

Product Performance Report July 2019

Cardiac Rhythm Management
Cumulative Survival Probability

**Product
Performance Report
July 2019**

Cardiac Rhythm Management
Pacemakers
ICDs
Leads

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Quality Excellence

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

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

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

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

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

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

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

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

BIOTRONIK, July 2019



A handwritten signature in blue ink that reads "R. Borkowski".

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



Terms and Definitions

1. Terms and Definitions

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

Elective Replacement Indicator

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

Battery Depletion

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

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

Out of Specification

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

Device Malfunctions

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

malfunctions. Devices damaged due to interaction with other implanted devices (i.e., leads) are also not considered as malfunctions for the purposes of this Product Performance Report.

Malfunctions with Compromised Therapy

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

Malfunctions without Compromised Therapy

The condition when a pacemaker or ICD is found to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Therapy is not compromised as long as critical patient-protective pacing and defibrillation therapies are available as determined through device analysis.

Lead Complications

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

- Verified by medical records to have been implanted and in-service, and
- Reported to have been removed from service,

- Modified to remedy the malfunction, or
- Left in service based on medical judgment.

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

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

- Failure to Capture
- Failure to Sense
- Oversensing
- Abnormal Pacing Impedance
- Abnormal Defibrillation Impedance
- Insulation Breach
- Conductor Fracture
- Lead Dislodgement
- Extracardiac Stimulation
- Cardiac Perforation
- Other

Survival Probability Estimates

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

Cumulative Survival Probability Estimates

The survival probability over a device's service time is the cumulative survival probability. It is calculated from all discrete survival probabilities of

previous time intervals. This characteristic is calculated separately for malfunction-free survival and all-cause survival (including normal battery depletions). Specific populations that are subject to a safety advisory notification are excluded and shown separately.

Implanted Devices

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

Active Implants

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

Underreporting

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

Safety Advisory Notifications

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



Methodology for Pacemaker and ICD Survival Estimates

2. Methodology for Pacemaker and ICD Survival Estimates

2.1 Cumulative Survival Probability

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

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

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

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

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

2.2 Data Acquisition

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

In order to be included in the population under observation, a device must be registered and implanted for at least one calendar day. The cutoff date for the data included in this report is December 31, 2018. The number of U.S. devices that are implanted and remain active as well as the total number of products distributed worldwide are provided for each product family in this report. Information is provided for separate

product families, in that devices with nearly identical hardware and therapy functions are combined. For example, Lexos VR and VR-T (with Home Monitoring) ICDs are combined into a single family, Lexos Single Chamber ICDs.

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

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

2.3 Returned Product Analysis

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

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

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

2.4 Product Performance Graphs and Data

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

For each product, the report provides:

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

The survival plots provide:

1. Total Survival

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

2. Malfunction-Free Survival

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

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

The cumulative survival data and the 95% confidence intervals according to the Greenwood's Formula¹ are shown in numerical form for the observed population.

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

Performance of BIOTRONIK Pacemakers

- 3.1 Single-Chamber Pacemakers
- 3.2 Dual-Chamber Pacemakers
- 3.3 CRT Pacemakers

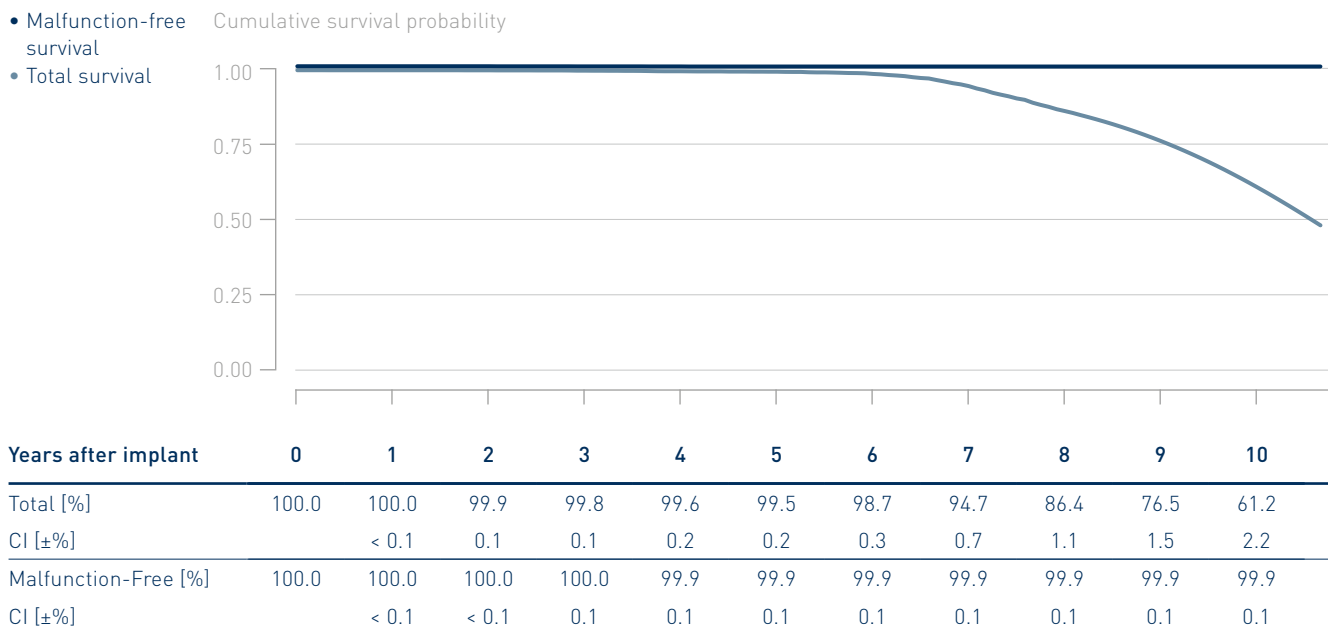


3.1 Single-Chamber Pacemakers

Cylos and Cylos 990

Product Versions* _____	VR
NBG Codes _____	VVIR
US Market Release _____	Jan 2006
CE Market Release _____	Nov 2005 / Mar 2008
Worldwide Distributed Devices _____	25 900
Registered U.S. Implants _____	6 150
Estimated Active U.S. Implants _____	2 730
U.S. Normal Battery Depletions _____	702

	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

3.1 Single-Chamber Pacemakers

Edora 8

Product Versions _____	SR, SR-T
NBG Codes _____	VVIR
US Market Release _____	May 2017
CE Market Release _____	Sep 2016
Worldwide Distributed Devices _____	13 200
Registered U.S. Implants _____	2 180
Estimated Active U.S. Implants _____	2 070
U.S. Normal Battery Depletions _____	0

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



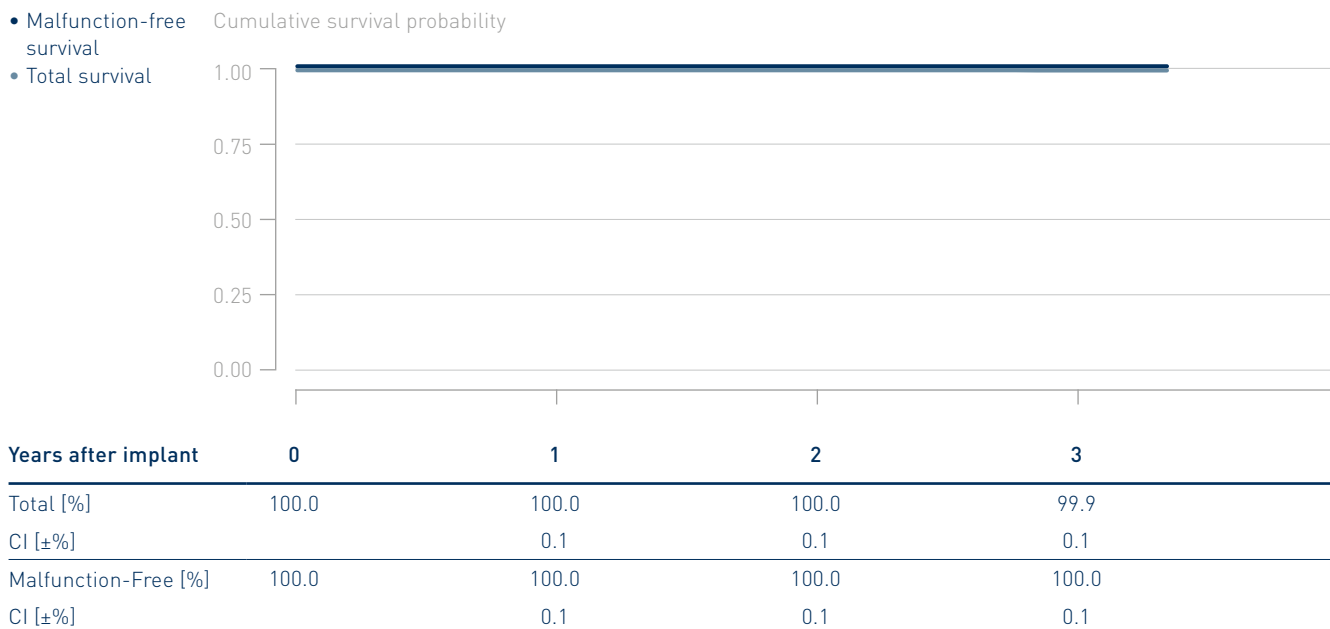
Years after implant	0	1
Total [%]	100.0	100.0
CI [±%]		0.1
Malfunction-Free [%]	100.0	100.0
CI [±%]		0.1

3.1 Single-Chamber Pacemakers

Eluna 8

Product Versions _____	SR, SR-T
NBG Codes _____	AAIR, WIR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	19 500
Registered U.S. Implants _____	5 550
Estimated Active U.S. Implants _____	4 770
U.S. Normal Battery Depletions _____	1

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

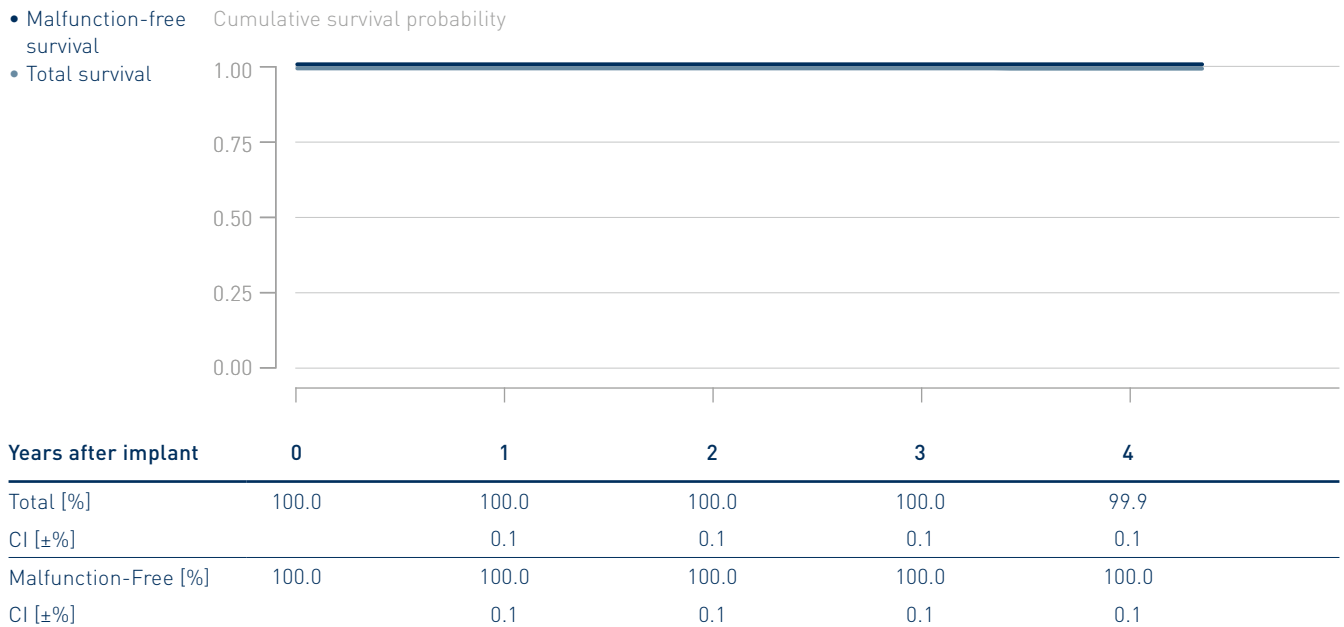


3.1 Single-Chamber Pacemakers

Entovis

Product Versions _____	SR, SR-T
NBG Codes _____	AAIR, VVIR
US Market Release _____	Jun 2010
CE Market Release _____	Nov 2009
Worldwide Distributed Devices _____	28 100
Registered U.S. Implants _____	2400
Estimated Active U.S. Implants _____	1870
U.S. Normal Battery Depletions _____	1

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

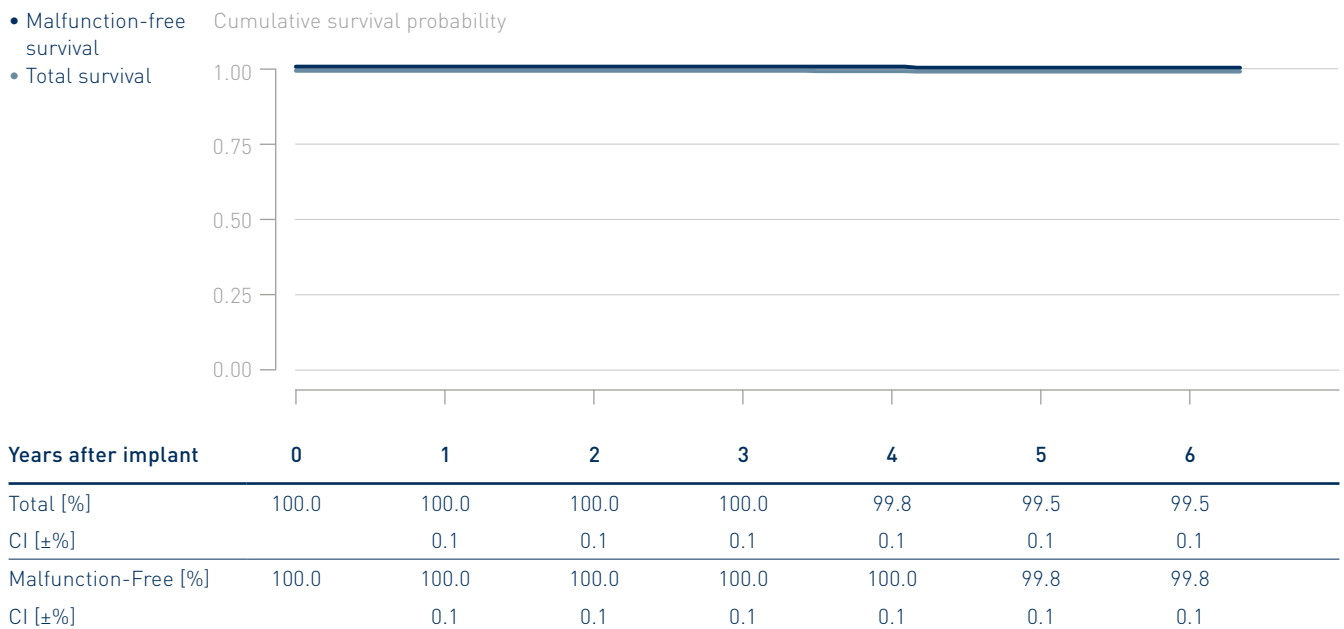


3.1 Single-Chamber Pacemakers

Estella

Product Versions _____	SR, SR-T
NBG Codes _____	AAIR, WIR
US Market Release _____	Feb 2011
CE Market Release _____	Feb 2011
Worldwide Distributed Devices _____	32800
Registered U.S. Implants _____	610
Estimated Active U.S. Implants _____	420
U.S. Normal Battery Depletions _____	1

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

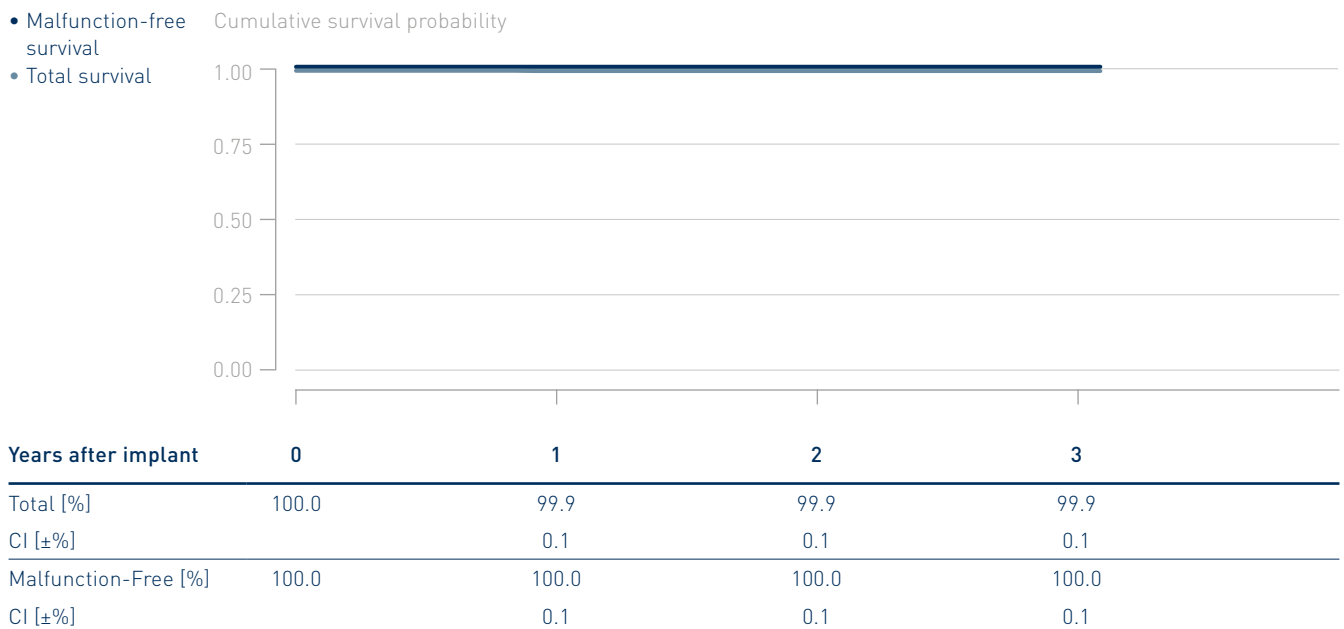


3.1 Single-Chamber Pacemakers

Etrinsa 8

Product Versions _____	SR-T
NBG Codes _____	AAIR, WIR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	18600
Registered U.S. Implants _____	1660
Estimated Active U.S. Implants _____	1420
U.S. Normal Battery Depletions _____	1

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

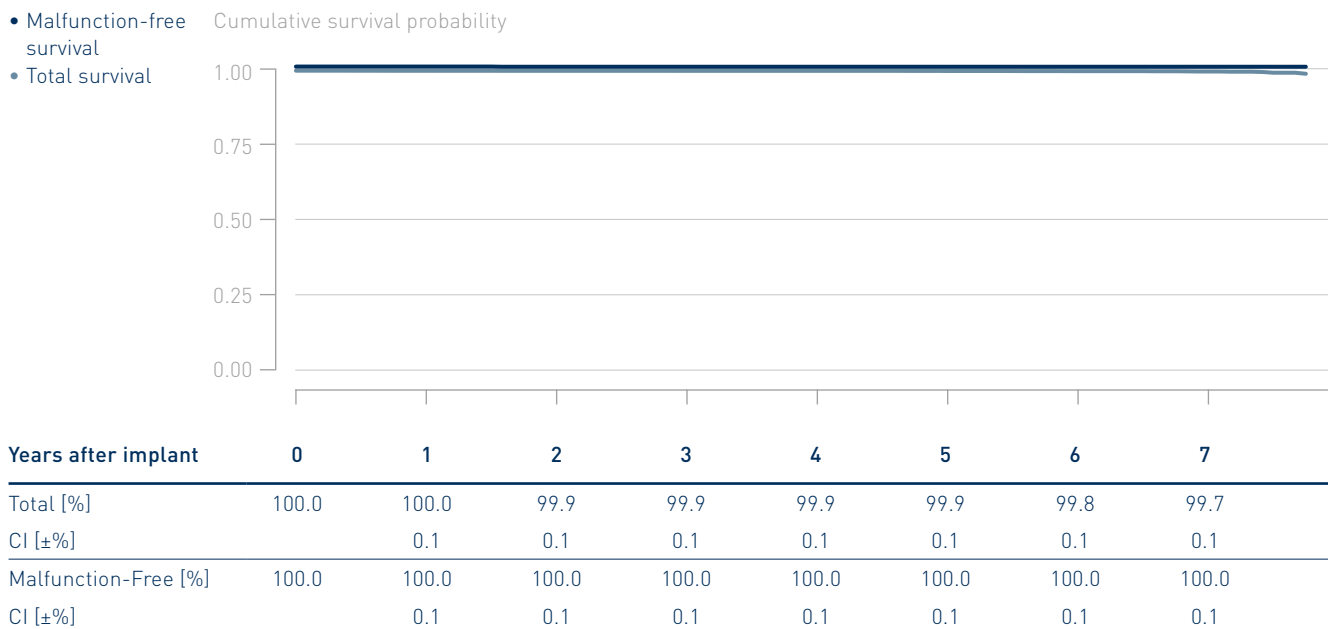


3.1 Single-Chamber Pacemakers

Evia

Product Versions _____	SR, SR-T
NBG Codes _____	AAIR, WIR
US Market Release _____	May 2010
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	60 000
Registered U.S. Implants _____	12 000
Estimated Active U.S. Implants _____	8 360
U.S. Normal Battery Depletions _____	23

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

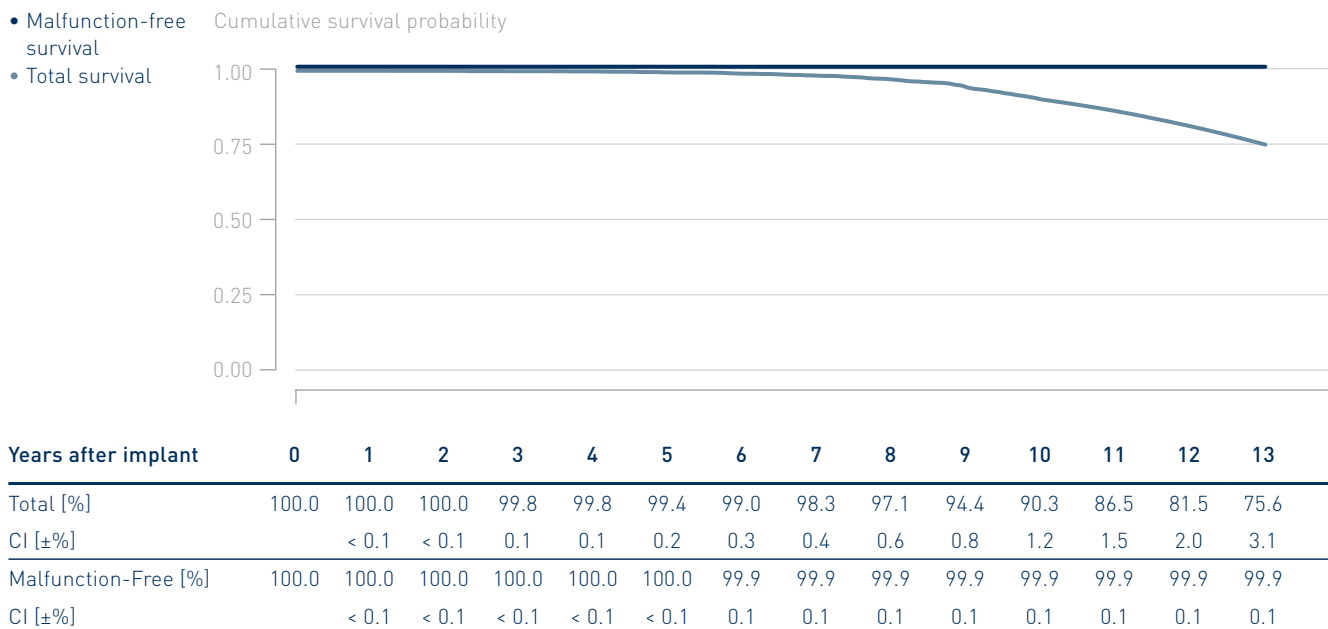


3.1 Single-Chamber Pacemakers

Philos II and Talos

Product Versions* _____	S, SR
NBG Codes _____	SSI, SSIR
US Market Release _____	Sep 2004
CE Market Release _____	Feb 2004 / May 2006
Worldwide Distributed Devices _____	215 000
Registered U.S. Implants _____	5 240
Estimated Active U.S. Implants _____	2 620
U.S. Normal Battery Depletions _____	300

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



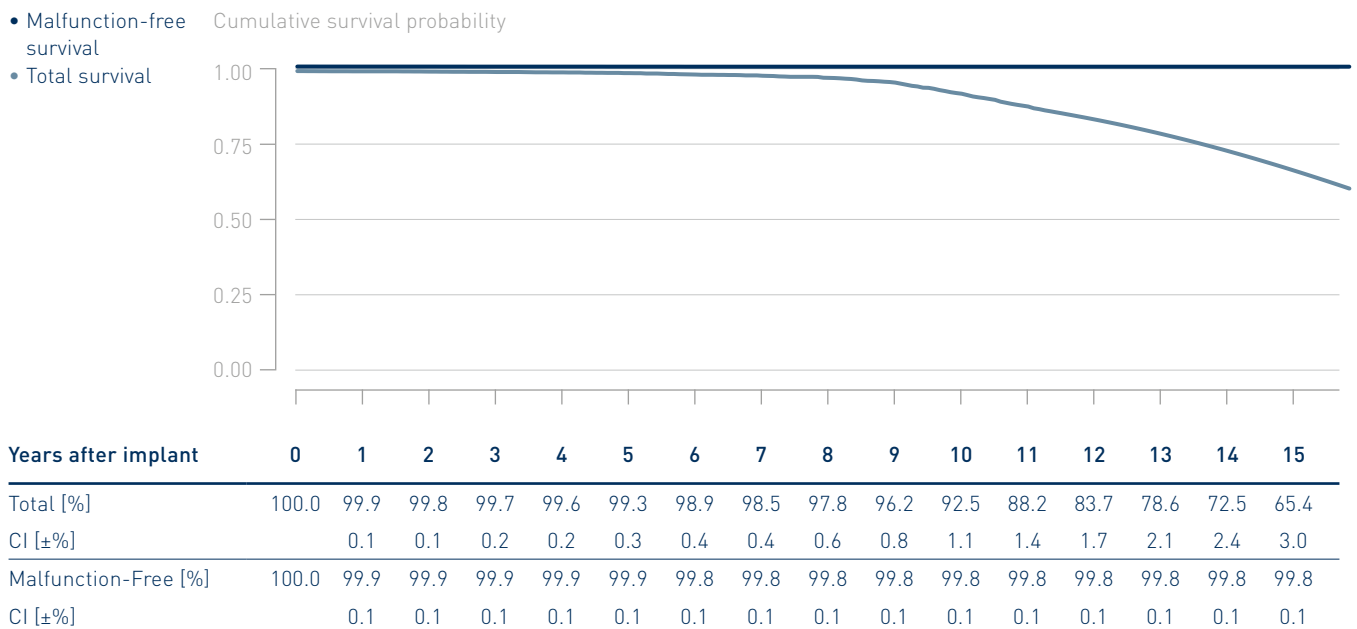
* While Talos SR and Talos S are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products

3.1 Single-Chamber Pacemakers

Philos

Product Versions _____	S, SR
NBG Codes _____	SSI, SSIR
US Market Release _____	Sep 2000
CE Market Release _____	Aug 2000
Worldwide Distributed Devices _____	109 000
Registered U.S. Implants _____	5 780
Estimated Active U.S. Implants _____	1 530
U.S. Normal Battery Depletions _____	274

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

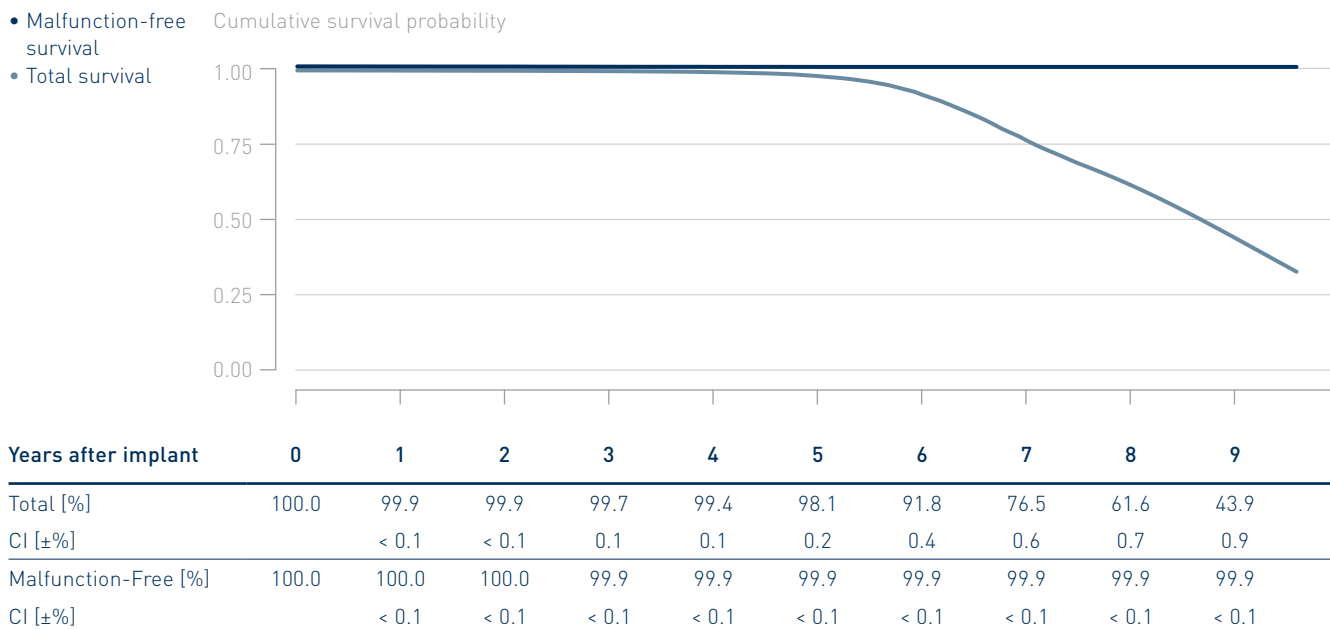


3.2 Dual-Chamber Pacemakers

Cylos and Cylos 990

Product Versions* _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Jan 2006
CE Market Release _____	Nov 2005 / Mar 2008
Worldwide Distributed Devices _____	81 300
Registered U.S. Implants _____	30 400
Estimated Active U.S. Implants _____	8 570
U.S. Normal Battery Depletions _____	7 360

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



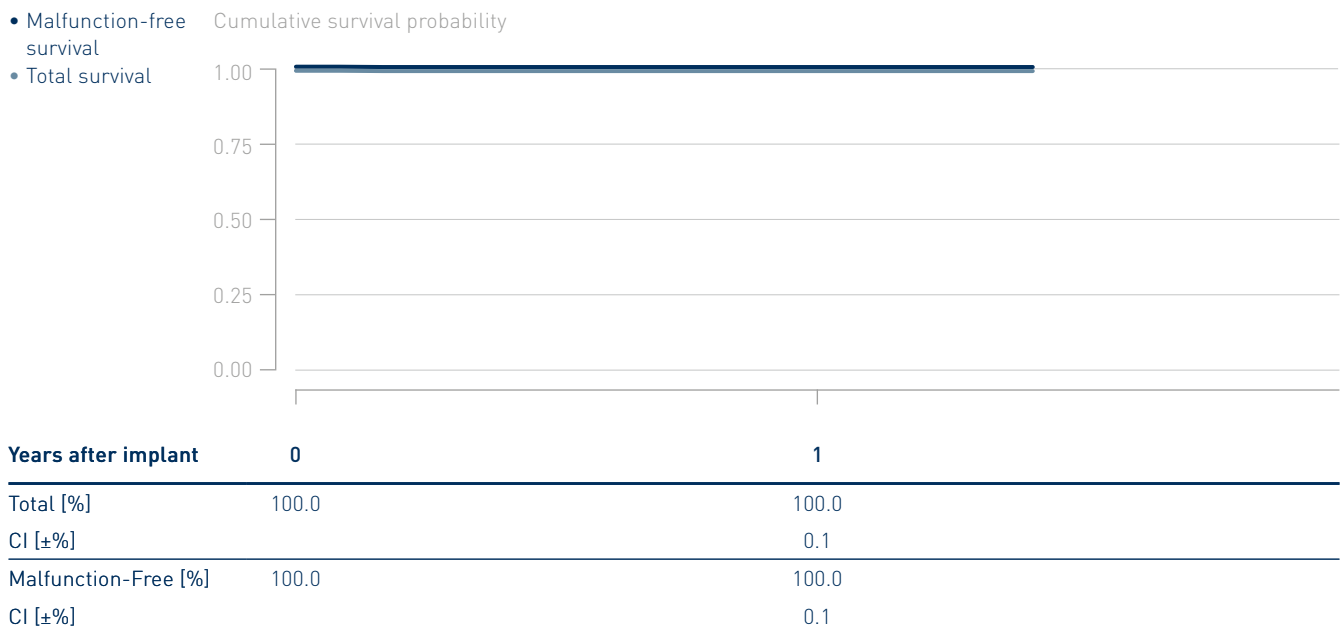
*While Cylos 990 DR and Cylos 990 DR-T are not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products

3.2 Dual-Chamber Pacemakers

Edora 8

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	May 2017
CE Market Release _____	Jul 2016
Worldwide Distributed Devices _____	63300
Registered U.S. Implants _____	20400
Estimated Active U.S. Implants _____	19500
U.S. Normal Battery Depletions _____	0

