Product Performance Report

2nd Edition 2022

Cardiac Rhythm Management
Cumulative Survival Probability

BIOTRONIK
excellence for life

Product Performance Report 2nd Edition 2022

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, November 2022

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

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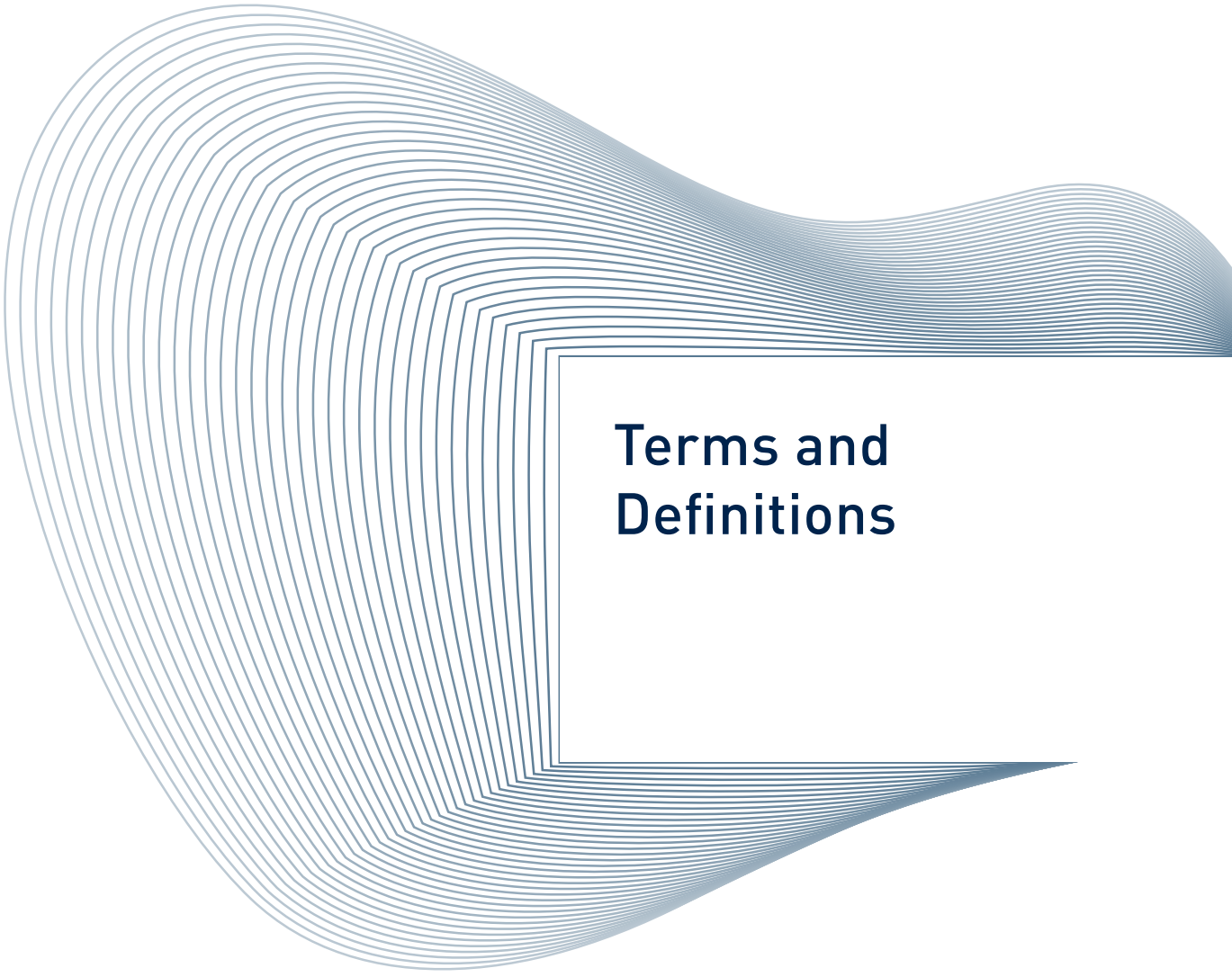

Terms and Definitions

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, 2021. The number of U.S. devices that are implanted and remain active as well as the total number of products distributed worldwide are provided for each product family in this report. Information is provided for separate product families, in that devices with nearly identical hardware and therapy functions are combined. For example, Edora 8 DR and DR-T (with Home Monitoring) IPGs are combined into a single family, Edora 8 Single Chamber IPGs.

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

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

2.3 Returned Product Analysis

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

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

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

2.4 Product Performance Graphs and Data

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

For each product, the report provides:

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

The survival plots provide:

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

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

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

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

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

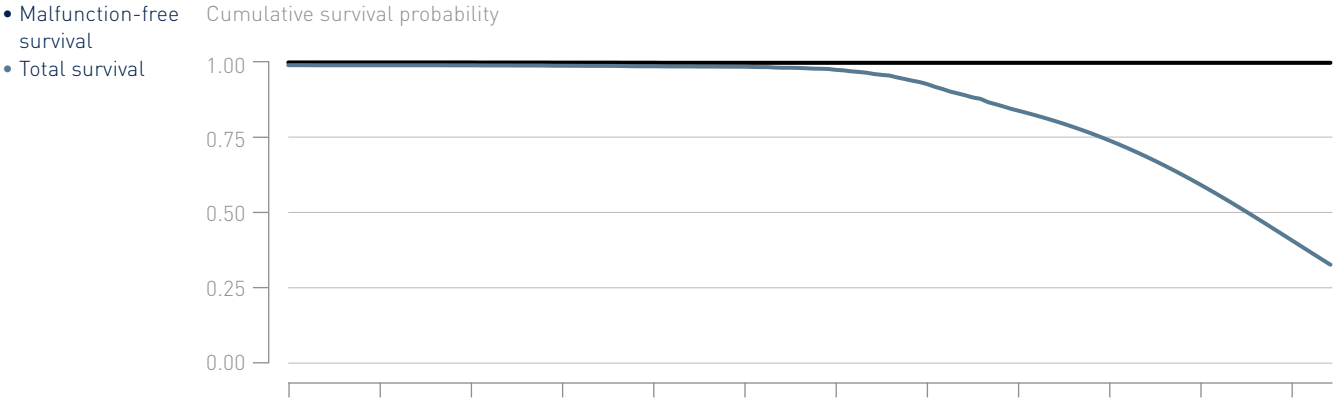
Performance of BIOTRONIK Pacemakers

Performance of BIOTRONIK Pacemakers

Cylos and Cylos 990*

Product Versions	VR
NBG Codes	VVIR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	25 900
Registered U.S. Implants	6 149
Estimated Active U.S. Implants	2 340
U.S. Normal Battery Depletions	854

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



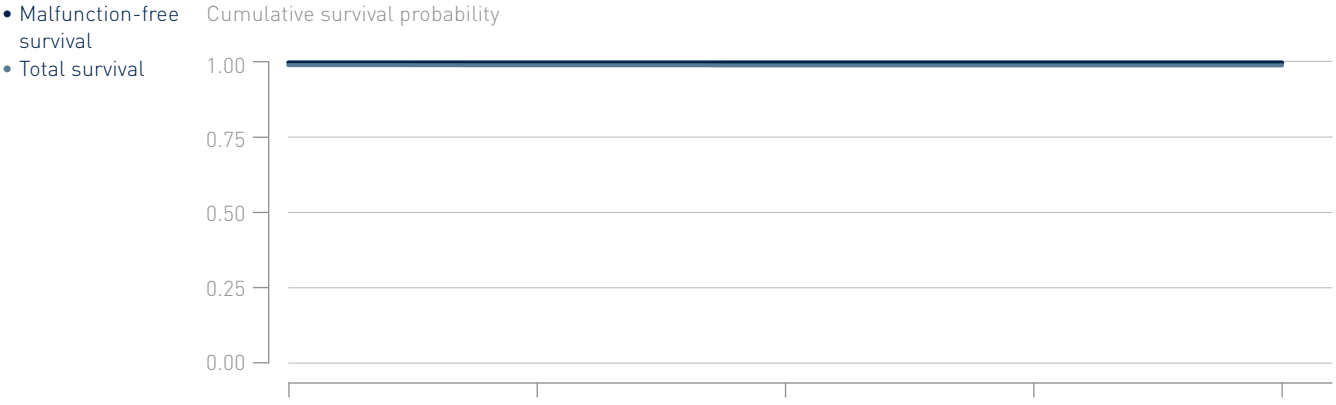
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.9	99.9	99.8	99.6	99.5	98.4	93.7	84.8	74.8	60.0	41.4
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.4	0.8	1.2	1.4	1.7	2.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	6 149	5 406	4 909	4 540	4 222	4 005	3 818	3 499	3 037	2 631	2 034	963

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

Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	37 000
Registered U.S. Implants	6 847
Estimated Active U.S. Implants	5 920
U.S. Normal Battery Depletions	3

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

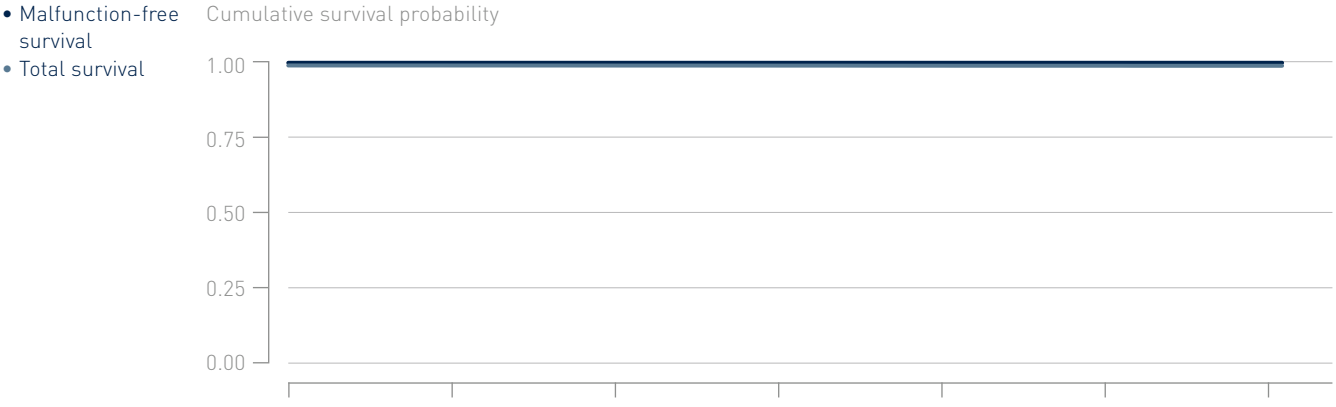


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	6 847	5 061	3 424	1 719	282

Eluna 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	19 600
Registered U.S. Implants	5 801
Estimated Active U.S. Implants	4 290
U.S. Normal Battery Depletions	14

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

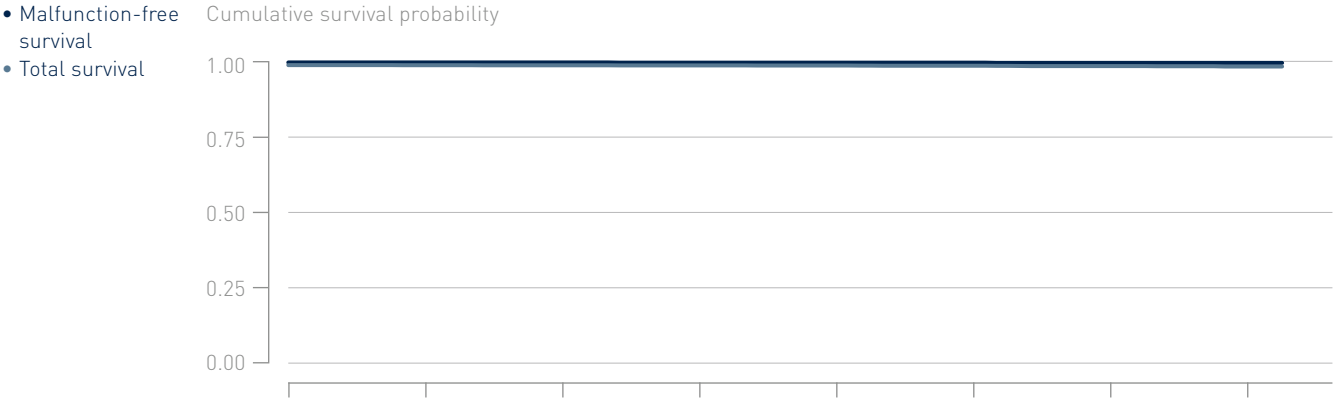


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.8	99.7	99.7	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	5 801	5 361	4 988	4 519	3 865	2 234	380

Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28000
Registered U.S. Implants	2399
Estimated Active U.S. Implants	1560
U.S. Normal Battery Depletions	9

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

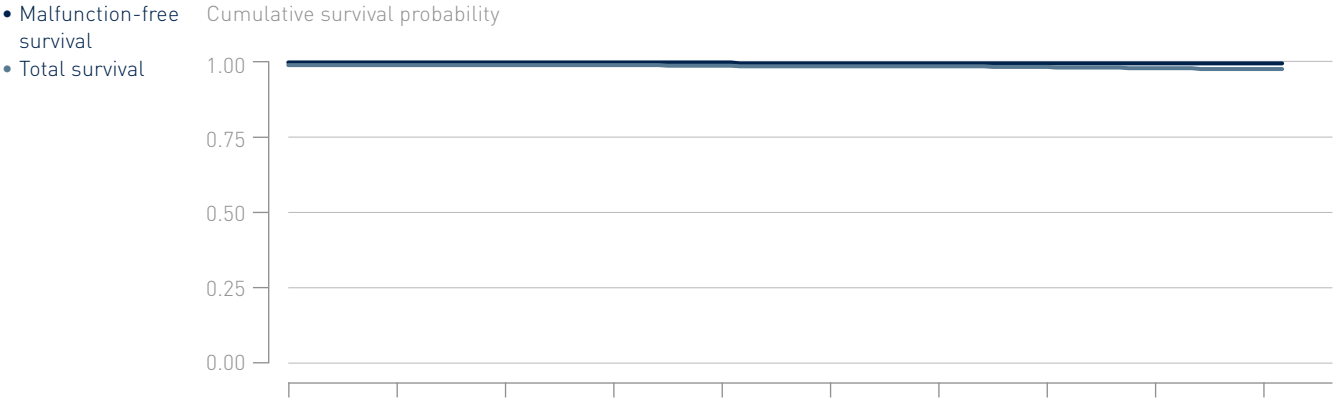


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.9	99.8	99.7	99.5	99.3
CI [±%]	-	0.1	0.1	0.2	0.2	0.2	0.3	0.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	2399	2188	2066	1938	1824	1721	1447	545

Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	41 000
Registered U.S. Implants	613
Estimated Active U.S. Implants	379
U.S. Normal Battery Depletions	6

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

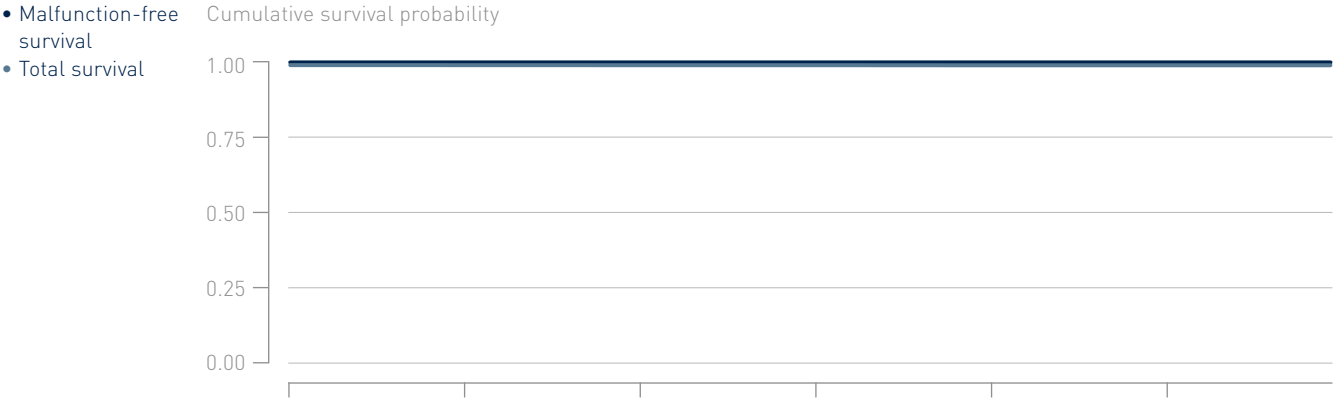


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.5	99.3	98.8	98.5
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.6	0.6	0.8	1.1	1.2
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.8	99.8	99.8	99.8	99.8
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.5	0.5	0.5	0.5	0.5
Sample Size	613	535	494	453	432	420	416	406	354	223

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18500
Registered U.S. Implants	1711
Estimated Active U.S. Implants	1270
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%

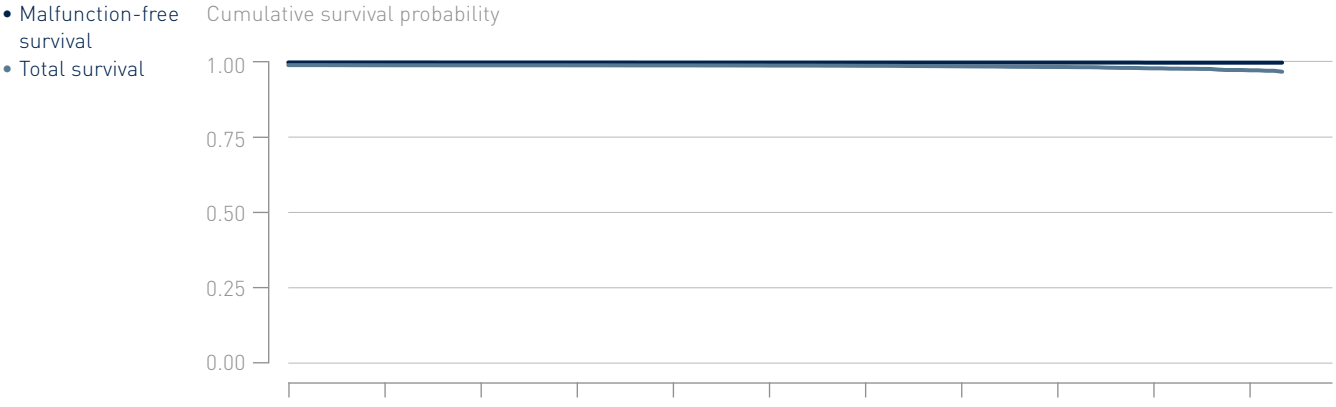


Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.9	99.9	99.7	99.7
CI [±%]	-	0.1	0.2	0.2	0.3	0.3
Malfunction-Free [%]	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1711	1572	1479	1342	1127	742

Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	63 700
Registered U.S. Implants	11 974
Estimated Active U.S. Implants	7 100
U.S. Normal Battery Depletions	85

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

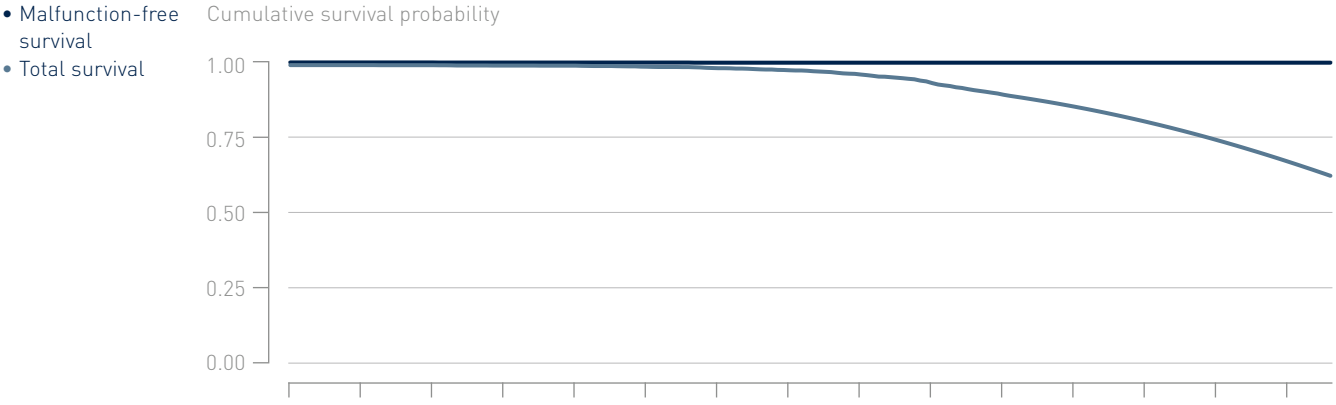


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.6	99.3	98.8	98.1
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.3	0.5
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1
Sample Size	11 974	10 737	10 099	9 620	9 286	8 759	8 225	7 219	5 210	2 945	854

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	5 240
Estimated Active U.S. Implants	2 280
U.S. Normal Battery Depletions	401

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	100.0	100.0	99.8	99.8	99.5	99.0	98.3	96.9	94.0	90.1	86.1	81.0	74.9	67.6
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.2	0.3	0.4	0.6	0.8	1.1	1.2	1.5	1.8	2.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5240	4433	4039	3707	3491	3312	3171	3084	2963	2811	2624	2405	1901	1208	542

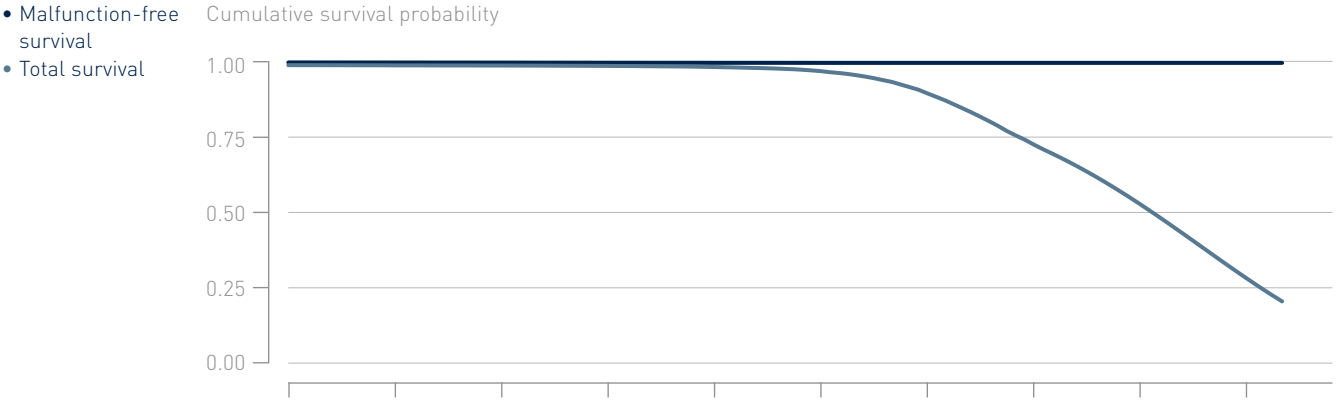
* While Talos SR and Talos S are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products.

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	7 080
U.S. Normal Battery Depletions	8 466

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



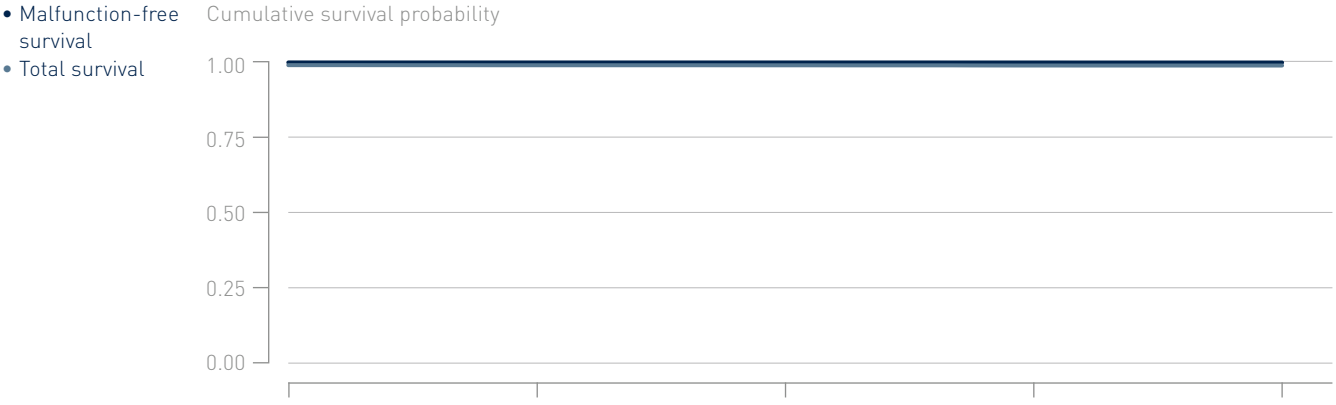
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.9	99.7	99.4	98.0	90.6	73.5	53.6	28.9
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.2	0.4	0.6	0.7	1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	30 373	28 179	26 454	24 995	23 564	21 805	18 753	13 731	9 058	3 075

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

Edora 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2017
CE Market Release	Jul 2016
Worldwide Distributed Devices	203 000
Registered U.S. Implants	66 945
Estimated Active U.S. Implants	58 500
U.S. Normal Battery Depletions	28

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.01%
Therapy Compromised	3	0.00%
Therapy Available	3	0.00%

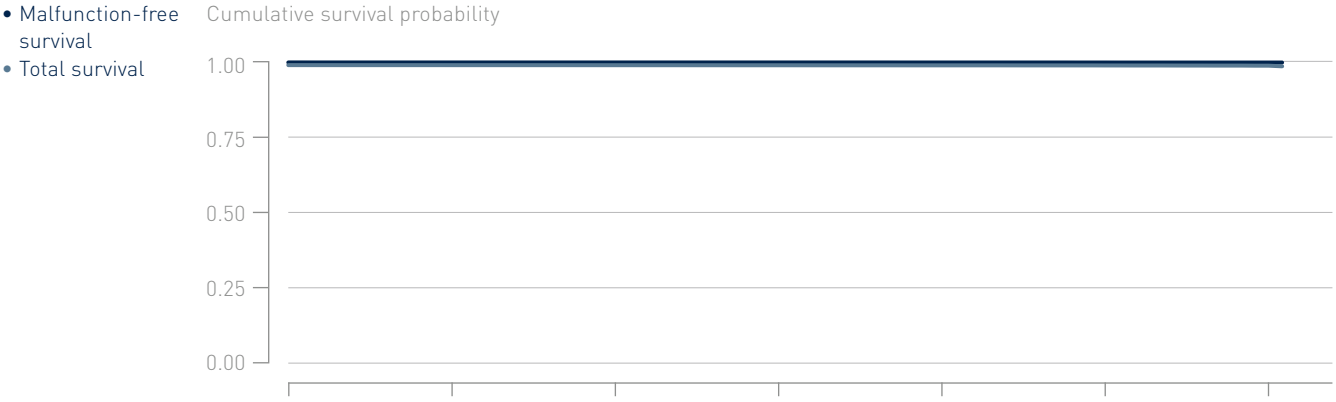


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	66 945	47 194	31 113	15 094	789

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	42 084
Estimated Active U.S. Implants	31 600
U.S. Normal Battery Depletions	56

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.01%
Therapy Compromised	0	0.00%
Therapy Available	5	0.01%

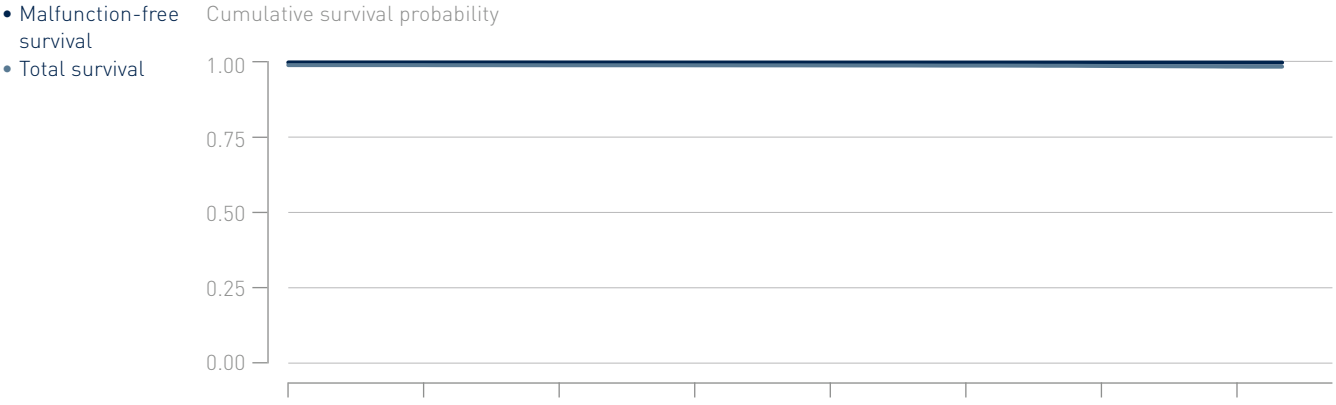


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.7
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	42 084	39 152	35 726	31 457	26 722	15 072	1 102

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	121 28
Estimated Active U.S. Implants	7 850
U.S. Normal Battery Depletions	53

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

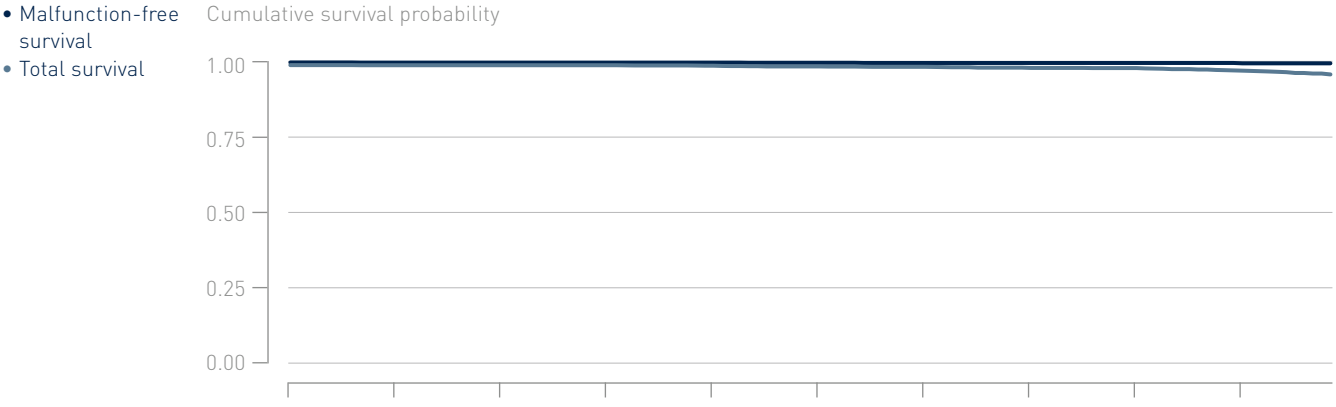


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.9	99.8	99.8	99.6	99.3
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	12 128	11 335	10 621	9 986	9 373	8 815	7 586	2 900

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	52 400
Registered U.S. Implants	2 949
Estimated Active U.S. Implants	1 740
U.S. Normal Battery Depletions	42

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

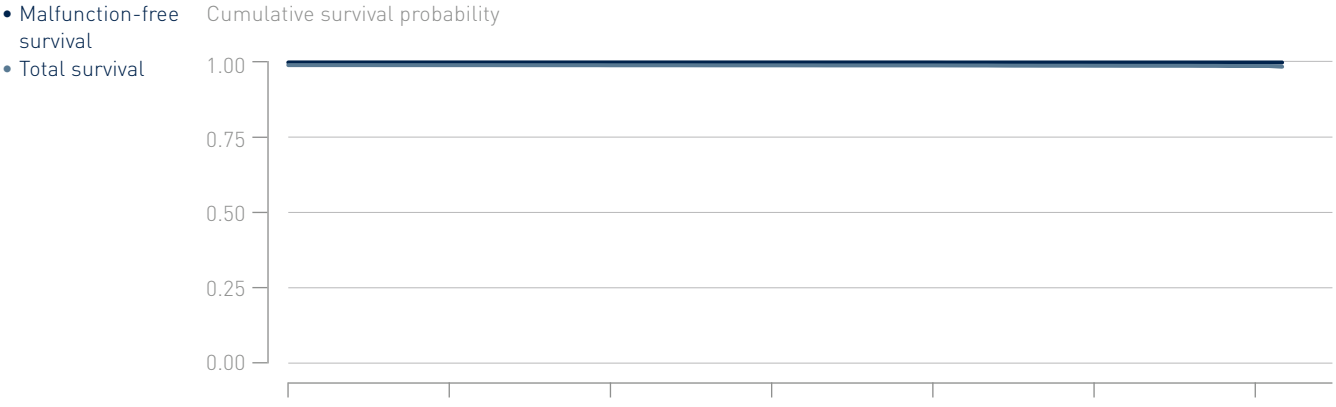


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5	99.4	99.0	98.9	98.0
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.7
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Sample Size	2 949	2 741	2 591	2 466	2 329	2 192	2 060	1 927	1 702	1 107

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	76300
Registered U.S. Implants	11707
Estimated Active U.S. Implants	8700
U.S. Normal Battery Depletions	28

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

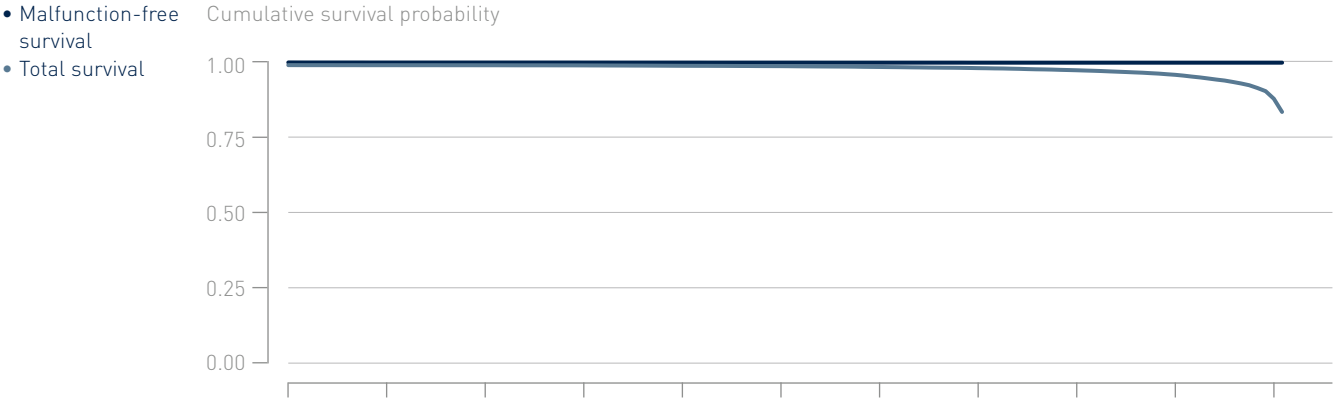


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.9	99.9	99.7	99.6
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.2
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	11707	10983	10331	9406	7829	4851	933

Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	222 000
Registered U.S. Implants	61 913
Estimated Active U.S. Implants	36 000
U.S. Normal Battery Depletions	1 309

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

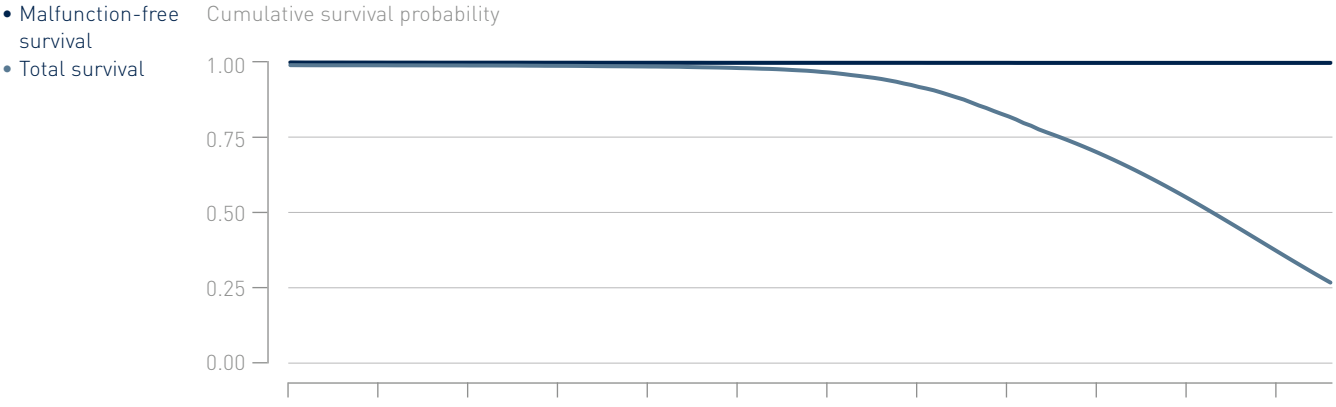


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	99.9	99.9	99.8	99.6	99.4	99.0	98.3	96.7	88.7
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.2	1.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	61 913	57 986	54 511	51 281	48 192	45 322	42 460	36 817	24 680	12 363	1 285

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	23 207
Estimated Active U.S. Implants	6 650
U.S. Normal Battery Depletions	4 750

	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	1.1
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	23207	21217	19909	18752	17718	16834	15844	14195	11596	9043	6520	3093

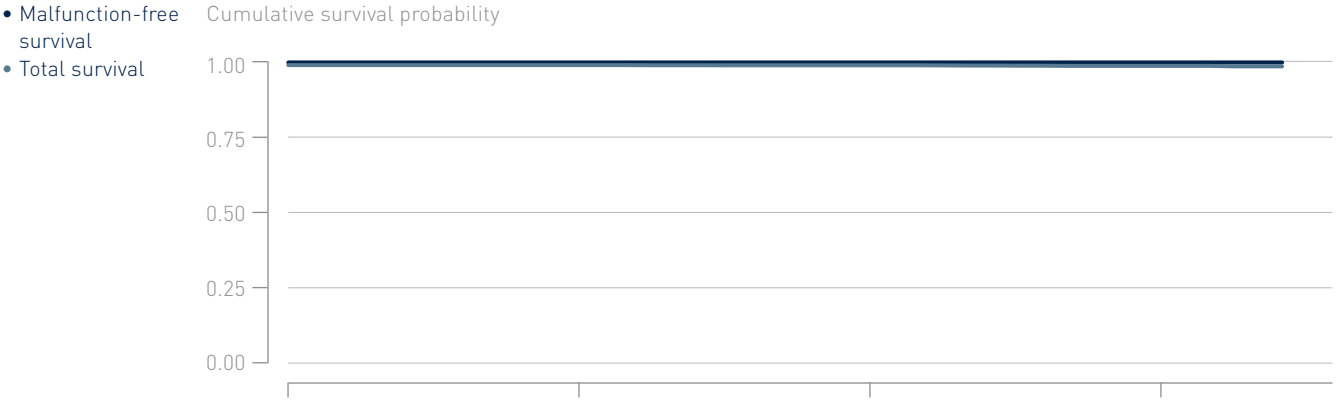
* While Philos II SLR, Talos D, Talos DR and Talos SLR are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products.

