Product Performance Report
January 2018

Cardiac Rhythm Management
Cumulative Survival Probability

BIOTRONIK
excellence for life

Product Performance Report January 2018

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 our U.S. Compliance Department (888) 345-0374 or Worldwide CRM Technical Service Department 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, January 2018

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

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

1. Methodology for Pacemaker and ICD Survival Estimates

1.1 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 100.0 %. 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.

1.2 Data Acquisition

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

In order to be included in the population under observation, a device must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is June 30, 2017. 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, Lexos VR and VR-T (with Home Monitoring) ICDs are combined into a single family, Lexos Single-Chamber ICDs.

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.

1.3 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.

1.4 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.

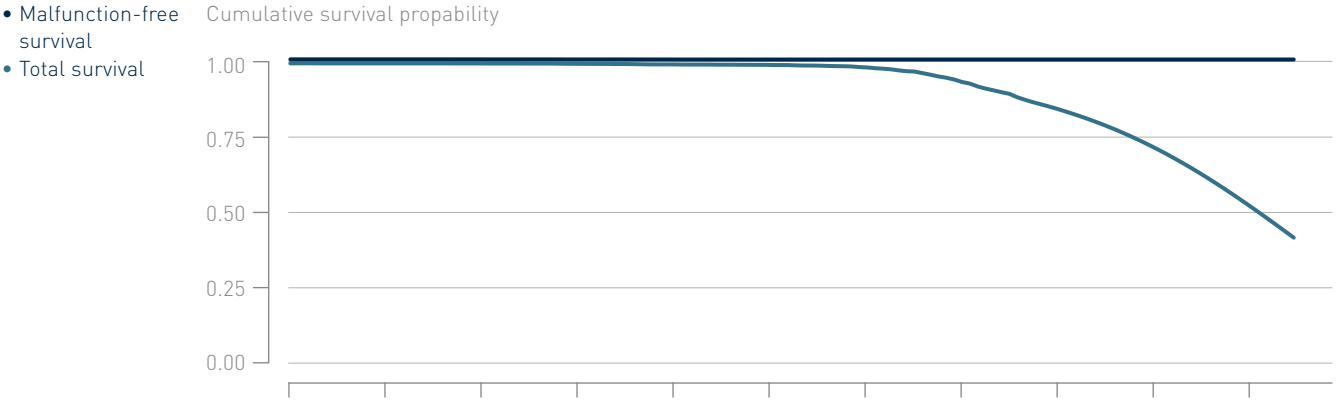
1 Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926.

Performance of BIOTRONIK Pacemakers

Cylos and Cylos 990

Product Versions*	VR, 990 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	6 150
Estimated Active U.S. Implants	2 950
U.S. Normal Battery Depletions	560

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



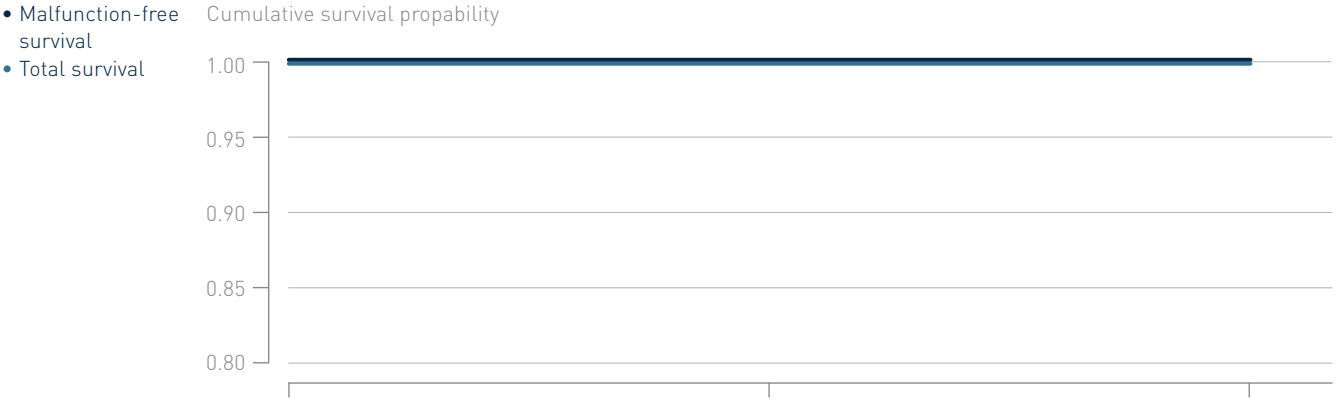
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	100.0	100.0	99.9	99.6	99.5	98.8	94.6	85.7	73.7	55.1
CI [±%]			0.1	0.1	0.2	0.2	0.3	0.7	1.3	1.5	1.3
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]				0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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

Eluna 8

NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	16 500
Registered U.S. Implants	4 490
Estimated Active U.S. Implants	4 180
U.S. Normal Battery Depletions	0

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

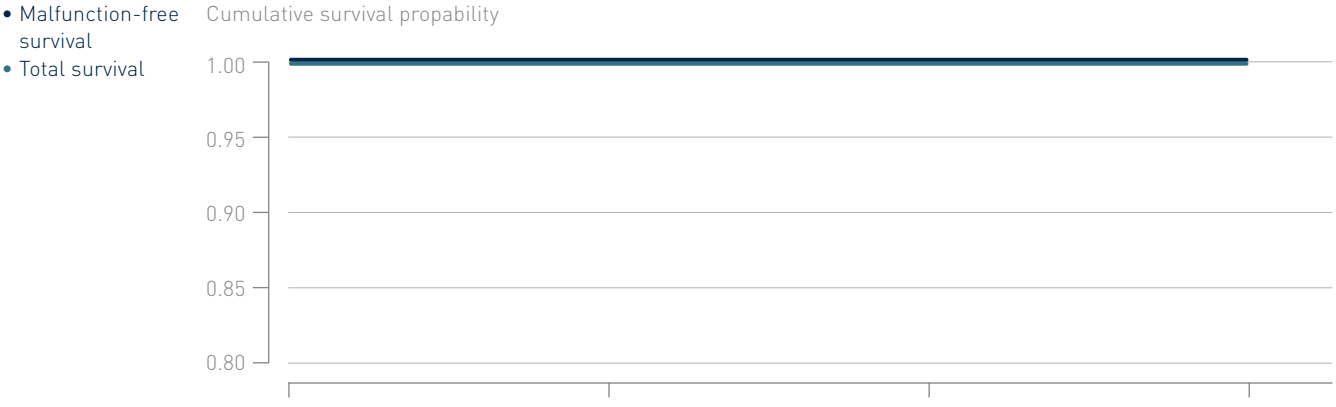


Years after implant	0	1	2
Total [%]	100.0	100.0	
CI [±%]	0.1	0.1	
Malfunction-Free [%]	100.0	100.0	
CI [±%]	0.1	0.1	

Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28 100
Registered U.S. Implants	2 400
Estimated Active U.S. Implants	2 020
U.S. Normal Battery Depletions	0

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

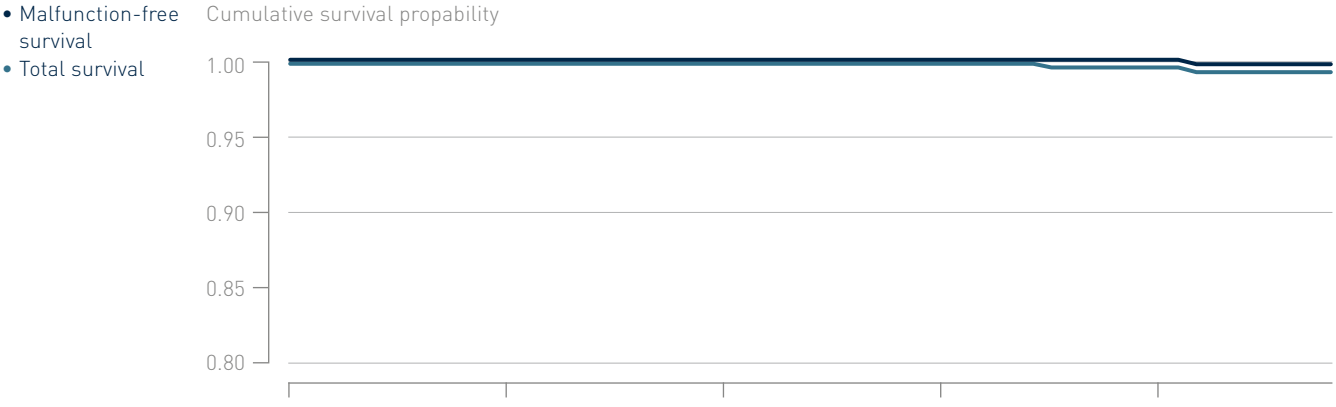


Years after implant	0	1	2	3
Total [%]	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1

Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	24 800
Registered U.S. Implants	609
Estimated Active U.S. Implants	425
U.S. Normal Battery Depletions	1

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

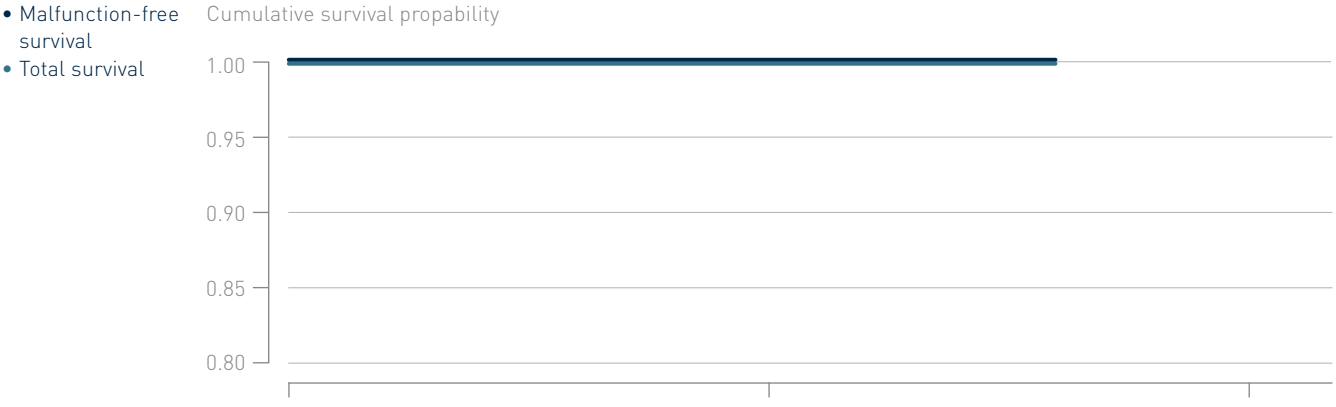


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	100.0	99.7
CI [±%]	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	14 900
Registered U.S. Implants	1 300
Estimated Active U.S. Implants	1 190
U.S. Normal Battery Depletions	1

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

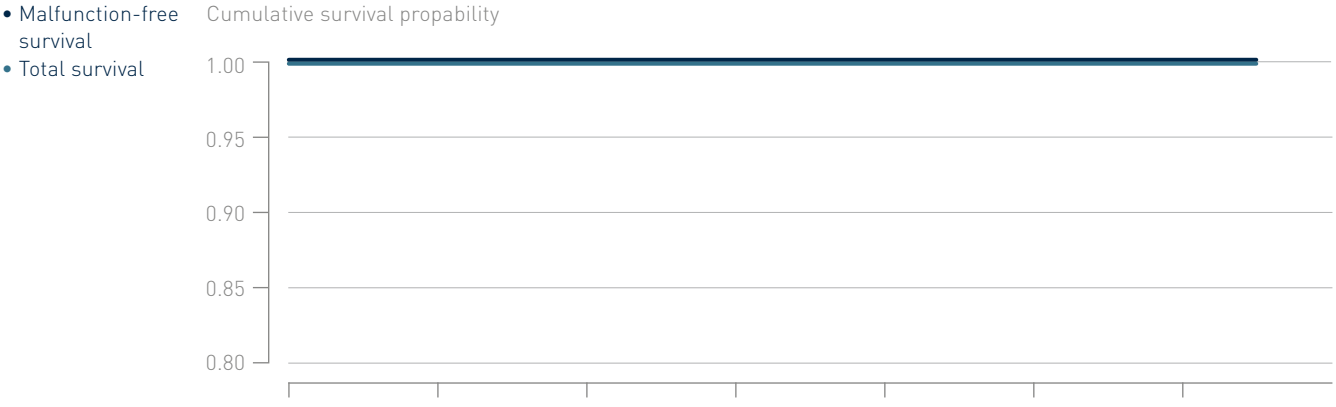


Years after implant	0	1	2
Total [%]	100.0	99.9	
CI [±%]	0.1	0.1	
Malfunction-Free [%]	100.0	100.0	
CI [±%]	0.1	0.1	

Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	57 200
Registered U.S. Implants	12 000
Estimated Active U.S. Implants	9 100
U.S. Normal Battery Depletions	10

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

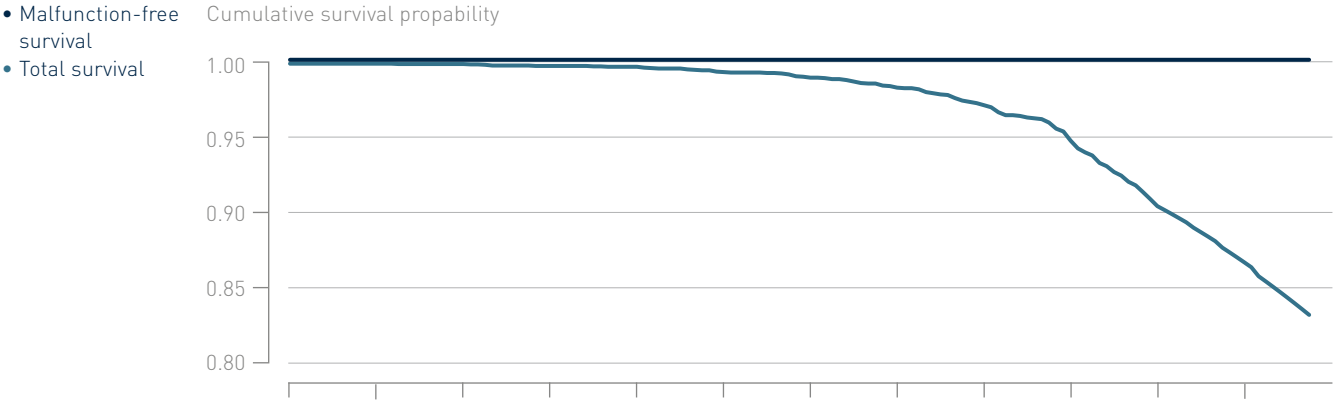


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.8
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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	214 000
Registered U.S. Implants	5 240
Estimated Active U.S. Implants	2 770
U.S. Normal Battery Depletions	199

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



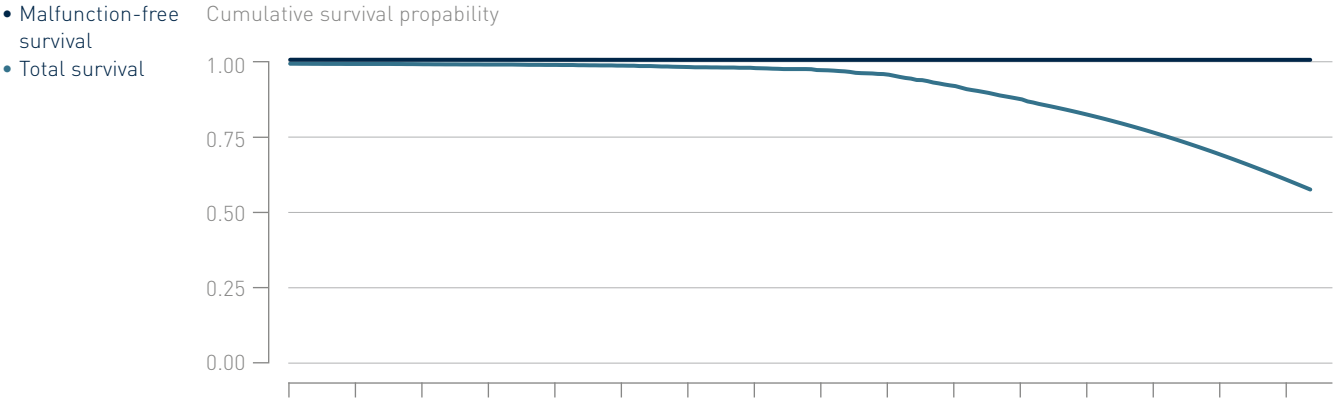
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	100.0	100.0	99.8	99.8	99.4	99.1	98.4	97.2	94.9	90.5	86.7
CI [±%]				0.1	0.1	0.2	0.3	0.4	0.6	0.9	1.4	1.7
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]												

* 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

Philos

Product Versions	S, SR
NBG Codes	SSI, SSIR
US Market Release	Sep 2000
CE Market Release	Aug 2000
Worldwide Distributed Devices	109 000
Registered U.S. Implants	5 770
Estimated Active U.S. Implants	1 570
U.S. Normal Battery Depletions	254

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.12%
Therapy Compromised	0	0.00%
Therapy Available	7	0.12%

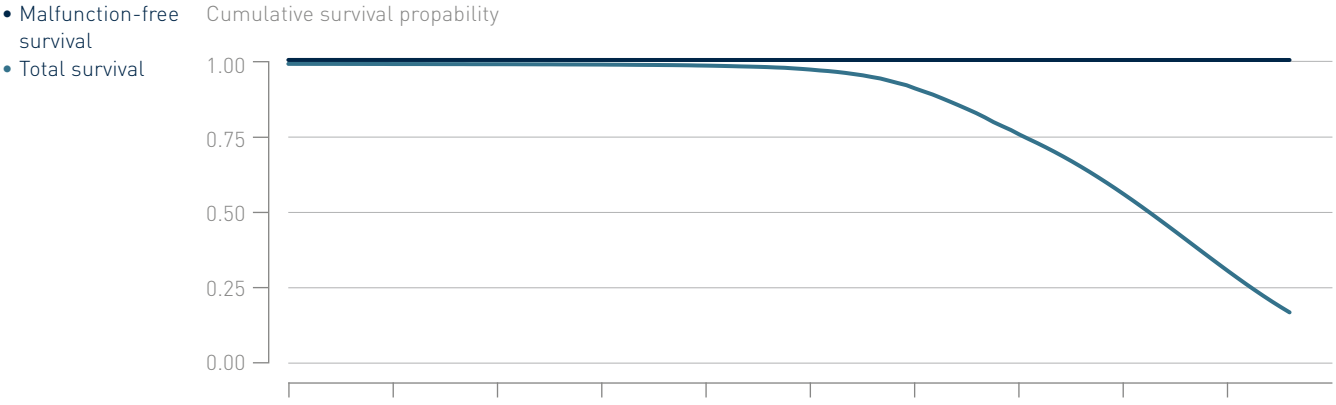


Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.9	99.8	99.7	99.6	99.4	98.9	98.5	97.8	96.3	92.5	88.1	82.9	76.8	69.4	60.9
CI [±%]		0.1	0.1	0.2	0.2	0.3	0.4	0.4	0.6	0.8	1.1	1.5	1.7	1.6	1.5	1.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
CI [±%]		0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Cylos and Cylos 990

Product Versions*	DR, DR-T, 990 DR, 990 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	30 400
Estimated Active U.S. Implants	10 600
U.S. Normal Battery Depletions	6 354

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



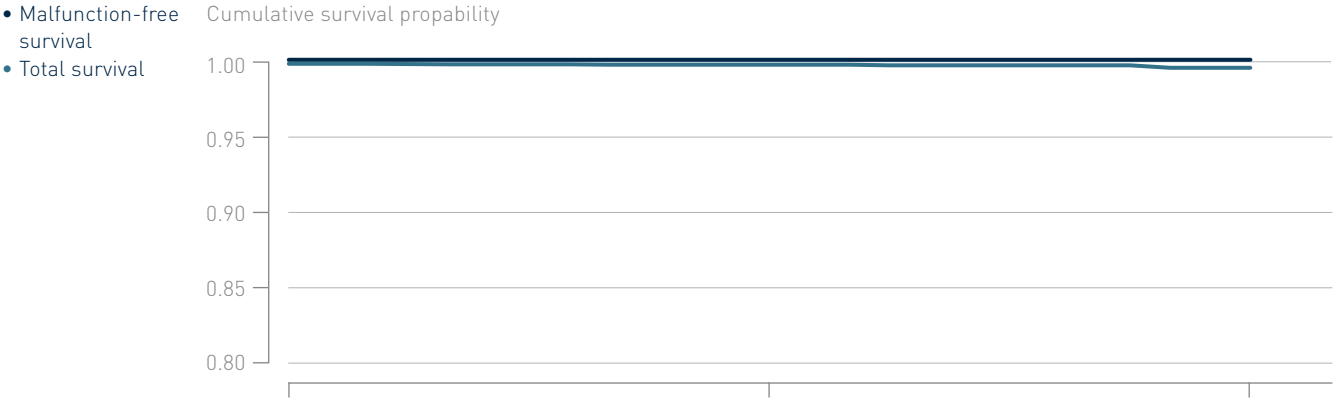
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.9	99.8	99.4	98.1	91.8	76.5	56.6	31
CI [±%]				0.1	0.1	0.2	0.4	0.6	0.7	0.5
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]										

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

Eluna 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	78 100
Registered U.S. Implants	31 400
Estimated Active U.S. Implants	29 700
U.S. Normal Battery Depletions	5

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

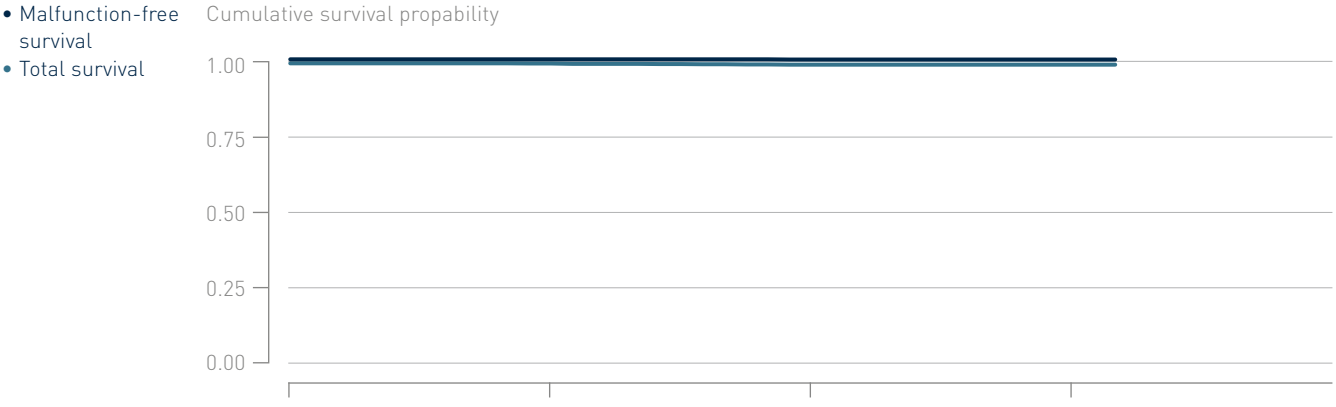


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1

Entovis

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	106 000
Registered U.S. Implants	12 200
Estimated Active U.S. Implants	10 400
U.S. Normal Battery Depletions	6

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

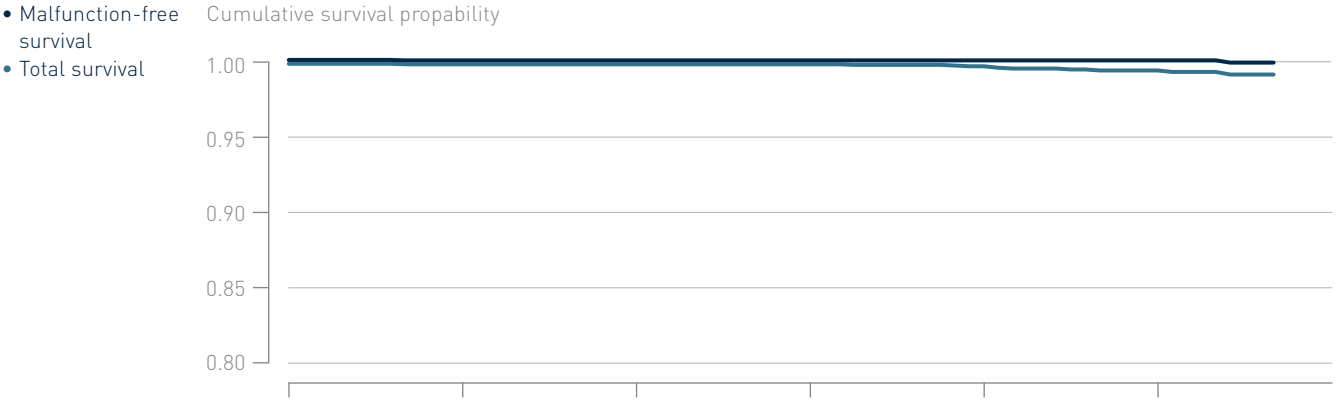


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.9
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	29 400
Registered U.S. Implants	2 950
Estimated Active U.S. Implants	2 250
U.S. Normal Battery Depletions	9

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.07%
Therapy Compromised	0	0.00%
Therapy Available	2	0.07%

