Product Performance Report

1st Edition 2025

Cardiac Rhythm Management

Cumulative Survival Probability

BIOTRONIK

excellence for life

Product Performance Report 1st Edition 2025

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

Contents

Quality and Excellence

BIOTRONIK has a long history of high quality in product design and performance. For 60 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 US Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. As an active member of AdvaMed and theirs 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, June 2025

Stephan Schwerzel
Vice President
Quality Management CRM
BIOTRONIK SE & Co. KG

Terms and Definitions

1 Terms and Conditions

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 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 also known as 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. 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).

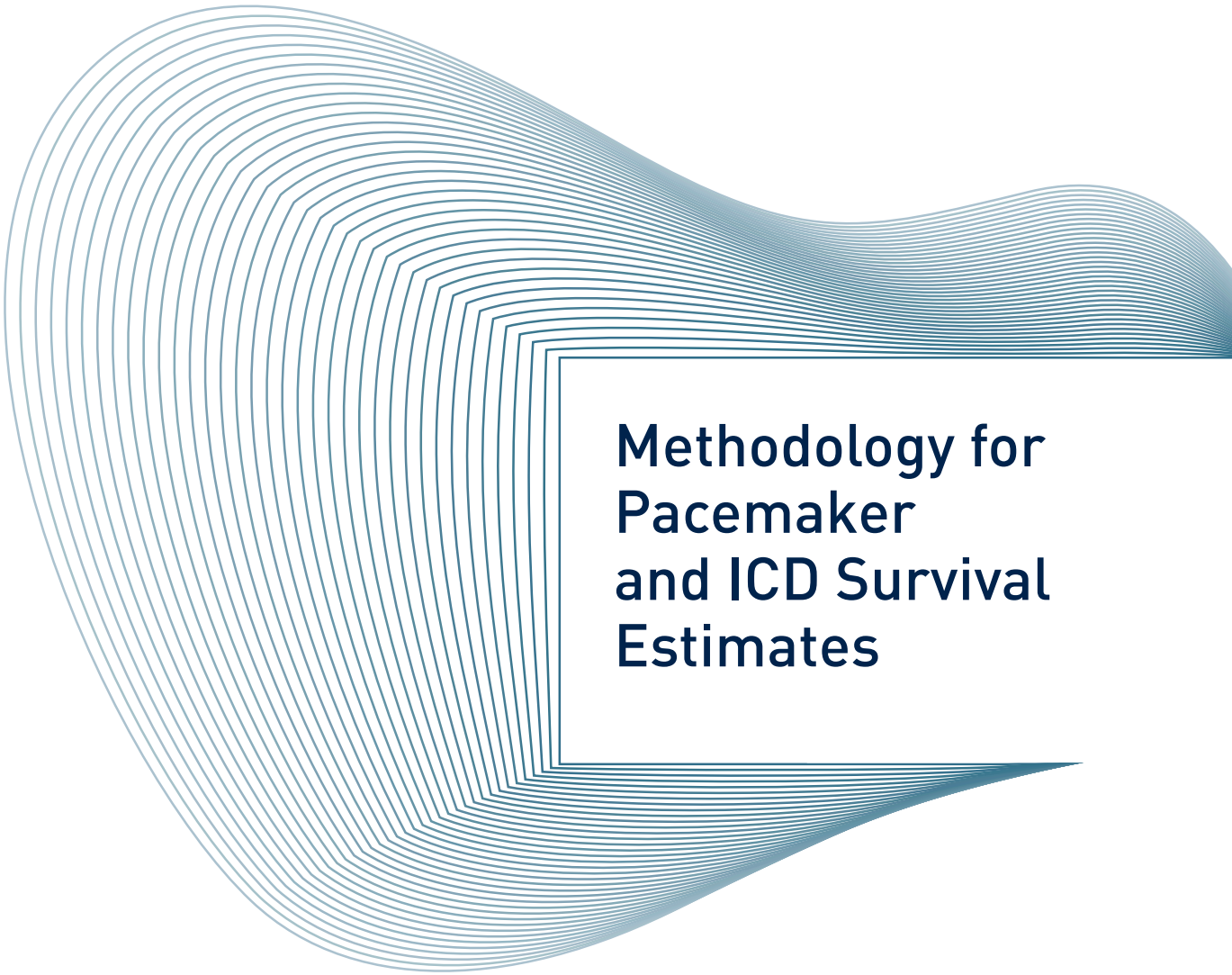
Cumulative Survival Probability Estimates The survival probability over a device's service time is the cumulative survival probability. It is calculated from all discrete survival probabilities of previous time intervals. This characteristic is calculated separately for malfunction-free survival and 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.



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 US 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 US Social Security Administration, the use of US 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 US 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, 2024. The number of US 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 US 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 Information

- Product versions that contribute to the evaluation
- Worldwide quantity of products that have been distributed
- US registered implants (number of products included in this report)
- Estimated active US implants
- Number of US normal battery depletions
- Number of US confirmed malfunctions

Survival Plot

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).

Malfunction-Free Survival

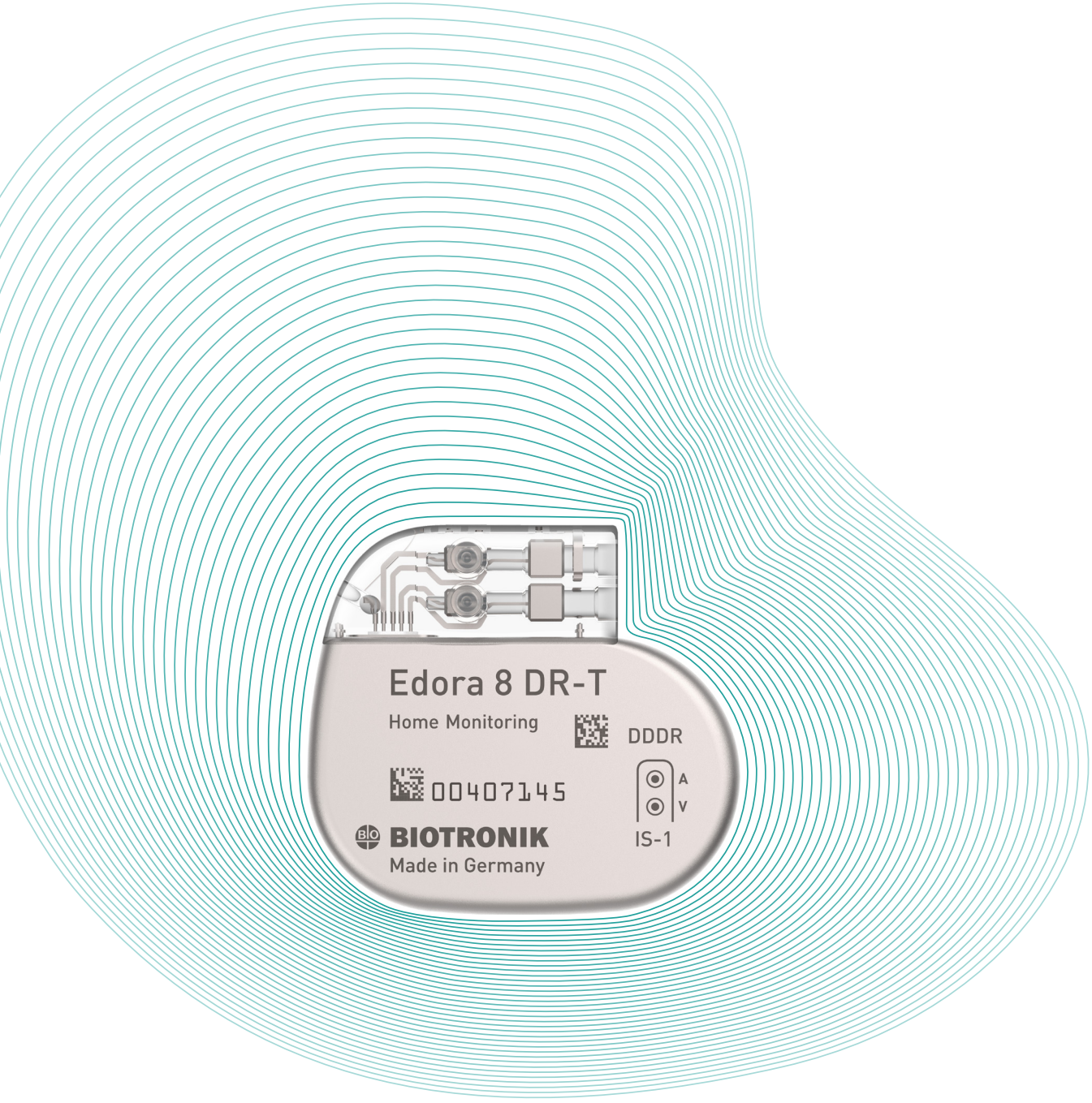
The cumulative survival probability free of component or software malfunctions excluding normal battery depletions, but including premature battery depletions. Normal battery depletions only have an impact on the total cumulative survival.

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



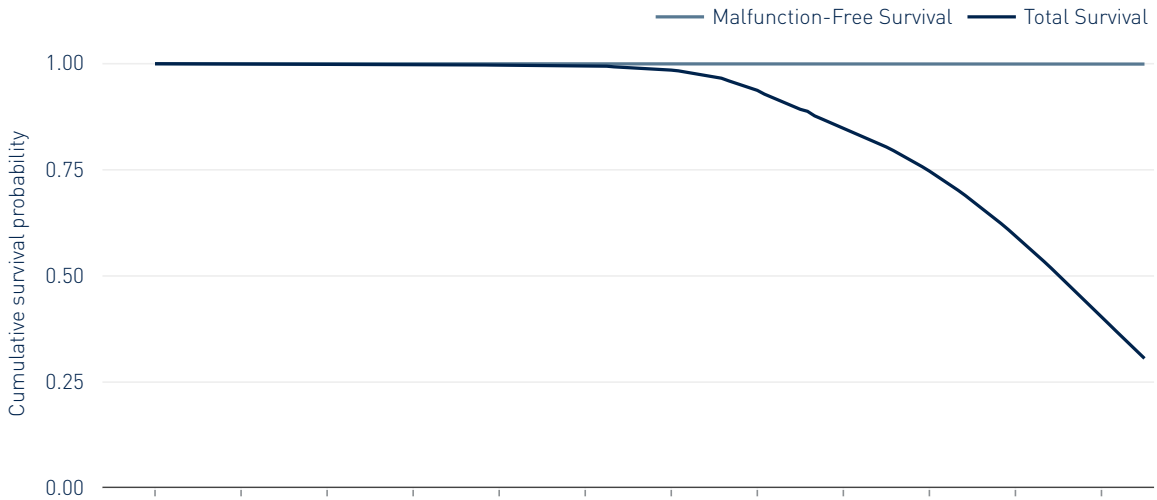
Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber 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 US Implants	6 148
Estimated Active US Implants	2 040
US Normal Battery Depletions	857

	Count	Rate
US 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	100	100	99.9	99.7	99.5	98.5	93.7	84.8	74.7	59.5	40.4
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.2	0.2	0.4	0.8	1.2	1.4	1.7	2.2
Malfunction-Free [%]	100	100	100	100	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
Sample Size	6148	5413	4919	4554	4235	4018	3830	3512	3046	2637	2020	980

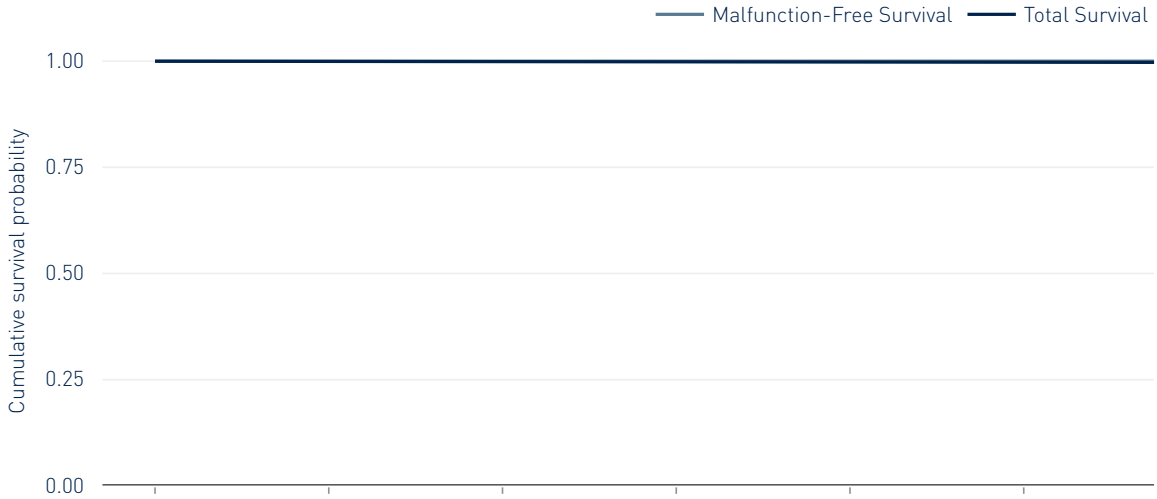
*While Cylos 990 VR is not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products.

3.1 Single-Chamber Pacemakers

Edora 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	57 900
Registered US Implants	10 650
Estimated Active US Implants	8 320
US Normal Battery Depletions	12

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



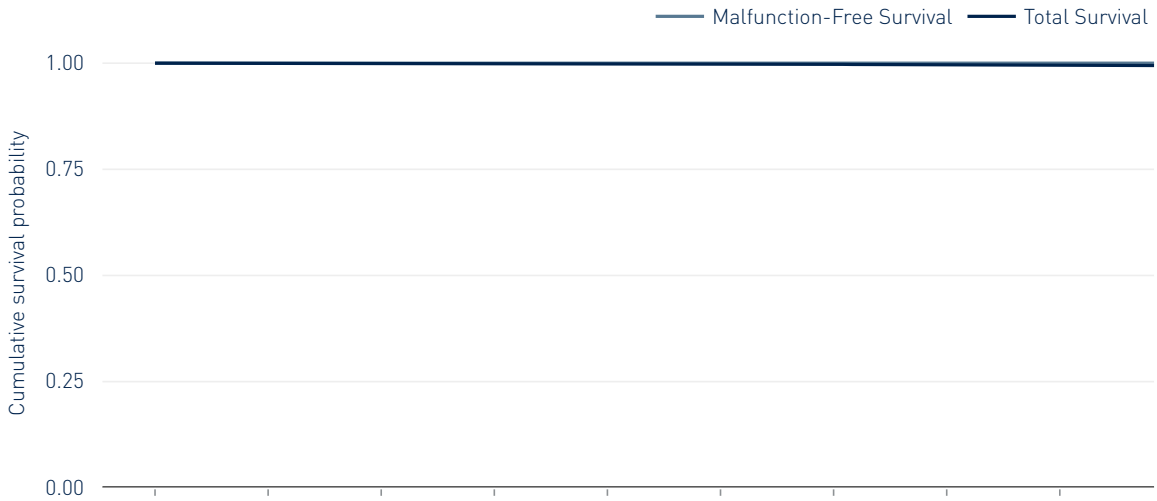
Years after implant	0	1	2	3	4	5
Total [%]	100	100	100	100	99.9	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	9703	7732	5926	4353	2883	1324

3.1 Single-Chamber Pacemakers

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 US Implants	5 799
Estimated Active US Implants	3 680
US Normal Battery Depletions	20

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



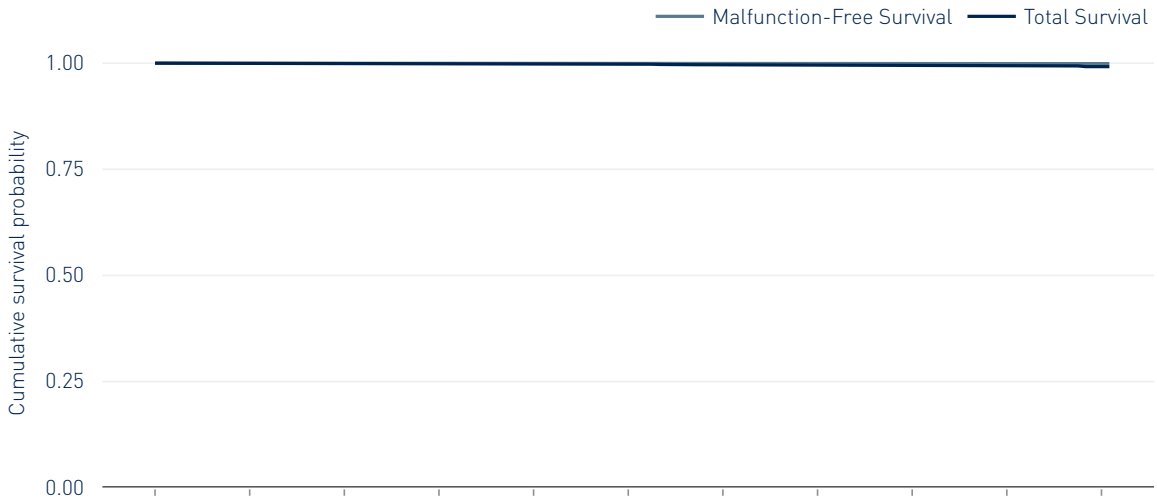
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.9	99.8	99.8	99.7	99.6	99.5
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	5799	5364	5029	4730	4454	4179	3797	3235	1729

3.1 Single-Chamber Pacemakers

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 US Implants	2 398
Estimated Active US Implants	1 340
US Normal Battery Depletions	11

	Count	Rate
US Confirmed Malfunctions	2	0.08%
Therapy Compromised	1	0.04%
Therapy Available	1	0.04%



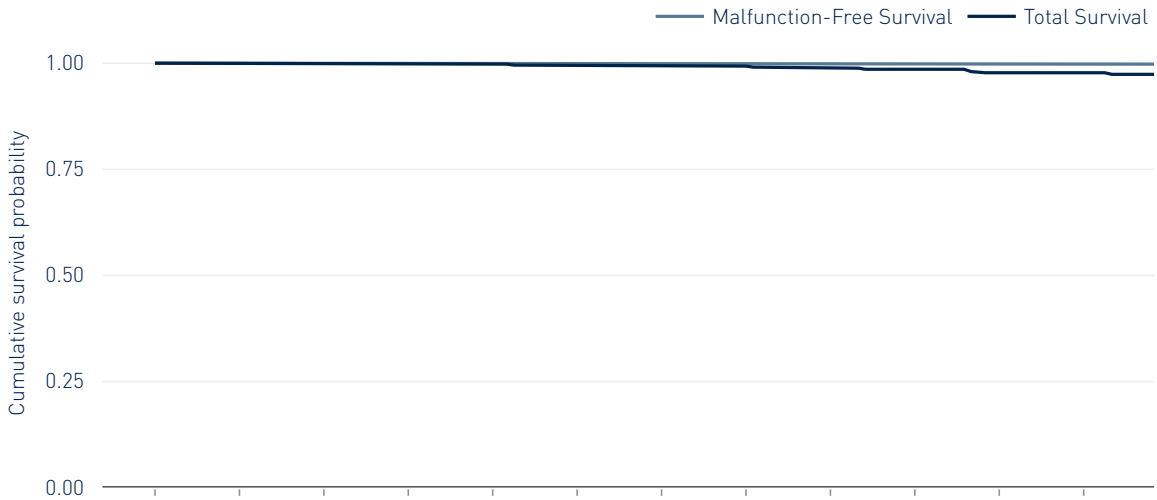
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.9	99.9	99.8	99.8	99.6	99.4	99.4	99.4	99.2
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.5
Malfunction-Free [%]	100	100	100	100	100	100	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2
Sample Size	2398	2187	2067	1941	1830	1730	1628	1534	1457	1218	361

3.1 Single-Chamber Pacemakers

Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	41 600
Registered US Implants	613
Estimated Active US Implants	323
US Normal Battery Depletions	10

	Count	Rate
US Confirmed Malfunctions	1	0.16%
Therapy Compromised	0	0.00%
Therapy Available	1	0.16%



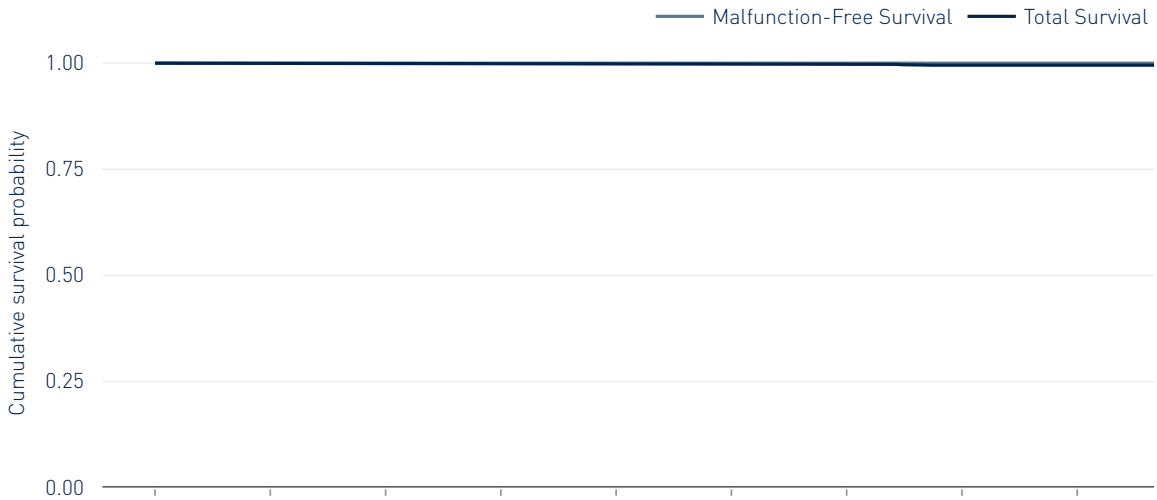
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	100	100	99.8	99.5	99.5	99.3	98.8	98.6	97.7	97.7
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.8	1.0	1.1	1.5	1.5
Malfunction-Free [%]	100	100	100	100	100	99.8	99.8	99.8	99.8	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	613	535	495	455	435	423	419	411	396	374	351	295

3.1 Single-Chamber Pacemakers

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 US Implants	1 711
Estimated Active US Implants	1 090
US Normal Battery Depletions	6

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



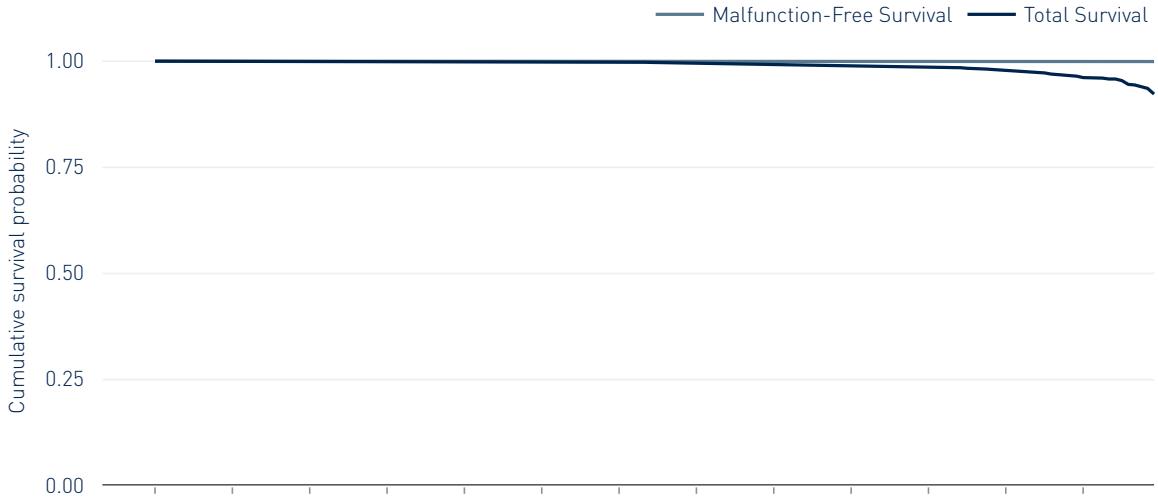
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.9	99.9	99.9	99.7	99.7	99.7	99.5	99.5
CI [± %]	< 0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1711	1572	1479	1392	1313	1245	1132	945	582

3.1 Single-Chamber Pacemakers

Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	63 900
Registered US Implants	11 972
Estimated Active US Implants	6 090
US Normal Battery Depletions	230

	Count	Rate
US Confirmed Malfunctions	6	0.05%
Therapy Compromised	2	0.02%
Therapy Available	4	0.03%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	100	99.9	99.9	99.9	99.8	99.8	99.6	99.4	99.0	98.6	97.8	96.1
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.4	0.6
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100	100	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
Sample Size	12k	10.7k	10.1k	9635	9307	8785	8293	7831	7394	6947	6048	4153	2008

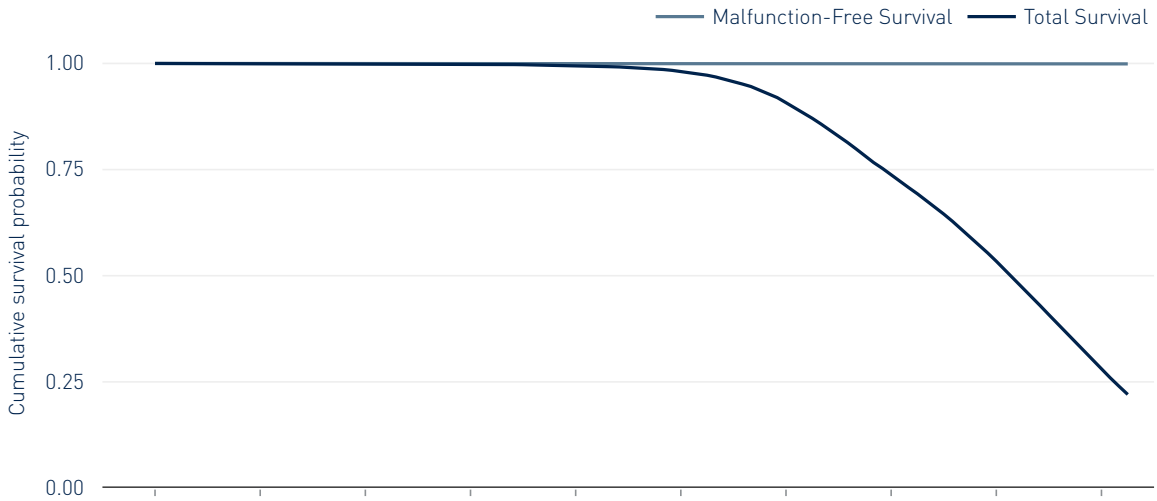
Performance of BIOTRONIK Pacemakers

3.2 Dual-Chamber 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 US Implants	30 374
Estimated Active US Implants	6 310
US Normal Battery Depletions	8 489

	Count	Rate
US 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	100	99.9	99.8	99.5	98.1	90.8	73.7	53.4	28.0
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.2	0.4	0.6	0.7	1.0
Malfunction-Free [%]	100	100	100	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
Sample Size	30.4k	28.2k	26.5k	25.1k	23.7k	21.9k	18.8k	13.8k	9042	2827

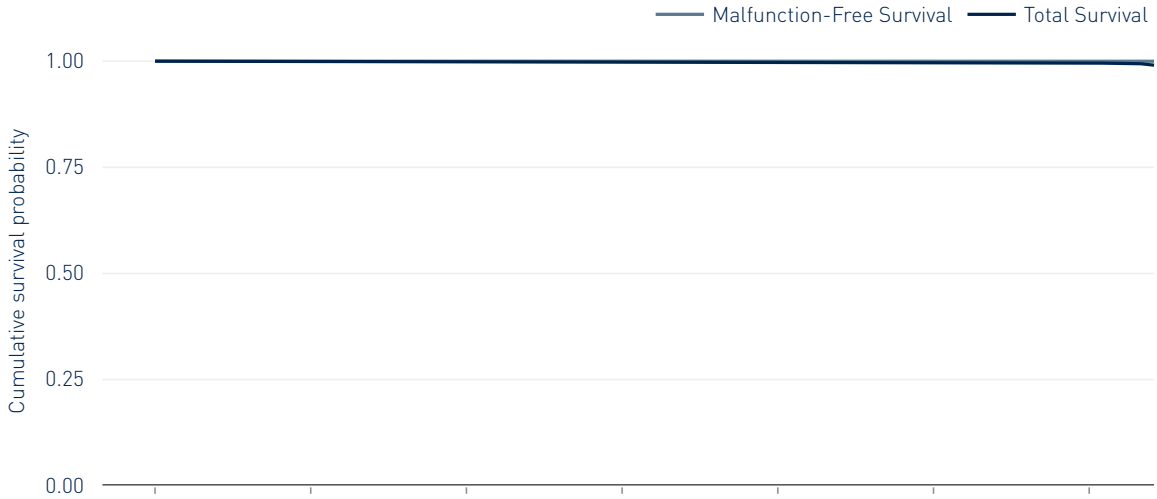
*While Cylos 990 DR and Cylos 990 DR-T is not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products.

3.2 Dual-Chamber Pacemakers

Edora 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2017
CE Market Release	Jul 2016
Worldwide Distributed Devices	356 000
Registered US Implants	112 719
Estimated Active US Implants	91 500
US Normal Battery Depletions	149

	Count	Rate
US Confirmed Malfunctions	9	0.01%
Therapy Compromised	4	0.00%
Therapy Available	5	0.00%



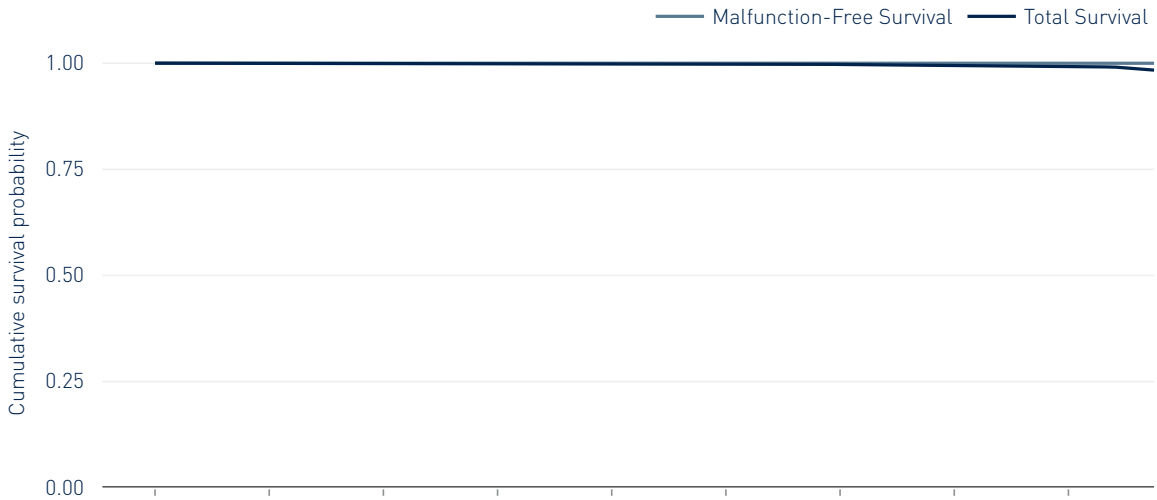
Years after implant	0	1	2	3	4	5	6
Total [%]	100	100	100	99.9	99.9	99.8	99.6
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	113k	95.6k	73.6k	53.2k	35.3k	21k	6503

3.2 Dual-Chamber Pacemakers

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 US Implants	42 071
Estimated Active US Implants	27 400
US Normal Battery Depletions	251

	Count	Rate
US Confirmed Malfunctions	6	0.01%
Therapy Compromised	0	0.00%
Therapy Available	6	0.01%



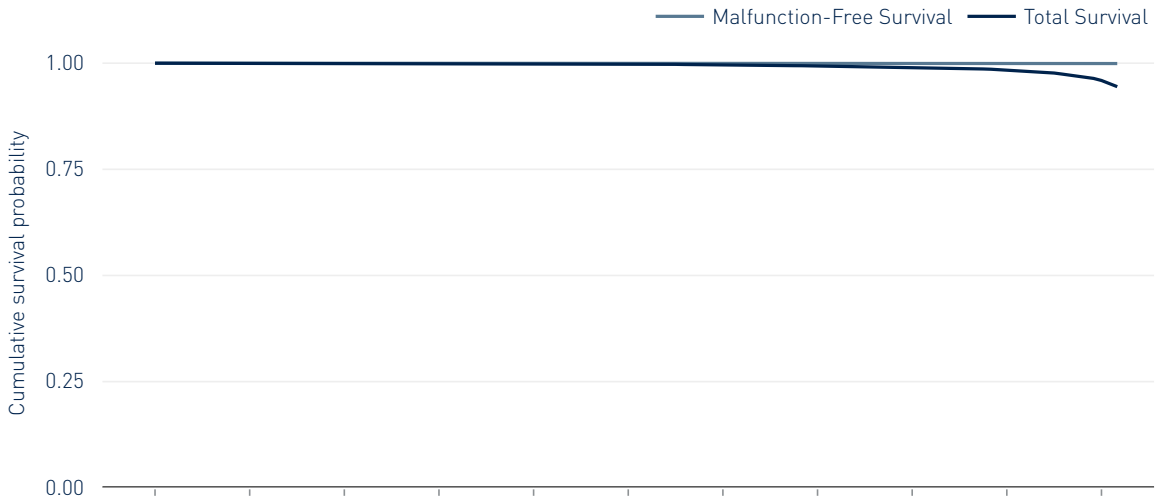
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	100	99.9	99.9	99.8	99.7	99.5	99.3
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	42.1k	39.4k	37k	34.8k	32.6k	29.8k	26.2k	21.9k	11.2k

3.2 Dual-Chamber Pacemakers

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 US Implants	12 119
Estimated Active US Implants	6 870
US Normal Battery Depletions	288

	Count	Rate
US Confirmed Malfunctions	7	0.06%
Therapy Compromised	2	0.02%
Therapy Available	5	0.04%



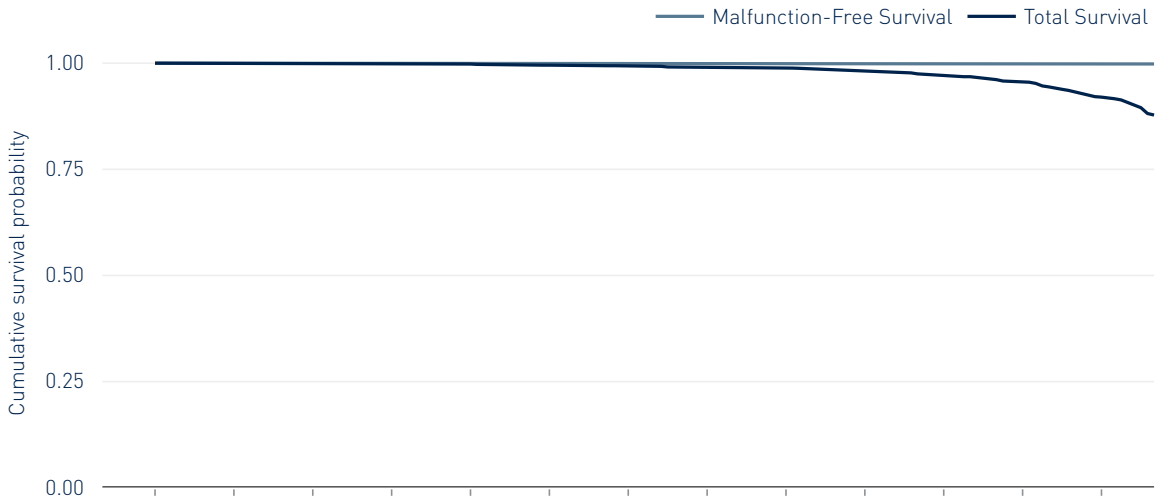
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.9	99.9	99.8	99.8	99.6	99.4	99.1	98.4	95.9
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.6
Malfunction-Free [%]	100	100	100	100	100	100	100	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1
Sample Size	12.1k	11.3k	10.6k	10k	9424	8876	8354	7844	7388	6259	1811

3.2 Dual-Chamber Pacemakers

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	53 500
Registered US Implants	2 945
Estimated Active US Implants	1 390
US Normal Battery Depletions	149

	Count	Rate
US Confirmed Malfunctions	4	0.14%
Therapy Compromised	0	0.00%
Therapy Available	4	0.14%



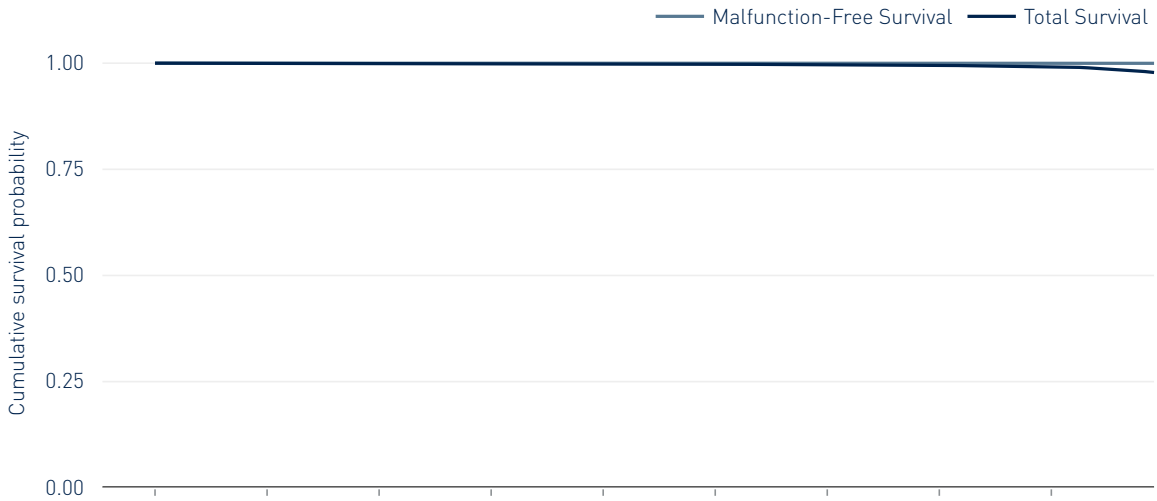
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	100	100	100	99.8	99.5	99.4	99.0	98.9	98.2	97.2	95.6	92.0
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.6	0.7	1.0	1.4
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9	99.9	99.9	99.9	99.8	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2
Sample Size	2945	2740	2593	2468	2332	2199	2070	1953	1850	1737	1614	1383	814

3.2 Dual-Chamber Pacemakers

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 US Implants	11 701
Estimated Active US Implants	7 540
US Normal Battery Depletions	91

	Count	Rate
US Confirmed Malfunctions	3	0.03%
Therapy Compromised	0	0.00%
Therapy Available	3	0.03%



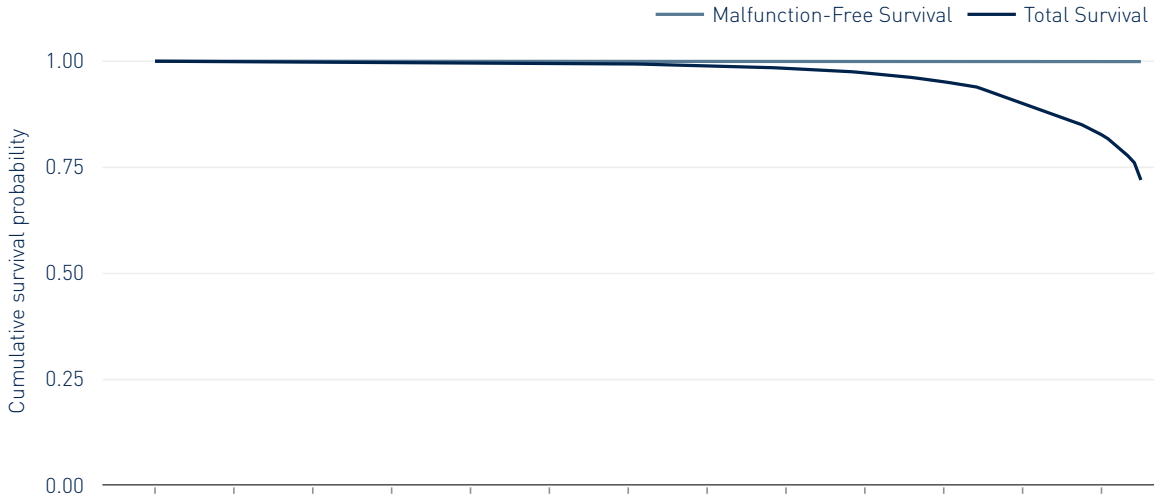
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.9	99.9	99.7	99.6	99.5	99.2
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	11.7k	11k	10.4k	9765	9227	8705	7920	6498	3754

3.2 Dual-Chamber Pacemakers

Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	224 000
Registered US Implants	61 901
Estimated Active US Implants	28 600
US Normal Battery Depletions	4 359

	Count	Rate
US Confirmed Malfunctions	37	0.06%
Therapy Compromised	12	0.02%
Therapy Available	25	0.04%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	100	99.9	99.9	99.8	99.6	99.4	99.0	98.3	97.3	95.1	90.1	82.7
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.6
Malfunction-Free [%]	100	100	100	100	100	100	100	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
Sample Size	61.9k	58.1k	54.6k	51.4k	48.4k	45.5k	42.8k	40.3k	37.8k	35.3k	29.7k	17.7k	6017

