Product Performance Report

1st Edition 2024

Cardiac Rhythm Management

Cumulative Survival Probability

BIOTRONIK

excellence for life

Product Performance Report 1st Edition 2024

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

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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 2024

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).

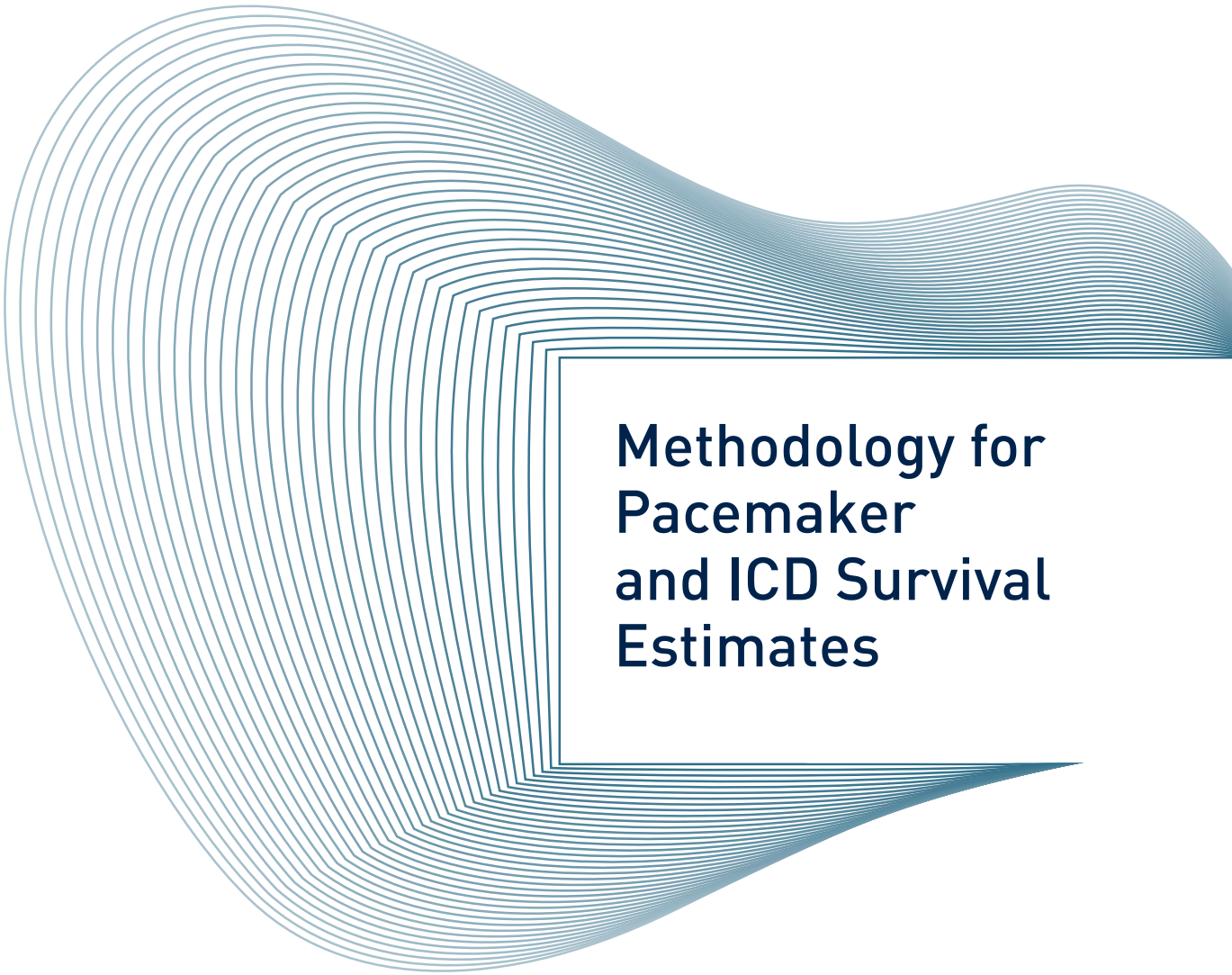
Cumulative Survival Probability Estimates The survival probability over a device's service time is the cumulative survival probability. It is calculated from all discrete survival probabilities of previous time intervals. This characteristic is calculated separately for malfunction-free survival and 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 June 30, 2023. 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.

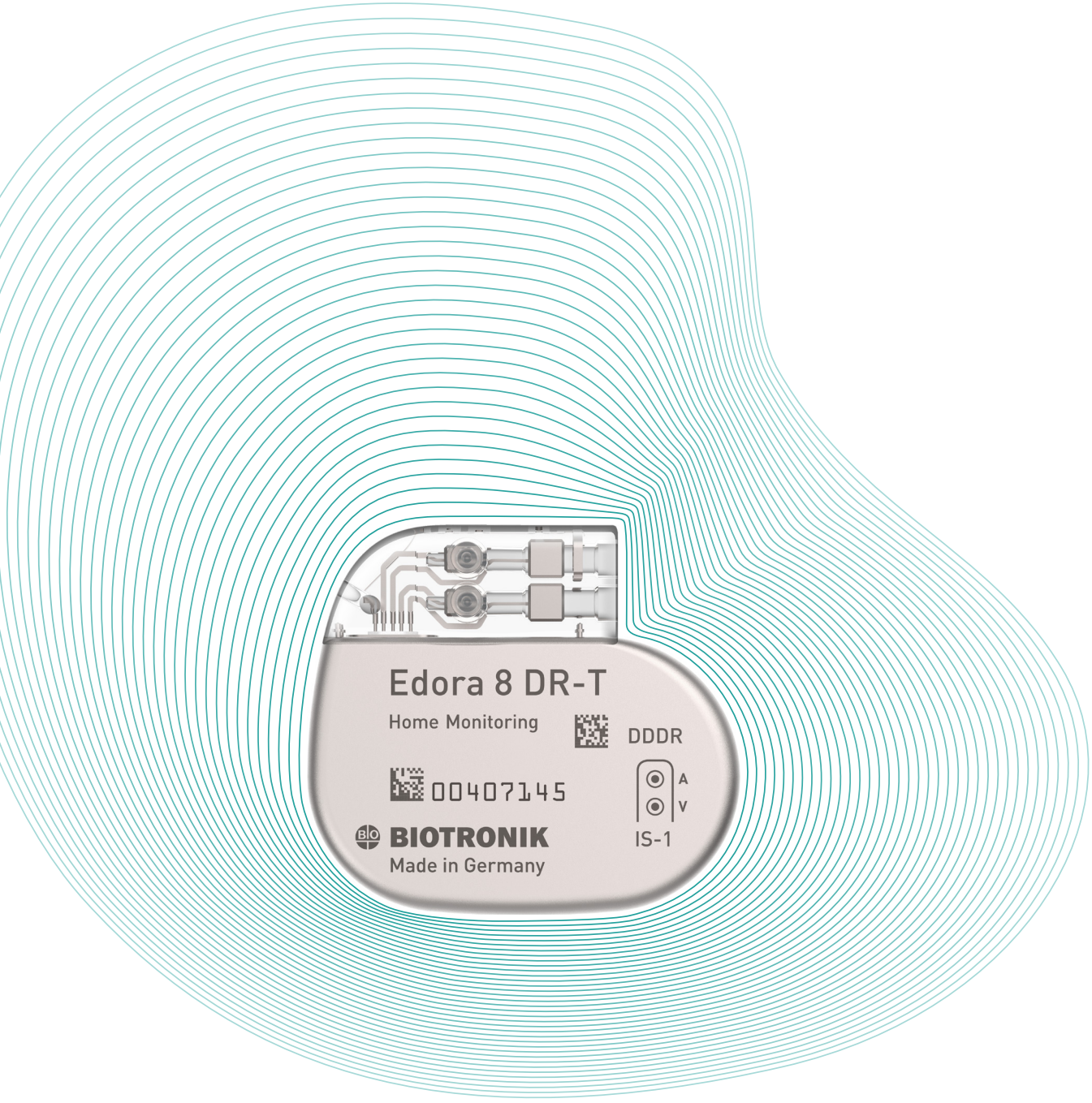
Products or subgroups of products may become subject to safety advisory notifications that can significantly impact the overall product performance. However, as these subgroups are clearly defined they are separated from the non-advisory devices. The impact of the advisory notification is then shown 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

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



Performance of BIOTRONIK Pacemakers

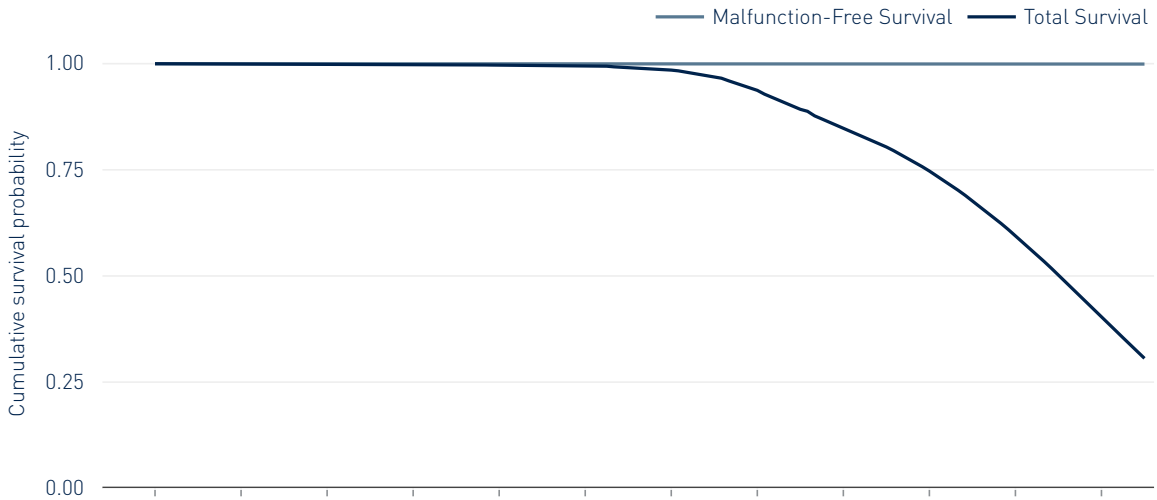
3.1 Single-Chamber Pacemakers
3.2 Dual-Chamber Pacemakers
3.3 CRT Pacemakers

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	3
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	5414	4920	4555	4236	4019	3831	3513	3047	2639	2018	979

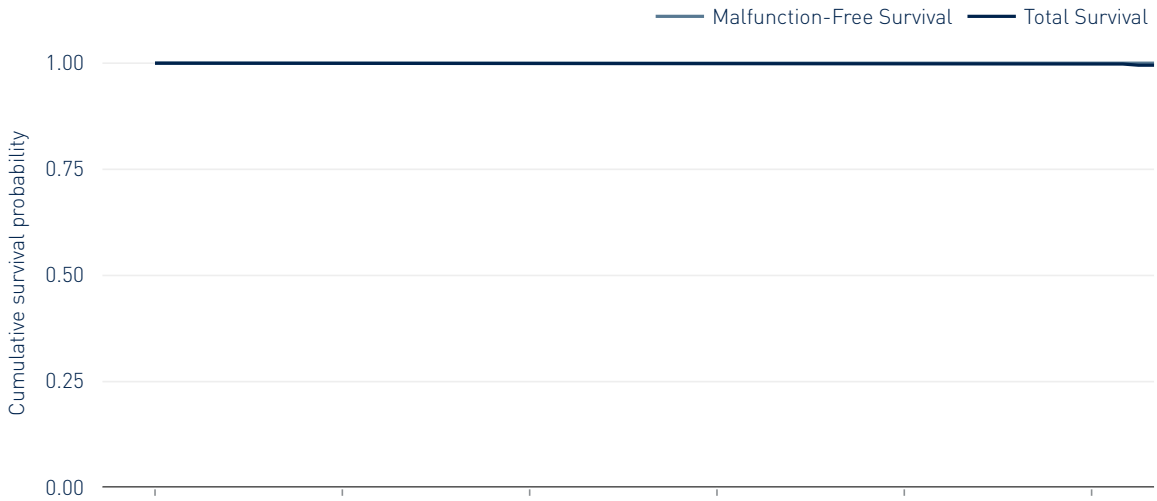
*While Cylos 990 VR is not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products.

3.1 Single-Chamber Pacemakers

Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	48 100
Registered US Implants	9 041
Estimated Active US Implants	7 270
US Normal Battery Depletions	6

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



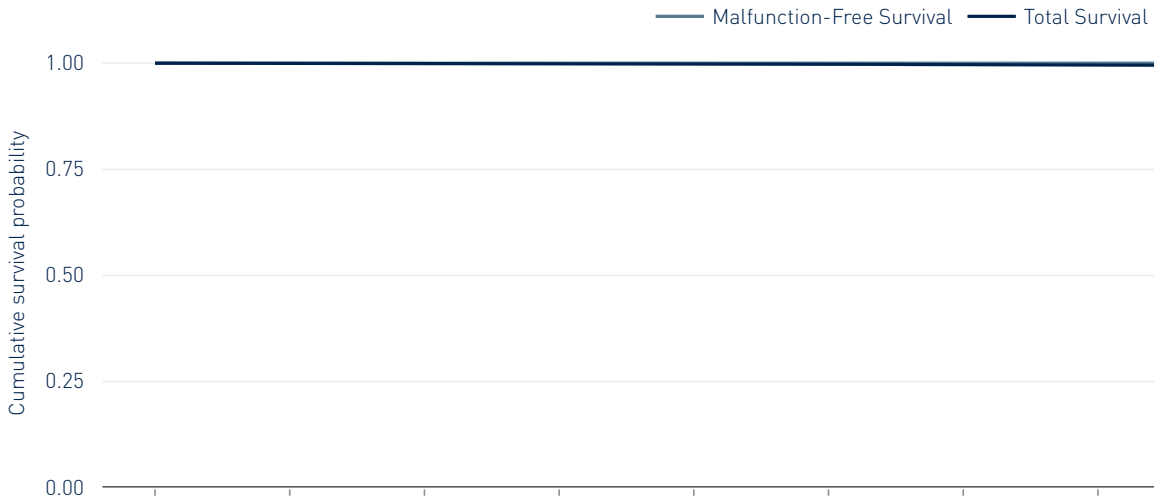
Years after implant	0	1	2	3	4	5
Total [%]	100	100	100	100	100	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	9041	7028	5367	3709	2203	736

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	3 690
US Normal Battery Depletions	17

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



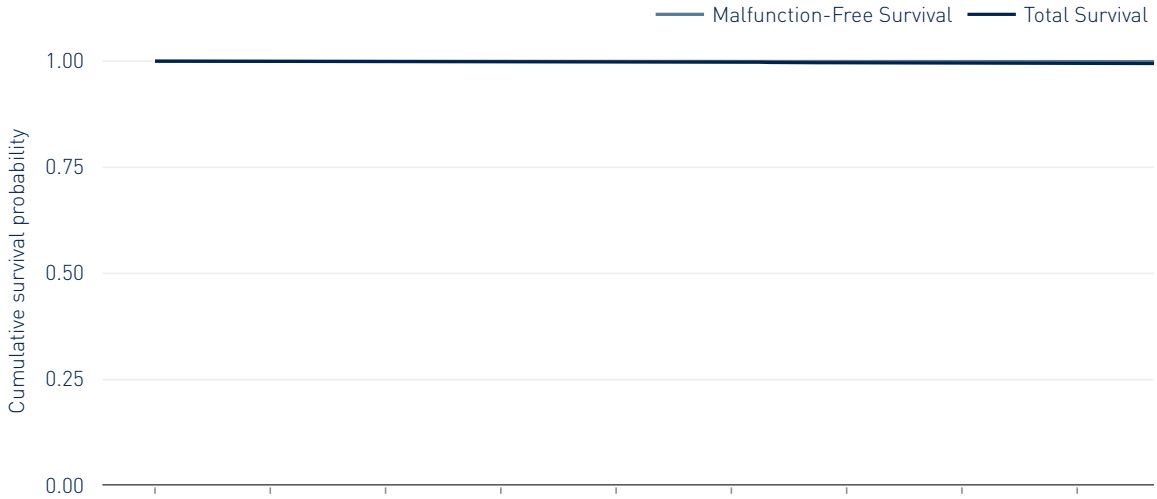
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	100	99.9	99.9	99.8	99.8	99.7	99.5
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	0.3
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	5799	5364	5029	4728	4360	3884	3002	1032

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	1 270
US Normal Battery Depletions	9

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



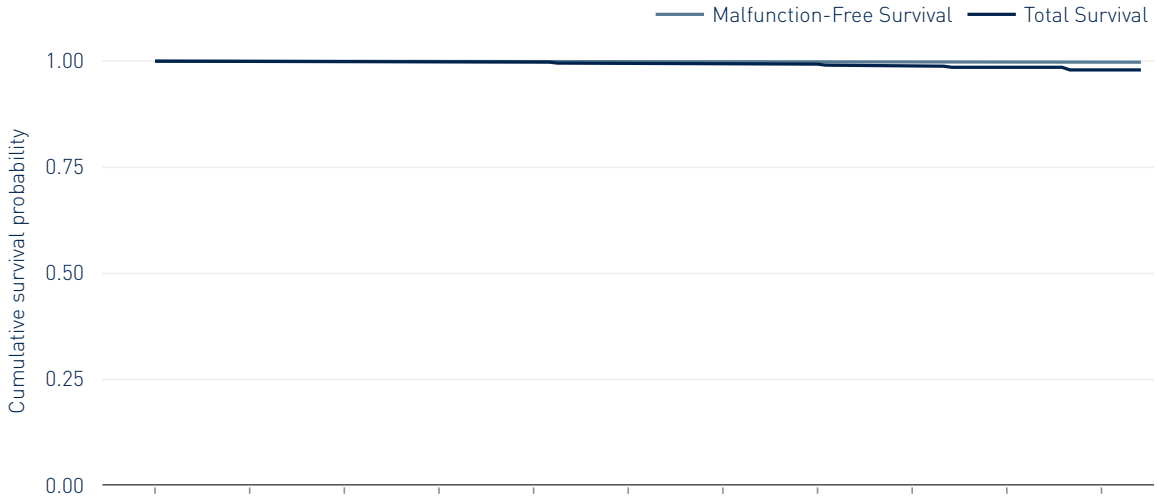
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.9	99.8	99.8	99.6	99.4	99.4
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3
Malfunction-Free [%]	100	100	100	100	100	100	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.2	0.2
Sample Size	2398	2188	2068	1942	1831	1731	1629	1499	1068

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	153
US Normal Battery Depletions	7

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



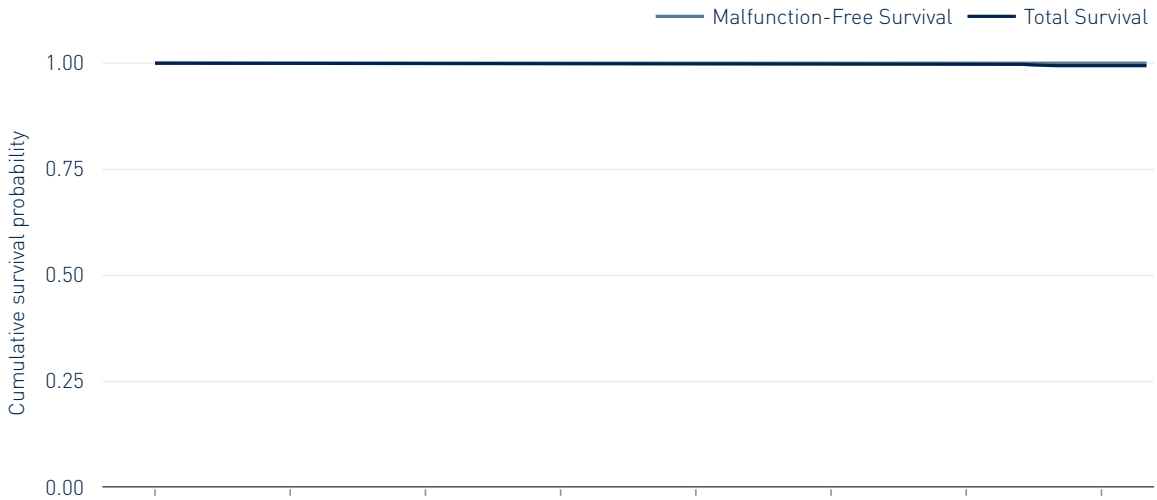
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	100	100	99.8	99.5	99.5	99.3	98.8	98.6	97.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.8	1.0	1.1	1.4
Malfunction-Free [%]	100	100	100	100	100	99.8	99.8	99.8	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	613	535	495	455	435	423	419	411	395	365	260

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	999
US Normal Battery Depletions	6

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



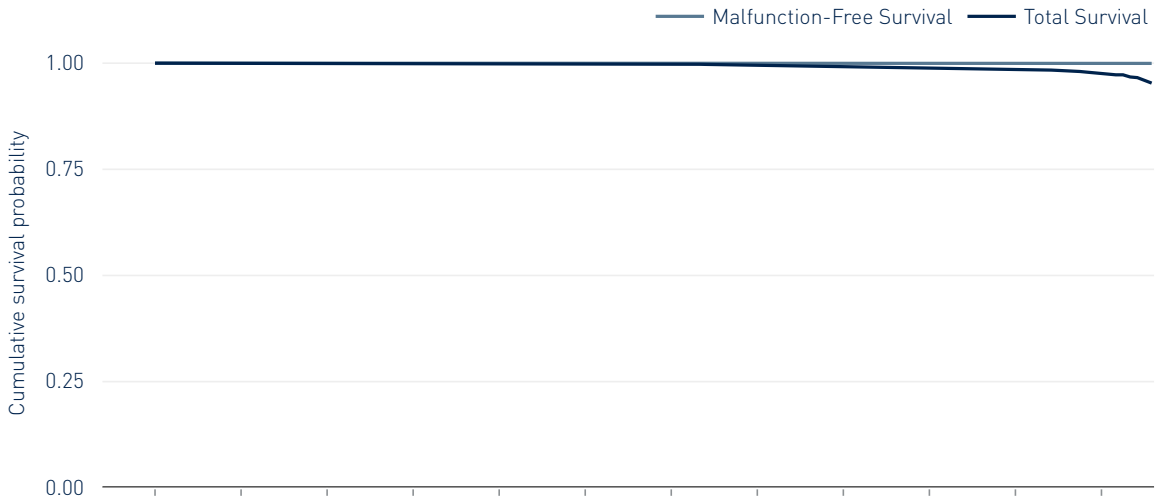
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.9	99.9	99.7	99.7	99.7	99.4
CI [± %]	< 0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.5
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1711	1572	1479	1392	1310	1144	864	396

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	6 390
US Normal Battery Depletions	143

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	99.9	99.9	99.9	99.8	99.8	99.6	99.4	99.0	98.5	97.5
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.3	0.5
Malfunction-Free [%]	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
Sample Size	12k	10.7k	10.1k	9638	9308	8785	8295	7820	7246	5796	3577	1467

Performance of BIOTRONIK Pacemakers

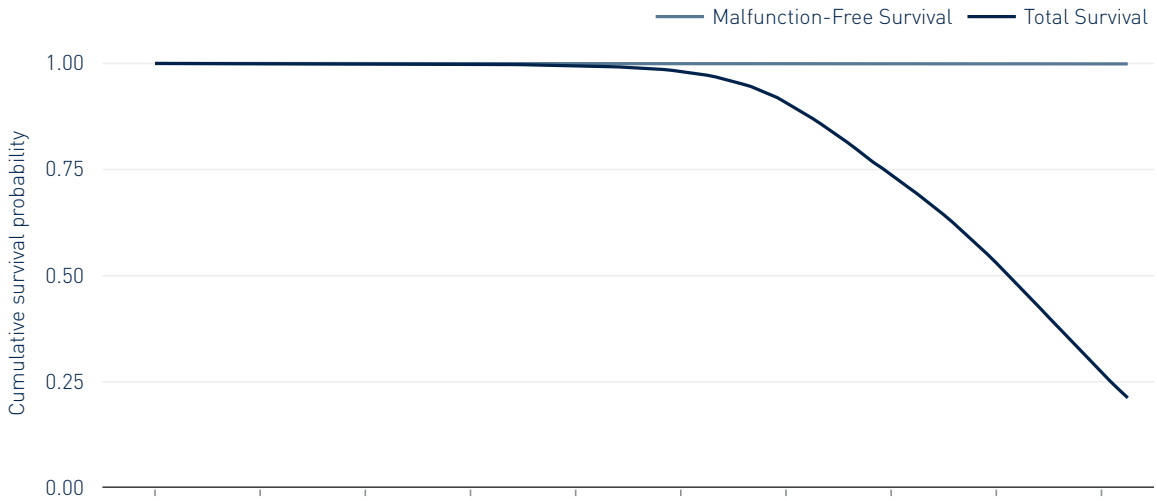
3.1 Single-Chamber Pacemakers
3.2 Dual-Chamber Pacemakers
3.3 CRT Pacemakers

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	0
US Normal Battery Depletions	8 480

	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	53.0	27.2
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.2	0.4	0.6	0.7	1.1
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	8972	2583

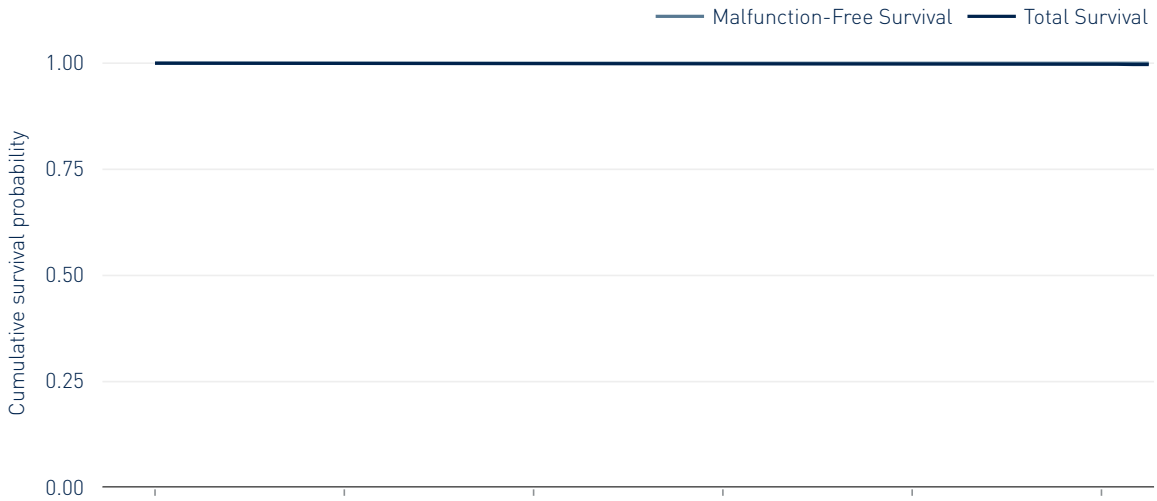
*While Cylos 990 DR and Cylos 990 DR-T is not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products.

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	289 000
Registered US Implants	93 246
Estimated Active US Implants	79 500
US Normal Battery Depletions	64

	Count	Rate
US Confirmed Malfunctions	7	0.01%
Therapy Compromised	3	0.00%
Therapy Available	4	0.00%



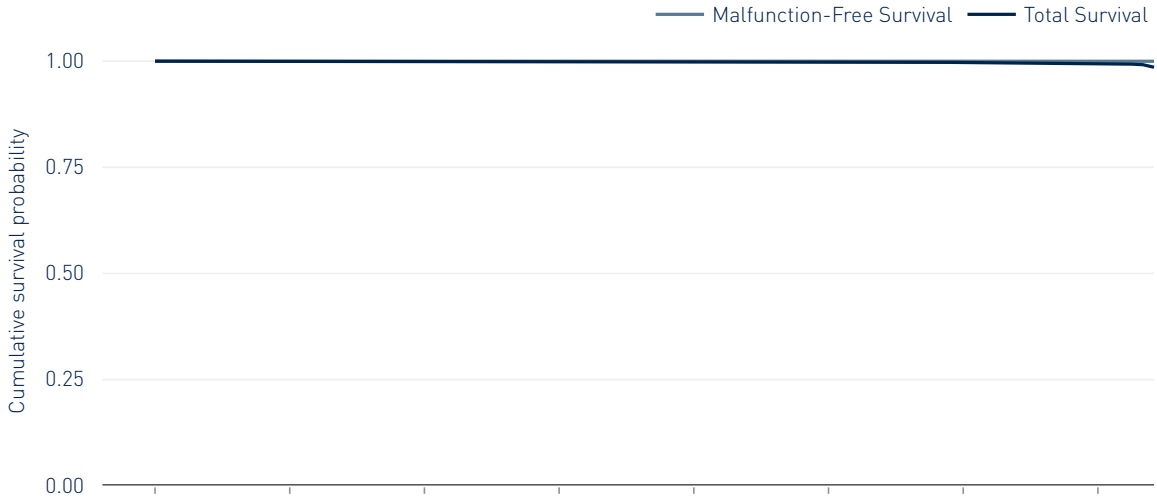
Years after implant	0	1	2	3	4	5
Total [%]	100	100	100	99.9	99.9	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	93.2k	70.9k	51k	33.4k	18.7k	4057

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	29 200
US Normal Battery Depletions	129

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



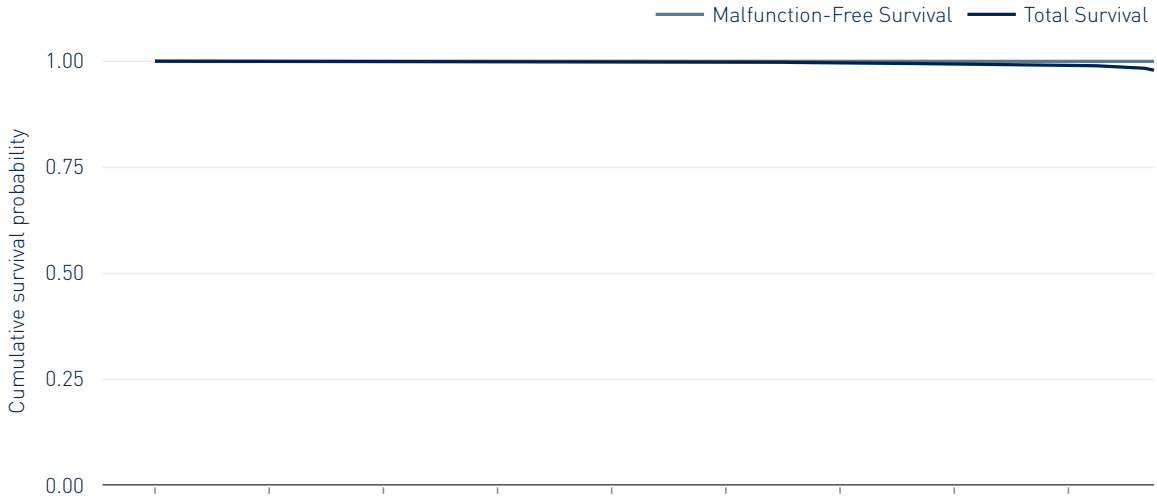
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	100	100	99.9	99.9	99.8	99.7	99.4
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	42.1k	39.4k	37k	34.2k	30.8k	26.7k	20.6k	5835

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	7 160
US Normal Battery Depletions	112

	Count	Rate
US Confirmed Malfunctions	5	0.04%
Therapy Compromised	2	0.02%
Therapy Available	3	0.02%



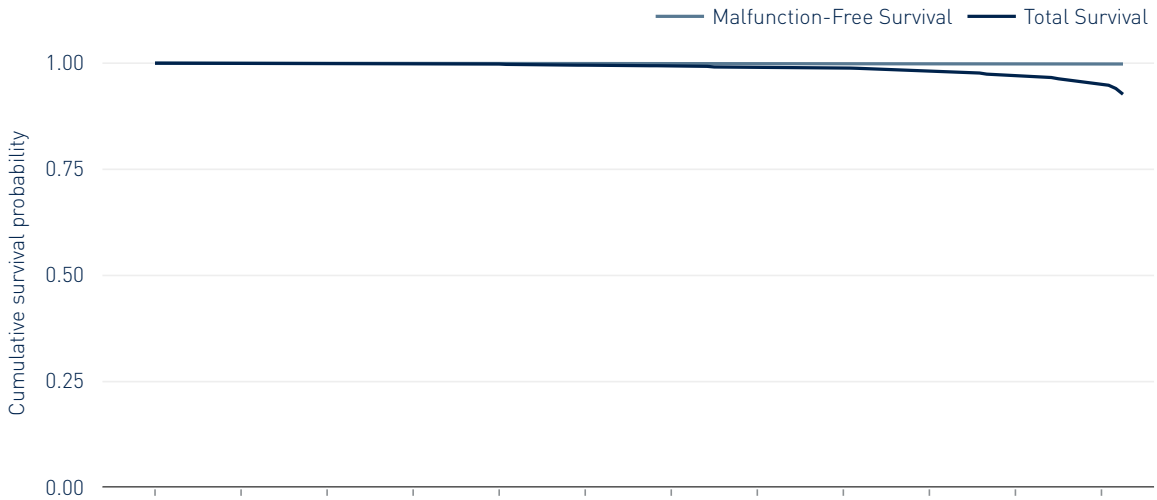
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.9	99.8	99.8	99.6	99.4	99.1
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	12.1k	11.3k	10.6k	10k	9424	8876	8354	7649	5836

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	1 360
US Normal Battery Depletions	83

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



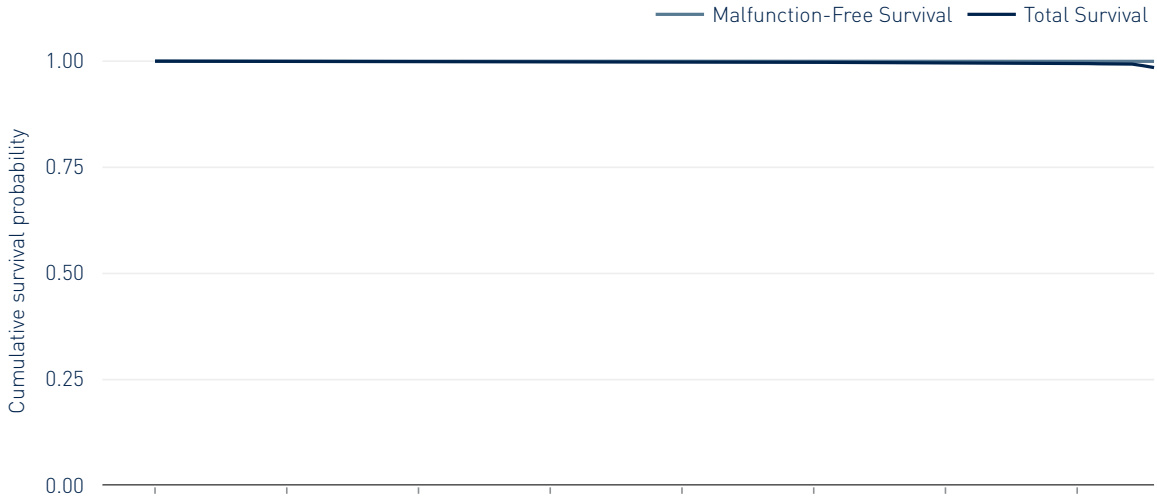
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	100	100	99.8	99.5	99.4	99.0	98.9	98.2	97.1	95.0
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.6	0.8	1.2
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9	99.9	99.9	99.9	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	2945	2740	2593	2468	2332	2199	2070	1952	1850	1705	1303	537

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	8 140
US Normal Battery Depletions	43

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



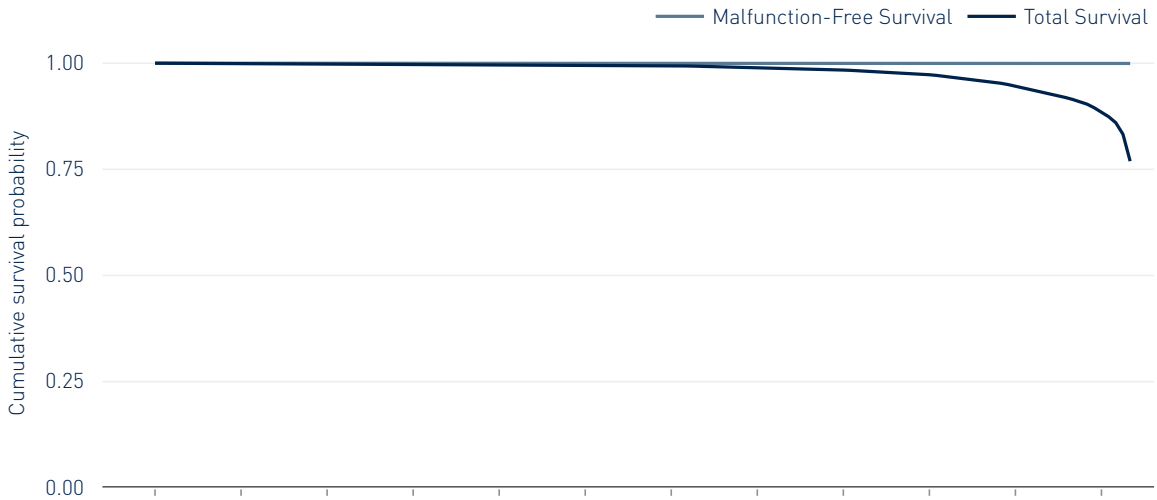
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	100	99.9	99.9	99.9	99.7	99.6	99.5
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	11.7k	11k	10.4k	9765	9196	8010	5969	2569

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	61 902
Estimated Active US Implants	32 600
US Normal Battery Depletions	2 652

	Count	Rate
US Confirmed Malfunctions	33	0.05%
Therapy Compromised	11	0.02%
Therapy Available	22	0.04%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	100	100	99.9	99.8	99.7	99.4	99.0	98.4	97.3	94.6	88.6
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	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
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	61.9k	58.1k	54.6k	51.4k	48.4k	45.5k	42.8k	40.3k	37.2k	28.4k	15.3k	4061

