Product Performance Report

1st Edition 2023

Cardiac Rhythm Management
Cumulative Survival Probability

BIOTRONIK
excellence for life

Product Performance Report 1st Edition 2023

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

Contents

Quality 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 U.S. Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. As an active member of AdvaMed and their Pacemaker/ICD Working Group, BIOTRONIK has worked extensively with the CRM industry to ensure comparable product performance data is reported by all manufacturers.
The data provided in BIOTRONIK's Product Performance Report incorporates the requirements and definitions as defined in AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators, except as noted herein.

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

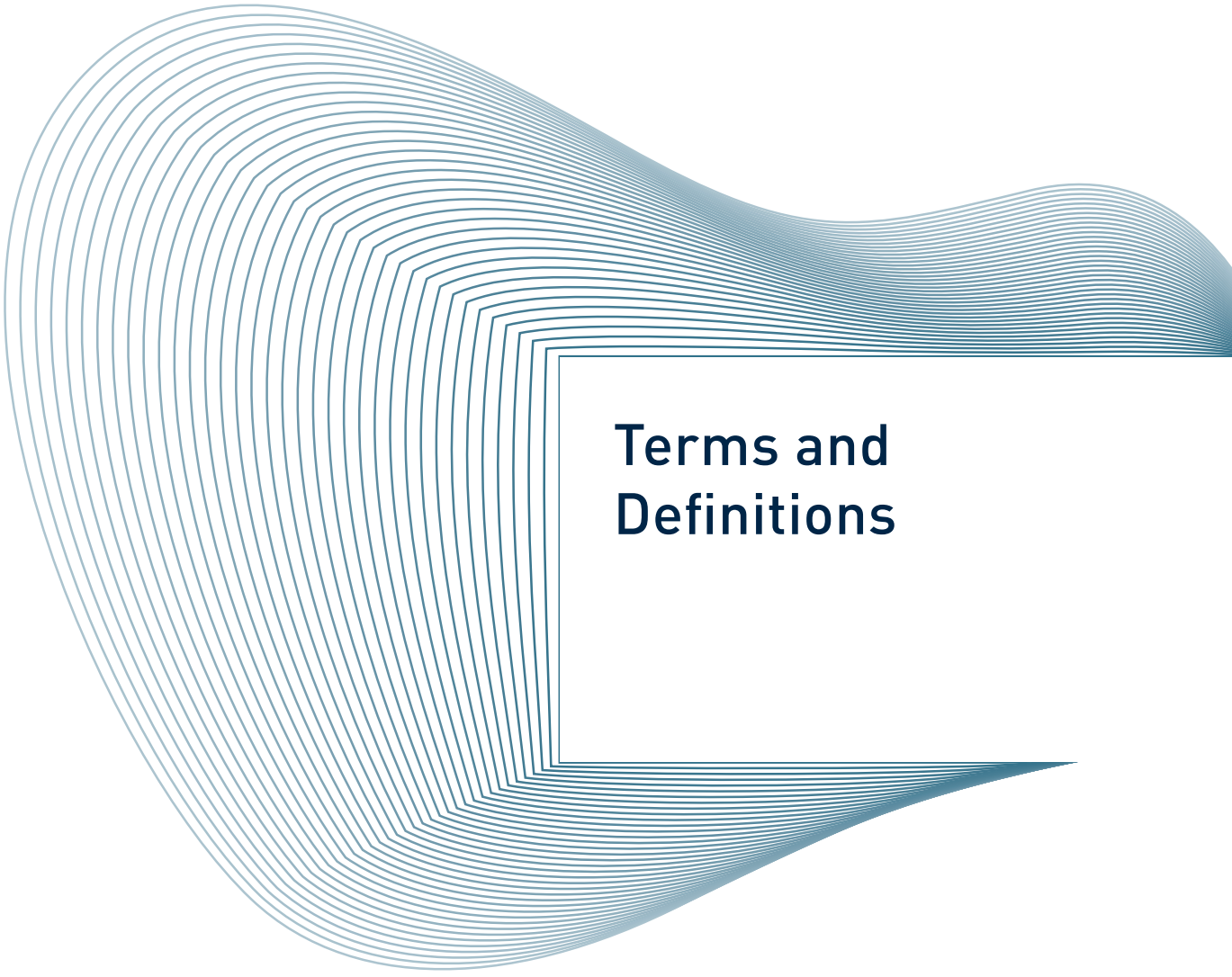
1 The ISO 5841-2:2014(E) is replacing the previous version ISO 5841-2:2000. As part of the update, AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators were incorporated in the new ISO 5841-2:2014(E).

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

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

BIOTRONIK, June 2023

Stephan Schwerzel
Senior Director Quality Assurance
Quality Assurance CRM
BIOTRONIK SE & Co. KG



Terms and Definitions

1. Terms and Definitions

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

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

Battery Depletion
Battery depletions are classified as either normal (expected) or premature. Premature battery depletions are defined as device malfunctions, while normal battery depletions are not device malfunctions. Batteries of returned devices are considered to have depleted normally when (a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or (b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using the longevity calculation tool available at time of product introduction, calculated using the device's actual use conditions and settings. Batteries of returned devices are considered to have depleted normally if they have reached their elective replacement indicator and testing indicates that the battery and associated circuitry are within specifications.

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

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

Malfunctions with Compromised Therapy
The condition when a pacemaker or ICD is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if critical patient-protective pacing or defibrillation therapy is not available. Examples include: sudden loss of battery voltage; accelerated current drain such that a depleted battery was not detected before loss of therapy; sudden malfunction during a tachycardia or fibrillation event resulting in aborted delivery of therapy; intermittent malfunction where therapy is sporadically unavailable.

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

Lead Complications

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

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

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

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

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

Survival Probability Estimates

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

Cumulative Survival Probability Estimates

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

Implanted Devices

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

Active Implants

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

Underreporting

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

Safety Advisory Notifications

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

2

Methodology for Pacemaker and ICD Survival Estimates

2. Methodology for Pacemaker and ICD Survival Estimates

2.1 Cumulative Survival Probability

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

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

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

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

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

2.2 Data Acquisition

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

In order to be included in the population under observation, a device must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is June 30, 2022. The number of U.S. devices that are implanted and remain active as well as the total number of products distributed worldwide are provided for each product family in this report. Information is provided for separate product families, in that devices with nearly identical hardware and therapy functions are combined. For example, Edora 8 DR and DR-T (with Home Monitoring) IPGs are combined into a single family, Edora 8 Single Chamber IPGs.

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

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

2.3 Returned Product Analysis

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

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

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

2.4 Product Performance Graphs and Data

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

For each product, the report provides:

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

The survival plots provide:

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

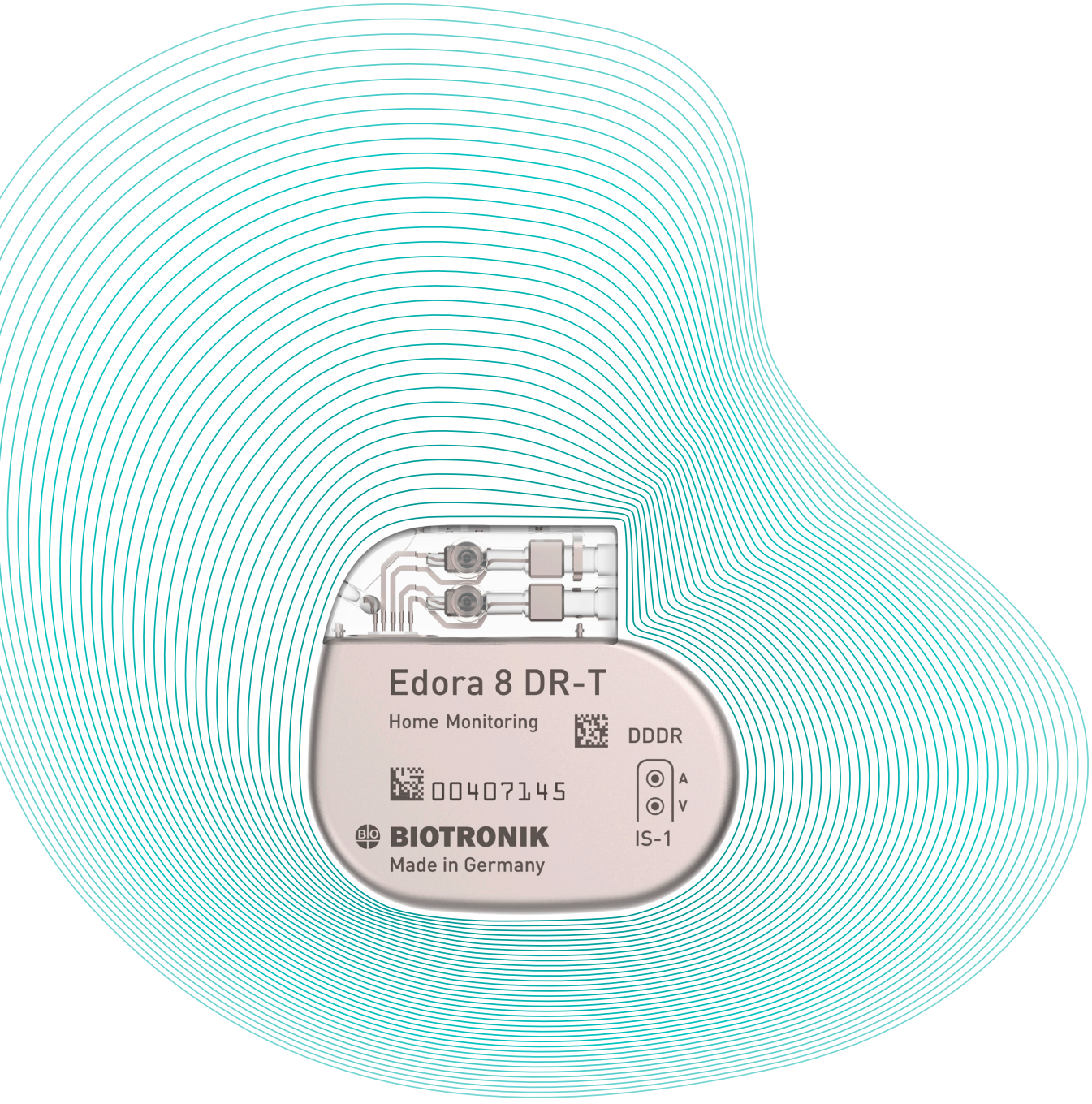
2. Malfunction-Free Survival
The cumulative survival probability free of component or software malfunctions excluding normal battery depletions, but including premature battery depletions. Normal battery depletions only have an impact on the total cumulative survival.

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

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

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

Performance of BIOTRONIK Pacemakers

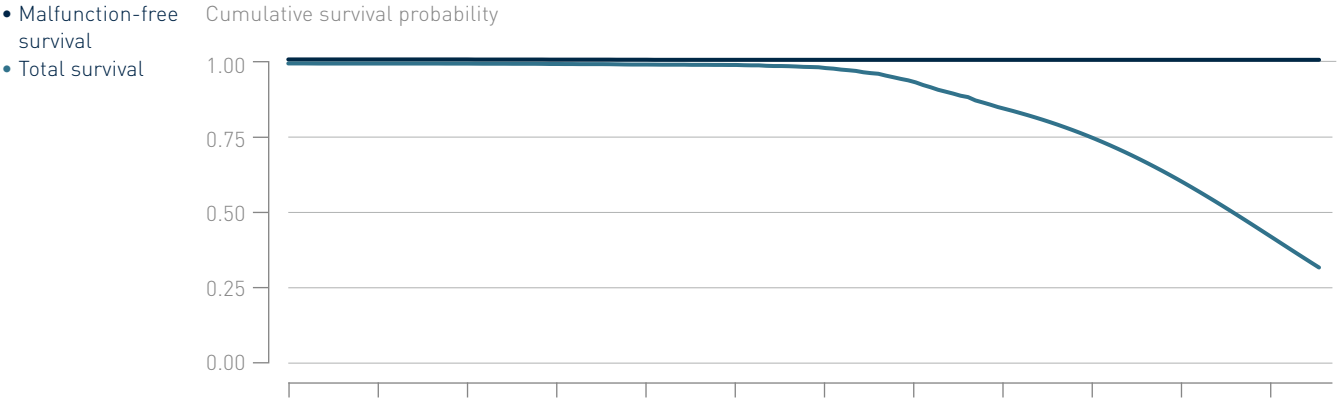


Performance of BIOTRONIK Pacemakers

Cylos and Cylos 990*

Product Versions	VR
NBG Codes	VVIR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	25 900
Registered U.S. Implants	6 149
Estimated Active U.S. Implants	2 270
U.S. Normal Battery Depletions	854

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



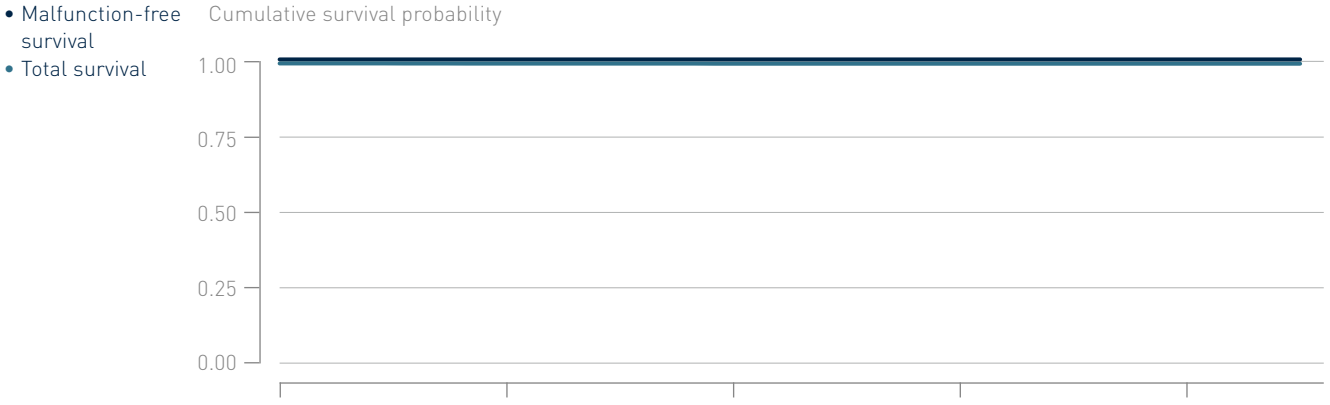
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.9	99.9	99.8	99.6	99.5	98.4	93.7	84.8	74.8	60.0	41.4
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.4	0.8	1.2	1.4	1.7	2.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	6 149	5 406	4 909	4 540	4 222	4 005	3 818	3 499	3 037	2 631	2 034	1 024

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

Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	40 600
Registered U.S. Implants	7 562
Estimated Active U.S. Implants	6 400
U.S. Normal Battery Depletions	3

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

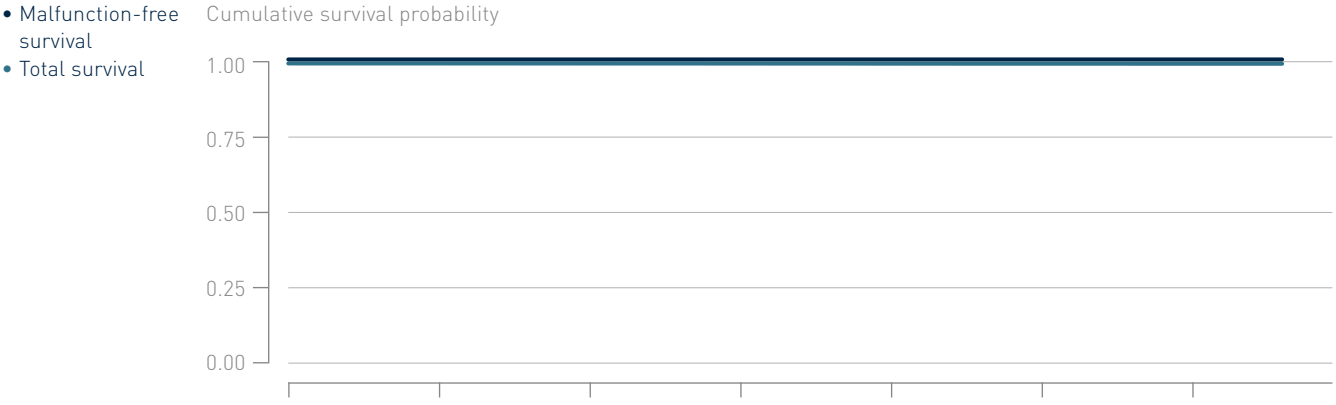


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	7 562	5 766	4 029	2 439	922

Eluna 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	19 600
Registered U.S. Implants	5 801
Estimated Active U.S. Implants	4 100
U.S. Normal Battery Depletions	14

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

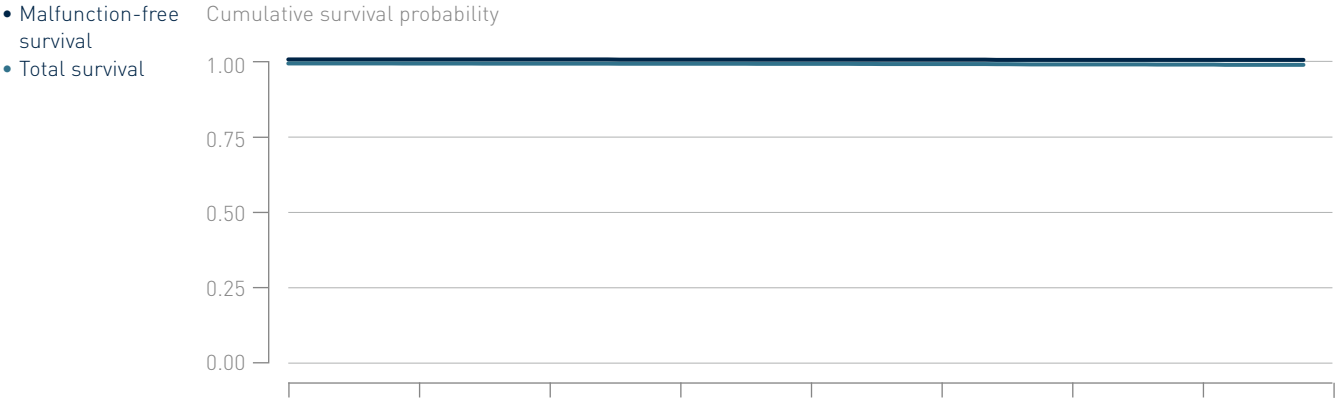


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.8	99.7	99.7	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	5 801	5 361	5 013	4 618	4 108	3 191	1 190

Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28 000
Registered U.S. Implants	2 399
Estimated Active U.S. Implants	1 550
U.S. Normal Battery Depletions	9

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

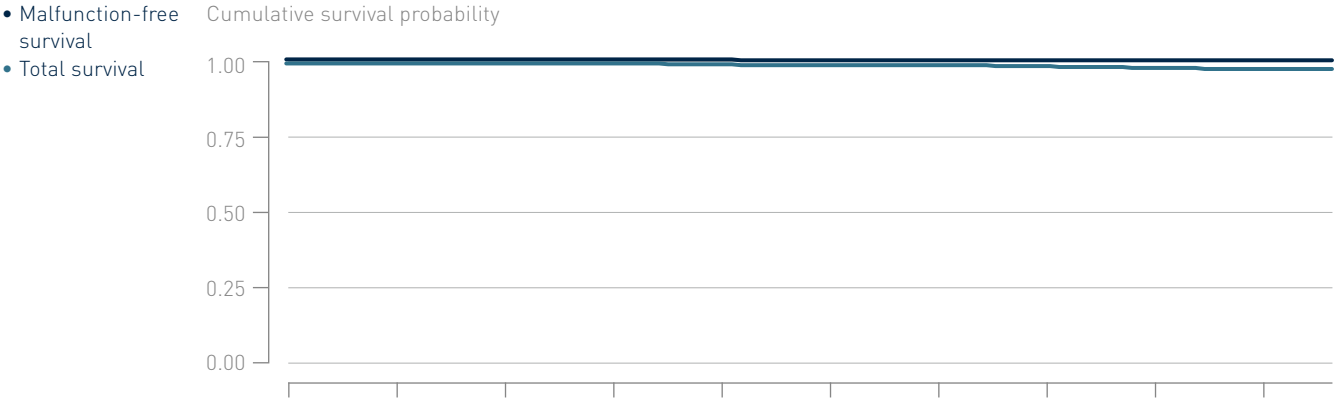


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.9	99.8	99.7	99.5	99.4
CI [±%]	-	0.1	0.1	0.2	0.2	0.2	0.3	0.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	2 399	2 188	2 066	1 938	1 824	1 722	1 585	1 137

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 U.S. Implants	614
Estimated Active U.S. Implants	361
U.S. Normal Battery Depletions	7

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

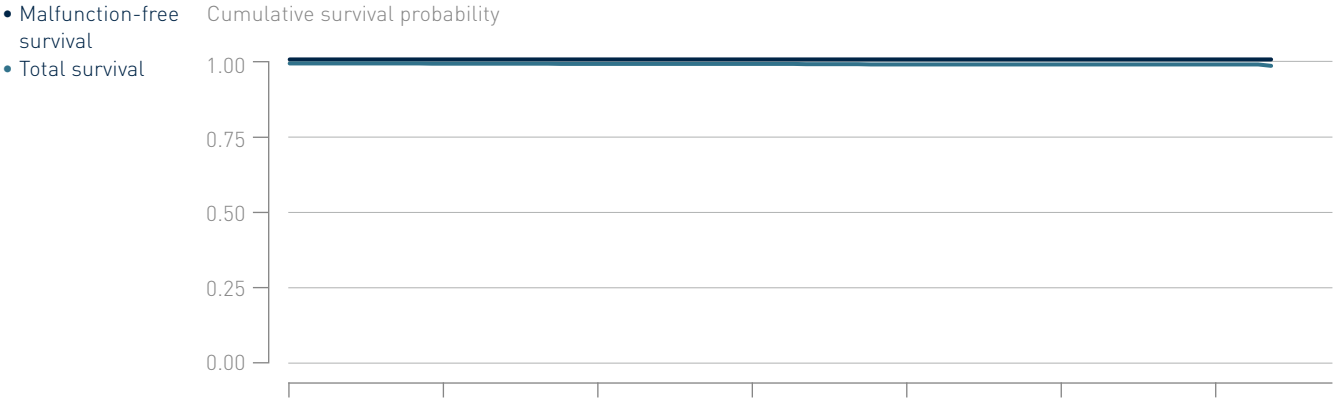


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.5	99.3	98.8	98.5
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.8	1	1.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.8	99.8	99.8	99.8	99.8
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.5	0.5	0.5	0.5	0.5
Sample Size	614	536	495	454	433	421	416	406	384	278

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18500
Registered U.S. Implants	1 711
Estimated Active U.S. Implants	1250
U.S. Normal Battery Depletions	5

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

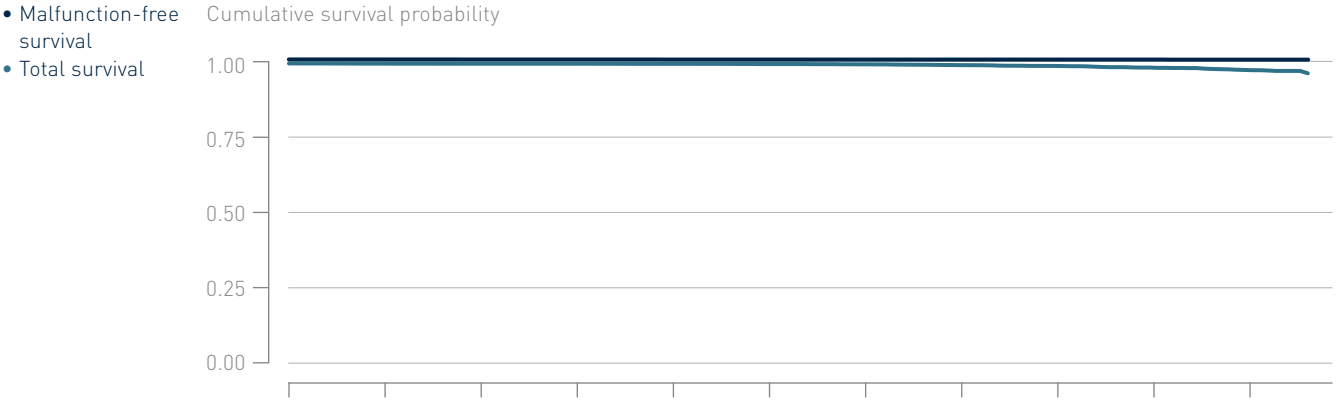


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.9	99.9	99.7	99.7	99.7
CI [±%]	-	0.1	0.2	0.2	0.3	0.3	0.3
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 711	1 572	1 479	1 387	1 207	921	444

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 U.S. Implants	11 974
Estimated Active U.S. Implants	7 030
U.S. Normal Battery Depletions	99

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



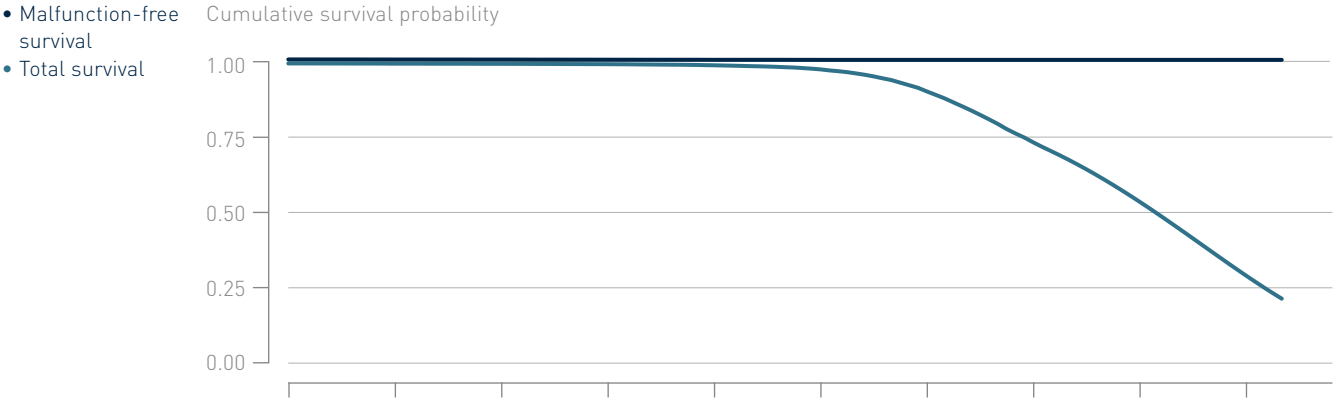
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.6	99.3	98.9	98.2
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.3	0.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1
Sample Size	11 974	10 737	10 099	9 620	9 288	8 762	8 258	7 651	6 164	3 902	1 767

Performance of BIOTRONIK Pacemakers

Cylos and Cylos 990*

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	81 300
Registered U.S. Implants	30 374
Estimated Active U.S. Implants	6 840
U.S. Normal Battery Depletions	8 466

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



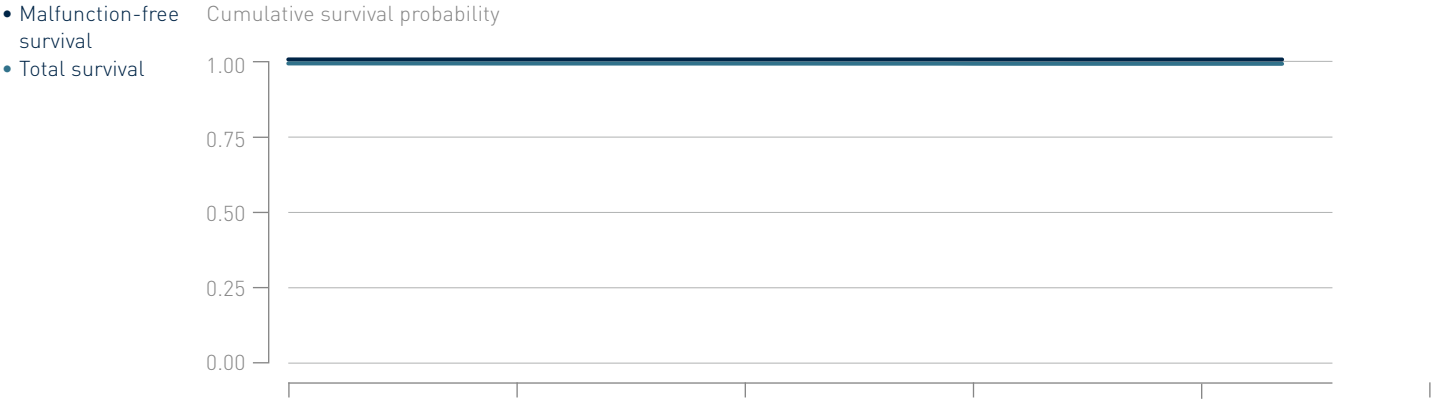
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.9	99.7	99.4	98.0	90.6	73.5	53.6	28.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.2	0.4	0.6	0.7	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	30 374	28 180	26 455	24 996	23 565	21 803	18 751	13 729	9 055	3 072

* 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.

Edora 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2017
CE Market Release	Jul 2016
Worldwide Distributed Devices	230 000
Registered U.S. Implants	75 413
Estimated Active U.S. Implants	65 200
U.S. Normal Battery Depletions	36

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.01%
Therapy Compromised	3	0.00%
Therapy Available	4	0.01%

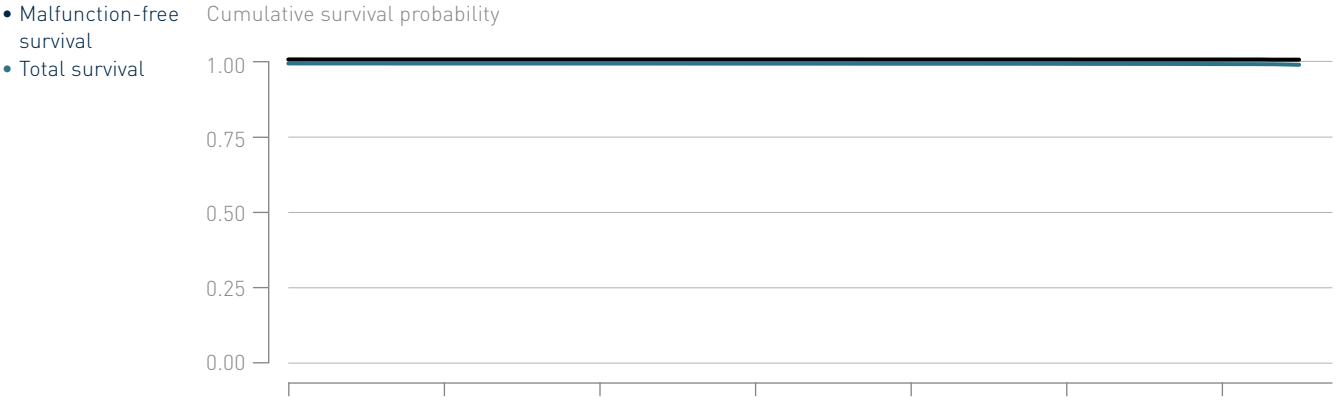


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	75 413	55 071	36 814	21 601	6 529

Eluna 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	97200
Registered U.S. Implants	42086
Estimated Active U.S. Implants	30300
U.S. Normal Battery Depletions	80

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.01%
Therapy Compromised	0	0.00%
Therapy Available	6	0.01%

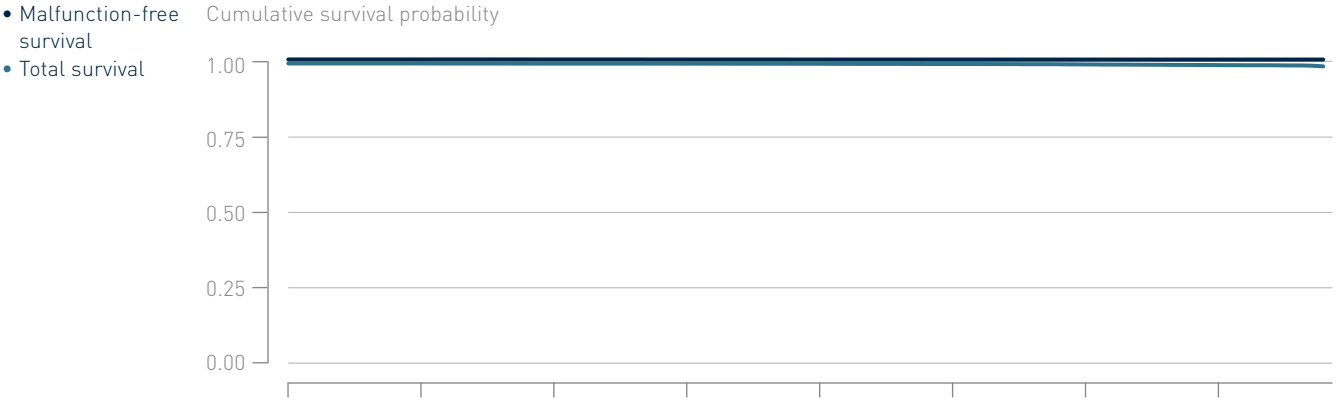


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.7
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	42086	39282	36 246	32540	28283	21942	6994

Entovis

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	105 000
Registered U.S. Implants	12 130
Estimated Active U.S. Implants	7 770
U.S. Normal Battery Depletions	63

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

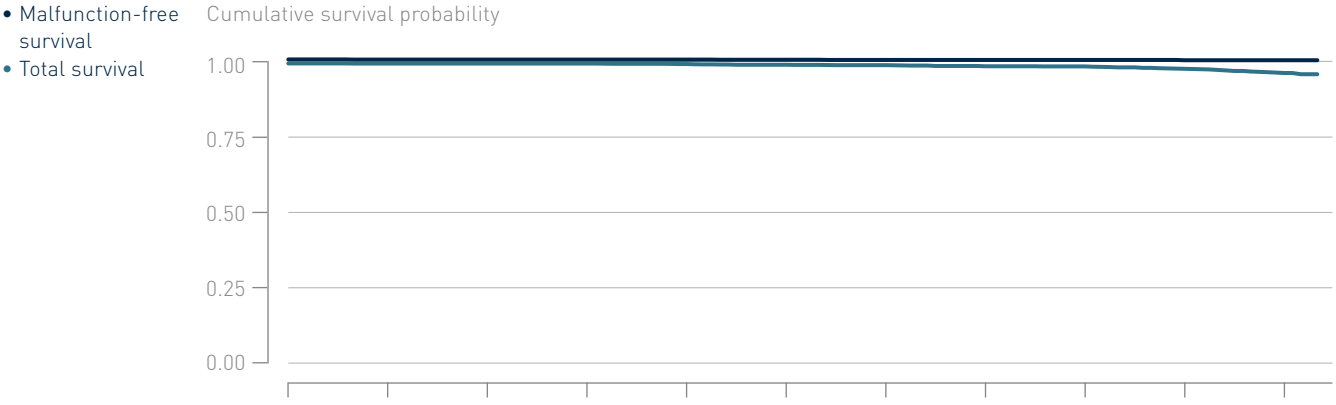


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.9	99.8	99.7	99.6	99.3
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	12 130	11 335	10 622	9 986	9 373	8 813	8 088	6 201

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 U.S. Implants	2 951
Estimated Active U.S. Implants	1 720
U.S. Normal Battery Depletions	52

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

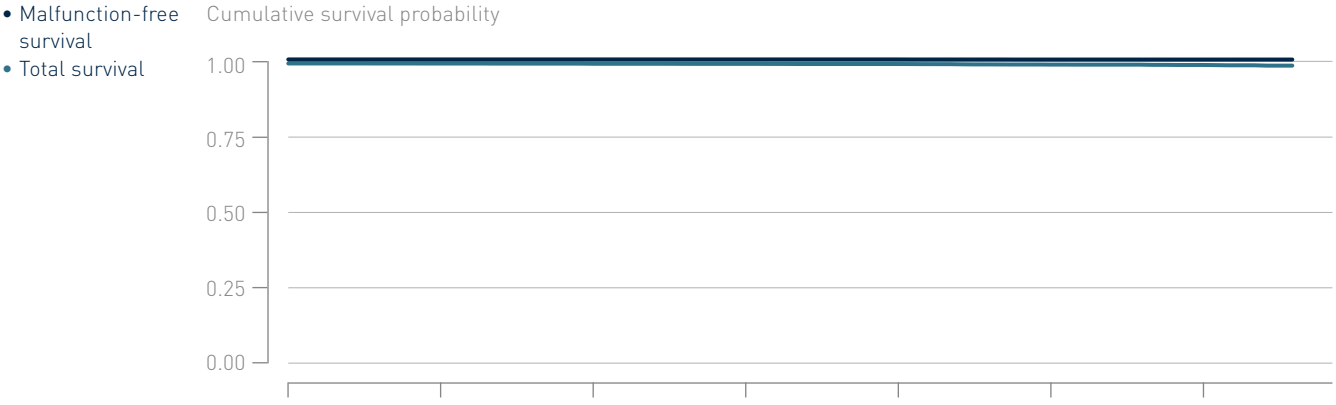


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.4	99.0	98.9	98.1	96.6
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.6	1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	2 951	2 743	2 593	2 469	2 331	2 195	2 062	1 939	1 804	1 400	619

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	76300
Registered U.S. Implants	11709
Estimated Active U.S. Implants	8580
U.S. Normal Battery Depletions	31

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.02%
Therapy Compromised	0	0.00%
Therapy Available	2	0.02%

