

Product Performance Report 2nd Edition 2024

Cardiac Rhythm Management
Cumulative Survival Probability

**Product
Performance Report
2nd Edition 2024**

Cardiac Rhythm Management
Pacemakers
ICDs
Leads



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Quality and 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 US 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.

¹The 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 2024



Stephan Schwerzel
Vice President
Quality Management CRM
BIOTRONIK SE & Co. KG



Terms and Definitions



1 Terms and Conditions

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 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 also known as 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 US 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 US Social Security Administration, the use of US 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 US 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, 2023. The number of US 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 US 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 Information

- Product versions that contribute to the evaluation
- Worldwide quantity of products that have been distributed
- US registered implants (number of products included in this report)
- Estimated active US implants
- Number of US normal battery depletions
- Number of US confirmed malfunctions

Survival Plot

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).

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.

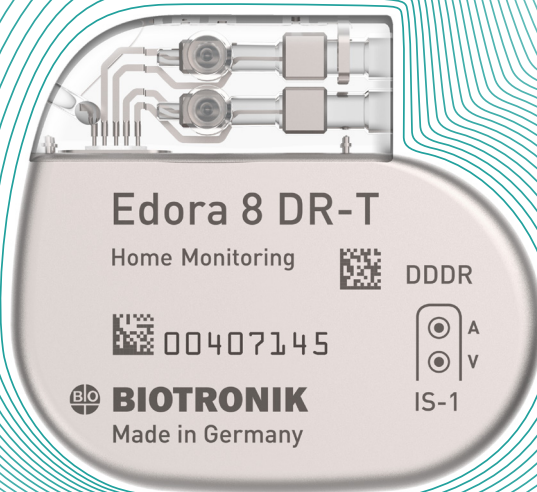
¹Greenwood, M. The natural duration of cancer. Reports on Public Health and Medical Subjects 33, London: Her Majesty's Stationery Office, 1-26, 1926

Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers



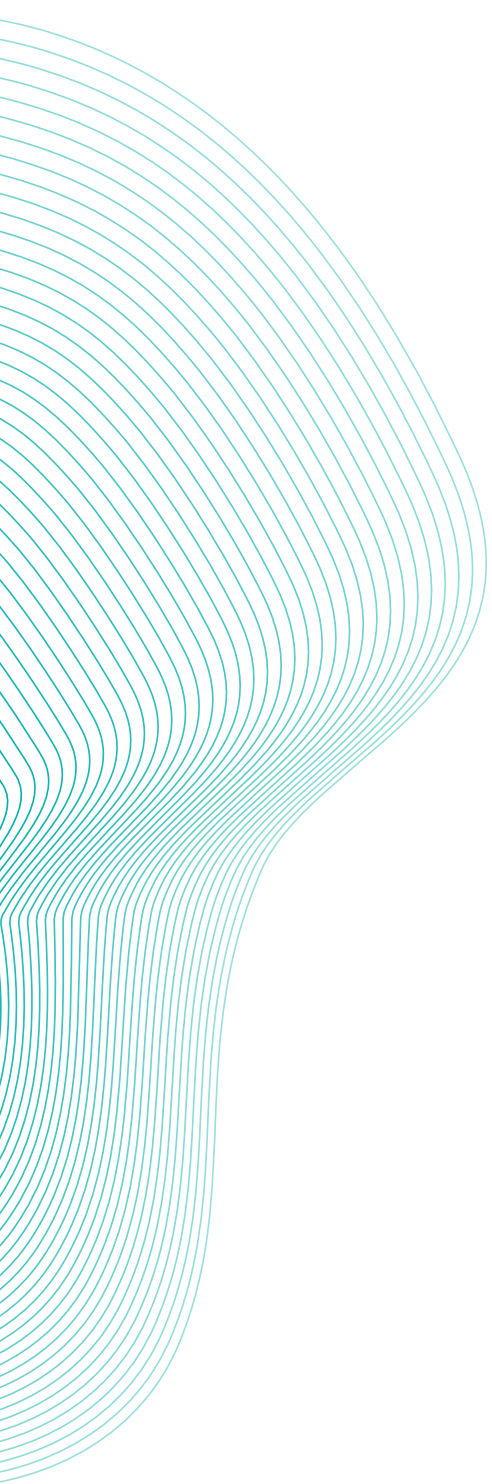


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers



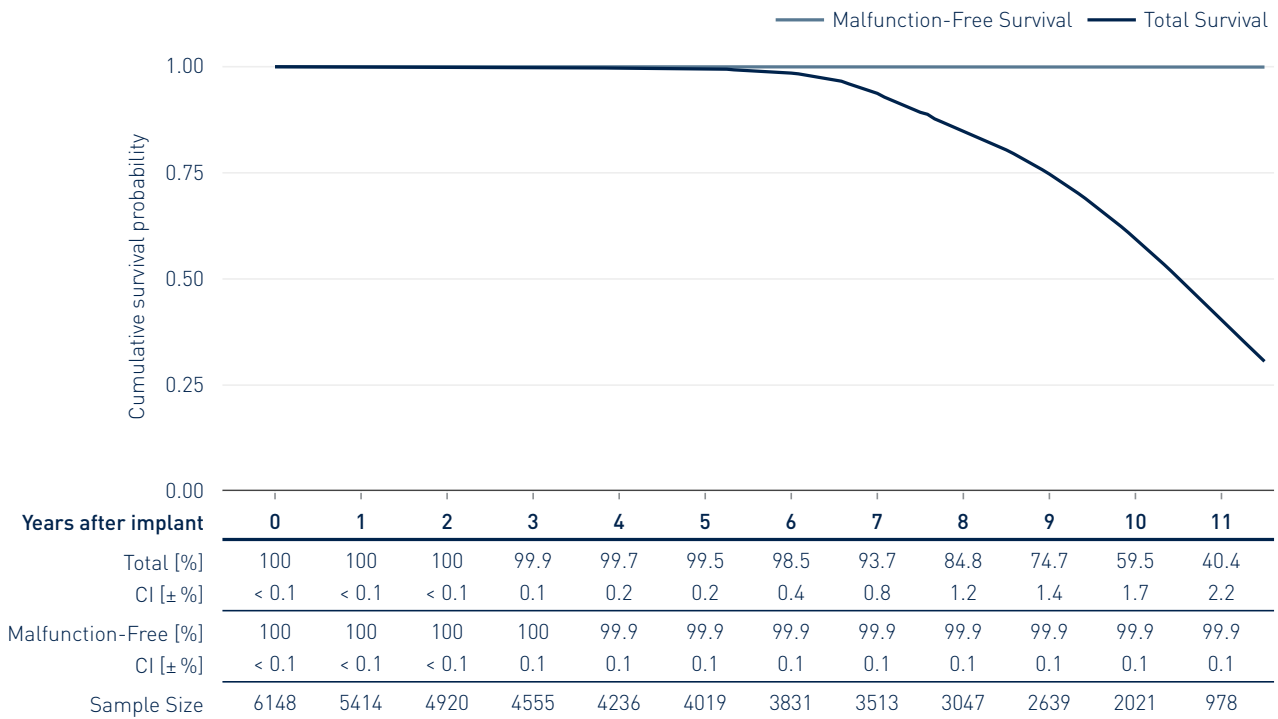


3.1 Single-Chamber Pacemakers

Cylos and Cylos 990*

Product Versions	VR
NBG Codes	VVIR
US Market Release	Jan 2006
CE Market Release	Nov 2005 / Mar 2008
Worldwide Distributed Devices	25 900
Registered US Implants	6 148
Estimated Active US Implants	2 120
US Normal Battery Depletions	857

	Count	Rate
US 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.

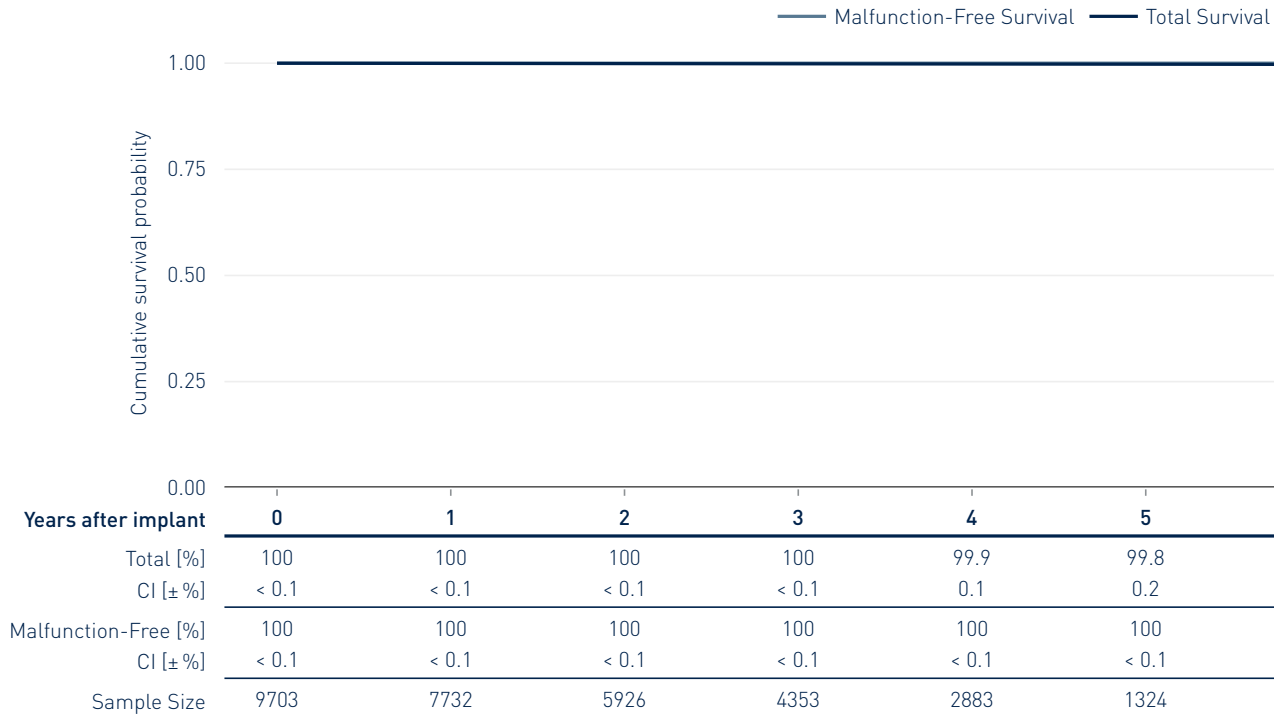


3.1 Single-Chamber Pacemakers

Edora 8

Product Versions	SR, SR-T
NBG Codes	AAIR, VVIR
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	52 100
Registered US Implants	9 703
Estimated Active US Implants	7 870
US Normal Battery Depletions	8

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



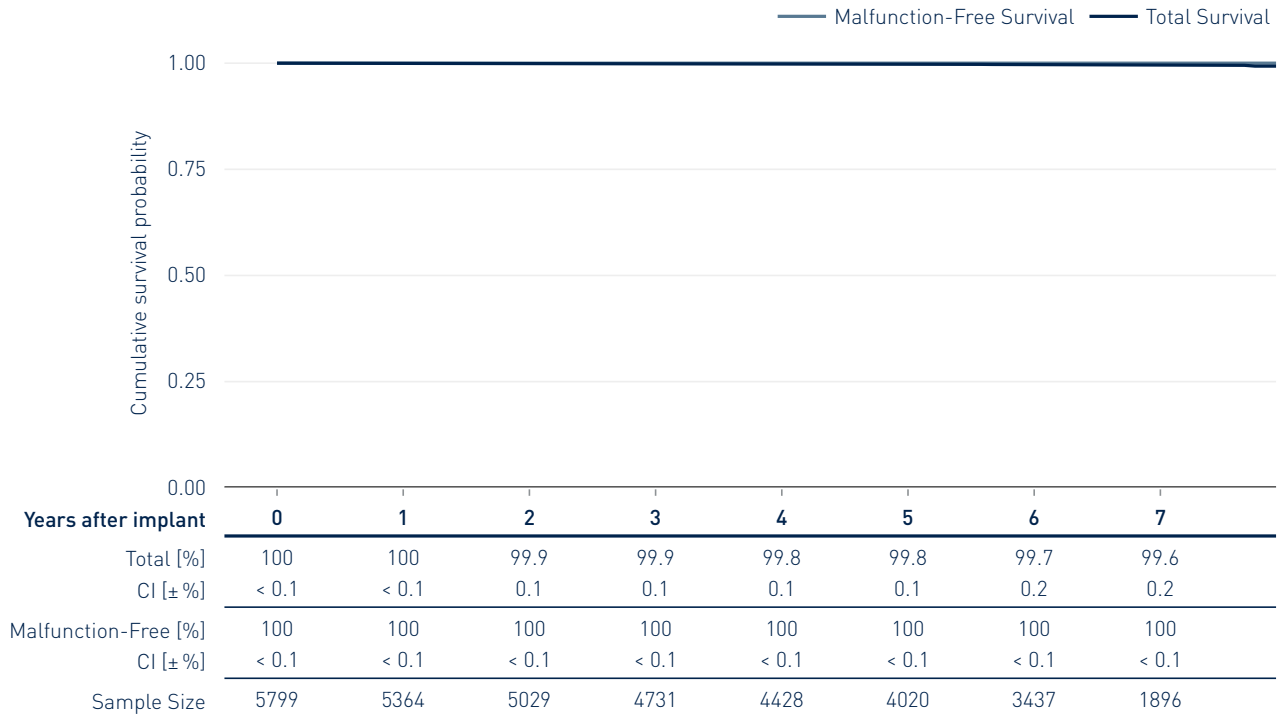


3.1 Single-Chamber Pacemakers

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 US Implants	5 799
Estimated Active US Implants	3 860
US Normal Battery Depletions	19

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



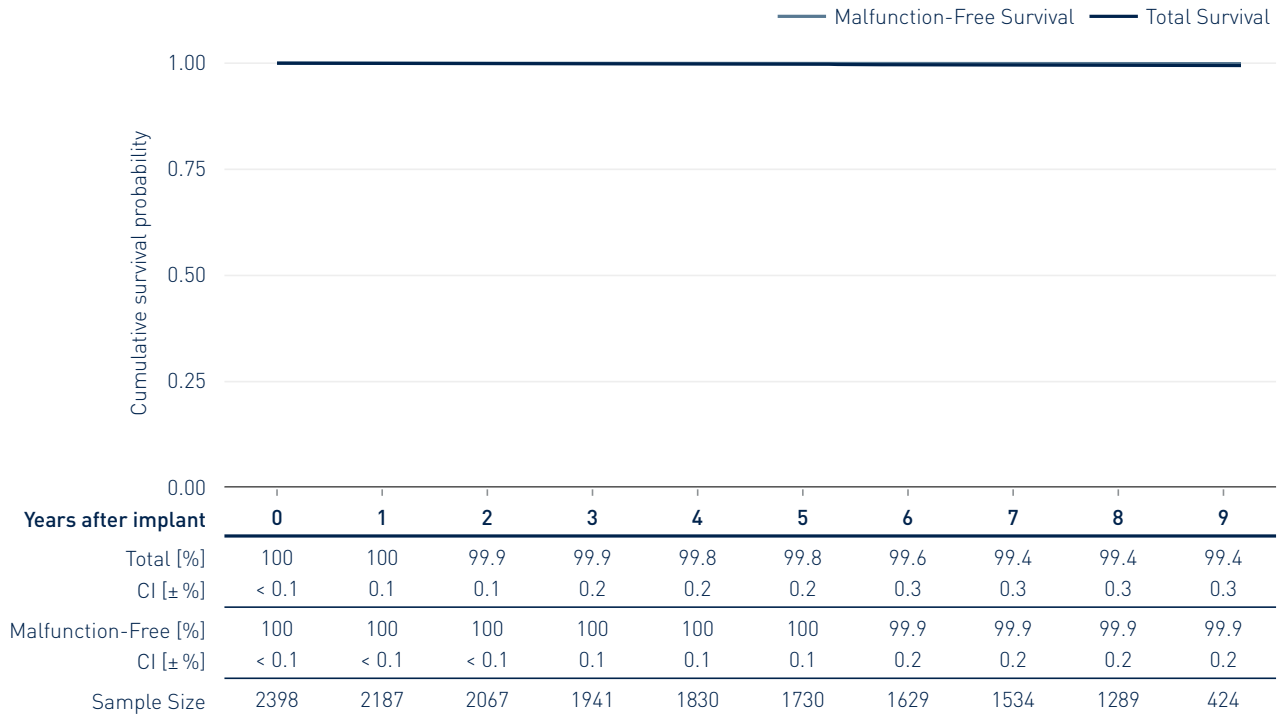


3.1 Single-Chamber Pacemakers

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 US Implants	2 398
Estimated Active US Implants	1 440
US Normal Battery Depletions	10

	Count	Rate
US Confirmed Malfunctions	2	0.08%
Therapy Compromised	1	0.04%
Therapy Available	1	0.04%



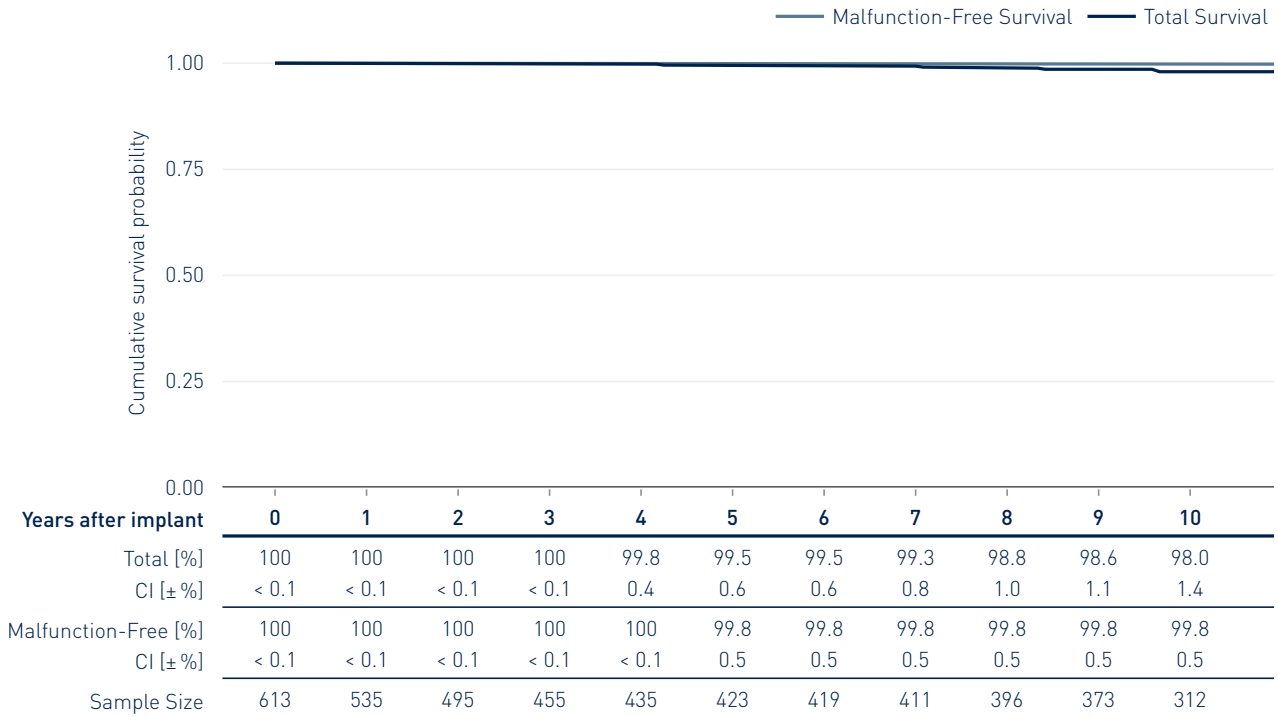


3.1 Single-Chamber Pacemakers

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 US Implants	613
Estimated Active US Implants	337
US Normal Battery Depletions	7

	Count	Rate
US Confirmed Malfunctions	1	0.16%
Therapy Compromised	0	0.00%
Therapy Available	1	0.16%



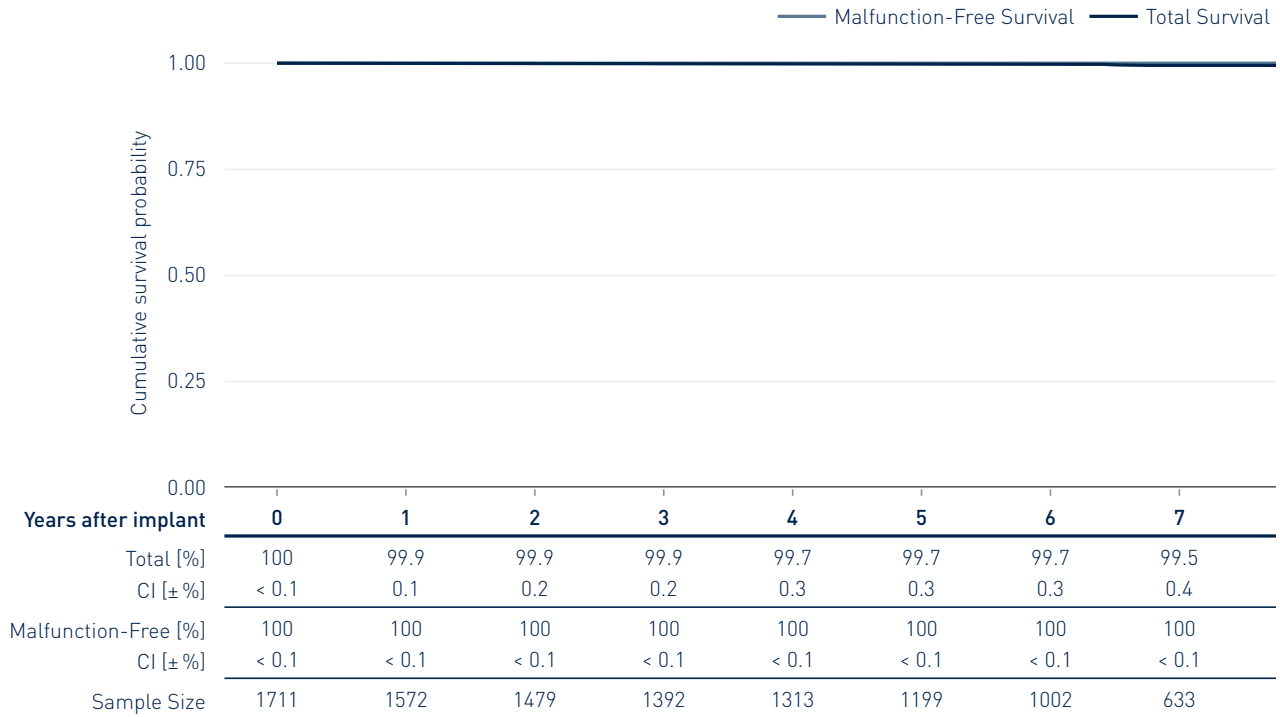


3.1 Single-Chamber Pacemakers

Etrinsa 8

Product Versions	SR-T
NBG Codes	AAIR, VVIR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	18 500
Registered US Implants	1 711
Estimated Active US Implants	1 140
US Normal Battery Depletions	6

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



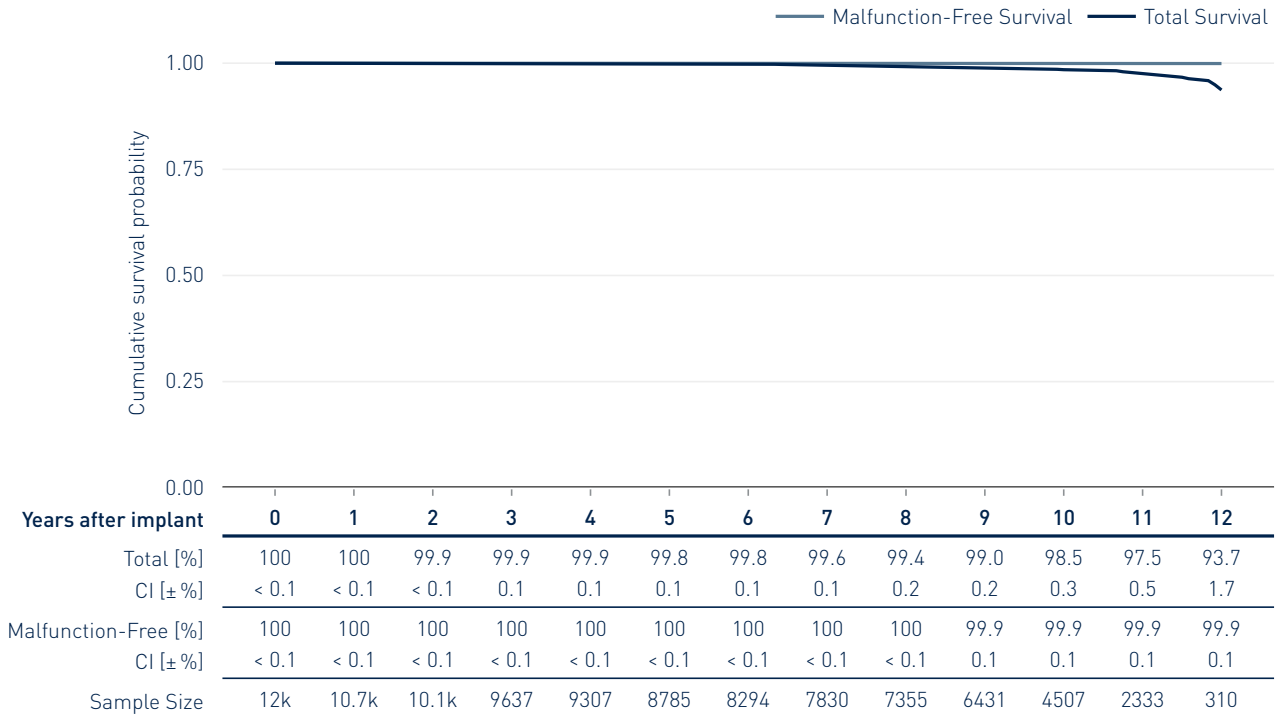


3.1 Single-Chamber Pacemakers

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 US Implants	11 972
Estimated Active US Implants	6 460
US Normal Battery Depletions	174

	Count	Rate
US Confirmed Malfunctions	5	0.04%
Therapy Compromised	2	0.02%
Therapy Available	3	0.03%



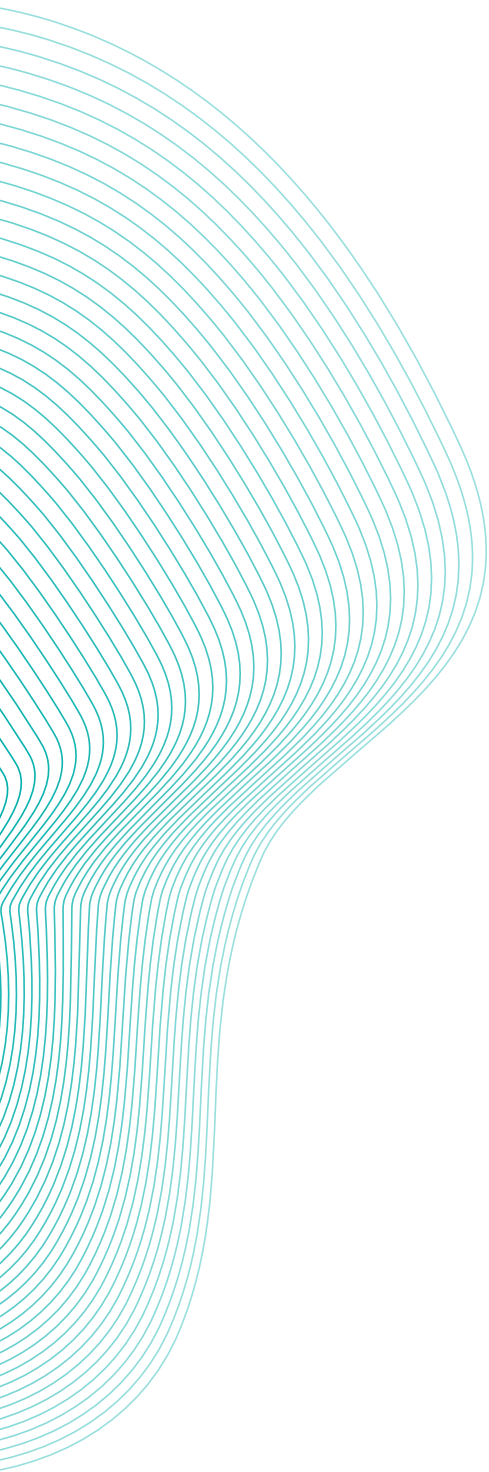


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers



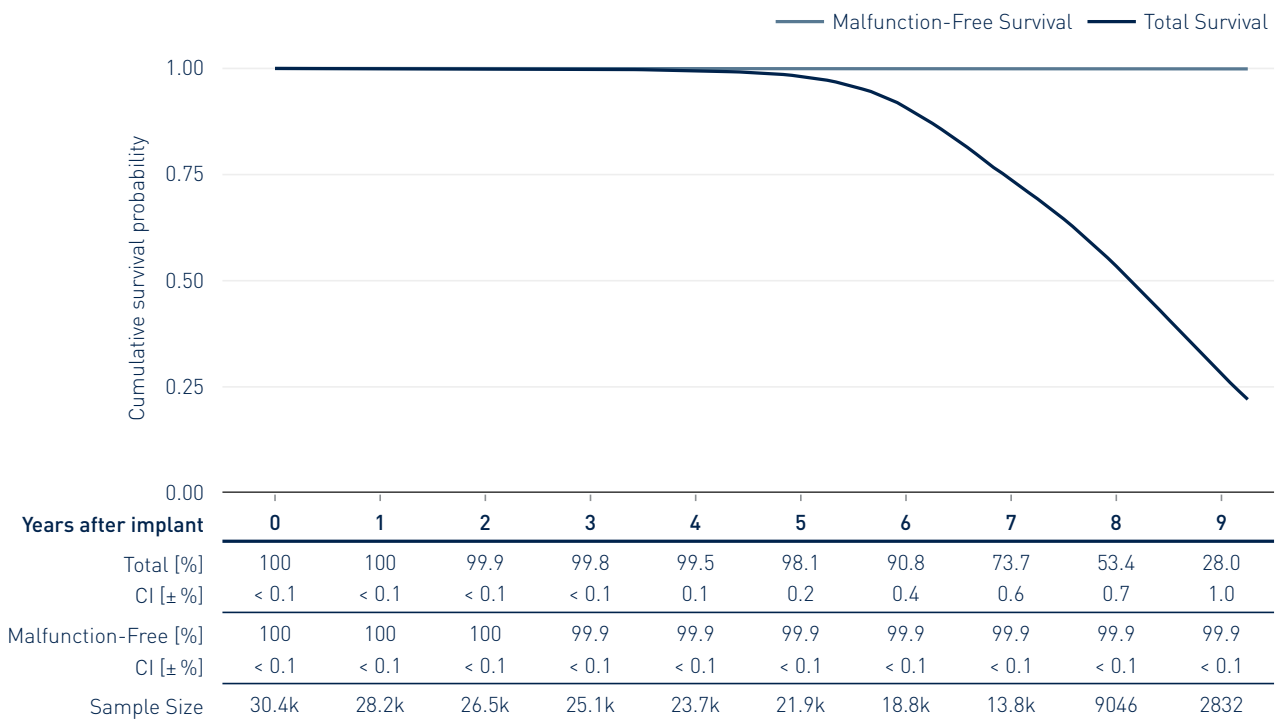


3.2 Dual-Chamber Pacemakers

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	81 300
Registered US Implants	30 374
Estimated Active US Implants	6 580
US Normal Battery Depletions	8 482

	Count	Rate
US 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.

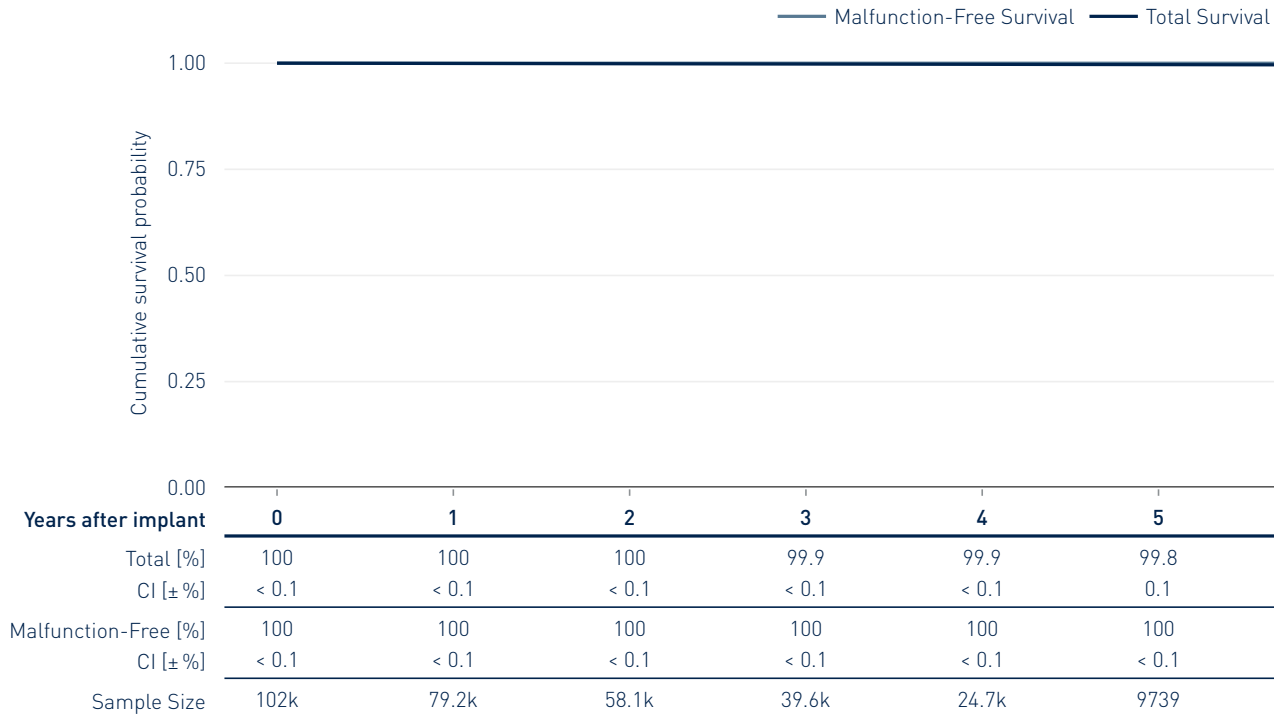


3.2 Dual-Chamber Pacemakers

Edora 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	May 2017
CE Market Release	Jul 2016
Worldwide Distributed Devices	316 000
Registered US Implants	101 708
Estimated Active US Implants	85 900
US Normal Battery Depletions	85

	Count	Rate
US Confirmed Malfunctions	8	0.01%
Therapy Compromised	3	0.00%
Therapy Available	5	0.00%



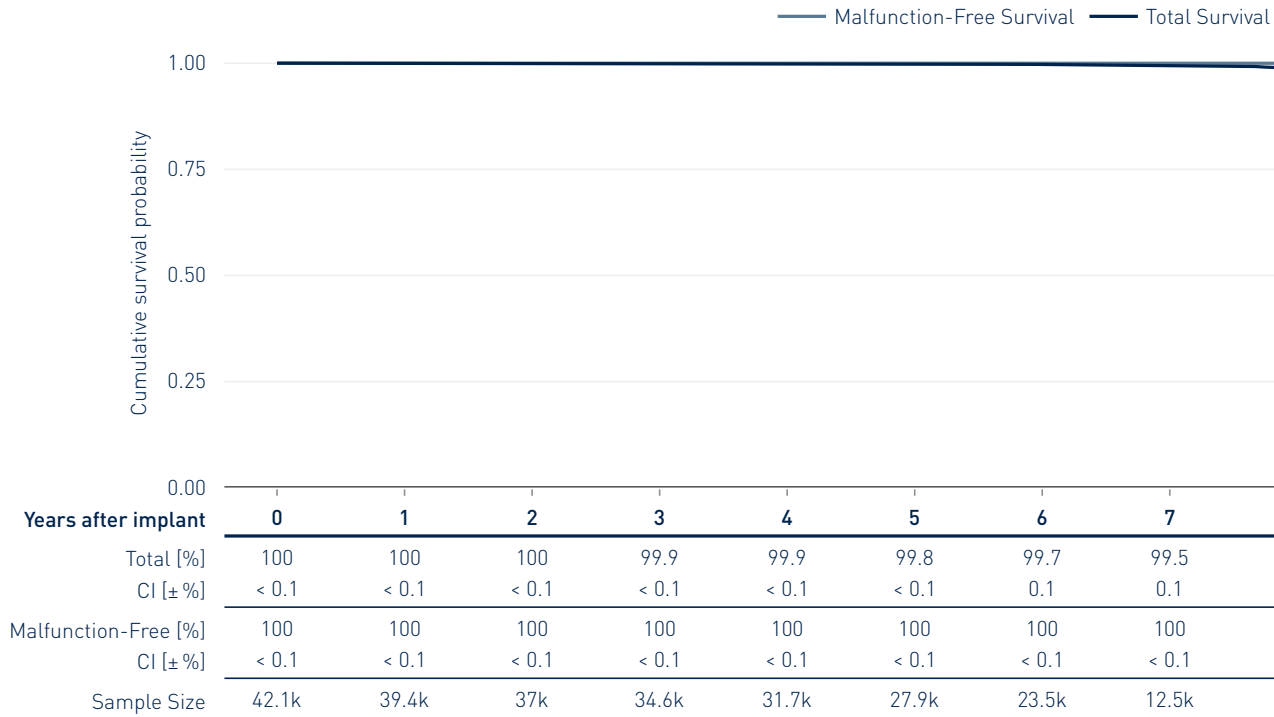


3.2 Dual-Chamber Pacemakers

Eluna 8

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	97 200
Registered US Implants	42 071
Estimated Active US Implants	28 900
US Normal Battery Depletions	158

	Count	Rate
US Confirmed Malfunctions	6	0.01%
Therapy Compromised	0	0.00%
Therapy Available	6	0.01%



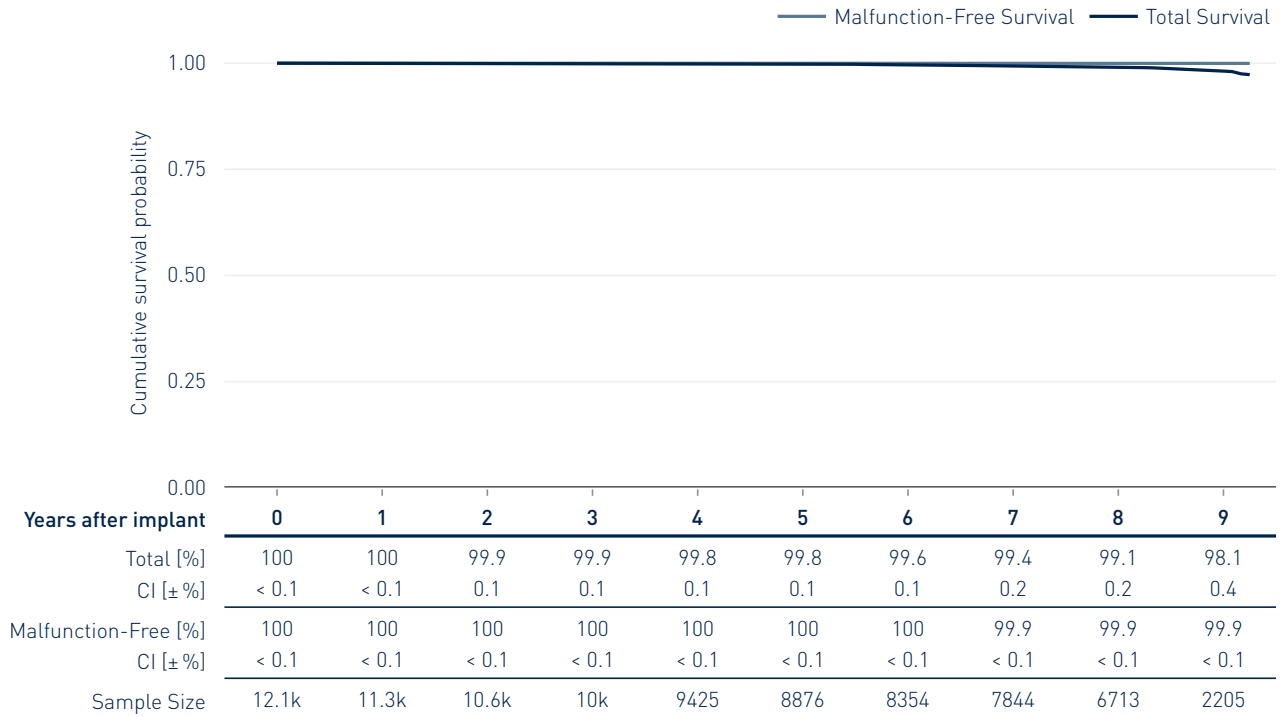


3.2 Dual-Chamber Pacemakers

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 US Implants	12 120
Estimated Active US Implants	7 070
US Normal Battery Depletions	147

	Count	Rate
US Confirmed Malfunctions	5	0.04%
Therapy Compromised	2	0.02%
Therapy Available	3	0.02%



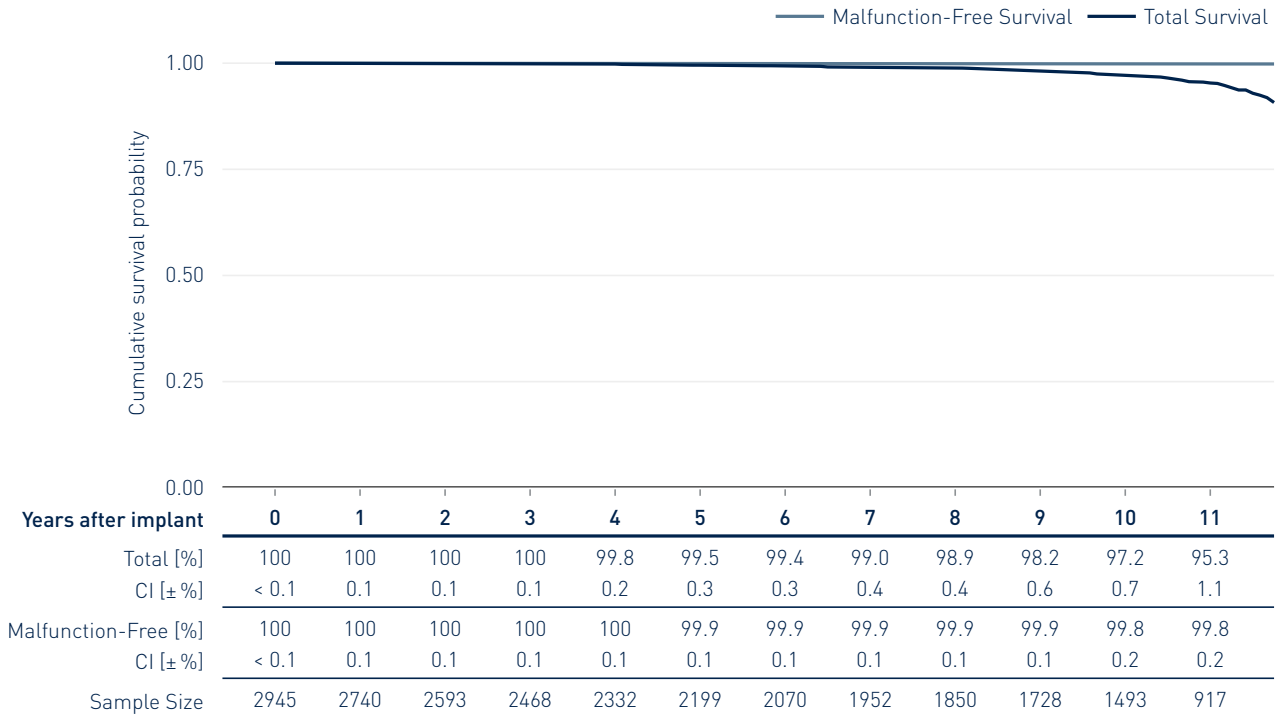


3.2 Dual-Chamber Pacemakers

Estella

Product Versions	DR, DR-T
NBG Codes	DDDR
US Market Release	Feb 2011
CE Market Release	Feb 2011
Worldwide Distributed Devices	53 500
Registered US Implants	2 945
Estimated Active US Implants	1 520
US Normal Battery Depletions	101

	Count	Rate
US Confirmed Malfunctions	4	0.14%
Therapy Compromised	0	0.00%
Therapy Available	4	0.14%



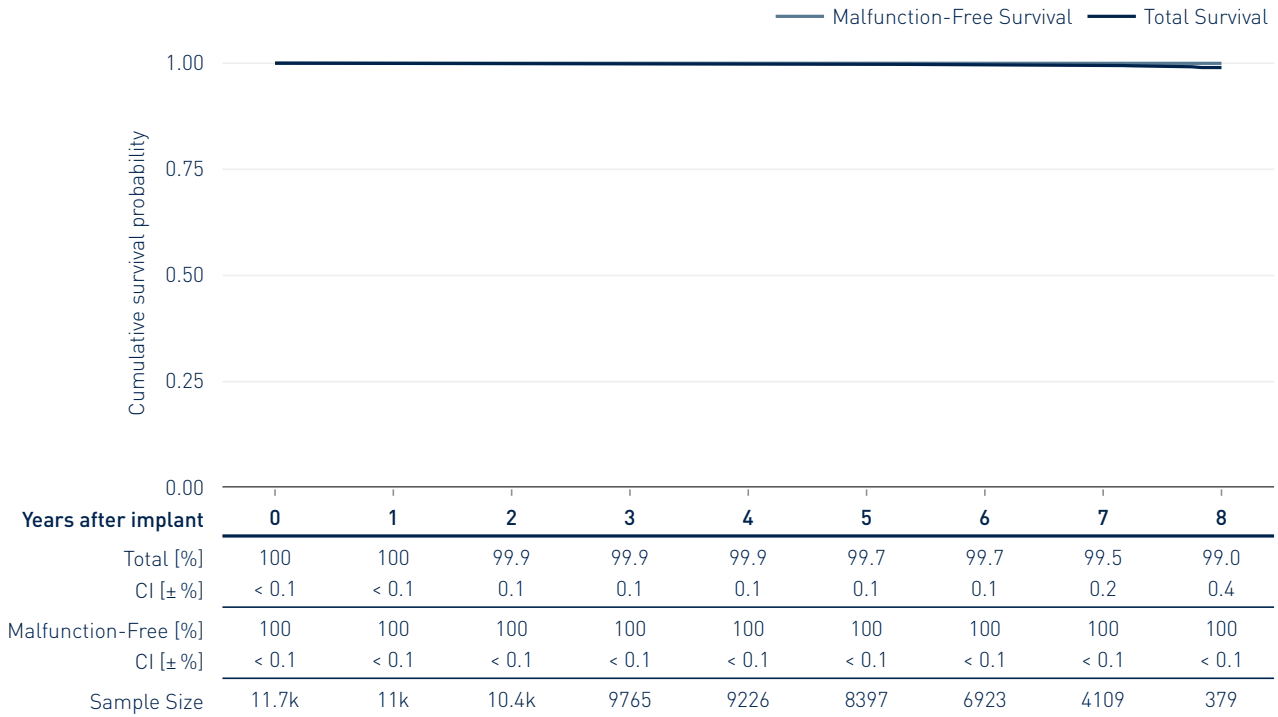


3.2 Dual-Chamber Pacemakers

Etrinsa 8

Product Versions	DR-T
NBG Codes	DDDR
US Market Release	Dec 2014
CE Market Release	Aug 2014
Worldwide Distributed Devices	76 300
Registered US Implants	11 701
Estimated Active US Implants	8 020
US Normal Battery Depletions	52

	Count	Rate
US Confirmed Malfunctions	3	0.03%
Therapy Compromised	0	0.00%
Therapy Available	3	0.03%



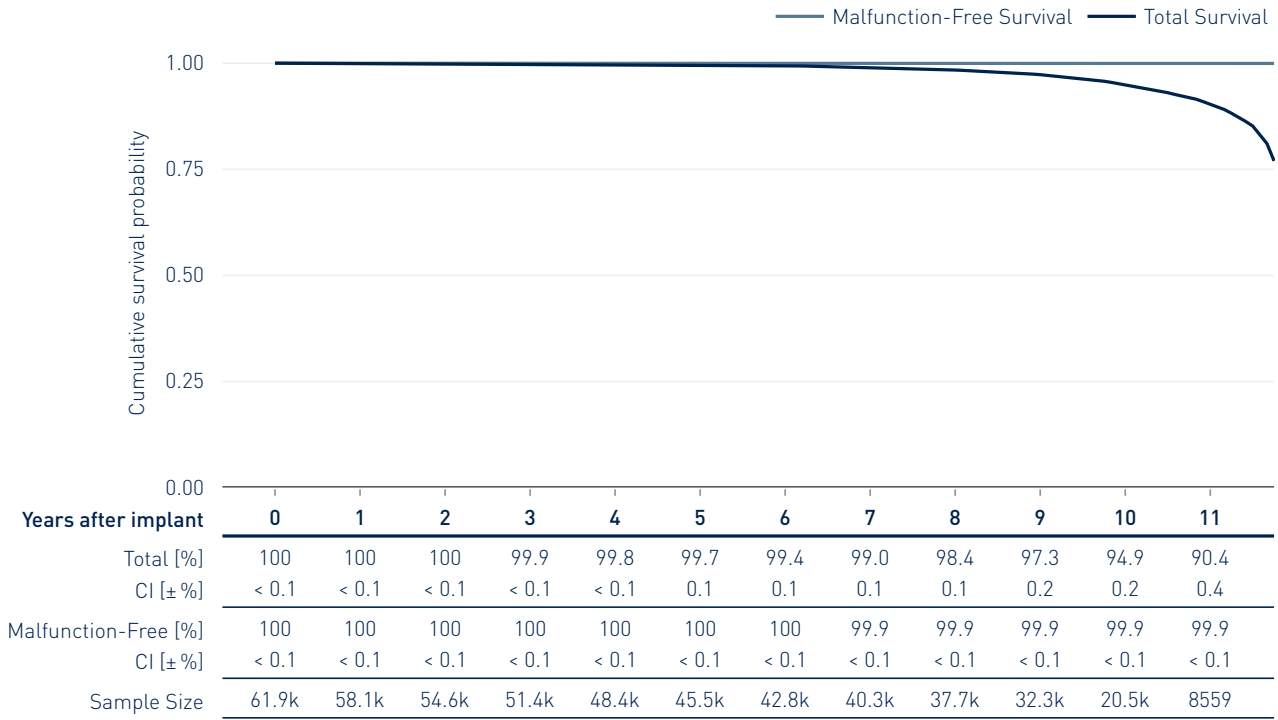


3.2 Dual-Chamber Pacemakers

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 US Implants	61 902
Estimated Active US Implants	31 300
US Normal Battery Depletions	3 172

	Count	Rate
US Confirmed Malfunctions	33	0.05%
Therapy Compromised	11	0.02%
Therapy Available	22	0.04%

