



Product Performance Report 2nd Edition 2023

Cardiac Rhythm Management
Cumulative Survival Probability

Product
Performance Report
2nd Edition 2023

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

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

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

As a means to obtain continuous improvement of the designs, BIOTRONIK carefully analyzes returned products and incorporates all findings into our quality assurance system. This Product Performance Report was prepared in accordance with International Standard ISO 5841-2: 2014 [E]¹ and is in compliance with the recommendations from the U.S. Heart Rhythm Society Task Force on Device Performance Policies and Guidelines. As an active member of AdvaMed and their Pacemaker/ICD Working Group, BIOTRONIK has worked extensively with the CRM industry to ensure comparable product performance data is reported by all manufacturers.

The data provided in BIOTRONIK's Product Performance Report incorporates the requirements and definitions as defined in AdvaMed's Requirements for Uniform Reporting of Clinical Performance of Pulse Generators, except as noted herein.

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

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



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

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

BIOTRONIK, December 2023



Stephan Schwerzel
Senior Director Quality Assurance
Quality Assurance 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.

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, 2022. The number of U.S. devices that are implanted and remain

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

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

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

2.3 Returned Product Analysis

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

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

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

2.4 Product Performance Graphs and Data

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

For each product, the report provides:

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

The survival plots provide:

1. Total Survival

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

2. Malfunction-Free Survival

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

Products or subgroups of products may become subject to safety advisory notifications that can significantly impact the overall product performance. However, as these subgroups are clearly defined they are separated from the non-advisory

devices. The impact of the advisory notification is then shown in a separate graph for total cumulative survival and for malfunction-free survival of the device population affected by the advisory notification. Current advisories are listed in chapter 11 of this report.

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

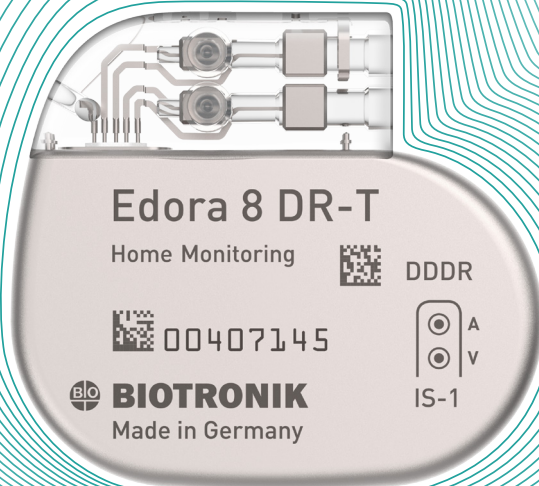
¹ Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1–26, 1926

Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers

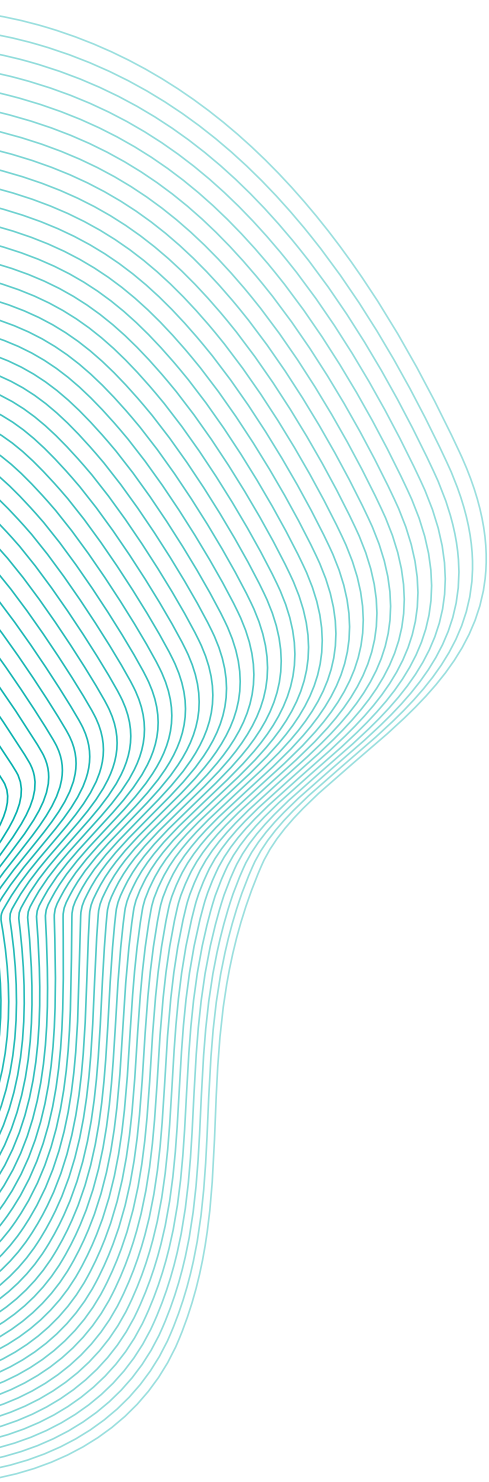


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers

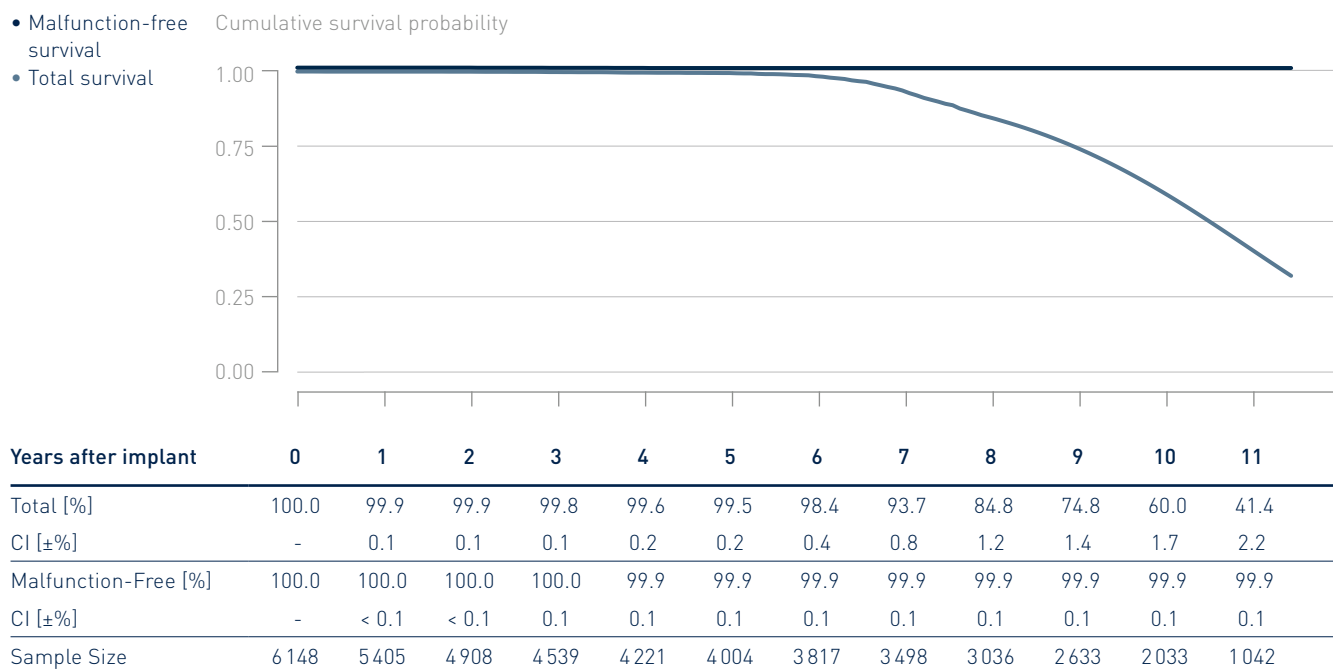


3.1 Single-Chamber Pacemakers

Cylos and Cylos 990*

Product Versions	VR
NBG Codes	WVIR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	25 900
Registered U.S. Implants	6 148
Estimated Active U.S. Implants	2 220
U.S. Normal Battery Depletions	856

	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.

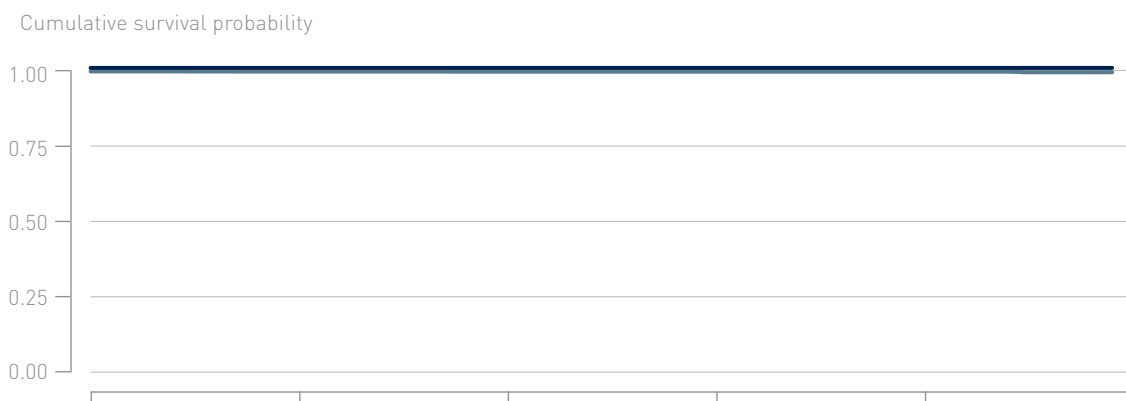
3.1 Single-Chamber Pacemakers

Edora 8

Product Versions	SR, SR-T
NBG Codes	VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	44 400
Registered U.S. Implants	8 325
Estimated Active U.S. Implants	6 940
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%

- Malfunction-free survival
- Total survival



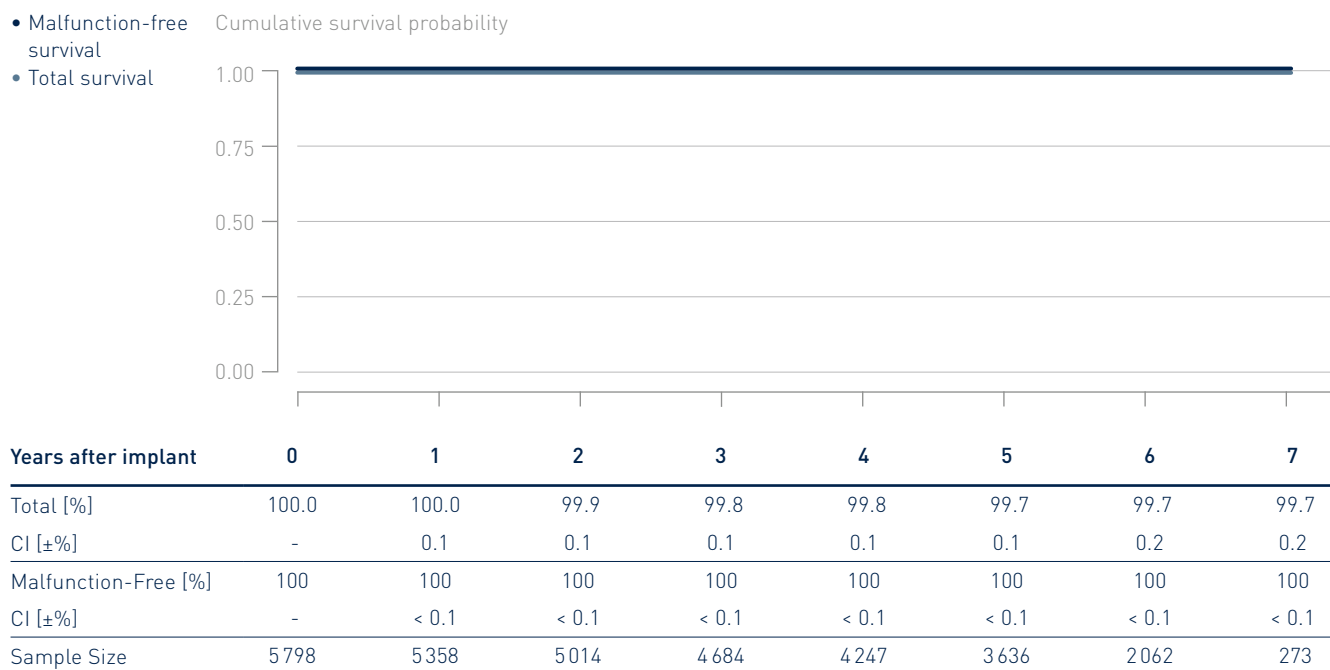
Years after implant	0	1	2	3	4
Total [%]	100	100	100	100	100
CI [±%]	-	< 0.1	0.1	0.1	0.1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	8 325	6 350	4 693	3 138	1 529

3.1 Single-Chamber Pacemakers

Eluna 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	19 600
Registered U.S. Implants	5 798
Estimated Active U.S. Implants	4 040
U.S. Normal Battery Depletions	14

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

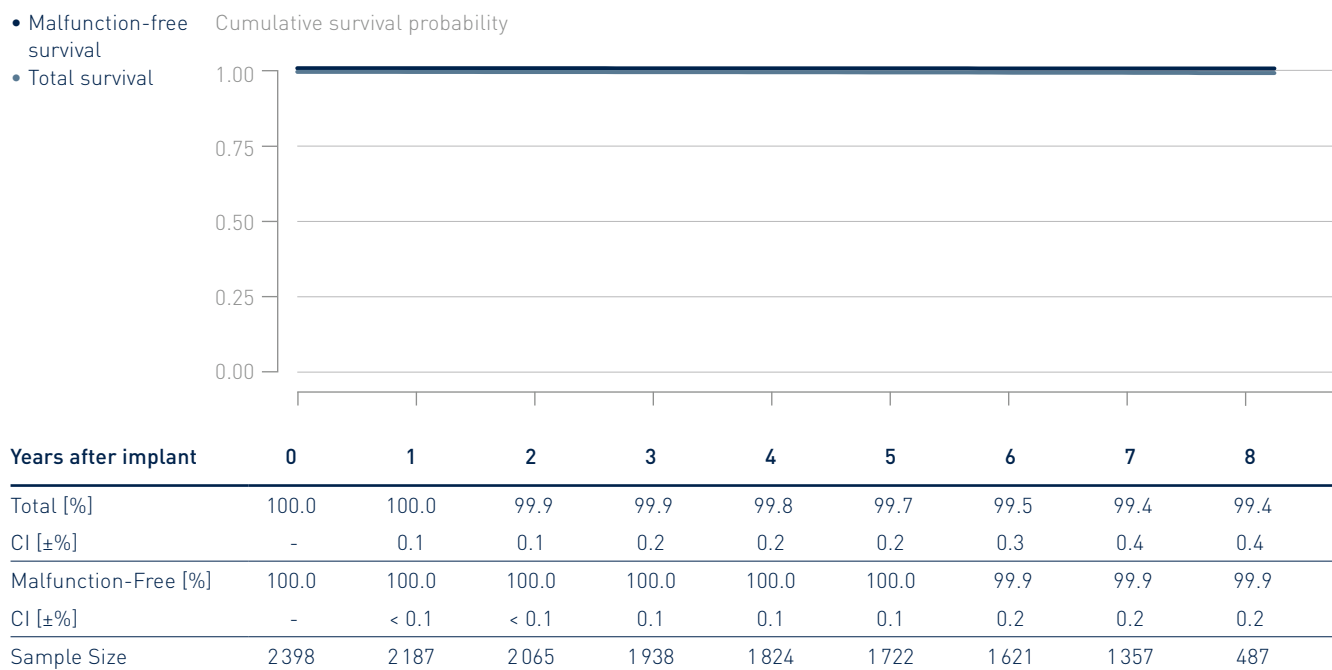


3.1 Single-Chamber Pacemakers

Entovis

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Jun 2010
CE Market Release	Nov 2009
Worldwide Distributed Devices	28 000
Registered U.S. Implants	2 398
Estimated Active U.S. Implants	1 520
U.S. Normal Battery Depletions	9

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

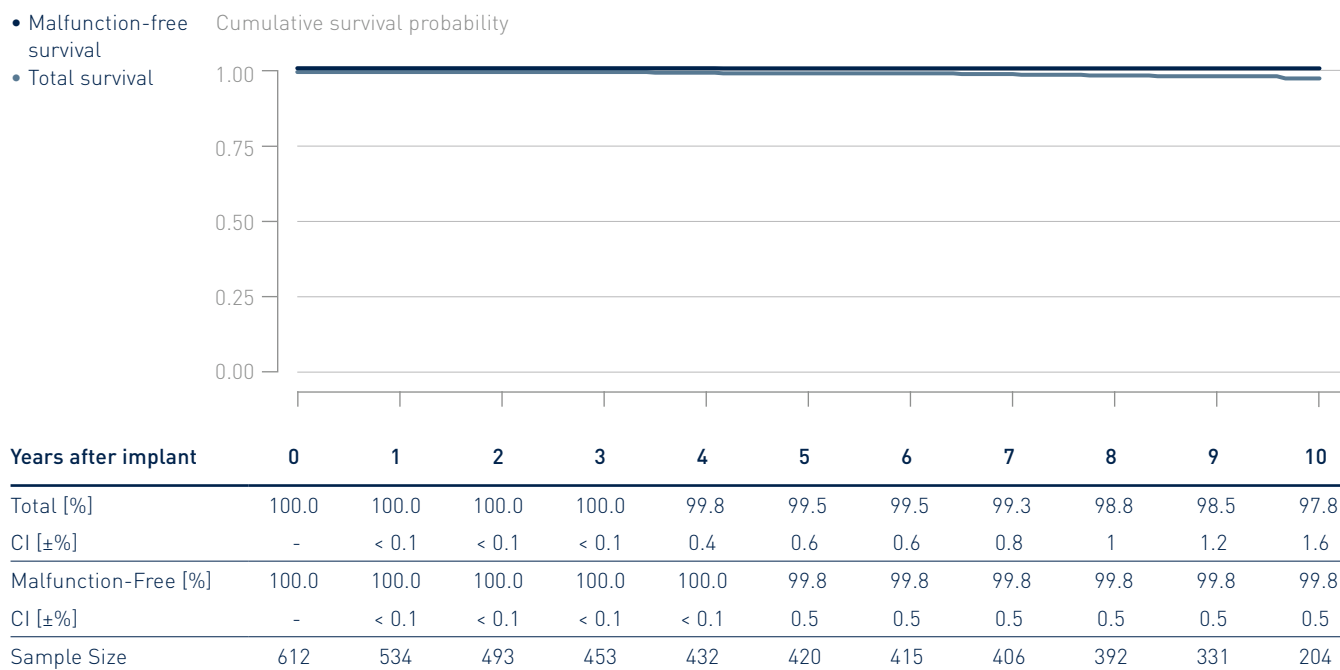


3.1 Single-Chamber Pacemakers

Estella

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	41 600
Registered U.S. Implants	612
Estimated Active U.S. Implants	356
U.S. Normal Battery Depletions	7

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

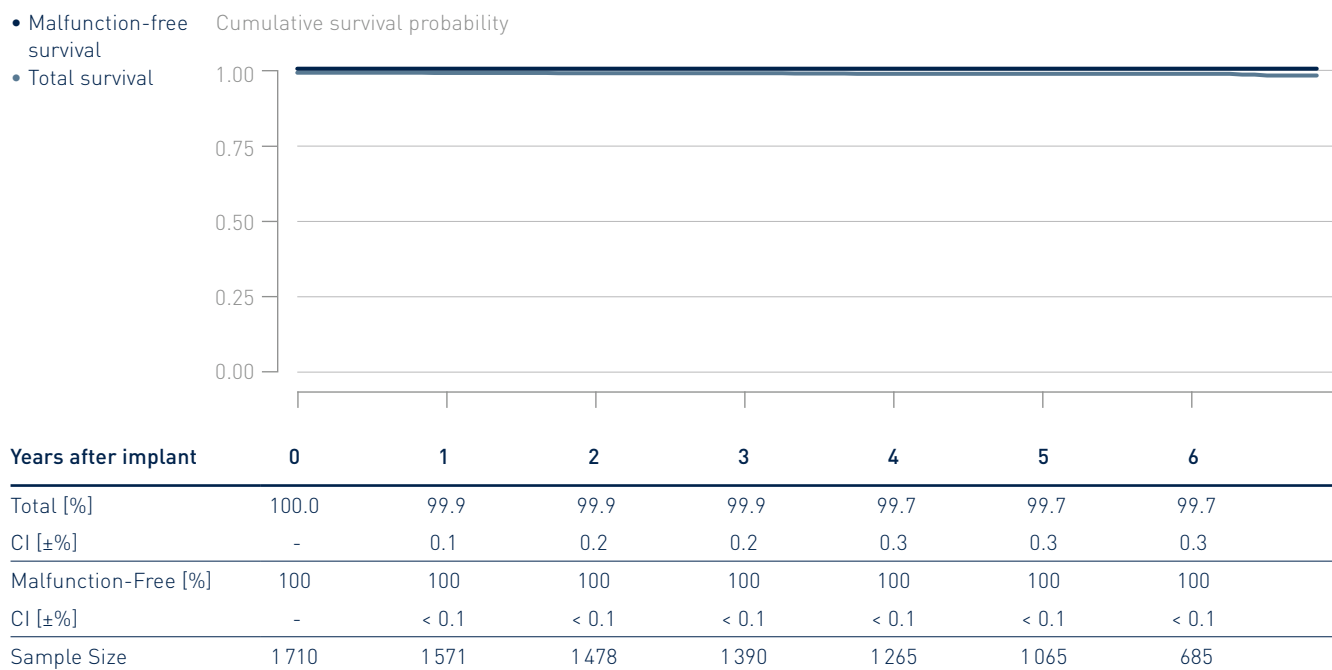


3.1 Single-Chamber Pacemakers

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18500
Registered U.S. Implants	1710
Estimated Active U.S. Implants	1200
U.S. Normal Battery Depletions	6

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

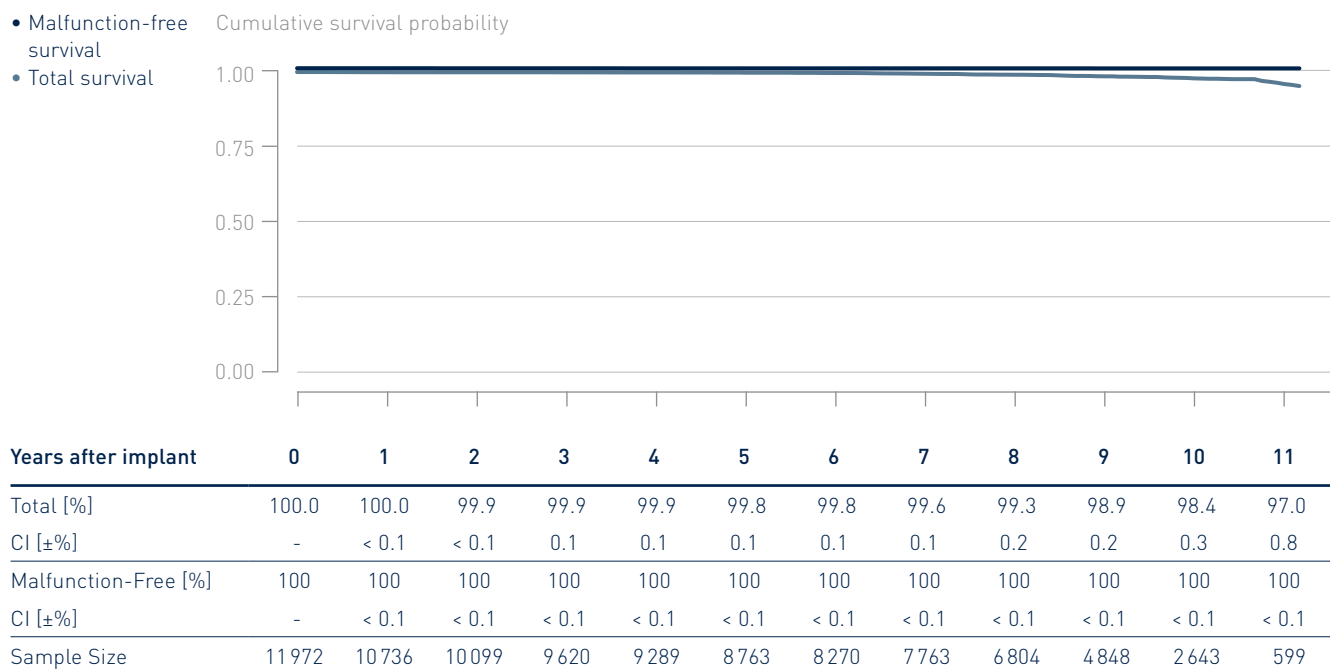


3.1 Single-Chamber Pacemakers

Evia

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	63 900
Registered U.S. Implants	11 972
Estimated Active U.S. Implants	6 800
U.S. Normal Battery Depletions	115

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

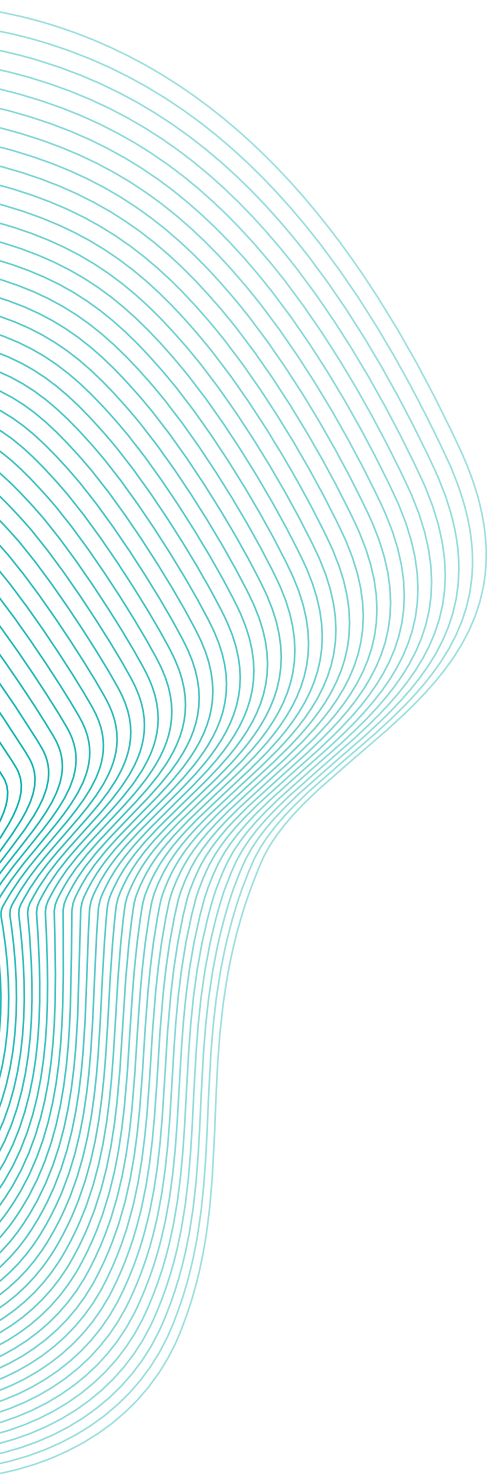


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers

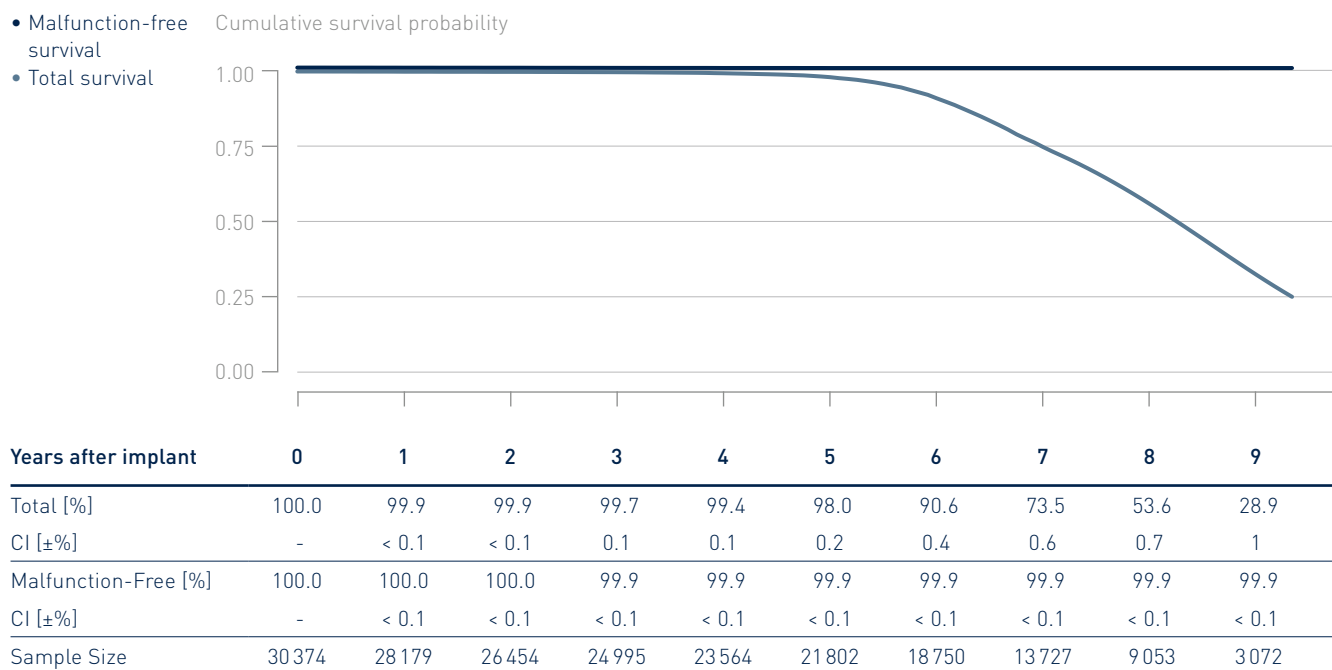


3.2 Dual-Chamber Pacemakers

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	81300
Registered U.S. Implants	30374
Estimated Active U.S. Implants	6800
U.S. Normal Battery Depletions	8470

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



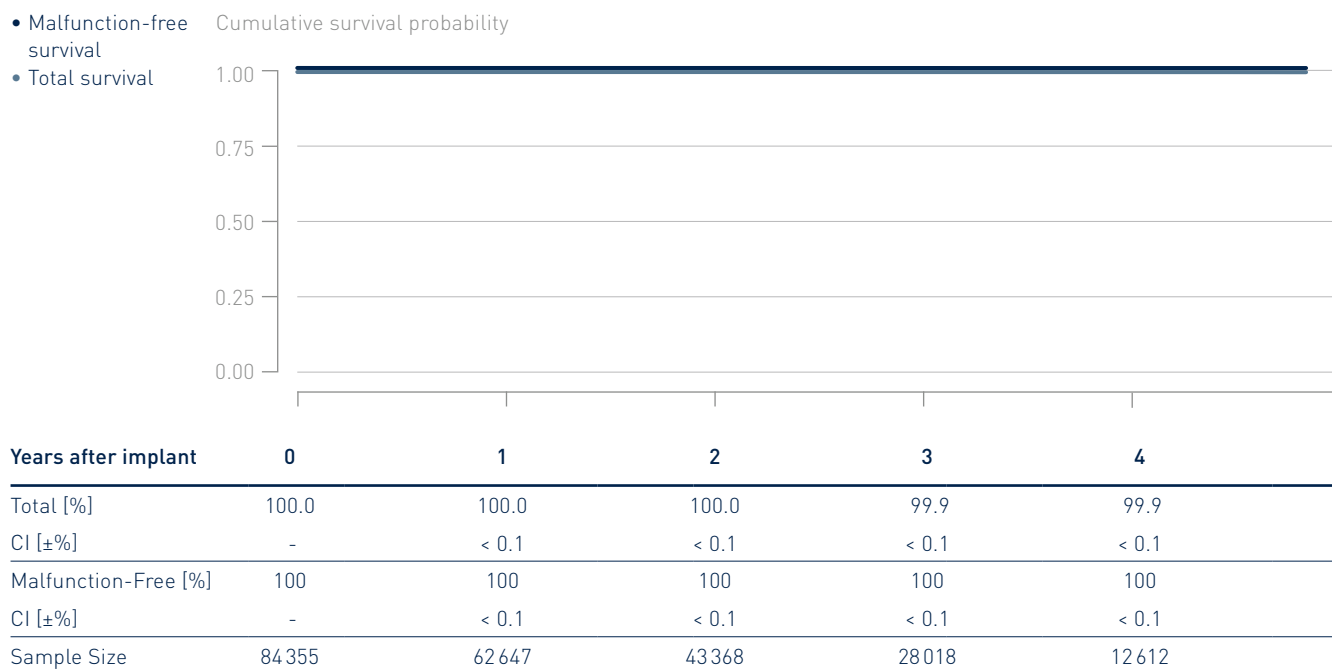
* While Cylos 990 DR and Cylos 990 DR-T is not distributed in the U.S., the performance is expected to be similar to the U.S. distributed products.

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	261 000
Registered U.S. Implants	84 355
Estimated Active U.S. Implants	72 100
U.S. Normal Battery Depletions	48

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.01%
Therapy Compromised	3	0.00%
Therapy Available	4	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	97200
Registered U.S. Implants	42068
Estimated Active U.S. Implants	29900
U.S. Normal Battery Depletions	103

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.01%
Therapy Compromised	0	0.00%
Therapy Available	6	0.01%

- Malfunction-free survival
- Total survival



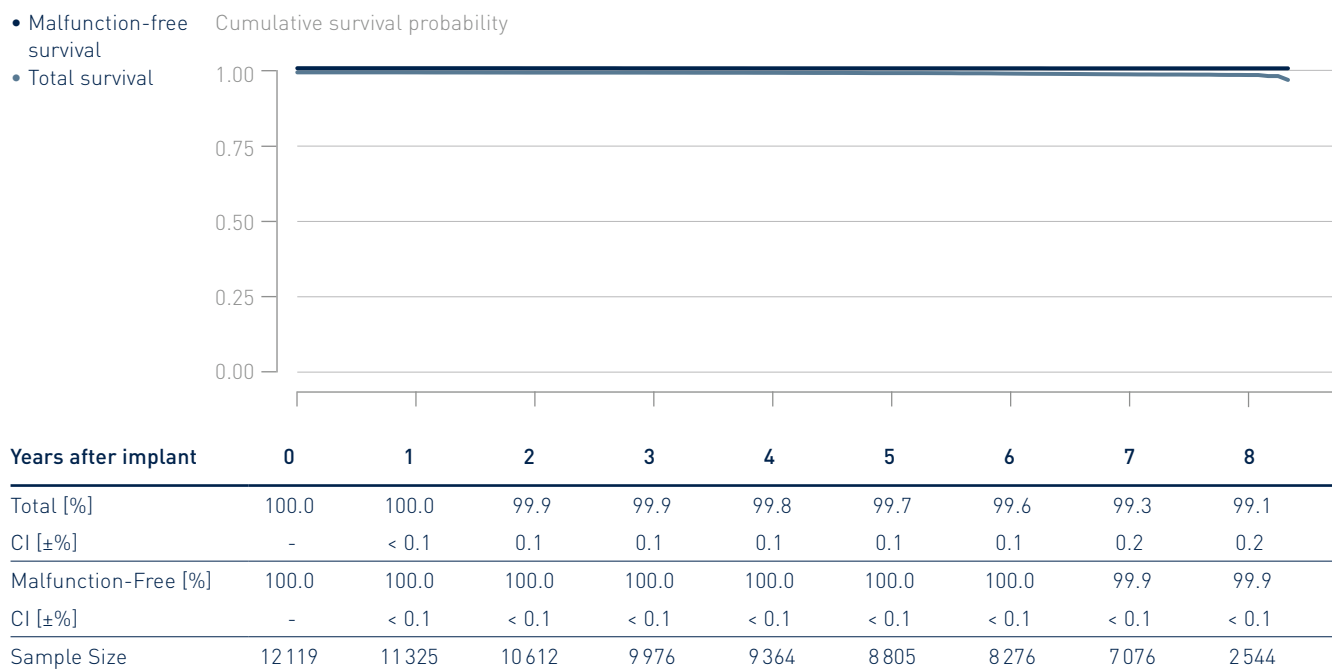
Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	100.0	100.0	99.9	99.9	99.8	99.7
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1
Malfunction-Free [%]	100	100	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	42068	39266	36686	33477	29482	24950	13710

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	105 000
Registered U.S. Implants	12 119
Estimated Active U.S. Implants	7 660
U.S. Normal Battery Depletions	75

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.04%
Therapy Compromised	2	0.02%
Therapy Available	3	0.02%

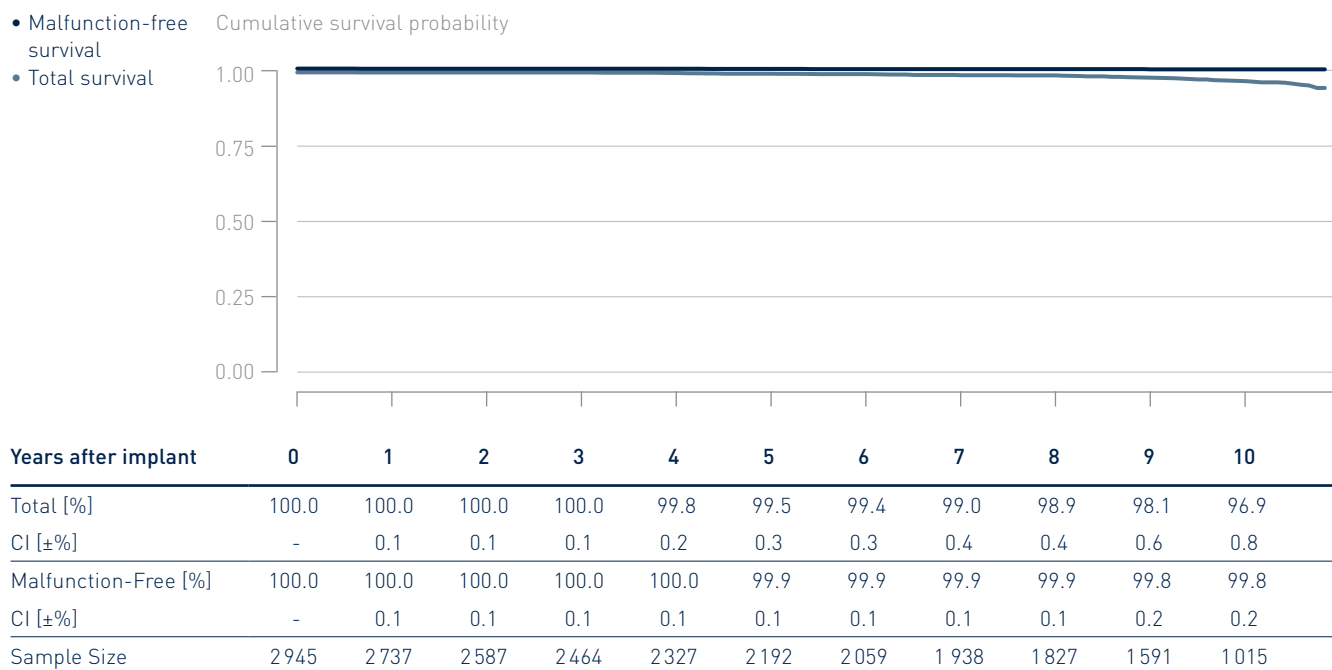


3.2 Dual-Chamber Pacemakers

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	53500
Registered U.S. Implants	2945
Estimated Active U.S. Implants	1610
U.S. Normal Battery Depletions	63

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

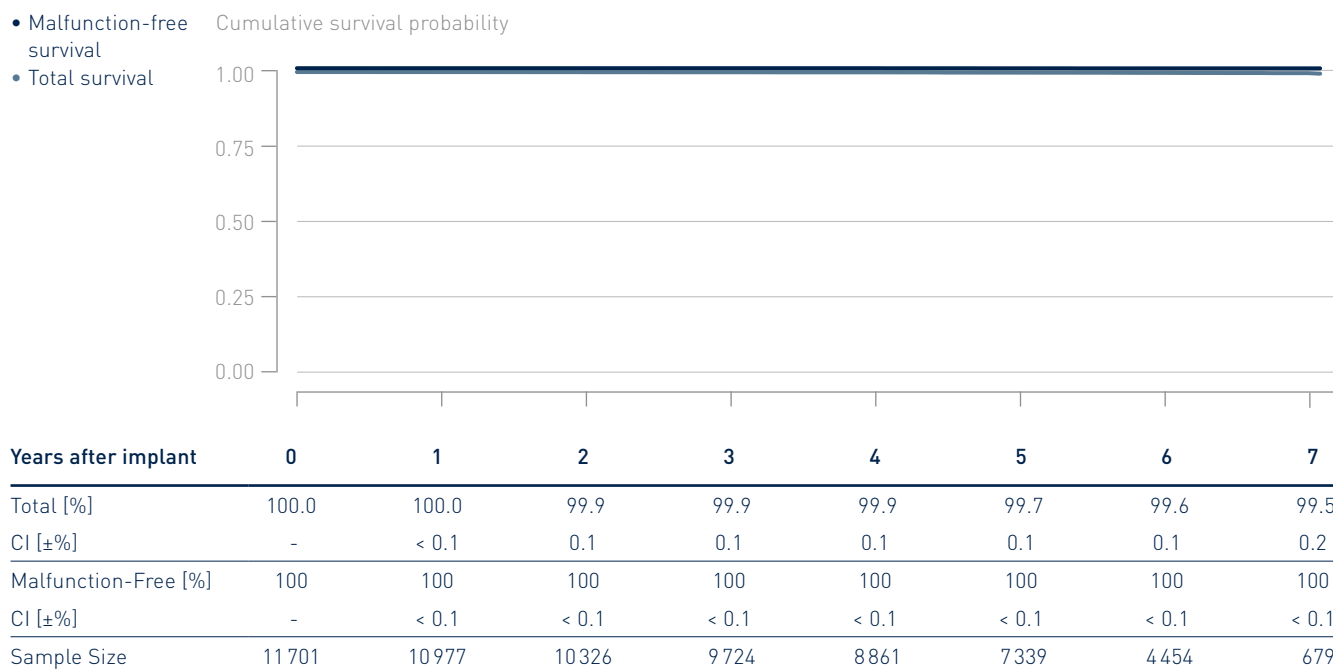


3.2 Dual-Chamber Pacemakers

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	76300
Registered U.S. Implants	11701
Estimated Active U.S. Implants	8450
U.S. Normal Battery Depletions	35

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.03%
Therapy Compromised	0	0.00%
Therapy Available	3	0.03%

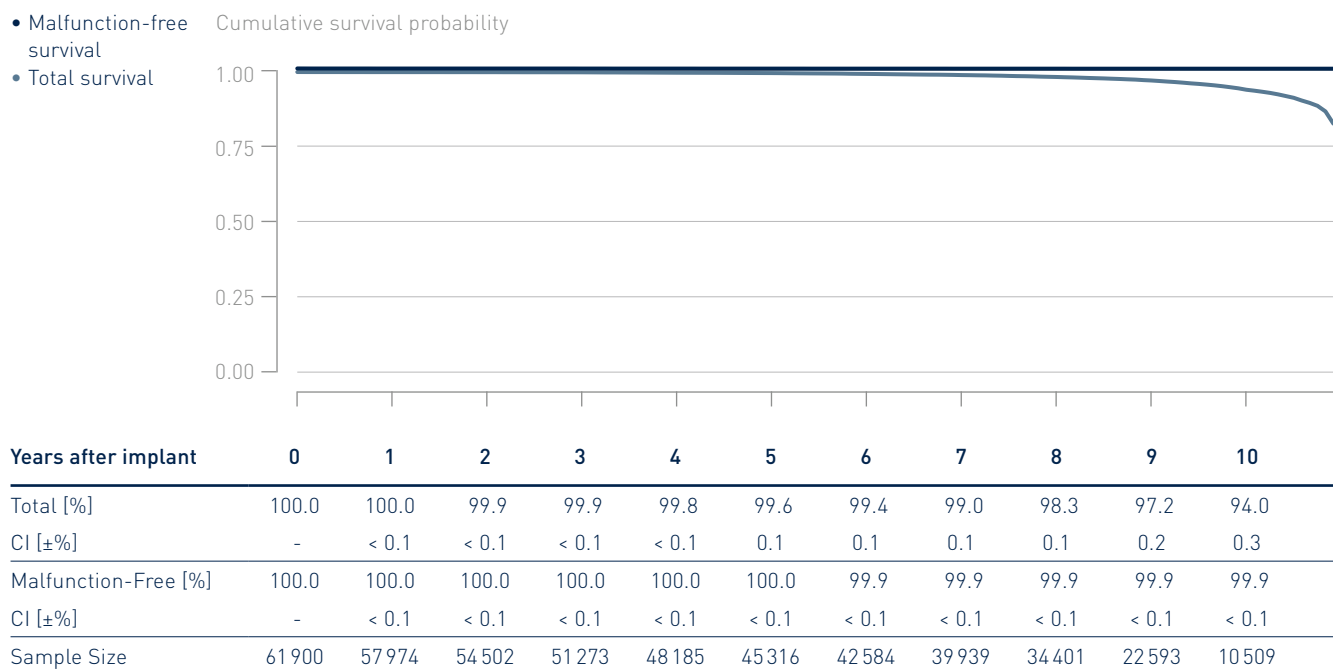


3.2 Dual-Chamber Pacemakers

Evia

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	224 000
Registered U.S. Implants	61 900
Estimated Active U.S. Implants	33 500
U.S. Normal Battery Depletions	1 880