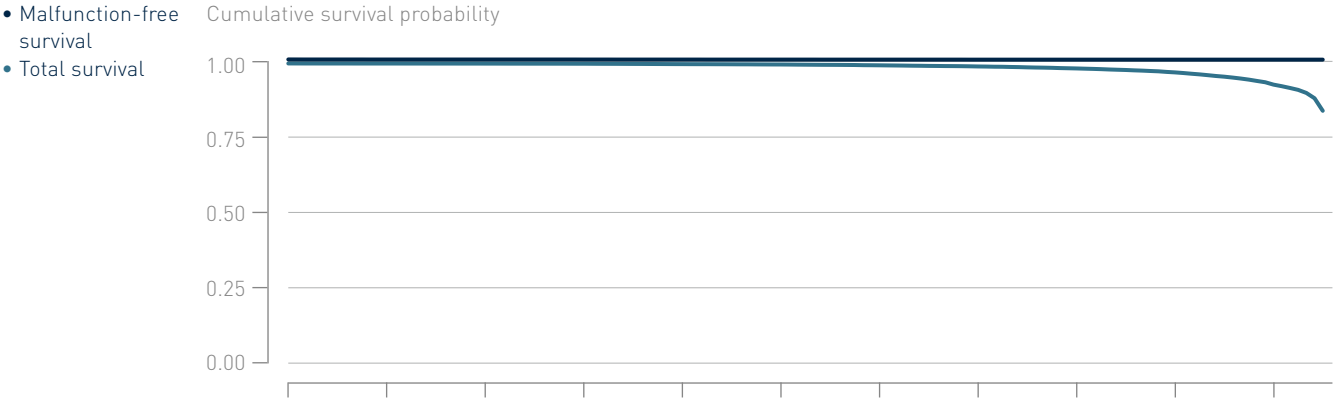


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.9	99.9	99.7	99.6
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	11709	10984	10334	9700	8474	6365	2888

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 U.S. Implants	61 919
Estimated Active U.S. Implants	34 800
U.S. Normal Battery Depletions	1 572

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



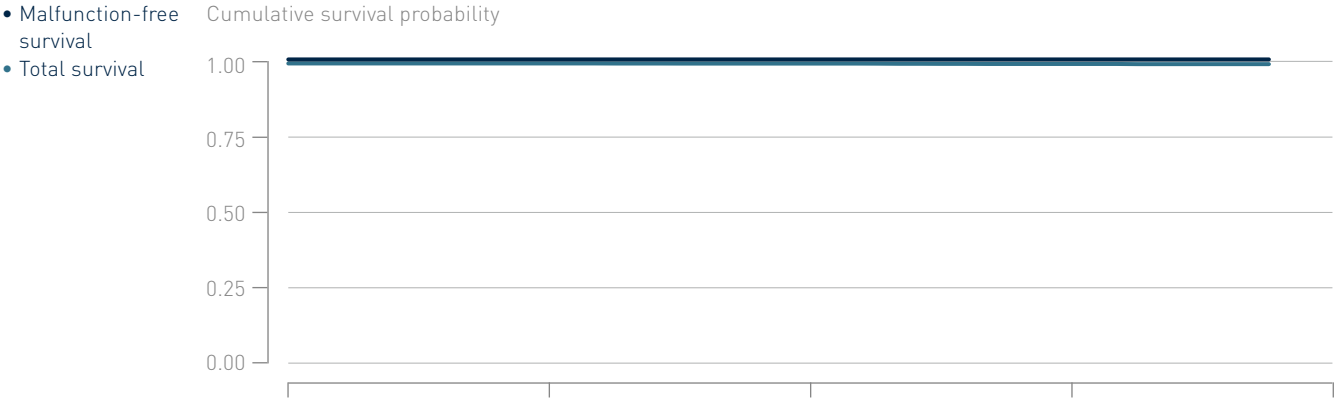
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	99.9	99.9	99.8	99.6	99.4	99.0	98.3	97.0	92.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	0.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	61 919	57 990	54 515	51 286	48 196	45 326	42 574	39 419	30 454	17 265	5 849

Performance of BIOTRONIK 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	17 600
Registered U.S. Implants	6 249
Estimated Active U.S. Implants	4 890
U.S. Normal Battery Depletions	10

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

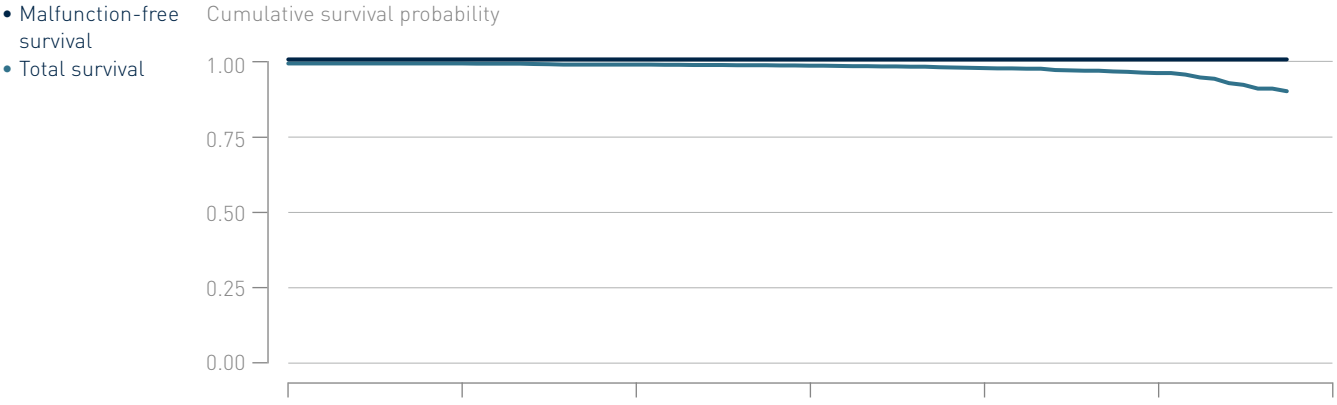


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.7
CI [±%]	-	< 0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	6 249	4 246	2 527	1 140

Etrinsa 8

Product Versions	HF-T
NBG Codes	DDDRV
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	8 670
Registered U.S. Implants	1 860
Estimated Active U.S. Implants	967
U.S. Normal Battery Depletions	63

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

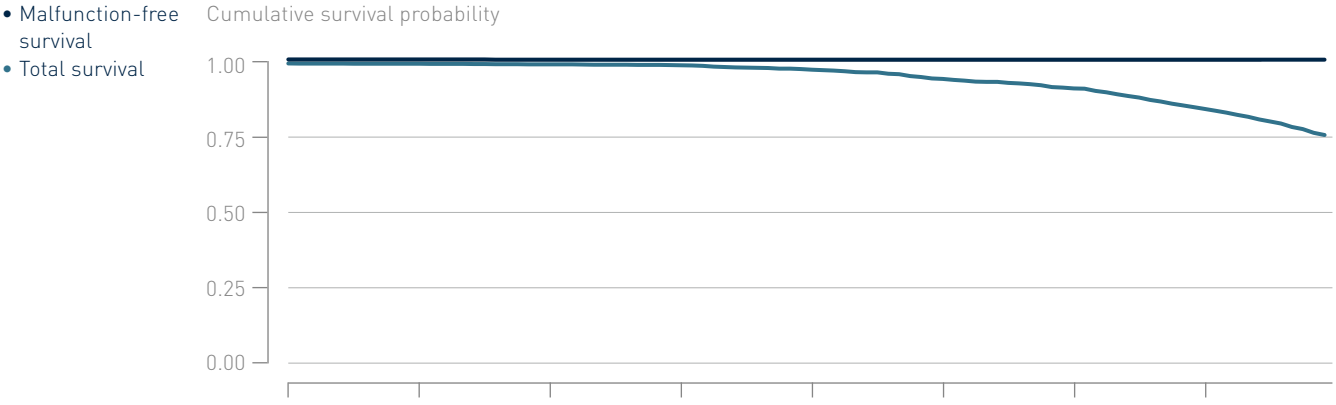


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.6	99.2	98.4	96.7
CI [±%]	-	< 0.1	0.3	0.5	0.7	1.1
Malfunction-Free [%]	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 860	1 625	1 431	1 255	981	654

Evia

Product Versions	HF, HF-T
NBG Codes	DDDRV
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	8 880
Registered U.S. Implants	2 249
Estimated Active U.S. Implants	784
U.S. Normal Battery Depletions	234

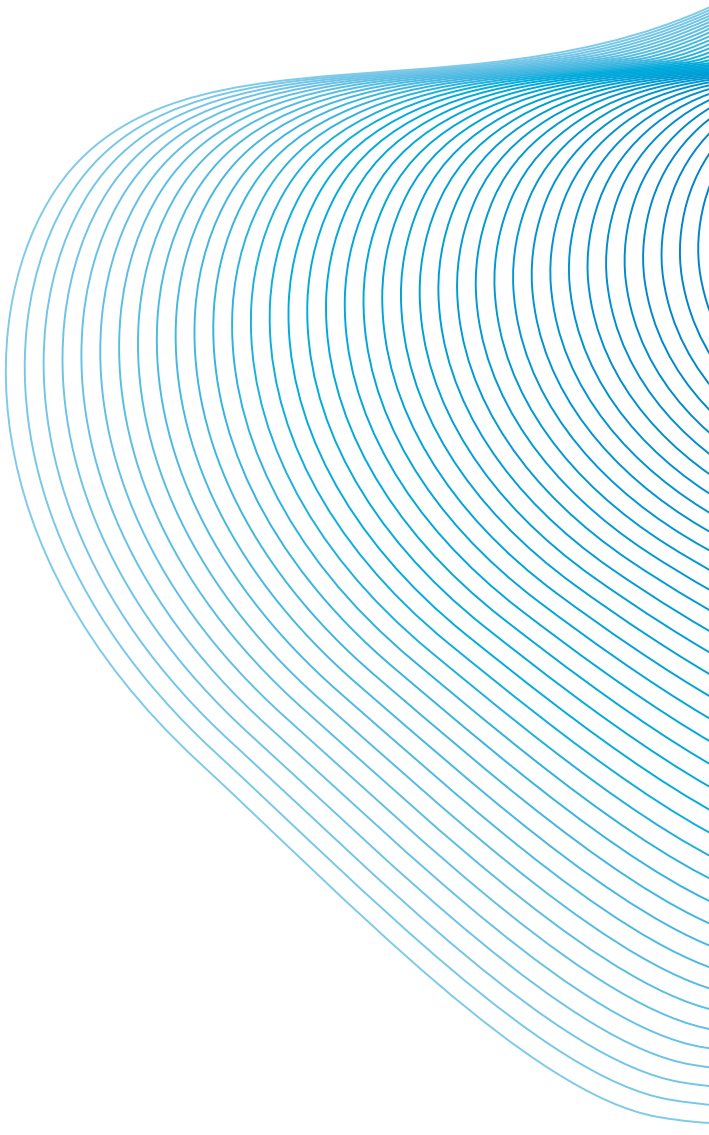
	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.04%
Therapy Compromised	0	0.00%
Therapy Available	1	0.04%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.7	99.4	97.9	94.8	91.6	84.7
CI [±%]	-	0.1	0.2	0.4	0.7	1.2	1.5	2.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	2 249	1 987	1 765	1 568	1 363	1 176	1 013	779

Performance of BIOTRONIK ICDs

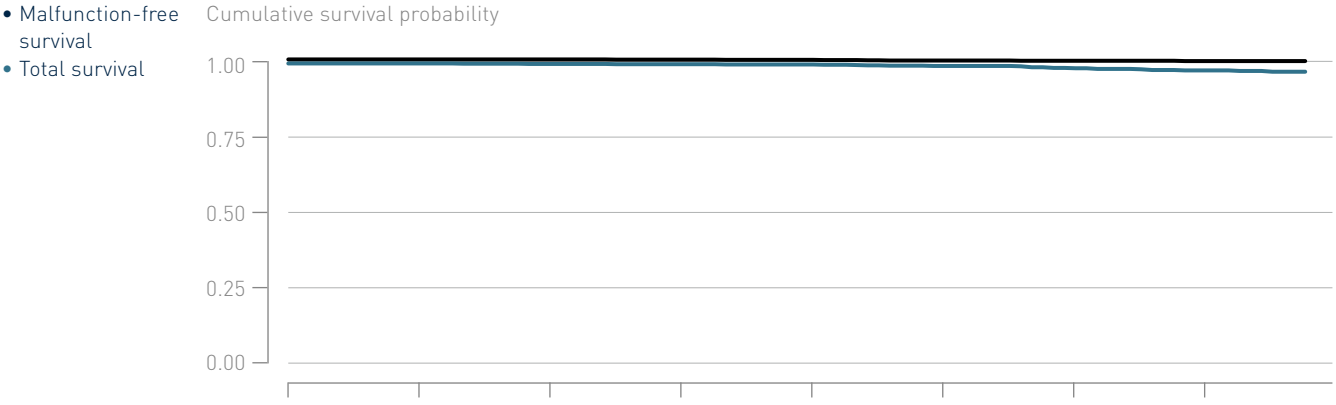
Performance of BIOTRONIK ICDs



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 U.S. Implants	1 271
Estimated Active U.S. Implants	730
U.S. Normal Battery Depletions	19

	Quantity	Rate
U.S. Confirmed Malfunctions*	7	0.55%
Therapy Compromised	4	0.31%
Therapy Available	3	0.24%



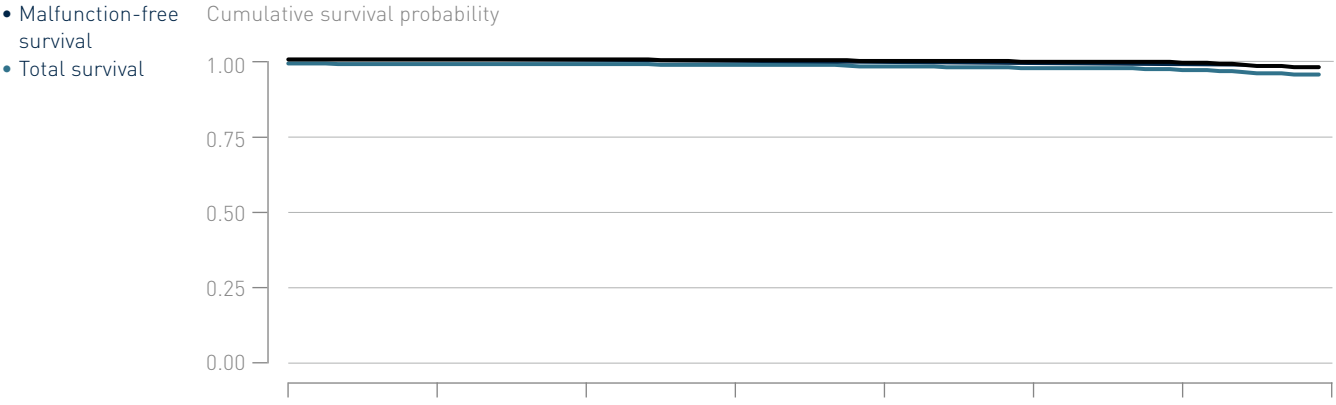
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.8	99.7	99.6	99.1	98.3	97.5
CI [±%]	-	< 0.1	0.2	0.3	0.4	0.6	0.8	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.5	99.4	99.2
CI [±%]	-	< 0.1	< 0.1	0.2	0.3	0.5	0.5	0.6
Sample Size	1 271	1 180	1 100	1 030	957	887	817	631

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

Ilesto 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2390
Registered U.S. Implants	466
Estimated Active U.S. Implants	287
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions*	8	1.72%
Therapy Compromised	3	0.64%
Therapy Available	5	1.07%



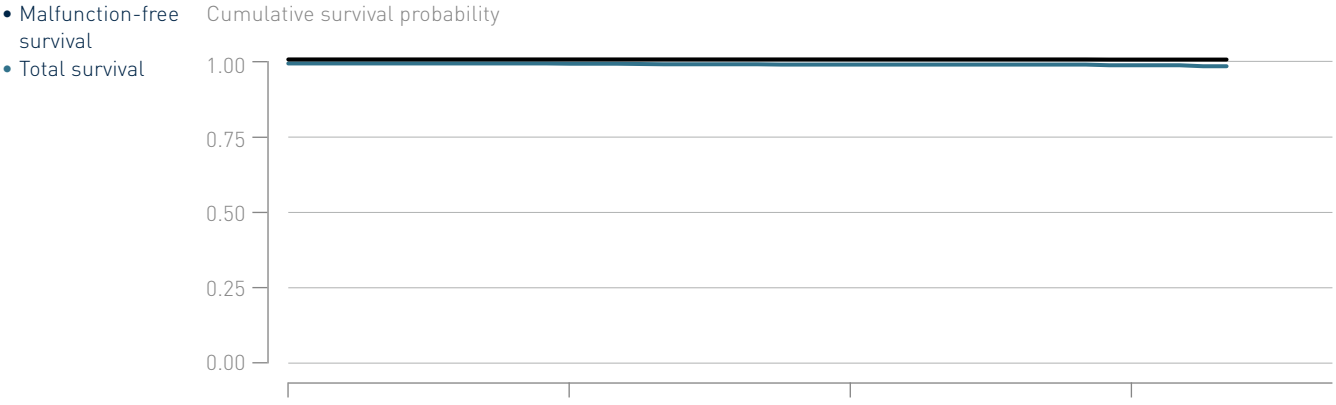
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.8	99.5	98.9	98.3	97.7
CI [±%]	-	0.4	0.4	0.7	1	1.3	1.6
Malfunction-Free [%]	100.0	100.0	100.0	99.7	99.4	99.1	98.8
CI [±%]	-	< 0.1	< 0.1	0.5	0.8	1	1.2
Sample Size	466	429	392	365	341	317	281

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

Ilivia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	2390
Registered U.S. Implants	964
Estimated Active U.S. Implants	785
U.S. Normal Battery Depletions	5

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



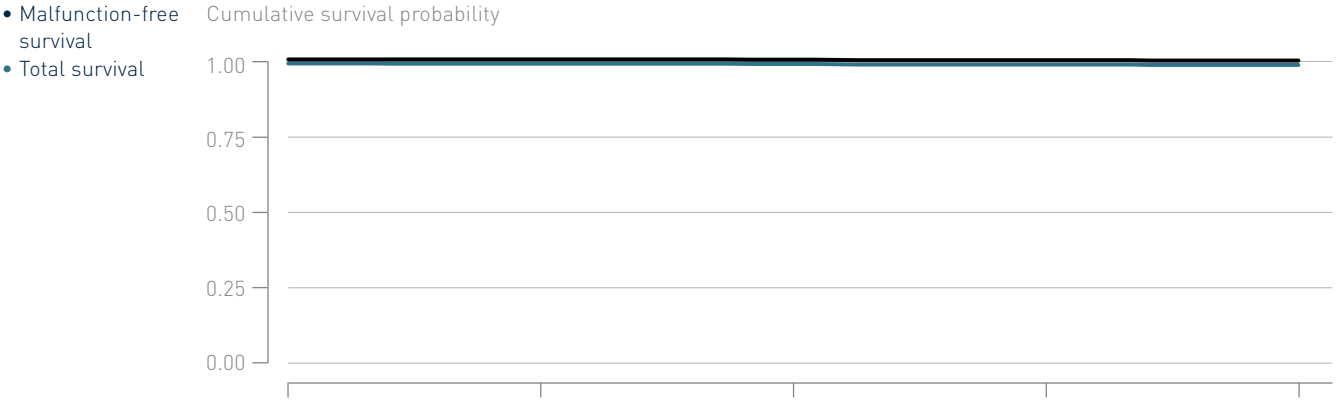
Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.5	99.3
CI [±%]	-	0.2	0.5	0.7
Malfunction-Free [%]	100	100	100	99.7
CI [±%]	-	< 0.1	< 0.1	0.5
Sample Size	964	885	688	328

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

Ilivia 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Aug 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	4 250
Registered U.S. Implants	878
Estimated Active U.S. Implants	677
U.S. Normal Battery Depletions	1

	Quantity	Rate
U.S. Confirmed Malfunctions*	4	0.46%
Therapy Compromised	1	0.11%
Therapy Available	3	0.34%



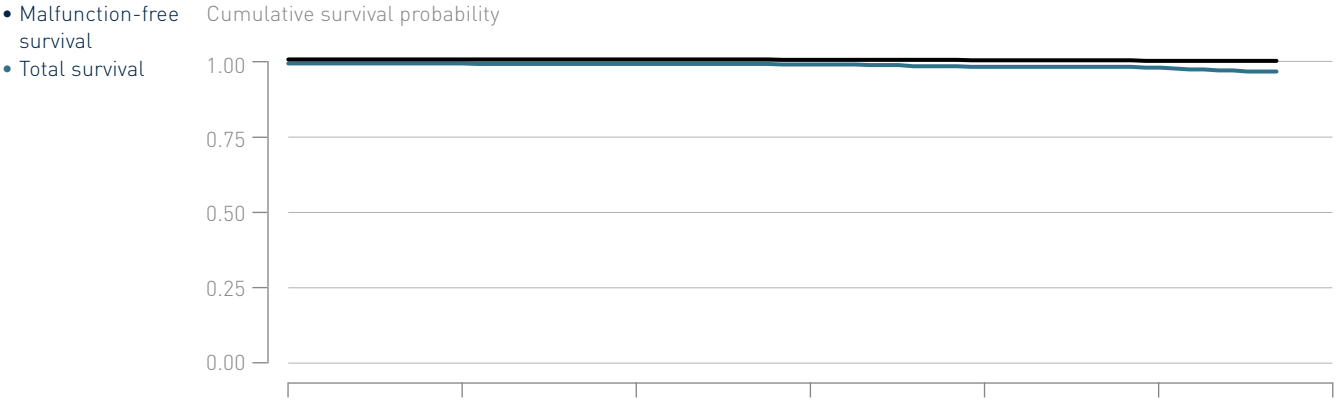
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.8	99.5	99.3
CI [±%]	-	0.2	0.3	0.5	0.6
Malfunction-Free [%]	100.0	100.0	99.9	99.6	99.4
CI [±%]	-	< 0.1	0.3	0.5	0.6
Sample Size	878	809	751	618	224

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

Itrevia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 280
Registered U.S. Implants	618
Estimated Active U.S. Implants	402
U.S. Normal Battery Depletions	9

	Quantity	Rate
U.S. Confirmed Malfunctions*	4	0.65%
Therapy Compromised	4	0.65%
Therapy Available	0	0.00%



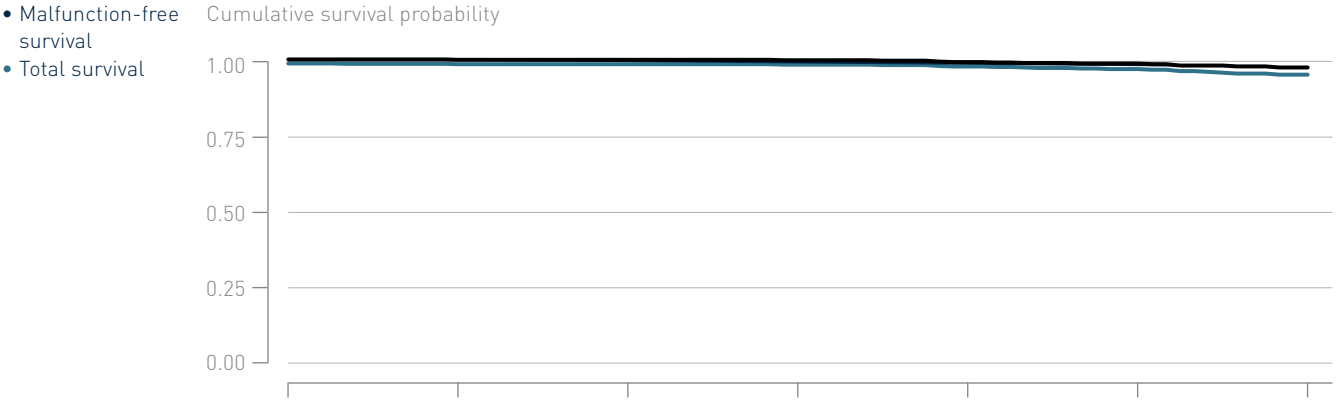
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.8	99.6	98.8	98.5
CI [±%]	-	< 0.1	0.3	0.5	1	1.1
Malfunction-Free [%]	100.0	100.0	100.0	99.8	99.6	99.3
CI [±%]	-	< 0.1	< 0.1	0.4	0.6	0.8
Sample Size	618	567	530	491	448	317

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

Itrevia 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 420
Registered U.S. Implants	804
Estimated Active U.S. Implants	544
U.S. Normal Battery Depletions	6

	Quantity	Rate
U.S. Confirmed Malfunctions*	15	1.87%
Therapy Compromised	3	0.37%
Therapy Available	12	1.49%



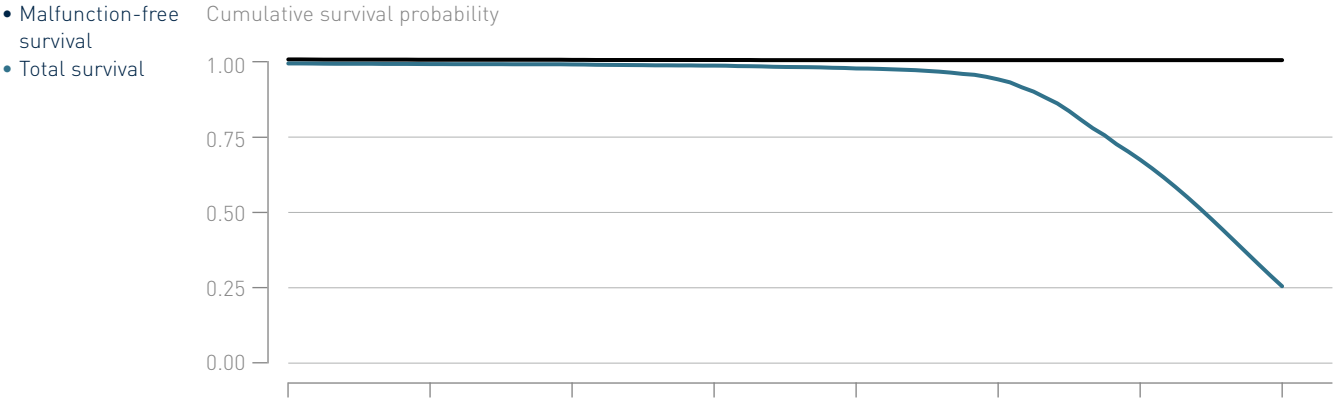
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.7	99.7	99.6	98.9	98.0	96.0
CI [±%]	-	0.4	0.4	0.5	0.8	1.1	1.8
Malfunction-Free [%]	100.0	99.9	99.9	99.7	99.1	98.5	97.1
CI [±%]	-	0.3	0.3	0.4	0.8	1	1.6
Sample Size	804	738	683	636	587	453	202

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

Lumax 340

Product Versions	VR, VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	27 100
Registered U.S. Implants	3 985
Estimated Active U.S. Implants	839
U.S. Normal Battery Depletions	935

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

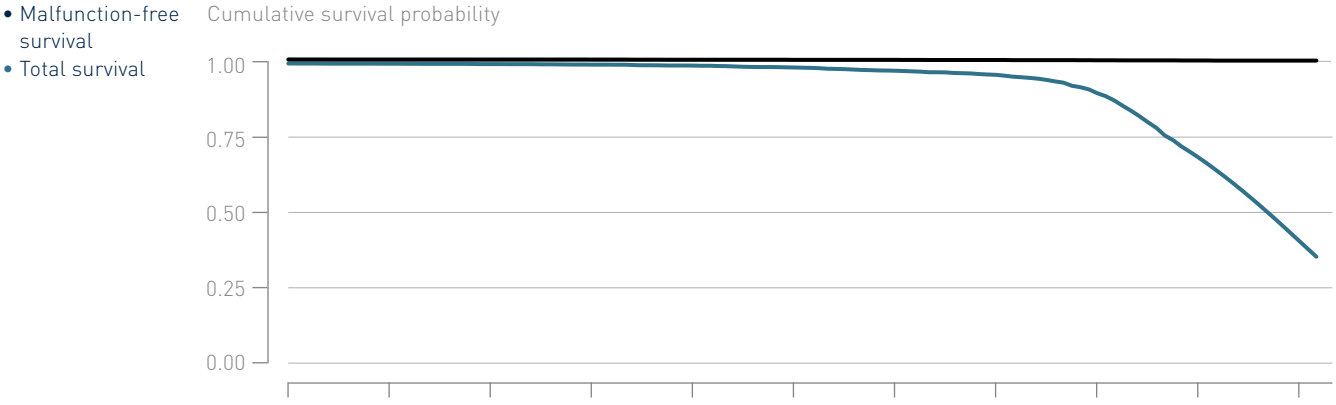


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.7	99.3	98.3	94.7	67.9	25.6
CI [±%]	-	0.1	0.2	0.3	0.4	0.8	1.9	4.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3 985	3 616	3 393	3 155	2 908	2 550	1 506	272

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	20000
Registered U.S. Implants	4544
Estimated Active U.S. Implants	1330
U.S. Normal Battery Depletions	915

	Quantity	Rate
U.S. Confirmed Malfunctions	17	0.37%
Therapy Compromised	13	0.29%
Therapy Available	4	0.09%

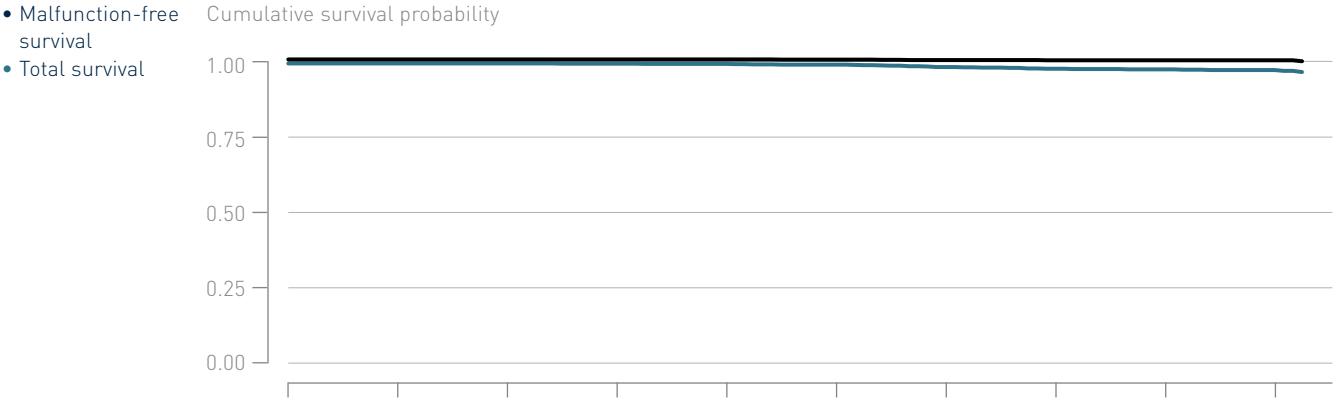


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.9	99.8	99.6	99.3	98.6	97.5	96.2	90.0	68.5	40.4
CI [±%]	-	0.1	0.1	0.2	0.3	0.4	0.5	0.7	1.1	1.8	2.6
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.8	99.8	99.7	99.5	99.4	99.4
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3
Sample Size	4544	4191	3897	3623	3372	3134	2880	2646	2308	1571	519

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 U.S. Implants	1 574
Estimated Active U.S. Implants	848
U.S. Normal Battery Depletions	23

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.32%
Therapy Compromised	3	0.19%
Therapy Available	2	0.13%

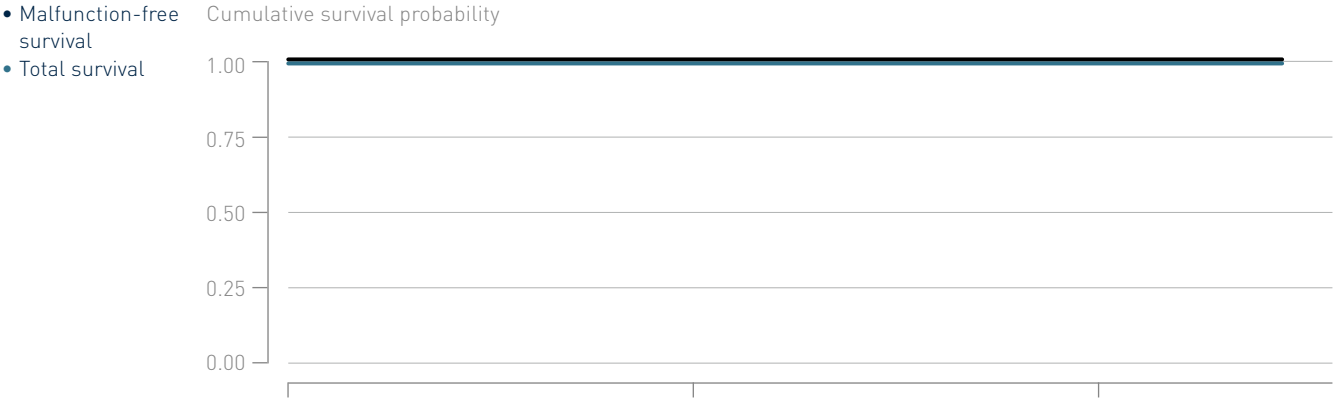


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	100.0	99.9	99.8	99.6	98.7	98.1	97.9	97.6
CI [±%]	-	< 0.1	< 0.1	0.2	0.2	0.4	0.7	0.8	0.9	0.9
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.7	99.6	99.6	99.6
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.4
Sample Size	1 574	1 446	1 346	1 253	1 159	1 079	995	925	848	383

Rivacor 7 DF4

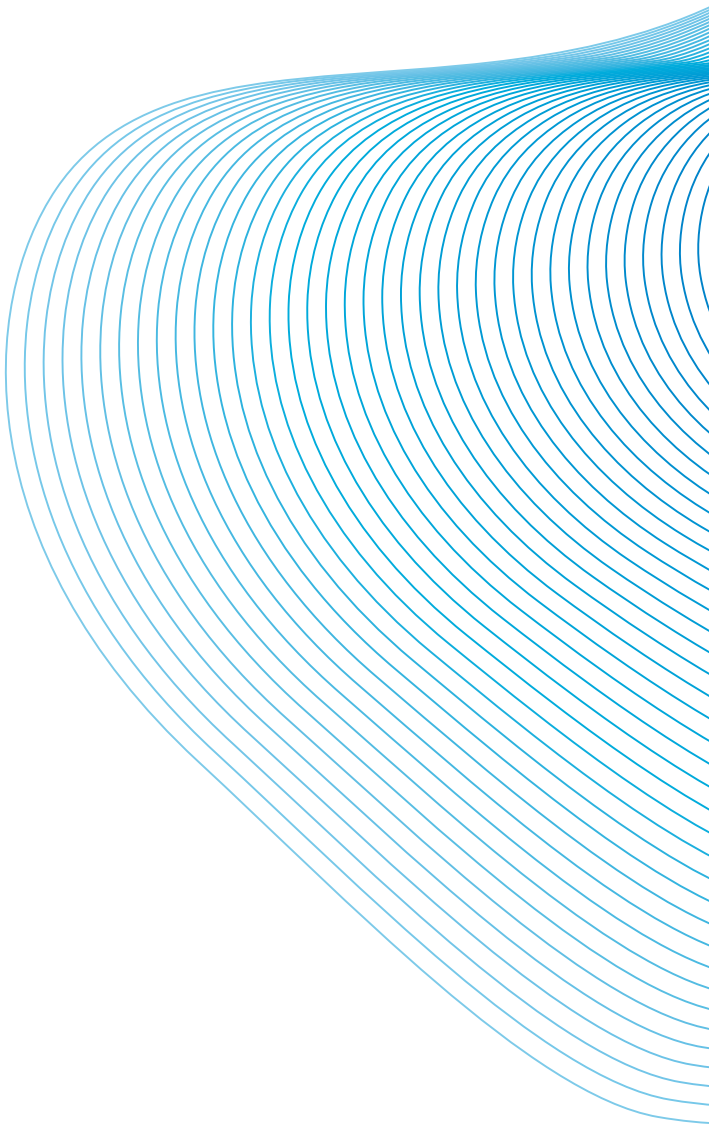
Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	4 210
Registered U.S. Implants	1 202
Estimated Active U.S. Implants	1 100
U.S. Normal Battery Depletions	0

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



Years after implant	0	1	2
Total [%]	100	100	100
CI [±%]	-	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100
CI [±%]	-	< 0.1	< 0.1
Sample Size	1 202	759	333

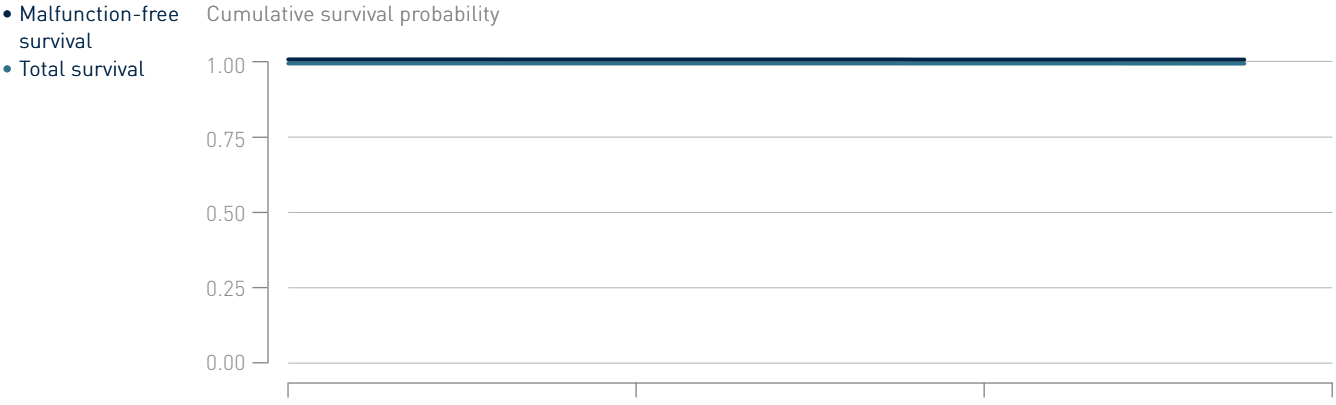
Performance of BIOTRONIK ICDs



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	14 500
Registered U.S. Implants	10 609
Estimated Active U.S. Implants	9 600
U.S. Normal Battery Depletions	6

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.02%
Therapy Compromised	2	0.02%
Therapy Available	0	0.00%

