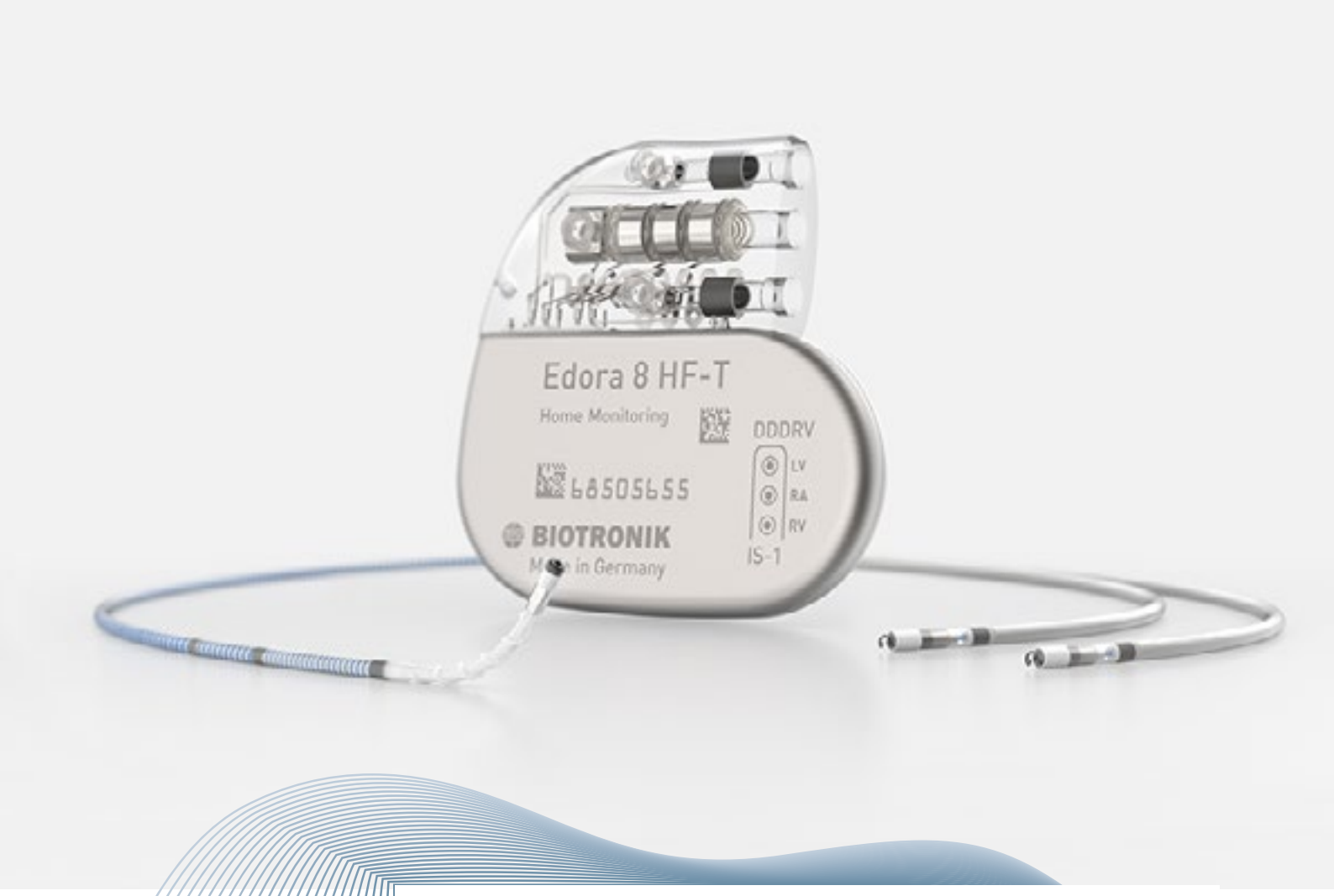


# Product Performance Report

## 2nd Edition 2021

Cardiac Rhythm Management
Cumulative Survival Probability

BIOTRONIK
excellence for life

# Product Performance Report 2nd Edition 2021

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

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# Quality Excellence

BIOTRONIK has a long history of high quality in product design and performance. For more than 50 years, the name BIOTRONIK has been synonymous with excellent workmanship and reliable patient safety. Our quality concept follows an integrated approach and extends from preventative risk measures during a product's development phase through all the steps of the manufacturing and design process.

BIOTRONIK's quality assurance system guarantees strict adherence to internal quality standards as well as compliance with international standards and guidelines. Regular reviews of our product performance and manufacturing evaluations contribute significantly to the achievement of extraordinary quality. Our customers, patients, and physicians can rely on the highest degree of safety built into our products. We always welcome suggestions from users about how we can improve the quality of our products.

This Product Performance Report is an integral component of BIOTRONIK's commitment to provide detailed, accurate information regarding long term reliability. The Product Performance Report exemplifies BIOTRONIK's policy of transparent and timely communication with our customers.

As a means to obtain continuous improvement of the designs, BIOTRONIK carefully analyzes returned products and incorporates all findings into our quality assurance system. This Product Performance Report was prepared in accordance with International Standard ISO 5841-2: 2014 (E)[1] and is in compliance with the recommendations from the U.S. Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. As an active member of AdvaMed and their Pacemaker/ICD Working Group, BIOTRONIK has worked extensively with the CRM industry to ensure comparable product performance data is reported by all manufacturers.

The data provided in BIOTRONIK's Product Performance Report incorporates the requirements and definitions as defined in AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators, except as noted herein.

In BIOTRONIK's continuous efforts to provide accurate and transparent information and to ensure that a conservative estimate for device performance is reported, the Survival Probability calculations presented herein also consider reported pacemaker and ICD battery depletions as well as lead complications without the device having been returned for analysis.

**1** The ISO 5841-2:2014(E) is replacing the previous version ISO 5841-2:2000. As part of the update, AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators were incorporated in the new ISO 5841-2:2014(E).

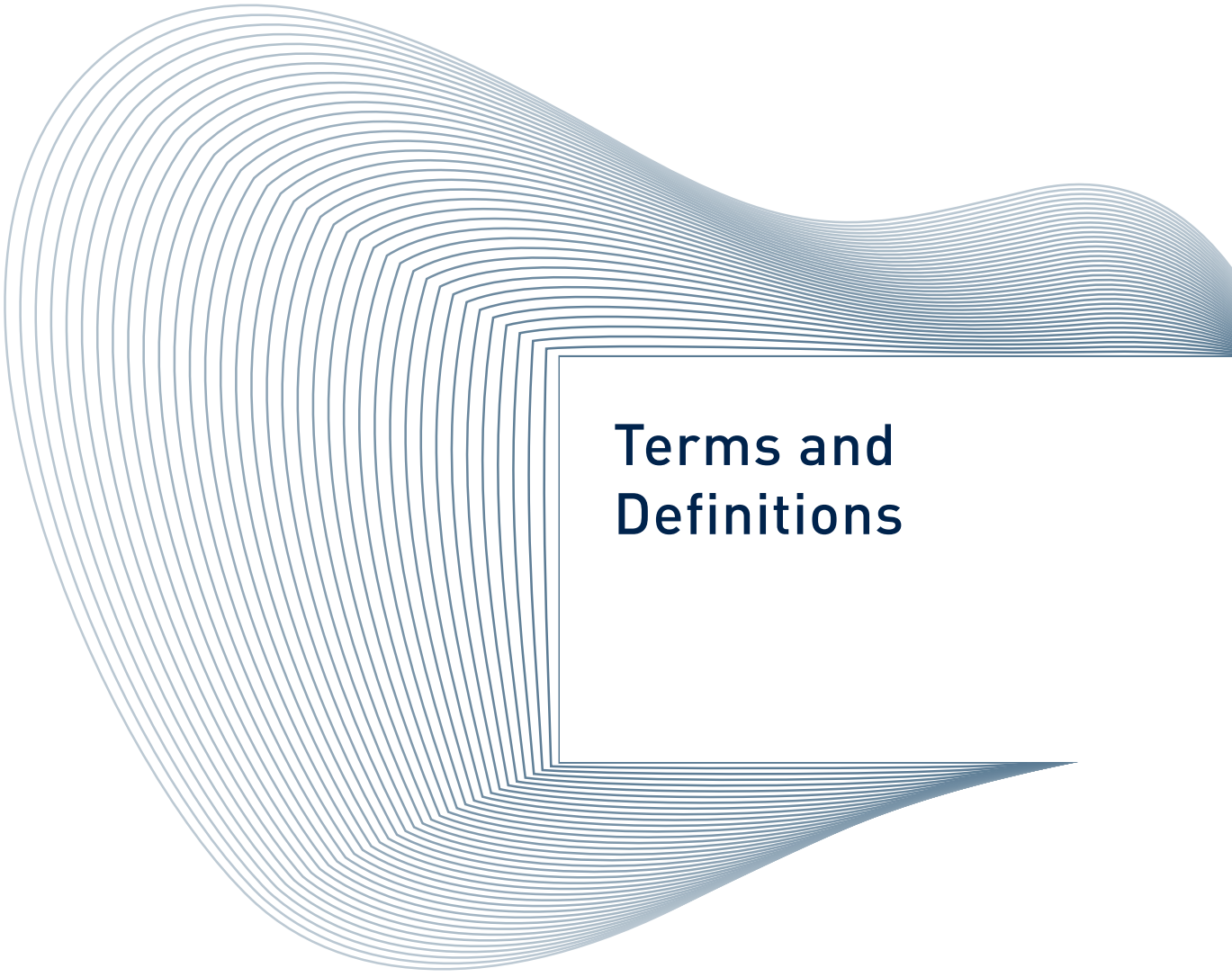
Because a significant portion of this report is based on analyses of returned products, BIOTRONIK urges all physicians to return explanted devices and to notify us when a product is explanted or no longer in use for any reason.

BIOTRONIK aims to continually improve and enhance the scope of this report while integrating the latest information and data concerning the performance of our products. Please contact Advanced Product Support (800) 547-0394 or the PPR Support Team at ppr@biotronik.com with any comments, suggestions or questions regarding this report. Your feedback is highly appreciated and will be used to further develop this report.

BIOTRONIK, December 2021

**Roman Borkowski**
Senior Vice President
Quality Management
& Regulatory Affairs CRM
BIOTRONIK SE & Co. KG

1



# Terms and Definitions

# 1. Terms and Definitions

The following terms and definitions are used for pacemakers and implantable cardioverter-defibrillators (ICDs) as well as pacing and ICD leads throughout this Product Performance Report. These definitions form the basis for this Product Performance Report by clearly articulating the status of each device return and product analysis classification.

**Elective Replacement Indicator**
All active implantable devices that are powered by an internal battery need to be replaced when their battery is depleted. BIOTRONIK pacemakers and ICDs have an Elective Replacement Indicator (ERI) feature aka Recommended Replacement Time (RRT) that notifies the health care provider when the device's battery is nearing the end of its useful life. Display of ERI is BIOTRONIK's recommendation to the user that the battery's present state will require device replacement in the near future. For further details please refer to the corresponding manual.

**Battery Depletion**
Battery depletions are classified as either normal (expected) or premature. Premature battery depletions are defined as device malfunctions, while normal battery depletions are not device malfunctions. Batteries of returned devices are considered to have depleted normally 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 75% of the expected longevity using the longevity calculation tool available at time of product introduction, calculated using the device's actual use conditions and settings.

For consistency with previous Product Performance Reports, for ICDs released prior to Lumax and pacemakers released prior to Philos II, batteries of returned devices are considered to have depleted normally if they have reached their elective replacement indicator and testing indicates that the battery and associated circuitry are within specifications.

**Out of Specification**
Any component or software related event that causes the device's characteristics to not meet pre-defined performance specifications and requirements while implanted and in service. Returned product analysis that determines a device to be out of specification is considered a device malfunction. Normal battery depletions are not considered device malfunctions. BIOTRONIK defines the requirements and performance specifications for each product.

**Device Malfunctions**
Any component or software related event that causes the device's characteristics to be out of specification while implanted and in service are considered as device malfunctions. Because it is impossible to verify that a device has malfunctioned without analyzing it, only returned devices can be classified as malfunctions for this report. Each returned lead, ICD and pacemaker is analyzed to determine if it has malfunctioned. If the analysis determines that a pacemaker or ICD failed to meet its specifications while implanted and in service, it is further classified as either a malfunction with compromised therapy or as a malfunction without compromised therapy. Devices damaged during implant, revision or after explant, damaged due to external causes (i.e. electrocautery) or due to failure to follow instructions, warnings or contraindications in its associated technical manual are not considered malfunctions. Devices damaged due to interaction with other implanted devices (i.e., leads) are also not considered as malfunctions for the purposes of this Product Performance Report.

**Malfunctions with Compromised Therapy**
The condition when a pacemaker or ICD 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. Therapy is considered to have been compromised if critical patient-protective pacing or defibrillation therapy is not available.

Examples include: sudden loss of battery voltage; accelerated current drain such that a depleted battery was not detected before loss of therapy; sudden malfunction during a tachycardia or fibrillation event resulting in aborted delivery of therapy; intermittent malfunction where therapy is sporadically unavailable.

**Malfunctions without Compromised Therapy**
The condition when a pacemaker or ICD is found to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Therapy is not compromised as long as critical patient-protective pacing and defibrillation therapies are available as determined through device analysis.

### Lead Complications

A lead performance issue where a complaint, associated with at least one of the clinical manifestations listed below, is reported and where the non-returned lead is:

- Verified by medical records to have been implanted and in-service, and
- Reported to have been removed from service,
- Modified to remedy the malfunction, or
- Left in service based on medical judgment.

Complications for leads implanted greater than 30 days are reported as qualifying lead complications, whereas complications occurring during the first 30 days are reported as acute lead observations.

In accordance with the latest AdvaMed guidelines and ISO 5841-2:2014(E), the complications are classified in the following categories:

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

### Survival Probability Estimates

The probability that a device remains operational during a discrete time interval is defined as survival probability. Survival probability, as presented in this report, is related to device survival only and not survival of the patient. The survival probability estimates in this report are based on BIOTRONIK's analysis of returned products as well as events that are reported to BIOTRONIK (e.g., battery depletions or lead complications).

### Cumulative Survival Probability Estimates

The survival probability over a device's service time is the cumulative survival probability. It is calculated from all discrete survival probabilities of previous time intervals. This characteristic is calculated separately for malfunction-free survival and all-cause survival (including normal battery depletions). Specific populations that are subject to a safety advisory notification are excluded and shown separately.

### Implanted Devices

Only devices remaining implanted for at least one calendar day after the implantation date are considered as implanted. Devices that are removed from the patient on the same calendar day as the implant procedure do not contribute to the survival statistics.

### Active Implants

The number of devices that remain operational within a discrete observation interval are active implants. Units are removed from this cohort due to patient death or explant for any reason.

### Underreporting

A device status may change without being accounted for in the Product Performance database due to a lack of information being provided to BIOTRONIK. Underreporting adjustments deemed to be necessary are detailed in this report.

### Safety Advisory Notifications

Any action taken by the manufacturer to inform clinicians concerning a device performance issue that may cause the device to not meet its predefined specifications is referred to as a Safety Advisory Notification.

2

# Methodology for Pacemaker and ICD Survival Estimates

# 2. Methodology for Pacemaker and ICD Survival Estimates

## 2.1 Cumulative Survival Probability

This report has been prepared in accordance with ISO 5841-2:2014(E) applying actuarial analysis for the calculation of survival probabilities. Survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK devices.

The cumulative survival probability is an estimate based on the percentage of pacemakers and ICDs that remain implanted and operational at various points of the product's service time in absence of concurrent events such as morbidity and voluntary explants for various reasons (e.g., device upgrade). The device survival estimate over time is displayed in cumulative curves (Kaplan-Meier). The product's performance is evaluated in discrete one-month intervals. The survival probability for each month is given by the number of devices that remain implanted and operational through this month divided by the number of devices that entered the interval. The cumulative survival probability for any period is given by multiplying all survival probabilities of previous months.

At the time of implantation, the cumulative survival probability is 100%. Even though they are analyzed as part of our quality system monitoring, devices that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time. Because this report is provided to describe product performance based on returned product analyses, the pacemaker and ICD data does not include information regarding medical complications such as erosion, infection or diaphragmatic stimulation.

In general, during the initial phase of the service time, devices which are out of specification are the primary contribution to reduction of survival probability. As the product lifecycle lengthens, normal battery depletion assumes a greater impact on the survival curve and becomes the dominating factor.

In order to make these two effects distinguishable, the cumulative survival probability curves are shown separately for devices that are confirmed to have malfunctioned only, and for total (all-cause) cumulative survival. In case of a device being subject to a safety advisory notification that significantly impacts the survival probability, this factor is displayed separately.

## 2.2 Data Acquisition

This report is based on the observation of BIOTRONIK's U.S. products through review of our device registration and tracking systems and analyses of returned products from all sources. Because the ability to perform decedent searches of patients with BIOTRONIK devices via the U.S. Social Security Administration, the use of U.S. data more accurately represents the active patient population for reporting purposes. In addition, device tracking regulations and vigilance reporting regulations vary throughout the world; therefore, use of the U.S. data is most appropriate for accurate and consistent reporting of product performance.

In order to be included in the population under observation, a device must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is December 31, 2020. The number of U.S. devices that are implanted and remain active as well as the total number of products distributed worldwide are provided for each product family in this report. Information is provided for separate product families, in that devices with nearly identical hardware and therapy functions are combined. For example, Edora 8 DR and DR-T (with Home Monitoring) IPGs are combined into a single family, Edora 8 Single Chamber IPGs.

Survival estimates are calculated for product families having accumulated at least 10,000 cumulative implant months. Because 10,000 implant months may take some time to accumulate, there may be a gap between U.S. market release and the start of graphical representation of survival probability. Products no longer being distributed with less than 500 active implants may be excluded from this report.

ISO 5841-2 describes a method for adjusting the device survival probability to compensate for underreported malfunctions and unrelated patient deaths. The factor for underreporting of malfunctions is unknown as currently no systematic data is available that reveals this factor. Consequently, this factor remains unaccounted for this report. Patient mortality is artificially elevated if the reported rate from our registration and tracking systems is below the annual mortality in clinical studies. Normal battery depletion rate is assumed if the reported rate of depletion decreases over time.

## 2.3 Returned Product Analysis

Information on malfunctioning for the pacemaker and ICD portions of this report is taken exclusively from the analysis of returned products. The outcome of this analysis is the basis for the final classification of the device's cause of explantation. Only analyzed products with confirmed device malfunctions are utilized in the calculation of malfunction-free survival probability.

Every pacemaker and ICD returned to BIOTRONIK is analyzed per internal procedures and classified as functioning normally, normal battery depletion, or malfunctioning (including premature battery depletion) while implanted and in service. These device classifications are the basis for BIOTRONIK's cumulative survival estimates on pacemakers and ICDs.

As a significant portion of pacemakers and ICDs with normal battery depletion are not returned for analysis, BIOTRONIK also considers unconfirmed pacemaker and ICD battery depletions (reported, but device not returned) in the total survival estimates to ensure that a conservative estimate for device performance is reported.

## 2.4 Product Performance Graphs and Data

The product performance information is shown in each section in alphabetical order and by product type.

For each product, the report provides:

- Product versions that contribute to the evaluation
- U.S. and CE market release dates
- Worldwide quantity of products that have been distributed
- U.S. registered implants (number of products included in this report)
- Estimated active U.S. implants
- Number of U.S. normal battery depletions
- Number of U.S. confirmed malfunctions

The survival plots provide:

**1. Total Survival**
The combined cumulative survival probability for all causes that result in device removal or a system out of operation, excluding removals for clinical reasons unrelated to the device's performance (i.e., infections).

**2. Malfunction-Free Survival**
The cumulative survival probability free of component or software malfunctions excluding normal battery depletions, but including premature battery depletions. Normal battery depletions only have an impact on the total cumulative survival.

Products or subgroups of products may become subject to safety advisory notifications that can significantly impact the overall product performance. However, as these subgroups are clearly defined they are separated from the non-advisory devices. The impact of the advisory notification is then shown in a separate graph for total cumulative survival and for malfunction-free survival of the device population affected by the advisory notification. Current advisories are listed in chapter 11 of this report.

The cumulative survival data and the 95% confidence intervals according to the Greenwood's Formula[1] are shown in numerical form for the observed population.

1 Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1-26, 1926

# Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers
3.2 Dual-Chamber Pacemakers
3.3 CRT Pacemakers

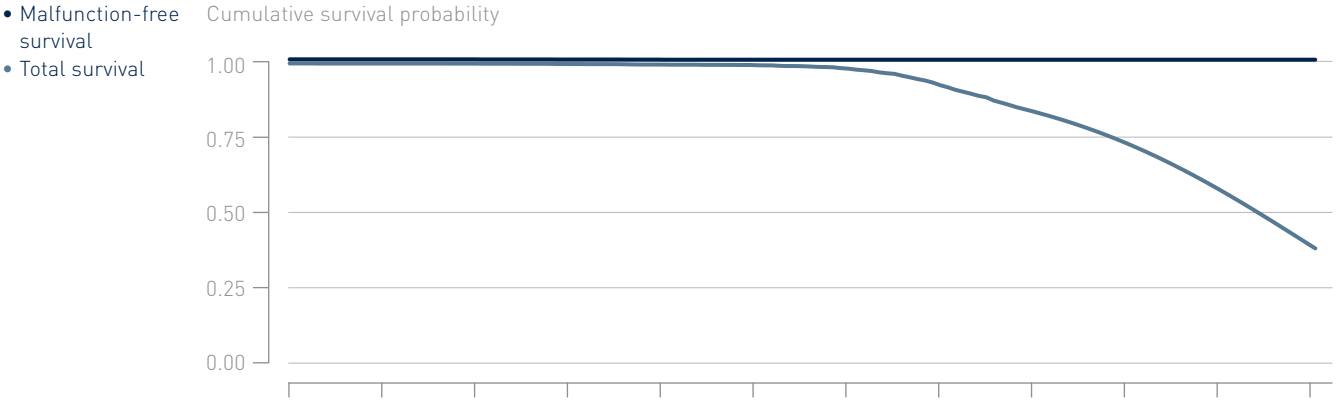
# Performance of BIOTRONIK Pacemakers

**3.1 Single-Chamber Pacemakers**
3.2 Dual-Chamber Pacemakers
3.3 CRT Pacemakers

# Cylos and Cylos 990

| | |
|---|---|
| Product Versions | VR |
| NBG Codes | VVIR |
| US Market Release | Jan 2006 |
| CE Market Release | Nov 2005 / Mar 2008 |
| Worldwide Distributed Devices | 25 900 |
| Registered U.S. Implants | 6 149 |
| Estimated Active U.S. Implants | 2 460 |
| U.S. Normal Battery Depletions | 844 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.07% |
| Therapy Compromised | 1 | 0.02% |
| Therapy Available | 3 | 0.05% |

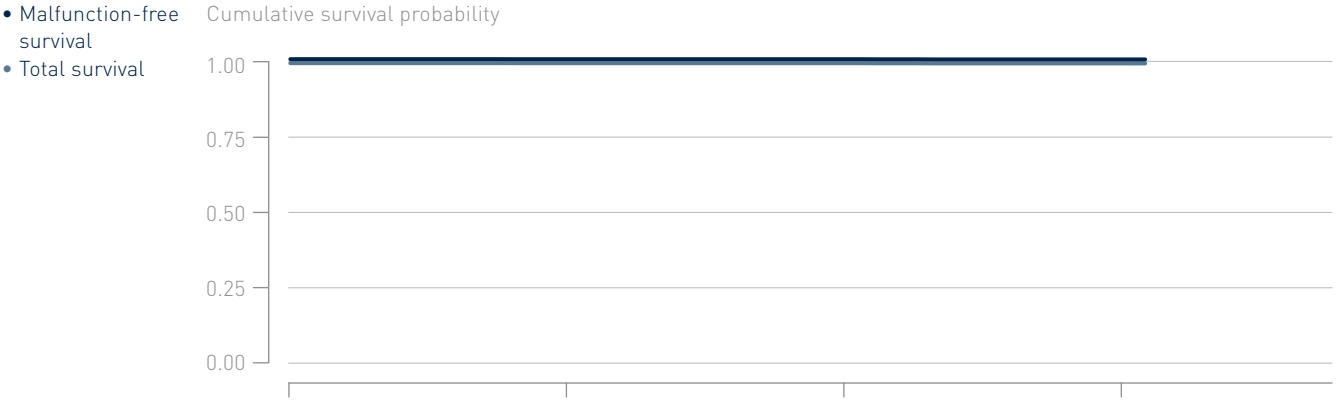



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.6 | 99.5 | 98.4 | 93.7 | 84.8 | 74.9 | 60.3 | 41.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.4 | 0.8 | 1.2 | 1.4 | 1.7 | 2.8 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 6149 | 5407 | 4910 | 4541 | 4224 | 4007 | 3820 | 3504 | 3040 | 2646 | 1968 | 523 |

# Edora 8

| | |
|---|---|
| Product Versions | SR, SR-T |
| NBG Codes | VVIR |
| US Market Release | May 2017 |
| CE Market Release | Sep 2016 |
| Worldwide Distributed Devices | 29 400 |
| Registered U.S. Implants | 5 414 |
| Estimated Active U.S. Implants | 4 790 |
| U.S. Normal Battery Depletions | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

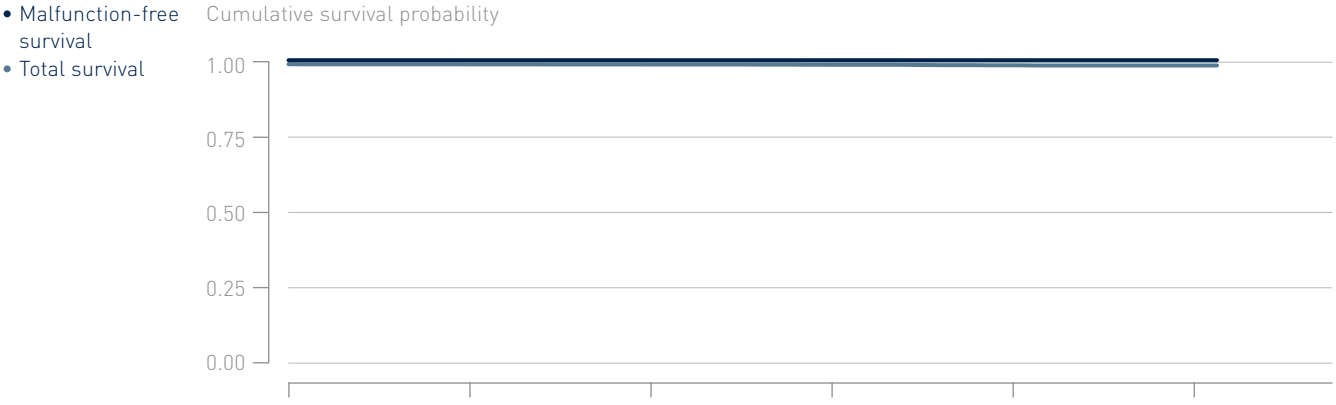



| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 5414 | 3686 | 1845 | 303 |

# Eluna 8

| | |
|---|---|
| Product Versions | SR, SR-T |
| NBG Codes | AAIR, VVIR |
| US Market Release | Dec 2014 |
| CE Market Release | Aug 2014 |
| Worldwide Distributed Devices | 19 600 |
| Registered U.S. Implants | 5 800 |
| Estimated Active U.S. Implants | 4 570 |
| U.S. Normal Battery Depletions | 12 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

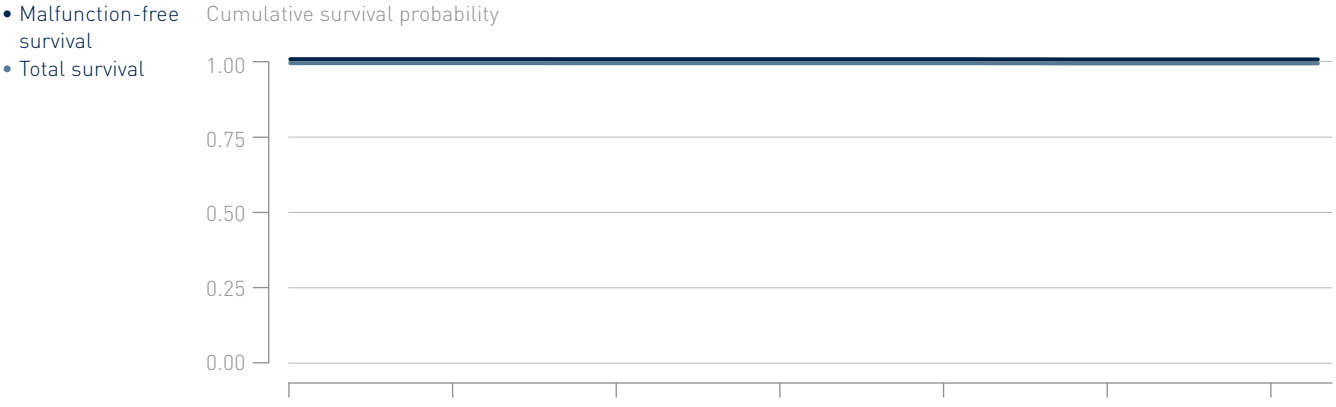



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.7 | 99.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 5800 | 5335 | 4808 | 4099 | 2363 | 393 |

# Entovis

| | |
|---|---|
| Product Versions | SR, SR-T |
| NBG Codes | AAIR, VVIR |
| US Market Release | Jun 2010 |
| CE Market Release | Nov 2009 |
| Worldwide Distributed Devices | 28 000 |
| Registered U.S. Implants | 2 398 |
| Estimated Active U.S. Implants | 1 670 |
| U.S. Normal Battery Depletions | 7 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.08% |
| Therapy Compromised | 1 | 0.04% |
| Therapy Available | 1 | 0.04% |

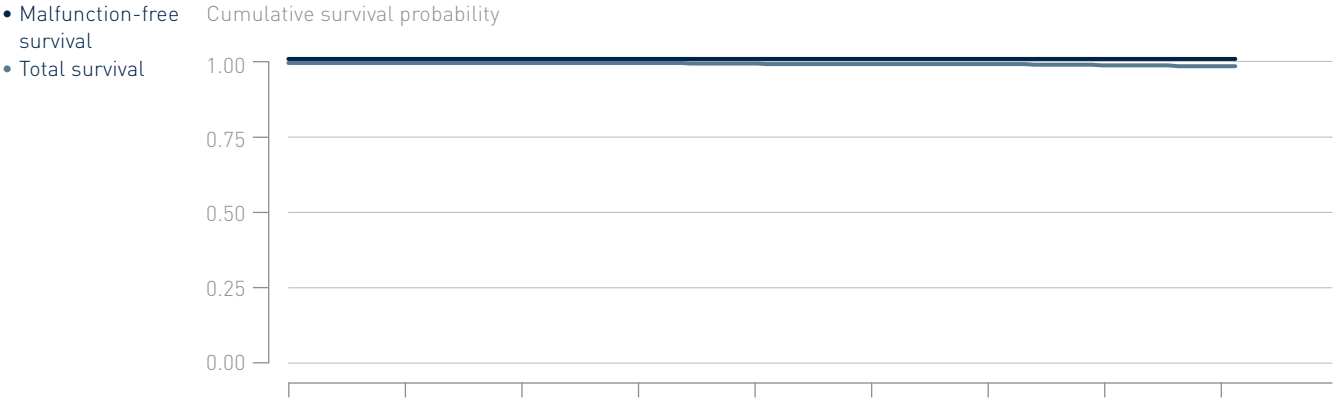



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 | 99.7 | 99.5 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 2398 | 2190 | 2064 | 1936 | 1821 | 1534 | 562 |

# Estella

| | |
|---|---|
| Product Versions | SR, SR-T |
| NBG Codes | AAIR, VVIR |
| US Market Release | Feb 2011 |
| CE Market Release | Feb 2011 |
| Worldwide Distributed Devices | 38 400 |
| Registered U.S. Implants | 612 |
| Estimated Active U.S. Implants | 395 |
| U.S. Normal Battery Depletions | 5 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.16% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.16% |

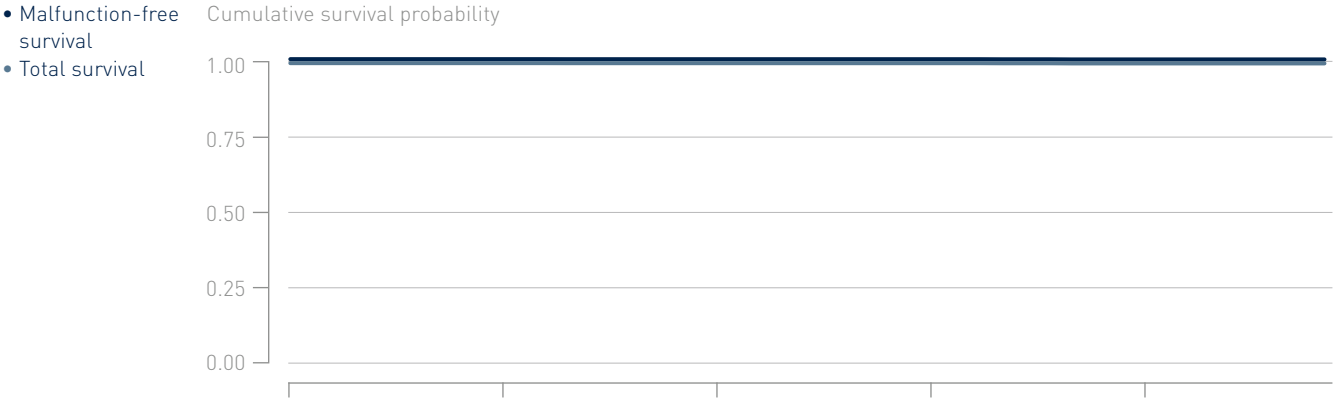



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 | 99.5 | 99.5 | 99.3 | 98.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 | 99.8 | 99.8 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 612 | 535 | 493 | 453 | 432 | 422 | 417 | 370 | 240 |

# Etrinsa 8

| | |
|---|---|
| Product Versions | SR-T |
| NBG Codes | AAIR, VVIR |
| US Market Release | Dec 2014 |
| CE Market Release | Aug 2014 |
| Worldwide Distributed Devices | 18 500 |
| Registered U.S. Implants | 1 722 |
| Estimated Active U.S. Implants | 1 320 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

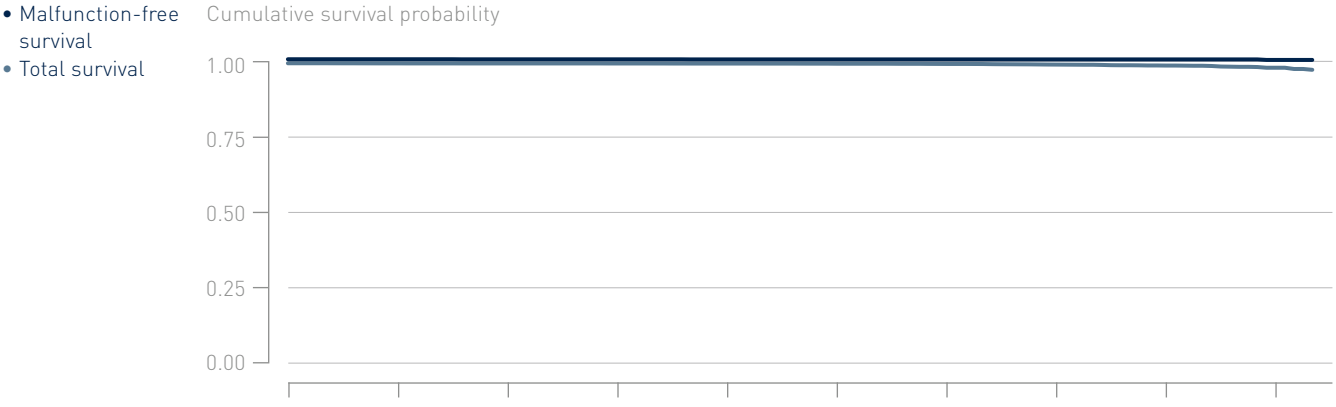



| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1722 | 1572 | 1429 | 1193 | 770 |

# Evia

| | |
|---|---|
| Product Versions | SR, SR-T |
| NBG Codes | AAIR, VVIR |
| US Market Release | May 2010 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 62 100 |
| Registered U.S. Implants | 11 973 |
| Estimated Active U.S. Implants | 7 620 |
| U.S. Normal Battery Depletions | 70 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 3 | 0.03% |
| Therapy Compromised | 2 | 0.02% |
| Therapy Available | 1 | 0.01% |

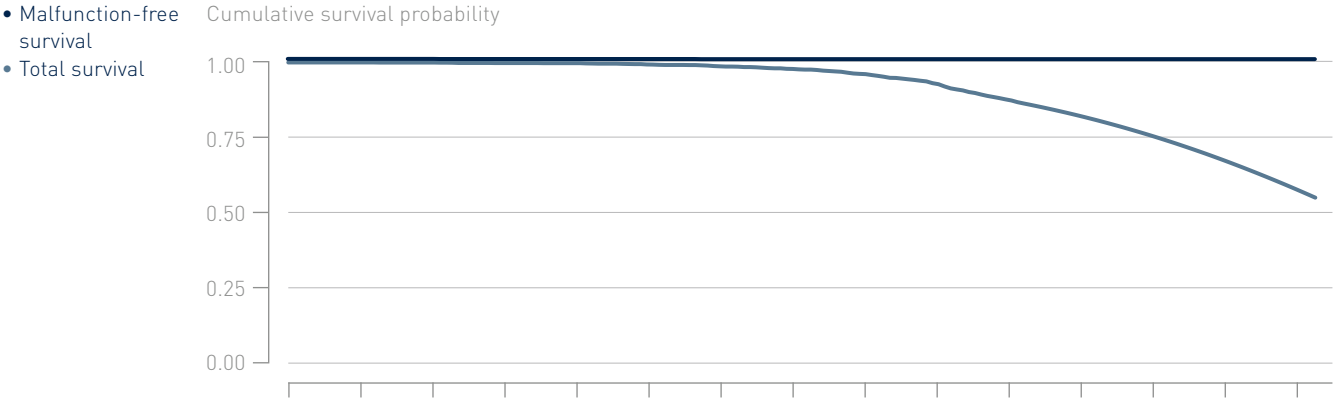



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 | 99.8 | 99.5 | 99.2 | 98.4 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 11973 | 10742 | 10109 | 9633 | 9294 | 8725 | 7668 | 5529 | 3135 | 939 |

# Philos II and Talos

| | |
|---|---|
| Product Versions | S, SR |
| NBG Codes | SSI, SSIR |
| US Market Release | Sep 2004 |
| CE Market Release | Feb 2004 / May 2006 |
| Worldwide Distributed Devices | 215 000 |
| Registered U.S. Implants | 5 238 |
| Estimated Active U.S. Implants | 2 400 |
| U.S. Normal Battery Depletions | 394 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.04% |
| Therapy Compromised | 1 | 0.02% |
| Therapy Available | 1 | 0.02% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.8 | 99.8 | 99.5 | 99.0 | 98.3 | 96.8 | 94.0 | 90.1 | 85.9 | 80.7 | 74.3 | 66.8 |
| CI [±%] | - | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.2 | 0.3 | 0.4 | 0.6 | 0.8 | 1.1 | 1.3 | 1.6 | 2 | 3.2 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 5238 | 4431 | 4037 | 3705 | 3489 | 3310 | 3169 | 3082 | 2959 | 2814 | 2555 | 2060 | 1458 | 798 | 254 |

* While Talos SR and Talos S are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products

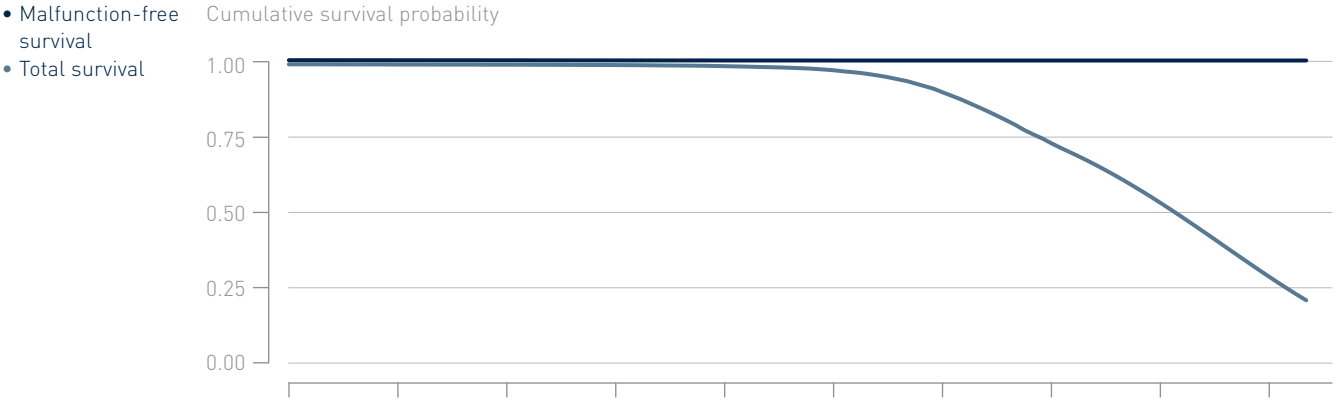
# Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers
**3.2 Dual-Chamber Pacemakers**
3.3 CRT Pacemakers

# Cylos and Cylos 990

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | Jan 2006 |
| CE Market Release | Nov 2005 / Mar 2008 |
| Worldwide Distributed Devices | 81 300 |
| Registered U.S. Implants | 30 373 |
| Estimated Active U.S. Implants | 7 430 |
| U.S. Normal Battery Depletions | 8 436 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 27 | 0.09% |
| Therapy Compromised | 7 | 0.02% |
| Therapy Available | 20 | 0.07% |



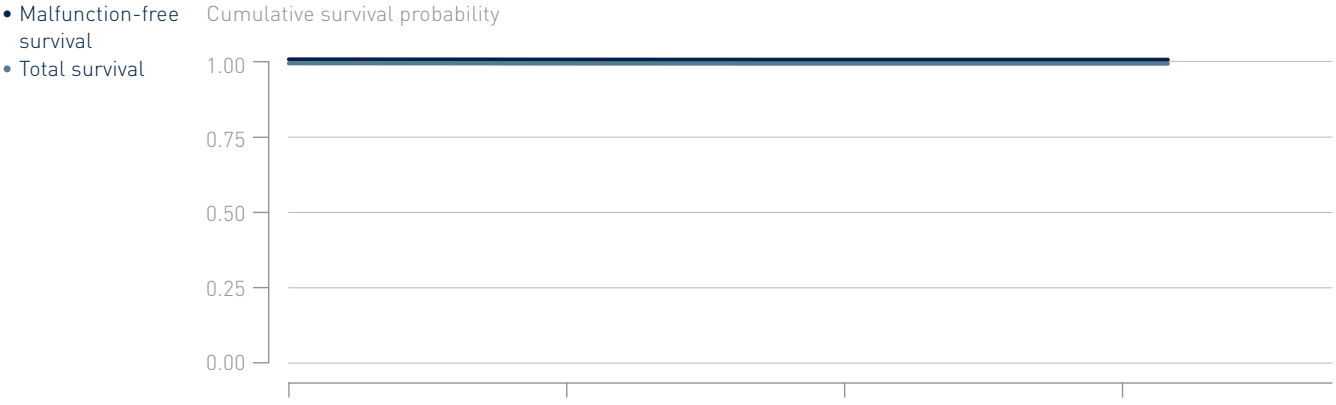

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.7 | 99.4 | 98.0 | 90.6 | 73.6 | 53.7 | 29.0 |
| CI [±%] | - | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.2 | 0.4 | 0.6 | 0.7 | 1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 30373 | 28180 | 26455 | 24996 | 23566 | 21807 | 18757 | 13745 | 9077 | 3110 |

*While Cylos 990 DR and Cylos 990 DR-T are not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products

# Edora 8

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | May 2017 |
| CE Market Release | Jul 2016 |
| Worldwide Distributed Devices | 155 000 |
| Registered U.S. Implants | 50 371 |
| Estimated Active U.S. Implants | 45 800 |
| U.S. Normal Battery Depletions | 20 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 3 | 0.01% |
| Therapy Compromised | 2 | 0.00% |
| Therapy Available | 1 | 0.00% |

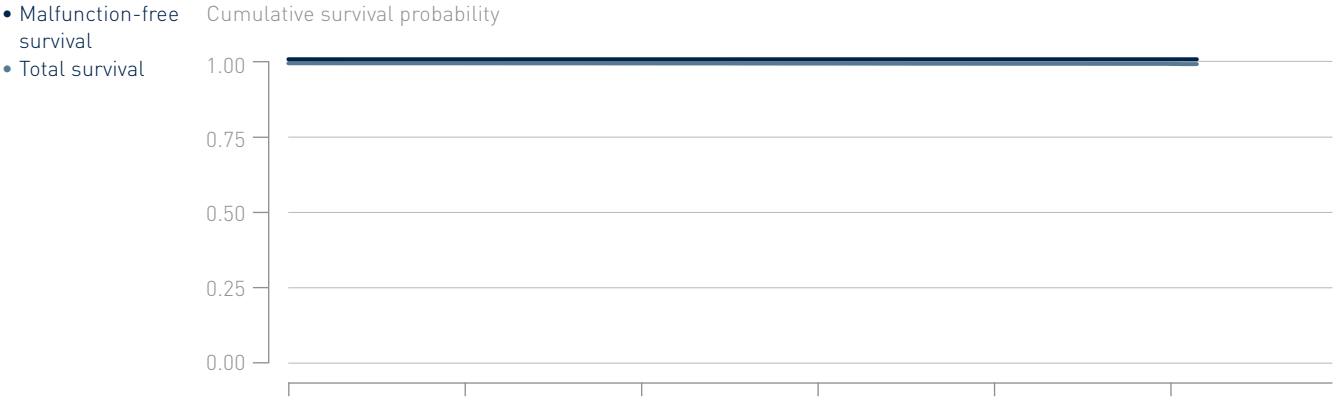



| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100 | 100 | 100 | 100 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 50371 | 33965 | 17162 | 2133 |

# Eluna 8

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | Dec 2014 |
| CE Market Release | Aug 2014 |
| Worldwide Distributed Devices | 97 200 |
| Registered U.S. Implants | 41 930 |
| Estimated Active U.S. Implants | 32 800 |
| U.S. Normal Battery Depletions | 40 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 2 | 0.00% |