	Quantity	Rate
U.S. Confirmed Malfunctions	32	0.05%
Therapy Compromised	11	0.02%
Therapy Available	21	0.03%

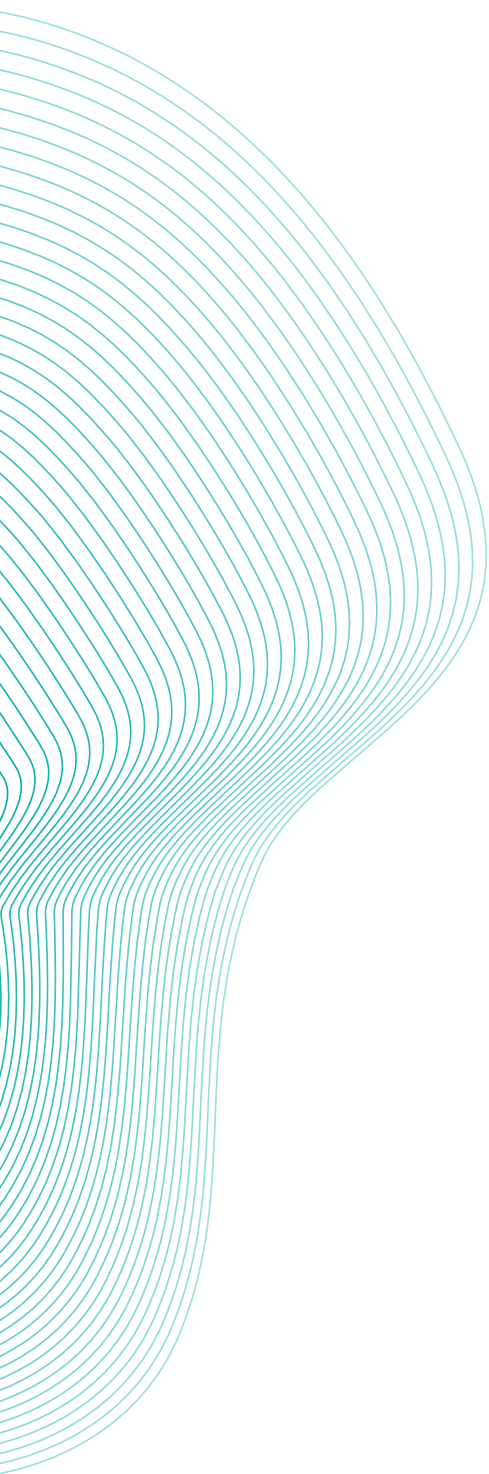


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers



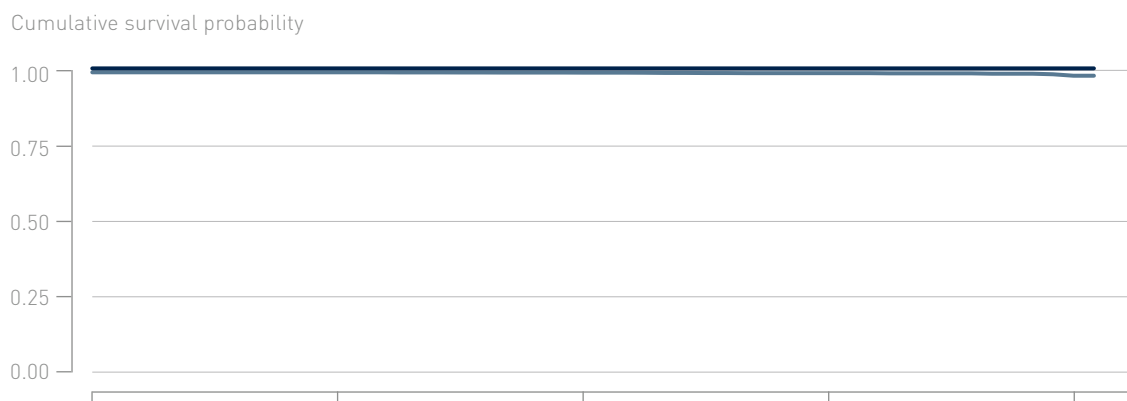
3.3 CRT Pacemakers

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	19800
Registered U.S. Implants	7001
Estimated Active U.S. Implants	5360
U.S. Normal Battery Depletions	15

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

- Malfunction-free survival
- Total survival



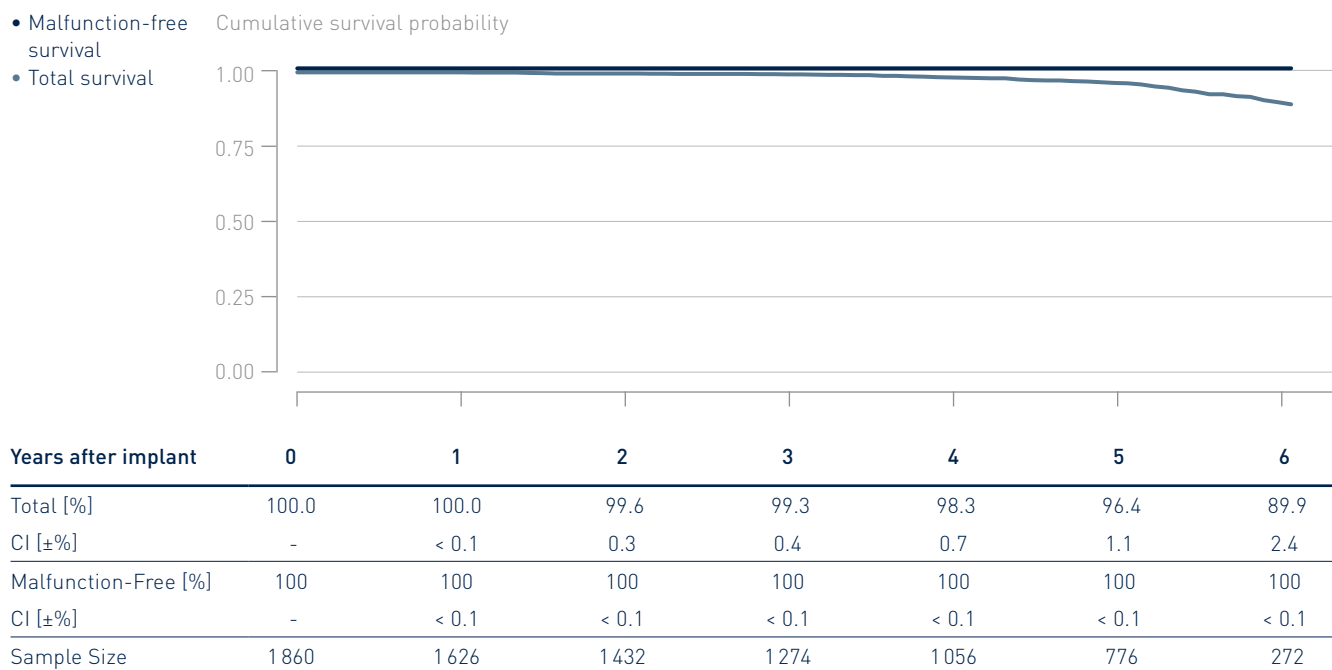
Years after implant	0	1	2	3	4
Total [%]	100.0	100.0	99.9	99.7	98.6
CI [±%]	-	< 0.1	0.1	0.2	1
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	7001	4839	3070	1611	339

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	8 670
Registered U.S. Implants	1 860
Estimated Active U.S. Implants	897
U.S. Normal Battery Depletions	85

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

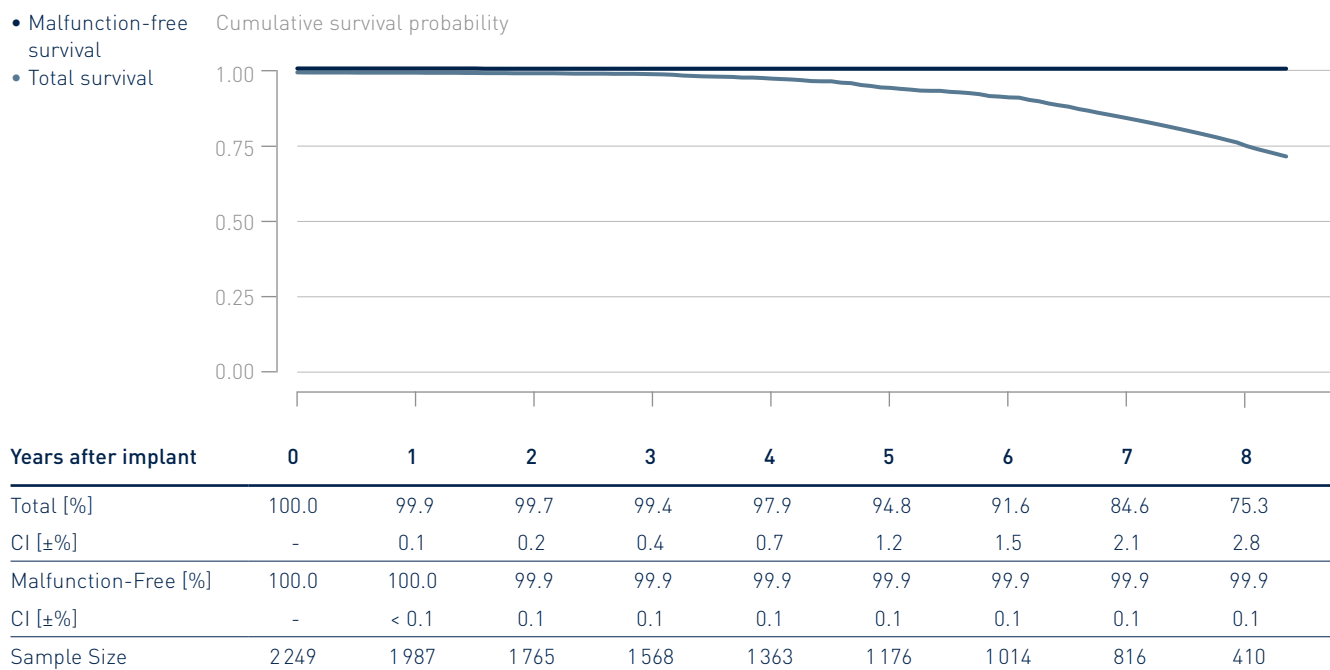


3.3 CRT Pacemakers

Evia

Product Versions	HF, HF-T
NBG Codes	DDDRV
US Market Release	May 2010
CE Market Release	Oct 2009
Worldwide Distributed Devices	8 880
Registered U.S. Implants	2 249
Estimated Active U.S. Implants	672
U.S. Normal Battery Depletions	260

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



Performance of BIOTRONIK ICDs

- 4.1 Single-Chamber ICDs
- 4.2 Dual-Chamber ICDs
- 4.3 CRT ICDs

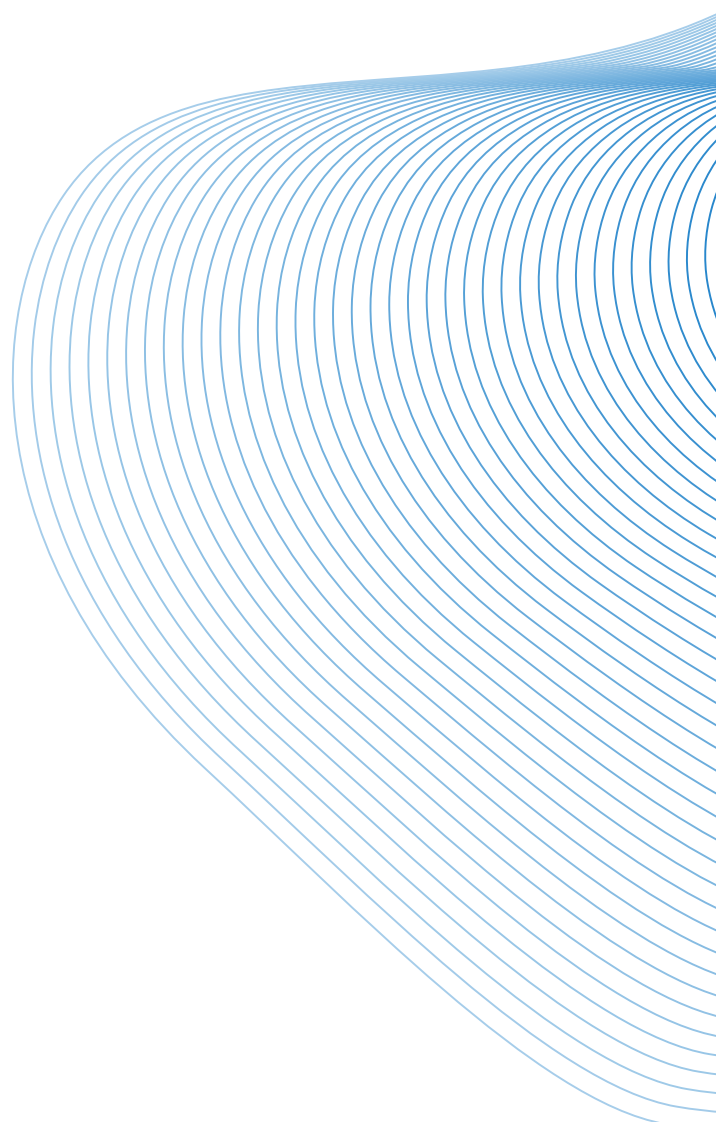


Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs

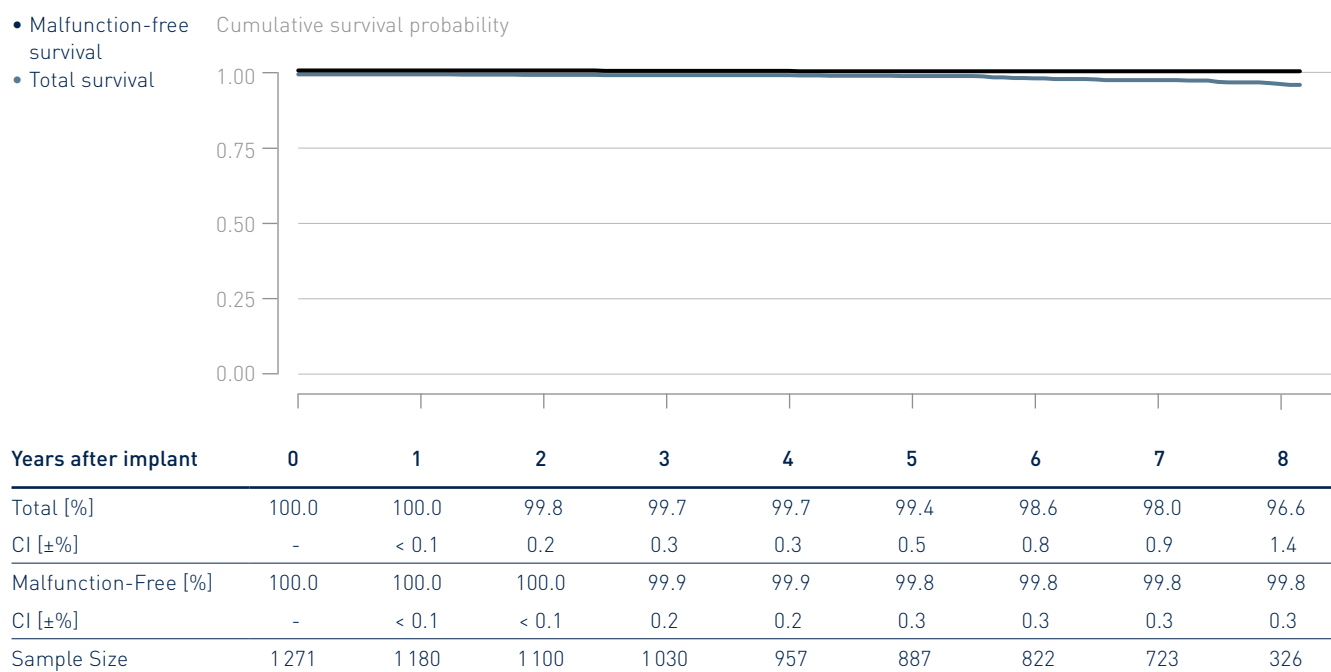


4.1 Single-Chamber ICDs

Ilesto 7

Product Versions	VR-T
NBG Codes	WE-WVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2 460
Registered U.S. Implants	1 271
Estimated Active U.S. Implants	713
U.S. Normal Battery Depletions	25

	Quantity	Rate
U.S. Confirmed Malfunctions*	2	0.16%
Therapy Compromised	1	0.08%
Therapy Available	1	0.08%



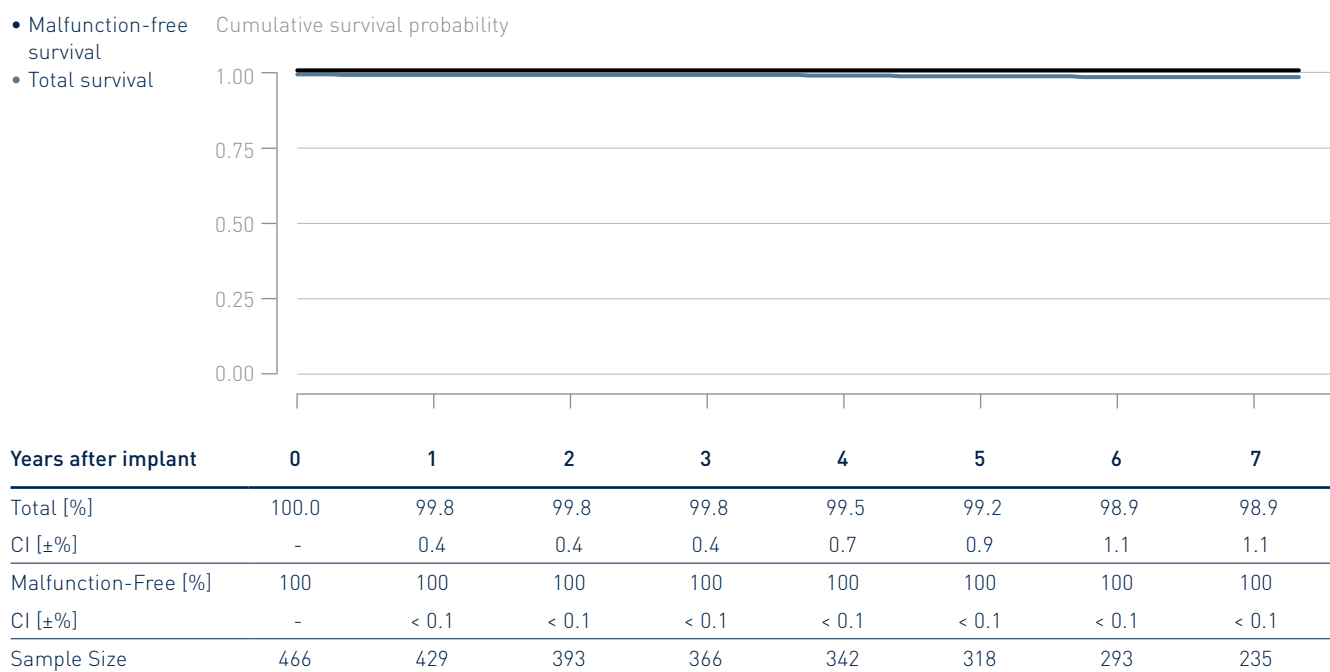
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.1 Single-Chamber ICDs

Ilesto 7 DF4

Product Versions	VR-T
NBG Codes	WE-WVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2390
Registered U.S. Implants	466
Estimated Active U.S. Implants	263
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%



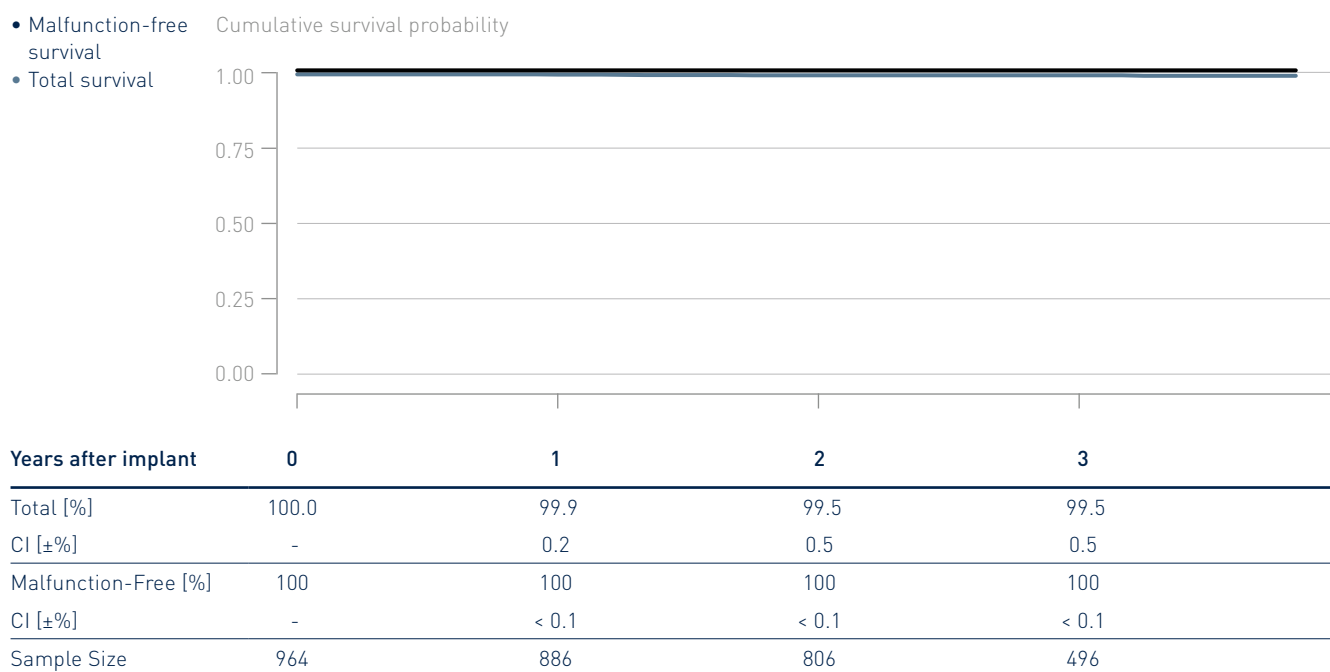
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.1 Single-Chamber ICDs

Ilivia 7

Product Versions	VR-T
NBG Codes	WE-WVR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	2390
Registered U.S. Implants	964
Estimated Active U.S. Implants	758
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%



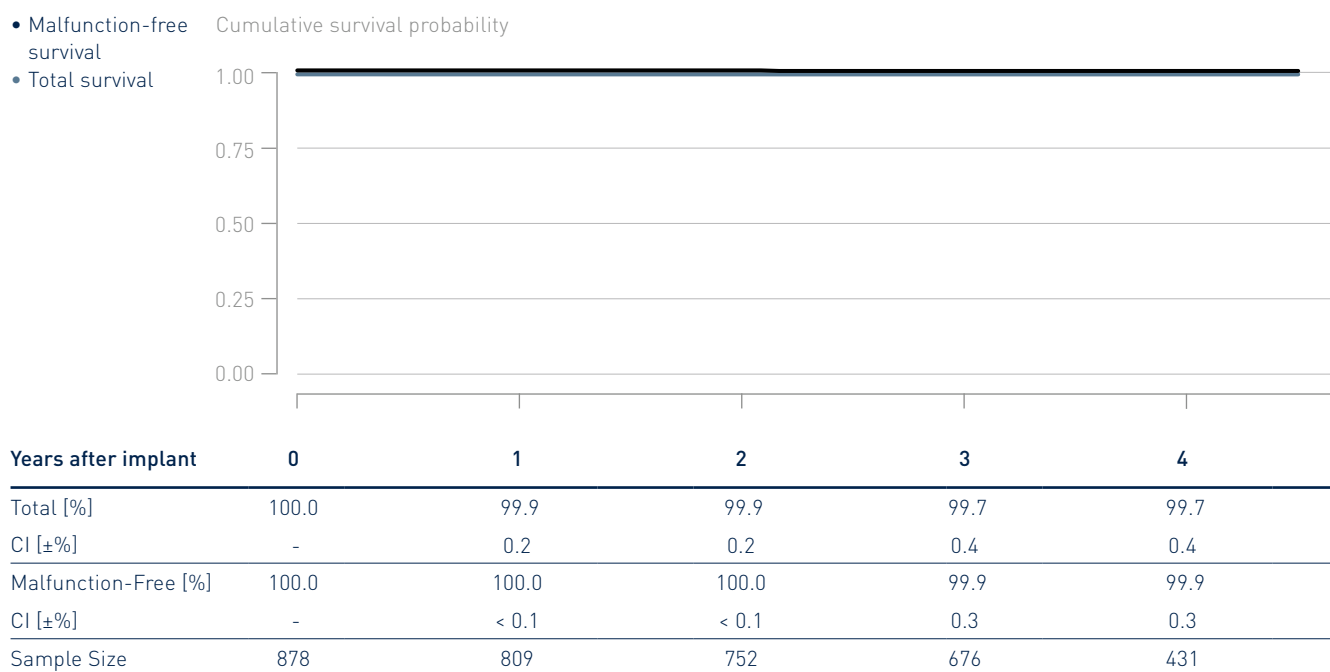
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.1 Single-Chamber ICDs

Ilivia 7 DF4

Product Versions	VR-T
NBG Codes	WE-WVIR
Maximum Energy J	40
US Market Release	Aug 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	4 250
Registered U.S. Implants	878
Estimated Active U.S. Implants	637
U.S. Normal Battery Depletions	1

	Quantity	Rate
U.S. Confirmed Malfunctions*	1	0.11%
Therapy Compromised	0	0.00%
Therapy Available	1	0.11%



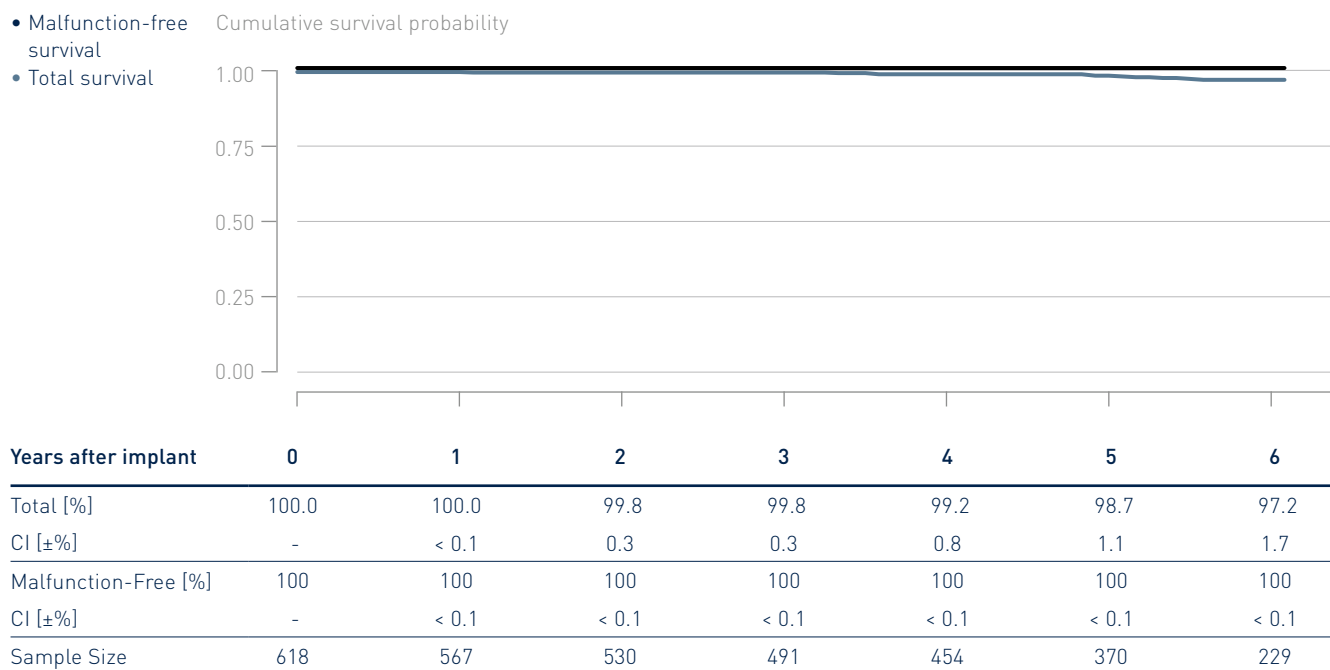
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.1 Single-Chamber ICDs

Itrevia 7

Product Versions	VR-T
NBG Codes	WE-WVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 280
Registered U.S. Implants	618
Estimated Active U.S. Implants	381
U.S. Normal Battery Depletions	13

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



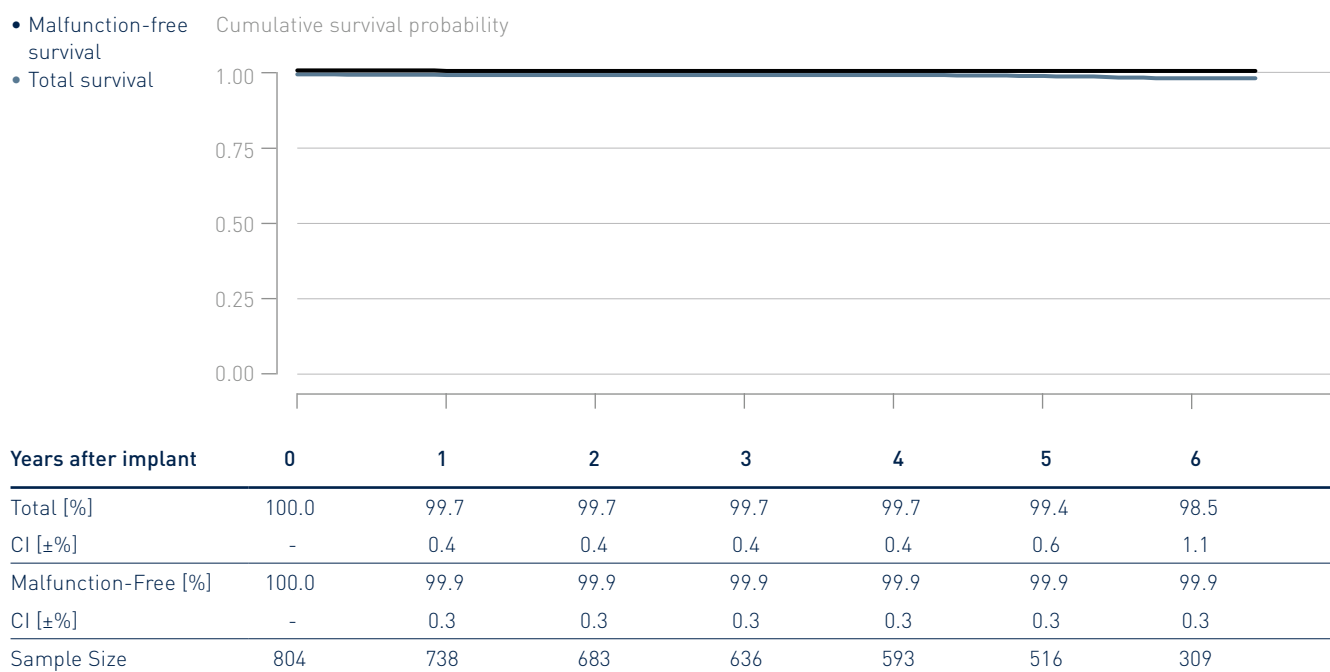
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4.1 Single-Chamber ICDs

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	1 420
Registered U.S. Implants	804
Estimated Active U.S. Implants	498
U.S. Normal Battery Depletions	8

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



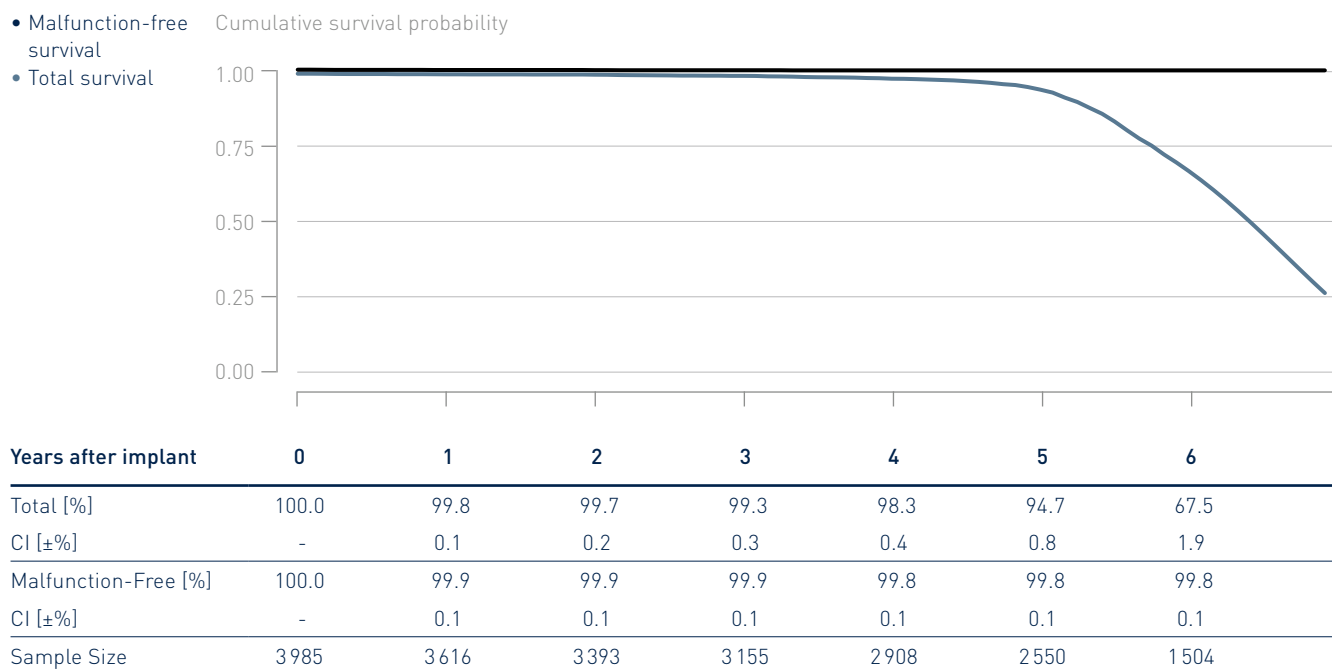
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.1 Single-Chamber ICDs

Lumax 340

Product Versions	VR, VR-T
NBG Codes	WVE-WVIR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	27 100
Registered U.S. Implants	3985
Estimated Active U.S. Implants	836
U.S. Normal Battery Depletions	935

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

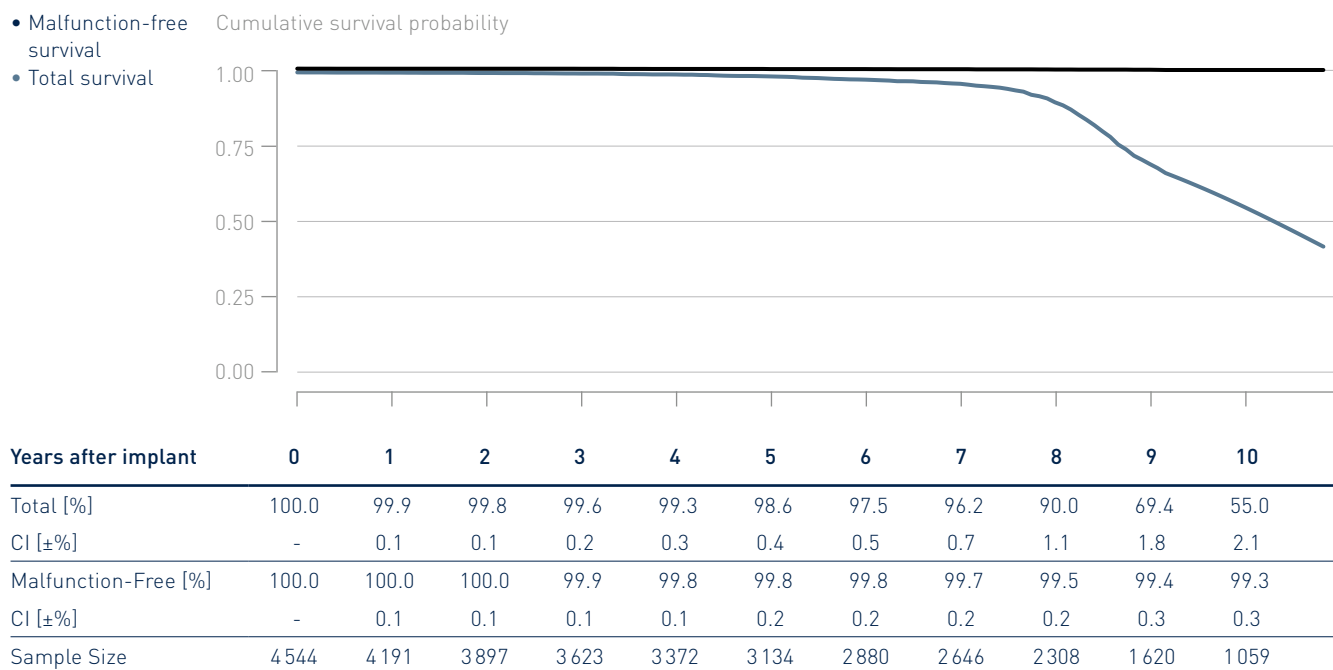


4.1 Single-Chamber ICDs

Lumax 540

Product Versions	VR-T
NBG Codes	VWE-VWIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20 000
Registered U.S. Implants	4 544
Estimated Active U.S. Implants	1 320
U.S. Normal Battery Depletions	921

	Quantity	Rate
U.S. Confirmed Malfunctions	18	0.40%
Therapy Compromised	14	0.31%
Therapy Available	4	0.09%

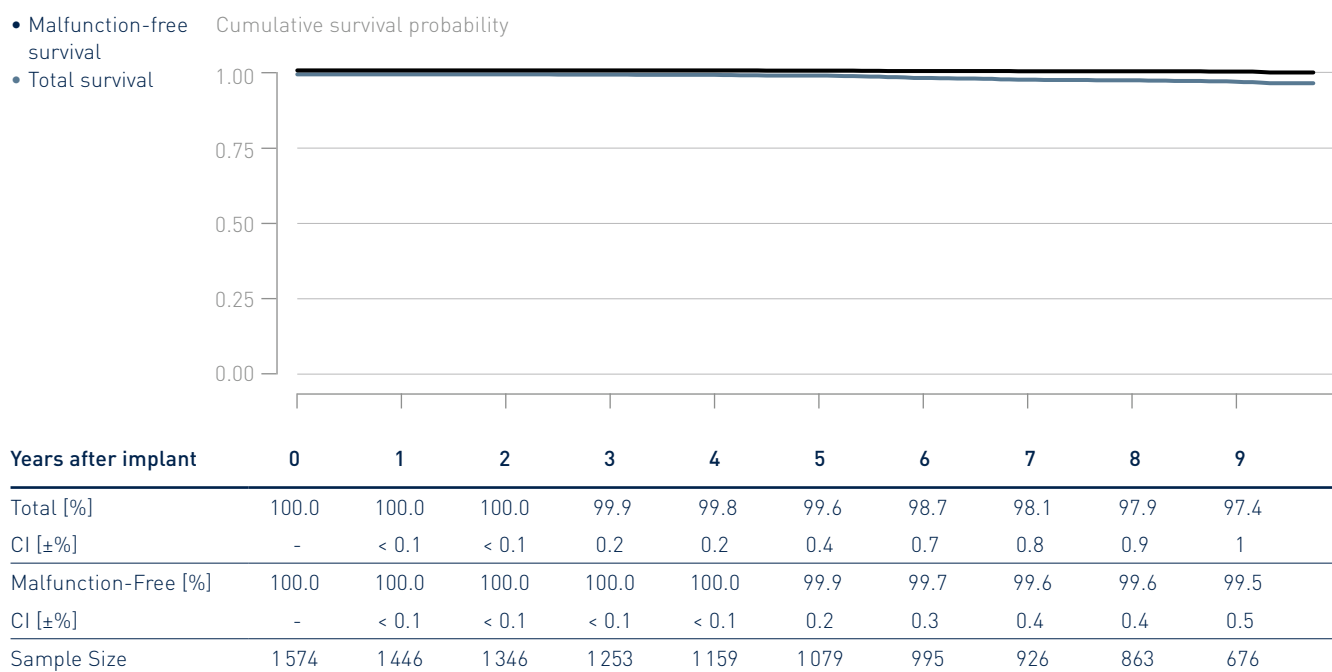


4.1 Single-Chamber ICDs

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	1574
Estimated Active U.S. Implants	825
U.S. Normal Battery Depletions	25

	Quantity	Rate
U.S. Confirmed Malfunctions	7	0.44%
Therapy Compromised	5	0.32%
Therapy Available	2	0.13%



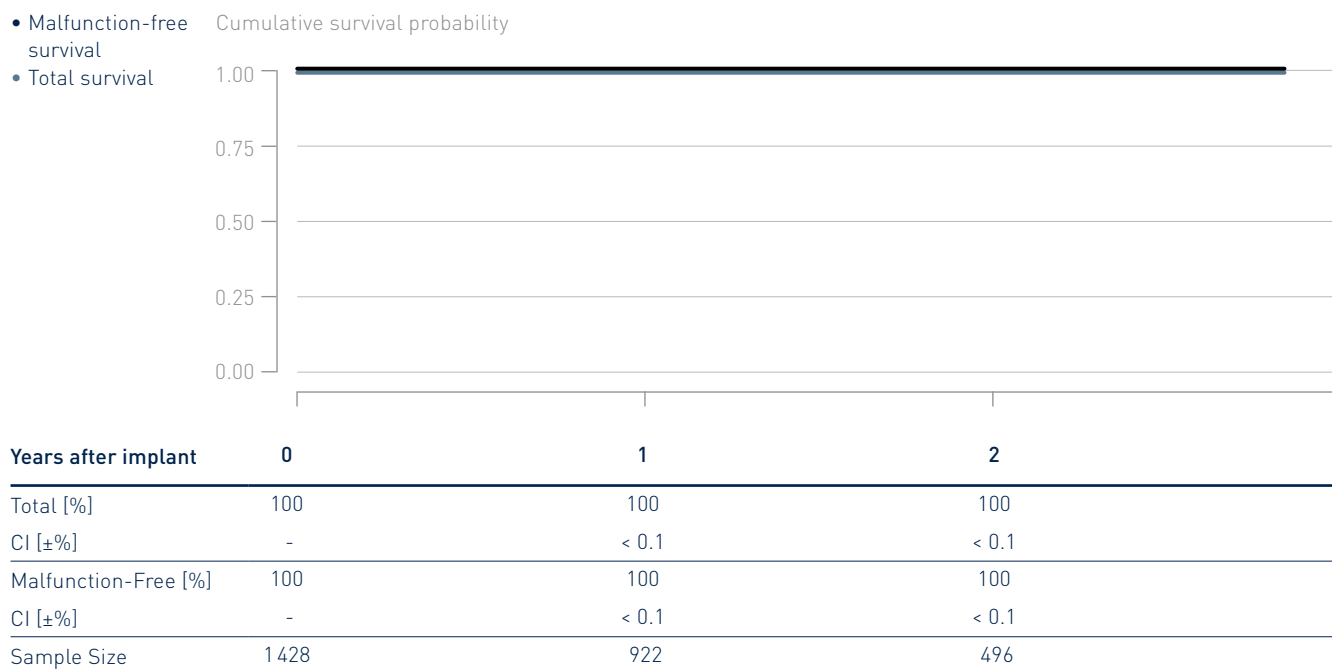


4.1 Single-Chamber ICDs

Rivacor 7 DF4

Product Versions	VR-T
NBG Codes	WE-WVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	4 960
Registered U.S. Implants	1 428
Estimated Active U.S. Implants	1 280
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%