Performance of BIOTRONIK Pacemakers

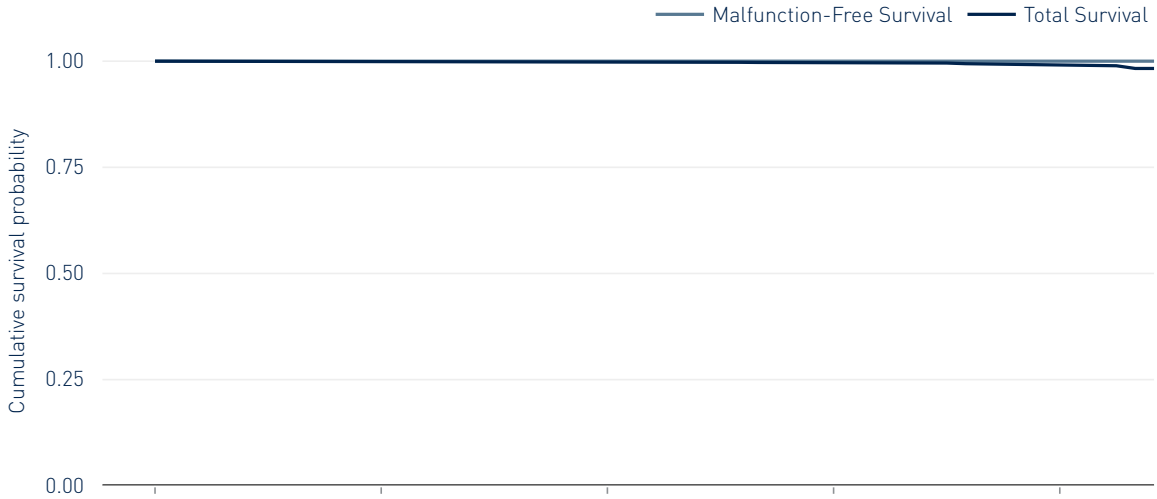
3.1 Single-Chamber Pacemakers
3.2 Dual-Chamber Pacemakers
3.3 CRT Pacemakers

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	22 100
Registered US Implants	7 746
Estimated Active US Implants	5 740
US Normal Battery Depletions	35

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



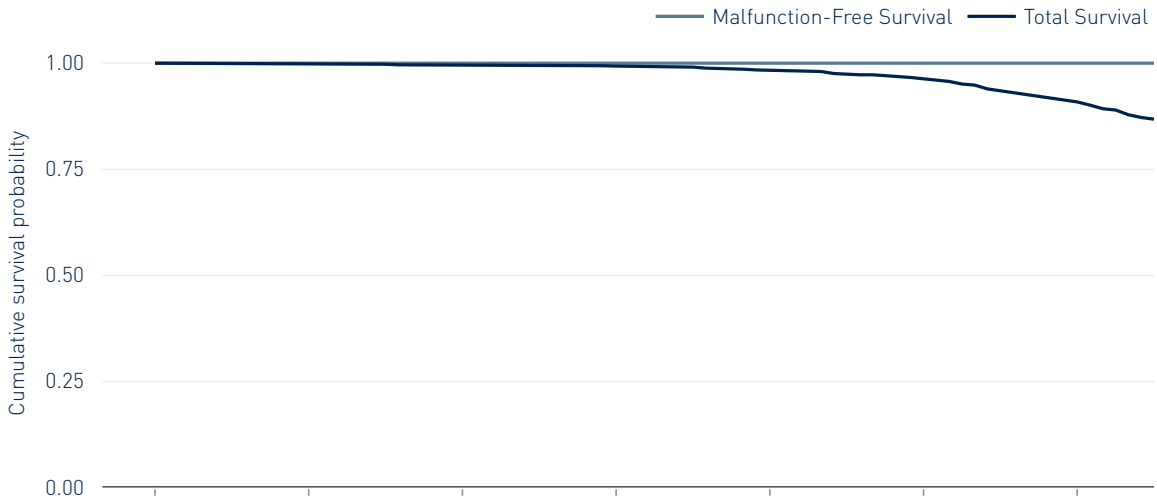
Years after implant	0	1	2	3	4
Total [%]	100	100	99.9	99.7	98.9
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.6
Malfunction-Free [%]	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	7746	5488	3637	2028	722

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	654
US Normal Battery Depletions	121

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



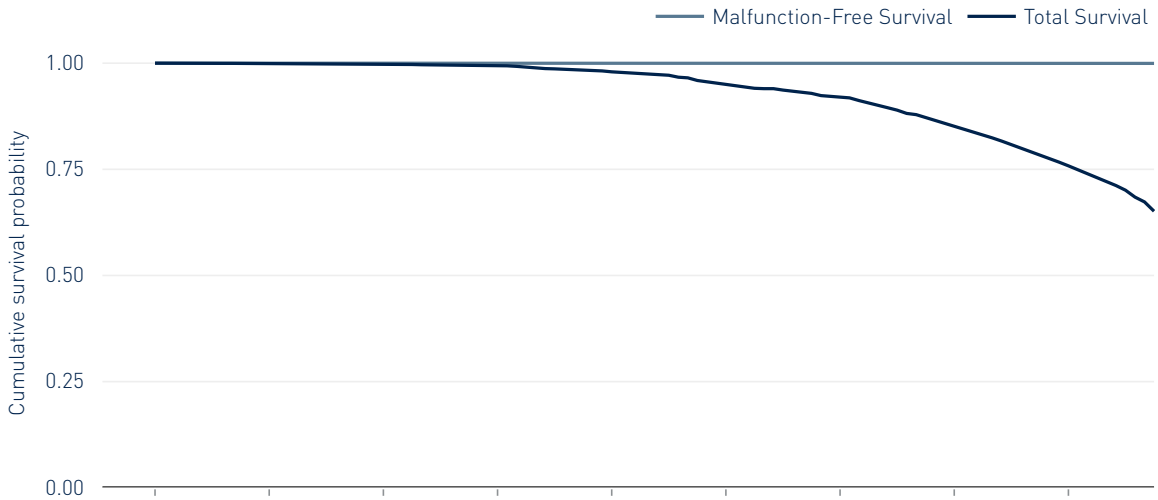
Years after implant	0	1	2	3	4	5	6
Total [%]	100	100	99.6	99.3	98.3	96.3	90.9
CI [± %]	< 0.1	< 0.1	0.3	0.4	0.7	1.1	2.0
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1861	1632	1441	1283	1119	854	524

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	401
US Normal Battery Depletions	325

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



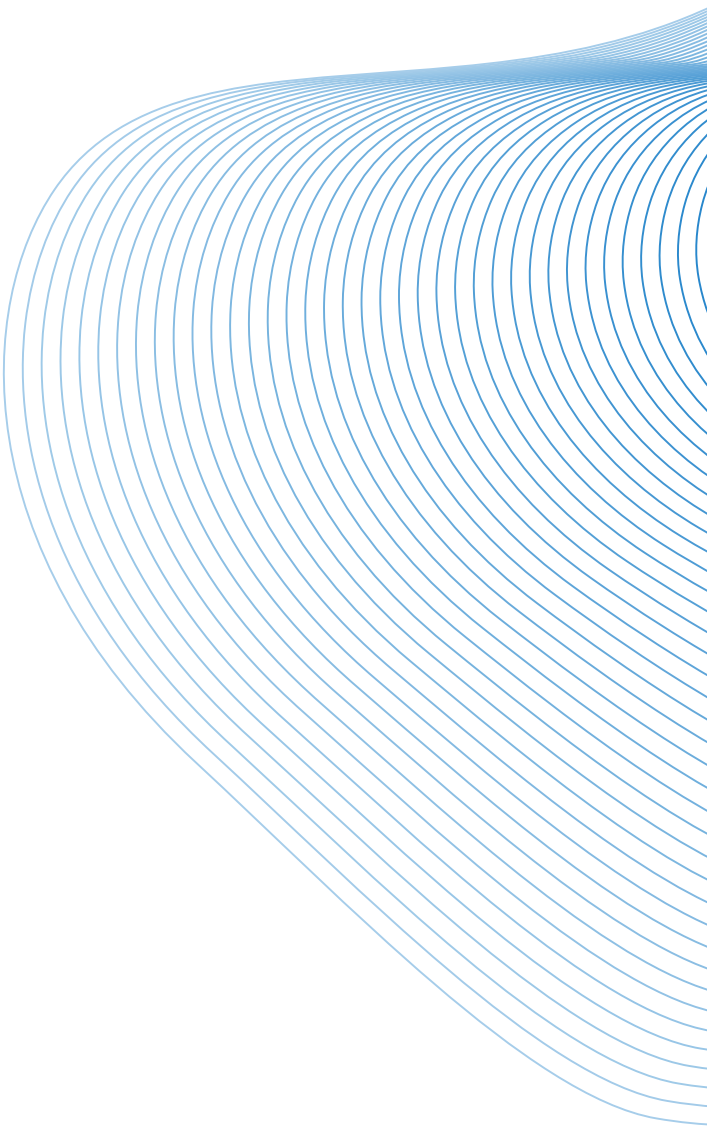
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.7	99.4	98.0	95.0	91.9	85.4	75.8
CI [± %]	< 0.1	0.1	0.2	0.3	0.7	1.1	1.5	2.0	2.6
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	2249	1993	1773	1580	1379	1194	1031	848	625

Performance of BIOTRONIK ICDs

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

Performance of BIOTRONIK ICDs

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

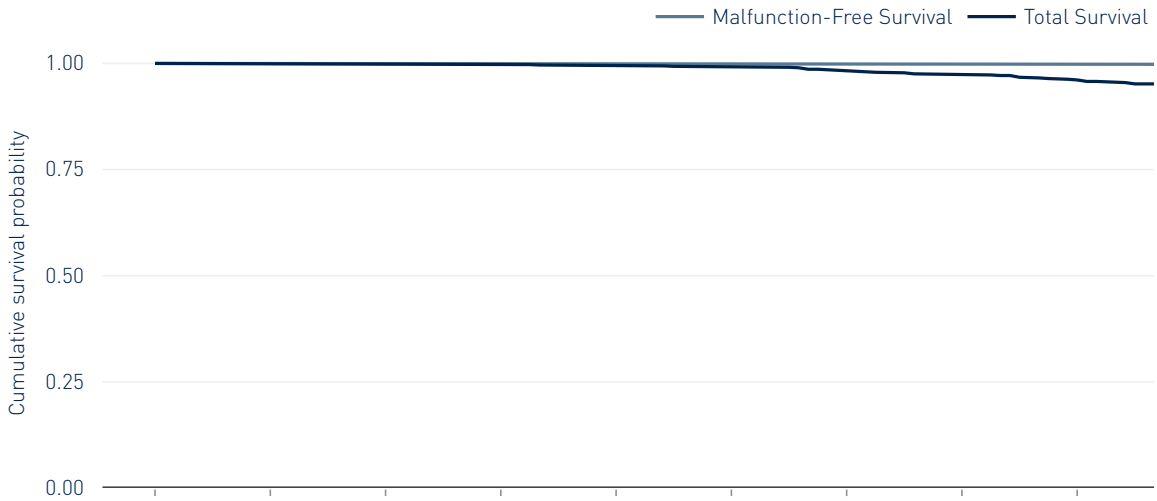


4.1 Single-Chamber ICDs

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	521
US Normal Battery Depletions	27

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



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.8	99.7	99.6	99.2	98.3	97.4	96.1
CI [± %]	< 0.1	< 0.1	0.2	0.3	0.4	0.6	0.8	1.0	1.3
Malfunction-Free [%]	100	100	100	99.9	99.9	99.8	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	0.2	0.2	0.3	0.3	0.3	0.3
Sample Size	1271	1181	1102	1032	961	892	829	761	580

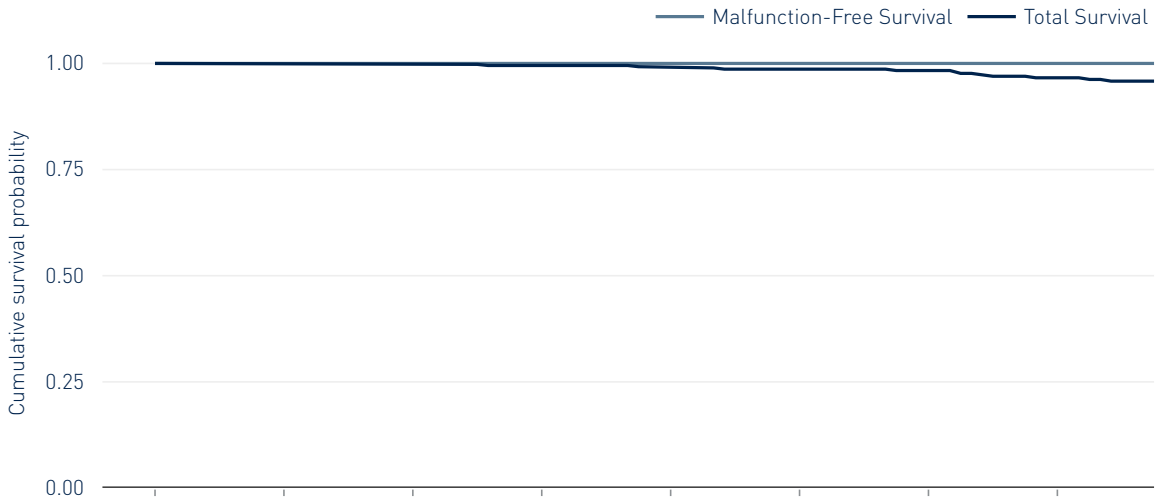
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	60
US Normal Battery Depletions	8

	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	99.8	99.8	99.5	98.9	98.7	98.3	96.6
CI [± %]	< 0.1	0.4	0.4	0.7	1.0	1.2	1.3	2.0
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	466	432	396	369	345	322	297	260

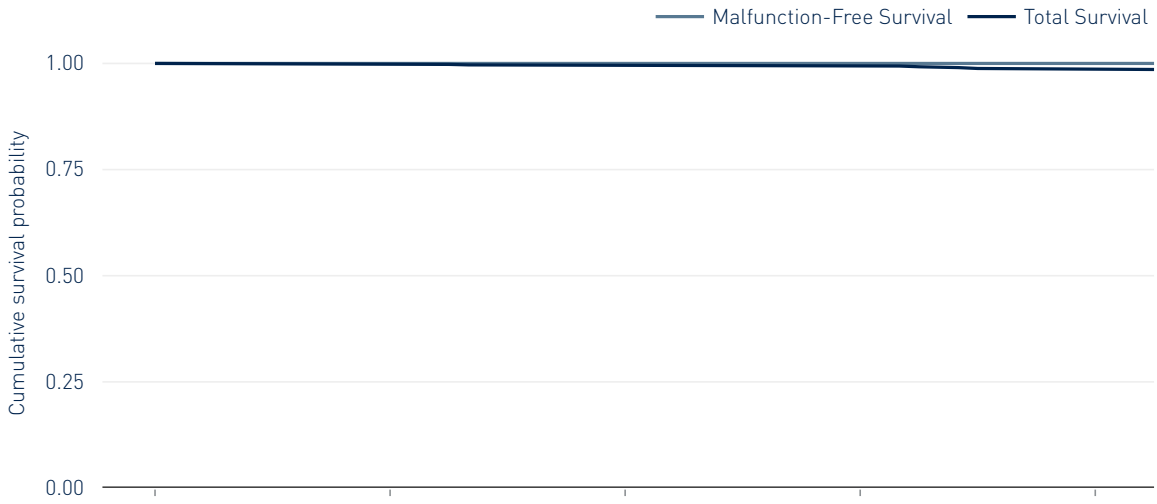
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	553
US Normal Battery Depletions	8

	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
Total [%]	100	99.9	99.5	99.4	98.6
CI [± %]	< 0.1	0.2	0.4	0.5	1.0
Malfunction-Free [%]	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	964	892	833	651	294

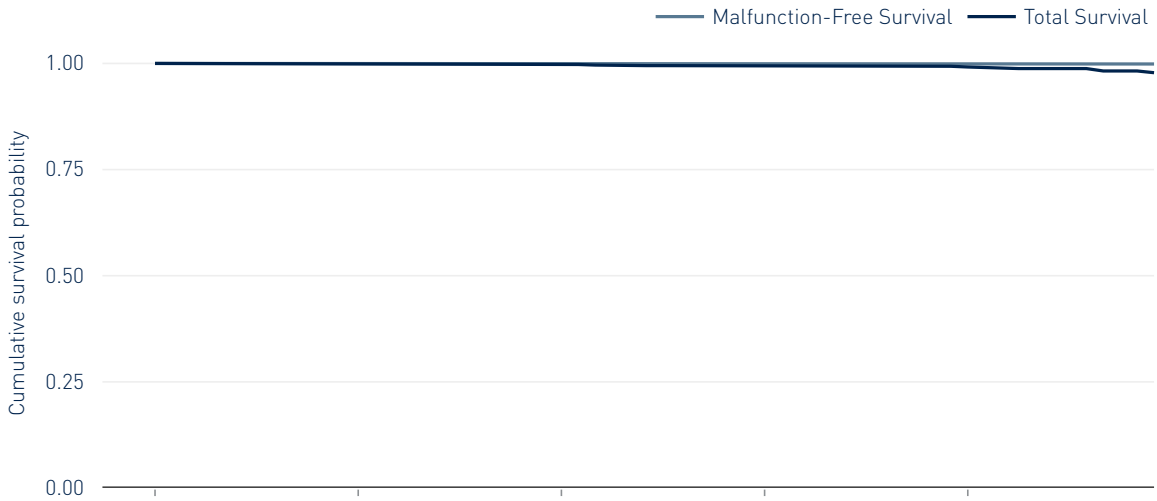
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	417
US Normal Battery Depletions	3

	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
Total [%]	100	99.9	99.8	99.5	99.2
CI [± %]	< 0.1	0.2	0.3	0.5	0.7
Malfunction-Free [%]	100	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	0.3	0.3
Sample Size	878	812	754	698	575

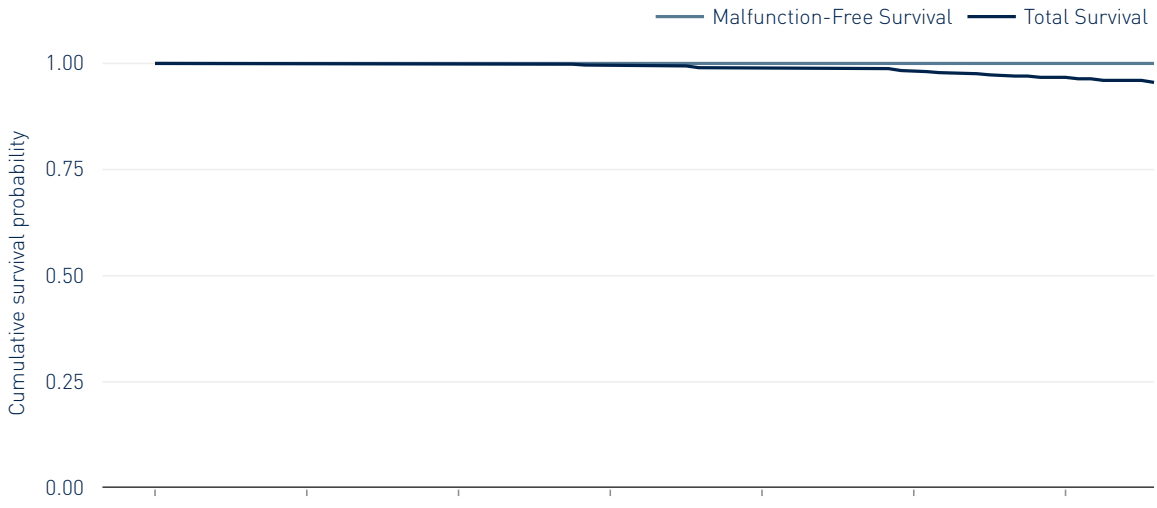
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	192
US Normal Battery Depletions	13

	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	99.8	99.6	98.8	98.3	96.7
CI [± %]	< 0.1	< 0.1	0.3	0.5	1.0	1.2	1.7
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	618	567	530	492	458	418	288

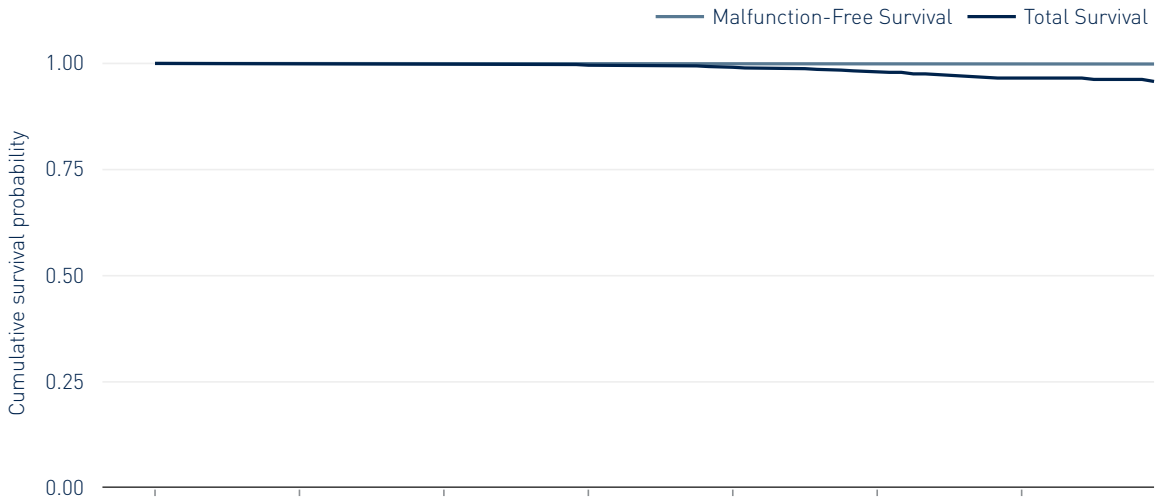
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	320
US Normal Battery Depletions	9

	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
Total [%]	100	99.9	99.7	99.6	99.1	98.1	96.6
CI [± %]	< 0.1	0.3	0.4	0.5	0.7	1.1	1.5
Malfunction-Free [%]	100	100	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
Sample Size	804	747	694	648	608	557	425

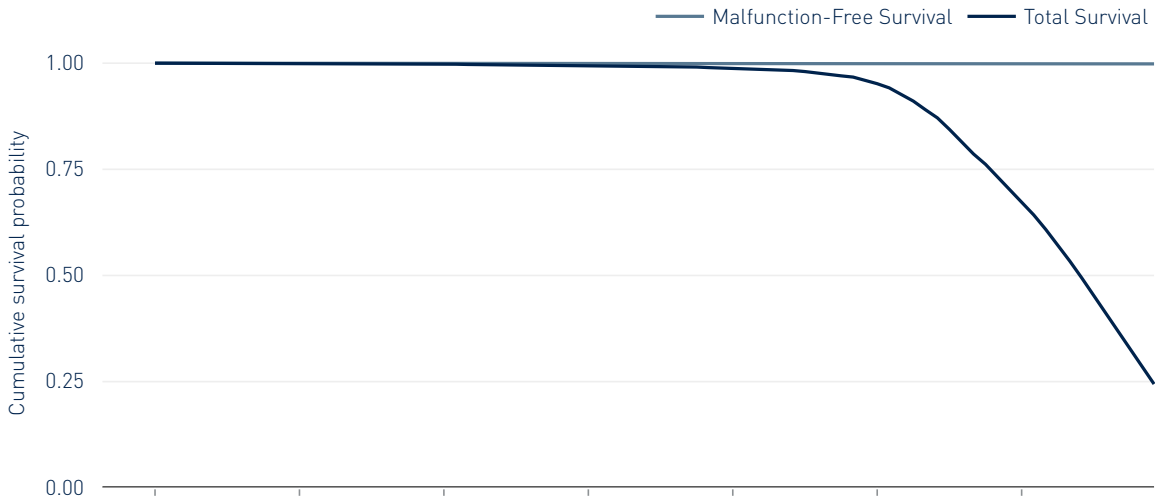
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1
US Normal Battery Depletions	935

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



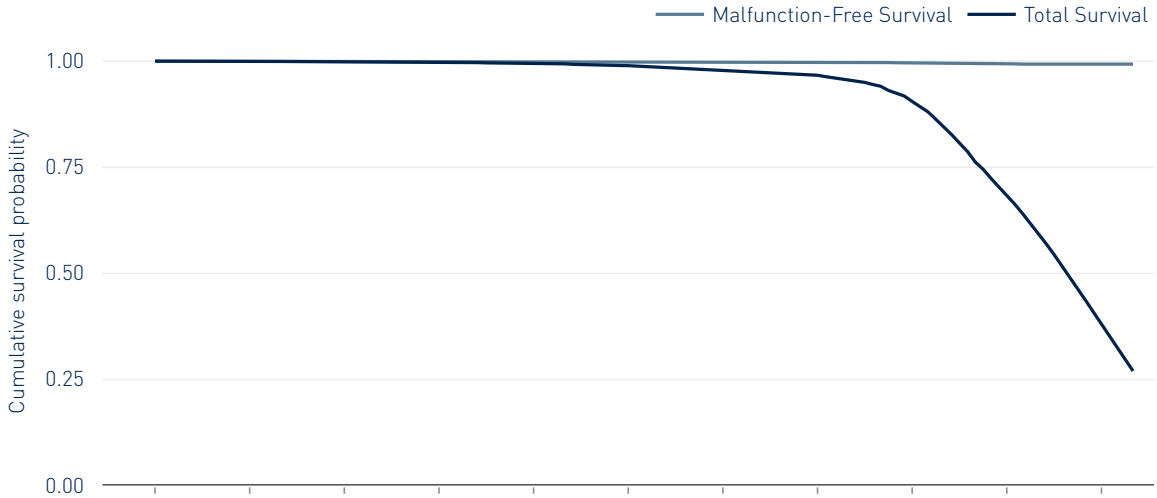
Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.8	99.8	99.6	98.8	95.2	67.5
CI [± %]	< 0.1	0.1	0.2	0.2	0.4	0.8	1.9
Malfunction-Free [%]	100	99.9	99.9	99.9	99.8	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3985	3627	3408	3177	2932	2578	1514

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	118
US Normal Battery Depletions	926

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



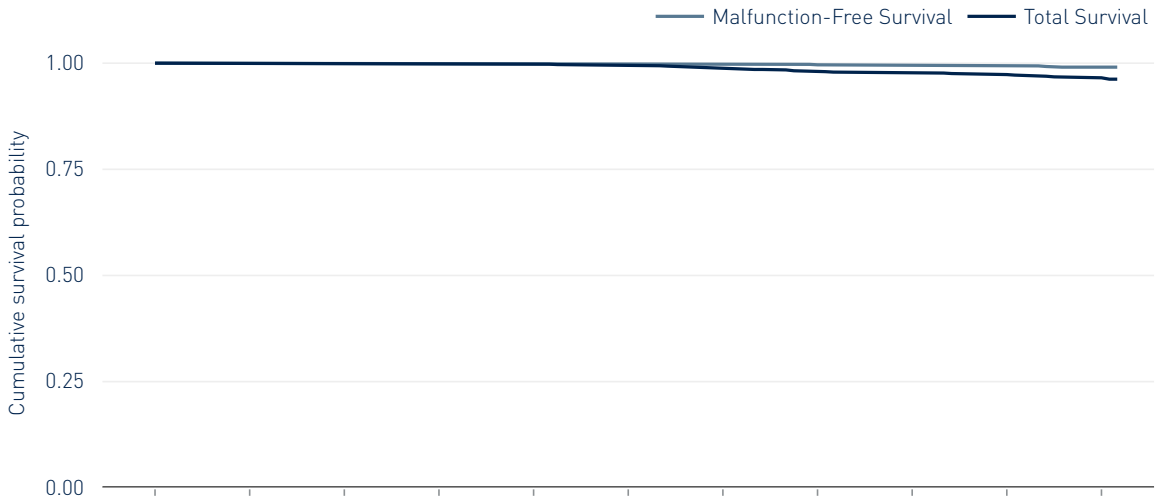
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.9	99.8	99.5	98.9	98.0	96.7	90.5	68.5	38.0
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.5	0.6	1.1	1.8	2.4
Malfunction-Free [%]	100	100	100	99.9	99.8	99.8	99.8	99.7	99.6	99.4	99.3
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3
Sample Size	4544	4200	3920	3648	3405	3171	2926	2698	2355	1632	719

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	1 574
Estimated Active US Implants	580
US Normal Battery Depletions	26

	Count	Rate
US Confirmed Malfunctions	8	0.51%
Therapy Compromised	6	0.38%
Therapy Available	2	0.13%



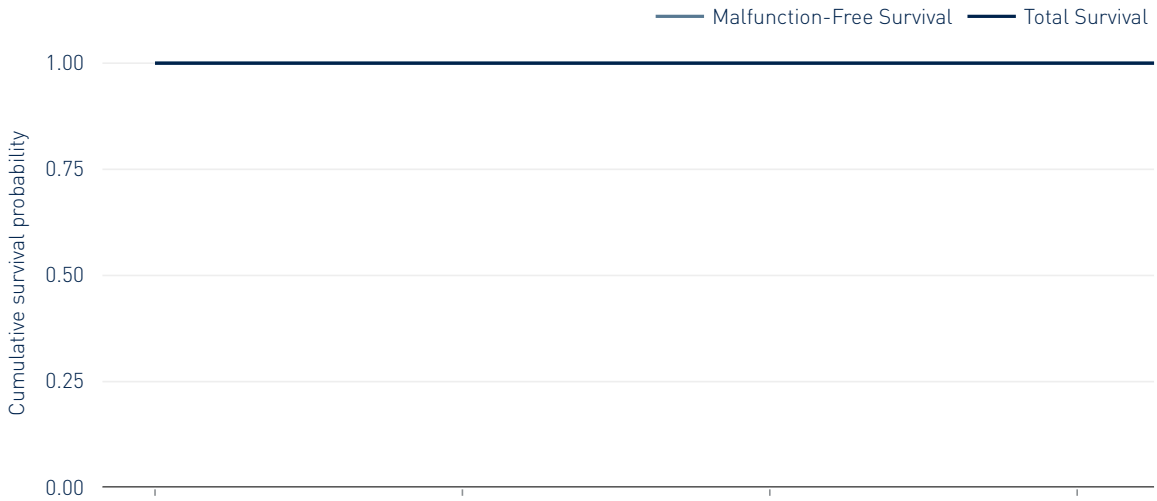
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	100	99.9	99.8	99.6	98.7	98.0	97.8	97.3	96.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.2	0.2	0.4	0.7	0.8	0.9	1.0	1.2
Malfunction-Free [%]	100	100	100	100	100	99.9	99.7	99.6	99.6	99.5	99.1
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.4	0.7
Sample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

4.1 Single-Chamber ICDs

Rivacor 7 DF4

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	5 610
Registered US Implants	1 616
Estimated Active US Implants	1 240
US Normal Battery Depletions	0

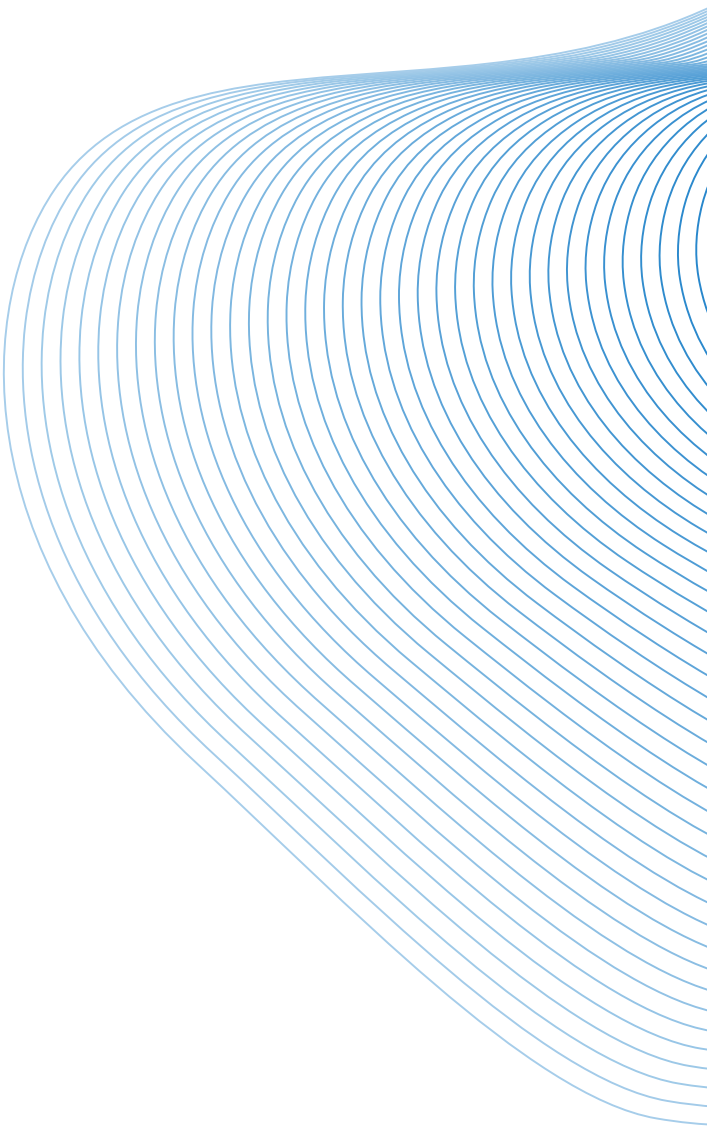
	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



Years after implant	0	1	2	3
Total [%]	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1616	1127	690	280

Performance of BIOTRONIK ICDs

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

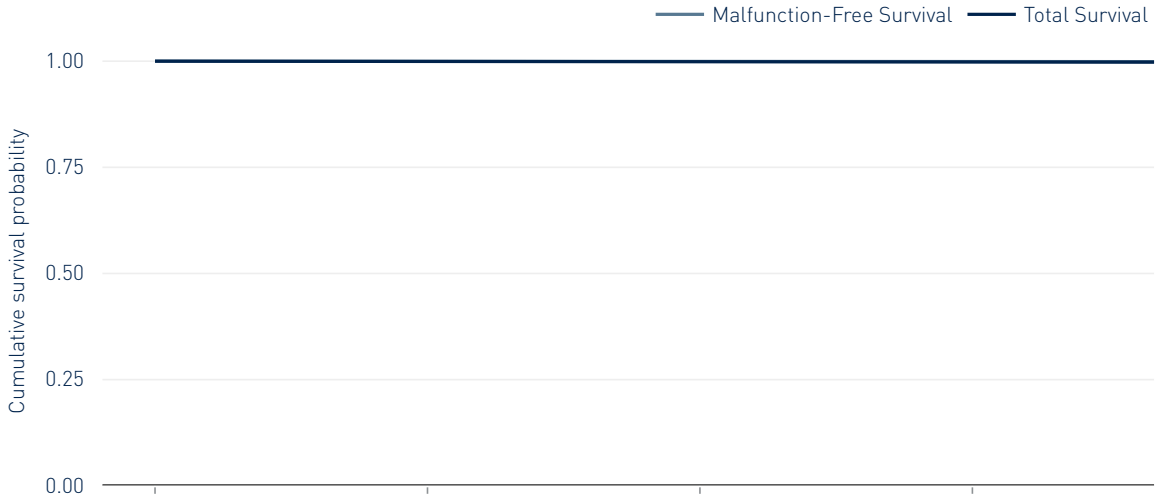


4.2 Dual-Chamber ICDs

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	19 700
Registered US Implants	14 676
Estimated Active US Implants	13 000
US Normal Battery Depletions	7

	Count	Rate
US Confirmed Malfunctions	9	0.06%
Therapy Compromised	8	0.05%
Therapy Available	1	0.01%



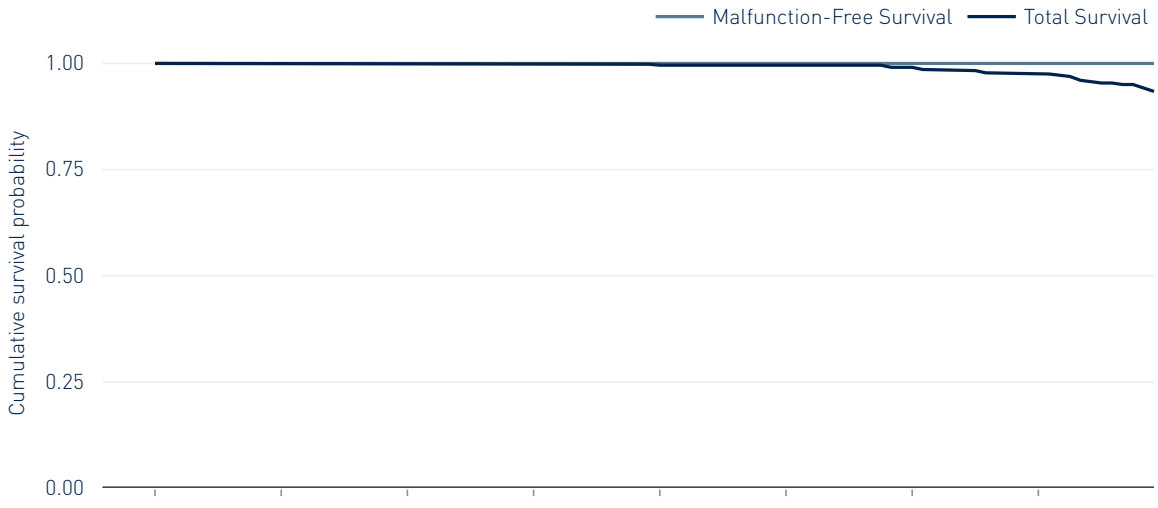
Years after implant	0	1	2	3
Total [%]	100	100	99.9	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1
Malfunction-Free [%]	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.1	0.1
Sample Size	14.7k	9944	5770	2035

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	121
US Normal Battery Depletions	47

	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	100	99.8	99.6	99.6	99.1	97.5
CI [± %]	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.9	1.5
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	614	564	532	489	455	425	389	353