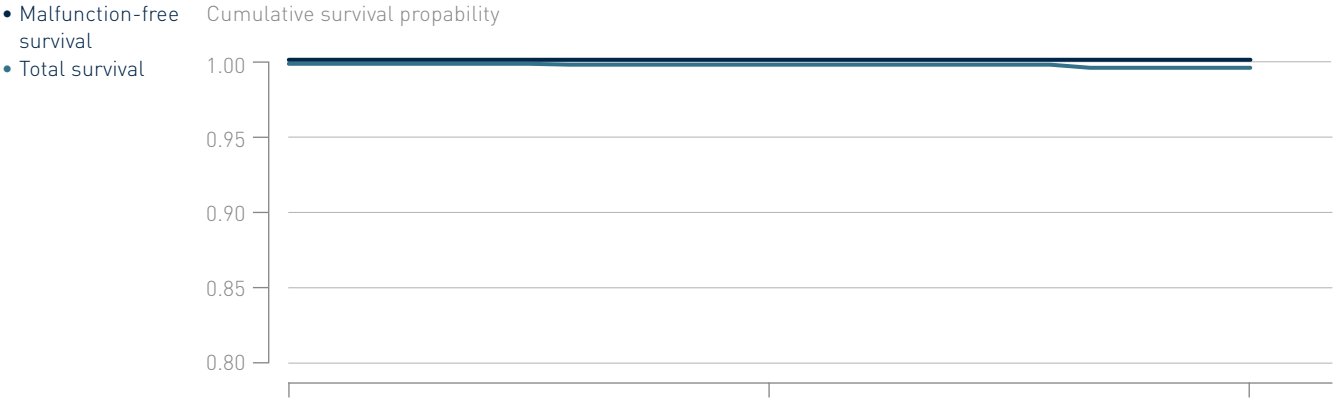


Years after implant	0	1	2	3	4	5
Total [%]	100.0	100.0	100.0	100.0	99.8	99.5
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	61 500
Registered U.S. Implants	8 870
Estimated Active U.S. Implants	8 420
U.S. Normal Battery Depletions	2

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

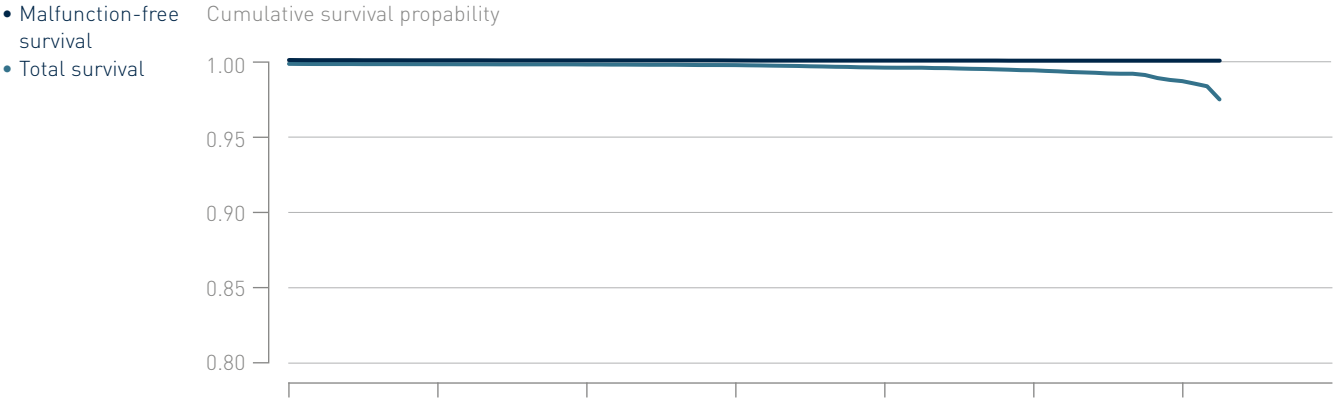


Years after implant	0	1	2
Total [%]	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1

Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	197 000
Registered U.S. Implants	61 900
Estimated Active U.S. Implants	47 500
U.S. Normal Battery Depletions	146

	Quantity	Rate
U.S. Confirmed Malfunctions	19	0.03%
Therapy Compromised	10	0.02%
Therapy Available	9	0.01%

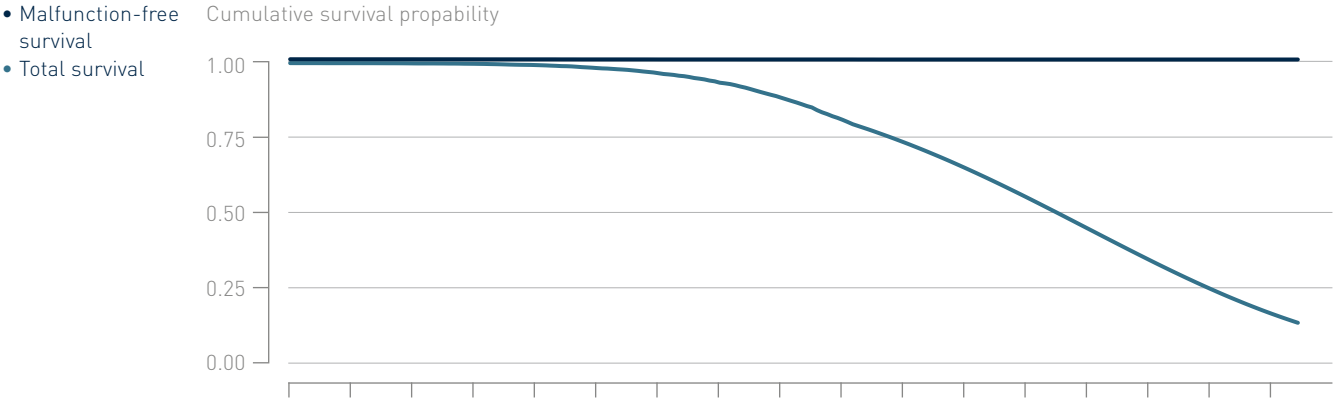


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.9	99.8	99.7	99.1
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Philos

Product Versions	D, DR, DR-T, SLR
NBG Codes	DDD, DDDR, VDDR
US Market Release	Sep 2000
CE Market Release	Aug 2000
Worldwide Distributed Devices	172 000
Registered U.S. Implants	20 700
Estimated Active U.S. Implants	5 330
U.S. Normal Battery Depletions	2 499

	Quantity	Rate
U.S. Confirmed Malfunctions	28	0.14%
Therapy Compromised	5	0.02%
Therapy Available	23	0.11%

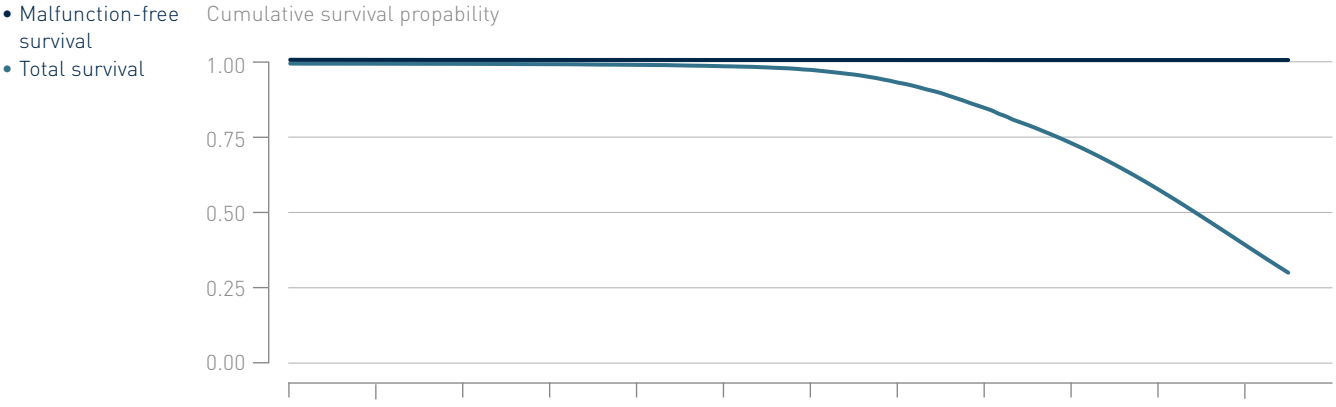


Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Total [%]	100.0	100.0	99.9	99.8	99.3	98.4	96.7	93.5	88.5	81.2	73.8	65.3	55.6	45.2	34.8	25.2	17
CI [±%]				0.1	0.1	0.2	0.3	0.4	0.6	0.8	0.9	0.8	0.7	0.6	0.5	0.3	0.2
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
CI [±%]						0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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	370 000
Registered U.S. Implants	23 200
Estimated Active U.S. Implants	9 610
U.S. Normal Battery Depletions	3 205

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



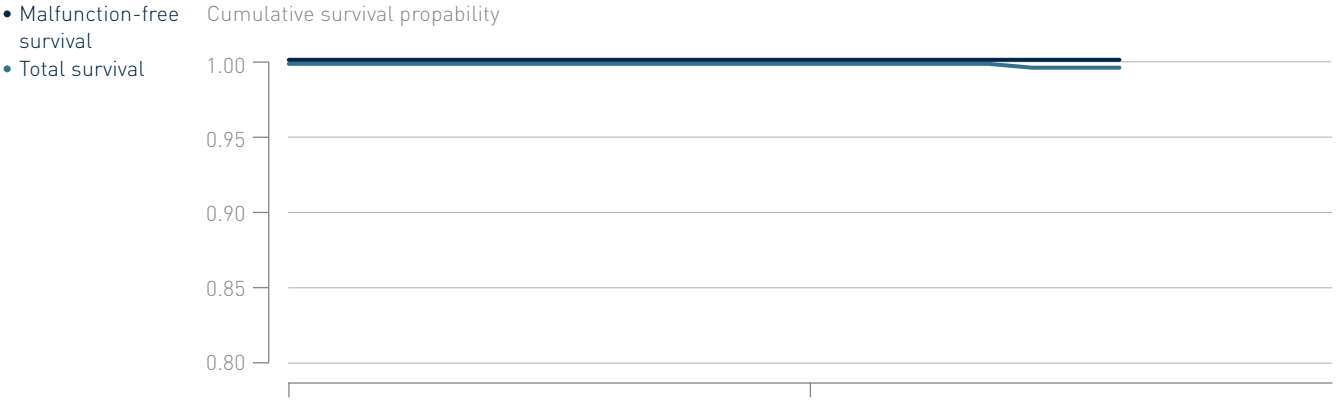
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	100.0	99.9	99.8	99.6	99.1	97.9	93.7	85.3	73.5	58.2	39.7
CI [±%]	0	0	0	0.1	0.1	0.1	0.2	0.4	0.6	0.9	0.9	0.7
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	0	0	0	0	0	0	0	0	0	0.1	0.1	0.1

* 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

Etrinsa 8

Product Versions	HF-T
NBG Codes	DDDRV
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	7 060
Registered U.S. Implants	1 370
Estimated Active U.S. Implants	1 210
U.S. Normal Battery Depletions	1

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

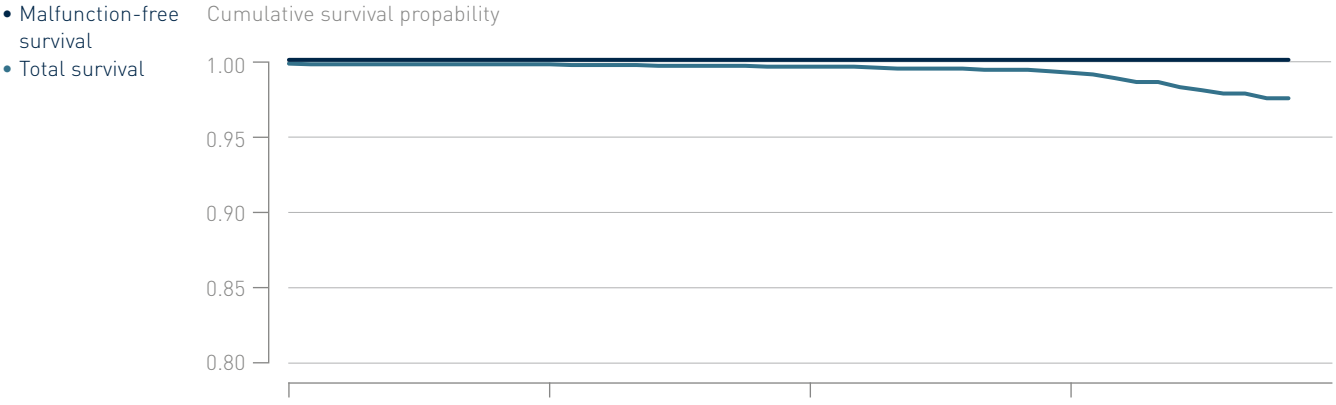


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

Evia

Product Versions	HF, HF-T
NBG Codes	DDDRV
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	8 620
Registered U.S. Implants	2 250
Estimated Active U.S. Implants	1 540
U.S. Normal Battery Depletions	20

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

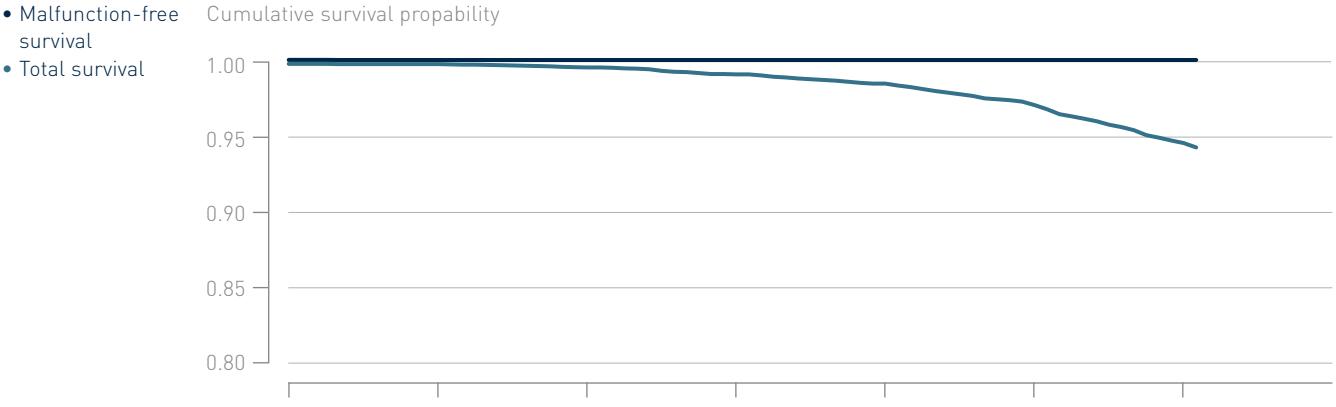


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.8	99.4
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1

Stratos

Product Versions	LV, LV-T
NBG Codes	DDDRV
US Market Release	May 2008
CE Market Release	Nov 2002
Worldwide Distributed Devices	21 400
Registered U.S. Implants	1 310
Estimated Active U.S. Implants	420
U.S. Normal Battery Depletions	204

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.08%
Therapy Compromised	0	0.00%
Therapy Available	1	0.08%



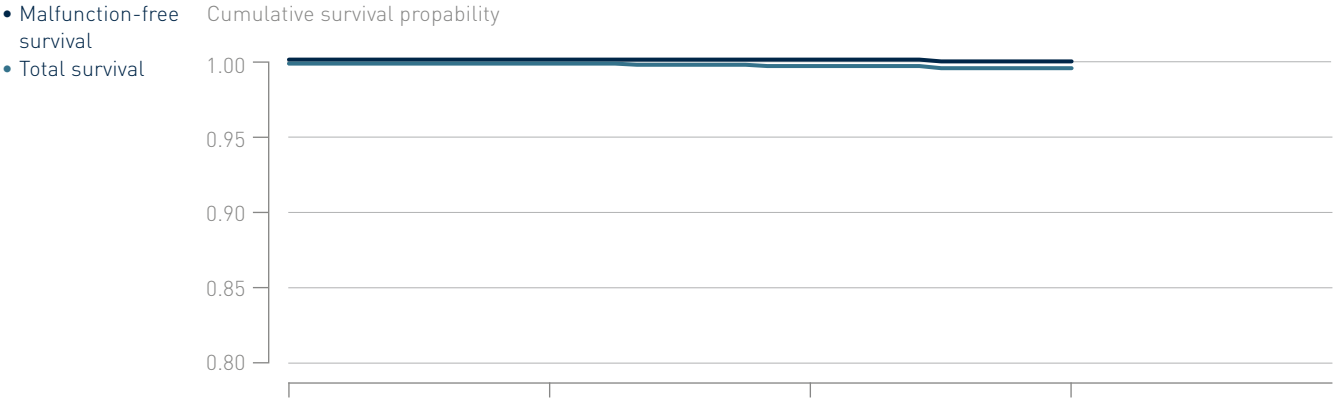
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	98.8	96.5	93.4	86.1	73.4
CI [±%]		0.2	0.7	1.2	1.6	2.4	3.7
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]		0.2	0.2	0.2	0.2	0.2	0.2

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	2 490
Registered U.S. Implants	1 270
Estimated Active U.S. Implants	1 080
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.08%
Therapy Compromised	0	0.00%
Therapy Available	1	0.08%

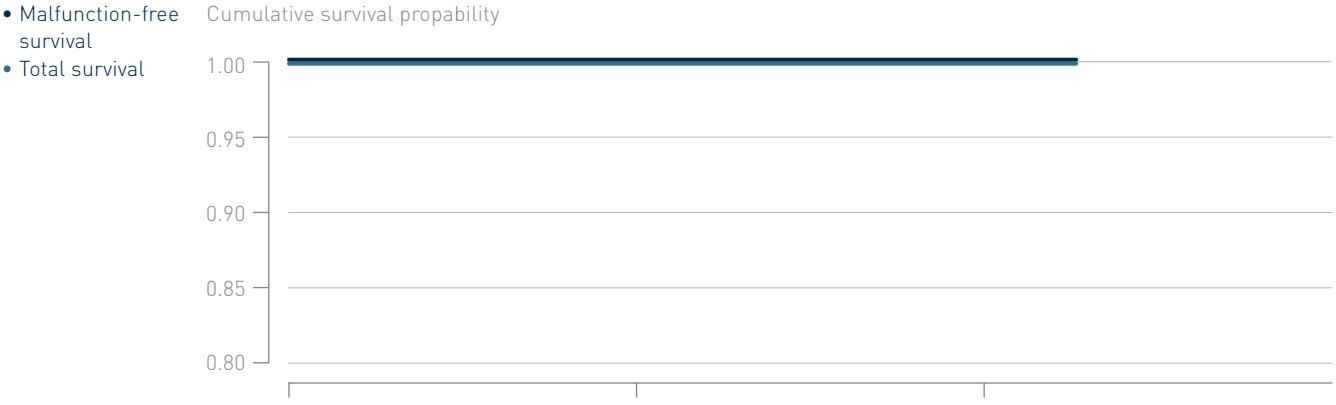


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.8	99.6
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.8
CI [±%]	0.1	0.1	0.1	0.1

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	2420
Registered U.S. Implants	466
Estimated Active U.S. Implants	410
U.S. Normal Battery Depletions	1

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

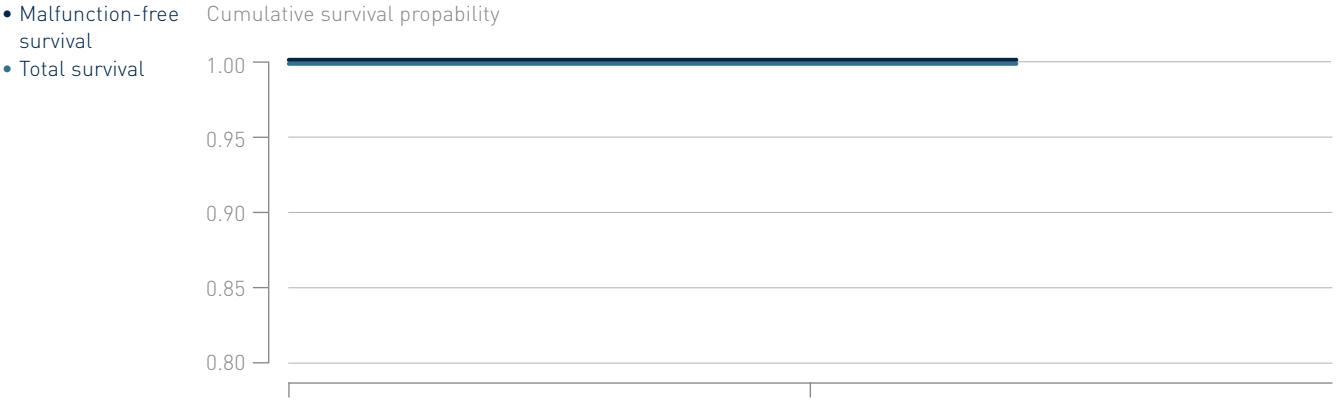


Years after implant	0	1	2
Total [%]	100.0	99.8	99.8
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1

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	676
Estimated Active U.S. Implants	619
U.S. Normal Battery Depletions	0

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

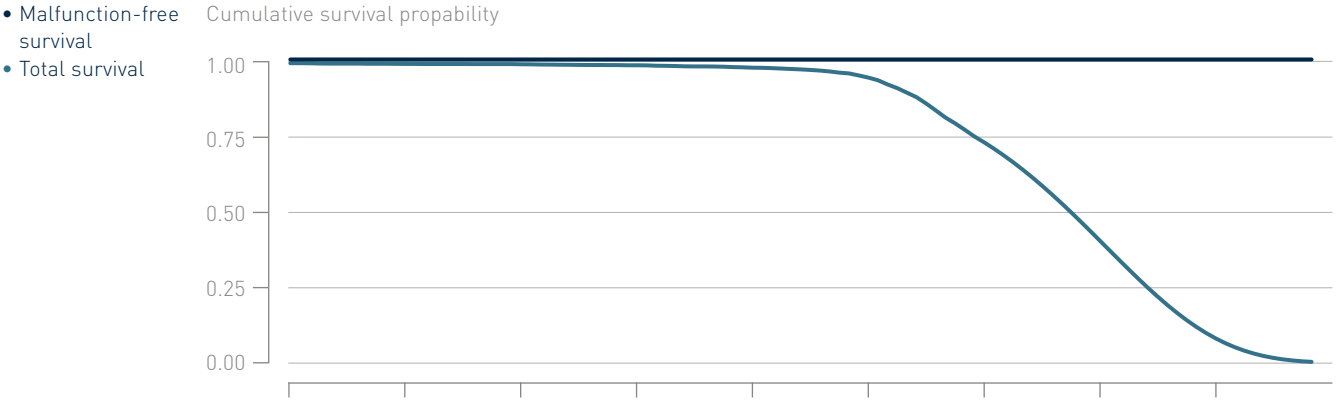


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	27 200
Registered U.S. Implants	3 990
Estimated Active U.S. Implants	1 160
U.S. Normal Battery Depletions	727

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

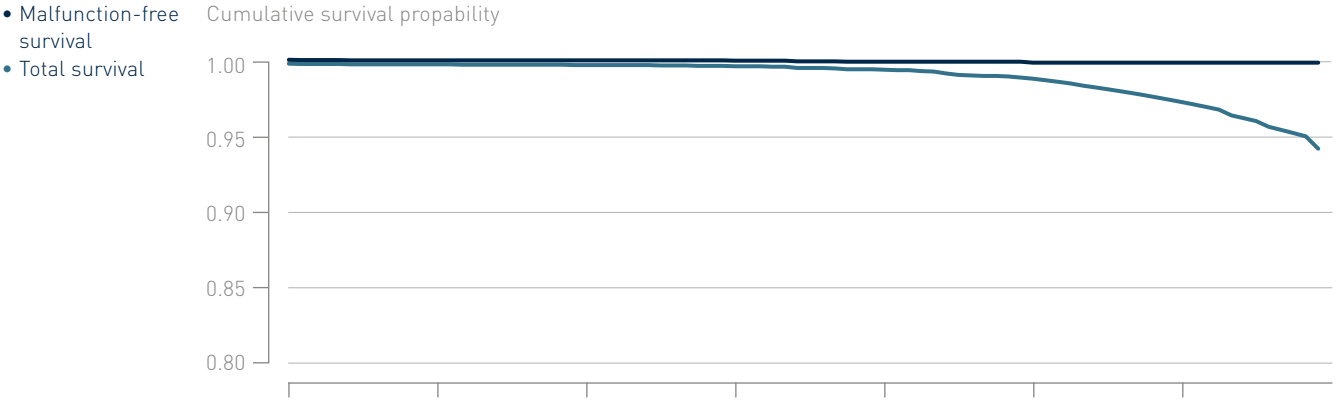


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.8	99.6	99.3	98.5	95.2	73.6	40.9	8.3
CI [±%]		0.2	0.2	0.3	0.4	0.8	1.8	1.2	0.3
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8
CI [±%]		0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Lumax 540

Product Versions	VR-T
NBG Codes	VVE-VVIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20 000
Registered U.S. Implants	4 550
Estimated Active U.S. Implants	2 960
U.S. Normal Battery Depletions	50

	Quantity	Rate
U.S. Confirmed Malfunctions	8	0.18%
Therapy Compromised	4	0.09%
Therapy Available	4	0.09%

