Product Performance Report

1st Edition 2021

Cardiac Rhythm Management
Cumulative Survival Probability

BIOTRONIK
excellence for life

Product Performance Report 1st Edition 2021

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

Contents

Quality Excellence

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

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

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

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

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

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

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

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

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

BIOTRONIK, July 2021

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

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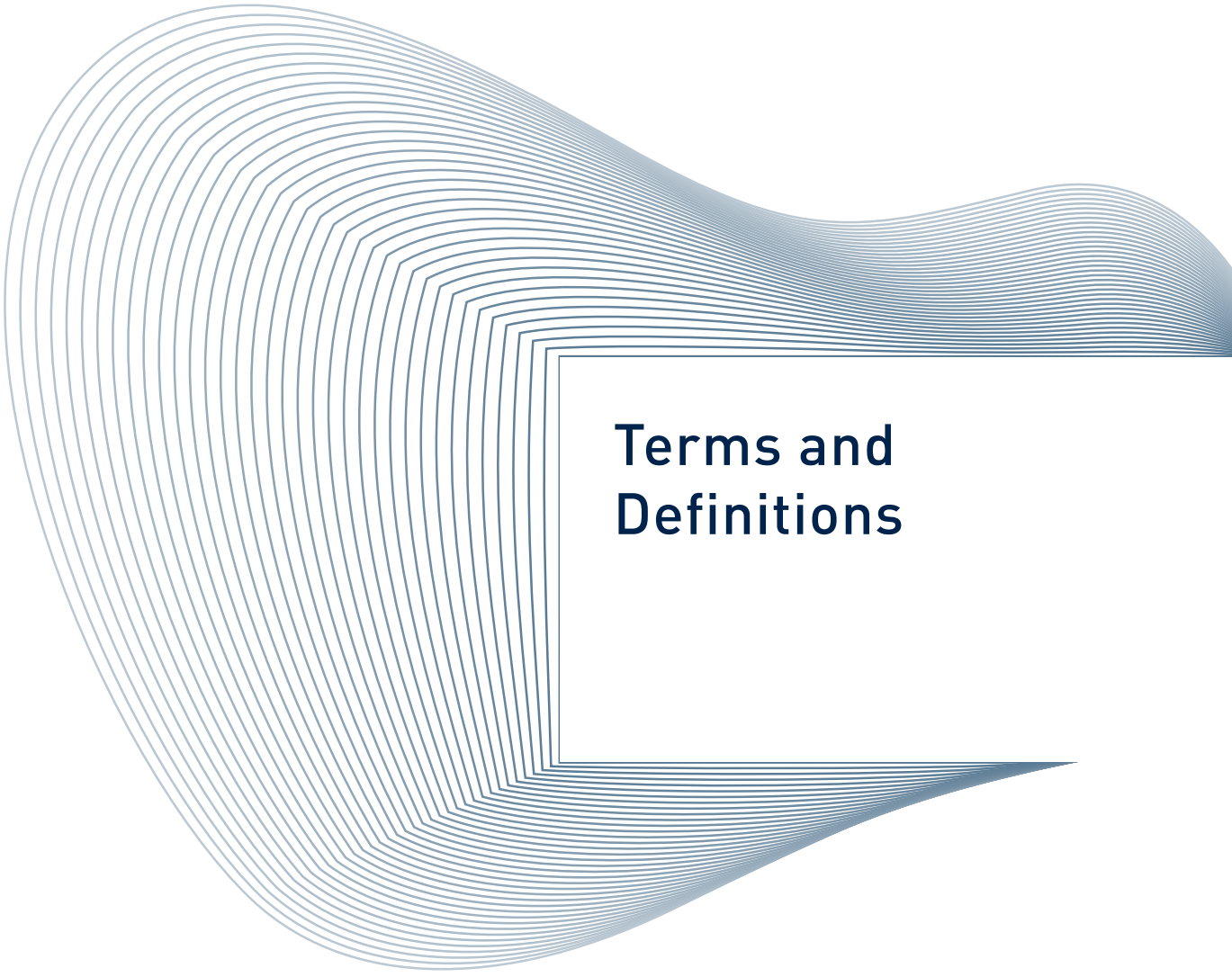

Terms and Definitions

1. Terms and Definitions

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

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

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

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

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

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

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

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

Lead Complications

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

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

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

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

- Failure to capture
- Failure to sense
- Oversensing
- Abnormal pacing impedance
- Abnormal defibrillation impedance
- Insulation breach
- Conductor fracture
- Lead dislodgement
- Extracardiac stimulation
- Cardiac perforation
- Other

Survival Probability Estimates

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

Cumulative Survival Probability Estimates

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

Implanted Devices

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

Active Implants

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

Underreporting

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

Safety Advisory Notifications

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

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Methodology for Pacemaker and ICD Survival Estimates

2. Methodology for Pacemaker and ICD Survival Estimates

2.1 Cumulative Survival Probability

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

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

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

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

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

2.2 Data Acquisition

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

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

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

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

2.3 Returned Product Analysis

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

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

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

2.4 Product Performance Graphs and Data

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

For each product, the report provides:

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

The survival plots provide:

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

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

Products or subgroups of products may become subject to safety advisory notifications that can significantly impact the overall product performance. However, as these subgroups are clearly defined they are separated from the non-advisory devices. The impact of the advisory notification is then shown in a separate graph for total cumulative survival and for malfunction-free survival of the device population affected by the advisory notification. Current advisories are listed in chapter 9 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

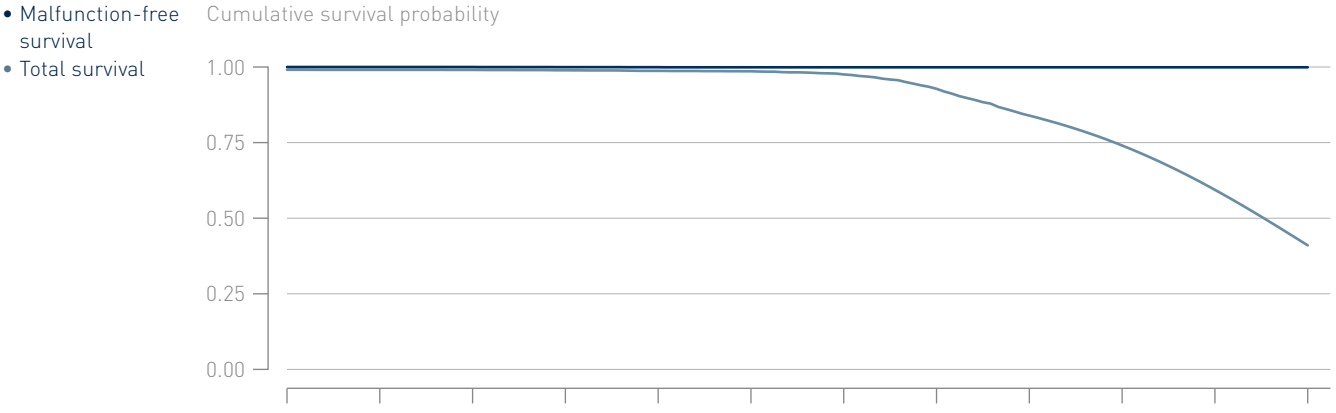
Performance of BIOTRONIK Pacemakers

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	6 148
Estimated Active U.S. Implants	2 520
U.S. Normal Battery Depletions	838

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

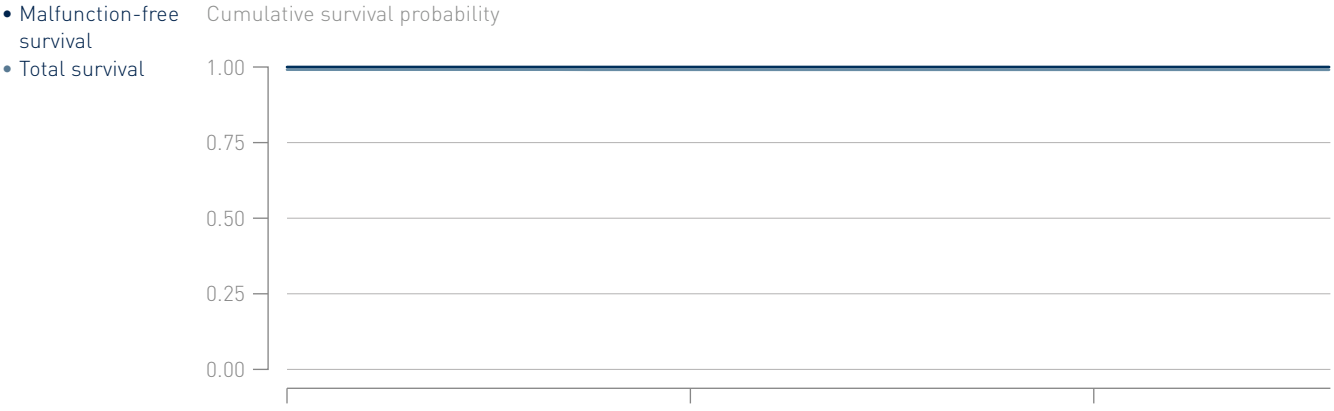


Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.9	99.9	99.8	99.6	99.5	98.4	93.7	84.8	74.9	60.3	41.9
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.4	0.8	1.2	1.4	1.7	3.6
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	6148	5406	4909	4540	4223	4006	3819	3500	3039	2625	1817	318

Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	25 600
Registered U.S. Implants	4 647
Estimated Active U.S. Implants	4 250
U.S. Normal Battery Depletions	1

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

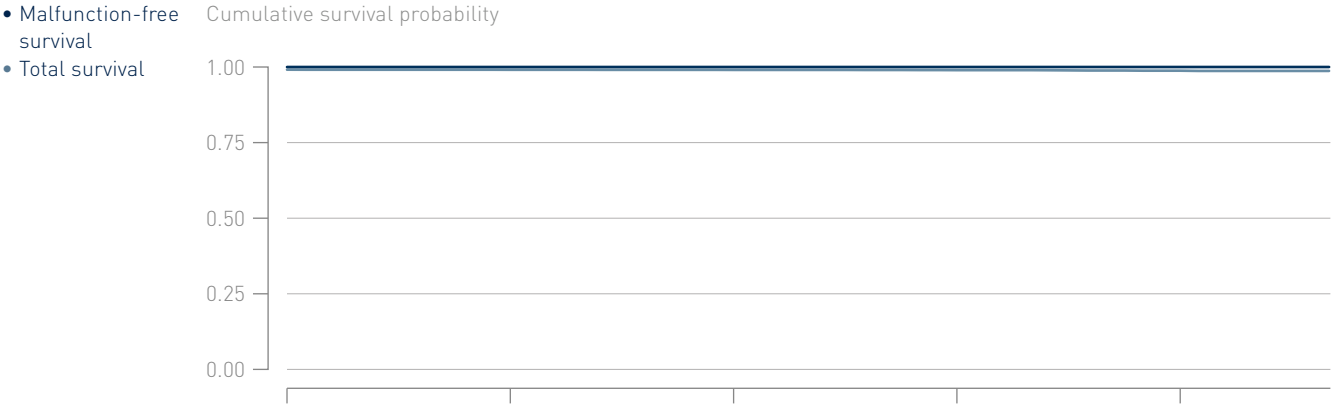


Years after implant	0	1	2
Total [%]	100.0	100.0	100.0
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	4 647	2 882	1 158

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	5 796
Estimated Active U.S. Implants	4 630
U.S. Normal Battery Depletions	12

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

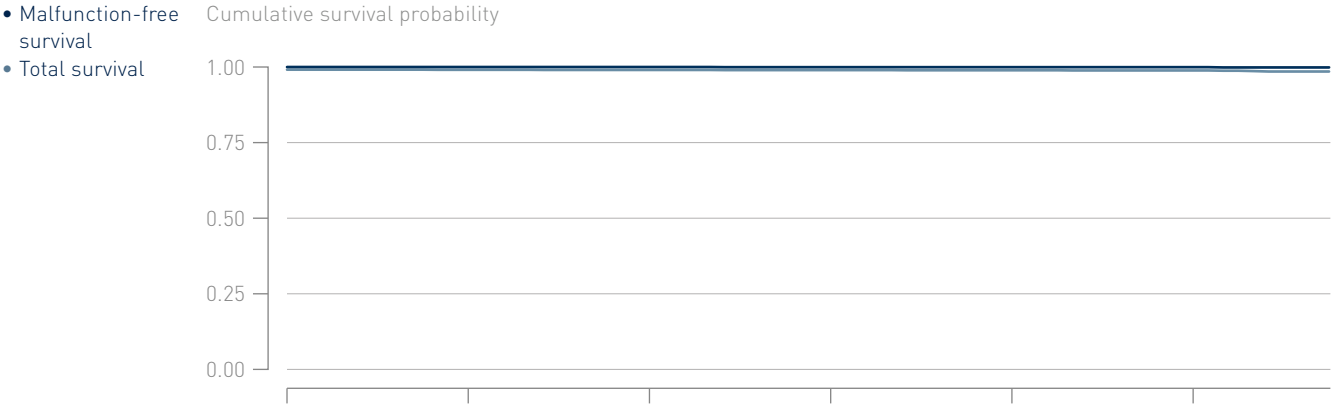


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.8	99.7
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	5 796	5 251	4 641	3 613	1 422

Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28 000
Registered U.S. Implants	2 398
Estimated Active U.S. Implants	1 690
U.S. Normal Battery Depletions	6

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

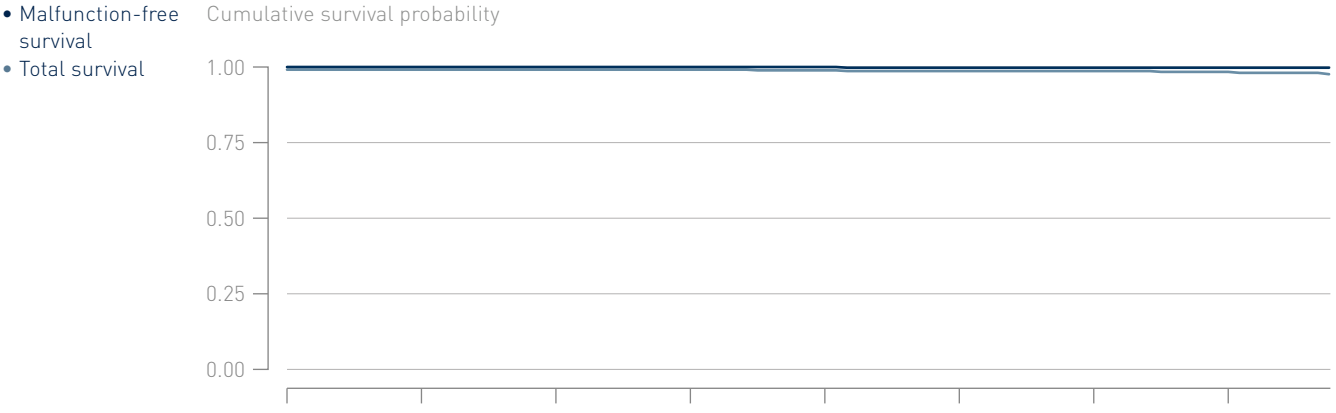


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.9	99.9	99.8	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	2398	2190	2064	1936	1784	1298

Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	38 100
Registered U.S. Implants	611
Estimated Active U.S. Implants	404
U.S. Normal Battery Depletions	4

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

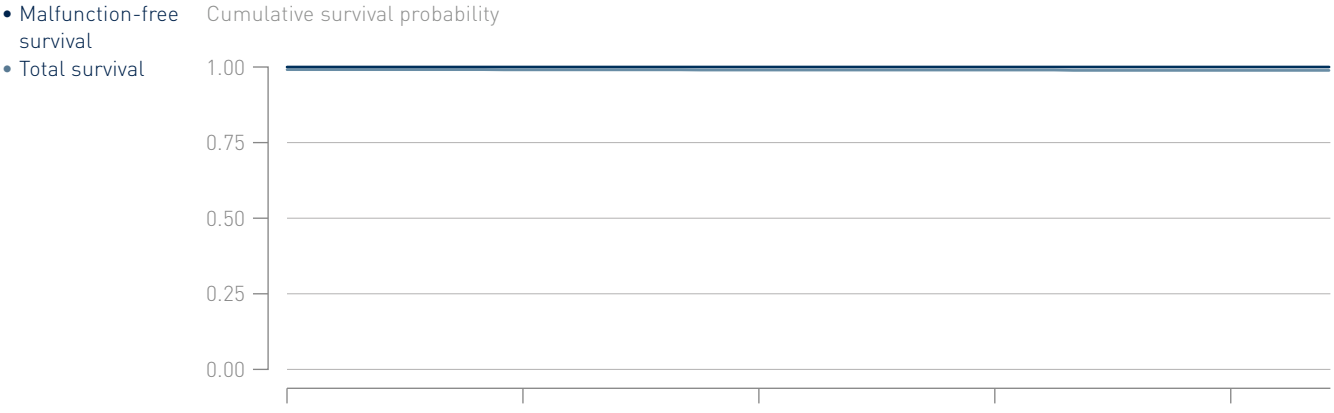


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.5	99.3
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.8	99.8	99.8
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	611	534	493	453	432	421	408	312

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18 500
Registered U.S. Implants	1 723
Estimated Active U.S. Implants	1 380
U.S. Normal Battery Depletions	3

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

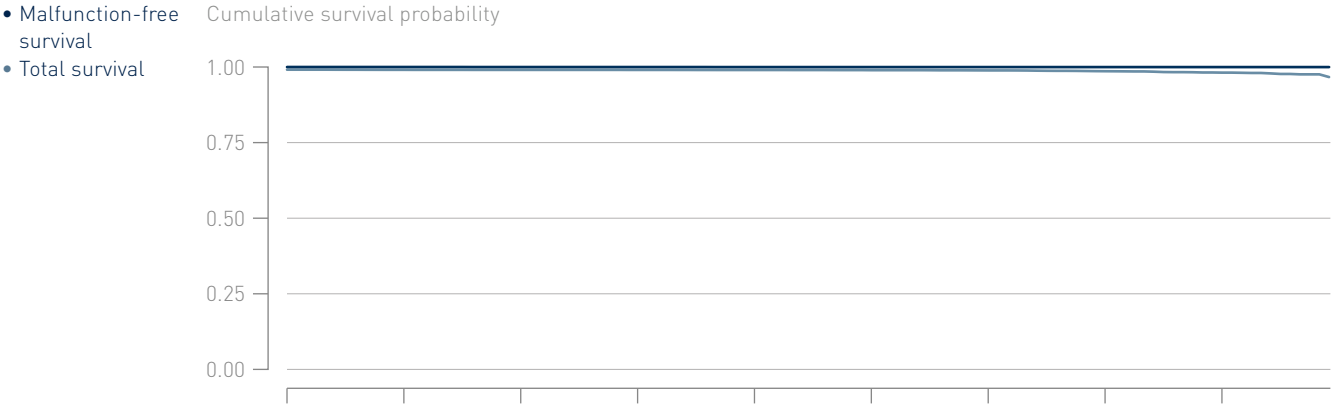


Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.9	99.9	99.8
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	1 723	1 569	1 365	1 036	510

Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	61 800
Registered U.S. Implants	11 972
Estimated Active U.S. Implants	7 820
U.S. Normal Battery Depletions	59

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

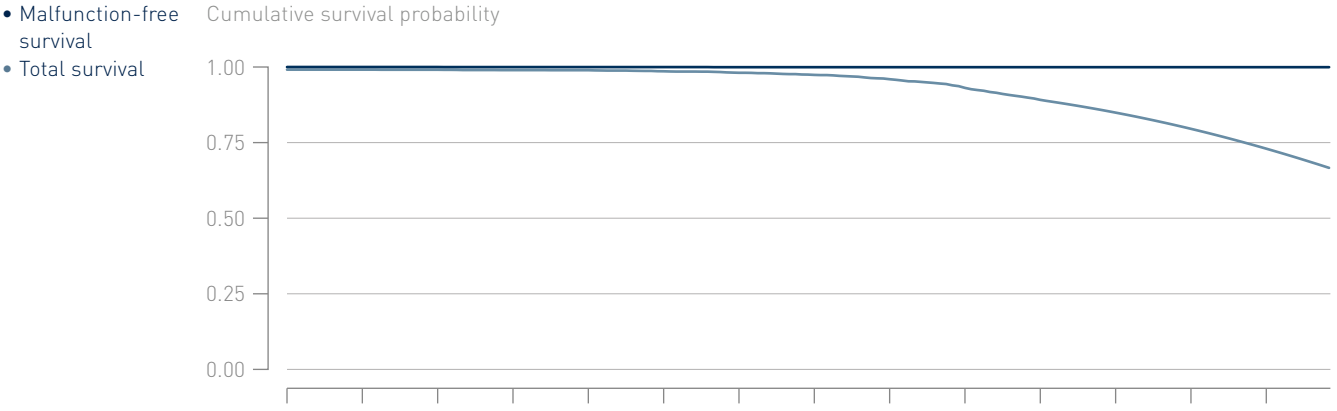


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.5	99.0
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	11 972	10 742	10 109	9 633	9 283	8 605	6 976	4 518	2 221

Philos II and Talos

Product Versions	S, SR
NBG Codes	SSI, SSIR
US Market Release	Sep 2004
CE Market Release	Feb 2004 / May 2006
Worldwide Distributed Devices	215 000
Registered U.S. Implants	5 238
Estimated Active U.S. Implants	2 480
U.S. Normal Battery Depletions	385

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	100.0	100.0	99.8	99.8	99.5	99.0	98.3	96.8	94.0	90.0	85.8	80.4	73.9
CI [±%]	-	<0.1	<0.1	0.1	0.1	0.2	0.3	0.4	0.6	0.8	1.1	1.3	1.6	2.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5 238	4 431	4 037	3 705	3 489	3 310	3 169	3 078	2 958	2 797	2 420	1 804	1 235	651

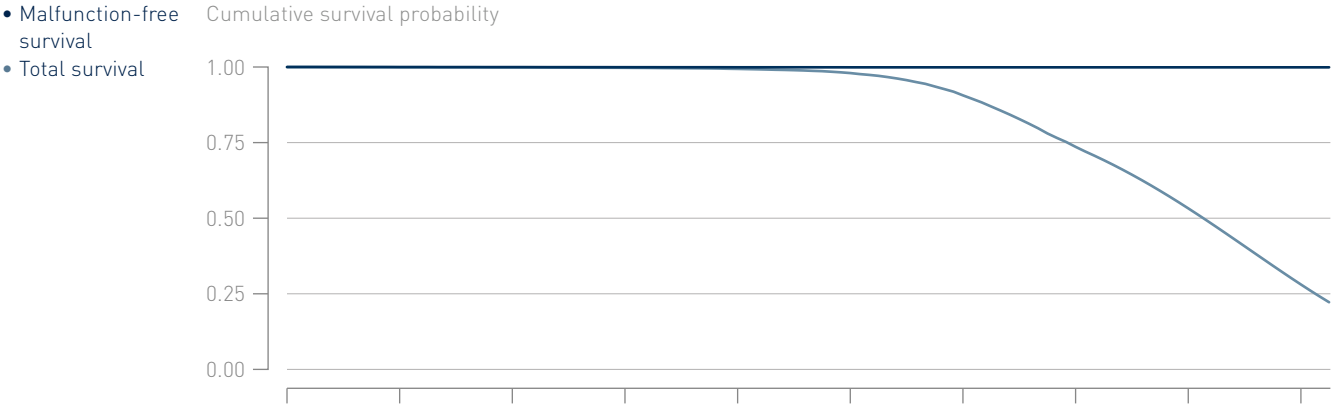
* While Talos SR and Talos S are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products

Performance of BIOTRONIK Pacemakers

Cylos and Cylos 990

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	81 300
Registered U.S. Implants	30 373
Estimated Active U.S. Implants	7 670
U.S. Normal Battery Depletions	8 425

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



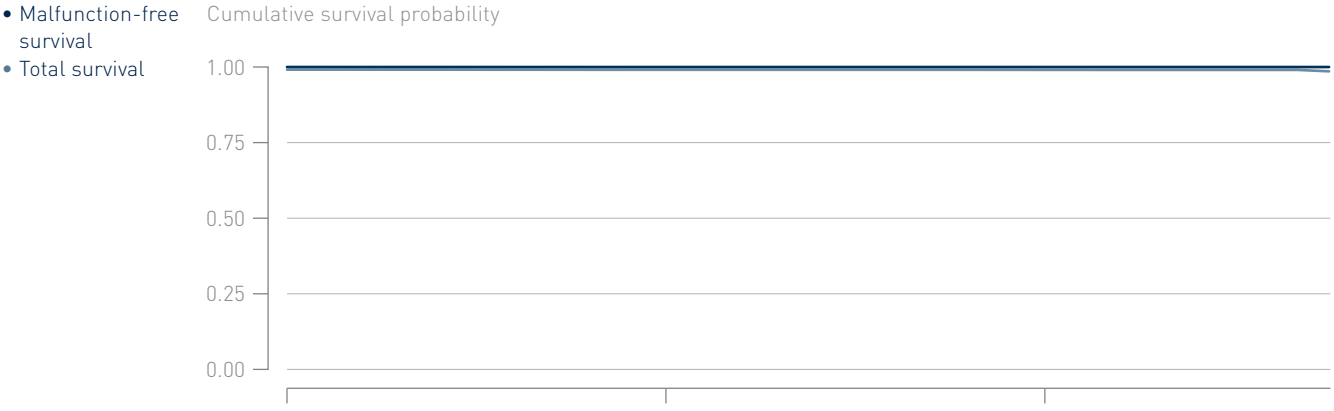
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.9	99.7	99.4	98.0	90.6	73.6	53.3	28.1
CI [±%]	-	<0.1	<0.1	0.1	0.1 -	0.2	0.4	0.6	0.7	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	30 373	28 180	26 456	24 997	23 567	21 809	18 759	13 743	8 997	2 810

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

Edora 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2017
CE Market Release	Jul 2016
Worldwide Distributed Devices	131 000
Registered U.S. Implants	42 702
Estimated Active U.S. Implants	39 400
U.S. Normal Battery Depletions	19

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.00%
Therapy Compromised	1	0.00%
Therapy Available	1	0.00%

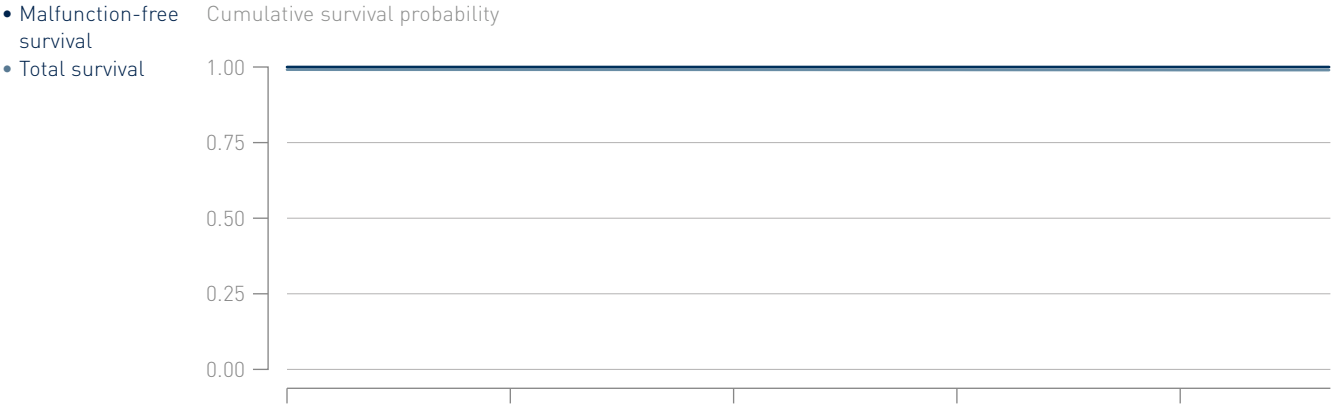


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	42 702	26 588	10 220

Eluna 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	97 200
Registered U.S. Implants	41 434
Estimated Active U.S. Implants	33 600
U.S. Normal Battery Depletions	33

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

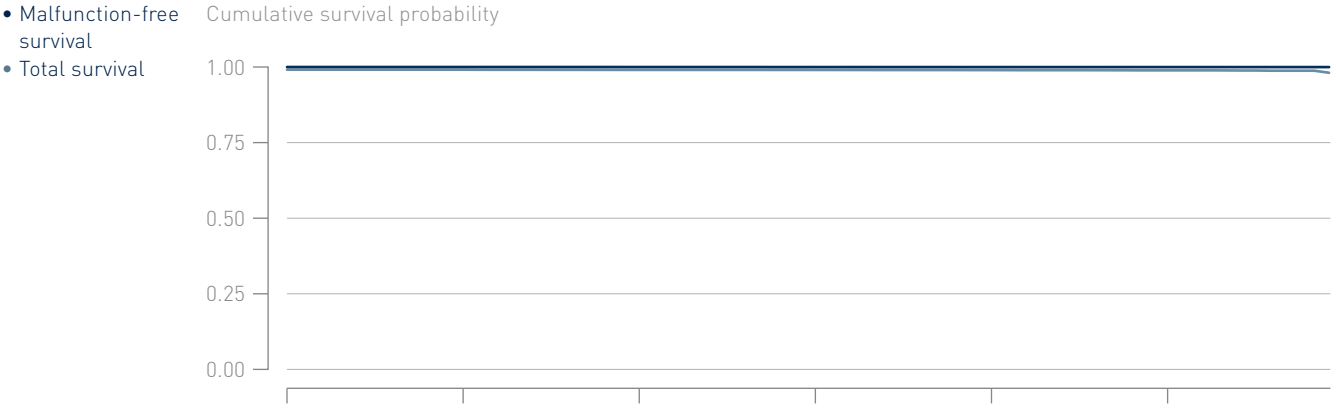


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	41 434	37 157	32 364	25 369	9 263

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	12 126
Estimated Active U.S. Implants	8 820
U.S. Normal Battery Depletions	26

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

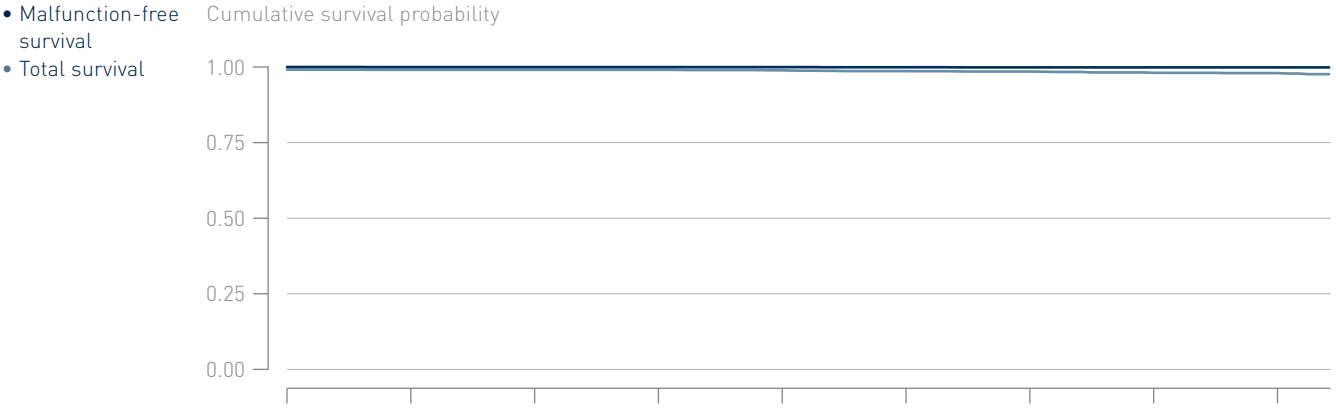


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.9	9.9	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	12 126	11 334	10 620	9 984	9 153	7 151

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	43 600
Registered U.S. Implants	2 949
Estimated Active U.S. Implants	1 930
U.S. Normal Battery Depletions	23

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.10%
Therapy Compromised	0	0.00%
Therapy Available	3	0.10%

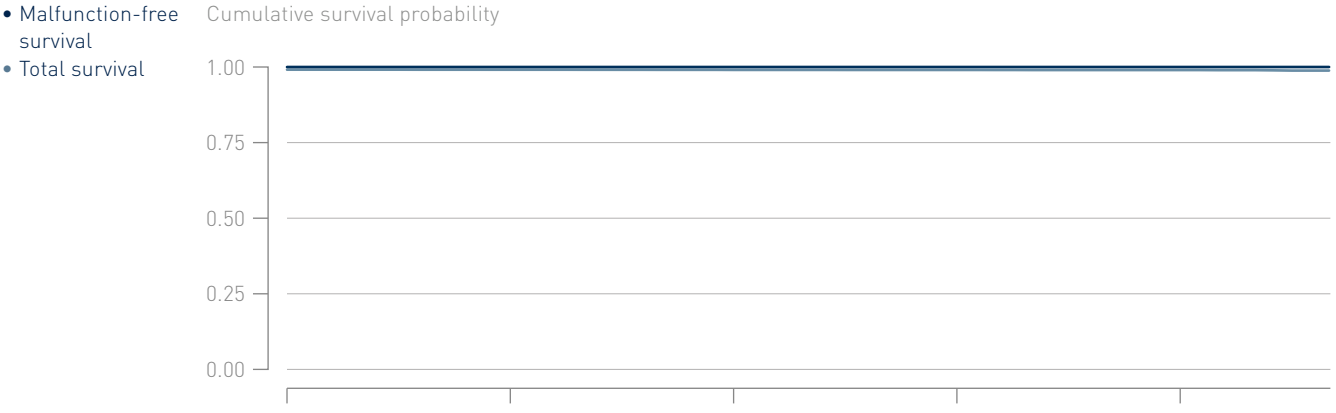


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.4	99.0	98.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	2 949	2 741	2 590	2 467	2 328	2 193	2 026	1 588	764