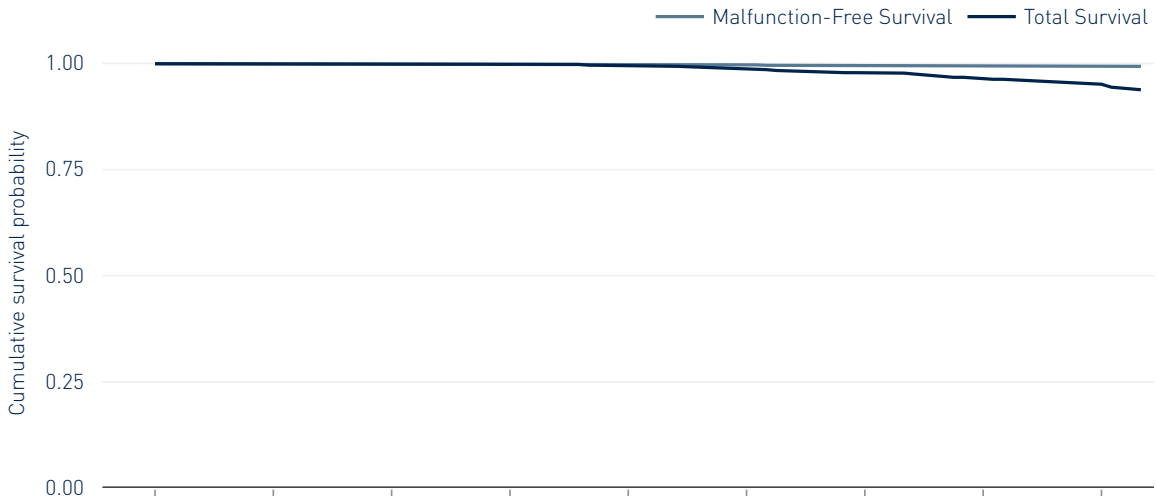
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	599
US Normal Battery Depletions	26

	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
Total [%]	99.9	99.9	99.9	99.9	99.5	98.9	97.8	96.4	95.1
CI [± %]	0.1	0.1	0.2	0.2	0.4	0.6	0.9	1.2	1.4
Malfunction-Free [%]	99.9	99.9	99.9	99.9	99.9	99.7	99.6	99.6	99.6
CI [± %]	0.1	0.1	0.2	0.2	0.2	0.3	0.4	0.4	0.4
Sample Size	1460	1361	1277	1189	1099	1010	924	836	462

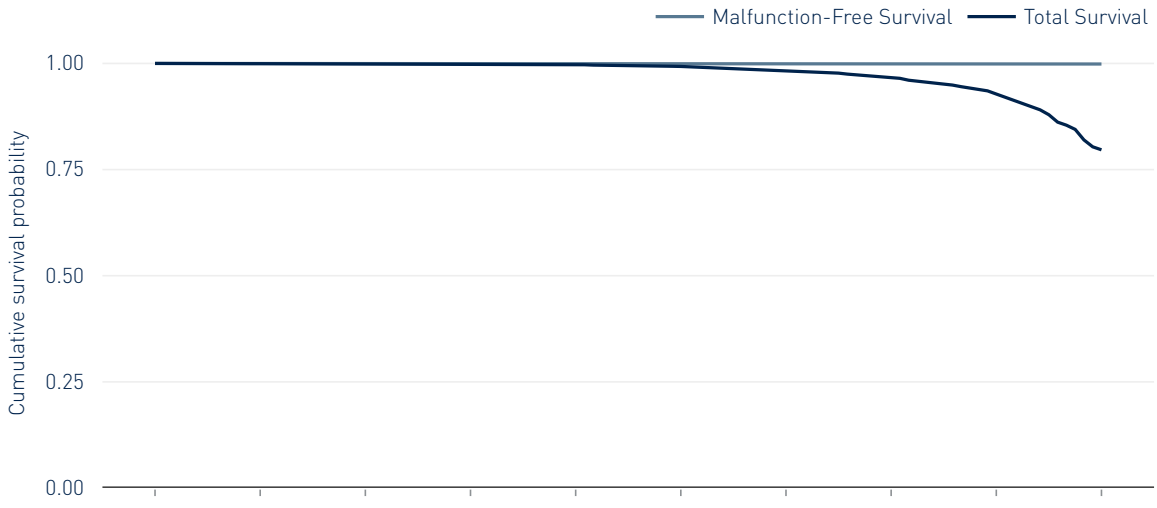
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1 440
US Normal Battery Depletions	267

	Count	Rate
US Confirmed Malfunctions	3	0.09%
Therapy Compromised	2	0.06%
Therapy Available	1	0.03%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.9	99.9	99.8	99.7	99.3	98.2	96.7	92.8	79.7
CI [± %]	< 0.1	0.1	0.1	0.1	0.2	0.3	0.5	0.7	1.1	2.6
Malfunction-Free [%]	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	0.2	0.2
Sample Size	3486	3224	3007	2798	2602	2406	2226	2013	1526	316

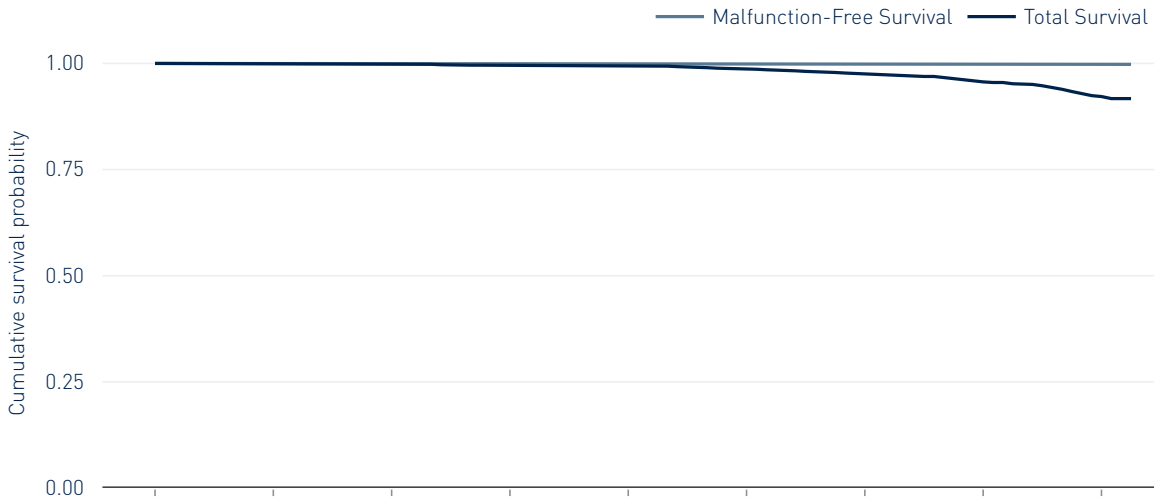
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	436
US Normal Battery Depletions	52

	Count	Rate
US Confirmed Malfunctions	2	0.17%
Therapy Compromised	0	0.00%
Therapy Available	2	0.17%



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	100	99.9	99.6	99.5	98.8	97.5	95.7	92.2
CI [± %]	< 0.1	< 0.1	0.2	0.4	0.5	0.7	1.1	1.4	2.0
Malfunction-Free [%]	100	100	100	99.9	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
Sample Size	1147	1062	992	922	863	804	736	663	423

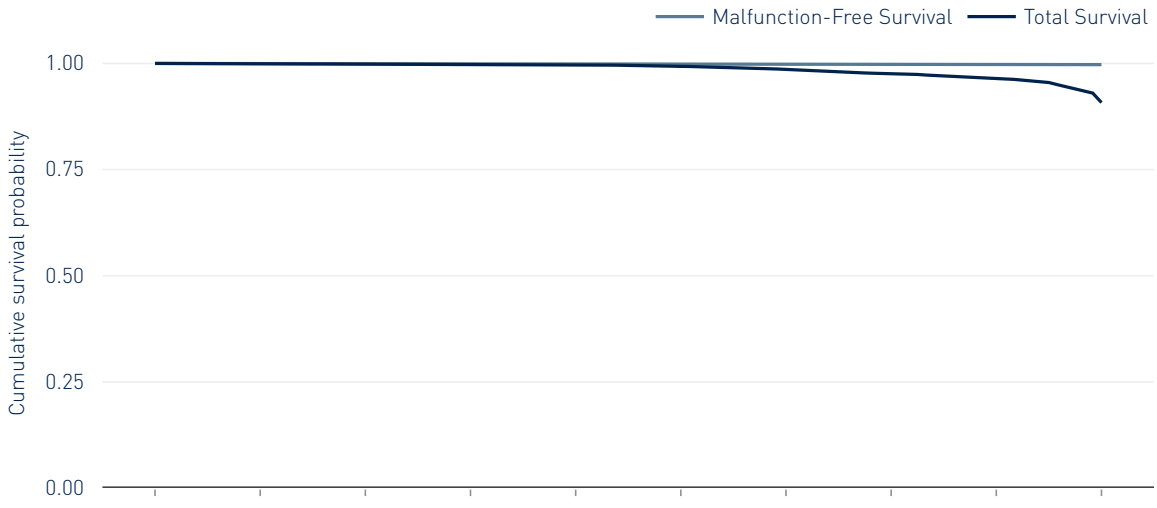
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	2 320
US Normal Battery Depletions	121

	Count	Rate
US Confirmed Malfunctions	9	0.19%
Therapy Compromised	4	0.08%
Therapy Available	5	0.11%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.9	99.9	99.7	99.6	99.3	98.6	97.7	96.5	90.8
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.3	0.4	0.5	0.7	2.1
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9	99.8	99.7	99.7
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2
Sample Size	4720	4376	4105	3845	3574	3324	3077	2806	2244	291

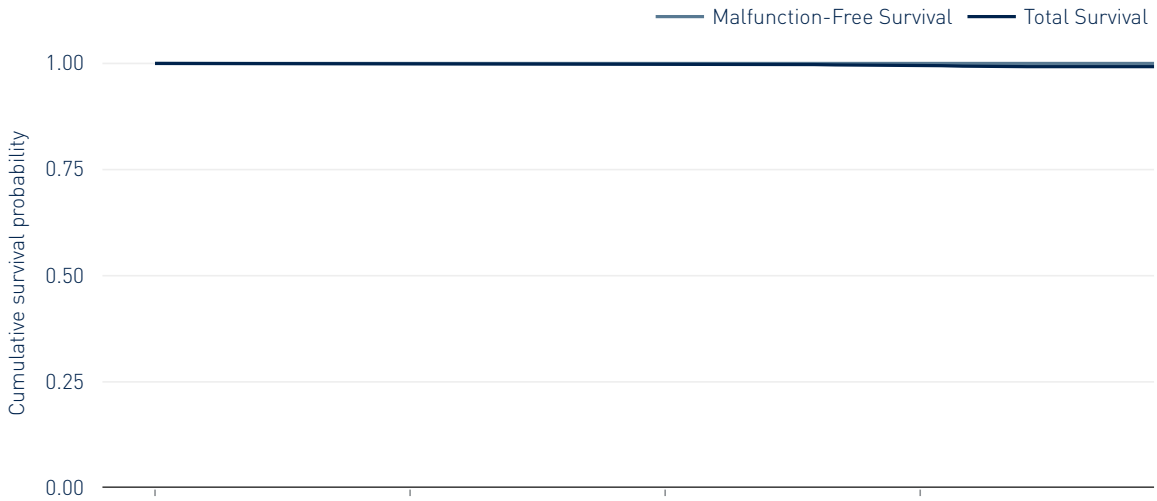
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	3 470
Registered US Implants	1 628
Estimated Active US Implants	1 080
US Normal Battery Depletions	5

	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
Total [%]	100	99.9	99.8	99.5
CI [± %]	< 0.1	0.2	0.2	0.4
Malfunction-Free [%]	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1628	1499	1408	1036

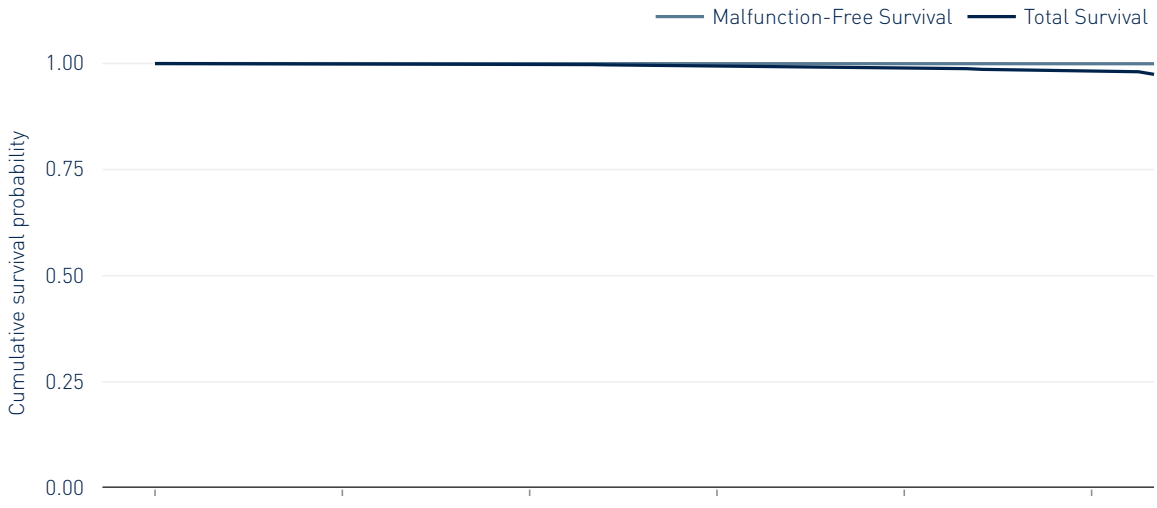
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	3 994
Estimated Active US Implants	2 650
US Normal Battery Depletions	24

	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
Total [%]	100	99.9	99.8	99.4	99.0	98.0
CI [± %]	< 0.1	0.1	0.1	0.3	0.4	0.6
Malfunction-Free [%]	100	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3994	3692	3446	3087	2392	827

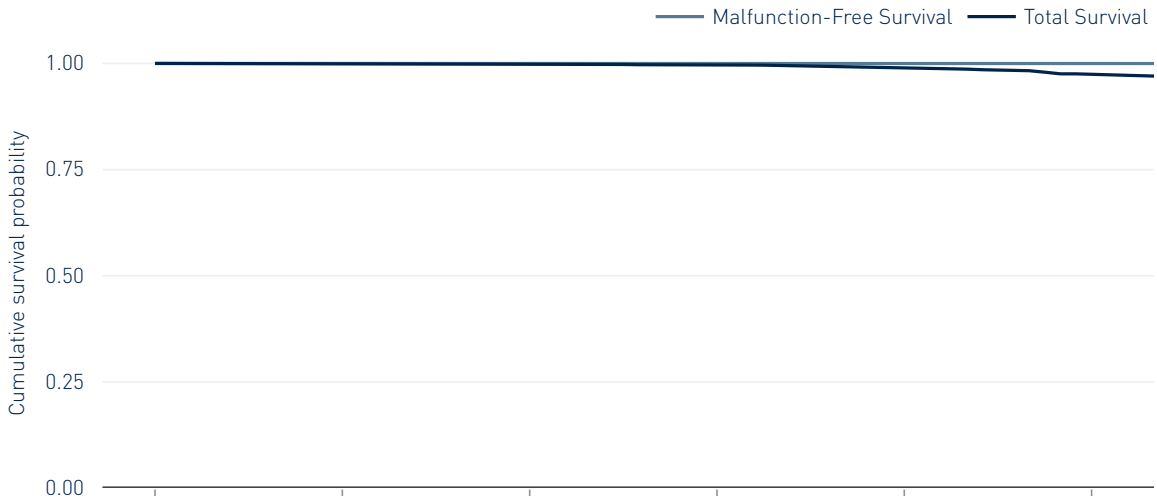
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	3 200
US Normal Battery Depletions	29

	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	98.9	97.4
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.3	0.7
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	4628	4296	4018	3636	2884	894

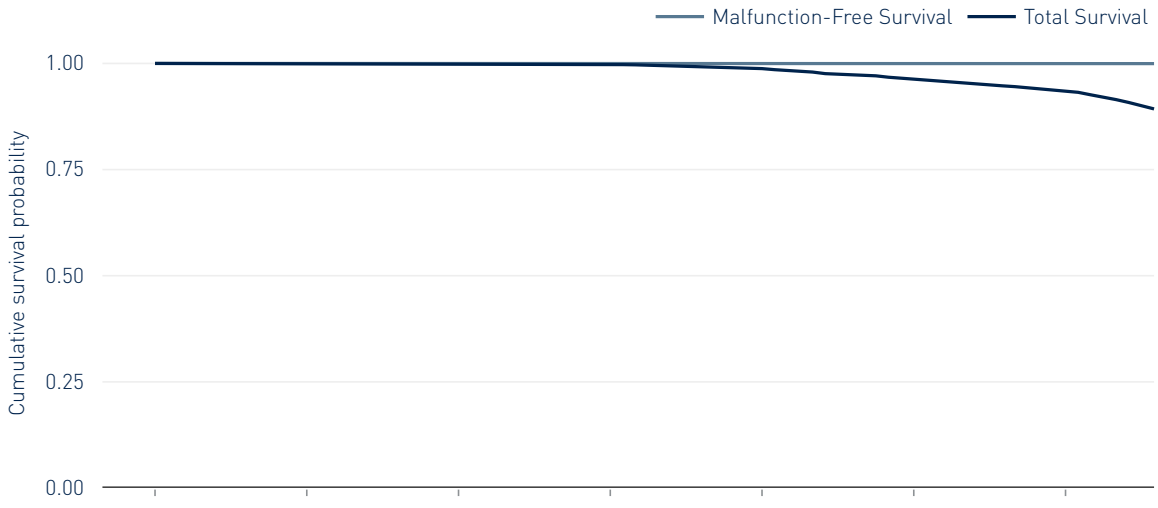
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	3 440
US Normal Battery Depletions	75

	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

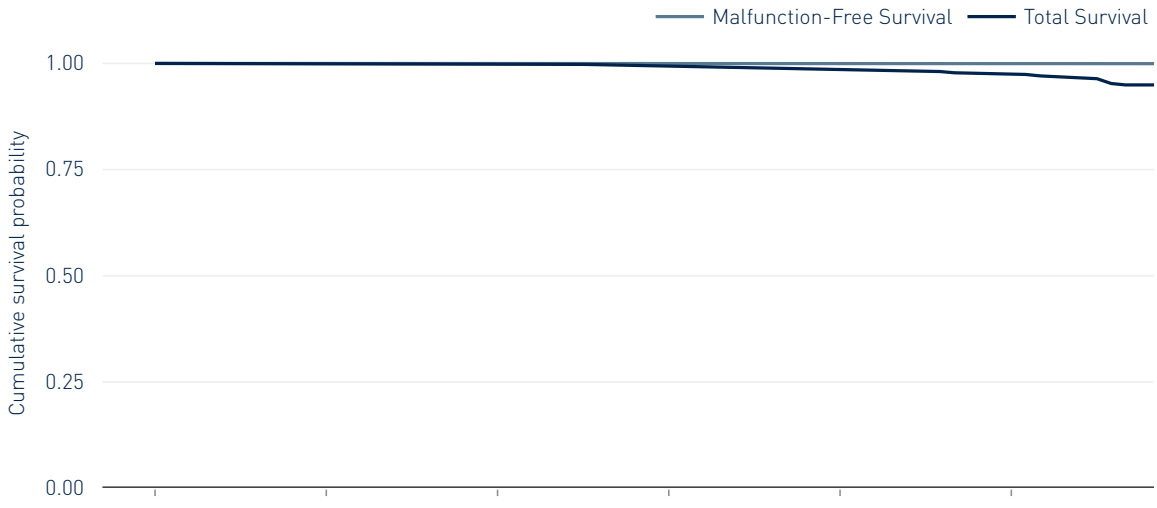
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1 160
US Normal Battery Depletions	42

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



Years after implant	0	1	2	3	4	5
Total [%]	100	99.9	99.9	99.4	98.5	97.6
CI [± %]	< 0.1	0.1	0.2	0.4	0.6	0.8
Malfunction-Free [%]	100	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	1965	1824	1706	1585	1433	703

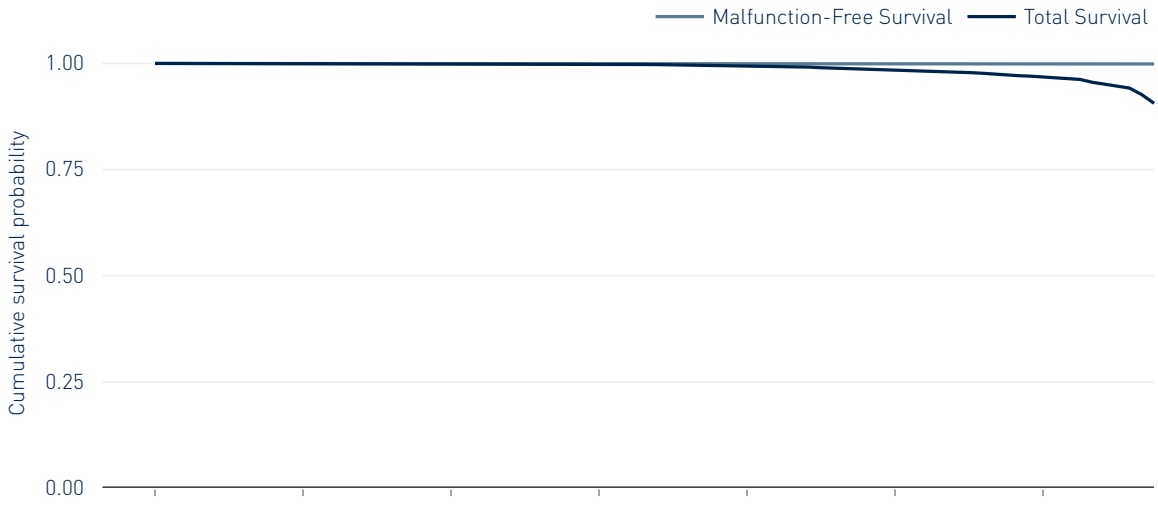
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	2 360
US Normal Battery Depletions	106

	Count	Rate
US Confirmed Malfunctions	4	0.10%
Therapy Compromised	1	0.02%
Therapy Available	3	0.07%



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

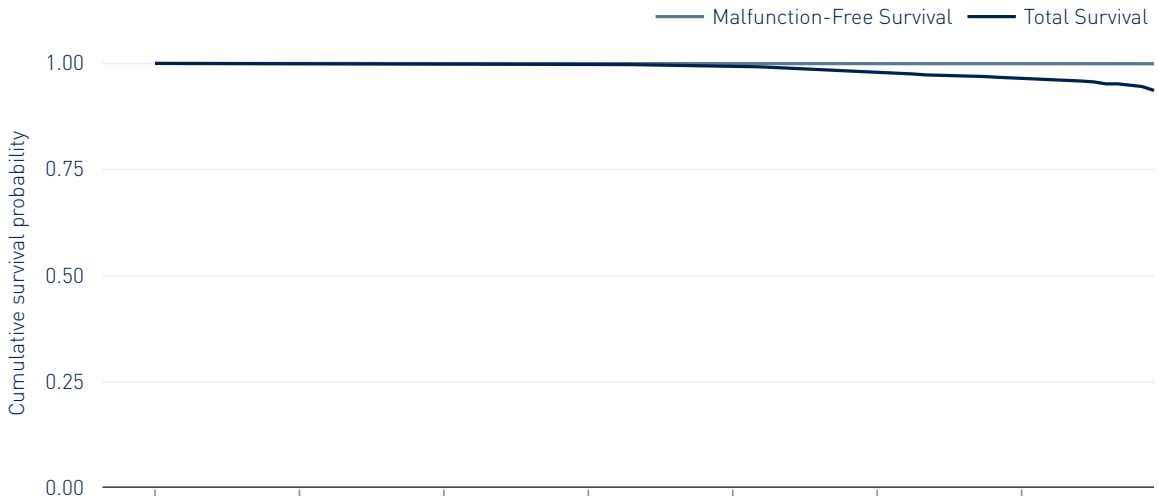
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	3 030
US Normal Battery Depletions	58

	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	100	99.8	99.4	97.9	96.5
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.2	0.5	0.6
Malfunction-Free [%]	100	100	100	100	100	100	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1
Sample Size	4835	4508	4226	3950	3640	2983	1997

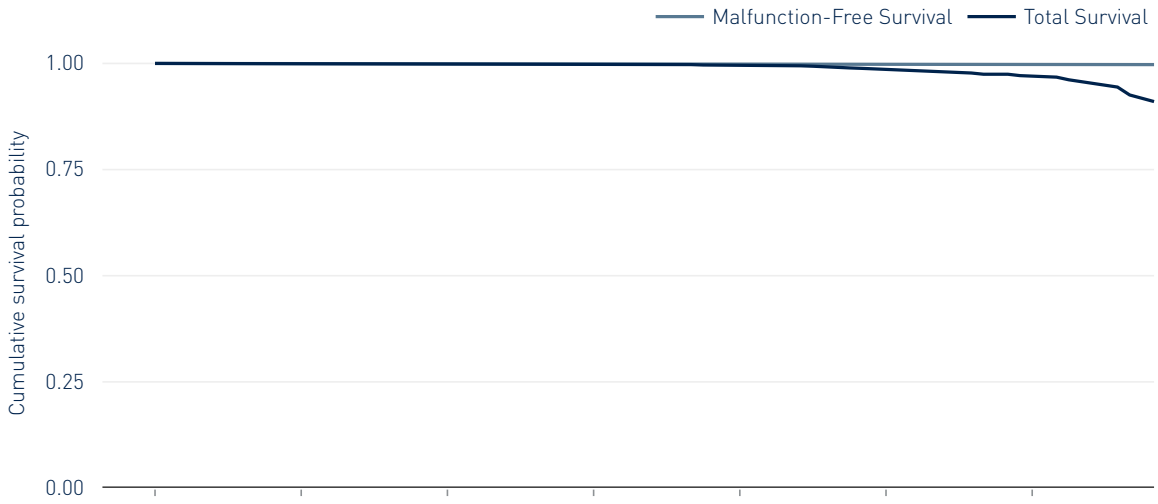
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	682
US Normal Battery Depletions	62

	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
Total [%]	100	100	100	100	99.5	98.6	97.0
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.4	0.7	1.2
Malfunction-Free [%]	100	100	100	100	99.9	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.2	0.2
Sample Size	1416	1306	1214	1132	1052	912	561

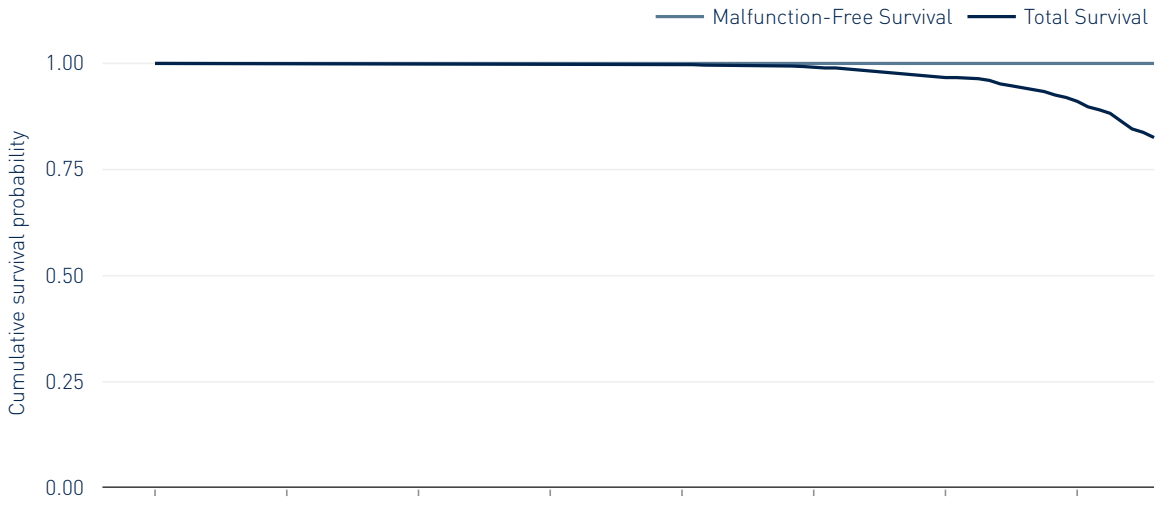
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	520
US Normal Battery Depletions	104

	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	99.9	99.8	99.7	99.1	96.7	91.1
CI [± %]	< 0.1	< 0.1	0.2	0.3	0.3	0.6	1.2	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	1268	1173	1086	1010	938	876	783	513

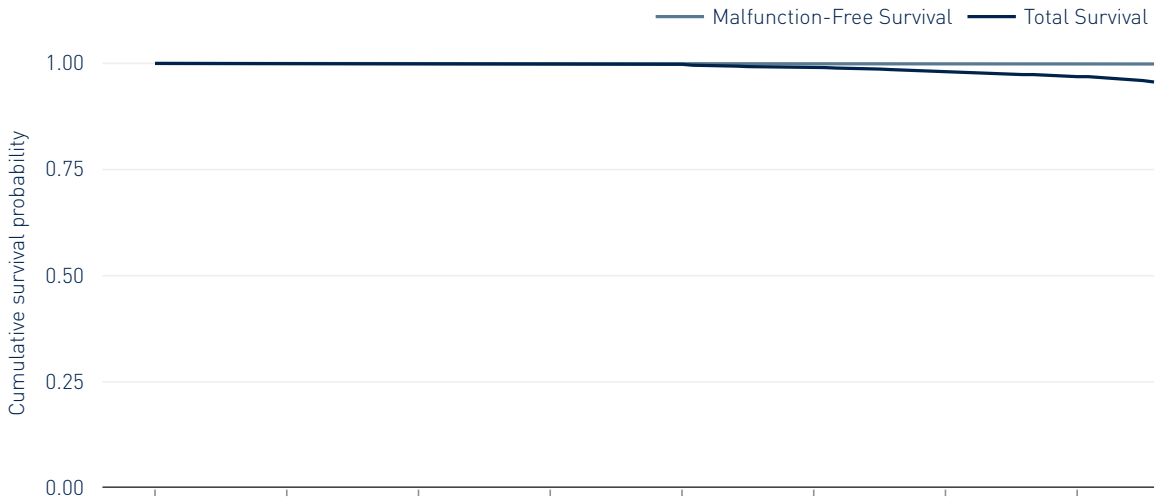
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	537
US Normal Battery Depletions	17

	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
Total [%]	100	100	100	100	99.8	99.0	98.2	96.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.6	0.9	1.2
Malfunction-Free [%]	100	100	100	100	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.3
Sample Size	1247	1154	1078	1008	943	867	772	562

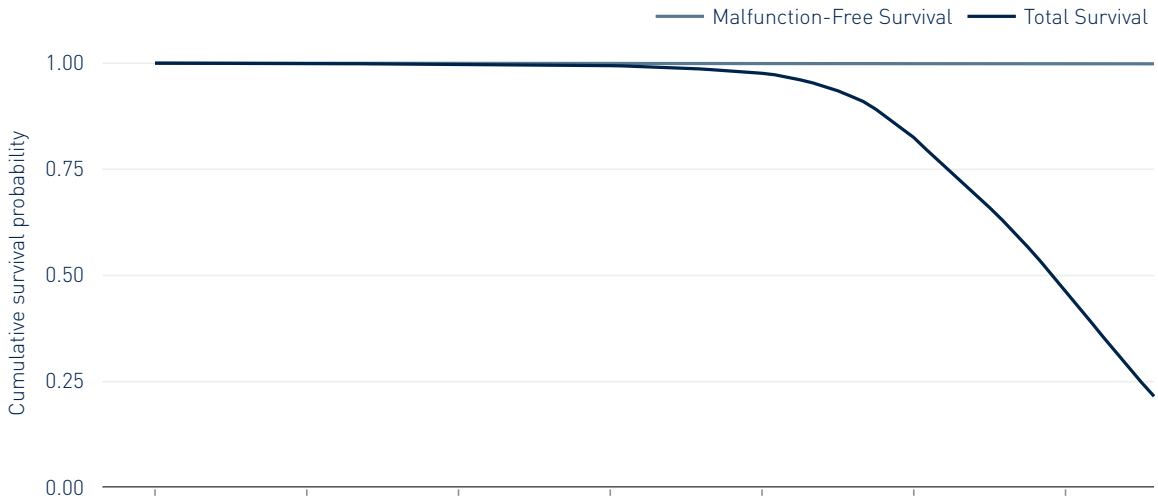
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	0
US Normal Battery Depletions	2 158

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



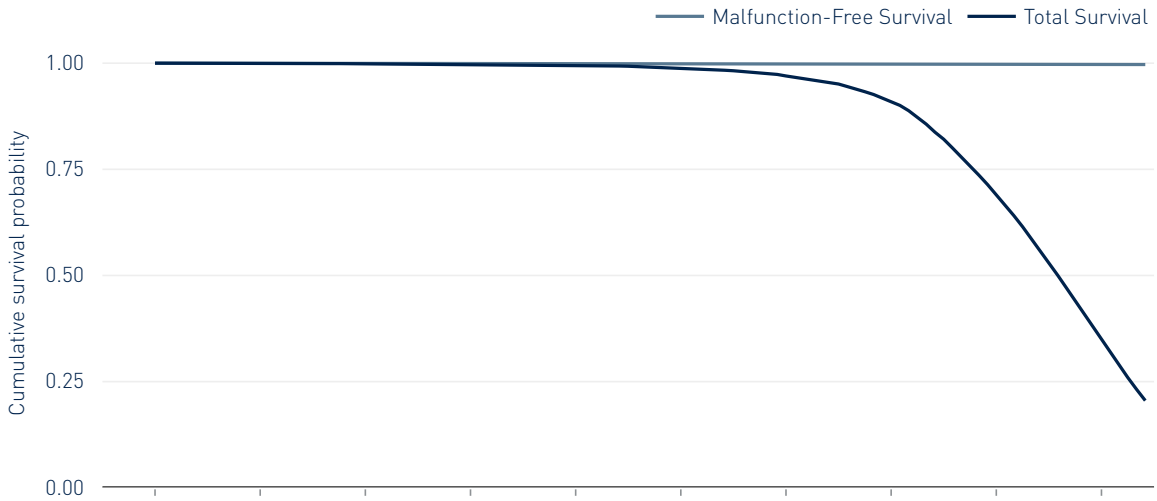
Years after implant	0	1	2	3	4	5	6
Total [%]	100	99.9	99.8	99.4	97.6	82.5	46.4
CI [± %]	< 0.1	0.1	0.1	0.2	0.4	1.0	1.5
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.8	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8219	7531	7031	6491	5921	4403	1933

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	0
US Normal Battery Depletions	2 930

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



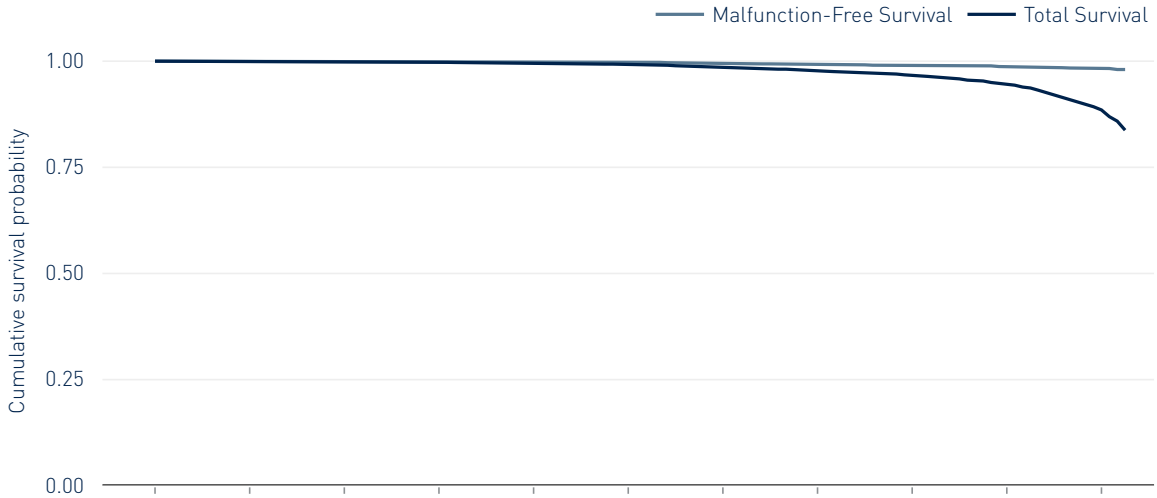
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.9	99.9	99.8	99.5	98.8	97.0	91.0	69.1	34.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.4	0.7	1.1	1.4
Malfunction-Free [%]	100	100	100	99.9	99.9	99.8	99.8	99.8	99.8	99.7
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	11.5k	10.7k	9939	9258	8590	7952	7289	6345	4414	1878

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	3 814
Estimated Active US Implants	1 440
US Normal Battery Depletions	236

	Count	Rate
US Confirmed Malfunctions	38	1.00%
Therapy Compromised	26	0.68%
Therapy Available	12	0.31%



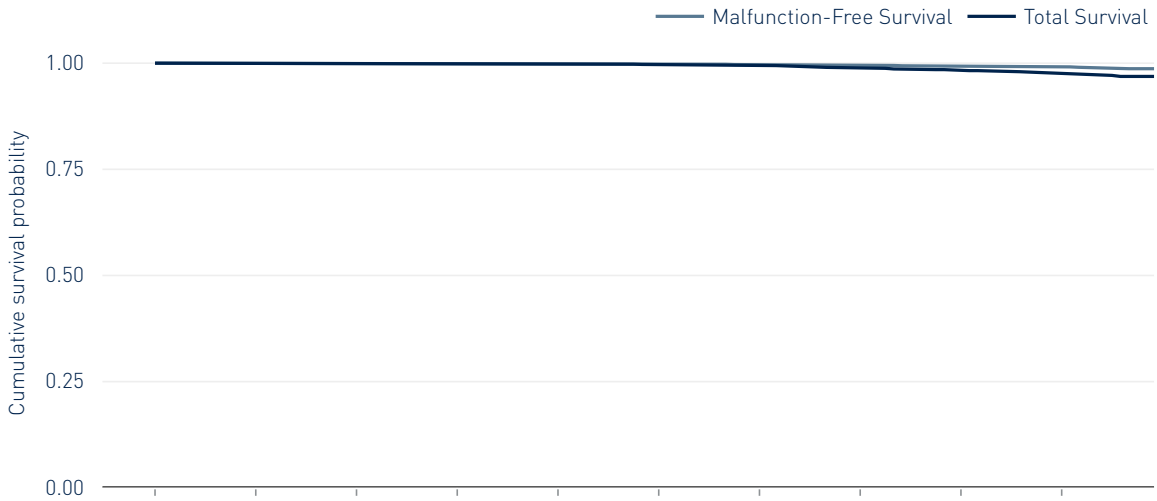
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	100	99.9	99.7	99.6	99.3	98.5	97.8	96.7	94.6	88.5
CI [± %]	< 0.1	< 0.1	0.1	0.2	0.2	0.3	0.5	0.6	0.7	0.9	1.6
Malfunction-Free [%]	100	100	100	100	99.9	99.8	99.4	99.3	99.0	98.7	98.3
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.3	0.3	0.4	0.5	0.6
Sample Size	3814	3547	3311	3074	2862	2649	2446	2262	2075	1801	712