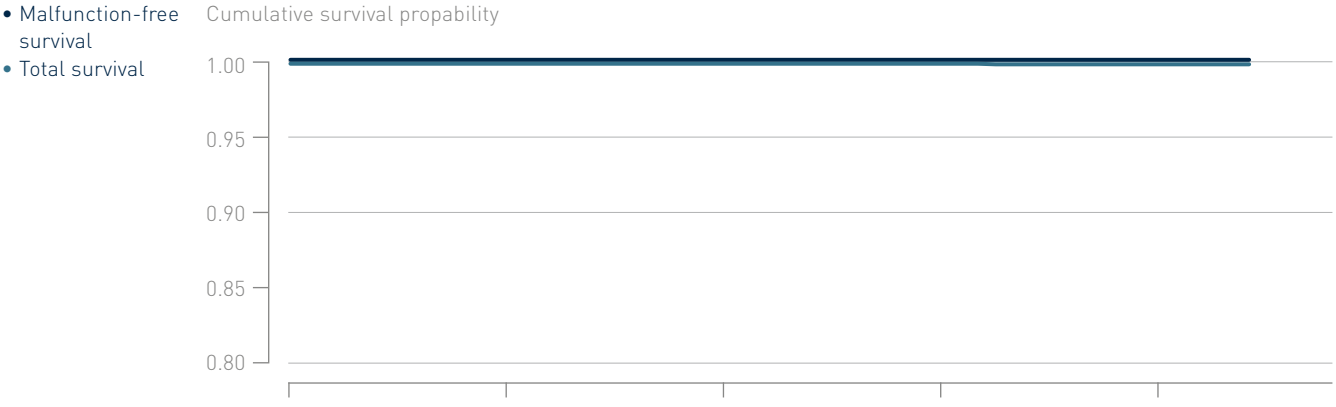


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.9	99.8	99.6	99.0	97.4
CI [±%]		0.1	0.1	0.1	0.2	0.3	0.5
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.8	99.8	99.8
CI [±%]		0.1	0.1	0.1	0.1	0.2	0.2

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	4 790
Registered U.S. Implants	1 580
Estimated Active U.S. Implants	1 230
U.S. Normal Battery Depletions	2

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

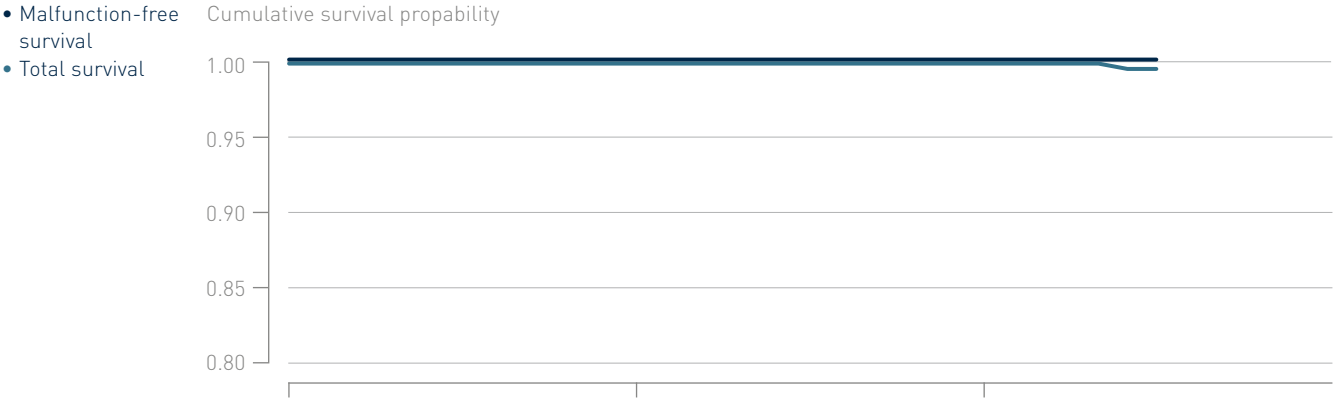


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1

Iforia 7

Product Versions	DR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	1 010
Registered U.S. Implants	614
Estimated Active U.S. Implants	530
U.S. Normal Battery Depletions	1

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

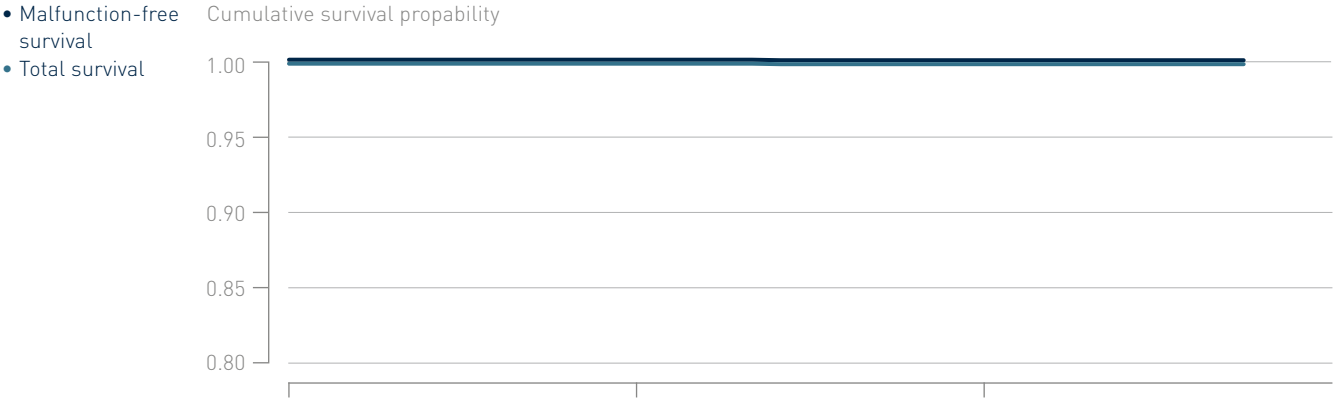


Years after implant	0	1	2
Total [%]	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1

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	2490
Registered U.S. Implants	1470
Estimated Active U.S. Implants	1290
U.S. Normal Battery Depletions	0

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.14%
Therapy Compromised	2	0.14%
Therapy Available	0	0.00%

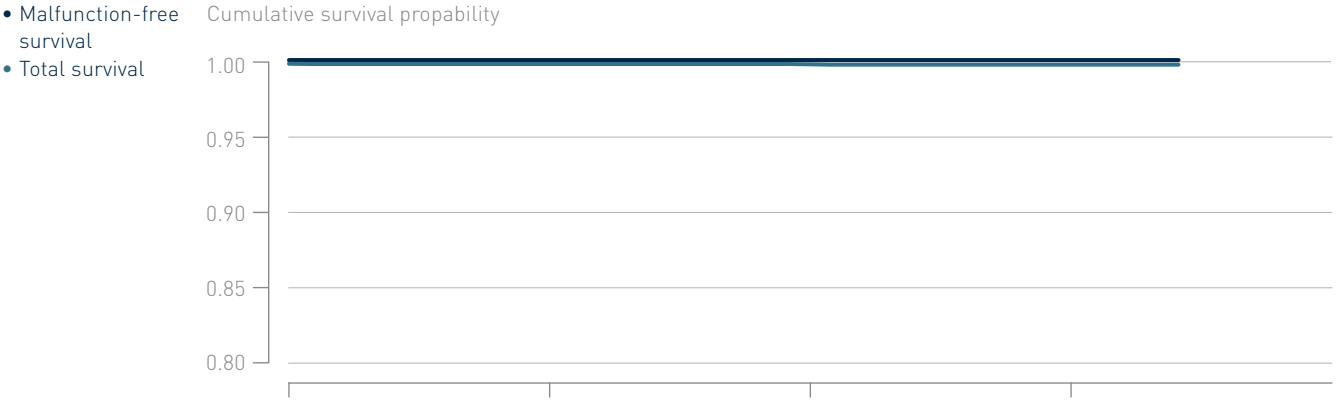


Years after implant	0	1	2
Total [%]	99.9	99.9	99.9
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	99.9	99.9	99.9
CI [±%]	0.1	0.1	0.1

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	5 140
Registered U.S. Implants	3 490
Estimated Active U.S. Implants	2 930
U.S. Normal Battery Depletions	2

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

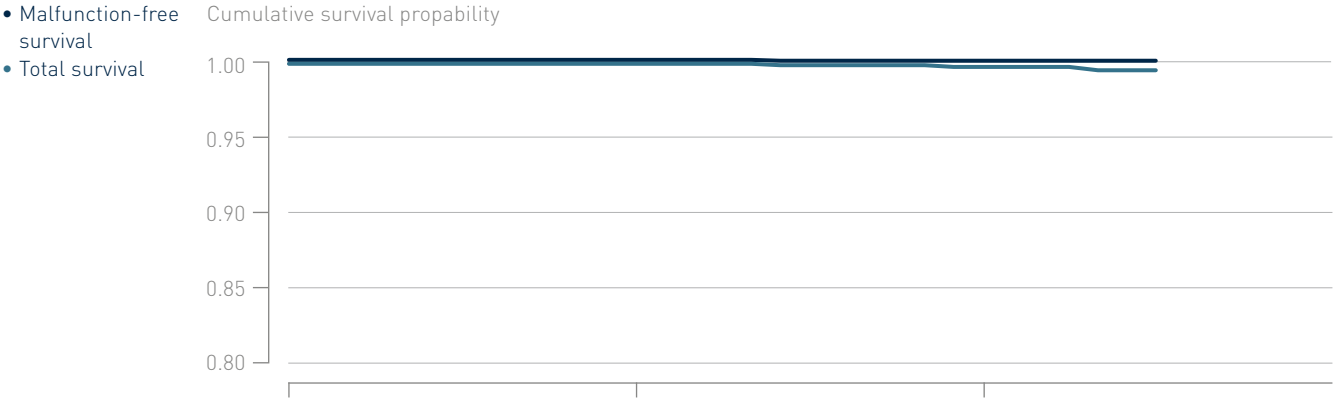


Years after implant	0	1	2	3
Total [%]	100.0	100.0	99.9	99.9
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1

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	3 780
Registered U.S. Implants	1 150
Estimated Active U.S. Implants	1 000
U.S. Normal Battery Depletions	2

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.09%
Therapy Compromised	0	0.00%
Therapy Available	1	0.09%

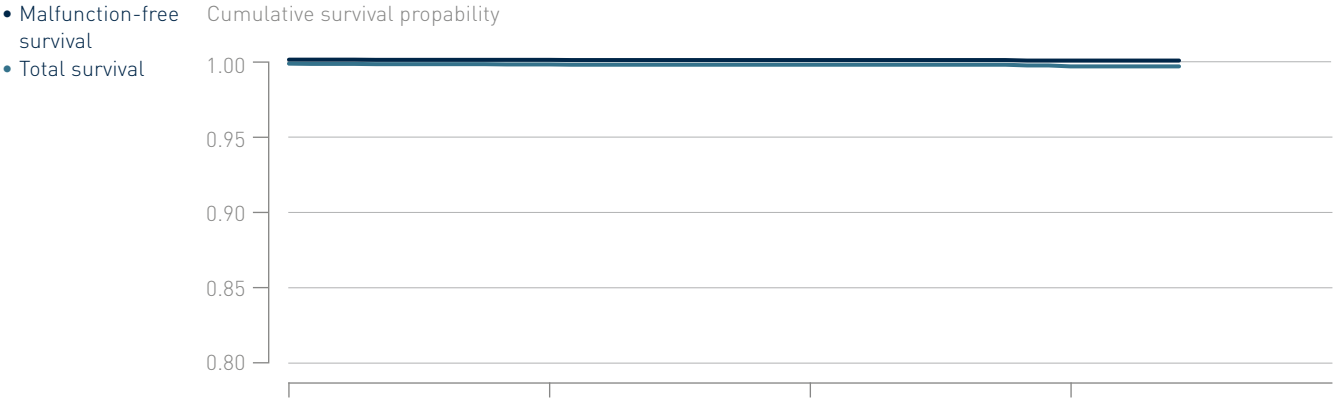


Years after implant	0	1	2
Total [%]	100.0	100.0	99.8
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1

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	6 620
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	3 970
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.06%
Therapy Compromised	1	0.02%
Therapy Available	2	0.04%

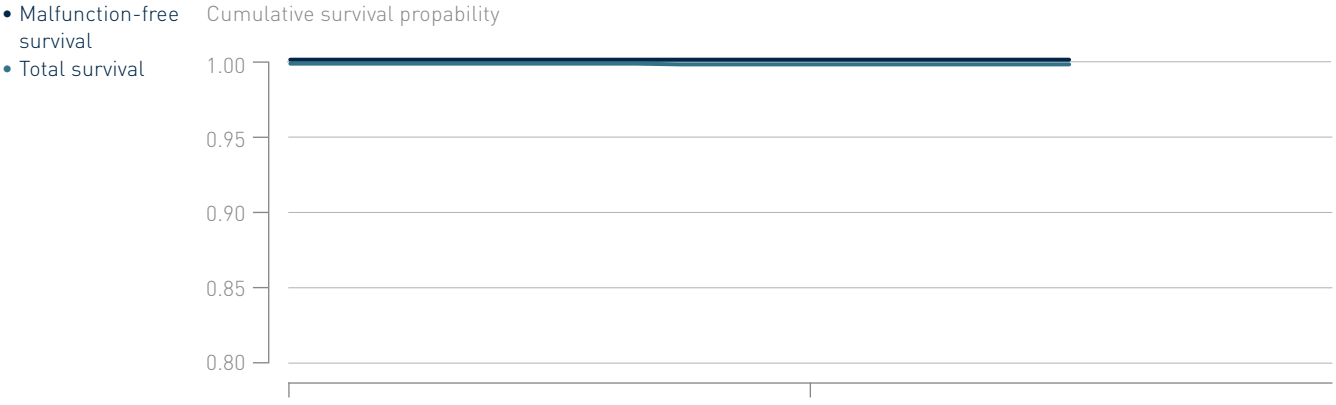


Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.9	99.8
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1	0.1

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	2 980
Registered U.S. Implants	2 330
Estimated Active U.S. Implants	2 190
U.S. Normal Battery Depletions	1

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

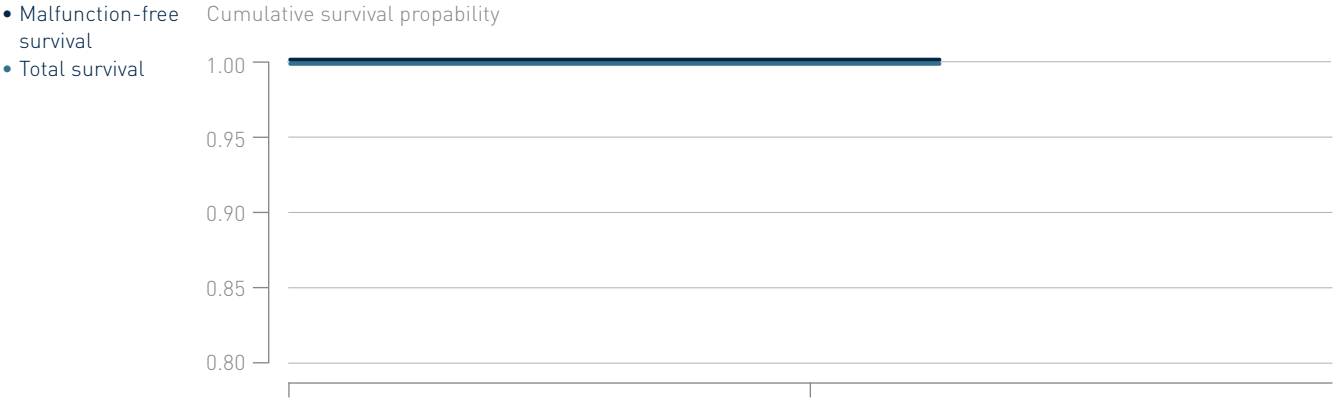


Years after implant	0	1
Total [%]	100.0	99.9
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	6 260
Registered U.S. Implants	2 710
Estimated Active U.S. Implants	2 600
U.S. Normal Battery Depletions	0

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

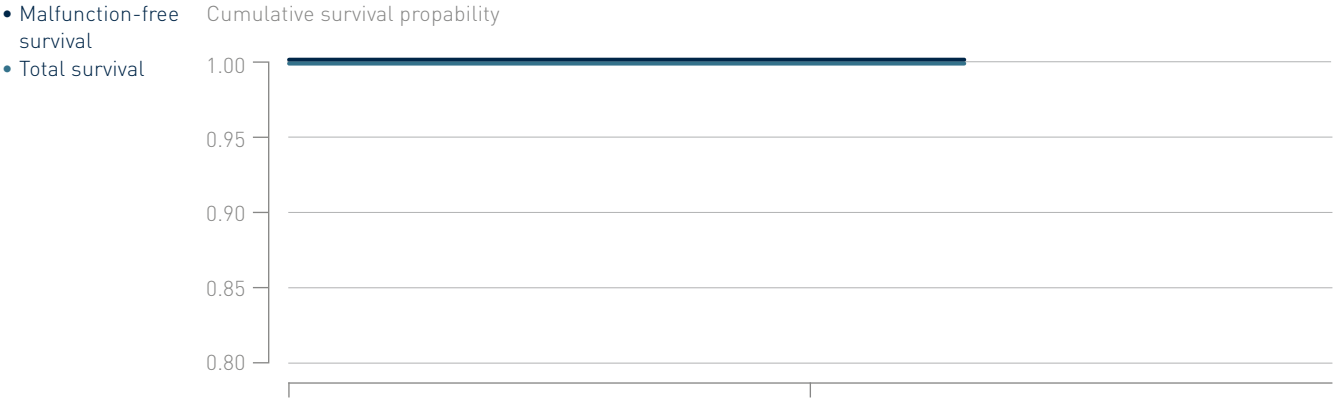


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	5870
Registered U.S. Implants	3390
Estimated Active U.S. Implants	3280
U.S. Normal Battery Depletions	0

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

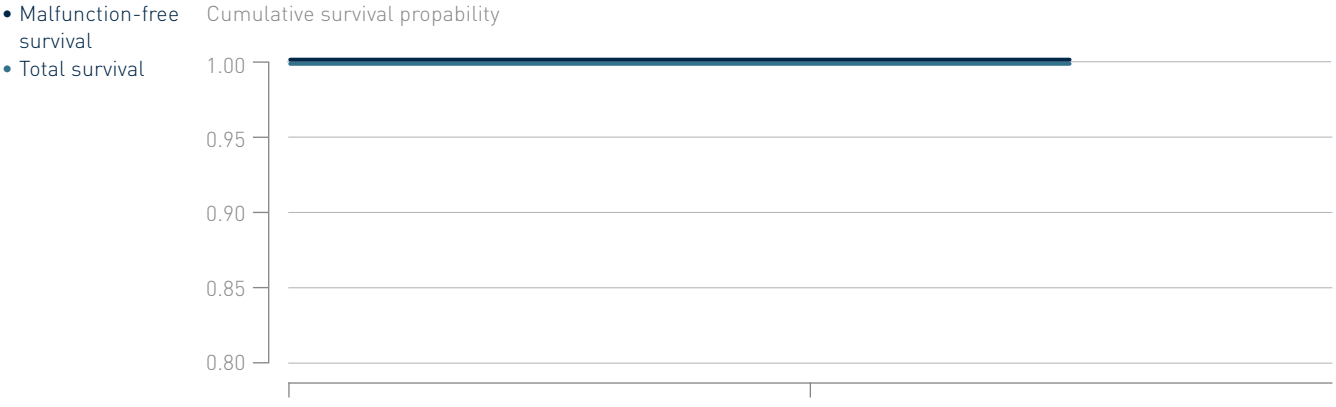


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	1 880
Registered U.S. Implants	949
Estimated Active U.S. Implants	895
U.S. Normal Battery Depletions	0

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

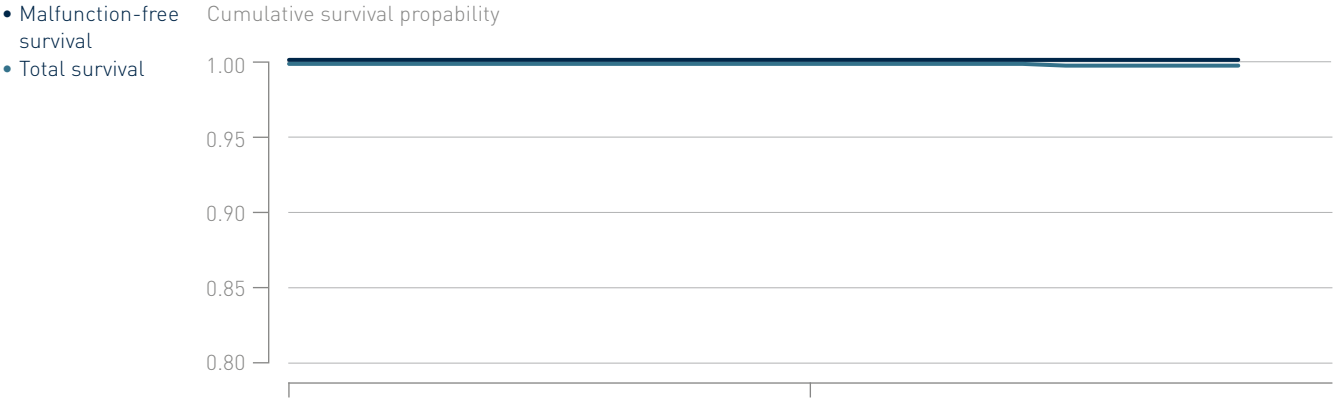


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

Itrevia 7 DF4

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 250
Registered U.S. Implants	1 260
Estimated Active U.S. Implants	1 120
U.S. Normal Battery Depletions	1

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

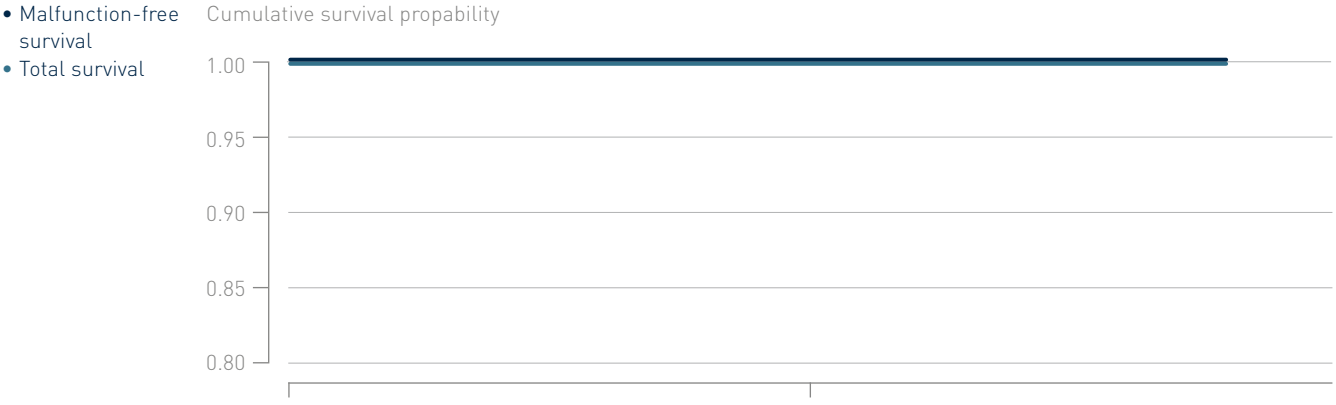


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	1 220
Estimated Active U.S. Implants	1 090
U.S. Normal Battery Depletions	0

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

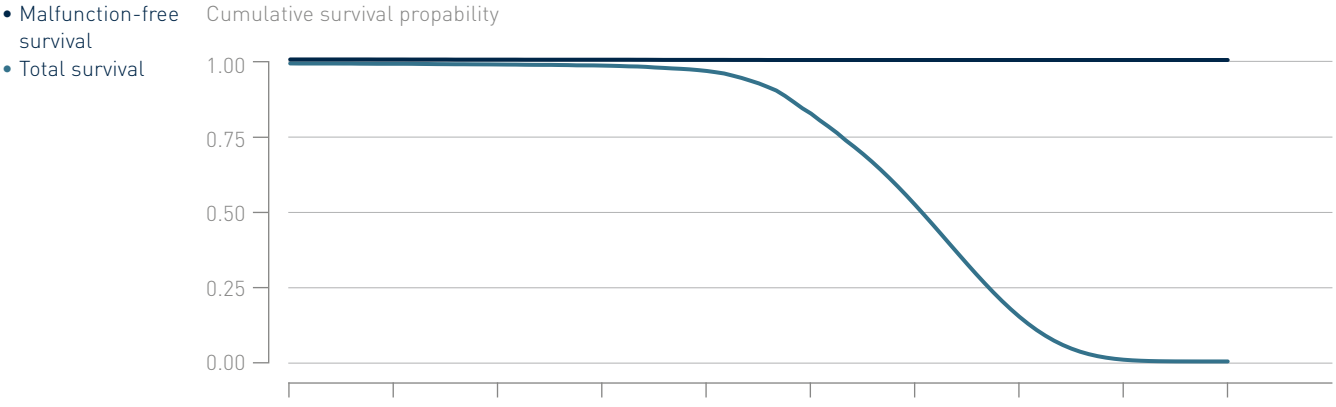


Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

Lumax 340

Product Versions	DR, DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26 400
Registered U.S. Implants	8 220
Estimated Active U.S. Implants	2 060
U.S. Normal Battery Depletions	1 824

