Product Performance Report

July 2014

BIOTRONIK
excellence for life

Product Performance Report

July 2014

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1 Quality excellence

BIOTRONIK has a long history of high quality in product design and performance. For 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.

In the current report – for the first time – survival results for the Linox SD ICD lead from BIOTRONIK's post approval clinical studies are integrated. See sections 8 and 9 for more information.

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 5841-2:2000 (E) 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.

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 +49-30-68905-1133 (Germany) with any comments, suggestions or questions. Your feedback is highly appreciated and will be used to further develop this report.

BIOTRONIK, July 2014

Dr. Volker Lang
Vice President Global Quality Management
BIOTRONIK SE & Co. KG

2 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 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 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 guidlines, 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.

3 Methodology for pacemaker and ICD survival estimates

3.1 Cumulative Survival Probability

This report has been prepared in accordance with ISO 5841-2:2000 (E) applying actuarial analysis for the calculation of survival probabilities. Survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK devices.

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

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

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

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

3.2 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 cut-off date for the data included in this report is December 31, 2013. 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 in this report. Patient mortality is assumed to be 10 % p.a. if the reported rate from our registration and tracking systems is below 10 % p.a. Normal battery depletion rate is assumed if the reported rate of depletion decreases over time.

3.3 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.

3.4 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.

4 Performance of BIOTRONIK pacemakers

4.1 Single-chamber pacemakers

4.2 Dual-chamber pacemakers

4.3 CRT pacemakers

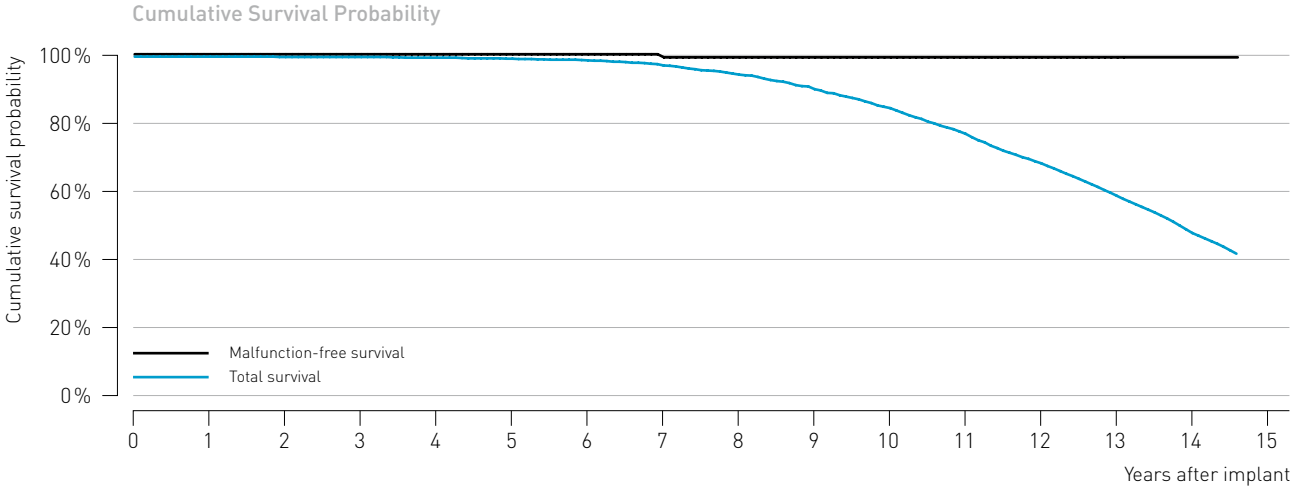
4.1 Single-chamber pacemakers

Actros

Product details

Product versions	Actros S, Actros SR
NBG code(s)	SSI, SSIR
U.S. market release	Mar 1998
CE market release	Apr 1997
Worldwide distributed devices	128,000
Registered U.S. implants	6,740
Estimated active U.S. implants	987
U.S. normal battery depletions	377

	Quantity	Rate
U.S. confirmed malfunctions	2	0.03%
▪ Therapy compromised	0	0.00%
▪ Therapy available	2	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	100.0	99.9	99.9	99.7	99.4	98.9	97.4	94.7	90.4	84.8	77.2	68.5	58.9	47.9	-
(95% confidence interval)			±0.1	±0.1	±0.2	±0.3	±0.4	±0.6	±0.9	±1.2	±1.6	±2.0	±2.3	±2.5	2.8	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	-
(95% confidence interval)			±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	-

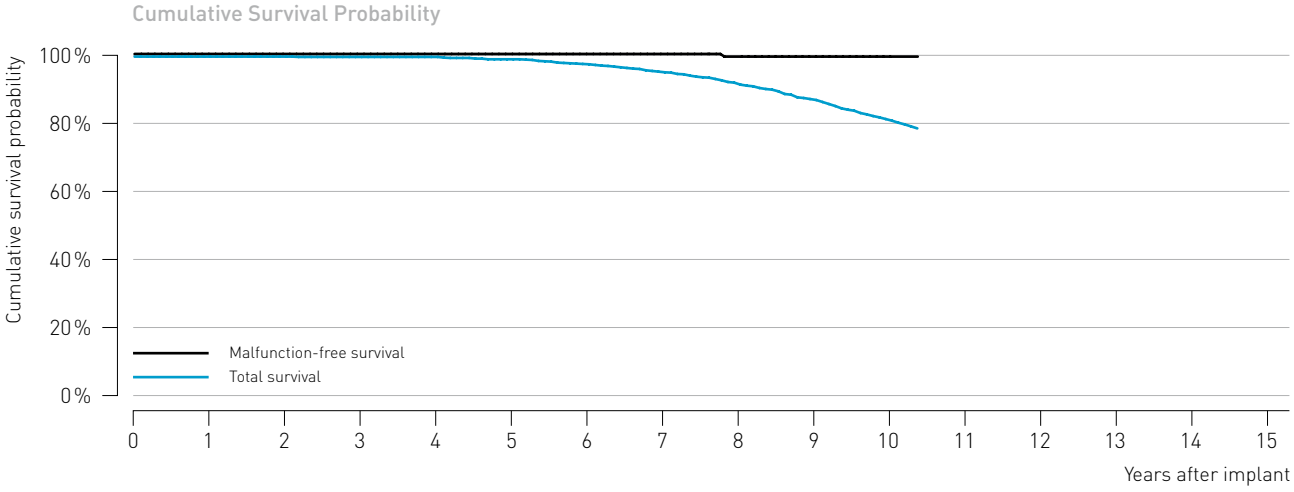
4.1 Single-chamber pacemakers

Axios

Product details

Product versions	Axios S, Axios SR
NBG code(s)	SSI, SSIR
U.S. market release	Nov 2001
CE market release	Oct 2001
Worldwide distributed devices	141,000
Registered U.S. implants	1,370
Estimated active U.S. implants	370
U.S. normal battery depletions	28

	Quantity	Rate
U.S. confirmed malfunctions	1	0.07%
▪ Therapy compromised	0	0.00%
▪ Therapy available	1	0.07%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	100.0	100.0	99.9	99.9	99.2	97.7	95.3	91.6	87.0	80.8	-	-	-	-	-
(95% confidence interval)				±0.2	±0.2	±0.7	±1.2	±1.7	±2.3	±3.0	±3.6	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.8	99.8	-	-	-	-	-
(95% confidence interval)									±0.4	±0.4	±0.4	-	-	-	-	-

4.1 Single-chamber pacemakers

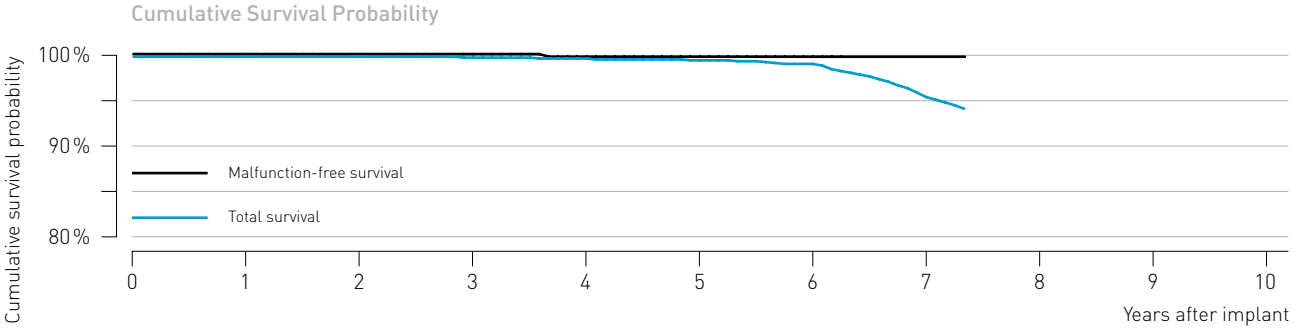
Cylos and Cylos 990

Product details

Product versions*	Cylos VR, Cylos 990 VR
NBG code(s)	VVIR
U.S. market release	Jan 2006
CE market release	Nov 2005/Mar 2008
Worldwide distributed devices	25,900
Registered U.S. implants	6,140
Estimated active U.S. implants	4,090
U.S. normal battery depletions	19

	Quantity	Rate
U.S. confirmed malfunctions	4	0.07%
▪ Therapy compromised	1	0.02%
▪ Therapy available	3	0.05%

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



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	99.9	99.8	99.6	99.2	95.5	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.2	±0.4	±1.4	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	-	-	-	-
(95 % confidence interval)				±0.1	±0.1	±0.1	±0.1	±0.1	-	-	-	-

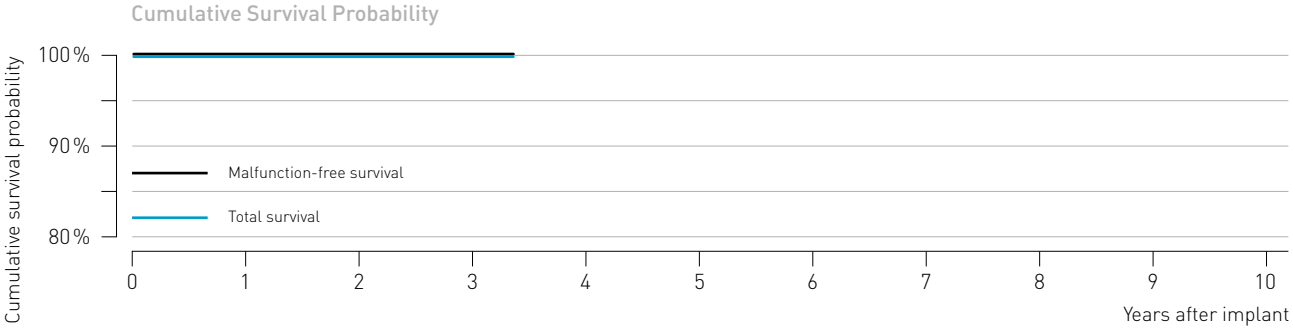
4.1 Single-chamber pacemakers

Evia

Product details

Product versions	Evia SR, Evia SR-T
NBG code(s)	AAIR, VVIR
U.S. market release	May 2010
CE market release	Oct 2009
Worldwide distributed devices	39,400
Registered U.S. implants	8,790
Estimated active U.S. implants	7,880
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-
(95 % confidence interval)					-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-
(95 % confidence interval)					-	-	-	-	-	-	-	-

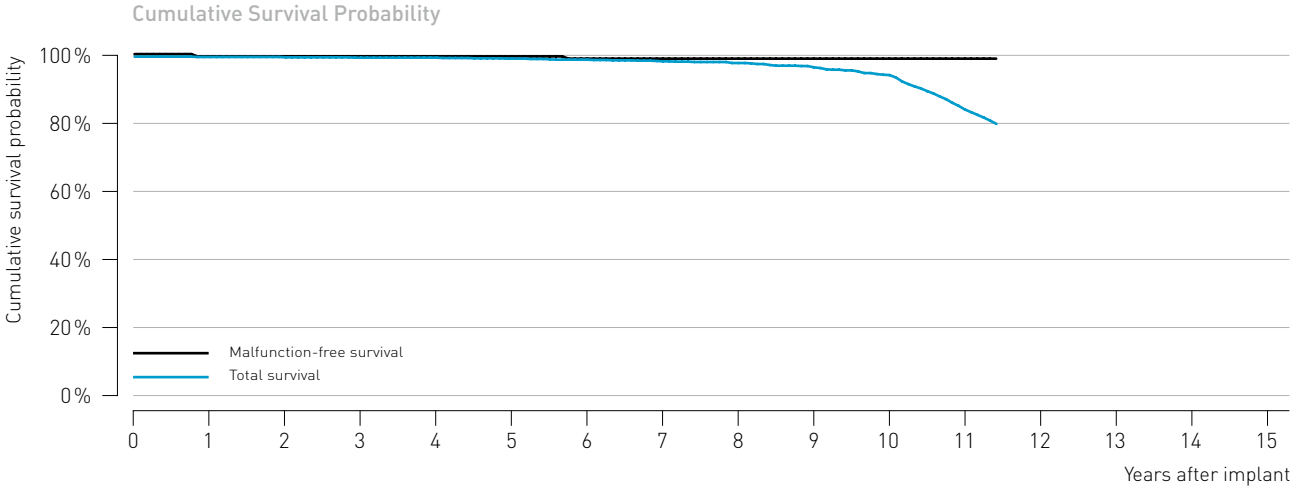
4.1 Single-chamber pacemakers

Philos

Product details

Product versions	Philos S, Philos SR
NBG code(s)	SSI, SSIR
U.S. market release	Sep 2000
CE market release	Aug 2000
Worldwide distributed devices	109,000
Registered U.S. implants	5,760
Estimated active U.S. implants	1,970
U.S. normal battery depletions	91

	Quantity	Rate
U.S. confirmed malfunctions	7	0.12%
▪ Therapy compromised	0	0.00%
▪ Therapy available	7	0.12%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.8	99.7	99.7	99.4	99.1	98.6	98.1	96.8	94.5	84.2
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	±0.4	±0.6	±0.8	±1.2	±2.5
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1

4.1 Single-chamber pacemakers

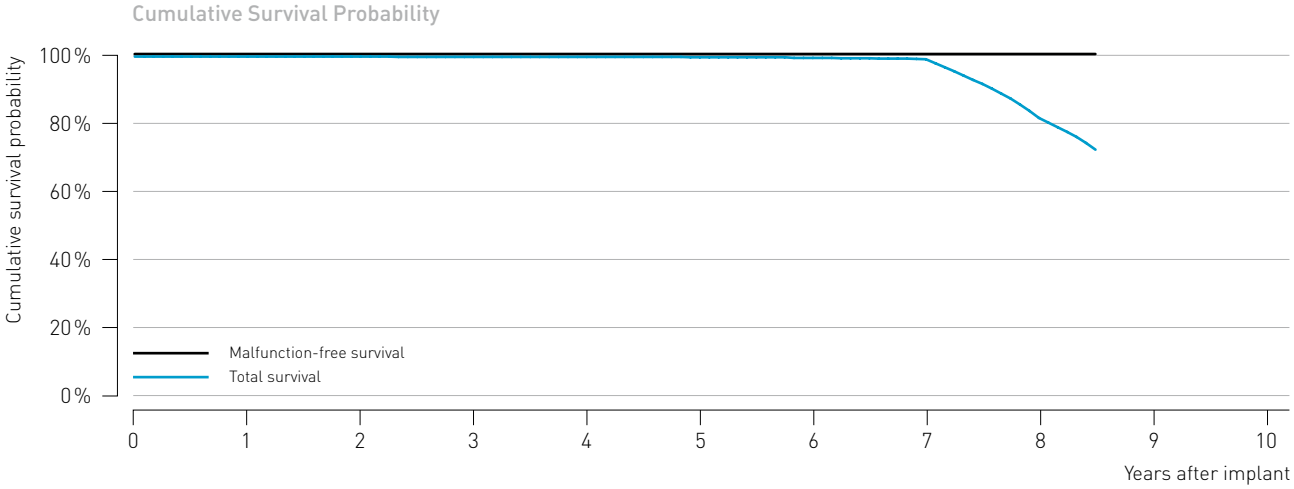
Philos II and Talos

Product details

Product versions*	Philos II S, Philos II SR, Talos S, Talos SR
NBG code(s)	SSI, SSIR
U.S. market release	Sep 2004
CE market release	Feb 2004/May 2006
Worldwide distributed devices	202,000
Registered U.S. implants	5,220
Estimated active U.S. implants	3,280
U.S. normal battery depletions	15

	Quantity	Rate
U.S. confirmed malfunctions	1	0.02%
▪ Therapy compromised	1	0.02%
▪ Therapy available	0	0.00%

* 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



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	99.9	99.9	99.8	99.6	99.2	81.6	-	-	-
(95 % confidence interval)				±0.1	±0.1	±0.2	±0.3	±0.4	±2.7	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-
(95 % confidence interval)				±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	-	-	-

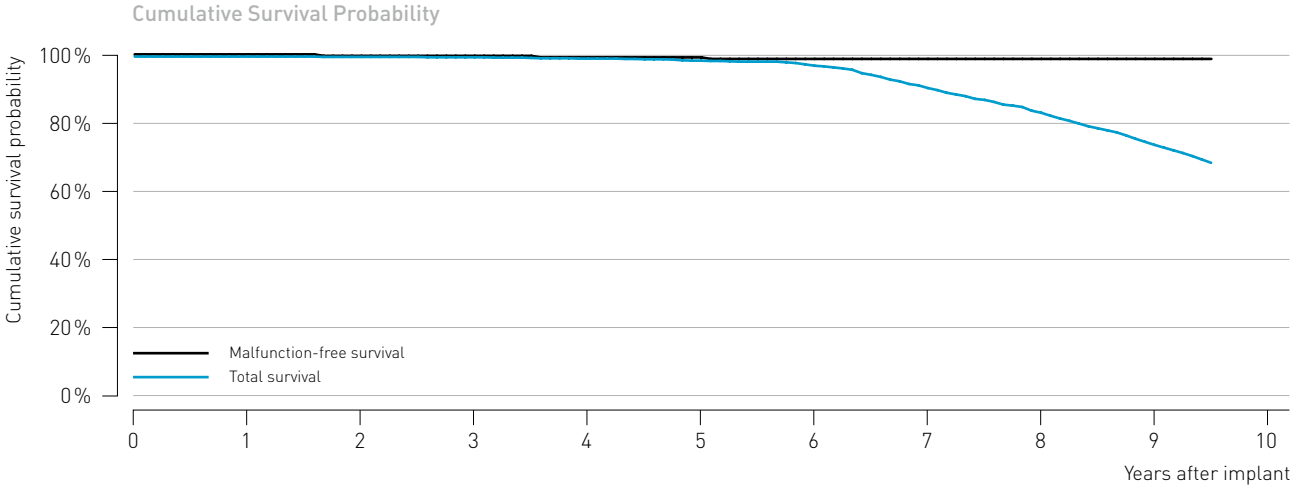
4.1 Single-chamber pacemakers

Protos

Product details

Product versions	Protos VR/CLS
NBG code(s)	VVIR
U.S. market release	Jan 2003
CE market release	Jul 2003
Worldwide distributed devices	9,820
Registered U.S. implants	3,250
Estimated active U.S. implants	933
U.S. normal battery depletions	203

	Quantity	Rate
U.S. confirmed malfunctions	6	0.18%
▪ Therapy compromised	2	0.06%
▪ Therapy available	4	0.12%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.8	99.4	98.8	97.3	90.7	83.4	73.9	-	-
(95 % confidence interval)			±0.1	±0.2	±0.3	±0.5	±0.7	±1.4	±2.0	±2.8	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7	99.7	-	-
(95 % confidence interval)			±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2	±0.2	-	-