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	15 500
Registered U.S. Implants	5 528
Estimated Active U.S. Implants	4 440
U.S. Normal Battery Depletions	8

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

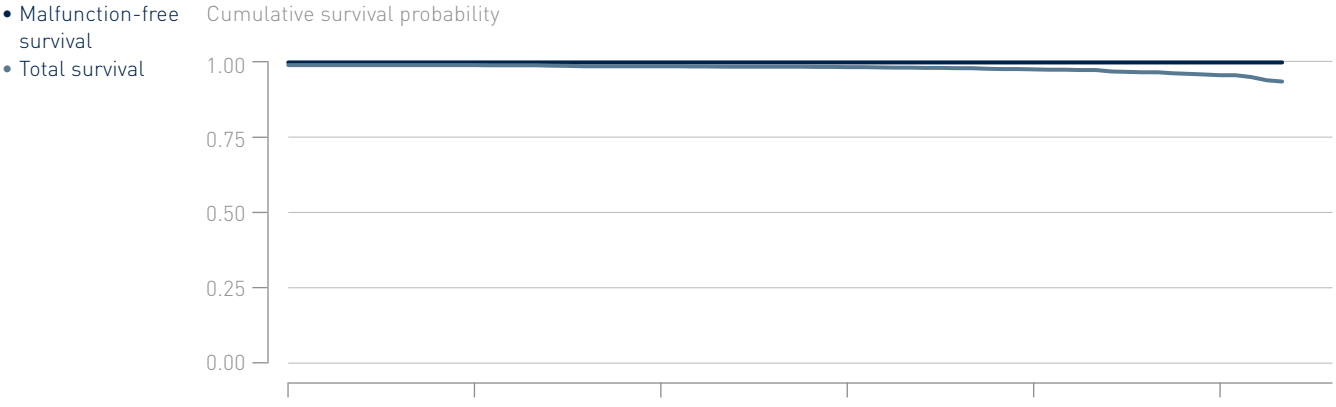


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.6
CI [±%]	-	< 0.1	0.1	0.3
Malfunction-Free [%]	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	5 528	3 607	2 048	666

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	1 050
U.S. Normal Battery Depletions	46

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

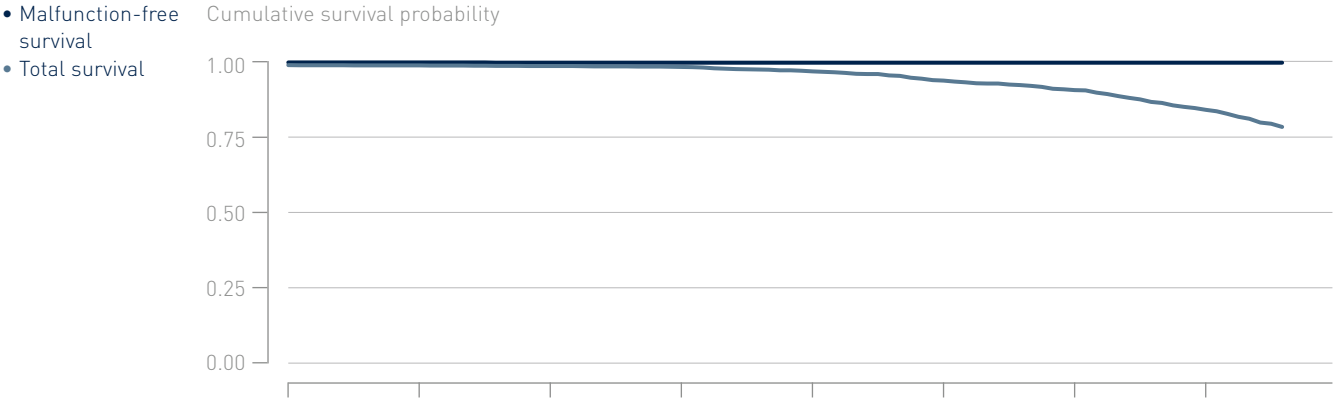


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.6	99.3	98.5	96.5
CI [±%]	-	< 0.1	0.3	0.4	0.7	1.3
Malfunction-Free [%]	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 860	1 626	1 432	1 200	907	383

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	772
U.S. Normal Battery Depletions	206

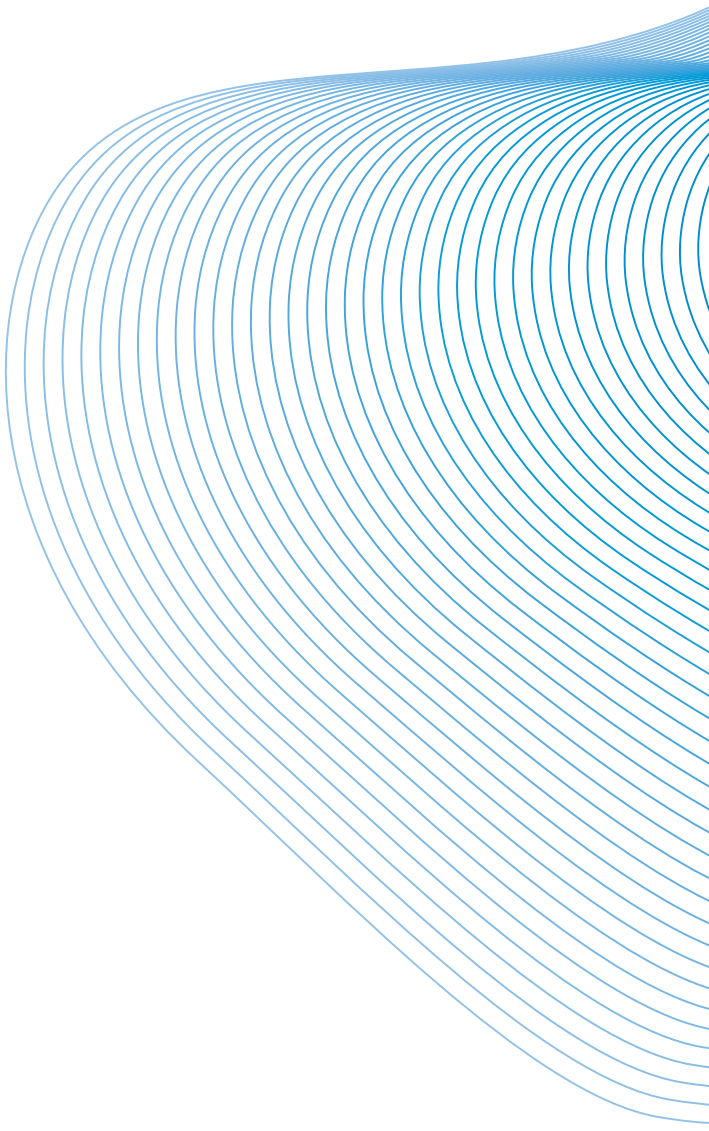
	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.04%
Therapy Compromised	0	0.00%
Therapy Available	1	0.04%



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.7	99.4	97.9	94.8	91.6	85.0
CI [±%]	-	0.1	0.2	0.4	0.7	1.2	1.5	2.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	2 249	1 987	1 765	1 568	1 363	1 176	1 003	571

Performance of BIOTRONIK ICDs

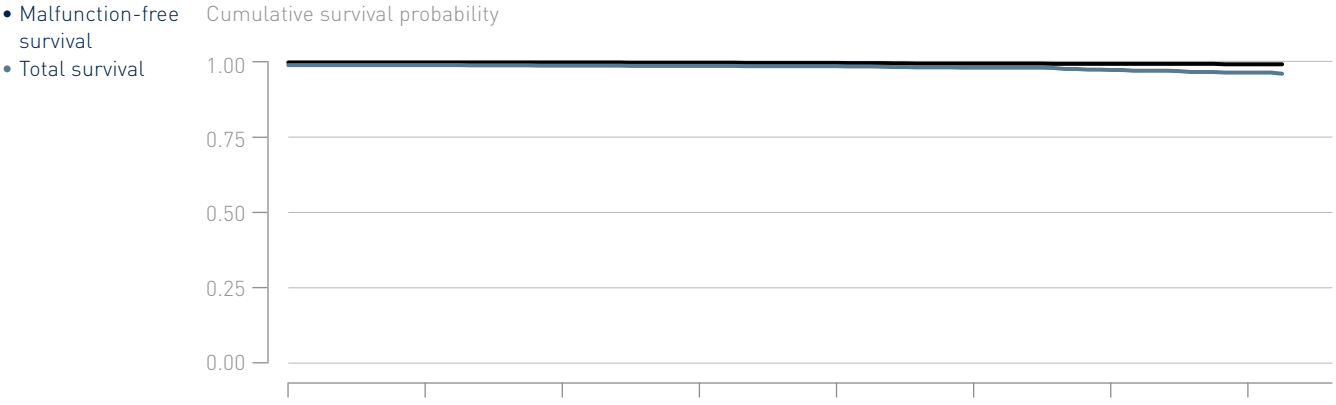
Performance of BIOTRONIK ICDs



Ilesto 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2 460
Registered U.S. Implants	1 271
Estimated Active U.S. Implants	787
U.S. Normal Battery Depletions	18

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



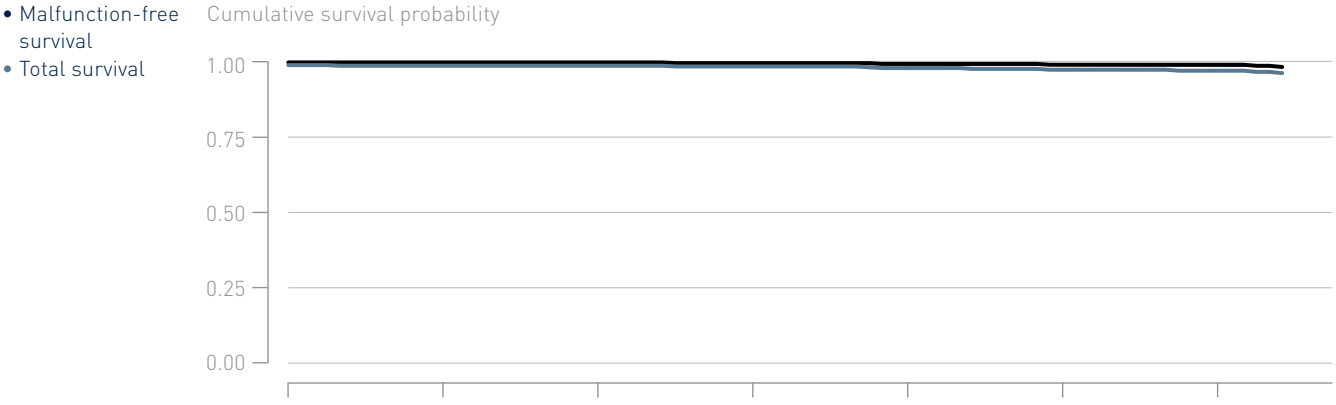
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.8	99.7	99.6	99.1	98.3	97.3
CI [±%]	-	< 0.1	0.2	0.3	0.4	0.6	0.9	1.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.5	99.4	99.2
CI [±%]	-	< 0.1	< 0.1	0.2	0.3	0.5	0.5	0.6
Sample Size	1 271	1 180	1 100	1 030	957	886	783	371

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

Ilesto 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2390
Registered U.S. Implants	466
Estimated Active U.S. Implants	294
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions*	6	1.29%
Therapy Compromised	3	0.64%
Therapy Available	3	0.64%



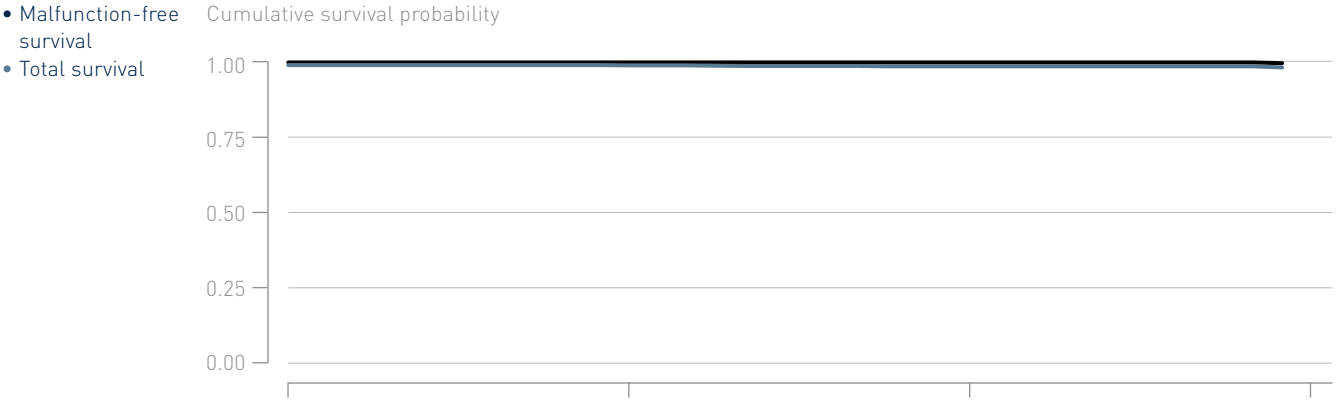
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.8	99.5	98.9	98.3	98.0
CI [±%]	-	0.4	0.4	0.7	1	1.3	1.5
Malfunction-Free [%]	100.0	100.0	100.0	99.7	99.4	99.1	99.1
CI [±%]	-	< 0.1	< 0.1	0.5	0.8	1	1
Sample Size	466	429	392	365	341	317	258

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

Ilivia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	2390
Registered U.S. Implants	964
Estimated Active U.S. Implants	801
U.S. Normal Battery Depletions	5

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



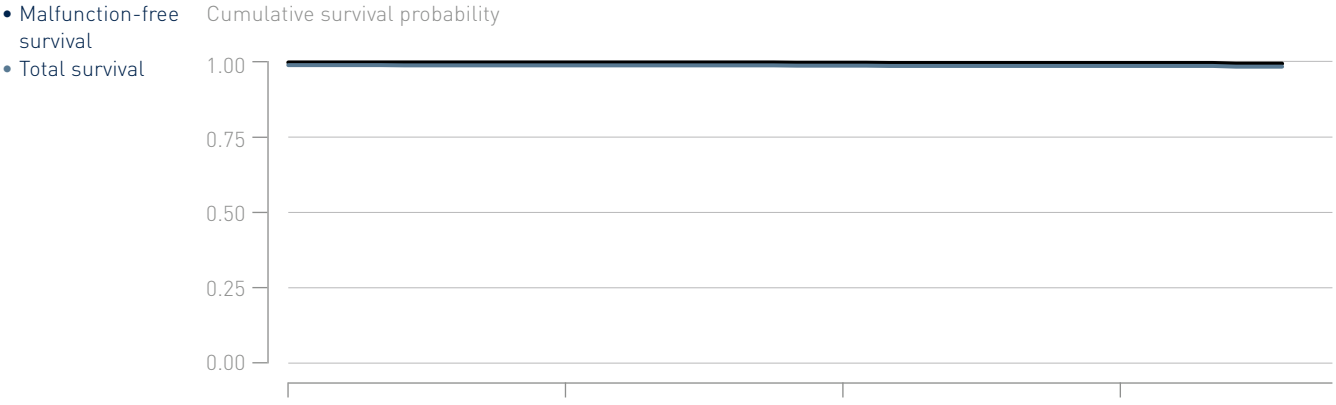
Years after implant	0	1	2
Total [%]	100.0	99.9	99.5
CI [±%]	-	0.2	0.5
Malfunction-Free [%]	100	100	100
CI [±%]	-	< 0.1	< 0.1
Sample Size	964	868	540

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

Ilivia 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Aug 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	4 250
Registered U.S. Implants	878
Estimated Active U.S. Implants	695
U.S. Normal Battery Depletions	1

	Quantity	Rate
U.S. Confirmed Malfunctions*	3	0.34%
Therapy Compromised	1	0.11%
Therapy Available	2	0.23%



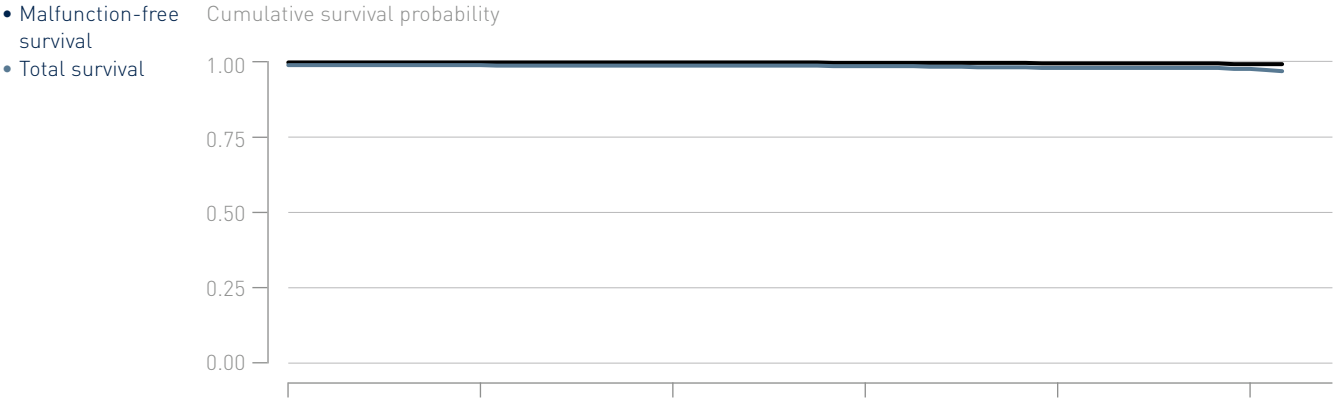
Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.7	99.6
CI [±%]	-	0.2	0.3	0.4
Malfunction-Free [%]	100.0	100.0	99.9	99.7
CI [±%]	-	< 0.1	0.3	0.4
Sample Size	878	809	732	474

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

Itrevia 7

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 280
Registered U.S. Implants	618
Estimated Active U.S. Implants	428
U.S. Normal Battery Depletions	7

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



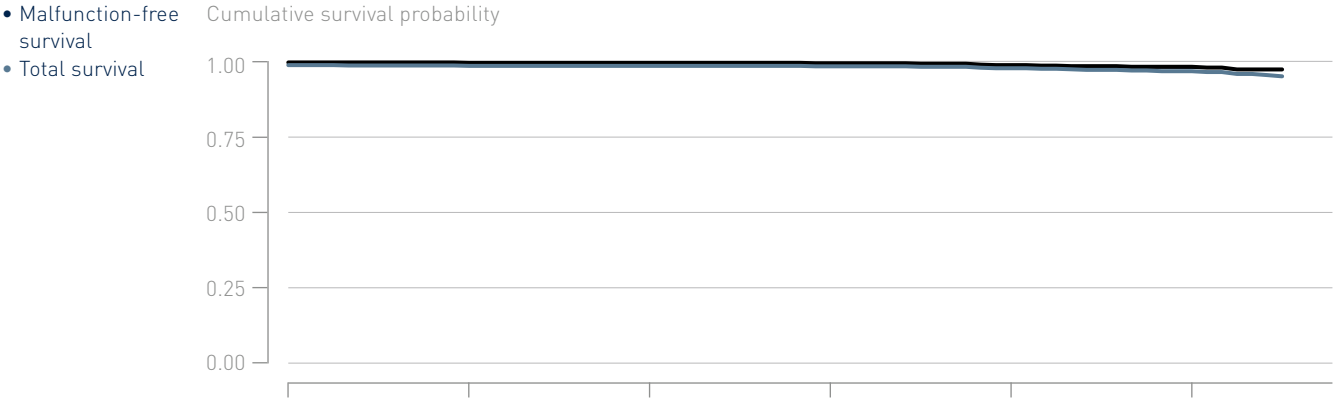
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.8	99.6	99.0	98.6
CI [±%]	-	< 0.1	0.3	0.5	0.9	1.1
Malfunction-Free [%]	100.0	100.0	100.0	99.8	99.6	99.2
CI [±%]	-	< 0.1	< 0.1	0.4	0.6	0.9
Sample Size	618	567	530	491	403	258

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

Itrevia 7 DF4

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 420
Registered U.S. Implants	804
Estimated Active U.S. Implants	550
U.S. Normal Battery Depletions	5

	Quantity	Rate
U.S. Confirmed Malfunctions*	14	1.74%
Therapy Compromised	3	0.37%
Therapy Available	11	1.37%



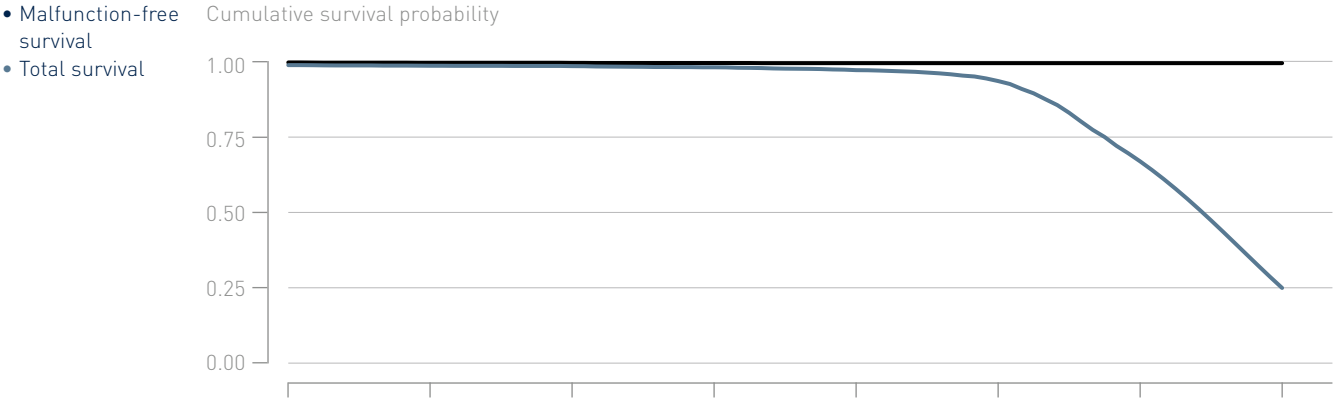
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.7	99.7	99.6	98.9	97.9
CI [±%]	-	0.4	0.4	0.5	0.8	1.2
Malfunction-Free [%]	100.0	99.9	99.9	99.7	99.0	98.4
CI [±%]	-	0.3	0.3	0.4	0.8	1
Sample Size	804	738	683	636	558	349

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

Lumax 340

Product Versions	VR, VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	27 100
Registered U.S. Implants	3 985
Estimated Active U.S. Implants	880
U.S. Normal Battery Depletions	932

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

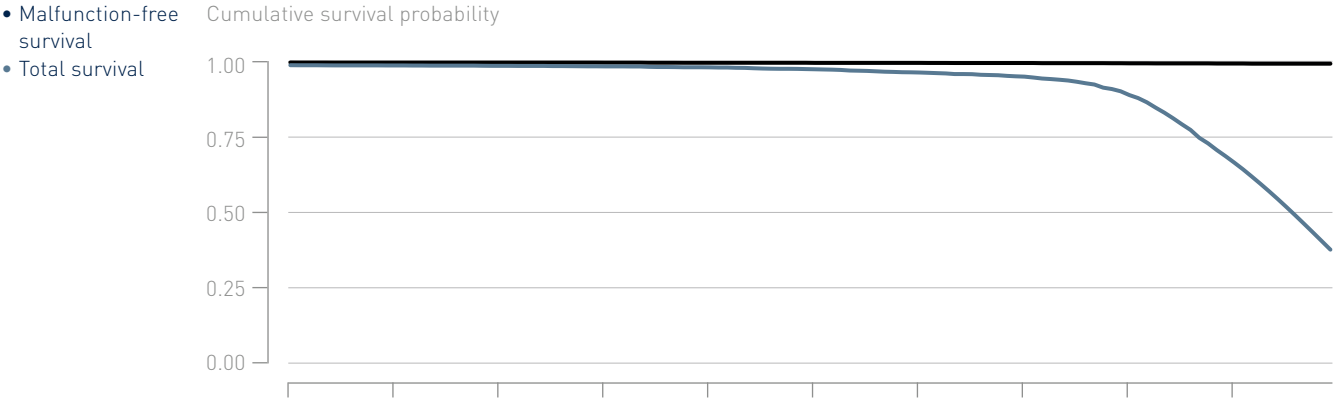


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.7	99.3	98.3	94.7	67.9	25.7
CI [±%]	-	0.1	0.2	0.3	0.4	0.8	1.9	4.2
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	3 985	3 616	3 393	3 155	2 908	2 550	1 506	275

Lumax 540

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20000
Registered U.S. Implants	4544
Estimated Active U.S. Implants	1350
U.S. Normal Battery Depletions	901

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

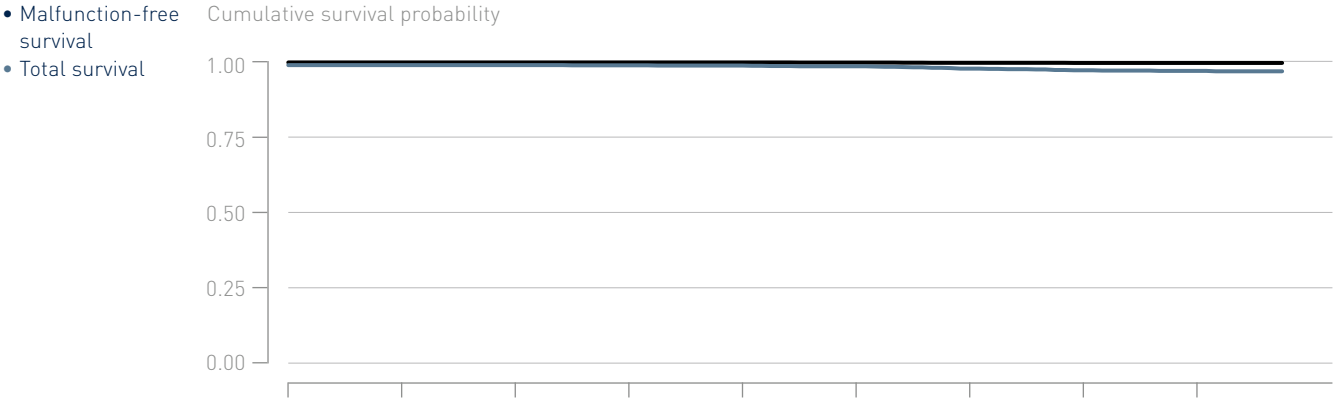


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.8	99.6	99.3	98.6	97.5	96.2	90.0	67.5
CI [±%]	-	0.1	0.1	0.2	0.3	0.4	0.5	0.7	1.1	1.9
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.8	99.8	99.7	99.5	99.4
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3
Sample Size	4544	4191	3897	3623	3371	3133	2880	2645	2308	1461

Lumax 740

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	4 810
Registered U.S. Implants	1 574
Estimated Active U.S. Implants	847
U.S. Normal Battery Depletions	21

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

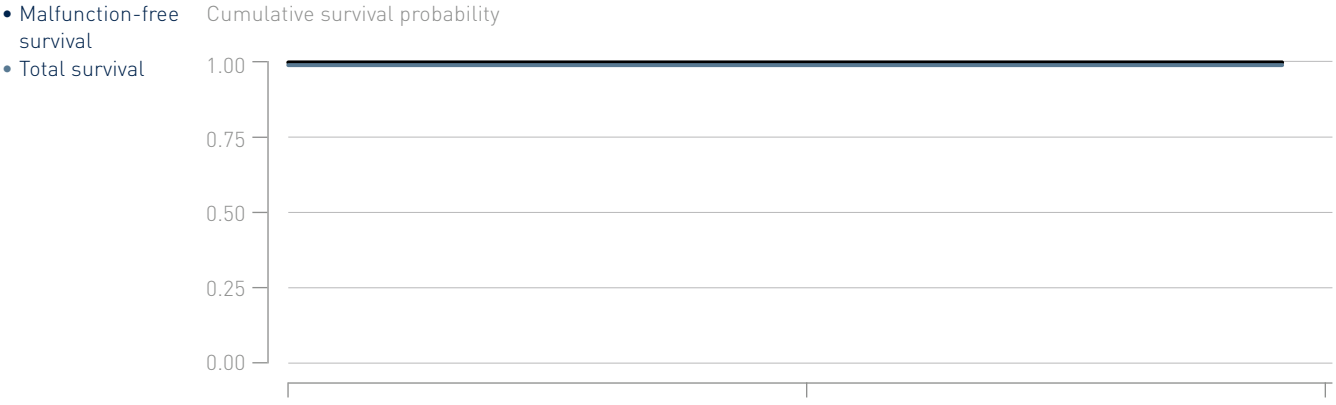


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	100.0	99.9	99.8	99.6	98.7	98.1	97.9
CI [±%]	-	< 0.1	< 0.1	0.2	0.2	0.4	0.7	0.8	0.9
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.7	99.6	99.6
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4
Sample Size	1 574	1 446	1 346	1 253	1 159	1 079	995	924	731

Rivacor 7 DF4

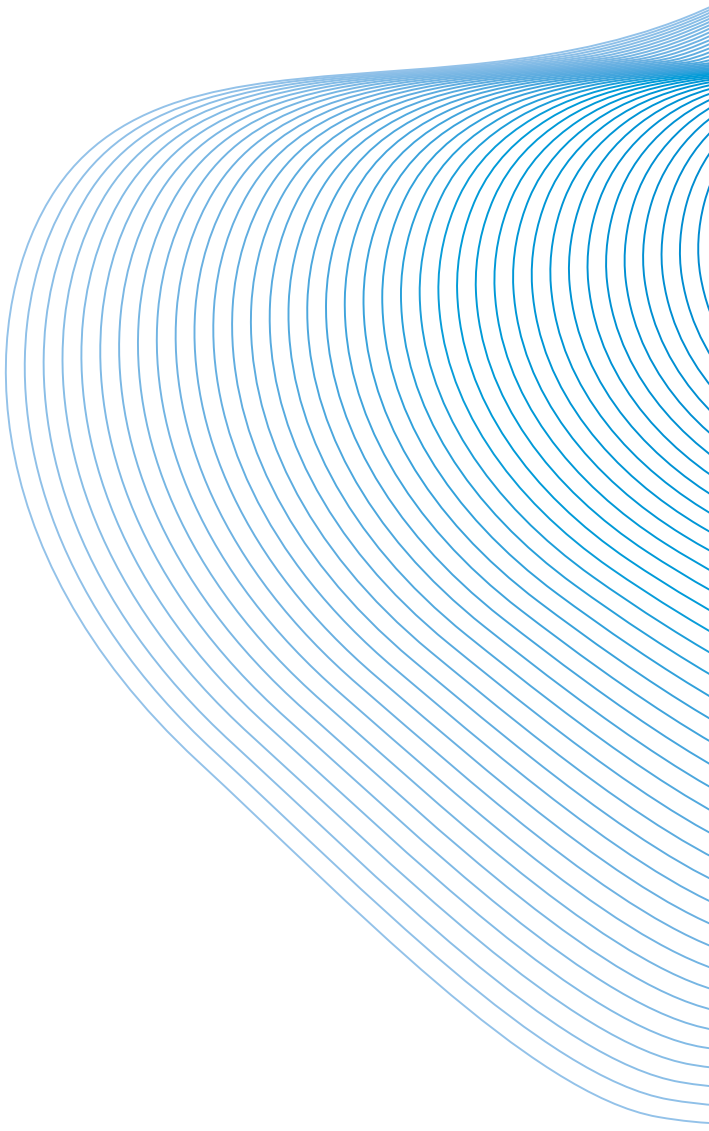
Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	3 570
Registered U.S. Implants	985
Estimated Active U.S. Implants	911
U.S. Normal Battery Depletions	0

	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	100
CI [±%]	-	< 0.1
Malfunction-Free [%]	100	100
CI [±%]	-	< 0.1
Sample Size	985	553

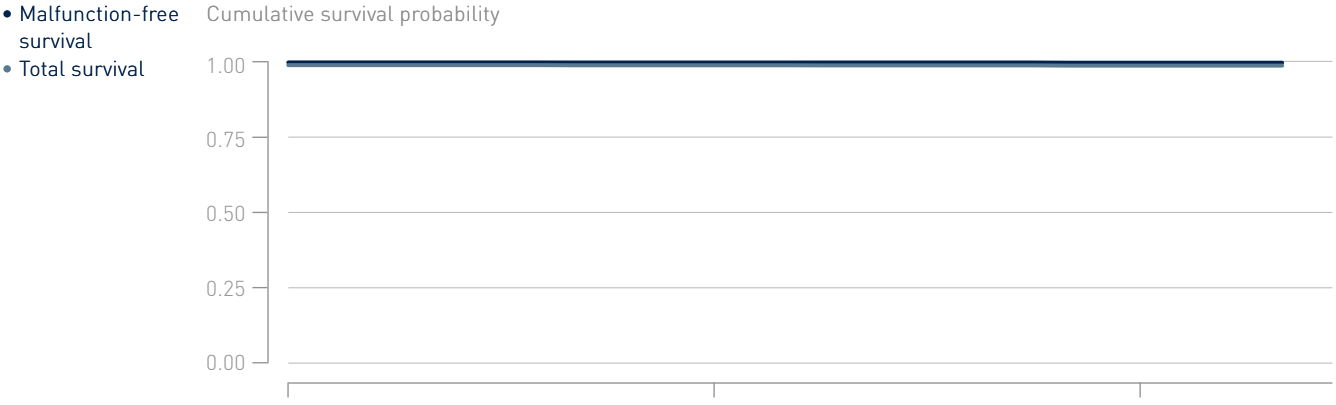
Performance of BIOTRONIK ICDs



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	12200
Registered U.S. Implants	8710
Estimated Active U.S. Implants	8030
U.S. Normal Battery Depletions	3

