Product Performance Report
January 2013

Worldwide
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin · Germany
Tel +49 (0) 30 68905–0
Fax +49 (0) 30 6852804
www.biotronik.com

U.S.
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-05369
Tel (800) 547-0394 (24-hour)
Fax (800) 291-0470
www.biotronik.com

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BIOTRONIK
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Product Performance Report

January 2013

50 years

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Cardiac Rhythm Management

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1 Quality Excellence

BIOTRONIK has a long history of high quality in product design and performance. For over 40 years, the name BIOTRONIK has been synonymous with excellent workmanship and reliable patient safety. Our quality concept follows an integrated approach and extends from preventative risk measures during a product's development phase through all the steps of the manufacturing and design process.

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

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

As a means to obtain continuous improvement of the designs, BIOTRONIK carefully analyzes returned products and incorporates all findings into our quality assurance system. This Product Performance Report was prepared in accordance with International Standard ISO 5841-2:2000 (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, January 2013

Arnold Kaspar
Vice President of 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 July 1, 2012. 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 1,000 cumulative implant months. Because 1,000 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.

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

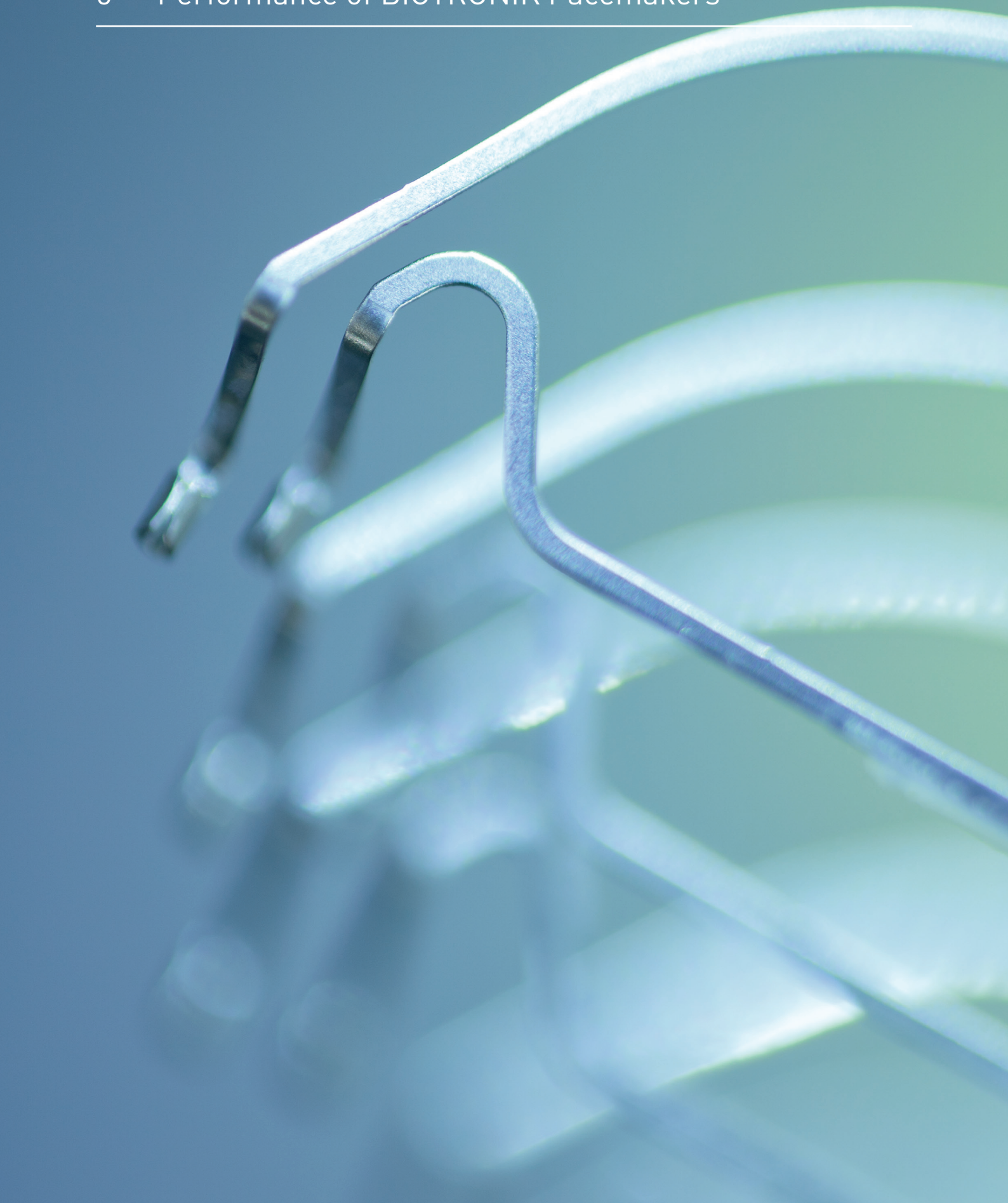
The Cumulative Survival Probability free of component or software malfunctions excluding normal battery depletions, but including premature battery depletions. Normal battery depletions only have an impact on the total cumulative survival.

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.

5 Performance of BIOTRONIK Pacemakers



5.1 Single-Chamber Pacemakers

5.2 Dual-Chamber Pacemakers

5.3 CRT Pacemakers

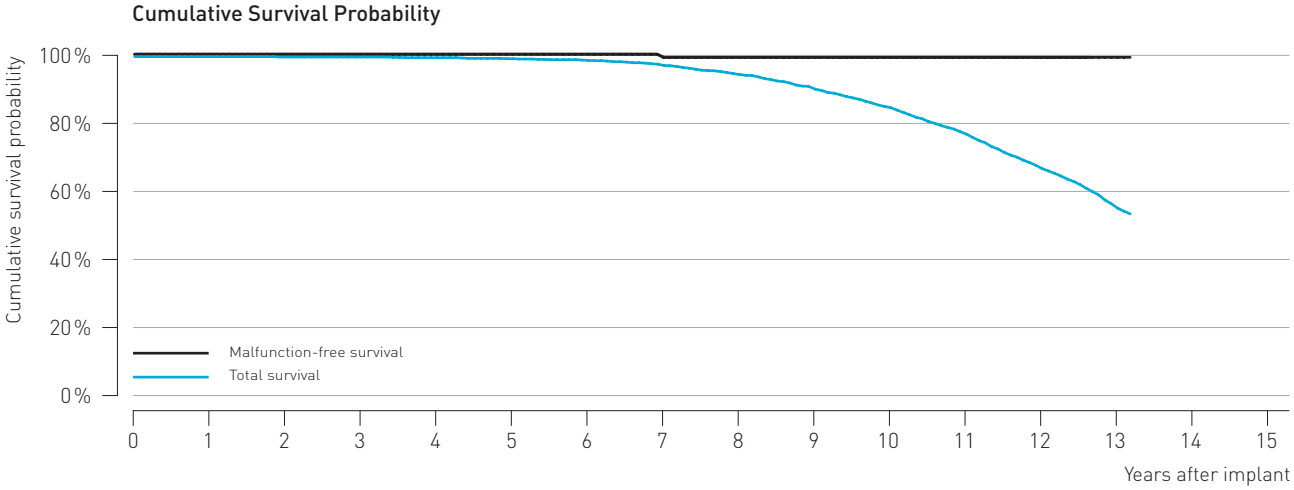
5.1 Single-chamber pacemakers

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	1,040
U.S. normal battery depletions	376

	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.
Total survival (%)	100.0	100.0	99.9	99.9	99.7	99.4	98.9	97.4	94.7	90.4	84.9	77.1	66.9	55.2
(95 % confidence interval)			±0.1	±0.1	±0.2	±0.3	±0.4	±0.6	±0.9	±1.2	±1.6	±2.0	±2.5	±3.2
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
(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

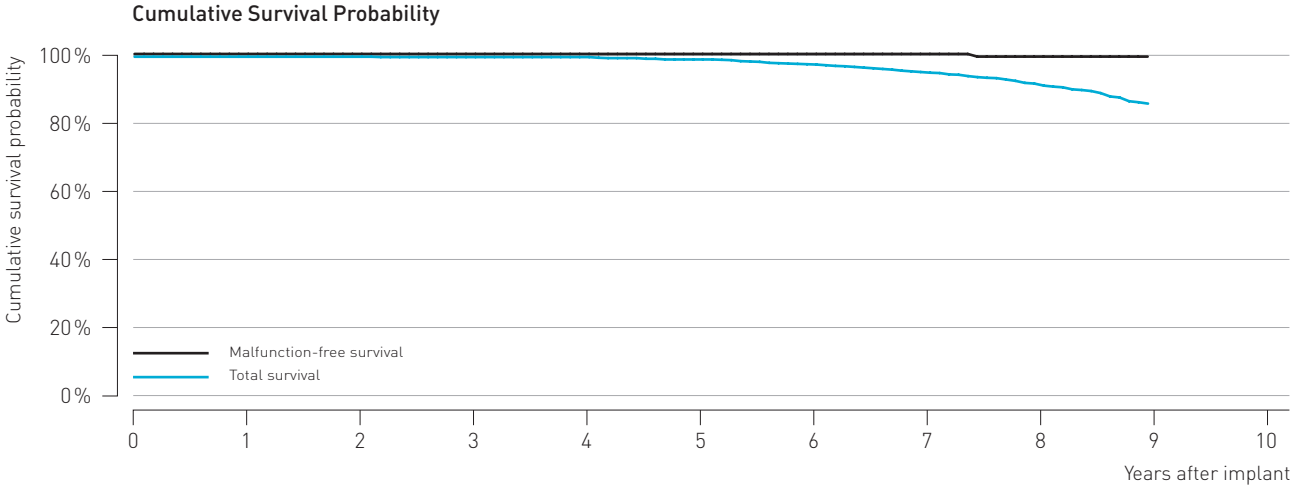
5.1 Single-chamber pacemakers

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	140,000
Registered U.S. implants	1,370
Estimated active U.S. implants	411
U.S. normal battery depletions	26

	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.
Total survival (%)	100.0	100.0	100.0	99.9	99.9	99.2	97.7	95.3	91.5	-	-	-
(95% confidence interval)				±0.2	±0.2	±0.7	±1.2	±1.7	±2.3	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.8	-	-	-
(95% confidence interval)									±0.4	-	-	-

5.1 Single-chamber pacemakers

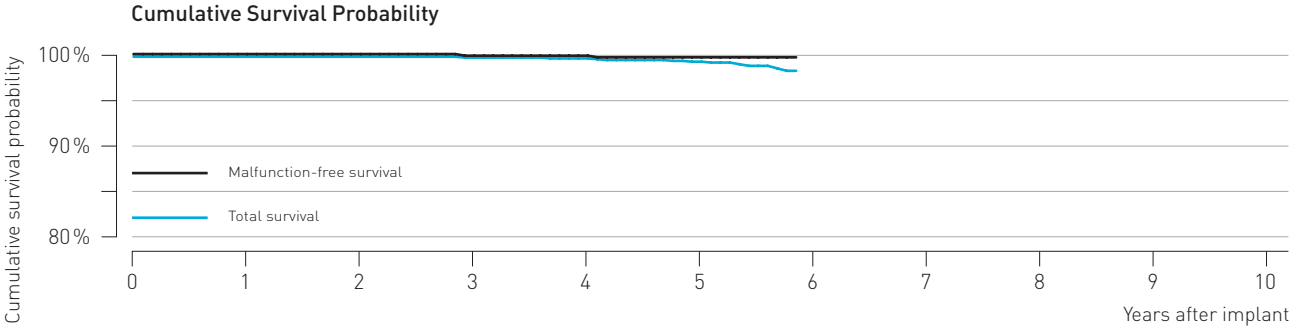
Cylos and Cylos 990

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	24,800
Registered U.S. implants	6,140
Estimated active U.S. implants	4,400
U.S. normal battery depletions	13

	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	99.4	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.2	±0.4	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	99.8	-	-	-	-	-	-
(95 % confidence interval)				±0.1	±0.1	±0.2	-	-	-	-	-	-

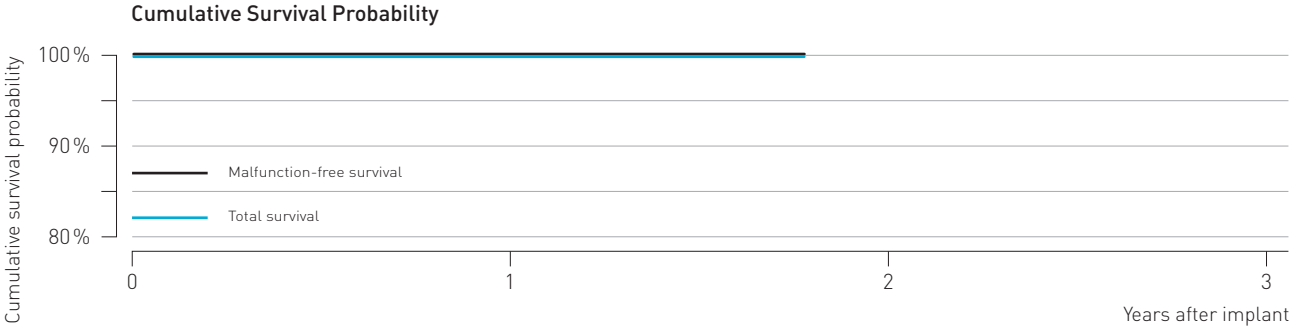
5.1 Single-chamber pacemakers

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	22,900
Registered U.S. implants	4,570
Estimated active U.S. implants	4,190
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)		-	-	-	-	-	-	-	-	-	-	-

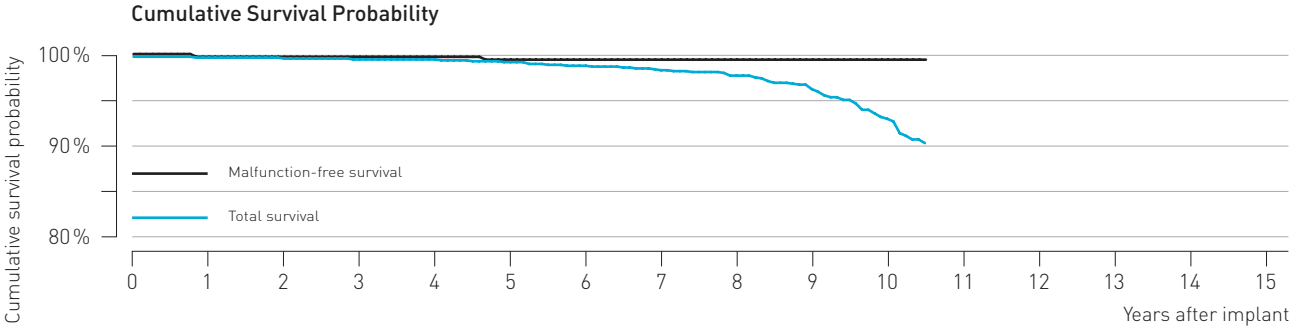
5.1 Single-chamber pacemakers

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	2,180
U.S. normal battery depletions	88

	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	99.0	98.5	97.9	96.4	93.1	-
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	±0.5	±0.6	±0.9	±1.6	-
Malfunction-free survival (%)	100.0	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	±0.2	±0.2	±0.2	±0.2	±0.2	-