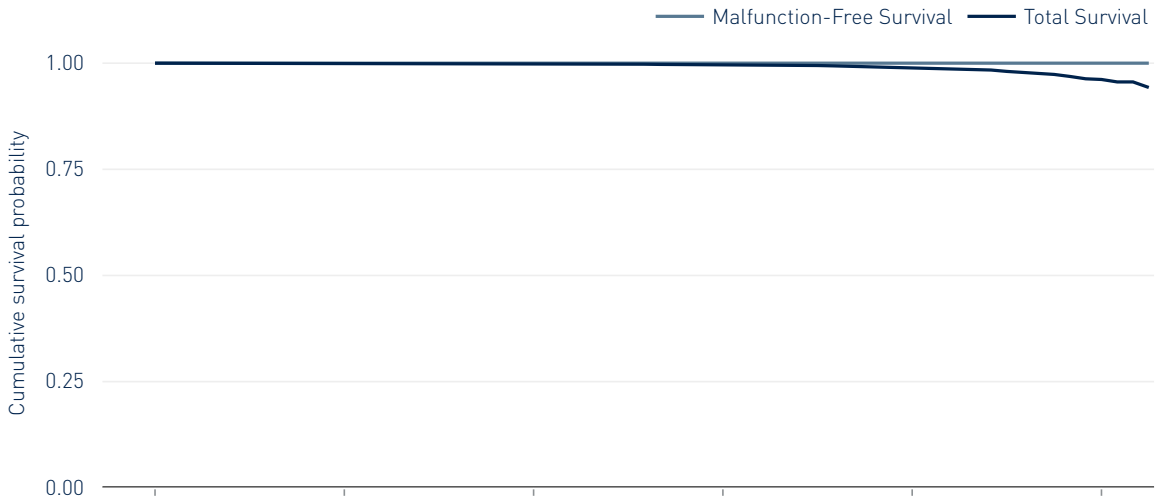
Performance of BIOTRONIK Pacemakers

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	26 400
Registered US Implants	9 712
Estimated Active US Implants	6 930
US Normal Battery Depletions	103

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



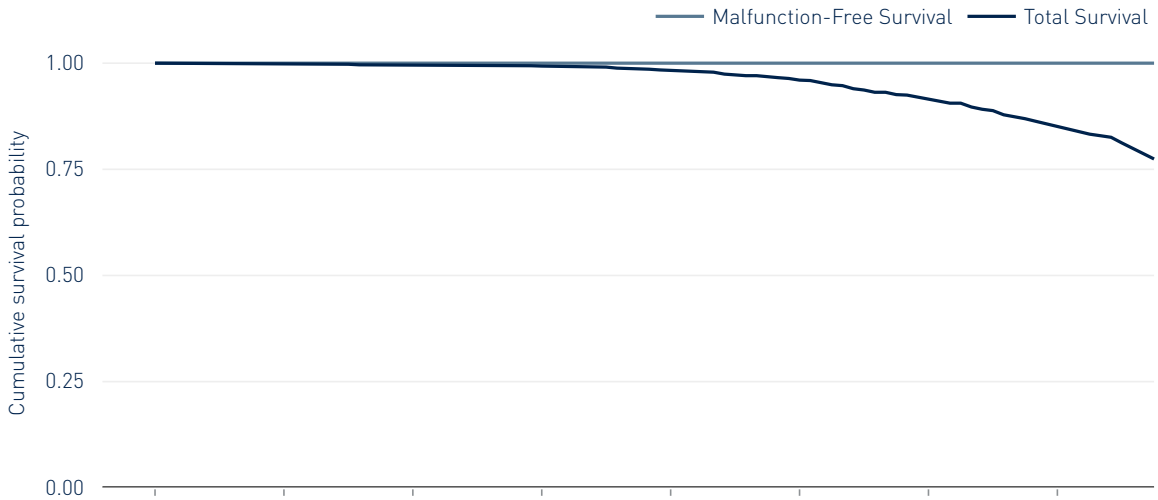
Years after implant	0	1	2	3	4	5
Total [%]	100	100	99.9	99.6	99.0	96.2
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.4	1.1
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	9712	7485	5328	3472	1896	594

3.3 CRT Pacemakers

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 US Implants	1 861
Estimated Active US Implants	656
US Normal Battery Depletions	193

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



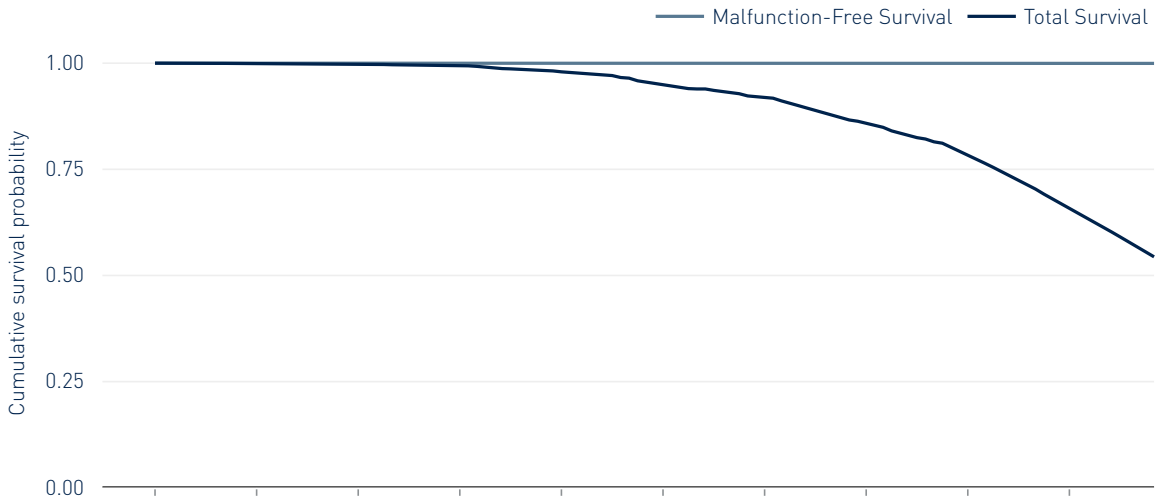
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	100	99.6	99.3	98.3	96.0	91.7	85.0
CI [± %]	< 0.1	< 0.1	0.3	0.4	0.7	1.1	1.7	2.4
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1861	1632	1441	1283	1137	993	783	525

3.3 CRT Pacemakers

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 US Implants	2 249
Estimated Active US Implants	434
US Normal Battery Depletions	415

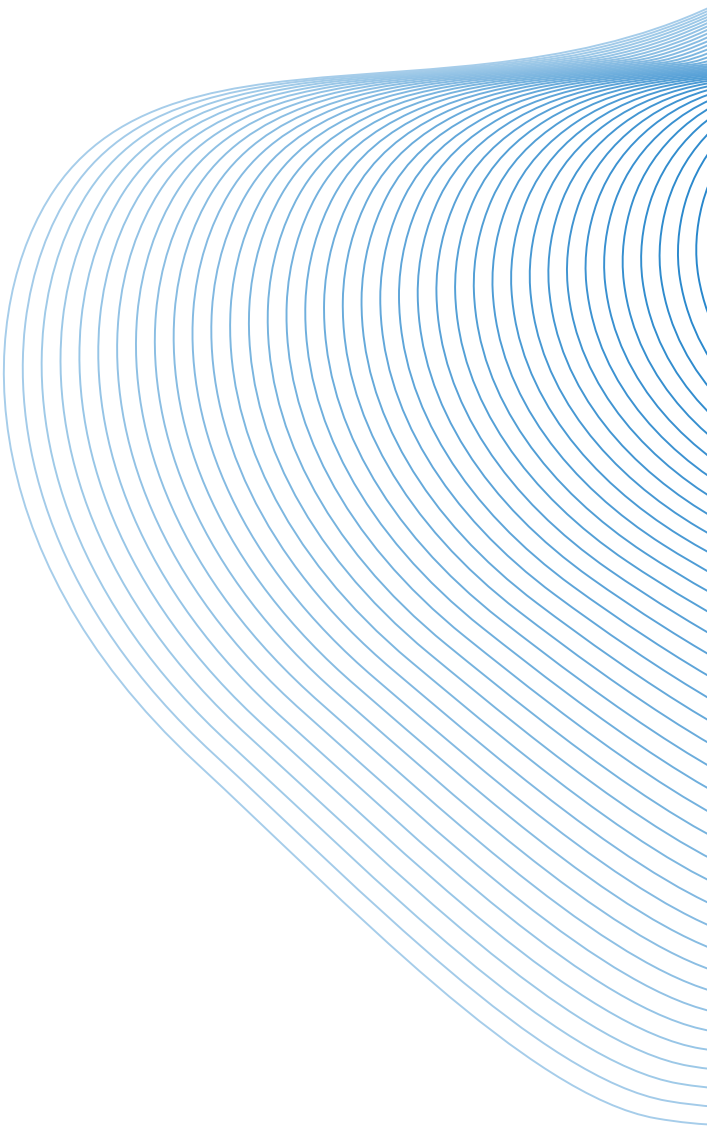
	Count	Rate
US Confirmed Malfunctions	1	0.04%
Therapy Compromised	0	0.00%
Therapy Available	1	0.04%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	100	99.7	99.4	98.0	94.9	91.8	85.9	78.4	65.9
CI [± %]	< 0.1	0.1	0.2	0.3	0.7	1.2	1.5	2.0	2.5	3.1
Malfunction-Free [%]	100	100	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
Sample Size	2249	1993	1773	1580	1379	1193	1029	851	695	512

Performance of BIOTRONIK ICDs

Performance of BIOTRONIK ICDs

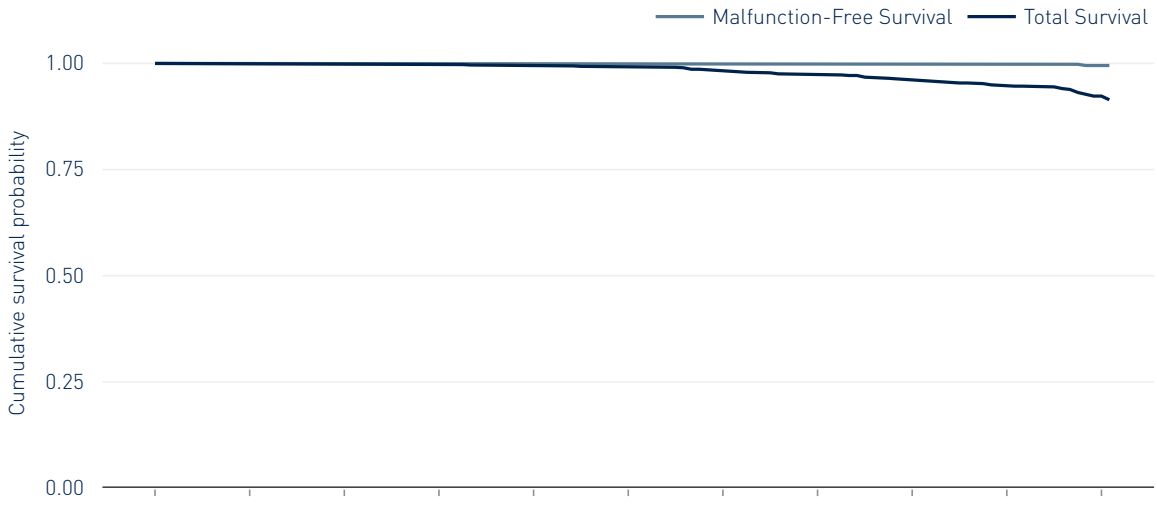


4.1 Single-Chamber ICDs

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	2 460
Registered US Implants	1 271
Estimated Active US Implants	638
US Normal Battery Depletions	55

	Count	Rate
US Confirmed Malfunctions	3	0.24%
Therapy Compromised	2	0.16%
Therapy Available	1	0.08%



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.8	99.7	99.6	99.2	98.3	97.4	96.1	94.6	92.3
CI [± %]	< 0.1	< 0.1	0.2	0.3	0.4	0.6	0.8	1.0	1.3	1.6	2.1
Malfunction-Free [%]	100	100	100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.5
CI [± %]	< 0.1	< 0.1	< 0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.6
Sample Size	1271	1181	1102	1032	961	892	829	767	704	617	244

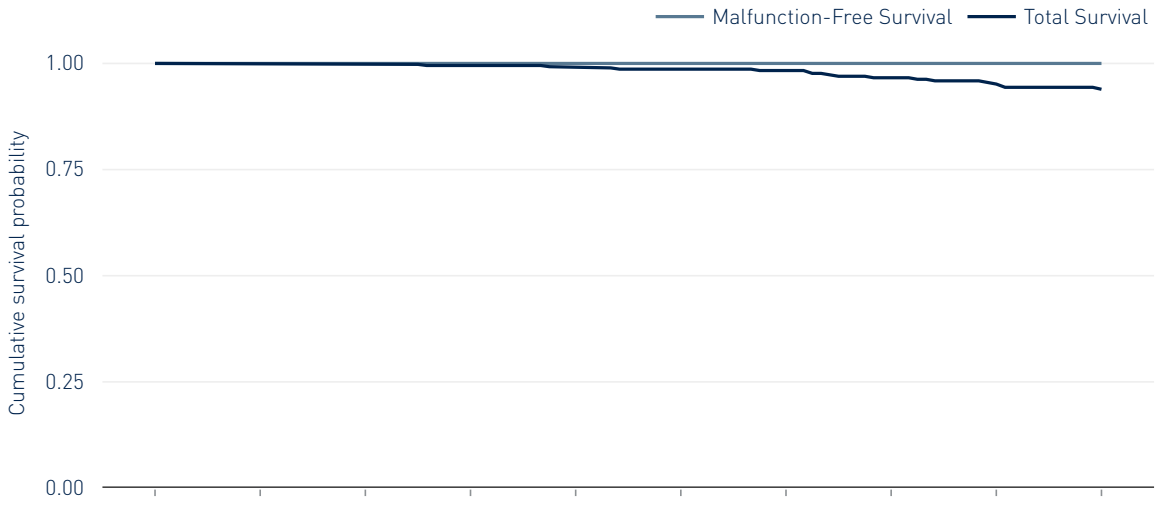
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

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	2 390
Registered US Implants	466
Estimated Active US Implants	237
US Normal Battery Depletions	12

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.8	99.8	99.5	98.9	98.7	98.3	96.6	95.1	93.9
CI [± %]	< 0.1	0.4	0.4	0.7	1.0	1.2	1.3	2.0	2.4	2.8
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	466	432	396	369	345	322	297	271	249	204

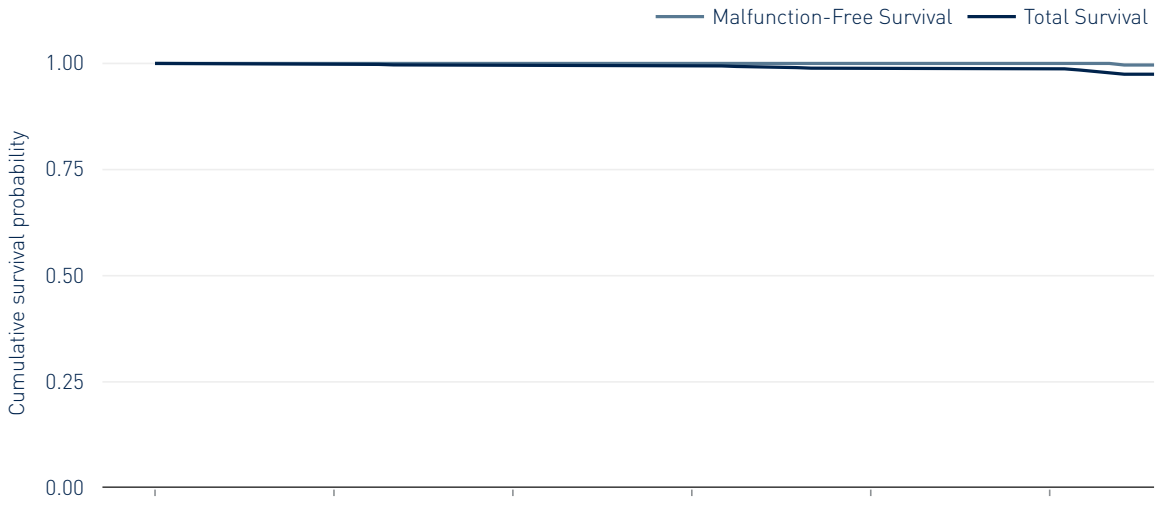
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

Ilivia 7*

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	2 390
Registered US Implants	964
Estimated Active US Implants	676
US Normal Battery Depletions	9

	Count	Rate
US Confirmed Malfunctions	1	0.10%
Therapy Compromised	0	0.00%
Therapy Available	1	0.10%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.9	99.5	99.4	98.9	98.7
CI [± %]	< 0.1	0.2	0.4	0.5	0.7	0.8
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	964	892	834	781	703	416

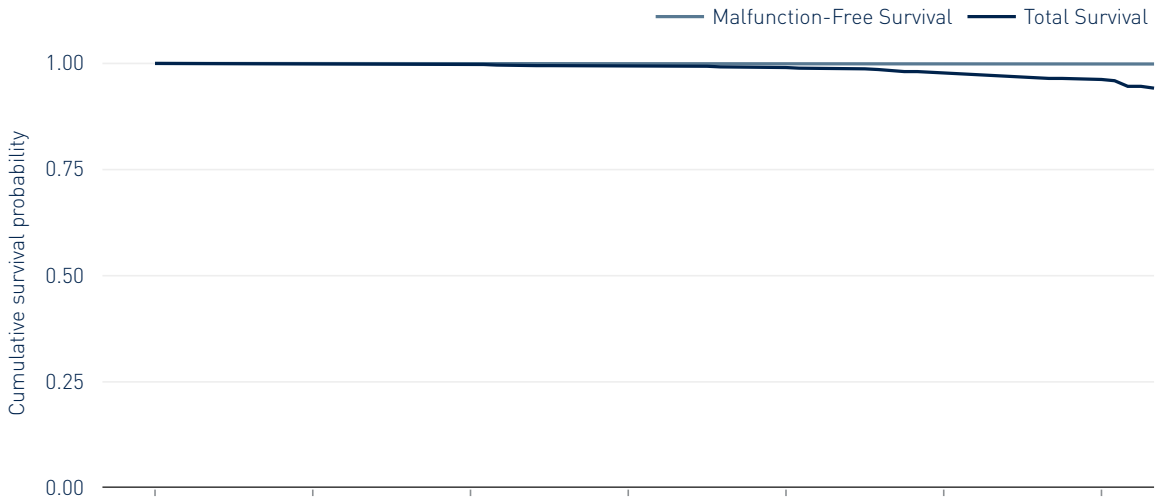
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

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	4 250
Registered US Implants	878
Estimated Active US Implants	528
US Normal Battery Depletions	10

	Count	Rate
US Confirmed Malfunctions	1	0.11%
Therapy Compromised	0	0.00%
Therapy Available	1	0.11%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.9	99.8	99.5	99.0	97.7	96.2
CI [± %]	< 0.1	0.2	0.3	0.5	0.7	1.1	1.5
Malfunction-Free [%]	100	100	100	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	0.3	0.3	0.3	0.3
Sample Size	878	812	754	699	649	580	352

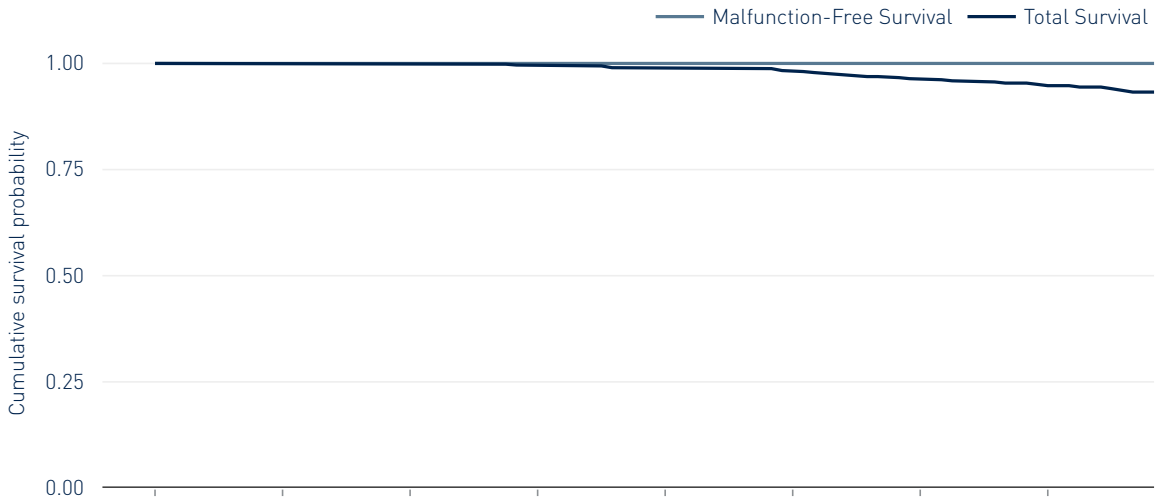
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

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 US Implants	618
Estimated Active US Implants	338
US Normal Battery Depletions	27

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	100	99.8	99.6	98.8	98.3	96.4	94.8
CI [± %]	< 0.1	< 0.1	0.3	0.5	1.0	1.2	1.7	2.1
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	618	567	530	492	458	424	388	309

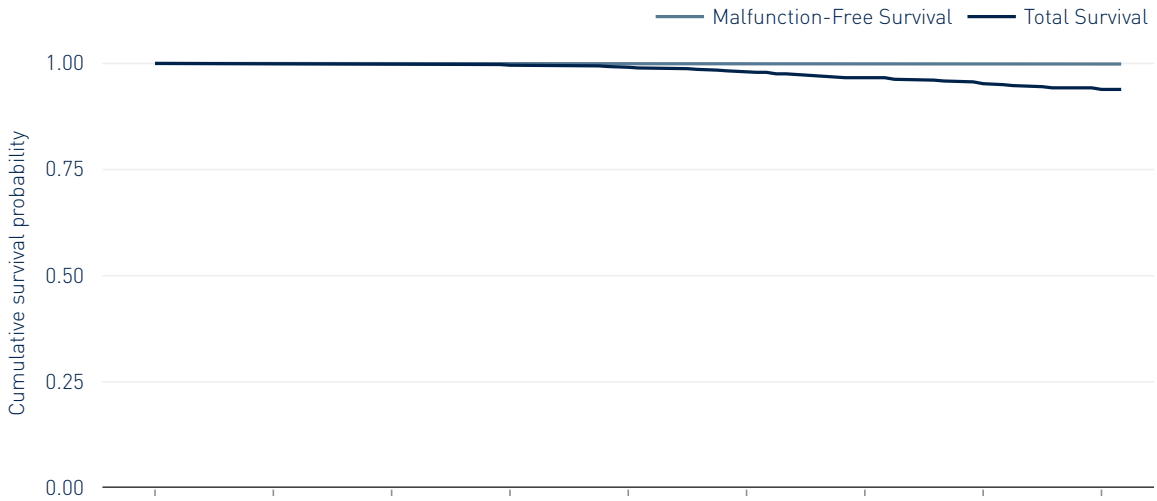
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

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 US Implants	804
Estimated Active US Implants	444
US Normal Battery Depletions	17

	Count	Rate
US Confirmed Malfunctions	1	0.12%
Therapy Compromised	0	0.00%
Therapy Available	1	0.12%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.9	99.7	99.6	99.1	98.1	96.6	95.2	93.9
CI [± %]	< 0.1	0.3	0.4	0.5	0.7	1.1	1.5	1.8	2.1
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	804	747	694	648	608	562	519	447	254

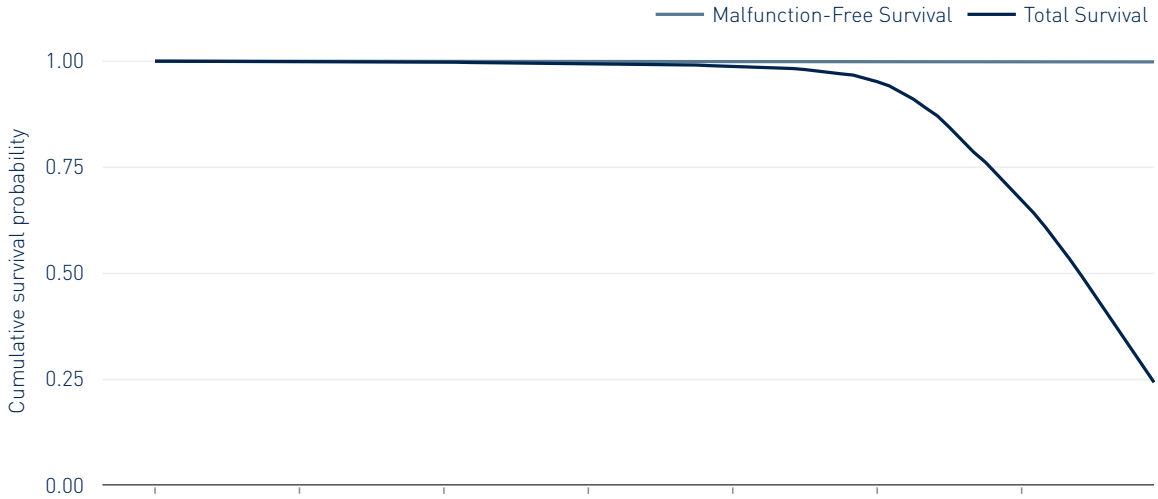
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.1 Single-Chamber ICDs

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 US Implants	3 985
Estimated Active US Implants	762
US Normal Battery Depletions	938

	Count	Rate
US Confirmed Malfunctions	6	0.15%
Therapy Compromised	4	0.10%
Therapy Available	2	0.05%



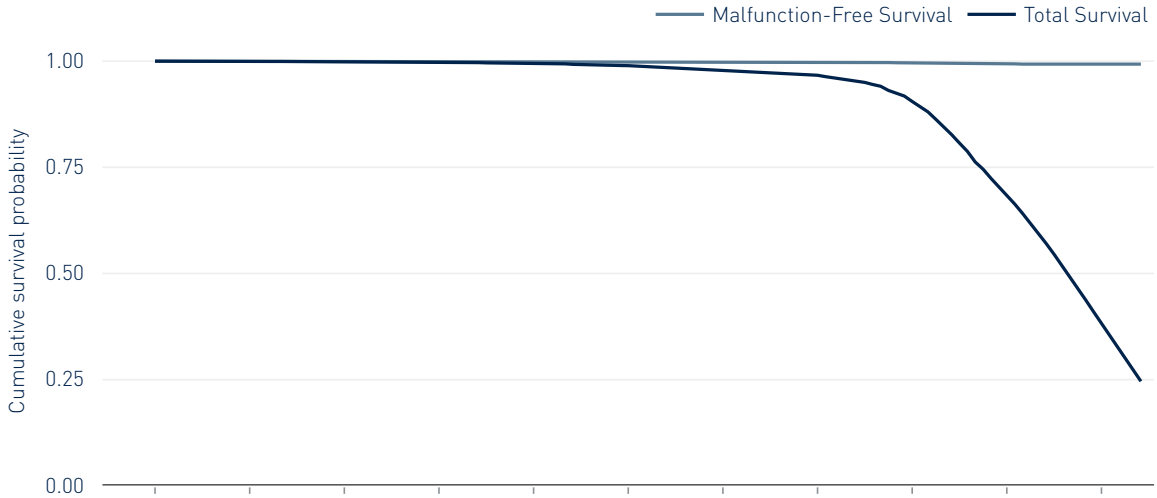
Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.8	99.8	99.6	98.8	95.2	67.5
CI [± %]	< 0.1	0.1	0.2	0.2	0.4	0.8	1.9
Malfunction-Free [%]	100	99.9	99.9	99.9	99.8	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3985	3627	3408	3177	2932	2578	1515

4.1 Single-Chamber ICDs

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 US Implants	4 544
Estimated Active US Implants	1 160
US Normal Battery Depletions	934

	Count	Rate
US Confirmed Malfunctions	18	0.40%
Therapy Compromised	14	0.31%
Therapy Available	4	0.09%



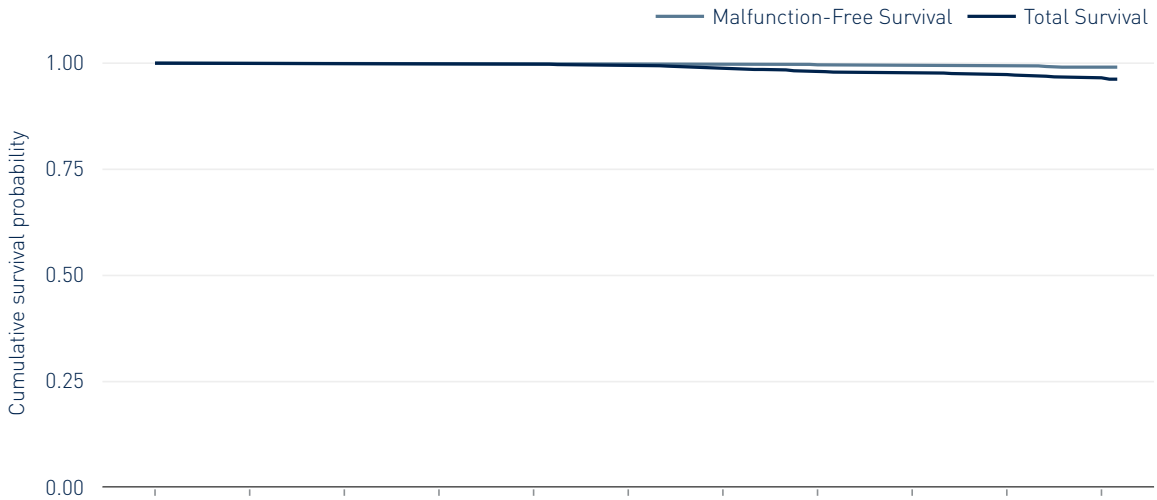
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.9	99.8	99.5	98.9	98.0	96.7	90.5	68.5	38.2
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.5	0.6	1.1	1.8	2.3
Malfunction-Free [%]	100	100	100	99.9	99.8	99.8	99.8	99.7	99.6	99.4	99.3
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3
Sample Size	4544	4200	3920	3648	3405	3171	2926	2698	2355	1632	761

4.1 Single-Chamber ICDs

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	4 810
Registered US Implants	1 573
Estimated Active US Implants	694
US Normal Battery Depletions	45

	Count	Rate
US Confirmed Malfunctions	10	0.64%
Therapy Compromised	8	0.51%
Therapy Available	2	0.13%



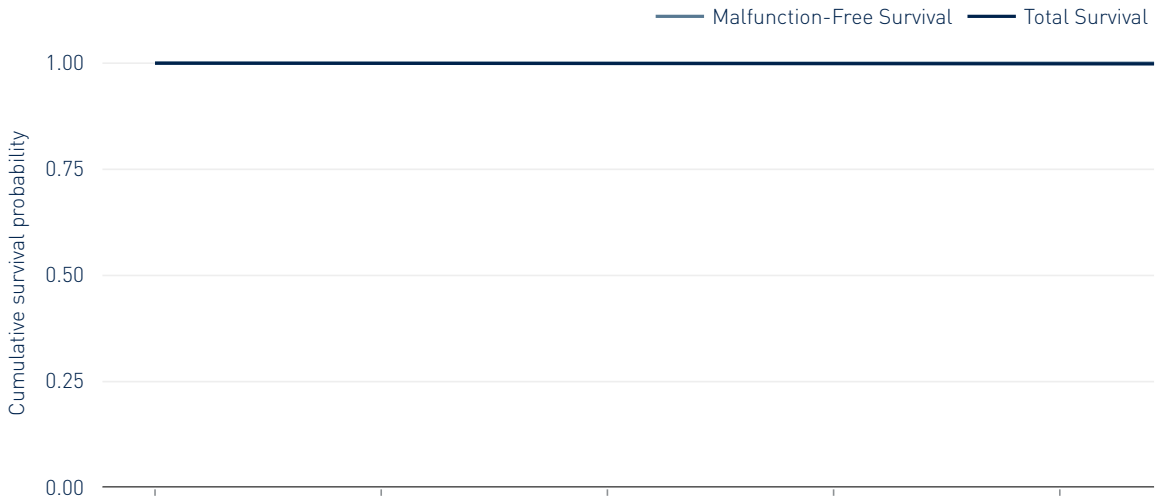
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	100	99.9	99.8	99.6	98.7	98.0	97.8	97.3	96.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.2	0.2	0.4	0.7	0.8	0.9	1.0	1.2
Malfunction-Free [%]	100	100	100	100	100	99.9	99.7	99.6	99.6	99.5	99.1
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.4	0.7
Sample Size	1574	1449	1350	1258	1166	1088	1003	935	872	798	339

4.1 Single-Chamber ICDs

Rivacor 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	7 320
Registered US Implants	2 097
Estimated Active US Implants	1 760
US Normal Battery Depletions	2

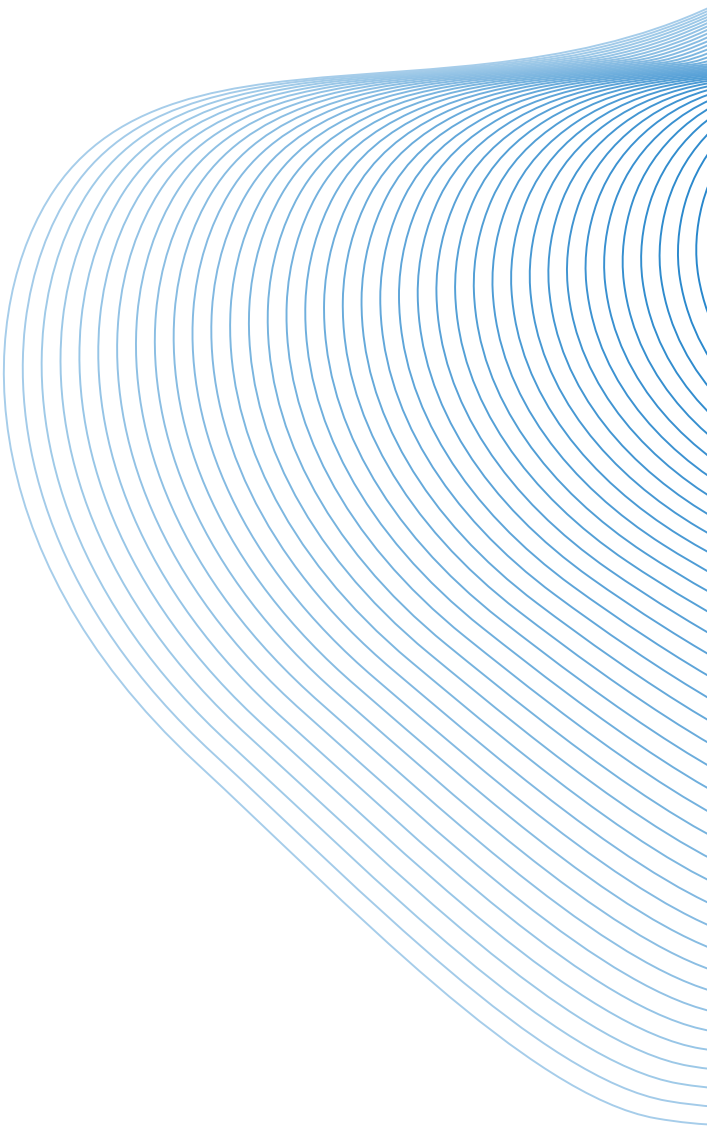
	Count	Rate
US Confirmed Malfunctions	1	0.05%
Therapy Compromised	0	0.00%
Therapy Available	1	0.05%



Years after implant	0	1	2	3	4
Total [%]	100	99.9	99.9	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.3	0.3
Malfunction-Free [%]	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	2097	1684	1239	763	358

Performance of BIOTRONIK ICDs

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

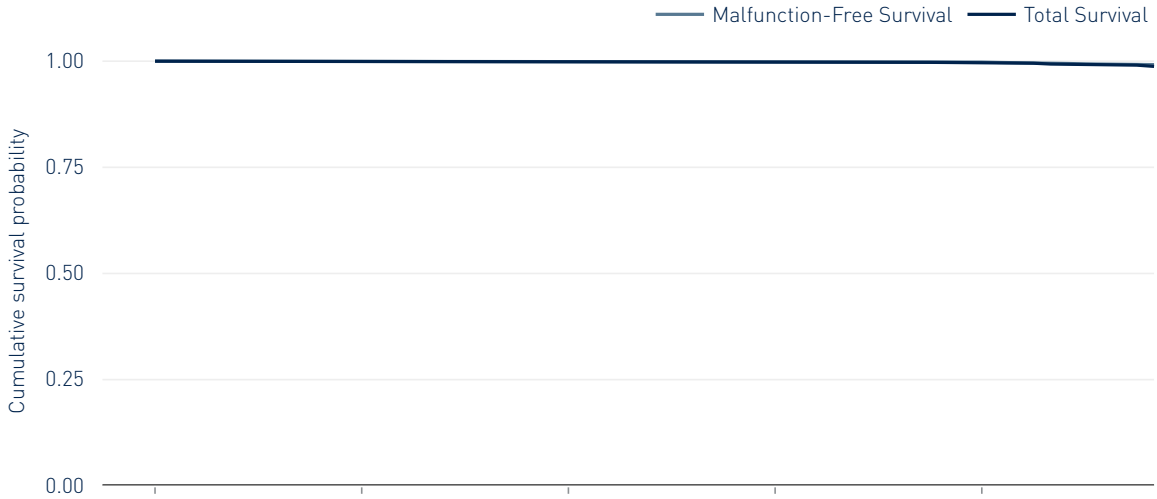


4.2 Dual-Chamber ICDs

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	26 900
Registered US Implants	20 744
Estimated Active US Implants	17 800
US Normal Battery Depletions	17

	Count	Rate
US Confirmed Malfunctions	29	0.14%
Therapy Compromised	12	0.06%
Therapy Available	17	0.08%



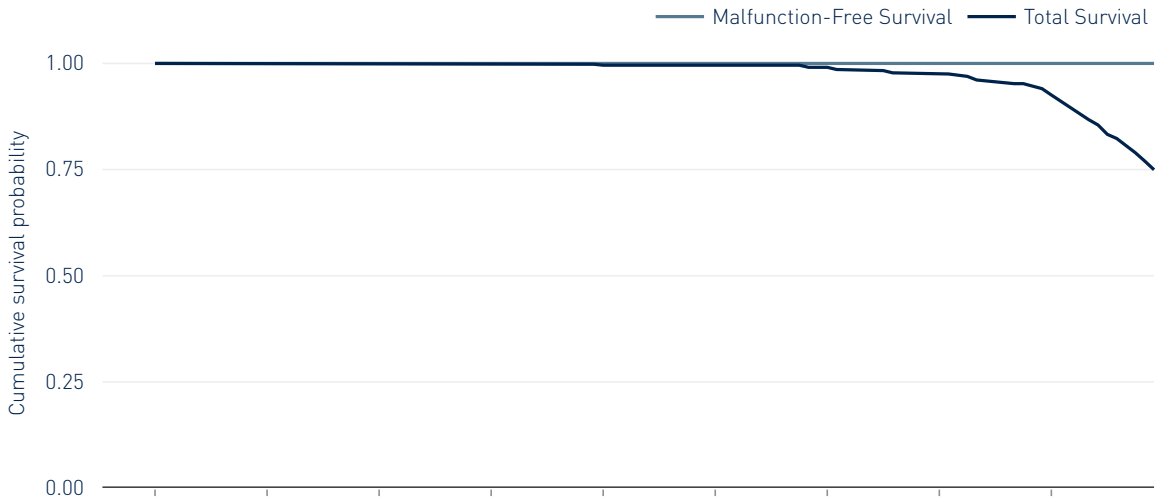
Years after implant	0	1	2	3	4
Total [%]	100	100	99.9	99.8	99.7
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	99.9	99.9	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1
Sample Size	20.7k	15.5k	10.8k	6518	2644

4.2 Dual-Chamber ICDs

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	2 000
Registered US Implants	614
Estimated Active US Implants	181
US Normal Battery Depletions	142

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	100	99.8	99.6	99.6	99.1	97.5	92.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.9	1.5	2.7
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	614	564	532	489	455	425	389	355	315