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

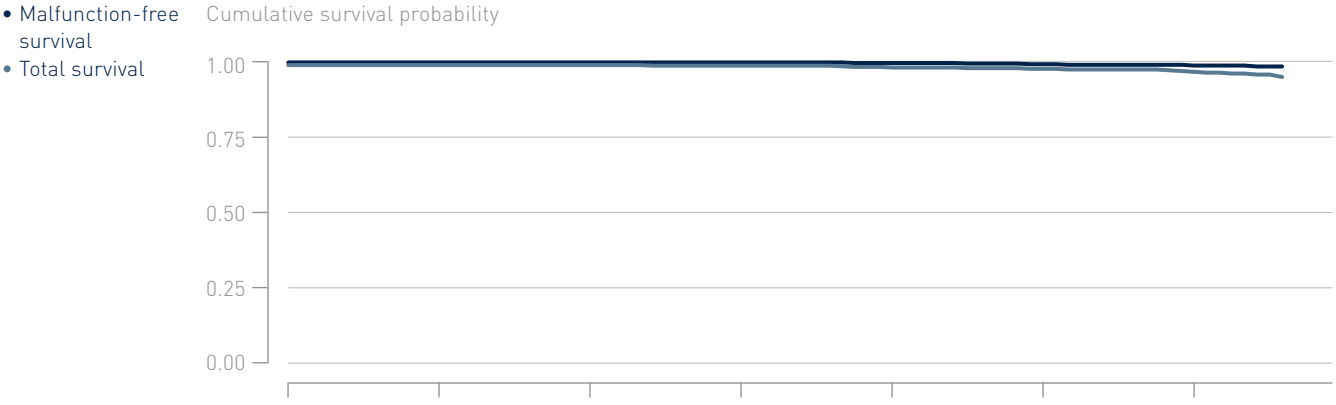


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	-	< 0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	-	< 0.1	0.1
Sample Size	8710	4485	1317

Iforia 7

Product Versions	DR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2000
Registered U.S. Implants	614
Estimated Active U.S. Implants	367
U.S. Normal Battery Depletions	11

	Quantity	Rate
U.S. Confirmed Malfunctions*	6	0.98%
Therapy Compromised	2	0.33%
Therapy Available	4	0.65%



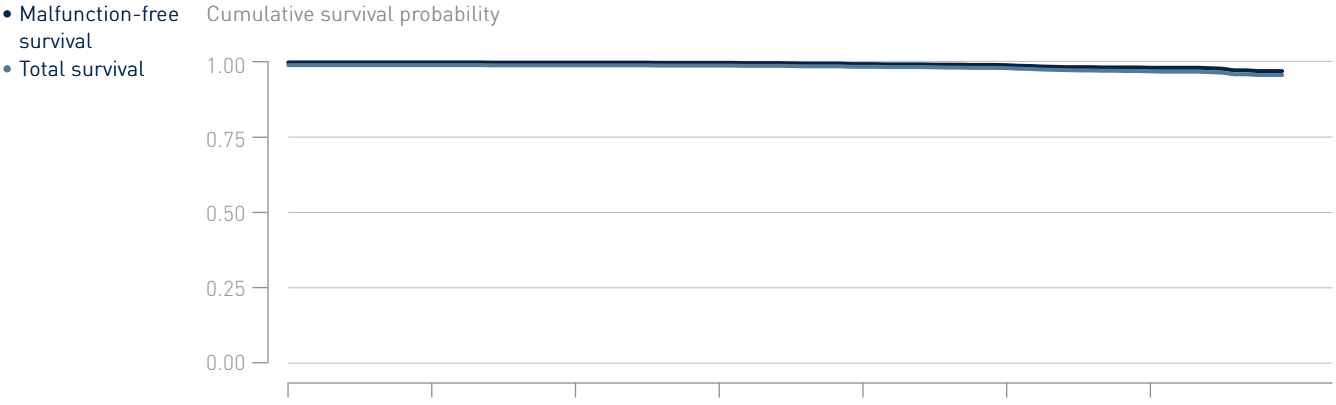
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.8	99.2	98.7	97.6
CI [±%]	-	< 0.1	< 0.1	0.4	0.8	1	1.5
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.8	99.3	98.8
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.8	1.1
Sample Size	614	564	529	486	451	419	346

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

Iforia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	4 780
Registered U.S. Implants	1 461
Estimated Active U.S. Implants	902
U.S. Normal Battery Depletions	9

	Quantity	Rate
U.S. Confirmed Malfunctions*	28	1.92%
Therapy Compromised	12	0.82%
Therapy Available	16	1.10%



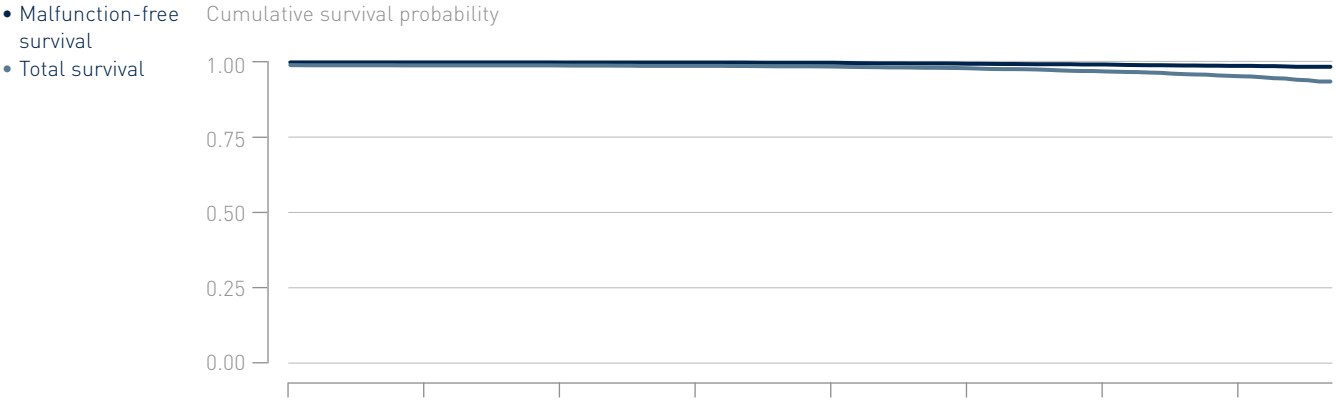
Years after implant	0	1	2	3	4	5	6
Total [%]	99.9	99.9	99.9	99.8	99.3	98.9	97.7
CI [±%]	-	0.1	0.2	0.3	0.5	0.6	0.9
Malfunction-Free [%]	99.9	99.9	99.9	99.8	99.3	98.9	98.0
CI [±%]	-	0.1	0.2	0.3	0.5	0.6	0.8
Sample Size	1 461	1 358	1 271	1 184	1 092	1 003	865

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

Ilesto 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 110
Registered U.S. Implants	3 487
Estimated Active U.S. Implants	1 990
U.S. Normal Battery Depletions	84

	Quantity	Rate
U.S. Confirmed Malfunctions*	32	0.92%
Therapy Compromised	21	0.60%
Therapy Available	11	0.32%



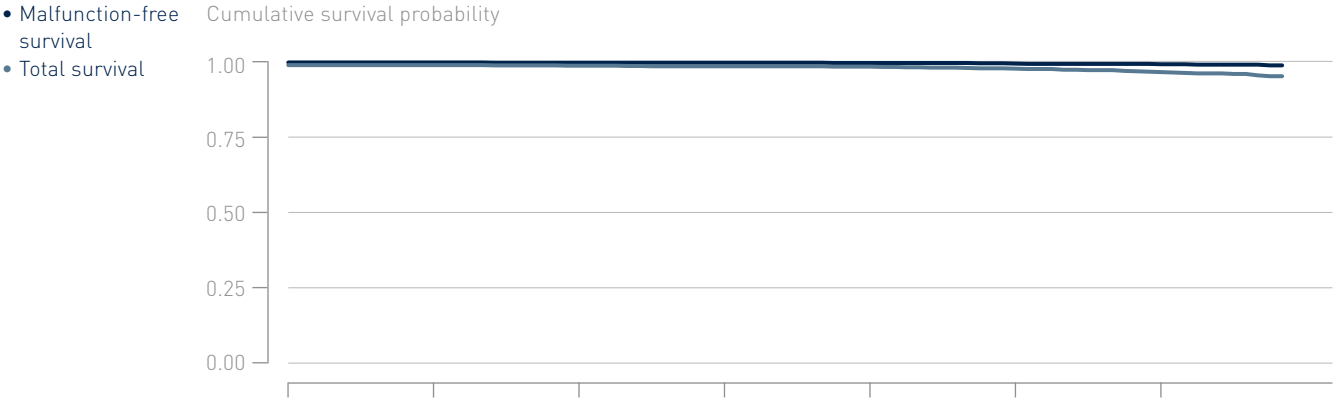
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.9	99.7	99.5	98.9	97.8	96.1
CI [±%]	-	0.1	0.1	0.2	0.3	0.4	0.6	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.5	99.2	98.7
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.3	0.3	0.5
Sample Size	3 487	3 218	2 995	2 783	2 585	2 386	2 089	1 239

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

Ilesto 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jul 2013
Worldwide Distributed Devices	3 730
Registered U.S. Implants	1 147
Estimated Active U.S. Implants	700
U.S. Normal Battery Depletions	21

	Quantity	Rate
U.S. Confirmed Malfunctions*	9	0.78%
Therapy Compromised	4	0.35%
Therapy Available	5	0.44%



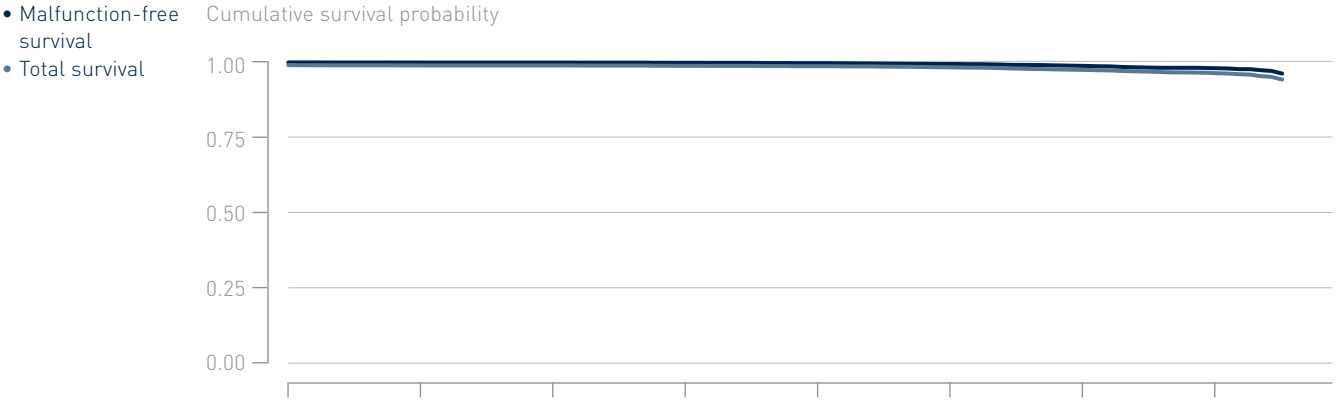
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.8	99.6	99.5	98.8	97.5
CI [±%]	-	< 0.1	0.3	0.4	0.5	0.7	1.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.8	99.5	99.3
CI [±%]	-	< 0.1	0.2	0.2	0.3	0.5	0.6
Sample Size	1 147	1 059	983	912	851	792	679

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

Ilesto 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	2 860
U.S. Normal Battery Depletions	51

	Quantity	Rate
U.S. Confirmed Malfunctions*	69	1.46%
Therapy Compromised	34	0.72%
Therapy Available	35	0.74%



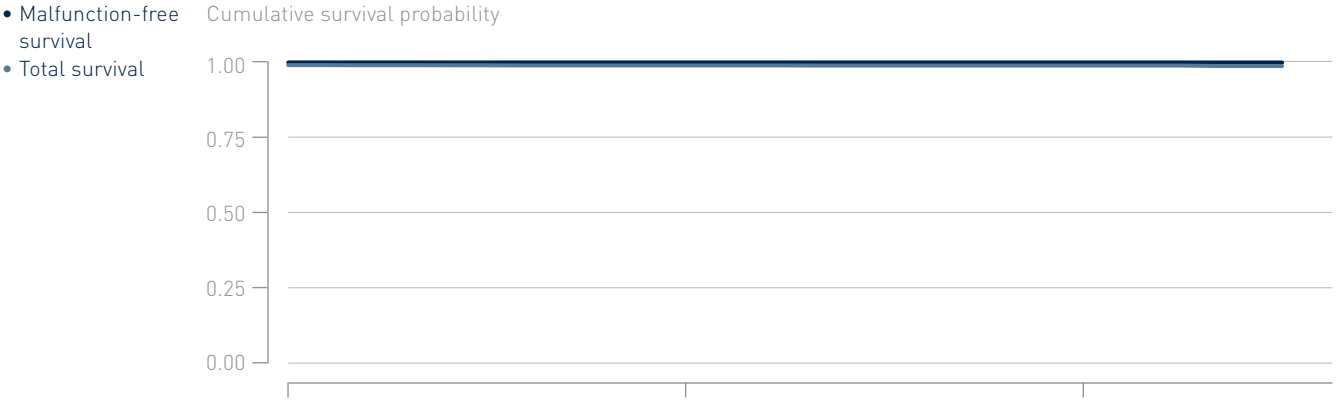
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.9	99.8	99.6	99.3	98.4	97.4
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.4	0.6
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.7	99.4	98.9	98.1
CI [±%]	-	< 0.1	0.1	0.1	0.2	0.2	0.4	0.5
Sample Size	4 720	4 369	4 088	3 825	3 552	3 301	2 964	1 534

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

Ilivia 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	3 260
Registered U.S. Implants	1 626
Estimated Active U.S. Implants	1 410
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions*	1	0.06%
Therapy Compromised	0	0.00%
Therapy Available	1	0.06%



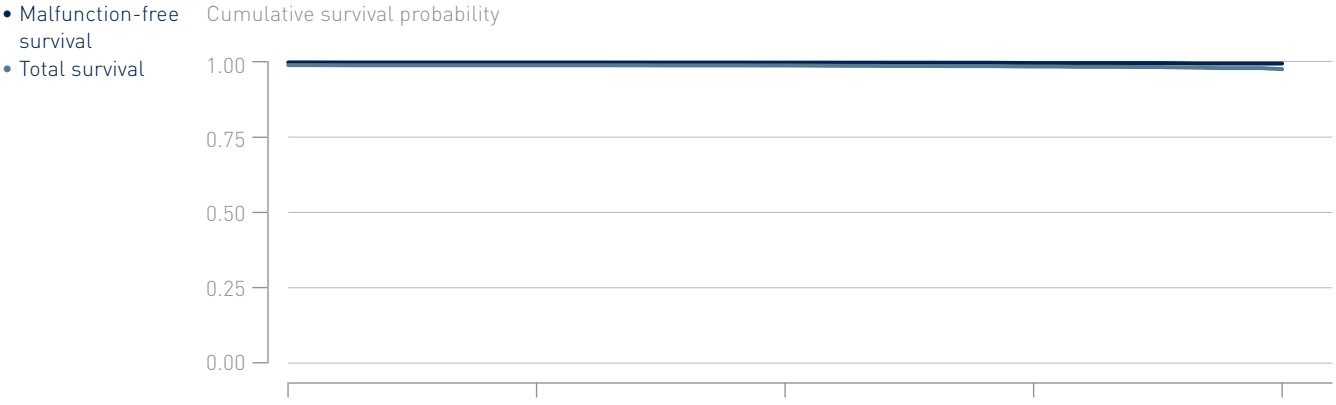
Years after implant	0	1	2
Total [%]	100.0	99.8	99.7
CI [±%]	-	0.2	0.3
Malfunction-Free [%]	100	100	100
CI [±%]	-	< 0.1	< 0.1
Sample Size	1 626	1 462	739

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

Ilivia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Aug 2016
Worldwide Distributed Devices	8560
Registered U.S. Implants	3994
Estimated Active U.S. Implants	3170
U.S. Normal Battery Depletions	11

	Quantity	Rate
U.S. Confirmed Malfunctions*	13	0.33%
Therapy Compromised	6	0.15%
Therapy Available	7	0.18%



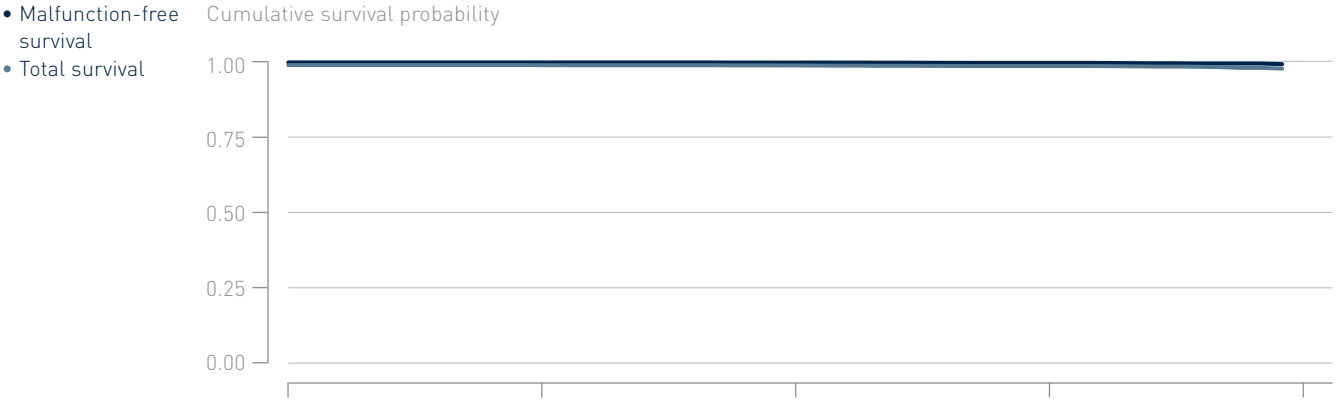
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.8	99.4	98.4
CI [±%]	-	0.1	0.1	0.3	1
Malfunction-Free [%]	100.0	99.9	99.9	99.6	99.4
CI [±%]	-	0.1	0.1	0.2	0.4
Sample Size	3994	3656	3072	1853	241

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

Intica 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 850
Registered U.S. Implants	4 627
Estimated Active U.S. Implants	3 680
U.S. Normal Battery Depletions	11

	Quantity	Rate
U.S. Confirmed Malfunctions*	12	0.26%
Therapy Compromised	1	0.02%
Therapy Available	11	0.24%



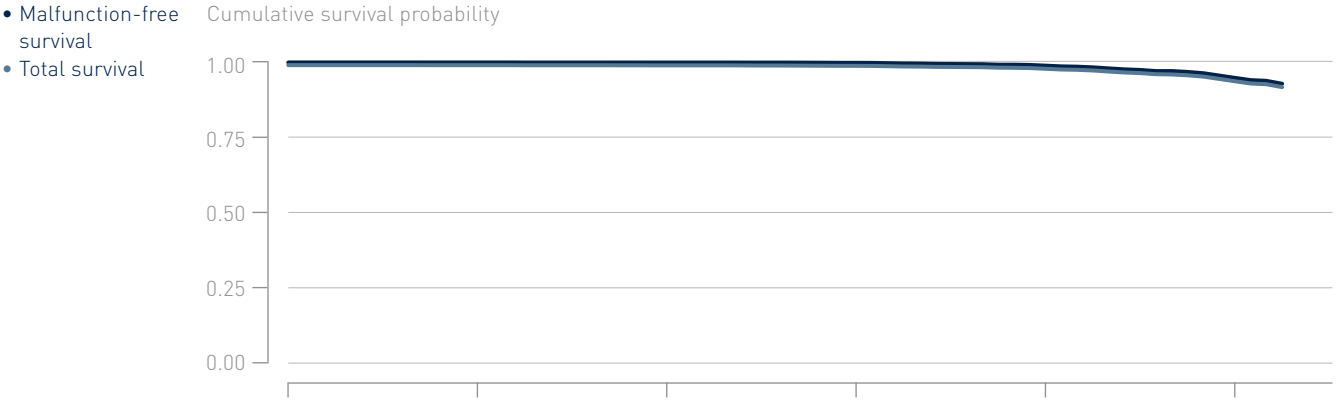
Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.6
CI [±%]	-	< 0.1	0.1	0.2
Malfunction-Free [%]	100.0	100.0	99.9	99.8
CI [±%]	-	< 0.1	0.1	0.2
Sample Size	4 627	4 267	3 654	2 229

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

Inventra 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	45
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 790
Registered U.S. Implants	5 450
Estimated Active U.S. Implants	4 000
U.S. Normal Battery Depletions	25

	Quantity	Rate
U.S. Confirmed Malfunctions*	88	1.61%
Therapy Compromised	26	0.48%
Therapy Available	62	1.14%



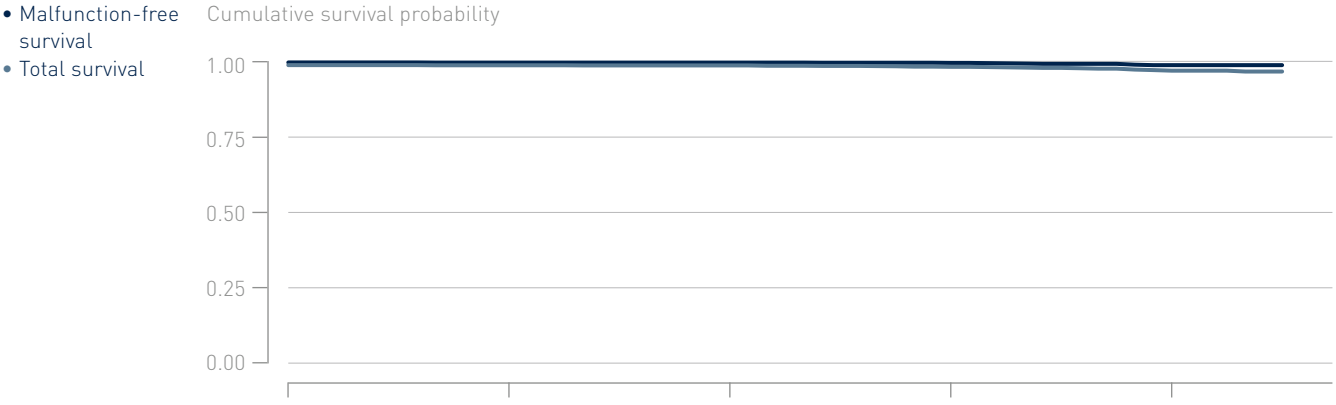
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	99.9	99.8	98.8	94.5
CI [±%]	-	< 0.1	0.1	0.2	0.4	1.3
Malfunction-Free [%]	100.0	100.0	100.0	99.9	98.9	94.7
CI [±%]	-	< 0.1	< 0.1	0.1	0.4	1.3
Sample Size	5 450	4 994	4 345	3 432	2 060	588

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

Iperia 7

Product Versions	DR-T
NBG Codes	VDE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 710
Registered U.S. Implants	1 965
Estimated Active U.S. Implants	1 500
U.S. Normal Battery Depletions	15

	Quantity	Rate
U.S. Confirmed Malfunctions*	12	0.61%
Therapy Compromised	4	0.20%
Therapy Available	8	0.41%



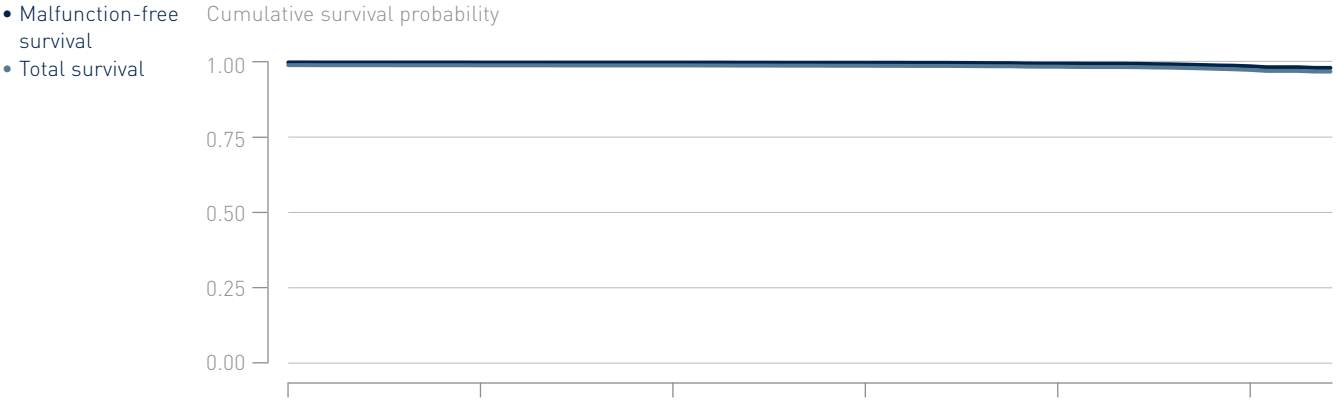
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.9	99.4	98.0
CI [±%]	-	0.1	0.2	0.4	1
Malfunction-Free [%]	100.0	99.9	99.9	99.8	98.9
CI [±%]	-	0.1	0.1	0.2	0.8
Sample Size	1 965	1 818	1 687	1 347	470

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

Iperia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	7510
Registered U.S. Implants	4110
Estimated Active U.S. Implants	2960
U.S. Normal Battery Depletions	16

	Quantity	Rate
U.S. Confirmed Malfunctions*	30	0.73%
Therapy Compromised	5	0.12%
Therapy Available	25	0.61%



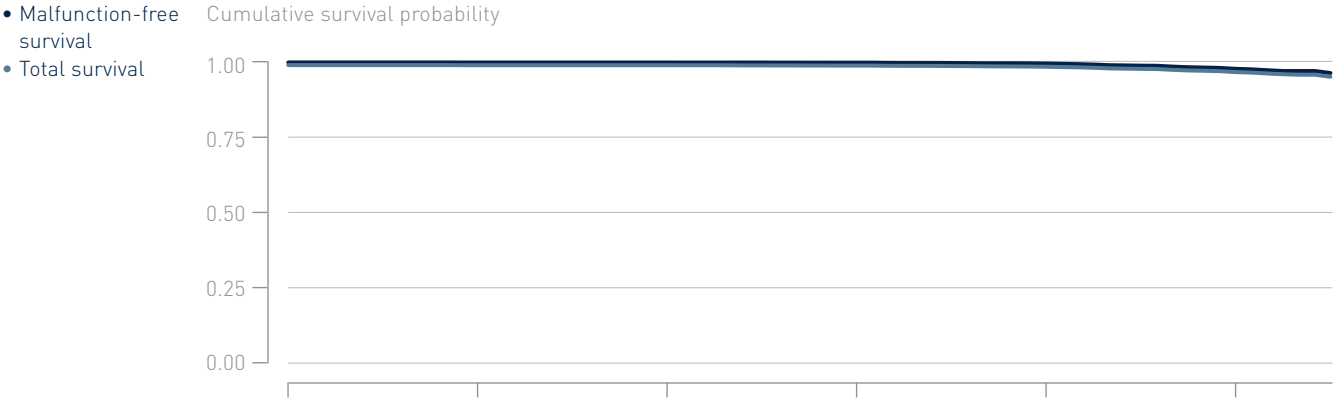
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.9	99.8	99.4	98.2
CI [±%]	-	0.1	0.1	0.2	0.3	0.6
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.6	98.6
CI [±%]	-	0.1	0.1	0.1	0.2	0.6
Sample Size	4110	3788	3480	3013	2340	923

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

Iperia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	6 540
Registered U.S. Implants	4 836
Estimated Active U.S. Implants	3 460
U.S. Normal Battery Depletions	24

	Quantity	Rate
U.S. Confirmed Malfunctions*	61	1.26%
Therapy Compromised	13	0.27%
Therapy Available	48	0.99%



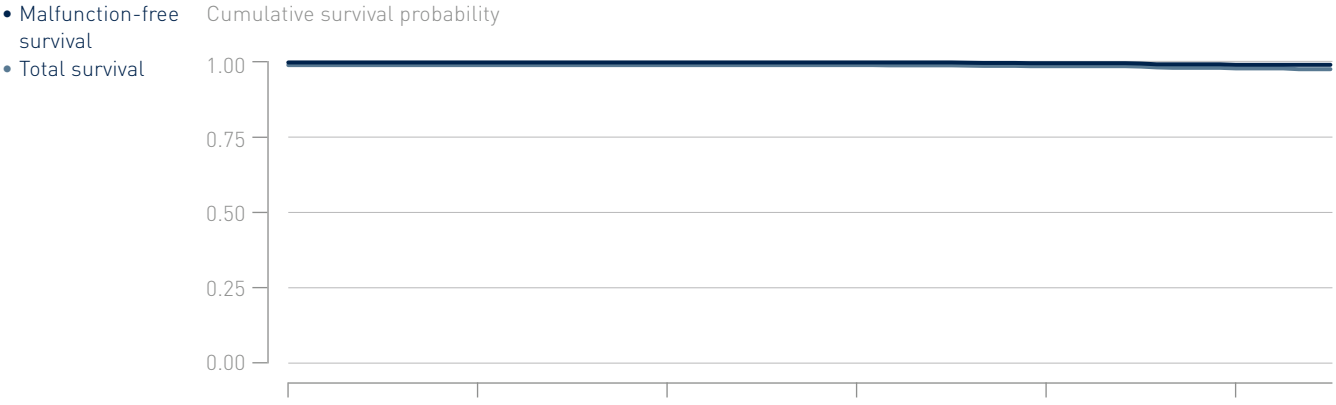
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	100.0	99.8	99.4	97.6
CI [±%]	-	< 0.1	< 0.1	0.1	0.3	0.7
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.6	97.7
CI [±%]	-	< 0.1	< 0.1	0.1	0.2	0.6
Sample Size	4 836	4 495	4 191	3 687	2 951	1 242

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

Itrevia 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 170
Registered U.S. Implants	1 416
Estimated Active U.S. Implants	1 030
U.S. Normal Battery Depletions	5

	Quantity	Rate
U.S. Confirmed Malfunctions*	8	0.56%
Therapy Compromised	4	0.28%
Therapy Available	4	0.28%



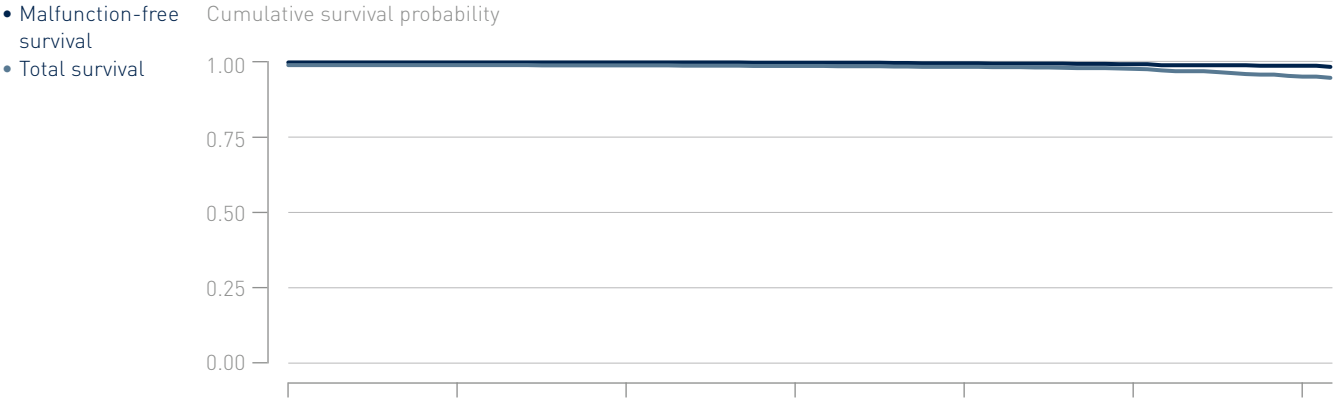
Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	100.0	100.0	99.6	98.7
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.9
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.7	99.0
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.4	0.8
Sample Size	1 416	1 298	1 205	1 118	833	455

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

Itrevia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2340
Registered U.S. Implants	1268
Estimated Active U.S. Implants	783
U.S. Normal Battery Depletions	22

	Quantity	Rate
U.S. Confirmed Malfunctions*	12	0.95%
Therapy Compromised	4	0.32%
Therapy Available	8	0.63%



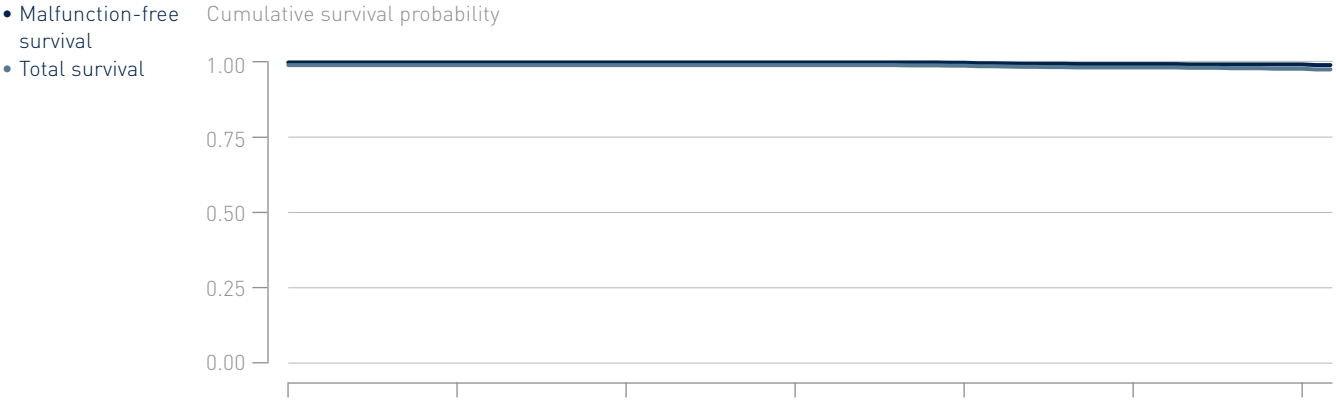
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.7	99.4	98.7	96.0
CI [±%]	-	< 0.1	0.2	0.3	0.5	0.7	1.5
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.7	99.3	98.7
CI [±%]	-	< 0.1	< 0.1	0.2	0.4	0.5	0.8
Sample Size	1268	1163	1069	993	920	765	366

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

Itrevia 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 750
Registered U.S. Implants	1 247
Estimated Active U.S. Implants	803
U.S. Normal Battery Depletions	5

	Quantity	Rate
U.S. Confirmed Malfunctions*	8	0.64%
Therapy Compromised	2	0.16%
Therapy Available	6	0.48%



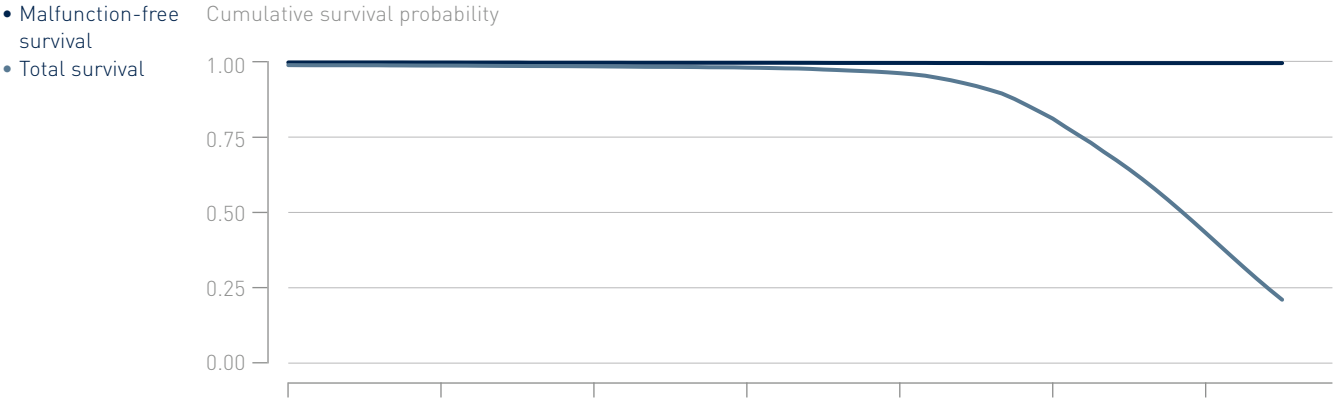
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	100.0	99.8	99.1	98.6
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.3	0.6	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.3	99.2
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.2	0.5	0.6
Sample Size	1 247	1 147	1 069	995	914	776	405