5.1 Single-chamber pacemakers

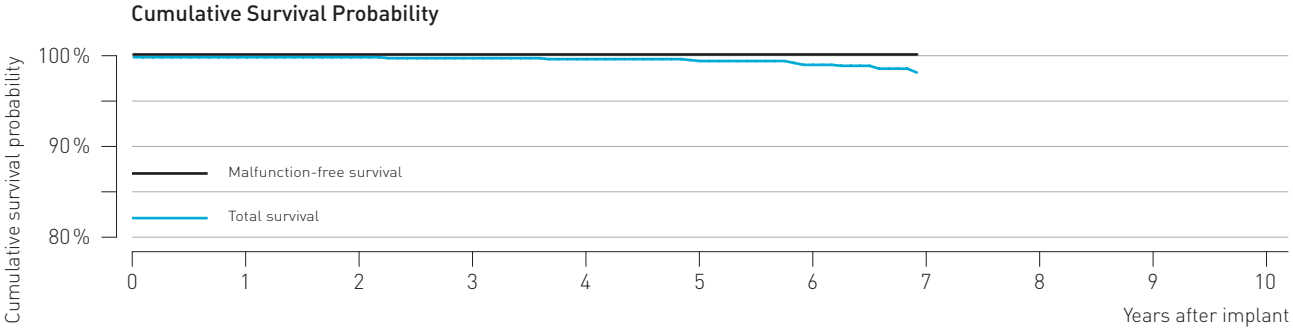
Philos II and Talos

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	172,000
Registered U.S. implants	5,220
Estimated active U.S. implants	3,460
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	99.8	99.6	99.2	-	-	-	-	-
(95 % confidence interval)				±0.1	±0.1	±0.2	±0.5	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-
(95 % confidence interval)				±0.1	±0.1	±0.1	±0.1	-	-	-	-	-

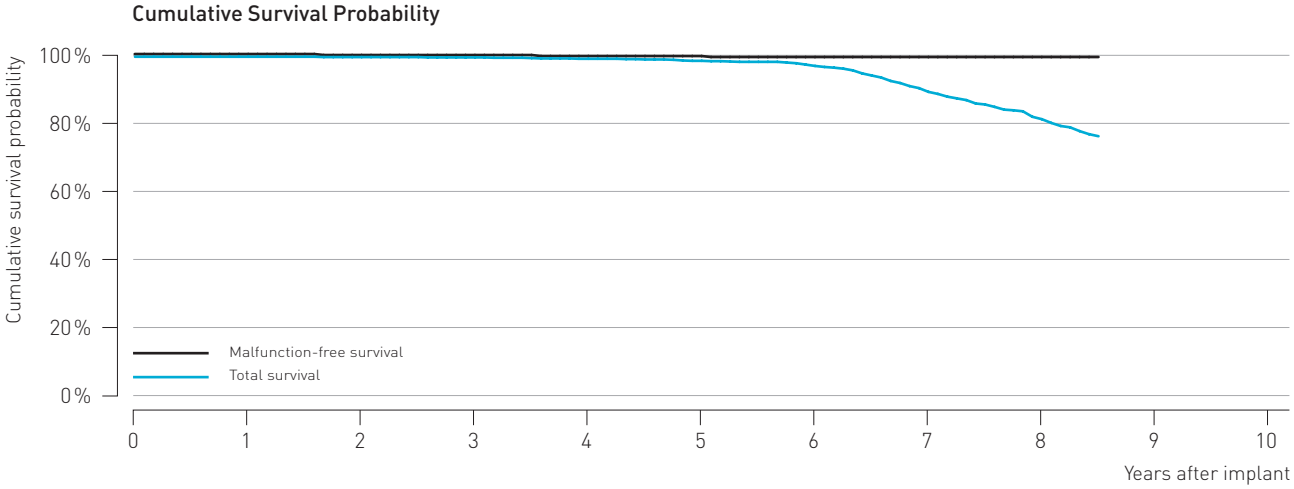
5.1 Single-chamber pacemakers

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	1,100
U.S. normal battery depletions	198

	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	89.7	81.7	-	-	-
(95 % confidence interval)			±0.1	±0.2	±0.3	±0.5	±0.7	±1.5	±2.5	-	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7	-	-	-
(95 % confidence interval)			±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2	-	-	-

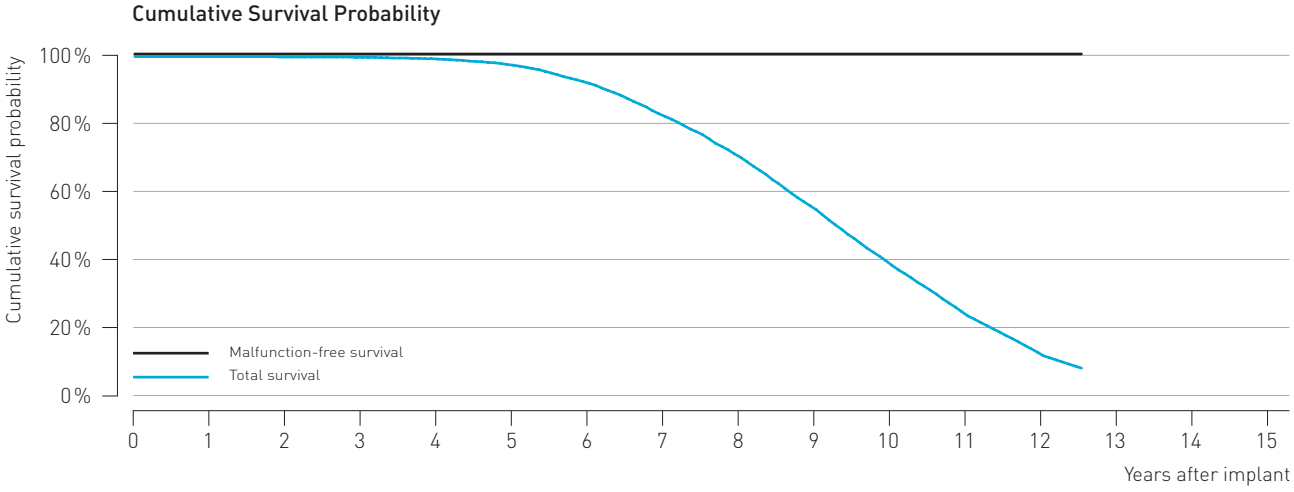
5.2 Dual-chamber pacemakers

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	2,200
U.S. normal battery depletions	2,452

	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	82.5	70.5	55.1	38.8	24.0	12.3
(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

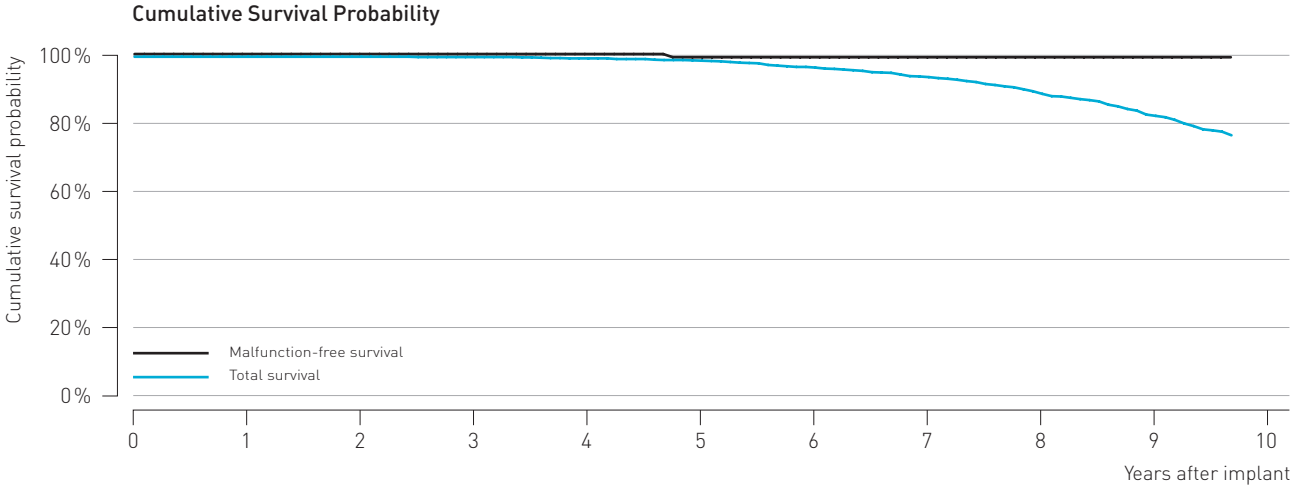
5.2 Dual-chamber pacemakers

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	853
U.S. normal battery depletions	205

	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.
Total survival (%)	100.0	100.0	100.0	99.9	99.5	98.8	96.7	93.8	88.7	82.0	-	-
(95% confidence interval)			±0.1	±0.2	±0.3	±0.5	±0.9	±1.2	±1.7	±2.4	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	-	-
(95% confidence interval)						±0.1	±0.1	±0.2	±0.2	±0.2	-	-

5.2 Dual-chamber pacemakers

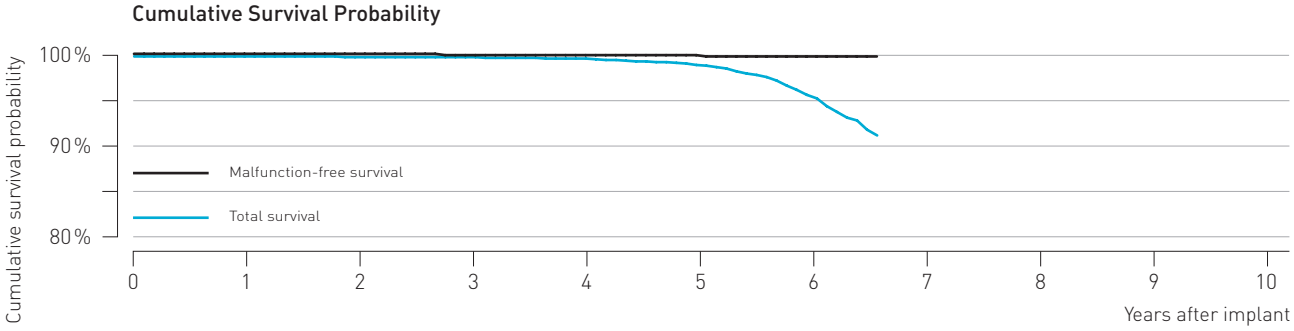
Cylos and Cylos 990

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	80,000
Registered U.S. implants	30,400
Estimated active U.S. implants	24,200
U.S. normal battery depletions	276

	Quantity	Rate
U.S. confirmed malfunctions	26	0.09%
▪ Therapy compromised	7	0.02%
▪ Therapy available	19	0.06%

* While Cylos 990 DR and Cylos 990 DR-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	100.0	99.9	99.8	99.5	97.9	91.0	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.3	±1.2	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	99.8	99.8	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	-	-	-	-	-

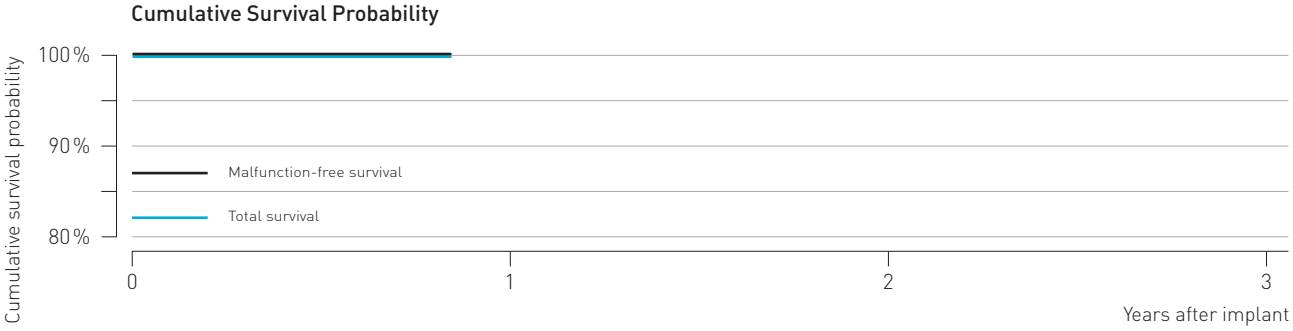
5.2 Dual-chamber pacemakers

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	6,870
Registered U.S. implants	1,460
Estimated active U.S. implants	1,420
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)		-	-	-	-	-	-	-	-	-	-	-

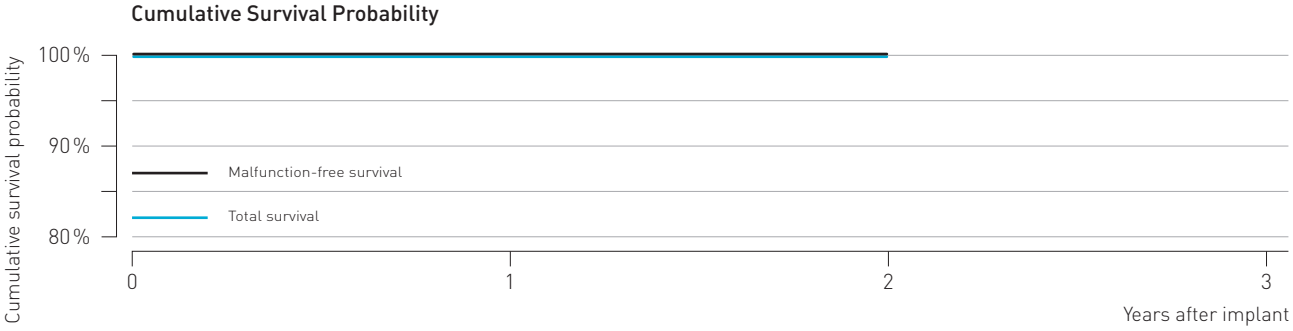
5.2 Dual-chamber pacemakers

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	75,800
Registered U.S. implants	23,600
Estimated active U.S. implants	22,500
U.S. normal battery depletions	0

	Quantity	Rate
U.S. confirmed malfunctions	8	0.03%
▪ Therapy compromised	3	0.01%
▪ Therapy available	5	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	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	-	-	-	-	-	-	-	-	-

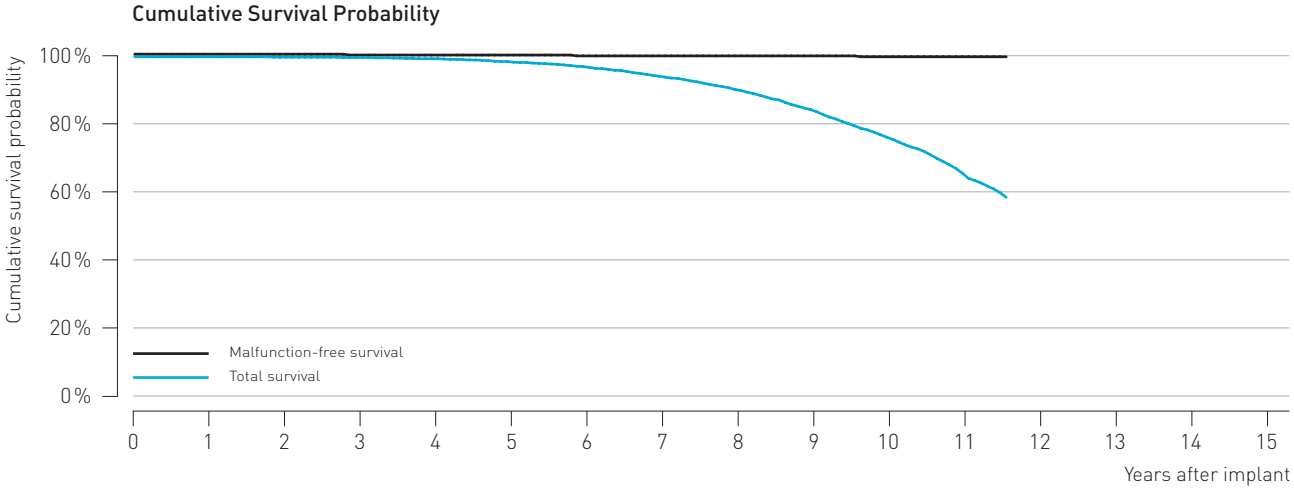
5.2 Dual-chamber pacemakers

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	172,000
Registered U.S. implants	20,700
Estimated active U.S. implants	7,490
U.S. normal battery depletions	1,681