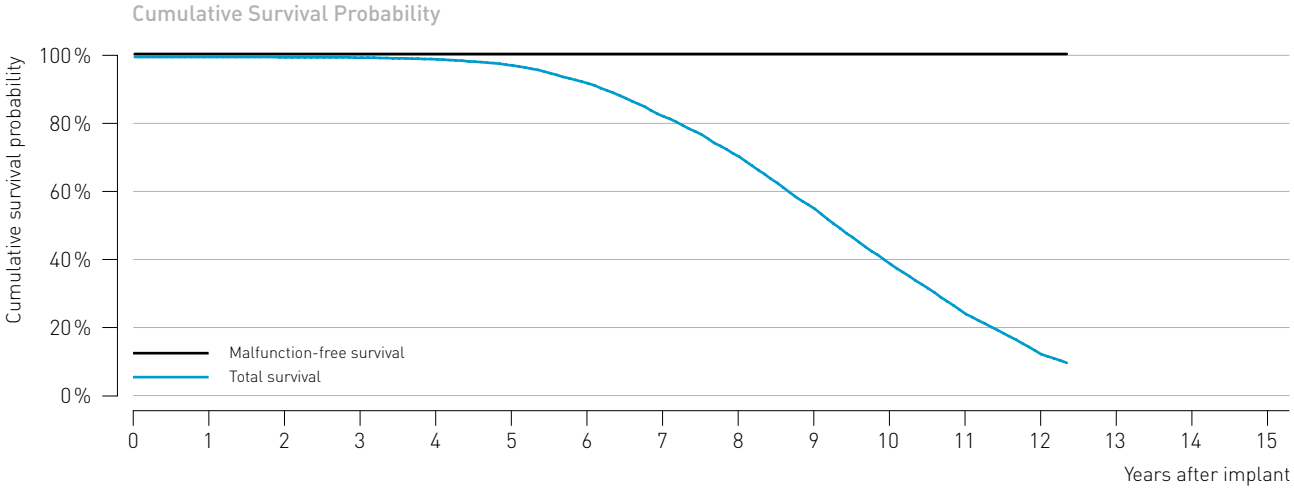
4.2 Dual-chamber pacemakers

Actros

Product details

Product versions	Actros D, Actros DR, Actros SLR
NBG code(s)	DDD, DDDR, VDDR
U.S. market release	Mar 1998
CE market release	Apr 1997
Worldwide distributed devices	110,000
Registered U.S. implants	13,700
Estimated active U.S. implants	2,110
U.S. normal battery depletions	2,456

	Quantity	Rate
U.S. confirmed malfunctions	3	0.02%
▪ Therapy compromised	3	0.02%
▪ Therapy available	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.
Total survival (%)	100.0	100.0	99.9	99.8	99.3	97.5	92.2	82.4	70.5	55.0	38.8	23.9	12.0
(95% confidence interval)		±0.0	±0.0	±0.1	±0.2	±0.3	±0.6	±0.9	±1.1	±1.3	±1.4	±1.3	±1.1
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
(95% confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0

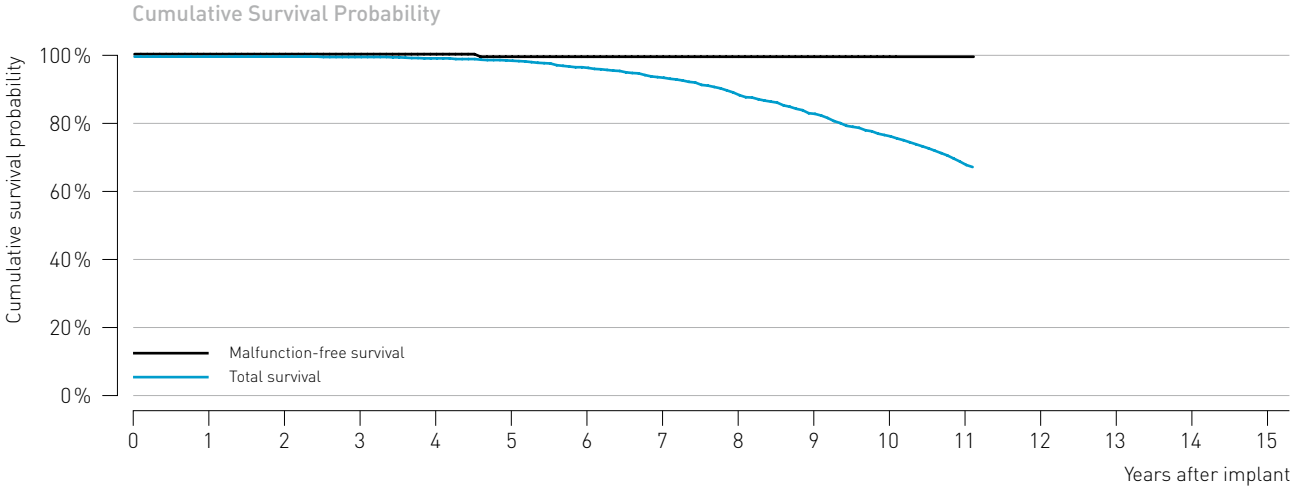
4.2 Dual-chamber pacemakers

Axios

Product details

Product versions	Axios D, Axios DR, Axios SLR
NBG code(s)	DDD, DDDR, VDDR
U.S. market release	Nov 2001
CE market release	Oct 2001
Worldwide distributed devices	110,000
Registered U.S. implants	2,740
Estimated active U.S. implants	683
U.S. normal battery depletions	206

	Quantity	Rate
U.S. confirmed malfunctions	2	0.07%
▪ Therapy compromised	0	0.00%
▪ Therapy available	2	0.07%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.
Total survival (%)	100.0	100.0	100.0	99.9	99.5	98.8	96.7	93.8	88.7	83.2	76.6	68.2	-
(95 % confidence interval)			±0.1	±0.2	±0.3	±0.5	±0.9	±1.2	±1.7	±2.2	±2.8	±3.4	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	-
(95 % confidence interval)						±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2	-

4.2 Dual-chamber pacemakers

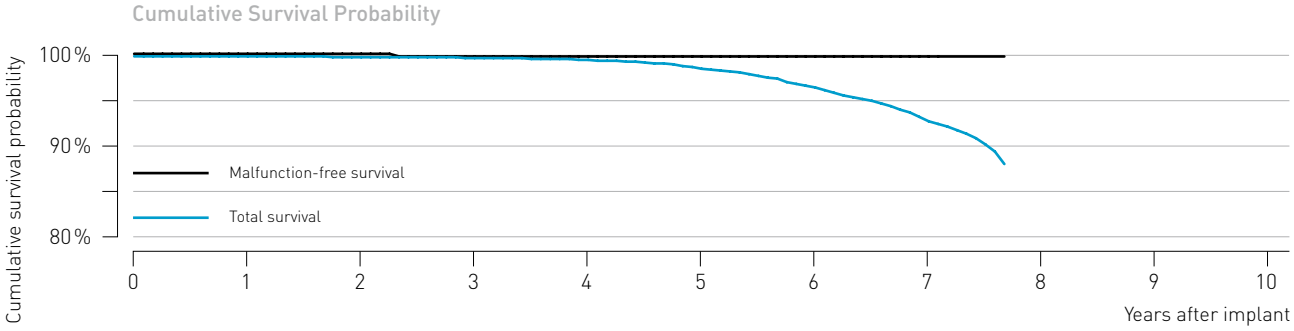
Cylos and Cylos 990

Product details

Product versions*	Cylos DR, Cylos DR-T, Cylos 990 DR, Cylos 990 DR-T
NBG code(s)	DDDR
U.S. 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	21,600
U.S. normal battery depletions	381

	Quantity	Rate
U.S. confirmed malfunctions	27	0.09%
▪ Therapy compromised	7	0.02%
▪ Therapy available	20	0.07%

* 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



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.8	99.6	98.6	96.5	92.7	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.2	±0.4	±0.8	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	-	-	-	-

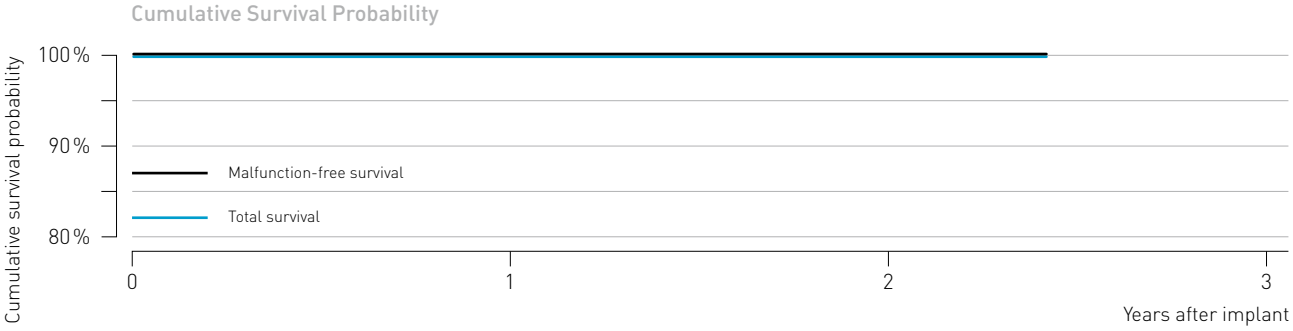
4.2 Dual-chamber pacemakers

Estella

Product details

Product versions	Estella DR, Estella DR-T
NBG code(s)	DDDR
U.S. market release	Feb 2011
CE market release	Feb 2011
Worldwide distributed devices	14,400
Registered U.S. implants	2,740
Estimated active U.S. implants	2,590
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)				-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)				-	-	-	-	-	-	-	-	-

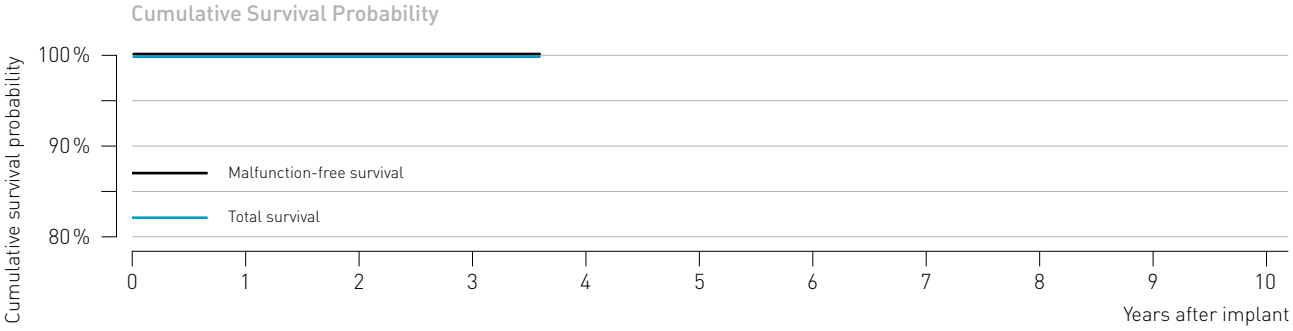
4.2 Dual-chamber pacemakers

Evia

Product details

Product versions	Evia DR, Evia DR-T
NBG code(s)	DDDR
U.S. market release	May 2010
CE market release	Oct 2009
Worldwide distributed devices	134,000
Registered U.S. implants	44,600
Estimated active U.S. implants	42,000
U.S. normal battery depletions	0

	Quantity	Rate
U.S. confirmed malfunctions	12	0.03%
▪ Therapy compromised	6	0.01%
▪ Therapy available	6	0.01%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	-	-	-	-	-	-	-	-

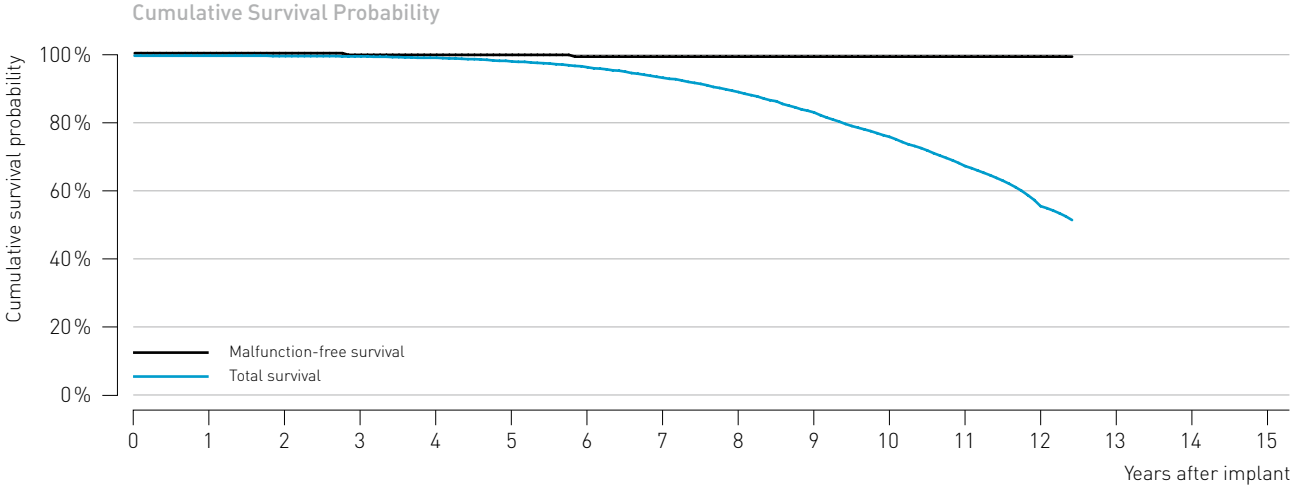
4.2 Dual-chamber pacemakers

Philos

Product details

Product versions	Philos D, Philos DR, Philos DR-T, Philos SLR
NBG code(s)	DDD, DDDR, VDDR
U.S. market release	Sep 2000
CE market release	Aug 2000
Worldwide distributed devices	173,000
Registered U.S. implants	20,700
Estimated active U.S. implants	6,700
U.S. normal battery depletions	1,703

	Quantity	Rate
U.S. confirmed malfunctions	28	0.14%
▪ Therapy compromised	5	0.02%
▪ Therapy available	23	0.11%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.
Total survival (%)	100.0	100.0	99.9	99.8	99.4	98.3	96.6	93.5	89.3	83.3	76.1	67.5	55.7
(95% confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.2	±0.3	±0.5	±0.6	±0.8	±1.0	±1.3	±1.8
Malfunction-free survival (%)	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
(95% confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1

4.2 Dual-chamber pacemakers

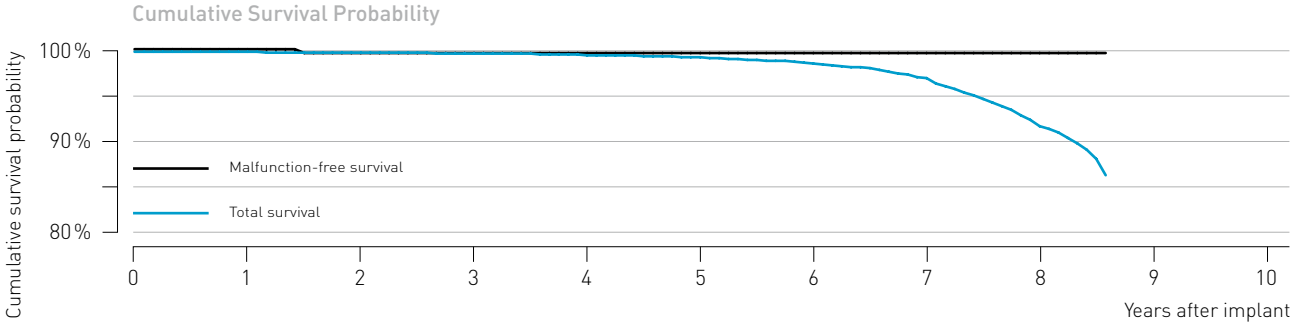
Philos II and Talos

Product details

Product versions*	Philos II D, Philos II DR(-T), Philos II SLR, Talos D, Talos DR, Talos SLR
NBG code(s)	DDD, DDDR, VDDR
U.S. market release	Sep 2004
CE market release	Feb 2004/May 2006
Worldwide distributed devices	329,000
Registered U.S. implants	23,200
Estimated active U.S. implants	15,900
U.S. normal battery depletions	258

	Quantity	Rate
U.S. confirmed malfunctions	20	0.09%
▪ Therapy compromised	0	0.00%
▪ Therapy available	20	0.09%

* 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



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.8	99.6	99.4	98.7	97.1	91.8	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.1	±0.2	±0.4	±0.9	-	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	-	-	-

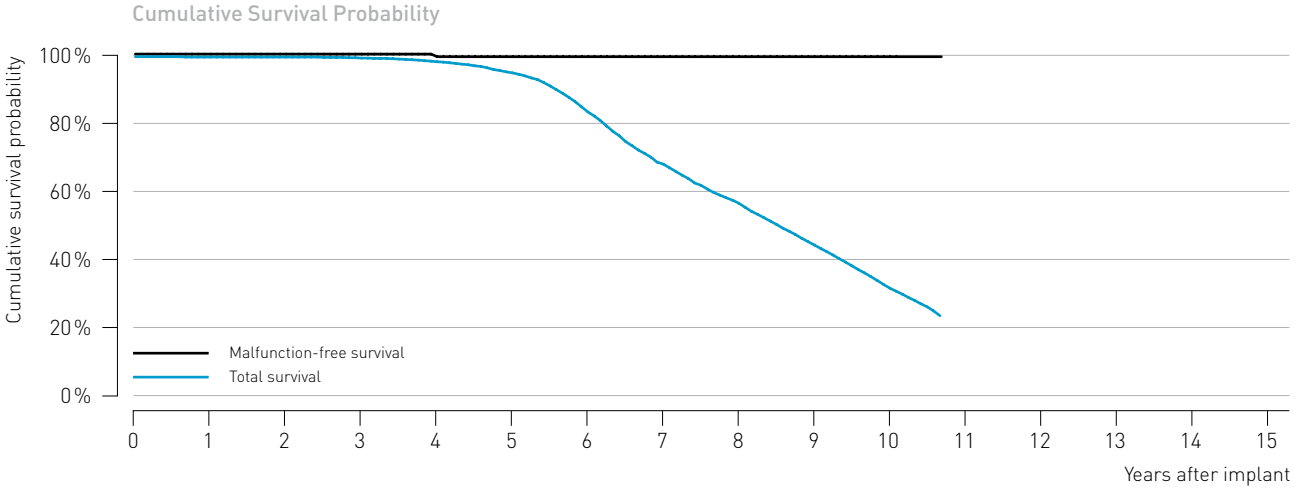
4.2 Dual-chamber pacemakers

Protos

Product details

Product versions	Protos DR/CLS
NBG code(s)	DDDR
U.S. market release	Jan 2003
CE market release	Jul 2003
Worldwide distributed devices	27,800
Registered U.S. implants	10,800
Estimated active U.S. implants	2,800
U.S. normal battery depletions	1,699

	Quantity	Rate
U.S. confirmed malfunctions	10	0.09%
▪ Therapy compromised	2	0.02%
▪ Therapy available	8	0.07%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.9	99.6	98.5	95.2	83.6	68.1	56.5	44.1	31.3	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.3	±0.5	±0.9	±1.4	±1.6	±1.9	±2.0	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	-