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

Lumax 340

Product Versions	DR, DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26400
Registered U.S. Implants	8219
Estimated Active U.S. Implants	1620
U.S. Normal Battery Depletions	2153

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

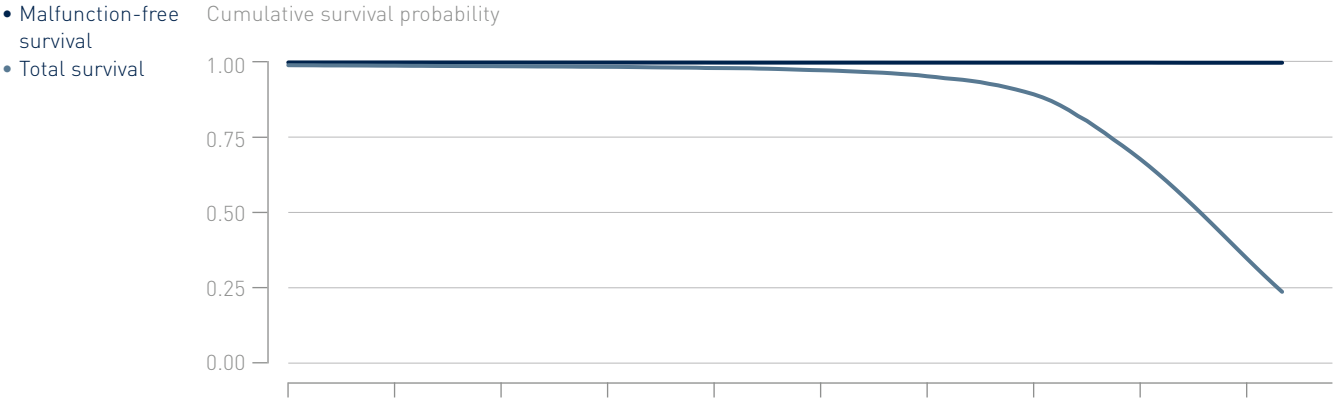


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.6	99.2	97.3	82.2	44.1
CI [±%]	-	0.1	0.1	0.2	0.4	1	1.5
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8219	7512	6992	6440	5874	4361	1817

Lumax 540

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered U.S. Implants	11 511
Estimated Active U.S. Implants	2 940
U.S. Normal Battery Depletions	2 897

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

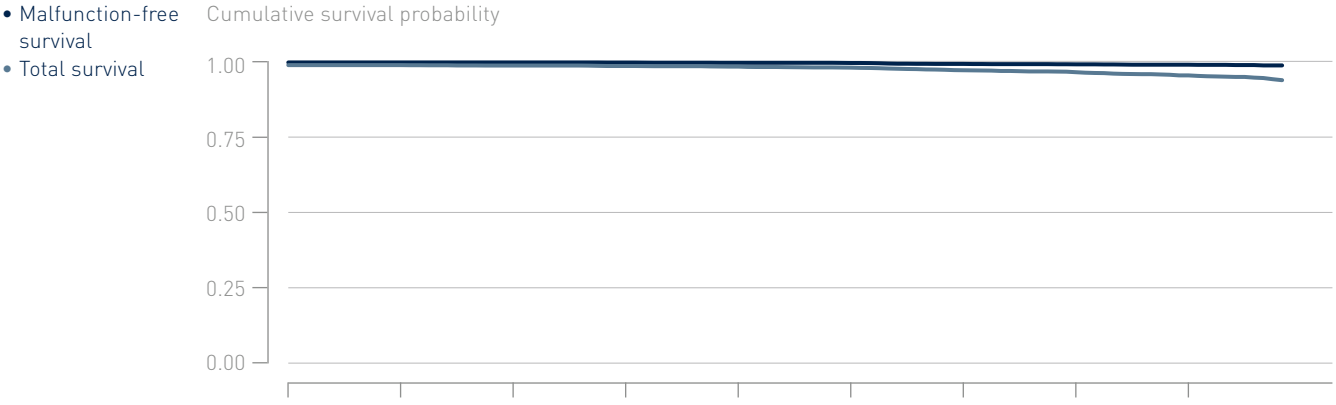


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.6	99.4	99.0	98.3	96.3	90.3	68.7	35.6
CI [±%]	-	0.1	0.1	0.1	0.2	0.3	0.4	0.7	1.1	1.4
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.7
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	11 511	10 617	9 875	9 165	8 476	7 828	7 152	6 214	4 329	1 743

Lumax 740

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7980
Registered U.S. Implants	3813
Estimated Active U.S. Implants	2070
U.S. Normal Battery Depletions	86

	Quantity	Rate
U.S. Confirmed Malfunctions	28	0.73%
Therapy Compromised	16	0.42%
Therapy Available	12	0.31%

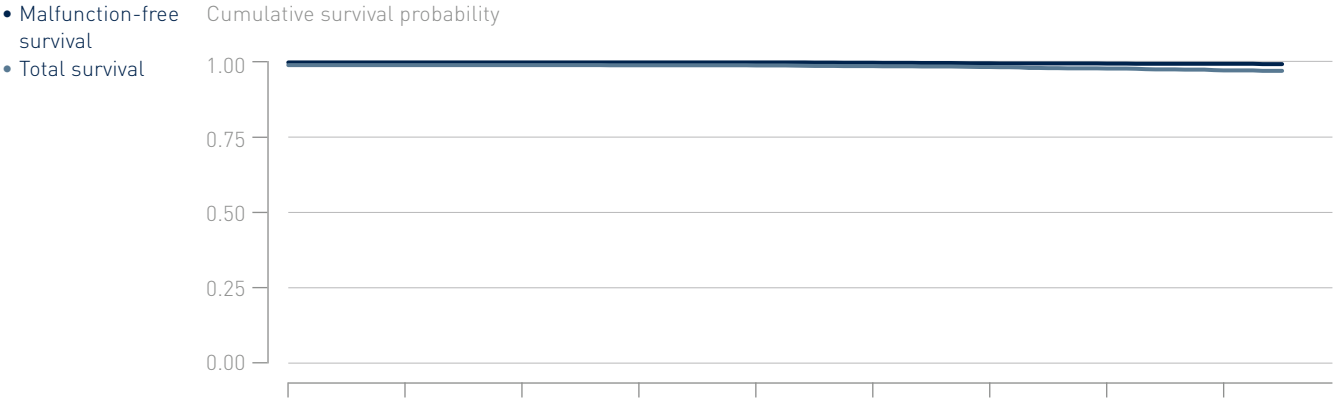


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	99.9	99.7	99.5	99.1	98.2	97.5	96.4
CI [±%]	-	< 0.1	0.1	0.2	0.3	0.3	0.5	0.6	0.7
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.8	99.4	99.2	99.1
CI [±%]	-	< 0.1	< 0.1	0.1	0.1	0.2	0.3	0.3	0.4
Sample Size	3813	3535	3291	3052	2838	2624	2419	2205	1711

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	2 223
Estimated Active U.S. Implants	1 290
U.S. Normal Battery Depletions	21

	Quantity	Rate
U.S. Confirmed Malfunctions	10	0.45%
Therapy Compromised	4	0.18%
Therapy Available	6	0.27%

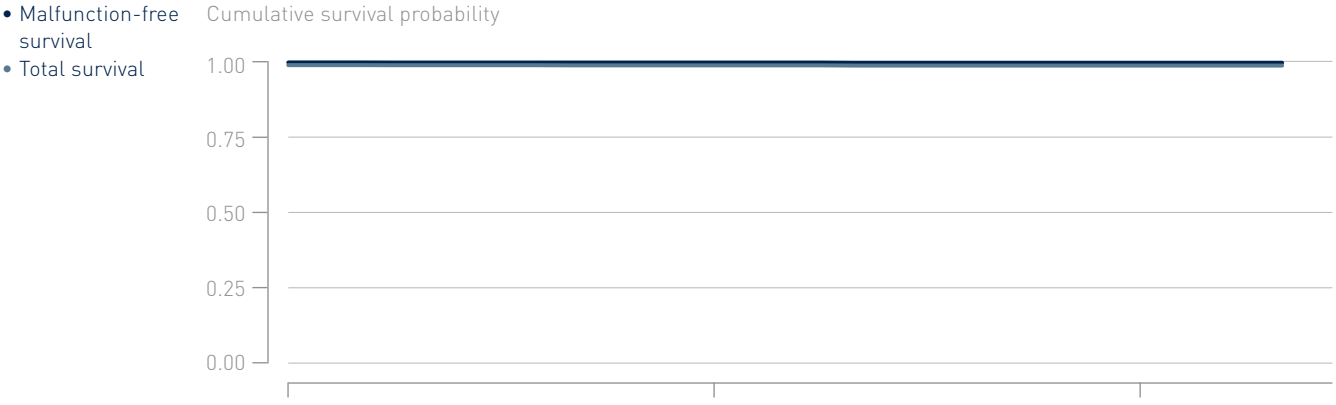


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	100.0	99.9	99.9	99.6	99.3	98.7	98.0
CI [±%]	-	< 0.1	< 0.1	0.1	0.2	0.3	0.4	0.6	0.7
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.6	99.5	99.4
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4
Sample Size	2 223	2 057	1 920	1 783	1 664	1 544	1 439	1 313	975

Rivacor 7 DF4

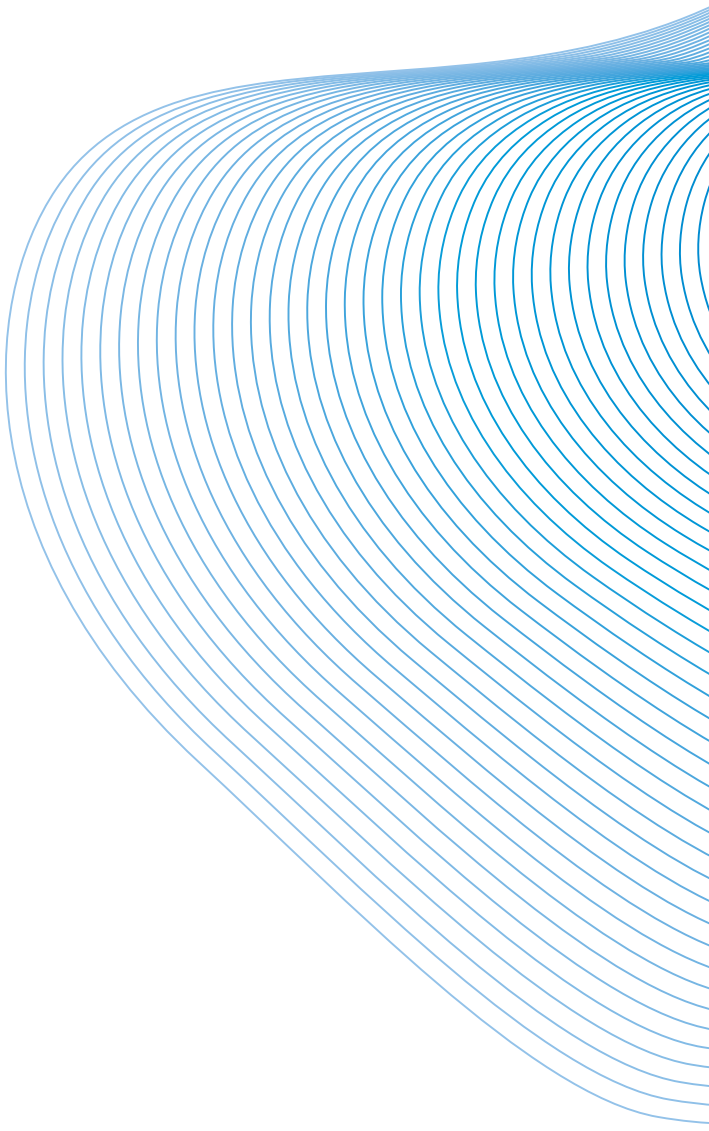
Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	8 960
Registered U.S. Implants	4 834
Estimated Active U.S. Implants	4 420
U.S. Normal Battery Depletions	1

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



Years after implant	0	1	2
Total [%]	100.0	99.9	99.9
CI [±%]	-	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	-	< 0.1	0.1
Sample Size	4 834	2 458	735

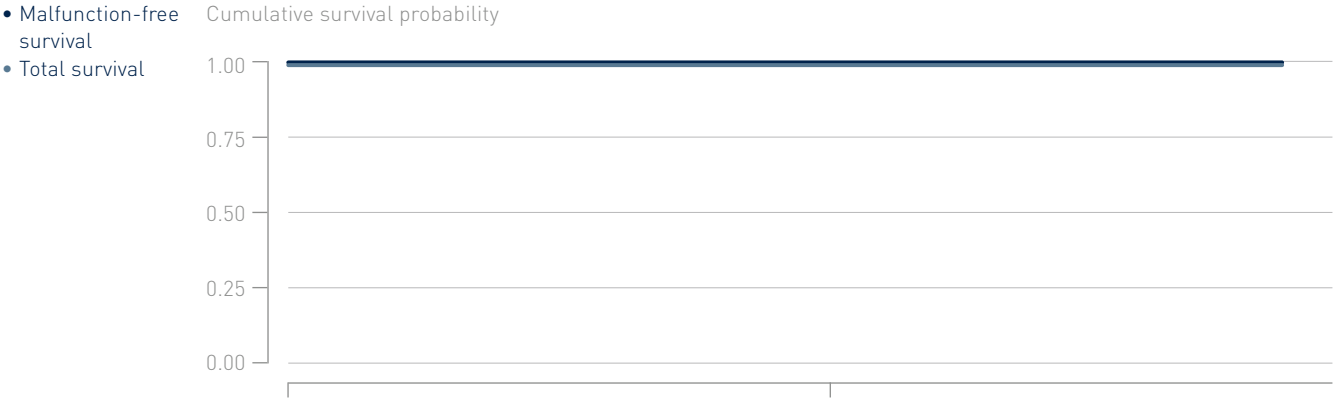
Performance of BIOTRONIK ICDs



Acticor 7

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	10200
Registered U.S. Implants	2449
Estimated Active U.S. Implants	2190
U.S. Normal Battery Depletions	0

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

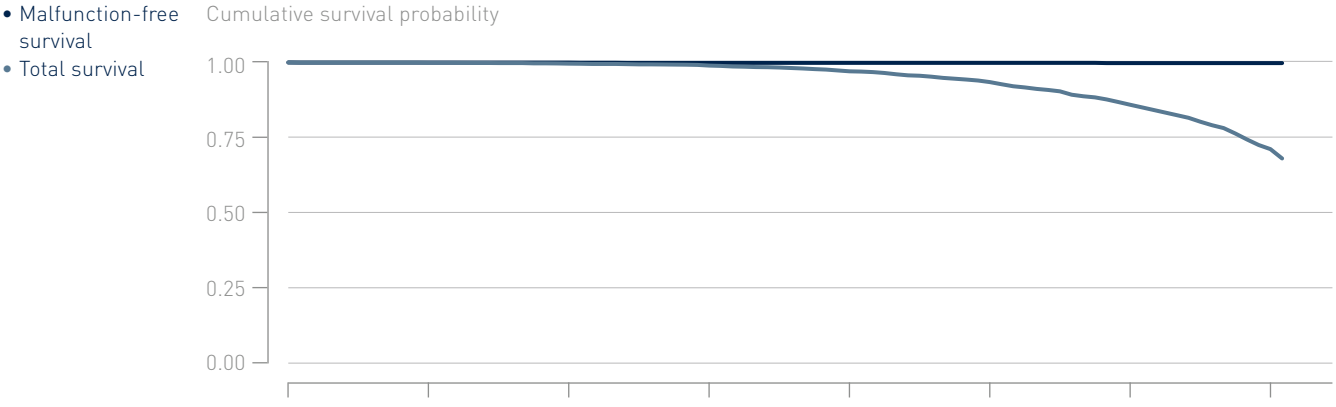


Years after implant	0	1
Total [%]	100	100
CI [±%]	-	0.1
Malfunction-Free [%]	100	100
CI [±%]	-	0.1
Sample Size	2449	1019

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	1 280
U.S. Normal Battery Depletions	501

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



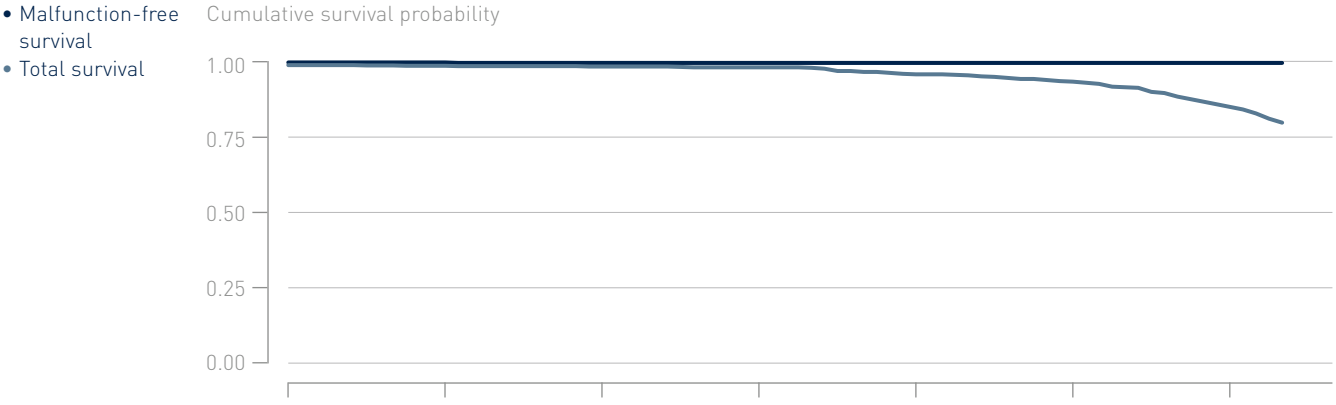
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.9	99.6	99.0	97.0	93.4	85.8	71.0
CI [±%]	-	0.1	0.2	0.4	0.6	1	1.5	2.5
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Sample Size	3 841	3 400	3 024	2 666	2 327	1 980	1 537	406

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

Ilesto 7 DF4

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jun 2013
Worldwide Distributed Devices	2360
Registered U.S. Implants	968
Estimated Active U.S. Implants	369
U.S. Normal Battery Depletions	102

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



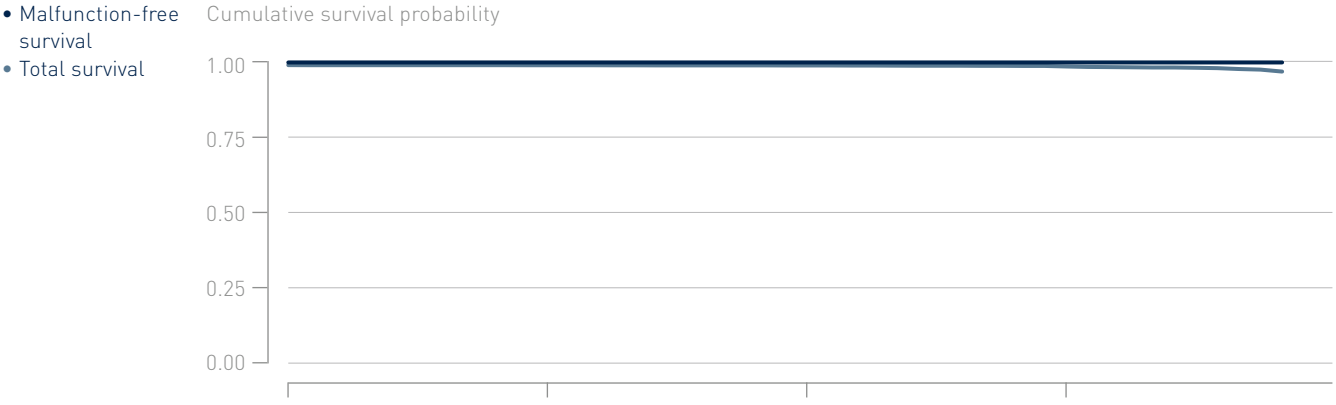
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.5	99.3	96.9	94.4	86.0
CI [±%]	-	0.3	0.5	0.6	1.3	1.8	3
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	< 0.1	0.2	0.2	0.2	0.2	0.2
Sample Size	968	858	766	681	594	513	360

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

Ilivia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	9 290
Registered U.S. Implants	4 778
Estimated Active U.S. Implants	3 360
U.S. Normal Battery Depletions	30

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



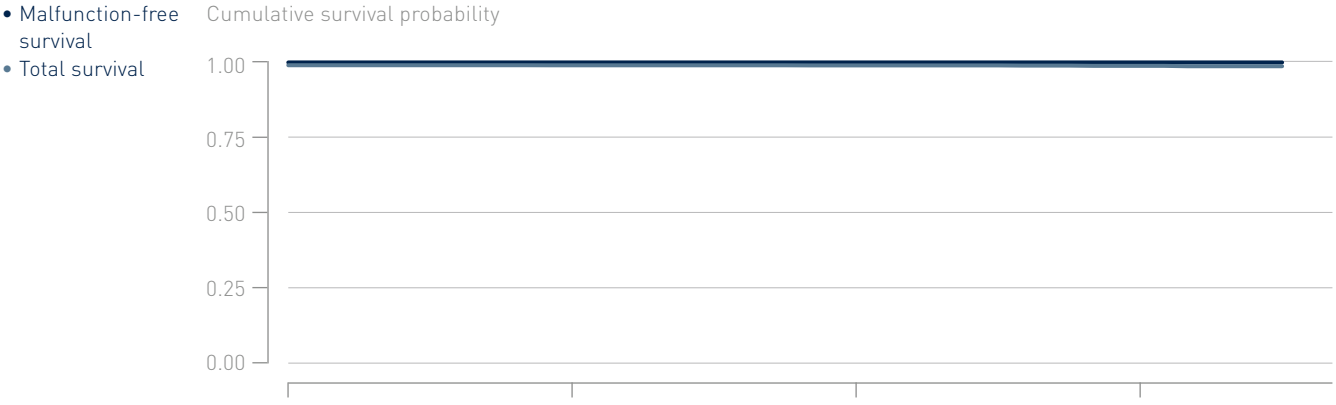
Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.5
CI [±%]	-	0.1	0.1	0.3
Malfunction-Free [%]	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	4 778	4 123	3 428	1 977

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

Intica 7 DF1

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	5460
Registered U.S. Implants	2956
Estimated Active U.S. Implants	2170
U.S. Normal Battery Depletions	6

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



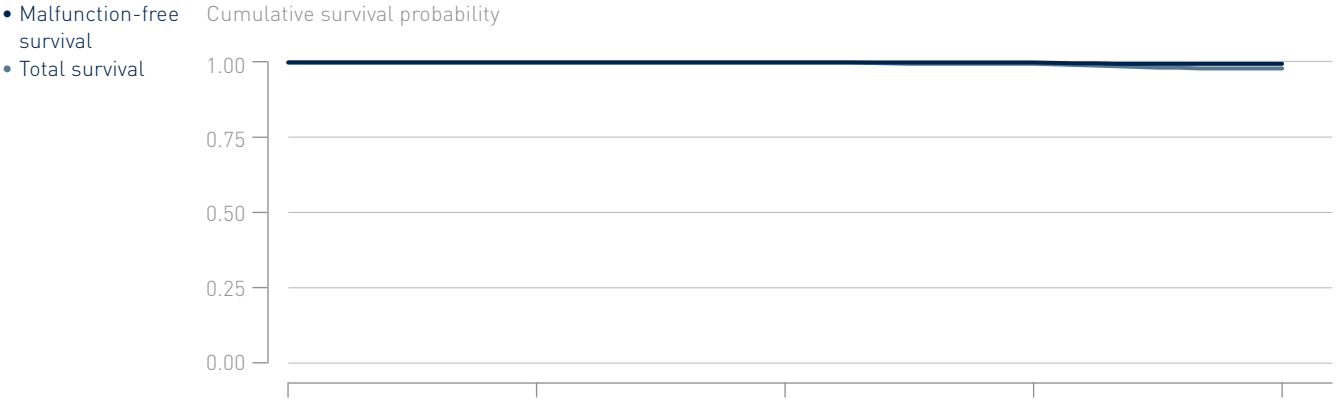
Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.9	99.6
CI [±%]	-	0.1	0.2	0.4
Malfunction-Free [%]	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1
Sample Size	2956	2419	1506	546

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

Inventra 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	45
US Market Release	Aug 2014
CE Market Release	Jul 2014
Worldwide Distributed Devices	2 110
Registered U.S. Implants	887
Estimated Active U.S. Implants	543
U.S. Normal Battery Depletions	9

	Quantity	Rate
U.S. Confirmed Malfunctions*	6	0.68%
Therapy Compromised	0	0.00%
Therapy Available	6	0.68%



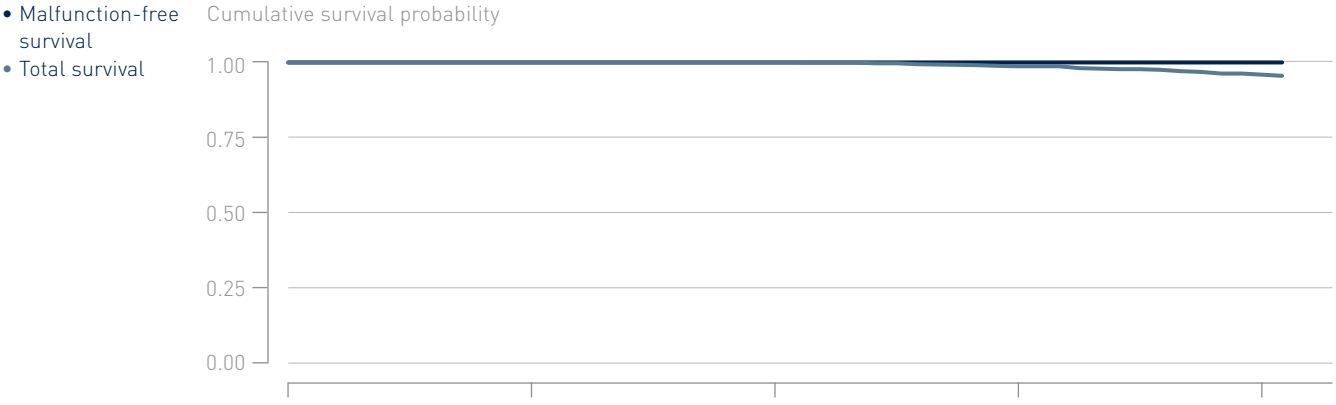
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.5	97.8
CI [±%]	-	< 0.1	< 0.1	0.6	1.4
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.3
CI [±%]	-	< 0.1	< 0.1	< 0.1	0.8
Sample Size	887	760	656	489	215

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

Iperia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	3 040
Registered U.S. Implants	1 479
Estimated Active U.S. Implants	956
U.S. Normal Battery Depletions	36

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



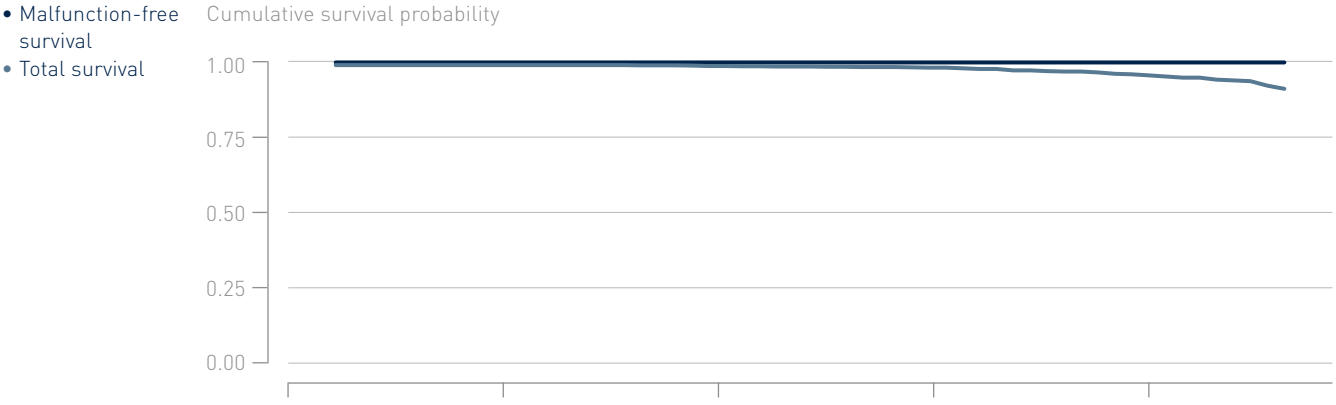
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	98.7	95.7
CI [±%]	-	< 0.1	< 0.1	0.8	1.8
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 479	1 296	1 115	746	253

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

Iperia 7 DF4

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2016
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 830
Registered U.S. Implants	1 617
Estimated Active U.S. Implants	963
U.S. Normal Battery Depletions	52

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



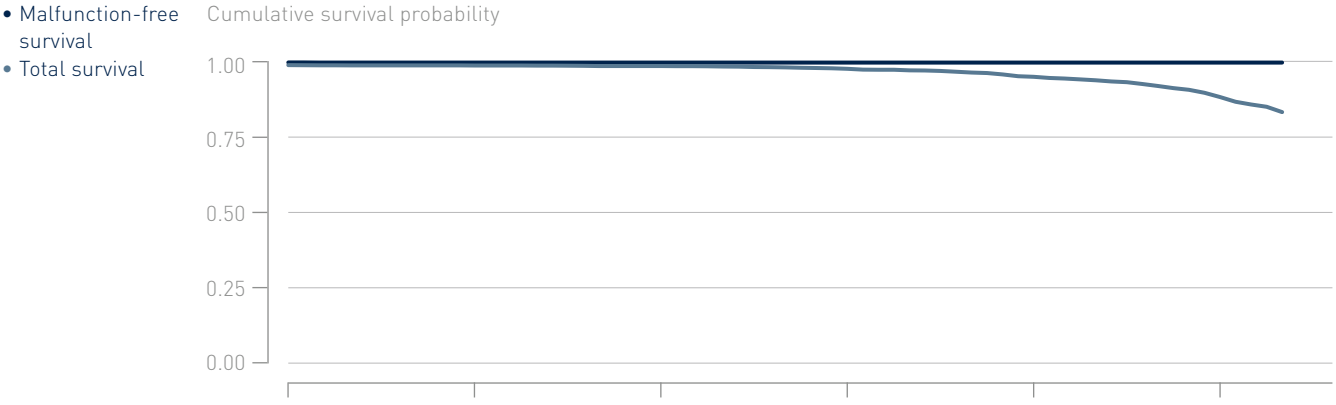
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.6	99.1	96.5
CI [±%]	-	< 0.1	0.3	0.5	1.3
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	1 617	1 415	1 225	920	534

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

Itrevia 7

Product Versions	HF-T
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	4 600
Registered U.S. Implants	3 316
Estimated Active U.S. Implants	1 730
U.S. Normal Battery Depletions	186

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



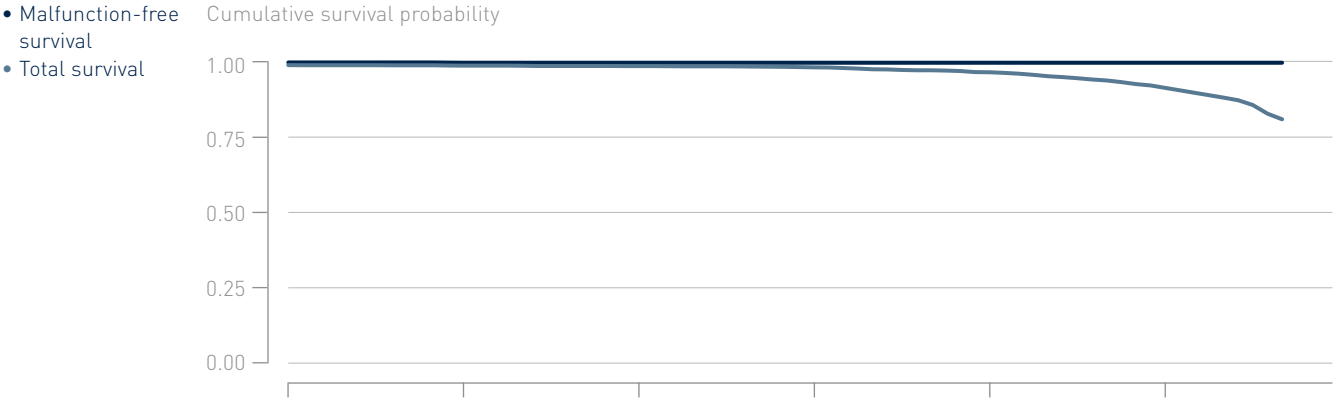
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.9	99.7	98.8	96.1	89.2
CI [±%]	-	0.1	0.2	0.4	0.9	1.8
Malfunction-Free [%]	100	100	100	100	100	100
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Sample Size	3316	2901	2572	2211	1528	631

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

Itrevia 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 680
Registered U.S. Implants	3 228
Estimated Active U.S. Implants	1 580
U.S. Normal Battery Depletions	195

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



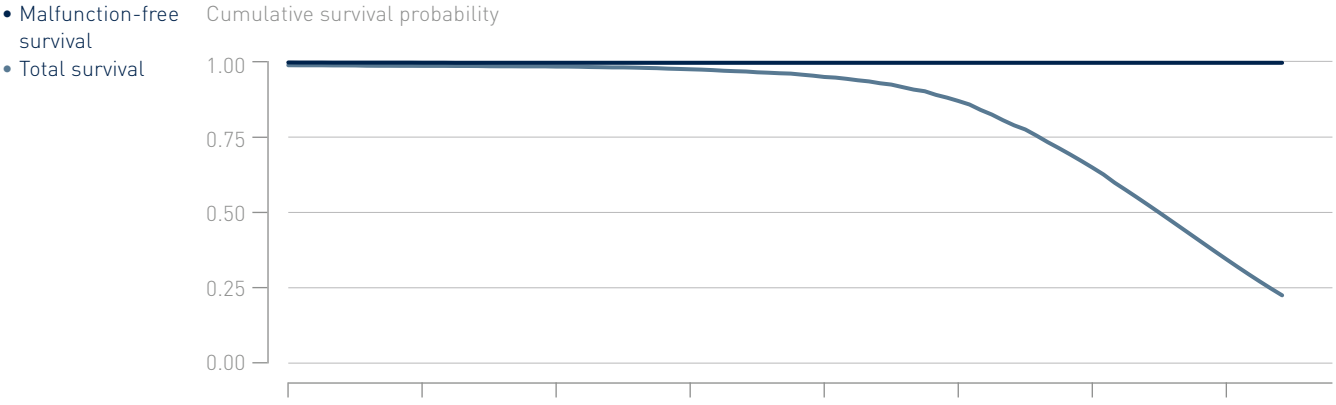
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.7	99.2	97.6	92.3
CI [±%]	-	0.1	0.2	0.3	0.6	1.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1
Sample Size	3 228	2 813	2 502	2 228	1 847	1 108

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

Lumax 340

Product Versions	HF, HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20700
Registered U.S. Implants	5310
Estimated Active U.S. Implants	502
U.S. Normal Battery Depletions	1271