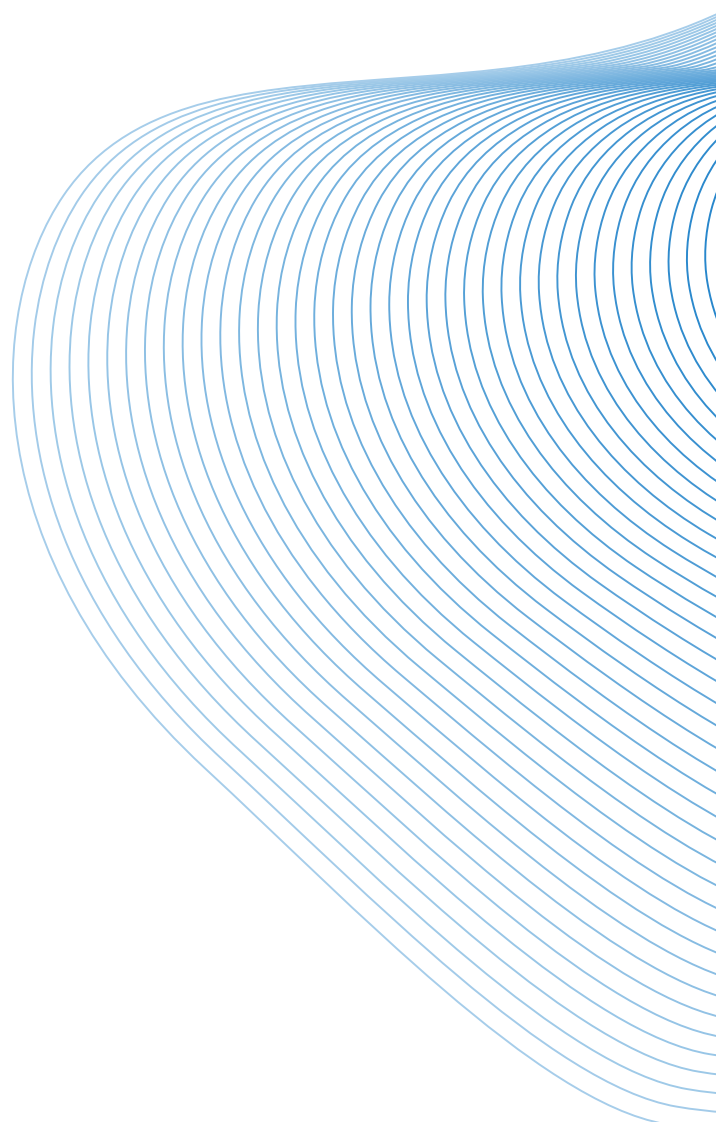


Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs

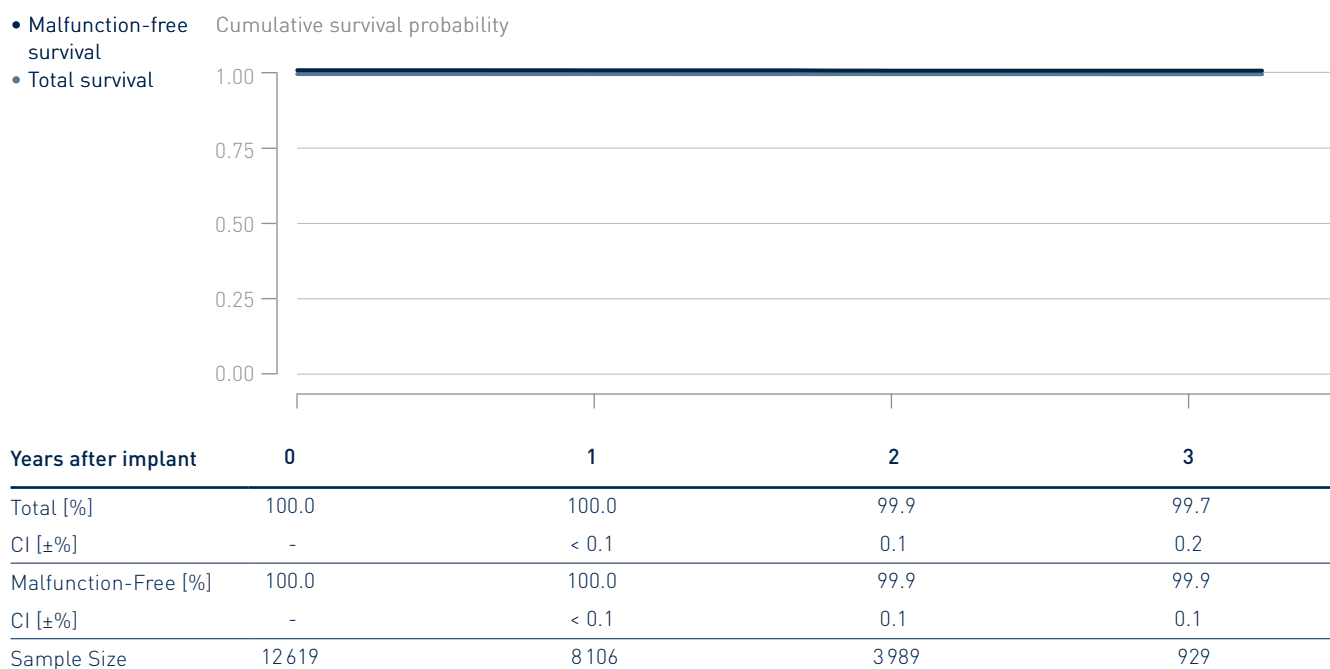


4.2 Dual-Chamber ICDs

Acticor 7 DX

Product Versions	VR-T
NBG Codes	VWE-VDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	17 100
Registered U.S. Implants	12 619
Estimated Active U.S. Implants	11 200
U.S. Normal Battery Depletions	7

	Quantity	Rate
U.S. Confirmed Malfunctions	6	0.05%
Therapy Compromised	6	0.05%
Therapy Available	0	0.00%

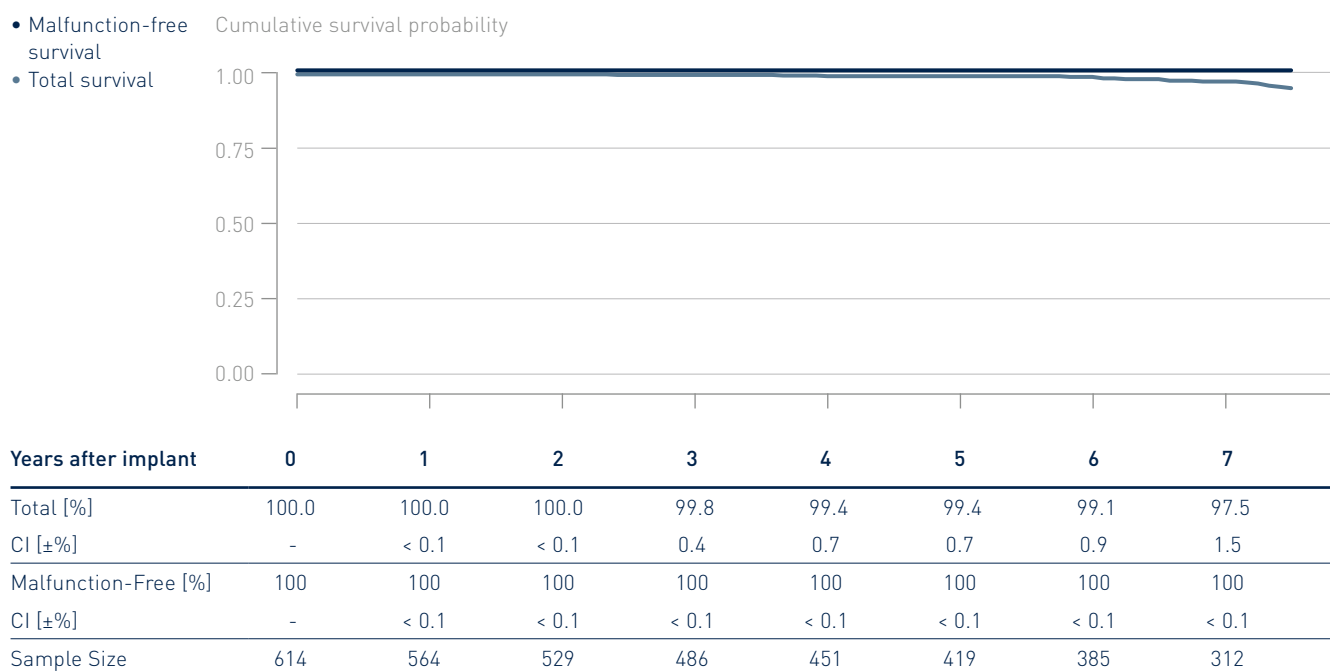


4.2 Dual-Chamber ICDs

Iforia 7

Product Versions	DR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2 000
Registered U.S. Implants	614
Estimated Active U.S. Implants	319
U.S. Normal Battery Depletions	25

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



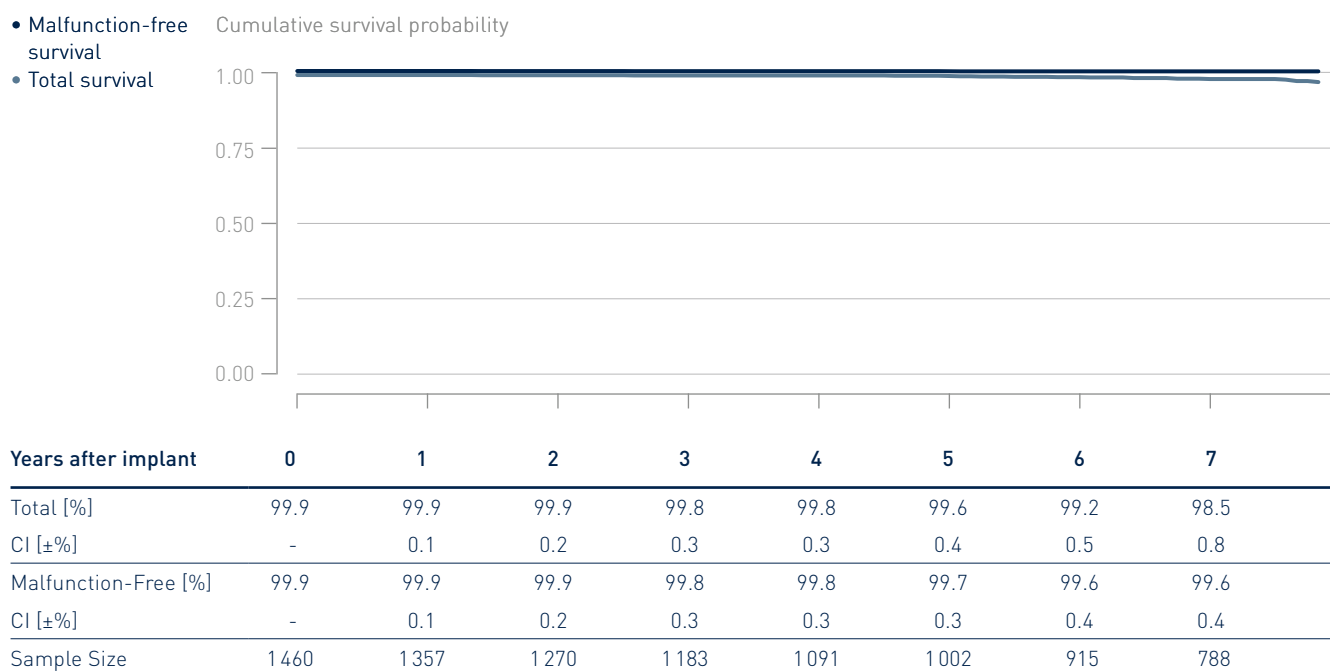
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Iforia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	4 780
Registered U.S. Implants	1 460
Estimated Active U.S. Implants	803
U.S. Normal Battery Depletions	18

	Quantity	Rate
U.S. Confirmed Malfunctions*	5	0.34%
Therapy Compromised	3	0.21%
Therapy Available	2	0.14%



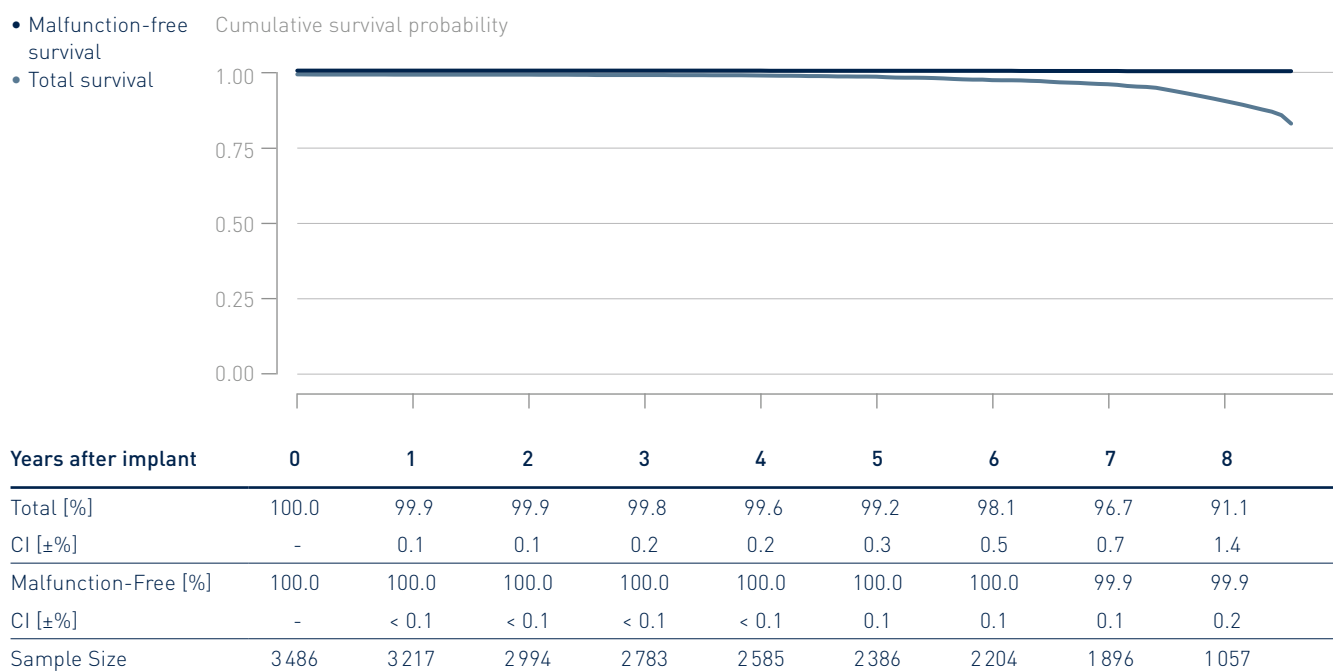
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4.2 Dual-Chamber ICDs

Ilesto 7

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 110
Registered U.S. Implants	3 486
Estimated Active U.S. Implants	1 860
U.S. Normal Battery Depletions	175

	Quantity	Rate
U.S. Confirmed Malfunctions*	3	0.09%
Therapy Compromised	2	0.06%
Therapy Available	1	0.03%



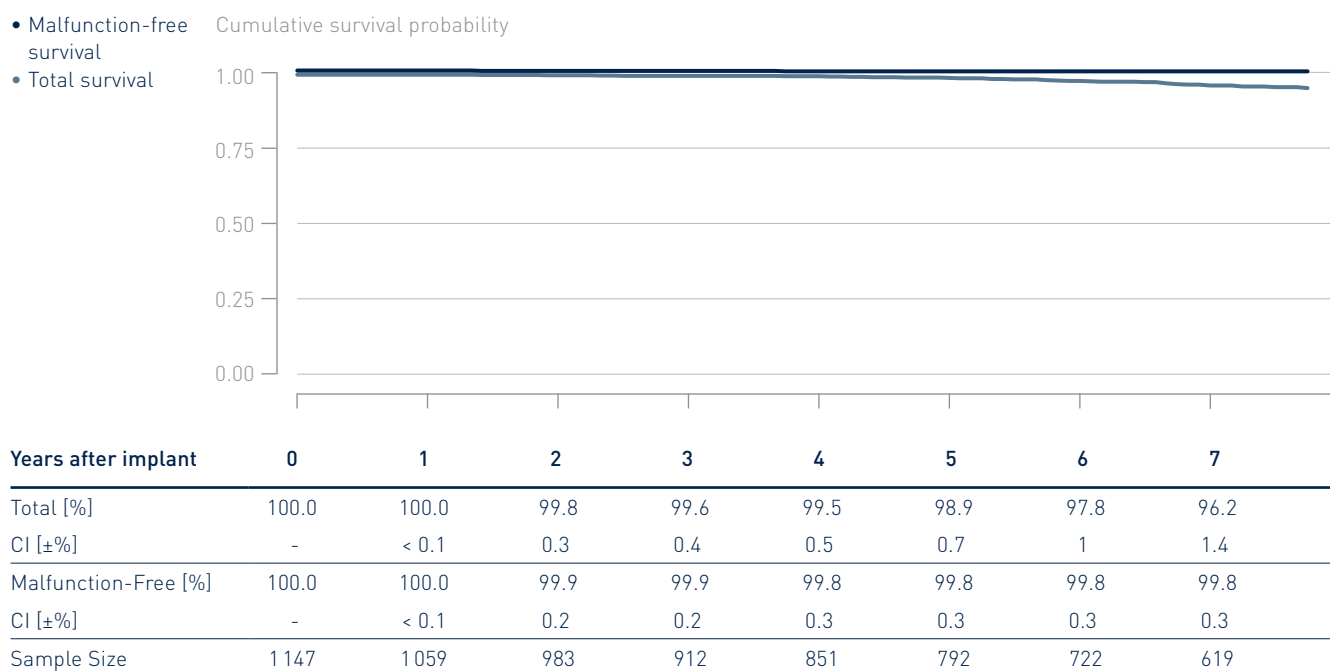
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	3 730
Registered U.S. Implants	1 147
Estimated Active U.S. Implants	624
U.S. Normal Battery Depletions	32

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



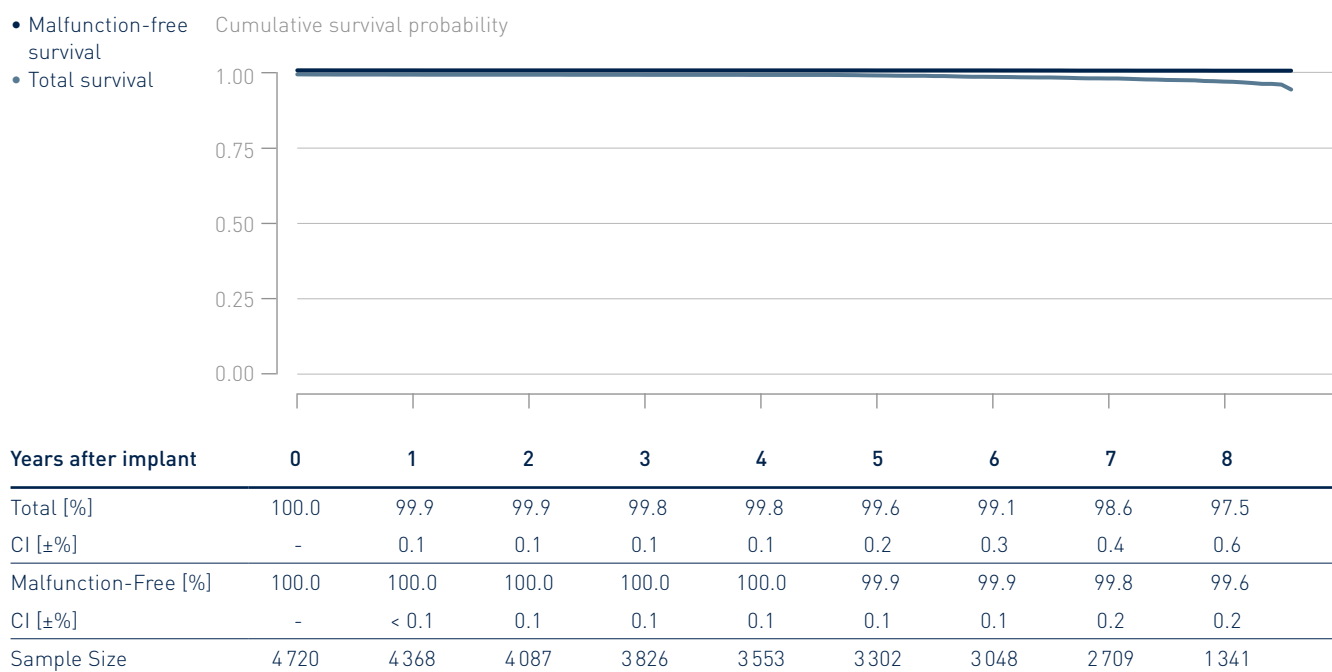
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Ilesto 7 DX

Product Versions	VR-T
NBG Codes	VWE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered U.S. Implants	4 720
Estimated Active U.S. Implants	2 600
U.S. Normal Battery Depletions	80

	Quantity	Rate
U.S. Confirmed Malfunctions*	10	0.21%
Therapy Compromised	4	0.08%
Therapy Available	6	0.13%



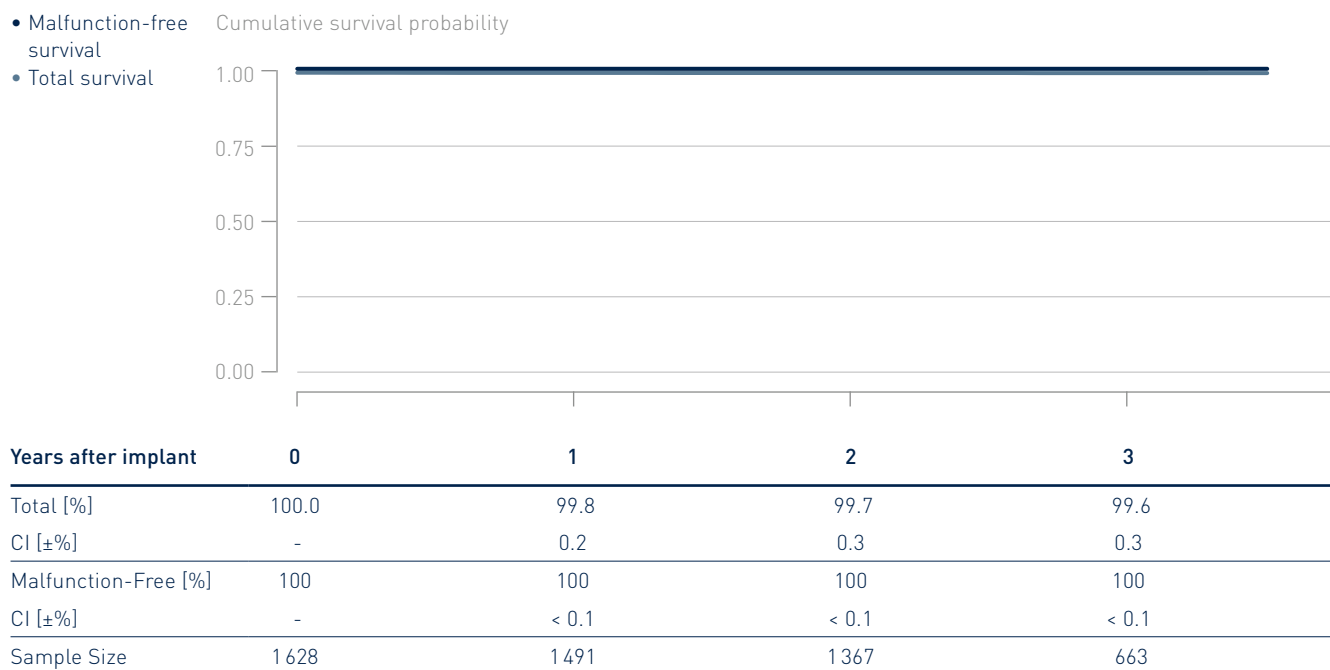
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Ilivia 7

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	3470
Registered U.S. Implants	1628
Estimated Active U.S. Implants	1330
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%



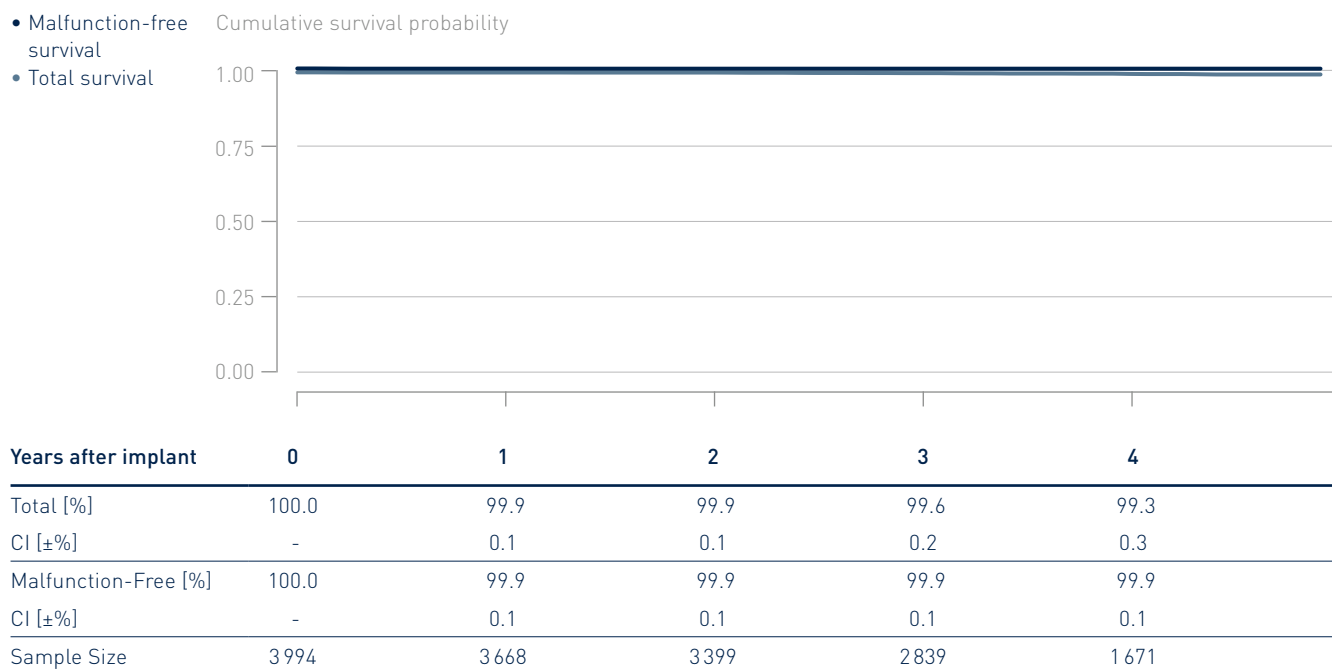
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	8 570
Registered U.S. Implants	3 994
Estimated Active U.S. Implants	2 930
U.S. Normal Battery Depletions	20

	Quantity	Rate
U.S. Confirmed Malfunctions*	3	0.08%
Therapy Compromised	3	0.08%
Therapy Available	0	0.00%



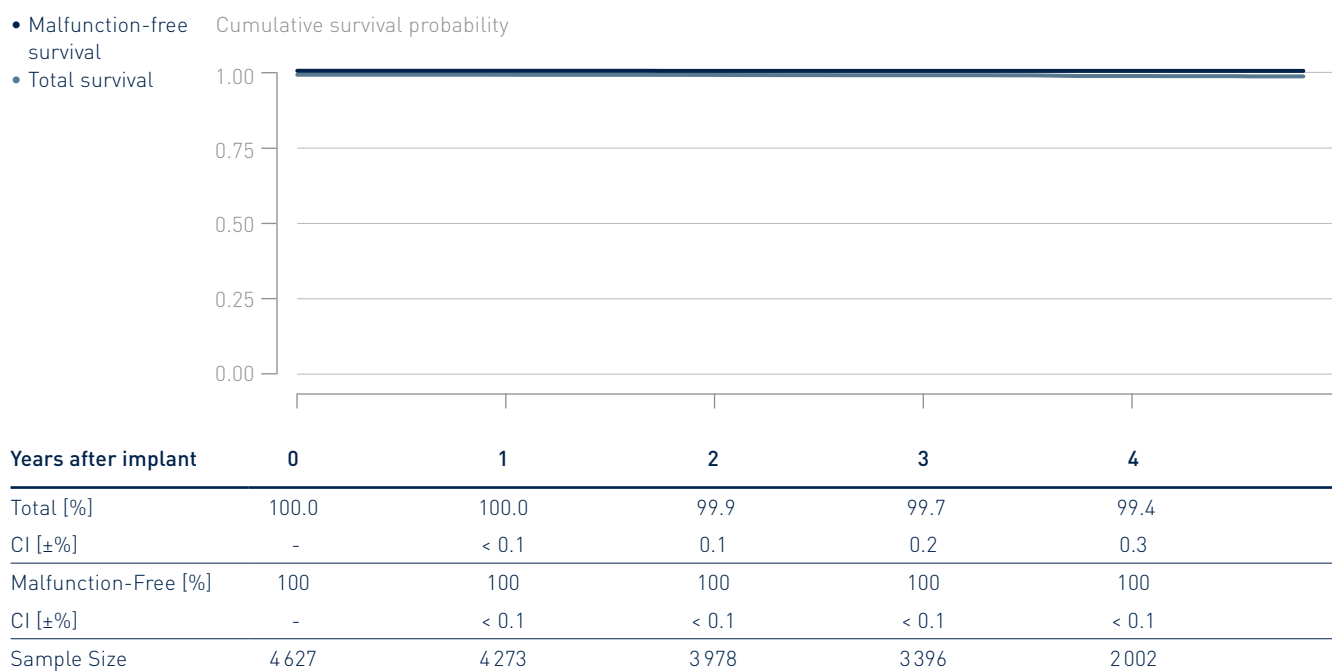
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Intica 7 DX

Product Versions	VR-T
NBG Codes	VWE-VDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 850
Registered U.S. Implants	4 627
Estimated Active U.S. Implants	3 410
U.S. Normal Battery Depletions	22

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



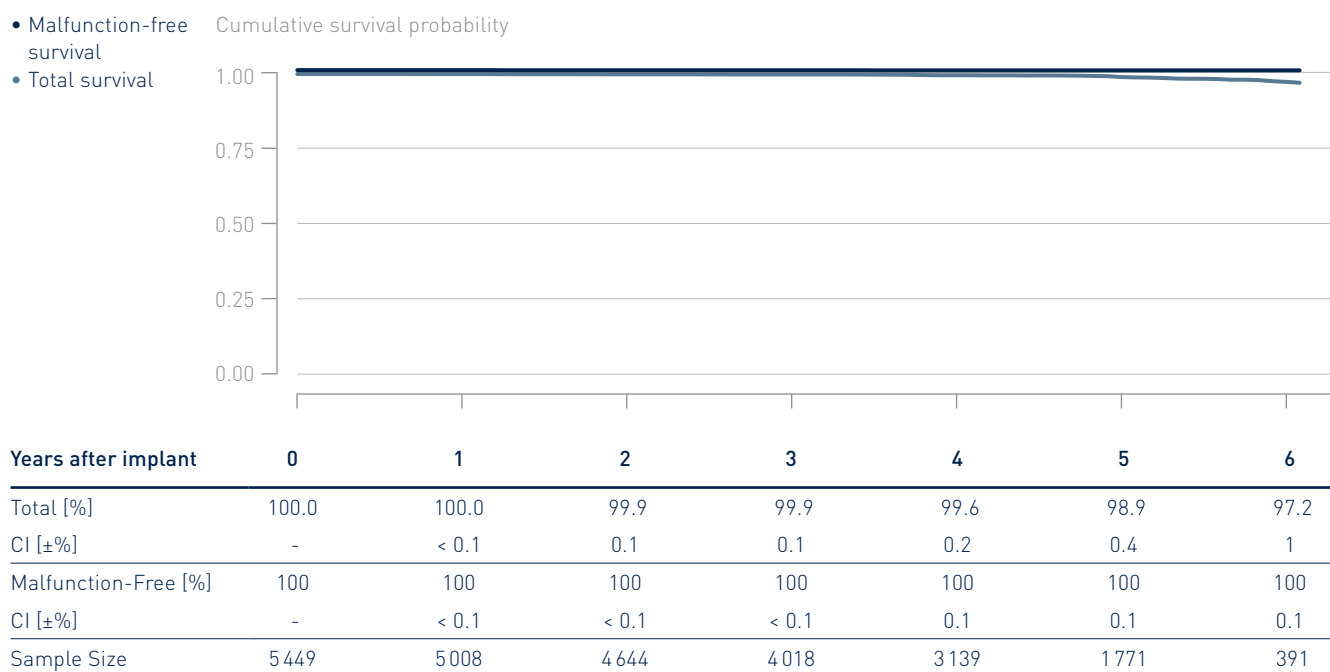
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	5 790
Registered U.S. Implants	5 449
Estimated Active U.S. Implants	3 650
U.S. Normal Battery Depletions	45

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



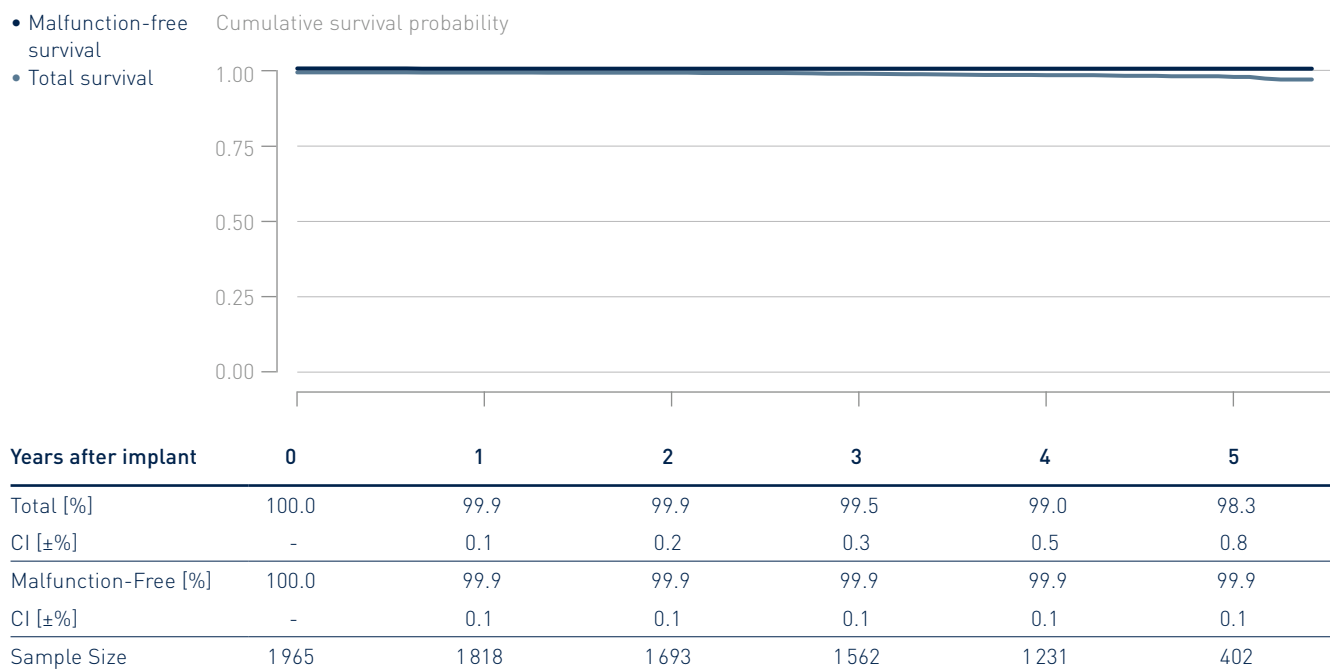
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Iperia 7

Product Versions	DR-T
NBG Codes	VDE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 710
Registered U.S. Implants	1 965
Estimated Active U.S. Implants	1 370
U.S. Normal Battery Depletions	27

	Quantity	Rate
U.S. Confirmed Malfunctions*	1	0.05%
Therapy Compromised	1	0.05%
Therapy Available	0	0.00%



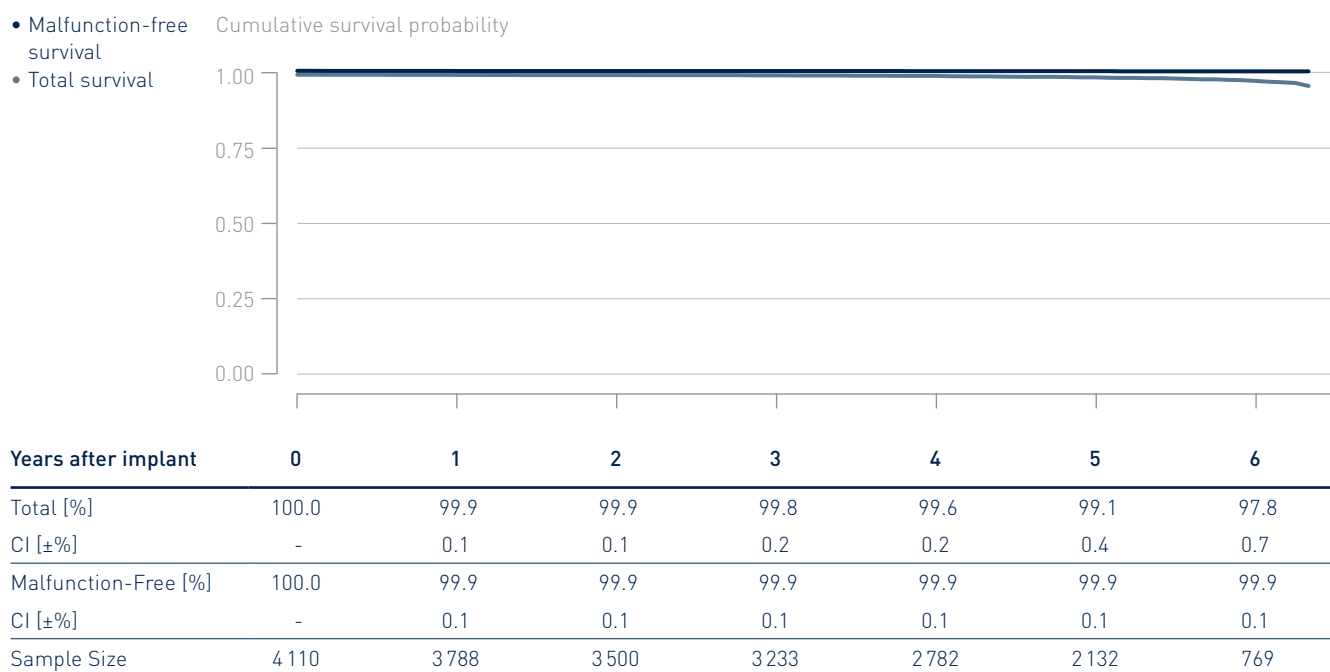
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	7 510
Registered U.S. Implants	4 110
Estimated Active U.S. Implants	2 680
U.S. Normal Battery Depletions	51

	Quantity	Rate
U.S. Confirmed Malfunctions*	4	0.10%
Therapy Compromised	1	0.02%
Therapy Available	3	0.07%



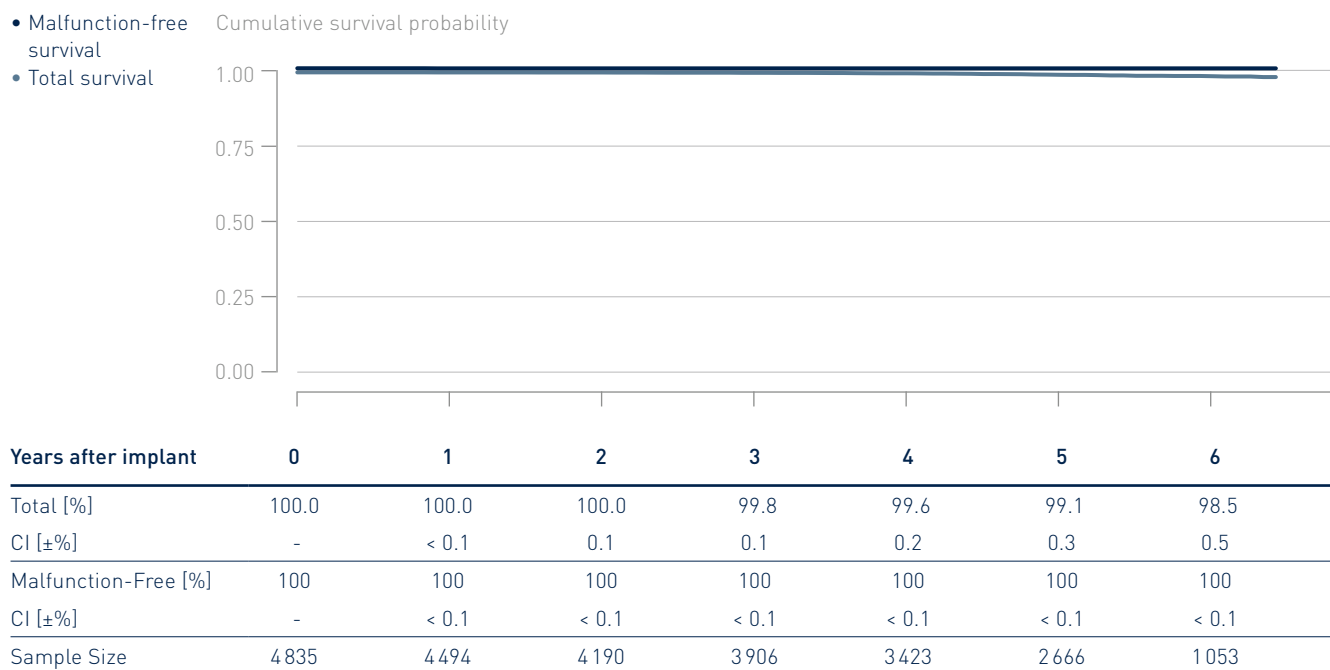
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4.2 Dual-Chamber ICDs

Iperia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	6 540
Registered U.S. Implants	4 835
Estimated Active U.S. Implants	3 150
U.S. Normal Battery Depletions	43

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



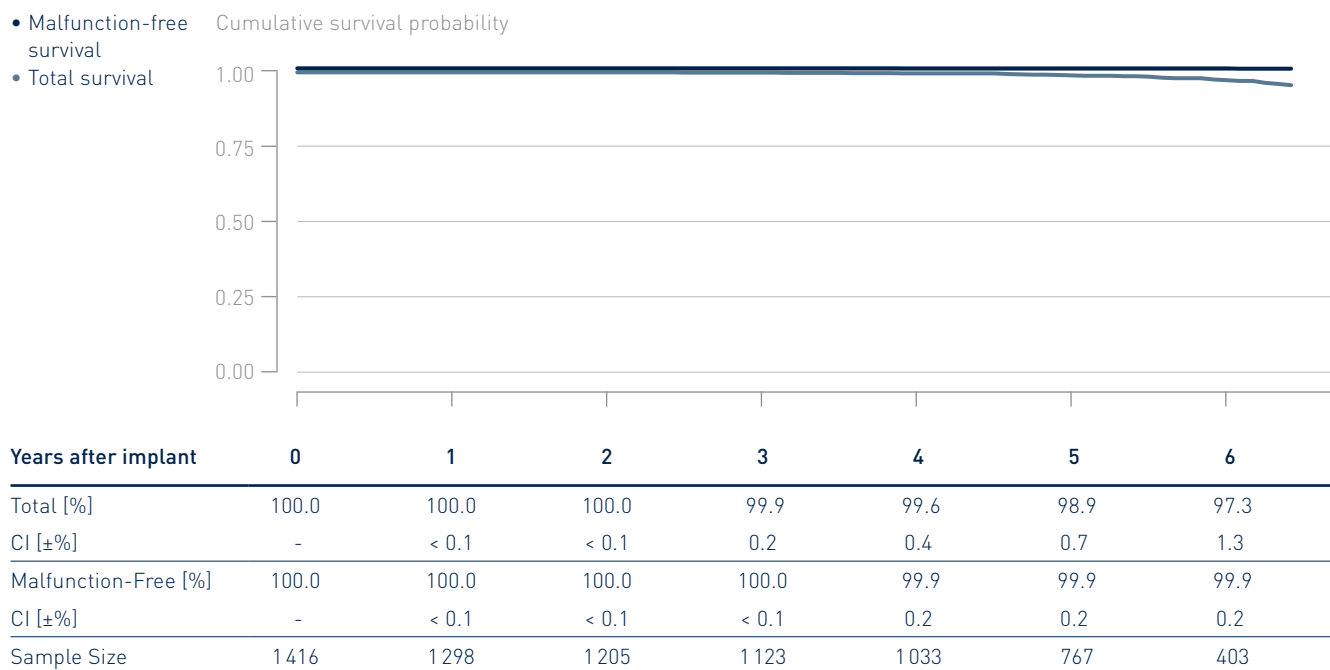
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4.2 Dual-Chamber ICDs