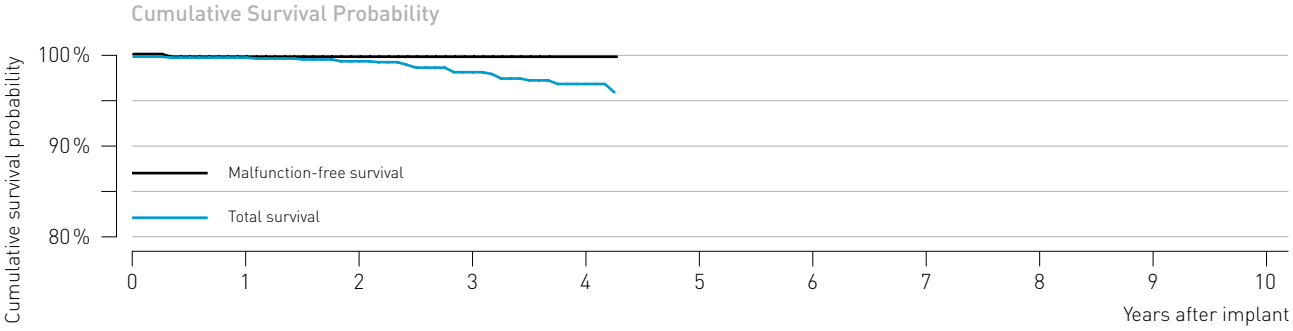
4.3 CRT pacemakers

Stratos

Product details

Product versions	Stratos LV, Stratos LV-T
NBG code(s)	DDDRV
U.S. market release	May 2008
CE market release	Nov 2002
Worldwide distributed devices	21,000
Registered U.S. implants	1,310
Estimated active U.S. implants	944
U.S. normal battery depletions	24

	Quantity	Rate
U.S. confirmed malfunctions	1	0.08%
▪ Therapy compromised	0	0.00%
▪ Therapy available	1	0.08%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.5	98.3	97.0	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.4	±1.0	±1.4	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.9	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.2	±0.2	±0.2	-	-	-	-	-	-	-

5 Performance of BIOTRONIK ICDs

5.1 Single-chamber ICDs

5.2 Dual-chamber ICDs

5.3 CRT ICDs

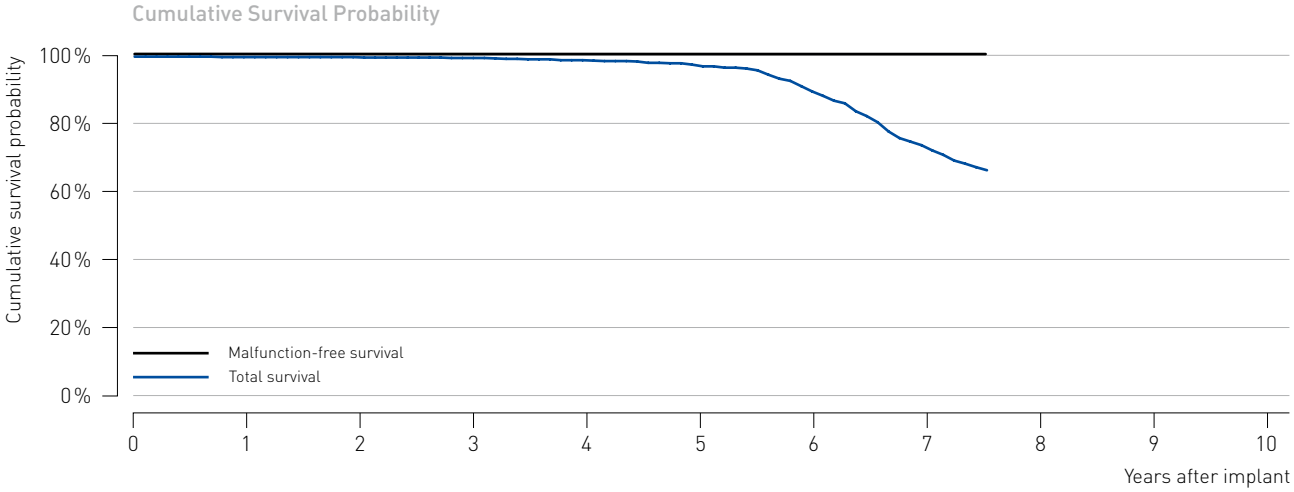
5.1 Single-chamber ICDs

Lexos

Product details

Product versions	Lexos VR, Lexos VR-T
NBG code(s)	VVIRD
Maximum energy (J)	30
U.S. market release	Feb 2004
CE market release	Oct 2003
Worldwide distributed devices	16,800
Registered U.S. implants	1,250
Estimated active U.S. implants	364
U.S. normal battery depletions	121

	Quantity	Rate
U.S. confirmed malfunctions	0	0.00%
▪ Therapy compromised	0	0.00%
▪ Therapy available	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.8	99.4	98.6	94.5	79.9	71.2	-	-	-	-
(95 % confidence interval)		±0.2	±0.3	±0.5	±0.8	±1.6	±3.4	±4.4	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-
(95 % confidence interval)									-	-	-	-

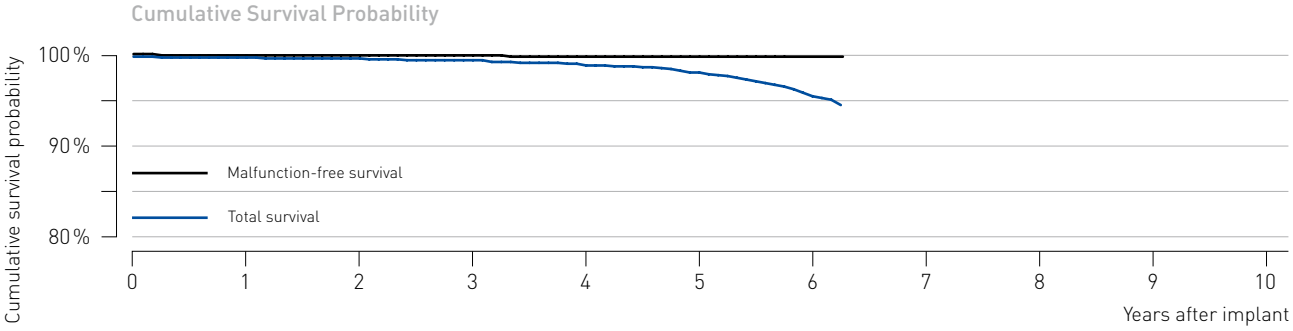
5.1 Single-chamber ICDs

Lumax 340

Product details

Product versions	Lumax 340 VR, Lumax 340 VR-T
NBG code(s)	VVE-VVIR
Maximum energy (J)	40
U.S. market release	Feb 2007
CE market release	Feb 2007
Worldwide distributed devices	25,600
Registered U.S. implants	3,980
Estimated active U.S. implants	2,560
U.S. normal battery depletions	39

	Quantity	Rate
U.S. confirmed malfunctions	6	0.15%
▪ Therapy compromised	4	0.10%
▪ Therapy available	2	0.05%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.8	99.6	99.0	98.2	95.5	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.3	±0.6	±1.2	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.8	99.8	99.8	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	-	-	-	-	-

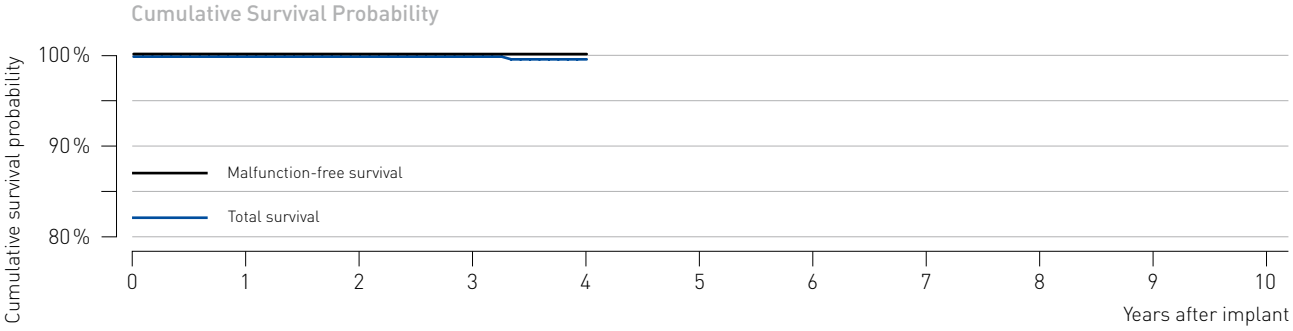
5.1 Single-chamber ICDs

Lumax 540

Product details

Product versions	Lumax 540 VR-T
NBG code(s)	VVE-VVIR
Maximum energy (J)	40
U.S. market release	May 2009
CE market release	Jun 2008
Worldwide distributed devices	16,200
Registered U.S. implants	4,530
Estimated active U.S. implants	3,970
U.S. normal battery depletions	1

	Quantity	Rate
U.S. confirmed malfunctions	2	0.04%
▪ Therapy compromised	1	0.02%
▪ Therapy available	1	0.02%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	100.0	99.8	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.2	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	-	-	-	-	-	-	-

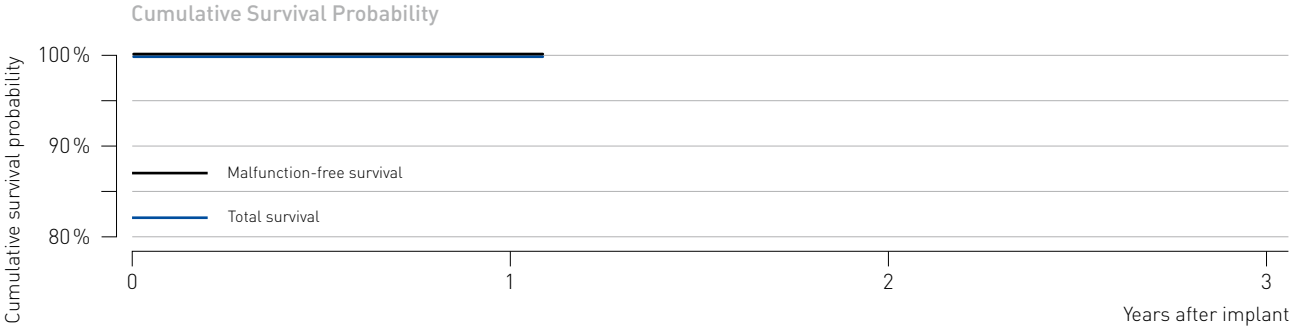
5.1 Single-chamber ICDs

Lumax 740

Product details

Product versions	Lumax 740 VR-T
NBG code(s)	VVE-VVIR
Maximum energy (J)	40
U.S. market release	Sep 2012
CE market release	Apr 2012
Worldwide distributed devices	4,310
Registered U.S. implants	1,360
Estimated active U.S. implants	1,310
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			-	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			-	-	-	-	-	-	-	-	-	-

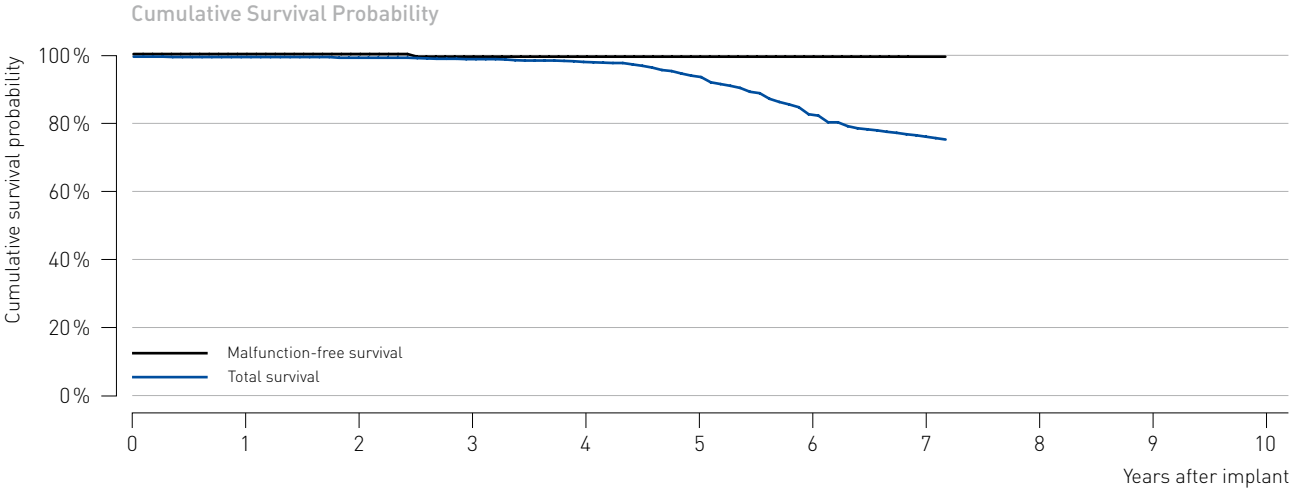
5.1 Single-chamber ICDs

Lumos

Product details

Product versions	Lumos VR-T
NBG code(s)	VVE-VVIR
Maximum energy (J)	30
U.S. market release	Sep 2005
CE market release	May 2005
Worldwide distributed devices	8,600
Registered U.S. implants	1,780
Estimated active U.S. implants	597
U.S. normal battery depletions	143

	Quantity	Rate
U.S. confirmed malfunctions	1	0.06%
▪ Therapy compromised	0	0.00%
▪ Therapy available	1	0.06%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.7	99.3	98.3	92.2	81.3	76.0	-	-	-	-
(95% confidence interval)		±0.2	±0.3	±0.4	±0.7	±1.6	±3.0	±3.7	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	-	-	-	-
(95% confidence interval)				±0.2	±0.2	±0.2	±0.2	±0.2	-	-	-	-

5.2 Dual-chamber ICDs

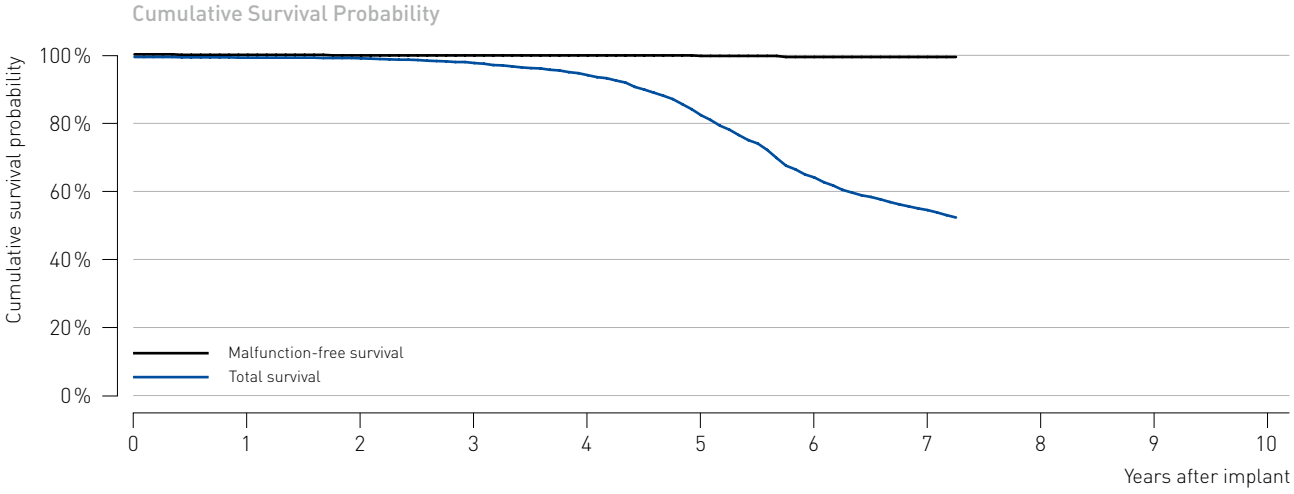
Lexos

Product details

Product versions*	Lexos DR, Lexos DR-T, Lexos A+, Lexos A+/T
NBG code(s)	DDDRD, VDDRD
Maximum energy (J)	30
U.S. market release	Feb 2004
CE market release	Oct 2003
Worldwide distributed devices	11,700
Registered U.S. implants	2,590
Estimated active U.S. implants	535
U.S. normal battery depletions	408

	Quantity	Rate
U.S. confirmed malfunctions	6	0.23%
▪ Therapy compromised	2	0.08%
▪ Therapy available	4	0.15%

* While Lexos A+ and Lexos A+/T are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.8	99.6	98.2	94.6	82.6	64.0	54.3	-	-	-	-
(95% confidence interval)		±0.2	±0.2	±0.5	±1.0	±1.9	±3.0	±3.7	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.8	99.8	99.8	99.7	99.5	99.5	-	-	-	-
(95% confidence interval)		±0.1	±0.2	±0.2	±0.2	±0.2	±0.5	±0.5	-	-	-	-

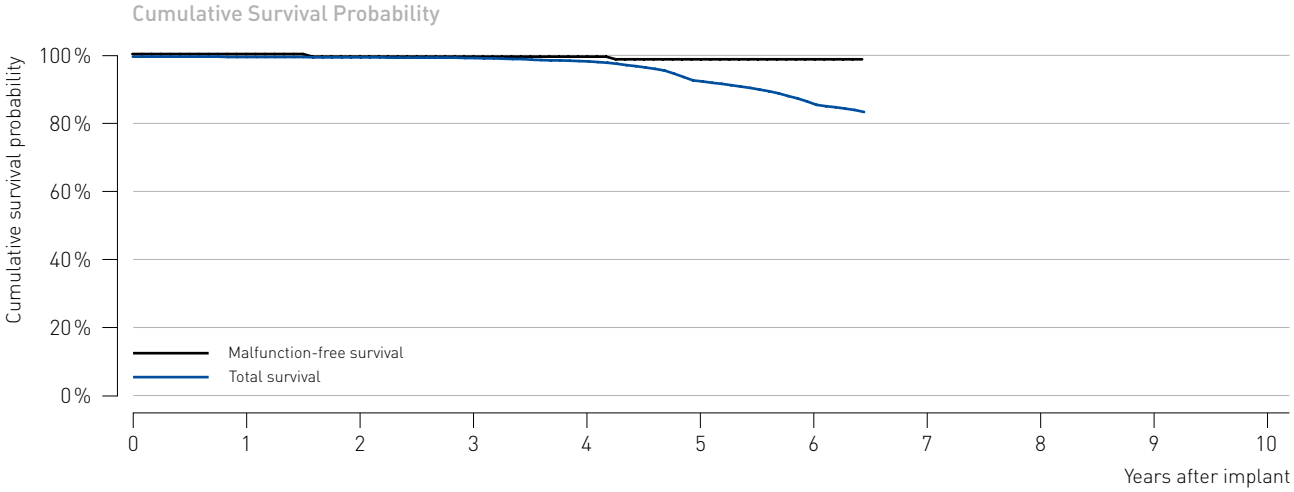
5.2 Dual-chamber ICDs

Lumax 340

Product details

Product versions	Lumax 340 DR, Lumax 340 DR-T
NBG code(s)	VVE-DDDR
Maximum energy (J)	40
U.S. market release	Feb 2007
CE market release	Feb 2007
Worldwide distributed devices	25,300
Registered U.S. implants	8,200
Estimated active U.S. implants	4,620
U.S. normal battery depletions	293

	Quantity	Rate
U.S. confirmed malfunctions	10	0.12%
▪ Therapy compromised	8	0.10%
▪ Therapy available	2	0.02%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100	99.9	99.8	99.6	98.6	92.7	85.8	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.3	±0.8	±1.7	-	-	-	-	-
Malfunction-free survival (%)	100	100.0	99.9	99.9	99.9	99.8	99.8	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	-	-	-	-	-