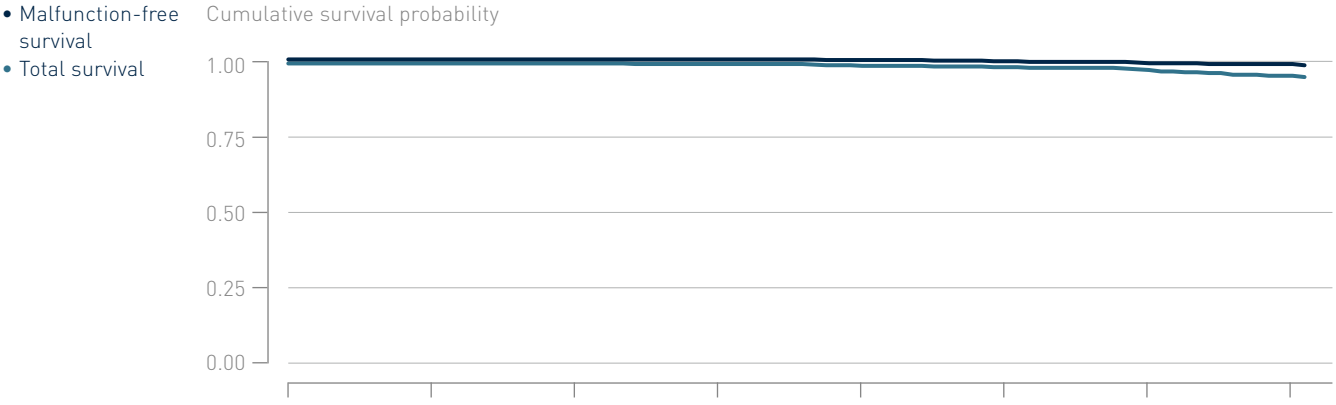


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	< 0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	< 0.1	0.1
Sample Size	10 609	6 372	2 528

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	2000
Registered U.S. Implants	614
Estimated Active U.S. Implants	359
U.S. Normal Battery Depletions	13

	Quantity	Rate
U.S. Confirmed Malfunctions*	8	1.30%
Therapy Compromised	3	0.49%
Therapy Available	5	0.81%



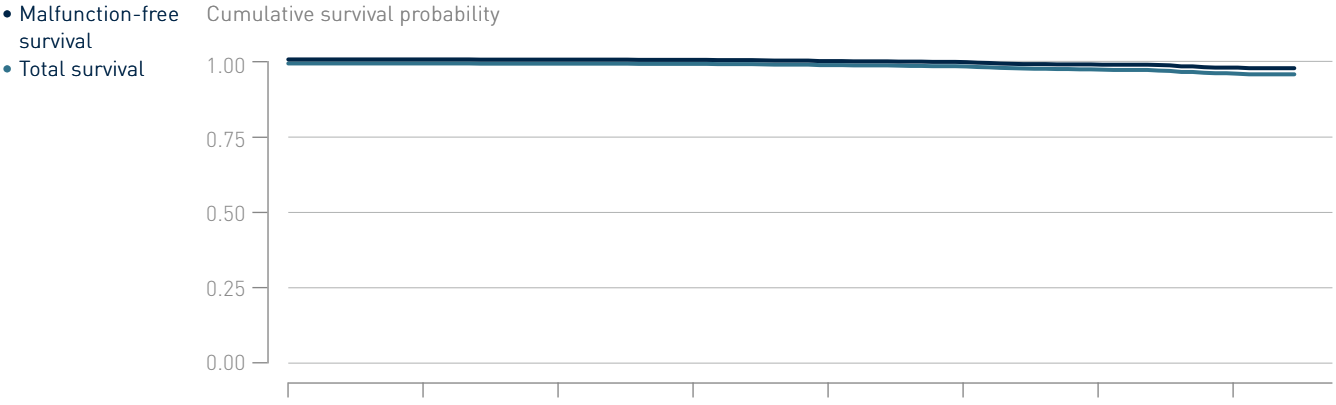
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	100.0	99.8	99.2	98.7	97.7	95.7
CI [±%]	-	< 0.1	< 0.1	0.4	0.8	1	1.4	2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.8	99.3	98.6	98.3
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.8	1.1	1.3
Sample Size	614	564	529	486	451	419	383	228

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

Iforia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	4 780
Registered U.S. Implants	1 461
Estimated Active U.S. Implants	881
U.S. Normal Battery Depletions	13

	Quantity	Rate
U.S. Confirmed Malfunctions*	30	2.05%
Therapy Compromised	13	0.89%
Therapy Available	17	1.16%



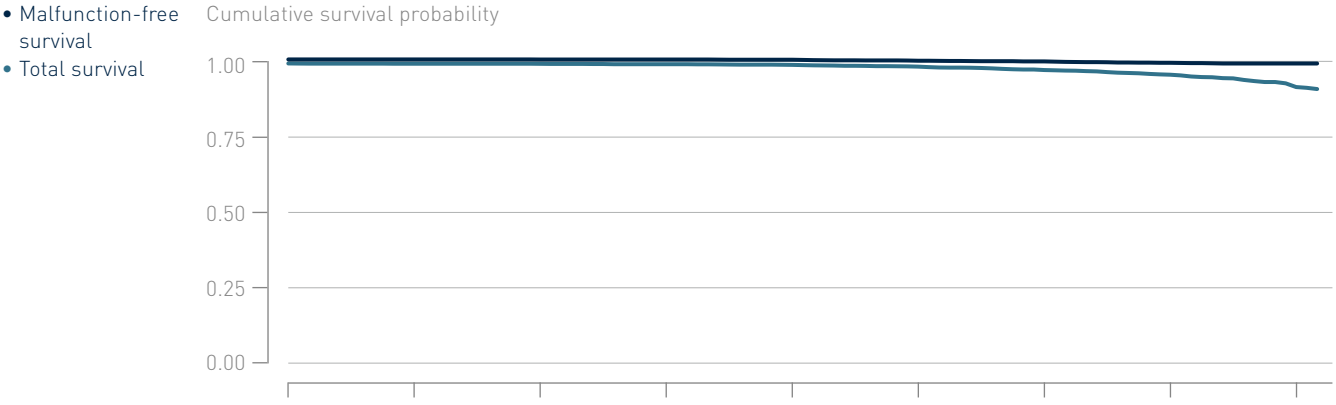
Years after implant	0	1	2	3	4	5	6	7
Total [%]	99.9	99.9	99.9	99.8	99.3	98.9	97.7	96.3
CI [±%]	-	0.1	0.2	0.3	0.5	0.6	0.9	1.2
Malfunction-Free [%]	99.9	99.9	99.9	99.8	99.3	98.9	98.0	97.0
CI [±%]	-	0.1	0.2	0.3	0.5	0.6	0.8	1.1
Sample Size	1 461	1 358	1 271	1 184	1 092	1 003	905	517

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

Ilesto 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 110
Registered U.S. Implants	3 487
Estimated Active U.S. Implants	1 940
U.S. Normal Battery Depletions	123

	Quantity	Rate
U.S. Confirmed Malfunctions*	34	0.98%
Therapy Compromised	23	0.66%
Therapy Available	11	0.32%



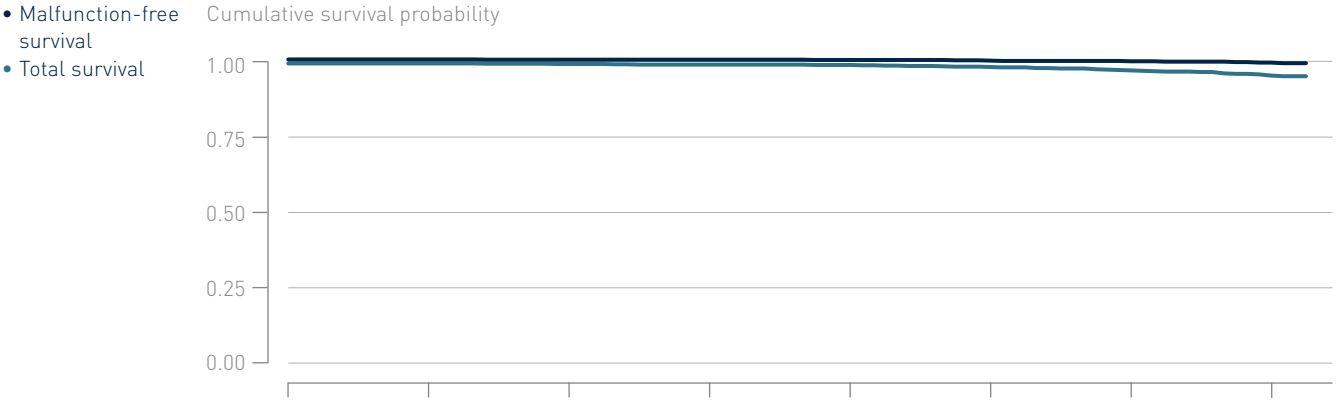
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.9	99.9	99.7	99.5	98.9	97.8	96.2	91.9
CI [±%]	-	0.1	0.1	0.2	0.3	0.4	0.6	0.8	1.6
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.5	99.2	98.7	98.4
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.3	0.3	0.5	0.5
Sample Size	3 487	3 218	2 995	2 784	2 586	2 387	2 196	1 704	513

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

Ilesto 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jul 2013
Worldwide Distributed Devices	3 730
Registered U.S. Implants	1 147
Estimated Active U.S. Implants	690
U.S. Normal Battery Depletions	26

	Quantity	Rate
U.S. Confirmed Malfunctions*	10	0.87%
Therapy Compromised	5	0.44%
Therapy Available	5	0.44%



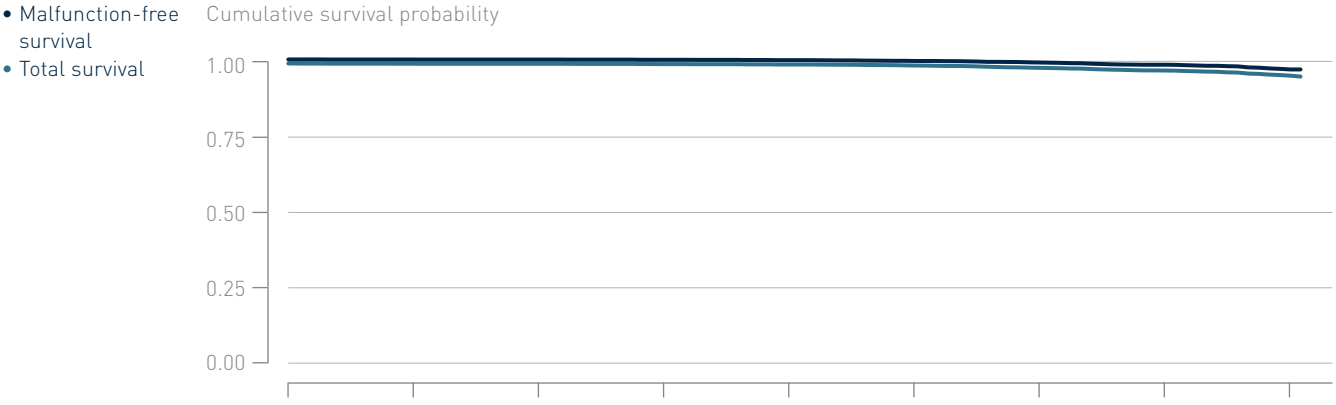
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.8	99.6	99.5	98.8	97.6	95.8
CI [±%]	-	< 0.1	0.3	0.4	0.5	0.7	1.1	1.5
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.8	99.5	99.3	98.8
CI [±%]	-	< 0.1	0.2	0.2	0.3	0.5	0.6	0.8
Sample Size	1 147	1 059	983	912	851	792	711	470

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

Ilesto 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	2 680
U.S. Normal Battery Depletions	57

	Quantity	Rate
U.S. Confirmed Malfunctions*	80	1.69%
Therapy Compromised	38	0.81%
Therapy Available	42	0.89%



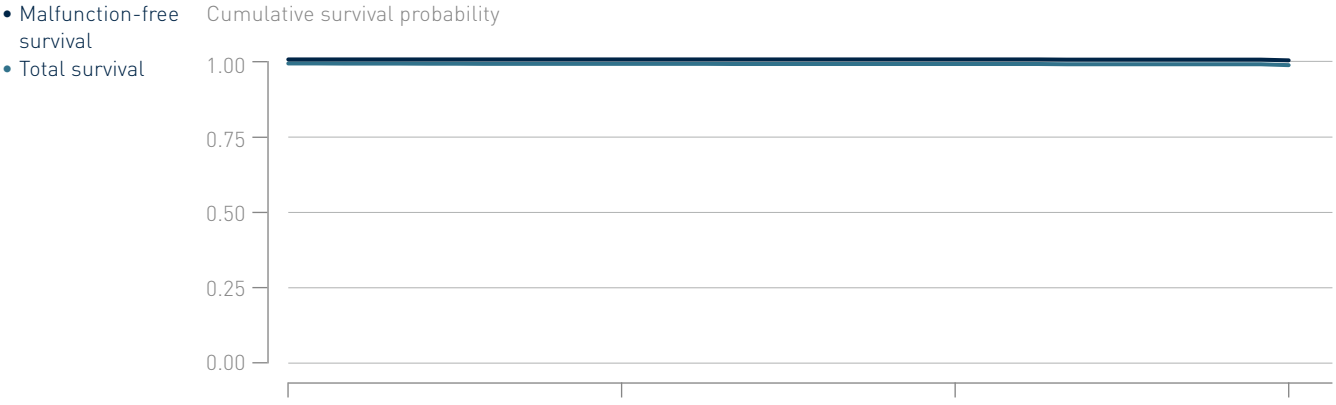
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.9	99.9	99.8	99.6	99.3	98.5	97.5	95.7
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.4	0.5	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.7	99.4	98.9	98.1	96.4
CI [±%]	-	< 0.1	0.1	0.1	0.2	0.2	0.4	0.5	1
Sample Size	4 720	4 368	4 087	3 826	3 553	3 302	3 031	2 440	451

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

Ilivia 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	3390
Registered U.S. Implants	1628
Estimated Active U.S. Implants	1380
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions*	2	0.12%
Therapy Compromised	0	0.00%
Therapy Available	2	0.12%



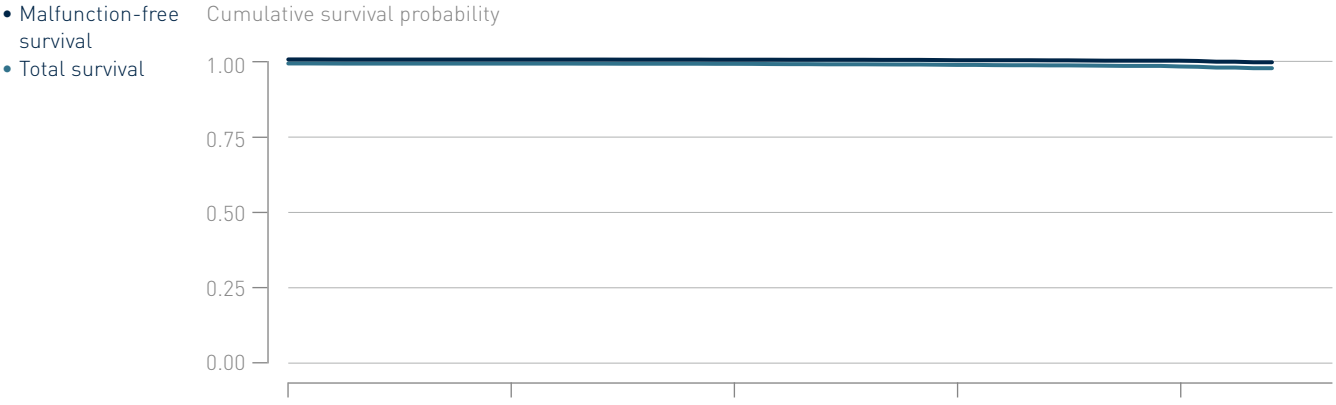
Years after implant	0	1	2	3
Total [%]	100.0	99.8	99.7	99.2
CI [±%]	-	0.2	0.3	0.9
Malfunction-Free [%]	100.0	100.0	100.0	99.5
CI [±%]	-	< 0.1	< 0.1	0.9
Sample Size	1628	1490	1123	236

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

Ilivia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Aug 2016
Worldwide Distributed Devices	8570
Registered U.S. Implants	3994
Estimated Active U.S. Implants	3020
U.S. Normal Battery Depletions	15

	Quantity	Rate
U.S. Confirmed Malfunctions*	18	0.45%
Therapy Compromised	7	0.18%
Therapy Available	11	0.28%



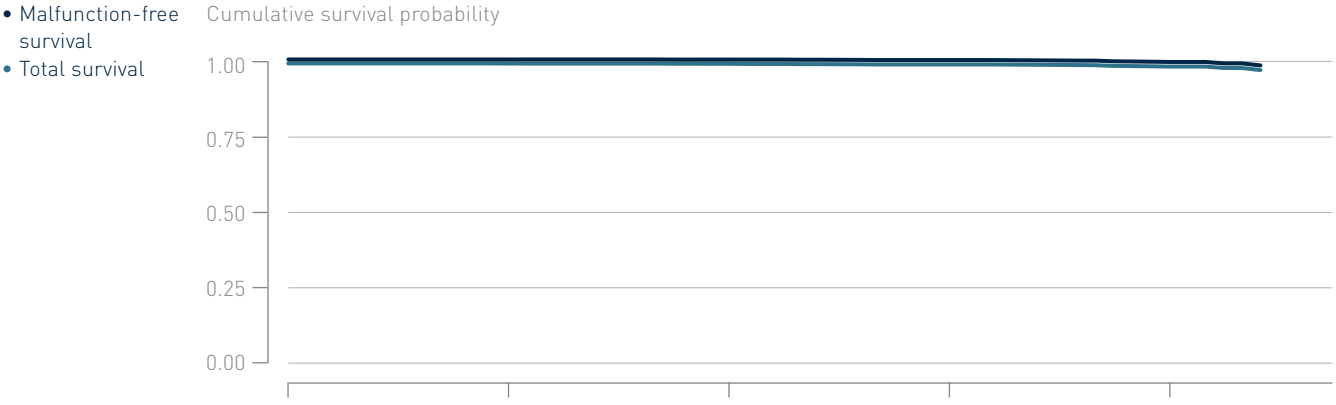
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.8	99.4	98.8
CI [±%]	-	0.1	0.1	0.3	0.5
Malfunction-Free [%]	100.0	99.9	99.9	99.6	99.5
CI [±%]	-	0.1	0.1	0.2	0.3
Sample Size	3994	3668	3286	2564	937

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

Intica 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 850
Registered U.S. Implants	4 628
Estimated Active U.S. Implants	3 610
U.S. Normal Battery Depletions	14

	Quantity	Rate
U.S. Confirmed Malfunctions*	25	0.54%
Therapy Compromised	2	0.04%
Therapy Available	23	0.50%



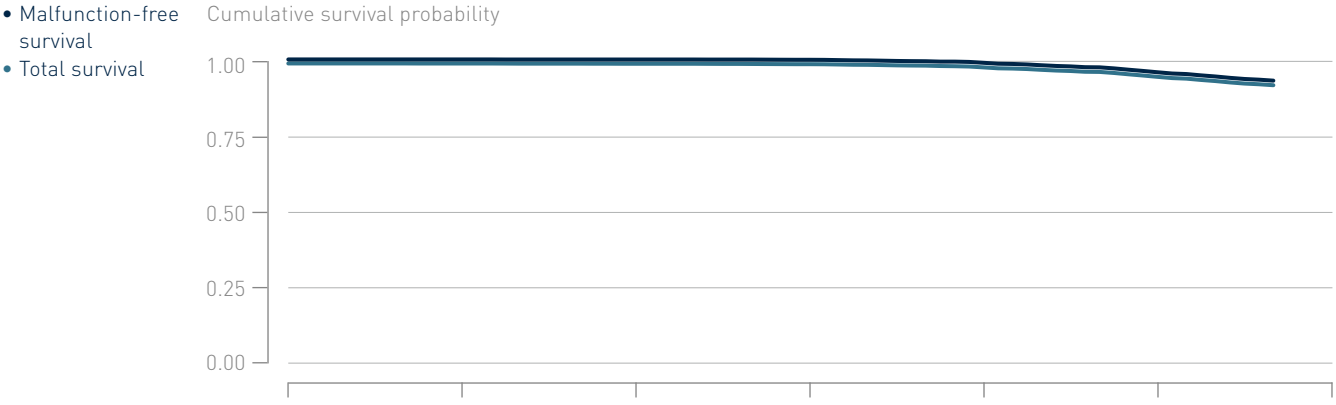
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.6	98.9
CI [±%]	-	< 0.1	0.1	0.2	0.5
Malfunction-Free [%]	100.0	100.0	100.0	99.8	99.1
CI [±%]	-	< 0.1	0.1	0.2	0.4
Sample Size	4 628	4 270	3 854	3 096	1 057

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

Inventra 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	45
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 790
Registered U.S. Implants	5 450
Estimated Active U.S. Implants	3 820
U.S. Normal Battery Depletions	32

	Quantity	Rate
U.S. Confirmed Malfunctions*	119	2.18%
Therapy Compromised	34	0.62%
Therapy Available	85	1.56%



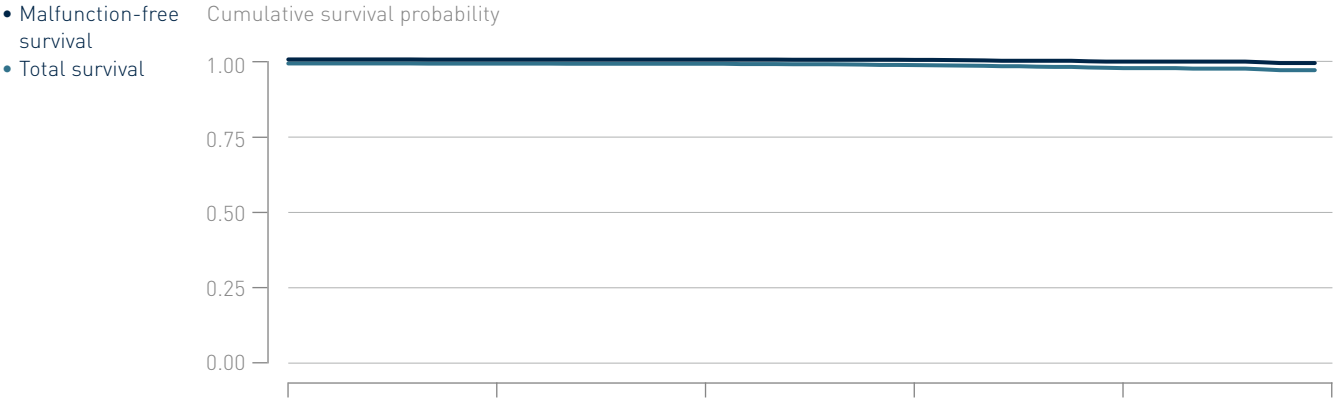
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.9	99.7	98.6	95.4
CI [±%]	-	< 0.1	0.1	0.1	0.4	0.9
Malfunction-Free [%]	100.0	100.0	100.0	99.9	98.8	95.6
CI [±%]	-	< 0.1	< 0.1	0.1	0.4	0.9
Sample Size	5 450	5 009	4 491	3 825	2 637	1 256

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

Iperia 7

Product Versions	DR-T
NBG Codes	VDE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 710
Registered U.S. Implants	1 965
Estimated Active U.S. Implants	1 430
U.S. Normal Battery Depletions	21

	Quantity	Rate
U.S. Confirmed Malfunctions*	13	0.66%
Therapy Compromised	4	0.20%
Therapy Available	9	0.46%



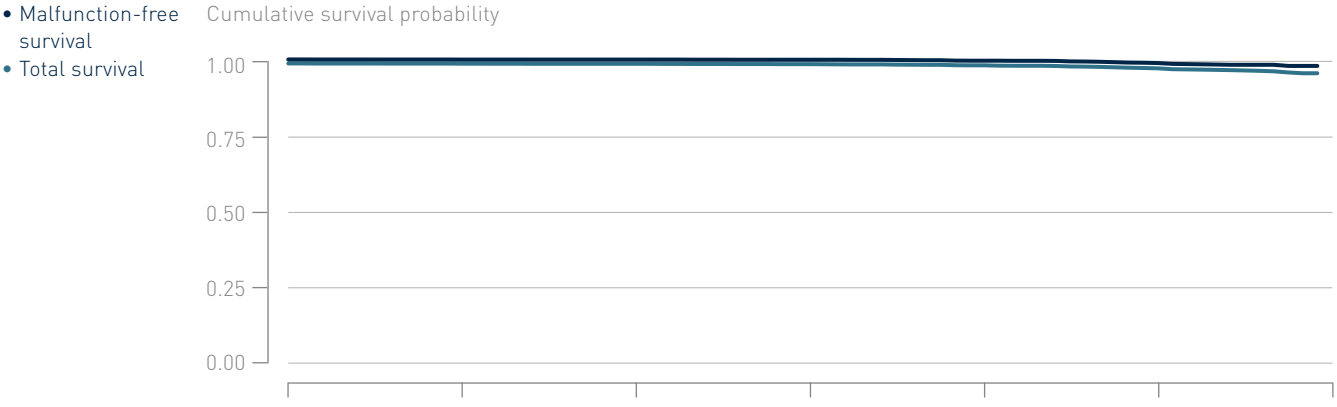
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.9	99.4	98.3
CI [±%]	-	0.1	0.2	0.4	0.7
Malfunction-Free [%]	100.0	99.9	99.9	99.8	99.1
CI [±%]	-	0.1	0.1	0.2	0.5
Sample Size	1 965	1 818	1 693	1 539	783

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

Iperia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	7 510
Registered U.S. Implants	4 110
Estimated Active U.S. Implants	2 760
U.S. Normal Battery Depletions	30

	Quantity	Rate
U.S. Confirmed Malfunctions*	45	1.09%
Therapy Compromised	9	0.22%
Therapy Available	36	0.88%



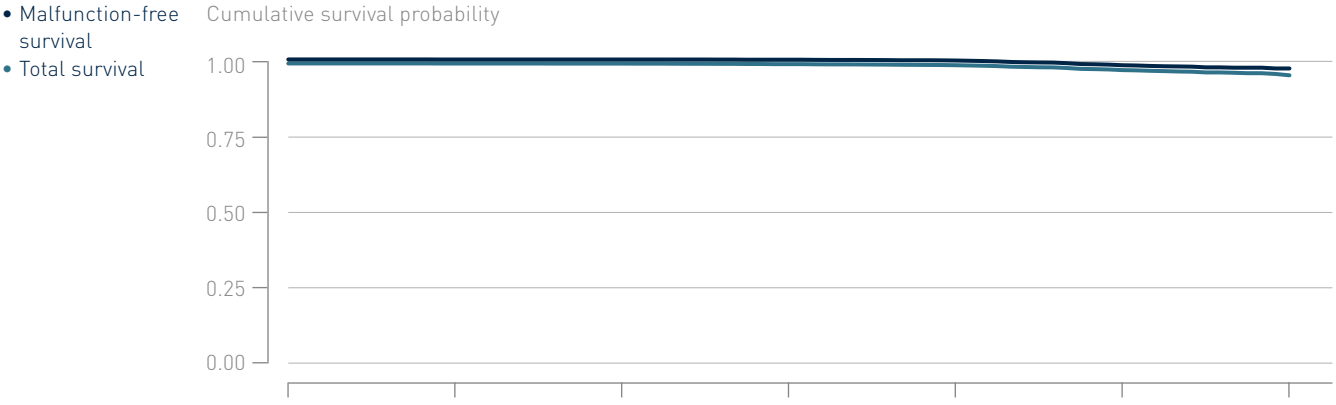
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.9	99.8	99.3	98.3
CI [±%]	-	0.1	0.1	0.2	0.3	0.5
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.5	98.7
CI [±%]	-	0.1	0.1	0.1	0.2	0.5
Sample Size	4 110	3 788	3 500	3 147	2 616	1 722

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

Iperia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	6 540
Registered U.S. Implants	4 836
Estimated Active U.S. Implants	3 380
U.S. Normal Battery Depletions	37

	Quantity	Rate
U.S. Confirmed Malfunctions*	77	1.59%
Therapy Compromised	17	0.35%
Therapy Available	60	1.24%



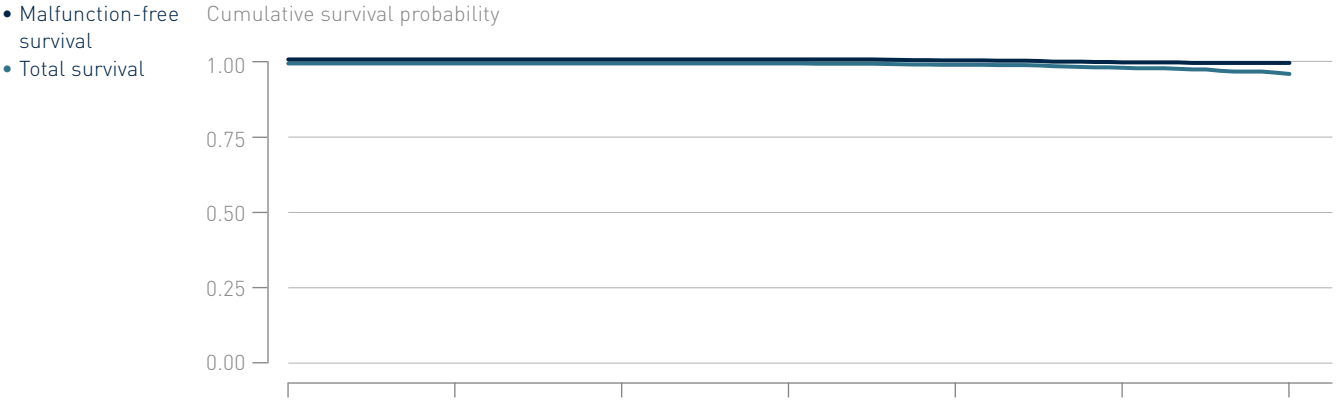
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.8	99.4	97.7	95.8
CI [±%]	-	< 0.1	0.1	0.2	0.3	0.6	1.3
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.6	97.9	96.8
CI [±%]	-	< 0.1	< 0.1	0.1	0.2	0.5	0.9
Sample Size	4 836	4 495	4 191	3 856	3 223	2 203	200

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

Itrevia 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 170
Registered U.S. Implants	1 416
Estimated Active U.S. Implants	940
U.S. Normal Battery Depletions	15

	Quantity	Rate
U.S. Confirmed Malfunctions*	12	0.85%
Therapy Compromised	5	0.35%
Therapy Available	7	0.49%



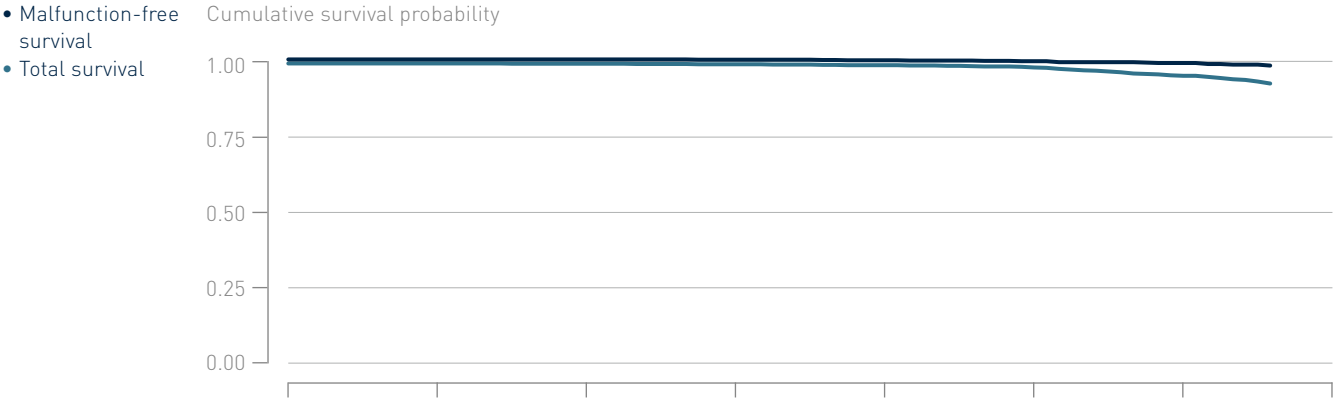
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	100.0	99.5	98.5	96.3
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.8	1.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.6	98.8	98.6
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.7	0.8
Sample Size	1 416	1 298	1 205	1 123	972	617	211

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

Itrevia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2340
Registered U.S. Implants	1268
Estimated Active U.S. Implants	765
U.S. Normal Battery Depletions	40

	Quantity	Rate
U.S. Confirmed Malfunctions*	15	1.18%
Therapy Compromised	6	0.47%
Therapy Available	9	0.71%



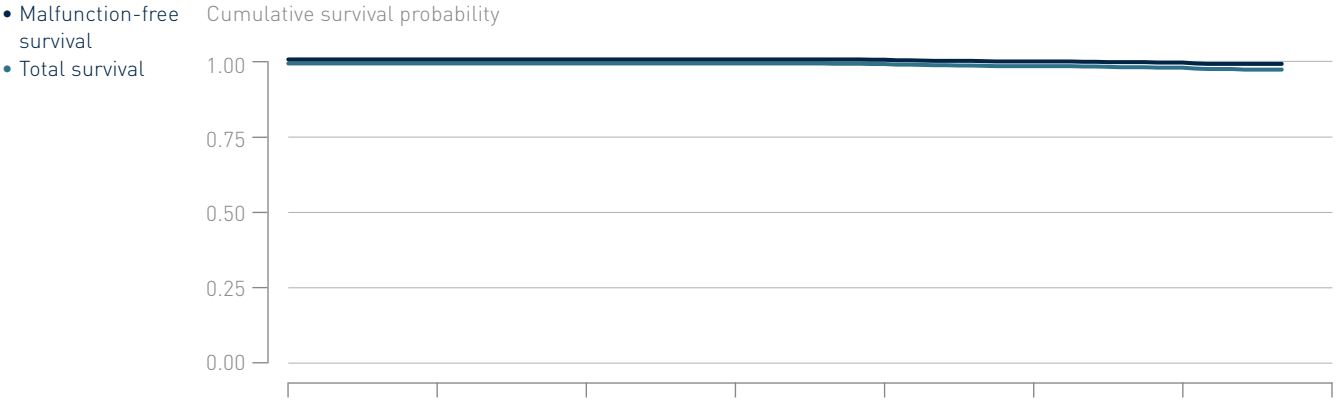
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.7	99.4	98.6	95.7
CI [±%]	-	< 0.1	0.2	0.3	0.5	0.8	1.4
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.7	99.4	98.7
CI [±%]	-	< 0.1	< 0.1	0.2	0.4	0.5	0.8
Sample Size	1268	1163	1070	994	921	848	570

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

Itrevia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 750
Registered U.S. Implants	1 247
Estimated Active U.S. Implants	794
U.S. Normal Battery Depletions	6

	Quantity	Rate
U.S. Confirmed Malfunctions*	13	1.04%
Therapy Compromised	6	0.48%
Therapy Available	7	0.56%



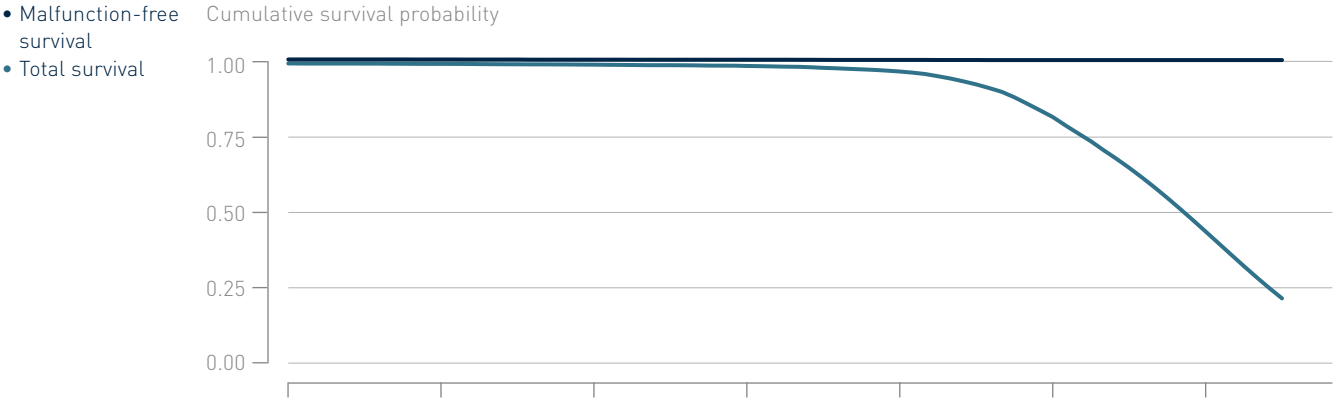
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	100.0	99.8	99.0	98.4
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.3	0.6	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.2	98.8
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.2	0.6	0.7
Sample Size	1 247	1 147	1 069	995	925	820	602

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

Lumax 340

Product Versions	DR, DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26400
Registered U.S. Implants	8219
Estimated Active U.S. Implants	1560
U.S. Normal Battery Depletions	2156

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

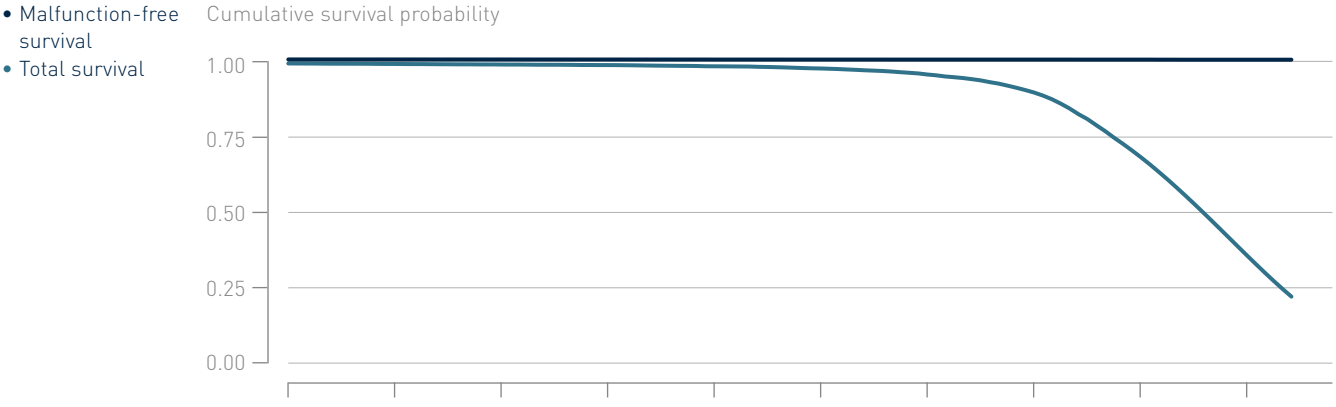


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.6	99.2	97.3	82.2	44.0
CI [±%]	-	0.1	0.1	0.2	0.4	1	1.5
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8219	7512	6991	6439	5873	4358	1812