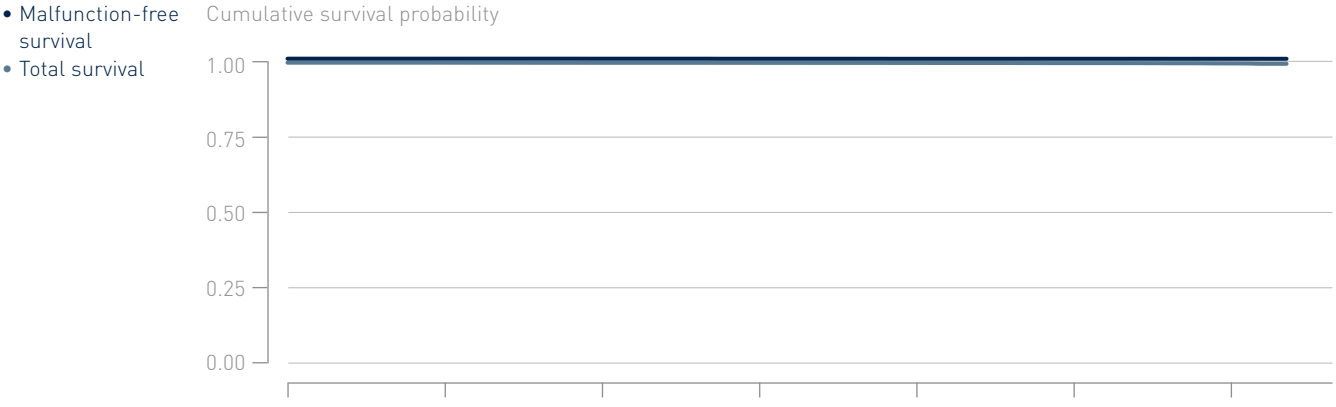



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 41930 | 38153 | 33638 | 28590 | 16358 | 1682 |

# Entovis

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | Feb 2010 |
| CE Market Release | Nov 2009 |
| Worldwide Distributed Devices | 105 000 |
| Registered U.S. Implants | 12 127 |
| Estimated Active U.S. Implants | 8 730 |
| U.S. Normal Battery Depletions | 35 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.03% |
| Therapy Compromised | 2 | 0.02% |
| Therapy Available | 2 | 0.02% |

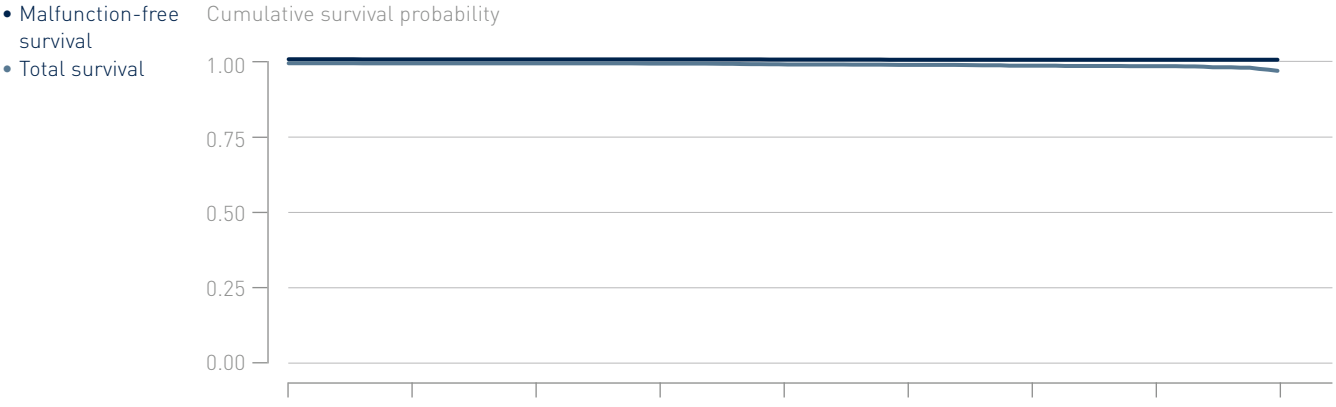



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 | 99.8 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 12127 | 11335 | 10621 | 9985 | 9370 | 8074 | 3211 |

# Estella

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | Feb 2011 |
| CE Market Release | Feb 2011 |
| Worldwide Distributed Devices | 45 100 |
| Registered U.S. Implants | 2 950 |
| Estimated Active U.S. Implants | 1 840 |
| U.S. Normal Battery Depletions | 29 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.14% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 4 | 0.14% |

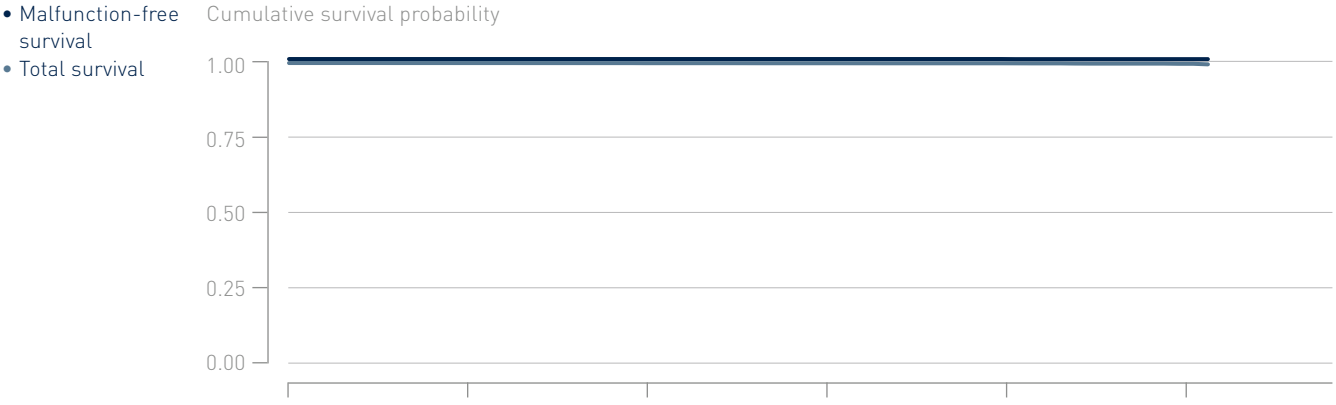



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 | 99.5 | 99.4 | 99.0 | 98.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 2950 | 2742 | 2591 | 2468 | 2329 | 2195 | 2051 | 1798 | 1180 |

# Etrinsa 8

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | DDDR |
| US Market Release | Dec 2014 |
| CE Market Release | Aug 2014 |
| Worldwide Distributed Devices | 76 300 |
| Registered U.S. Implants | 11 708 |
| Estimated Active U.S. Implants | 9 190 |
| U.S. Normal Battery Depletions | 20 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.01% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.01% |

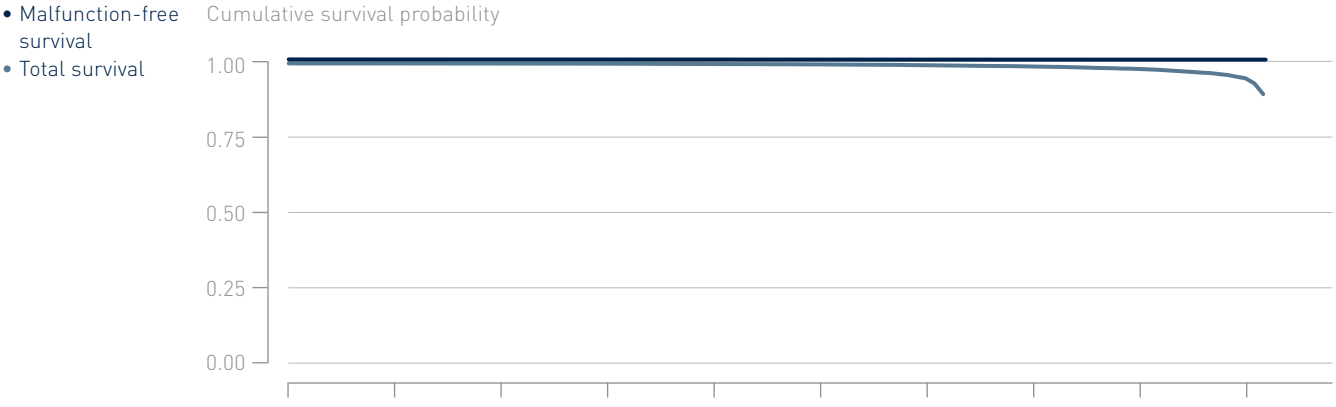



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 11708 | 10982 | 9992 | 8307 | 5171 | 1036 |

# Evia

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | DDDR |
| US Market Release | May 2010 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 217 000 |
| Registered U.S. Implants | 61909 |
| Estimated Active U.S. Implants | 38 900 |
| U.S. Normal Battery Depletions | 814 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 30 | 0.05% |
| Therapy Compromised | 11 | 0.02% |
| Therapy Available | 19 | 0.03% |

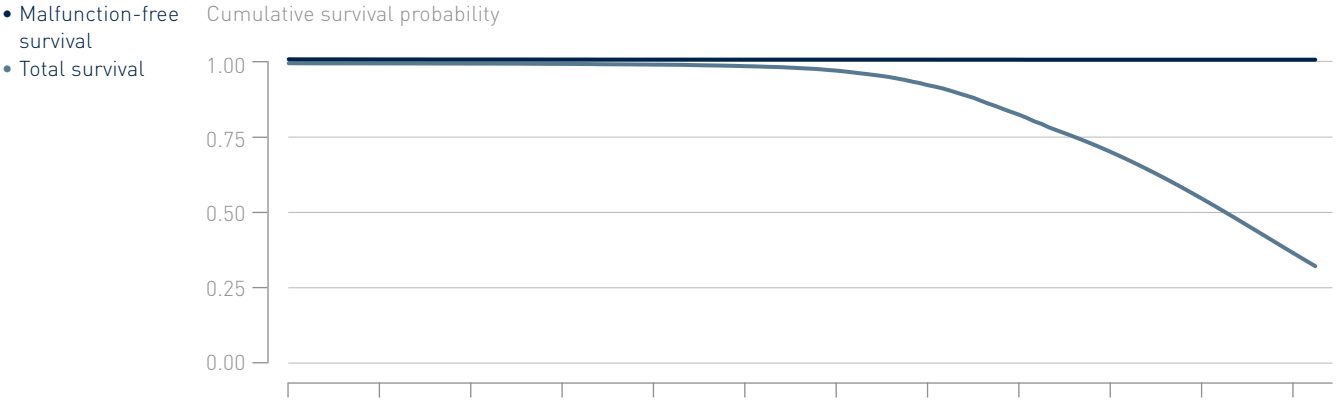



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 | 99.7 | 99.4 | 98.9 | 98.1 | 95.0 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 61909 | 57984 | 54511 | 51283 | 48206 | 45206 | 39172 | 26502 | 13588 | 2040 |

# Philos II and Talos

| | |
|---|---|
| Product Versions | D, DR, DR-T (Philos II only), SLR |
| NBG Codes | DDD, DDDR, VDDR |
| US Market Release | Sep 2004 |
| CE Market Release | Feb 2004 / May 2006 |
| Worldwide Distributed Devices | 372 000 |
| Registered U.S. Implants | 23 203 |
| Estimated Active U.S. Implants | 6 980 |
| U.S. Normal Battery Depletions | 4 741 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 21 | 0.09% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 21 | 0.09% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.5 | 99.0 | 97.5 | 92.7 | 82.9 | 70.6 | 55.0 | 36.9 |
| CI [±%] | - | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.4 | 0.6 | 0.8 | 0.9 | 1.3 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 23203 | 21214 | 19906 | 18749 | 17715 | 16832 | 15844 | 14191 | 11592 | 9032 | 6227 | 1815 |

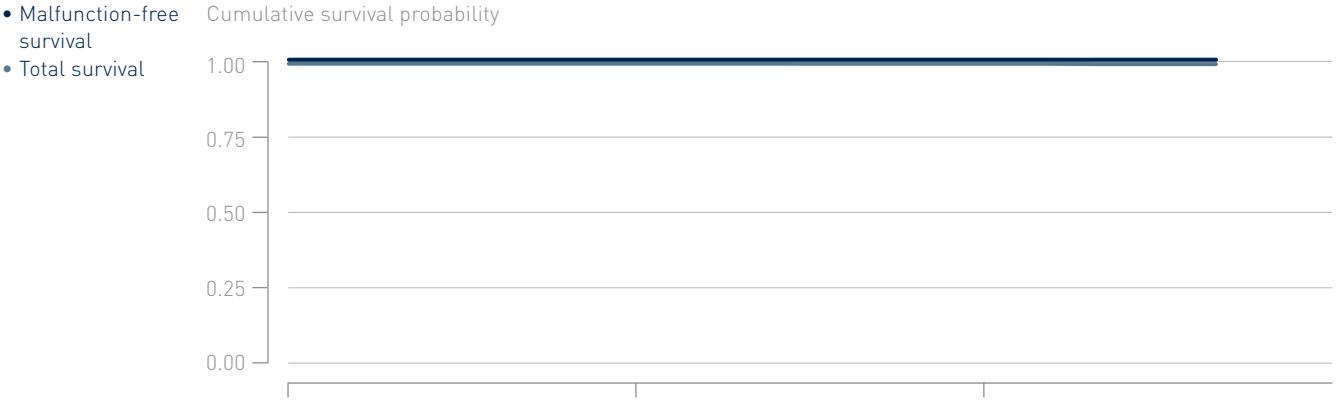
# Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers
3.2 Dual-Chamber Pacemakers
**3.3 CRT Pacemakers**

# Edora 8

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | DDDRV |
| US Market Release | Jun 2017 |
| CE Market Release | Mar 2017 |
| Worldwide Distributed Devices | 11 900 |
| Registered U.S. Implants | 4 134 |
| Estimated Active U.S. Implants | 3 510 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

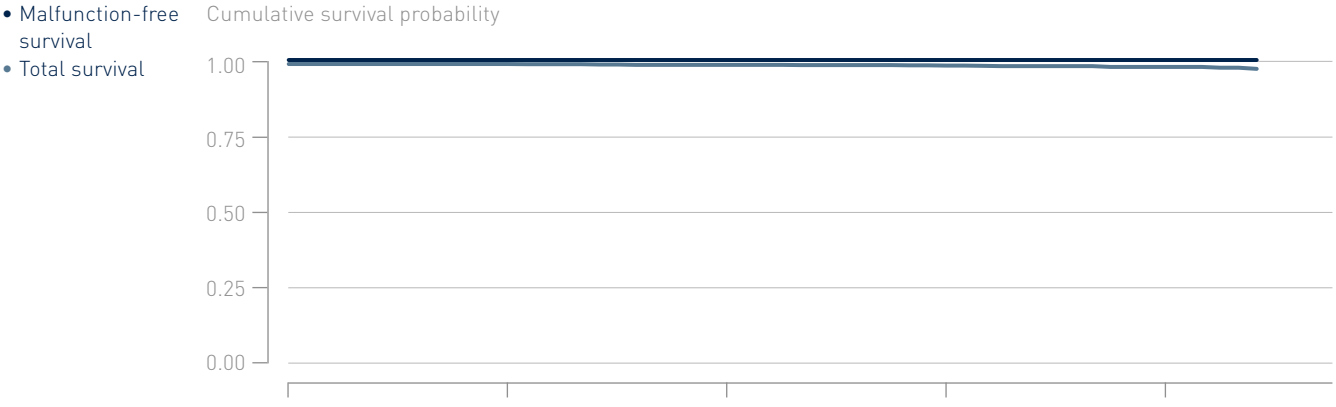



| Years after implant | 0 | 1 | 2 |
|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 |
| Sample Size | 4134 | 2453 | 972 |

# Etrinsa 8

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | DDDRV |
| US Market Release | Dec 2014 |
| CE Market Release | Aug 2014 |
| Worldwide Distributed Devices | 8 670 |
| Registered U.S. Implants | 1 860 |
| Estimated Active U.S. Implants | 1 200 |
| U.S. Normal Battery Depletions | 17 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

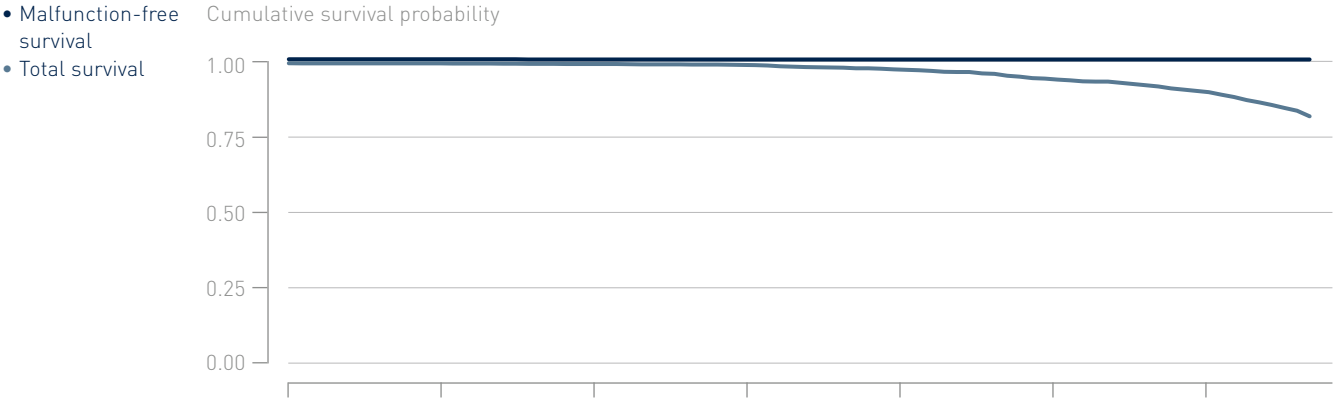



| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.7 | 99.4 | 98.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1860 | 1626 | 1357 | 1035 | 464 |

# Evia

| | |
|---|---|
| Product Versions | HF, HF-T |
| NBG Codes | DDDRV |
| US Market Release | May 2010 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 8 880 |
| Registered U.S. Implants | 2 249 |
| Estimated Active U.S. Implants | 941 |
| U.S. Normal Battery Depletions | 152 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.04% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.04% |



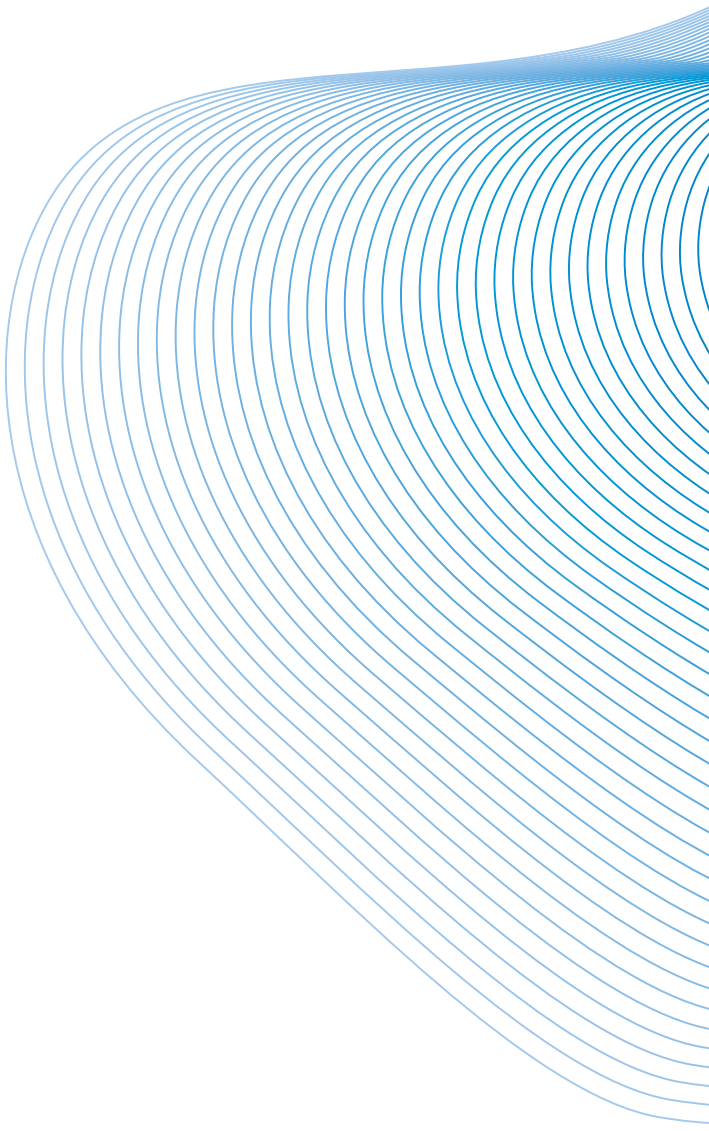

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.7 | 99.4 | 97.9 | 94.8 | 90.7 |
| CI [±%] | - | 0.1 | 0.2 | 0.3 | 0.7 | 1.2 | 1.7 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 2249 | 1987 | 1765 | 1569 | 1364 | 1166 | 727 |

# Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs
4.2 Dual-Chamber ICDs
4.3 CRT ICDs

# Performance of BIOTRONIK ICDs

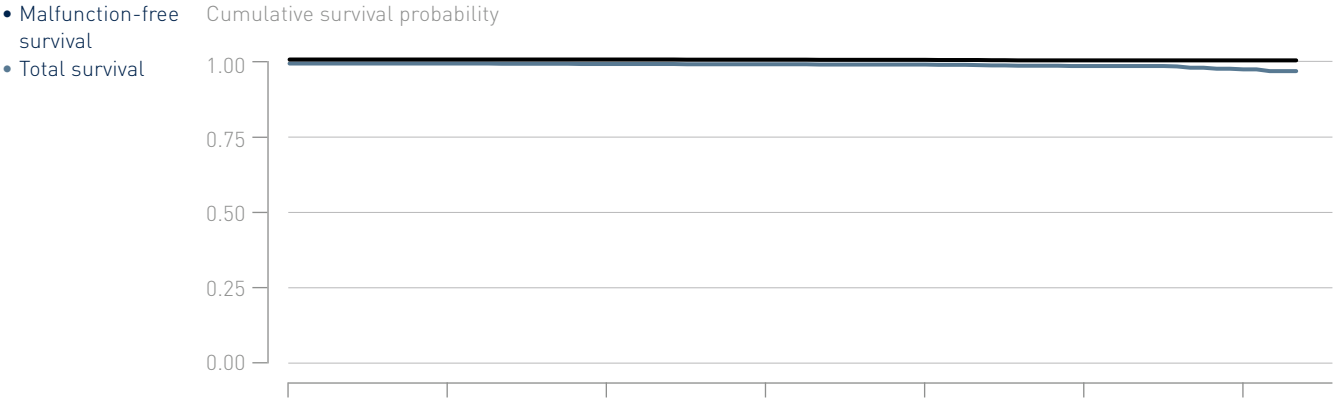
**4.1 Single-Chamber ICDs**
4.2 Dual-Chamber ICDs
4.3 CRT ICDs



# Ilesto 7

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 2460 |
| Registered U.S. Implants | 1271 |
| Estimated Active U.S. Implants | 839 |
| U.S. Normal Battery Depletions | 13 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 5 | 0.39% |
| Therapy Compromised | 3 | 0.24% |
| Therapy Available | 2 | 0.16% |

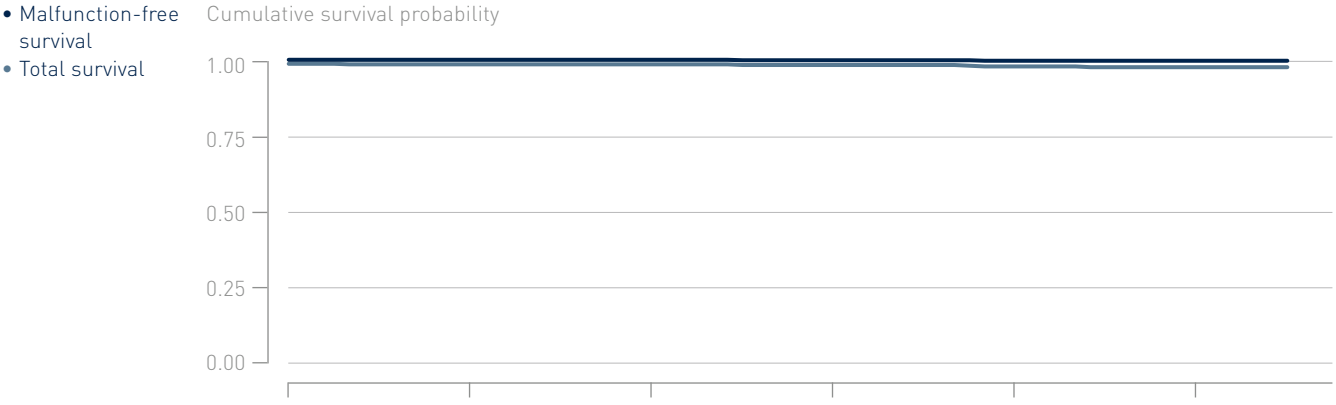



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.8 | 99.7 | 99.6 | 99.1 | 97.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.8 | 99.5 | 99.5 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1271 | 1182 | 1103 | 1032 | 958 | 849 | 414 |

# Ilesto 7 DF4

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 2390 |
| Registered U.S. Implants | 466 |
| Estimated Active U.S. Implants | 317 |
| U.S. Normal Battery Depletions | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 2 | 0.43% |
| Therapy Compromised | 2 | 0.43% |
| Therapy Available | 0 | 0.00% |



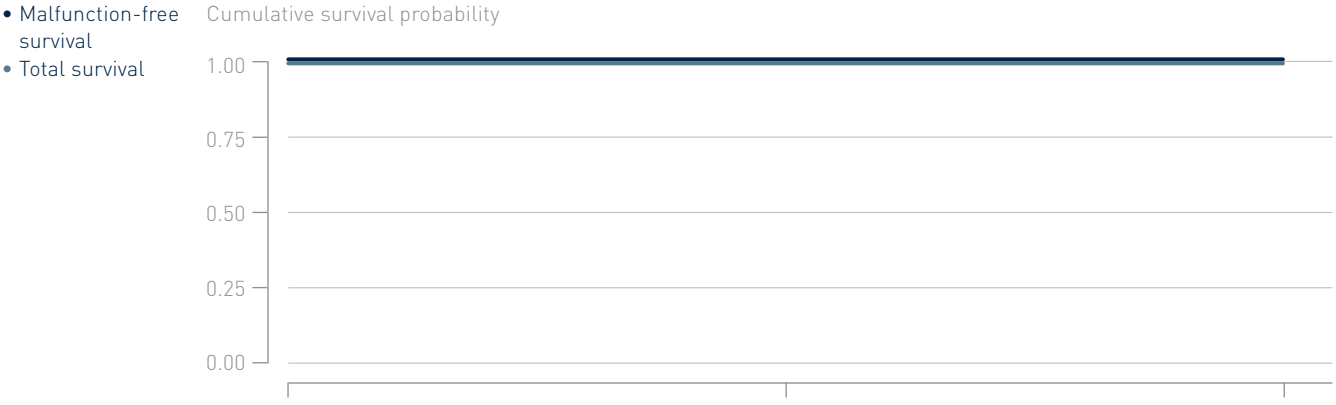

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.8 | 99.5 | 98.9 | 98.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.7 | 99.4 | 99.4 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 466 | 429 | 392 | 365 | 341 | 281 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilivia 7

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | May 2017 |
| Worldwide Distributed Devices | 2 300 |
| Registered U.S. Implants | 934 |
| Estimated Active U.S. Implants | 847 |
| U.S. Normal Battery Depletions | 0 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |



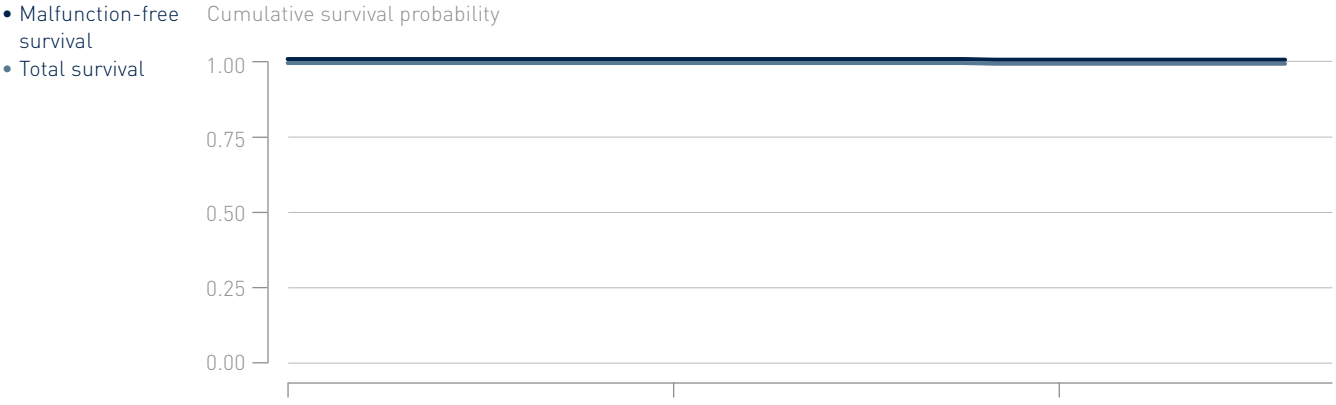

| Years after implant | 0 | 1 | 2 |
|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 |
| Sample Size | 934 | 594 | 211 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilivia 7 DF4

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Aug 2017 |
| CE Market Release | Mar 2017 |
| Worldwide Distributed Devices | 4 150 |
| Registered U.S. Implants | 878 |
| Estimated Active U.S. Implants | 763 |
| U.S. Normal Battery Depletions | 1 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 1 | 0.11% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.11% |



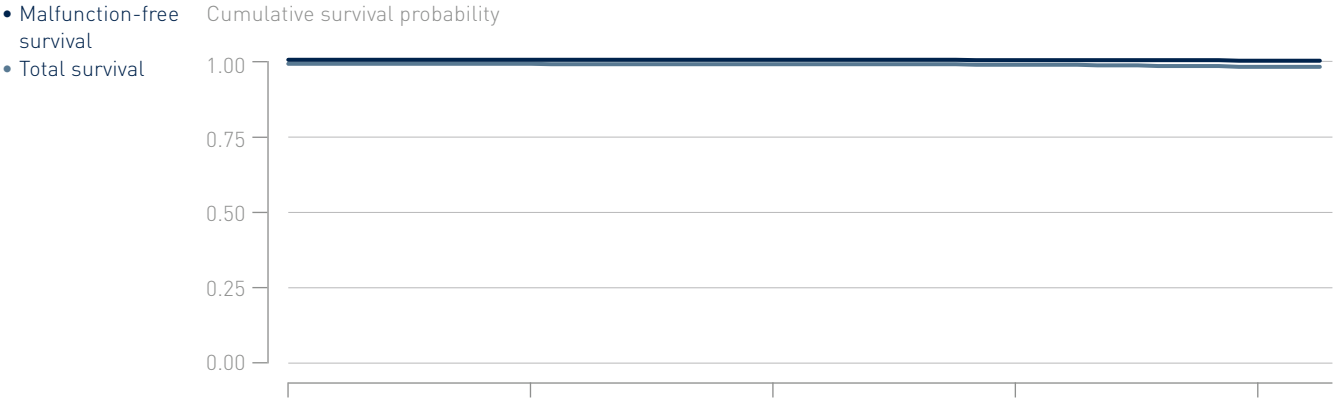

| Years after implant | 0 | 1 | 2 |
|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.7 |
| CI [±%] | - | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 |
| Sample Size | 878 | 788 | 517 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 1 280 |
| Registered U.S. Implants | 618 |
| Estimated Active U.S. Implants | 462 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 3 | 0.49% |
| Therapy Compromised | 3 | 0.49% |
| Therapy Available | 0 | 0.00% |



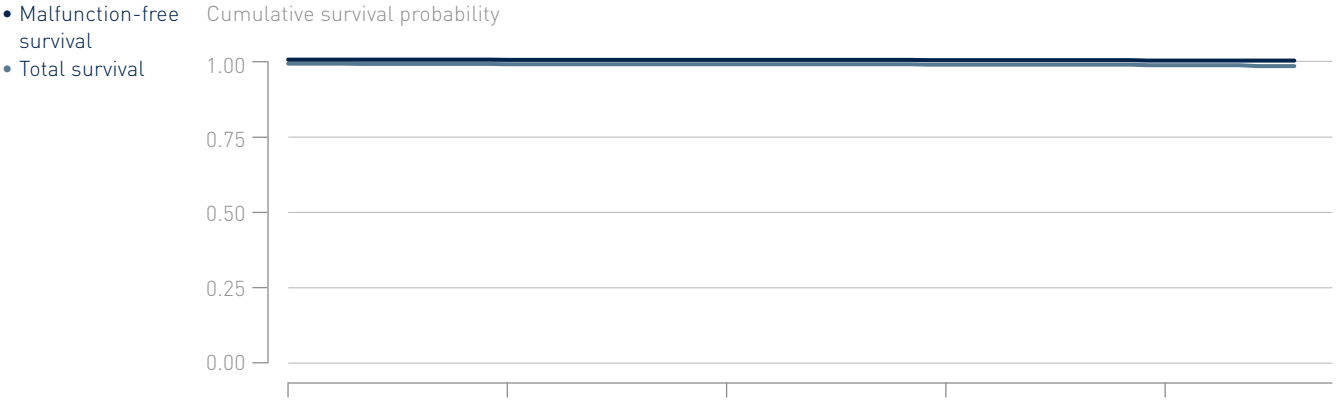

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.8 | 99.6 | 98.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.8 | 99.5 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 618 | 570 | 535 | 440 | 283 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7 DF4

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 1 420 |
| Registered U.S. Implants | 804 |
| Estimated Active U.S. Implants | 602 |
| U.S. Normal Battery Depletions | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 4 | 0.50% |
| Therapy Compromised | 2 | 0.25% |
| Therapy Available | 2 | 0.25% |



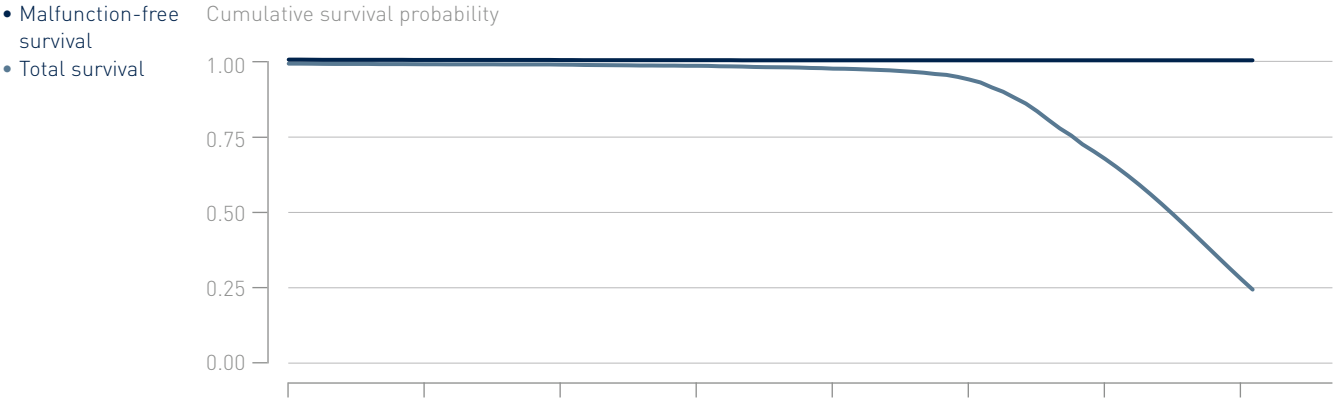

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.7 | 99.6 | 99.3 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.7 | 99.5 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 804 | 739 | 685 | 603 | 377 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Lumax 340

| | |
|---|---|
| Product Versions | VR, VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Feb 2007 |
| CE Market Release | Feb 2007 |
| Worldwide Distributed Devices | 27 100 |
| Registered U.S. Implants | 3 985 |
| Estimated Active U.S. Implants | 935 |
| U.S. Normal Battery Depletions | 928 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 6 | 0.15% |
| Therapy Compromised | 4 | 0.10% |
| Therapy Available | 2 | 0.05% |

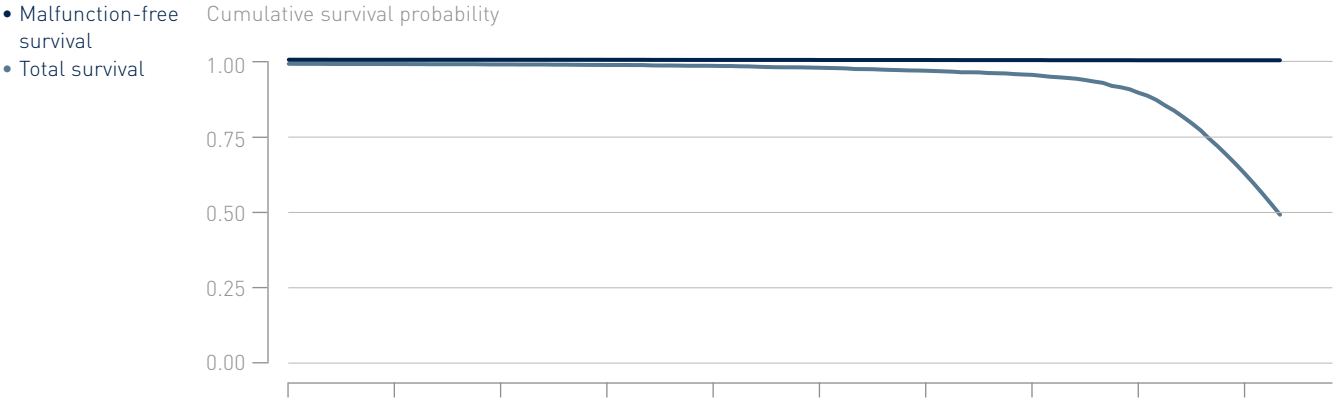



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.7 | 99.3 | 98.3 | 94.7 | 68.3 | 28.2 |
| CI [±%] | - | 0.1 | 0.2 | 0.3 | 0.4 | 0.8 | 1.9 | 3.3 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 | 99.8 | 99.8 | 99.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 3985 | 3616 | 3393 | 3155 | 2908 | 2550 | 1511 | 368 |

# Lumax 540

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | May 2009 |
| CE Market Release | Jun 2008 |
| Worldwide Distributed Devices | 20 000 |
| Registered U.S. Implants | 4 544 |
| Estimated Active U.S. Implants | 1 640 |
| U.S. Normal Battery Depletions | 731 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 13 | 0.29% |
| Therapy Compromised | 9 | 0.20% |
| Therapy Available | 4 | 0.09% |

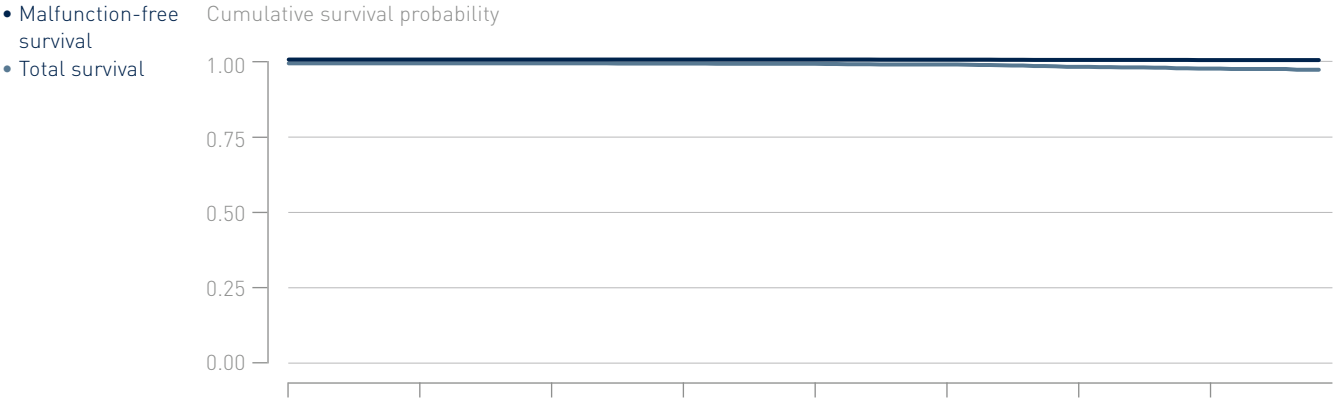



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.8 | 99.6 | 99.3 | 98.6 | 97.7 | 96.3 | 90.3 | 63.4 |
| CI [±%] | - | 0.1 | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 0.7 | 1.1 | 2.4 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.8 | 99.8 | 99.8 | 99.7 | 99.6 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Sample Size | 4544 | 4192 | 3897 | 3622 | 3370 | 3132 | 2879 | 2643 | 2129 | 682 |

# Lumax 740

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VVIR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2012 |
| CE Market Release | Apr 2012 |
| Worldwide Distributed Devices | 4810 |
| Registered U.S. Implants | 1574 |
| Estimated Active U.S. Implants | 968 |
| U.S. Normal Battery Depletions | 20 |

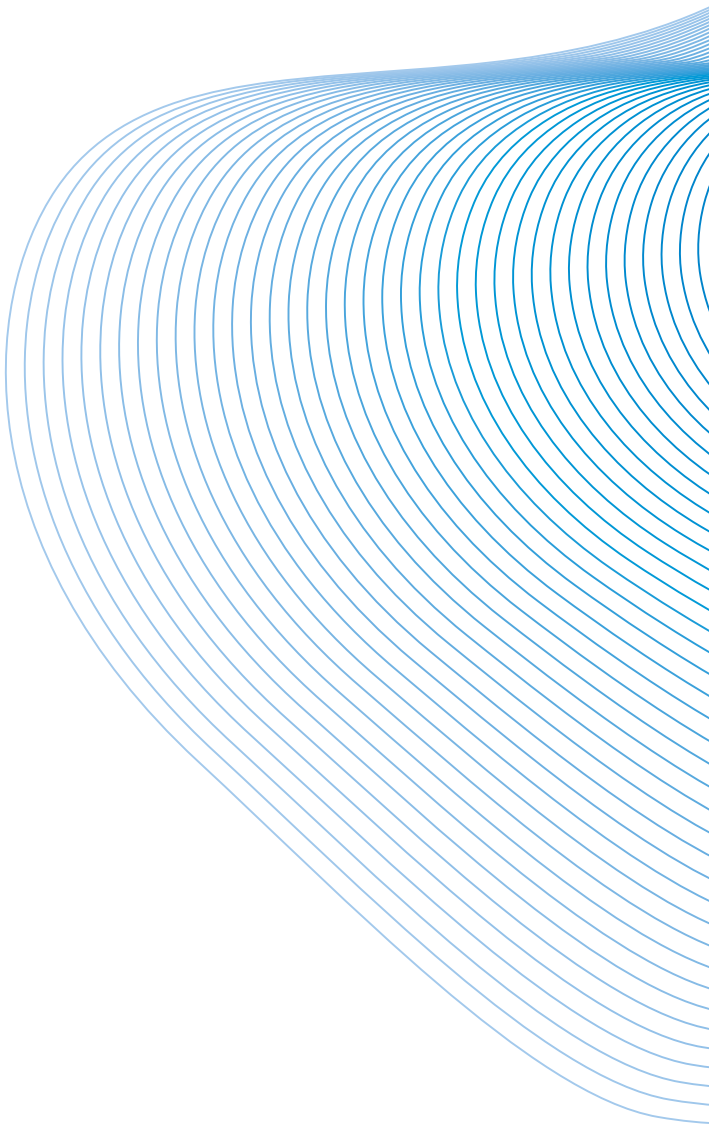
| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.25% |
| Therapy Compromised | 2 | 0.13% |
| Therapy Available | 2 | 0.13% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.8 | 99.6 | 98.7 | 98.1 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.7 | 99.6 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1574 | 1447 | 1347 | 1254 | 1160 | 1080 | 994 | 784 |

# Performance of BIOTRONIK ICDs

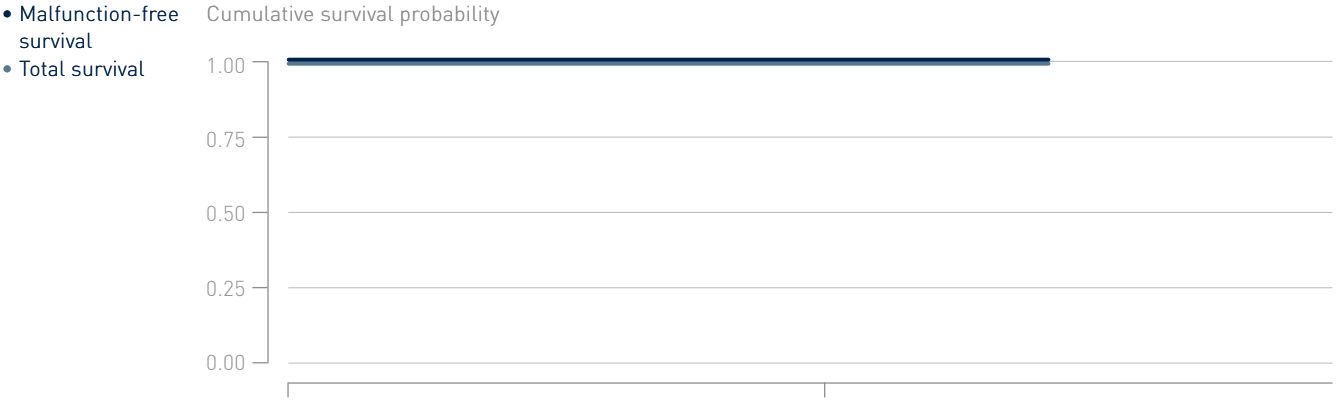
4.1 Single-Chamber ICDs
**4.2 Dual-Chamber ICDs**
4.3 CRT ICDs



# Acticor 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Apr 2019 |
| CE Market Release | Mar 2019 |
| Worldwide Distributed Devices | 7 190 |
| Registered U.S. Implants | 4 792 |
| Estimated Active U.S. Implants | 4 590 |
| U.S. Normal Battery Depletions | 0 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