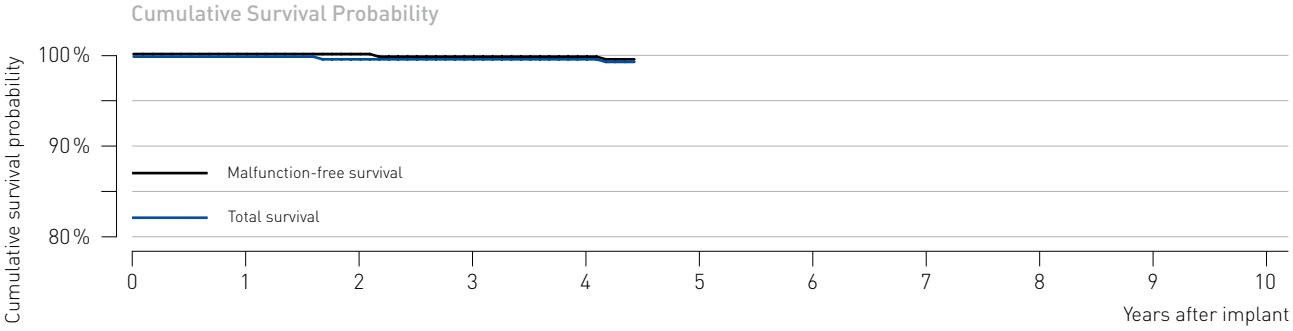
5.2 Dual-chamber ICDs

Lumax 540

Product details

Product versions	Lumax 540 DR-T
NBG code(s)	VVE-DDDR
Maximum energy (J)	40
U.S. market release	May 2009
CE market release	Jun 2008
Worldwide distributed devices	23,200
Registered U.S. implants	11,500
Estimated active U.S. implants	9,940
U.S. normal battery depletions	1

	Quantity	Rate
U.S. confirmed malfunctions	8	0.06%
▪ Therapy compromised	4	0.03%
▪ Therapy available	4	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.9	99.9	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	-	-	-	-	-	-	-

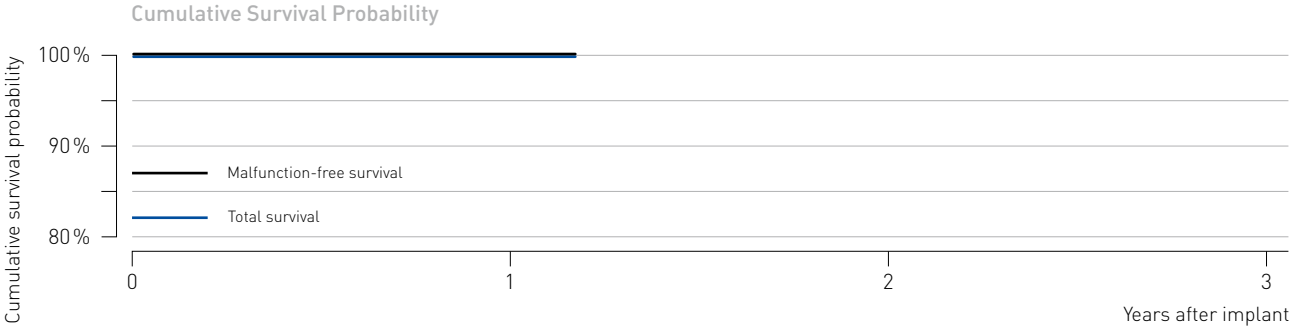
5.2 Dual-chamber ICDs

Lumax 740

Product details

Product versions	Lumax 740 DR-T
NBG code(s)	VVE-DDDR
Maximum energy (J)	40
U.S. market release	Sep 2012
CE market release	Apr 2012
Worldwide distributed devices	7,230
Registered U.S. implants	3,280
Estimated active U.S. implants	3,200
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			-	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			-	-	-	-	-	-	-	-	-	-

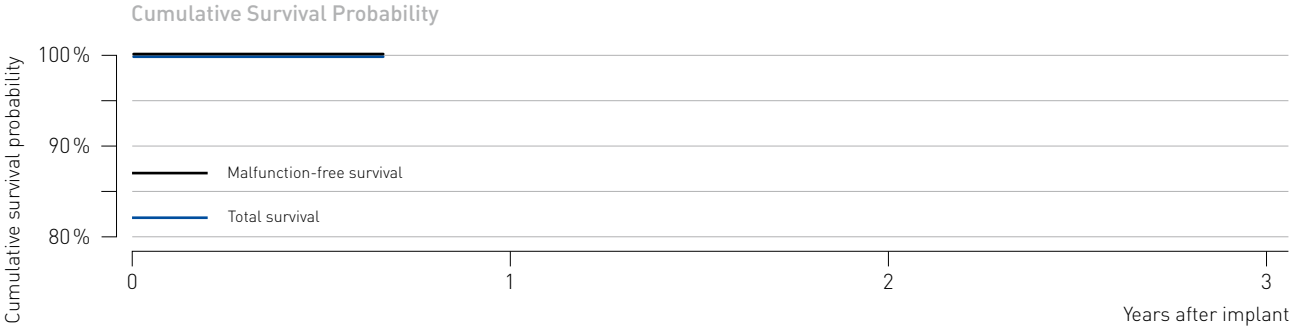
5.2 Dual-chamber ICDs

Lumax 740 DX

Product details

Product versions	Lumax 740 VR-T DX
NBG code(s)	VVE-VDDR
Maximum energy (J)	40
U.S. market release	May 2012
CE market release	Nov 2011
Worldwide distributed devices	4,280
Registered U.S. implants	1,850
Estimated active U.S. implants	1,820
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	-	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		-	-	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	-	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		-	-	-	-	-	-	-	-	-	-	-

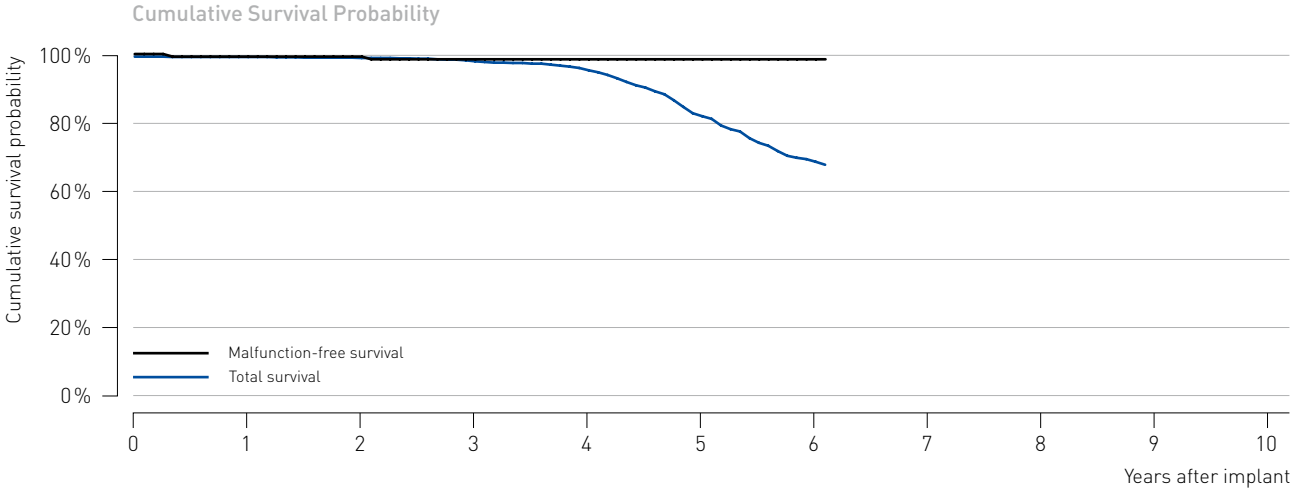
5.2 Dual-chamber ICDs

Lumos

Product details

Product versions	Lumos DR-T
NBG code(s)	VVE-DDDR
Maximum energy (J)	30
U.S. market release	Sep 2005
CE market release	May 2005
Worldwide distributed devices	6,600
Registered U.S. implants	2,240
Estimated active U.S. implants	573
U.S. normal battery depletions	254

	Quantity	Rate
U.S. confirmed malfunctions	4	0.18%
▪ Therapy compromised	2	0.09%
▪ Therapy available	2	0.09%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.6	98.6	95.9	82.1	68.4	-	-	-	-	-
(95% confidence interval)		±0.1	±0.2	±0.5	±0.9	±2.2	±3.4	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.8	99.8	99.8	99.8	-	-	-	-	-
(95% confidence interval)		±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	-	-	-	-	-

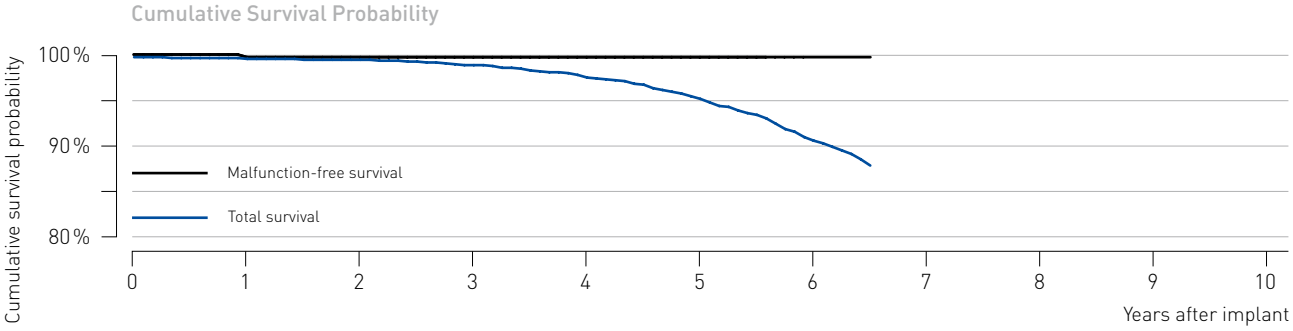
5.3 CRT ICDs

Lumax 340

Product details

Product versions	Lumax 340 HF, Lumax 340 HF-T
NBG code(s)	VVE-DDDRV
Maximum energy (J)	40
U.S. market release	Feb 2007
CE market release	Dec 2006
Worldwide distributed devices	19,800
Registered U.S. implants	5,310
Estimated active U.S. implants	3,060
U.S. normal battery depletions	156

	Quantity	Rate
U.S. confirmed malfunctions	4	0.08%
▪ Therapy compromised	2	0.04%
▪ Therapy available	2	0.04%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.8	99.7	99.1	97.7	95.3	90.6	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.2	±0.3	±0.4	±0.8	±1.5	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.9	99.9	99.9	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	-	-	-	-	-

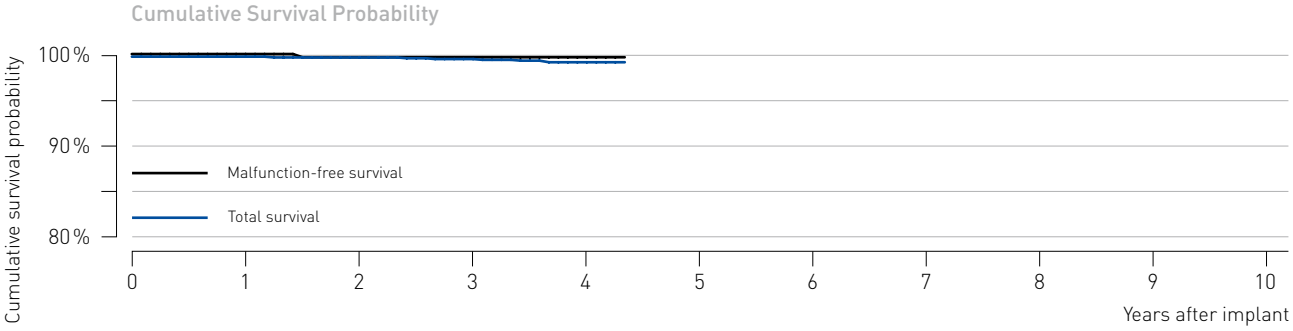
5.3 CRT ICDs

Lumax 540

Product details

Product versions	Lumax 540 HF-T
NBG code(s)	VVE-DDDRV
Maximum energy (J)	40
U.S. market release	May 2009
CE market release	Jun 2008
Worldwide distributed devices	22,400
Registered U.S. implants	8,640
Estimated active U.S. implants	7,230
U.S. normal battery depletions	18

	Quantity	Rate
U.S. confirmed malfunctions	5	0.05%
▪ Therapy compromised	2	0.02%
▪ Therapy available	3	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.7	99.3	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	±0.2	±0.3	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	99.9	99.9	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.1	-	-	-	-	-	-	-

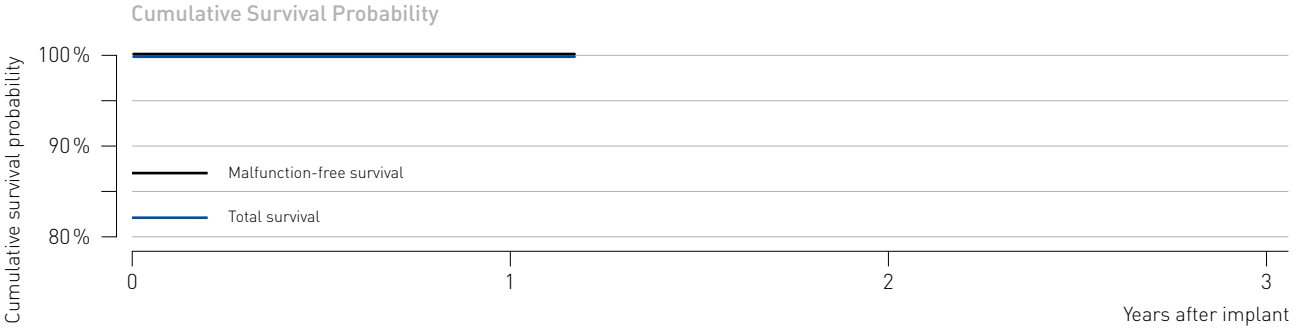
5.3 CRT ICDs

Lumax 740

Product details

Product versions	Lumax 740 HF-T
NBG code(s)	VVE-DDDRV
Maximum energy (J)	40
U.S. market release	Sep 2012
CE market release	Apr 2012
Worldwide distributed devices	6,400
Registered U.S. implants	2,940
Estimated active U.S. implants	2,870
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%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	-	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	-	-	-	-	-	-	-	-	-	-

6 Methodology for lead survival estimates based on returned product analysis and complaint information

6.1 Cumulative lead survival probability

This report has been prepared in accordance with ISO 5841-2:2000 (E) applying actuarial analysis for the calculation of lead survival probabilities. Lead survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK's pacing and ICD leads.

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

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

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

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

In order to minimize the effect of underreporting of lead malfunctions, BIOTRONIK is currently analyzing the usefulness of including long-term, post-market studies of our pacing and ICD leads to establish improved measurements of lead performance.

6.2 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 new prospective data form the GALAXY and CELESTIAL post-approval studies is presented separately in chapters 8 and 9.

In order to be included in the population under observation, a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is December 31, 2013. The sample size 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 (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 assumed to be 10 % p.a. if the reported rate from our registration and tracking systems is below 10 % p.a.

6.3 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 observations of 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:

- 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.

6.4 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 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, 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 Ω or > 3000 Ω
- Abnormal defibrillation impedance – Defibrillation impedance is typically considered abnormal if a measurement is < 20 Ω or > 200 Ω. 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.

6.5 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 observations of an anomaly. Removals for clinical reasons unrelated to the device's performance (i.e., infections) are excluded.

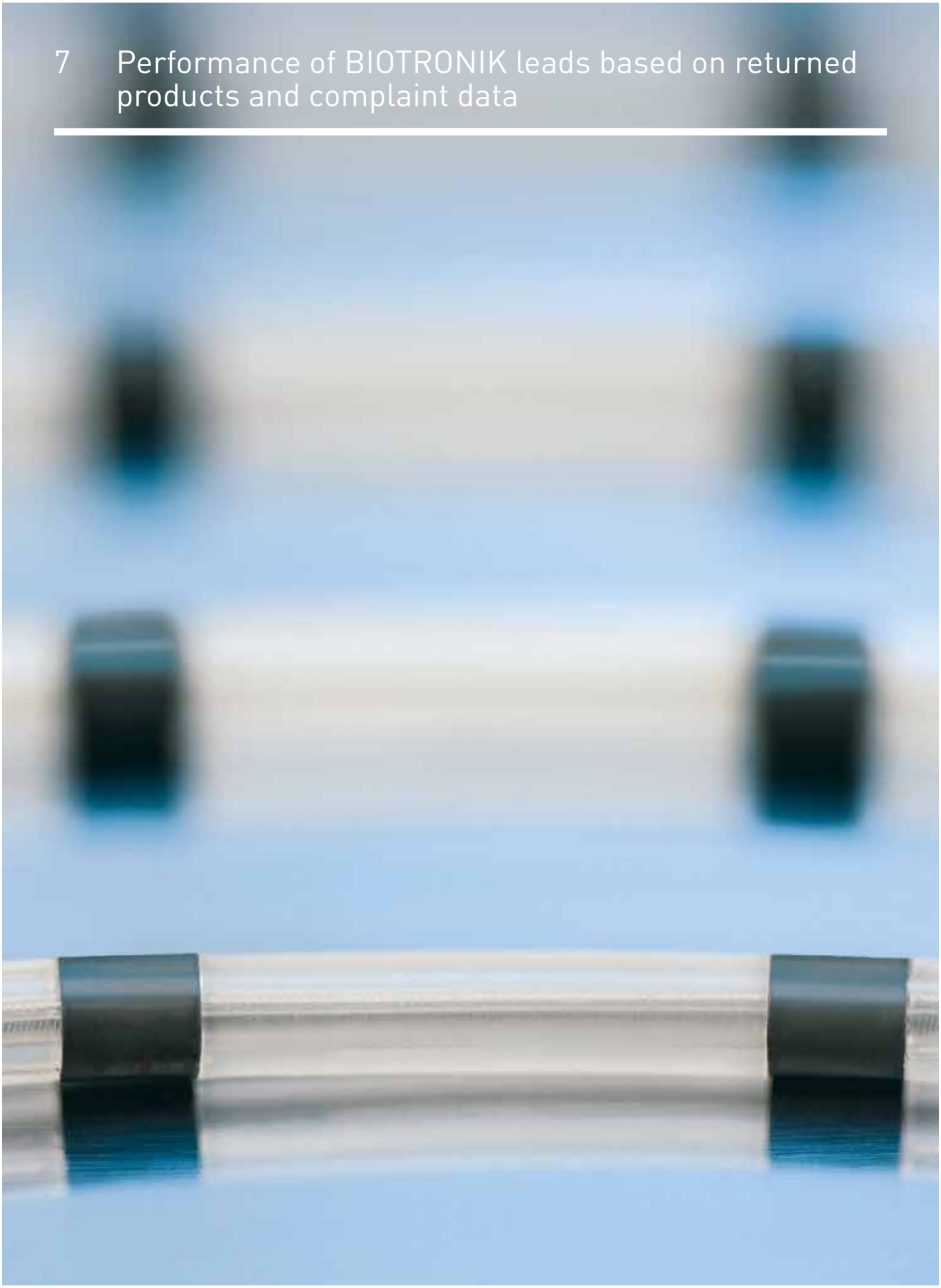
Products or subgroups of products may become subject to advisory notifications that can significantly impact the overall product performance.

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[2] are shown in numerical form for the observed population.