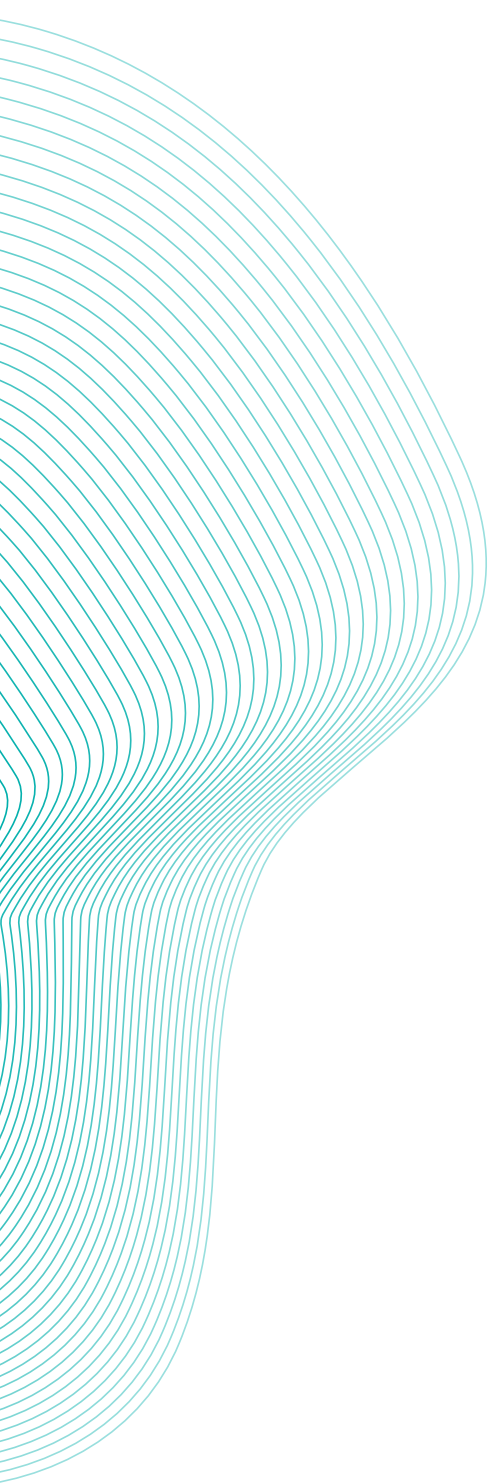


Performance of BIOTRONIK Pacemakers

3.1 Single-Chamber Pacemakers

3.2 Dual-Chamber Pacemakers

3.3 CRT Pacemakers



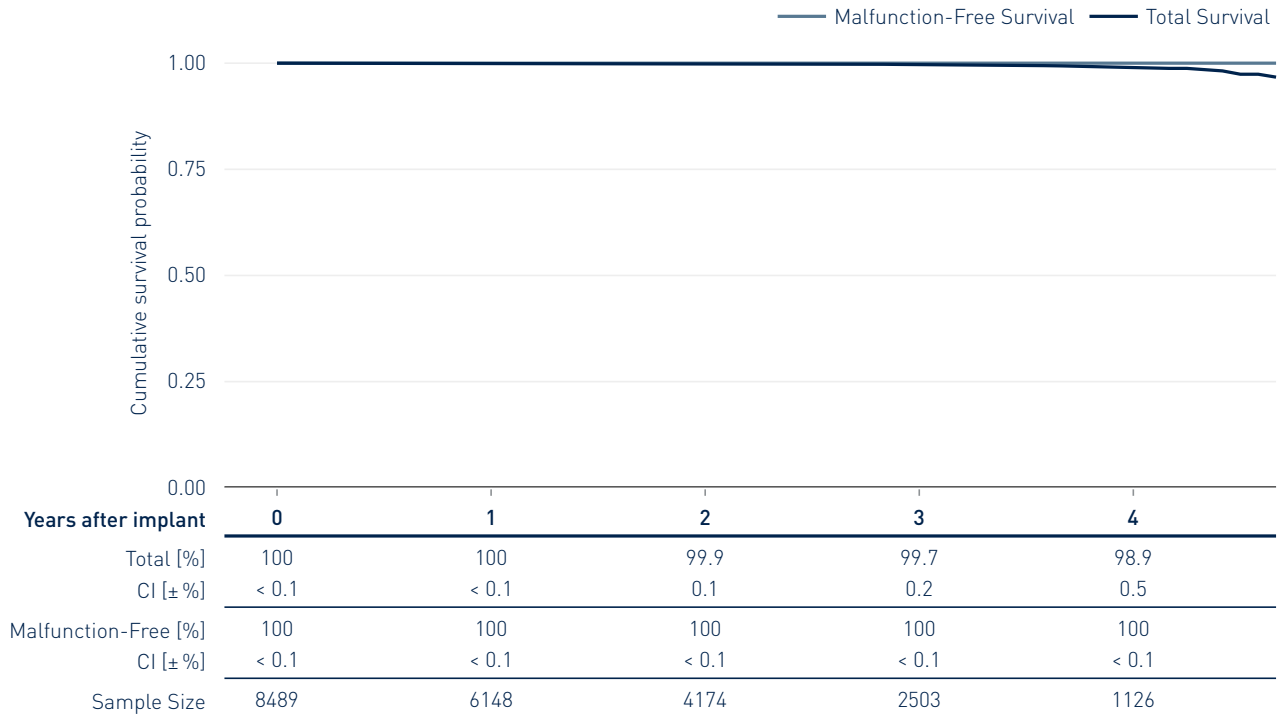


3.3 CRT Pacemakers

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	23 800
Registered US Implants	8 489
Estimated Active US Implants	6 370
US Normal Battery Depletions	47

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



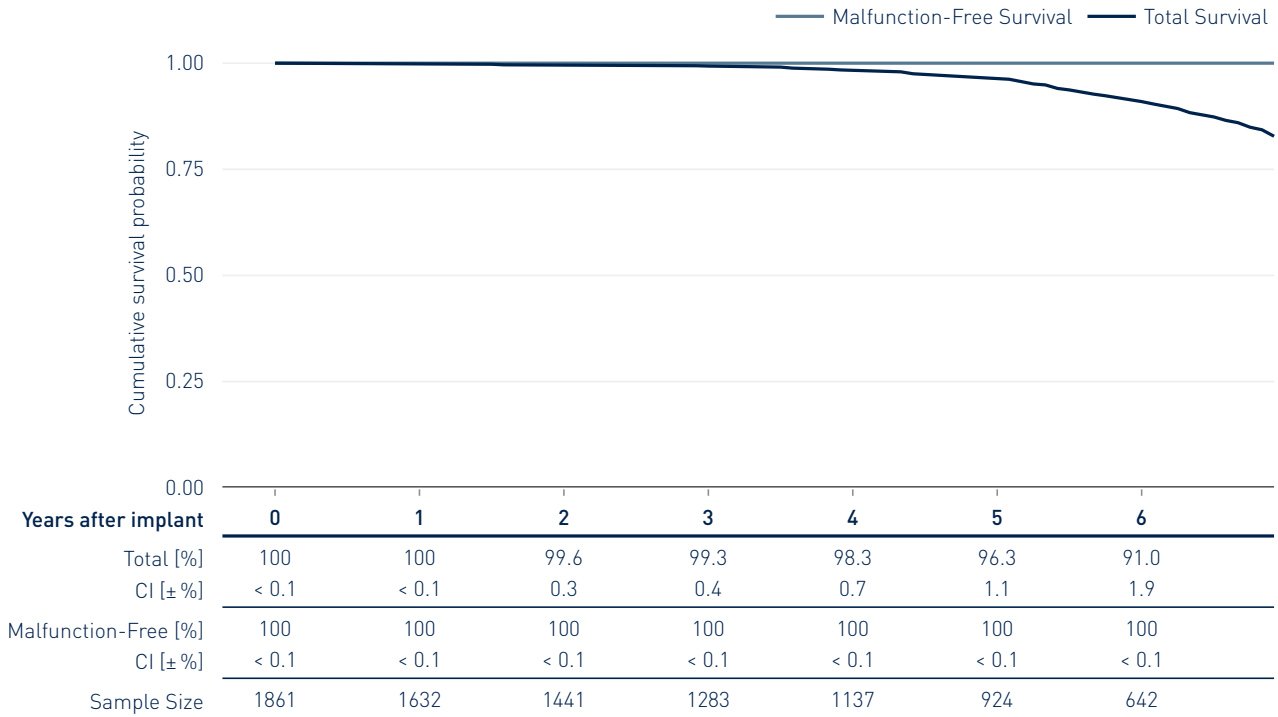


3.3 CRT Pacemakers

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 US Implants	1 861
Estimated Active US Implants	797
US Normal Battery Depletions	139

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%

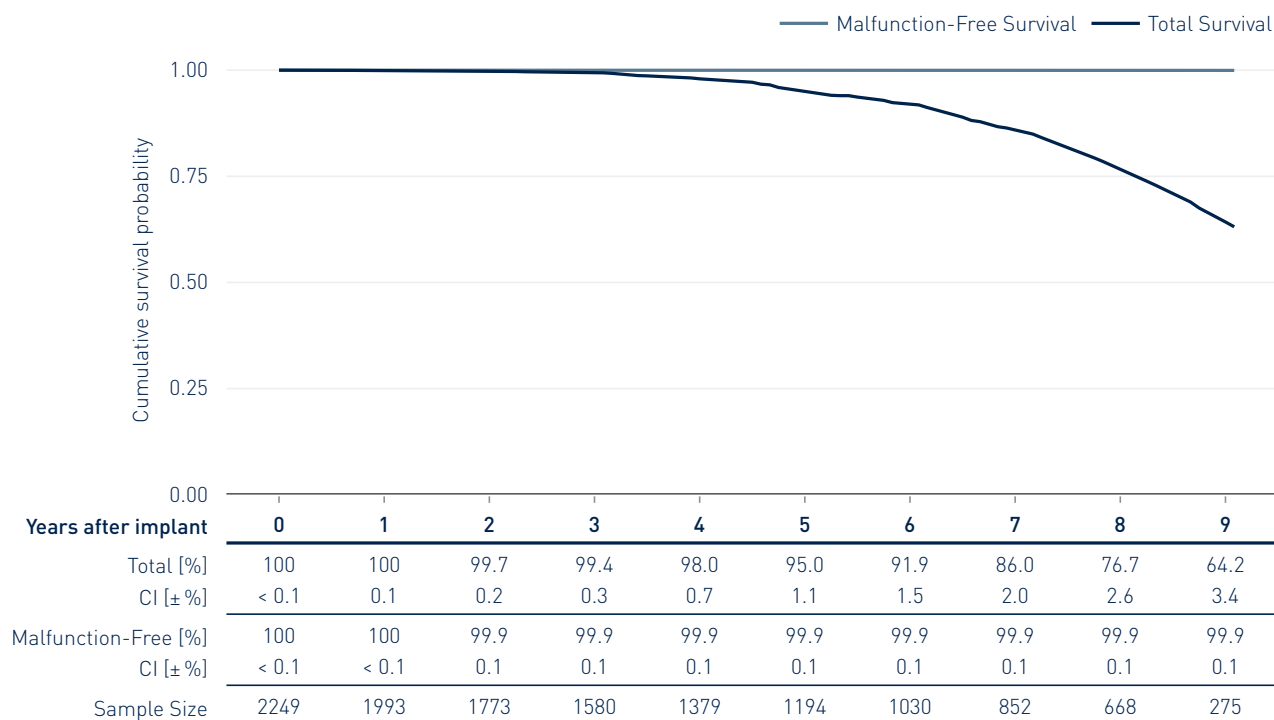


3.3 CRT Pacemakers

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 US Implants	2 249
Estimated Active US Implants	546
US Normal Battery Depletions	360

	Count	Rate
US 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



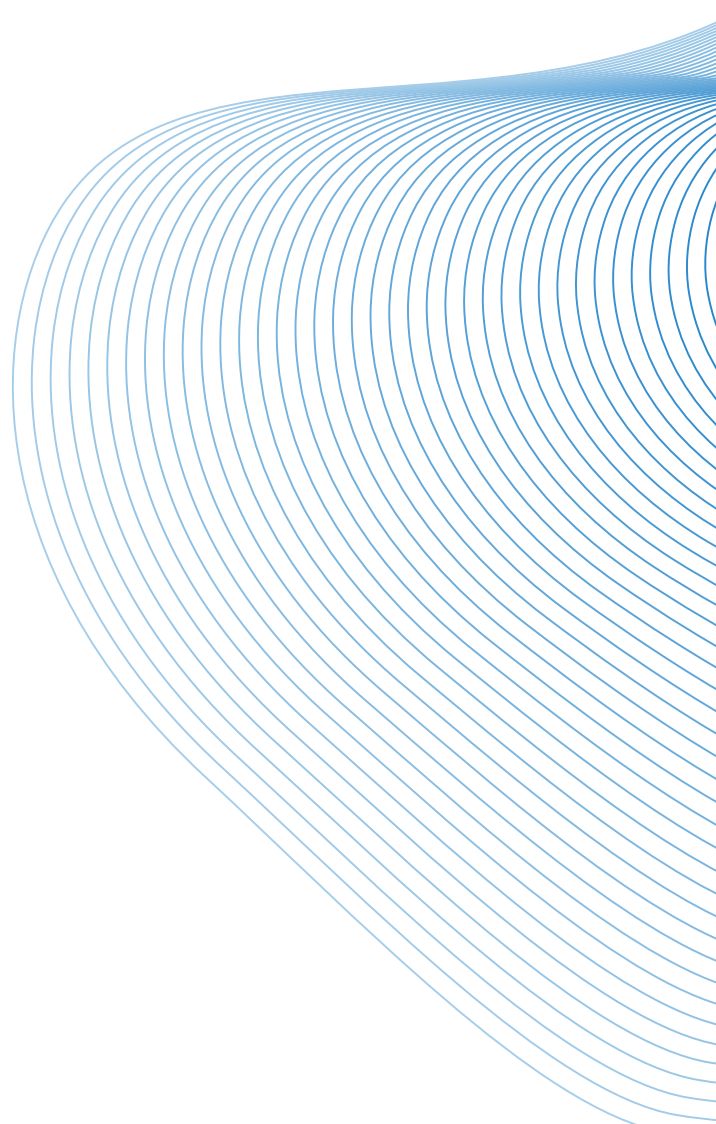


Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs



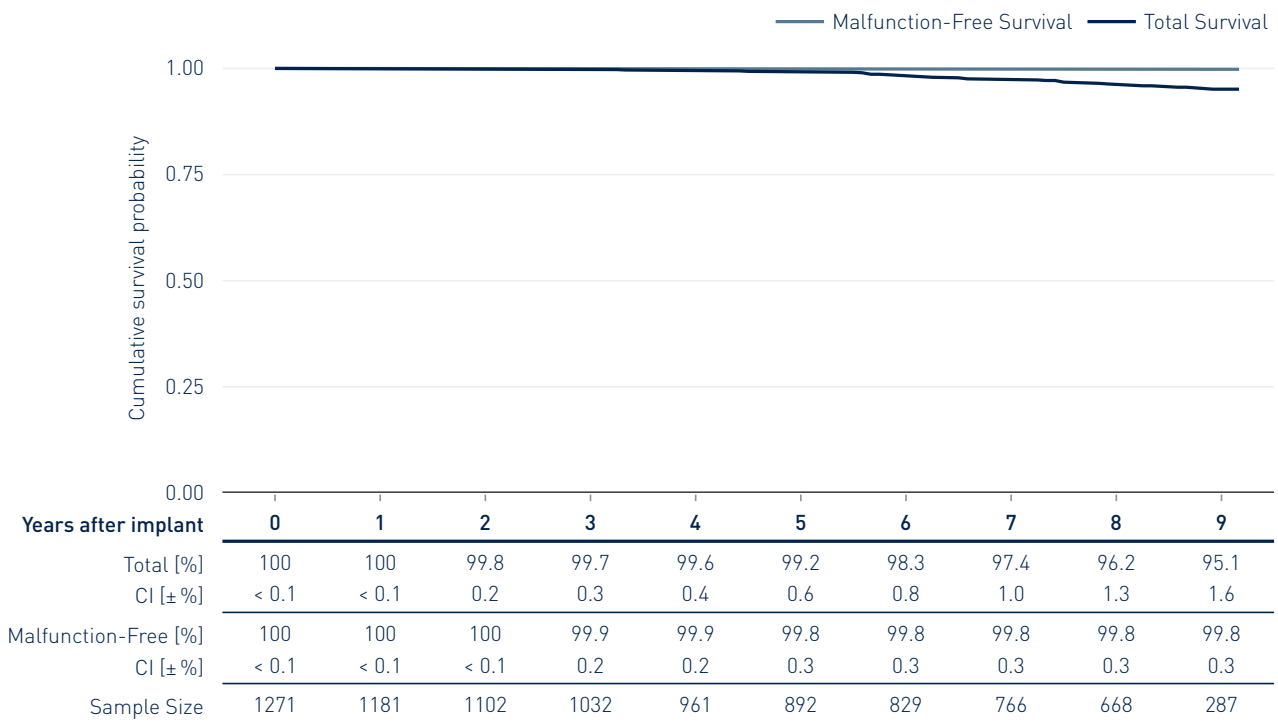


4.1 Single-Chamber ICDs

Ilesto 7*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2 460
Registered US Implants	1 271
Estimated Active US Implants	663
US Normal Battery Depletions	29

	Count	Rate
US 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 11 (Advisories) for details.

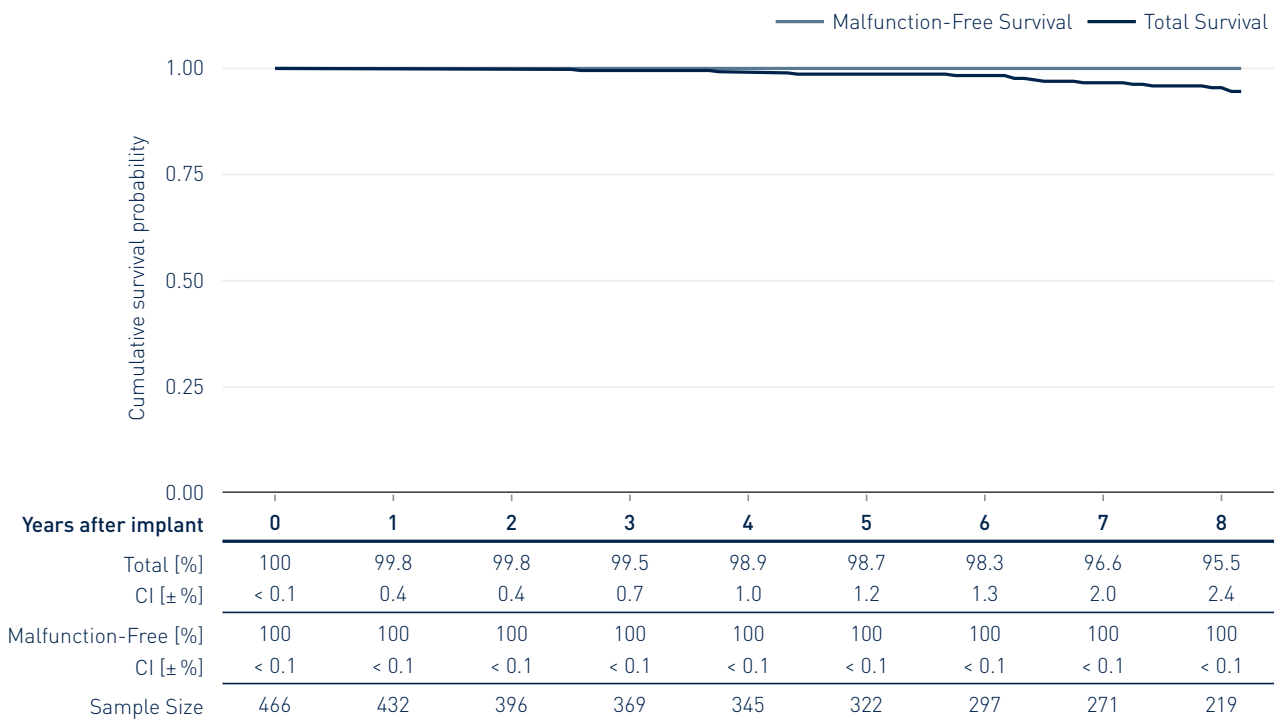


4.1 Single-Chamber ICDs

Ilesto 7 DF4*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2 390
Registered US Implants	466
Estimated Active US Implants	241
US Normal Battery Depletions	8

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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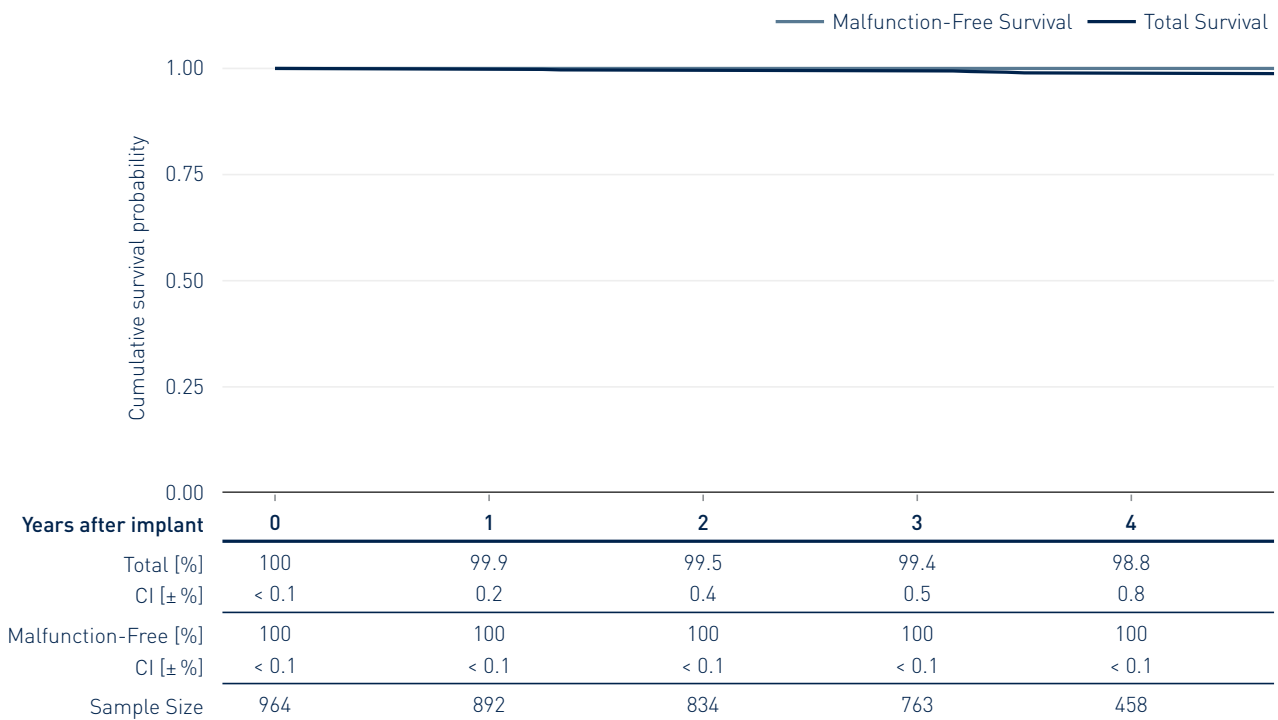


4.1 Single-Chamber ICDs

Ilivia 7*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	2 390
Registered US Implants	964
Estimated Active US Implants	721
US Normal Battery Depletions	8

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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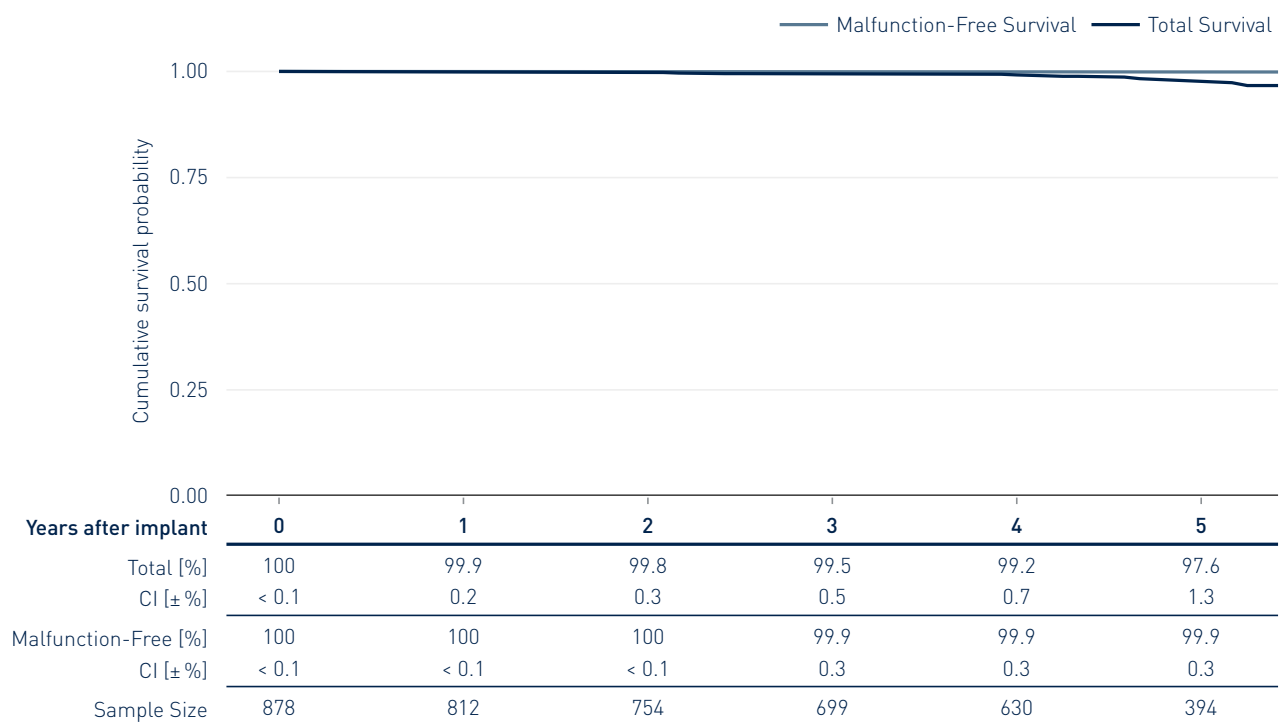


4.1 Single-Chamber ICDs

Ilivia 7 DF4*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Aug 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	4 250
Registered US Implants	878
Estimated Active US Implants	596
US Normal Battery Depletions	4

	Count	Rate
US Confirmed Malfunctions	1	0.11%
Therapy Compromised	0	0.00%
Therapy Available	1	0.11%



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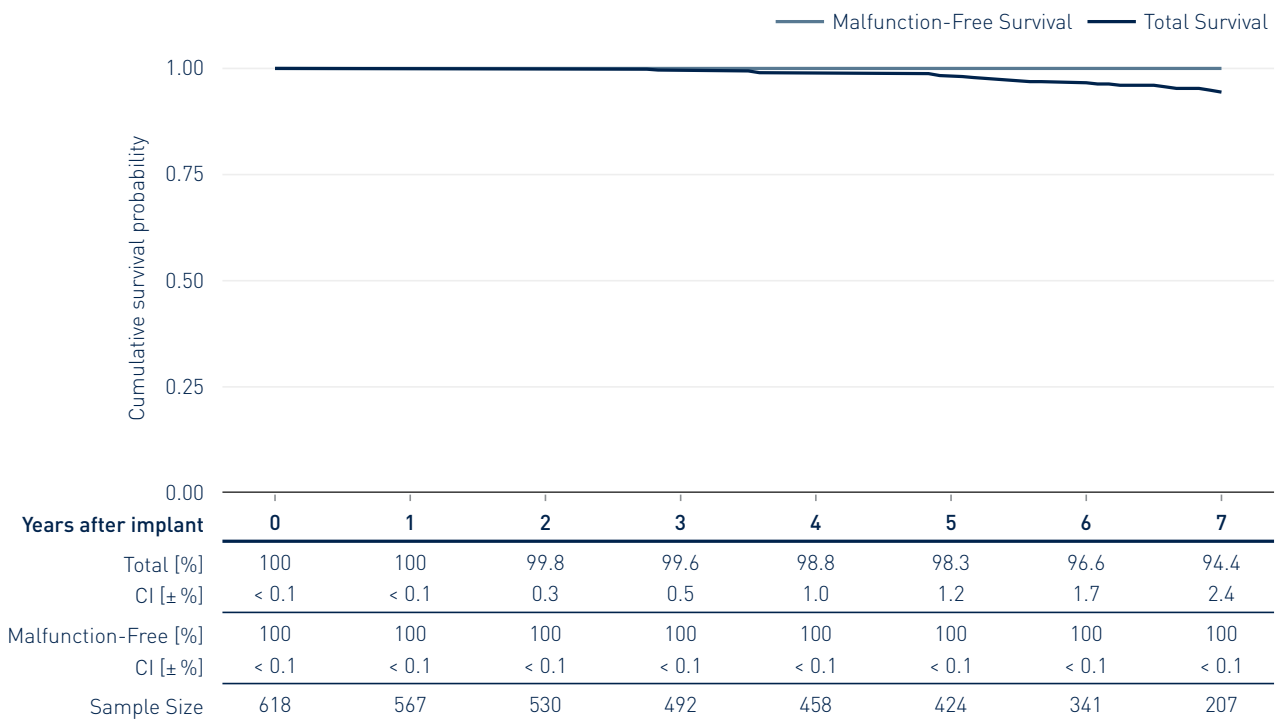


4.1 Single-Chamber ICDs

Itrevia 7*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 280
Registered US Implants	618
Estimated Active US Implants	367
US Normal Battery Depletions	18

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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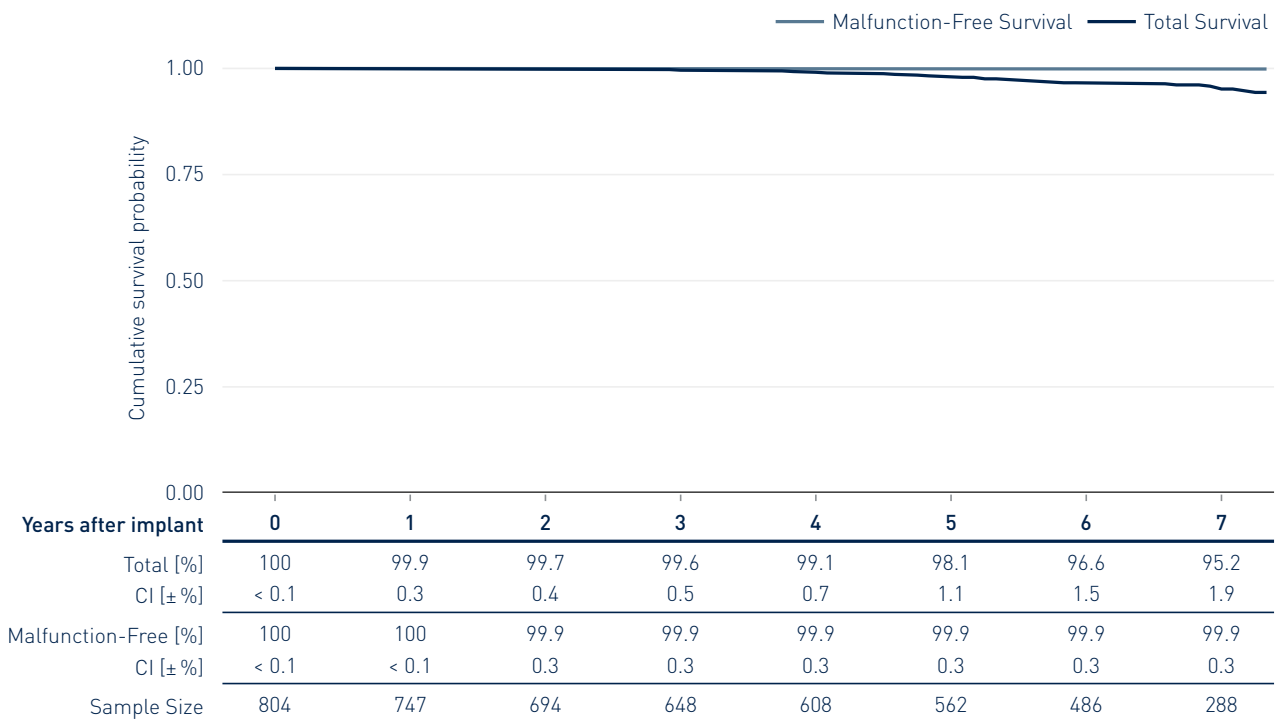


4.1 Single-Chamber ICDs

Itrevia 7 DF4*

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	1 420
Registered US Implants	804
Estimated Active US Implants	472
US Normal Battery Depletions	13

	Count	Rate
US Confirmed Malfunctions	1	0.12%
Therapy Compromised	0	0.00%
Therapy Available	1	0.12%



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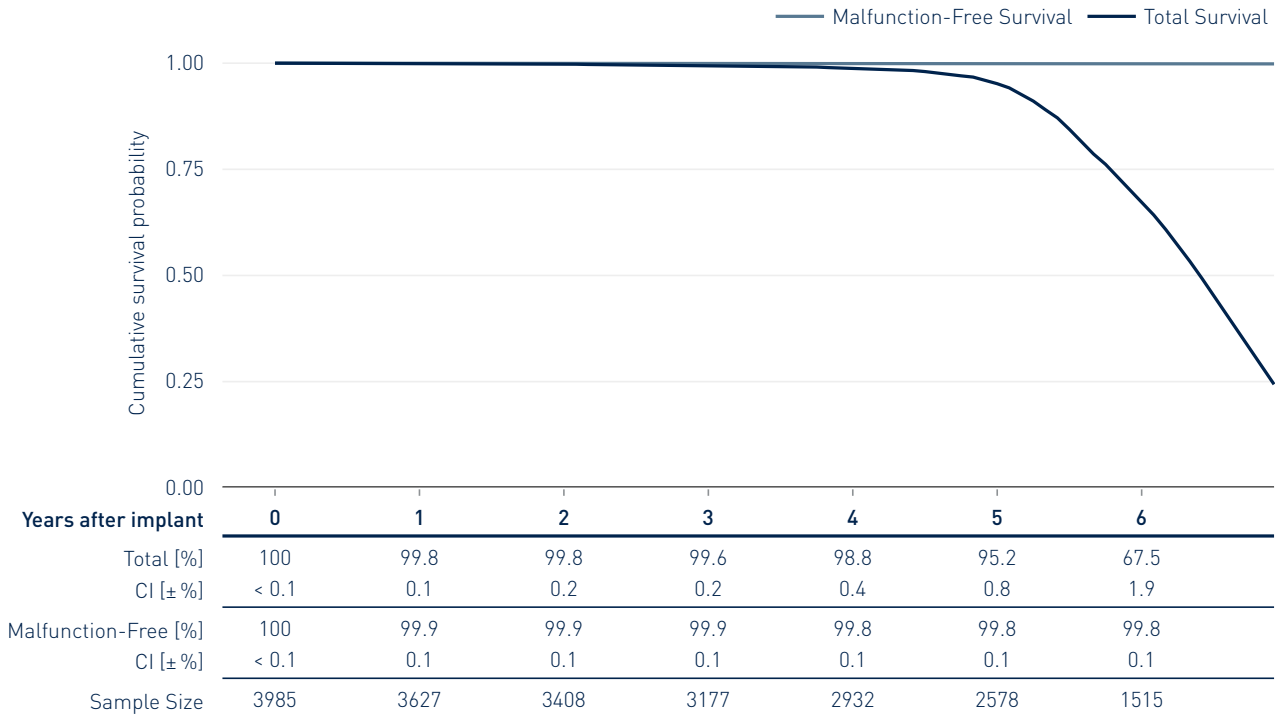


4.1 Single-Chamber ICDs

Lumax 340

Product Versions	VR, VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	27 100
Registered US Implants	3 985
Estimated Active US Implants	814
US Normal Battery Depletions	936

	Count	Rate
US Confirmed Malfunctions	6	0.15%
Therapy Compromised	4	0.10%
Therapy Available	2	0.05%



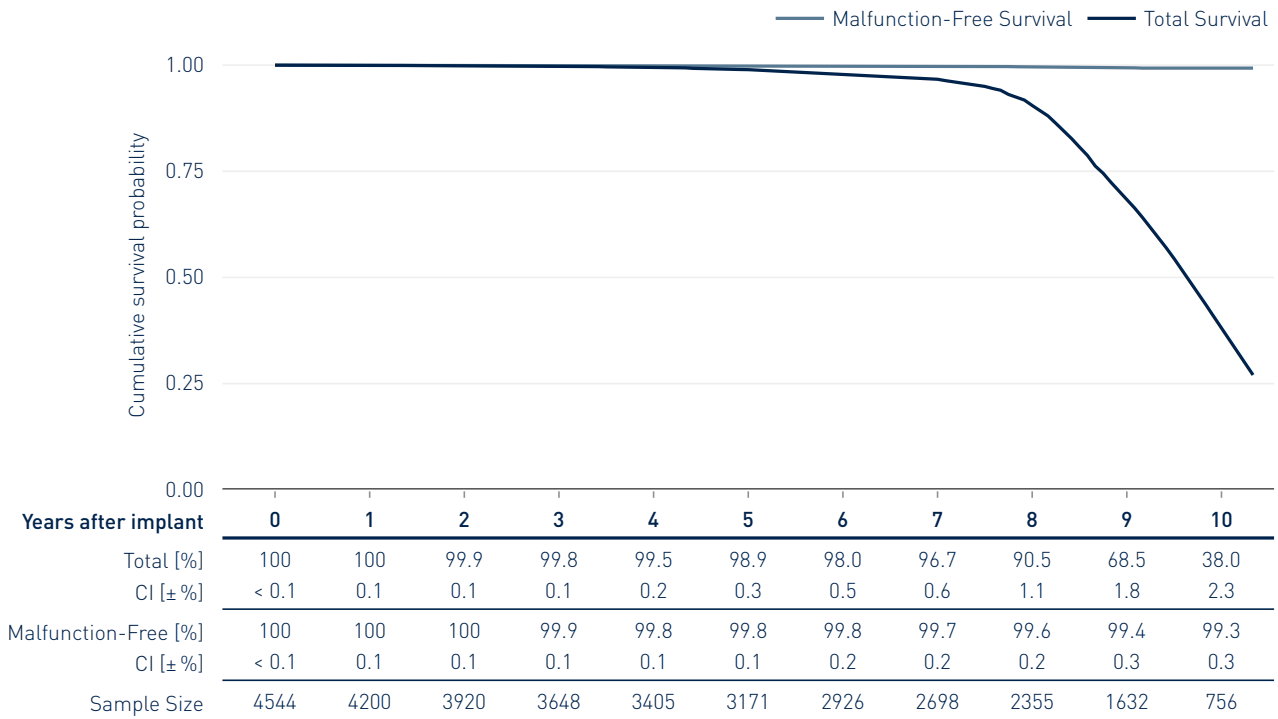


4.1 Single-Chamber ICDs

Lumax 540

Product Versions	VR-T
NBG Codes	VVE-VWIR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	20 000
Registered US Implants	4 544
Estimated Active US Implants	1 220
US Normal Battery Depletions	931

	Count	Rate
US Confirmed Malfunctions	18	0.40%
Therapy Compromised	14	0.31%
Therapy Available	4	0.09%



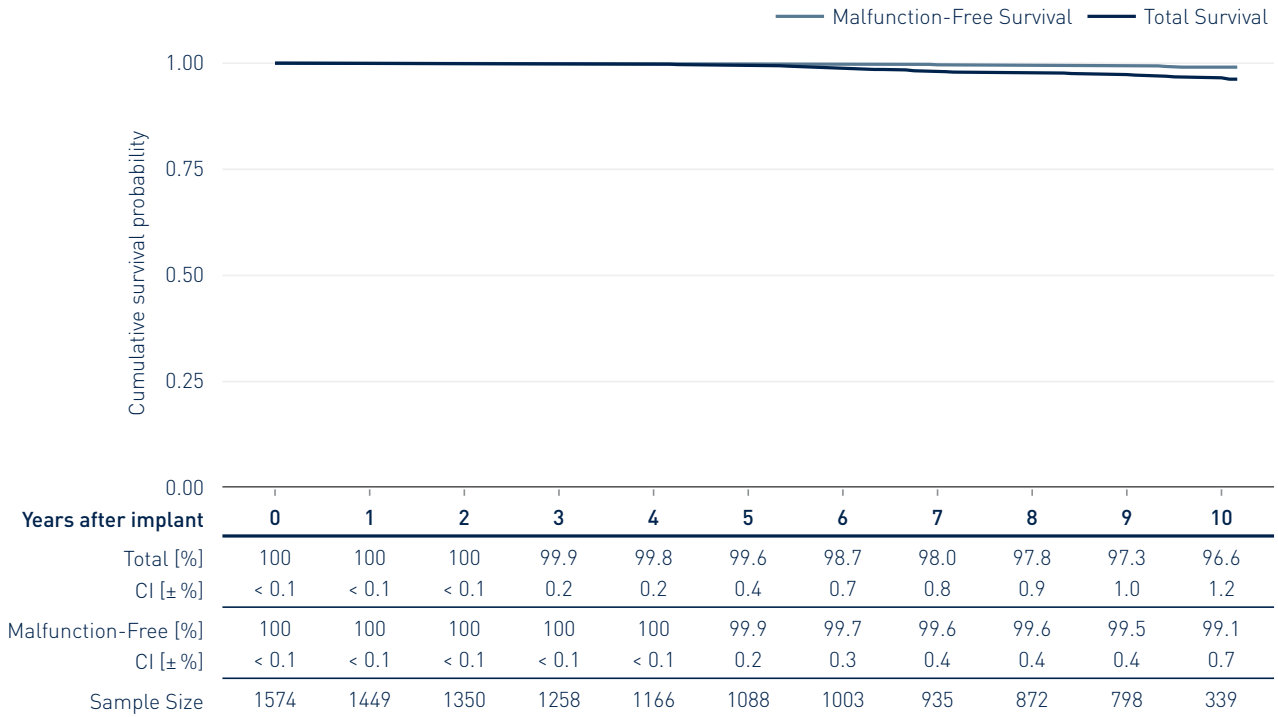


4.1 Single-Chamber ICDs

Lumax 740

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	4 810
Registered US Implants	1 573
Estimated Active US Implants	811
US Normal Battery Depletions	29

	Count	Rate
US Confirmed Malfunctions	8	0.51%
Therapy Compromised	6	0.38%
Therapy Available	2	0.13%



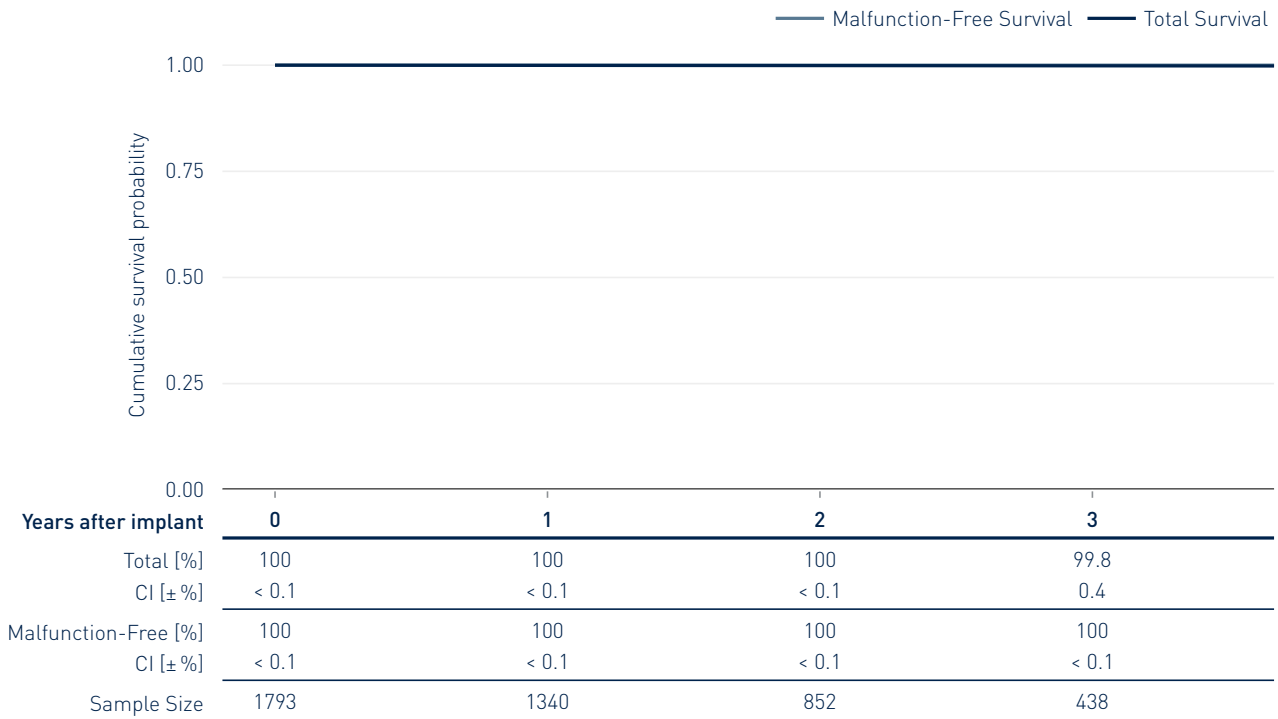


4.1 Single-Chamber ICDs

Rivacor 7

Product Versions	VR-T
NBG Codes	VVE-WVIR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	6 230
Registered US Implants	1 793
Estimated Active US Implants	1 580
US Normal Battery Depletions	1

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



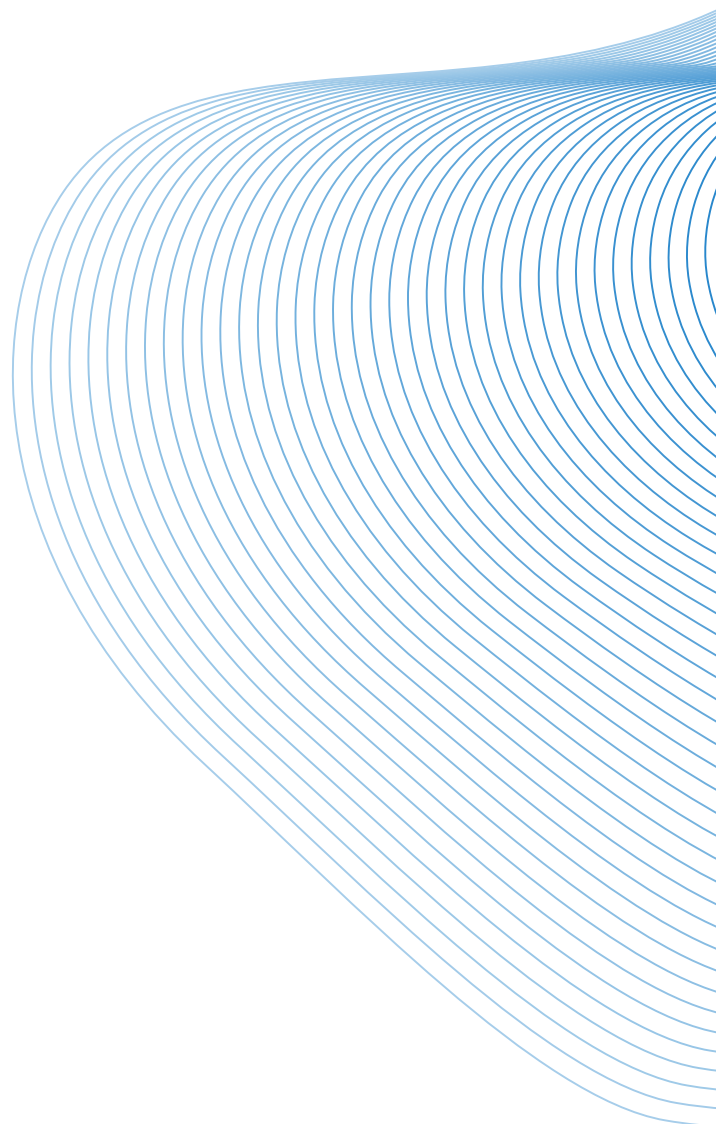


Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs



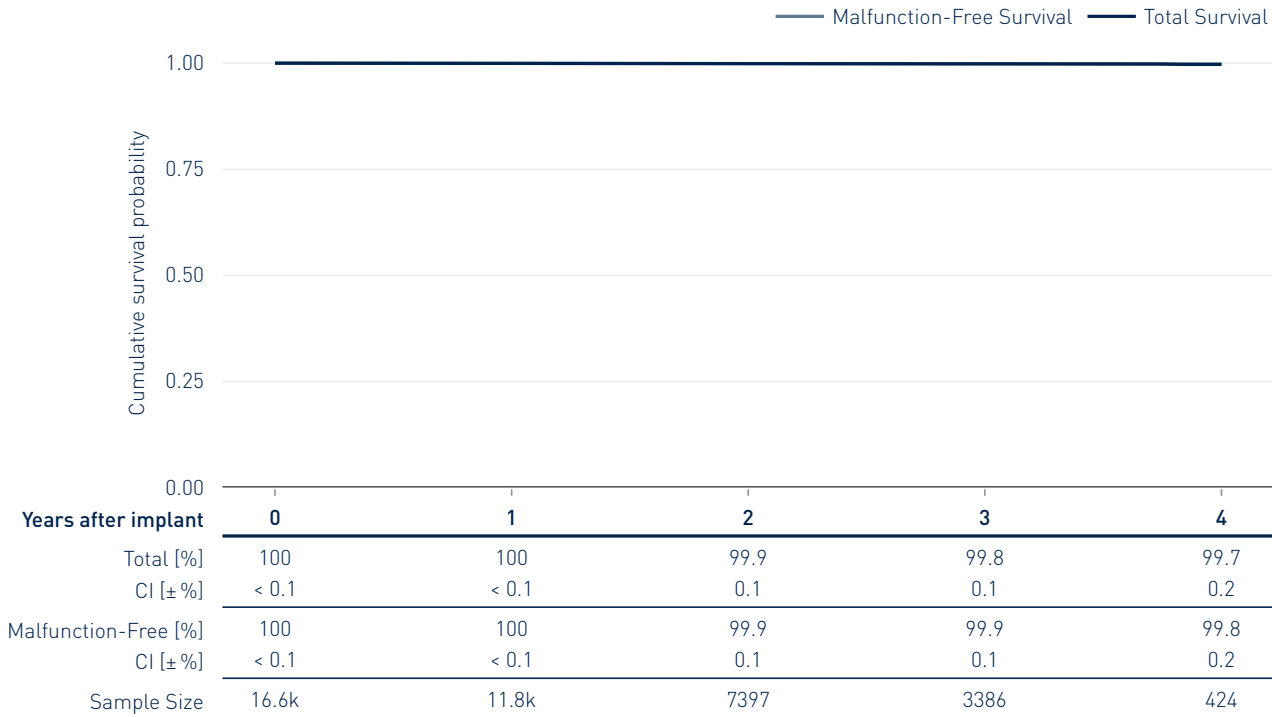


4.2 Dual-Chamber ICDs

Acticor 7 DX

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	22 000
Registered US Implants	16 630
Estimated Active US Implants	14 600
US Normal Battery Depletions	7

	Count	Rate
US Confirmed Malfunctions	12	0.07%
Therapy Compromised	9	0.05%
Therapy Available	3	0.02%



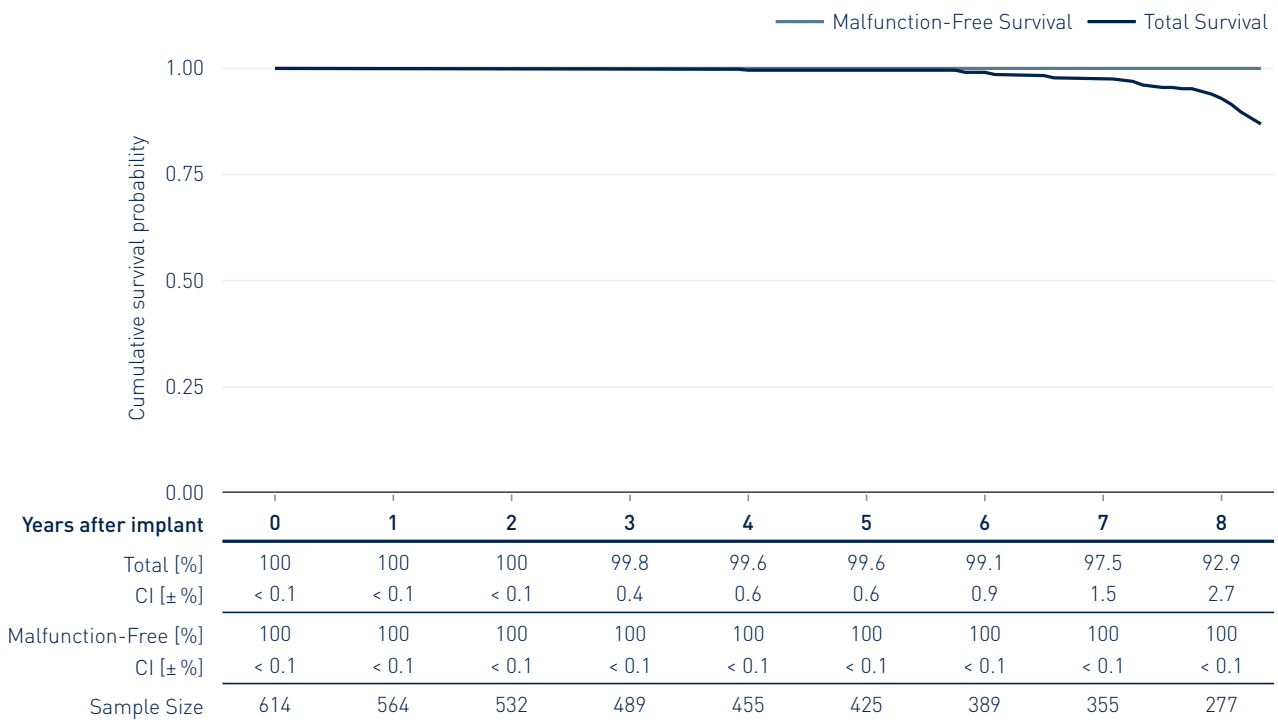


4.2 Dual-Chamber ICDs

Iforia 7*

Product Versions	DR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	2000
Registered US Implants	614
Estimated Active US Implants	268
US Normal Battery Depletions	70