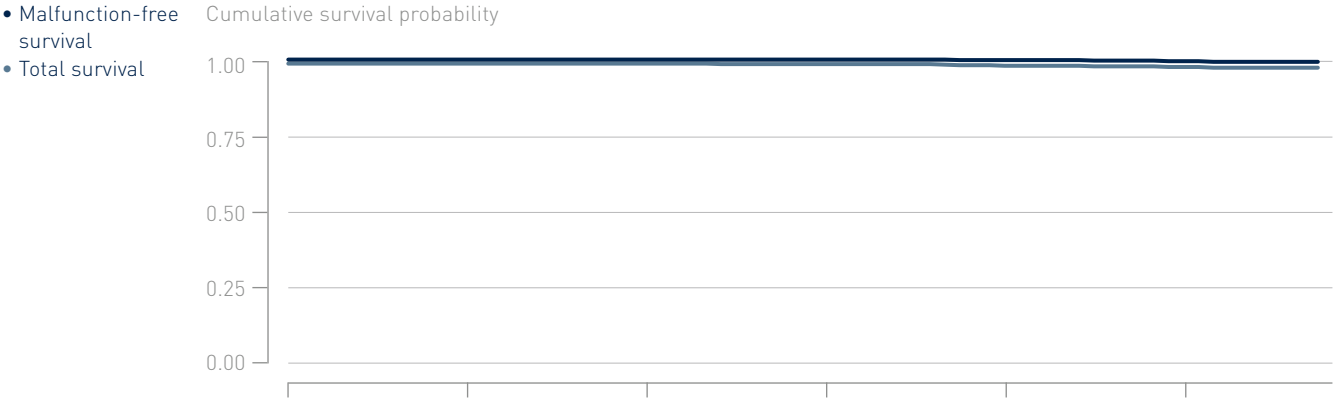



| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 100.0 |
| CI [±%] | - | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 |
| Sample Size | 4792 | 1610 |

# Iforia 7

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 1 790 |
| Registered U.S. Implants | 614 |
| Estimated Active U.S. Implants | 396 |
| U.S. Normal Battery Depletions | 4 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 4 | 0.65% |
| Therapy Compromised | 2 | 0.33% |
| Therapy Available | 2 | 0.33% |



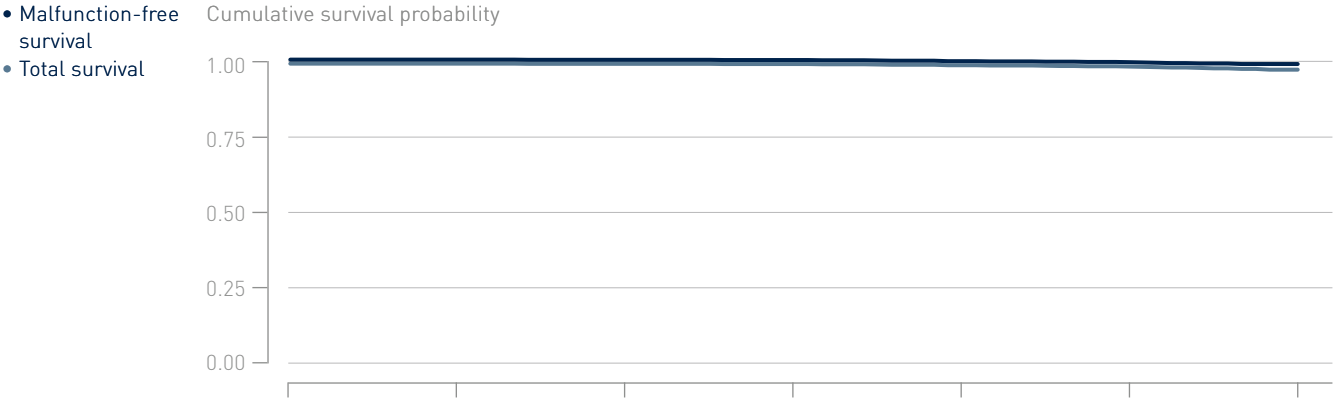

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.8 | 99.2 | 98.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 | 99.3 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 614 | 565 | 530 | 487 | 452 | 378 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iforia 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 4 270 |
| Registered U.S. Implants | 1 461 |
| Estimated Active U.S. Implants | 955 |
| U.S. Normal Battery Depletions | 5 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 17 | 1.16% |
| Therapy Compromised | 10 | 0.68% |
| Therapy Available | 7 | 0.48% |



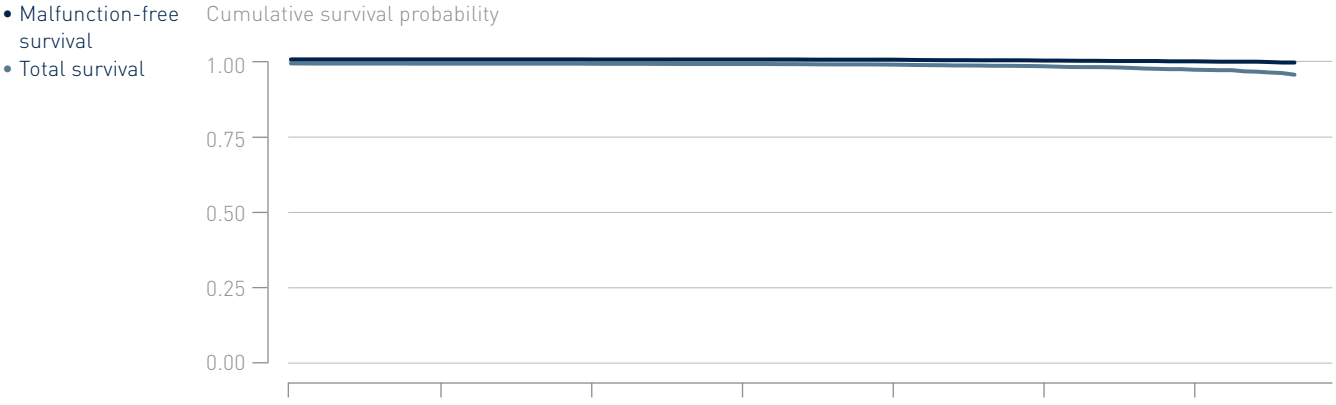

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 99.9 | 99.9 | 99.9 | 99.8 | 99.3 | 98.8 | 97.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 99.9 | 99.9 | 99.9 | 99.8 | 99.3 | 98.9 | 98.2 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1461 | 1359 | 1272 | 1184 | 1091 | 948 | 227 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilesto 7

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 5110 |
| Registered U.S. Implants | 3486 |
| Estimated Active U.S. Implants | 2320 |
| U.S. Normal Battery Depletions | 54 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 23 | 0.66% |
| Therapy Compromised | 13 | 0.37% |
| Therapy Available | 10 | 0.29% |



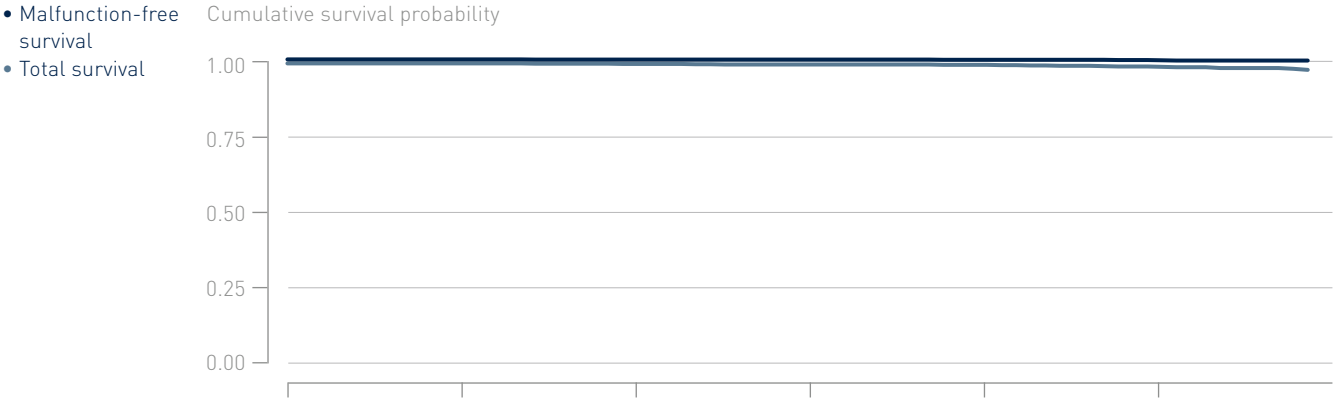

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.6 | 98.9 | 97.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.5 | 99.2 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 3486 | 3219 | 2997 | 2787 | 2587 | 2266 | 1366 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilesto 7 DF4

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Jul 2014 |
| CE Market Release | Jul 2013 |
| Worldwide Distributed Devices | 3 730 |
| Registered U.S. Implants | 1 147 |
| Estimated Active U.S. Implants | 759 |
| U.S. Normal Battery Depletions | 11 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 5 | 0.44% |
| Therapy Compromised | 2 | 0.17% |
| Therapy Available | 3 | 0.26% |



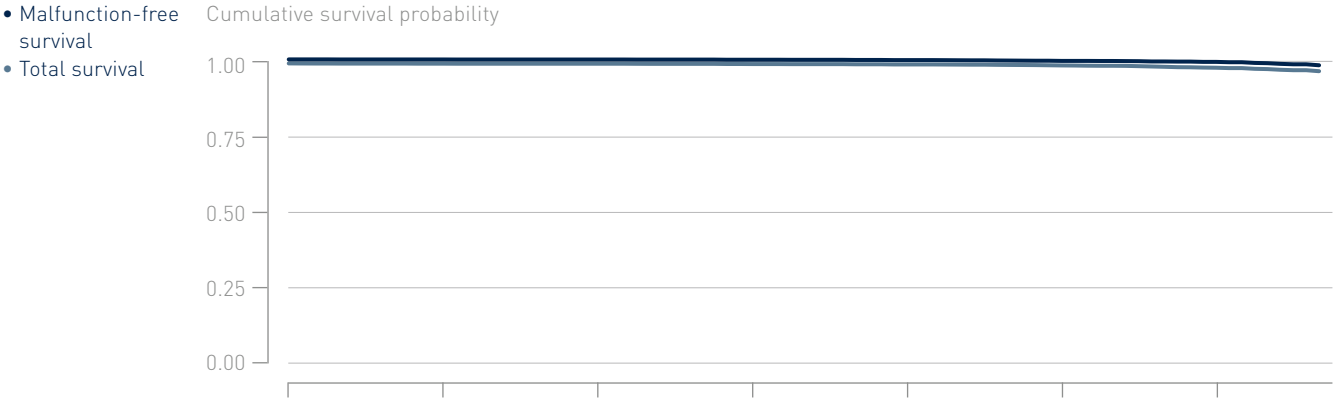

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.8 | 99.6 | 99.5 | 98.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 | 99.5 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1147 | 1060 | 984 | 913 | 851 | 745 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilesto 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 6 600 |
| Registered U.S. Implants | 4 720 |
| Estimated Active U.S. Implants | 3 060 |
| U.S. Normal Battery Depletions | 31 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 39 | 0.83% |
| Therapy Compromised | 21 | 0.44% |
| Therapy Available | 18 | 0.38% |



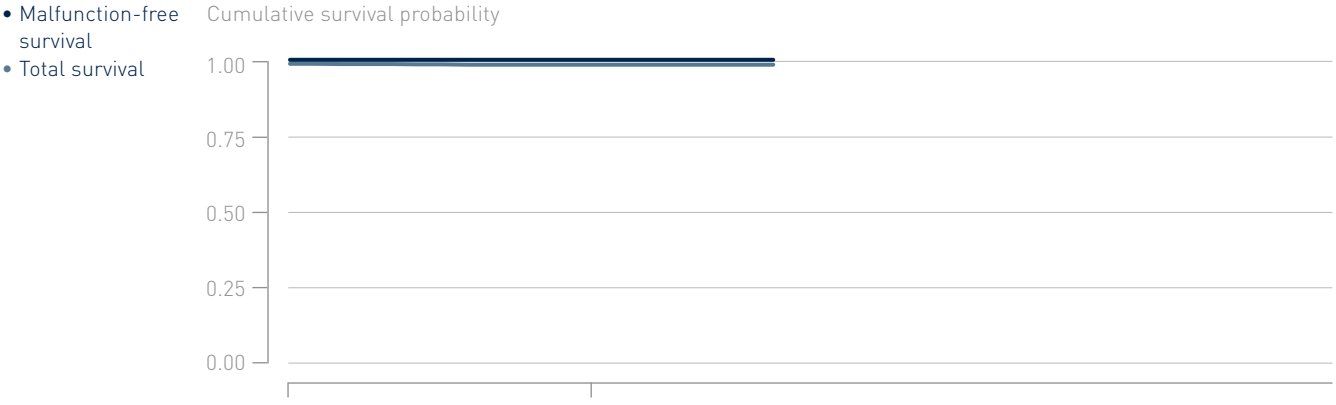

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.6 | 99.3 | 98.4 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.7 | 99.4 | 99.1 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 4720 | 4370 | 4090 | 3828 | 3555 | 3215 | 1695 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilivia 7

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | May 2017 |
| Worldwide Distributed Devices | 3080 |
| Registered U.S. Implants | 1590 |
| Estimated Active U.S. Implants | 1490 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |



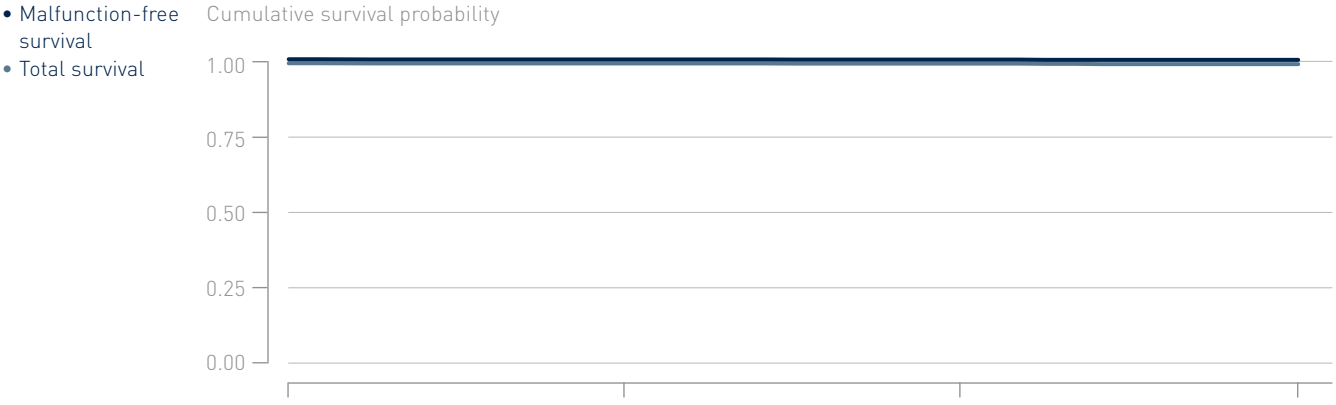

| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.8 |
| CI [±%] | - | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 |
| Sample Size | 1590 | 809 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilivia 7 DF4

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | Aug 2016 |
| Worldwide Distributed Devices | 8470 |
| Registered U.S. Implants | 3977 |
| Estimated Active U.S. Implants | 3450 |
| U.S. Normal Battery Depletions | 1 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 5 | 0.13% |
| Therapy Compromised | 5 | 0.13% |
| Therapy Available | 0 | 0.00% |



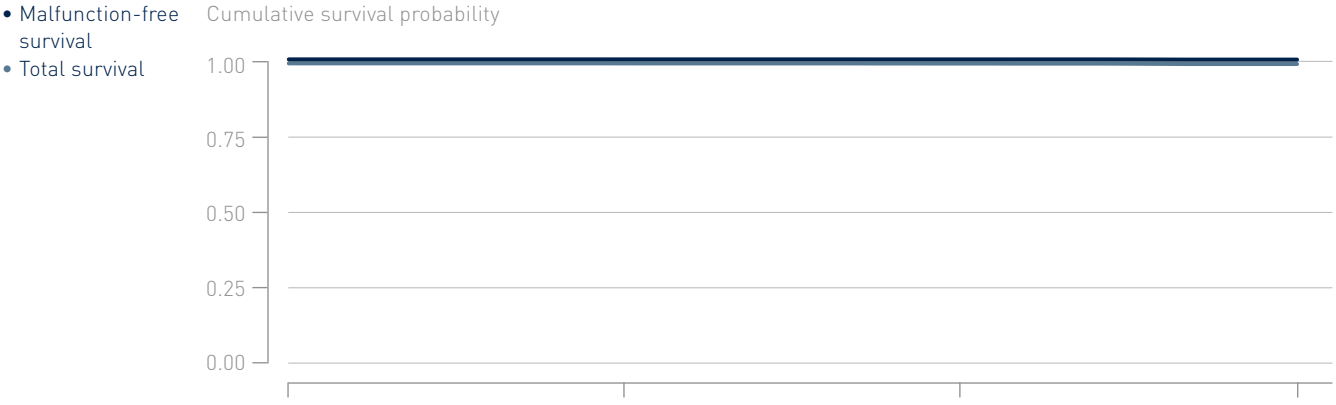

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 3977 | 3314 | 2020 | 288 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Intica 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | Sep 2016 |
| Worldwide Distributed Devices | 6 830 |
| Registered U.S. Implants | 4 622 |
| Estimated Active U.S. Implants | 4 000 |
| U.S. Normal Battery Depletions | 4 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 4 | 0.09% |
| Therapy Compromised | 1 | 0.02% |
| Therapy Available | 3 | 0.06% |



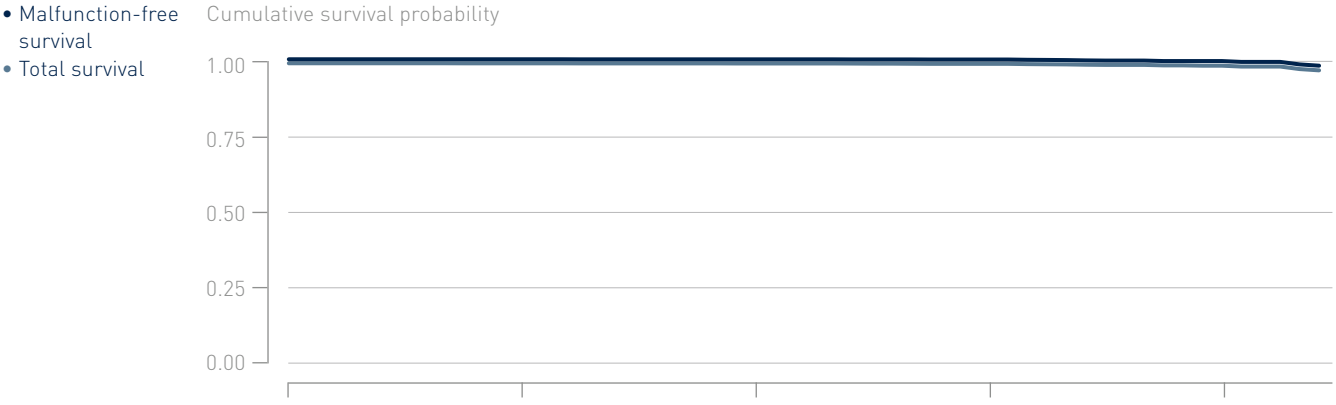

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.7 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 4622 | 3928 | 2416 | 271 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Inventra 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 45 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 5 790 |
| Registered U.S. Implants | 5 419 |
| Estimated Active U.S. Implants | 4 340 |
| U.S. Normal Battery Depletions | 6 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 20 | 0.37% |
| Therapy Compromised | 16 | 0.30% |
| Therapy Available | 4 | 0.07% |



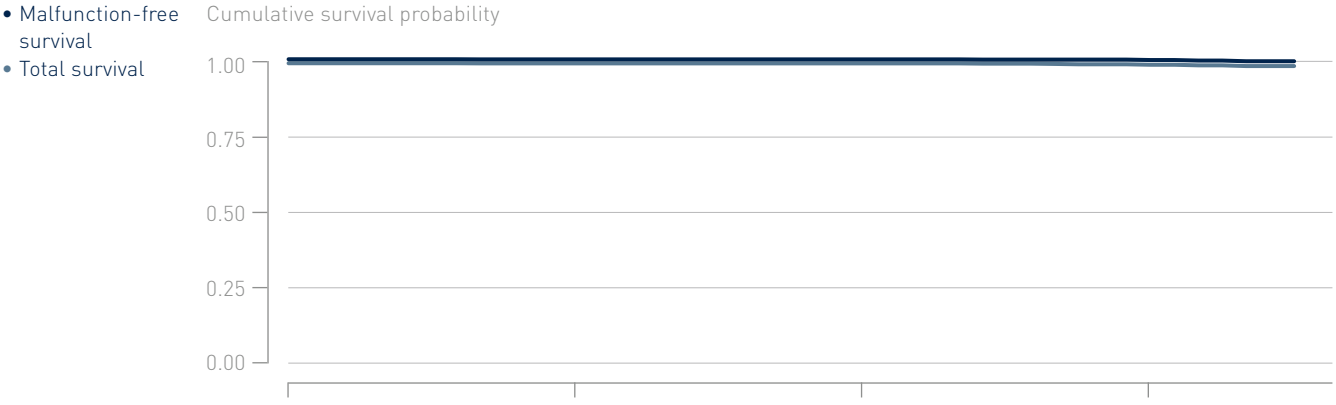

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.8 | 99.1 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.4 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 5419 | 4686 | 3732 | 2263 | 732 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iperia 7

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VDE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Dec 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 2 710 |
| Registered U.S. Implants | 1 966 |
| Estimated Active U.S. Implants | 1 600 |
| U.S. Normal Battery Depletions | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 5 | 0.25% |
| Therapy Compromised | 3 | 0.15% |
| Therapy Available | 2 | 0.10% |



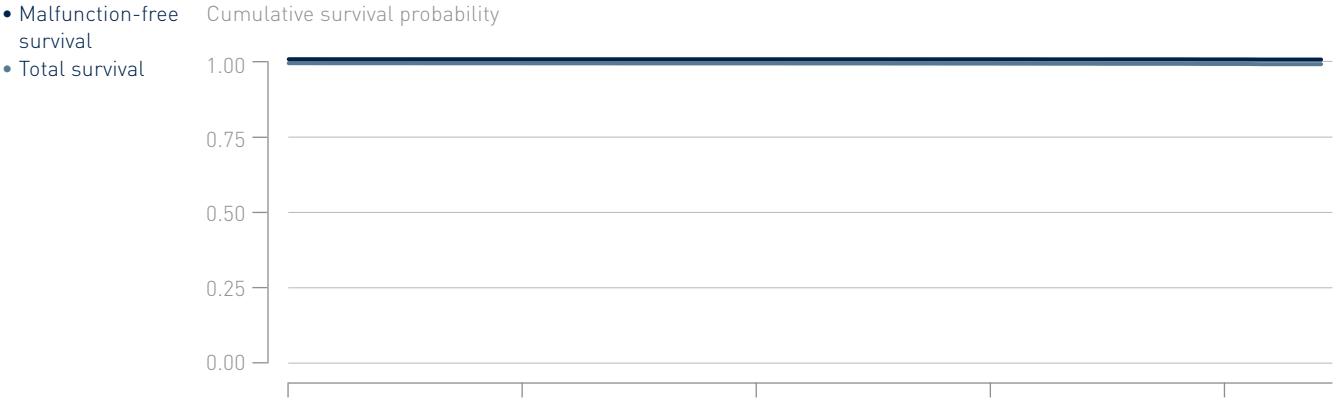

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.4 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.6 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1966 | 1816 | 1457 | 510 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iperia 7 DF4

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Dec 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 7510 |
| Registered U.S. Implants | 4110 |
| Estimated Active U.S. Implants | 3170 |
| U.S. Normal Battery Depletions | 6 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 7 | 0.17% |
| Therapy Compromised | 3 | 0.07% |
| Therapy Available | 4 | 0.10% |



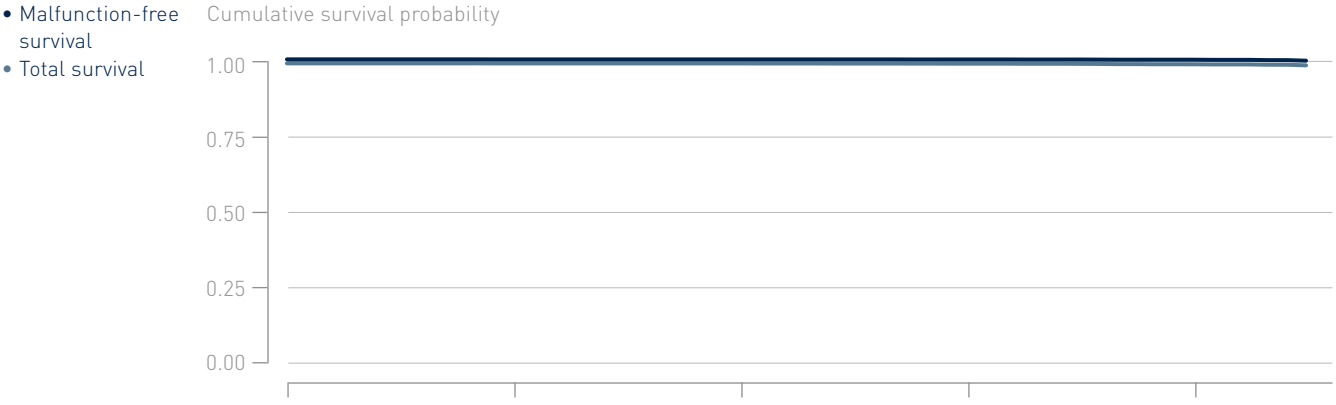

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 4110 | 3766 | 3250 | 2542 | 1028 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iperia 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Dec 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 6 540 |
| Registered U.S. Implants | 4 836 |
| Estimated Active U.S. Implants | 3 890 |
| U.S. Normal Battery Depletions | 7 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 9 | 0.19% |
| Therapy Compromised | 5 | 0.10% |
| Therapy Available | 4 | 0.08% |



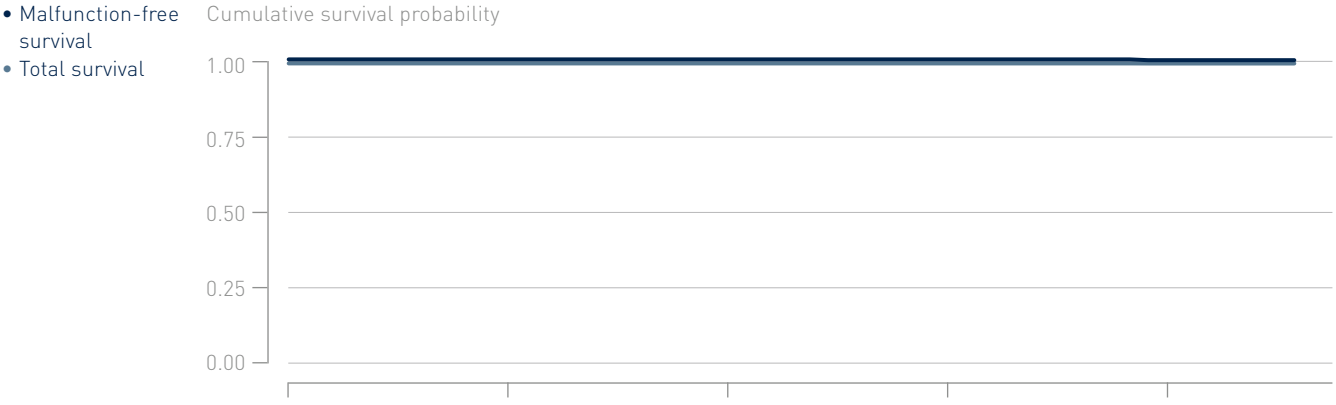

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 4836 | 4494 | 3963 | 3183 | 1401 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 2 170 |
| Registered U.S. Implants | 1 416 |
| Estimated Active U.S. Implants | 1 110 |
| U.S. Normal Battery Depletions | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 1 | 0.07% |
| Therapy Compromised | 1 | 0.07% |
| Therapy Available | 0 | 0.00% |



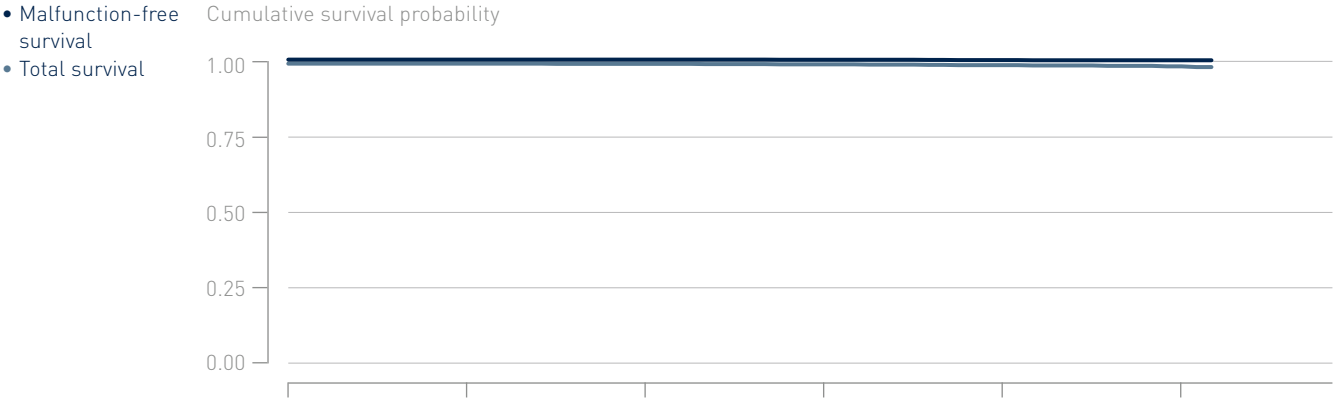

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1416 | 1302 | 1204 | 907 | 488 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7 DF4

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 2340 |
| Registered U.S. Implants | 1268 |
| Estimated Active U.S. Implants | 862 |
| U.S. Normal Battery Depletions | 7 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 4 | 0.32% |
| Therapy Compromised | 2 | 0.16% |
| Therapy Available | 2 | 0.16% |



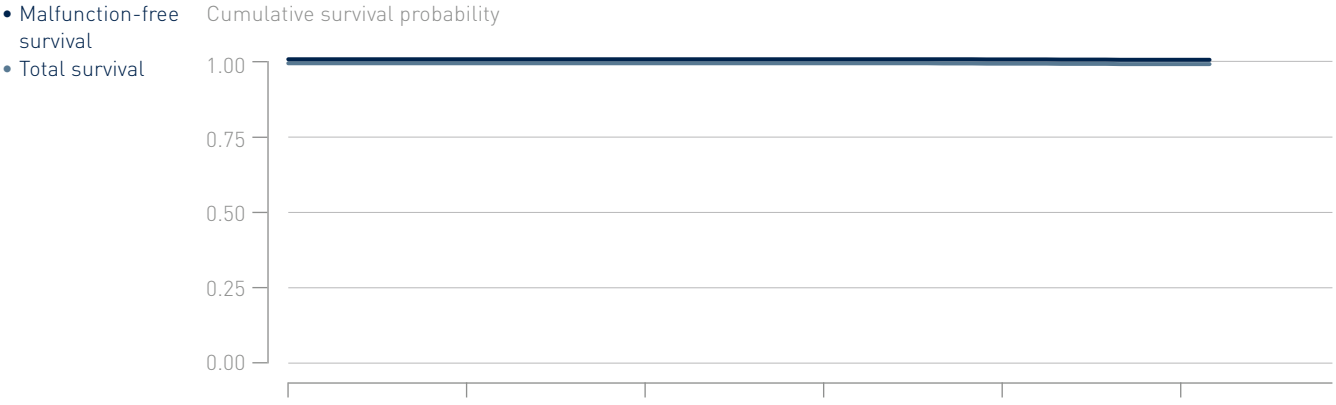

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.7 | 99.4 | 98.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.7 | 99.6 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1268 | 1164 | 1069 | 994 | 822 | 416 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 2 750 |
| Registered U.S. Implants | 1 247 |
| Estimated Active U.S. Implants | 871 |
| U.S. Normal Battery Depletions | 1 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 3 | 0.24% |
| Therapy Compromised | 2 | 0.16% |
| Therapy Available | 1 | 0.08% |



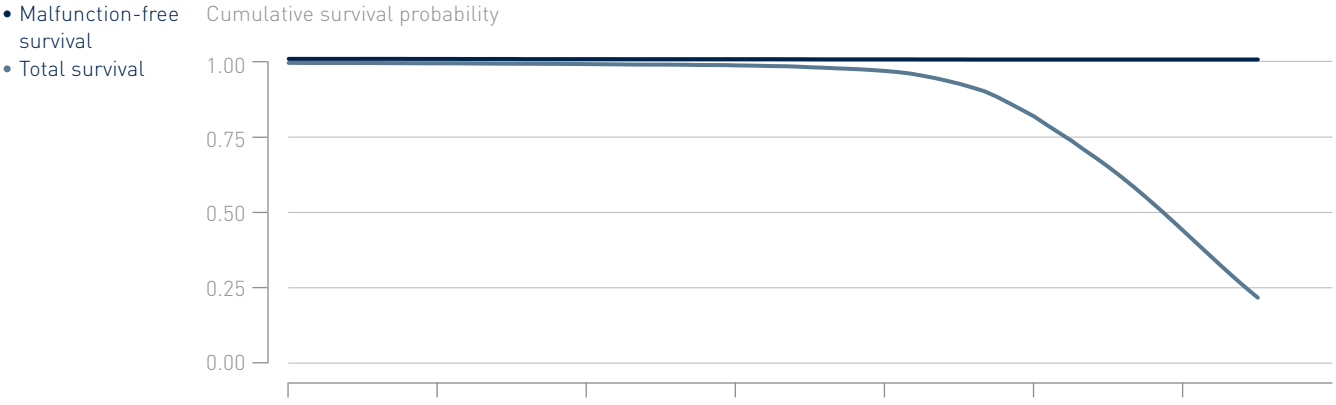

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.8 | 99.5 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.6 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1247 | 1145 | 1069 | 982 | 851 | 450 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Lumax 340

| | |
|---|---|
| Product Versions | DR, DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Feb 2007 |
| CE Market Release | Feb 2007 |
| Worldwide Distributed Devices | 26 400 |
| Registered U.S. Implants | 8 219 |
| Estimated Active U.S. Implants | 1 730 |
| U.S. Normal Battery Depletions | 2 151 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 10 | 0.12% |
| Therapy Compromised | 8 | 0.10% |
| Therapy Available | 2 | 0.02% |

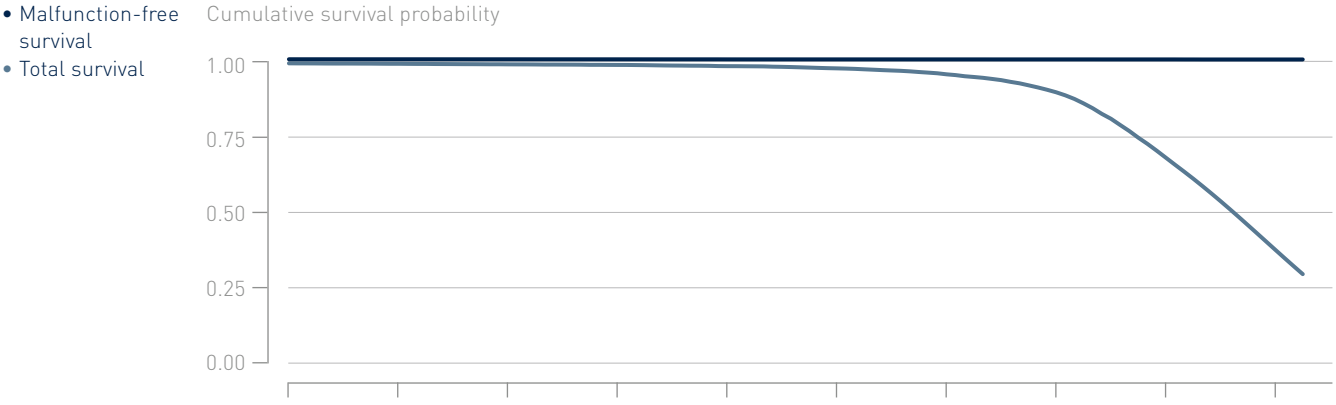



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.6 | 99.2 | 97.3 | 82.2 | 44.1 |
| CI [±%] | - | 0.1 | 0.1 | 0.2 | 0.4 | 1 | 1.5 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 | 99.8 |
| CI [±%] | - | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 8219 | 7512 | 6992 | 6441 | 5874 | 4362 | 1820 |

# Lumax 540

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | May 2009 |
| CE Market Release | Jun 2008 |
| Worldwide Distributed Devices | 26 000 |
| Registered U.S. Implants | 11 511 |
| Estimated Active U.S. Implants | 3 140 |
| U.S. Normal Battery Depletions | 2 816 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 22 | 0.19% |
| Therapy Compromised | 12 | 0.10% |
| Therapy Available | 10 | 0.09% |

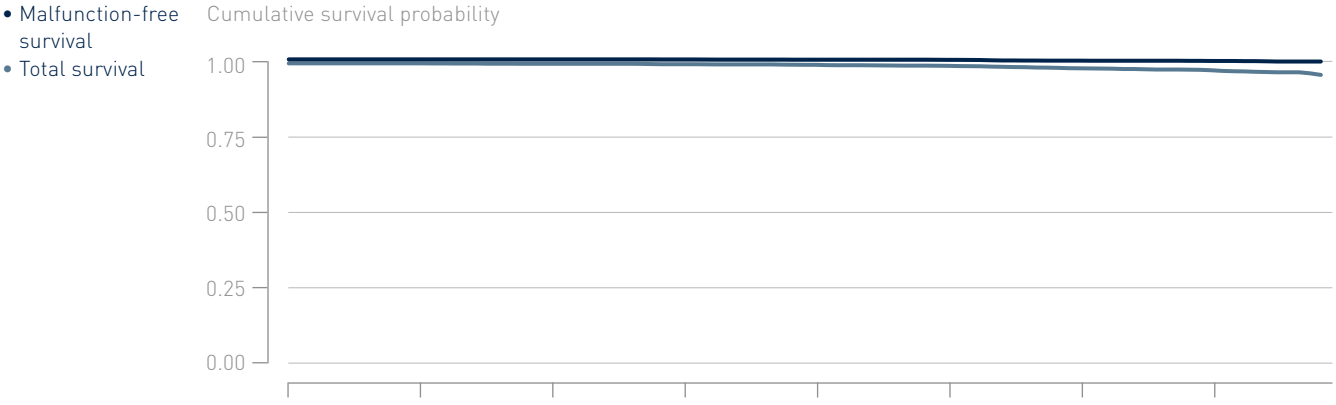



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.6 | 99.4 | 99.0 | 98.3 | 96.3 | 90.3 | 68.6 | 37.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.2 | 0.3 | 0.4 | 0.7 | 1.1 | 1.7 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.8 | 99.8 | 99.8 | 99.8 | 99.7 |
| CI [±%] | - | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 11511 | 10619 | 9877 | 9166 | 8480 | 7832 | 7155 | 6218 | 4107 | 988 |

# Lumax 740

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Sep 2012 |
| CE Market Release | Apr 2012 |
| Worldwide Distributed Devices | 7 980 |
| Registered U.S. Implants | 3 813 |
| Estimated Active U.S. Implants | 2 210 |
| U.S. Normal Battery Depletions | 65 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 21 | 0.55% |
| Therapy Compromised | 10 | 0.26% |
| Therapy Available | 10 | 0.29% |

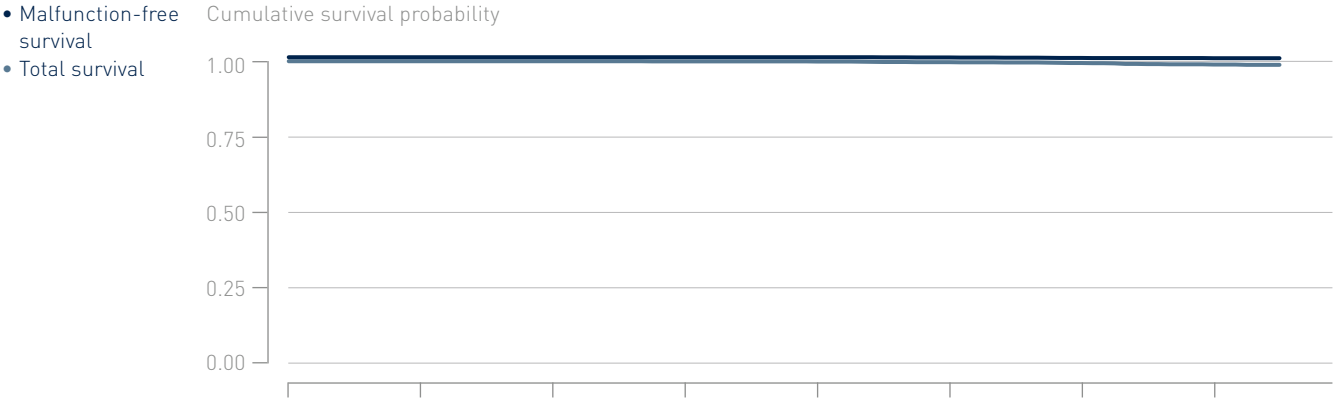



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 99.7 | 99.5 | 99.1 | 98.3 | 97.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.8 | 99.4 | 99.3 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 3813 | 3535 | 3290 | 3051 | 2838 | 2624 | 2387 | 1867 |

# Lumax 740 DX

| | |
|---|---|
| Product Versions | VR-T |
| NBG Codes | VVE-VDDR |
| Maximum Energy J | 40 |
| US Market Release | May 2012 |
| CE Market Release | Nov 2011 |
| Worldwide Distributed Devices | 4 560 |
| Registered U.S. Implants | 2 224 |
| Estimated Active U.S. Implants | 1 360 |
| U.S. Normal Battery Depletions | 12 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 8 | 0.36% |
| Therapy Compromised | 3 | 0.13% |
| Therapy Available | 5 | 0.22% |

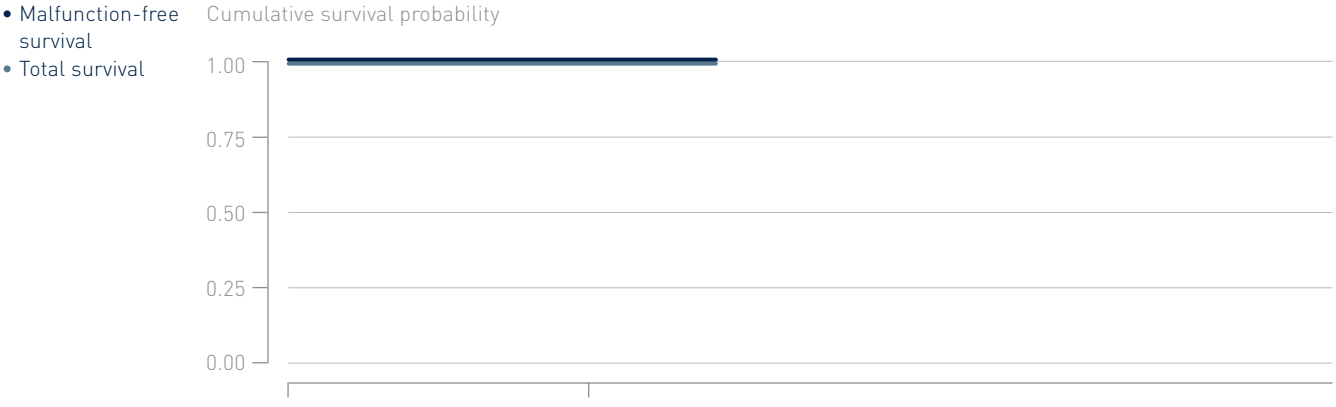



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.6 | 99.3 | 98.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 99.6 | 99.4 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 2224 | 2058 | 1922 | 1784 | 1666 | 1546 | 1418 | 1070 |

# Rivacor 7 DF4

| | |
|---|---|
| Product Versions | DR-T |
| NBG Codes | VVE-DDDR |
| Maximum Energy J | 40 |
| US Market Release | Apr 2019 |
| CE Market Release | Mar 2019 |
| Worldwide Distributed Devices | 5470 |
| Registered U.S. Implants | 2635 |
| Estimated Active U.S. Implants | 2510 |
| U.S. Normal Battery Depletions | 0 |

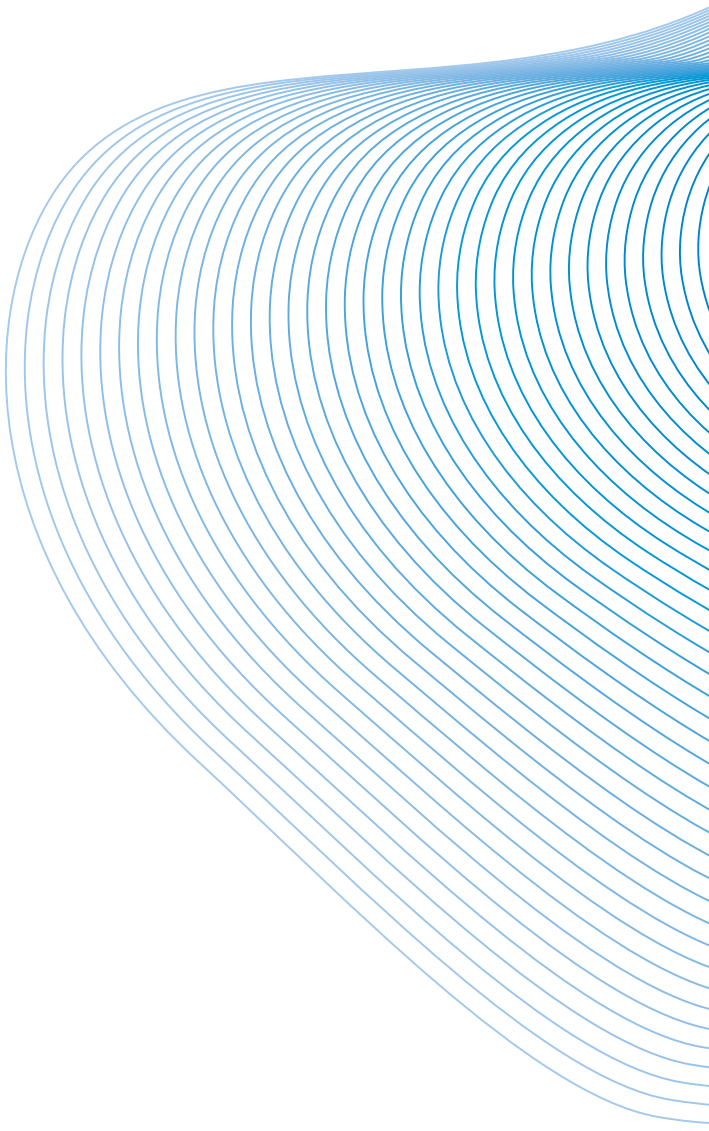
| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |




| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 100.0 |
| CI [±%] | - | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 |
| Sample Size | 2635 | 882 |