2 Greenwood, M. The Natural Duration of Cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926

7 Performance of BIOTRONIK leads based on returned products and complaint data



7.1 Pacing leads

7.2 ICD leads

7.1 Pacing leads

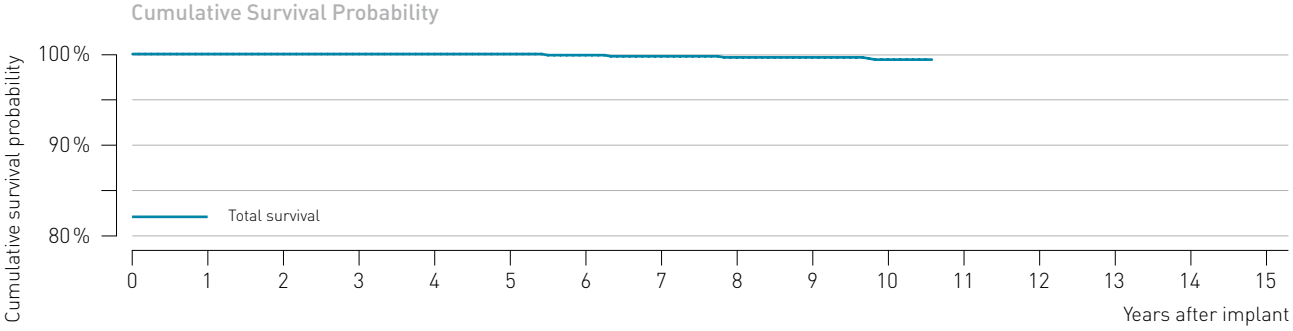
Arox

Product details

Product versions	Arox 53-BP, Arox 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	8,530
Estimated active U.S. implants	4,890
U.S. total returned	11

	Quantity	Rate
U.S. qualifying complications	15	0.18%
▪ Abnormal pacing impedance	5	0.06%
▪ Failure to capture	9	0.11%
▪ Insulation breach	1	0.01%
U.S. confirmed malfunctions	1	0.01%
▪ Insulation breach	1	0.01%

	Quantity	Rate
U.S. acute lead observations	2	0.02%
▪ Lead dislodgement	2	0.02%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.7	99.7	99.5	-
(95 % confidence interval)						±0.0	±0.1	±0.1	±0.2	±0.2	±0.3	-

7.1 Pacing leads

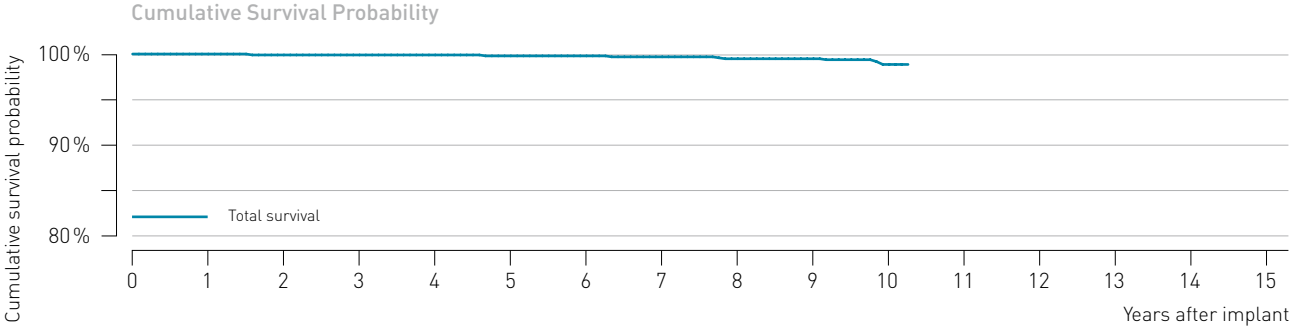
Arox J

Product details

Product versions	Arox 45-JBP, Arox 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	2,260
U.S. total returned	3

	Quantity	Rate
U.S. qualifying complications	12	0.35%
▪ Abnormal pacing impedance	1	0.03%
▪ Failure to capture	9	0.26%
▪ Lead dislodgement	2	0.06%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.7	99.5	99.5	98.9	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.3	±0.3	±0.8	-

7.1 Pacing leads

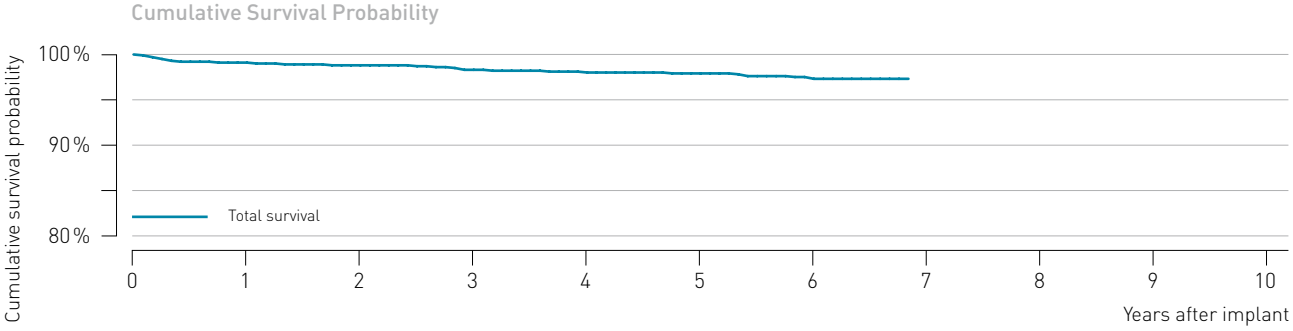
Corox

Product details

Product versions	Corox OTW 75-UP Steroid, 85-UP Steroid
Lead type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. market release	Aug 2006
CE market release	Apr 2004
Worldwide distributed devices	10,300
Registered U.S. implants	1,430
Estimated active U.S. implants	821
U.S. total returned	21

	Quantity	Rate
U.S. qualifying complications	28	1.96%
▪ Extracardiac stimulation	7	0.49%
▪ Failure to capture	13	0.91%
▪ Insulation breach	1	0.07%
▪ Lead dislodgement	7	0.49%
U.S. confirmed malfunctions	1	0.07%
▪ Insulation breach	1	0.07%

	Quantity	Rate
U.S. acute lead observations	4	0.28%
▪ Failure to capture	3	0.21%
▪ Lead dislodgement	1	0.07%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.1	98.8	98.3	98.0	97.9	97.3	-	-	-	-	-
(95 % confidence interval)		±0.5	±0.6	±0.7	±0.8	±0.8	±0.9	-	-	-	-	-

7.1 Pacing leads

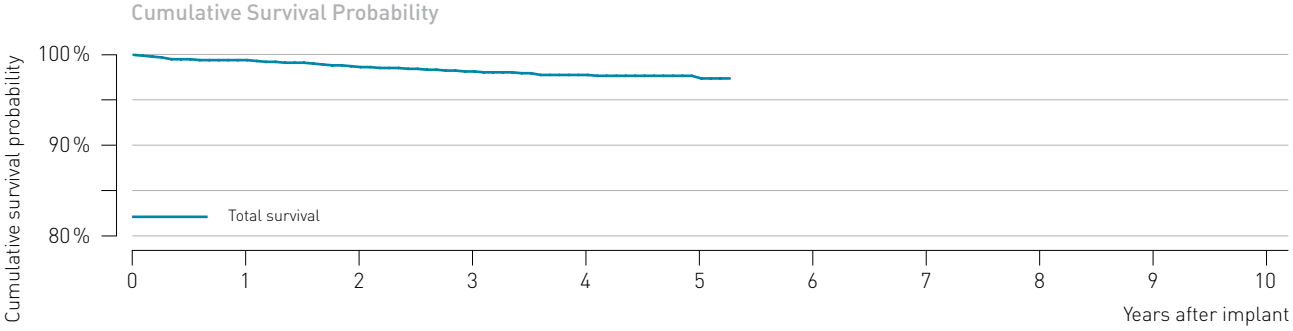
Corox

Product details

Product versions	Corox OTW 75-BP Steroid, 85-BP Steroid
Lead type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. market release	May 2008
CE market release	Dec 2006
Worldwide distributed devices	22,600
Registered U.S. implants	3,710
Estimated active U.S. implants	2,890
U.S. total returned	47

	Quantity	Rate
U.S. qualifying complications	51	1.37%
▪ Abnormal pacing impedance	2	0.05%
▪ Extracardiac stimulation	5	0.13%
▪ Failure to capture	17	0.46%
▪ Insulation breach	2	0.05%
▪ Lead dislodgement	25	0.67%
U.S. confirmed malfunctions	11	0.30%
▪ Conductor fracture	10	0.27%
▪ Insulation breach	1	0.03%

	Quantity	Rate
U.S. acute lead observations	9	0.25%
▪ Extracardiac stimulation	1	0.03%
▪ Failure to capture	1	0.03%
▪ Lead dislodgement	7	0.19%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.4	98.6	98.1	97.7	97.3	-	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.6	±0.6	-	-	-	-	-	-

7.1 Pacing leads

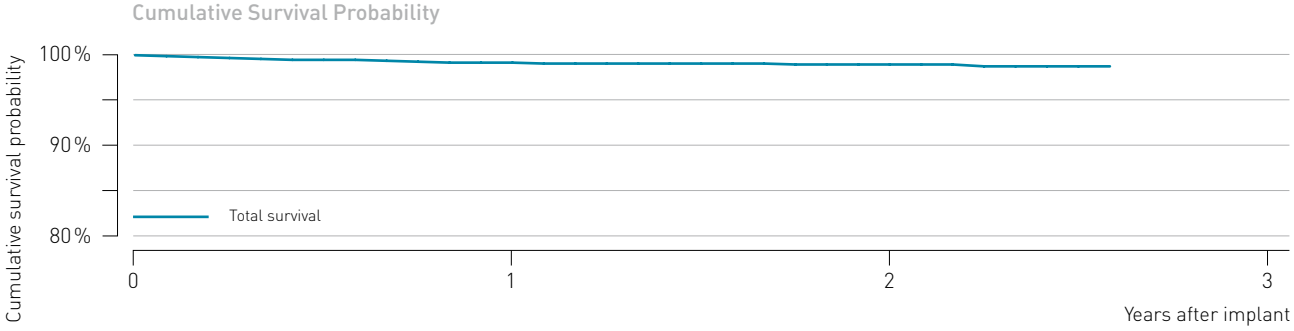
Corox

Product details

Product versions	Corox OTW-L 75-BP, Corox OTW-L 85-BP
Lead type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Jan 2011
CE market release	Dec 2009
Worldwide distributed devices	14,800
Registered U.S. implants	3,340
Estimated active U.S. implants	3,060
U.S. total returned	24

	Quantity	Rate
U.S. qualifying complications	24	0.72%
▪ Extracardiac stimulation	9	0.27%
▪ Failure to capture	8	0.24%
▪ Failure to sense	1	0.03%
▪ Lead dislodgement	6	0.18%
U.S. confirmed malfunctions	1	0.03%
▪ Conductor fracture	1	0.03%

	Quantity	Rate
U.S. acute lead observations	12	0.36%
▪ Extracardiac stimulation	4	0.12%
▪ Failure to capture	2	0.06%
▪ Lead dislodgement	6	0.18%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.2	99.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.4	±0.4	-	-	-	-	-	-	-	-	-

7.1 Pacing leads

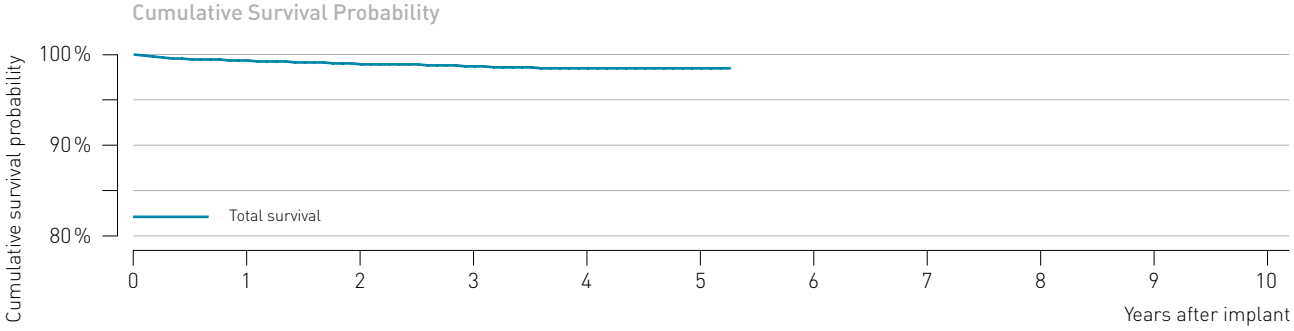
Corox

Product details

Product versions	Corox OTW-S 75-BP, 85-BP
Lead type	thread fixation
Polarity	bipolar
Steroid	yes
U.S. market release	May 2008
CE market release	Dec 2006
Worldwide distributed devices	18,700
Registered U.S. implants	6,180
Estimated active U.S. implants	5,020
U.S. total returned	51

	Quantity	Rate
U.S. qualifying complications	54	0.87%
▪ Abnormal pacing impedance	4	0.06%
▪ Conductor fracture	1	0.02%
▪ Extracardiac stimulation	7	0.11%
▪ Failure to capture	10	0.16%
▪ Insulation breach	4	0.06%
▪ Lead dislodgement	27	0.44%
▪ Oversensing	1	0.02%

	Quantity	Rate
U.S. confirmed malfunctions	6	0.09%
▪ Conductor fracture	2	0.03%
▪ Insulation breach	4	0.06%
U.S. acute lead observations	32	0.52%
▪ Abnormal pacing impedance	1	0.02%
▪ Extracardiac stimulation	3	0.05%
▪ Failure to capture	8	0.13%
▪ Lead dislodgement	20	0.32%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.4	99.0	98.8	98.6	98.6	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.3	±0.3	±0.4	±0.4	-	-	-	-	-	-

7.1 Pacing leads

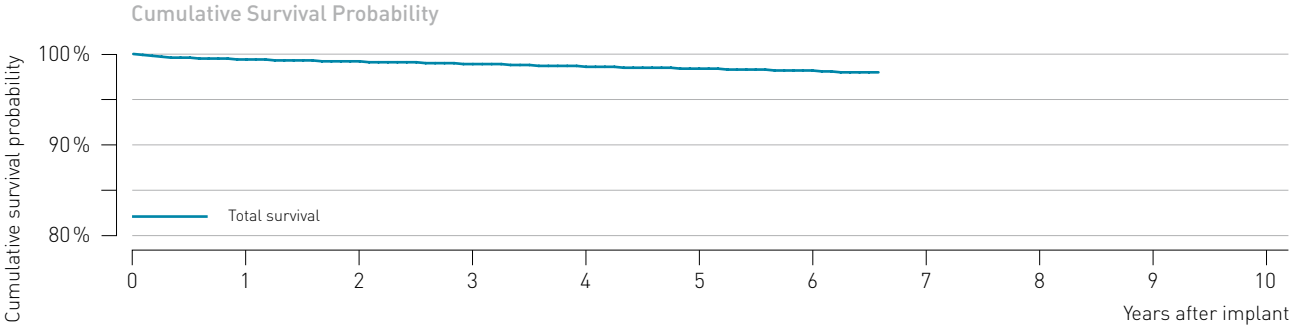
Dextrus

Product details

Product versions	Dextrus Model 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	366,000
Registered U.S. implants	267,000
Estimated active U.S. implants	213,000
U.S. total returned	1,281

	Quantity	Rate
U.S. qualifying complications	2,422	0.91%
▪ Abnormal pacing impedance	216	0.08%
▪ Cardiac perforation	29	0.01%
▪ Conductor fracture	30	0.01%
▪ Extracardiac stimulation	30	0.01%
▪ Failure to capture	705	0.26%
▪ Failure to sense	272	0.10%
▪ Insulation breach	7	< 0.01%
▪ Lead dislodgement	669	0.25%
▪ Oversensing	464	0.17%

	Quantity	Rate
U.S. confirmed malfunctions	134	0.05%
▪ Conductor fracture	48	0.02%
▪ Insulation breach	86	0.03%
U.S. acute lead observations	2,125	0.80%
▪ Abnormal pacing impedance	56	0.02%
▪ Cardiac perforation	99	0.04%
▪ Extracardiac stimulation	24	0.01%
▪ Failure to capture	405	0.15%
▪ Failure to sense	135	0.05%
▪ Insulation breach	4	< 0.01%
▪ Lead dislodgement	1,332	0.50%
▪ Oversensing	70	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.4	99.2	98.9	98.6	98.4	98.2	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	-	-	-	-	-

7.1 Pacing leads

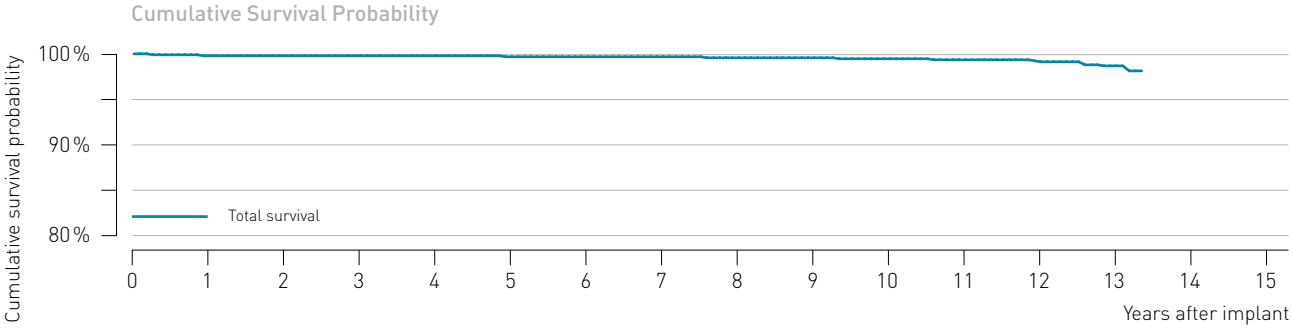
Elox

Product details

Product versions	Elox 45-BP, 53-BP, 60-BP
Lead type	straight, active fixation
Polarity	bipolar
Steroid	no
U.S. market release	May 2000
CE market release	May 2000
Worldwide distributed devices	36,000
Registered U.S. implants	11,000
Estimated active U.S. implants	3,990
U.S. total returned	44

	Quantity	Rate
U.S. qualifying complications	42	0.39%
▪ Abnormal pacing impedance	1	0.01%
▪ Conductor fracture	1	0.01%
▪ Extracardiac stimulation	1	0.01%
▪ Failure to capture	12	0.11%
▪ Failure to sense	11	0.10%
▪ Insulation breach	4	0.04%
▪ Lead dislodgement	2	0.02%
▪ Oversensing	10	0.09%

	Quantity	Rate
U.S. confirmed malfunctions	6	0.06%
▪ Conductor fracture	3	0.03%
▪ Insulation breach	3	0.03%
U.S. acute lead observations	9	0.09%
▪ Failure to capture	4	0.04%
▪ Failure to sense	1	0.01%
▪ Lead dislodgement	1	0.01%
▪ Oversensing	3	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	99.8	99.8	99.8	99.8	99.7	99.7	99.7	99.6	99.6	99.5	99.4	99.2	98.8	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.3	±0.3	-	-

7.1 Pacing leads

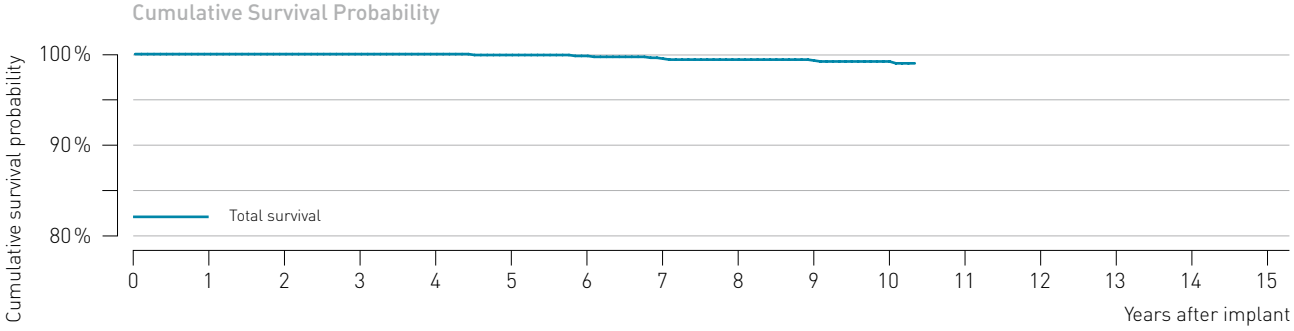
Elox P

Product details

Product versions	Elox P 45-BP, 53-BP, 60-BP
Lead type	straight, active fixation
Polarity	bipolar
Steroid	no
U.S. market release	May 2003
CE market release	Feb 2003
Worldwide distributed devices	21,900
Registered U.S. implants	3,030
Estimated active U.S. implants	1,430
U.S. total returned	15