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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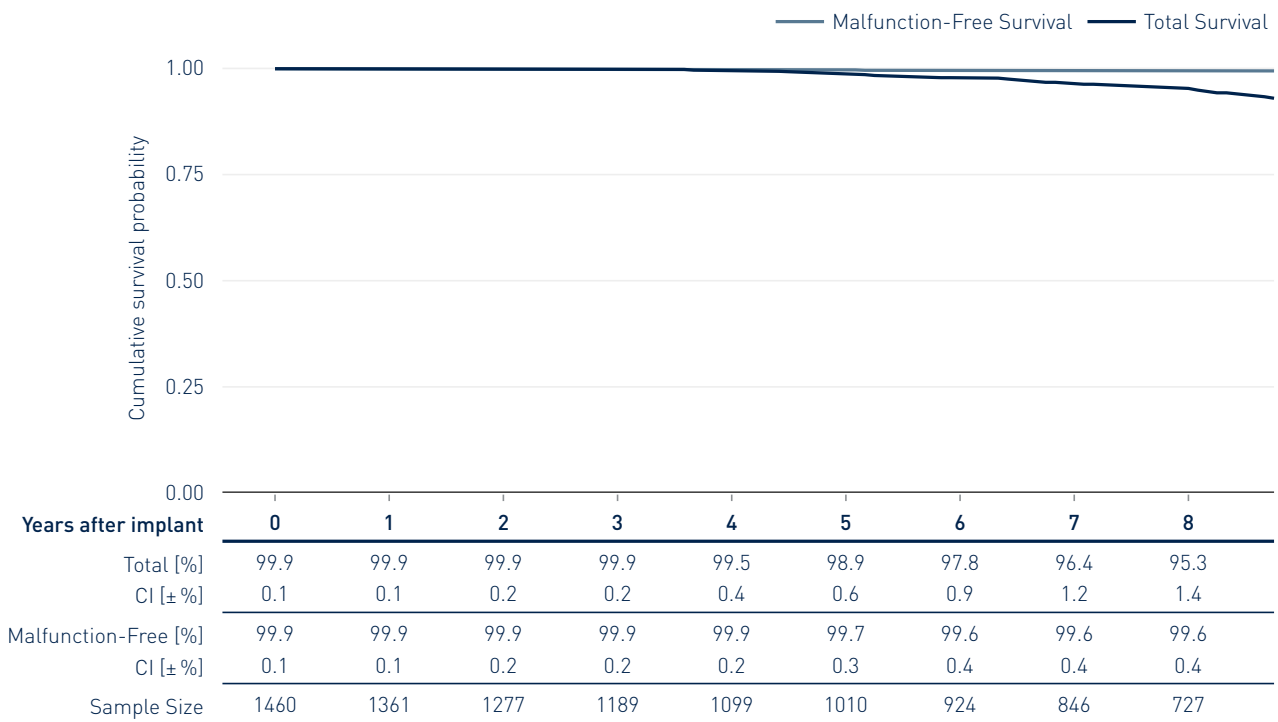


4.2 Dual-Chamber ICDs

Iforia 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	4 780
Registered US Implants	1 460
Estimated Active US Implants	733
US Normal Battery Depletions	32

	Count	Rate
US Confirmed Malfunctions	6	0.41%
Therapy Compromised	4	0.27%
Therapy Available	2	0.14%



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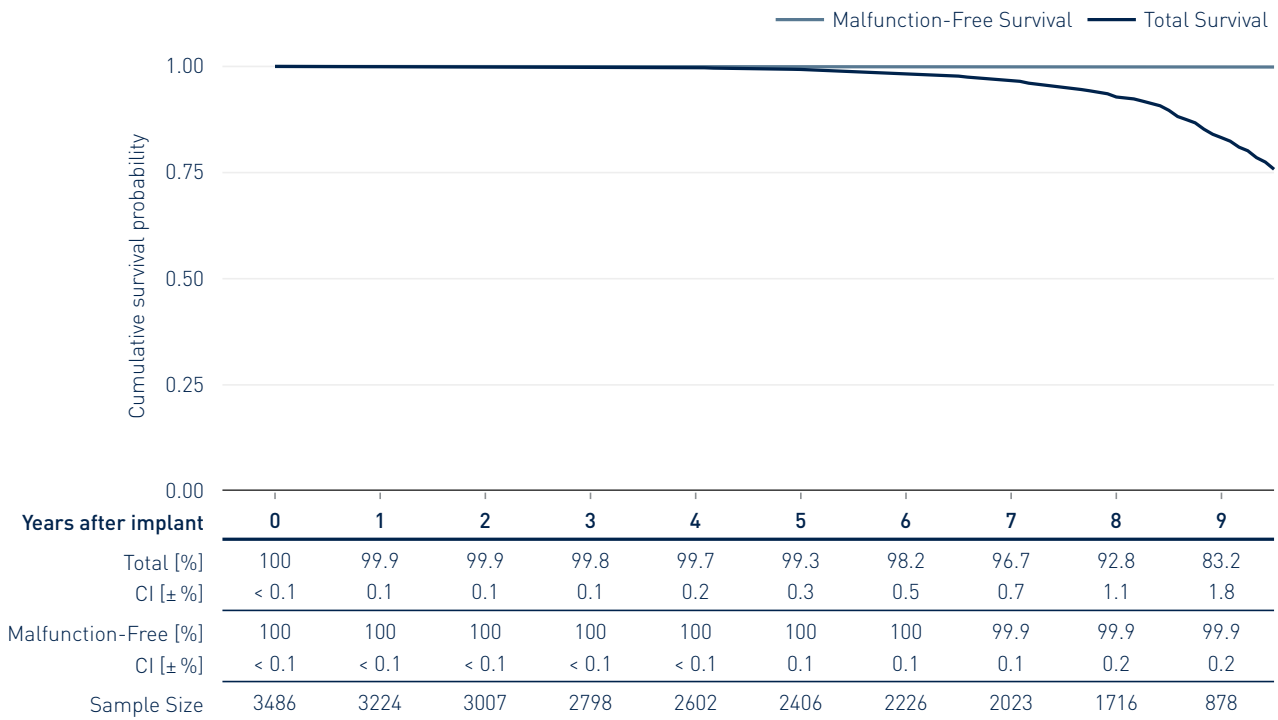


4.2 Dual-Chamber ICDs

Ilesto 7*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 110
Registered US Implants	3 486
Estimated Active US Implants	1 590
US Normal Battery Depletions	368

	Count	Rate
US Confirmed Malfunctions	3	0.09%
Therapy Compromised	2	0.06%
Therapy Available	1	0.03%



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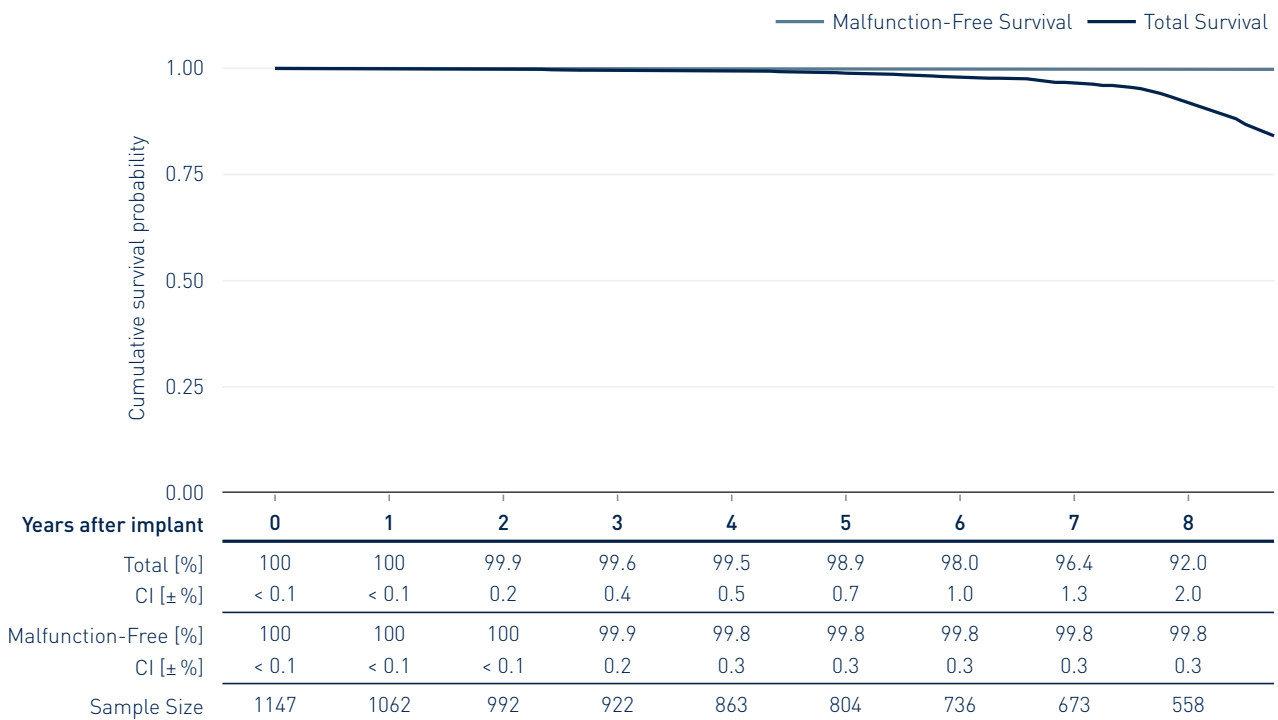


4.2 Dual-Chamber ICDs

Ilesto 7 DF4*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jul 2013
Worldwide Distributed Devices	3 730
Registered US Implants	1 147
Estimated Active US Implants	589
US Normal Battery Depletions	81

	Count	Rate
US Confirmed Malfunctions	2	0.17%
Therapy Compromised	0	0.00%
Therapy Available	2	0.17%



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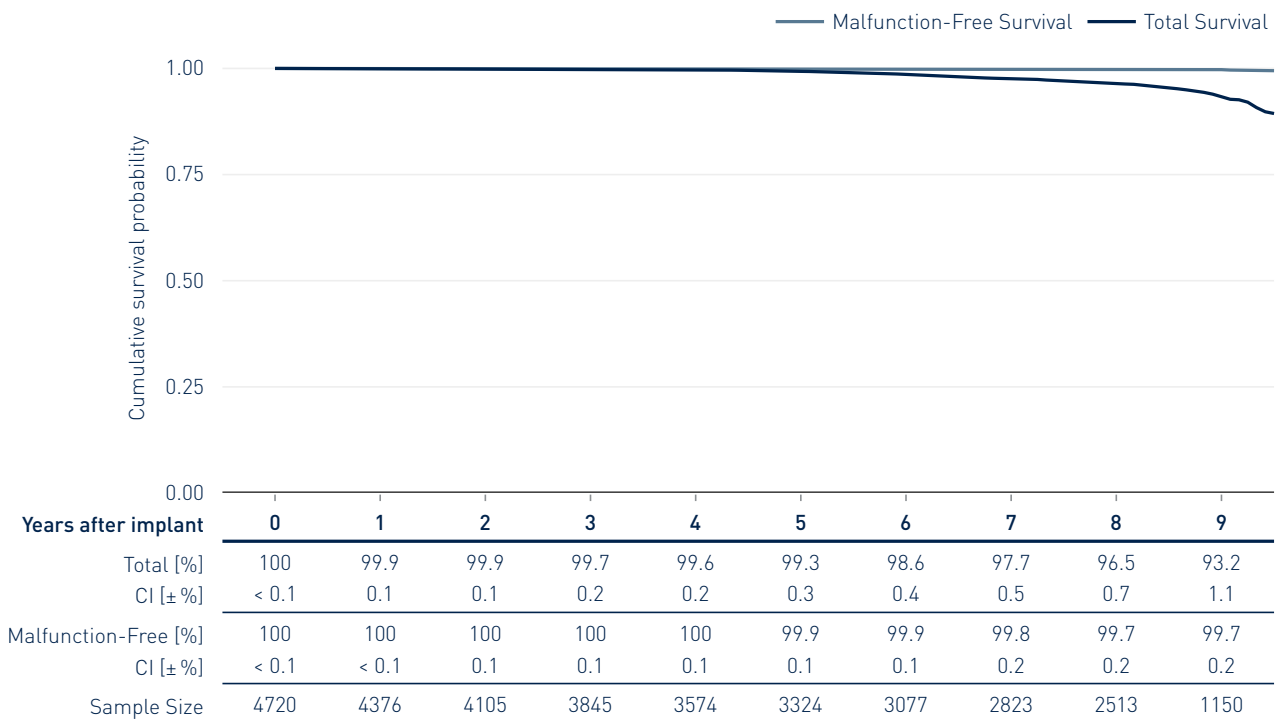


4.2 Dual-Chamber ICDs

Ilesto 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	6 600
Registered US Implants	4 720
Estimated Active US Implants	2 400
US Normal Battery Depletions	170

	Count	Rate
US Confirmed Malfunctions	12	0.25%
Therapy Compromised	7	0.15%
Therapy Available	5	0.11%



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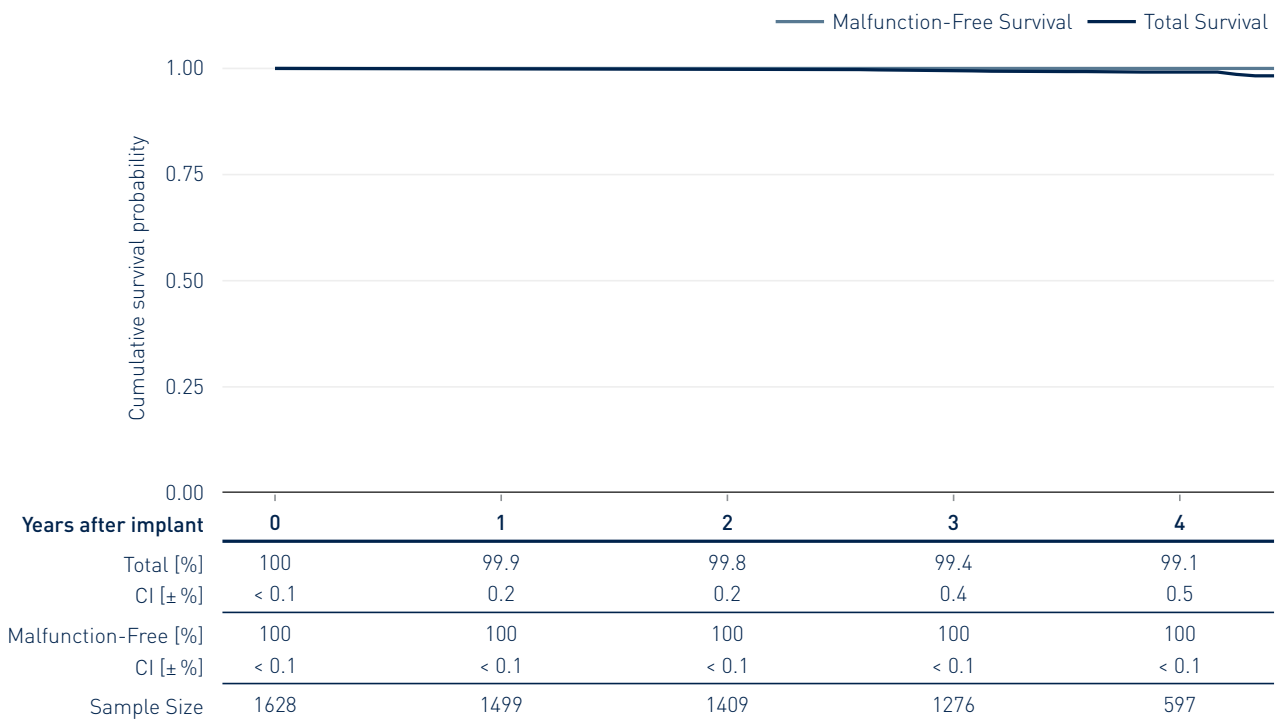


4.2 Dual-Chamber ICDs

Ilivia 7*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Mar 2017
Worldwide Distributed Devices	3 510
Registered US Implants	1 628
Estimated Active US Implants	1 250
US Normal Battery Depletions	5

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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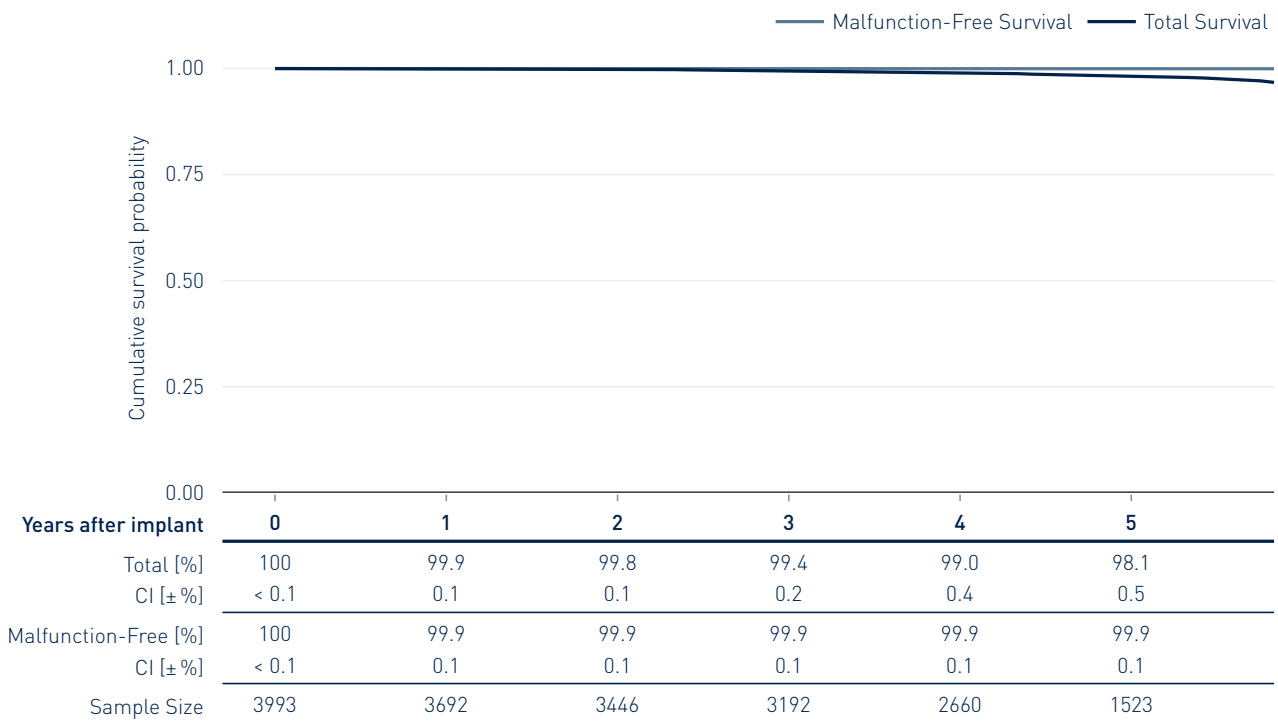


4.2 Dual-Chamber ICDs

Ilivia 7 DF4*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Aug 2016
Worldwide Distributed Devices	8 580
Registered US Implants	3 993
Estimated Active US Implants	2 780
US Normal Battery Depletions	34

	Count	Rate
US Confirmed Malfunctions	3	0.08%
Therapy Compromised	3	0.08%
Therapy Available	0	0.00%



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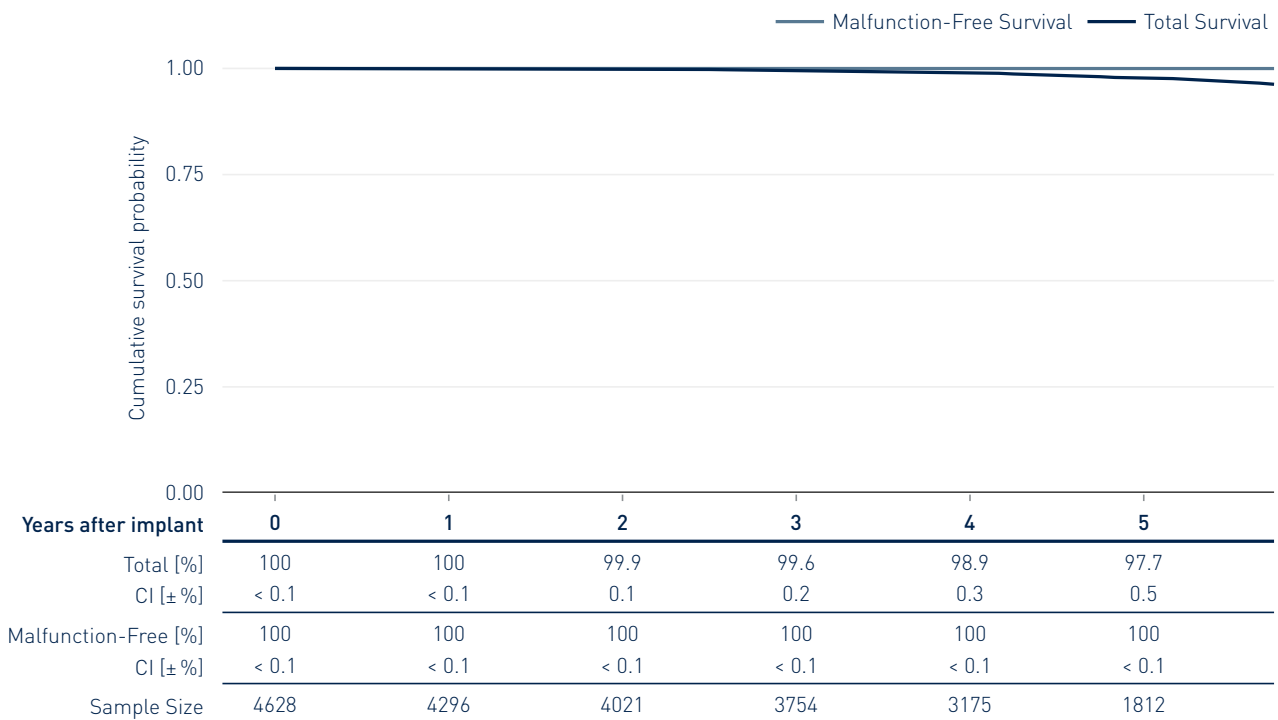


4.2 Dual-Chamber ICDs

Intica 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	May 2017
CE Market Release	Sep 2016
Worldwide Distributed Devices	6 850
Registered US Implants	4 628
Estimated Active US Implants	3 270
US Normal Battery Depletions	38

	Count	Rate
US Confirmed Malfunctions	1	0.02%
Therapy Compromised	1	0.02%
Therapy Available	0	0.00%



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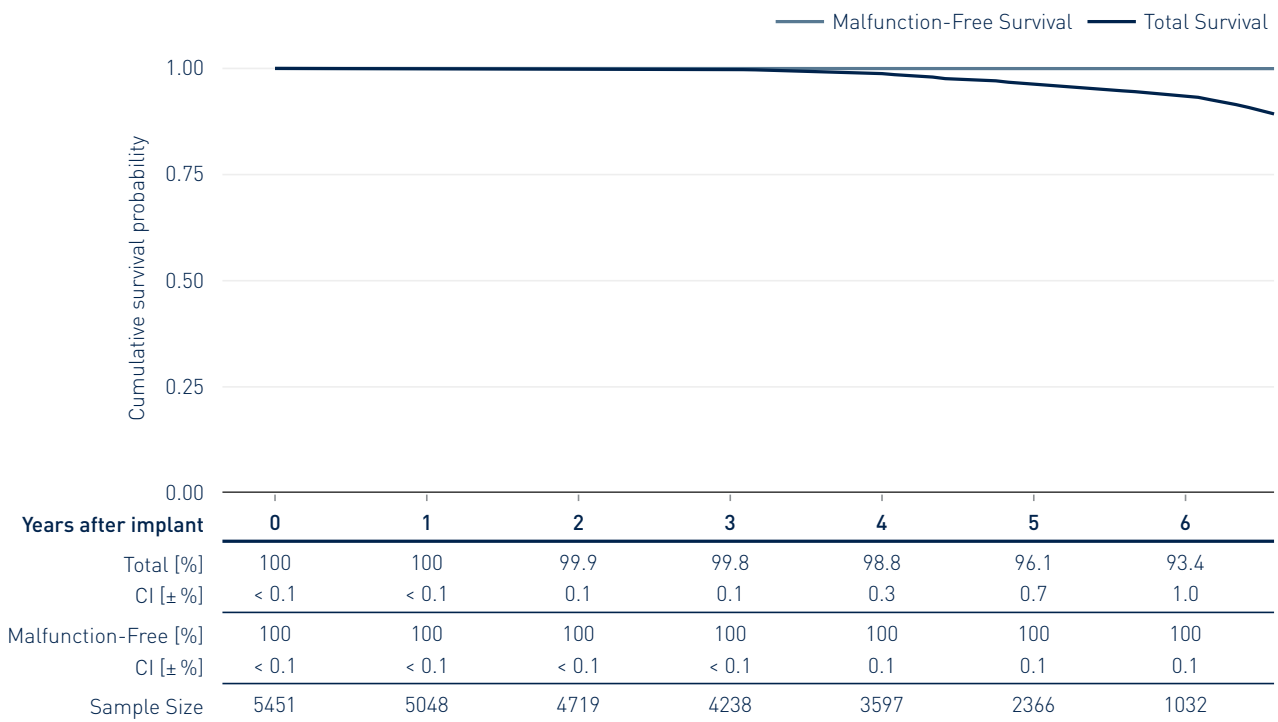


4.2 Dual-Chamber ICDs

Inventra 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	45
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	5 790
Registered US Implants	5 451
Estimated Active US Implants	3 450
US Normal Battery Depletions	82

	Count	Rate
US Confirmed Malfunctions	2	0.04%
Therapy Compromised	1	0.02%
Therapy Available	1	0.02%



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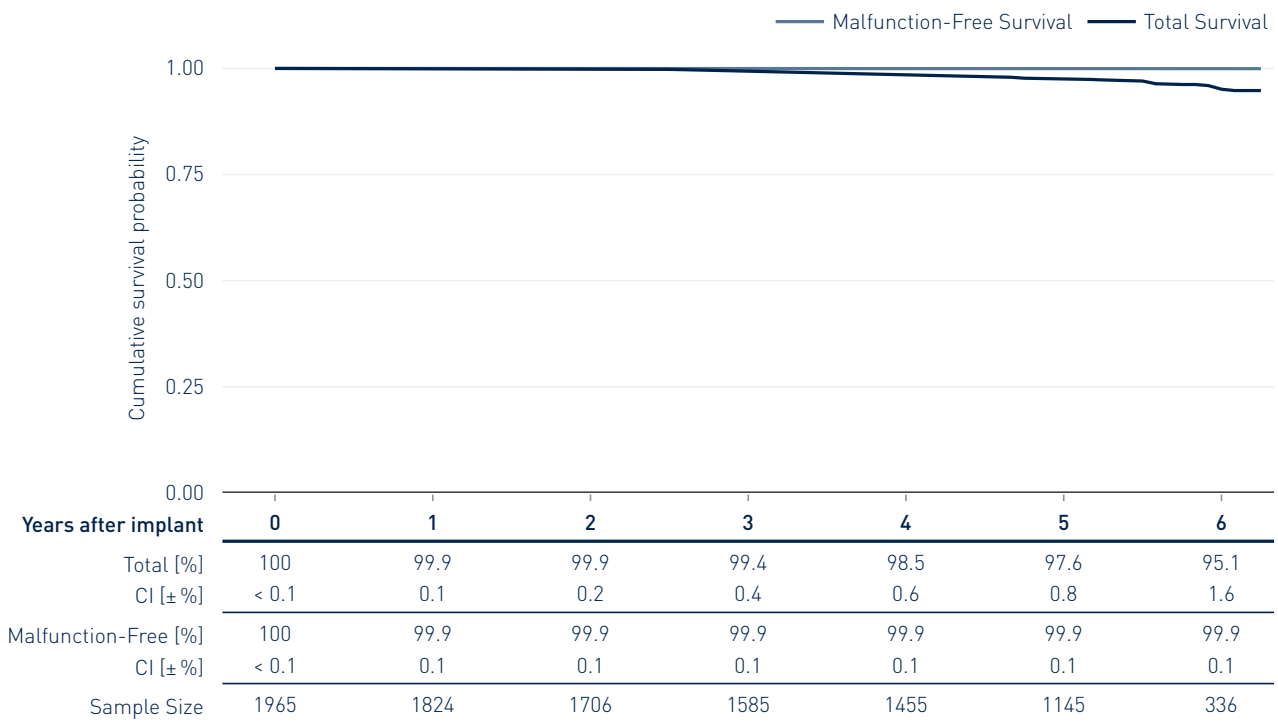


4.2 Dual-Chamber ICDs

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 US Implants	1 965
Estimated Active US Implants	1 290
US Normal Battery Depletions	54

	Count	Rate
US Confirmed Malfunctions	1	0.05%
Therapy Compromised	1	0.05%
Therapy Available	0	0.00%



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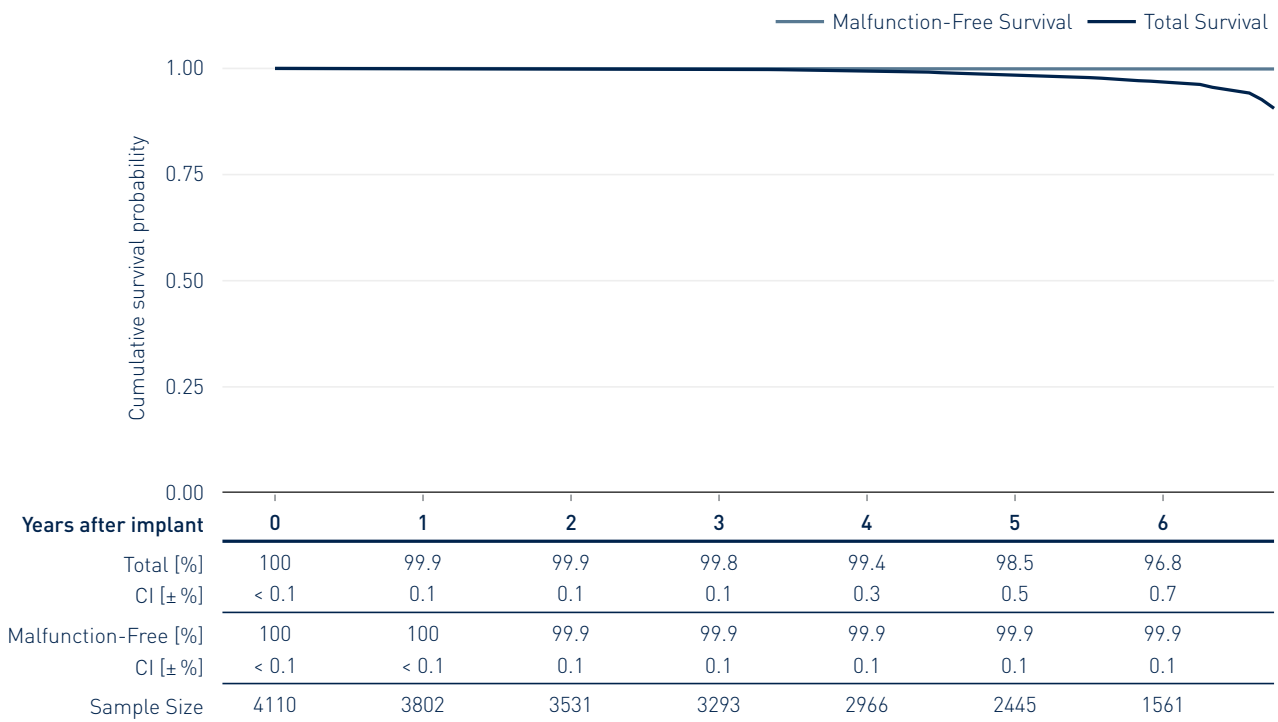


4.2 Dual-Chamber ICDs

Iperia 7 DF4*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	7 510
Registered US Implants	4 110
Estimated Active US Implants	2 500
US Normal Battery Depletions	167

	Count	Rate
US Confirmed Malfunctions	4	0.10%
Therapy Compromised	1	0.02%
Therapy Available	3	0.07%



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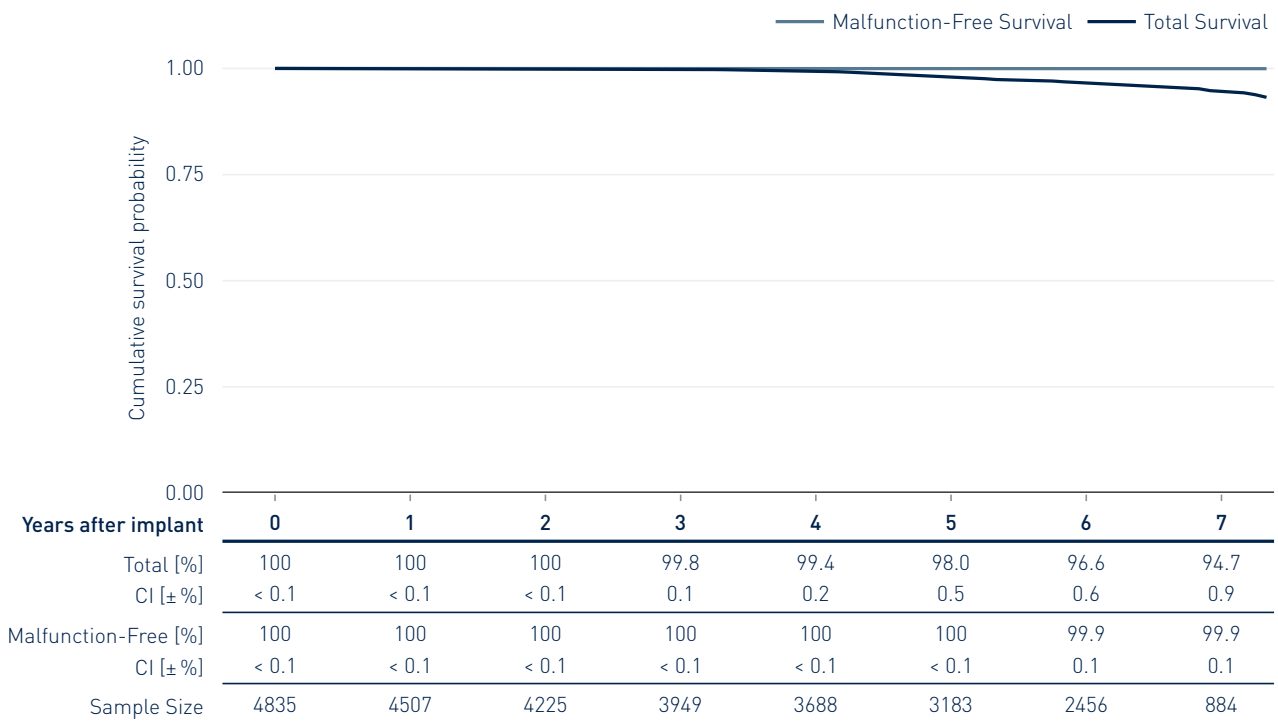


4.2 Dual-Chamber ICDs

Iperia 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Dec 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	6 540
Registered US Implants	4 835
Estimated Active US Implants	2 960
US Normal Battery Depletions	77

	Count	Rate
US Confirmed Malfunctions	2	0.04%
Therapy Compromised	1	0.02%
Therapy Available	1	0.02%



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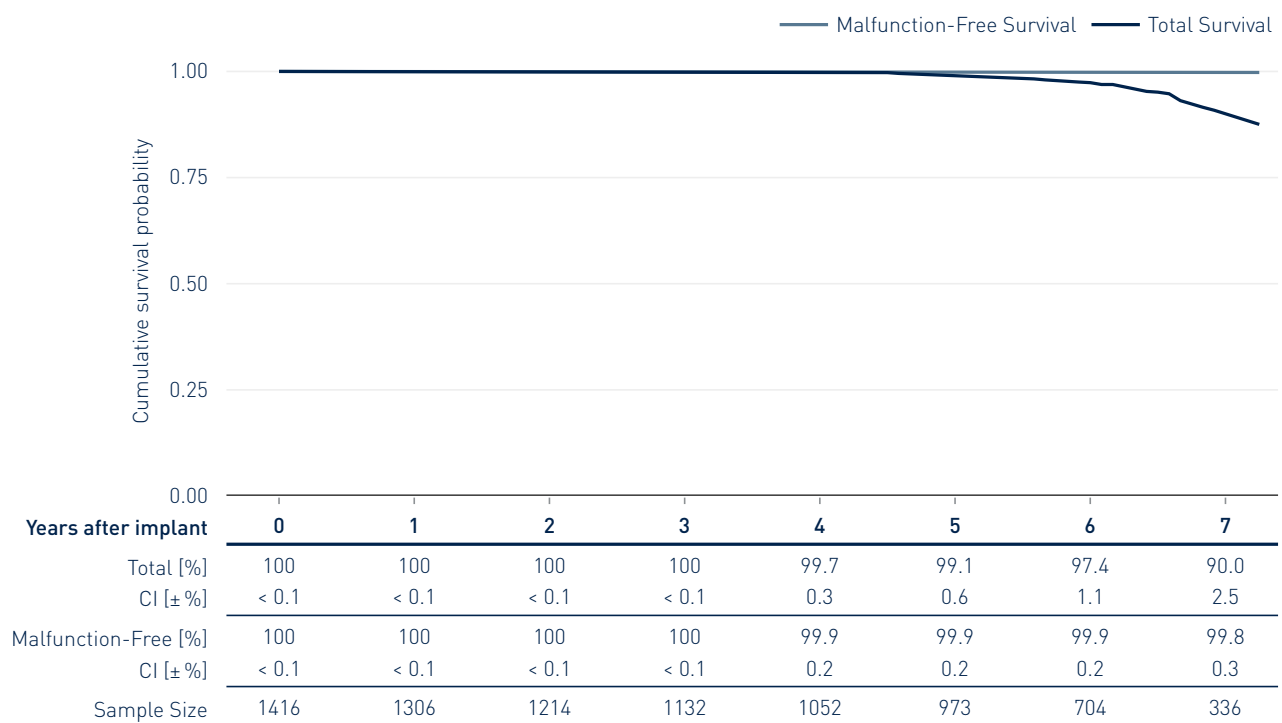


4.2 Dual-Chamber ICDs

Itrevia 7*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 170
Registered US Implants	1 416
Estimated Active US Implants	794
US Normal Battery Depletions	97

	Count	Rate
US Confirmed Malfunctions	2	0.14%
Therapy Compromised	2	0.14%
Therapy Available	0	0.00%



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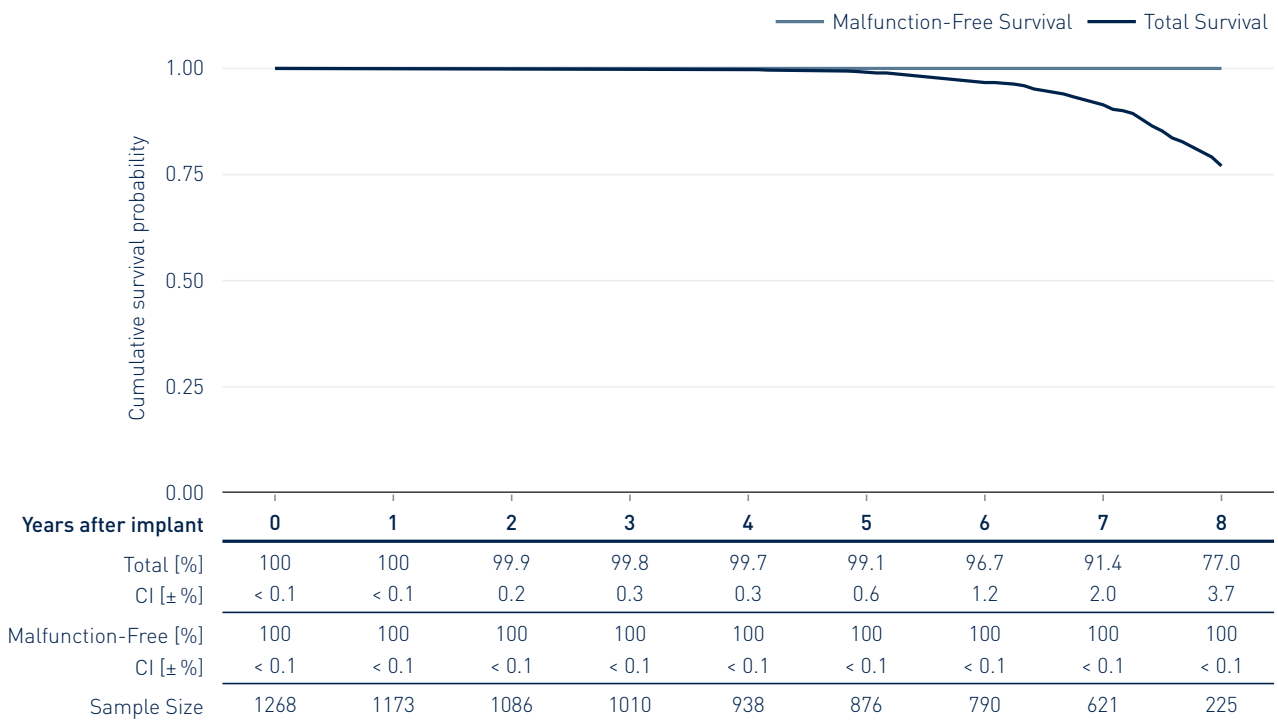


4.2 Dual-Chamber ICDs

Itrevia 7 DF4*

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2340
Registered US Implants	1 268
Estimated Active US Implants	597
US Normal Battery Depletions	150

	Count	Rate
US Confirmed Malfunctions	0	0.00%
Therapy Compromised	0	0.00%
Therapy Available	0	0.00%



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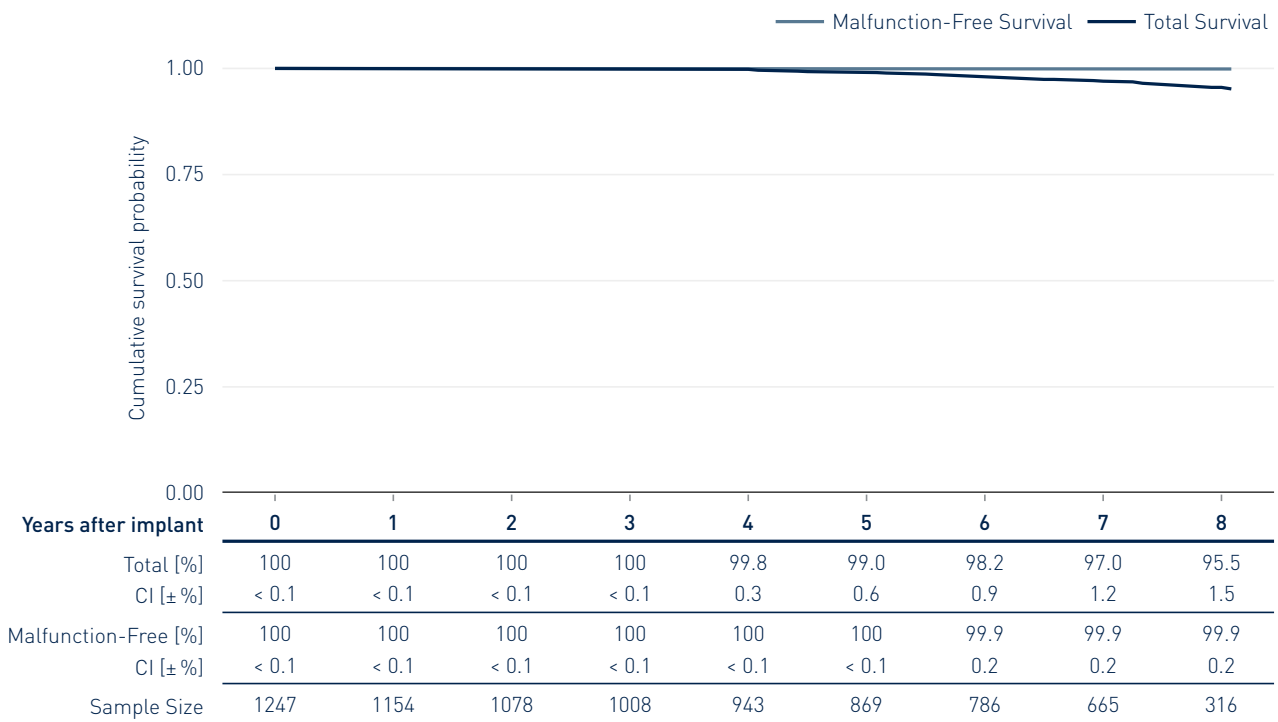


4.2 Dual-Chamber ICDs

Itrevia 7 DX*

Product Versions	VR-T
NBG Codes	VVE-VDDR
Maximum Energy J	40
US Market Release	Mar 2015
CE Market Release	Dec 2014
Worldwide Distributed Devices	2 750
Registered US Implants	1 247
Estimated Active US Implants	683
US Normal Battery Depletions	24

	Count	Rate
US Confirmed Malfunctions	1	0.08%
Therapy Compromised	1	0.08%
Therapy Available	0	0.00%



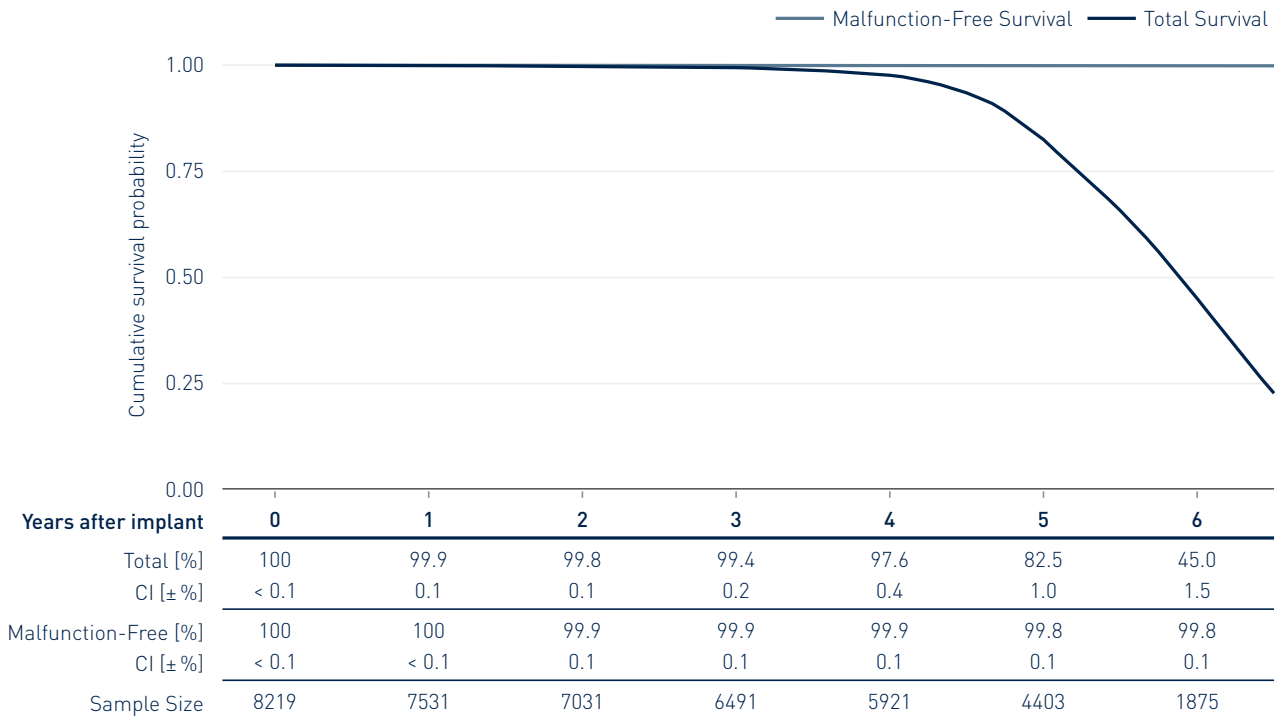
*A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.2 Dual-Chamber ICDs

Lumax 340

Product Versions	DR, DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Feb 2007
Worldwide Distributed Devices	26 400
Registered US Implants	8 219
Estimated Active US Implants	1 490
US Normal Battery Depletions	2 159

	Count	Rate
US Confirmed Malfunctions	10	0.12%
Therapy Compromised	8	0.10%
Therapy Available	2	0.02%



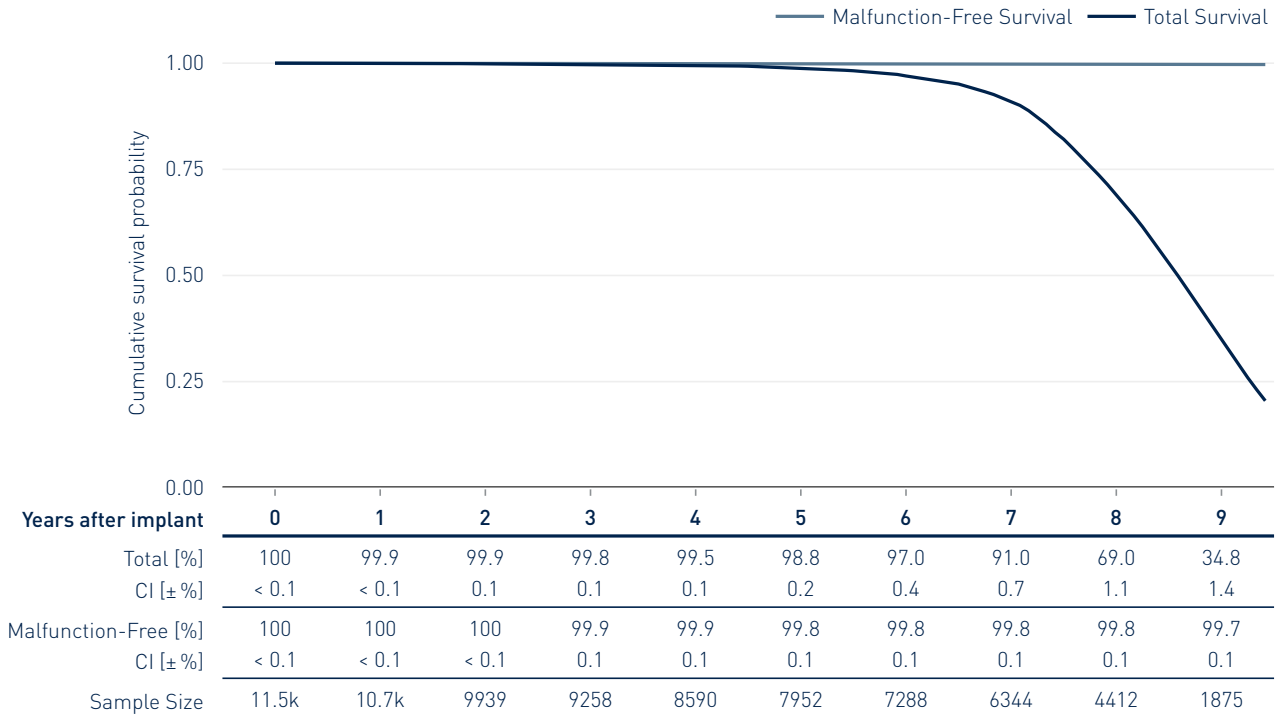


4.2 Dual-Chamber ICDs

Lumax 540

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	26 000
Registered US Implants	11 511
Estimated Active US Implants	2 710
US Normal Battery Depletions	2 932

	Count	Rate
US Confirmed Malfunctions	24	0.21%
Therapy Compromised	14	0.12%
Therapy Available	10	0.09%



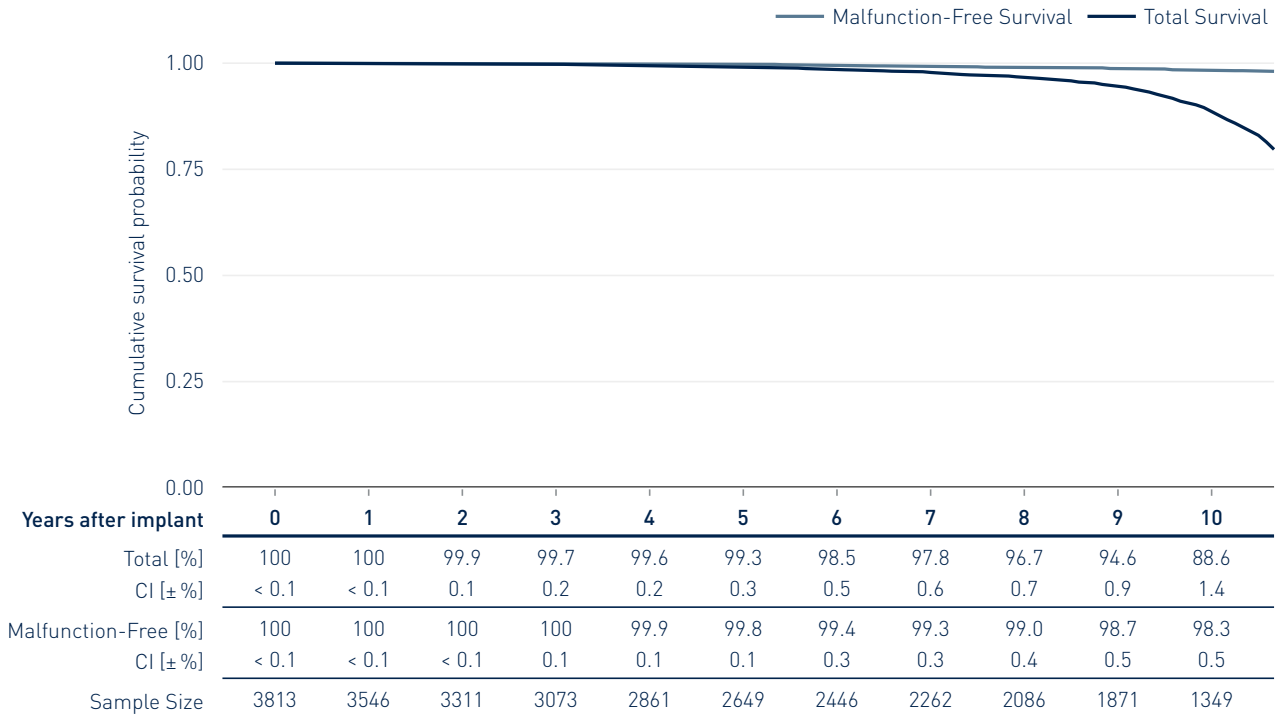


4.2 Dual-Chamber ICDs

Lumax 740

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Sep 2012
CE Market Release	Apr 2012
Worldwide Distributed Devices	7 980
Registered US Implants	3 813
Estimated Active US Implants	1 520
US Normal Battery Depletions	321

	Count	Rate
US Confirmed Malfunctions	43	1.13%
Therapy Compromised	31	0.81%
Therapy Available	12	0.31%