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

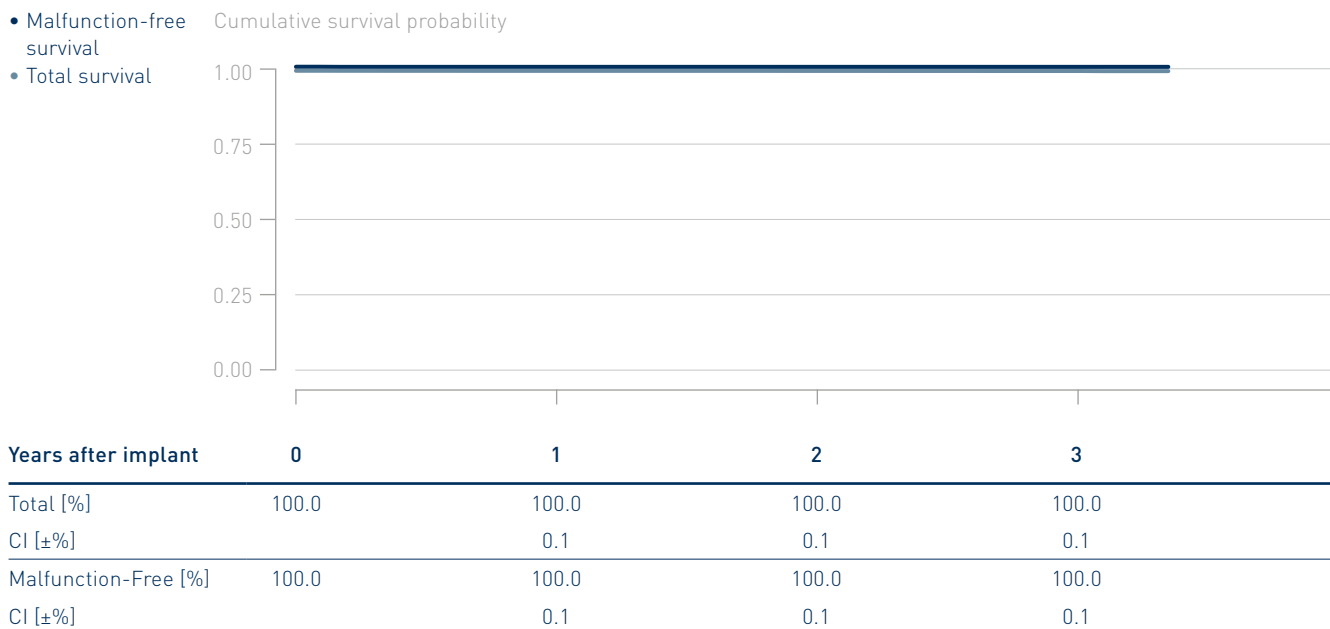


3.2 Dual-Chamber Pacemakers

Eluna 8

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	91 600
Registered U.S. Implants _____	38 600
Estimated Active U.S. Implants _____	33 500
U.S. Normal Battery Depletions _____	11

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

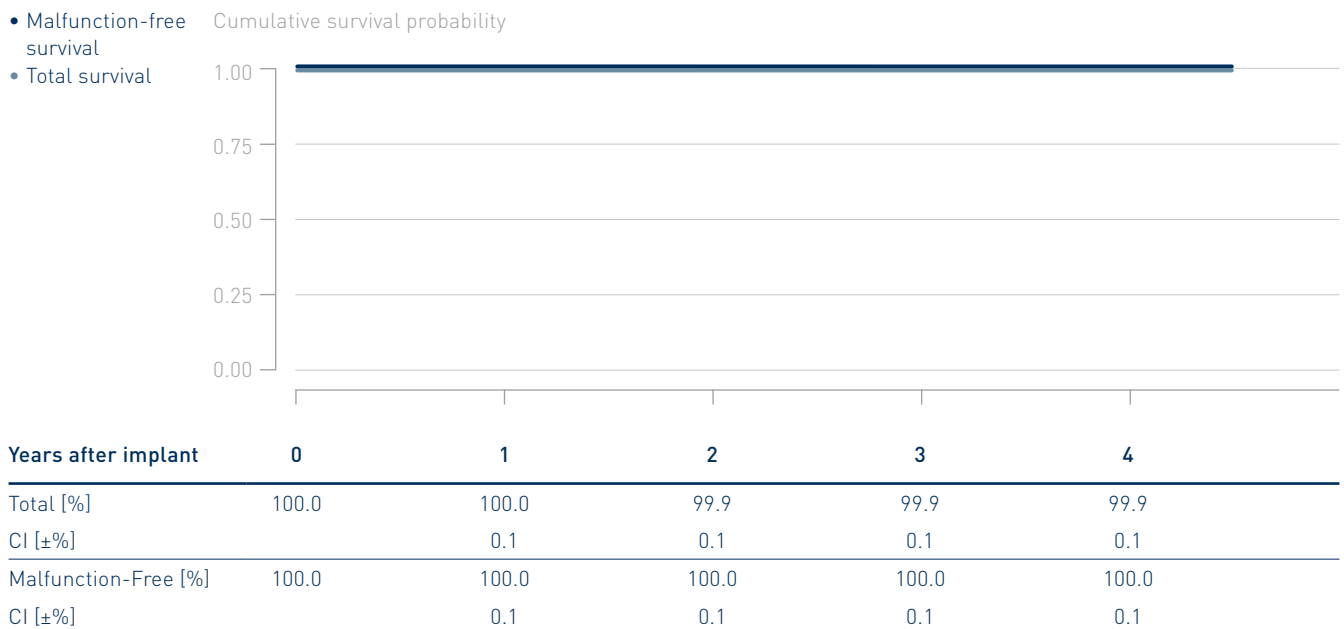


3.2 Dual-Chamber Pacemakers

Entovis

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Feb 2010
CE Market Release _____	Nov 2009
Worldwide Distributed Devices _____	106 000
Registered U.S. Implants _____	12 200
Estimated Active U.S. Implants _____	9 500
U.S. Normal Battery Depletions _____	9

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

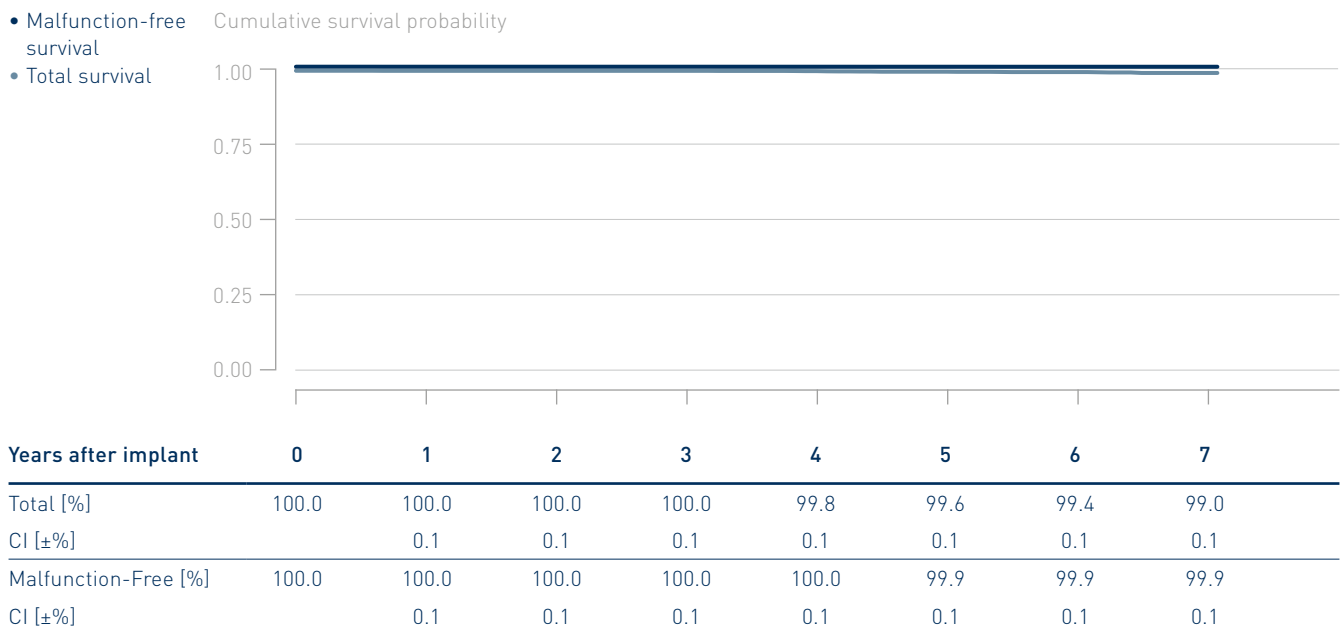


3.2 Dual-Chamber Pacemakers

Estella

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	Feb 2011
CE Market Release _____	Feb 2011
Worldwide Distributed Devices _____	35 800
Registered U.S. Implants _____	2 950
Estimated Active U.S. Implants _____	2 060
U.S. Normal Battery Depletions _____	14

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

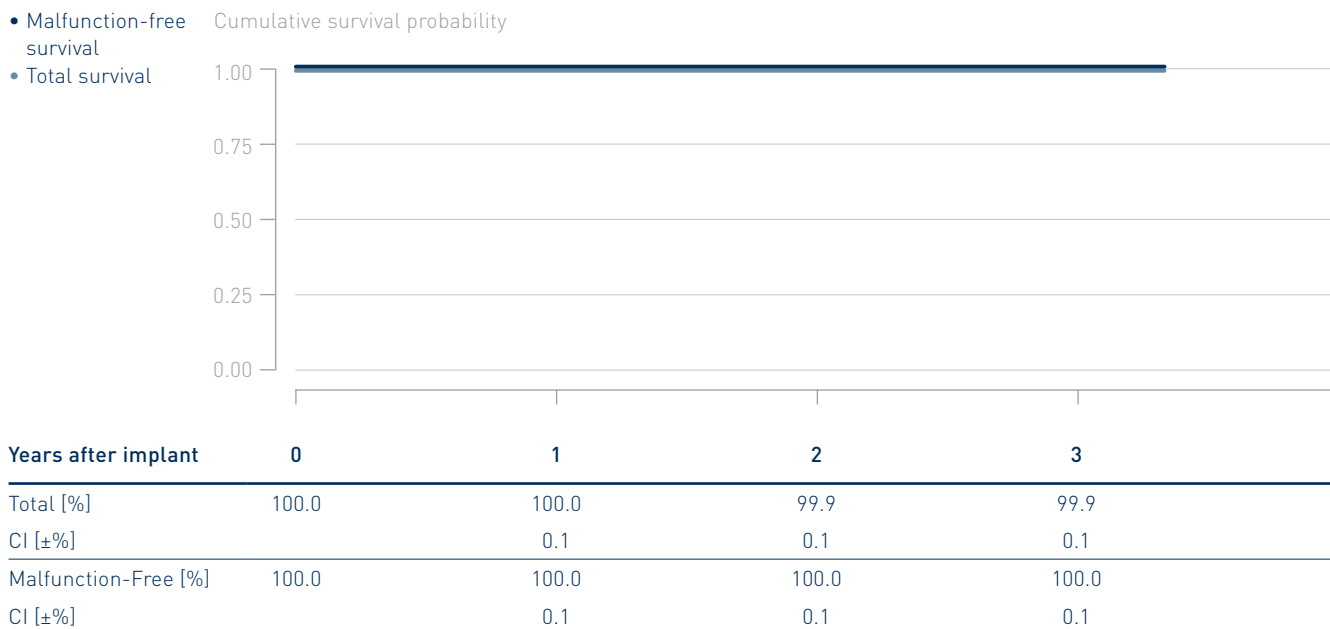


3.2 Dual-Chamber Pacemakers

Etrinsa 8

Product Versions _____	DR-T
NBG Codes _____	DDDR
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	76 600
Registered U.S. Implants _____	11 400
Estimated Active U.S. Implants _____	10 100
U.S. Normal Battery Depletions _____	5

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

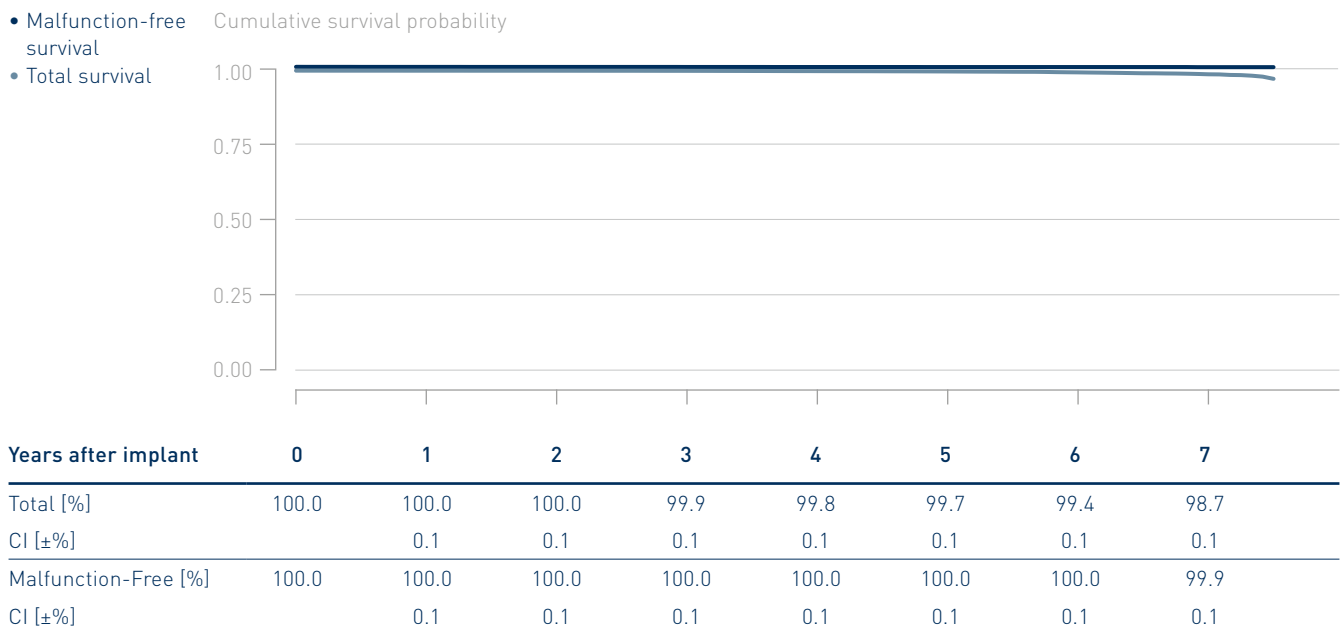


3.2 Dual-Chamber Pacemakers

Evia

Product Versions _____	DR, DR-T
NBG Codes _____	DDDR
US Market Release _____	May 2010
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	206 000
Registered U.S. Implants _____	61 900
Estimated Active U.S. Implants _____	43 700
U.S. Normal Battery Depletions _____	304

	Quantity	Rate
U.S. Confirmed Malfunctions _____	25	0.04%
Therapy Compromised _____	10	0.02%
Therapy Available _____	15	0.02%

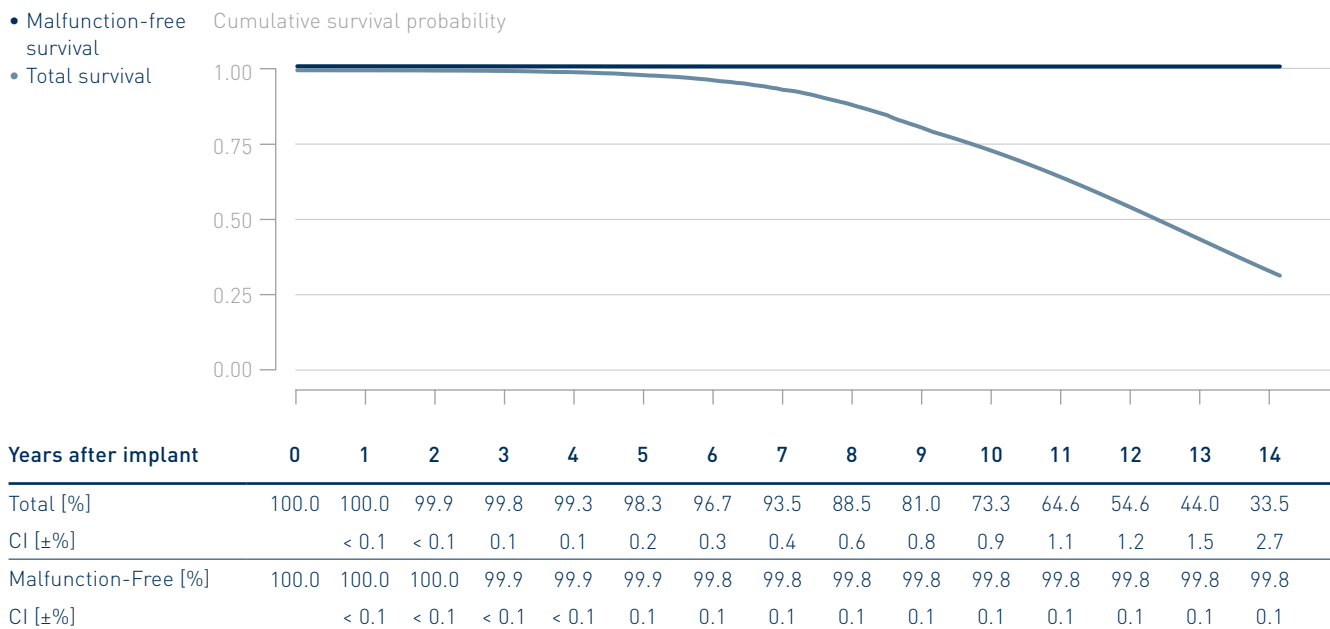


3.2 Dual-Chamber Pacemakers

Philos

Product Versions _____	D, DR, DR-T, SLR
NBG Codes _____	DDD, DDDR, VDDR
US Market Release _____	Sep 2000
CE Market Release _____	Aug 2000
Worldwide Distributed Devices _____	172 000
Registered U.S. Implants _____	20 700
Estimated Active U.S. Implants _____	5 140
U.S. Normal Battery Depletions _____	2 617

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

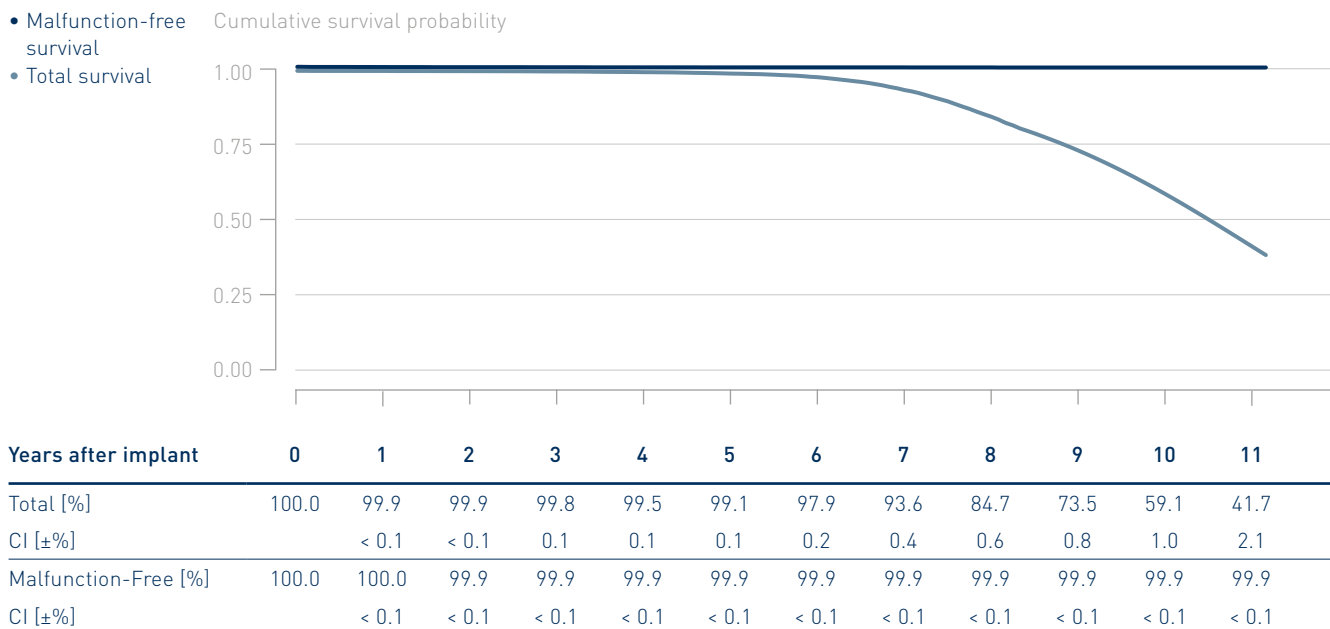


3.2 Dual-Chamber Pacemakers

Philos II and Talos

Product Versions* _____	D, DR, DR-T (Philos II only), SLR
NBG Codes _____	DDD, DDDR, VDDR
US Market Release _____	Sep 2004
CE Market Release _____	Feb 2004 / May 2006
Worldwide Distributed Devices _____	372 000
Registered U.S. Implants _____	23 200
Estimated Active U.S. Implants _____	7 960
U.S. Normal Battery Depletions _____	4 015

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



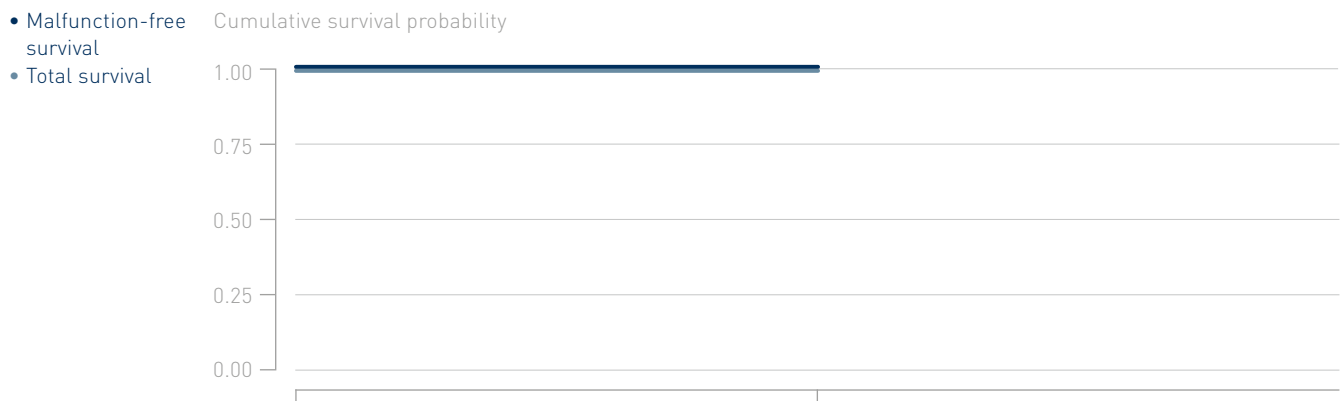
* While Philos II SLR, Talos D, Talos DR and Talos SLR are not distributed in the U.S., their performance is expected to be similar to the U.S. distributed products

3.3 CRT Pacemakers

Edora 8

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	DDDRV
US Market Release _____	Jun 2017
CE Market Release _____	Mar 2017
Worldwide Distributed Devices _____	4890
Registered U.S. Implants _____	1460
Estimated Active U.S. Implants _____	1350
U.S. Normal Battery Depletions _____	0

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



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

3.3 CRT Pacemakers

Etrinsa 8

Product Versions _____	HF-T
NBG Codes _____	DDDRV
US Market Release _____	Dec 2014
CE Market Release _____	Aug 2014
Worldwide Distributed Devices _____	8740
Registered U.S. Implants _____	1760
Estimated Active U.S. Implants _____	1360
U.S. Normal Battery Depletions _____	4

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



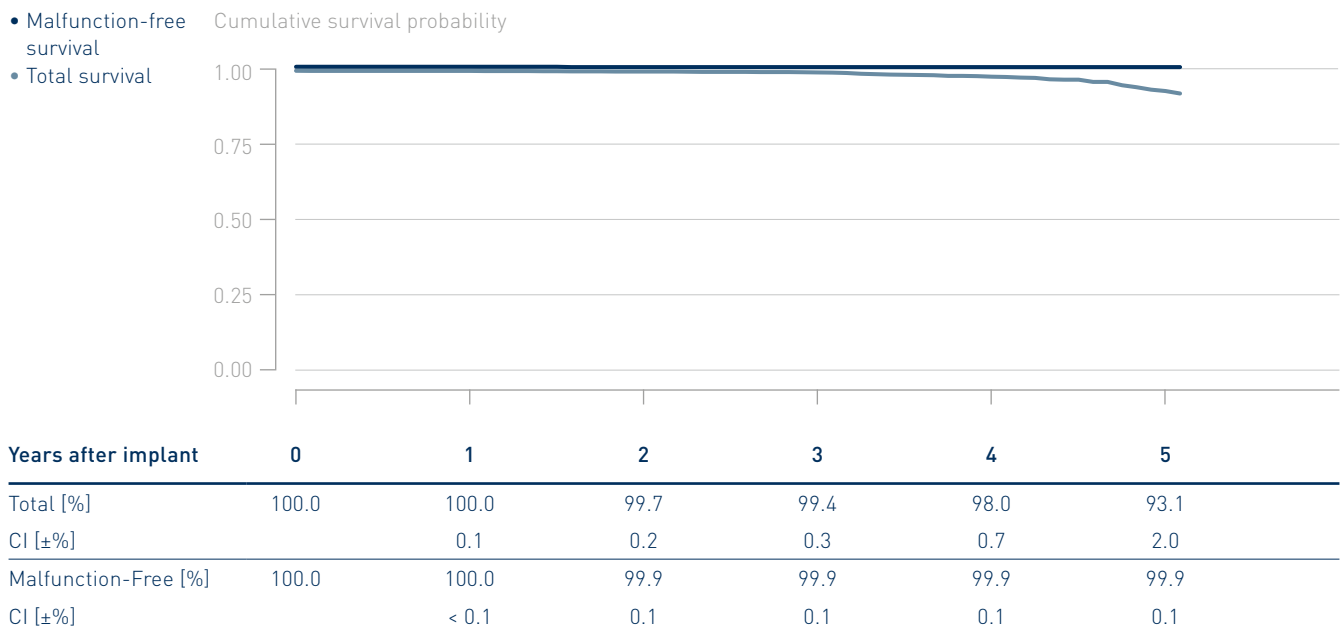
Years after implant	0	1	2
Total [%]	100.0	100.0	99.6
CI [±%]		0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]		0.1	0.1

3.3 CRT Pacemakers

Evia

Product Versions _____	HF, HF-T
NBG Codes _____	DDDRV
US Market Release _____	May 2010
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	8890
Registered U.S. Implants _____	2250
Estimated Active U.S. Implants _____	1270
U.S. Normal Battery Depletions _____	57

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

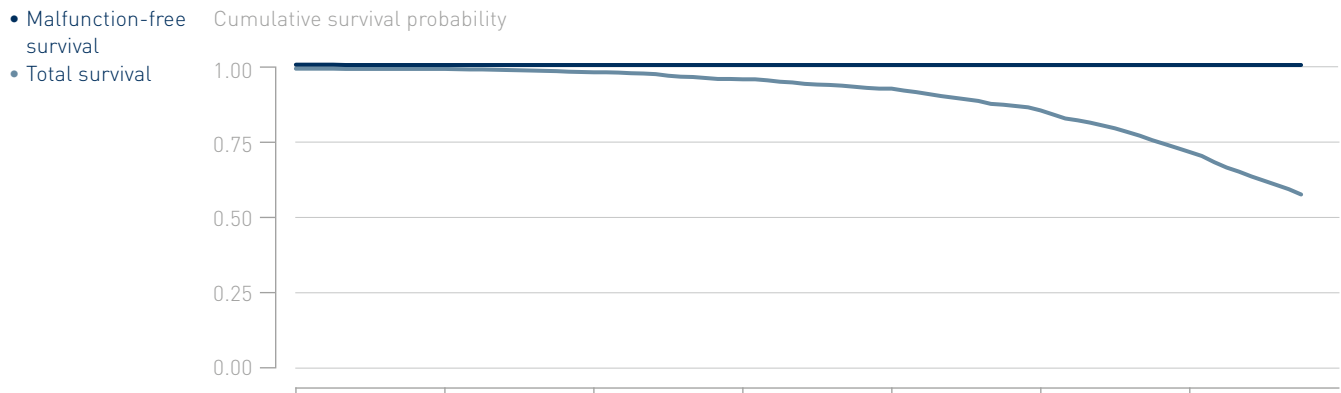


3.3 CRT Pacemakers

Stratos

Product Versions _____	LV, LV-T
NBG Codes _____	DDDRV
US Market Release _____	May 2008
CE Market Release _____	Nov 2002
Worldwide Distributed Devices _____	21 400
Registered U.S. Implants _____	1 310
Estimated Active U.S. Implants _____	269
U.S. Normal Battery Depletions _____	285

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



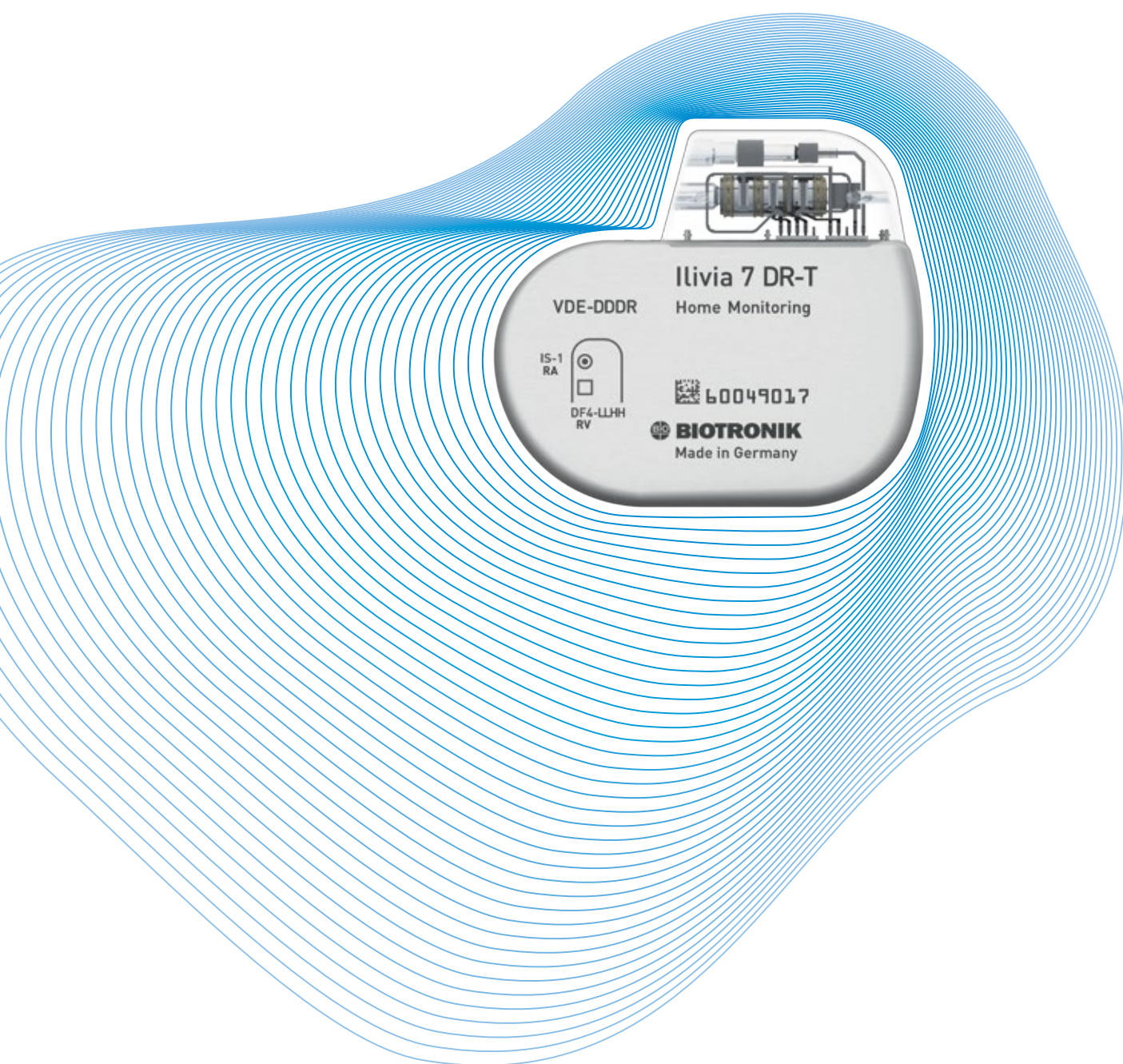
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	98.8	96.5	93.3	86.1	72.3
CI [±%]		0.2	0.7	1.2	1.6	2.4	3.4
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.9	99.9	99.9
CI [±%]		0.2	0.2	0.2	0.2	0.2	0.2

Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs

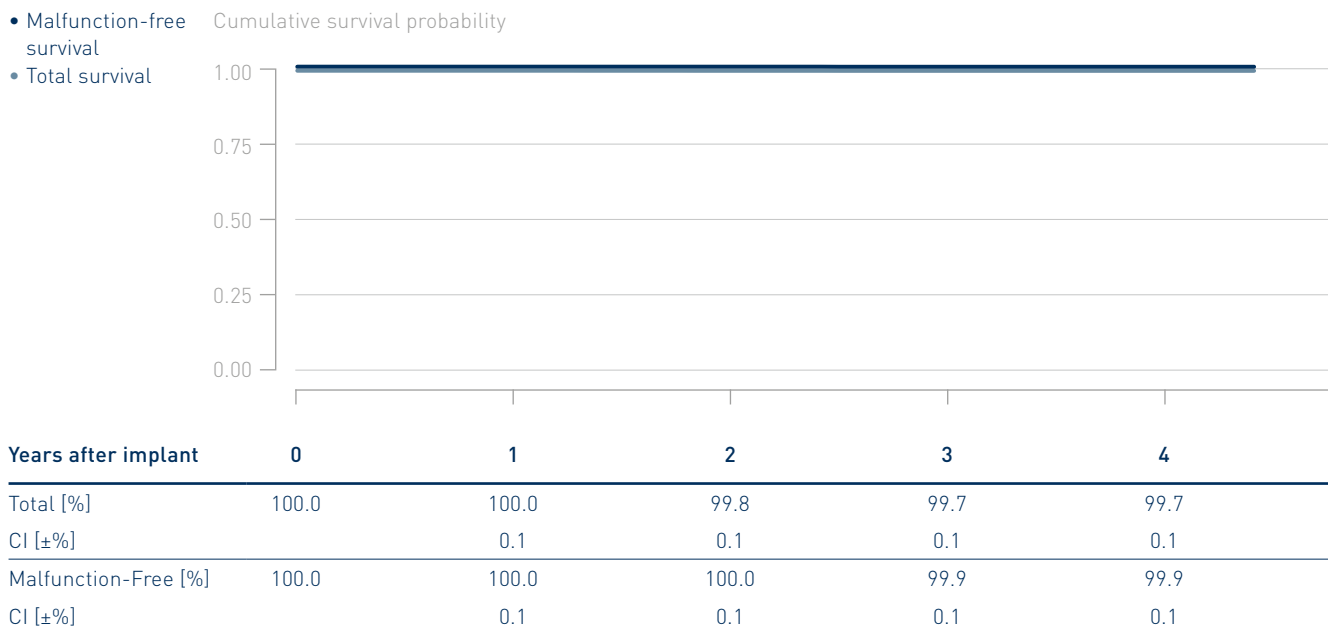


4.1 Single-Chamber ICDs

Ilesto 7

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2490
Registered U.S. Implants _____	1280
Estimated Active U.S. Implants _____	995
U.S. Normal Battery Depletions _____	2