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	76 300
Registered U.S. Implants	11 707
Estimated Active U.S. Implants	9 610
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%

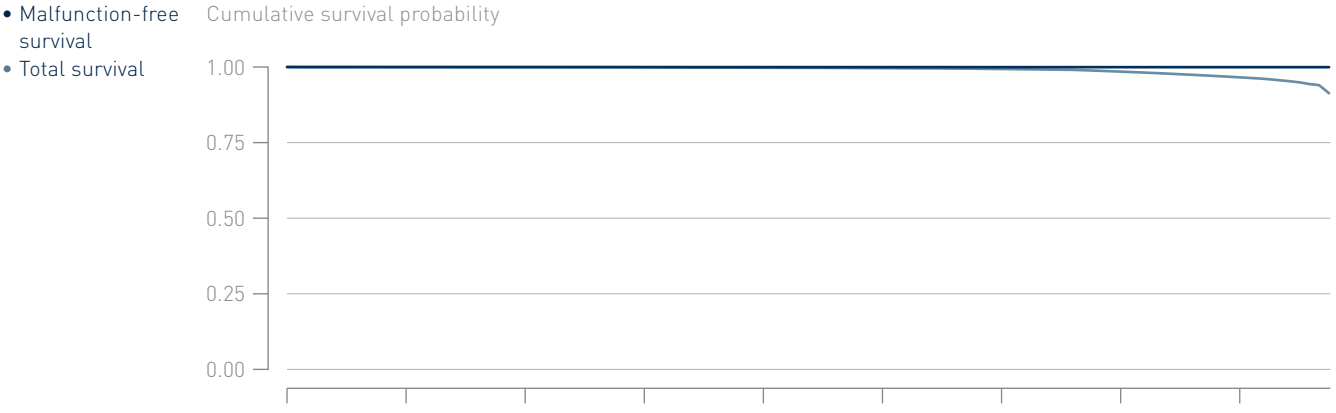


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	11 707	10 949	9 572	7 247	3 498

Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	215 000
Registered U.S. Implants	61 909
Estimated Active U.S. Implants	40 000
U.S. Normal Battery Depletions	653

	Quantity	Rate
U.S. Confirmed Malfunctions	28	0.05%
Therapy Compromised	11	0.02%
Therapy Available	17	0.03%

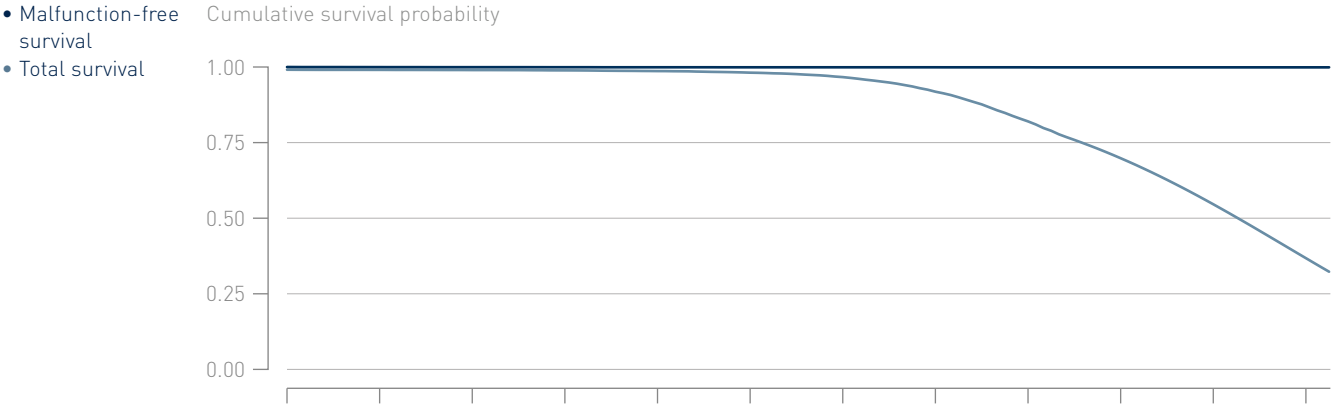


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	99.9	99.9	99.7	99.6	99.3	98.5	96.6
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	0.1	0.1	0.1	0.3
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	61 909	57 984	54 511	51 283	48 187	44 637	34 928	20 722	8 434

Philos II and Talos

Product Versions	D, DR, DR-T (Philos II only), SLR
NBG Codes	DDD, DDDR, VDDR
US Market Release	Sep 2004
CE Market Release	Feb 2004 / May 2006
Worldwide Distributed Devices	372 000
Registered U.S. Implants	23 203
Estimated Active U.S. Implants	7 230
U.S. Normal Battery Depletions	4 720

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



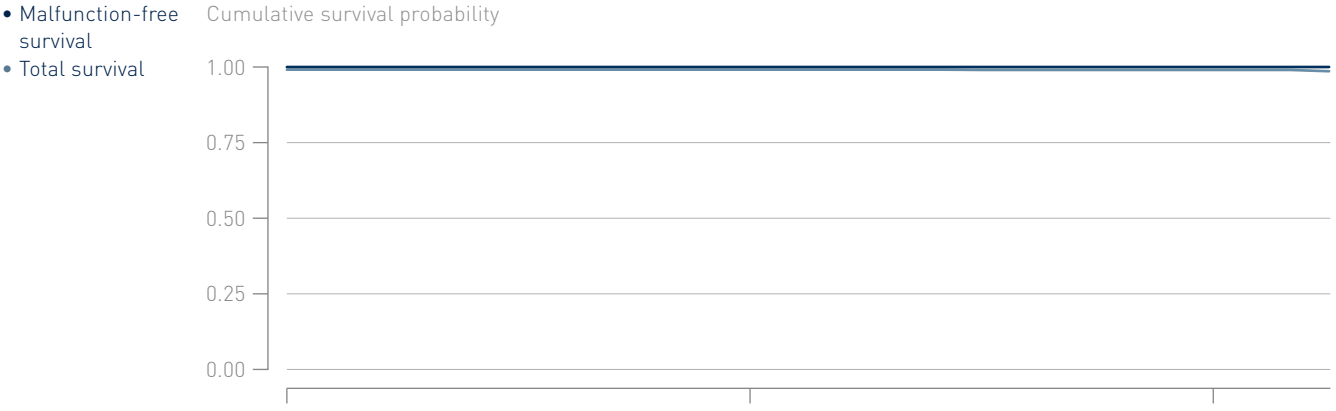
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.9	99.9	99.8	99.5	99.0	97.5	92.7	82.9	70.7	55.5	37.7
CI [±%]	-	<0.1	<0.1	0.1	0.1	0.1	0.2	0.4	0.6	0.8	0.9	1.5
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	23 203	21 214	19 906	18 749	17 714	16 832	15 843	14 185	11 595	9 027	5 823	1 427

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	10 100
Registered U.S. Implants	3 432
Estimated Active U.S. Implants	2 930
U.S. Normal Battery Depletions	3

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

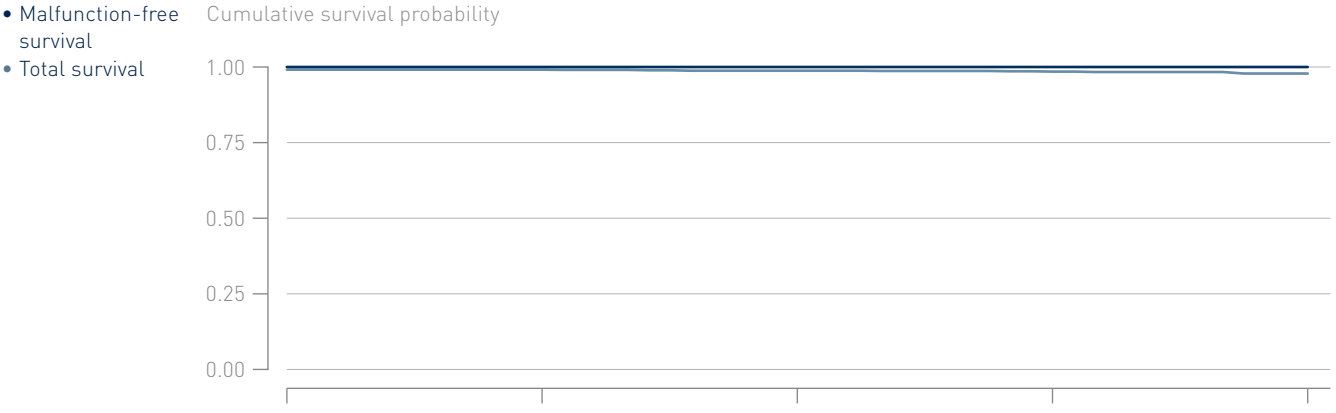


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	3 432	1 851	527

Etrinsa 8

Product Versions	HF-T
NBG Codes	DDDRV
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	8 670
Registered U.S. Implants	1 860
Estimated Active U.S. Implants	1 270
U.S. Normal Battery Depletions	11

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

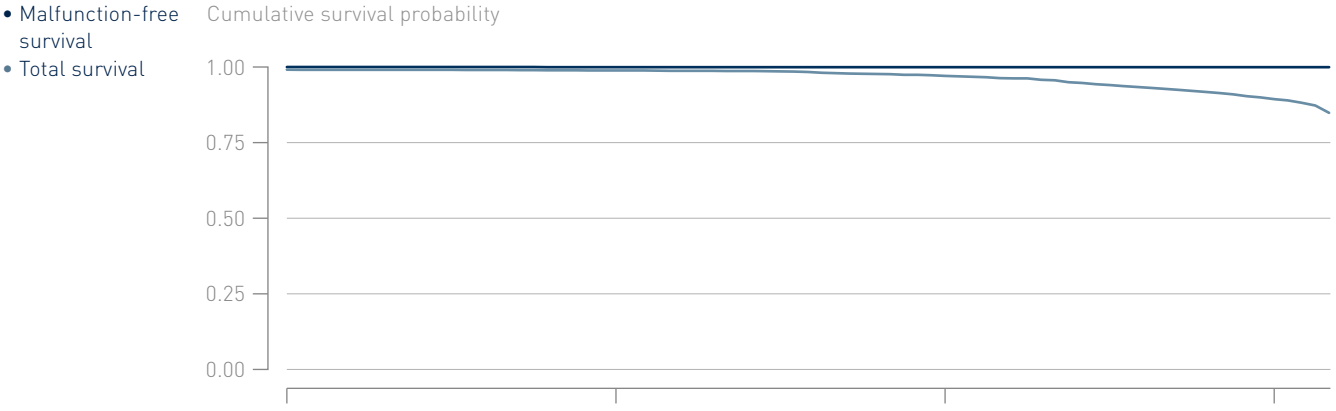


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.7	99.4	98.7
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	1 860	1 606	1 268	894	220

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	1 040
U.S. Normal Battery Depletions	116

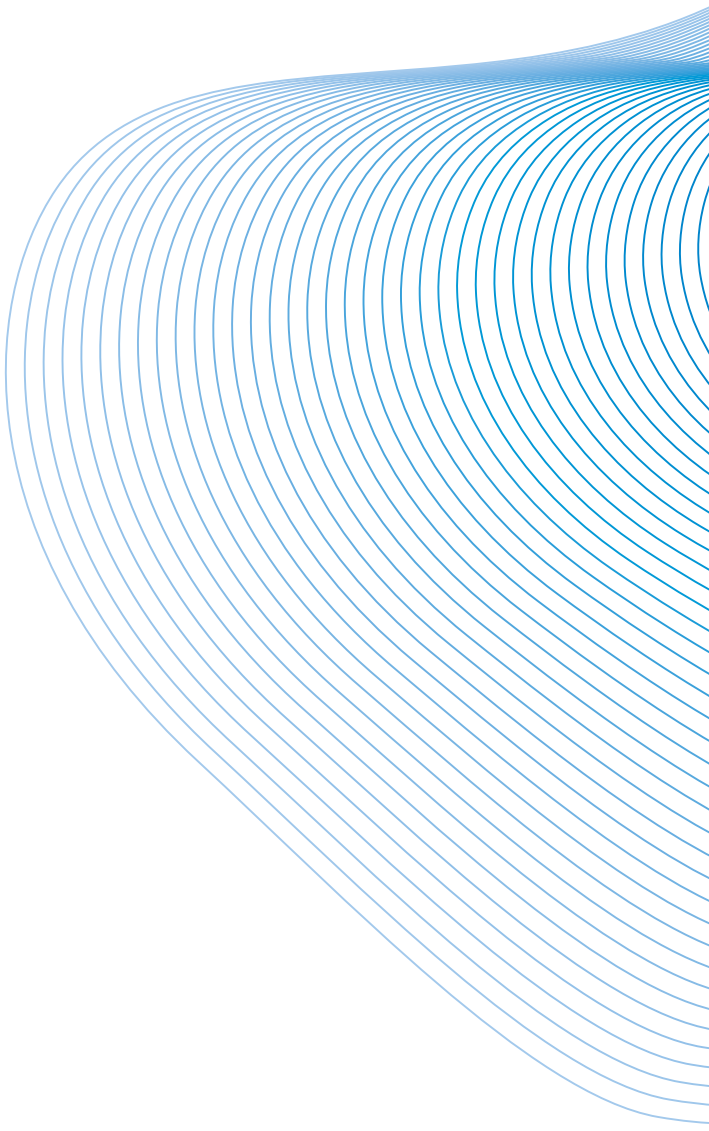
	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.04%
Therapy Compromised	0	0.00%
Therapy Available	1	0.04%



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.7	99.4	97.9	94.9	90.3
CI [±%]	-	0.1	0.2	0.3	0.7	1.2	1.9
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	2 249	1 987	1 765	1 569	1 363	1 126	465

Performance of BIOTRONIK ICDs

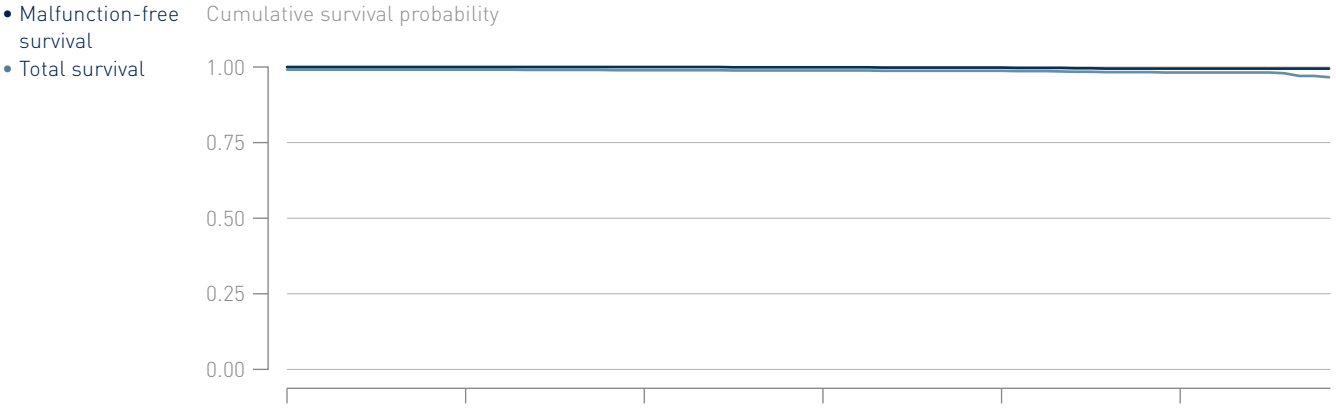
Performance of BIOTRONIK ICDs



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	2460
Registered U.S. Implants	1271
Estimated Active U.S. Implants	912
U.S. Normal Battery Depletions	12

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

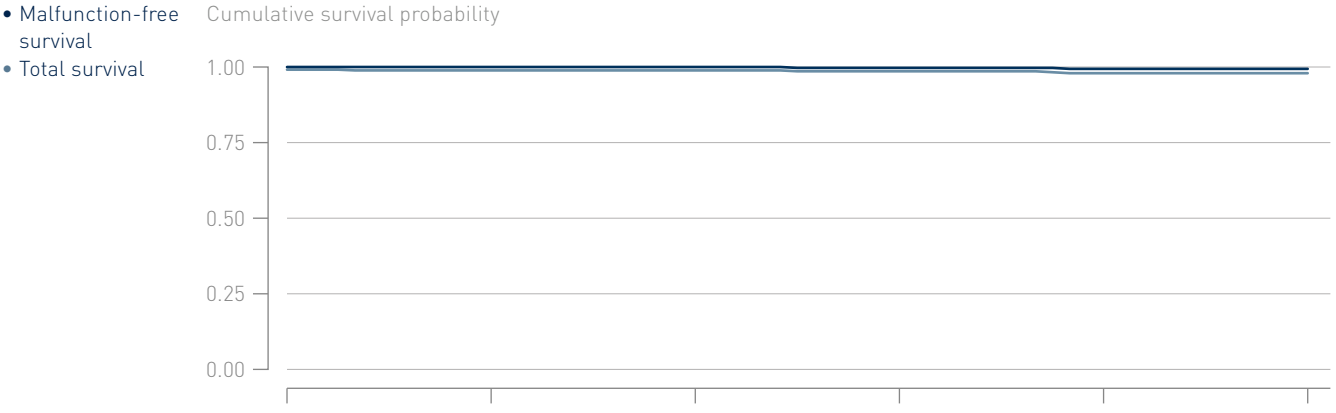


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.8	99.7	99.6	99.1
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.5
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	1271	1182	1103	1032	953	753

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	325
U.S. Normal Battery Depletions	2

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

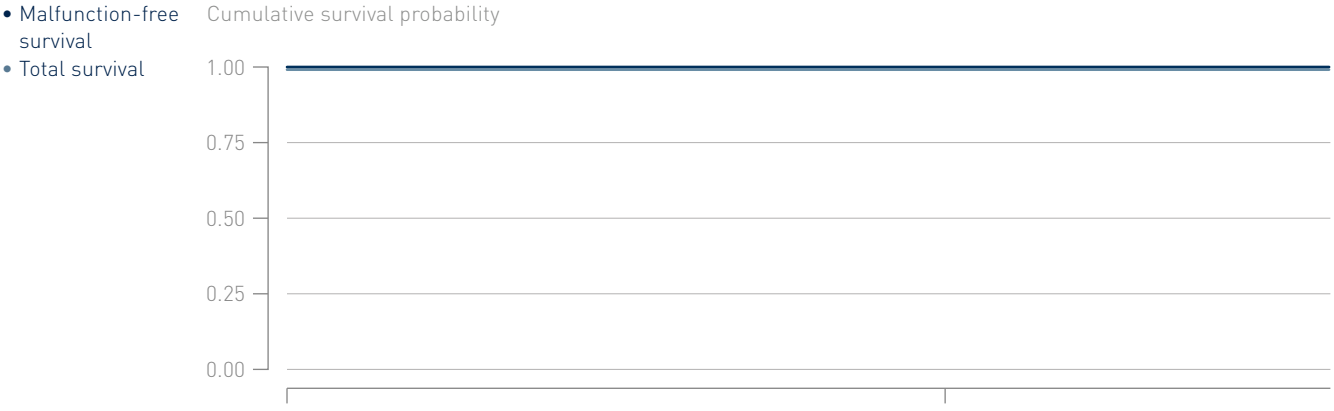


Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.8	99.5	98.9	98.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.7	99.4	99.4
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	466	429	392	365	328	223

Ilivia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	May 2017
Worldwide Distributed Devices	2140
Registered U.S. Implants	798
Estimated Active U.S. Implants	732
U.S. Normal Battery Depletions	0

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

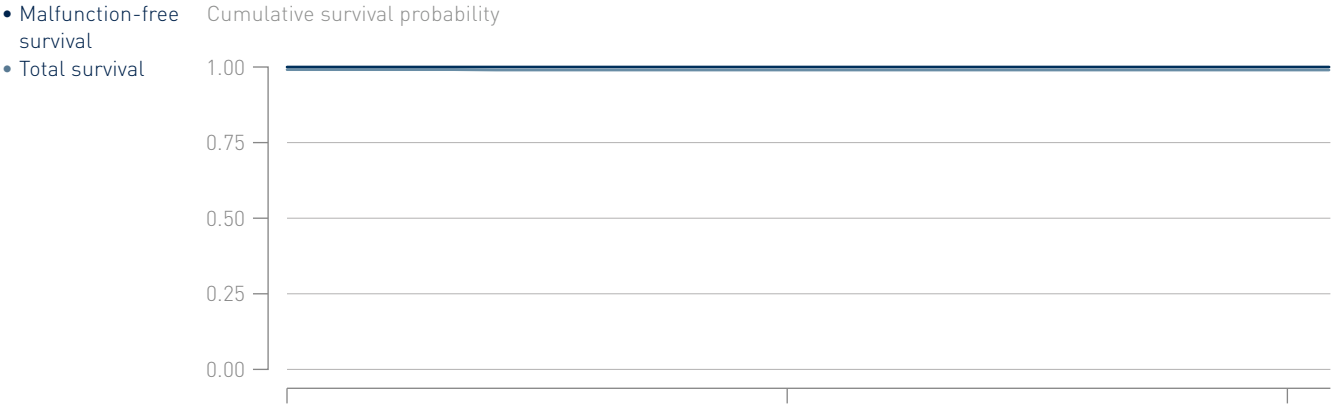


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	-	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	-	<0.1
Sample Size	798	411

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	4110
Registered U.S. Implants	876
Estimated Active U.S. Implants	773
U.S. Normal Battery Depletions	1

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

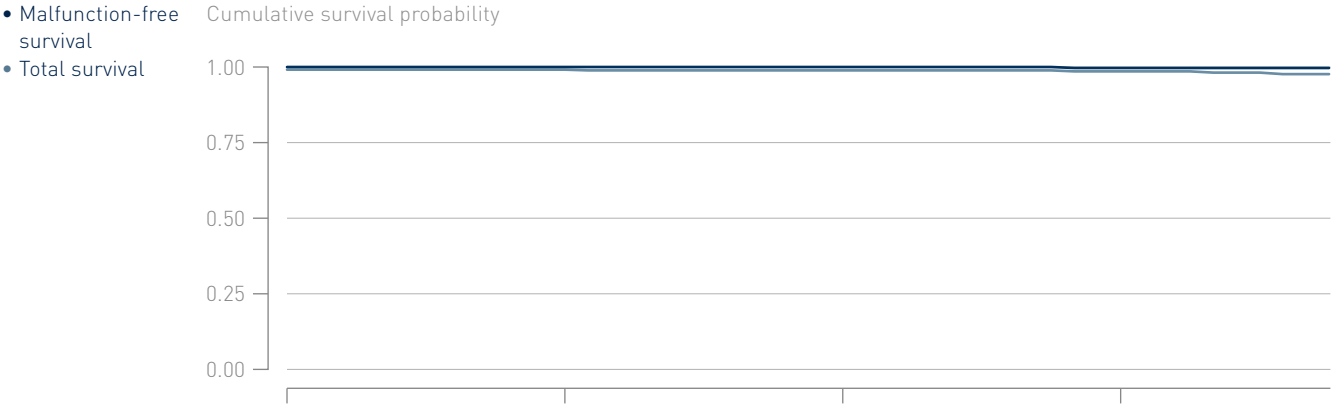


Years after implant	0	1	2
Total [%]	100.0	99.9	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	876	722	285

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	477
U.S. Normal Battery Depletions	3

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

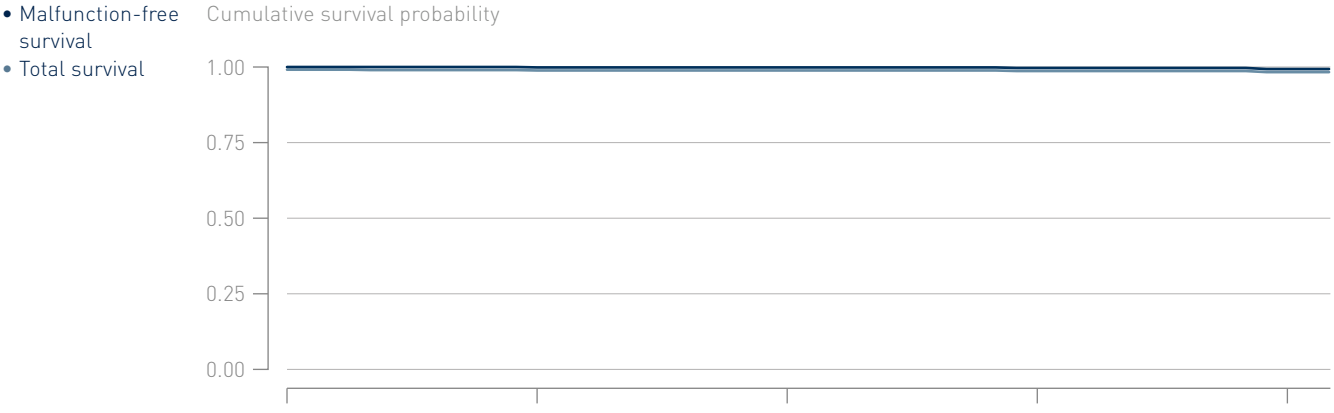


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.8	99.6
CI [±%]	-	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.8
CI [±%]	-	<0.1	<0.1	<0.1
Sample Size	618	570	526	380

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	607
U.S. Normal Battery Depletions	1

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.37%
Therapy Compromised	2	0.25%
Therapy Available	1	0.12%

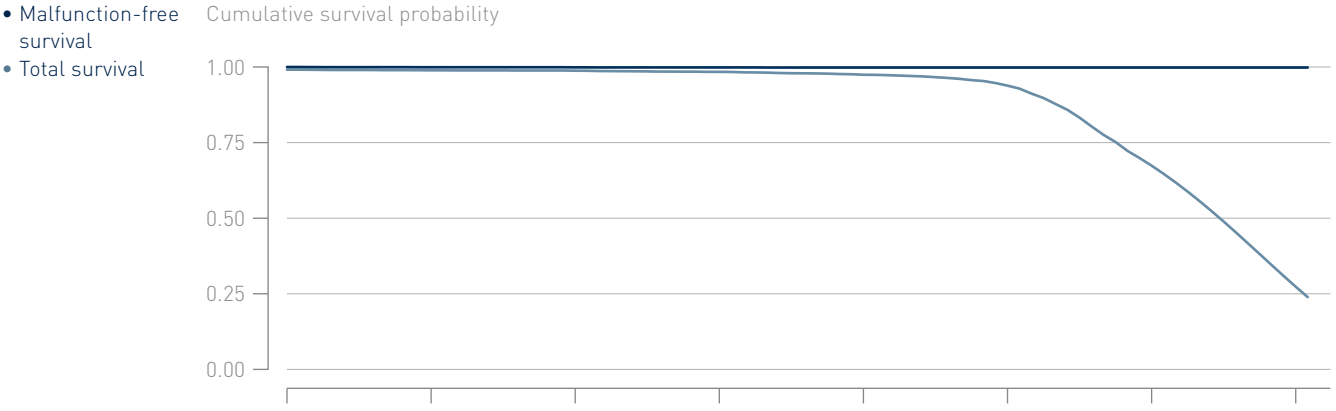


Years after implant	0	1	2	3	4
Total [%]	100.0	99.7	99.7	99.6	99.2
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	99.9	99.9	99.7	99.3
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	804	739	679	531	252

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	936
U.S. Normal Battery Depletions	926

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

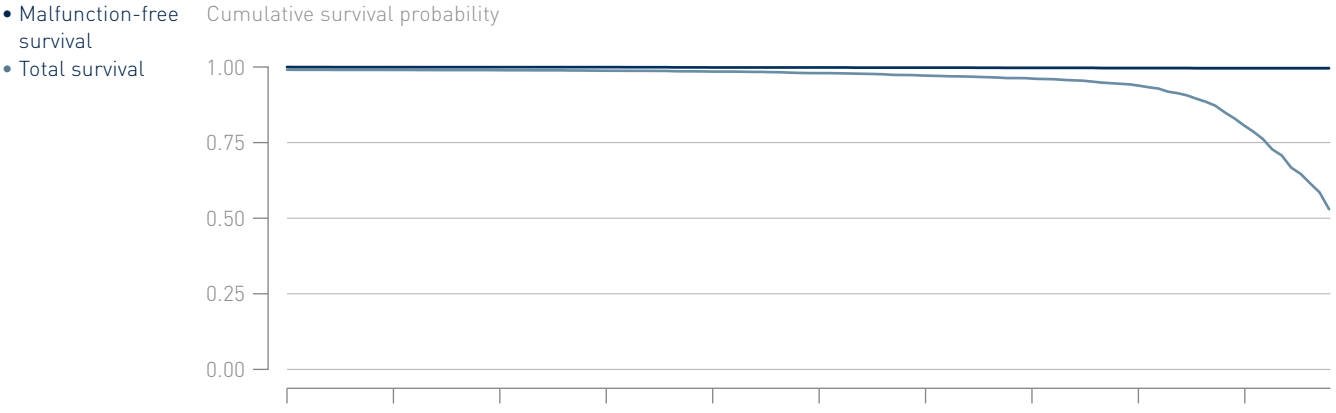


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.7	99.3	98.3	94.7	68.3	28.2
CI [±%]	-	0.1	0.2	0.3	0.4	0.8	1.9	3.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3985	3616	3393	3155	2908	2550	1511	361

Lumax 540

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20 000
Registered U.S. Implants	4 544
Estimated Active U.S. Implants	1 860
U.S. Normal Battery Depletions	577

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

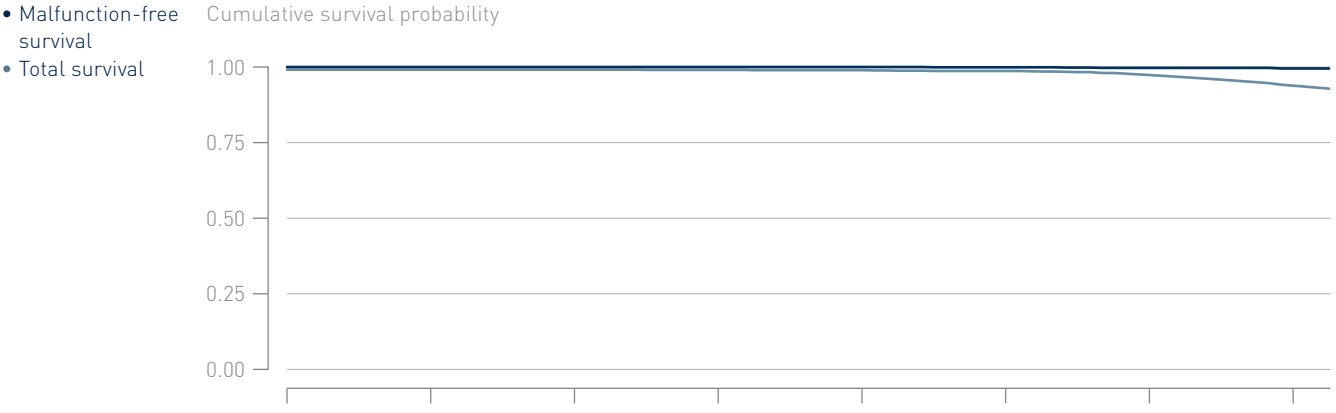


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.8	99.6	99.3	98.7	97.7	96.4	90.4	62.4
CI [±%]	-	0.1	0.1	0.2	0.3	0.4	0.5	0.7	1.2	3.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.8	99.8	99.7	99.6	99.6
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2
Sample Size	4544	4192	3897	3621	3370	3132	2879	2597	1794	357

Lumax 740

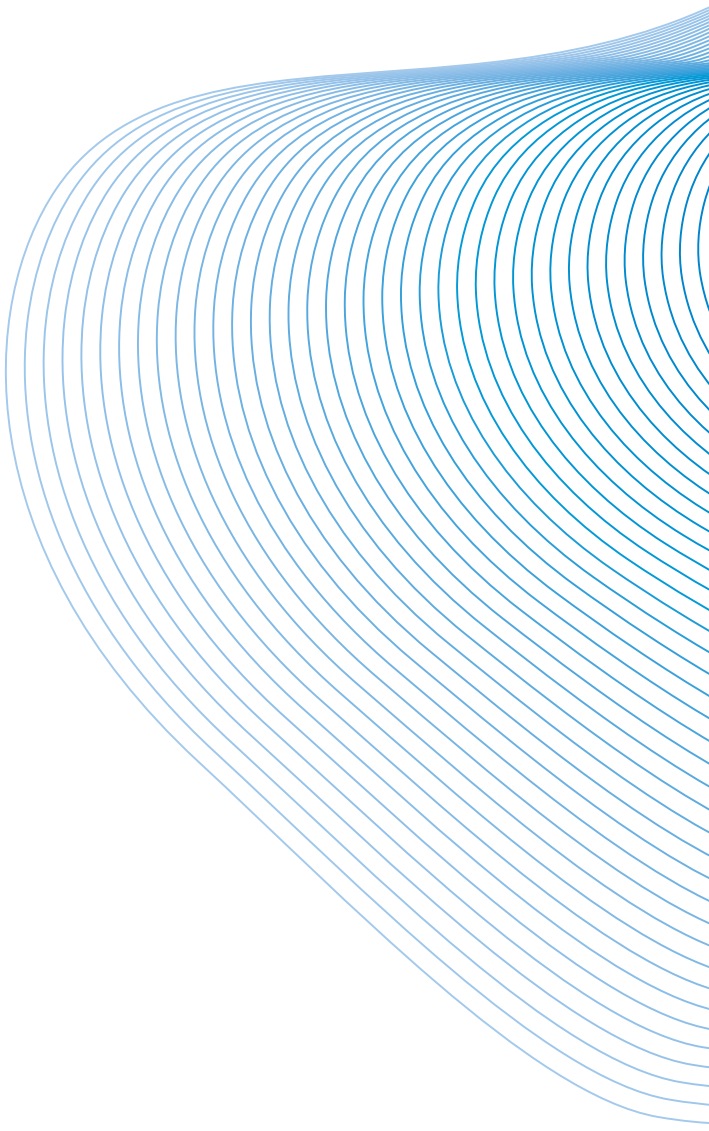
Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	4810
Registered U.S. Implants	1574
Estimated Active U.S. Implants	978
U.S. Normal Battery Depletions	18