	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.
Total survival (%)	100.0	100.0	99.9	99.8	99.4	98.3	96.6	93.5	89.2	82.4	73.6	61.1
(95% confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.2	±0.3	±0.5	±0.6	±0.8	±1.2	±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	99.7	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

5.2 Dual-chamber pacemakers

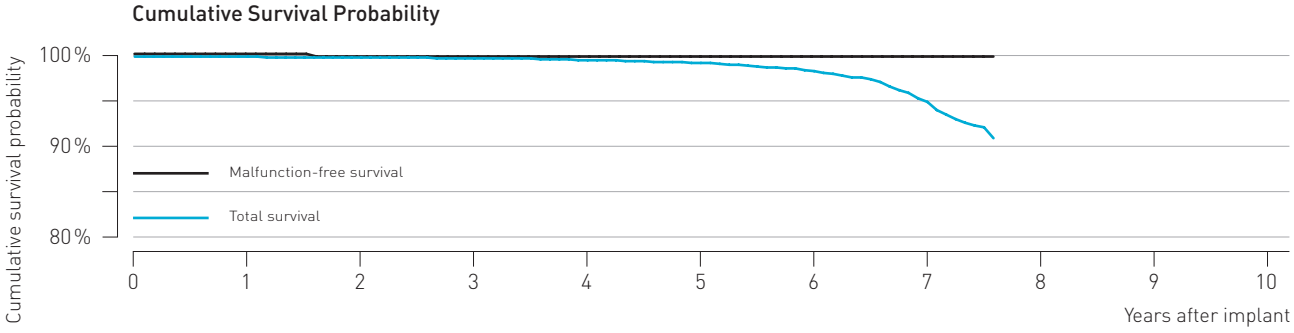
Philos II and Talos

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	305,000
Registered U.S. implants	23,200
Estimated active U.S. implants	17,000
U.S. normal battery depletions	242

	Quantity	Rate
U.S. confirmed malfunctions	19	0.08%
▪ Therapy compromised	0	0.00%
▪ Therapy available	19	0.08%

* 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	99.3	98.4	95.0	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.2	±0.3	±0.8	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	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	-	-	-	-

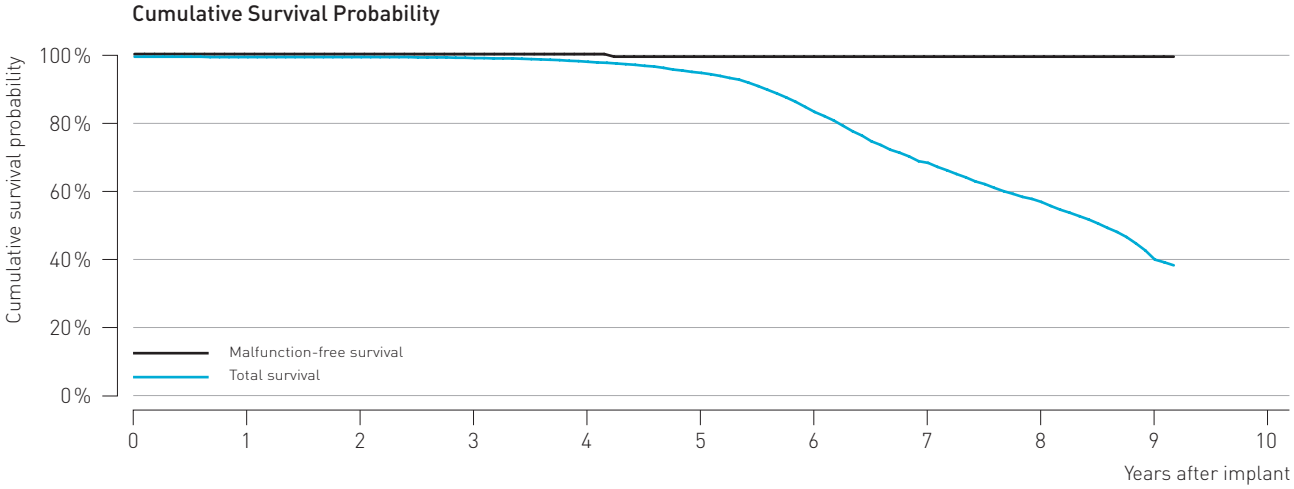
5.2 Dual-chamber pacemakers

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	3,190
U.S. normal battery depletions	1,689

	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	68.5	56.9	39.8	-	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.3	±0.5	±0.9	±1.4	±1.6	±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	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.1	-	-

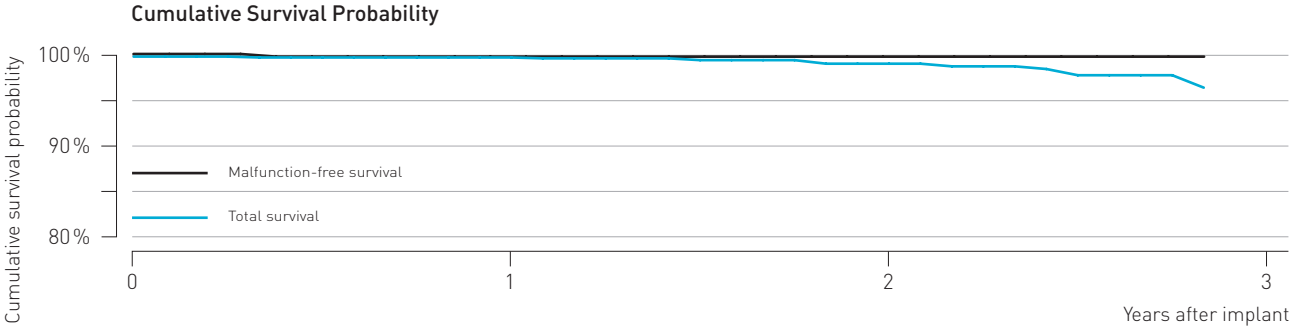
5.3 CRT pacemakers

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	19,900
Registered U.S. implants	1,180
Estimated active U.S. implants	946
U.S. normal battery depletions	20

	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	99.2	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.7	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.2	-	-	-	-	-	-	-	-	-

6 Performance of BIOTRONIK ICDs

6.1 Single-Chamber ICDs

6.2 Dual-Chamber ICDs

6.3 CRT ICDs

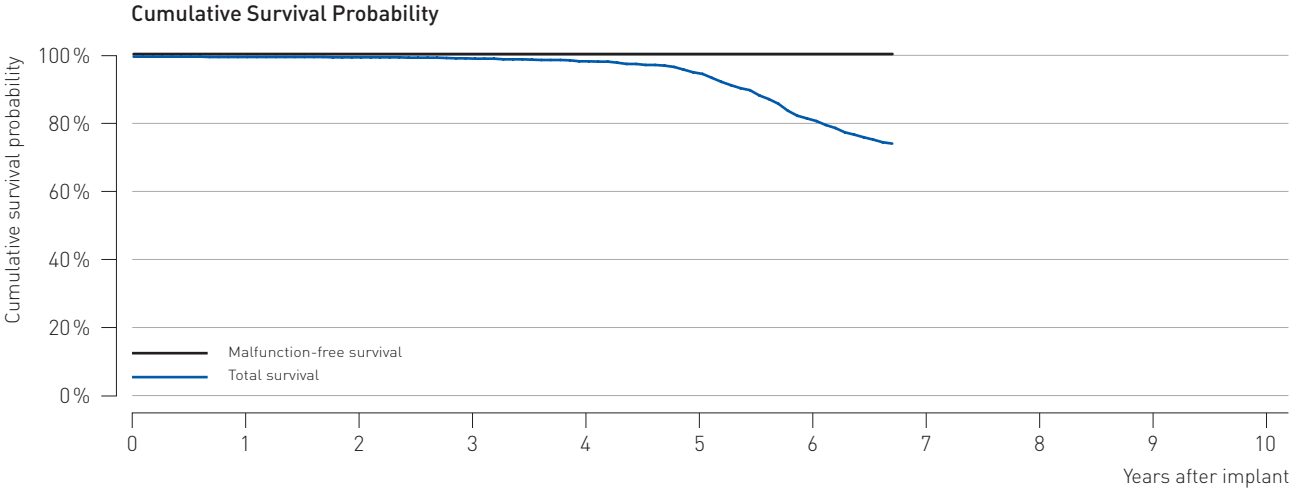
6.1 Single-chamber ICDs

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	397
U.S. normal battery depletions	116

	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	94.8	80.6	-	-	-	-	-
(95% confidence interval)		±0.2	±0.3	±0.5	±0.8	±1.6	±3.4	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	100.0	-	-	-	-	-
(95% confidence interval)								-	-	-	-	-

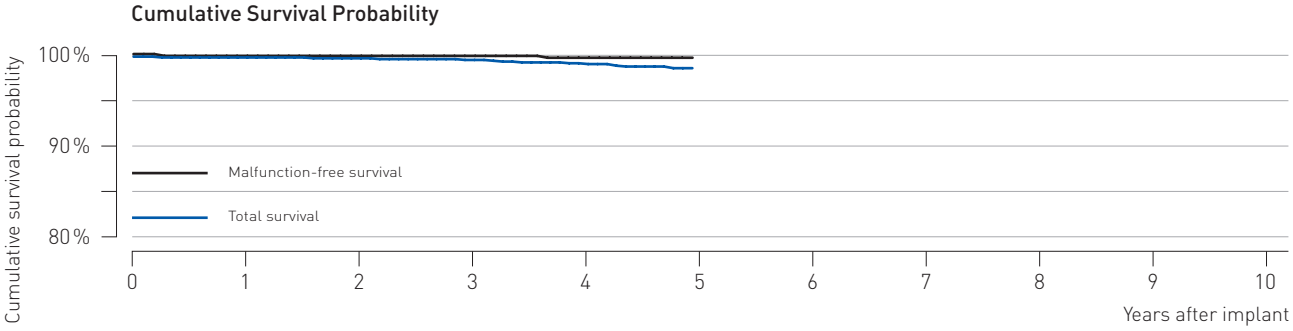
6.1 Single-chamber ICDs

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	21,500
Registered U.S. implants	3,970
Estimated active U.S. implants	3,080
U.S. normal battery depletions	19

	Quantity	Rate
U.S. confirmed malfunctions	5	0.13%
▪ Therapy compromised	3	0.08%
▪ 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	99.1	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.4	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.8	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.2	-	-	-	-	-	-	-

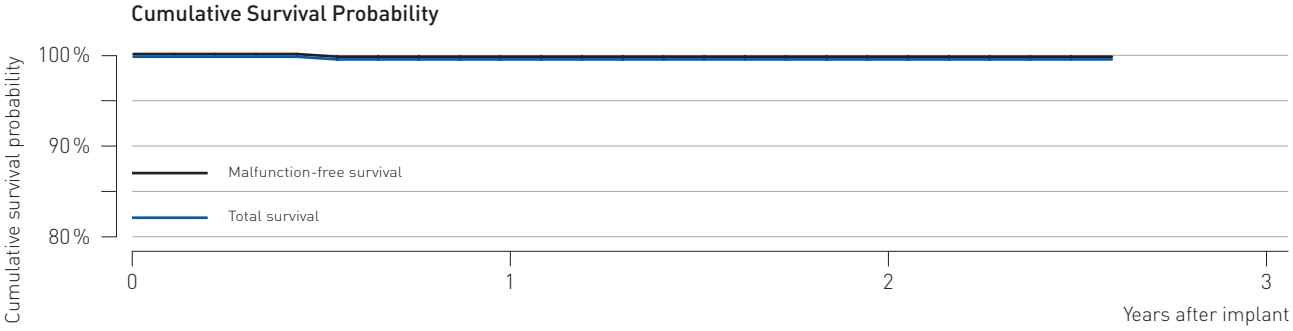
6.1 Single-chamber ICDs

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	14,300
Registered U.S. implants	3,740
Estimated active U.S. implants	3,430
U.S. normal battery depletions	0

	Quantity	Rate
U.S. confirmed malfunctions	2	0.05%
▪ Therapy compromised	1	0.03%
▪ 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	99.9	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	-	-	-	-	-	-	-	-	-

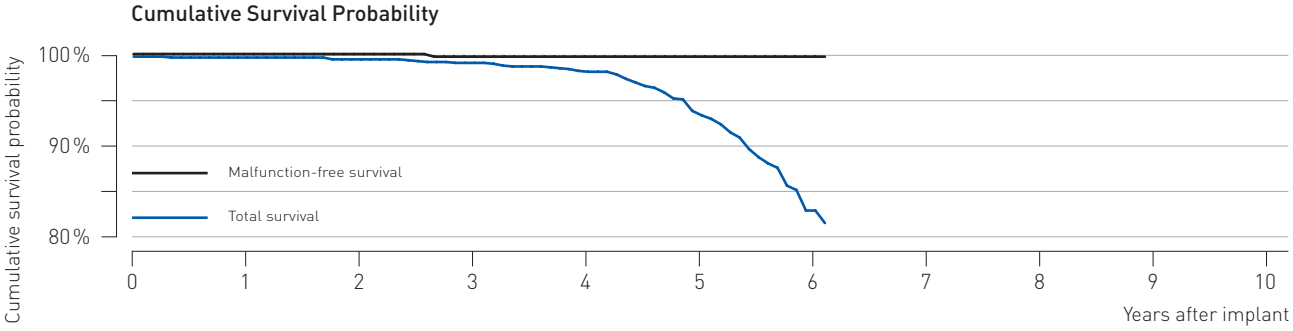
6.1 Single-chamber ICDs

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	782
U.S. normal battery depletions	129

	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	93.4	82.7	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.3	±0.4	±0.7	±1.5	±3.0	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	99.9	99.9	99.9	99.9	-	-	-	-	-
(95 % confidence interval)				±0.2	±0.2	±0.2	±0.2	-	-	-	-	-

6.2 Dual-chamber ICDs

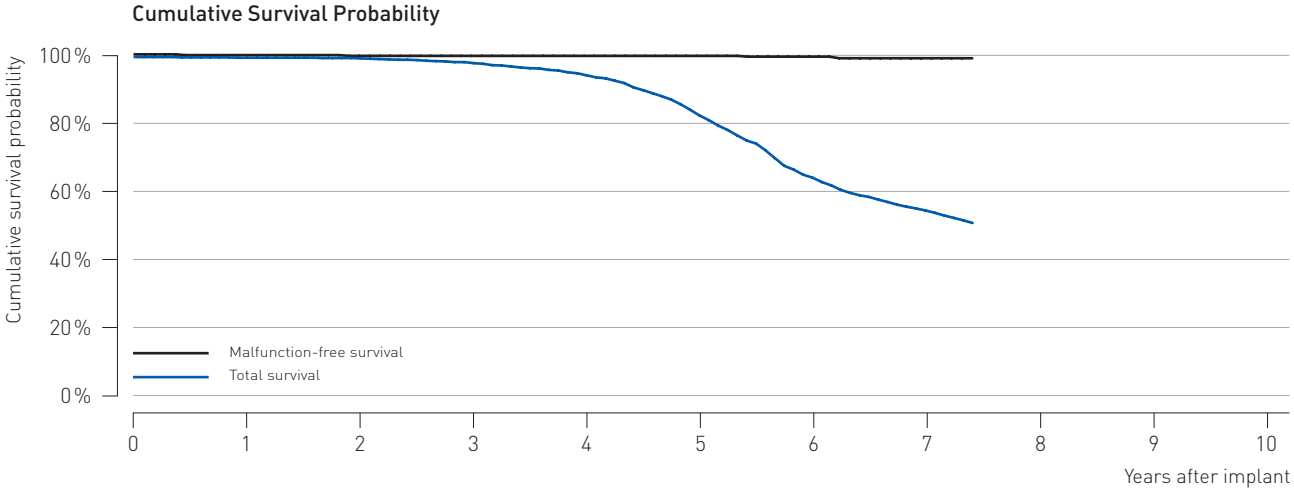
Lexos

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	570
U.S. normal battery depletions	406