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

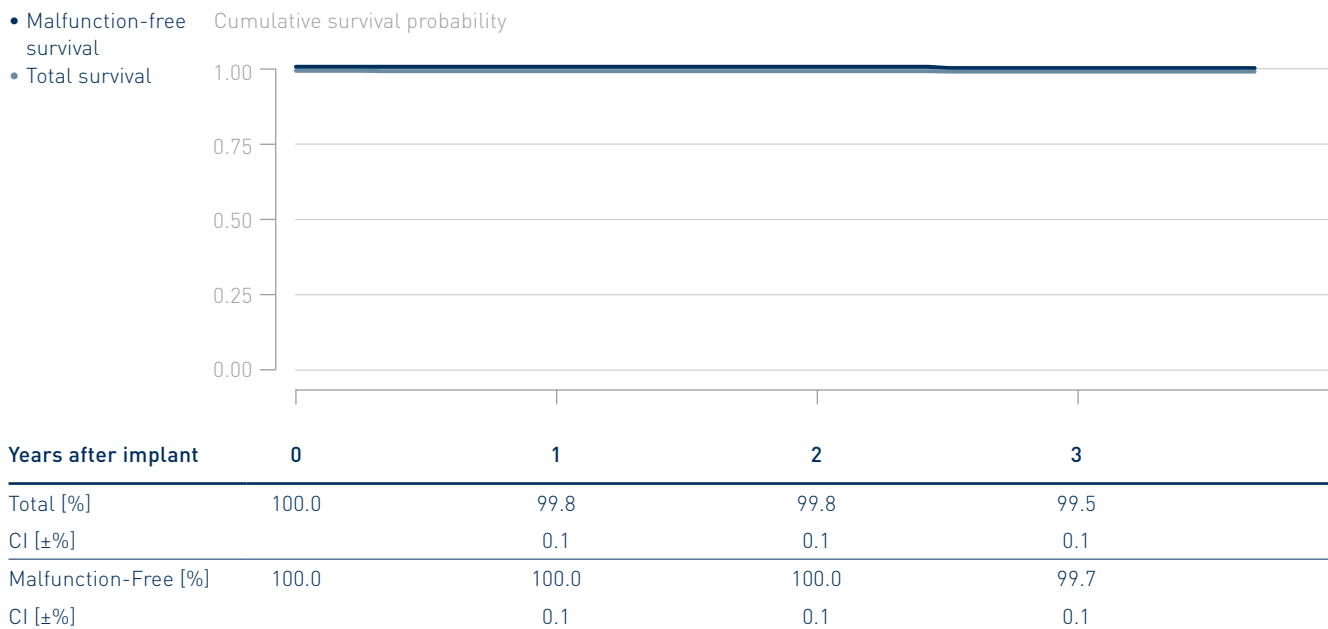


4.1 Single-Chamber ICDs

Ilesto 7 DF4

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2420
Registered U.S. Implants _____	466
Estimated Active U.S. Implants _____	365
U.S. Normal Battery Depletions _____	2

	Quantity	Rate
U.S. Confirmed Malfunctions _____	1	0.21%
Therapy Compromised _____	1	0.21%
Therapy Available _____	0	0.00%



4.1 Single-Chamber ICDs

Itrevia 7

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	1310
Registered U.S. Implants _____	618
Estimated Active U.S. Implants _____	540
U.S. Normal Battery Depletions _____	0

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



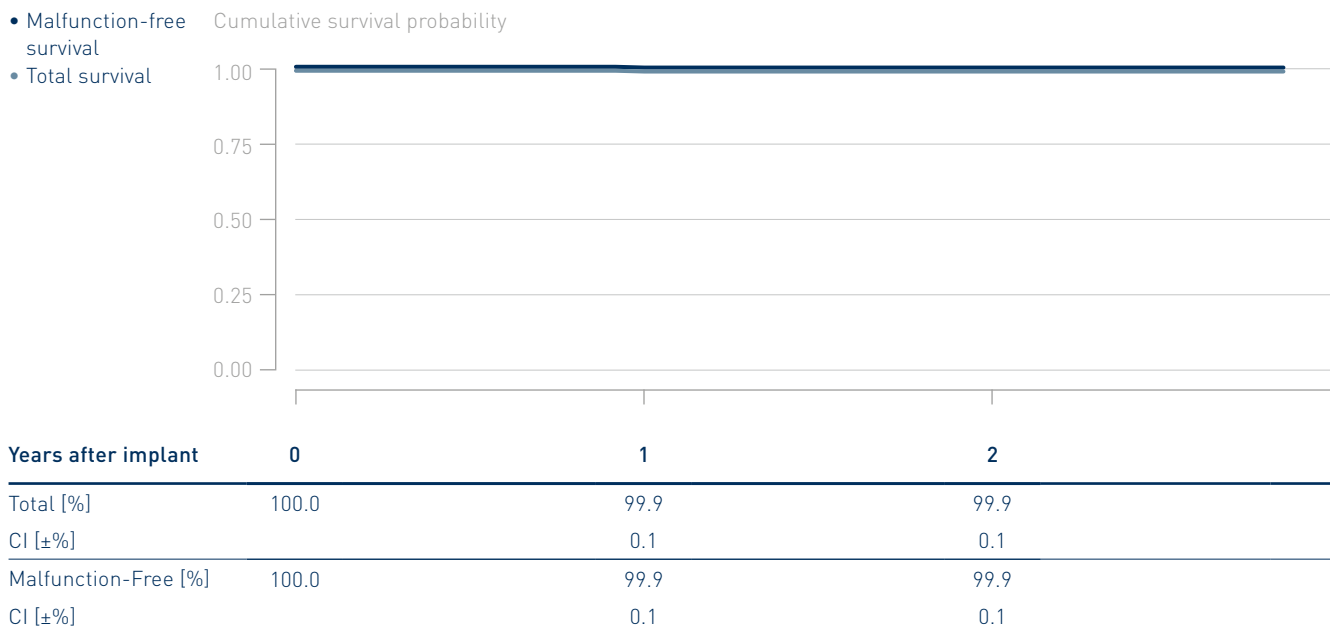
Years after implant	0	1	2
Total [%]	100.0	100.0	100.0
CI [±%]		0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]		0.1	0.1

4.1 Single-Chamber ICDs

Itrevia 7 DF4

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	1470
Registered U.S. Implants _____	804
Estimated Active U.S. Implants _____	680
U.S. Normal Battery Depletions _____	0

	Quantity	Rate
U.S. Confirmed Malfunctions _____	1	0.12%
Therapy Compromised _____	0	0.00%
Therapy Available _____	1	0.12%

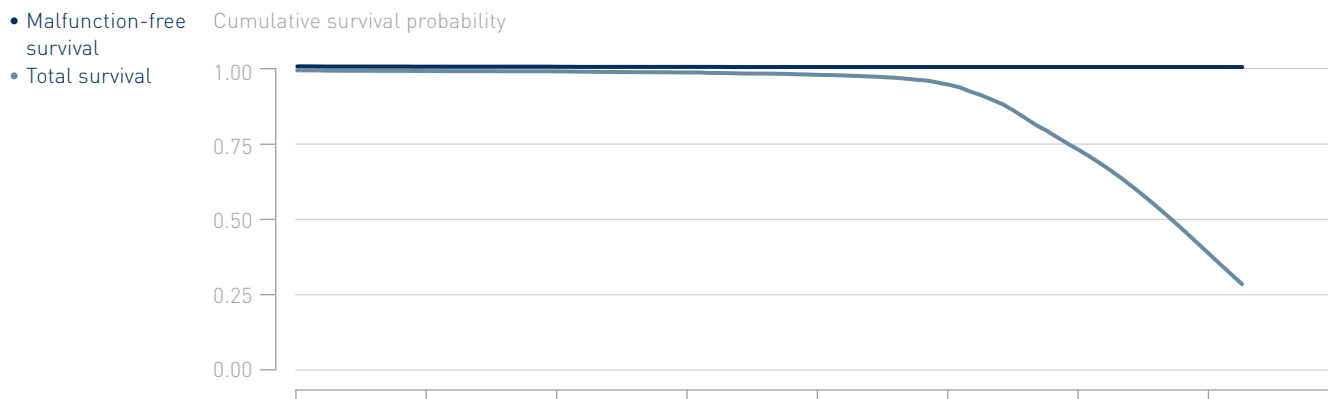


4.1 Single-Chamber ICDs

Lumax 340

Product Versions _____	VR, VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Feb 2007
CE Market Release _____	Feb 2007
Worldwide Distributed Devices _____	27 200
Registered U.S. Implants _____	3 990
Estimated Active U.S. Implants _____	1030
U.S. Normal Battery Depletions _____	765

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



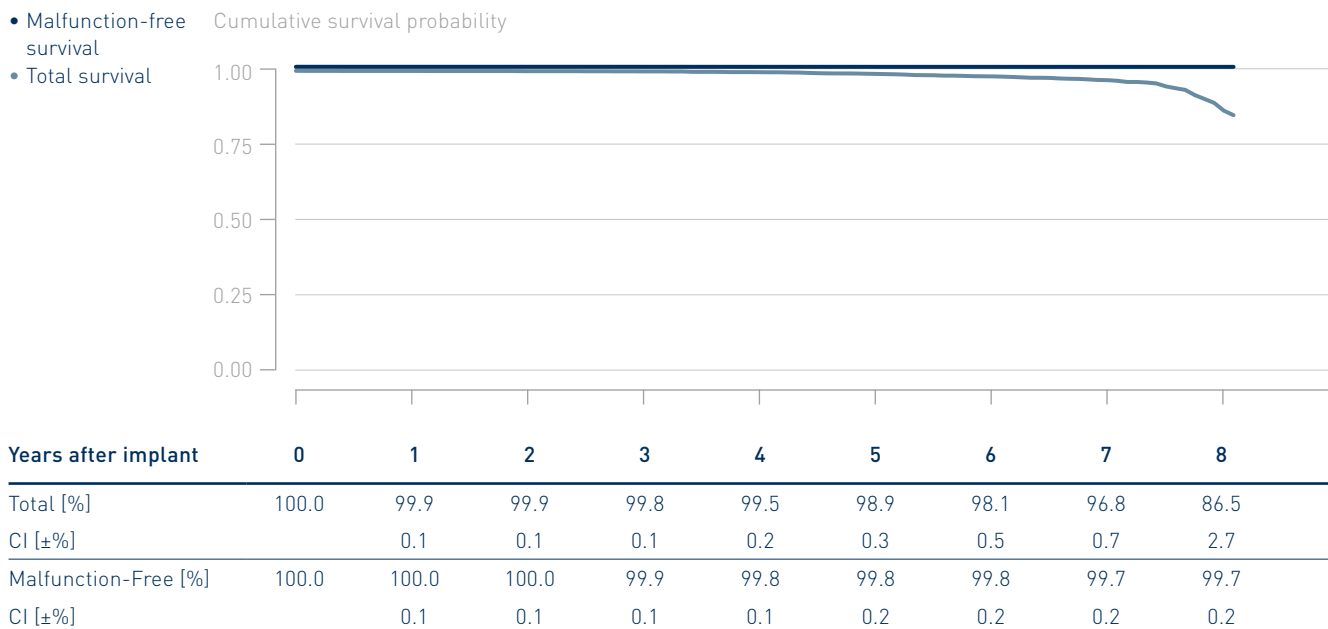
Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.8	99.6	99.3	98.5	95.2	73.4	38.7
CI [±%]		0.2	0.2	0.3	0.4	0.8	1.8	2.8
Malfunction-Free [%]	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
CI [±%]		0.1	0.1	0.1	0.1	0.1	0.1	0.1

4.1 Single-Chamber ICDs

Lumax 540

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	May 2009
CE Market Release _____	Jun 2008
Worldwide Distributed Devices _____	20 100
Registered U.S. Implants _____	4 550
Estimated Active U.S. Implants _____	2 530
U.S. Normal Battery Depletions _____	179

	Quantity	Rate
U.S. Confirmed Malfunctions _____	9	0.20%
Therapy Compromised _____	5	0.11%
Therapy Available _____	4	0.09%

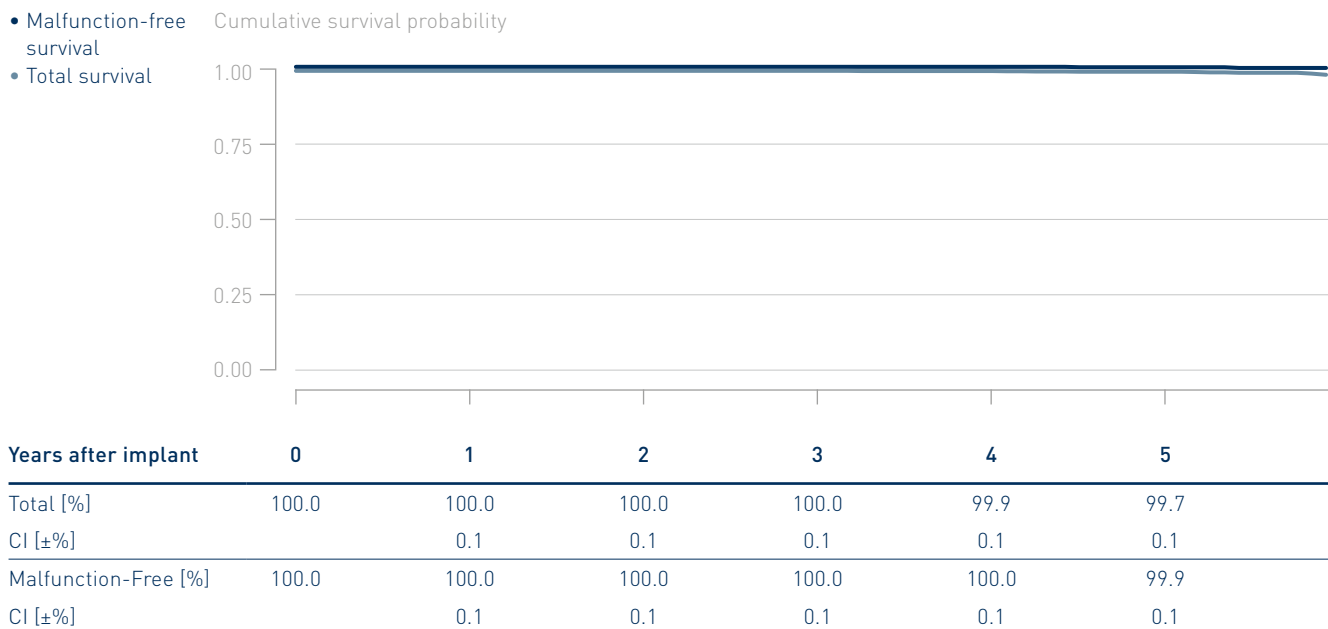


4.1 Single-Chamber ICDs

Lumax 740

Product Versions _____	VR-T
NBG Codes _____	VVE-VVIR
Maximum Energy J _____	40
US Market Release _____	Sep 2012
CE Market Release _____	Apr 2012
Worldwide Distributed Devices _____	4810
Registered U.S. Implants _____	1580
Estimated Active U.S. Implants _____	1090
U.S. Normal Battery Depletions _____	7

	Quantity	Rate
U.S. Confirmed Malfunctions _____	2	0.13%
Therapy Compromised _____	2	0.13%
Therapy Available _____	0	0.00%

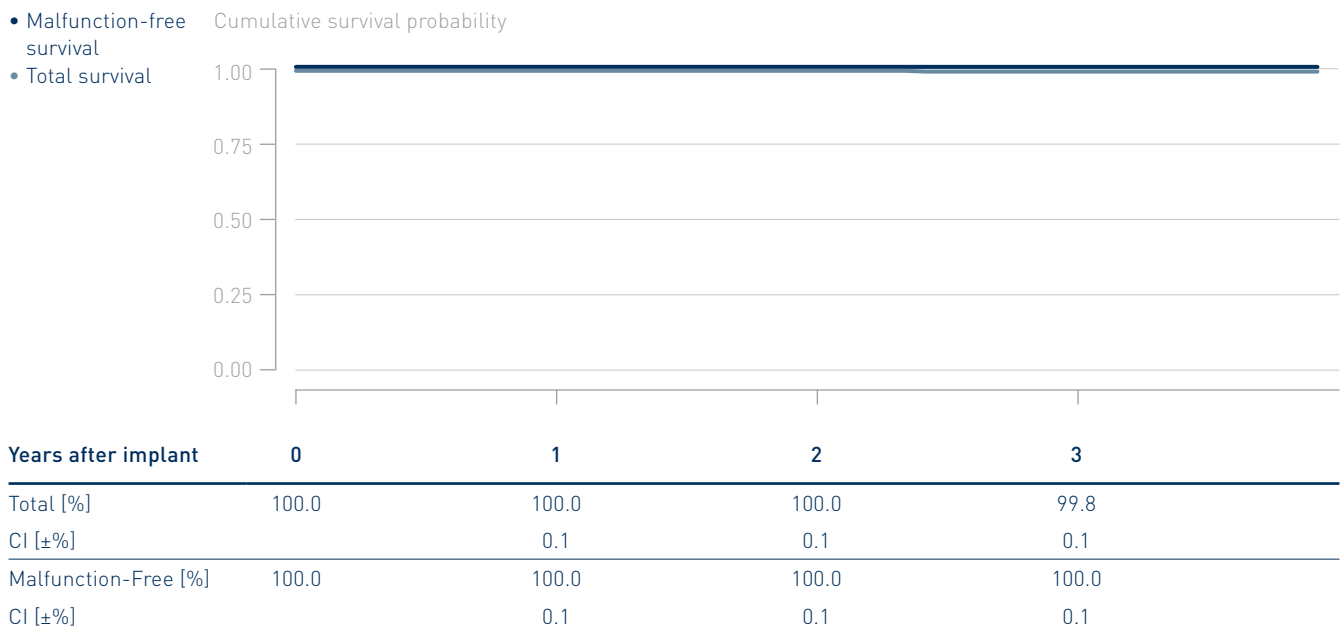


4.2 Dual-Chamber ICDs

Iforia 7

Product Versions _____	DR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	1240
Registered U.S. Implants _____	614
Estimated Active U.S. Implants _____	464
U.S. Normal Battery Depletions _____	1

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

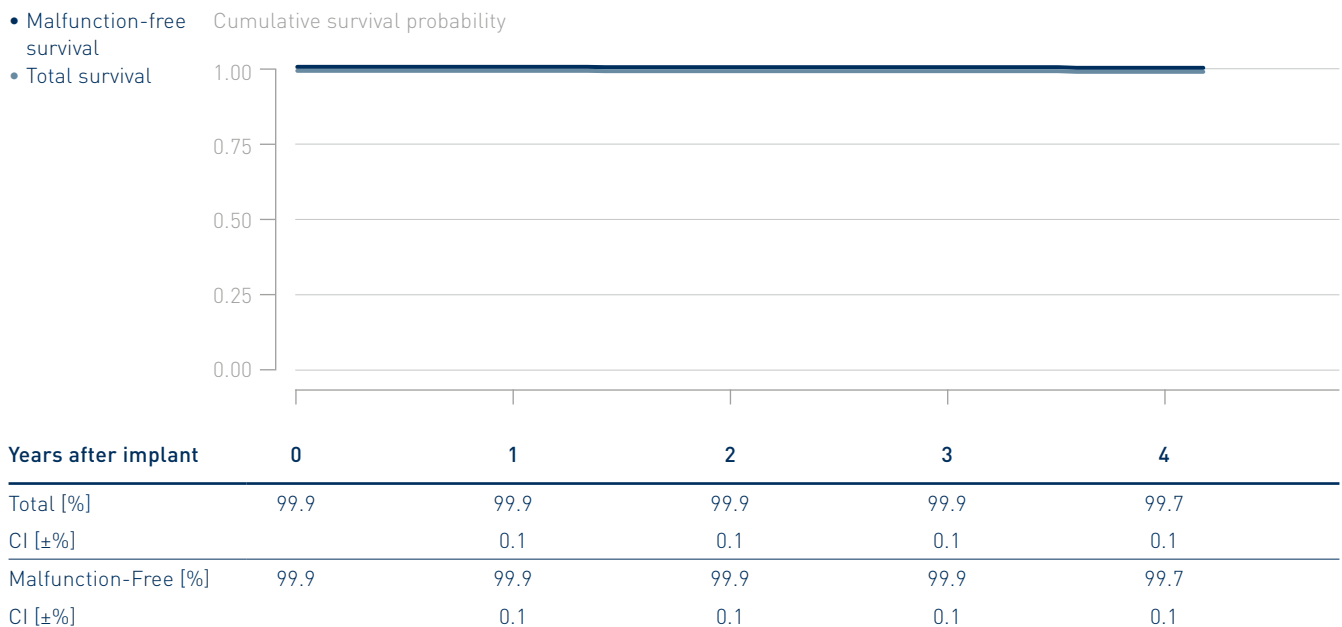


4.2 Dual-Chamber ICDs

Iforia 7 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2970
Registered U.S. Implants _____	1470
Estimated Active U.S. Implants _____	1140
U.S. Normal Battery Depletions _____	0

	Quantity	Rate
U.S. Confirmed Malfunctions _____	3	0.21%
Therapy Compromised _____	2	0.14%
Therapy Available _____	1	0.07%

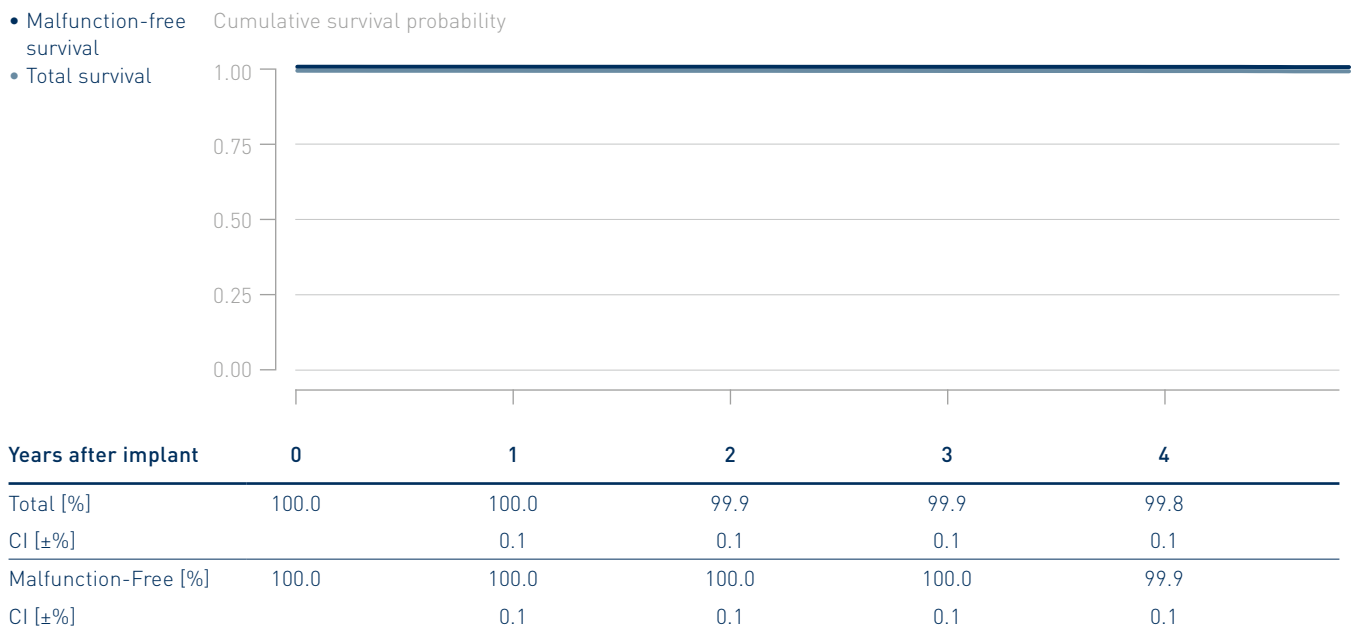


4.2 Dual-Chamber ICDs

Ilesto 7

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	45
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	5 140
Registered U.S. Implants _____	3 490
Estimated Active U.S. Implants _____	2 660
U.S. Normal Battery Depletions _____	3

	Quantity	Rate
U.S. Confirmed Malfunctions _____	5	0.14%
Therapy Compromised _____	4	0.11%
Therapy Available _____	1	0.03%

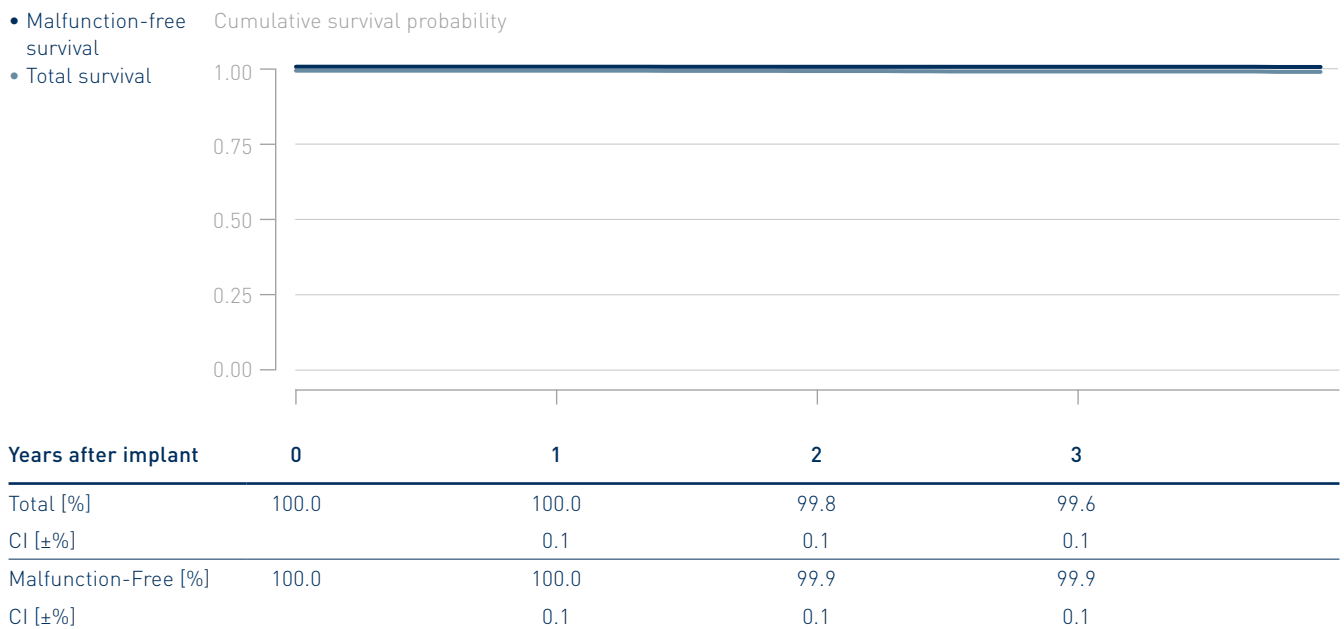


4.2 Dual-Chamber ICDs

Ilesto 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Jul 2014
CE Market Release _____	Jul 2013
Worldwide Distributed Devices _____	3780
Registered U.S. Implants _____	1150
Estimated Active U.S. Implants _____	913
U.S. Normal Battery Depletions _____	3

	Quantity	Rate
U.S. Confirmed Malfunctions _____	2	0.17%
Therapy Compromised _____	0	0.00%
Therapy Available _____	2	0.17%

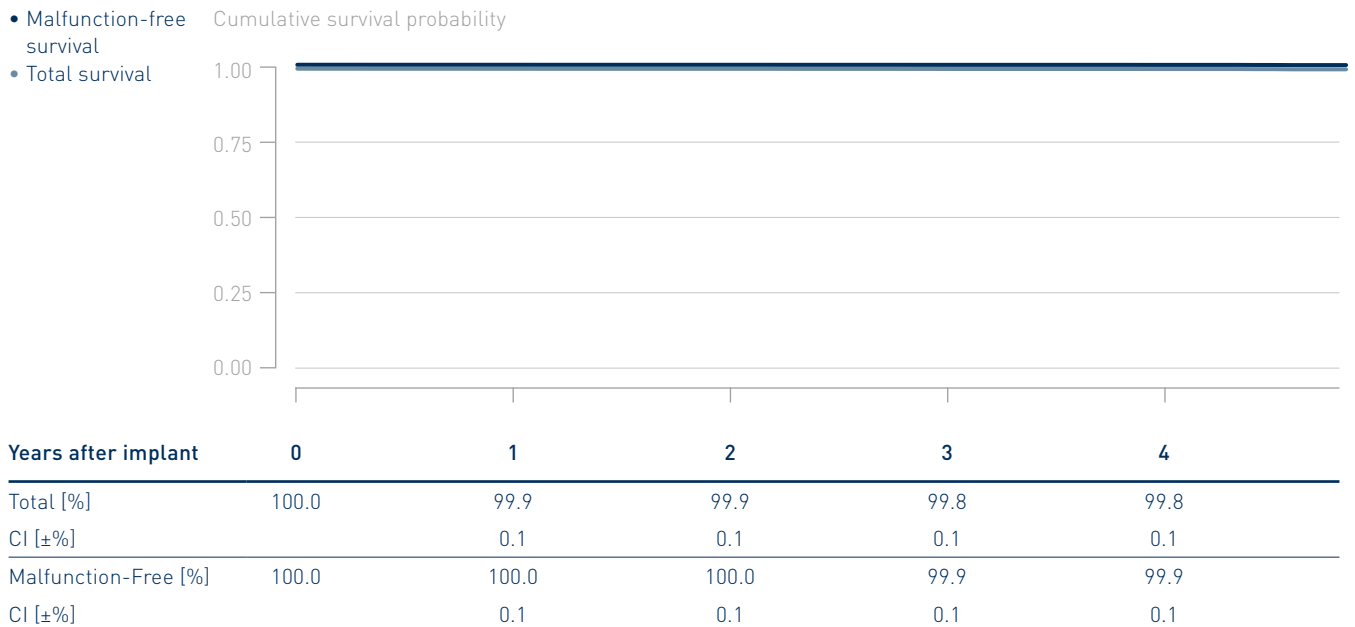


4.2 Dual-Chamber ICDs

Ilesto 7 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	6 620
Registered U.S. Implants _____	4 720
Estimated Active U.S. Implants _____	3 630
U.S. Normal Battery Depletions _____	6

	Quantity	Rate
U.S. Confirmed Malfunctions _____	7	0.15%
Therapy Compromised _____	4	0.08%
Therapy Available _____	3	0.06%

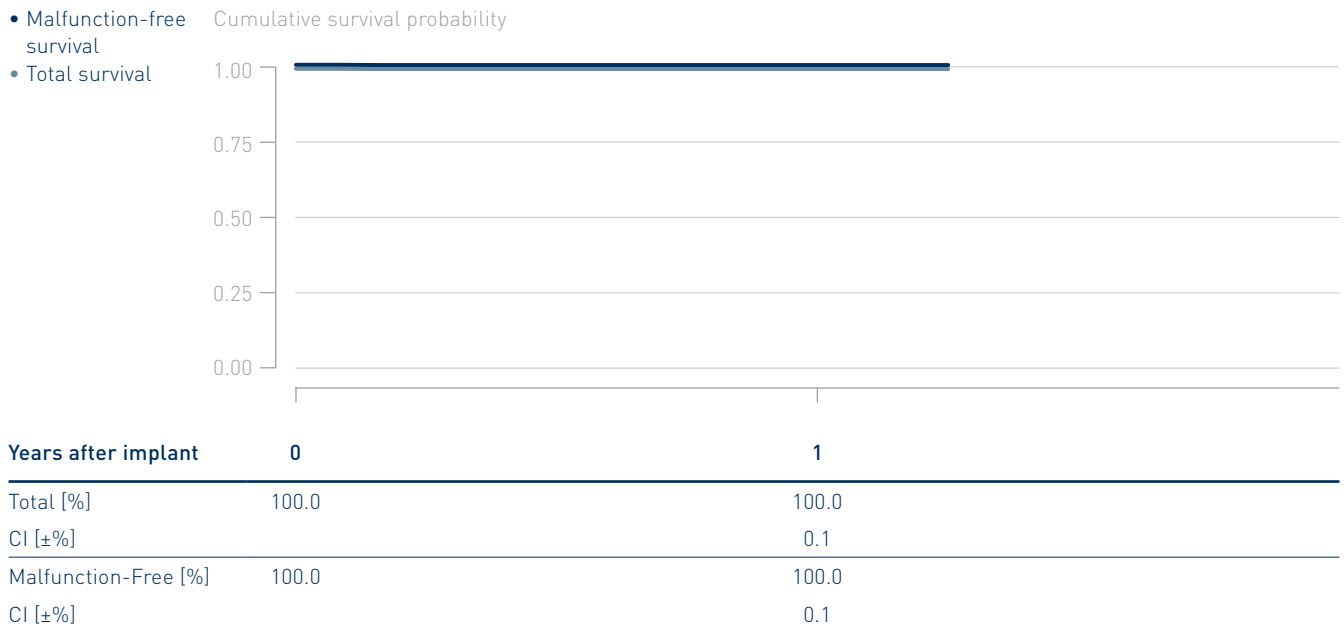


4.2 Dual-Chamber ICDs

Ilivia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Aug 2016
Worldwide Distributed Devices _____	6 700
Registered U.S. Implants _____	2 390
Estimated Active U.S. Implants _____	2 270
U.S. Normal Battery Depletions _____	0