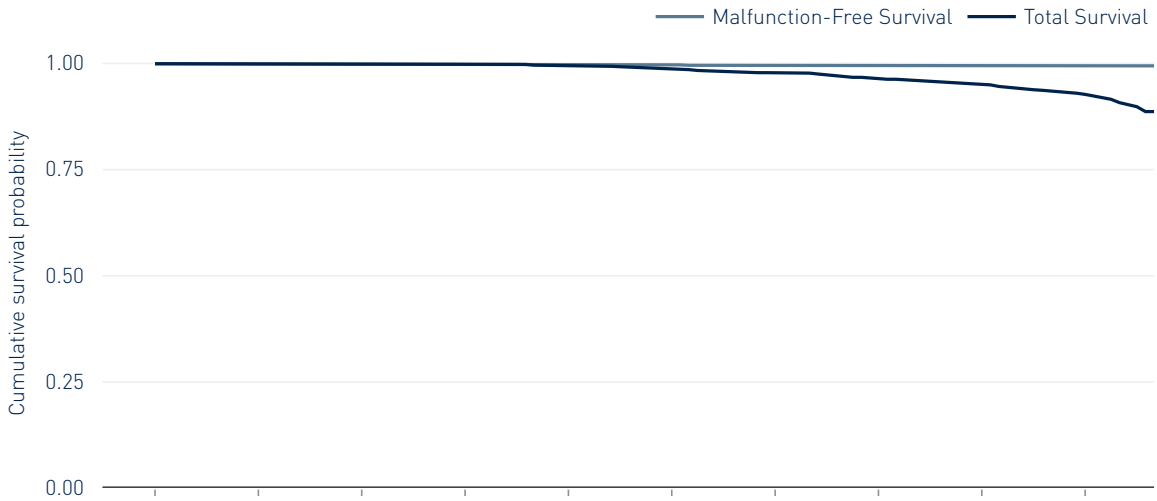
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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	4 780
Registered US Implants	1 460
Estimated Active US Implants	683
US Normal Battery Depletions	82

	Count	Rate
US Confirmed Malfunctions	6	0.41%
Therapy Compromised	4	0.27%
Therapy Available	2	0.14%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	99.9	99.9	99.9	99.9	99.5	98.9	97.8	96.4	95.3	92.7
CI [± %]	0.1	0.1	0.2	0.2	0.4	0.6	0.9	1.2	1.3	1.7
Malfunction-Free [%]	99.9	99.9	99.9	99.9	99.9	99.7	99.6	99.6	99.6	99.4
CI [± %]	0.1	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4	0.5
Sample Size	1460	1361	1277	1189	1099	1010	924	846	776	650

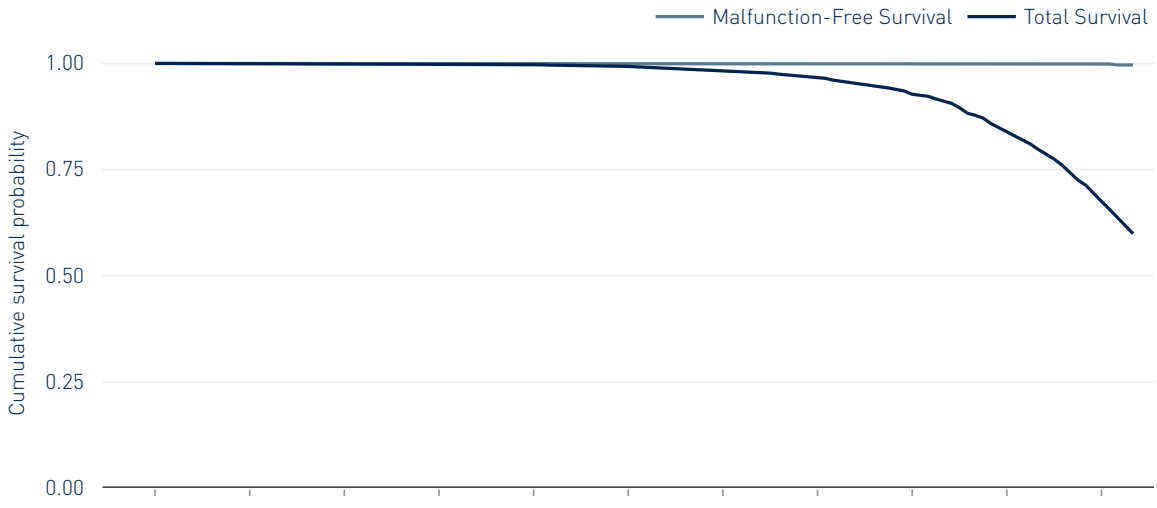
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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	5 110
Registered US Implants	3 486
Estimated Active US Implants	1 180
US Normal Battery Depletions	581

	Count	Rate
US Confirmed Malfunctions	5	0.14%
Therapy Compromised	4	0.11%
Therapy Available	1	0.03%



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.9	99.9	99.8	99.7	99.3	98.2	96.7	92.7	84.1	67.5
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.5	0.7	1.1	1.6	2.4
Malfunction-Free [%]	100	100	100	100	100	100	100	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	0.2	0.2	0.2
Sample Size	3486	3224	3007	2798	2602	2406	2226	2023	1820	1441	617

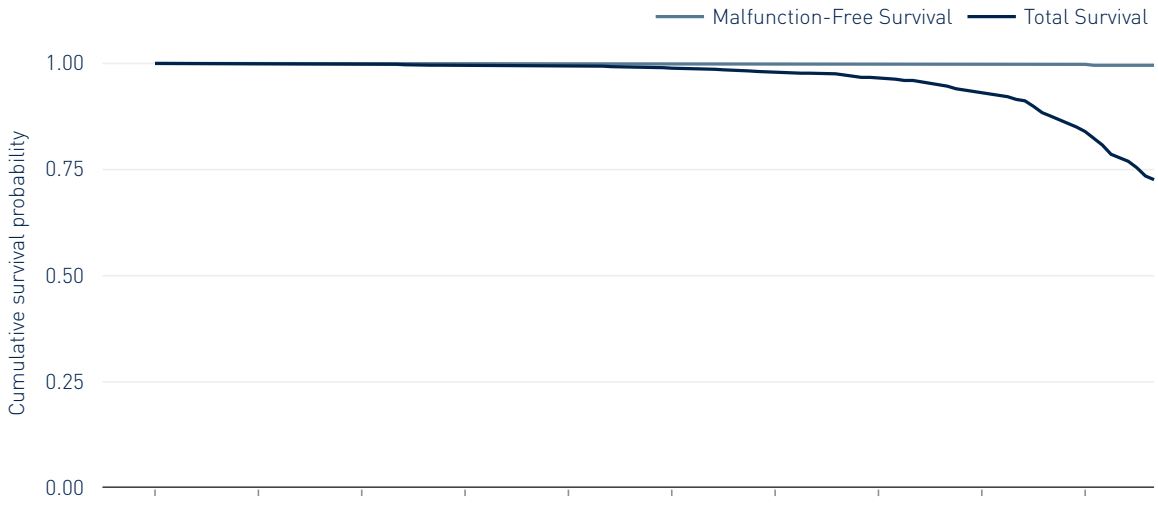
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	1 147
Estimated Active US Implants	467
US Normal Battery Depletions	171

	Count	Rate
US Confirmed Malfunctions	3	0.26%
Therapy Compromised	1	0.09%
Therapy Available	2	0.17%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	100	99.9	99.6	99.5	98.9	98.0	96.4	93.0	84.0
CI [± %]	< 0.1	< 0.1	0.2	0.4	0.5	0.7	1.0	1.3	1.9	2.8
Malfunction-Free [%]	100	100	100	99.9	99.8	99.8	99.8	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	0.2	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	1147	1062	992	922	863	804	736	673	600	476

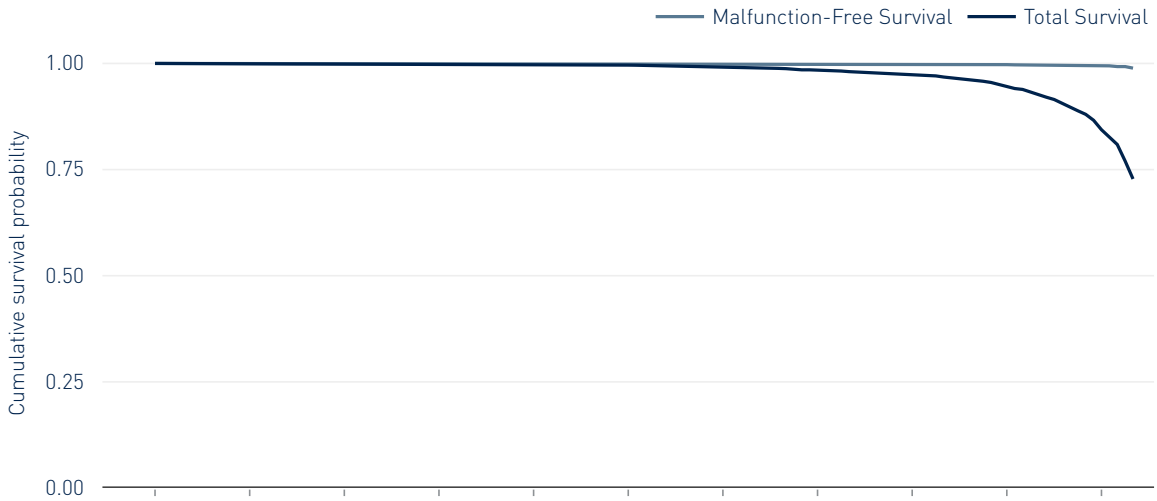
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	4 720
Estimated Active US Implants	1 920
US Normal Battery Depletions	455

	Count	Rate
US Confirmed Malfunctions	20	0.42%
Therapy Compromised	15	0.32%
Therapy Available	5	0.11%



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.9	99.9	99.8	99.8	99.6	99.1	98.5	97.4	94.6	84.4
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.2	0.3	0.4	0.6	0.9	1.7
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9	99.8	99.7	99.7	99.6
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3
Sample Size	4720	4376	4105	3845	3574	3324	3076	2822	2591	2265	893

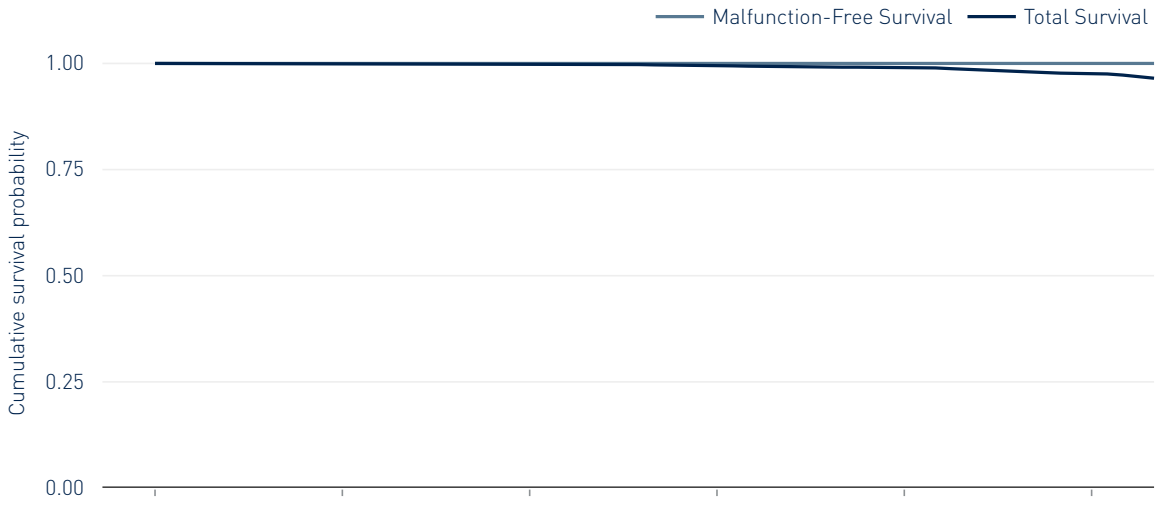
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

Ilivia 7*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	3 540
Registered US Implants	1 628
Estimated Active US Implants	1 150
US Normal Battery Depletions	7

	Count	Rate
US 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	99.9	99.8	99.4	99.0	97.5
CI [± %]	< 0.1	0.2	0.2	0.4	0.5	1.0
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1628	1499	1411	1305	1183	518

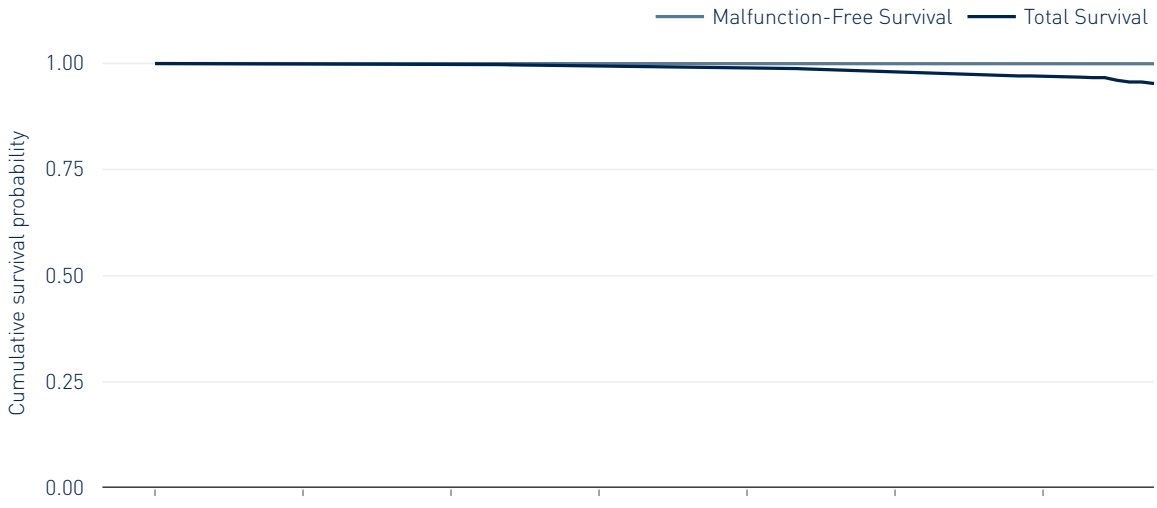
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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	8 580
Registered US Implants	3 993
Estimated Active US Implants	2 590
US Normal Battery Depletions	65

	Count	Rate
US Confirmed Malfunctions	3	0.08%
Therapy Compromised	3	0.08%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.9	99.8	99.4	99.0	98.0	97.1
CI [± %]	< 0.1	0.1	0.1	0.2	0.3	0.5	0.6
Malfunction-Free [%]	100	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	3993	3692	3446	3204	2961	2447	1345

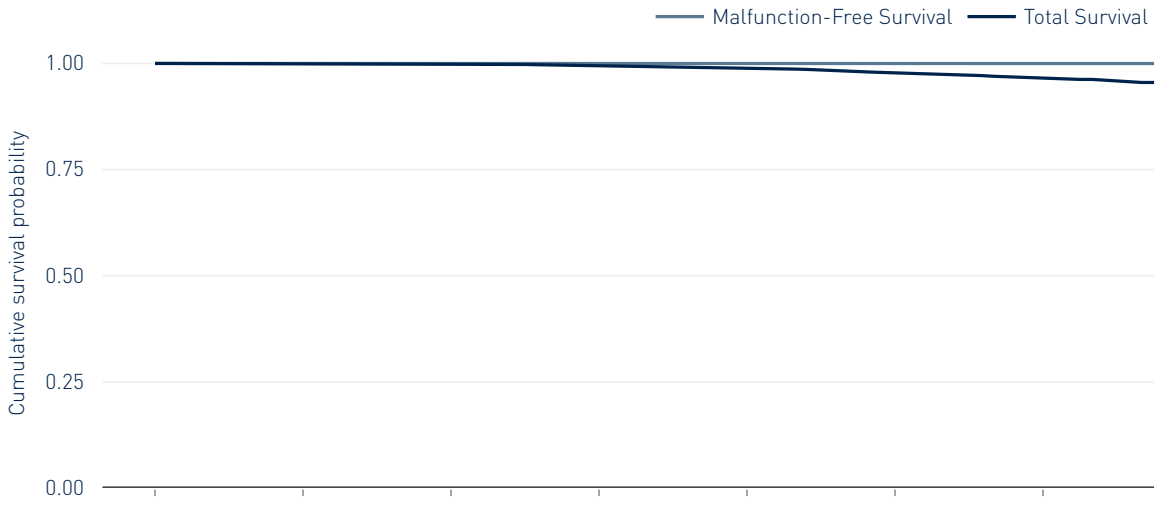
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

Intica 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 850
Registered US Implants	4 628
Estimated Active US Implants	2 980
US Normal Battery Depletions	53

	Count	Rate
US Confirmed Malfunctions	1	0.02%
Therapy Compromised	1	0.02%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	100	99.9	99.6	99.0	97.8	96.5
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.3	0.5	0.7
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	4628	4296	4022	3756	3478	2903	1603

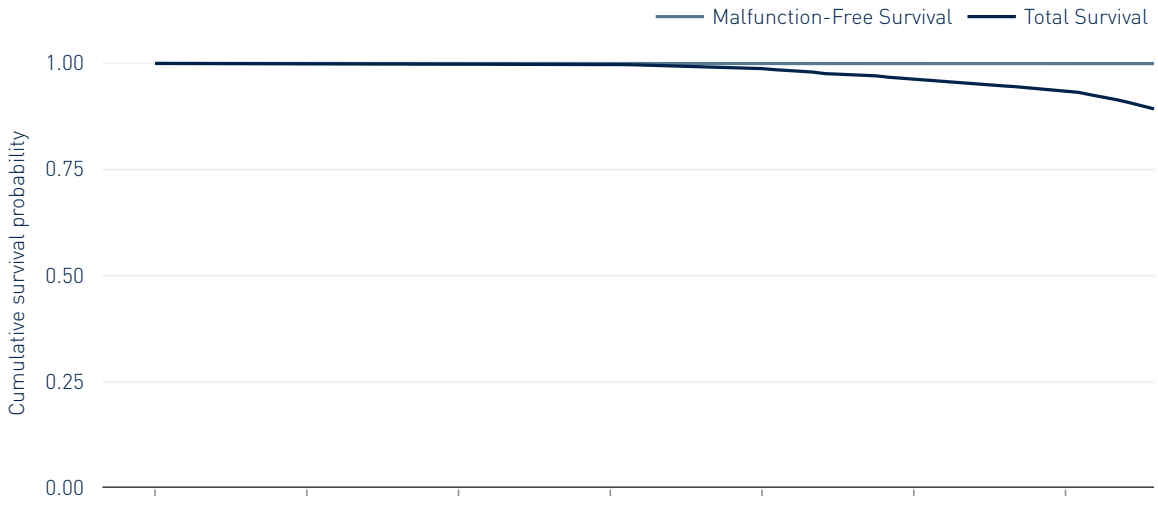
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	5 451
Estimated Active US Implants	3 090
US Normal Battery Depletions	127

	Count	Rate
US 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
Total [%]	100	100	99.9	99.8	98.8	96.1	93.4
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.3	0.7	1.0
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1
Sample Size	5451	5048	4719	4238	3597	2366	1032

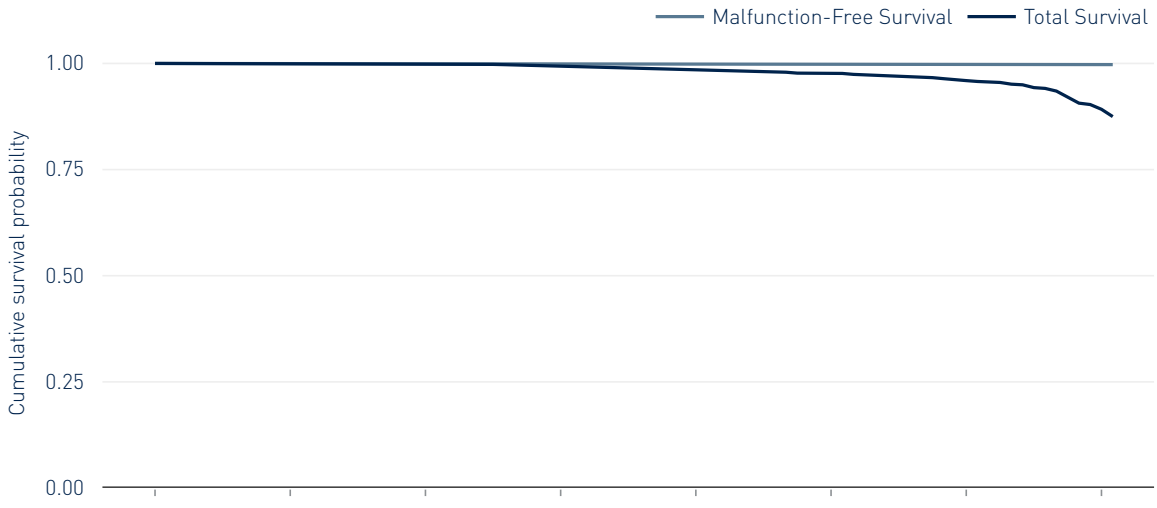
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	1 965
Estimated Active US Implants	1 140
US Normal Battery Depletions	112

	Count	Rate
US Confirmed Malfunctions	2	0.10%
Therapy Compromised	1	0.05%
Therapy Available	1	0.05%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.9	99.4	98.5	97.6	96.0	89.2
CI [± %]	< 0.1	0.1	0.2	0.4	0.6	0.8	1.0	2.6
Malfunction-Free [%]	100	99.9	99.9	99.9	99.9	99.9	99.9	99.7
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Sample Size	1965	1824	1706	1585	1461	1344	1046	241

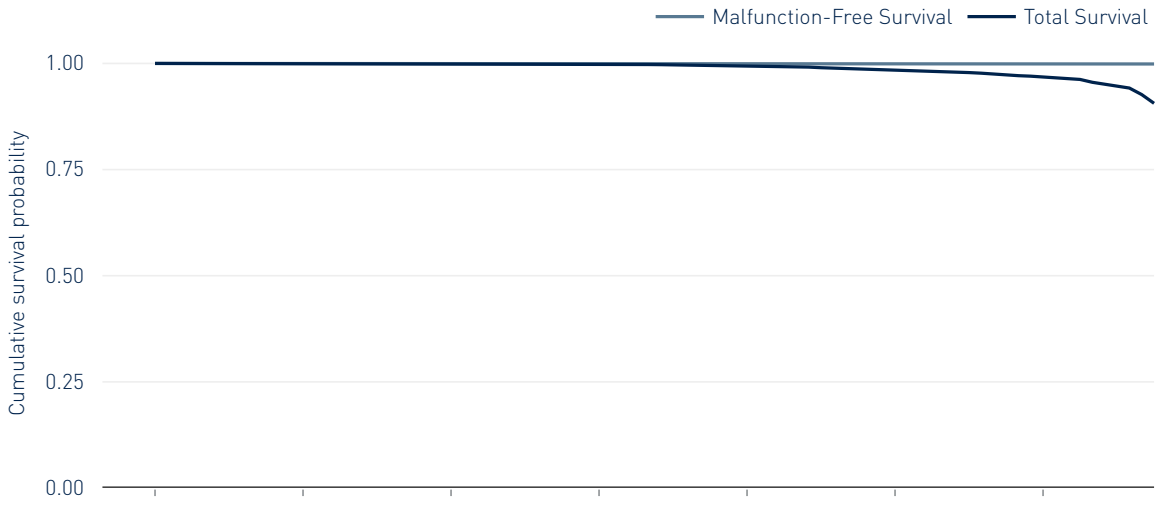
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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	7 510
Registered US Implants	4 110
Estimated Active US Implants	2 040
US Normal Battery Depletions	432

	Count	Rate
US Confirmed Malfunctions	6	0.15%
Therapy Compromised	2	0.05%
Therapy Available	4	0.10%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.9	99.9	99.8	99.4	98.5	96.8
CI [± %]	< 0.1	0.1	0.1	0.1	0.3	0.5	0.7
Malfunction-Free [%]	100	100	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	4110	3802	3531	3293	2966	2445	1561

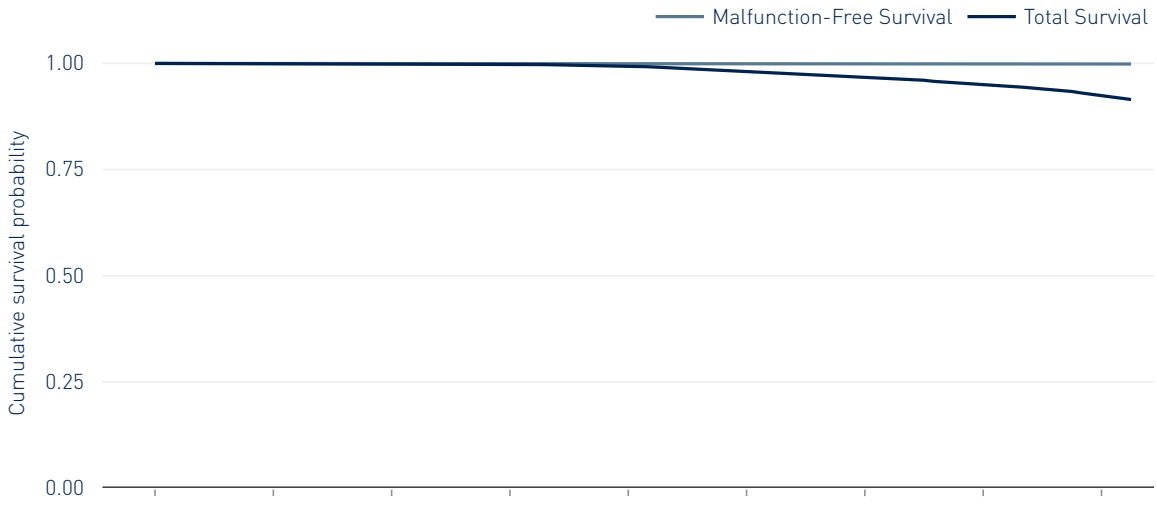
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	4 835
Estimated Active US Implants	2 830
US Normal Battery Depletions	121

	Count	Rate
US Confirmed Malfunctions	3	0.06%
Therapy Compromised	2	0.04%
Therapy Available	1	0.02%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	100	99.8	99.4	98.0	96.7	95.0	92.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.2	0.5	0.6	0.8	1.1
Malfunction-Free [%]	100	100	100	100	100	100	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.2
Sample Size	4835	4507	4225	3949	3688	3391	2907	2214	710

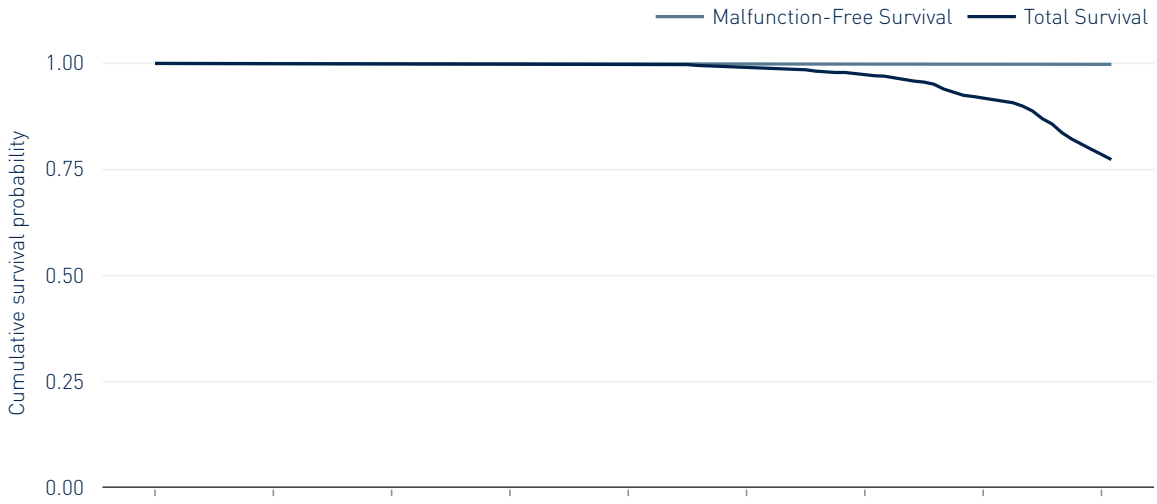
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	1 416
Estimated Active US Implants	689
US Normal Battery Depletions	139

	Count	Rate
US Confirmed Malfunctions	2	0.14%
Therapy Compromised	2	0.14%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	100	100	99.7	99.1	97.4	91.8	78.6
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.6	1.0	1.9	3.6
Malfunction-Free [%]	100	100	100	100	99.9	99.9	99.9	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.2	0.2	0.3	0.3
Sample Size	1416	1306	1214	1132	1052	978	893	608	248

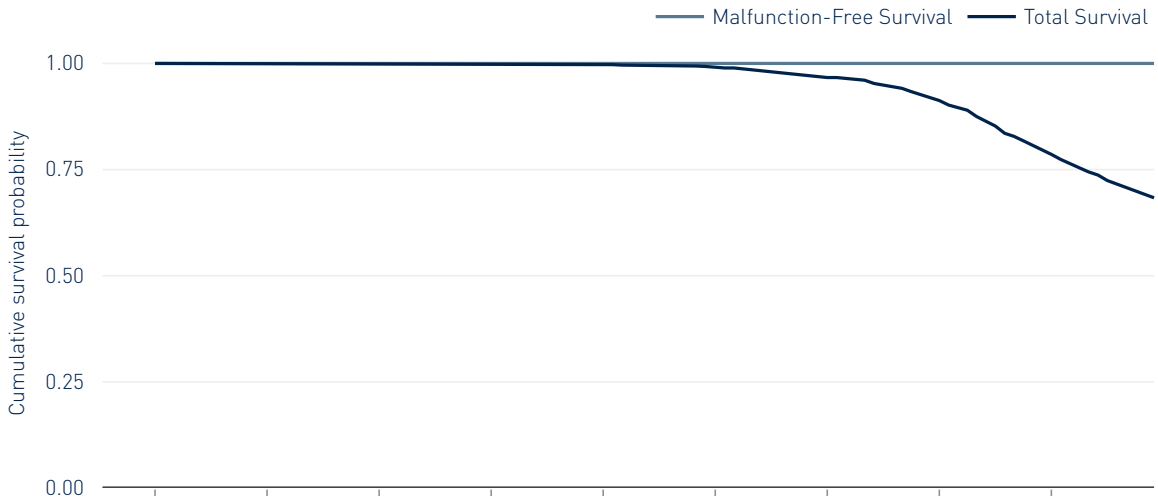
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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	2 340
Registered US Implants	1 268
Estimated Active US Implants	540
US Normal Battery Depletions	203

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.8	99.7	99.1	96.7	91.3	78.6
CI [± %]	< 0.1	< 0.1	0.2	0.3	0.3	0.6	1.2	2.0	3.0
Malfunction-Free [%]	100	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1268	1173	1086	1010	938	876	790	700	484

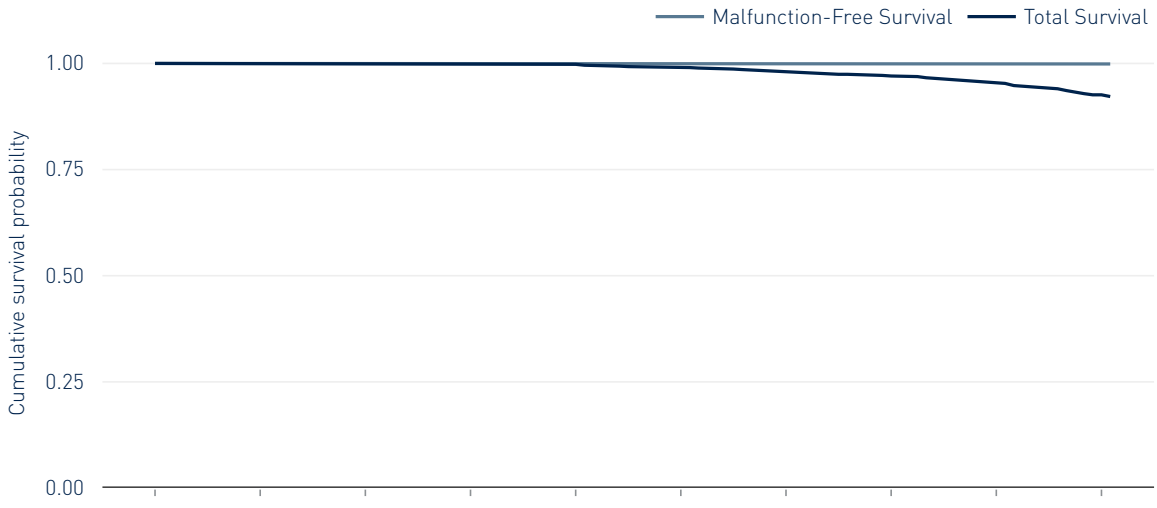
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	1 247
Estimated Active US Implants	646
US Normal Battery Depletions	41

	Count	Rate
US Confirmed Malfunctions	1	0.08%
Therapy Compromised	1	0.08%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	100	100	100	99.8	99.0	98.2	97.0	95.5	92.6
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.6	0.9	1.1	1.5	2.1
Malfunction-Free [%]	100	100	100	100	100	100	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.2	0.2	0.2
Sample Size	1247	1154	1078	1008	943	869	799	721	604	269

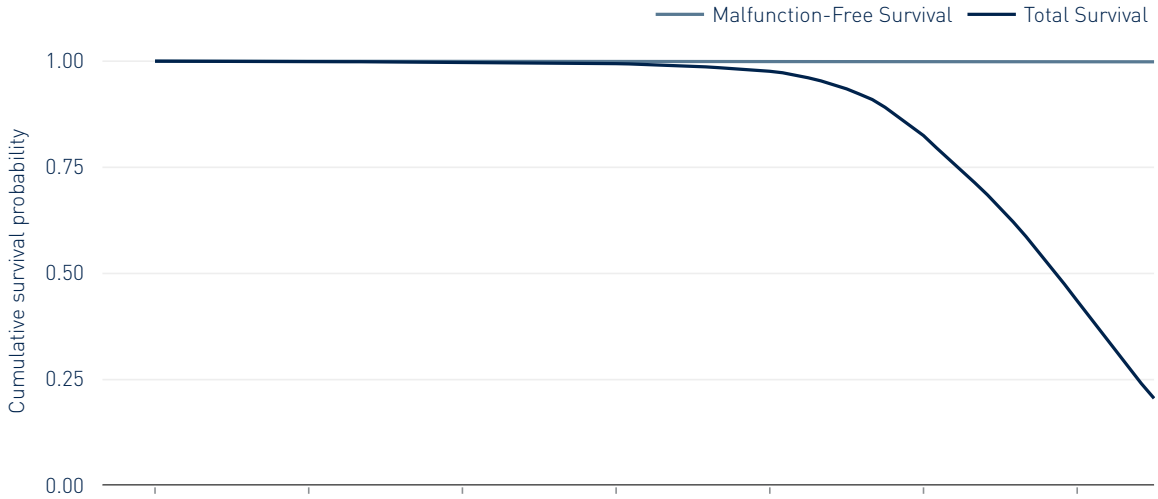
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

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 US Implants	8 219
Estimated Active US Implants	1 410
US Normal Battery Depletions	2 159

	Count	Rate
US Confirmed Malfunctions	10	0.12%
Therapy Compromised	8	0.10%
Therapy Available	2	0.02%



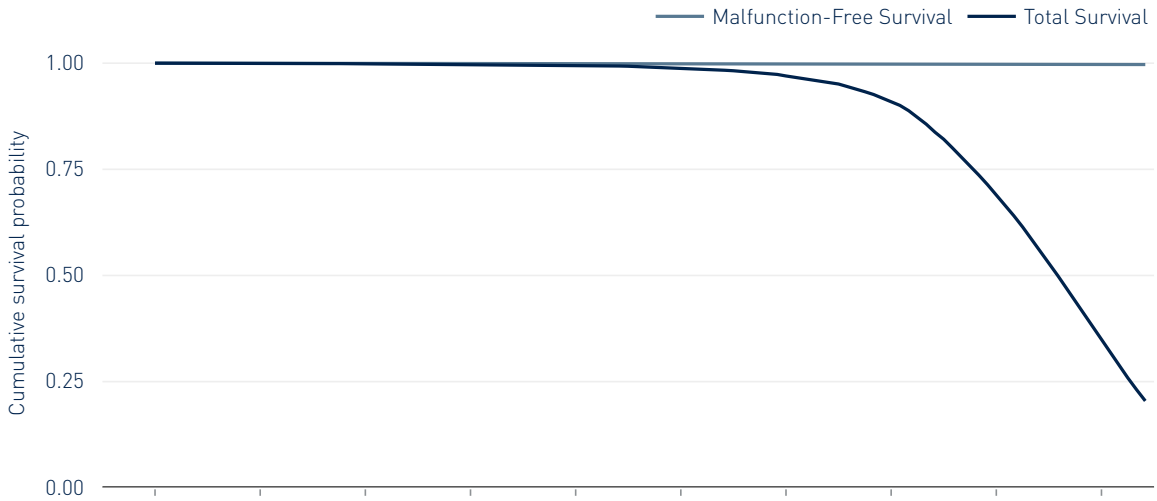
Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.9	99.8	99.4	97.6	82.5	43.5
CI [± %]	< 0.1	0.1	0.1	0.2	0.4	1.0	1.6
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.8	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8219	7531	7031	6491	5921	4403	1808

4.2 Dual-Chamber ICDs

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 US Implants	11 511
Estimated Active US Implants	2 570
US Normal Battery Depletions	2 936

	Count	Rate
US Confirmed Malfunctions	24	0.21%
Therapy Compromised	14	0.12%
Therapy Available	10	0.09%



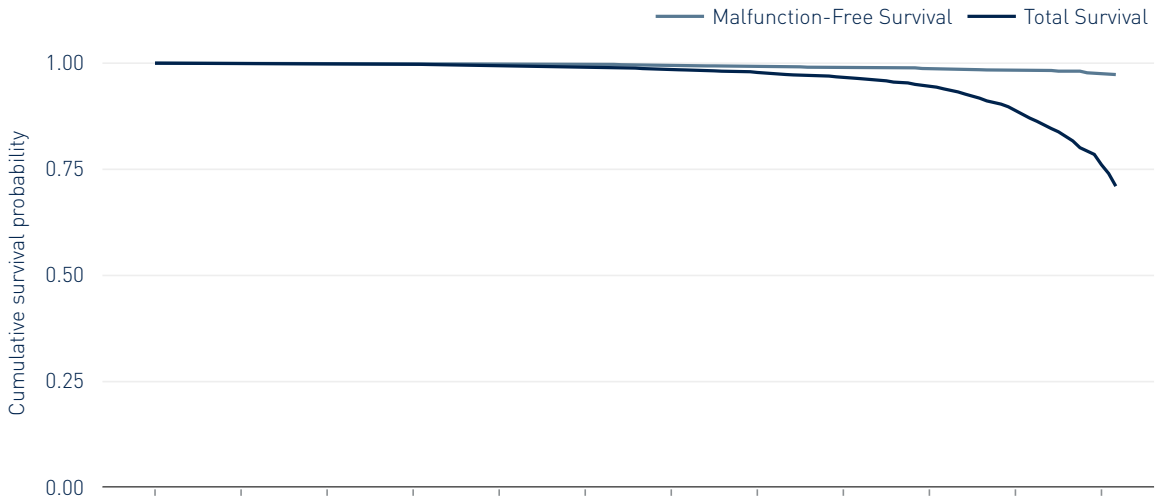
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.9	99.9	99.8	99.5	98.8	97.0	91.0	69.0	34.7
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.4	0.7	1.1	1.4
Malfunction-Free [%]	100	100	100	99.9	99.9	99.8	99.8	99.8	99.8	99.7
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	11.5k	10.7k	9939	9258	8590	7952	7288	6344	4411	1873

4.2 Dual-Chamber ICDs

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 US Implants	3 813
Estimated Active US Implants	1 360
US Normal Battery Depletions	515

	Count	Rate
US Confirmed Malfunctions	51	1.34%
Therapy Compromised	39	1.02%
Therapy Available	12	0.31%



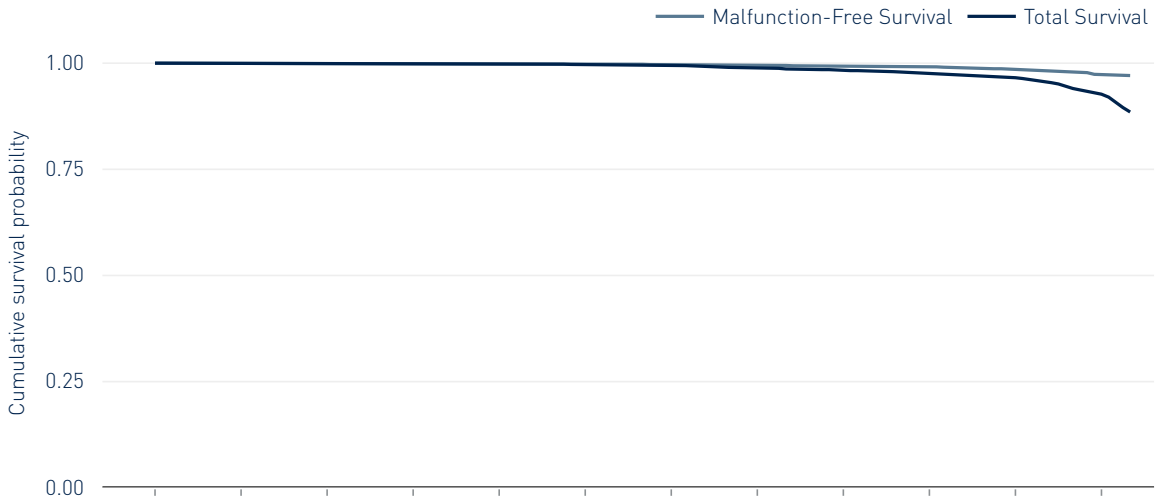
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	99.9	99.7	99.6	99.3	98.5	97.8	96.7	94.7	88.8	76.1
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.2	0.3	0.5	0.6	0.7	0.9	1.4	2.3
Malfunction-Free [%]	100	100	100	100	99.9	99.8	99.4	99.3	99.0	98.7	98.3	97.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.3	0.3	0.4	0.5	0.5	0.8
Sample Size	3813	3546	3311	3073	2861	2649	2446	2262	2086	1889	1569	515