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	939
US Normal Battery Depletions	32

	Count	Rate
US Confirmed Malfunctions	16	0.72%
Therapy Compromised	10	0.45%
Therapy Available	6	0.27%



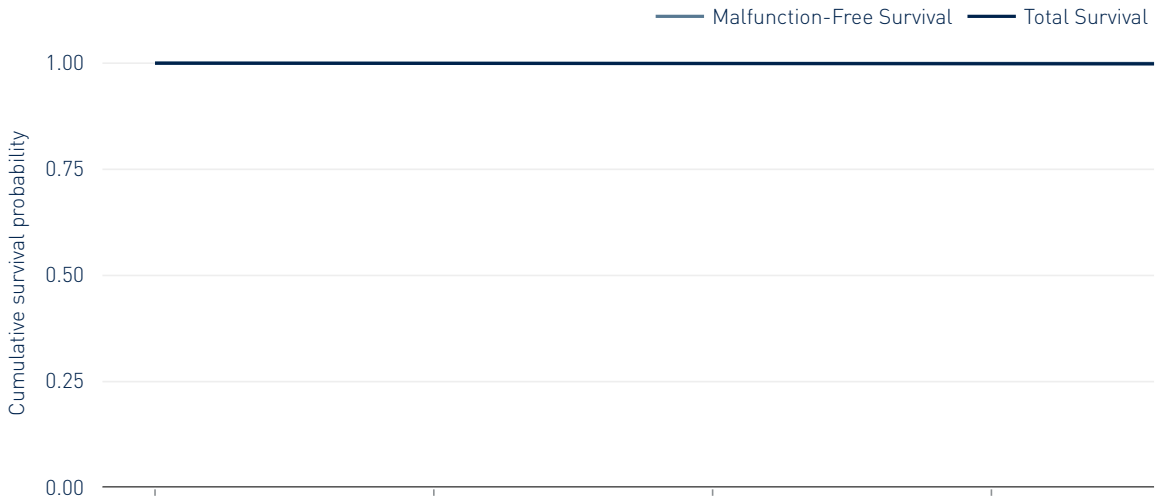
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	100	100	99.9	99.9	99.7	99.4	98.9	98.2	97.6
CI [± %]	< 0.1	< 0.1	< 0.1	0.1	0.2	0.3	0.4	0.5	0.7	0.8
Malfunction-Free [%]	100	100	100	100	100	99.9	99.6	99.5	99.4	99.1
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.5
Sample Size	2223	2064	1927	1792	1675	1555	1449	1349	1224	1085

4.2 Dual-Chamber ICDs

Rivacor 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	15 000
Registered US Implants	8 285
Estimated Active US Implants	7 110
US Normal Battery Depletions	6

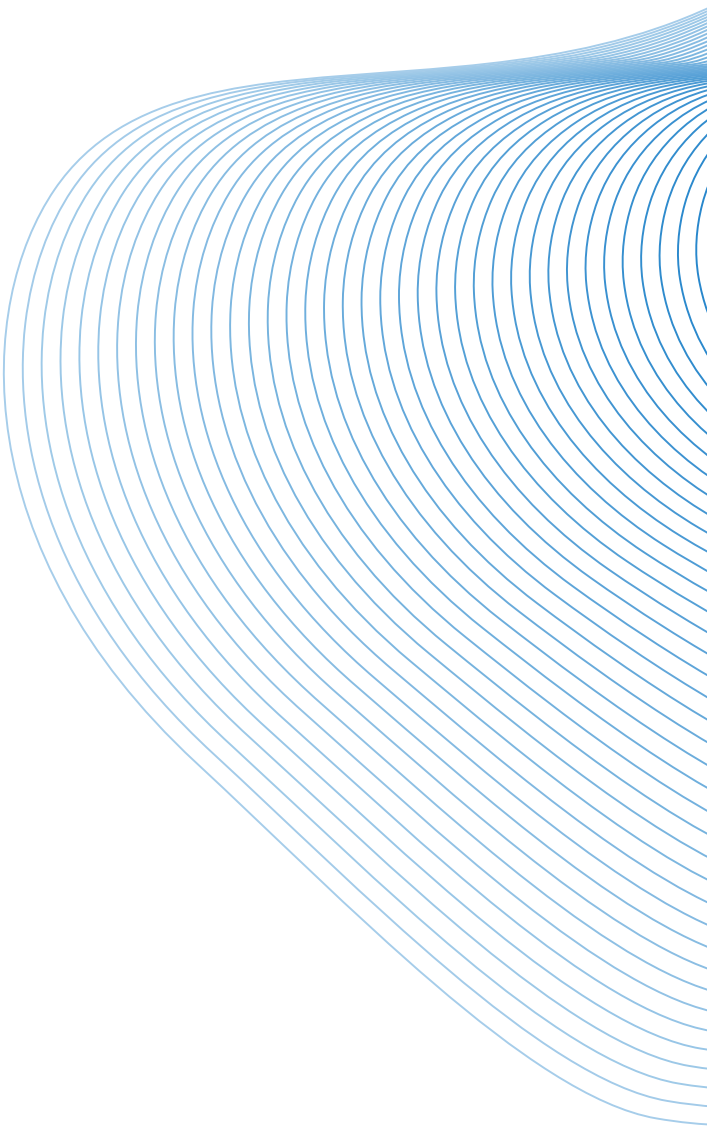
	Count	Rate
US Confirmed Malfunctions	4	0.05%
Therapy Compromised	4	0.05%
Therapy Available	0	0.00%



Years after implant	0	1	2	3
Total [%]	100	99.9	99.8	99.8
CI [± %]	< 0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.1	0.1
Sample Size	8285	5564	3168	1103

Performance of BIOTRONIK ICDs

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

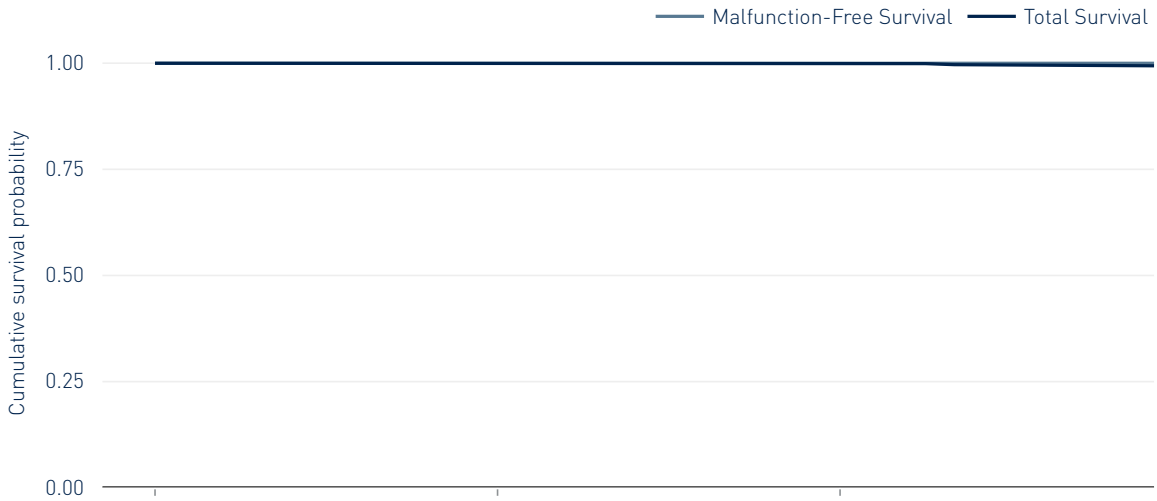


4.3 CRT ICDs

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	18 600
Registered US Implants	4 720
Estimated Active US Implants	3 800
US Normal Battery Depletions	8

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



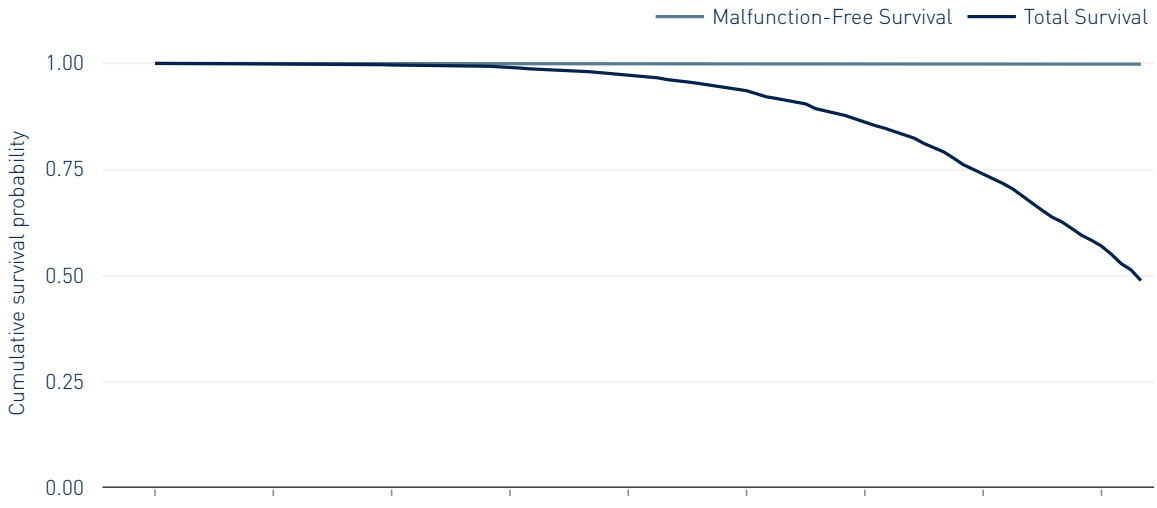
Years after implant	0	1	2
Total [%]	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1
Sample Size	4720	2753	1257

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	622
US Normal Battery Depletions	865

	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
Total [%]	100	99.9	99.6	99.0	97.1	93.6	86.0	74.0	57.0
CI [± %]	< 0.1	0.1	0.2	0.4	0.6	1.0	1.5	2.0	2.5
Malfunction-Free [%]	100	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	0.2	0.2	0.2
Sample Size	3841	3409	3040	2684	2343	1998	1630	1219	637

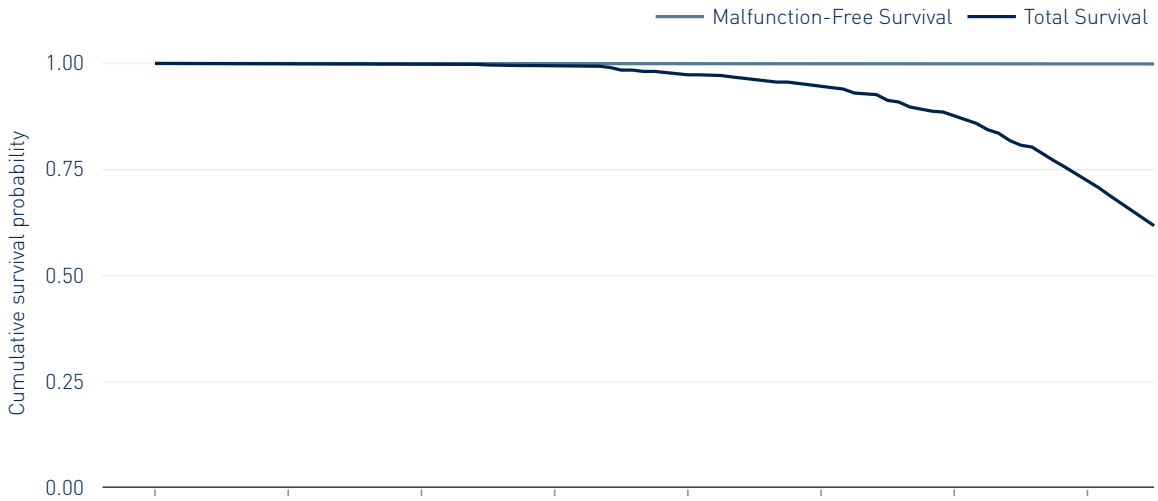
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	66
US Normal Battery Depletions	202

	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	72.4
CI [± %]	< 0.1	0.2	0.3	0.5	1.2	1.8	2.7	4.0
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	318

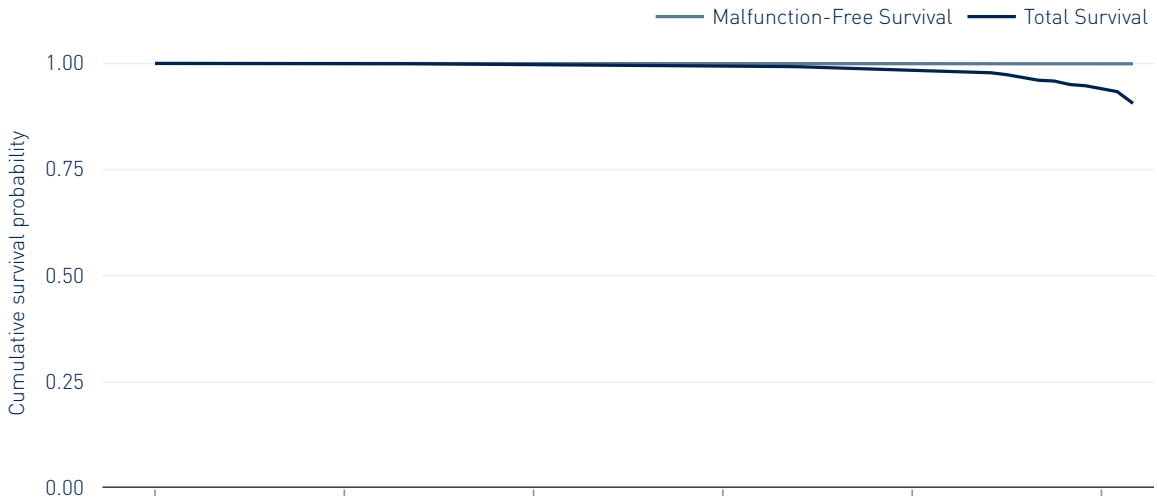
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	4 775
Estimated Active US Implants	2 720
US Normal Battery Depletions	132

	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

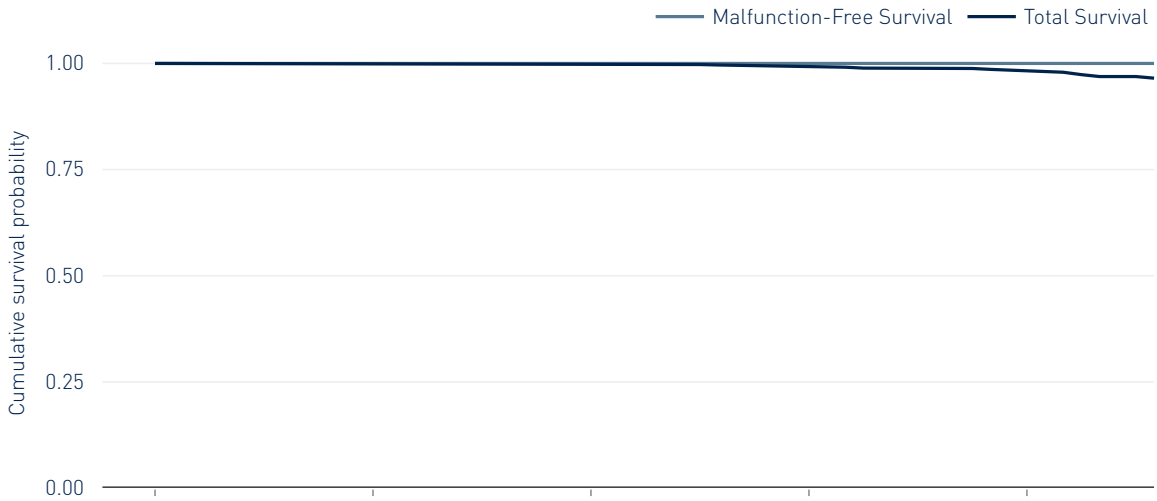
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1 660
US Normal Battery Depletions	49

	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
Total [%]	100	100	99.8	99.2	98.1
CI [± %]	< 0.1	0.1	0.2	0.4	0.8
Malfunction-Free [%]	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	2960	2577	2255	1650	753

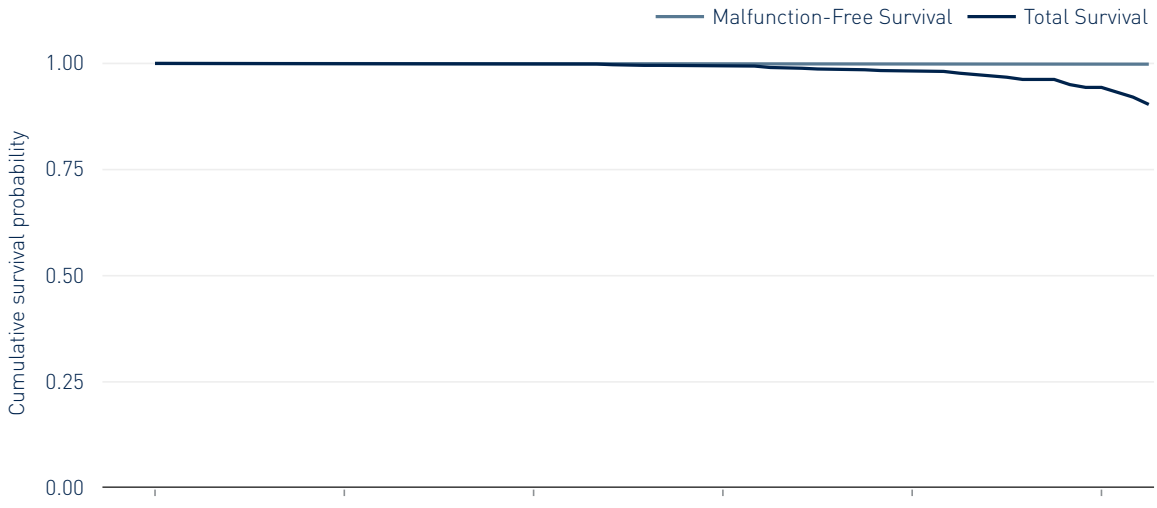
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	274
US Normal Battery Depletions	61

	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
Total [%]	100	100	100	99.5	98.3	94.4
CI [± %]	< 0.1	< 0.1	< 0.1	0.5	1.0	2.2
Malfunction-Free [%]	100	100	100	100	99.8	99.8
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	0.3	0.3
Sample Size	887	776	697	614	506	271

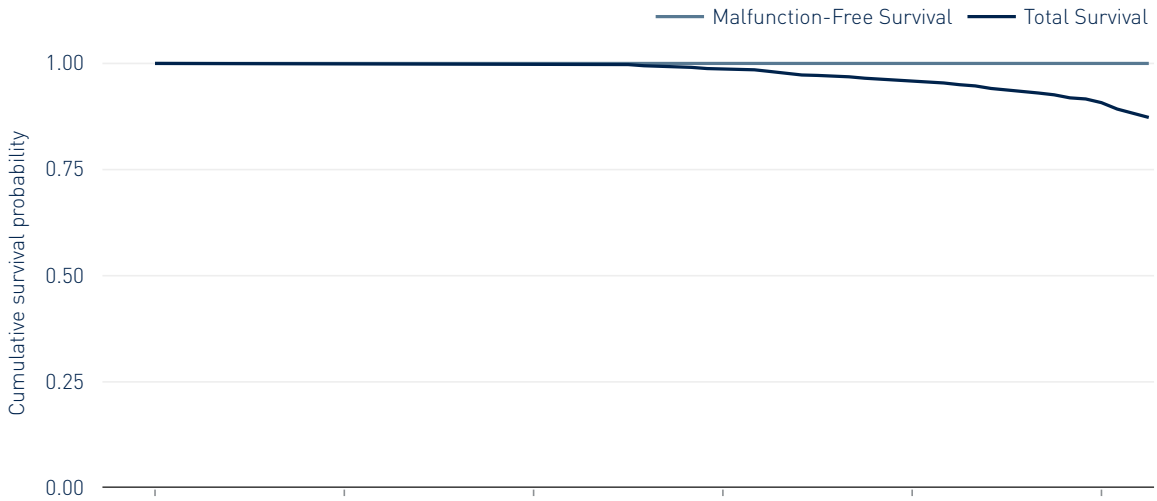
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	582
US Normal Battery Depletions	112

	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	98.7	95.9	90.8
CI [± %]	< 0.1	< 0.1	< 0.1	0.7	1.2	2.3
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1479	1305	1160	1024	783	330

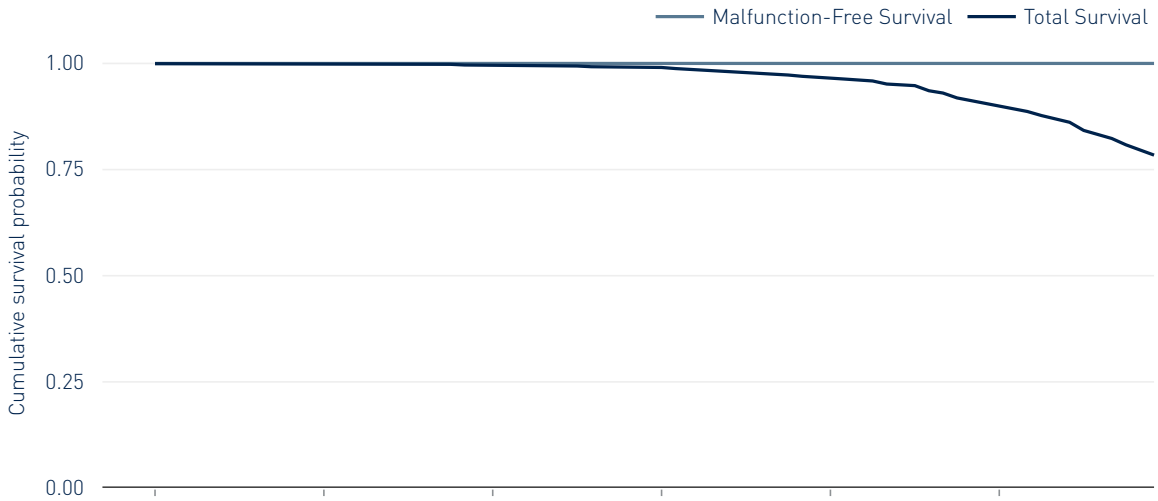
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1 618
Estimated Active US Implants	562
US Normal Battery Depletions	163

	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 [%]	99.9	99.9	99.6	99.1	96.5	90.0
CI [± %]	0.1	0.1	0.4	0.5	1.1	2.1
Malfunction-Free [%]	100	100	100	100	100	100
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1618	1423	1268	1131	908	567

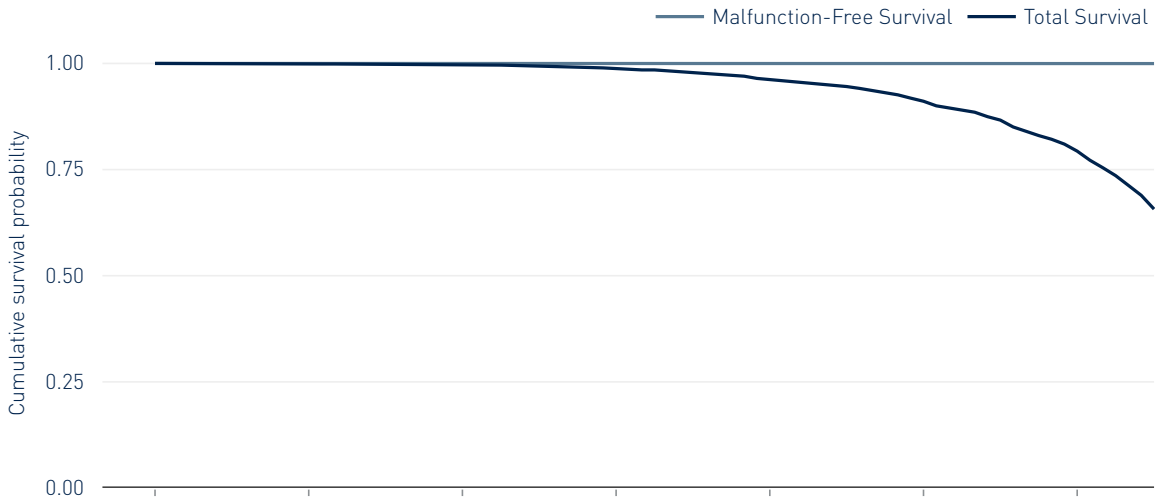
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	1 110
US Normal Battery Depletions	475

	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
Total [%]	100	99.9	99.7	98.8	96.2	91.1	79.3
CI [± %]	< 0.1	0.1	0.2	0.4	0.8	1.3	2.2
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	3316	2921	2596	2303	2000	1499	731

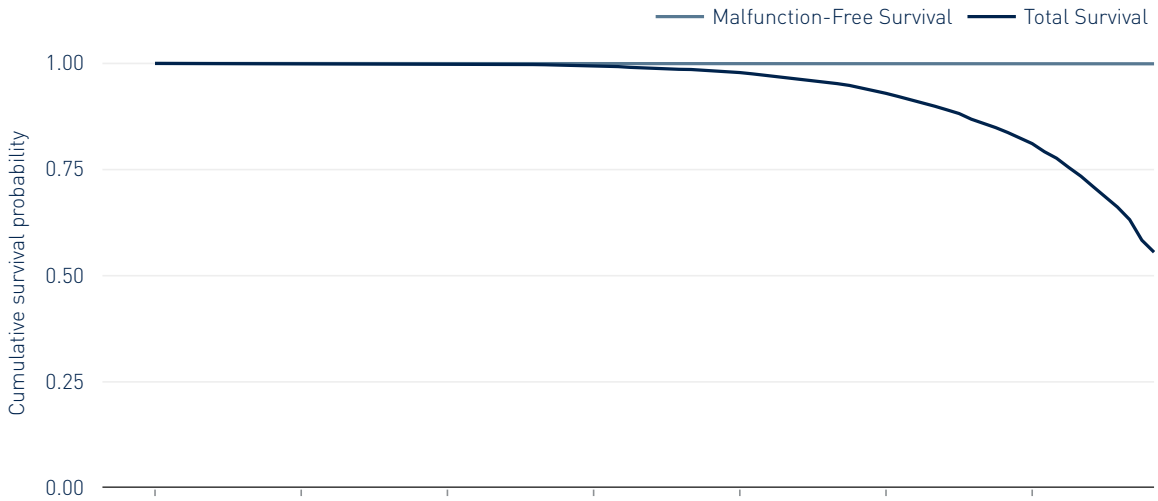
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	846
US Normal Battery Depletions	618

	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
Total [%]	100	100	99.9	99.4	97.8	93.0	81.1
CI [± %]	< 0.1	0.1	0.1	0.3	0.6	1.1	1.9
Malfunction-Free [%]	100	100	100	100	100	99.9	99.9
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3228	2857	2557	2286	2002	1693	1116

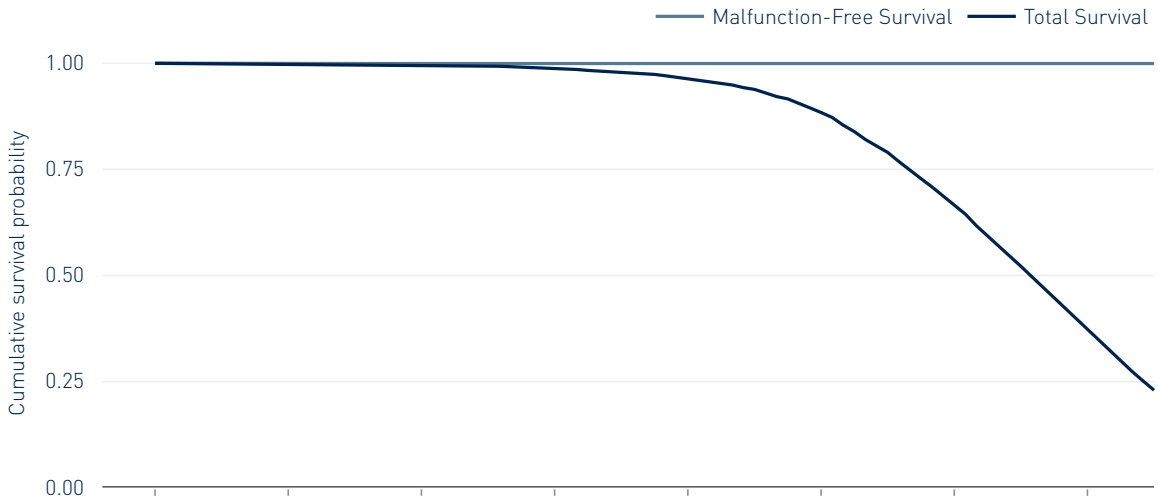
*A subset of devices from this product family is subject to a product advisory. Confirmed malfuctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

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	0
US Normal Battery Depletions	1 275

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



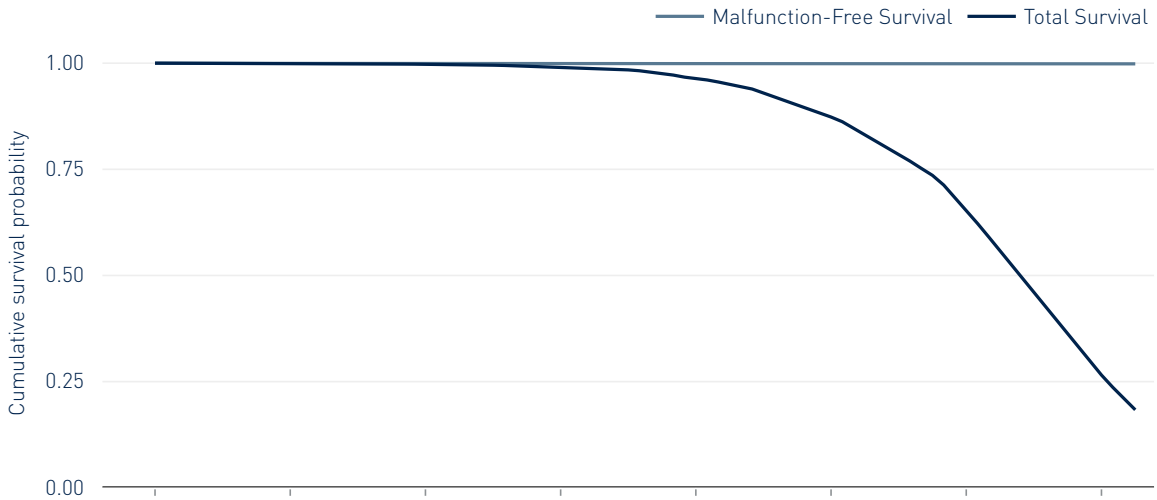
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.8	99.6	98.7	96.3	88.4	66.7	37.1
CI [± %]	0.1	0.1	0.2	0.3	0.6	1.1	1.8	2.3
Malfunction-Free [%]	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5310	4729	4232	3718	3194	2477	1499	627

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	0
US Normal Battery Depletions	2 600

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



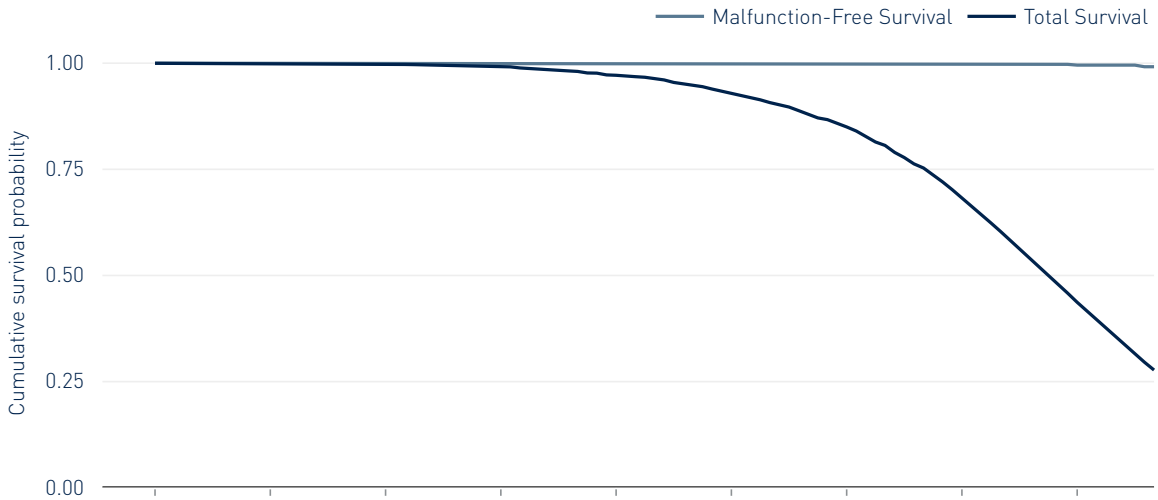
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.9	99.8	99.2	96.5	87.3	65.4	26.5
CI [± %]	< 0.1	0.1	0.1	0.2	0.5	0.9	1.4	1.9
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.8	99.8	99.8
CI [± %]	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8656	7682	6877	6112	5278	4204	2751	724

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	26
US Normal Battery Depletions	882

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



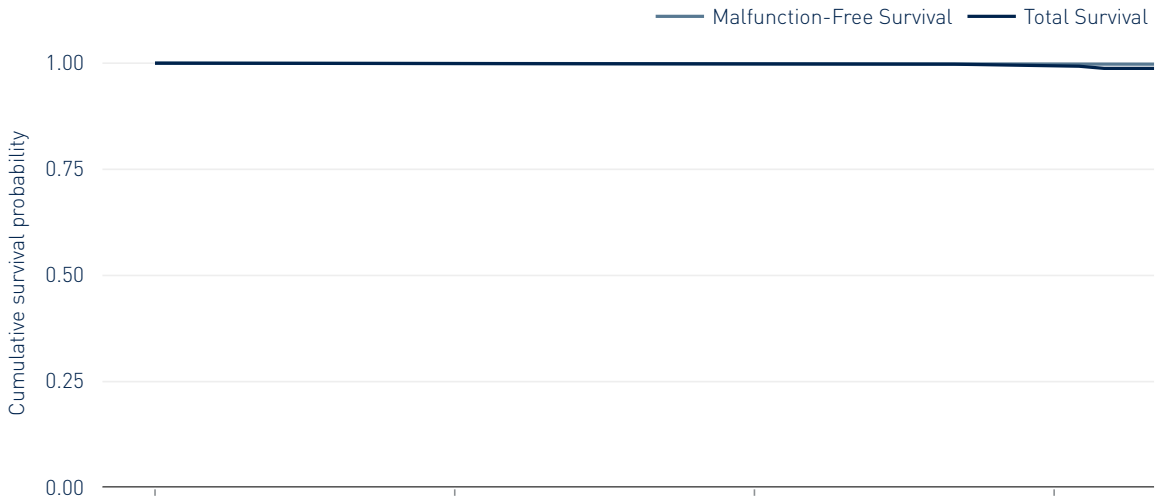
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.9	99.7	99.1	97.1	92.9	85.0	68.3	43.7
CI [± %]	0.1	0.1	0.2	0.4	0.7	1.1	1.6	2.2	2.7
Malfunction-Free [%]	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.5
CI [± %]	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Sample Size	3410	3033	2715	2411	2111	1792	1442	1027	547

4.3 CRT ICDs

Rivacor 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	18 200
Registered US Implants	6 983
Estimated Active US Implants	5 550
US Normal Battery Depletions	9

	Count	Rate
US Confirmed Malfunctions	5	0.07%
Therapy Compromised	4	0.06%
Therapy Available	1	0.01%



Years after implant	0	1	2	3
Total [%]	100	99.9	99.9	99.3
CI [± %]	< 0.1	0.1	0.1	0.5
Malfunction-Free [%]	100	100	100	99.8
CI [± %]	< 0.1	0.1	0.1	0.2
Sample Size	6983	4537	2523	699

Methodology for Lead Survial 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 June 30, 2023. 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.