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

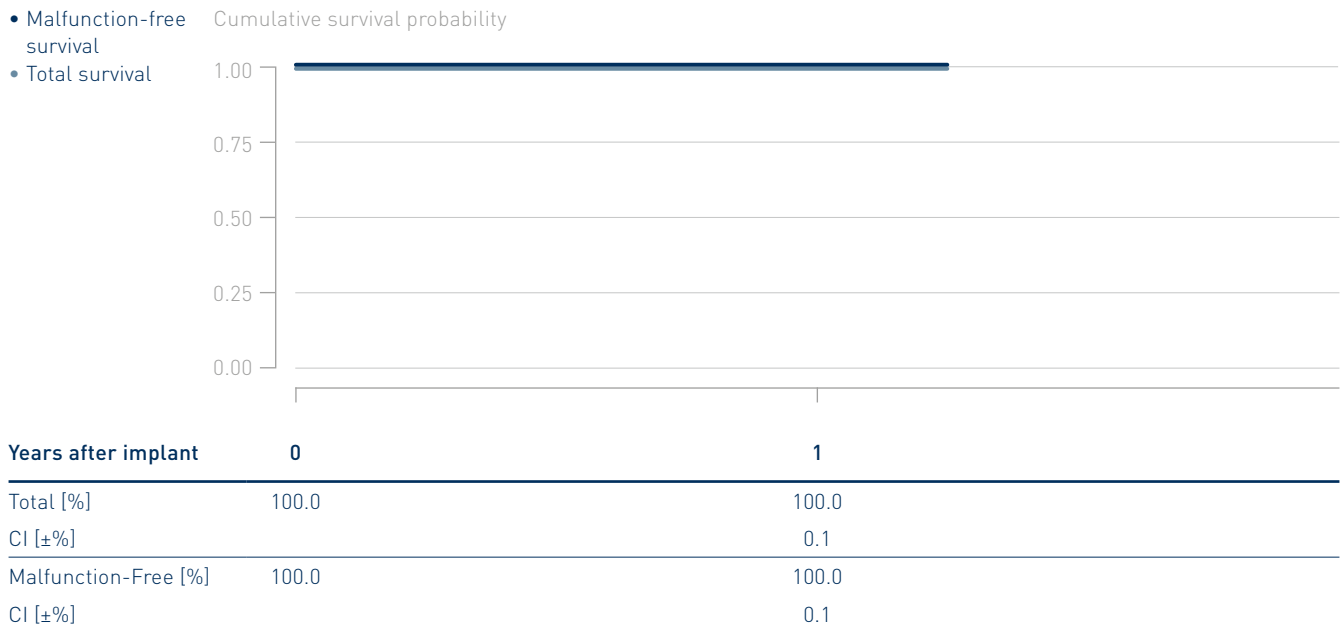


4.2 Dual-Chamber ICDs

Intica 7 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-DDDR
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Sep 2016
Worldwide Distributed Devices _____	5060
Registered U.S. Implants _____	2810
Estimated Active U.S. Implants _____	2680
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%

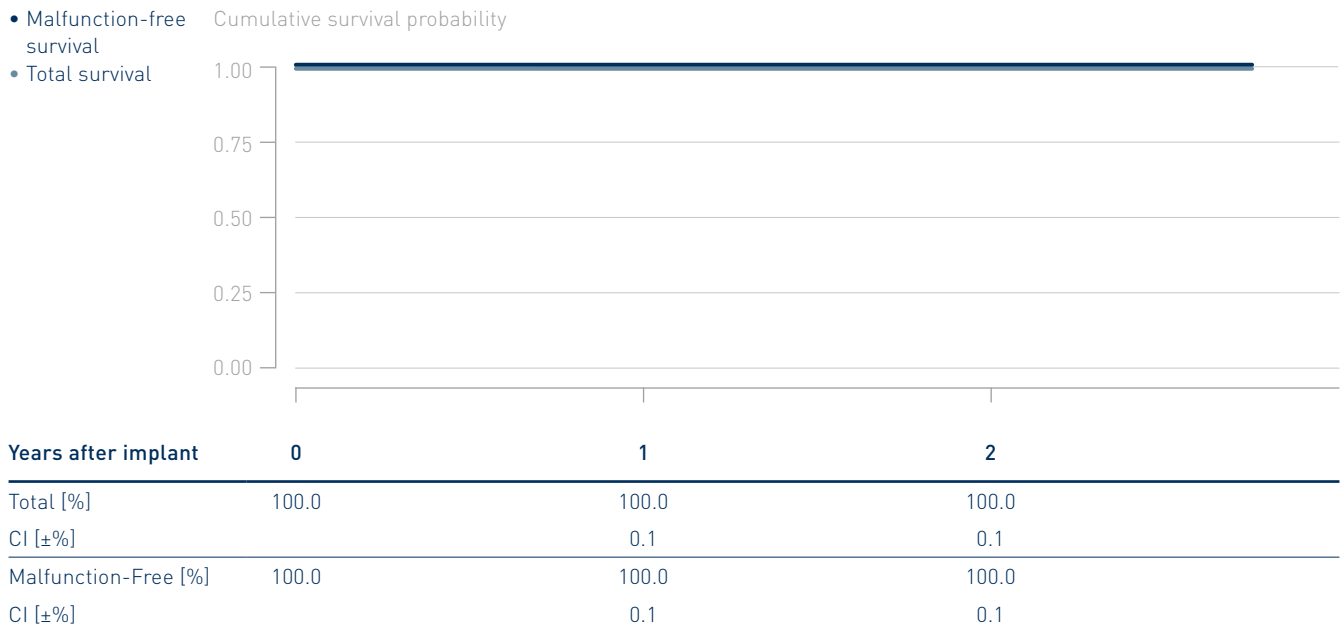


4.2 Dual-Chamber ICDs

Inventra 7 DX

Product Versions _____	VR-T
NBG Codes _____	WE-VDDR
Maximum Energy J _____	45
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	5 160
Registered U.S. Implants _____	4 380
Estimated Active U.S. Implants _____	3 920
U.S. Normal Battery Depletions _____	1

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

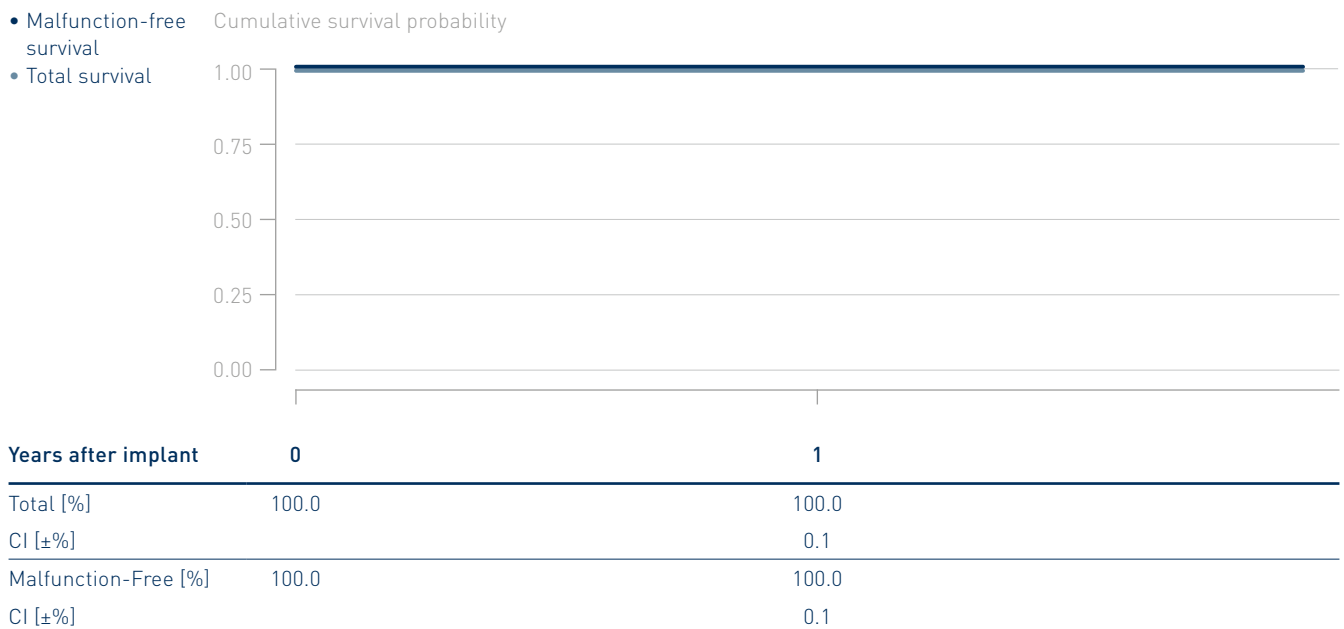


4.2 Dual-Chamber ICDs

Iperia 7

Product Versions _____	DR-T
NBG Codes _____	VWE-DDDR
Maximum Energy J _____	40
US Market Release _____	Dec 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	2750
Registered U.S. Implants _____	1 660
Estimated Active U.S. Implants _____	1 540
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%

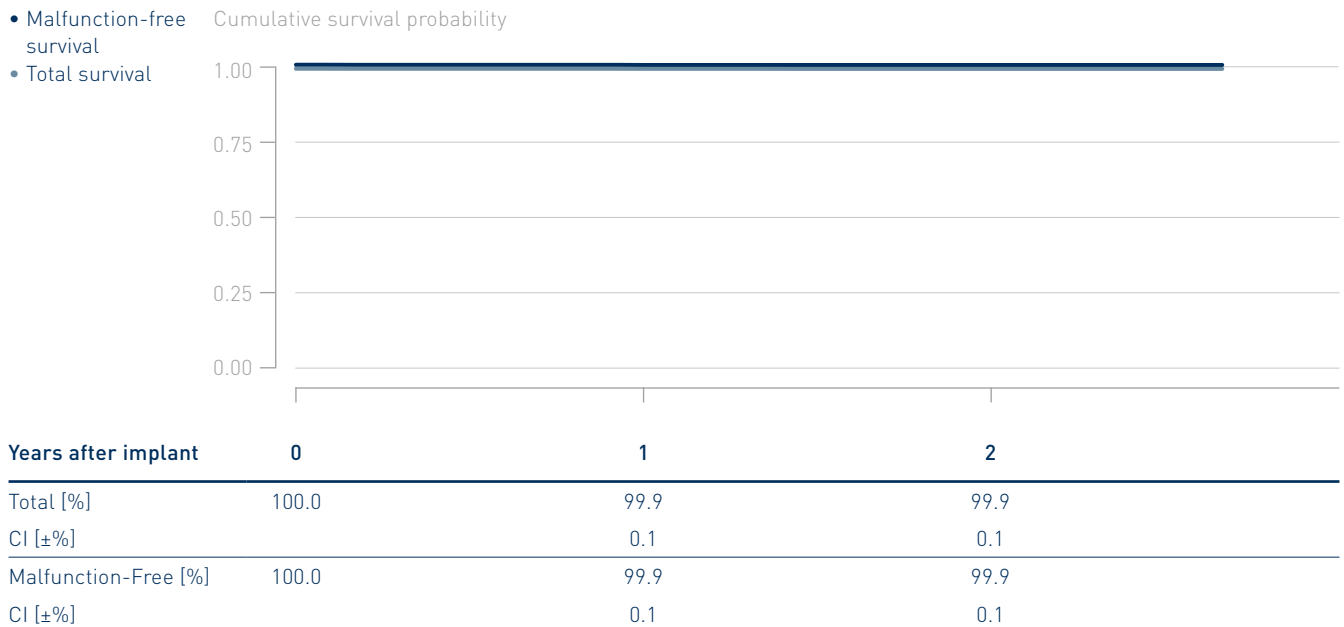


4.2 Dual-Chamber ICDs

Iperia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Dec 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	7410
Registered U.S. Implants _____	3840
Estimated Active U.S. Implants _____	3310
U.S. Normal Battery Depletions _____	1

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

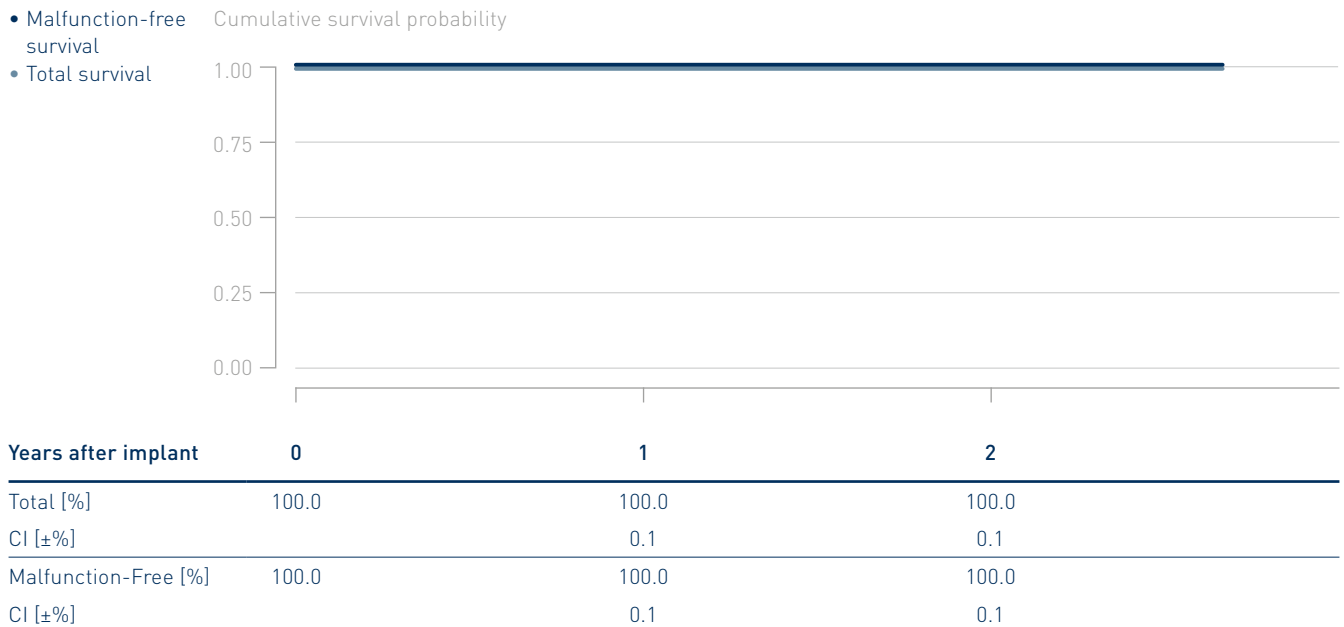


4.2 Dual-Chamber ICDs

Iperia 7 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	Dec 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	6 490
Registered U.S. Implants _____	4 580
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%

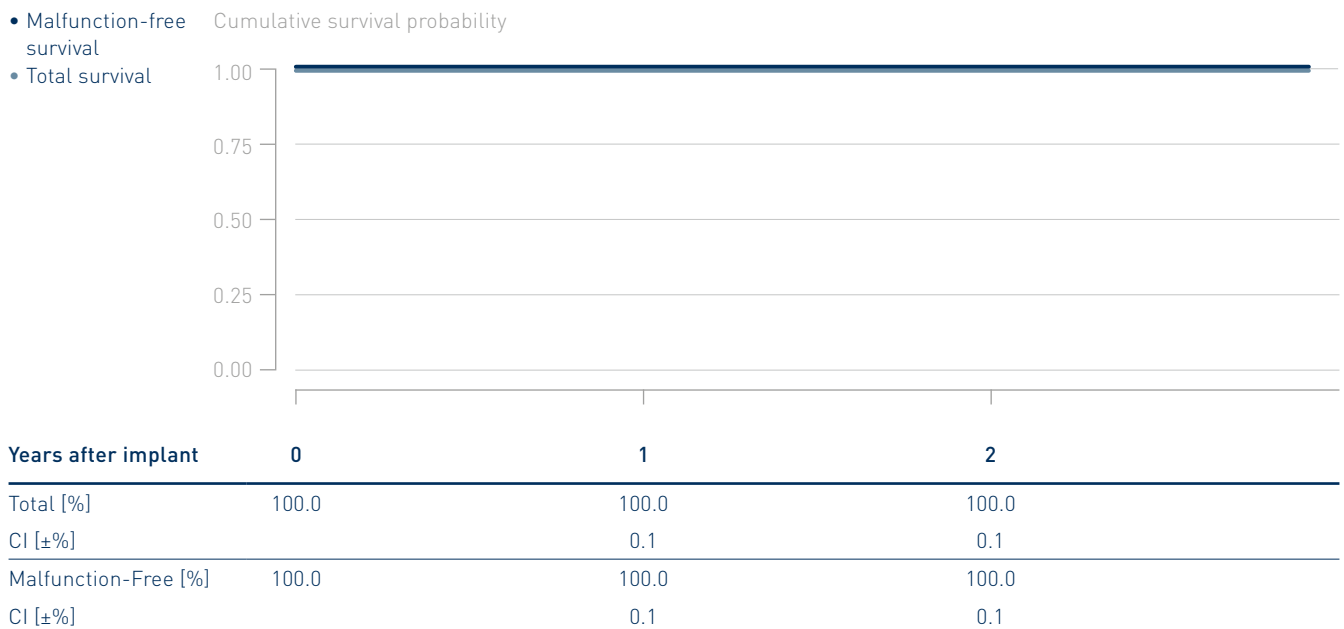


4.2 Dual-Chamber ICDs

Itrevia 7

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	2220
Registered U.S. Implants _____	1410
Estimated Active U.S. Implants _____	1220
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%

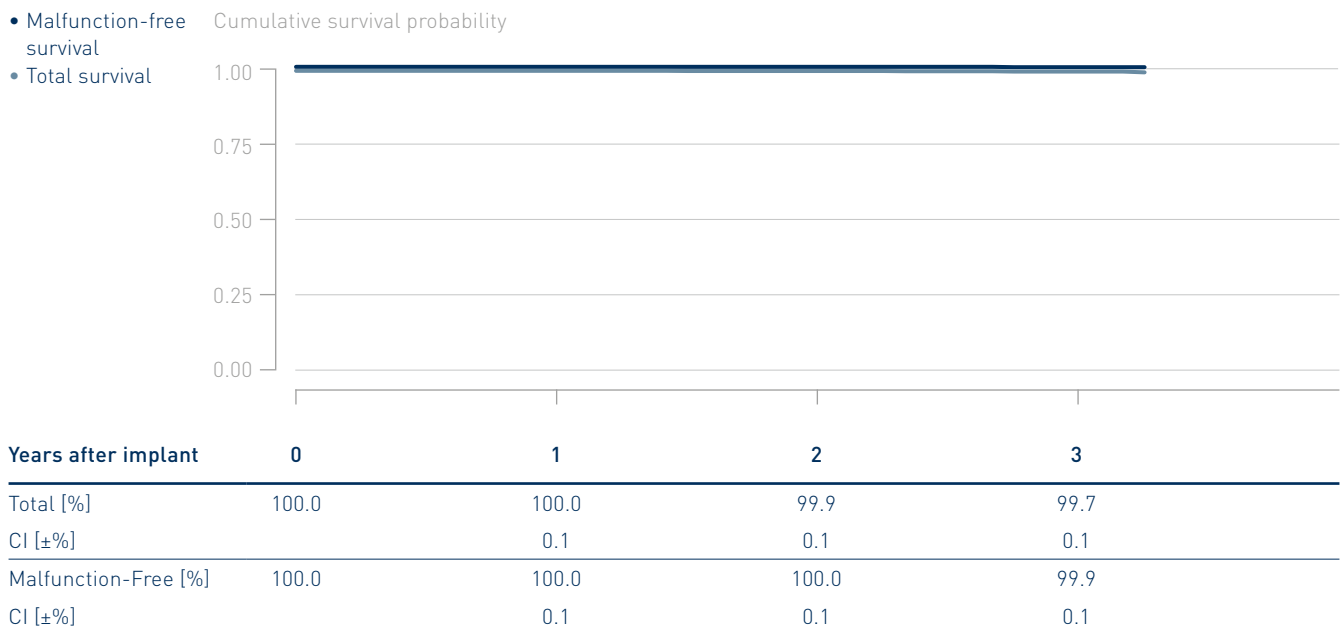


4.2 Dual-Chamber ICDs

Itrevia 7 DF4

Product Versions _____	DR-T
NBG Codes _____	VVE-DDDR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	2390
Registered U.S. Implants _____	1270
Estimated Active U.S. Implants _____	1060
U.S. Normal Battery Depletions _____	3

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

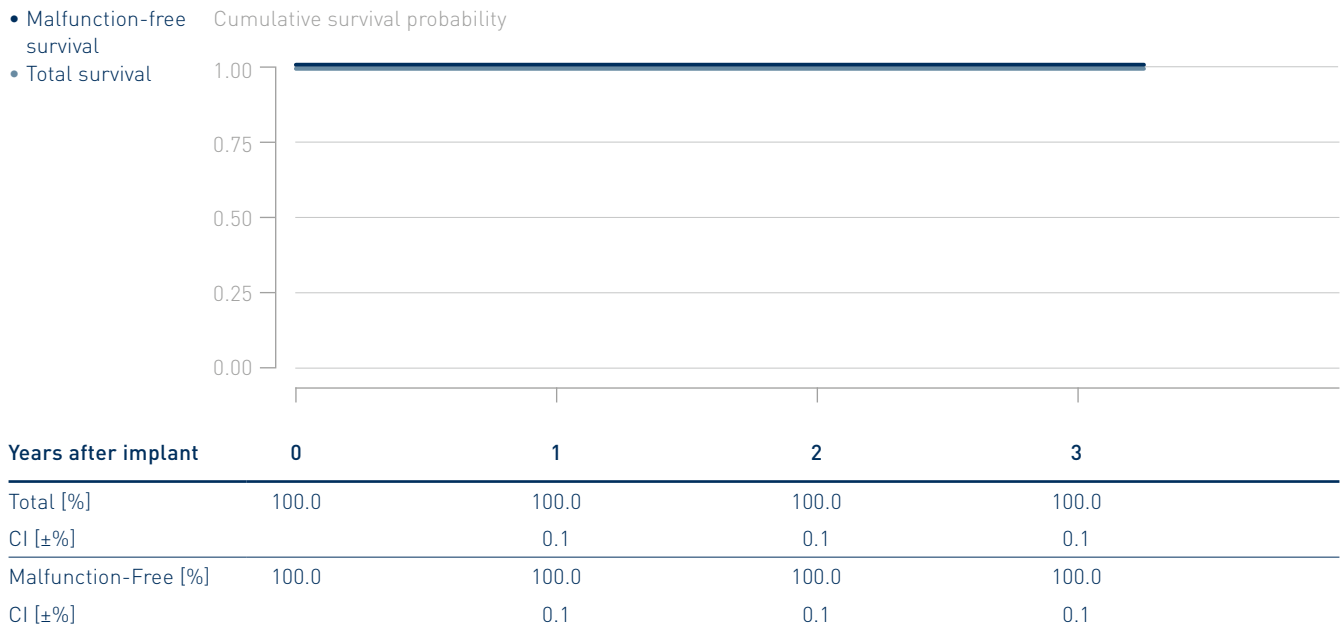


4.2 Dual-Chamber ICDs

Itrevia 7 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	2800
Registered U.S. Implants _____	1250
Estimated Active U.S. Implants _____	1010
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%

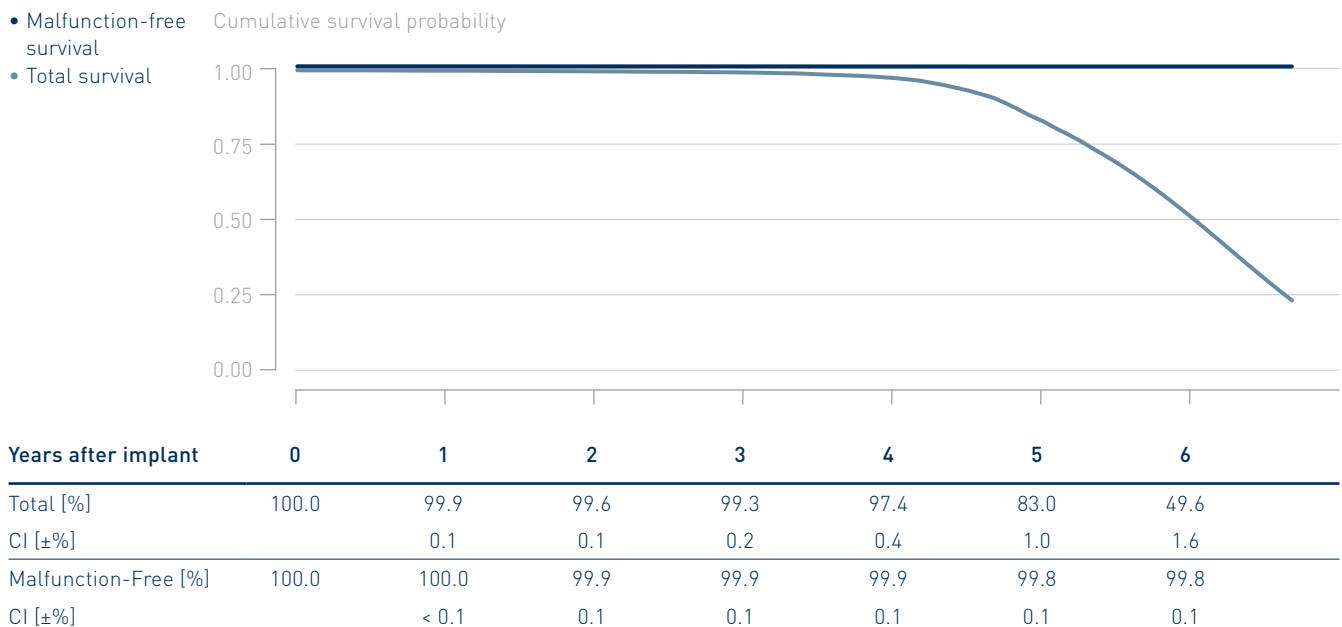


4.2 Dual-Chamber ICDs

Lumax 340

Product Versions _____	DR, DR-T
NBG Codes _____	VVE-DDDR
Maximum Energy J _____	40
US Market Release _____	Feb 2007
CE Market Release _____	Feb 2007
Worldwide Distributed Devices _____	26 500
Registered U.S. Implants _____	8 220
Estimated Active U.S. Implants _____	1 870
U.S. Normal Battery Depletions _____	1 873

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

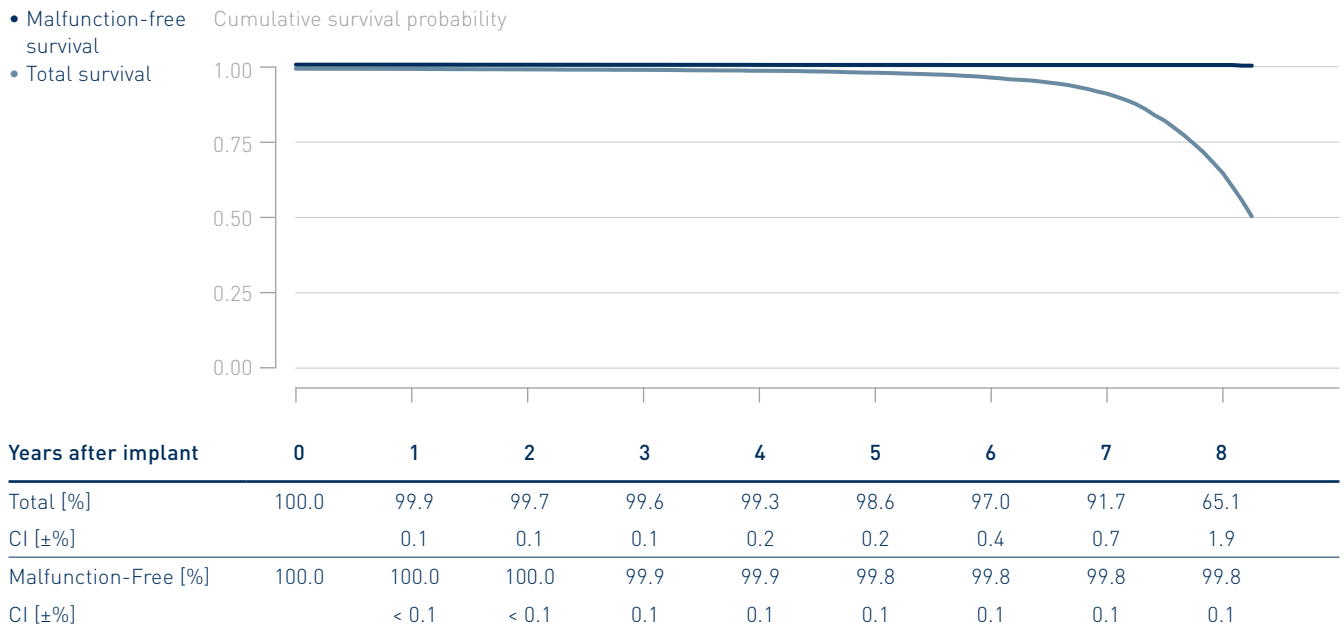


4.2 Dual-Chamber ICDs

Lumax 540

Product Versions _____	DR-T
NBG Codes _____	VVE-DDDR
Maximum Energy J _____	40
US Market Release _____	May 2009
CE Market Release _____	Jun 2008
Worldwide Distributed Devices _____	26 100
Registered U.S. Implants _____	11 600
Estimated Active U.S. Implants _____	5 150
U.S. Normal Battery Depletions _____	1 333

	Quantity	Rate
U.S. Confirmed Malfunctions _____	20	0.17%
Therapy Compromised _____	11	0.10%
Therapy Available _____	9	0.08%

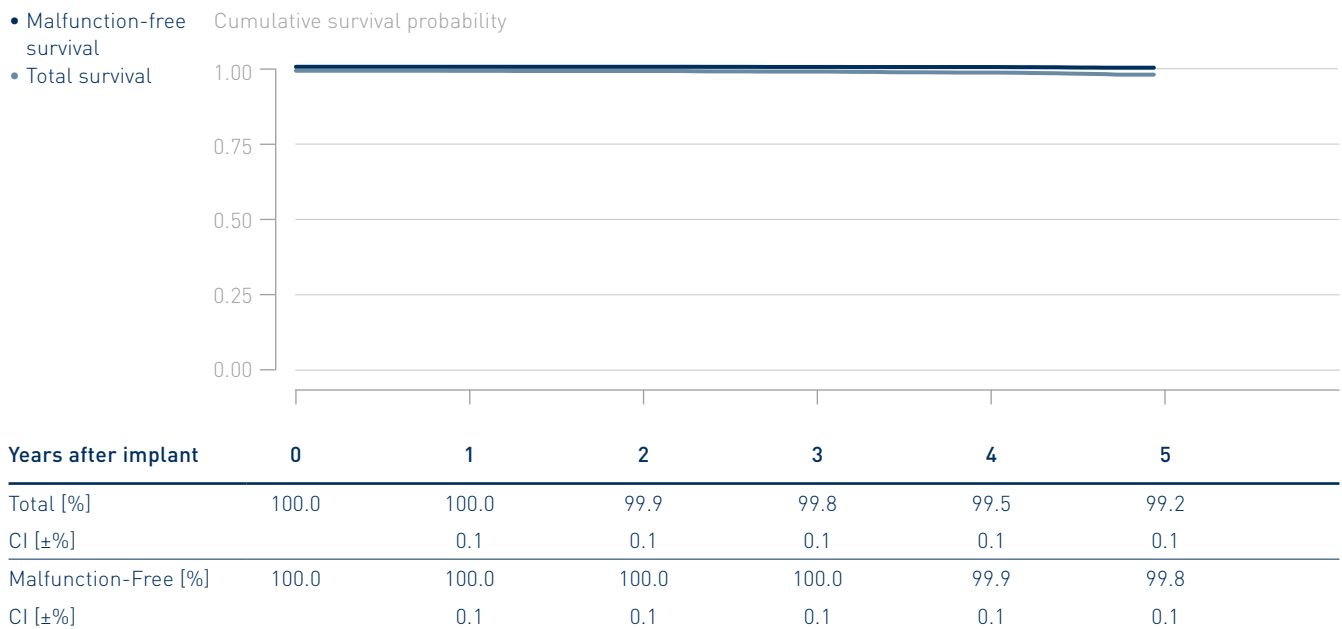


4.2 Dual-Chamber ICDs

Lumax 740

Product Versions _____	DR-T
NBG Codes _____	WE-DDDR
Maximum Energy J _____	40
US Market Release _____	Sep 2012
CE Market Release _____	Apr 2012
Worldwide Distributed Devices _____	7 980
Registered U.S. Implants _____	3 820
Estimated Active U.S. Implants _____	2 540
U.S. Normal Battery Depletions _____	26

	Quantity	Rate
U.S. Confirmed Malfunctions _____	11	0.29%
Therapy Compromised _____	5	0.13%
Therapy Available _____	6	0.16%