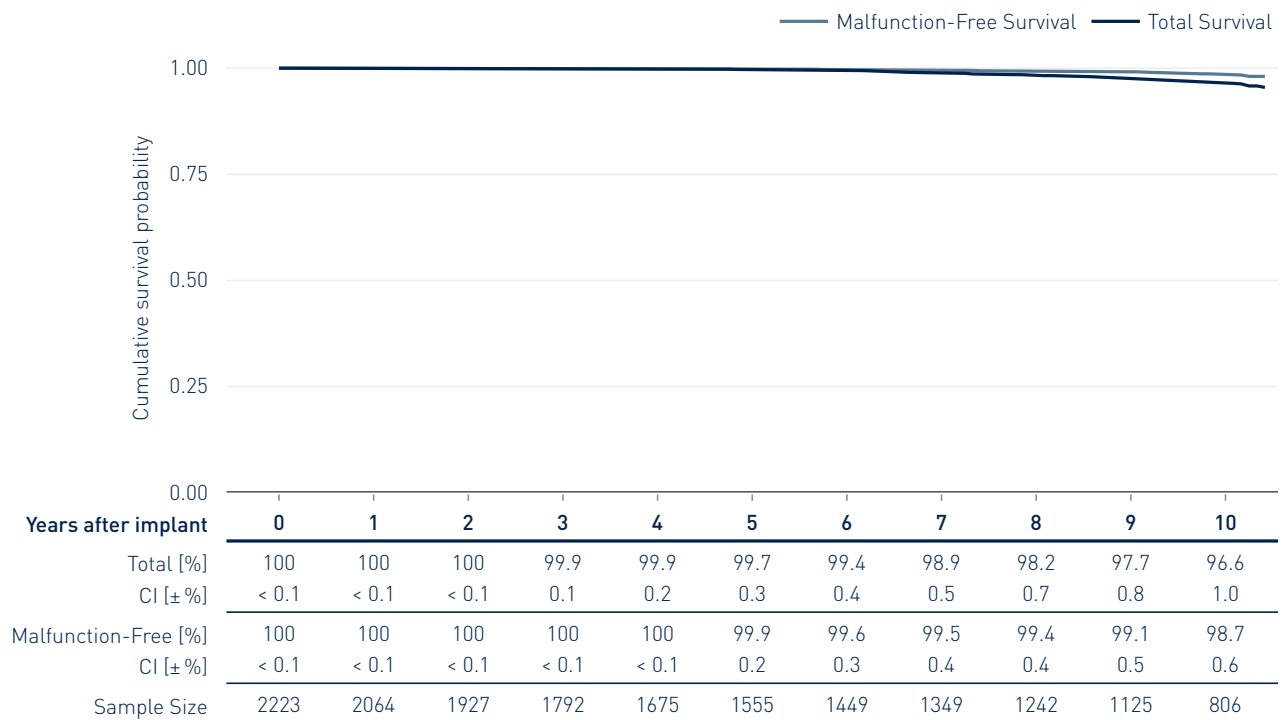


4.2 Dual-Chamber ICDs

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 US Implants	2 223
Estimated Active US Implants	1 070
US Normal Battery Depletions	42

	Count	Rate
US Confirmed Malfunctions	22	0.99%
Therapy Compromised	16	0.72%
Therapy Available	6	0.27%



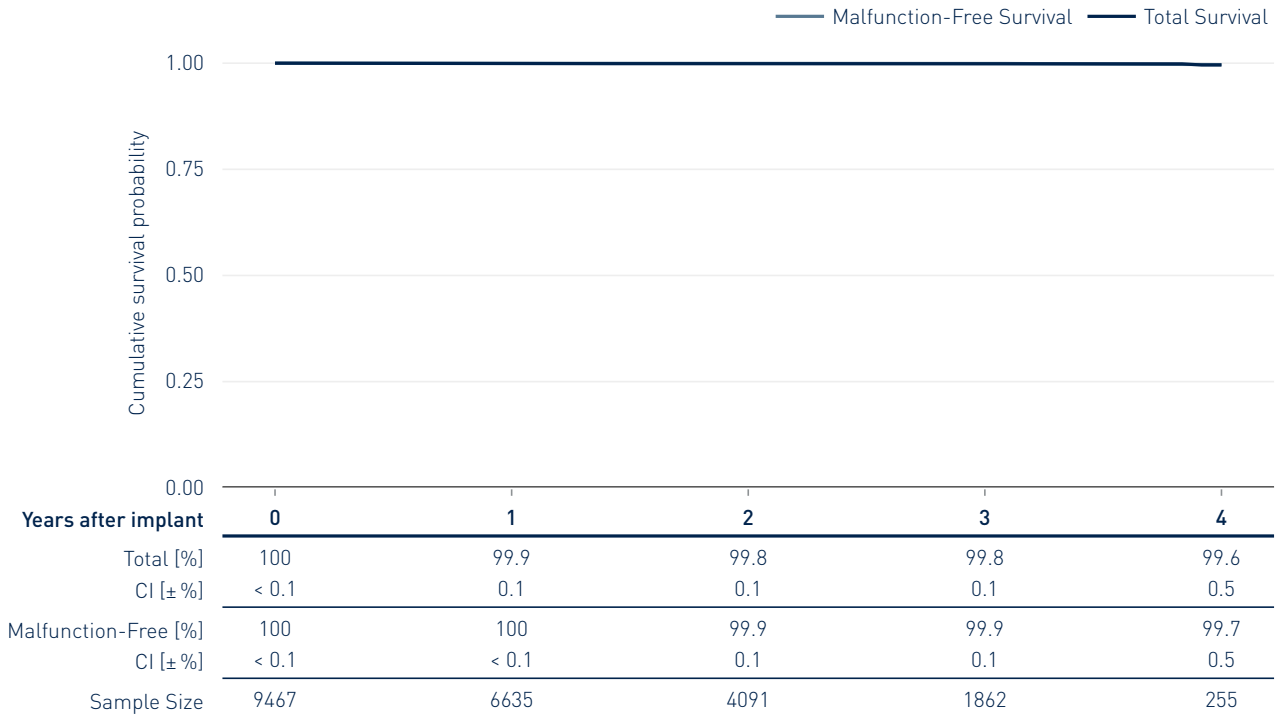


4.2 Dual-Chamber ICDs

Rivacor 7

Product Versions	DR-T
NBG Codes	VVE-DDDR
Maximum Energy J	40
US Market Release	Apr 2019
CE Market Release	Mar 2019
Worldwide Distributed Devices	17 100
Registered US Implants	9 467
Estimated Active US Implants	8 280
US Normal Battery Depletions	6

	Count	Rate
US Confirmed Malfunctions	6	0.06%
Therapy Compromised	5	0.05%
Therapy Available	1	0.01%



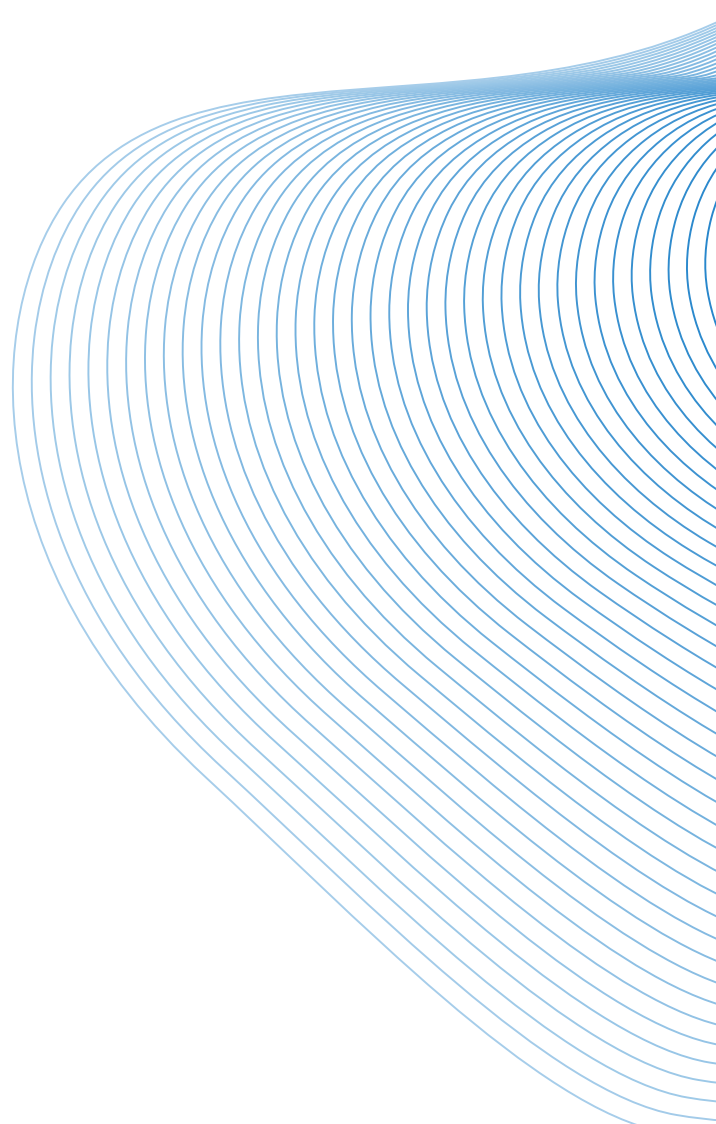


Performance of BIOTRONIK ICDs

4.1 Single-Chamber ICDs

4.2 Dual-Chamber ICDs

4.3 CRT ICDs



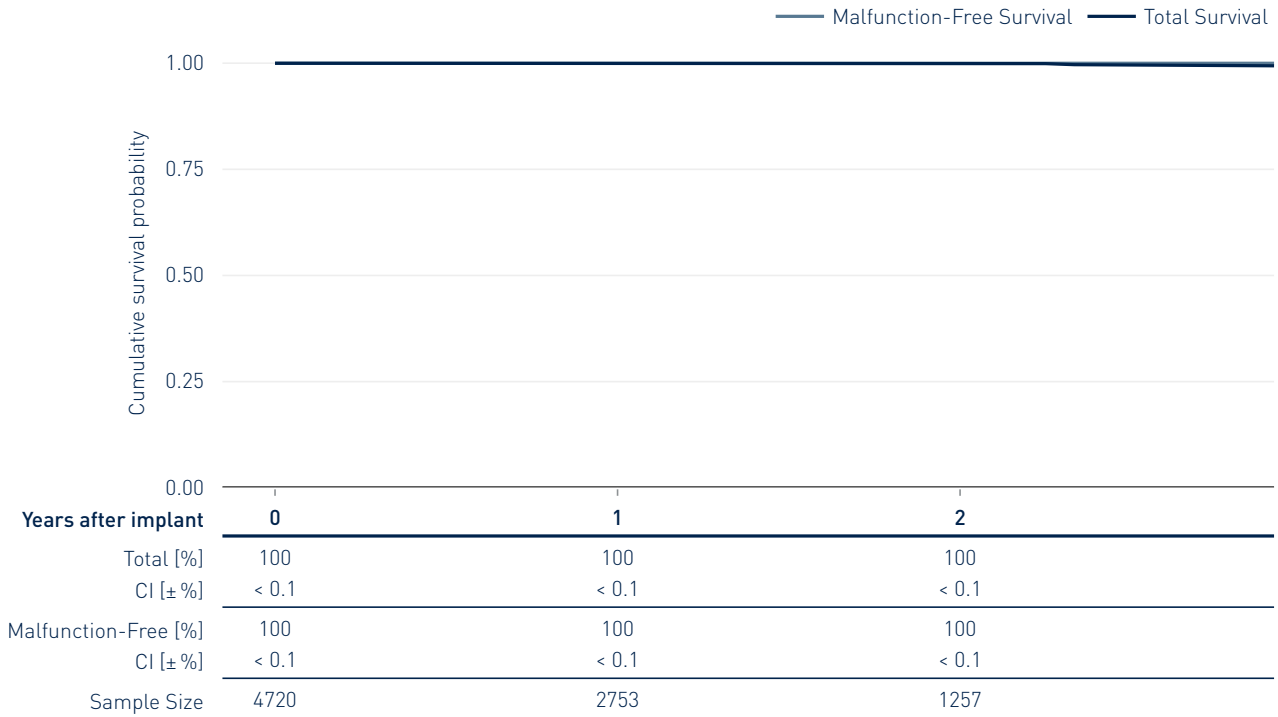


4.3 CRT ICDs

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	21 300
Registered US Implants	5 538
Estimated Active US Implants	4 550
US Normal Battery Depletions	12

	Count	Rate
US Confirmed Malfunctions	1	0.02%
Therapy Compromised	1	0.02%
Therapy Available	0	0.00%



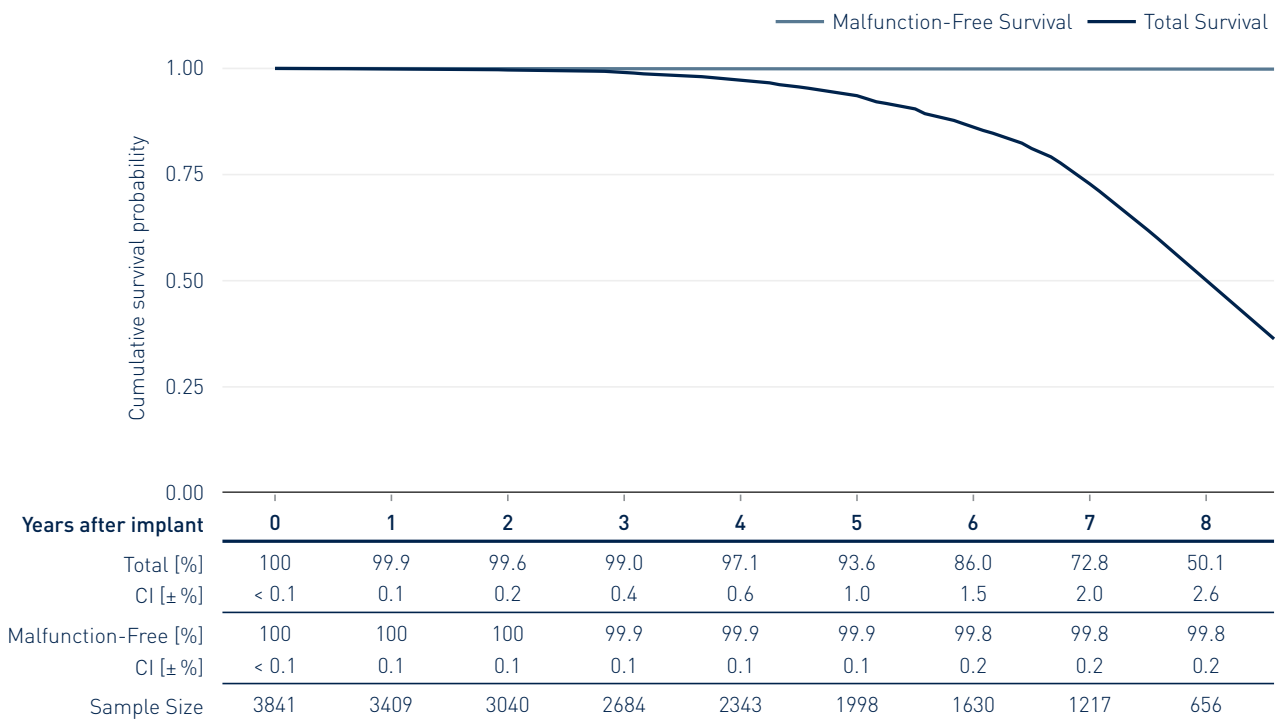


4.3 CRT ICDs

Ilesto 7*

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Sep 2013
CE Market Release	Jun 2013
Worldwide Distributed Devices	5 290
Registered US Implants	3 841
Estimated Active US Implants	684
US Normal Battery Depletions	914

	Count	Rate
US 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 11 (Advisories) for details.

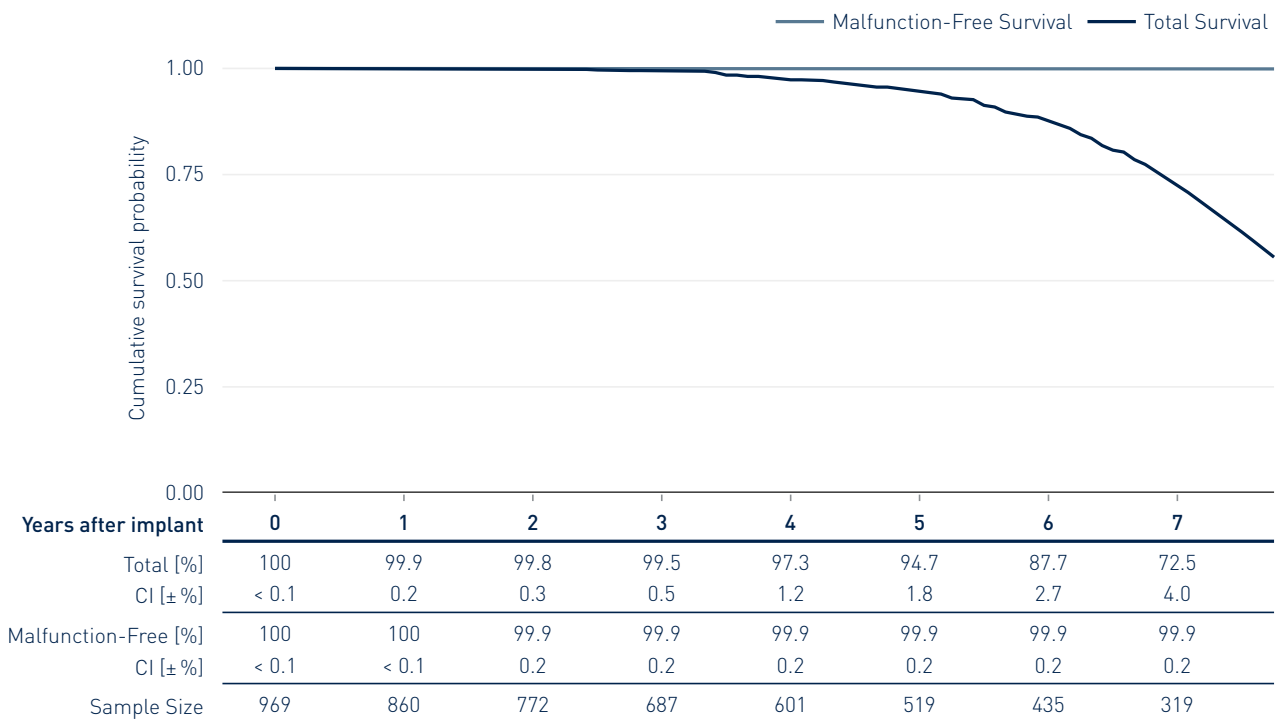


4.3 CRT ICDs

Ilesto 7 DF4*

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Jul 2014
CE Market Release	Jun 2013
Worldwide Distributed Devices	2360
Registered US Implants	969
Estimated Active US Implants	221
US Normal Battery Depletions	226

	Count	Rate
US 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 11 (Advisories) for details.

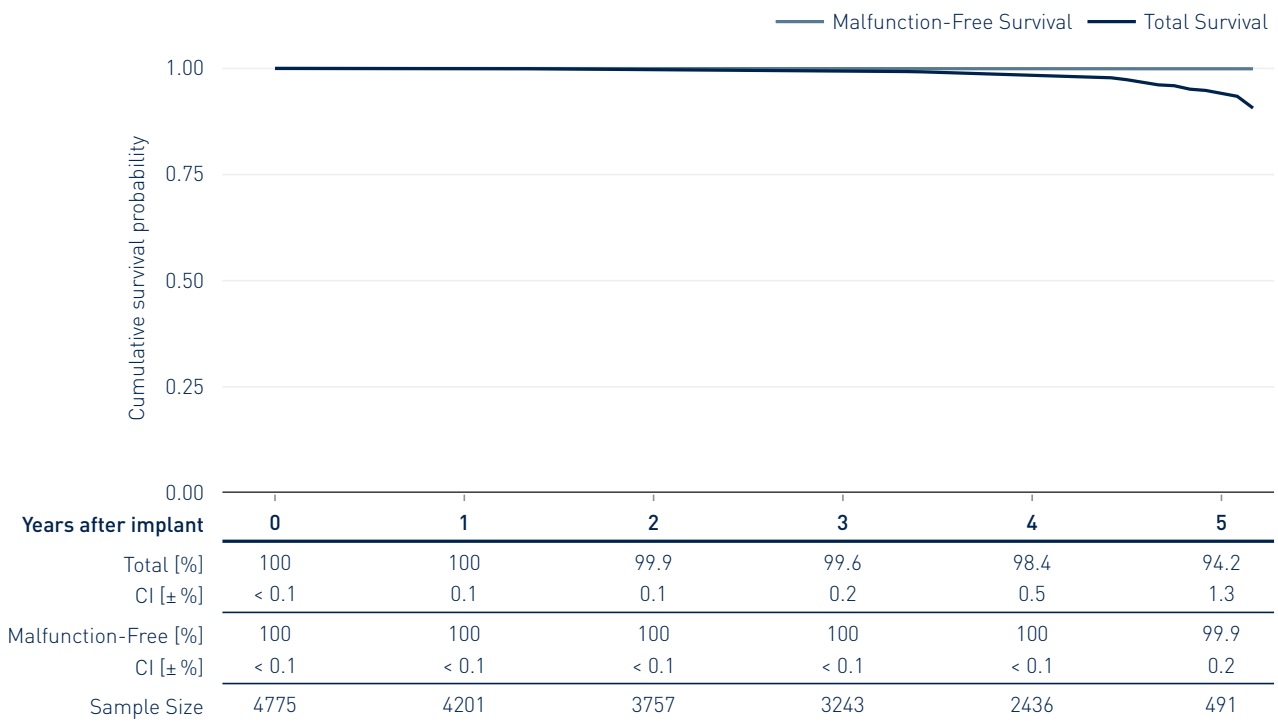


4.3 CRT ICDs

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 US Implants	4 776
Estimated Active US Implants	2 630
US Normal Battery Depletions	200

	Count	Rate
US 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 11 (Advisories) for details.

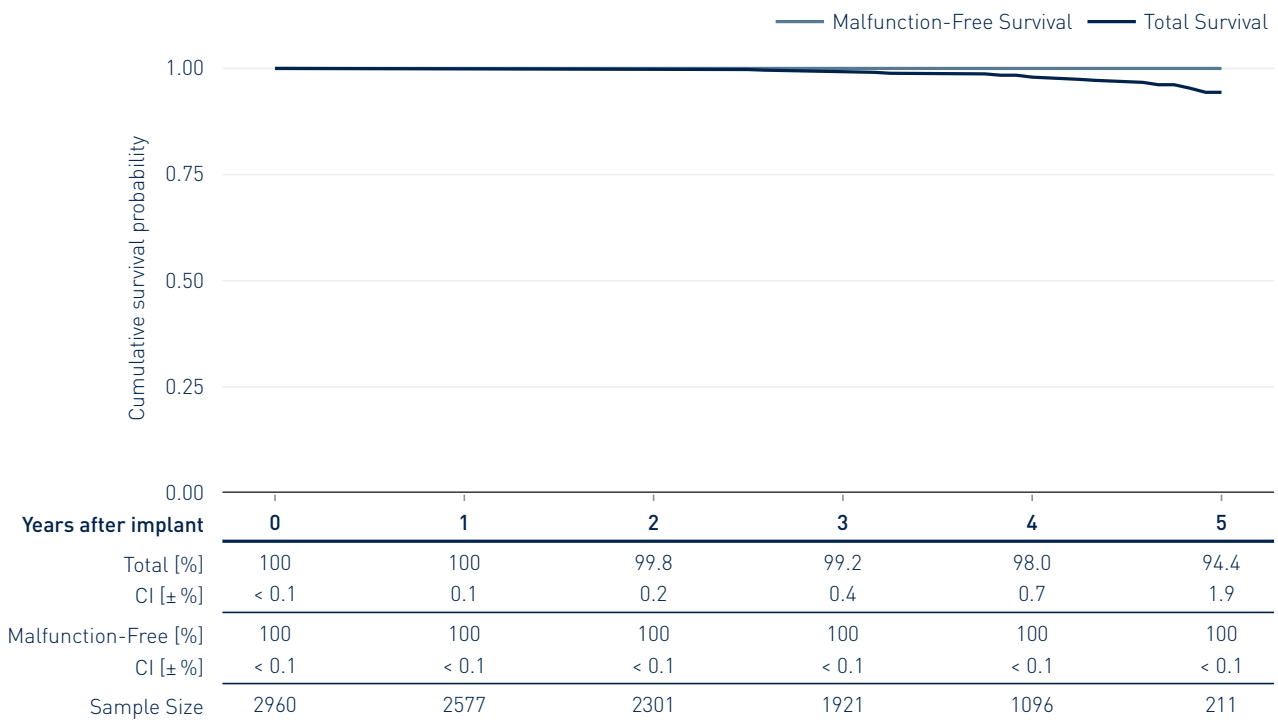


4.3 CRT ICDs

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 US Implants	2 960
Estimated Active US Implants	1 780
US Normal Battery Depletions	73

	Count	Rate
US 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 11 (Advisories) for details.

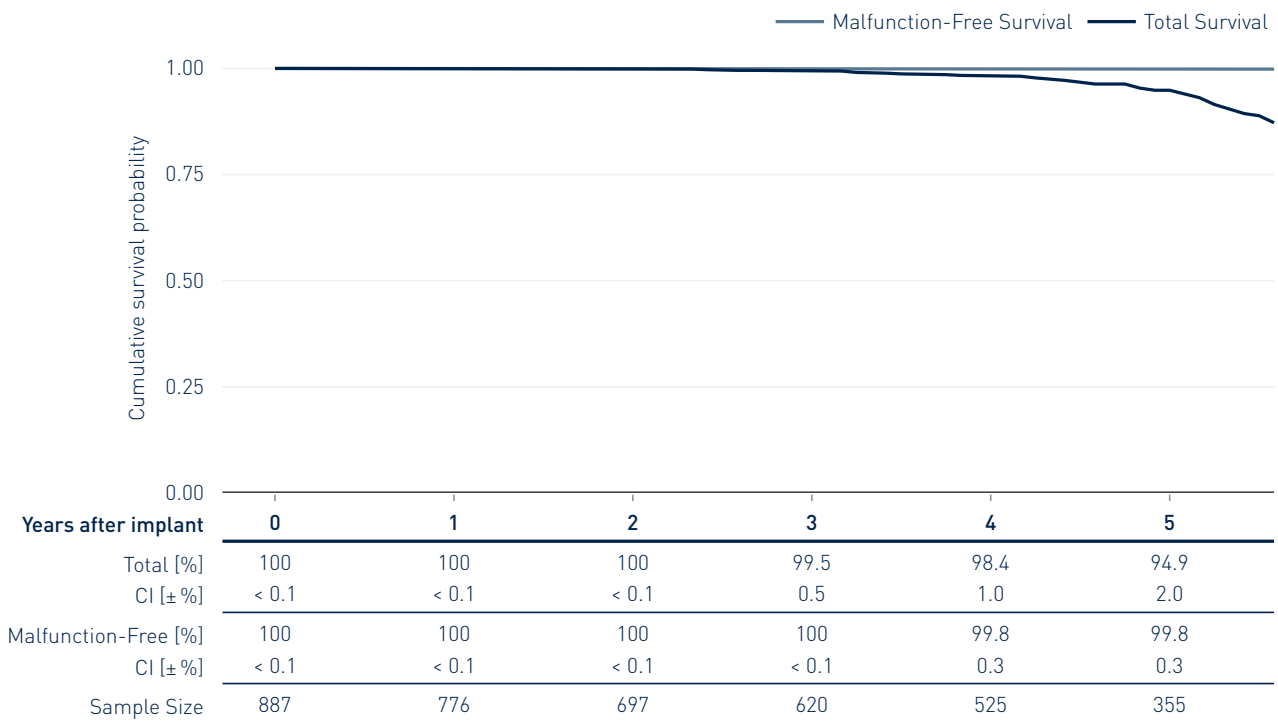


4.3 CRT ICDs

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 US Implants	887
Estimated Active US Implants	378
US Normal Battery Depletions	92

	Count	Rate
US 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 11 (Advisories) for details.

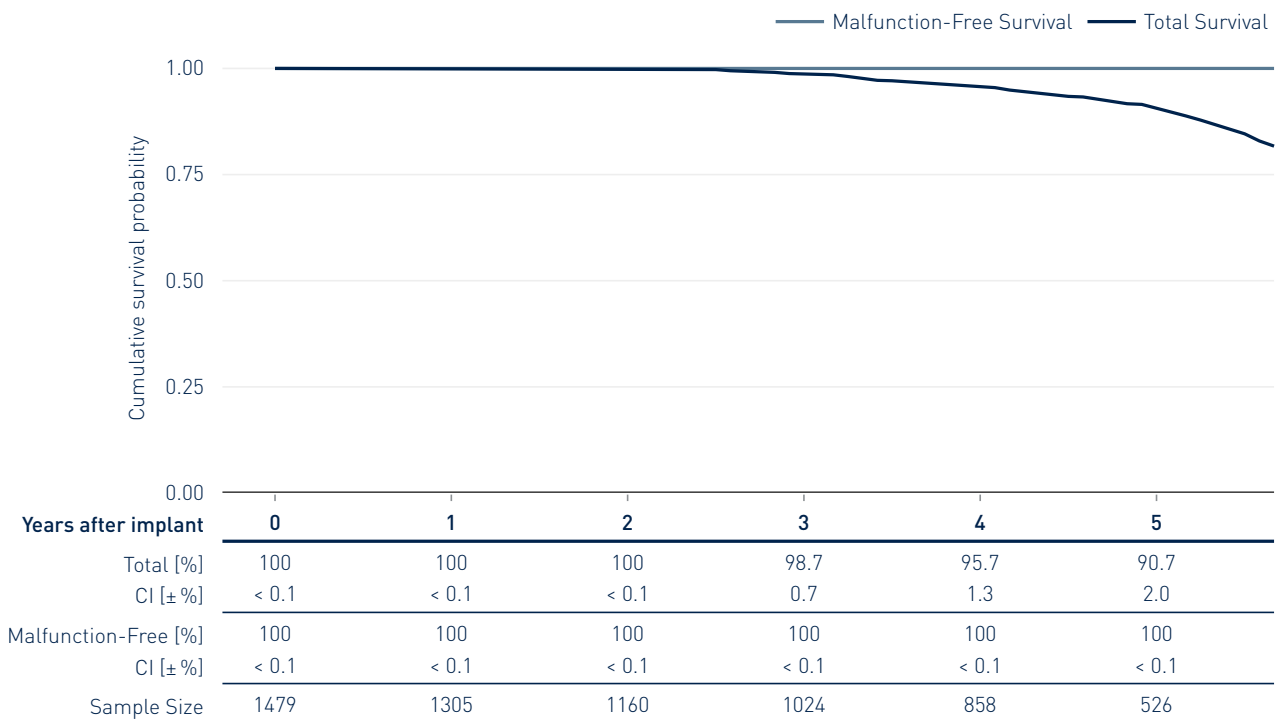


4.3 CRT ICDs

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 US Implants	1 479
Estimated Active US Implants	688
US Normal Battery Depletions	144

	Count	Rate
US 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 11 (Advisories) for details.

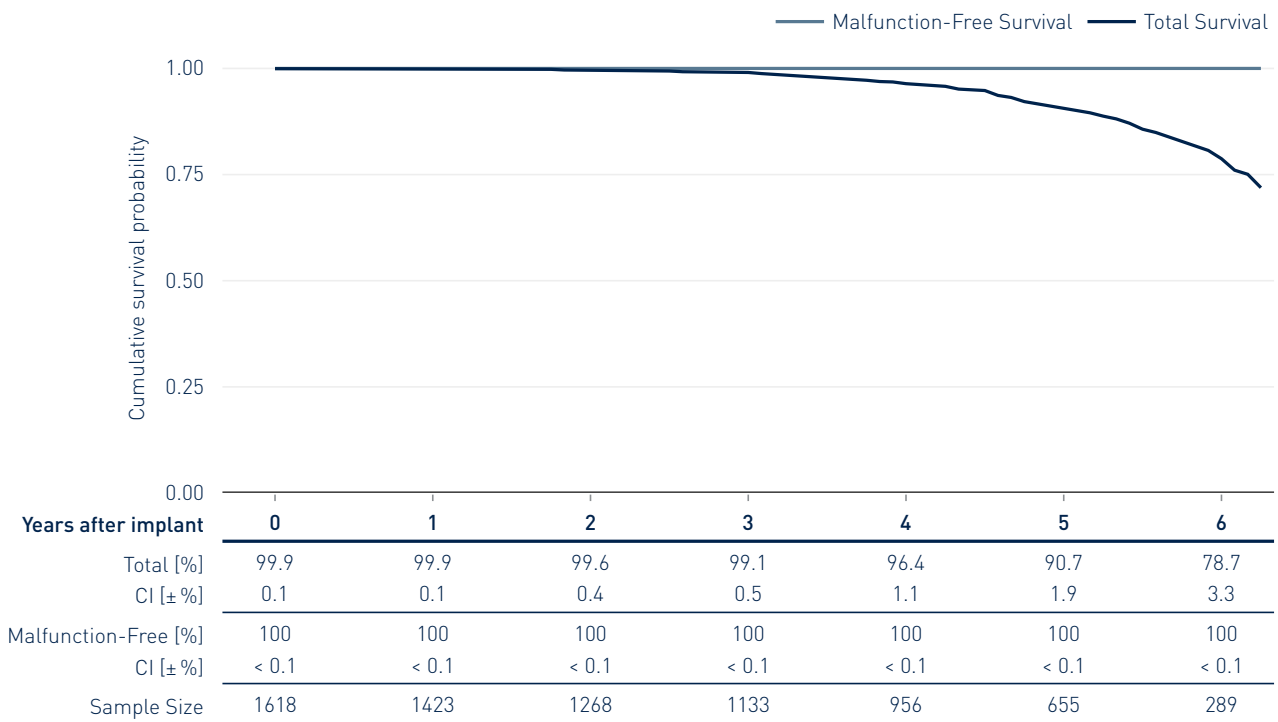


4.3 CRT ICDs

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 US Implants	1 618
Estimated Active US Implants	657
US Normal Battery Depletions	220

	Count	Rate
US 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 11 (Advisories) for details.

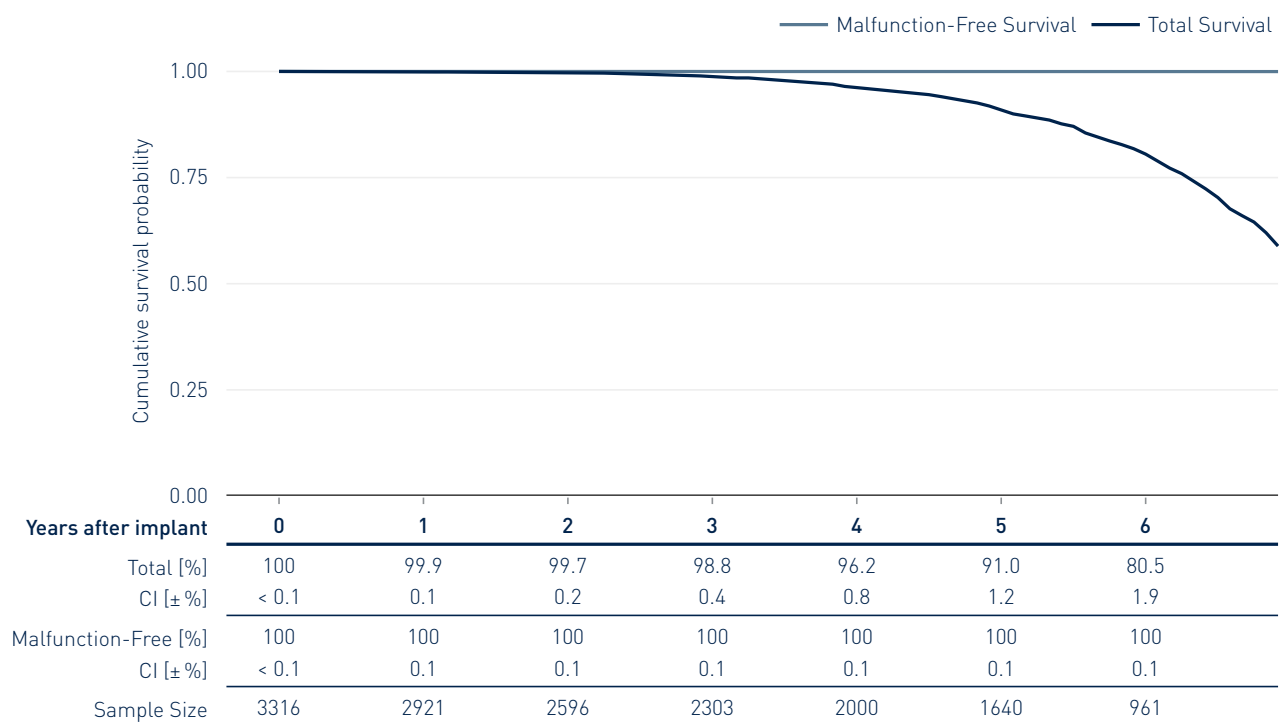


4.3 CRT ICDs

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 US Implants	3 316
Estimated Active US Implants	1 170
US Normal Battery Depletions	576

	Count	Rate
US 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 11 (Advisories) for details.

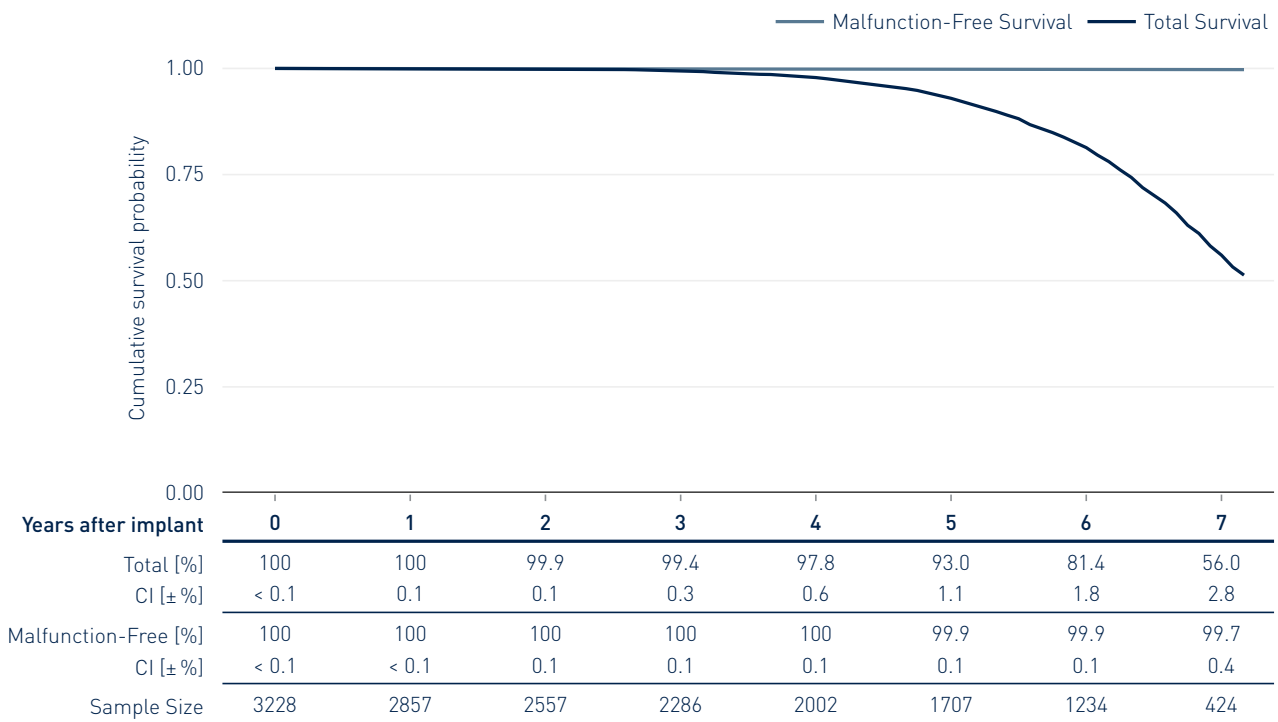


4.3 CRT ICDs

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 US Implants	3 228
Estimated Active US Implants	853
US Normal Battery Depletions	714

	Count	Rate
US Confirmed Malfunctions	3	0.09%
Therapy Compromised	1	0.03%
Therapy Available	2	0.06%



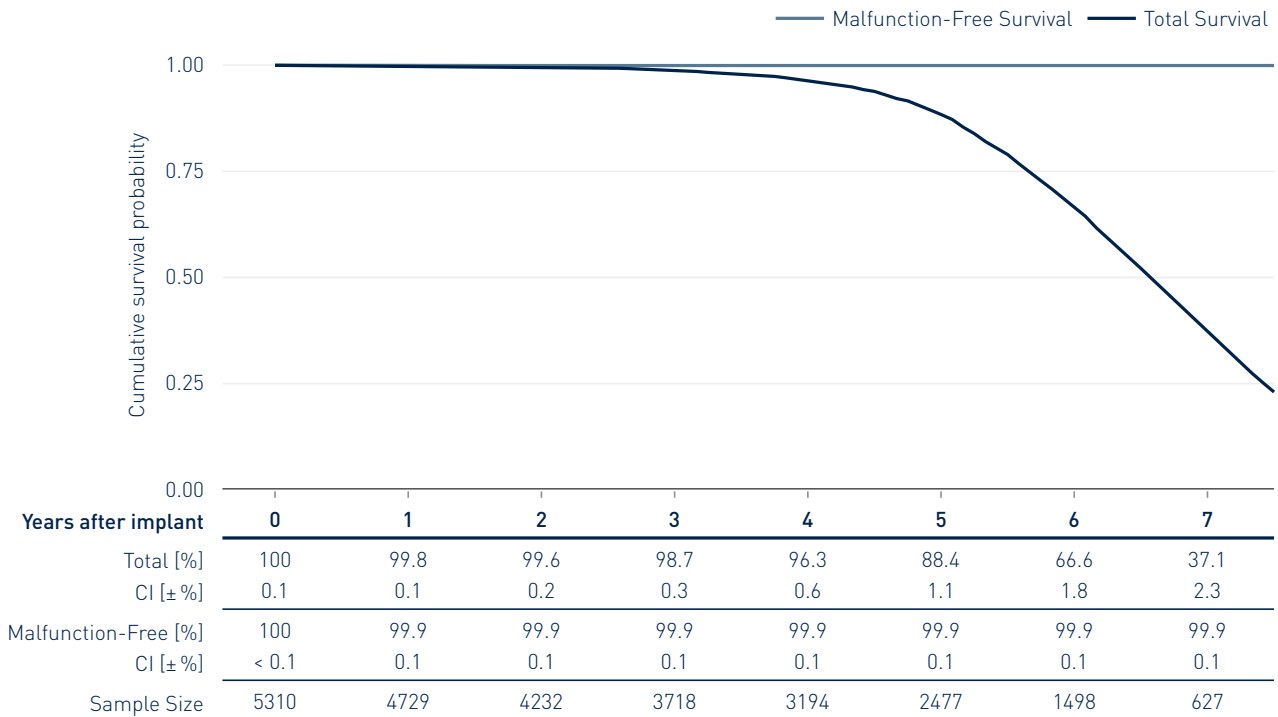
*A subset of devices from this product family is subject to a product advisory. Confirmed malfunctions related to specific failure modes of product advisories are not reported in this chapter. Refer to the chapter 11 (Advisories) for details.

4.3 CRT ICDs

Lumax 340

Product Versions	HF, HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	Feb 2007
CE Market Release	Dec 2006
Worldwide Distributed Devices	20 700
Registered US Implants	5 310
Estimated Active US Implants	410
US Normal Battery Depletions	1 276

	Count	Rate
US Confirmed Malfunctions	4	0.08%
Therapy Compromised	2	0.04%
Therapy Available	2	0.04%

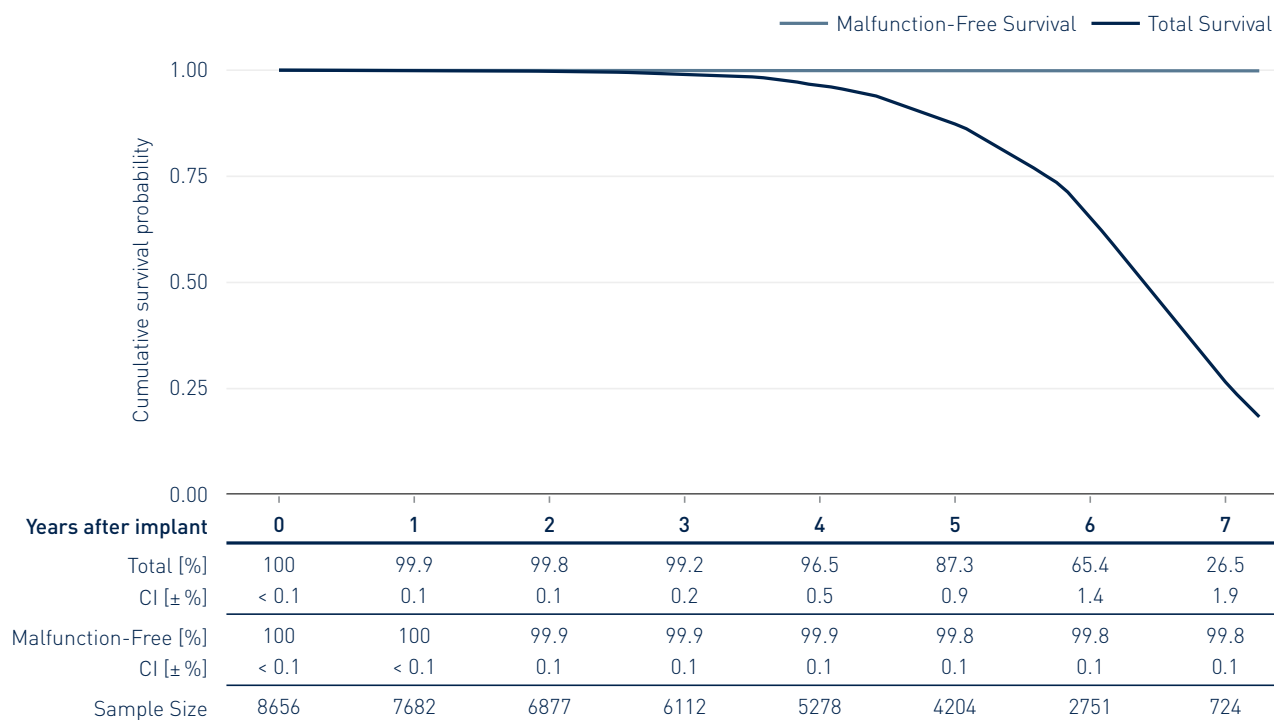


4.3 CRT ICDs

Lumax 540

Product Versions	HF-T
NBG Codes	VVE-DDDRV
Maximum Energy J	40
US Market Release	May 2009
CE Market Release	Jun 2008
Worldwide Distributed Devices	24 800
Registered US Implants	8 656
Estimated Active US Implants	780
US Normal Battery Depletions	2 601

	Count	Rate
US Confirmed Malfunctions	11	0.13%
Therapy Compromised	5	0.06%
Therapy Available	6	0.07%

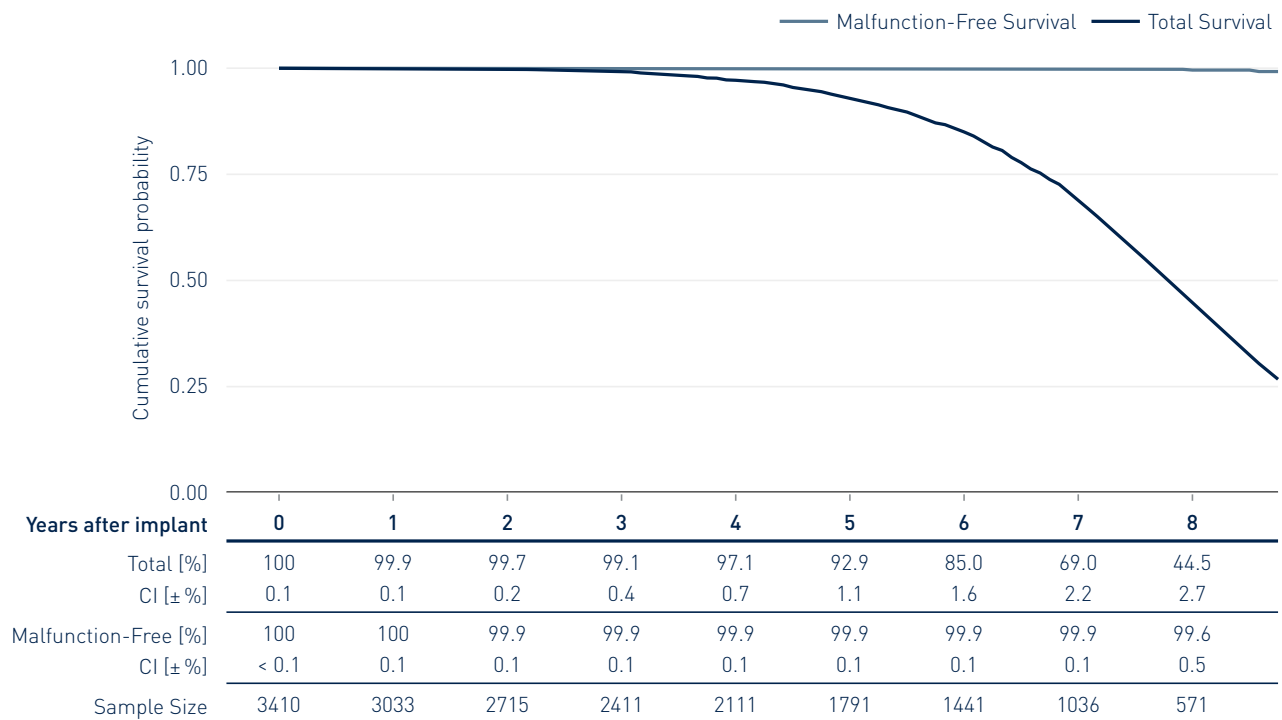


4.3 CRT ICDs

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	7040
Registered US Implants	3410
Estimated Active US Implants	463
US Normal Battery Depletions	886

	Count	Rate
US Confirmed Malfunctions	8	0.23%
Therapy Compromised	6	0.18%
Therapy Available	2	0.06%



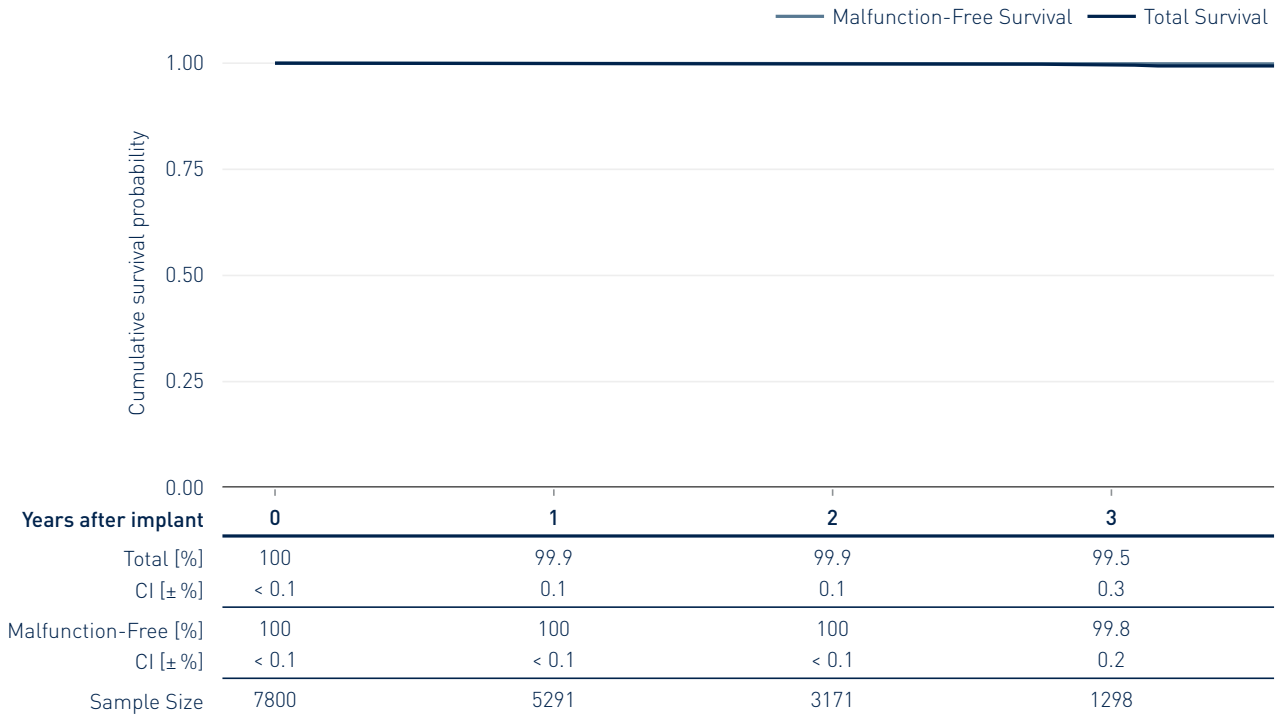


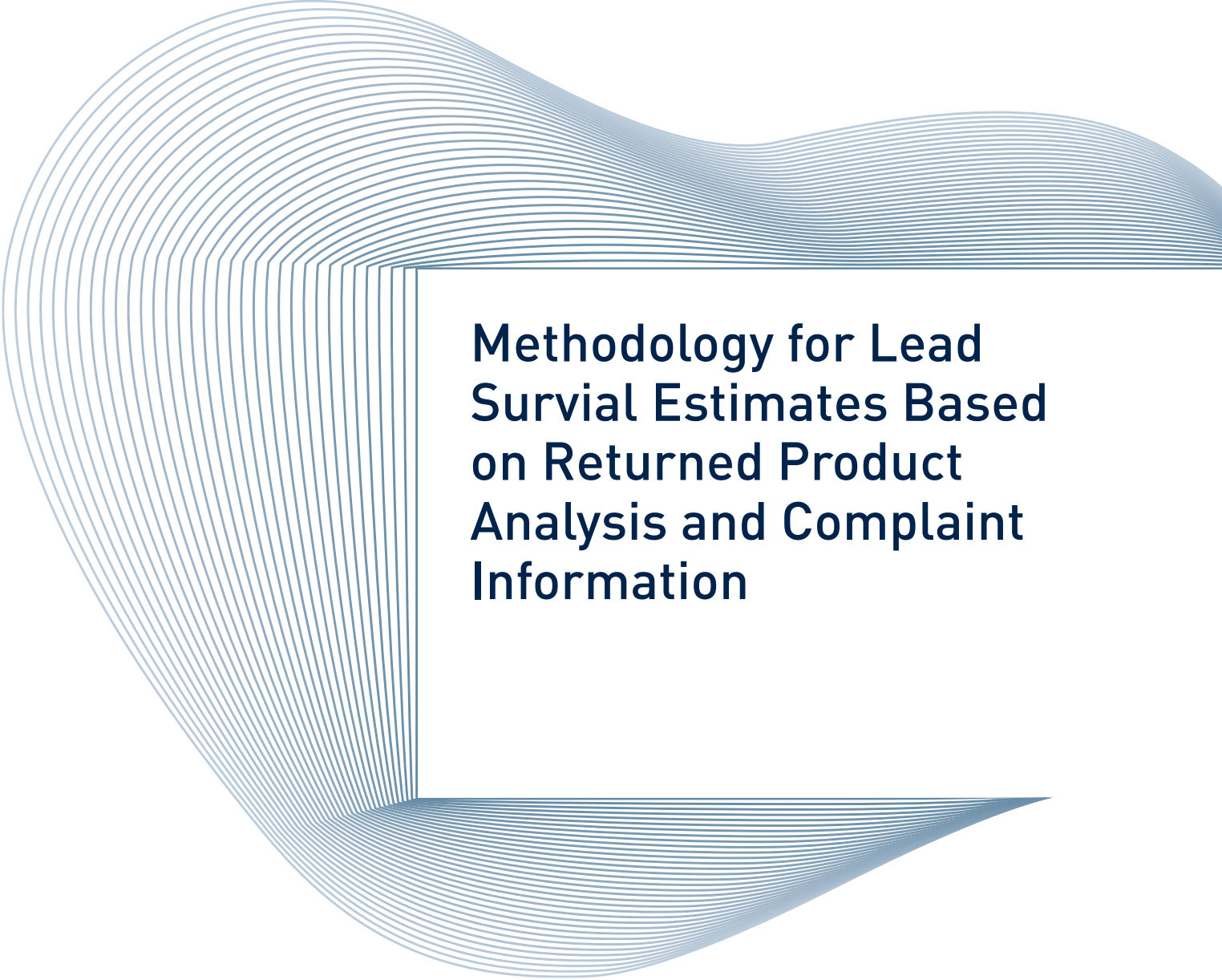
4.3 CRT ICDs

Rivacor 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	20 800
Registered US Implants	7 800
Estimated Active US Implants	6 280
US Normal Battery Depletions	11

	Count	Rate
US Confirmed Malfunctions	5	0.06%
Therapy Compromised	4	0.05%
Therapy Available	1	0.01%





Methodology for Lead Survial 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 US 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, 2023. The sample sizes of US 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 US 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 product, the report provides:

Product Information

- Product versions that contribute to the evaluation
- Types of leads

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

Survival Plot

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.