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



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	100.0	99.9	99.8	99.6	98.2	94.7
CI [±%]	-	<0.1	<0.1	0.2	0.2	0.4	0.8	1.6
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.7	99.5
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	0.2	0.3	0.5
Sample Size	1574	1447	1347	1254	1160	1079	974	447

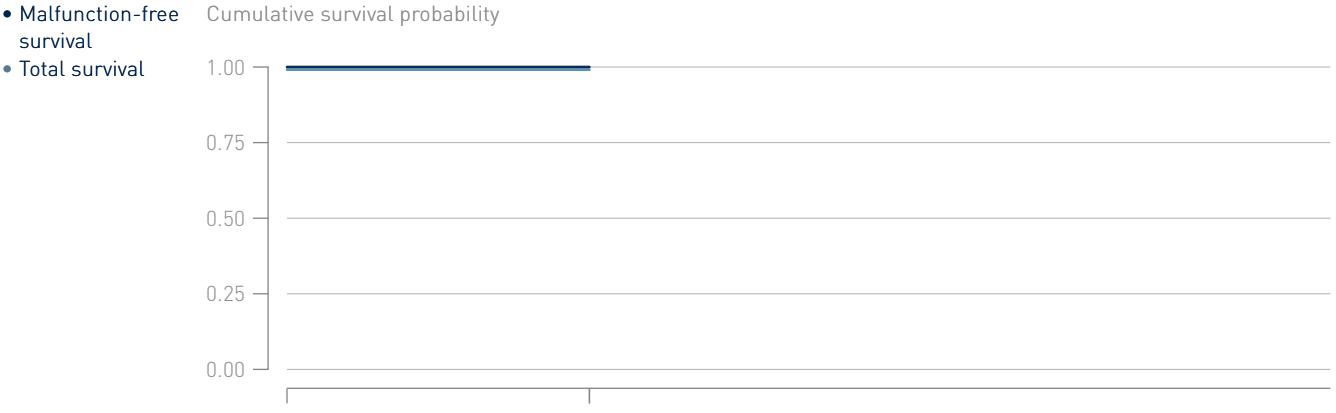
Performance of BIOTRONIK ICDs



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	5040
Registered U.S. Implants	3100
Estimated Active U.S. Implants	2960
U.S. Normal Battery Depletions	0

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

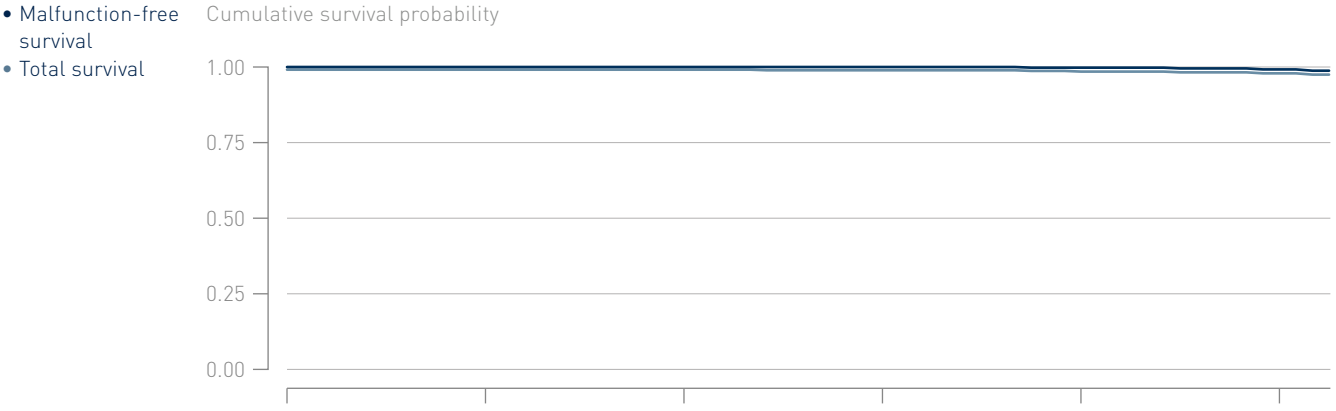


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	-	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	-	<0.1
Sample Size	3100	255

Iforia 7

Product Versions	DR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	1 660
Registered U.S. Implants	614
Estimated Active U.S. Implants	441
U.S. Normal Battery Depletions	2

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

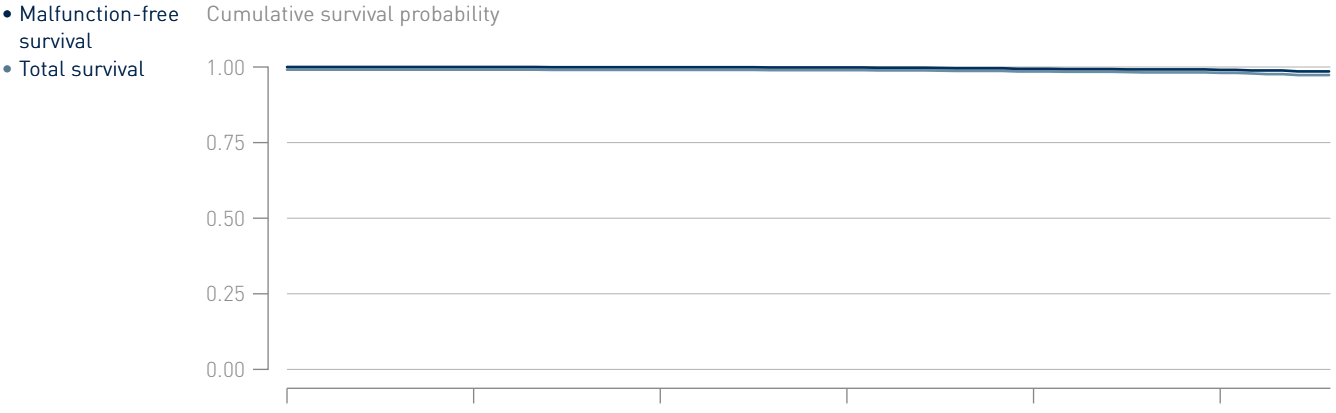


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	100.0	99.8	99.4	98.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.8	99.2
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	614	565	530	487	450	285

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	3 910
Registered U.S. Implants	1 461
Estimated Active U.S. Implants	1 030
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	14	0.96%
Therapy Compromised	9	0.62%
Therapy Available	5	0.34%

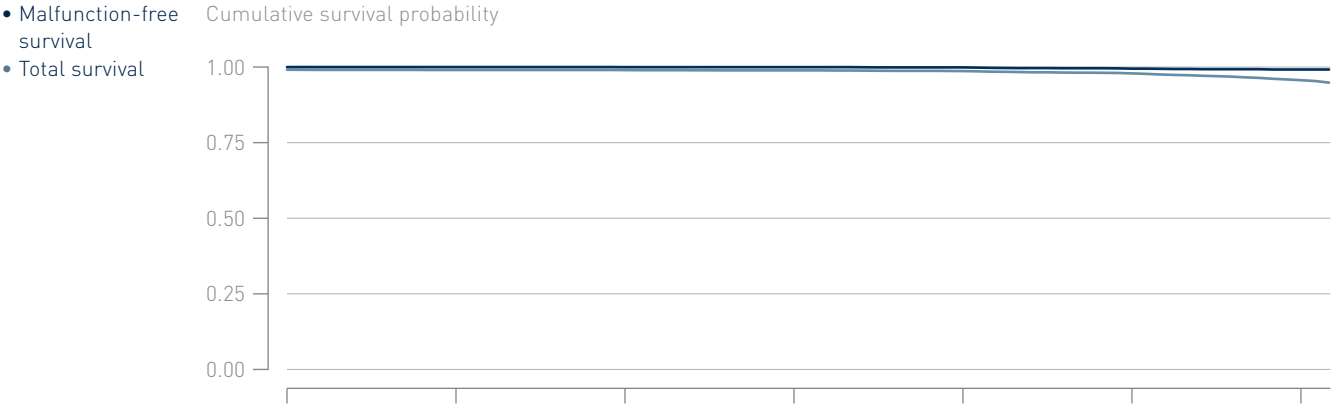


Years after implant	0	1	2	3	4	5
Total [%]	99.9	99.9	99.9	99.8	99.3	98.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	99.9	99.9	99.9	99.8	99.3	99.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	1461	1359	1272	1184	1081	643

Ilesto 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5110
Registered U.S. Implants	3486
Estimated Active U.S. Implants	2370
U.S. Normal Battery Depletions	38

	Quantity	Rate
U.S. Confirmed Malfunctions	17	0.49%
Therapy Compromised	10	0.29%
Therapy Available	7	0.20%

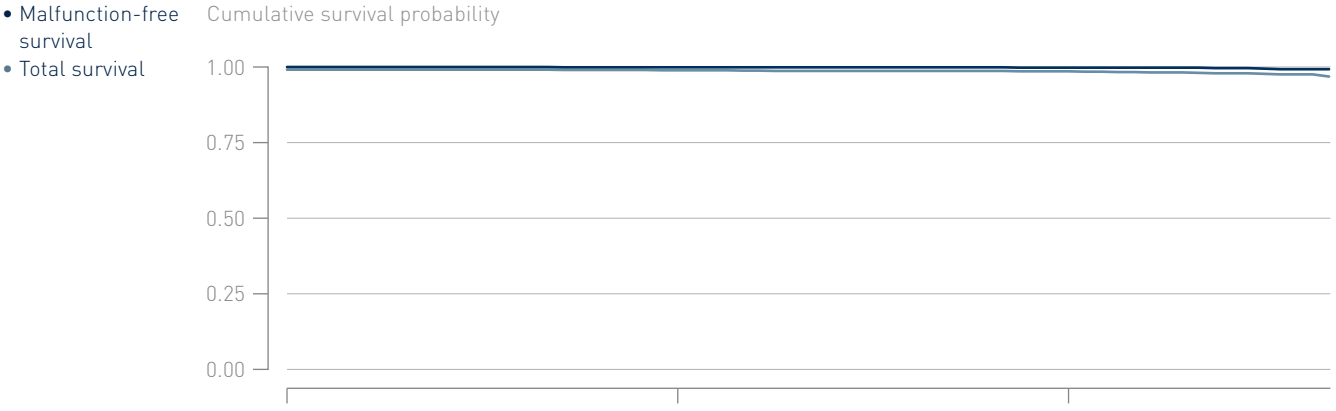


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.9	99.8	99.6	98.8	96.5
CI [±%]	-	0.1	0.1	0.2	0.2	0.4	0.9
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.5	99.2
CI [±%]	-	<0.1	0.1	0.1	0.1	0.3	0.4
Sample Size	3486	3219	2997	2787	2577	2052	689

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	824
U.S. Normal Battery Depletions	9

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

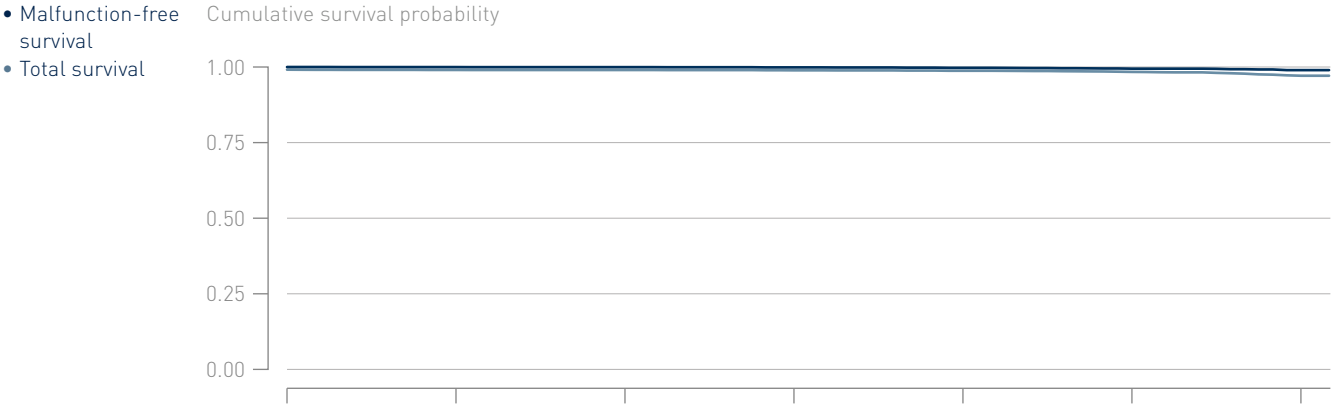


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.8	99.6	99.5	98.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.8	99.5
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	1147	1060	984	913	838	580

Ilesto 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	3 280
U.S. Normal Battery Depletions	28

	Quantity	Rate
U.S. Confirmed Malfunctions	25	0.53%
Therapy Compromised	14	0.30%
Therapy Available	11	0.23%

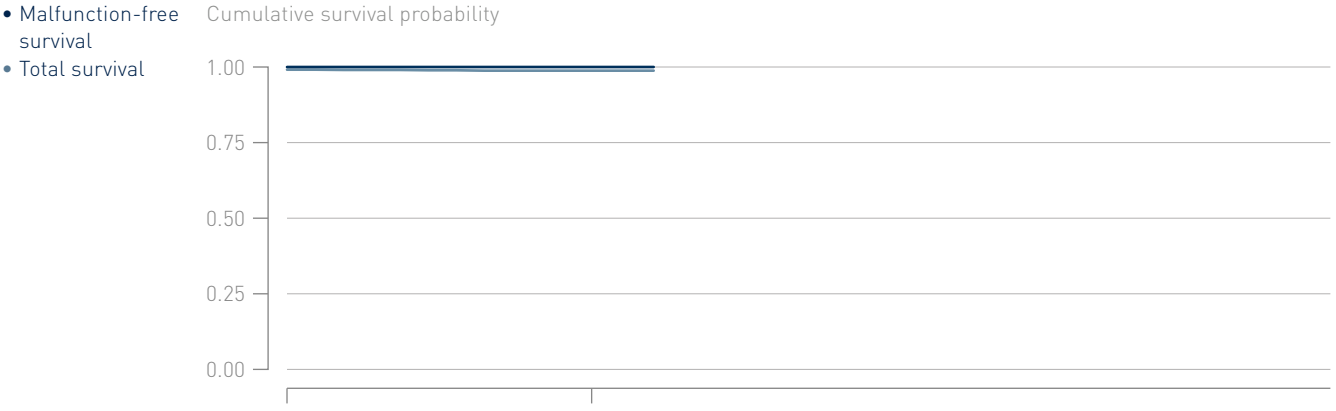


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.9	99.8	99.6	99.2	98.0
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.7	99.5	99.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	4720	4370	4090	3827	3535	2913	703

Ilivia 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	May 2017
Worldwide Distributed Devices	2 970
Registered U.S. Implants	1 275
Estimated Active U.S. Implants	1200
U.S. Normal Battery Depletions	3

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

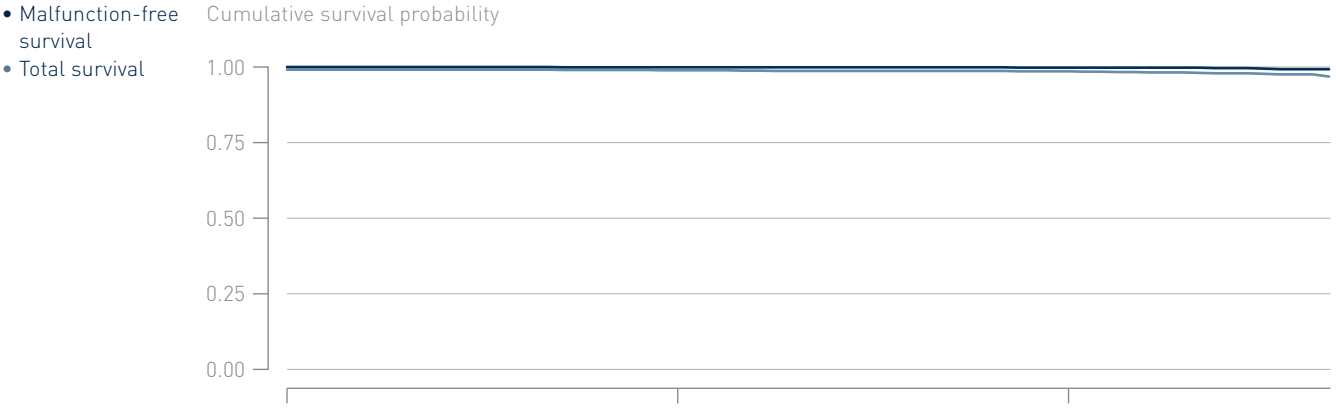


Years after implant	0	1
Total [%]	100.0	99.7
CI [±%]	-	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	-	<0.1
Sample Size	1275	341

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	8360
Registered U.S. Implants	3837
Estimated Active U.S. Implants	3370
U.S. Normal Battery Depletions	0

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.08%
Therapy Compromised	3	0.08%
Therapy Available	0	0.00%

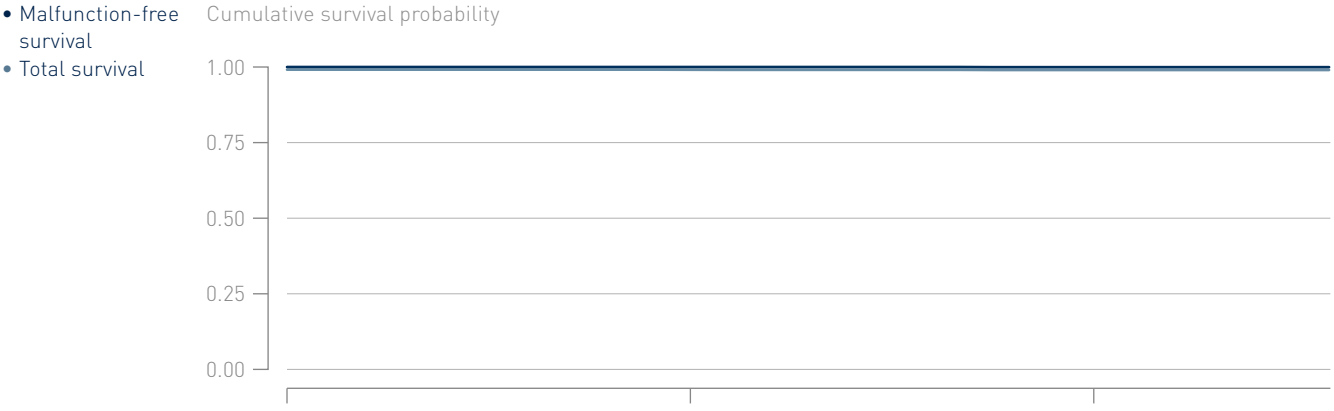


Years after implant	0	1	2
Total [%]	100.0	99.9	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	99.9	99.9
CI [±%]	-	<0.1	<0.1
Sample Size	3837	3006	1206

Intica 7 DX

Product Versions	VR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 760
Registered U.S. Implants	4 474
Estimated Active U.S. Implants	4 030
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.02%
Therapy Compromised	1	0.02%
Therapy Available	0	0.00%

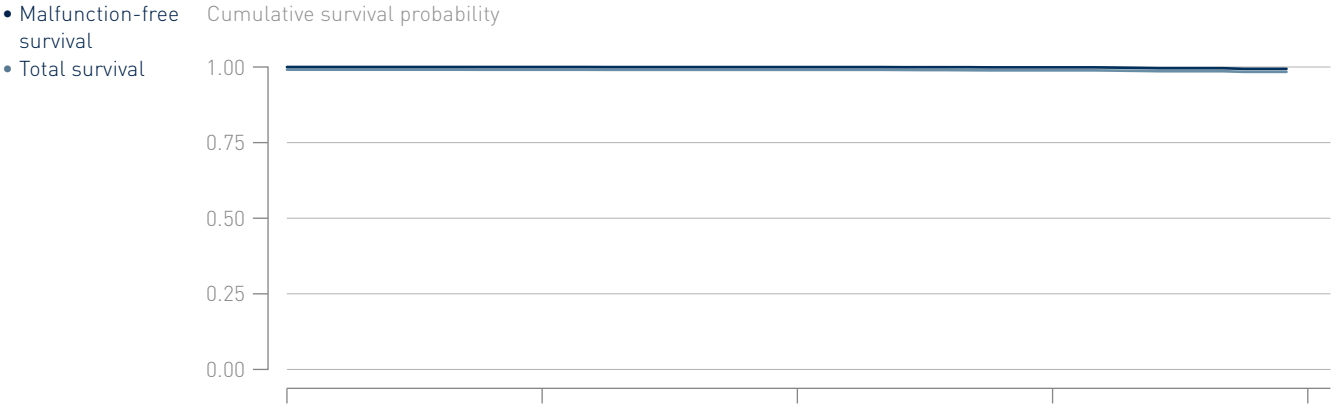


Years after implant	0	1	2
Total [%]	100.0	100	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	-	<0.1	<0.1
Sample Size	4474	3604	1386

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	5 254
Estimated Active U.S. Implants	4 290
U.S. Normal Battery Depletions	3

	Quantity	Rate
U.S. Confirmed Malfunctions	8	0.15%
Therapy Compromised	7	0.13%
Therapy Available	1	0.02%

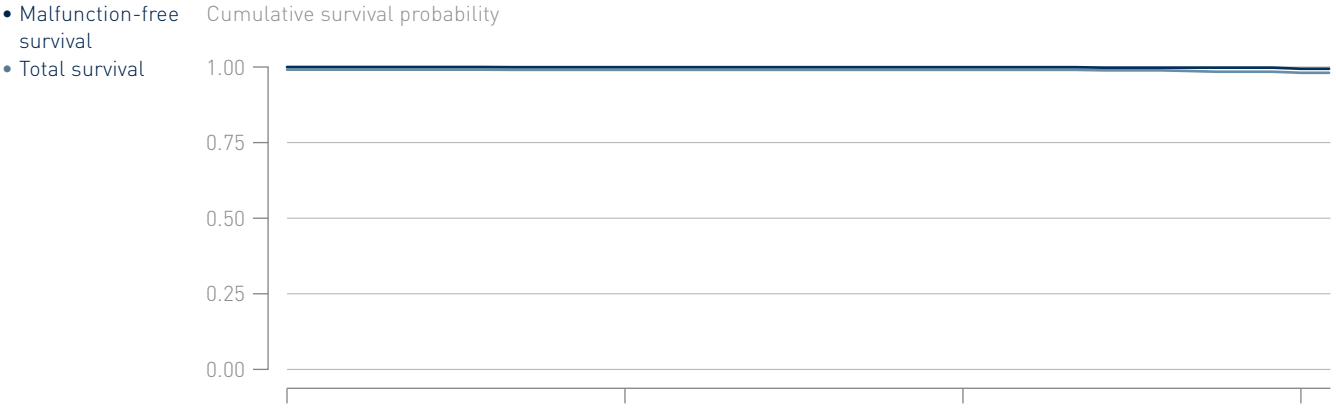


Years after implant	0	1	2	3	4
Total [%]	100	100	100	99.8	99.3
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	99.9	99.4
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	5254	4469	3173	1693	231

Iperia 7

Product Versions	DR-T
NBG Codes	VDE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 710
Registered U.S. Implants	1 966
Estimated Active U.S. Implants	1 660
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.15%
Therapy Compromised	2	0.10%
Therapy Available	1	0.05%

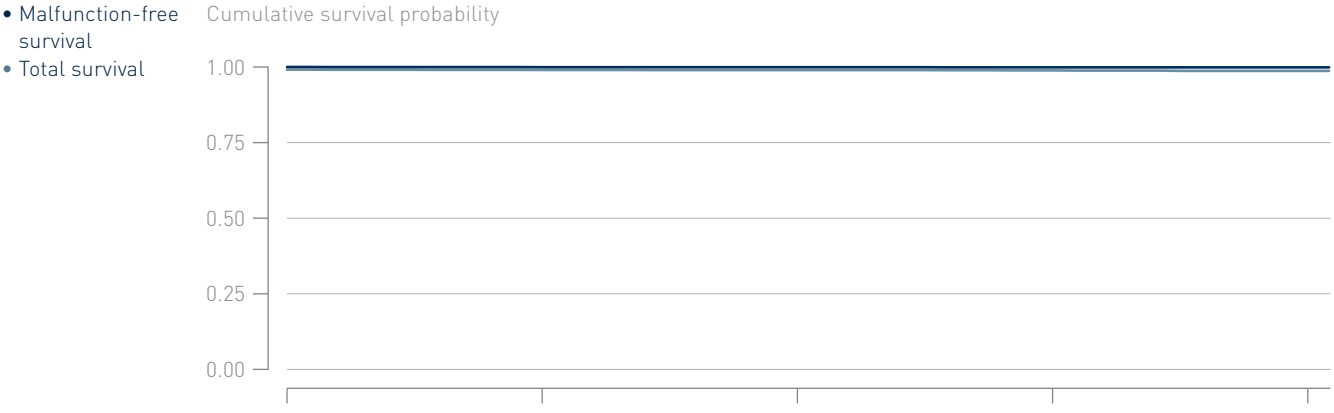


Years after implant	0	1	2	3
Total [%]	100	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1
Malfunction-Free [%]	100	99.9	99.9	99.4
CI [±%]	-	<0.1	<0.1	<0.1
Sample Size	1966	1790	950	273

Iperia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	7510
Registered U.S. Implants	4111
Estimated Active U.S. Implants	3330
U.S. Normal Battery Depletions	5

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.07%
Therapy Compromised	1	0.02%
Therapy Available	2	0.05%

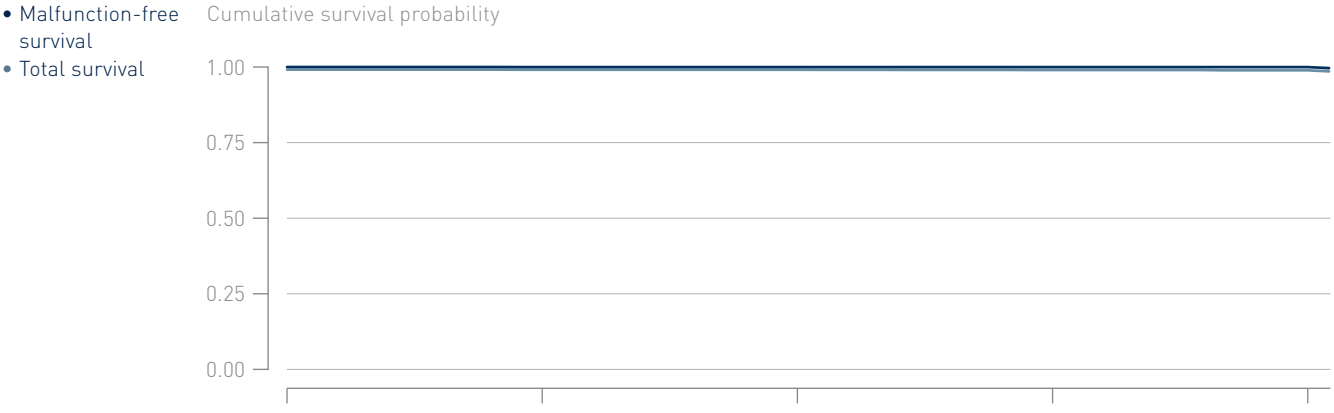


Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.9	99.8	99.7
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	4111	3668	3069	2087	274

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	3 950
U.S. Normal Battery Depletions	4

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

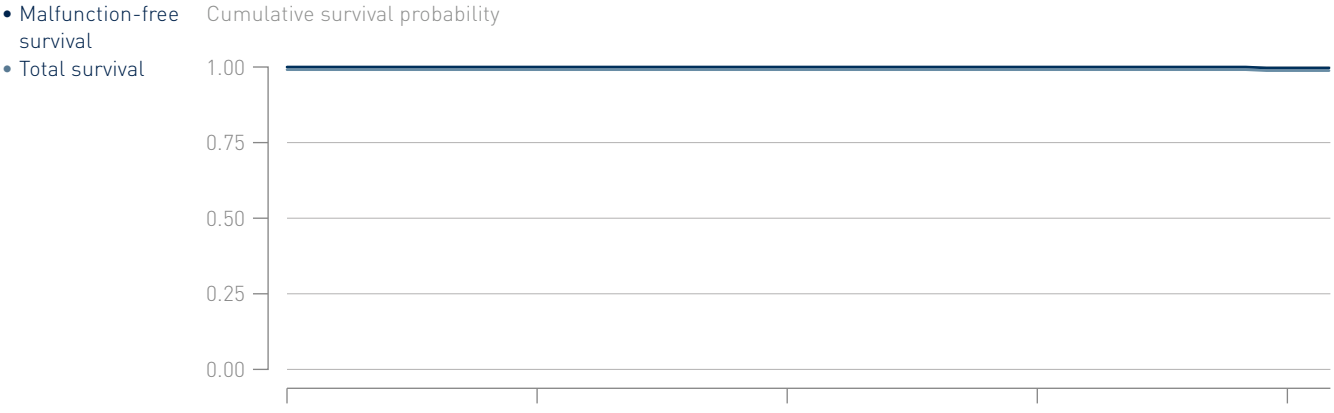


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.9	99.8
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	4 836	4 444	3 744	2 670	452

Itrevia 7

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

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

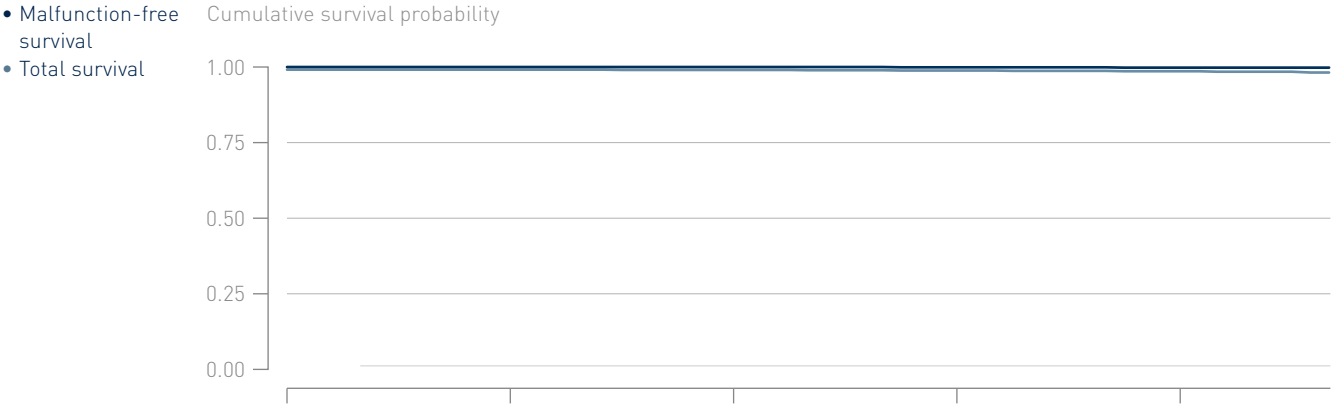


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	100.0	99.7
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.7
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	1 416	1 302	1 136	726	278

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	938
U.S. Normal Battery Depletions	5

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.16%
Therapy Compromised	2	0.16%
Therapy Available	0	0.00%

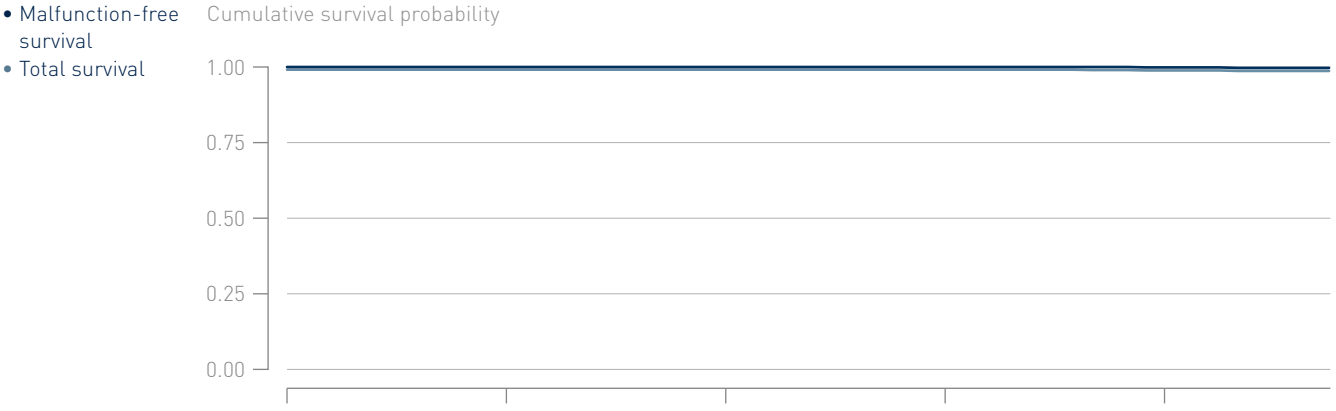


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.7	99.5
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	1268	1164	1070	986	696

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	964
U.S. Normal Battery Depletions	1

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.16%
Therapy Compromised	2	0.16%
Therapy Available	0	0.00%

