behaviors occur, the user should force close all open apps on the tablet, restart the tablet, and then restart the SmartSync app.

* Note that if the app disconnects during an analyzer session, pacing will continue at the programmed parameters for 60 minutes if the surgical/patient cables are connected to implantable device leads or 5 minutes without connection to implantable device leads.

**How to Restart Apple iPad**

How to restart an iPad tablet without a Home button:



1. Press and hold either volume button and the top button until the power off slider appears
2. Drag the slider, then wait 30 seconds for your device to turn off.
    - If your device is frozen or unresponsive, force restart your device: Press and quickly release the volume up button, press and quickly release the volume down button, then press and hold the top button. When the Apple logo appears, release the button.
3. To turn the tablet back on, press and hold the top button until you see the Apple logo.

How to restart an iPad tablet with a Home button:

1. Press and hold the top button until the power off slider appears
2. Drag the slider, then wait for 30 seconds for your device to turn off.
    - If your tablet is frozen or unresponsive, force restart your tablet: Press and hold the top button and the Home button at the same time. When the Apple logo appears, release both buttons.
3. To turn your tablet back on, press and hold the top button until you see the Apple logo.

# Product Education Brief: Micra TPS Monitoring and End of Service Behavior

## Micra™ TPS devices

Original Date of Communication: January 2025

**Overview**

This Product Education Brief provides a description of specific monitoring and follow-up recommendations, including a description of end of service behavior.

This Product Education Brief is consistent with existing labeling and reiterates precautions listed in the product's Instructions for Use (IFU).

**Micra Instructions for Use**

The Micra IFUs are available on the Medtronic electronic manuals website (manuals.medtronic.com).

**Monitoring, Follow-Up, and End of Service**

Remote monitoring of patients with a Micra device is recommended in the 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement.

The 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic states that in patients with CIEDs, remote monitoring (RM) is recommended as part of the standard of care. The consensus statement advises that patients with CIEDs on RM, in the absence of continuous connectivity, such as with Micra, remote transmissions are recommended at least every 3-12 months. It is also noted that there are some circumstances (e.g., if a patient is pacemaker dependent) where the transmission frequency may match or exceed every 3-6 months. As the device approaches elective replacement, the frequency of transmissions should be increased to every 1-3 months. The frequency recommendations apply whether the patient transmits data remotely or has an in-office visit.

Following recommended replacement time / elective replacement indicator (RRT/ERI) and as described in the IFU, the Micra device sets battery end of service (EOS) after measuring voltage ≤2.5V on 3 consecutive daily automatic measurements. When the Micra device reaches EOS, it permanently deactivates pacing and switches to the Device Off mode. This EOS mode differs from Medtronic transvenous pacemakers. The IFU indicates that the estimated time from RRT to EOS is 6 months, and the approximate time from ERI to EOS is 3 months. See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events.

**Product Performance**

Medtronic monitors and evaluates product performance, including battery performance, for all Micra devices. The device performance data is published on our product performance website productperformance.medtronic.com. Reports of Micra premature battery depletion and normal battery depletion are included on the product performance website.

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.

**References**


- medtronicacademy.com
- Micra MC1VR01 Clinician Manual - M042502C001
- Ferrick, A. M., et al. (2023). 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Europace, 25(5), euad123.

# Product Education Brief: Alert Threshold for Lead Impedances

## Azure™ and Astra™ pacemakers, and Percepta™, Serena™ and Solara™ CRT-P

Original Date of Communication: April 2023

**Overview**

This Product Education Brief describes a lead impedance alert behavior in Medtronic Azure™, Astra™, Percepta™, Serena™, and Solara™ devices that may be observed when the pacing lead impedance displayed is slightly above the programmed lower alert threshold.

**Details regarding CareAlerts and impedance measurements**

In Azure, Astra, Percepta, Serena, and Solara devices, a CareAlert may be triggered when the lead impedance displayed is slightly above the programmed lower alert threshold.
See Figure 1 and 2 for an example case where the lower threshold for a lead impedance alert is programmed at 200 ohms. In the Lead Impedance Trend (Figure 1) the precise measured impedance value is 209 ohms; and yet in the CareAlert display (Figure 2) an alert was triggered indicating the impedance crossed the 200 ohm impedance threshold, and suggesting the impedance is 190 ohms. This scenario can happen due to the range of impedance values used for alert monitoring. In this scenario, the devices are functioning within design specifications and tolerances.