4.2 Dual-Chamber ICDs

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 US Implants	2 223
Estimated Active US Implants	993
US Normal Battery Depletions	106

	Count	Rate
US Confirmed Malfunctions	30	1.35%
Therapy Compromised	24	1.08%
Therapy Available	6	0.27%



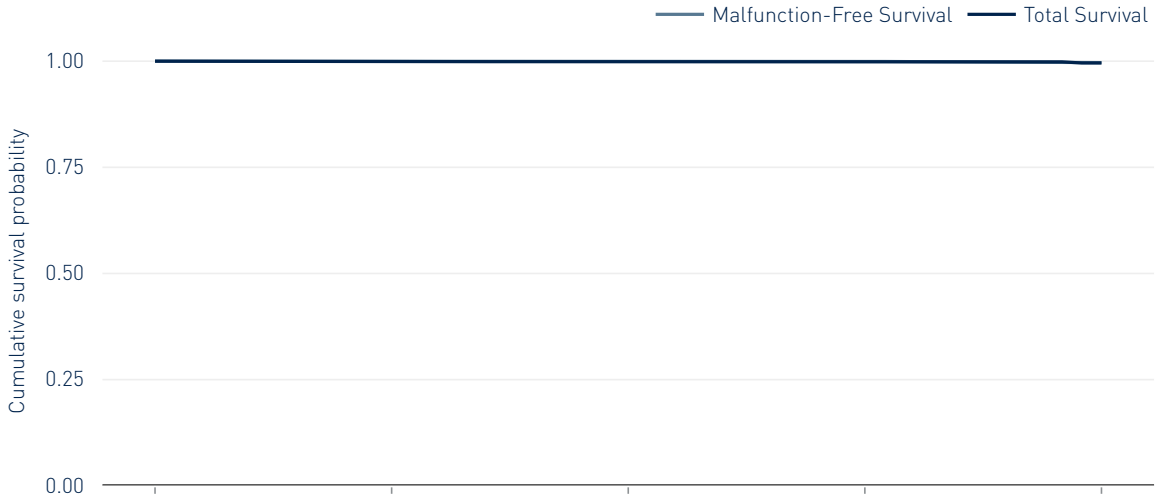
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	100	99.9	99.9	99.7	99.4	98.9	98.2	97.7	96.6	92.7
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.2	0.3	0.4	0.5	0.7	0.8	1.0	1.6
Malfunction-Free [%]	100	100	100	100	100	99.9	99.6	99.5	99.4	99.1	98.6	97.4
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.5	0.7	1.0
Sample Size	2223	2064	1927	1792	1675	1555	1449	1349	1242	1148	1027	696

4.2 Dual-Chamber ICDs

Rivacor 7

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	21 400
Registered US Implants	11 899
Estimated Active US Implants	10 100
US Normal Battery Depletions	11

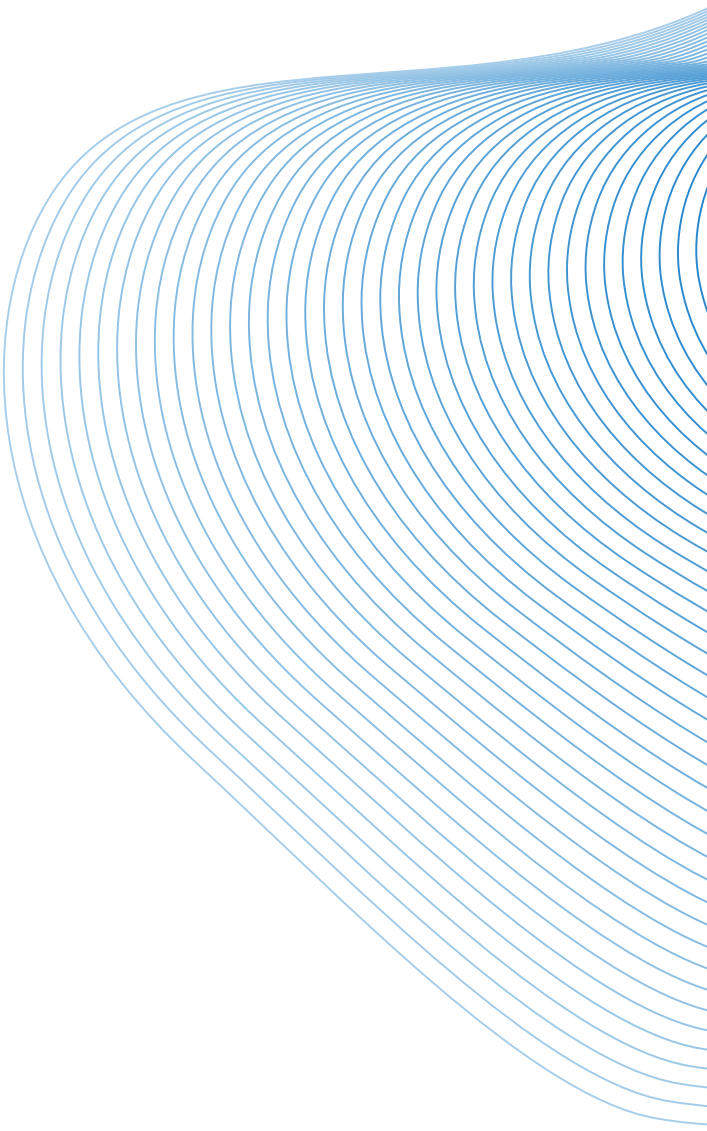
	Count	Rate
US Confirmed Malfunctions	8	0.07%
Therapy Compromised	5	0.04%
Therapy Available	3	0.03%



Years after implant	0	1	2	3	4
Total [%]	100	99.9	99.8	99.8	99.6
CI [± %]	< 0.1	0.1	0.1	0.1	0.5
Malfunction-Free [%]	100	100	99.9	99.9	99.7
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.5
Sample Size	9467	6635	4091	1862	255

Performance of BIOTRONIK ICDs

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

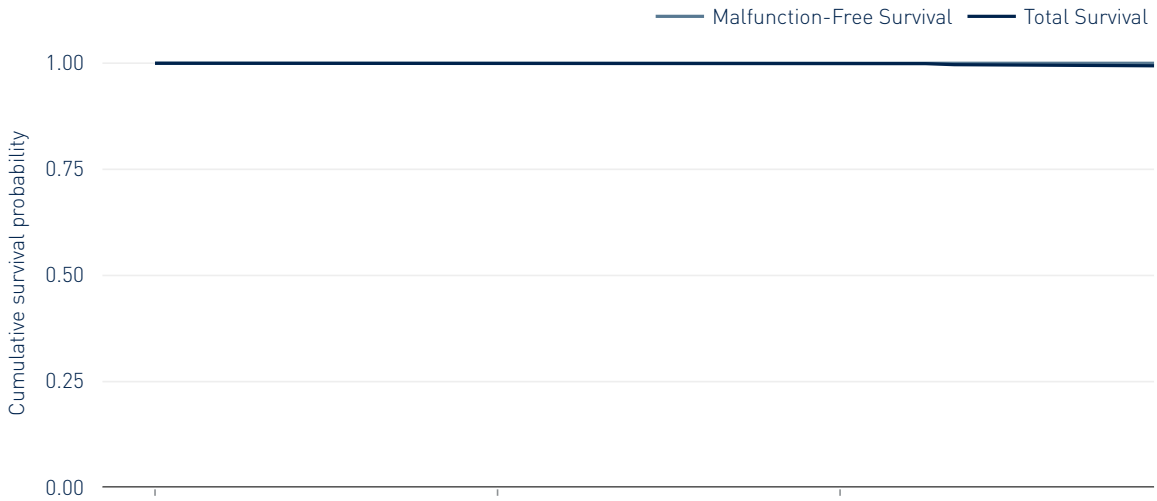


4.3 CRT ICDs

Acticor 7

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	26 500
Registered US Implants	7 370
Estimated Active US Implants	5 820
US Normal Battery Depletions	25

	Count	Rate
US Confirmed Malfunctions	6	0.08%
Therapy Compromised	3	0.04%
Therapy Available	3	0.04%



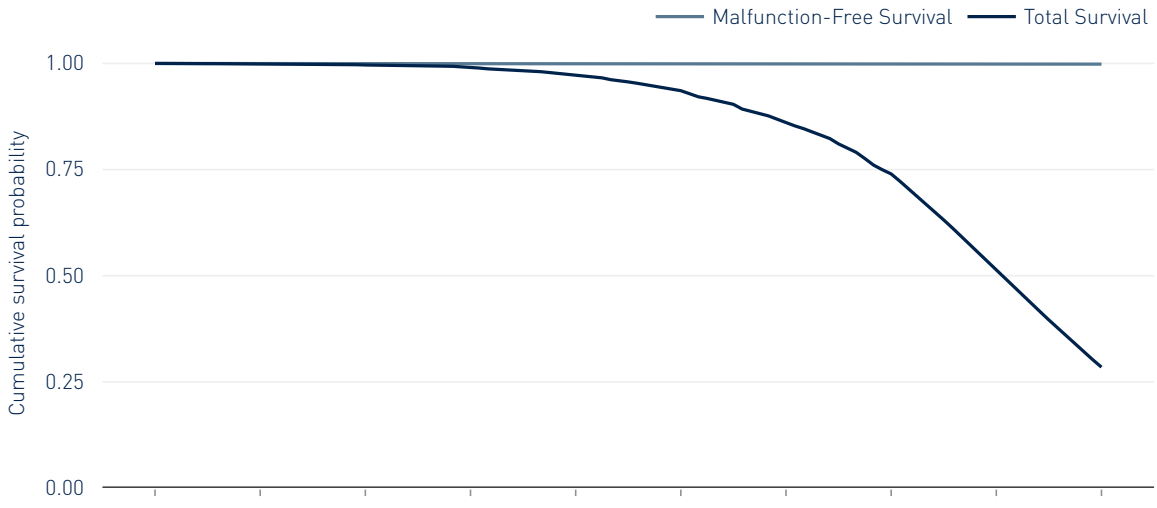
Years after implant	0	1	2
Total [%]	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1
Sample Size	4720	2753	1257

4.3 CRT ICDs

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 US Implants	3 841
Estimated Active US Implants	558
US Normal Battery Depletions	947

	Count	Rate
US Confirmed Malfunctions	4	0.10%
Therapy Compromised	2	0.05%
Therapy Available	2	0.05%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.9	99.6	99.0	97.1	93.6	85.9	74.0	51.4	28.5
CI [± %]	< 0.1	0.1	0.2	0.4	0.6	1.0	1.5	2.0	2.5	3.2
Malfunction-Free [%]	100	100	100	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	0.2	0.2	0.2	0.2
Sample Size	3841	3409	3040	2684	2343	1998	1628	1225	742	217

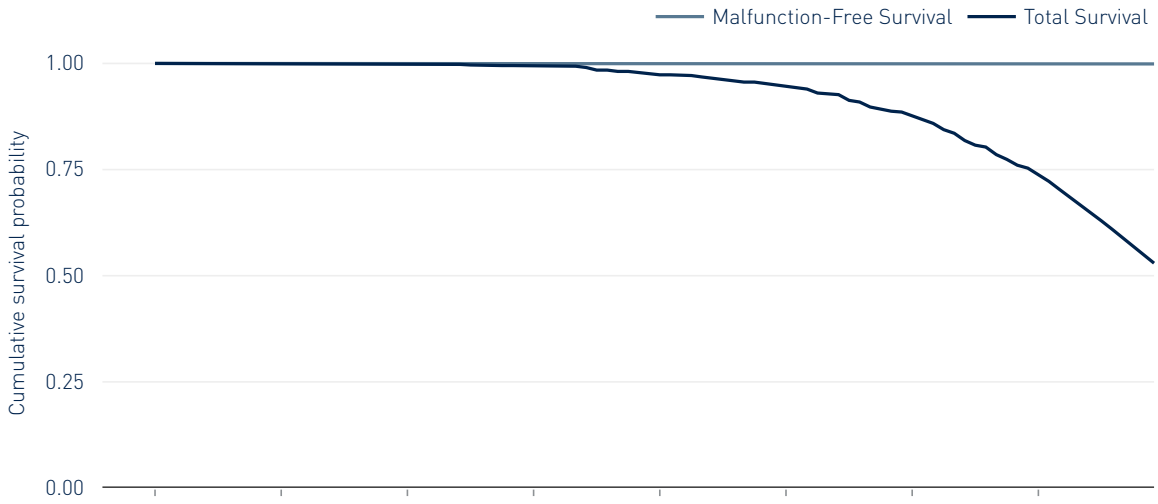
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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	2 360
Registered US Implants	969
Estimated Active US Implants	155
US Normal Battery Depletions	246

	Count	Rate
US Confirmed Malfunctions	1	0.10%
Therapy Compromised	1	0.10%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.8	99.5	97.3	94.7	87.7	73.9
CI [± %]	< 0.1	0.2	0.3	0.5	1.2	1.8	2.7	3.9
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.2	0.2	0.2	0.2	0.2	0.2
Sample Size	969	860	772	687	601	519	435	324

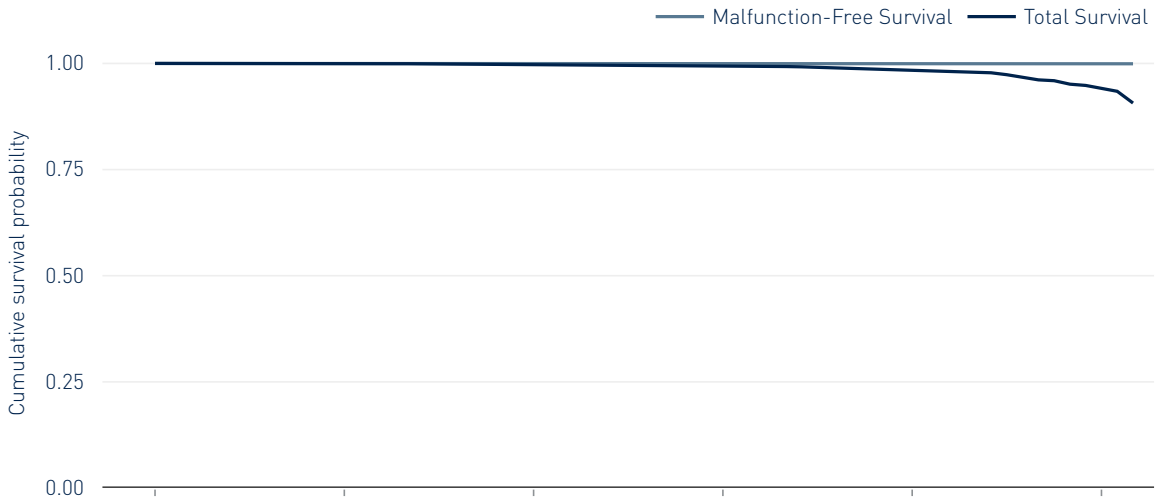
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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	9 290
Registered US Implants	4 774
Estimated Active US Implants	2 180
US Normal Battery Depletions	417

	Count	Rate
US Confirmed Malfunctions	1	0.02%
Therapy Compromised	1	0.02%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5
Total [%]	100	100	99.9	99.6	98.4	94.2
CI [± %]	< 0.1	0.1	0.1	0.2	0.5	1.3
Malfunction-Free [%]	100	100	100	100	100	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2
Sample Size	4775	4201	3757	3243	2436	491

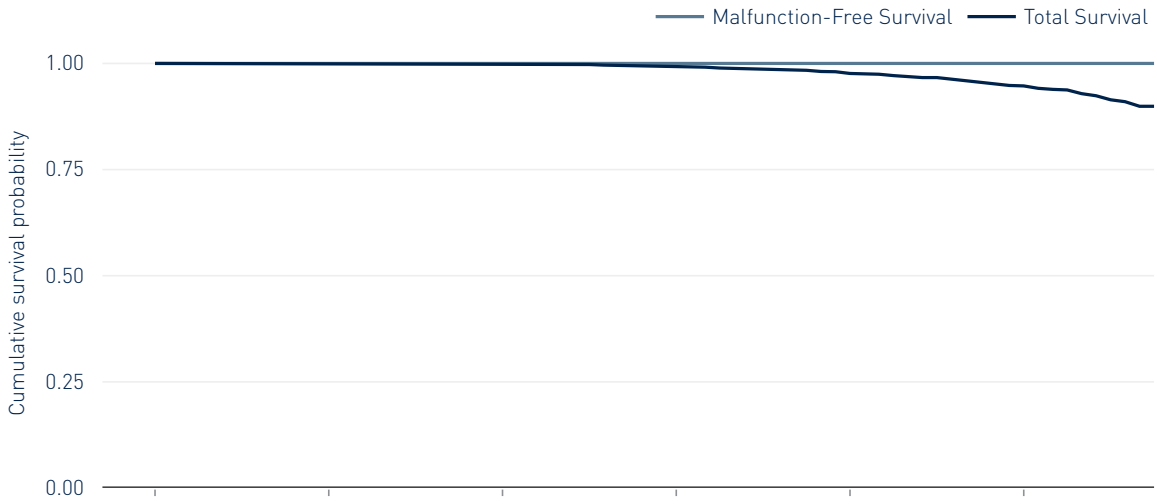
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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	5 460
Registered US Implants	2 960
Estimated Active US Implants	1 530
US Normal Battery Depletions	147

	Count	Rate
US 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	100	99.8	99.3	97.6	94.7
CI [± %]	< 0.1	0.1	0.2	0.4	0.7	1.2
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	2960	2577	2302	2040	1681	889

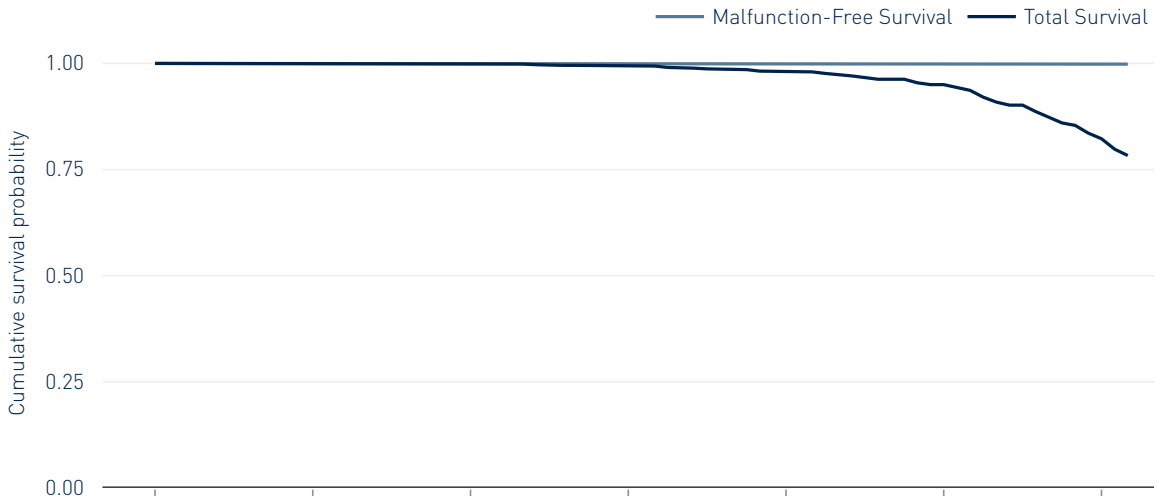
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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 US Implants	887
Estimated Active US Implants	271
US Normal Battery Depletions	170

	Count	Rate
US Confirmed Malfunctions	2	0.23%
Therapy Compromised	0	0.00%
Therapy Available	2	0.23%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	100	100	99.5	98.2	95.0	82.3
CI [± %]	< 0.1	< 0.1	< 0.1	0.5	1.1	1.8	3.7
Malfunction-Free [%]	100	100	100	100	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.3	0.3
Sample Size	887	776	697	620	546	438	255

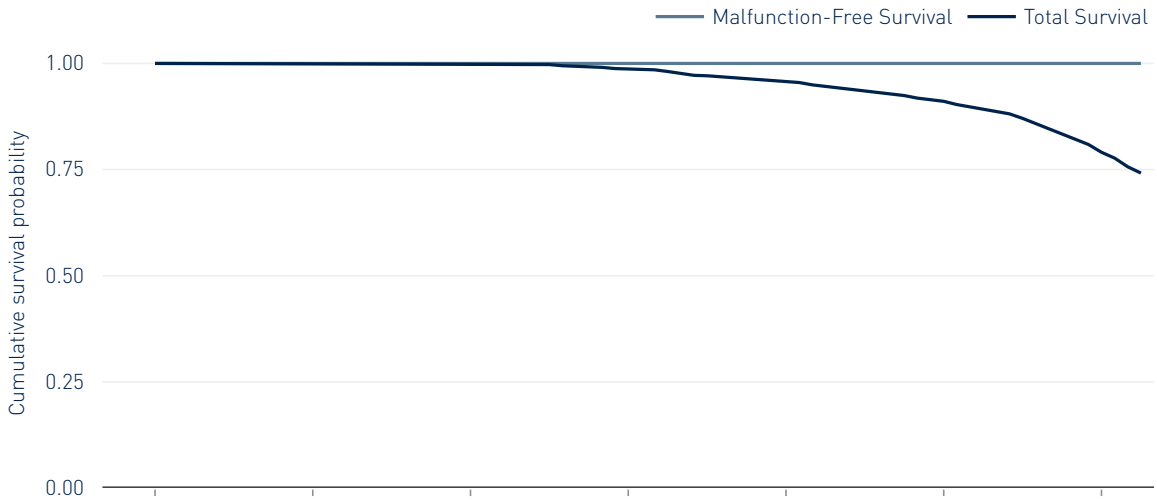
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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	3 040
Registered US Implants	1 479
Estimated Active US Implants	542
US Normal Battery Depletions	220

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	100	100	98.7	95.7	91.1	79.1
CI [± %]	< 0.1	< 0.1	< 0.1	0.7	1.3	1.8	3.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1479	1305	1160	1024	884	728	377

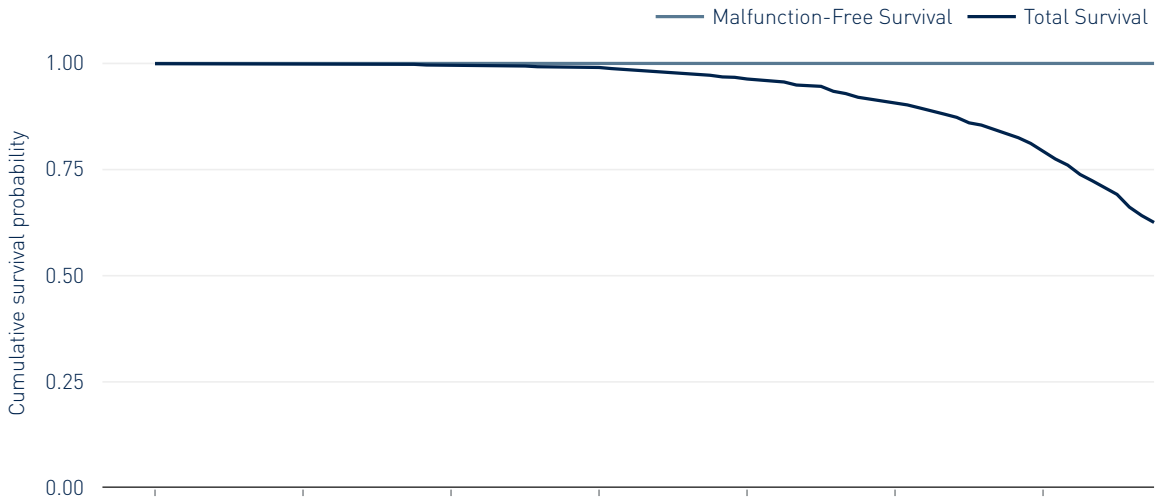
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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	5 830
Registered US Implants	1 617
Estimated Active US Implants	509
US Normal Battery Depletions	318

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3	4	5	6
Total [%]	99.9	99.9	99.6	99.1	96.3	90.6	79.2
CI [± %]	0.1	0.1	0.4	0.5	1.1	1.8	2.8
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1617	1423	1267	1132	980	802	496

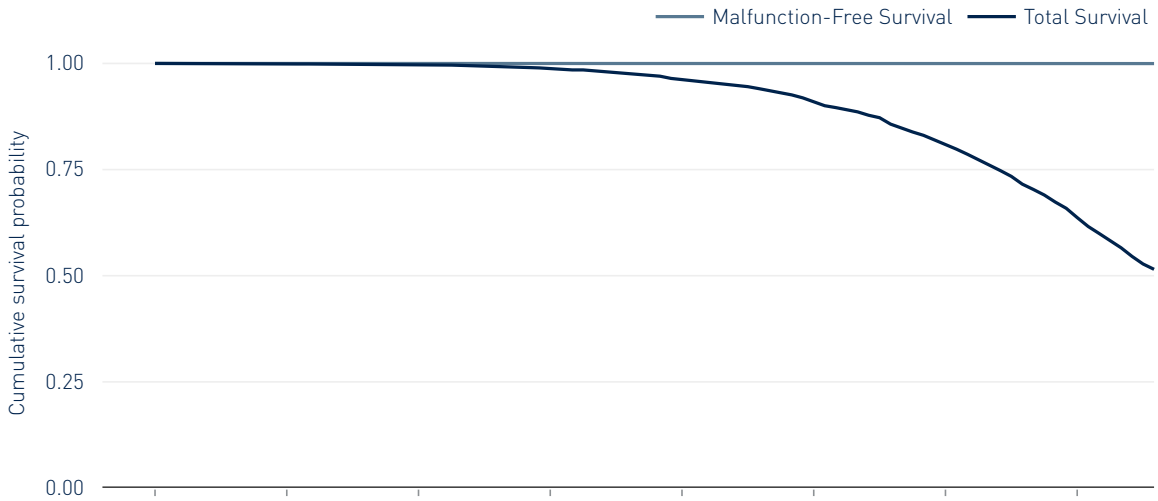
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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 US Implants	3 316
Estimated Active US Implants	872
US Normal Battery Depletions	733

	Count	Rate
US Confirmed Malfunctions	1	0.03%
Therapy Compromised	0	0.00%
Therapy Available	1	0.03%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.7	98.8	96.2	91.0	81.1	63.7
CI [± %]	< 0.1	0.1	0.2	0.4	0.8	1.2	1.8	2.5
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3316	2921	2596	2303	2000	1697	1288	633

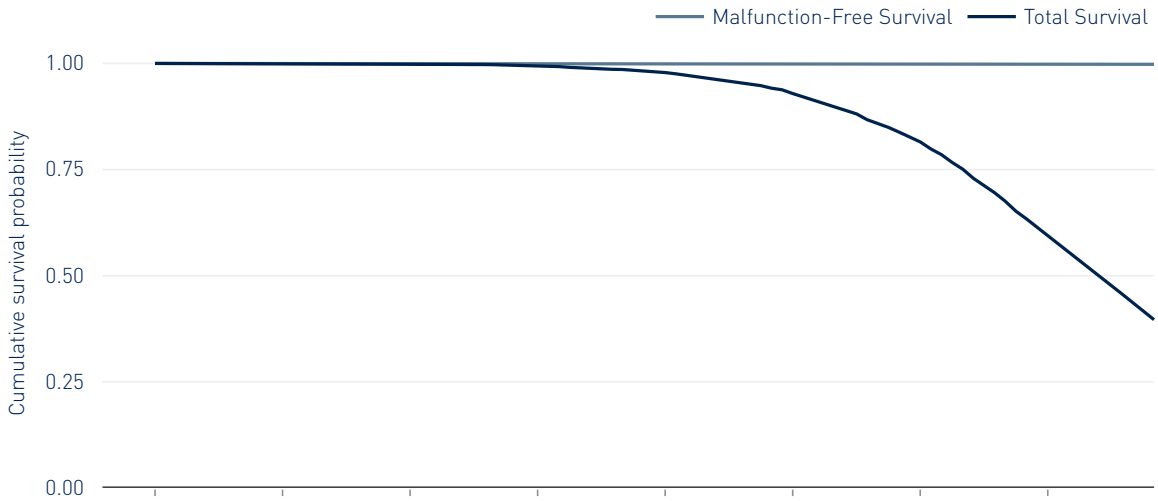
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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 US Implants	3 228
Estimated Active US Implants	619
US Normal Battery Depletions	873

	Count	Rate
US 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	100	99.9	99.4	97.8	92.9	81.5	59.5
CI [± %]	< 0.1	0.1	0.1	0.3	0.6	1.1	1.8	2.5
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.3
Sample Size	3228	2857	2557	2286	2002	1706	1313	772

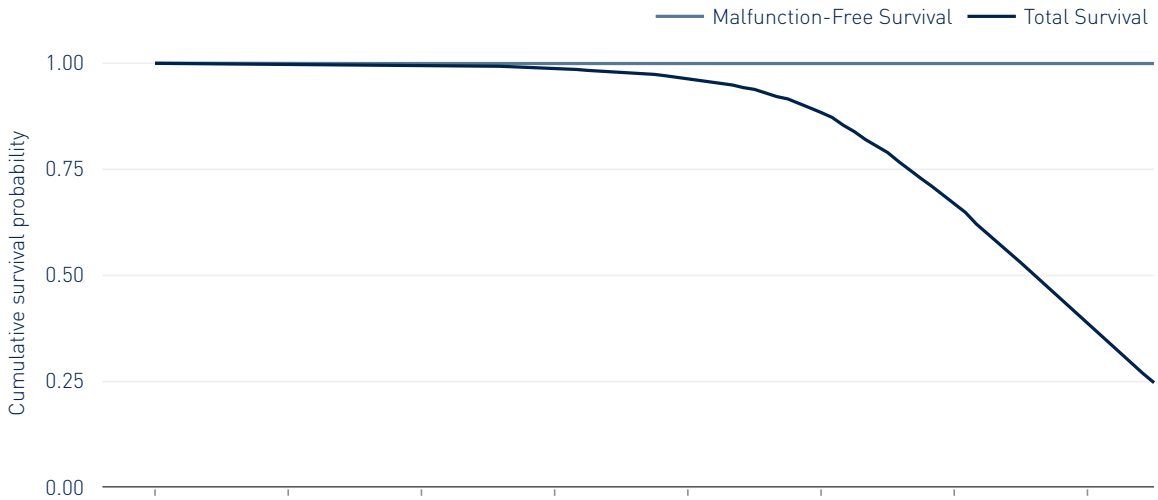
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

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 US Implants	5 310
Estimated Active US Implants	382
US Normal Battery Depletions	1 276

	Count	Rate
US Confirmed Malfunctions	4	0.08%
Therapy Compromised	2	0.04%
Therapy Available	2	0.04%



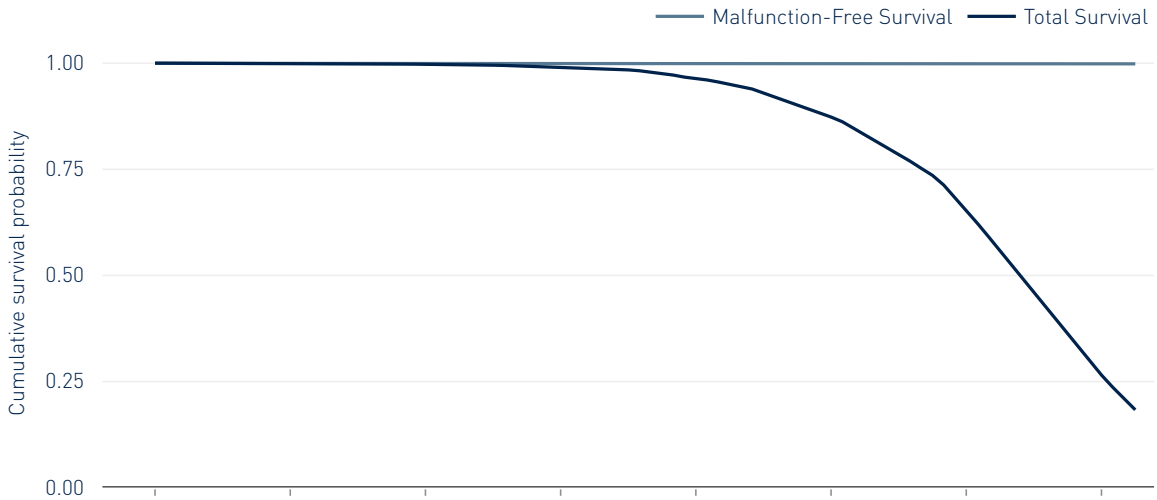
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.8	99.6	98.7	96.3	88.4	67.0	38.5
CI [± %]	0.1	0.1	0.2	0.3	0.6	1.1	1.8	2.3
Malfunction-Free [%]	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5310	4729	4232	3718	3194	2477	1504	664

4.3 CRT ICDs

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 US Implants	8 656
Estimated Active US Implants	685
US Normal Battery Depletions	2 603

	Count	Rate
US Confirmed Malfunctions	11	0.13%
Therapy Compromised	5	0.06%
Therapy Available	6	0.07%



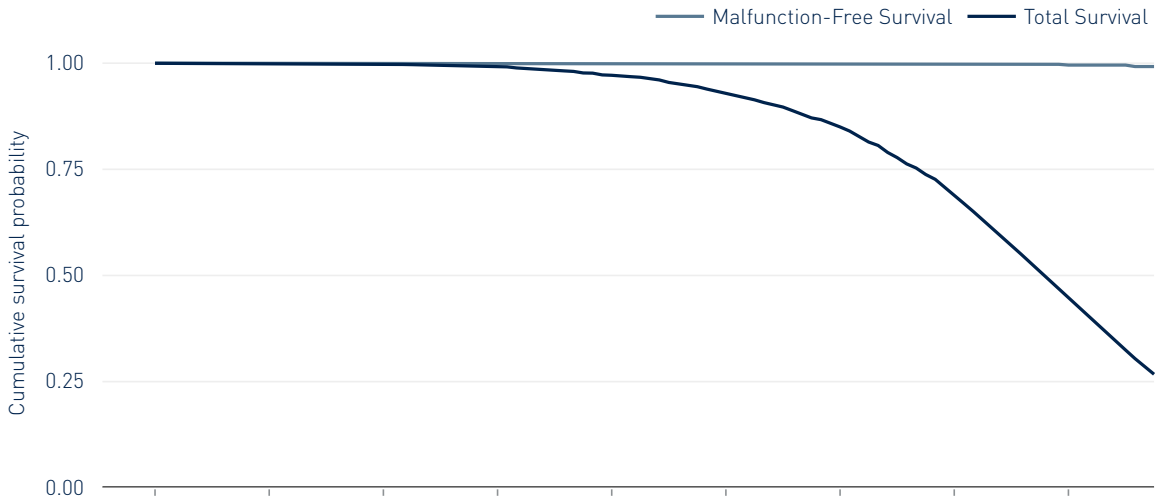
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.8	99.2	96.5	87.3	65.4	26.5
CI [± %]	< 0.1	0.1	0.1	0.2	0.5	0.9	1.4	1.9
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8656	7682	6877	6112	5278	4204	2751	724

4.3 CRT ICDs

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	7 040
Registered US Implants	3 410
Estimated Active US Implants	453
US Normal Battery Depletions	890

	Count	Rate
US Confirmed Malfunctions	8	0.23%
Therapy Compromised	6	0.18%
Therapy Available	2	0.06%



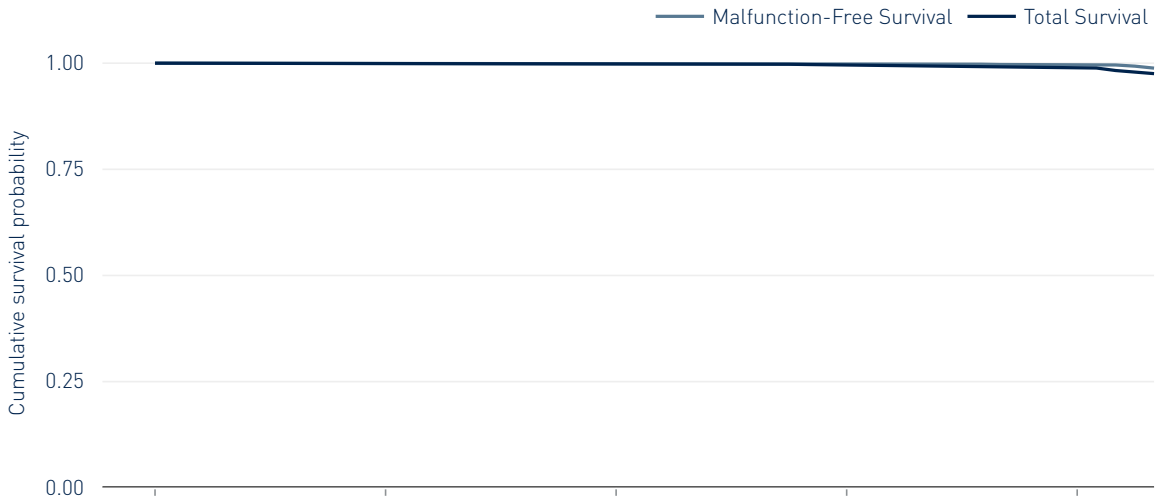
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.9	99.7	99.1	97.1	92.9	85.0	69.0	44.5
CI [± %]	0.1	0.1	0.2	0.4	0.7	1.1	1.6	2.2	2.7
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.6
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Sample Size	3410	3033	2715	2411	2111	1791	1441	1036	571

4.3 CRT ICDs

Rivacor 7

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	26 300
Registered US Implants	9 496
Estimated Active US Implants	7 230
US Normal Battery Depletions	41

	Count	Rate
US Confirmed Malfunctions	14	0.15%
Therapy Compromised	6	0.06%
Therapy Available	8	0.08%



Years after implant	0	1	2	3	4
Total [%]	100	99.9	99.9	99.6	99.0
CI [± %]	< 0.1	0.1	0.1	0.2	0.4
Malfunction-Free [%]	100	99.9	99.9	99.9	99.6
CI [± %]	< 0.1	0.1	0.1	0.1	0.3
Sample Size	9496	6857	4543	2521	738

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 US 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 cutoff date for the data included in this report is December 31, 2024. The sample sizes of US 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 US 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 Pacing 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 product, the report provides:

Product Information

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

Survival Plot

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.