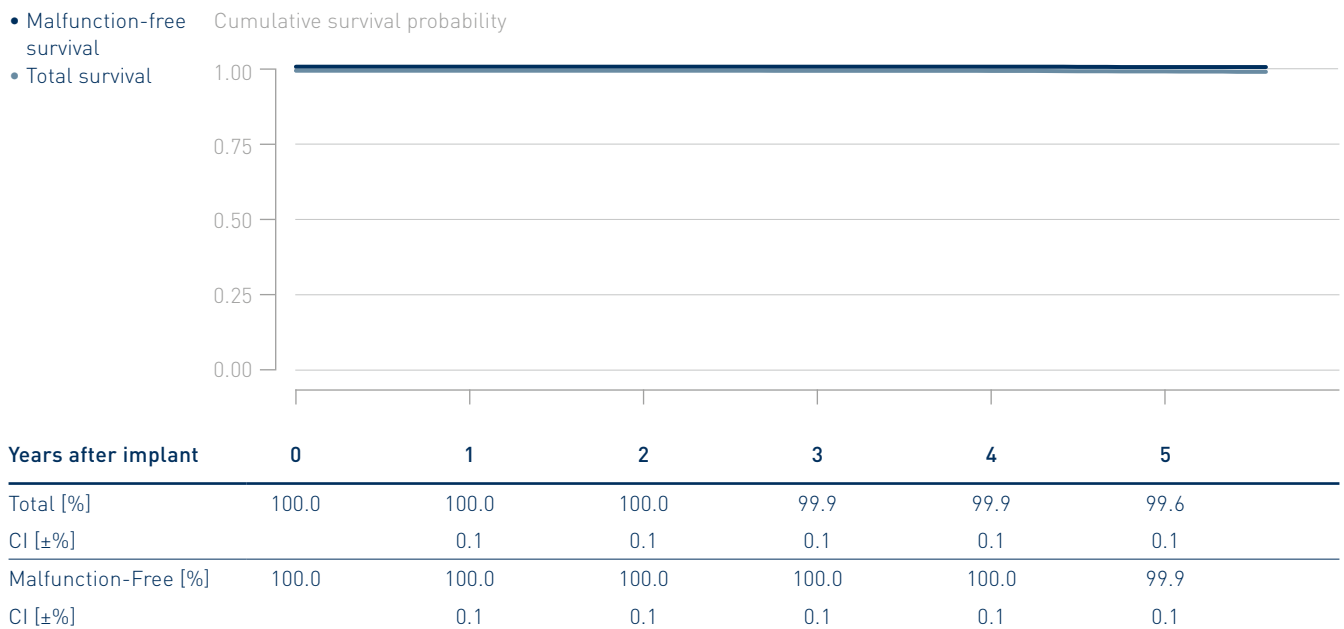


4.2 Dual-Chamber ICDs

Lumax 740 DX

Product Versions _____	VR-T
NBG Codes _____	VVE-VDDR
Maximum Energy J _____	40
US Market Release _____	May 2012
CE Market Release _____	Nov 2011
Worldwide Distributed Devices _____	4 570
Registered U.S. Implants _____	2 230
Estimated Active U.S. Implants _____	1 600
U.S. Normal Battery Depletions _____	6

	Quantity	Rate
U.S. Confirmed Malfunctions _____	2	0.09%
Therapy Compromised _____	1	0.04%
Therapy Available _____	1	0.04%

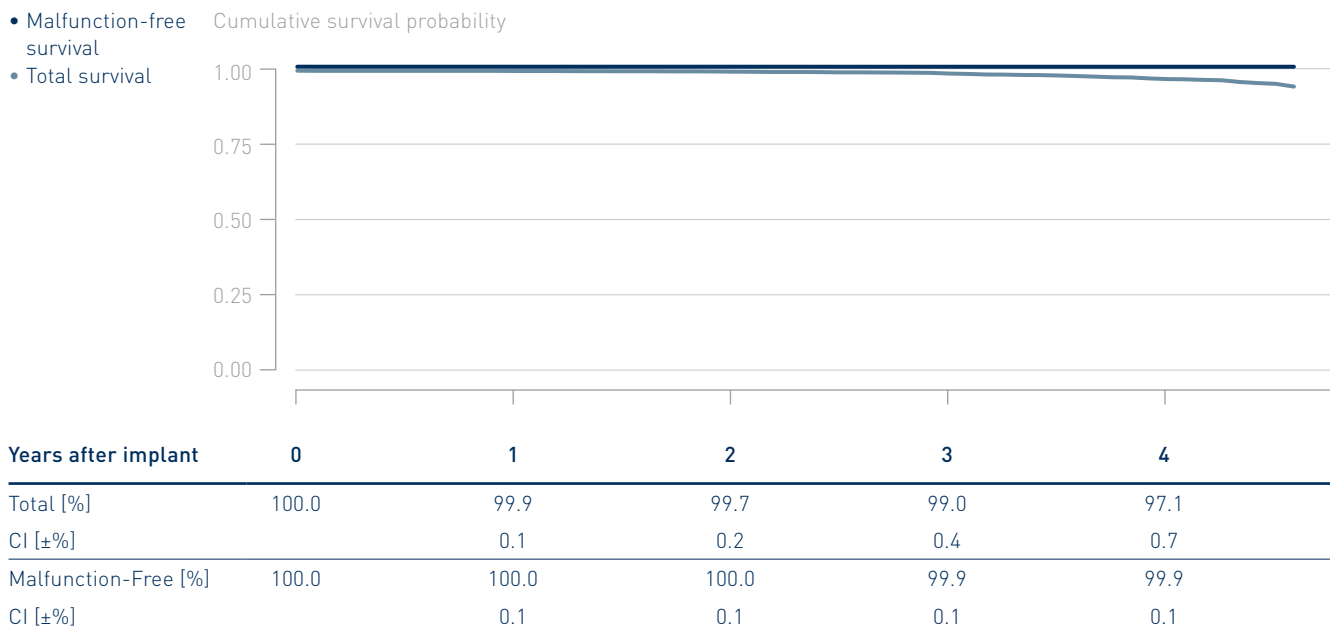


4.3 CRT ICDs

Ilesto 7

Product Versions _____	HF-T
NBG Codes _____	VVE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Sep 2013
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	5330
Registered U.S. Implants _____	3840
Estimated Active U.S. Implants _____	2390
U.S. Normal Battery Depletions _____	77

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

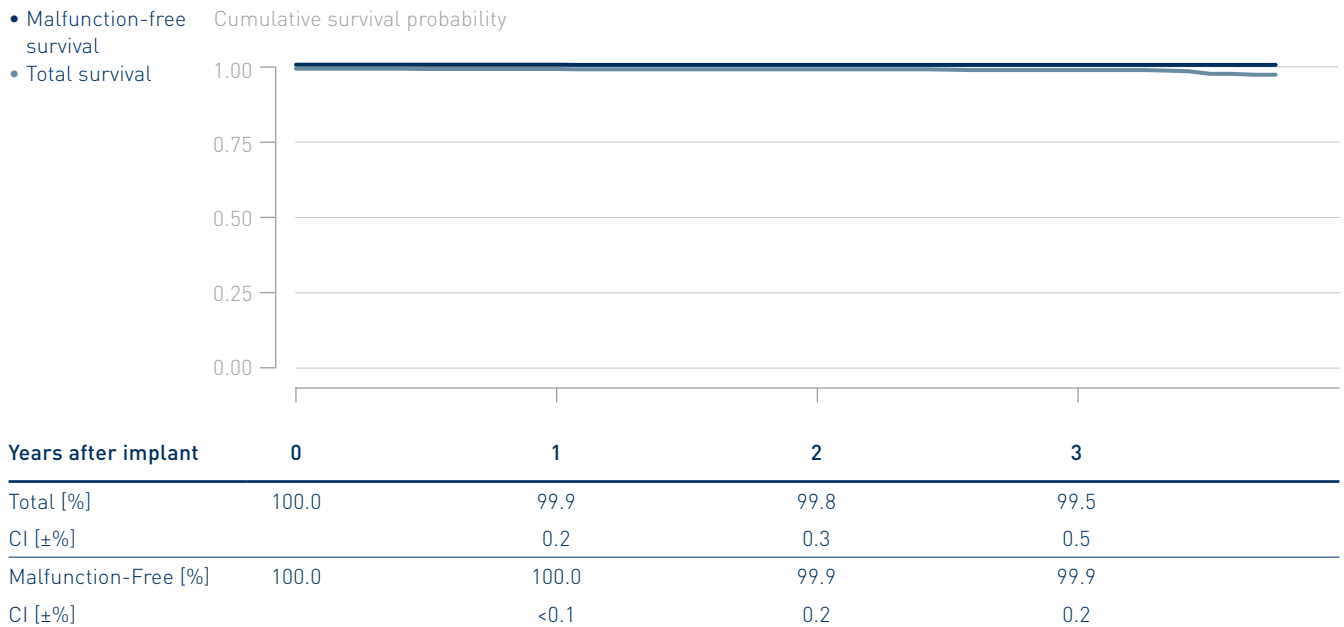


4.3 CRT ICDs

Ilesto 7 DF4

Product Versions _____	HF-T
NBG Codes _____	VVE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Jul 2014
CE Market Release _____	Jun 2013
Worldwide Distributed Devices _____	2400
Registered U.S. Implants _____	968
Estimated Active U.S. Implants _____	637
U.S. Normal Battery Depletions _____	13

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

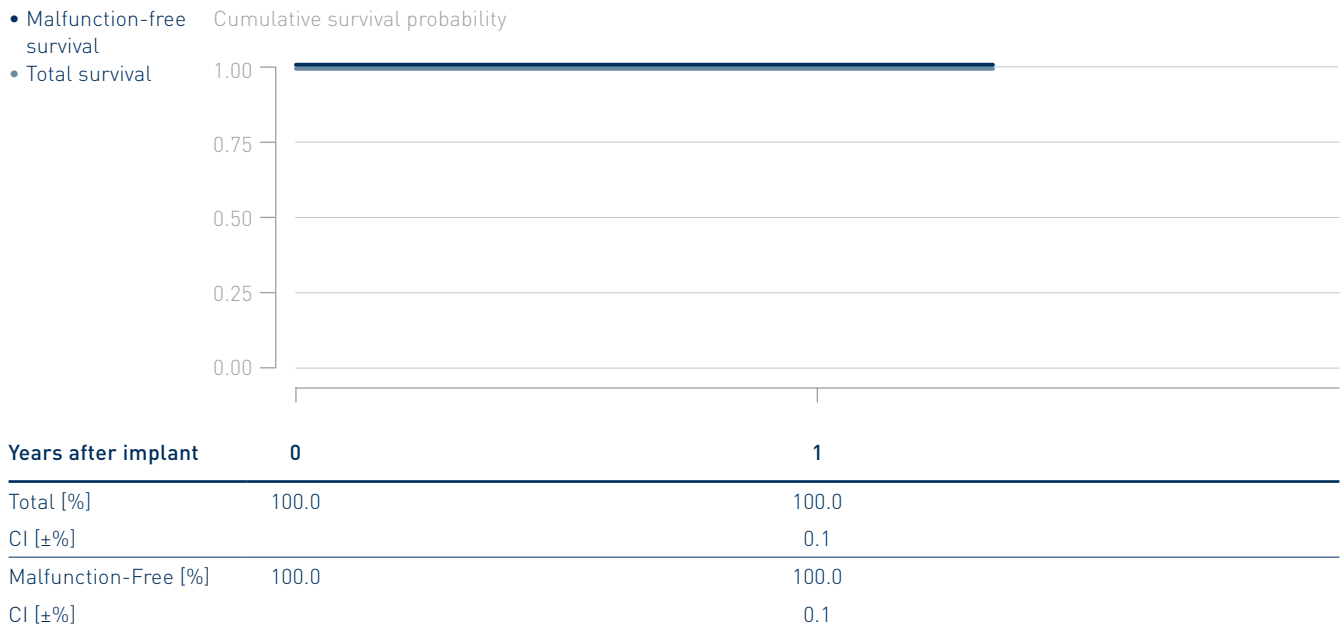


4.3 CRT ICDs

Ilivia 7 DF4

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Feb 2017
Worldwide Distributed Devices _____	6 750
Registered U.S. Implants _____	3 120
Estimated Active U.S. Implants _____	2 850
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%

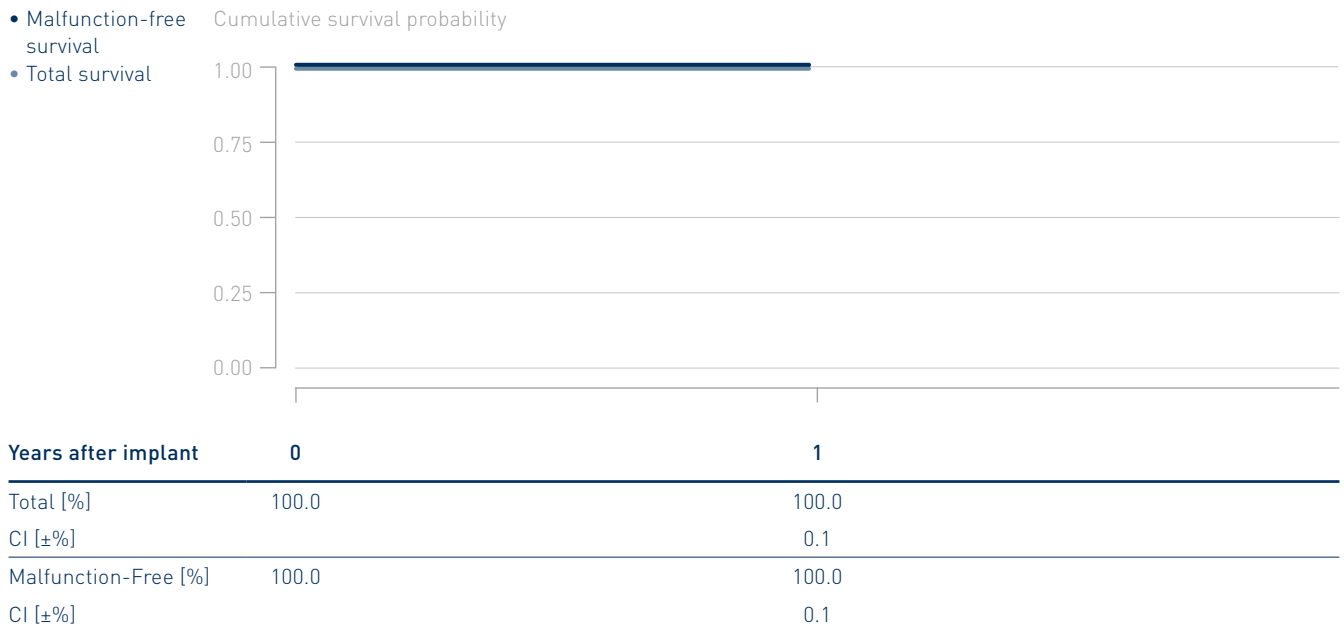


4.3 CRT ICDs

Intica 7 DF1

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	May 2017
CE Market Release _____	Sep 2016
Worldwide Distributed Devices _____	3310
Registered U.S. Implants _____	1090
Estimated Active U.S. Implants _____	974
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%

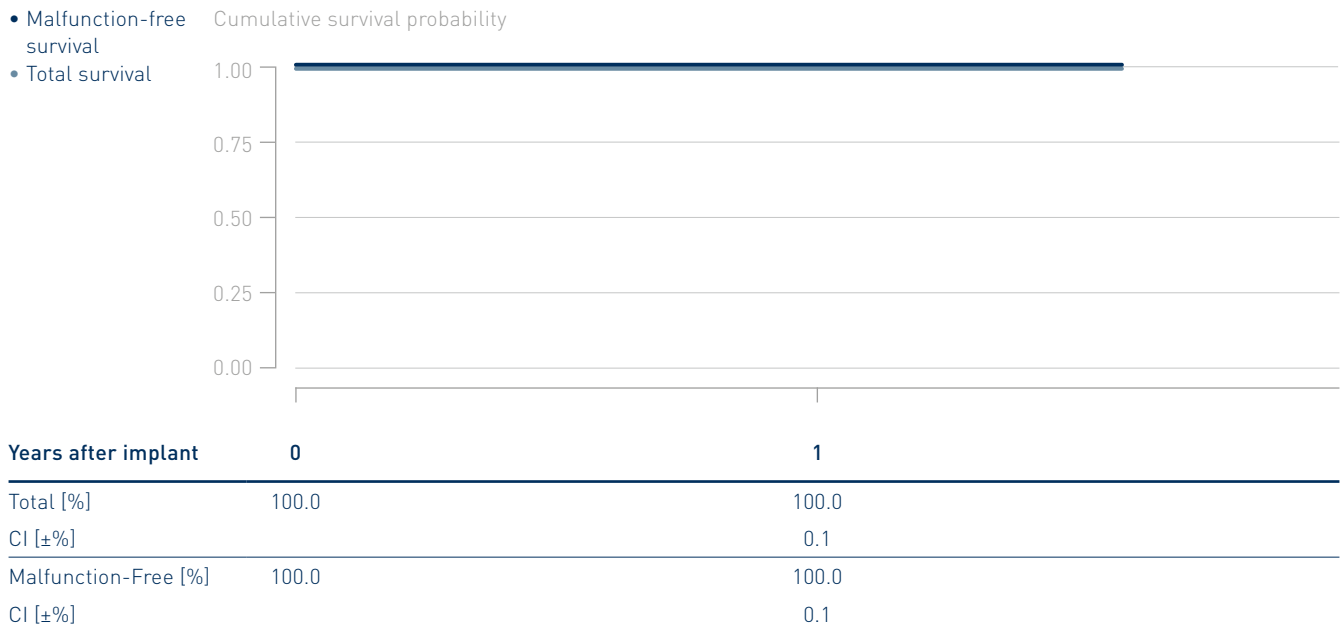


4.3 CRT ICDs

Inventra 7 DF4

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	45
US Market Release _____	Aug 2014
CE Market Release _____	Jul 2014
Worldwide Distributed Devices _____	2080
Registered U.S. Implants _____	739
Estimated Active U.S. Implants _____	638
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%

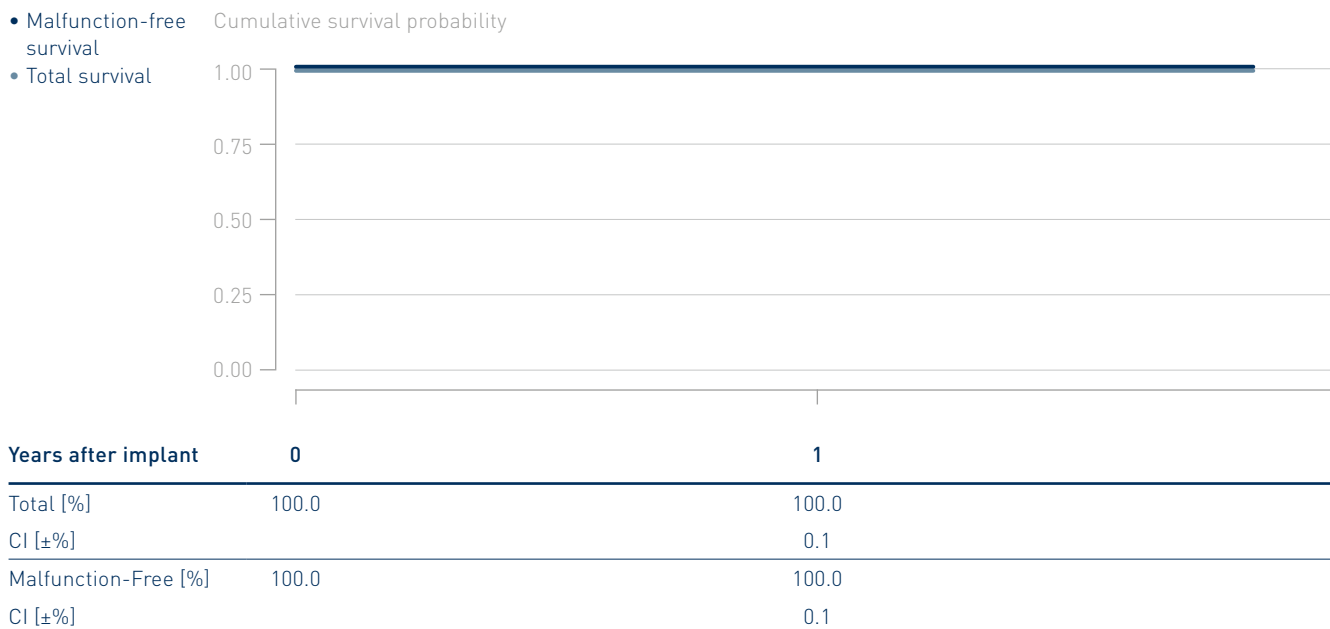


4.3 CRT ICDs

Iperia 7

Product Versions _____	HF-T
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Apr 2016
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	3050
Registered U.S. Implants _____	1140
Estimated Active U.S. Implants _____	978
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%

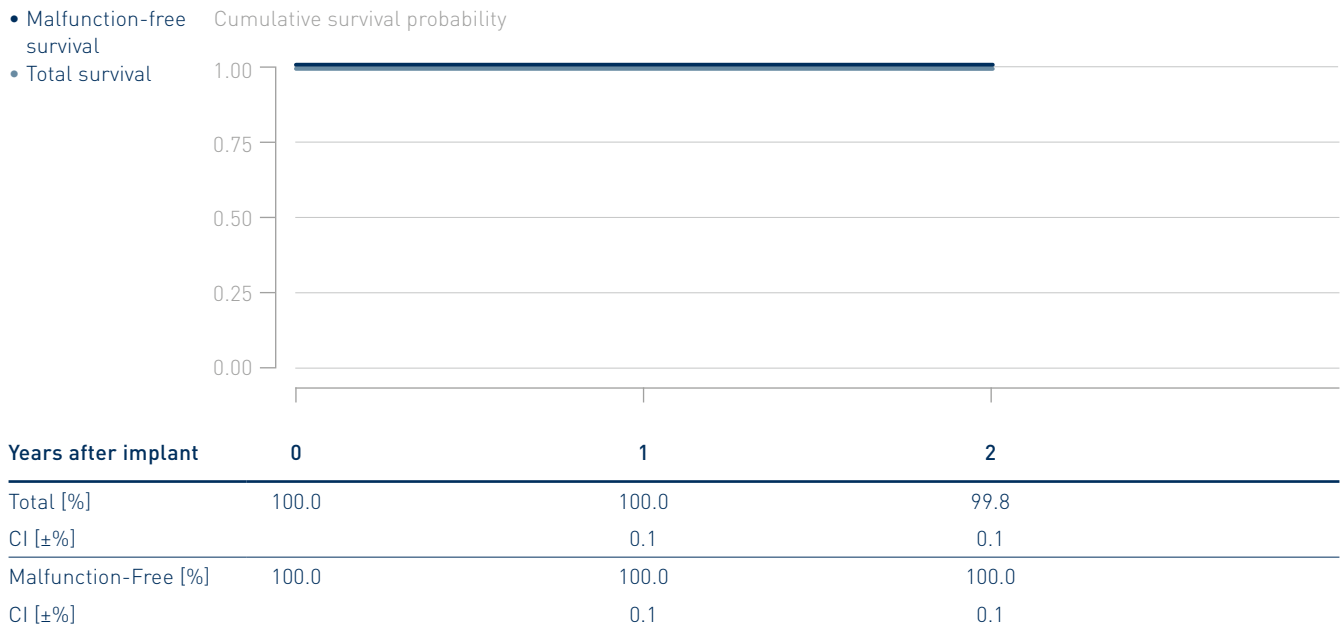


4.3 CRT ICDs

Iperia 7 DF4

Product Versions _____	HF-T
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Apr 2016
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	5790
Registered U.S. Implants _____	1380
Estimated Active U.S. Implants _____	1140
U.S. Normal Battery Depletions _____	1

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



4.3 CRT ICDs

Itrevia 7

Product Versions _____	HF-T
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	4 650
Registered U.S. Implants _____	3 240
Estimated Active U.S. Implants _____	2 560
U.S. Normal Battery Depletions _____	16

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



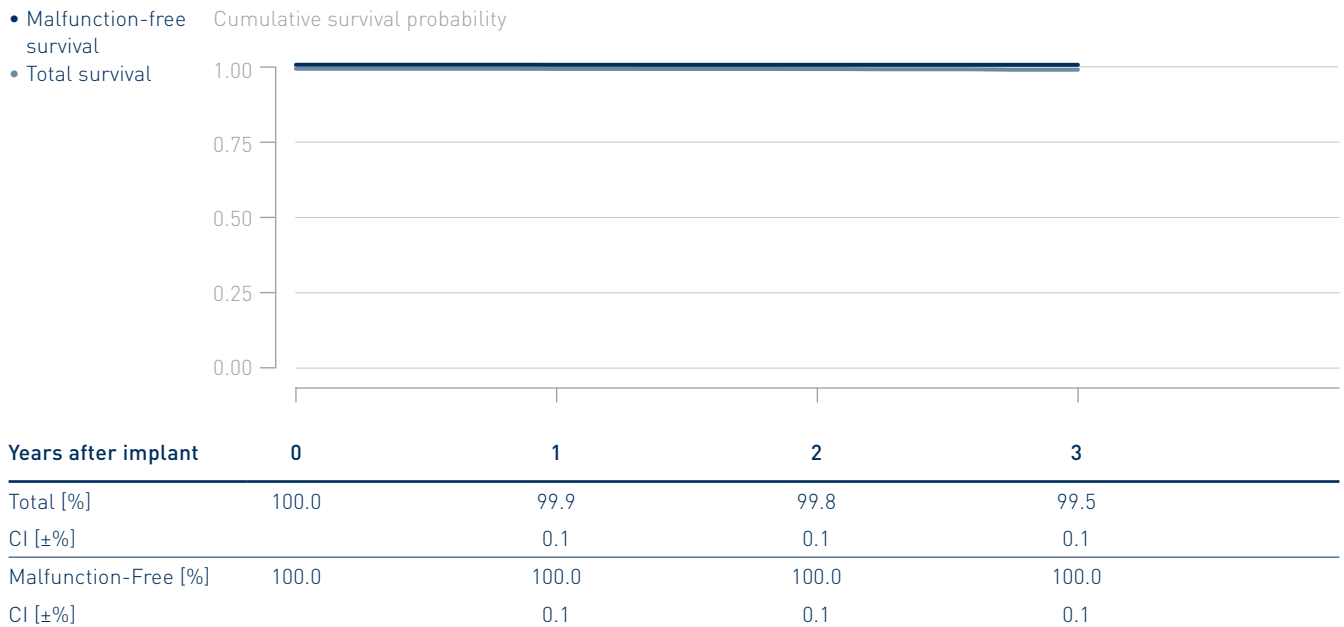
Years after implant	0	1	2
Total [%]	100.0	99.9	99.7
CI [±%]		0.1	0.1
Malfunction-Free [%]	100.0	100.0	100.0
CI [±%]		0.1	0.1

4.3 CRT ICDs

Itrevia 7 DF4

Product Versions _____	HF-T, HF-T QP
NBG Codes _____	VDE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Mar 2015
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	5810
Registered U.S. Implants _____	3230
Estimated Active U.S. Implants _____	2430
U.S. Normal Battery Depletions _____	7

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

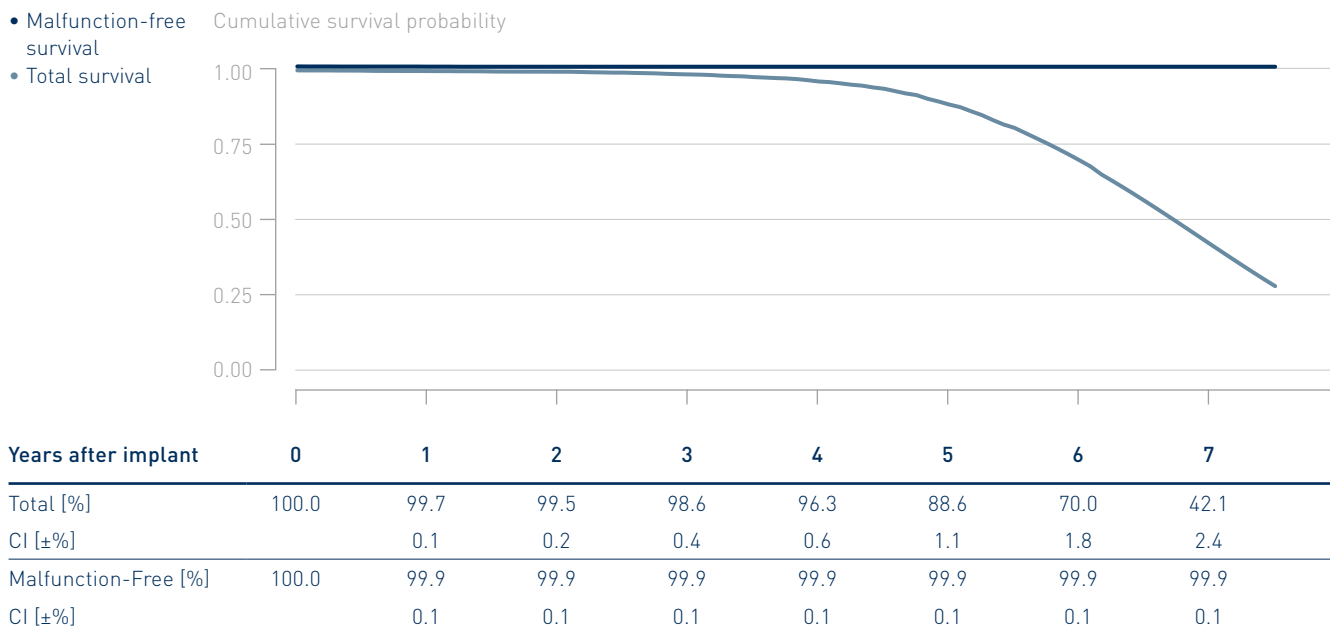


4.3 CRT ICDs

Lumax 340

Product Versions _____	HF, HF-T
NBG Codes _____	VVE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Feb 2007
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	20800
Registered U.S. Implants _____	5310
Estimated Active U.S. Implants _____	705
U.S. Normal Battery Depletions _____	1097

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

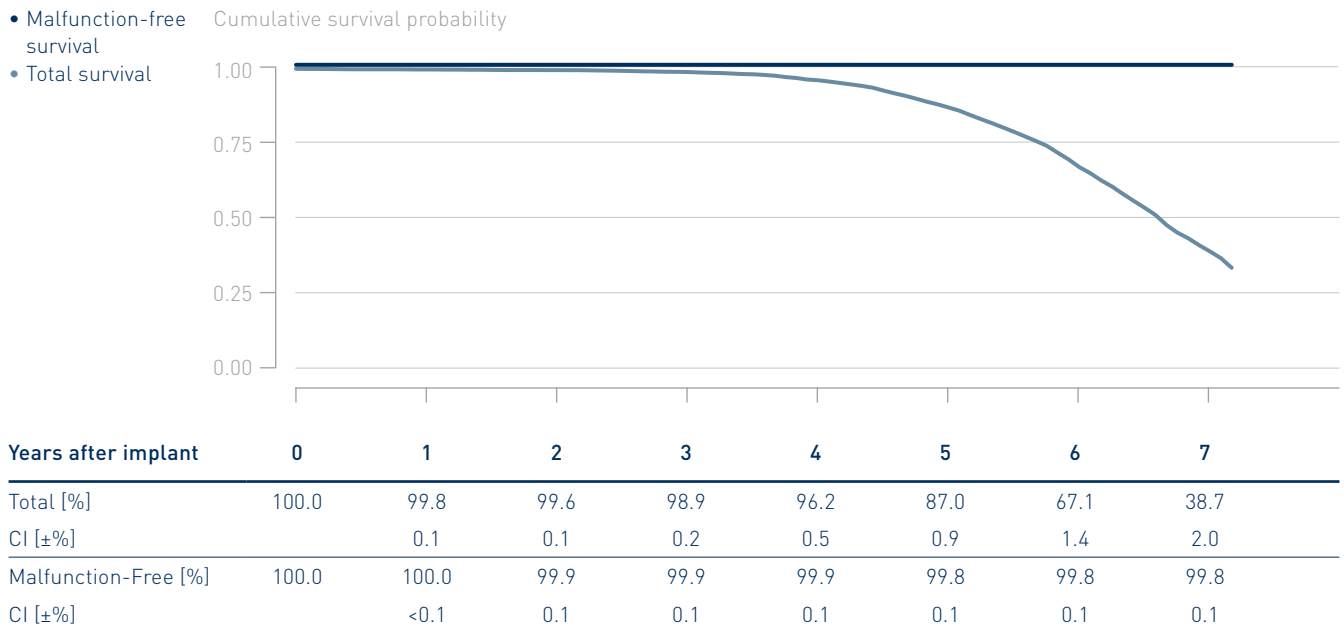


4.3 CRT ICDs

Lumax 540

Product Versions _____	HF-T
NBG Codes _____	VVE-DDDRV
Maximum Energy J _____	40
US Market Release _____	May 2009
CE Market Release _____	Jun 2008
Worldwide Distributed Devices _____	24 900
Registered U.S. Implants _____	8 660
Estimated Active U.S. Implants _____	1 530
U.S. Normal Battery Depletions _____	2 258

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

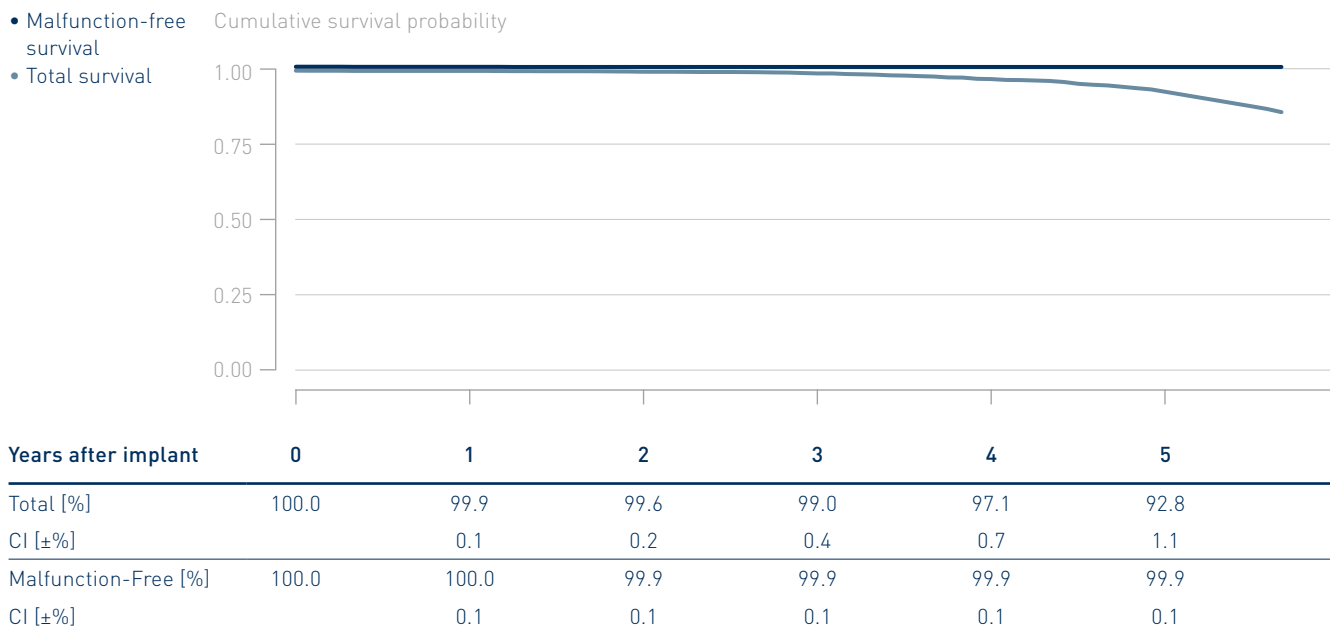


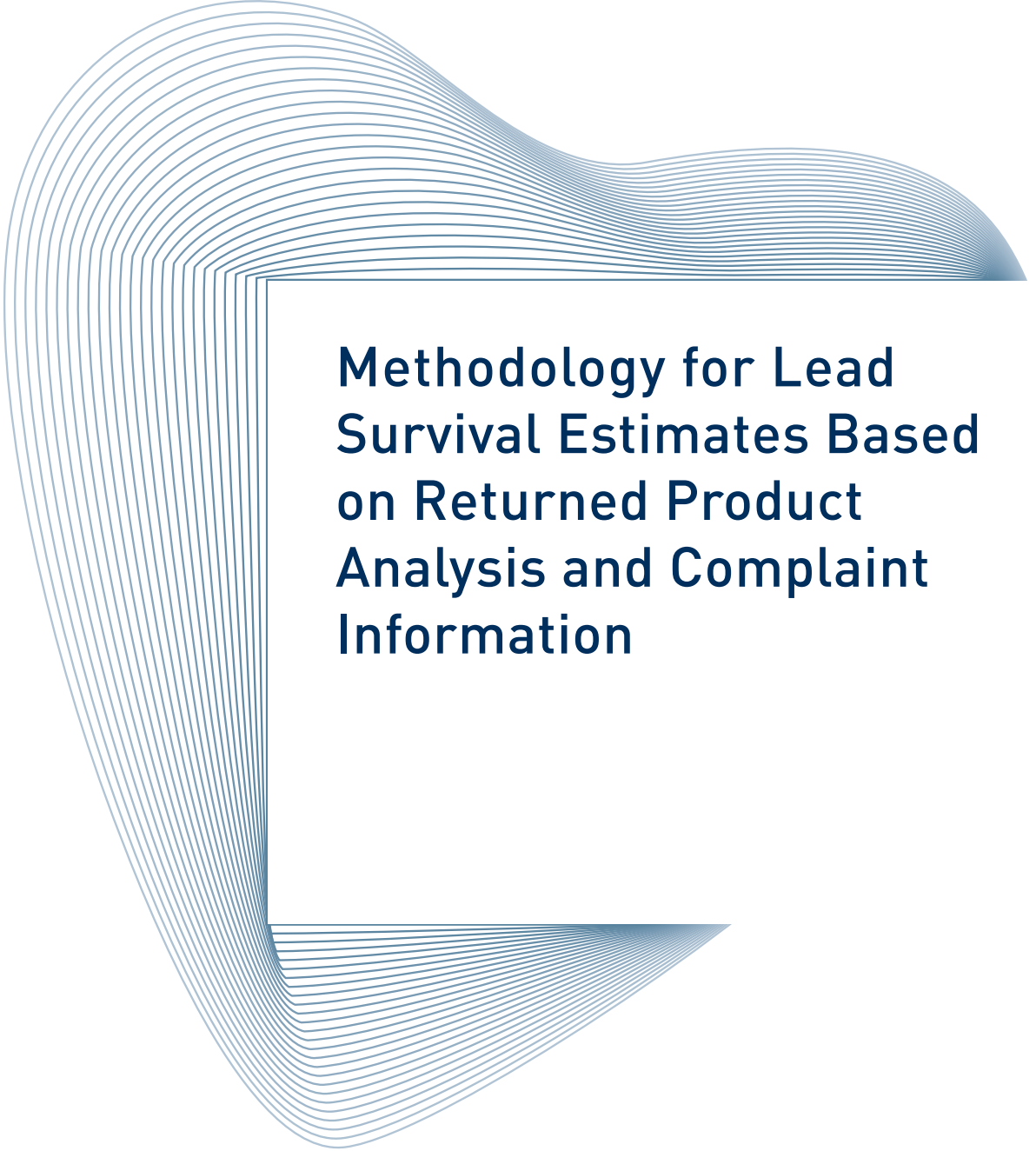
4.3 CRT ICDs

Lumax 740

Product Versions _____	HF-T
NBG Codes _____	VVE-DDDRV
Maximum Energy J _____	40
US Market Release _____	Sep 2012
CE Market Release _____	Apr 2012
Worldwide Distributed Devices _____	7 050
Registered U.S. Implants _____	3 420
Estimated Active U.S. Implants _____	1 750
U.S. Normal Battery Depletions _____	183

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





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

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

5.1 Cumulative Lead Survival Probability

This report has been prepared in accordance with ISO 5841-2:2014(E) applying actuarial analysis for the calculation of lead survival probabilities based on returned product analysis. Lead survival estimates given in this report are considered to be generally representative for worldwide performance of BIOTRONIK's pacing and ICD leads.