# Performance of BIOTRONIK ICDs

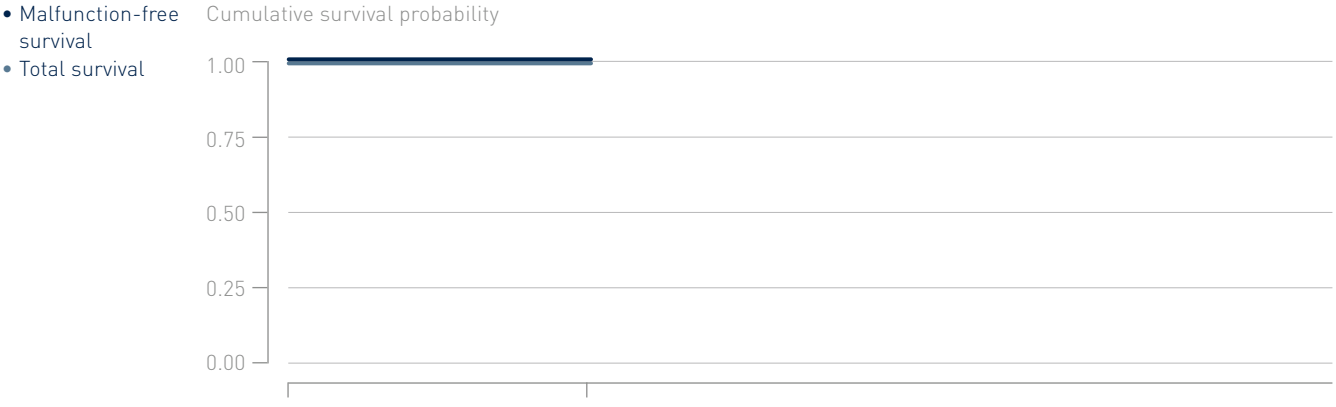
4.1 Single-Chamber ICDs
4.2 Dual-Chamber ICDs
**4.3 CRT ICDs**



# Acticor 7

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Apr 2019 |
| CE Market Release | Mar 2019 |
| Worldwide Distributed Devices | 5800 |
| Registered U.S. Implants | 1194 |
| Estimated Active U.S. Implants | 1110 |
| U.S. Normal Battery Depletions | 0 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

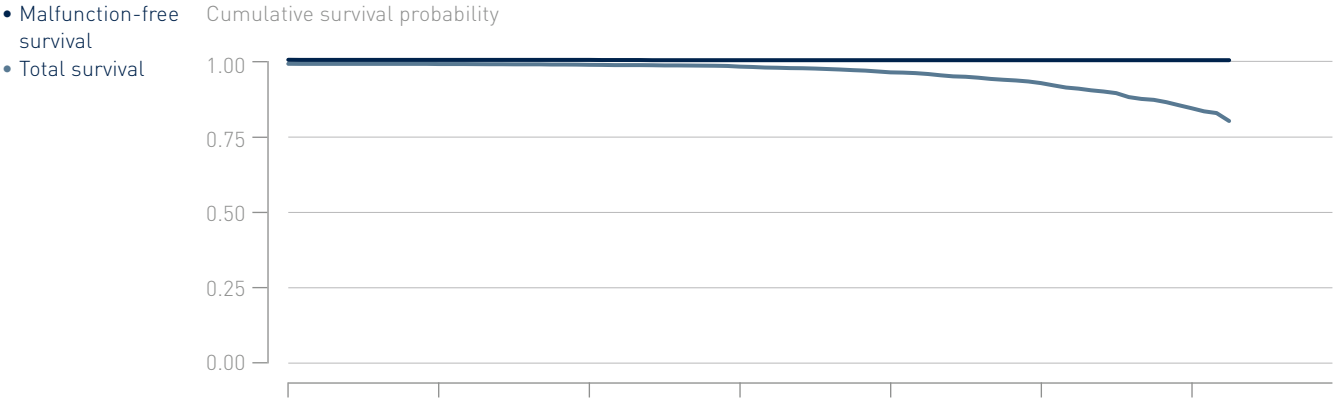



| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 100.0 |
| CI [±%] | - | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 |
| Sample Size | 1194 | 257 |

# Ilesto 7

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Sep 2013 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 5 290 |
| Registered U.S. Implants | 3 841 |
| Estimated Active U.S. Implants | 1 710 |
| U.S. Normal Battery Depletions | 306 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 3 | 0.08% |
| Therapy Compromised | 2 | 0.05% |
| Therapy Available | 1 | 0.03% |



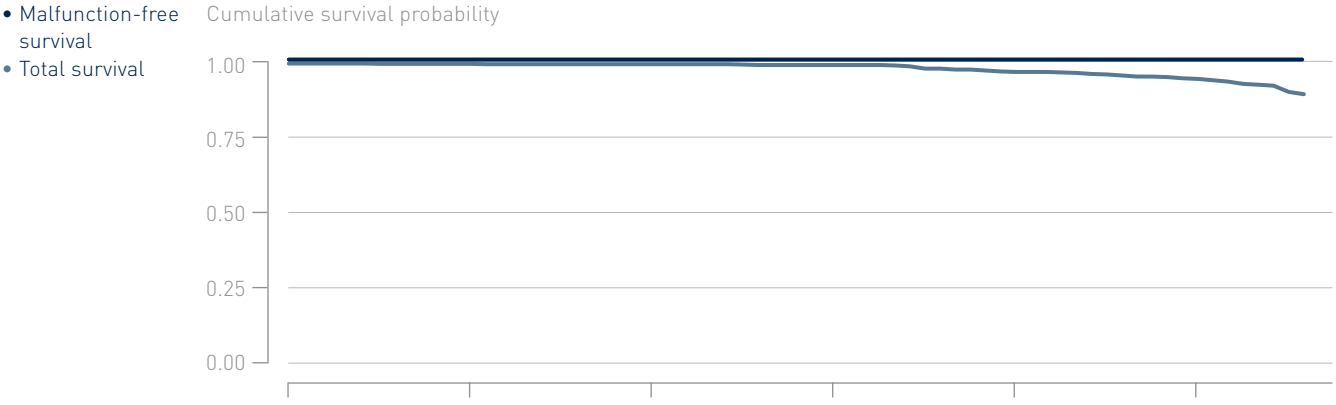

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.6 | 99.0 | 97.1 | 93.5 | 83.0 |
| CI [±%] | - | 0.1 | 0.2 | 0.4 | 0.6 | 1 | 1.9 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 3841 | 3403 | 3025 | 2667 | 2329 | 1893 | 657 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilesto 7 DF4

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Jul 2014 |
| CE Market Release | Jun 2013 |
| Worldwide Distributed Devices | 2360 |
| Registered U.S. Implants | 968 |
| Estimated Active U.S. Implants | 475 |
| U.S. Normal Battery Depletions | 52 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 1 | 0.10% |
| Therapy Compromised | 1 | 0.10% |
| Therapy Available | 0 | 0.00% |



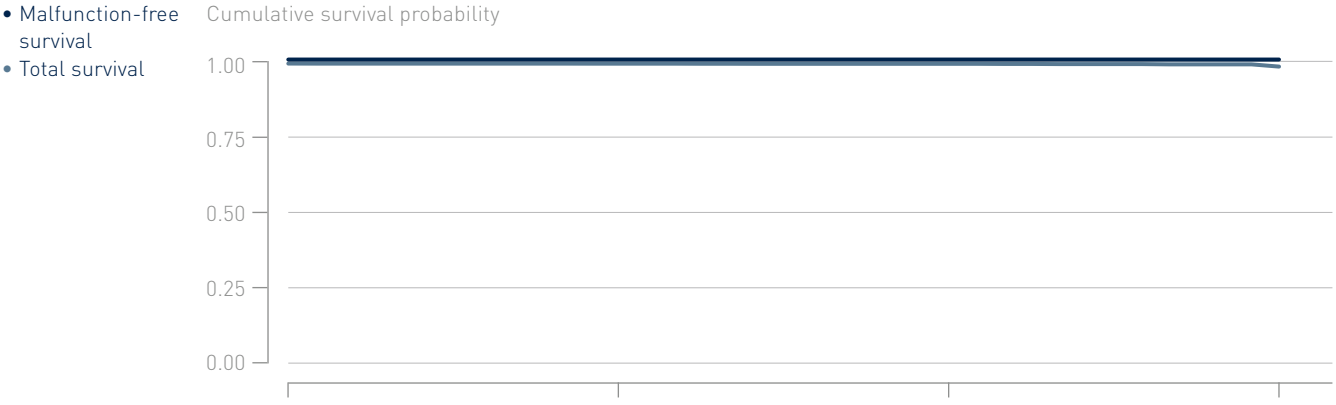

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.8 | 99.5 | 97.1 | 94.2 |
| CI [±%] | - | 0.2 | 0.3 | 0.5 | 1.3 | 1.9 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | < 0.1 | 0.2 | 0.2 | 0.2 | 0.2 |
| Sample Size | 968 | 858 | 766 | 681 | 594 | 448 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Ilivia 7 DF4

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 9 150 |
| Registered U.S. Implants | 4 727 |
| Estimated Active U.S. Implants | 3 660 |
| U.S. Normal Battery Depletions | 11 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |

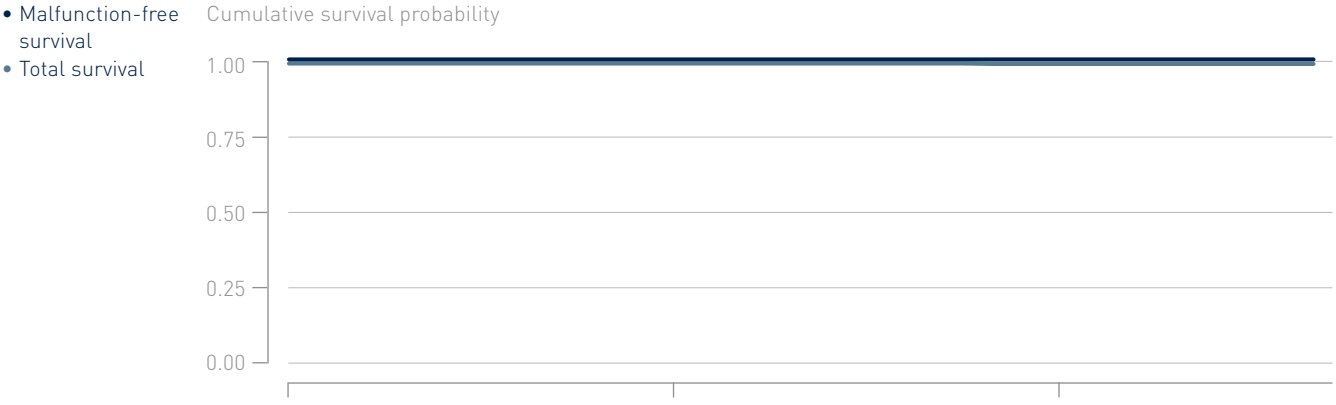



| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 | 98.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 4727 | 3855 | 2321 | 219 |

# Intica 7 DF1

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | May 2017 |
| CE Market Release | Sep 2016 |
| Worldwide Distributed Devices | 5380 |
| Registered U.S. Implants | 2798 |
| Estimated Active U.S. Implants | 2270 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |



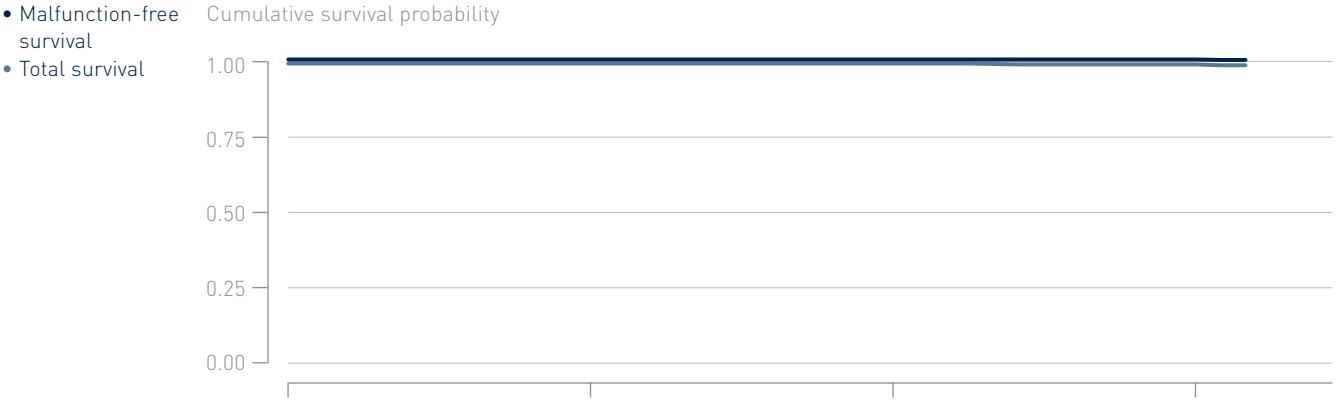

| Years after implant | 0 | 1 | 2 |
|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 |
| Sample Size | 2798 | 1745 | 721 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Inventra 7 DF4

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 45 |
| US Market Release | Aug 2014 |
| CE Market Release | Jul 2014 |
| Worldwide Distributed Devices | 2 110 |
| Registered U.S. Implants | 887 |
| Estimated Active U.S. Implants | 644 |
| U.S. Normal Battery Depletions | 3 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 1 | 0.11% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.11% |



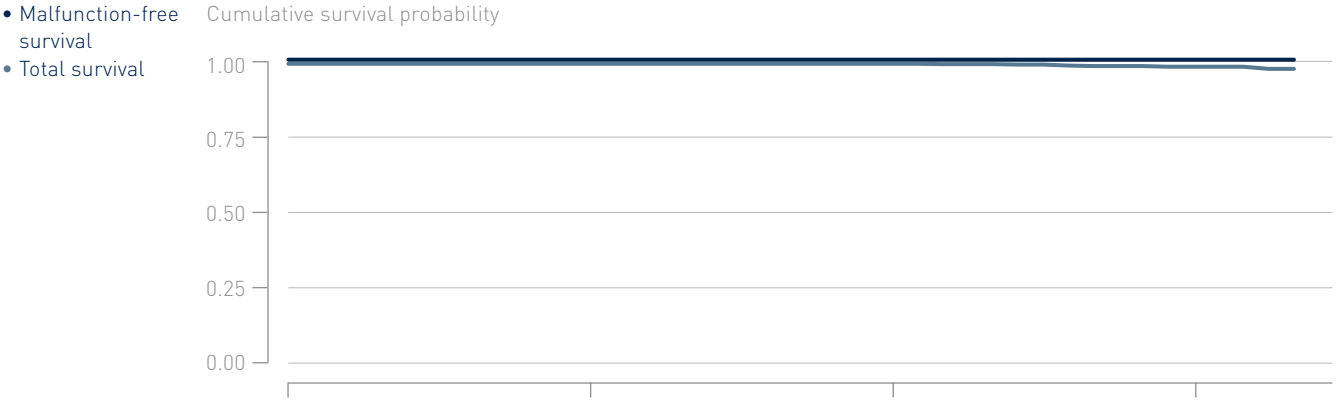

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 887 | 736 | 561 | 272 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iperia 7

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Apr 2016 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 3040 |
| Registered U.S. Implants | 1479 |
| Estimated Active U.S. Implants | 1090 |
| U.S. Normal Battery Depletions | 10 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |



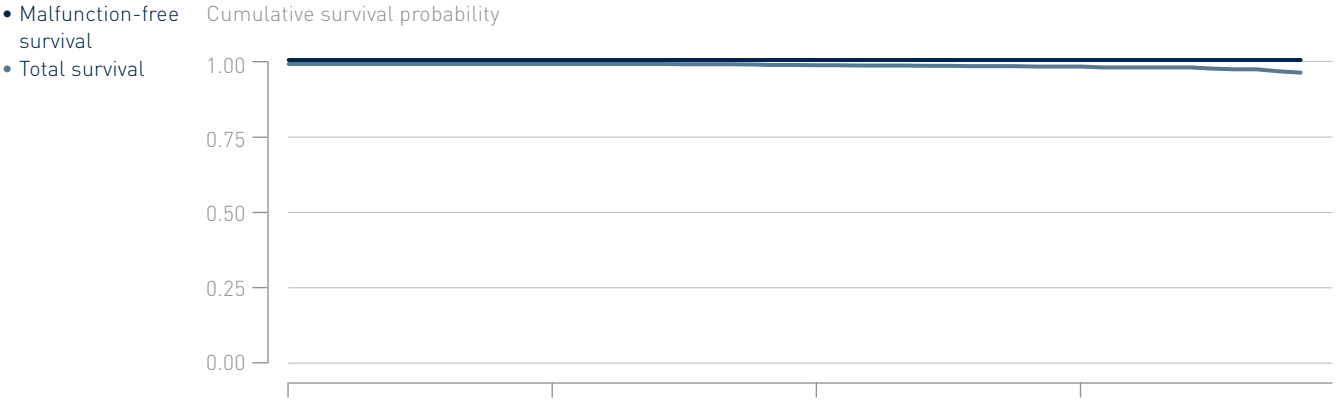

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 100.0 | 98.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1479 | 1262 | 869 | 334 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Iperia 7 DF4

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Apr 2016 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 5830 |
| Registered U.S. Implants | 1617 |
| Estimated Active U.S. Implants | 1100 |
| U.S. Normal Battery Depletions | 18 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 0 | 0.00% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 0 | 0.00% |



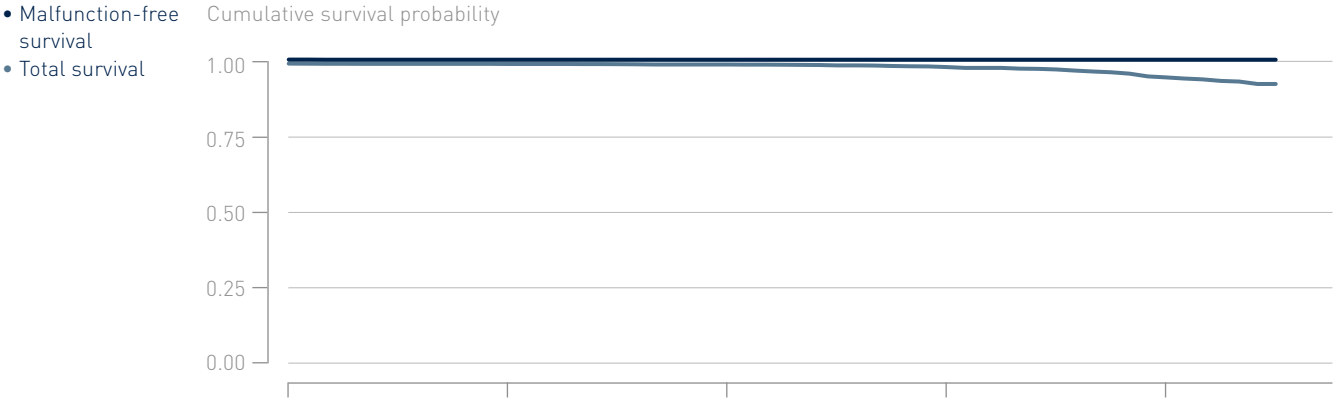

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.6 | 99.1 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 |
| Sample Size | 1617 | 1383 | 1046 | 657 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 4 600 |
| Registered U.S. Implants | 3 316 |
| Estimated Active U.S. Implants | 2 040 |
| U.S. Normal Battery Depletions | 88 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 1 | 0.03% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 1 | 0.03% |



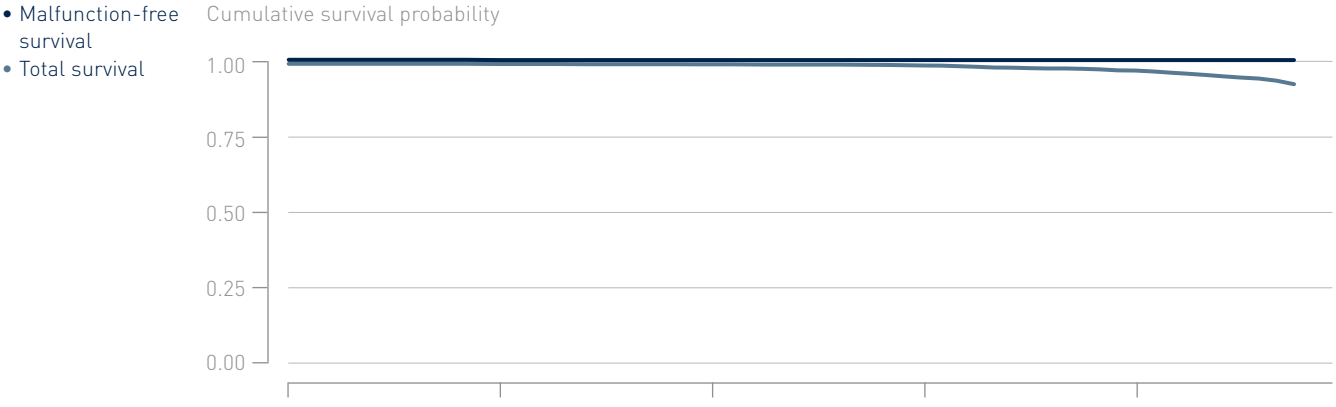

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.7 | 98.8 | 95.3 |
| CI [±%] | - | 0.1 | 0.2 | 0.5 | 1.2 |
| Malfunction-Free [%] | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 3316 | 2905 | 2506 | 1797 | 813 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Itrevia 7 DF4

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Mar 2015 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 5 680 |
| Registered U.S. Implants | 3 227 |
| Estimated Active U.S. Implants | 1 910 |
| U.S. Normal Battery Depletions | 80 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions*** | 2 | 0.06% |
| Therapy Compromised | 0 | 0.00% |
| Therapy Available | 2 | 0.06% |



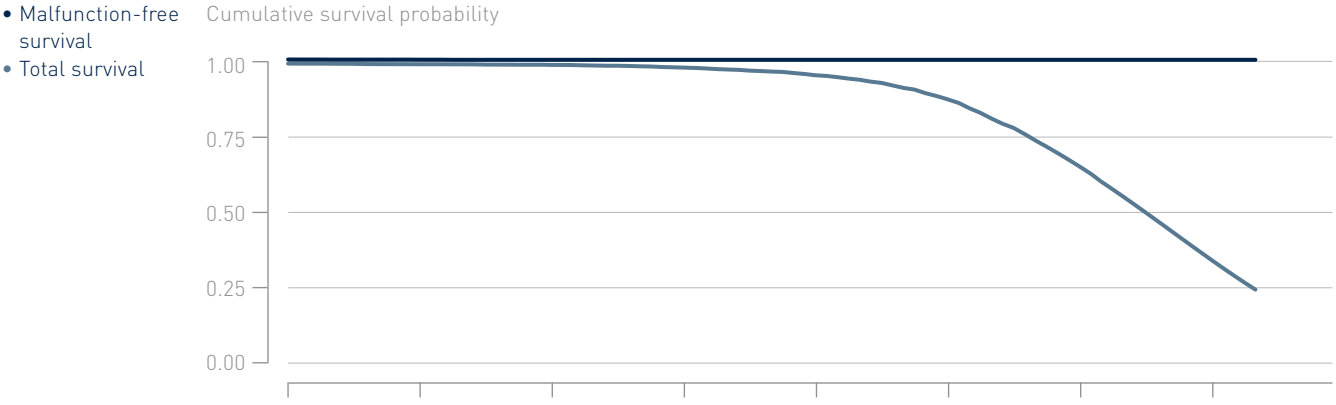

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.8 | 99.4 | 97.6 |
| CI [±%] | - | 0.1 | 0.2 | 0.3 | 0.7 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 3227 | 2810 | 2502 | 2130 | 1346 |

* A subset of devices from this product family is subject to the advisory BIO-LQC. Refer to the chapter "Advisories" for details.

# Lumax 340

| | |
|---|---|
| Product Versions | HF, HF-T |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Feb 2007 |
| CE Market Release | Dec 2006 |
| Worldwide Distributed Devices | 20 700 |
| Registered U.S. Implants | 5 310 |
| Estimated Active U.S. Implants | 558 |
| U.S. Normal Battery Depletions | 1 269 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.08% |
| Therapy Compromised | 2 | 0.04% |
| Therapy Available | 2 | 0.04% |

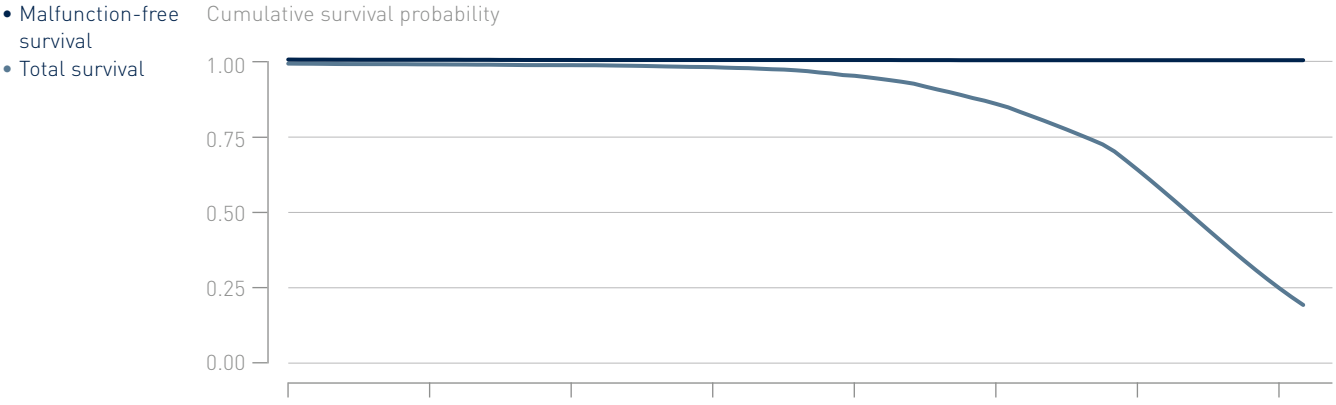



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.5 | 98.6 | 96.1 | 88.1 | 65.7 | 34.6 |
| CI [±%] | - | 0.1 | 0.2 | 0.4 | 0.6 | 1.1 | 1.9 | 2.4 |
| Malfunction-Free [%] | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 5310 | 4713 | 4208 | 3689 | 3159 | 2440 | 1467 | 553 |

# Lumax 540

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | May 2009 |
| CE Market Release | Jun 2008 |
| Worldwide Distributed Devices | 24 800 |
| Registered U.S. Implants | 8 656 |
| Estimated Active U.S. Implants | 1 080 |
| U.S. Normal Battery Depletions | 2 579 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 11 | 0.13% |
| Therapy Compromised | 5 | 0.06% |
| Therapy Available | 6 | 0.07% |

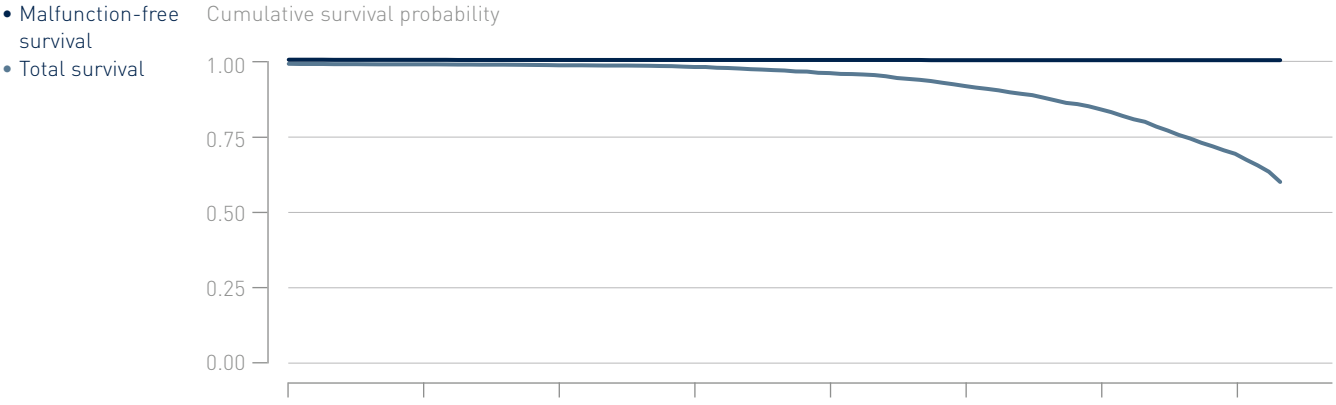



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.5 | 98.8 | 95.9 | 86.6 | 64.6 | 25.2 |
| CI [±%] | - | 0.1 | 0.2 | 0.3 | 0.5 | 0.9 | 1.4 | 2 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.8 | 99.8 | 99.8 |
| CI [±%] | - | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 8656 | 7648 | 6825 | 6046 | 5202 | 4127 | 2695 | 635 |

# Lumax 740

| | |
|---|---|
| Product Versions | HF-T |
| NBG Codes | VVE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Sep 2012 |
| CE Market Release | Apr 2012 |
| Worldwide Distributed Devices | 7040 |
| Registered U.S. Implants | 3410 |
| Estimated Active U.S. Implants | 998 |
| U.S. Normal Battery Depletions | 594 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 3 | 0.09% |
| Therapy Compromised | 1 | 0.03% |
| Therapy Available | 2 | 0.06% |

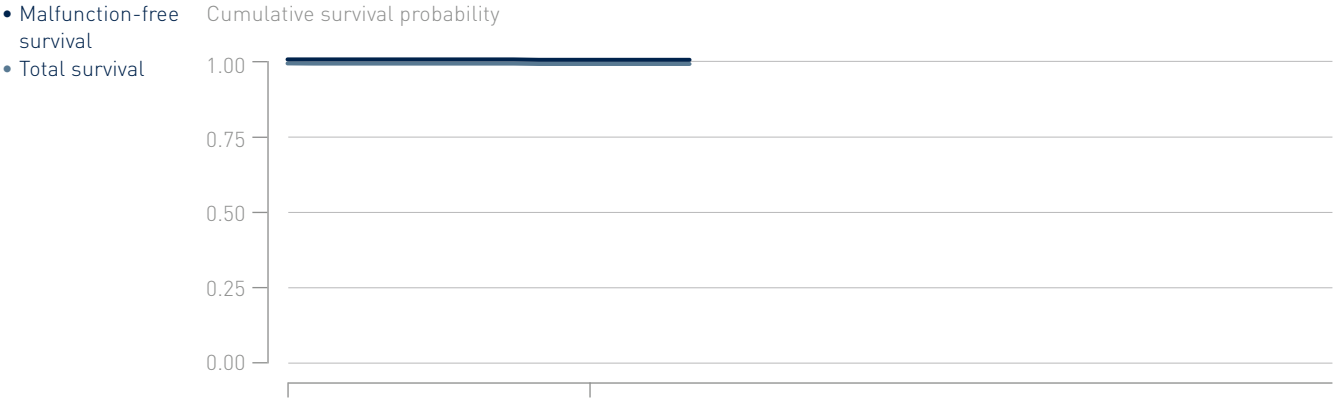



| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.5 | 98.9 | 96.9 | 92.6 | 84.8 | 69.9 |
| CI [±%] | - | 0.2 | 0.3 | 0.4 | 0.7 | 1.1 | 1.6 | 2.3 |
| Malfunction-Free [%] | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 | 99.9 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 3410 | 3023 | 2698 | 2394 | 2095 | 1778 | 1414 | 801 |

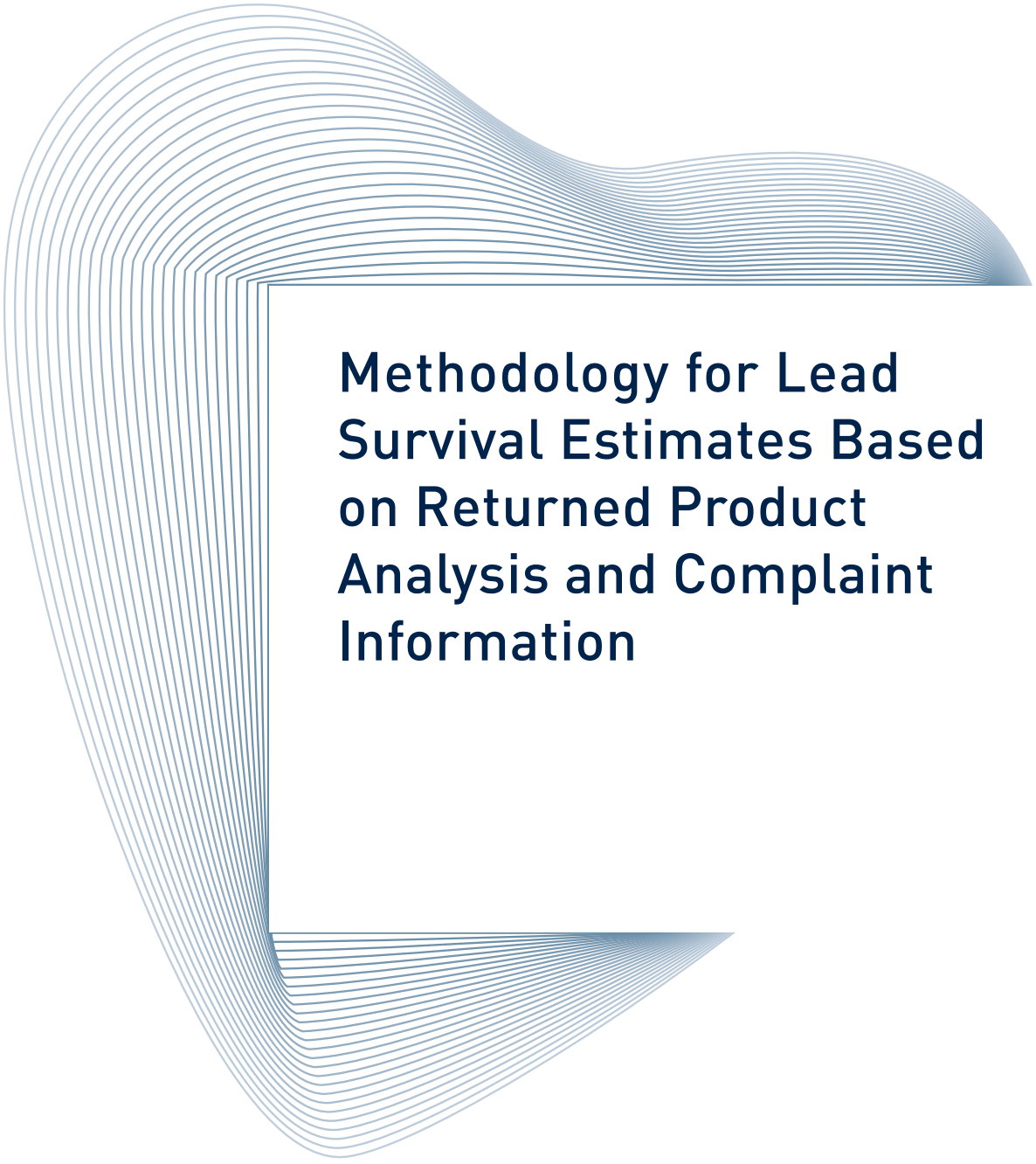
# Rivacor 7 DF4

| | |
|---|---|
| Product Versions | HF-T, HF-T QP |
| NBG Codes | VDE-DDDRV |
| Maximum Energy J | 40 |
| US Market Release | Apr 2019 |
| CE Market Release | Mar 2019 |
| Worldwide Distributed Devices | 6 730 |
| Registered U.S. Implants | 2 531 |
| Estimated Active U.S. Implants | 2 300 |
| U.S. Normal Battery Depletions | 1 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.04% |
| Therapy Compromised | 1 | 0.04% |
| Therapy Available | 0 | 0.00% |




| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.9 |
| CI [±%] | - | 0.1 |
| Malfunction-Free [%] | 100.0 | 99.9 |
| CI [±%] | - | < 0.1 |
| Sample Size | 2531 | 798 |



# Methodology for Lead Survival Estimates Based on Returned Product Analysis and Complaint Information

# 5. Methodology for Lead Survival Estimates Based on Returned Product Analysis and Complaint Information

## 5.1 Cumulative Lead Survival Probability

This report has been prepared in accordance with ISO 5841-2:2014(E) applying actuarial analysis for the calculation of lead survival probabilities based on returned product analysis. Lead survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK's pacing and ICD leads.

The cumulative survival probability for leads is an estimate based on the percentage of devices that remain implanted and in service at various points of the product's service time in the absence of concurrent events such as morbidity. The lead survival estimate over time is displayed in cumulative survival curves (Kaplan-Meier). The product's performance is evaluated in discrete one-month intervals. The survival probability for each month is given by the number of leads that remain implanted and active through this month divided by the number of leads that were actively implanted at the start of the interval. The cumulative survival probability for any period is given by multiplying all survival probabilities of previous months.

At the time of implantation, the cumulative lead survival probability is 100%. Even though they are analyzed as part of our quality system monitoring, leads that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time.

Because this report is provided to communicate information regarding product performance, it does not include data regarding medical complications such as erosion, infection or diaphragmatic stimulation.

Compared to pacemakers and ICDs, a considerable portion of leads with observed or suspected failures are not explanted and returned for laboratory analysis. This is primarily because it is much more difficult and risky to the patient to remove chronically implanted leads. In order to report a conservative measure of lead performance, unconfirmed reports of lead complications are therefore also included in the calculation of a lead's survival probability.

In order to be classified as a qualifying lead complication and thus contributing to the survival probability calculation the same way as a confirmed malfunction, the reported anomaly must have occurred at least 30 days post-implant. Otherwise, factors not related to the lead would likely be the root cause of the observed anomaly, (i.e., patientspecific conditions or implant techniques).

In order to minimize the effect of underreporting of lead malfunctions, BIOTRONIK additionally includes the long term performance post market study data if available.

## 5.2 Lead Data Acquisition

The following sections of this report provide performance data on BIOTRONIK's pacing and ICD leads and are based on the observation of BIOTRONIK's U.S. products through review of our device registration and tracking systems, and through the analyses of both, returned leads as well as reports of lead complications of non-returned leads. The prospective data from BIOTRONIK's post-approval studies is presented separately in chapters 7 and 8.

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is December 31, 2020. The sample sizes of U.S. leads that are implanted and remain active as well as the total number of products distributed worldwide are provided for each lead family in this report.

Survival estimates are calculated for lead families having accumulated at least 10,000 cumulative implant months. Products no longer being distributed with less than 500 active implants may be excluded from this report.

ISO 5841-2:2014(E) describes a method for adjusting the device survival probability for underreported malfunctions and unrelated patient deaths that result in an overestimation of the device's survival probability. The factor for U.S. underreporting of malfunctions of pacing and ICD leads is unknown as currently no systematic data is available that reveals this factor. Consequently, this factor remains unaccounted for in this report. Patient mortality is artificially elevated if the reported rate from our registration and tracking systems is below the annual mortality in clinical studies.

## 5.3 Returned Product Analysis

Information for the lead sections of this report is taken from the analysis of returned products. The outcome of this analysis is the basis for the final classification of the cause for explantation of the lead. Additionally, reports of lead complications not confirmed by laboratory analysis are taken into consideration. Both, leads with confirmed malfunctions as well as unconfirmed lead complications decrease a lead's total survival probability.

Every lead and lead segment returned to BIOTRONIK is analyzed per our internal procedures and classified as within specification, damaged by external causes, or out of specification (malfunction) while implanted and in service.

Those leads found to be out of specification, are divided into the following categories as proposed by AdvaMed and ISO 5841-2:2014(E):

**Conductor Fracture**
Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors)

**Crimps, Welds and Bonds**
Any interruption in the conductor or lead body associated with a point of connection

**Insulation Breach**
Any lead insulation breach

**Other**
Includes specific proprietary lead mechanical attributes.

## 5.4 Lead Complications

A considerable portion of leads with observed or suspected failures are not explanted and returned for laboratory analysis. A clinical observation is considered a lead complication if a complaint, associated with at least one of the clinical manifestations listed below, is reported and where the non-returned lead is:

- Verified by medical records to have been implanted and in-service, and
- Reported to have been removed from service,
- Modified surgically or electrically to remedy the malfunction, or
- Left in service based on medical judgment.

Complications for leads implanted greater than 30 days are reported as qualifying lead complications, whereas complications occurring during the first 30 days are reported as acute lead observations.

In accordance with the latest AdvaMed guidelines and ISO 5841-2:2014(E) such clinical observations are classified in the following categories:

**Failure to Capture**
Intermittent or complete failure to achieve cardiac stimulation at programmed output delivered outside of the cardiac refractory period. Sudden and significant increase in the pacing threshold value at which 2:1 safety margin can no longer be achieved.

**Failure to Sense**
Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals during non-refractory periods at programmed sensitivity settings

**Oversensing**
Misinterpretation of cardiac or non-cardiac events as cardiac depolarization

**Abnormal Pacing Impedance**
impedance is typically considered abnormal if a measurement is < 200 ohms or > 3000 ohms

**Abnormal Defibrillation Impedance**
Defibrillation impedance is typically considered abnormal if a measurement is < 20 ohms or > 200 ohms. Including high or low shock impedance when attempting to deliver a shock

**Insulation Breach**
A disruption or break in lead insulation observed visually, electrically, or radiographically

**Conductor Fracture**
A mechanical break within the lead conductor observed visually, electrically, or radiographically

**Lead Dislodgement**
Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance

**Extracardiac Stimulation**
Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle

**Cardiac Perforation**
Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance, chest pain, and tamponade

**Other**
Specific proprietary attributes of a lead such as sensors which affect a lead's ability to perform as designed or remain in service

In order to report a conservative measure of lead performance, qualifying lead complications are also included in the calculation of a lead's survival probability.

Acute Lead Observations may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. Therefore, acute lead observations are not included in lead survival probability.

## 5.5 Lead Product Performance Graphs and Data

The lead performance information is shown in each section in alphabetical order and by product name.

For each lead, the report provides:

- Product versions that contribute to the evaluation
- Types of leads
- Polarity
- Steroid
- CE and U.S. market release dates
- Worldwide quantity of products that have been distributed
- U.S. registered implants (number of products included in this report)
- Estimated active U.S. implants
- Number of U.S. qualifying complications
- Number of U.S. acute lead observations
- Number of U.S. confirmed malfunctions
- Number of U.S. leads or partial leads returned post-implant for analysis with a complaint

The survival plots provide:

**Total Survival**
The cumulative survival probability free of component malfunction or unconfirmed observation of an anomaly. Removals for clinical reasons unrelated to the device's performance (i.e., infections) are excluded.

Products or subgroups of products may become subject to advisory notifications that can significantly impact the overall product performance.

Current advisories are listed in chapter 11 of this report, however to date, BIOTRONIK has never had a pacing or ICD lead safety advisory notification, therefore no summary of lead advisories is provided.

The cumulative survival data and the 95% confidence intervals according to the Greenwood's formula[1] are shown in numerical form for the observed sample population.