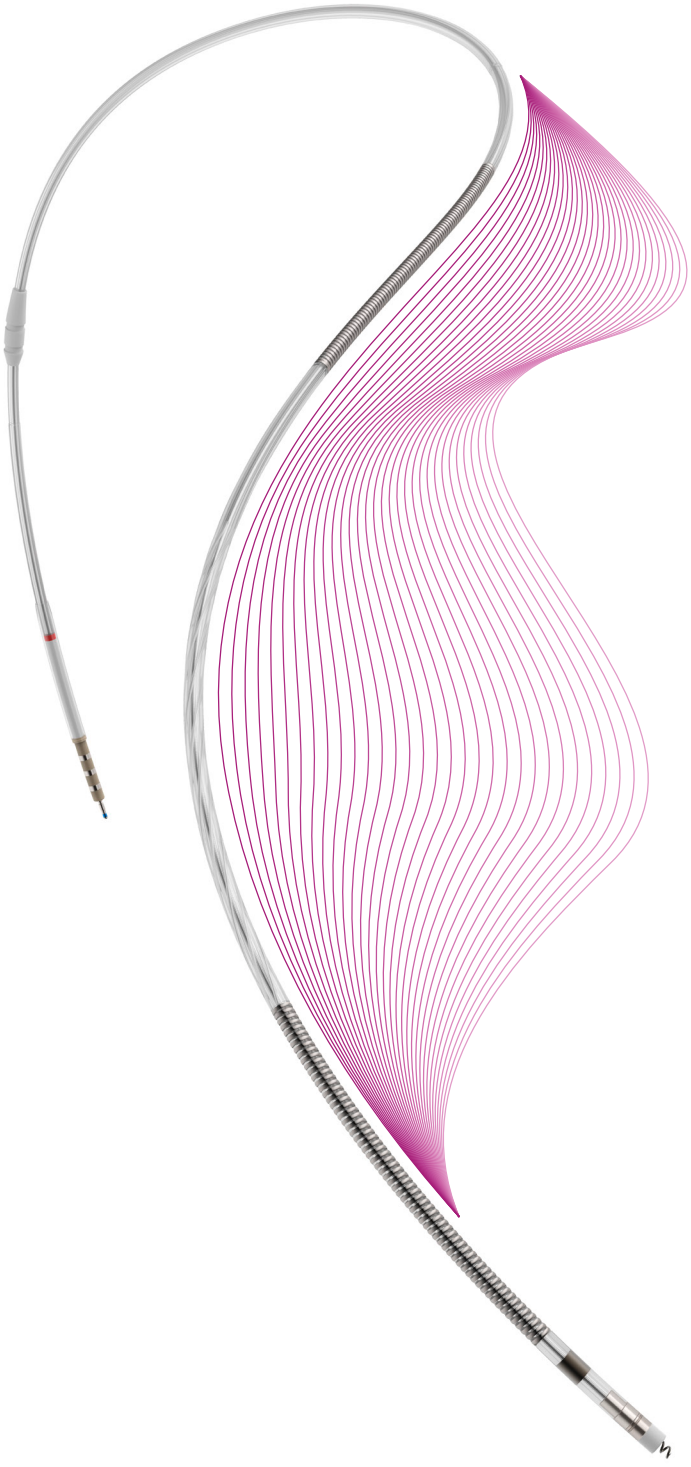
Products or subgroups of products may become subject to advisory notifications that can significantly impact the overall product performance. Current advisories are listed in chapter 11 of this report, however to date, BIOTRONIK has never had a pacing or ICD lead safety advisory notification, therefore 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

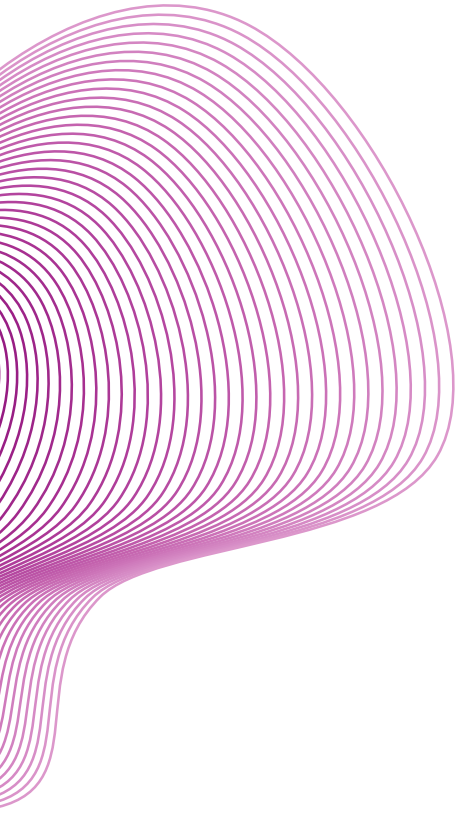
Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data



Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data



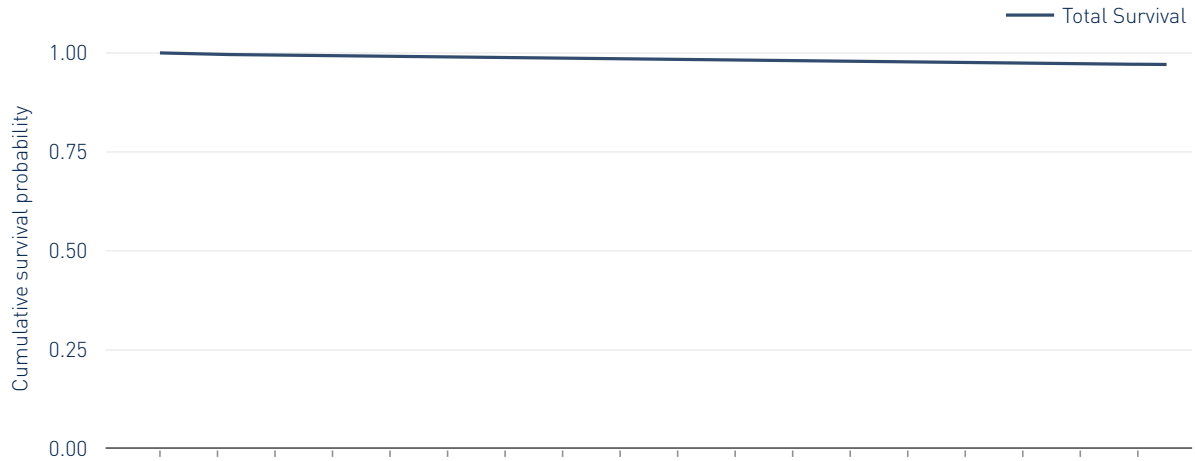
6.1 Performance of Pacing Leads – Postmarket Data

Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	480 000
Registered US Implants	378 912
Estimated Active US Implants	204 000
US Total Returned	2 533

	Count	Rate
US Qualifying Complications	5 947	1.55%
Abnormal pacing impedance	566	0.15%
Cardiac perforation	27	0.01%
Conductor fracture	206	0.05%
Extracardiac stimulation	27	0.01%
Failure to capture	1 368	0.36%
Failure to sense	208	0.05%
Insulation breach	101	0.03%
Lead dislodgement	610	0.16%
Oversensing	1 760	0.46%
Other	1 074	0.28%

	Count	Rate
US Confirmed Malfunctions	417	0.11%
Conductor fracture	127	0.03%
Insulation breach	278	0.07%
Other	12	0.00%
US Acute Lead Observations	1 783	0.46%
Abnormal pacing impedance	48	0.01%
Cardiac perforation	75	0.02%
Extracardiac stimulation	18	0.00%
Failure to capture	261	0.07%
Failure to sense	70	0.02%
Insulation breach	10	0.00%
Lead dislodgement	717	0.19%
Oversensing	48	0.01%
Other	536	0.14%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100	99.6	99.5	99.3	99.1	98.9	98.7	98.5	98.3	98.1	98.0	97.8	97.7	97.5	97.4	97.3	97.2	97.1
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	0.1	0.1	0.1	0.1
Sample Size	379k	336k	314k	295k	277k	262k	249k	238k	227k	205k	170k	136k	107k	81.9k	60.4k	40.2k	21.1k	5638

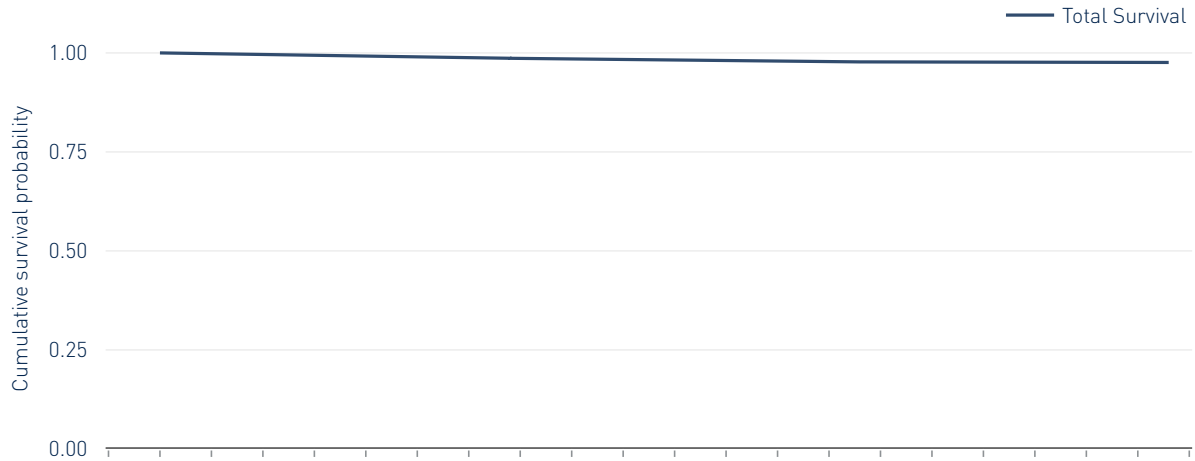
6.1 Performance of Pacing Leads – Postmarket Data

Selox JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	157 000
Registered US Implants	16 617
Estimated Active US Implants	11 600
US Total Returned	135

	Count	Rate
US Qualifying Complications	280	1.68%
Abnormal pacing impedance	47	0.28%
Cardiac perforation	1	0.01%
Conductor fracture	18	0.11%
Extracardiac stimulation	1	0.01%
Failure to capture	112	0.67%
Failure to sense	11	0.07%
Insulation breach	12	0.07%
Lead dislodgement	41	0.25%
Oversensing	14	0.08%
Other	23	0.14%

	Count	Rate
US Confirmed Malfunctions	12	0.07%
Insulation breach	11	0.07%
Other	1	0.01%
US Acute Lead Observations	45	0.27%
Failure to capture	8	0.05%
Lead dislodgement	34	0.20%
Other	3	0.02%



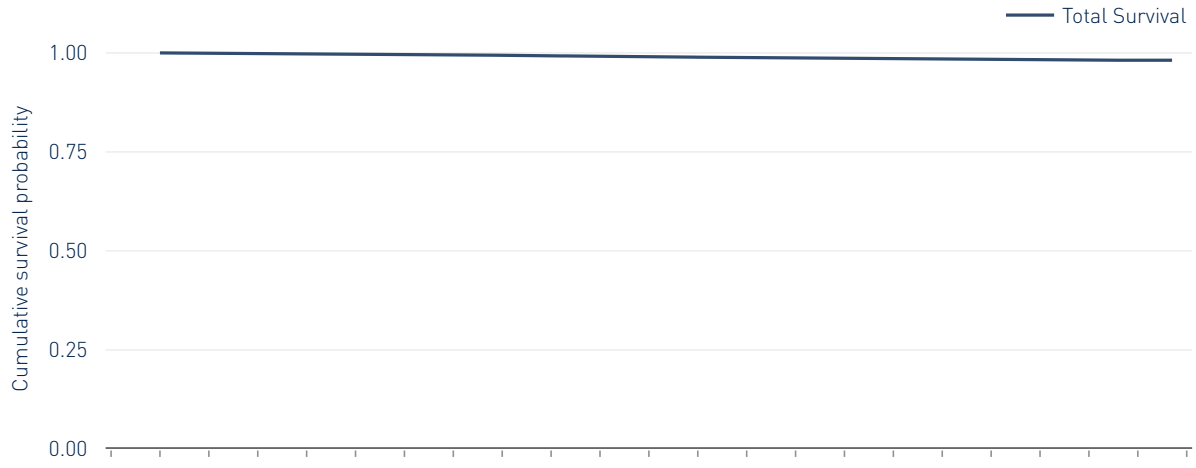
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Total [%]	100	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	98.2	98.1	98.0	97.9	97.8	97.7	97.6	97.6	97.6	97.6	97.6
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	16.6k	15.3k	14.7k	14k	13.6k	13.2k	12.8k	12.3k	11.7k	11k	10.3k	9178	8103	6999	5786	4596	3392	2268	1318	558

Selox SR

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2004
CE Market Release	Feb 2004
Worldwide Distributed Devices	172 000
Registered US Implants	14 335
Estimated Active US Implants	6 690
US Total Returned	65

	Count	Rate
US Qualifying Complications	139	0.97%
Abnormal pacing impedance	12	0.08%
Conductor fracture	12	0.08%
Extracardiac stimulation	2	0.01%
Failure to capture	52	0.36%
Failure to sense	1	0.01%
Insulation breach	6	0.04%
Lead dislodgement	16	0.11%
Oversensing	23	0.16%
Other	15	0.10%

	Count	Rate
US Confirmed Malfunctions	14	0.10%
Insulation breach	14	0.10%
US 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	17	18	19	20
Total [%]	100	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	98.4	98.4	98.2	98.2	98.1	98.1
CI [± %]	< 0.1	< 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	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	14.3k	12.4k	11.7k	10.9k	10k	9346	8727	8228	7870	7597	7391	7215	7143	7089	6997	6892	6793	6719	6646	5591	1921

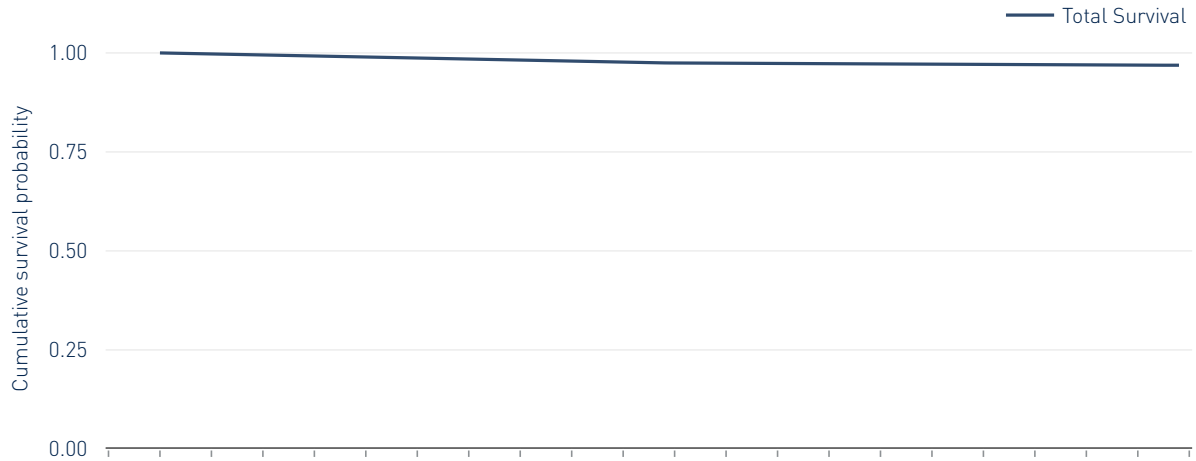
6.1 Performance of Pacing Leads – Postmarket Data

Selox ST

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	379 000
Registered US Implants	32 129
Estimated Active US Implants	21 300
US Total Returned	187

	Count	Rate
US Qualifying Complications	695	2.16%
Abnormal pacing impedance	157	0.49%
Cardiac perforation	3	0.01%
Conductor fracture	76	0.24%
Extracardiac stimulation	7	0.02%
Failure to capture	334	1.04%
Failure to sense	1	0.00%
Insulation breach	39	0.12%
Lead dislodgement	24	0.07%
Oversensing	20	0.06%
Other	34	0.11%

	Count	Rate
US Confirmed Malfunctions	20	0.06%
Conductor fracture	1	0.00%
Crimps, Welds and Bonds	1	0.00%
Insulation breach	18	0.06%
US Acute Lead Observations	50	0.16%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	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	16	17	18	19
Total [%]	100	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.6	97.5	97.3	97.2	97.1	97.1	97.0	97.0	97.0	96.9	96.9
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	0.2	0.2	0.2	0.2	0.2	0.2
Sample Size	32.1k	29.2k	27.7k	26.4k	25.3k	24.4k	23.6k	22.7k	21.7k	20.5k	19.2k	17.3k	15.3k	13.2k	10.9k	8845	6801	4822	3088	1443

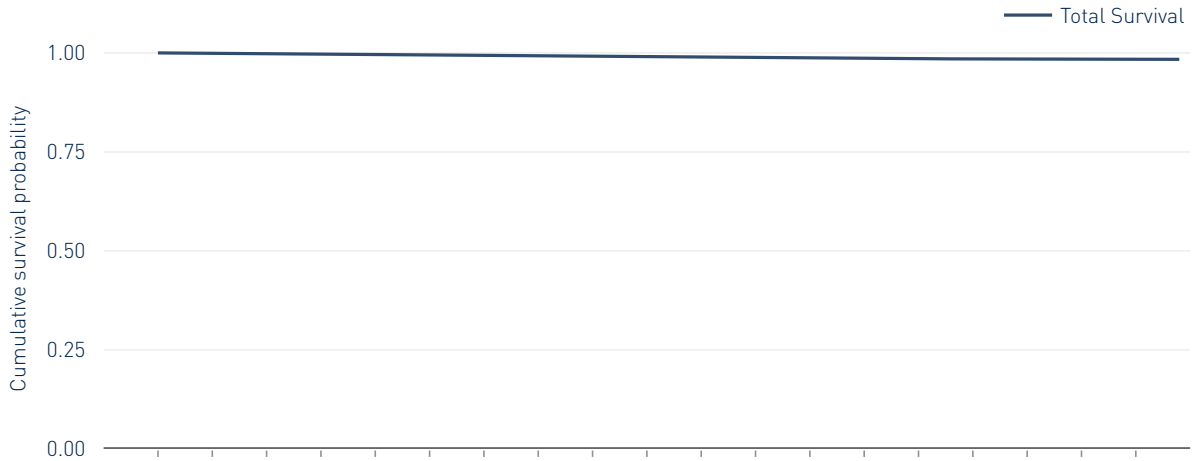
6.1 Performance of Pacing Leads – Postmarket Data

Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	681 000
Registered US Implants	245 599
Estimated Active US Implants	182 000
US Total Returned	1 823

	Count	Rate
US Qualifying Complications	2 453	1.00%
Abnormal pacing impedance	242	0.10%
Cardiac perforation	10	0.00%
Conductor fracture	183	0.07%
Extracardiac stimulation	12	0.00%
Failure to capture	800	0.33%
Failure to sense	63	0.03%
Insulation breach	93	0.04%
Lead dislodgement	396	0.16%
Oversensing	476	0.19%
Other	178	0.07%

	Count	Rate
US Confirmed Malfunctions	243	0.10%
Conductor fracture	64	0.03%
Insulation breach	171	0.07%
Other	8	0.00%
US Acute Lead Observations	271	0.11%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	24	0.01%
Failure to capture	34	0.01%
Failure to sense	3	0.00%
Insulation breach	4	0.00%
Lead dislodgement	189	0.08%
Other	16	0.01%



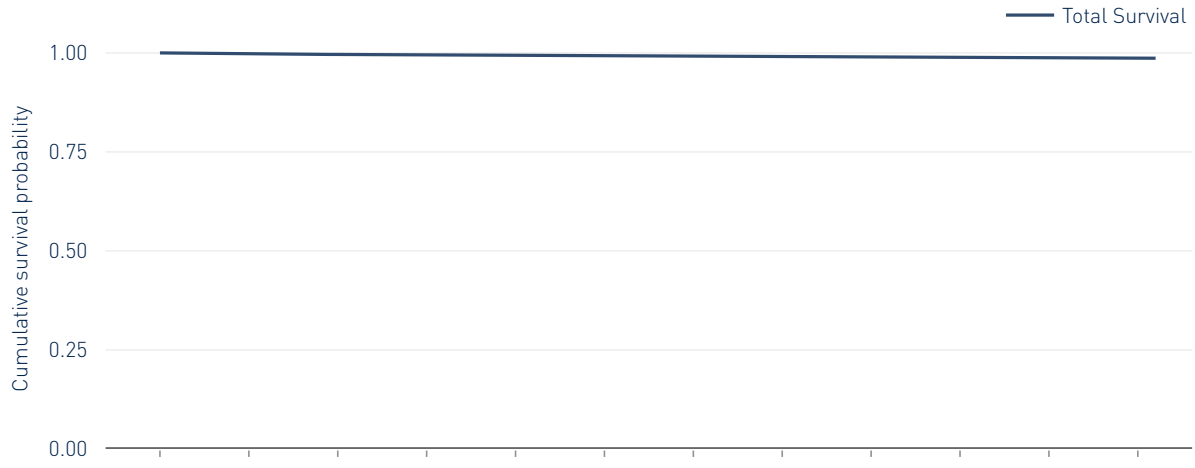
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Total [%]	100	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.1	98.9	98.8	98.7	98.6	98.6	98.5	98.5	98.4	98.4	98.4
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	246k	229k	221k	214k	208k	203k	198k	193k	187k	164k	134k	110k	89.8k	70.3k	52.9k	36.9k	23.1k	12k	4195

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	3 421 000
Registered US Implants	308 432
Estimated Active US Implants	278 000
US Total Returned	1 616

	Count	Rate
US Qualifying Complications	1 671	0.54%
Abnormal pacing impedance	127	0.04%
Cardiac perforation	26	0.01%
Conductor fracture	69	0.02%
Extracardiac stimulation	10	0.00%
Failure to capture	429	0.14%
Failure to sense	60	0.02%
Insulation breach	31	0.01%
Lead dislodgement	663	0.21%
Oversensing	170	0.06%
Other	86	0.03%

	Count	Rate
US Confirmed Malfunctions	94	0.03%
Conductor fracture	27	0.01%
Insulation breach	41	0.01%
Other	26	0.01%
US Acute Lead Observations	721	0.23%
Abnormal pacing impedance	16	0.01%
Cardiac perforation	51	0.02%
Conductor fracture	1	0.00%
Extracardiac stimulation	1	0.00%
Failure to capture	98	0.03%
Failure to sense	11	0.00%
Insulation breach	5	0.00%
Lead dislodgement	475	0.15%
Oversensing	28	0.01%
Other	35	0.01%



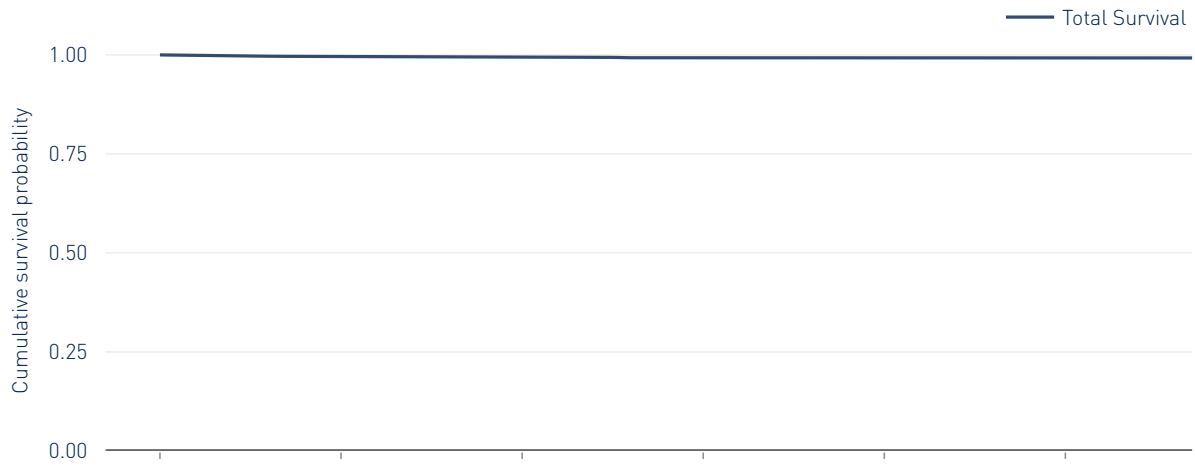
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.7	99.6	99.5	99.4	99.3	99.2	99.1	99.0	99.0	98.9	98.7
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.4
Sample Size	308k	263k	224k	185k	150k	119k	83k	47.1k	14.9k	2253	1688	449

Siello JT / Solia JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	195 000
Registered US Implants	4 159
Estimated Active US Implants	3 760
US Total Returned	18

	Count	Rate
US Qualifying Complications	23	0.55%
Abnormal pacing impedance	1	0.02%
Conductor fracture	1	0.02%
Failure to capture	4	0.10%
Failure to sense	1	0.02%
Insulation breach	1	0.02%
Lead dislodgement	11	0.26%
Oversensing	3	0.07%
Other	1	0.02%

	Count	Rate
US Confirmed Malfunctions	1	0.02%
Other	1	0.02%
US Acute Lead Observations	26	0.62%
Failure to capture	2	0.05%
Failure to sense	1	0.02%
Lead dislodgement	23	0.55%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.5	99.5	99.2	99.2	99.2
CI [± %]	< 0.1	0.2	0.2	0.3	0.3	0.3
Sample Size	4159	3285	2495	1724	1162	619

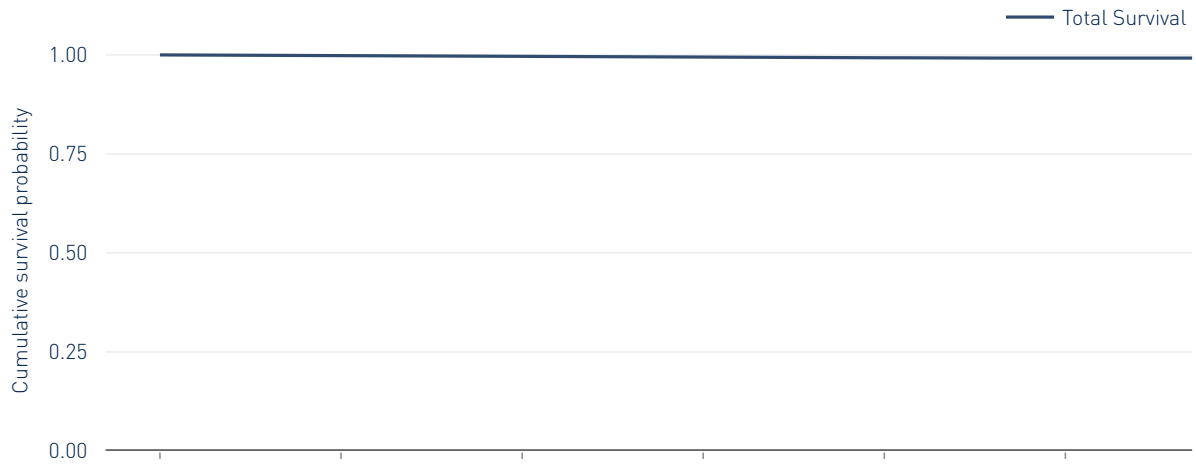
6.1 Performance of Pacing Leads – Postmarket Data

Siello T / Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	247 000
Registered US Implants	4 675
Estimated Active US Implants	4 140
US Total Returned	17

	Count	Rate
US Qualifying Complications	24	0.51%
Abnormal pacing impedance	4	0.09%
Conductor fracture	2	0.04%
Failure to capture	9	0.19%
Insulation breach	2	0.04%
Lead dislodgement	6	0.13%
Oversensing	1	0.02%

	Count	Rate
US Confirmed Malfunctions	2	0.04%
Insulation breach	1	0.02%
Other	1	0.02%
US Acute Lead Observations	16	0.34%
Failure to capture	4	0.09%
Lead dislodgement	12	0.26%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	99.5	99.3	99.3	99.2
CI [± %]	< 0.1	0.2	0.2	0.3	0.3	0.3
Sample Size	4675	3759	2976	2216	1462	732

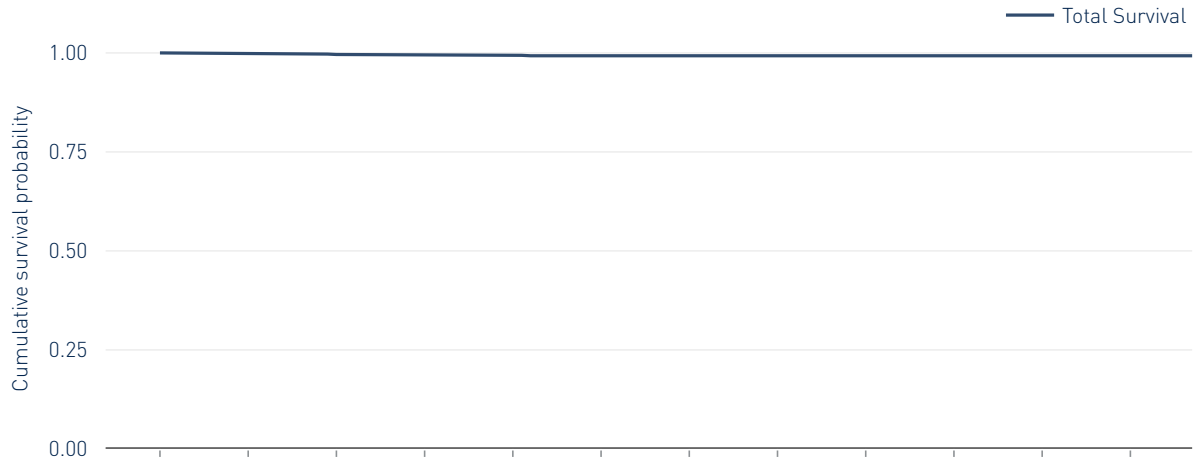
6.1 Performance of Pacing Leads – Postmarket Data

Tilda JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2012
CE Market Release	Sep 2011
Worldwide Distributed Devices	17 300
Registered US Implants	1 023
Estimated Active US Implants	864
US Total Returned	0

	Count	Rate
US Qualifying Complications	7	0.68%
Abnormal pacing impedance	2	0.20%
Failure to capture	2	0.20%
Lead dislodgement	3	0.29%

	Count	Rate
US Confirmed Malfunctions	0	0.00%
US Acute Lead Observations	1	0.10%
Lead dislodgement	1	0.10%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3	99.3	99.3	99.3
CI [± %]	< 0.1	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1023	989	963	932	912	899	854	797	733	579	446	314

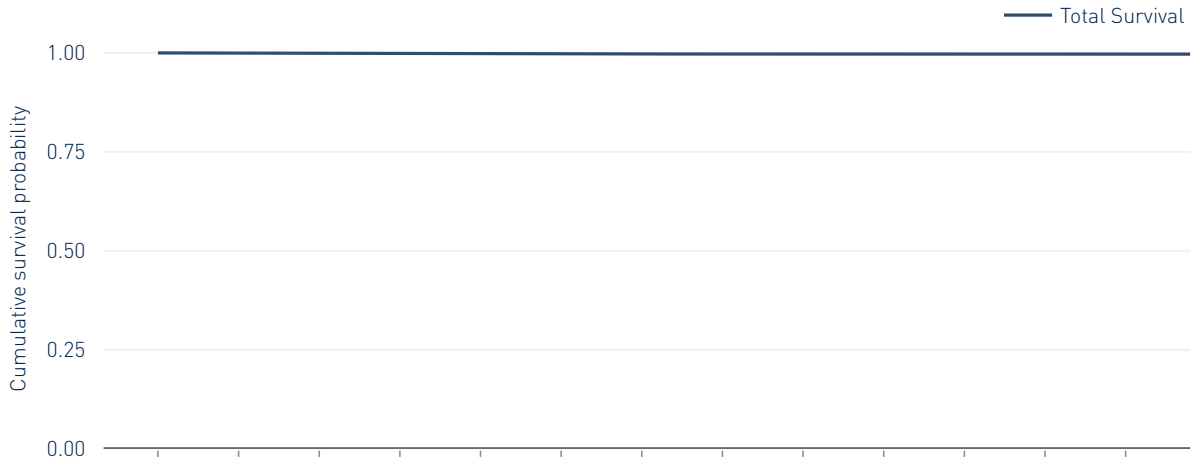
6.1 Performance of Pacing Leads – Postmarket Data

Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41 300
Registered US Implants	12 759
Estimated Active US Implants	10 800
US Total Returned	16

	Count	Rate
US Qualifying Complications	35	0.27%
Abnormal pacing impedance	1	0.01%
Conductor fracture	6	0.05%
Extracardiac stimulation	1	0.01%
Failure to capture	7	0.05%
Insulation breach	2	0.02%
Lead dislodgement	9	0.07%
Oversensing	5	0.04%
Other	4	0.03%

	Count	Rate
US Confirmed Malfunctions	1	0.01%
Conductor fracture	1	0.01%
US Acute Lead Observations	10	0.08%
Failure to capture	2	0.02%
Lead dislodgement	8	0.06%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	99.9	99.8	99.8	99.8	99.8	99.7	99.7	99.7	99.7	99.7	99.7	99.7
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	12.8k	12.1k	11.8k	11.5k	11.3k	11.2k	10.8k	10.2k	9075	7348	6101	4286	2232

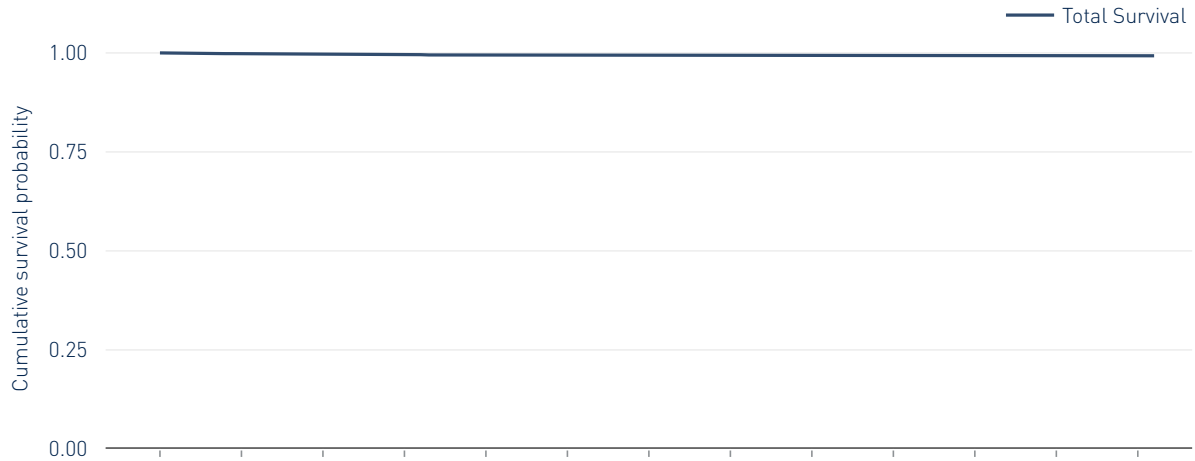
6.1 Performance of Pacing Leads – Postmarket Data

Tilda T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22 400
Registered US Implants	1 666
Estimated Active US Implants	1 330
US Total Returned	2

	Count	Rate
US Qualifying Complications	11	0.66%
Abnormal pacing impedance	4	0.24%
Conductor fracture	2	0.12%
Insulation breach	1	0.06%
Lead dislodgement	4	0.24%

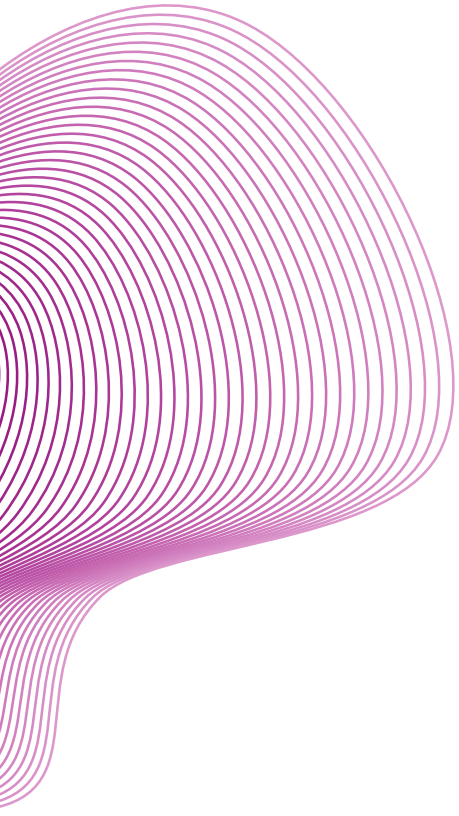
	Count	Rate
US Confirmed Malfunctions	0	0.00%
US Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	99.8	99.8	99.6	99.5	99.3	99.3	99.3	99.3	99.3	99.3	99.3	99.3
CI [± %]	< 0.1	0.2	0.2	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Sample Size	1666	1575	1528	1478	1442	1408	1349	1305	1200	971	833	581	265

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data



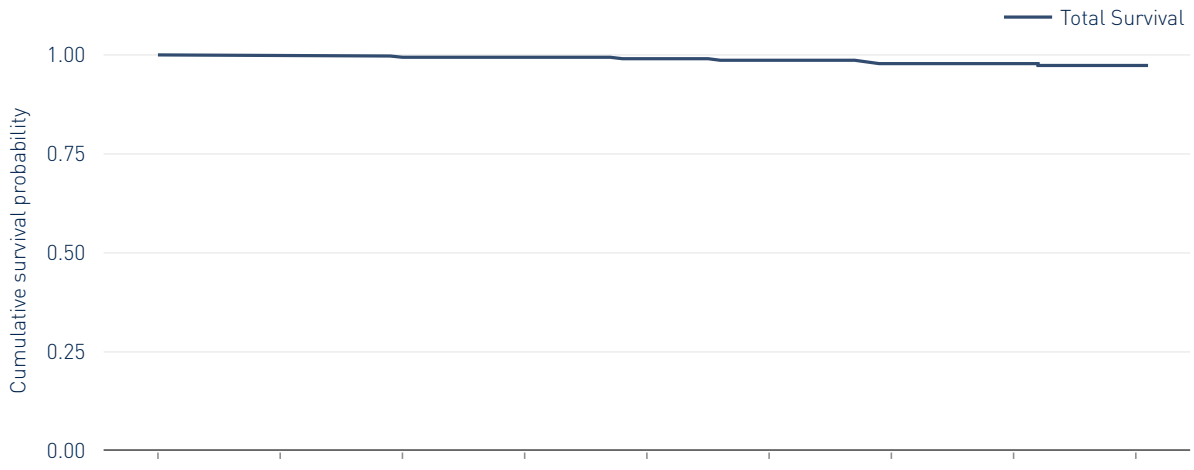
6.2 Performance of ICD Leads – Postmarket Data

Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5 460
Registered US Implants	406
Estimated Active US Implants	155
US Total Returned	8

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	2	0.49%
Conductor fracture	1	0.25%
Insulation breach	1	0.25%
US Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.7	99.4	99.4	99.0	98.6	97.8	97.8	97.3
CI [± %]	< 0.1	0.6	0.8	0.8	1.1	1.3	1.8	1.8	2.0
Sample Size	406	353	318	286	269	243	228	211	201

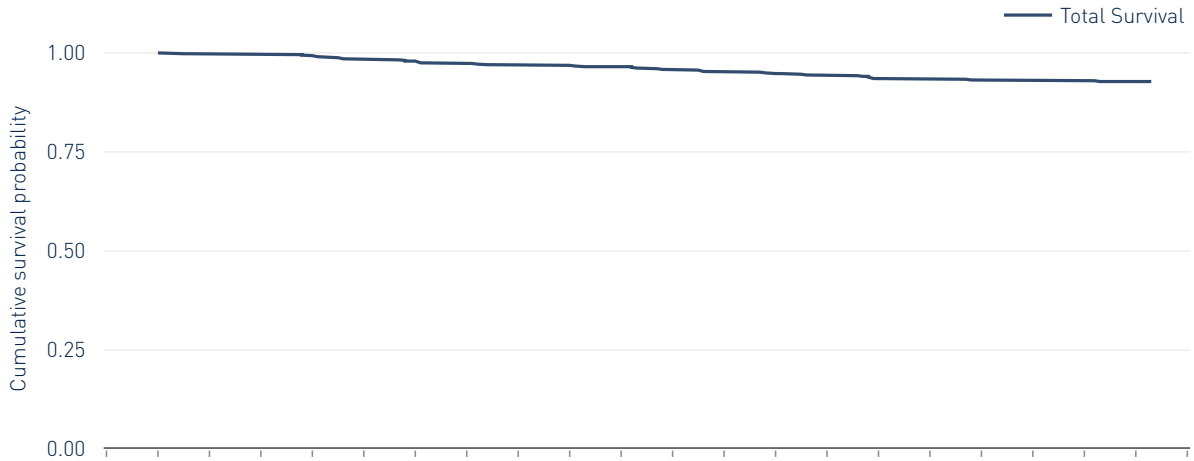
6.2 Performance of ICD Leads – Postmarket Data

Kentrox SL

Product Versions	65, 75, 100, -Steroid
Lead Type	dual coil, passive fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Oct 2004
CE Market Release	Dec 2003 / Dec 2004
Worldwide Distributed Devices	8 440
Registered US Implants	1 003
Estimated Active US Implants	501
US Total Returned	19

	Count	Rate
US Qualifying Complications	41	4.06%
Abnormal defibrillation impedance	2	0.20%
Abnormal pacing impedance	4	0.40%
Conductor fracture	3	0.30%
Failure to capture	4	0.40%
Insulation breach	6	0.59%
Oversensing	20	1.98%
Other	2	0.20%

	Count	Rate
US Confirmed Malfunctions	5	0.50%
Insulation breach	5	0.50%
US 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	16	17	18	19
Total [%]	100	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	93.2	93.0	93.0	92.8
CI [± %]	< 0.1	0.3	0.4	0.6	0.9	1.0	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.9	2.0	2.0	2.0	2.0
Sample Size	1003	898	834	777	707	662	616	596	576	565	553	545	537	529	518	514	506	499	486	282

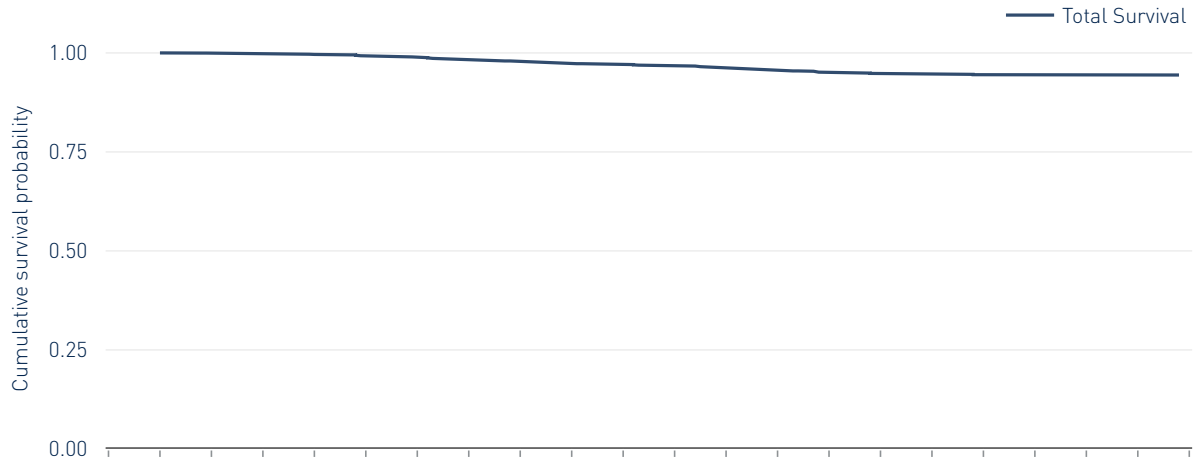
6.2 Performance of ICD Leads – Postmarket Data