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

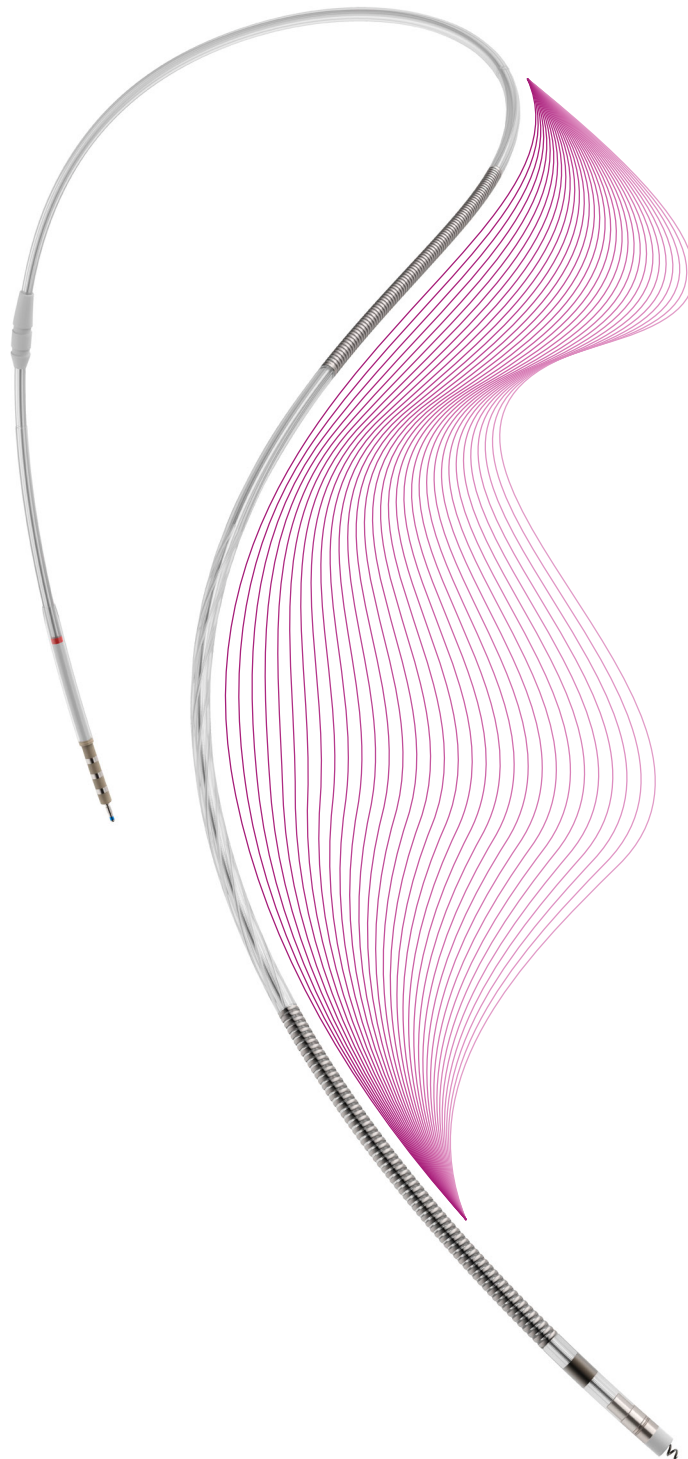
Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads





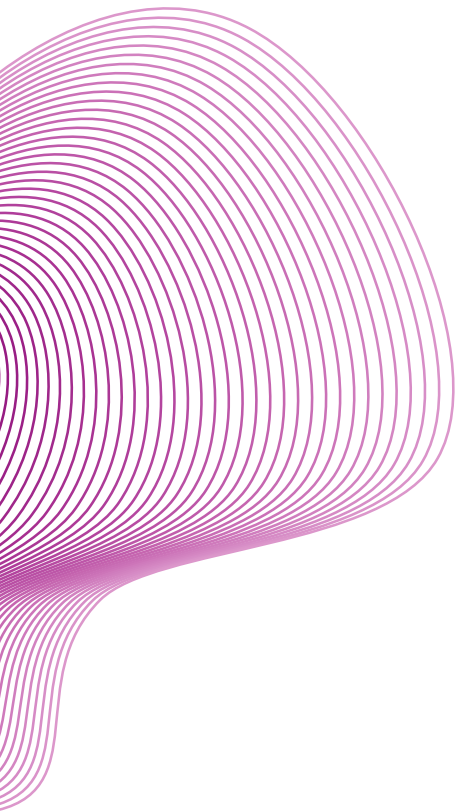
Performance of BIOTRONIK Leads

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



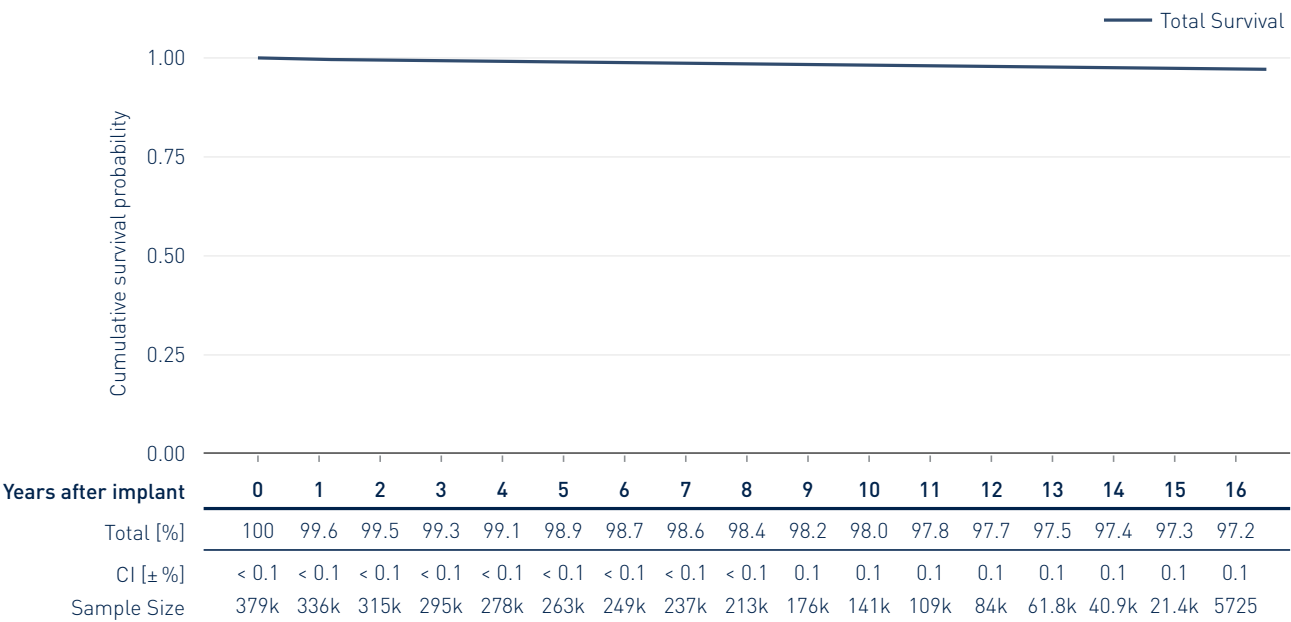


6.1 Performance of Pacing Leads – Postmarket Data

Dextrus

Product Versions	4135, 4136, 4137
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2007
CE Market Release	May 2007
Worldwide Distributed Devices	480 000
Registered US Implants	379 038
Estimated Active US Implants	208 000
US Total Returned	2 498

	Count	Rate		Count	Rate
US Qualifying Complications	5 619	1.46%	US Confirmed Malfunctions	401	0.10%
Abnormal pacing impedance	525	0.14%	Conductor Fracture	127	0.03%
Cardiac perforation	27	0.01%	Insulation Breach	265	0.07%
Conductor fracture	192	0.05%	Other	9	0.00%
Extracardiac stimulation	26	0.01%	US Acute Lead Observations	1 775	0.46%
Failure to capture	1 311	0.34%	Abnormal pacing impedance	47	0.01%
Failure to sense	202	0.05%	Cardiac perforation	74	0.02%
Insulation breach	100	0.03%	Extracardiac stimulation	16	0.00%
Lead dislodgement	601	0.16%	Failure to capture	262	0.07%
Oversensing	1 613	0.42%	Failure to sense	70	0.02%
Other	1 022	0.27%	Insulation breach	10	0.00%
			Lead dislodgement	716	0.19%
			Oversensing	48	0.01%
			Other	532	0.14%



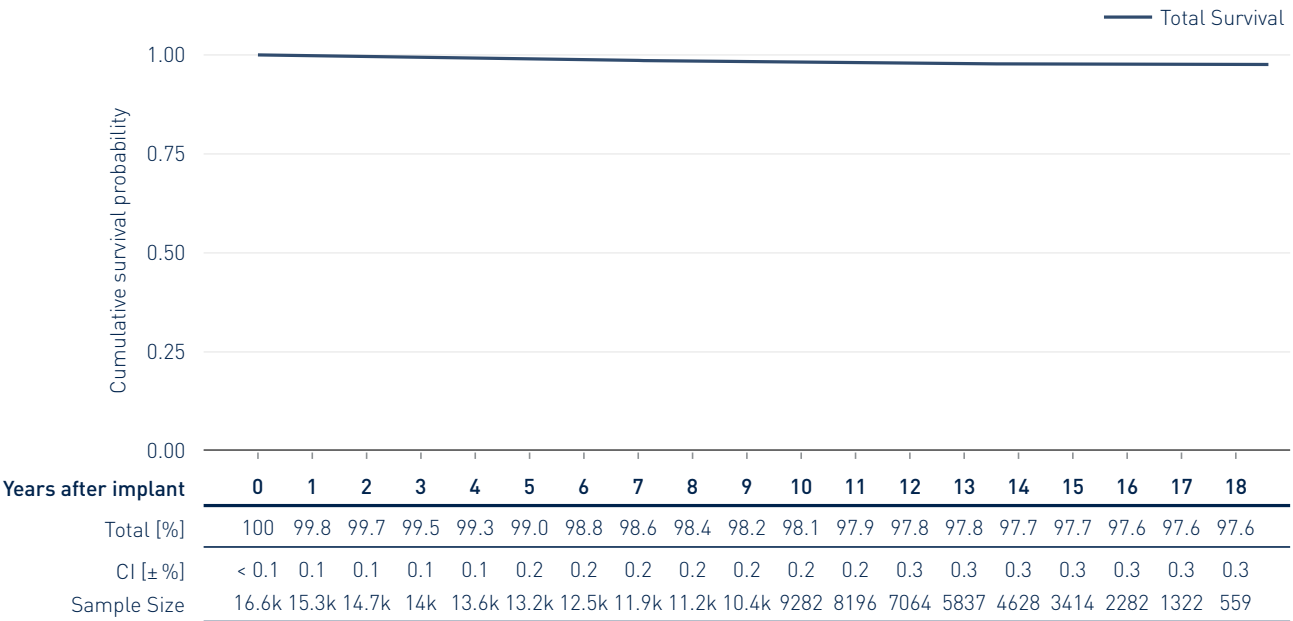


6.1 Performance of Pacing Leads – Postmarket Data

Selox JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	157 000
Registered US Implants	16 617
Estimated Active US Implants	11 600
US Total Returned	130

	Count	Rate		Count	Rate
US Qualifying Complications	272	1.63%	US Confirmed Malfunctions	11	0.07%
Abnormal pacing impedance	45	0.27%	Insulation Breach	10	0.06%
Cardiac perforation	1	0.01%	Other	1	0.01%
Conductor fracture	17	0.10%	US Acute Lead Observations	45	0.27%
Extracardiac stimulation	1	0.01%	Failure to capture	8	0.05%
Failure to capture	111	0.67%	Lead dislodgement	34	0.20%
Failure to sense	11	0.07%	Other	3	0.02%
Insulation breach	12	0.07%			
Lead dislodgement	40	0.24%			
Oversensing	12	0.07%			
Other	22	0.13%			



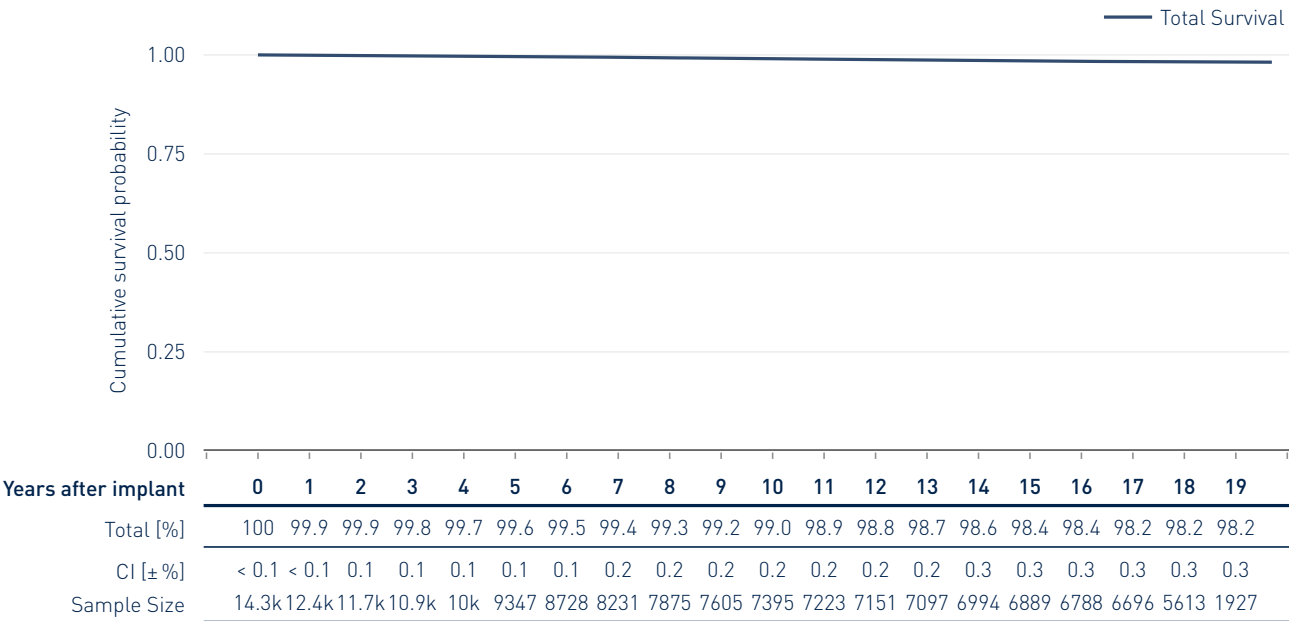


6.1 Performance of Pacing Leads – Postmarket Data

Selox SR

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2004
CE Market Release	Feb 2004
Worldwide Distributed Devices	172 000
Registered US Implants	14 335
Estimated Active US Implants	6 720
US Total Returned	63

	Count	Rate		Count	Rate
US Qualifying Complications	138	0.96%	US Confirmed Malfunctions	13	0.09%
Abnormal pacing impedance	11	0.08%	Insulation Breach	13	0.09%
Conductor fracture	12	0.08%	US Acute Lead Observations	21	0.15%
Extracardiac stimulation	2	0.01%	Cardiac perforation	1	0.01%
Failure to capture	52	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	16	0.11%			
Oversensing	23	0.16%			
Other	15	0.10%			



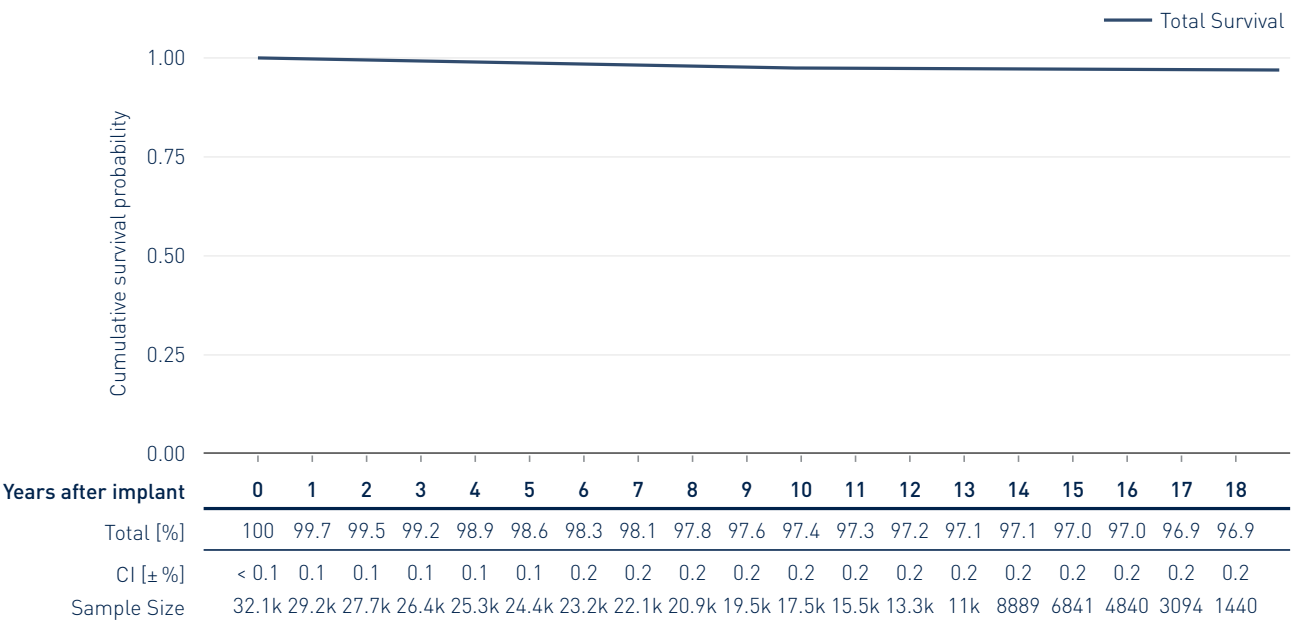


6.1 Performance of Pacing Leads – Postmarket Data

Selox ST

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2004
CE Market Release	Nov 2004
Worldwide Distributed Devices	379 000
Registered US Implants	32 129
Estimated Active US Implants	21 500
US Total Returned	184

	Count	Rate		Count	Rate
US Qualifying Complications	677	2.10%	US Confirmed Malfunctions	20	0.06%
Abnormal pacing impedance	151	0.47%	Conductor Fracture	1	0.00%
Cardiac perforation	3	0.01%	Crimps, Welds and Bonds	1	0.00%
Conductor fracture	72	0.22%	Insulation Breach	18	0.06%
Extracardiac stimulation	7	0.02%	US Acute Lead Observations	50	0.16%
Failure to capture	326	1.01%	Abnormal pacing impedance	1	0.00%
Failure to sense	1	0.00%	Cardiac perforation	1	0.00%
Insulation breach	39	0.12%	Failure to capture	21	0.07%
Lead dislodgement	24	0.07%	Lead dislodgement	21	0.07%
Oversensing	20	0.06%	Other	6	0.02%
Other	34	0.11%			



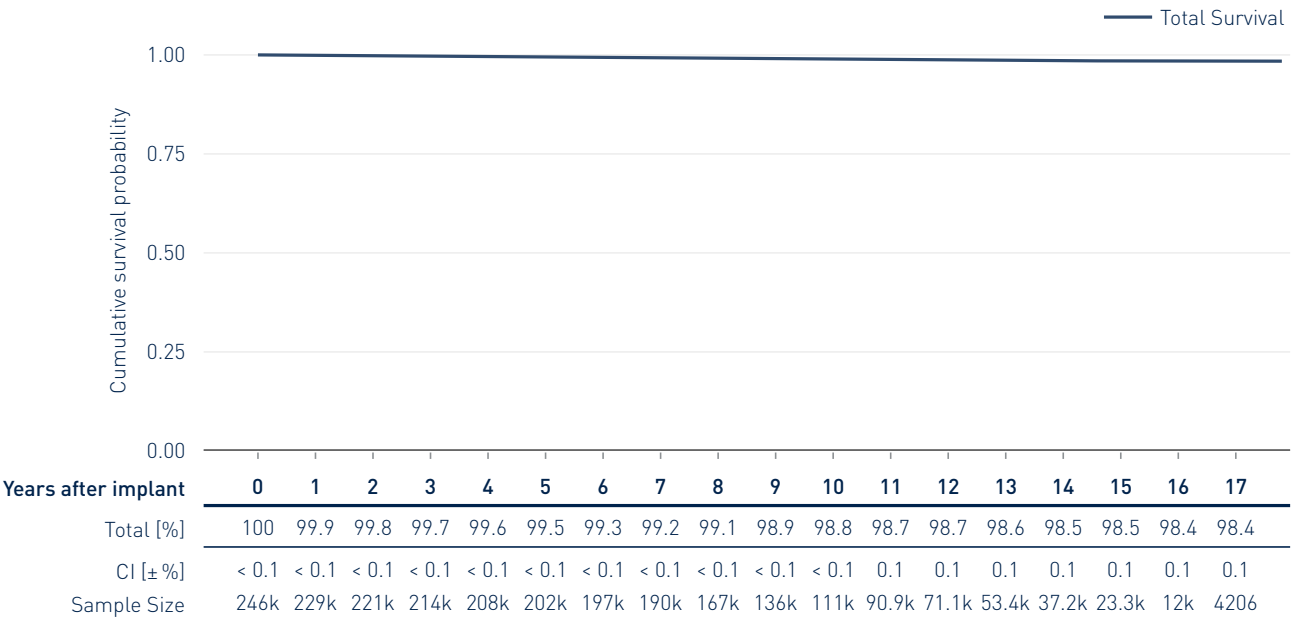


6.1 Performance of Pacing Leads – Postmarket Data

Setrox S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Mar 2006
Worldwide Distributed Devices	681 000
Registered US Implants	245 601
Estimated Active US Implants	184 000
US Total Returned	1 791

	Count	Rate		Count	Rate
US Qualifying Complications	2 311	0.94%	US Confirmed Malfunctions	231	0.09%
Abnormal pacing impedance	215	0.09%	Conductor Fracture	64	0.03%
Cardiac perforation	10	0.00%	Insulation Breach	160	0.07%
Conductor fracture	168	0.07%	Other	7	0.00%
Extracardiac stimulation	12	0.00%	US Acute Lead Observations	271	0.11%
Failure to capture	762	0.31%	Abnormal pacing impedance	1	0.00%
Failure to sense	64	0.03%	Cardiac perforation	24	0.01%
Insulation breach	91	0.04%	Failure to capture	34	0.01%
Lead dislodgement	387	0.16%	Failure to sense	3	0.00%
Oversensing	429	0.17%	Insulation breach	4	0.00%
Other	173	0.07%	Lead dislodgement	189	0.08%
			Other	16	0.01%



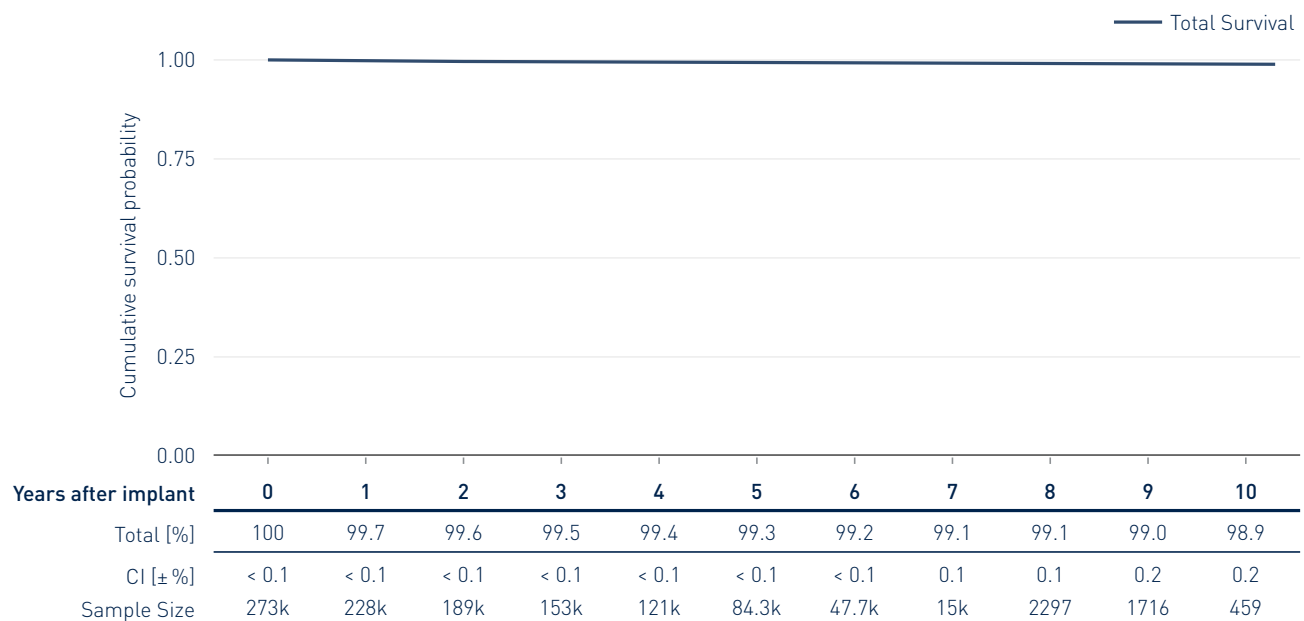


6.1 Performance of Pacing Leads – Postmarket Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 962 000
Registered US Implants	272 604
Estimated Active US Implants	248 000
US Total Returned	1 368

	Count	Rate		Count	Rate
US Qualifying Complications	1 364	0.50%	US Confirmed Malfunctions	78	0.03%
Abnormal pacing impedance	85	0.03%	Conductor Fracture	24	0.01%
Cardiac perforation	23	0.01%	Insulation Breach	37	0.01%
Conductor fracture	48	0.02%	Other	17	0.01%
Extracardiac stimulation	9	0.00%	US Acute Lead Observations	606	0.22%
Failure to capture	349	0.13%	Abnormal pacing impedance	11	0.00%
Failure to sense	49	0.02%	Cardiac perforation	43	0.02%
Insulation breach	24	0.01%	Conductor fracture	1	0.00%
Lead dislodgement	560	0.21%	Extracardiac stimulation	1	0.00%
Oversensing	143	0.05%	Failure to capture	88	0.03%
Other	74	0.03%	Failure to sense	11	0.00%
			Insulation breach	5	0.00%
			Lead dislodgement	393	0.14%
			Oversensing	21	0.01%
			Other	32	0.01%



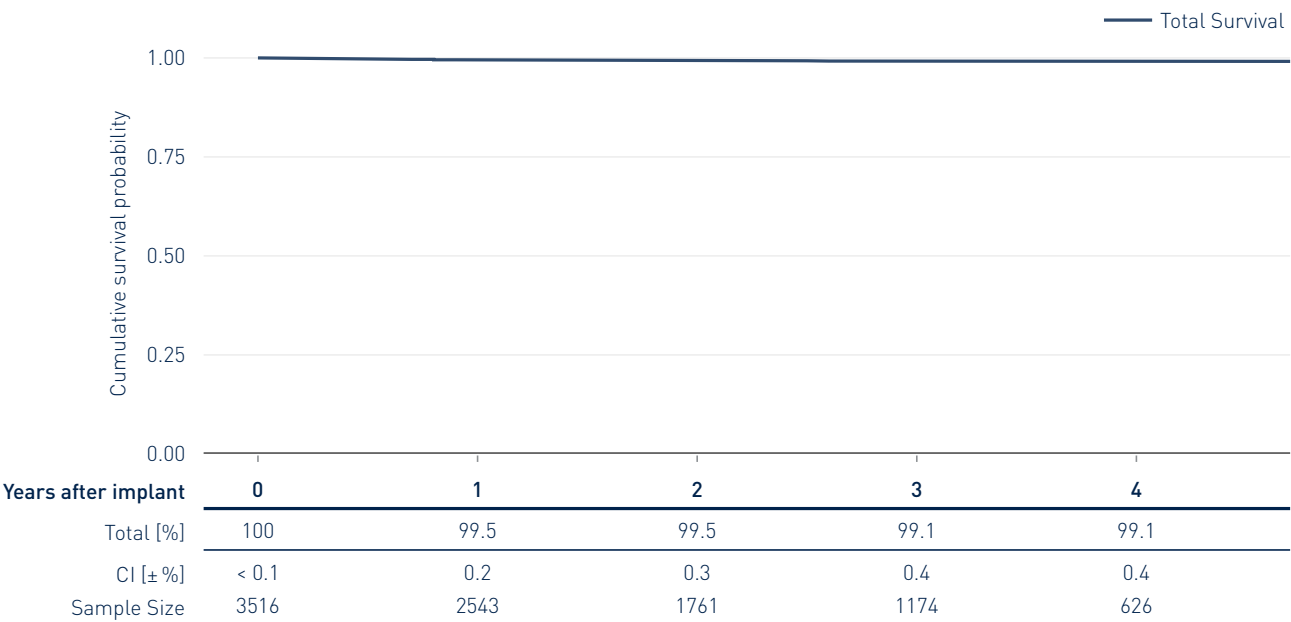


6.1 Performance of Pacing Leads – Postmarket Data

Siello JT / Solia JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	177 000
Registered US Implants	3 516
Estimated Active US Implants	3 180
US Total Returned	16

	Count	Rate		Count	Rate
US Qualifying Complications	20	0.57%	US Confirmed Malfunctions	1	0.03%
Conductor fracture	1	0.03%	Other	1	0.03%
Failure to capture	4	0.11%	US Acute Lead Observations	20	0.57%
Failure to sense	1	0.03%	Failure to capture	1	0.03%
Insulation breach	1	0.03%	Lead dislodgement	19	0.54%
Lead dislodgement	9	0.26%			
Oversensing	3	0.09%			
Other	1	0.03%			



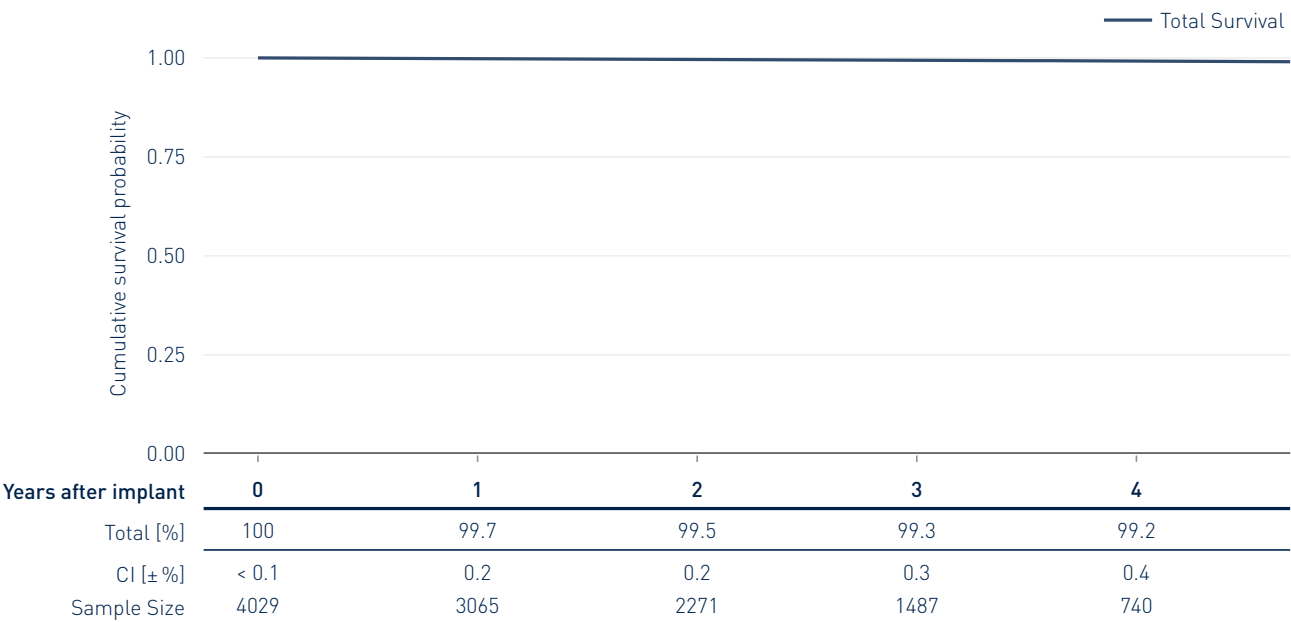


6.1 Performance of Pacing Leads – Postmarket Data

Siello T / Solia T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Nov 2018
CE Market Release	Oct 2009
Worldwide Distributed Devices	236 000
Registered US Implants	4 029
Estimated Active US Implants	3 580
US Total Returned	12

	Count	Rate		Count	Rate
US Qualifying Complications	21	0.52%	US Confirmed Malfunctions	1	0.02%
Abnormal pacing impedance	4	0.10%	Other	1	0.02%
Conductor fracture	2	0.05%	US Acute Lead Observations	14	0.35%
Failure to capture	8	0.20%	Failure to capture	4	0.10%
Insulation breach	2	0.05%	Lead dislodgement	10	0.25%
Lead dislodgement	4	0.10%			
Oversensing	1	0.02%			



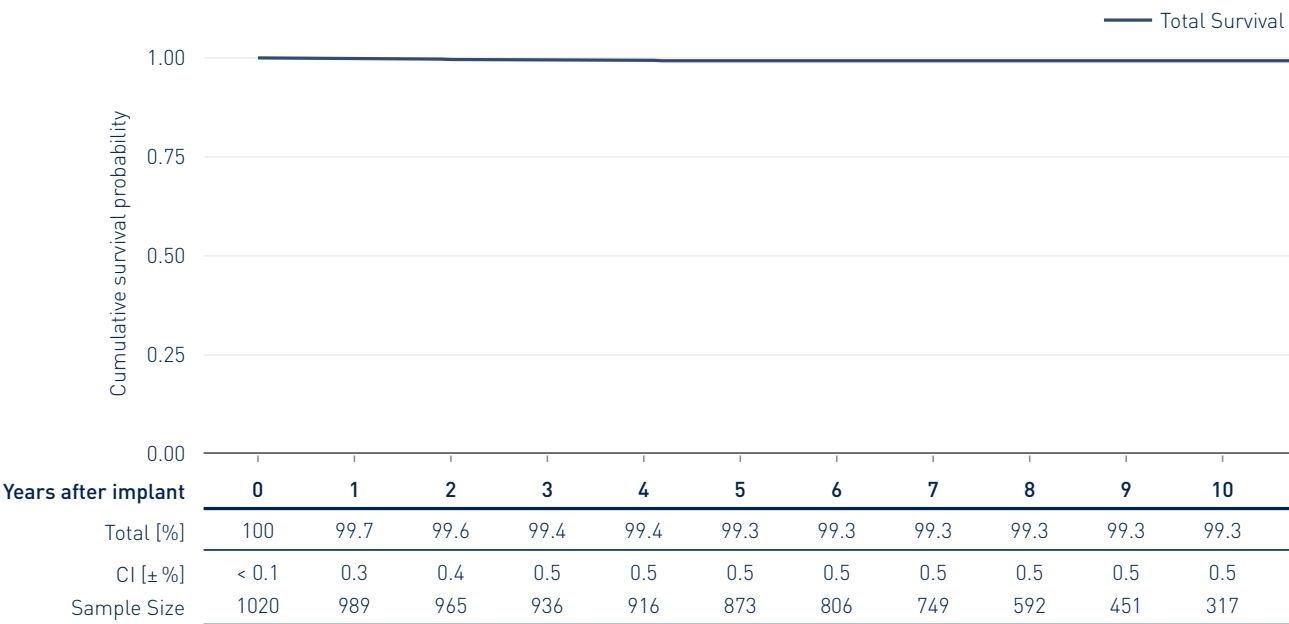


6.1 Performance of Pacing Leads – Postmarket Data

Tilda JT

Product Versions	45, 53
Lead Type	J-shape, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2012
CE Market Release	Sep 2011
Worldwide Distributed Devices	17 300
Registered US Implants	1 020
Estimated Active US Implants	877
US Total Returned	0

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



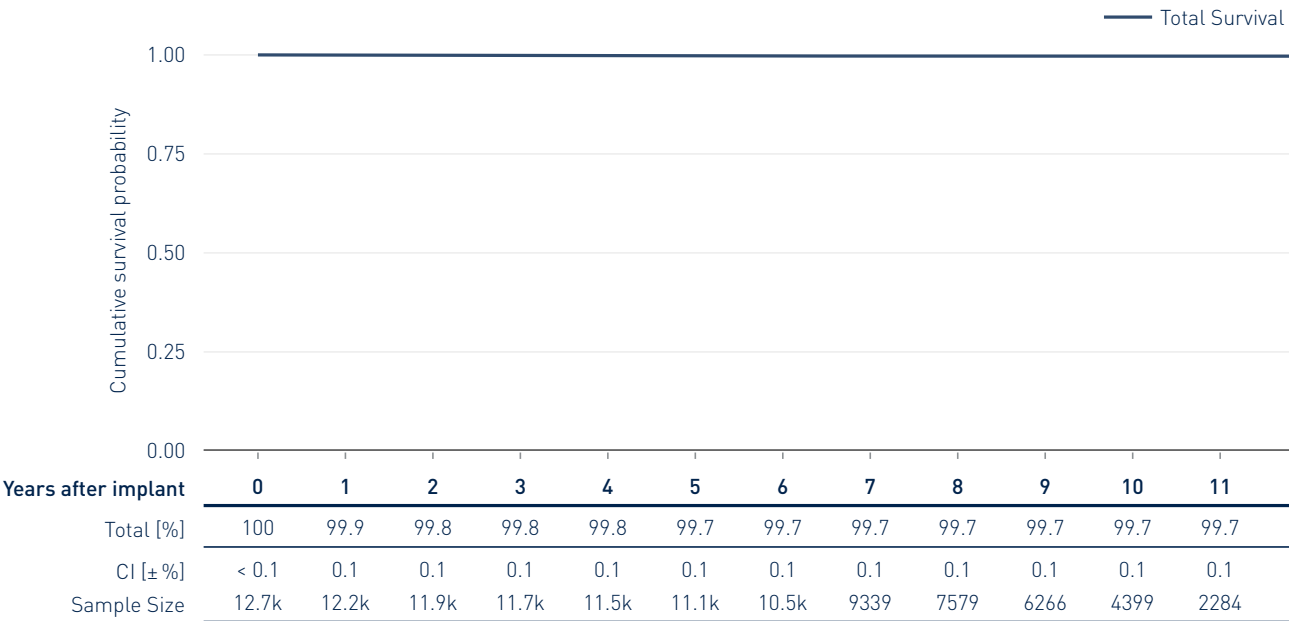


6.1 Performance of Pacing Leads – Postmarket Data

Tilda R

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	41 300
Registered US Implants	12 721
Estimated Active US Implants	11 100
US Total Returned	16

	Count	Rate		Count	Rate
US Qualifying Complications	36	0.28%	US Confirmed Malfunctions	1	0.01%
Abnormal pacing impedance	1	0.01%	Conductor Fracture	1	0.01%
Conductor fracture	6	0.05%	US 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%			



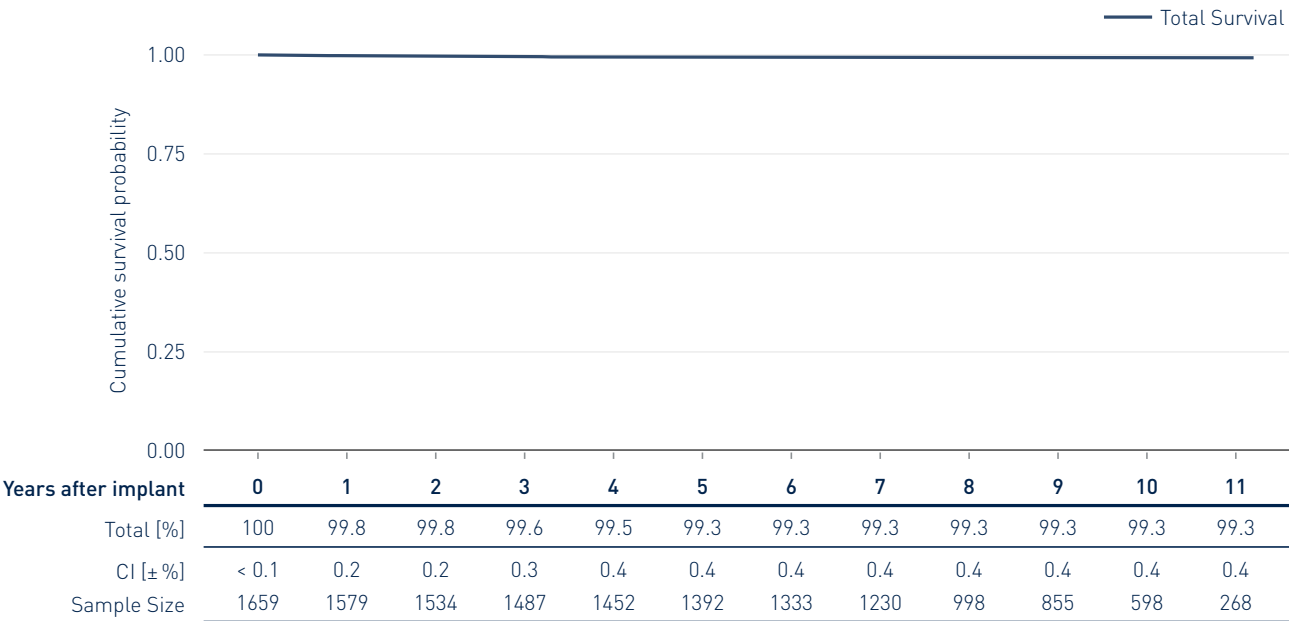


6.1 Performance of Pacing Leads – Postmarket Data

Tilda T

Product Versions	53, 60
Lead Type	straight, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Dec 2011
CE Market Release	Aug 2011
Worldwide Distributed Devices	22 400
Registered US Implants	1 659
Estimated Active US Implants	1 360
US Total Returned	2

	Count	Rate		Count	Rate
US Qualifying Complications	11	0.66%	US Confirmed Malfunctions	0	0.00%
Abnormal pacing impedance	4	0.24%	US Acute Lead Observations	0	0.00%
Conductor fracture	2	0.12%			
Insulation breach	1	0.06%			
Lead dislodgement	4	0.24%			





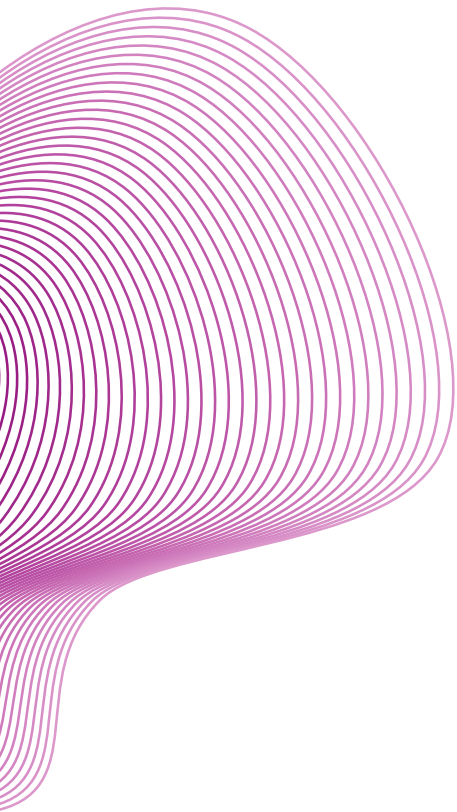
Performance of **BIOTRONIK Leads**

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



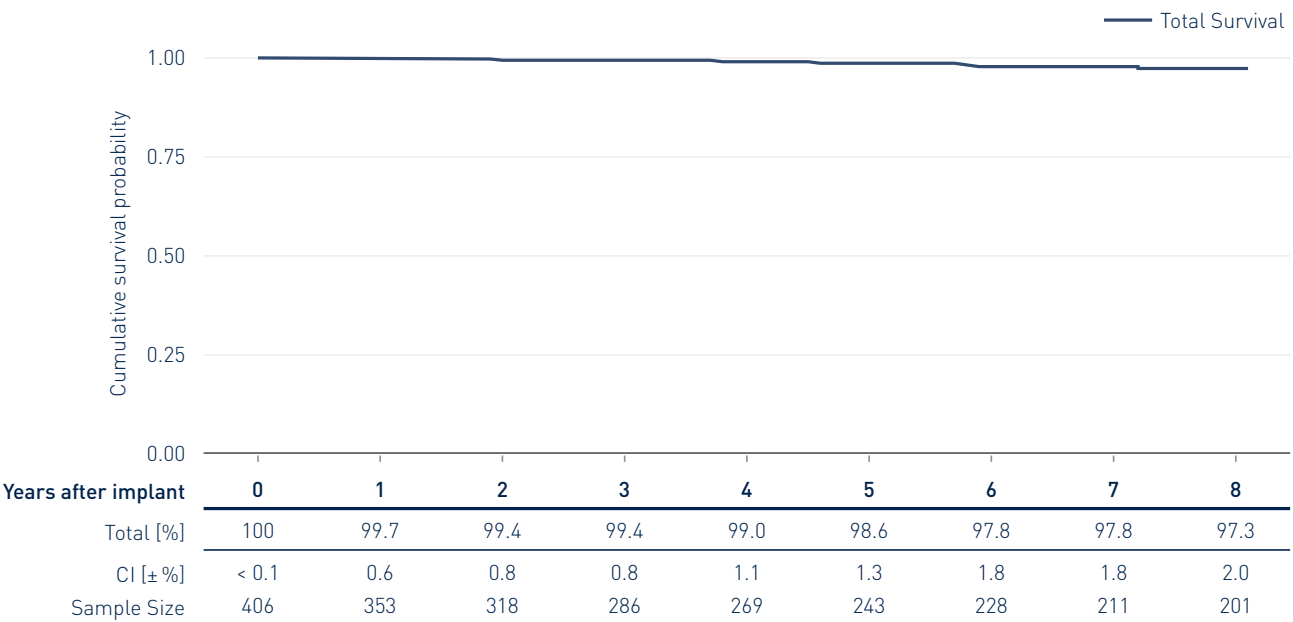


6.2 Performance of ICD Leads – Postmarket Data

Kentrox RV

Product Versions	65, 75, -Steroid
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Mar 2002 / Oct 2004
CE Market Release	Jan 2001 / Dec 2004
Worldwide Distributed Devices	5460
Registered US Implants	406
Estimated Active US Implants	155
US Total Returned	8

	Count	Rate		Count	Rate
US Qualifying Complications	10	2.46%	US 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%	US Acute Lead Observations	0	0.00%
Oversensing	4	0.98%			



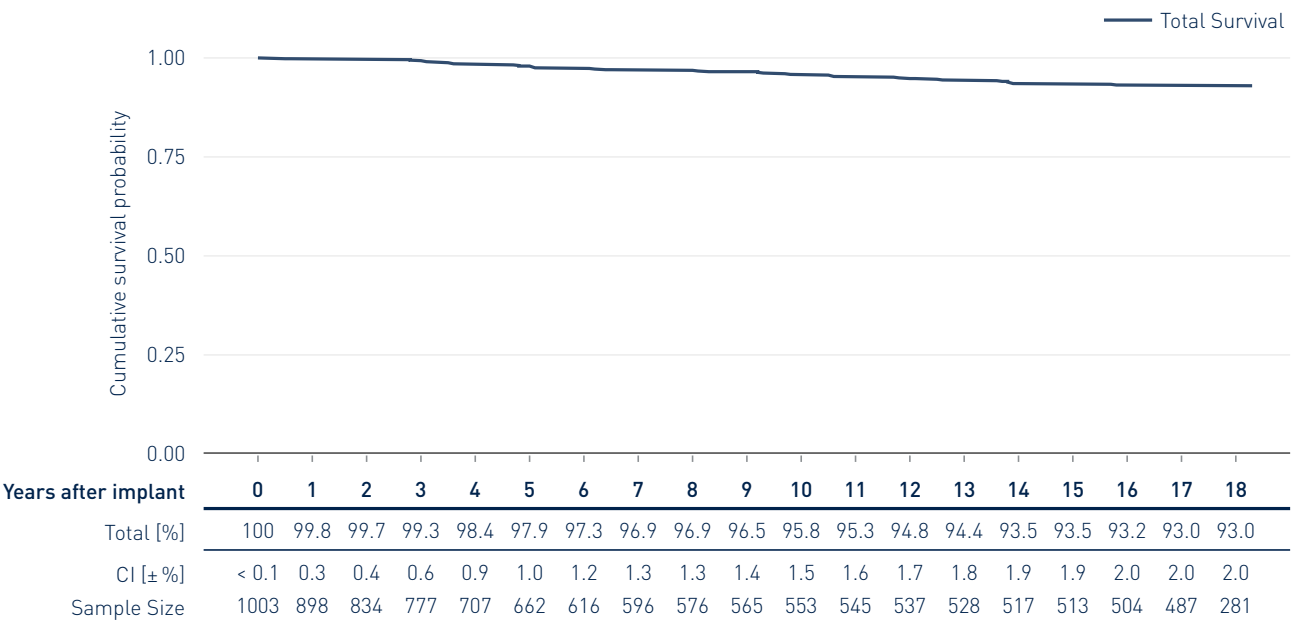


6.2 Performance of ICD Leads – Postmarket Data

Kentrox SL

Product Versions	65, 75, 100, -Steroid
Lead Type	dual coil, passive fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Oct 2004
CE Market Release	Dec 2003 / Dec 2004
Worldwide Distributed Devices	8 440
Registered US Implants	1 003
Estimated Active US Implants	503
US Total Returned	19