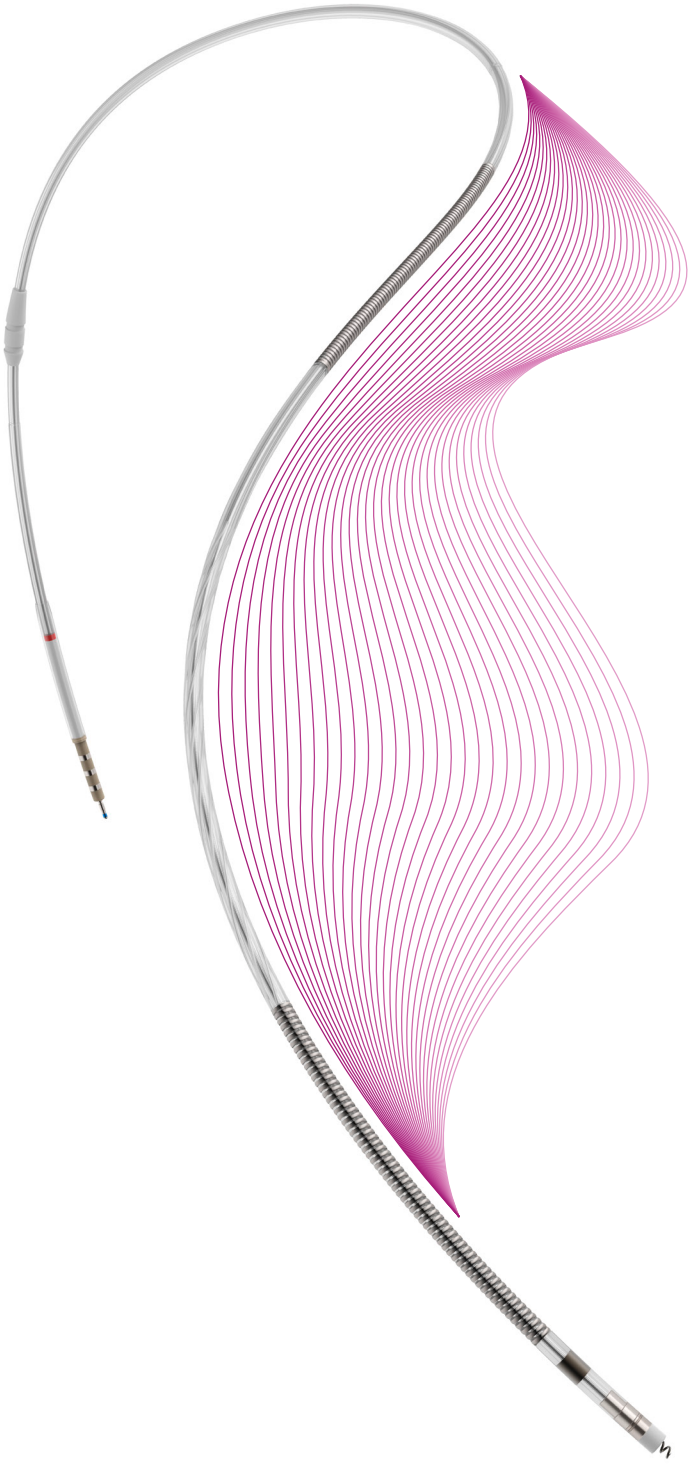
The cumulative survival data and the 95 % confidence intervals according to the Greenwood's formula[1] are shown in numerical form for the observed sample population.

[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

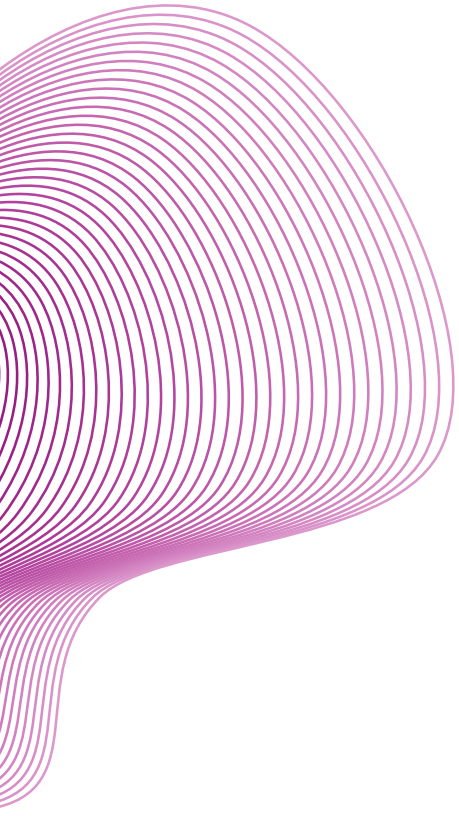
6.1 Pacing Leads
6.2 ICD Leads
6.3 CRT Leads



Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

6.1 Pacing Leads
6.2 ICD Leads
6.3 CRT Leads

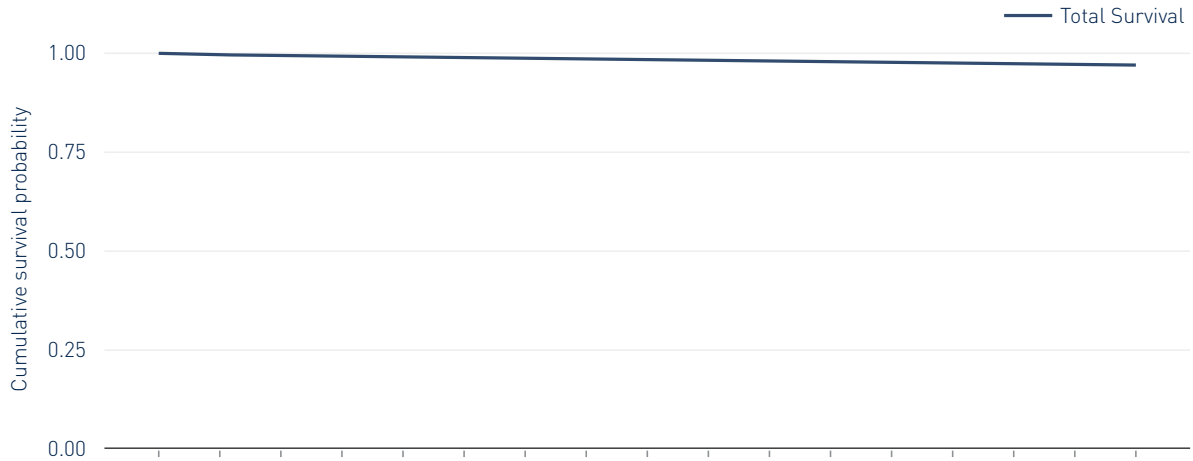


Dextrus

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	379 170
Estimated Active US Implants	209 000
US Total Returned	2 487

	Count	Rate
US Qualifying Complications	5 477	1.43%
Abnormal pacing impedance	519	0.14%
Cardiac perforation	27	0.01%
Conductor fracture	179	0.05%
Extracardiac stimulation	25	0.01%
Failure to capture	1 280	0.33%
Failure to sense	203	0.05%
Insulation breach	99	0.03%
Lead dislodgement	596	0.16%
Oversensing	1 563	0.41%
Other	986	0.26%

	Count	Rate
US Confirmed Malfunctions	396	0.10%
Conductor Fracture	126	0.03%
Insulation Breach	262	0.07%
Other	8	0.00%
US Acute Lead Observations	1 775	0.46%
Abnormal pacing impedance	47	0.01%
Cardiac perforation	74	0.02%
Extracardiac stimulation	16	0.00%
Failure to capture	262	0.07%
Failure to sense	70	0.02%
Insulation breach	10	0.00%
Lead dislodgement	716	0.19%
Oversensing	48	0.01%
Other	532	0.14%



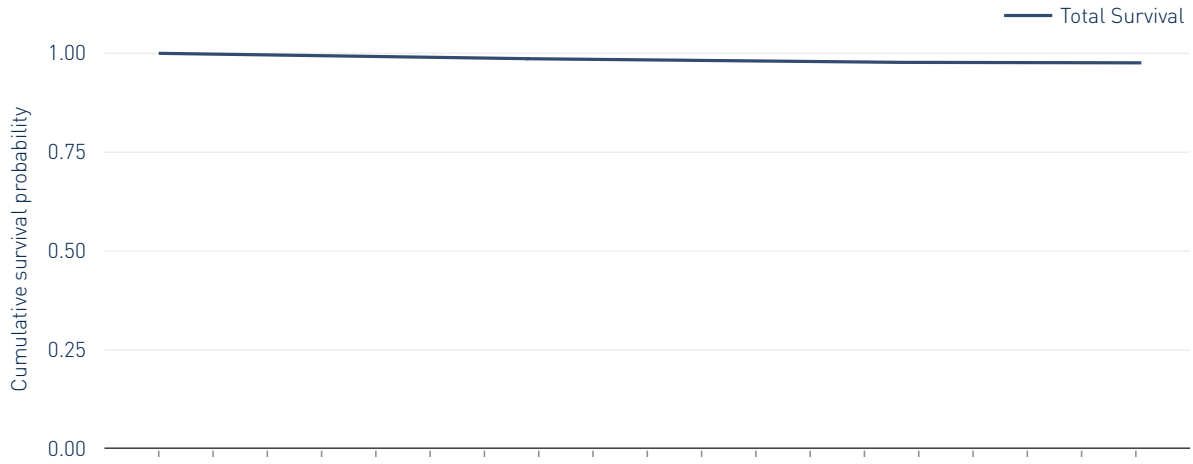
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100	99.6	99.5	99.3	99.1	98.9	98.7	98.6	98.4	98.2	98.0	97.8	97.7	97.5	97.4	97.2	97.0
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Sample Size	379k	337k	315k	295k	278k	263k	249k	235k	199k	160k	126k	97.7k	73.6k	51.8k	31.2k	13.3k	314

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	16 618
Estimated Active US Implants	11 700
US Total Returned	130

	Count	Rate
US Qualifying Complications	269	1.62%
Abnormal pacing impedance	44	0.26%
Cardiac perforation	1	0.01%
Conductor fracture	16	0.10%
Extracardiac stimulation	1	0.01%
Failure to capture	111	0.67%
Failure to sense	11	0.07%
Insulation breach	12	0.07%
Lead dislodgement	40	0.24%
Oversensing	12	0.07%
Other	21	0.13%

	Count	Rate
US Confirmed Malfunctions	11	0.07%
Insulation Breach	10	0.06%
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
Total [%]	100	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	98.2	98.1	97.9	97.8	97.7	97.7	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	0.3	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	13.1k	12.4k	11.7k	10.9k	9998	8748	7666	6527	5251	4071	2870	1805	914	277

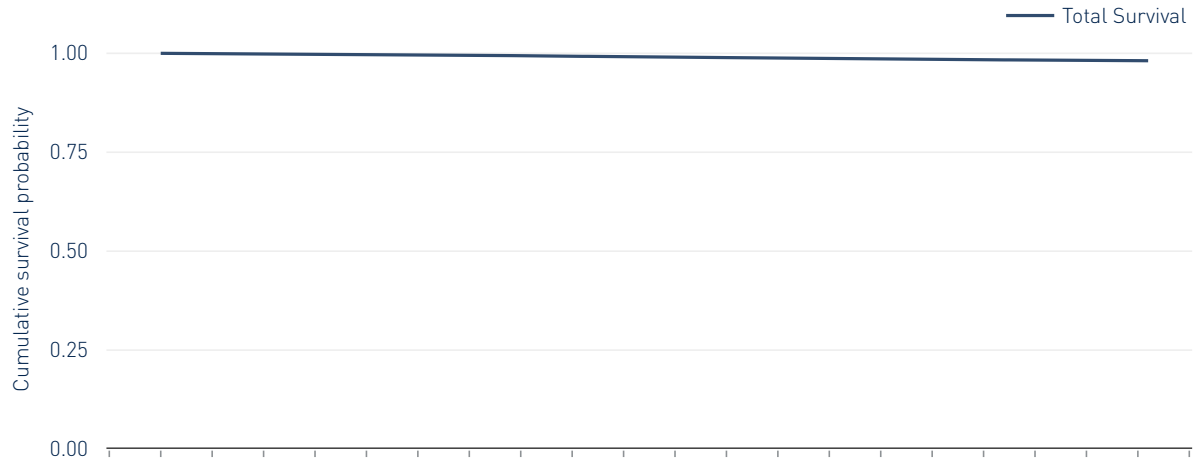
6.1 Performance of Pacing Leads – Postmarket Data

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	14 334
Estimated Active US Implants	6 740
US Total Returned	63

	Count	Rate
US Qualifying Complications	138	0.96%
Abnormal pacing impedance	11	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	13	0.09%
Insulation Breach	13	0.09%
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
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
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
Sample Size	14.3k	12.4k	11.7k	10.9k	10k	9347	8728	8231	7875	7603	7395	7223	7151	7095	6988	6881	6778	6629	3612	620

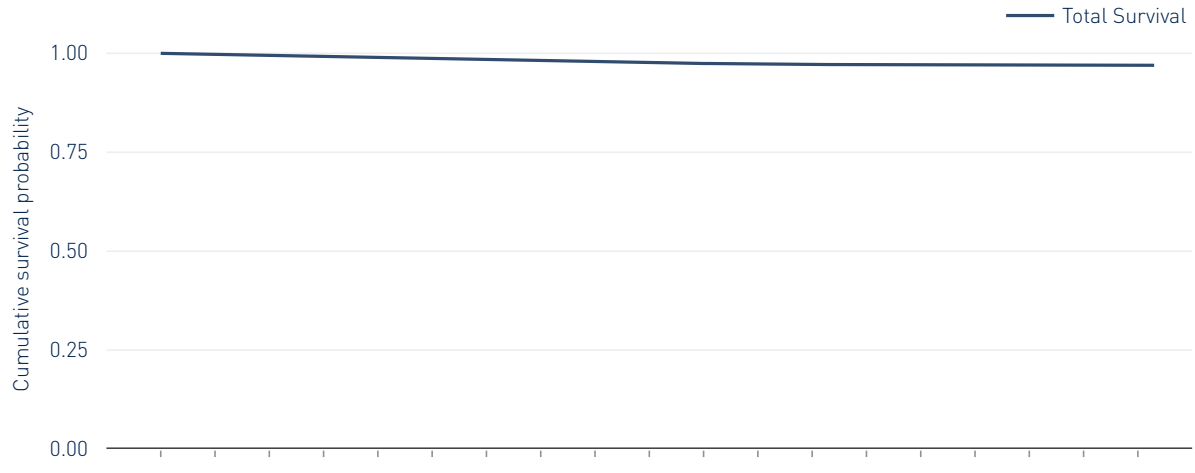
6.1 Performance of Pacing Leads – Postmarket Data

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	21 600
US Total Returned	184

	Count	Rate
US Qualifying Complications	666	2.07%
Abnormal pacing impedance	149	0.46%
Cardiac perforation	3	0.01%
Conductor fracture	70	0.22%
Extracardiac stimulation	6	0.02%
Failure to capture	321	1.00%
Failure to sense	1	0.00%
Insulation breach	39	0.12%
Lead dislodgement	24	0.07%
Oversensing	19	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
Total [%]	100	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.6	97.4	97.3	97.2	97.1	97.1	97.1	97.0	97.0	97.0
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
Sample Size	32.1k	29.2k	27.7k	26.4k	25.3k	24.1k	22.9k	21.8k	20.4k	18.7k	16.5k	14.5k	12.2k	9969	7919	5869	3970	2237	681

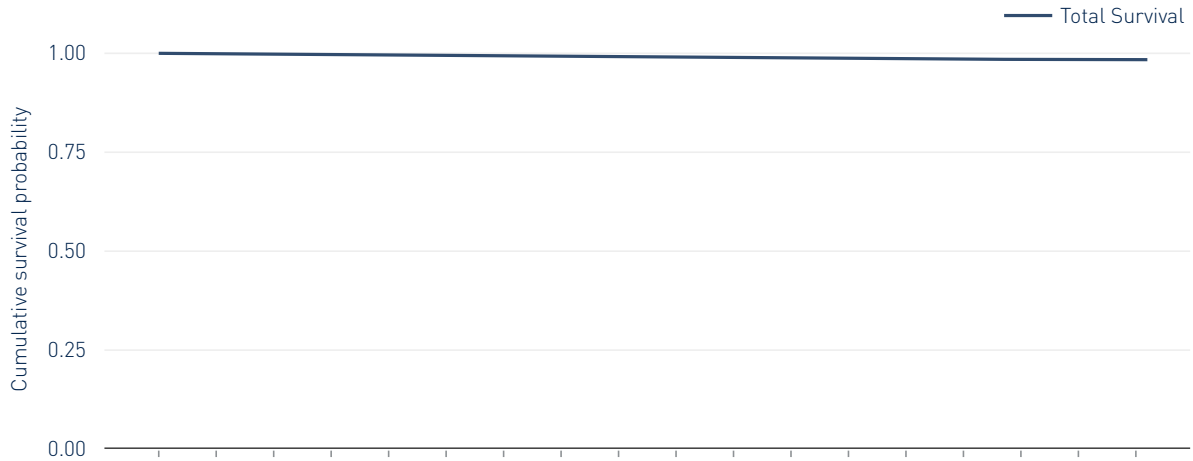
6.1 Performance of Pacing Leads – Postmarket Data

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	245 600
Estimated Active US Implants	185 000
US Total Returned	1 783

	Count	Rate
US Qualifying Complications	2 246	0.91%
Abnormal pacing impedance	209	0.08%
Cardiac perforation	10	0.00%
Conductor fracture	161	0.07%
Extracardiac stimulation	12	0.00%
Failure to capture	745	0.30%
Failure to sense	64	0.03%
Insulation breach	89	0.04%
Lead dislodgement	381	0.15%
Oversensing	405	0.16%
Other	170	0.07%

	Count	Rate
US Confirmed Malfunctions	226	0.09%
Conductor Fracture	64	0.03%
Insulation Breach	155	0.06%
Other	7	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%



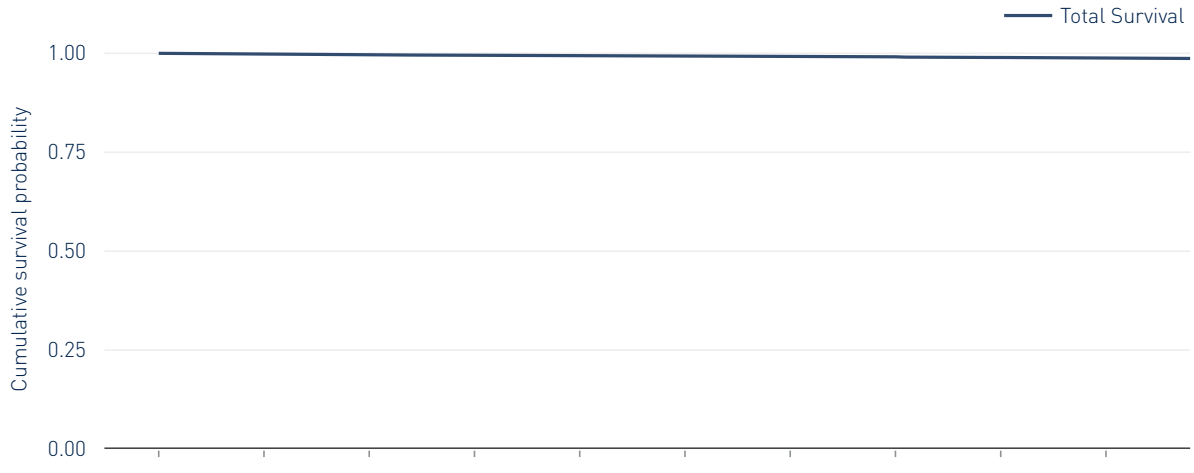
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.1	98.9	98.8	98.7	98.6	98.6	98.5	98.5	98.4	98.4
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	246k	229k	221k	214k	208k	202k	196k	186k	152k	124k	102k	81.6k	62.3k	45.3k	30.4k	17.4k	7982	1340

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	2 748 000
Registered US Implants	254 385
Estimated Active US Implants	232 000
US Total Returned	1 263

	Count	Rate
US Qualifying Complications	1 236	0.49%
Abnormal pacing impedance	80	0.03%
Cardiac perforation	21	0.01%
Conductor fracture	41	0.02%
Extracardiac stimulation	9	0.00%
Failure to capture	325	0.13%
Failure to sense	48	0.02%
Insulation breach	22	0.01%
Lead dislodgement	487	0.19%
Oversensing	135	0.05%
Other	68	0.03%

	Count	Rate
US Confirmed Malfunctions	69	0.03%
Conductor Fracture	22	0.01%
Insulation Breach	33	0.01%
Other	14	0.01%
US Acute Lead Observations	557	0.22%
Abnormal pacing impedance	9	0.00%
Cardiac perforation	42	0.02%
Conductor fracture	1	0.00%
Extracardiac stimulation	1	0.00%
Failure to capture	81	0.03%
Failure to sense	11	0.00%
Insulation breach	4	0.00%
Lead dislodgement	358	0.14%
Oversensing	20	0.01%
Other	30	0.01%



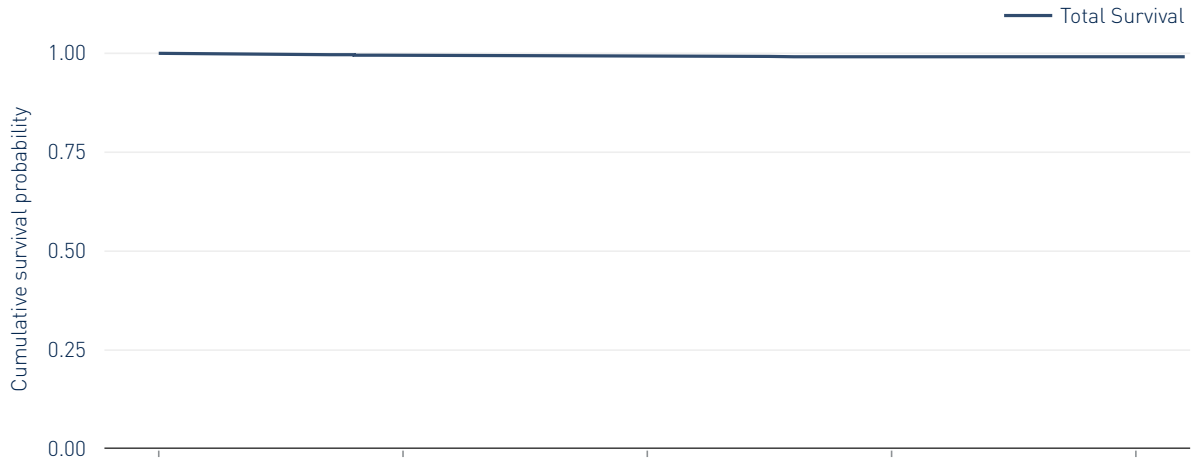
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.7	99.6	99.5	99.4	99.3	99.2	99.1	99.0	98.9
CI [± %]	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.2	0.2
Sample Size	254k	210k	173k	137k	104k	66.4k	30.8k	2812	2280	1157

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	168 000
Registered US Implants	3 142
Estimated Active US Implants	2 850
US Total Returned	13

	Count	Rate
US Qualifying Complications	18	0.57%
Conductor fracture	1	0.03%
Failure to capture	4	0.13%
Failure to sense	1	0.03%
Insulation breach	1	0.03%
Lead dislodgement	8	0.25%
Oversensing	2	0.06%
Other	1	0.03%

	Count	Rate
US Confirmed Malfunctions	0	0.00%
US Acute Lead Observations	19	0.60%
Failure to capture	1	0.03%
Lead dislodgement	18	0.57%



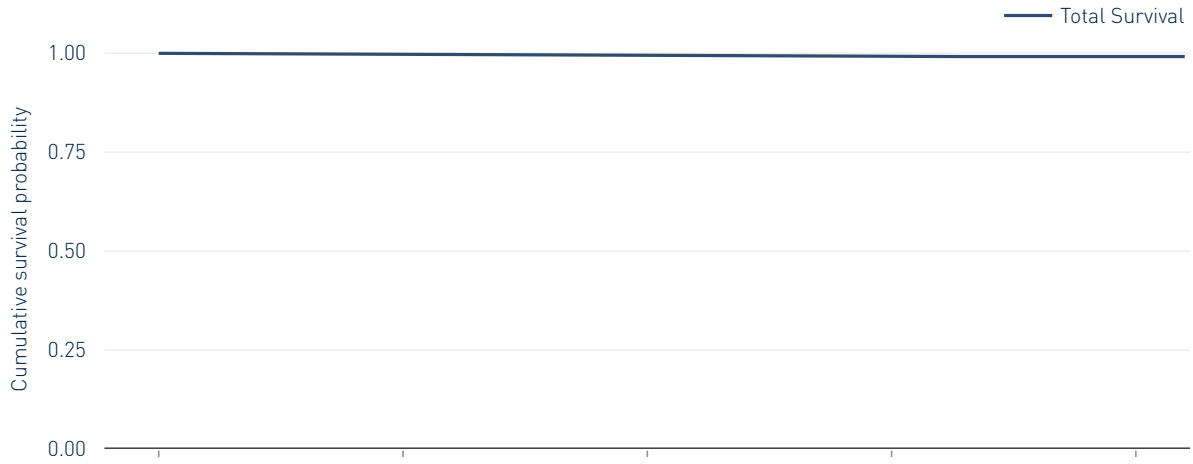
Years after implant	0	1	2	3	4
Total [%]	100	99.5	99.5	99.1	99.1
CI [± %]	< 0.1	0.3	0.3	0.4	0.4
Sample Size	3142	2186	1474	890	291

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	229 000
Registered US Implants	3 685
Estimated Active US Implants	3 300
US Total Returned	11

	Count	Rate
US Qualifying Complications	19	0.52%
Abnormal pacing impedance	4	0.11%
Conductor fracture	2	0.05%
Failure to capture	7	0.19%
Insulation breach	1	0.03%
Lead dislodgement	4	0.11%
Oversensing	1	0.03%

	Count	Rate
US Confirmed Malfunctions	1	0.03%
Other	1	0.03%
US Acute Lead Observations	12	0.33%
Failure to capture	4	0.11%
Lead dislodgement	8	0.22%



Years after implant	0	1	2	3	4
Total [%]	100	99.6	99.5	99.2	99.2
CI [± %]	< 0.1	0.2	0.3	0.4	0.4
Sample Size	3685	2695	1949	1127	348

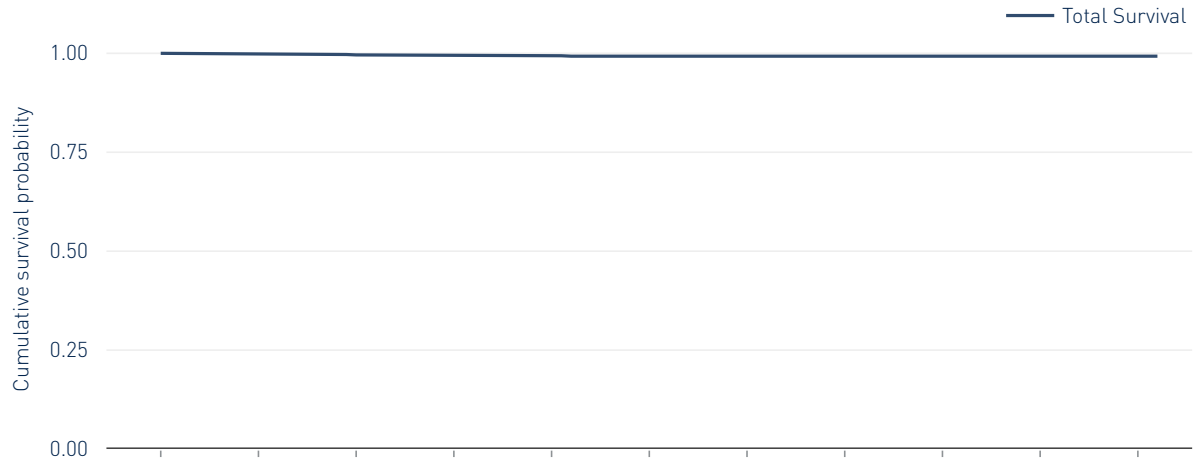
6.1 Performance of Pacing Leads – Postmarket Data

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	1 020
Estimated Active US Implants	877
US Total Returned	0

	Count	Rate
US Qualifying Complications	7	0.69%
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%



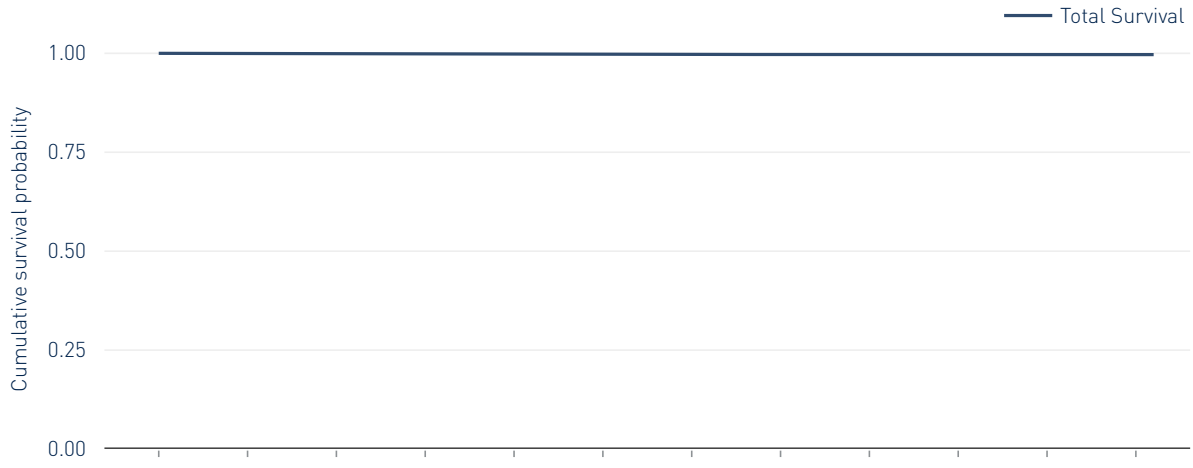
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3	99.3	99.3
CI [± %]	< 0.1	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1020	989	965	936	904	853	787	685	528	391	241

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	12 719
Estimated Active US Implants	11 100
US Total Returned	16

	Count	Rate
US Qualifying Complications	36	0.28%
Abnormal pacing impedance	1	0.01%
Conductor fracture	6	0.05%
Extracardiac stimulation	1	0.01%
Failure to capture	8	0.06%
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	9	0.07%
Failure to capture	1	0.01%
Lead dislodgement	8	0.06%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.9	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
Sample Size	12.7k	12.2k	11.9k	11.7k	11.4k	10.8k	10.1k	8613	7024	5397	3391	975

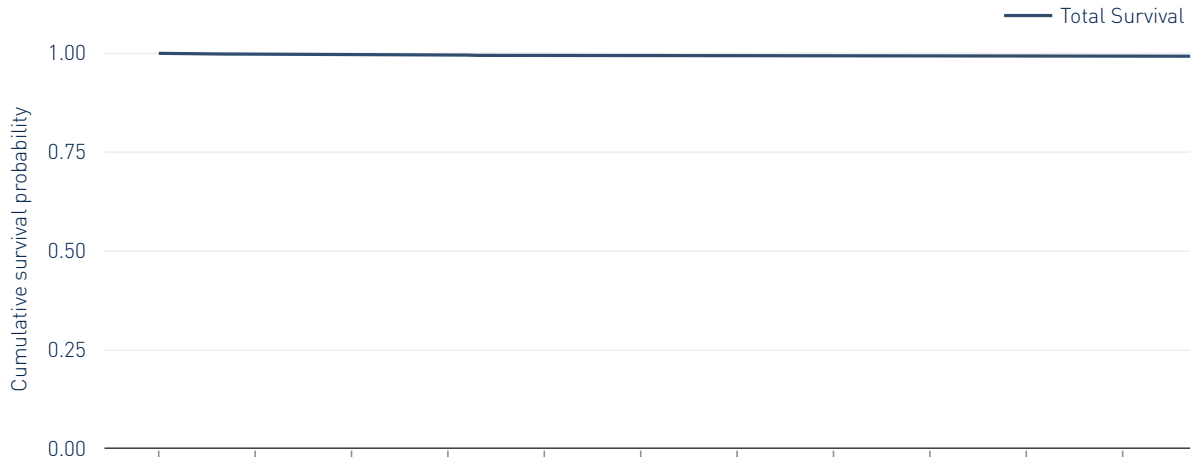
6.1 Performance of Pacing Leads – Postmarket Data

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	1 659
Estimated Active US Implants	1 360
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%

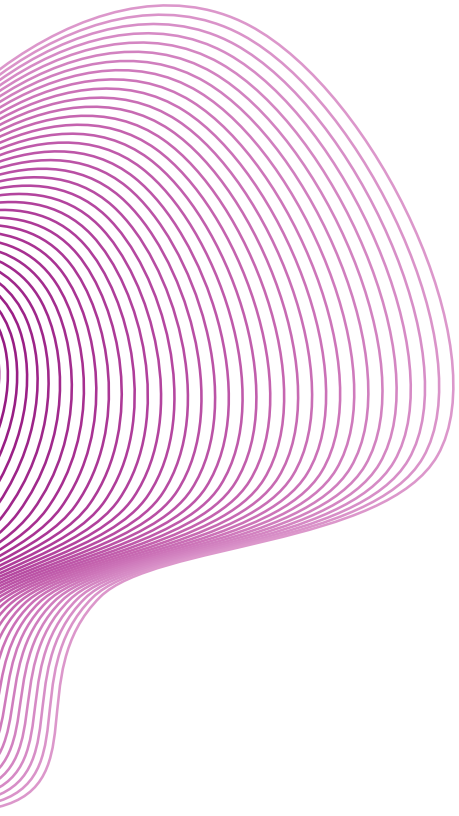


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.8	99.8	99.6	99.5	99.3	99.3	99.3	99.3	99.3	99.3
CI [± %]	< 0.1	0.2	0.2	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Sample Size	1659	1579	1534	1487	1440	1381	1292	1122	936	740	451

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

6.1 Pacing Leads
6.2 ICD Leads
6.3 CRT Leads



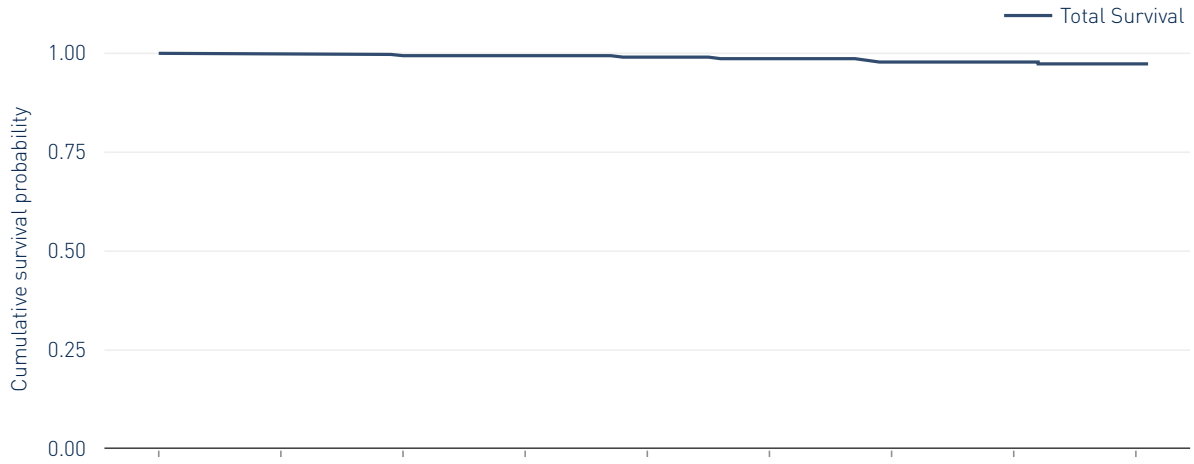
6.2 Performance of ICD Leads – Postmarket Data

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	160
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

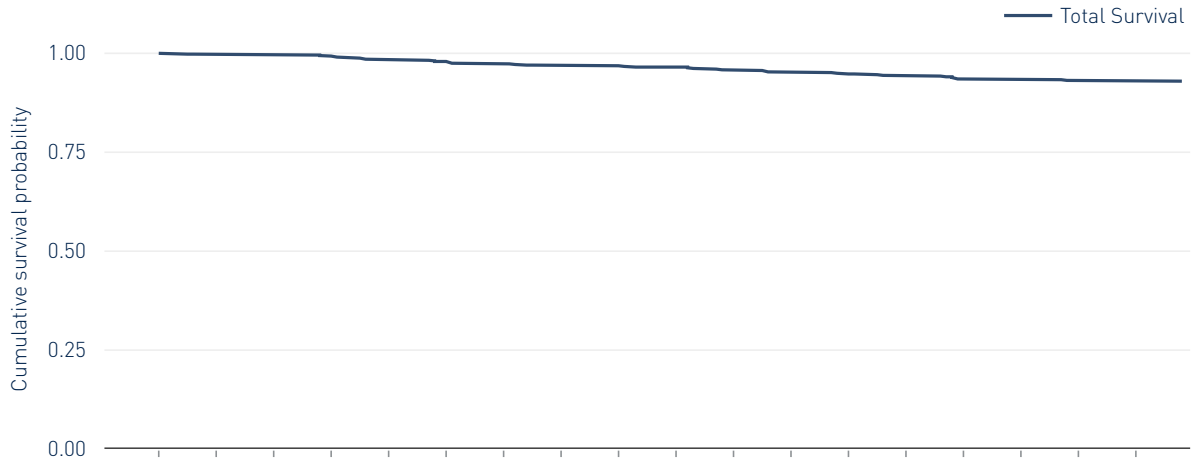
6.2 Performance of ICD Leads – Postmarket Data

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	503
US Total Returned	19

	Count	Rate
US Qualifying Complications	40	3.96%
Abnormal defibrillation impedance	1	0.10%
Abnormal pacing impedance	4	0.40%
Conductor fracture	3	0.30%
Failure to capture	4	0.40%
Insulation breach	6	0.59%
Oversensing	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
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
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
Sample Size	1003	898	834	777	707	662	616	596	576	565	553	545	536	528	517	511	503	429

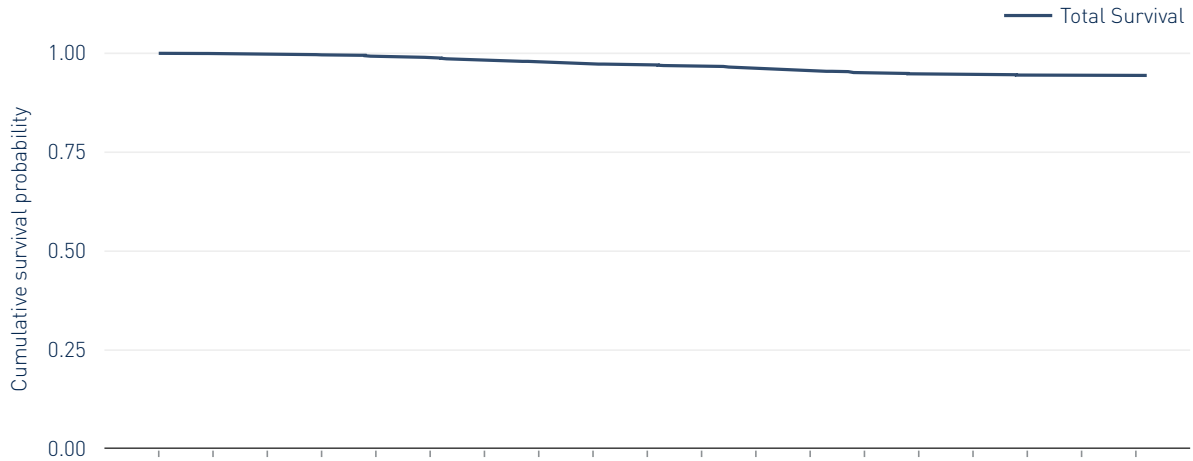
6.2 Performance of ICD Leads – Postmarket Data