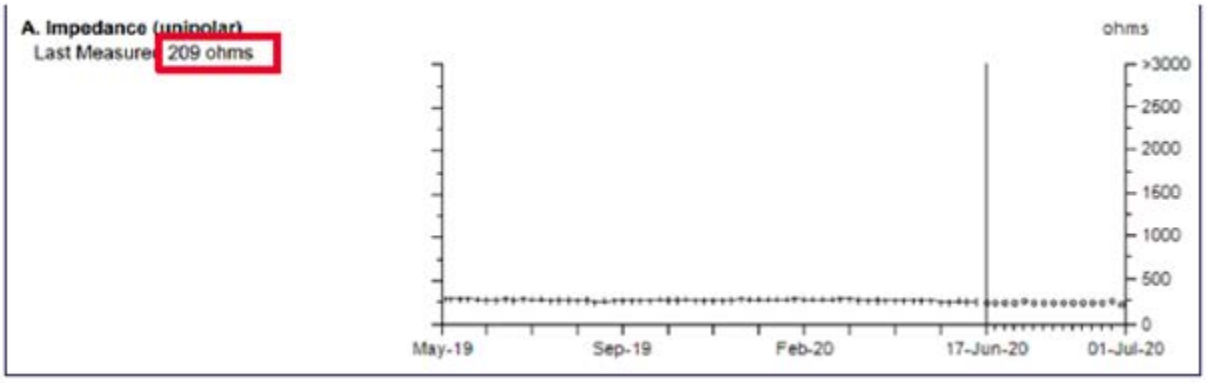



**Figure 1**– Lead Impedance Trend showing precise impedance values over time

| Date/Time | Event | Threshold |
|---|---|---|
| 01-Jul-2020 03:00:00 | *A. Unipolar lead impedanc | 190 ohms. 200 ohms |

**Figure 2**– CareAlert triggered showing 190 ohms impedance value with a 200ohm alert threshold

While most leads are programmed to pace bipolar, every night the device will assess all lead impedance vectors. Unipolar measurements tend to be lower than bipolar measurements in the same system. Therefore, the nightly unipolar lead impedance measurement will likely be closer to the programmed lower alert threshold than the bipolar measurement.

The impedance value range for alerts is never higher than the measured impedance, so all impedance values that are below the programmed threshold will generate an alert as programmed.

**Patient Management**

Clinicians should continue to follow patients per their standard clinical practice when a CareAlert triggers for lead impedances. Impedance alerts are designed to prompt the clinician to review impedances in the Lead Impedance Trend Log. The Lead Impedance Trend records precise lead impedance measurements over time. These historic impedance measurements provide evidence as to whether the impedance is stable and functioning as designed (albeit near the programmed threshold); or unstable and necessitating further assessment and/or close monitoring. Note: If impedance values reported in the Lead Impedance Trend indicate impedances are below the programmed lower threshold, then the lead should be assessed for possible insulation breach per standard clinical practice.

# Procedure Education Brief: Micra TPS Implant

## Micra™ TPS devices

Original Date of Communication: November 2021

**Overview**

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

**Micra IFU and Implant Procedure Training**

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

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

**Micra Safety and Effectiveness Data**

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

While regulatory agencies and Micra implanters are aware that cardiac perforation is a known risk, the FDA Letter to Healthcare Providers included data for which implanters may be seeking additional context. The letter indicated that

risk of cardiac perforation between transvenous pacing implants and Micra implants are similar, and that Micra implant complication rates are within expectations. The letter also indicated that in some scenarios, when a perforation occurs with a Micra implant procedure, the severity of the perforation complications can be higher than when a perforation occurs with a transvenous implant procedure.