	Count	Rate		Count	Rate
US Qualifying Complications	40	3.96%	US Confirmed Malfunctions	5	0.50%
Abnormal defibrillation impedance	1	0.10%	Insulation Breach	5	0.50%
Abnormal pacing impedance	4	0.40%	US 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%			



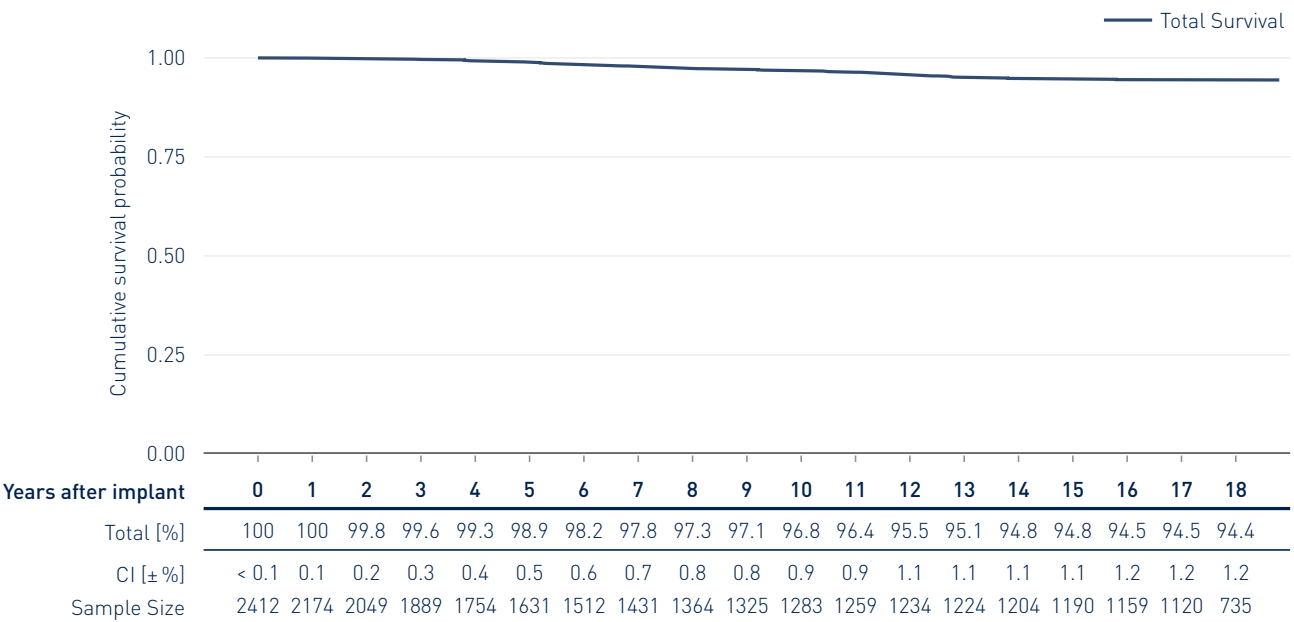


6.2 Performance of ICD Leads – Postmarket Data

Kentrox SL-S

Product Versions	65/16, 18 -Steroid
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes/no
US Market Release	Oct 2004
CE Market Release	Jun 2004
Worldwide Distributed Devices	8 740
Registered US Implants	2 412
Estimated Active US Implants	1 160
US Total Returned	44

	Count	Rate		Count	Rate
US Qualifying Complications	68	2.80%	US Confirmed Malfunctions	14	0.58%
Abnormal defibrillation impedance	2	0.08%	Insulation Breach	14	0.58%
Abnormal pacing impedance	5	0.21%	US 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%			



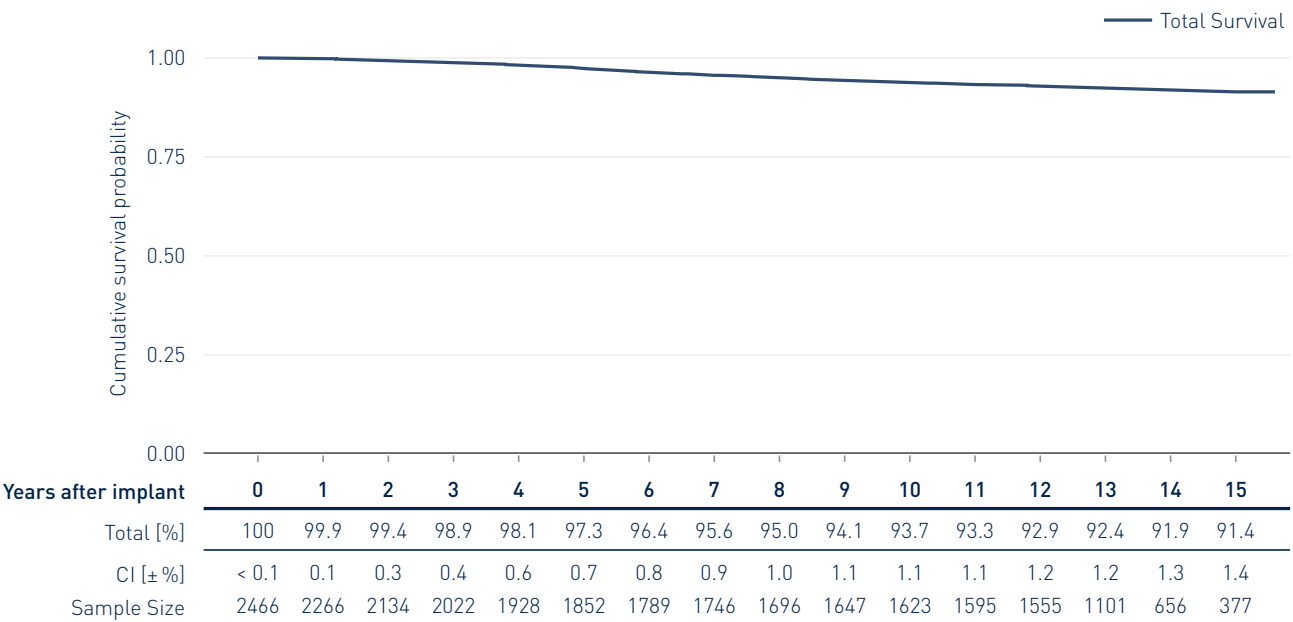


6.2 Performance of ICD Leads – Postmarket Data

Linux S

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
Registered US Implants	2 466
Estimated Active US Implants	1 550
US Total Returned	90

	Count	Rate		Count	Rate
US Qualifying Complications	100	4.01%	US Confirmed Malfunctions	50	2.01%
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%	Other	1	0.04%
Failure to capture	13	0.52%	US Acute Lead Observations	2	0.08%
Failure to sense	1	0.04%	Lead dislodgement	1	0.04%
Insulation breach	4	0.16%	Other	1	0.04%
Oversensing	47	1.89%			
Other	7	0.28%			



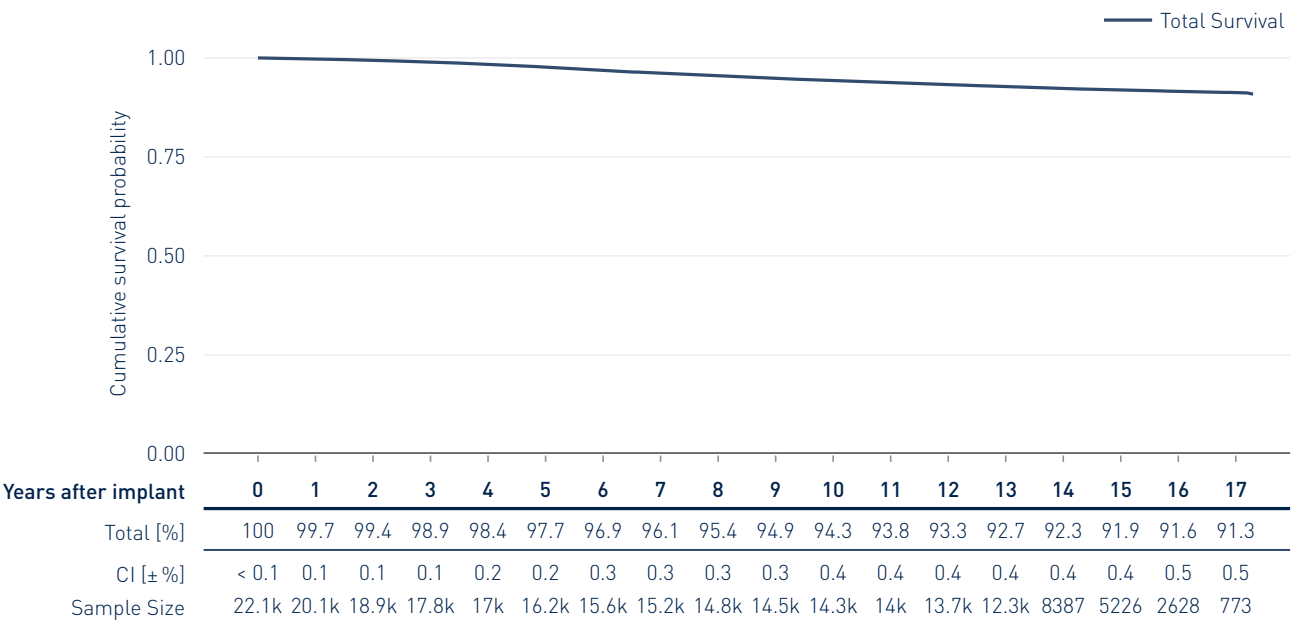


6.2 Performance of ICD Leads – Postmarket Data

Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
Registered US Implants	22 100
Estimated Active US Implants	13 300
US Total Returned	555

	Count	Rate		Count	Rate
US Qualifying Complications	1 053	4.73%	US Confirmed Malfunctions	232	1.04%
Abnormal defibrillation impedance	106	0.48%	Conductor Fracture	38	0.17%
Abnormal pacing impedance	76	0.34%	Insulation Breach	191	0.86%
Cardiac perforation	3	0.01%	Other	3	0.01%
Conductor fracture	135	0.61%	US Acute Lead Observations	11	0.05%
Failure to capture	81	0.36%	Abnormal pacing impedance	1	0.00%
Failure to sense	18	0.08%	Cardiac perforation	1	0.00%
Insulation breach	65	0.29%	Failure to capture	1	0.00%
Lead dislodgement	34	0.15%	Lead dislodgement	6	0.03%
Oversensing	483	2.17%	Oversensing	1	0.00%
Other	52	0.23%	Other	1	0.00%



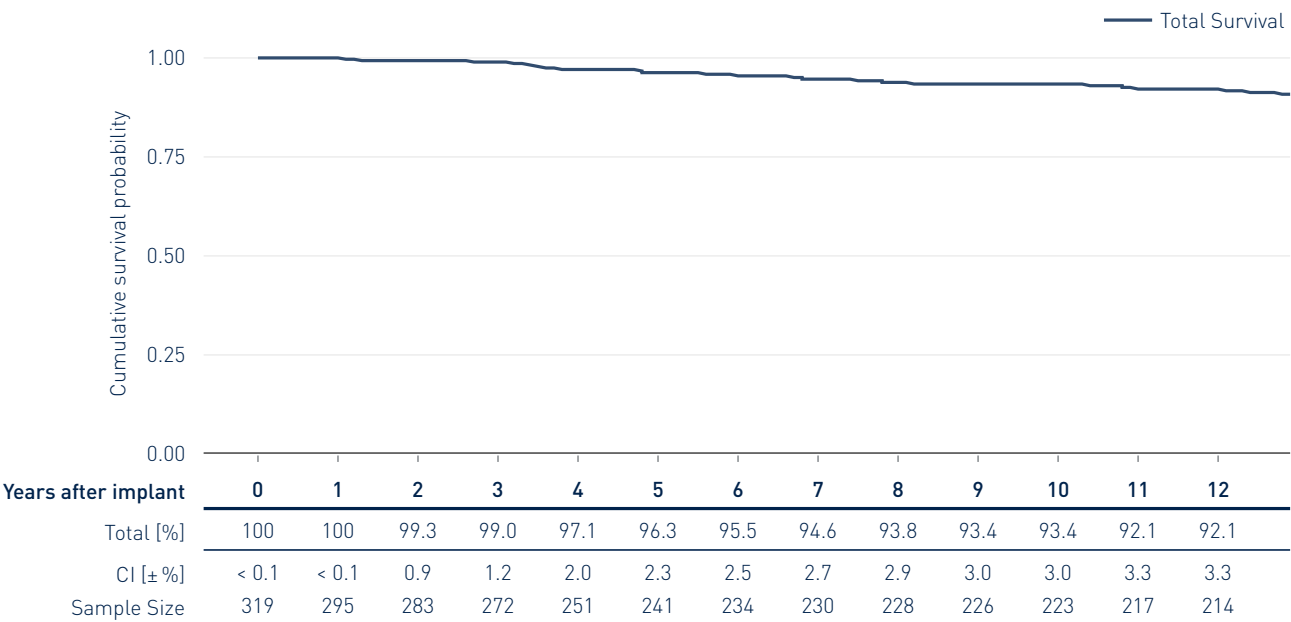


6.2 Performance of ICD Leads – Postmarket Data

Linux T

Product Versions	65, 75
Lead Type	single-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	2 260
Registered US Implants	319
Estimated Active US Implants	209
US Total Returned	4

	Count	Rate		Count	Rate
US Qualifying Complications	21	6.52%	US 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%	US Acute Lead Observations	1	0.31%
Insulation breach	1	0.31%	Other	1	0.31%
Oversensing	11	3.42%			
Other	1	0.31%			



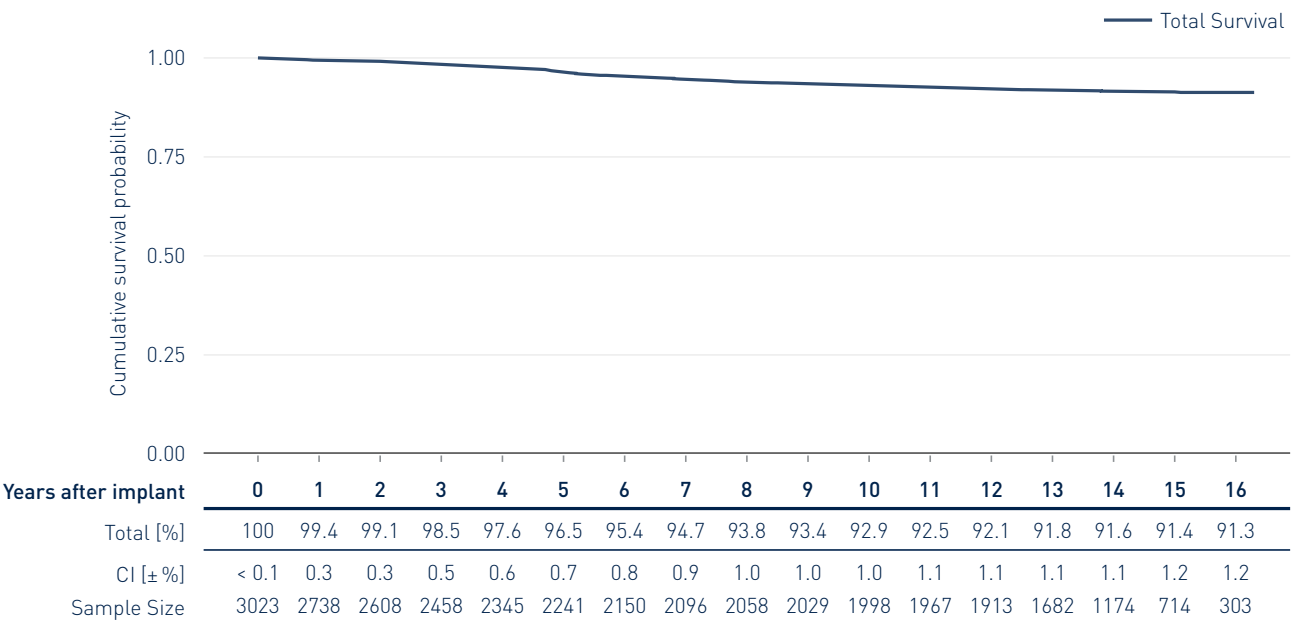


6.2 Performance of ICD Leads – Postmarket Data

Linux TD

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
Registered US Implants	3 023
Estimated Active US Implants	1 900
US Total Returned	82

	Count	Rate		Count	Rate
US Qualifying Complications	158	5.18%	US Confirmed Malfunctions	39	1.28%
Abnormal defibrillation impedance	18	0.59%	Conductor Fracture	7	0.23%
Abnormal pacing impedance	14	0.46%	Insulation Breach	32	1.05%
Cardiac perforation	1	0.03%	US Acute Lead Observations	3	0.10%
Conductor fracture	24	0.79%	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	53	1.74%			
Other	3	0.10%			



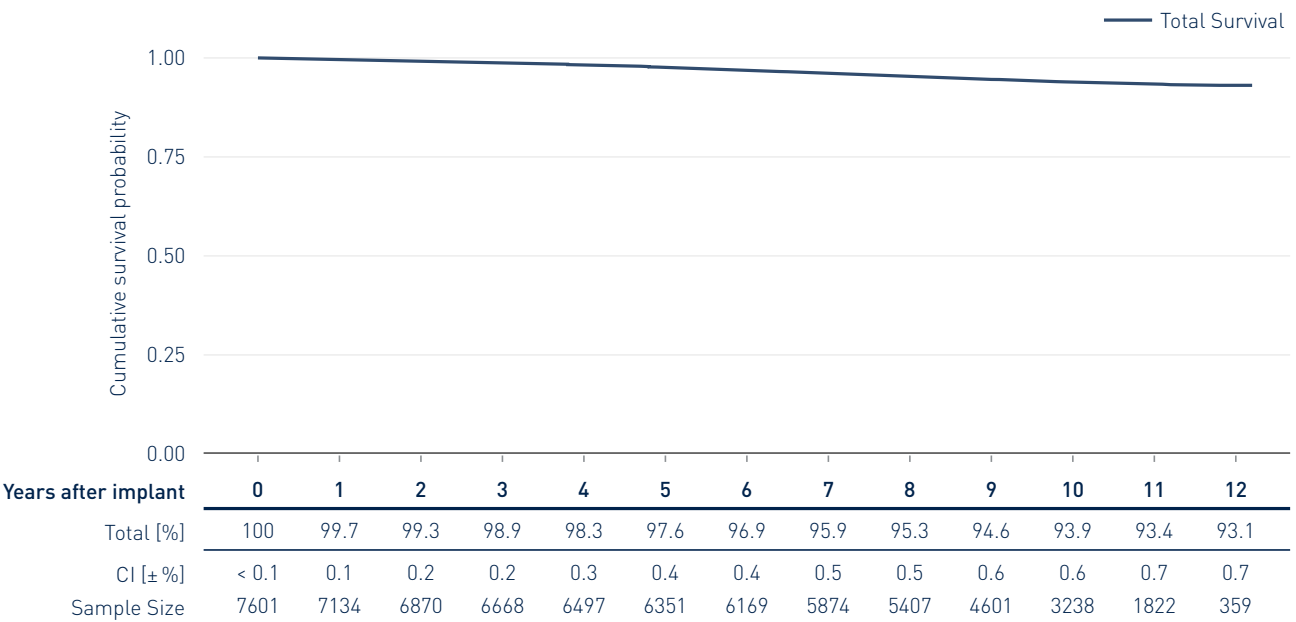


6.2 Performance of ICD Leads – Postmarket Data

Linux Smart S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
Registered US Implants	7 601
Estimated Active US Implants	5 620
US Total Returned	216

	Count	Rate		Count	Rate
US Qualifying Complications	304	3.97%	US Confirmed Malfunctions	88	1.15%
Abnormal defibrillation impedance	25	0.33%	Conductor Fracture	18	0.24%
Abnormal pacing impedance	26	0.34%	Insulation Breach	69	0.90%
Cardiac perforation	1	0.01%	Other	1	0.01%
Conductor fracture	44	0.58%	US Acute Lead Observations	10	0.13%
Failure to capture	24	0.31%	Abnormal pacing impedance	1	0.01%
Failure to sense	15	0.20%	Cardiac perforation	1	0.01%
Insulation breach	5	0.07%	Lead dislodgement	7	0.09%
Lead dislodgement	14	0.18%	Other	1	0.01%
Oversensing	140	1.83%			
Other	10	0.13%			



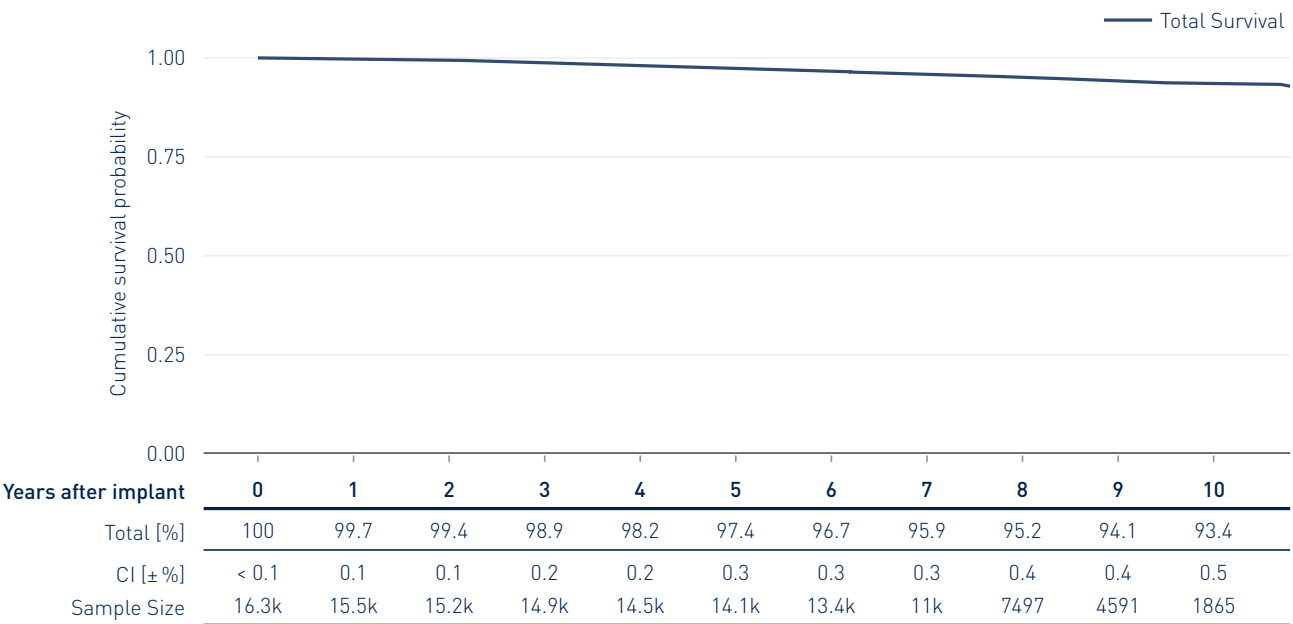


6.2 Performance of ICD Leads – Postmarket Data

Linux Smart S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 300
Registered US Implants	16 311
Estimated Active US Implants	13 100
US Total Returned	415

	Count	Rate		Count	Rate
US Qualifying Complications	617	3.76%	US Confirmed Malfunctions	141	0.86%
Abnormal defibrillation impedance	73	0.44%	Conductor Fracture	15	0.09%
Abnormal pacing impedance	49	0.30%	Insulation Breach	122	0.74%
Conductor fracture	71	0.43%	Other	4	0.02%
Failure to capture	44	0.27%	US Acute Lead Observations	39	0.24%
Failure to sense	20	0.12%	Cardiac perforation	4	0.02%
Insulation breach	10	0.06%	Failure to capture	9	0.05%
Lead dislodgement	49	0.30%	Lead dislodgement	16	0.10%
Oversensing	286	1.74%	Oversensing	3	0.02%
Other	15	0.09%	Other	7	0.04%



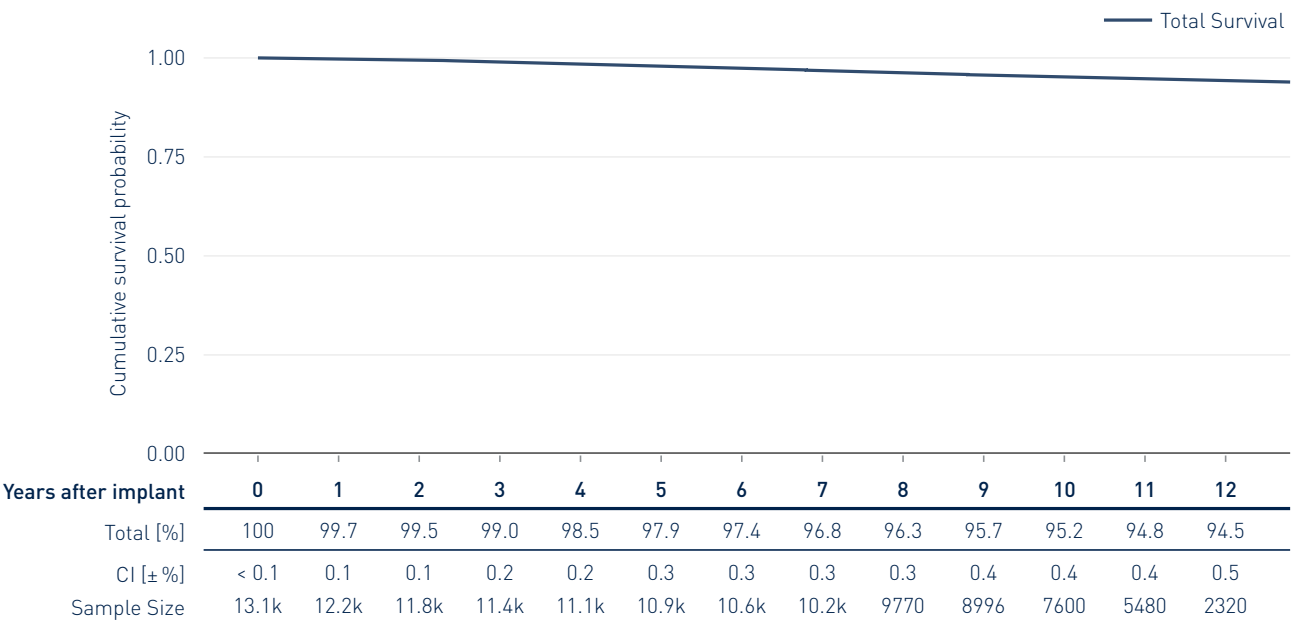


6.2 Performance of ICD Leads – Postmarket Data

Linux Smart SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
Registered US Implants	13 131
Estimated Active US Implants	9 660
US Total Returned	285

	Count	Rate		Count	Rate
US Qualifying Complications	473	3.57%	US Confirmed Malfunctions	92	0.69%
Abnormal defibrillation impedance	53	0.40%	Conductor Fracture	13	0.10%
Abnormal pacing impedance	31	0.23%	Insulation Breach	75	0.57%
Cardiac perforation	1	0.01%	Other	4	0.03%
Conductor fracture	55	0.42%	US Acute Lead Observations	29	0.22%
Extracardiac stimulation	1	0.01%	Abnormal defibrillation impedance	1	0.01%
Failure to capture	40	0.30%	Cardiac perforation	2	0.02%
Failure to sense	12	0.09%	Failure to capture	4	0.03%
Insulation breach	12	0.09%	Insulation breach	1	0.01%
Lead dislodgement	31	0.23%	Lead dislodgement	12	0.09%
Oversensing	226	1.71%	Oversensing	2	0.02%
Other	11	0.08%	Other	7	0.05%



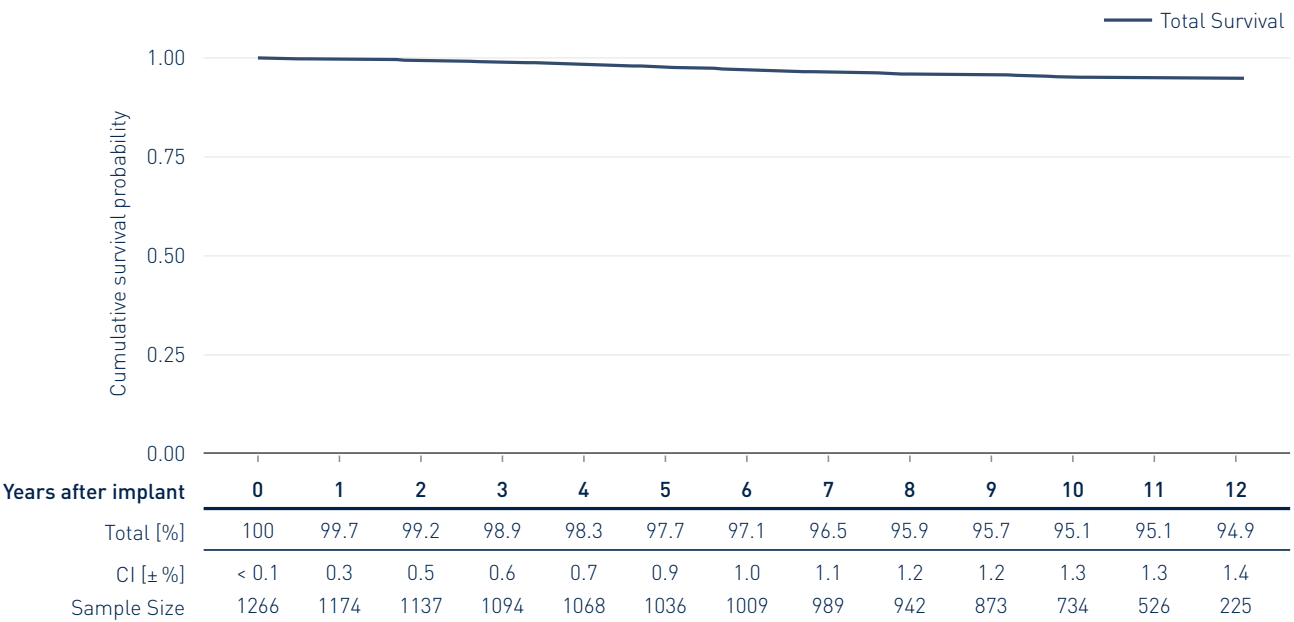


6.2 Performance of ICD Leads – Postmarket Data

Linux Smart TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	7 720
Registered US Implants	1 266
Estimated Active US Implants	928
US Total Returned	23

	Count	Rate		Count	Rate
US Qualifying Complications	51	4.00%	US Confirmed Malfunctions	1	0.08%
Abnormal defibrillation impedance	8	0.63%	Insulation Breach	1	0.08%
Abnormal pacing impedance	5	0.39%	US Acute Lead Observations	3	0.24%
Conductor fracture	4	0.31%	Lead dislodgement	3	0.24%
Failure to capture	13	1.02%			
Insulation breach	3	0.24%			
Lead dislodgement	4	0.31%			
Oversensing	13	1.02%			
Other	1	0.08%			



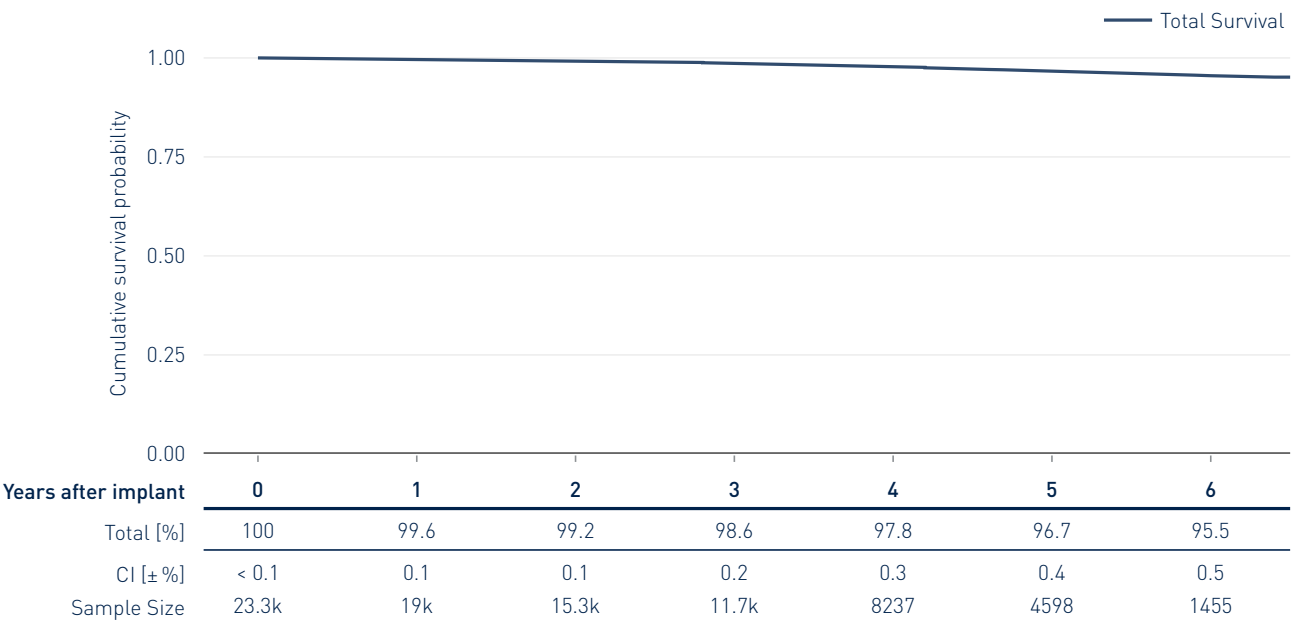


6.2 Performance of ICD Leads – Postmarket Data

Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	165 000
Registered US Implants	23 264
Estimated Active US Implants	20 900
US Total Returned	252

	Count	Rate		Count	Rate
US Qualifying Complications	345	1.48%	US Confirmed Malfunctions	78	0.33%
Abnormal defibrillation impedance	21	0.09%	Conductor Fracture	10	0.04%
Abnormal pacing impedance	12	0.05%	Insulation Breach	61	0.26%
Cardiac perforation	1	0.00%	Other	7	0.03%
Conductor fracture	25	0.11%	US Acute Lead Observations	52	0.22%
Extracardiac stimulation	1	0.00%	Abnormal pacing impedance	3	0.01%
Failure to capture	36	0.15%	Cardiac perforation	6	0.03%
Failure to sense	13	0.06%	Conductor fracture	1	0.00%
Insulation breach	2	0.01%	Failure to capture	11	0.05%
Lead dislodgement	37	0.16%	Lead dislodgement	26	0.11%
Oversensing	185	0.79%	Oversensing	2	0.01%
Other	12	0.05%	Other	3	0.01%



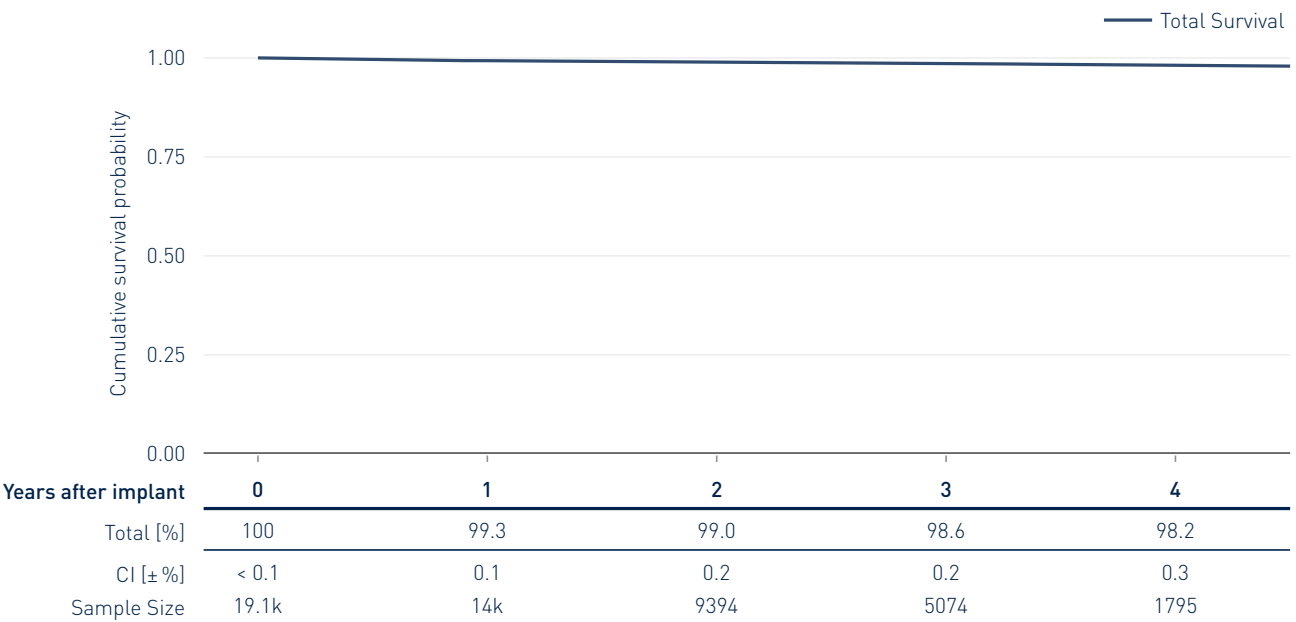


6.2 Performance of ICD Leads – Postmarket Data

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	44 600
Registered US Implants	19 057
Estimated Active US Implants	17 800
US Total Returned	158

	Count	Rate		Count	Rate
US Qualifying Complications	175	0.92%	US Confirmed Malfunctions	25	0.13%
Abnormal defibrillation impedance	8	0.04%	Conductor Fracture	2	0.01%
Abnormal pacing impedance	9	0.05%	Insulation Breach	22	0.12%
Cardiac perforation	3	0.02%	Other	1	0.01%
Conductor fracture	5	0.03%	US Acute Lead Observations	62	0.33%
Failure to capture	23	0.12%	Cardiac perforation	4	0.02%
Failure to sense	13	0.07%	Failure to capture	12	0.06%
Insulation breach	1	0.01%	Failure to sense	6	0.03%
Lead dislodgement	50	0.26%	Lead dislodgement	27	0.14%
Oversensing	54	0.28%	Oversensing	10	0.05%
Other	9	0.05%	Other	3	0.02%



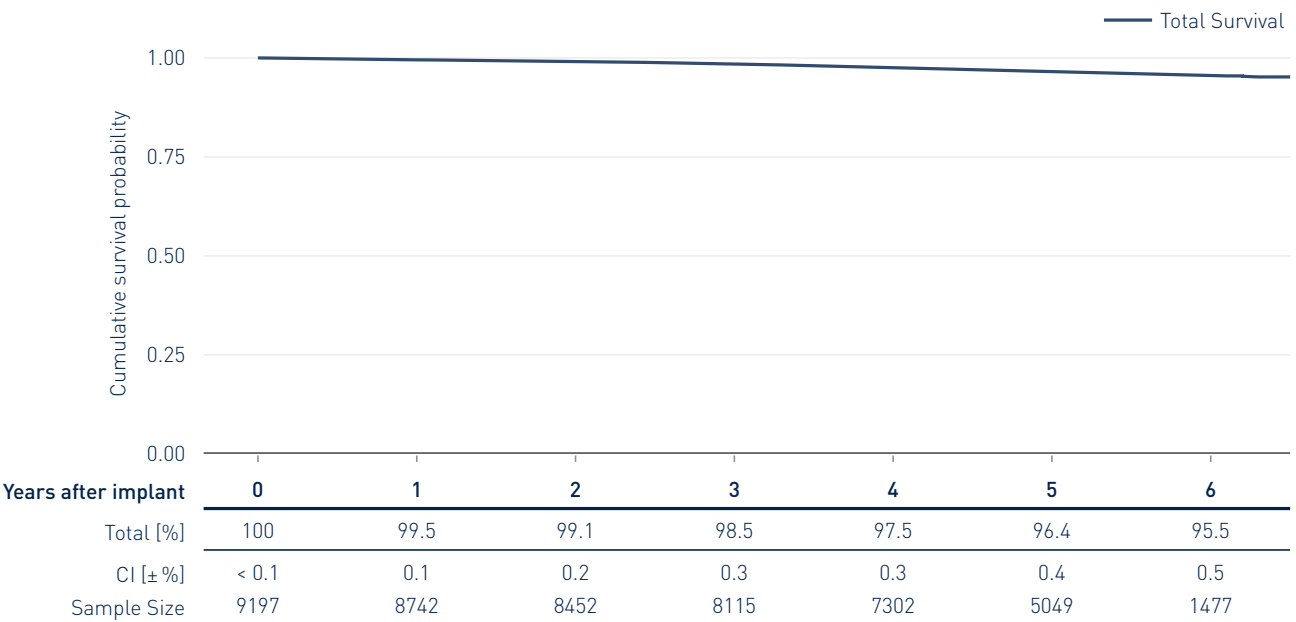


6.2 Performance of ICD Leads – Postmarket Data

Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	23 800
Registered US Implants	9 197
Estimated Active US Implants	7 880
US Total Returned	179

	Count	Rate		Count	Rate
US Qualifying Complications	235	2.54%	US Confirmed Malfunctions	78	0.84%
Abnormal defibrillation impedance	27	0.29%	Conductor Fracture	5	0.05%
Abnormal pacing impedance	11	0.12%	Insulation Breach	72	0.78%
Conductor fracture	15	0.16%	Other	1	0.01%
Failure to capture	17	0.18%	US Acute Lead Observations	21	0.23%
Failure to sense	9	0.10%	Abnormal defibrillation impedance	1	0.01%
Insulation breach	4	0.04%	Cardiac perforation	2	0.02%
Lead dislodgement	20	0.22%	Failure to capture	2	0.02%
Oversensing	128	1.39%	Failure to sense	1	0.01%
Other	4	0.04%	Lead dislodgement	12	0.13%
			Oversensing	1	0.01%
			Other	2	0.02%



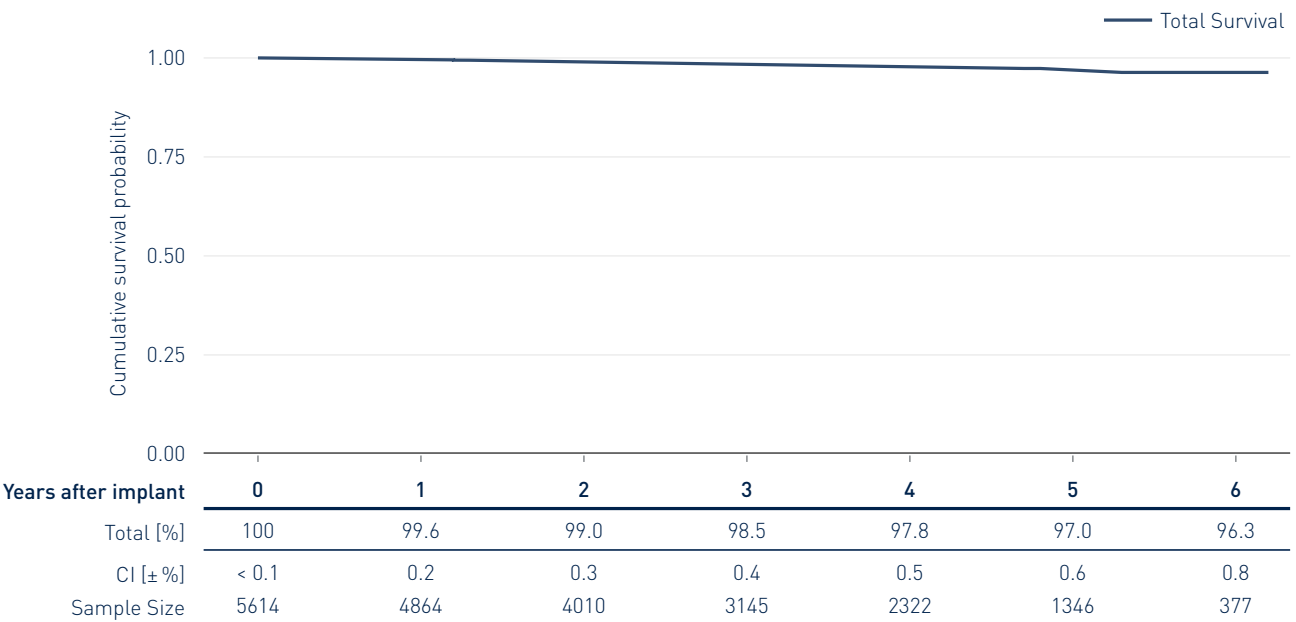


6.2 Performance of ICD Leads – Postmarket Data

Plexa SD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	18 400
Registered US Implants	5 614
Estimated Active US Implants	4 940
US Total Returned	38

	Count	Rate		Count	Rate
US Qualifying Complications	99	1.76%	US Confirmed Malfunctions	10	0.18%
Abnormal defibrillation impedance	9	0.16%	Conductor Fracture	3	0.05%
Abnormal pacing impedance	4	0.07%	Insulation Breach	6	0.11%
Conductor fracture	8	0.14%	Other	1	0.02%
Extracardiac stimulation	1	0.02%	US Acute Lead Observations	16	0.28%
Failure to capture	9	0.16%	Abnormal defibrillation impedance	3	0.05%
Failure to sense	5	0.09%	Abnormal pacing impedance	2	0.04%
Insulation breach	3	0.05%	Cardiac perforation	2	0.04%
Lead dislodgement	8	0.14%	Failure to capture	3	0.05%
Oversensing	49	0.87%	Lead dislodgement	2	0.04%
Other	3	0.05%	Oversensing	2	0.04%
			Other	2	0.04%



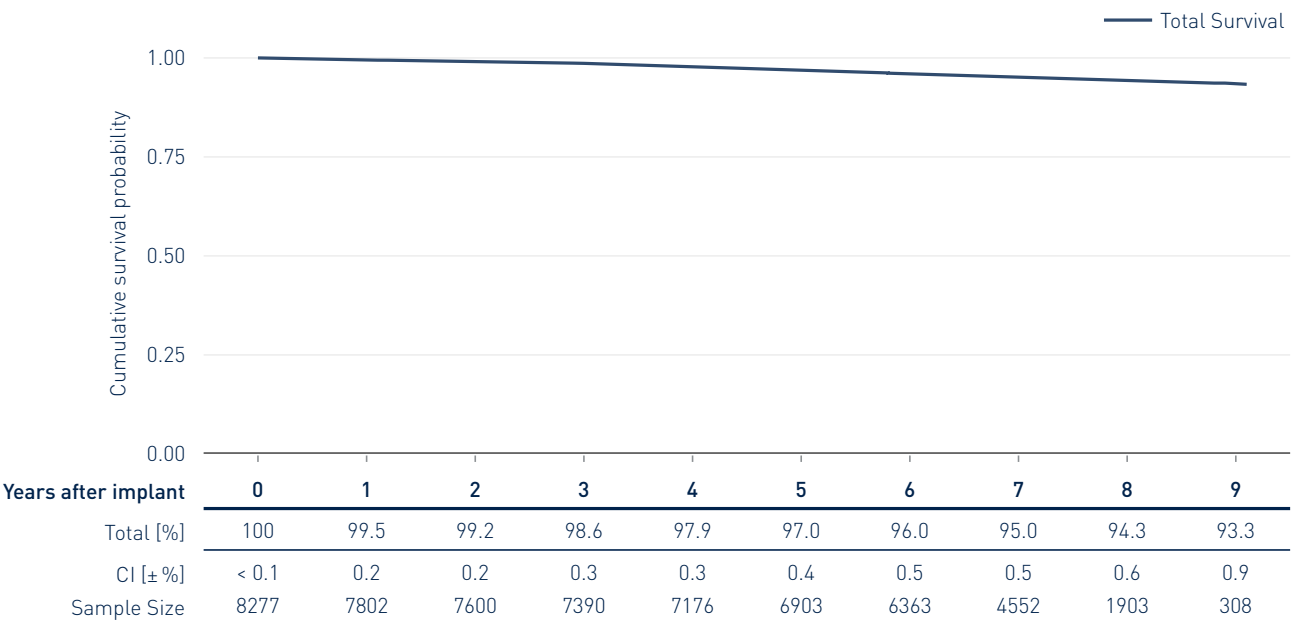


6.2 Performance of ICD Leads – Postmarket Data

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
Registered US Implants	8 277
Estimated Active US Implants	6 450
US Total Returned	153

	Count	Rate		Count	Rate
US Qualifying Complications	316	3.79%	US Confirmed Malfunctions	70	0.84%
Abnormal defibrillation impedance	20	0.24%	Conductor Fracture	13	0.16%
Abnormal pacing impedance	10	0.12%	Insulation Breach	55	0.66%
Cardiac perforation	2	0.02%	Other	2	0.02%
Conductor fracture	41	0.49%	US Acute Lead Observations	28	0.34%
Extracardiac stimulation	3	0.04%	Cardiac perforation	2	0.02%
Failure to capture	27	0.32%	Extracardiac stimulation	1	0.01%
Failure to sense	6	0.07%	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	170	2.04%			
Other	10	0.12%			



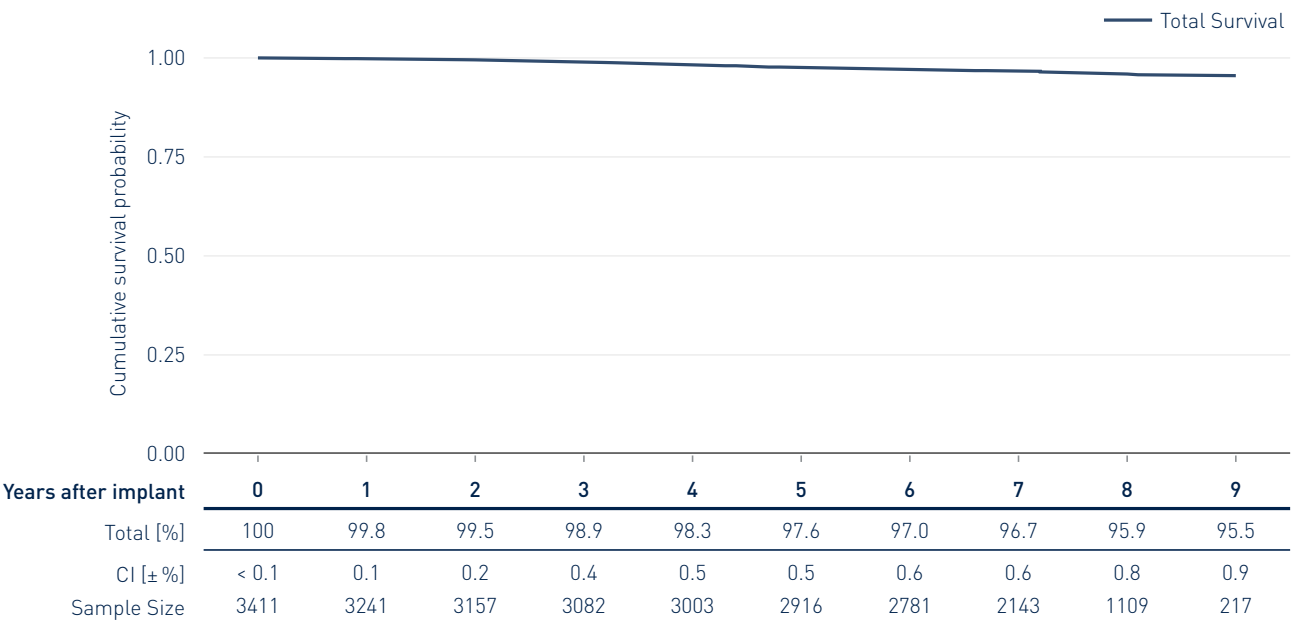


6.2 Performance of ICD Leads – Postmarket Data

Protego SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18 400
Registered US Implants	3 411
Estimated Active US Implants	2 770
US Total Returned	51

	Count	Rate		Count	Rate
US Qualifying Complications	99	2.88%	US Confirmed Malfunctions	18	0.52%
Abnormal defibrillation impedance	9	0.26%	Conductor Fracture	1	0.03%
Abnormal pacing impedance	6	0.17%	Insulation Breach	16	0.47%
Conductor fracture	14	0.41%	Other	1	0.03%
Failure to capture	10	0.29%	US Acute Lead Observations	3	0.09%
Failure to sense	2	0.06%	Lead dislodgement	2	0.06%
Insulation breach	2	0.06%	Other	1	0.03%
Lead dislodgement	6	0.17%			
Oversensing	49	1.43%			
Other	1	0.03%			



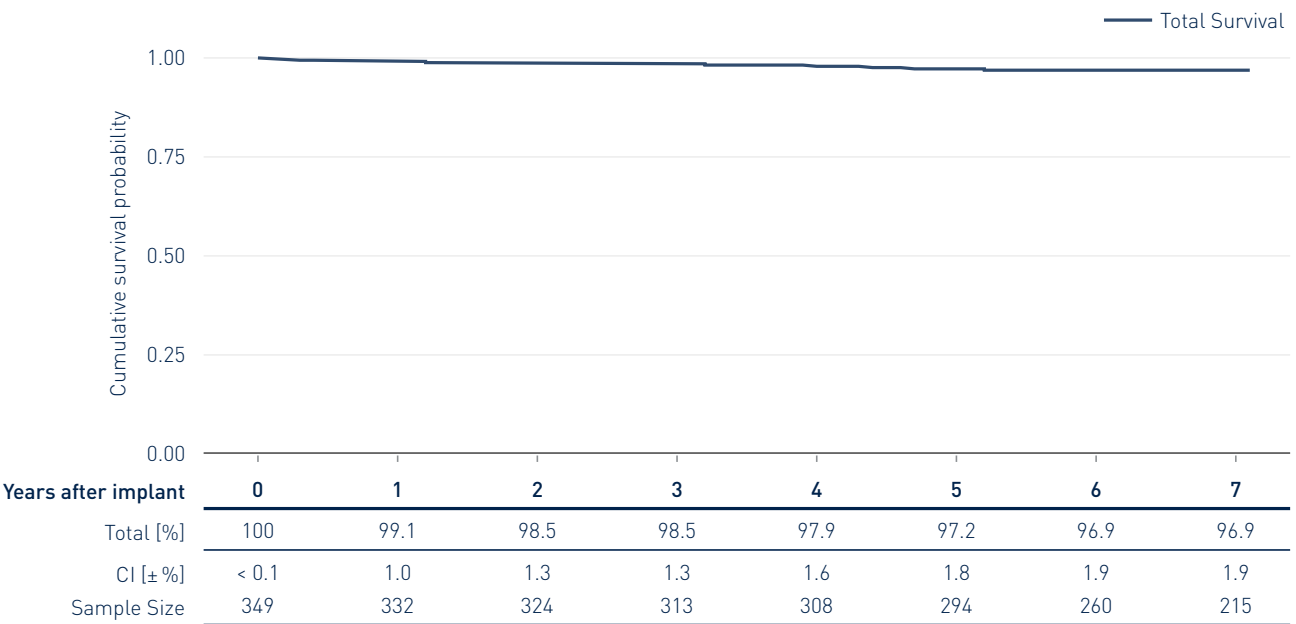


6.2 Performance of ICD Leads – Postmarket Data

Protego TD

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Jan 2014
Worldwide Distributed Devices	1 450
Registered US Implants	349
Estimated Active US Implants	286
US Total Returned	4