	Quantity	Rate
U.S. qualifying complications	14	0.46%
▪ Abnormal pacing impedance	1	0.03%
▪ Failure to capture	6	0.20%
▪ Failure to sense	1	0.03%
▪ Insulation breach	1	0.03%
▪ Lead dislodgement	3	0.10%
▪ Oversensing	2	0.07%
U.S. confirmed malfunctions	1	0.03%
▪ Insulation breach	1	0.03%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.5	99.4	99.3	99.2	-
(95 % confidence interval)			±0.1	±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	±0.3	±0.4	-

7.1 Pacing leads

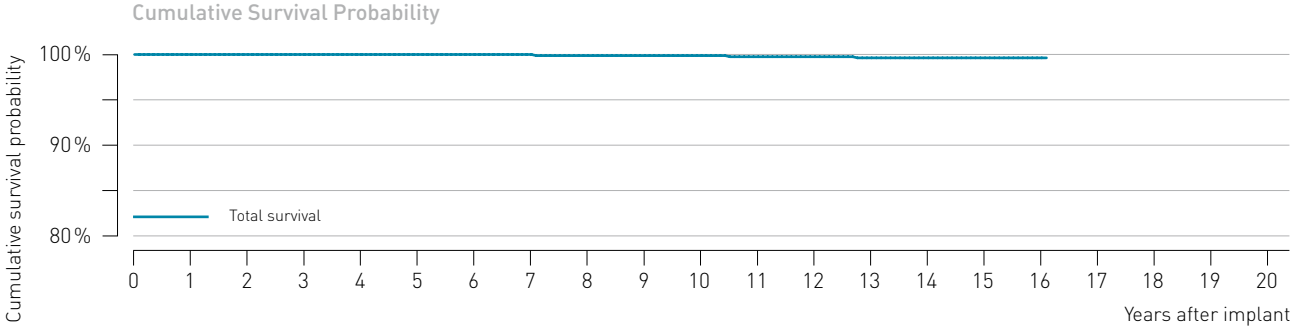
Polyrox

Product details

Product versions	Polyrox 60-UP, 53-BP, 53/15-BP, 60-BP, 60/15-BP
Lead type	straight, passive fixation
Polarity	unipolar/bipolar
Steroid	no
U.S. market release	Mar 1997
CE market release	Jul 1996
Worldwide distributed devices	351,000
Registered U.S. implants	15,100
Estimated active U.S. implants	4,900
U.S. total returned	19

	Quantity	Rate
U.S. qualifying complications	12	0.09%
▪ Conductor fracture	2	0.01%
▪ Failure to capture	7	0.05%
▪ Insulation breach	1	0.01%
▪ Lead dislodgement	1	0.01%
▪ Oversensing	1	0.01%
U.S. confirmed malfunctions	2	0.01%
▪ Insulation breach	2	0.01%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.	16 yr.
Total survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.7	99.7	99.7	99.7
(95% confidence interval)					±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2

7.1 Pacing leads

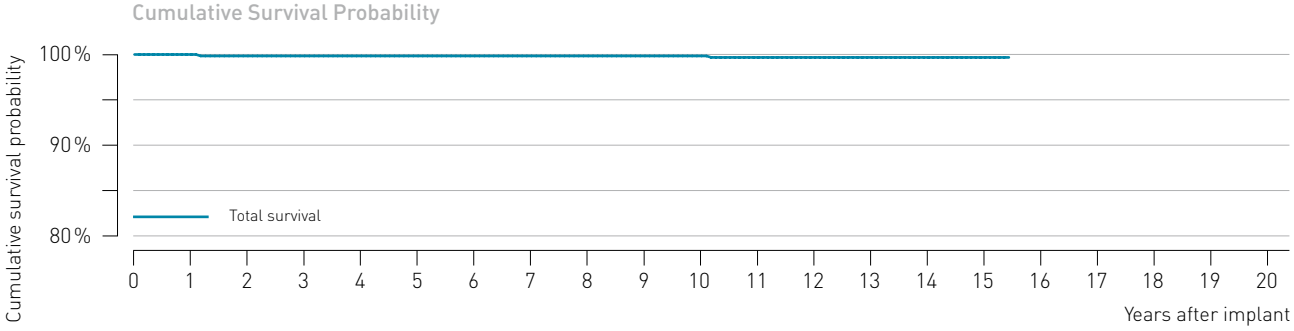
Polyrox J

Product details

Product versions	Polyrox 45-JBP, 53-JBP, 53-JUP
Lead type	J-shape, passive fixation
Polarity	unipolar/bipolar
Steroid	no
U.S. market release	Mar 1997
CE market release	Jul 1996
Worldwide distributed devices	45,900
Registered U.S. implants	3,730
Estimated active U.S. implants	1,280
U.S. total returned	4

	Quantity	Rate
U.S. qualifying complications	4	0.11%
▪ Abnormal pacing impedance	1	0.03%
▪ Failure to sense	2	0.05%
▪ Lead dislodgement	1	0.03%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	1	0.03%
▪ Failure to capture	1	0.03%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8
(95% confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2

7.1 Pacing leads

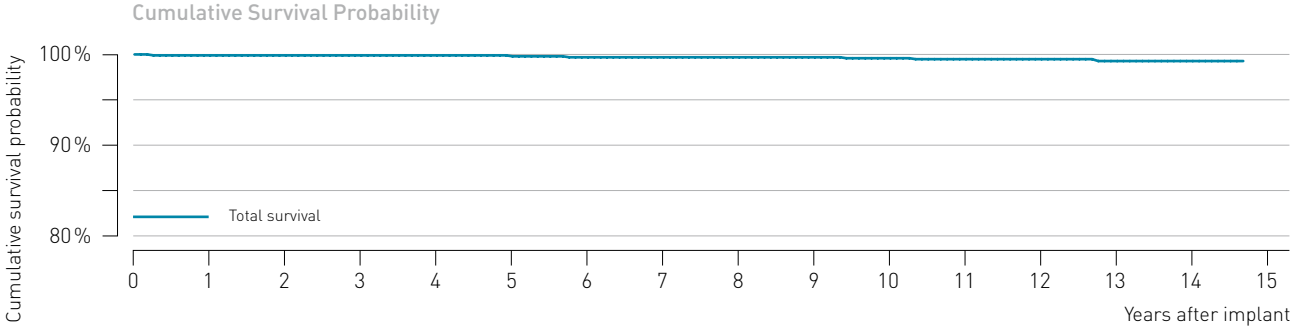
Retrox J

Product details

Product versions	Retrox 45-JBP, 53-JBP
Lead type	J-shape, active fixation
Polarity	bipolar
Steroid	no
U.S. market release	Aug 1998
CE market release	Mar 1997
Worldwide distributed devices	14,000
Registered U.S. implants	4,250
Estimated active U.S. implants	1,380
U.S. total returned	11

	Quantity	Rate
U.S. qualifying complications	13	0.31%
▪ Abnormal pacing impedance	2	0.05%
▪ Failure to capture	6	0.14%
▪ Failure to sense	2	0.05%
▪ Lead dislodgement	1	0.02%
▪ Oversensing	2	0.05%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	2	0.04%
▪ Failure to capture	1	0.02%
▪ Oversensing	1	0.02%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	99.9	99.9	99.9	99.9	99.8	99.7	99.7	99.7	99.7	99.6	99.5	99.5	99.3	99.3	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.3	±0.3	±0.3	±0.3	±0.3	-

7.1 Pacing leads

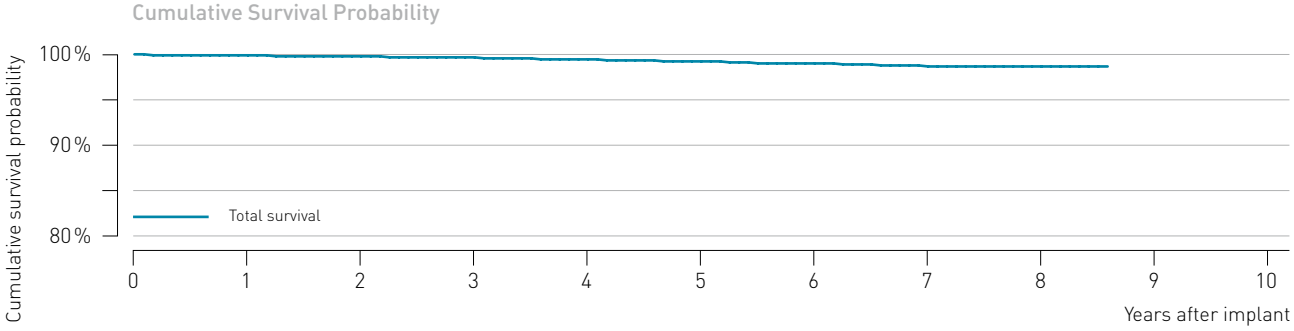
Selox JT

Product details

Product versions	Selox JT 45, JT 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	116,000
Registered U.S. implants	13,400
Estimated active U.S. implants	10,800
U.S. total returned	51

	Quantity	Rate
U.S. qualifying complications	66	0.49%
▪ Abnormal pacing impedance	4	0.03%
▪ Cardiac perforation	1	0.01%
▪ Conductor fracture	1	0.01%
▪ Extracardiac stimulation	1	0.01%
▪ Failure to capture	31	0.23%
▪ Failure to sense	8	0.06%
▪ Insulation breach	1	0.01%
▪ Lead dislodgement	16	0.12%
▪ Oversensing	3	0.02%

	Quantity	Rate
U.S. confirmed malfunctions	4	0.03%
▪ Insulation breach	4	0.03%
U.S. acute lead observations	25	0.19%
▪ Abnormal pacing impedance	1	0.01%
▪ Failure to capture	4	0.03%
▪ Lead dislodgement	20	0.15%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.8	99.7	99.5	99.3	99.1	98.8	98.8	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	-	-	

7.1 Pacing leads

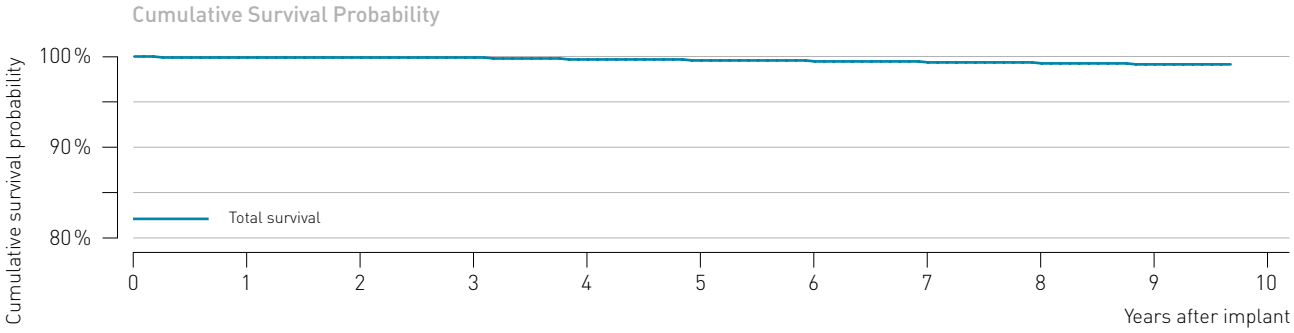
Selox SR

Product details

Product versions	Selox SR 45, SR 53, SR 60
Lead type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Mar 2004
CE market release	Feb 2004
Worldwide distributed devices	161,000
Registered U.S. implants	14,300
Estimated active U.S. implants	7,900
U.S. total returned	37

	Quantity	Rate
U.S. qualifying complications	61	0.42%
▪ Abnormal pacing impedance	2	0.01%
▪ Conductor fracture	1	< 0.01%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	32	0.22%
▪ Failure to sense	3	0.02%
▪ Insulation breach	2	0.01%
▪ Lead dislodgement	14	0.10%
▪ Oversensing	6	0.04%
U.S. confirmed malfunctions	8	0.06%
▪ Insulation breach	8	0.06%

	Quantity	Rate
U.S. acute lead observations	22	0.16%
▪ Cardiac perforation	2	0.01%
▪ Failure to capture	8	0.06%
▪ Insulation breach	1	0.01%
▪ Lead dislodgement	11	0.08%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.9	99.9	99.7	99.6	99.5	99.4	99.3	99.2	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	-	-

7.1 Pacing leads

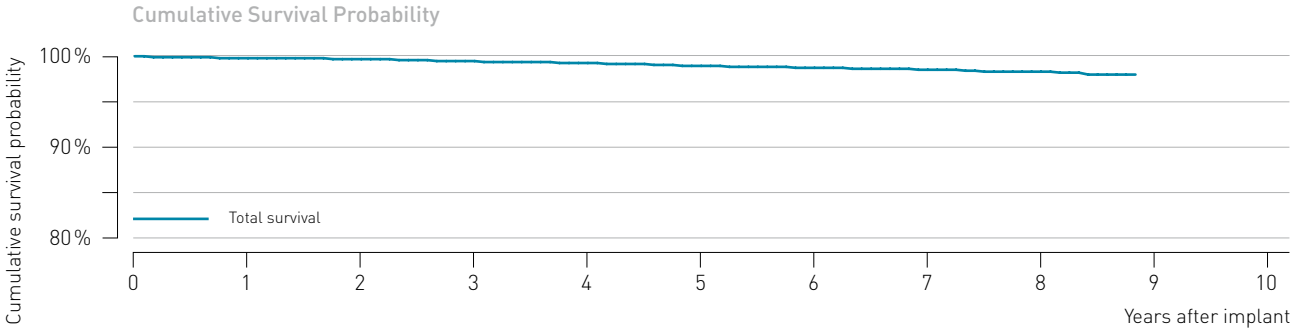
Selox ST

Product details

Product versions	Selox ST 53, ST 60
Lead type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Nov 2004
CE market release	Nov 2004
Worldwide distributed devices	326,000
Registered U.S. implants	26,400
Estimated active U.S. implants	20,400
U.S. total returned	73

	Quantity	Rate
U.S. qualifying complications	176	0.67%
▪ Abnormal pacing impedance	44	0.17%
▪ Cardiac perforation	1	< 0.01%
▪ Conductor fracture	8	0.03%
▪ Extracardiac stimulation	3	0.01%
▪ Failure to capture	98	0.37%
▪ Failure to sense	2	0.01%
▪ Insulation breach	8	0.03%
▪ Lead dislodgement	11	0.04%
▪ Oversensing	1	< 0.01%

	Quantity	Rate
U.S. confirmed malfunctions	8	0.03%
▪ Conductor fracture	1	< 0.01%
▪ Crimps, welds and bonds	1	< 0.01%
▪ Insulation breach	6	0.02%
U.S. acute lead observations	22	0.08%
▪ Failure to capture	9	0.03%
▪ Failure to sense	1	< 0.01%
▪ Lead dislodgement	12	0.05%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.3	-	-	-

7.1 Pacing leads

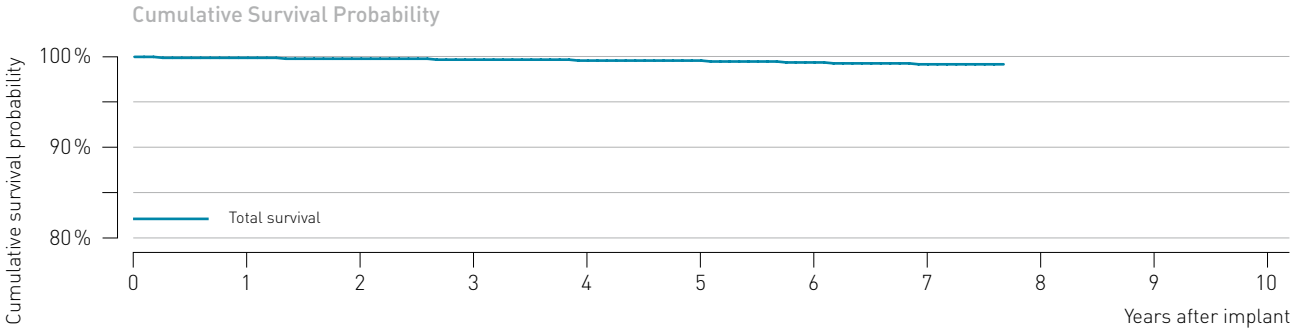
Setrox S

Product details

Product versions	Setrox S-45, S-53, S-60
Lead type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Apr 2006
CE market release	Mar 2006
Worldwide distributed devices	516,000
Registered U.S. implants	153,000
Estimated active U.S. implants	131,000
U.S. total returned	586

	Quantity	Rate
U.S. qualifying complications	370	0.24%
▪ Abnormal pacing impedance	26	0.02%
▪ Cardiac perforation	5	< 0.01%
▪ Conductor fracture	6	< 0.01%
▪ Extracardiac stimulation	4	< 0.01%
▪ Failure to capture	106	0.07%
▪ Failure to sense	14	0.01%
▪ Insulation breach	14	0.01%
▪ Lead dislodgement	159	0.10%
▪ Oversensing	36	0.02%

	Quantity	Rate
U.S. confirmed malfunctions	60	0.04%
▪ Conductor fracture	21	0.01%
▪ Insulation breach	39	0.03%
U.S. acute lead observations	153	0.10%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Cardiac perforation	9	< 0.01%
▪ Failure to capture	22	0.01%
▪ Failure to sense	3	< 0.01%
▪ Lead dislodgement	118	0.08%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	99.8	99.7	99.6	99.6	99.4	99.2	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	-	-	-	-

7.1 Pacing leads

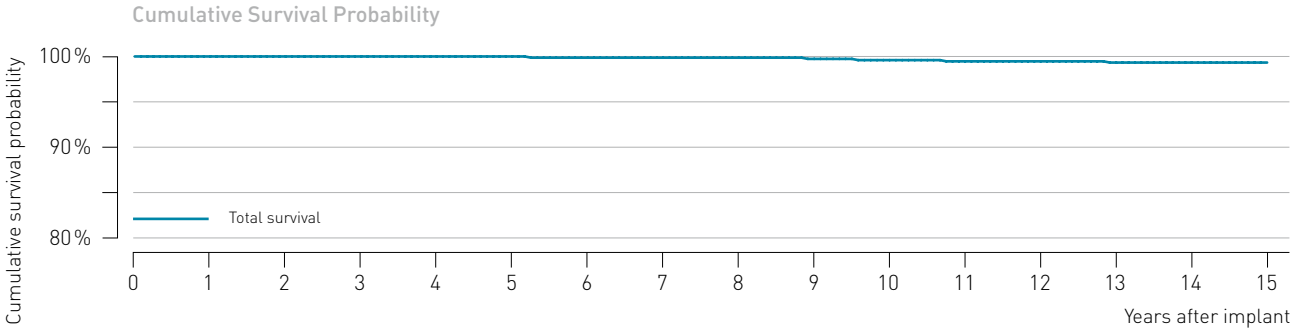
Synox

Product details

Product versions	Synox 60-UP, 53-BP, 60-BP
Lead type	straight, passive fixation
Polarity	unipolar/bipolar
Steroid	no
U.S. market release	Sep 1998
CE market release	Jul 1996
Worldwide distributed devices	169,000
Registered U.S. implants	17,600
Estimated active U.S. implants	6,650
U.S. total returned	38

	Quantity	Rate
U.S. qualifying complications	28	0.16%
▪ Abnormal pacing impedance	2	0.01%
▪ Conductor fracture	2	0.01%
▪ Failure to capture	16	0.09%
▪ Failure to sense	1	0.01%
▪ Insulation breach	4	0.02%
▪ Lead dislodgement	1	0.01%
▪ Oversensing	2	0.01%
U.S. confirmed malfunctions	3	0.02%
▪ Conductor fracture	2	0.01%
▪ Insulation breach	1	0.01%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.7	99.6	99.6	99.5	99.5	99.5
(95% confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.2