	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	82.7	64.3	54.6	-	-	-	-
(95% confidence interval)		±0.2	±0.2	±0.5	±1.0	±1.9	±3.0	±3.6	-	-	-	-
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	-	-	-	-

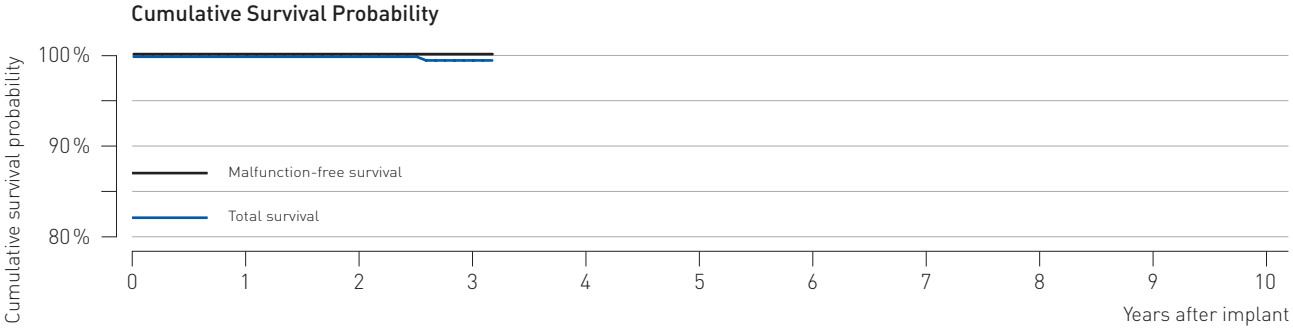
6.2 Dual-chamber ICDs

Lumax 300

Product Details

Product versions	Lumax 300 DR-T
NBG code(s)	VVE-DDDR
Maximum energy (J)	30
U.S. market release	Feb 2007
CE market release	Feb 2007
Worldwide distributed devices	5,280
Registered U.S. implants	379
Estimated active U.S. implants	276
U.S. normal battery depletions	2

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



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	99.6	-	-	-	-	-	-	-	-
(95 % confidence interval)				±0.8	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	100.0	-	-	-	-	-	-	-	-
(95 % confidence interval)				-	-	-	-	-	-	-	-	-

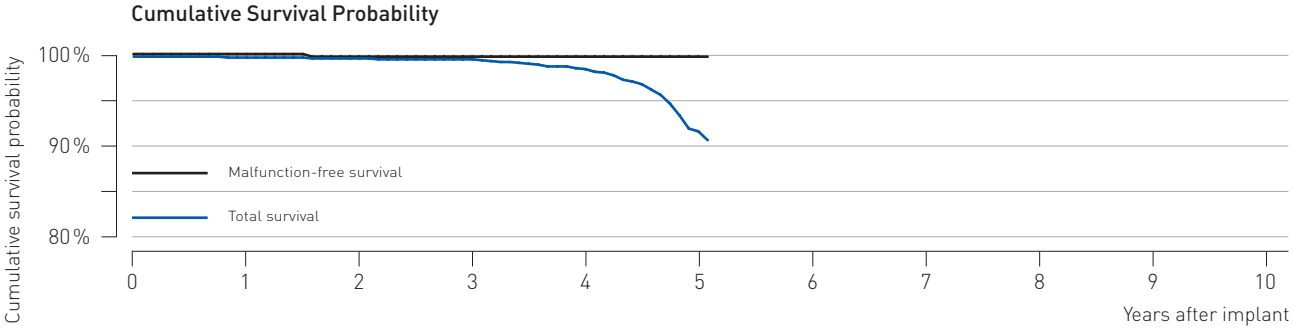
6.2 Dual-chamber ICDs

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	22,000
Registered U.S. implants	8,160
Estimated active U.S. implants	6,120
U.S. normal battery depletions	107

	Quantity	Rate
U.S. confirmed malfunctions	7	0.09%
▪ Therapy compromised	5	0.06%
▪ 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 (%)	100.0	99.9	99.8	99.7	98.6	91.6	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.4	±2.0	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	99.9	99.9	99.9	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.1	±0.1	-	-	-	-	-	-

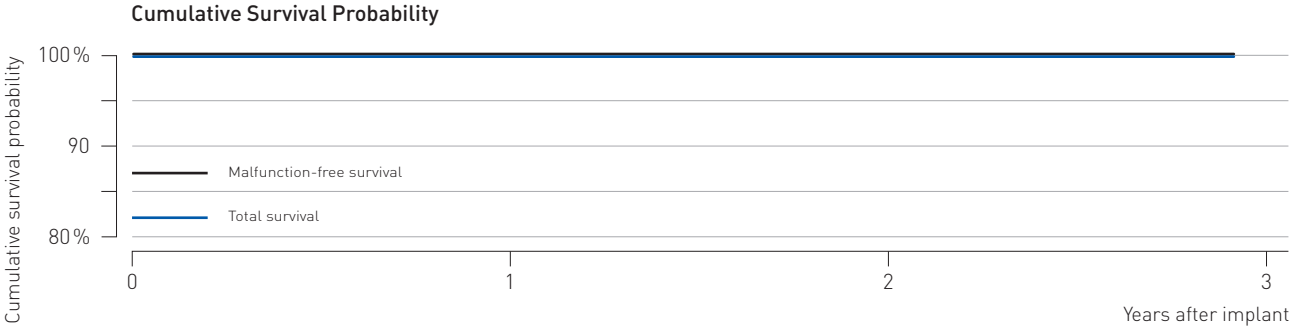
6.2 Dual-chamber ICDs

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	21,000
Registered U.S. implants	9,920
Estimated active U.S. implants	9,010
U.S. normal battery depletions	0

	Quantity	Rate
U.S. confirmed malfunctions	3	0.03%
▪ Therapy compromised	2	0.02%
▪ Therapy available	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	100.0	100.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			±0.0	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	100.0	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			±0.0	-	-	-	-	-	-	-	-	-

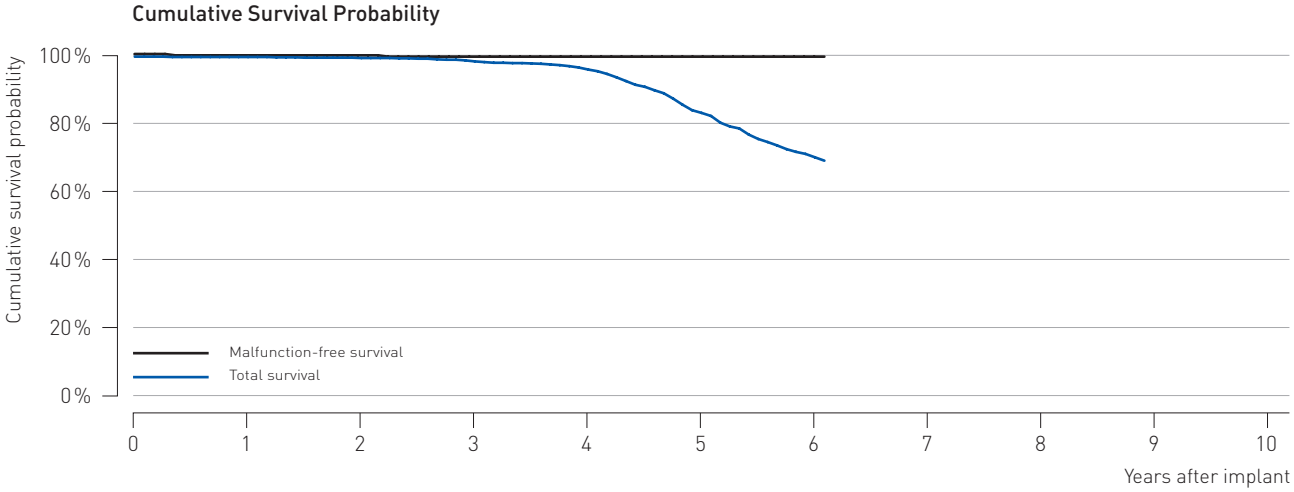
6.2 Dual-chamber ICDs

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	742
U.S. normal battery depletions	236

	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	96.2	83.4	70.3	-	-	-	-	-
(95% confidence interval)		±0.1	±0.2	±0.5	±0.9	±2.1	±3.2	-	-	-	-	-
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	-	-	-	-	-

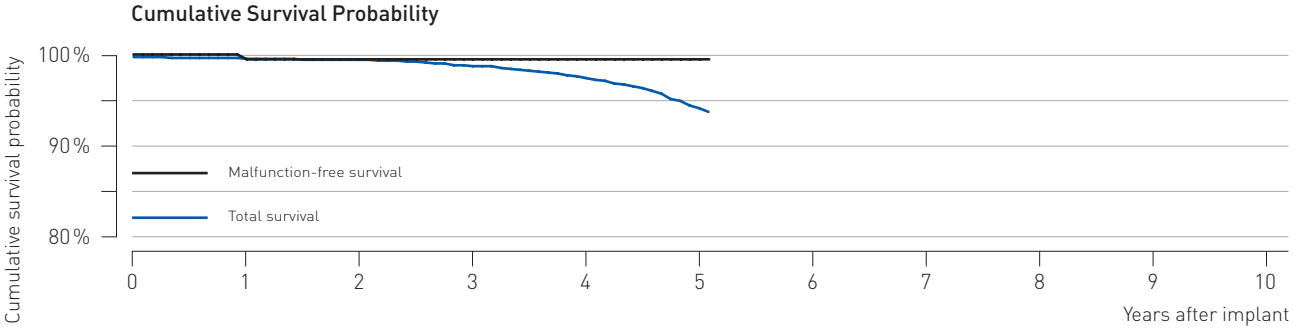
6.3 CRT ICDs

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	17,200
Registered U.S. implants	5,280
Estimated active U.S. implants	3,710
U.S. normal battery depletions	88

	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	99.0	97.7	94.4	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.2	±0.3	±0.6	±1.5	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	99.9	99.9	99.9	99.9	99.9	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	-	-	-	-	-	-

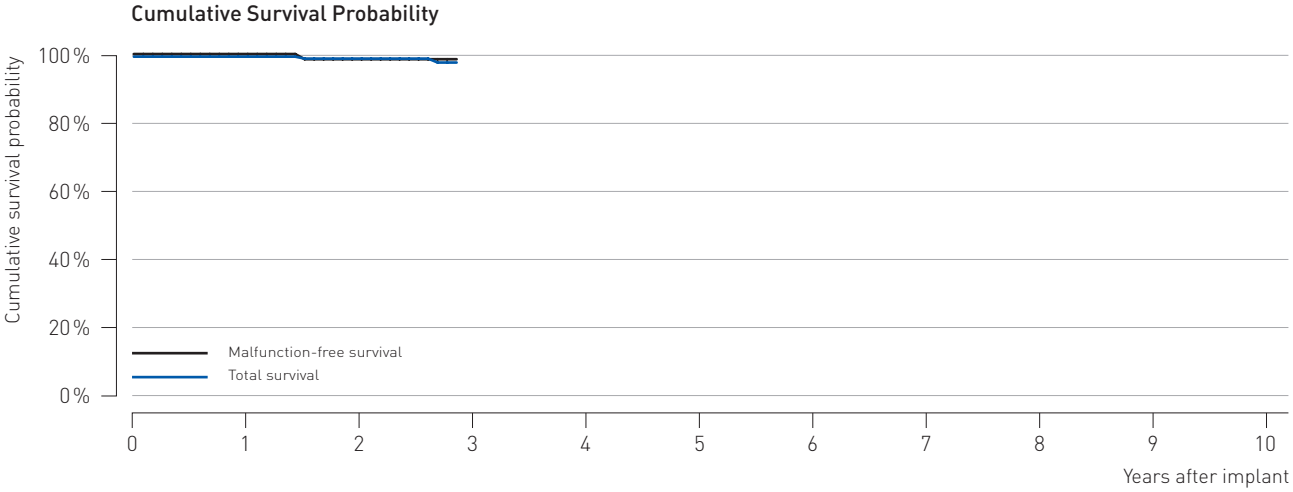
6.3 CRT ICDs

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	20,100
Registered U.S. implants	7,510
Estimated active U.S. implants	6,650
U.S. normal battery depletions	3

	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.
Total survival (%)	100.0	100.0	99.9	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	-	-	-	-	-	-	-	-	-
Malfunction-free survival (%)	100.0	100.0	99.9	-	-	-	-	-	-	-	-	-
(95 % confidence interval)			±0.1	-	-	-	-	-	-	-	-	-

7 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
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

8 Methodology for Lead Survival Estimates

8.1 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.

8.2 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.

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 July 1, 2012. 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 1,000 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.

8.3 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.

8.4 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.

9 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.

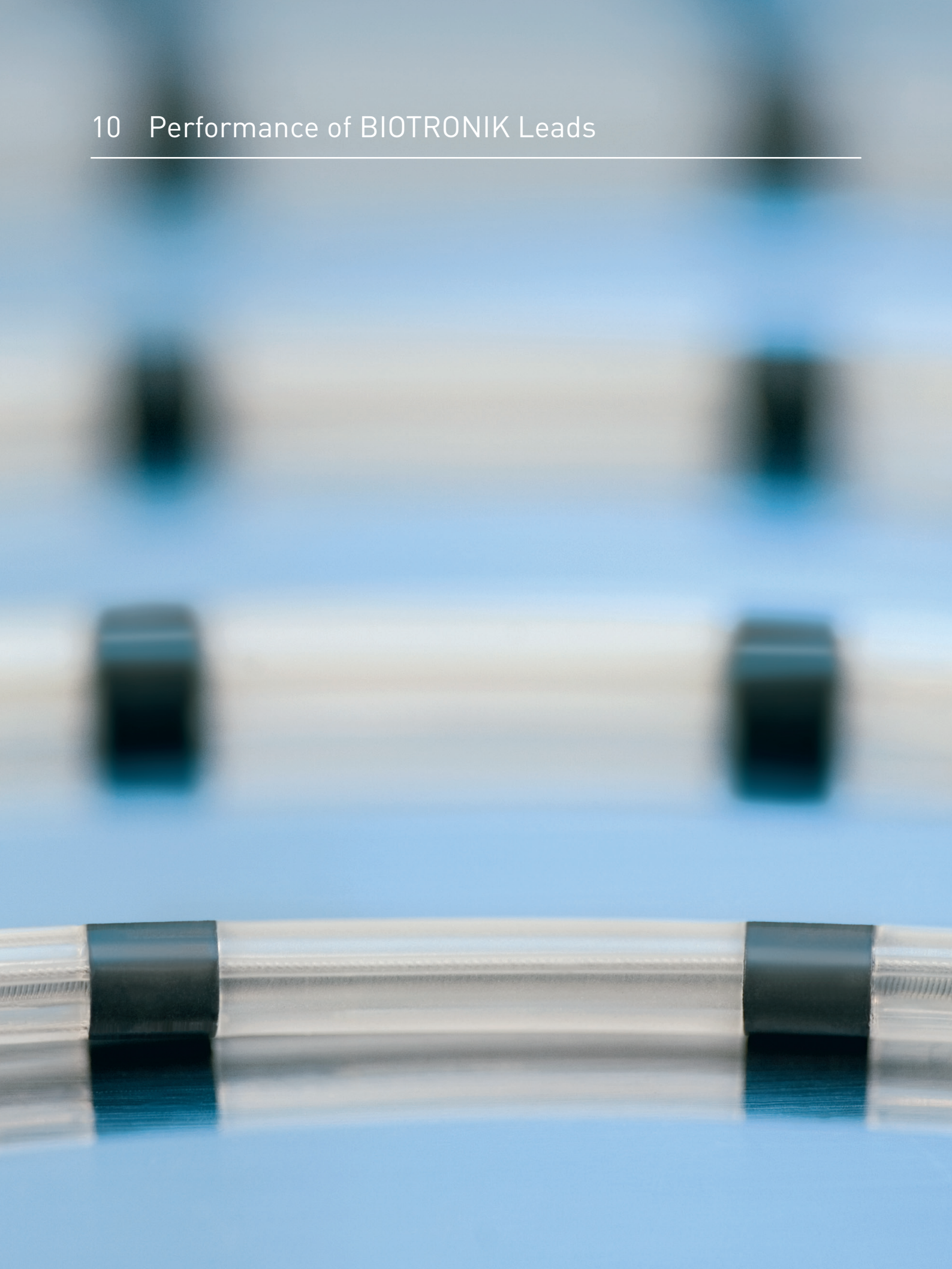
Products or subgroups of products may become subject to advisory notifications that can significantly impact the overall product performance.