Kentrox SL-S

Product Versions	65/16, 18 -Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8 740
Registered US Implants	2 412
Estimated Active US Implants	1 150
US Total Returned	44

	Count	Rate
US Qualifying Complications	68	2.80%
Abnormal defibrillation impedance	2	0.08%
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	4	0.16%

	Count	Rate
US Confirmed Malfunctions	14	0.58%
Insulation breach	14	0.58%
US Acute Lead Observations	2	0.08%
Insulation breach	1	0.04%
Oversensing	1	0.04%



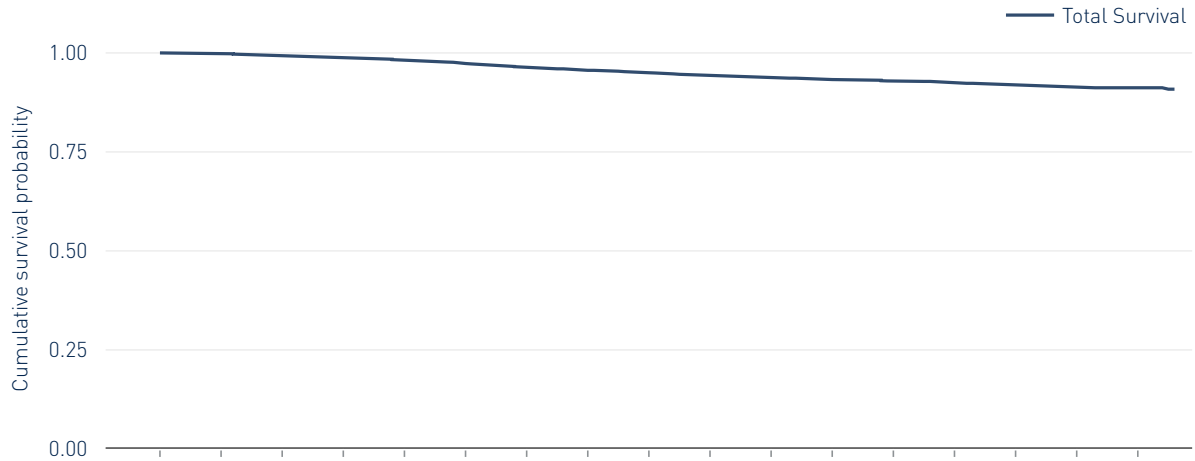
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Total [%]	100	100	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.7	94.5	94.5	94.4	94.4
CI [± %]	< 0.1	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2
Sample Size	2412	2174	2049	1889	1752	1629	1510	1429	1362	1322	1280	1257	1231	1221	1200	1190	1165	1150	1104	728

Linox S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered US Implants	2 466
Estimated Active US Implants	1 530
US Total Returned	92

	Count	Rate
US Qualifying Complications	106	4.25%
Abnormal defibrillation impedance	16	0.64%
Abnormal pacing impedance	6	0.24%
Conductor fracture	11	0.44%
Failure to capture	13	0.52%
Failure to sense	1	0.04%
Insulation breach	4	0.16%
Oversensing	49	1.97%
Other	6	0.24%

	Count	Rate
US Confirmed Malfunctions	52	2.09%
Conductor fracture	9	0.36%
Insulation breach	42	1.69%
Other	1	0.04%
US 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	13	14	15	16
Total [%]	100	99.9	99.4	98.9	98.1	97.3	96.4	95.6	95.0	94.1	93.7	93.3	92.9	92.4	91.7	91.3	91.2
CI [± %]	< 0.1	0.1	0.3	0.4	0.6	0.7	0.8	0.9	1.0	1.1	1.1	1.1	1.2	1.2	1.3	1.3	1.4
Sample Size	2466	2266	2134	2022	1928	1852	1789	1746	1696	1647	1623	1594	1577	1537	1088	650	376

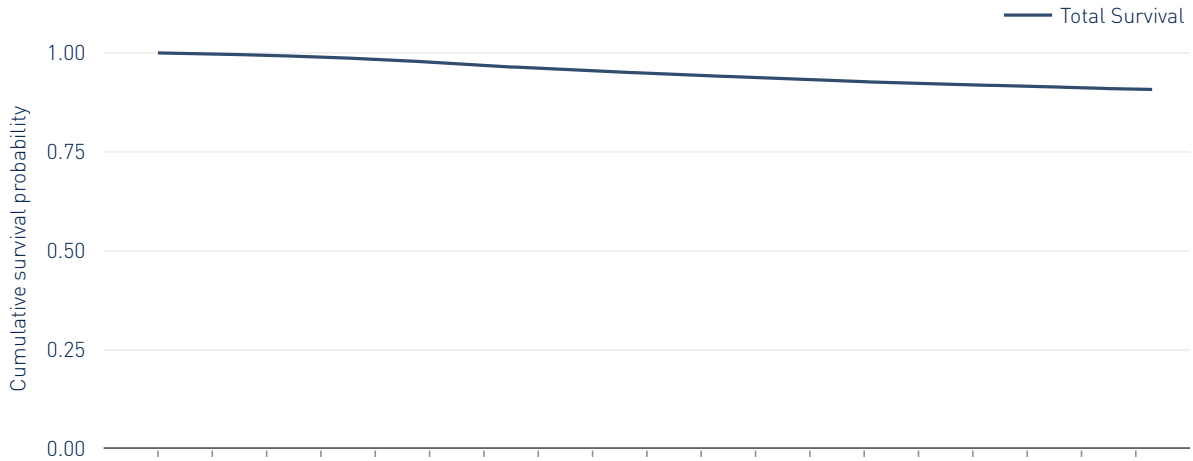
6.2 Performance of ICD Leads – Postmarket Data

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered US Implants	22 100
Estimated Active US Implants	13 200
US Total Returned	566

	Count	Rate
US Qualifying Complications	1 098	4.94%
Abnormal defibrillation impedance	113	0.51%
Abnormal pacing impedance	79	0.36%
Cardiac perforation	3	0.01%
Conductor fracture	140	0.63%
Failure to capture	82	0.37%
Failure to sense	18	0.08%
Insulation breach	66	0.30%
Lead dislodgement	34	0.15%
Oversensing	509	2.29%
Other	54	0.24%

	Count	Rate
US Confirmed Malfunctions	240	1.08%
Conductor fracture	41	0.18%
Insulation breach	195	0.88%
Other	4	0.02%
US 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	15	16	17	18
Total [%]	100	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.8	93.2	92.7	92.3	91.9	91.6	91.2	90.9
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.5
Sample Size	22.1k	20.1k	18.9k	17.8k	17k	16.2k	15.6k	15.2k	14.8k	14.5k	14.3k	14k	13.7k	13.5k	12.1k	8282	5182	2597	765

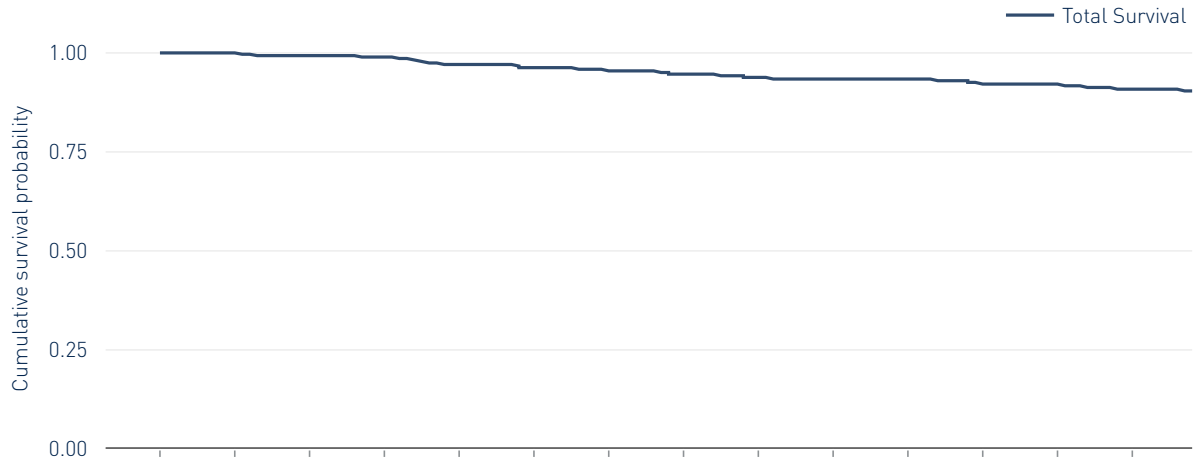
6.2 Performance of ICD Leads – Postmarket Data

Linox T

Product Versions	65, 75
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	2 260
Registered US Implants	319
Estimated Active US Implants	207
US Total Returned	4

	Count	Rate
US Qualifying Complications	21	6.52%
Abnormal pacing impedance	3	0.93%
Conductor fracture	1	0.31%
Failure to capture	4	1.24%
Insulation breach	1	0.31%
Oversensing	11	3.42%
Other	1	0.31%

	Count	Rate
US Confirmed Malfunctions	3	0.93%
Conductor fracture	1	0.31%
Insulation breach	2	0.62%
US Acute Lead Observations	1	0.31%
Other	1	0.31%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100	100	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4	93.4	92.1	92.1	90.8
CI [± %]	< 0.1	< 0.1	0.9	1.2	2.0	2.3	2.5	2.7	2.9	3.0	3.0	3.3	3.3	3.6
Sample Size	319	295	283	272	251	241	234	230	228	226	223	217	215	210

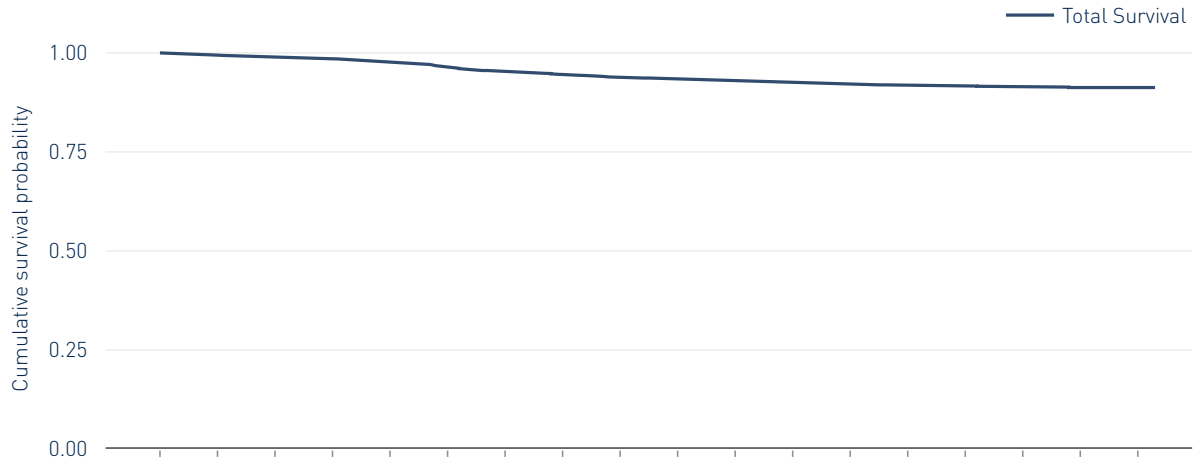
6.2 Performance of ICD Leads – Postmarket Data

Linox TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered US Implants	3 023
Estimated Active US Implants	1 880
US Total Returned	82

	Count	Rate
US Qualifying Complications	161	5.28%
Abnormal defibrillation impedance	18	0.59%
Abnormal pacing impedance	15	0.49%
Cardiac perforation	1	0.03%
Conductor fracture	25	0.82%
Failure to capture	24	0.79%
Failure to sense	4	0.13%
Insulation breach	13	0.43%
Lead dislodgement	5	0.16%
Oversensing	53	1.74%
Other	3	0.10%

	Count	Rate
US Confirmed Malfunctions	39	1.28%
Conductor fracture	7	0.23%
Insulation breach	32	1.05%
US Acute Lead Observations	3	0.10%
Failure to capture	1	0.03%
Lead dislodgement	2	0.07%



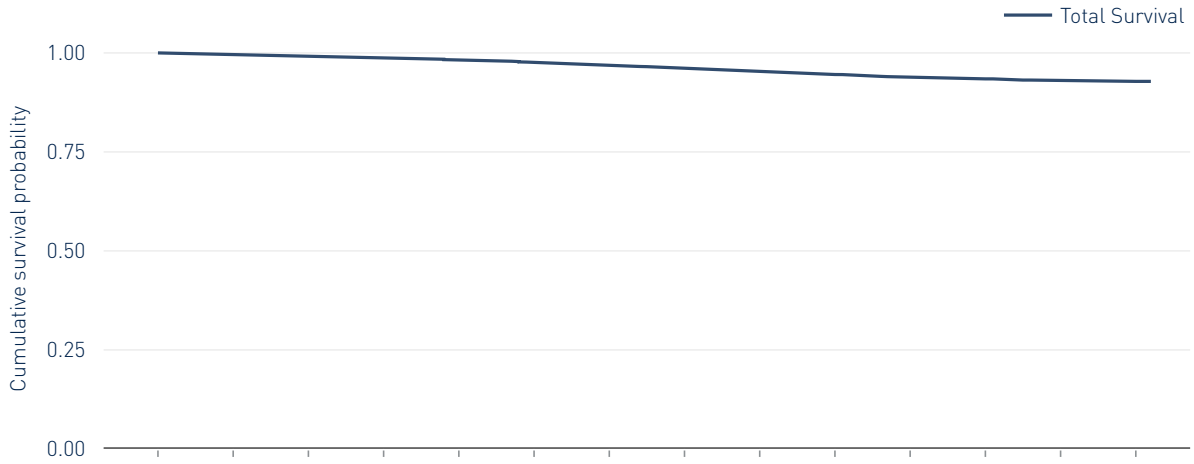
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100	99.4	99.1	98.5	97.6	96.5	95.3	94.6	93.7	93.4	92.8	92.5	92.1	91.8	91.6	91.4	91.3	91.3
CI [± %]	< 0.1	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.2	1.2
Sample Size	3023	2738	2607	2457	2344	2240	2149	2095	2057	2028	1997	1975	1940	1883	1667	1163	713	300

Linox Smart S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered US Implants	7 600
Estimated Active US Implants	5 550
US Total Returned	222

	Count	Rate
US Qualifying Complications	327	4.28%
Abnormal defibrillation impedance	29	0.38%
Abnormal pacing impedance	27	0.35%
Cardiac perforation	1	0.01%
Conductor fracture	48	0.63%
Failure to capture	26	0.34%
Failure to sense	15	0.20%
Insulation breach	5	0.07%
Lead dislodgement	14	0.18%
Oversensing	151	1.97%
Other	11	0.14%

	Count	Rate
US Confirmed Malfunctions	94	1.23%
Conductor fracture	19	0.25%
Insulation breach	73	0.95%
Other	2	0.03%
US 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%



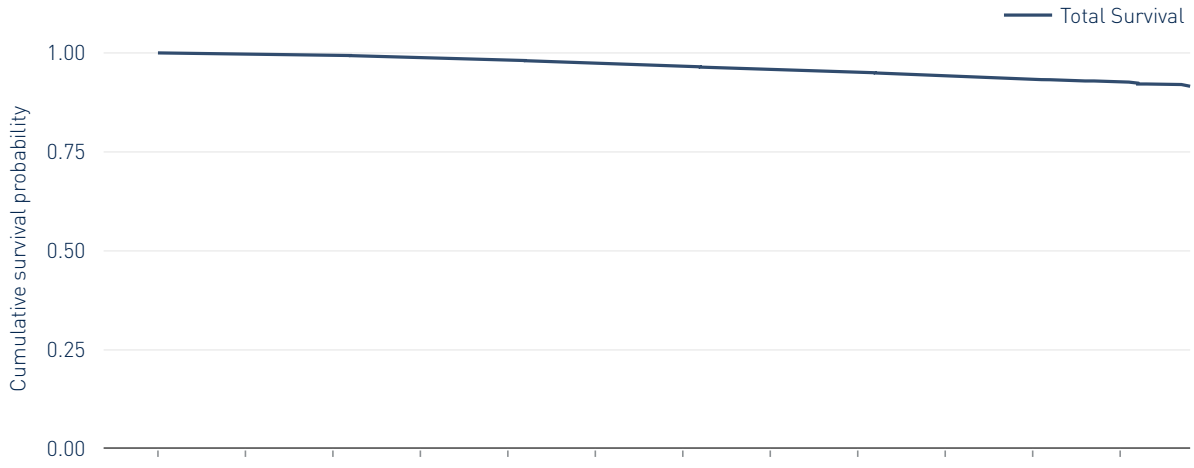
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100	99.7	99.3	98.9	98.3	97.6	96.9	96.0	95.3	94.5	93.8	93.4	93.1	92.8
CI [± %]	< 0.1	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7
Sample Size	7600	7133	6869	6667	6496	6351	6195	5999	5714	5291	4516	3183	1809	364

Linox Smart S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 300
Registered US Implants	16 309
Estimated Active US Implants	12 800
US Total Returned	451

	Count	Rate
US Qualifying Complications	717	4.37%
Abnormal defibrillation impedance	82	0.50%
Abnormal pacing impedance	56	0.34%
Conductor fracture	84	0.51%
Failure to capture	48	0.29%
Failure to sense	25	0.15%
Insulation breach	12	0.07%
Lead dislodgement	49	0.30%
Oversensing	343	2.09%
Other	18	0.11%

	Count	Rate
US Confirmed Malfunctions	163	0.99%
Conductor fracture	22	0.13%
Insulation breach	136	0.83%
Other	5	0.03%
US 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%



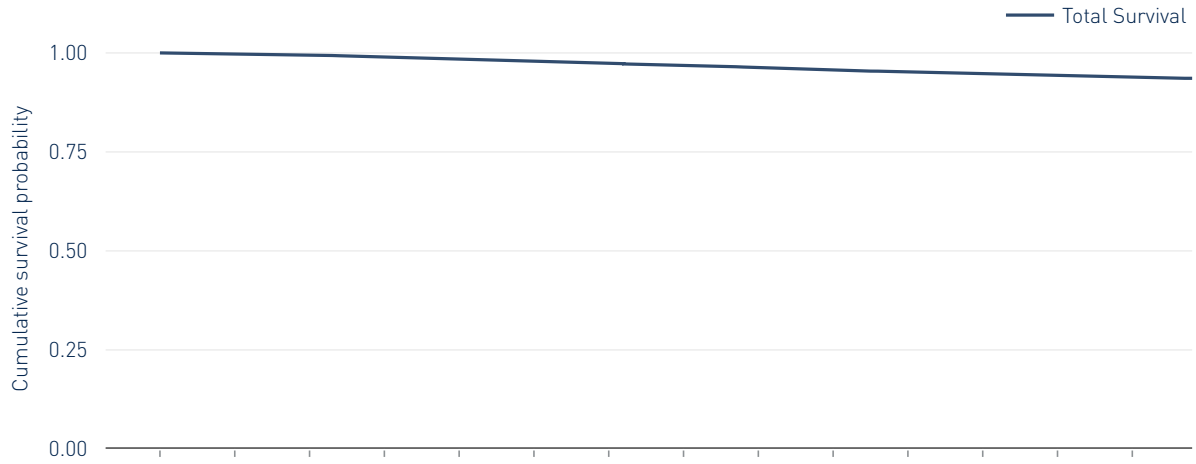
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.7	99.4	98.9	98.2	97.4	96.7	95.8	95.1	94.1	93.3	92.7
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.5	0.5
Sample Size	16.3k	15.5k	15.2k	14.9k	14.5k	14.1k	13.7k	13.1k	10.8k	7328	4489	1834

Linox Smart SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered US Implants	13 130
Estimated Active US Implants	9 510
US Total Returned	292

	Count	Rate
US Qualifying Complications	525	3.97%
Abnormal defibrillation impedance	60	0.45%
Abnormal pacing impedance	38	0.29%
Cardiac perforation	1	0.01%
Conductor fracture	65	0.49%
Extracardiac stimulation	1	0.01%
Failure to capture	43	0.32%
Failure to sense	12	0.09%
Insulation breach	13	0.10%
Lead dislodgement	31	0.23%
Oversensing	250	1.89%
Other	11	0.08%

	Count	Rate
US Confirmed Malfunctions	97	0.73%
Conductor fracture	14	0.11%
Insulation breach	78	0.59%
Other	5	0.04%
US 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	10	11	12	13
Total [%]	100	99.7	99.5	99.0	98.5	97.9	97.4	96.8	96.3	95.6	95.2	94.8	94.3	93.7
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	0.5
Sample Size	13.1k	12.2k	11.8k	11.4k	11.1k	10.9k	10.6k	10.4k	10k	9547	8830	7489	5418	2294

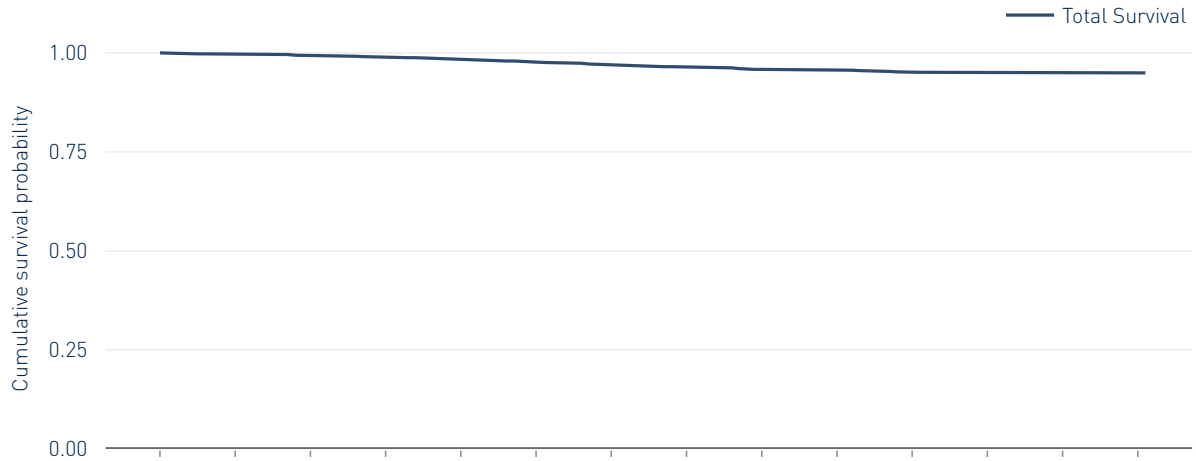
6.2 Performance of ICD Leads – Postmarket Data

Linox Smart TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered US Implants	1 266
Estimated Active US Implants	918
US Total Returned	23

	Count	Rate
US Qualifying Complications	52	4.08%
Abnormal defibrillation impedance	8	0.63%
Abnormal pacing impedance	6	0.47%
Conductor fracture	4	0.31%
Failure to capture	13	1.02%
Insulation breach	3	0.24%
Lead dislodgement	4	0.31%
Oversensing	13	1.02%
Other	1	0.08%

	Count	Rate
US Confirmed Malfunctions	1	0.08%
Insulation breach	1	0.08%
US Acute Lead Observations	3	0.24%
Lead dislodgement	3	0.24%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100	99.7	99.2	98.9	98.3	97.7	97.1	96.5	95.8	95.6	95.1	95.1	95.0	95.0
CI [± %]	< 0.1	0.3	0.5	0.6	0.7	0.9	1.0	1.1	1.2	1.2	1.3	1.3	1.3	1.3
Sample Size	1266	1174	1137	1094	1068	1036	1009	989	971	928	854	725	523	225

6.2 Performance of ICD Leads – Postmarket Data

Pamira S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2023
CE Market Release	May 2023
Worldwide Distributed Devices	10 800
Registered US Implants	886
Estimated Active US Implants	863
US Total Returned	2

	Count	Rate
US Qualifying Complications	1	0.11%
Oversensing	1	0.11%

	Count	Rate
US Confirmed Malfunctions	0	0.00%
US Acute Lead Observations	3	0.34%
Cardiac perforation	1	0.11%
Lead dislodgement	2	0.23%

6.2 Performance of ICD Leads – Postmarket Data

Pamira S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2023
CE Market Release	May 2023
Worldwide Distributed Devices	4 270
Registered US Implants	1 404
Estimated Active US Implants	1 360
US Total Returned	13

	Count	Rate
US Qualifying Complications	2	0.14%
Oversensing	2	0.14%

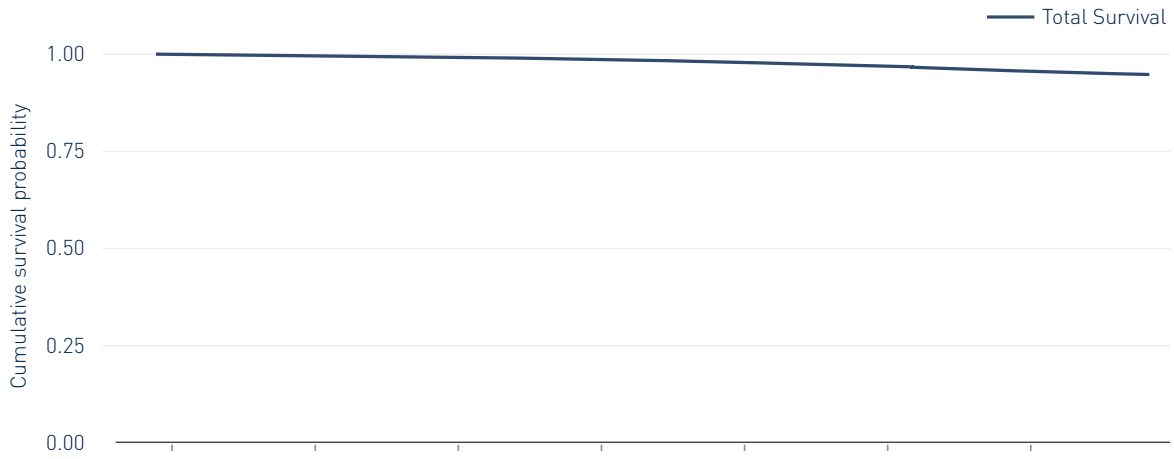
	Count	Rate
US Confirmed Malfunctions	1	0.07%
Insulation breach	1	0.07%
US Acute Lead Observations	6	0.43%
Abnormal defibrillation impedance	1	0.07%
Cardiac perforation	1	0.07%
Lead dislodgement	4	0.28%

Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	187 000
Registered US Implants	25 730
Estimated Active US Implants	22 800
US Total Returned	310

	Count	Rate
US Qualifying Complications	470	1.82%
Abnormal defibrillation impedance	30	0.12%
Abnormal pacing impedance	13	0.05%
Cardiac perforation	1	0.00%
Conductor fracture	37	0.14%
Extracardiac stimulation	1	0.00%
Failure to capture	43	0.17%
Failure to sense	15	0.06%
Insulation breach	3	0.01%
Lead dislodgement	41	0.16%
Oversensing	269	1.04%
Other	17	0.07%

	Count	Rate
US Confirmed Malfunctions	107	0.41%
Conductor fracture	14	0.05%
Insulation breach	81	0.31%
Other	12	0.05%
US Acute Lead Observations	63	0.24%
Abnormal pacing impedance	3	0.01%
Cardiac perforation	6	0.02%
Conductor fracture	1	0.00%
Failure to capture	13	0.05%
Lead dislodgement	31	0.12%
Oversensing	6	0.02%
Other	3	0.01%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.6	99.3	98.7	97.9	97.0	95.7
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.3	0.4
Sample Size	25.7k	22.3k	18.5k	14.8k	11.4k	8031	4483

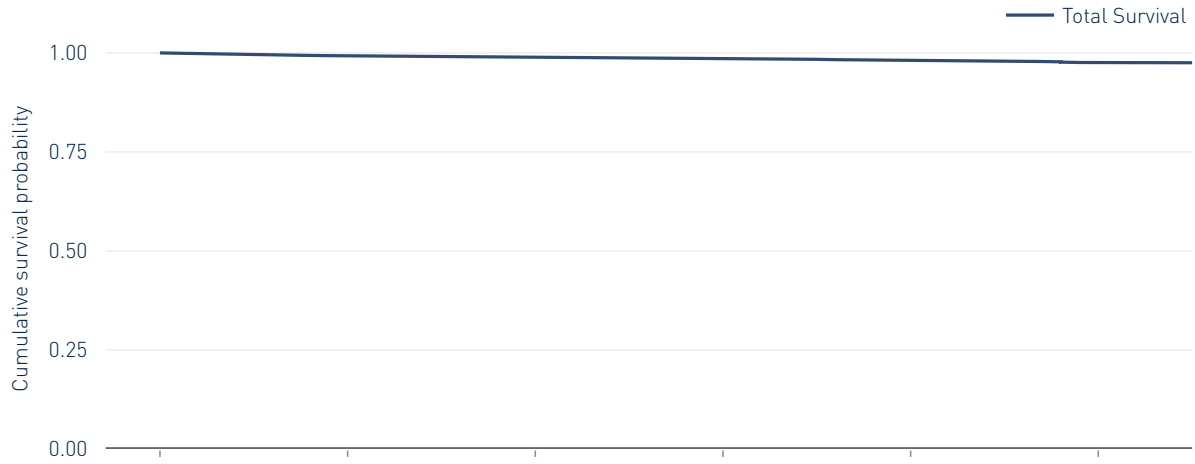
6.2 Performance of ICD Leads – Postmarket Data

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	52 800
Registered US Implants	22 519
Estimated Active US Implants	20 900
US Total Returned	210

	Count	Rate
US Qualifying Complications	253	1.12%
Abnormal defibrillation impedance	13	0.06%
Abnormal pacing impedance	14	0.06%
Cardiac perforation	5	0.02%
Conductor fracture	7	0.03%
Failure to capture	34	0.15%
Failure to sense	19	0.08%
Insulation breach	1	0.00%
Lead dislodgement	62	0.28%
Oversensing	84	0.37%
Other	14	0.06%

	Count	Rate
US Confirmed Malfunctions	40	0.18%
Conductor fracture	5	0.02%
Insulation breach	31	0.14%
Other	4	0.02%
US Acute Lead Observations	81	0.36%
Abnormal defibrillation impedance	1	0.00%
Cardiac perforation	5	0.02%
Failure to capture	13	0.06%
Failure to sense	8	0.04%
Lead dislodgement	35	0.16%
Oversensing	15	0.07%
Other	4	0.02%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.3	99.0	98.6	98.2	97.6
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.4
Sample Size	22.5k	18.4k	13.7k	9189	5006	1773

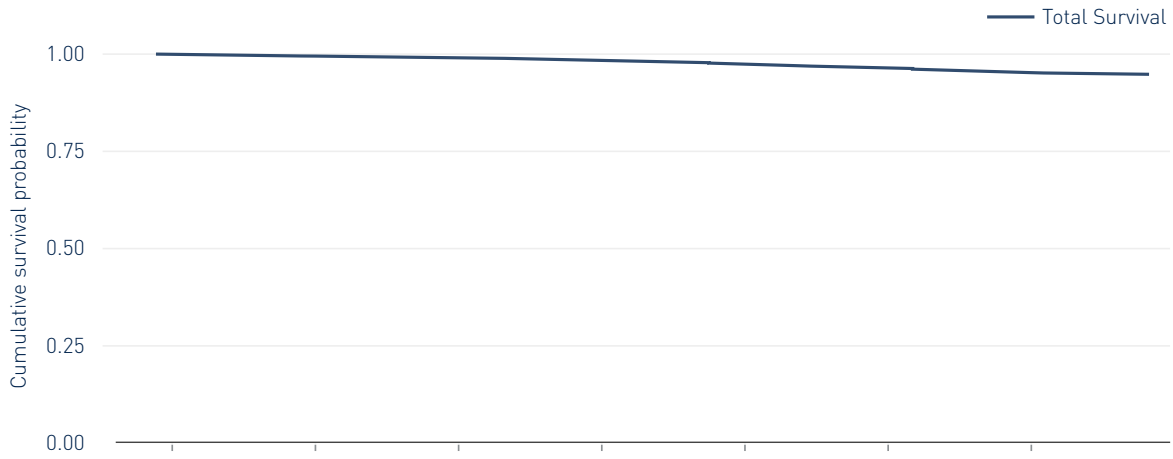
6.2 Performance of ICD Leads – Postmarket Data

Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	24 700
Registered US Implants	9 293
Estimated Active US Implants	7 790
US Total Returned	202

	Count	Rate
US Qualifying Complications	297	3.18%
Abnormal defibrillation impedance	31	0.33%
Abnormal pacing impedance	15	0.16%
Conductor fracture	19	0.20%
Failure to capture	17	0.18%
Failure to sense	10	0.11%
Insulation breach	5	0.05%
Lead dislodgement	21	0.22%
Oversensing	173	1.85%
Other	6	0.06%

	Count	Rate
US Confirmed Malfunctions	97	1.04%
Conductor fracture	6	0.06%
Insulation breach	90	0.96%
Other	1	0.01%
US Acute Lead Observations	21	0.22%
Abnormal defibrillation impedance	1	0.01%
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	4	5	6
Total [%]	100	99.5	99.1	98.5	97.5	96.4	95.2
CI [± %]	< 0.1	0.1	0.2	0.3	0.3	0.4	0.5
Sample Size	9293	8835	8543	8205	7888	7109	4936

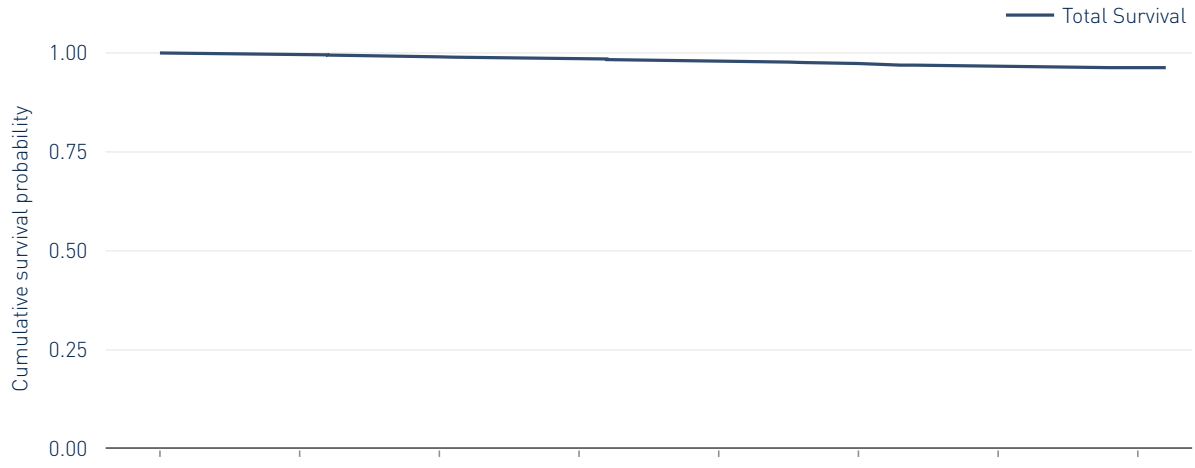
6.2 Performance of ICD Leads – Postmarket Data

Plexa SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	20 700
Registered US Implants	6 061
Estimated Active US Implants	5 280
US Total Returned	41

	Count	Rate
US Qualifying Complications	117	1.92%
Abnormal defibrillation impedance	9	0.15%
Abnormal pacing impedance	5	0.08%
Conductor fracture	12	0.20%
Extracardiac stimulation	1	0.02%
Failure to capture	9	0.15%
Failure to sense	7	0.12%
Insulation breach	4	0.07%
Lead dislodgement	8	0.13%
Oversensing	59	0.97%
Other	3	0.05%

	Count	Rate
US Confirmed Malfunctions	12	0.20%
Conductor fracture	3	0.05%
Insulation breach	6	0.10%
Other	3	0.05%
US Acute Lead Observations	16	0.26%
Abnormal defibrillation impedance	3	0.05%
Abnormal pacing impedance	2	0.03%
Cardiac perforation	2	0.03%
Failure to capture	3	0.05%
Lead dislodgement	2	0.03%
Oversensing	2	0.03%
Other	2	0.03%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.6	99.0	98.6	97.9	97.3	96.5	96.3
CI [± %]	< 0.1	0.2	0.3	0.3	0.4	0.5	0.7	0.7
Sample Size	6061	5381	4710	3889	3050	2265	1315	376

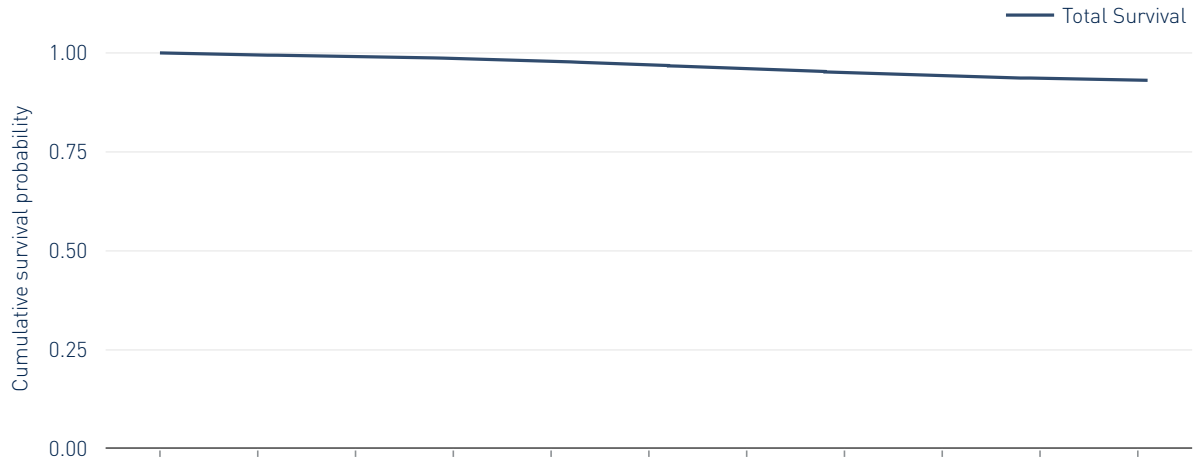
6.2 Performance of ICD Leads – Postmarket Data

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered US Implants	8 278
Estimated Active US Implants	6 320
US Total Returned	159

	Count	Rate
US Qualifying Complications	358	4.29%
Abnormal defibrillation impedance	23	0.28%
Abnormal pacing impedance	13	0.16%
Cardiac perforation	2	0.02%
Conductor fracture	45	0.54%
Extracardiac stimulation	3	0.04%
Failure to capture	28	0.34%
Failure to sense	6	0.07%
Insulation breach	3	0.04%
Lead dislodgement	27	0.32%
Oversensing	197	2.36%
Other	11	0.13%

	Count	Rate
US Confirmed Malfunctions	75	0.90%
Conductor fracture	15	0.18%
Insulation breach	58	0.70%
Other	2	0.02%
US 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%



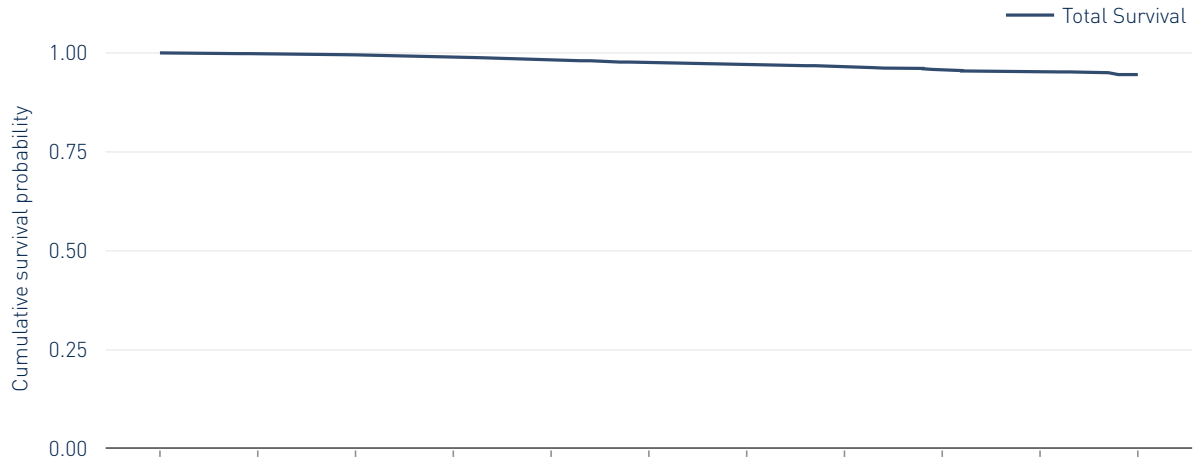
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.5	99.2	98.6	97.9	97.0	96.0	95.1	94.3	93.6	93.1
CI [± %]	< 0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.8
Sample Size	8278	7803	7601	7391	7177	6930	6684	6185	4466	1872	304