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

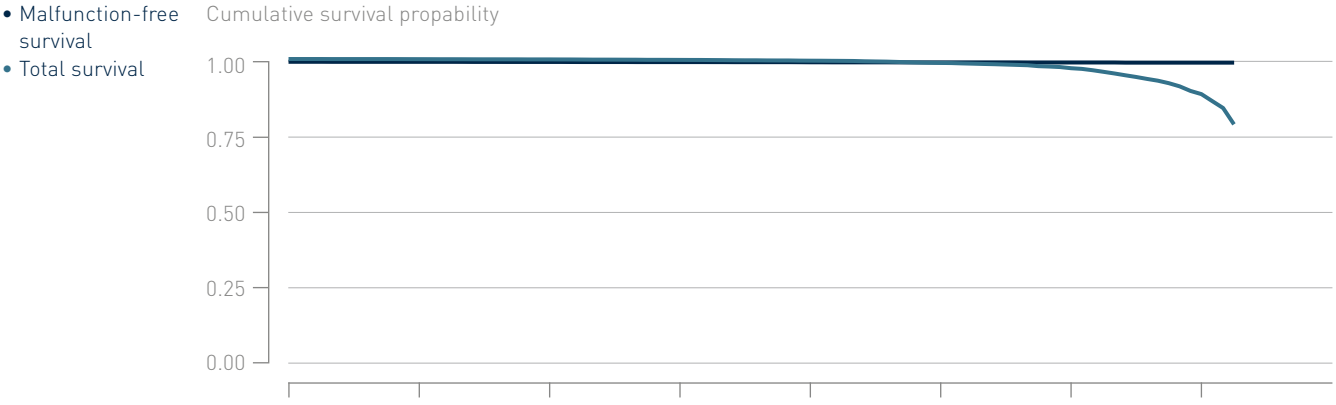


Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.9	99.6	99.3	97.5	83.2	52.5	15	0.6	
CI [±%]		0.1	0.1	0.2	0.4	1	1.1	0.3		
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8
CI [±%]			0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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	11 600
Estimated Active U.S. Implants	7 150
U.S. Normal Battery Depletions	324

	Quantity	Rate
U.S. Confirmed Malfunctions	16	0.14%
Therapy Compromised	8	0.07%
Therapy Available	8	0.07%

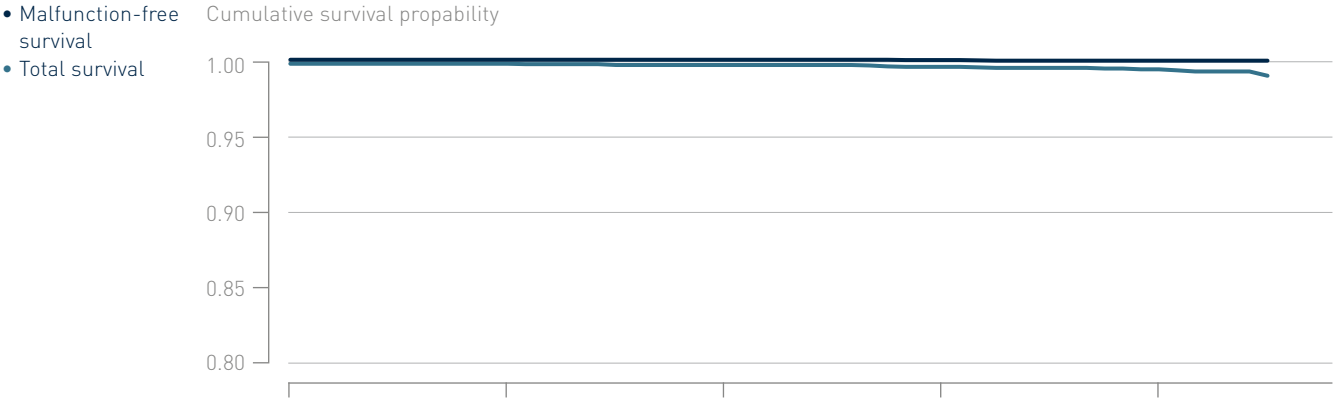


Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.9	99.7	99.5	98.8	97.2	89.4
CI [±%]			0.1	0.1	0.1	0.2	0.4	1.3
Malfunction-Free [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8
CI [±%]				0.1	0.1	0.1	0.1	0.1

Lumax 740

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7 980
Registered U.S. Implants	3 820
Estimated Active U.S. Implants	2 850
U.S. Normal Battery Depletions	12

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

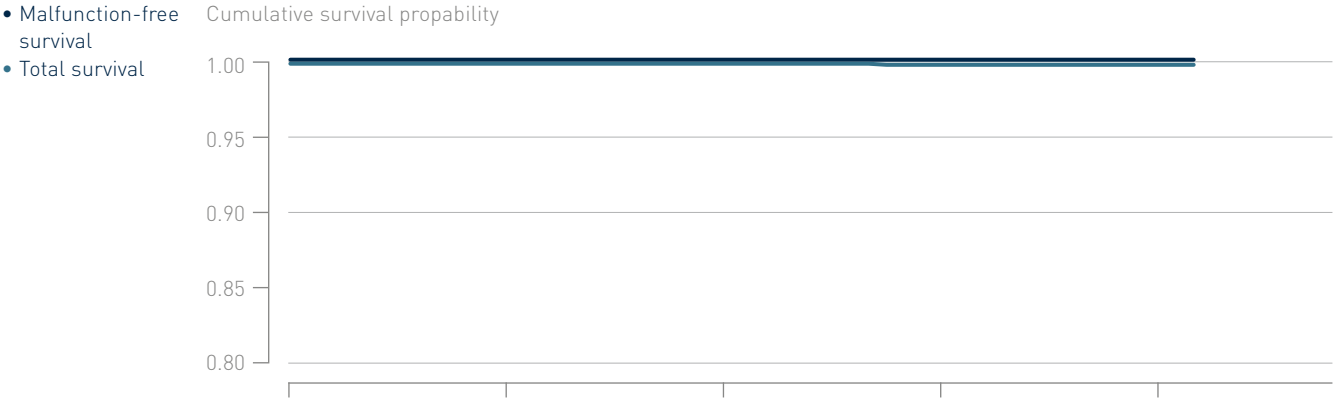


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.8	99.6
CI [±%]	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1	0.1	0.1

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	4 570
Registered U.S. Implants	2 230
Estimated Active U.S. Implants	1 690
U.S. Normal Battery Depletions	1

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

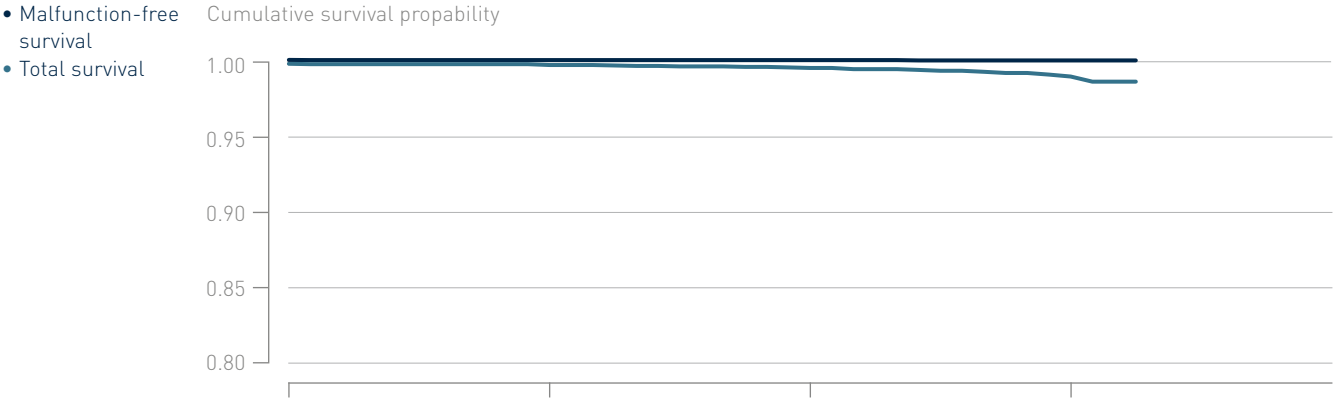


Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	100.0	99.9	99.9
CI [±%]	0.1	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0
CI [±%]	0.1	0.1	0.1	0.1	0.1

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	5330
Registered U.S. Implants	3840
Estimated Active U.S. Implants	2870
U.S. Normal Battery Depletions	18

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.05%
Therapy Compromised	2	0.05%
Therapy Available	0	0.00%

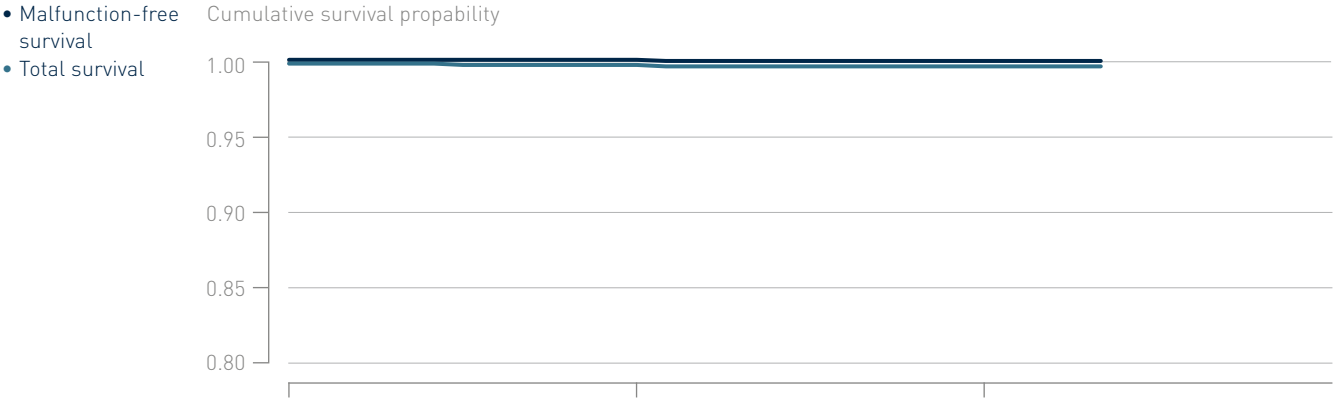


Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.7	99.1
CI [±%]	0.1	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1	0.1

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	2410
Registered U.S. Implants	967
Estimated Active U.S. Implants	774
U.S. Normal Battery Depletions	1

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

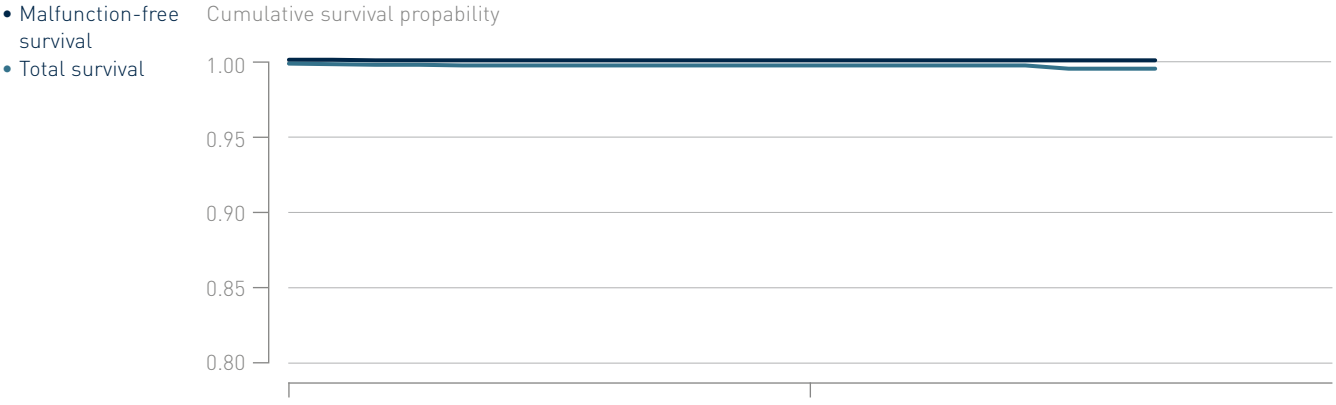


Years after implant	0	1	2
Total [%]	100.0	99.9	99.8
CI [±%]	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9
CI [±%]	0.1	0.1	0.1

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	4 130
Registered U.S. Implants	2 420
Estimated Active U.S. Implants	2 140
U.S. Normal Battery Depletions	3

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

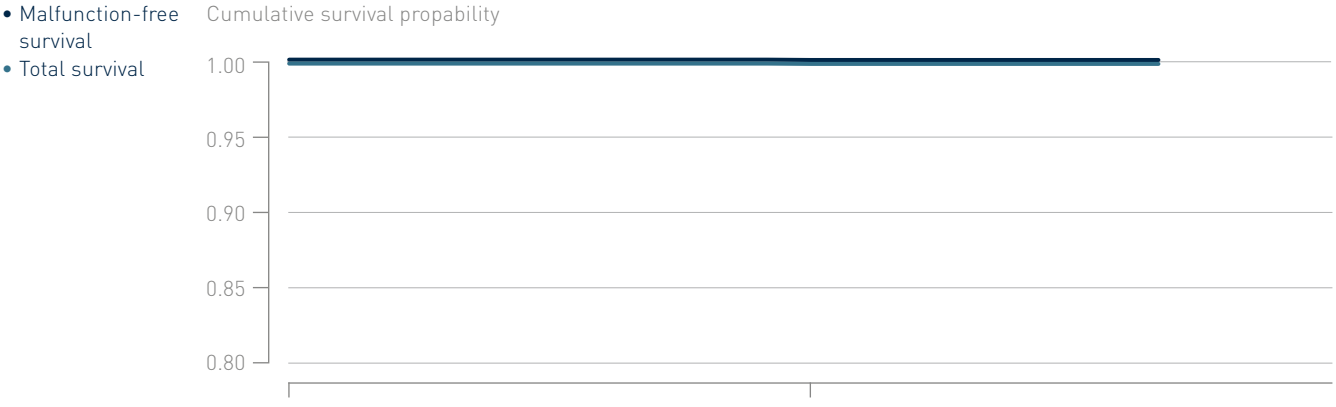


Years after implant	0	1
Total [%]	100.0	99.9
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]	0.1	0.1

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	5 750
Registered U.S. Implants	2 940
Estimated Active U.S. Implants	2 560
U.S. Normal Battery Depletions	0

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

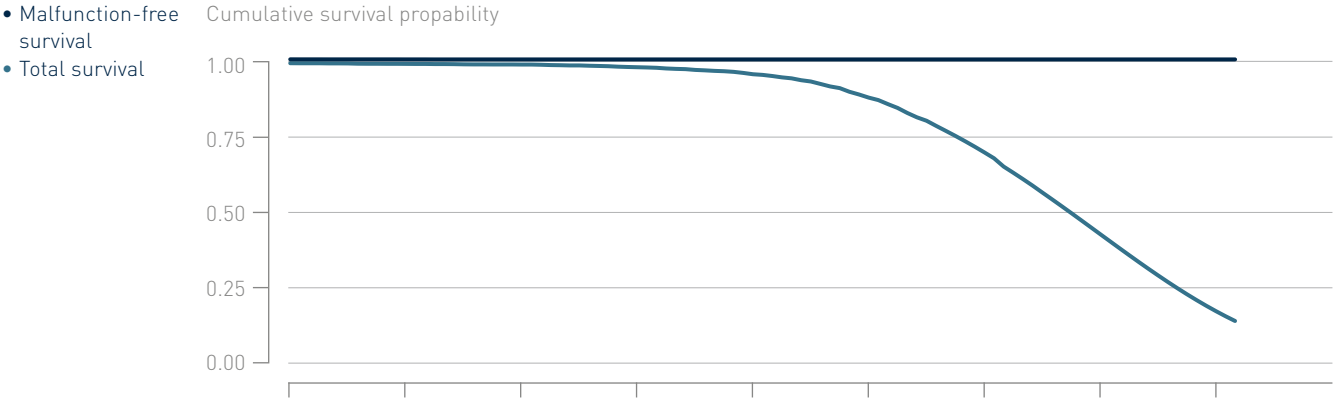


Years after implant	0	1
Total [%]	100.0	99.9
CI [±%]	0.1	0.1
Malfunction-Free [%]	100.0	99.9
CI [±%]	0.1	0.1

Lumax 340

Product Versions	HF, HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20 800
Registered U.S. Implants	5 310
Estimated Active U.S. Implants	834
U.S. Normal Battery Depletions	1 058

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

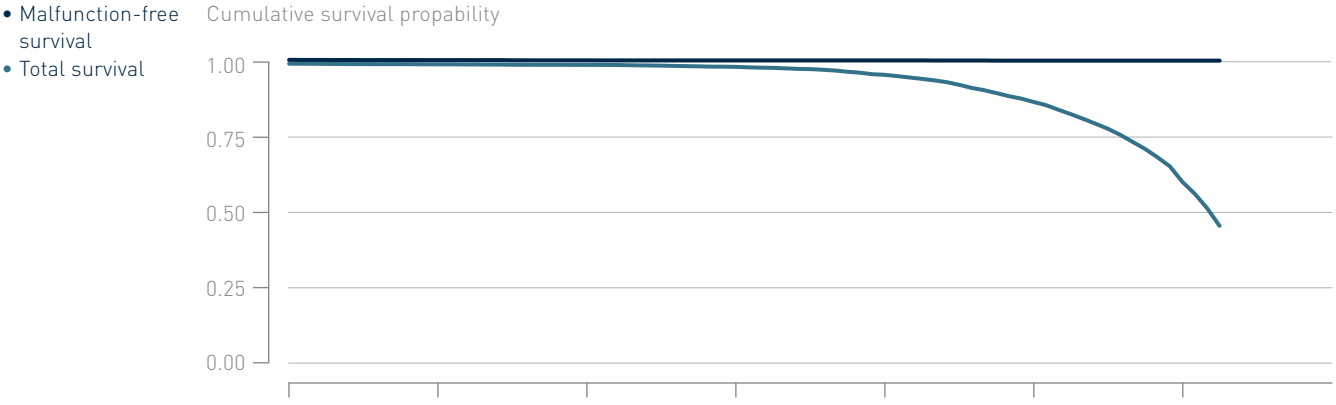


Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.5	98.6	96.3	88.5	70.3	43.1	17.5
CI [±%]	0.1	0.1	0.2	0.4	0.6	1.1	1.7	1.8	0.8
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]	0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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	8 660
Estimated Active U.S. Implants	2 980
U.S. Normal Battery Depletions	1 345

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

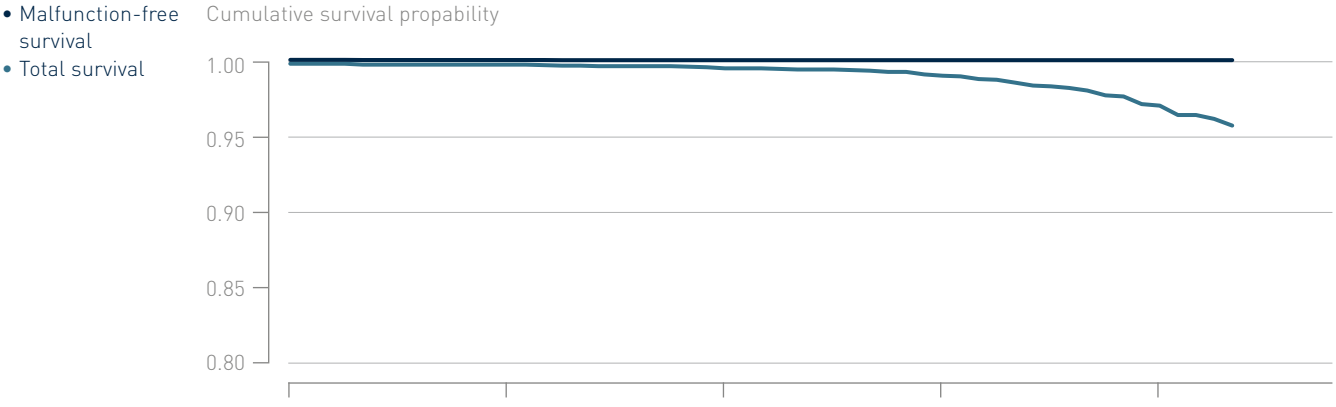


Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.6	98.9	96.3	87.3	60.8
CI [±%]		0.1	0.1	0.2	0.5	0.9	2.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8
CI [±%]			0.1	0.1	0.1	0.1	0.1

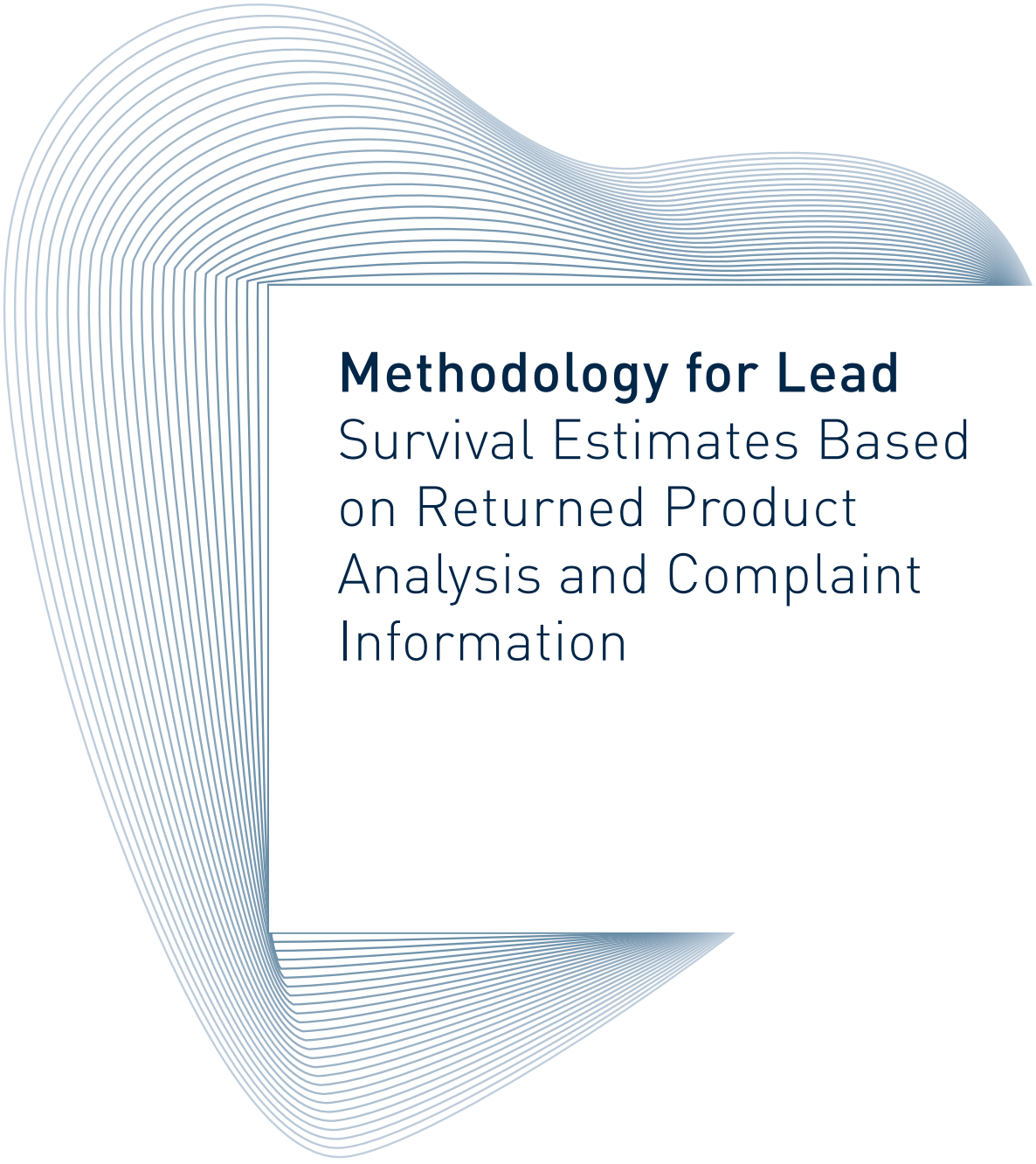
Lumax 740

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7 050
Registered U.S. Implants	3 410
Estimated Active U.S. Implants	2 250
U.S. Normal Battery Depletions	60

	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
Total [%]	100.0	99.9	99.7	99.2	97.2
CI [±%]	0.1	0.1	0.2	0.3	0.8
Malfunction-Free [%]	100.0	100.0	99.9	99.9	99.9
CI [±%]		0.1	0.1	0.1	0.1



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

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

4.1 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 100.0 %. Even though they are analyzed as part of our quality system monitoring, leads that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time. Because this report is provided to communicate information regarding product performance, it does not include data regarding medical complications such as erosion, infection or diaphragmatic stimulation.

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

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

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

4.2 Lead Data Acquisition

The following sections of this report provide performance data on BIOTRONIK's pacing and ICD leads and are based on the observation of BIOTRONIK's U.S. products through

review of our device registration and tracking systems, and through the analyses of both, returned leads as well as reports of lead complications of non-returned leads. The prospective data from BIOTRONIK's post-approval studies is presented separately in chapters 8 and 9.

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is June 30, 2017. 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.

4.3 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.

4.4 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.