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

At the time of implantation, the cumulative lead survival probability is 100%. Even though they are analyzed as part of our quality system monitoring, leads that are found to be out of specification prior to or during the implantation procedure are removed from the statistics as they do not contribute to a patient's risk of being subject to a device malfunction or replacement during the device's service time.

Because this report is provided to communicate information regarding product performance, it does not include data regarding medical complications such as erosion, infection or diaphragmatic stimulation.

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

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

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

5.2 Lead Data Acquisition

The following sections of this report provide performance data on BIOTRONIK's pacing and ICD leads and are based on the observation of BIOTRONIK's U.S. products through review of our device registration and tracking systems, and through the

analyses of both, returned leads as well as reports of lead complications of non-returned leads. The prospective data from BIOTRONIK's post-approval studies is presented separately in chapters 7 and 8.

In order to be included in the population under observation a lead must be registered and implanted for at least one calendar day. The cut-off date for the data included in this report is December 31, 2018. The sample sizes of U.S. leads that are implanted and remain active as well as the total number of products distributed worldwide are provided for each lead family in this report.

Survival estimates are calculated for lead families having accumulated at least 10000 cumulative implant months. Products no longer being distributed with less than 500 active implants may be excluded from this report.

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

5.3 Returned Product Analysis

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

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

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

Conductor Fracture

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

Crimps, Welds and Bonds

Any interruption in the conductor or lead body associated with a point of connection

Insulation Breach

Any lead insulation breach

Other

Includes specific proprietary lead mechanical attributes.

5.4 Lead Complications

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

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

Complications for leads implanted greater than 30 days are reported as Qualifying lead complications, whereas complications occurring during the

first 30 days are reported as Acute Lead Observations.

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

Failure to Capture

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

Failure to Sense

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

Oversensing

Misinterpretation of cardiac or non-cardiac events as cardiac depolarization

Abnormal Pacing Impedance

Pacing impedance is typically considered abnormal if a measurement is < 200 ohms or > 3000 ohms

Abnormal Defibrillation Impedance

Defibrillation impedance is typically considered abnormal if a measurement is < 20 ohms or > 200 ohms. Including high or low shock impedance when attempting to deliver a shock

Insulation Breach

A disruption or break in lead insulation observed visually, electrically, or radiographically

Conductor Fracture

A mechanical break within the lead conductor observed visually, electrically, or radiographically

Lead Dislodgement

Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance

Extracardiac Stimulation

Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle

Cardiac Perforation

Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance, chest pain, and tamponade

Other

Specific proprietary attributes of a lead such as sensors which affect a lead's ability to perform as designed or remain in service

In order to report a conservative measure of lead performance, qualifying lead complications are also included in the calculation of a lead's survival probability.

Acute Lead Observations may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. Therefore, acute lead observations are not included in lead survival probability.

5.5 Lead Product Performance Graphs and Data

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

For each lead, the report provides:

- Product versions that contribute to the evaluation
- Types of leads
- Polarity
- Steroid
- CE and U.S. market release dates
- Worldwide quantity of products that have been distributed
- U.S. registered implants (number of products included in this report)
- Estimated active U.S. implants
- Number of U.S. qualifying complications
- Number of U.S. acute lead observations
- Number of U.S. confirmed malfunctions
- Number of U.S. leads or partial leads returned post-implant for analysis with a complaint

The survival plots provide:

Total Survival

The cumulative survival probability free of component malfunction or unconfirmed observation of an anomaly. Removals for clinical reasons unrelated to the device's performance (i.e., infections) are excluded.

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

Current advisories are listed in chapter 11 of this report, however to date, BIOTRONIK has never had a pacing or ICD lead safety advisory notification, therefore no summary of lead advisories is provided.

The cumulative survival data and the 95 % confidence intervals according to the Greenwood's formula¹ are shown in numerical form for the observed sample population.

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

Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



6.1 Pacing Leads

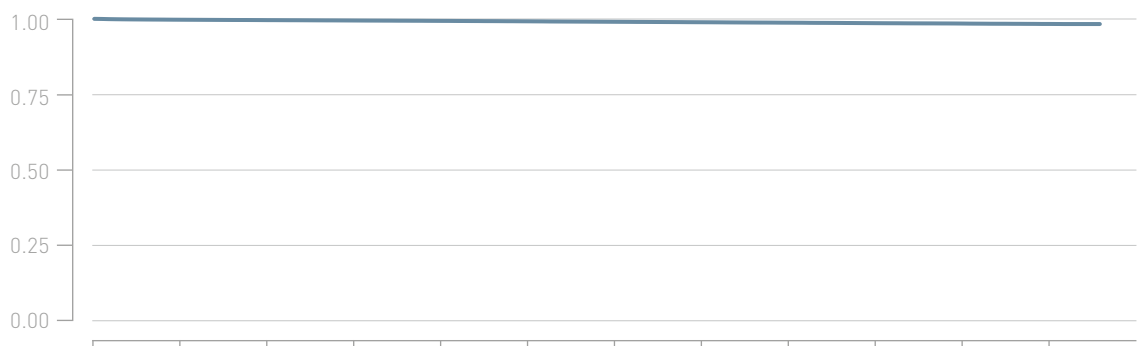
Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	487 000
Registered U.S. Implants	385 000
Estimated Active U.S. Implants	253 000
U.S. Total Returned	2 260

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	3362	0.88%	U.S. Confirmed Malfunctions	318	0.08%
Abnormal Pacing Impedance	282	0.07%	Conductor Fracture	118	0.03%
Cardiac Perforation	24	0.01%	Insulation Breach	195	0.05%
Conductor Fracture	99	0.03%	Other	5	0.00%
Extracardiac Stimulation	18	0.00%			
Failure to Capture	921	0.24%	U.S. Acute Lead Observations	1 598	0.42%
Failure to Sense	133	0.03%	Abnormal Pacing Impedance	33	0.01%
Insulation Breach	75	0.02%	Cardiac Perforation	67	0.02%
Lead Dislodgement	509	0.13%	Extracardiac Stimulation	15	0.00%
Oversensing	723	0.19%	Failure to Capture	225	0.06%
Other	578	0.15%	Failure to Sense	61	0.02%
			Insulation Breach	9	0.00%
			Lead Dislodgement	642	0.17%
			Oversensing	42	0.01%
			Other	504	0.13%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.7	99.5	99.4	99.2	99.1	98.9	98.7	98.5	98.4	98.2	98.1
CI [±%]		< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1

6.1 Pacing Leads

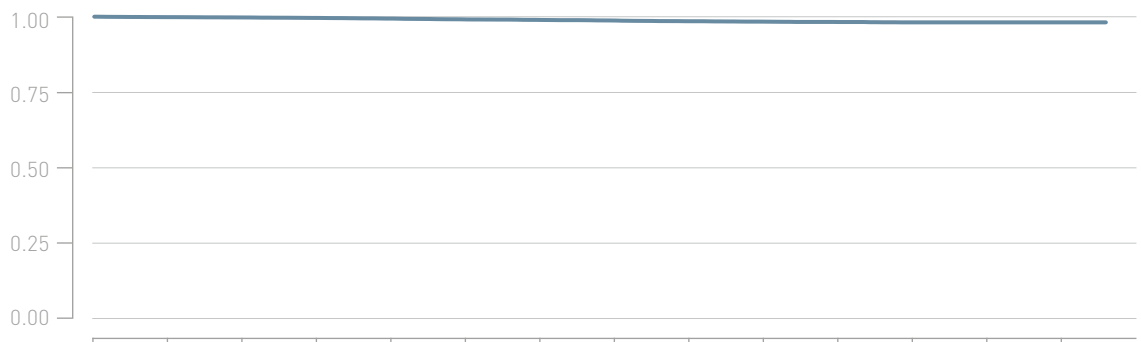
Selox JT

Product Versions _____	45, 53
Lead Type _____	J-shape, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Nov 2004
CE Market Release _____	Nov 2004
Worldwide Distributed Devices _____	152 000
Registered U.S. Implants _____	16 700
Estimated Active U.S. Implants _____	12 500
U.S. Total Returned _____	118

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	200	1.20%	U.S. Confirmed Malfunctions _____	9	0.05%
Abnormal Pacing Impedance _____	28	0.17%	Insulation Breach _____	9	0.05%
Cardiac Perforation _____	1	0.01%			
Conductor Fracture _____	7	0.04%	U.S. Acute Lead Observations _____	44	0.26%
Extracardiac Stimulation _____	1	0.01%	Failure to Capture _____	8	0.05%
Failure to Capture _____	92	0.55%	Lead Dislodgement _____	33	0.20%
Failure to Sense _____	9	0.05%	Other _____	3	0.02%
Insulation Breach _____	9	0.05%			
Lead Dislodgement _____	31	0.19%			
Oversensing _____	5	0.03%			
Other _____	17	0.10%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.3	98.1	98.0	97.9	97.9	97.9
CI [±%]		0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3

6.1 Pacing Leads

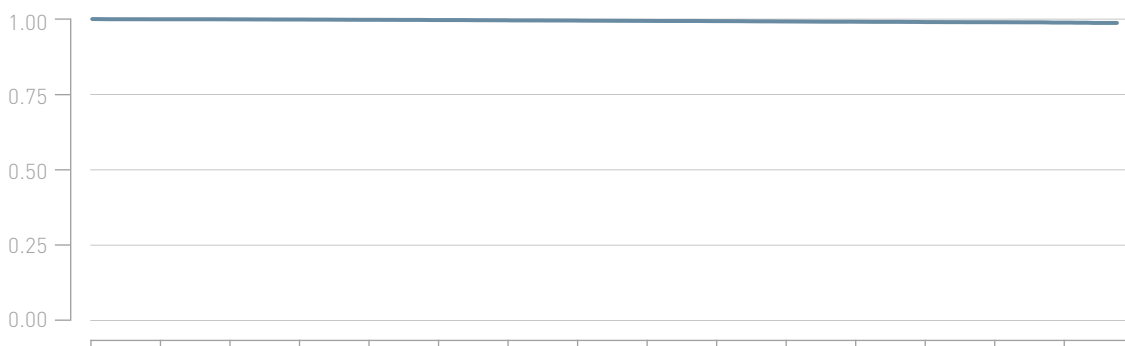
Selox SR

Product Versions _____	45, 53, 60
Lead Type _____	straight, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Mar 2004
CE Market Release _____	Feb 2004
Worldwide Distributed Devices _____	172 000
Registered U.S. Implants _____	14 400
Estimated Active U.S. Implants _____	7 110
U.S. Total Returned _____	61

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	107	0.75%	U.S. Confirmed Malfunctions _____	11	0.08%
Abnormal Pacing Impedance _____	4	0.03%	Insulation Breach _____	11	0.08%
Conductor Fracture _____	9	0.06%			
Extracardiac Stimulation _____	2	0.01%	U.S. Acute Lead Observations _____	21	0.15%
Failure to Capture _____	41	0.29%	Cardiac Perforation _____	1	0.01%
Failure to Sense _____	1	0.01%	Failure to Capture _____	11	0.08%
Insulation Breach _____	6	0.04%	Insulation Breach _____	1	0.01%
Lead Dislodgement _____	14	0.10%	Lead Dislodgement _____	8	0.06%
Oversensing _____	16	0.11%			
Other _____	14	0.10%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6
CI [±%]		<0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3

6.1 Pacing Leads

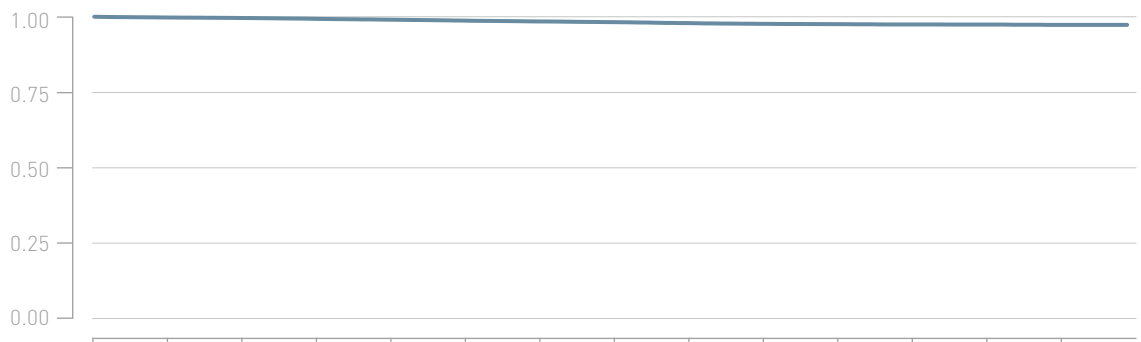
Selox ST

Product Versions _____	53, 60
Lead Type _____	straight, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Nov 2004
CE Market Release _____	Nov 2004
Worldwide Distributed Devices _____	377 000
Registered U.S. Implants _____	32 100
Estimated Active U.S. Implants _____	23 000
U.S. Total Returned _____	174

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	529	1.65%	U.S. Confirmed Malfunctions _____	17	0.05%
Abnormal Pacing Impedance _____	116	0.36%	Conductor Fracture _____	1	0.00%
Cardiac Perforation _____	3	0.01%	Crimps, Welds and Bonds _____	1	0.00%
Conductor Fracture _____	54	0.17%	Insulation Breach _____	15	0.05%
Extracardiac Stimulation _____	7	0.02%			
Failure to Capture _____	257	0.80%	U.S. Acute Lead Observations _____	49	0.15%
Failure to Sense _____	1	0.00%	Abnormal Pacing Impedance _____	1	0.00%
Insulation Breach _____	35	0.11%	Failure to Capture _____	21	0.07%
Lead Dislodgement _____	21	0.07%	Lead Dislodgement _____	21	0.07%
Oversensing _____	11	0.03%	Other _____	6	0.02%
Other _____	24	0.07%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.0	97.7	97.4	97.3	97.2	97.2	97.1
CI [±%]		0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3

6.1 Pacing Leads

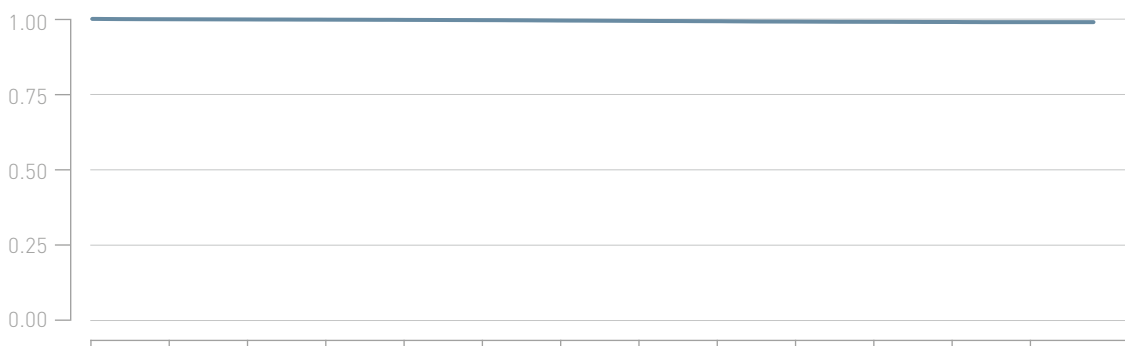
Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	672 000
Registered U.S. Implants	246 000
Estimated Active U.S. Implants	199 000
U.S. Total Returned	1 575

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	1333	0.54%	U.S. Confirmed Malfunctions	149	0.06%
Abnormal Pacing Impedance	95	0.04%	Conductor Fracture	52	0.02%
Cardiac Perforation	8	0.00%	Insulation Breach	95	0.04%
Conductor Fracture	70	0.03%	Other	2	0.00%
Extracardiac Stimulation	11	0.00%			
Failure to Capture	480	0.20%	U.S. Acute Lead Observations	270	0.11%
Failure to Sense	37	0.02%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	63	0.03%	Cardiac Perforation	23	0.01%
Lead Dislodgement	298	0.12%	Failure to Capture	35	0.01%
Oversensing	175	0.07%	Failure to Sense	3	0.00%
Other	96	0.04%	Insulation Breach	4	0.00%
			Lead Dislodgement	188	0.08%
			Other	16	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.9	99.8	99.7	99.6	99.5	99.3	99.2	99.1	98.9	98.8	98.8	98.7
CI [±%]		<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1

6.1 Pacing Leads

Siello S/Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jun 2016
CE Market Release	Jul 2009
Worldwide Distributed Devices	1 155 000
Registered U.S. Implants	94 200
Estimated Active U.S. Implants	90 400
U.S. Total Returned	347

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	161	0.17%	U.S. Confirmed Malfunctions	18	0.02%
Abnormal Pacing Impedance	4	0.00%	Conductor Fracture	6	0.01%
Cardiac Perforation	10	0.01%	Insulation Breach	11	0.01%
Conductor Fracture	5	0.01%	Other	1	0.00%
Extracardiac Stimulation	2	0.00%			
Failure to Capture	53	0.06%	U.S. Acute Lead Observations	123	0.13%
Failure to Sense	3	0.00%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	1	0.00%	Cardiac Perforation	9	0.01%
Lead Dislodgement	77	0.08%	Conductor Fracture	1	0.00%
Oversensing	4	0.00%	Failure to Capture	34	0.04%
Other	2	0.00%	Failure to Sense	2	0.00%
			Insulation Breach	1	0.00%
			Lead Dislodgement	71	0.08%
			Oversensing	2	0.00%
			Other	2	0.00%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.8	99.7	99.7	99.6	99.5
CI [±%]		<0.1	<0.1	0.1	0.1	0.2

6.1 Pacing Leads

Tilda JT

Product Versions _____	45, 53
Lead Type _____	J-shape, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Feb 2012
CE Market Release _____	Sep 2011
Worldwide Distributed Devices _____	17400
Registered U.S. Implants _____	764
Estimated Active U.S. Implants _____	743
U.S. Total Returned _____	0

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	7	0.92%	U.S. Confirmed Malfunctions	0	0.00%
Abnormal Pacing Impedance _____	2	0.26%			
Failure to Capture _____	2	0.26%	U.S. Acute Lead Observations	1	0.13%
Lead Dislodgement _____	3	0.39%	Lead Dislodgement	1	0.13%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	99.5	99.2	99.2	99.0
CI [±%]		0.4	0.5	0.7	0.7	0.8

6.1 Pacing Leads

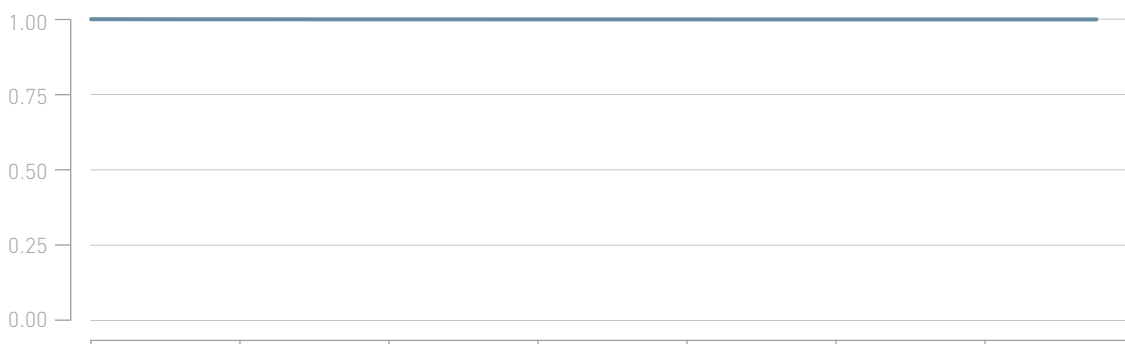
Tilda R

Product Versions _____	45, 53, 60
Lead Type _____	straight, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Dec 2011
CE Market Release _____	Aug 2011
Worldwide Distributed Devices _____	42 000
Registered U.S. Implants _____	9 660
Estimated Active U.S. Implants _____	9 280
U.S. Total Returned _____	15

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	27	0.28%	U.S. Confirmed Malfunctions _____	1	0.01%
Abnormal Pacing Impedance _____	1	0.01%	Conductor Fracture _____	1	0.01%
Conductor Fracture _____	3	0.03%	U.S. Acute Lead Observations _____	9	0.09%
Extracardiac Stimulation _____	1	0.01%	Failure to Capture _____	1	0.01%
Failure to Capture _____	7	0.07%	Lead Dislodgement _____	8	0.08%
Insulation Breach _____	2	0.02%			
Lead Dislodgement _____	9	0.09%			
Oversensing _____	1	0.01%			
Other _____	3	0.03%			

• Total survival

Cumulative survival probability



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

6.1 Pacing Leads

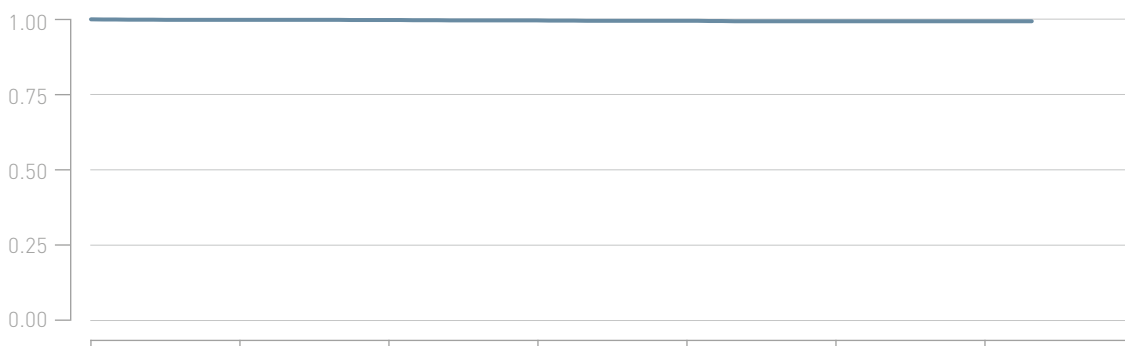
Tilda T

Product Versions _____	53, 60
Lead Type _____	straight, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Dec 2011
CE Market Release _____	Aug 2011
Worldwide Distributed Devices _____	22 700
Registered U.S. Implants _____	1310
Estimated Active U.S. Implants _____	1260
U.S. Total Returned _____	1

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	10	0.77%	U.S. Confirmed Malfunctions _____	0	0.00%
Abnormal Pacing Impedance _____	4	0.31%			
Conductor Fracture _____	1	0.08%	U.S. Acute Lead Observations _____	0	0.00%
Insulation Breach _____	1	0.08%			
Lead Dislodgement _____	4	0.31%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.8	99.7	99.5	99.3	99.1	99.1
CI [±%]		0.3	0.3	0.4	0.5	0.5	0.5

6.2 ICD Leads

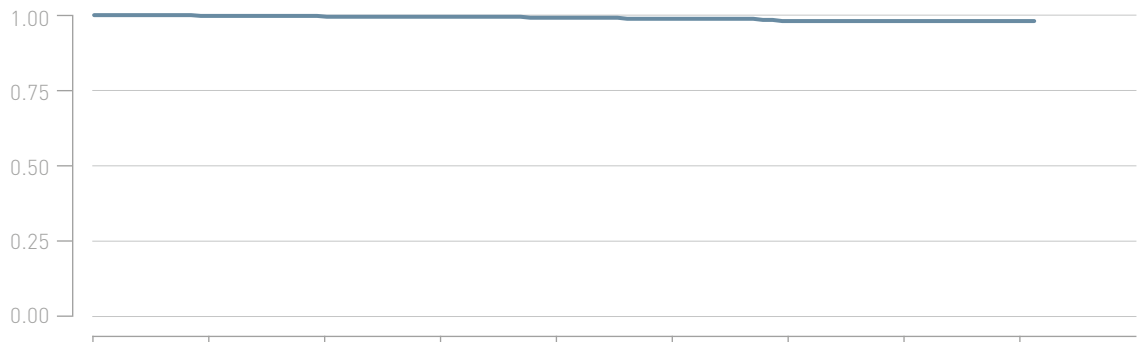
Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5490
Registered U.S. Implants	409
Estimated Active U.S. Implants	172
U.S. Total Returned	8

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	8	1.96%	U.S. Confirmed Malfunctions	2	0.49%
Conductor Fracture	1	0.24%	Conductor Fracture	1	0.24%
Failure to Capture	2	0.49%	Insulation Breach	1	0.24%
Insulation Breach	1	0.24%			
Oversensing	4	0.98%	U.S. Acute Lead Observations	0	0.00%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.7	99.4	99.4	99.0	98.7	97.8	97.8	97.8
CI [±%]		0.6	0.8	0.8	1.1	1.3	1.8	1.8	1.8

6.2 ICD Leads

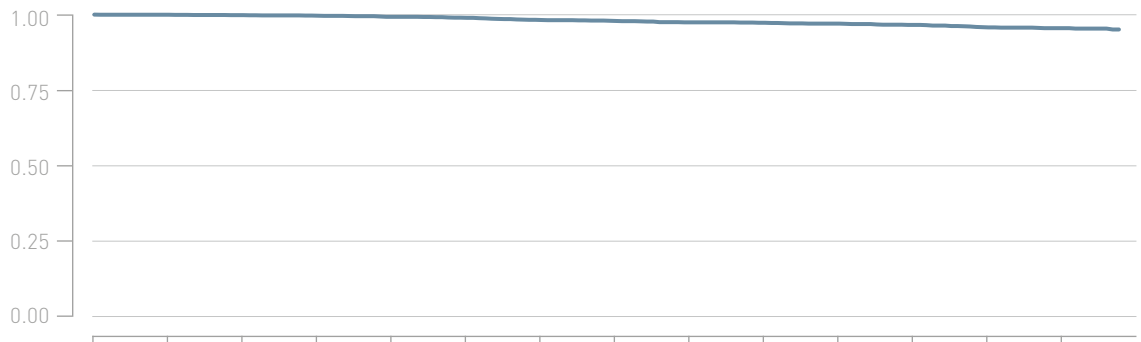
Kentrox SL-S

Product Versions _____	65/16, 18 -Steroid
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes/no
U.S. Market Release _____	Oct 2004
CE Market Release _____	Jun 2004
Worldwide Distributed Devices _____	8730
Registered U.S. Implants _____	2440
Estimated Active U.S. Implants _____	1240
U.S. Total Returned _____	41

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	59	2.42%	U.S. Confirmed Malfunctions _____	14	0.57%
Abnormal Defibrillation Impedance _____	1	0.04%	Insulation Breach _____	14	0.57%
Abnormal Pacing Impedance _____	3	0.12%			
Conductor Fracture _____	5	0.21%	U.S. Acute Lead Observations _____	2	0.08%
Failure to Capture _____	3	0.12%	Insulation Breach _____	1	0.04%
Failure to Sense _____	1	0.04%	Oversensing _____	1	0.04%
Insulation Breach _____	3	0.12%			
Lead Dislodgement _____	3	0.12%			
Oversensing _____	38	1.56%			
Other _____	2	0.08%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	100.0	99.8	99.6	99.2	98.9	98.1	97.8	97.3	97.2	96.9	96.4	95.5	95.3
CI [±%]		0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.1

6.2 ICD Leads

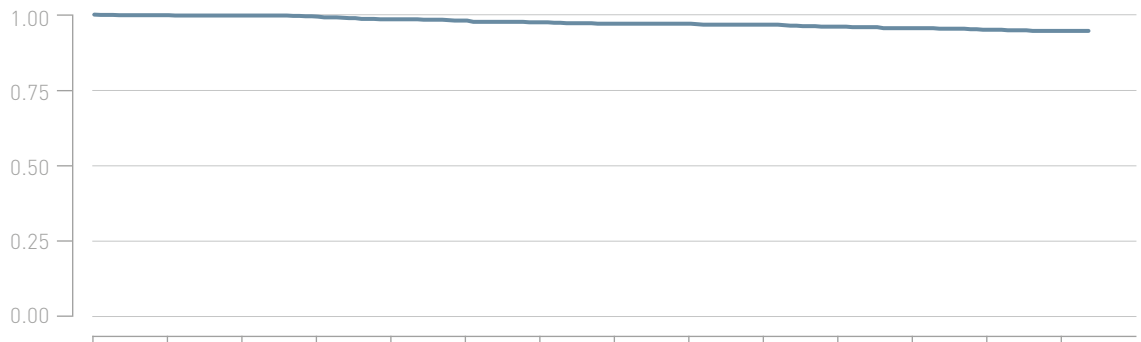
Kentrox SL

Product Versions _____	65, 75, 100, -Steroid
Lead Type _____	dual coil, passive fixation
Polarity _____	bipolar
Steroid _____	yes/no
U.S. Market Release _____	Oct 2004
CE Market Release _____	Dec 2003 / Dec 2004
Worldwide Distributed Devices _____	8480
Registered U.S. Implants _____	1020
Estimated Active U.S. Implants _____	536
U.S. Total Returned _____	19

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	32	3.16%	U.S. Confirmed Malfunctions _____	5	0.49%
Abnormal Defibrillation Impedance _____	1	0.10%	Insulation Breach _____	5	0.49%
Abnormal Pacing Impedance _____	3	0.30%			
Conductor Fracture _____	3	0.30%	U.S. Acute Lead Observations _____	0	0.00%
Failure to Capture _____	1	0.10%			
Insulation Breach _____	6	0.59%			
Oversensing _____	16	1.58%			
Other _____	2	0.20%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.9	96.9	96.5	95.8	95.3	94.8	94.4
CI [±%]		0.3	0.4	0.6	0.9	1.0	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8