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	2 170
Registered U.S. Implants	1 416
Estimated Active U.S. Implants	912
U.S. Normal Battery Depletions	28

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



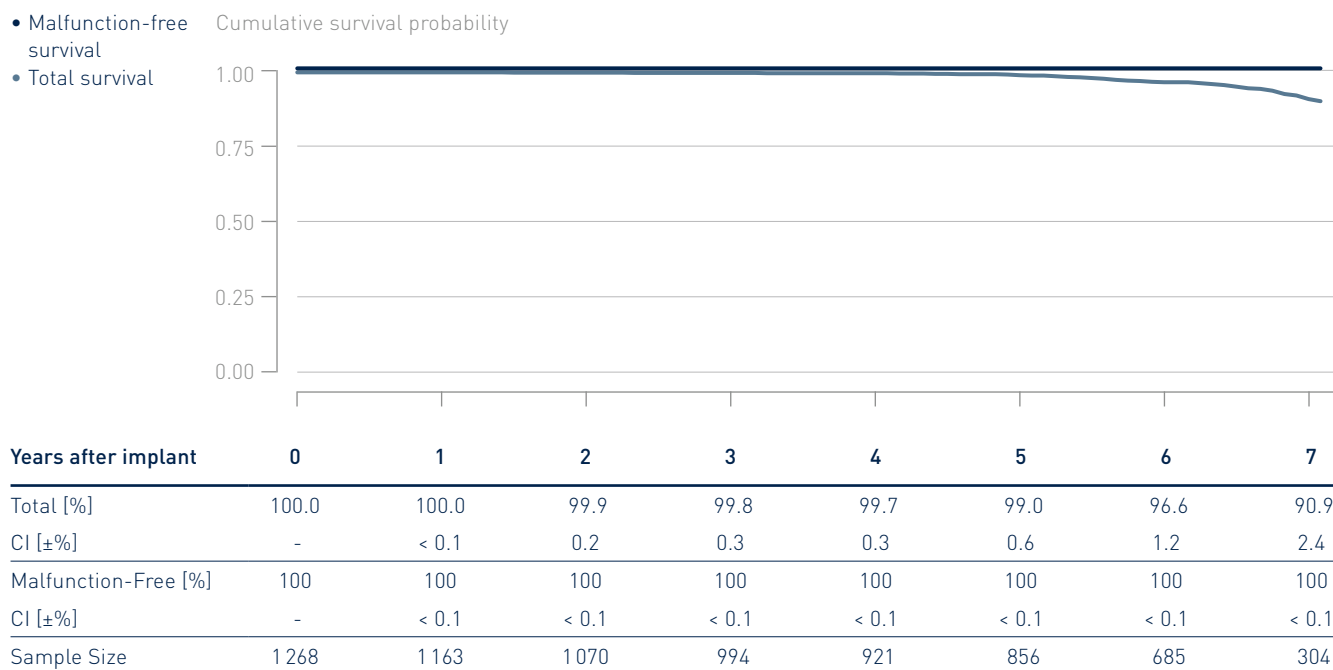
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Itrevia 7 DF4

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	2340
Registered U.S. Implants	1268
Estimated Active U.S. Implants	734
U.S. Normal Battery Depletions	61

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



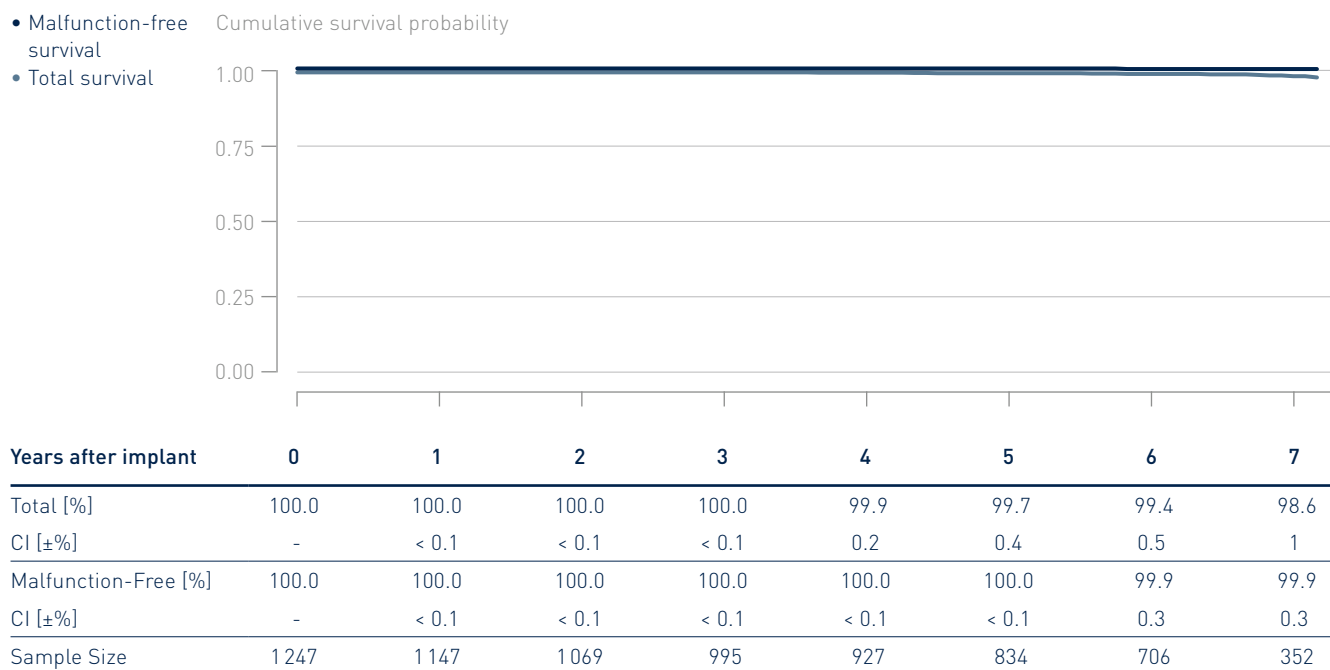
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Itrevia 7 DX

Product Versions	VR-T
NBG Codes	WE-VDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 750
Registered U.S. Implants	1 247
Estimated Active U.S. Implants	769
U.S. Normal Battery Depletions	10

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



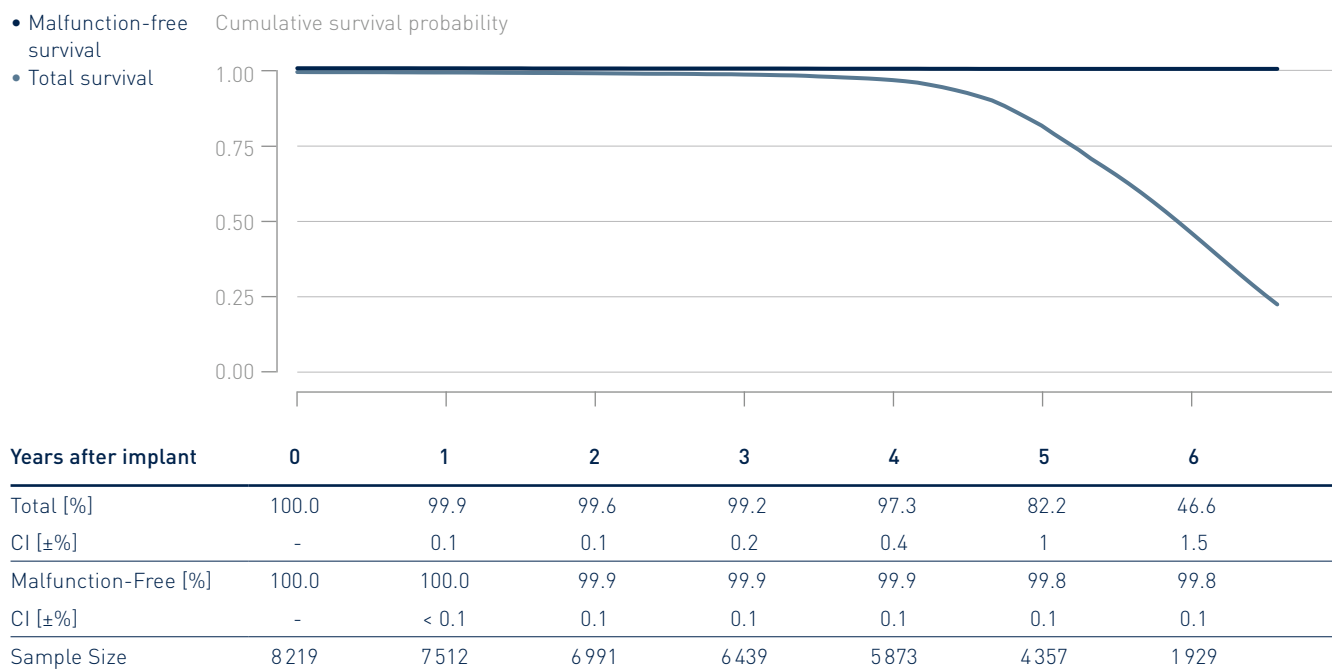
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.2 Dual-Chamber ICDs

Lumax 340

Product Versions	DR, DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26 400
Registered U.S. Implants	8 219
Estimated Active U.S. Implants	1 540
U.S. Normal Battery Depletions	2 156

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

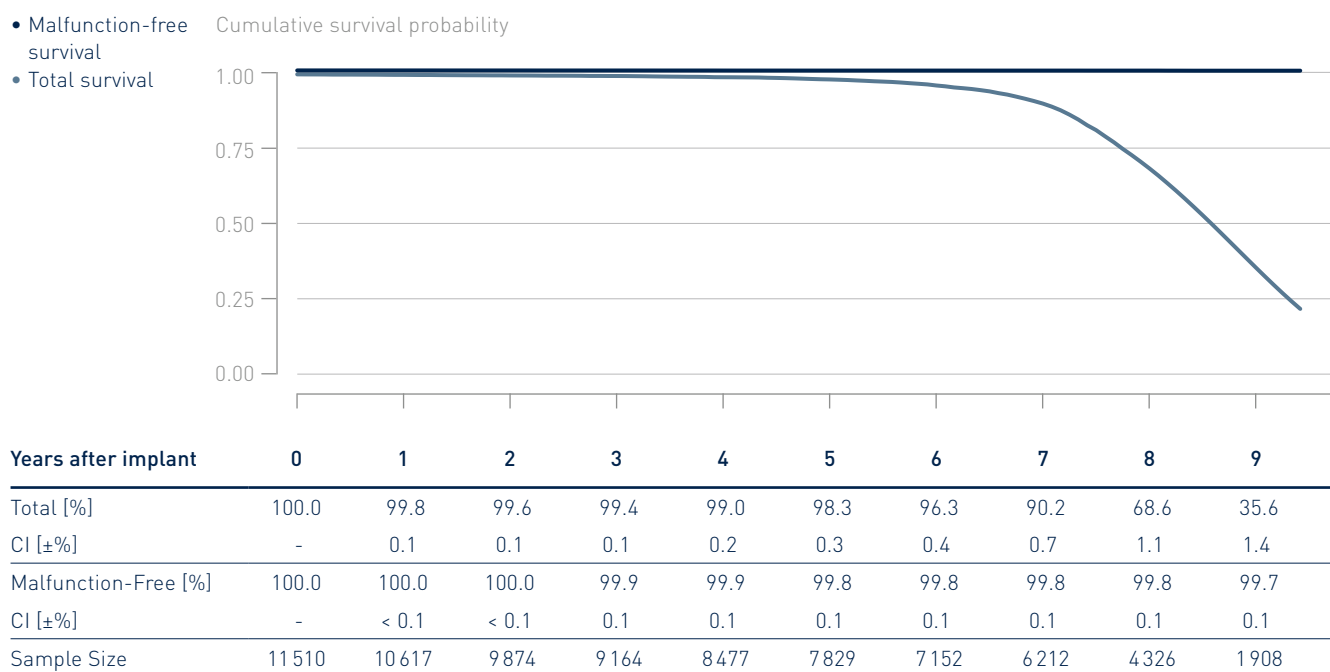


4.2 Dual-Chamber ICDs

Lumax 540

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered U.S. Implants	11 510
Estimated Active U.S. Implants	2 780
U.S. Normal Battery Depletions	2 922

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

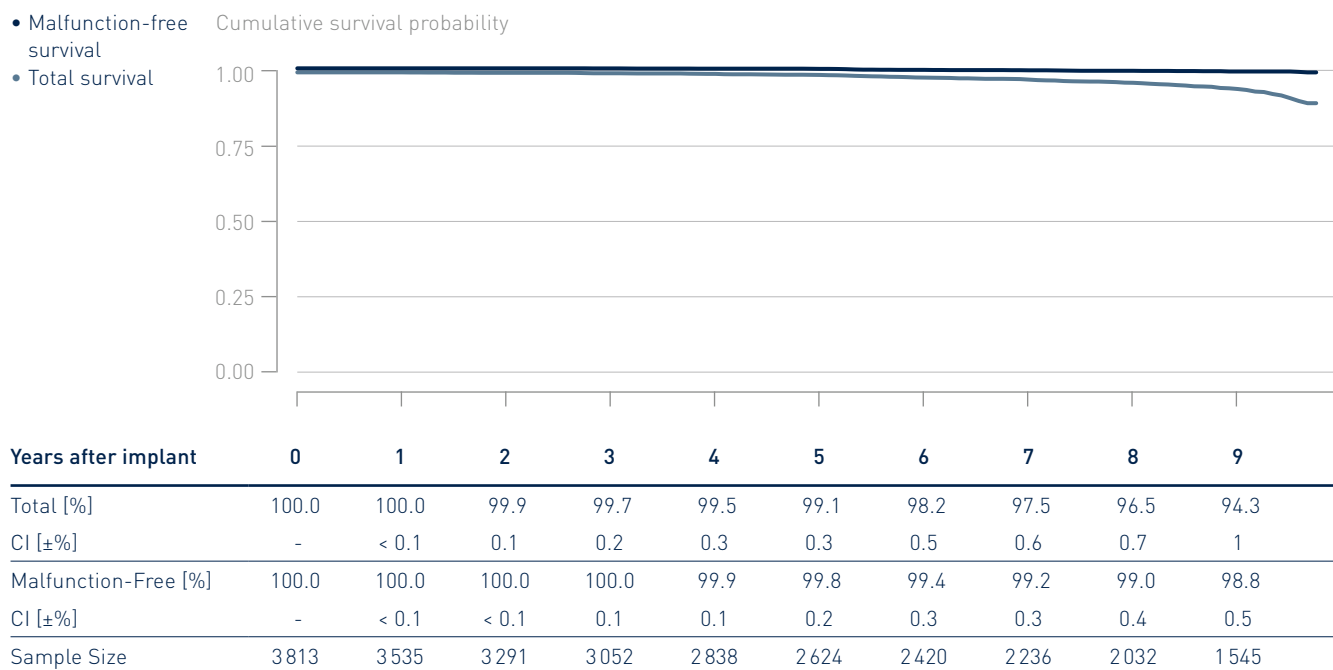


4.2 Dual-Chamber ICDs

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	3 813
Estimated Active U.S. Implants	1 790
U.S. Normal Battery Depletions	163

	Quantity	Rate
U.S. Confirmed Malfunctions	31	0.81%
Therapy Compromised	19	0.50%
Therapy Available	12	0.31%





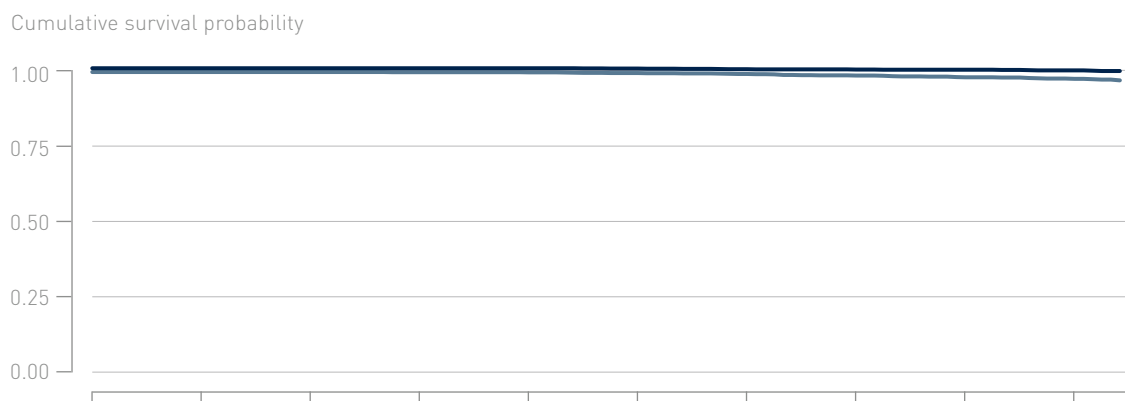
4.2 Dual-Chamber ICDs

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	4 560
Registered U.S. Implants	2 223
Estimated Active U.S. Implants	1 240
U.S. Normal Battery Depletions	26

	Quantity	Rate
U.S. Confirmed Malfunctions	15	0.67%
Therapy Compromised	9	0.40%
Therapy Available	6	0.27%

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	100.0	100.0	99.9	99.9	99.6	99.3	98.7	98.1	97.5
CI [±%]	-	< 0.1	< 0.1	0.1	0.2	0.3	0.4	0.6	0.7	0.8
Malfunction-Free [%]	100.0	100.0	100.0	100.0	100.0	99.9	99.6	99.5	99.4	99.1
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	0.2	0.3	0.4	0.4	0.5
Sample Size	2 223	2 058	1 921	1 784	1 665	1 546	1 440	1 337	1 205	887

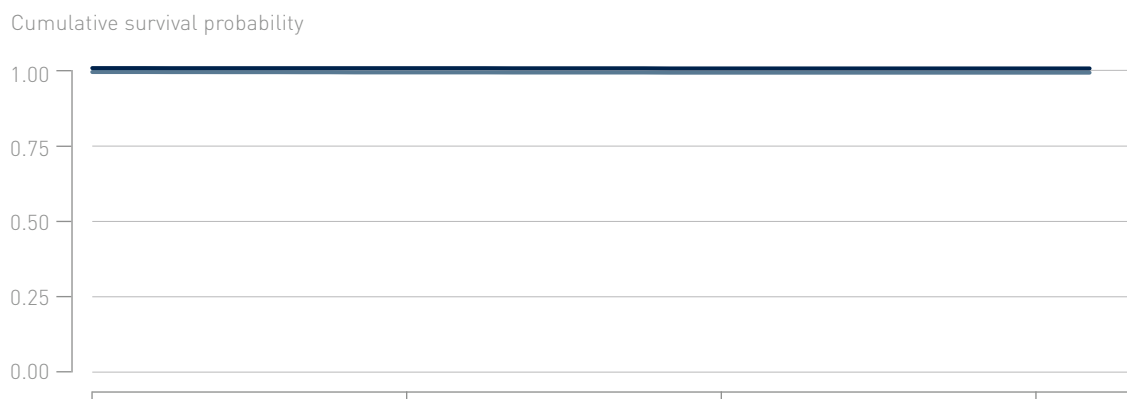
4.2 Dual-Chamber ICDs

Rivacor 7 DF4

Product Versions	DR-T
NBG Codes	WE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	13 000
Registered U.S. Implants	7 152
Estimated Active U.S. Implants	6 420
U.S. Normal Battery Depletions	4

	Quantity	Rate
U.S. Confirmed Malfunctions	3	0.04%
Therapy Compromised	3	0.04%
Therapy Available	0	0.00%

- Malfunction-free survival
- Total survival



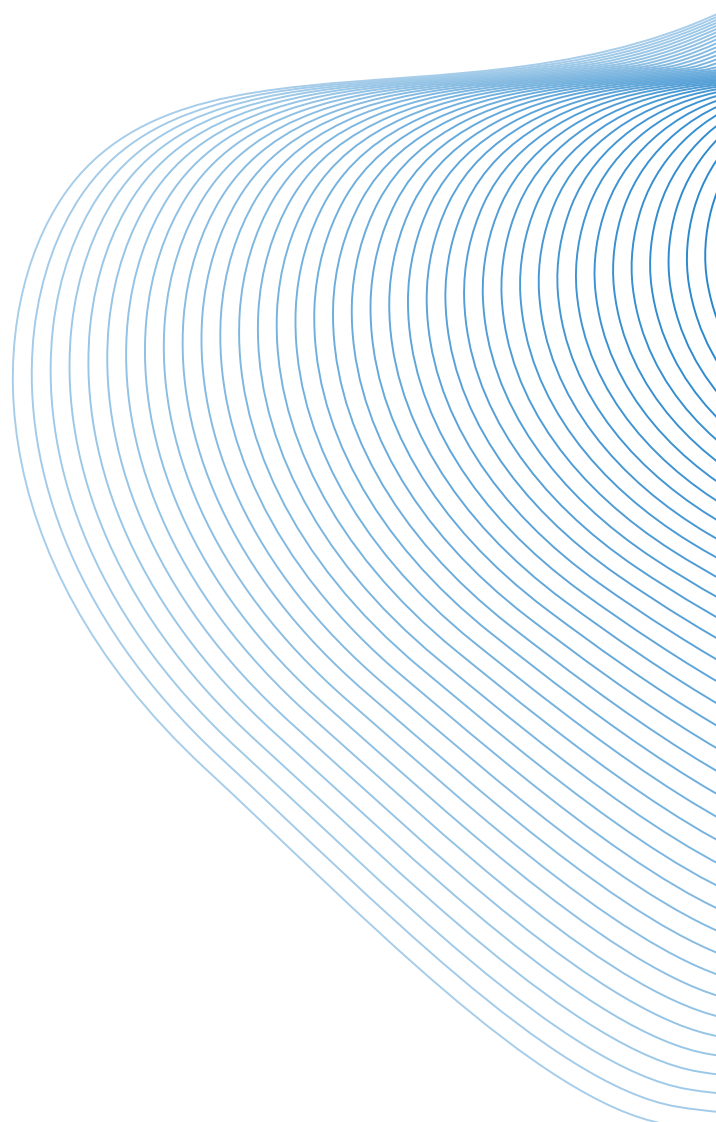
Years after implant	0	1	2	3
Total [%]	100.0	99.9	99.8	99.8
CI [±%]	-	0.1	0.1	0.1
Malfunction-Free [%]	100.0	100.0	99.9	99.9
CI [±%]	-	< 0.1	0.1	0.1
Sample Size	7 152	4 502	2 184	529

Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs

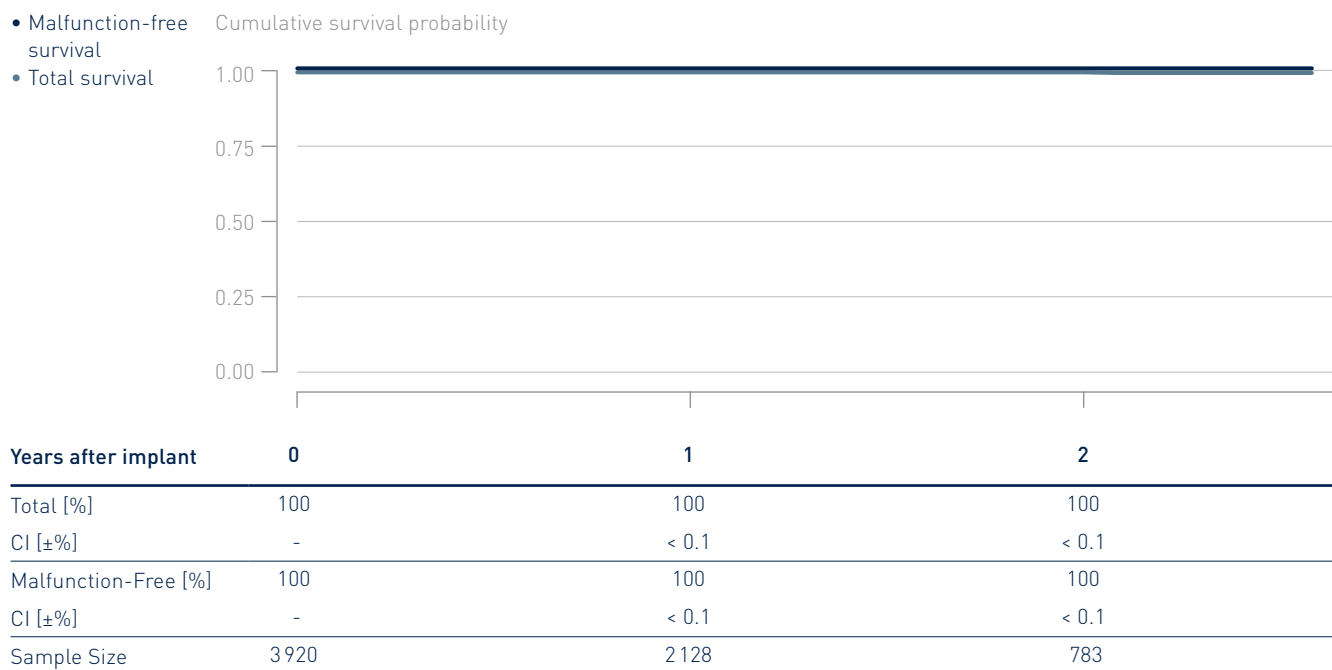


4.3 CRT ICDs

Acticor 7

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	15400
Registered U.S. Implants	3920
Estimated Active U.S. Implants	3290
U.S. Normal Battery Depletions	2

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

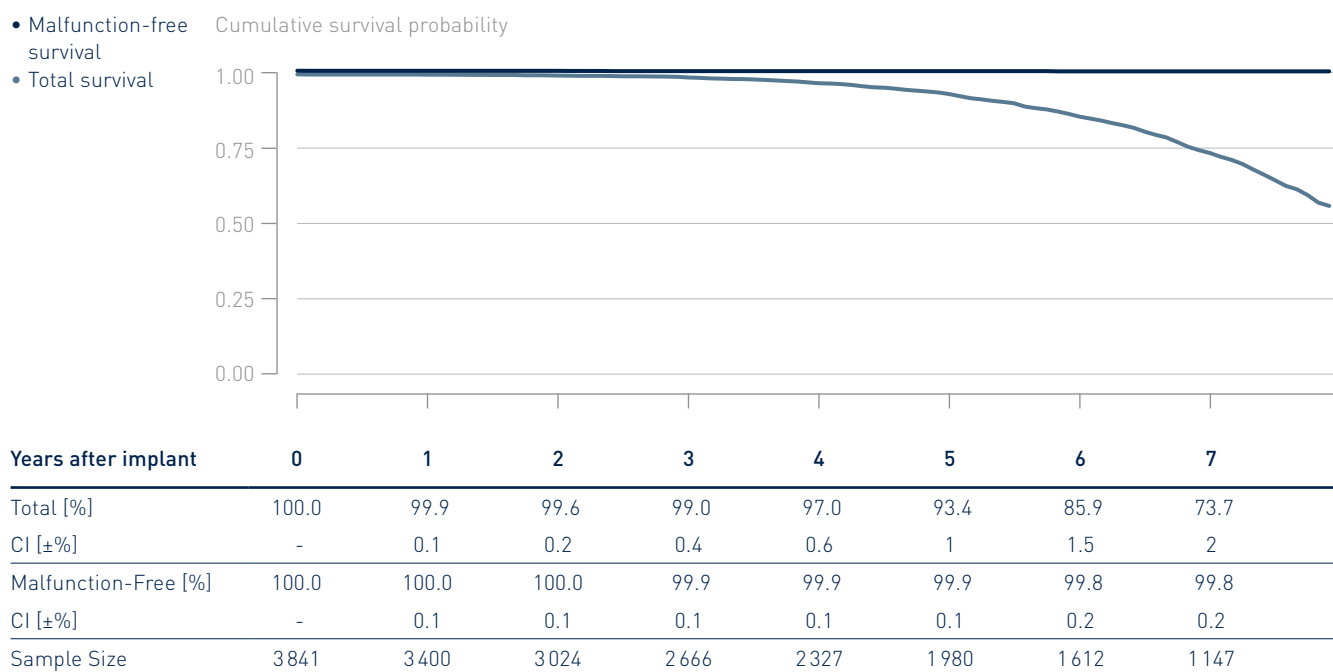


4.3 CRT ICDs

Ilesto 7

Product Versions	HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 290
Registered U.S. Implants	3841
Estimated Active U.S. Implants	921
U.S. Normal Battery Depletions	727

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



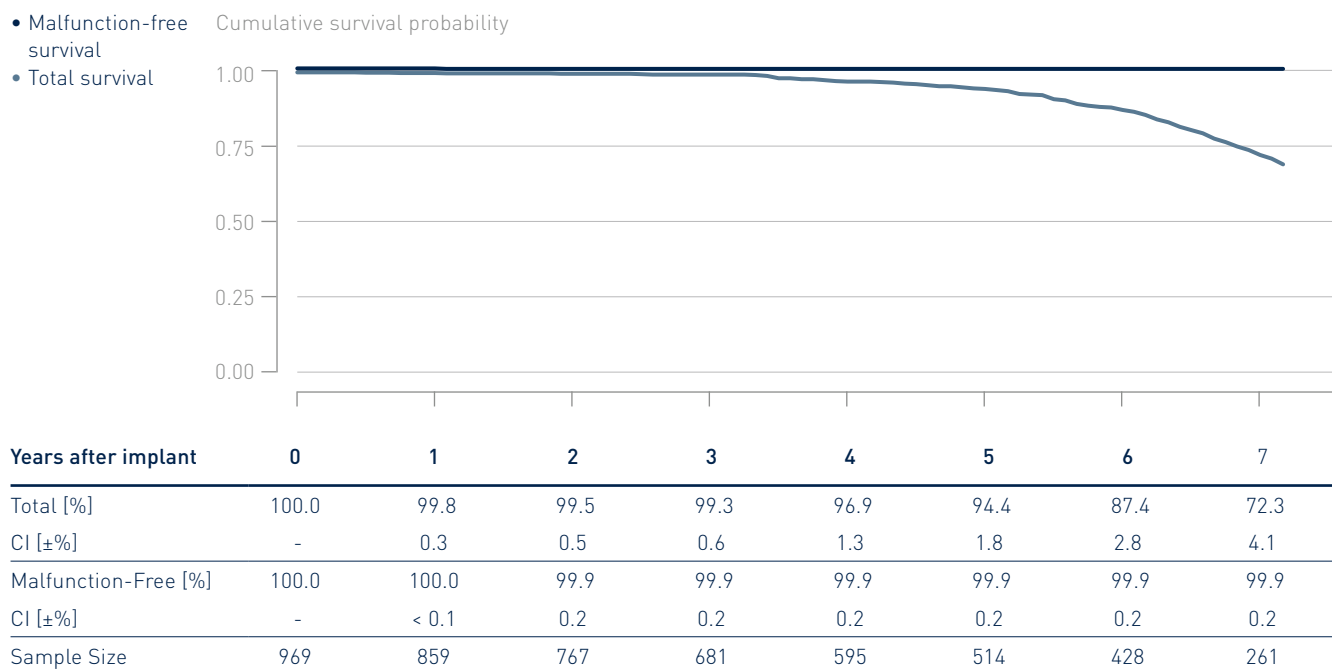
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.3 CRT ICDs

Ilesto 7 DF4

Product Versions	HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jun 2013
Worldwide Distributed Devices	2360
Registered U.S. Implants	969
Estimated Active U.S. Implants	287
U.S. Normal Battery Depletions	154

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



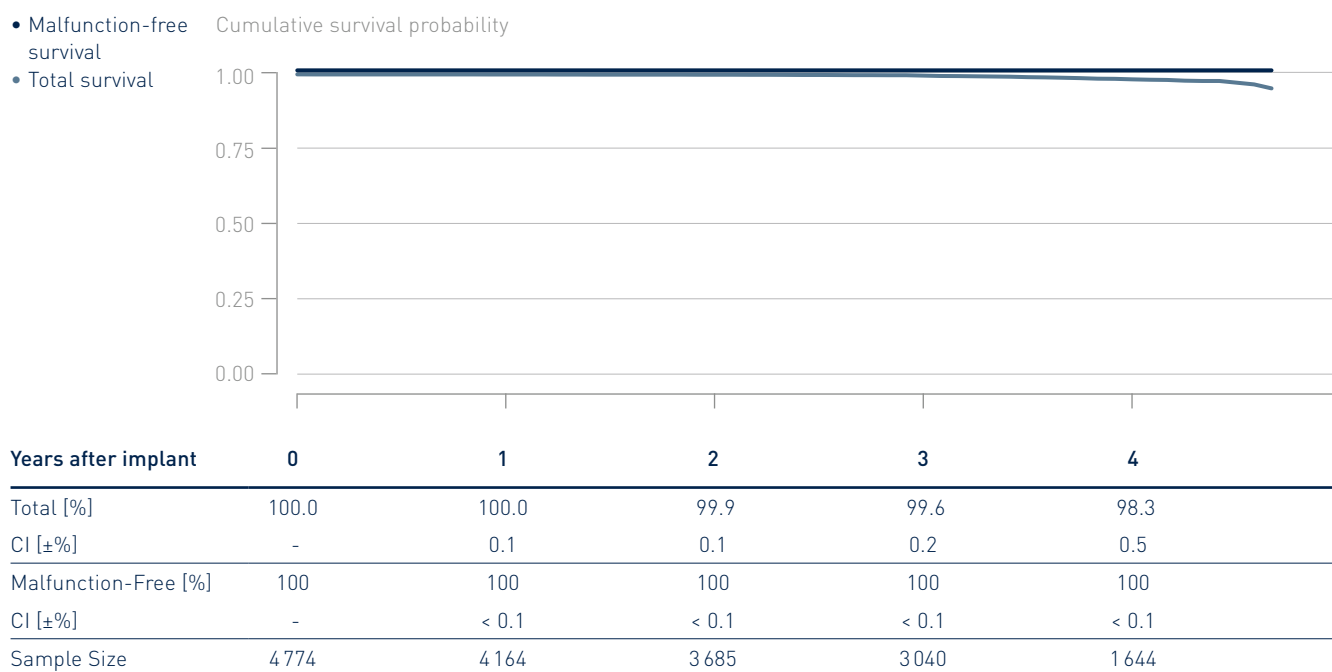
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	9 290
Registered U.S. Implants	4 774
Estimated Active U.S. Implants	2 970
U.S. Normal Battery Depletions	69

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



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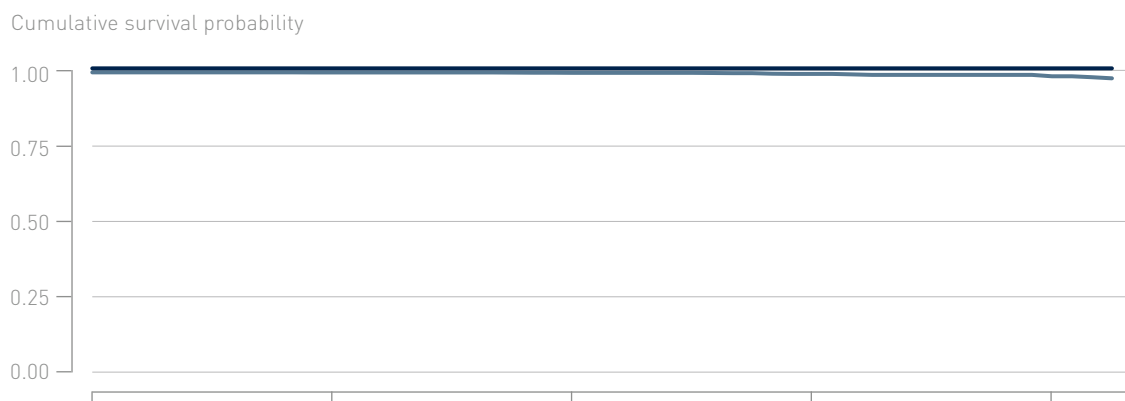
4.3 CRT ICDs

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	5 460
Registered U.S. Implants	2 960
Estimated Active U.S. Implants	1 920
U.S. Normal Battery Depletions	20

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

- Malfunction-free survival
- Total survival



Years after implant	0	1	2	3	4
Total [%]	100.0	99.9	99.8	99.4	98.5
CI [±%]	-	0.1	0.2	0.4	0.9
Malfunction-Free [%]	100	100	100	100	100
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1
Sample Size	2 960	2 551	2 146	1 281	381

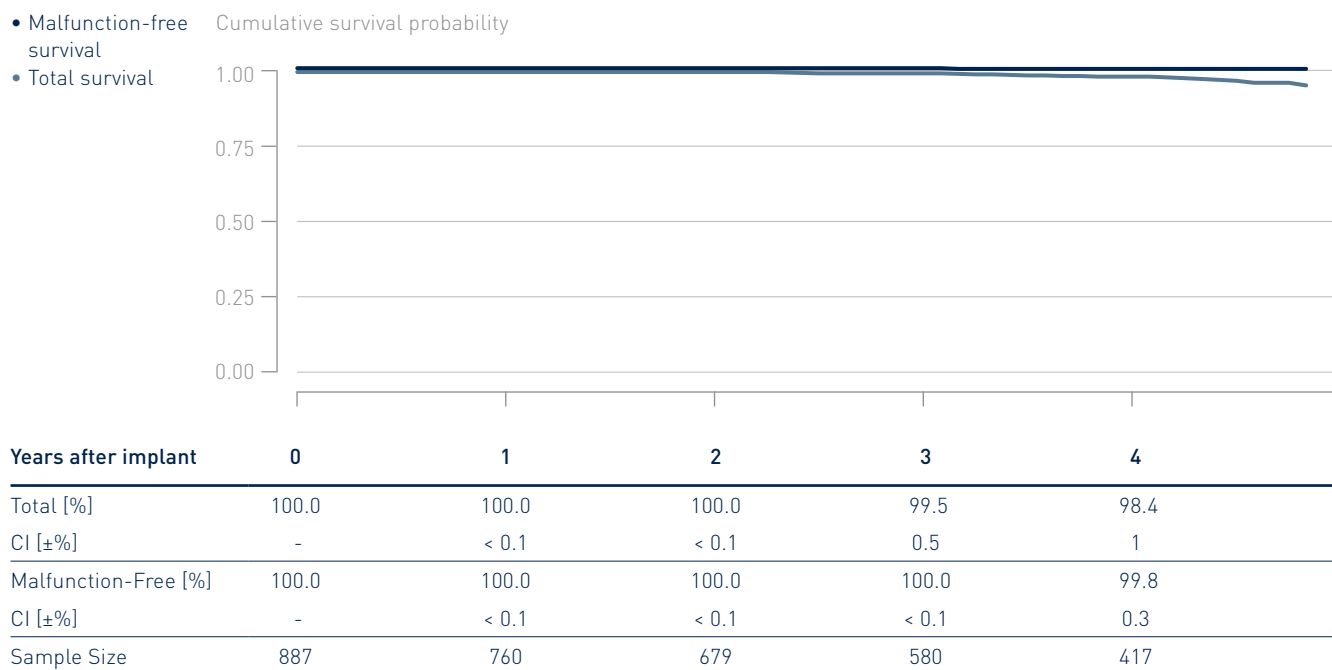
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	2 110
Registered U.S. Implants	887
Estimated Active U.S. Implants	469
U.S. Normal Battery Depletions	32

	Quantity	Rate
U.S. Confirmed Malfunctions*	1	0.11%
Therapy Compromised	0	0.00%
Therapy Available	1	0.11%



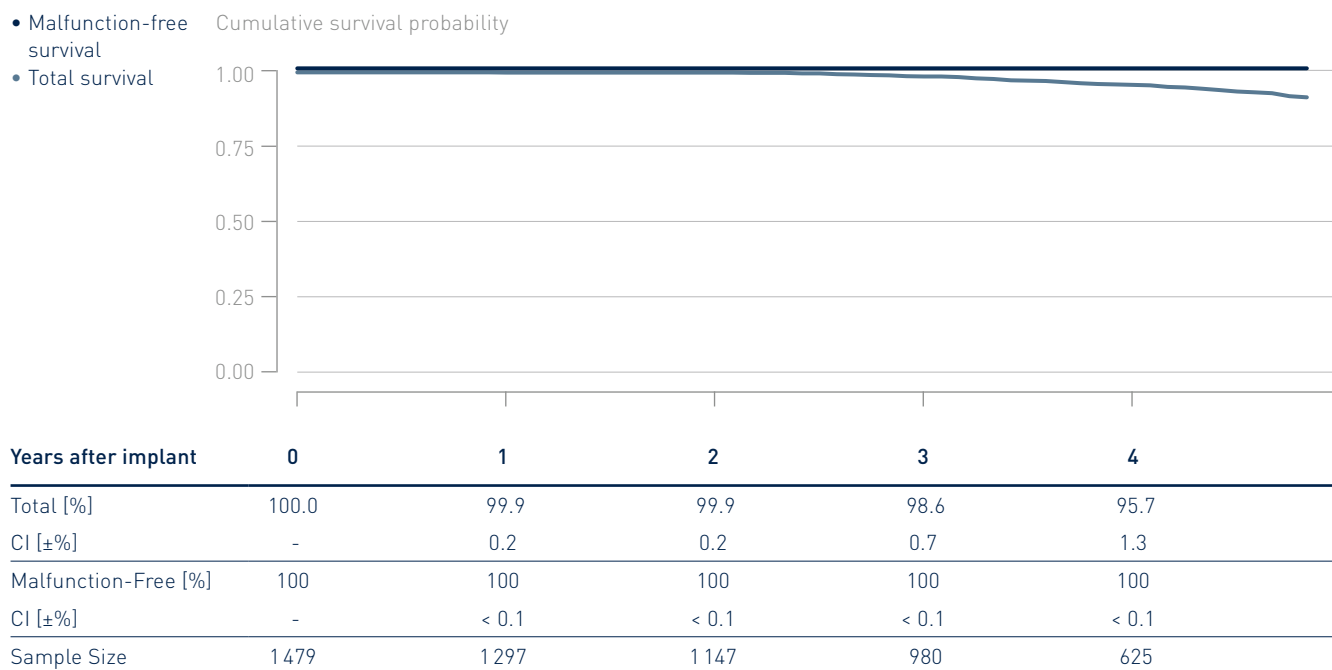
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	3 040
Registered U.S. Implants	1 479
Estimated Active U.S. Implants	817
U.S. Normal Battery Depletions	69

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



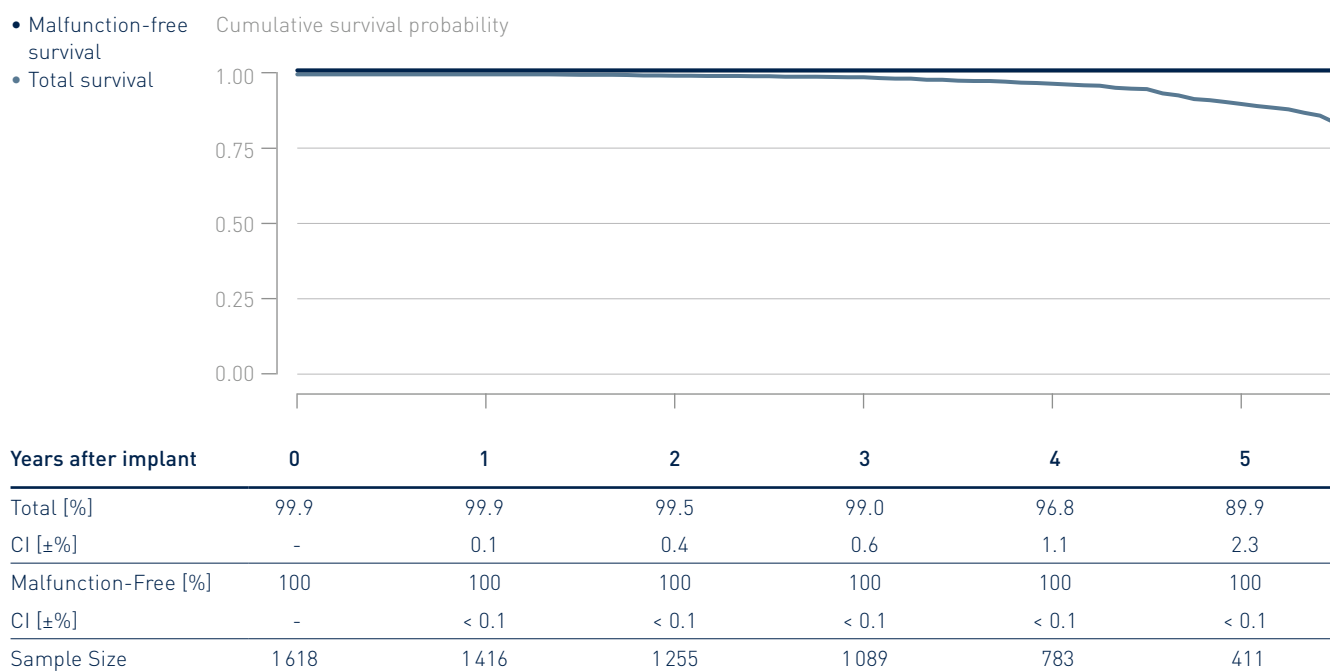
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	5 830
Registered U.S. Implants	1 618
Estimated Active U.S. Implants	836
U.S. Normal Battery Depletions	103