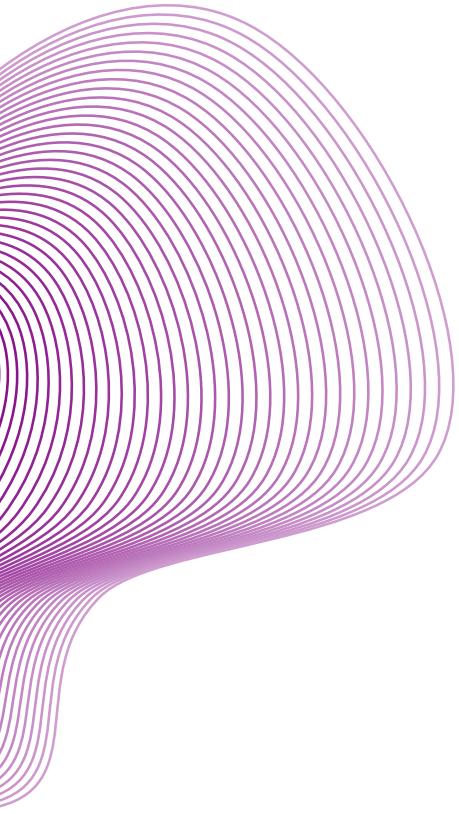
1 Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926

# Performance of BIOTRONIK Leads
## Based on Returned Products and Complaint Data

6.1 Pacing Leads – Postmarket Data
6.2 ICD Leads – Postmarket Data
6.3 CRT Leads – Postmarket Data

# Performance of BIOTRONIK Leads
## Based on Returned Products and Complaint Data

**6.1 Pacing Leads – Postmarket Data**
6.2 ICD Leads – Postmarket Data
6.3 CRT Leads – Postmarket Data



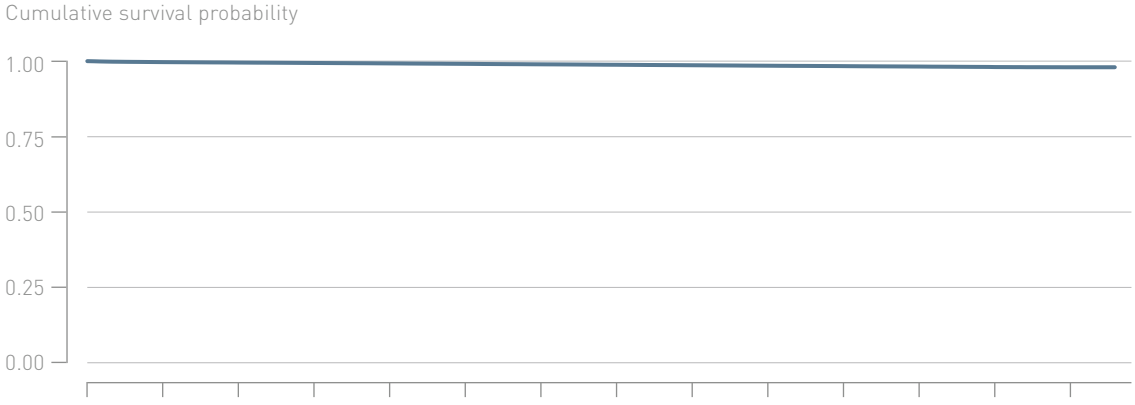
# Dextrus

| | |
|---|---|
| Product Versions | 4135, 4136, 4137 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Apr 2007 |
| CE Market Release | May 2007 |
| Worldwide Distributed Devices | 480 000 |
| Registered U.S. Implants | 379 643 |
| Estimated Active U.S. Implants | 229 000 |
| U.S. Total Returned | 2 385 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 4 265 | 1.11% |
| Abnormal Pacing Impedance | 379 | 0.10% |
| Cardiac Perforation | 25 | 0.01% |
| Conductor Fracture | 119 | 0.03% |
| Extracardiac Stimulation | 22 | 0.01% |
| Failure to Capture | 1 103 | 0.29% |
| Failure to Sense | 163 | 0.04% |
| Insulation Breach | 86 | 0.02% |
| Lead Dislodgement | 548 | 0.14% |
| Oversensing | 1 063 | 0.28% |
| Other | 757 | 0.20% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 361 | 0.09% |
| Conductor Fracture | 125 | 0.03% |
| Insulation Breach | 231 | 0.06% |
| Other | 5 | 0.00% |
| **U.S. Acute Lead Observations** | 1 694 | 0.44% |
| Abnormal Pacing Impedance | 41 | 0.01% |
| Cardiac Perforation | 68 | 0.02% |
| Extracardiac Stimulation | 15 | 0.00% |
| Failure to Capture | 248 | 0.06% |
| Failure to Sense | 64 | 0.02% |
| Insulation Breach | 10 | 0.00% |
| Lead Dislodgement | 681 | 0.18% |
| Oversensing | 48 | 0.01% |
| Other | 519 | 0.14% |

• Total survival



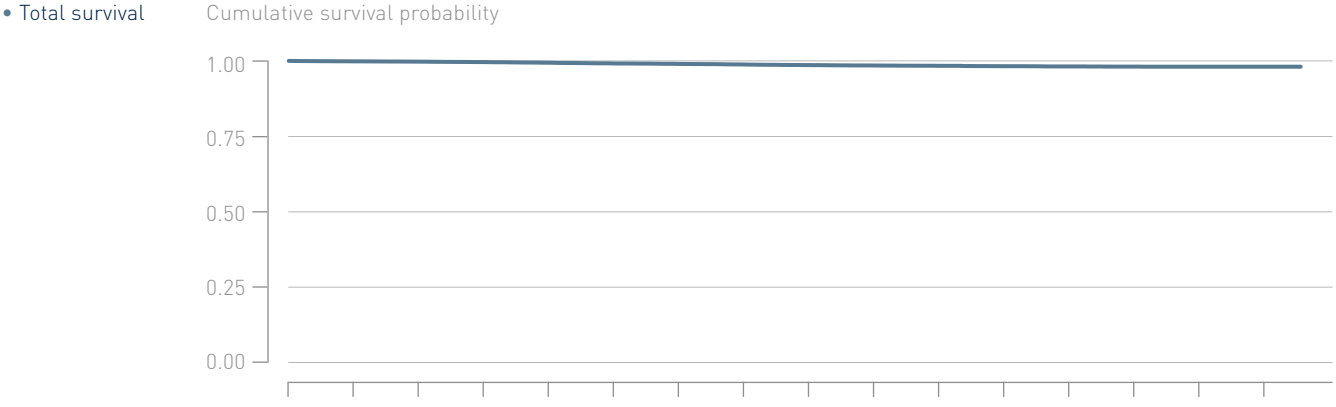

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.6 | 99.5 | 99.3 | 99.2 | 99.0 | 98.8 | 98.7 | 98.5 | 98.3 | 98.2 | 98.0 | 97.8 | 97.7 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 379643 | 336750 | 315277 | 295963 | 277982 | 248221 | 203562 | 161615 | 124947 | 95128 | 69712 | 45806 | 23840 | 6374 |

# Selox JT

| | |
|---|---|
| Product Versions | 45, 53 |
| Lead Type | J-shape, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Nov 2004 |
| CE Market Release | Nov 2004 |
| Worldwide Distributed Devices | 157 000 |
| Registered U.S. Implants | 16 621 |
| Estimated Active U.S. Implants | 12 300 |
| U.S. Total Returned | 126 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 234 | 1.41% |
| Abnormal Pacing Impedance | 34 | 0.20% |
| Cardiac Perforation | 1 | 0.01% |
| Conductor Fracture | 9 | 0.05% |
| Extracardiac Stimulation | 1 | 0.01% |
| Failure to Capture | 104 | 0.62% |
| Failure to Sense | 9 | 0.05% |
| Insulation Breach | 12 | 0.07% |
| Lead Dislodgement | 37 | 0.22% |
| Oversensing | 9 | 0.05% |
| Other | 18 | 0.11% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 10 | 0.06% |
| Insulation Breach | 10 | 0.06% |
| **U.S. Acute Lead Observations** | 45 | 0.27% |
| Failure to Capture | 8 | 0.05% |
| Lead Dislodgement | 34 | 0.20% |
| Other | 3 | 0.02% |



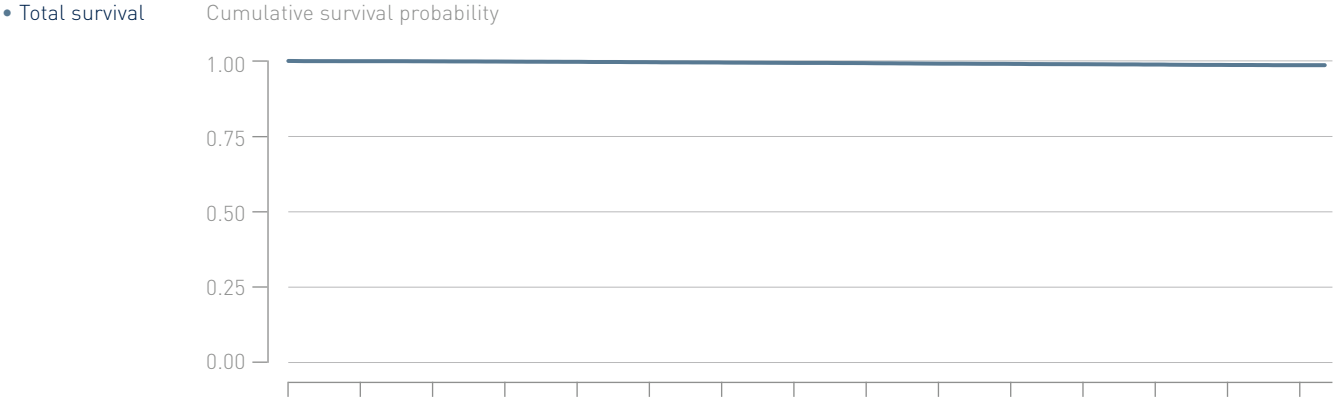

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.7 | 99.5 | 99.3 | 99.0 | 98.8 | 98.6 | 98.4 | 98.2 | 98.1 | 97.9 | 97.8 | 97.8 | 97.7 | 97.7 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| Sample Size | 16621 | 15305 | 14646 | 13766 | 12949 | 12105 | 11135 | 9852 | 8612 | 7378 | 6062 | 4800 | 3532 | 2377 | 1380 | 592 |

# Selox SR

| | |
|---|---|
| Product Versions | 45, 53, 60 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2004 |
| CE Market Release | Feb 2004 |
| Worldwide Distributed Devices | 172 000 |
| Registered U.S. Implants | 14 343 |
| Estimated Active U.S. Implants | 7 050 |
| U.S. Total Returned | 63 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 122 | 0.85% |
| Abnormal Pacing Impedance | 9 | 0.06% |
| Conductor Fracture | 12 | 0.08% |
| Extracardiac Stimulation | 2 | 0.01% |
| Failure to Capture | 44 | 0.31% |
| Failure to Sense | 1 | 0.01% |
| Insulation Breach | 6 | 0.04% |
| Lead Dislodgement | 14 | 0.10% |
| Oversensing | 20 | 0.14% |
| Other | 14 | 0.10% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 13 | 0.09% |
| Insulation Breach | 13 | 0.09% |
| **U.S. Acute Lead Observations** | 21 | 0.15% |
| Cardiac Perforation | 1 | 0.01% |
| Failure to Capture | 11 | 0.08% |
| Insulation Breach | 1 | 0.01% |
| Lead Dislodgement | 8 | 0.06% |



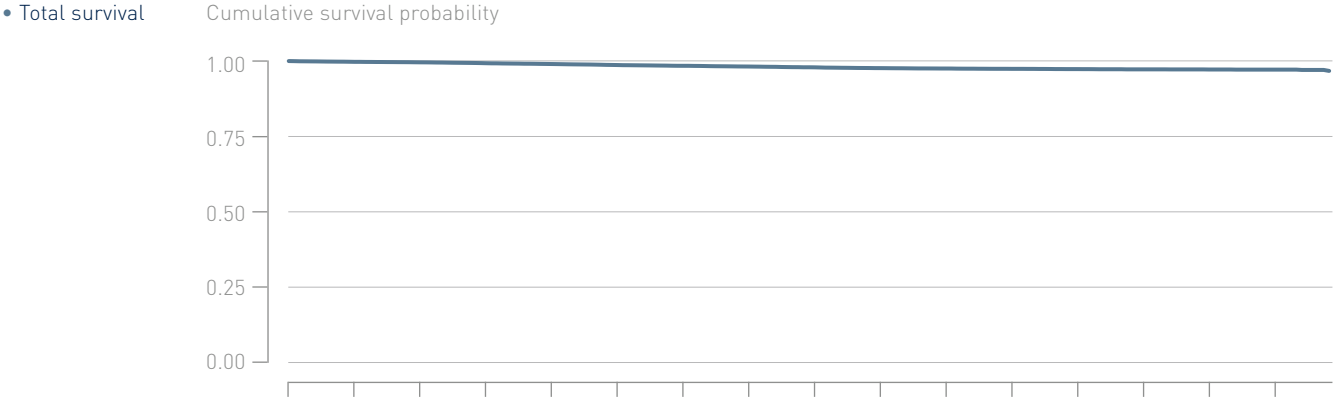

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.9 | 99.8 | 99.7 | 99.6 | 99.5 | 99.4 | 99.3 | 99.2 | 99.0 | 98.9 | 98.8 | 98.7 | 98.6 | 98.5 | 98.4 |
| CI [±%] | - | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.3 | 0.3 |
| Sample Size | 14343 | 12431 | 11657 | 10860 | 10042 | 9354 | 8735 | 8235 | 7877 | 7605 | 7394 | 7208 | 7124 | 7059 | 6975 | 5856 | 2016 |

# Selox ST

| | |
|---|---|
| Product Versions | 53, 60 |
| Lead Type | straight, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Nov 2004 |
| CE Market Release | Nov 2004 |
| Worldwide Distributed Devices | 379 000 |
| Registered U.S. Implants | 32 138 |
| Estimated Active U.S. Implants | 22 800 |
| U.S. Total Returned | 181 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 614 | 1.91% |
| Abnormal Pacing Impedance | 139 | 0.43% |
| Cardiac Perforation | 3 | 0.01% |
| Conductor Fracture | 64 | 0.20% |
| Extracardiac Stimulation | 6 | 0.02% |
| Failure to Capture | 300 | 0.93% |
| Failure to Sense | 1 | 0.00% |
| Insulation Breach | 38 | 0.12% |
| Lead Dislodgement | 24 | 0.07% |
| Oversensing | 12 | 0.04% |
| Other | 27 | 0.08% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 19 | 0.06% |
| Conductor Fracture | 1 | 0.00% |
| Crimps, Welds and Bonds | 1 | 0.00% |
| Insulation Breach | 17 | 0.05% |
| **U.S. Acute Lead Observations** | 49 | 0.15% |
| Abnormal Pacing Impedance | 1 | 0.00% |
| Failure to Capture | 21 | 0.07% |
| Lead Dislodgement | 21 | 0.07% |
| Other | 6 | 0.02% |



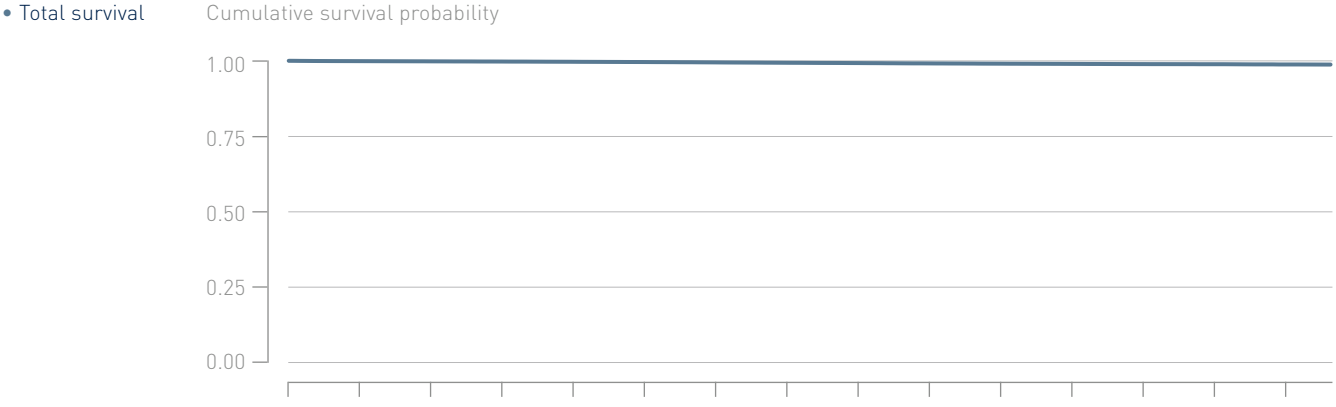

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.5 | 99.2 | 98.9 | 98.6 | 98.3 | 98.1 | 97.8 | 97.5 | 97.3 | 97.2 | 97.1 | 97.0 | 97.0 | 97.0 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.3 | 0.3 |
| Sample Size | 32138 | 29236 | 27641 | 25840 | 24245 | 22637 | 20867 | 18654 | 16310 | 13912 | 11424 | 9176 | 7054 | 5001 | 3198 | 1496 |

# Setrox S

| | |
|---|---|
| Product Versions | 45, 53, 60 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Apr 2006 |
| CE Market Release | Mar 2006 |
| Worldwide Distributed Devices | 681 000 |
| Registered U.S. Implants | 245 511 |
| Estimated Active U.S. Implants | 197 000 |
| U.S. Total Returned | 1 688 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 1 726 | 0.70% |
| Abnormal Pacing Impedance | 149 | 0.06% |
| Cardiac Perforation | 9 | 0.00% |
| Conductor Fracture | 101 | 0.04% |
| Extracardiac Stimulation | 12 | 0.00% |
| Failure to Capture | 603 | 0.25% |
| Failure to Sense | 49 | 0.02% |
| Insulation Breach | 77 | 0.03% |
| Lead Dislodgement | 340 | 0.14% |
| Oversensing | 276 | 0.11% |
| Other | 110 | 0.04% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 183 | 0.07% |
| Conductor Fracture | 59 | 0.02% |
| Insulation Breach | 120 | 0.05% |
| Other | 4 | 0.00% |
| **U.S. Acute Lead Observations** | 273 | 0.11% |
| Abnormal Pacing Impedance | 1 | 0.00% |
| Cardiac Perforation | 24 | 0.01% |
| Failure to Capture | 35 | 0.01% |
| Failure to Sense | 3 | 0.00% |
| Insulation Breach | 4 | 0.00% |
| Lead Dislodgement | 189 | 0.08% |
| Oversensing | 1 | 0.00% |
| Other | 16 | 0.01% |



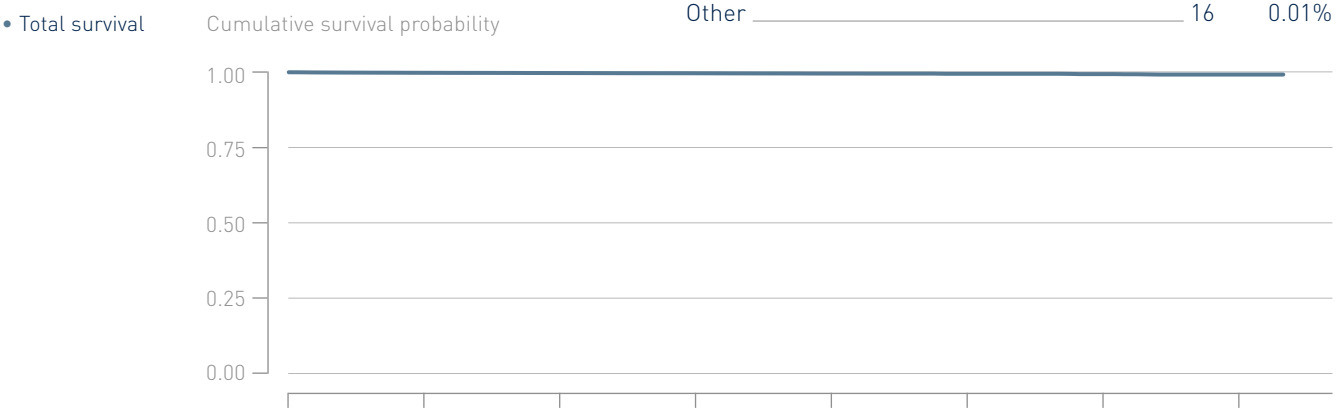

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.8 | 99.7 | 99.6 | 99.5 | 99.3 | 99.2 | 99.1 | 98.9 | 98.8 | 98.8 | 98.7 | 98.7 | 98.6 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 245511 | 229122 | 220061 | 212476 | 204827 | 178708 | 144638 | 117846 | 95540 | 74445 | 55842 | 38785 | 24244 | 12583 | 4369 |

# Siello S / Solia S

| | |
|---|---|
| Product Versions | 45, 53, 60 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2013 |
| CE Market Release | Jul 2009 |
| Worldwide Distributed Devices | 1 781 000 |
| Registered U.S. Implants | 165 205 |
| Estimated Active U.S. Implants | 157 000 |
| U.S. Total Returned | 714 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 561 | 0.34% |
| Abnormal Pacing Impedance | 33 | 0.02% |
| Cardiac Perforation | 16 | 0.01% |
| Conductor Fracture | 13 | 0.01% |
| Extracardiac Stimulation | 10 | 0.00% |
| Failure to Capture | 150 | 0.09% |
| Failure to Sense | 27 | 0.02% |
| Insulation Breach | 10 | 0.01% |
| Lead Dislodgement | 241 | 0.15% |
| Oversensing | 43 | 0.03% |
| Other | 18 | 0.01% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 35 | 0.02% |
| Conductor Fracture | 16 | 0.01% |
| Insulation Breach | 17 | 0.01% |
| Other | 2 | 0.00% |
| **U.S. Acute Lead Observations** | 307 | 0.19% |
| Abnormal Pacing Impedance | 4 | 0.00% |
| Cardiac Perforation | 27 | 0.02% |
| Conductor Fracture | 1 | 0.00% |
| Failure to Capture | 53 | 0.03% |
| Failure to Sense | 7 | 0.00% |
| Insulation Breach | 2 | 0.00% |
| Lead Dislodgement | 190 | 0.11% |
| Oversensing | 7 | 0.00% |
| Other | 16 | 0.01% |



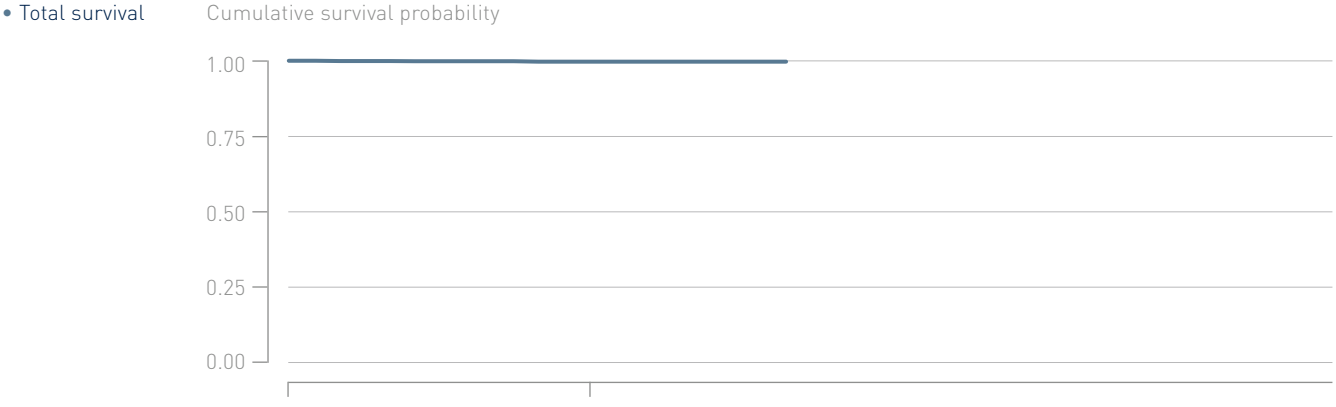

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.7 | 99.6 | 99.4 | 99.3 | 99.2 | 99.0 |
| CI [±%] | - | < 0.1 | < 0.1 | < 0.1 | 0.1 | 0.1 | 0.2 | 0.3 |
| Sample Size | 165205 | 129751 | 90906 | 51445 | 16154 | 2430 | 1827 | 476 |

# Siello JT / Solia JT

| | |
|---|---|
| Product Versions | 42, 53 |
| Lead Type | J-shape, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Nov 2018 |
| CE Market Release | Okt 2009 |
| Worldwide Distributed Devices | 1 160 000 |
| Registered U.S. Implants | 1 291 |
| Estimated Active U.S. Implants | 1 220 |
| U.S. Total Returned | 7 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 5 | 0.39% |
| Failure to Capture | 2 | 0.15% |
| Lead Dislodgement | 3 | 0.23% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 7 | 0.54% |
| Failure to Capture | 1 | 0.08% |
| Lead Dislodgement | 6 | 0.46% |



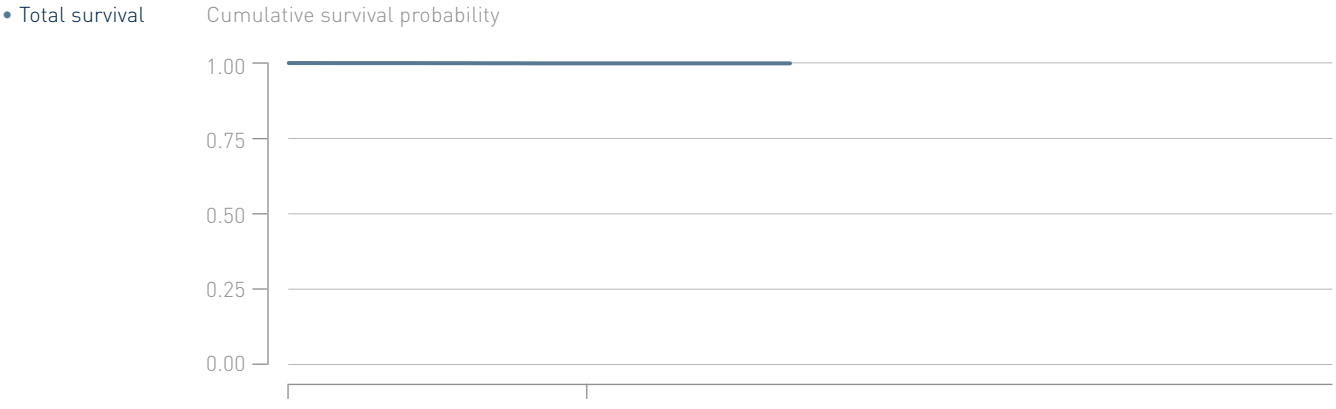

| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.5 |
| CI [±%] | - | 0.5 |
| Sample Size | 1291 | 671 |

# Siello T / Solia T

| | |
|---|---|
| Product Versions | 53, 60 |
| Lead Type | straight, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Nov 2018 |
| CE Market Release | Okt 2009 |
| Worldwide Distributed Devices | 188 000 |
| Registered U.S. Implants | 1 690 |
| Estimated Active U.S. Implants | 1 590 |
| U.S. Total Returned | 7 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 4 | 0.24% |
| Abnormal Pacing Impedance | 2 | 0.12% |
| Failure to Capture | 2 | 0.12% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 8 | 0.47% |
| Failure to Capture | 3 | 0.18% |
| Lead Dislodgement | 5 | 0.30% |



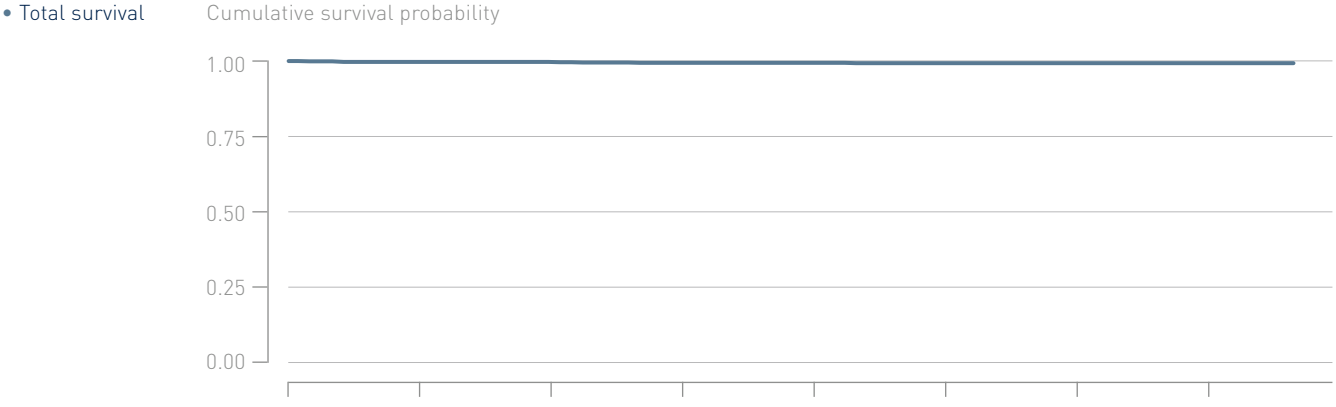

| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.7 |
| CI [±%] | - | 0.3 |
| Sample Size | 1690 | 820 |

# Tilda JT

| | |
|---|---|
| Product Versions | 45, 53 |
| Lead Type | J-shape, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2012 |
| CE Market Release | Sep 2011 |
| Worldwide Distributed Devices | 17300 |
| Registered U.S. Implants | 810 |
| Estimated Active U.S. Implants | 787 |
| U.S. Total Returned | 0 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 7 | 0.86% |
| Abnormal Pacing Impedance | 2 | 0.25% |
| Failure to Capture | 2 | 0.25% |
| Lead Dislodgement | 3 | 0.37% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 1 | 0.12% |
| Lead Dislodgement | 1 | 0.12% |



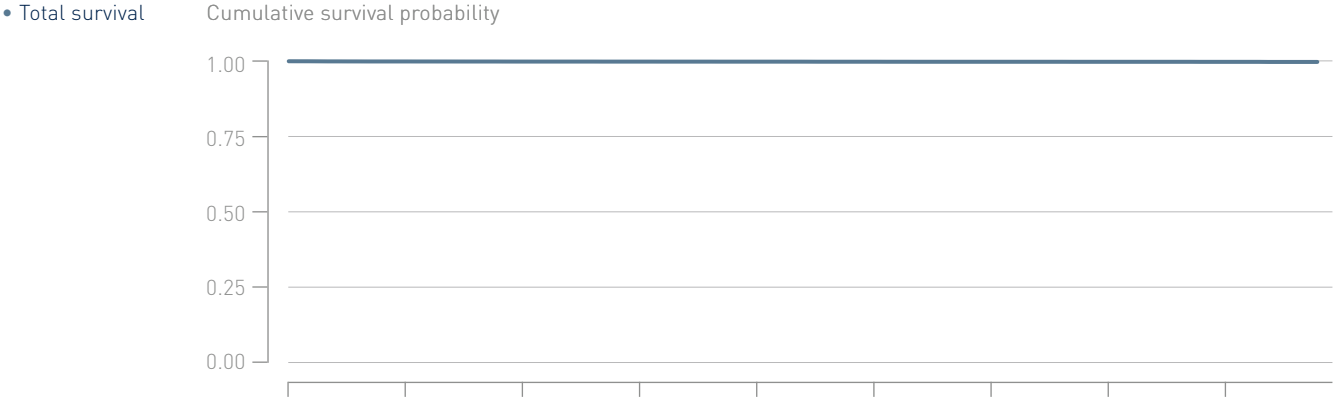

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.6 | 99.5 | 99.2 | 99.2 | 99.1 | 99.1 | 99.1 |
| CI [±%] | - | 0.4 | 0.5 | 0.6 | 0.6 | 0.7 | 0.7 | 0.7 |
| Sample Size | 810 | 797 | 778 | 748 | 717 | 636 | 498 | 352 |

# Tilda R

| | |
|---|---|
| Product Versions | 45, 53, 60 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Dec 2011 |
| CE Market Release | Aug 2011 |
| Worldwide Distributed Devices | 41 300 |
| Registered U.S. Implants | 10 225 |
| Estimated Active U.S. Implants | 9 830 |
| U.S. Total Returned | 16 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 35 | 0.34% |
| Abnormal Pacing Impedance | 1 | 0.01% |
| Conductor Fracture | 6 | 0.06% |
| Extracardiac Stimulation | 1 | 0.01% |
| Failure to Capture | 8 | 0.08% |
| Insulation Breach | 2 | 0.02% |
| Lead Dislodgement | 9 | 0.09% |
| Oversensing | 4 | 0.04% |
| Other | 4 | 0.04% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.01% |
| Conductor Fracture | 1 | 0.01% |
| **U.S. Acute Lead Observations** | 9 | 0.09% |
| Failure to Capture | 1 | 0.01% |
| Lead Dislodgement | 8 | 0.08% |



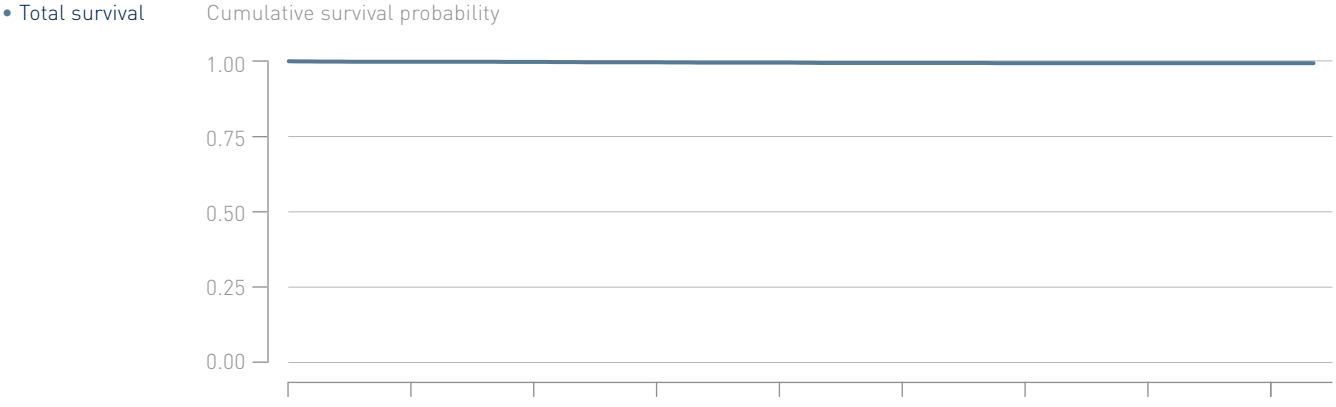

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.8 | 99.8 | 99.7 | 99.7 | 99.7 | 99.6 | 99.6 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Sample Size | 10225 | 9973 | 9809 | 9570 | 9011 | 8106 | 6830 | 4807 | 2506 |

# Tilda T

| | |
|---|---|
| Product Versions | 53, 60 |
| Lead Type | straight, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Dec 2011 |
| CE Market Release | Aug 2011 |
| Worldwide Distributed Devices | 22 400 |
| Registered U.S. Implants | 1 357 |
| Estimated Active U.S. Implants | 1 310 |
| U.S. Total Returned | 2 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 11 | 0.81% |
| Abnormal Pacing Impedance | 4 | 0.29% |
| Conductor Fracture | 2 | 0.15% |
| Insulation Breach | 1 | 0.07% |
| Lead Dislodgement | 4 | 0.29% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 0 | 0.00% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.7 | 99.5 | 99.4 | 99.2 | 99.1 | 99.1 | 99.1 |
| CI [±%] | - | 0.3 | 0.3 | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 |
| Sample Size | 1357 | 1324 | 1304 | 1282 | 1229 | 1111 | 975 | 691 | 318 |

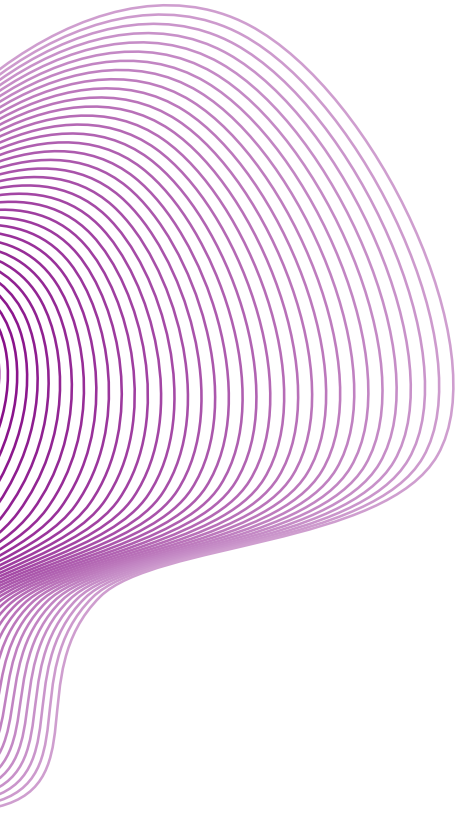
# Performance of BIOTRONIK Leads

## Based on Returned Products and Complaint Data


6.1 Pacing Leads – Postmarket Data

**6.2 ICD Leads – Postmarket Data**

6.3 CRT Leads – Postmarket Data

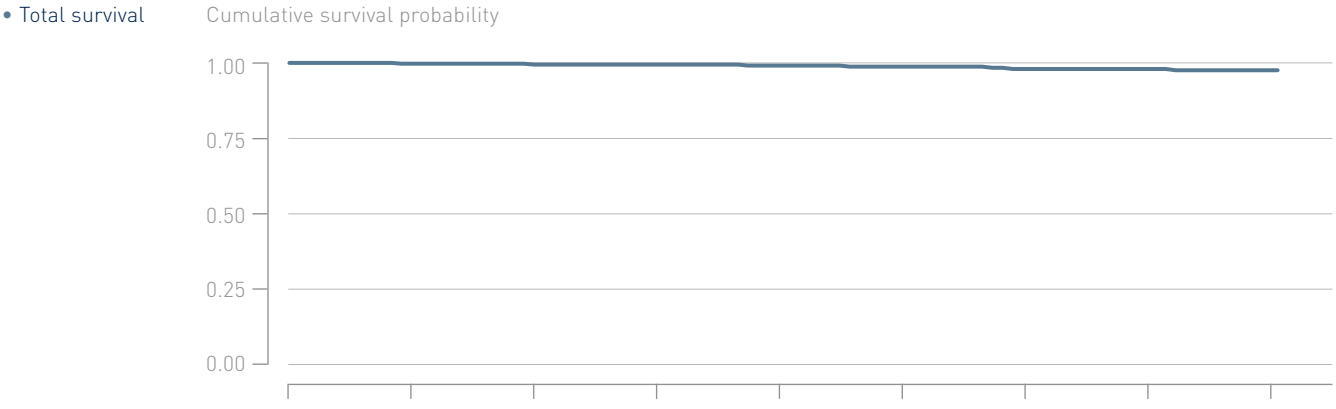



# Kentrox RV

| | |
|---|---|
| Product Versions | 65, 75, -Steroid |
| Lead Type | single-coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes/no |
| U.S. Market Release | Mar 2002 / Oct 2004 |
| CE Market Release | Jan 2001 / Dec 2004 |
| Worldwide Distributed Devices | 5460 |
| Registered U.S. Implants | 406 |
| Estimated Active U.S. Implants | 171 |
| U.S. Total Returned | 8 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 10 | 2.46% |
| Conductor Fracture | 1 | 0.25% |
| Failure to Capture | 4 | 0.98% |
| Insulation Breach | 1 | 0.25% |
| Oversensing | 4 | 0.98% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.49% |
| Conductor Fracture | 1 | 0.25% |
| Insulation Breach | 1 | 0.25% |
| **U.S. Acute Lead Observations** | 0 | 0.00% |



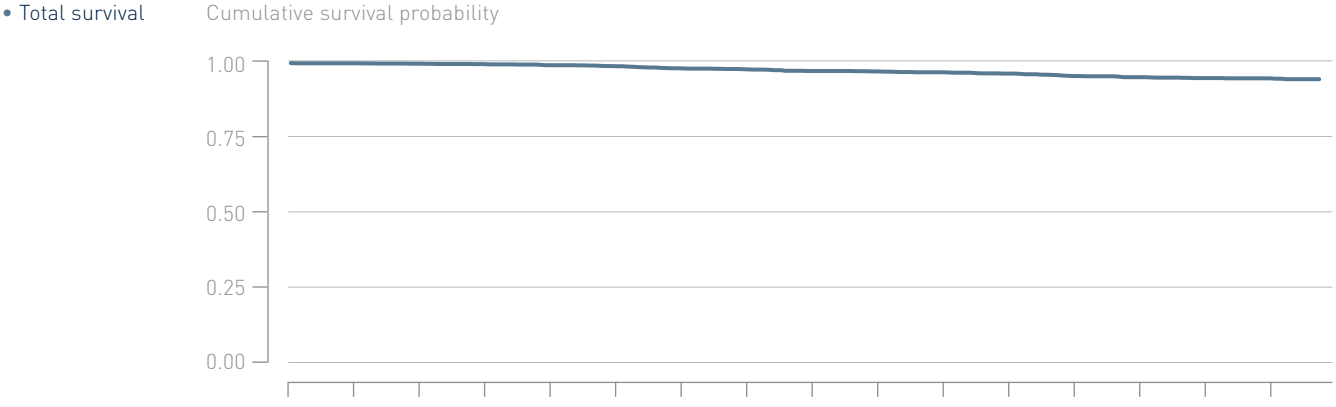

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.4 | 99.4 | 99.0 | 98.6 | 97.8 | 97.8 | 97.3 |
| CI [±%] | - | 0.6 | 0.8 | 0.8 | 1.1 | 1.3 | 1.8 | 1.8 | 2 |
| Sample Size | 406 | 353 | 318 | 286 | 269 | 243 | 228 | 211 | 201 |

# Kentrox SL-S

| | |
|---|---|
| Product Versions | 65/16, 18 -Steroid |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes/no |
| U.S. Market Release | Oct 2004 |
| CE Market Release | Jun 2004 |
| Worldwide Distributed Devices | 8740 |
| Registered U.S. Implants | 2414 |
| Estimated Active U.S. Implants | 1210 |
| U.S. Total Returned | 41 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 66 | 2.72% |
| Abnormal Defibrillation Impedance | 1 | 0.04% |
| Abnormal Pacing Impedance | 5 | 0.21% |
| Conductor Fracture | 6 | 0.25% |
| Failure to Capture | 3 | 0.12% |
| Failure to Sense | 1 | 0.04% |
| Insulation Breach | 3 | 0.12% |
| Lead Dislodgement | 2 | 0.08% |
| Oversensing | 42 | 1.73% |
| Other | 3 | 0.12% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 14 | 0.58% |
| Insulation Breach | 14 | 0.58% |
| **U.S. Acute Lead Observations** | 2 | 0.08% |
| Insulation Breach | 1 | 0.04% |
| Oversensing | 1 | 0.04% |



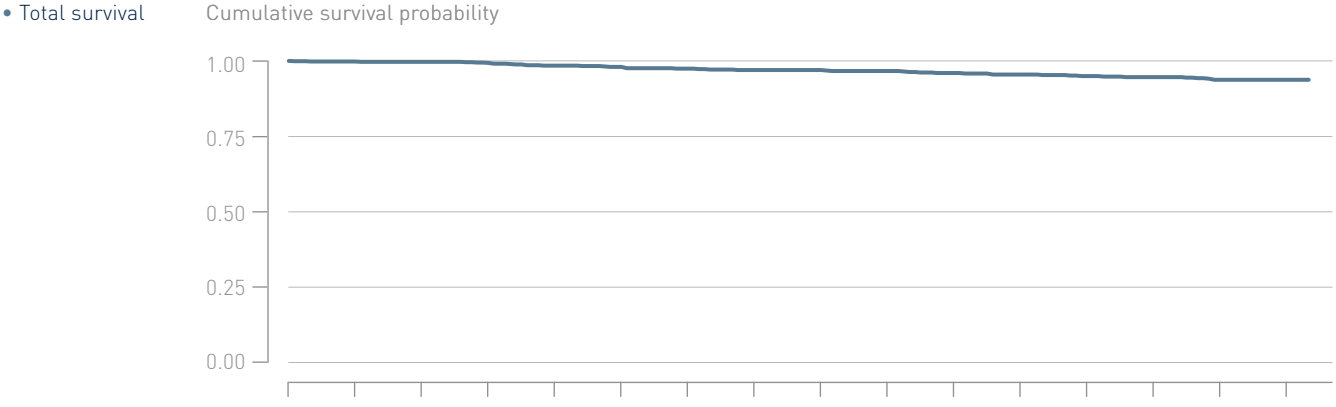

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.8 | 99.6 | 99.3 | 98.9 | 98.2 | 97.8 | 97.3 | 97.1 | 96.8 | 96.4 | 95.5 | 95.1 | 94.8 | 94.7 |
| CI [±%] | - | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.7 | 0.8 | 0.8 | 0.9 | 0.9 | 1.1 | 1.1 | 1.1 | 1.2 |
| Sample Size | 2414 | 2176 | 2051 | 1891 | 1756 | 1632 | 1512 | 1432 | 1364 | 1325 | 1283 | 1260 | 1230 | 1212 | 1163 | 767 |

# Kentrox SL

| | |
|---|---|
| Product Versions | 65, 75, 100, -Steroid |
| Lead Type | dual coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes/no |
| U.S. Market Release | Oct 2004 |
| CE Market Release | Dec 2003 / Dec 2004 |
| Worldwide Distributed Devices | 8 440 |
| Registered U.S. Implants | 1 003 |
| Estimated Active U.S. Implants | 523 |
| U.S. Total Returned | 19 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 37 | 3.66% |
| Abnormal Defibrillation Impedance | 1 | 0.10% |
| Abnormal Pacing Impedance | 4 | 0.40% |
| Conductor Fracture | 3 | 0.30% |
| Failure to Capture | 4 | 0.40% |
| Insulation Breach | 6 | 0.59% |
| Oversensing | 17 | 1.68% |
| Other | 2 | 0.20% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 5 | 0.49% |
| Insulation Breach | 5 | 0.49% |
| **U.S. Acute Lead Observations** | 0 | 0.00% |



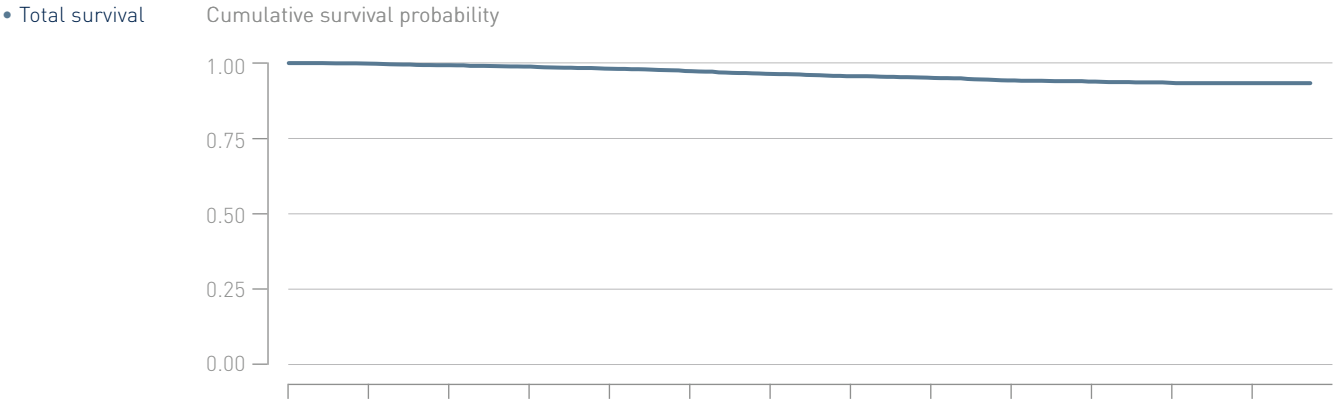

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.7 | 99.3 | 98.4 | 97.9 | 97.3 | 96.9 | 96.9 | 96.5 | 95.8 | 95.3 | 94.8 | 94.4 | 93.5 | 93.5 |
| CI [±%] | - | 0.3 | 0.4 | 0.6 | 0.9 | 1 | 1.2 | 1.3 | 1.3 | 1.4 | 1.5 | 1.6 | 1.7 | 1.8 | 1.9 | 1.9 |
| Sample Size | 1003 | 898 | 834 | 777 | 707 | 662 | 616 | 596 | 576 | 565 | 552 | 543 | 534 | 527 | 505 | 295 |

# Linox S

| | |
|---|---|
| Product Versions | 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2007 |
| CE Market Release | Mar 2007 |
| Worldwide Distributed Devices | 32 700 |
| Registered U.S. Implants | 2 466 |
| Estimated Active U.S. Implants | 1 640 |
| U.S. Total Returned | 85 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 81 | 3.25% |
| Abnormal Defibrillation Impedance | 8 | 0.32% |
| Abnormal Pacing Impedance | 6 | 0.24% |
| Conductor Fracture | 7 | 0.28% |
| Failure to Capture | 9 | 0.36% |
| Failure to Sense | 1 | 0.04% |
| Insulation Breach | 4 | 0.16% |
| Oversensing | 40 | 1.60% |
| Other | 6 | 0.24% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 46 | 1.85% |
| Conductor Fracture | 8 | 0.32% |
| Insulation Breach | 38 | 1.52% |
| **U.S. Acute Lead Observations** | 2 | 0.08% |
| Lead Dislodgement | 1 | 0.04% |
| Other | 1 | 0.04% |