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

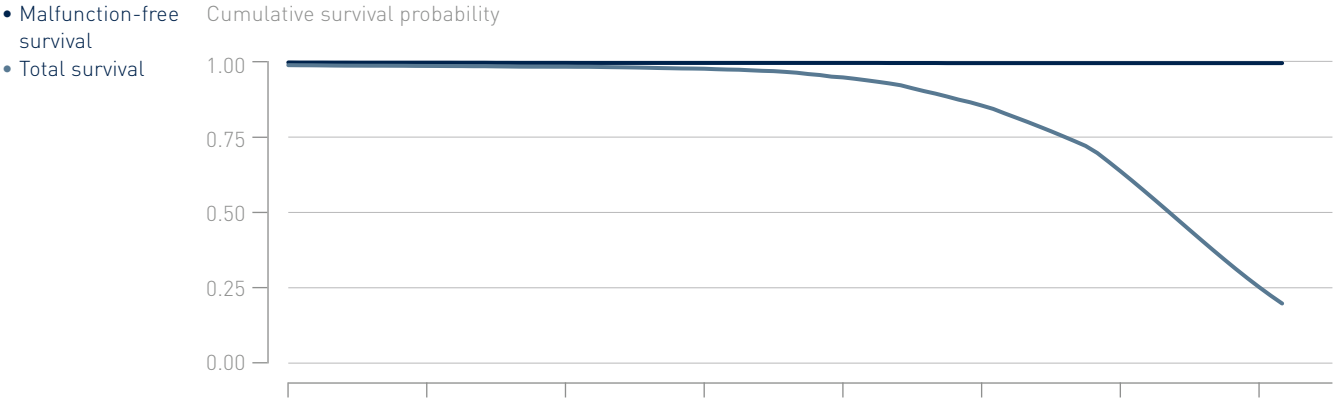


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.6	96.1	88.1	65.9	35.3
CI [±%]	-	0.1	0.2	0.4	0.6	1.1	1.9	2.4
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	5310	4713	4208	3688	3158	2439	1468	571

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	953
U.S. Normal Battery Depletions	2 589

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

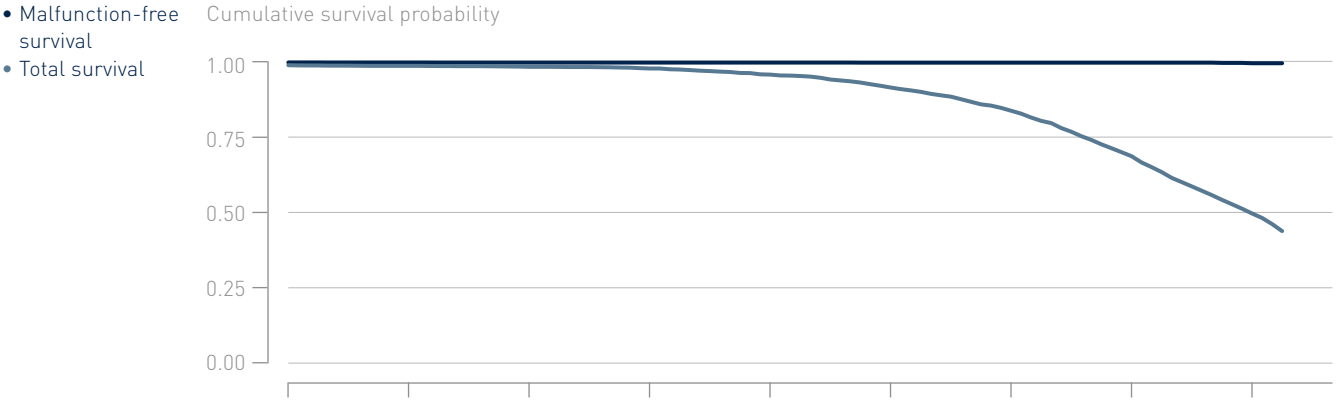


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	98.8	95.9	86.5	64.7	26.0
CI [±%]	-	0.1	0.2	0.3	0.5	0.9	1.4	1.9
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	8 656	7 647	6 823	6 044	5 200	4 126	2 695	685

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	743
U.S. Normal Battery Depletions	774

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.15%
Therapy Compromised	3	0.09%
Therapy Available	2	0.06%

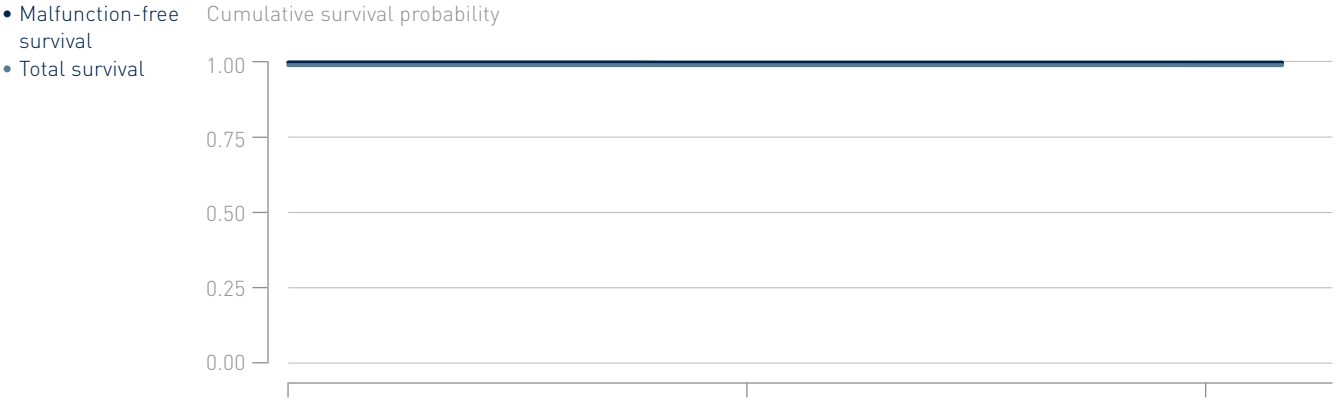


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.8	99.4	98.9	96.8	92.5	84.8	69.6	50.5
CI [±%]	-	0.2	0.3	0.4	0.7	1.1	1.6	2.2	2.7
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.5
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.5
Sample Size	3410	3023	2699	2395	2094	1777	1432	1016	465

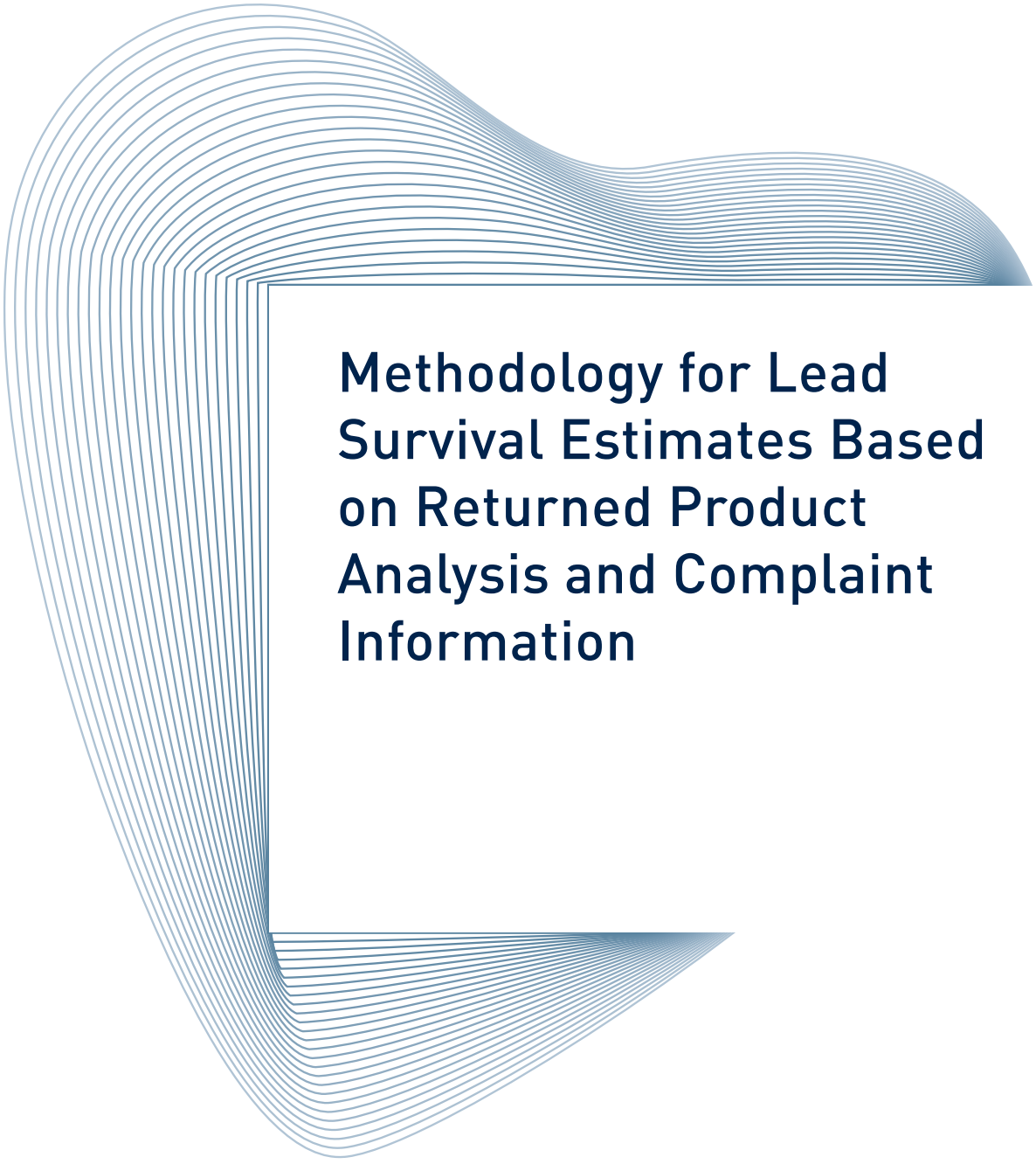
Rivacor 7 DF4

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	10 900
Registered U.S. Implants	4 281
Estimated Active U.S. Implants	3 720
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	99.9	99.8
CI [±%]	-	0.1	0.4
Malfunction-Free [%]	100	100	100
CI [±%]	-	0.1	0.1
Sample Size	4 281	2 187	551



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., patient-specific conditions or implant techniques).

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

5.2 Lead Data Acquisition

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

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is December 31, 2021. 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.

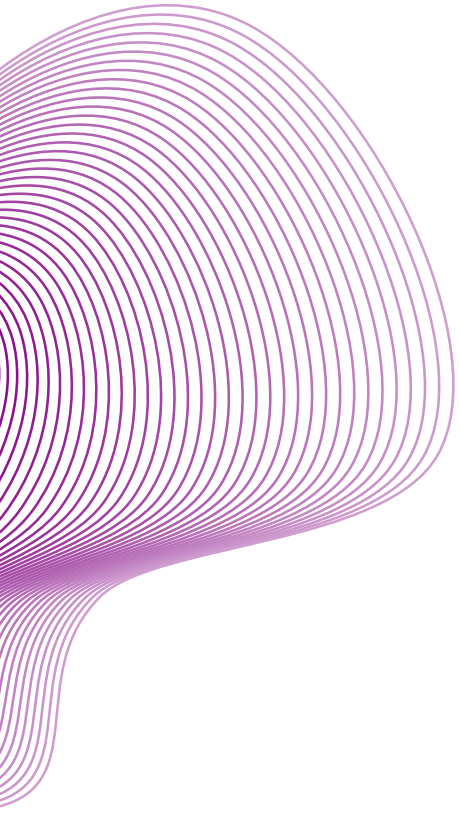
1 Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

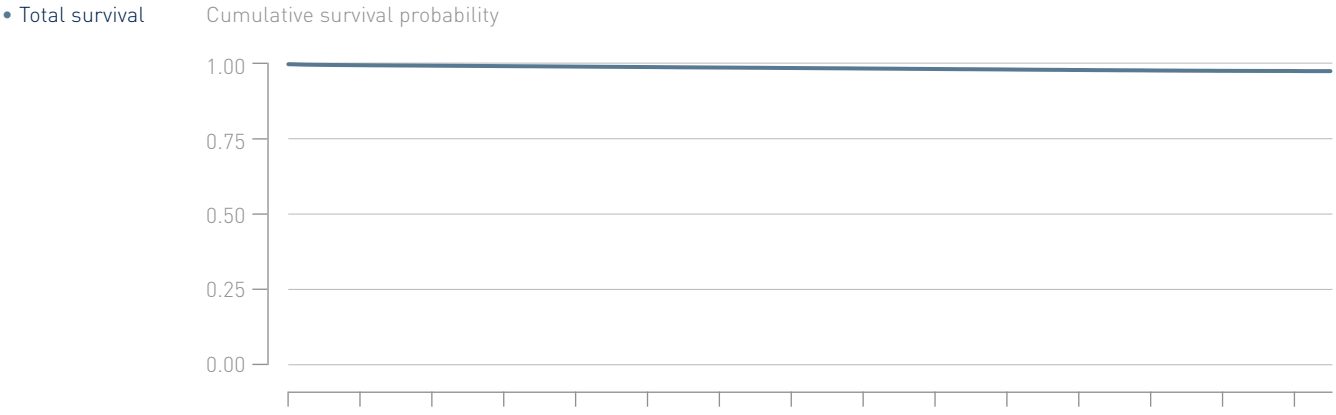


Dextrus

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	379 534
Estimated Active U.S. Implants	219 000
U.S. Total Returned	2 429

	Quantity	Rate
U.S. Qualifying Complications	4,817	1.25%
Abnormal pacing impedance	442	0.12%
Cardiac perforation	25	0.01%
Conductor fracture	136	0.04%
Extracardiac stimulation	23	0.01%
Failure to capture	1,193	0.31%
Failure to sense	181	0.05%
Insulation breach	91	0.02%
Lead dislodgement	574	0.15%
Oversensing	1,298	0.34%
Other	854	0.22%

	Quantity	Rate
U.S. Confirmed Malfunctions	376	0.10%
Conductor Fracture	126	0.03%
Insulation Breach	243	0.06%
Other	7	0.00%
U.S. Acute Lead Observations	1,733	0.45%
Abnormal pacing impedance	44	0.01%
Cardiac perforation	71	0.02%
Extracardiac stimulation	16	0.00%
Failure to capture	249	0.06%
Failure to sense	68	0.02%
Insulation breach	10	0.00%
Lead dislodgement	701	0.18%
Oversensing	47	0.01%
Other	527	0.14%



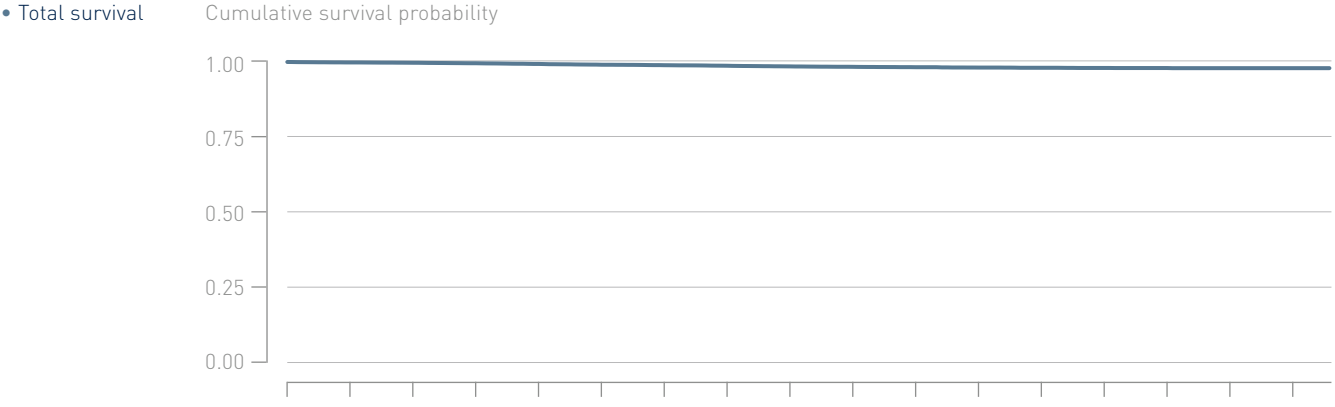
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.6	99.5	99.3	99.1	99.0	98.8	98.6	98.4	98.2	98.1	97.9	97.7	97.6	97.5
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	379534	336351	314668	295247	278324	262244	234588	192668	153166	118622	90760	66396	43758	22745	6059

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	16 620
Estimated Active U.S. Implants	12 200
U.S. Total Returned	127

	Quantity	Rate
U.S. Qualifying Complications	247	1.48%
Abnormal pacing impedance	39	0.23%
Cardiac perforation	1	0.01%
Conductor fracture	11	0.07%
Extracardiac stimulation	1	0.01%
Failure to capture	106	0.64%
Failure to sense	10	0.06%
Insulation breach	12	0.07%
Lead dislodgement	39	0.23%
Oversensing	9	0.05%
Other	19	0.11%

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	98.2	98.1	97.9	97.9	97.8	97.8	97.7	97.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	16620	15304	14674	14039	13331	12581	11773	10895	9673	8474	7291	6008	4768	3517	2361	1374	589

Selox SR

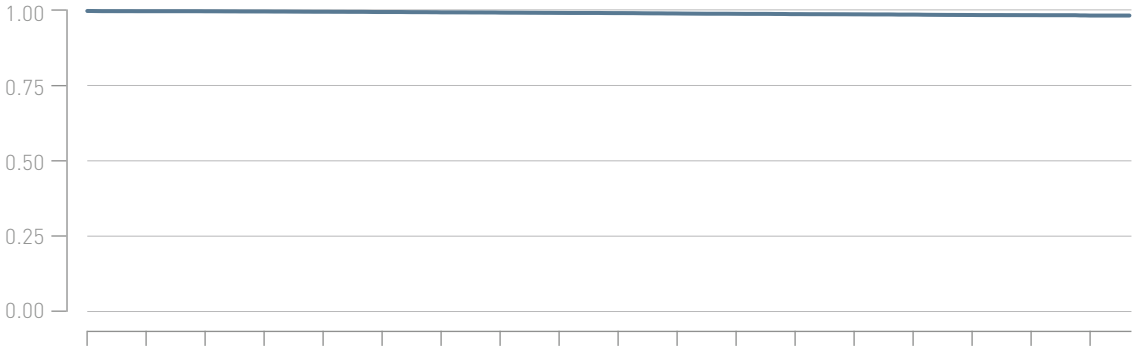
Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2004
CE Market Release	Feb 2004
Worldwide Distributed Devices	172 000
Registered U.S. Implants	14 344
Estimated Active U.S. Implants	7 020
U.S. Total Returned	63

	Quantity	Rate
U.S. Qualifying Complications	127	0.88%
Abnormal pacing impedance	10	0.07%
Conductor fracture	12	0.08%
Extracardiac stimulation	2	0.01%
Failure to capture	47	0.33%
Failure to sense	1	0.01%
Insulation breach	6	0.04%
Lead dislodgement	14	0.10%
Oversensing	21	0.15%
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%

• Total survival

Cumulative survival probability



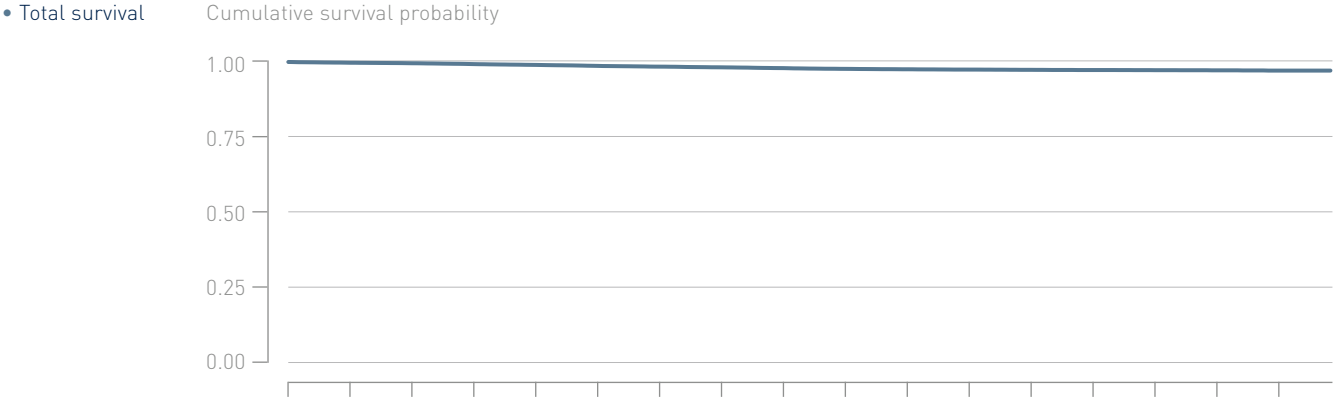
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6	98.5	98.4	98.2
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.4
Sample Size	14344	12432	11658	10861	10043	9355	8736	8240	7880	7607	7400	7222	7139	7074	7009	6941	5833	638

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	32137
Estimated Active U.S. Implants	22 600
U.S. Total Returned	181

	Quantity	Rate
U.S. Qualifying Complications	638	1.98%
Abnormal pacing impedance	144	0.45%
Cardiac perforation	3	0.01%
Conductor fracture	66	0.21%
Extracardiac stimulation	6	0.02%
Failure to capture	310	0.96%
Failure to sense	1	0.00%
Insulation breach	39	0.12%
Lead dislodgement	24	0.07%
Oversensing	17	0.05%
Other	28	0.09%

	Quantity	Rate
U.S. Confirmed Malfunctions	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	16
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.5	97.4	97.3	97.2	97.1	97.1	97.0	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	0.2	0.2	0.2	0.3
Sample Size	32137	29233	27730	26323	24820	23439	21991	20445	18315	16047	13755	11326	9126	7014	4972	3188	1488

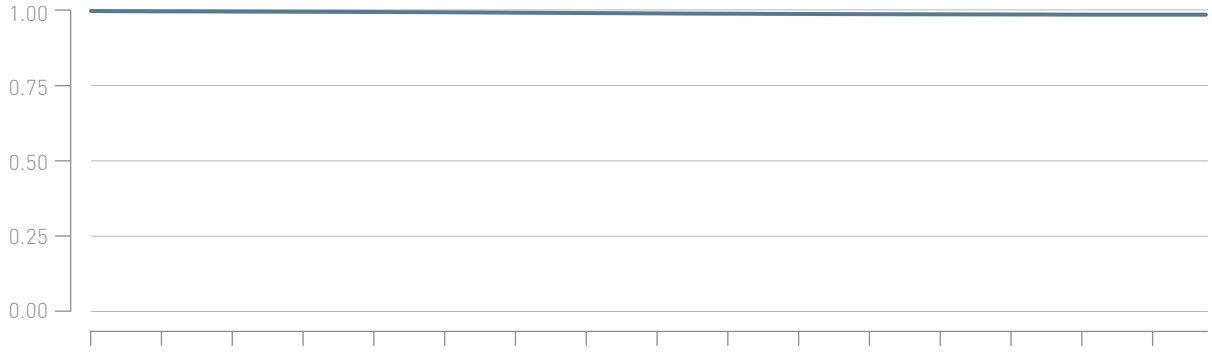
Setrox S

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	245 627
Estimated Active U.S. Implants	195 000
U.S. Total Returned	1 739

	Quantity	Rate
U.S. Qualifying Complications	1,952	0.79%
Abnormal pacing impedance	173	0.07%
Cardiac perforation	9	0.00%
Conductor fracture	129	0.05%
Extracardiac stimulation	12	0.00%
Failure to capture	667	0.27%
Failure to sense	58	0.02%
Insulation breach	83	0.03%
Lead dislodgement	357	0.15%
Oversensing	327	0.13%
Other	137	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	204	0.08%
Conductor Fracture	62	0.03%
Insulation Breach	136	0.06%
Other	6	0.00%
U.S. Acute Lead Observations	273	0.11%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	24	0.01%
Failure to capture	35	0.01%
Failure to sense	3	0.00%
Insulation breach	4	0.00%
Lead dislodgement	189	0.08%
Oversensing	1	0.00%
Other	16	0.01%

• Total survival Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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	98.5
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	245627	229379	220556	213324	207258	200530	175458	142206	116192	94462	73829	55435	38556	24128	12524	4350

Siello S / Solia S

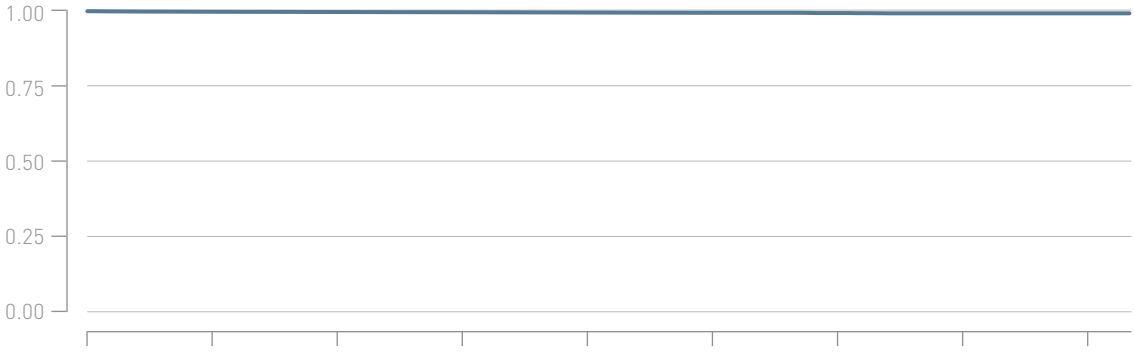
Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 134 000
Registered U.S. Implants	199 855
Estimated Active U.S. Implants	189 000
U.S. Total Returned	916

	Quantity	Rate
U.S. Qualifying Complications	802	0.40%
Abnormal pacing impedance	49	0.02%
Cardiac perforation	18	0.01%
Conductor fracture	22	0.01%
Extracardiac stimulation	9	0.00%
Failure to capture	213	0.11%
Failure to sense	39	0.02%
Insulation breach	13	0.01%
Lead dislodgement	330	0.16%
Oversensing	78	0.04%
Other	31	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	46	0.02%
Conductor Fracture	16	0.01%
Insulation Breach	23	0.01%
Other	7	0.00%
U.S. Acute Lead Observations	409	0.20%
Abnormal pacing impedance	6	0.00%
Cardiac perforation	34	0.02%
Conductor fracture	1	0.00%
Extracardiac stimulation	1	0.00%
Failure to capture	71	0.04%
Failure to sense	9	0.00%
Insulation breach	3	0.00%
Lead dislodgement	250	0.12%
Oversensing	10	0.00%
Other	24	0.01%

• Total survival

Cumulative survival probability



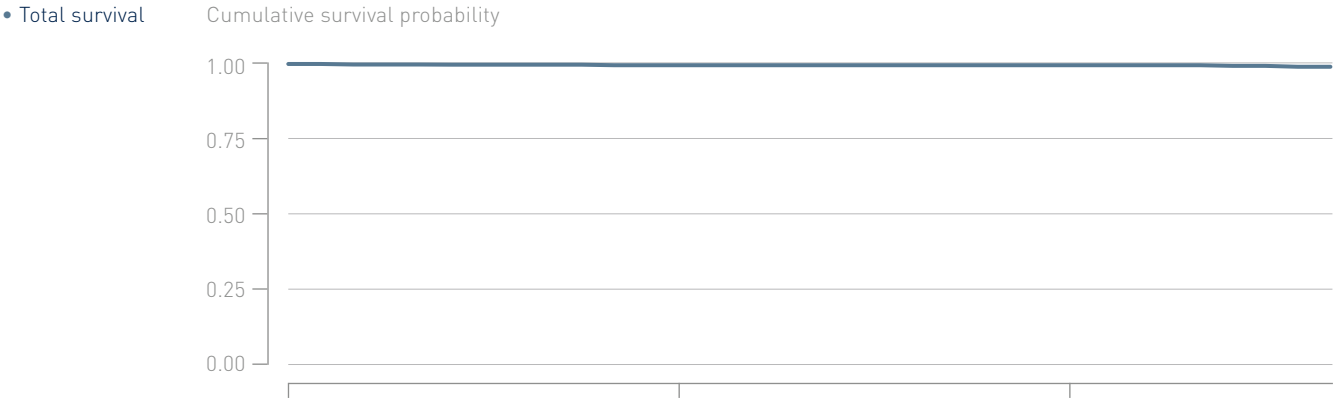
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.8	99.6	99.5	99.4	99.3	99.2	99.1	99.1
CI [±%]	-	<0.1	<0.1	<0.1	<0.1	0.1	0.2	0.2	0.2
Sample Size	199 855	160 631	127 871	89 767	50 839	15 954	2 405	1 809	476

Siello JT / Solia JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	138 000
Registered U.S. Implants	1 930
Estimated Active U.S. Implants	1 800
U.S. Total Returned	10

	Quantity	Rate
U.S. Qualifying Complications	10	0.52%
Conductor fracture	1	0.05%
Failure to capture	3	0.16%
Failure to sense	1	0.05%
Insulation breach	1	0.05%
Lead dislodgement	4	0.21%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	13	0.67%
Failure to capture	1	0.05%
Lead dislodgement	12	0.62%

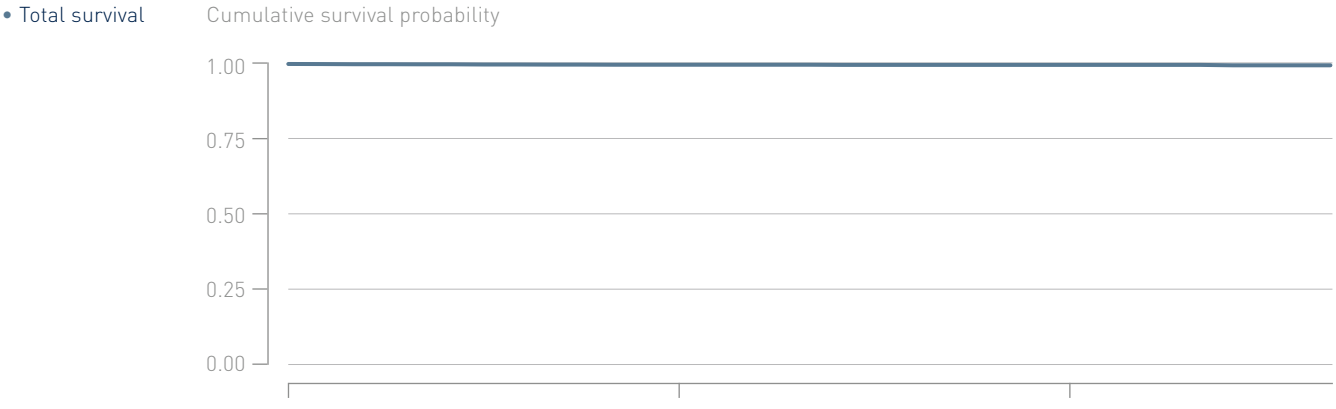


Years after implant	0	1	2
Total [%]	100.0	99.5	99.5
CI [±%]	-	0.4	0.4
Sample Size	1 930	1 235	665

Siello T / Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	205 000
Registered U.S. Implants	2 512
Estimated Active U.S. Implants	2 330
U.S. Total Returned	8

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	10	0.40%	**U.S. Confirmed Malfunctions**	0	0.00%
Abnormal pacing impedance	2	0.08%	**U.S. Acute Lead Observations**	9	0.36%
Failure to capture	5	0.20%	Failure to capture	3	0.12%
Lead dislodgement	3	0.12%	Lead dislodgement	6	0.24%



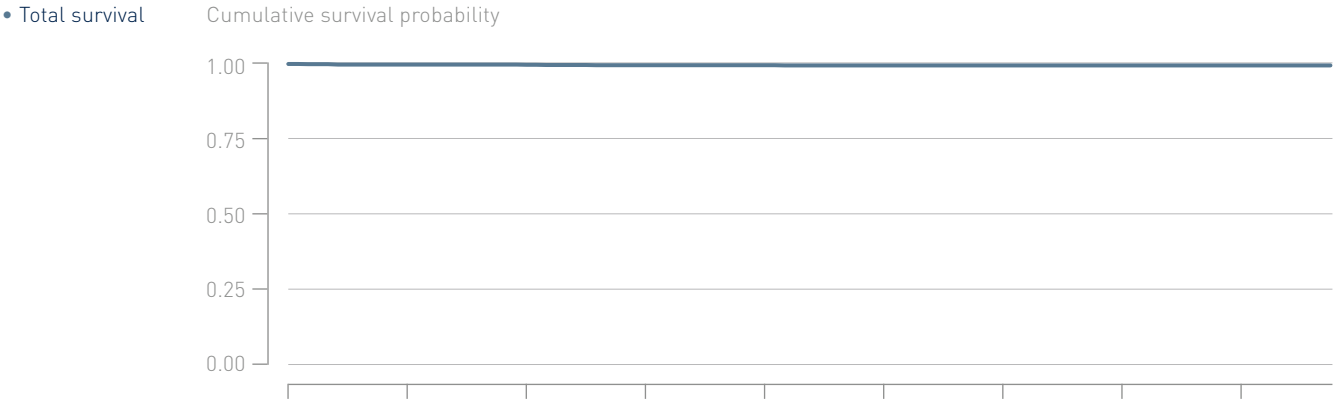
Years after implant	0	1	2
Total [%]	100.0	99.6	99.5
CI [±%]	-	0.3	0.3
Sample Size	2512	1592	811

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	1016
Estimated Active U.S. Implants	947
U.S. Total Returned	0

	Quantity	Rate
U.S. Qualifying Complications	7	0.69%
Abnormal pacing impedance	2	0.20%
Failure to capture	2	0.20%
Lead dislodgement	3	0.30%

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



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3
CI [±%]	-	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1016	995	984	940	879	816	653	507	356

Tilda R

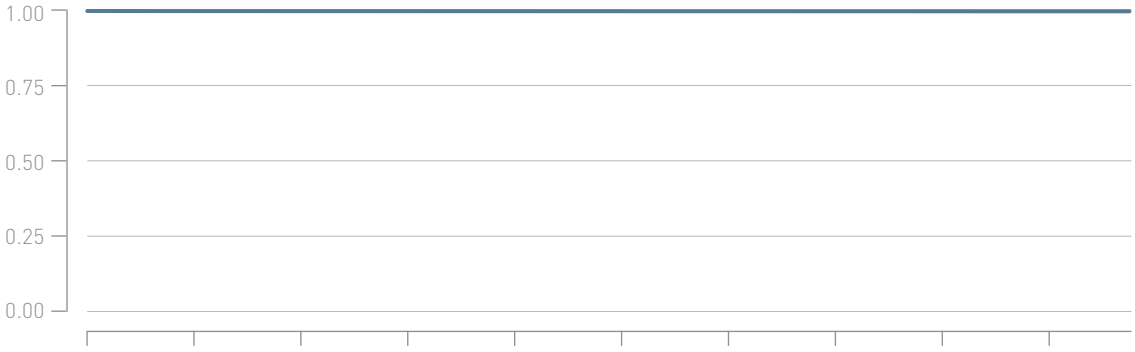
Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41300
Registered U.S. Implants	12640
Estimated Active U.S. Implants	11800
U.S. Total Returned	16

	Quantity	Rate
U.S. Qualifying Complications	36	0.28%
Abnormal pacing impedance	1	0.01%
Conductor fracture	6	0.05%
Extracardiac stimulation	1	0.01%
Failure to capture	8	0.06%
Insulation breach	2	0.02%
Lead dislodgement	9	0.07%
Oversensing	5	0.04%
Other	4	0.03%

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

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	12640	12282	12101	11800	11275	10115	8333	6951	4884	2534

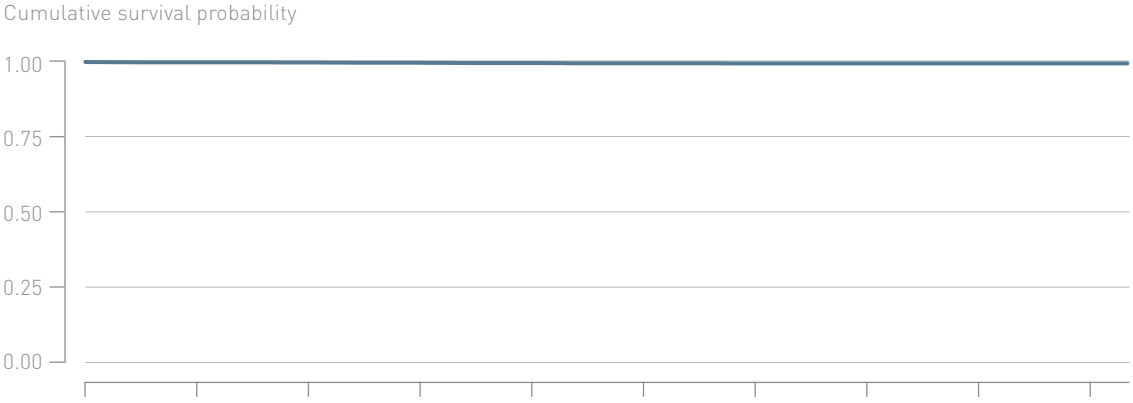
Tilda T

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	1 653
Estimated Active U.S. Implants	1 510
U.S. Total Returned	2