Protego SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18 400
Registered US Implants	3 411
Estimated Active US Implants	2 720
US Total Returned	55

	Count	Rate
US Qualifying Complications	120	3.49%
Abnormal defibrillation impedance	10	0.29%
Abnormal pacing impedance	8	0.23%
Conductor fracture	17	0.49%
Failure to capture	13	0.38%
Failure to sense	2	0.06%
Insulation breach	2	0.06%
Lead dislodgement	6	0.17%
Oversensing	61	1.77%
Other	1	0.03%

	Count	Rate
US Confirmed Malfunctions	20	0.58%
Conductor fracture	1	0.03%
Insulation breach	16	0.47%
Other	3	0.09%
US 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	7	8	9	10
Total [%]	100	99.8	99.5	98.9	98.3	97.6	97.0	96.6	95.8	95.2	94.5
CI [± %]	< 0.1	0.1	0.2	0.4	0.5	0.5	0.6	0.6	0.7	0.8	1.1
Sample Size	3411	3241	3157	3082	3003	2916	2854	2732	2111	1096	215

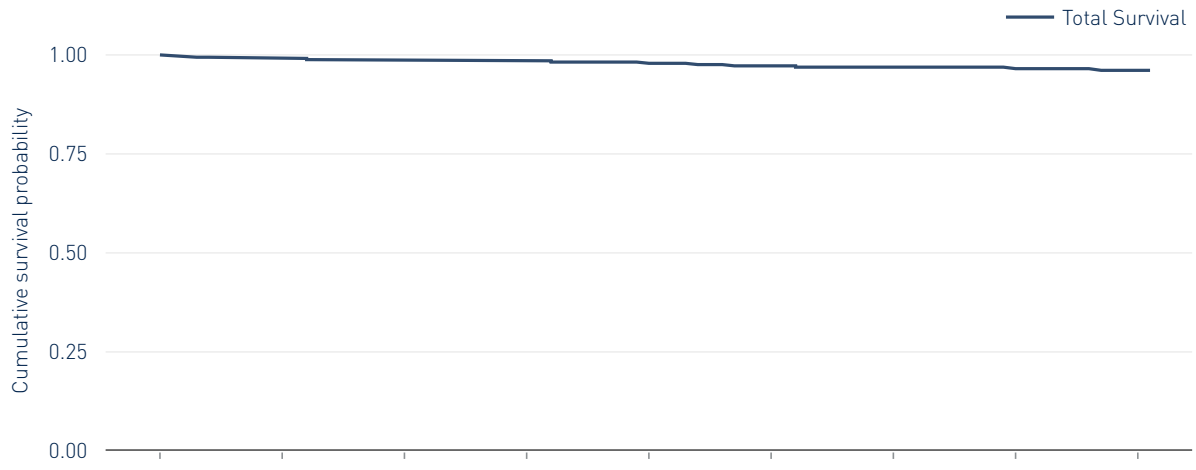
6.2 Performance of ICD Leads – Postmarket Data

Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered US Implants	349
Estimated Active US Implants	283
US Total Returned	4

	Count	Rate
US Qualifying Complications	12	3.42%
Abnormal pacing impedance	1	0.28%
Conductor fracture	4	1.14%
Failure to capture	3	0.85%
Failure to sense	1	0.28%
Insulation breach	1	0.28%
Oversensing	1	0.28%
Other	1	0.28%

	Count	Rate
US Confirmed Malfunctions	0	0.00%
US Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.1	98.5	98.5	97.9	97.2	96.9	96.5	96.1
CI [± %]	< 0.1	1.0	1.3	1.3	1.6	1.8	1.9	2.0	2.2
Sample Size	349	332	324	313	308	299	289	254	211

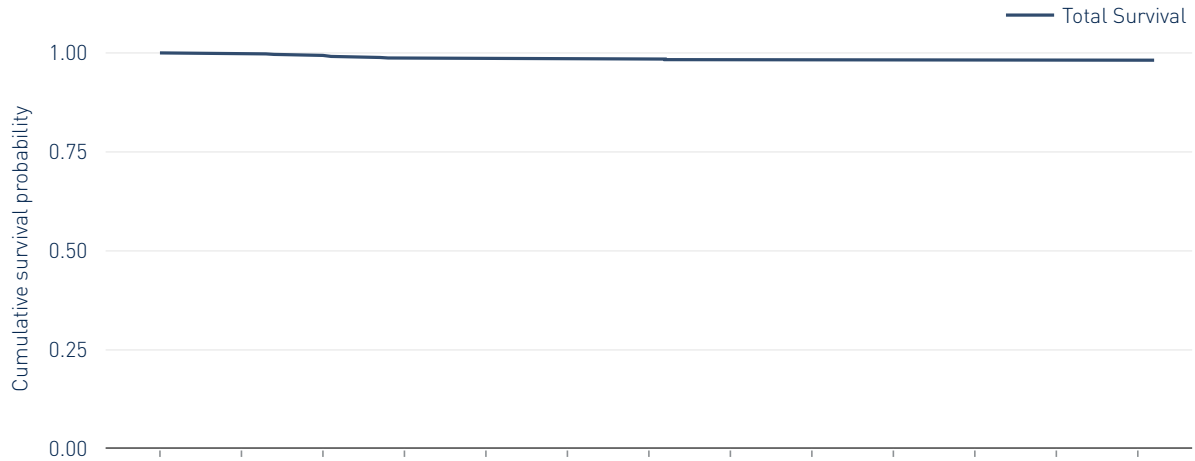
6.2 Performance of ICD Leads – Postmarket Data

Vigila 2CR

Product Versions	60/16, 65/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2012
CE Market Release	Oct 2011
Worldwide Distributed Devices	2 730
Registered US Implants	859
Estimated Active US Implants	657
US Total Returned	12

	Count	Rate
US Qualifying Complications	10	1.16%
Abnormal pacing impedance	1	0.12%
Conductor fracture	1	0.12%
Lead dislodgement	3	0.35%
Oversensing	5	0.58%

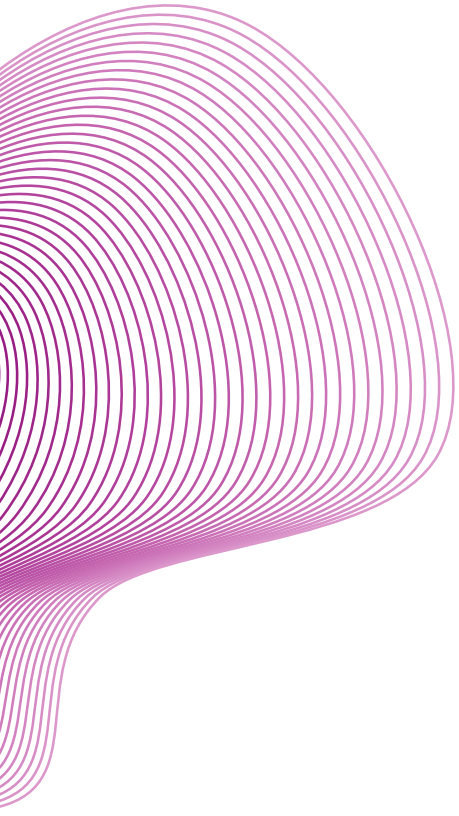
	Count	Rate
US Confirmed Malfunctions	4	0.47%
Insulation breach	4	0.47%
US Acute Lead Observations	1	0.12%
Oversensing	1	0.12%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	99.9	99.4	98.7	98.4	98.4	98.4	98.2	98.2	98.2	98.2	98.2	98.2
CI [± %]	< 0.1	0.2	0.6	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.0	1.0	1.0
Sample Size	859	796	771	742	714	699	686	671	665	658	657	588	291

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data



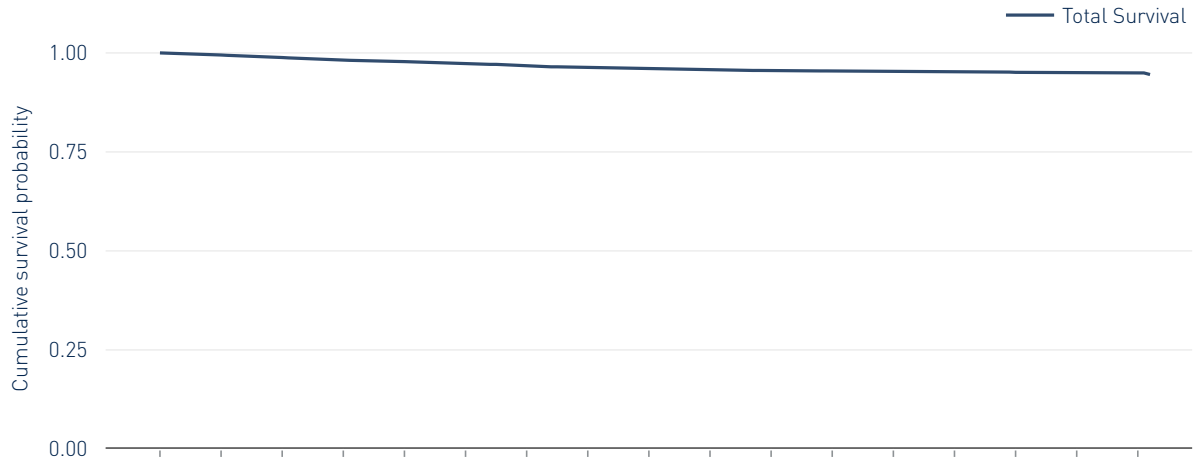
6.3 Performance of CRT Leads – Postmarket Data

Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered US Implants	4 117
Estimated Active US Implants	2 460
US Total Returned	83

	Count	Rate
US Qualifying Complications	136	3.29%
Abnormal pacing impedance	9	0.22%
Conductor fracture	5	0.12%
Extracardiac stimulation	10	0.24%
Failure to capture	50	1.21%
Insulation breach	3	0.07%
Lead dislodgement	39	0.94%
Oversensing	6	0.15%
Other	14	0.34%

	Count	Rate
US Confirmed Malfunctions	16	0.39%
Conductor fracture	15	0.36%
Insulation breach	1	0.02%
US 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	13	14	15	16
Total [%]	100	99.5	98.8	98.2	97.8	97.2	96.8	96.3	96.0	95.8	95.5	95.4	95.3	95.2	95.1	95.1	94.9
CI [± %]	< 0.1	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8
Sample Size	4117	3561	3318	3122	2999	2894	2799	2723	2648	2528	2391	2234	2002	1761	1457	840	300

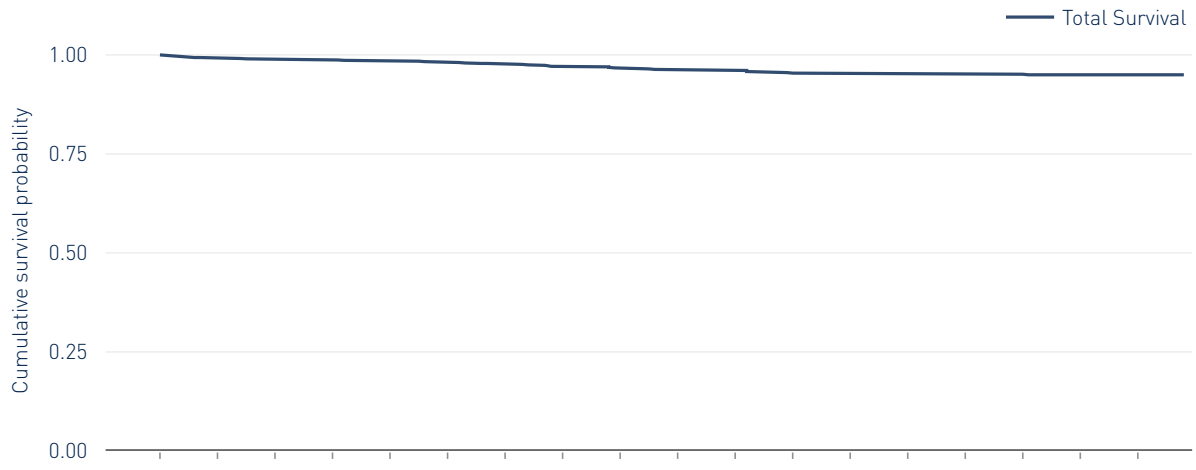
6.3 Performance of CRT Leads – Postmarket Data

Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
US Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered US Implants	1 423
Estimated Active US Implants	662
US Total Returned	26

	Count	Rate
US Qualifying Complications	44	3.09%
Abnormal pacing impedance	1	0.07%
Conductor fracture	2	0.14%
Extracardiac stimulation	7	0.49%
Failure to capture	15	1.05%
Insulation breach	2	0.14%
Lead dislodgement	10	0.70%
Oversensing	2	0.14%
Other	5	0.35%

	Count	Rate
US Confirmed Malfunctions	2	0.14%
Insulation breach	2	0.14%
US 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	14	15	16	17
Total [%]	100	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.3	96.1	95.4	95.3	95.1	95.1	95.1	95.0	95.0
CI [± %]	< 0.1	0.5	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.4	1.4	1.4	1.4	1.5	1.5
Sample Size	1423	1237	1121	1017	932	865	810	776	750	733	716	707	691	681	670	666	658	501

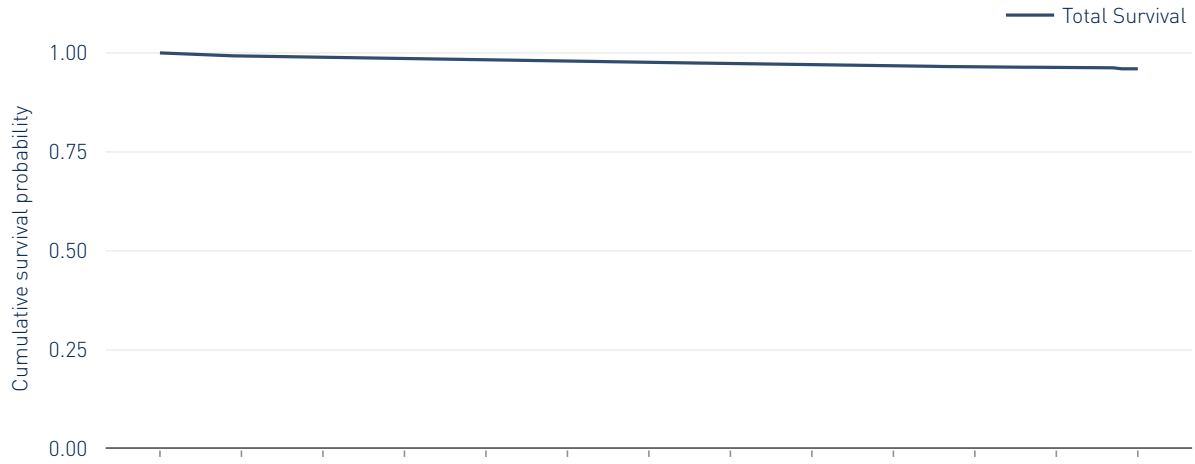
6.3 Performance of CRT Leads – Postmarket Data

Corox OTW-L BP

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Registered US Implants	6 257
Estimated Active US Implants	4 510
US Total Returned	92

	Count	Rate
US Qualifying Complications	176	2.79%
Abnormal pacing impedance	7	0.11%
Conductor fracture	7	0.11%
Extracardiac stimulation	27	0.43%
Failure to capture	77	1.22%
Failure to sense	2	0.03%
Insulation breach	2	0.03%
Lead dislodgement	41	0.65%
Oversensing	5	0.08%
Other	8	0.13%

	Count	Rate
US Confirmed Malfunctions	8	0.13%
Conductor fracture	4	0.06%
Insulation breach	1	0.02%
Other	3	0.05%
US 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	10	11	12
Total [%]	100	99.2	98.9	98.5	98.2	98.0	97.6	97.3	97.0	96.8	96.5	96.4	96.0
CI [± %]	< 0.1	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.8
Sample Size	6254	5685	5437	5241	5115	4993	4825	4167	3464	2648	1757	889	249

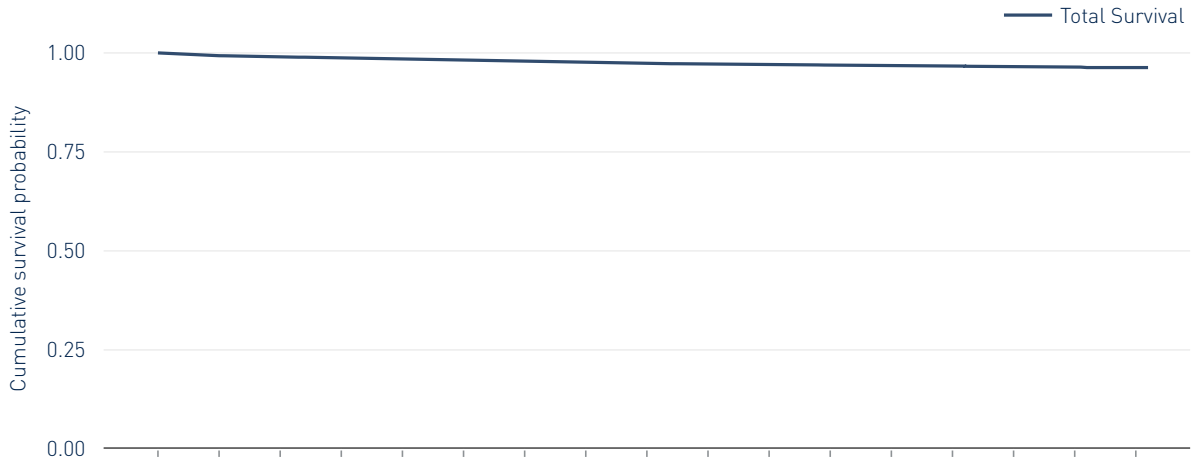
6.3 Performance of CRT Leads – Postmarket Data

Corox OTW-S BP

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
Registered US Implants	8 159
Estimated Active US Implants	5 210
US Total Returned	137

	Count	Rate
US Qualifying Complications	196	2.39%
Abnormal pacing impedance	12	0.15%
Conductor fracture	8	0.10%
Extracardiac stimulation	18	0.22%
Failure to capture	59	0.72%
Failure to sense	1	0.01%
Insulation breach	4	0.05%
Lead dislodgement	64	0.78%
Oversensing	8	0.10%
Other	22	0.27%

	Count	Rate
US Confirmed Malfunctions	14	0.17%
Conductor fracture	8	0.10%
Insulation breach	5	0.06%
Other	1	0.01%
US 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	13	14	15	16
Total [%]	100	99.3	99.0	98.8	98.5	98.1	97.8	97.5	97.4	97.2	97.1	96.9	96.8	96.7	96.5	96.4	96.3
CI [± %]	< 0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.6
Sample Size	8159	7156	6755	6414	6191	5986	5803	5661	5348	4866	4346	3781	3180	2631	1974	961	306

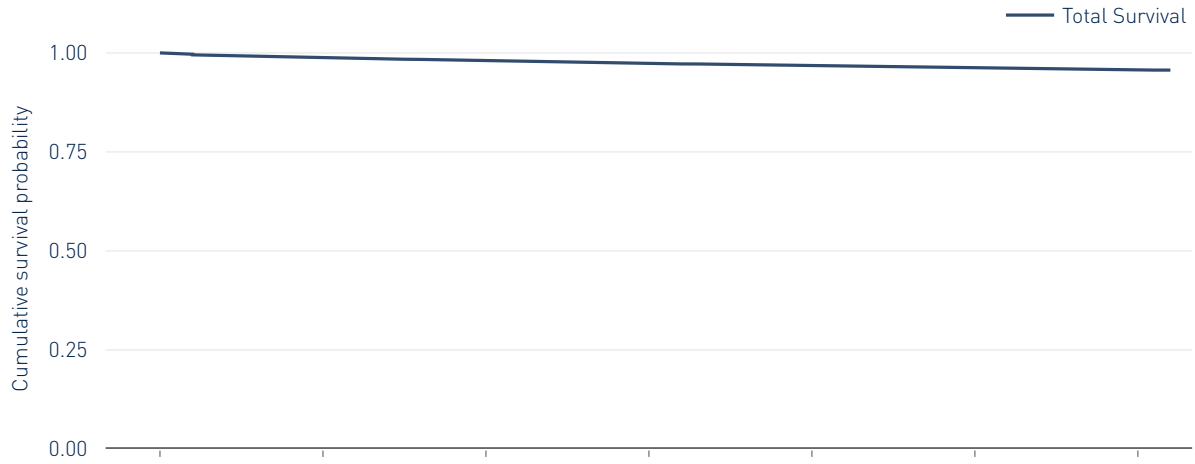
6.3 Performance of CRT Leads – Postmarket Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	167 000
Registered US Implants	26 062
Estimated Active US Implants	21 600
US Total Returned	353

	Count	Rate
US Qualifying Complications	593	2.26%
Abnormal pacing impedance	87	0.33%
Conductor fracture	30	0.11%
Extracardiac stimulation	30	0.11%
Failure to capture	148	0.56%
Failure to sense	2	0.01%
Lead dislodgement	198	0.75%
Oversensing	69	0.26%
Other	29	0.11%

	Count	Rate
US Confirmed Malfunctions	87	0.33%
Conductor fracture	80	0.30%
Insulation breach	1	0.00%
Other	6	0.02%
US Acute Lead Observations	73	0.28%
Abnormal pacing impedance	2	0.01%
Conductor fracture	1	0.00%
Extracardiac stimulation	8	0.03%
Failure to capture	12	0.05%
Lead dislodgement	43	0.16%
Oversensing	4	0.02%
Other	3	0.01%



Years after implant	0	1	2	3	4	5	6
Total [%]	100	98.8	98.1	97.4	96.8	96.2	95.7
CI [± %]	< 0.1	0.2	0.2	0.3	0.3	0.4	0.5
Sample Size	21k	16k	12.6k	9056	6026	2918	397

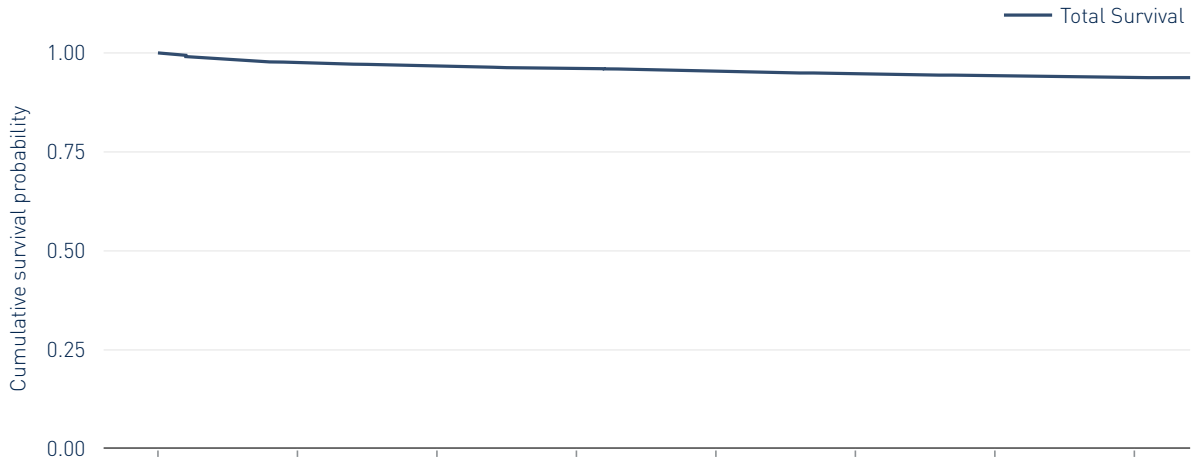
6.3 Performance of CRT Leads – Postmarket Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	29 100
Registered US Implants	6 016
Estimated Active US Implants	4 250
US Total Returned	172

	Count	Rate
US Qualifying Complications	213	3.50%
Abnormal pacing impedance	19	0.31%
Conductor fracture	11	0.18%
Extracardiac stimulation	8	0.13%
Failure to capture	49	0.80%
Failure to sense	1	0.02%
Insulation breach	1	0.02%
Lead dislodgement	100	1.64%
Oversensing	18	0.30%
Other	6	0.10%

	Count	Rate
US Confirmed Malfunctions	14	0.23%
Conductor fracture	14	0.23%
US Acute Lead Observations	105	1.72%
Abnormal pacing impedance	1	0.02%
Extracardiac stimulation	4	0.07%
Failure to capture	15	0.25%
Failure to sense	2	0.03%
Lead dislodgement	76	1.25%
Oversensing	5	0.08%
Other	2	0.03%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	97.5	96.7	96.1	95.3	94.7	94.3	93.8
CI [± %]	< 0.1	0.4	0.5	0.6	0.6	0.7	0.8	0.9
Sample Size	6016	4364	3744	3183	2601	2034	1359	563

Methodology for Lead Survival Estimates Based on Clinical Studies

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 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, 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 8.1 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 chapter 9). The lead-related complication free survival probabilities provided for the Sentus QP lead in Section 8.3 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 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 – 2000 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
- A bnormal pacing impedance (based on lead model, but normal range is typically 200 – 2000 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

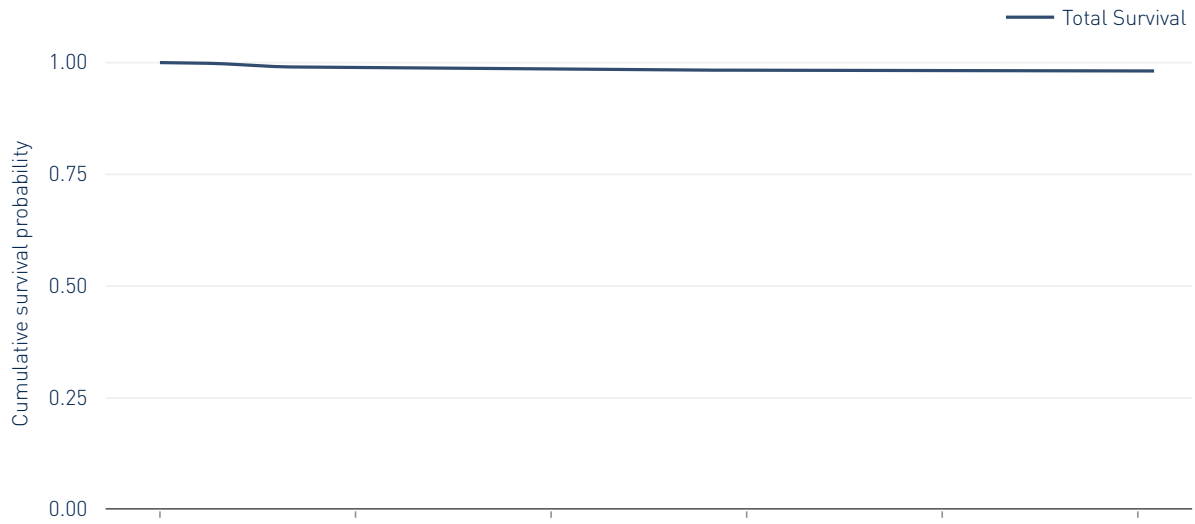
Performance of BIOTRONIK Leads Based on Clinical Study Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	3 421 000
US Implants in Studies	3 250

	Count	Rate
US Qualifying Complications	52	1.60%
Abnormal pacing impedance	4	0.12%
Cardiac perforation	2	0.06%
Conductor fracture	2	0.06%
Failure to capture	23	0.71%
Failure to sense (undersensing)	10	0.31%
Lead dislodgement	9	0.28%
Oversensing	1	0.03%
Other	1	0.03%

	Count	Rate
US Confirmed Malfunctions	3	0.09%
Conductor Fracture	1	0.03%
Insulation Breach	1	0.03%
Other	1	0.03%
US 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	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 Pacing Leads
8.2 ICD Leads
8.3 CRT Leads

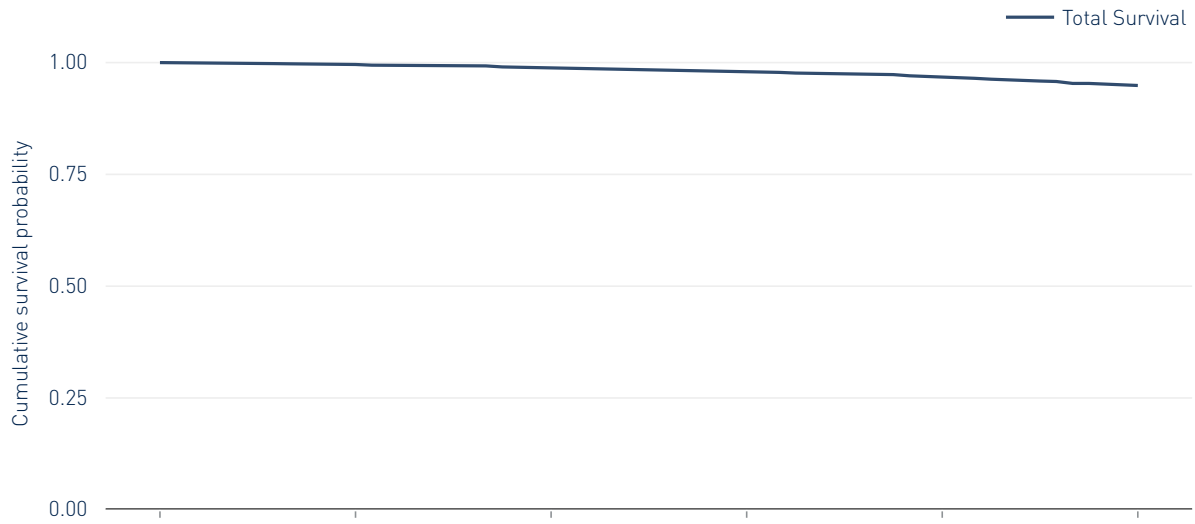
8.2 Performance of ICD Leads – Study Data

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
US Implants in Studies	2 280

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	27	1.19%
Conductor Fracture	4	0.18%
Insulation Breach	23	1.01%
US 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%



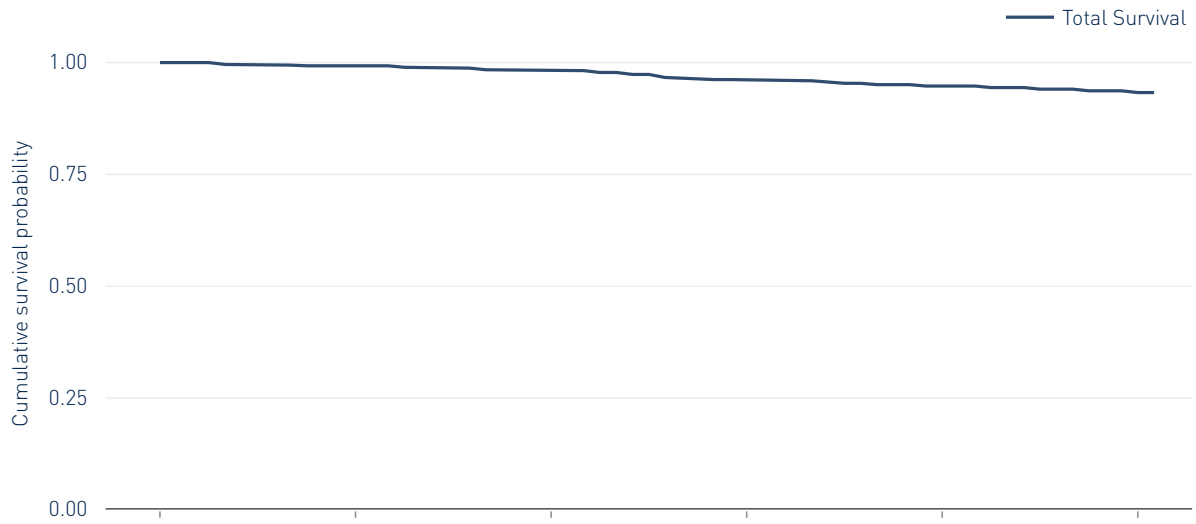
Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	98.8	98.0	96.7	94.9
CI [± %]	-	0.3	0.5	0.7	0.9	1.3
Sample Size	2272	1937	1618	1302	1014	392

Linox Smart SD

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

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	8	1.09%
Insulation Breach	8	1.09%
US Acute Lead Observations	2	0.27%
Lead dislodgement	2	0.27%



Years after implant	0	1	2	3	4	5
Total [%]	100	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
8.2 ICD Leads
8.3 CRT Leads

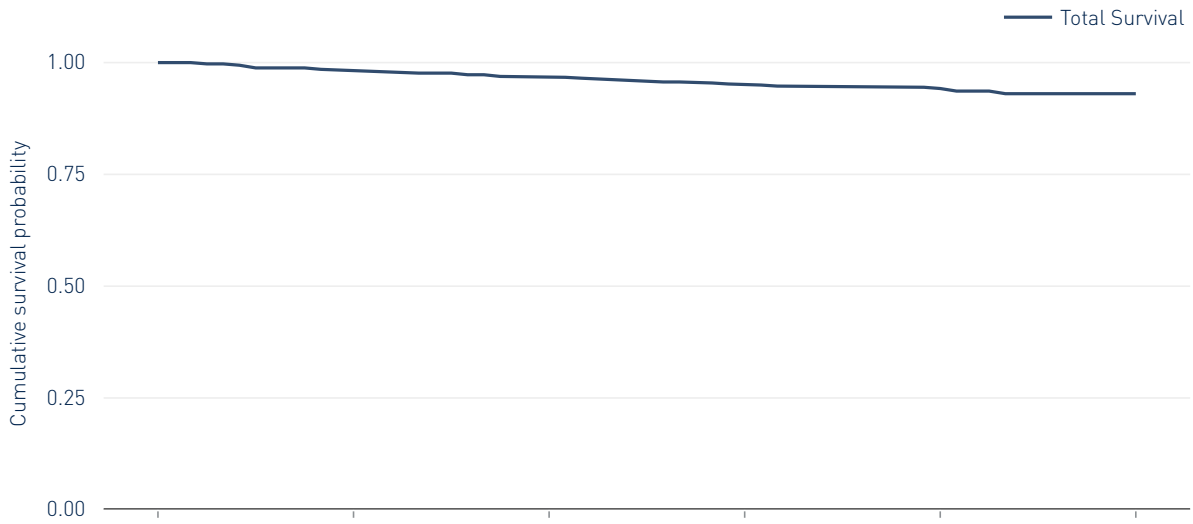
8.3 Performance of CRT Leads – Study Data

Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
US Implants in Studies	696

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	6	0.86%
Conductor Fracture	6	0.86%
US 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	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

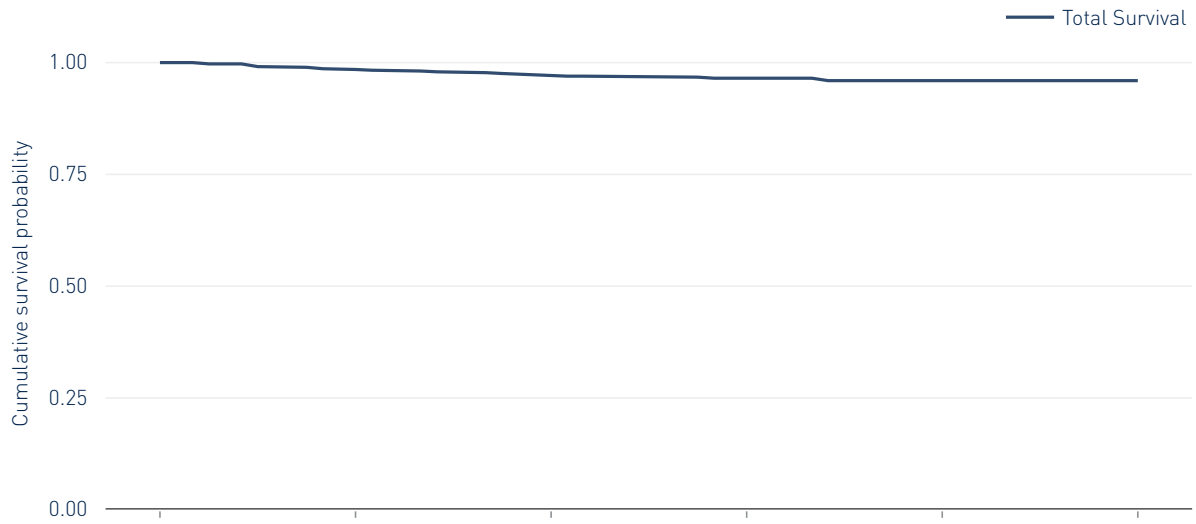
8.3 Performance of CRT Leads – Study Data

Corox OTW-L BP

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
US Implants in Studies	699

	Count	Rate
US Qualifying Complications	22	3.15%
Extracardiac stimulation	4	0.57%
Failure to capture	8	1.14%
Lead dislodgement	10	1.43%

	Count	Rate
US Confirmed Malfunctions	1	0.14%
Other	1	0.14%
US 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	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

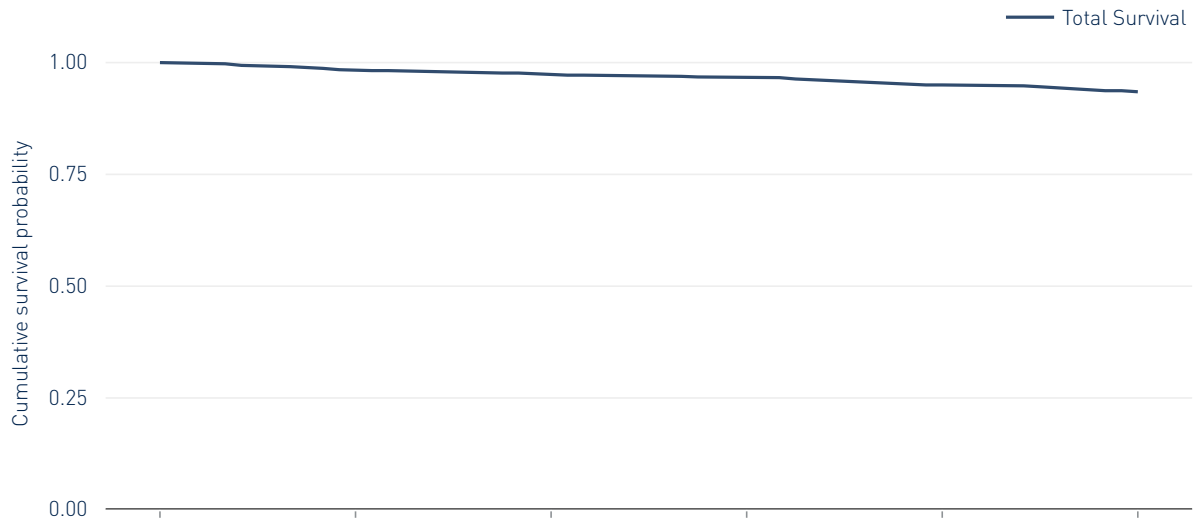
8.3 Performance of CRT Leads – Study Data

Corox OTW-S BP

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
US Implants in Studies	1 150

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	1	0.09%
Insulation Breach	1	0.09%
US 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	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

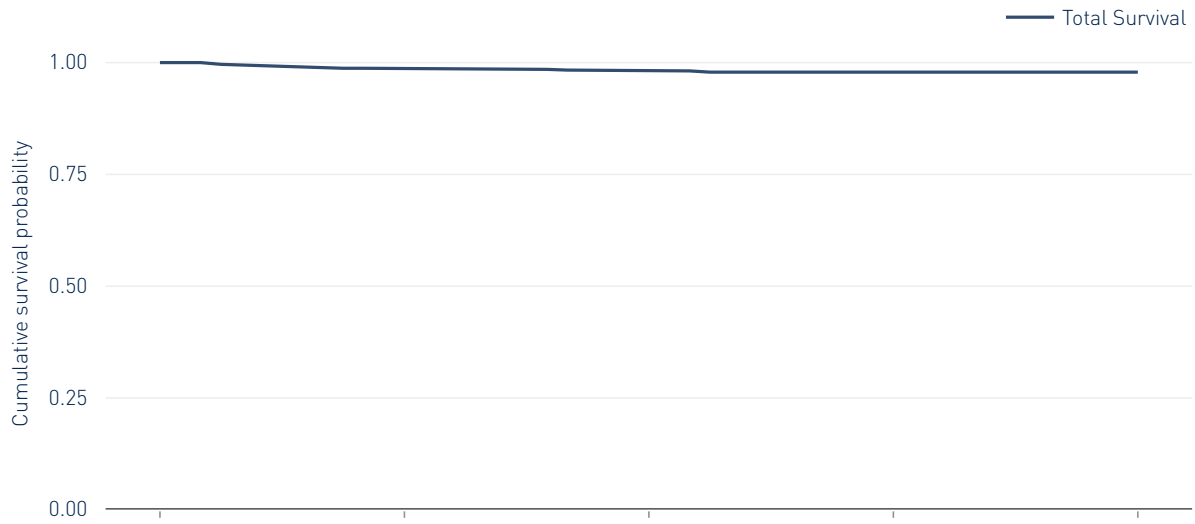
8.3 Performance of CRT Leads – Study Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	167 000
US Implants in Studies	1 310

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	15	1.15%
Conductor Fracture	14	1.07%
NA	1	0.08%
US 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	98.7	98.1	97.9	97.9
CI [± %]	-	0.7	0.9	1.1	1.1
Sample Size	1308	863	418	138	0

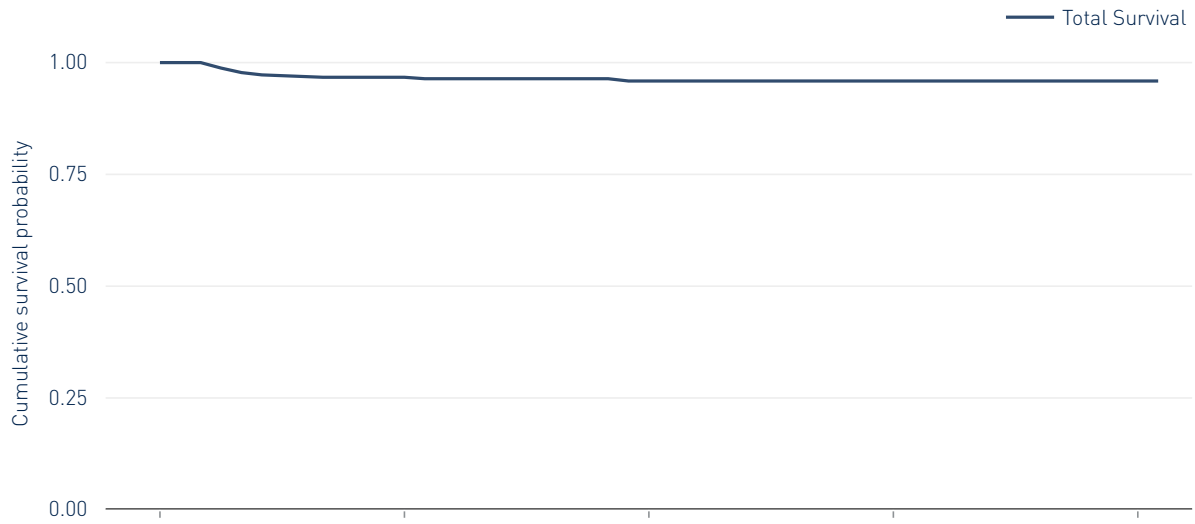
8.3 Performance of CRT Leads – Study Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	29 100
US Implants in Studies	436

	Count	Rate
US 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%

	Count	Rate
US Confirmed Malfunctions	5	1.15%
Conductor Fracture	5	1.15%
US 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	96.7	95.9	95.9	95.9
CI [± %]	-	1.8	2.2	2.2	2.2
Sample Size	436	299	170	55	0

Methodology for Lead Survival Estimates based on Insurance Claims Data

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 US 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

[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.