	Count	Rate		Count	Rate
US Qualifying Complications	11	3.13%	US Confirmed Malfunctions	0	0.00%
Conductor fracture	4	1.14%	US Acute Lead Observations	0	0.00%
Failure to capture	3	0.85%			
Failure to sense	1	0.28%			
Insulation breach	1	0.28%			
Oversensing	1	0.28%			
Other	1	0.28%			



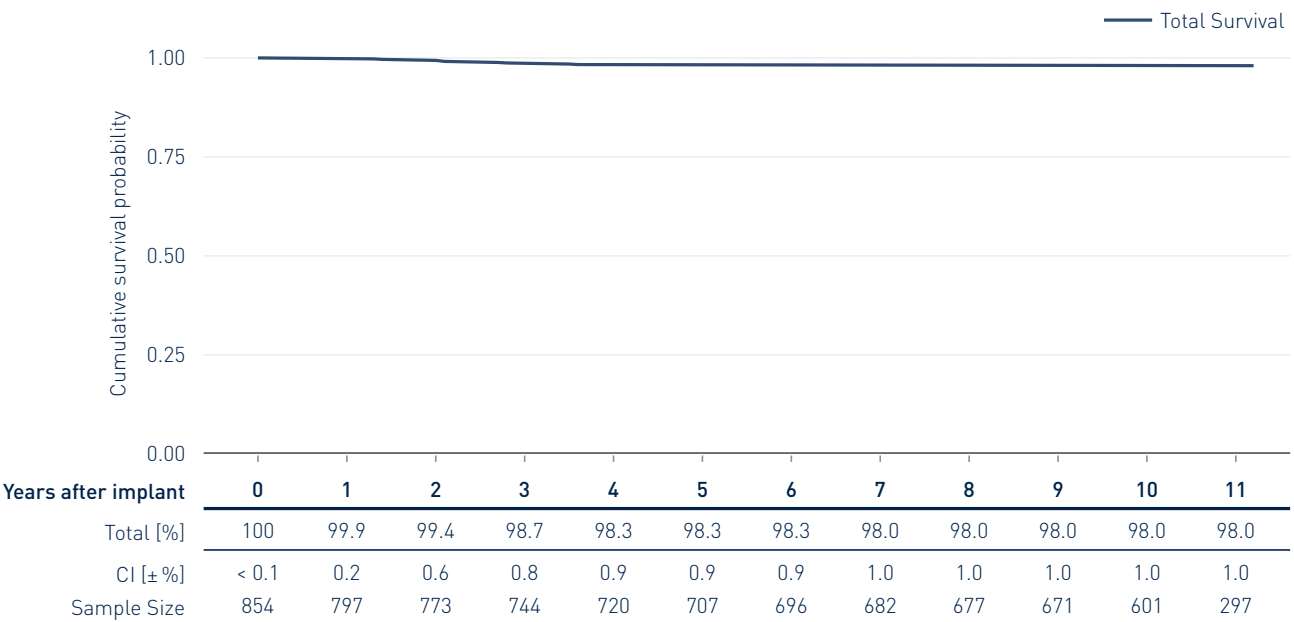


6.2 Performance of ICD Leads – Postmarket Data

Vigila 2CR

Product Versions	60/16, 65/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2012
CE Market Release	Oct 2011
Worldwide Distributed Devices	2 730
Registered US Implants	854
Estimated Active US Implants	671
US Total Returned	12

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





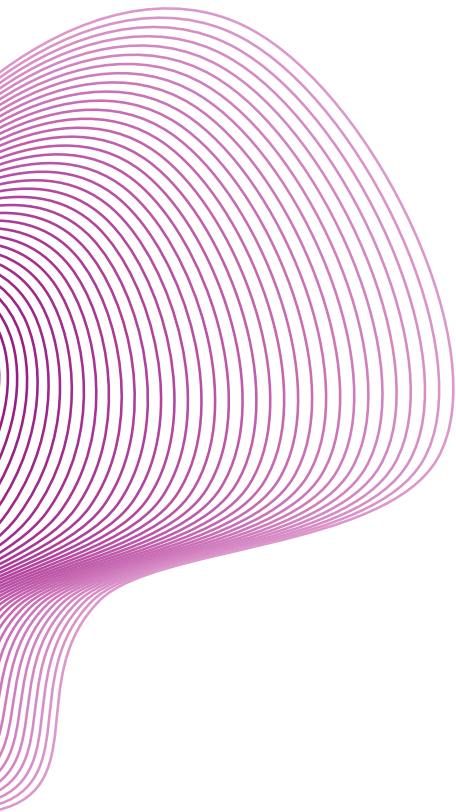
Performance of **BIOTRONIK Leads**

Based on Returned Products
and Complaint Data

6.1 Pacing Leads

6.2 ICD Leads

6.3 CRT Leads



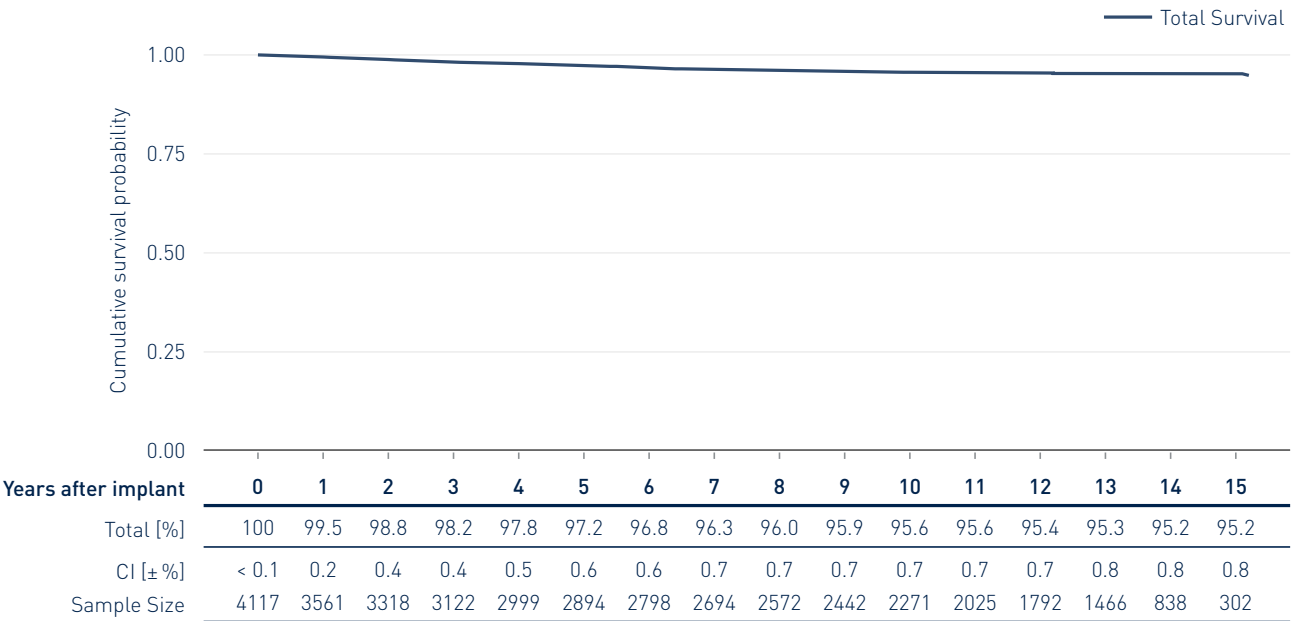


6.3 Performance of CRT Leads – Postmarket Data

Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
Registered US Implants	4 117
Estimated Active US Implants	2 480
US Total Returned	82

	Count	Rate		Count	Rate
US Qualifying Complications	129	3.12%	US Confirmed Malfunctions	16	0.39%
Abnormal pacing impedance	7	0.17%	Conductor Fracture	15	0.36%
Conductor fracture	5	0.12%	Insulation Breach	1	0.02%
Extracardiac stimulation	9	0.22%	US 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	39	0.94%			
Oversensing	6	0.15%			
Other	14	0.34%			



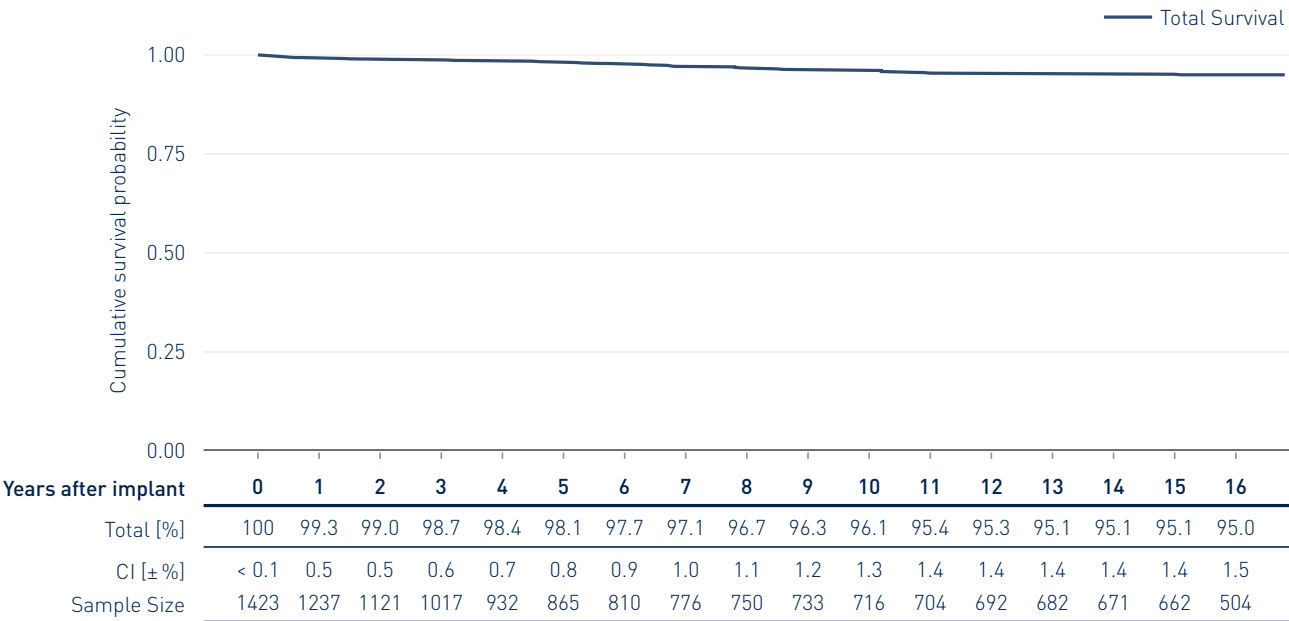


6.3 Performance of CRT Leads – Postmarket Data

Corox OTW UP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	unipolar
Steroid	yes
US Market Release	Aug 2006
CE Market Release	Apr 2004
Worldwide Distributed Devices	10 400
Registered US Implants	1 423
Estimated Active US Implants	667
US Total Returned	26

	Count	Rate		Count	Rate
US Qualifying Complications	44	3.09%	US Confirmed Malfunctions	2	0.14%
Abnormal pacing impedance	1	0.07%	Insulation Breach	2	0.14%
Conductor fracture	2	0.14%	US 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%			



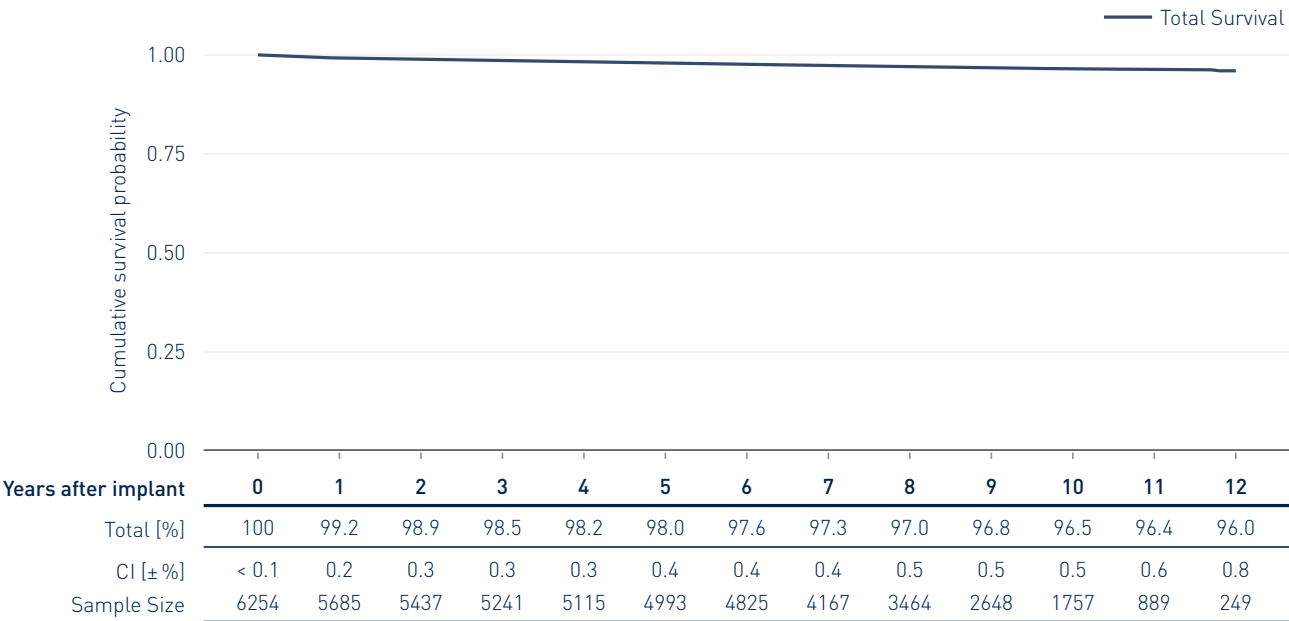


6.3 Performance of CRT Leads – Postmarket Data

Corox OTW-L BP

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
Registered US Implants	6 256
Estimated Active US Implants	4 580
US Total Returned	92

	Count	Rate		Count	Rate
US Qualifying Complications	170	2.70%	US Confirmed Malfunctions	8	0.13%
Abnormal pacing impedance	5	0.08%	Conductor Fracture	4	0.06%
Conductor fracture	7	0.11%	Insulation Breach	1	0.02%
Extracardiac stimulation	27	0.43%	Other	3	0.05%
Failure to capture	74	1.17%	US 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%			



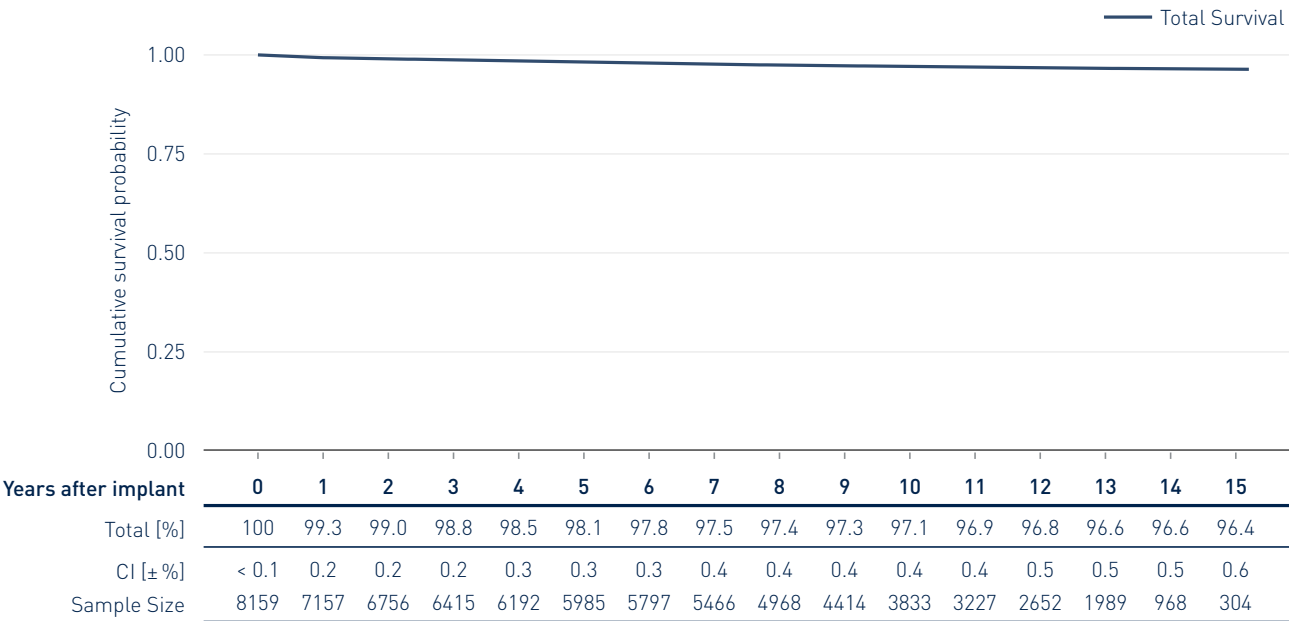


6.3 Performance of CRT Leads – Postmarket Data

Corox OTW-S BP

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
Registered US Implants	8 159
Estimated Active US Implants	5 260
US Total Returned	136

	Count	Rate		Count	Rate
US Qualifying Complications	190	2.31%	US Confirmed Malfunctions	13	0.16%
Abnormal pacing impedance	12	0.15%	Conductor Fracture	8	0.10%
Conductor fracture	8	0.10%	Insulation Breach	4	0.05%
Extracardiac stimulation	16	0.19%	Other	1	0.01%
Failure to capture	57	0.69%	US 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	63	0.77%	Failure to capture	6	0.07%
Oversensing	7	0.09%	Lead dislodgement	20	0.24%
Other	22	0.27%	Other	1	0.01%



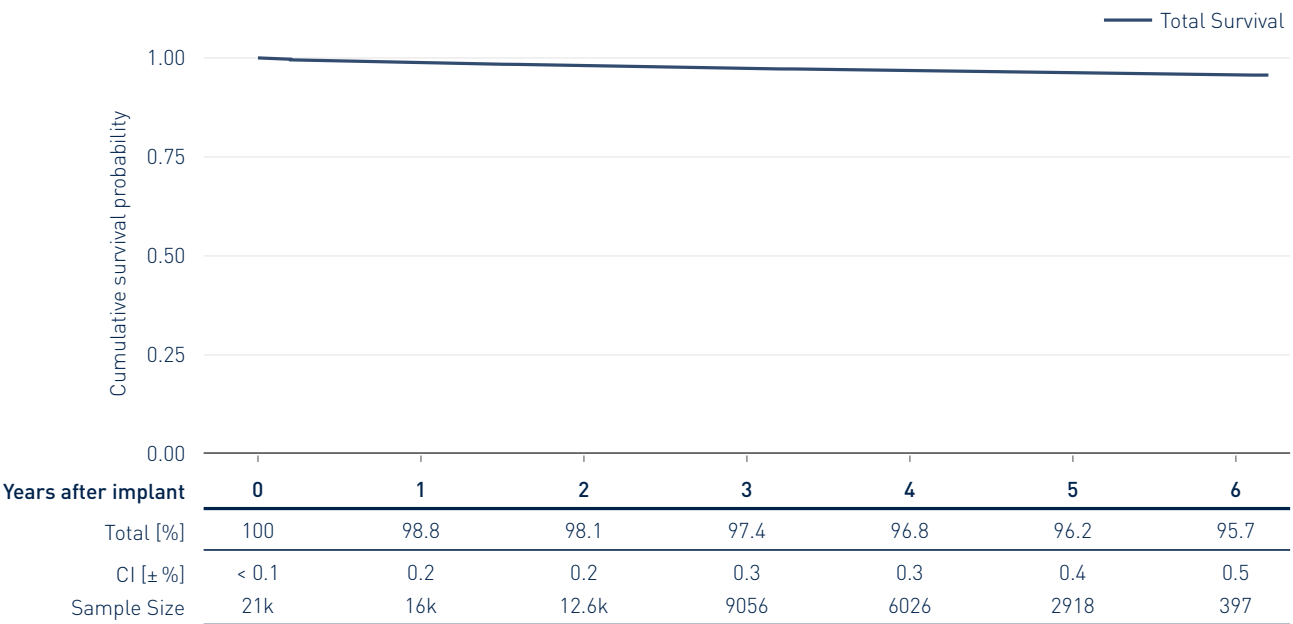


6.3 Performance of CRT Leads – Postmarket Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	146 000
Registered US Implants	22 613
Estimated Active US Implants	19 000
US Total Returned	287

	Count	Rate		Count	Rate
US Qualifying Complications	467	2.05%	US Confirmed Malfunctions	68	0.30%
Abnormal pacing impedance	54	0.24%	Conductor Fracture	63	0.28%
Conductor fracture	21	0.09%	Insulation Breach	1	0.00%
Extracardiac stimulation	19	0.08%	Other	4	0.02%
Failure to capture	123	0.54%	US Acute Lead Observations	63	0.28%
Failure to sense	2	0.01%	Abnormal pacing impedance	2	0.01%
Lead dislodgement	164	0.72%	Conductor fracture	1	0.00%
Oversensing	59	0.26%	Extracardiac stimulation	7	0.03%
Other	25	0.11%	Failure to capture	13	0.06%
			Lead dislodgement	34	0.15%
			Oversensing	3	0.01%
			Other	3	0.01%



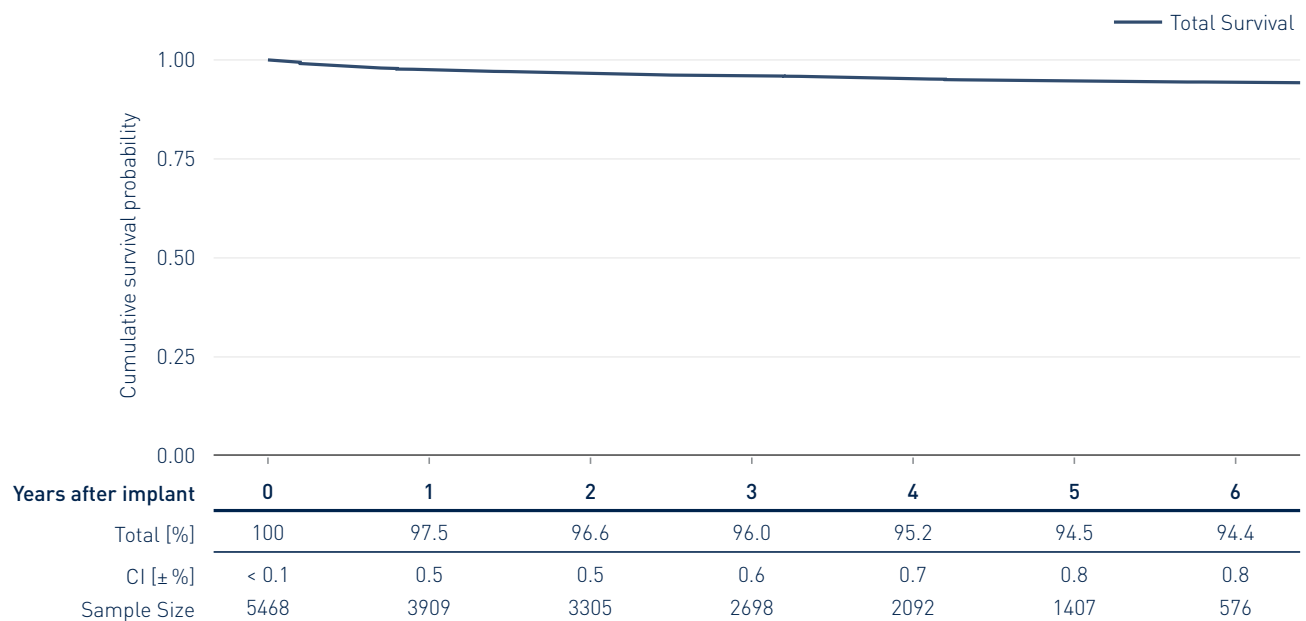


6.3 Performance of CRT Leads – Postmarket Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	27 100
Registered US Implants	5 468
Estimated Active US Implants	3 930
US Total Returned	152

	Count	Rate		Count	Rate
US Qualifying Complications	183	3.30%	US Confirmed Malfunctions	13	0.23%
Abnormal pacing impedance	12	0.22%	Conductor Fracture	13	0.23%
Conductor fracture	8	0.14%	US Acute Lead Observations	99	1.79%
Extracardiac stimulation	7	0.13%	Abnormal pacing impedance	1	0.02%
Failure to capture	44	0.79%	Extracardiac stimulation	4	0.07%
Insulation breach	1	0.02%	Failure to capture	14	0.25%
Lead dislodgement	90	1.62%	Failure to sense	1	0.02%
Oversensing	16	0.29%	Lead dislodgement	73	1.32%
Other	5	0.09%	Oversensing	4	0.07%
			Other	2	0.04%





Methodology for Lead Survival Estimates Based on Clinical Studies

7.1 Introduction

7.2 BIOTRONIK's Clinical Studies

7.3 Lead Complications

7.3 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 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, 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 8.1 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 chapter 9). The lead-related complication free survival probabilities provided for the Sentus QP lead in Section 8.3 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 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 – 2000 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 – 2000 Ohm)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

7.4 Lead Product Performance Graphs and Data

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

Returned Product Analysis Results

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



Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Pacing Leads

8.2 ICD Leads

8.3 CRT Leads



Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Pacing Leads

8.2 ICD Leads

8.3 CRT Leads

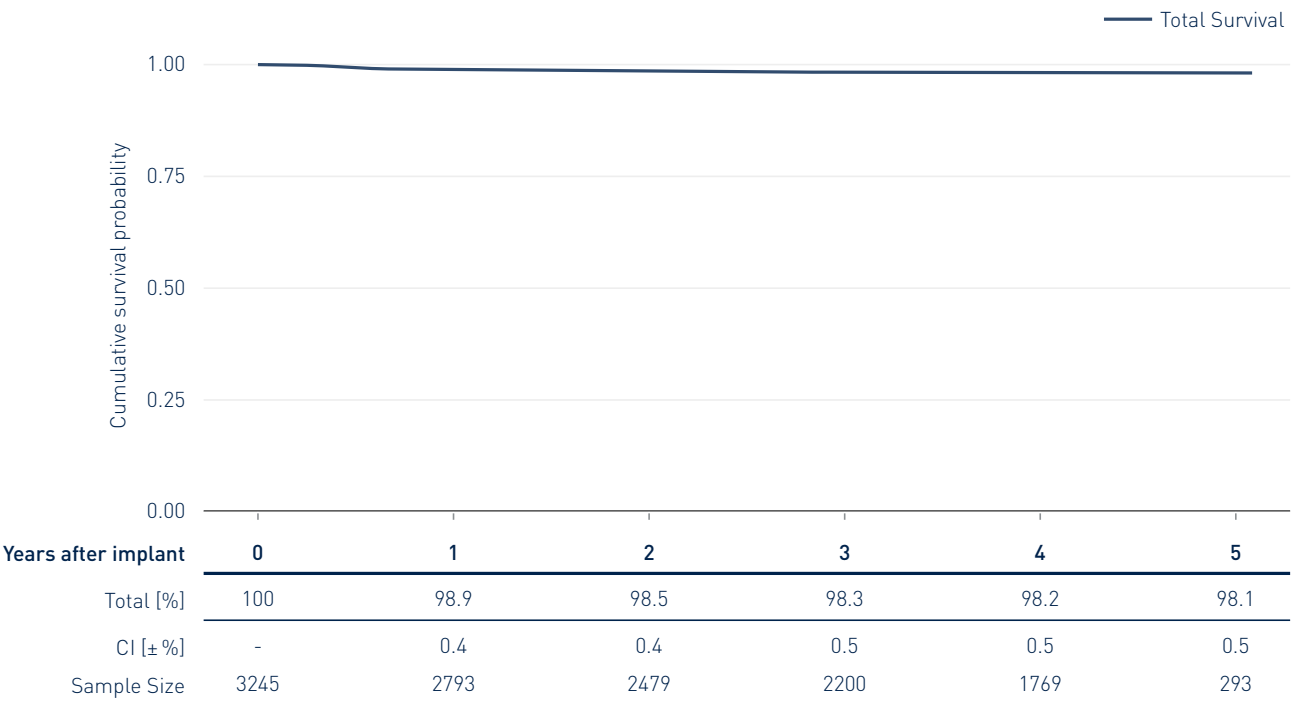


8.1 Performance of Pacing Leads – Study Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 962 000
US Implants in Studies	3 250

	Count	Rate		Count	Rate
US Qualifying Complications	52	1.60%	US Confirmed Malfunctions	3	0.09%
Abnormal pacing impedance	4	0.12%	Conductor Fracture	1	0.03%
Cardiac perforation	2	0.06%	Insulation Breach	1	0.03%
Conductor fracture	2	0.06%	Other	1	0.03%
Failure to capture	23	0.71%	US Acute Lead Observations	26	0.80%
Failure to sense (undersensing)	10	0.31%	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%





Performance of **BIOTRONIK** Leads Based on Clinical Study Data

8.1 Pacing Leads

8.2 ICD Leads

8.3 CRT Leads

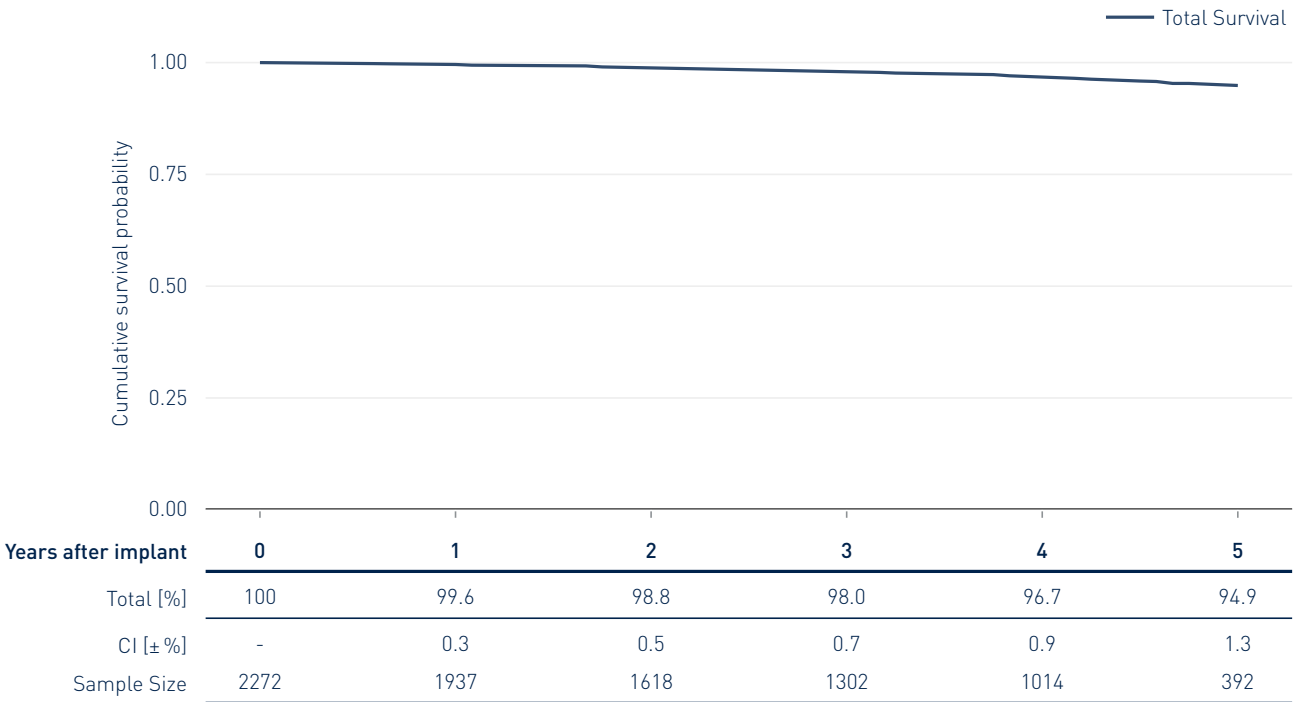


8.2 Performance of ICD Leads – Study Data

Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
US Implants in Studies	2 280

	Count	Rate		Count	Rate
US Qualifying Complications	68	2.99%	US Confirmed Malfunctions	27	1.19%
Abnormal defibrillation impedance	4	0.18%	Conductor Fracture	4	0.18%
Abnormal pacing impedance	10	0.44%	Insulation Breach	23	1.01%
Cardiac perforation	1	0.04%	US 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%			



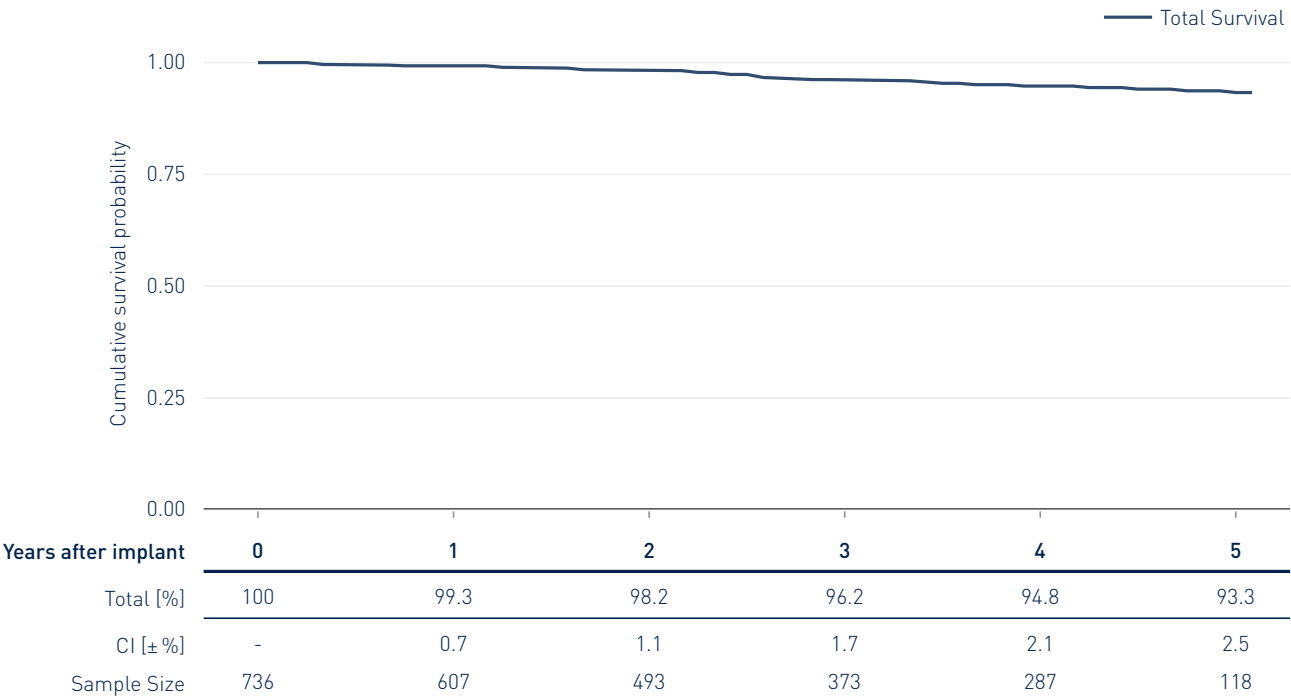


8.2 Performance of ICD Leads – Study Data

Linux Smart SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
US Implants in Studies	736

	Count	Rate		Count	Rate
US Qualifying Complications	29	3.94%	US Confirmed Malfunctions	8	1.09%
Abnormal defibrillation impedance	2	0.27%	Insulation Breach	8	1.09%
Abnormal pacing impedance	2	0.27%	US 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%			





Performance of BIOTRONIK Leads Based on Clinical Study Data

8.1 Pacing Leads

8.2 ICD Leads

8.3 CRT Leads

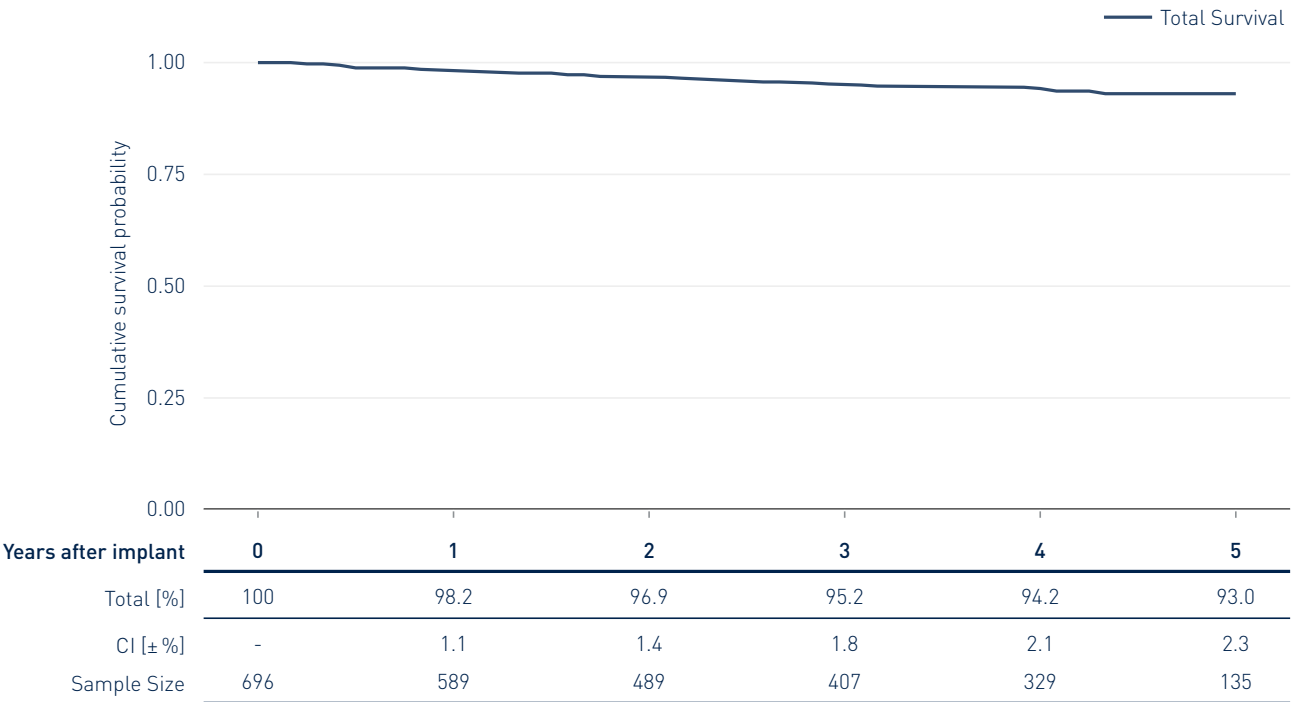


8.3 Performance of CRT Leads – Study Data

Corox OTW BP

Product Versions	75, 85
Lead Type	helix fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	28 700
US Implants in Studies	696

	Count	Rate		Count	Rate
US Qualifying Complications	35	5.03%	US Confirmed Malfunctions	6	0.86%
Abnormal pacing impedance	6	0.86%	Conductor Fracture	6	0.86%
Conductor fracture	5	0.72%	US 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%			



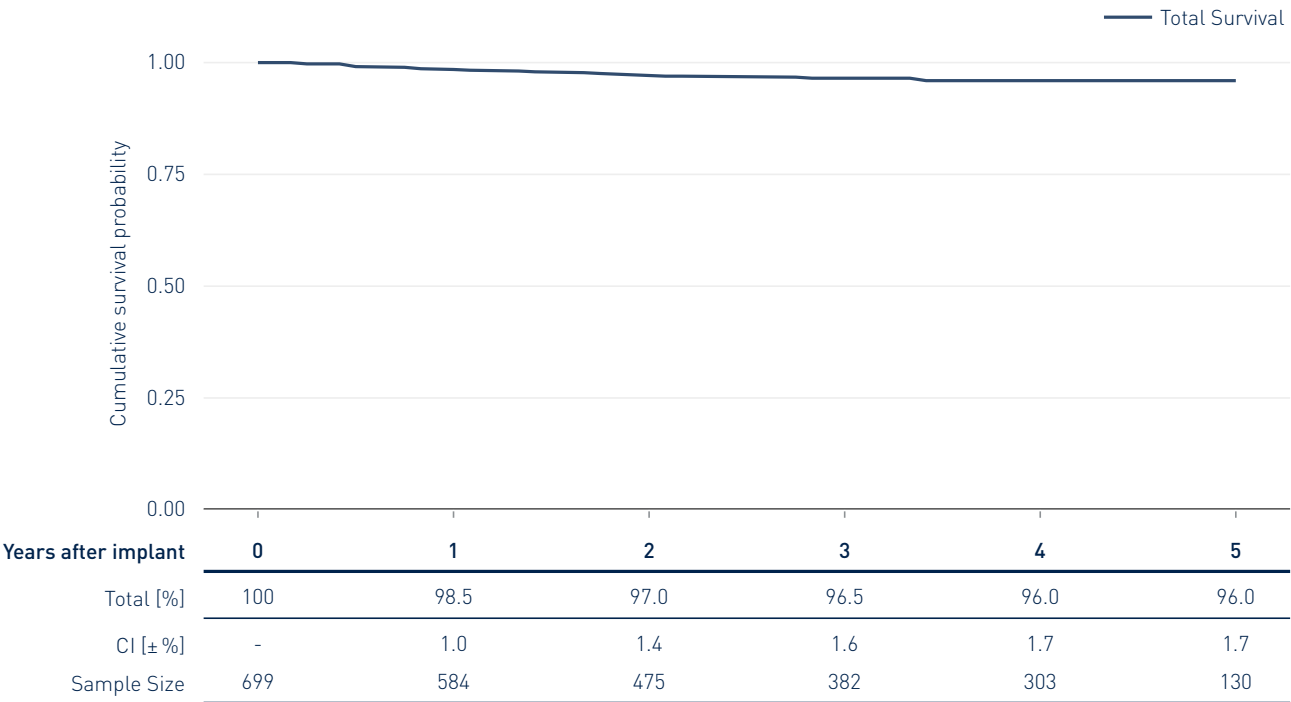


8.3 Performance of CRT Leads – Study Data

Corox OTW-L BP

Product Versions	75, 85
Lead Type	dual-curve fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Dec 2009
Worldwide Distributed Devices	32 000
US Implants in Studies	699

	Count	Rate		Count	Rate
US Qualifying Complications	22	3.15%	US Confirmed Malfunctions	1	0.14%
Extracardiac stimulation	4	0.57%	Other	1	0.14%
Failure to capture	8	1.14%	US Acute Lead Observations	4	0.57%
Lead dislodgement	10	1.43%	Extracardiac stimulation	3	0.43%
			Lead dislodgement	1	0.14%



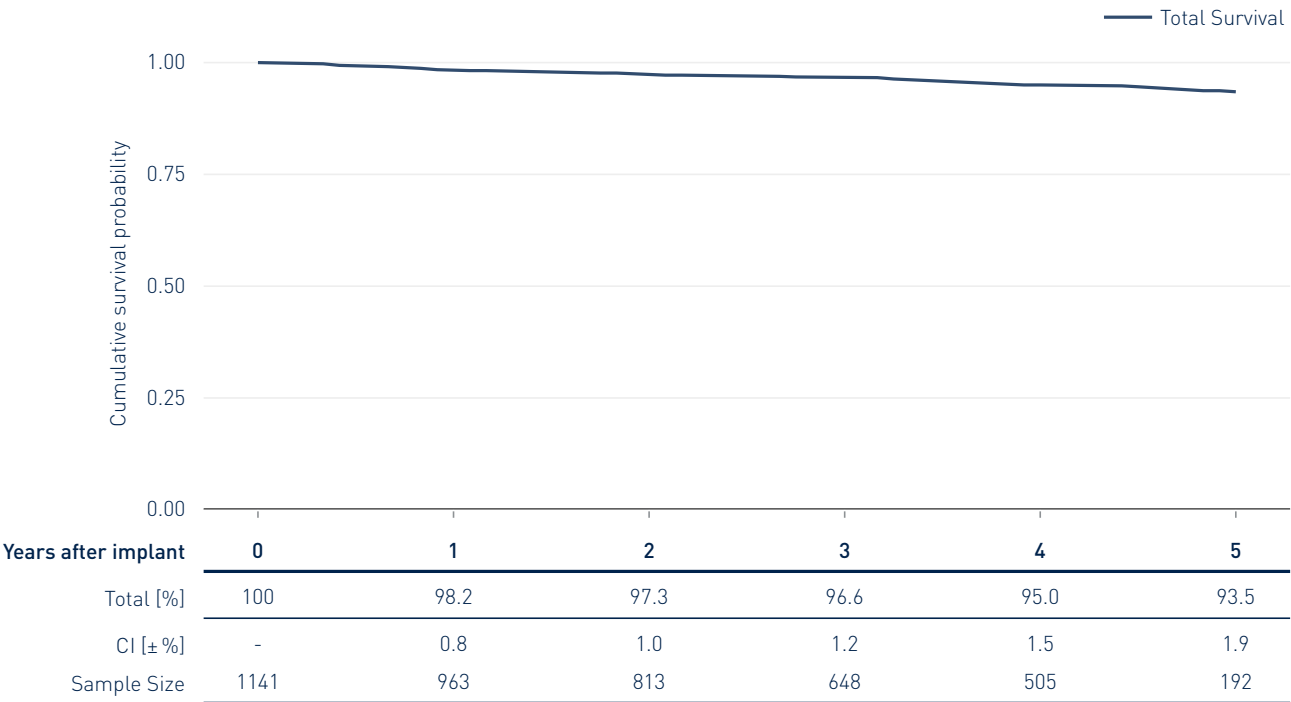


8.3 Performance of CRT Leads – Study Data

Corox OTW-S BP

Product Versions	75, 85
Lead Type	thread fixation
Polarity	bipolar
Steroid	yes
US Market Release	May 2008
CE Market Release	Dec 2006
Worldwide Distributed Devices	26 400
US Implants in Studies	1 150

	Count	Rate		Count	Rate
US Qualifying Complications	49	4.29%	US Confirmed Malfunctions	1	0.09%
Abnormal pacing impedance	13	1.14%	Insulation Breach	1	0.09%
Extracardiac stimulation	9	0.79%	US 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%



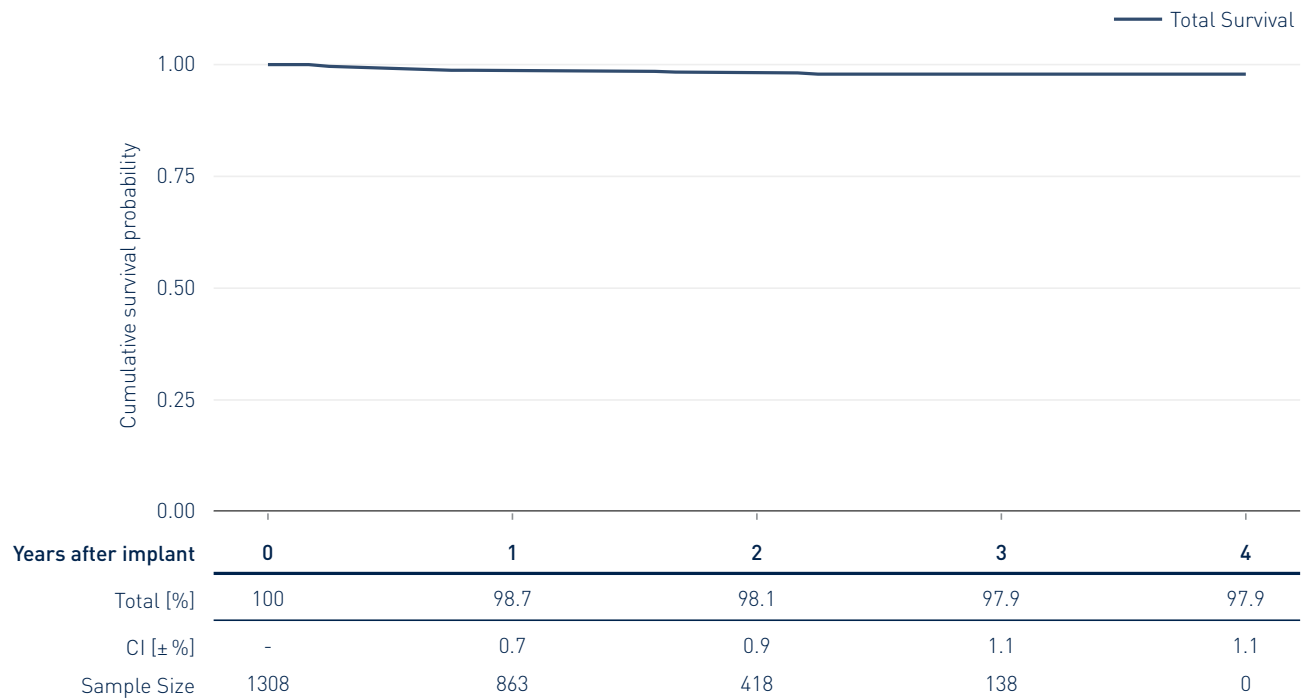


8.3 Performance of CRT Leads – Study Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	146 000
US Implants in Studies	1 310

	Count	Rate		Count	Rate
US Qualifying Complications	21	1.61%	US Confirmed Malfunctions	15	1.15%
Abnormal pacing impedance	3	0.23%	Conductor Fracture	14	1.07%
Conductor fracture	1	0.08%	NA	1	0.08%
Extracardiac Stimulation	2	0.15%	US Acute Lead Observations	7	0.54%
Failure to Capture	4	0.31%	Extracardiac Stimulation	1	0.08%
Lead dislodgement	11	0.84%	Failure to Capture	4	0.31%
			Lead dislodgement	2	0.15%



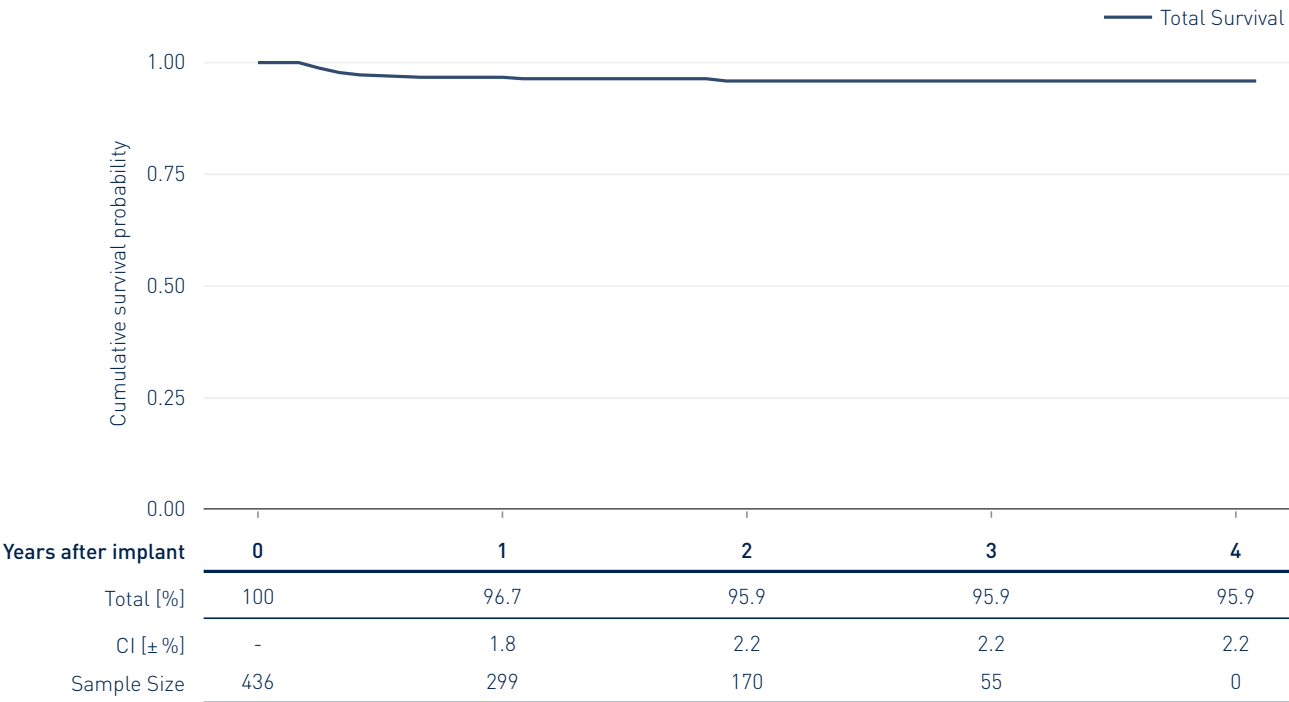


8.3 Performance of CRT Leads – Study Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	27 100
US Implants in Studies	436

	Count	Rate		Count	Rate
US Qualifying Complications	15	3.44%	US Confirmed Malfunctions	5	1.15%
Conductor fracture	1	0.23%	Conductor Fracture	5	1.15%
Extracardiac Stimulation	1	0.23%	US 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%





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 US 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

¹Hicks 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.