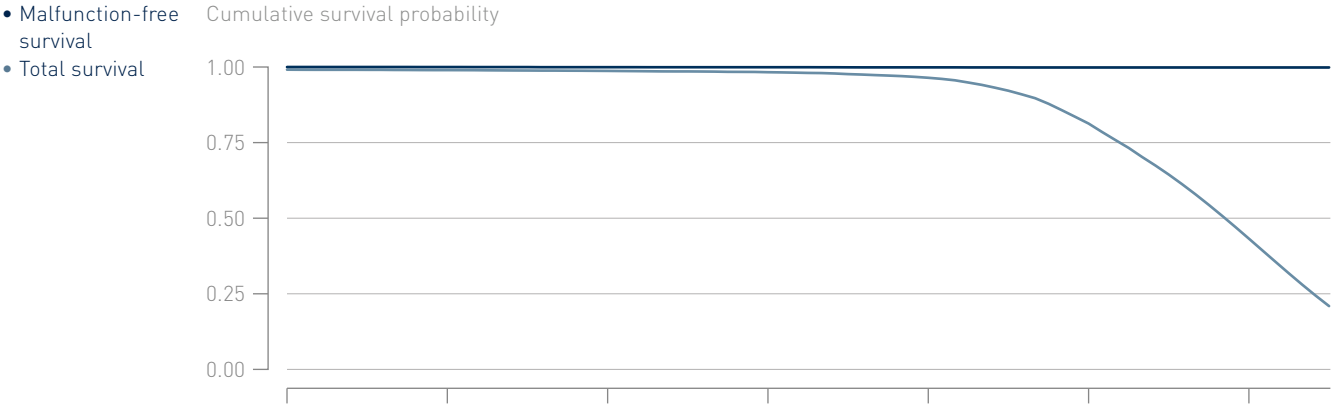


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	100.0	99.7
CI [±%]	-	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9
CI [±%]	-	<0.1	<0.1	<0.1	<0.1
Sample Size	1 247	1 145	1 067	968	728

Lumax 340

Product Versions	DR, DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26 400
Registered U.S. Implants	8 219
Estimated Active U.S. Implants	1 730
U.S. Normal Battery Depletions	2 149

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

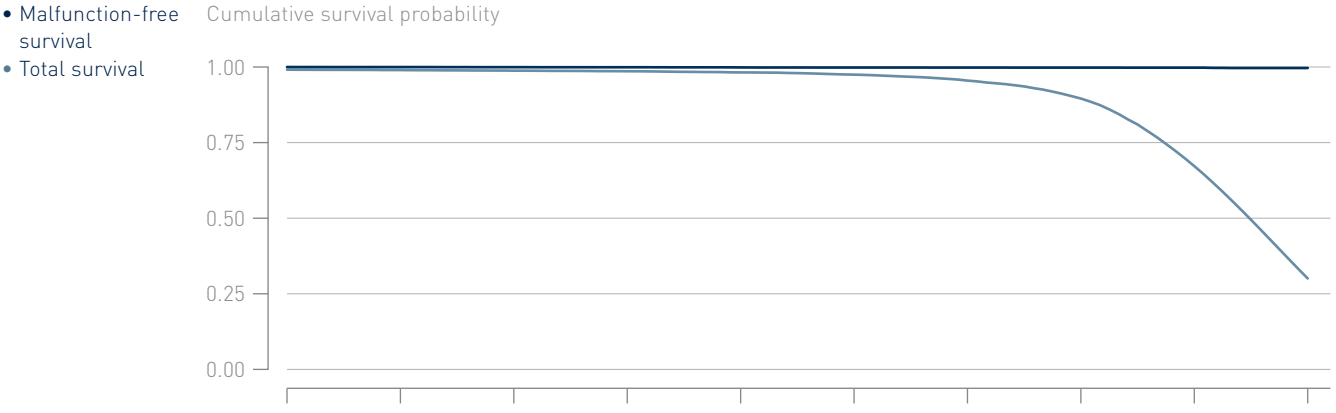


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.6	99.2	97.3	82.2	44.1
CI [±%]	-	0.1	0.1	0.2	0.4	1	1.5
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	<0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8 219	7 512	6 992	6 441	5 874	4 362	1 820

Lumax 540

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered U.S. Implants	11 511
Estimated Active U.S. Implants	3 490
U.S. Normal Battery Depletions	2 608

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

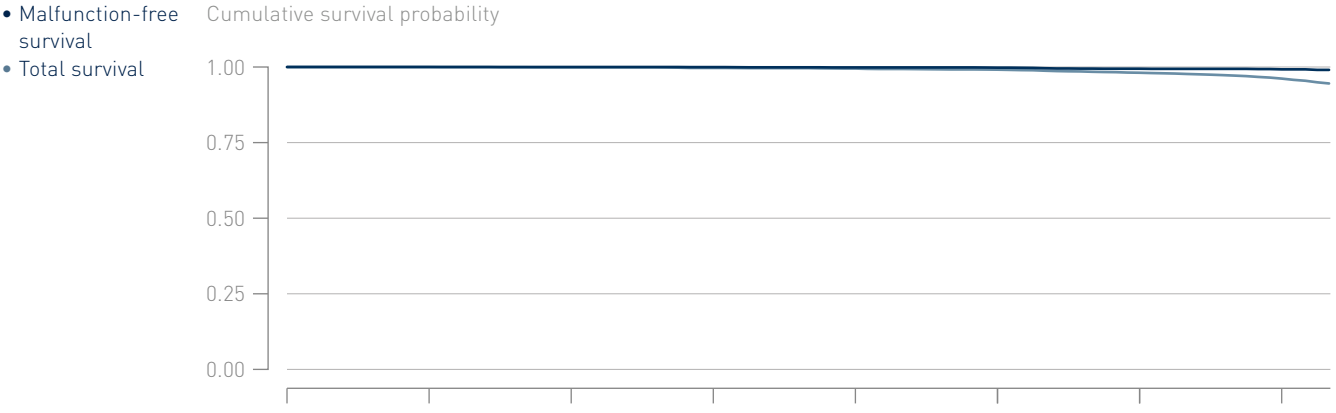


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.7	99.5	99.1	98.3	96.4	90.4	68.1	30.9
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.4	0.7	1.2	3.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.7
CI [±%]	-	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Sample Size	11 511	10 619	9 877	9 165	8 479	7 831	7 154	6 115	3 540	283

Lumax 740

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7 980
Registered U.S. Implants	3 813
Estimated Active U.S. Implants	2 270
U.S. Normal Battery Depletions	52

	Quantity	Rate
U.S. Confirmed Malfunctions	20	0.52%
Therapy Compromised	10	0.26%
Therapy Available	10	0.26%

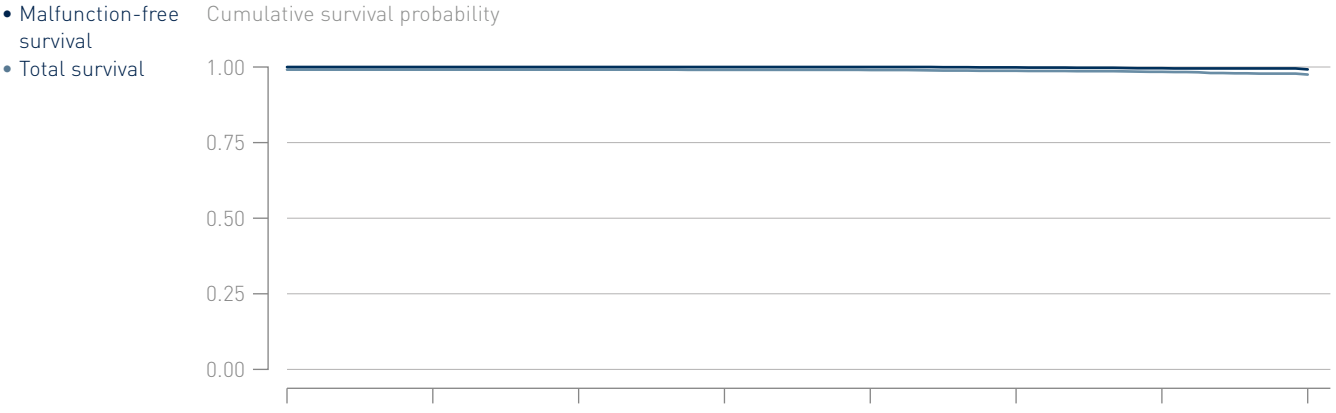


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.7	99.5	99.1	98.1	96.2
CI [±%]	-	<0.1	0.1	0.2	0.3	0.3	0.5	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.8	99.4	99.2
CI [±%]	-	<0.1	<0.1	0.1	0.1	0.2	0.3	0.4
Sample Size	3813	3535	3290	3051	2838	2612	2311	1094

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	1 370
U.S. Normal Battery Depletions	11

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

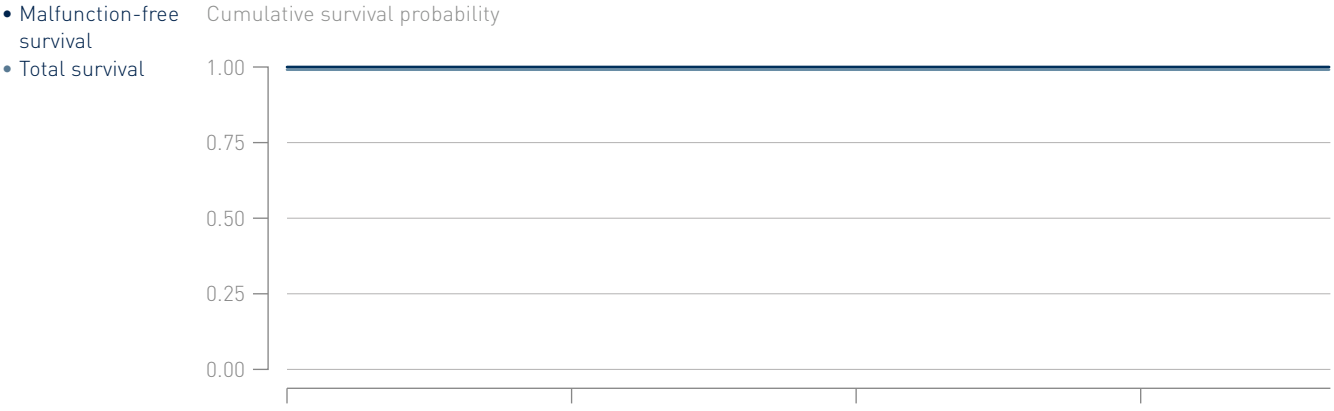


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	100.0	99.9	99.9	99.6	99.3	98.4
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.6	99.2
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sample Size	2 224	2 057	1 921	1 784	1 665	1 528	1 373	311

Rivacor 7 DF4

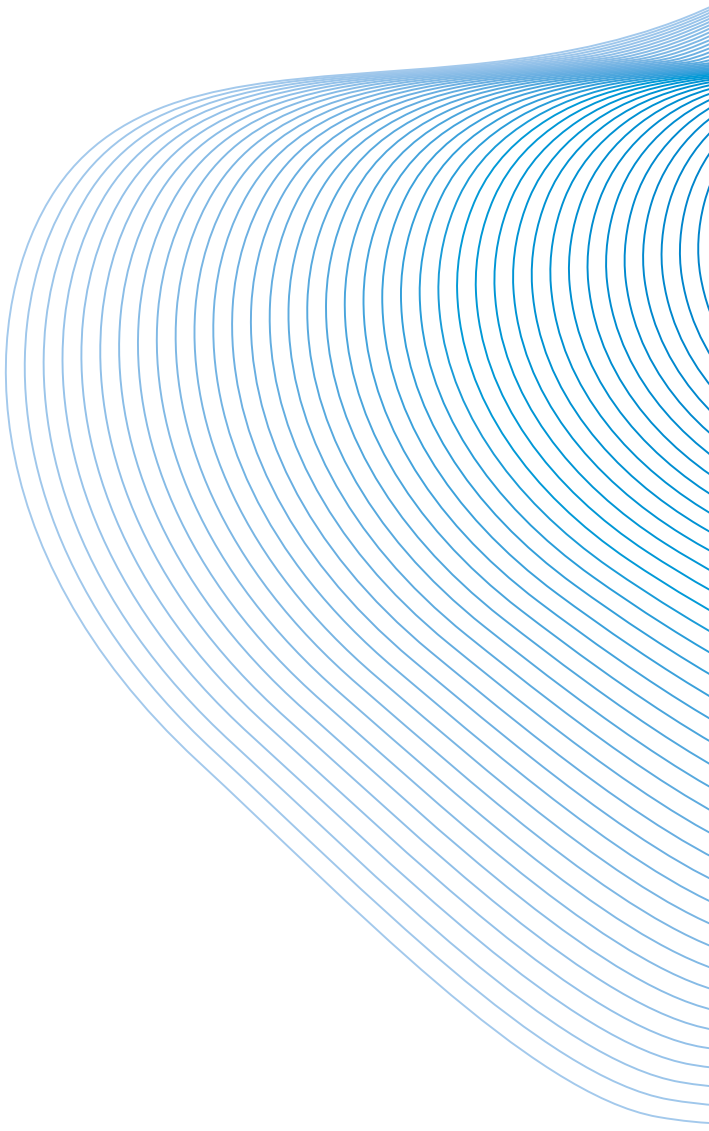
Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	3 790
Registered U.S. Implants	1 657
Estimated Active U.S. Implants	1 610
U.S. Normal Battery Depletions	0

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



Years after implant	**0**
Total [%]	100.0
CI [±%]	-
Malfunction-Free [%]	100.0
CI [±%]	-
Sample Size	1 657

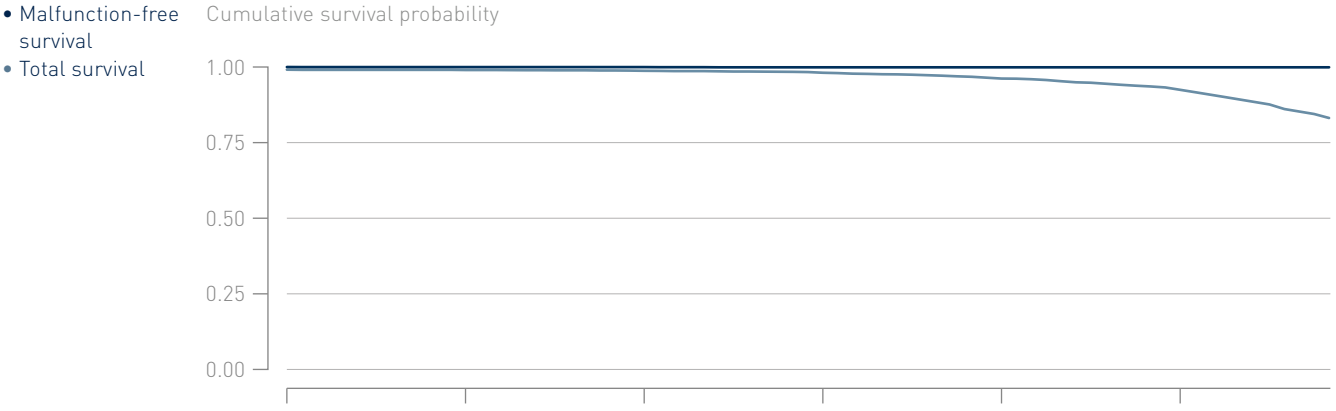
Performance of BIOTRONIK ICDs



Ilesto 7

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 290
Registered U.S. Implants	3 841
Estimated Active U.S. Implants	1 930
U.S. Normal Battery Depletions	220

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

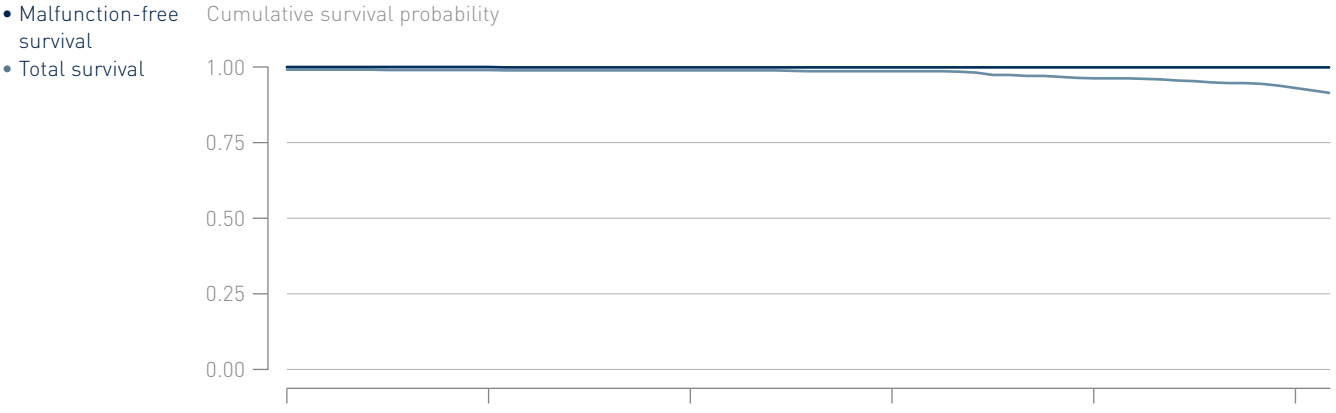


Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.6	99.0	97.1	93.3
CI [±%]	-	0.1	0.2	0.4	0.6	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Sample Size	3 841	3 403	3 025	2 667	2 320	1 684

Ilesto 7 DF4

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jun 2013
Worldwide Distributed Devices	2360
Registered U.S. Implants	968
Estimated Active U.S. Implants	556
U.S. Normal Battery Depletions	36

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

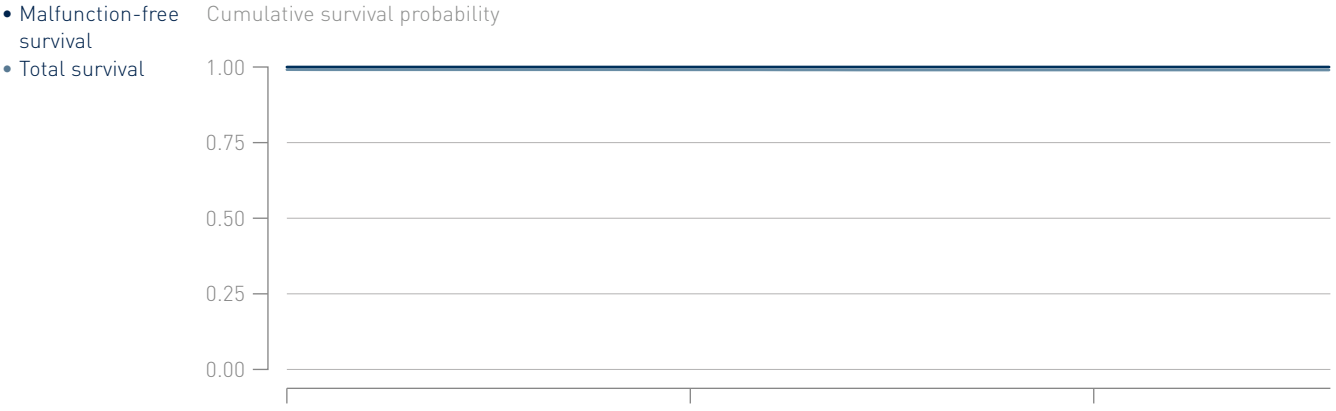


Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.8	99.5	97.1	93.9
CI [±%]	-	0.2	0.3	0.5	1.3	2.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9
CI [±%]	-	<0.1	0.2	0.2	0.2	0.2
Sample Size	968	858	766	681	594	297

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	8 990
Registered U.S. Implants	4 609
Estimated Active U.S. Implants	3 770
U.S. Normal Battery Depletions	4

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

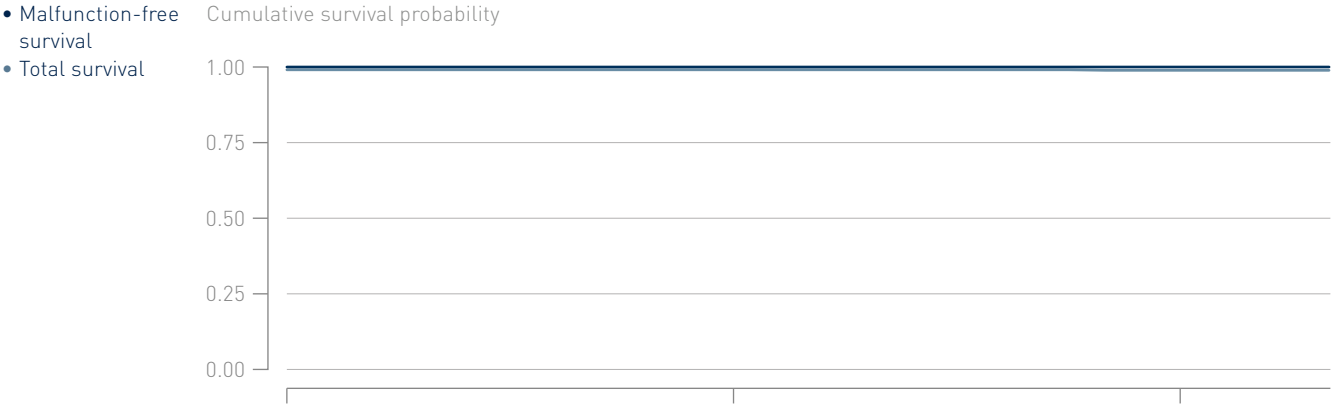


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	4 609	3 562	1 373

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	5120
Registered U.S. Implants	2428
Estimated Active U.S. Implants	2080
U.S. Normal Battery Depletions	2

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

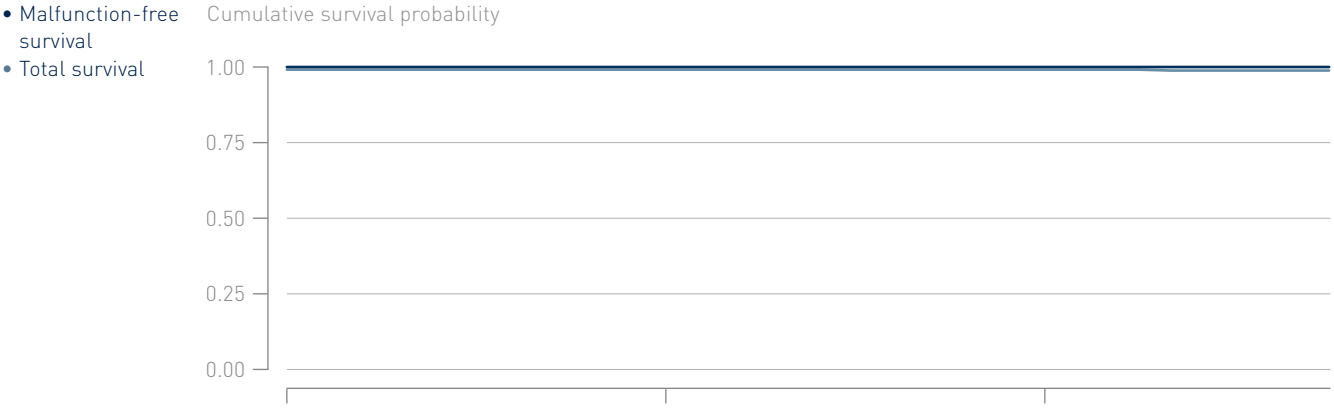


Years after implant	0	1	2
Total [%]	100.0	100.0	99.8
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	2428	1351	438

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	877
Estimated Active U.S. Implants	645
U.S. Normal Battery Depletions	1

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

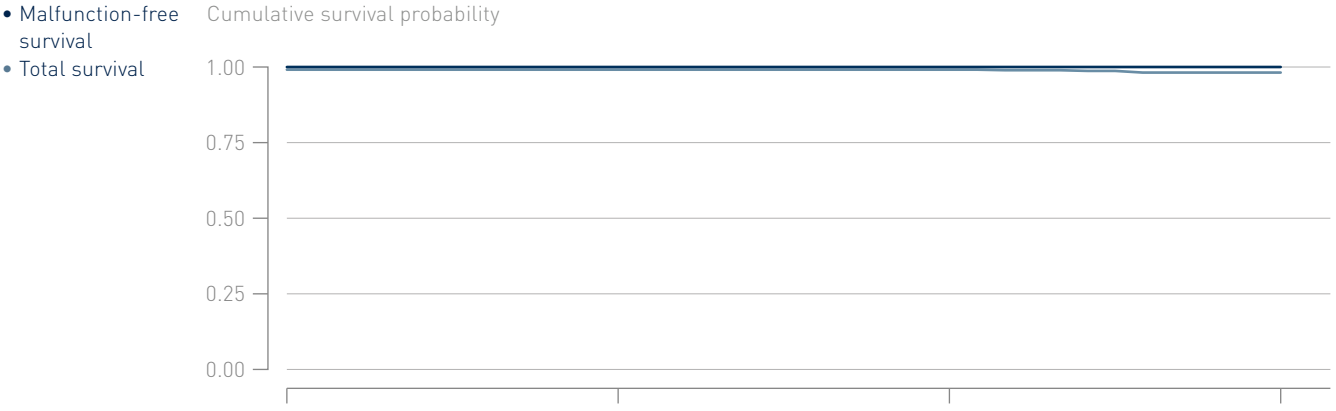


Years after implant	0	1	2
Total [%]	100.0	100.0	100.0
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1
Sample Size	877	714	464

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	1 150
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%

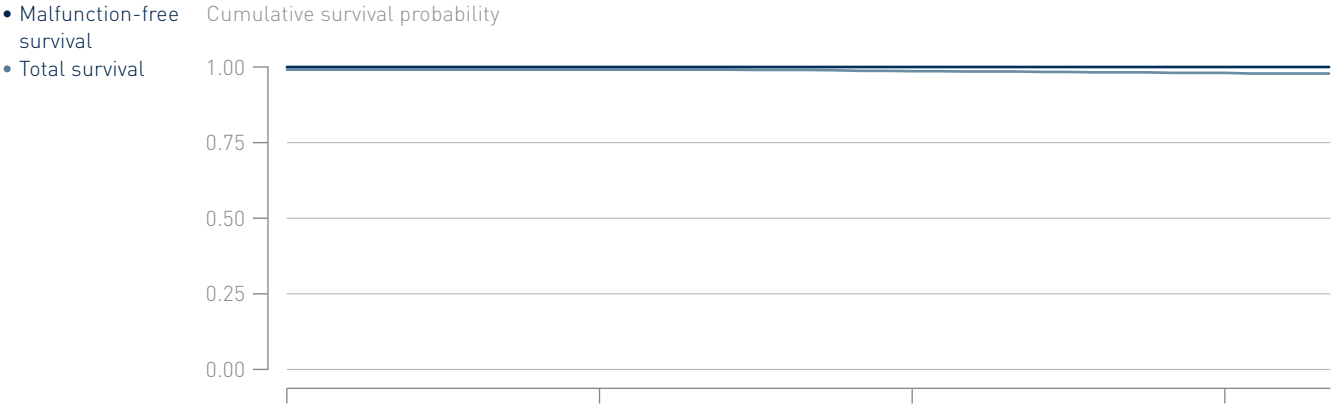


Years after implant	0	1	2	3
Total [%]	100.0	100.0	100.0	99
CI [±%]	-	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1
Sample Size	1 479	1179	640	204

Iperia 7 DF4

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	5830
Registered U.S. Implants	1612
Estimated Active U.S. Implants	1200
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%

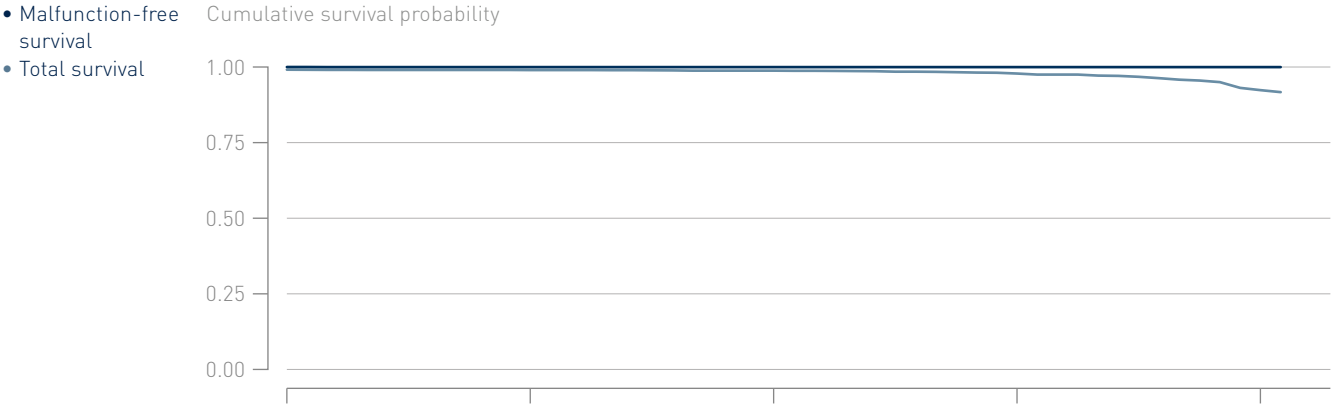


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.5	98.9
CI [±%]	-	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	-	<0.1	<0.1	<0.1
Sample Size	1612	1328	943	506

Itrevia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	4 600
Registered U.S. Implants	3 316
Estimated Active U.S. Implants	2 180
U.S. Normal Battery Depletions	68

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

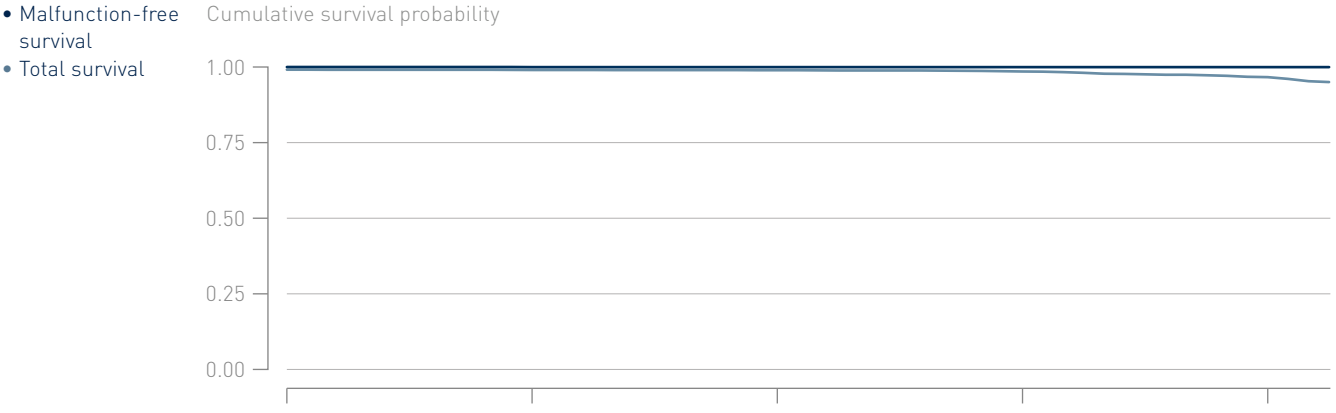


Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.7	98.7	93.2
CI [±%]	-	0.1	0.2	0.5	1.9
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	0.1	0.1	0.1	0.1
Sample Size	3316	2905	2337	1512	375

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	2 080
U.S. Normal Battery Depletions	52

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

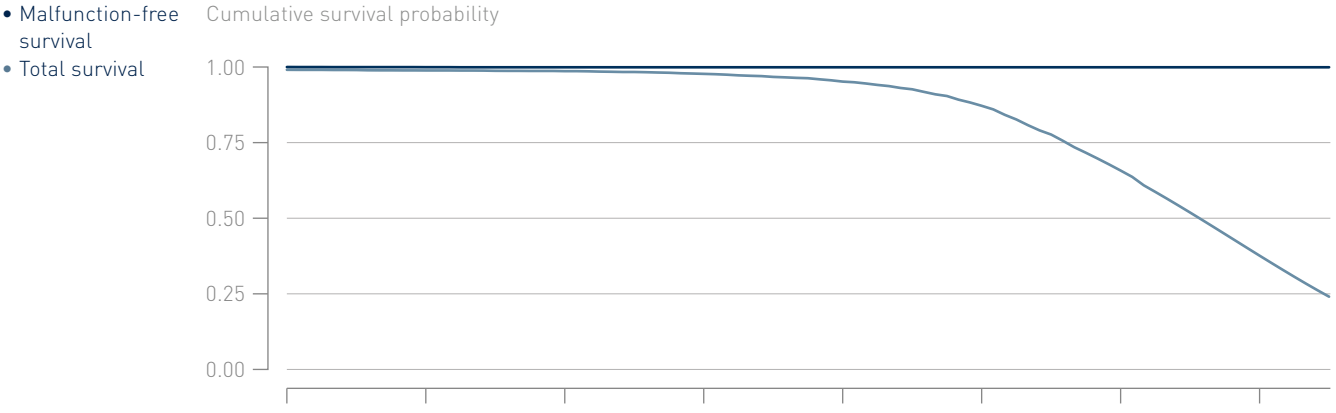


Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.8	99.4	97.5
CI [±%]	-	0.1	0.2	0.3	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	-	0.1	0.1	0.1	0.1
Sample Size	3 228	2 809	2 484	1 984	804

Lumax 340

Product Versions	HF, HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20 700
Registered U.S. Implants	5 310
Estimated Active U.S. Implants	561
U.S. Normal Battery Depletions	1 268