4.5 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

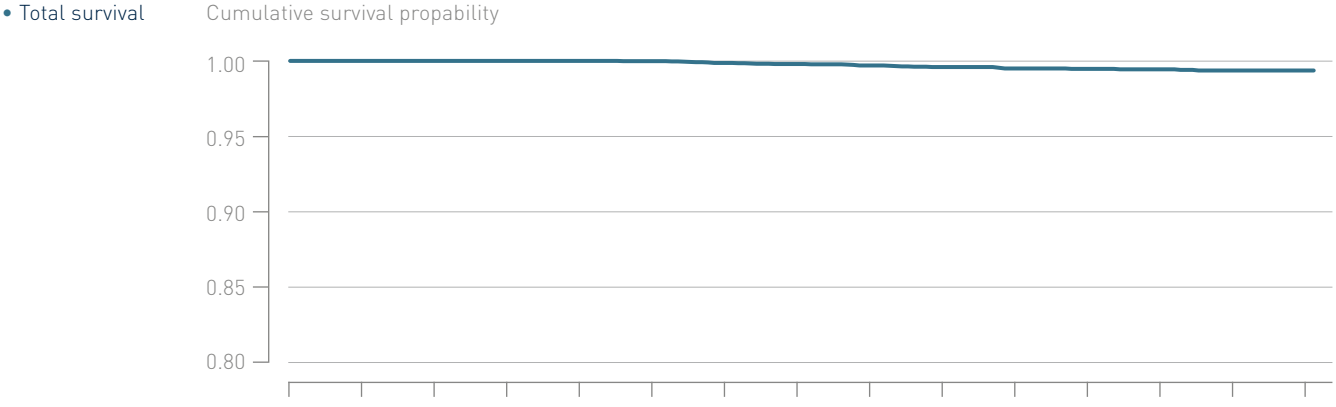
Based on Returned Products and Complaint Data Information

Arox

Product Versions	53-BP, 60-BP
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	no
U.S. Market Release	Sep 2002
CE Market Release	Jan 2002
Worldwide Distributed Devices	36 500
Registered U.S. Implants	8 550
Estimated Active U.S. Implants	4 500
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	29	0.34%
Abnormal pacing impedance	9	0.11%
Conductor fracture	2	0.02%
Failure to capture	14	0.16%
Insulation breach	2	0.02%
Other	2	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.01%
Insulation Breach	1	0.01%
U.S. Acute Lead Observations	2	0.02%
Lead dislodgement	2	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	100.0	100.0	100.0	99.9	99.8	99.7	99.6	99.5	99.4	99.4	99.3	99.3
CI [±%]							0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3	0.3

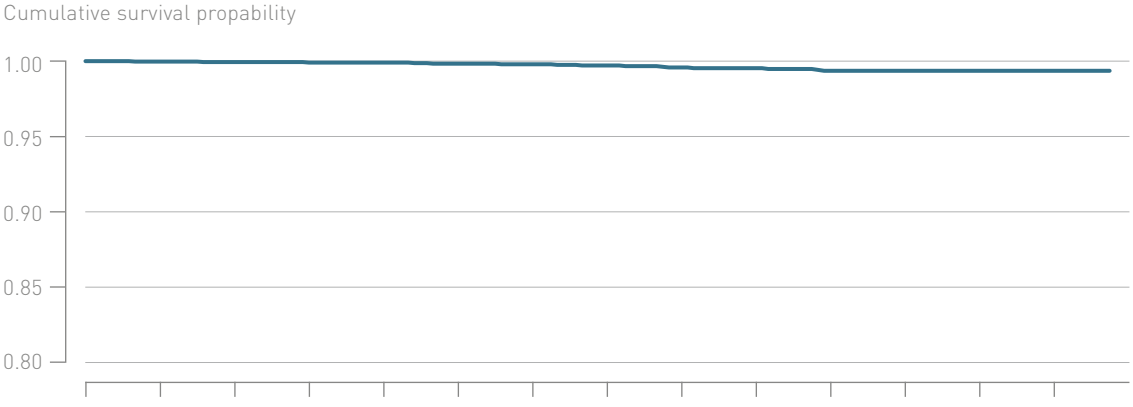
Arox J

Product Versions	45-JBP, 53-JBP
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	no
U.S. Market Release	Sep 2002
CE Market Release	Jan 2002
Worldwide Distributed Devices	8 760
Registered U.S. Implants	3 470
Estimated Active U.S. Implants	2 080
U.S. Total Returned	8

	Quantity	Rate
U.S. Qualifying Complications	15	0.43%
Abnormal pacing impedance	2	0.06%
Conductor fracture	1	0.03%
Failure to capture	9	0.26%
Lead dislodgement	2	0.06%
Oversensing	1	0.03%

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

• Total survival



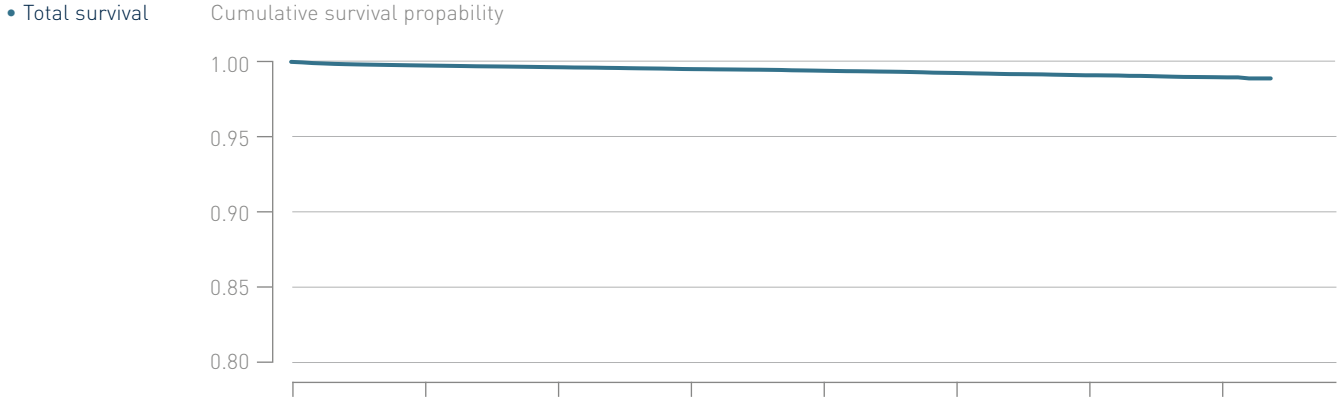
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.7	99.6	99.5	99.3	99.3	99.3	99.3
CI [±%]		0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.4	0.4	0.4	0.4

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	487 000
Registered U.S. Implants	281 000
Estimated Active U.S. Implants	218 000
U.S. Total Returned	1 461

	Quantity	Rate
U.S. Qualifying Complications	1 372	0.49%
Abnormal pacing impedance	95	0.03%
Cardiac perforation	12	0.00%
Conductor fracture	43	0.02%
Extracardiac stimulation	6	0.00%
Failure to capture	370	0.13%
Failure to sense	31	0.01%
Insulation breach	22	0.01%
Lead dislodgement	244	0.09%
Oversensing	245	0.09%
Other	304	0.11%

	Quantity	Rate
U.S. Confirmed Malfunctions	166	0.06%
Conductor Fracture	79	0.03%
Insulation Breach	83	0.03%
Other	4	0.00%
U.S. Acute Lead Observations	1 072	0.38%
Abnormal pacing impedance	18	0.01%
Cardiac perforation	43	0.02%
Extracardiac stimulation	12	0.00%
Failure to capture	139	0.05%
Failure to sense	29	0.01%
Insulation breach	3	0.00%
Lead dislodgement	374	0.13%
Oversensing	15	0.01%
Other	439	0.16%



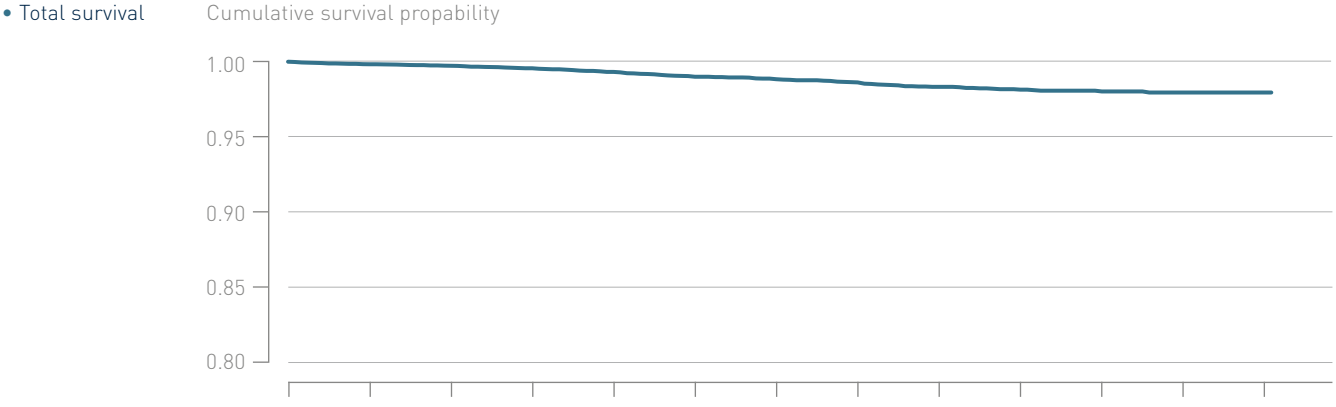
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.6	99.5	99.4	99.2	99.1	98.9
CI [±%]							0.1	0.1

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	144 000
Registered U.S. Implants	16 200
Estimated Active U.S. Implants	12 200
U.S. Total Returned	106

	Quantity	Rate
U.S. Qualifying Complications	165	1.02%
Abnormal pacing impedance	20	0.12%
Cardiac perforation	1	0.01%
Conductor fracture	6	0.04%
Extracardiac stimulation	1	0.01%
Failure to capture	75	0.47%
Failure to sense	7	0.04%
Insulation breach	8	0.05%
Lead dislodgement	27	0.17%
Oversensing	3	0.02%
Other	17	0.11%

	Quantity	Rate
U.S. Confirmed Malfunctions	8	0.05%
Insulation Breach	8	0.05%
U.S. Acute Lead Observations	44	0.27%
Failure to capture	8	0.05%
Lead dislodgement	33	0.20%
Other	3	0.02%



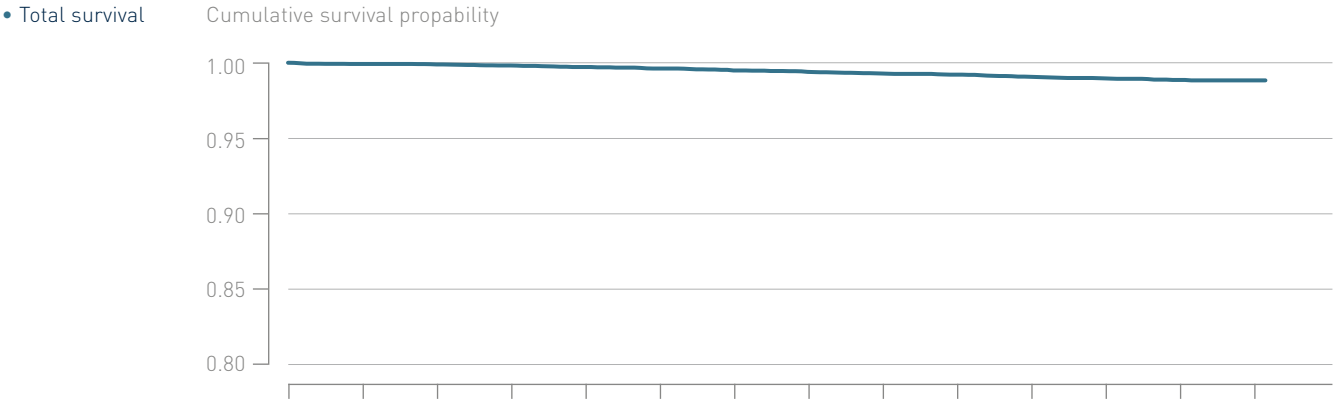
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.8	99.7	99.6	99.3	99.0	98.8	98.6	98.3	98.1	98.0	97.9	97.9
CI [±%]		0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4

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	14 400
Estimated Active U.S. Implants	7 170
U.S. Total Returned	60

	Quantity	Rate
U.S. Qualifying Complications	94	0.66%
Abnormal pacing impedance	3	0.02%
Conductor fracture	7	0.05%
Extracardiac stimulation	2	0.01%
Failure to capture	38	0.27%
Failure to sense	1	0.01%
Insulation breach	6	0.04%
Lead dislodgement	13	0.09%
Oversensing	10	0.07%
Other	14	0.10%

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



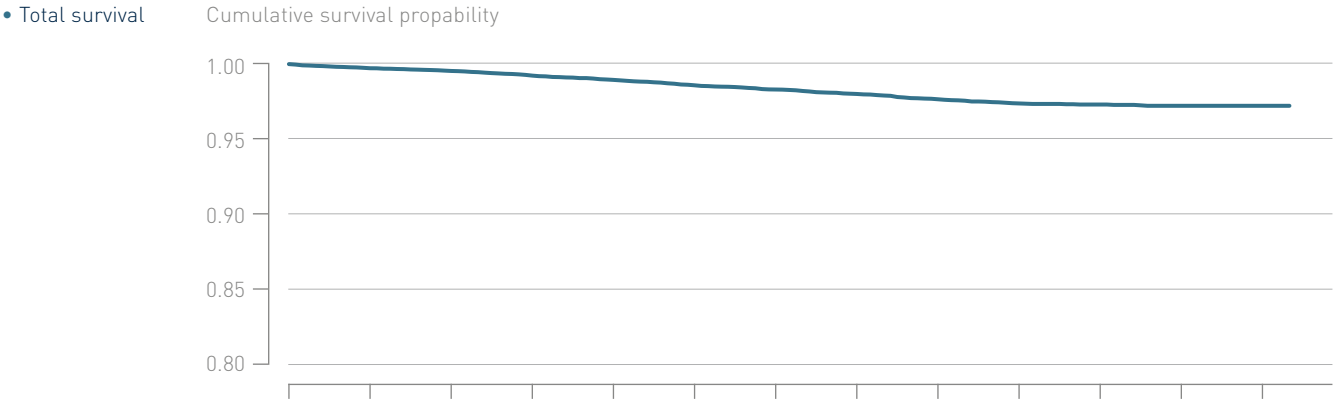
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.8
CI [±%]			0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2

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	370 000
Registered U.S. Implants	31 300
Estimated Active U.S. Implants	22 600
U.S. Total Returned	157

	Quantity	Rate
U.S. Qualifying Complications	458	1.47%
Abnormal pacing impedance	101	0.32%
Cardiac perforation	3	0.01%
Conductor fracture	45	0.14%
Extracardiac stimulation	7	0.02%
Failure to capture	222	0.71%
Failure to sense	1	0.00%
Insulation breach	33	0.11%
Lead dislodgement	19	0.06%
Oversensing	6	0.02%
Other	21	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	14	0.04%
Conductor Fracture	1	0.00%
Crimps, Welds and Bonds	1	0.00%
Insulation Breach	12	0.04%
U.S. Acute Lead Observations	44	0.14%
Abnormal pacing impedance	1	0.00%
Failure to capture	17	0.05%
Lead dislodgement	20	0.06%
Other	6	0.02%



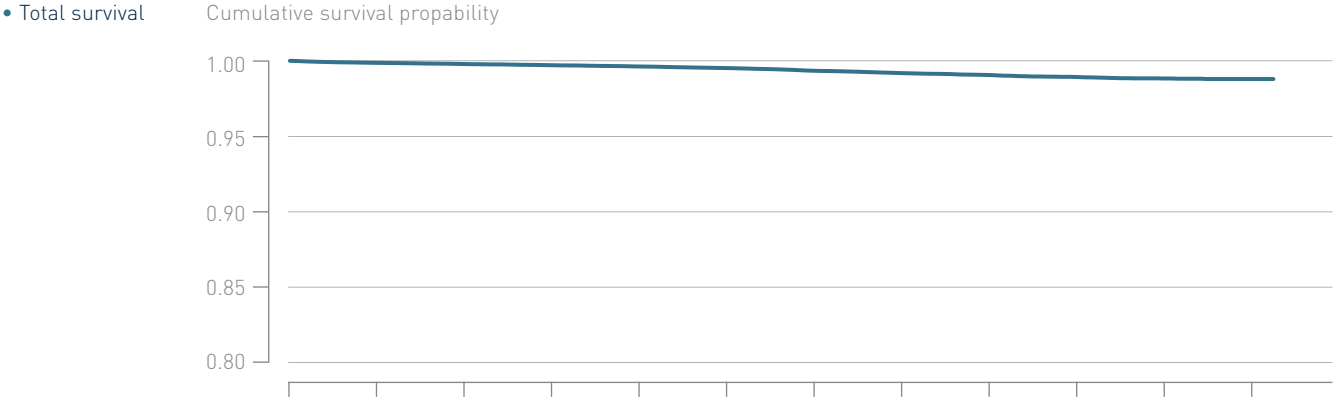
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.0	97.6	97.3	97.3	97.2	97.2
CI [±%]		0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3

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	659 000
Registered U.S. Implants	244 000
Estimated Active U.S. Implants	20 100
U.S. Total Returned	1 445

	Quantity	Rate
U.S. Qualifying Complications	1 045	0.43%
Abnormal pacing impedance	74	0.03%
Cardiac perforation	8	0.00%
Conductor fracture	42	0.02%
Extracardiac stimulation	9	0.00%
Failure to capture	357	0.15%
Failure to sense	29	0.01%
Insulation breach	58	0.02%
Lead dislodgement	262	0.11%
Oversensing	114	0.05%
Other	92	0.04%

	Quantity	Rate
U.S. Confirmed Malfunctions	125	0.05%
Conductor Fracture	46	0.02%
Insulation Breach	78	0.03%
Other	1	0.00%
U.S. Acute Lead Observations	270	0.11%
Abnormal pacing impedance	1	0.00%
Cardiac perforation	20	0.01%
Failure to capture	36	0.01%
Failure to sense	3	0.00%
Insulation breach	4	0.00%
Lead dislodgement	191	0.08%
Other	15	0.01%



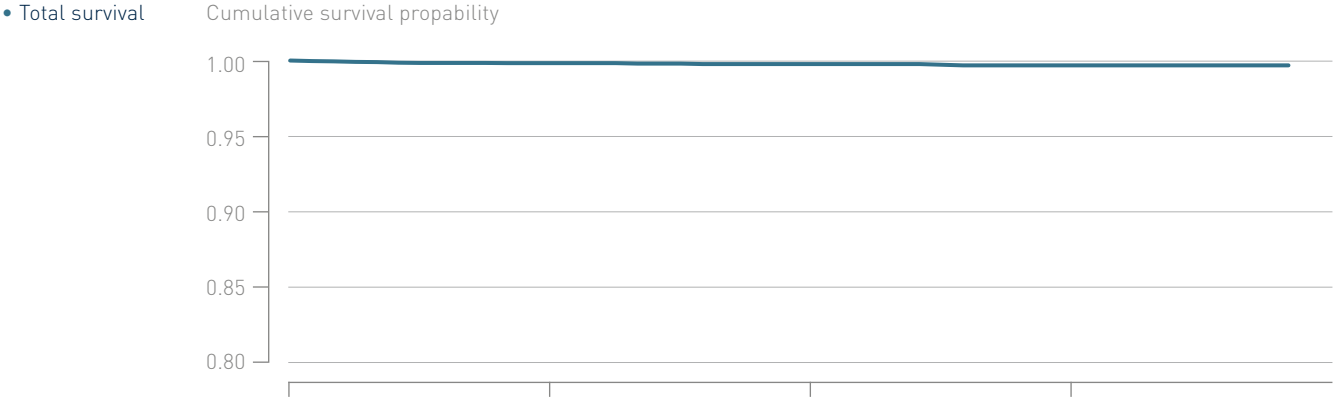
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.0	98.9	98.8	98.7
CI [±%]								0.1	0.1	0.1	0.1	0.1

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jun 2016
CE Market Release	Jul 2009
Worldwide Distributed Devices	779 000
Registered U.S. Implants	34 300
Estimated Active U.S. Implants	33 100
U.S. Total Returned	102

	Quantity	Rate
U.S. Qualifying Complications	45	0.13%
Cardiac perforation	5	0.01%
Conductor fracture	1	0.00%
Failure to capture	16	0.05%
Failure to sense	2	0.01%
Lead dislodgement	19	0.06%
Oversensing	1	0.00%
Other	1	0.00%

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.01%
Conductor Fracture	1	0.00%
Insulation Breach	4	0.01%
U.S. Acute Lead Observations	35	0.10%
Cardiac perforation	6	0.02%
Failure to capture	8	0.02%
Failure to sense	1	0.00%
Lead dislodgement	17	0.05%
Oversensing	1	0.00%
Other	2	0.01%



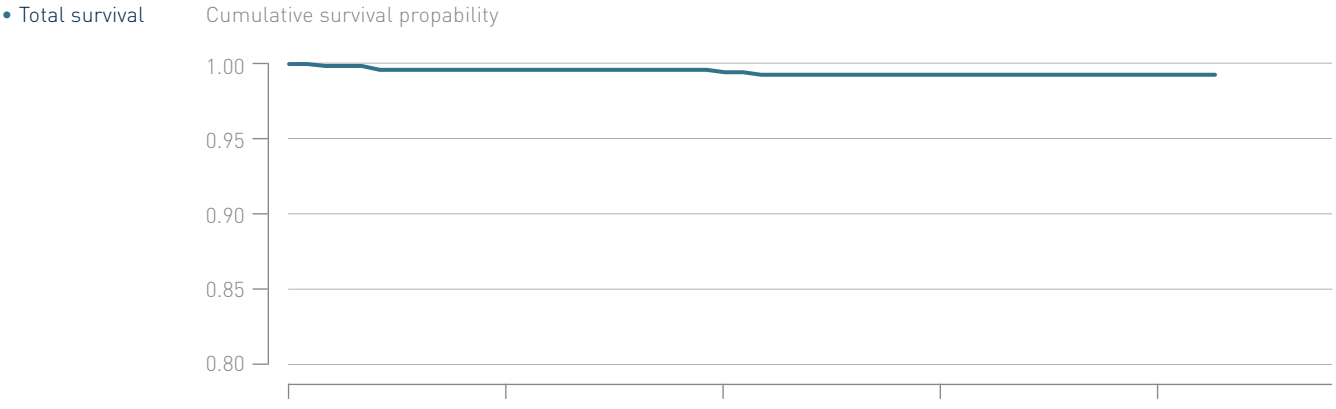
Years after implant	0	1	2	3
Total [%]	100.0	99.8	99.7	99.6
CI [±%]		0.1	0.1	0.2

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	15800
Registered U.S. Implants	736
Estimated Active U.S. Implants	717
U.S. Total Returned	0

	Quantity	Rate
U.S. Qualifying Complications	5	0.68%
Abnormal pacing impedance	1	0.14%
Failure to capture	1	0.14%
Lead dislodgement	3	0.41%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	1	0.14%
Lead dislodgement	1	0.14%



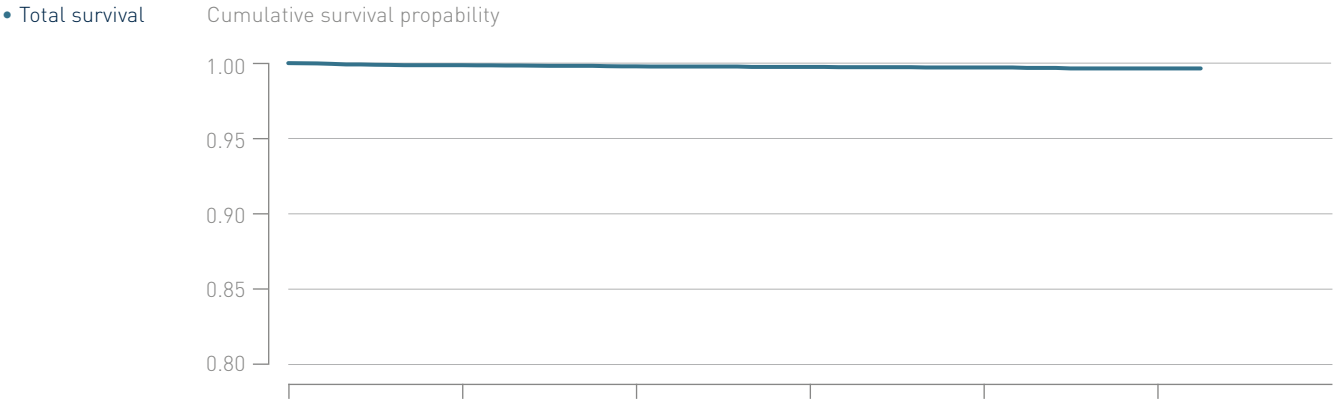
Years after implant	0	1	2	3	4
Total [%]	100.0	99.6	99.4	99.2	99.2
CI [±%]		0.5	0.6	0.7	0.7

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	40 600
Registered U.S. Implants	9 340
Estimated Active U.S. Implants	8 990
U.S. Total Returned	15

	Quantity	Rate
U.S. Qualifying Complications	27	0.29%
Abnormal pacing impedance	1	0.01%
Conductor fracture	3	0.03%
Extracardiac stimulation	1	0.01%
Failure to capture	7	0.07%
Insulation breach	2	0.02%
Lead dislodgement	9	0.10%
Oversensing	1	0.01%
Other	3	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.01%
Conductor Fracture	1	0.01%
U.S. Acute Lead Observations	8	0.09%
Failure to capture	1	0.01%
Lead dislodgement	7	0.07%



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.8	99.7	99.7	99.6
CI [±%]		0.1	0.1	0.1	0.1	0.2