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	1 170
US Total Returned	42

	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
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
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	1.1	1.2	1.2	1.2
Sample Size	2412	2174	2049	1889	1754	1631	1512	1431	1364	1325	1282	1259	1234	1224	1204	1189	1148	1057	387

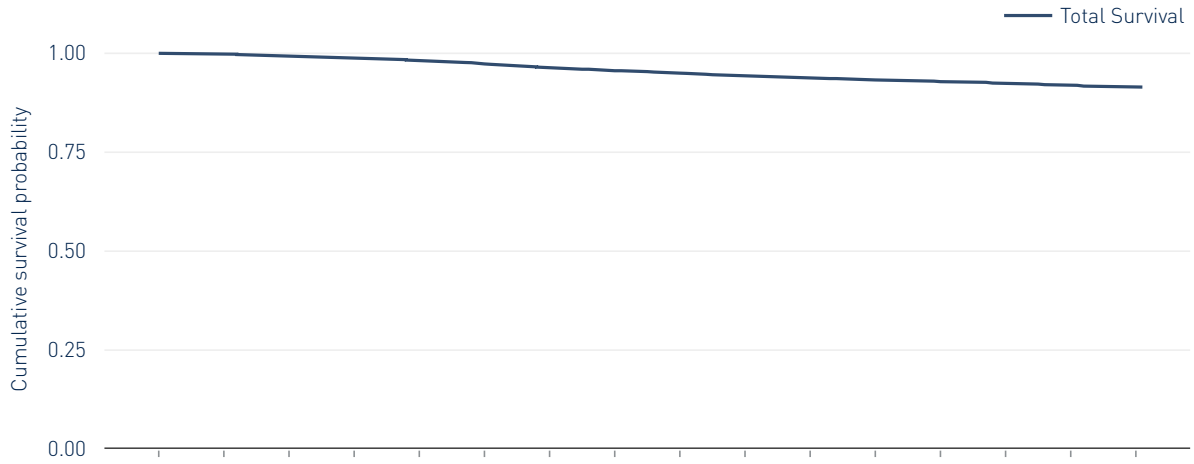
6.2 Performance of ICD Leads – Postmarket Data

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
Registered US Implants	2 466
Estimated Active US Implants	1 560
US Total Returned	89

	Count	Rate
US Qualifying Complications	96	3.85%
Abnormal defibrillation impedance	12	0.48%
Abnormal pacing impedance	6	0.24%
Conductor fracture	10	0.40%
Failure to capture	13	0.52%
Failure to sense	1	0.04%
Insulation breach	4	0.16%
Oversensing	44	1.77%
Other	6	0.24%

	Count	Rate
US Confirmed Malfunctions	49	1.97%
Conductor Fracture	9	0.36%
Insulation Breach	40	1.61%
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
Total [%]	100	99.9	99.4	98.9	98.1	97.3	96.4	95.6	95.0	94.1	93.7	93.3	92.8	92.5	91.9	91.5
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	1.5
Sample Size	2466	2266	2134	2022	1928	1852	1789	1746	1696	1647	1623	1590	1422	875	495	256

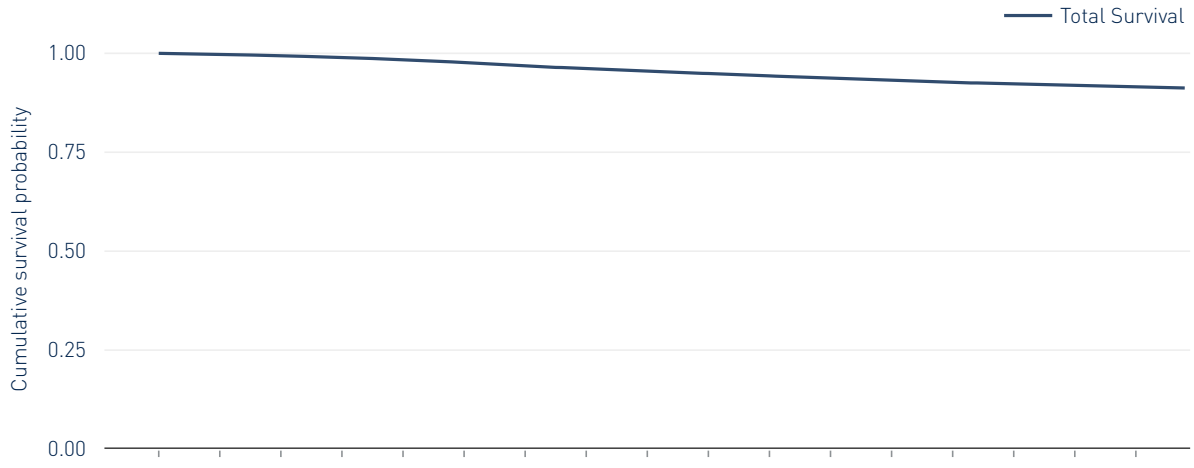
6.2 Performance of ICD Leads – Postmarket Data

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	22 096
Estimated Active US Implants	13 400
US Total Returned	550

	Count	Rate
US Qualifying Complications	1 025	4.61%
Abnormal defibrillation impedance	101	0.45%
Abnormal pacing impedance	74	0.33%
Cardiac perforation	3	0.01%
Conductor fracture	129	0.58%
Failure to capture	80	0.36%
Failure to sense	18	0.08%
Insulation breach	64	0.29%
Lead dislodgement	33	0.15%
Oversensing	471	2.12%
Other	52	0.23%

	Count	Rate
US Confirmed Malfunctions	230	1.03%
Conductor Fracture	37	0.17%
Insulation Breach	191	0.86%
Other	2	0.01%
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
Total [%]	100	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.8	93.3	92.7	92.3	91.9	91.5
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	0.5	0.5
Sample Size	22.1k	20.1k	18.9k	17.8k	17k	16.2k	15.6k	15.2k	14.8k	14.5k	14.2k	14k	13.4k	10.5k	6919	3871	1653

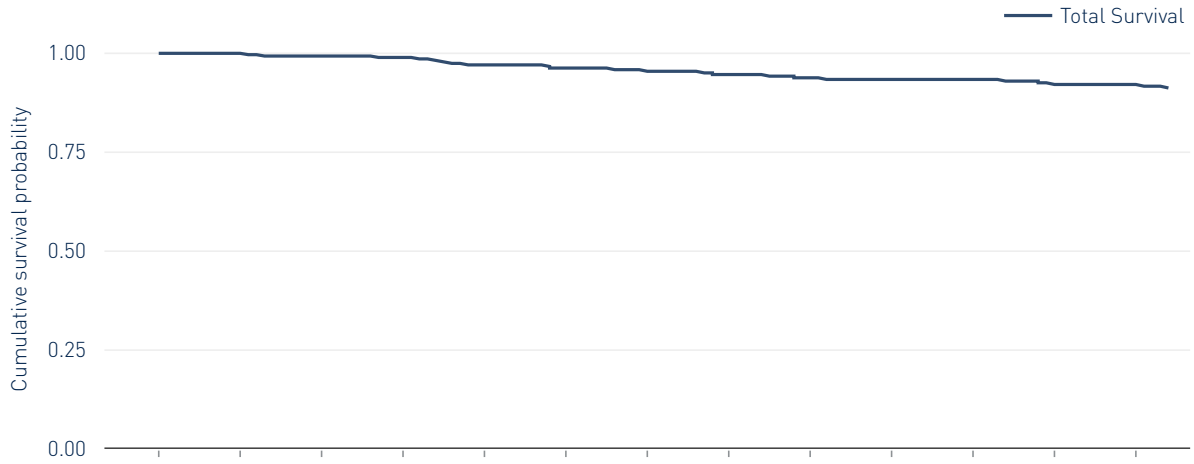
6.2 Performance of ICD Leads – Postmarket Data

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	209
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
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
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
Sample Size	319	295	283	272	251	241	234	230	228	226	223	217	212

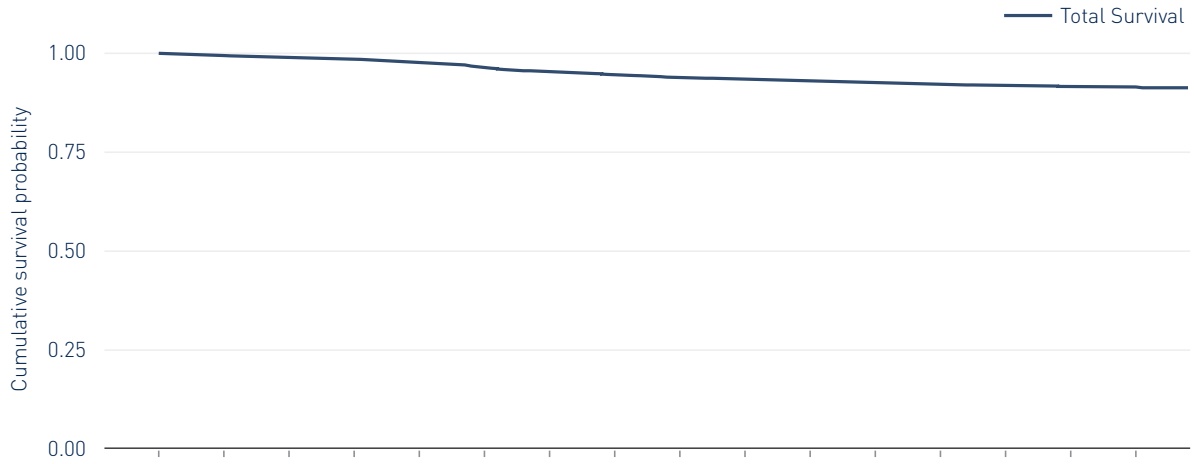
6.2 Performance of ICD Leads – Postmarket Data

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	1 910
US Total Returned	82

	Count	Rate
US Qualifying Complications	155	5.08%
Abnormal defibrillation impedance	18	0.59%
Abnormal pacing impedance	14	0.46%
Cardiac perforation	1	0.03%
Conductor fracture	20	0.66%
Failure to capture	24	0.79%
Failure to sense	4	0.13%
Insulation breach	13	0.43%
Lead dislodgement	4	0.13%
Oversensing	54	1.77%
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
Total [%]	100	99.4	99.1	98.5	97.6	96.5	95.4	94.7	93.8	93.4	92.9	92.5	92.2	91.9	91.6	91.5
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	1.2
Sample Size	3023	2738	2608	2458	2345	2241	2150	2096	2058	2029	1989	1963	1855	1475	945	482

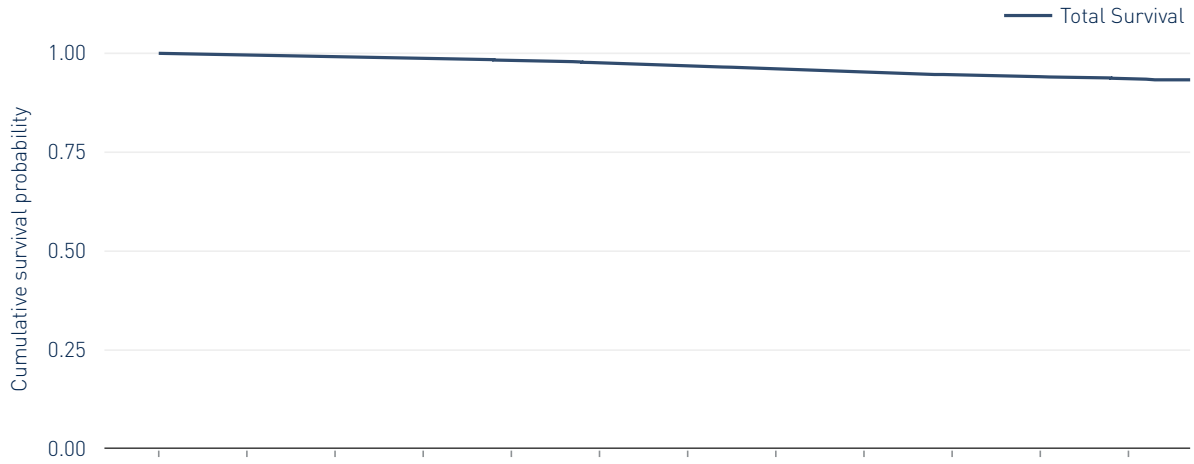
6.2 Performance of ICD Leads – Postmarket Data

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
Registered US Implants	7 600
Estimated Active US Implants	5 690
US Total Returned	211

	Count	Rate
US Qualifying Complications	282	3.69%
Abnormal defibrillation impedance	22	0.29%
Abnormal pacing impedance	25	0.33%
Cardiac perforation	1	0.01%
Conductor fracture	41	0.54%
Failure to capture	24	0.31%
Failure to sense	14	0.18%
Insulation breach	5	0.07%
Lead dislodgement	14	0.18%
Oversensing	126	1.65%
Other	10	0.13%

	Count	Rate
US Confirmed Malfunctions	84	1.10%
Conductor Fracture	16	0.21%
Insulation Breach	67	0.88%
Other	1	0.01%
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
Total [%]	100	99.7	99.3	98.9	98.3	97.6	96.9	95.9	95.3	94.6	94.1	93.7
CI [± %]	< 0.1	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7
Sample Size	7600	7133	6869	6667	6495	6346	6133	5745	5137	4018	2603	1032

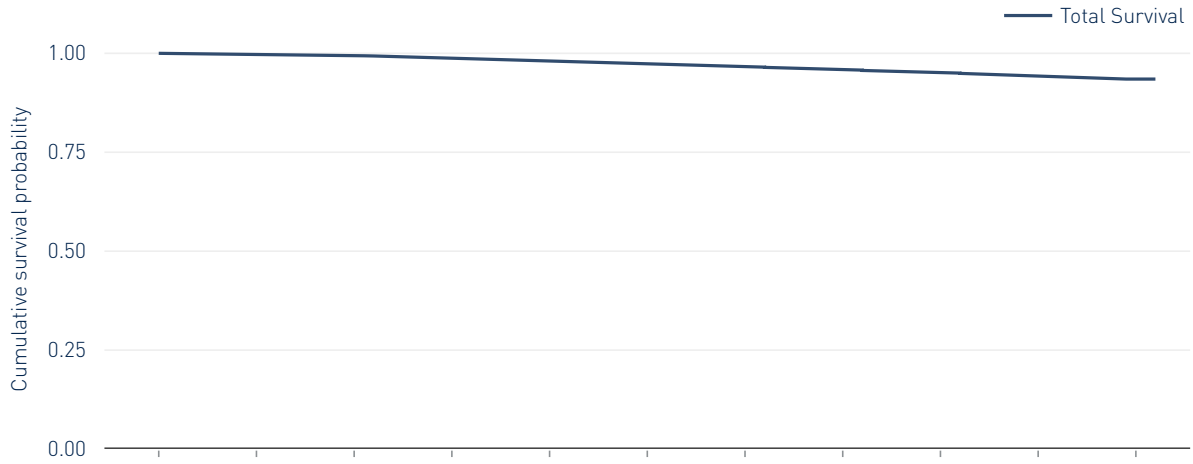
6.2 Performance of ICD Leads – Postmarket Data

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
Registered US Implants	16 309
Estimated Active US Implants	13 300
US Total Returned	405

	Count	Rate
US Qualifying Complications	567	3.46%
Abnormal defibrillation impedance	67	0.41%
Abnormal pacing impedance	45	0.27%
Conductor fracture	67	0.41%
Failure to capture	42	0.26%
Failure to sense	20	0.12%
Insulation breach	8	0.05%
Lead dislodgement	48	0.29%
Oversensing	255	1.55%
Other	15	0.09%

	Count	Rate
US Confirmed Malfunctions	136	0.83%
Conductor Fracture	15	0.09%
Insulation Breach	117	0.71%
Other	4	0.02%
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
Total [%]	100	99.7	99.4	98.9	98.2	97.4	96.7	95.9	95.2	94.0	93.5
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.5	0.6
Sample Size	16.3k	15.5k	15.2k	14.9k	14.5k	14k	12.9k	9402	6183	3211	689

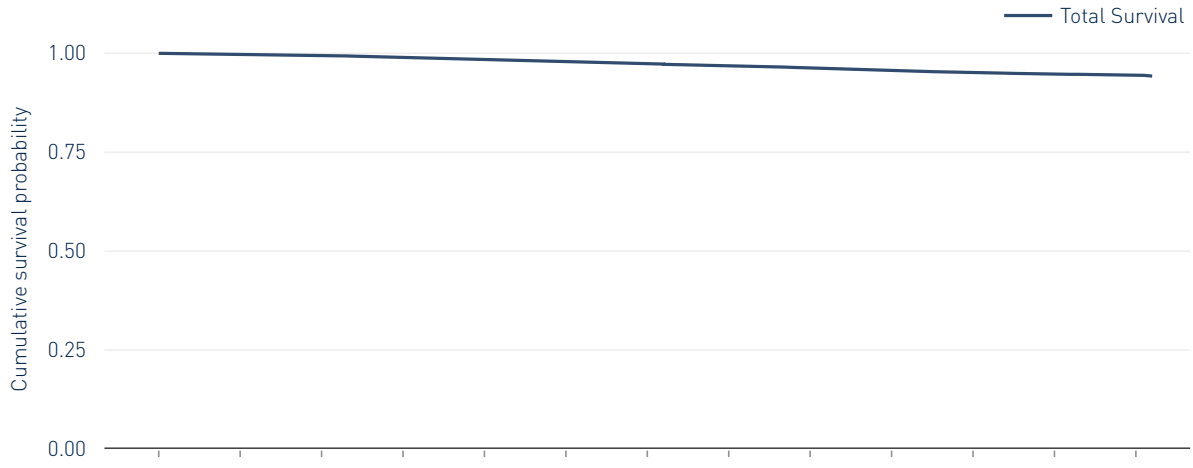
6.2 Performance of ICD Leads – Postmarket Data

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
Registered US Implants	13 131
Estimated Active US Implants	9 740
US Total Returned	281

	Count	Rate
US Qualifying Complications	455	3.44%
Abnormal defibrillation impedance	47	0.35%
Abnormal pacing impedance	31	0.23%
Cardiac perforation	1	0.01%
Conductor fracture	54	0.41%
Extracardiac stimulation	1	0.01%
Failure to capture	39	0.29%
Failure to sense	11	0.08%
Insulation breach	11	0.08%
Lead dislodgement	31	0.23%
Oversensing	218	1.65%
Other	11	0.08%

	Count	Rate
US Confirmed Malfunctions	89	0.67%
Conductor Fracture	11	0.08%
Insulation Breach	74	0.56%
Other	4	0.03%
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
Total [%]	100	99.7	99.5	99.0	98.5	97.9	97.4	96.8	96.3	95.6	95.2	94.8	94.4
CI [± %]	< 0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5
Sample Size	13.1k	12.2k	11.8k	11.4k	11.1k	10.9k	10.6k	10.1k	9551	8488	6740	3978	881

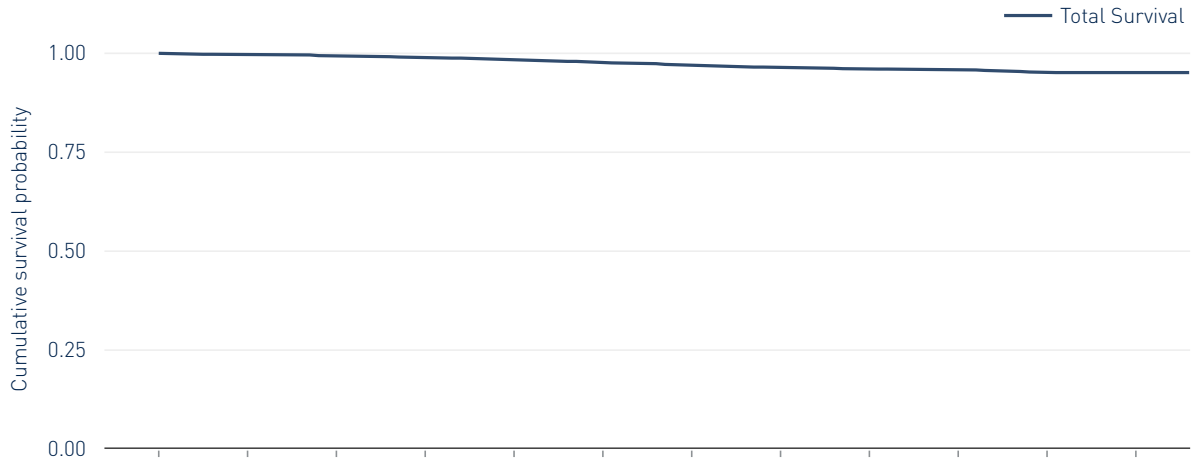
6.2 Performance of ICD Leads – Postmarket Data

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	934
US Total Returned	22

	Count	Rate
US Qualifying Complications	49	3.84%
Abnormal defibrillation impedance	8	0.63%
Abnormal pacing impedance	5	0.39%
Conductor fracture	3	0.24%
Failure to capture	12	0.94%
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%



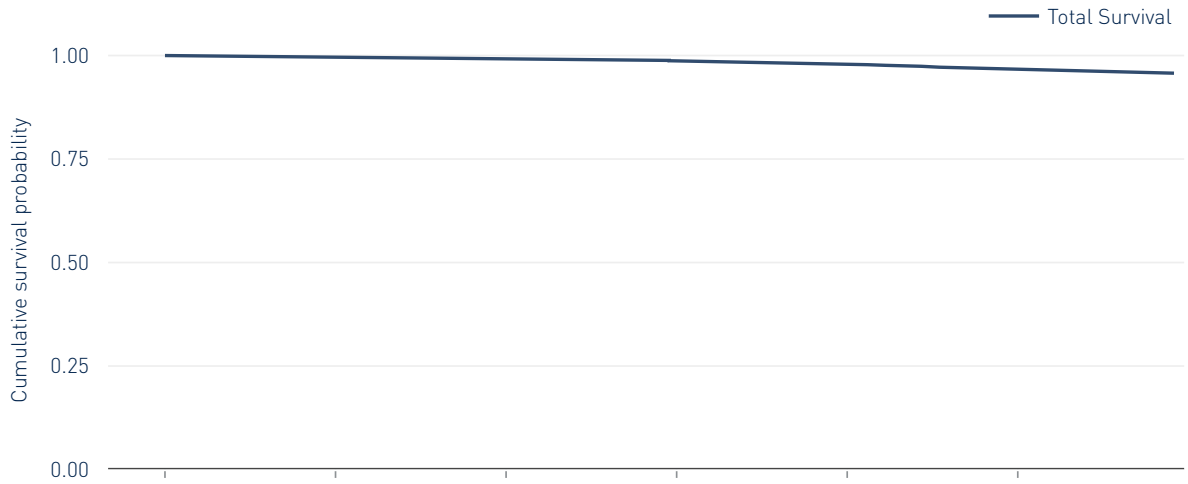
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100	99.7	99.2	98.9	98.3	97.7	97.1	96.5	96.0	95.8	95.1	95.1
CI [± %]	< 0.1	0.3	0.5	0.6	0.7	0.9	1.0	1.1	1.2	1.2	1.3	1.3
Sample Size	1266	1174	1137	1094	1068	1036	1009	976	926	832	660	366

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	151 000
Registered US Implants	21 590
Estimated Active US Implants	19 500
US Total Returned	229

	Count	Rate
US Qualifying Complications	294	1.36%
Abnormal defibrillation impedance	20	0.09%
Abnormal pacing impedance	10	0.05%
Cardiac perforation	1	0.00%
Conductor fracture	21	0.10%
Failure to capture	31	0.14%
Failure to sense	11	0.05%
Insulation breach	2	0.01%
Lead dislodgement	34	0.16%
Oversensing	153	0.71%
Other	11	0.05%

	Count	Rate
US Confirmed Malfunctions	69	0.32%
Conductor Fracture	9	0.04%
Insulation Breach	55	0.25%
Other	5	0.02%
US Acute Lead Observations	52	0.24%
Abnormal pacing impedance	4	0.02%
Cardiac perforation	6	0.03%
Conductor fracture	1	0.00%
Failure to capture	11	0.05%
Lead dislodgement	25	0.12%
Oversensing	2	0.01%
Other	3	0.01%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	99.2	98.6	97.6	96.5
CI [± %]	< 0.1	0.1	0.1	0.2	0.3	0.4
Sample Size	21.6k	17.3k	13.7k	10k	6452	3069

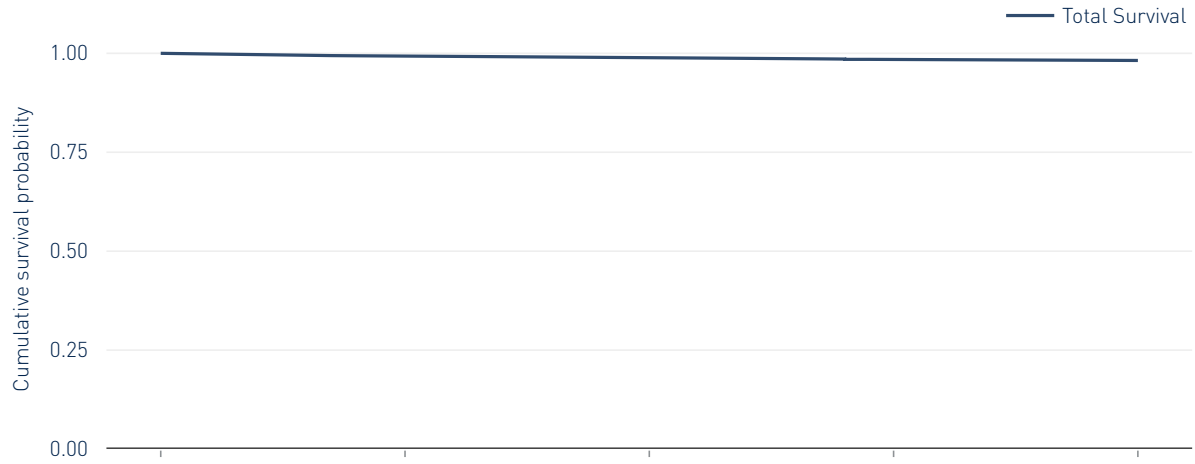
6.2 Performance of ICD Leads – Postmarket Data

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	39 500
Registered US Implants	16 833
Estimated Active US Implants	15 900
US Total Returned	131

	Count	Rate
US Qualifying Complications	147	0.87%
Abnormal defibrillation impedance	7	0.04%
Abnormal pacing impedance	5	0.03%
Cardiac perforation	3	0.02%
Conductor fracture	3	0.02%
Failure to capture	20	0.12%
Failure to sense	10	0.06%
Insulation breach	1	0.01%
Lead dislodgement	46	0.27%
Oversensing	45	0.27%
Other	7	0.04%

	Count	Rate
US Confirmed Malfunctions	20	0.12%
Conductor Fracture	2	0.01%
Insulation Breach	17	0.10%
Other	1	0.01%
US Acute Lead Observations	56	0.33%
Cardiac perforation	3	0.02%
Failure to capture	12	0.07%
Failure to sense	6	0.04%
Lead dislodgement	24	0.14%
Oversensing	8	0.05%
Other	3	0.02%



Years after implant	0	1	2	3	4
Total [%]	100	99.3	98.9	98.5	98.2
CI [± %]	< 0.1	0.1	0.2	0.3	0.4
Sample Size	16.8k	11.8k	7365	3289	329

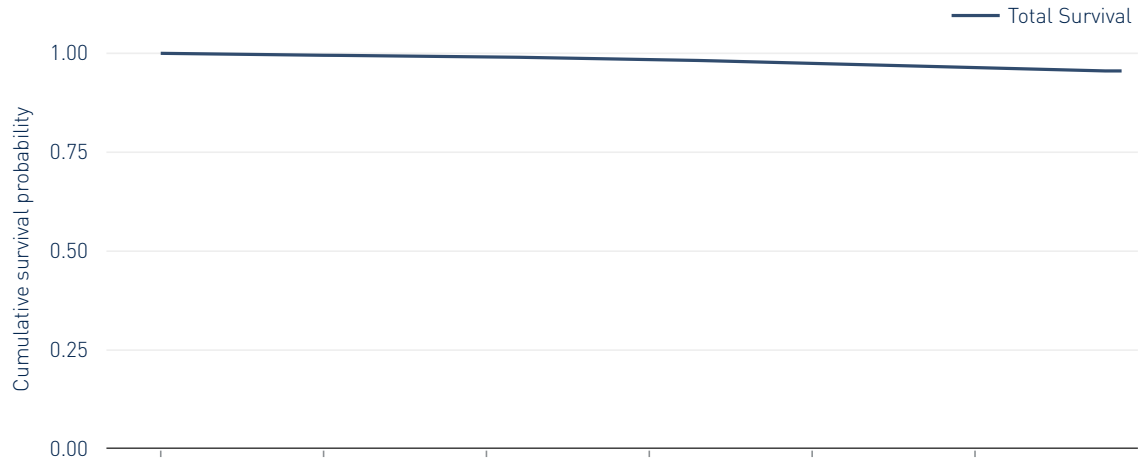
6.2 Performance of ICD Leads – Postmarket Data

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	23 400
Registered US Implants	9 159
Estimated Active US Implants	7 950
US Total Returned	169

	Count	Rate
US Qualifying Complications	213	2.31%
Abnormal defibrillation impedance	25	0.27%
Abnormal pacing impedance	9	0.10%
Conductor fracture	12	0.13%
Failure to capture	17	0.18%
Failure to sense	8	0.09%
Insulation breach	4	0.04%
Lead dislodgement	20	0.22%
Oversensing	115	1.25%
Other	3	0.03%

	Count	Rate
US Confirmed Malfunctions	70	0.76%
Conductor Fracture	5	0.05%
Insulation Breach	64	0.70%
Other	1	0.01%
US Acute Lead Observations	21	0.23%
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
Total [%]	100	99.5	99.1	98.4	97.5	96.3
CI [± %]	< 0.1	0.1	0.2	0.3	0.3	0.5
Sample Size	9159	8694	8429	7859	6728	3294

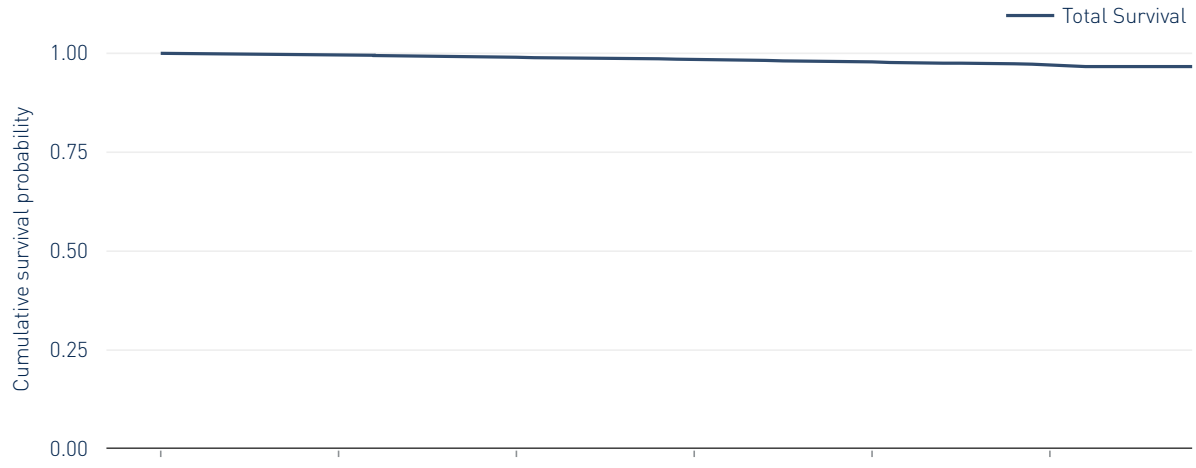
6.2 Performance of ICD Leads – Postmarket Data

Plexa SD

Product Versions	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	17 300
Registered US Implants	5 349
Estimated Active US Implants	4 740
US Total Returned	32

	Count	Rate
US Qualifying Complications	85	1.58%
Abnormal defibrillation impedance	7	0.13%
Abnormal pacing impedance	4	0.07%
Conductor fracture	5	0.09%
Extracardiac stimulation	1	0.02%
Failure to capture	8	0.15%
Failure to sense	4	0.07%
Insulation breach	2	0.04%
Lead dislodgement	8	0.15%
Oversensing	43	0.80%
Other	3	0.06%

	Count	Rate
US Confirmed Malfunctions	5	0.09%
Conductor Fracture	2	0.04%
Insulation Breach	3	0.06%
US Acute Lead Observations	13	0.24%
Abnormal defibrillation impedance	2	0.04%
Abnormal pacing impedance	2	0.04%
Cardiac perforation	2	0.04%
Failure to capture	2	0.04%
Lead dislodgement	1	0.02%
Oversensing	2	0.04%
Other	2	0.04%



Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	99.0	98.5	97.8	97.0
CI [± %]	< 0.1	0.2	0.3	0.4	0.5	0.7
Sample Size	5349	4526	3682	2764	1873	867

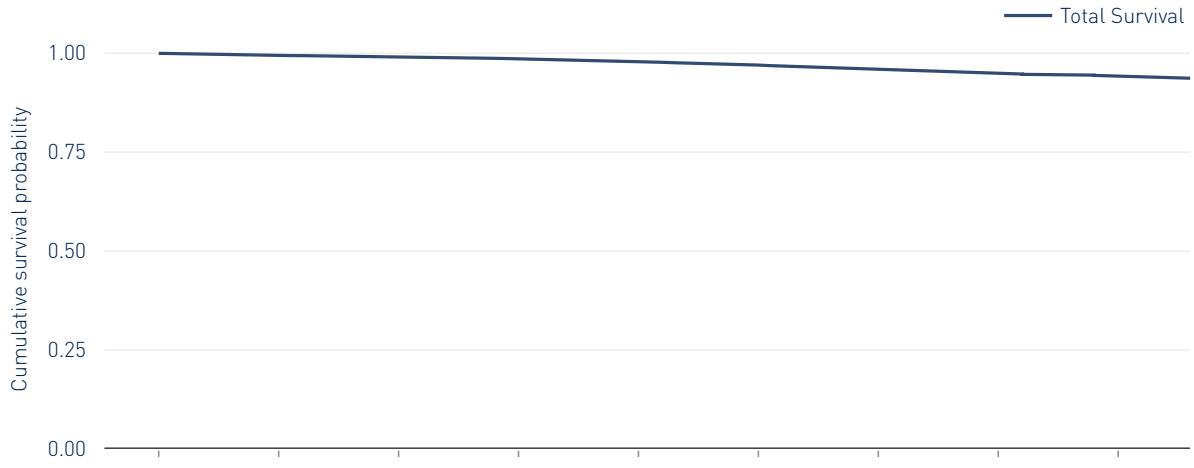
6.2 Performance of ICD Leads – Postmarket Data

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	8 276
Estimated Active US Implants	6 520
US Total Returned	150

	Count	Rate
US Qualifying Complications	291	3.49%
Abnormal defibrillation impedance	19	0.23%
Abnormal pacing impedance	8	0.10%
Cardiac perforation	2	0.02%
Conductor fracture	35	0.42%
Extracardiac stimulation	3	0.04%
Failure to capture	26	0.31%
Failure to sense	6	0.07%
Insulation breach	3	0.04%
Lead dislodgement	24	0.29%
Oversensing	155	1.86%
Other	10	0.12%

	Count	Rate
US Confirmed Malfunctions	68	0.82%
Conductor Fracture	13	0.16%
Insulation Breach	53	0.64%
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
Total [%]	100	99.5	99.2	98.6	97.9	97.0	95.9	95.0	94.2
CI [± %]	< 0.1	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.7
Sample Size	8276	7801	7599	7389	7171	6781	5888	3203	971

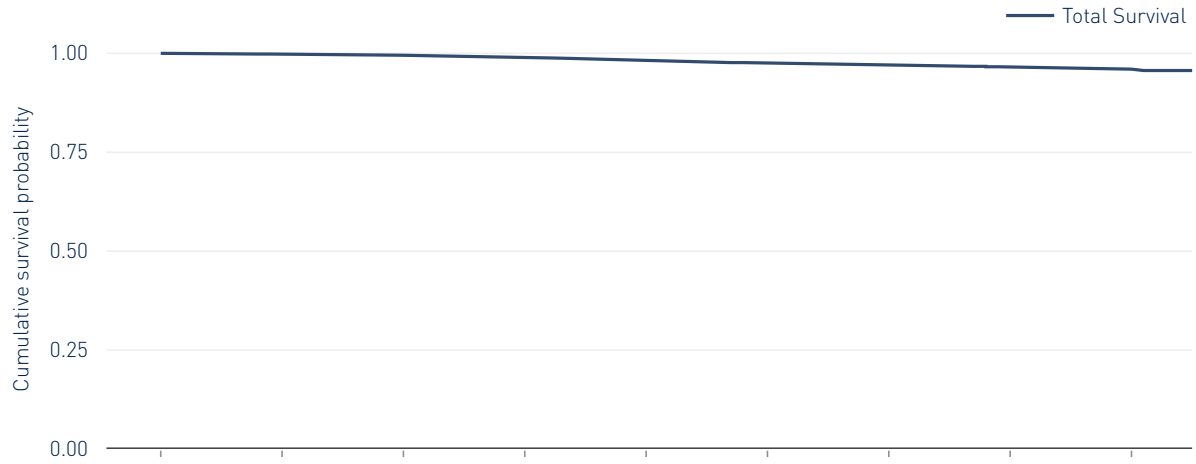
6.2 Performance of ICD Leads – Postmarket Data