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

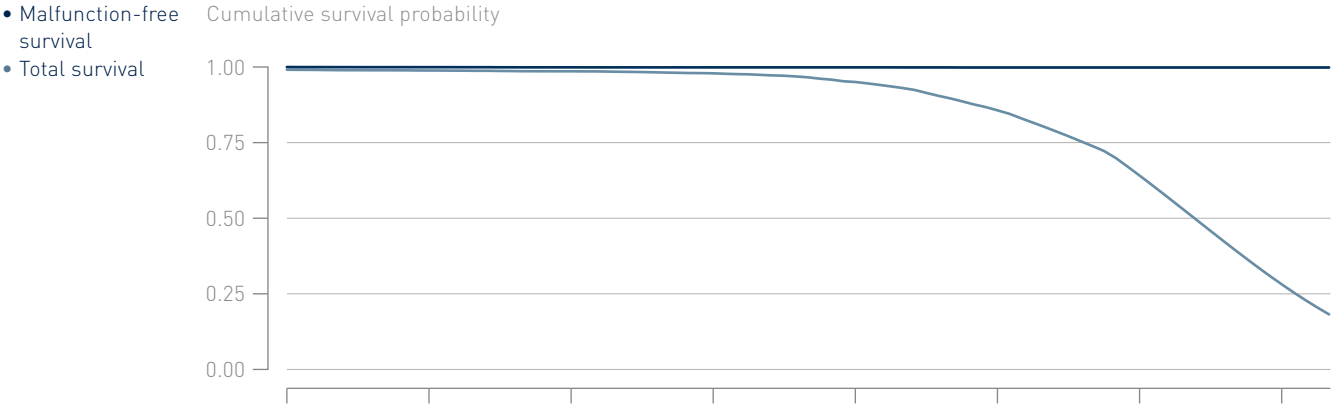


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.6	96.1	88.1	66.6	38.5
CI [±%]	-	0.1	0.2	0.4	0.6	1.1	1.8	2.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5 310	4 713	4 208	3 689	3 159	2 440	1 484	651

Lumax 540

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	24 800
Registered U.S. Implants	8 656
Estimated Active U.S. Implants	1 090
U.S. Normal Battery Depletions	2 566

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

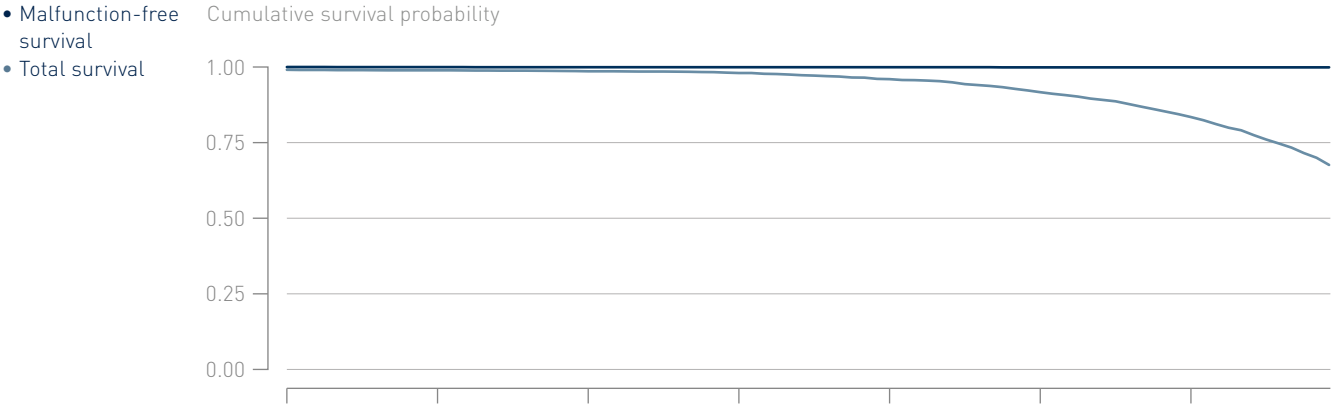


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.8	95.9	86.6	65.0	29.0
CI [±%]	-	0.1	0.2	0.3	0.5	0.9	1.4	1.8
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8 656	7 648	6 825	6 046	5 202	4 128	2 704	822

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	1220
U.S. Normal Battery Depletions	479

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

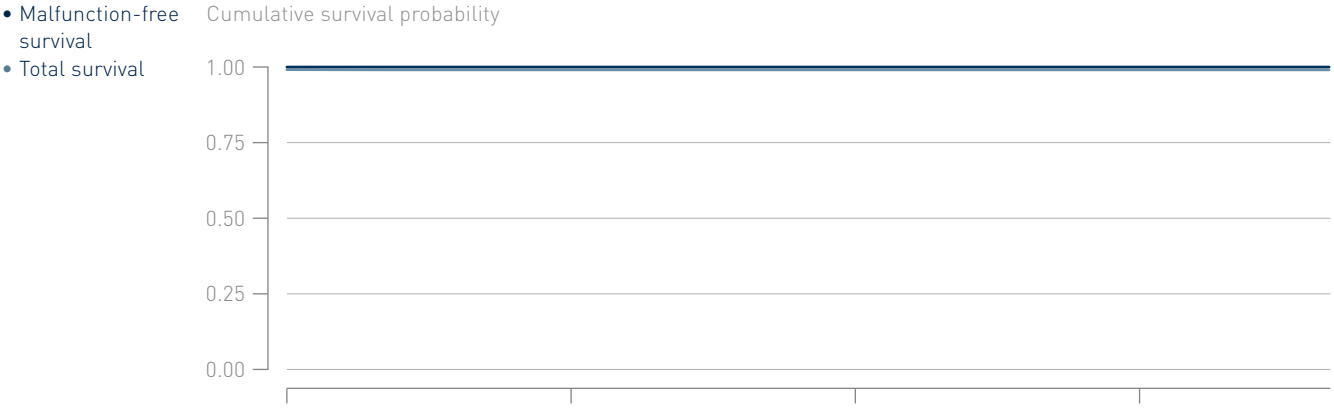


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.5	98.9	96.9	92.6	84.3
CI [±%]	-	0.2	0.3	0.4	0.7	1.1	1.6
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3410	3023	2698	2394	2095	1772	1338

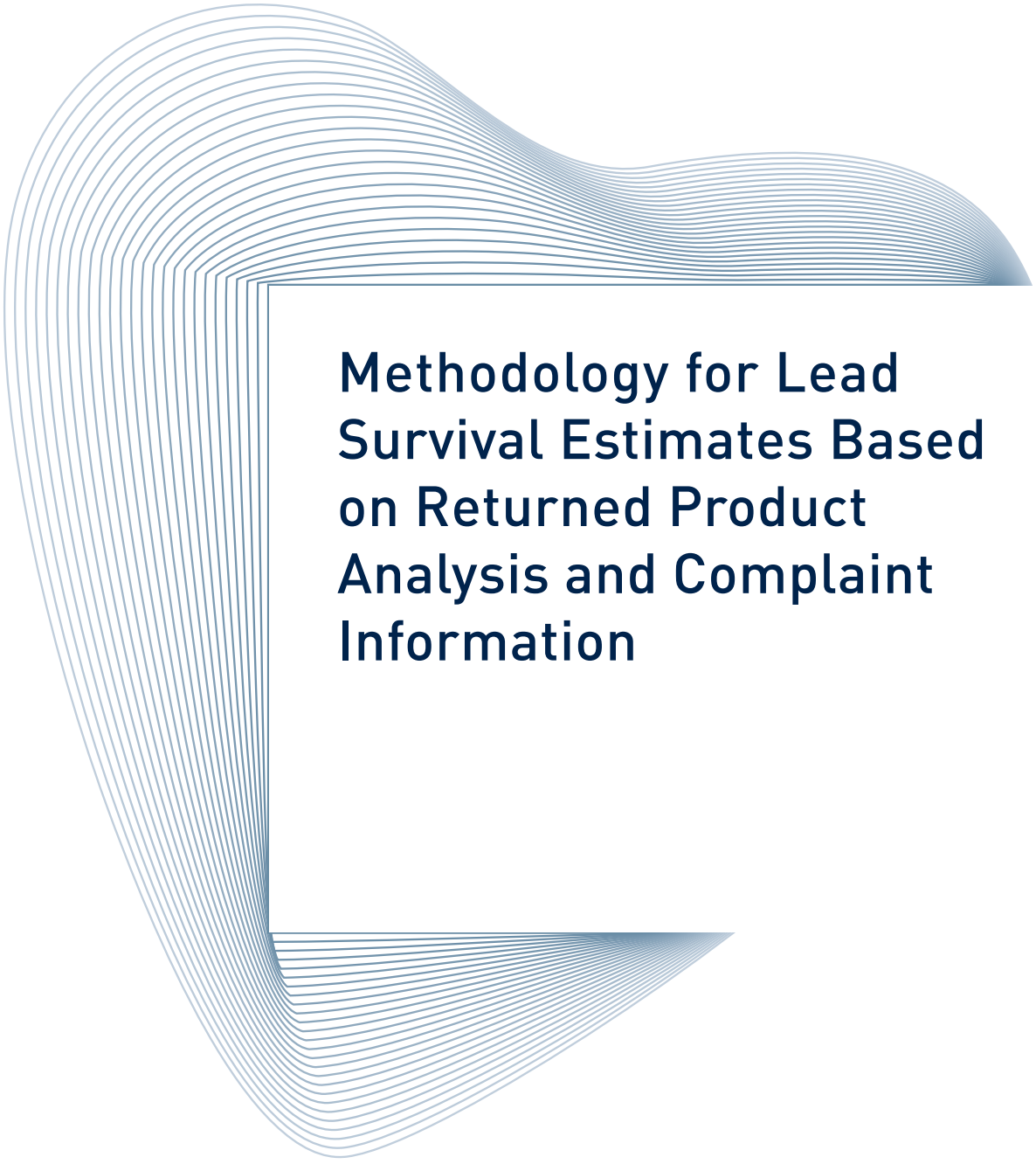
Rivacor 7 DF4

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	4 600
Registered U.S. Implants	1 635
Estimated Active U.S. Implants	1 520
U.S. Normal Battery Depletions	1

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



Years after implant	**0**
Total [%]	100.0
CI [±%]	-
Malfunction-Free [%]	100.0
CI [±%]	-
Sample Size	1 635



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 8 and 9.

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

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

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

5.3 Returned Product Analysis

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

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

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

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

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

Insulation Breach
Any lead insulation breach

Other
Includes specific proprietary lead mechanical attributes.

5.4 Lead Complications

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

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

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

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

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

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

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

Abnormal Pacing Impedance
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.

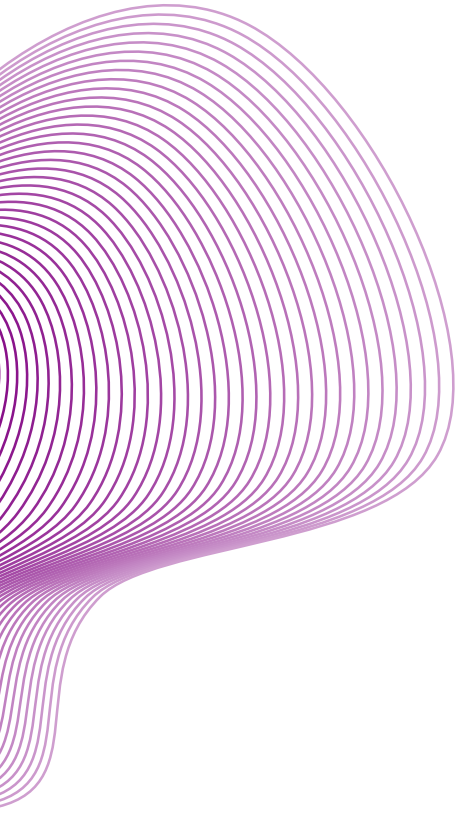
1 Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

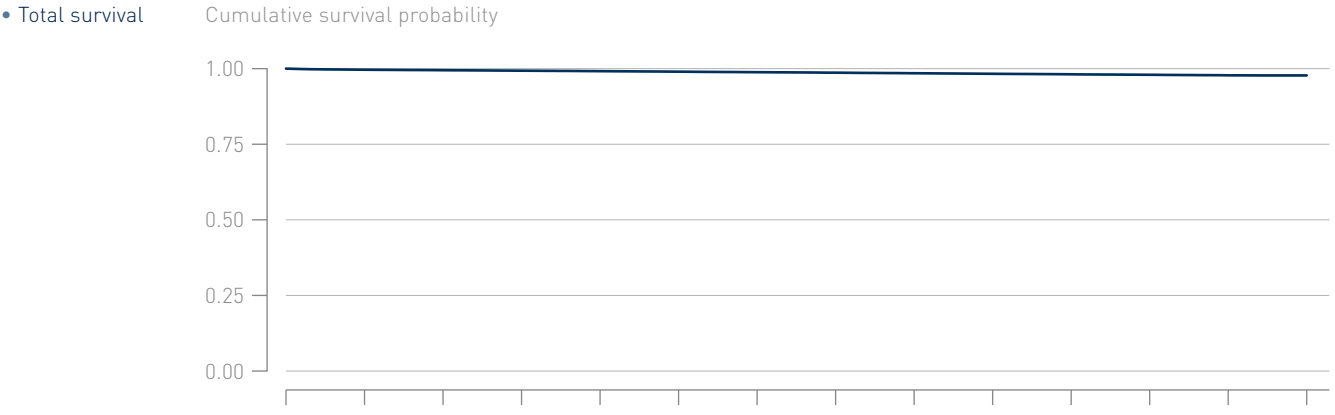


Dextrus

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	379 779
Estimated Active U.S. Implants	232 000
U.S. Total Returned	2 358

	Quantity	Rate
U.S. Qualifying Complications	4 107	1.07%
Abnormal Pacing Impedance	370	0.10%
Cardiac Perforation	25	0.01%
Conductor Fracture	117	0.03%
Extracardiac Stimulation	22	0.01%
Failure to Capture	1 077	0.28%
Failure to Sense	158	0.04%
Insulation Breach	82	0.02%
Lead Dislodgement	542	0.14%
Oversensing	994	0.26%
Other	720	0.19%

	Quantity	Rate
U.S. Confirmed Malfunctions	353	0.09%
Conductor Fracture	123	0.03%
Insulation Breach	224	0.06%
Other	6	0.00%
U.S. Acute Lead Observations	1 694	0.44%
Abnormal Pacing Impedance	41	0.01%
Cardiac Perforation	68	0.02%
Extracardiac Stimulation	15	0.00%
Failure to Capture	247	0.06%
Failure to Sense	64	0.02%
Insulation Breach	10	0.00%
Lead Dislodgement	682	0.18%
Oversensing	48	0.01%
Other	519	0.14%



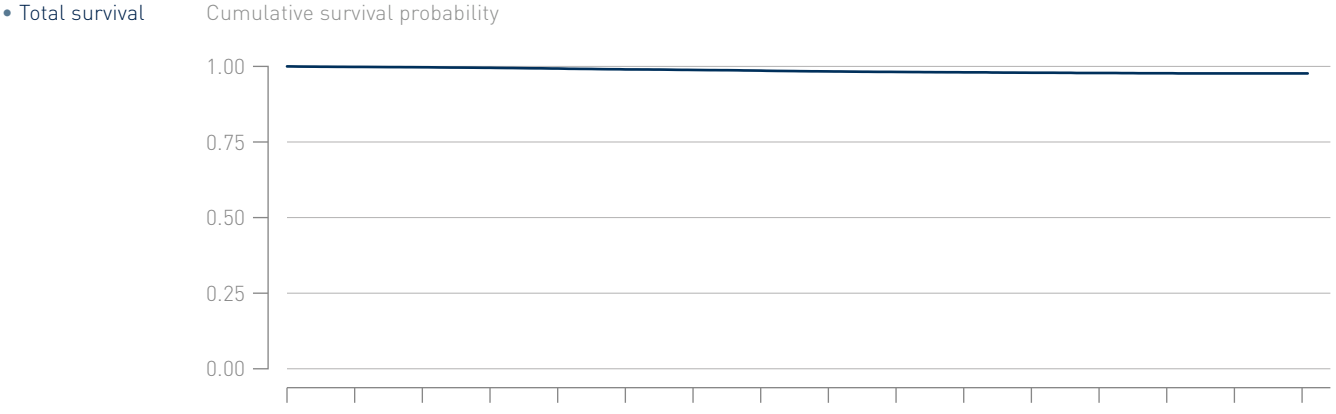
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.6	99.5	99.3	99.2	99.0	98.8	98.7	98.5	98.3	98.1	98.0	97.8	97.8
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	379 779	336 901	315 431	295 478	275 722	231 852	186 596	145 946	111 828	83 603	58 619	35 084	14 840	347

Selox JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	157 000
Registered U.S. Implants	16 621
Estimated Active U.S. Implants	12 300
U.S. Total Returned	124

	Quantity	Rate
U.S. Qualifying Complications	226	1.36%
Abnormal Pacing Impedance	33	0.20%
Cardiac Perforation	1	0.01%
Conductor Fracture	9	0.05%
Extracardiac Stimulation	1	0.01%
Failure to Capture	101	0.61%
Failure to Sense	9	0.05%
Insulation Breach	12	0.07%
Lead Dislodgement	34	0.20%
Oversensing	9	0.05%
Other	17	0.10%

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



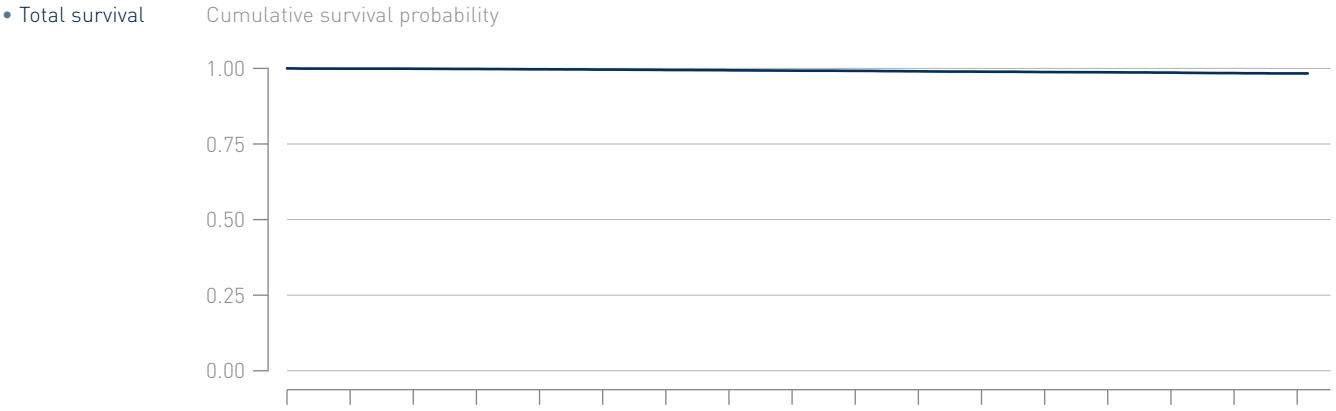
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.3	98.2	98.0	97.9	97.8	97.7	97.7	97.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	16 621	15 303	14 529	13 585	12 708	11 804	10 686	9 264	8 049	6 804	5 448	4 219	2 969	1 875	957	293

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	14 342
Estimated Active U.S. Implants	7 050
U.S. Total Returned	63

	Quantity	Rate
U.S. Qualifying Complications	121	0.84%
Abnormal Pacing Impedance	9	0.06%
Conductor Fracture	11	0.08%
Extracardiac Stimulation	2	0.01%
Failure to Capture	44	0.31%
Failure to Sense	1	0.01%
Insulation Breach	6	0.04%
Lead Dislodgement	14	0.10%
Oversensing	20	0.14%
Other	14	0.10%

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



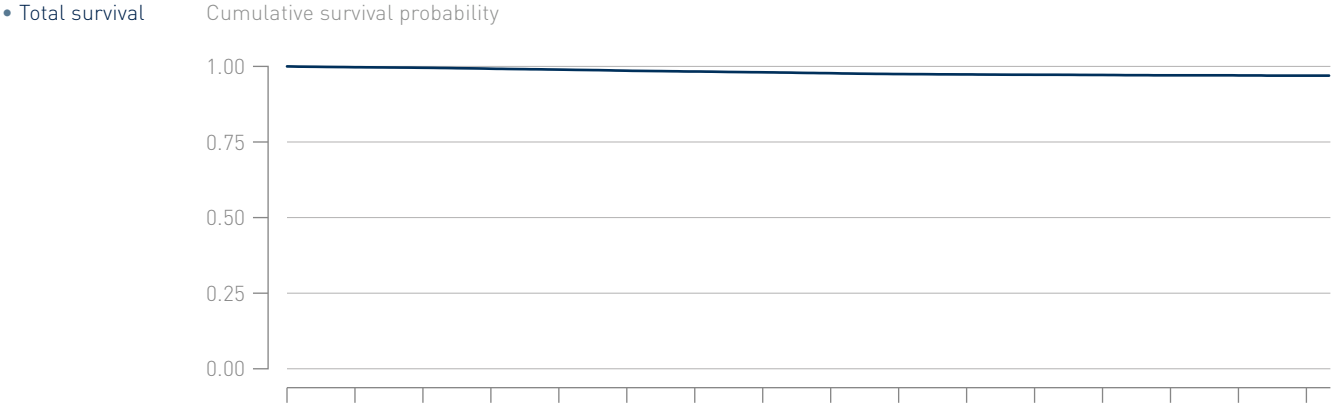
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6	98.5	98.3
CI [±%]	-	<0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3
Sample Size	14 342	12 430	11 656	10 859	10 041	9 353	8 732	8 234	7 876	7 602	7 391	7 199	7 114	7 048	6 909	3 760	643

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	32 136
Estimated Active U.S. Implants	22 800
U.S. Total Returned	181

	Quantity	Rate
U.S. Qualifying Complications	592	1.84%
Abnormal Pacing Impedance	136	0.42%
Cardiac Perforation	3	0.01%
Conductor Fracture	63	0.20%
Extracardiac Stimulation	6	0.02%
Failure to Capture	285	0.89%
Failure to Sense	1	0.00%
Insulation Breach	38	0.12%
Lead Dislodgement	23	0.07%
Oversensing	12	0.04%
Other	25	0.08%

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.0	97.8	97.5	97.3	97.2	97.2	97.0	97.0	96.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3
Sample Size	32 136	29 228	27 389	25 573	23 848	22 118	20 084	17 569	15 246	12 759	10 306	8 165	6 044	4 105	2 312	714

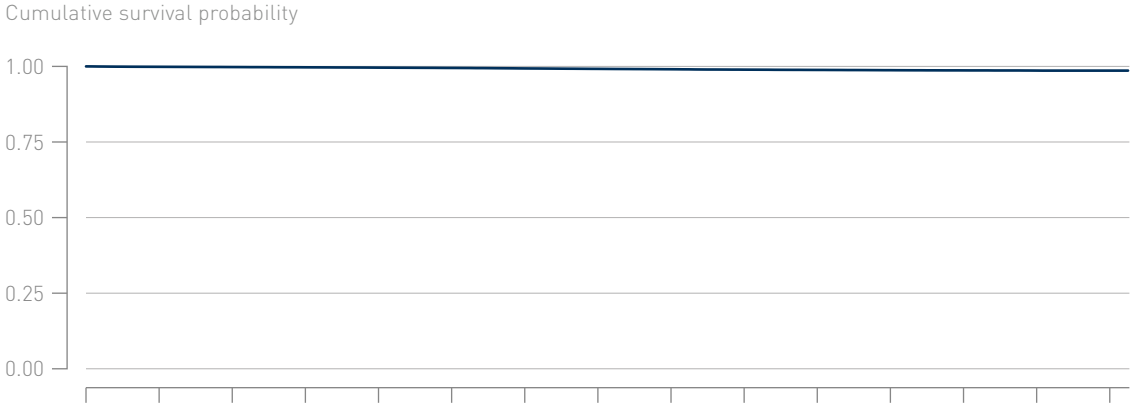
Setrox S

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	245 381
Estimated Active U.S. Implants	197 000
U.S. Total Returned	1 658

	Quantity	Rate
U.S. Qualifying Complications	1 647	0.67%
Abnormal Pacing Impedance	139	0.06%
Cardiac Perforation	8	0.00%
Conductor Fracture	96	0.04%
Extracardiac Stimulation	12	0.00%
Failure to Capture	568	0.23%
Failure to Sense	46	0.02%
Insulation Breach	73	0.03%
Lead Dislodgement	336	0.14%
Oversensing	261	0.11%
Other	108	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	178	0.07%
Conductor Fracture	58	0.02%
Insulation Breach	117	0.05%
Other	3	0.00%
U.S. Acute Lead Observations	272	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%
Other	16	0.01%

• Total survival



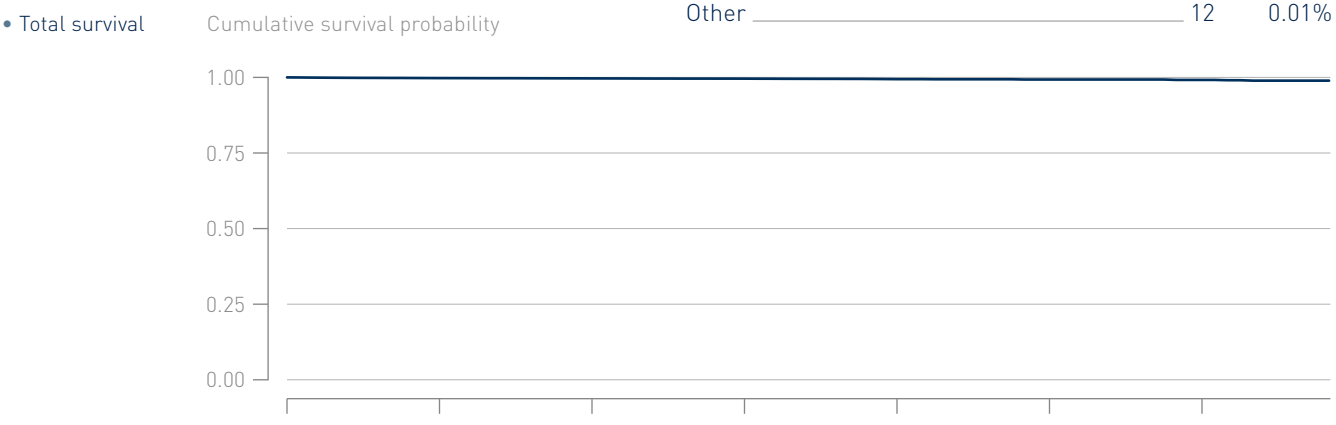
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.1	98.9	98.8	98.7	98.7	98.6	98.6
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	245381	228878	219681	211651	199794	162632	131510	107464	85574	65070	47286	31637	18145	8319	1397

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	1 616 000
Registered U.S. Implants	148 093
Estimated Active U.S. Implants	142 000
U.S. Total Returned	632

	Quantity	Rate
U.S. Qualifying Complications	444	0.30%
Abnormal Pacing Impedance	26	0.02%
Cardiac Perforation	14	0.01%
Conductor Fracture	10	0.01%
Extracardiac Stimulation	5	0.00%
Failure to Capture	123	0.08%
Failure to Sense	16	0.01%
Insulation Breach	7	0.00%
Lead Dislodgement	199	0.13%
Oversensing	30	0.02%
Other	14	0.01%

	Quantity	Rate
U.S. Confirmed Malfunctions	33	0.02%
Conductor Fracture	14	0.01%
Insulation Breach	17	0.01%
Other	2	0.00%
U.S. Acute Lead Observations	260	0.18%
Abnormal Pacing Impedance	4	0.00%
Cardiac Perforation	24	0.02%
Conductor Fracture	1	0.00%
Failure to Capture	49	0.03%
Failure to Sense	5	0.00%
Insulation Breach	2	0.00%
Lead Dislodgement	158	0.11%
Oversensing	5	0.00%
Other	12	0.01%



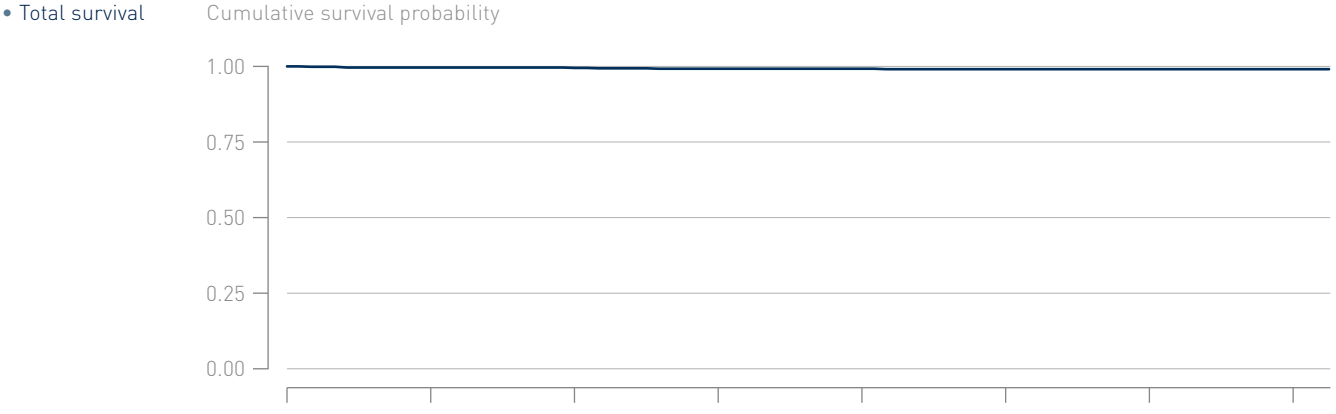
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.7	99.6	99.4	99.3	99.2
CI [±%]	-	<0.1	<0.1	<0.1	0.1	0.2	0.3
Sample Size	148 093	111 369	71 491	33 109	3 007	2 415	1 229

Tilda JT

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

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

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



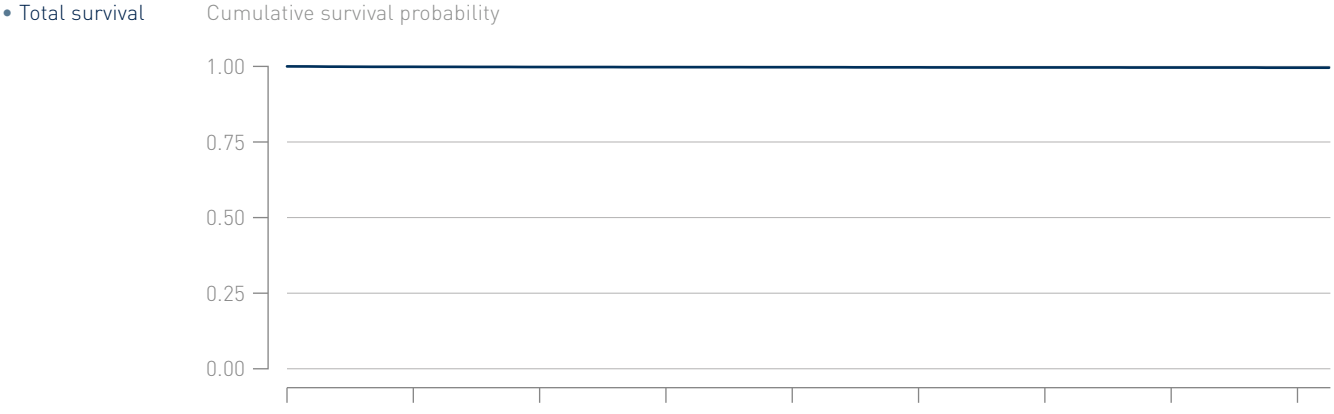
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.6	99.5	99.2	99.2	99.1	99.1	99.1
CI [±%]	-	0.4	0.5	0.6	0.6	0.7	0.7	0.7
Sample Size	810	790	770	738	680	577	436	268

Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41 300
Registered U.S. Implants	10 228
Estimated Active U.S. Implants	9 830
U.S. Total Returned	16

	Quantity	Rate
U.S. Qualifying Complications	34	0.33%
Abnormal Pacing Impedance	1	0.01%
Conductor Fracture	6	0.06%
Extracardiac Stimulation	1	0.01%
Failure to Capture	8	0.08%
Insulation Breach	2	0.02%
Lead Dislodgement	9	0.09%
Oversensing	3	0.03%
Other	4	0.04%

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



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.9	99.8	99.8	99.7	99.7	99.6	99.6	99.6
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Sample Size	10 228	9 954	9 709	9 369	8 636	7 580	5 896	3 717	1 078

Tilda T

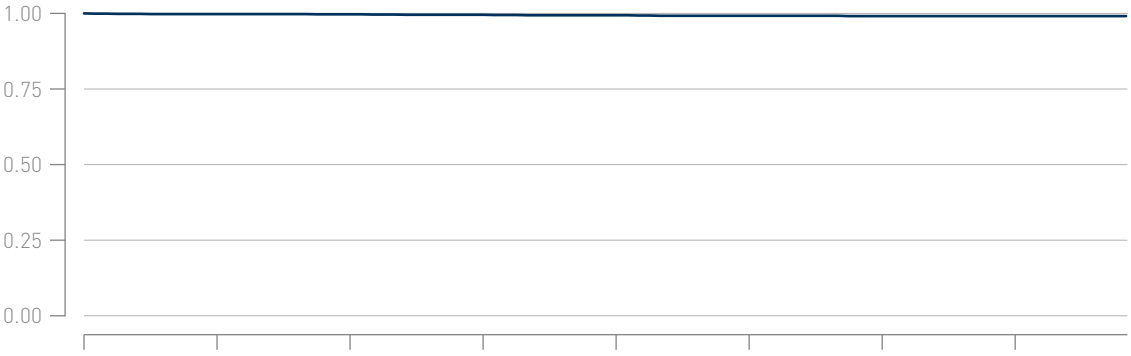
Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22 400
Registered U.S. Implants	1 357
Estimated Active U.S. Implants	1 310
U.S. Total Returned	2