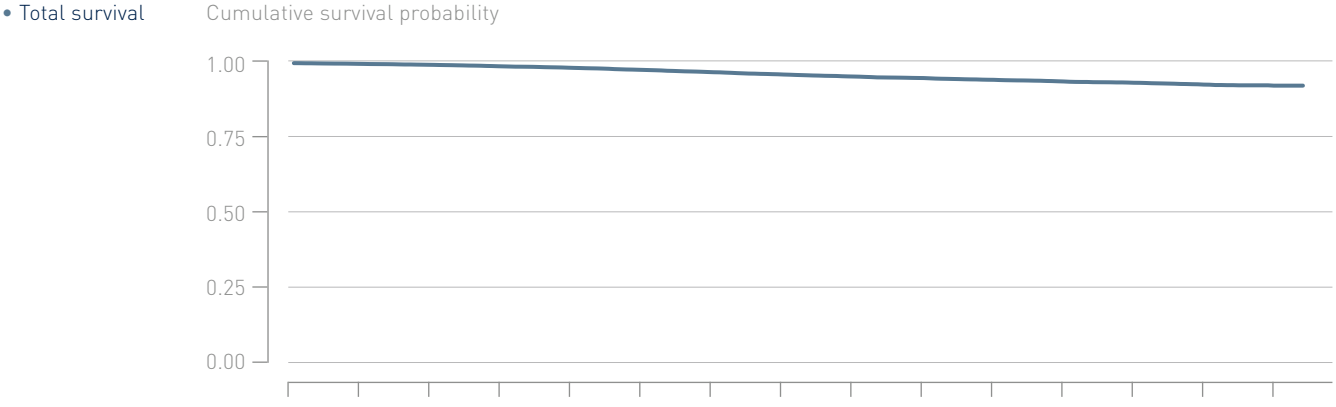

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.3 | 98.8 | 98.1 | 97.2 | 96.3 | 95.5 | 94.9 | 94.0 | 93.6 | 93.1 | 93.1 |
| CI [±%] | - | 0.2 | 0.3 | 0.5 | 0.6 | 0.7 | 0.8 | 0.9 | 1 | 1.1 | 1.1 | 1.2 | 1.2 |
| Sample Size | 2466 | 2261 | 2129 | 2018 | 1925 | 1848 | 1785 | 1742 | 1696 | 1632 | 1154 | 685 | 391 |

# Linox SD

| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Apr 2006 |
| CE Market Release | Aug 2006 |
| Worldwide Distributed Devices | 55 100 |
| Registered U.S. Implants | 22 093 |
| Estimated Active U.S. Implants | 14 200 |
| U.S. Total Returned | 522 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 866 | 3.89% |
| Abnormal Defibrillation Impedance | 77 | 0.35% |
| Abnormal Pacing Impedance | 62 | 0.28% |
| Cardiac Perforation | 3 | 0.01% |
| Conductor Fracture | 99 | 0.44% |
| Failure to Capture | 73 | 0.33% |
| Failure to Sense | 16 | 0.07% |
| Insulation Breach | 61 | 0.27% |
| Lead Dislodgement | 31 | 0.14% |
| Oversensing | 397 | 1.78% |
| Other | 47 | 0.21% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 218 | 0.98% |
| Conductor Fracture | 31 | 0.14% |
| Insulation Breach | 185 | 0.83% |
| Other | 2 | 0.01% |
| | | |
| **U.S. Acute Lead Observations** | 11 | 0.05% |
| Abnormal Pacing Impedance | 1 | 0.00% |
| Cardiac Perforation | 1 | 0.00% |
| Failure to Capture | 1 | 0.00% |
| Lead Dislodgement | 6 | 0.03% |
| Oversensing | 1 | 0.00% |
| Other | 1 | 0.00% |



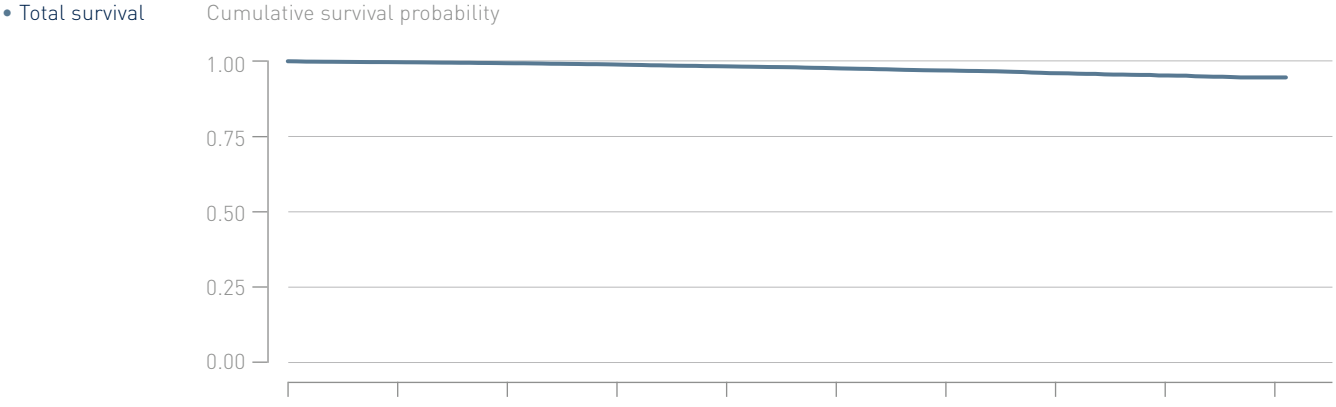

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.4 | 98.9 | 98.4 | 97.7 | 96.9 | 96.1 | 95.4 | 94.9 | 94.3 | 93.7 | 93.3 | 92.7 | 92.3 |
| CI [±%] | - | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 | 0.4 | 0.5 | 0.6 |
| Sample Size | 22093 | 20082 | 18843 | 17787 | 16939 | 16201 | 15600 | 15148 | 14778 | 14469 | 13007 | 8870 | 5524 | 2760 | 817 |

# Linox$^{smart}$ S

| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Aug 2011 |
| CE Market Release | Dec 2010 |
| Worldwide Distributed Devices | 46 700 |
| Registered U.S. Implants | 7 597 |
| Estimated Active U.S. Implants | 6 160 |
| U.S. Total Returned | 186 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 206 | 2.69% |
| Abnormal Defibrillation Impedance | 13 | 0.17% |
| Abnormal Pacing Impedance | 19 | 0.25% |
| Cardiac Perforation | 1 | 0.01% |
| Conductor Fracture | 23 | 0.30% |
| Failure to Capture | 23 | 0.30% |
| Failure to Sense | 11 | 0.14% |
| Insulation Breach | 5 | 0.07% |
| Lead Dislodgement | 14 | 0.18% |
| Oversensing | 88 | 1.15% |
| Other | 9 | 0.12% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 69 | 0.90% |
| Conductor Fracture | 9 | 0.12% |
| Insulation Breach | 60 | 0.78% |
| **U.S. Acute Lead Observations** | 10 | 0.13% |
| Abnormal Pacing Impedance | 1 | 0.01% |
| Cardiac Perforation | 1 | 0.01% |
| Lead Dislodgement | 7 | 0.09% |
| Other | 1 | 0.01% |



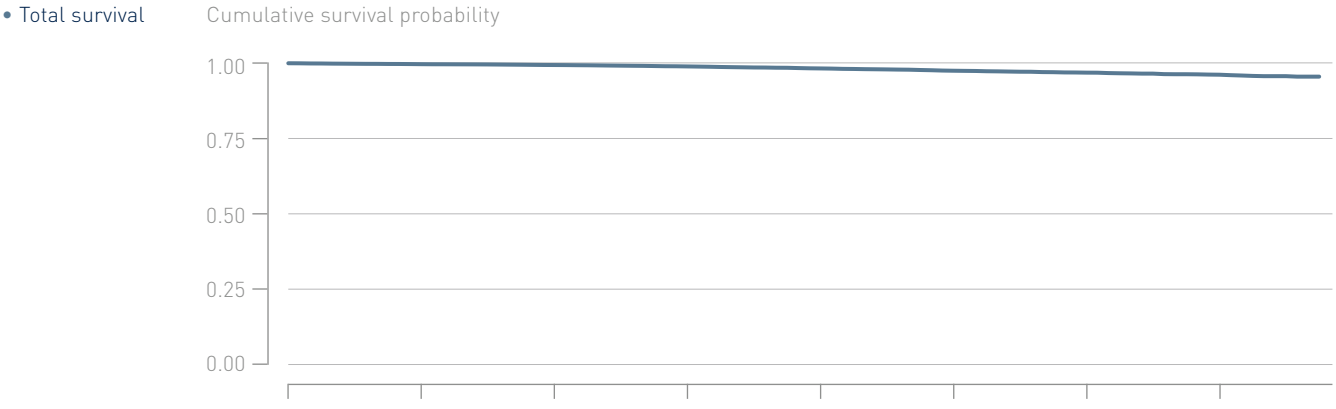

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.3 | 98.9 | 98.3 | 97.6 | 96.8 | 95.9 | 95.1 | 94.4 |
| CI [±%] | - | 0.1 | 0.2 | 0.2 | 0.3 | 0.4 | 0.4 | 0.5 | 0.6 | 0.8 |
| Sample Size | 7597 | 7133 | 6871 | 6649 | 6352 | 5898 | 5038 | 3516 | 1953 | 384 |

# Linox$^{smart}$ S DX

| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2013 |
| CE Market Release | Mar 2010 |
| Worldwide Distributed Devices | 36300 |
| Registered U.S. Implants | 16305 |
| Estimated Active U.S. Implants | 14400 |
| U.S. Total Returned | 355 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 322 | 1.96% |
| Abnormal Defibrillation Impedance | 35 | 0.21% |
| Abnormal Pacing Impedance | 22 | 0.13% |
| Conductor Fracture | 38 | 0.23% |
| Failure to Capture | 30 | 0.18% |
| Failure to Sense | 13 | 0.08% |
| Insulation Breach | 6 | 0.04% |
| Lead Dislodgement | 45 | 0.27% |
| Oversensing | 125 | 0.76% |
| Other | 8 | 0.05% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 104 | 0.63% |
| Conductor Fracture | 8 | 0.05% |
| Insulation Breach | 96 | 0.59% |
| **U.S. Acute Lead Observations** | 39 | 0.24% |
| Cardiac Perforation | 4 | 0.02% |
| Failure to Capture | 9 | 0.05% |
| Lead Dislodgement | 16 | 0.10% |
| Oversensing | 3 | 0.02% |
| Other | 7 | 0.04% |



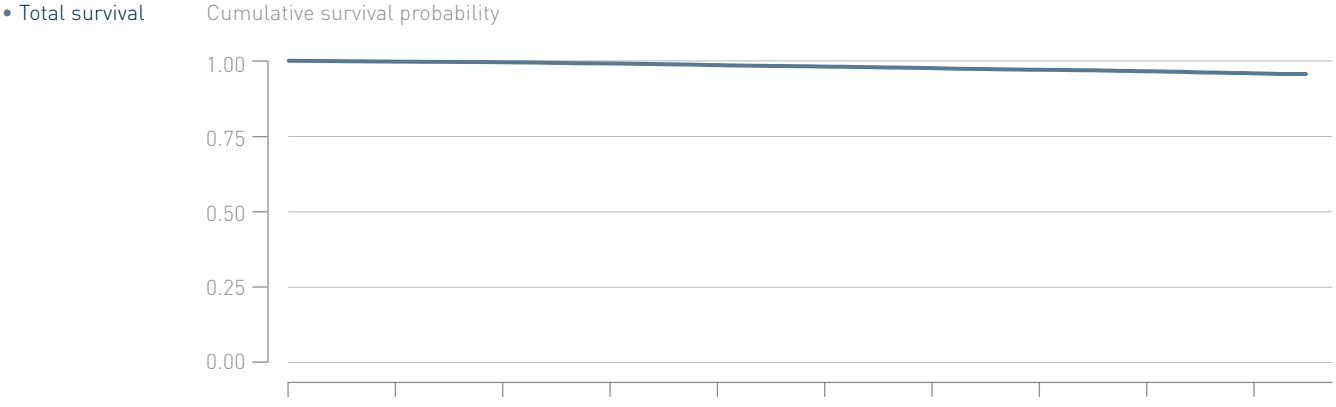

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.4 | 98.9 | 98.2 | 97.4 | 96.7 | 96.0 |
| CI [±%] | - | 0.1 | 0.1 | 0.2 | 0.2 | 0.3 | 0.3 | 0.4 |
| Sample Size | 16305 | 15521 | 15164 | 14566 | 12008 | 8163 | 5017 | 2039 |

# Linox$^{smart}$ SD

| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 55 700 |
| Registered U.S. Implants | 13 128 |
| Estimated Active U.S. Implants | 10 500 |
| U.S. Total Returned | 252 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 332 | 2.51% |
| Abnormal Defibrillation Impedance | 29 | 0.22% |
| Abnormal Pacing Impedance | 18 | 0.14% |
| Cardiac Perforation | 1 | 0.01% |
| Conductor Fracture | 44 | 0.33% |
| Extracardiac Stimulation | 1 | 0.01% |
| Failure to Capture | 26 | 0.20% |
| Failure to Sense | 10 | 0.08% |
| Insulation Breach | 8 | 0.06% |
| Lead Dislodgement | 25 | 0.19% |
| Oversensing | 163 | 1.23% |
| Other | 7 | 0.05% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 73 | 0.55% |
| Conductor Fracture | 10 | 0.08% |
| Insulation Breach | 61 | 0.46% |
| Other | 2 | 0.02% |
| **U.S. Acute Lead Observations** | 29 | 0.22% |
| Abnormal Defibrillation Impedance | 1 | 0.01% |
| Cardiac Perforation | 2 | 0.02% |
| Failure to Capture | 4 | 0.03% |
| Insulation Breach | 1 | 0.01% |
| Lead Dislodgement | 12 | 0.09% |
| Oversensing | 2 | 0.02% |
| Other | 7 | 0.05% |



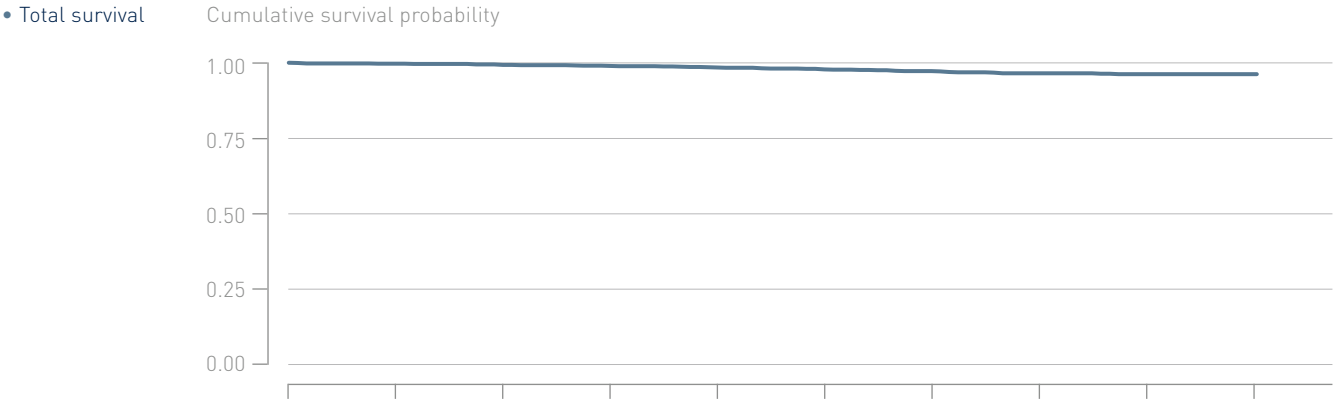

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.5 | 99.0 | 98.5 | 98.0 | 97.5 | 96.9 | 96.4 | 95.8 |
| CI [±%] | - | 0.1 | 0.1 | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 |
| Sample Size | 13128 | 12176 | 11787 | 11411 | 10972 | 10478 | 9699 | 8207 | 5889 | 2488 |

# Linox$^{smart}$ TD

| | |
|---|---|
| Product Versions | 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 7 720 |
| Registered U.S. Implants | 1 265 |
| Estimated Active U.S. Implants | 1 010 |
| U.S. Total Returned | 22 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 40 | 3.14% |
| Abnormal Defibrillation Impedance | 5 | 0.39% |
| Abnormal Pacing Impedance | 5 | 0.39% |
| Conductor Fracture | 3 | 0.24% |
| Failure to Capture | 9 | 0.71% |
| Insulation Breach | 2 | 0.16% |
| Lead Dislodgement | 4 | 0.31% |
| Oversensing | 11 | 0.86% |
| Other | 1 | 0.08% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.08% |
| Insulation Breach | 1 | 0.08% |
| **U.S. Acute Lead Observations** | 3 | 0.24% |
| Lead Dislodgement | 3 | 0.24% |



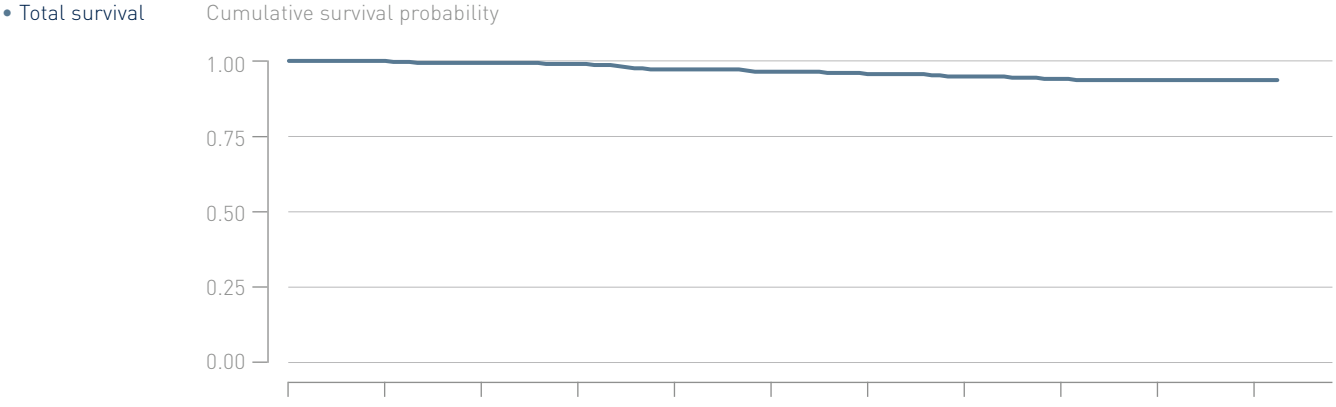

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.7 | 99.2 | 98.9 | 98.3 | 97.7 | 97.1 | 96.3 | 96.0 | 96.0 |
| CI [±%] | - | 0.3 | 0.5 | 0.6 | 0.7 | 0.9 | 1 | 1.1 | 1.2 | 1.2 |
| Sample Size | 1265 | 1174 | 1138 | 1096 | 1070 | 1005 | 924 | 782 | 558 | 239 |

# Linox T

| | |
|---|---|
| Product Versions | 65, 75 |
| Lead Type | single-coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2007 |
| CE Market Release | Mar 2007 |
| Worldwide Distributed Devices | 2 260 |
| Registered U.S. Implants | 319 |
| Estimated Active U.S. Implants | 217 |
| U.S. Total Returned | 4 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 19 | 5.90% |
| Abnormal Pacing Impedance | 3 | 0.93% |
| Conductor Fracture | 1 | 0.31% |
| Failure to Capture | 4 | 1.24% |
| Insulation Breach | 1 | 0.31% |
| Oversensing | 9 | 2.80% |
| Other | 1 | 0.31% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 3 | 0.93% |
| Conductor Fracture | 1 | 0.31% |
| Insulation Breach | 2 | 0.62% |
| **U.S. Acute Lead Observations** | 1 | 0.31% |
| Other | 1 | 0.31% |



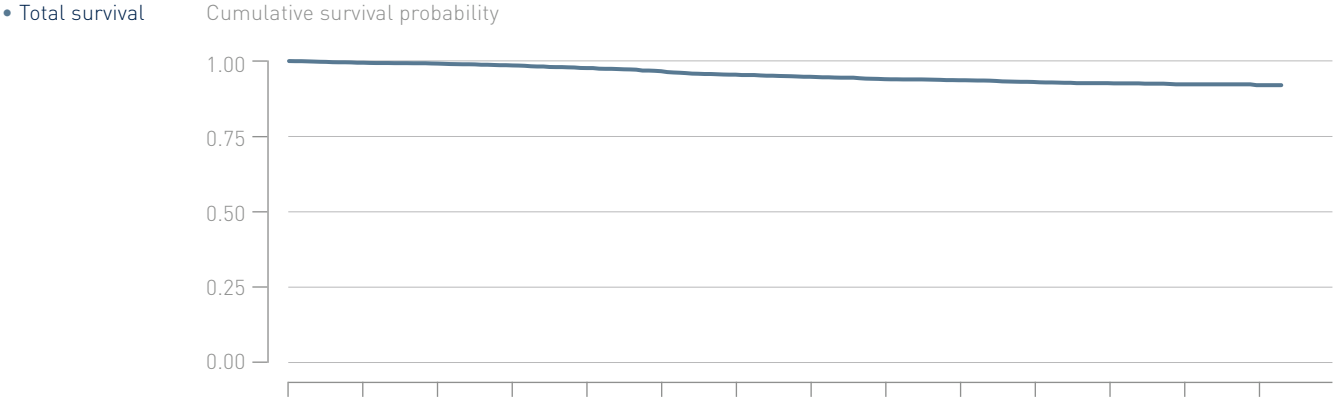

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 100.0 | 99.3 | 99.0 | 97.1 | 96.3 | 95.5 | 94.6 | 93.8 | 93.4 | 93.4 |
| CI [±%] | - | < 0.1 | 0.9 | 1.2 | 2 | 2.3 | 2.5 | 2.7 | 2.9 | 3 | 3 |
| Sample Size | 319 | 295 | 283 | 272 | 251 | 241 | 234 | 230 | 228 | 225 | 208 |

# Linox TD

| | |
|---|---|
| Product Versions | 65/16, 75/16, 100/16, 100/18 |
| Lead Type | dual-coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Oct 2006 |
| CE Market Release | Oct 2006 |
| Worldwide Distributed Devices | 14 600 |
| Registered U.S. Implants | 3 021 |
| Estimated Active U.S. Implants | 1 990 |
| U.S. Total Returned | 80 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 142 | 4.65% |
| Abnormal Defibrillation Impedance | 15 | 0.49% |
| Abnormal Pacing Impedance | 13 | 0.43% |
| Cardiac Perforation | 1 | 0.03% |
| Conductor Fracture | 18 | 0.59% |
| Failure to Capture | 22 | 0.72% |
| Failure to Sense | 4 | 0.13% |
| Insulation Breach | 13 | 0.43% |
| Lead Dislodgement | 4 | 0.13% |
| Oversensing | 49 | 1.61% |
| Other | 3 | 0.10% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 38 | 1.25% |
| Conductor Fracture | 6 | 0.20% |
| Insulation Breach | 32 | 1.05% |
| **U.S. Acute Lead Observations** | 3 | 0.10% |
| Failure to Capture | 1 | 0.03% |
| Lead Dislodgement | 2 | 0.07% |



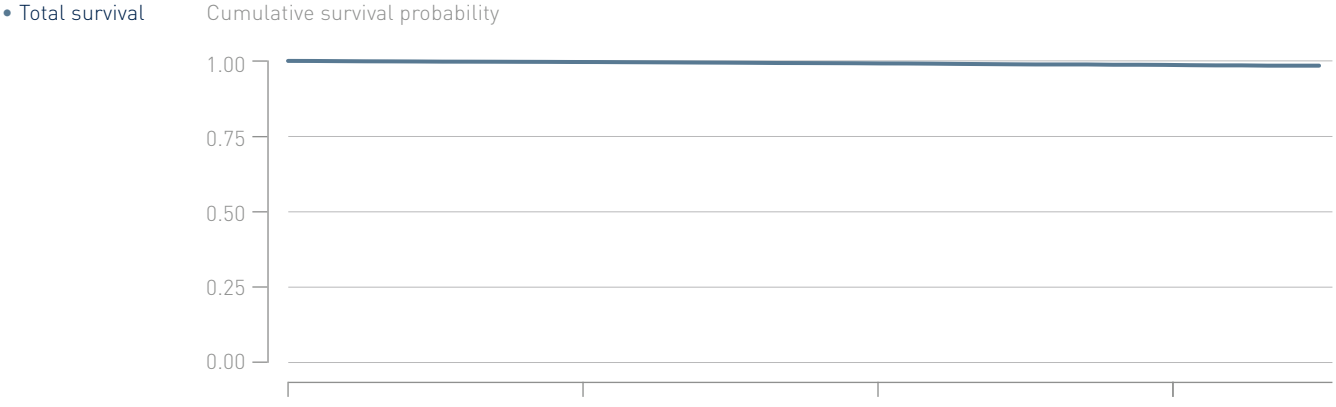

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.4 | 99.1 | 98.5 | 97.6 | 96.5 | 95.4 | 94.6 | 93.8 | 93.5 | 92.9 | 92.5 | 92.1 | 91.8 |
| CI [±%] | - | 0.3 | 0.3 | 0.5 | 0.6 | 0.7 | 0.8 | 0.9 | 1 | 1 | 1 | 1.1 | 1.1 | 1.3 |
| Sample Size | 3021 | 2730 | 2598 | 2451 | 2338 | 2235 | 2146 | 2093 | 2049 | 1996 | 1758 | 1227 | 739 | 317 |

# Plexa S

| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 83 500 |
| Registered U.S. Implants | 12 855 |
| Estimated Active U.S. Implants | 12 200 |
| U.S. Total Returned | 99 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 92 | 0.71% |
| Abnormal Defibrillation Impedance | 11 | 0.09% |
| Abnormal Pacing Impedance | 1 | 0.01% |
| Cardiac Perforation | 1 | 0.01% |
| Conductor Fracture | 3 | 0.02% |
| Failure to Capture | 12 | 0.09% |
| Failure to Sense | 5 | 0.04% |
| Insulation Breach | 1 | 0.01% |
| Lead Dislodgement | 18 | 0.14% |
| Oversensing | 34 | 0.26% |
| Other | 6 | 0.05% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 16 | 0.12% |
| Conductor Fracture | 4 | 0.03% |
| Insulation Breach | 12 | 0.09% |
| **U.S. Acute Lead Observations** | 28 | 0.22% |
| Abnormal Pacing Impedance | 2 | 0.02% |
| Cardiac Perforation | 4 | 0.03% |
| Failure to Capture | 6 | 0.05% |
| Lead Dislodgement | 15 | 0.12% |
| Oversensing | 1 | 0.01% |



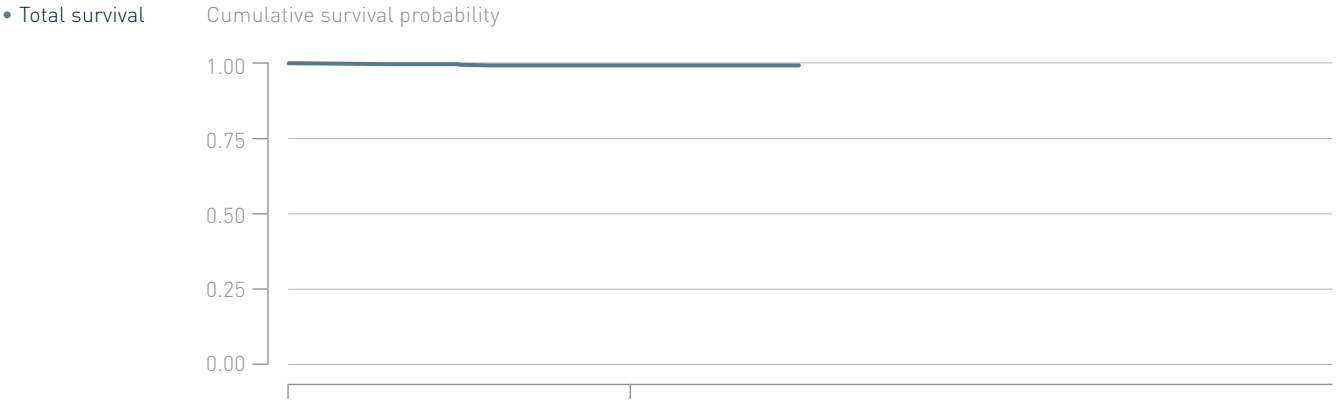

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.6 | 99.0 | 98.4 |
| CI [±%] | - | 0.1 | 0.2 | 0.4 |
| Sample Size | 12855 | 9059 | 5122 | 1631 |

# Plexa S DX

| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2019 |
| CE Market Release | Dec 2018 |
| Worldwide Distributed Devices | 14 100 |
| Registered U.S. Implants | 5 434 |
| Estimated Active U.S. Implants | 5 240 |
| U.S. Total Returned | 40 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 23 | 0.42% |
| Abnormal Defibrillation Impedance | 1 | 0.02% |
| Abnormal Pacing Impedance | 1 | 0.02% |
| Cardiac Perforation | 1 | 0.02% |
| Failure to Capture | 3 | 0.06% |
| Lead Dislodgement | 9 | 0.17% |
| Oversensing | 8 | 0.15% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.02% |
| Insulation Breach | 1 | 0.02% |
| **U.S. Acute Lead Observations** | 18 | 0.33% |
| Failure to Capture | 7 | 0.13% |
| Failure to Sense | 2 | 0.04% |
| Lead Dislodgement | 8 | 0.15% |
| Oversensing | 1 | 0.02% |



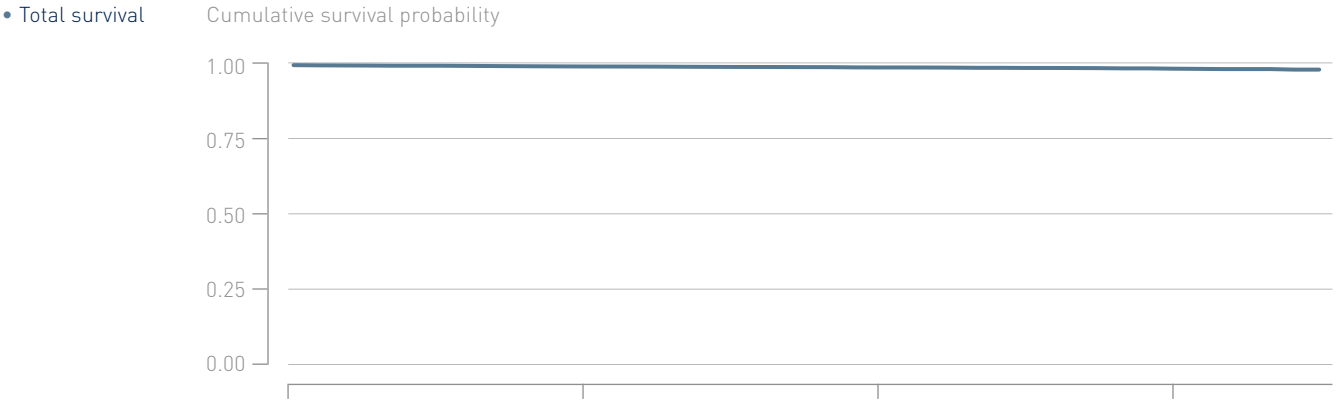

| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.5 |
| CI [±%] | - | 0.2 |
| Sample Size | 5434 | 1922 |

# Plexa S DX DF1

| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 19 700 |
| Registered U.S. Implants | 8 910 |
| Estimated Active U.S. Implants | 8 400 |
| U.S. Total Returned | 101 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 64 | 0.72% |
| Abnormal Defibrillation Impedance | 10 | 0.11% |
| Abnormal Pacing Impedance | 1 | 0.01% |
| Conductor Fracture | 1 | 0.01% |
| Failure to Capture | 6 | 0.07% |
| Failure to Sense | 5 | 0.06% |
| Insulation Breach | 2 | 0.02% |
| Lead Dislodgement | 17 | 0.19% |
| Oversensing | 22 | 0.25% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 22 | 0.25% |
| Conductor Fracture | 1 | 0.01% |
| Insulation Breach | 21 | 0.23% |
| **U.S. Acute Lead Observations** | 20 | 0.22% |
| Cardiac Perforation | 2 | 0.02% |
| Failure to Capture | 2 | 0.02% |
| Failure to Sense | 1 | 0.01% |
| Lead Dislodgement | 12 | 0.13% |
| Oversensing | 1 | 0.01% |
| Other | 2 | 0.02% |



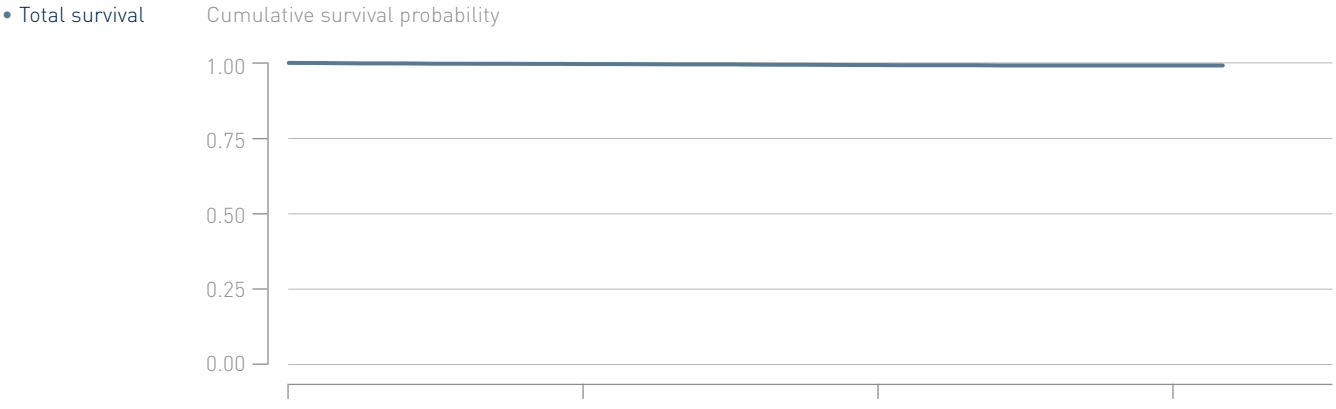

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.1 | 98.6 |
| CI [±%] | - | 0.2 | 0.2 | 0.3 |
| Sample Size | 8910 | 7945 | 5562 | 1634 |

# Plexa SD

| | |
|---|---|
| Product Versions | 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 11 000 |
| Registered U.S. Implants | 3 514 |
| Estimated Active U.S. Implants | 3 320 |
| U.S. Total Returned | 16 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 23 | 0.65% |
| Abnormal Defibrillation Impedance | 3 | 0.08% |
| Extracardiac Stimulation | 1 | 0.03% |
| Failure to Capture | 1 | 0.03% |
| Failure to Sense | 1 | 0.03% |
| Lead Dislodgement | 7 | 0.20% |
| Oversensing | 9 | 0.25% |
| Other | 1 | 0.03% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.06% |
| Conductor Fracture | 1 | 0.03% |
| Insulation Breach | 1 | 0.03% |
| **U.S. Acute Lead Observations** | 10 | 0.28% |
| Abnormal Defibrillation Impedance | 2 | 0.06% |
| Abnormal Pacing Impedance | 1 | 0.03% |
| Cardiac Perforation | 1 | 0.03% |
| Failure to Capture | 2 | 0.06% |
| Lead Dislodgement | 1 | 0.03% |
| Oversensing | 2 | 0.06% |
| Other | 1 | 0.03% |



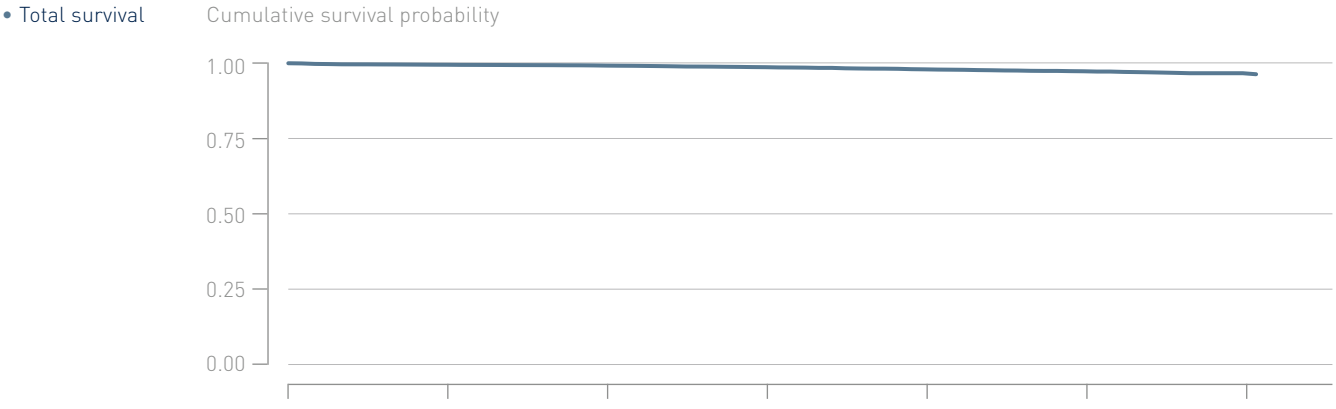

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.1 | 98.9 |
| CI [±%] | - | 0.2 | 0.4 | 0.4 |
| Sample Size | 3514 | 2569 | 1491 | 413 |

# Protego S

| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jul 2014 |
| CE Market Release | Feb 2014 |
| Worldwide Distributed Devices | 54 900 |
| Registered U.S. Implants | 8 277 |
| Estimated Active U.S. Implants | 7 240 |
| U.S. Total Returned | 113 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 148 | 1.78% |
| Abnormal Defibrillation Impedance | 5 | 0.06% |
| Abnormal Pacing Impedance | 8 | 0.10% |
| Cardiac Perforation | 1 | 0.01% |
| Conductor Fracture | 14 | 0.17% |
| Extracardiac Stimulation | 1 | 0.01% |
| Failure to Capture | 19 | 0.23% |
| Failure to Sense | 4 | 0.05% |
| Insulation Breach | 3 | 0.04% |
| Lead Dislodgement | 24 | 0.29% |
| Oversensing | 64 | 0.77% |
| Other | 5 | 0.06% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 43 | 0.52% |
| Conductor Fracture | 7 | 0.08% |
| Insulation Breach | 35 | 0.42% |
| Other | 1 | 0.01% |
| **U.S. Acute Lead Observations** | 28 | 0.34% |
| Cardiac Perforation | 2 | 0.02% |
| Extracardiac Stimulation | 1 | 0.01% |
| Failure to Capture | 3 | 0.04% |
| Lead Dislodgement | 13 | 0.16% |
| Other | 9 | 0.11% |



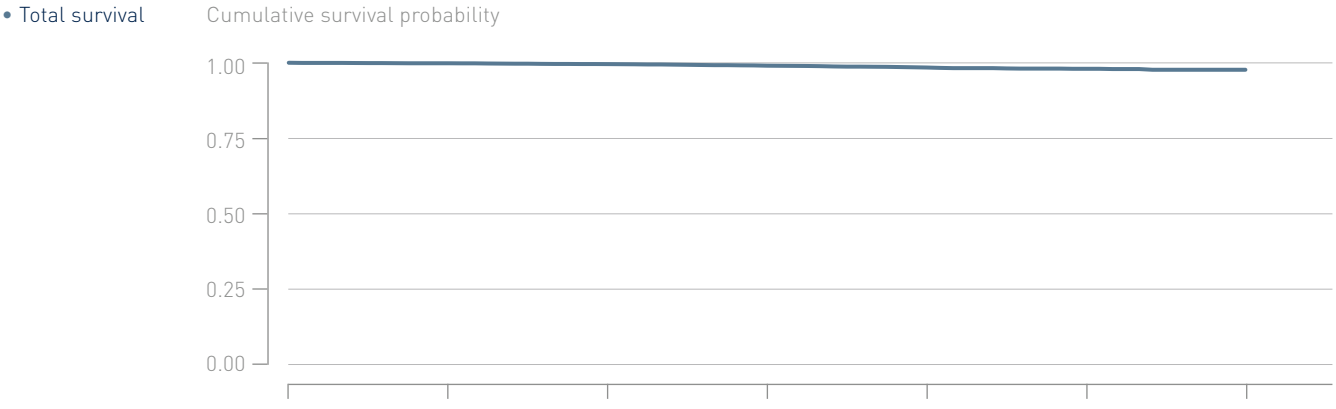

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.2 | 98.6 | 97.8 | 97.2 | 96.5 |
| CI [±%] | - | 0.2 | 0.2 | 0.3 | 0.3 | 0.4 | 0.6 |
| Sample Size | 8277 | 7789 | 7568 | 7060 | 5095 | 2121 | 337 |

# Protego SD

| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jul 2014 |
| CE Market Release | May 2013 |
| Worldwide Distributed Devices | 18 400 |
| Registered U.S. Implants | 3 410 |
| Estimated Active U.S. Implants | 3 030 |
| U.S. Total Returned | 38 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 55 | 1.60% |
| Abnormal Defibrillation Impedance | 5 | 0.15% |
| Abnormal Pacing Impedance | 2 | 0.06% |
| Conductor Fracture | 6 | 0.17% |
| Failure to Capture | 8 | 0.23% |
| Failure to Sense | 1 | 0.03% |
| Insulation Breach | 1 | 0.03% |
| Lead Dislodgement | 4 | 0.12% |
| Oversensing | 26 | 0.76% |
| Other | 2 | 0.06% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 9 | 0.26% |
| Insulation Breach | 9 | 0.26% |
| **U.S. Acute Lead Observations** | 3 | 0.09% |
| Lead Dislodgement | 2 | 0.06% |
| Other | 1 | 0.03% |



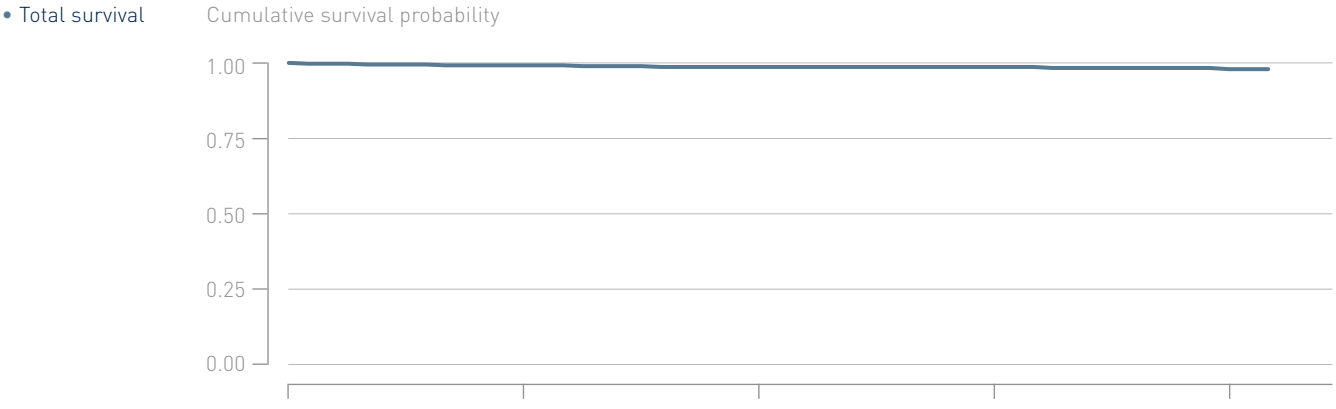

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.8 | 99.5 | 98.9 | 98.3 | 97.8 | 97.4 |
| CI [±%] | - | 0.1 | 0.2 | 0.4 | 0.5 | 0.6 | 0.7 |
| Sample Size | 3410 | 3234 | 3157 | 3018 | 2301 | 1182 | 231 |

# Protego TD

| | |
|---|---|
| Product Versions | 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, passvie fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jul 2014 |
| CE Market Release | Jan 2014 |
| Worldwide Distributed Devices | 1 450 |
| Registered U.S. Implants | 349 |
| Estimated Active U.S. Implants | 307 |
| U.S. Total Returned | 4 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 9 | 2.56% |
| Conductor Fracture | 4 | 1.14% |
| Failure to Capture | 2 | 0.57% |
| Failure to Sense | 1 | 0.28% |
| Insulation Breach | 1 | 0.28% |
| Other | 1 | 0.28% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 0 | 0.00% |



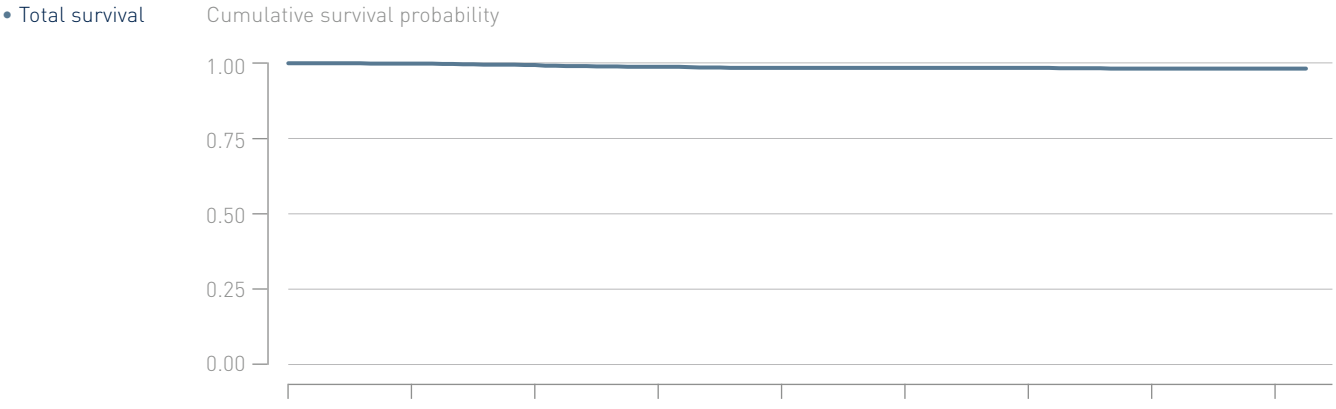

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.1 | 98.5 | 98.5 | 97.7 |
| CI [±%] | - | 1 | 1.3 | 1.3 | 1.7 |
| Sample Size | 349 | 331 | 316 | 276 | 230 |

# Vigila 2CR

| | |
|---|---|
| Product Versions | 60/16, 65/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2012 |
| CE Market Release | Oct 2011 |
| Worldwide Distributed Devices | 2 730 |
| Registered U.S. Implants | 795 |
| Estimated Active U.S. Implants | 724 |
| U.S. Total Returned | 12 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 11 | 1.38% |
| Abnormal Pacing Impedance | 1 | 0.13% |
| Conductor Fracture | 1 | 0.13% |
| Lead Dislodgement | 3 | 0.38% |
| Oversensing | 6 | 0.75% |