7.1 Pacing leads

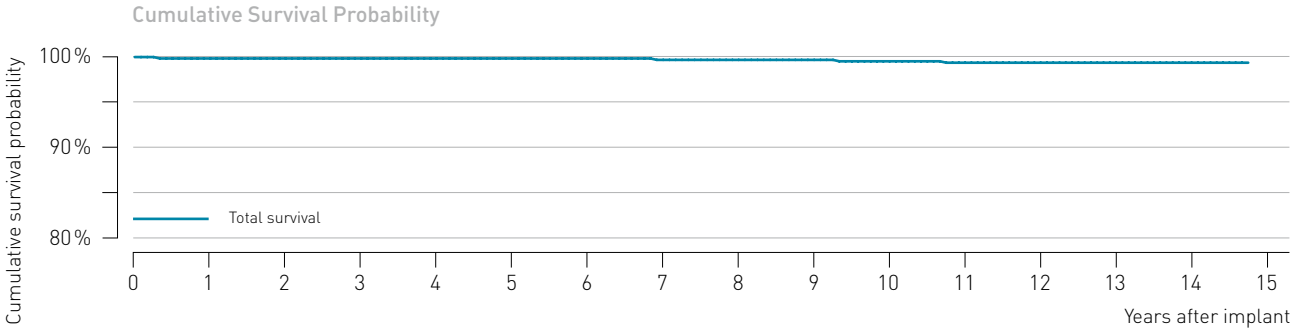
Synox J

Product details

Product versions	Synox 45-JBP, 53-JBP
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	no
U.S. market release	Sep 1998
CE market release	Jul 1996
Worldwide distributed devices	81,400
Registered U.S. implants	8,160
Estimated active U.S. implants	3,560
U.S. total returned	17

	Quantity	Rate
U.S. qualifying complications	16	0.20%
▪ Abnormal pacing impedance	1	0.01%
▪ Conductor fracture	2	0.02%
▪ Failure to capture	3	0.04%
▪ Failure to sense	4	0.05%
▪ Lead dislodgement	2	0.02%
▪ Oversensing	4	0.05%
U.S. confirmed malfunctions	2	0.02%
▪ Crimps, welds and bonds	1	0.01%
▪ Insulation breach	1	0.01%

	Quantity	Rate
U.S. acute lead observations	2	0.02%
▪ Failure to capture	1	0.01%
▪ Oversensing	1	0.01%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.8	99.8	99.8	99.7	99.6	99.6	99.6	99.6	-
(95% confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2	-

7.1 Pacing leads

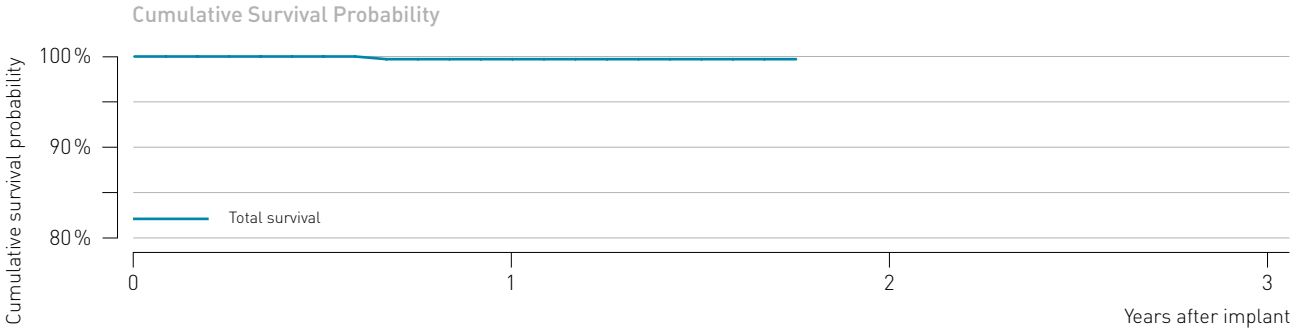
Tilda R

Product details

Product versions	Tilda R45, R53, R60
Lead type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Dec 2011
CE market release	Aug 2011
Worldwide distributed devices	31,500
Registered U.S. implants	4,920
Estimated active U.S. implants	4,870
U.S. total returned	5

	Quantity	Rate
U.S. qualifying complications	3	0.06%
▪ Extracardiac stimulation	1	0.02%
▪ Lead dislodgement	1	0.02%
▪ Oversensing	1	0.02%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	3	0.06%
▪ Lead dislodgement	2	0.04%
▪ Other	1	0.02%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.9	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	-	-	-	-	-	-	-	-	-	-

7.2 ICD leads

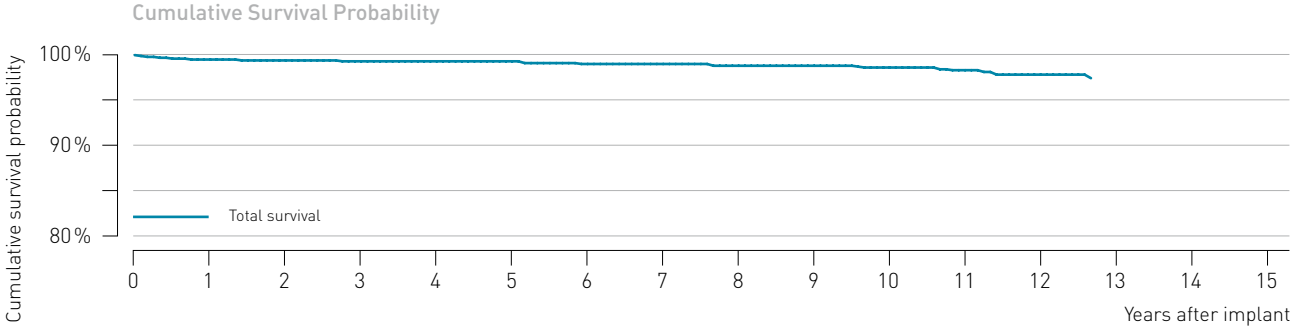
Kainox SL

Product details

Product versions	Kainox SL 65, 75, 100
Lead type	dual-coil, passive fixation
Polarity	bipolar
Steroid	no
U.S. market release	Nov 1998
CE market release	Sep 1997
Worldwide distributed devices	9,600
Registered U.S. implants	2,500
Estimated active U.S. implants	954
U.S. total returned	15

	Quantity	Rate
U.S. qualifying complications	28	1.12%
▪ Abnormal defibrillation impedance	2	0.08%
▪ Abnormal pacing impedance	3	0.12%
▪ Conductor fracture	1	0.04%
▪ Failure to capture	7	0.28%
▪ Failure to sense	1	0.04%
▪ Insulation breach	1	0.04%
▪ Lead dislodgement	1	0.04%
▪ Oversensing	12	0.48%

	Quantity	Rate
U.S. confirmed malfunctions	1	0.04%
▪ Insulation breach	1	0.04%
U.S. acute lead observations	4	0.16%
▪ Failure to capture	3	0.12%
▪ Oversensing	1	0.04%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.	12 yr.	13 yr.	14 yr.	15 yr.
Total survival (%)	100.0	99.5	99.4	99.3	99.3	99.3	99.0	99.0	98.8	98.8	98.6	98.3	97.8	-	-	-
(95% confidence interval)		±0.3	±0.3	±0.3	±0.3	±0.4	±0.4	±0.5	±0.5	±0.5	±0.6	±0.7	±1.0	-	-	-

7.2 ICD leads

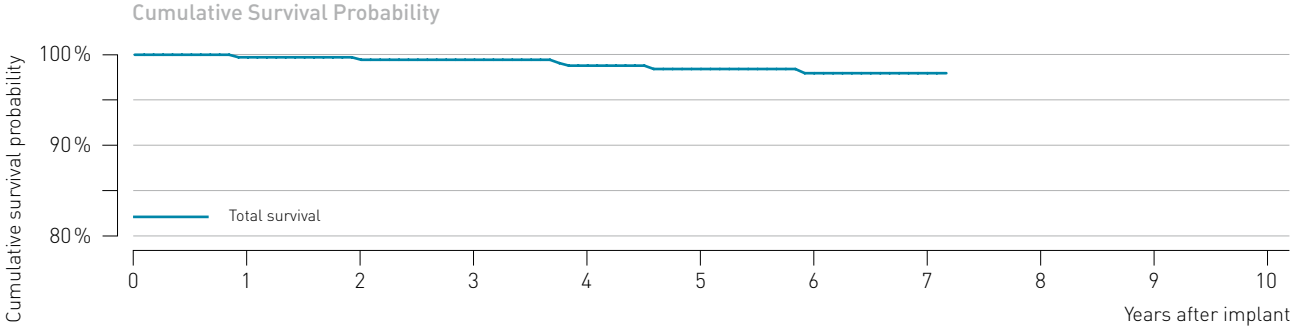
Kentrox RV

Product details

Product versions	Kentrox RV 65, -Steroid, 75, -Steroid
Lead type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. market release	Mar 2002/Oct 2004
CE market release	Jan 2001/Dec 2004
Worldwide distributed devices	5,490
Registered U.S. implants	400
Estimated active U.S. implants	189
U.S. total returned	7

	Quantity	Rate
U.S. qualifying complications	5	1.25%
▪ Conductor fracture	1	0.25%
▪ Failure to capture	1	0.25%
▪ Oversensing	3	0.75%
U.S. confirmed malfunctions	2	0.50%
▪ Conductor fracture	1	0.25%
▪ Insulation breach	1	0.25%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.7	99.4	99.4	98.7	98.3	97.8	97.8	-	-	-	-
(95 % confidence interval)		±0.6	±0.6	±0.8	±1.3	±1.5	±1.7	±1.7	-	-	-	-

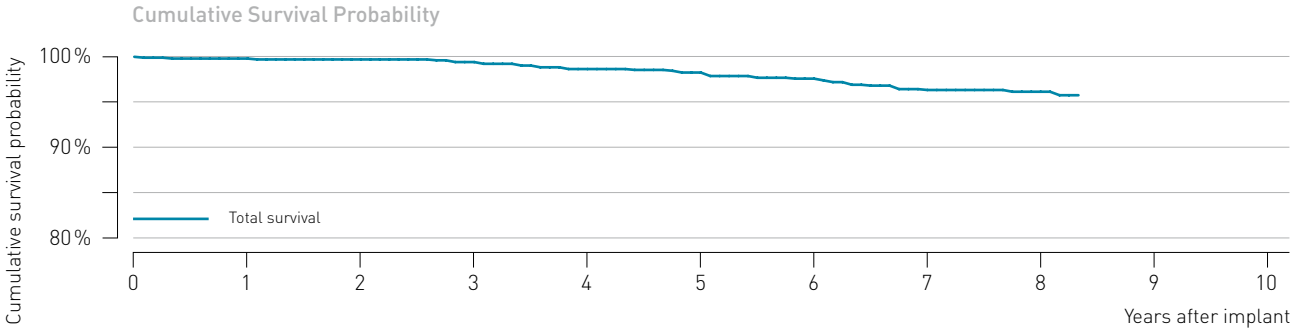
Kentrox SL

Product details

Product versions	Kentrox SL 65, 75, Kentrox SL 65, 75, 100 Steroid
Lead type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. market release	Oct 2004
CE market release	Dec 2003/Dec 2004
Worldwide distributed devices	8,480
Registered U.S. implants	1,010
Estimated active U.S. implants	584
U.S. total returned	18

	Quantity	Rate
U.S. qualifying complications	26	2.57%
▪ Abnormal defibrillation impedance	1	0.10%
▪ Abnormal pacing impedance	3	0.30%
▪ Failure to capture	1	0.10%
▪ Insulation breach	5	0.50%
▪ Oversensing	16	1.58%
U.S. confirmed malfunctions	4	0.40%
▪ Insulation breach	4	0.40%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.8	99.7	99.4	98.6	98.2	97.5	96.2	96.0	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.8	±0.9	±1.1	±1.4	±1.5	-	-	-

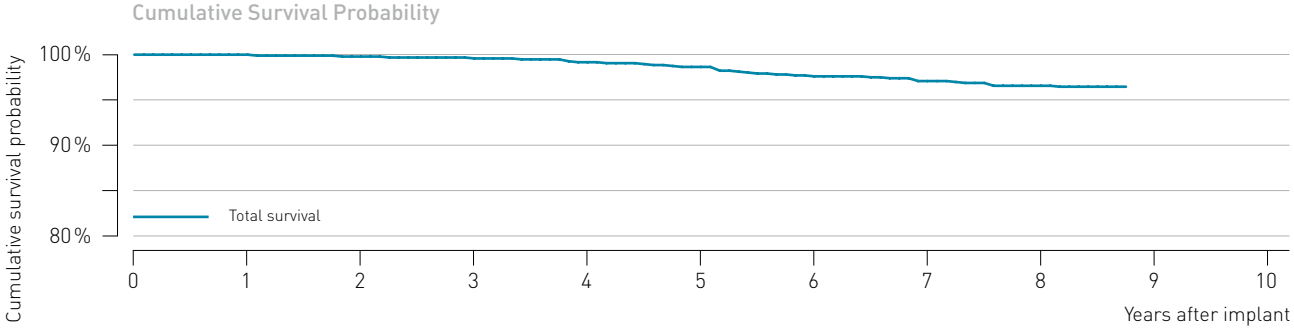
Kentrox SL-S

Product details

Product versions	Kentrox SL-S 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	1,410
U.S. total returned	31

	Quantity	Rate
U.S. qualifying complications	45	1.84%
▪ Abnormal defibrillation impedance	3	0.12%
▪ Abnormal pacing impedance	4	0.16%
▪ Conductor fracture	1	0.04%
▪ Extracardiac stimulation	1	0.04%
▪ Failure to capture	3	0.12%
▪ Insulation breach	2	0.08%
▪ Lead dislodgement	3	0.12%
▪ Oversensing	28	1.15%
U.S. confirmed malfunctions	9	0.37%
▪ Insulation breach	9	0.37%

	Quantity	Rate
U.S. acute lead observations	2	0.08%
▪ Oversensing	2	0.08%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.8	99.6	99.2	98.7	97.7	97.2	96.7	-	-	-
(95 % confidence interval)		±0.1	±0.2	±0.2	±0.4	±0.5	±0.7	±0.8	±0.9	-	-	-

7.2 ICD leads

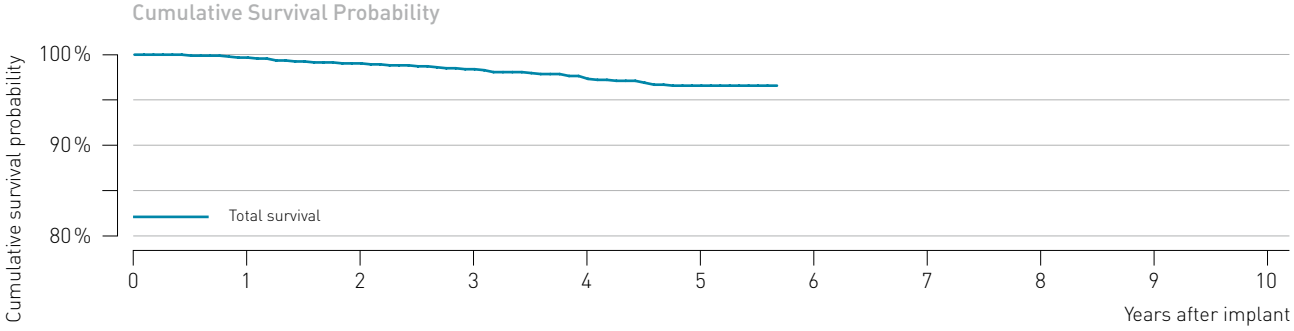
Linox S

Product details

Product versions	Linox S 65, Linox S 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	31,000
Registered U.S. implants	2,490
Estimated active U.S. implants	1,990
U.S. total returned	46

	Quantity	Rate
U.S. qualifying complications	23	0.92%
▪ Abnormal defibrillation impedance	3	0.12%
▪ Abnormal pacing impedance	1	0.04%
▪ Failure to capture	3	0.12%
▪ Failure to sense	1	0.04%
▪ Lead dislodgement	2	0.08%
▪ Oversensing	13	0.52%
U.S. confirmed malfunctions	24	0.96%
▪ Conductor fracture	3	0.12%
▪ Insulation breach	21	0.84%

	Quantity	Rate
U.S. acute lead observations	7	0.28%
▪ Failure to capture	1	0.04%
▪ Failure to sense	1	0.04%
▪ Lead dislodgement	4	0.16%
▪ Oversensing	1	0.04%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.7	99.1	98.5	97.5	96.8	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.4	±0.5	±0.7	±1.0	-	-	-	-	-	-

7.2 ICD leads

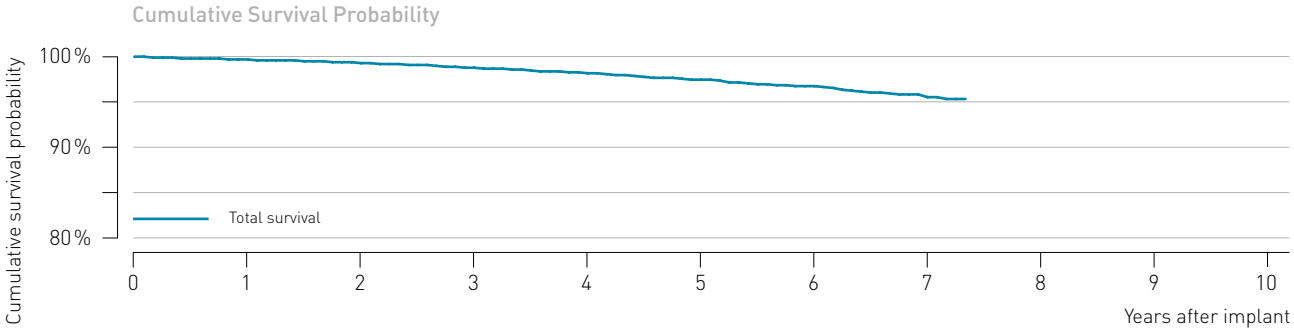
Linox SD

Product details

Product versions	Linox SD 60, 65, 75/16,18
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	16,900
U.S. total returned	284

	Quantity	Rate
U.S. qualifying complications	327	1.47%
▪ Abnormal defibrillation impedance	18	0.08%
▪ Abnormal pacing impedance	20	0.09%
▪ Cardiac perforation	2	0.01%
▪ Conductor fracture	13	0.06%
▪ Extracardiac stimulation	3	0.01%
▪ Failure to capture	40	0.18%
▪ Failure to sense	9	0.04%
▪ Insulation breach	23	0.10%
▪ Lead dislodgement	28	0.13%
▪ Oversensing	171	0.77%

	Quantity	Rate
U.S. confirmed malfunctions	103	0.46%
▪ Conductor fracture	12	0.05%
▪ Insulation breach	91	0.41%
U.S. acute lead observations	30	0.13%
▪ Abnormal defibrillation impedance	1	< 0.01%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Failure to capture	8	0.04%
▪ Lead dislodgement	17	0.08%
▪ Oversensing	3	0.01%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.7	99.3	98.8	98.2	97.5	96.8	95.6	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	±0.5	-	-	-	-

7.2 ICD leads

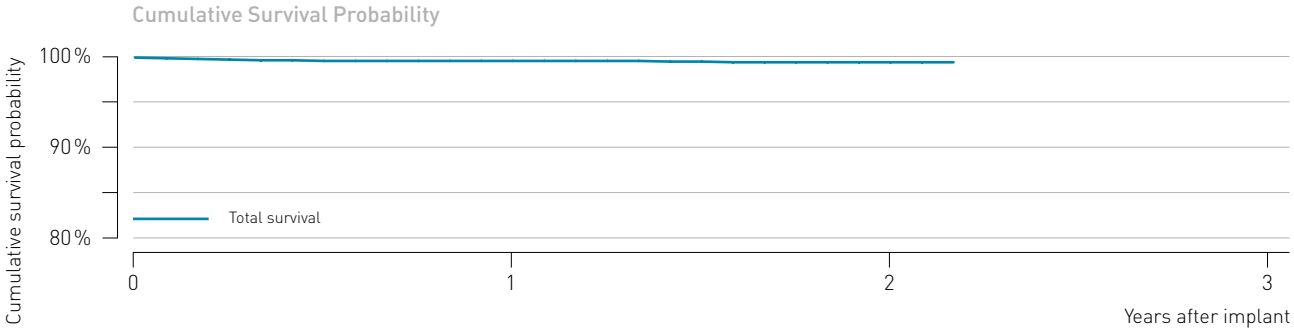
Linox^{smart} S

Product details

Product versions	Linox^{smart} S 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	17,200
Registered U.S. implants	4,350
Estimated active U.S. implants	4,130
U.S. total returned	32