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

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

• Total survival

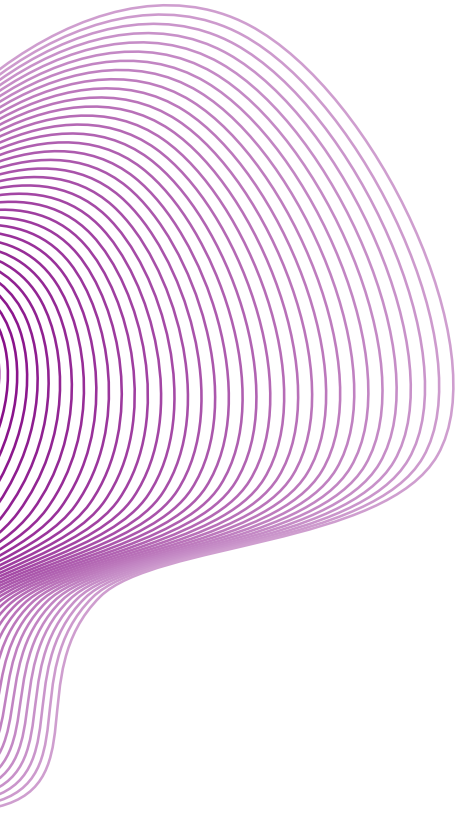
Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.7	99.5	99.4	99.2	99.1	99.1
CI [±%]	-	0.3	0.3	0.4	0.4	0.5	0.5	0.5
Sample Size	1 357	1 318	1 298	1 261	1 171	1 051	853	520

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

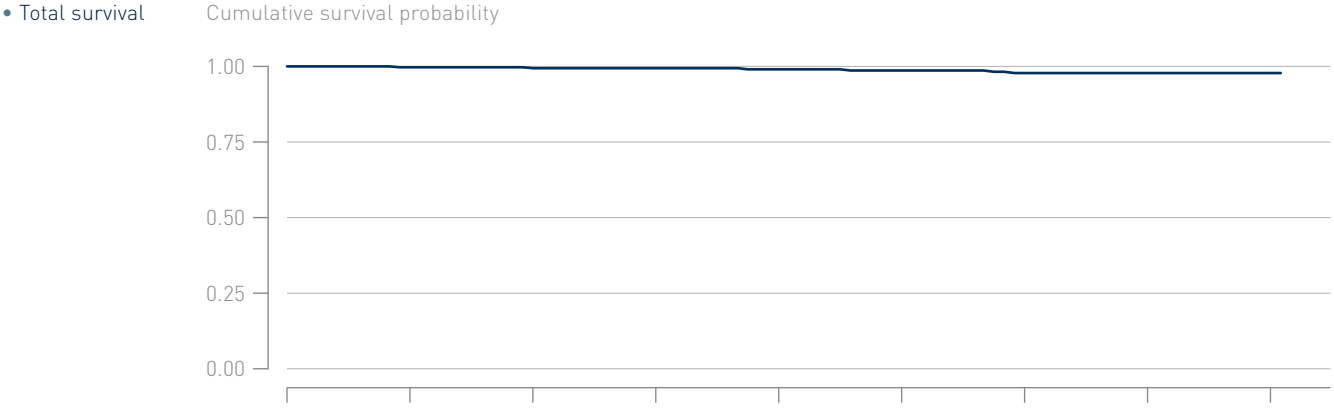


Kentrox RV

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	5460
Registered U.S. Implants	406
Estimated Active U.S. Implants	172
U.S. Total Returned	8

	Quantity	Rate
U.S. Qualifying Complications	8	1.97%
Conductor Fracture	1	0.25%
Failure to Capture	2	0.49%
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%



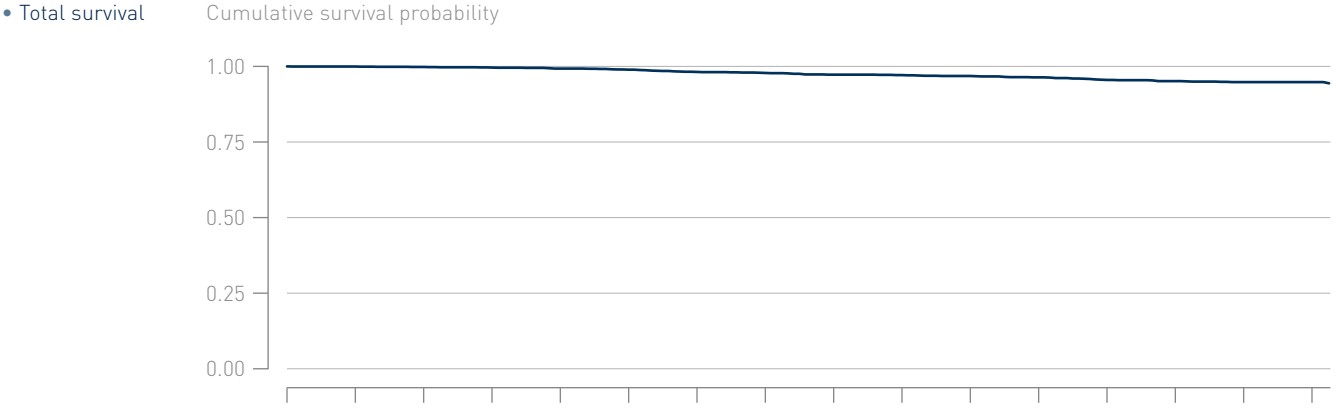
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	99.4	99.0	98.6	97.8	97.8	97.8
CI [±%]	-	0.6	0.8	0.8	1.1	1.3	1.8	1.8	1.8
Sample Size	406	353	318	286	269	243	228	211	201

Kentrox SL-S

Product Versions	65/16, 18 -Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8740
Registered U.S. Implants	2412
Estimated Active U.S. Implants	1220
U.S. Total Returned	41

	Quantity	Rate
U.S. Qualifying Complications	64	2.64%
Abnormal Defibrillation Impedance	1	0.04%
Abnormal Pacing Impedance	5	0.21%
Conductor Fracture	5	0.21%
Failure to Capture	3	0.12%
Failure to Sense	1	0.04%
Insulation Breach	3	0.12%
Lead Dislodgement	2	0.08%
Oversensing	41	1.69%
Other	3	0.12%

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



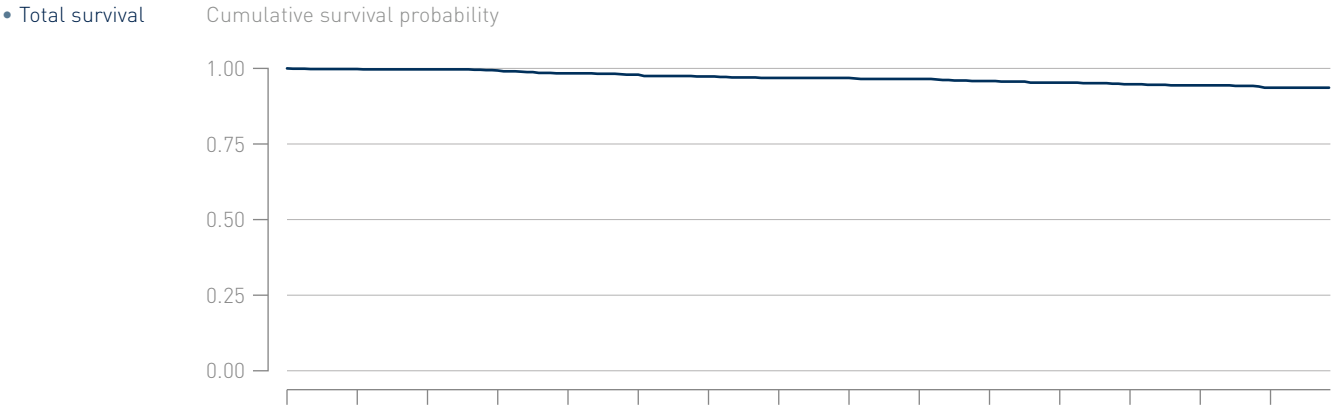
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	100.0	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.8
CI [±%]	-	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.1
Sample Size	2412	2174	2049	1889	1754	1630	1510	1429	1362	1323	1281	1258	1229	1200	1100	403

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	1 001
Estimated Active U.S. Implants	523
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	36	3.57%
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	16	1.59%
Other	2	0.20%

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.50%
Insulation Breach	5	0.50%
U.S. Acute Lead Observations	0	0.00%



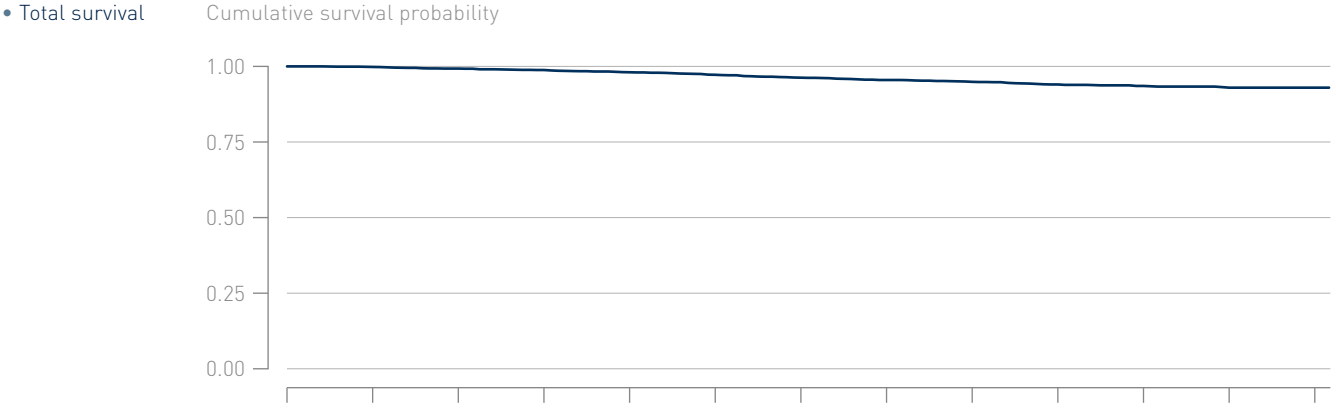
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.8	96.8	96.5	95.8	95.3	94.8	94.4	93.6
CI [±%]	-	0.3	0.4	0.6	0.9	1	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9
Sample Size	1 001	896	832	775	705	660	614	594	574	562	550	541	530	522	445

Linox S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	2 466
Estimated Active U.S. Implants	1 640
U.S. Total Returned	84

	Quantity	Rate
U.S. Qualifying Complications	80	3.21%
Abnormal Defibrillation Impedance	8	0.32%
Abnormal Pacing Impedance	6	0.24%
Conductor Fracture	7	0.28%
Failure to Capture	9	0.36%
Failure to Sense	1	0.04%
Insulation Breach	4	0.16%
Oversensing	39	1.56%
Other	6	0.24%

	Quantity	Rate
U.S. Confirmed Malfunctions	45	1.81%
Conductor Fracture	7	0.28%
Insulation Breach	38	1.52%
U.S. Acute Lead Observations	2	0.08%
Lead Dislodgement	1	0.04%
Other	1	0.04%



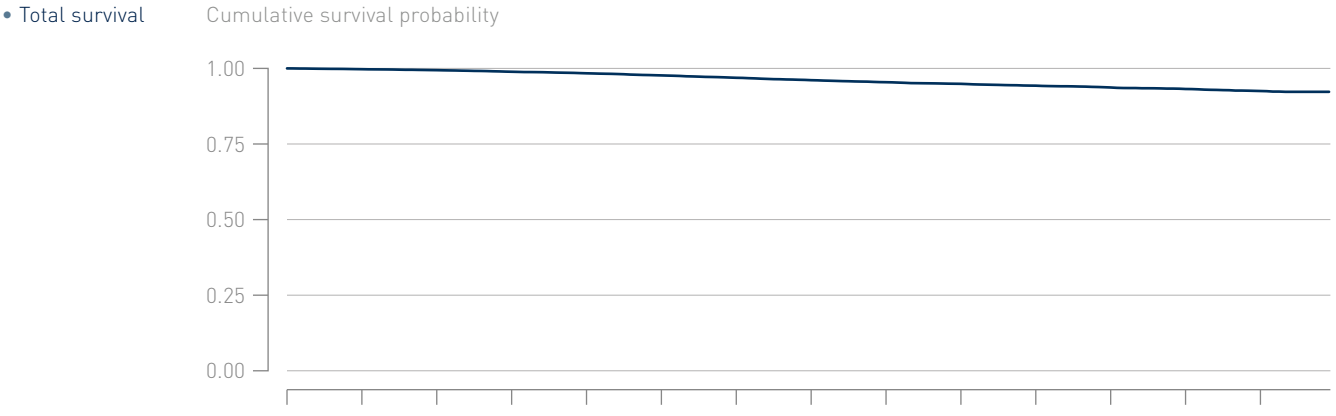
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.8	99.3	98.8	98.1	97.2	96.3	95.5	94.9	94.0	93.5	93.0	93.0
CI [±%]	-	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1	1.1	1.3	1.3
Sample Size	2 466	2 261	2 129	2 018	1 925	1 848	1 785	1 742	1 692	1 489	914	516	267

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	22 093
Estimated Active U.S. Implants	14 200
U.S. Total Returned	515

	Quantity	Rate
U.S. Qualifying Complications	842	3.78%
Abnormal Defibrillation Impedance	72	0.32%
Abnormal Pacing Impedance	60	0.27%
Cardiac Perforation	3	0.01%
Conductor Fracture	96	0.43%
Failure to Capture	73	0.33%
Failure to Sense	16	0.07%
Insulation Breach	59	0.27%
Lead Dislodgement	31	0.14%
Oversensing	385	1.73%
Other	47	0.21%

	Quantity	Rate
U.S. Confirmed Malfunctions	214	0.96%
Conductor Fracture	30	0.13%
Insulation Breach	182	0.82%
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
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.7	93.2	92.5
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.5
Sample Size	22 093	20 081	18 842	17 786	16 938	16 200	15 599	15 130	14 774	14 186	11 061	7 301	4 081	1 745

Linox^{smart} S

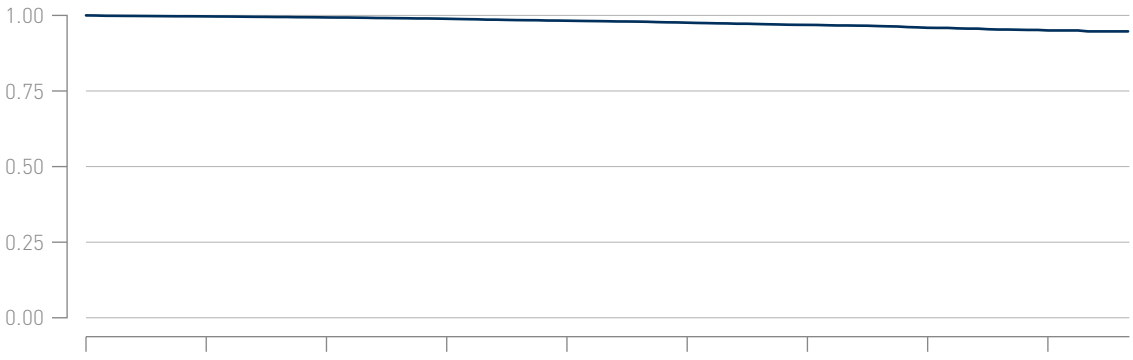
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	7 597
Estimated Active U.S. Implants	6 220
U.S. Total Returned	182

	Quantity	Rate
U.S. Qualifying Complications	181	2.37%
Abnormal Defibrillation Impedance	10	0.13%
Abnormal Pacing Impedance	14	0.18%
Cardiac Perforation	1	0.01%
Conductor Fracture	20	0.26%
Failure to Capture	22	0.29%
Failure to Sense	8	0.10%
Insulation Breach	5	0.07%
Lead Dislodgement	14	0.18%
Oversensing	78	1.02%
Other	9	0.12%

	Quantity	Rate
U.S. Confirmed Malfunctions	68	0.89%
Conductor Fracture	8	0.10%
Insulation Breach	60	0.78%
U.S. Acute Lead Observations	10	0.13%
Abnormal Pacing Impedance	1	0.01%
Cardiac Perforation	1	0.01%
Lead Dislodgement	7	0.09%
Other	1	0.01%

• Total survival

Cumulative survival probability



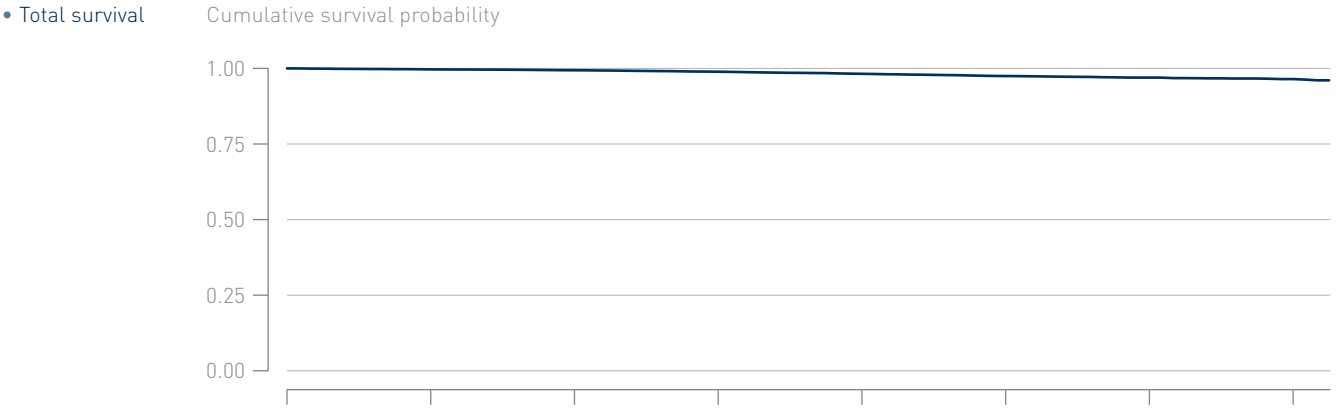
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.3	98.9	98.2	97.6	96.9	95.9	95.0
CI [±%]	-	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.7
Sample Size	7597	7132	6867	6610	6211	5607	4389	2805	1097

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	16 299
Estimated Active U.S. Implants	14 500
U.S. Total Returned	338

	Quantity	Rate
U.S. Qualifying Complications	257	1.57%
Abnormal Defibrillation Impedance	25	0.15%
Abnormal Pacing Impedance	19	0.12%
Conductor Fracture	33	0.20%
Failure to Capture	23	0.14%
Failure to Sense	11	0.07%
Insulation Breach	6	0.04%
Lead Dislodgement	39	0.24%
Oversensing	94	0.57%
Other	7	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	94	0.57%
Conductor Fracture	7	0.04%
Insulation Breach	87	0.53%
U.S. Acute Lead Observations	39	0.24%
Cardiac Perforation	4	0.02%
Failure to Capture	9	0.05%
Lead Dislodgement	16	0.10%
Oversensing	3	0.02%
Other	7	0.04%



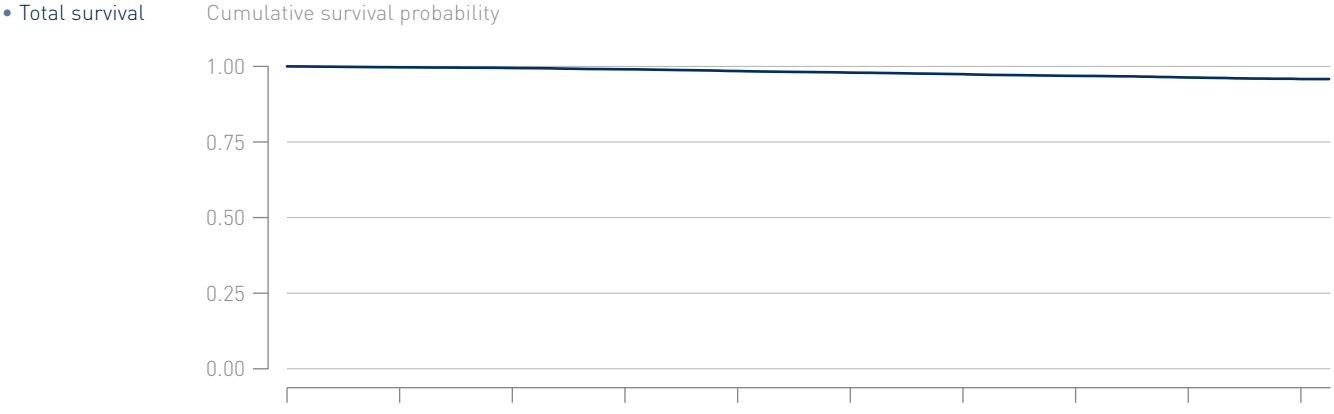
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.4	98.9	98.2	97.5	97.0	96.5
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.5
Sample Size	16 299	15 516	15 049	13 982	10 217	6 715	3 513	739

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	13 126
Estimated Active U.S. Implants	10 600
U.S. Total Returned	245

	Quantity	Rate
U.S. Qualifying Complications	310	2.34%
Abnormal Defibrillation Impedance	26	0.20%
Abnormal Pacing Impedance	16	0.12%
Cardiac Perforation	1	0.01%
Conductor Fracture	40	0.30%
Extracardiac Stimulation	1	0.01%
Failure to Capture	26	0.20%
Failure to Sense	8	0.06%
Insulation Breach	8	0.06%
Lead Dislodgement	25	0.19%
Oversensing	152	1.15%
Other	7	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	68	0.51%
Conductor Fracture	9	0.07%
Insulation Breach	57	0.43%
Other	2	0.02%
U.S. Acute Lead Observations	29	0.22%
Abnormal Defibrillation Impedance	1	0.01%
Cardiac Perforation	2	0.02%
Failure to Capture	4	0.03%
Insulation Breach	1	0.01%
Lead Dislodgement	12	0.09%
Oversensing	2	0.02%
Other	7	0.05%



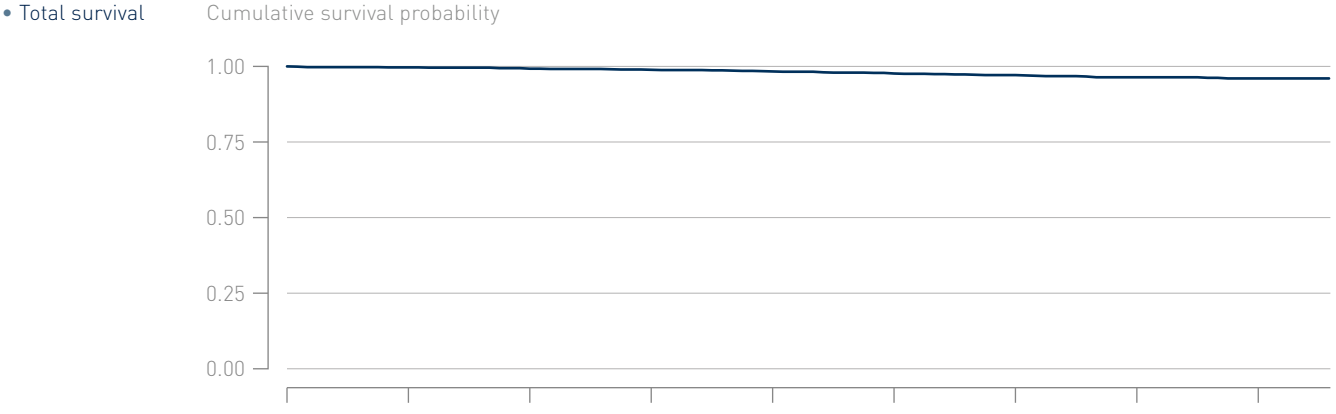
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.5	99.0	98.5	97.9	97.4	96.9	96.3	95.8
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.5
Sample Size	13 126	12 173	11 775	11 376	10 838	10 240	9 130	7 266	4 285	935

Linox^{smart} TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered U.S. Implants	1 265
Estimated Active U.S. Implants	1 010
U.S. Total Returned	21

	Quantity	Rate
U.S. Qualifying Complications	38	2.98%
Abnormal Defibrillation Impedance	5	0.39%
Abnormal Pacing Impedance	4	0.31%
Conductor Fracture	3	0.24%
Failure to Capture	9	0.71%
Insulation Breach	2	0.16%
Lead Dislodgement	4	0.31%
Oversensing	10	0.78%
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%



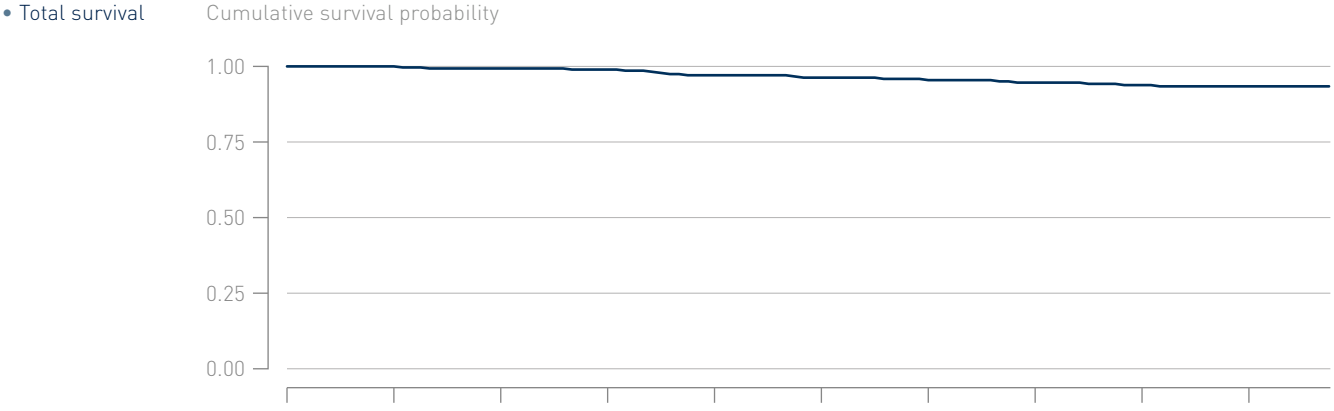
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.2	98.9	98.3	97.7	97.1	96.4	96.0
CI [±%]	-	0.3	0.5	0.6	0.7	0.9	1	1.1	1.3
Sample Size	1 265	1 174	1 138	1 096	1 056	987	879	699	387

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	218
U.S. Total Returned	4

	Quantity	Rate
U.S. Qualifying Complications	18	5.59%
Abnormal Pacing Impedance	2	0.62%
Conductor Fracture	1	0.31%
Failure to Capture	4	1.24%
Insulation Breach	1	0.31%
Oversensing	9	2.80%
Other	1	0.31%

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



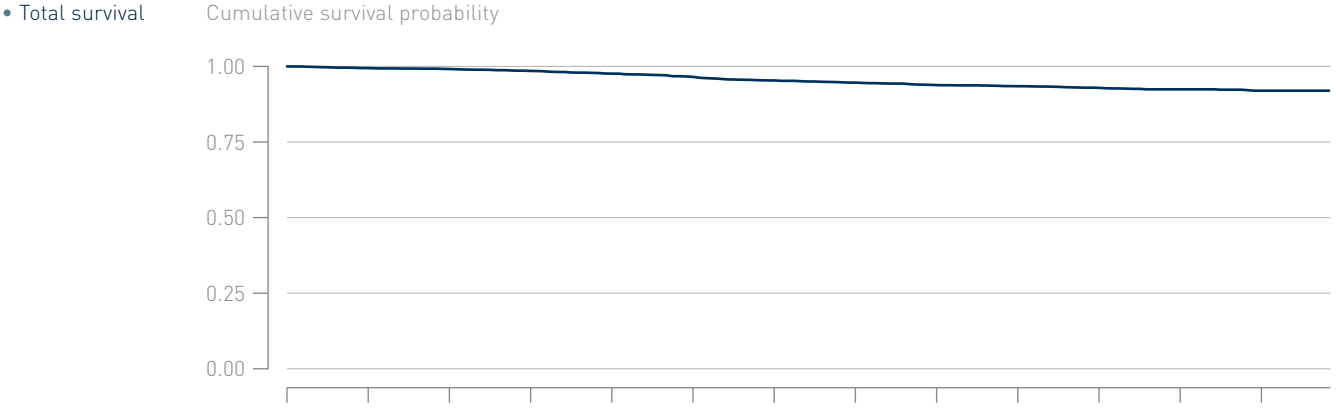
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4
CI [±%]	-	<0.1	0.9	1.2	2	2.3	2.5	2.7	2.9	3
Sample Size	319	295	283	272	251	241	234	230	228	223

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	3 022
Estimated Active U.S. Implants	2 000
U.S. Total Returned	80

	Quantity	Rate
U.S. Qualifying Complications	139	4.55%
Abnormal Defibrillation Impedance	15	0.49%
Abnormal Pacing Impedance	13	0.43%
Cardiac Perforation	1	0.03%
Conductor Fracture	18	0.59%
Failure to Capture	21	0.69%
Failure to Sense	4	0.13%
Insulation Breach	13	0.43%
Lead Dislodgement	4	0.13%
Oversensing	47	1.54%
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%



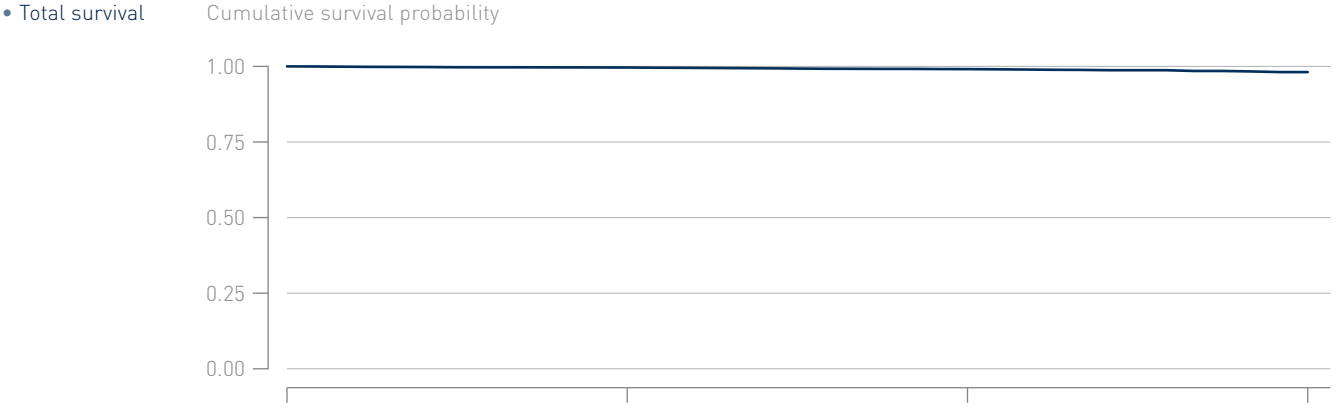
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.4	94.6	93.8	93.4	92.9	92.4	92.0
CI [±%]	-	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1	1	1	1.1	1.2
Sample Size	3022	2731	2599	2452	2338	2236	2147	2085	2046	1935	1543	981	502

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	71 100
Registered U.S. Implants	11 005
Estimated Active U.S. Implants	10 500
U.S. Total Returned	71

	Quantity	Rate
U.S. Qualifying Complications	70	0.63%
Abnormal Defibrillation Impedance	8	0.07%
Abnormal Pacing Impedance	1	0.01%
Cardiac Perforation	1	0.01%
Conductor Fracture	2	0.02%
Failure to Capture	8	0.07%
Failure to Sense	3	0.03%
Insulation Breach	1	0.01%
Lead Dislodgement	16	0.14%
Oversensing	26	0.24%
Other	4	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.06%
Conductor Fracture	1	0.01%
Insulation Breach	6	0.05%
U.S. Acute Lead Observations	18	0.16%
Abnormal Pacing Impedance	2	0.02%
Cardiac Perforation	3	0.03%
Failure to Capture	4	0.04%
Lead Dislodgement	9	0.08%



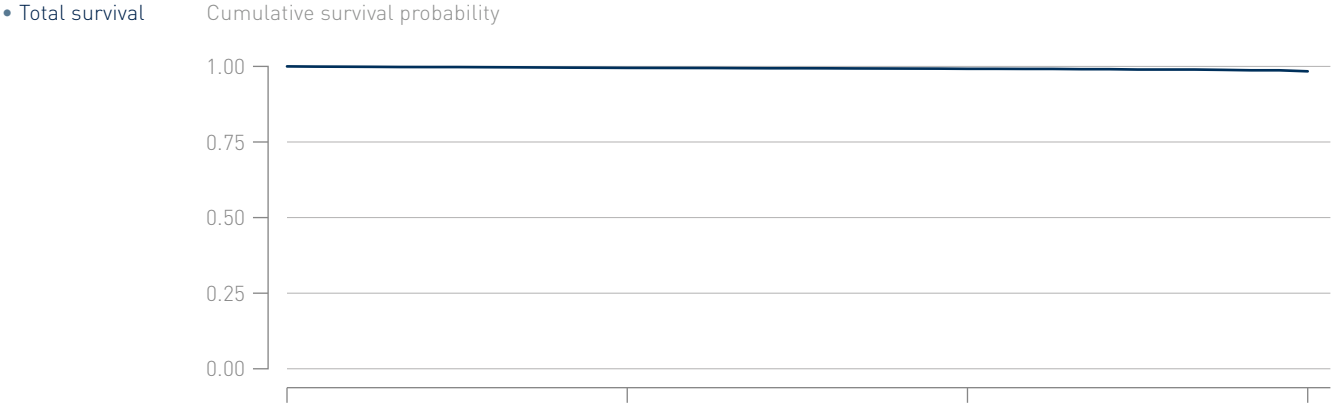
Years after implant	0	1	2	3
Total [%]	100.0	99.6	99.1	98.1
CI [±%]	-	0.1	0.2	0.7
Sample Size	11 005	7 118	3 412	256