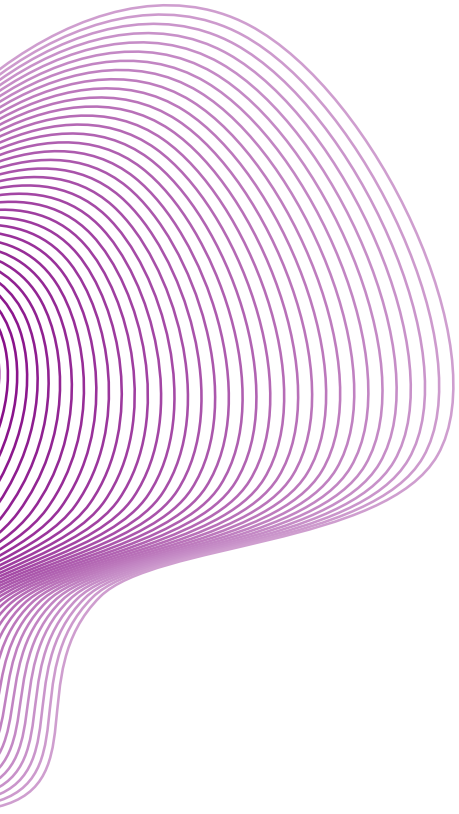
| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.50% |
| Insulation Breach | 4 | 0.50% |
| **U.S. Acute Lead Observations** | 0 | 0.00% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.9 | 99.3 | 98.7 | 98.3 | 98.3 | 98.3 | 98.0 | 98.0 |
| CI [±%] | - | 0.3 | 0.6 | 0.8 | 0.9 | 0.9 | 0.9 | 1 | 1 |
| Sample Size | 795 | 764 | 747 | 733 | 726 | 726 | 726 | 647 | 318 |

# Performance of BIOTRONIK Leads
## Based on Returned Products and Complaint Data

6.1 Pacing Leads – Postmarket Data
6.2 ICD Leads – Postmarket Data
**6.3 CRT Leads – Postmarket Data**

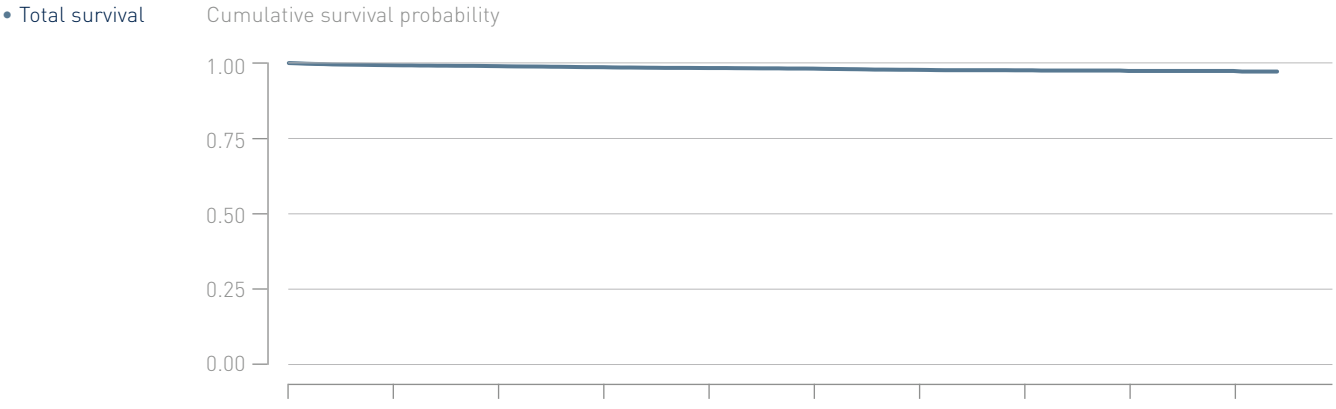


# Corox OTW-L BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | dual-curve fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Dec 2009 |
| Worldwide Distributed Devices | 32 000 |
| Registered U.S. Implants | 6 253 |
| Estimated Active U.S. Implants | 4 970 |
| U.S. Total Returned | 79 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 133 | 2.11% |
| Abnormal Pacing Impedance | 4 | 0.06% |
| Conductor Fracture | 5 | 0.08% |
| Extracardiac Stimulation | 20 | 0.32% |
| Failure to Capture | 55 | 0.87% |
| Failure to Sense | 2 | 0.03% |
| Insulation Breach | 2 | 0.03% |
| Lead Dislodgement | 36 | 0.57% |
| Oversensing | 2 | 0.03% |
| Other | 7 | 0.11% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 4 | 0.06% |
| Conductor Fracture | 3 | 0.05% |
| Insulation Breach | 1 | 0.02% |
| **U.S. Acute Lead Observations** | 21 | 0.33% |
| Extracardiac Stimulation | 6 | 0.10% |
| Failure to Capture | 2 | 0.03% |
| Lead Dislodgement | 10 | 0.16% |
| Other | 3 | 0.05% |



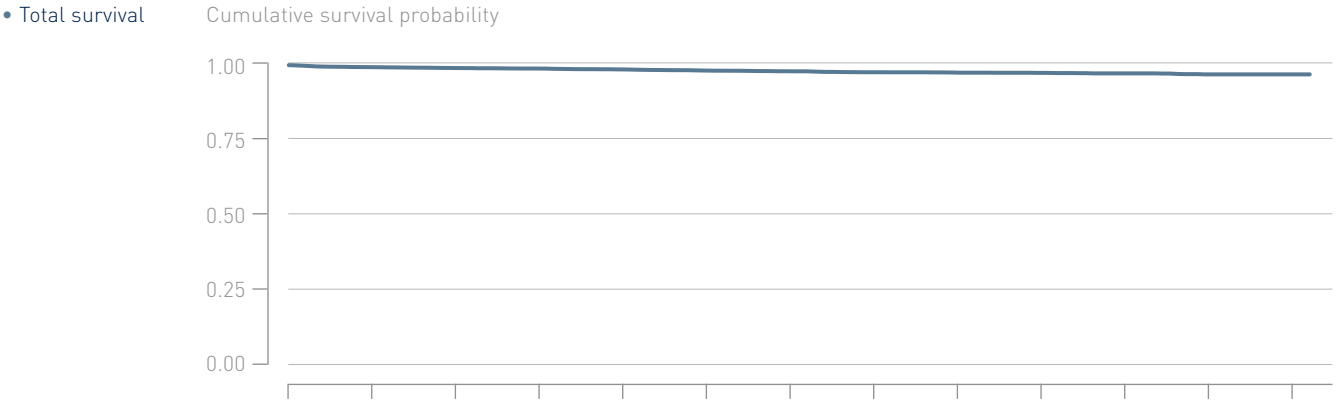

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.2 | 98.9 | 98.5 | 98.2 | 98.0 | 97.6 | 97.4 | 97.2 | 97.2 |
| CI [±%] | - | 0.2 | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 |
| Sample Size | 6253 | 5697 | 5448 | 5250 | 4798 | 4077 | 3235 | 2370 | 1370 | 579 |

# Corox OTW-S BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | thread fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | May 2008 |
| CE Market Release | Dec 2006 |
| Worldwide Distributed Devices | 26 400 |
| Registered U.S. Implants | 8 158 |
| Estimated Active U.S. Implants | 5 710 |
| U.S. Total Returned | 131 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 166 | 2.02% |
| Abnormal Pacing Impedance | 8 | 0.10% |
| Conductor Fracture | 5 | 0.06% |
| Extracardiac Stimulation | 15 | 0.18% |
| Failure to Capture | 51 | 0.62% |
| Failure to Sense | 1 | 0.01% |
| Insulation Breach | 4 | 0.05% |
| Lead Dislodgement | 59 | 0.72% |
| Oversensing | 5 | 0.06% |
| Other | 18 | 0.22% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 13 | 0.16% |
| Conductor Fracture | 8 | 0.10% |
| Insulation Breach | 4 | 0.05% |
| Other | 1 | 0.01% |
| **U.S. Acute Lead Observations** | 33 | 0.40% |
| Cardiac Perforation | 1 | 0.01% |
| Extracardiac Stimulation | 5 | 0.06% |
| Failure to Capture | 6 | 0.07% |
| Lead Dislodgement | 20 | 0.24% |
| Other | 1 | 0.01% |



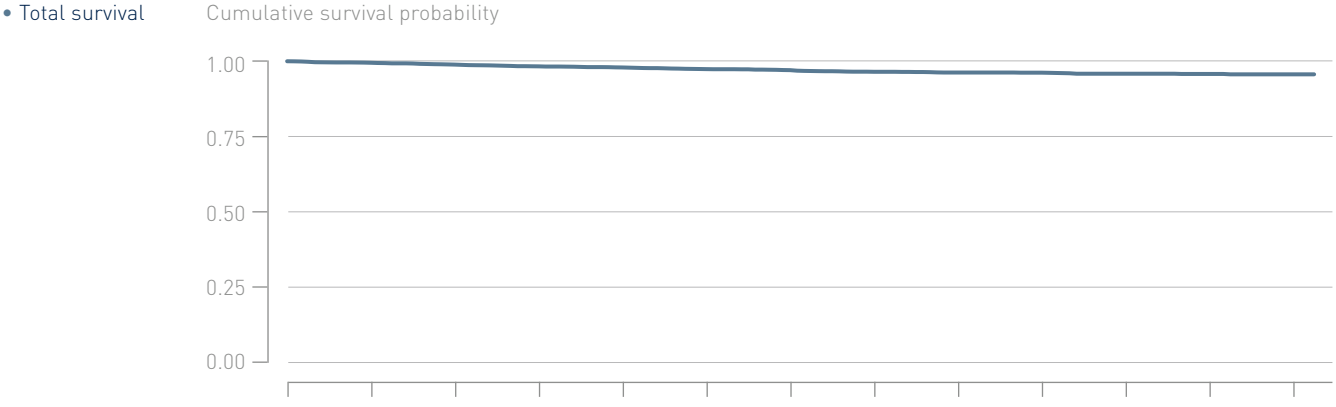

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.3 | 99.0 | 98.8 | 98.5 | 98.1 | 97.8 | 97.5 | 97.3 | 97.2 | 97.1 | 96.7 | 96.7 |
| CI [±%] | - | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 |
| Sample Size | 8158 | 7170 | 6767 | 6434 | 6007 | 5388 | 4746 | 4082 | 3420 | 2820 | 2105 | 1022 | 327 |

# Corox OTW BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | helix fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | May 2008 |
| CE Market Release | Dec 2006 |
| Worldwide Distributed Devices | 28 700 |
| Registered U.S. Implants | 4 116 |
| Estimated Active U.S. Implants | 2 670 |
| U.S. Total Returned | 78 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 116 | 2.81% |
| Abnormal Pacing Impedance | 7 | 0.17% |
| Conductor Fracture | 3 | 0.07% |
| Extracardiac Stimulation | 8 | 0.19% |
| Failure to Capture | 42 | 1.02% |
| Insulation Breach | 3 | 0.07% |
| Lead Dislodgement | 38 | 0.92% |
| Oversensing | 4 | 0.10% |
| Other | 11 | 0.27% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 16 | 0.39% |
| Conductor Fracture | 15 | 0.36% |
| Insulation Breach | 1 | 0.02% |
| **U.S. Acute Lead Observations** | 9 | 0.22% |
| Lead Dislodgement | 7 | 0.17% |
| Other | 2 | 0.05% |



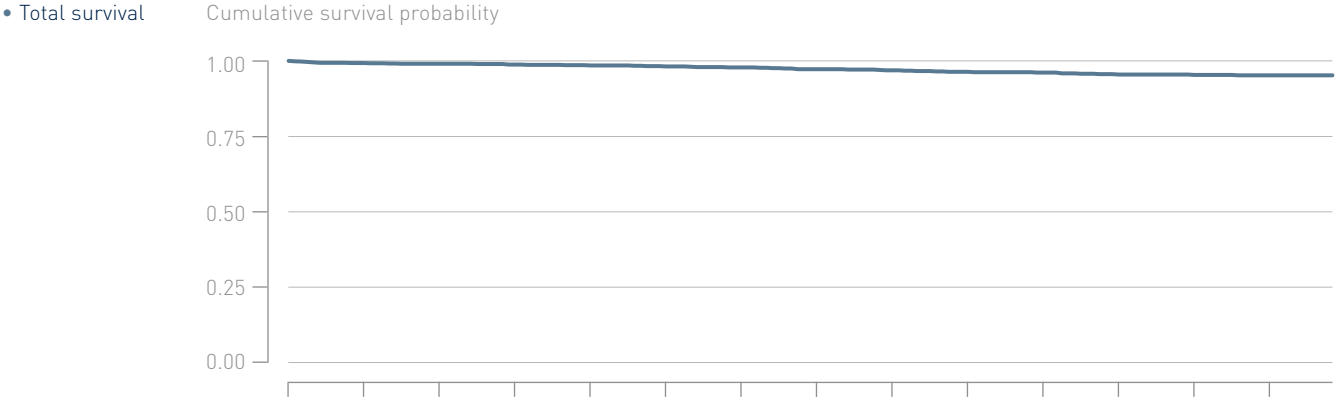

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 98.8 | 98.2 | 97.8 | 97.3 | 96.9 | 96.3 | 96.1 | 96.0 | 95.6 | 95.6 | 95.4 |
| CI [±%] | - | 0.2 | 0.4 | 0.4 | 0.5 | 0.6 | 0.6 | 0.7 | 0.7 | 0.7 | 0.7 | 0.8 | 0.8 |
| Sample Size | 4116 | 3556 | 3311 | 3117 | 2967 | 2784 | 2601 | 2401 | 2138 | 1897 | 1556 | 881 | 316 |

# Corox OTW UP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | helix fixation |
| Polarity | unipolar |
| Steroid | yes |
| U.S. Market Release | Aug 2006 |
| CE Market Release | Apr 2004 |
| Worldwide Distributed Devices | 10 400 |
| Registered U.S. Implants | 1 423 |
| Estimated Active U.S. Implants | 696 |
| U.S. Total Returned | 26 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 44 | 3.09% |
| Abnormal Pacing Impedance | 1 | 0.07% |
| Conductor Fracture | 2 | 0.14% |
| Extracardiac Stimulation | 7 | 0.49% |
| Failure to Capture | 16 | 1.12% |
| Insulation Breach | 2 | 0.14% |
| Lead Dislodgement | 10 | 0.70% |
| Oversensing | 1 | 0.07% |
| Other | 5 | 0.35% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.14% |
| Insulation Breach | 2 | 0.14% |
| **U.S. Acute Lead Observations** | 4 | 0.28% |
| Failure to Capture | 3 | 0.21% |
| Lead Dislodgement | 1 | 0.07% |



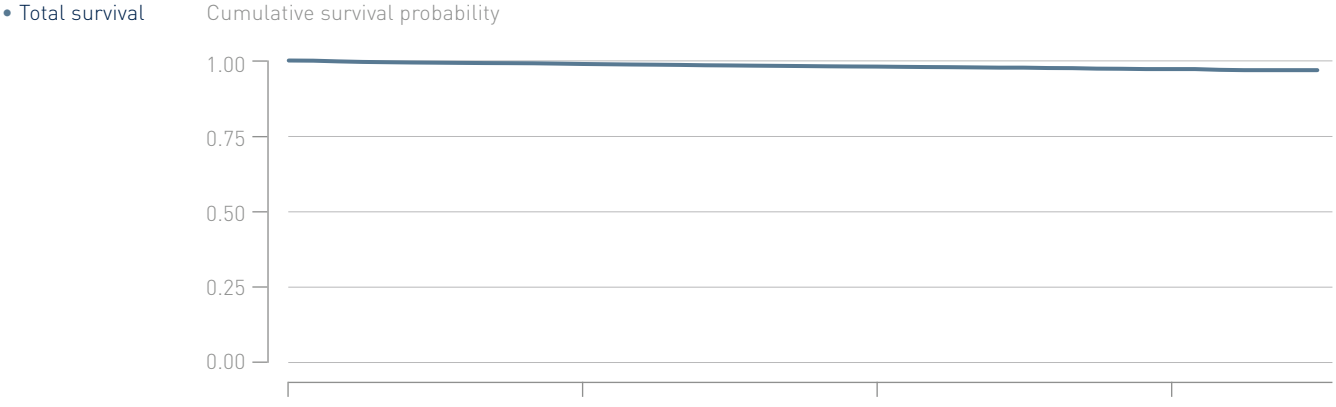

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.3 | 99.0 | 98.7 | 98.4 | 98.1 | 97.7 | 97.1 | 96.7 | 96.2 | 95.9 | 95.3 | 95.1 | 95.0 |
| CI [±%] | - | 0.5 | 0.5 | 0.6 | 0.7 | 0.8 | 0.9 | 1 | 1.1 | 1.2 | 1.3 | 1.4 | 1.4 | 1.5 |
| Sample Size | 1423 | 1237 | 1121 | 1016 | 932 | 865 | 810 | 776 | 746 | 729 | 712 | 704 | 692 | 528 |

# Sentus OTW QP L

| | |
|---|---|
| Product Versions | 75, 75/49, 85, 85/49 |
| Lead Type | dual-curve fixation |
| Polarity | quadripolar |
| Steroid | yes |
| U.S. Market Release | May 2017 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 87 000 |
| Registered U.S. Implants | 12 508 |
| Estimated Active U.S. Implants | 11 200 |
| U.S. Total Returned | 125 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 189 | 1.49% |
| Abnormal Pacing Impedance | 26 | 0.20% |
| Conductor Fracture | 2 | 0.02% |
| Extracardiac Stimulation | 12 | 0.09% |
| Failure to Capture | 43 | 0.34% |
| Failure to Sense | 2 | 0.02% |
| Lead Dislodgement | 77 | 0.61% |
| Oversensing | 19 | 0.15% |
| Other | 8 | 0.06% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 30 | 0.24% |
| Conductor Fracture | 29 | 0.23% |
| Other | 1 | 0.01% |
| | | |
| **U.S. Acute Lead Observations** | 43 | 0.34% |
| Abnormal Pacing Impedance | 1 | 0.01% |
| Conductor Fracture | 1 | 0.01% |
| Extracardiac Stimulation | 7 | 0.06% |
| Failure to Capture | 7 | 0.06% |
| Lead Dislodgement | 24 | 0.19% |
| Oversensing | 2 | 0.02% |
| Other | 1 | 0.01% |



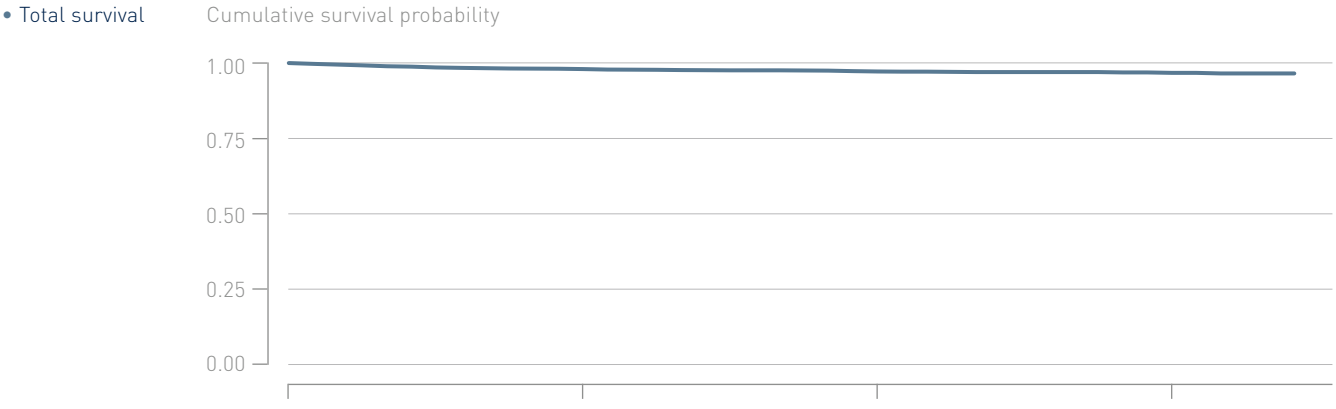

| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 98.8 | 97.9 | 97.0 |
| CI [±%] | - | 0.2 | 0.3 | 0.5 |
| Sample Size | 12508 | 8354 | 4840 | 1652 |

# Sentus OTW QP S

| | |
|---|---|
| Product Versions | 75, 75/49, 85, 85/49 |
| Lead Type | thread fixation |
| Polarity | quadripolar |
| Steroid | yes |
| U.S. Market Release | May 2017 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 19 600 |
| Registered U.S. Implants | 3 556 |
| Estimated Active U.S. Implants | 2 870 |
| U.S. Total Returned | 84 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 80 | 2.20% |
| Abnormal Pacing Impedance | 5 | 0.14% |
| Conductor Fracture | 1 | 0.03% |
| Extracardiac Stimulation | 4 | 0.11% |
| Failure to Capture | 17 | 0.47% |
| Lead Dislodgement | 43 | 1.18% |
| Oversensing | 9 | 0.25% |
| Other | 1 | 0.03% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 5 | 0.14% |
| Conductor Fracture | 5 | 0.14% |
| **U.S. Acute Lead Observations** | 66 | 1.81% |
| Abnormal Pacing Impedance | 1 | 0.03% |
| Extracardiac Stimulation | 4 | 0.11% |
| Failure to Capture | 8 | 0.22% |
| Failure to Sense | 1 | 0.03% |
| Lead Dislodgement | 49 | 1.35% |
| Oversensing | 3 | 0.08% |




| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 97.9 | 97.0 | 96.5 |
| CI [±%] | - | 0.5 | 0.7 | 0.8 |
| Sample Size | 3556 | 2380 | 1624 | 658 |

# Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction
7.2 BIOTRONIK's Clinical Studies
7.3 Lead Complications
7.4 Lead Product Performance Graphs and Data

# 7. Methodology for Lead Survival Estimates Based on Clinical Studies

## 7.1 Introduction

All leads and lead segments returned to BIOTRONIK are thoroughly analyzed to determine whether or not they meet BIOTRONIK's long term quality standards.

Although analysis of returned product is an excellent method for gaining insight into lead failure mechanisms, this data relies on the return of explanted leads. For the majority of complications the lead is not received for analysis as challenging clinical environments may not allow for the return, e.g. the extraction of an implanted lead may not be possible.

BIOTRONIK includes all reported chronic complications in the calculation of the survival estimates as described in chapter 6, i.e. reports with returned and without returned products.

However, BIOTRONIK can only report events in the survival estimates if those events were reported to BIOTRONIK. In order to eliminate possible biased survival estimates due to underreporting, BIOTRONIK performs clinical surveillance studies with active follow-up's under FDA guidance yielding the most reliable lead performance data.

In the following chapter BIOTRONIK shows – in addition to the survival data based on returned product analysis and chronic complication information – the lead performance data from clinical trials. These studies are designed to record clinical observations representative of the total clinical experience.

## 7.2 BIOTRONIK's Clinical Studies

### 7.2.1 GALAXY and CELESTIAL

BIOTRONIK's GALAXY and CELESTIAL Registries are prospective, non-randomized, observational studies. The key purpose of these registries is to confirm the long-term safety and reliability of BIOTRONIK leads as used in conjunction with a BIOTRONIK ICD (GALAXY) or CRT (CELESTIAL) system. All devices in the registries are legally marketed and available to physicians according to approved FDA indications for use. GALAXY and CELESTIAL Registries are registered on clinicaltrials.gov under NCT00836589 and NCT00810264 respectively.

The evaluation of safety for GALAXY is based on the analysis of BIOTRONIK Linox ICD lead-related adverse events. The evaluation of safety for CELESTIAL is based on the analysis of BIOTRONIK Corox LV pacing lead-related adverse events. However, many CELESTIAL patients also have a Linox ICD lead implanted and the Linox clinical studies data in this report represents combined data from the GALAXY and CELESTIAL registries. Both registries are designed to continue for a 5 year follow-up duration per patient. The GALAXY Registry was completed in December 2016, while CELESTIAL completed in November 2018. The lead-related complication free survival probabilities provided for Corox LV and Linox ICD leads within chapter 8 utilize all data collected through registry closure. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the

range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits per their institutional standard of care 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 of once every six months follow-up requirement.

During each follow up at a study center the following steps are required during the follow-up visit:

- Interrogate programmed parameters
- Determine lead electrical parameters
- Evaluate device diagnostics and programmed parameters to ensure the device is providing appropriate therapy
- Determine if there are any reportable lead-related, pulse generator-related or implant procedure-related adverse events. If there are, complete an adverse event electronic case report form (eCRF)
- Complete all appropriate eCRFs

This active surveillance model ensures a robust dataset for effectively monitoring product performance.

**Patient Enrollment Criteria**
To support the objectives of these registries, participants are required to meet the following inclusion criteria prior to enrollment:

- Successfully implanted BIOTRONIK ICD (GALAXY) or BIOTRONIK CRT (CELESTIAL) system, including the study lead
- Able to understand the nature of the registry and give informed consent
- Available for follow-up visits on a regular basis at the study site
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures, regardless of the incidence rates, are investigated

## 7.2.2 SIELLO Clinical Study

BIOTRONIK's SIELLO Clinical Study is a prospective, non-randomized, combined Pre-Market Study and Post-Approval Registry designed to demonstrate the safety and effectiveness of the Siello pacing lead as used in conjunction with any market-released BIOTRONIK pacemaker device. The SIELLO Clinical Study is registered on clinicaltrials.gov under NCT01791127.

For the Pre-Market Study, the evaluation of safety is based on the analysis of Siello lead-related adverse events through a follow-up time of 12 months post-implant, while the evaluation of effectiveness is based on analysis of the success rate of the implanted system including one or two Siello leads to sense and deliver pacing at 12 months post-implant.

For the Post-Approval Registry, the evaluation of long-term safety is based on the analysis of Siello lead-related adverse events through a follow-up time of 5 years post-implant. In April 2019, the Siello Post-Approval Registry was converted to utilize real-world data sources as part of the EP PASSION Project (as described in Section 9). The lead-related complication free survival probabilities provided for the Siello lead in Section 8 includes all data collected through study transition. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, with required follow-ups at 3 and 6 months post-implant and every 6 months thereafter.

During each study follow-up visit the following steps are required:

- Interrogate programmed parameters
- Record electrical parameters of the implanted leads. Perform all pacing threshold measurements at 0.4 ms or 0.5 ms pulse width when feasible
- Evaluate device diagnostics, electrical parameters and programmed parameters to ensure the device is correctly pacing and sensing
- Determine if there are any lead-related, pulse generator-related or procedure related adverse events. If any are recorded, complete the Adverse Event eCRF
- Complete all appropriate eCRFs

This active surveillance model ensures a robust dataset for effectively monitoring product performance.

**Patient Enrollment Criteria**
To support the objectives of the study, participants are required to meet the following inclusion criteria prior to enrollment:

- Candidate for de novo implantation of a market-released BIOTRONIK pacemaker system, including one or two Siello leads. Candidate meets recommendation for pacemaker system implant put forth by guidelines of relevant professional societies

- Able to understand the nature of the study and provide informed consent
- Available for follow-up visits on a regular basis at the investigational site for the expected 5 years of follow-up
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures, regardless of the incidence rates, are investigated.

### 7.2.3 QP ExCELs

BIOTRONIK's QP ExCELs Clinical Study is a combined Pre-Market and Post-Approval, non-randomized, multi-center registry designed to confirm the safety and efficacy of BIOTRONIK's Sentus QP leads in a clinical investigation to support regulatory approval as well as a long-term post-approval evaluation of the devices in the United States. The QP ExCELs Clinical Study is registered on clinicaltrials.gov under NCT02290028.

For the Post-Approval Study, the evaluation of safety will be based on the analysis of Sentus QP lead-related adverse events through a follow-up time of 5 years post-implant. In January 2020, the QP ExCELs Clinical Study was converted to utilize real-world data sources as part of the EP PASSION Project (as described in Section 9). The lead-related complication free survival probabilities provided for the Sentus QP lead in Section 8 includes all data collected through study transition. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits per their institutional standard of care until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, which required follow-ups at discharge/wound check, 3 and 6 months post-implant, and every 6 months thereafter.

**Patient Enrollment Criteria**
To support the objectives of the study, participants are required to meet the following inclusion criteria prior to enrollment:

- Standard CRT-D indication according to clinical routine
- De novo implantation or upgrade from existing ICD or pacemaker implant (with no prior attempt at LV lead placement) utilizing a BIOTRONIK CRT-D system with IS4 LV port and Sentus QP LV lead
- Patient is able and willing to complete all routine study visits at the investigational site through 5 years of follow-up
- Patient is able to understand the nature of the clinical investigation and provide written informed consent
- Patient accepts Home Monitoring concept
- Age greater than or equal to 18 years

Each site must inform BIOTRONIK whenever a lead complication has occurred or when a patient is no longer participating.

All leads that experience a complication and are subsequently explanted and returned to BIOTRONIK undergo root-cause analyses. Product performance is analyzed as a function of time using the survival analysis method. Root causes for any failures, regardless of the incidence rates, are investigated.

## 7.3 Lead Complications

The data presented characterizes chronic lead performance by estimating lead-related complication free survival probabilities. Following industry practice, 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.

### 7.3.1 GALAXY and CELESTIAL

All reported lead-related adverse events within the GALAXY and CELESTIAL Registries are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation, is classified with at least one of the following event classifications and at least one of the following clinical actions is made. Any Clinical Event without a related Clinical Action is not considered a Qualifying Complication. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

**Event Classifications**
- Failure to capture
- Failure to sense/undersensing
- Oversensing
- 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 25 – 150 ohms)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation

- Cardiac perforation
- Lead dislodgement

**Clinical Actions**
- Lead surgically abandoned/capped
- Lead electrically abandoned
- Lead explanted
- Lead replaced
- Lead conductor taken out of service
- Lead use continued based on medical judgment despite a known clinical performance issue
- Other lead-related surgery

### 7.3.2 SIELLO

All reported lead-related adverse events within the SIELLO Clinical Study are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation and is classified with at least one of the following event classifications. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

**Event Classifications**
- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 – 2,000 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

### 7.3.3 QP ExCELs

All reported lead-related adverse events within the QP ExCELs registry are classified by the reporting investigator and are adjudicated by an independent event adjudication committee. A lead related complication is considered to have occurred if a clinical observation happens after successful implantation and is classified with at least one of the following event classifications. Events with an onset date 30 days or less after the implant are acute observations and are listed separately.

**Event Classifications**
- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 – 2,000 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

## 7.4 Lead Product Performance Graphs and Data

The clinical data presented on the following page is intended to show the long term clinical performance of leads based on clinical studies. The same analysis methods as described in chapter 5 are applied.

**Returned Product Analysis Results**
Although the returned product analysis data is not used to generate the survival estimates for the clinical data, it provides valuable insight into the causes of lead malfunction. Following the same approach as for complaint data, a malfunction is reported as described in section 5.3 of this report.

# Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads
8.2 Performance of ICD Leads
8.3 Performance of CRT Leads

# Performance of BIOTRONIK Leads Based on Clinical Study Data

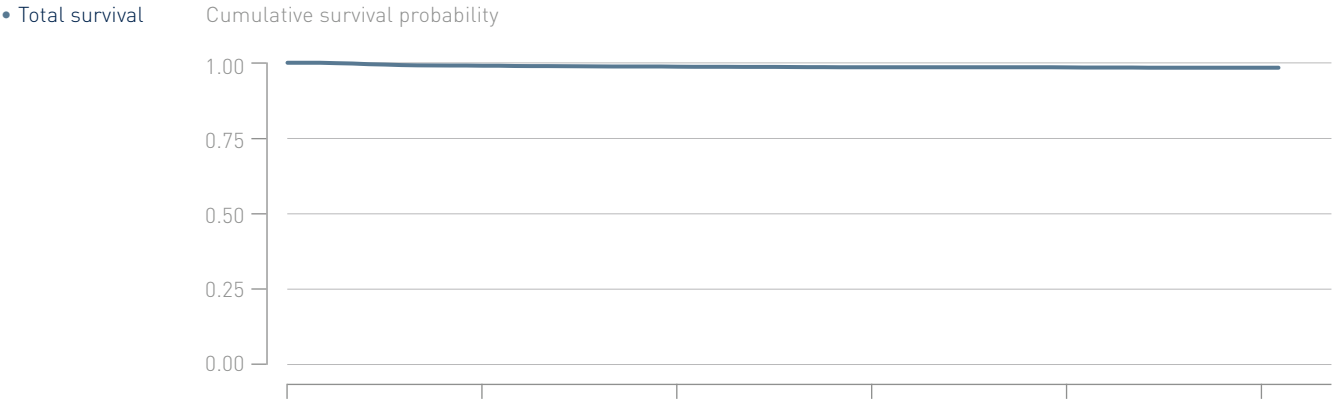
**8.1 Performance of Pacing Leads**
8.2 Performance of ICD Leads
8.3 Performance of CRT Leads

# Siello S / Solia S

| | |
|---|---|
| Product Versions | 45, 53, 60 |
| Lead Type | straight, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jun 2016 |
| CE Market Release | Jul 2009 |
| Worldwide Distributed Devices | 1 616 000 |
| Registered U.S. Implants | 3 245 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 54 | 1.66% |
| Abnormal Pacing Impedance | 4 | 0.12% |
| Cardiac Perforation | 3 | 0.09% |
| Conductor Fracture | 2 | 0.06% |
| Failure to Capture | 23 | 0.71% |
| Failure to Sense (undersensing) | 11 | 0.34% |
| Lead Dislodgement | 9 | 0.28% |
| Oversensing | 1 | 0.03% |
| Other | 1 | 0.03% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 3 | 0.09% |
| Conductor Fracture | 1 | 0.03% |
| Insulation Breach | 1 | 0.03% |
| Other | 1 | 0.03% |
| **U.S. Acute Lead Observations** | 26 | 0.80% |
| Cardiac Perforation | 8 | 0.25% |
| Extracardiac Stimulation | 2 | 0.06% |
| Failure to Capture | 6 | 0.18% |
| Failure to Sense (undersensing) | 5 | 0.15% |
| Lead Dislodgement | 5 | 0.15% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 98.9 | 98.5 | 98.3 | 98.2 | 98.1 |
| CI [±%] | – | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 |
| Sample Size | 3245 | 2793 | 2479 | 2200 | 1769 | 293 |

# Performance of BIOTRONIK Leads Based on Clinical Study Data

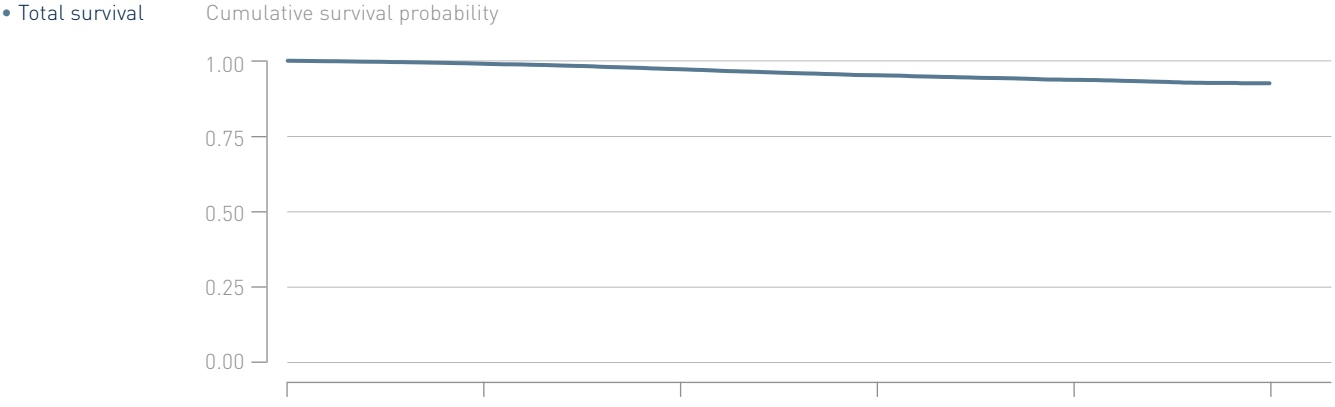
8.1 Performance of Pacing Leads
**8.2 Performance of ICD Leads**
8.3 Performance of CRT Leads

# Linox SD

| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Apr 2006 |
| CE Market Release | Aug 2006 |
| Worldwide Distributed Devices | 55 100 |
| Registered U.S. Implants | 2 272 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 68 | 2.99% |
| Abnormal Defibrillation Impedance | 4 | 0.18% |
| Abnormal Pacing Impedance | 10 | 0.44% |
| Cardiac Perforation | 1 | 0.04% |
| Conductor Fracture | 10 | 0.44% |
| Failure to Capture | 7 | 0.31% |
| Failure to Sense | 3 | 0.13% |
| Insulation Breach | 13 | 0.57% |
| Lead Dislodgement | 3 | 0.13% |
| Oversensing | 17 | 0.75% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 24 | 1.06% |
| Conductor Fracture | 3 | 0.13% |
| Insulation Breach | 21 | 0.92% |
| | | |
| **U.S. Acute Lead Observations** | 8 | 0.35% |
| Cardiac Perforation | 4 | 0.18% |
| Conductor Fracture | 1 | 0.04% |
| Failure to Capture | 1 | 0.04% |
| Lead Dislodgement | 1 | 0.04% |
| Other | 1 | 0.04% |



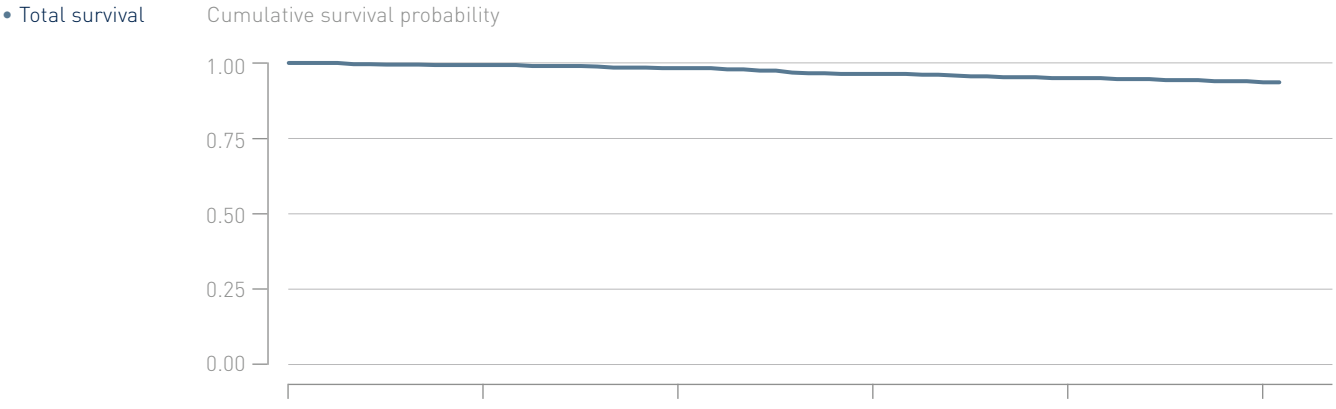

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.6 | 98.8 | 98.0 | 96.7 | 94.9 |
| CI [±%] | – | 0.3 | 0.5 | 0.7 | 0.9 | 1.3 |
| Sample Size | 2272 | 1937 | 1618 | 1302 | 1014 | 392 |

# Linox$^{smart}$ SD

| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 55 700 |
| Registered U.S. Implants | 736 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 29 | 3.94% |
| Abnormal Defibrillation Impedance | 2 | 0.27% |
| Abnormal Pacing Impedance | 2 | 0.27% |
| Conductor Fracture | 3 | 0.41% |
| Failure to Capture | 3 | 0.41% |
| Insulation Breach | 4 | 0.54% |
| Lead Dislodgement | 6 | 0.82% |
| Oversensing | 9 | 1.22% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 7 | 0.95% |
| Insulation Breach | 7 | 0.95% |
| **U.S. Acute Lead Observations** | 2 | 0.27% |
| Lead Dislodgement | 2 | 0.27% |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.3 | 98.2 | 96.2 | 94.8 | 93.3 |
| CI [±%] | – | 0.7 | 1.1 | 1.7 | 2.1 | 2.5 |
| Sample Size | 736 | 607 | 493 | 373 | 287 | 118 |

# Performance of BIOTRONIK Leads Based on Clinical Study Data

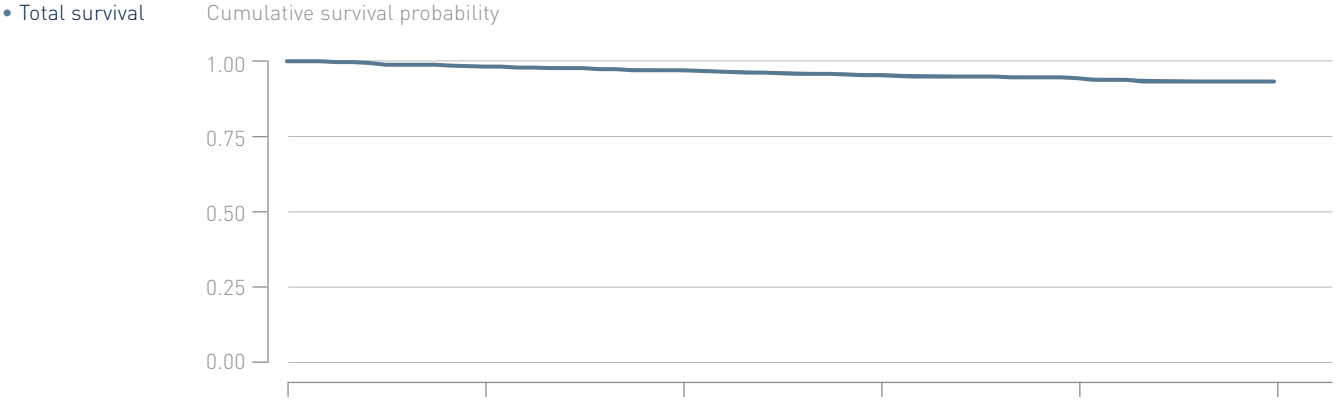
8.1 Pacing Leads Performance
8.2 ICD Leads Performance
**8.3 CRT Leads Performance**

# Corox OTW BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | helix fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | May 2008 |
| CE Market Release | Dec 2006 |
| Worldwide Distributed Devices | 28 700 |
| Leads registered in study | 696 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 35 | 5.03% |
| Abnormal Pacing Impedance | 6 | 0.86% |
| Conductor Fracture | 5 | 0.72% |
| Extracardiac Stimulation | 3 | 0.43% |
| Failure to Capture | 5 | 0.72% |
| Lead Dislodgement | 16 | 2.30% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 6 | 0.86% |
| Conductor Fracture | 6 | 0.86% |
| **U.S. Acute Lead Observations** | 4 | 0.57% |
| Extracardiac Stimulation | 1 | 0.14% |
| Lead Dislodgement | 3 | 0.43% |



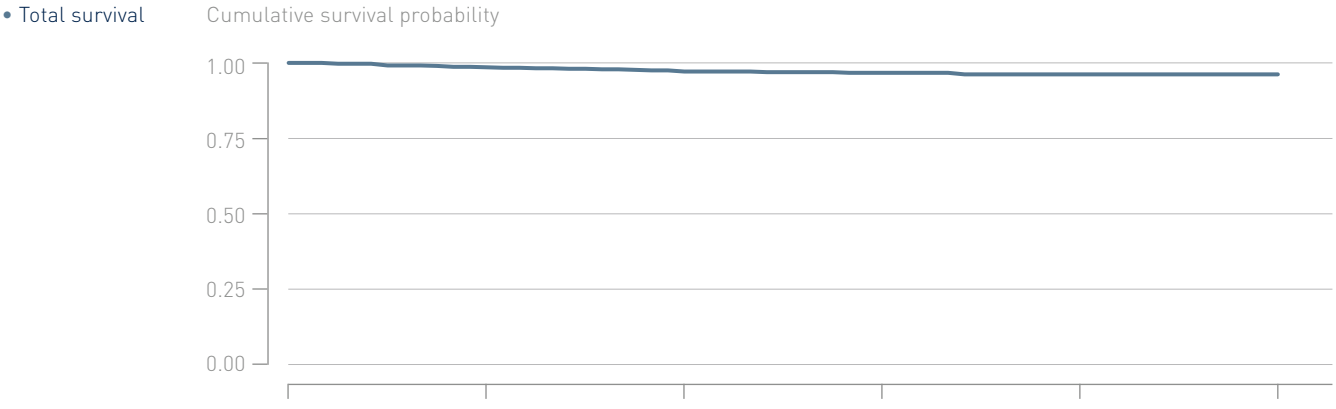

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 98.2 | 96.9 | 95.2 | 94.2 | 93.0 |
| CI [±%] | - | 1.1 | 1.4 | 1.8 | 2.1 | 2.3 |
| Sample Size | 696 | 589 | 489 | 407 | 329 | 135 |

# Corox OTW-L BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | dual-curve fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Dec 2009 |
| Worldwide Distributed Devices | 32000 |
| Leads registered in study | 699 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 22 | 3.15% |
| Extracardiac Stimulation | 4 | 0.57% |
| Failure to Capture | 8 | 1.14% |
| Lead Dislodgement | 10 | 1.43% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 0 | 0.00% |
| **U.S. Acute Lead Observations** | 4 | 0.57% |
| Extracardiac Stimulation | 3 | 0.43% |
| Lead Dislodgement | 1 | 0.14% |



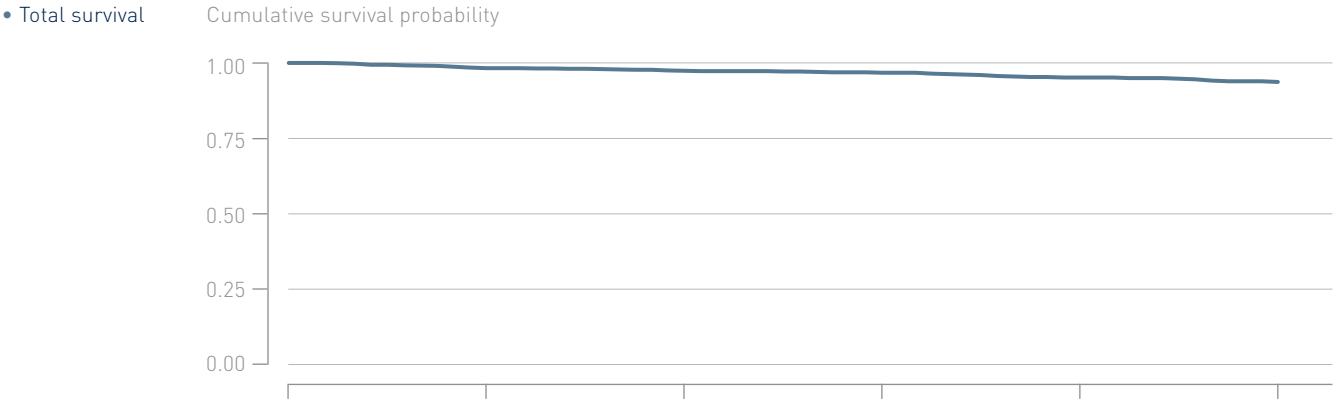

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 98.5 | 97.0 | 96.5 | 96.0 | 96.0 |
| CI [±%] | - | 1.0 | 1.4 | 1.6 | 1.7 | 1.7 |
| Sample Size | 699 | 584 | 475 | 382 | 303 | 130 |