6.2 ICD Leads

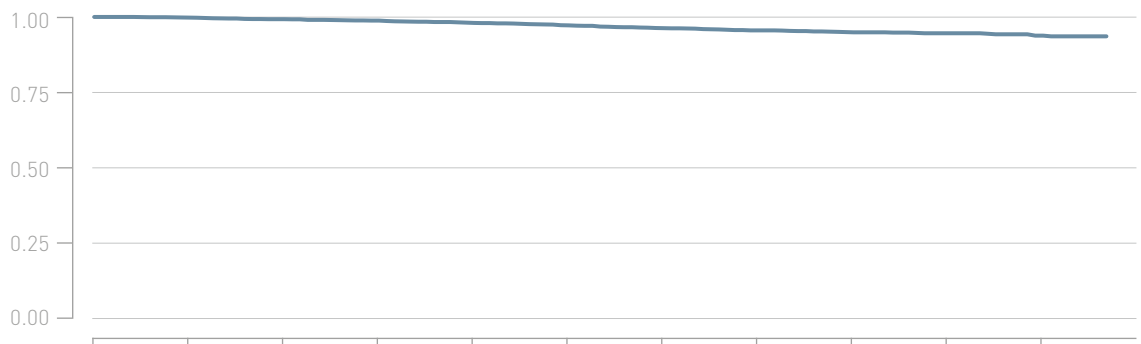
Linux S

Product Versions _____	65, 75
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Feb 2007
CE Market Release _____	Mar 2007
Worldwide Distributed Devices _____	32 700
Registered U.S. Implants _____	2 500
Estimated Active U.S. Implants _____	1 670
U.S. Total Returned _____	79

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	69	2.77%	U.S. Confirmed Malfunctions _____	40	1.61%
Abnormal Defibrillation Impedance _____	6	0.24%	Conductor Fracture _____	5	0.20%
Abnormal Pacing Impedance _____	5	0.20%	Insulation Breach _____	35	1.40%
Conductor Fracture _____	6	0.24%			
Failure to Capture _____	8	0.32%	U.S. Acute Lead Observations _____	2	0.08%
Insulation Breach _____	4	0.16%	Lead Dislodgement _____	1	0.04%
Oversensing _____	34	1.36%	Other _____	1	0.04%
Other _____	6	0.24%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.8	99.2	98.8	98.0	97.1	96.2	95.4	94.7	94.4	93.6
CI [±%]		0.2	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.3

6.2 ICD Leads

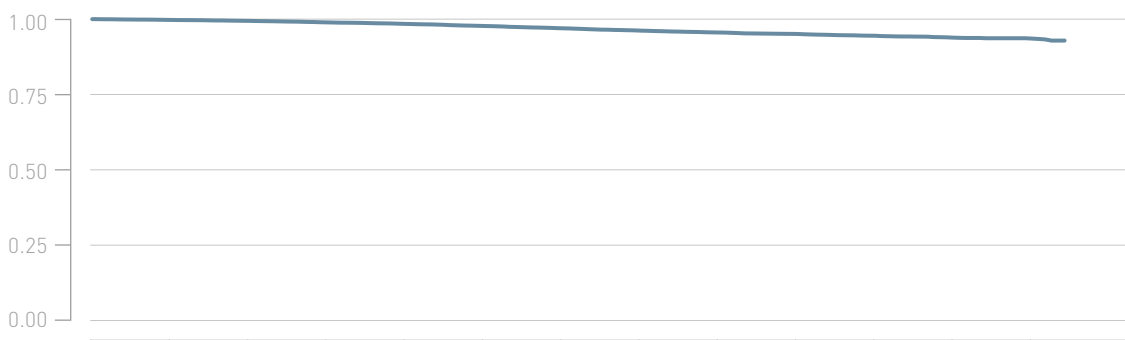
Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	22 300
Estimated Active U.S. Implants	14 400
U.S. Total Returned	483

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	729	3.28%	U.S. Confirmed Malfunctions	195	0.88%
Abnormal Defibrillation Impedance	54	0.24%	Conductor Fracture	27	0.12%
Abnormal Pacing Impedance	50	0.22%	Insulation Breach	167	0.75%
Cardiac Perforation	3	0.01%	Other	1	0.00%
Conductor Fracture	80	0.36%			
Failure to Capture	68	0.31%	U.S. Acute Lead Observations	11	0.05%
Failure to Sense	12	0.05%	Abnormal Pacing Impedance	1	0.00%
Insulation Breach	57	0.26%	Cardiac Perforation	1	0.00%
Lead Dislodgement	31	0.14%	Failure to Capture	1	0.00%
Oversensing	329	1.48%	Lead Dislodgement	6	0.03%
Other	45	0.20%	Oversensing	1	0.00%
			Other	1	0.00%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12
Total [%]	100.0	99.7	99.4	98.9	98.4	97.7	96.9	96.1	95.4	94.9	94.3	93.7	93.3
CI [±%]		0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.5

6.2 ICD Leads

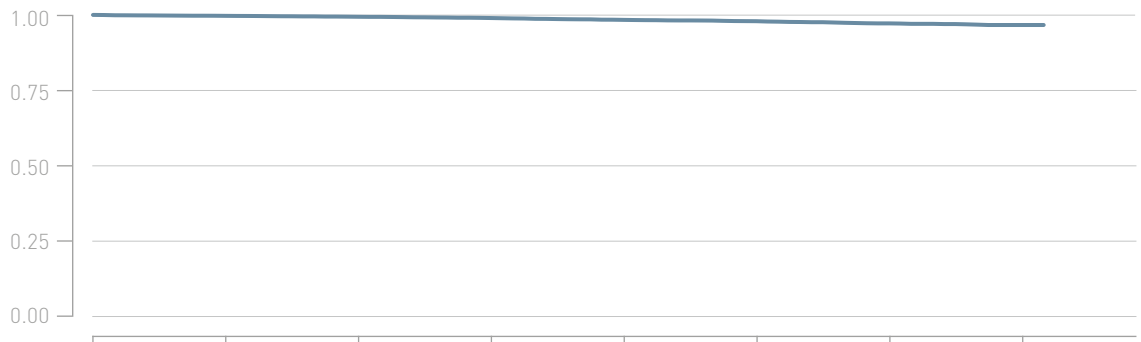
Linux^{smart} S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	47 000
Registered U.S. Implants	7 660
Estimated Active U.S. Implants	6 410
U.S. Total Returned	155

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	113	1.48%	U.S. Confirmed Malfunctions	52	0.68%
Abnormal Defibrillation Impedance	5	0.07%	Conductor Fracture	7	0.09%
Abnormal Pacing Impedance	6	0.08%	Insulation Breach	45	0.59%
Cardiac Perforation	1	0.01%			
Conductor Fracture	10	0.13%	U.S. Acute Lead Observations	11	0.14%
Failure to Capture	19	0.25%	Abnormal Pacing Impedance	1	0.01%
Failure to Sense	4	0.05%	Cardiac Perforation	1	0.01%
Insulation Breach	3	0.04%	Lead Dislodgement	8	0.10%
Lead Dislodgement	14	0.18%	Other	1	0.01%
Oversensing	45	0.59%			
Other	6	0.08%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.3	98.9	98.2	97.8	97.0	96.4
CI [±%]		0.1	0.2	0.2	0.3	0.4	0.5	0.7

6.2 ICD Leads

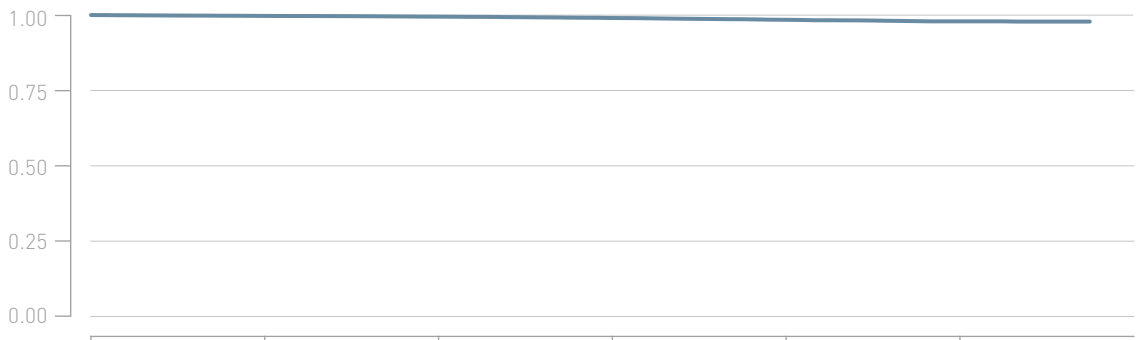
Linux^{smart} S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 200
Registered U.S. Implants	16 400
Estimated Active U.S. Implants	14 900
U.S. Total Returned	274

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	144	0.88%	U.S. Confirmed Malfunctions	59	0.36%
Abnormal Defibrillation Impedance	10	0.06%	Conductor Fracture	3	0.02%
Abnormal Pacing Impedance	6	0.04%	Insulation Breach	56	0.34%
Conductor Fracture	19	0.12%			
Failure to Capture	16	0.10%	U.S. Acute Lead Observations	38	0.23%
Failure to Sense	6	0.04%	Cardiac Perforation	4	0.02%
Insulation Breach	2	0.01%	Failure to Capture	9	0.06%
Lead Dislodgement	31	0.19%	Lead Dislodgement	16	0.10%
Oversensing	50	0.31%	Oversensing	2	0.01%
Other	4	0.02%	Other	7	0.04%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.7	99.4	98.9	98.3	97.7
CI [±%]		0.1	0.1	0.2	0.3	0.4

6.2 ICD Leads

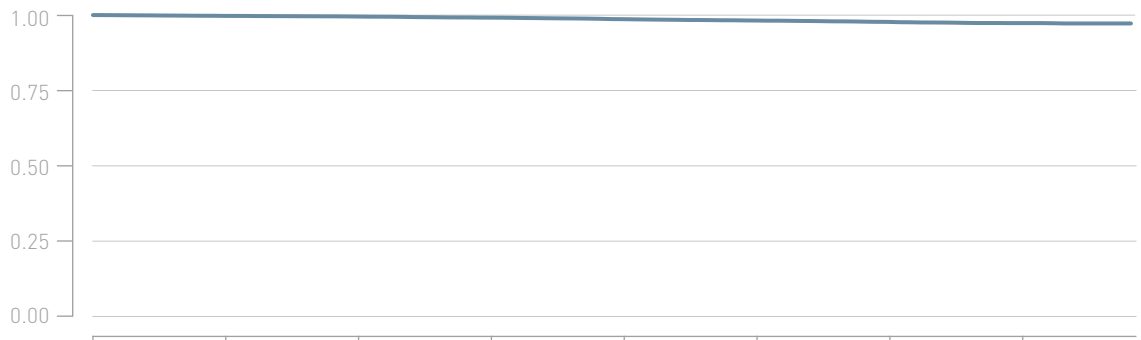
Linux^{smart} SD

Product Versions _____	60/16, 65/16, 65/18, 75/18
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jan 2011
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	55700
Registered U.S. Implants _____	13300
Estimated Active U.S. Implants _____	10900
U.S. Total Returned _____	222

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	222	1.68%	U.S. Confirmed Malfunctions _____	55	0.42%
Abnormal Defibrillation Impedance _____	17	0.13%	Conductor Fracture _____	4	0.03%
Abnormal Pacing Impedance _____	9	0.07%	Insulation Breach _____	50	0.38%
Conductor Fracture _____	29	0.22%	Other _____	1	0.01%
Extracardiac Stimulation _____	1	0.01%			
Failure to Capture _____	19	0.14%	U.S. Acute Lead Observations _____	29	0.22%
Failure to Sense _____	5	0.04%	Abnormal Defibrillation Impedance _____	1	0.01%
Insulation Breach _____	7	0.05%	Cardiac Perforation _____	2	0.02%
Lead Dislodgement _____	22	0.17%	Failure to Capture _____	4	0.03%
Oversensing _____	107	0.81%	Insulation Breach _____	1	0.01%
Other _____	6	0.05%	Lead Dislodgement _____	12	0.09%
			Oversensing _____	2	0.02%
			Other _____	7	0.05%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.7	99.5	99.1	98.5	98.0	97.5	97.1
CI [±%]		0.1	0.1	0.2	0.2	0.3	0.3	0.4

6.2 ICD Leads

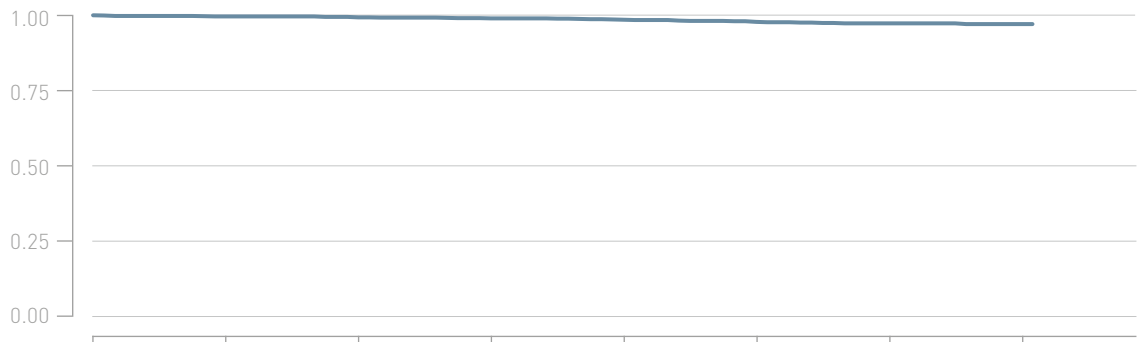
Linux^{smart} TD

Product Versions _____	65/16, 65/18, 75/18
Lead Type _____	dual-coil, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jan 2011
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	7740
Registered U.S. Implants _____	1280
Estimated Active U.S. Implants _____	1030
U.S. Total Returned _____	19

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	29	2.27%	U.S. Confirmed Malfunctions _____	1	0.08%
Abnormal Defibrillation Impedance _____	4	0.31%	Insulation Breach _____	1	0.08%
Abnormal Pacing Impedance _____	3	0.24%			
Conductor Fracture _____	1	0.08%	U.S. Acute Lead Observations _____	3	0.24%
Failure to Capture _____	7	0.55%	Lead Dislodgement _____	3	0.24%
Insulation Breach _____	2	0.16%			
Lead Dislodgement _____	5	0.39%			
Oversensing _____	7	0.55%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.6	99.2	98.9	98.4	97.6	97.1	96.8
CI [±%]		0.4	0.5	0.6	0.7	0.9	1.1	1.2

6.2 ICD Leads

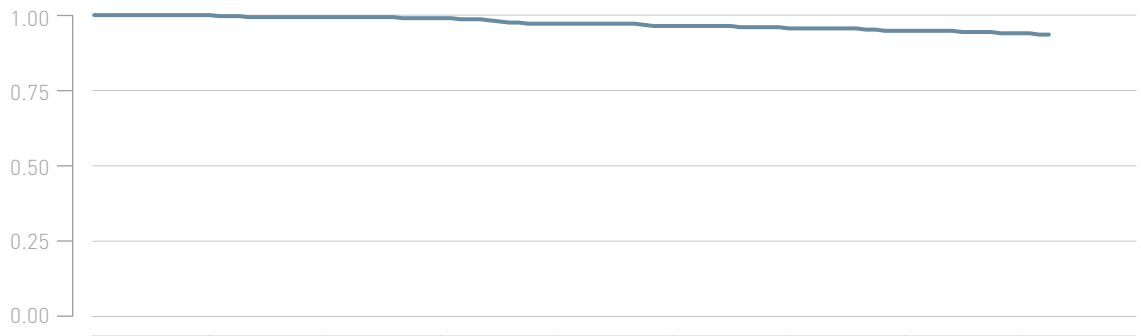
Linux T

Product Versions _____	65, 75
Lead Type _____	single-coil, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Feb 2007
CE Market Release _____	Mar 2007
Worldwide Distributed Devices _____	2280
Registered U.S. Implants _____	322
Estimated Active U.S. Implants _____	224
U.S. Total Returned _____	4

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	14	4.35%	U.S. Confirmed Malfunctions _____	3	0.93%
Abnormal Pacing Impedance _____	2	0.62%	Conductor Fracture _____	1	0.31%
Failure to Capture _____	4	1.24%	Insulation Breach _____	2	0.62%
Insulation Breach _____	1	0.31%			
Oversensing _____	6	1.86%	U.S. Acute Lead Observations _____	1	0.31%
Other _____	1	0.31%	Other _____	1	0.31%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.4	94.6	93.8
CI [±%]		<0.1	0.9	1.2	2.0	2.3	2.5	2.8	3.0

6.2 ICD Leads

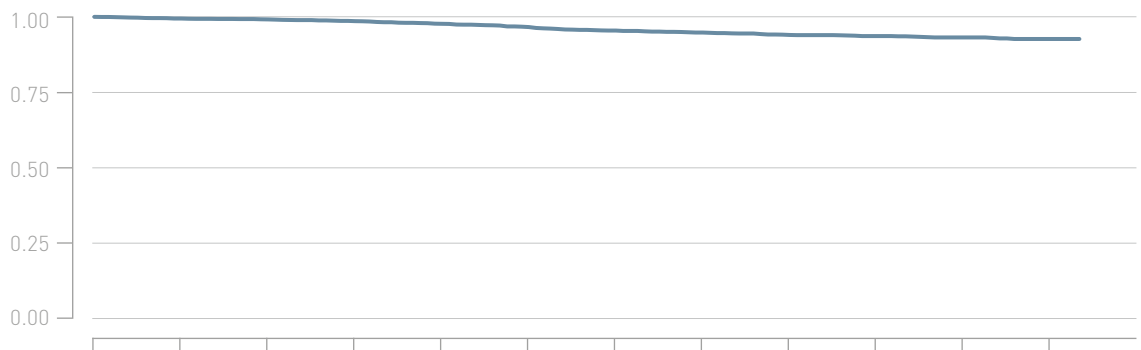
Linux TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered U.S. Implants	3 060
Estimated Active U.S. Implants	2 030
U.S. Total Returned	77

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	123	4.03%	U.S. Confirmed Malfunctions	37	1.21%
Abnormal Defibrillation Impedance	10	0.33%	Conductor Fracture	6	0.20%
Abnormal Pacing Impedance	12	0.39%	Insulation Breach	31	1.02%
Conductor Fracture	16	0.52%			
Failure to Capture	19	0.62%	U.S. Acute Lead Observations	3	0.10%
Failure to Sense	4	0.13%	Failure to Capture	1	0.03%
Insulation Breach	13	0.43%	Lead Dislodgement	2	0.07%
Lead Dislodgement	4	0.13%			
Oversensing	42	1.38%			
Other	3	0.10%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.3	94.6	93.8	93.4	93.0	92.4
CI [±%]		0.3	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.0	1.1	1.2

6.2 ICD Leads

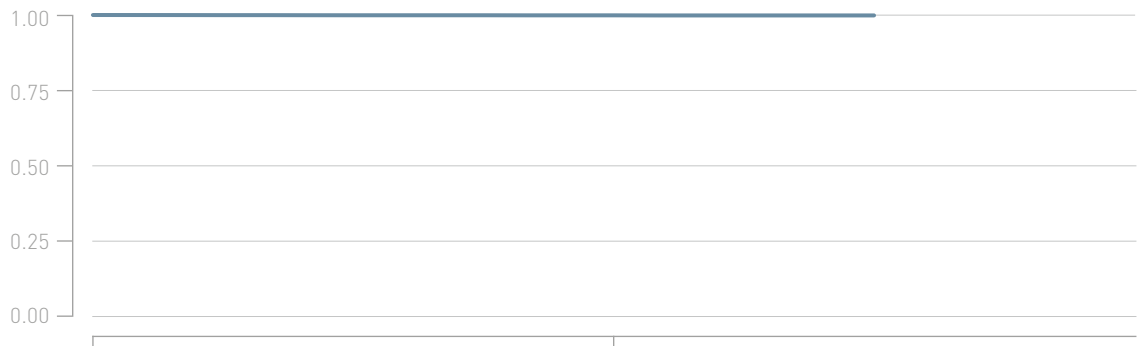
Plexa S

Product Versions _____	65, 75
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Mar 2017
CE Market Release _____	Feb 2017
Worldwide Distributed Devices _____	34 900
Registered U.S. Implants _____	5330
Estimated Active U.S. Implants _____	5 140
U.S. Total Returned _____	24

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	9	0.17%	U.S. Confirmed Malfunctions _____	0	0.00%
Abnormal pacing impedance _____	1	0.02%			
Cardiac Perforation _____	1	0.02%	U.S. Acute Lead Observations _____	9	0.17%
Lead Dislodgement _____	6	0.11%	Cardiac Perforation _____	1	0.02%
Oversensing _____	1	0.02%	Failure to Capture _____	2	0.04%
			Lead Dislodgement _____	6	0.11%

• Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	99.8
CI [±%]		0.1

6.2 ICD Leads

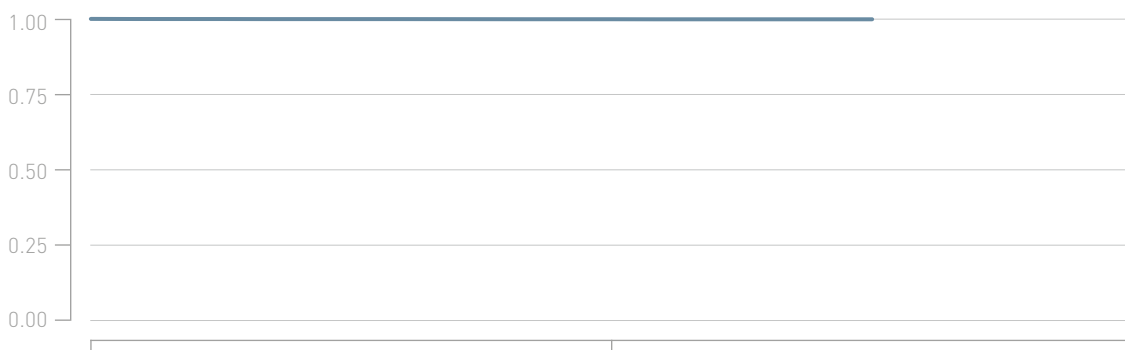
Plexa S DX DF1

Product Versions _____	65/15, 65/17
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Mar 2017
CE Market Release _____	Feb 2017
Worldwide Distributed Devices _____	13300
Registered U.S. Implants _____	5700
Estimated Active U.S. Implants _____	5540
U.S. Total Returned _____	35

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	9	0.16%	U.S. Confirmed Malfunctions _____	4	0.07%
Failure to Capture _____	3	0.05%	Insulation Breach _____	4	0.07%
Lead Dislodgement _____	5	0.09%	U.S. Acute Lead Observations _____	4	0.07%
Oversensing _____	1	0.02%	Failure to Capture _____	1	0.02%
			Lead Dislodgement _____	3	0.05%

• Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	99.7
CI [±%]		0.2

6.2 ICD Leads

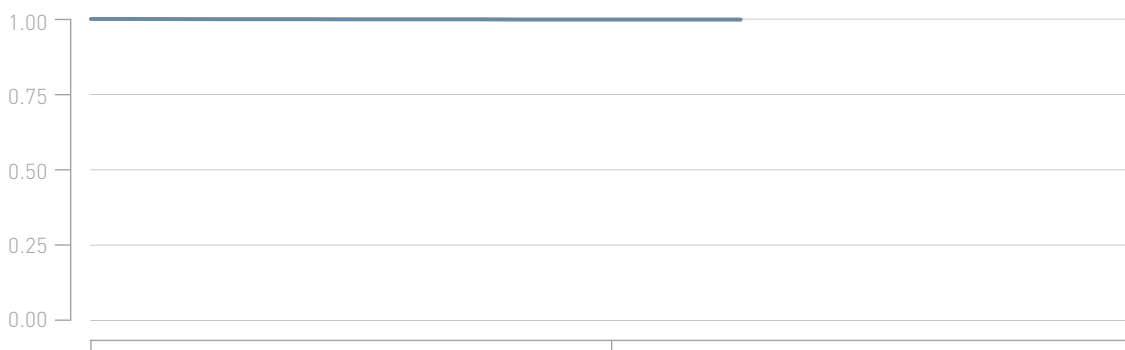
Plexa SD

Product Versions _____	65/16, 65/18, 75/18
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Mar 2017
CE Market Release _____	Feb 2017
Worldwide Distributed Devices _____	5260
Registered U.S. Implants _____	1550
Estimated Active U.S. Implants _____	1490
U.S. Total Returned _____	6

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	4	0.26%	U.S. Confirmed Malfunctions _____	0	0.00%
Failure to Capture _____	1	0.06%			
Lead Dislodgement _____	2	0.13%	U.S. Acute Lead Observations _____	1	0.06%
Oversensing _____	1	0.06%	Cardiac Perforation _____	1	0.06%

• Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	99.6
CI [±%]		0.4

6.2 ICD Leads

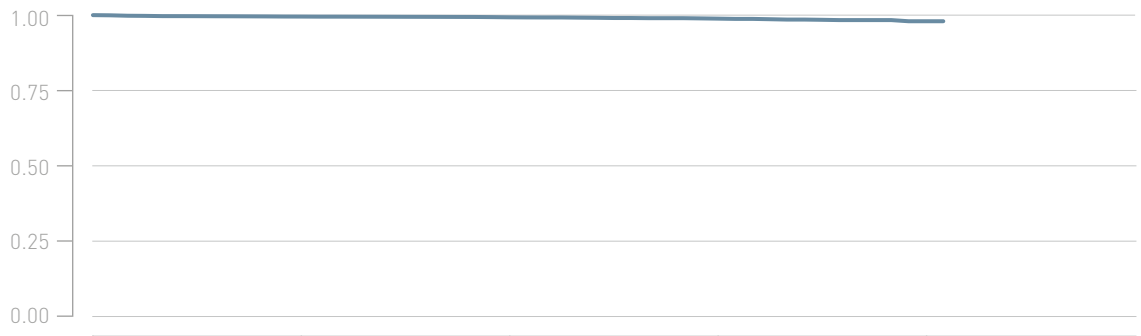
Protego S

Product Versions _____	60, 65, 75
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jul 2014
CE Market Release _____	Feb 2014
Worldwide Distributed Devices _____	54 800
Registered U.S. Implants _____	8 290
Estimated Active U.S. Implants _____	7 500
U.S. Total Returned _____	79

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	68	0.82%	U.S. Confirmed Malfunctions _____	18	0.22%
Abnormal Pacing Impedance _____	3	0.04%	Conductor Fracture _____	3	0.04%
Cardiac Perforation _____	1	0.01%	Insulation Breach _____	14	0.17%
Conductor Fracture _____	3	0.04%	Other _____	1	0.01%
Extracardiac Stimulation _____	1	0.01%			
Failure to Capture _____	13	0.16%	U.S. Acute Lead Observations _____	28	0.34%
Failure to Sense _____	3	0.04%	Cardiac Perforation _____	2	0.02%
Insulation Breach _____	1	0.01%	Extracardiac Stimulation _____	1	0.01%
Lead Dislodgement _____	22	0.27%	Failure to Capture _____	3	0.04%
Oversensing _____	17	0.21%	Lead Dislodgement _____	13	0.16%
Other _____	4	0.05%	Other _____	9	0.11%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.2	98.7	97.7
CI [±%]		0.2	0.2	0.3	0.8

6.2 ICD Leads

Protego SD

Product Versions _____	60/16, 65/16, 65/18, 75/18
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jul 2014
CE Market Release _____	May 2013
Worldwide Distributed Devices _____	18700
Registered U.S. Implants _____	3440
Estimated Active U.S. Implants _____	3120
U.S. Total Returned _____	33

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	25	0.73%	U.S. Confirmed Malfunctions _____	6	0.17%
Abnormal Pacing Impedance _____	2	0.06%	Insulation Breach _____	6	0.17%
Conductor Fracture _____	3	0.09%			
Failure to Capture _____	4	0.12%	U.S. Acute Lead Observations _____	3	0.09%
Insulation Breach _____	1	0.03%	Lead Dislodgement _____	2	0.06%
Lead Dislodgement _____	4	0.12%	Other _____	1	0.03%
Oversensing _____	10	0.29%			
Other _____	1	0.03%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.8	99.5	98.8	98.4
CI [±%]		0.1	0.3	0.5	0.6

6.2 ICD Leads

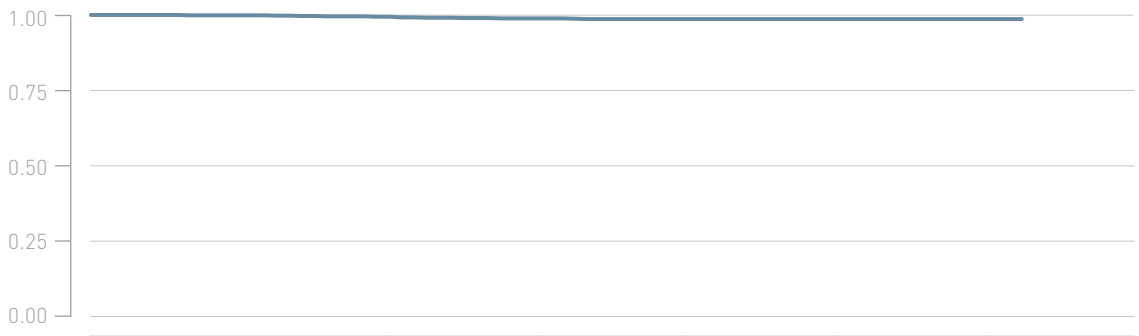
Vigila 2CR

Product Versions _____	60/16, 65/18
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Feb 2012
CE Market Release _____	Oct 2011
Worldwide Distributed Devices _____	3010
Registered U.S. Implants _____	798
Estimated Active U.S. Implants _____	726
U.S. Total Returned _____	11

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	9	1.13%	U.S. Confirmed Malfunctions _____	3	0.38%
Conductor Fracture _____	1	0.13%	Insulation Breach _____	3	0.38%
Lead Dislodgement _____	3	0.38%			
Oversensing _____	5	0.63%	U.S. Acute Lead Observations _____	0	0.00%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.9	99.3	98.7	98.4	98.4	98.4
CI [±%]		0.3	0.6	0.8	0.9	0.9	0.9

6.3 CRT Leads

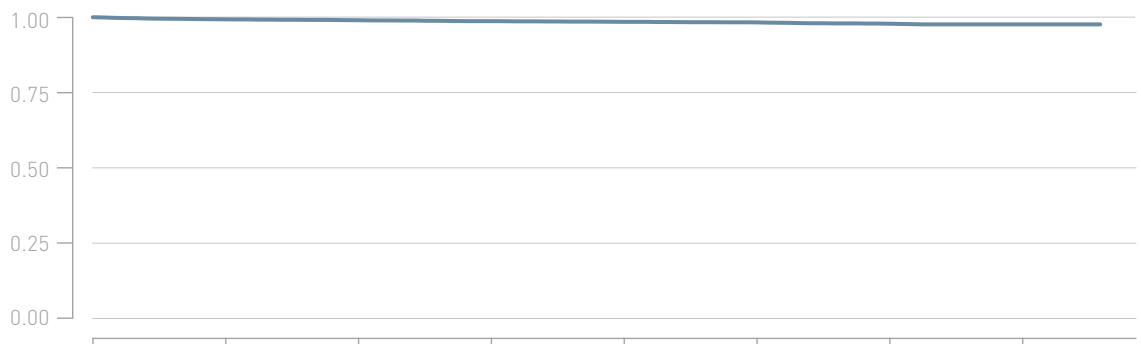
Corox OTW-L

Product Versions _____	75, 85
Lead Type _____	dual-curve fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jan 2011
CE Market Release _____	Dec 2009
Worldwide Distributed Devices _____	32 000
Registered U.S. Implants _____	6 300
Estimated Active U.S. Implants _____	5 090
U.S. Total Returned _____	72

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	105	1.67%	U.S. Confirmed Malfunctions _____	4	0.06%
Abnormal Pacing Impedance _____	1	0.02%	Conductor Fracture _____	3	0.05%
Conductor Fracture _____	4	0.06%	Insulation Breach _____	1	0.02%
Extracardiac Stimulation _____	17	0.27%			
Failure to Capture _____	43	0.68%	U.S. Acute Lead Observations _____	21	0.33%
Failure to Sense _____	1	0.02%	Extracardiac Stimulation _____	6	0.10%
Insulation Breach _____	1	0.02%	Failure to Capture _____	2	0.03%
Lead Dislodgement _____	32	0.51%	Lead Dislodgement _____	10	0.16%
Oversensing _____	1	0.02%	Other _____	3	0.05%
Other _____	5	0.08%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7
Total [%]	100.0	99.2	98.9	98.6	98.3	98.1	97.6	97.4
CI [±%]		0.2	0.3	0.3	0.4	0.4	0.5	0.6

6.3 CRT Leads

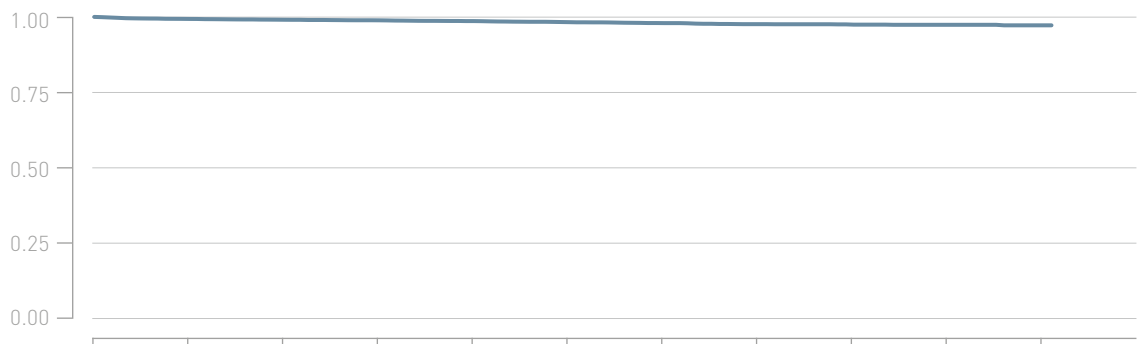
Corox OTW-S

Product Versions _____	75, 85
Lead Type _____	thread fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	26 600
Registered U.S. Implants _____	8 220
Estimated Active U.S. Implants _____	5 760
U.S. Total Returned _____	127