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	18 900
Registered U.S. Implants	8 611
Estimated Active U.S. Implants	8 170
U.S. Total Returned	87

	Quantity	Rate
U.S. Qualifying Complications	48	0.55%
Abnormal Defibrillation Impedance	7	0.08%
Abnormal Pacing Impedance	1	0.01%
Conductor Fracture	1	0.01%
Failure to Capture	5	0.06%
Failure to Sense	4	0.05%
Insulation Breach	1	0.01%
Lead Dislodgement	16	0.18%
Oversensing	13	0.15%

	Quantity	Rate
U.S. Confirmed Malfunctions	15	0.17%
Insulation Breach	15	0.17%
U.S. Acute Lead Observations	18	0.21%
Cardiac Perforation	2	0.02%
Failure to Capture	2	0.02%
Failure to Sense	1	0.01%
Lead Dislodgement	10	0.12%
Oversensing	1	0.01%
Other	2	0.02%



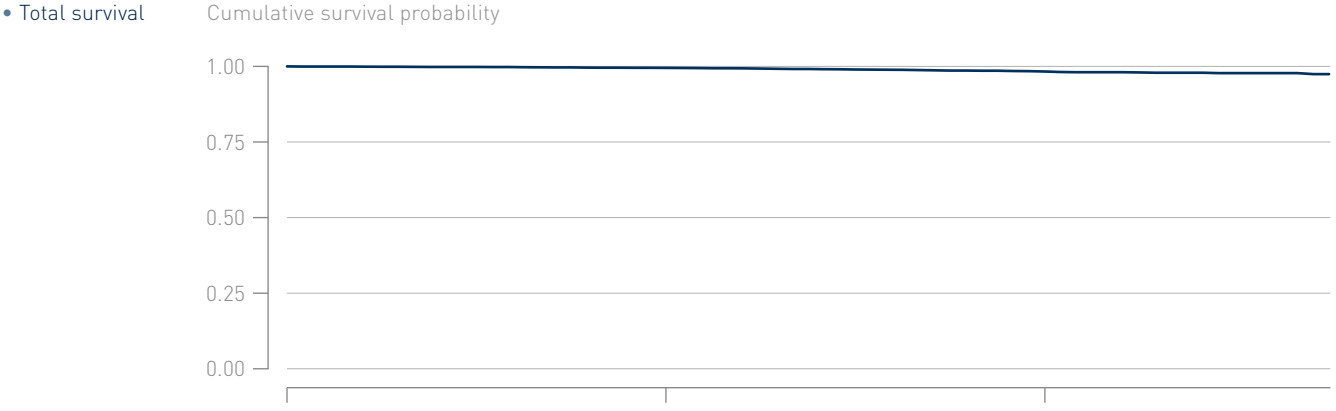
Years after implant	0	1	2	3
Total [%]	100.0	99.5	99.2	98.4
CI [±%]	-	0.2	0.2	0.8
Sample Size	8 611	7 323	3 608	294

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	9 590
Registered U.S. Implants	3 054
Estimated Active U.S. Implants	2 910
U.S. Total Returned	13

	Quantity	Rate
U.S. Qualifying Complications	12	0.39%
Extracardiac Stimulation	1	0.03%
Failure to Capture	1	0.03%
Failure to Sense	1	0.03%
Lead Dislodgement	6	0.20%
Oversensing	3	0.10%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.03%
Conductor Fracture	1	0.03%
U.S. Acute Lead Observations	7	0.23%
Abnormal Defibrillation Impedance	1	0.03%
Cardiac Perforation	1	0.03%
Failure to Capture	1	0.03%
Lead Dislodgement	1	0.03%
Oversensing	2	0.07%
Other	1	0.03%



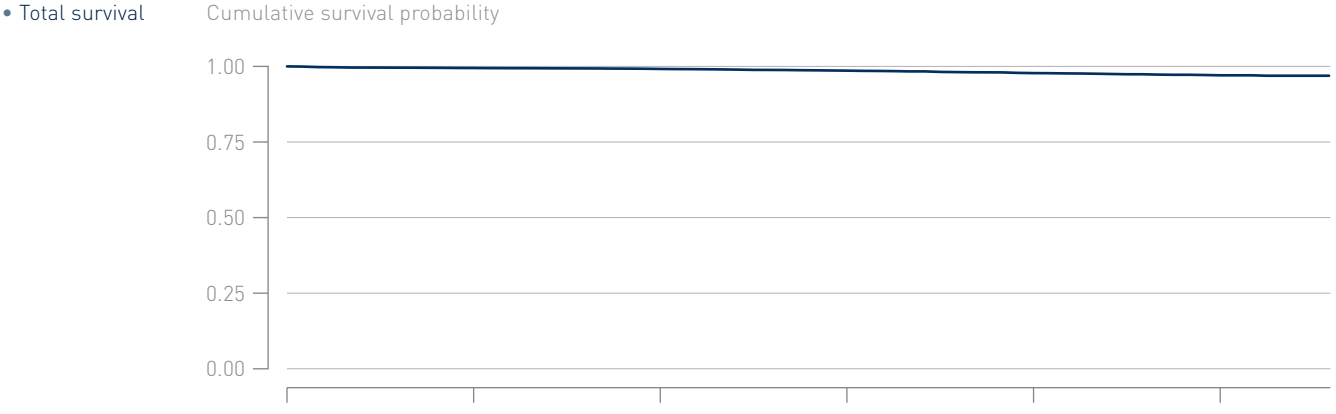
Years after implant	0	1	2
Total [%]	100.0	99.6	99.5
CI [±%]	-	0.2	0.3
Sample Size	3 054	2 054	949

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	54 800
Registered U.S. Implants	8 275
Estimated Active U.S. Implants	7 290
U.S. Total Returned	108

	Quantity	Rate
U.S. Qualifying Complications	126	1.51%
Abnormal Defibrillation Impedance	3	0.04%
Abnormal Pacing Impedance	7	0.08%
Cardiac Perforation	1	0.01%
Conductor Fracture	12	0.14%
Extracardiac Stimulation	1	0.01%
Failure to Capture	17	0.20%
Failure to Sense	4	0.05%
Insulation Breach	3	0.04%
Lead Dislodgement	24	0.29%
Oversensing	49	0.59%
Other	5	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	37	0.44%
Conductor Fracture	6	0.07%
Insulation Breach	30	0.36%
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%



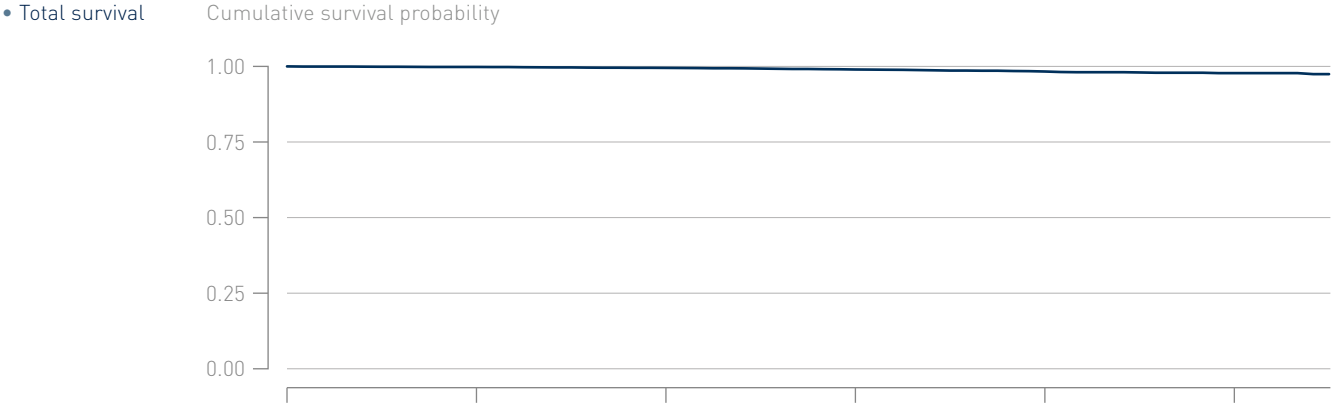
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.5	99.2	98.6	97.8	97.1
CI [±%]	-	0.2	0.2	0.3	0.4	0.5
Sample Size	8 275	7 782	7 434	6 535	3 585	1 071

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	3 409
Estimated Active U.S. Implants	3 040
U.S. Total Returned	36

	Quantity	Rate
U.S. Qualifying Complications	48	1.40%
Abnormal Defibrillation Impedance	4	0.12%
Abnormal Pacing Impedance	2	0.06%
Conductor Fracture	5	0.15%
Failure to Capture	6	0.17%
Insulation Breach	1	0.03%
Lead Dislodgement	4	0.12%
Oversensing	24	0.70%
Other	2	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.20%
Insulation Breach	7	0.20%
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
Total [%]	100.0	99.8	99.5	99.0	98.3	97.8
CI [±%]	-	0.1	0.2	0.4	0.5	0.6
Sample Size	3 409	3 233	3 149	2 831	1 812	669

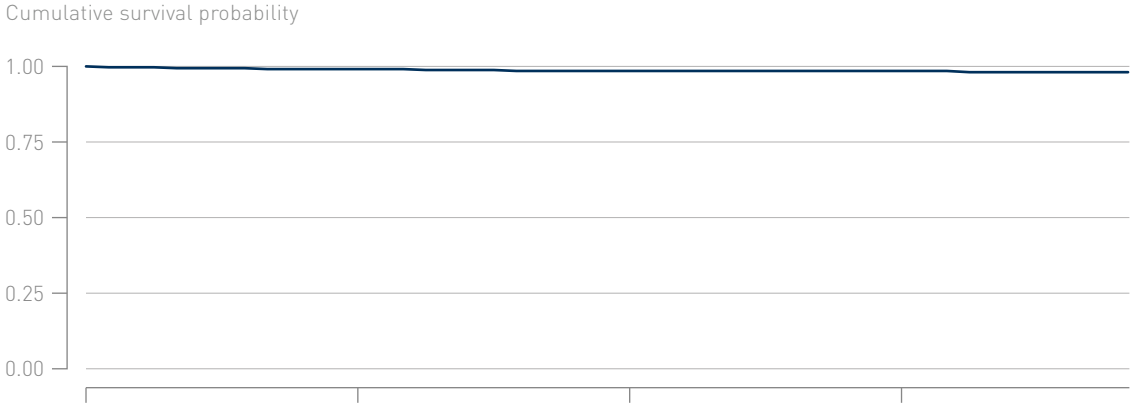
Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passvie fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered U.S. Implants	349
Estimated Active U.S. Implants	308
U.S. Total Returned	4

	Quantity	Rate
U.S. Qualifying Complications	8	2.28%
Conductor Fracture	3	0.85%
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%

• Total survival



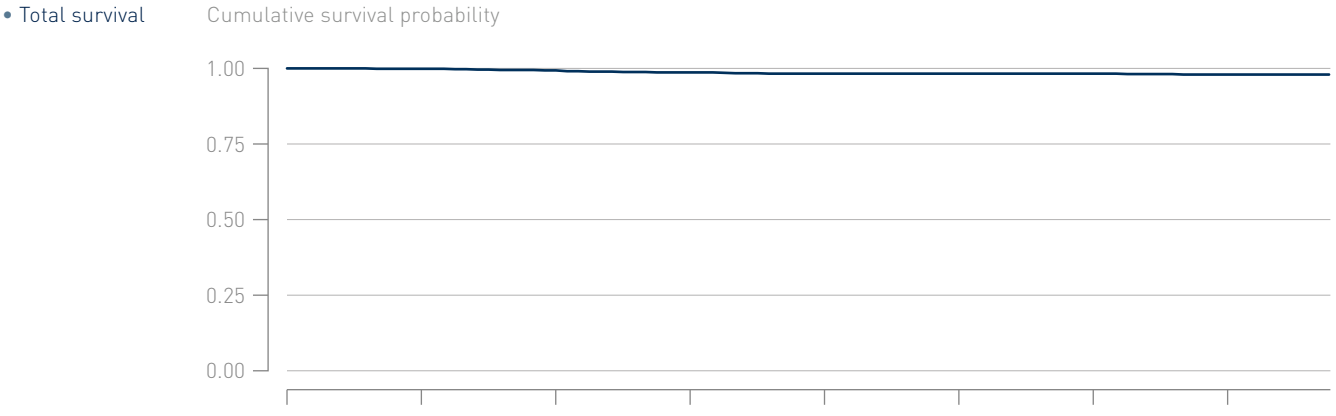
Years after implant	0	1	2	3
Total [%]	100.0	99.1	98.5	98.5
CI [±%]	-	1	1.3	1.3
Sample Size	349	331	302	258

Vigila 2CR

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

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

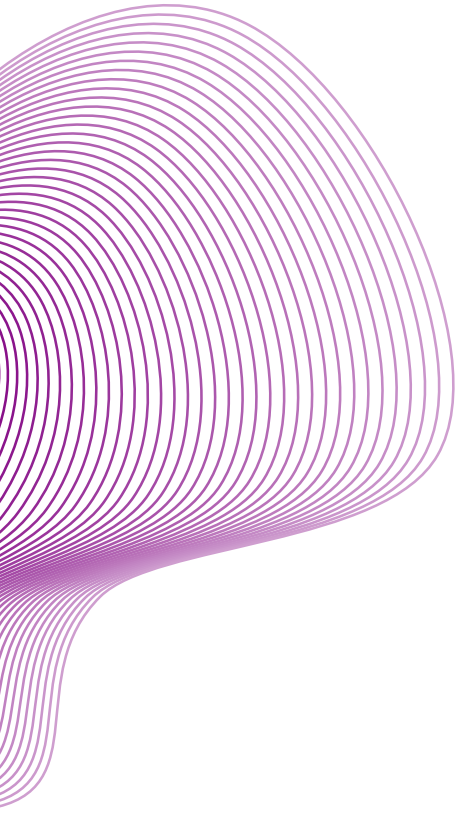
	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.50%
Insulation Breach	4	0.50%
U.S. Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.3	98.7	98.3	98.3	98.3	98.0
CI [±%]	-	0.3	0.6	0.8	0.9	0.9	0.9	1
Sample Size	795	764	747	733	726	726	710	503

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

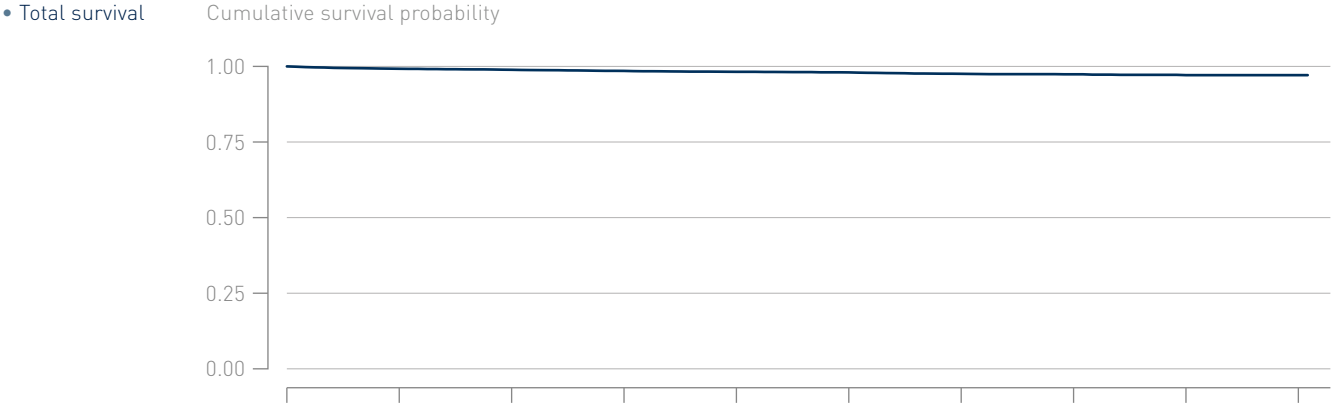


Corox OTW-L

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	6 252
Estimated Active U.S. Implants	4 990
U.S. Total Returned	77

	Quantity	Rate
U.S. Qualifying Complications	128	2.03%
Abnormal Pacing Impedance	3	0.05%
Conductor Fracture	5	0.08%
Extracardiac Stimulation	21	0.33%
Failure to Capture	54	0.86%
Failure to Sense	1	0.02%
Insulation Breach	2	0.03%
Lead Dislodgement	35	0.56%
Oversensing	1	0.02%
Other	6	0.10%

	Quantity	Rate
U.S. Confirmed Malfunctions	44	0.06%
Conductor Fracture	3	0.05%
Insulation Breach	1	0.02%
U.S. Acute Lead Observations	21	0.33%
Extracardiac Stimulation	6	0.10%
Failure to Capture	2	0.03%
Lead Dislodgement	10	0.16%
Other	3	0.05%



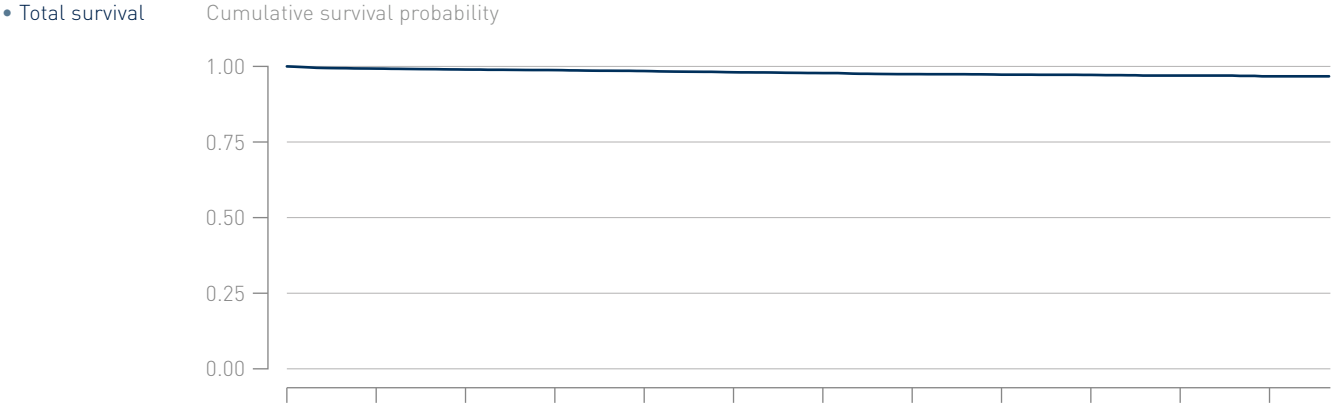
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.2	98.9	98.5	98.2	98.0	97.5	97.4	97.1	97.1
CI [±%]	-	0.2	0.3	0.3	0.3	0.4	0.4	0.5	0.5	0.5
Sample Size	6 252	5 696	5 440	5 201	4 473	3 737	2 847	1 885	948	265

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	8 157
Estimated Active U.S. Implants	5 740
U.S. Total Returned	129

	Quantity	Rate
U.S. Qualifying Complications	161	1.96%
Abnormal Pacing Impedance	8	0.10%
Conductor Fracture	5	0.06%
Extracardiac Stimulation	15	0.18%
Failure to Capture	49	0.60%
Failure to Sense	1	0.01%
Insulation Breach	4	0.05%
Lead Dislodgement	57	0.69%
Oversensing	4	0.05%
Other	18	0.22%

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



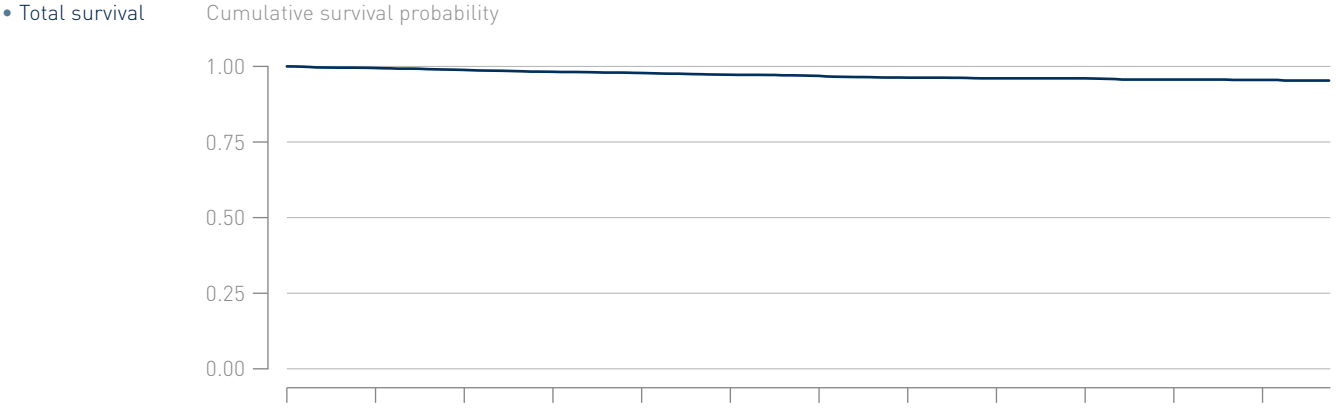
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.3	99.0	98.8	98.5	98.1	97.8	97.4	97.3	97.2	97.0	96.7
CI [±%]	-	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.6
Sample Size	8 157	7 169	6 761	6 392	5 790	5 170	4 458	3 772	3 142	2 507	1 545	656

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	4 115
Estimated Active U.S. Implants	2 680
U.S. Total Returned	78

	Quantity	Rate
U.S. Qualifying Complications	114	2.76%
Abnormal Pacing Impedance	7	0.17%
Conductor Fracture	3	0.07%
Extracardiac Stimulation	8	0.19%
Failure to Capture	42	1.02%
Insulation Breach	3	0.07%
Lead Dislodgement	38	0.92%
Oversensing	2	0.05%
Other	11	0.27%

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



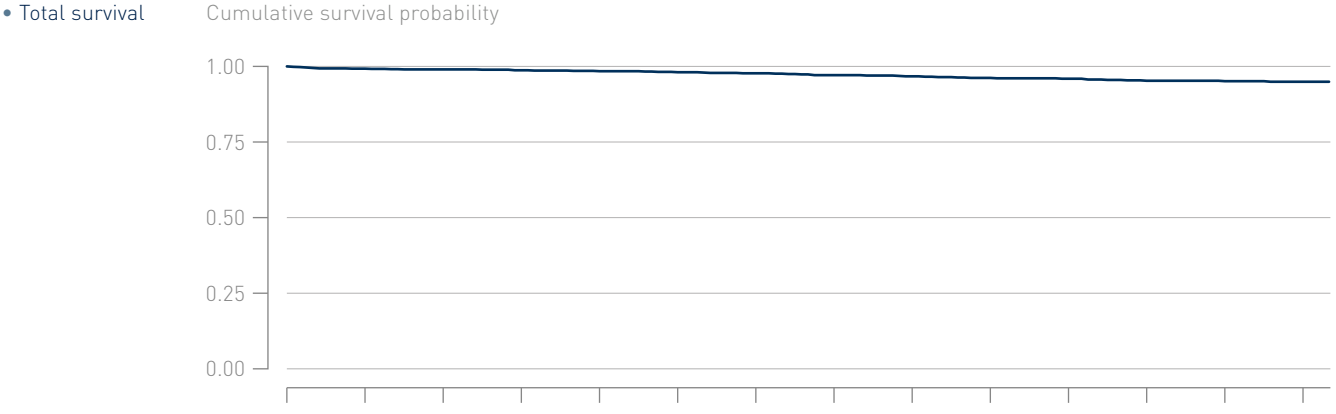
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.5	98.8	98.2	97.8	97.2	96.9	96.3	96.1	96.1	95.6	95.5
CI [±%]	-	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.8	0.8
Sample Size	4 115	3 555	3 310	3 113	2 928	2 748	2 540	2 284	2 033	1 765	1 279	592

Corox OTW

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	697
U.S. Total Returned	26

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

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



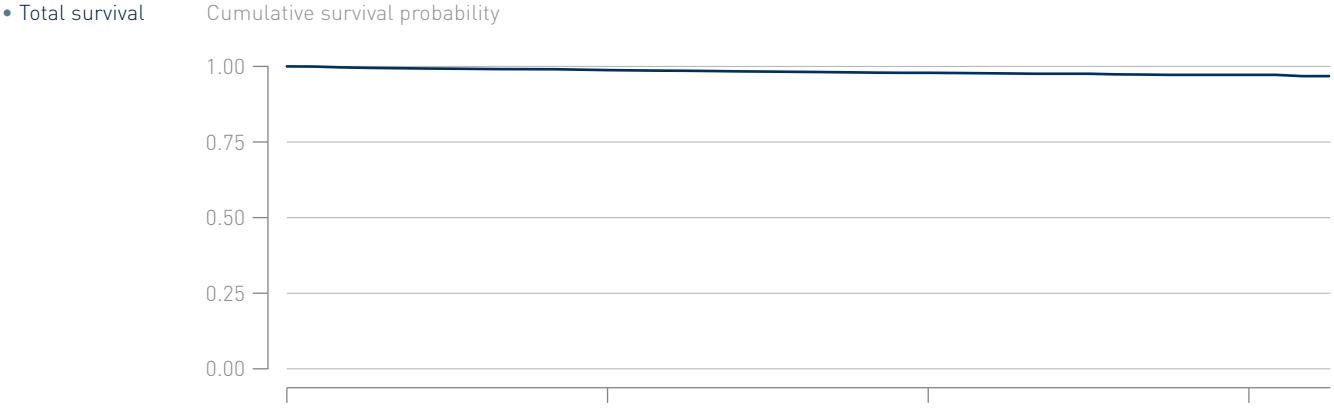
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.2	95.9	95.3	95.1	94.9
CI [±%]	-	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.4	1.5
Sample Size	1 423	1 237	1 121	1 016	932	865	810	772	746	729	712	703	674	337

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	77 600
Registered U.S. Implants	10 642
Estimated Active U.S. Implants	9 530
U.S. Total Returned	97

	Quantity	Rate
U.S. Qualifying Complications	141	1.30%
Abnormal Pacing Impedance	16	0.15%
Conductor Fracture	2	0.02%
Extracardiac Stimulation	9	0.08%
Failure to Capture	32	0.30%
Failure to Sense	2	0.02%
Lead Dislodgement	63	0.58%
Oversensing	11	0.10%
Other	6	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	23	0.21%
Conductor Fracture	22	0.20%
Other	1	0.01%
U.S. Acute Lead Observations	34	0.31%
Abnormal Pacing Impedance	1	0.01%
Conductor Fracture	1	0.01%
Extracardiac Stimulation	6	0.06%
Failure to Capture	4	0.04%
Lead Dislodgement	20	0.18%
Oversensing	1	0.01%
Other	1	0.01%



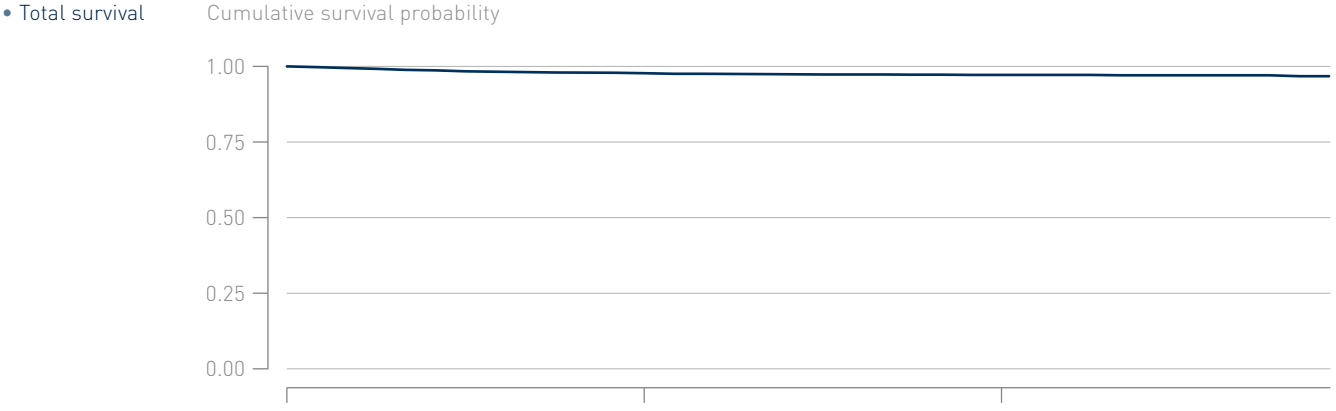
Years after implant	0	1	2	3
Total [%]	100.0	98.8	97.9	97.2
CI [±%]	-	0.2	0.4	0.5
Sample Size	10 642	6712	3240	434

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	18 200
Registered U.S. Implants	3 210
Estimated Active U.S. Implants	2 610
U.S. Total Returned	77

	Quantity	Rate
U.S. Qualifying Complications	66	2.00%
Abnormal Pacing Impedance	4	0.12%
Conductor Fracture	1	0.03%
Extracardiac Stimulation	4	0.12%
Failure to Capture	13	0.39%
Lead Dislodgement	38	1.15%
Oversensing	6	0.18%

	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.12%
Conductor Fracture	4	0.12%
U.S. Acute Lead Observations	57	1.73%
Abnormal Pacing Impedance	1	0.03%
Extracardiac Stimulation	4	0.12%
Failure to Capture	7	0.21%
Failure to Sense	1	0.03%
Lead Dislodgement	43	1.31%
Oversensing	1	0.03%



Years after implant	0	1	2
Total [%]	100.0	97.8	97.2
CI [±%]	-	0.6	0.7
Sample Size	3 210	2 040	1 140

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 Section 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 6 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 6.3 of this report.