Lumax 540

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered U.S. Implants	11 511
Estimated Active U.S. Implants	2 810
U.S. Normal Battery Depletions	2 910

	Quantity	Rate
U.S. Confirmed Malfunctions	23	0.20%
Therapy Compromised	13	0.11%
Therapy Available	10	0.09%

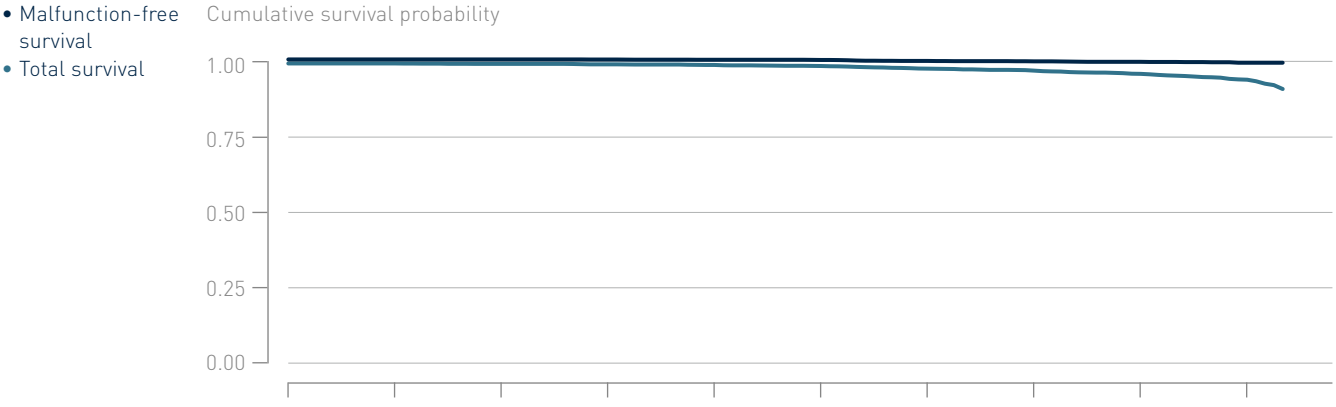


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.6	99.4	99.0	98.3	96.3	90.2	68.7	35.7
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.4	0.7	1.1	1.4
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.7
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	11 511	10 617	9 875	9 165	8 478	7 830	7 153	6 212	4 327	1 843

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	7980
Registered U.S. Implants	3813
Estimated Active U.S. Implants	2040
U.S. Normal Battery Depletions	120

	Quantity	Rate
U.S. Confirmed Malfunctions	29	0.76%
Therapy Compromised	17	0.45%
Therapy Available	12	0.31%

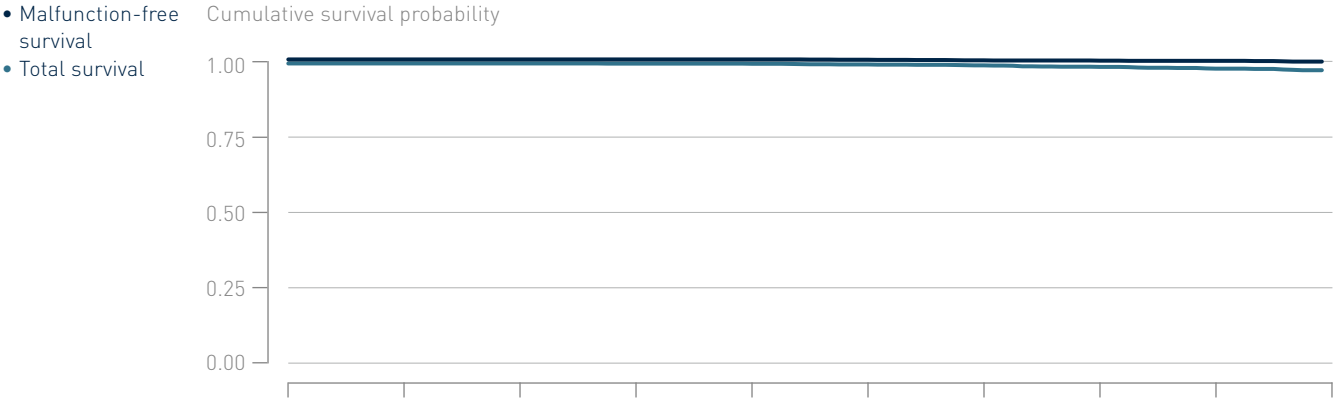


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	99.9	99.7	99.5	99.1	98.2	97.5	96.4	94.4
CI [±%]	-	< 0.1	0.1	0.2	0.3	0.3	0.5	0.6	0.7	1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.8	99.4	99.2	99.0	98.7
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.5
Sample Size	3813	3535	3291	3052	2838	2624	2420	2225	1960	874

Lumax 740 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	May 2012
CE Market Release	Nov 2011
Worldwide Distributed Devices	4 560
Registered U.S. Implants	2 224
Estimated Active U.S. Implants	1 280
U.S. Normal Battery Depletions	24

	Quantity	Rate
U.S. Confirmed Malfunctions	12	0.54%
Therapy Compromised	6	0.27%
Therapy Available	6	0.27%

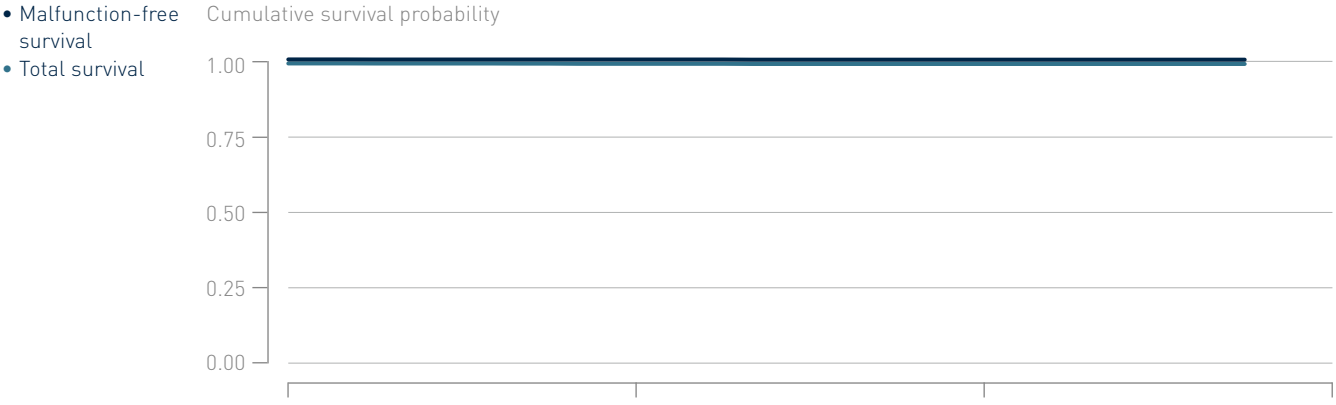


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	100.0	99.9	99.9	99.6	99.3	98.7	98.1
CI [±%]	-	< 0.1	< 0.1	0.1	0.2	0.3	0.4	0.6	0.7
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.6	99.5	99.4
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4
Sample Size	2 224	2 059	1 922	1 784	1 666	1 546	1 440	1 320	1 166

Rivacor 7 DF4

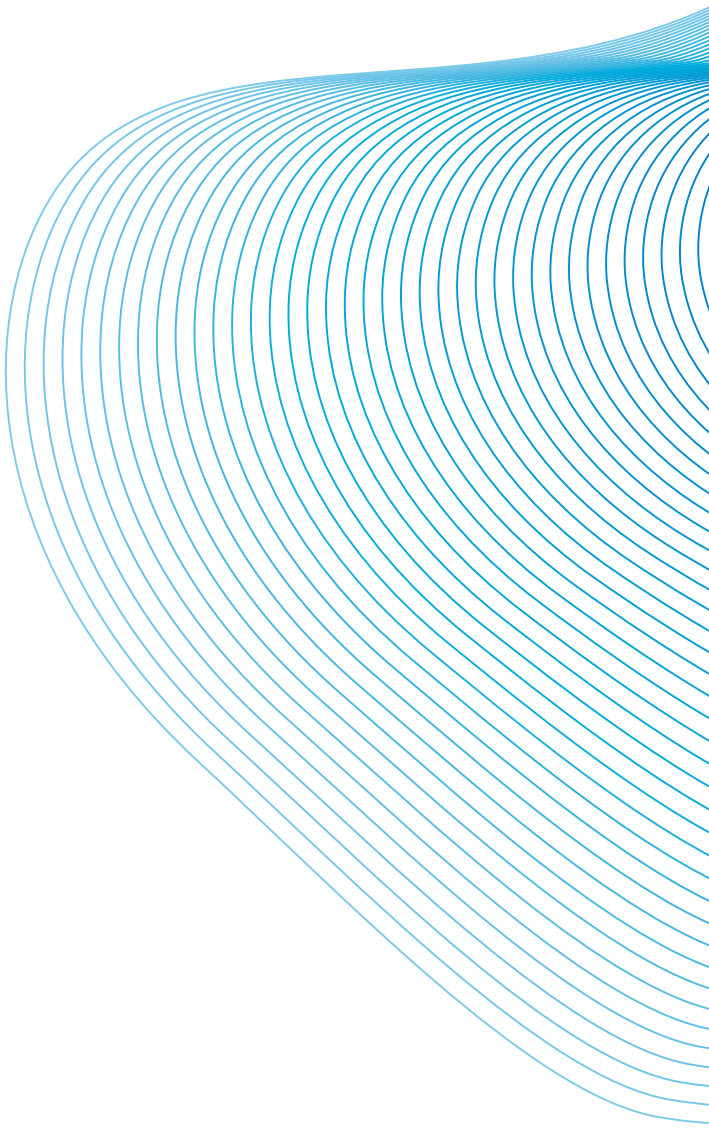
Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	11 100
Registered U.S. Implants	5 976
Estimated Active U.S. Implants	5 470
U.S. Normal Battery Depletions	3

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.03%
Therapy Compromised	2	0.03%
Therapy Available	0	0.00%



Years after implant	0	1	2
Total [%]	100.0	99.9	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	-	< 0.1	0.1
Sample Size	5 976	3 505	1 370

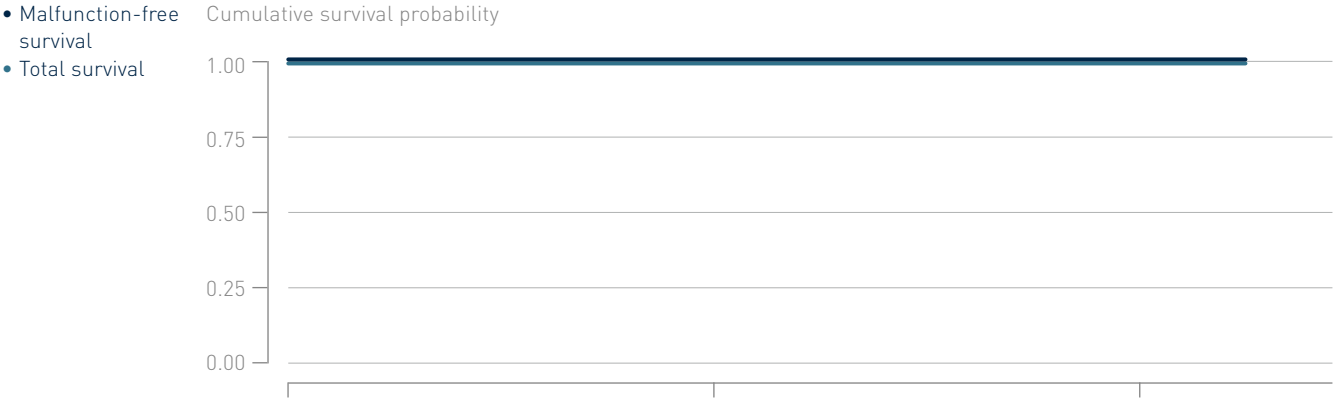
Performance of BIOTRONIK ICDs



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	12800
Registered U.S. Implants	3158
Estimated Active U.S. Implants	2730
U.S. Normal Battery Depletions	0

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

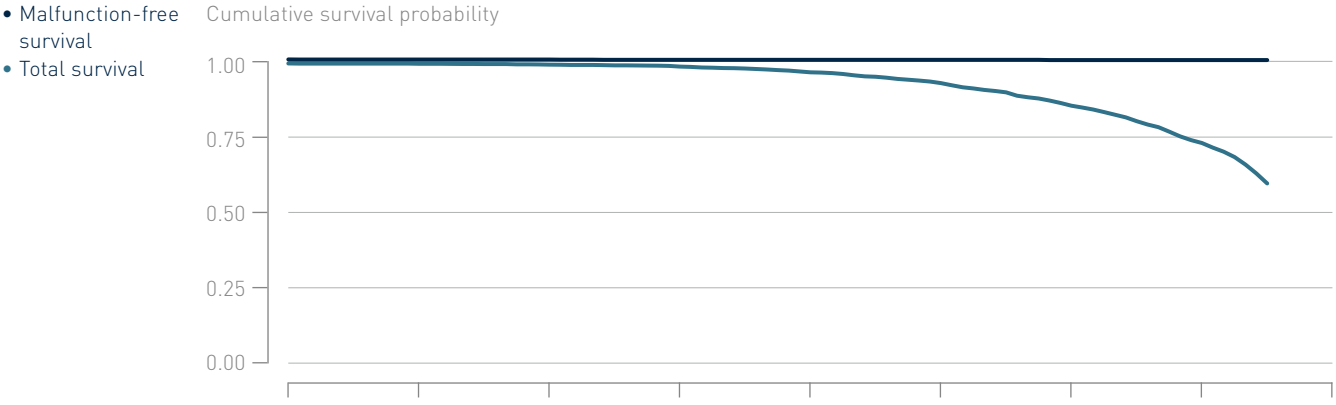


Years after implant	0	1	2
Total [%]	100.0	100.0	100.0
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	0.1	0.1
Sample Size	3158	1562	387

Ilesto 7

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 290
Registered U.S. Implants	3 841
Estimated Active U.S. Implants	1 100
U.S. Normal Battery Depletions	628

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



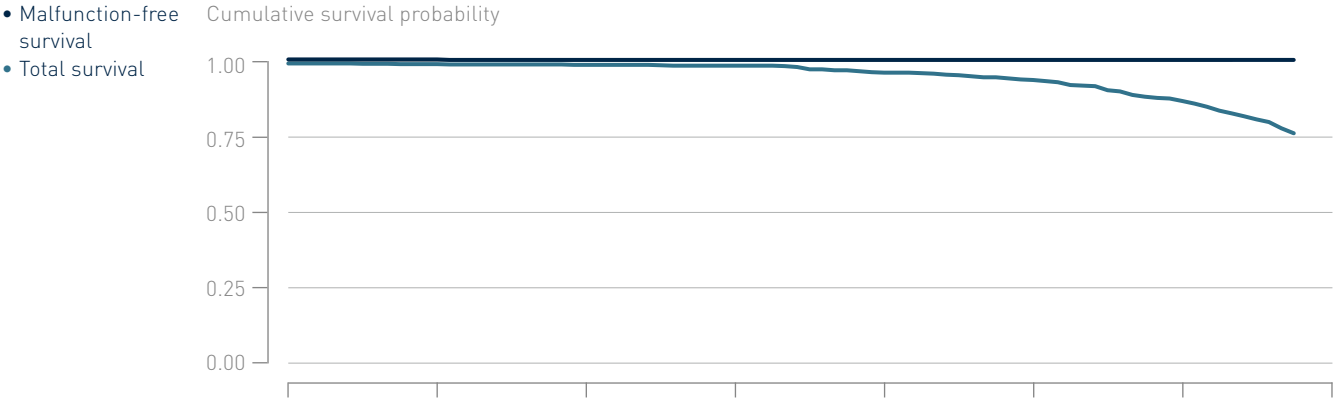
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.6	99.0	97.0	93.4	85.9	73.4
CI [±%]	-	0.1	0.2	0.4	0.6	1	1.5	2.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	3 841	3 400	3 024	2 666	2 327	1 980	1 603	982

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

Ilesto 7 DF4

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jun 2013
Worldwide Distributed Devices	2360
Registered U.S. Implants	969
Estimated Active U.S. Implants	352
U.S. Normal Battery Depletions	132

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



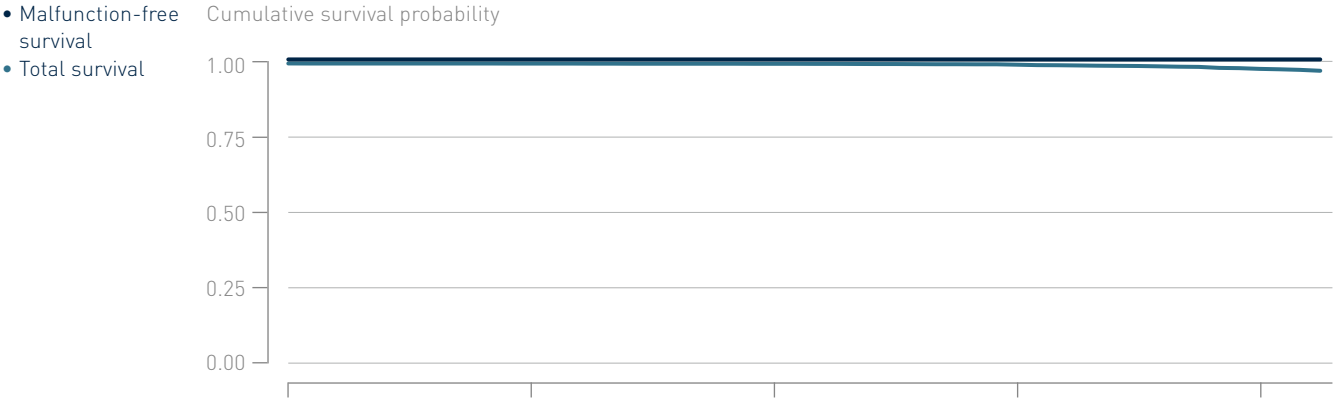
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.5	99.3	96.9	94.4	87.4
CI [±%]	-	0.3	0.5	0.6	1.3	1.8	2.8
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.2	0.2	0.2	0.2	0.2
Sample Size	969	859	767	681	595	514	428

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

Ilivia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	9 290
Registered U.S. Implants	4 777
Estimated Active U.S. Implants	3 200
U.S. Normal Battery Depletions	41

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



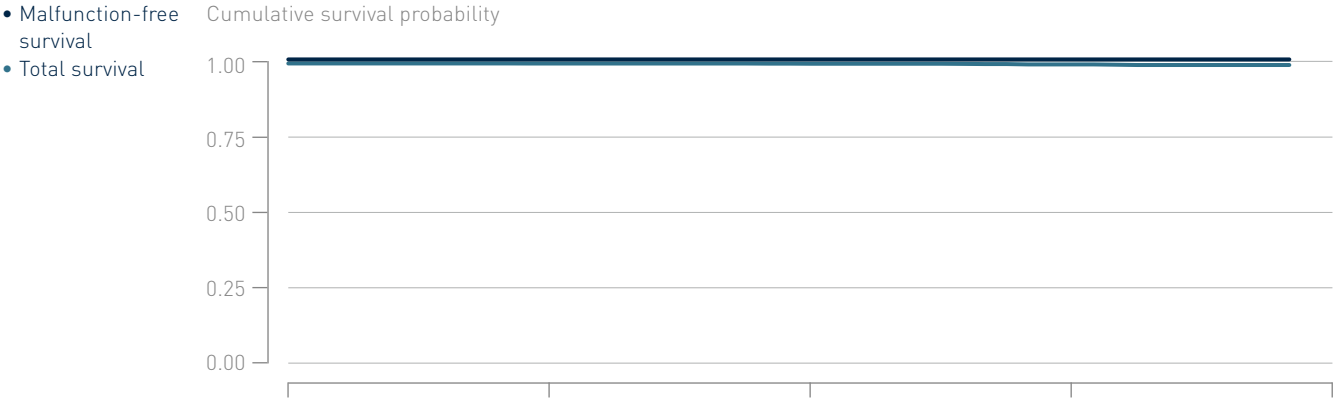
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.5	98.0
CI [±%]	-	0.1	0.1	0.2	0.7
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	4 777	4 149	3 597	2 767	770

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

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	5460
Registered U.S. Implants	2960
Estimated Active U.S. Implants	2080
U.S. Normal Battery Depletions	12

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



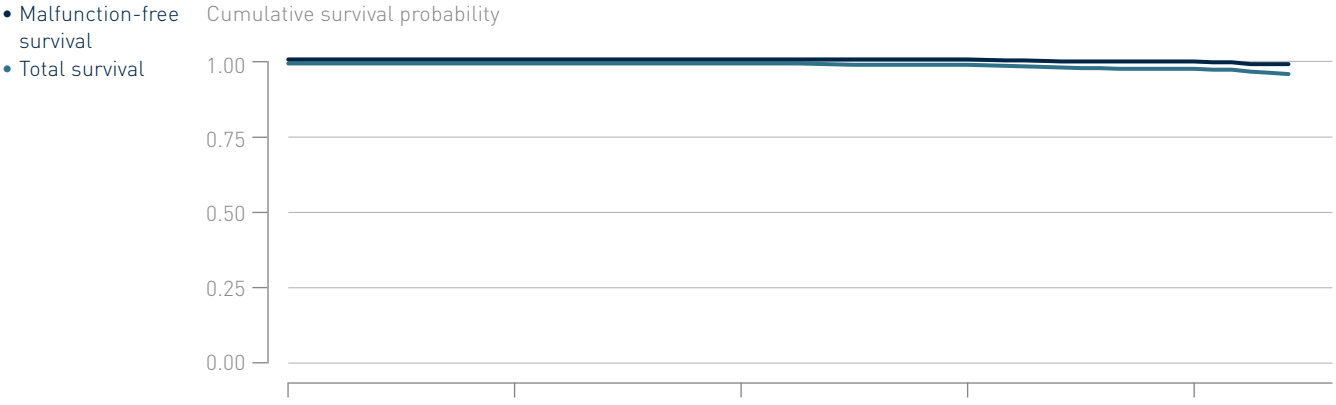
Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.8	99.5
CI [±%]	-	0.1	0.2	0.4
Malfunction-Free [%]	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	2960	2502	1860	916

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

Inventra 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	45
US Market Release	Aug 2014
CE Market Release	Jul 2014
Worldwide Distributed Devices	2 110
Registered U.S. Implants	887
Estimated Active U.S. Implants	532
U.S. Normal Battery Depletions	17

	Quantity	Rate
U.S. Confirmed Malfunctions*	8	0.90%
Therapy Compromised	1	0.11%
Therapy Available	7	0.79%



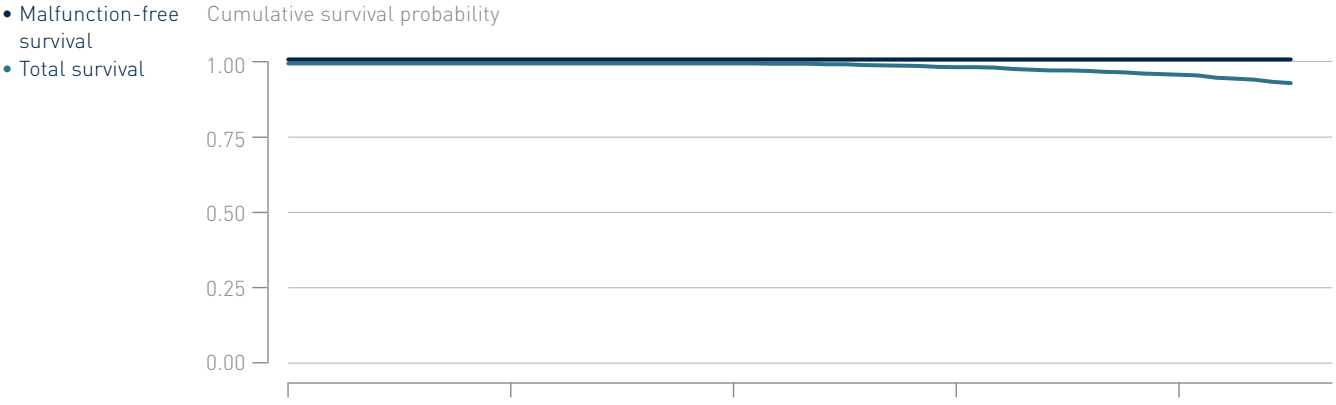
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.5	98.1
CI [±%]	-	< 0.1	< 0.1	0.5	1.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.2
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.8
Sample Size	887	760	671	561	331

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

Iperia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	3 040
Registered U.S. Implants	1 479
Estimated Active U.S. Implants	865
U.S. Normal Battery Depletions	52

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



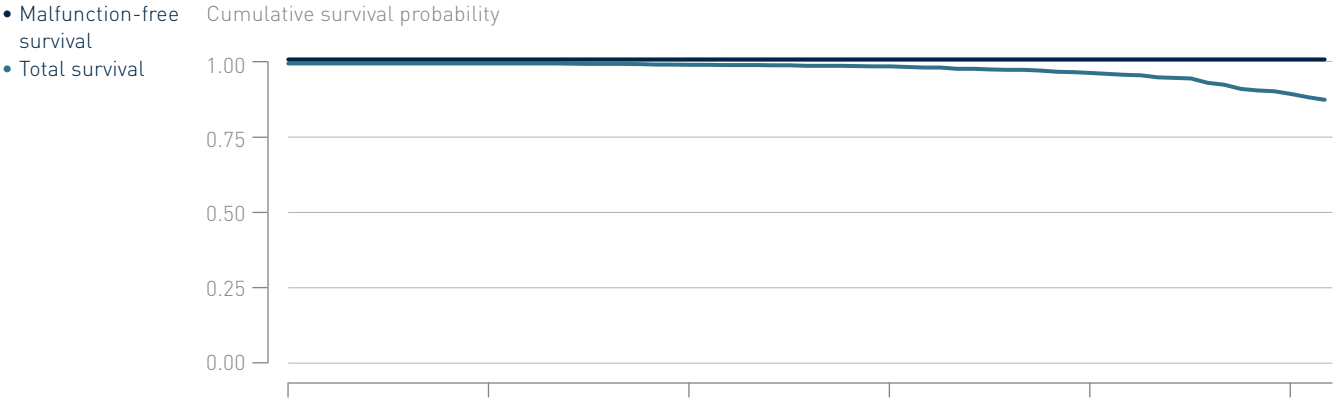
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	98.7	96.1
CI [±%]	-	< 0.1	< 0.1	0.7	1.4
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 479	1 297	1 147	905	428

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

Iperia 7 DF4

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 830
Registered U.S. Implants	1 617
Estimated Active U.S. Implants	931
U.S. Normal Battery Depletions	74

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



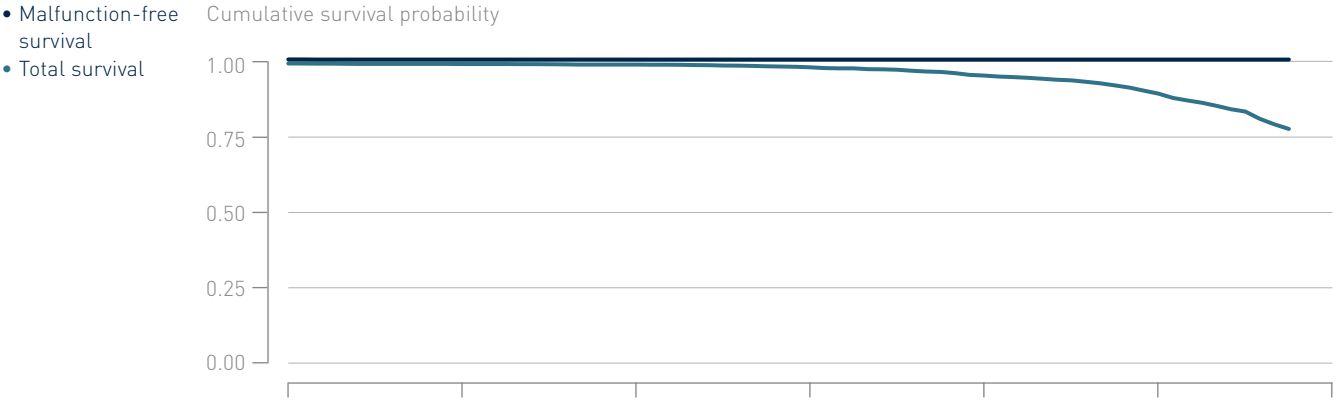
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.5	99.0	96.8	89.6
CI [±%]	-	< 0.1	0.4	0.6	1.1	2.6
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 617	1 416	1 253	1 034	690	294

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

Itrevia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	4 600
Registered U.S. Implants	3 316
Estimated Active U.S. Implants	1 580
U.S. Normal Battery Depletions	261

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



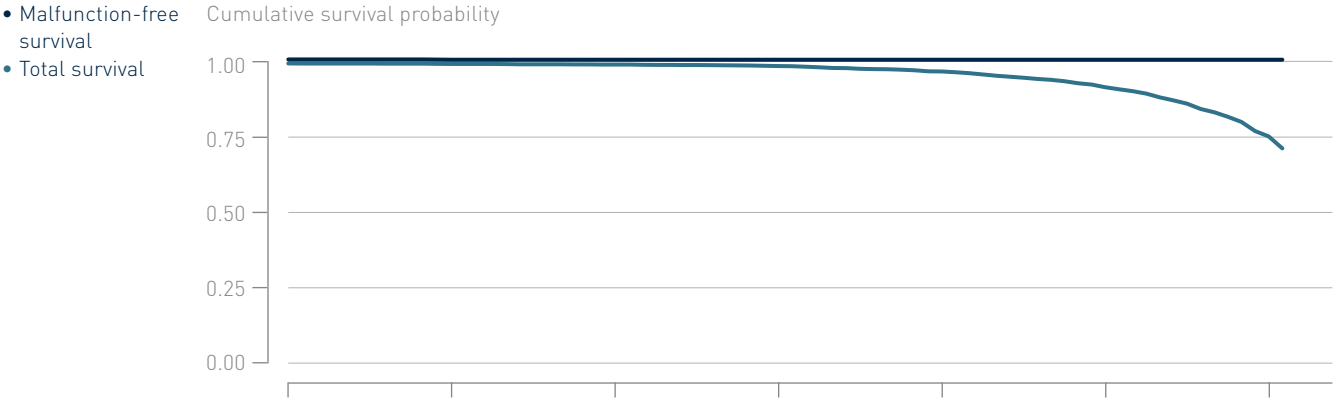
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.6	98.7	95.9	89.9
CI [±%]	-	0.2	0.2	0.4	0.8	1.5
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Sample Size	3316	2902	2573	2272	1756	1000

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

Itrevia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 680
Registered U.S. Implants	3 228
Estimated Active U.S. Implants	1 360
U.S. Normal Battery Depletions	312

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



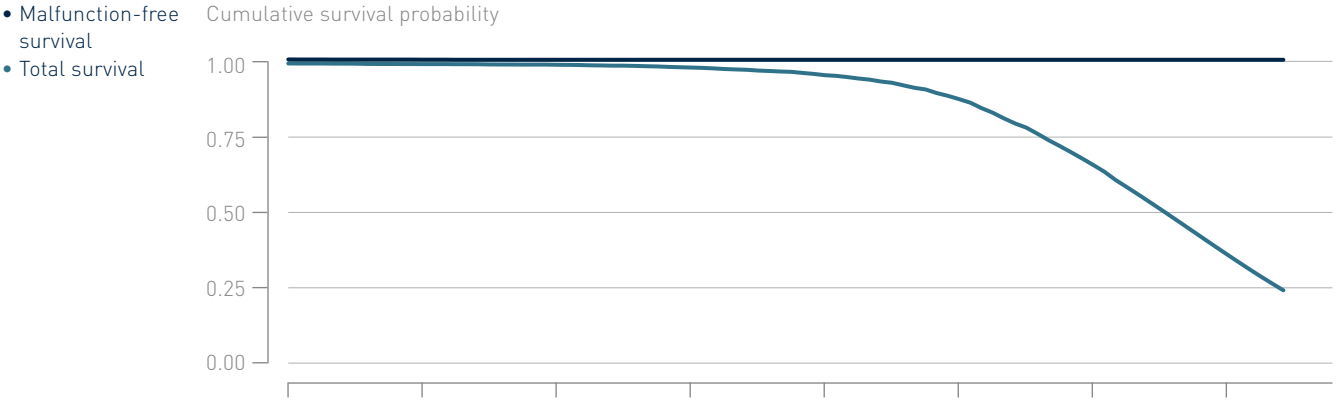
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.6	99.1	97.3	92.0	75.5
CI [±%]	-	0.1	0.2	0.4	0.7	1.2	2.8
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3 228	2 813	2 502	2 228	1 925	1 432	341

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

Lumax 340

Product Versions	HF, HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20700
Registered U.S. Implants	5310
Estimated Active U.S. Implants	462
U.S. Normal Battery Depletions	1274

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

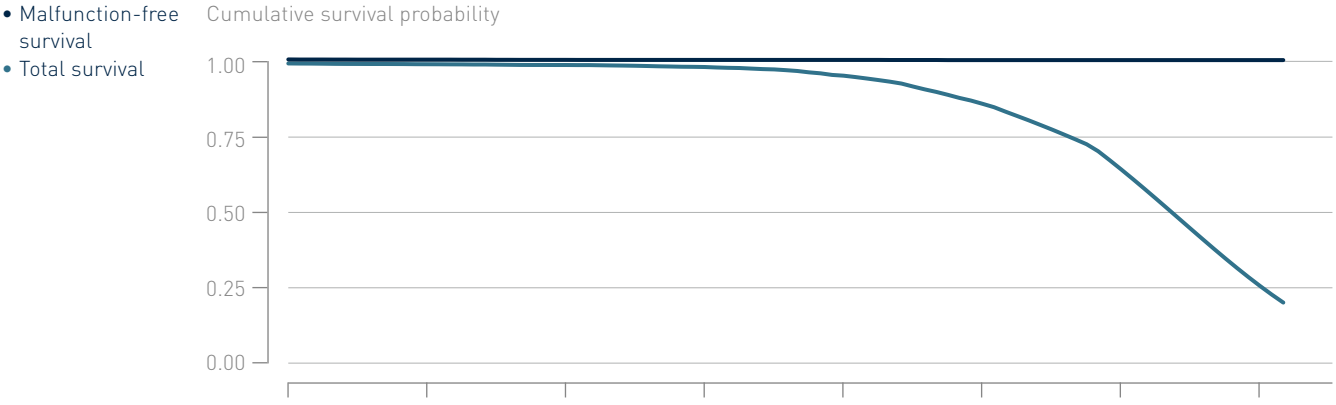


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.6	96.0	88.0	66.0	36.0
CI [±%]	-	0.1	0.2	0.4	0.6	1.1	1.9	2.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5310	4713	4208	3688	3158	2439	1472	593

Lumax 540

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	24 800
Registered U.S. Implants	8 656
Estimated Active U.S. Implants	858
U.S. Normal Battery Depletions	2 594

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

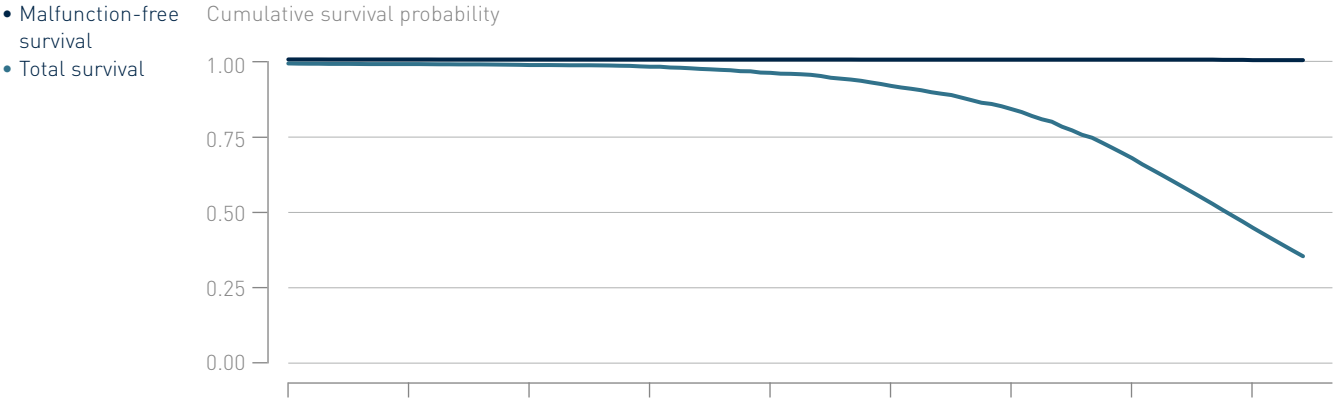


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.8	95.9	86.5	64.6	25.8
CI [±%]	-	0.1	0.2	0.3	0.5	0.9	1.4	1.9
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8 656	7 647	6 823	6 044	5 200	4 126	2 695	671

Lumax 740

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7040
Registered U.S. Implants	3410
Estimated Active U.S. Implants	589
U.S. Normal Battery Depletions	842

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.18%
Therapy Compromised	4	0.12%
Therapy Available	2	0.06%

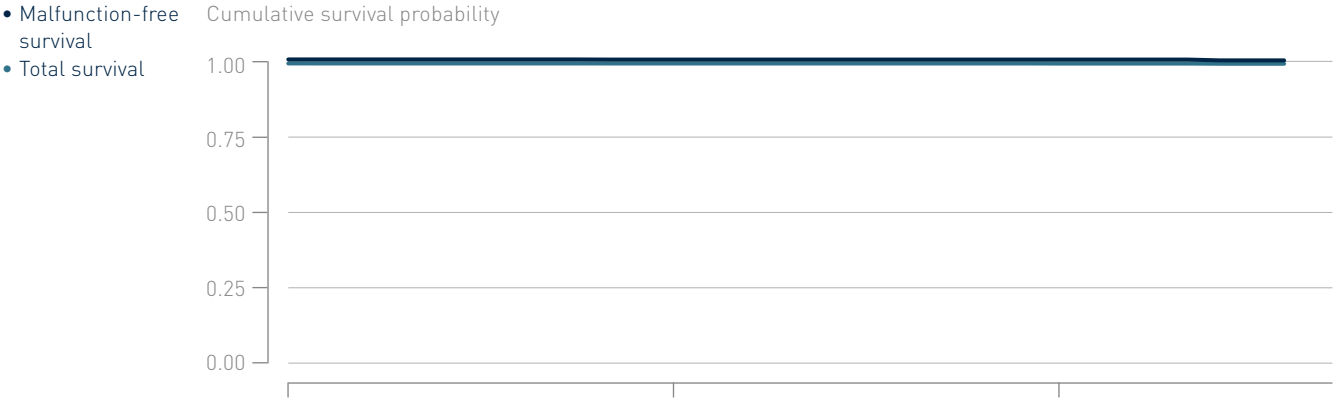


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.8	99.4	98.9	96.8	92.5	84.7	68.4	45.2
CI [±%]	-	0.2	0.3	0.4	0.7	1.1	1.6	2.2	2.7
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.5
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Sample Size	3410	3023	2699	2395	2094	1777	1431	1016	516

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	13 400
Registered U.S. Implants	5 180
Estimated Active U.S. Implants	4 430
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.04%
Therapy Compromised	2	0.04%
Therapy Available	0	0.00%



Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	0.1	0.2
Malfunction-Free [%]	100	100	100
CI [±%]	-	0.1	0.1
Sample Size	5 180	3 016	1 106

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

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

5.1 Cumulative Lead Survival Probability

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

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

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

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

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

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

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

5.2 Lead Data Acquisition

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

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is June 30, 2022. The sample sizes of U.S. leads that are implanted and remain active as well as the total number of products distributed worldwide are provided for each lead family in this report.