	Quantity	Rate
U.S. Qualifying Complications	11	0.67%
Abnormal pacing impedance	4	0.24%
Conductor fracture	2	0.12%
Insulation breach	1	0.06%
Lead dislodgement	4	0.24%

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

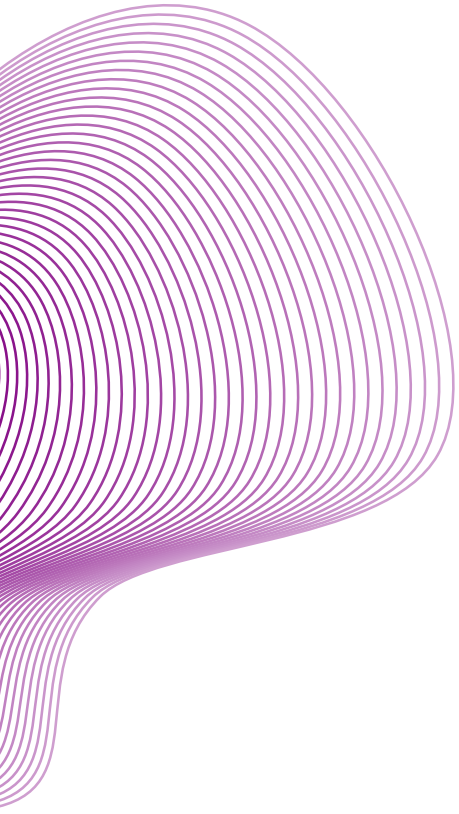
• Total survival



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.8	99.6	99.5	99.4	99.3	99.3	99.3	99.3
CI [±%]	-	0.2	0.2	0.3	0.3	0.4	0.4	0.4	0.4	0.4
Sample Size	1 653	1 602	1 582	1 536	1 487	1 377	1 138	993	702	321

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

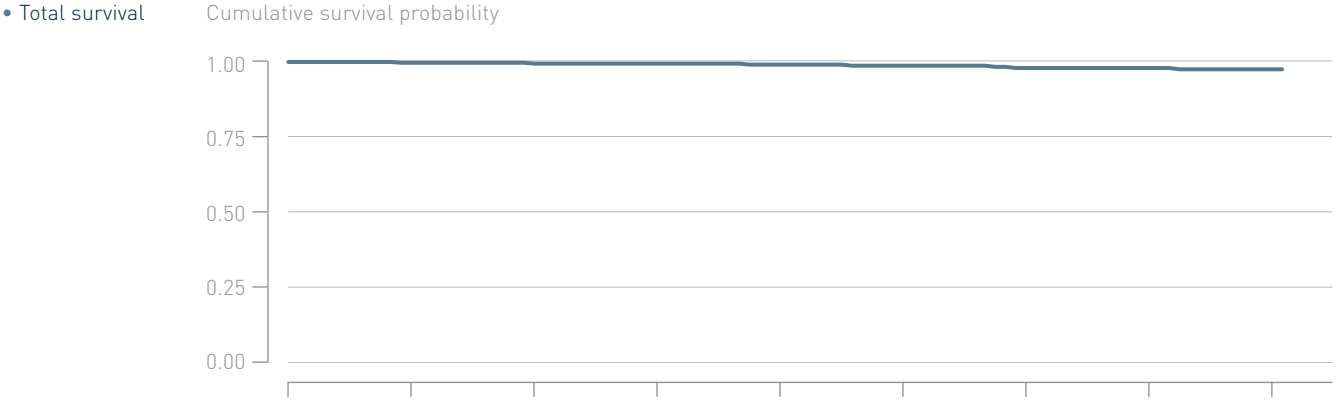


Kentrox RV

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	171
U.S. Total Returned	8

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

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



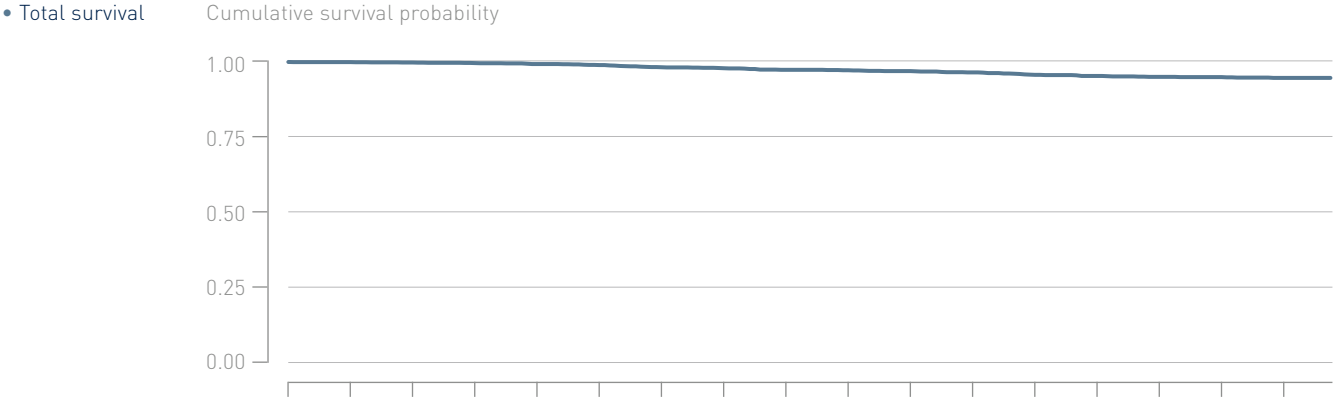
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	99.4	99.0	98.6	97.8	97.8	97.3
CI [±%]	-	0.6	0.8	0.8	1.1	1.3	1.8	1.8	2
Sample Size	406	353	318	286	269	243	228	211	201

Kentrox SL-S

Product Versions	65/16, 18-Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8740
Registered U.S. Implants	2414
Estimated Active U.S. Implants	1210
U.S. Total Returned	42

	Quantity	Rate
U.S. Qualifying Complications	67	2.76%
Abnormal defibrillation impedance	2	0.08%
Abnormal pacing impedance	5	0.21%
Conductor fracture	6	0.25%
Failure to capture	3	0.12%
Failure to sense	1	0.04%
Insulation breach	3	0.12%
Lead dislodgement	2	0.08%
Oversensing	42	1.73%
Other	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%



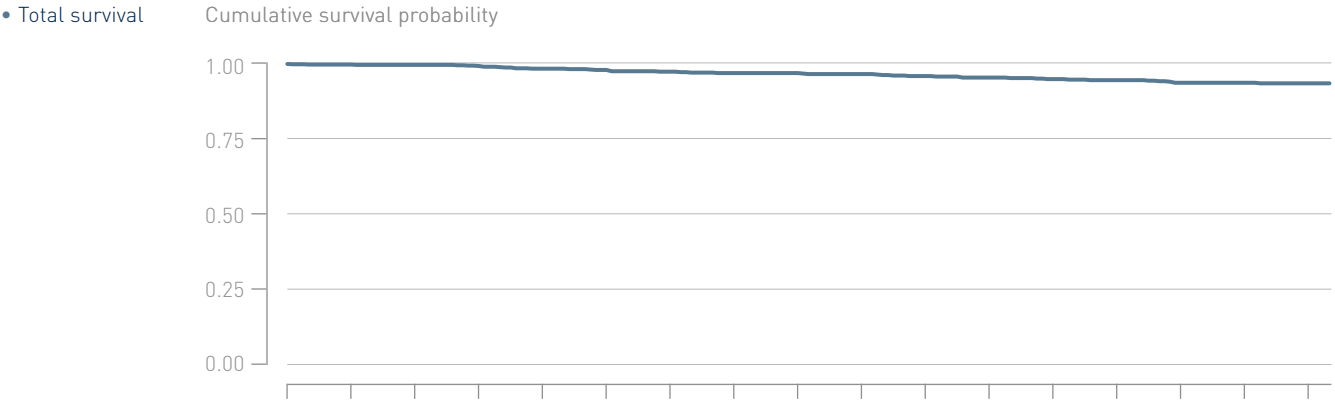
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	100.0	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.8	94.5
CI [±%]	-	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.1	1.2
Sample Size	2414	2176	2051	1891	1756	1632	1512	1432	1365	1325	1283	1260	1235	1221	1198	1159	763

Kentrox SL

Product Versions	65, 75, 100, -Steroid
Lead Type	dual coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Dec 2003 / Dec 2004
Worldwide Distributed Devices	8 440
Registered U.S. Implants	1 003
Estimated Active U.S. Implants	522
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	38	3.76%
Abnormal defibrillation impedance	1	0.10%
Abnormal pacing impedance	4	0.40%
Conductor fracture	3	0.30%
Failure to capture	4	0.40%
Insulation breach	6	0.59%
Oversensing	18	1.78%
Other	2	0.20%

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



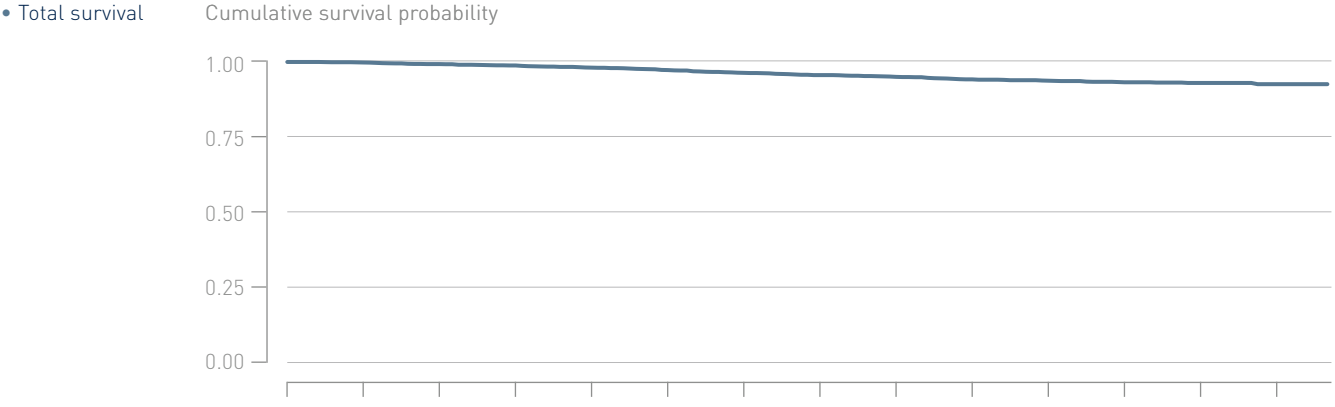
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.9	96.9	96.5	95.8	95.3	94.8	94.4	93.5	93.5	93.3
CI [±%]	-	0.3	0.4	0.6	0.9	1	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.9	2
Sample Size	1003	898	834	777	707	662	616	596	576	565	553	544	535	529	520	504	293

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	1 620
U.S. Total Returned	86

	Quantity	Rate
U.S. Qualifying Complications	90	3.61%
Abnormal defibrillation impedance	10	0.40%
Abnormal pacing impedance	6	0.24%
Conductor fracture	9	0.36%
Failure to capture	11	0.44%
Failure to sense	1	0.04%
Insulation breach	4	0.16%
Oversensing	43	1.72%
Other	6	0.24%

	Quantity	Rate
U.S. Confirmed Malfunctions	47	1.89%
Conductor Fracture	8	0.32%
Insulation Breach	39	1.56%
U.S. Acute Lead Observations	2	0.08%
Lead dislodgement	1	0.04%
Other	1	0.04%



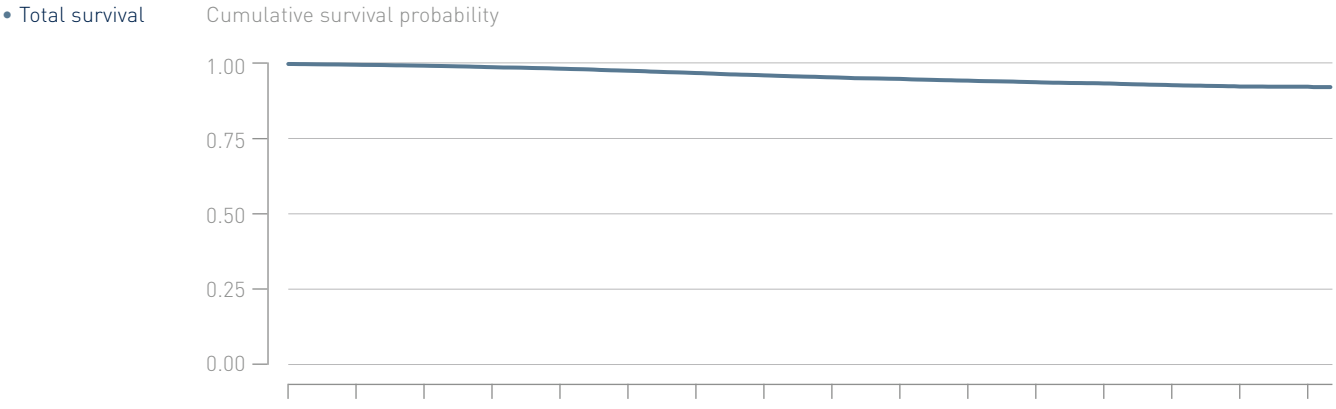
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.8	99.3	98.8	98.1	97.2	96.3	95.5	94.9	94.0	93.6	93.1	92.8	92.4
CI [±%]	-	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1	1.1	1.2	1.2	1.3
Sample Size	2 466	2 261	2 129	2 017	1 924	1 848	1 784	1 741	1 695	1 655	1 614	1 139	682	389

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	55100
Registered U.S. Implants	22096
Estimated Active U.S. Implants	14000
U.S. Total Returned	538

	Quantity	Rate
U.S. Qualifying Complications	924	4.15%
Abnormal defibrillation impedance	87	0.39%
Abnormal pacing impedance	66	0.30%
Cardiac perforation	3	0.01%
Conductor fracture	106	0.48%
Failure to capture	79	0.35%
Failure to sense	18	0.08%
Insulation breach	62	0.28%
Lead dislodgement	32	0.14%
Oversensing	423	1.90%
Other	48	0.22%

	Quantity	Rate
U.S. Confirmed Malfunctions	222	1.00%
Conductor Fracture	33	0.15%
Insulation Breach	187	0.84%
Other	2	0.01%
U.S. Acute Lead Observations	11	0.05%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	1	0.00%
Failure to capture	1	0.00%
Lead dislodgement	6	0.03%
Oversensing	1	0.00%
Other	1	0.00%



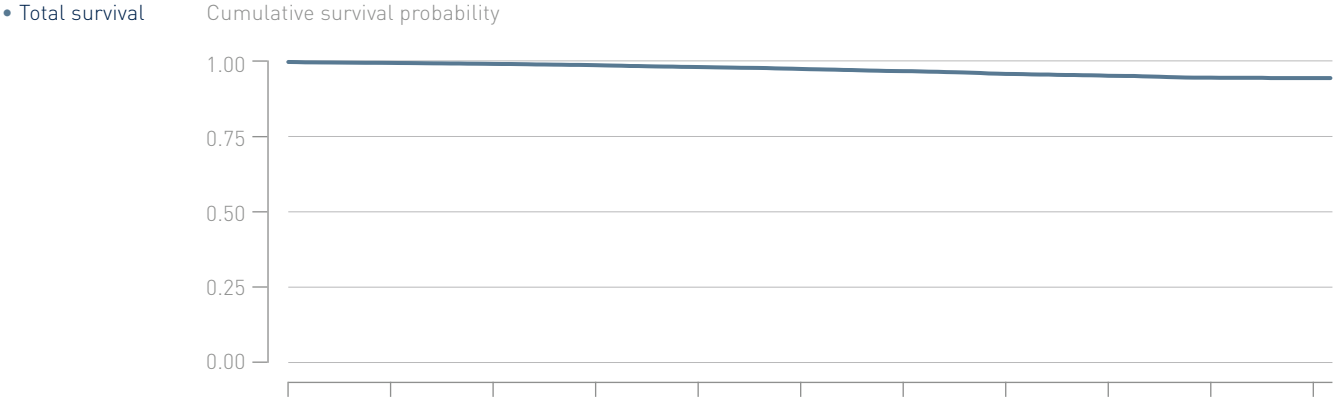
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.8	93.3	92.8	92.3	92.3
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.5
Sample Size	22096	20086	18847	17791	16943	16205	15604	15150	14796	14534	14267	12860	8778	5462	2734	813

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	7 599
Estimated Active U.S. Implants	6 080
U.S. Total Returned	202

	Quantity	Rate
U.S. Qualifying Complications	232	3.03%
Abnormal defibrillation impedance	15	0.20%
Abnormal pacing impedance	21	0.27%
Cardiac perforation	1	0.01%
Conductor fracture	29	0.38%
Failure to capture	24	0.31%
Failure to sense	11	0.14%
Insulation breach	5	0.07%
Lead dislodgement	14	0.18%
Oversensing	103	1.35%
Other	9	0.12%

	Quantity	Rate
U.S. Confirmed Malfunctions	78	1.02%
Conductor Fracture	13	0.17%
Insulation Breach	65	0.85%
U.S. Acute Lead Observations	10	0.13%
Abnormal pacing impedance	1	0.01%
Cardiac perforation	1	0.01%
Lead dislodgement	7	0.09%
Other	1	0.01%



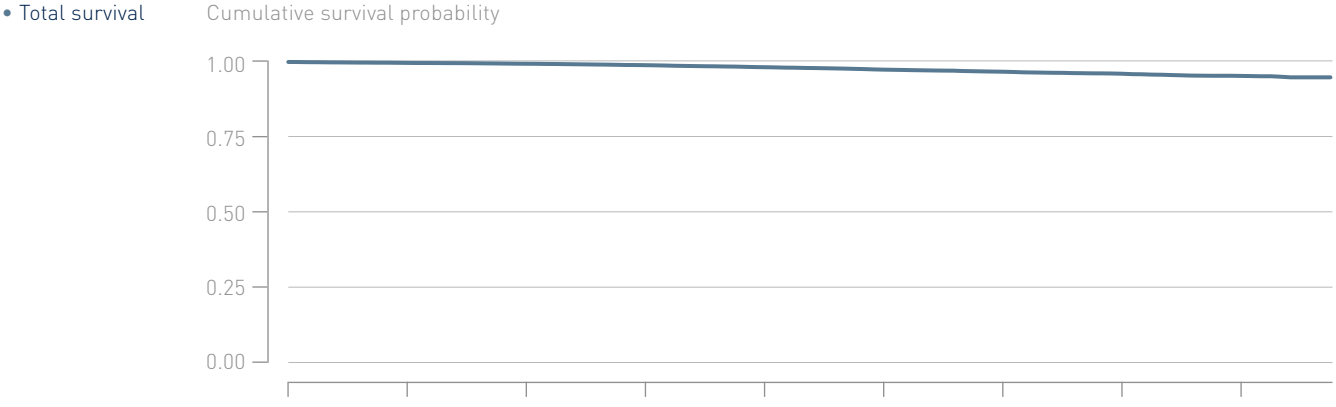
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.3	98.9	98.2	97.6	96.8	95.9	95.3	94.6	94.5
CI [±%]	-	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6
Sample Size	7599	7135	6874	6678	6491	6230	5792	4945	3456	1922	380

Linox^{smart} S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	16305
Estimated Active U.S. Implants	14200
U.S. Total Returned	370

	Quantity	Rate
U.S. Qualifying Complications	426	2.60%
Abnormal defibrillation impedance	53	0.32%
Abnormal pacing impedance	30	0.18%
Conductor fracture	44	0.27%
Failure to capture	36	0.22%
Failure to sense	16	0.10%
Insulation breach	7	0.04%
Lead dislodgement	47	0.29%
Oversensing	183	1.12%
Other	10	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	114	0.69%
Conductor Fracture	9	0.05%
Insulation Breach	103	0.63%
Other	2	0.01%
U.S. Acute Lead Observations	39	0.24%
Cardiac perforation	4	0.02%
Failure to capture	9	0.05%
Lead dislodgement	16	0.10%
Oversensing	3	0.02%
Other	7	0.04%



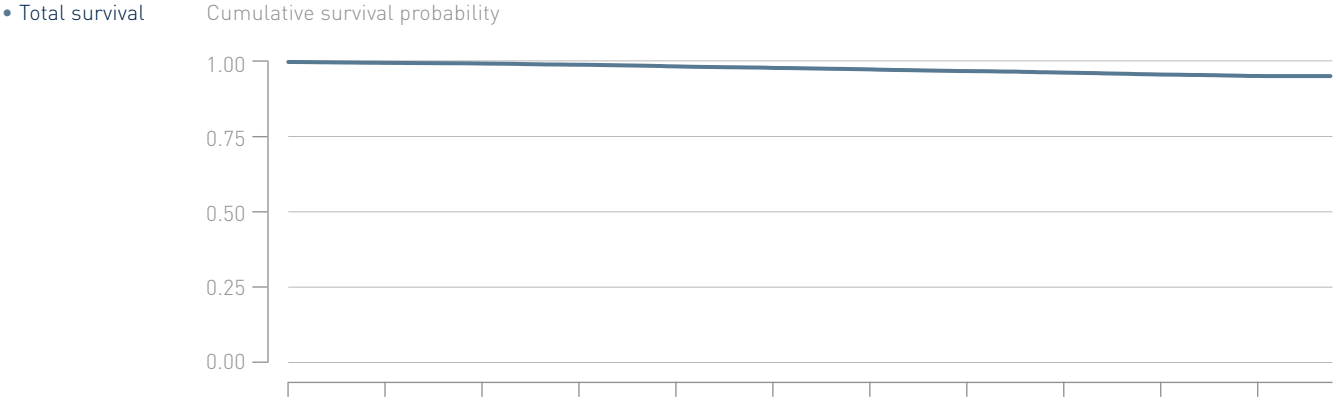
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	98.9	98.2	97.4	96.6	96.0	95.2
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.5
Sample Size	16305	15519	15208	14886	14318	11778	8030	4947	2011

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	13 129
Estimated Active U.S. Implants	10 400
U.S. Total Returned	267

	Quantity	Rate
U.S. Qualifying Complications	390	2.94%
Abnormal defibrillation impedance	36	0.27%
Abnormal pacing impedance	27	0.20%
Cardiac perforation	1	0.01%
Conductor fracture	47	0.35%
Extracardiac stimulation	1	0.01%
Failure to capture	31	0.23%
Failure to sense	11	0.08%
Insulation breach	10	0.08%
Lead dislodgement	26	0.20%
Oversensing	191	1.44%
Other	9	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	82	0.62%
Conductor Fracture	10	0.08%
Insulation Breach	70	0.53%
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%



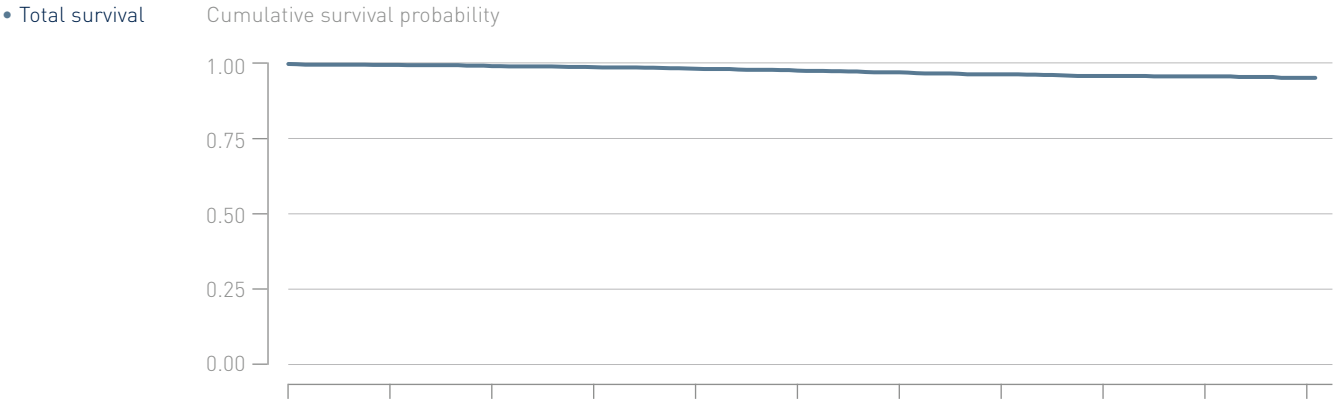
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.5	99.0	98.5	97.9	97.4	96.8	96.3	95.6	95.2
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.5
Sample Size	13 129	12 176	11 792	11 438	11 115	10 758	10 291	9 549	8 091	5 815	2 457

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	990
U.S. Total Returned	22

	Quantity	Rate
U.S. Qualifying Complications	46	3.61%
Abnormal defibrillation impedance	8	0.63%
Abnormal pacing impedance	5	0.39%
Conductor fracture	3	0.24%
Failure to capture	9	0.71%
Insulation breach	2	0.16%
Lead dislodgement	4	0.31%
Oversensing	14	1.10%
Other	1	0.08%

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



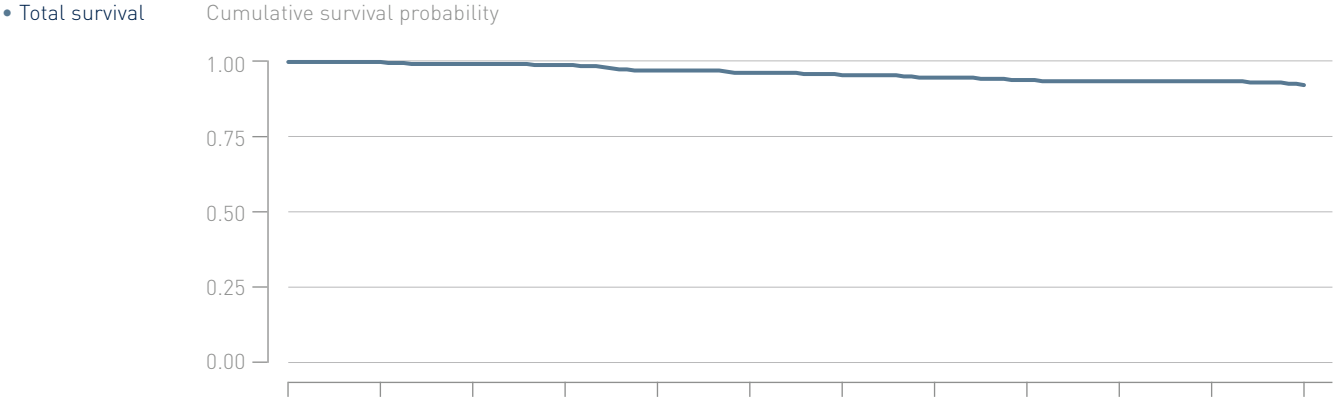
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.2	98.9	98.3	97.7	97.1	96.4	95.8	95.7	95.2
CI [±%]	-	0.3	0.5	0.6	0.7	0.9	1	1.1	1.2	1.2	1.4
Sample Size	1 265	1 174	1 138	1 096	1 070	1 039	984	914	777	556	235

Linox T

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

	Quantity	Rate
U.S. Qualifying Complications	19	5.90%
Abnormal pacing impedance	3	0.93%
Conductor fracture	1	0.31%
Failure to capture	4	1.24%
Insulation breach	1	0.31%
Oversensing	9	2.80%
Other	1	0.31%

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



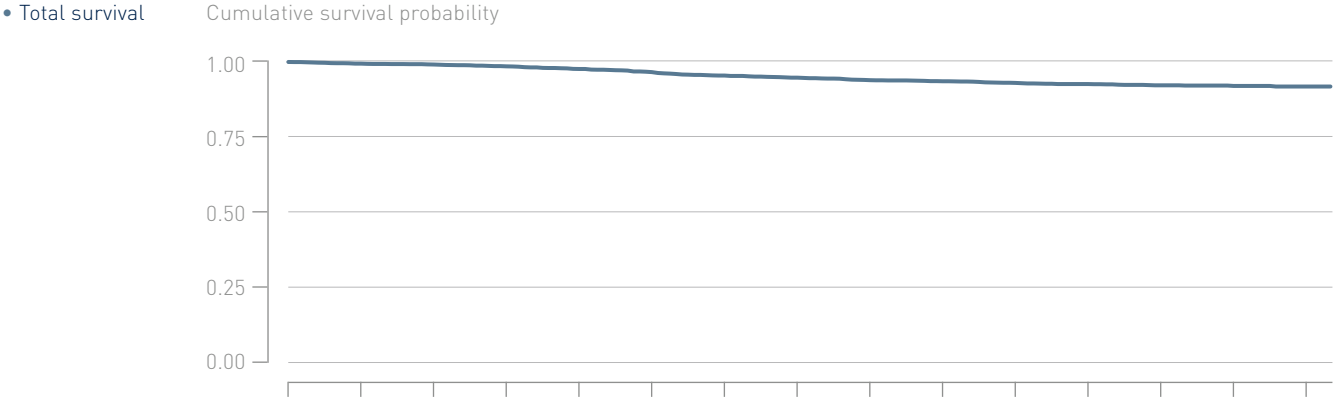
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4	93.4	92.1
CI [±%]	-	< 0.1	0.9	1.2	2	2.3	2.5	2.7	2.9	3	3	3.3
Sample Size	319	295	283	272	251	241	234	230	228	226	223	205

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	1 980
U.S. Total Returned	81

	Quantity	Rate
U.S. Qualifying Complications	149	4.88%
Abnormal defibrillation impedance	17	0.56%
Abnormal pacing impedance	14	0.46%
Cardiac perforation	1	0.03%
Conductor fracture	18	0.59%
Failure to capture	24	0.79%
Failure to sense	4	0.13%
Insulation breach	13	0.43%
Lead dislodgement	4	0.13%
Oversensing	51	1.67%
Other	3	0.10%

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



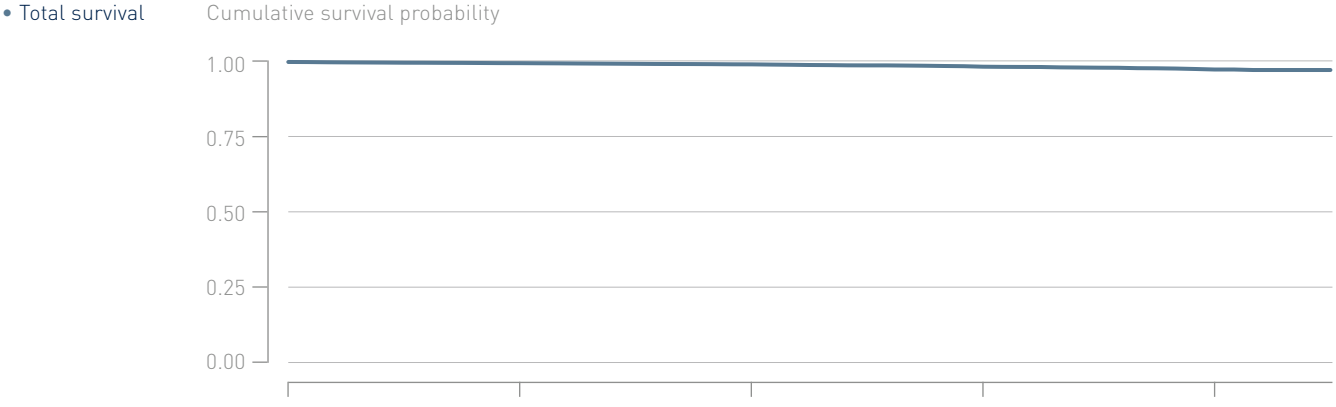
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.4	94.6	93.8	93.4	92.9	92.5	92.0	91.8	91.6
CI [±%]	-	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1	1	1	1.1	1.1	1.2	1.2
Sample Size	3022	2731	2599	2451	2338	2235	2145	2091	2056	2025	1972	1739	1217	737	314

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	109 000
Registered U.S. Implants	16 326
Estimated Active U.S. Implants	15 300
U.S. Total Returned	154

	Quantity	Rate
U.S. Qualifying Complications	160	0.98%
Abnormal defibrillation impedance	16	0.10%
Abnormal pacing impedance	2	0.01%
Cardiac perforation	1	0.01%
Conductor fracture	11	0.07%
Failure to capture	21	0.13%
Failure to sense	8	0.05%
Insulation breach	1	0.01%
Lead dislodgement	22	0.13%
Oversensing	70	0.43%
Other	8	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	31	0.19%
Conductor Fracture	5	0.03%
Insulation Breach	25	0.15%
Other	1	0.01%
U.S. Acute Lead Observations	38	0.23%
Abnormal pacing impedance	2	0.01%
Cardiac perforation	5	0.03%
Failure to capture	11	0.07%
Lead dislodgement	18	0.11%
Oversensing	2	0.01%



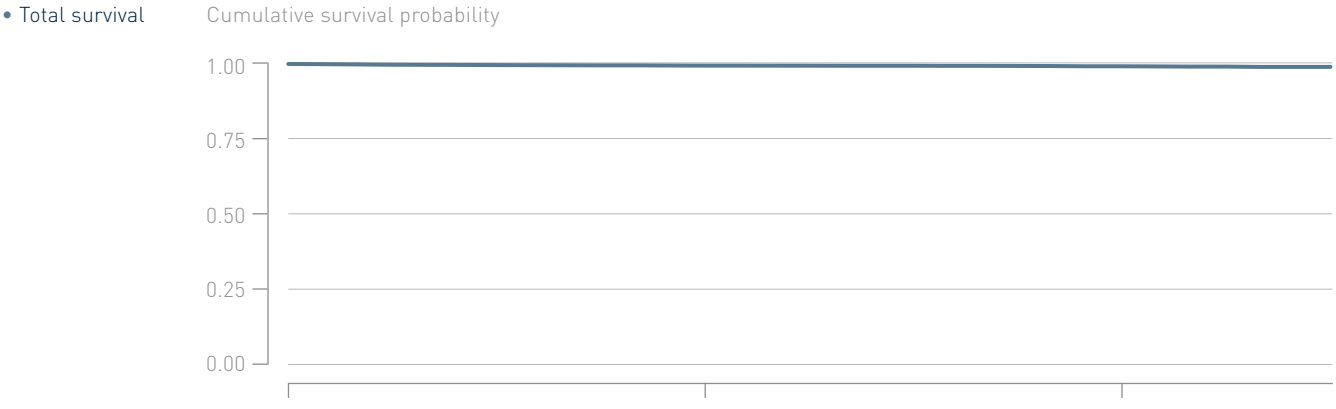
Years after implant	0	1	2	3	4
Total [%]	100.0	99.6	99.1	98.3	97.3
CI [±%]	-	0.1	0.2	0.3	0.5
Sample Size	16 326	12 418	8 888	5 025	1 600

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	23 500
Registered U.S. Implants	9 936
Estimated Active U.S. Implants	9 520
U.S. Total Returned	70

	Quantity	Rate
U.S. Qualifying Complications	59	0.59%
Abnormal defibrillation impedance	4	0.04%
Abnormal pacing impedance	2	0.02%
Cardiac perforation	1	0.01%
Failure to capture	7	0.07%
Failure to sense	4	0.04%
Insulation breach	1	0.01%
Lead dislodgement	23	0.23%
Oversensing	17	0.17%

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.06%
Conductor Fracture	1	0.01%
Insulation Breach	4	0.04%
Other	1	0.01%
U.S. Acute Lead Observations	35	0.35%
Failure to capture	8	0.08%
Failure to sense	4	0.04%
Lead dislodgement	17	0.17%
Oversensing	4	0.04%
Other	2	0.02%