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

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

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

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

| **Measure** | **Unadjusted Results**<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

# Legacy Models

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

**GENERATORS**

## Cardiac Resynchronization Therapy (CRT) Defibrillators

| Product Name | Model | Final Issue |
|---|---|---|
| Cardia CRT-D | D384TRG | 2023 2nd Edition (Issue 89) |
| Concerto CRT-D | C154DWK | 2016 1st Edition (Issue 74) |
| Concerto CRT-D | C164AWK | 2016 1st Edition (Issue 74) |
| Concerto CRT-D | C174AWK | 2016 1st Edition (Issue 74) |
| Concerto II CRT-D | D274TRK | 2023 2nd Edition (Issue 89) |
| Concerto II CRT-D | D294TRK | 2023 2nd Edition (Issue 89) |
| Consulta CRT-D | D204TRM | 2023 2nd Edition (Issue 89) |
| Consulta CRT-D | D214TRM | 2023 2nd Edition (Issue 89) |
| Consulta CRT-D | D224TRK | 2024 1st Edition (Issue 90) |
| Consulta CRT-D | D234TRK | 2023 2nd Edition (Issue 89) |
| InSync II Marquis | 7289 | 2012 1st Edition (Issue 66) |
| InSync Maximo | 7303 | 2012 1st Edition (Issue 66) |
| InSync Maximo | 7304 | 2016 1st Edition (Issue 74) |
| InSync Sentry | 7297 | 2012 1st Edition (Issue 66) |
| InSync Sentry | 7299 | 2016 1st Edition (Issue 74) |
| Maximo II CRT-D | D264TRM | 2023 2nd Edition (Issue 89) |
| Protecta CRT-D | D334TRG | 2023 2nd Edition (Issue 89) |
| Protecta CRT-D | D334TRM | 2023 2nd Edition (Issue 89) |
| Protecta XT CRT-D | D314TRM | 2023 2nd Edition (Issue 89) |

## Cardiac Resynchronization Therapy (CRT) Pacemakers

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

## Implantable Cardioverter Defibrillators (ICDs)

| Product Name | Model | Final Issue |
|---|---|---|
| Cardia DR | D384DRG | 2025 1st Edition (Issue 92) |
| Entrust AT | D153ATG | 2019 2nd Edition (Issue 81) |
| Entrust AT | D154ATG | 2019 2nd Edition (Issue 81) |
| Entrust DR | D153DRG | 2019 2nd Edition (Issue 81) |
| Entrust DR | D154DRG | 2019 2nd Edition (Issue 81) |

| Product Name | Model | Final Issue |
|---|---|---|
| Entrust Escudo | D144DRG | 2019 2nd Edition (Issue 81) |
| Entrust Escudo | D144VRC | 2019 2nd Edition (Issue 81) |
| Entrust VR | D153VRC | 2019 2nd Edition (Issue 81) |
| Entrust VR | D154VRC | 2019 2nd Edition (Issue 81) |
| GEM | 7227B | 2011 1st Edition (Issue 64) |
| GEM | 7227Cx | 2011 1st Edition (Issue 64) |
| GEM | 7227D | 2011 1st Edition (Issue 64) |
| GEM | 7227E | 2011 1st Edition (Issue 64) |
| GEM DR | 7271 | 2011 1st Edition (Issue 64) |
| GEM III DR | 7275 | 2012 1st Edition (Issue 66) |
| GEM III VR | 7231Cx | 2016 1st Edition (Issue 74) |
| Intrinsic | 7288 | 2016 1st Edition (Issue 74) |
| Marquis DR | 7274 | 2016 1st Edition (Issue 74) |
| Marquis VR | 7230B | 2019 2nd Edition (Issue 81) |
| Marquis VR | 7230Cx | 2019 2nd Edition (Issue 81) |
| Marquis VR | 7230E | 2019 2nd Edition (Issue 81) |
| Maximo DR | 7278 | 2017 1st Edition (Issue 76) |
| Maximo II DR | D264DRM | 2025 1st Edition (Issue 92) |
| Maximo VR | 7232B | 2019 2nd Edition (Issue 81) |
| Maximo VR | 7232Cx | 2023 2nd Edition (Issue 89) |
| Maximo VR | 7232E | 2019 2nd Edition (Issue 81) |
| Onyx | 7290Cx | 2013 1st Edition (Issue 68) |
| Protecta DR | D334DRG | 2023 2nd Edition (Issue 89) |
| Protecta DR | D334DRM | 2023 2nd Edition (Issue 89) |
| Protecta VR | D334VRG | 2023 2nd Edition (Issue 89) |
| Protecta VR | D334VRM | 2023 2nd Edition (Issue 89) |
| Protecta XT DR | D314DRM | 2025 1st Edition (Issue 92) |
| Protecta XT VR | D314VRG | 2024 1st Edition (Issue 90) |
| Protecta XT VR | D314VRM | 2024 1st Edition (Issue 90) |
| Secura DR | D204DRM | 2023 2nd Edition (Issue 89) |
| Secura DR | D214DRM | 2023 2nd Edition (Issue 89) |
| Secura DR | D224DRG | 2024 1st Edition (Issue 90) |
| Secura DR | D234DRG | 2023 2nd Edition (Issue 89) |
| Secura VR | D204VRM | 2023 2nd Edition (Issue 89) |
| Secura VR | D214VRM | 2025 1st Edition (Issue 92) |
| Secura VR | D224VRC | 2023 2nd Edition (Issue 89) |
| Virtuoso DR | D154AWG | 2019 2nd Edition (Issue 81) |
| Virtuoso DR | D164AWG | 2023 2nd Edition (Issue 89) |
| Virtuoso II DR | D274DRG | 2023 2nd Edition (Issue 89) |
| Virtuoso II DR | D294DRG | 2023 2nd Edition (Issue 89) |
| Virtuoso II VR | D274VRC | 2023 2nd Edition (Issue 89) |
| Virtuoso VR | D154VWC | 2019 2nd Edition (Issue 81) |