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

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

5.3 Returned Product Analysis

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

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

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

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

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

Insulation Breach
Any lead insulation breach

Other
Includes specific proprietary lead mechanical attributes.

5.4 Lead Complications

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

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

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

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

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

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

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

Abnormal Pacing Impedance
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 lead, the report provides:

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

The survival plots provide:

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

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

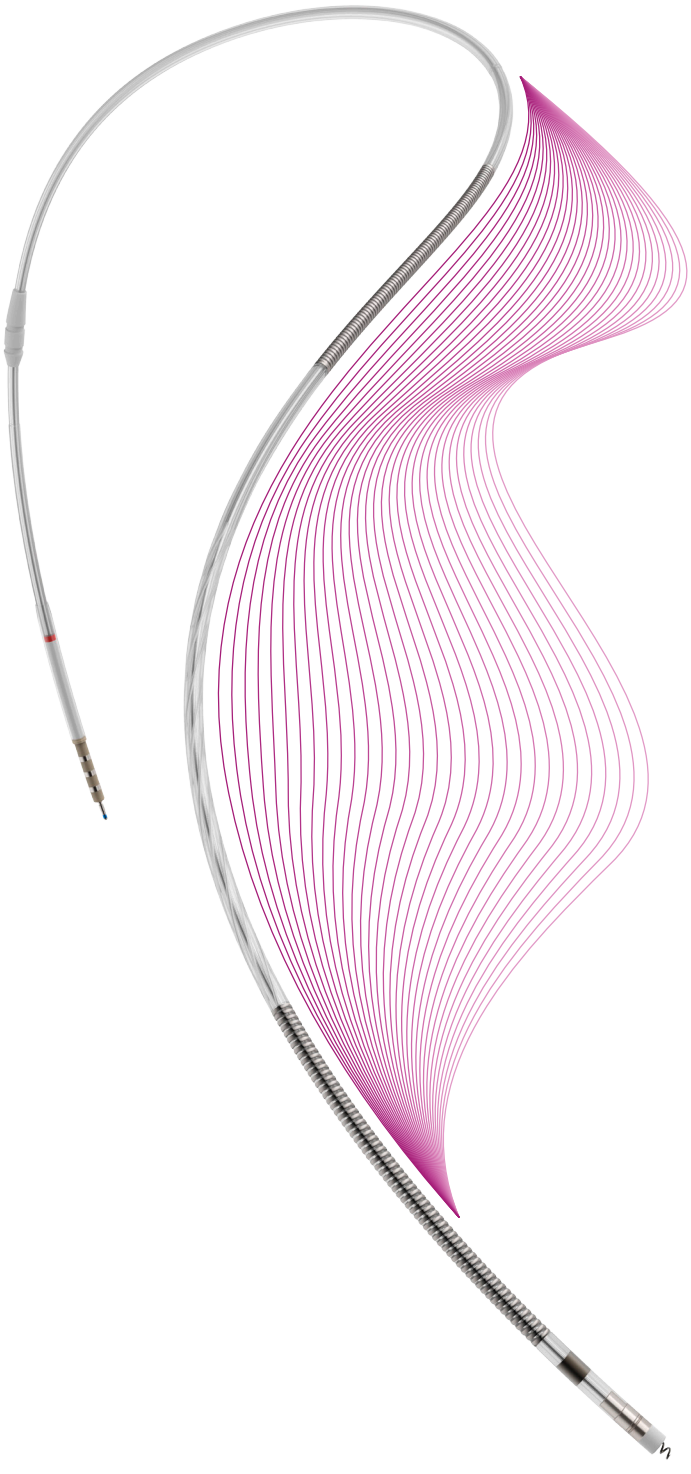
Current advisories are listed in chapter 11 of this report, however to date, BIOTRONIK has never had a pacing or ICD lead safety advisory notification, therefore no summary of lead advisories is provided.

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

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

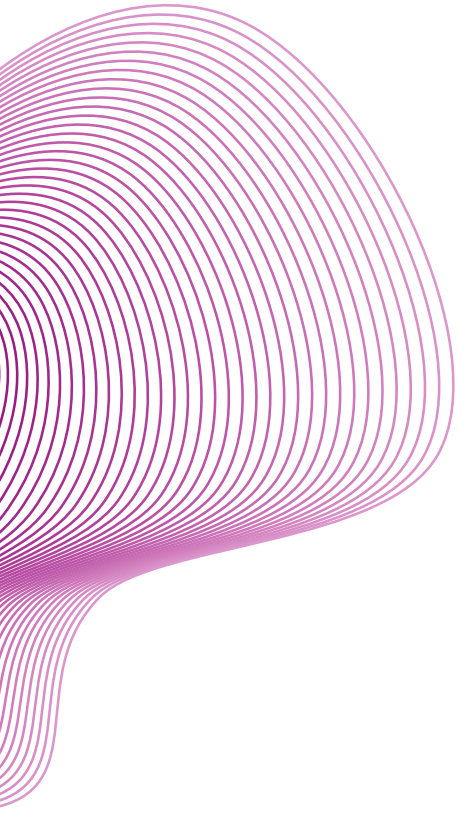
Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data



Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

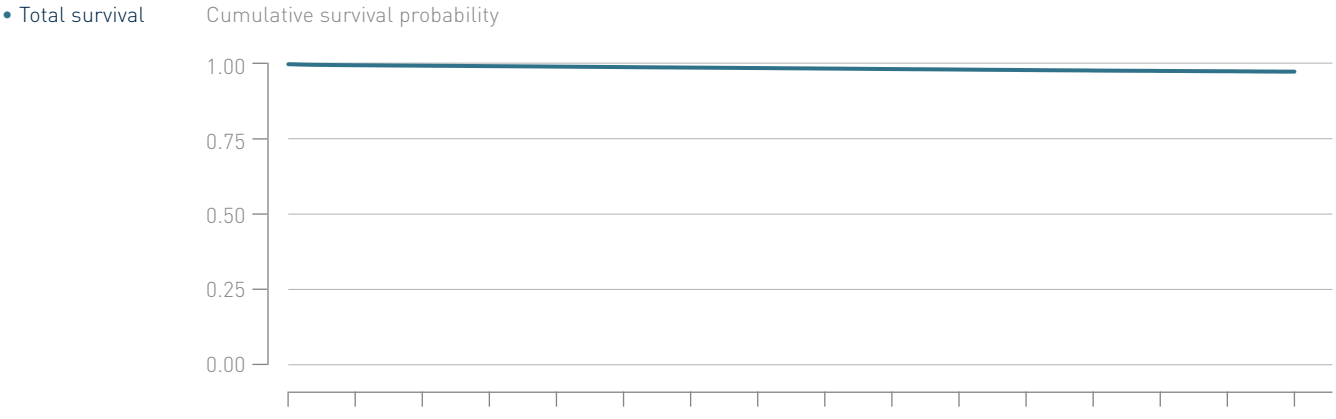


Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	480 000
Registered U.S. Implants	379 458
Estimated Active U.S. Implants	216 000
U.S. Total Returned	2 460

	Quantity	Rate
U.S. Qualifying Complications	5,027	1.31%
Abnormal pacing impedance	470	0.12%
Cardiac perforation	27	0.01%
Conductor fracture	144	0.04%
Extracardiac stimulation	24	0.01%
Failure to capture	1,221	0.32%
Failure to sense	189	0.05%
Insulation breach	92	0.02%
Lead dislodgement	580	0.15%
Oversensing	1,378	0.36%
Other	902	0.23%

	Quantity	Rate
U.S. Confirmed Malfunctions	390	0.10%
Conductor Fracture	126	0.03%
Insulation Breach	257	0.07%
Other	7	0.00%
U.S. Acute Lead Observations	1,745	0.45%
Abnormal pacing impedance	45	0.01%
Cardiac perforation	71	0.02%
Extracardiac stimulation	17	0.00%
Failure to capture	252	0.07%
Failure to sense	69	0.02%
Insulation breach	10	0.00%
Lead dislodgement	706	0.18%
Oversensing	48	0.01%
Other	527	0.14%



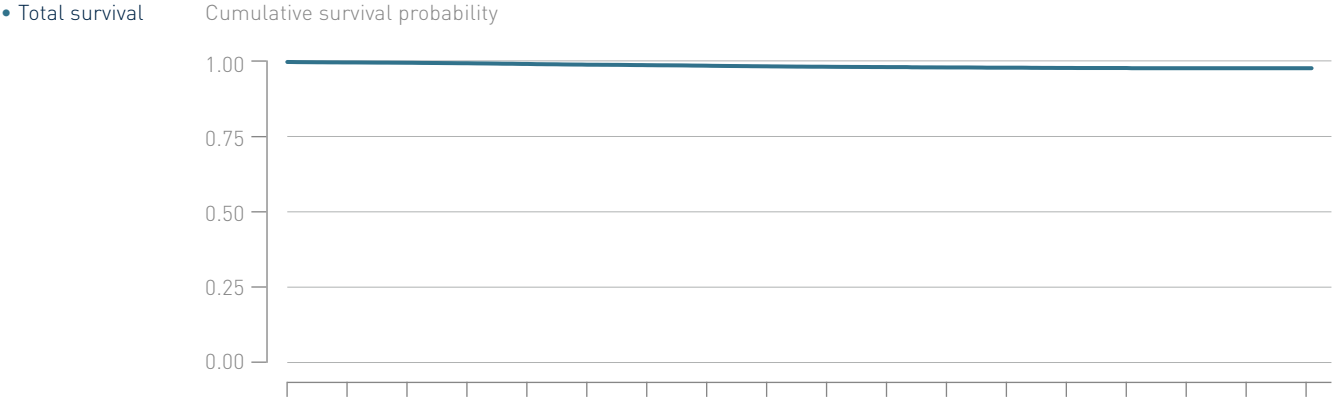
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.6	99.5	99.3	99.1	98.9	98.8	98.6	98.4	98.2	98.1	97.9	97.7	97.5	97.4	97.3
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	379458	336198	314461	294955	278055	262588	246657	208252	168018	131755	101753	76348	53720	32263	13701	323

Selox JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	157 000
Registered U.S. Implants	16 624
Estimated Active U.S. Implants	11 800
U.S. Total Returned	128

	Quantity	Rate
U.S. Qualifying Complications	251	1.51%
Abnormal pacing impedance	40	0.24%
Cardiac perforation	1	0.01%
Conductor fracture	13	0.08%
Extracardiac stimulation	1	0.01%
Failure to capture	106	0.64%
Failure to sense	11	0.07%
Insulation breach	12	0.07%
Lead dislodgement	39	0.23%
Oversensing	9	0.05%
Other	19	0.11%

	Quantity	Rate
U.S. Confirmed Malfunctions	11	0.07%
Insulation Breach	10	0.06%
Other	1	0.01%
U.S. Acute Lead Observations	45	0.27%
Failure to capture	8	0.05%
Lead dislodgement	34	0.20%
Other	3	0.02%



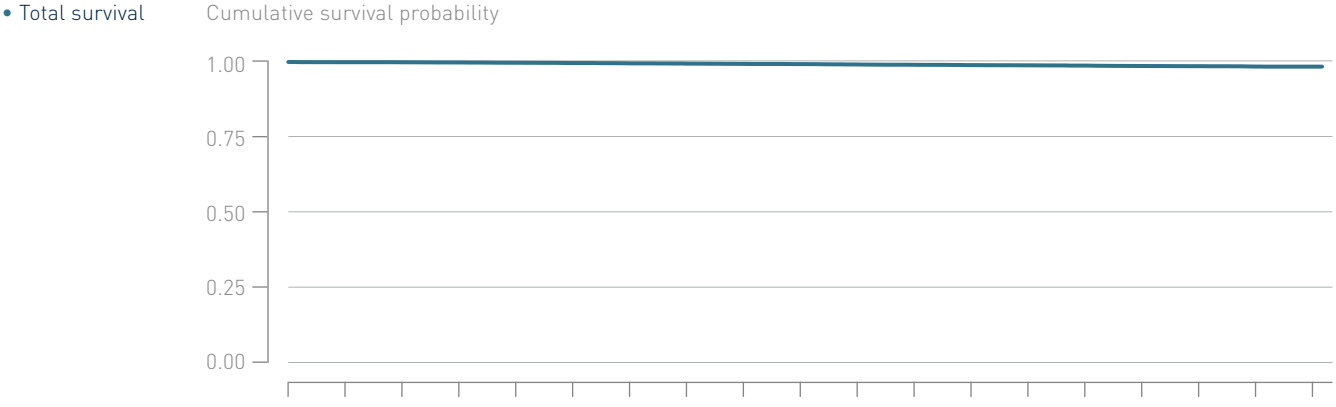
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	98.2	98.1	98.0	97.9	97.8	97.8	97.7	97.7	97.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	16624	15300	14660	14037	13446	12745	11954	11166	10185	8882	7759	6606	5303	4113	2894	1822	924	280

Selox SR

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2004
CE Market Release	Feb 2004
Worldwide Distributed Devices	172 000
Registered U.S. Implants	14 350
Estimated Active U.S. Implants	6 800
U.S. Total Returned	63

	Quantity	Rate
U.S. Qualifying Complications	132	0.92%
Abnormal pacing impedance	10	0.07%
Conductor fracture	12	0.08%
Extracardiac stimulation	2	0.01%
Failure to capture	49	0.34%
Failure to sense	1	0.01%
Insulation breach	6	0.04%
Lead dislodgement	15	0.10%
Oversensing	22	0.15%
Other	15	0.10%

	Quantity	Rate
U.S. Confirmed Malfunctions	13	0.09%
Insulation Breach	13	0.09%
U.S. Acute Lead Observations	21	0.15%
Cardiac perforation	1	0.01%
Failure to capture	11	0.08%
Insulation breach	1	0.01%
Lead dislodgement	8	0.06%



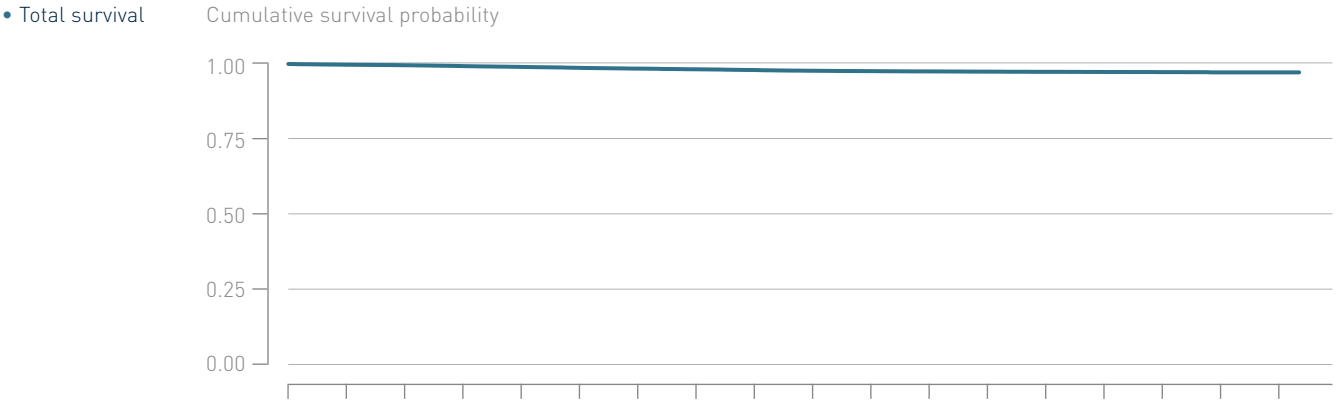
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6	98.5	98.4	98.2	98.2
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
Sample Size	14350	12438	11664	10867	10049	9361	8742	8246	7888	7615	7407	7231	7155	7083	6975	6863	6687	3636	628

Selox ST

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	379 000
Registered U.S. Implants	32 142
Estimated Active U.S. Implants	21 800
U.S. Total Returned	183

	Quantity	Rate
U.S. Qualifying Complications	642	2.00%
Abnormal pacing impedance	144	0.45%
Cardiac perforation	3	0.01%
Conductor fracture	67	0.21%
Extracardiac stimulation	6	0.02%
Failure to capture	313	0.97%
Failure to sense	1	0.00%
Insulation breach	39	0.12%
Lead dislodgement	24	0.07%
Oversensing	17	0.05%
Other	28	0.09%

	Quantity	Rate
U.S. Confirmed Malfunctions	20	0.06%
Conductor Fracture	1	0.00%
Crimps, Welds and Bonds	1	0.00%
Insulation Breach	18	0.06%
U.S. Acute Lead Observations	49	0.15%
Abnormal pacing impedance	1	0.00%
Failure to capture	21	0.07%
Lead dislodgement	21	0.07%
Other	6	0.02%



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.5	97.4	97.3	97.2	97.1	97.1	97.1	97.0	97.0
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3
Sample Size	32142	29219	27702	26356	24987	23658	22281	20904	19130	16785	14653	12367	10067	7986	5916	4008	2251	688

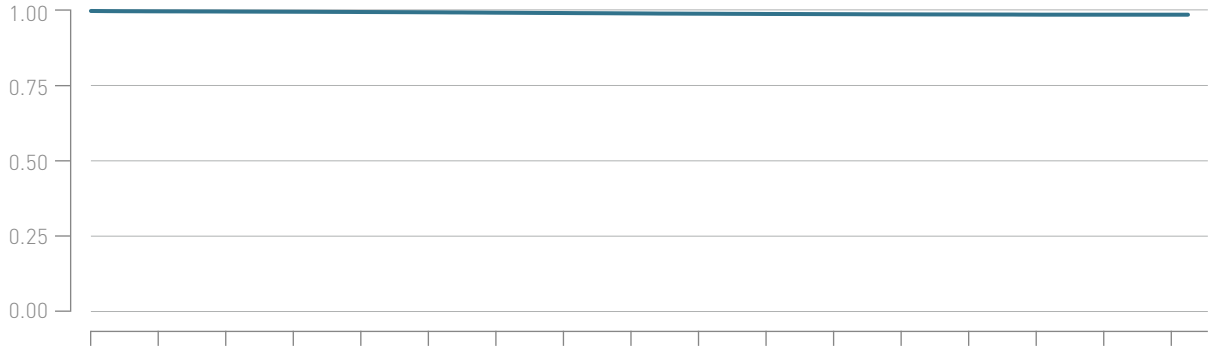
Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	681 000
Registered U.S. Implants	245 665
Estimated Active U.S. Implants	187 000
U.S. Total Returned	1 750

	Quantity	Rate
U.S. Qualifying Complications	2,053	0.83%
Abnormal pacing impedance	185	0.08%
Cardiac perforation	9	0.00%
Conductor fracture	136	0.06%
Extracardiac stimulation	12	0.00%
Failure to capture	696	0.28%
Failure to sense	58	0.02%
Insulation breach	85	0.03%
Lead dislodgement	366	0.15%
Oversensing	360	0.15%
Other	146	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	207	0.08%
Conductor Fracture	62	0.03%
Insulation Breach	139	0.06%
Other	6	0.00%
U.S. Acute Lead Observations	273	0.11%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	24	0.01%
Failure to capture	35	0.01%
Failure to sense	3	0.00%
Insulation breach	4	0.00%
Lead dislodgement	189	0.08%
Oversensing	1	0.00%
Other	16	0.01%

• Total survival Cumulative survival probability



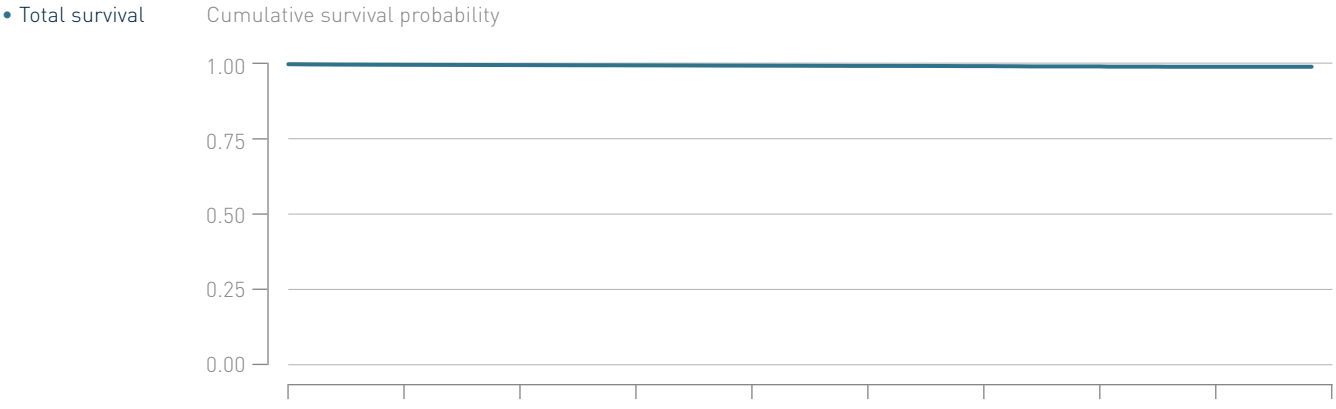
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.0	98.9	98.8	98.7	98.7	98.6	98.5	98.5	98.5
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	245665	229384	220595	213311	207080	200654	189922	155023	125870	103378	82671	63069	45855	30664	17609	8051	1347

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 325 000
Registered U.S. Implants	217 474
Estimated Active U.S. Implants	200 000
U.S. Total Returned	1 005

	Quantity	Rate
U.S. Qualifying Complications	953	0.44%
Abnormal pacing impedance	65	0.03%
Cardiac perforation	18	0.01%
Conductor fracture	22	0.01%
Extracardiac stimulation	9	0.00%
Failure to capture	255	0.12%
Failure to sense	42	0.02%
Insulation breach	14	0.01%
Lead dislodgement	378	0.17%
Oversensing	103	0.05%
Other	47	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	52	0.02%
Conductor Fracture	17	0.01%
Insulation Breach	27	0.01%
Other	8	0.00%
U.S. Acute Lead Observations	449	0.21%
Abnormal pacing impedance	6	0.00%
Cardiac perforation	34	0.02%
Conductor fracture	1	0.00%
Extracardiac stimulation	1	0.00%
Failure to capture	74	0.03%
Failure to sense	11	0.01%
Insulation breach	3	0.00%
Lead dislodgement	278	0.13%
Oversensing	16	0.01%
Other	25	0.01%



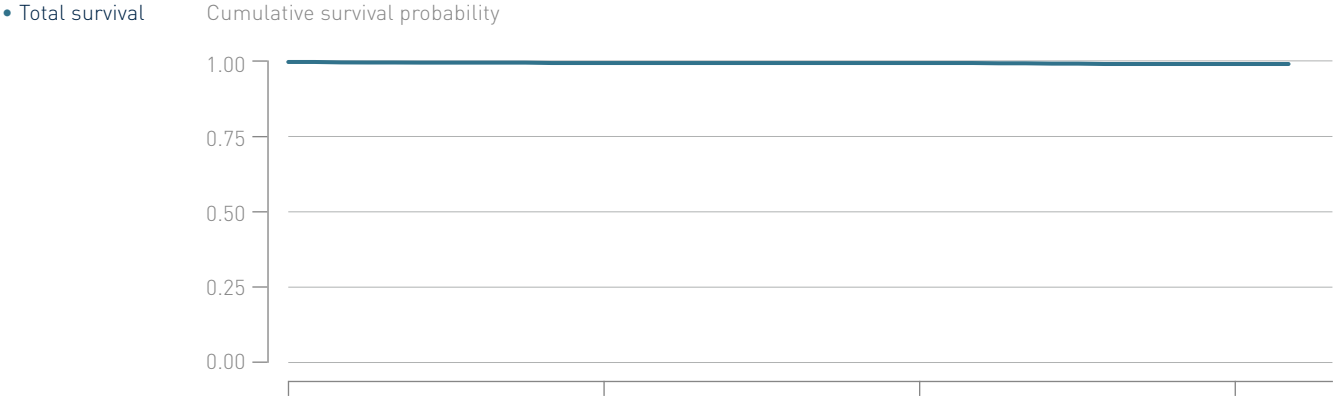
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.6	99.5	99.4	99.3	99.2	99.1	98.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.2	0.2
Sample Size	217 474	177 281	140 819	106 313	67 798	31 364	2 852	2 323	1 168

Siello JT / Solia JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	149 000
Registered U.S. Implants	2 327
Estimated Active U.S. Implants	2 130
U.S. Total Returned	11

	Quantity	Rate
U.S. Qualifying Complications	12	0.52%
Conductor fracture	1	0.04%
Failure to capture	3	0.13%
Failure to sense	1	0.04%
Insulation breach	1	0.04%
Lead dislodgement	5	0.21%
Oversensing	1	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	16	0.69%
Failure to capture	1	0.04%
Lead dislodgement	15	0.64%

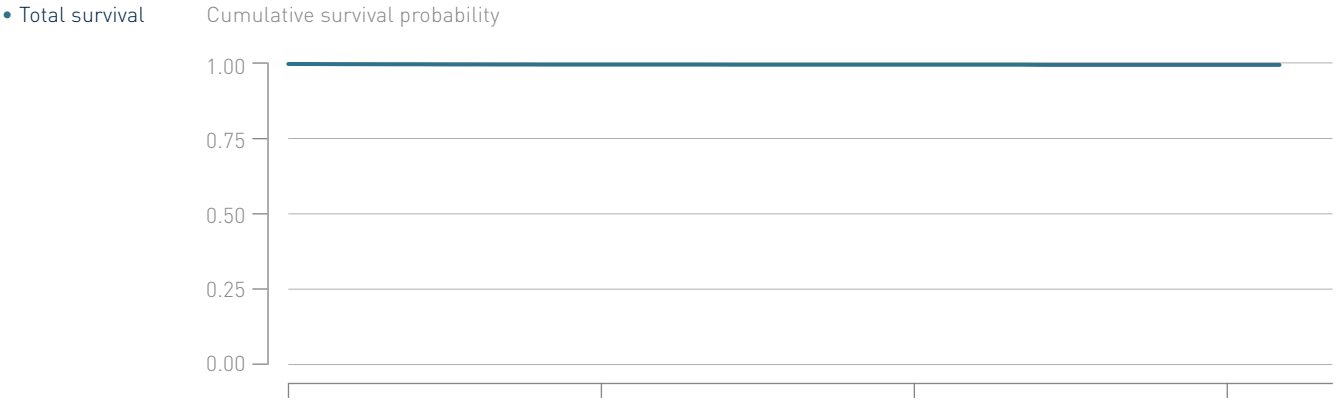


Years after implant	0	1	2	3
Total [%]	100.0	99.5	99.5	99.1
CI [±%]	-	0.3	0.3	0.6
Sample Size	2327	1509	915	296

Siello T / Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	214 000
Registered U.S. Implants	2 887
Estimated Active U.S. Implants	2 620
U.S. Total Returned	10

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	11	0.38%	**U.S. Confirmed Malfunctions**	0	0.00%
Abnormal pacing impedance	2	0.07%	**U.S. Acute Lead Observations**	10	0.35%
Failure to capture	5	0.17%	Failure to capture	3	0.10%
Lead dislodgement	4	0.14%	Lead dislodgement	7	0.24%



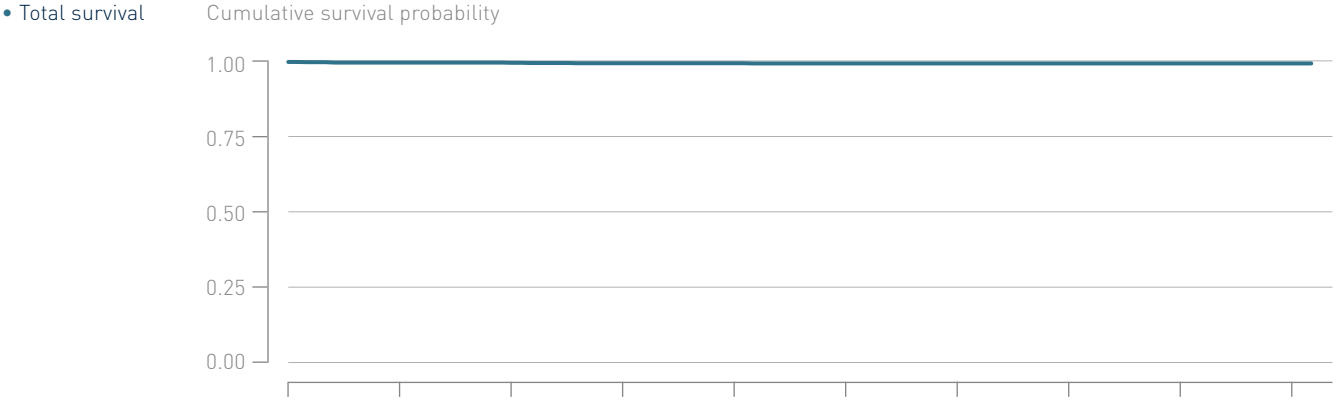
Years after implant	0	1	2	3
Total [%]	100.0	99.6	99.6	99.5
CI [±%]	-	0.2	0.3	0.3
Sample Size	2887	2011	1168	360

Tilda JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2012
CE Market Release	Sep 2011
Worldwide Distributed Devices	17300
Registered U.S. Implants	1018
Estimated Active U.S. Implants	888
U.S. Total Returned	0

	Quantity	Rate
U.S. Qualifying Complications	7	0.69%
Abnormal pacing impedance	2	0.20%
Failure to capture	2	0.20%
Lead dislodgement	3	0.29%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	1	0.10%
Lead dislodgement	1	0.10%



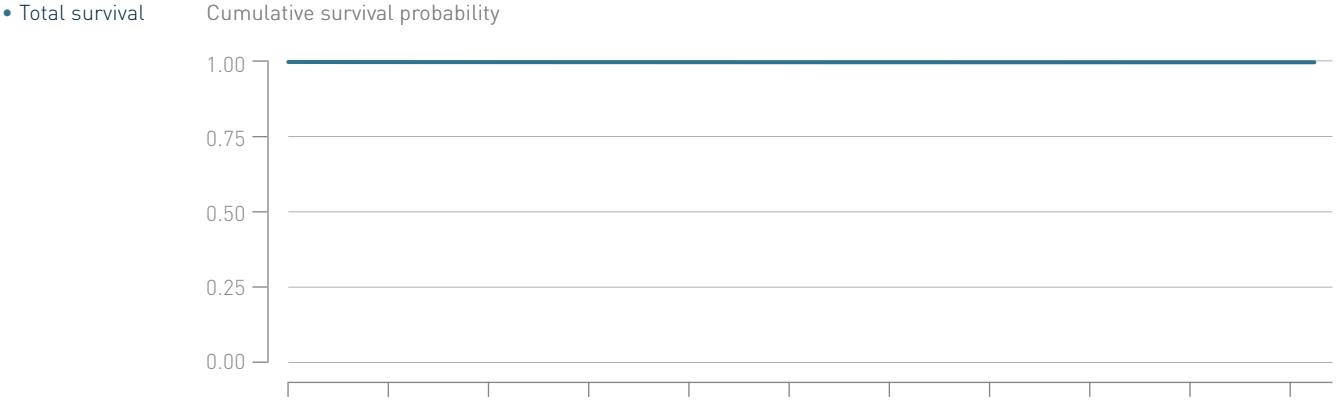
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3	99.3
CI [±%]	-	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1018	988	969	929	872	809	696	543	400	245

Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41 300
Registered U.S. Implants	12 718
Estimated Active U.S. Implants	11 200
U.S. Total Returned	16

	Quantity	Rate
U.S. 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%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.01%
Conductor Fracture	1	0.01%
U.S. Acute Lead Observations	9	0.07%
Failure to capture	1	0.01%
Lead dislodgement	8	0.06%



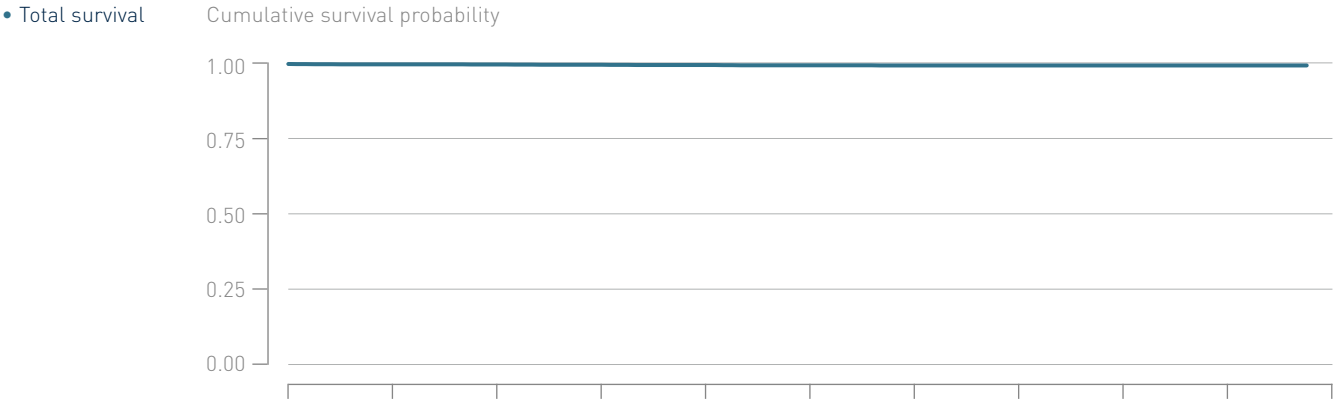
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7	99.7	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	12 718	12 225	11 918	11 664	11 034	10 279	8 796	7 180	5 530	3 458	999

Tilda T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22 400
Registered U.S. Implants	1 657
Estimated Active U.S. Implants	1 390
U.S. Total Returned	2

	Quantity	Rate
U.S. 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%

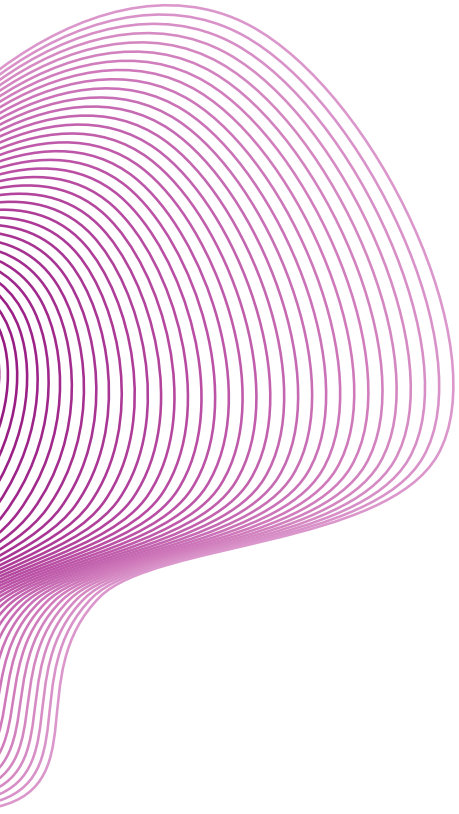
	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.8	99.6	99.5	99.3	99.3	99.3	99.3	99.3
CI [±%]	-	0.2	0.2	0.3	0.4	0.4	0.4	0.4	0.4	0.4
Sample Size	1 657	1 582	1 544	1 488	1 427	1 338	1 153	968	768	463