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

10 Performance of BIOTRONIK Leads



10.1 Pacing Leads

10.2 ICD Leads

10.1 Pacing leads

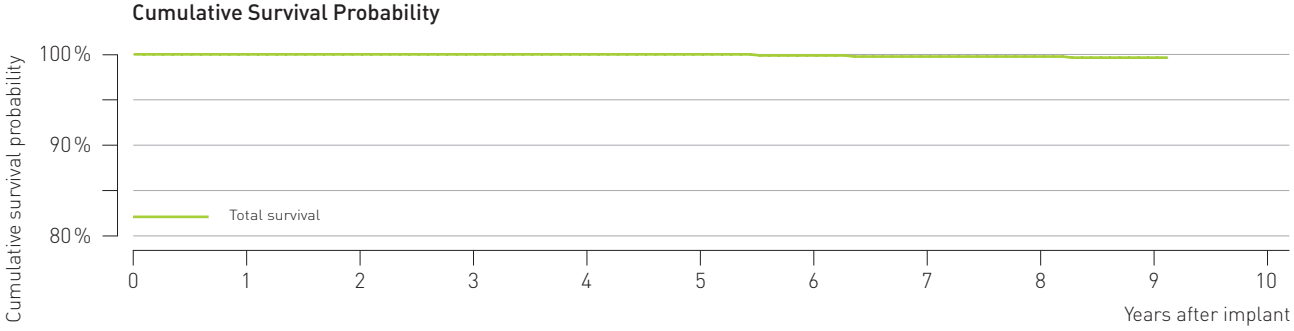
Arox

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	36,400
Registered U.S. implants	8,530
Estimated active U.S. implants	5,060
U.S. total returned	10

	Quantity	Rate
U.S. qualifying complications	8	0.09%
▪ Abnormal pacing impedance	3	0.04%
▪ Failure to capture	4	0.05%
▪ 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	99.8	99.7	-	-
(95 % confidence interval)						±0.0	±0.1	±0.1	±0.1	±0.2	-	-

10.1 Pacing leads

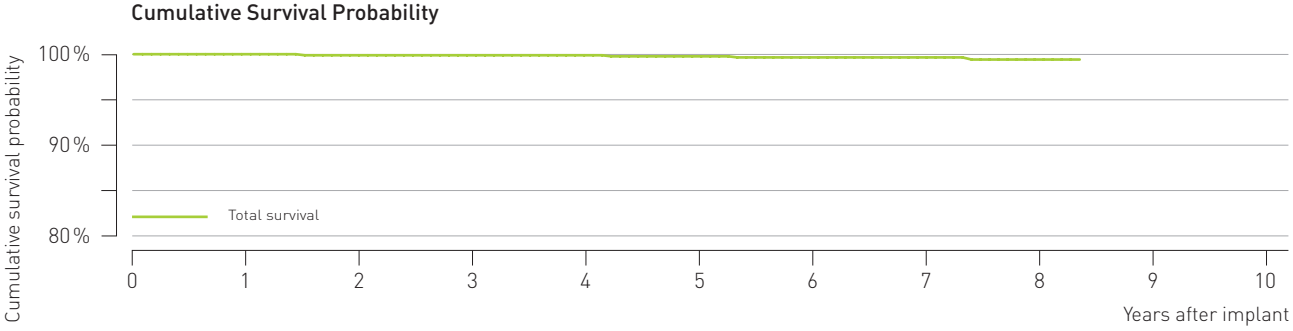
Arox J

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	8,720
Registered U.S. implants	3,470
Estimated active U.S. implants	2,320
U.S. total returned	3

	Quantity	Rate
U.S. qualifying complications	8	0.23%
▪ Failure to capture	6	0.17%
▪ 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	99.7	99.7	99.5	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.3	±0.4	-	-	-

10.1 Pacing leads

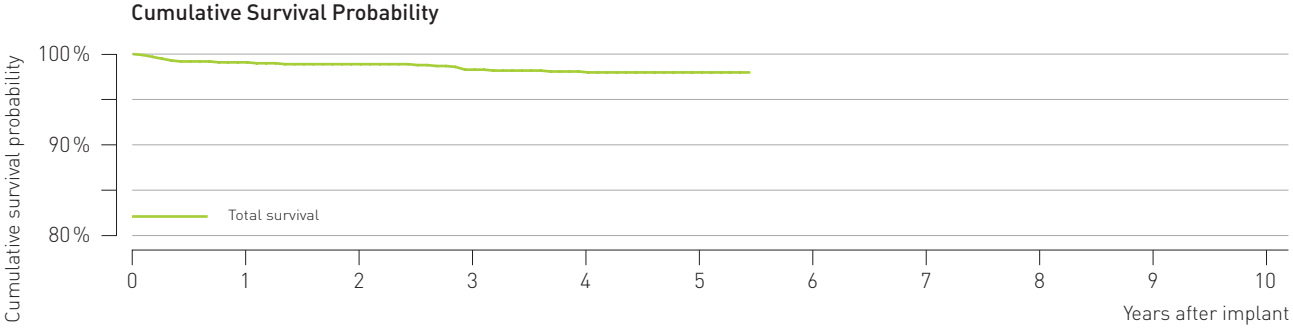
Corox

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	10,100
Registered U.S. implants	1,430
Estimated active U.S. implants	882
U.S. total returned	17

	Quantity	Rate
U.S. qualifying complications	22	1.54%
▪ Extracardiac stimulation	5	0.35%
▪ Failure to capture	11	0.77%
▪ Insulation breach	1	0.07%
▪ Lead dislodgement	5	0.35%
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	98.9	98.3	98.0	98.0	-	-	-	-	-	-
(95 % confidence interval)		±0.5	±0.6	±0.7	±0.8	±0.8	-	-	-	-	-	-

10.1 Pacing leads

Corox

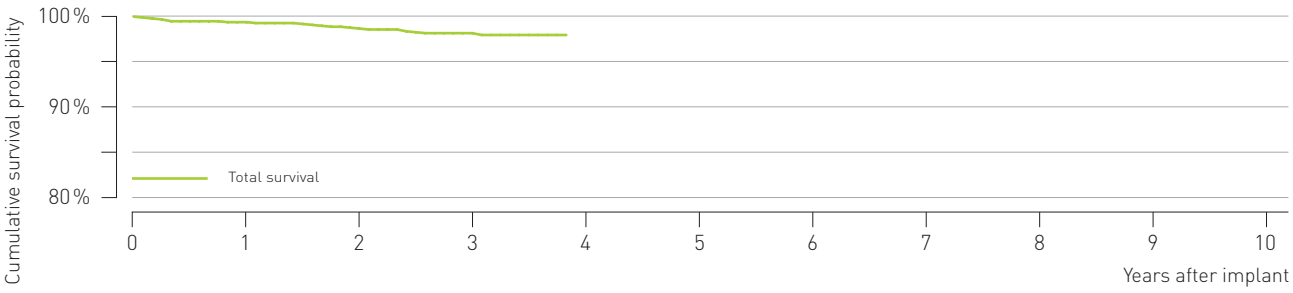
Product Details

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	19,700
Registered U.S. implants	3,250
Estimated active U.S. implants	2,610
U.S. total returned	39

	Quantity	Rate
U.S. qualifying complications	32	0.98%
▪ Abnormal pacing impedance	1	0.03%
▪ Extracardiac stimulation	3	0.09%
▪ Failure to capture	8	0.25%
▪ Insulation breach	1	0.03%
▪ Lead dislodgement	19	0.58%
U.S. confirmed malfunctions	8	0.25%
▪ Conductor fracture	7	0.22%
▪ Insulation breach	1	0.03%

	Quantity	Rate
U.S. acute lead observations	7	0.22%
▪ Lead dislodgement	7	0.22%

Cumulative Survival Probability



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	98.7	98.2	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.6	-	-	-	-	-	-	-	-

10.1 Pacing leads

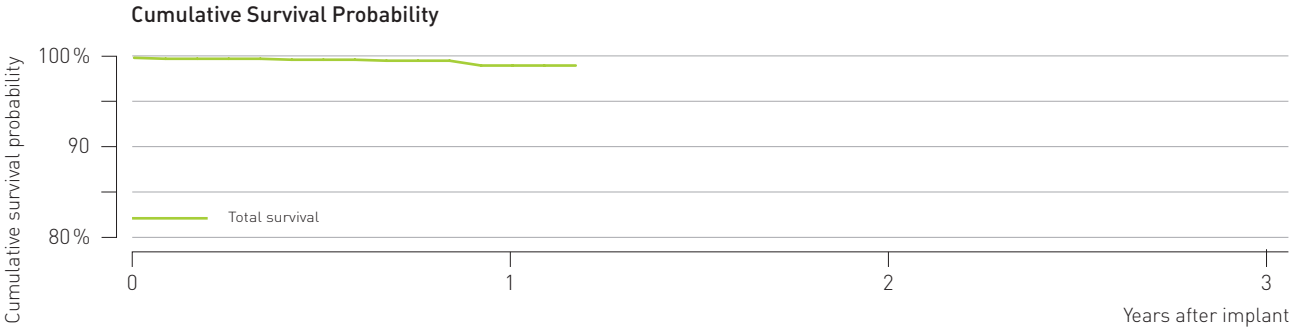
Corox

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	10,300
Registered U.S. implants	1,390
Estimated active U.S. implants	1,300
U.S. total returned	8

	Quantity	Rate
U.S. qualifying complications	5	0.36%
▪ Extracardiac stimulation	2	0.14%
▪ Failure to capture	1	0.07%
▪ Lead dislodgement	2	0.14%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	4	0.29%
▪ Extracardiac stimulation	3	0.22%
▪ 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	99.2	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.8	-	-	-	-	-	-	-	-	-	-

10.1 Pacing leads

Corox

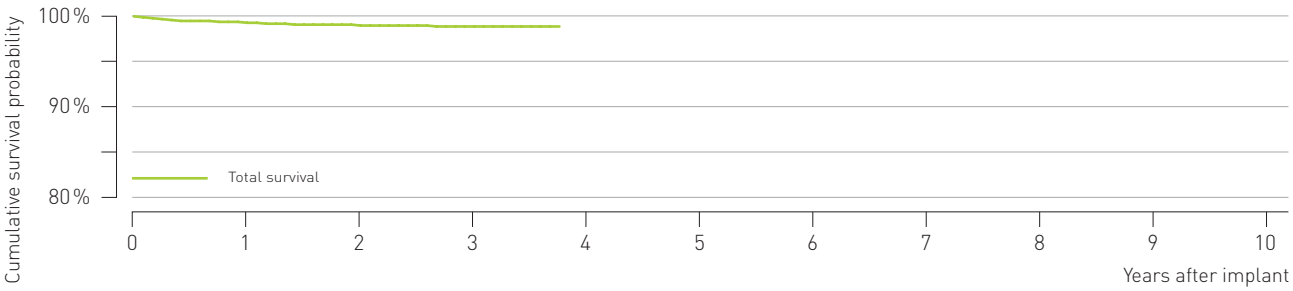
Product Details

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	16,200
Registered U.S. implants	4,910
Estimated active U.S. implants	4,070
U.S. total returned	33

	Quantity	Rate
U.S. qualifying complications	36	0.73%
▪ Conductor fracture	1	0.02%
▪ Extracardiac stimulation	5	0.10%
▪ Failure to capture	7	0.14%
▪ Insulation breach	3	0.06%
▪ Lead dislodgement	20	0.41%
U.S. confirmed malfunctions	4	0.08%
▪ Conductor fracture	2	0.04%
▪ Insulation breach	2	0.04%

	Quantity	Rate
U.S. acute lead observations	21	0.43%
▪ Extracardiac stimulation	2	0.04%
▪ Failure to capture	5	0.10%
▪ Lead dislodgement	14	0.29%

Cumulative Survival Probability



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	98.9	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.3	±0.4	-	-	-	-	-	-	-	-

10.1 Pacing leads

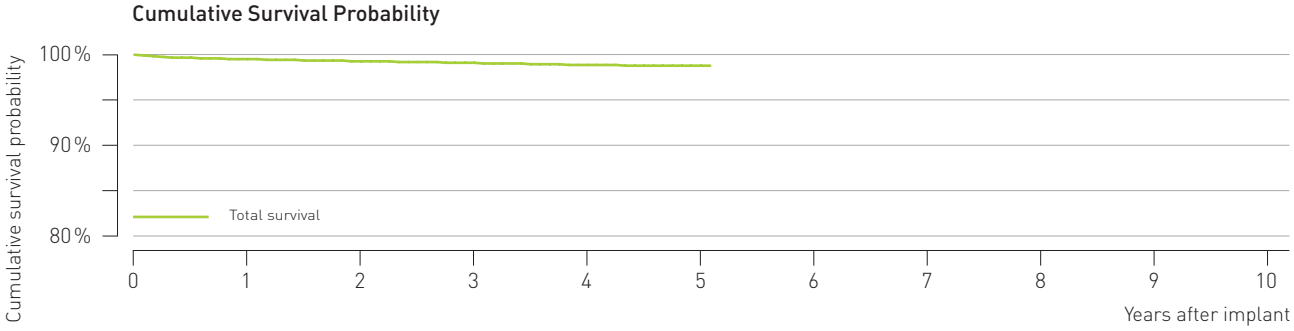
Dextrus

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	272,000
Registered U.S. implants	202,000
Estimated active U.S. implants	164,000
U.S. total returned	912

	Quantity	Rate
U.S. qualifying complications	1,666	0.82%
▪ Abnormal pacing impedance	135	0.07%
▪ Cardiac perforation	20	< 0.01%
▪ Conductor fracture	20	< 0.01%
▪ Extracardiac stimulation	25	0.01%
▪ Failure to capture	480	0.24%
▪ Failure to sense	189	0.09%
▪ Insulation breach	5	< 0.01%
▪ Lead dislodgement	517	0.26%
▪ Oversensing	275	0.14%
U.S. confirmed malfunctions	80	0.04%
▪ Conductor fracture	31	0.02%
▪ Insulation breach	49	0.02%