# Corox OTW-S BP

| | |
|---|---|
| Product Versions | 75, 85 |
| Lead Type | thread fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | May 2008 |
| CE Market Release | Dec 2006 |
| Worldwide Distributed Devices | 26 400 |
| Leads registered in study | 1 141 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 49 | 4.29% |
| Abnormal Pacing Impedance | 13 | 1.14% |
| Extracardiac Stimulation | 9 | 0.79% |
| Failure to Capture | 9 | 0.79% |
| Lead Dislodgement | 18 | 1.58% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 1 | 0.09% |
| Insulation Breach | 1 | 0.09% |
| **U.S. Acute Lead Observations** | 5 | 0.44% |
| Extracardiac Stimulation | 1 | 0.09% |
| Failure to Capture | 1 | 0.09% |
| Lead Dislodgement | 3 | 0.26% |



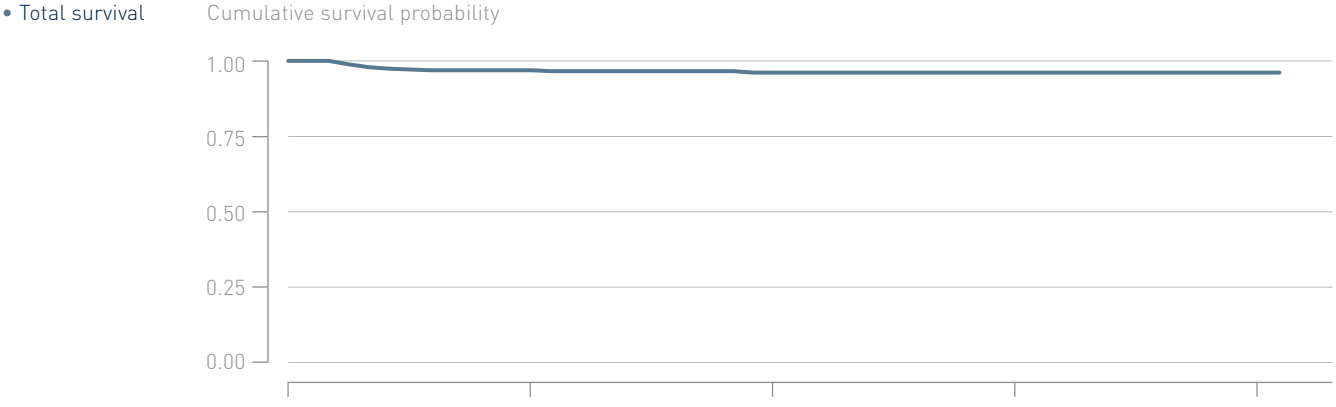

| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 98.2 | 97.3 | 96.6 | 95.0 | 93.5 |
| CI [±%] | - | 0.8 | 1.0 | 1.2 | 1.5 | 1.9 |
| Sample Size | 1141 | 963 | 813 | 648 | 505 | 192 |

# Sentus OTW QP S

| | |
|---|---|
| Product Versions | 75, 75/49, 85, 85/49 |
| Lead Type | thread fixation |
| Polarity | quadripolar |
| Steroid | yes |
| U.S. Market Release | May 2017 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 18 200 |
| Registered U.S. Implants | 436 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 15 | 3.44% |
| Conductor Fracture | 1 | 0.23% |
| Extracardiac Stimulation | 1 | 0.23% |
| Failure to Capture | 3 | 0.69% |
| Lead Dislodgement | 10 | 2.29% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 2 | 0.46% |
| Conductor Fracture | 2 | 0.46% |
| **U.S. Acute Lead Observations** | 10 | 2.29% |
| Cardiac Perforation | 1 | 0.23% |
| Failure to Capture | 1 | 0.23% |
| Lead Dislodgement | 8 | 1.83% |



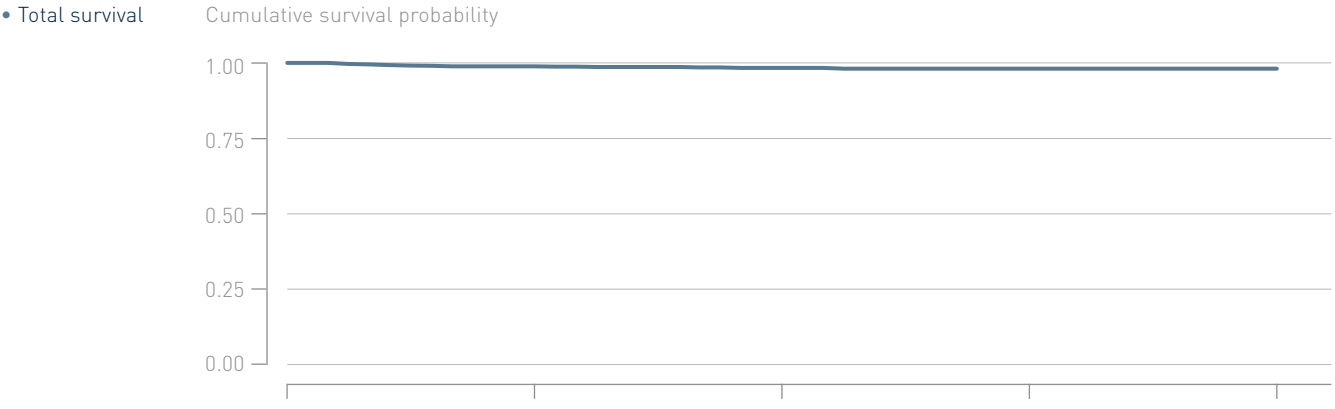

| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 96.7 | 95.9 | 95.9 | 95.9 |
| CI [±%] | - | 1.8 | 2.2 | 2.2 | 2.2 |
| Sample Size | 436 | 299 | 170 | 55 | 0 |

# Sentus OTW QP L

| | |
|---|---|
| Product Versions | 75, 75/49, 85, 85/49 |
| Lead Type | dual-curve fixation |
| Polarity | quadripolar |
| Steroid | yes |
| U.S. Market Release | May 2017 |
| CE Market Release | Dec 2014 |
| Worldwide Distributed Devices | 77 600 |
| Registered U.S. Implants | 1 308 |

| | Quantity | Rate |
|---|---|---|
| **U.S. Qualifying Complications** | 21 | 1.61% |
| Abnormal Pacing Impedance | 3 | 0.23% |
| Conductor Fracture | 1 | 0.08% |
| Extracardiac Stimulation | 2 | 0.15% |
| Failure to Capture | 4 | 0.31% |
| Lead Dislodgement | 11 | 0.84% |

| | Quantity | Rate |
|---|---|---|
| **U.S. Confirmed Malfunctions** | 8 | 0.61% |
| Conductor Fracture | 7 | 0.54% |
| | 1 | 0.08% |
| **U.S. Acute Lead Observations** | 7 | 0.54% |
| Extracardiac Stimulation | 1 | 0.08% |
| Failure to Capture | 4 | 0.31% |
| Lead Dislodgement | 2 | 0.15% |




| Years after implant | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Total [%] | 100.0 | 98.7 | 98.1 | 97.9 | 97.9 |
| CI [±%] | - | 0.7 | 0.9 | 1.1 | 1.1 |
| Sample Size | 1 308 | 863 | 418 | 138 | 0 |

9

# Methodology for Lead Survival Estimates based on Insurance Claims Data

9.1 Introduction
9.2 Claims Data Methodologies and Data Sets

# 9. Methodology for Lead Survival Estimates based on Insurance Claims Data

## 9.1 Introduction

All leads and lead segments returned to BIOTRONIK are thoroughly analyzed to determine whether or not they meet BIOTRONIK's long term quality standards. Although analysis of returned product is an excellent method for gaining insight into lead failure mechanisms, this data relies on the return of explanted leads. For the majority of complications the lead is not received for analysis as challenging clinical environments may not allow for the return, e.g. the extraction of an implanted lead may not be possible.

BIOTRONIK includes all reported chronic complications in the calculation of the survival estimates as described in chapter 5, i.e. reports with returned and without returned products. However, BIOTRONIK can only report events in the survival estimates if those events were reported to BIOTRONIK. In order to eliminate possible biased survival estimates due to underreporting, active surveillance methodologies utilizing extant real-world data sources have been developed in collaboration with FDA and other key stakeholders under the Device Pilot Project EP PASSION, established under Section 708 of the FDA Reauthorization Act of 2017 (FDARA). Identical methodology is being applied to the analysis provided in this PPR.

In the following chapter BIOTRONIK shows – in addition to the survival data based on returned product analysis and chronic complication information from customer reported complaints as well as clinical studies – the lead performance data from active surveillance of real-world data sources. These analyses are designed to record clinical observations representative of the total real-world clinical experience.

## 9.2 Claims Data Methodologies and Data Sets

To perform real-world analysis, insurance claims data obtained via the Centers for Medicare and Medicaid Services (CMS), as well as data from BIOTRONIK's device tracking database, are utilized to identify lead-related complications. As the source of the claims data is CMS, the U.S. federal health insurance program, the analysis is limited to the sub-set of patients with a device implant that receive benefits through CMS with coverage that was active at the time of device implant. Diagnosis and procedure codes from CMS insurance claims that correspond to lead-related complications are identified and each event is evaluated to identify the related system component(s). This approach combines the advantages from passive complaint reporting (large device populations) with the advantage from clinical studies (reliable, consistent reporting) to ensure statistically sound device performance figures. However, due to the nature of insurance claims, fewer details of the device complications are known.

As part of the Device Pilot Project EP PASSION, the real-world methodology developed in collaboration with the stakeholders was validated in a proof of concept analysis. Results demonstrated high agreement of 99.7% between the real-world data outcomes and results from a prospective study[1]. Based on the proof of concept results, BIOTRONIK received FDA approval to utilize this methodology to fulfil post-approval reporting requirements for both low and high voltage leads.

For PPR analysis, the complication criteria are aligned with the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads". Specifically, the codes identify lead-related complications that would result in a cardiac lead being removed or replaced, or result in a new lead being implanted as a result of the lead-related complication. Identified complications are limited to events with an onset date of more than 30 days after implant. Acute complications, those with an onset date of 30 days or less after implant, are excluded from analysis.

To protect patient confidentiality, CMS restricts direct reporting of data cell values of 1 to 10. Therefore, lead models with 10 or less identified complications will not be reported within the PPR. In addition, lead models that are no longer distributed with less than 500 leads available for analysis are excluded.

**Lead Tracking and Reporting**
Patients implanted with a BIOTRONIK lead after U.S. market approval as identified in BIOTRONIK's U.S. device registration system are directly linked with CMS beneficiary information and claims data. The claims datasets will be updated for each Product Performance Report.

Lead-related complications identified from CMS claims data and identified to be related to the BIOTRONIK leads are reported. The overall lead-related complication rate by lead model is provided.

In order to provide statistically sound data, sample sizes of less than 100 subjects are not reported.

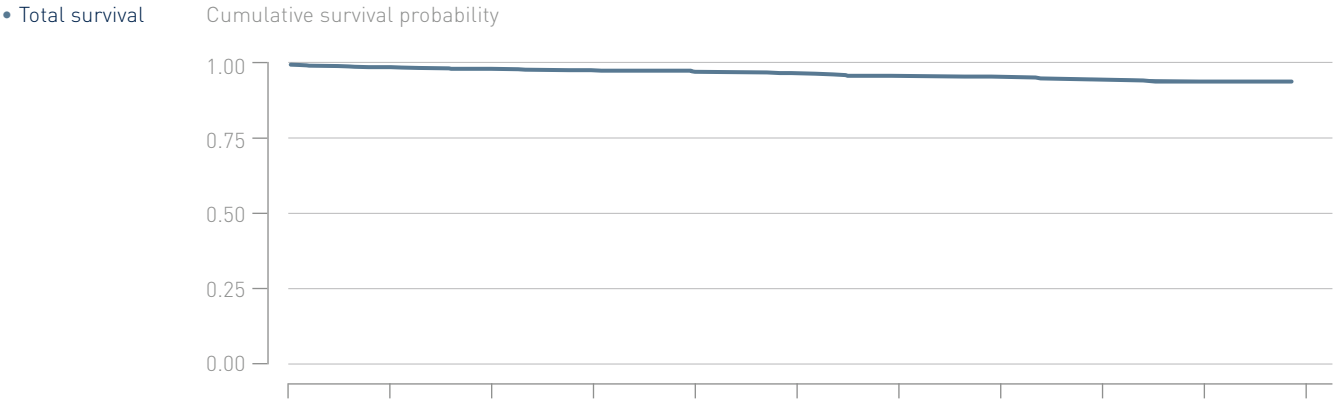
**1** Hicks J, Keith M, Moll P, Simeles J, Offer E, Diani C, Rock A, and Mitchell K. Novel Method to Identify Lead Complications in Pacemaker Systems from Real-World Data: Proof of Concept for the Siello S Pacing Lead. Heart Rhythm. 2019; 16(5), Supplement, S-PO03-089.

# Performance of BIOTRONIK Leads Based on Insurance Claims Data

## 10.1 ICD Leads Performance – Insurance Claims Data

# Linox S

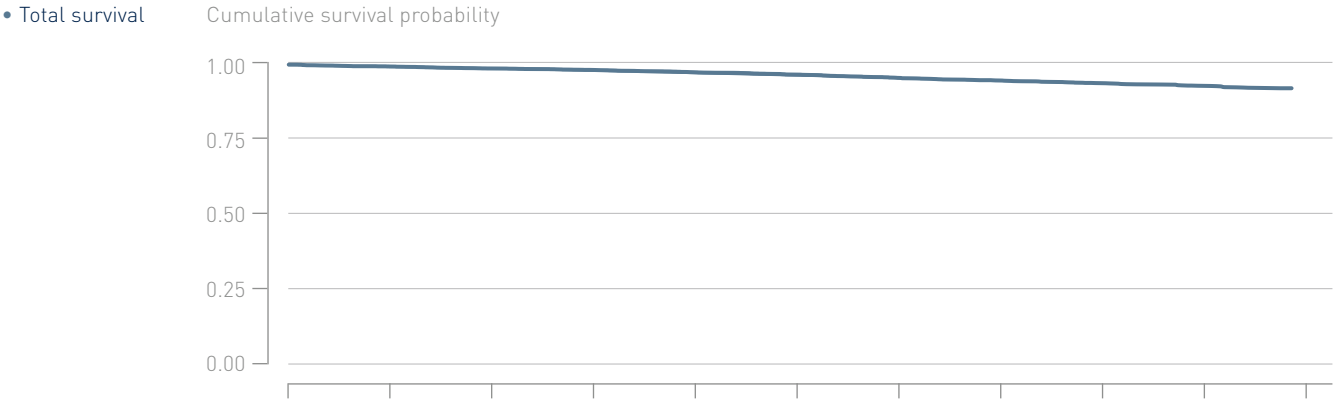
| | |
|---|---|
| Product Versions | 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2007 |
| CE Market Release | Mar 2007 |
| Worldwide Distributed Devices | 32 700 |
| Registered U.S. Implants | 869 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.1 | 98.6 | 98.1 | 97.5 | 97.1 | 96.2 | 95.9 | 94.9 | 94.2 | 94.2 |
| CI [±%] | 0.0 | 0.7 | 0.9 | 1.1 | 1.4 | 1.5 | 1.9 | 2.1 | 2.5 | 3.0 | 3.9 |
| Sample Size | 869 | 737 | 647 | 571 | 496 | 439 | 380 | 335 | 280 | 228 | 129 |

# Linox SD

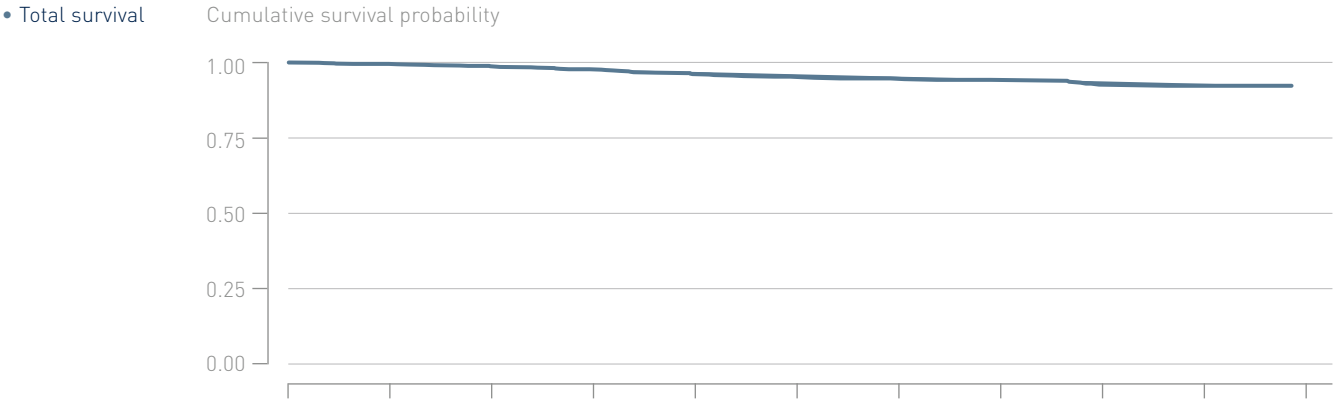
| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Apr 2006 |
| CE Market Release | Aug 2006 |
| Worldwide Distributed Devices | 55 100 |
| Registered U.S. Implants | 7 270 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.4 | 98.7 | 98.2 | 97.4 | 96.6 | 95.5 | 94.6 | 93.7 | 92.8 | 91.9 |
| CI [±%] | 0.0 | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.8 | 0.9 | 1.1 | 1.3 | 1.6 |
| Sample Size | 7270 | 6031 | 5208 | 4489 | 3768 | 3151 | 2616 | 2166 | 1815 | 1461 | 1035 |

# Linox TD

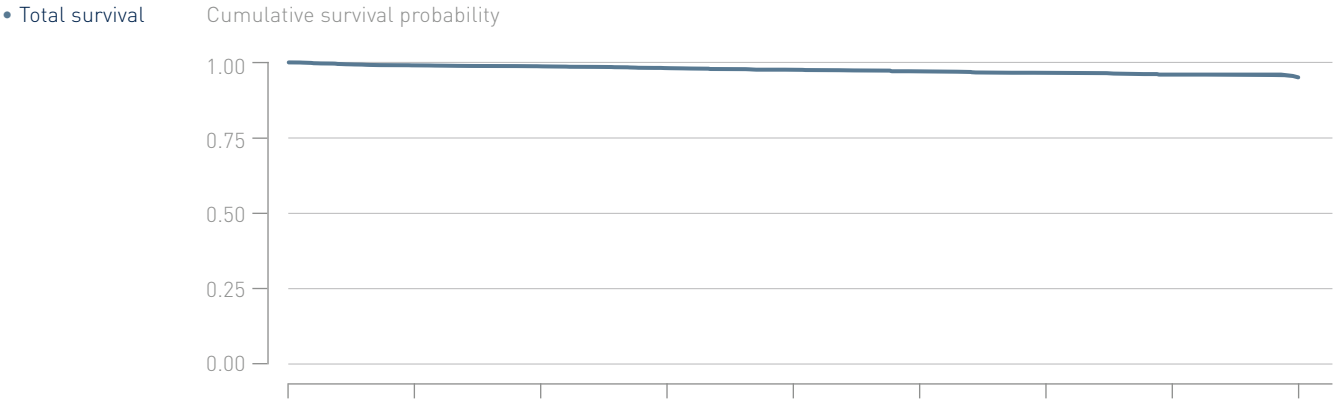
| | |
|---|---|
| Product Versions | 65/16, 75/16, 100/16, 100/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Oct 2006 |
| CE Market Release | Oct 2006 |
| Worldwide Distributed Devices | 14 600 |
| Registered U.S. Implants | 1 148 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 98.7 | 97.7 | 96.0 | 95.2 | 94.6 | 94.1 | 92.4 | 92.0 | 92.0 |
| CI [±%] | 0.0 | 0.4 | 0.8 | 1.1 | 1.5 | 1.9 | 2.1 | 2.4 | 3.0 | 3.4 | 4.1 |
| Sample Size | 1148 | 954 | 820 | 697 | 590 | 487 | 405 | 340 | 274 | 222 | 157 |

# Linox Smart S

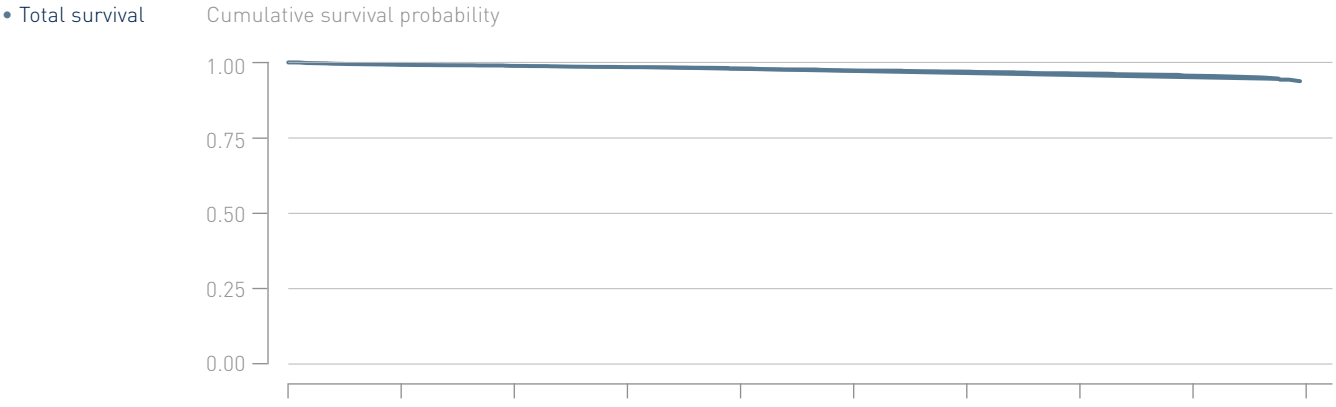
| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Aug 2011 |
| CE Market Release | Dec 2010 |
| Worldwide Distributed Devices | 46 700 |
| Registered U.S. Implants | 2 985 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.0 | 98.7 | 98.0 | 97.5 | 96.9 | 96.4 | 95.8 | 95.3 |
| CI [±%] | 0.0 | 0.4 | 0.5 | 0.6 | 0.8 | 0.9 | 1.2 | 1.7 | 2.8 |
| Sample Size | 2985 | 2495 | 2162 | 1872 | 1596 | 1293 | 903 | 525 | 204 |

# Linox Smart SD

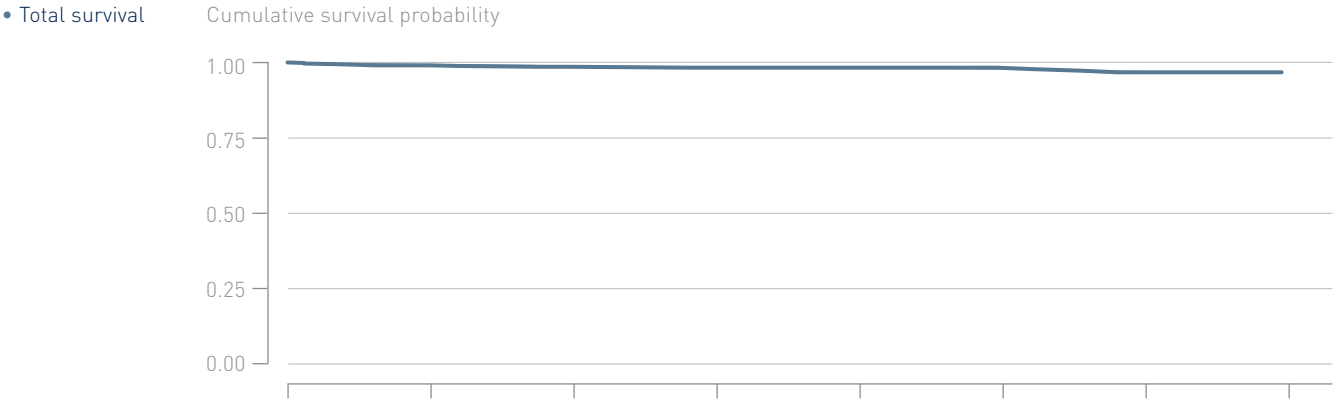
| | |
|---|---|
| Product Versions | 60/16, 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 55 700 |
| Registered U.S. Implants | 5 269 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.1 | 98.8 | 98.4 | 97.9 | 97.2 | 96.8 | 96.1 | 95.4 | 93.4 |
| CI [±%] | 0.0 | 0.3 | 0.3 | 0.4 | 0.5 | 0.7 | 0.8 | 1.0 | 1.5 | 3.6 |
| Sample Size | 5269 | 4311 | 3725 | 3244 | 2782 | 2326 | 1861 | 1298 | 724 | 169 |

# Linox Smart TD

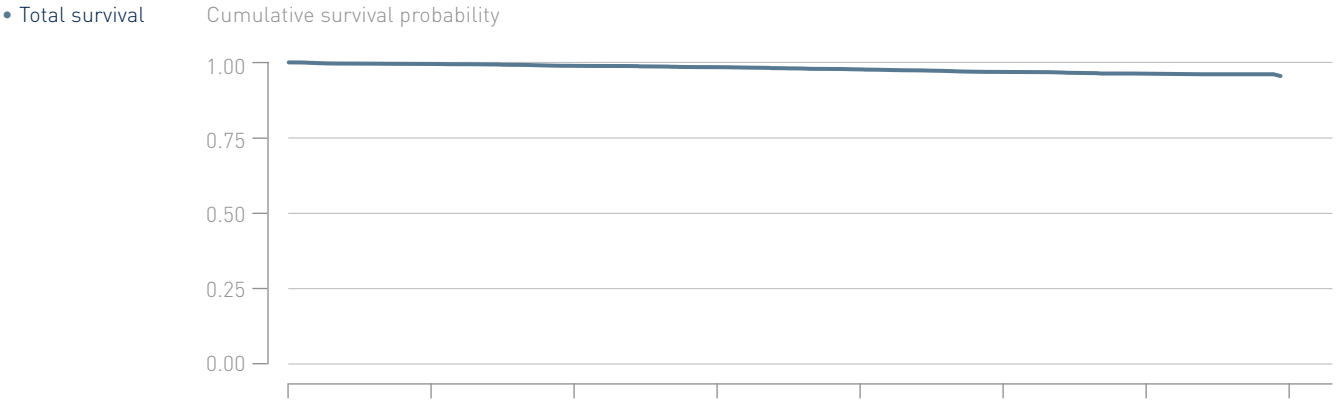
| | |
|---|---|
| Product Versions | 65/16, 65/18, 75/18 |
| Lead Type | dual-coil, passive fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jan 2011 |
| CE Market Release | Oct 2009 |
| Worldwide Distributed Devices | 7 720 |
| Registered U.S. Implants | 523 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.0 | 98.4 | 98.1 | 98.1 | 98.1 | 96.5 | 96.5 |
| CI [±%] | 0.0 | 1.0 | 1.3 | 1.5 | 1.7 | 1.8 | 2.8 | 3.4 |
| Sample Size | 523 | 423 | 356 | 297 | 246 | 203 | 160 | 109 |

# Linox Smart S DX

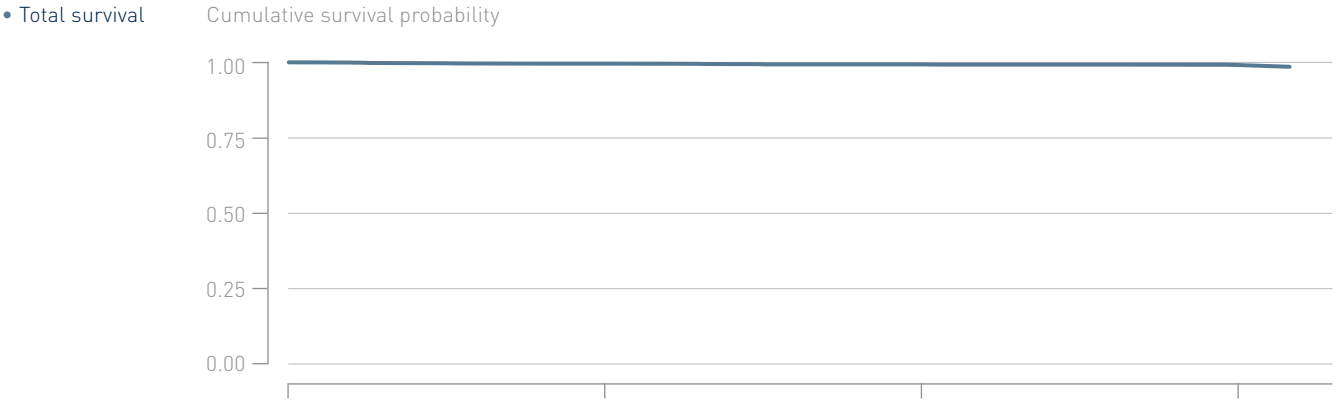
| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Feb 2013 |
| CE Market Release | Mar 2010 |
| Worldwide Distributed Devices | 36 300 |
| Registered U.S. Implants | 4 634 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 98.8 | 98.4 | 97.6 | 96.7 | 96.1 | 95.2 |
| CI [±%] | 0.0 | 0.2 | 0.4 | 0.5 | 0.7 | 1.0 | 1.5 | 3.3 |
| Sample Size | 4634 | 3864 | 3399 | 2859 | 1924 | 1181 | 597 | 150 |

# Plexa S

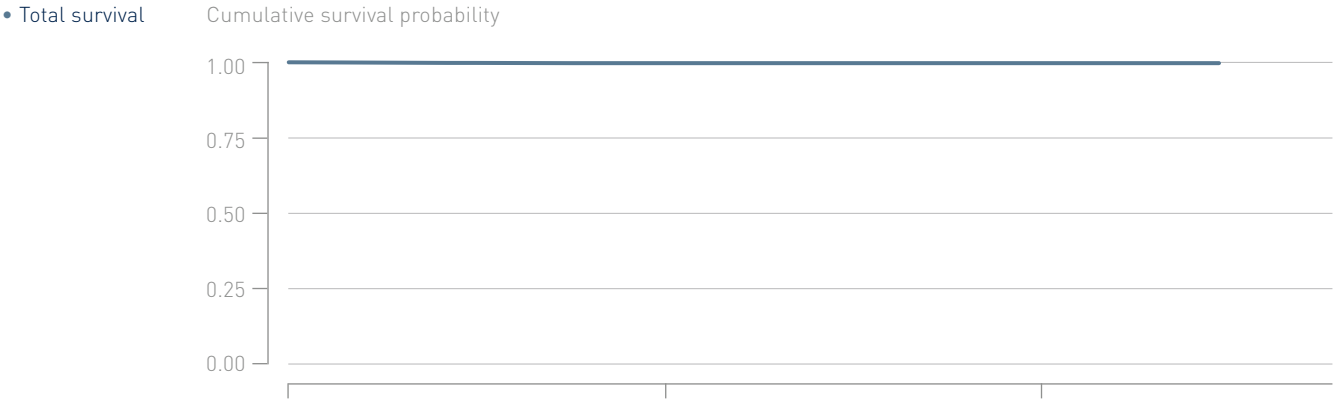
| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 83 500 |
| Registered U.S. Implants | 4 228 |




| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.2 | 99.1 |
| CI [±%] | 0.0 | 0.3 | 0.5 | 1.0 |
| Sample Size | 4228 | 2466 | 1326 | 228 |

# Plexa SD

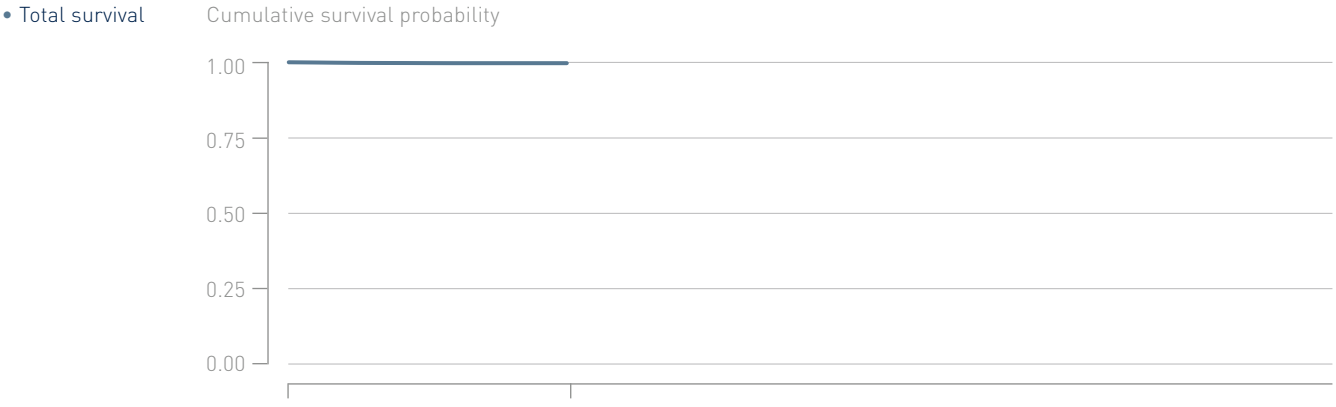
| | |
|---|---|
| Product Versions | 60/16, 65/18, 75/18 |
| Lead Type | dual-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 11 000 |
| Registered U.S. Implants | 981 |




| Years after implant | 0 | 1 | 2 |
|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.5 |
| CI [±%] | 0.0 | 0.5 | 0.6 |
| Sample Size | 981 | 620 | 346 |

# Plexa S DX

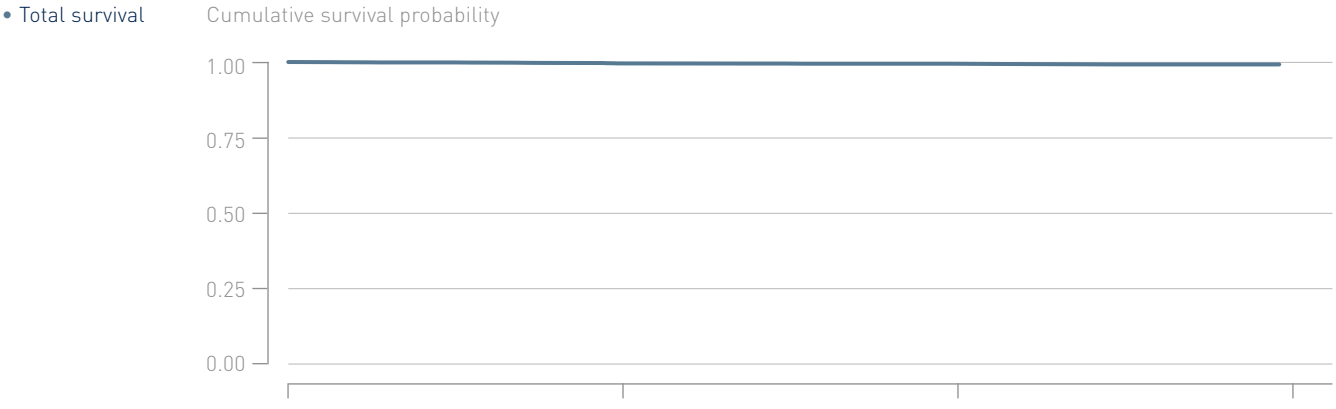
| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2019 |
| CE Market Release | Dec 2018 |
| Worldwide Distributed Devices | 14 100 |
| Registered U.S. Implants | 1 164 |




| Years after implant | 0 | 1 |
|---|---|---|
| Total [%] | 100.0 | 99.1 |
| CI [±%] | 0.0 | 1.4 |
| Sample Size | 1164 | 106 |

# Plexa S DX DF1

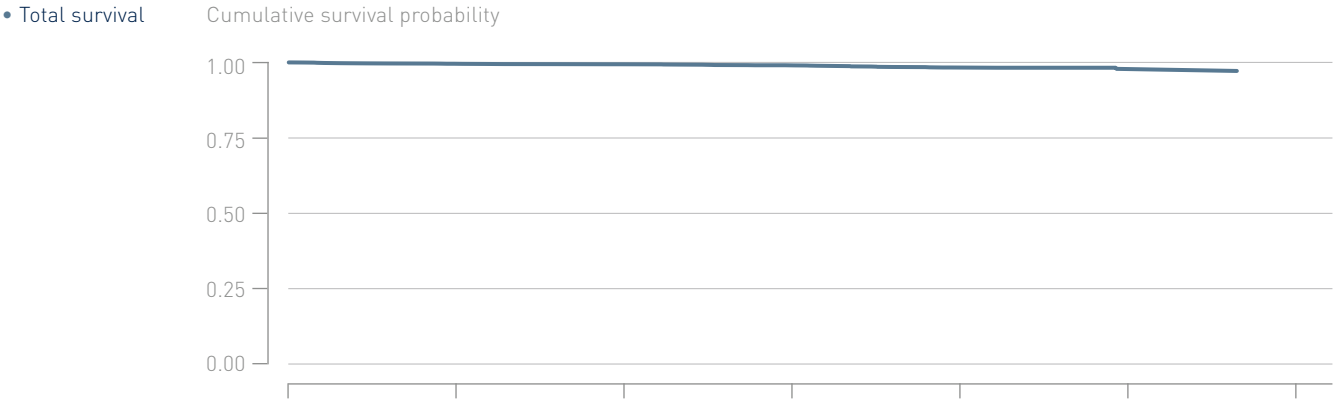
| | |
|---|---|
| Product Versions | 65/15, 65/17 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Mar 2017 |
| CE Market Release | Feb 2017 |
| Worldwide Distributed Devices | 19 700 |
| Registered U.S. Implants | 2 290 |




| Years after implant | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Total [%] | 100.0 | 99.4 | 99.3 | 99.0 |
| CI [±%] | 0.0 | 0.3 | 0.5 | 1.2 |
| Sample Size | 2290 | 1882 | 1013 | 184 |

# Protego S

| | |
|---|---|
| Product Versions | 60, 65, 75 |
| Lead Type | single-coil, active fixation |
| Polarity | bipolar |
| Steroid | yes |
| U.S. Market Release | Jul 2014 |
| CE Market Release | Feb 2014 |
| Worldwide Distributed Devices | 54 900 |
| Registered U.S. Implants | 3 055 |




| Years after implant | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|---|
| Total [%] | 100.0 | 99.5 | 99.3 | 99.0 | 98.2 | 97.7 | 96.9 |
| CI [±%] | 0.0 | 0.3 | 0.3 | 0.4 | 0.7 | 1.3 | 2.9 |
| Sample Size | 3055 | 2805 | 2634 | 2357 | 1426 | 492 | 128 |

11

# Advisories

## BIO-LQC potential premature battery depletion in a subset of ICD and CRT-D devices

162,000 devices worldwide, 38,000 in the United States

**Status Update**
FDA has classified this advisory as a class II recall.

The updated software version 2100 or later is available. It has been released on April 30th, 2021 in the United States. The corresponding CE-Version has been released on March 31st, 2021.

Since the start of the FSCA the distribution of all devices with an affected battery has been immediately stopped. All data of returned and analyzed devices have been carefully assessed to provide a comprehensive update to the FSN.

As of November 2021
- The cumulative failure rate is 0.40%
- No failures for devices with less than 2 years of implant duration have been reported.
- The failure probability after 2 years remains constant at 0.0012%. The failure probability after 5 years of implant has increased to 0.41%
- One event has been reported with patient death related to early battery depletion after the patient was lost to follow-up for two years. All other events are associated with an additional replacement surgery only.
- Availability of therapy has been assessed for all returned devices to update risks for loss of therapy depending on the service time:

**Risk for loss of pacing therapy**

| Service Time | Risk per month for loss of pacing |
|---|---|
| 0 – 24 months | < 0.00001% |
| 24 – 48 months | 0.0008% |
| 48 – 72 months | 0.0063% |

**Risk for loss of high-voltage therapy**

| Service Time | Risk per month for loss of shock therapy |
|---|---|
| 0 – 24 months | < 0.00001% |
| 24 – 48 months | 0.0015% |
| 48 – 72 months | 0.0125% |

**Original communication: March 2021**
BIOTRONIK has become aware of an increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators ("ICDs") and Cardiac Resynchronization Therapy Defibrillators ("CRT-Ds").

- Idova, Iforia, Ilesto
- Inventra, Iperia, Itrevia
- Ilivia, Inlexa, Intica
- Ilivia Neo, Intica Neo ICDs and CRT-Ds

These devices have been distributed since 2013. Please note that not all devices of the above models are affected, nor are other ICD or CRT-D families.

We have received no reports of serious injury or death associated with this issue. To date, all reports describe devices that fell short of expected longevity, resulting in an earlier than expected need for device exchange.

**Reason for this Communication**
The current observed rate of confirmed premature battery depletion events is 0.1% of all devices susceptible to this issue. Since every case of battery depletion may not be reported to BIOTRONIK, the exact number of devices that have experienced this issue is not entirely known. BIOTRONIK estimates the number of active devices which are potentially susceptible to this issue to be approximately 162,000 worldwide.

Analyses of returned devices has revealed the potential for a certain mode of lithium deposition on the anodes of the batteries, known as lithium plating, to occur.

Lithium plating is a very rare phenomenon that may cause a battery drain at a higher rate than under typical use.

The observed onset for devices experiencing this issue is about 2 years with a failure rate of 0.0012%. The projected failure rate at 5 years after implantation is estimated to be 0.17%.

**Risk to Health**
There is a very low risk that premature battery depletion could result in sudden loss of high-voltage or pacing therapy. Analyses of returned devices indicate that the risk for loss of high-voltage therapy is 0.0069% and the risk for loss of pacing therapy is 0.0015% on a per month basis.
Due to the identified issue, the interval between the elective replacement indicator ("ERI") being triggered and the loss of ability to provide therapy may be shorter than expected. Our records show, that for impacted devices, the median interval from ERI to loss of high-voltage therapy was 58 days. The median interval until loss of pacing therapy was 6 months.

**Early Battery Failure Detection**
By design, BIOTRONIK's programmer and Home Monitoring system are equipped with a battery depletion detector. This feature allows a battery

# 11. Advisories

depletion, including any premature depletion, to be detected early and displayed by an ERI during in-office follow-up, or via daily remote monitoring using BIOTRONIK Home Monitoring.

**Patient Management Recommendations**

Following a consultation with our medical advisory board, BIOTRONIK recommends you consider the following management options:

- Devices in stock: Do not implant any potentially affected devices, which include all models identified in this communication. Local BIOTRONIK representatives will replace affected devices in hospital inventory.
- Continue with the standard patient follow-up schedule.
  - During follow-ups: Verify the status of the device and battery during in-office or Home Monitoring follow-ups. Please note that unresponsive devices or those that are not transmitting data may be experiencing this issue and your BIOTRONIK representative should be informed if you observe any unusual device behavior.
  - Home Monitoring should be utilized whenever possible as it provides timely ERI warnings to reduce the risk of sudden loss of therapy. If you do not yet use Home Monitoring, please consider if this option is appropriate for you and your patients. BIOTRONIK will provide CardioMessenger devices free of charge to monitor implants affected by this advisory.

If you would like to register for Home Monitoring, please contact your local BIOTRONIK representative. Also, visit www.biotronik.com/en-de/products/home-monitoring for further information about Home Monitoring and how it can help you with remote monitoring of your patients in daily practice.

- If there is an unexpected ERI notification for a device that is subject to this advisory, a timely replacement should be considered based on the patient's underlying conditions:
  - For patients that are not pacemaker dependent, or patients with a primary prevention ICD, device replacement within one week after ERI notification is recommended.
  - For pacemaker dependent patients, replacement of the device is recommended immediately after ERI notification.

In consultation with our medical advisory board, BIOTRONIK does not recommend prophylactic replacement. The risk of complications for ICD exchange[1,2,3], outweighs the risk associated with this issue. We refer to the above patient management recommendations in case an unexpected ERI is observed.

We recognize that individual patients have unique clinical needs. Ultimately, patient care—including the frequency of follow-ups—is determined by the physician's clinical judgement, based on individual patient circumstances.

**1** McCarthy KJ, Locke AH, Coletti M, Young D, Merchant FM, Kramer DB. Outcomes Following Implantable Cardioverter-Defibrillator Generator Replacement in Adults: A Systematic Review. Heart Rhythm. 2020. [median: 4.57% for complications including reoperation]

**2** Biffi M, Ammendola E, Menardi E, et al. Real-life outcome of implantable cardioverter-defibrillator and cardiac resynchronization defibrillator replacement/upgrade in a contemporary population: Observations from the multicentre DECODE registry. Europace. 2019;21(10):1527-1536. [4.4% patients needed at least one surgical action to treat an adverse event following device replacement]

**3** Lewis KB, Stacey D, Carroll SL, Boland L, Sikora L, Birnie D. Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review. Pacing and clinical electrophysiology : PACE. 2016;39(7). [median rates: 4.0% major complications, 3.5% minor complications]

# X-Ray Identifiers for Pacemakers and ICDs

| Pacemaker/ICD Product Versions | X-Ray ID |
|---|---|
| Acticor 7 VR-T DX, HF-T |  |
| Cylos DR, DR-T, VR | RZ |
| Cylos 990 DR, DR-T, VR | FV |
| Edora 8 DR, DR-T, SR, SR-T, HF-T |  |
| Entovis DR, DR-T, SR, SR-T | SF |
| Eluna 8 DR, DR-T | SF |
| Estella SR, SR-T, DR, DR-T | SF |
| Etrinsa 8 SR-T, DR-T, HF-T | SF |
| Evia DR, DR–T, SR, SR-T, HF, HF-T | SF |
| Iforia 7 VR-T DX, DR-T | NT |
| Ilesto 7 DR-T, HF-T, VR-T DX, VR-T, DR-T DF4 | NT |
| Ilivia 7 VR-T, DR-T, DR-T DF4, VR-T DX, VR-T DF4, HF-T DF4 | NK |
| Intica 7 VR-T DX, HF-T | NK |
| Inventra 7 VR-T DX, HF-T DF4 | AH |
| Iperia 7 VR-T, DR-T, VR-T DX, VR-T DF4, HF-T DF4 | NH |
| Itrevia 7 VR-T, DR-T, VR-T DX, DR-T DF4, HF-T, HF-T DF4 | NH |
| Lumax 340 DR-T, HF-T, VR-T | HR |
| Lumax 540 DR-T, HF-T, VR-T | SH |
| Lumax 740 DR-T, HF-T, VR-T, VR-T DX | RH |
| Philos II DR, D, S, SLR, SR | ET |
| Philos II DR-T | KP |
| Rivacor 7 DR-T, HF-T |  |
| Talos DR, D, SLR, SR, S | PV |

# Contacting BIOTRONIK

## Regarding this Report

BIOTRONIK invites your suggestions and questions related to this Product Performance Report. Please send your comments to:

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**E-mail** PPR@biotronik.com

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12359 Berlin, Germany

## Regarding Products

BIOTRONIK invites customers to call the following locations with suggestions, comments or specific questions related to BIOTRONIK products:

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