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

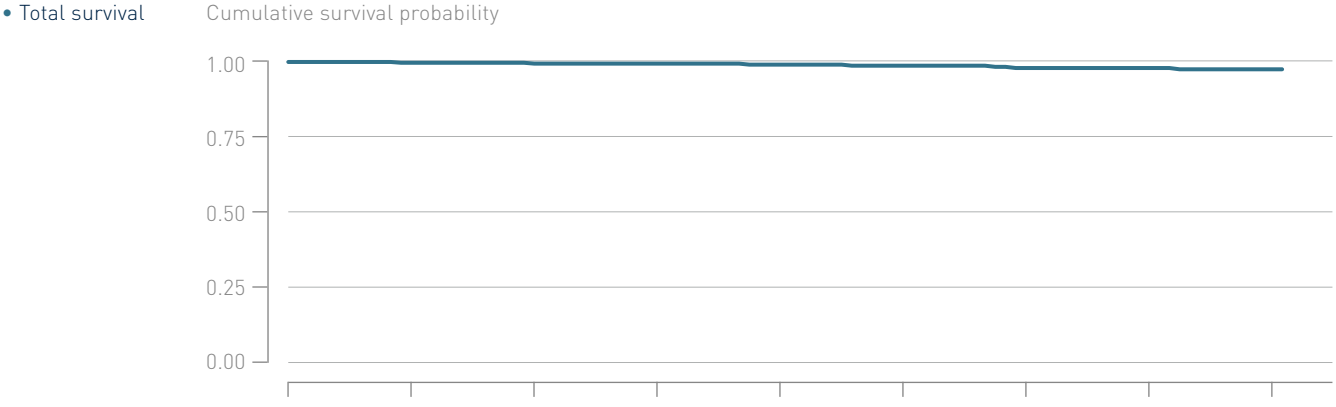


Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5 460
Registered U.S. Implants	406
Estimated Active U.S. Implants	162
U.S. Total Returned	8

	Quantity	Rate
U.S. Qualifying Complications	10	2.46%
Conductor fracture	1	0.25%
Failure to capture	4	0.98%
Insulation breach	1	0.25%
Oversensing	4	0.98%

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



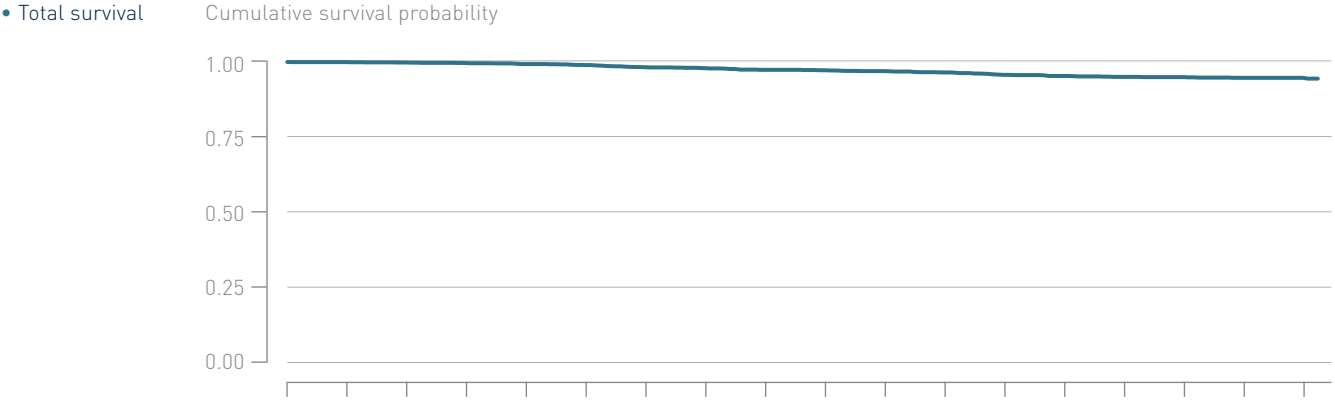
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	99.4	99.0	98.6	97.8	97.8	97.3
CI [±%]	-	0.6	0.8	0.8	1.1	1.3	1.8	1.8	2
Sample Size	406	353	318	286	269	243	228	211	201

Kentrox SL-S

Product Versions	65/16, 18-Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8 740
Registered U.S. Implants	2 414
Estimated Active U.S. Implants	1 170
U.S. Total Returned	42

	Quantity	Rate
U.S. 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%

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



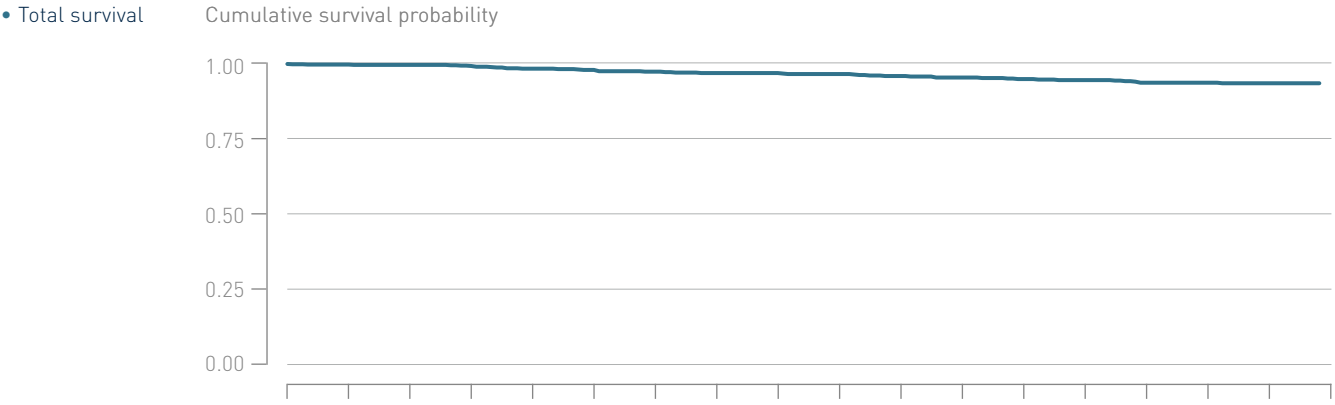
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	100.0	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.8	94.5	94.5
CI [±%]	-	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.1	1.2	1.2
Sample Size	2414	2176	2051	1891	1756	1632	1512	1432	1365	1325	1283	1260	1235	1226	1199	1169	1062	392

Kentrox SL

Product Versions	65, 75, 100, -Steroid
Lead Type	dual coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Dec 2003 / Dec 2004
Worldwide Distributed Devices	8 440
Registered U.S. Implants	1 004
Estimated Active U.S. Implants	510
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	38	3.76%
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	18	1.78%
Other	2	0.20%

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



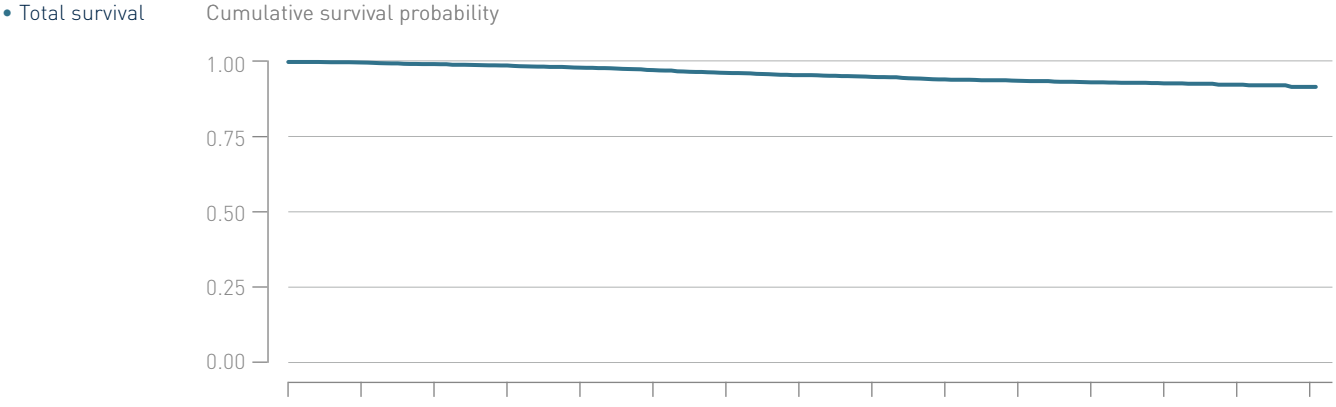
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.9	96.9	96.5	95.8	95.3	94.8	94.4	93.5	93.5	93.3
CI [±%]	-	0.3	0.4	0.6	0.9	1	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.9	2
Sample Size	1 004	899	835	778	708	663	617	596	576	565	553	544	536	528	515	511	435

Linox S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	2 467
Estimated Active U.S. Implants	1 570
U.S. Total Returned	89

	Quantity	Rate
U.S. Qualifying Complications	94	3.77%
Abnormal defibrillation impedance	12	0.48%
Abnormal pacing impedance	6	0.24%
Conductor fracture	10	0.40%
Failure to capture	12	0.48%
Failure to sense	1	0.04%
Insulation breach	4	0.16%
Oversensing	43	1.72%
Other	6	0.24%

	Quantity	Rate
U.S. Confirmed Malfunctions	49	1.97%
Conductor Fracture	9	0.36%
Insulation Breach	40	1.60%
U.S. Acute Lead Observations	2	0.08%
Lead dislodgement	1	0.04%
Other	1	0.04%



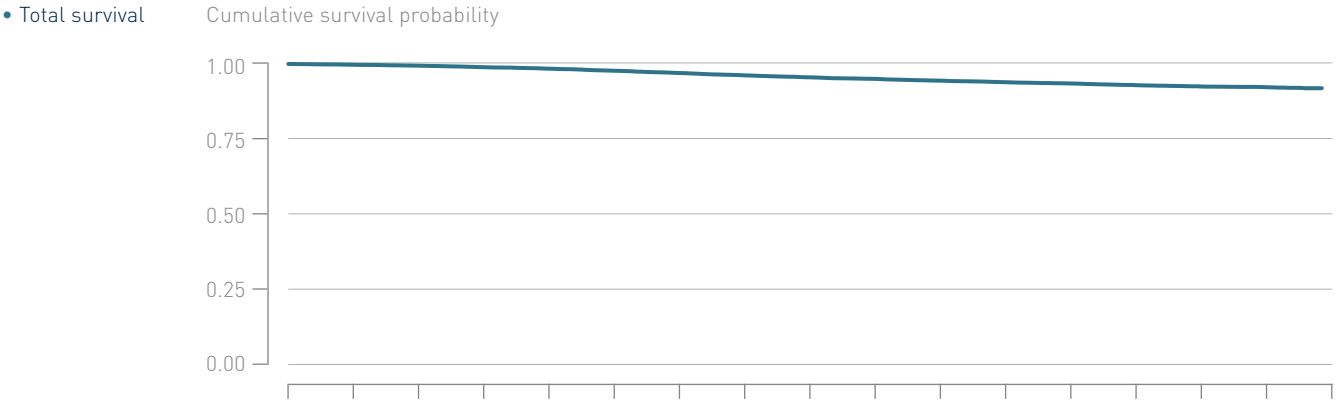
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.8	99.3	98.8	98.1	97.2	96.3	95.5	94.9	94.0	93.6	93.0	92.7	92.2
CI [±%]	-	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1	1.1	1.2	1.2	1.3
Sample Size	2467	2261	2129	2017	1924	1848	1785	1741	1691	1643	1614	1432	882	501

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	22 109
Estimated Active U.S. Implants	13 600
U.S. Total Returned	539

	Quantity	Rate
U.S. Qualifying Complications	960	4.31%
Abnormal defibrillation impedance	92	0.41%
Abnormal pacing impedance	68	0.31%
Cardiac perforation	3	0.01%
Conductor fracture	112	0.50%
Failure to capture	79	0.35%
Failure to sense	18	0.08%
Insulation breach	63	0.28%
Lead dislodgement	32	0.14%
Oversensing	443	1.99%
Other	50	0.22%

	Quantity	Rate
U.S. Confirmed Malfunctions	223	1.00%
Conductor Fracture	33	0.15%
Insulation Breach	188	0.84%
Other	2	0.01%
U.S. Acute Lead Observations	11	0.05%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	1	0.00%
Failure to capture	1	0.00%
Lead dislodgement	6	0.03%
Oversensing	1	0.00%
Other	1	0.00%



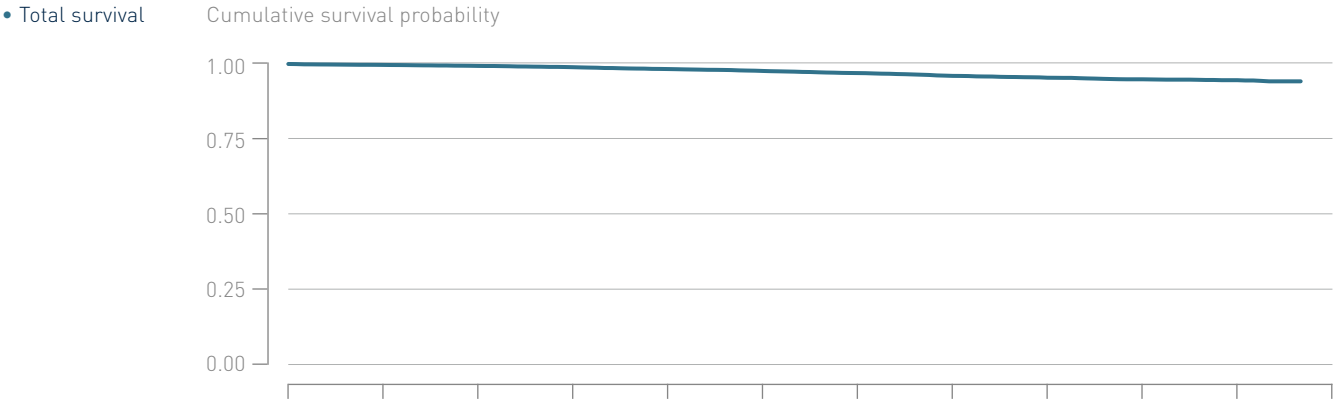
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.8	93.3	92.7	92.3	92.0
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5
Sample Size	22109	20097	18858	17802	16954	16213	15606	15147	14789	14490	14214	13646	10628	7005	3916	1672

Linox^{smart} S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	7 602
Estimated Active U.S. Implants	5 790
U.S. Total Returned	204

	Quantity	Rate
U.S. Qualifying Complications	245	3.20%
Abnormal defibrillation impedance	16	0.21%
Abnormal pacing impedance	21	0.27%
Cardiac perforation	1	0.01%
Conductor fracture	33	0.43%
Failure to capture	24	0.31%
Failure to sense	13	0.17%
Insulation breach	5	0.07%
Lead dislodgement	14	0.18%
Oversensing	108	1.41%
Other	10	0.13%

	Quantity	Rate
U.S. Confirmed Malfunctions	80	1.05%
Conductor Fracture	14	0.18%
Insulation Breach	66	0.86%
U.S. Acute Lead Observations	10	0.13%
Abnormal pacing impedance	1	0.01%
Cardiac perforation	1	0.01%
Lead dislodgement	7	0.09%
Other	1	0.01%



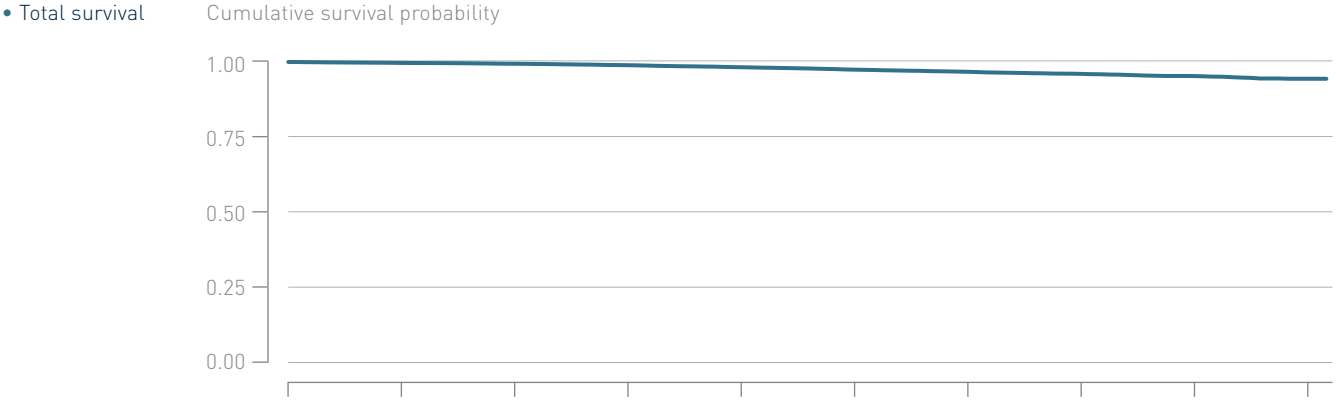
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.3	98.9	98.2	97.6	96.8	95.9	95.2	94.7	94.4
CI [±%]	-	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6
Sample Size	7 602	7 127	6 866	6 662	6 486	6 281	5 910	5 285	4 108	2 646	1 047

Linox^{smart} S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 300
Registered U.S. Implants	16 310
Estimated Active U.S. Implants	13 500
U.S. Total Returned	380

	Quantity	Rate
U.S. Qualifying Complications	480	2.93%
Abnormal defibrillation impedance	57	0.35%
Abnormal pacing impedance	36	0.22%
Conductor fracture	54	0.33%
Failure to capture	39	0.24%
Failure to sense	17	0.10%
Insulation breach	8	0.05%
Lead dislodgement	47	0.29%
Oversensing	210	1.28%
Other	12	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	121	0.74%
Conductor Fracture	9	0.05%
Insulation Breach	109	0.66%
Other	3	0.02%
U.S. Acute Lead Observations	39	0.24%
Cardiac perforation	4	0.02%
Failure to capture	9	0.05%
Lead dislodgement	16	0.10%
Oversensing	3	0.02%
Other	7	0.04%

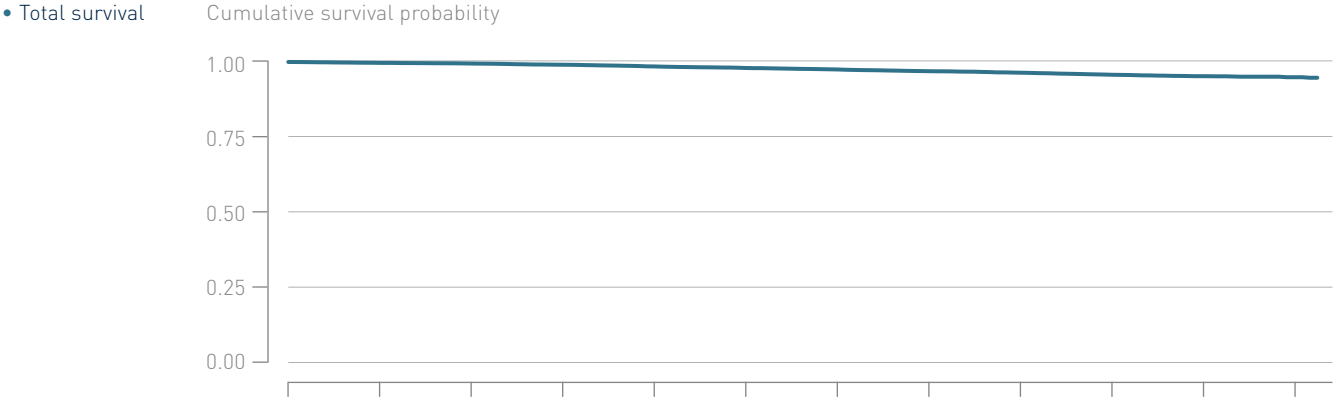


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	98.9	98.2	97.3	96.6	95.9	95.1
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.4
Sample Size	16 310	15 505	15 176	14 859	14 366	13 249	9 640	6 328	3 298

Linox^{smart} SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	13 134
Estimated Active U.S. Implants	9 880
U.S. Total Returned	273

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	419	3.16%	**U.S. Confirmed Malfunctions**	86	0.65%
Abnormal defibrillation impedance	41	0.31%	Conductor Fracture	11	0.08%
Abnormal pacing impedance	28	0.21%	Insulation Breach	72	0.54%
Cardiac perforation	1	0.01%	Other	3	0.02%
Conductor fracture	50	0.38%	**U.S. Acute Lead Observations**	29	0.22%
Extracardiac stimulation	1	0.01%	Abnormal defibrillation impedance	1	0.01%
Failure to capture	35	0.26%	Cardiac perforation	2	0.02%
Failure to sense	11	0.08%	Failure to capture	4	0.03%
Insulation breach	10	0.08%	Insulation breach	1	0.01%
Lead dislodgement	29	0.22%	Lead dislodgement	12	0.09%
Oversensing	204	1.54%	Oversensing	2	0.02%
Other	9	0.07%	Other	7	0.05%



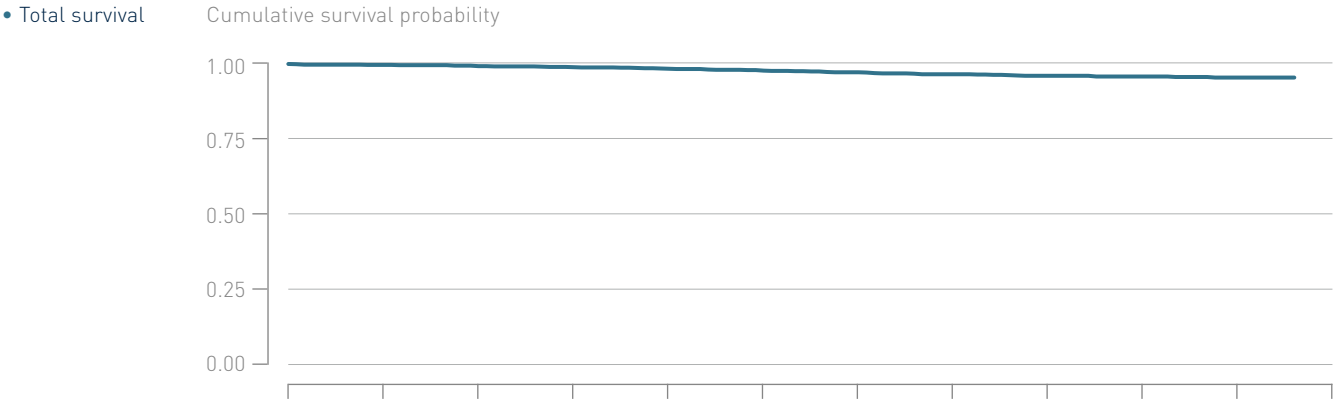
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.7	99.5	99.0	98.5	97.9	97.4	96.8	96.3	95.6	95.1	94.7
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5
Sample Size	13 134	12 159	11 771	11 412	11 090	10 815	10 365	9 771	8 679	6 870	4 035	890

Linox^{smart} TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered U.S. Implants	1 265
Estimated Active U.S. Implants	955
U.S. Total Returned	22

	Quantity	Rate
U.S. Qualifying Complications	47	3.69%
Abnormal defibrillation impedance	8	0.63%
Abnormal pacing impedance	5	0.39%
Conductor fracture	3	0.24%
Failure to capture	10	0.78%
Insulation breach	2	0.16%
Lead dislodgement	4	0.31%
Oversensing	14	1.10%
Other	1	0.08%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.08%
Insulation Breach	1	0.08%
U.S. Acute Lead Observations	3	0.24%
Lead dislodgement	3	0.24%



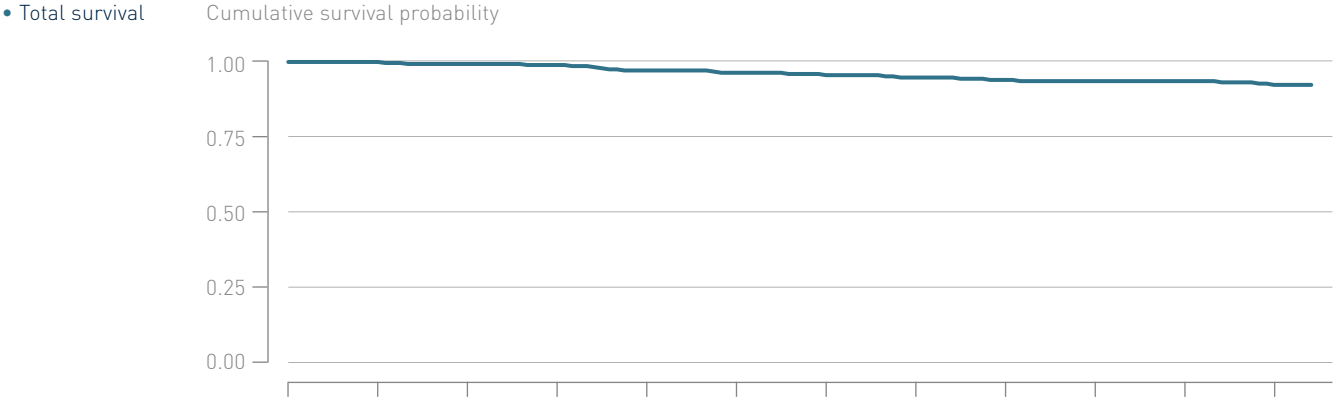
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.2	98.9	98.3	97.7	97.1	96.4	95.9	95.6	95.2
CI [±%]	-	0.3	0.5	0.6	0.7	0.9	1	1.1	1.2	1.2	1.3
Sample Size	1 265	1 173	1 136	1 093	1 067	1 035	996	942	844	675	372

Linox T

Product Versions	65, 75
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	2 260
Registered U.S. Implants	319
Estimated Active U.S. Implants	211
U.S. Total Returned	4

	Quantity	Rate
U.S. Qualifying Complications	20	6.21%
Abnormal pacing impedance	3	0.93%
Conductor fracture	1	0.31%
Failure to capture	4	1.24%
Insulation breach	1	0.31%
Oversensing	10	3.11%
Other	1	0.31%

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



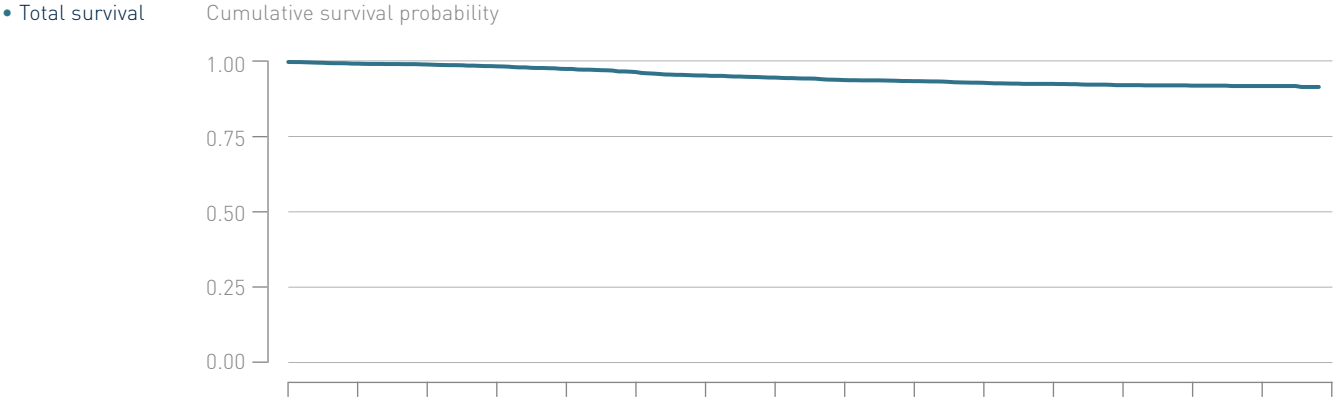
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4	93.4	92.1
CI [±%]	-	< 0.1	0.9	1.2	2	2.3	2.5	2.7	2.9	3	3	3.3
Sample Size	319	295	283	272	251	241	234	230	228	226	223	214

Linox TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered U.S. Implants	3 023
Estimated Active U.S. Implants	1 920
U.S. Total Returned	81

	Quantity	Rate
U.S. Qualifying Complications	151	4.95%
Abnormal defibrillation impedance	17	0.56%
Abnormal pacing impedance	14	0.46%
Cardiac perforation	1	0.03%
Conductor fracture	19	0.62%
Failure to capture	24	0.79%
Failure to sense	4	0.13%
Insulation breach	13	0.43%
Lead dislodgement	4	0.13%
Oversensing	52	1.70%
Other	3	0.10%

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



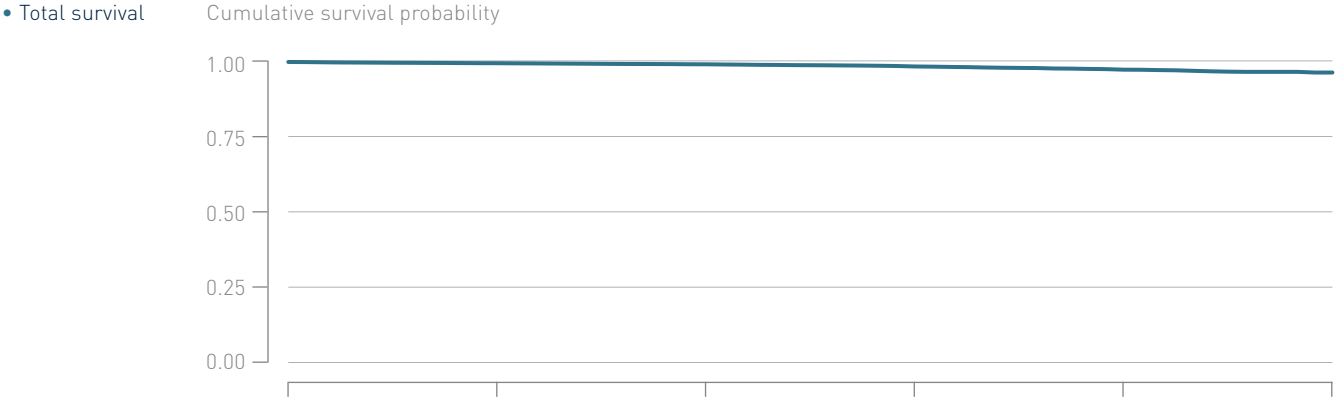
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.4	94.6	93.8	93.4	92.9	92.5	92.0	91.9	91.7
CI [±%]	-	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1	1	1	1.1	1.1	1.1	1.2
Sample Size	3023	2732	2600	2452	2339	2236	2146	2092	2054	2017	1982	1875	1492	952	484

Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	122 000
Registered U.S. Implants	18 087
Estimated Active U.S. Implants	16 500
U.S. Total Returned	178

	Quantity	Rate
U.S. Qualifying Complications	209	1.15%
Abnormal defibrillation impedance	19	0.10%
Abnormal pacing impedance	2	0.01%
Cardiac perforation	1	0.01%
Conductor fracture	14	0.08%
Failure to capture	28	0.15%
Failure to sense	11	0.06%
Insulation breach	2	0.01%
Lead dislodgement	28	0.15%
Oversensing	95	0.52%
Other	9	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	43	0.24%
Conductor Fracture	7	0.04%
Insulation Breach	33	0.18%
Other	3	0.02%
U.S. Acute Lead Observations	43	0.24%
Abnormal pacing impedance	3	0.02%
Cardiac perforation	6	0.03%
Failure to capture	11	0.06%
Lead dislodgement	20	0.11%
Oversensing	2	0.01%
Other	1	0.01%



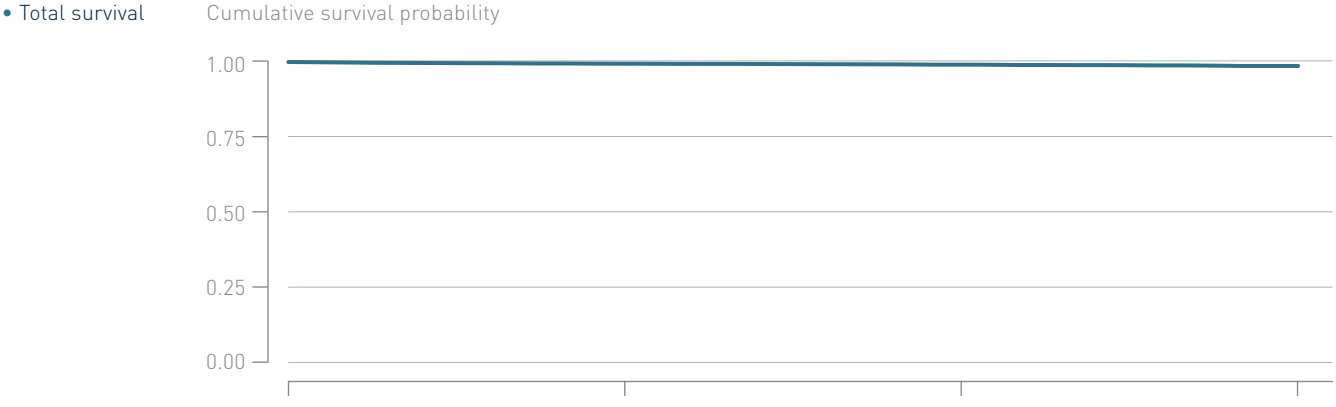
Years after implant	0	1	2	3	4
Total [%]	100.0	99.6	99.2	98.4	97.3
CI [±%]	-	0.1	0.2	0.2	0.4
Sample Size	18 087	14 065	10 361	6 673	3 160

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	28 800
Registered U.S. Implants	12 141
Estimated Active U.S. Implants	11 500
U.S. Total Returned	93

	Quantity	Rate
U.S. Qualifying Complications	85	0.70%
Abnormal defibrillation impedance	7	0.06%
Abnormal pacing impedance	3	0.02%
Cardiac perforation	1	0.01%
Failure to capture	10	0.08%
Failure to sense	5	0.04%
Insulation breach	1	0.01%
Lead dislodgement	30	0.25%
Oversensing	26	0.21%
Other	2	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	11	0.09%
Conductor Fracture	1	0.01%
Insulation Breach	9	0.07%
Other	1	0.01%
U.S. Acute Lead Observations	40	0.33%
Cardiac perforation	1	0.01%
Failure to capture	8	0.07%
Failure to sense	5	0.04%
Lead dislodgement	19	0.16%
Oversensing	5	0.04%
Other	2	0.02%



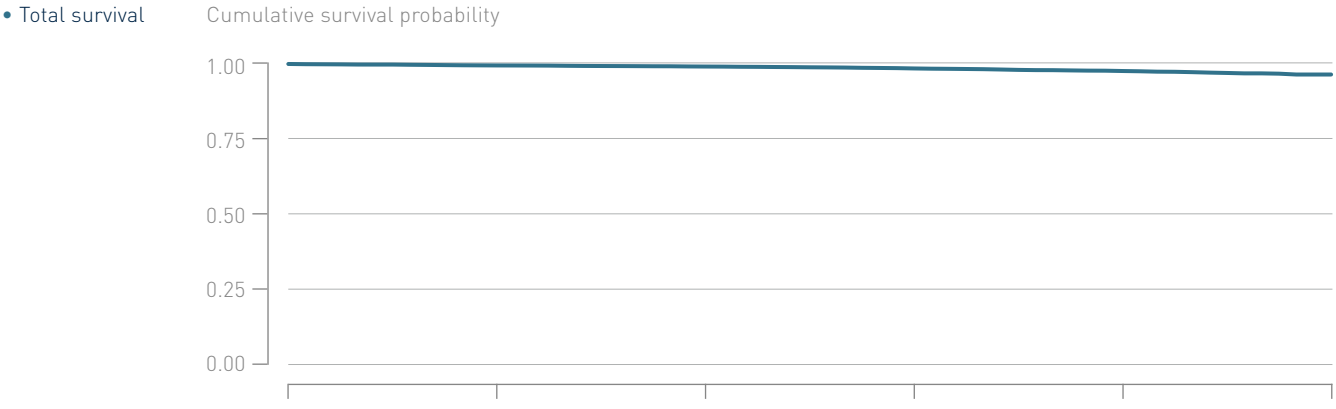
Years after implant	0	1	2	3
Total [%]	100.0	99.3	99.0	98.4
CI [±%]	-	0.2	0.2	0.5
Sample Size	12 141	7 545	3 369	336

Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	22 200
Registered U.S. Implants	9 060
Estimated Active U.S. Implants	8 050
U.S. Total Returned	139

	Quantity	Rate
U.S. Qualifying Complications	151	1.66%
Abnormal defibrillation impedance	20	0.22%
Abnormal pacing impedance	6	0.07%
Conductor fracture	6	0.07%
Failure to capture	13	0.14%
Failure to sense	7	0.08%
Insulation breach	2	0.02%
Lead dislodgement	18	0.20%
Oversensing	76	0.84%
Other	3	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	48	0.53%
Conductor Fracture	3	0.03%
Insulation Breach	44	0.48%
Other	1	0.01%
U.S. 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%



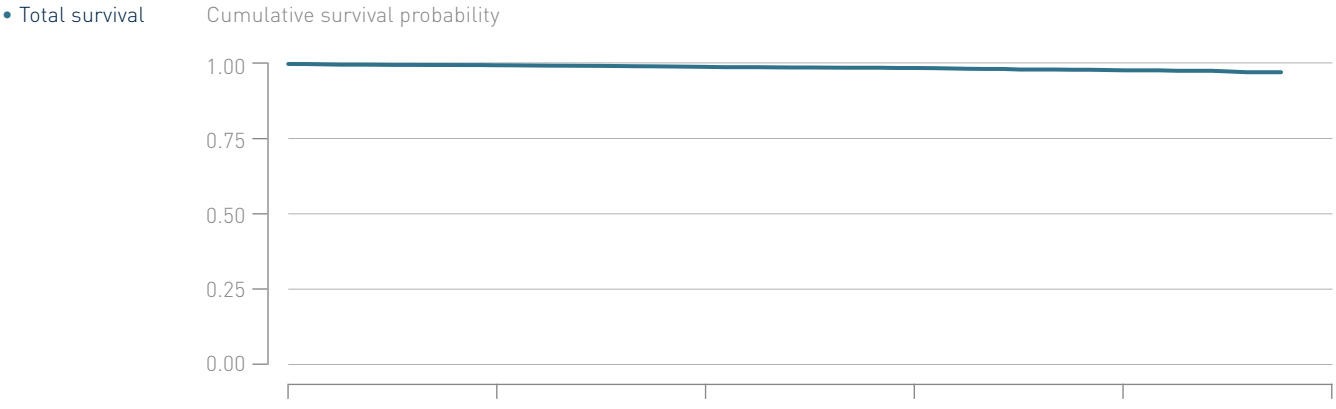
Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.1	98.4	97.5
CI [±%]	-	0.2	0.2	0.3	0.4
Sample Size	9 060	8 621	8 100	6 925	3 391

Plexa SD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	14 500
Registered U.S. Implants	4 726
Estimated Active U.S. Implants	4 260
U.S. Total Returned	22