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
Registered US Implants	3 411
Estimated Active US Implants	2 800
US Total Returned	49

	Count	Rate
US Qualifying Complications	94	2.73%
Abnormal defibrillation impedance	8	0.23%
Abnormal pacing impedance	4	0.12%
Conductor fracture	14	0.41%
Failure to capture	10	0.29%
Failure to sense	2	0.06%
Insulation breach	2	0.06%
Lead dislodgement	6	0.17%
Oversensing	47	1.37%
Other	1	0.03%

	Count	Rate
US Confirmed Malfunctions	16	0.47%
Conductor Fracture	1	0.03%
Insulation Breach	14	0.41%
Other	1	0.03%
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
Total [%]	100	99.8	99.5	98.9	98.3	97.6	97.0	96.5	96.0
CI [± %]	< 0.1	0.1	0.2	0.4	0.5	0.5	0.6	0.7	0.8
Sample Size	3411	3241	3157	3082	3004	2910	2625	1687	627

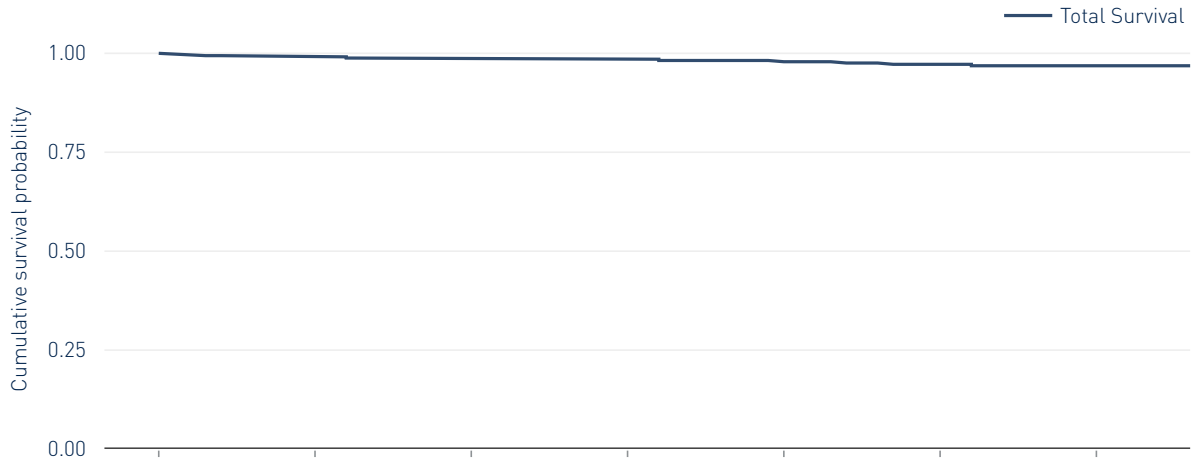
6.2 Performance of ICD Leads – Postmarket Data

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	289
US Total Returned	4

	Count	Rate
US Qualifying Complications	11	3.13%
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
Total [%]	100	99.1	98.5	98.5	97.9	97.2	96.9
CI [± %]	< 0.1	1.0	1.3	1.3	1.6	1.8	1.9
Sample Size	349	332	324	313	308	281	242

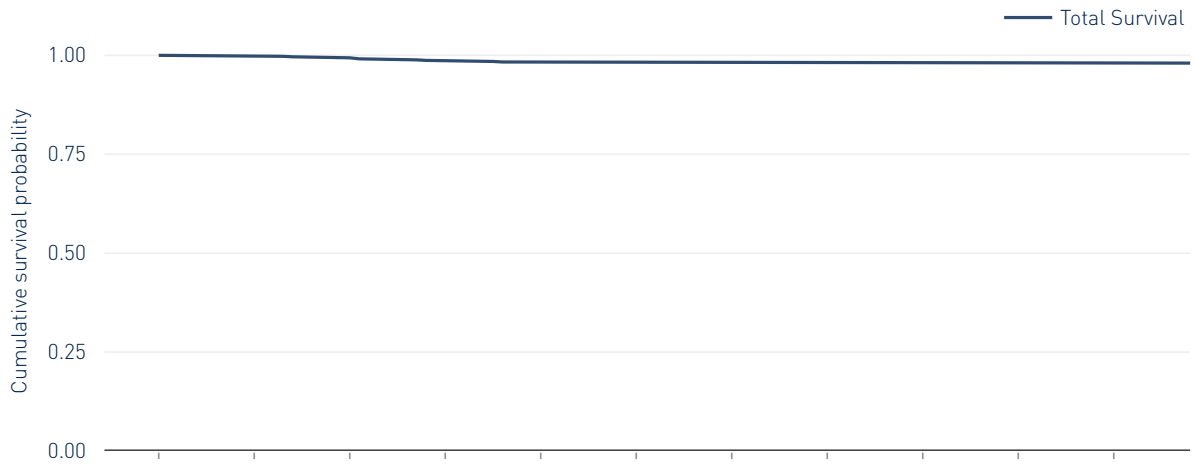
6.2 Performance of ICD Leads – Postmarket Data

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	854
Estimated Active US Implants	671
US Total Returned	12

	Count	Rate
US Qualifying Complications	11	1.28%
Abnormal pacing impedance	1	0.12%
Conductor fracture	1	0.12%
Lead dislodgement	3	0.35%
Oversensing	6	0.70%

	Count	Rate
US Confirmed Malfunctions	4	0.47%
Insulation Breach	4	0.47%
US Acute Lead Observations	0	0.00%

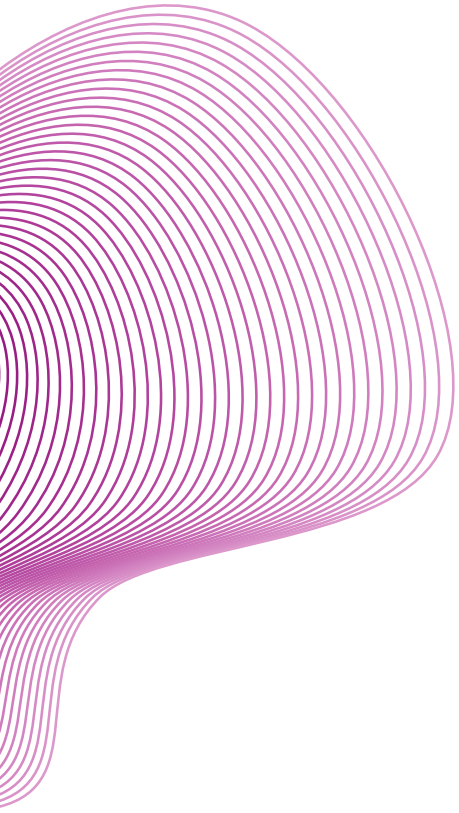


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.9	99.4	98.7	98.3	98.3	98.3	98.0	98.0	98.0	98.0
CI [± %]	< 0.1	0.2	0.6	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.0
Sample Size	854	797	773	744	720	707	696	682	677	656	469

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

6.1 Pacing Leads
6.2 ICD Leads
6.3 CRT Leads



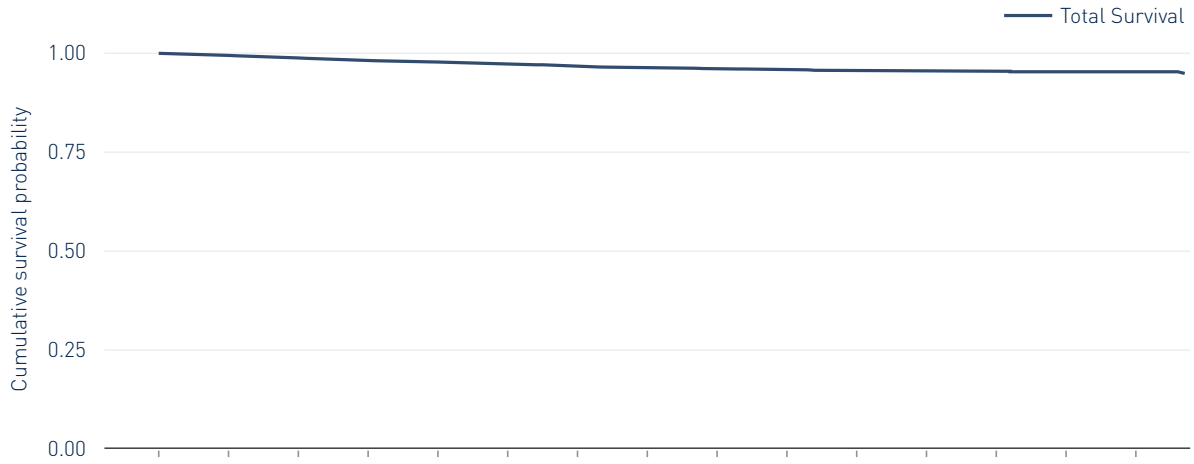
6.3 Performance of CRT Leads – Postmarket Data

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	4 115
Estimated Active US Implants	2 500
US Total Returned	82

	Count	Rate
US Qualifying Complications	126	3.05%
Abnormal pacing impedance	8	0.19%
Conductor fracture	3	0.07%
Extracardiac stimulation	9	0.22%
Failure to capture	46	1.11%
Insulation breach	3	0.07%
Lead dislodgement	38	0.92%
Oversensing	6	0.15%
Other	13	0.31%

	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
Total [%]	100	99.5	98.8	98.2	97.8	97.2	96.8	96.3	96.1	96.0	95.7	95.6	95.5	95.3	95.3
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	0.7	0.8	0.8
Sample Size	4115	3559	3316	3120	2997	2892	2793	2656	2536	2387	2161	1928	1669	1208	564

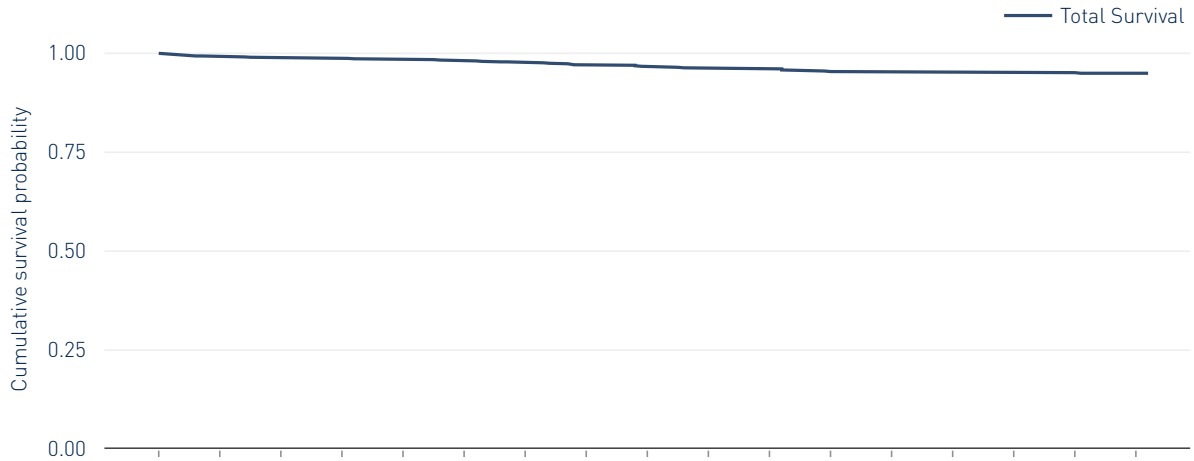
6.3 Performance of CRT Leads – Postmarket Data

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	669
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
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
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
Sample Size	1423	1237	1121	1017	932	865	810	776	750	733	712	704	692	682	670	644	321

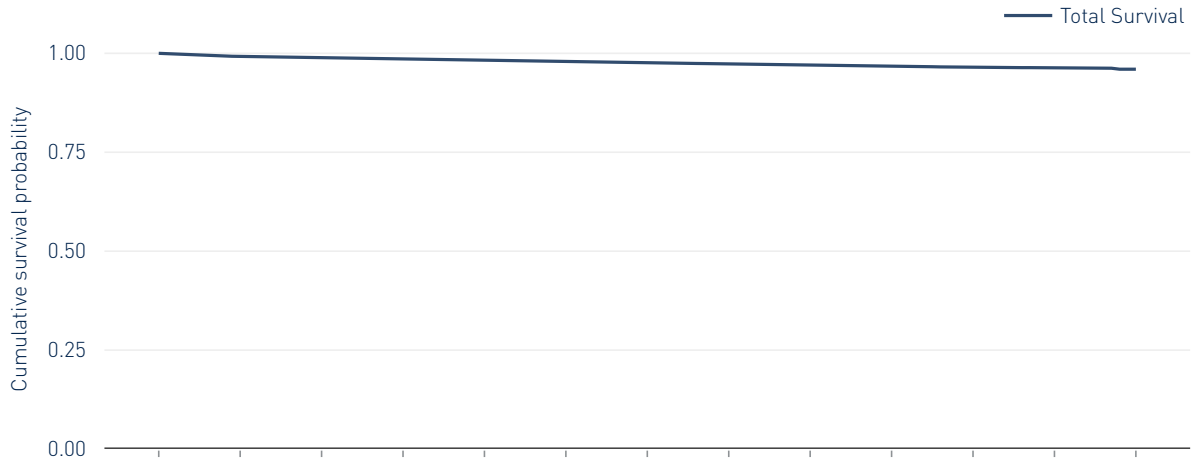
6.3 Performance of CRT Leads – Postmarket Data

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	6 254
Estimated Active US Implants	4 600
US Total Returned	91

	Count	Rate
US Qualifying Complications	166	2.63%
Abnormal pacing impedance	4	0.06%
Conductor fracture	7	0.11%
Extracardiac stimulation	27	0.43%
Failure to capture	71	1.13%
Failure to sense	2	0.03%
Insulation breach	2	0.03%
Lead dislodgement	41	0.65%
Oversensing	4	0.06%
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

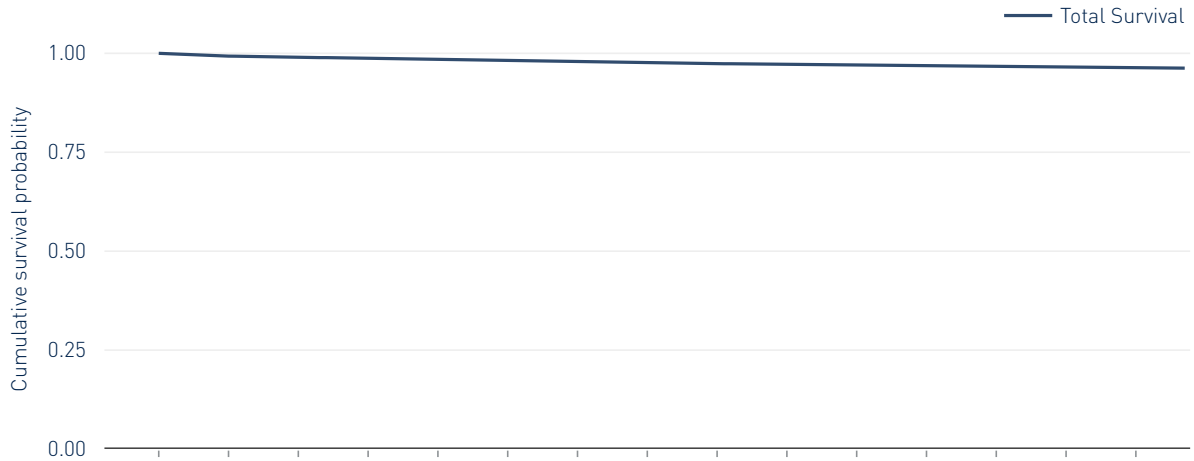
6.3 Performance of CRT Leads – Postmarket Data

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	8 158
Estimated Active US Implants	5 300
US Total Returned	136

	Count	Rate
US Qualifying Complications	188	2.29%
Abnormal pacing impedance	11	0.13%
Conductor fracture	8	0.10%
Extracardiac stimulation	15	0.18%
Failure to capture	57	0.69%
Failure to sense	1	0.01%
Insulation breach	4	0.05%
Lead dislodgement	63	0.77%
Oversensing	7	0.09%
Other	22	0.27%

	Count	Rate
US Confirmed Malfunctions	13	0.16%
Conductor Fracture	8	0.10%
Insulation Breach	4	0.05%
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
Total [%]	100	99.3	99.0	98.8	98.5	98.1	97.8	97.5	97.4	97.3	97.1	96.9	96.7	96.5	96.4
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	0.5	0.5	0.6
Sample Size	8158	7156	6755	6414	6194	5984	5765	5278	4775	4153	3549	2963	2361	1457	619

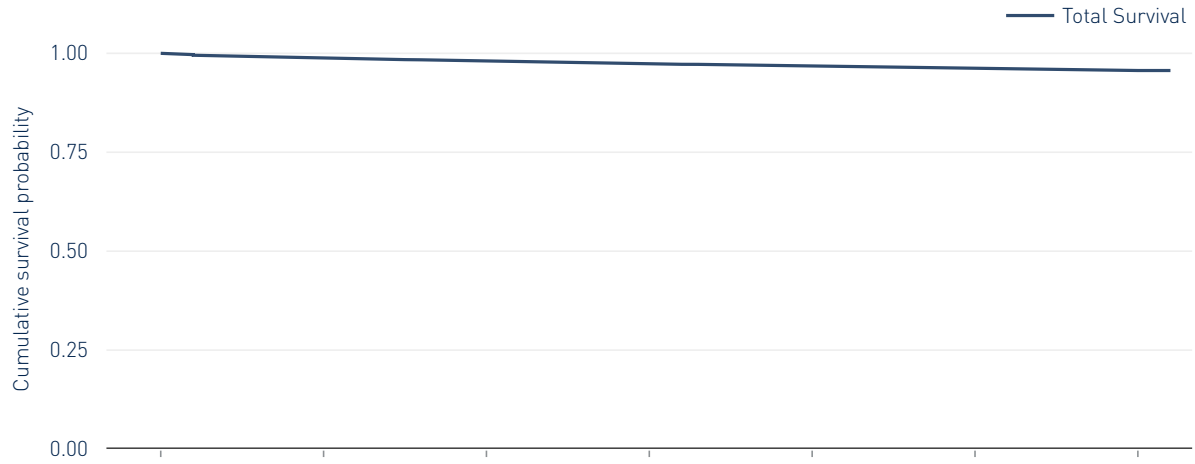
6.3 Performance of CRT Leads – Postmarket Data

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	136 000
Registered US Implants	21 030
Estimated Active US Implants	17 800
US Total Returned	257

	Count	Rate
US Qualifying Complications	423	1.99%
Abnormal pacing impedance	49	0.23%
Conductor fracture	17	0.08%
Extracardiac stimulation	17	0.08%
Failure to capture	111	0.52%
Failure to sense	2	0.01%
Lead dislodgement	153	0.72%
Oversensing	50	0.24%
Other	24	0.11%

	Count	Rate
US Confirmed Malfunctions	61	0.29%
Conductor Fracture	58	0.27%
Other	3	0.01%
US Acute Lead Observations	60	0.28%
Abnormal pacing impedance	2	0.01%
Conductor fracture	1	0.00%
Extracardiac stimulation	7	0.03%
Failure to capture	12	0.06%
Lead dislodgement	32	0.15%
Oversensing	3	0.01%
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	9057	6026	2918	397

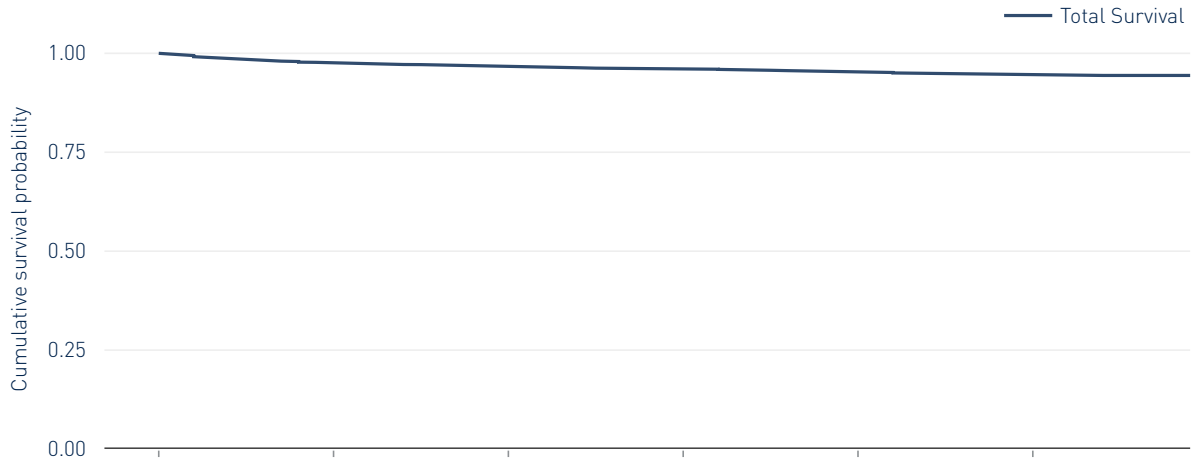
6.3 Performance of CRT Leads – Postmarket Data

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	25 900
Registered US Implants	5 160
Estimated Active US Implants	3 740
US Total Returned	144

	Count	Rate
US Qualifying Complications	166	3.17%
Abnormal pacing impedance	12	0.23%
Conductor fracture	5	0.10%
Extracardiac stimulation	7	0.13%
Failure to capture	40	0.76%
Insulation breach	1	0.02%
Lead dislodgement	81	1.55%
Oversensing	15	0.29%
Other	5	0.10%

	Count	Rate
US Confirmed Malfunctions	12	0.23%
Conductor Fracture	12	0.23%
US Acute Lead Observations	96	1.83%
Abnormal pacing impedance	1	0.02%
Extracardiac stimulation	4	0.08%
Failure to capture	14	0.27%
Failure to sense	1	0.02%
Lead dislodgement	70	1.34%
Oversensing	4	0.08%
Other	2	0.04%



Years after implant	0	1	2	3	4	5
Total [%]	100	97.6	96.7	96.1	95.2	94.4
CI [± %]	< 0.1	0.5	0.6	0.6	0.7	0.9
Sample Size	5160	3700	3095	2458	1787	987

Methodology for Lead Survial Estimates Based on Clinical Studies

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

7 Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

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

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

BIOTRONIK includes all reported chronic complications in the calculation of the survival estimates as described in chapter 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

8.1 Pacing Leads
8.2 ICD Leads
8.3 CRT Leads

Performance of BIOTRONIK Leads Based on Clinical Study Data

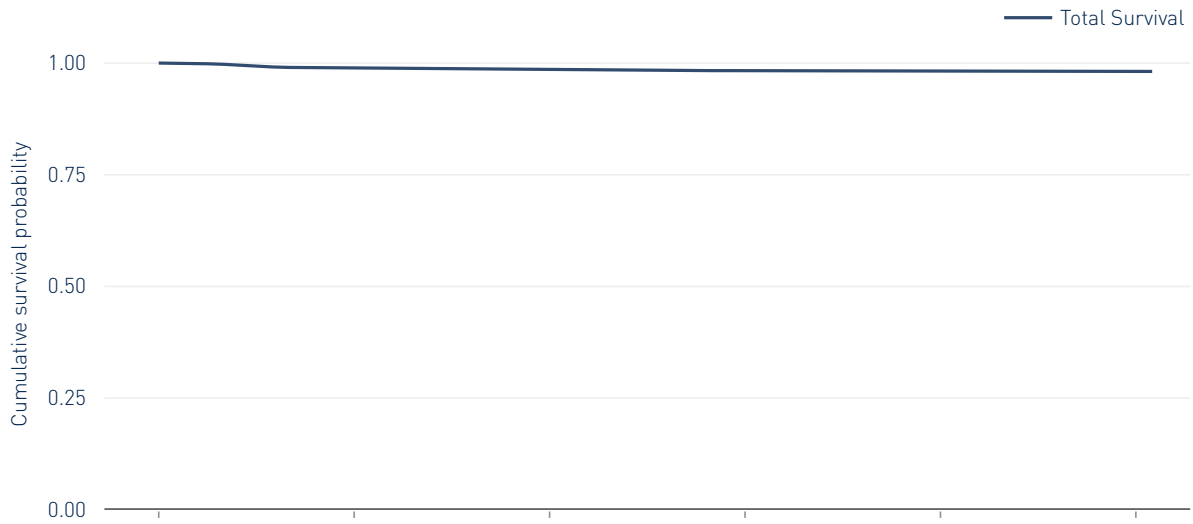
8.1 Pacing Leads
8.2 ICD Leads
8.3 CRT Leads

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	2 748 000
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

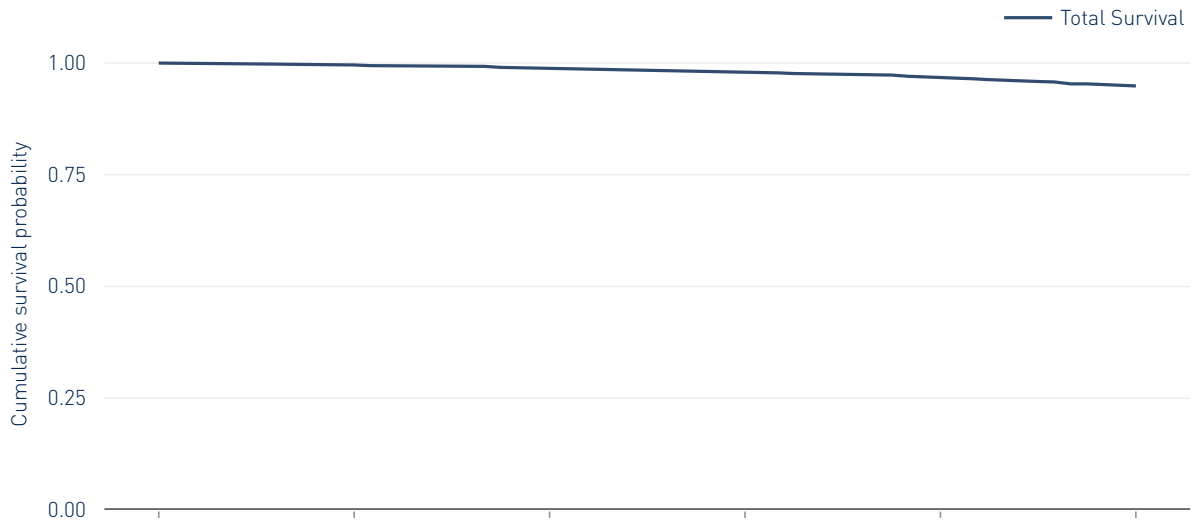
8.2 Performance of ICD Leads – Study Data

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%



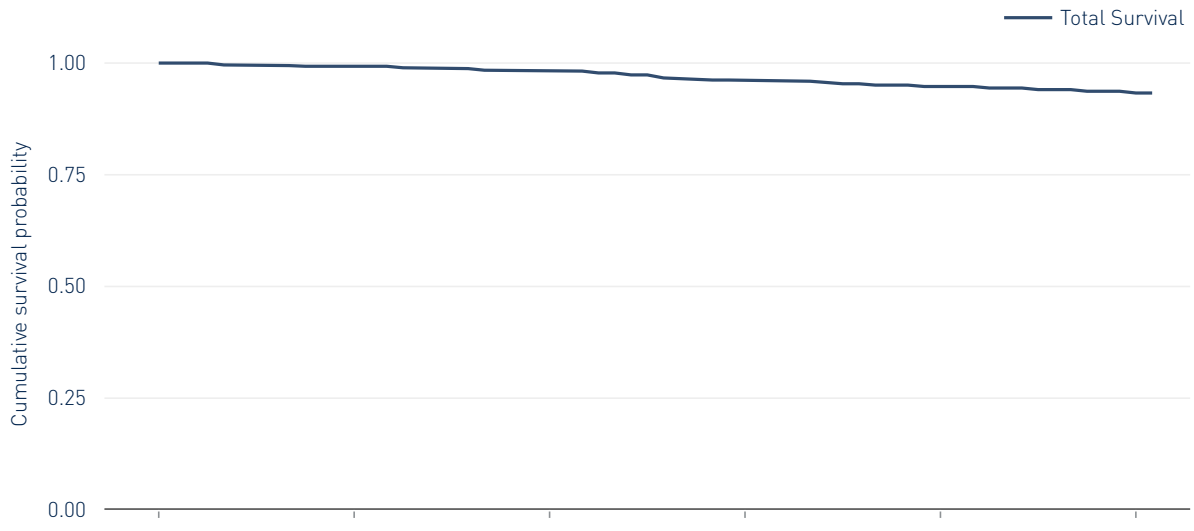
Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	98.8	98.0	96.7	94.9
CI [± %]	-	0.3	0.5	0.7	0.9	1.3
Sample Size	2272	1937	1618	1302	1014	392

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

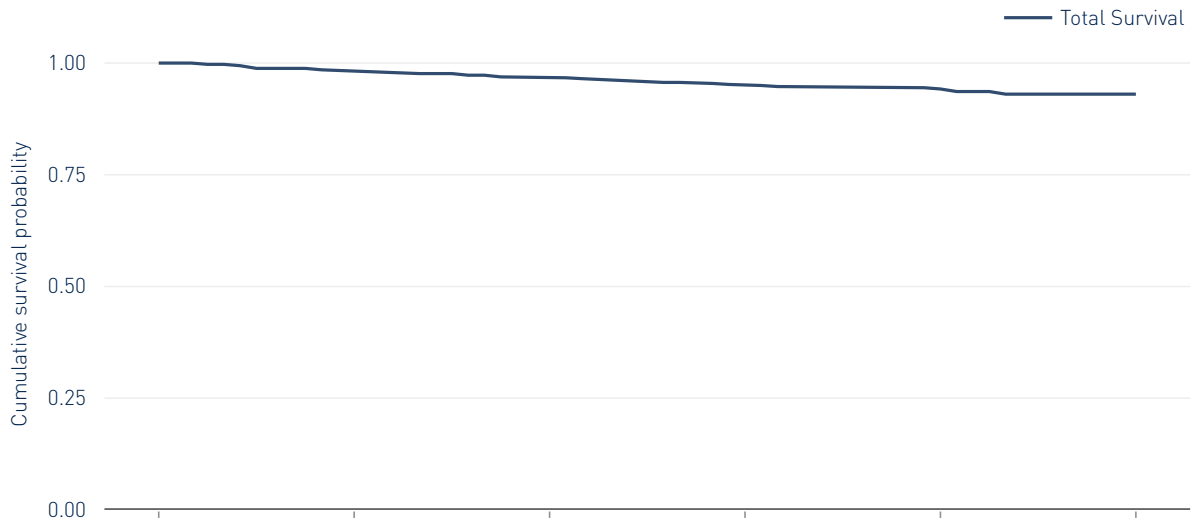
8.3 Performance of CRT Leads – Study Data

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

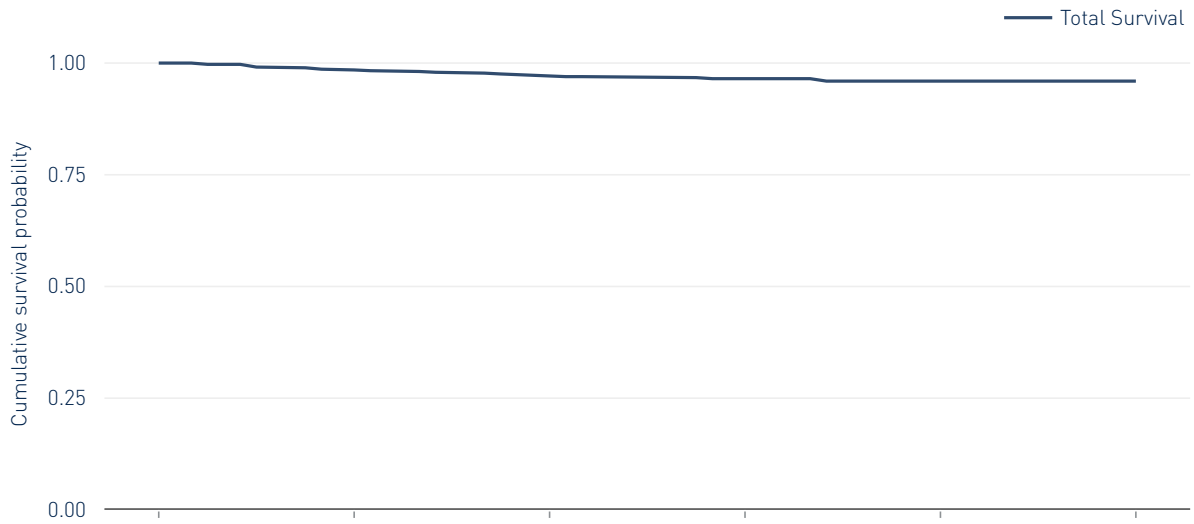
8.3 Performance of CRT Leads – Study Data

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

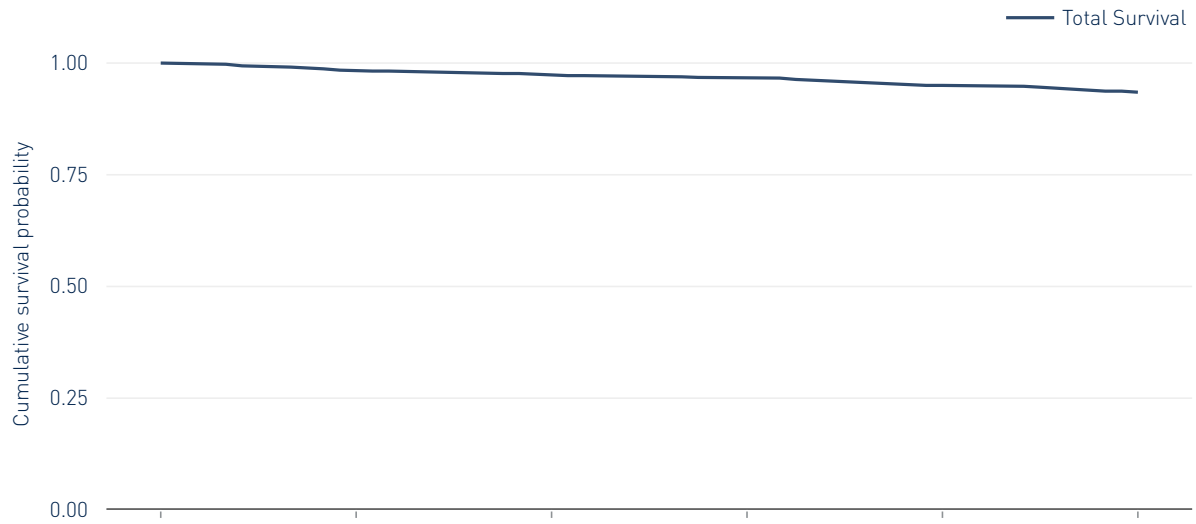
8.3 Performance of CRT Leads – Study Data

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

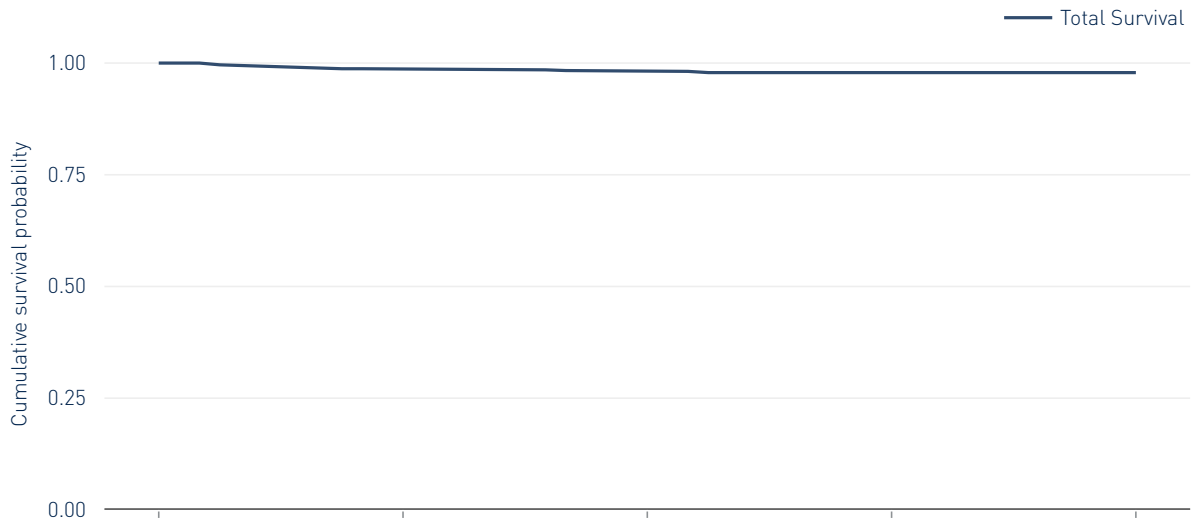
8.3 Performance of CRT Leads – Study Data

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	136 000
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

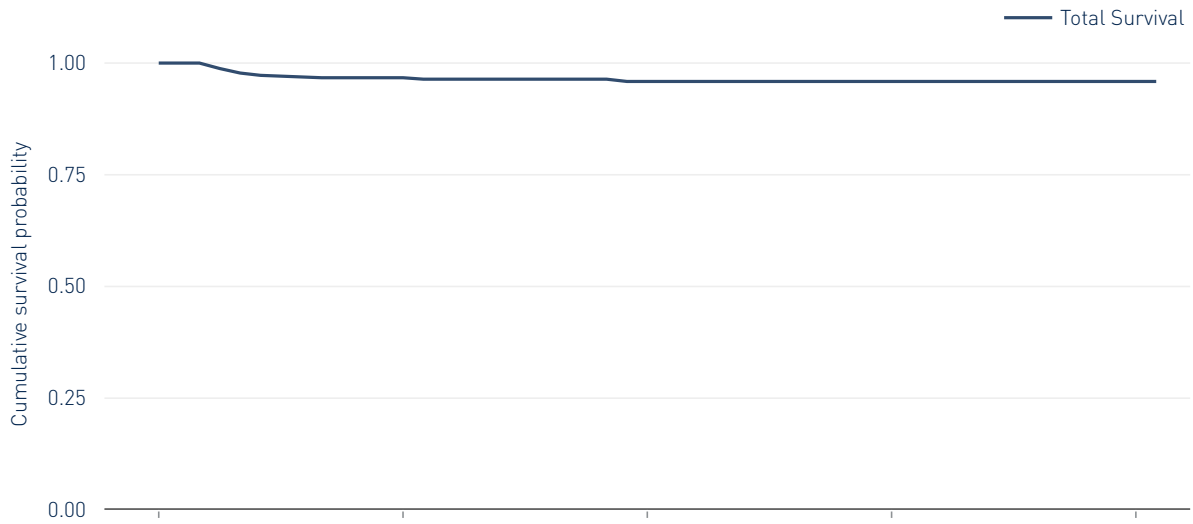
8.3 Performance of CRT Leads – Study Data

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	25 900
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

9.1 Introduction

9.2 Claims Data Methologies and Data Sets

9 Methodology for Lead Survival Estimates Based on Insurance Claims Data

9.1 Introduction

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

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

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

9.2 Claims Data Methodologies and Data Sets

To perform real-world analysis, insurance claims data obtained via the Centers for Medicare and Medicaid Services (CMS), as well as data from BIOTRONIK's device tracking database, are utilized to identify lead-related complications. As the source of the claims data is CMS, the 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-P003-089.