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



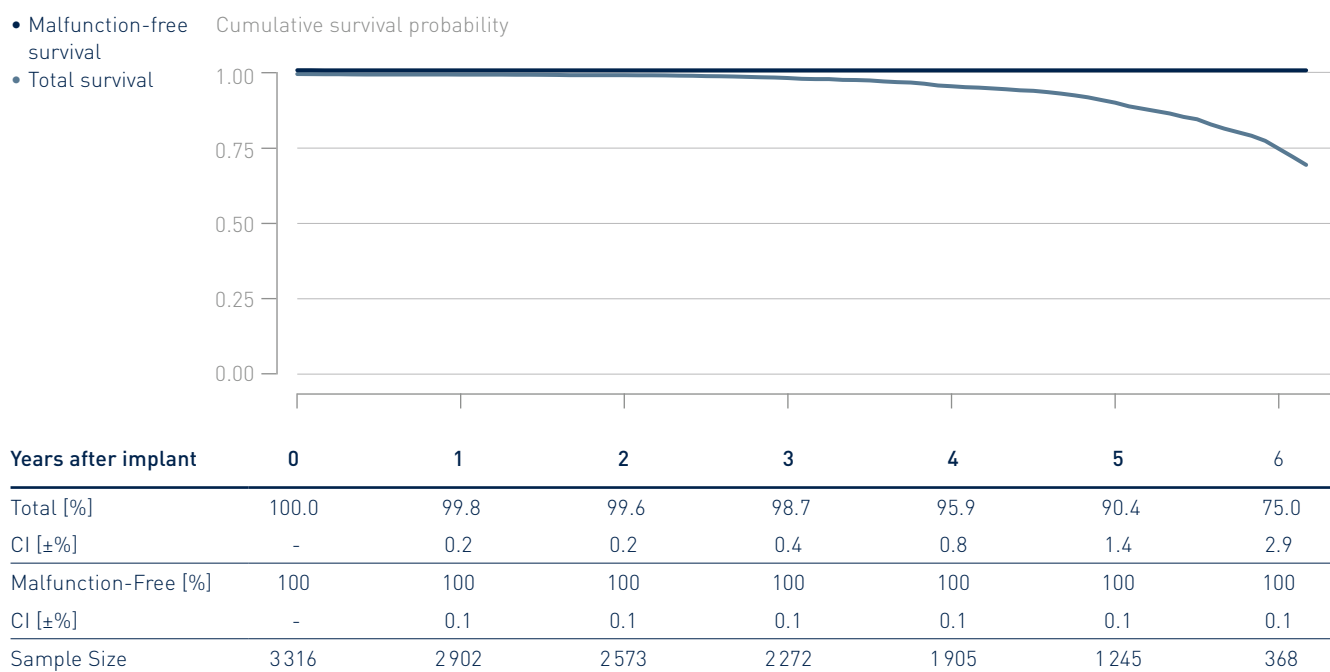
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	4 600
Registered U.S. Implants	3 316
Estimated Active U.S. Implants	1 400
U.S. Normal Battery Depletions	337

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



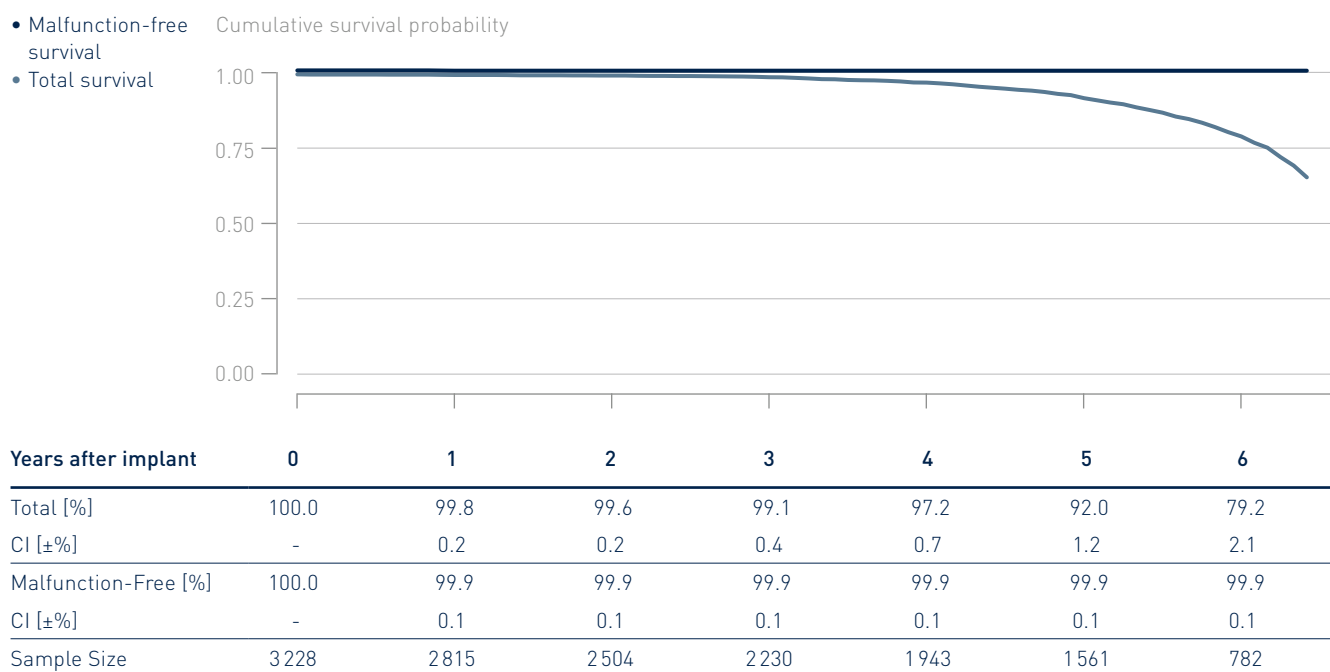
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

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	5 680
Registered U.S. Implants	3 228
Estimated Active U.S. Implants	1 150
U.S. Normal Battery Depletions	431

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



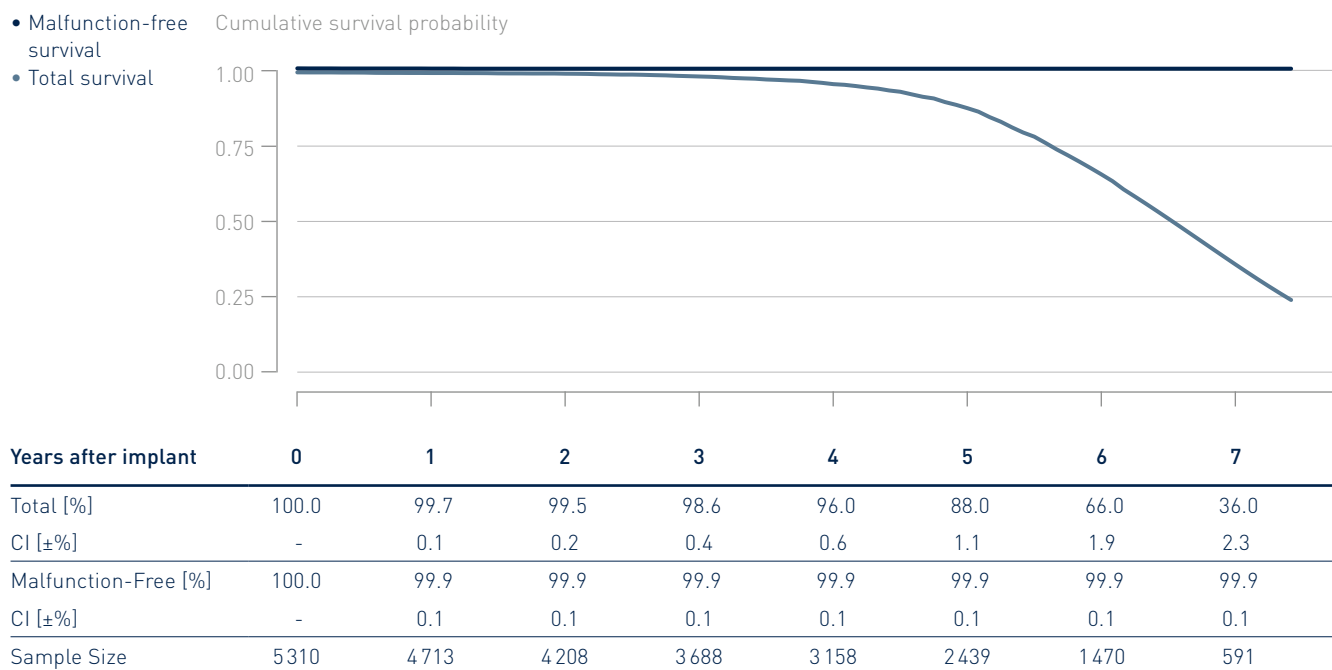
* A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter "Advisories" for details.

4.3 CRT ICDs

Lumax 340

Product Versions	HF, HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20700
Registered U.S. Implants	5310
Estimated Active U.S. Implants	457
U.S. Normal Battery Depletions	1275

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

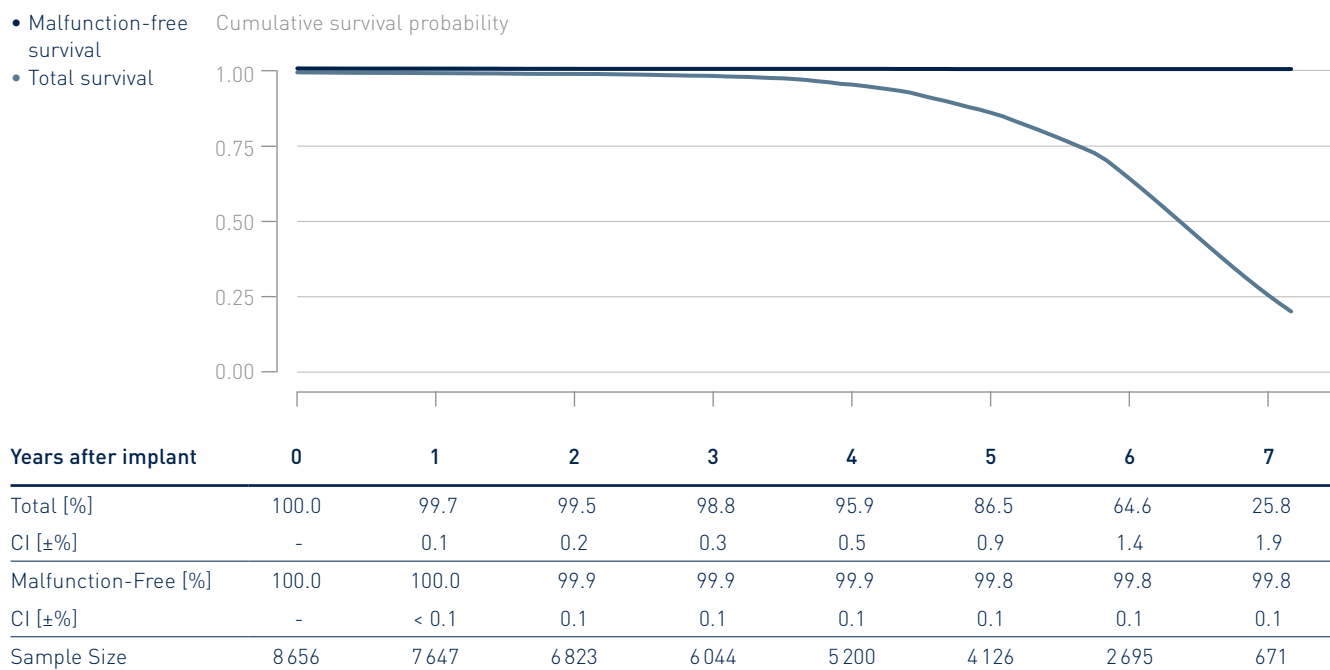


4.3 CRT ICDs

Lumax 540

Product Versions	HF-T
NBG Codes	WE-DDDRV
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	24 800
Registered U.S. Implants	8 656
Estimated Active U.S. Implants	852
U.S. Normal Battery Depletions	2 597

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

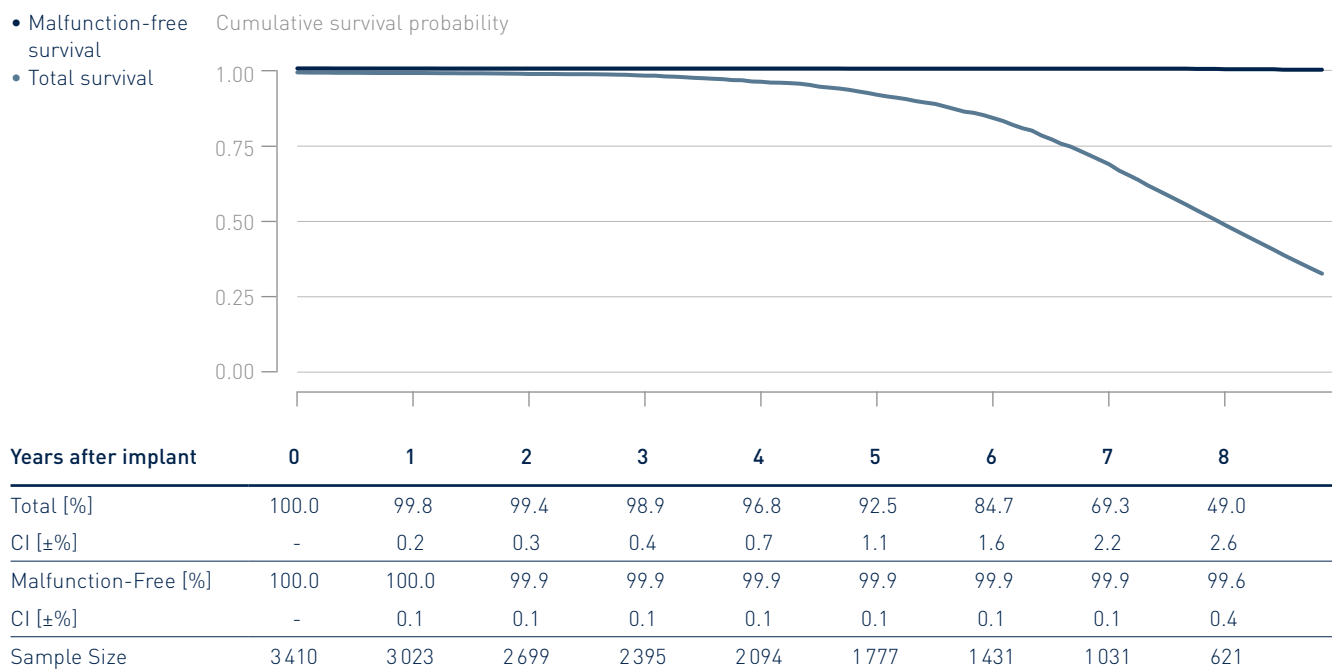


4.3 CRT ICDs

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	7 040
Registered U.S. Implants	3 410
Estimated Active U.S. Implants	570
U.S. Normal Battery Depletions	869

	Quantity	Rate
U.S. Confirmed Malfunctions	8	0.23%
Therapy Compromised	6	0.18%
Therapy Available	2	0.06%

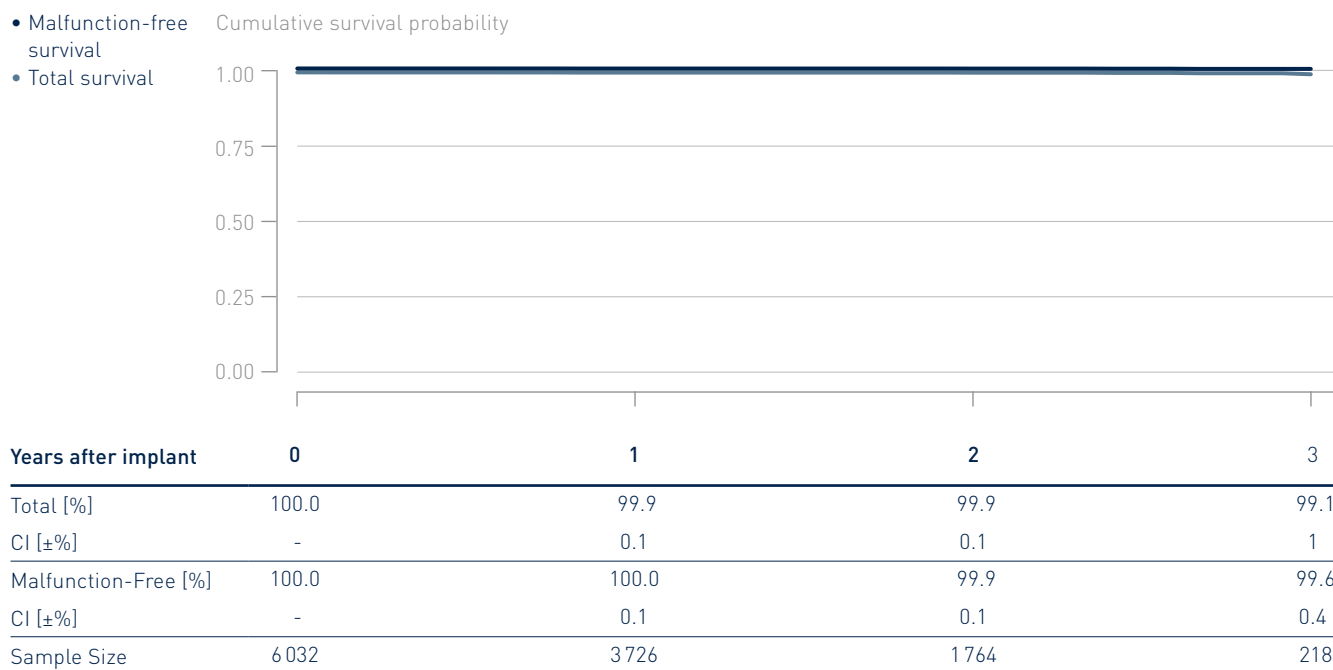


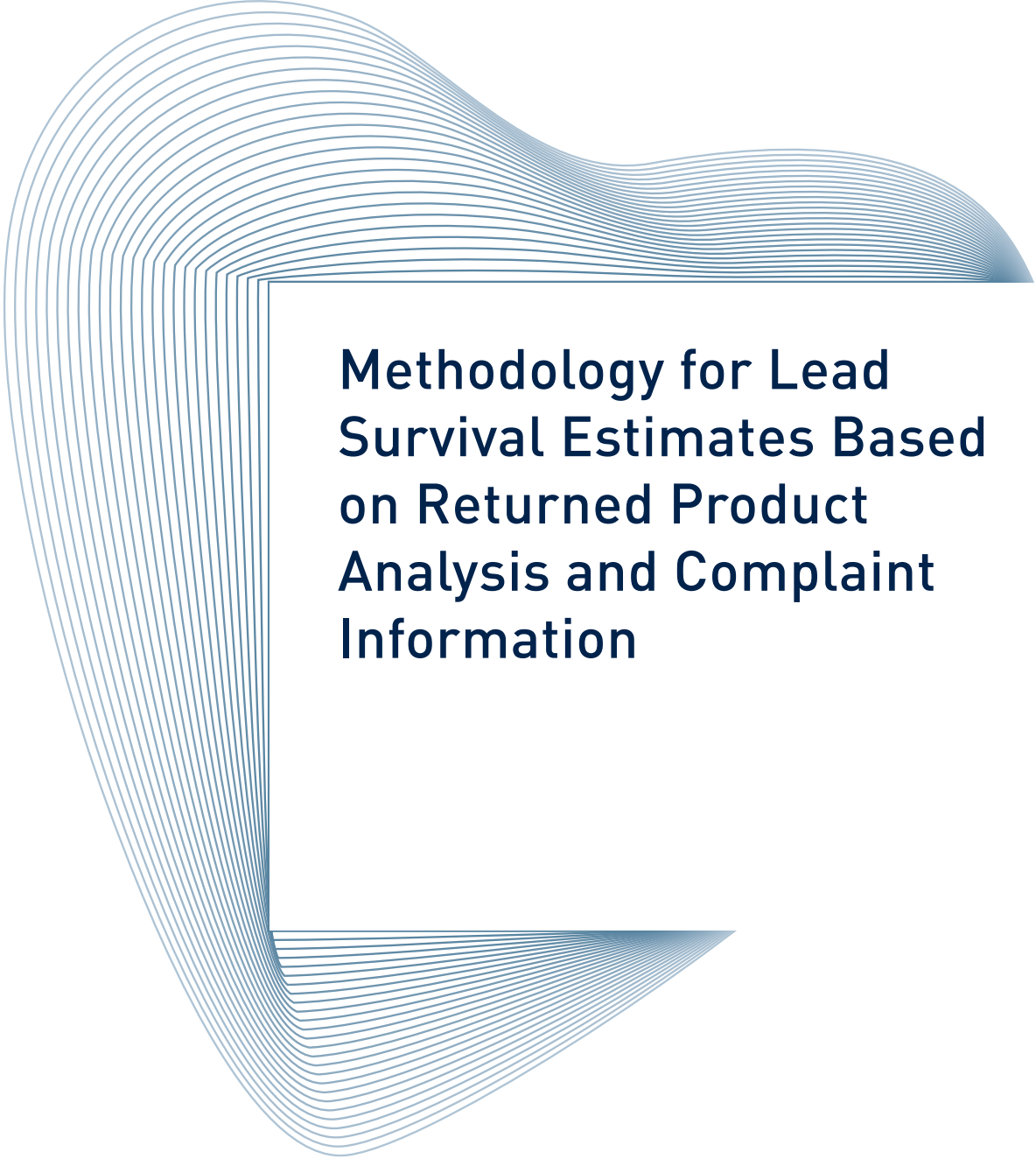
4.3 CRT ICDs

Rivacor 7 DF4

Product Versions	HF-T, HF-T QP
NBG Codes	VDE-DDDRV
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	15 600
Registered U.S. Implants	6 032
Estimated Active U.S. Implants	5 050
U.S. Normal Battery Depletions	7

	Quantity	Rate
U.S. Confirmed Malfunctions	5	0.08%
Therapy Compromised	4	0.07%
Therapy Available	1	0.02%





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 cutoff date for the data included in this report is December 31, 2022. The sample sizes of U.S. leads that are implanted and remain active as well as the total number of products distributed worldwide are provided for each lead family in this report.

Survival estimates are calculated for lead families having accumulated at least 10,000 cumulative implant months. Products no longer being distributed with less than 500 active implants may be excluded from this report.

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

5.3 Returned Product Analysis

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

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

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

Conductor Fracture

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

Crimps, Welds and Bonds

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

Insulation Breach

Any lead insulation breach

Other

Includes specific proprietary lead mechanical attributes.

5.4 Lead Complications

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

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

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

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

Failure to Capture

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

Failure to Sense

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

Oversensing

Misinterpretation of cardiac or non-cardiac events as cardiac depolarization

Abnormal Pacing Impedance

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

Abnormal Defibrillation Impedance

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

Insulation Breach

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

Conductor Fracture

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

Lead Dislodgement

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

Extracardiac Stimulation

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

Cardiac Perforation

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

Other

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

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

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

5.5 Lead Product Performance Graphs and Data

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

For each lead, the report provides:

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

- Number of U.S. leads or partial leads returned post-implant for analysis with a complaint

The survival plots provide:

Total Survival

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

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

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

The cumulative survival data and the 95% confidence intervals according to the Greenwood's 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

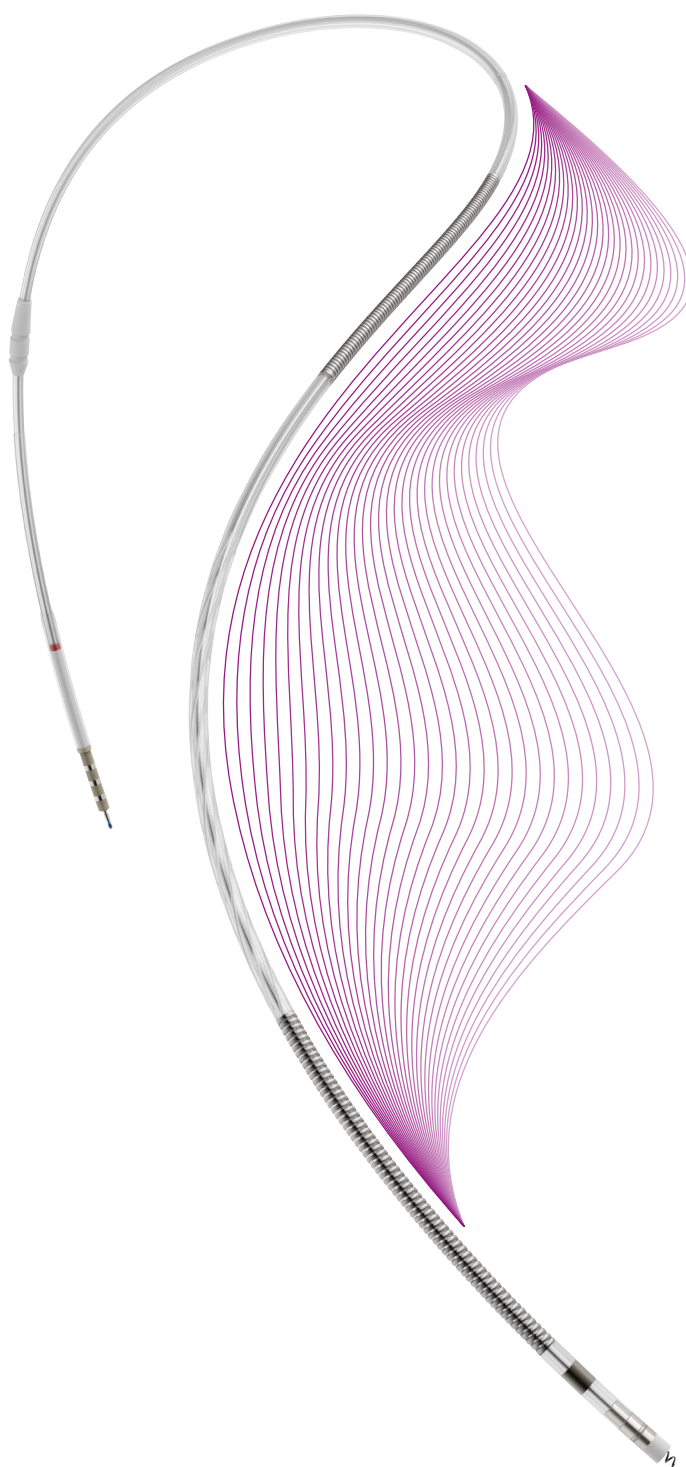
Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



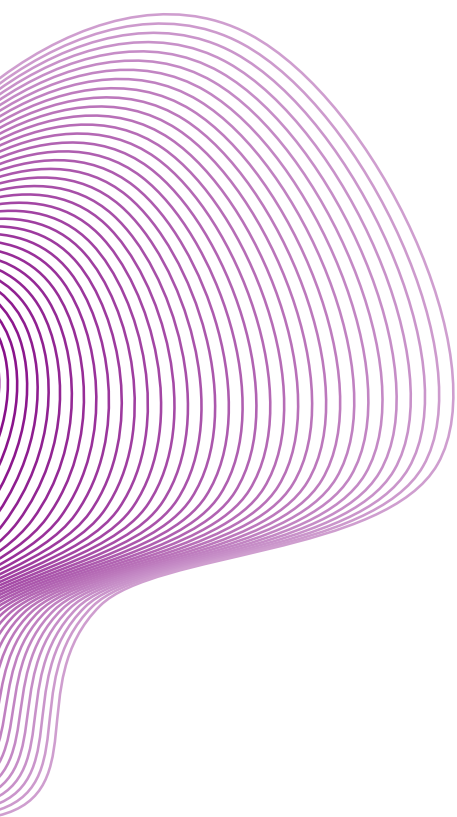
Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads





6.1 Pacing Leads – Postmarket Data

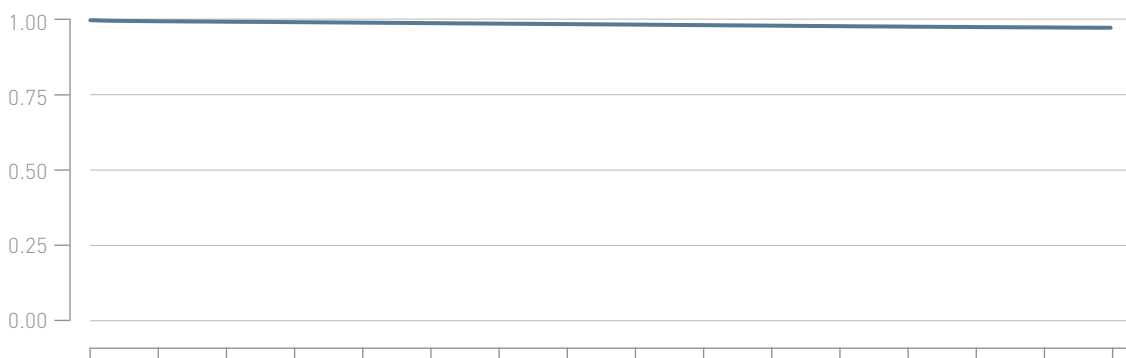
Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	480 000
Registered U.S. Implants	379 536
Estimated Active U.S. Implants	214 000
U.S. Total Returned	2 463

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	5,085	1.32%	U.S. Confirmed Malfunctions	390	0.10%
Abnormal pacing impedance	479	0.12%	Conductor Fracture	126	0.03%
Cardiac perforation	27	0.01%	Insulation Breach	257	0.07%
Conductor fracture	144	0.04%	Other	7	0.00%
Extracardiac stimulation	24	0.01%	U.S. Acute Lead Observations	1,760	0.46%
Failure to capture	1,227	0.32%	Abnormal pacing impedance	47	0.01%
Failure to sense	195	0.05%	Cardiac perforation	71	0.02%
Insulation breach	92	0.02%	Extracardiac stimulation	17	0.00%
Lead dislodgement	580	0.15%	Failure to capture	255	0.07%
Oversensing	1,410	0.37%	Failure to sense	70	0.02%
Other	907	0.24%	Insulation breach	10	0.00%
			Lead dislodgement	711	0.19%
			Oversensing	50	0.01%
			Other	529	0.14%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.6	99.5	99.3	99.1	98.9	98.7	98.6	98.4	98.2	98.0	97.8	97.7	97.5	97.4	97.3
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	379536	336216	314446	294886	277925	262382	246333	207916	167683	131474	101503	76123	53538	32137	13627	324



6.1 Pacing Leads – Postmarket Data

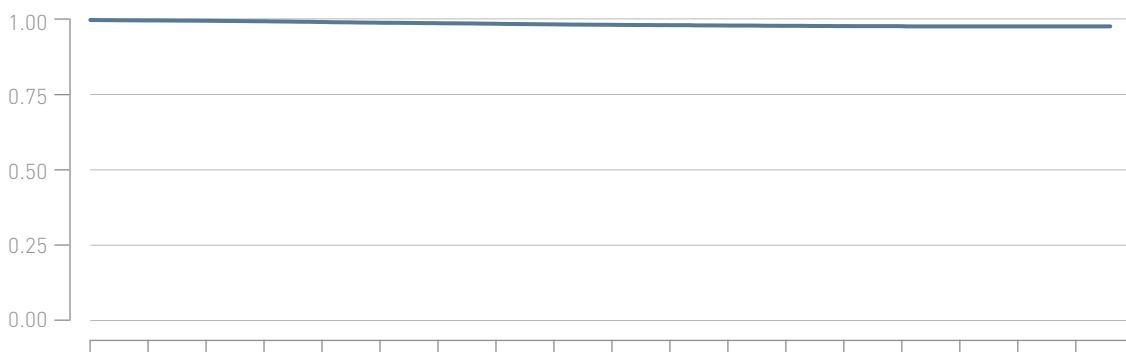
Selox JT

Product Versions _____	45, 53
Lead Type _____	J-shape, passive fixation
Polarity _____	bipolar
Steroid _____	yes
U.S. Market Release _____	Nov 2004
CE Market Release _____	Nov 2004
Worldwide Distributed Devices _____	157 000
Registered U.S. Implants _____	16 620
Estimated Active U.S. Implants _____	11 700
U.S. Total Returned _____	129

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	261	1.57%	U.S. Confirmed Malfunctions _____	11	0.07%
Abnormal pacing impedance _____	41	0.25%	Insulation Breach _____	10	0.06%
Cardiac perforation _____	1	0.01%	Other _____	1	0.01%
Conductor fracture _____	16	0.10%	U.S. Acute Lead Observations _____	45	0.27%
Extracardiac stimulation _____	1	0.01%	Failure to capture _____	8	0.05%
Failure to capture _____	110	0.66%	Lead dislodgement _____	34	0.20%
Failure to sense _____	11	0.07%	Other _____	3	0.02%
Insulation breach _____	12	0.07%			
Lead dislodgement _____	39	0.23%			
Oversensing _____	11	0.07%			
Other _____	19	0.11%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	99.8	99.7	99.5	99.3	99.0	98.8	98.6	98.4	98.2	98.1	97.9	97.8	97.7	97.7	97.6	97.6	97.6
CI [±%]	-	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sample Size	16620	15296	14656	14034	13554	12912	12180	11447	10607	9418	8294	7150	5892	4675	3441	2303	1334	565

6.1 Pacing Leads – Postmarket Data

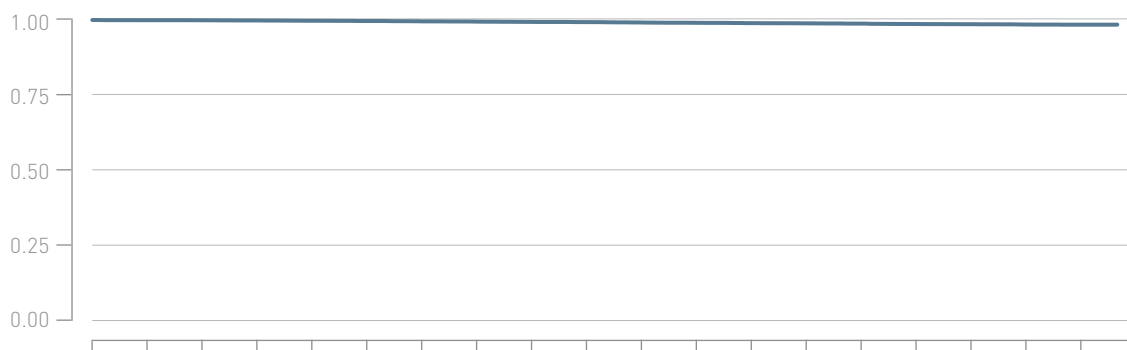
Selox SR

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	14 335
Estimated Active U.S. Implants	6 760
U.S. Total Returned	63

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	134	0.93%	U.S. Confirmed Malfunctions	13	0.09%
Abnormal pacing impedance	11	0.08%	Insulation Breach	13	0.09%
Conductor fracture	12	0.08%	U.S. Acute Lead Observations	21	0.15%
Extracardiac stimulation	2	0.01%	Cardiac perforation	1	0.01%
Failure to capture	51	0.36%	Failure to capture	11	0.08%
Failure to sense	1	0.01%	Insulation breach	1	0.01%
Insulation breach	6	0.04%	Lead dislodgement	8	0.06%
Lead dislodgement	15	0.10%			
Oversensing	21	0.15%			
Other	15	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	15	16	17	18
Total [%]	100.0	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.6	98.5	98.4	98.3	98.2
CI [±%]	-	< 0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
Sample Size	14335	12423	11649	10852	10034	9346	8727	8231	7875	7600	7394	7222	7149	7083	6979	6871	6752	5644	1942



6.1 Pacing Leads – Postmarket Data

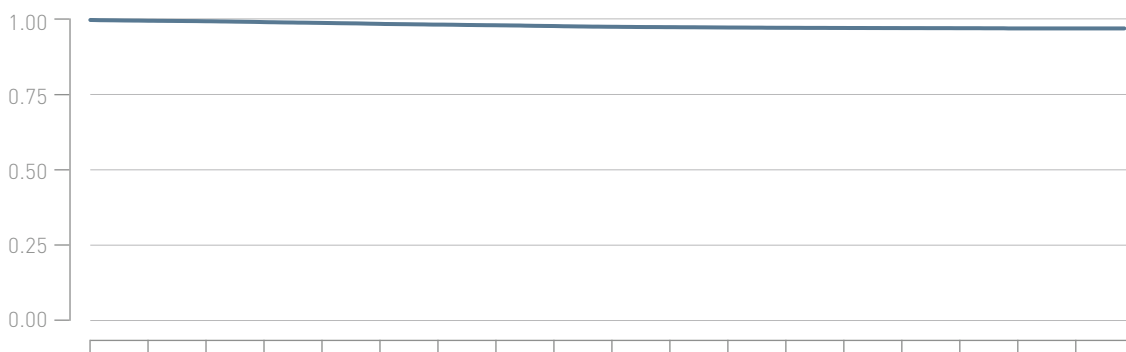
Selox ST

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	379 000
Registered U.S. Implants	32 132
Estimated Active U.S. Implants	21 600
U.S. Total Returned	183

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	658	2.05%	U.S. Confirmed Malfunctions	20	0.06%
Abnormal pacing impedance	147	0.46%	Conductor Fracture	1	0.00%
Cardiac perforation	3	0.01%	Crimps, Welds and Bonds	1	0.00%
Conductor fracture	69	0.21%	Insulation Breach	18	0.06%
Extracardiac stimulation	6	0.02%	U.S. Acute Lead Observations	49	0.15%
Failure to capture	319	0.99%	Abnormal pacing impedance	1	0.00%
Failure to sense	1	0.00%	Failure to capture	21	0.07%
Insulation breach	39	0.12%	Lead dislodgement	21	0.07%
Lead dislodgement	24	0.07%	Other	6	0.02%
Oversensing	19	0.06%			
Other	31	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	15	16	17
Total [%]	100.0	99.7	99.5	99.2	98.9	98.6	98.3	98.1	97.8	97.5	97.4	97.3	97.2	97.1	97.1	97.0	96.9	96.9
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3
Sample Size	32132	29209	27692	26353	25217	23896	22647	21371	19856	17778	15643	13442	11114	8965	6890	4881	3110	1449

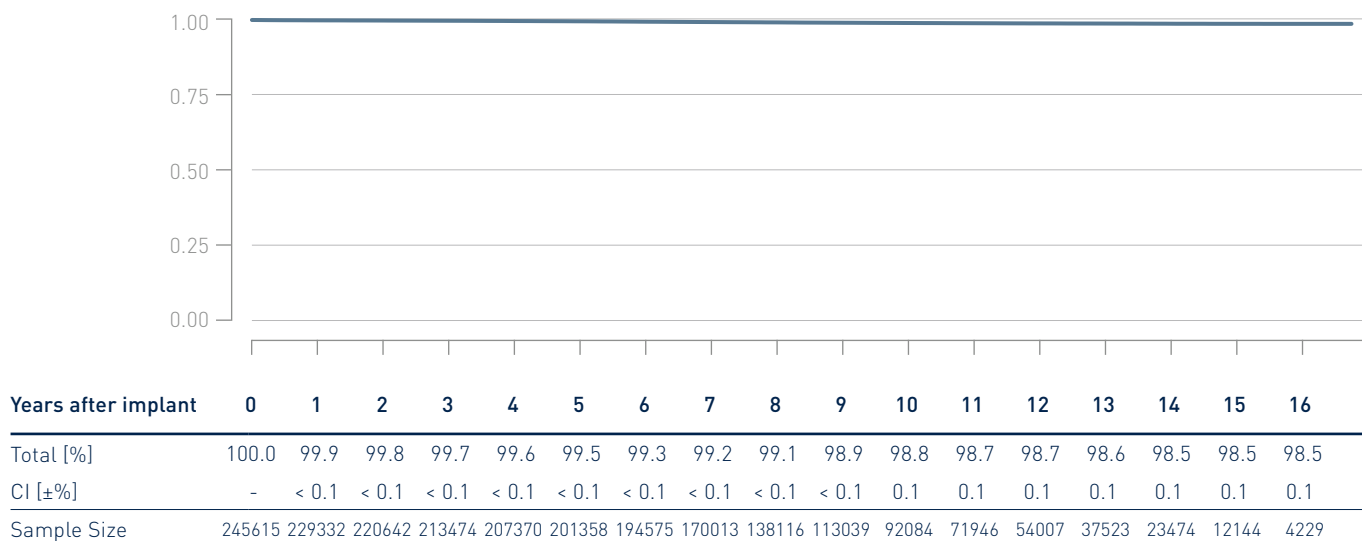
6.1 Pacing Leads – Postmarket Data

Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	681 000
Registered U.S. Implants	245 615
Estimated Active U.S. Implants	186 000
U.S. Total Returned	1 770

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	2,147	0.87%	U.S. Confirmed Malfunctions	217	0.09%
Abnormal pacing impedance	189	0.08%	Conductor Fracture	63	0.03%
Cardiac perforation	9	0.00%	Insulation Breach	148	0.06%
Conductor fracture	151	0.06%	Other	6	0.00%
Extracardiac stimulation	12	0.00%	U.S. Acute Lead Observations	272	0.11%
Failure to capture	719	0.29%	Abnormal pacing impedance	1	0.00%
Failure to sense	63	0.03%	Cardiac perforation	24	0.01%
Insulation breach	88	0.04%	Failure to capture	35	0.01%
Lead dislodgement	376	0.15%	Failure to sense	3	0.00%
Oversensing	383	0.16%	Insulation breach	4	0.00%
Other	157	0.06%	Lead dislodgement	189	0.08%
			Oversensing	16	0.01%
			Other	16	0.01%

• Total survival Cumulative survival probability



6.1 Pacing Leads – Postmarket Data

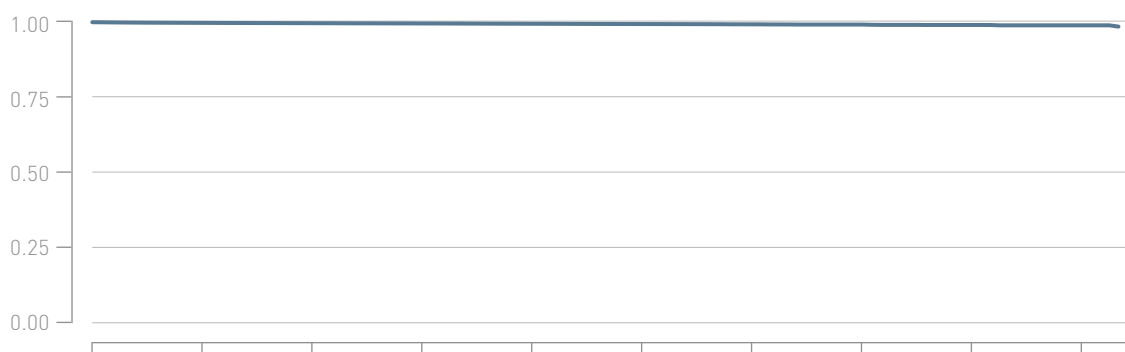
Siello S/Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 526 000
Registered U.S. Implants	236 152
Estimated Active U.S. Implants	216 000
U.S. Total Returned	1 124