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	137	1.67%	U.S. Confirmed Malfunctions _____	13	0.16%
Abnormal Pacing Impedance _____	7	0.09%	Conductor Fracture _____	8	0.10%
Conductor Fracture _____	4	0.05%	Insulation Breach _____	4	0.05%
Extracardiac Stimulation _____	13	0.16%	Other _____	1	0.01%
Failure to Capture _____	37	0.45%			
Failure to Sense _____	1	0.01%	U.S. Acute Lead Observations _____	34	0.41%
Insulation Breach _____	4	0.05%	Cardiac Perforation _____	1	0.01%
Lead Dislodgement _____	53	0.65%	Extracardiac Stimulation _____	6	0.07%
Oversensing _____	2	0.02%	Failure to Capture _____	6	0.07%
Other _____	16	0.19%	Lead Dislodgement _____	20	0.24%
			Other _____	1	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.3	99.0	98.8	98.5	98.1	97.8	97.4	97.2	97.2	97.0
CI [±%]		0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.5	0.5	0.6

6.3 CRT Leads

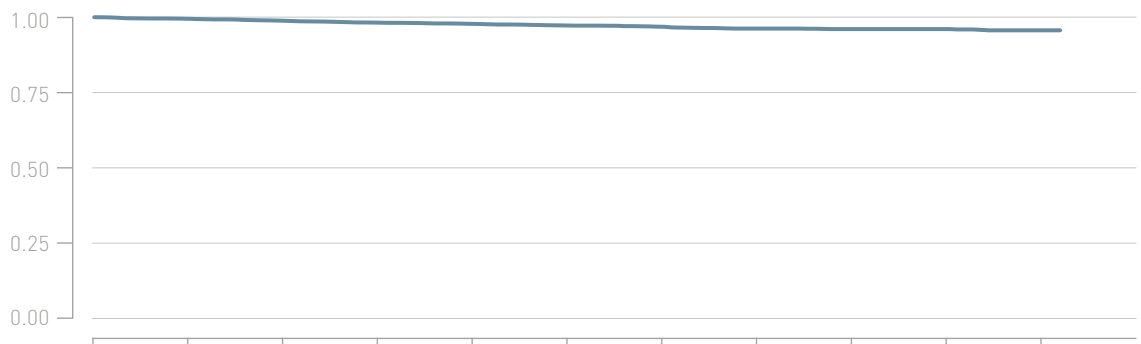
Corox OTW

Product Versions _____	75, 85
Lead Type _____	helix fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	28800
Registered U.S. Implants _____	4 140
Estimated Active U.S. Implants _____	2 650
U.S. Total Returned _____	75

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	102	2.47%	U.S. Confirmed Malfunctions _____	16	0.39%
Abnormal Pacing Impedance _____	3	0.07%	Conductor Fracture _____	15	0.36%
Conductor Fracture _____	3	0.07%	Insulation Breach _____	1	0.02%
Extracardiac Stimulation _____	8	0.19%			
Failure to Capture _____	36	0.87%	U.S. Acute Lead Observations _____	9	0.22%
Insulation Breach _____	2	0.05%	Lead Dislodgement _____	7	0.17%
Lead Dislodgement _____	37	0.90%	Other _____	2	0.05%
Oversensing _____	2	0.05%			
Other _____	11	0.27%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.5	98.8	98.1	97.7	97.2	96.7	96.1	95.9	95.9	95.5
CI [±%]		0.2	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.7	0.9

6.3 CRT Leads

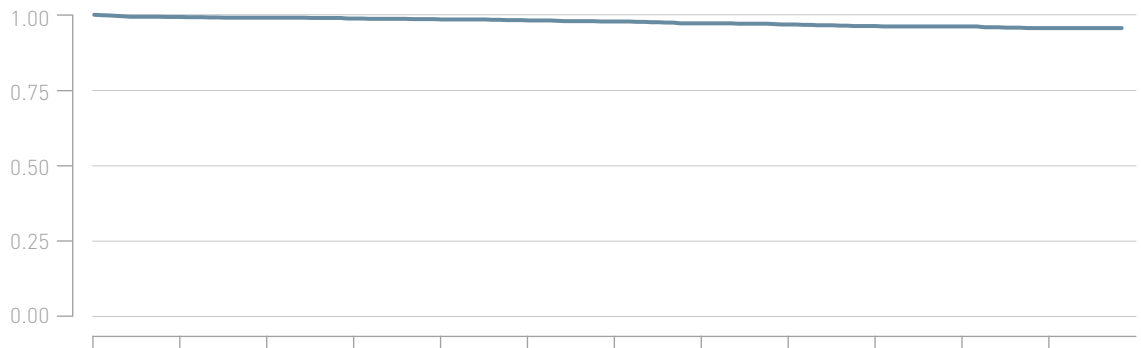
Corox OTW

Product Versions _____	75, 85
Lead Type _____	helix fixation
Polarity _____	unipolar
Steroid _____	yes
U.S. Market Release _____	Aug 2006
CE Market Release _____	Apr 2004
Worldwide Distributed Devices _____	10 400
Registered U.S. Implants _____	1 430
Estimated Active U.S. Implants _____	682
U.S. Total Returned _____	26

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	40	2.81%	U.S. Confirmed Malfunctions _____	2	0.14%
Extracardiac Stimulation _____	7	0.49%	Insulation Breach _____	2	0.14%
Failure to Capture _____	15	1.05%	U.S. Acute Lead Observations _____	4	0.28%
Insulation Breach _____	2	0.14%	Failure to Capture _____	3	0.21%
Lead Dislodgement _____	10	0.70%	Lead Dislodgement _____	1	0.07%
Oversensing _____	1	0.07%			
Other _____	5	0.35%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	99.2	99.0	98.7	98.4	98.0	97.7	97.0	96.6	96.1	95.9	95.4
CI [±%]		0.5	0.6	0.6	0.7	0.8	0.9	1.1	1.2	1.3	1.3	1.4

6.3 CRT Leads

Sentus OTW QP L

Product Versions _____	75, 75/49, 85, 85/49
Lead Type _____	dual-curve fixation
Polarity _____	quadripolar
Steroid _____	yes
U.S. Market Release _____	May 2017
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	52 100
Registered U.S. Implants _____	5 500
Estimated Active U.S. Implants _____	4 920
U.S. Total Returned _____	41

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	38	0.69%	U.S. Confirmed Malfunctions _____	3	0.05%
Abnormal Pacing Impedance _____	1	0.02%	Conductor Fracture _____	3	0.05%
Extracardiac Stimulation _____	3	0.05%			
Failure to Capture _____	8	0.15%	U.S. Acute Lead Observations _____	12	0.22%
Lead Dislodgement _____	25	0.46%	Extracardiac Stimulation _____	3	0.05%
Other _____	1	0.02%	Lead Dislodgement _____	8	0.15%
			Oversensing _____	1	0.02%

• Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	99.0
CI [±%]		0.3

6.3 CRT Leads

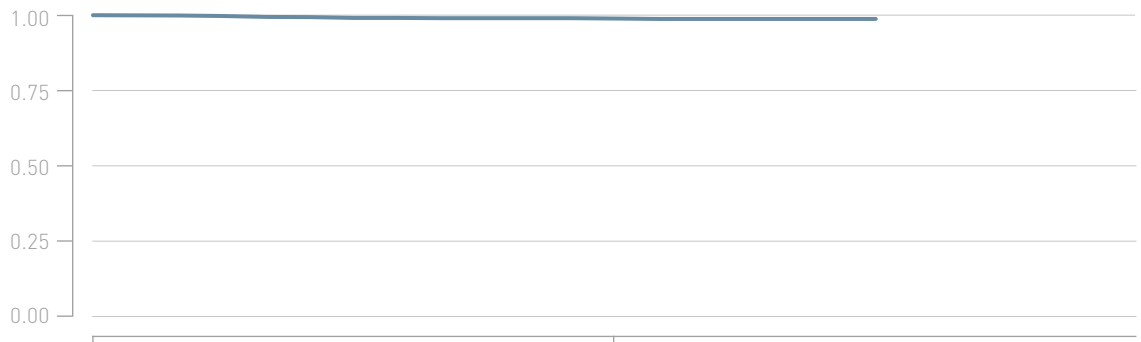
Sentus OTW QP S

Product Versions _____	75, 75/49, 85, 85/49
Lead Type _____	thread fixation
Polarity _____	quadripolar
Steroid _____	yes
U.S. Market Release _____	May 2017
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	13 400
Registered U.S. Implants _____	2 000
Estimated Active U.S. Implants _____	1 660
U.S. Total Returned _____	48

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	16	0.80%	U.S. Confirmed Malfunctions _____	2	0.10%
Extracardiac Stimulation _____	1	0.05%	Conductor Fracture _____	2	0.10%
Failure to Capture _____	3	0.15%			
Lead Dislodgement _____	12	0.60%	U.S. Acute Lead Observations _____	30	1.50%
			Extracardiac Stimulation _____	2	0.10%
			Failure to Capture _____	4	0.20%
			Lead Dislodgement _____	24	1.20%

• Total survival

Cumulative survival probability



Years after implant	0	1
Total [%]	100.0	98.7
CI [±%]		0.6



Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

7.2 BIOTRONIK's Clinical Studies

7.3 Lead Complications

7.4 Lead Product Performance Graphs
and Data

7. Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

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

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

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

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

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

7.2 BIOTRONIK's Clinical Studies

7.2.1 GALAXY and CELESTIAL

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

The evaluation of safety for GALAXY is based on the analysis of BIOTRONIK Linx ICD lead-related adverse events. The evaluation of safety for CELESTIAL is based on the analysis of BIOTRONIK Corox LV pacing lead-related adverse events. However, many CELESTIAL patients also have a Linx ICD lead implanted and the Linx clinical studies data in this report represents combined data from the GALAXY and CELESTIAL registries. Both registries are designed to continue for a 5 year follow-up duration per patient. As of the January 2018 PPR, incremental updates to Linx data originate from the CELESTIAL Registry, as the GALAXY Registry is complete. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be

seen for routine follow-up visits per their institutional standard of care until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum of once every six months follow-up requirement.

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

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

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

Patient Enrollment Criteria

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

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

Each site must inform BIOTRONIK whenever a lead complication has

occurred or when a patient is no longer participating.

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

7.2.2 SIELLO Clinical Study

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

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

For the Post-Approval Registry, the evaluation of long-term safety is based on the analysis of Siello lead-related adverse events through a follow-up time of 5 years post-implant. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm products are used. Patients will be seen for routine follow-up visits until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study

follow-up schedule consistent with typical care practices has been established, with required follow-ups at 3 and 6 months post-implant and every 6 months thereafter.

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

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

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

Patient Enrollment Criteria

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

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

Each site must inform BIOTRONIK whenever a lead complication has

occurred or when a patient is no longer participating.

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

7.2.3 Protego Post-Approval Registry

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

The evaluation of safety will be based on the analysis of Protego DF4 lead related or header related adverse events through a follow-up time of 5 years post-implant. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

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

During each study visit, the following are required:

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

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

Patient Enrollment Criteria

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

- Candidate for implant or successfully implanted with a BIOTRONIK ICD or BIOTRONIK CRT-D system, including a Protego lead
- Able to understand the nature of the registry and give informed consent
- Available for follow-up visits on a regular basis at the study site
- Age greater than or equal to 18 years

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

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

7.2.4 QP ExCELS

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

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

For the Post-Approval Study, the evaluation of safety will be based on the analysis of Sentus QP lead-related adverse events through a follow-up time of 5 years post-implant. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

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

Patient Enrollment Criteria

To support the objectives of the study, participants are required to meet the

following inclusion criteria prior to enrollment:

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

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

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

7.3 Lead Complications

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

7.3.1 GALAXY and CELESTIAL

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

Event Classifications

- Failure to Capture
- Failure to Sense/Undersensing
- Oversensing
- Abnormal Pacing Impedance (based on lead model, but normal range is typically 200- 2,000 ohms)
- Abnormal Defibrillation Impedance (based on lead model, but normal range is 25 – 150 ohms)
- Insulation Breach
- Conductor Fracture, confirmed electrically, visually or radiographically
- Extracardiac Stimulation
- Cardiac Perforation
- Lead Dislodgement

Clinical Actions

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

7.3.2 SIELLO

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

Event Classifications

- Failure to Capture
- Failure to Sense/Undersensing
- Oversensing
- Abnormal Pacing Impedance (based on lead model, but normal range is typically 200 - 2,000 Ohm)
- Insulation Breach
- Conductor Fracture, confirmed electrically, visually or radiographically
- Extracardiac Stimulation
- Cardiac Perforation
- Lead Dislodgement

7.3.3 Protego

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

Event Classifications

- Failure to Capture
- Failure to Sense/Undersensing
- Oversensing

- Abnormal Pacing Impedance (based on lead model, but normal range is typically 200 - 2,000 Ohm)
- Abnormal Defibrillation Impedance (based on lead model, but normal range is 25 to 150 Ohm)
- Insulation Breach
- Conductor Fracture, confirmed electrically, visually or radiographically
- Extracardiac Stimulation
- Cardiac Perforation
- Lead Dislodgement

7.3.4 QP ExCELS

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

Event Classifications

- Failure to Capture
- Failure to Sense/Undersensing
- Oversensing
- Abnormal Pacing Impedance (based on lead model, but normal range is typically 200 - 2000 Ohm)
- Insulation Breach
- Conductor Fracture, confirmed electrically, visually or radiographically
- Extracardiac Stimulation
- Cardiac Perforation
- Lead Dislodgement

7.4 Lead Product Performance Graphs and Data

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

Returned Product Analysis Results

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



Performance of BIOTRONIK Leads Based on Clinical Study Data

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

8.1 Performance of Pacing Leads

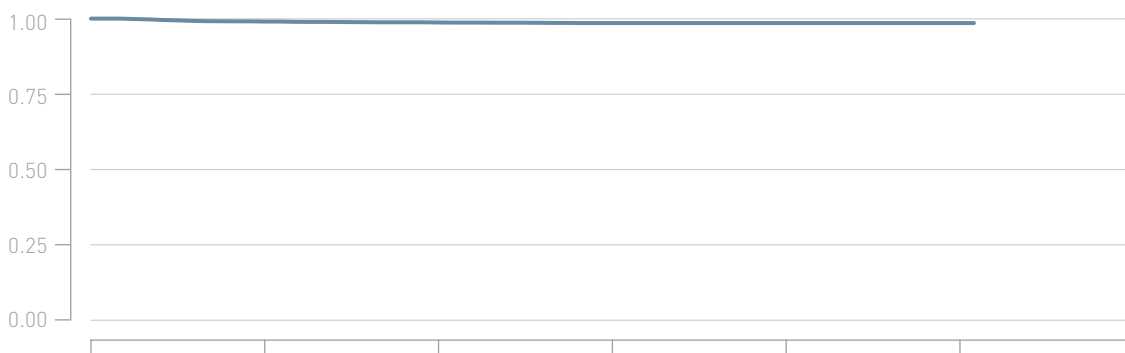
Siello S / Solia S Study Data

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jun 2016
CE Market Release	Jul 2009
Worldwide Distributed Devices	1 155 000
Registered U.S. Implants	3242

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	51	1.57%	U.S. Confirmed Malfunctions	2	0.06%
Abnormal Pacing Impedance	2	0.06%	Conductor Fracture	1	0.03%
Cardiac Perforation	3	0.09%	Insulation Breach	1	0.03%
Conductor Fracture	1	0.03%			
Failure to Capture	23	0.71%	U.S. Acute Lead Observations	26	0.80%
Failure to Sense (undersensing)	11	0.34%	Cardiac Perforation	8	0.25%
Lead Dislodgement	9	0.28%	Extracardiac Stimulation	2	0.06%
Oversensing	1	0.03%	Failure to Capture	6	0.19%
Other	1	0.03%	Failure to Sense (undersensing)	5	0.15%
			Lead Dislodgement	5	0.15%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.9	98.5	98.3	98.3	98.3
CI [±%]		0.4	0.4	0.5	0.5	0.5

8.2 Performance of ICD Leads

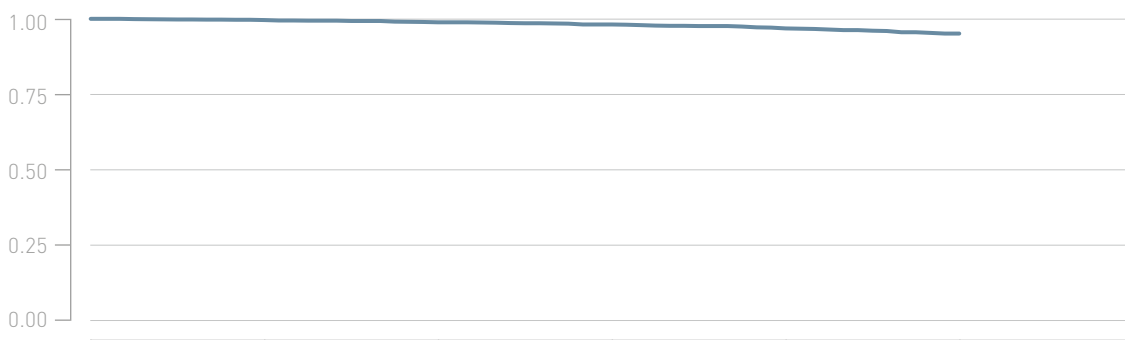
Linux SD Study Data

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

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	68	2.99%	U.S. Confirmed Malfunctions	23	1.01%
Abnormal Defibrillation Impedance	4	0.18%	Conductor Fracture	3	0.13%
Abnormal Pacing Impedance	10	0.44%	Insulation Breach	20	0.88%
Cardiac Perforation	1	0.04%			
Conductor Fracture	10	0.44%	U.S. Acute Lead Observations	8	0.35%
Failure to Capture	7	0.31%	Cardiac Perforation	4	0.18%
Failure to Sense (undersensing)	3	0.13%	Conductor Fracture	1	0.04%
Insulation Breach	13	0.57%	Failure to Capture	1	0.04%
Lead Dislodgement	3	0.13%	Lead Dislodgement	1	0.04%
Oversensing	17	0.75%	Other	1	0.04%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	98.8	98.0	96.7	94.9
CI [±%]		0.3	0.5	0.7	0.9	1.3

8.2 Performance of ICD Leads

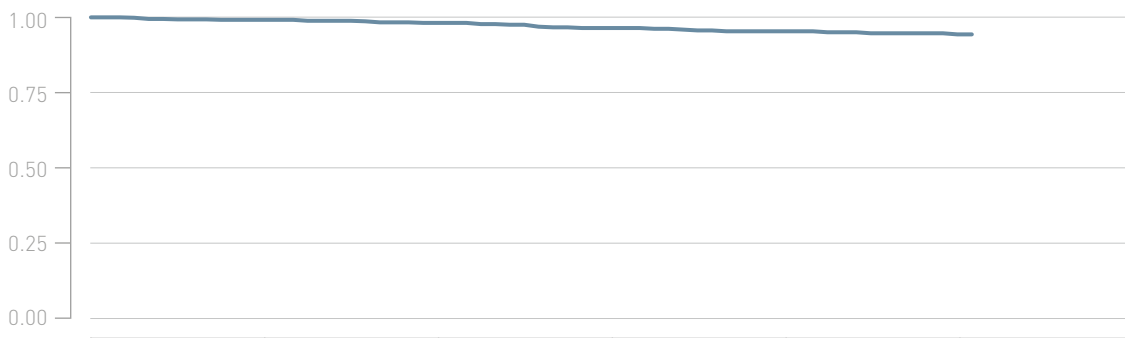
Linux^{smart} SD Study Data

Product Versions _____	60/16, 65/16, 65/18, 75/18
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jan 2011
CE Market Release _____	Oct 2009
Worldwide Distributed Devices _____	55700
Registered U.S. Implants _____	736

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	27	3.67%	U.S. Confirmed Malfunctions _____	7	0.95%
Abnormal Defibrillation Impedance _____	2	0.27%	Insulation Breach _____	7	0.95%
Abnormal Pacing Impedance _____	1	0.14%			
Conductor Fracture _____	3	0.41%	U.S. Acute Lead Observations _____	2	0.27%
Failure to Capture _____	2	0.27%	Lead Dislodgement _____	2	0.27%
Insulation Breach _____	4	0.54%			
Lead Dislodgement _____	6	0.82%			
Oversensing _____	9	1.22%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.1	98.1	96.3	95.2	94.1
CI [±%]		0.8	1.1	1.7	2.0	2.3

8.2 Performance of ICD Leads

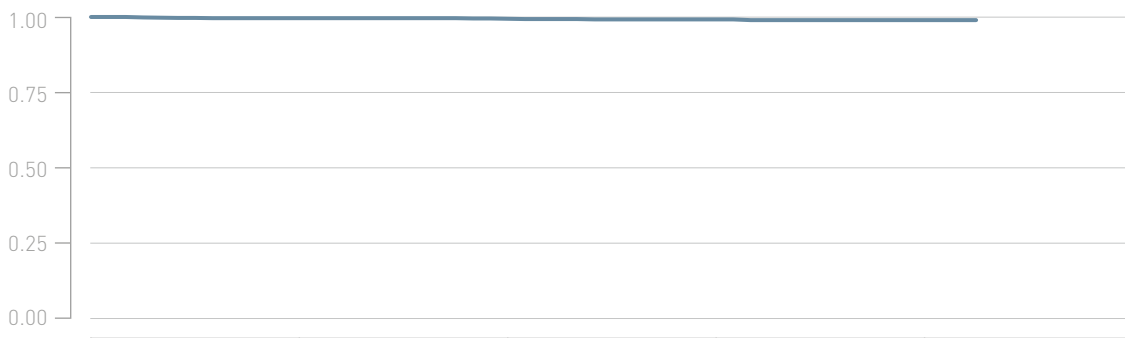
Protego S Study Data

Product Versions _____	60, 65, 75
Lead Type _____	single-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Jul 2014
CE Market Release _____	Feb 2014
Worldwide Distributed Devices _____	54 800
Leads registered in study _____	1 090

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	10	0.92%	U.S. Confirmed Malfunctions _____	8	0.73%
Conductor Fracture _____	2	0.18%	Conductor Fracture _____	2	0.18%
Failure to Capture _____	1	0.09%	Insulation Breach _____	6	0.55%
Failure to Sense _____	1	0.09%			
Lead Dislodgement _____	2	0.18%	U.S. Acute Lead Observations _____	4	0.37%
Oversensing _____	4	0.37%	Cardiac Perforation _____	3	0.27%
			Lead Dislodgement _____	1	0.09%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.5	99.3	99.0	98.7
CI [±%]		0.5	0.6	0.7	0.9

8.2 Performance of ICD Leads

Protego SD Study Data

Product Versions _____ 60/16, 65/16, 65/18, 75/18
 Lead Type _____ dual-coil, active fixation
 Polarity _____ bipolar
 Steroid _____ yes
 U.S. Market Release _____ Jul 2014
 CE Market Release _____ May 2013
 Worldwide Distributed Devices _____ 18 700
 Leads registered in study _____ 533

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	4	0.75%	U.S. Confirmed Malfunctions	2	0.38%
Abnormal Defibrillation Impedance	2	0.38%	Insulation Breach	2	0.38%
Conductor Fracture	1	0.19%	U.S. Acute Lead Observations	2	0.38%
Failure to Capture	1	0.19%	Lead Dislodgement	2	0.38%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4
Total [%]	100.0	99.4	99.4	99.4	98.9
CI [±%]		0.9	0.9	0.9	1.4

8.3 Performance of CRT Leads

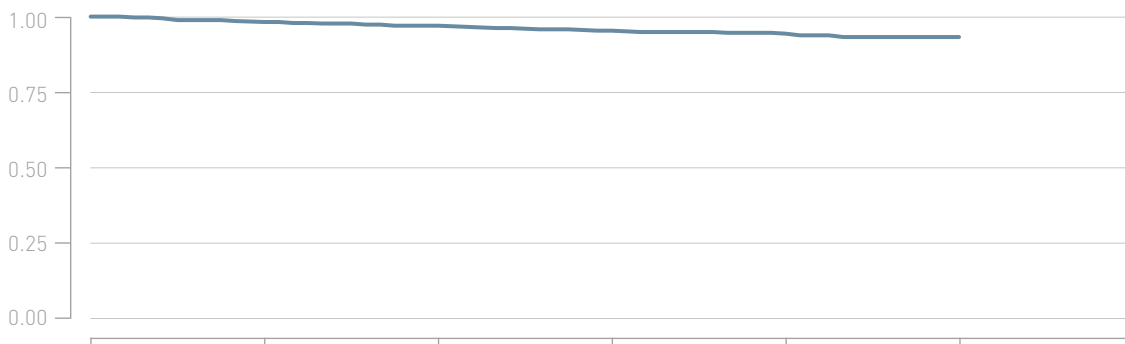
Corox OTW Study Data

Product Versions _____	75, 85
Lead Type _____	helix fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	28 800
Leads registered in study _____	696

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	35	5.03%	U.S. Confirmed Malfunctions _____	6	0.86%
Abnormal Pacing Impedance _____	6	0.86%	Conductor Fracture _____	6	0.86%
Conductor Fracture _____	5	0.72%	U.S. Acute Lead Observations _____	4	0.57%
Extracardiac Stimulation _____	3	0.43%	Extracardiac Stimulation _____	1	0.14%
Failure to Capture _____	5	0.72%	Lead Dislodgement _____	3	0.43%
Lead Dislodgement _____	16	2.30%			

• Total survival

Cumulative survival probability



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

8.3 Performance of CRT Leads

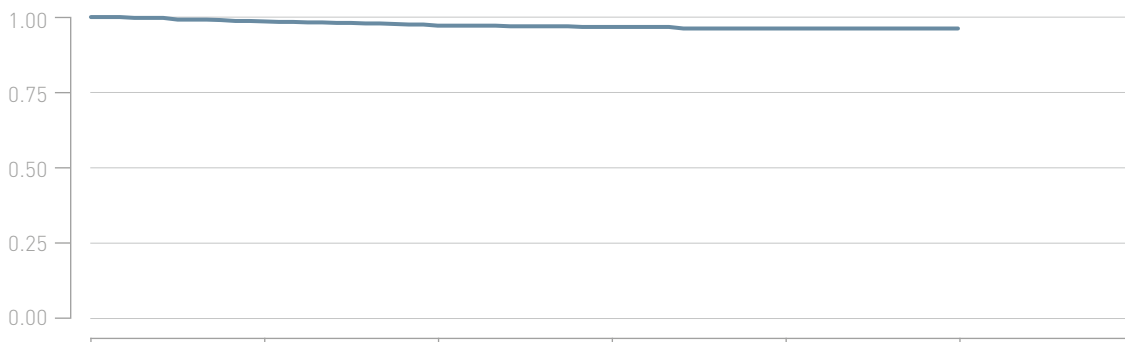
Corox OTW-L Study Data

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

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	22	3.15%	U.S. Confirmed Malfunctions _____	0	0.00%
Extracardiac Stimulation _____	4	0.57%			
Failure to Capture _____	8	1.14%	U.S. Acute Lead Observations _____	4	0.57%
Lead Dislodgement _____	10	1.43%	Extracardiac Stimulation _____	3	0.43%
			Lead Dislodgement _____	1	0.14%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.5	97.0	96.5	96.0	96.0
CI [±%]		1.0	1.4	1.6	1.7	1.7

8.3 Performance of CRT Leads

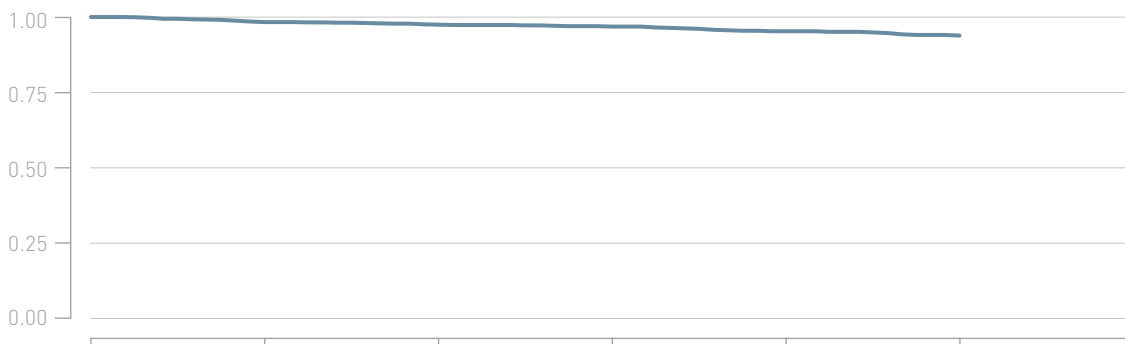
Corox OTW-S Study Data

Product Versions _____	75, 85
Lead Type _____	thread fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	May 2008
CE Market Release _____	Dec 2006
Worldwide Distributed Devices _____	26 600
Leads registered in study _____	1 141

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	49	4.29%	U.S. Confirmed Malfunctions _____	1	0.09%
Abnormal Pacing Impedance _____	13	1.14%	Insulation Breach _____	1	0.09%
Extracardiac Stimulation _____	9	0.79%			
Failure to Capture _____	9	0.79%	U.S. Acute Lead Observations _____	5	0.44%
Lead Dislodgement _____	18	1.58%	Extracardiac Stimulation _____	1	0.09%
			Failure to Capture _____	1	0.09%
			Lead Dislodgement _____	3	0.26%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.2	97.3	96.6	95.0	93.5
CI [±%]		0.8	1.0	1.2	1.5	1.9

8.3 Performance of CRT Leads

Sentus OTW QP S Study Data

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	13 400
Leads registered in study	408

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	14	3.43%	U.S. Confirmed Malfunctions	2	0.49%
Conductor Fracture	1	0.25%	Conductor Fracture	2	0.49%
Extracardiac Stimulation	1	0.25%			
Failure to Capture	2	0.49%	U.S. Acute Lead Observations	10	2.45%
Lead Dislodgement	10	2.45%	Cardiac Perforation	1	0.25%
			Failure to Capture	1	0.25%
			Lead Dislodgement	8	1.96%

• Total survival

Cumulative survival probability



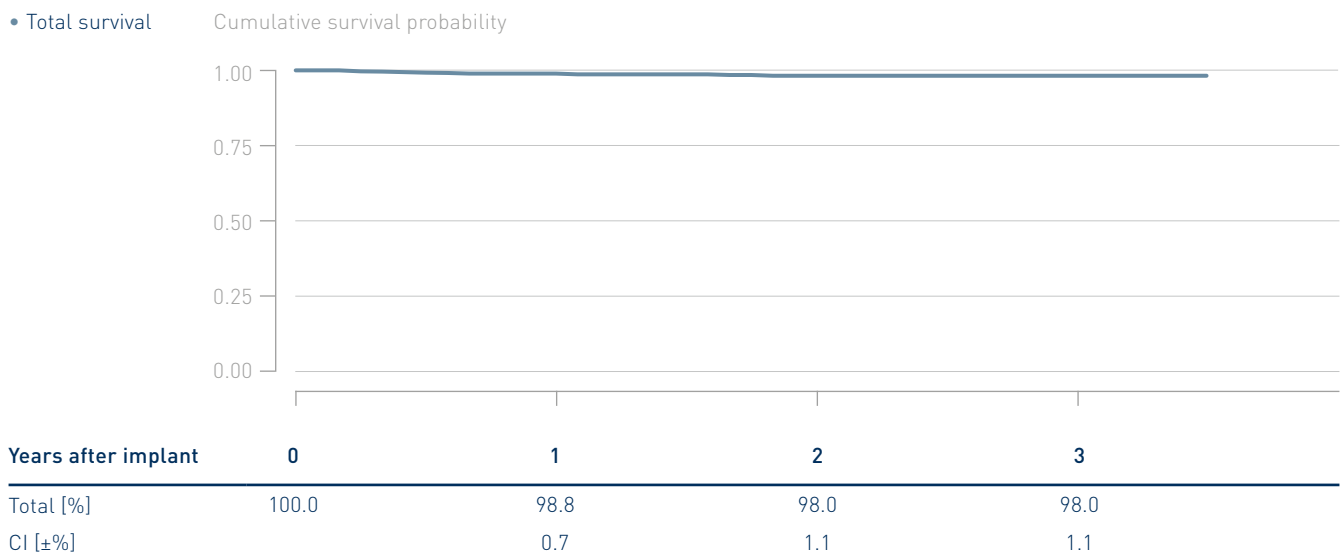
Years after implant	0	1	2	3
Total [%]	100.0	96.5	96.1	96.1
CI [±%]		2.0	2.1	2.1

8.3 Performance of CRT Leads

Sentus OTW QP L Study Data

Product Versions _____	75, 75/49, 85, 85/49
Lead Type _____	dual-curve fixation
Polarity _____	quadripolar
Steroid _____	yes
U.S. Market Release _____	May 2017
CE Market Release _____	Dec 2014
Worldwide Distributed Devices _____	52 100
Leads registered in study _____	1 133

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	16	1.41%	U.S. Confirmed Malfunctions _____	2	0.18%
Abnormal Pacing Impedance _____	3	0.26%	Conductor Fracture _____	2	0.18%
Extracardiac Stimulation _____	2	0.18%			
Failure to Capture _____	3	0.26%	U.S. Acute Lead Observations _____	7	0.62%
Lead Dislodgement _____	8	0.71%	Extracardiac Stimulation _____	2	0.18%
			Failure to Capture _____	3	0.26%
			Lead Dislodgement _____	2	0.18%





Advisories

9. Advisories

Stratos LV-T Potentially Defective Low Voltage Capacitors 84 Devices World-wide, None in the United States

Status Update As of December 2018

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

Original communication July 2006

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

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

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

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

hospitals and may have been implanted.

Based on preliminary data received from the component supplier, the projected rate of occurrence is expected to less than 1 out of 1 000 devices.

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


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

We have tried to be as specific as possible with our recommendations. As always, individual circumstances and medical judgement determine

decisions about patient care, the urgency of follow-ups and possible replacement of devices.

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

X-Ray Identifiers for Pacemakers and ICDs

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

Contacting BIOTRONIK

Regarding this Report

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

PPR Support Team

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

Address

BIOTRONIK SE & Co. KG
Attn: Quality Patient Safety
Woermannkehre 1
12359 Berlin, Germany

Regarding Products

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

Worldwide CRM Product Support

Phone + 49 (0) 30 68905 1133
Fax + 49 (0) 30 68905 1960
Email product.support@biotronik.com

Address

BIOTRONIK SE & Co. KG
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Woermannkehre 1
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Within the U.S.:

Phone (800) 284 6689
Fax (800) 387 2681
E-mail technical.services@biotronik.com

Address

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