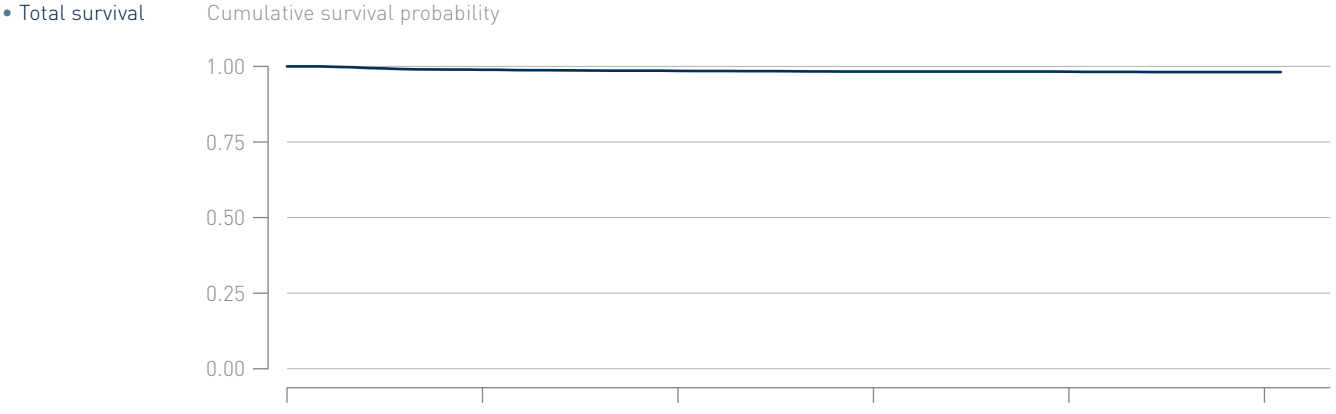
Performance of BIOTRONIK Leads Based on Clinical Study Data

Siello S / Solia S

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

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

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



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

Performance of BIOTRONIK Leads Based on Clinical Study Data

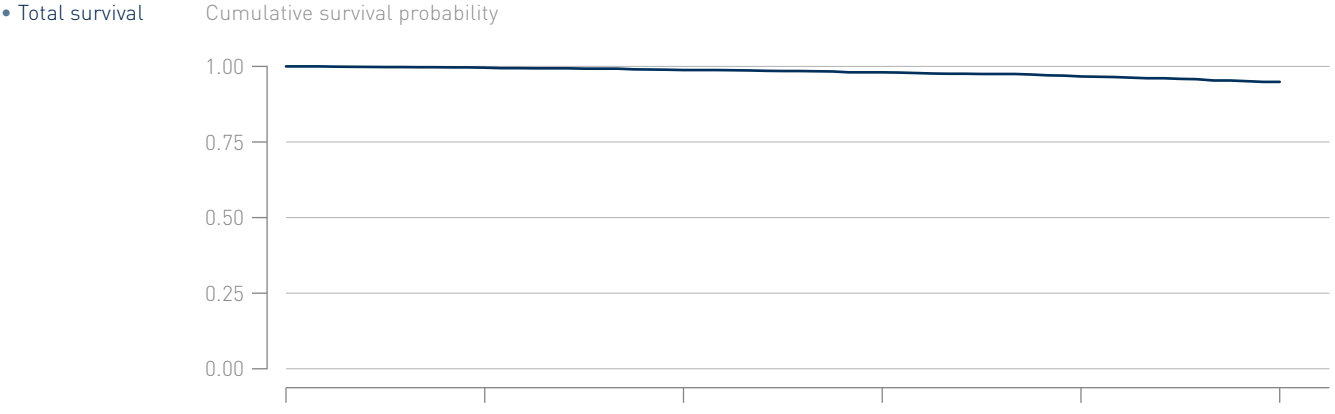
8.1 Performance of Pacing Leads
8.2 Performance of ICD Leads
8.3 Performance of CRT Leads

Linox SD

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

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

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



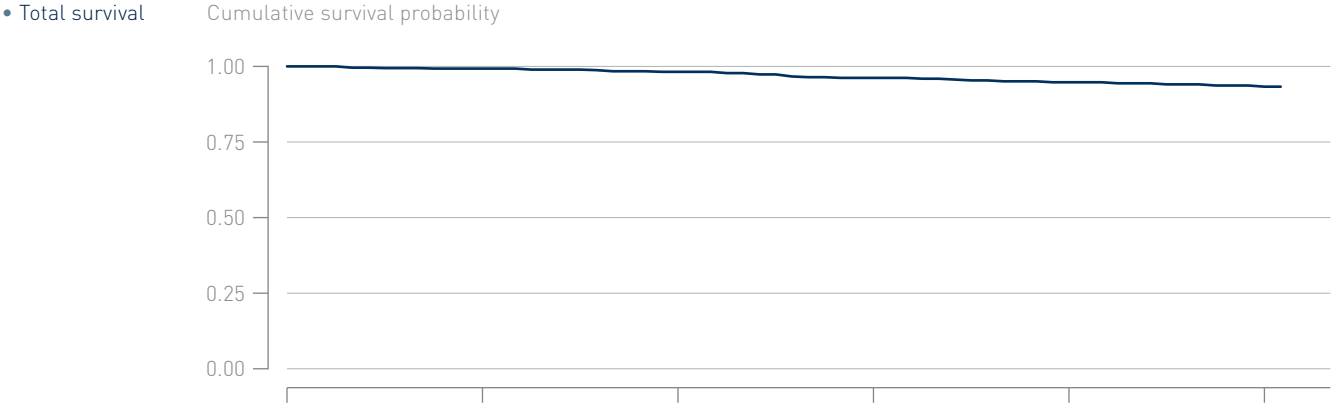
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	98.8	98.0	96.7	94.9
CI [±%]	–	0.3	0.5	0.7	0.9	1.3
Sample Size	2 272	1 937	1 618	1 302	1 014	392

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	7	0.95%
Insulation Breach	7	0.95%
U.S. Acute Lead Observations	2	0.27%
Lead Dislodgement	2	0.27%



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

Performance of BIOTRONIK Leads Based on Clinical Study Data

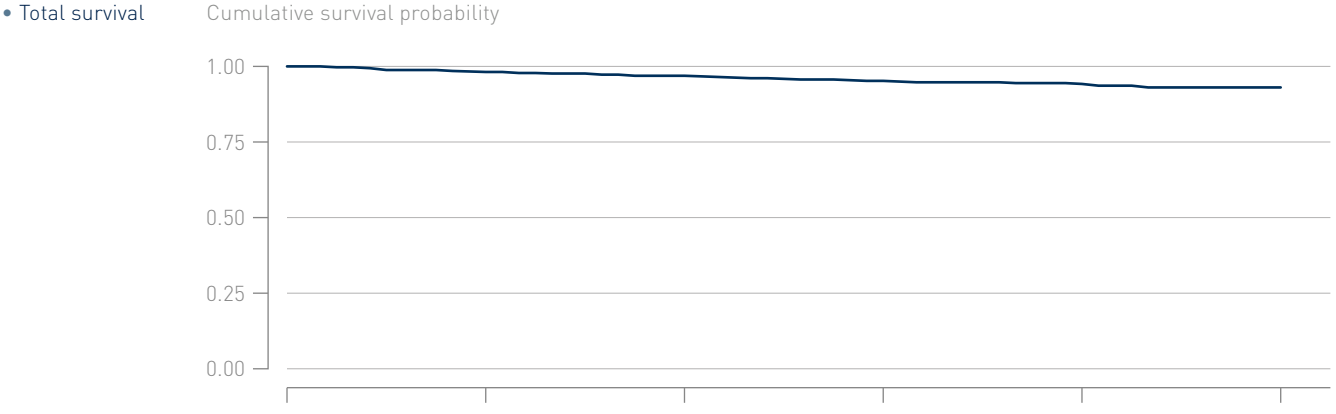
8.1 Pacing Leads Performance
8.2 ICD Leads Performance
8.3 CRT Leads Performance

Corox OTW

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

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

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



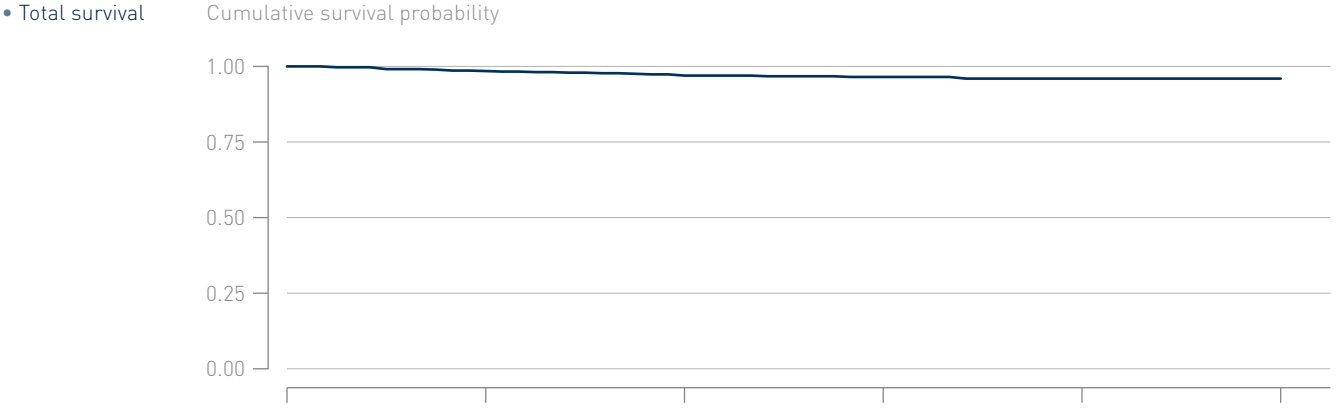
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	96.9	95.2	94.2	93.0
CI [±%]	-	1.1	1.4	1.8	2.1	2.3
Sample Size	696	589	489	407	329	135

Corox OTW-L

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

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

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



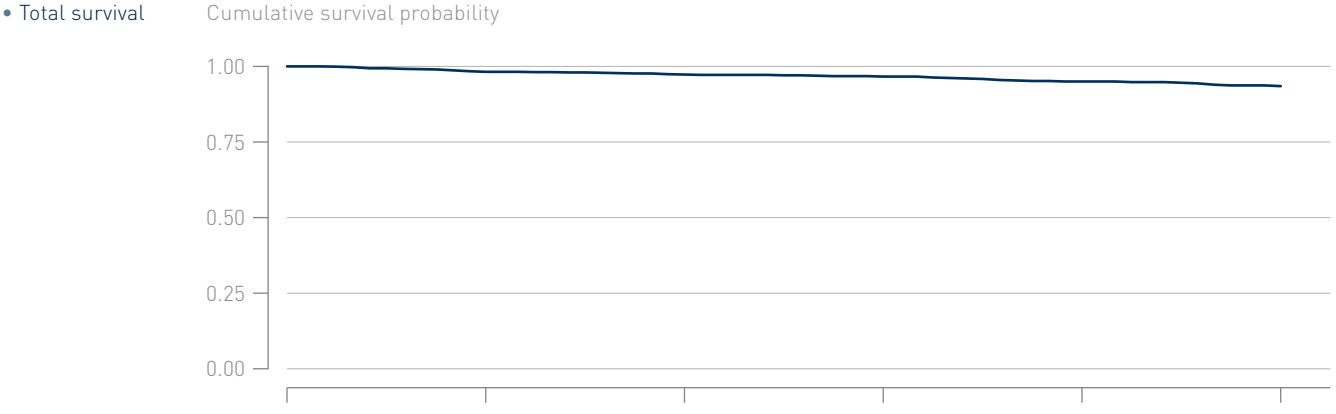
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.0	96.5	96.0	96.0
CI [±%]	-	1.0	1.4	1.6	1.7	1.7
Sample Size	699	584	475	382	303	130

Corox OTW-S

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

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

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



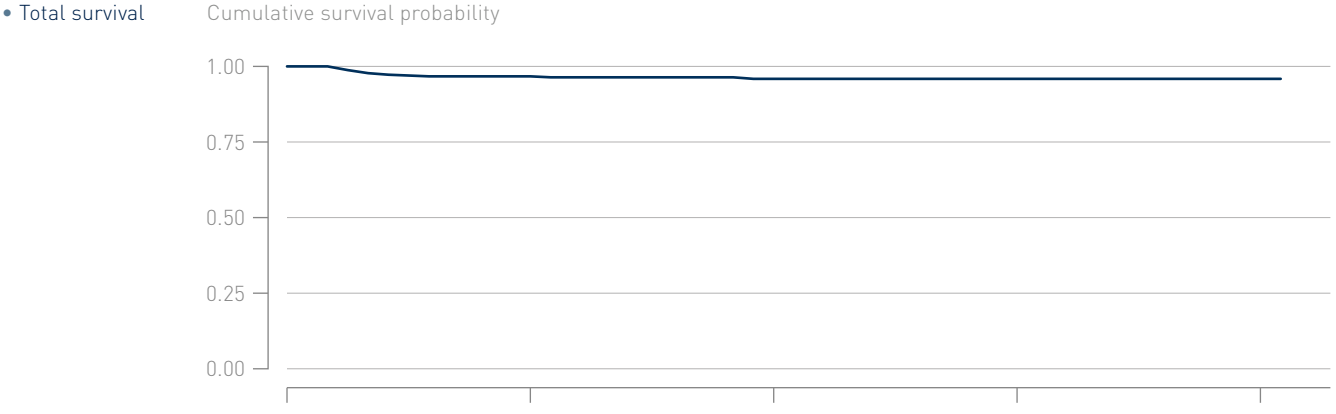
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	97.3	96.6	95.0	93.5
CI [±%]	-	0.8	1.0	1.2	1.5	1.9
Sample Size	1141	963	813	648	505	192

Sentus OTW QP S

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

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

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



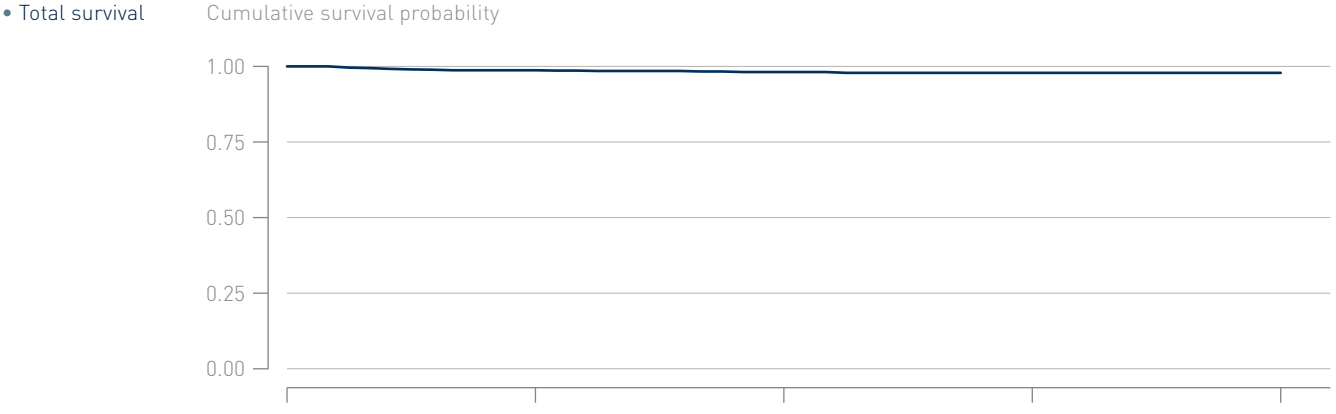
Years after implant	0	1	2	3	4
Total [%]	100	96.7	95.9	95.9	95.9
CI [±%]	-	1.8	2.2	2.2	2.2
Sample Size	436	299	170	55	0

Sentus OTW QP L

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

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

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



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

9

Methodology for Lead Survival Estimates based on Insurance Claims Data

9. 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 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, 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

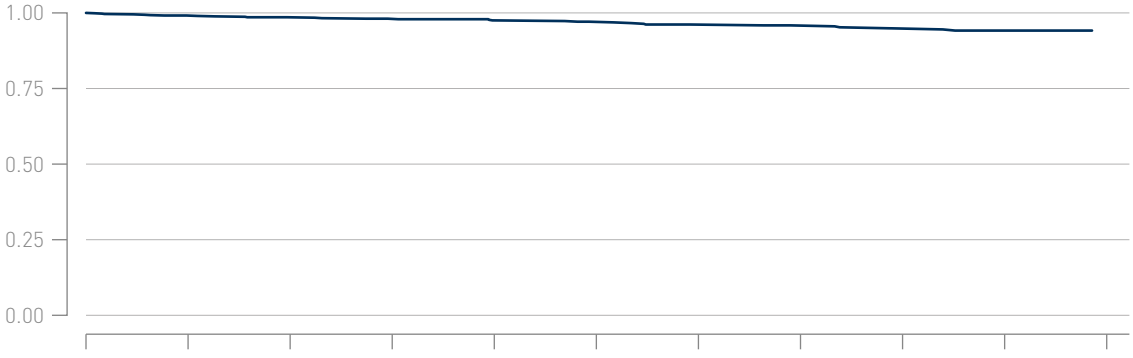
ICD Leads Performance – Insurance Claims Data

Linox S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	870

• Total survival

Cumulative survival probability

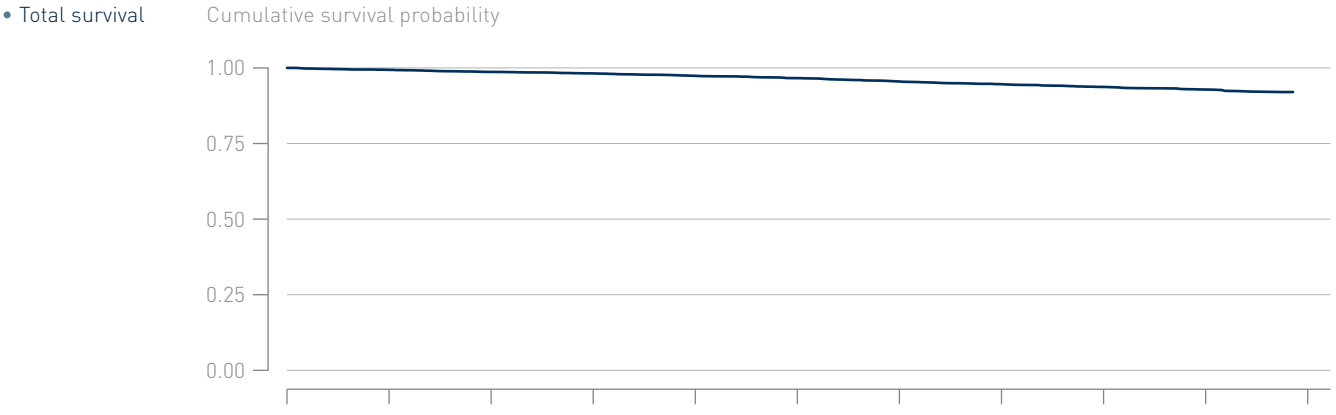


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.1	98.6	98.1	97.5	97.1	96.2	95.9	94.9	94.2	94.2
CI [±%]	0.0	0.7	0.9	1.1	1.4	1.5	1.9	2.1	2.5	3.0	4.1
Sample Size	870	🔒	647	571	496	439	380	335	280	221	116

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

Linox SD

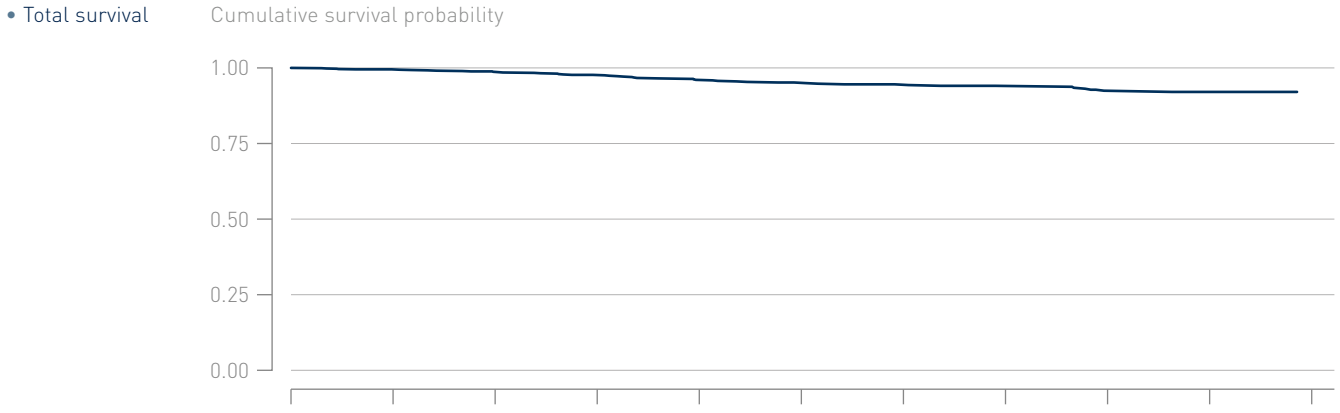
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	7 248



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.4	98.7	98.2	97.4	96.6	95.5	94.7	93.7	92.9	92.0
CI [±%]	0.0	0.2	0.3	0.4	0.5	0.6	0.8	0.9	1.1	1.3	1.6
Sample Size	7 248	6 010	5 188	4 471	3 754	3 139	2 606	2 158	1 808	1 448	973

Linox TD

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

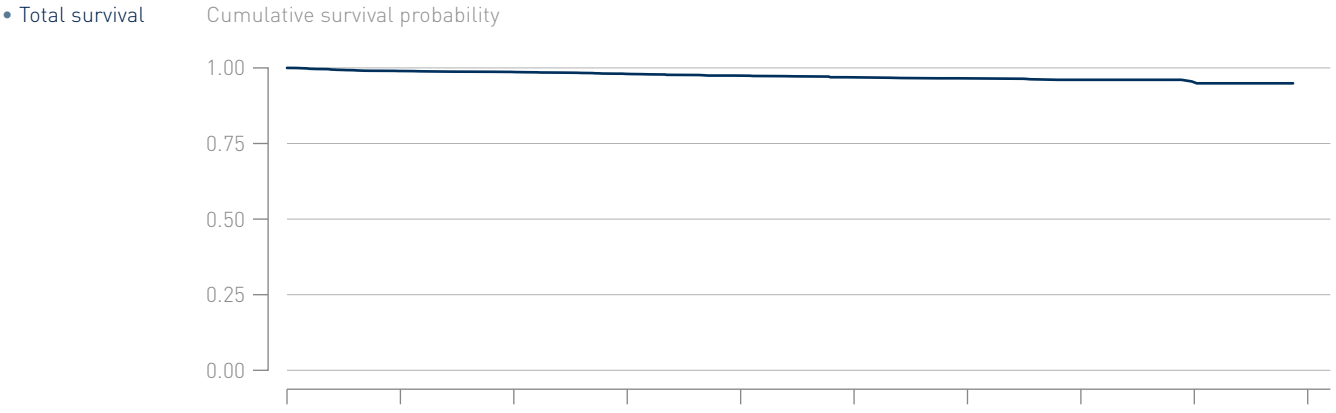


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.5	98.7	97.7	96.0	95.2	94.6	94.1	92.5	92.1	92.1
CI [±%]	0.0	0.4	0.8	1.1	1.5	1.9	2.1	2.4	3.0	3.4	4.1
Sample Size	1148	🔒	820	697	591	488	406	341	275	221	152

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

Linox Smart S

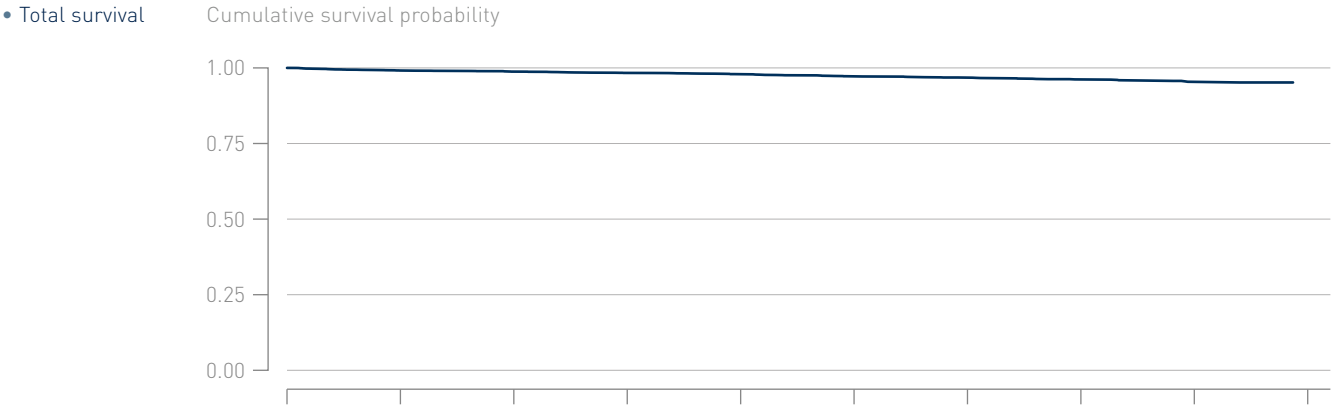
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	2 974



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.0	98.7	98.0	97.5	96.9	96.6	96.1	95.5	94.9
CI [±%]	0.0	0.4	0.5	0.6	0.8	0.9	1.2	1.6	3.0	9.1
Sample Size	2 974	2 489	2 156	1 864	1 584	1 278	871	498	171	8

Linox Smart SD

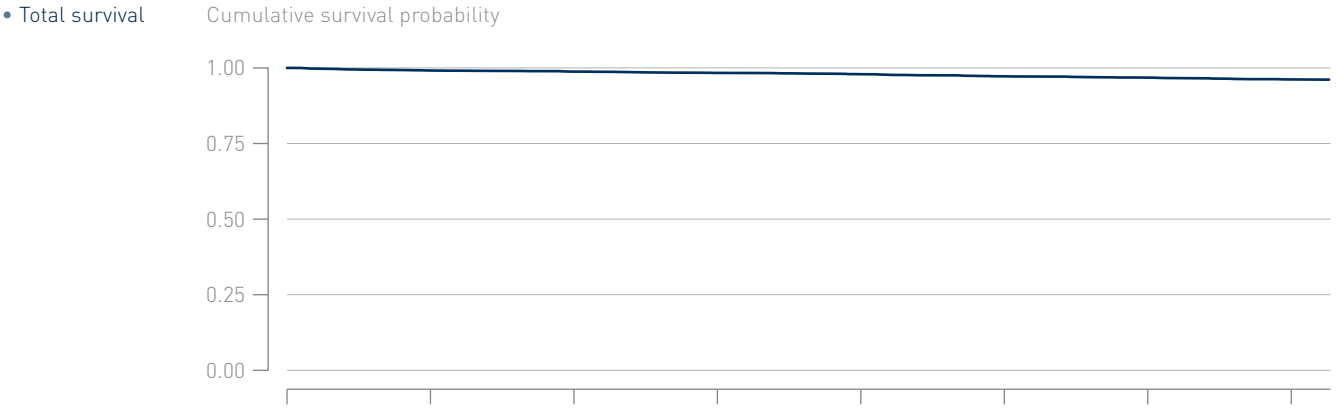
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	5 251



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.1	98.8	98.4	98.0	97.2	96.8	96.2	95.4	95.2
CI [±%]	0.0	0.3	0.4	0.4	0.5	0.7	0.8	1.0	1.5	2.0
Sample Size	5 251	4 299	3 714	3 234	2 770	2 313	1 842	1 260	676	161

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	522

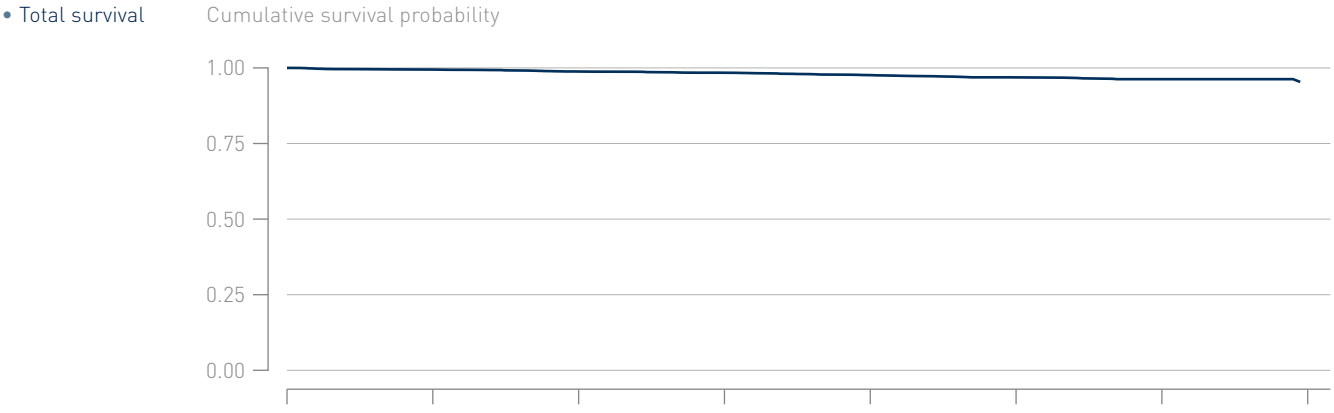


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.0	98.4	98.1	98.1	98.1	96.5	96.5
CI [±%]	0.0	1.0	1.3	1.5	1.7	1.8	2.8	3.4
Sample Size	522	🔒	🔒	🔒	🔒	🔒	157	107

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

Linox Smart S DX

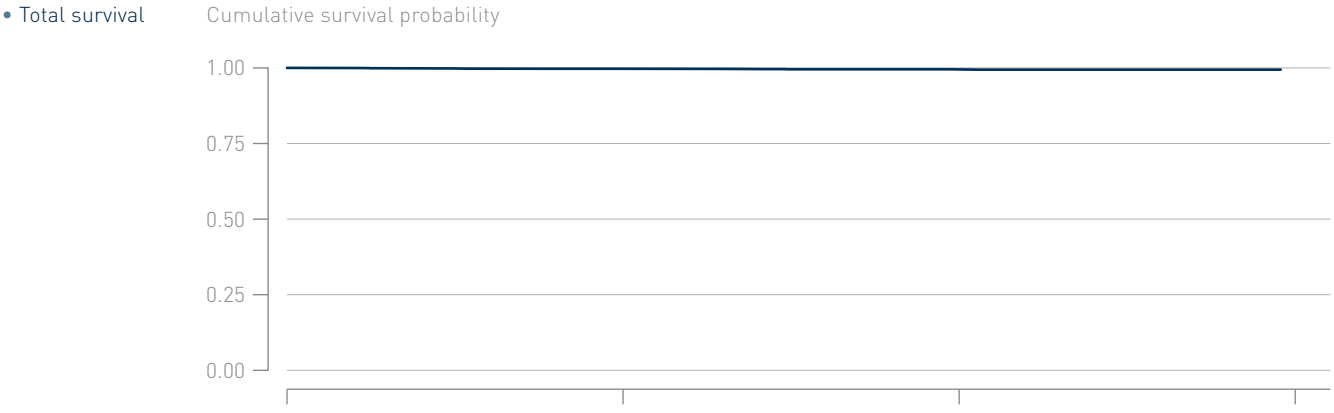
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	4628



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.5	98.8	98.4	97.7	96.9	96.3	95.4
CI [±%]	0.0	0.2	0.4	0.5	0.7	1.0	1.5	3.9
Sample Size	4628	3860	3397	2849	1880	1141	557	104

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	71 100
Registered U.S. Implants	3 280

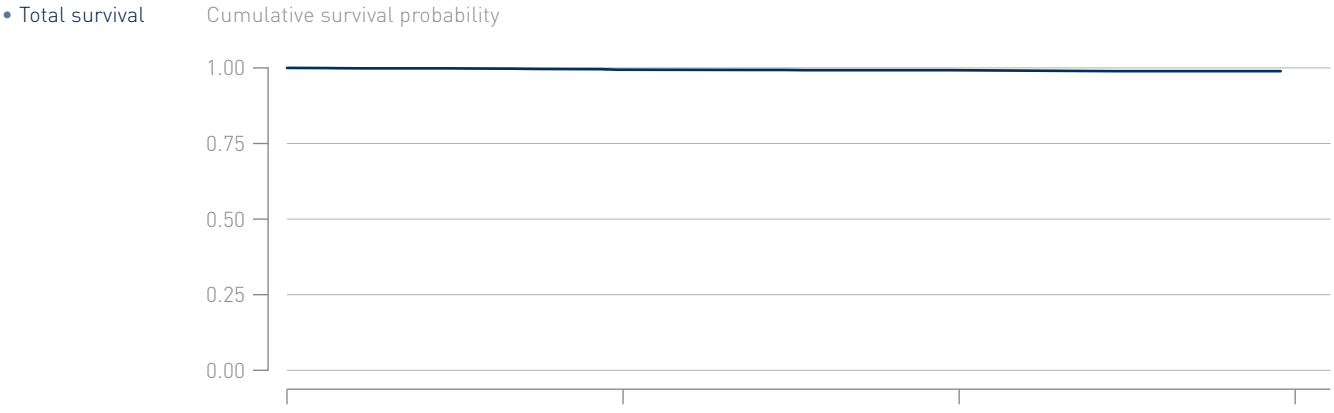


Years after implant	0	1	2	3
Total [%]	100.0	99.7	99.5	99.4
CI [±%]	0.0	0.2	0.4	1.2
Sample Size	3 280	🔒	1 017	70

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

Plexa S DX DF1

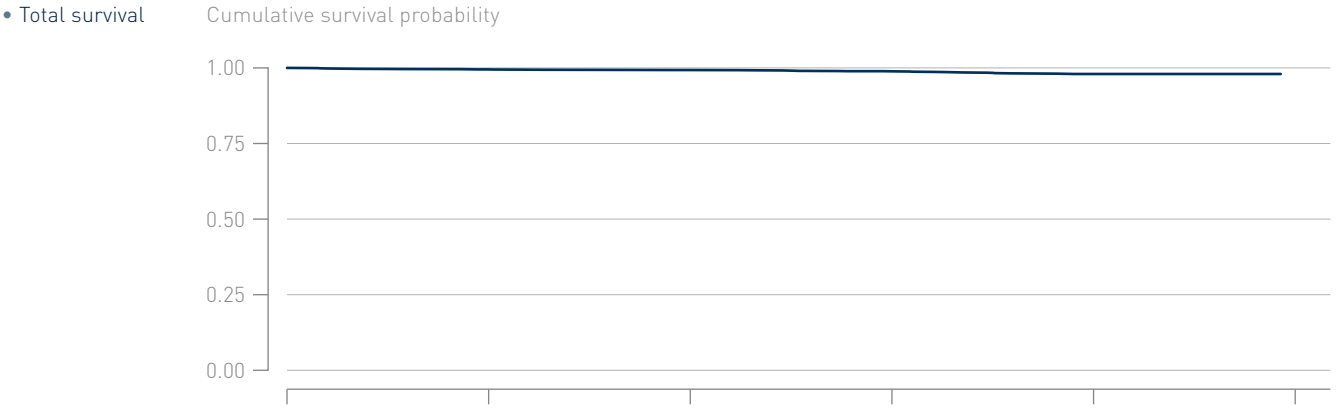
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	18 900
Registered U.S. Implants	2 145



Years after implant	0	1	2	3
Total [%]	100.0	99.4	99.2	98.9
CI [±%]	0.0	0.4	0.6	0.9
Sample Size	2 145	1 687	743	68

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	54 800
Registered U.S. Implants	3 050



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.5	99.3	98.9	98.0	98.0
CI [±%]	0.0	0.3	0.3	0.5	0.9	1.8
Sample Size	3 050	2 600	2 262	1 852	892	214

11

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
As of June 2021

- No reports of deaths or serious injuries were received associated with this advisory.
- FDA has classified this advisory as a class II recall
- The updated software version 2100 or later is now available. It has been released on April 30th, 2021 in the United States. The corresponding CE-Version has been released on March 31th, 2021.

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 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
Cylos DR, DR-T, VR	RZ
Cylos 990 DR, DR-T, VR	FV
Edora 8 DR, DR-T, SR, SR-T, HF-T	
Entovis DR, DR-T, SR, SR-T	SF
Eluna 8 DR, DR-T	SF
Estella SR, SR-T, DR, DR-T	SF
Etrinsa 8 SR-T, DR-T, HF-T	SF
Evia DR, DR–T, SR, SR-T, HF, HF-T	SF
Iforia 7 VR-T DX, DR-T	NT
Ilesto 7 DR-T, HF-T, VR-T DX, VR-T, DR-T DF4	NT
Ilivia 7 VR-T, DR-T, DR-T DF4, VR-T DX, VR-T DF4, HF-T DF4	NK
Intica 7 VR-T DX, HF-T	NK
Inventra 7 VR-T DX, HF-T DF4	AH
Iperia 7 VR-T, DR-T, VR-T DX, VR-T DF4, HF-T DF4	NH
Itrevia 7 VR-T, DR-T, VR-T DX, DR-T DF4, HF-T, HF-T DF4	NH
Lumax 340 DR-T, HF-T, VR-T	HR
Lumax 540 DR-T, HF-T, VR-T	SH
Lumax 740 DR-T, HF-T, VR-T, VR-T DX	RH
Philos II DR, D, S, SLR, SR	ET
Philos II DR-T	KP
Stratos LV, LV-T	SV
Talos DR, D, SLR, SR, S	PV

Contacting BIOTRONIK

Regarding this Report

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

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Fax +49 (0) 30 68905 96 1920
E-mail PPR@biotronik.com

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12359 Berlin, Germany

Regarding Products

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

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