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	1,104	0.47%	U.S. Confirmed Malfunctions	56	0.02%
Abnormal pacing impedance	73	0.03%	Conductor Fracture	17	0.01%
Cardiac perforation	18	0.01%	Insulation Breach	28	0.01%
Conductor fracture	34	0.01%	Other	11	0.00%
Extracardiac stimulation	9	0.00%	U.S. Acute Lead Observations	502	0.21%
Failure to capture	297	0.13%	Abnormal pacing impedance	9	0.00%
Failure to sense	45	0.02%	Cardiac perforation	38	0.02%
Insulation breach	18	0.01%	Conductor fracture	1	0.00%
Lead dislodgement	431	0.18%	Extracardiac stimulation	1	0.00%
Oversensing	121	0.05%	Failure to capture	78	0.03%
Other	58	0.02%	Failure to sense	11	0.00%
			Insulation breach	4	0.00%
			Lead dislodgement	316	0.13%
			Oversensing	17	0.01%
			Other	27	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.6	99.5	99.4	99.3	99.2	99.1	98.9	98.8
CI [±%]	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	0.1	0.1	0.2	0.3
Sample Size	236 152	193 253	156 480	123 586	86 038	48 483	15 231	2 329	1 732	455



6.1 Pacing Leads – Postmarket Data

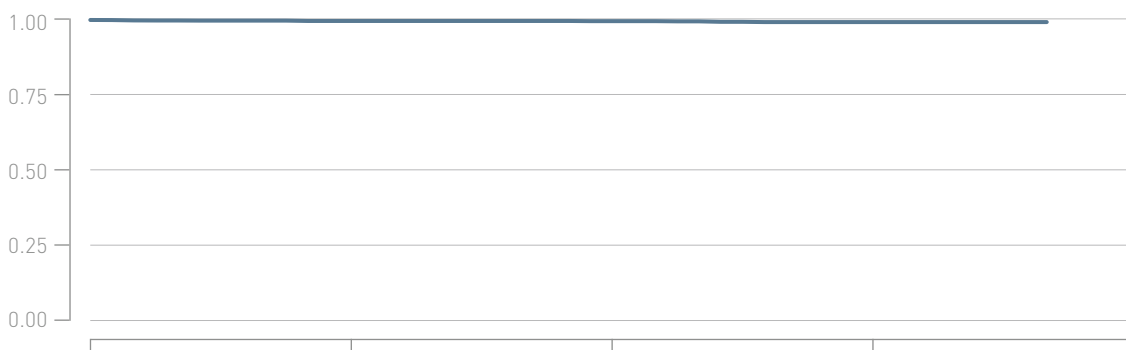
Siello JT/Solia JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	158 000
Registered U.S. Implants	2 722
Estimated Active U.S. Implants	2 480
U.S. Total Returned	11

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	15	0.55%	U.S. Confirmed Malfunctions	0	0.00%
Conductor fracture	1	0.04%	U.S. Acute Lead Observations	19	0.70%
Failure to capture	3	0.11%	Failure to capture	1	0.04%
Failure to sense	1	0.04%	Lead dislodgement	18	0.66%
Insulation breach	1	0.04%			
Lead dislodgement	6	0.22%			
Oversensing	2	0.07%			
Other	1	0.04%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	99.6	99.5	99.1
CI [±%]	-	0.3	0.3	0.5
Sample Size	2 722	1 802	1 200	632



6.1 Pacing Leads – Postmarket Data

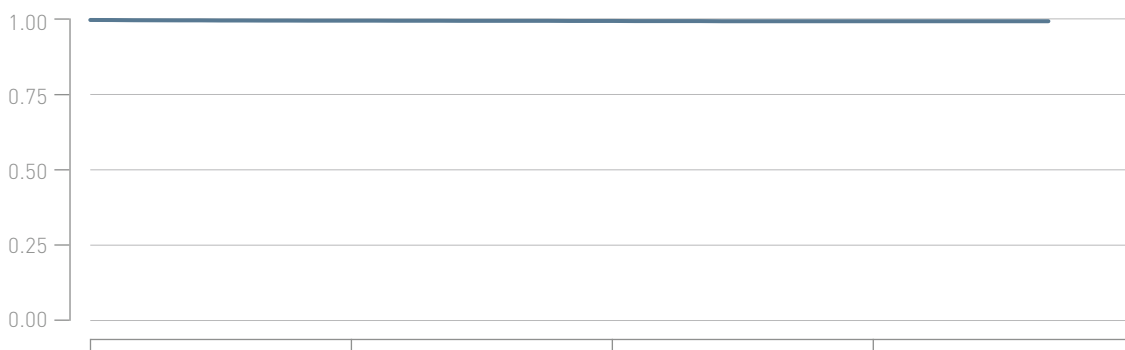
Siello T/Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	221 000
Registered U.S. Implants	3 289
Estimated Active U.S. Implants	2 960
U.S. Total Returned	11

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	14	0.43%	U.S. Confirmed Malfunctions	1	0.03%
Abnormal pacing impedance	3	0.09%	Other	1	0.03%
Conductor fracture	1	0.03%	U.S. Acute Lead Observations	11	0.33%
Failure to capture	5	0.15%	Failure to capture	3	0.09%
Lead dislodgement	4	0.12%	Lead dislodgement	8	0.24%
Oversensing	1	0.03%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	99.6	99.5	99.3
CI [±%]	-	0.2	0.3	0.3
Sample Size	3 289	2 346	1 529	757



6.1 Pacing Leads – Postmarket Data

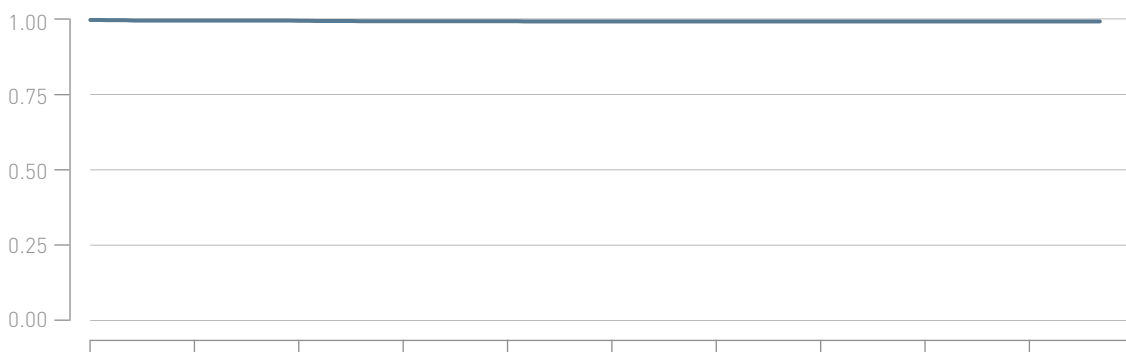
Tilda JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2012
CE Market Release	Sep 2011
Worldwide Distributed Devices	17300
Registered U.S. Implants	1020
Estimated Active U.S. Implants	890
U.S. Total Returned	0

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	7	0.69%	U.S. Confirmed Malfunctions	0	0.00%
Abnormal pacing impedance	2	0.20%	U.S. Acute Lead Observations	1	0.10%
Failure to capture	2	0.20%	Lead dislodgement	1	0.10%
Lead dislodgement	3	0.29%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.6	99.4	99.4	99.3	99.3	99.3	99.3	99.3
CI [±%]	-	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sample Size	1020	990	971	943	894	831	764	609	463	323



6.1 Pacing Leads – Postmarket Data

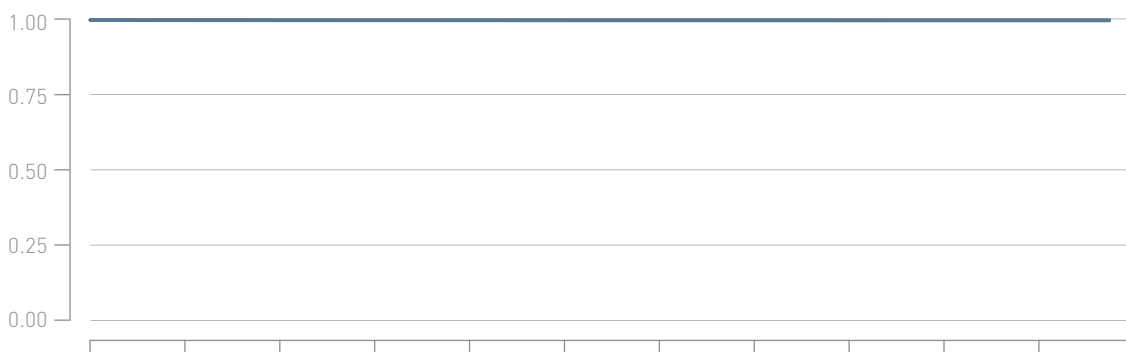
Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41300
Registered U.S. Implants	12725
Estimated Active U.S. Implants	11200
U.S. Total Returned	16

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

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7	99.7	99.7
CI [±%]	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sample Size	12725	12232	11925	11728	11316	10697	9532	7741	6419	4493	2324



6.1 Pacing Leads – Postmarket Data

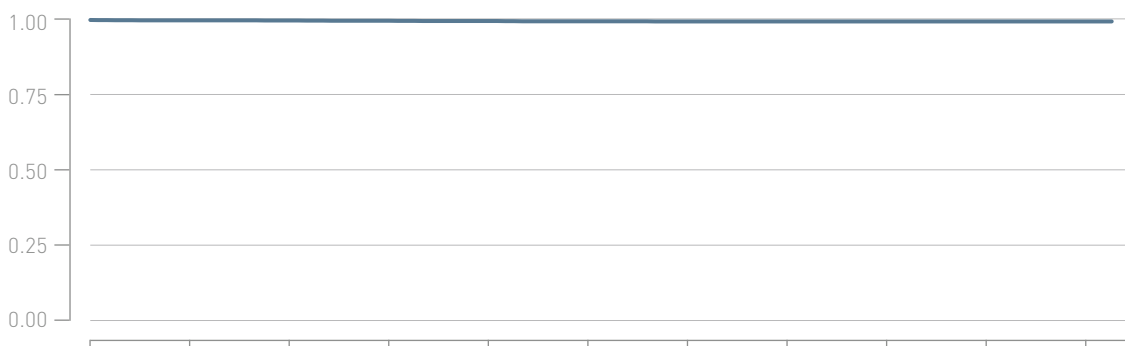
Tilda T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22 400
Registered U.S. Implants	1 658
Estimated Active U.S. Implants	1 390
U.S. Total Returned	2

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	11	0.66%	U.S. Confirmed Malfunctions	0	0.00%
Abnormal pacing impedance	4	0.24%	U.S. Acute Lead Observations	0	0.00%
Conductor fracture	2	0.12%			
Insulation breach	1	0.06%			
Lead dislodgement	4	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	99.8	99.6	99.5	99.3	99.3	99.3	99.3	99.3	99.3
CI [±%]	-	0.2	0.2	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Sample Size	1 658	1 583	1 545	1 501	1 439	1 380	1 264	1 031	886	615	274

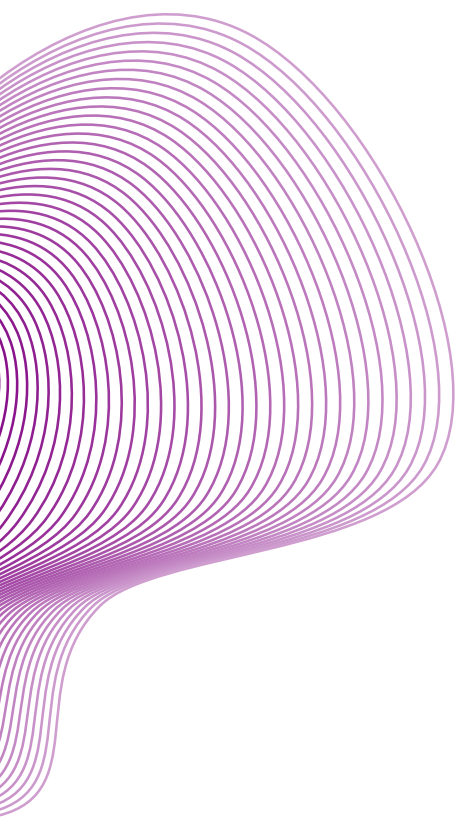
Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



6.2 ICD Leads – Postmarket Data

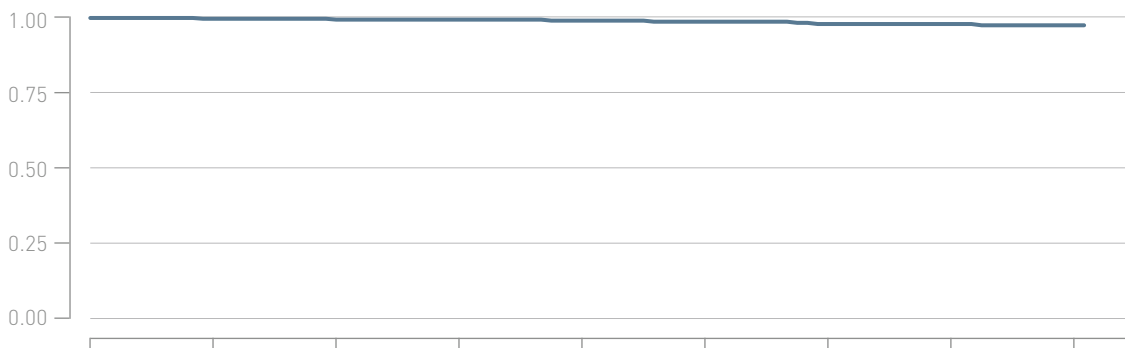
Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
U.S. Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5460
Registered U.S. Implants	406
Estimated Active U.S. Implants	161
U.S. Total Returned	8

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	10	2.46%	U.S. Confirmed Malfunctions	2	0.49%
Conductor fracture	1	0.25%	Conductor Fracture	1	0.25%
Failure to capture	4	0.98%	Insulation Breach	1	0.25%
Insulation breach	1	0.25%	U.S. Acute Lead Observations	0	0.00%
Oversensing	4	0.98%			

• 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	98.6	97.8	97.8	97.3
CI [±%]	-	0.6	0.8	0.8	1.1	1.3	1.8	1.8	2
Sample Size	406	353	318	286	269	243	228	211	201

6.2 ICD Leads – Postmarket Data

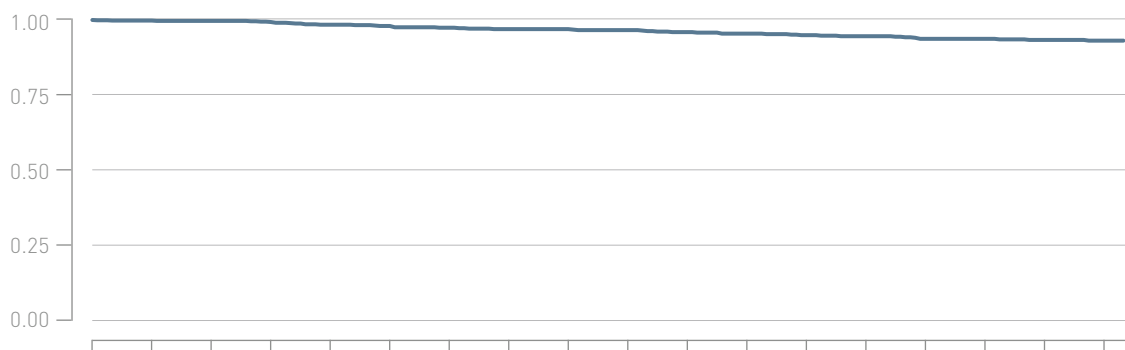
Kentrox SL

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	8440
Registered U.S. Implants	1 003
Estimated Active U.S. Implants	505
U.S. Total Returned	19

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	40	3.96%	U.S. Confirmed Malfunctions	5	0.50%
Abnormal defibrillation impedance	1	0.10%	Insulation Breach	5	0.50%
Abnormal pacing impedance	4	0.40%	U.S. Acute Lead Observations	0	0.00%
Conductor fracture	3	0.30%			
Failure to capture	4	0.40%			
Insulation breach	6	0.59%			
Oversensing	20	1.98%			
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	14	15	16	17
Total [%]	100.0	99.8	99.7	99.3	98.4	97.9	97.3	96.9	96.9	96.5	95.8	95.3	94.8	94.4	93.5	93.5	93.1	92.9
CI [±%]	-	0.3	0.4	0.6	0.9	1	1.2	1.3	1.3	1.4	1.5	1.6	1.7	1.8	1.9	1.9	2	2
Sample Size	1003	898	834	777	707	662	616	595	575	564	552	544	535	526	515	510	491	282

6.2 ICD Leads – Postmarket Data

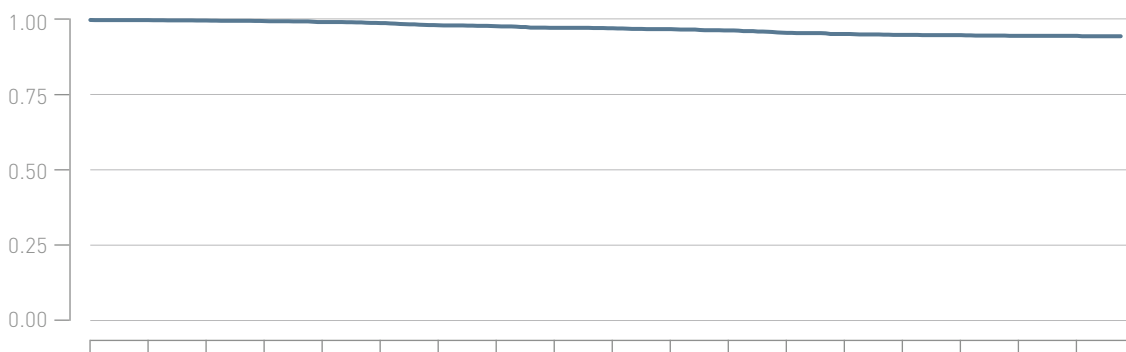
Kentrox SL-S

Product Versions _____	65/16, 18-Steroid
Lead Type _____	dual-coil, active fixation
Polarity _____	bipolar
Steroid _____	yes/no
U.S. Market Release _____	Oct 2004
CE Market Release _____	Jun 2004
Worldwide Distributed Devices _____	8 740
Registered U.S. Implants _____	2 412
Estimated Active U.S. Implants _____	1 170
U.S. Total Returned _____	42

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	68	2.80%	U.S. Confirmed Malfunctions	14	0.58%
Abnormal defibrillation impedance	2	0.08%	Insulation Breach	14	0.58%
Abnormal pacing impedance	5	0.21%	U.S. Acute Lead Observations	2	0.08%
Conductor fracture	6	0.25%	Insulation breach	1	0.04%
Failure to capture	3	0.12%	Oversensing	1	0.04%
Failure to sense	1	0.04%			
Insulation breach	3	0.12%			
Lead dislodgement	2	0.08%			
Oversensing	42	1.73%			
Other	4	0.16%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Total [%]	100.0	100.0	99.8	99.6	99.3	98.9	98.2	97.8	97.3	97.1	96.8	96.4	95.5	95.1	94.8	94.7	94.5	94.5
CI [±%]	-	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.1	1.1	1.1	1.1	1.2	1.2
Sample Size	2 412	2 174	2 049	1 889	1 754	1 630	1 510	1 430	1 363	1 324	1 281	1 258	1 233	1 224	1 200	1 180	1 125	744



6.2 ICD Leads – Postmarket Data

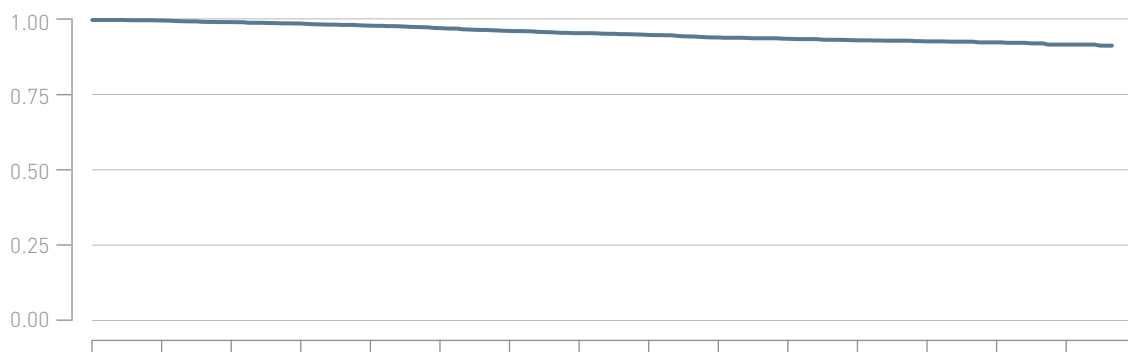
Linux S

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	2 466
Estimated Active U.S. Implants	1 560
U.S. Total Returned	89

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	96	3.85%	U.S. Confirmed Malfunctions	49	1.97%
Abnormal defibrillation impedance	12	0.48%	Conductor Fracture	9	0.36%
Abnormal pacing impedance	6	0.24%	Insulation Breach	40	1.61%
Conductor fracture	10	0.40%	U.S. Acute Lead Observations	2	0.08%
Failure to capture	13	0.52%	Lead dislodgement	1	0.04%
Failure to sense	1	0.04%	Other	1	0.04%
Insulation breach	4	0.16%			
Oversensing	44	1.77%			
Other	6	0.24%			

• 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	99.8	99.3	98.8	98.1	97.2	96.3	95.5	94.9	94.0	93.6	93.1	92.7	92.4	91.6
CI [±%]	-	0.2	0.3	0.5	0.6	0.7	0.8	0.9	1	1.1	1.1	1.1	1.2	1.2	1.4
Sample Size	2466	2260	2128	2016	1923	1847	1784	1741	1691	1643	1619	1566	1110	662	377

6.2 ICD Leads – Postmarket Data

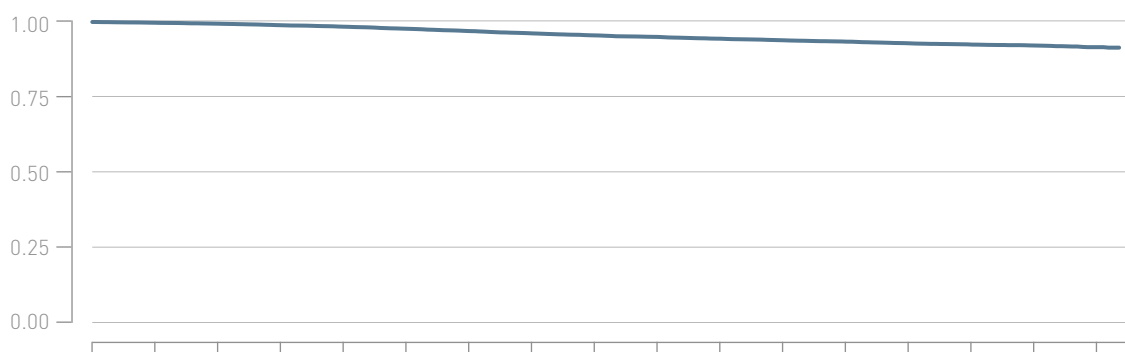
Linux SD

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 _____	22 102
Estimated Active U.S. Implants _____	13 500
U.S. Total Returned _____	542

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	997	4.48%	U.S. Confirmed Malfunctions	226	1.02%
Abnormal defibrillation impedance	97	0.44%	Conductor Fracture	35	0.16%
Abnormal pacing impedance	70	0.31%	Insulation Breach	189	0.85%
Cardiac perforation	3	0.01%	Other	2	0.01%
Conductor fracture	121	0.54%	U.S. Acute Lead Observations	11	0.05%
Failure to capture	80	0.36%	Abnormal pacing impedance	1	0.00%
Failure to sense	18	0.08%	Cardiac perforation	1	0.00%
Insulation breach	64	0.29%	Failure to capture	1	0.00%
Lead dislodgement	33	0.15%	Lead dislodgement	6	0.03%
Oversensing	460	2.07%	Oversensing	1	0.00%
Other	51	0.23%	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	13	14	15	16
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	92.7	92.3	92.0	91.4
CI [±%]	-	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.6
Sample Size	22 102	20 089	18 850	17 794	16 946	16 205	15 598	15 139	14 781	14 499	14 212	13 909	12 479	8 494	5 292	2 649	779

6.2 ICD Leads – Postmarket Data

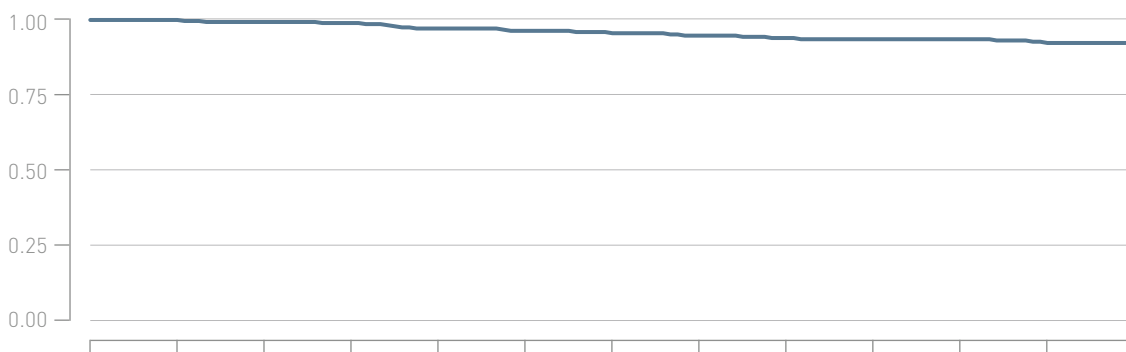
Linux T

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	2 260
Registered U.S. Implants	319
Estimated Active U.S. Implants	209
U.S. Total Returned	4

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	21	6.52%	U.S. Confirmed Malfunctions	3	0.93%
Abnormal pacing impedance	3	0.93%	Conductor Fracture	1	0.31%
Conductor fracture	1	0.31%	Insulation Breach	2	0.62%
Failure to capture	4	1.24%	U.S. Acute Lead Observations	1	0.31%
Insulation breach	1	0.31%	Other	1	0.31%
Oversensing	11	3.42%			
Other	1	0.31%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11
Total [%]	100.0	100.0	99.3	99.0	97.1	96.3	95.5	94.6	93.8	93.4	93.4	92.1
CI [±%]	-	< 0.1	0.9	1.2	2	2.3	2.5	2.7	2.9	3	3	3.3
Sample Size	319	295	283	272	251	241	234	230	228	226	223	216



6.2 ICD Leads – Postmarket Data

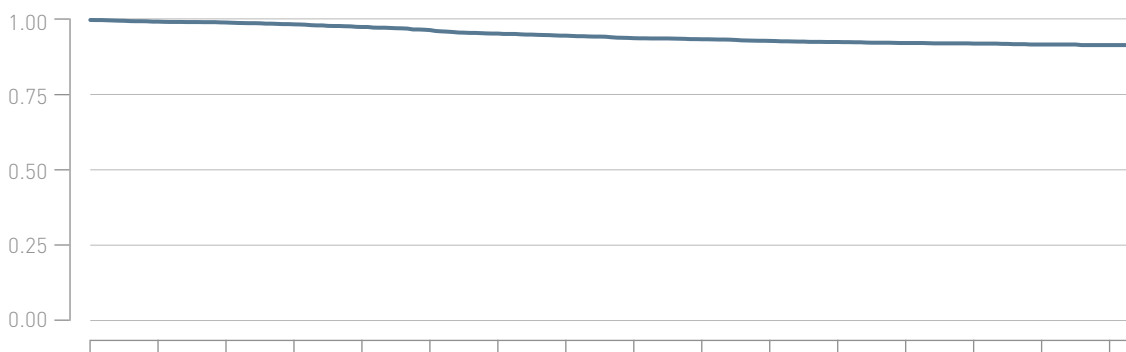
Linux TD

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 _____	3 023
Estimated Active U.S. Implants _____	1 920
U.S. Total Returned _____	82

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications _____	152	4.98%	U.S. Confirmed Malfunctions _____	39	1.28%
Abnormal defibrillation impedance _____	17	0.56%	Conductor Fracture _____	7	0.23%
Abnormal pacing impedance _____	14	0.46%	Insulation Breach _____	32	1.05%
Cardiac perforation _____	1	0.03%	U.S. Acute Lead Observations _____	3	0.10%
Conductor fracture _____	20	0.66%	Failure to capture _____	1	0.03%
Failure to capture _____	24	0.79%	Lead dislodgement _____	2	0.07%
Failure to sense _____	4	0.13%			
Insulation breach _____	13	0.43%			
Lead dislodgement _____	4	0.13%			
Oversensing _____	52	1.70%			
Other _____	3	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	15
Total [%]	100.0	99.4	99.1	98.5	97.6	96.5	95.4	94.6	93.8	93.4	92.9	92.5	92.1	91.9	91.6	91.4
CI [±%]	-	0.3	0.3	0.5	0.6	0.7	0.8	0.9	1	1	1	1.1	1.1	1.1	1.2	1.2
Sample Size	3023	2732	2600	2452	2339	2236	2146	2092	2054	2026	1986	1934	1703	1185	717	303

6.2 ICD Leads – Postmarket Data

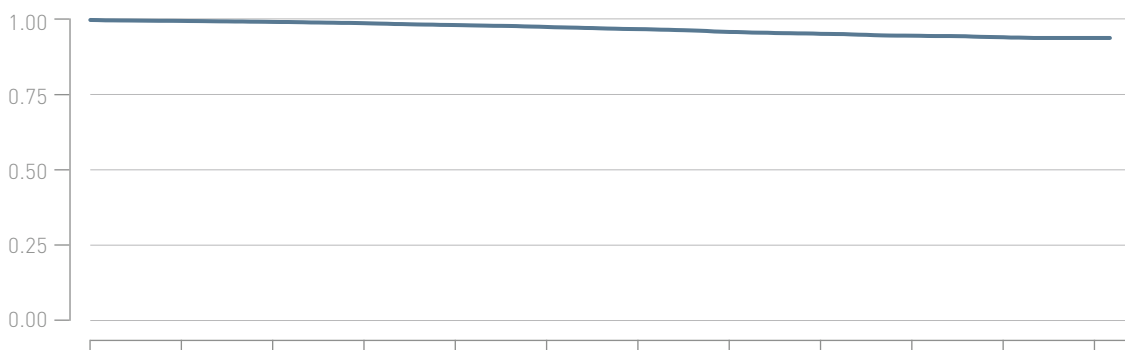
Linux^{smart} S

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	46 700
Registered U.S. Implants	7 601
Estimated Active U.S. Implants	5 720
U.S. Total Returned	208

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	269	3.52%	U.S. Confirmed Malfunctions	82	1.07%
Abnormal defibrillation impedance	19	0.25%	Conductor Fracture	15	0.20%
Abnormal pacing impedance	23	0.30%	Insulation Breach	67	0.88%
Cardiac perforation	1	0.01%	U.S. Acute Lead Observations	10	0.13%
Conductor fracture	39	0.51%	Abnormal pacing impedance	1	0.01%
Failure to capture	24	0.31%	Cardiac perforation	1	0.01%
Failure to sense	13	0.17%	Lead dislodgement	7	0.09%
Insulation breach	5	0.07%	Other	1	0.01%
Lead dislodgement	14	0.18%			
Oversensing	121	1.58%			
Other	10	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	99.3	98.9	98.2	97.6	96.8	95.9	95.2	94.6	94.0	93.8
CI [±%]	-	0.1	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7
Sample Size	7 601	7 126	6 865	6 662	6 489	6 317	6 037	5 561	4 704	3 291	1 850	362

6.2 ICD Leads – Postmarket Data

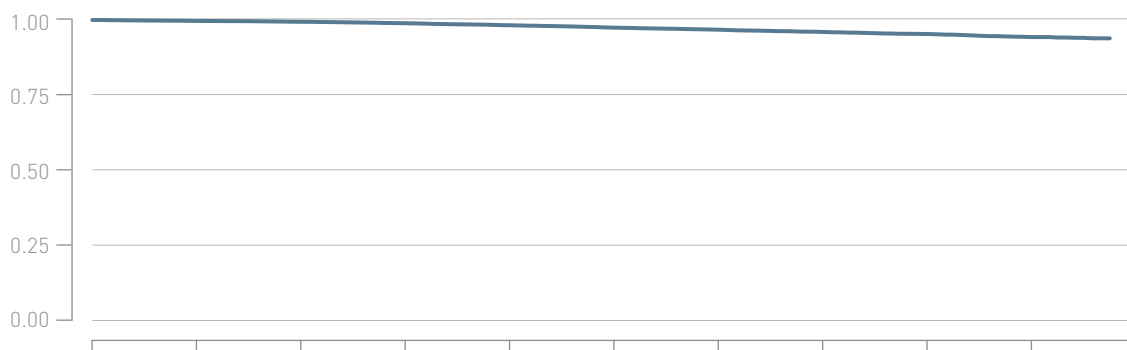
Linux^{smart} S DX

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	36 300
Registered U.S. Implants	16 309
Estimated Active U.S. Implants	13 400
U.S. Total Returned	391

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	523	3.19%	U.S. Confirmed Malfunctions	129	0.79%
Abnormal defibrillation impedance	62	0.38%	Conductor Fracture	14	0.09%
Abnormal pacing impedance	40	0.24%	Insulation Breach	112	0.68%
Conductor fracture	60	0.37%	Other	3	0.02%
Failure to capture	42	0.26%	U.S. Acute Lead Observations	39	0.24%
Failure to sense	19	0.12%	Cardiac perforation	4	0.02%
Insulation breach	8	0.05%	Failure to capture	9	0.05%
Lead dislodgement	48	0.29%	Lead dislodgement	16	0.10%
Oversensing	230	1.40%	Oversensing	3	0.02%
Other	14	0.09%	Other	7	0.04%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9
Total [%]	100.0	99.7	99.4	98.9	98.2	97.4	96.7	95.9	95.2	94.1
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.5
Sample Size	16 309	15 504	15 175	14 859	14 471	13 791	11 299	7 662	4 701	1 902

6.2 ICD Leads – Postmarket Data

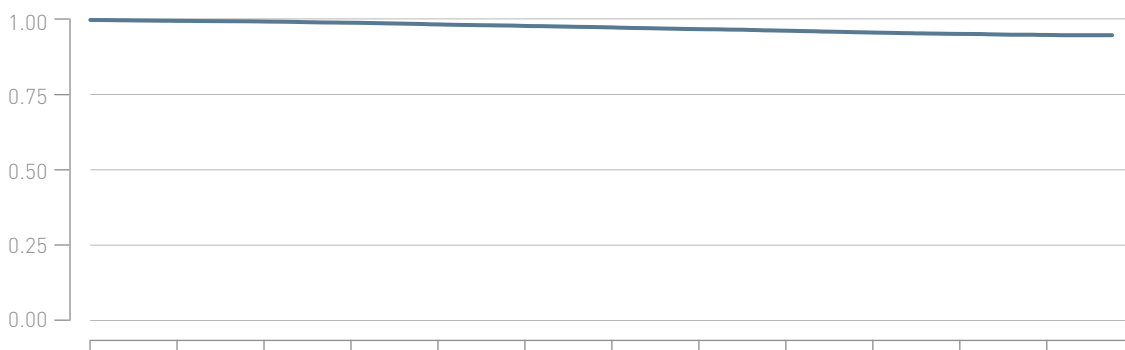
Linux^{smart} SD

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	55 700
Registered U.S. Implants	13 132
Estimated Active U.S. Implants	9 800
U.S. Total Returned	275

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	435	3.29%	U.S. Confirmed Malfunctions	86	0.65%
Abnormal defibrillation impedance	43	0.32%	Conductor Fracture	11	0.08%
Abnormal pacing impedance	29	0.22%	Insulation Breach	72	0.54%
Cardiac perforation	1	0.01%	Other	3	0.02%
Conductor fracture	52	0.39%	U.S. Acute Lead Observations	29	0.22%
Extracardiac stimulation	1	0.01%	Abnormal defibrillation impedance	1	0.01%
Failure to capture	37	0.28%	Cardiac perforation	2	0.02%
Failure to sense	11	0.08%	Failure to capture	4	0.03%
Insulation breach	10	0.08%	Insulation breach	1	0.01%
Lead dislodgement	29	0.22%	Lead dislodgement	12	0.09%
Oversensing	211	1.59%	Oversensing	2	0.02%
Other	11	0.08%	Other	7	0.05%

• 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	99.0	98.5	97.9	97.4	96.8	96.3	95.6	95.2	94.8
CI [±%]	-	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5
Sample Size	13 132	12 157	11 768	11 409	11 095	10 842	10 477	9 990	9 201	7 741	5 547	2 350

6.2 ICD Leads – Postmarket Data

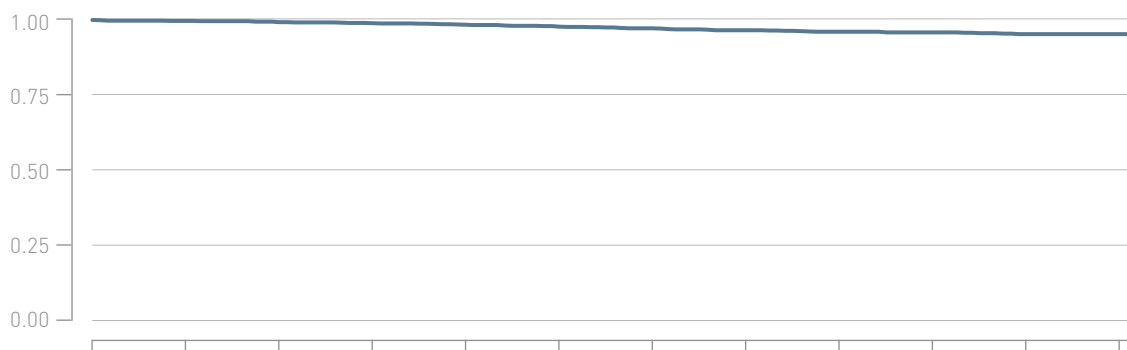
Linux^{smart} TD

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	7 720
Registered U.S. Implants	1 265
Estimated Active U.S. Implants	939
U.S. Total Returned	22

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	49	3.84%	U.S. Confirmed Malfunctions	1	0.08%
Abnormal defibrillation impedance	8	0.63%	Insulation Breach	1	0.08%
Abnormal pacing impedance	5	0.39%	U.S. Acute Lead Observations	3	0.24%
Conductor fracture	3	0.24%	Lead dislodgement	3	0.24%
Failure to capture	12	0.94%			
Insulation breach	2	0.16%			
Lead dislodgement	4	0.31%			
Oversensing	14	1.10%			
Other	1	0.08%			

• 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	99.2	98.9	98.3	97.7	97.1	96.4	95.9	95.7	95.1	95.1
CI [±%]	-	0.3	0.5	0.6	0.7	0.9	1	1.1	1.2	1.2	1.4	1.4
Sample Size	1 265	1 173	1 136	1 093	1 067	1 035	1 008	957	885	750	532	226

6.2 ICD Leads – Postmarket Data

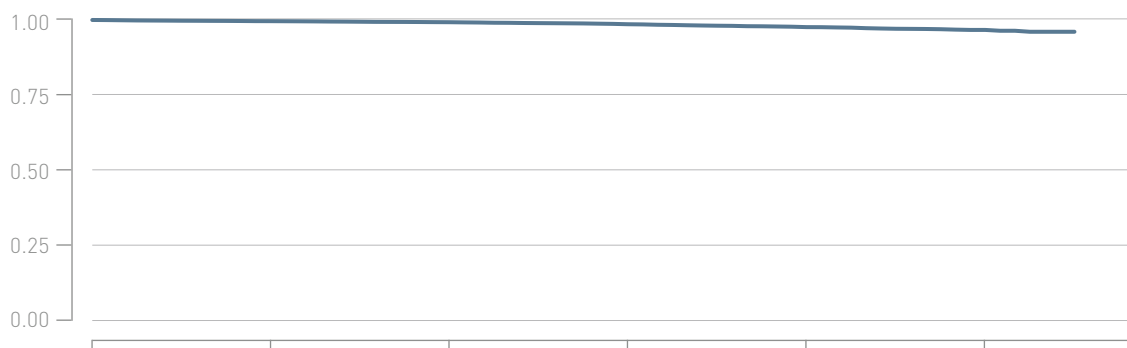
Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	136 000
Registered U.S. Implants	19 839
Estimated Active U.S. Implants	18 000
U.S. Total Returned	202

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	249	1.25%	U.S. Confirmed Malfunctions	52	0.26%
Abnormal defibrillation impedance	20	0.10%	Conductor Fracture	8	0.04%
Abnormal pacing impedance	6	0.03%	Insulation Breach	40	0.20%
Cardiac perforation	1	0.01%	Other	4	0.02%
Conductor fracture	17	0.09%	U.S. Acute Lead Observations	49	0.25%
Failure to capture	31	0.16%	Abnormal pacing impedance	4	0.02%
Failure to sense	11	0.06%	Cardiac perforation	6	0.03%
Insulation breach	2	0.01%	Failure to capture	11	0.06%
Lead dislodgement	32	0.16%	Lead dislodgement	24	0.12%
Oversensing	119	0.60%	Oversensing	2	0.01%
Other	10	0.05%	Other	2	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.6	99.2	98.5	97.5	96.5
CI [±%]	-	0.1	0.1	0.2	0.3	0.5
Sample Size	19 839	15 660	12 014	8 492	4 734	1 497

6.2 ICD Leads – Postmarket Data

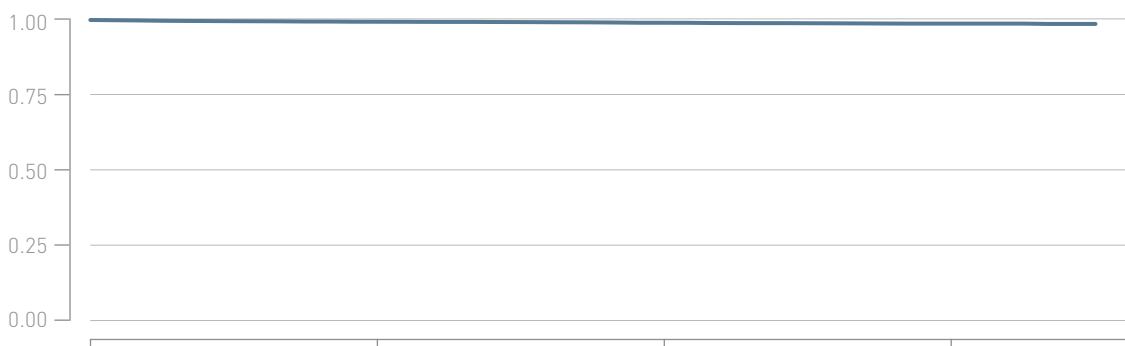
Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	34 100
Registered U.S. Implants	14 455
Estimated Active U.S. Implants	13 600
U.S. Total Returned	111

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	113	0.78%	U.S. Confirmed Malfunctions	14	0.10%
Abnormal defibrillation impedance	7	0.05%	Conductor Fracture	2	0.01%
Abnormal pacing impedance	4	0.03%	Insulation Breach	11	0.08%
Cardiac perforation	2	0.01%	Other	1	0.01%
Conductor fracture	1	0.01%	U.S. Acute Lead Observations	48	0.33%
Failure to capture	17	0.12%	Cardiac perforation	2	0.01%
Failure to sense	6	0.04%	Failure to capture	9	0.06%
Insulation breach	1	0.01%	Failure to sense	6	0.04%
Lead dislodgement	35	0.24%	Lead dislodgement	21	0.15%
Oversensing	35	0.24%	Oversensing	8	0.06%
Other	5	0.03%	Other	2	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3
Total [%]	100.0	99.3	98.9	98.6
CI [±%]	-	0.1	0.2	0.3
Sample Size	14 455	9 612	5 196	1 813

6.2 ICD Leads – Postmarket Data

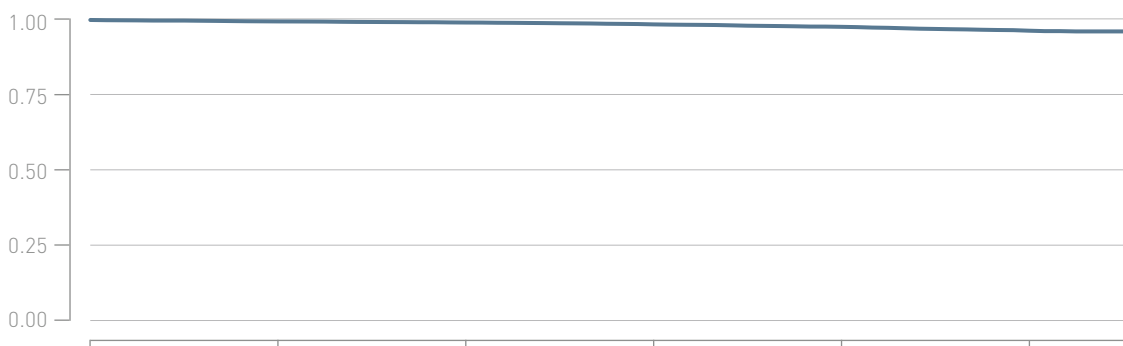
Plexa S DX DF1

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	22 800
Registered U.S. Implants	9 109
Estimated Active U.S. Implants	7 990
U.S. Total Returned	149