	Quantity	Rate
U.S. Qualifying Complications	61	1.29%
Abnormal defibrillation impedance	6	0.13%
Abnormal pacing impedance	3	0.06%
Conductor fracture	2	0.04%
Extracardiac stimulation	1	0.02%
Failure to capture	6	0.13%
Failure to sense	4	0.08%
Insulation breach	2	0.04%
Lead dislodgement	7	0.15%
Oversensing	28	0.59%
Other	2	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.08%
Conductor Fracture	2	0.04%
Insulation Breach	2	0.04%
U.S. Acute Lead Observations	12	0.25%
Abnormal defibrillation impedance	2	0.04%
Abnormal pacing impedance	1	0.02%
Cardiac perforation	2	0.04%
Failure to capture	2	0.04%
Lead dislodgement	1	0.02%
Oversensing	2	0.04%
Other	2	0.04%



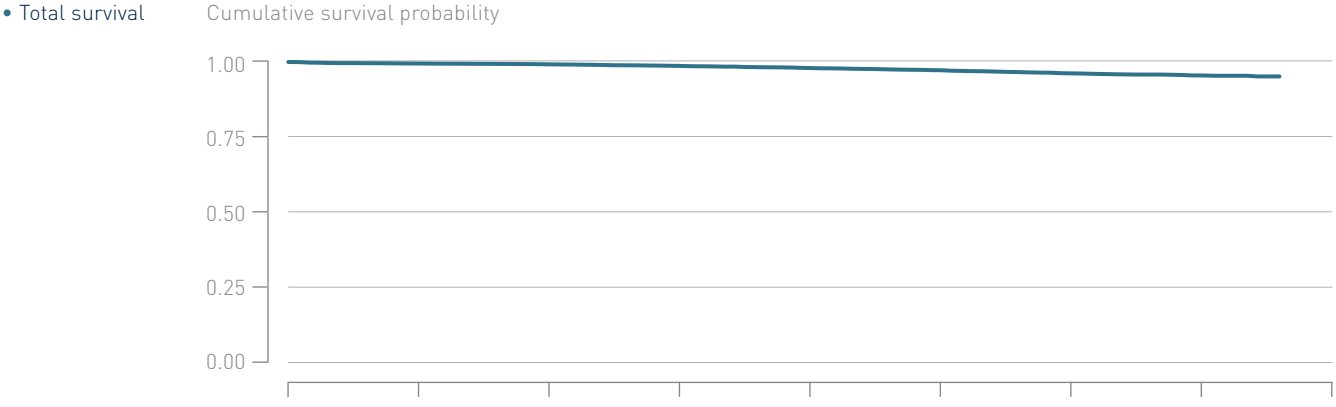
Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	98.9	98.5	97.7
CI [±%]	-	0.2	0.3	0.4	0.6
Sample Size	4726	3805	2857	1930	891

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	8 283
Estimated Active U.S. Implants	6 700
U.S. Total Returned	134

	Quantity	Rate
U.S. Qualifying Complications	225	2.70%
Abnormal defibrillation impedance	15	0.18%
Abnormal pacing impedance	8	0.10%
Cardiac perforation	1	0.01%
Conductor fracture	23	0.28%
Extracardiac stimulation	3	0.04%
Failure to capture	23	0.28%
Failure to sense	5	0.06%
Insulation breach	3	0.04%
Lead dislodgement	24	0.29%
Oversensing	114	1.37%
Other	6	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	59	0.71%
Conductor Fracture	10	0.12%
Insulation Breach	48	0.58%
Other	1	0.01%
U.S. Acute Lead Observations	28	0.34%
Cardiac perforation	2	0.02%
Extracardiac stimulation	1	0.01%
Failure to capture	3	0.04%
Lead dislodgement	13	0.16%
Other	9	0.11%



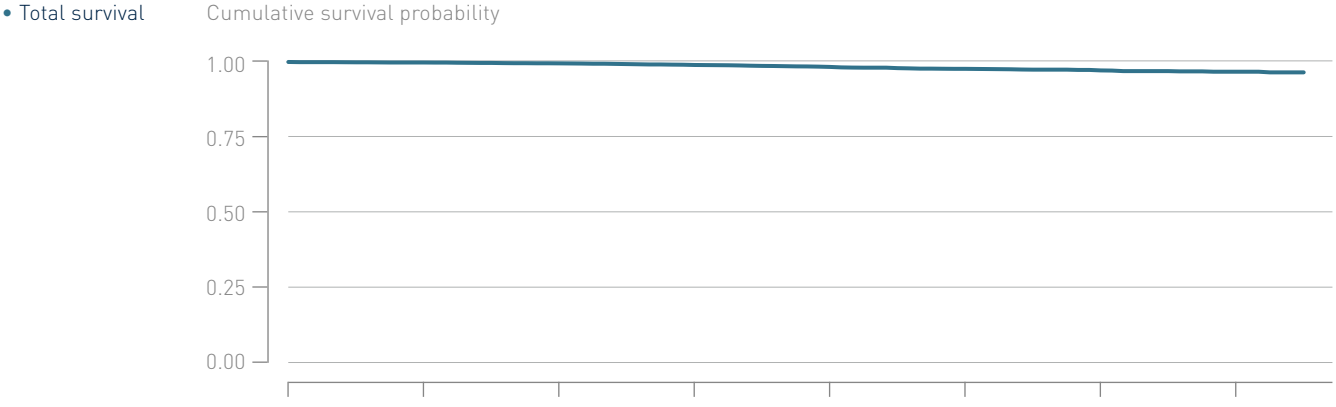
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.5	99.2	98.6	97.9	97.1	96.0	95.3
CI [±%]	-	0.2	0.2	0.3	0.3	0.4	0.5	0.6
Sample Size	8 283	7 780	7 577	7 362	7 003	6 079	3 296	992

Protego SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18 400
Registered U.S. Implants	3 412
Estimated Active U.S. Implants	2 840
U.S. Total Returned	46

	Quantity	Rate
U.S. Qualifying Complications	81	2.36%
Abnormal defibrillation impedance	7	0.20%
Abnormal pacing impedance	3	0.09%
Conductor fracture	10	0.29%
Failure to capture	9	0.26%
Failure to sense	2	0.06%
Insulation breach	2	0.06%
Lead dislodgement	5	0.15%
Oversensing	42	1.22%
Other	1	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	14	0.41%
Conductor Fracture	1	0.03%
Insulation Breach	13	0.38%
U.S. Acute Lead Observations	3	0.09%
Lead dislodgement	2	0.06%
Other	1	0.03%



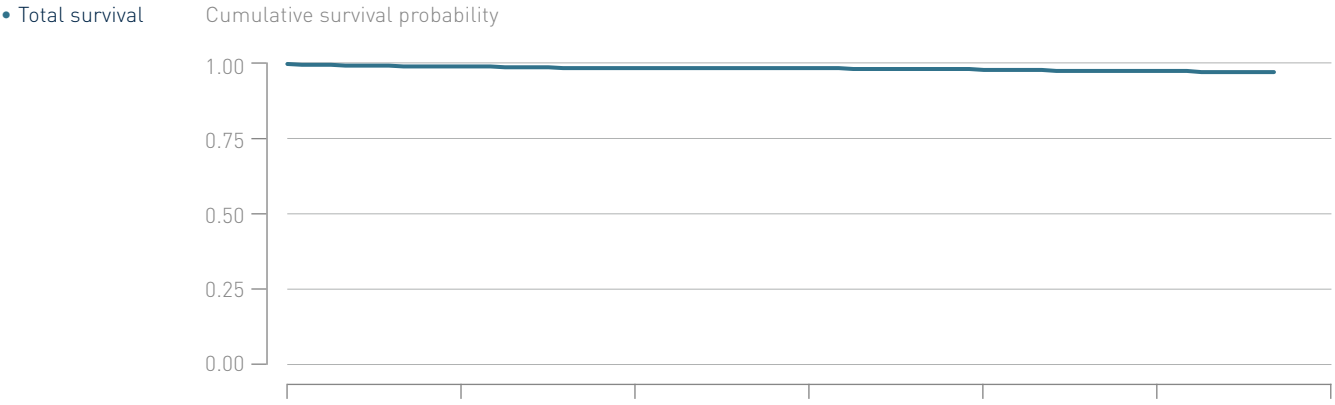
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.5	98.9	98.2	97.6	97.0	96.5
CI [±%]	-	0.1	0.2	0.4	0.5	0.5	0.6	0.7
Sample Size	3412	3233	3149	3074	2989	2671	1719	634

Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered U.S. Implants	349
Estimated Active U.S. Implants	293
U.S. Total Returned	4

	Quantity	Rate
U.S. Qualifying Complications	9	2.56%
Conductor fracture	4	1.14%
Failure to capture	2	0.57%
Failure to sense	1	0.28%
Insulation breach	1	0.28%
Other	1	0.28%

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



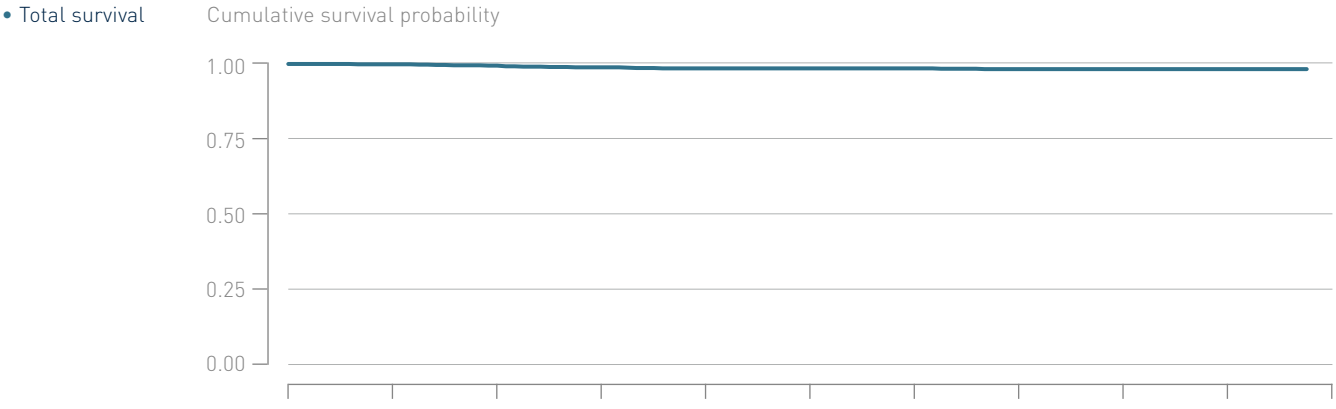
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.1	98.5	98.5	97.8	97.5
CI [±%]	-	1	1.3	1.3	1.6	1.7
Sample Size	349	331	322	312	289	247

Vigila 2CR

Product Versions	60/16, 65/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2012
CE Market Release	Oct 2011
Worldwide Distributed Devices	2 730
Registered U.S. Implants	855
Estimated Active U.S. Implants	682
U.S. Total Returned	12

	Quantity	Rate
U.S. 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%

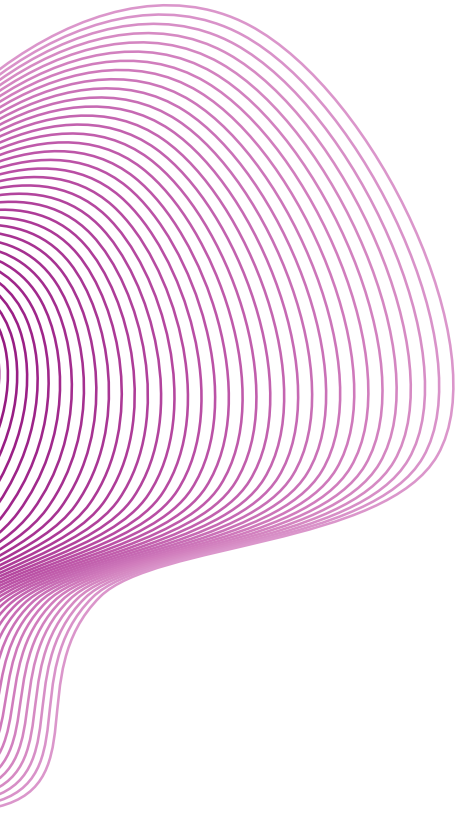
	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.47%
Insulation Breach	4	0.47%
U.S. Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.4	98.7	98.3	98.3	98.3	98.1	98.1	98.1
CI [±%]	-	0.2	0.5	0.8	0.9	0.9	0.9	1	1	1
Sample Size	855	803	780	751	728	716	704	690	671	475

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

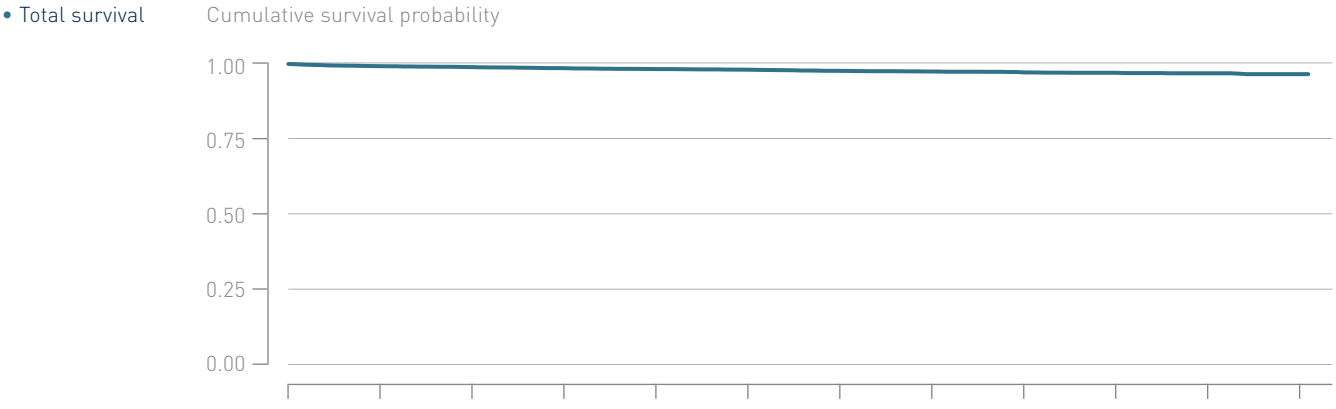


Corox OTW-L

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Registered U.S. Implants	6 253
Estimated Active U.S. Implants	4 680
U.S. Total Returned	85

	Quantity	Rate
U.S. Qualifying Complications	154	2.44%
Abnormal pacing impedance	4	0.06%
Conductor fracture	6	0.10%
Extracardiac stimulation	26	0.41%
Failure to capture	65	1.03%
Failure to sense	2	0.03%
Insulation breach	2	0.03%
Lead dislodgement	38	0.60%
Oversensing	3	0.05%
Other	8	0.13%

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.10%
Conductor Fracture	4	0.06%
Insulation Breach	1	0.02%
Other	1	0.02%
U.S. Acute Lead Observations	21	0.33%
Extracardiac stimulation	6	0.10%
Failure to capture	2	0.03%
Lead dislodgement	10	0.16%
Other	3	0.05%



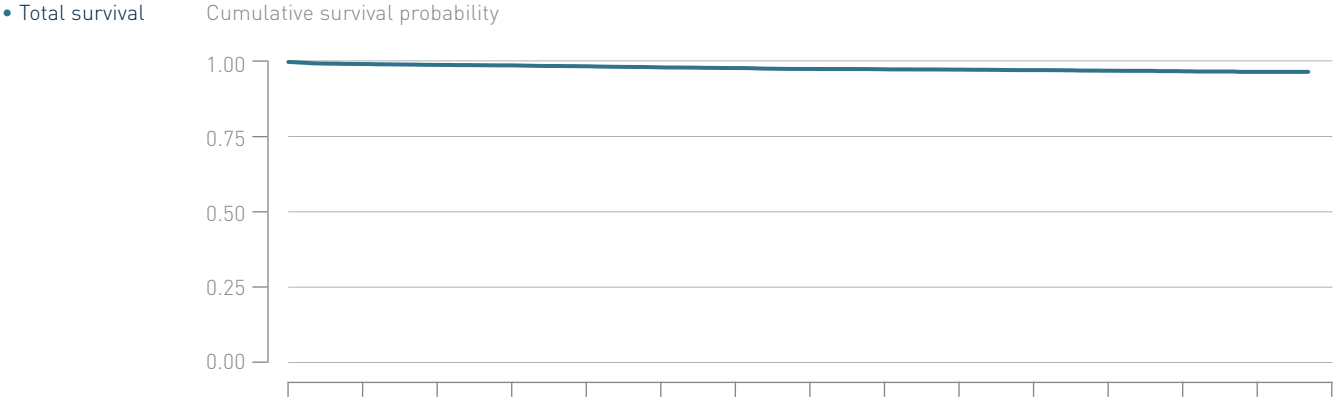
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.2	98.9	98.5	98.2	98.0	97.6	97.3	97.0	96.9	96.7	96.4
CI [±%]	-	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.7
Sample Size	6253	5681	5433	5239	5103	4938	4258	3545	2694	1787	902	252

Corox OTW-S

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
Registered U.S. Implants	8 159
Estimated Active U.S. Implants	5 370
U.S. Total Returned	134

	Quantity	Rate
U.S. Qualifying Complications	180	2.19%
Abnormal pacing impedance	11	0.13%
Conductor fracture	7	0.09%
Extracardiac stimulation	15	0.18%
Failure to capture	56	0.68%
Failure to sense	1	0.01%
Insulation breach	4	0.05%
Lead dislodgement	60	0.73%
Oversensing	6	0.07%
Other	20	0.24%

	Quantity	Rate
U.S. Confirmed Malfunctions	13	0.16%
Conductor Fracture	8	0.10%
Insulation Breach	4	0.05%
Other	1	0.01%
U.S. Acute Lead Observations	33	0.40%
Cardiac perforation	1	0.01%
Extracardiac stimulation	5	0.06%
Failure to capture	6	0.07%
Lead dislodgement	20	0.24%
Other	1	0.01%



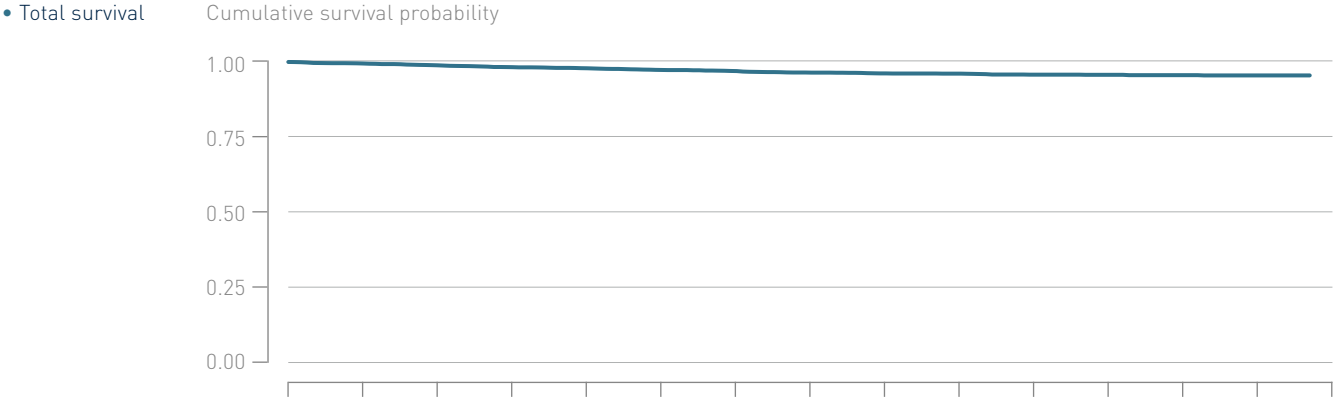
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.3	98.9	98.8	98.5	98.1	97.8	97.5	97.4	97.3	97.1	96.9	96.7	96.5
CI [±%]	-	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.5	0.6
Sample Size	8 159	7 144	6 739	6 401	6 176	5 934	5 397	4 868	4 227	3 594	3 004	2 394	1 467	623

Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered U.S. Implants	4 117
Estimated Active U.S. Implants	2 530
U.S. Total Returned	79

	Quantity	Rate
U.S. Qualifying Complications	124	3.00%
Abnormal pacing impedance	7	0.17%
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	12	0.29%

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



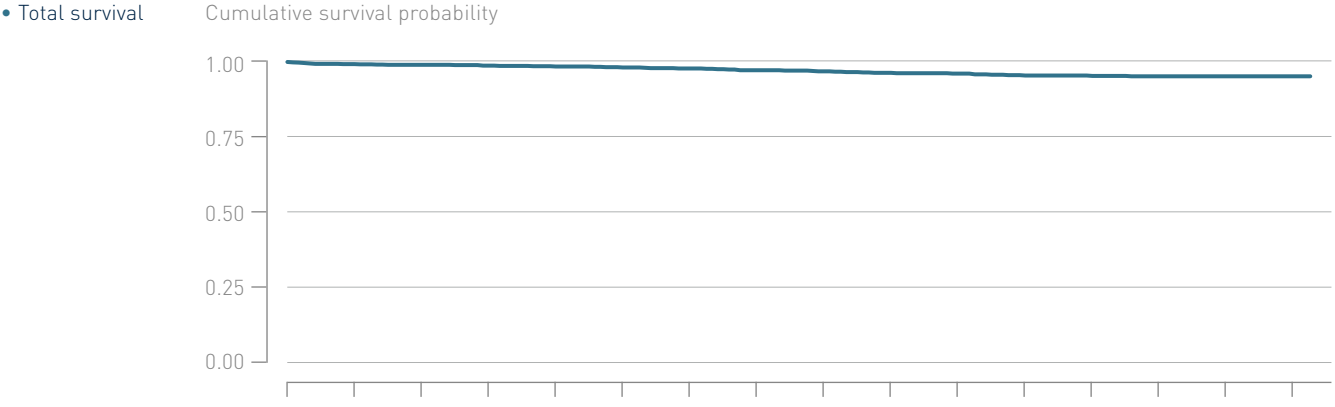
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.5	98.8	98.2	97.8	97.2	96.8	96.3	96.0	95.9	95.6	95.5	95.4	95.3
CI [±%]	-	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.8
Sample Size	4 117	3 554	3 310	3 116	2 994	2 883	2 723	2 577	2 420	2 200	1 953	1 682	1 221	567

Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered U.S. Implants	1 423
Estimated Active U.S. Implants	671
U.S. Total Returned	26

	Quantity	Rate
U.S. Qualifying Complications	44	3.09%
Abnormal pacing impedance	1	0.07%
Conductor fracture	2	0.14%
Extracardiac stimulation	7	0.49%
Failure to capture	16	1.12%
Insulation breach	2	0.14%
Lead dislodgement	10	0.70%
Oversensing	1	0.07%
Other	5	0.35%

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.14%
Insulation Breach	2	0.14%
U.S. Acute Lead Observations	4	0.28%
Failure to capture	3	0.21%
Lead dislodgement	1	0.07%



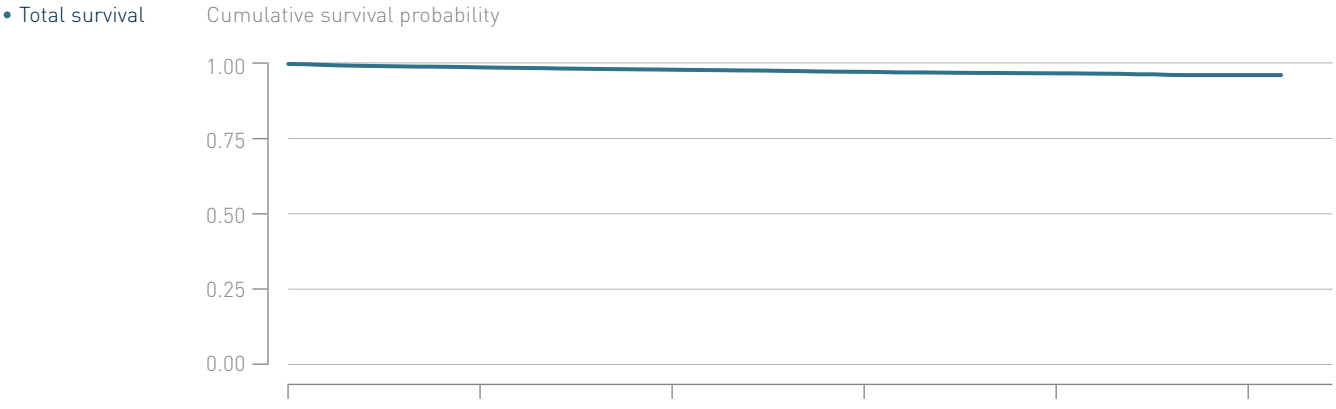
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.2	95.9	95.3	95.1	95.0	95.0	95.0
CI [±%]	-	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.4	1.4	1.4	1.4
Sample Size	1423	1237	1121	1016	932	865	810	776	750	729	712	704	692	681	648	322

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	116 000
Registered U.S. Implants	17 682
Estimated Active U.S. Implants	15 100
U.S. Total Returned	196

	Quantity	Rate
U.S. Qualifying Complications	330	1.85%
Abnormal pacing impedance	42	0.24%
Conductor fracture	7	0.04%
Extracardiac stimulation	15	0.08%
Failure to capture	81	0.45%
Failure to sense	2	0.01%
Lead dislodgement	123	0.69%
Oversensing	44	0.25%
Other	16	0.09%

	Quantity	Rate
U.S. Confirmed Malfunctions	44	0.25%
Conductor Fracture	43	0.24%
Other	1	0.01%
U.S. Acute Lead Observations	53	0.30%
Abnormal pacing impedance	2	0.01%
Conductor fracture	1	0.01%
Extracardiac stimulation	7	0.04%
Failure to capture	9	0.05%
Lead dislodgement	29	0.16%
Oversensing	3	0.02%
Other	2	0.01%



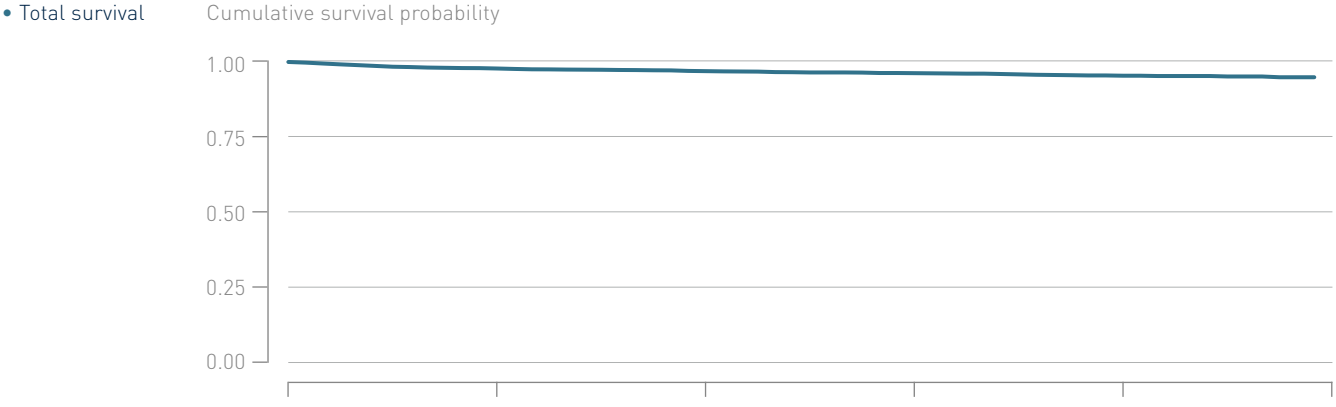
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.8	98.0	97.2	96.7	96.0
CI [±%]	-	0.2	0.2	0.3	0.4	0.5
Sample Size	17 682	12 966	9 384	6 164	2 979	396

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	23 500
Registered U.S. Implants	4 576
Estimated Active U.S. Implants	3 390
U.S. Total Returned	119

	Quantity	Rate
U.S. Qualifying Complications	134	2.88%
Abnormal pacing impedance	9	0.19%
Conductor fracture	4	0.09%
Extracardiac stimulation	7	0.15%
Failure to capture	33	0.71%
Insulation breach	1	0.02%
Lead dislodgement	66	1.42%
Oversensing	13	0.28%
Other	1	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	9	0.19%
Conductor Fracture	9	0.19%
U.S. Acute Lead Observations	87	1.87%
Abnormal pacing impedance	1	0.02%
Extracardiac stimulation	4	0.09%
Failure to capture	12	0.26%
Failure to sense	1	0.02%
Lead dislodgement	64	1.38%
Oversensing	3	0.06%
Other	2	0.04%



Years after implant	0	1	2	3	4
Total [%]	100.0	97.7	96.8	96.1	95.2
CI [±%]	-	0.5	0.6	0.7	0.8
Sample Size	4 576	3 227	2 541	1 850	1 010

Methodology for Lead Survival Estimates Based on Clinical Studies

7. Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

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

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

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

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

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

7.2 BIOTRONIK's Clinical Studies

7.2.1 GALAXY and CELESTIAL

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

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

Every effort is made to ensure participants are representative of the

range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits per their institutional standard of care until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum of once every six months follow-up requirement.

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

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

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

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

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

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

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

7.2.2 SIELLO Clinical Study

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

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

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

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

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

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

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

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

- Candidate for de novo implantation of a market-released BIOTRONIK pacemaker system, including one or two Siello leads. Candidate meets recommendation for pacemaker system implant put forth by guidelines of relevant professional societies
- Able to understand the nature of the study and provide informed consent
- Available for follow-up visits on a regular basis at the investigational site for the expected 5 years of follow-up
- Age greater than or equal to 18 years

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

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

7.2.3 QP ExCELs

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

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

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

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

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

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

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

7.3 Lead Complications

The data presented characterizes chronic lead performance by estimating lead-related complication free survival probabilities. Following industry practice, for analysis purposes, the complication criteria, which align with the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", are defined below.

7.3.1 GALAXY and CELESTIAL

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

Event Classifications
- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 – 2,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is 25 – 150 ohms)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

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

7.3.2 SIELLO

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

Event Classifications

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

7.3.3 QP ExCELs

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

Event Classifications

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

7.4 Lead Product Performance Graphs and Data

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

Returned Product Analysis Results

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

Performance of BIOTRONIK Leads Based on Clinical Study Data

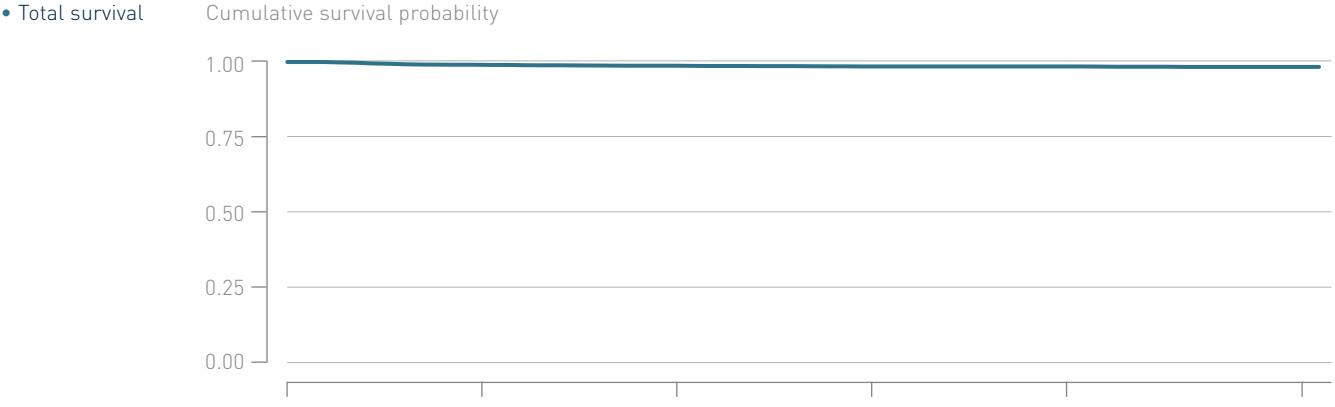
Performance of BIOTRONIK Leads Based on Clinical Study Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 134 000
Registered U.S. Implants	3 245

	Quantity	Rate
U.S. Qualifying Complications	54	1.66%
Abnormal pacing impedance	4	0.12%
Cardiac perforation	3	0.09%
Conductor fracture	2	0.06%
Failure to capture	23	0.71%
Failure to sense (undersensing)	11	0.34%
Lead dislodgement	9	0.28%
Oversensing	1	0.03%
Other	1	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.09%
Conductor Fracture	1	0.03%
Insulation Breach	1	0.03%
Other	1	0.03%
U.S. Acute Lead Observations	26	0.80%
Cardiac perforation	8	0.25%
Extracardiac stimulation	2	0.06%
Failure to capture	6	0.18%
Failure to sense (undersensing)	5	0.15%
Lead dislodgement	5	0.15%



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.9	98.5	98.3	98.2	98.1
CI [±%]	-	0.4	0.4	0.5	0.5	0.5
Sample Size	3 245	2 793	2 479	2 200	1 769	293

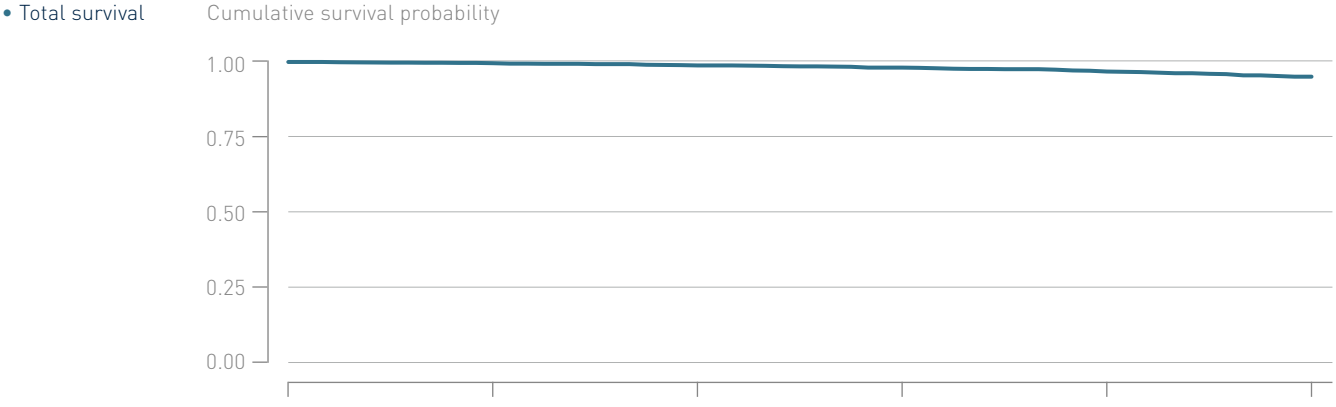
Performance of BIOTRONIK Leads Based on Clinical Study Data

Linox SD

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

	Quantity	Rate
U.S. Qualifying Complications	68	2.99%
Abnormal defibrillation impedance	4	0.18%
Abnormal pacing impedance	10	0.44%
Cardiac perforation	1	0.04%
Conductor fracture	10	0.44%
Failure to capture	7	0.31%
Failure to sense	3	0.13%
Insulation breach	13	0.57%
Lead dislodgement	3	0.13%
Oversensing	17	0.75%

	Quantity	Rate
U.S. Confirmed Malfunctions	24	1.06%
Conductor Fracture	3	0.13%
Insulation Breach	21	0.92%
U.S. Acute Lead Observations	8	0.35%
Cardiac perforation	4	0.18%
Conductor fracture	1	0.04%
Failure to capture	1	0.04%
Lead dislodgement	1	0.04%
Other	1	0.04%



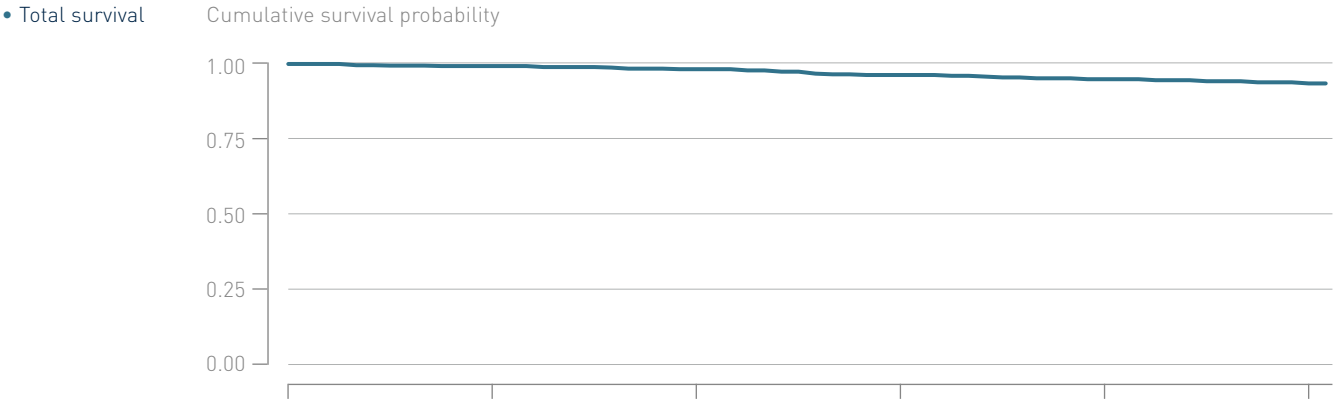
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	98.8	98.0	96.7	94.9
CI [±%]	-	0.3	0.5	0.7	0.9	1.3
Sample Size	2 272	1 937	1 618	1 302	1 014	392

Linox^{smart} SD

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

	Quantity	Rate
U.S. Qualifying Complications	29	3.94%
Abnormal defibrillation impedance	2	0.27%
Abnormal pacing impedance	2	0.27%
Conductor fracture	3	0.41%
Failure to capture	3	0.41%
Insulation breach	4	0.54%
Lead dislodgement	6	0.82%
Oversensing	9	1.22%

	Quantity	Rate
U.S. Confirmed Malfunctions	8	1.09%
Insulation Breach	8	1.09%
U.S. Acute Lead Observations	2	0.27%
Lead dislodgement	2	0.27%