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 US market approval as identified in BIOTRONIK's US 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.

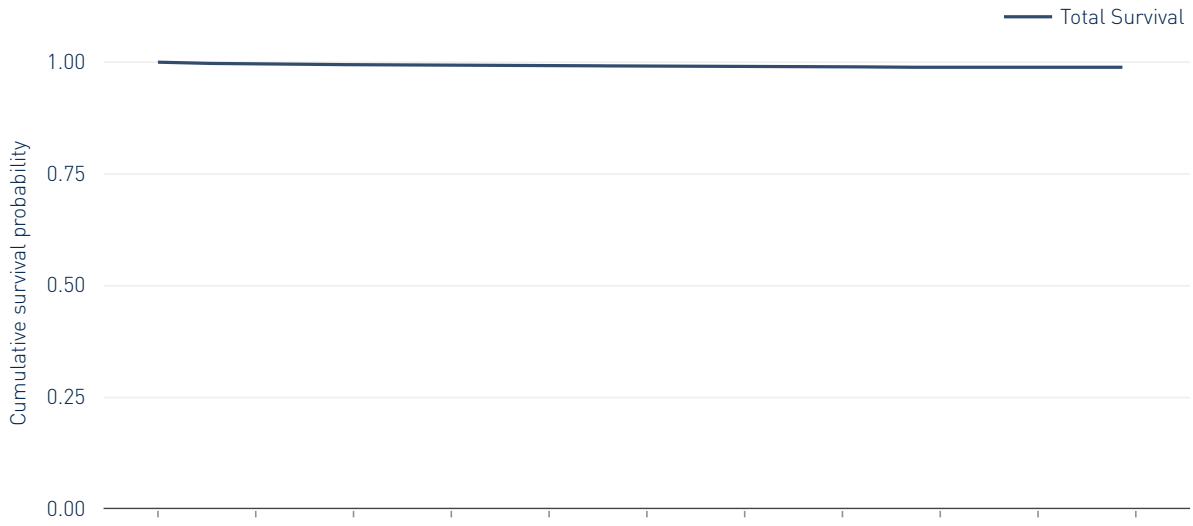
Performance of BIOTRONIK Leads Based on Insurance Claims Data

Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Performance of Pacing Leads – Insurance Claims Data

Siello S / Solia S*

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	3 421 000
US Implants in EP PASSION	94 700



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.6	99.4	99.4	99.2	99.1	99.1	99.0	98.9	98.9	98.9
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.9	1.3	6.5
Sample Size	94625	72618	55811	41355	28866	19364	14044	6358	500	171	🔒

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

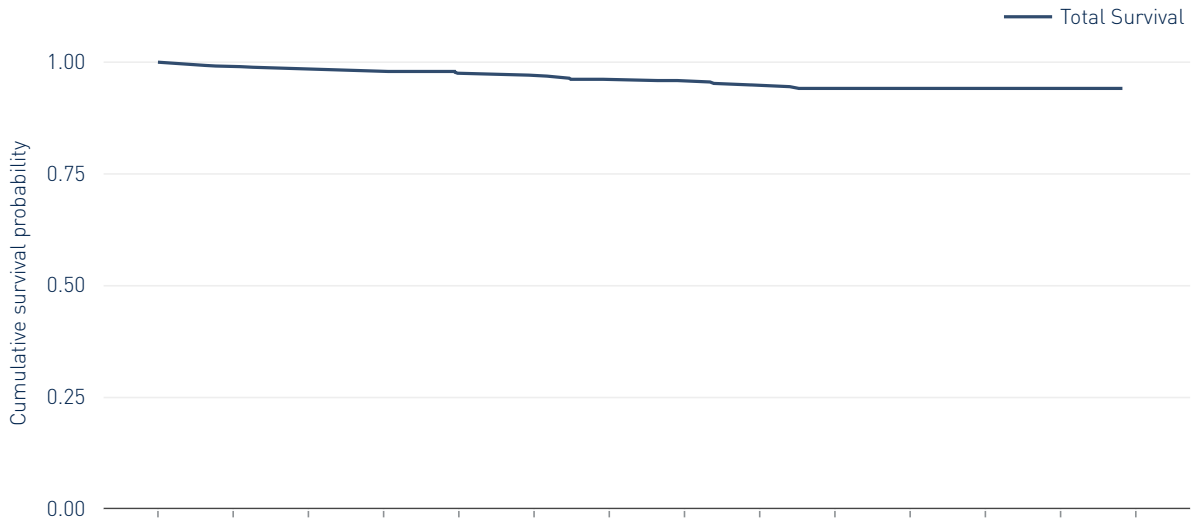
Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads
10.2 ICD Leads
10.3 CRT Leads

10.2 Performance of ICD Leads – Insurance Claims Data

Linox S*

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
US Implants in EP PASSION	870



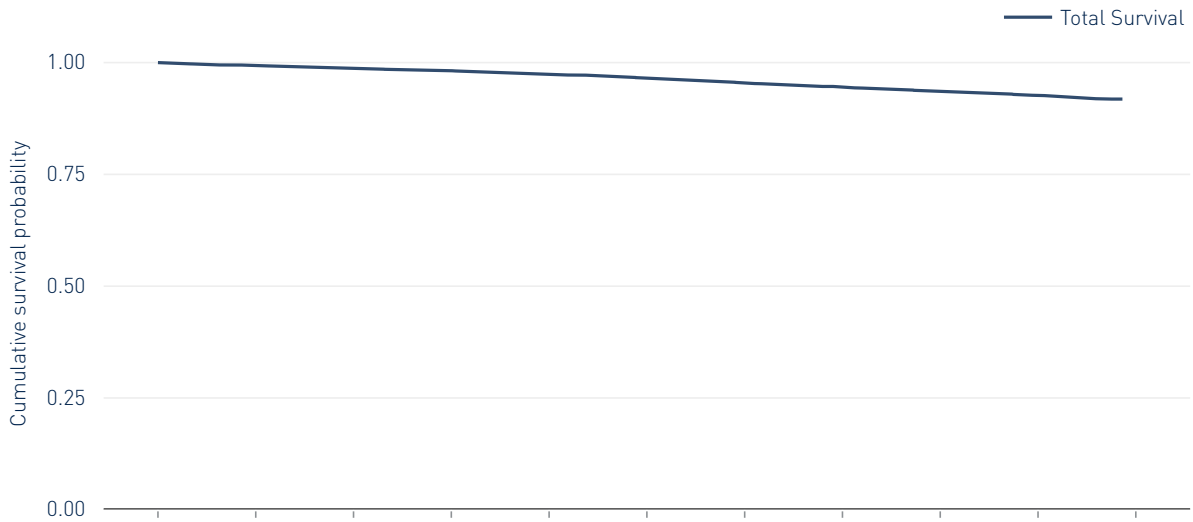
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100	99.1	98.6	98.1	97.5	97.1	96.2	95.9	94.9	94.1	94.1	94.1	94.1	94.1
CI [± %]	< 0.1	0.7	0.9	1.1	1.3	1.5	1.9	2.1	2.5	3.0	3.3	3.6	3.8	4.4
Sample Size	870	🔒	649	574	499	443	382	334	273	221	185	154	135	102

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
US Implants in EP PASSION	7 260

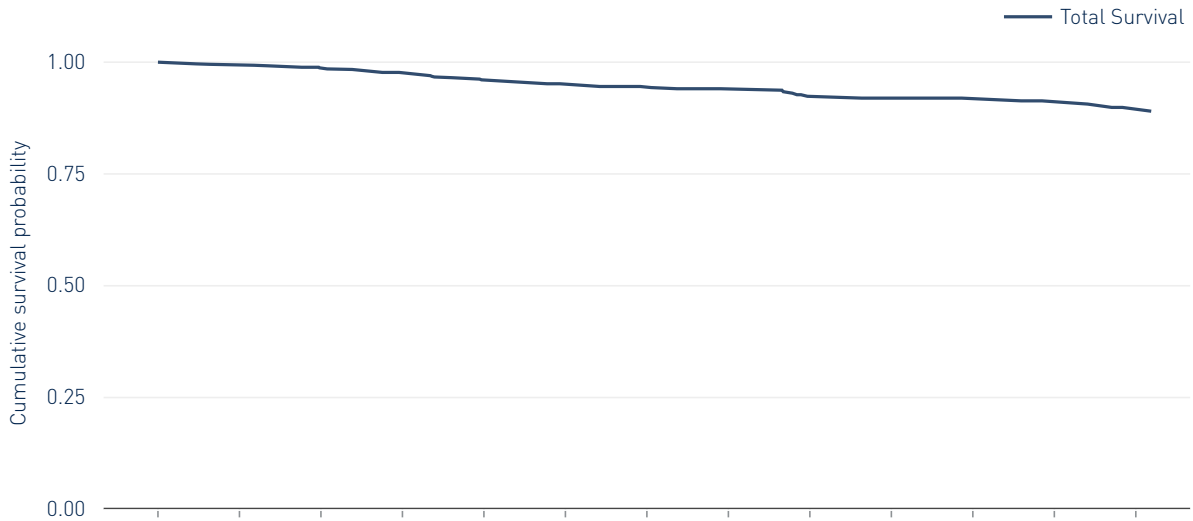


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.4	98.7	98.2	97.4	96.6	95.5	94.6	93.6	92.7	91.8
CI [± %]	< 0.1	0.2	0.3	0.4	0.5	0.6	0.8	0.9	1.1	1.3	1.5
Sample Size	7251	6020	5199	4480	3780	3139	2594	2121	1751	1406	1170

10.2 Performance of ICD Leads – Insurance Claims Data

Linox TD*

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
US Implants in EP PASSION	1 150



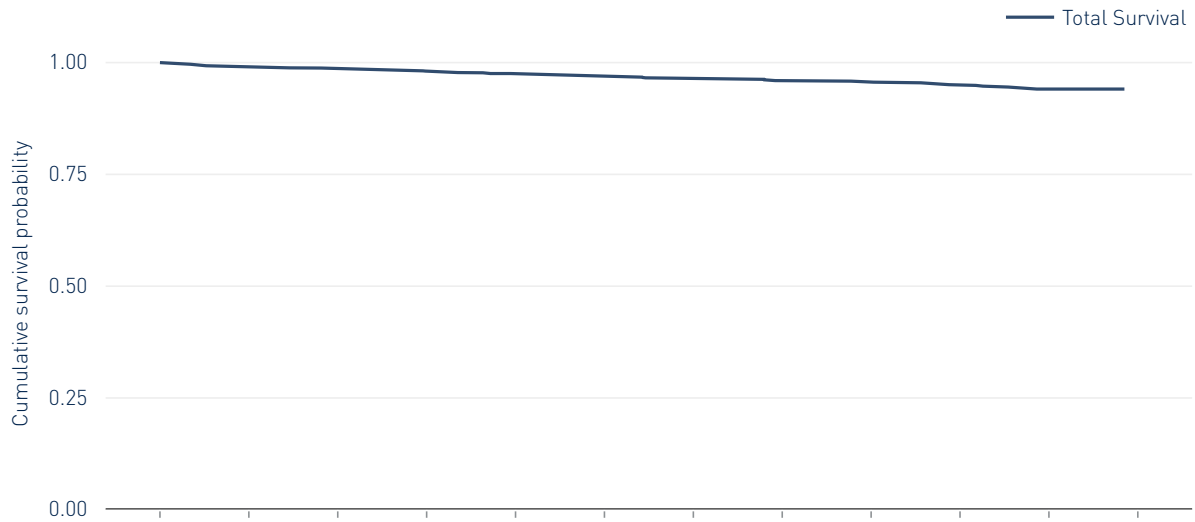
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100	99.5	98.7	97.7	96.0	95.2	94.6	94.1	92.4	92.0	92.0	91.3	89.9
CI [± %]	< 0.1	0.4	0.8	1.1	1.5	1.9	2.2	2.5	3.1	3.5	3.8	4.4	5.2
Sample Size	1149	🔒	821	698	589	484	400	330	264	218	183	144	115

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Linox Smart S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
US Implants in EP PASSION	3 020

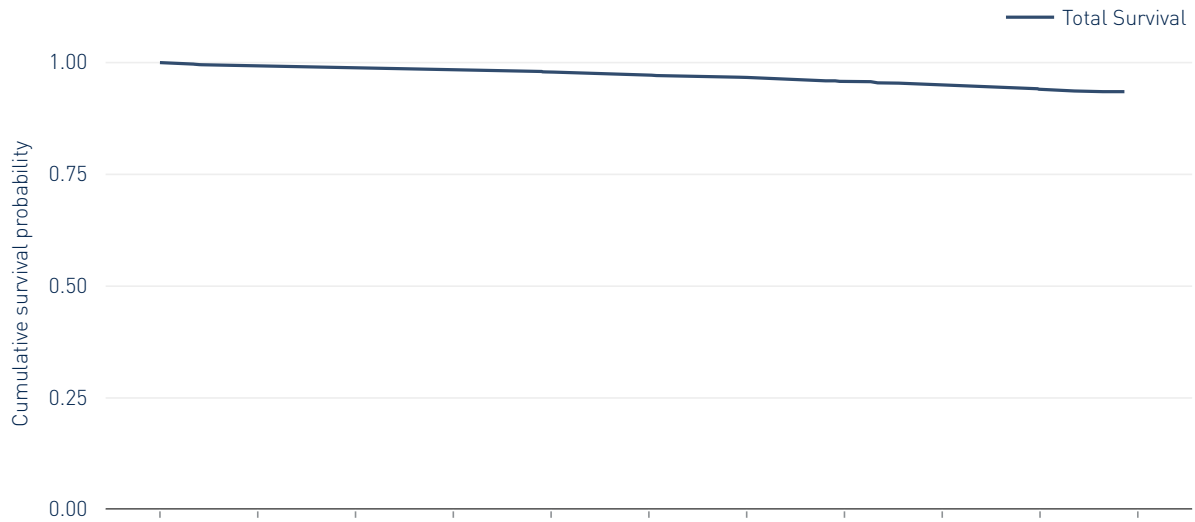


Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.0	98.7	98.1	97.5	97.0	96.5	96.0	95.7	95.1	94.1	94.1
CI [± %]	< 0.1	0.4	0.5	0.6	0.7	0.9	1.0	1.2	1.4	1.6	2.2	3.0
Sample Size	3014	2518	2185	1893	1647	1413	1204	1019	810	645	408	227

10.2 Performance of ICD Leads – Insurance Claims Data

Linox Smart SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
US Implants in EP PASSION	5 290

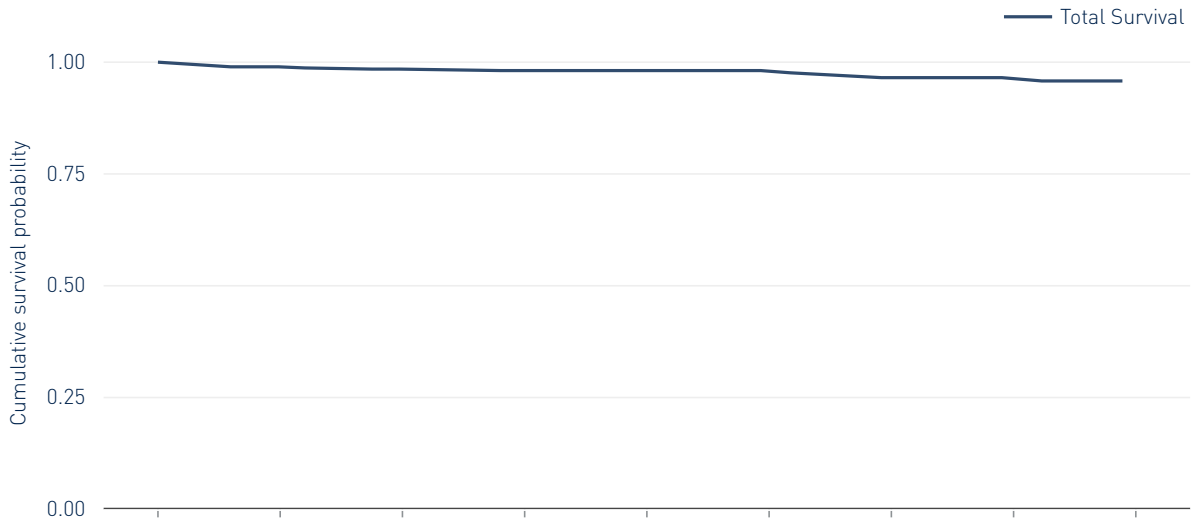


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.1	98.8	98.3	97.9	97.2	96.7	95.8	95.0	94.0	93.5
CI [± %]	< 0.1	0.3	0.4	0.4	0.5	0.7	0.8	1.0	1.2	1.6	2.1
Sample Size	5286	4322	3730	3240	2800	2380	1980	1578	1225	836	517

10.2 Performance of ICD Leads – Insurance Claims Data

Linox Smart TD*

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
US Implants in EP PASSION	522



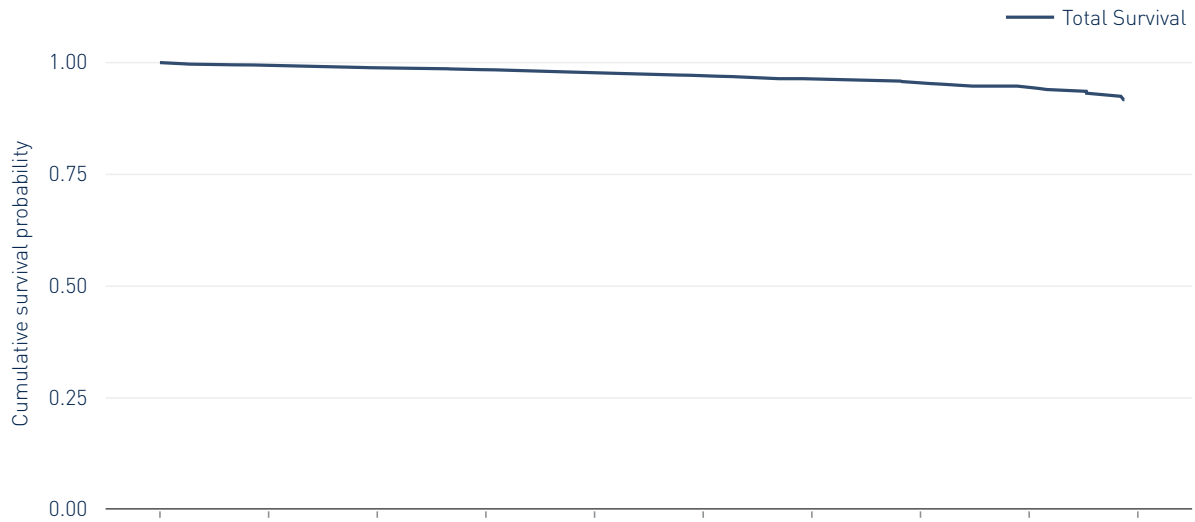
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.0	98.5	98.1	98.1	98.1	96.5	96.5	95.8
CI [± %]	< 0.1	1.0	1.3	1.5	1.7	1.9	2.7	3.0	3.7
Sample Size	522	🔒	🔒	🔒	🔒	🔒	171	141	110

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Linox Smart S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 300
US Implants in EP PASSION	4 670

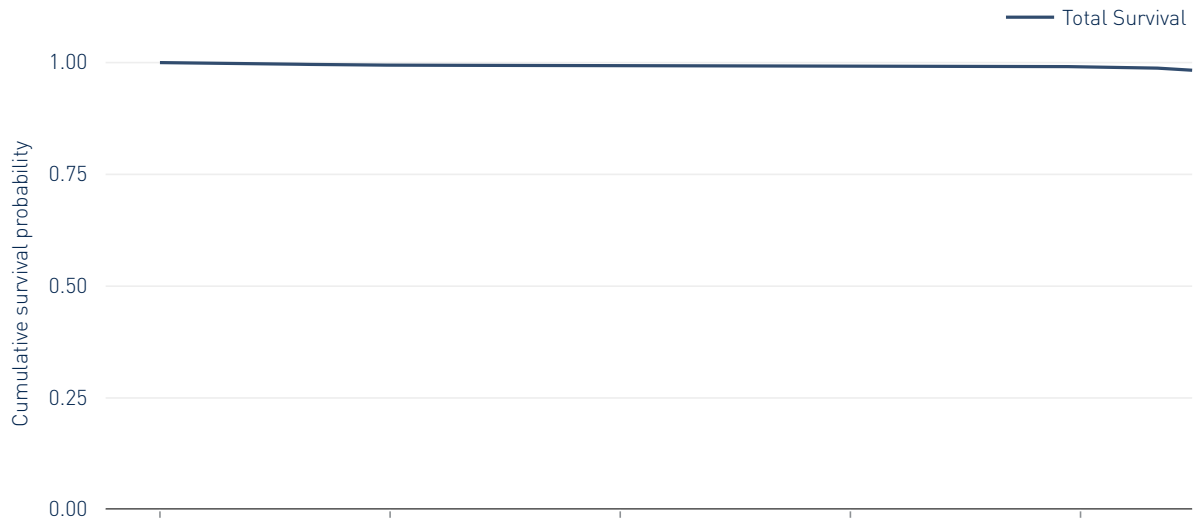


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.4	98.9	98.4	97.8	97.1	96.4	95.4	94.7	91.7
CI [± %]	< 0.1	0.2	0.4	0.4	0.6	0.7	1.0	1.4	2.0	4.6
Sample Size	4659	3850	3373	2919	2491	2051	1401	858	440	124

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	52 800
US Implants in EP PASSION	4 210

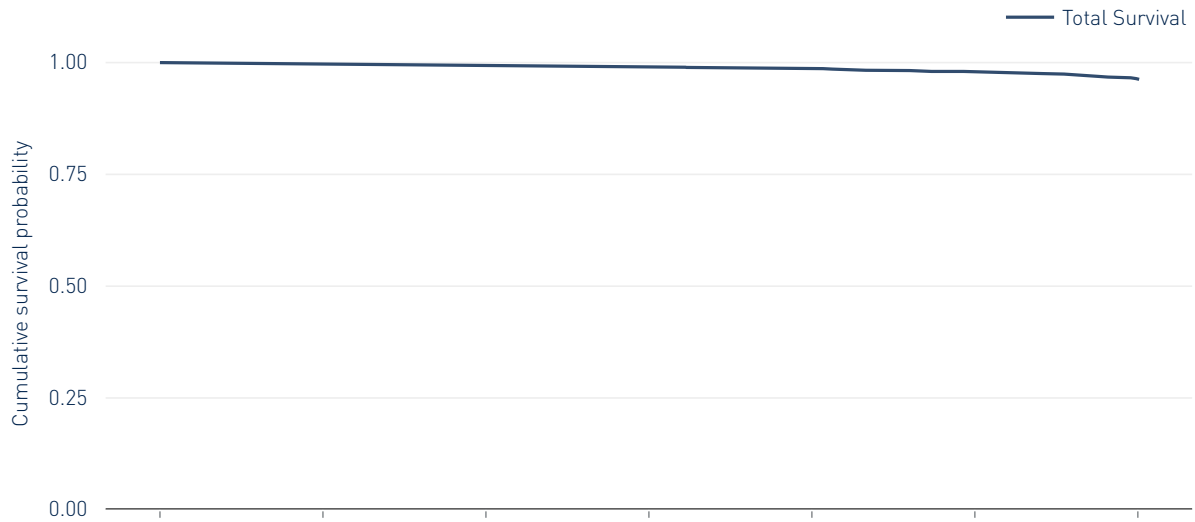


Years after implant	0	1	2	3	4
Total [%]	100	99.4	99.4	99.3	99.1
CI [± %]	< 0.1	0.3	0.4	0.5	0.9
Sample Size	4210	2801	1782	993	431

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	187 000
US Implants in EP PASSION	7 550

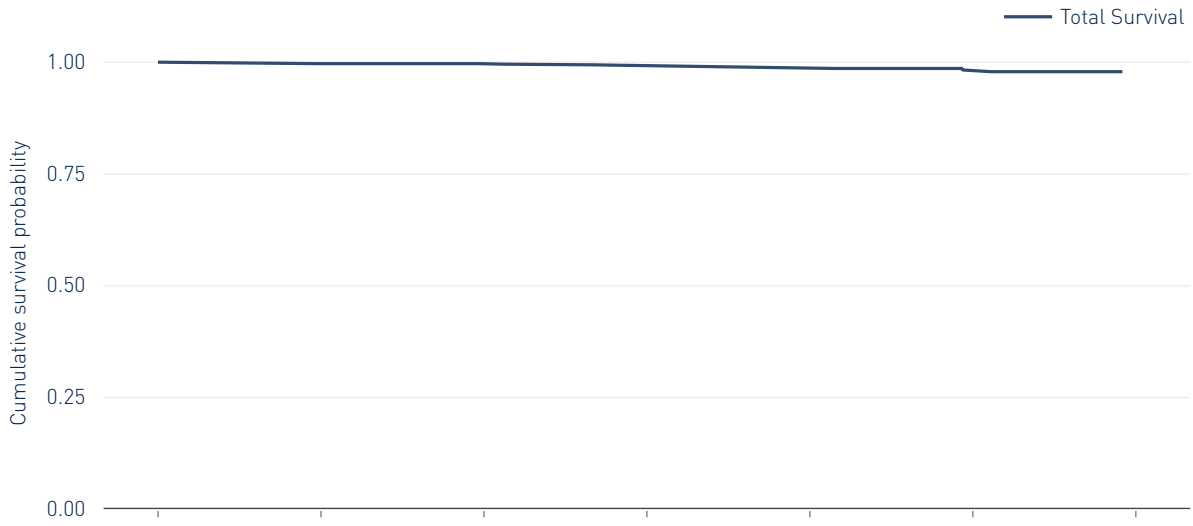


Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.6	99.4	99.1	98.8	98.0	96.4
CI [± %]	< 0.1	0.2	0.2	0.3	0.5	0.8	1.5
Sample Size	7543	5641	4248	3062	2073	1293	561

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa SD*

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	20 700
US Implants in EP PASSION	1 400



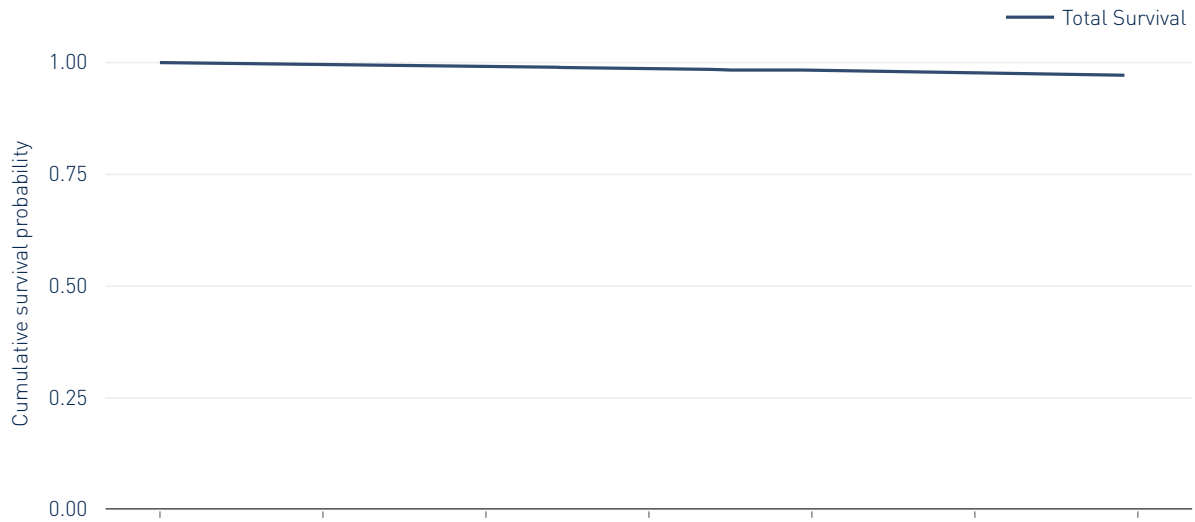
Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.7	99.7	99.2	98.8	98.2	97.9
CI [± %]	< 0.1	0.3	0.4	0.7	1.0	1.5	2.1
Sample Size	1398	🔒	🔒	🔒	🔒	285	130

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	24 700
US Implants in EP PASSION	2 430

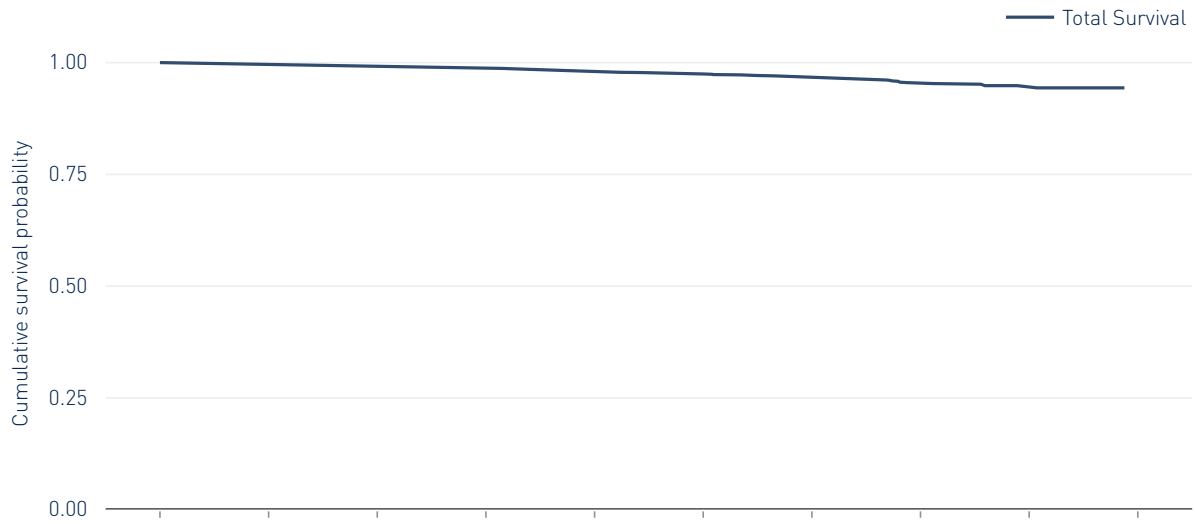


Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.5	99.3	98.8	98.3	97.8	97.2
CI [± %]	< 0.1	0.3	0.4	0.6	0.7	0.9	1.5
Sample Size	2428	2013	1692	1455	1202	948	429

10.2 Performance of ICD Leads – Insurance Claims Data

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
US Implants in EP PASSION	3 090

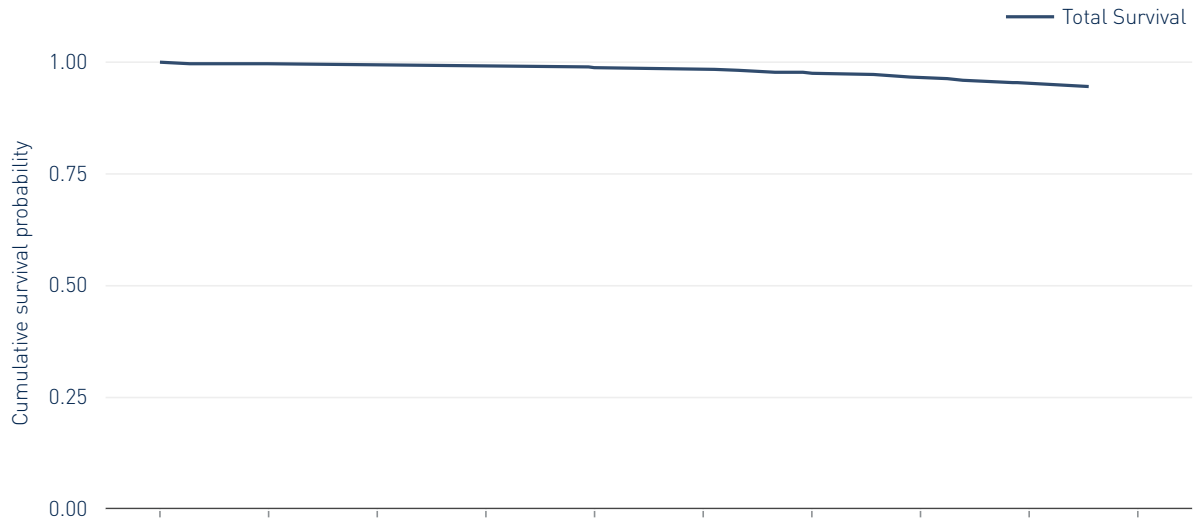


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.5	99.3	98.9	98.0	97.5	96.9	95.5	94.8	94.3
CI [± %]	< 0.1	0.3	0.3	0.5	0.6	0.8	1.0	1.3	1.7	4.2
Sample Size	3090	2614	2299	2027	1743	1503	1231	961	439	111

10.2 Performance of ICD Leads – Insurance Claims Data

Protego SD*

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18 400
US Implants in EP PASSION	1 190



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.7	99.5	99.3	98.8	98.6	97.7	96.7	95.4	94.5
CI [± %]	< 0.1	0.4	0.5	0.6	0.9	1.0	1.4	1.9	3.0	4.2
Sample Size	1184	🔒	🔒	🔒	🔒	504	428	329	183	107

*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

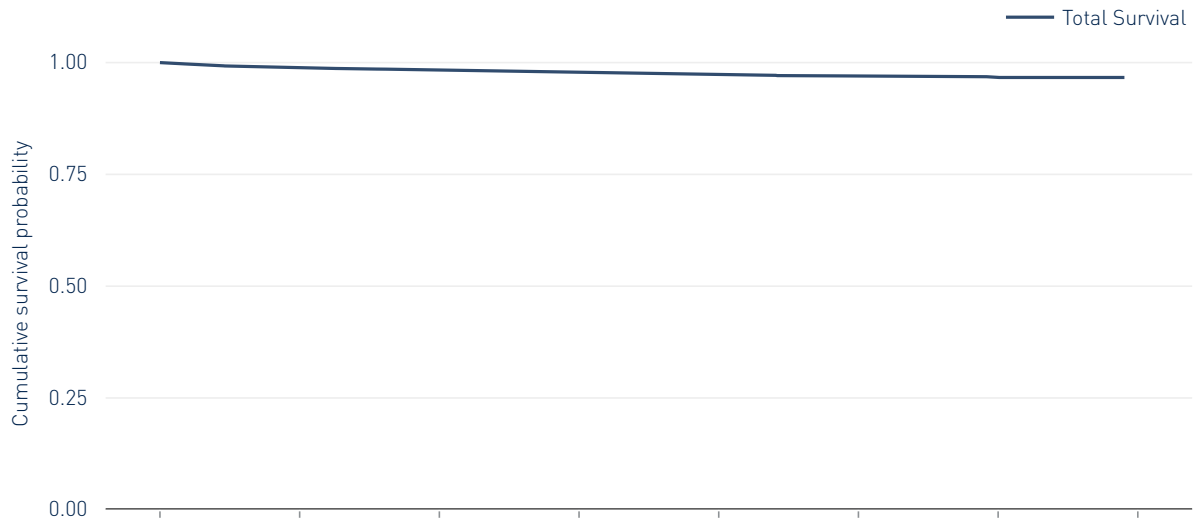
Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads
10.2 ICD Leads
10.3 CRT Leads

10.3 Performance of CRT Leads – Insurance Claims Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	167 000
US Implants in EP PASSION	8 400

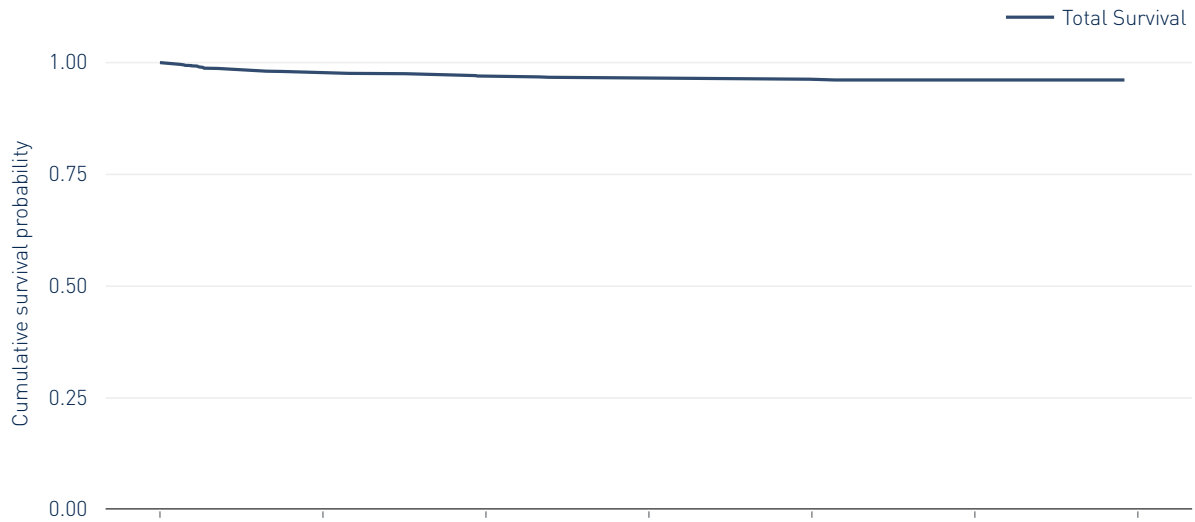


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	98.9	98.4	97.9	97.5	97.0	96.8	96.7
CI [± %]	< 0.1	0.3	0.4	0.5	0.7	0.9	1.4	2.4
Sample Size	8400	6120	4564	3298	2186	1354	623	103

10.3 Performance of CRT Leads – Insurance Claims Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	29 100
US Implants in EP PASSION	1 910



Years after implant	0	1	2	3	4	5	6
Total [%]	100	97.8	97.0	96.6	96.3	96.1	96.1
CI [± %]	< 0.1	0.8	1.0	1.2	1.5	1.9	2.7
Sample Size	1901	1408	1096	854	579	383	194

Advisories

11.1 BIO-LQC – Potential premature battery depletion in a subset of ICD and CRT-D devices

162 000 devices world-wide, 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 30, 2021 in the United States. The corresponding CE-Version has been released on March 31, 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 Nov 2024:

- The cumulative failure rate is 1.8 %.
- 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 is 0.56 %.
- 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 risk estimation for loss of therapy depending on the service time:

Risk for loss of pacing therapy

Service Time	Risk per month
0 - 24 months	< 0.00001 %
24 - 48 months	0.0013 %
48 - 72 months	0.0090 %

Risk for loss of high voltage therapy

Service Time	Risk per month
0 - 24 months	< 0.00001 %
24 - 48 months	0.0021 %
48 - 72 months	0.0147 %

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 and 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 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 outweighs the risk associated with this issue[1,2,3]. 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
Rivacor 7 DR-T, HF-T, VR-T DF4	

Contact 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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Regarding Products

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