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	182	1.99%	U.S. Confirmed Malfunctions	55	0.60%
Abnormal defibrillation impedance	23	0.25%	Conductor Fracture	3	0.03%
Abnormal pacing impedance	8	0.09%	Insulation Breach	51	0.56%
Conductor fracture	10	0.11%	Other	1	0.01%
Failure to capture	15	0.16%	U.S. Acute Lead Observations	21	0.23%
Failure to sense	7	0.08%	Abnormal defibrillation impedance	1	0.01%
Insulation breach	2	0.02%	Cardiac perforation	2	0.02%
Lead dislodgement	20	0.22%	Failure to capture	2	0.02%
Oversensing	94	1.03%	Failure to sense	1	0.01%
Other	3	0.03%	Lead dislodgement	12	0.13%
			Oversensing	1	0.01%
			Other	2	0.02%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.5	99.1	98.4	97.6	96.2
CI [±%]	-	0.1	0.2	0.3	0.3	0.5
Sample Size	9 109	8 643	8 360	7 511	5 189	1 518

6.2 ICD Leads – Postmarket Data

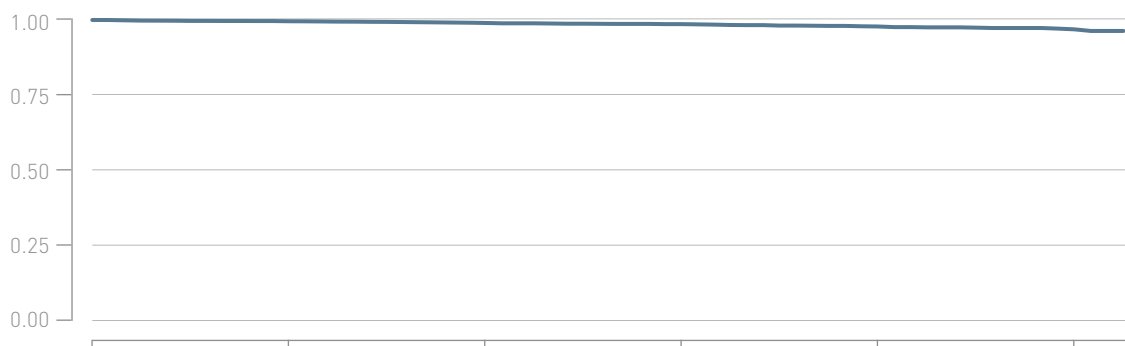
Plexa SD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	15 900
Registered U.S. Implants	5 088
Estimated Active U.S. Implants	4 530
U.S. Total Returned	28

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	76	1.49%	U.S. Confirmed Malfunctions	5	0.10%
Abnormal defibrillation impedance	6	0.12%	Conductor Fracture	2	0.04%
Abnormal pacing impedance	4	0.08%	Insulation Breach	3	0.06%
Conductor fracture	5	0.10%	U.S. Acute Lead Observations	12	0.23%
Extracardiac stimulation	1	0.02%	Abnormal defibrillation impedance	2	0.04%
Failure to capture	7	0.14%	Abnormal pacing impedance	1	0.02%
Failure to sense	4	0.08%	Cardiac perforation	2	0.04%
Insulation breach	2	0.04%	Failure to capture	2	0.04%
Lead dislodgement	8	0.16%	Lead dislodgement	1	0.02%
Oversensing	36	0.70%	Oversensing	2	0.04%
Other	3	0.06%	Other	2	0.04%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	99.5	98.9	98.5	97.7	96.7
CI [±%]	-	0.2	0.3	0.4	0.6	1
Sample Size	5 088	4 140	3 248	2 391	1 387	384



6.2 ICD Leads – Postmarket Data

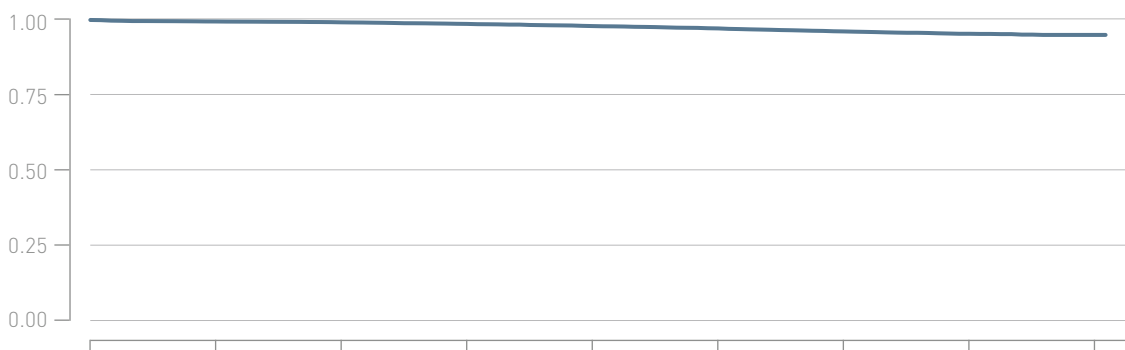
Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	8 285
Estimated Active U.S. Implants	6 610
U.S. Total Returned	142

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	253	3.04%	U.S. Confirmed Malfunctions	63	0.76%
Abnormal defibrillation impedance	16	0.19%	Conductor Fracture	12	0.14%
Abnormal pacing impedance	8	0.10%	Insulation Breach	50	0.60%
Cardiac perforation	1	0.01%	Other	1	0.01%
Conductor fracture	32	0.38%	U.S. Acute Lead Observations	28	0.34%
Extracardiac stimulation	3	0.04%	Cardiac perforation	2	0.02%
Failure to capture	26	0.31%	Extracardiac stimulation	1	0.01%
Failure to sense	5	0.06%	Failure to capture	3	0.04%
Insulation breach	3	0.04%	Lead dislodgement	13	0.16%
Lead dislodgement	24	0.29%	Other	9	0.11%
Oversensing	126	1.51%			
Other	9	0.11%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.5	99.2	98.6	97.9	97.0	96.0	95.2	94.8
CI [±%]	-	0.2	0.2	0.3	0.3	0.4	0.5	0.6	0.7
Sample Size	8 285	7 781	7 578	7 366	7 128	6 561	4 682	1 942	313

6.2 ICD Leads – Postmarket Data

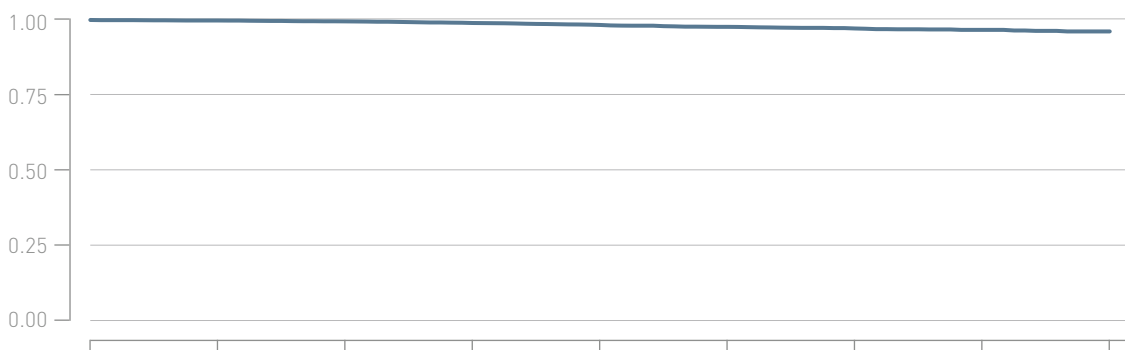
Protego SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18400
Registered U.S. Implants	3411
Estimated Active U.S. Implants	2810
U.S. Total Returned	47

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	88	2.56%	U.S. Confirmed Malfunctions	15	0.44%
Abnormal defibrillation impedance	7	0.20%	Conductor Fracture	1	0.03%
Abnormal pacing impedance	4	0.12%	Insulation Breach	14	0.41%
Conductor fracture	12	0.35%	U.S. Acute Lead Observations	3	0.09%
Failure to capture	9	0.26%	Lead dislodgement	2	0.06%
Failure to sense	2	0.06%	Other	1	0.03%
Insulation breach	2	0.06%			
Lead dislodgement	6	0.17%			
Oversensing	45	1.31%			
Other	1	0.03%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8
Total [%]	100.0	99.8	99.5	98.9	98.2	97.6	97.0	96.5	96.0
CI [±%]	-	0.1	0.2	0.4	0.5	0.5	0.6	0.7	0.9
Sample Size	3411	3232	3148	3073	2994	2832	2175	1120	217

6.2 ICD Leads – Postmarket Data

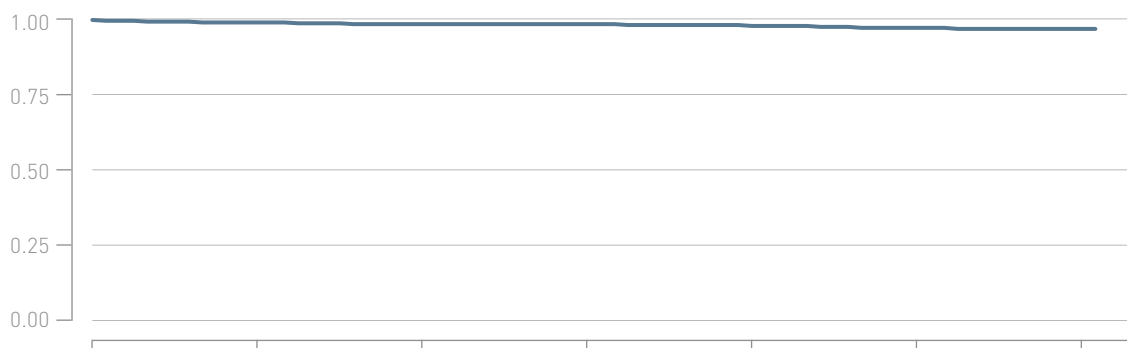
Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered U.S. Implants	349
Estimated Active U.S. Implants	291
U.S. Total Returned	4

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	10	2.85%	U.S. Confirmed Malfunctions	0	0.00%
Conductor fracture	4	1.14%	U.S. Acute Lead Observations	0	0.00%
Failure to capture	2	0.57%			
Failure to sense	1	0.28%			
Insulation breach	1	0.28%			
Oversensing	1	0.28%			
Other	1	0.28%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6
Total [%]	100.0	99.1	98.5	98.5	97.9	97.2	96.8
CI [±%]	-	1	1.3	1.3	1.6	1.8	2
Sample Size	349	331	322	312	302	265	219



6.2 ICD Leads – Postmarket Data

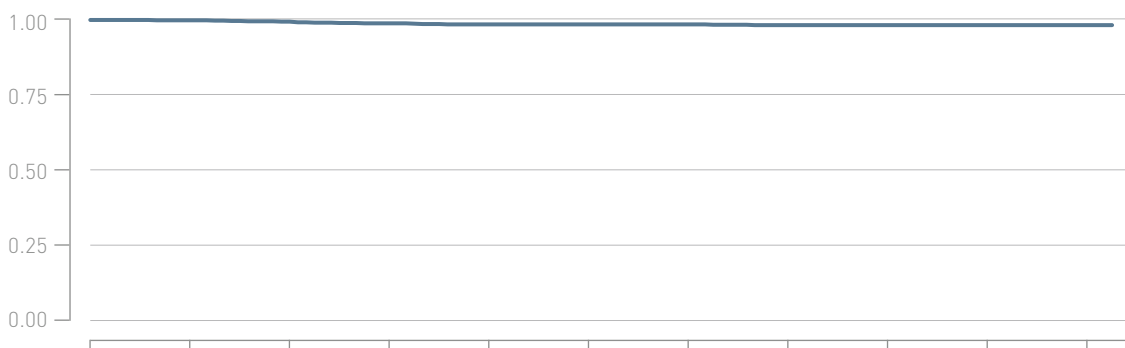
Vigila 2CR

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	2 730
Registered U.S. Implants	855
Estimated Active U.S. Implants	682
U.S. Total Returned	12

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	11	1.28%	U.S. Confirmed Malfunctions	4	0.47%
Abnormal pacing impedance	1	0.12%	Insulation Breach	4	0.47%
Conductor fracture	1	0.12%	U.S. Acute Lead Observations	0	0.00%
Lead dislodgement	3	0.35%			
Oversensing	6	0.70%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10
Total [%]	100.0	99.9	99.4	98.7	98.3	98.3	98.3	98.1	98.1	98.1	98.1
CI [±%]	-	0.2	0.5	0.8	0.9	0.9	0.9	1	1	1	1
Sample Size	855	803	780	751	728	716	704	690	686	609	303

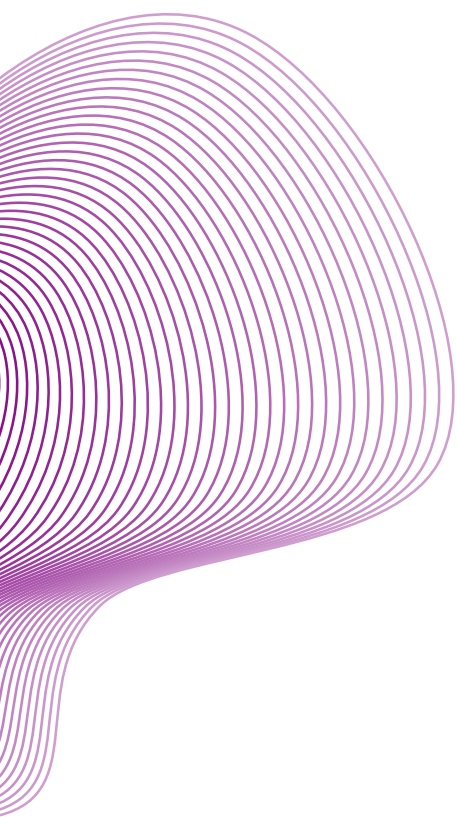
Performance of **BIOTRONIK Leads**

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



6.3 CRT Leads – Postmarket Data

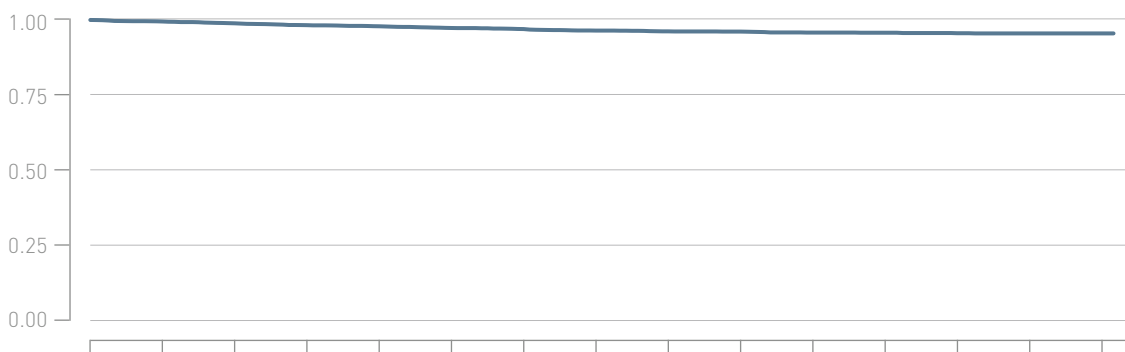
Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered U.S. Implants	4 116
Estimated Active U.S. Implants	2 510
U.S. Total Returned	80

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	125	3.02%	U.S. Confirmed Malfunctions	16	0.39%
Abnormal pacing impedance	8	0.19%	Conductor Fracture	15	0.36%
Conductor fracture	3	0.07%	Insulation Breach	1	0.02%
Extracardiac stimulation	9	0.22%	U.S. Acute Lead Observations	9	0.22%
Failure to capture	46	1.11%	Lead dislodgement	7	0.17%
Insulation breach	3	0.07%	Other	2	0.05%
Lead dislodgement	38	0.92%			
Oversensing	6	0.15%			
Other	12	0.29%			

• 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	99.5	98.8	98.2	97.8	97.2	96.8	96.3	96.0	95.9	95.6	95.5	95.4	95.3	95.3
CI [±%]	-	0.2	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8
Sample Size	4 116	3 553	3 309	3 115	2 993	2 885	2 758	2 610	2 475	2 312	2 051	1 803	1 485	840	300



6.3 CRT Leads – Postmarket Data

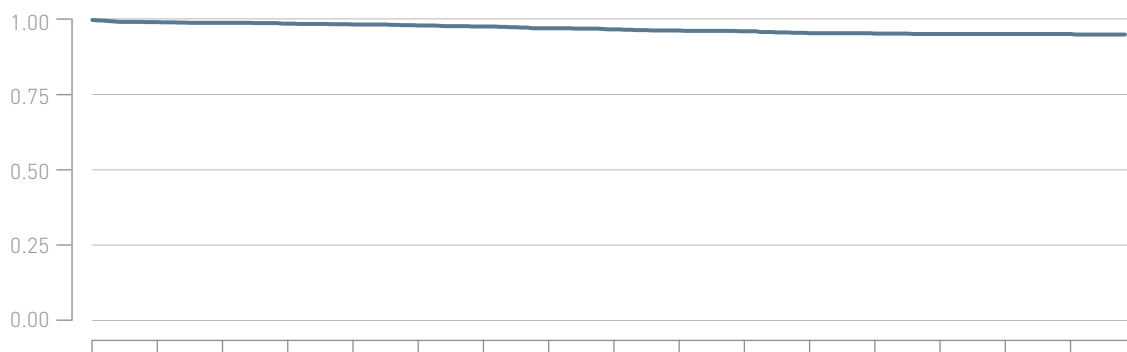
Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
U.S. Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered U.S. Implants	1 423
Estimated Active U.S. Implants	669
U.S. Total Returned	26

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	44	3.09%	U.S. Confirmed Malfunctions	2	0.14%
Abnormal pacing impedance	1	0.07%	Insulation Breach	2	0.14%
Conductor fracture	2	0.14%	U.S. Acute Lead Observations	4	0.28%
Extracardiac stimulation	7	0.49%	Failure to capture	3	0.21%
Failure to capture	15	1.05%	Lead dislodgement	1	0.07%
Insulation breach	2	0.14%			
Lead dislodgement	10	0.70%			
Oversensing	2	0.14%			
Other	5	0.35%			

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Total [%]	100.0	99.3	99.0	98.7	98.4	98.1	97.7	97.1	96.7	96.3	96.1	95.4	95.3	95.1	95.1	95.1
CI [±%]	-	0.5	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.4	1.4	1.4	1.4
Sample Size	1423	1237	1121	1016	932	865	810	776	750	733	712	704	692	682	666	506

6.3 CRT Leads – Postmarket Data

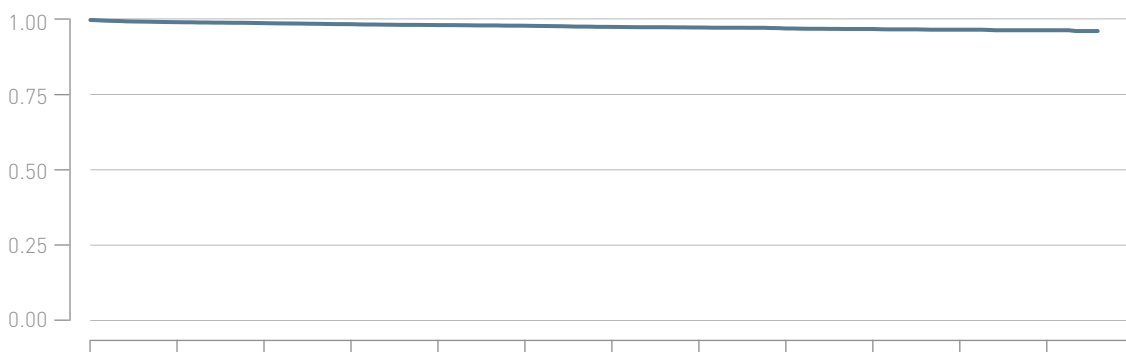
Corox OTW-L

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Registered U.S. Implants	6 254
Estimated Active U.S. Implants	4 630
U.S. Total Returned	89

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	161	2.56%	U.S. Confirmed Malfunctions	7	0.11%
Abnormal pacing impedance	4	0.06%	Conductor Fracture	4	0.06%
Conductor fracture	6	0.10%	Insulation Breach	1	0.02%
Extracardiac stimulation	26	0.41%	Other	2	0.03%
Failure to capture	68	1.08%	U.S. Acute Lead Observations	21	0.33%
Failure to sense	2	0.03%	Extracardiac stimulation	6	0.10%
Insulation breach	2	0.03%	Failure to capture	2	0.03%
Lead dislodgement	41	0.65%	Lead dislodgement	10	0.16%
Oversensing	4	0.06%	Other	3	0.05%
Other	8	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	99.2	98.9	98.5	98.2	98.0	97.6	97.3	97.0	96.8	96.6	96.4
CI [±%]	-	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6
Sample Size	6 254	5 682	5 433	5 239	5 109	4 983	4 557	3 866	3 054	2 236	1 304	551

6.3 CRT Leads – Postmarket Data

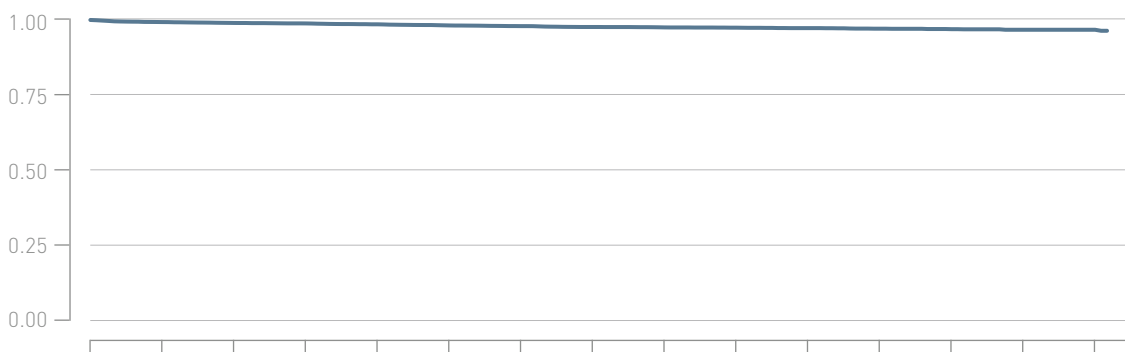
Corox OTW-S

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
Registered U.S. Implants	8 160
Estimated Active U.S. Implants	5 330
U.S. Total Returned	136

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	183	2.23%	U.S. Confirmed Malfunctions	13	0.16%
Abnormal pacing impedance	11	0.13%	Conductor Fracture	8	0.10%
Conductor fracture	8	0.10%	Insulation Breach	4	0.05%
Extracardiac stimulation	15	0.18%	Other	1	0.01%
Failure to capture	56	0.68%	U.S. Acute Lead Observations	33	0.40%
Failure to sense	1	0.01%	Cardiac perforation	1	0.01%
Insulation breach	4	0.05%	Extracardiac stimulation	5	0.06%
Lead dislodgement	61	0.74%	Failure to capture	6	0.07%
Oversensing	6	0.07%	Lead dislodgement	20	0.24%
Other	21	0.26%	Other	1	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Total [%]	100.0	99.3	98.9	98.8	98.5	98.1	97.8	97.5	97.4	97.3	97.1	96.9	96.7	96.5	96.5
CI [±%]	-	0.2	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5
Sample Size	8 160	7 145	6 740	6 402	6 181	5 969	5 589	5 063	4 493	3 881	3 269	2 686	2 001	976	307

6.3 CRT Leads – Postmarket Data

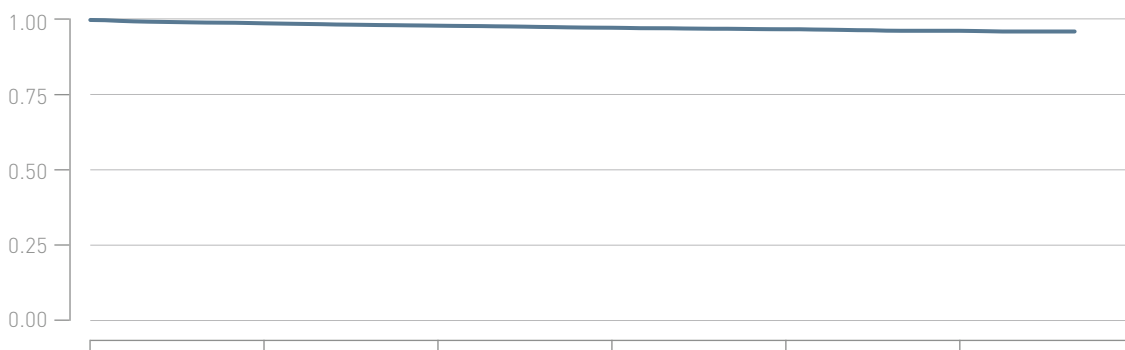
Sentus OTW QP L

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	126 000
Registered U.S. Implants	19 346
Estimated Active U.S. Implants	16 400
U.S. Total Returned	226

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	378	1.94%	U.S. Confirmed Malfunctions	50	0.26%
Abnormal pacing impedance	46	0.24%	Conductor Fracture	48	0.25%
Conductor fracture	12	0.06%	Other	2	0.01%
Extracardiac stimulation	16	0.08%	U.S. Acute Lead Observations	57	0.29%
Failure to capture	100	0.51%	Abnormal pacing impedance	2	0.01%
Failure to sense	2	0.01%	Conductor fracture	1	0.01%
Lead dislodgement	136	0.70%	Extracardiac stimulation	7	0.04%
Oversensing	45	0.23%	Failure to capture	11	0.06%
Other	21	0.11%	Lead dislodgement	31	0.16%
			Oversensing	3	0.02%
			Other	2	0.01%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	98.8	98.0	97.3	96.7	96.2
CI [±%]	-	0.2	0.2	0.3	0.3	0.4
Sample Size	19 346	14 466	10 947	7 656	4 443	1 516

6.3 CRT Leads – Postmarket Data

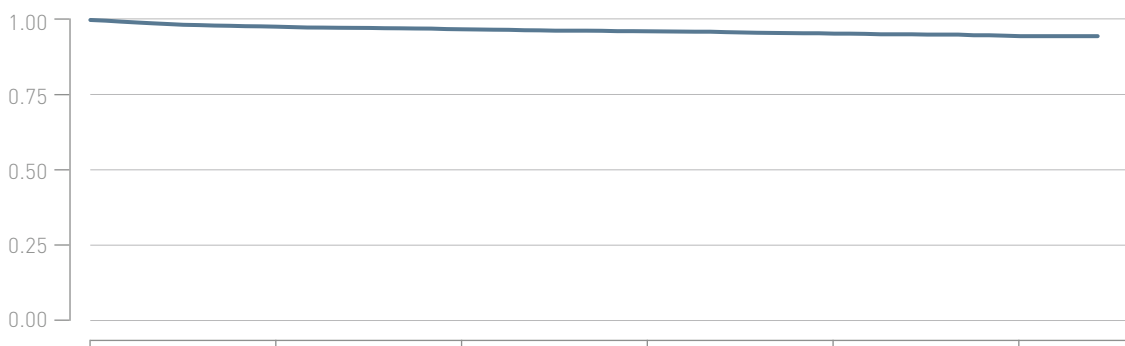
Sentus OTW QP S

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	24 800
Registered U.S. Implants	4 867
Estimated Active U.S. Implants	3 560
U.S. Total Returned	131

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	149	3.01%	U.S. Confirmed Malfunctions	12	0.24%
Abnormal pacing impedance	10	0.20%	Conductor Fracture	12	0.24%
Conductor fracture	5	0.10%	U.S. Acute Lead Observations	91	1.84%
Extracardiac stimulation	7	0.14%	Abnormal pacing impedance	1	0.02%
Failure to capture	35	0.71%	Extracardiac stimulation	4	0.08%
Insulation breach	1	0.02%	Failure to capture	12	0.24%
Lead dislodgement	75	1.52%	Failure to sense	1	0.02%
Oversensing	13	0.26%	Lead dislodgement	67	1.36%
Other	3	0.06%	Oversensing	4	0.08%
			Other	2	0.04%

• Total survival

Cumulative survival probability



Years after implant	0	1	2	3	4	5
Total [%]	100.0	97.7	96.8	96.1	95.3	94.4
CI [±%]	-	0.5	0.6	0.7	0.8	1
Sample Size	4 867	3 443	2 786	2 161	1 440	585



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. The GALAXY Registry was completed in December 2016, while CELESTIAL completed in November 2018. The lead-related complication free survival probabilities provided for Corox LV and Linx ICD leads within chapter 8 utilize all data collected through registry closure. To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria.

Every effort is made to ensure participants are representative of the



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

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

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

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

Patient Enrollment Criteria

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

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

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

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

7.2.2 SIELLO Clinical Study

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

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

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

Every effort is made to ensure participants are representative of the range of clinical environments in which BIOTRONIK's cardiac rhythm

products are used. Patients will be seen for routine follow-up visits until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, with required follow-ups at 3 and 6 months post-implant and every 6 months thereafter.

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

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

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

Patient Enrollment Criteria

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

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

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

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

7.2.3 QP ExCELS

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

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

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

status assessments are completed, a study follow-up schedule consistent with typical care practices has been established, which required follow-ups at discharge/wound check, 3 and 6 months post-implant, and every 6 months thereafter.

Patient Enrollment Criteria

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

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

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

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

7.3 Lead Complications

The data presented characterizes chronic lead performance by estimating lead-related complication free survival probabilities. Following industry practice, for analysis purposes, the complication criteria, which align with

the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", are defined below.

7.3.1 GALAXY and CELESTIAL

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

Event Classifications

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

Clinical Actions

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

7.3.2 SIELLO

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

Event Classifications

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

7.3.3 QP ExCELS

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

Event Classifications

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

7.4 Lead Product Performance Graphs and Data

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

Returned Product Analysis Results

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



Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads

8.2 Performance of ICD Leads

8.3 Performance of CRT Leads



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 – Study Data

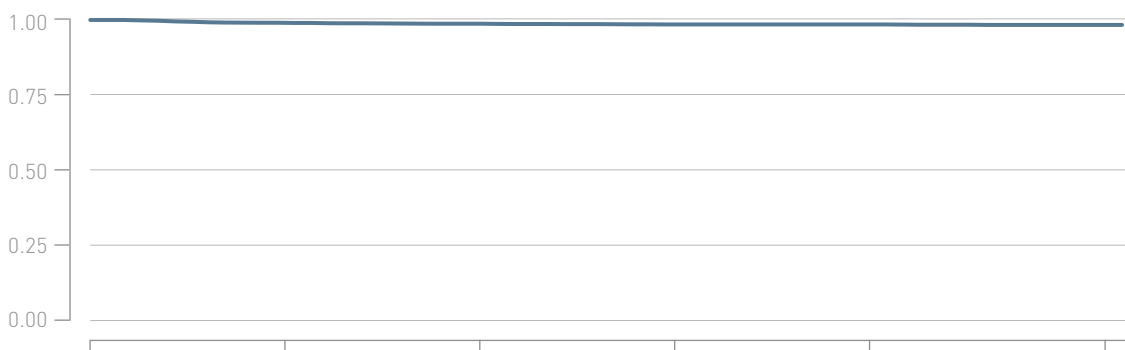
Siello S / Solia S

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

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	54	1.66%	U.S. Confirmed Malfunctions	3	0.09%
Abnormal pacing impedance	4	0.12%	Conductor Fracture	1	0.03%
Cardiac perforation	3	0.09%	Insulation Breach	1	0.03%
Conductor fracture	2	0.06%	Other	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	0.18%
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	98.2	98.1
CI [±%]	-	0.4	0.4	0.5	0.5	0.5
Sample Size	3 245	2 793	2 479	2 200	1 769	293



Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads

8.2 Performance of ICD Leads

8.3 Performance of CRT Leads

8.2 Performance of ICD Leads – Study Data

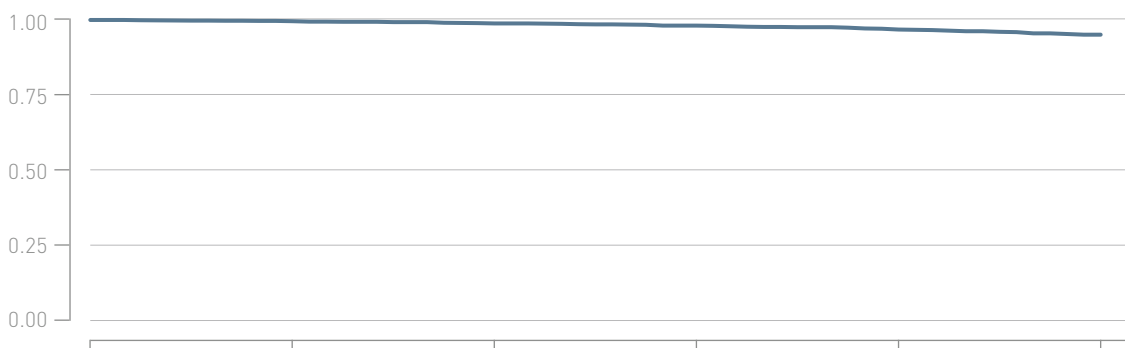
Linux SD

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	2 272

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	68	2.99%	U.S. Confirmed Malfunctions	24	1.06%
Abnormal defibrillation impedance	4	0.18%	Conductor Fracture	3	0.13%
Abnormal pacing impedance	10	0.44%	Insulation Breach	21	0.92%
Cardiac perforation	1	0.04%	U.S. Acute Lead Observations	8	0.35%
Conductor fracture	10	0.44%	Cardiac perforation	4	0.18%
Failure to capture	7	0.31%	Conductor fracture	1	0.04%
Failure to sense	3	0.13%	Failure to capture	1	0.04%
Insulation breach	13	0.57%	Lead dislodgement	1	0.04%
Lead dislodgement	3	0.13%	Other	1	0.04%
Oversensing	17	0.75%			

• 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
Sample Size	2 272	1 937	1 618	1 302	1 014	392

8.2 Performance of ICD Leads – Study Data

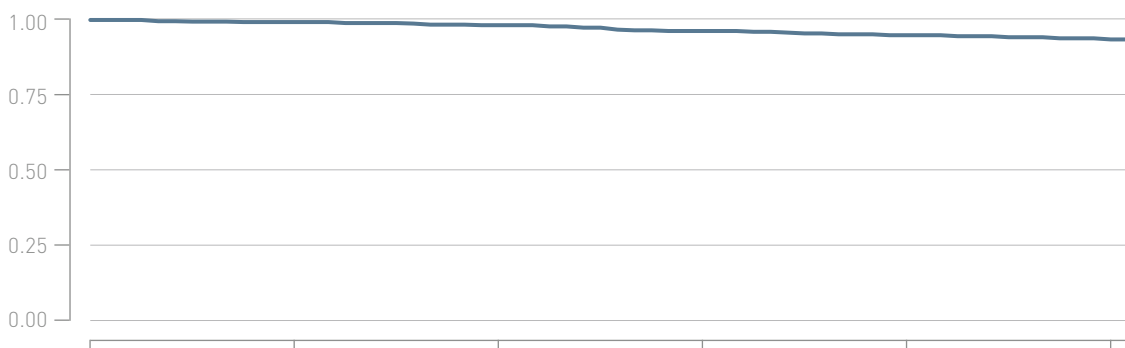
Linux^{smart} SD

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	736

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	29	3.94%	U.S. Confirmed Malfunctions	8	1.09%
Abnormal defibrillation impedance	2	0.27%	Insulation Breach	8	1.09%
Abnormal pacing impedance	2	0.27%	U.S. Acute Lead Observations	2	0.27%
Conductor fracture	3	0.41%	Lead dislodgement	2	0.27%
Failure to capture	3	0.41%			
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	99.3	98.2	96.2	94.8	93.3
CI [±%]	-	0.7	1.1	1.7	2.1	2.5
Sample Size	736	607	493	373	287	118



Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Performance of Pacing Leads

8.2 Performance of ICD Leads

8.3 Performance of CRT Leads

8.3 CRT Leads Performance – Study Data

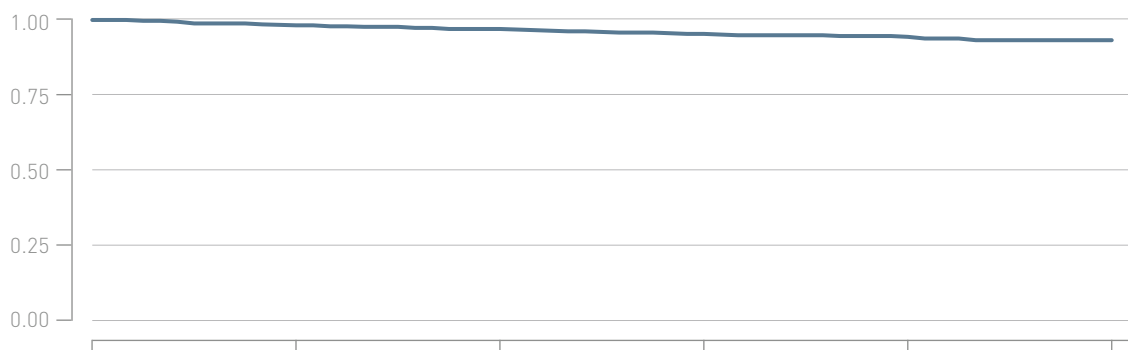
Corox OTW

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28700
Leads registered in study	696

	Quantity	Rate		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
Sample Size	696	589	489	407	329	135

8.3 CRT Leads Performance – Study Data

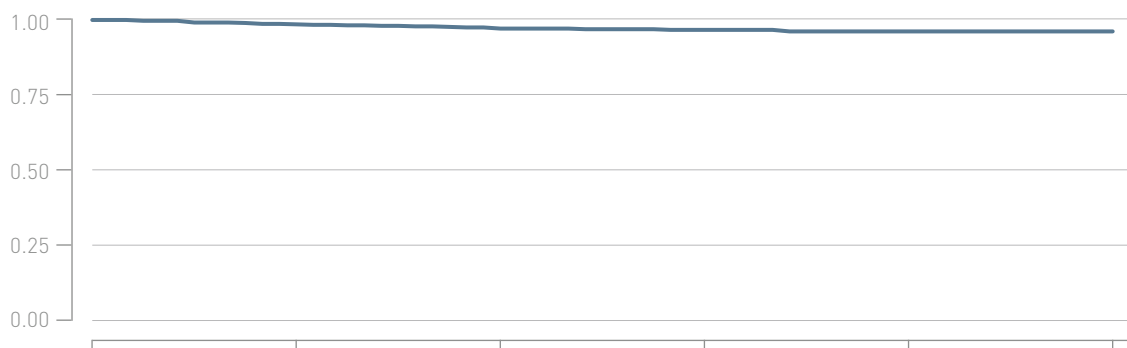
Corox OTW-L

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
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%	U.S. Acute Lead Observations	4	0.57%
Failure to capture	8	1.14%	Extracardiac stimulation	3	0.43%
Lead dislodgement	10	1.43%	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
Sample Size	699	584	475	382	303	130

8.3 CRT Leads Performance – Study Data

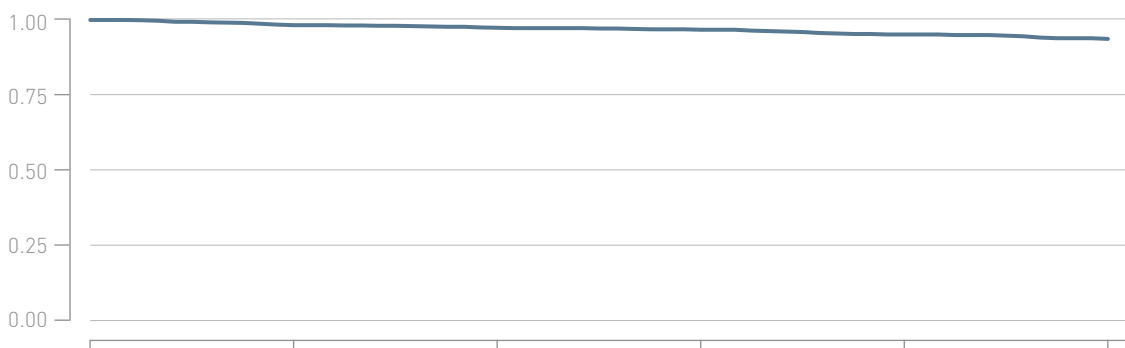
Corox OTW-S

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

	Quantity	Rate		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%	U.S. Acute Lead Observations	5	0.44%
Failure to capture	9	0.79%	Extracardiac stimulation	1	0.09%
Lead dislodgement	18	1.58%	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
Sample Size	1 141	963	813	648	505	192



8.3 CRT Leads Performance – Study Data

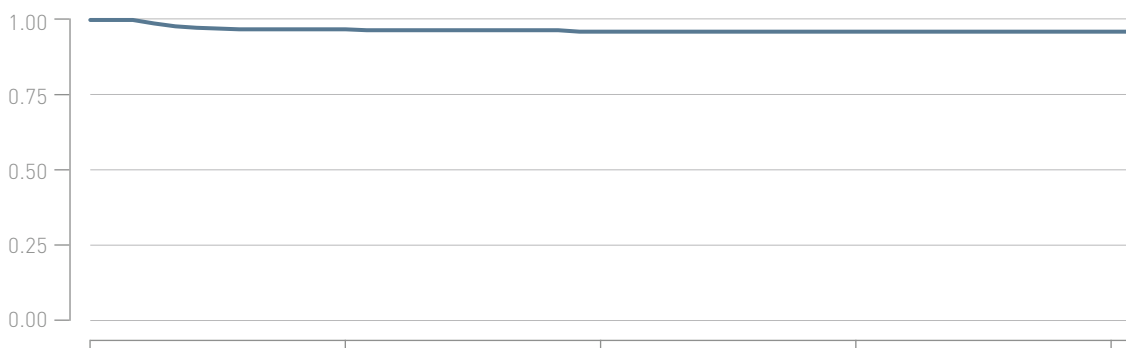
Sentus OTW QP S

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

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	15	3.44%	U.S. Confirmed Malfunctions	5	1.15%
Conductor fracture	1	0.23%	Conductor Fracture	5	1.15%
Extracardiac Stimulation	1	0.23%	U.S. Acute Lead Observations	10	2.29%
Failure to Capture	3	0.69%	Cardiac perforation	1	0.23%
Lead dislodgement	10	2.29%	Failure to Capture	1	0.23%
			Lead dislodgement	8	1.83%

• Total survival

Cumulative survival probability



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

8.3 CRT Leads Performance – Study Data

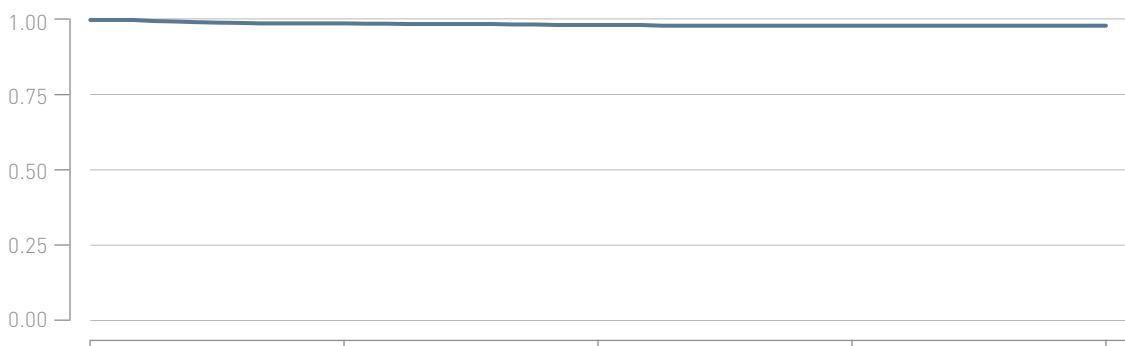
Sentus OTW QP L

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

	Quantity	Rate		Quantity	Rate
U.S. Qualifying Complications	21	1.61%	U.S. Confirmed Malfunctions	11	0.84%
Abnormal pacing impedance	3	0.23%	Conductor Fracture	10	0.76%
Conductor fracture	1	0.08%	U.S. Acute Lead Observations	7	0.54%
Extracardiac Stimulation	2	0.15%	Extracardiac Stimulation	1	0.08%
Failure to Capture	4	0.31%	Failure to Capture	4	0.31%
Lead dislodgement	11	0.84%	Lead dislodgement	2	0.15%

• Total survival

Cumulative survival probability



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



Methodology for Lead Survival Estimates based on Insurance Claims Data

9.1 Introduction

9.2 Claims Data Methodologies
and Data Sets

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

9.1 Introduction

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

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

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

9.2 Claims Data Methodologies and Data Sets

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

As part of the Device Pilot Project EP PASSION, the real-world methodology developed in collaboration with the stakeholders was validated in a proof of concept analysis. Results demonstrated high agreement of 99.7% between the real-world data outcomes and results from a prospective study¹. Based on the proof of concept results, BIOTRONIK received FDA approval to utilize this methodology to fulfil post-approval reporting requirements for both low and high voltage leads.