## Implantable Cardioverter Defibrillators (ICDs) continued

| Product Name | Model | Final Issue |
|---|---|---|
| Virtuoso VR | D164VWC | 2023 2nd Edition (Issue 89) |

## Implantable Pulse Generators (IPGs)

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

| Product Name | Model | Final Issue |
|---|---|---|
| Kappa 700 DR | KDR721 | 2017 1st Edition (Issue 76) |
| Kappa 700 SR | KSR700 | 2016 2nd Edition (Issue 75) |
| Kappa 700 SR | KSR701 | 2017 1st Edition (Issue 76) |
| Kappa 700 SR | KSR703 | 2017 1st Edition (Issue 76) |
| Kappa 700 SR | KSR706 | 2017 1st Edition (Issue 76) |
| Kappa 700 VDD | KVDD701 | 2012 2nd Edition (Issue 67) |
| Kappa 800 DR | KDR801 | 2013 1st Edition (Issue 68) |
| Kappa 800 DR | KDR803 | 2013 1st Edition (Issue 68) |
| Kappa 900 D | KD901 | 2017 1st Edition (Issue 76) |
| Kappa 900 D | KD903 | 2017 1st Edition (Issue 76) |
| Kappa 900 D | KD906 | 2017 1st Edition (Issue 76) |
| Kappa 900 DR | KDR901 | 2017 1st Edition (Issue 76) |
| Kappa 900 DR | KDR903 | 2017 1st Edition (Issue 76) |
| Kappa 900 DR | KDR906 | 2017 1st Edition (Issue 76) |
| Kappa 900 DR | KDR921 | 2017 1st Edition (Issue 76) |
| Kappa 900 SR | KSR901 | 2017 1st Edition (Issue 76) |
| Kappa 900 SR | KSR903 | 2017 1st Edition (Issue 76) |
| Kappa 900 SR | KSR906 | 2017 1st Edition (Issue 76) |
| Kappa 900 VDD | KVDD901 | 2017 1st Edition (Issue 76) |
| Legend II | 8424 | 2012 1st Edition (Issue 66) |
| Legend II | 8426 | 2012 1st Edition (Issue 66) |
| Legend II | 8427 | 2012 1st Edition (Issue 66) |
| Minix | 8340 | 2012 1st Edition (Issue 66) |
| Minix | 8341 | 2012 1st Edition (Issue 66) |
| Minix | 8341M | 2012 1st Edition (Issue 66) |
| Minix | 8342 | 2012 1st Edition (Issue 66) |
| Minix ST | 8330 | 2012 1st Edition (Issue 66) |
| Minix ST | 8331 | 2012 1st Edition (Issue 66) |
| Minix ST | 8331M | 2012 1st Edition (Issue 66) |
| Minuet | 7107 | 2012 1st Edition (Issue 66) |
| Minuet | 7108 | 2012 1st Edition (Issue 66) |
| Preva DR | 7088 | 2012 1st Edition (Issue 66) |
| Preva DR | 7089 | 2012 1st Edition (Issue 66) |
| Preva SR | 8088 | 2012 1st Edition (Issue 66) |
| Preva SR | 8089 | 2012 1st Edition (Issue 66) |
| Prevail S | 8085 | 2012 1st Edition (Issue 66) |
| Prevail S | 8086 | 2012 1st Edition (Issue 66) |
| Prodigy DR | 7860 | 2012 1st Edition (Issue 66) |
| Prodigy DR | 7861 | 2012 1st Edition (Issue 66) |
| Prodigy DR | 7862 | 2012 1st Edition (Issue 66) |
| Prodigy SR | 8158 | 2013 1st Edition (Issue 68) |
| Prodigy SR | 8160 | 2013 1st Edition (Issue 68) |