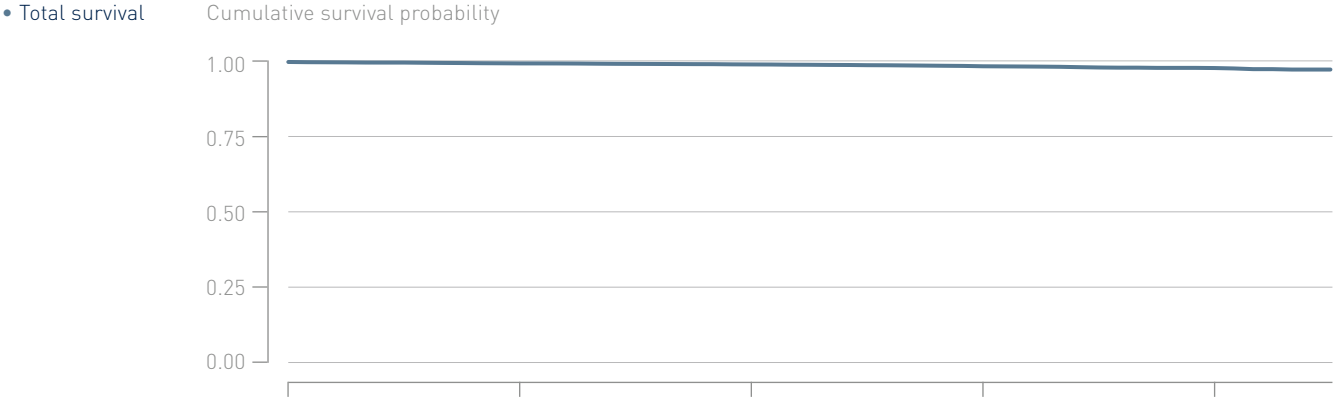
Years after implant	0	1	2
Total [%]	100.0	99.3	99.1
CI [±%]	-	0.2	0.3
Sample Size	9 936	5 355	1 890

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	21 700
Registered U.S. Implants	9 018
Estimated Active U.S. Implants	8 340
U.S. Total Returned	121

	Quantity	Rate
U.S. Qualifying Complications	115	1.27%
Abnormal defibrillation impedance	16	0.18%
Abnormal pacing impedance	2	0.02%
Conductor fracture	5	0.06%
Failure to capture	11	0.12%
Failure to sense	7	0.08%
Insulation breach	2	0.02%
Lead dislodgement	18	0.20%
Oversensing	52	0.57%
Other	2	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	33	0.36%
Conductor Fracture	2	0.02%
Insulation Breach	31	0.34%
U.S. Acute Lead Observations	21	0.23%
Abnormal defibrillation impedance	1	0.01%
Cardiac perforation	2	0.02%
Failure to capture	2	0.02%
Failure to sense	1	0.01%
Lead dislodgement	12	0.13%
Oversensing	1	0.01%
Other	2	0.02%



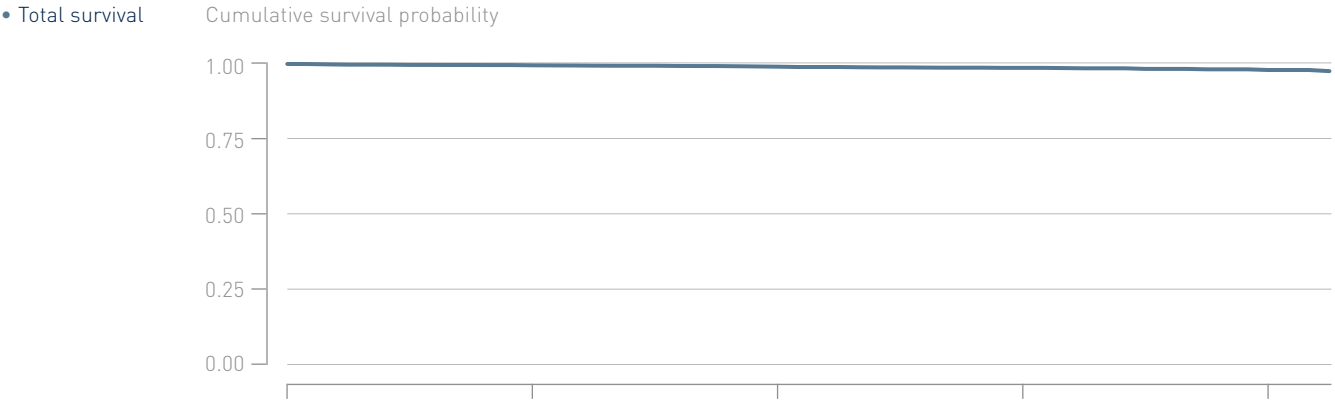
Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.1	98.5	97.8
CI [±%]	-	0.1	0.2	0.3	0.4
Sample Size	9 018	8 571	7 825	5 464	1 611

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	13300
Registered U.S. Implants	4337
Estimated Active U.S. Implants	4060
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	47	1.08%
Abnormal defibrillation impedance	6	0.14%
Abnormal pacing impedance	3	0.07%
Conductor fracture	1	0.02%
Extracardiac stimulation	1	0.02%
Failure to capture	3	0.07%
Failure to sense	2	0.05%
Insulation breach	2	0.05%
Lead dislodgement	7	0.16%
Oversensing	20	0.46%
Other	2	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.05%
Conductor Fracture	1	0.02%
Insulation Breach	1	0.02%
U.S. Acute Lead Observations	12	0.28%
Abnormal defibrillation impedance	2	0.05%
Abnormal pacing impedance	1	0.02%
Cardiac perforation	2	0.05%
Failure to capture	2	0.05%
Lead dislodgement	1	0.02%
Oversensing	2	0.05%
Other	2	0.05%



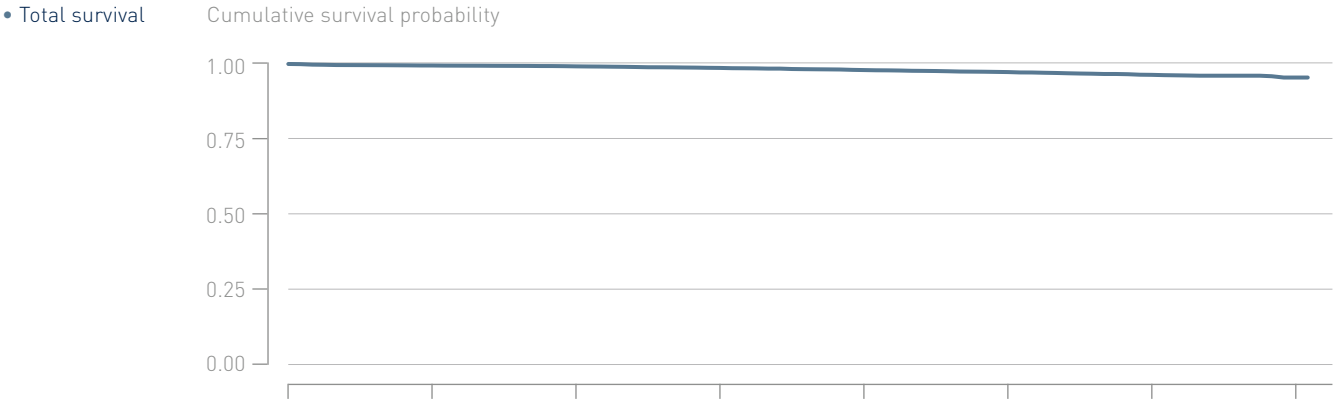
Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.0	98.6	97.8
CI [±%]	-	0.2	0.3	0.4	0.8
Sample Size	4337	3386	2522	1466	408

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	8 279
Estimated Active U.S. Implants	7 110
U.S. Total Returned	127

	Quantity	Rate
U.S. Qualifying Complications	193	2.32%
Abnormal defibrillation impedance	11	0.13%
Abnormal pacing impedance	8	0.10%
Cardiac perforation	1	0.01%
Conductor fracture	19	0.23%
Extracardiac stimulation	3	0.04%
Failure to capture	21	0.25%
Failure to sense	4	0.05%
Insulation breach	3	0.04%
Lead dislodgement	24	0.29%
Oversensing	94	1.13%
Other	5	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	53	0.64%
Conductor Fracture	10	0.12%
Insulation Breach	42	0.50%
Other	1	0.01%
U.S. Acute Lead Observations	28	0.34%
Cardiac perforation	2	0.02%
Extracardiac stimulation	1	0.01%
Failure to capture	3	0.04%
Lead dislodgement	13	0.16%
Other	9	0.11%



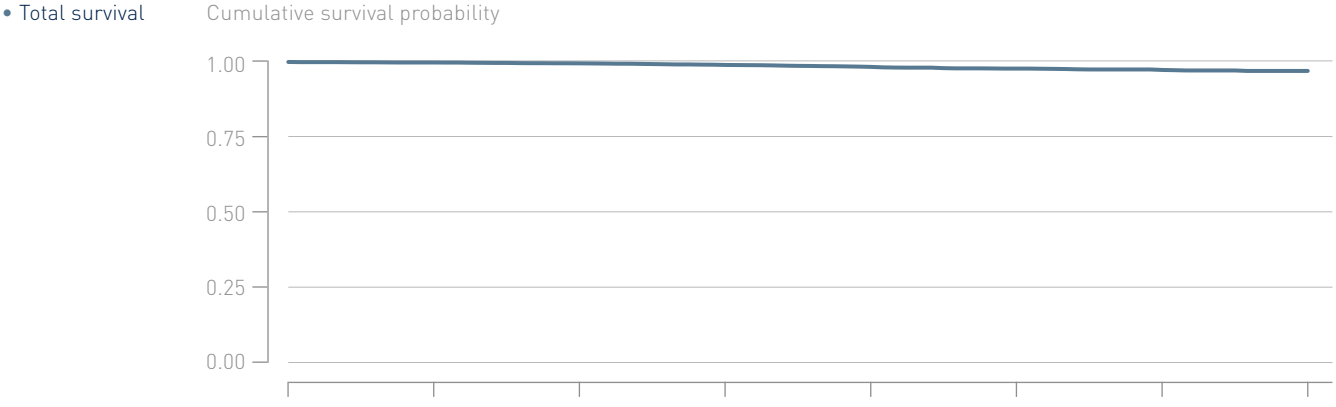
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.5	99.2	98.6	97.9	97.2	96.3	95.3
CI [±%]	-	0.2	0.2	0.3	0.3	0.4	0.5	0.9
Sample Size	8 279	7 789	7 599	7 405	6 937	5 005	2 077	333

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	18400
Registered U.S. Implants	3411
Estimated Active U.S. Implants	3000
U.S. Total Returned	44

	Quantity	Rate
U.S. Qualifying Complications	71	2.07%
Abnormal defibrillation impedance	7	0.20%
Abnormal pacing impedance	3	0.09%
Conductor fracture	9	0.26%
Failure to capture	8	0.23%
Failure to sense	2	0.06%
Insulation breach	1	0.03%
Lead dislodgement	4	0.12%
Oversensing	35	1.02%
Other	2	0.06%

	Quantity	Rate
U.S. Confirmed Malfunctions	13	0.38%
Conductor Fracture	1	0.03%
Insulation Breach	12	0.35%
U.S. Acute Lead Observations	3	0.09%
Lead dislodgement	2	0.06%
Other	1	0.03%



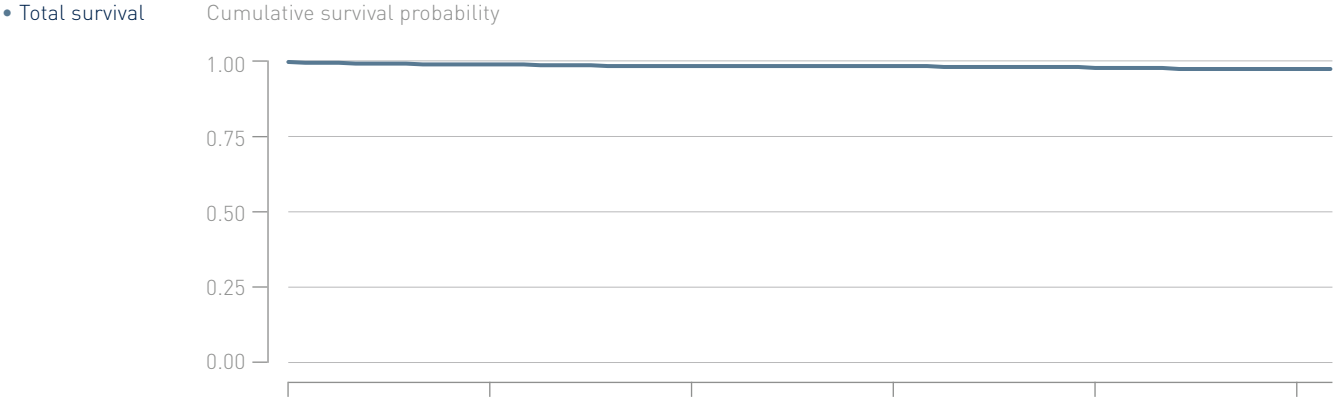
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.5	98.9	98.3	97.7	97.2	96.8
CI [±%]	-	0.1	0.2	0.4	0.5	0.5	0.6	0.7
Sample Size	3411	3235	3158	3099	2965	2276	1175	231

Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered U.S. Implants	349
Estimated Active U.S. Implants	305
U.S. Total Returned	4

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

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



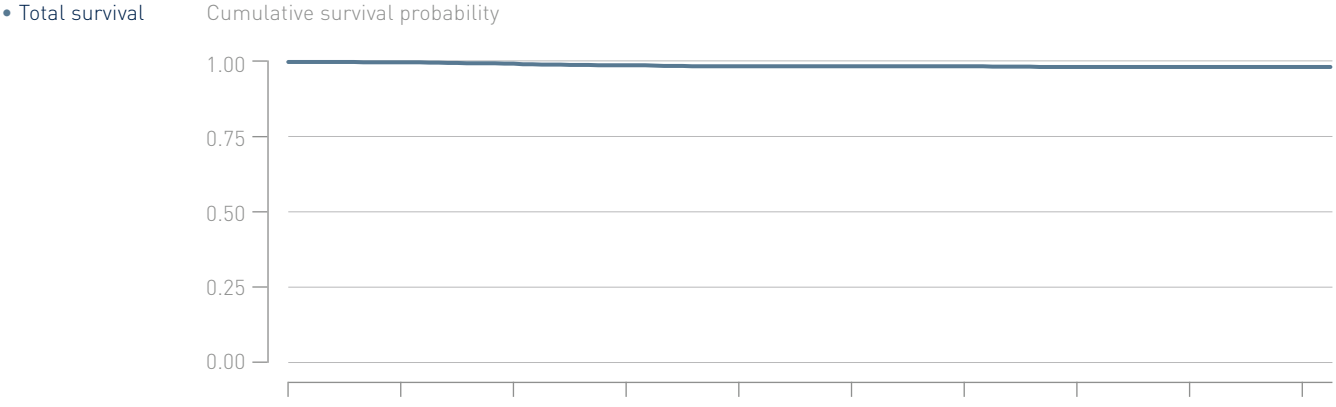
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.1	98.5	98.5	97.8	97.4
CI [±%]	-	1	1.3	1.3	1.6	1.8
Sample Size	349	331	322	308	273	228

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	2730
Registered U.S. Implants	854
Estimated Active U.S. Implants	740
U.S. Total Returned	12

	Quantity	Rate
U.S. Qualifying Complications	11	1.28%
Abnormal pacing impedance	1	0.12%
Conductor fracture	1	0.12%
Lead dislodgement	3	0.35%
Oversensing	6	0.70%

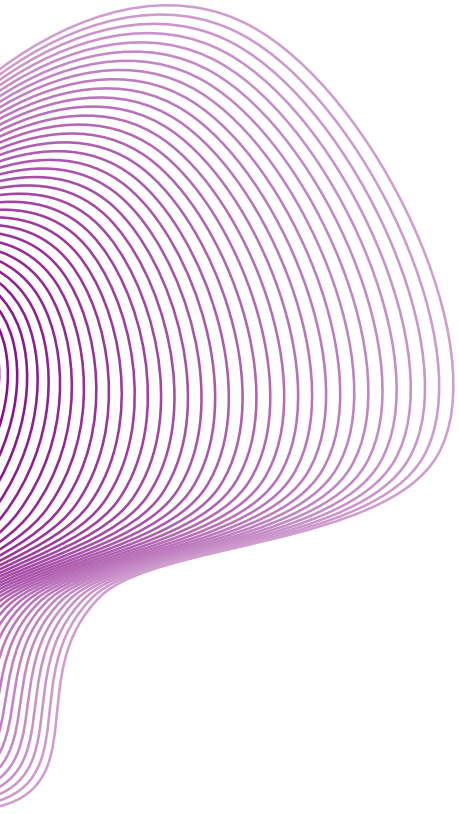
	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.47%
Insulation Breach	4	0.47%
U.S. Acute Lead Observations	0	0.00%



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.4	98.8	98.4	98.4	98.4	98.1	98.1	98.1
CI [±%]	-	0.2	0.5	0.8	0.9	0.9	0.9	0.9	0.9	0.9
Sample Size	854	816	796	775	759	755	750	742	662	327

Performance of BIOTRONIK Leads

Based on Returned Products and Complaint Data

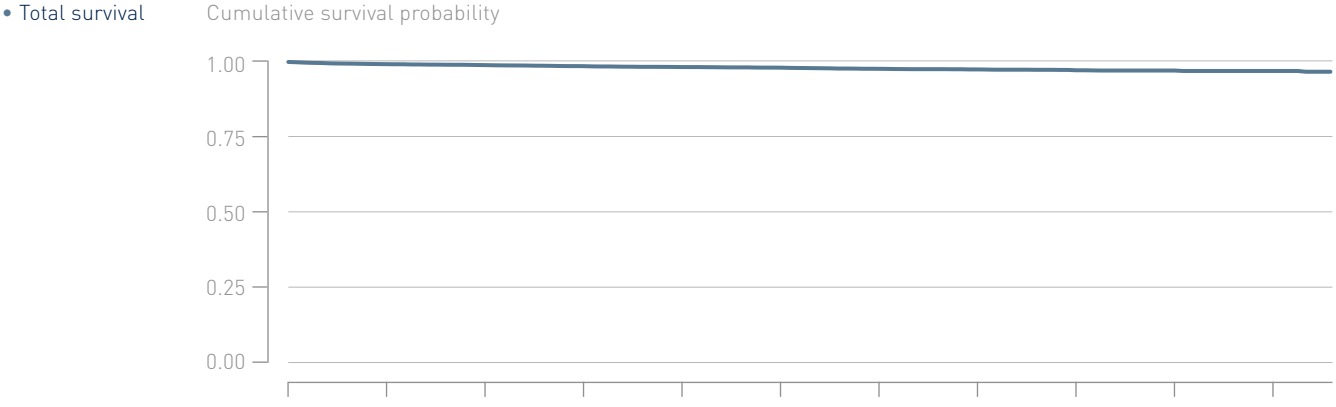


Corox OTW-L

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	4 910
U.S. Total Returned	83

	Quantity	Rate
U.S. Qualifying Complications	147	2.33%
Abnormal pacing impedance	4	0.06%
Conductor fracture	6	0.10%
Extracardiac stimulation	24	0.38%
Failure to capture	61	0.97%
Failure to sense	2	0.03%
Insulation breach	2	0.03%
Lead dislodgement	38	0.60%
Oversensing	3	0.05%
Other	7	0.11%

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.08%
Conductor Fracture	4	0.06%
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%



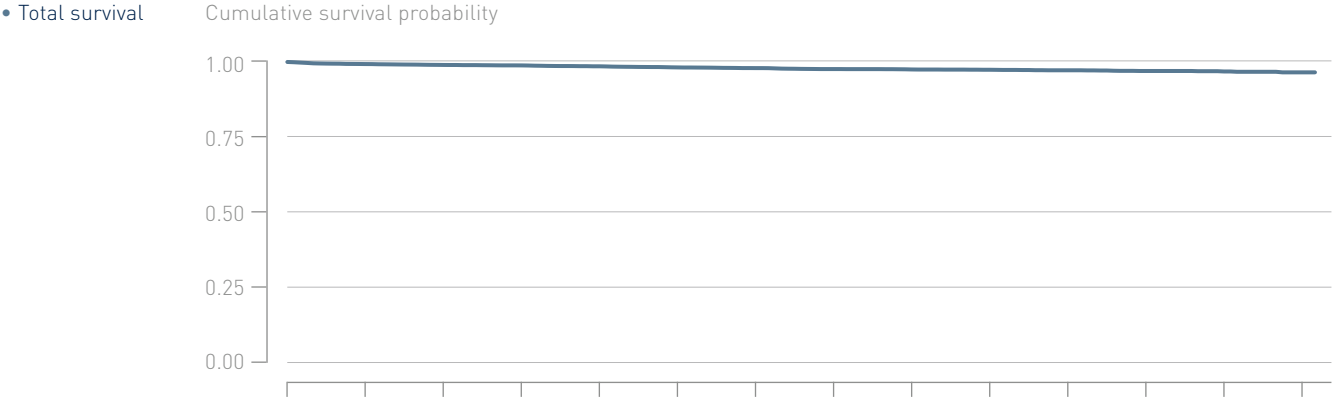
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.2	98.9	98.5	98.2	98.0	97.6	97.4	97.1	97.0	96.8
CI [±%]	-	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5
Sample Size	6 252	5 695	5 450	5 260	5 139	4 717	4 012	3 186	2 338	1 358	576

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	5 650
U.S. Total Returned	131

	Quantity	Rate
U.S. Qualifying Complications	178	2.17%
Abnormal pacing impedance	10	0.12%
Conductor fracture	7	0.09%
Extracardiac stimulation	15	0.18%
Failure to capture	55	0.67%
Failure to sense	1	0.01%
Insulation breach	4	0.05%
Lead dislodgement	60	0.73%
Oversensing	6	0.07%
Other	20	0.24%

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



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.3	98.9	98.8	98.5	98.1	97.8	97.5	97.3	97.2	97.1	96.8	96.6	96.3
CI [±%]	-	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.5	0.7
Sample Size	8 157	7 167	6 765	6 438	6 222	5 822	5 249	4 642	4 021	3 382	2 792	2 080	1 012	325

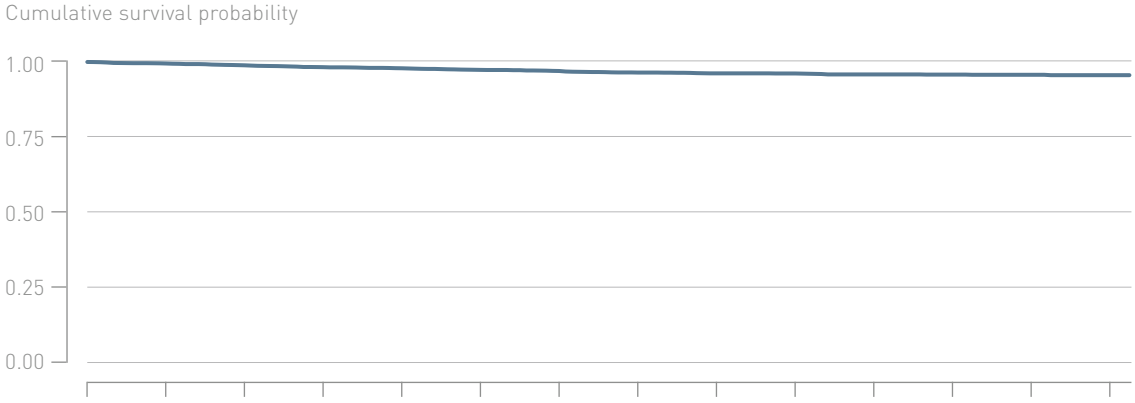
Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered U.S. Implants	4 117
Estimated Active U.S. Implants	2 660
U.S. Total Returned	79

	Quantity	Rate
U.S. Qualifying Complications	120	2.90%
Abnormal pacing impedance	7	0.17%
Conductor fracture	3	0.07%
Extracardiac stimulation	8	0.19%
Failure to capture	44	1.06%
Insulation breach	3	0.07%
Lead dislodgement	38	0.92%
Oversensing	5	0.12%
Other	12	0.29%

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

• Total survival



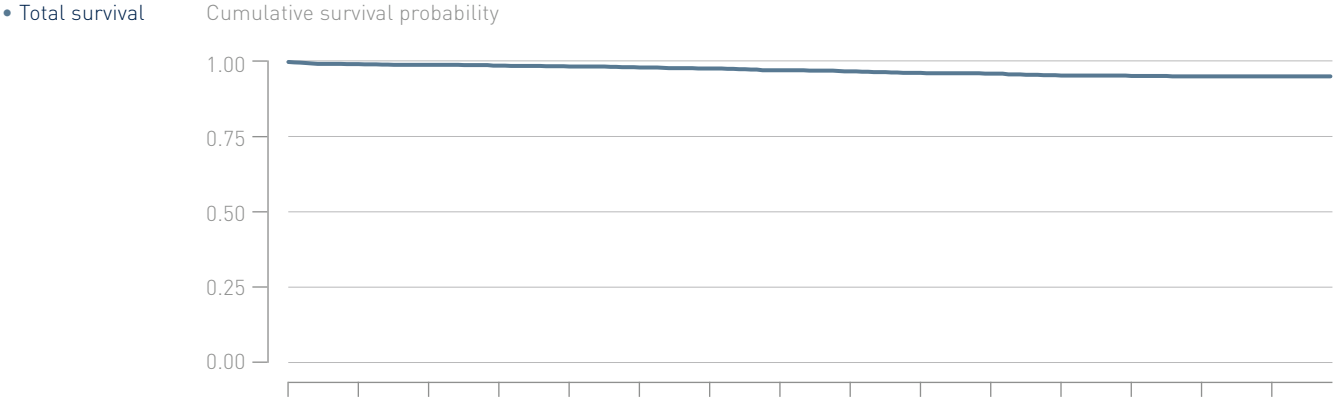
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.5	98.8	98.2	97.8	97.2	96.9	96.3	96.0	96.0	95.7	95.6	95.5	95.4
CI [±%]	-	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.8
Sample Size	4 117	3 557	3 313	3 119	3 001	2 866	2 697	2 539	2 367	2 124	1 874	1 540	879	315

Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered U.S. Implants	1 423
Estimated Active U.S. Implants	695
U.S. Total Returned	26

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

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



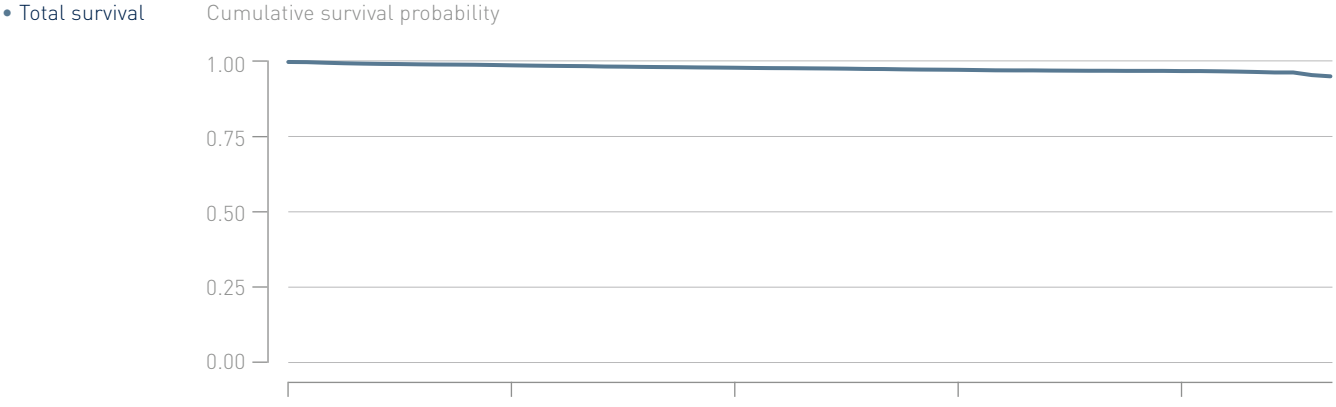
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.2	95.9	95.3	95.1	95.0	95.0
CI [±%]	-	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.4	1.4	1.4
Sample Size	1 423	1 237	1 121	1 016	932	865	810	776	750	729	712	704	697	687	527

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	106 000
Registered U.S. Implants	15 965
Estimated Active U.S. Implants	14 100
U.S. Total Returned	172

	Quantity	Rate
U.S. Qualifying Complications	269	1.66%
Abnormal pacing impedance	33	0.20%
Conductor fracture	7	0.04%
Extracardiac stimulation	14	0.09%
Failure to capture	63	0.39%
Failure to sense	2	0.01%
Lead dislodgement	104	0.64%
Oversensing	34	0.21%
Other	12	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	38	0.24%
Conductor Fracture	36	0.22%
Other	2	0.01%
U.S. Acute Lead Observations	52	0.32%
Abnormal pacing impedance	2	0.01%
Conductor fracture	1	0.01%
Extracardiac stimulation	7	0.04%
Failure to capture	9	0.06%
Lead dislodgement	29	0.18%
Oversensing	3	0.02%
Other	1	0.01%



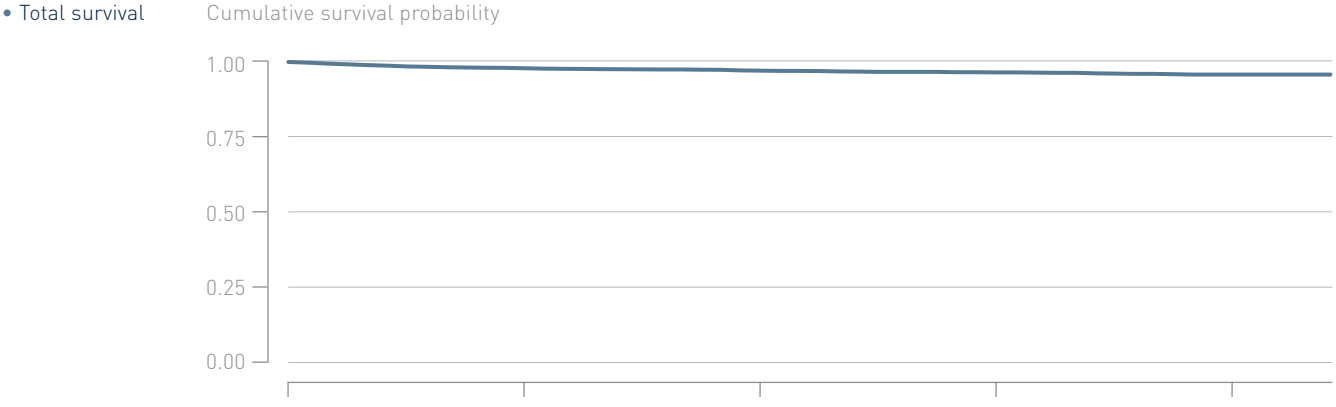
Years after implant	0	1	2	3	4
Total [%]	100.0	98.8	98.0	97.3	96.9
CI [±%]	-	0.2	0.3	0.3	0.4
Sample Size	15 965	11 451	8 146	4 737	1 621

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	22 200
Registered U.S. Implants	4 249
Estimated Active U.S. Implants	3 340
U.S. Total Returned	110

	Quantity	Rate
U.S. Qualifying Complications	110	2.54%
Abnormal pacing impedance	7	0.16%
Conductor fracture	1	0.02%
Extracardiac stimulation	7	0.16%
Failure to capture	24	0.55%
Insulation breach	1	0.02%
Lead dislodgement	59	1.36%
Oversensing	10	0.23%
Other	1	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	9	0.21%
Conductor Fracture	9	0.21%
U.S. Acute Lead Observations	78	1.80%
Abnormal pacing impedance	1	0.02%
Extracardiac stimulation	4	0.09%
Failure to capture	10	0.23%
Failure to sense	1	0.02%
Lead dislodgement	57	1.32%
Oversensing	3	0.07%
Other	2	0.05%



Years after implant	0	1	2	3	4
Total [%]	100.0	97.8	97.0	96.4	95.7
CI [±%]	-	0.5	0.6	0.7	0.8
Sample Size	4 249	2 948	2 312	1 584	644

Methodology for Lead Survival Estimates Based on Clinical Studies

7. Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

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

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

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

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

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

7.2 BIOTRONIK's Clinical Studies

7.2.1 GALAXY and CELESTIAL

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

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

Every effort is made to ensure participants are representative of the

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

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

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

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

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

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

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

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

7.2.2 SIELLO Clinical Study

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

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

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

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

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

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

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

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

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

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

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

7.2.3 QP ExCELs

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

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

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

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

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

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

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

7.3 Lead Complications

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

7.3.1 GALAXY and CELESTIAL

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

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

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

7.3.2 SIELLO

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

Event Classifications

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

7.3.3 QP ExCELs

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

Event Classifications

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

7.4 Lead Product Performance Graphs and Data

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

Returned Product Analysis Results

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

Performance of BIOTRONIK Leads Based on Clinical Study Data

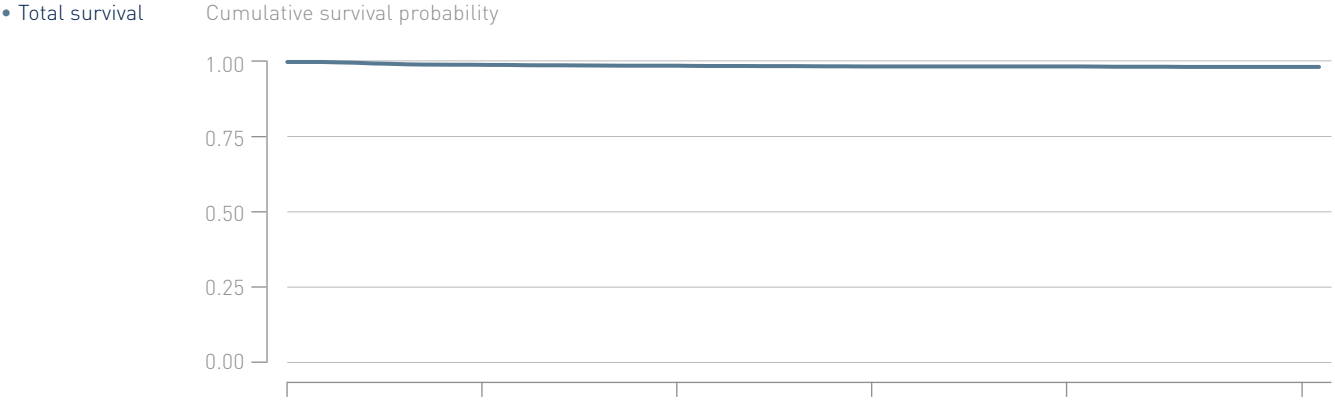
Performance of BIOTRONIK Leads Based on Clinical Study Data

Siello S / Solia S

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

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

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



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

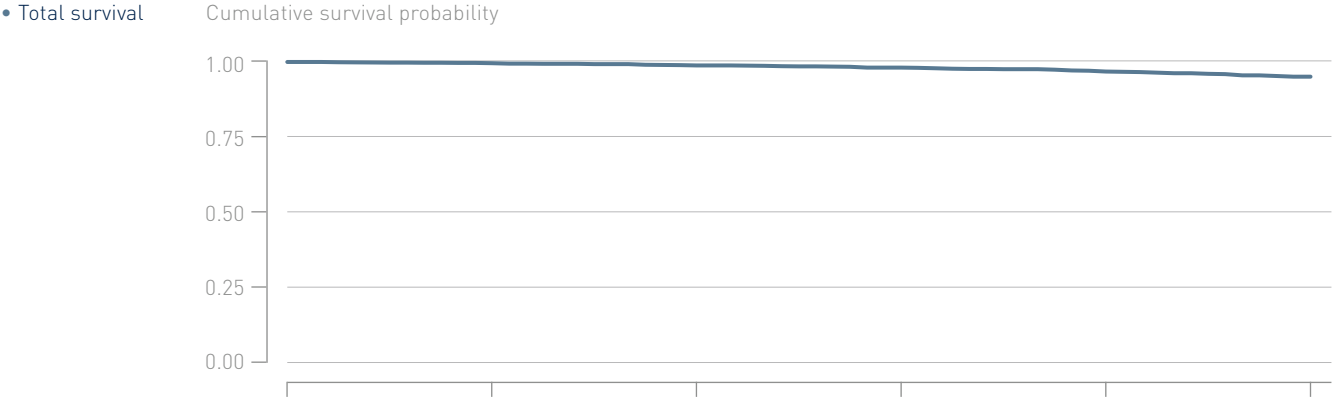
Performance of BIOTRONIK Leads Based on Clinical Study Data