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

Performance of BIOTRONIK Leads Based on Clinical Study Data

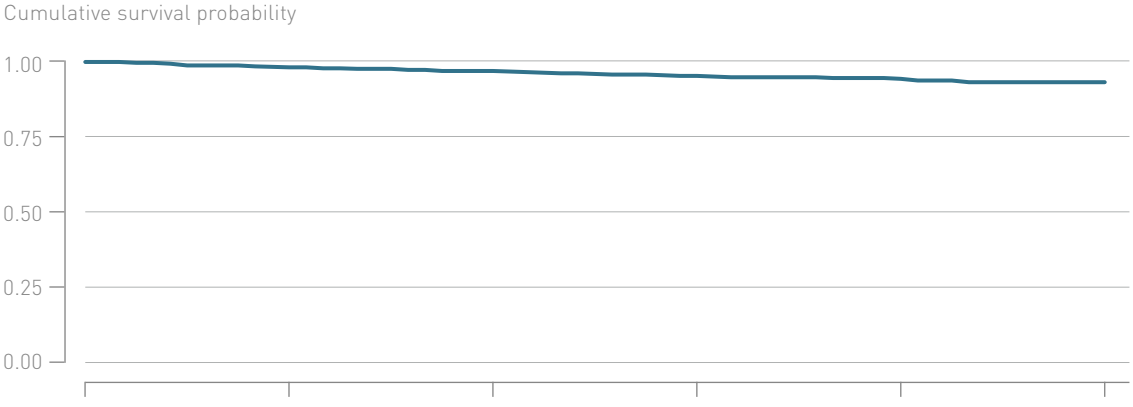
Corox OTW

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

	Quantity	Rate
U.S. Qualifying Complications	35	5.03%
Abnormal pacing impedance	6	0.86%
Conductor fracture	5	0.72%
Extracardiac stimulation	3	0.43%
Failure to capture	5	0.72%
Lead dislodgement	16	2.30%

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.86%
Conductor Fracture	6	0.86%
U.S. Acute Lead Observations	4	0.57%
Extracardiac stimulation	1	0.14%
Lead dislodgement	3	0.43%

• Total survival



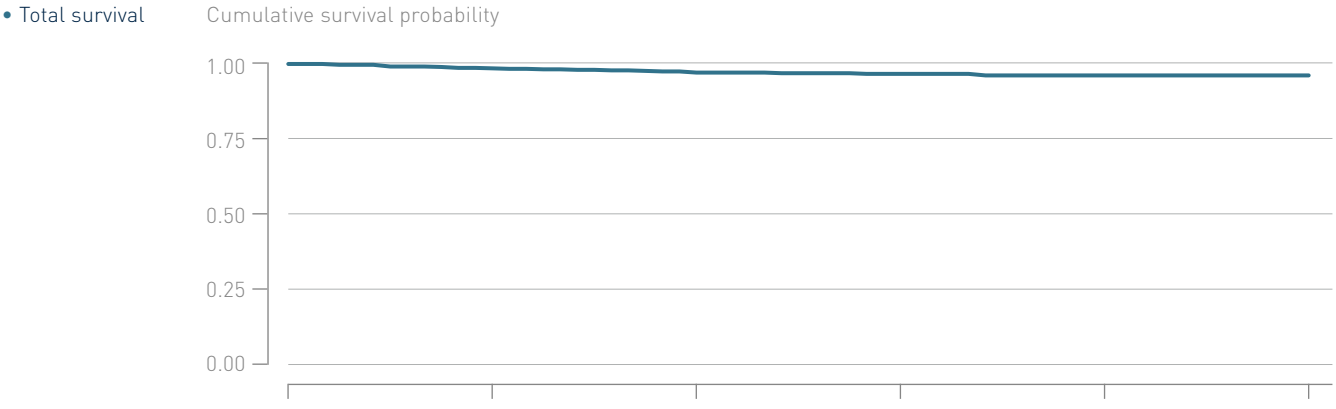
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	96.9	95.2	94.2	93.0
CI [±%]	-	1.1	1.4	1.8	2.1	2.3
Sample Size	696	589	489	407	329	135

Corox OTW-L

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Leads registered in study	699

	Quantity	Rate
U.S. Qualifying Complications	22	3.15%
Extracardiac stimulation	4	0.57%
Failure to capture	8	1.14%
Lead dislodgement	10	1.43%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	4	0.57%
Extracardiac stimulation	3	0.43%
Lead dislodgement	1	0.14%



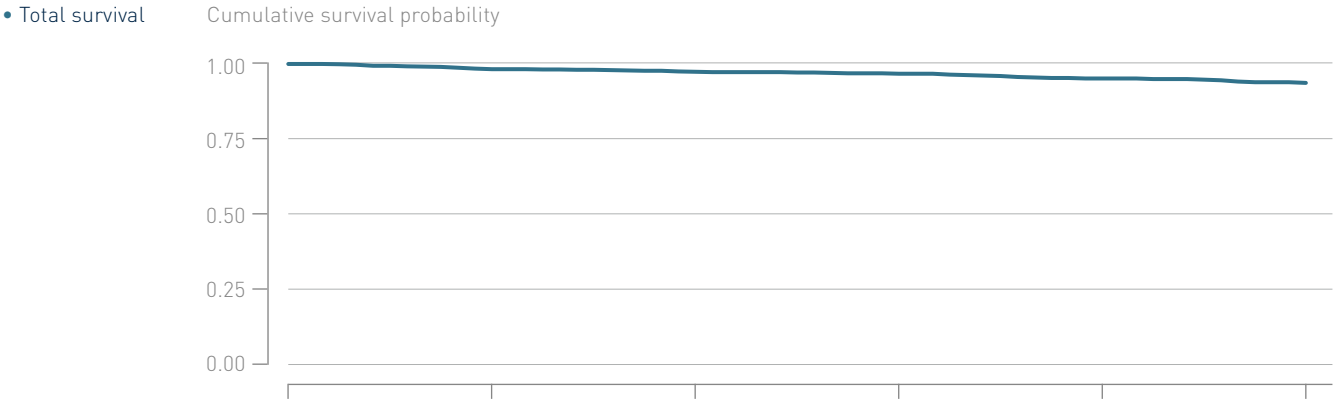
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.0	96.5	96.0	96.0
CI [±%]	-	1.0	1.4	1.6	1.7	1.7
Sample Size	699	584	475	382	303	130

Corox OTW-S

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

	Quantity	Rate
U.S. Qualifying Complications	49	4.29%
Abnormal pacing impedance	13	1.14%
Extracardiac stimulation	9	0.79%
Failure to capture	9	0.79%
Lead dislodgement	18	1.58%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.09%
Insulation Breach	1	0.09%
U.S. Acute Lead Observations	5	0.44%
Extracardiac stimulation	1	0.09%
Failure to capture	1	0.09%
Lead dislodgement	3	0.26%



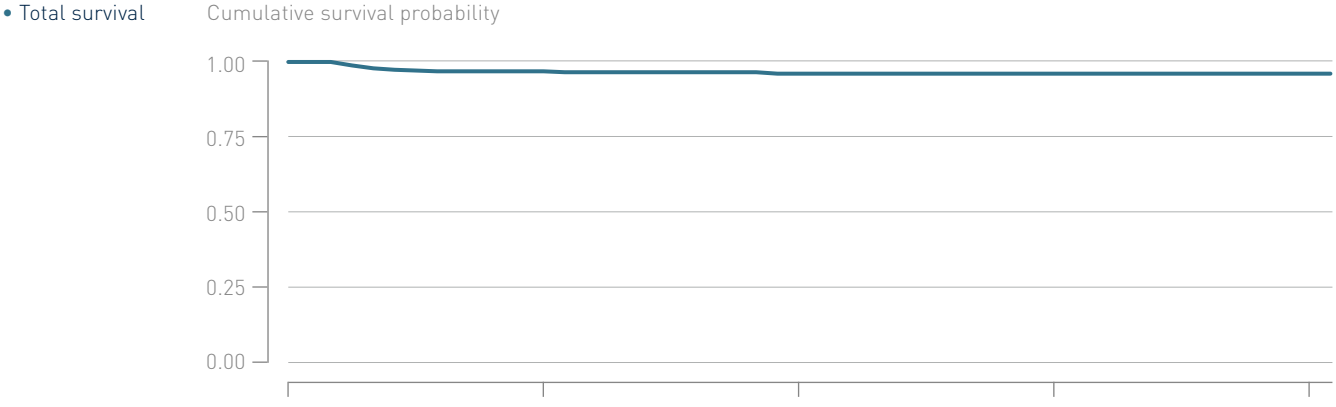
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	97.3	96.6	95.0	93.5
CI [±%]	-	0.8	1.0	1.2	1.5	1.9
Sample Size	1 141	963	813	648	505	192

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	22 200
Registered U.S. Implants	436

	Quantity	Rate
U.S. Qualifying Complications	15	3.44%
Conductor fracture	1	0.23%
Extracardiac Stimulation	1	0.23%
Failure to Capture	3	0.69%
Lead dislodgement	10	2.29%

	Quantity	Rate
U.S. Confirmed Malfunctions	5	1.15%
Conductor Fracture	5	1.15%
U.S. Acute Lead Observations	10	2.29%
Cardiac perforation	1	0.23%
Failure to Capture	1	0.23%
Lead dislodgement	8	1.83%



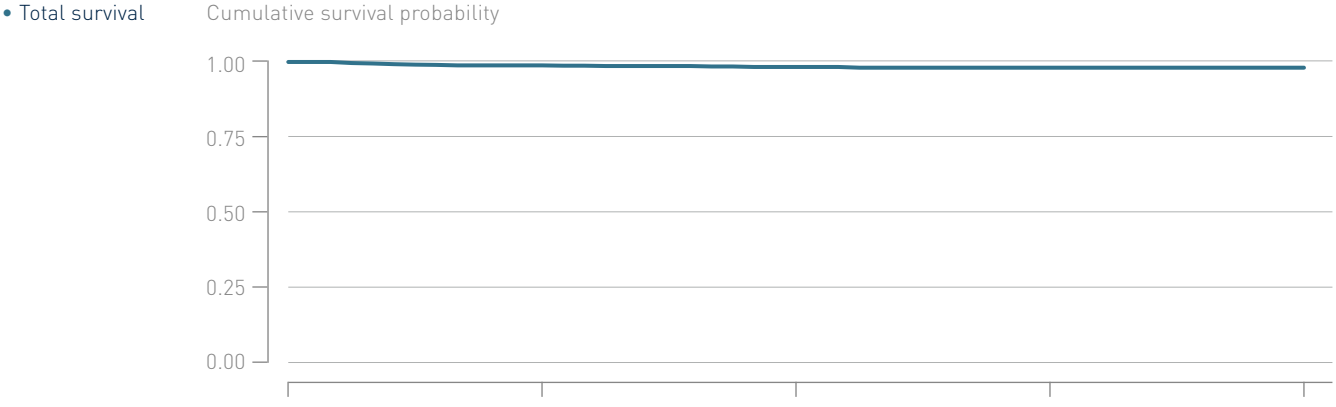
Years after implant	0	1	2	3	4
Total [%]	100.0	96.7	95.9	95.9	95.9
CI [±%]	-	1.8	2.2	2.2	2.2
Sample Size	436	299	170	55	0

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	106 000
Registered U.S. Implants	1 308

	Quantity	Rate
U.S. Qualifying Complications	21	1.61%
Abnormal pacing impedance	3	0.23%
Conductor fracture	1	0.08%
Extracardiac Stimulation	2	0.15%
Failure to Capture	4	0.31%
Lead dislodgement	11	0.84%

	Quantity	Rate
U.S. Confirmed Malfunctions	11	0.84%
Conductor Fracture	10	0.76%
U.S. Acute Lead Observations	7	0.54%
Extracardiac Stimulation	1	0.08%
Failure to Capture	4	0.31%
Lead dislodgement	2	0.15%



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

9

Methodology for Lead Survival Estimates based on Insurance Claims Data

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

9.1 Introduction

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

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

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

9.2 Claims Data Methodologies and Data Sets

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

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

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

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

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

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

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

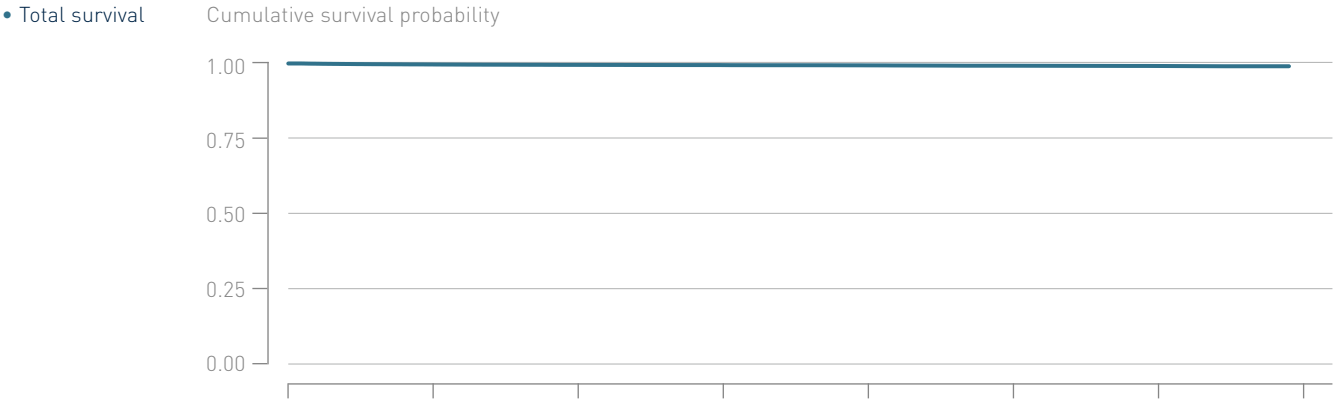
1 Hicks J, Keith M, Moll P, Simeles J, Offer E, Diani C, Rock A, and Mitchell K. Novel Method to Identify Lead Complications in Pacemaker Systems from Real-World Data: Proof of Concept for the Siello S Pacing Lead. Heart Rhythm. 2019; 16(5), Supplement, S-PO03-089.

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Siello S / Solia S EP-Passion Data

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 325 000
Registered U.S. Implants	81 223

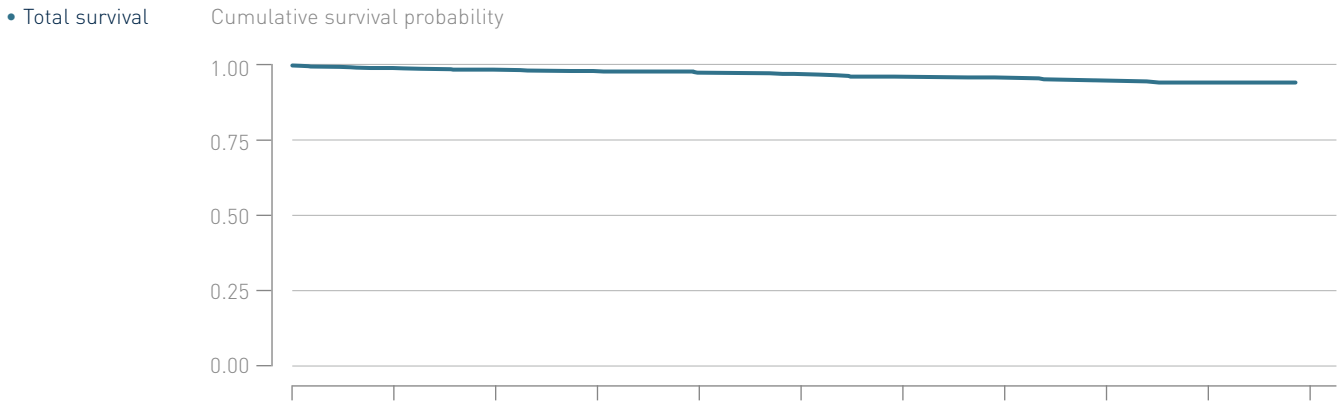


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.6	99.4	99.3	99.2	99.1	99.0	98.9
CI [±%]	0.0	0.1	0.1	0.1	0.2	0.4	0.6	0.9
Sample Size	81 223	55 347	40 216	24 526	10 901	1 818	1 021	535

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Linox S EP-Passion Data

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32700
Registered U.S. Implants	866

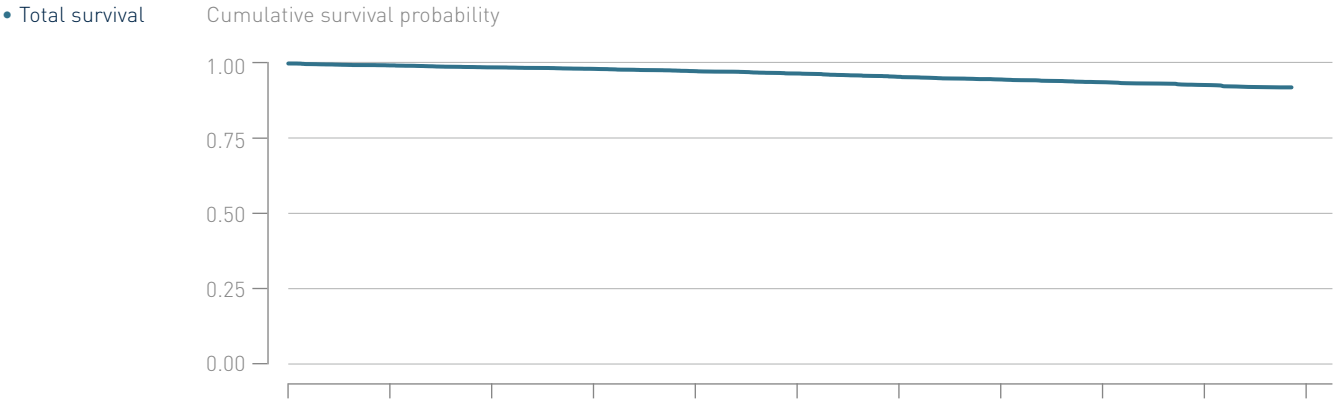


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.1	98.6	98.1	97.5	97.1	96.2	95.9	94.9	94.1	94.1
CI [±%]	0.0	0.7	0.9	1.1	1.4	1.6	1.9	2.1	2.6	3.0	3.4
Sample Size	866	🔒	646	571	496	440	379	331	271	219	177

🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

Linox SD EP-Passion Data

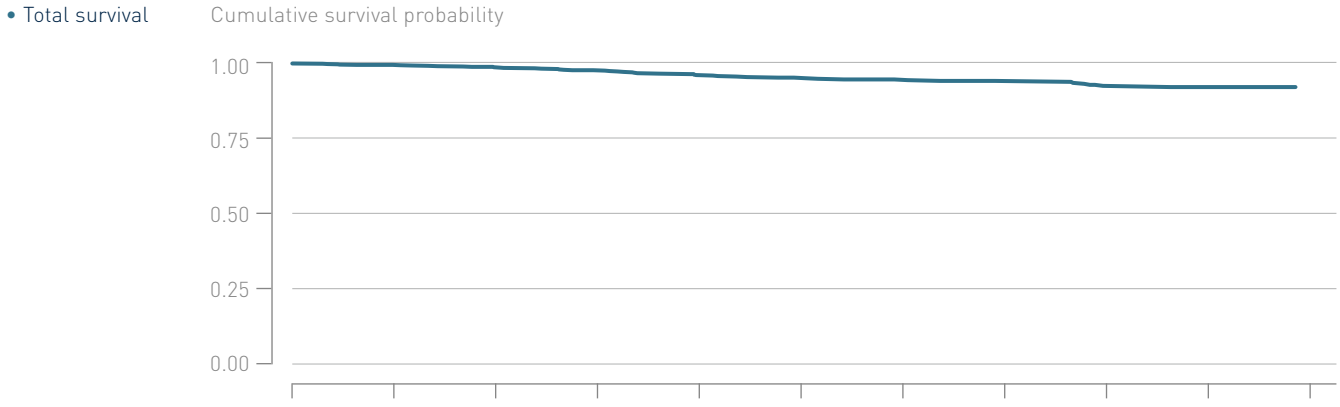
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	7 247



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.4	98.7	98.2	97.4	96.6	95.4	94.6	93.6	92.7	91.8
CI [±%]	0.0	0.2	0.3	0.4	0.5	0.6	0.8	0.9	1.1	1.3	1.5
Sample Size	7 247	6 016	5 194	4 476	3 755	3 136	2 591	2 118	1 748	1 403	1 150

Linox TD EP-Passion Data

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

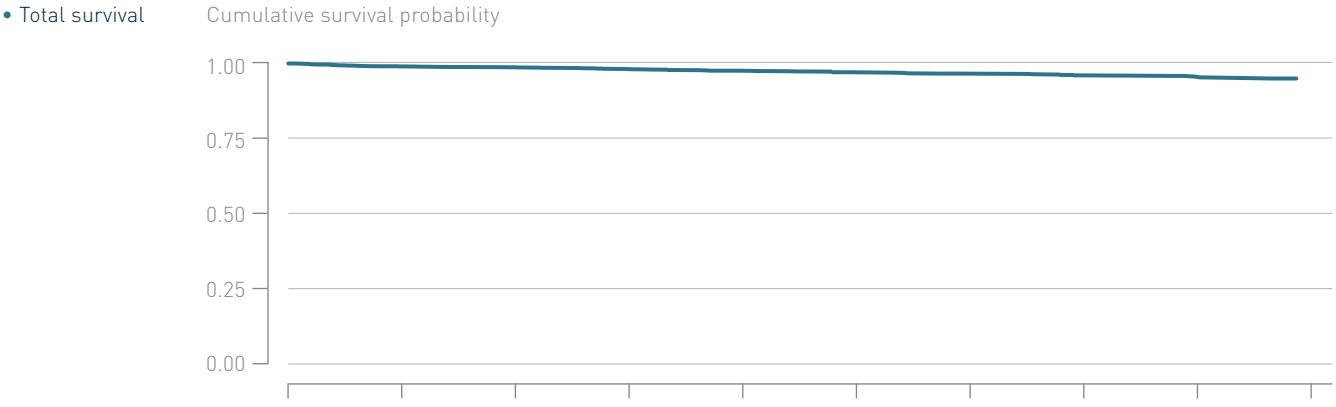


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.5	98.7	97.7	96.0	95.2	94.5	94.0	92.3	91.9	91.9
CI [±%]	0.0	0.4	0.8	1.1	1.5	1.9	2.2	2.5	3.1	3.5	3.9
Sample Size	1 148	🔒	819	696	587	482	398	328	262	216	175

🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

Linox Smart S EP-Passion Data

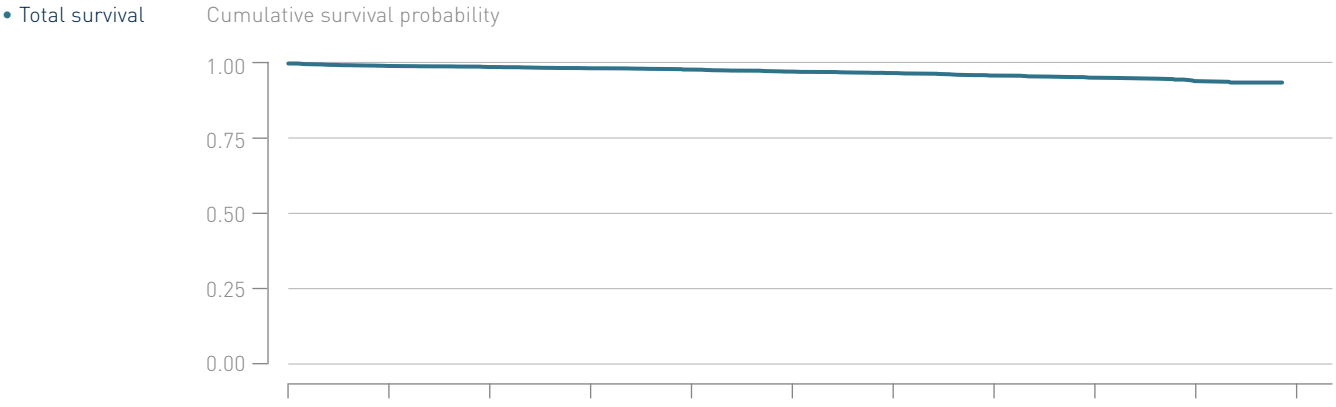
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	3 006



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.0	98.7	98.0	97.5	97.0	96.5	95.9	95.4	94.8
CI [±%]	0.0	0.4	0.5	0.6	0.8	0.9	1.1	1.4	2.0	3.2
Sample Size	3 006	2 509	2 176	1 883	1 622	1 340	1 068	742	390	175

Linox Smart SD EP-Passion Data

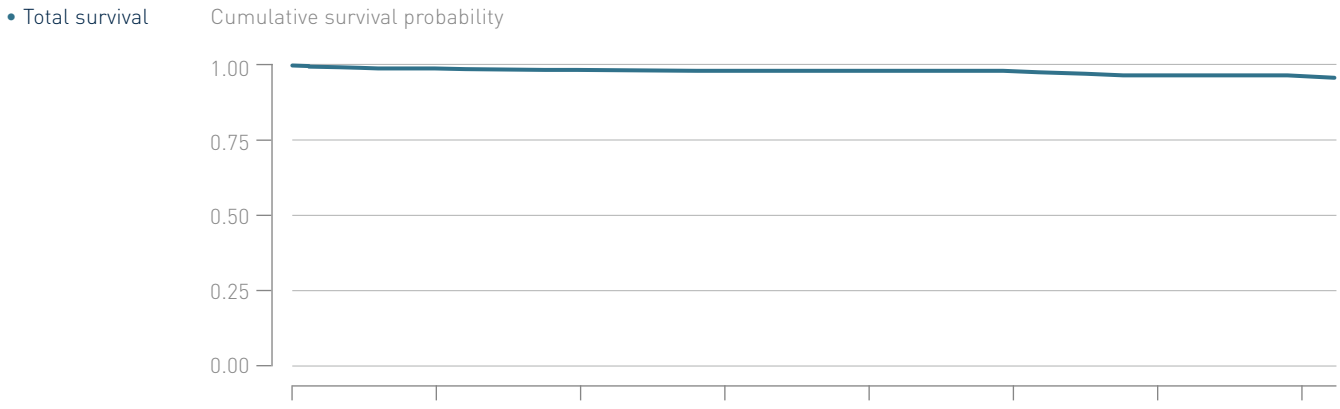
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	5 285



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.1	98.8	98.4	97.9	97.2	96.7	95.9	95.1	93.9	93.4
CI [±%]	0.0	0.3	0.3	0.4	0.5	0.7	0.8	1.0	1.3	2.0	3.7
Sample Size	5 285	4 317	3 725	3 232	2 791	2 341	1 928	1 460	1 011	538	162

Linox Smart TD EP-Passion Data

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

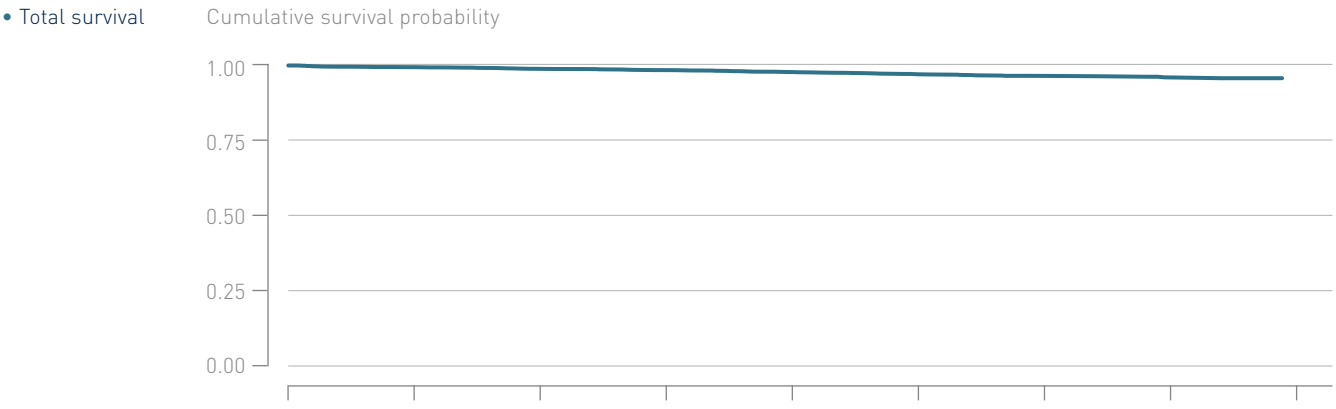


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.0	98.4	98.1	98.1	98.1	96.5	96.5
CI [±%]	0.0	1.0	1.3	1.5	1.7	1.8	2.7	3.1
Sample Size	523	🔒	🔒	🔒	🔒	🔒	168	126

🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

Linox Smart S DX EP-Passion Data

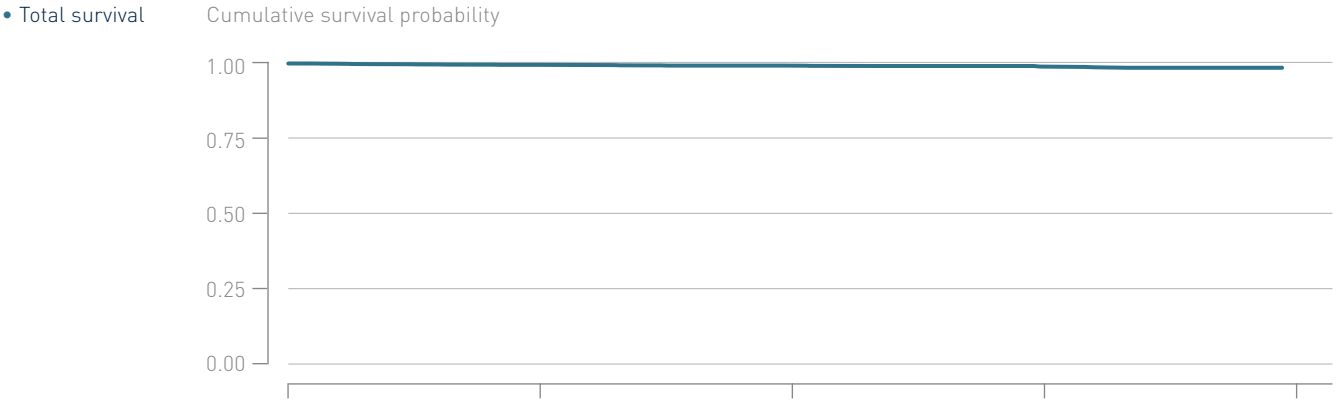
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	4665



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.4	98.8	98.4	97.7	97.0	96.4	95.9	95.5
CI [±%]	0.0	0.2	0.4	0.5	0.6	0.8	1.1	1.8	2.3
Sample Size	4665	3852	3375	2908	2403	1585	981	464	131

Plexa S EP-Passion Data

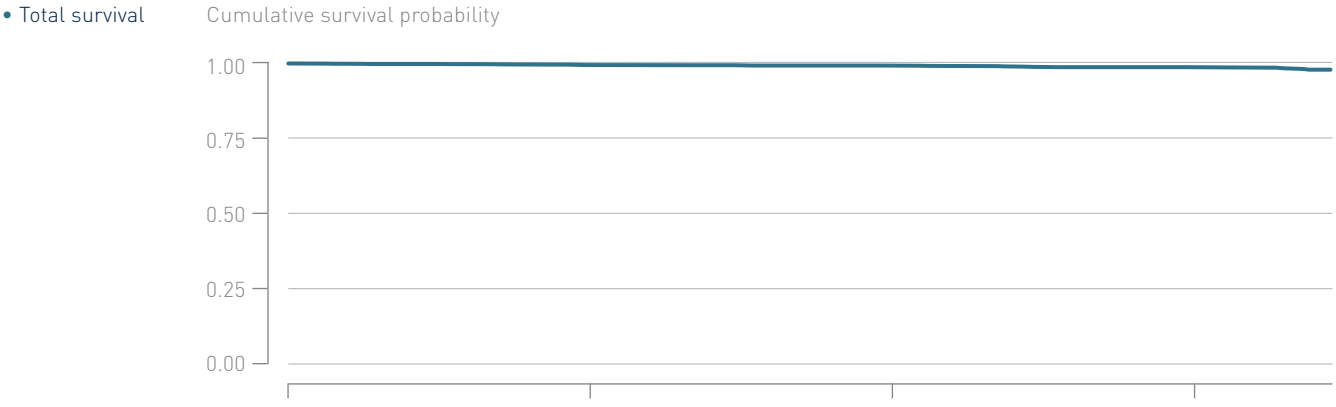
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	122 000
Registered U.S. Implants	5 181



Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.2	98.8	98.4
CI [±%]	0.0	0.3	0.4	0.7	1.9
Sample Size	5 181	3 210	2 004	897	100

Plexa S DX DF1 EP-Passion Data

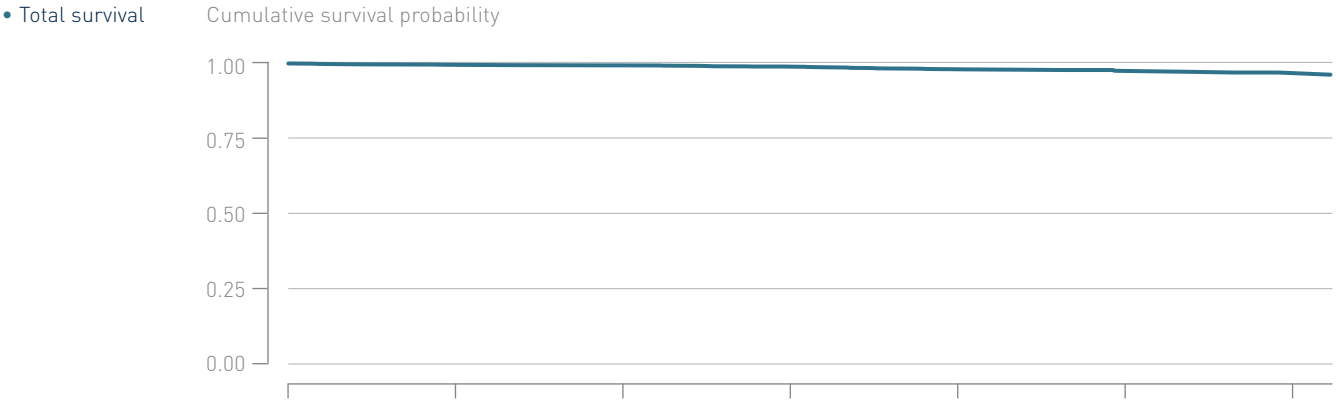
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	22 200
Registered U.S. Implants	2 345



Years after implant	0	1	2	3
Total [%]	100.0	99.4	99.2	98.7
CI [±%]	0.0	0.3	0.4	0.8
Sample Size	2 345	1 904	1 484	715

Protego S EP-Passion Data

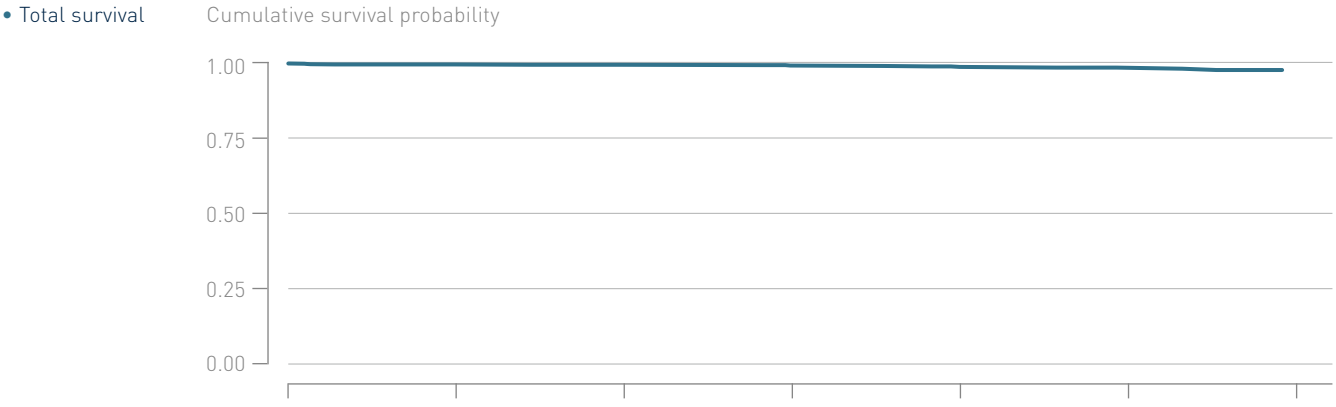
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	3 087



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.5	99.3	98.9	98.0	97.4	96.8
CI [±%]	0.0	0.3	0.3	0.5	0.7	1.1	2.3
Sample Size	3 087	2 614	2 297	1 984	1 581	783	222

Protego SD EP-Passion Data

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18400
Registered U.S. Implants	1178



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.7	99.5	99.2	98.7	98.5	97.6
CI [±%]	0.0	0.4	0.5	0.6	0.9	1.3	2.4
Sample Size	1178	🔒	🔒	🔒	🔒	321	123

🔒 cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

Advisories

11. Advisories

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

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

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

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

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

As of May 2023
- The cumulative failure rate is 1.05%
- 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 for loss of pacing
0 – 24 months	< 0.00001%
24 – 48 months	0.0013%
48 – 72 months	0.0096%

Risk for loss of high-voltage therapy

Service Time	Risk per month for loss of shock therapy
0 – 24 months	< 0.00001%
24 – 48 months	0.0021%
48 – 72 months	0.0148%

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

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

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

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

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

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

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

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

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

Early Battery Failure Detection
By design, BIOTRONIK's programmer and Home Monitoring system are equipped with a battery depletion detector. This feature allows a battery depletion, including any premature depletion, to be detected early and displayed by an ERI during in-office follow-up, or via daily remote

11. Advisories

monitoring using BIOTRONIK Home Monitoring.

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

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

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

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

In consultation with our medical advisory board, BIOTRONIK does not recommend prophylactic replacement. The risk of complications for ICD exchange[1,2,3] outweighs the risk associated with this issue. We refer to the above patient management recommendations in case an unexpected ERI is observed.
We recognize that individual patients have unique clinical needs. Ultimately, patient care—including the frequency of follow-ups—is determined by the physician's clinical judgement, based on individual patient circumstances.

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

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

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

X-Ray Identifiers for Pacemakers and ICDs

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

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Regarding this Report

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