	Quantity	Rate
U.S. acute lead observations	1,658	0.82%
▪ Abnormal pacing impedance	41	0.02%
▪ Cardiac perforation	82	0.04%
▪ Extracardiac stimulation	17	< 0.01%
▪ Failure to capture	321	0.16%
▪ Failure to sense	112	0.06%
▪ Insulation breach	4	< 0.01%
▪ Lead dislodgement	1,026	0.51%
▪ Oversensing	55	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	99.1	98.9	98.6	98.5	-	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.1	-	-	-	-	-	-

10.1 Pacing leads

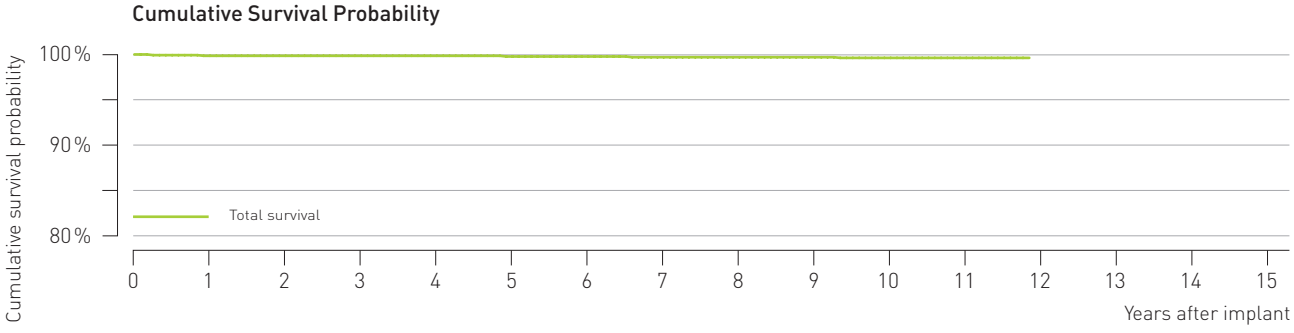
Elox

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	4,210
U.S. total returned	34

	Quantity	Rate
U.S. qualifying complications	30	0.27%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Conductor fracture	1	< 0.01%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	3	0.03%
▪ Failure to sense	10	0.09%
▪ Insulation breach	4	0.04%
▪ Lead dislodgement	2	0.02%
▪ Oversensing	8	0.07%
U.S. confirmed malfunctions	3	0.03%
▪ Conductor fracture	1	< 0.01%
▪ Insulation breach	2	0.02%

	Quantity	Rate
U.S. acute lead observations	9	0.08%
▪ 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.
Total survival (%)	100.0	99.8	99.8	99.8	99.8	99.7	99.7	99.6	99.6	99.6	99.5	99.5
(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

10.1 Pacing leads

Elox P

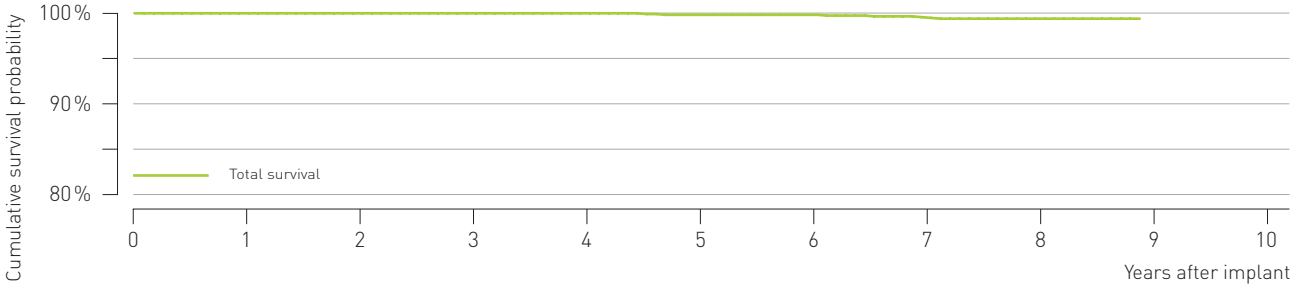
Product Details

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	1,500
U.S. total returned	13

	Quantity	Rate
U.S. qualifying complications	9	0.30%
▪ Abnormal pacing impedance	1	0.03%
▪ Failure to capture	3	0.10%
▪ Insulation breach	1	0.03%
▪ Lead dislodgement	2	0.07%
▪ 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



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	99.8	99.8	99.4	99.3	-	-	-
(95 % confidence interval)			±0.1	±0.1	±0.1	±0.2	±0.2	±0.4	±0.4	-	-	-

10.1 Pacing leads

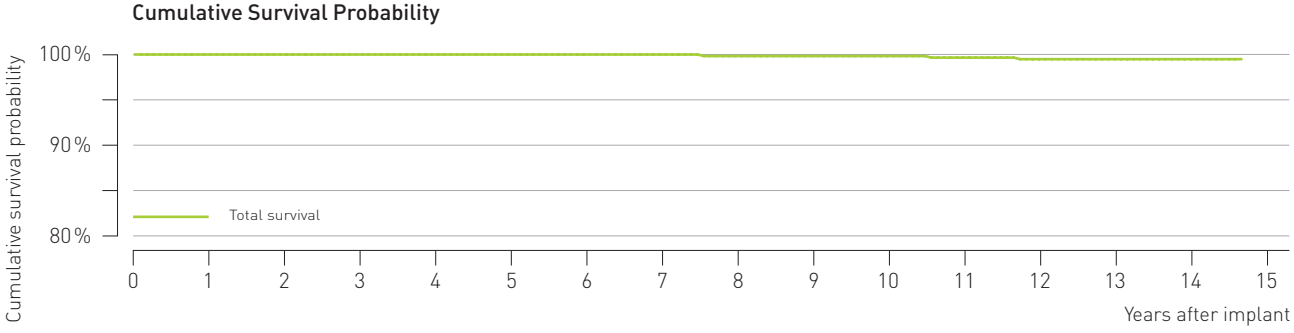
Polyrox

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	5,110
U.S. total returned	13

	Quantity	Rate
U.S. qualifying complications	11	0.07%
▪ Conductor fracture	2	0.01%
▪ Failure to capture	7	0.05%
▪ Insulation breach	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.
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	99.7	99.7	99.7	-
(95 % confidence interval)					±0.0	±0.0	±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	-

Polyrox J

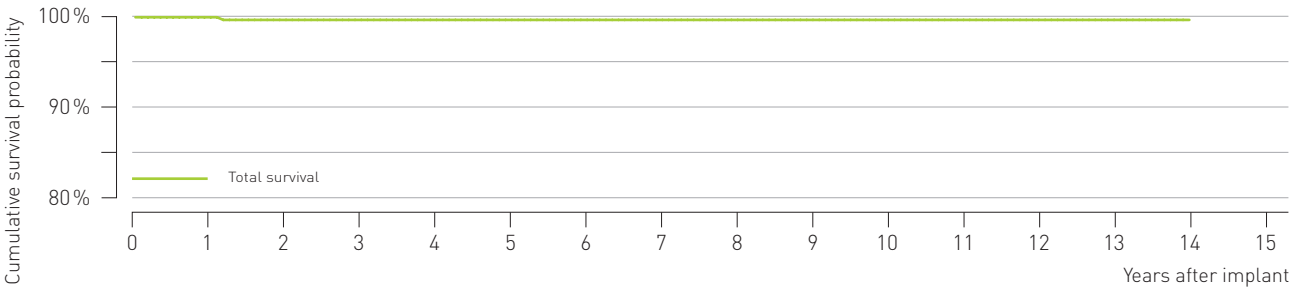
Product Details

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	1,340
U.S. total returned	3

	Quantity	Rate
U.S. qualifying complications	3	0.08%
▪ 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



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	99.9	99.9	99.9	99.9	-
(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	±0.1	±0.1	±0.1	-

10.1 Pacing leads

Retrox J

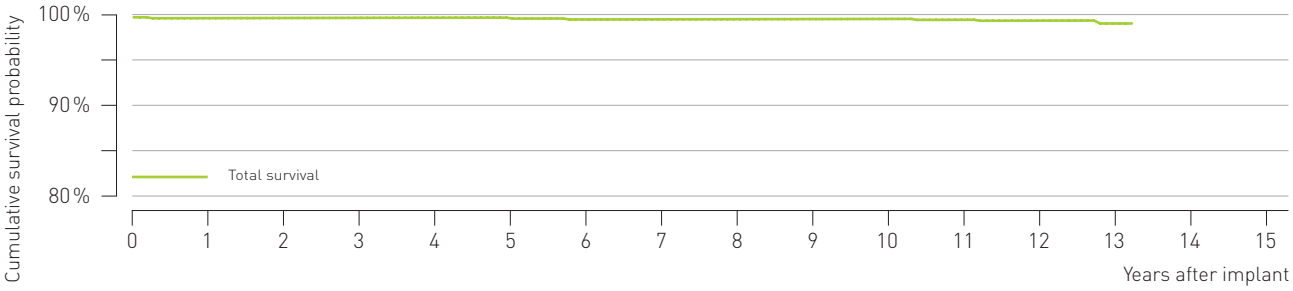
Product Details

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	1,450
U.S. total returned	10

	Quantity	Rate
U.S. qualifying complications	12	0.28%
▪ Abnormal pacing impedance	1	0.02%
▪ 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	0.05%
▪ Failure to capture	1	0.02%
▪ Oversensing	1	0.02%

Cumulative Survival Probability



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	99.7	99.6	99.5	99.2	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	±0.2	±0.2	±0.3	±0.3	±0.6	-	-

10.1 Pacing leads

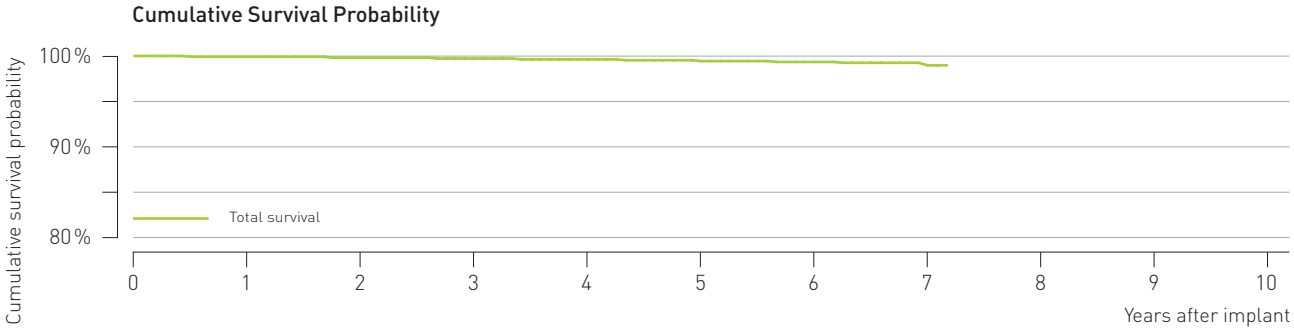
Selox JT

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	96,400
Registered U.S. implants	11,500
Estimated active U.S. implants	9,240
U.S. total returned	38

	Quantity	Rate
U.S. qualifying complications	34	0.30%
▪ Abnormal pacing impedance	3	0.03%
▪ Cardiac perforation	1	< 0.01%
▪ Conductor fracture	1	< 0.01%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	14	0.12%
▪ Failure to sense	5	0.04%
▪ Insulation breach	1	< 0.01%
▪ Lead dislodgement	7	0.06%
▪ Oversensing	1	< 0.01%
U.S. confirmed malfunctions	4	0.03%
▪ Insulation breach	4	0.03%

	Quantity	Rate
U.S. acute lead observations	17	0.15%
▪ Failure to capture	3	0.03%
▪ Lead dislodgement	14	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	99.6	99.4	99.3	98.9	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.1	±0.2	±0.2	±0.3	±0.3	-	-	-	

10.1 Pacing leads

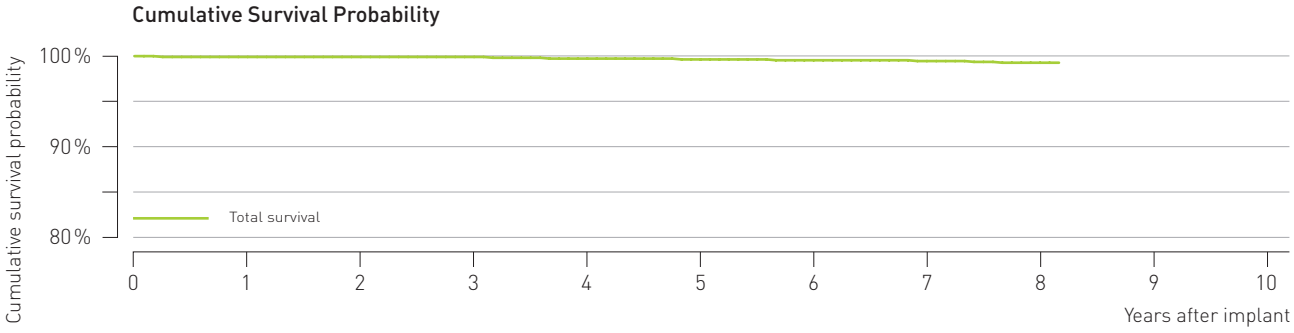
Selox SR

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	153,000
Registered U.S. implants	14,300
Estimated active U.S. implants	8,300
U.S. total returned	32

	Quantity	Rate
U.S. qualifying complications	51	0.36%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Conductor fracture	1	< 0.01%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	28	0.20%
▪ Failure to sense	2	0.01%
▪ Insulation breach	2	0.01%
▪ Lead dislodgement	12	0.08%
▪ Oversensing	4	0.03%
U.S. confirmed malfunctions	7	0.05%
▪ Insulation breach	7	0.05%

	Quantity	Rate
U.S. acute lead observations	22	0.15%
▪ 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	99.2	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.1	±0.1	±0.1	±0.1	±0.2	±0.2	-	-	-

10.1 Pacing leads

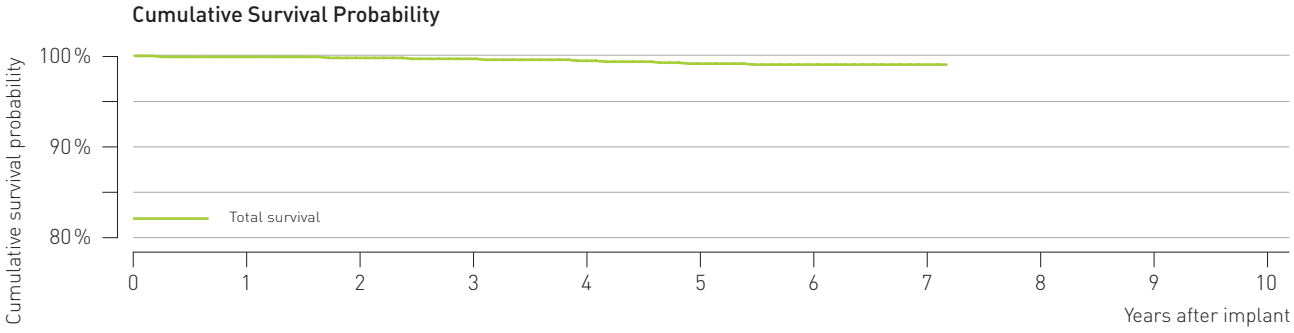
Selox ST

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	281,000
Registered U.S. implants	22,500
Estimated active U.S. implants	17,500
U.S. total returned	43

	Quantity	Rate
U.S. qualifying complications	84	0.37%
▪ Abnormal pacing impedance	19	0.08%
▪ Conductor fracture	5	0.02%
▪ Extracardiac stimulation	2	< 0.01%
▪ Failure to capture	43	0.19%
▪ Failure to sense	1	< 0.01%
▪ Insulation breach	7	0.03%
▪ Lead dislodgement	7	0.03%
U.S. confirmed malfunctions	2	< 0.01%
▪ Crimps, welds and bonds	1	< 0.01%
▪ Insulation breach	1	< 0.01%