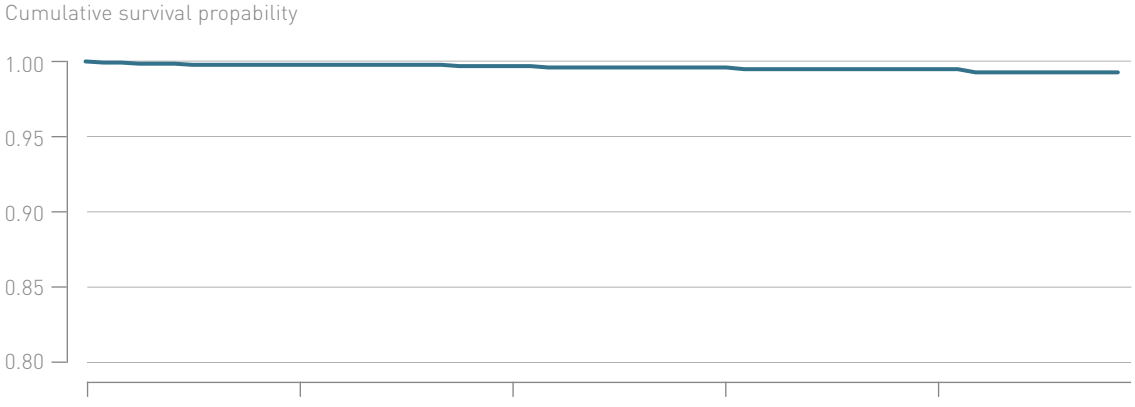
Tilda T

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	21 100
Registered U.S. Implants	1 280
Estimated Active U.S. Implants	1 230
U.S. Total Returned	1

	Quantity	Rate
U.S. Qualifying Complications	7	0.55%
Abnormal pacing impedance	3	0.24%
Insulation breach	1	0.08%
Lead dislodgement	3	0.24%

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

• Total survival



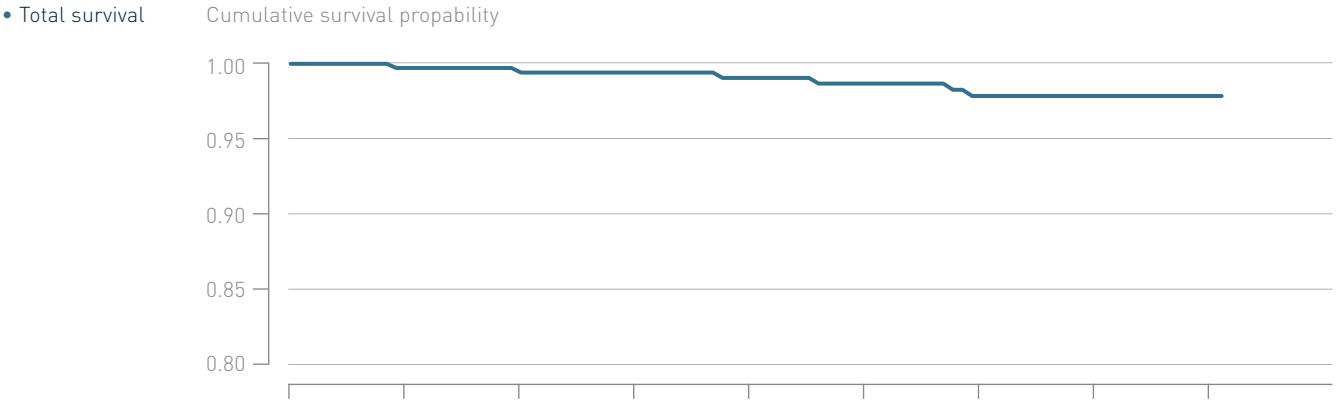
Years after implant	0	1	2	3	4
Total [%]	100.0	99.8	99.7	99.6	99.5
CI [±%]		0.3	0.3	0.4	0.4

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	5490
Registered U.S. Implants	409
Estimated Active U.S. Implants	175
U.S. Total Returned	8

	Quantity	Rate
U.S. Qualifying Complications	7	1.71%
Conductor fracture	1	0.24%
Failure to capture	1	0.24%
Insulation breach	1	0.24%
Oversensing	4	0.98%

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.49%
Conductor Fracture	1	0.24%
Insulation Breach	1	0.24%
U.S. Acute Lead Observations	0	0.00%



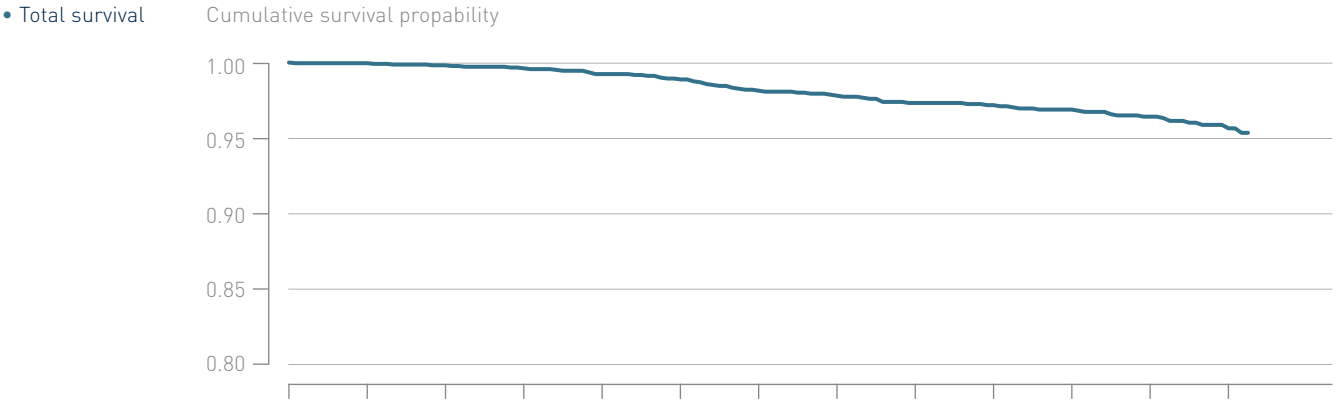
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100	99.7	99.4	99.4	99.0	98.7	97.8	97.8	97.8
CI [±%]		0.6	0.8	0.8	1.1	1.3	1.8	1.8	1.8

Kentrox SL-S

Product Versions	65/16, 18 -Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8 730
Registered U.S. Implants	2 440
Estimated Active U.S. Implants	1 260
U.S. Total Returned	41

	Quantity	Rate
U.S. Qualifying Complications	50	2.05%
Abnormal defibrillation impedance	1	0.04%
Abnormal pacing impedance	3	0.12%
Conductor fracture	4	0.16%
Failure to capture	3	0.12%
Insulation breach	3	0.12%
Lead dislodgement	3	0.12%
Oversensing	31	1.27%
Other	2	0.08%

	Quantity	Rate
U.S. Confirmed Malfunctions	14	0.57%
Insulation Breach	14	0.57%
U.S. Acute Lead Observations	2	0.08%
Insulation breach	1	0.04%
Oversensing	1	0.04%



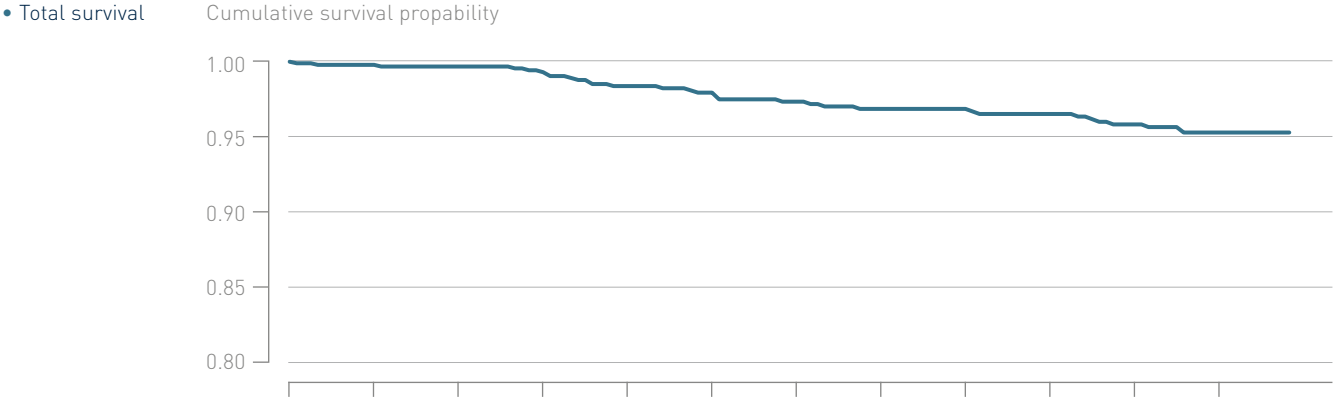
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	100.0	99.8	99.6	99.2	98.9	98.1	97.8	97.3	97.2	96.9	96.4	95.6
CI [±%]		0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1

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	8480
Registered U.S. Implants	1010
Estimated Active U.S. Implants	540
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	27	2.68%
Abnormal pacing impedance	3	0.3%
Conductor fracture	2	0.2%
Failure to capture	1	0.1%
Insulation breach	6	0.6%
Oversensing	13	1.29%
Other	2	0.2%

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.5%
Insulation Breach	5	0.5%
U.S. Acute Lead Observations	0	0.00%



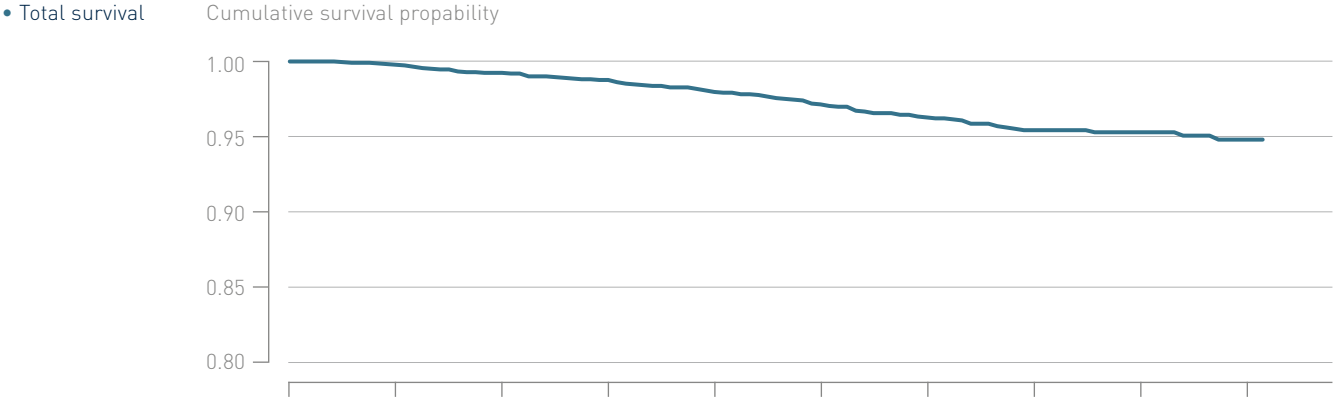
Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.8	96.8	96.5	95.8	95.3
CI [±%]		0.3	0.4	0.6	0.9	1.0	1.2	1.3	1.3	1.4	1.5	1.6

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	32 200
Registered U.S. Implants	2 500
Estimated Active U.S. Implants	1 730
U.S. Total Returned	70

	Quantity	Rate
U.S. Qualifying Complications	55	2.21%
Abnormal defibrillation impedance	6	0.24%
Abnormal pacing impedance	3	0.12%
Conductor fracture	4	0.16%
Failure to capture	7	0.28%
Insulation breach	4	0.16%
Oversensing	25	1,00%
Other	6	0.24%

	Quantity	Rate
U.S. Confirmed Malfunctions	34	1.36%
Conductor Fracture	5	0.20%
Insulation Breach	29	1.16%
U.S. Acute Lead Observations	2	0.08%
Lead dislodgement	1	0.04%
Other	1	0.04%



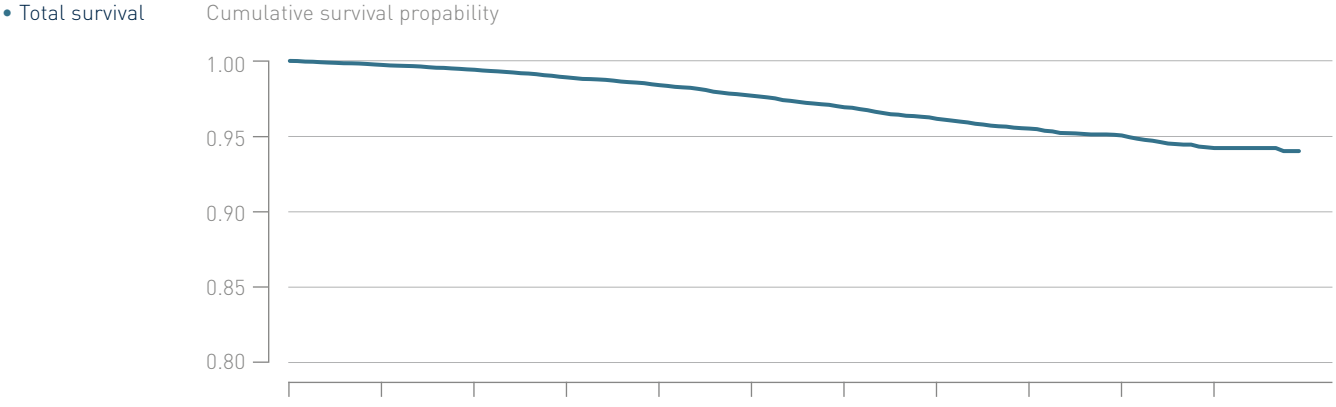
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.8	99.2	98.8	98.0	97.1	96.2	95.4	95.3	94.8
CI [±%]		0.2	0.4	0.5	0.6	0.7	0.8	1.0	1.0	1.2

Linox SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	22 300
Estimated Active U.S. Implants	14 800
U.S. Total Returned	447

	Quantity	Rate
U.S. Qualifying Complications	604	2.71%
Abnormal defibrillation impedance	45	0.20%
Abnormal pacing impedance	43	0.19%
Cardiac perforation	3	0.01%
Conductor fracture	54	0.24%
Failure to capture	62	0.28%
Failure to sense	9	0.04%
Insulation breach	54	0.24%
Lead dislodgement	31	0.14%
Oversensing	259	1.16%
Other	44	0.20%

	Quantity	Rate
U.S. Confirmed Malfunctions	178	0.80%
Conductor Fracture	25	0.11%
Insulation Breach	152	0.68%
Other	1	0.00%
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%



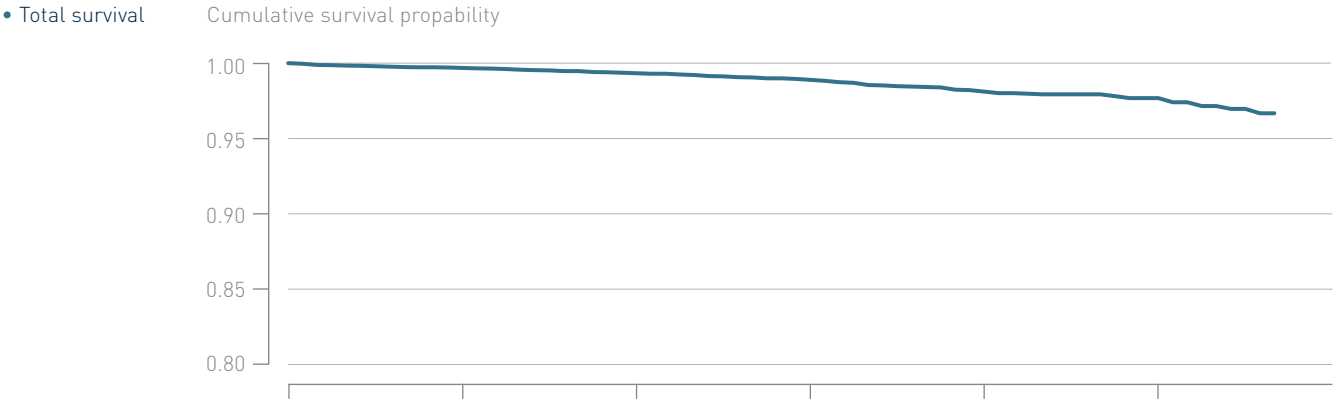
Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.5	95.0	94.1
CI [±%]		0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.5

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	46 400
Registered U.S. Implants	7 580
Estimated Active U.S. Implants	6 510
U.S. Total Returned	129

	Quantity	Rate
U.S. Qualifying Complications	80	1.06%
Abnormal defibrillation impedance	3	0.04%
Abnormal pacing impedance	3	0.04%
Cardiac perforation	1	0.01%
Conductor fracture	5	0.07%
Failure to capture	13	0.17%
Failure to sense	3	0.04%
Insulation breach	2	0.03%
Lead dislodgement	14	0.18%
Oversensing	31	0.41%
Other	5	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	36	0.48%
Conductor Fracture	7	0.09%
Insulation Breach	29	0.38%
U.S. Acute Lead Observations	11	0.15%
Abnormal pacing impedance	1	0.01%
Cardiac perforation	1	0.01%
Lead dislodgement	8	0.11%
Other	1	0.01%



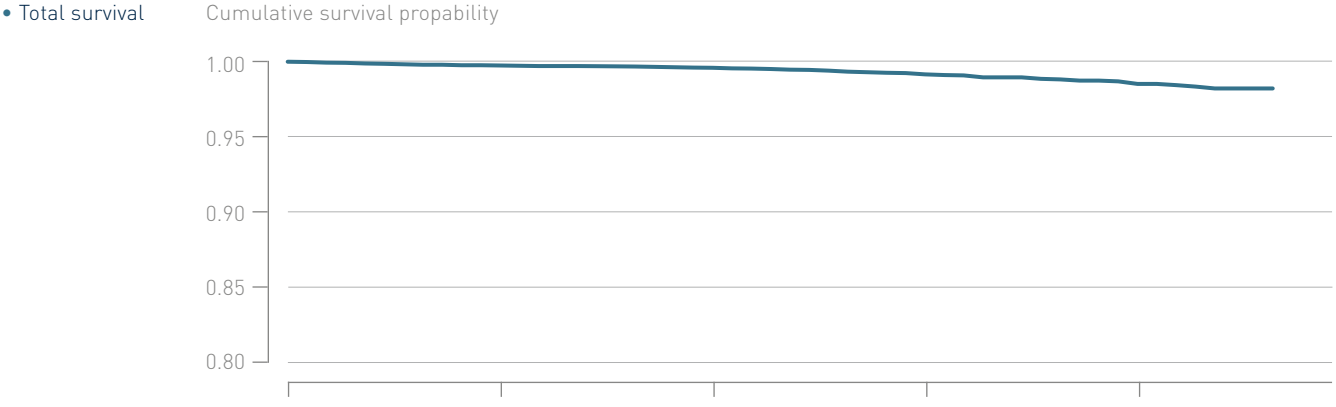
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.7	99.3	98.9	98.1	97.6
CI [±%]		0.1	0.2	0.3	0.4	0.5

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	35 000
Registered U.S. Implants	15 300
Estimated Active U.S. Implants	14 300
U.S. Total Returned	198

	Quantity	Rate
U.S. Qualifying Complications	63	0.41%
Abnormal defibrillation impedance	3	0.02%
Abnormal pacing impedance	1	0.01%
Conductor fracture	7	0.05%
Failure to capture	6	0.04%
Failure to sense	3	0.02%
Lead dislodgement	23	0.15%
Oversensing	16	0.10%
Other	3	0.02%

	Quantity	Rate
U.S. Confirmed Malfunctions	33	0.22%
Conductor Fracture	2	0.01%
Insulation Breach	31	0.20%
U.S. Acute Lead Observations	38	0.25%
Cardiac perforation	4	0.03%
Failure to capture	8	0.05%
Lead dislodgement	17	0.11%
Oversensing	2	0.01%
Other	7	0.05%



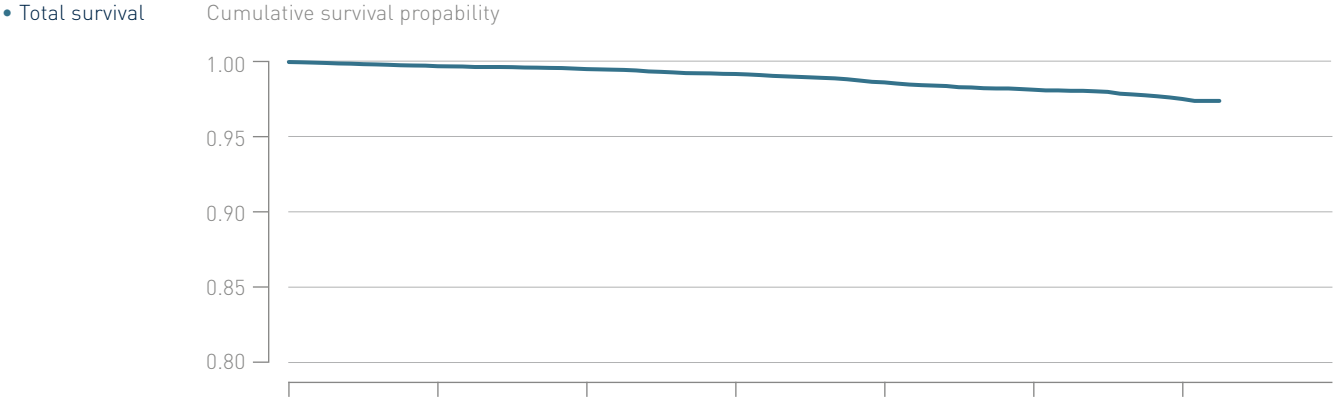
Years after implant	0	1	2	3	4
Total [%]	100.0	99.7	99.5	98.9	98.2
CI [±%]		0.1	0.1	0.3	0.5

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	54 200
Registered U.S. Implants	13 200
Estimated Active U.S. Implants	11 100
U.S. Total Returned	202

	Quantity	Rate
U.S. Qualifying Complications	143	1.09%
Abnormal defibrillation impedance	10	0.08%
Abnormal pacing impedance	4	0.03%
Conductor fracture	17	0.13%
Extracardiac stimulation	1	0.01%
Failure to capture	12	0.09%
Failure to sense	3	0.02%
Insulation breach	6	0.05%
Lead dislodgement	19	0.14%
Oversensing	65	0.49%
Other	6	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	44	0.33%
Conductor Fracture	4	0.03%
Insulation Breach	40	0.30%
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%



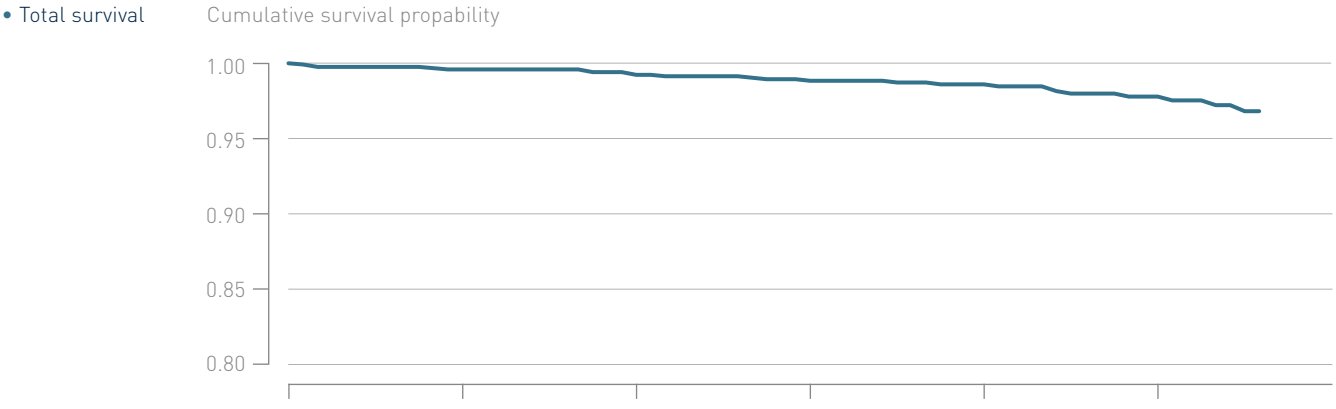
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.7	99.5	99.2	98.6	98.1	97.5
CI [±%]		0.1	0.1	0.2	0.2	0.3	0.5

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	7 690
Registered U.S. Implants	1 280
Estimated Active U.S. Implants	1 070
U.S. Total Returned	19

	Quantity	Rate
U.S. Qualifying Complications	22	1.73%
Abnormal defibrillation impedance	2	0.16%
Abnormal pacing impedance	2	0.16%
Conductor fracture	1	0.08%
Failure to capture	5	0.39%
Insulation breach	2	0.16%
Lead dislodgement	4	0.31%
Oversensing	6	0.47%