For PPR analysis, the complication criteria are aligned with the AdvaMed "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse

Generators and Leads". Specifically, the codes identify lead-related complications that would result in a cardiac lead being removed or replaced, or result in a new lead being implanted as a result of the lead-related complication. Identified complications are limited to events with an onset date of more than 30 days after implant. Acute complications, those with an onset date of 30 days or less after implant, are excluded from analysis.

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

Lead Tracking and Reporting

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

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

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

¹ Hicks J, Keith M, Moll P, Simeles J, Offer E, Diani C, Rock A, and Mitchell K. Novel Method to Identify Lead Complications in Pacemaker Systems from Real-World Data: Proof of Concept for the Siello S Pacing Lead. Heart Rhythm. 2019; 16(5), Supplement, S-P003-089.



Performance of BIOTRONIK Leads Based on Insurance Claims Data

- 10.1 Pacing Leads Performance – Insurance Claims Data
- 10.2 ICD Leads Performance – Insurance Claims Data
- 10.3 CRT Leads Performance – Insurance Claims Data



Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads Performance – Insurance Claims Data

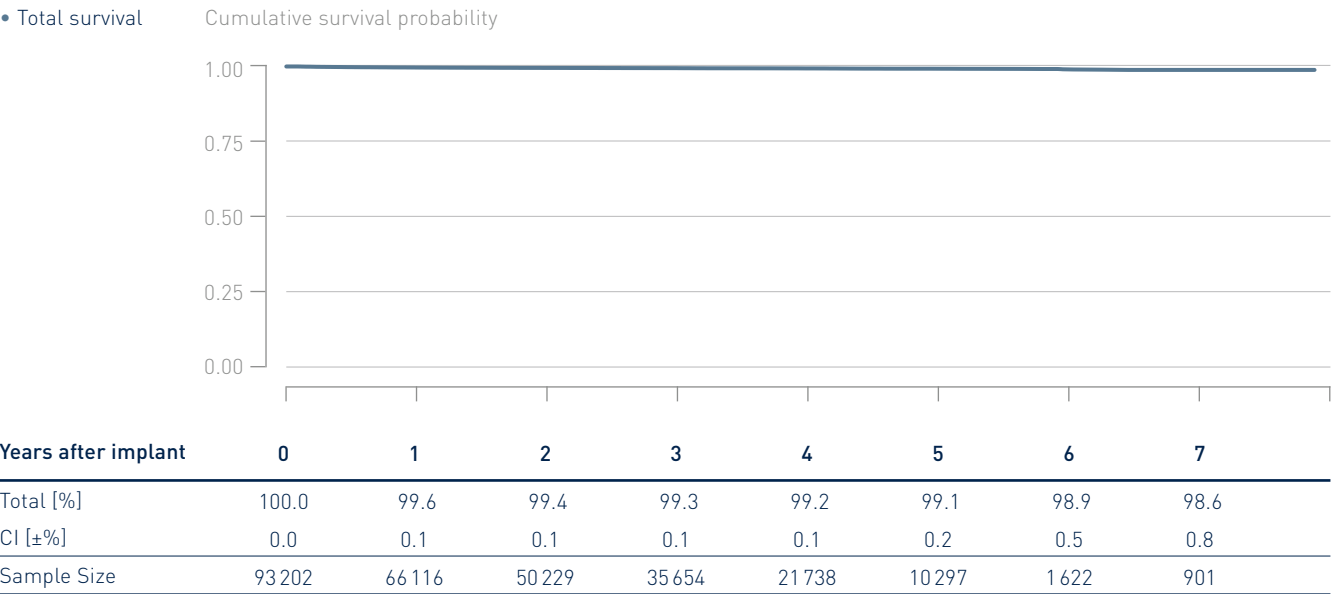
10.2 ICD Leads Performance – Insurance Claims Data

10.3 CRT Leads Performance – Insurance Claims Data

10.1 Pacing Leads Performance – Insurance Claims Data

Siello S / Solia S EP-Passion Data

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 526 000
Registered U.S. Implants	93 202





Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads Performance –
Insurance Claims Data

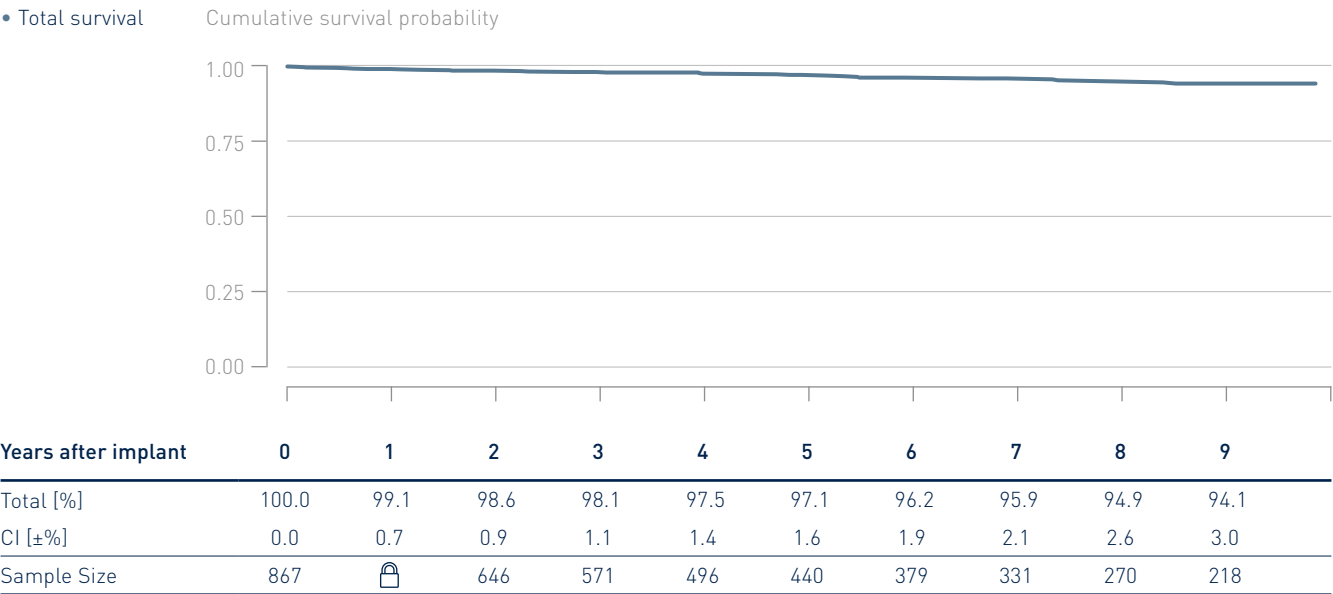
**10.2 ICD Leads Performance –
Insurance Claims Data**

10.3 CRT Leads Performance –
Insurance Claims Data

10.2 ICD Leads Performance – Insurance Claims Data

Linux S EP-Passion Data

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered U.S. Implants	867

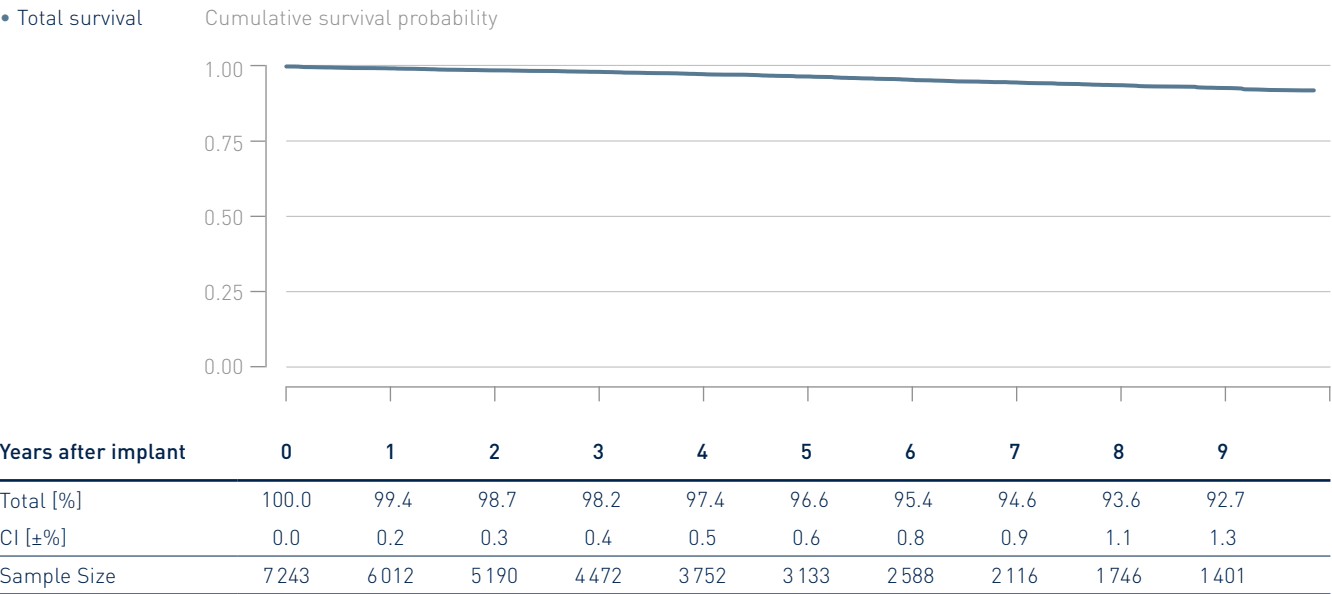


cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux SD EP-Passion Data

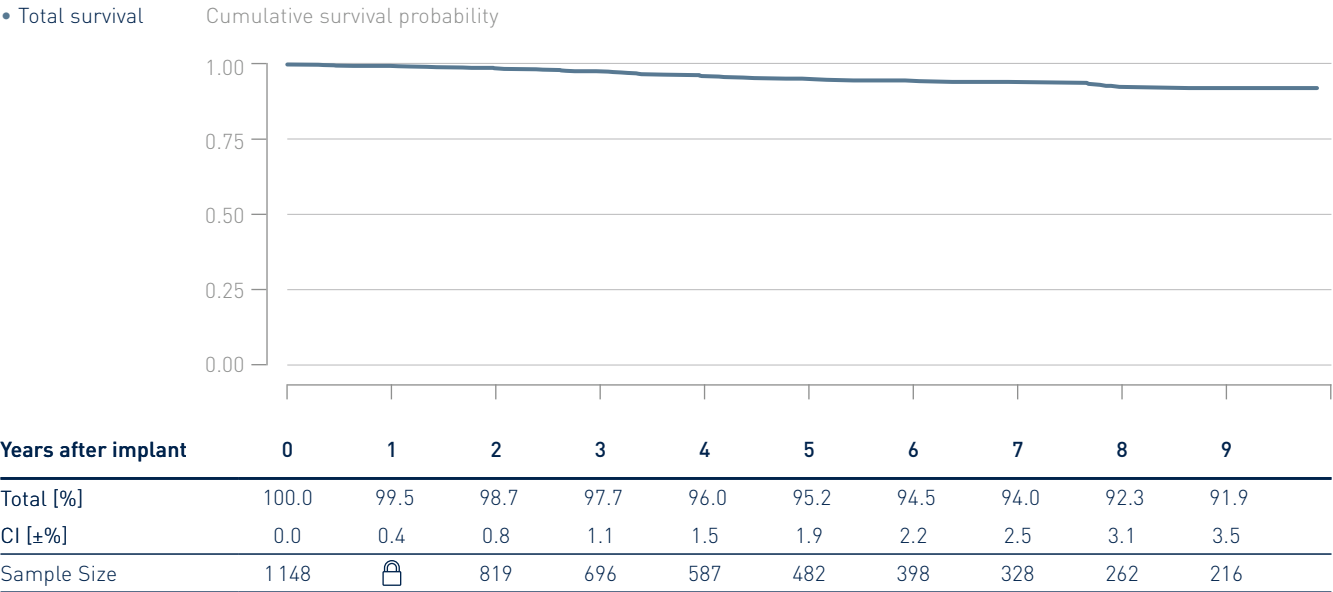
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered U.S. Implants	7 243



10.2 ICD Leads Performance – Insurance Claims Data

Linux TD EP-Passion Data

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

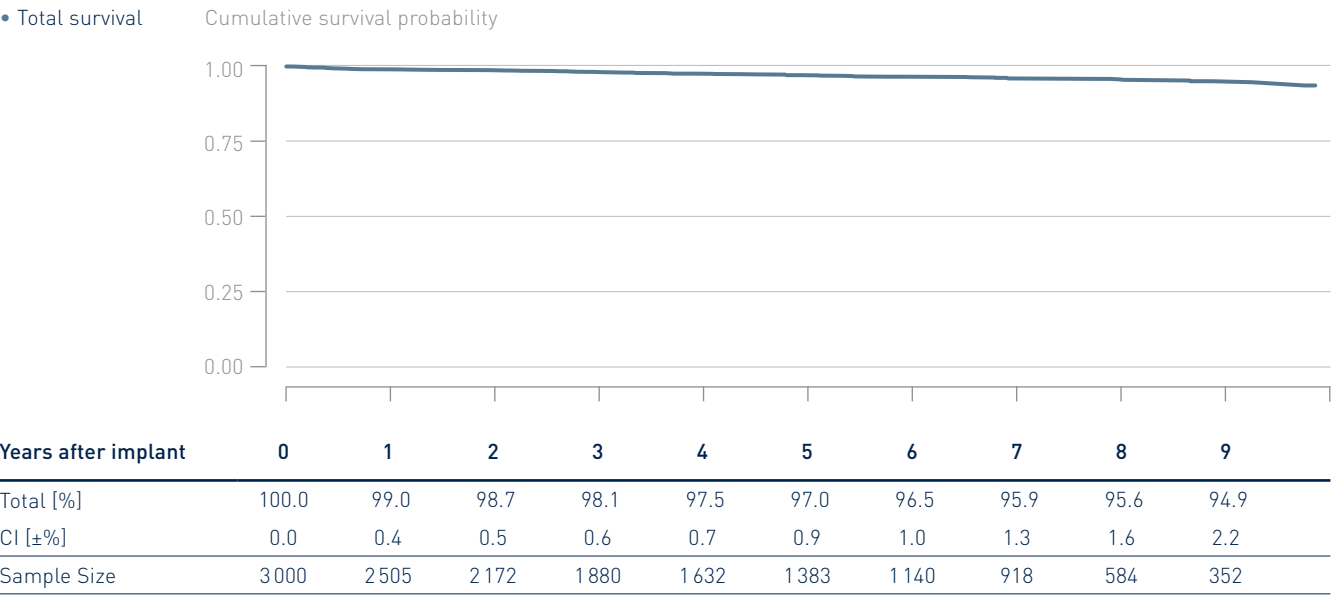


cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux^{Smart} S EP-Passion Data

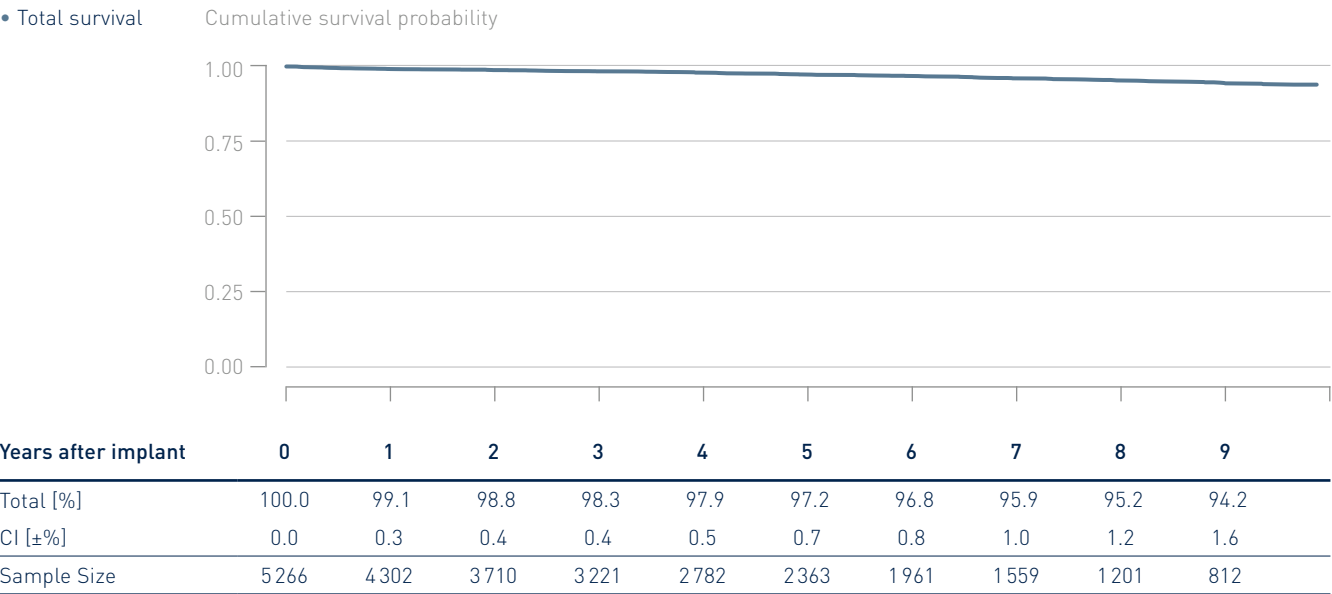
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered U.S. Implants	3 000



10.2 ICD Leads Performance – Insurance Claims Data

Linux^{Smart} SD EP-Passion Data

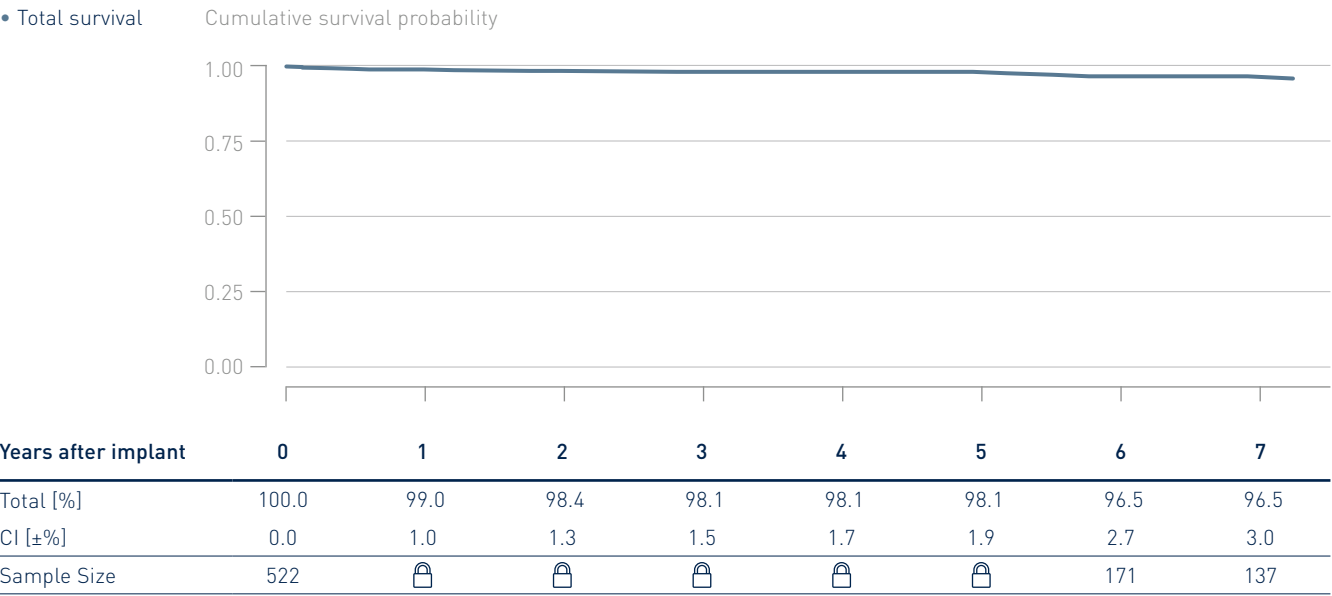
Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered U.S. Implants	5 266



10.2 ICD Leads Performance – Insurance Claims Data

Linux^{Smart} TD EP-Passion Data

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered U.S. Implants	522

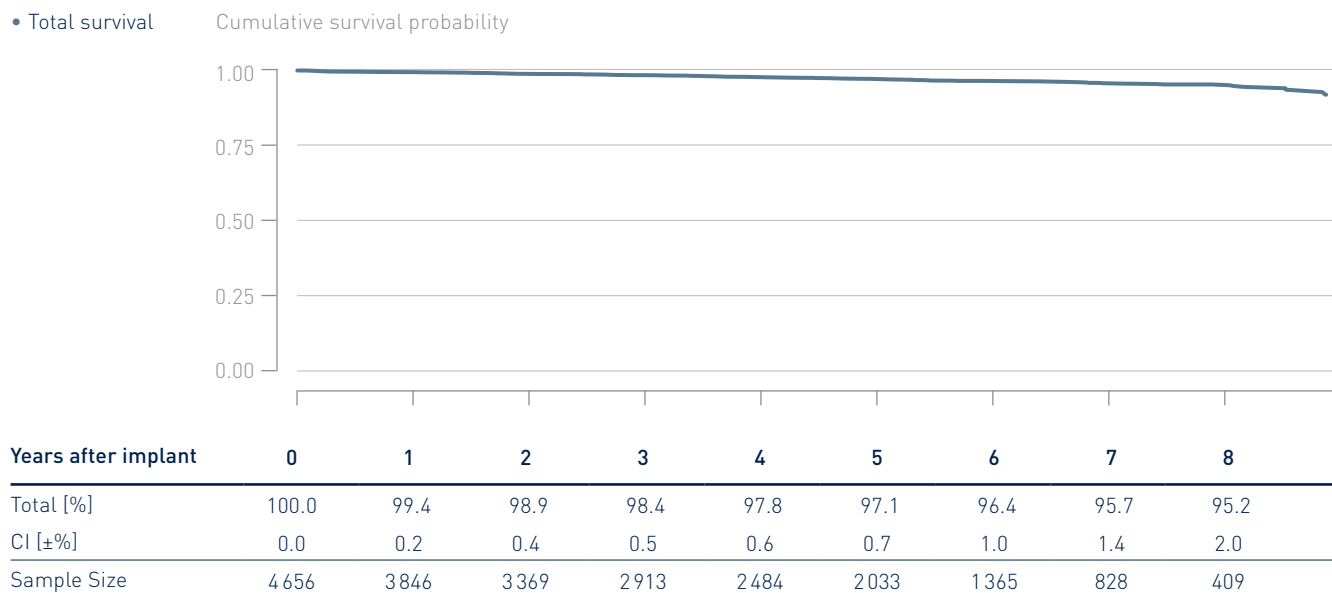


cell size suppression criteria defined by CMS do not allow to report these data, see section 9.2

10.2 ICD Leads Performance – Insurance Claims Data

Linux^{Smart} S DX EP-Passion Data

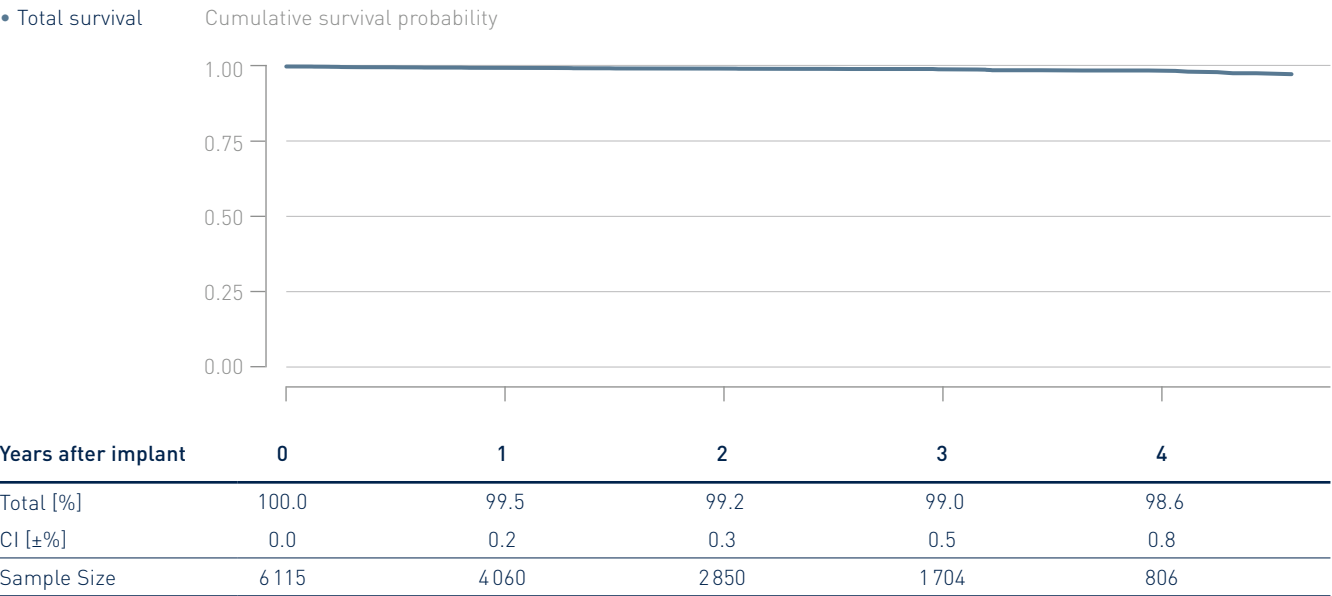
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36300
Registered U.S. Implants	4656



10.2 ICD Leads Performance – Insurance Claims Data

Plexa S EP-Passion Data

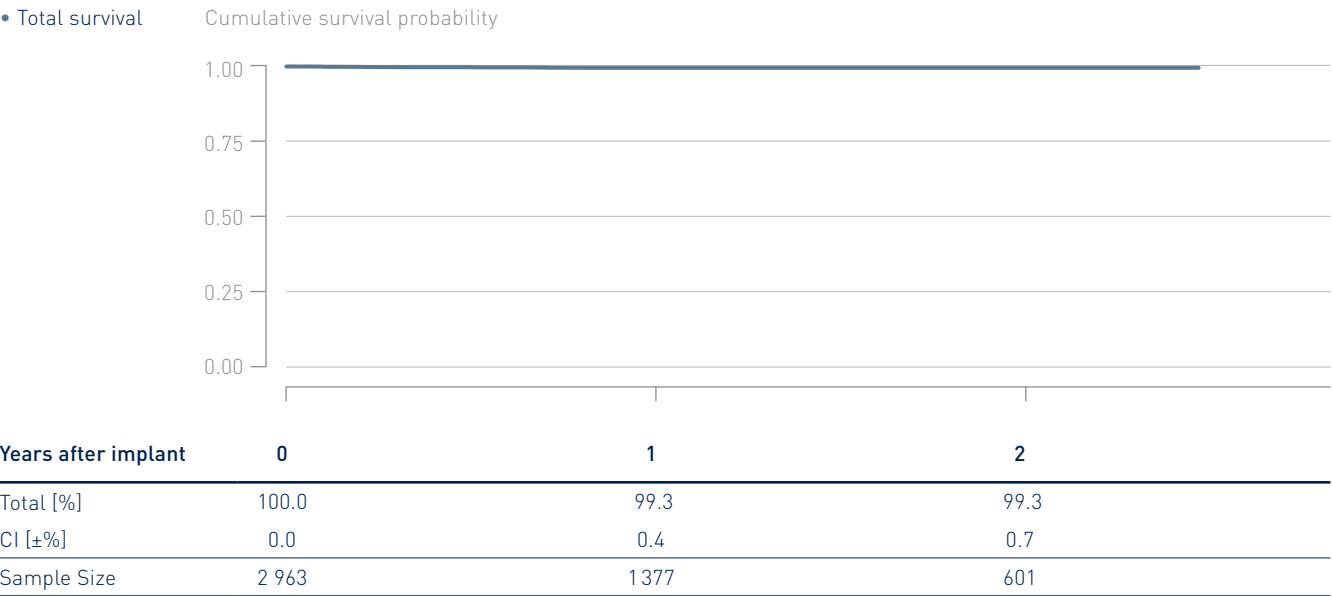
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	136 000
Registered U.S. Implants	6 115



10.2 ICD Leads Performance – Insurance Claims Data

Plexa S DX EP-Passion Data

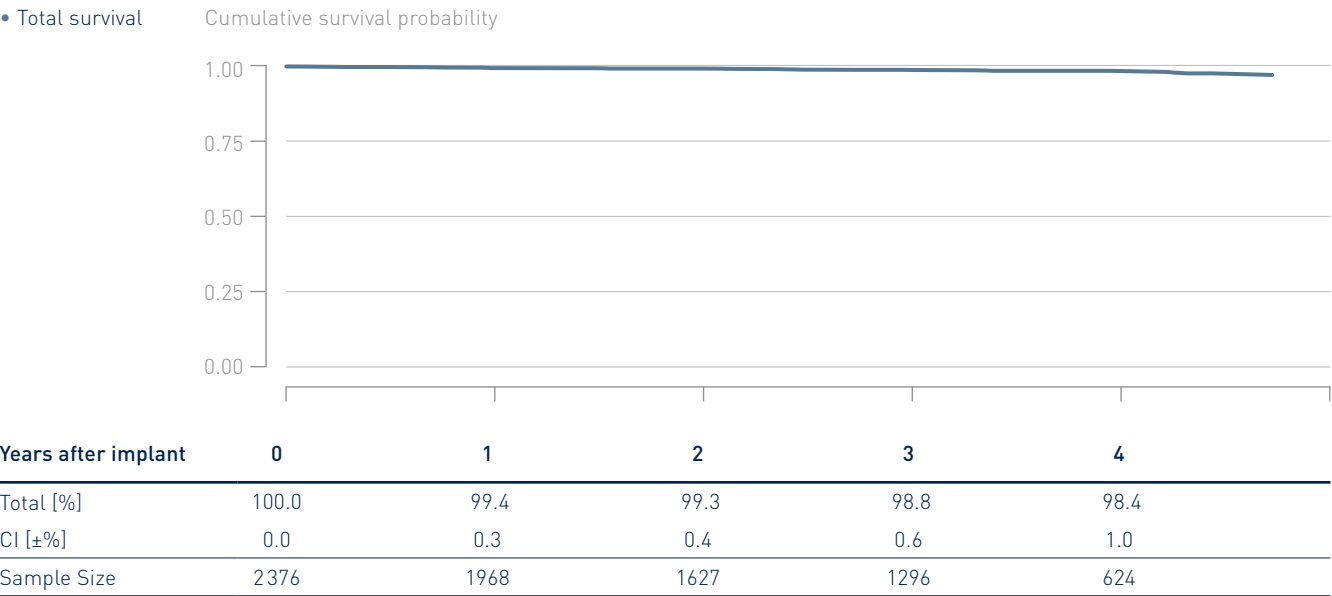
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	34 100
Registered U.S. Implants	2 963



10.2 ICD Leads Performance – Insurance Claims Data

Plexa S DX DF1 EP-Passion Data

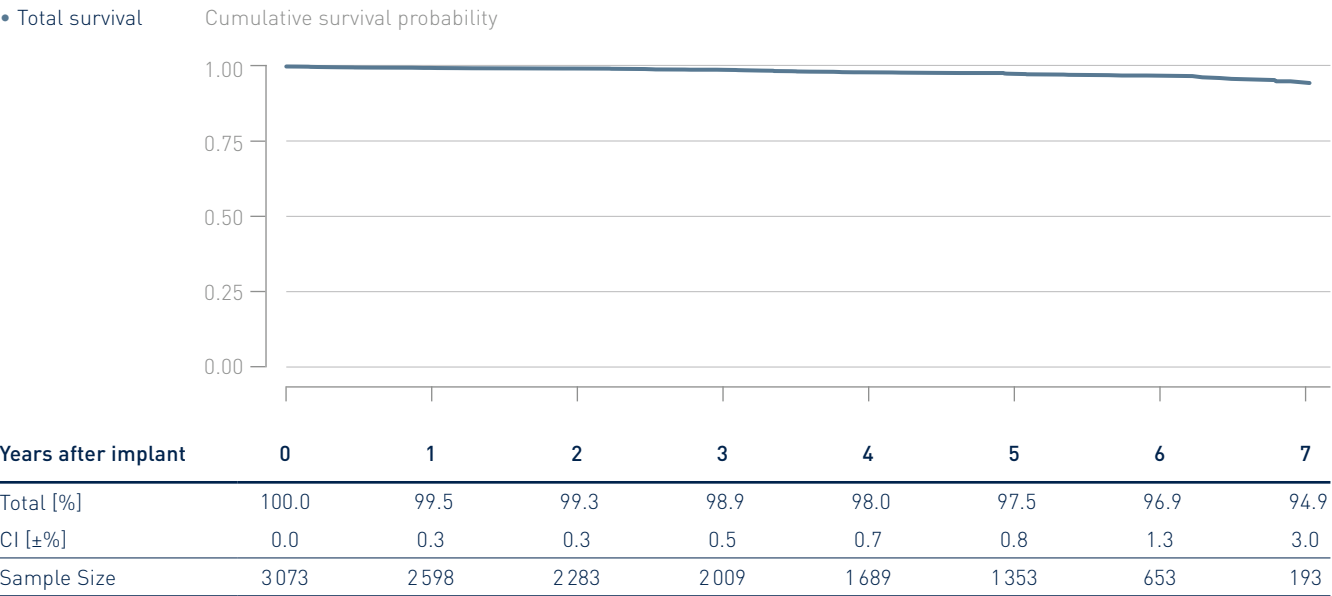
Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	22 800
Registered U.S. Implants	2 376



10.2 ICD Leads Performance – Insurance Claims Data

Protego S EP-Passion Data

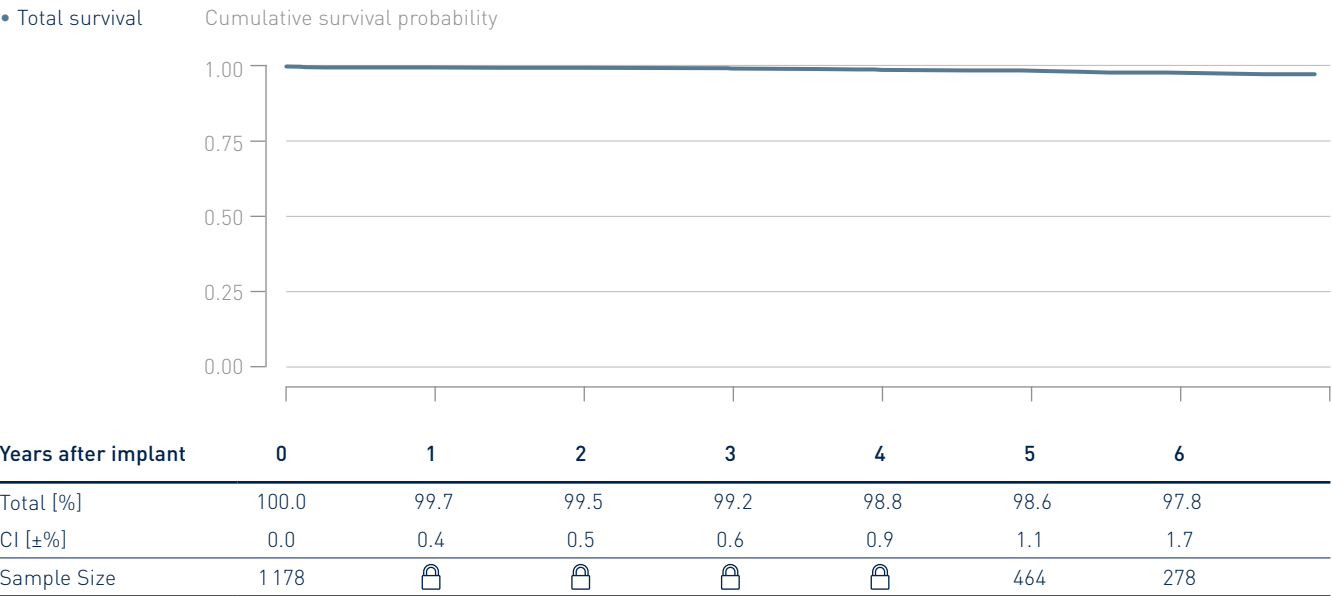
Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered U.S. Implants	3 073



10.2 ICD Leads Performance – Insurance Claims Data

Protego SD EP-Passion Data

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
U.S. Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18400
Registered U.S. Implants	1 178



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



Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads Performance –
Insurance Claims Data

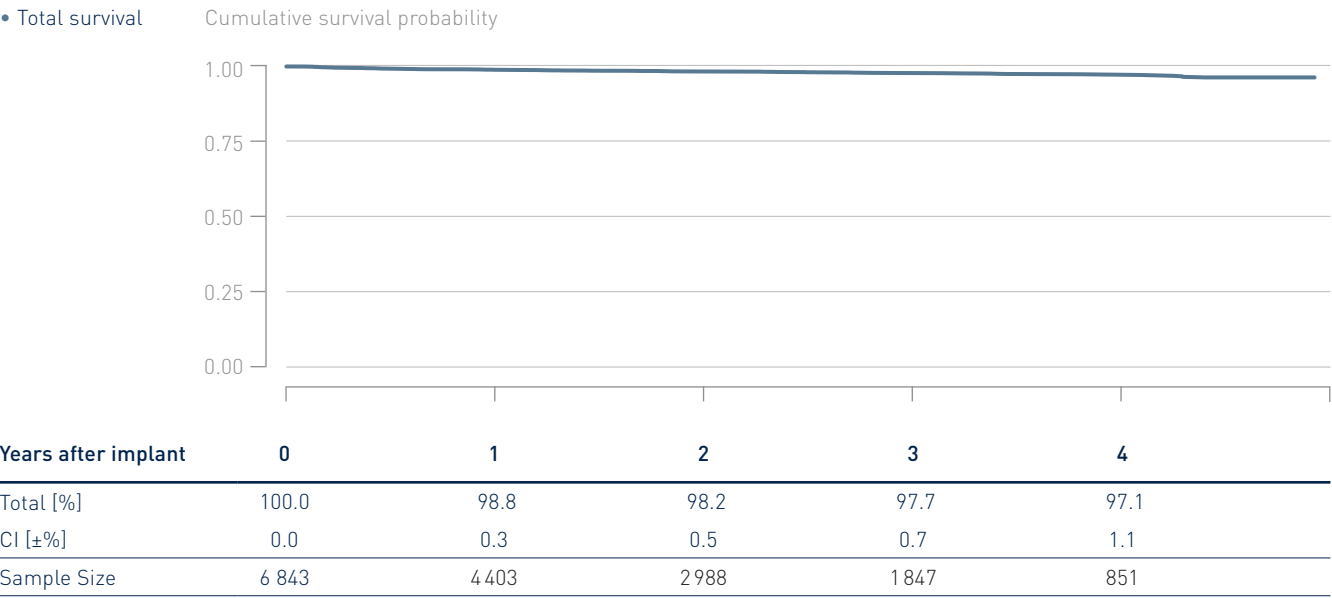
10.2 ICD Leads Performance –
Insurance Claims Data

**10.3 CRT Leads Performance –
Insurance Claims Data**

10.3 CRT Leads Performance – Insurance Claims Data

Sentus OTW QP L EP-Passion Data

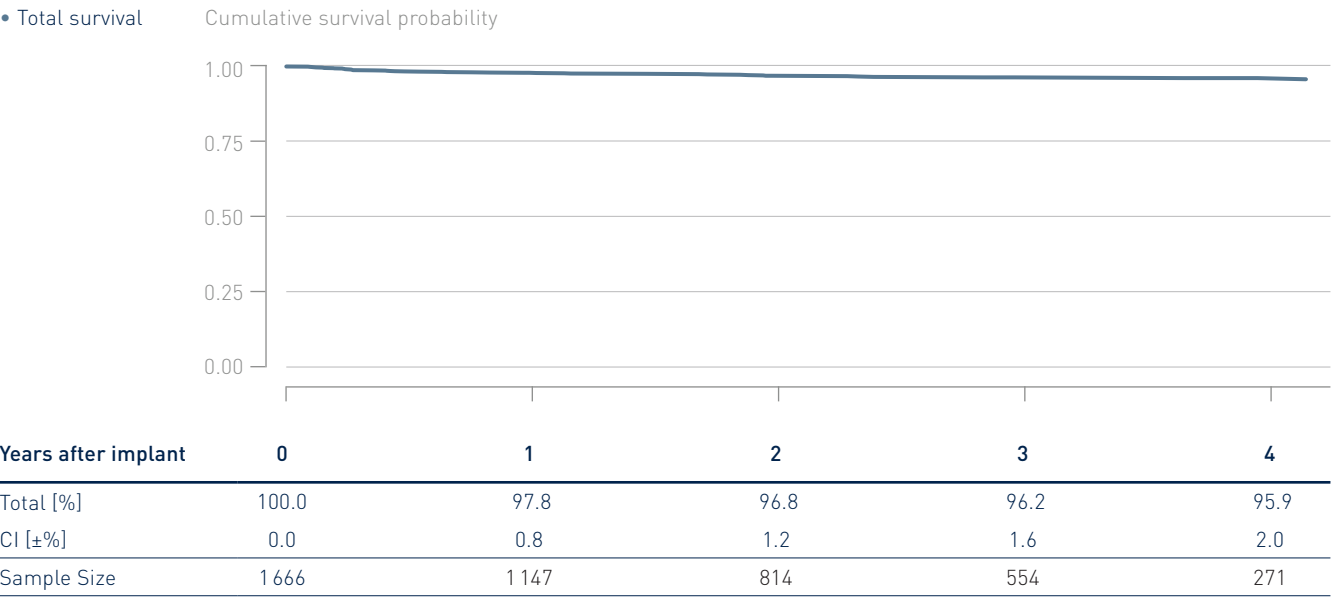
Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
U.S. Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	126 000
Registered U.S. Implants	6 843



10.3 CRT Leads Performance – Insurance Claims Data

Sentus OTW QP S EP-Passion 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	24 800
Registered U.S. Implants	1 666





Advisories

11. Advisories

BIO-LQC Potential premature battery depletion in a subset of ICD and CRT-D devices 162,000 devices world-wide, 38,000 in the United States

Status Update

FDA has classified this advisory as a class II recall.

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

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

As of October 2023

- The cumulative failure rate is 1.2%
- No failures for devices with less than 2 years of implant duration have been reported.
- The failure probability after 2 years remains constant at 0.0012%. The failure probability after 5 years of implant is 0.56%
- One event has been reported with patient death related to early battery depletion after the patient was lost to follow-up for two years. All other events are associated with an additional replacement surgery only.
- Availability of therapy has been assessed for all returned devices to update risk estimation for loss of therapy depending on the service time:

Risk for loss of pacing therapy

Service Time	Risk per month for loss of pacing
0 – 24 months	< 0.00001%
24 – 48 months	0.0013%
48 – 72 months	0.0093%

Risk for loss of high-voltage therapy

Service Time	Risk per month for loss of shock therapy
0 – 24 months	< 0.00001%
24 – 48 months	0.0020%
48 – 72 months	0.0145%

Original communication: March 2021

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

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

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

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

Reason for this Communication

The current observed rate of confirmed premature battery depletion events is 0.1% of all devices susceptible to this issue. Since every case of battery depletion may not be reported to BIOTRONIK, the exact number of devices that have experienced this issue is not entirely

known. BIOTRONIK estimates the number of active devices which are potentially susceptible to this issue to be approximately 162,000 worldwide.

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

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

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

Risk to Health

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

Early Battery Failure Detection

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

11. Advisories

monitoring using BIOTRONIK Home Monitoring.

Patient Management

Recommendations

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

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

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

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

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

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

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

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

X-Ray Identifiers for Pacemakers and ICDs

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

Contacting BIOTRONIK

Regarding this Report

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

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Fax +49 (0) 30 68905 96 1920

E-mail PPR@biotronik.com

Address

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Regarding Products

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

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Fax +49 (0) 30 689 05 96 2200

Email technical.services@biotronik.com

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