	Quantity	Rate
U.S. acute lead observations	16	0.07%
▪ Failure to capture	6	0.03%
▪ Lead dislodgement	10	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	99.9	99.8	99.7	99.5	99.2	99.1	99.1	-	-	-	-
(95 % confidence interval)		±0.0	±0.1	±0.1	±0.1	±0.2	±0.2	±0.2	-	-	-	-

10.1 Pacing leads

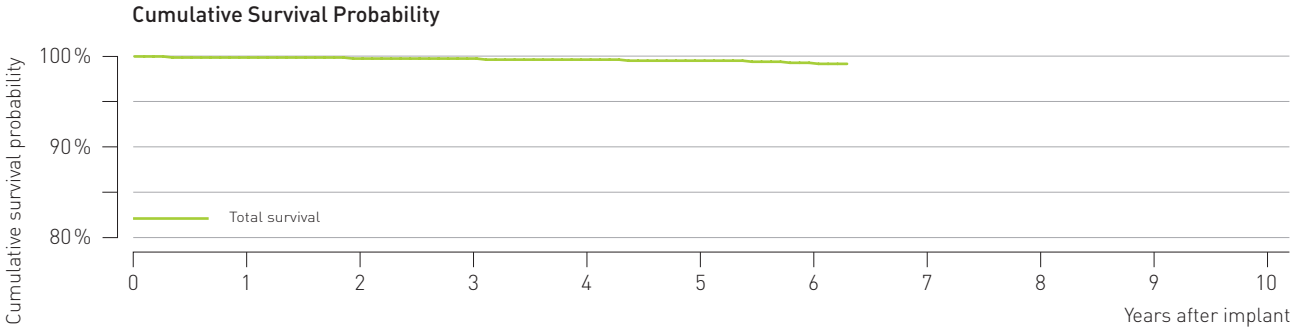
Setrox S

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	419,000
Registered U.S. implants	116,000
Estimated active U.S. implants	98,900
U.S. total returned	375

	Quantity	Rate
U.S. qualifying complications	203	0.18%
▪ Abnormal pacing impedance	14	0.01%
▪ Cardiac perforation	1	< 0.01%
▪ Conductor fracture	1	< 0.01%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	54	0.05%
▪ Failure to sense	7	< 0.01%
▪ Insulation breach	14	0.01%
▪ Lead dislodgement	93	0.08%
▪ Oversensing	18	0.02%

	Quantity	Rate
U.S. confirmed malfunctions	32	0.03%
▪ Conductor fracture	16	0.01%
▪ Insulation breach	16	0.01%
U.S. acute lead observations	85	0.07%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Cardiac perforation	5	< 0.01%
▪ Failure to capture	14	0.01%
▪ Failure to sense	3	< 0.01%
▪ Lead dislodgement	62	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	99.8	99.7	99.6	99.3	-	-	-	-	-
(95 % confidence interval)		±0.0	±0.0	±0.0	±0.0	±0.1	±0.2	-	-	-	-	-

10.1 Pacing leads

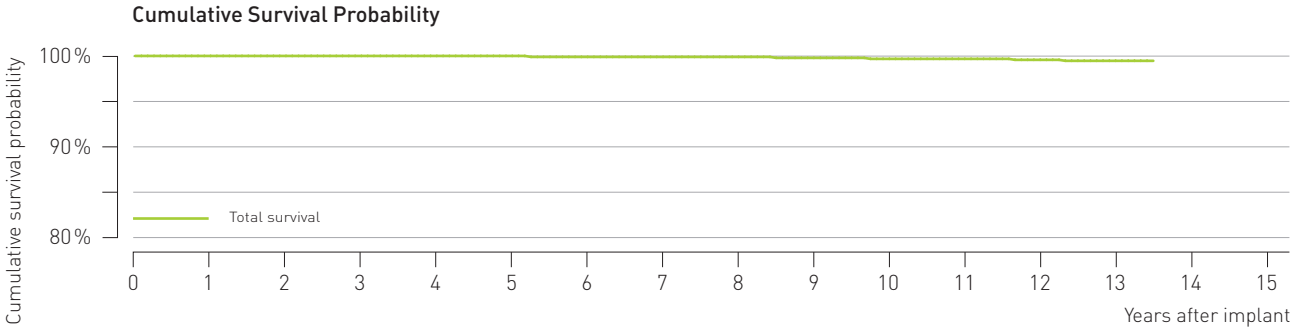
Synox

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	166,000
Registered U.S. implants	17,600
Estimated active U.S. implants	6,920
U.S. total returned	31

	Quantity	Rate
U.S. qualifying complications	22	0.13%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Conductor fracture	2	0.01%
▪ Failure to capture	11	0.06%
▪ Failure to sense	1	< 0.01%
▪ Insulation breach	4	0.02%
▪ Lead dislodgement	1	< 0.01%
▪ Oversensing	2	0.01%
U.S. confirmed malfunctions	2	0.01%
▪ Conductor fracture	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.
Total survival (%)	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.7	99.7	99.6	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

10.1 Pacing leads

Synox J

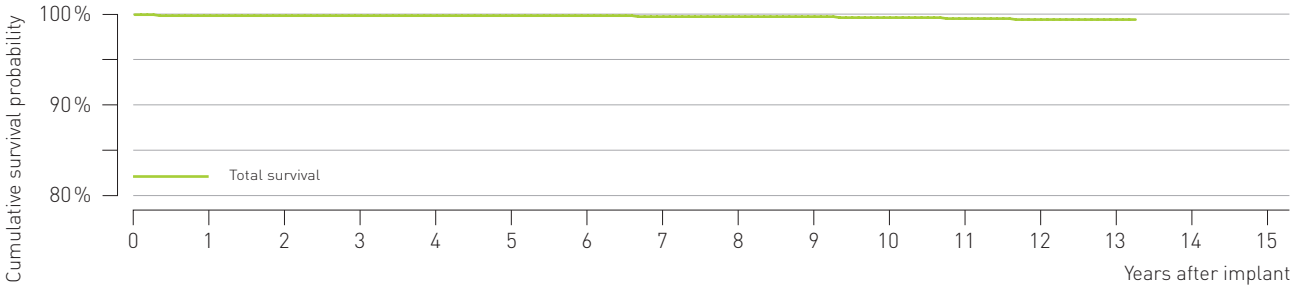
Product Details

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	77,300
Registered U.S. implants	8,160
Estimated active U.S. implants	3,700
U.S. total returned	11

	Quantity	Rate
U.S. qualifying complications	15	0.18%
▪ Abnormal pacing impedance	1	0.01%
▪ Conductor fracture	2	0.02%
▪ Failure to capture	2	0.02%
▪ Failure to sense	4	0.05%
▪ Lead dislodgement	2	0.02%
▪ Oversensing	4	0.05%
U.S. confirmed malfunctions	1	0.01%
▪ Crimps, welds and bonds	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



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.
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	99.5	99.5
(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

10.2 ICD leads

Kainox SL

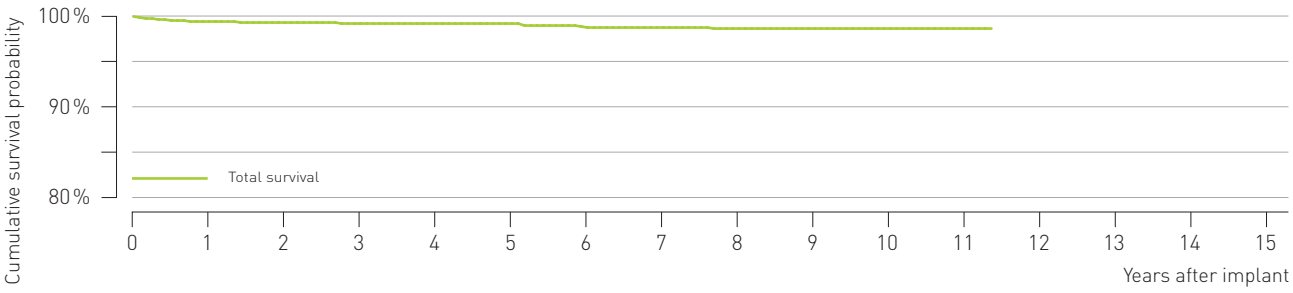
Product Details

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	1,010
U.S. total returned	13

	Quantity	Rate
U.S. qualifying complications	23	0.92%
▪ Abnormal defibrillation impedance	1	0.04%
▪ Abnormal pacing impedance	1	0.04%
▪ 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	10	0.40%
U.S. confirmed malfunctions	1	0.04%
▪ Insulation breach	1	0.04%

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

Cumulative Survival Probability



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	99.4	99.3	99.3	99.3	98.9	98.9	98.8	98.8	98.8	98.8
(95 % confidence interval)		±0.3	±0.3	±0.3	±0.3	±0.4	±0.4	±0.5	±0.5	±0.5	±0.5	±0.5

10.2 ICD leads

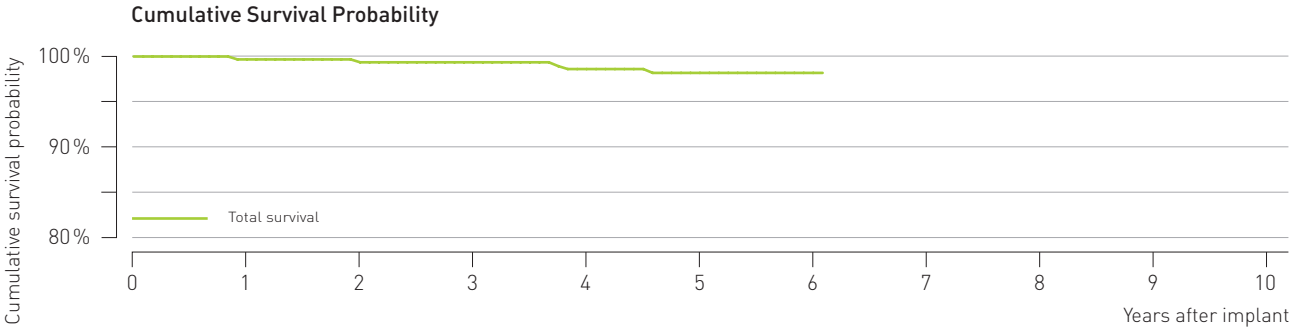
Kentrox RV

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	399
Estimated active U.S. implants	205
U.S. total returned	6

	Quantity	Rate
U.S. qualifying complications	4	1.00%
▪ Conductor fracture	1	0.25%
▪ Oversensing	3	0.75%
U.S. confirmed malfunctions	1	0.25%
▪ Conductor fracture	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	98.3	-	-	-	-	-
(95 % confidence interval)		±0.6	±0.6	±0.8	±1.3	±1.5	±1.5	-	-	-	-	-

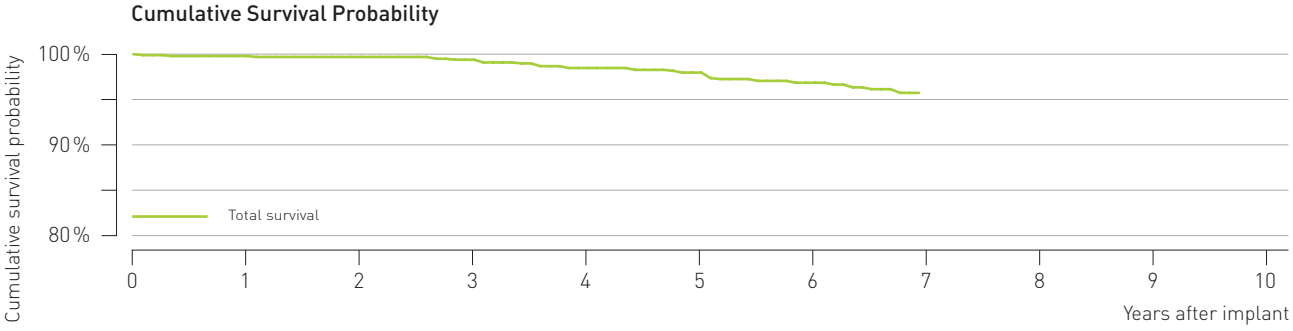
Kentrox SL

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	609
U.S. total returned	15

	Quantity	Rate
U.S. qualifying complications	21	2.08%
▪ Abnormal pacing impedance	2	0.20%
▪ Failure to capture	1	0.10%
▪ Insulation breach	6	0.59%
▪ Oversensing	12	1.19%
U.S. confirmed malfunctions	3	0.30%
▪ Insulation breach	3	0.30%

	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	98.5	98.0	96.9	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.9	±1.1	±1.4	-	-	-	-	-

10.2 ICD leads

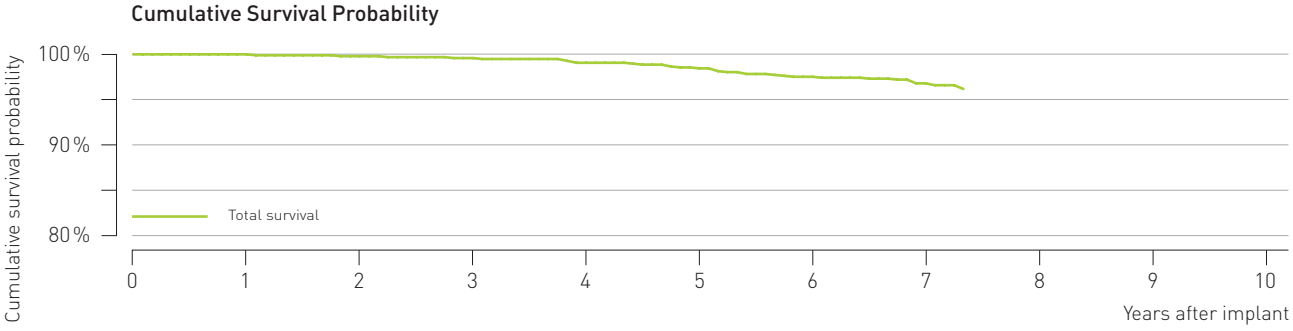
Kentrox SL-S

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	2,430
Estimated active U.S. implants	1,480
U.S. total returned	22

	Quantity	Rate
U.S. qualifying complications	38	1.56%
■ 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	2	0.08%
■ Oversensing	22	0.91%
U.S. confirmed malfunctions	6	0.25%
■ Insulation breach	6	0.25%

	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	99.1	98.5	97.6	96.9	-	-	-	-
(95 % confidence interval)		±0.1	±0.2	±0.3	±0.4	±0.6	±0.8	±1.0	-	-	-	-

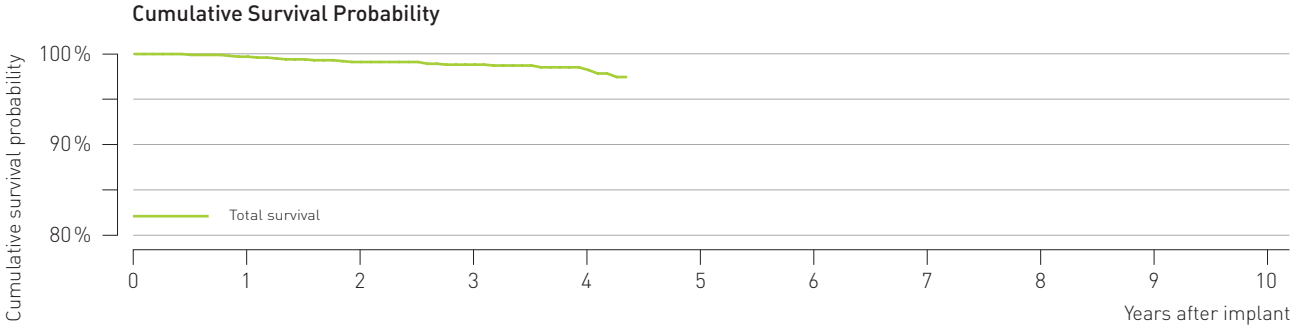
Linox S

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	29,800
Registered U.S. implants	2,480
Estimated active U.S. implants	2,110
U.S. total returned	30