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 US market approval as identified in BIOTRONIK's US 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.



Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads

10.2 ICD Leads

10.3 CRT Leads



Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads

10.2 ICD Leads

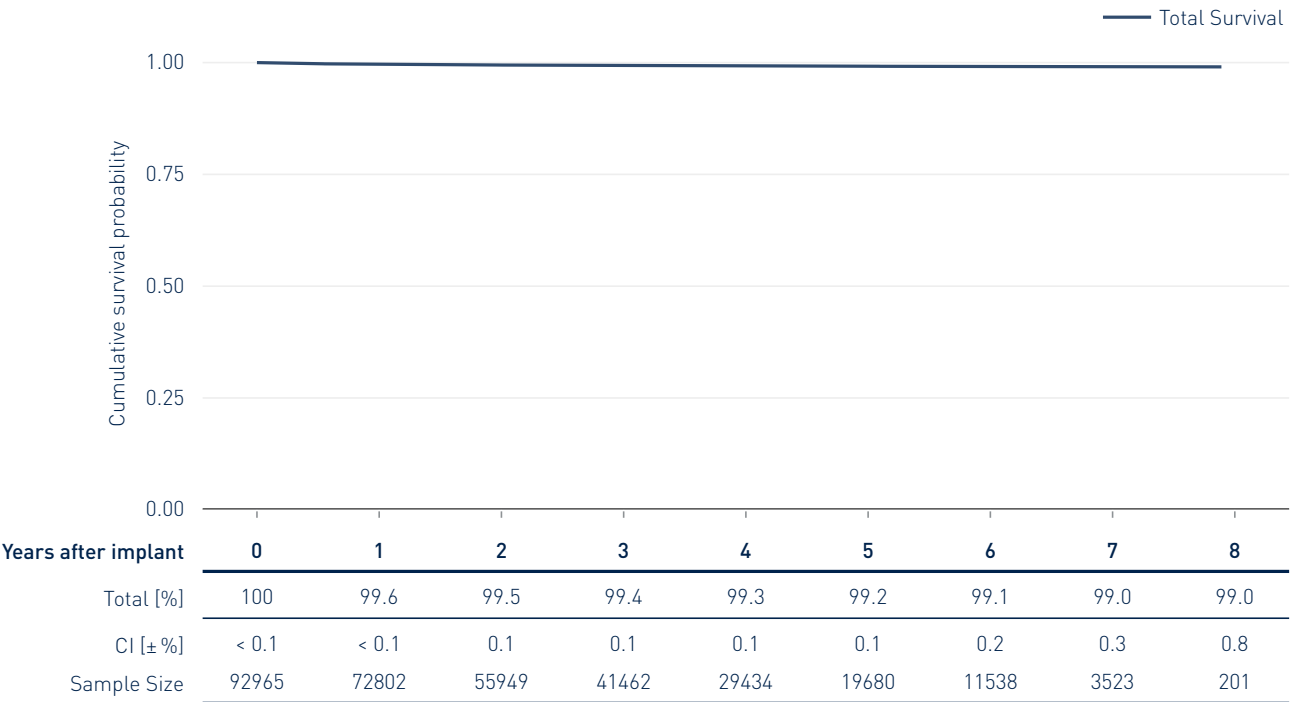
10.3 CRT Leads



10.1 Performance of Pacing Leads – Insurance Claims Data

Siello S / Solia S

Product Versions	45, 53, 60
Lead Type	straight, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2013
CE Market Release	Jul 2009
Worldwide Distributed Devices	2 962 000
US Implants in EP PASSION	93 000





Performance of **BIOTRONIK** Leads Based on Insurance Claims Data

10.1 Pacing Leads

10.2 ICD Leads

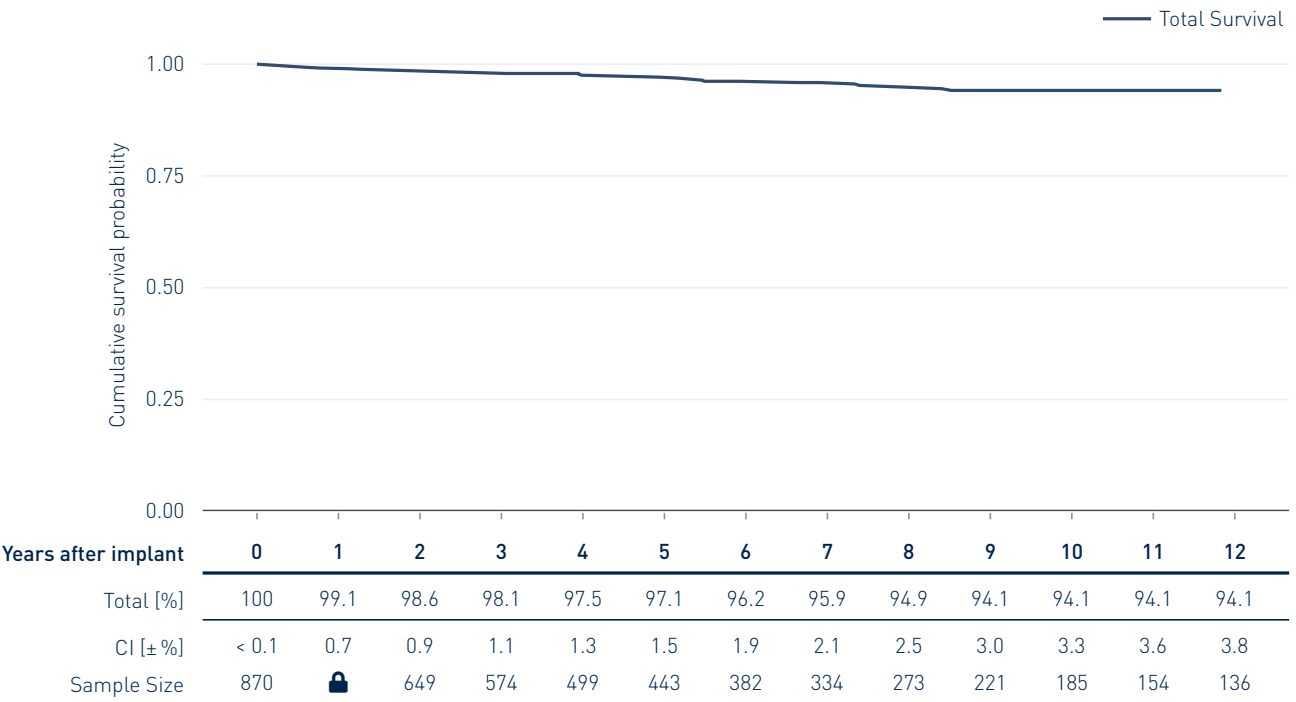
10.3 CRT Leads



10.2 Performance of ICD Leads – Insurance Claims Data

Linux S*

Product Versions	65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2007
CE Market Release	Mar 2007
Worldwide Distributed Devices	32 700
US Implants in EP PASSION	870



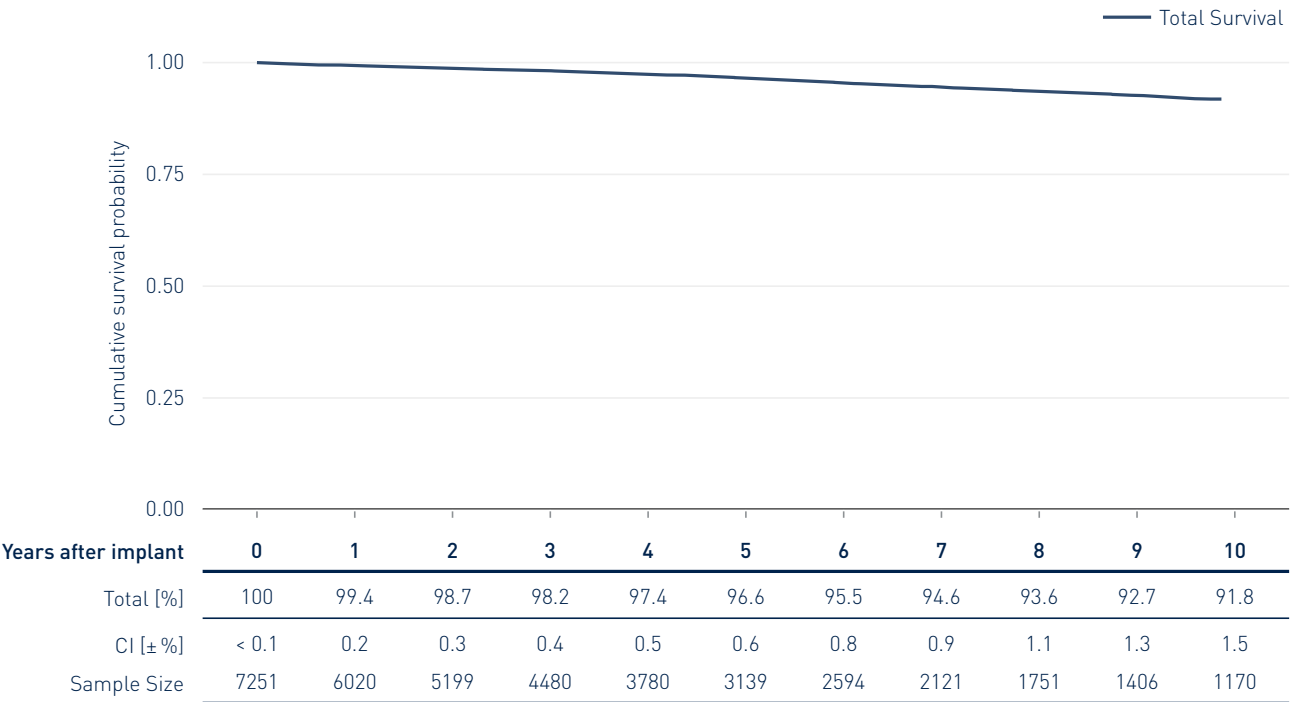
*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2



10.2 Performance of ICD Leads – Insurance Claims Data

Linux SD

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Apr 2006
CE Market Release	Aug 2006
Worldwide Distributed Devices	55 100
US Implants in EP PASSION	7 260

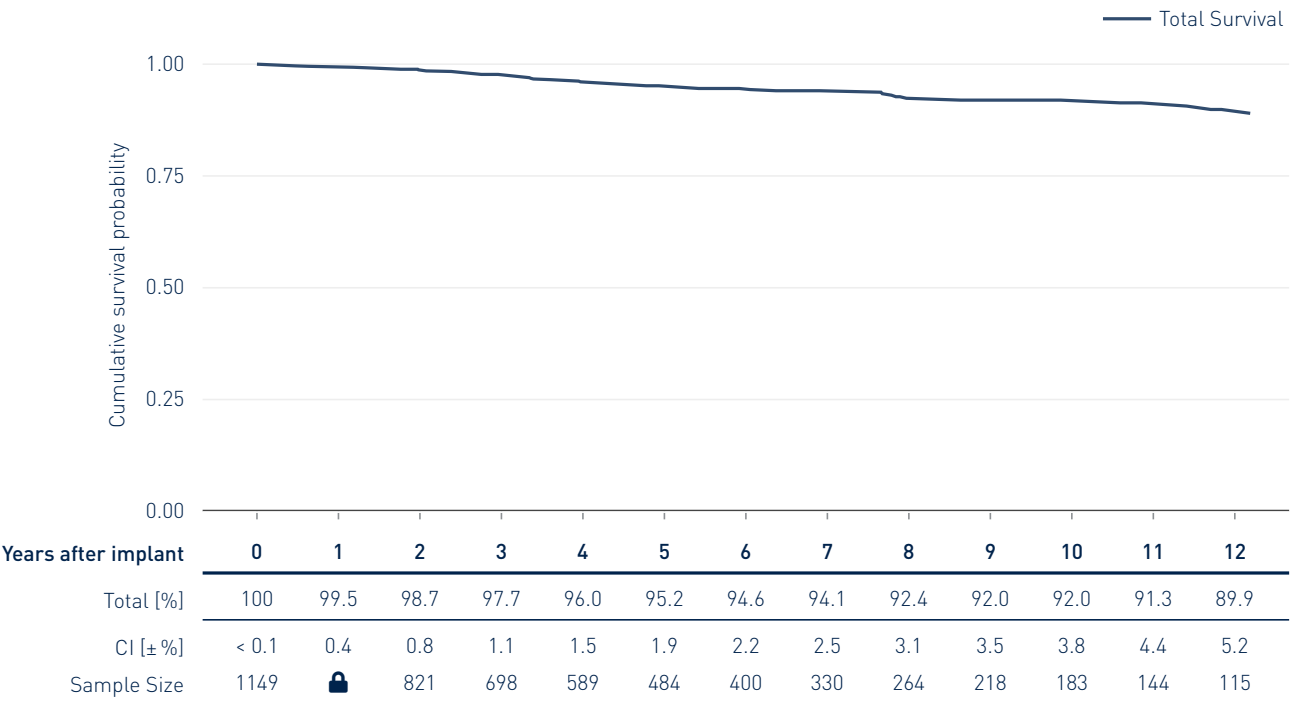




10.2 Performance of ICD Leads – Insurance Claims Data

Linux TD*

Product Versions	65/16, 75/16, 100/16, 100/18
Lead Type	dual-coil, passive fixation
Polarity	bipolar
Steroid	yes
US Market Release	Oct 2006
CE Market Release	Oct 2006
Worldwide Distributed Devices	14 600
US Implants in EP PASSION	1 150

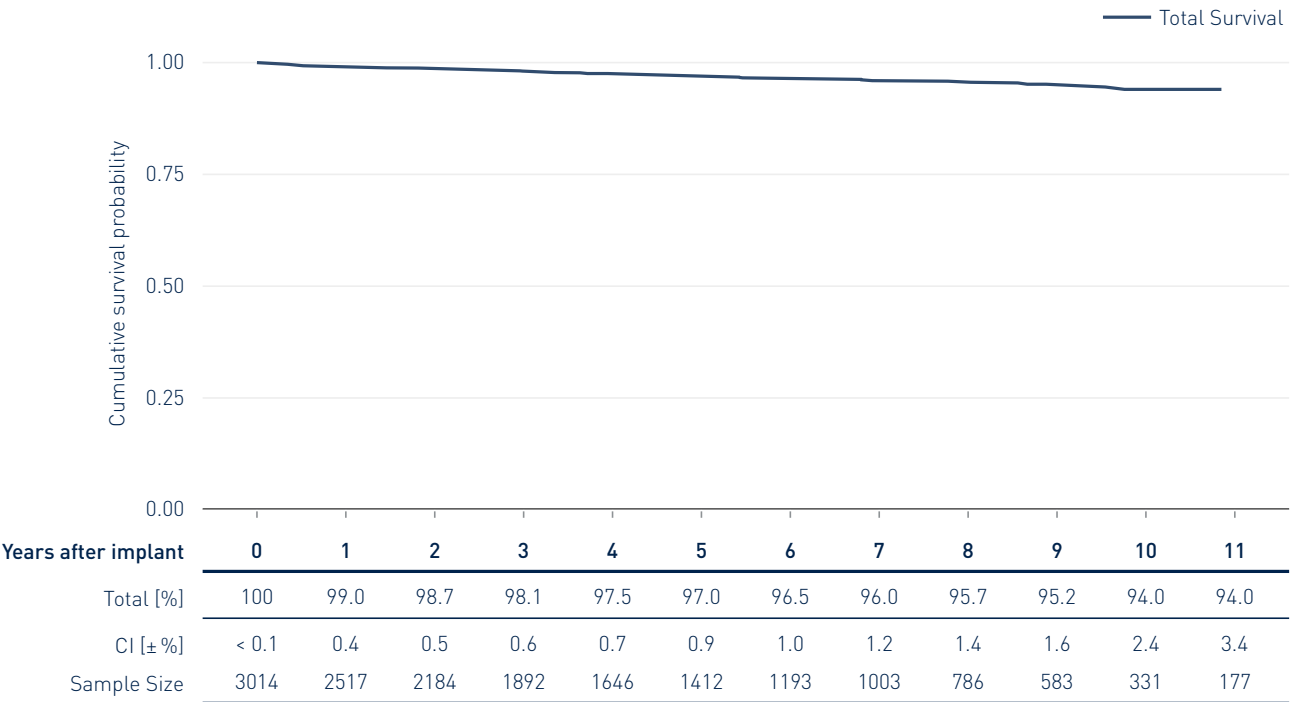


*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Linux Smart S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Aug 2011
CE Market Release	Dec 2010
Worldwide Distributed Devices	46 700
US Implants in EP PASSION	3 020

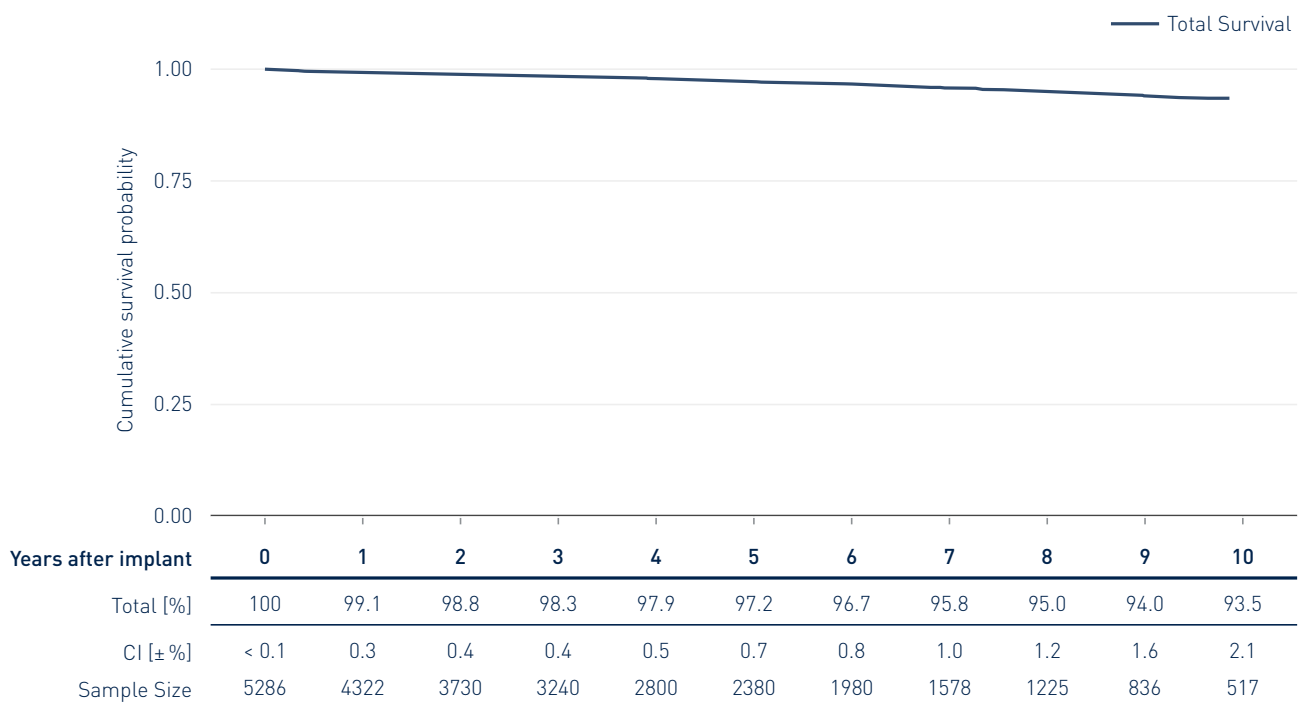




10.2 Performance of ICD Leads – Insurance Claims Data

Linux Smart SD*

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jan 2011
CE Market Release	Oct 2009
Worldwide Distributed Devices	55 700
US Implants in EP PASSION	5 290



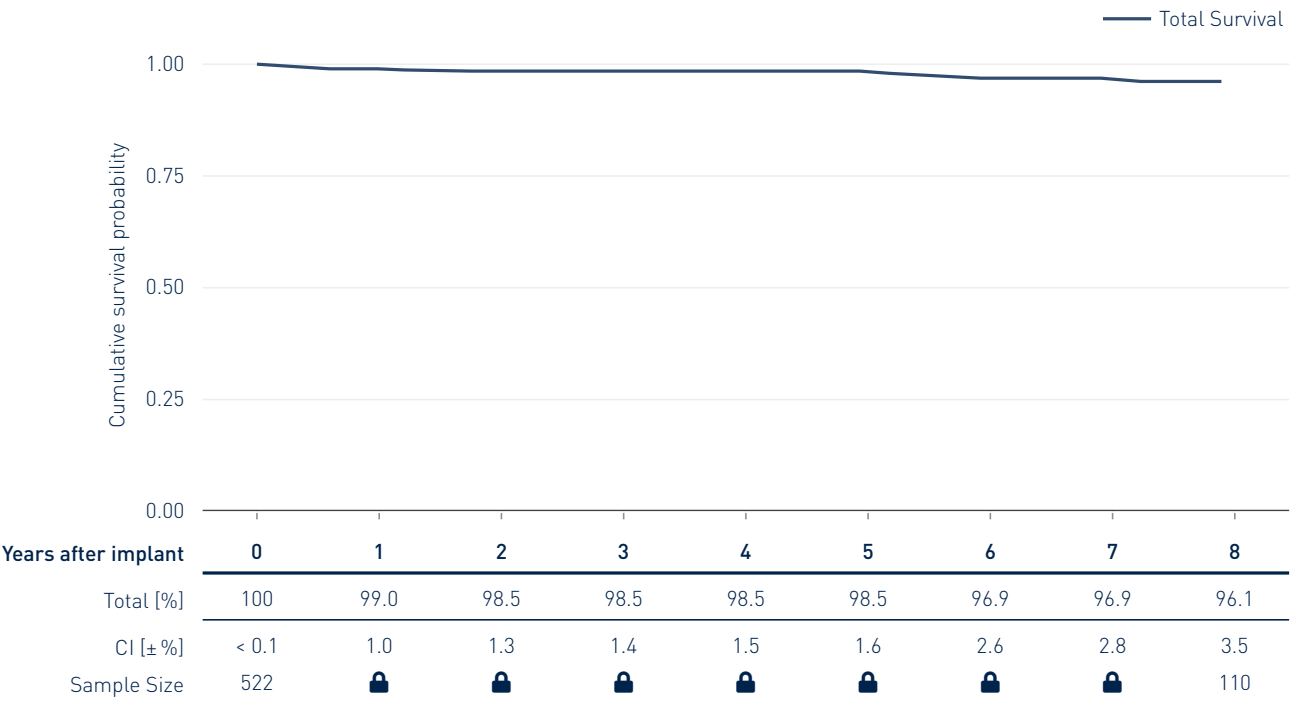
*Cell size suppression criteria defined by CMS do not allow to report data marked with a , see section 9.2



10.2 Performance of ICD Leads – Insurance Claims Data

Linux Smart TD*

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

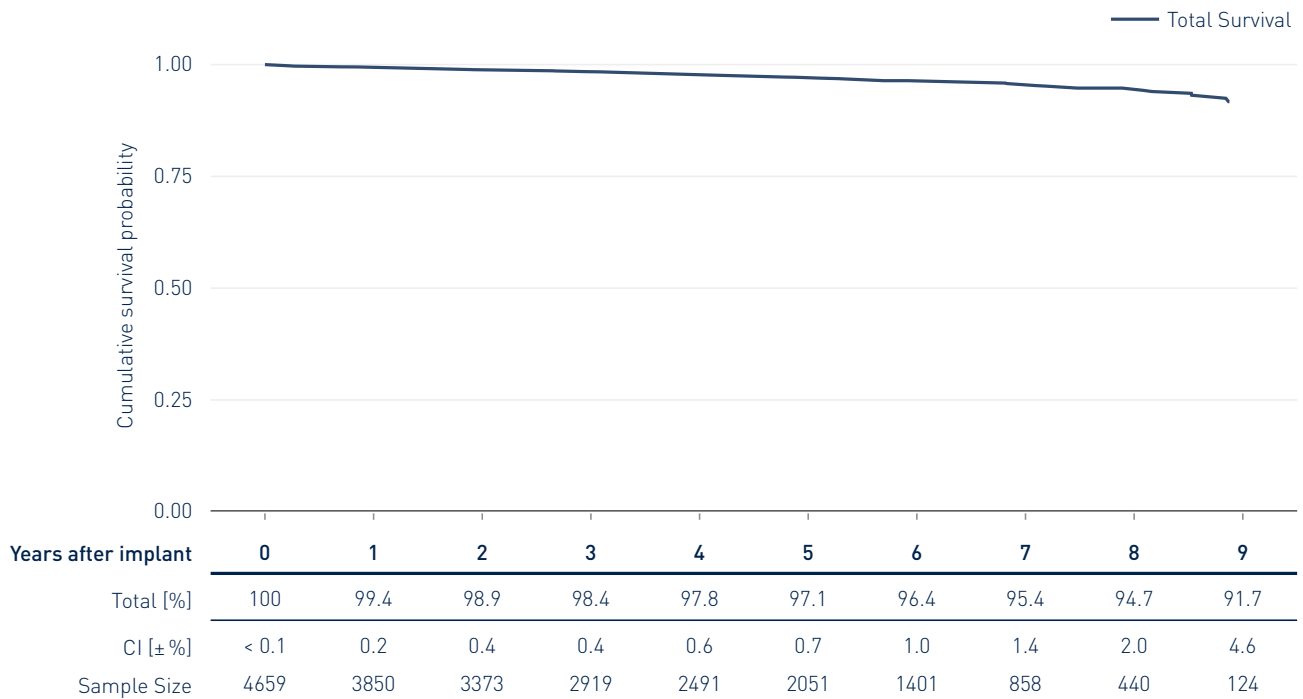


*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2

10.2 Performance of ICD Leads – Insurance Claims Data

Linux Smart S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Feb 2013
CE Market Release	Mar 2010
Worldwide Distributed Devices	36 300
US Implants in EP PASSION	4 660

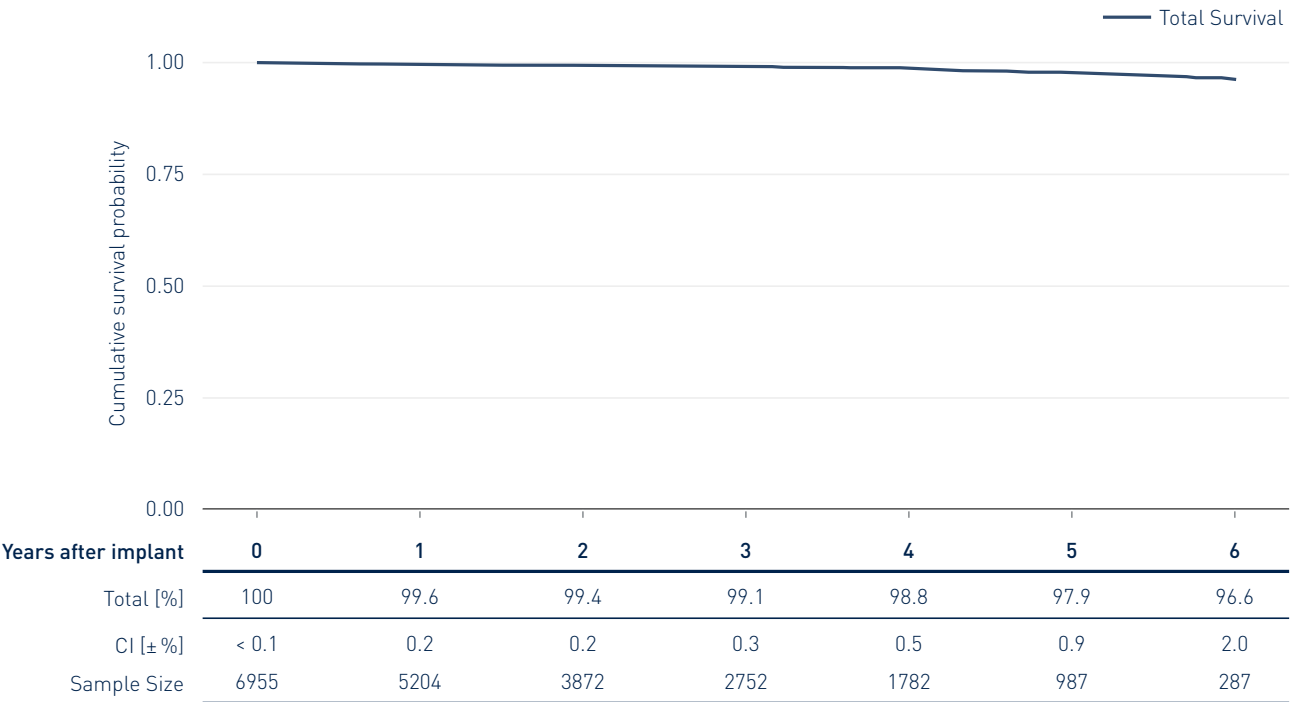




10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	165 000
US Implants in EP PASSION	6 960

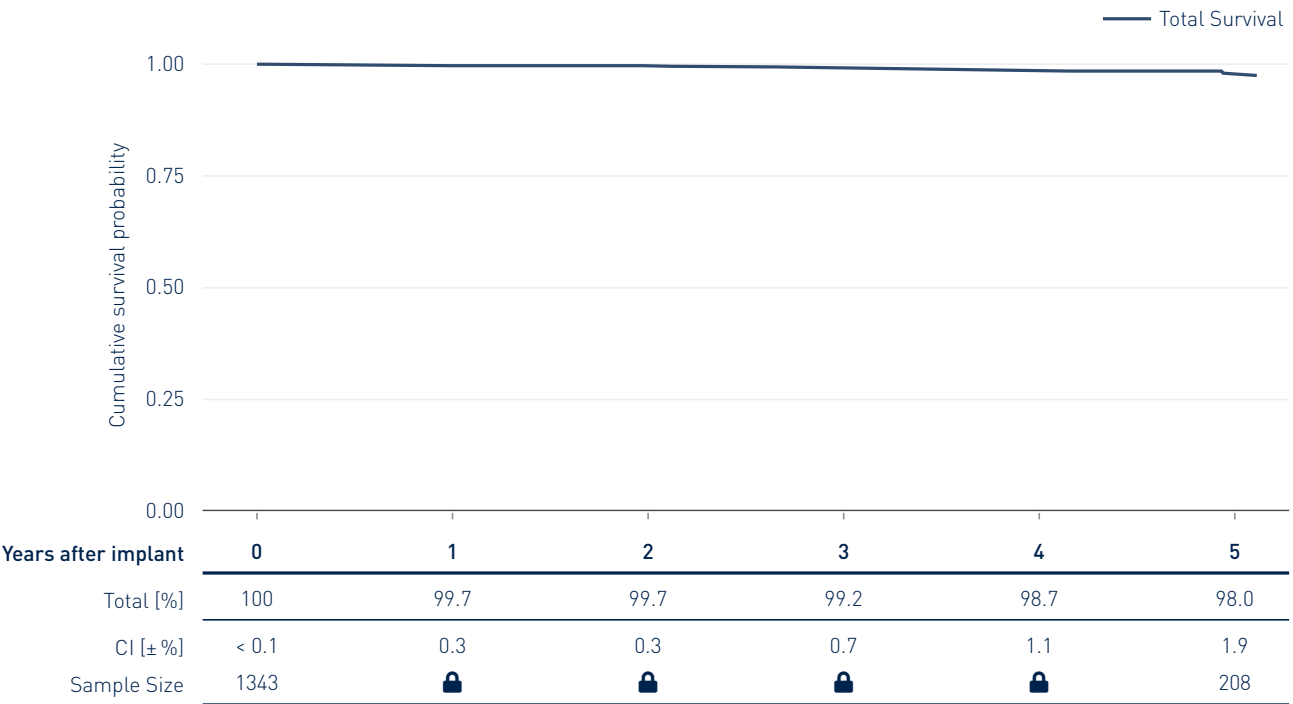




10.2 Performance of ICD Leads – Insurance Claims Data

Plexa SD*

Product Versions	65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	18 400
US Implants in EP PASSION	1 350



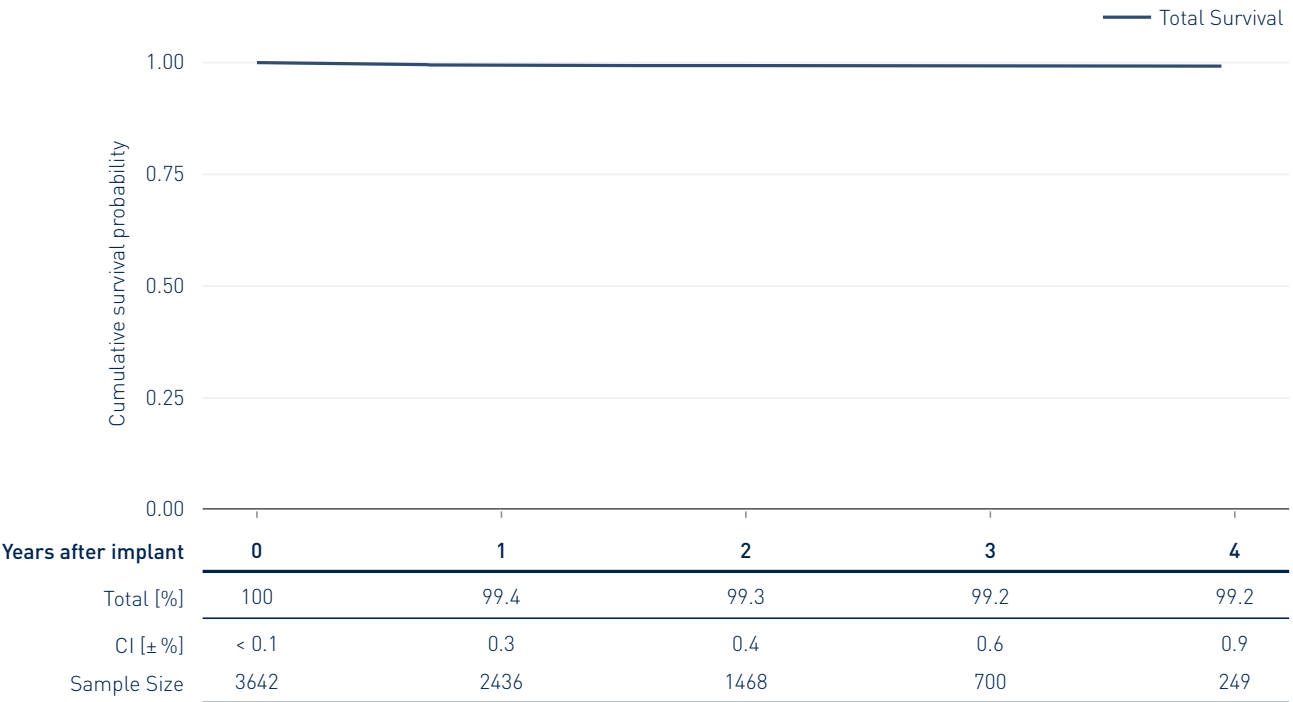
*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2



10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S DX

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2019
CE Market Release	Dec 2018
Worldwide Distributed Devices	44 600
US Implants in EP PASSION	3 650

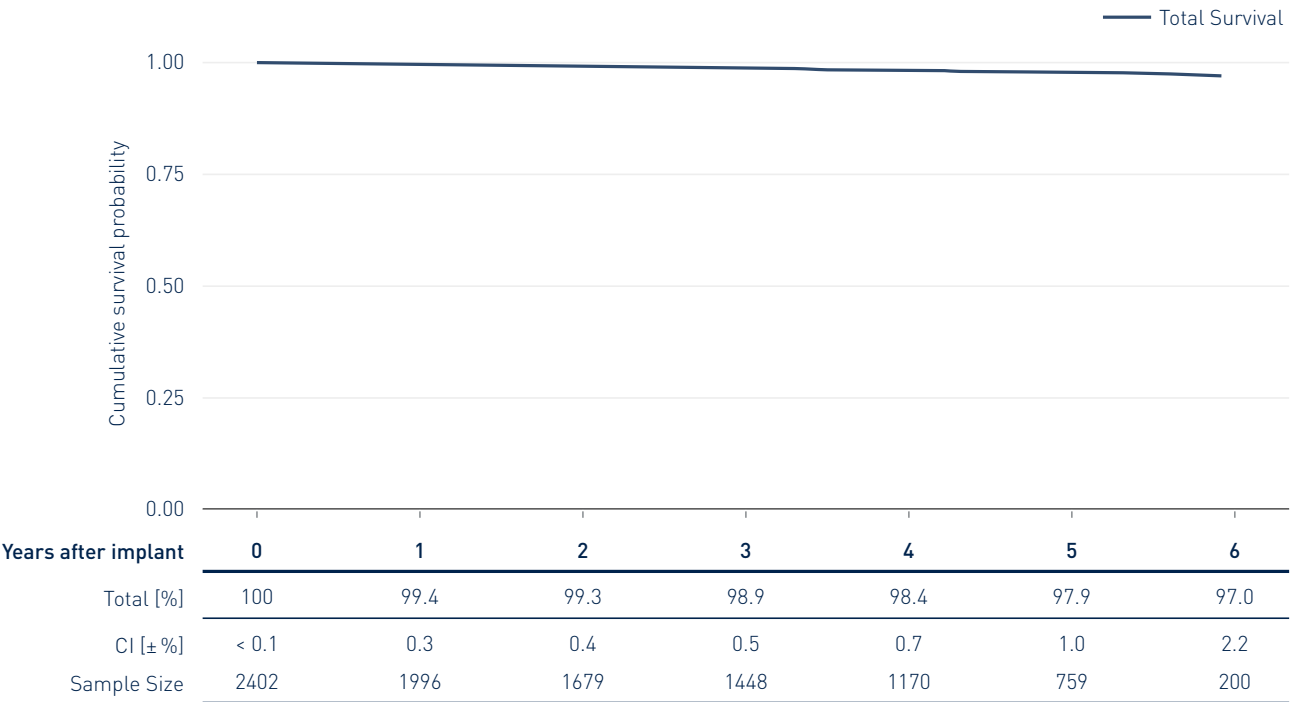




10.2 Performance of ICD Leads – Insurance Claims Data

Plexa S DX DF1

Product Versions	65/15, 65/17
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Mar 2017
CE Market Release	Feb 2017
Worldwide Distributed Devices	23 800
US Implants in EP PASSION	2 410

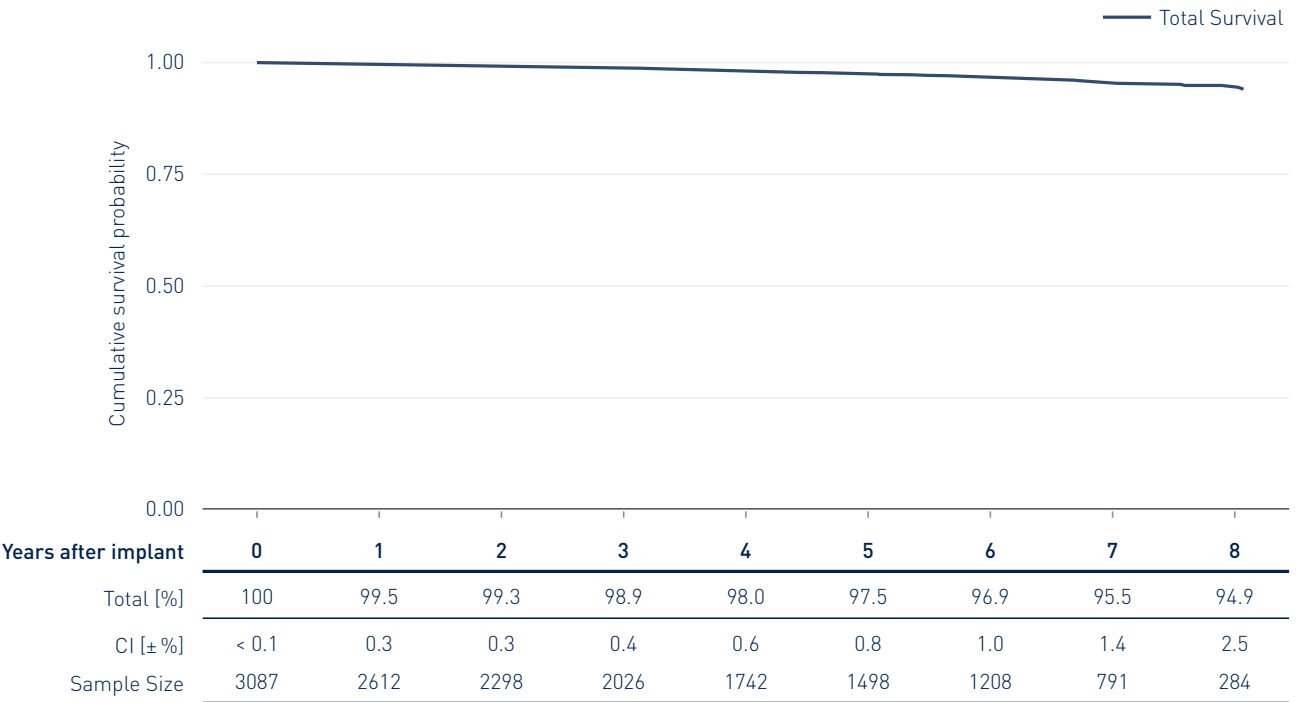




10.2 Performance of ICD Leads – Insurance Claims Data

Protego S

Product Versions	60, 65, 75
Lead Type	single-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	Feb 2014
Worldwide Distributed Devices	54 900
US Implants in EP PASSION	3 090

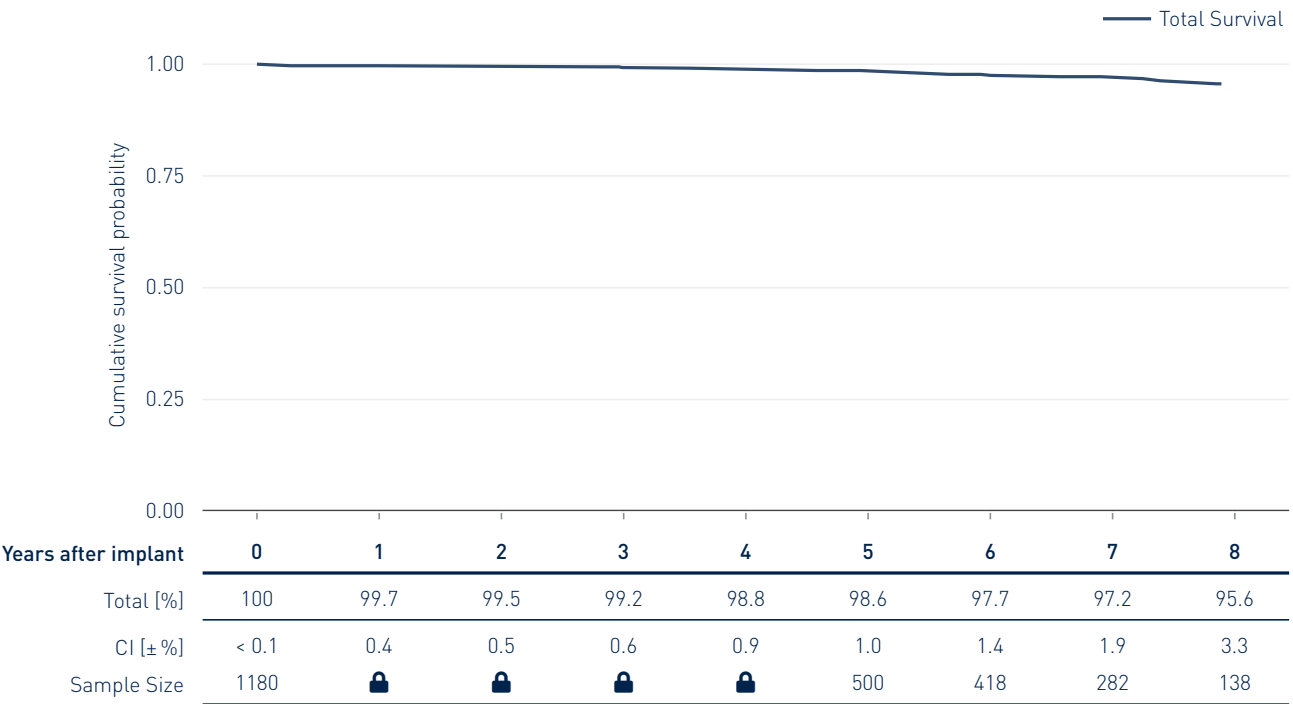




10.2 Performance of ICD Leads – Insurance Claims Data

Protego SD*

Product Versions	60/16, 65/16, 65/18, 75/18
Lead Type	dual-coil, active fixation
Polarity	bipolar
Steroid	yes
US Market Release	Jul 2014
CE Market Release	May 2013
Worldwide Distributed Devices	18 400
US Implants in EP PASSION	1 180



*Cell size suppression criteria defined by CMS do not allow to report data marked with a 🔒, see section 9.2



Performance of BIOTRONIK Leads Based on Insurance Claims Data

10.1 Pacing Leads

10.2 ICD Leads

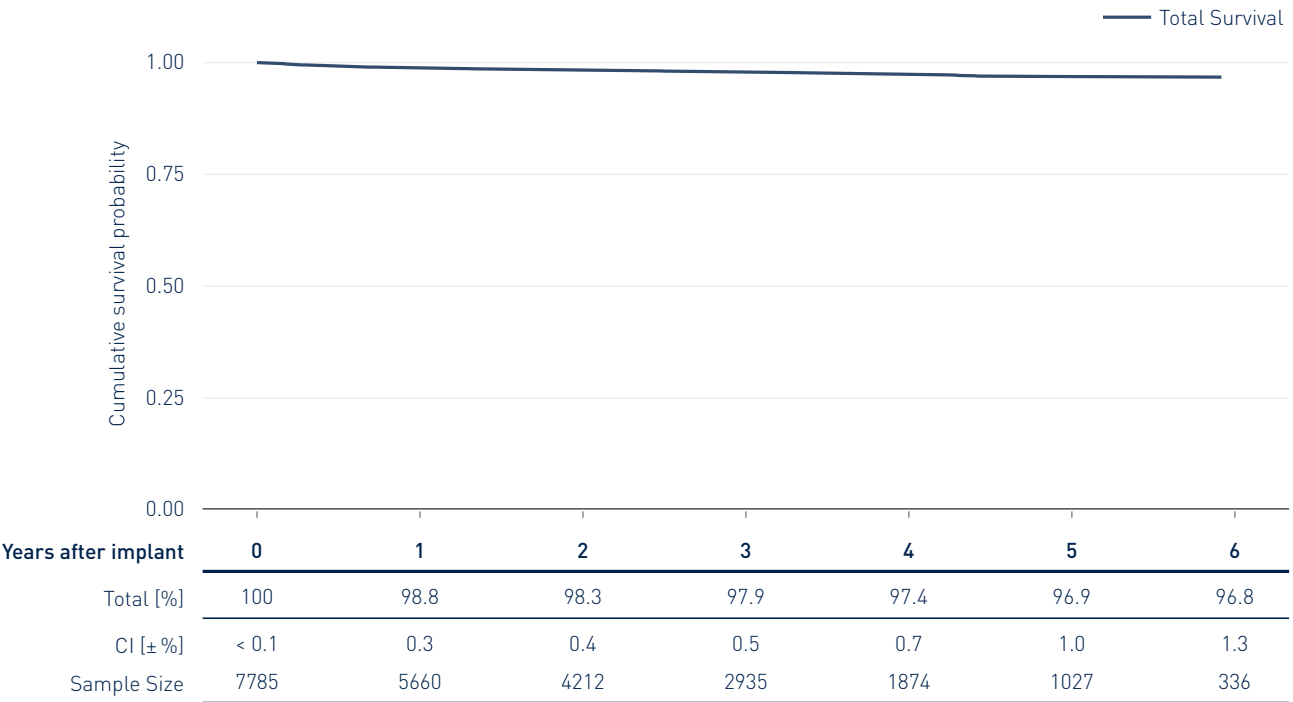
10.3 CRT Leads



10.3 Performance of CRT Leads – Insurance Claims Data

Sentus OTW QP L

Product Versions	75, 75/49, 85, 85/49
Lead Type	dual-curve fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	146 000
US Implants in EP PASSION	7 790

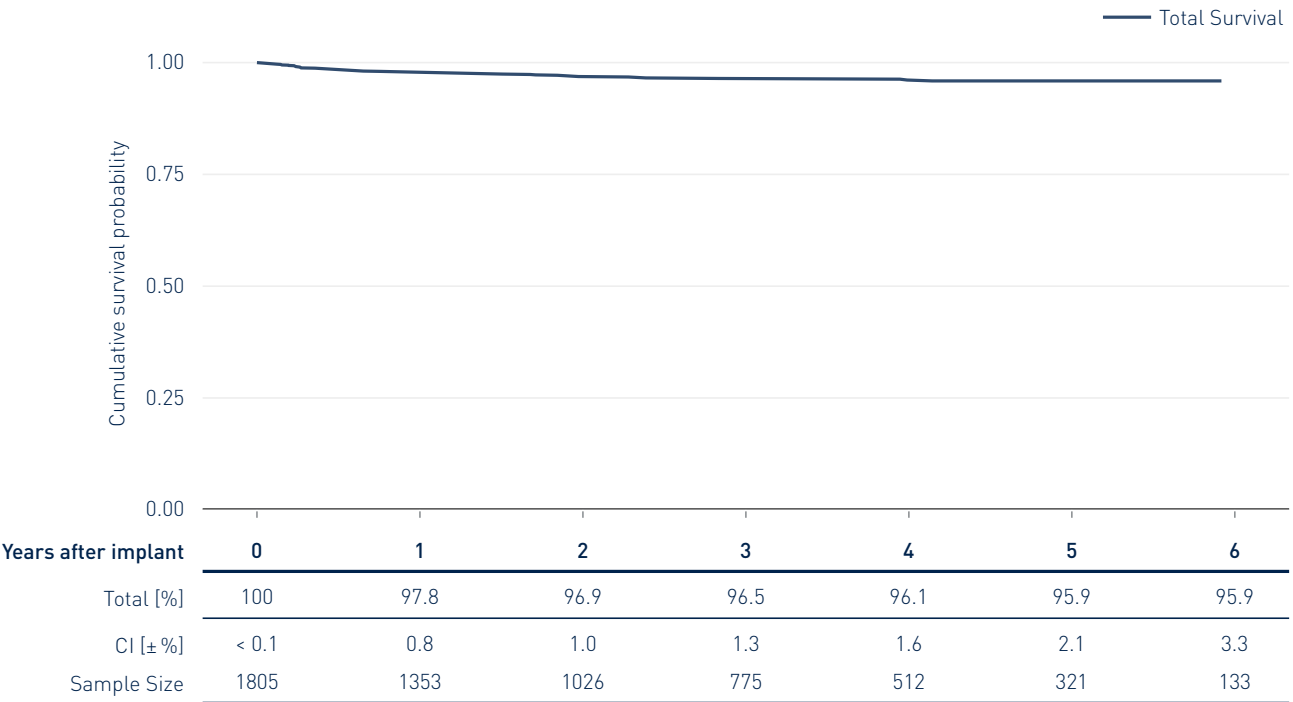




10.3 Performance of CRT Leads – Insurance Claims Data

Sentus OTW QP S

Product Versions	75, 75/49, 85, 85/49
Lead Type	thread fixation
Polarity	quadripolar
Steroid	yes
US Market Release	May 2017
CE Market Release	Dec 2014
Worldwide Distributed Devices	27 100
US Implants in EP PASSION	1 810





Advisories



11.1 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 30, 2021 in the United States. The corresponding CE-Version has been released on March 31, 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 Nov 2024:

- The cumulative failure rate is 1.6 %.
- 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
0 - 24 months	< 0.00001 %
24 - 48 months	0.0013 %
48 - 72 months	0.0090 %

Risk for loss of high voltage therapy

Service Time	Risk per month
0 - 24 months	< 0.00001 %
24 - 48 months	0.0020 %
48 - 72 months	0.0146 %

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):

- Idova, Iforia, Ilesto,
- Inventra, Iperia, Itrevia,
- Ilivia, Inlexa, Intica,
- Ilivia Neo and 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 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 outweighs the risk associated with this issue^{1,2,3}. 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.

¹McCarthy 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]

²Biffi 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]

³Lewis 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	



Contact BIOTRONIK

Regarding this Report

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

PPR Support Team

Phone +49 (0) 30 68905 1368

Fax +49 (0) 30 68905 96 1920

E-mail PPR@biotronik.com

Address

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

Regarding Products

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

CRM Technical Service

Phone +49 (0) 30 689 05 2200

Fax +49 (0) 30 689 05 96 2200

Email technical.services@biotronik.com

Address

BIOTRONIK SE & Co. KG
Attn: Technical Services CENEMEA
Woermannkehre 1
12359 Berlin, Germany

Within the US

Phone (800) 547 0394

Fax (800) 451 8529

E-mail advancedproductsupport@biotronik.com

Address

BIOTRONIK, Inc.
Attn: Advanced Product Support
6024 Jean Road
Lake Oswego, OR 97035