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

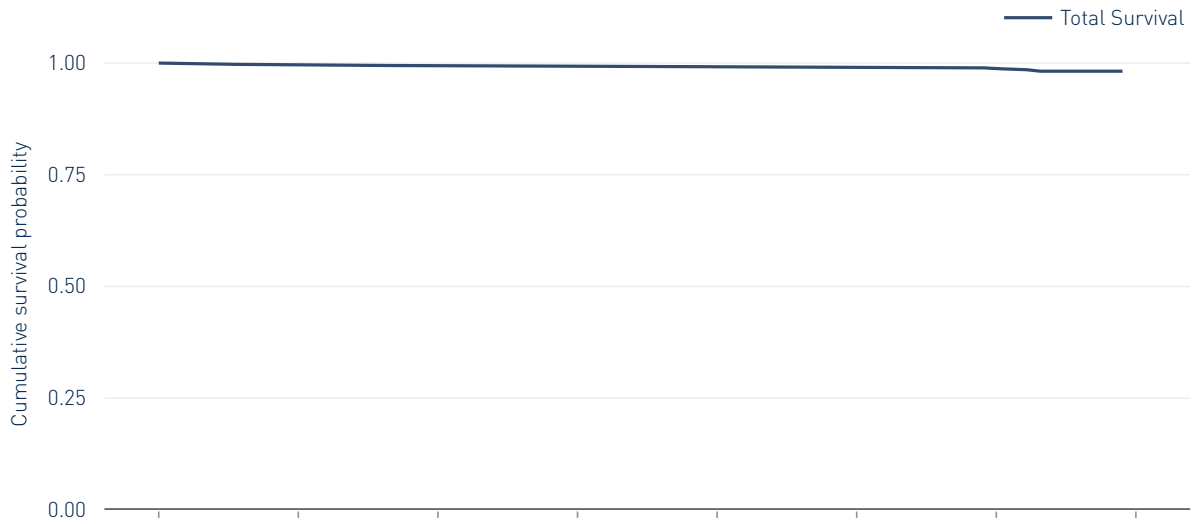
10.1 Pacing Leads
10.2 ICD Leads
10.3 CRT Leads

Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads
10.2 ICD Leads
10.3 CRT Leads

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	2 748 000
US Implants in EP PASSION	96 000



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.6	99.4	99.3	99.2	99.1	98.8	98.2
CI [± %]	< 0.1	0.0	0.1	0.1	0.1	0.2	0.6	1.5
Sample Size	95916	63111	47783	33710	20949	9964	1439	289

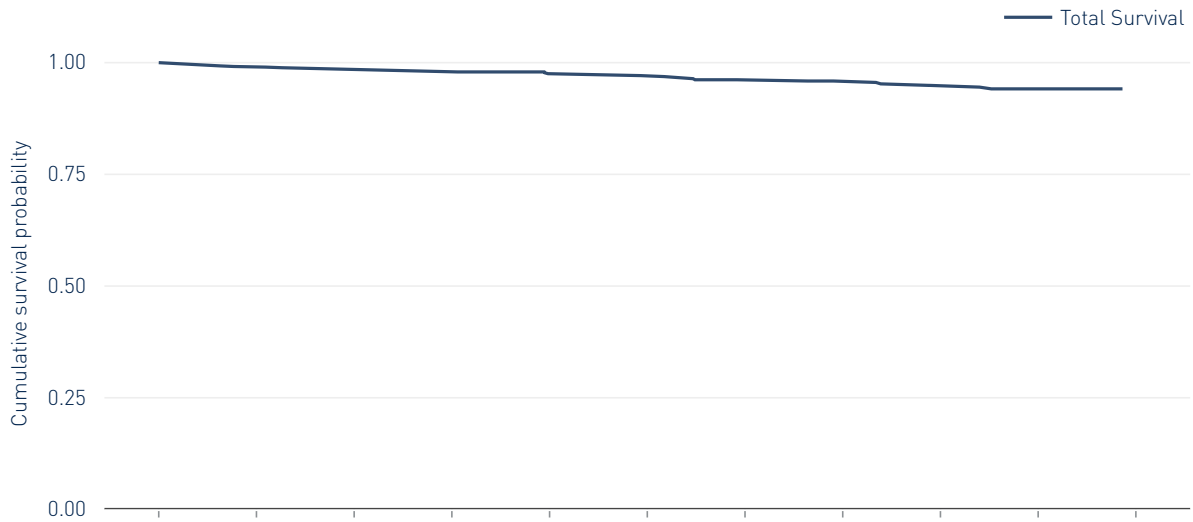
Performance of BIOTRONIK Leads Based on Insurance Claims Data

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



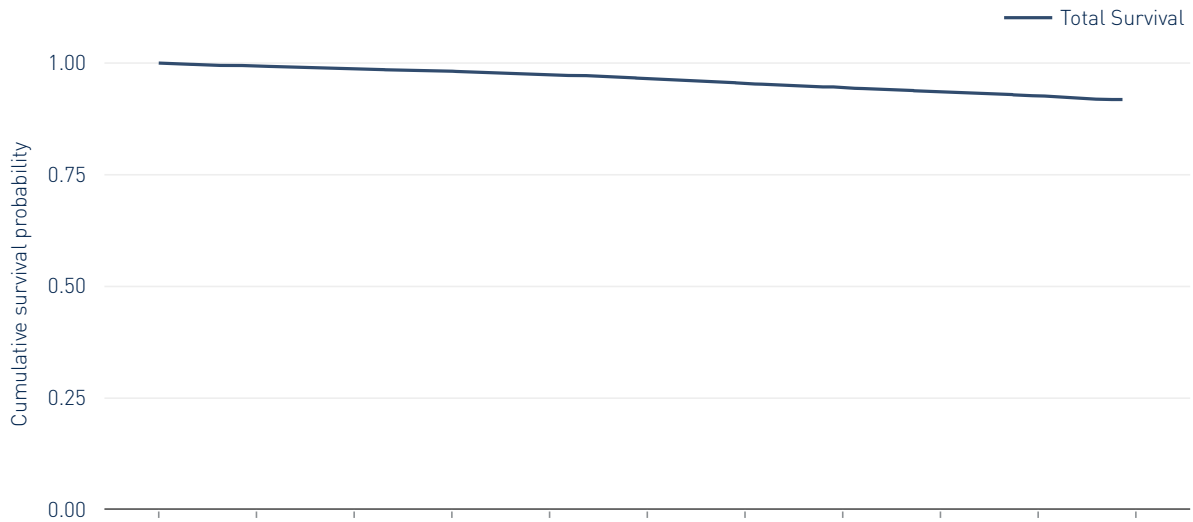
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.1	98.6	98.1	97.5	97.1	96.2	95.9	94.9	94.1	94.1
CI [± %]	< 0.1	0.7	0.9	1.1	1.3	1.5	1.9	2.1	2.5	3.0	3.3
Sample Size	870	🔒	649	574	499	443	382	334	273	221	185

*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

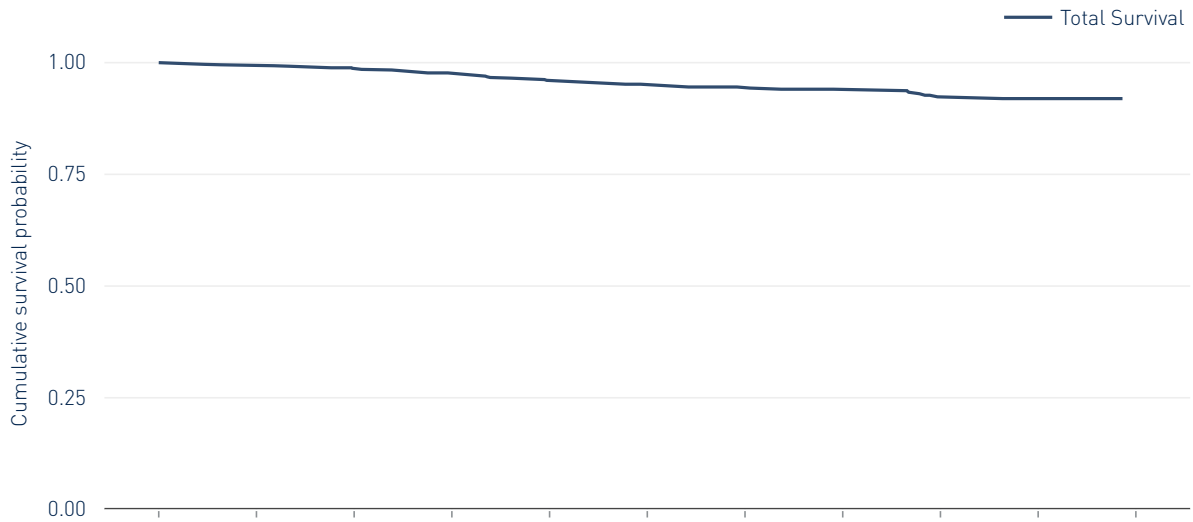


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.4	98.7	98.2	97.4	96.6	95.5	94.6	93.6	92.7	91.8
CI [± %]	< 0.1	0.2	0.3	0.4	0.5	0.6	0.8	0.9	1.1	1.3	1.5
Sample Size	7251	6020	5199	4480	3780	3139	2594	2121	1751	1406	1170

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



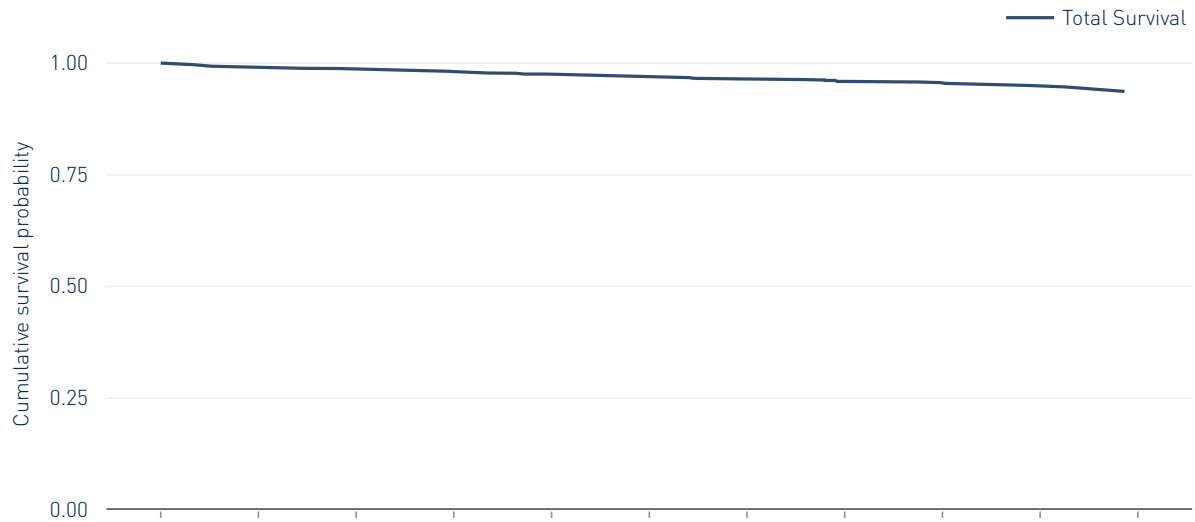
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.5	98.7	97.7	96.0	95.2	94.5	94.0	92.3	92.0	92.0
CI [± %]	< 0.1	0.4	0.8	1.1	1.5	1.9	2.2	2.5	3.1	3.5	3.8
Sample Size	1149	🔒	820	697	588	483	399	329	263	217	182

*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

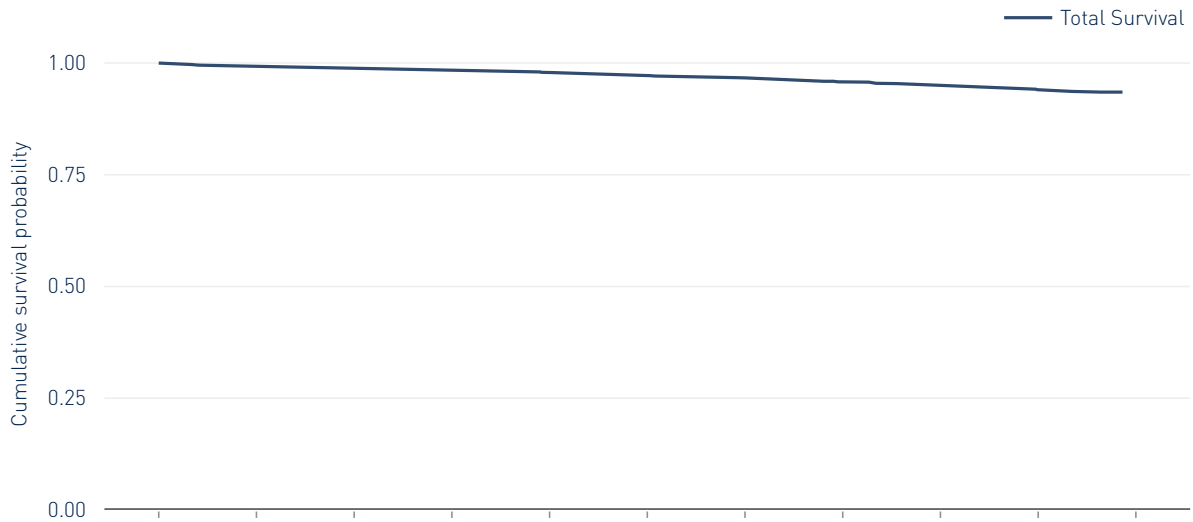


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.0	98.7	98.1	97.5	97.0	96.5	95.9	95.6	95.0	93.7
CI [± %]	< 0.1	0.4	0.5	0.6	0.7	0.9	1.0	1.3	1.6	2.2	3.4
Sample Size	3013	2516	2183	1891	1643	1395	1154	931	611	377	155

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

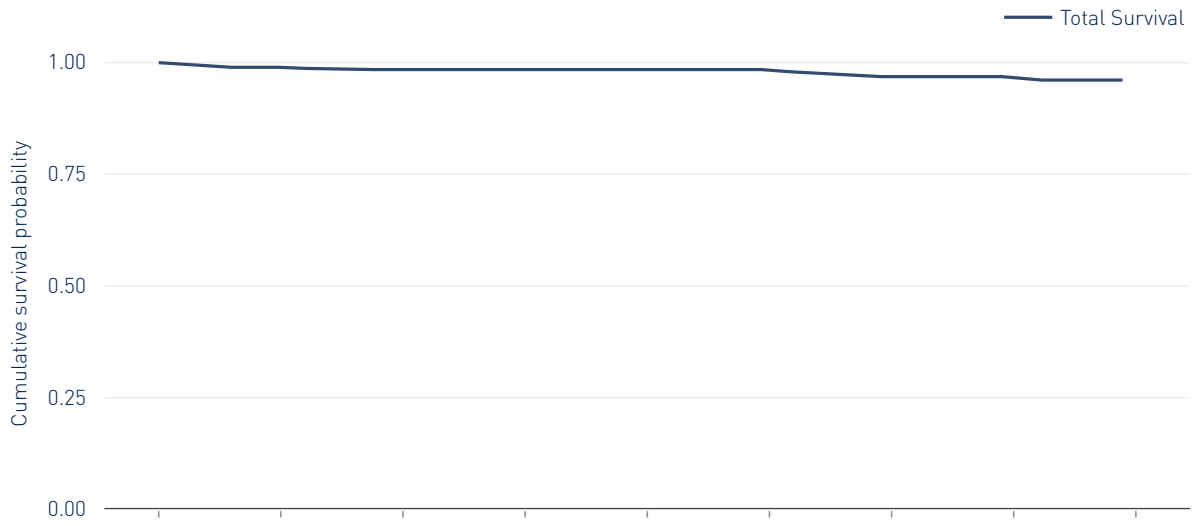


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100	99.1	98.8	98.3	97.9	97.2	96.7	95.8	95.0	94.0	93.5
CI [± %]	< 0.1	0.3	0.4	0.4	0.5	0.7	0.8	1.0	1.2	1.6	2.1
Sample Size	5286	4322	3730	3240	2800	2380	1980	1578	1225	836	517

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



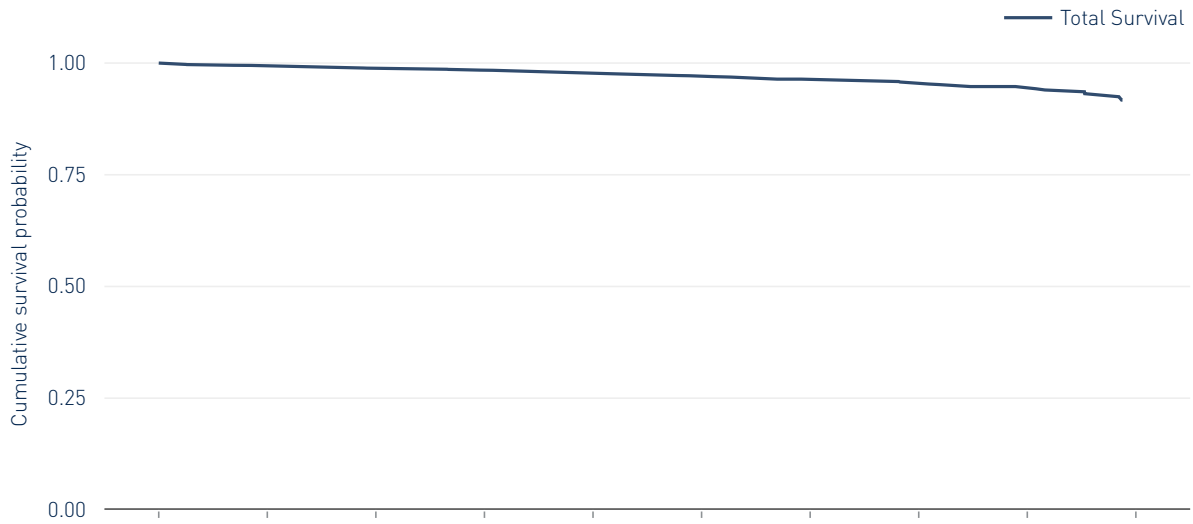
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.0	98.5	98.5	98.5	98.5	96.9	96.9	96.1
CI [± %]	< 0.1	1.0	1.3	1.4	1.5	1.6	2.6	2.8	3.7
Sample Size	522	🔒	🔒	🔒	🔒	🔒	🔒	🔒	102

*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 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	4 660

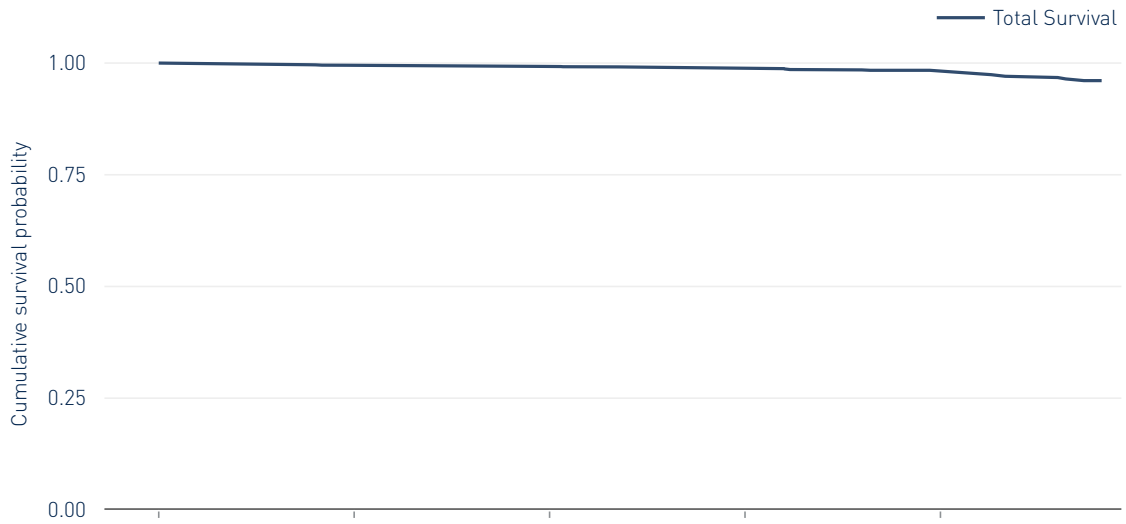


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100	99.4	98.9	98.4	97.8	97.1	96.4	95.4	94.7	91.7
CI [± %]	< 0.1	0.2	0.4	0.4	0.6	0.7	1.0	1.4	2.0	4.6
Sample Size	4659	3850	3373	2919	2491	2051	1401	858	440	124

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S

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	151 000
US Implants in EP PASSION	6 640

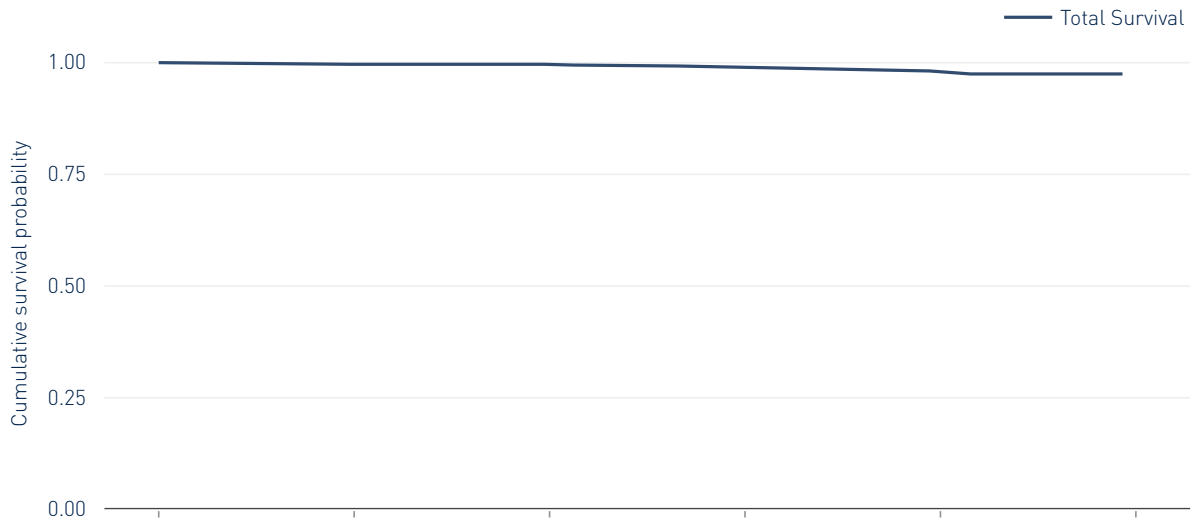


Years after implant	0	1	2	3	4
Total [%]	100	99.5	99.2	98.9	98.3
CI [± %]	< 0.1	0.2	0.3	0.5	0.9
Sample Size	6636	4066	2871	1737	828

10.2 Performance of ICD Leads – Insurance Claims Data

Plexa SD*

Product Versions	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	17 300
US Implants in EP PASSION	1 320



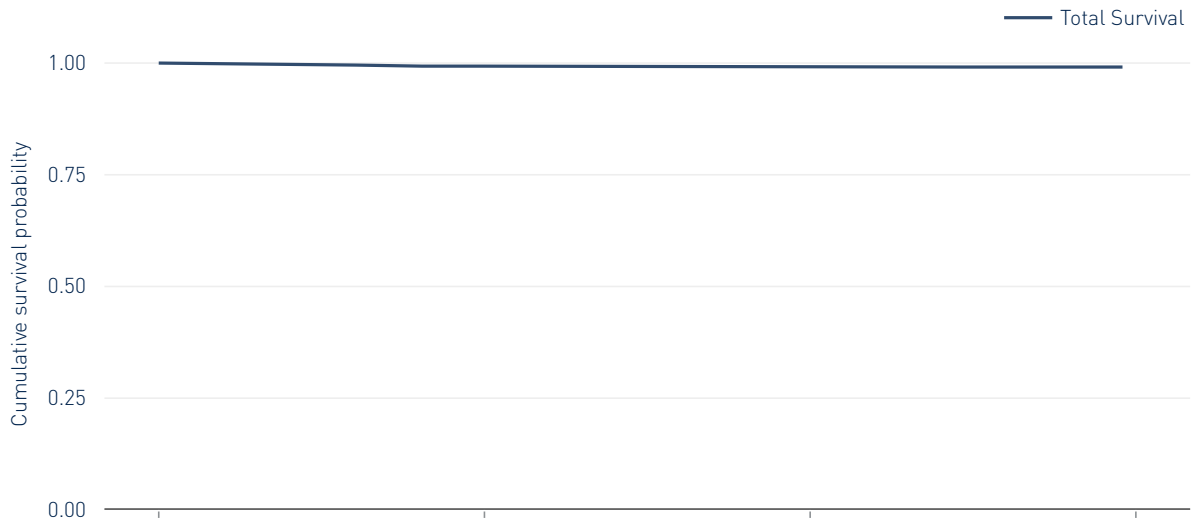
Years after implant	0	1	2	3	4	5
Total [%]	100	99.6	99.6	99.0	98.1	97.5
CI [± %]	< 0.1	0.4	0.4	1.0	1.9	4.0
Sample Size	1314	🔒	🔒	🔒	🔒	🔒

*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

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	39 500
US Implants in EP PASSION	3 390

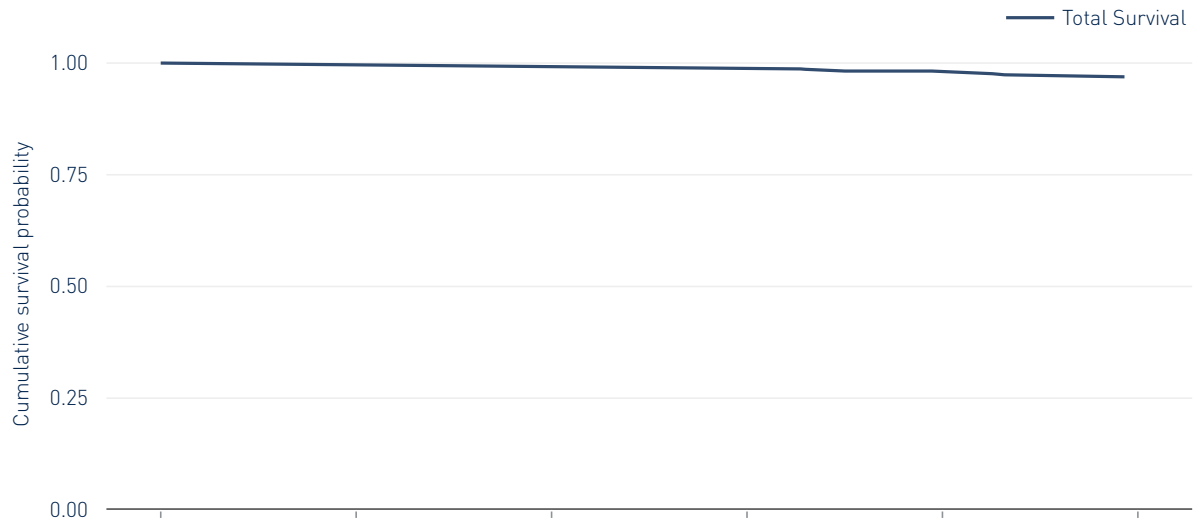


Years after implant	0	1	2	3
Total [%]	100	99.3	99.1	99.1
CI [± %]	< 0.1	0.4	0.6	0.9
Sample Size	3382	1377	625	110

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	23 400
US Implants in EP PASSION	2 400

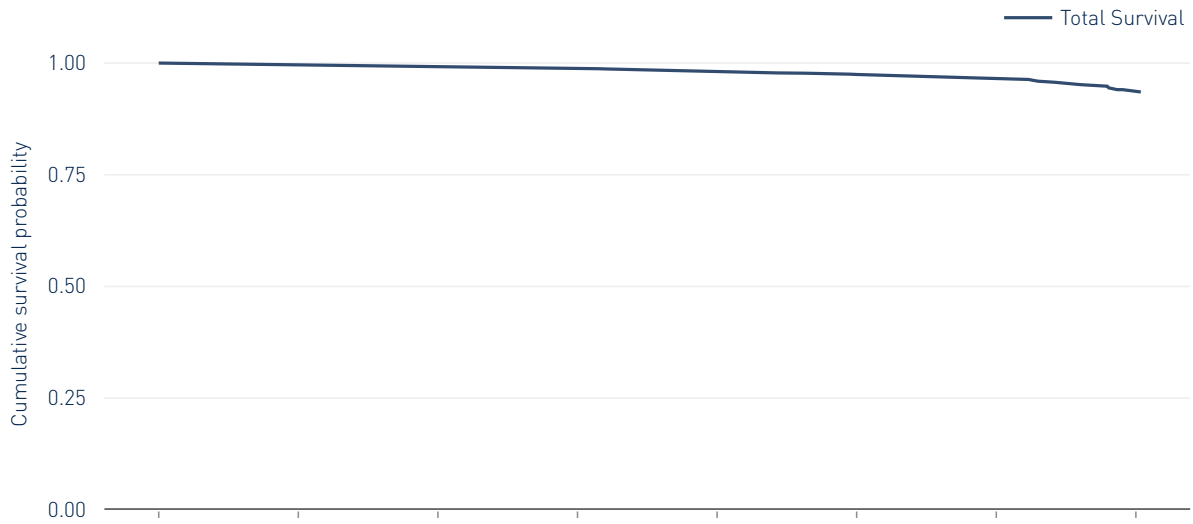


Years after implant	0	1	2	3	4	5
Total [%]	100	99.4	99.3	98.9	98.2	96.9
CI [± %]	< 0.1	0.3	0.4	0.6	1.0	2.8
Sample Size	2391	1969	1629	1305	647	139

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

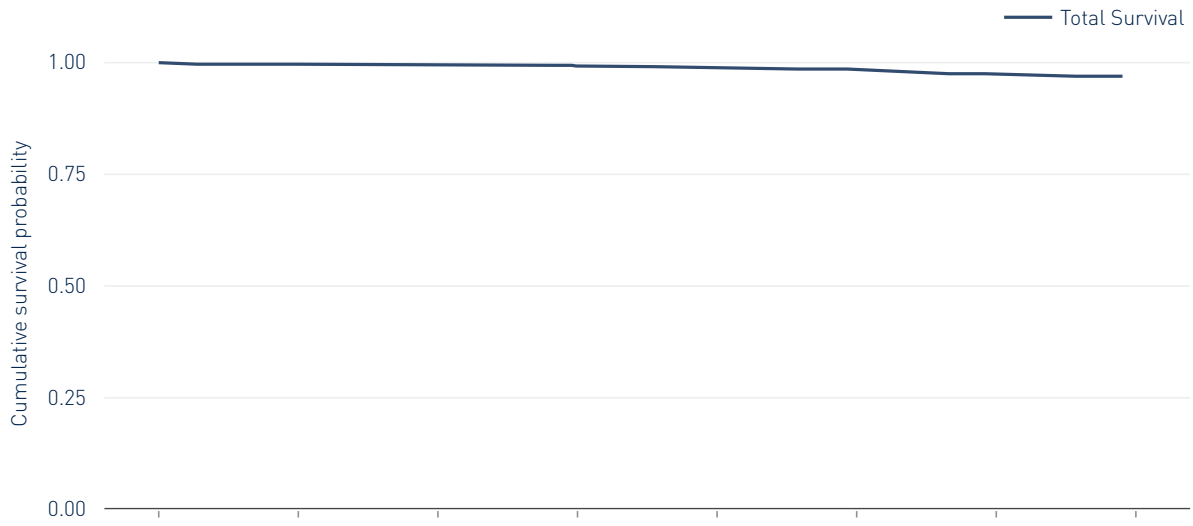


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.5	99.3	98.9	98.0	97.5	96.7	94.0
CI [± %]	< 0.1	0.3	0.3	0.4	0.7	0.8	1.3	3.1
Sample Size	3085	2611	2297	2023	1703	1373	694	216

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	1 180



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100	99.7	99.5	99.2	98.8	98.6	97.5	97.0
CI [± %]	< 0.1	0.4	0.5	0.6	0.9	1.1	1.8	2.5
Sample Size	1180	🔒	🔒	🔒	🔒	467	286	114

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

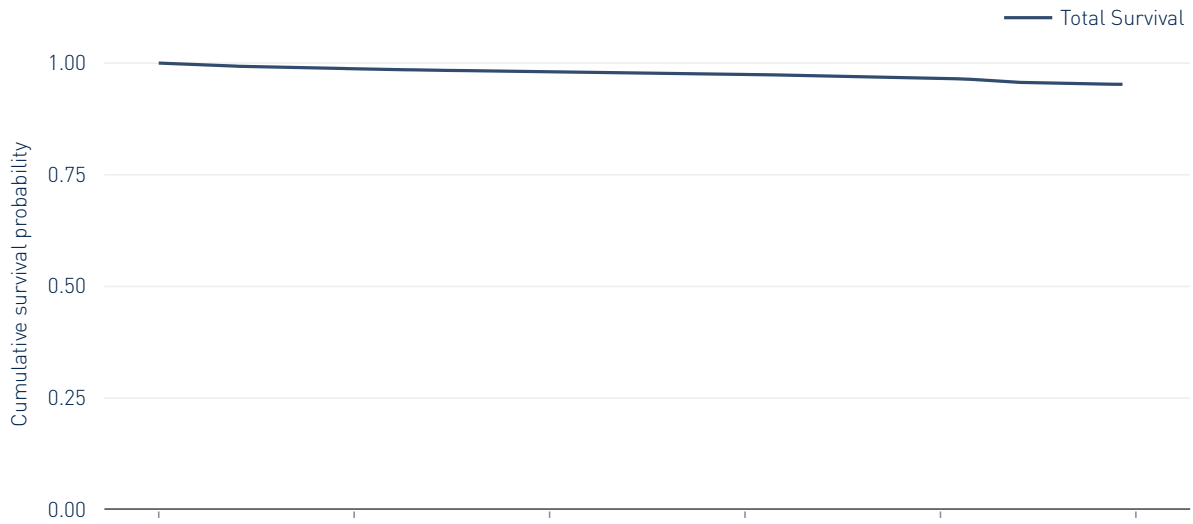
Performance of BIOTRONIK Leads Based on Insurance Claims Data

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	136 000
US Implants in EP PASSION	7 420

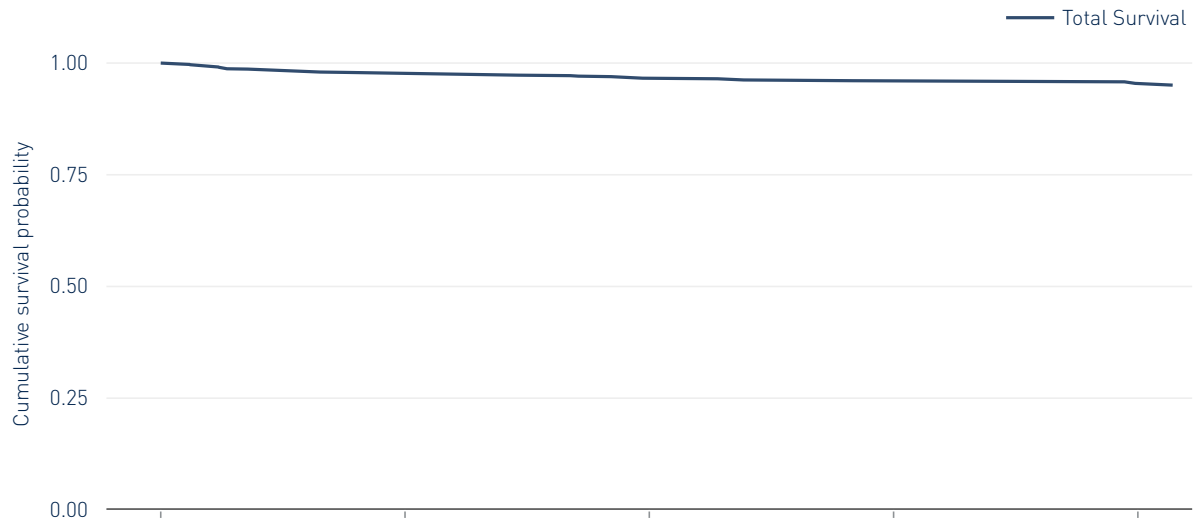


Years after implant	0	1	2	3	4	5
Total [%]	100	98.7	98.0	97.5	96.6	95.2
CI [± %]	< 0.1	0.3	0.5	0.7	1.2	2.7
Sample Size	7420	4410	3021	1890	897	214

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	25 900
US Implants in EP PASSION	1 740



Years after implant	0	1	2	3	4
Total [%]	100	97.7	96.6	96.0	95.5
CI [± %]	< 0.1	0.9	1.2	1.6	2.4
Sample Size	1740	1144	817	558	272

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 May 2024:

- The cumulative failure rate is 1.4 %.
- 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	0.0088 %

Risk for loss of high voltage therapy

Service Time	Risk per month
0 - 24 months	< 0.00001 %
24 - 48 months	0.0020 %
48 - 72 months	0.0140 %

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

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Fax +49 (0) 30 68905 96 1920
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Regarding Products

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