	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%



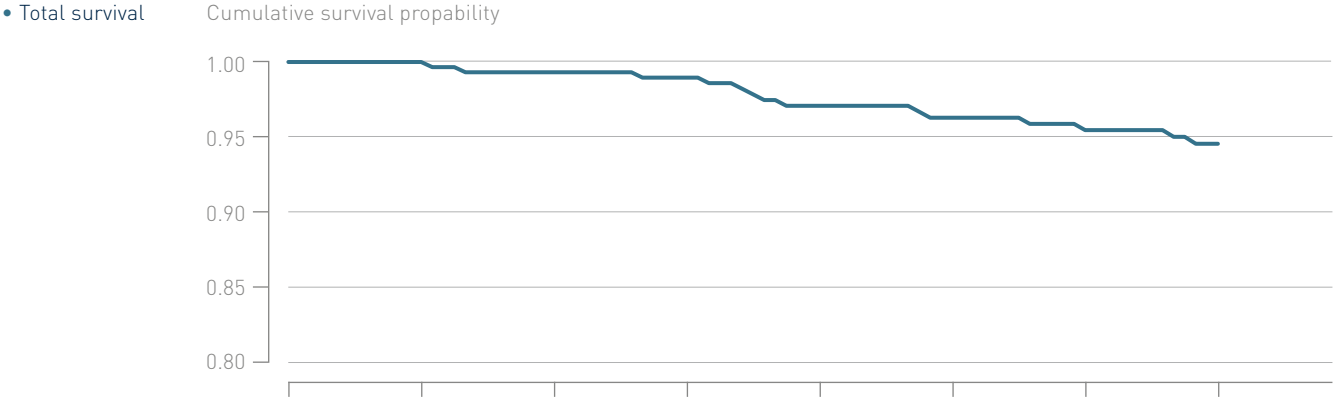
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	99.2	98.8	98.6	97.8
CI [±%]		0.4	0.5	0.6	0.7	1.0

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	2 280
Registered U.S. Implants	322
Estimated Active U.S. Implants	225
U.S. Total Returned	4

	Quantity	Rate
U.S. Qualifying Complications	13	4.04%
Abnormal pacing impedance	2	0.62%
Failure to capture	3	0.93%
Insulation breach	1	0.31%
Oversensing	6	1.86%
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%



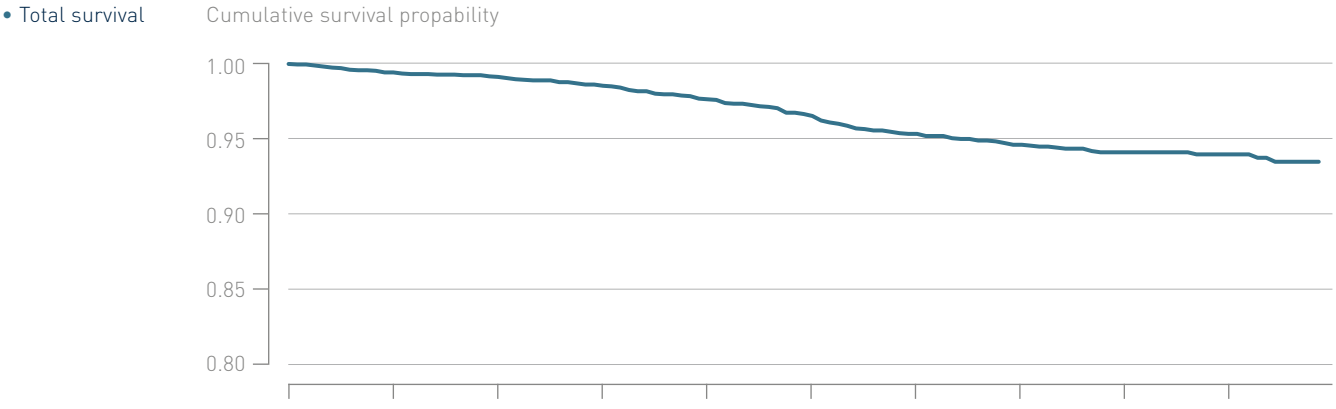
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.4	94.5
CI [±%]			0.9	1.2	2.0	2.3	2.5	2.8

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	3 060
Estimated Active U.S. Implants	2 070
U.S. Total Returned	74

	Quantity	Rate
U.S. Qualifying Complications	103	3.37%
Abnormal defibrillation impedance	9	0.29%
Abnormal pacing impedance	11	0.36%
Conductor fracture	13	0.43%
Failure to capture	16	0.52%
Failure to sense	2	0.07%
Insulation breach	13	0.43%
Lead dislodgement	4	0.13%
Oversensing	33	1.08%
Other	2	0.07%

	Quantity	Rate
U.S. Confirmed Malfunctions	35	1.15%
Conductor Fracture	6	0.20%
Insulation Breach	29	0.95%
U.S. Acute Lead Observations	3	0.10%
Failure to capture	1	0.03%
Lead dislodgement	2	0.07%



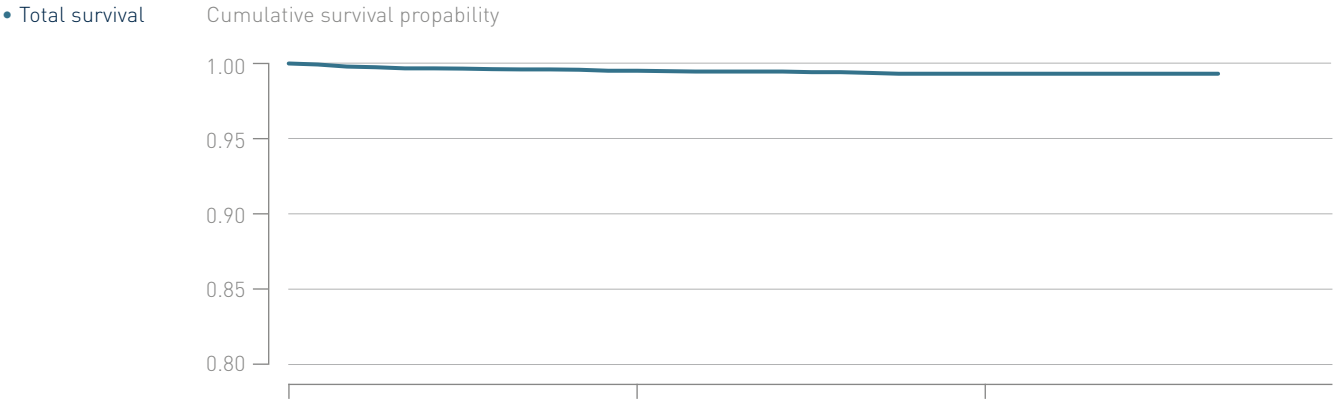
Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.3	94.6	94.1	93.9
CI [±%]		0.3	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.0

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	50300
Registered U.S. Implants	7310
Estimated Active U.S. Implants	6840
U.S. Total Returned	45

	Quantity	Rate
U.S. Qualifying Complications	32	0.44%
Cardiac perforation	1	0.01%
Conductor fracture	1	0.01%
Extracardiac stimulation	1	0.01%
Failure to capture	6	0.08%
Lead dislodgement	17	0.23%
Oversensing	2	0.03%
Other	4	0.05%

	Quantity	Rate
U.S. Confirmed Malfunctions	4	0.05%
Conductor Fracture	2	0.03%
Insulation Breach	2	0.03%
U.S. Acute Lead Observations	23	0.31%
Cardiac perforation	1	0.01%
Extracardiac stimulation	1	0.01%
Failure to capture	3	0.04%
Lead dislodgement	11	0.15%
Other	7	0.10%



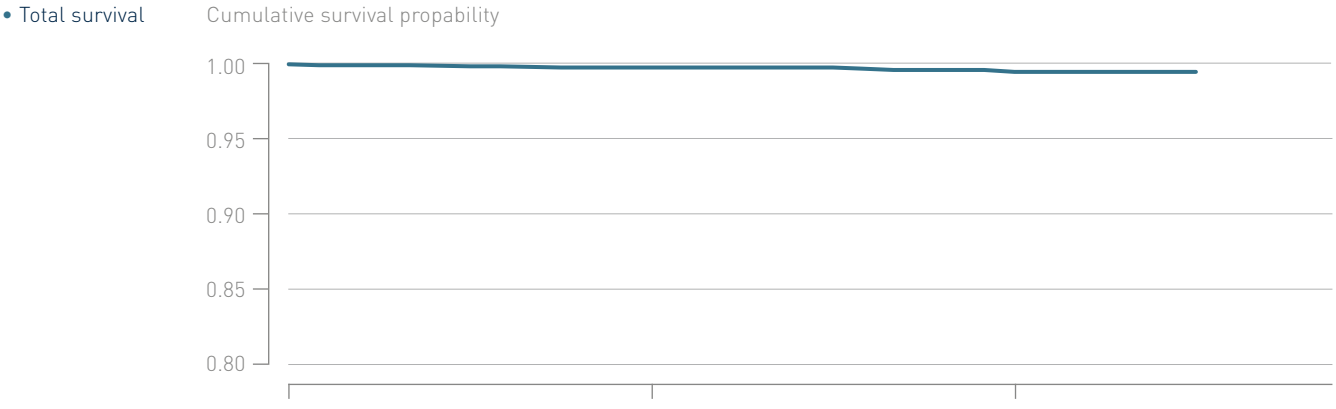
Years after implant	0	1	2
Total [%]	100.0	99.5	99.3
CI [±%]		0.2	0.3

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	17 800
Registered U.S. Implants	3 120
Estimated Active U.S. Implants	2 920
U.S. Total Returned	20

	Quantity	Rate
U.S. Qualifying Complications	8	0.26%
Abnormal pacing impedance	1	0.03%
Conductor fracture	1	0.03%
Failure to capture	1	0.03%
Insulation breach	1	0.03%
Lead dislodgement	3	0.10%
Oversensing	1	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.03%
Insulation Breach	1	0.03%
U.S. Acute Lead Observations	3	0.10%
Lead dislodgement	2	0.06%
Other	1	0.03%



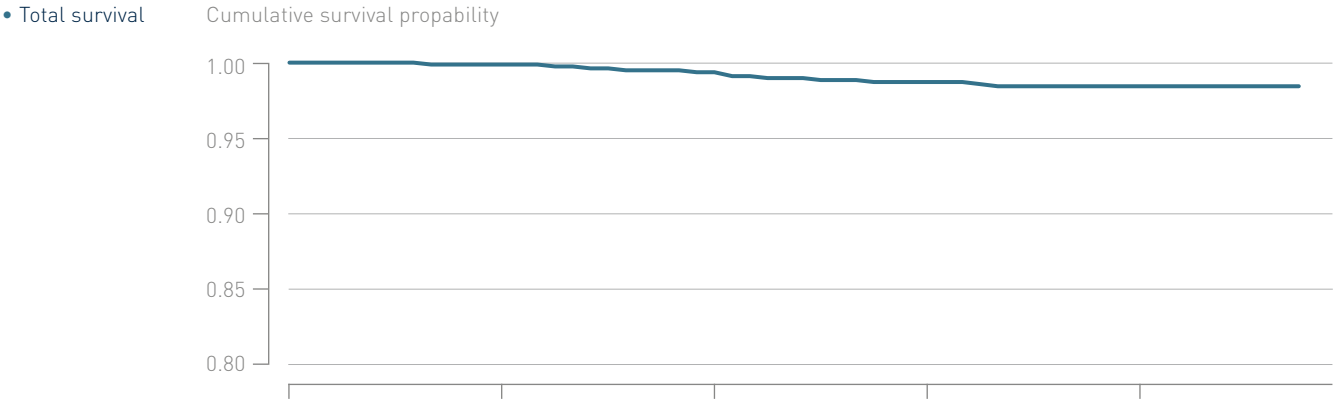
Years after implant	0	1	2
Total [%]	100.0	99.8	99.5
CI [±%]		0.2	0.4

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	3 010
Registered U.S. Implants	799
Estimated Active U.S. Implants	729
U.S. Total Returned	11

	Quantity	Rate
U.S. Qualifying Complications	9	1.13%
Conductor fracture	1	0.13%
Lead dislodgement	3	0.38%
Oversensing	5	0.63%

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.38%
Insulation Breach	3	0.38%
U.S. Acute Lead Observations	0	0.00%



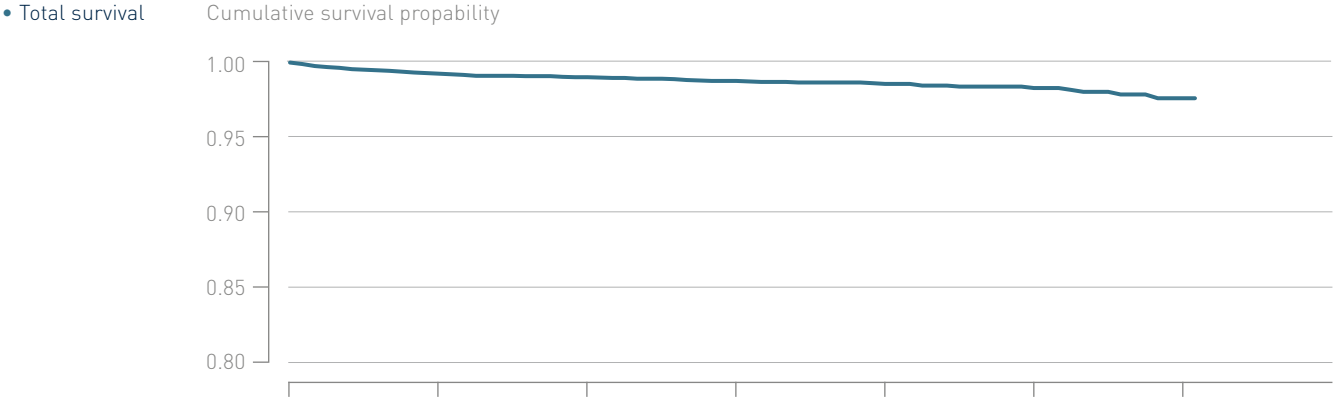
Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.3	98.7	98.4
CI [±%]		0.3	0.6	0.8	0.9

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	31 000
Registered U.S. Implants	6 220
Estimated Active U.S. Implants	5 200
U.S. Total Returned	60

	Quantity	Rate
U.S. Qualifying Complications	72	1.16%
Conductor fracture	2	0.03%
Extracardiac stimulation	13	0.21%
Failure to capture	26	0.42%
Failure to sense	1	0.02%
Lead dislodgement	24	0.39%
Oversensing	1	0.02%
Other	5	0.08%

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.05%
Conductor Fracture	2	0.03%
Insulation Breach	1	0.02%
U.S. Acute Lead Observations	20	0.32%
Extracardiac stimulation	6	0.10%
Failure to capture	2	0.03%
Lead dislodgement	9	0.14%
Other	3	0.05%



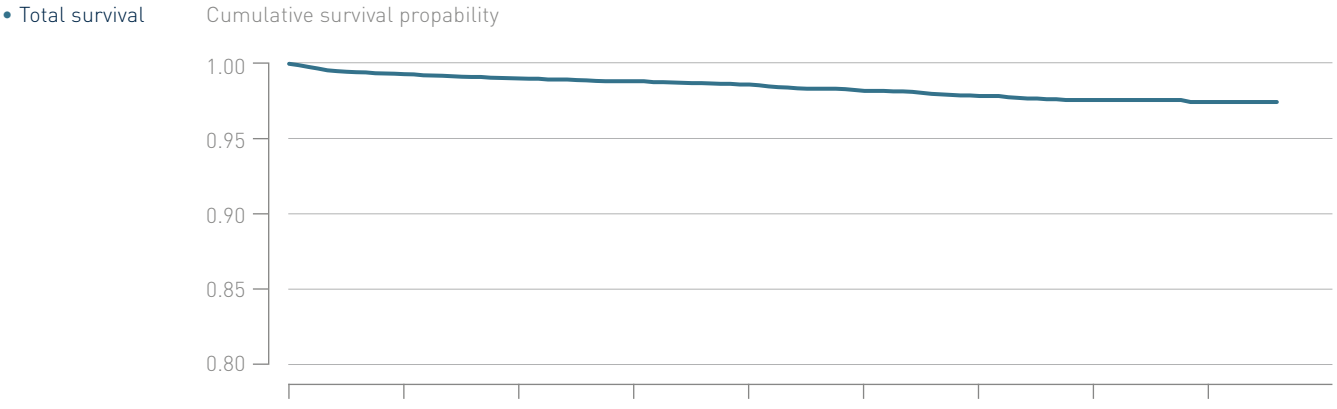
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.2	99.0	98.8	98.6	98.3	97.6
CI [±%]		0.2	0.3	0.3	0.4	0.5	0.8

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	26 100
Registered U.S. Implants	8 160
Estimated Active U.S. Implants	5 850
U.S. Total Returned	116

	Quantity	Rate
U.S. Qualifying Complications	111	1.36%
Abnormal pacing impedance	4	0.05%
Conductor fracture	2	0.02%
Extracardiac stimulation	10	0.12%
Failure to capture	27	0.33%
Insulation breach	4	0.05%
Lead dislodgement	48	0.59%
Oversensing	1	0.01%
Other	15	0.18%

	Quantity	Rate
U.S. Confirmed Malfunctions	11	0.13%
Conductor Fracture	6	0.07%
Insulation Breach	4	0.05%
Other	1	0.01%
U.S. Acute Lead Observations	32	0.39%
Cardiac perforation	1	0.01%
Extracardiac stimulation	5	0.06%
Failure to capture	6	0.07%
Lead dislodgement	19	0.23%
Other	1	0.01%



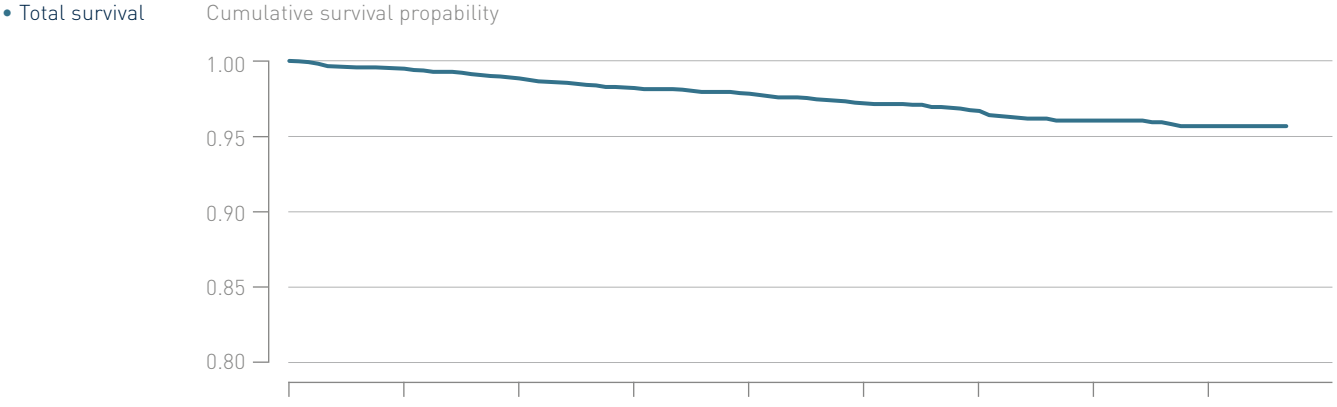
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.3	99.0	98.8	98.6	98.2	97.8	97.5	97.4
CI [±%]		0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5

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	28 100
Registered U.S. Implants	4 130
Estimated Active U.S. Implants	2 710
U.S. Total Returned	71

	Quantity	Rate
U.S. Qualifying Complications	92	2.23%
Abnormal pacing impedance	2	0.05%
Conductor fracture	3	0.07%
Extracardiac stimulation	8	0.19%
Failure to capture	31	0.75%
Insulation breach	2	0.05%
Lead dislodgement	33	0.80%
Oversensing	2	0.05%
Other	11	0.27%

	Quantity	Rate
U.S. Confirmed Malfunctions	16	0.39%
Conductor Fracture	15	0.36%
Insulation Breach	1	0.02%
U.S. Acute Lead Observations	8	0.19%
Lead dislodgement	6	0.15%
Other	2	0.05%



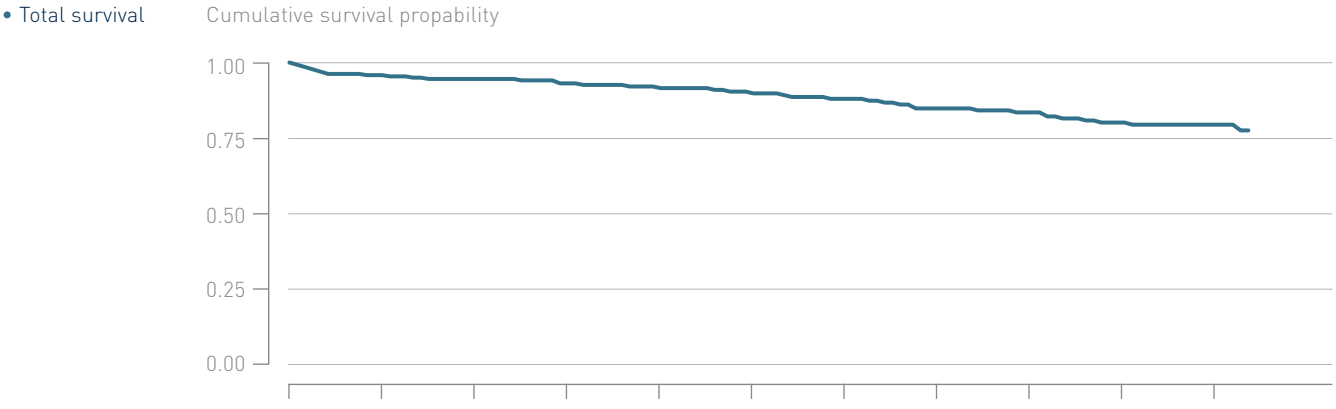
Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.5	98.8	98.2	97.8	97.2	96.6	96.0	95.6
CI [±%]		0.2	0.4	0.5	0.5	0.6	0.7	0.8	0.9

Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered U.S. Implants	1 430
Estimated Active U.S. Implants	695
U.S. Total Returned	26

	Quantity	Rate
U.S. Qualifying Complications	38	2.67%
Extracardiac stimulation	7	0.49%
Failure to capture	13	0.91%
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
Total [%]	100.0	99.2	98.9	98.6	98.3	97.9	97.6	96.9	96.7	96	95.9
CI [±%]		0.5	0.6	0.7	0.7	0.8	0.9	1.1	1.1	1.3	1.3

Methodology for Lead Survival Estimates Based on Clinical Studies

6. Methodology for Lead Survival Estimates Based on Clinical Studies

6.1 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.

6.2 BIOTRONIK's Clinical Studies

6.2.1 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. As of the January 2018 PPR, incremental updates to Linox data originate from the CELESTIAL Registry, as the GALAXY Registry is complete. 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.

6.2.2 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. 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.

6.2.3 Protego Post-Approval Registry

BIOTRONIK's Protego Post-Approval Registry is a prospective, single-arm, non-randomized registry to confirm the long-term safety and reliability of the Protego DF4 ICD lead when used in conjunction with a BIOTRONIK DF4 compatible ICD or CRT-D pulse generator. The Protego DF4 Post-Approval Registry is registered on clinicaltrials.gov under NCT02243696.

The evaluation of safety will be based on the analysis of Protego DF4 lead related or header related adverse events through a follow-up time of 5 years post-implant. 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, with required follow-ups at 3 and 6 months post-implant, and every 6 months thereafter.
During each study visit, the following 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 and programmed parameters to ensure the device is providing appropriate therapy
- 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 implant or successfully implanted with a BIOTRONIK ICD or BIOTRONIK CRT-D system, including a Protego 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.

6.2.4 QP ExCELs

BIOTRONIK's QP ExCELs Clinical Study is a combined Pre-Market and Post-Approval, prospective, 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 Pre-Market Study, the evaluation of safety is based on the analysis of Sentus QP lead-related adverse events through a follow-up time of 6 months post-implant, while the evaluation of effectiveness is based on analysis on the percentage of subjects with an acceptable LV pacing threshold in the permanently programmed vector at 3-months post-implant.

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. 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.

6.3 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.

6.3.1 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

6.3.2 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

6.3.3 Protego

All reported lead-related adverse events within the Protego 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)
- Abnormal defibrillation impedance (based on lead model, but normal range is 25 to 150 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

6.3.4 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

6.4 Lead Product Performance Graphs and Data

The clinical data presented on the following page is intended to show the long term clinical performance of leads based on clinical studies. The same analysis methods as described in chapter 6 are applied.

Returned Product Analysis Results

Although the returned product analysis data is not used to generate the survival estimates for the clinical data, it provides valuable insight into the causes of lead malfunction. Following the same approach as for complaint data, a malfunction is reported as described in section 6.3 of this report.