	Quantity	Rate
U.S. qualifying complications	22	0.51%
▪ Abnormal defibrillation impedance	1	0.02%
▪ Cardiac perforation	1	0.02%
▪ Extracardiac stimulation	1	0.02%
▪ Failure to capture	2	0.05%
▪ Failure to sense	1	0.02%
▪ Lead dislodgement	12	0.28%
▪ Oversensing	4	0.09%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	11	0.25%
▪ Cardiac perforation	1	0.02%
▪ Failure to capture	2	0.05%
▪ Lead dislodgement	8	0.18%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.5	99.3	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.3	-	-	-	-	-	-	-	-	-

7.2 ICD leads

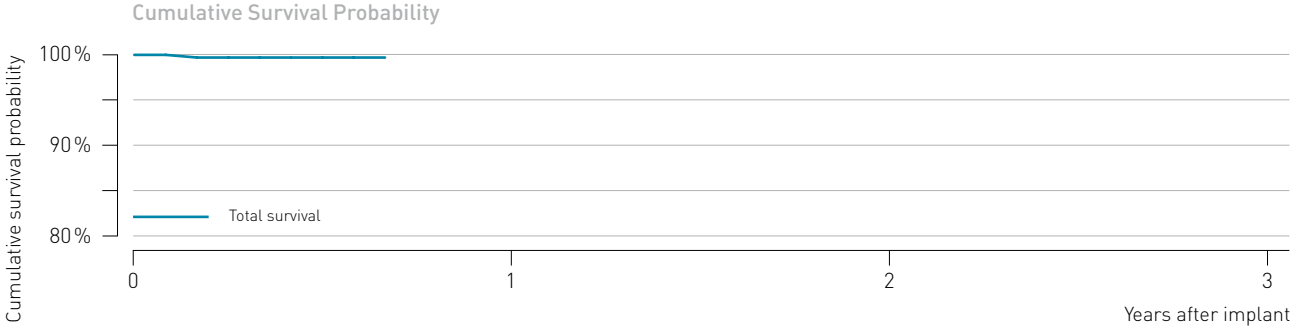
Linox^{smart} S DX

Product details

Product versions	Linox^{smart} S DX 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	12,000
Registered U.S. implants	2,370
Estimated active U.S. implants	2,300
U.S. total returned	16

	Quantity	Rate
U.S. qualifying complications	4	0.17%
▪ Abnormal defibrillation impedance	1	0.04%
▪ Lead dislodgement	3	0.13%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	9	0.38%
▪ Failure to capture	2	0.08%
▪ Lead dislodgement	7	0.30%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	-	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		-	-	-	-	-	-	-	-	-	-	-

7.2 ICD leads

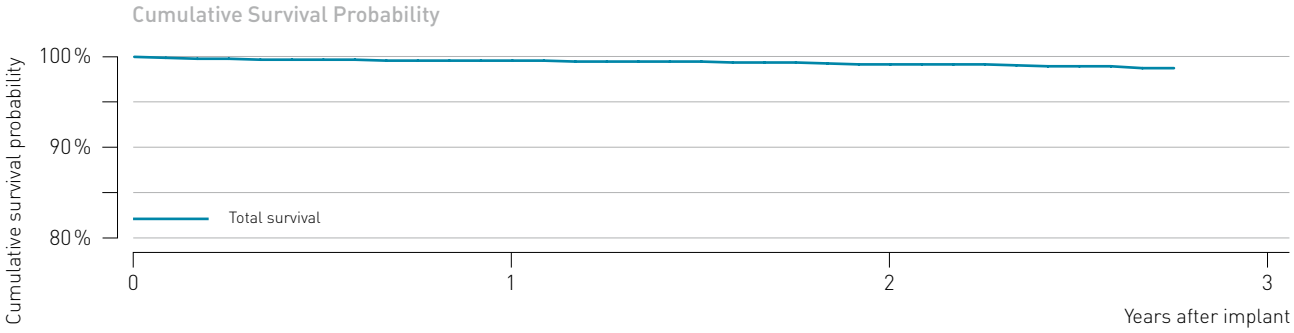
Linox^{smart} SD

Product details

Product versions	Linox^{smart} SD 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	37,500
Registered U.S. implants	10,300
Estimated active U.S. implants	9,490
U.S. total returned	93

	Quantity	Rate
U.S. qualifying complications	47	0.46%
▪ Abnormal defibrillation impedance	3	0.03%
▪ Abnormal pacing impedance	1	0.01%
▪ Failure to capture	5	0.05%
▪ Failure to sense	3	0.03%
▪ Lead dislodgement	19	0.18%
▪ Oversensing	16	0.16%
U.S. confirmed malfunctions	11	0.11%
▪ Conductor fracture	1	0.01%
▪ Insulation breach	10	0.10%

	Quantity	Rate
U.S. acute lead observations	34	0.33%
▪ Abnormal defibrillation impedance	2	0.02%
▪ Abnormal pacing impedance	1	0.01%
▪ Cardiac perforation	1	0.01%
▪ Failure to capture	5	0.05%
▪ Failure to sense	1	0.01%
▪ Lead dislodgement	23	0.22%
▪ Oversensing	1	0.01%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.6	99.2	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.2	-	-	-	-	-	-	-	-	-

7.2 ICD leads

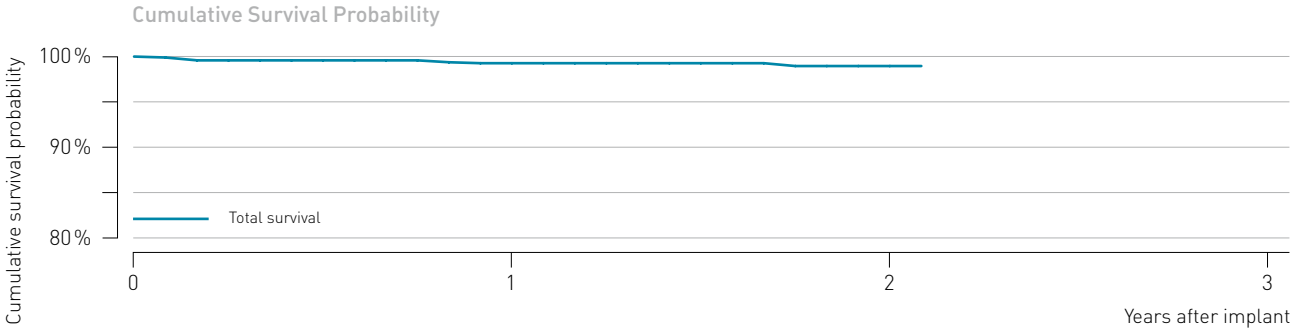
Linox^{smart} TD

Product details

Product versions	Linox^{smart} TD 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	6,300
Registered U.S. implants	986
Estimated active U.S. implants	914
U.S. total returned	3

	Quantity	Rate
U.S. qualifying complications	7	0.71%
▪ Conductor fracture	1	0.10%
▪ Failure to capture	2	0.20%
▪ Lead dislodgement	3	0.30%
▪ Oversensing	1	0.10%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	4	0.41%
▪ Lead dislodgement	4	0.41%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.3	99.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.6	±0.8	-	-	-	-	-	-	-	-	-

7.2 ICD leads

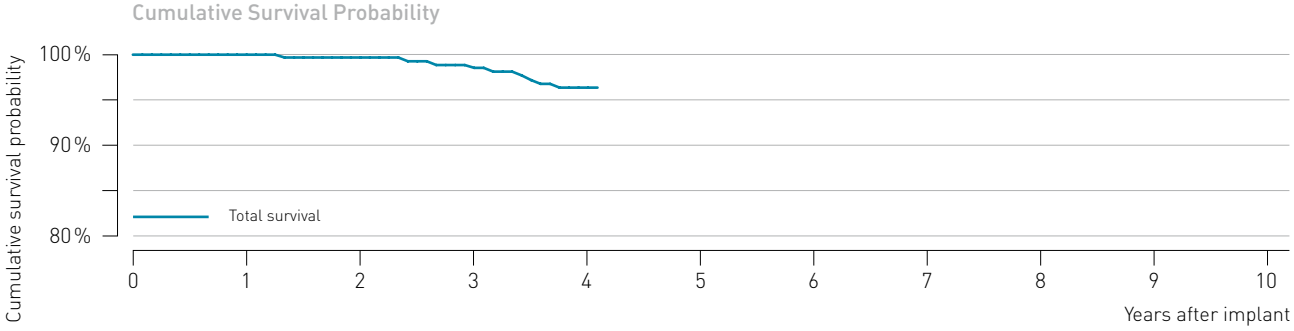
Linox T

Product details

Product versions	Linox T 65, Linox T 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	248
U.S. total returned	3

	Quantity	Rate
U.S. qualifying complications	8	2.48%
▪ Failure to capture	2	0.62%
▪ Oversensing	6	1.86%
U.S. confirmed malfunctions	2	0.62%
▪ Insulation breach	2	0.62%

	Quantity	Rate
U.S. acute lead observations	0	0.00%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	100.0	99.7	98.6	96.5	-	-	-	-	-	-	-
(95 % confidence interval)			±0.7	±1.2	±2.3	-	-	-	-	-	-	-

7.2 ICD leads

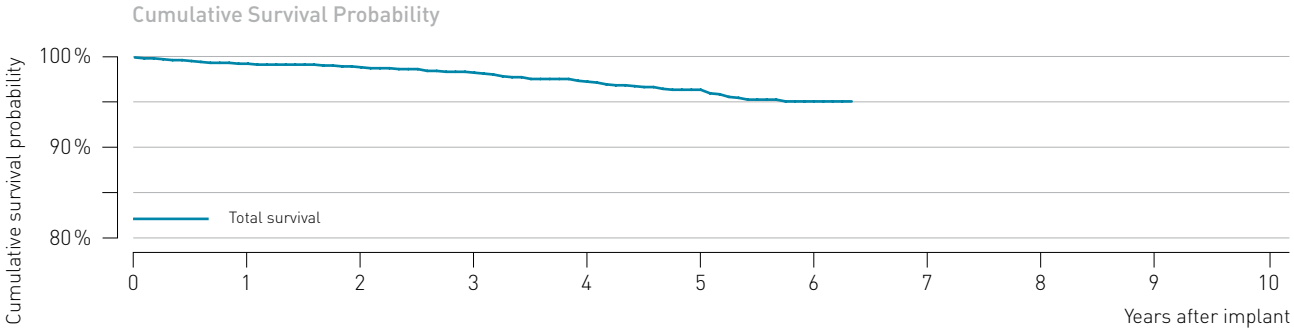
Linox TD

Product details

Product versions	Linox TD 65, 75, 100/16, 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	3,040
Estimated active U.S. implants	2,330
U.S. total returned	41

	Quantity	Rate
U.S. qualifying complications	64	2.11%
▪ Abnormal defibrillation impedance	6	0.20%
▪ Abnormal pacing impedance	8	0.26%
▪ Conductor fracture	2	0.07%
▪ Failure to capture	15	0.49%
▪ Failure to sense	1	0.03%
▪ Insulation breach	6	0.20%
▪ Lead dislodgement	4	0.13%
▪ Oversensing	22	0.72%

	Quantity	Rate
U.S. confirmed malfunctions	20	0.65%
▪ Conductor fracture	5	0.16%
▪ Insulation breach	15	0.49%
U.S. acute lead observations	4	0.13%
▪ Failure to capture	1	0.03%
▪ Lead dislodgement	3	0.10%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.3	98.9	98.3	97.3	96.4	95.1	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.7	±0.9	±1.2	-	-	-	-	-

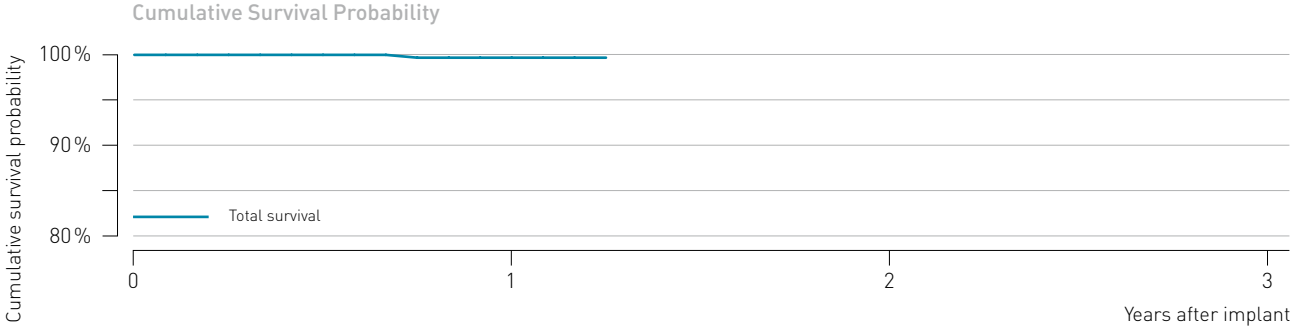
7.2 ICD leads

Vigila

Product details

Product versions	Vigila 2CR 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	702
Estimated active U.S. implants	691
U.S. total returned	2

	Quantity	Rate		Quantity	Rate
U.S. qualifying complications	1	0.14%	U.S. acute lead observations	1	0.14%
■ Lead dislodgement	1	0.14%	■ Other	1	0.14%
U.S. confirmed malfunctions	0	0.00%			



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.8	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.5	-	-	-	-	-	-	-	-	-	-

8 Methodology for lead survival estimates based on clinical studies

8.1 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.

Biotronik now has available – in addition to the survival data based on returned product analysis and chronic complication information – the combined performance data from the prospective GALAXY and CELESTIAL clinical registries. Both registries are designed to record clinical observations representative of the total clinical experience.

8.2 BIOTRONIK's clinical studies

BIOTRONIK has been monitoring the performance of cardiac therapy products within its GALAXY and CELESTIAL multicenter post-approval registries since 2008 and has evaluated the performance of more than 2,300 LINOX SD leads, with data reported from multiple centers within the US.

The following summarizes current registry requirements:

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. All devices in the registry 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 is based on the analysis of BIOTRONIK ICD lead-related adverse events. Both registries are designed to continue for a 5 year followup duration per patient. 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 cardiac-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 enrolment criteria

To support the objectives of this registry, subjects are required to meet the following inclusion criteria prior to enrolment:

- Successfully implanted BIOTRONIK ICD system, including a BIOTRONIK 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. Chronic 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.

8.3 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.

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 more than 30 days after implant, is adjudicated 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 therefore not included into the survival probability.

Event classifications

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200–2,500 Ohm)
- Abnormal defibrillation impedance (based on lead model, but normal range is 25–150 Ohm)
- 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

8.4 Lead product performance graphs and data

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

9 Performance of LINOX SD defibrillation leads based on clinical studies

9.1 Linox SD study data

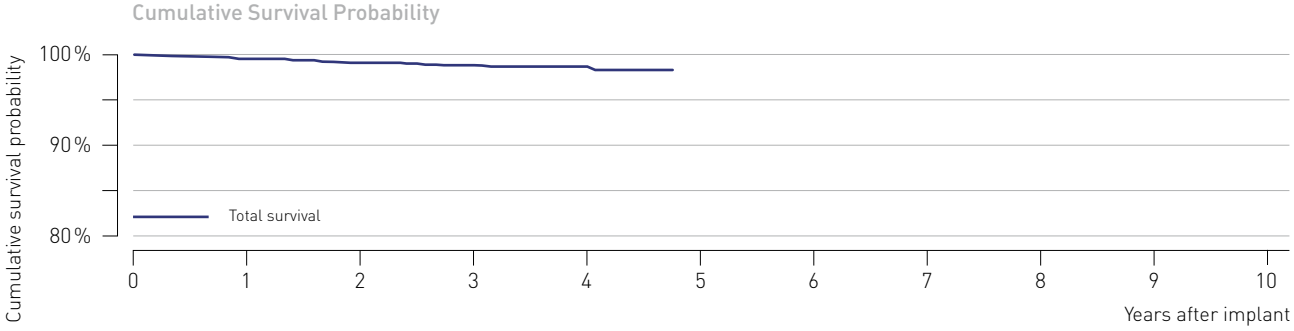
Linox SD study data

Product details

Product versions	Linox SD 60, 65, 75/16, 75/18
Lead type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Nov 2008
CE market release	Jan 2009
Worldwide distributed devices	55,100
Registered U.S. implants	2,386

	Quantity	Rate
U.S. qualifying complications	50	2.10%
▪ Abnormal pacing impedance	5	0.21%
▪ Cardiac perforation	1	0.04%
▪ Conductor fracture	6	0.25%
▪ Failure to capture	8	0.34%
▪ Failure to sense	3	0.13%
▪ Insulation breach	1	0.04%
▪ Lead dislodgement	7	0.29%
▪ Other	1	0.04%
▪ Oversensing	18	0.75%

	Quantity	Rate
U.S. confirmed malfunctions	5	0.21%
▪ Conductor fracture	1	0.04%
▪ Insulation breach	4	0.17%



Cumulative Survival Probability after	Impl.	1 yr.	2 yr.	3 yr.	4 yr.	5 yr.	6 yr.	7 yr.	8 yr.	9 yr.	10 yr.	11 yr.
Total survival (%)	100.0	99.5	99.1	98.8	98.3	-	-	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.8	-	-	-	-	-	-	-

10 Advisories

Stratos LV-T

Potentially defective low voltage capacitors
84 devices world-wide, none in the United States

Status update

As of July 2014

- 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 1000 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.

11 X-Ray identifiers for pacemakers and ICDs

Pacemaker / ICD product versions	X-Ray ID
Actros DR, Actros D, Actros SLR, Actros SR, Actros S	LC
Axios DR, Axios D, Axios SLR, Axios SR, Axios S	ER
Cylos DR, Cylos DR-T, Cylos VR	RZ
Cylos 990 DR, Cylos 990 DR-T, Cylos 990 VR	FV
Evia DR, Evia DR–T, Evia SR, Evia SR-T, Estella DR, Estella DR-T	SF
Lexos DR, Lexos DR-T, Lexos A+, Lexos A+/T, Lexos VR, Lexos VR-T	KV
Lumax 300 DR-T, Lumax 340 DR-T, Lumax 340 HF-T, Lumax 340 VR-T	HR
Lumax 540 DR-T, Lumax 540 HF-T, Lumax 540 VR-T	SH
Lumax 740 DR-T, Lumax 740 HF-T, Lumax 740 VR-T, Lumax 740 VR-T DX	RH
Lumos DR-T, Lumos VR-T	LT
Philos DR, Philos D, Philos SLR, Philos SR, Philos S	LE
Philos DR-T	VV
Philos II DR, Philos II D, Philos II S, Philos II SLR, Philos II SR	ET
Philos II DR-T	KP
Stratos LV, Stratos LV-T	SV
Talos DR, Talos D, Talos SLR, Talos SR, Talos S	PV
Protos DR/CLS, Protos VR/CLS	EZ

12 Index

Single-chamber pacemakers

Dual-chamber pacemakers

CRT pacemakers

Single-chamber ICDs

Dual-chamber ICDs

CRT ICDs

Pacing leads

ICD leads

13 Contacting BIOTRONIK

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E-mail	PPR@biotronik.com
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Product Performance Report

July 2014

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