	Quantity	Rate
U.S. qualifying complications	13	0.52%
▪ Failure to capture	2	0.08%
▪ Lead dislodgement	2	0.08%
▪ Oversensing	9	0.36%
U.S. confirmed malfunctions	12	0.48%
▪ Conductor fracture	2	0.08%
▪ Insulation breach	10	0.40%

	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	98.8	98.2	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	±0.4	±0.6	±0.7	-	-	-	-	-	-	-

10.2 ICD leads

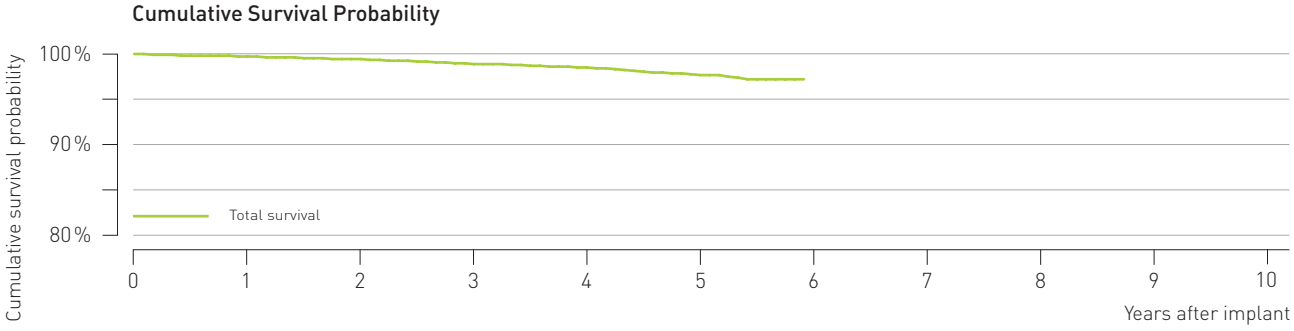
Linox SD

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	53,900
Registered U.S. implants	22,300
Estimated active U.S. implants	17,900
U.S. total returned	212

	Quantity	Rate
U.S. qualifying complications	183	0.82%
▪ Abnormal defibrillation impedance	5	0.02%
▪ Abnormal pacing impedance	5	0.02%
▪ Cardiac perforation	2	< 0.01%
▪ Conductor fracture	10	0.04%
▪ Extracardiac stimulation	1	< 0.01%
▪ Failure to capture	23	0.10%
▪ Failure to sense	4	0.02%
▪ Insulation breach	21	0.09%
▪ Lead dislodgement	23	0.10%
▪ Oversensing	89	0.40%
U.S. confirmed malfunctions	73	0.33%
▪ Conductor fracture	10	0.04%
▪ Insulation breach	63	0.28%

	Quantity	Rate
U.S. acute lead observations	30	0.13%
▪ Abnormal defibrillation impedance	1	< 0.01%
▪ Abnormal pacing impedance	1	< 0.01%
▪ Failure to capture	7	0.03%
▪ Lead dislodgement	18	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	99.4	98.8	98.4	97.5	-	-	-	-	-	-
(95 % confidence interval)		±0.1	±0.1	±0.2	±0.2	±0.4	-	-	-	-	-	-

10.2 ICD leads

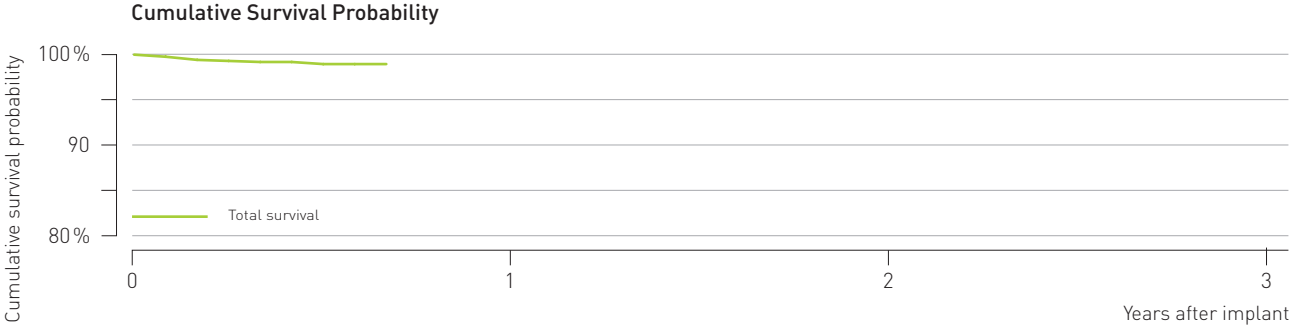
Linox^{smart} S

Product Details

Product versions	Linox^{smart} S 60, Linox^{smart} S 65, Linox^{smart} S 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	10,300
Registered U.S. implants	1,390
Estimated active U.S. implants	1,340
U.S. total returned	6

	Quantity	Rate
U.S. qualifying complications	9	0.65%
▪ Cardiac perforation	1	0.07%
▪ Failure to capture	1	0.07%
▪ Failure to sense	1	0.07%
▪ Lead dislodgement	5	0.36%
▪ Oversensing	1	0.07%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	6	0.43%
▪ Cardiac perforation	1	0.07%
▪ Lead dislodgement	4	0.29%
▪ Oversensing	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	-	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		-	-	-	-	-	-	-	-	-	-	-

10.2 ICD leads

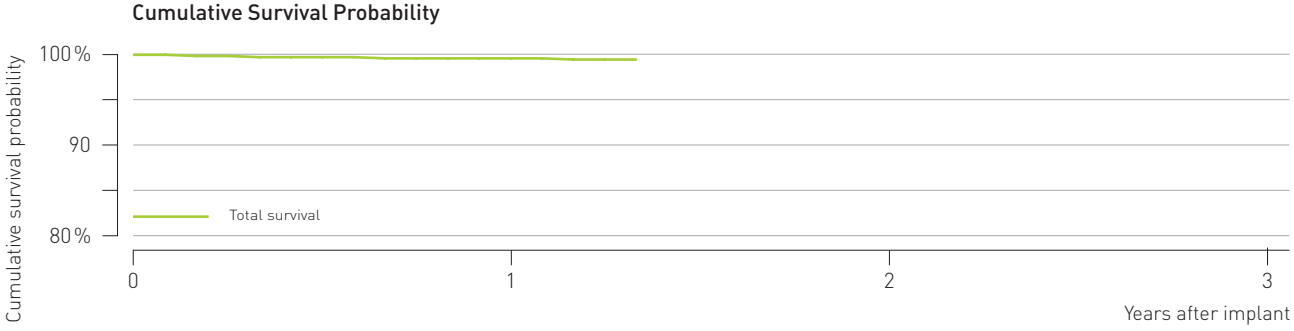
Linox^{smart} SD

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	27,800
Registered U.S. implants	5,350
Estimated active U.S. implants	5,080
U.S. total returned	41

	Quantity	Rate
U.S. qualifying complications	8	0.15%
▪ Abnormal defibrillation impedance	1	0.02%
▪ Failure to capture	1	0.02%
▪ Lead dislodgement	3	0.06%
▪ Oversensing	3	0.06%
U.S. confirmed malfunctions	3	0.06%
▪ Conductor fracture	1	0.02%
▪ Insulation breach	2	0.04%

	Quantity	Rate
U.S. acute lead observations	13	0.24%
▪ Abnormal defibrillation impedance	1	0.02%
▪ Abnormal pacing impedance	1	0.02%
▪ Failure to capture	2	0.04%
▪ Lead dislodgement	8	0.15%
▪ 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.
Total survival (%)	100.0	99.7	-	-	-	-	-	-	-	-	-	-
(95 % confidence interval)		±0.2	-	-	-	-	-	-	-	-	-	-

10.2 ICD leads

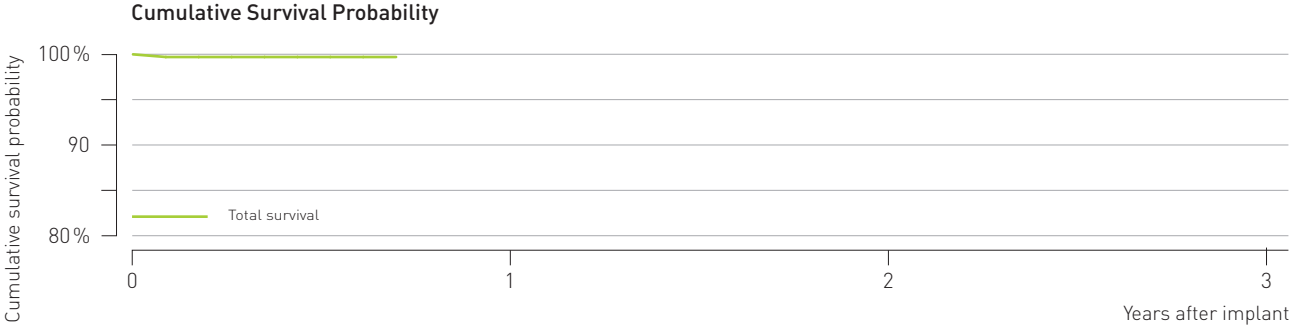
Linox^{smart} TD

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	4,510
Registered U.S. implants	494
Estimated active U.S. implants	464
U.S. total returned	2

	Quantity	Rate
U.S. qualifying complications	1	0.20%
▪ Lead dislodgement	1	0.20%
U.S. confirmed malfunctions	0	0.00%

	Quantity	Rate
U.S. acute lead observations	1	0.20%
▪ Lead dislodgement	1	0.20%



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)		-	-	-	-	-	-	-	-	-	-	-

10.2 ICD leads

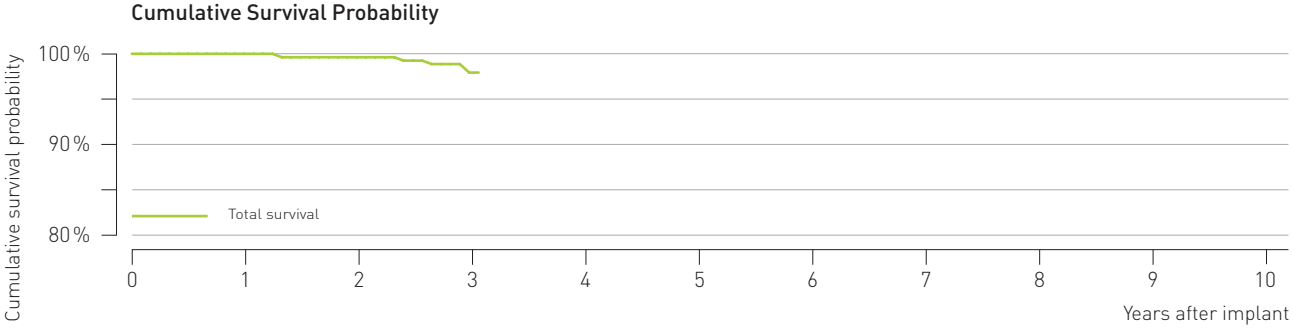
Linox T

Product Details

Product versions	Linox T 65, 75
Lead type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. market release	Feb 2007
CE market release	Mar 2007
Worldwide distributed devices	2,260
Registered U.S. implants	322
Estimated active U.S. implants	263
U.S. total returned	1

	Quantity	Rate
U.S. qualifying complications	7	2.17%
▪ Insulation breach	1	0.31%
▪ Oversensing	6	1.86%
U.S. confirmed malfunctions	1	0.31%
▪ Insulation breach	1	0.31%

	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	99.6	97.8	-	-	-	-	-	-	-	-
(95 % confidence interval)			±0.7	±1.3	-	-	-	-	-	-	-	-

10.2 ICD leads

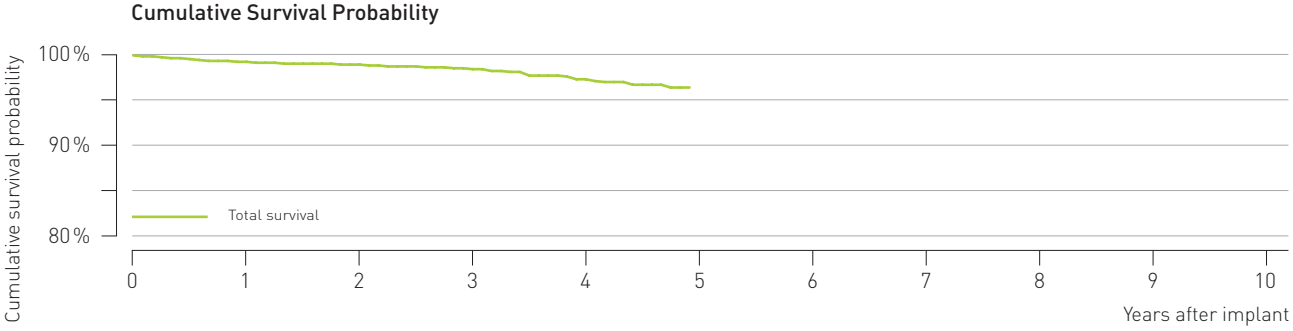
Linox TD

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	14,200
Registered U.S. implants	3,040
Estimated active U.S. implants	2,460
U.S. total returned	30

	Quantity	Rate
U.S. qualifying complications	35	1.15%
▪ Abnormal defibrillation impedance	1	0.03%
▪ Abnormal pacing impedance	2	0.07%
▪ Conductor fracture	1	0.03%
▪ Failure to capture	12	0.39%
▪ Insulation breach	6	0.20%
▪ Lead dislodgement	2	0.07%
▪ Oversensing	11	0.36%

	Quantity	Rate
U.S. confirmed malfunctions	15	0.49%
▪ Conductor fracture	3	0.10%
▪ Insulation breach	12	0.39%
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	99.0	98.5	97.4	-	-	-	-	-	-	-
(95 % confidence interval)		±0.3	±0.4	±0.5	±0.9	-	-	-	-	-	-	-

11 Advisories

Stratos LV-T

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

Status update

As of January 2013

- 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.

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13 Contacting BIOTRONIK

Regarding this Report

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

Worldwide CRM Technical Services:

Phone	+49 (0) 30 68905-1133
Fax	+49 (0) 30 68905-1960
E-mail	PPR@biotronik.com
Address	BIOTRONIK SE & Co. KG Attn: Technical Services Woermannkehre 1 12359 Berlin, Germany

Within the U.S.:

Phone	(888) 345-0374
Fax	(503) 635-9936
E-mail	PPR@biotronik.com
Address	BIOTRONIK, Inc. Attn: Compliance Department 6024 Jean Road Lake Oswego, OR 97035

Regarding Products

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

Worldwide CRM Technical Services:

Phone	+49 (0) 30 68905-1133
Fax	+49 (0) 30 68905-1960
E-mail	global.technical.services@biotronik.com
Address	BIOTRONIK SE & Co. KG Attn: Technical Services Woermannkehre 1 12359 Berlin, Germany

Within the U.S.:

Phone	(800) 284-6689
Fax	(800) 387-2681
E-mail	global.technical.services@biotronik.com
Address	BIOTRONIK, Inc. Attn: Technical Services 6024 Jean Road Lake Oswego, OR 97035