Implantable Pulse Generators (IPGs) continued

| Product Name | Model | Final Issue |
|---|---|---|
| Prodigy SR | 8161 | 2013 1st Edition (Issue 68) |
| Prodigy SR | 8162 | 2013 1st Edition (Issue 68) |
| Sigma 100 S | SS103 | 2017 2nd Edition (Issue 77) |
| Sigma 100 S | SS106 | 2017 2nd Edition (Issue 77) |
| Sigma 200 D | SD203 | 2017 2nd Edition (Issue 77) |
| Sigma 200 DR | SDR203 | 2017 2nd Edition (Issue 77) |
| Sigma 200 S | SS203 | 2017 2nd Edition (Issue 77) |
| Sigma 200 SR | SSR203 | 2017 2nd Edition (Issue 77) |
| Sigma 300 D | SD303 | 2023 2nd Edition (Issue 89) |
| Sigma 300 DR | SDR303 | 2023 2nd Edition (Issue 89) |
| Sigma 300 DR | SDR306 | 2019 2nd Edition (Issue 81) |
| Sigma 300 S | SS303 | 2023 2nd Edition (Issue 89) |
| Sigma 300 SR | SSR303 | 2023 2nd Edition (Issue 89) |
| Sigma 300 SR | SSR306 | 2019 2nd Edition (Issue 81) |
| Sigma 300 VDD | SVDD303 | 2019 2nd Edition (Issue 81) |
| Thera-i DR | 7960i | 2012 1st Edition (Issue 66) |
| Thera-i DR | 7961i | 2012 1st Edition (Issue 66) |
| Thera-i DR | 7962i | 2012 1st Edition (Issue 66) |
| Thera-i SR | 8960i | 2012 1st Edition (Issue 66) |
| Thera-i SR | 8961i | 2012 1st Edition (Issue 66) |
| Thera-i SR | 8962i | 2012 1st Edition (Issue 66) |
| Thera-i VDD | 8968i | 2012 1st Edition (Issue 66) |

## LEADS

### Pacing Leads

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

## Pacing Leads continued

| Product Name | Model | Final Issue |
|---|---|---|
| CapSure Z | 5034 | 2016 1st Edition (Issue 74) |
| CapSure Z | 5534 | 2016 1st Edition (Issue 74) |
| CapSureFix | 4067 | 2012 2nd Edition (Issue 67) |
| CapSureFix | 4068 | 2016 1st Edition (Issue 74) |
| CapSureFix | 4568 | 2017 2nd Edition (Issue 77) |
| CapSureFix | 5068 | 2017 1st Edition (Issue 76) |
| CapSureFix | 5568 | 2016 1st Edition (Issue 74) |
| CapSureFix | 6940 | 2018 1st Edition (Issue 78) |
| Screw-In | 4558M | 2016 1st Edition (Issue 74) |
| SureFix | 5072 | 2018 1st Edition (Issue 78) |

## Defibrillation Leads

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

## Left Heart Pacing Leads

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

## Epicardial/Myocardial Pacing Leads

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

## VDD Single Pass Pacing Leads

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

# Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRM Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet US postal regulations for mailing biohazard materials.

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

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CRM Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
Email: crdm.returnedproduct@medtronic.com

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Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
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