Linox SD

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

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

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



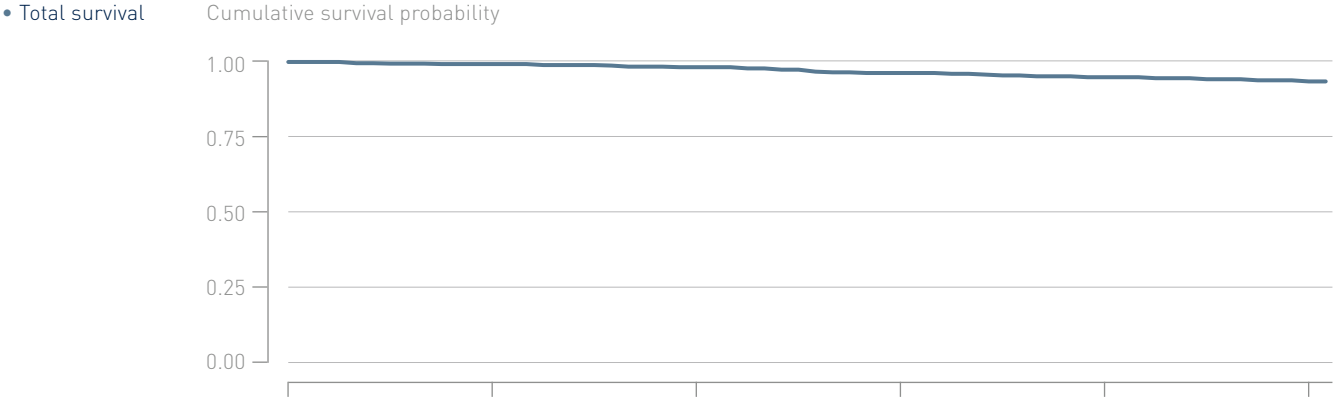
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	98.8	98.0	96.7	94.9
CI [±%]	-	0.3	0.5	0.7	0.9	1.3
Sample Size	2 272	1 937	1 618	1 302	1 014	392

Linox^{smart} SD

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

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

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



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

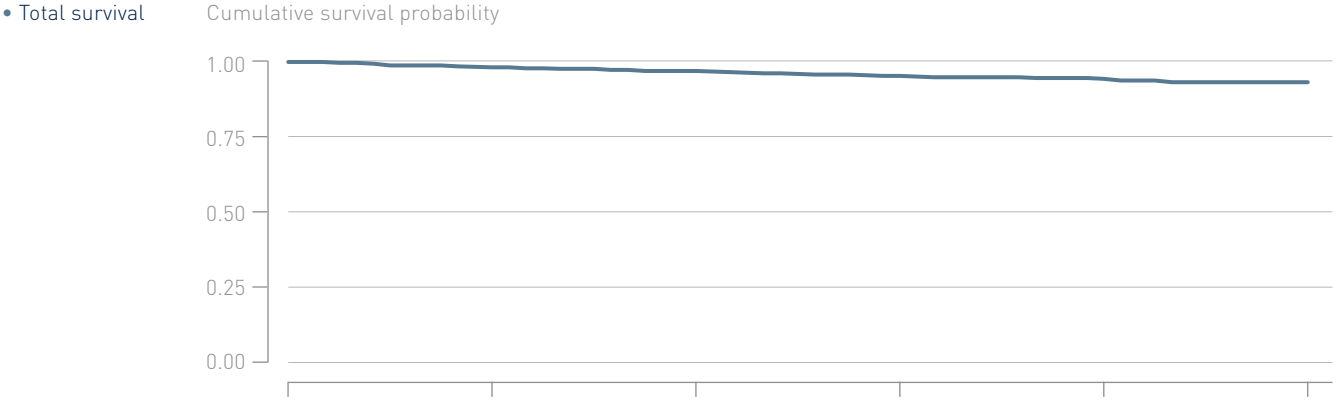
Performance of BIOTRONIK Leads Based on Clinical Study Data

Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28700
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%



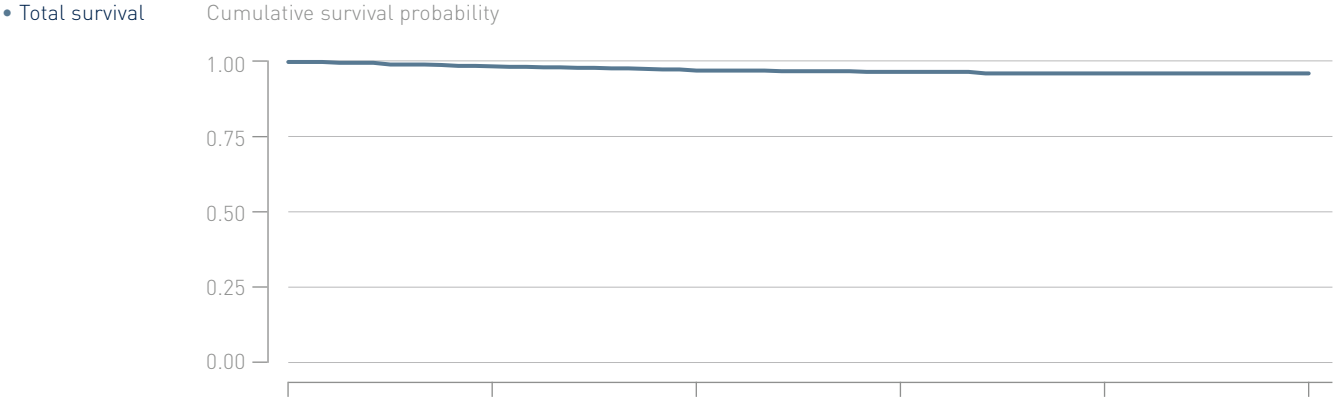
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	96.9	95.2	94.2	93.0
CI [±%]	-	1.1	1.4	1.8	2.1	2.3
Sample Size	696	589	489	407	329	135

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	32 000
Leads registered in study	699

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

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



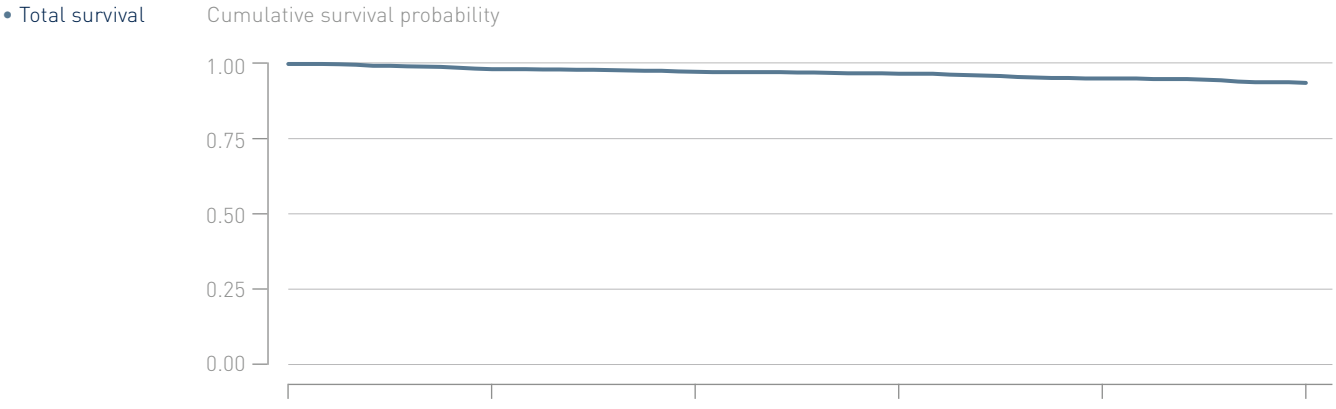
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.0	96.5	96.0	96.0
CI [±%]	-	1.0	1.4	1.6	1.7	1.7
Sample Size	699	584	475	382	303	130

Corox OTW-S

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

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

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



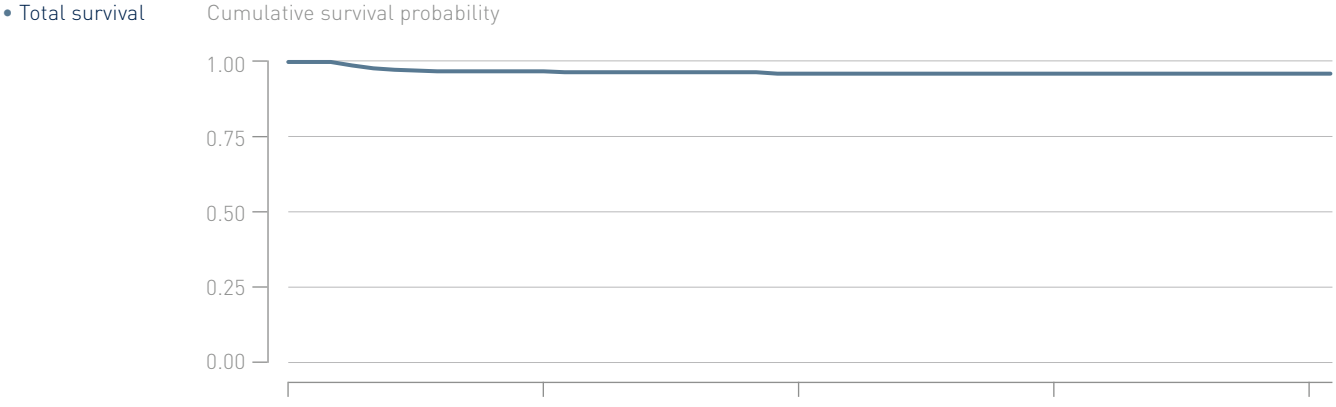
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	97.3	96.6	95.0	93.5
CI [±%]	-	0.8	1.0	1.2	1.5	1.9
Sample Size	1 141	963	813	648	505	192

Sentus OTW QP S

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

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

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



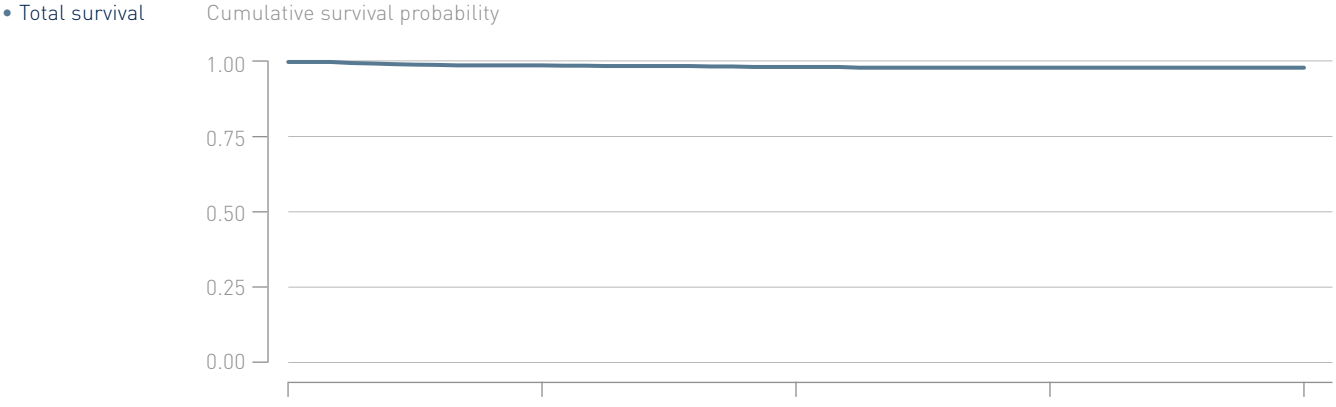
Years after implant	0	1	2	3	4
Total [%]	100.0	96.7	95.9	95.9	95.9
CI [±%]	-	1.8	2.2	2.2	2.2
Sample Size	436	299	170	55	0

Sentus OTW QP L

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

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

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



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

9

Methodology for Lead Survival Estimates based on Insurance Claims Data

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

9.1 Introduction

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

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

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

9.2 Claims Data Methodologies and Data Sets

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

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

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

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

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

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

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

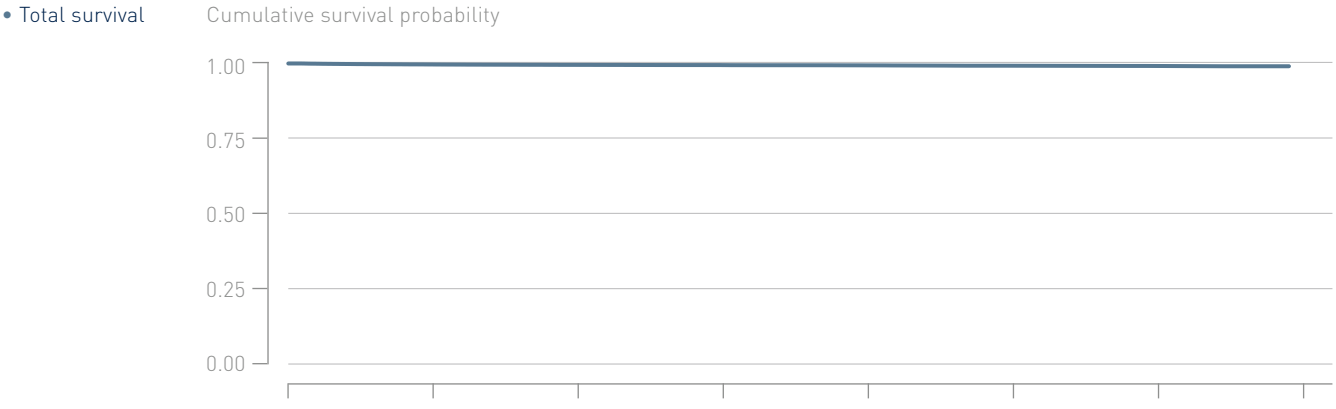
1 Hicks J, Keith M, Moll P, Simeles J, Offer E, Diani C, Rock A, and Mitchell K. Novel Method to Identify Lead Complications in Pacemaker Systems from Real-World Data: Proof of Concept for the Siello S Pacing Lead. Heart Rhythm. 2019; 16(5), Supplement, S-PO03-089.

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Siello S / Solia S EP-Passion Data

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 134 000
Registered U.S. Implants	81 223

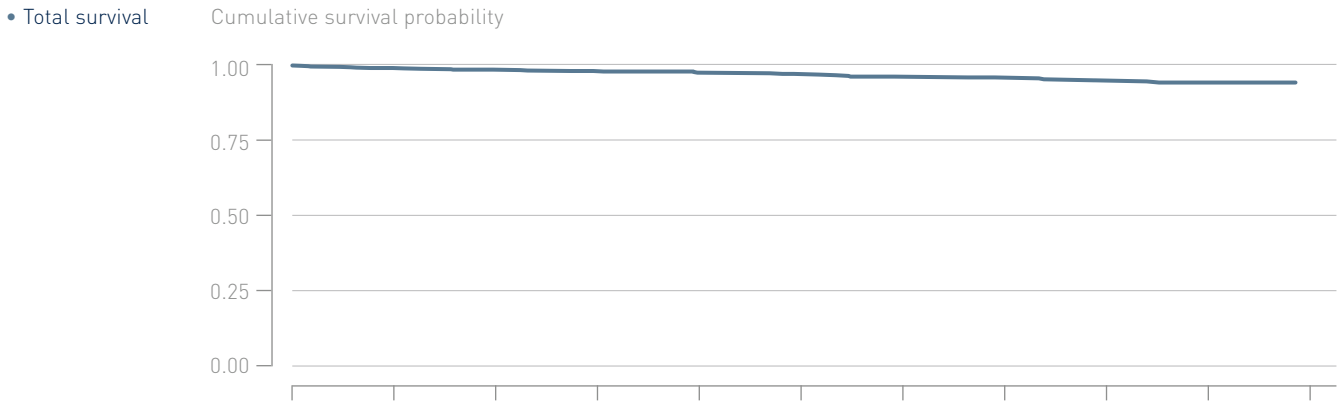


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.6	99.4	99.3	99.2	99.1	99.0	98.9
CI [±%]	0.0	0.1	0.1	0.1	0.2	0.4	0.6	0.9
Sample Size	81 223	55 347	40 216	24 526	10 901	1 818	1 021	535

Performance of BIOTRONIK Leads Based on Insurance Claims Data

Linox S EP-Passion Data

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

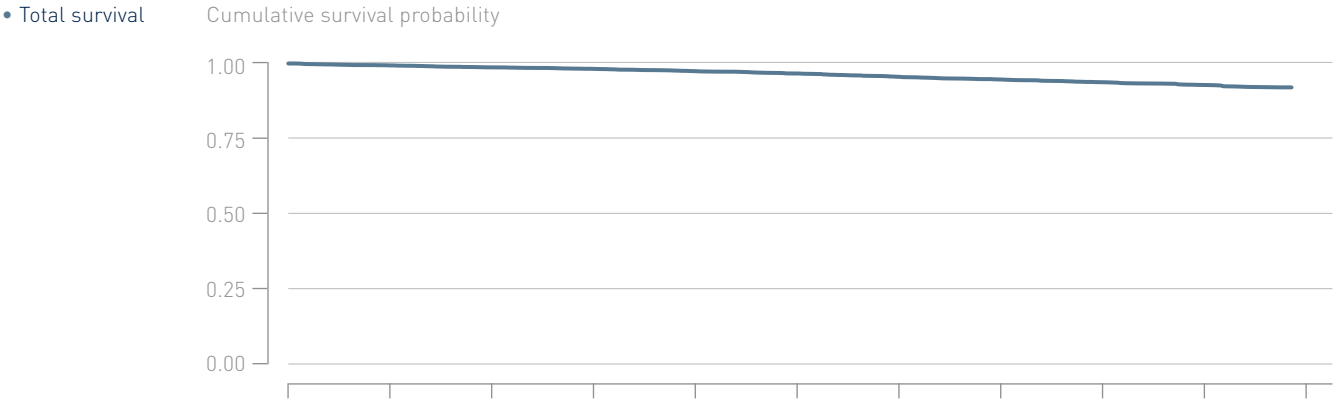


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.1	98.6	98.1	97.5	97.1	96.2	95.9	94.9	94.1	94.1
CI [±%]	0.0	0.7	0.9	1.1	1.4	1.6	1.9	2.1	2.6	3.0	3.4
Sample Size	866	🔒	646	571	496	440	379	331	271	219	177

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

Linox SD EP-Passion Data

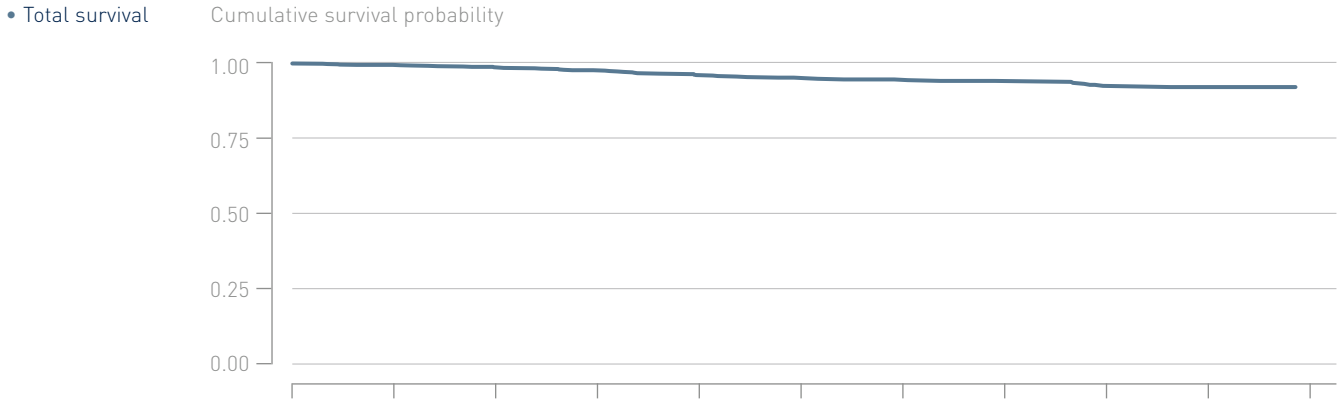
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	7 247



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

Linox TD EP-Passion Data

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

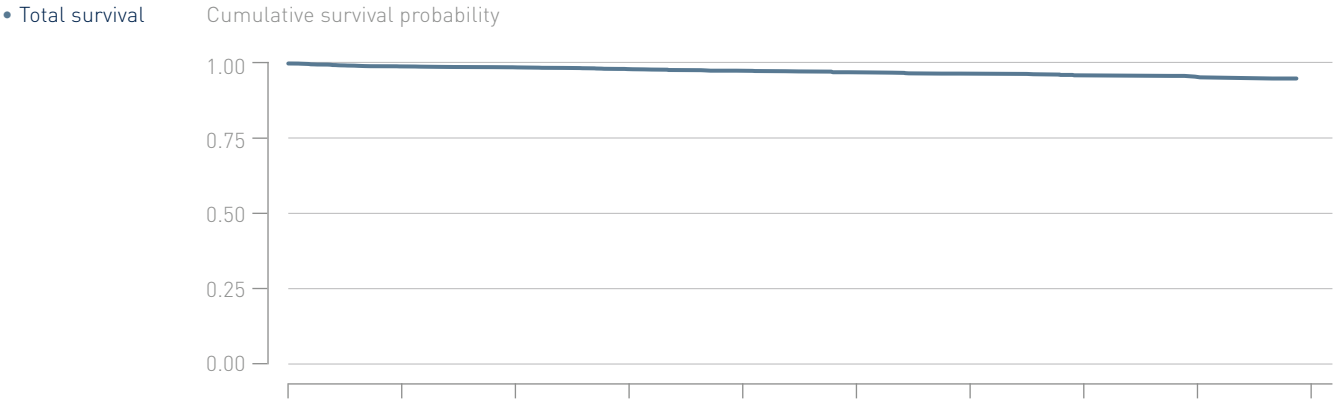


Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.5	98.7	97.7	96.0	95.2	94.5	94.0	92.3	91.9	91.9
CI [±%]	0.0	0.4	0.8	1.1	1.5	1.9	2.2	2.5	3.1	3.5	3.9
Sample Size	1 148	🔒	819	696	587	482	398	328	262	216	175

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

Linox Smart S EP-Passion Data

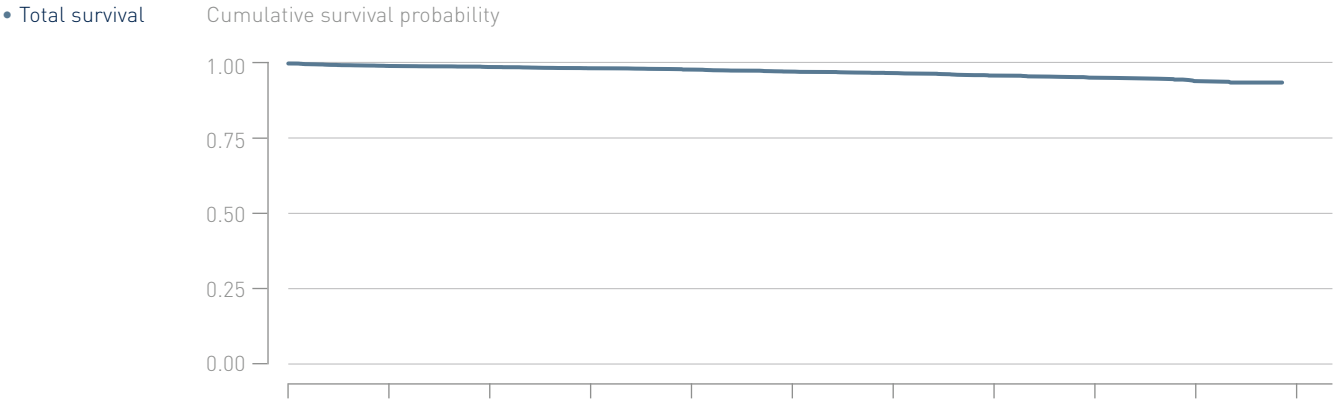
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	3 006



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

Linox Smart SD EP-Passion Data

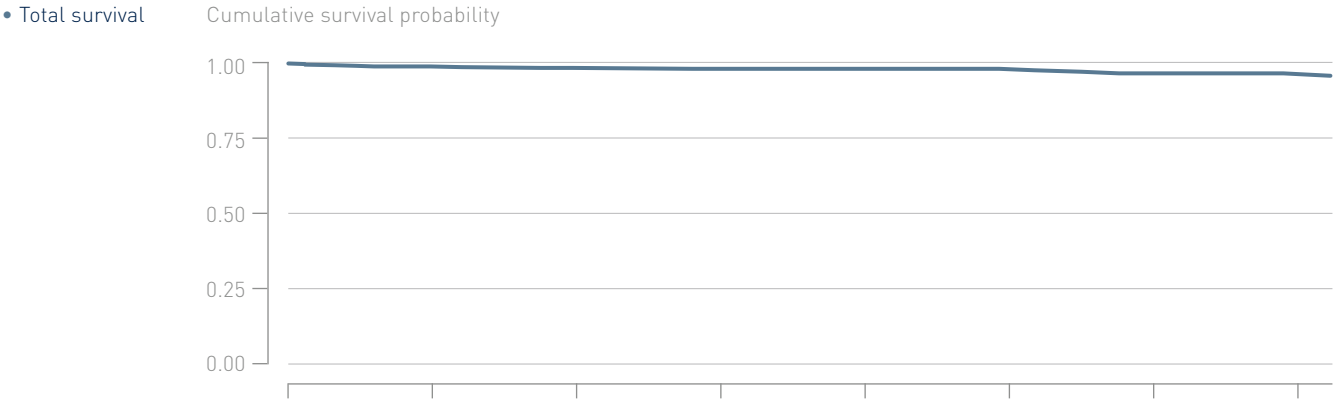
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	5 285



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

Linox Smart TD EP-Passion Data

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

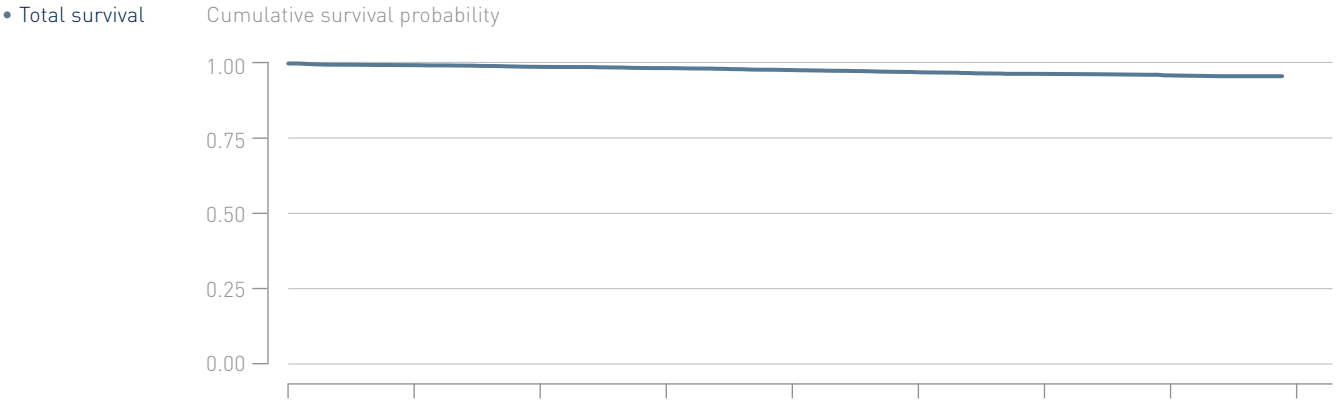


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.0	98.4	98.1	98.1	98.1	96.5	96.5
CI [±%]	0.0	1.0	1.3	1.5	1.7	1.8	2.7	3.1
Sample Size	523	🔒	🔒	🔒	🔒	🔒	168	126

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

Linox Smart S DX EP-Passion Data

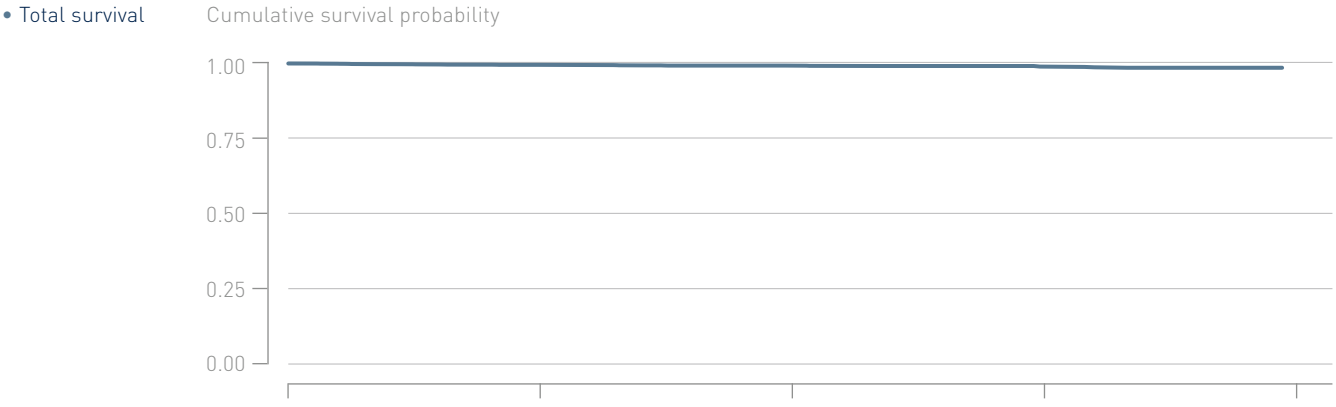
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	4665



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

Plexa S EP-Passion Data

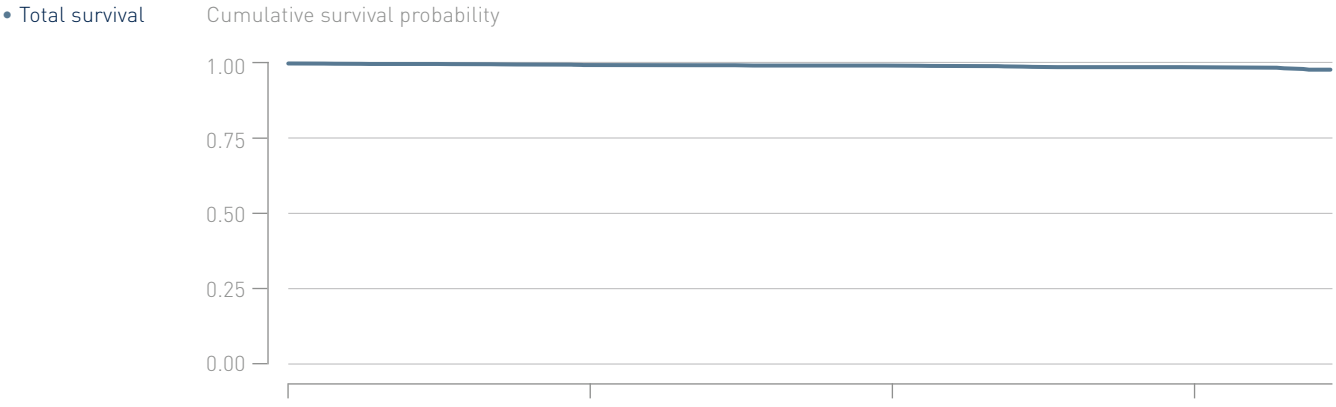
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	109 000
Registered U.S. Implants	5 181



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

Plexa S DX DF1 EP-Passion Data

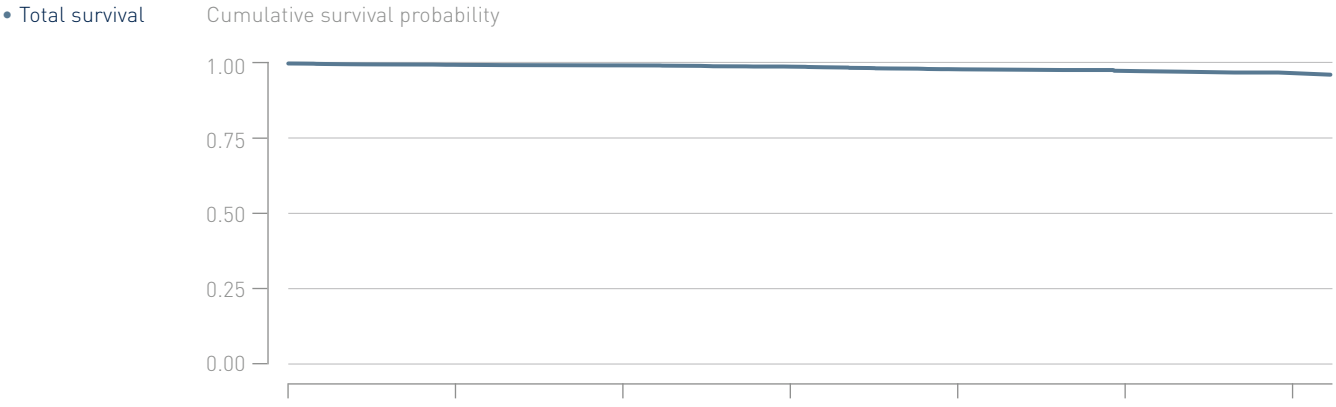
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	21 700
Registered U.S. Implants	2 345



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

Protego S EP-Passion Data

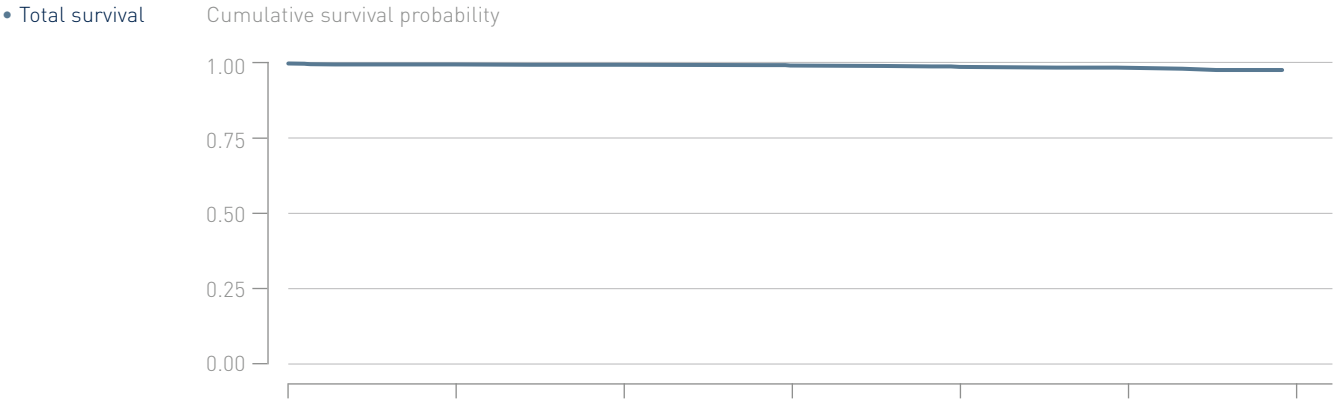
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	3 087



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

Protego SD EP-Passion Data

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



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

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

11

Advisories

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

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

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

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

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

As of October 2022
- The cumulative failure rate is 0.79%
- No failures for devices with less than 2 years of implant duration have been reported.
- The failure probability after 2 years remains constant at 0.0012%. The failure probability after 5 years of implant is 0.53%
- One event has been reported with patient death related to early battery depletion after the patient was lost to follow-up for two years. All other events are associated with an additional replacement surgery only.
- Availability of therapy has been assessed for all returned devices to update risk estimation for loss of therapy depending on the service time:

Risk for loss of pacing therapy

Service Time	Risk per month for loss of pacing
0 – 24 months	< 0.00001%
24 – 48 months	0.0013%
48 – 72 months	0.0094%

Risk for loss of high-voltage therapy

Service Time	Risk per month for loss of shock therapy
0 – 24 months	< 0.00001%
24 – 48 months	0.0020%
48 – 72 months	0.0149%

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

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

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

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

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

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

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

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

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

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

11. Advisories

monitoring using BIOTRONIK Home Monitoring.

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

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

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

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

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

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

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

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

X-Ray Identifiers for Pacemakers and ICDs

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

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Regarding this Report

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Regarding Products

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