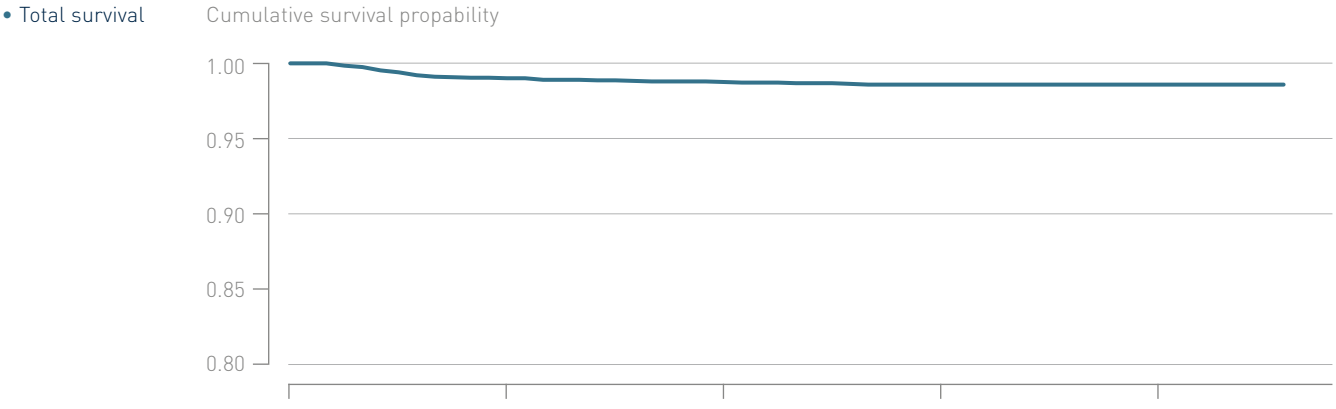
Performance of BIOTRONIK Leads Based on Clinical Study Data

Siello S / Solia S Study Data

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jun 2016
CE Market Release	Jul 2009
Worldwide Distributed Devices	779 000
Leads registered in study	3 238

	Quantity	Rate
U.S. Qualifying Complications	42	1.30%
Abnormal pacing impedance	2	0.06%
Cardiac perforation	2	0.06%
Failure to capture	18	0.56%
Failure to sense	10	0.31%
Lead dislodgement	8	0.25%
Oversensing	1	0.03%
Other	1	0.03%

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.06%
Conductor fracture	1	0.03%
Insulation breach	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	0.19%
Failure to sense (undersensing)	5	0.15%
Lead dislodgement	5	0.15%



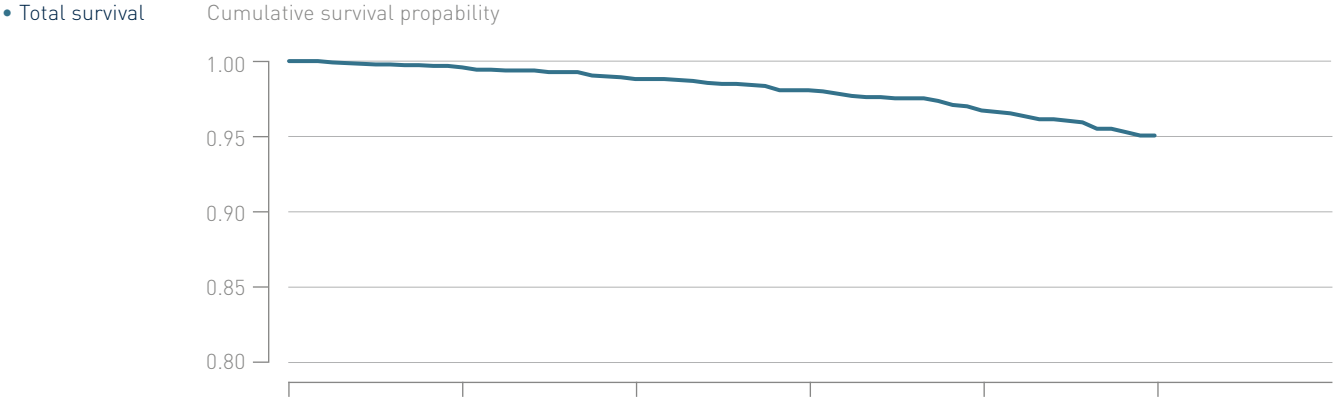
Years after implant	0	1	2	3	4
Total [%]	100.0	99,0	98.7	98.5	98.5
CI [±%]		0.4	0.4	0.4	0.4

Linox SD Study 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
Leads registered in study	2 272

	Quantity	Rate
U.S. Qualifying Complications	67	2.95%
Abnormal defibrillation impedance	3	0.13%
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	23	1.01%
Conductor Fracture	3	0.13%
Insulation Breach	20	0.88%
U.S. Acute Lead Observations	9	0.40%
Cardiac perforation	4	0.18%
Conductor fracture	1	0.04%
Failure to capture	2	0.09%
Lead dislodgement	1	0.04%
Other	1	0.04%



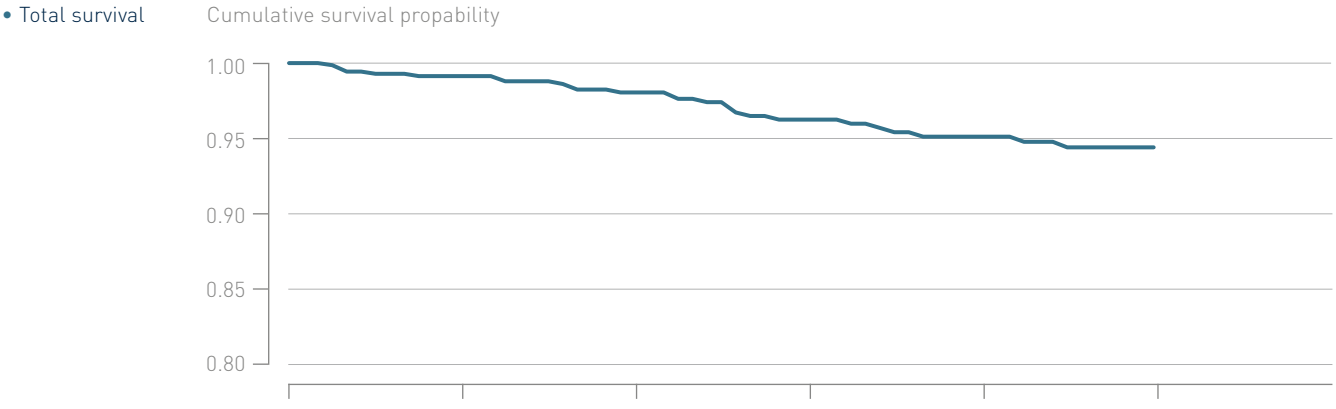
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	98.8	98.0	96.7	95.0
CI [±%]		0.3	0.5	0.7	0.9	1.2

Linox^{smart} SD Study 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	54 200
Leads registered in study	736

	Quantity	Rate
U.S. Qualifying Complications	27	3.67%
Abnormal defibrillation impedance	1	0.14%
Abnormal pacing impedance	2	0.27%
Conductor fracture	3	0.41%
Failure to capture	2	0.27%
Insulation breach	4	0.54%
Lead dislodgement	6	0.82%
Oversensing	9	1.22%

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.95%
Insulation Breach	7	0.95%
U.S. Acute Lead Observations	2	0.27%
Lead dislodgement	2	0.27%



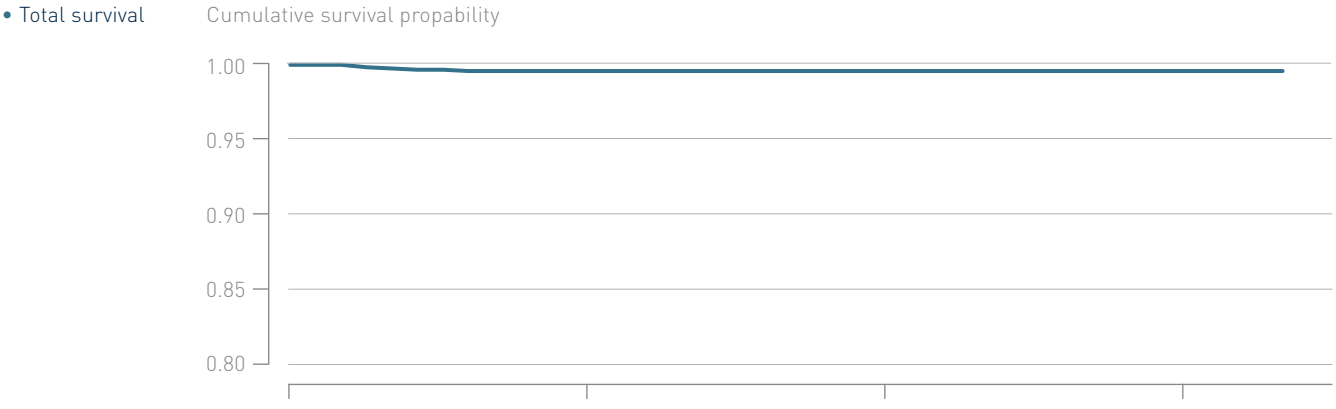
Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.1	98.1	96.3	95.2	94.5
CI [±%]		0.8	1.1	1.7	2.0	2.2

Protego S Study 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	50300
Leads registered in study	1087

	Quantity	Rate
U.S. Qualifying Complications	5	0.46%
Conductor fracture	1	0.09%
Failure to capture	1	0.09%
Failure to sense (undersensing)	1	0.09%
Lead dislodgement	2	0.18%

	Quantity	Rate
U.S. Confirmed Malfunctions	2	0.18%
Conductor Fracture	2	0.18%
U.S. Acute Lead Observations	4	0.37%
Cardiac perforation	3	0.28%
Lead dislodgement	1	0.09%



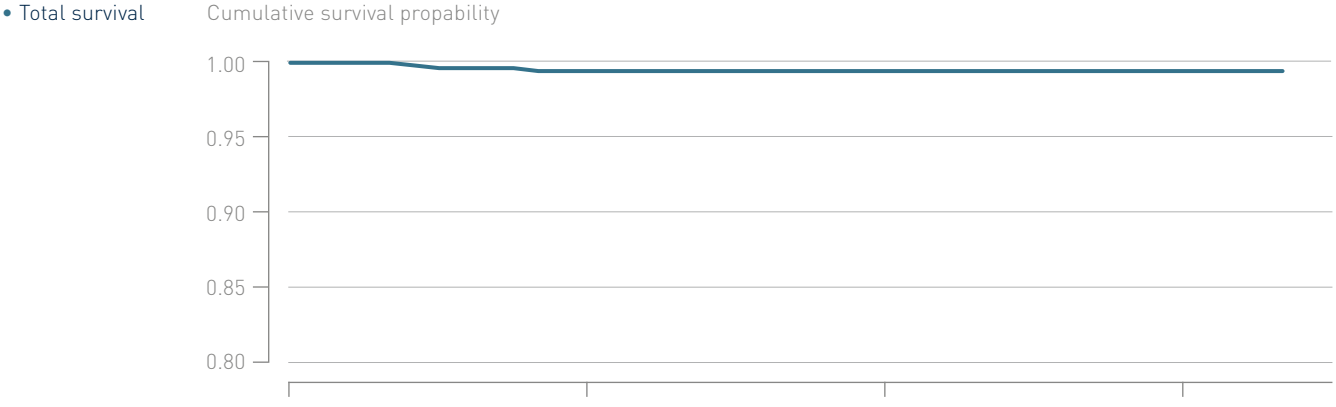
Years after implant	0	1	2	3
Total [%]	100	99.5	99.5	99.5
CI [±%]	NA	0.5	0.5	0.5

Protego SD Study 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	17800
Leads registered in study	533

	Quantity	Rate
U.S. Qualifying Complications	3	0.56%
Abnormal defibrillation impedance	1	0.19%
Conductor fracture	1	0.19%
Failure to capture	1	0.19%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0%
U.S. Acute Lead Observations	2	0.38%
Lead dislodgement	2	0.38%



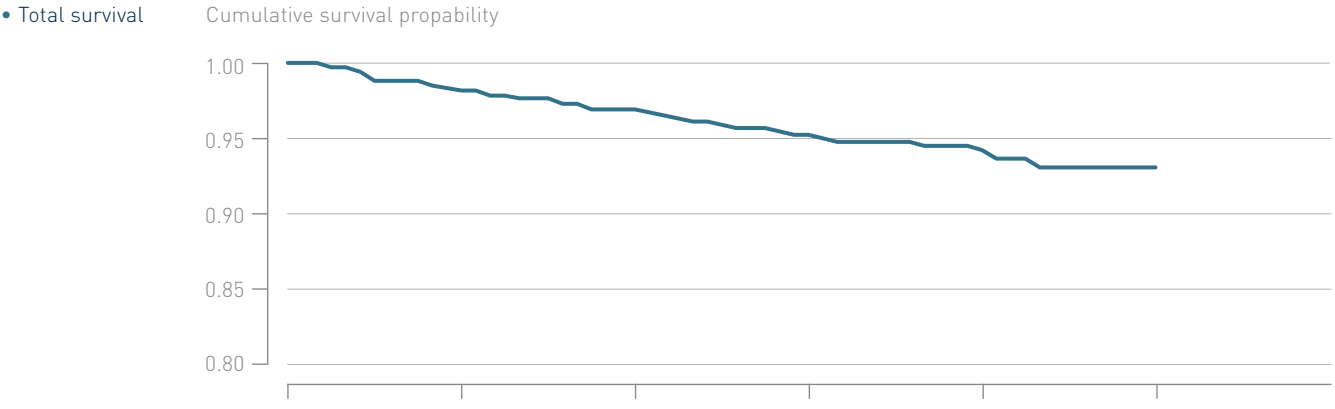
Years after implant	0	1	2	3
Total [%]	100	99.4	99.4	99.4
CI [±%]	NA	0.8	0.8	0.8

Corox OTW Study Data

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	28 100
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%



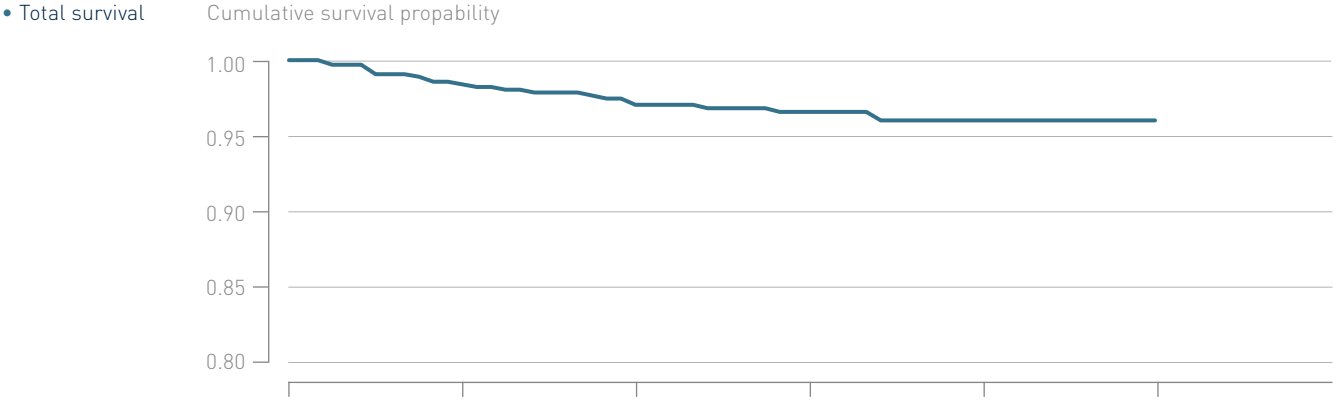
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	96.9	95.2	94.2	93.0
CI [±%]		1.1	1.4	1.8	2.1	2.3

Corox OTW-L Study Data

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	31 000
Leads registered in study	698

	Quantity	Rate
U.S. Qualifying Complications	21	3.01%
Extracardiac stimulation	4	0.57%
Failure to capture	7	1.00%
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%



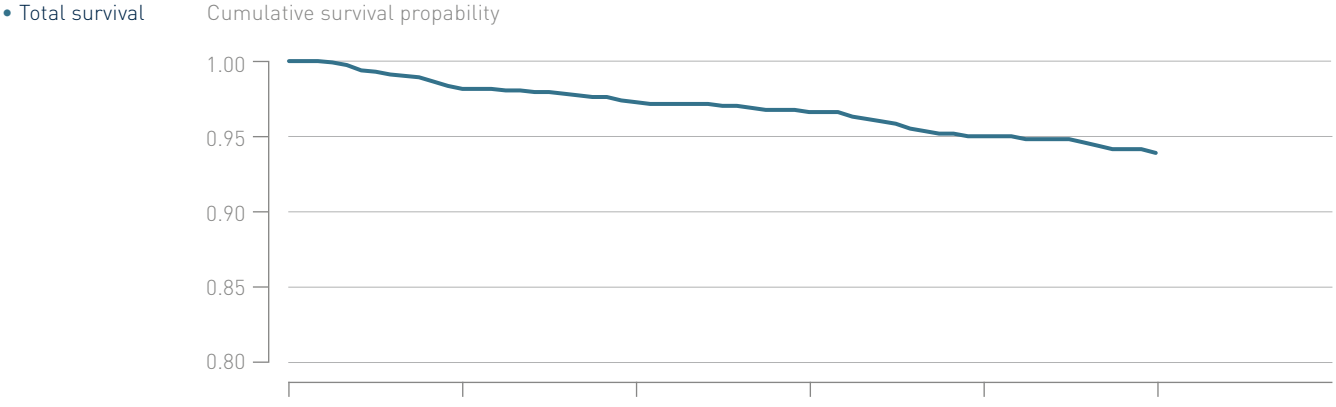
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.1	96.7	96.1	96.1
CI [±%]		1.0	1.4	1.5	1.7	1.7

Corox OTW-S Study Data

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	26 100
Leads registered in study	1 142

	Quantity	Rate
U.S. Qualifying Complications	48	4.20%
Abnormal pacing impedance	11	0.96%
Extracardiac stimulation	9	0.79%
Failure to capture	9	0.79%
Lead dislodgement	19	1.66%

	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%



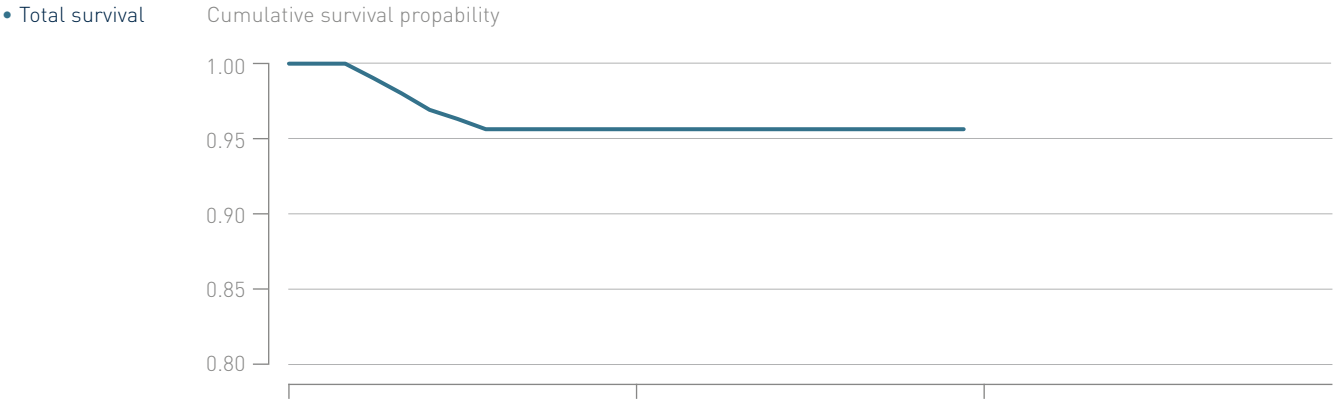
Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.1	97.2	96.6	94.9	93.8
CI [±%]		0.8	1.0	1.2	1.5	1.8

Sentus OTW QP S Study Data

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	7 120
Leads registered in study	224

	Quantity	Rate
U.S. Qualifying Complications	8	3.57%
Extracardiac Stimulation	1	0.45%
Failure to Capture	2	0.89%
Lead dislodgement	5	2.23%

	Quantity	Rate
U.S. Confirmed Malfunctions	1	0.45%
Conductor Fracture	1	0.45%
U.S. Acute Lead Observations	6	2.68%
Cardiac perforation	1	0.45%
Failure to Capture	1	0.45%
Lead dislodgement	4	1.79%



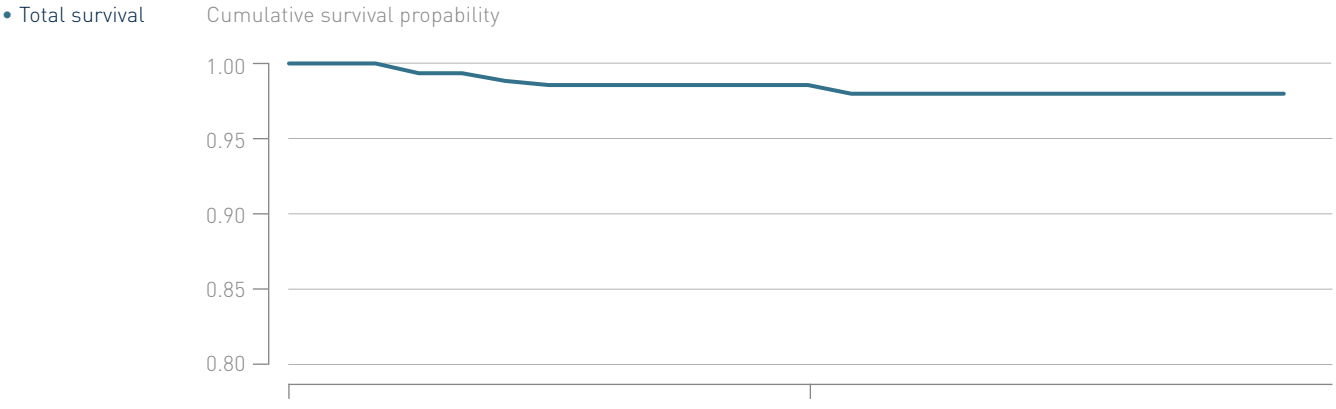
Years after implant	0	1	2
Total [%]	100.0	95.5	95.5
CI [±%]		3.30	3.30

Sentus OTW QP L Study Data

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	27 600
Leads registered in study	513

	Quantity	Rate
U.S. Qualifying Complications	7	1.36%
Extracardiac Stimulation	2	0.39%
Failure to Capture	2	0.39%
Lead dislodgement	3	0.58%

	Quantity	Rate
U.S. Confirmed Malfunctions	0	0.00%
U.S. Acute Lead Observations	4	0.78%
Extracardiac Stimulation	1	0.19%
Failure to Capture	2	0.39%
Lead dislodgement	1	0.19%



Years after implant	0	1
Total [%]	100.0	98.5
CI [±%]		1.3

Stratos LV-T Potentially defective low voltage capacitors

84 devices world-wide, none in the U.S.

Status Update
As of January 2018

- No reports of malfunctioning pacemakers associated with this capacitor lot were received.
- No reports of deaths or serious injuries were received associated with this advisory.
- An extended test program yielded no malfunctions of the capacitors under question.

Original communication July 2006
A limited number of our Stratos LV-T pacemakers may exhibit a device malfunction resulting in increased battery current and in loss of output, very likely simultaneously on all channels.

BIOTRONIK has identified a specific batch of low voltage capacitors from a single component supplier as the root cause. Please be assured that the capacitors from this batch are no longer being used in any BIOTRONIK device, and that no other pacemaker or ICD manufactured by BIOTRONIK is affected.

To date, no field reports related to this phenomenon were received.

The anomaly is limited to 84 devices world-wide. BIOTRONIK has taken immediate action to retrieve all potentially affected devices not yet delivered to hospitals. According to our records, 14 devices were delivered to hospitals and may have been implanted.

Based on preliminary data received from the component supplier, the projected rate of occurrence is expected to less than 1 out of 100.00 devices.

Our records show that you are the implanting and/or follow-up physician for one or more patients with an affected device. We recommend the following actions:

- If Home Monitoring is **activated**, please check the Cardio Report and the pacing impedance history. A rapid and significant increase of the pacing impedance on one or more channels may indicate a possible loss of output. In this case we recommend to schedule a patient follow-up as soon as possible.
- If Home Monitoring is **not activated** or pacing impedance data from Cardio Reports are not available we recommend to schedule a patient follow-up as soon as possible.
- During a **follow-up session** please perform the "Battery Lead Telemetry" test. A significantly increased pacing impedance on one or more channels or a significantly increased battery current may indicate a possible loss of output.
- If no anomaly is detected please **activate Home Monitoring**. You may use regular follow-up intervals if Home Monitoring is used for remote monitoring between follow-ups.
- **In any case we recommend to replace the device of a pacemaker-dependent patient without underlying intrinsic rhythm.**

We have tried to be as specific as possible with our recommendations. As always, individual circumstances and medical judgement determine decisions about patient care, the urgency of follow-ups and possible replacement of devices.

If a Stratos LV-T is replaced for the reason explained in this notification, BIOTRONIK will provide a replacement device consistent with the terms of our warranty. For activation of the warranty, please return the explanted device to BIOTRONIK within 30 days of the explantation.

X-Ray Identifiers for Pacemakers and ICDs

Pacemaker/ICD Product Versions	X-Ray ID
Cylos DR, DR-T, VR	RZ
Cylos 990 DR, DR-T, VR	FV
Evia DR, DR–T, SR, SR-T, HF, HF-T	SF
Estella SR, SR-T, DR, DR-T	SF
Entovis DR, DR-T, SR, SR-T	SF
Eluna 8 DR, Eluna 8 DR-T	SF
Etrinsa 8 SR-T, DR-T, HF-T	BIO SF
Iforia 7 VR-T DX, DR-T	NT
Ilesto 7 DR-T, HF-T, VR-T DX, VR-T, DR-T DF4	NT
Inventra 7 VR-T SX	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 DR, D, SLR, SR, S	LE
Philos DR-T	VV
Philos II DR, D, S, SLR, SR	ET
Philos II DR-T	KP
Stratos LV, LV-T	SV
Talos DR, D, SLR, SR, S	PV

Contacting BIOTRONIK

Regarding this Report

BIOTRONIK invites your suggestions and questions related to this Product Performance Report. Please send your comments to: **Worldwide CRM Technical Services**

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Regarding Products

BIOTRONIK invites customers to call the following locations with suggestions, comments or specific questions related to BIOTRONIK products: **Worldwide CRM Product Support**

Phone + 49 (0) 30 689 05 1133
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Email product.support@biotronik.com

Address
BIOTRONIK SE & Co. KG
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Woermannkehre 1
12359 Berlin, Germany

Within the U.S.:

Phone (888) 345 0374
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Lake Oswego, OR 97035

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