

Product Performance Report

2025 Second Edition



Letter from Abbott

As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, Abbott continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose health and well-being depend on their performance. From product design through patient follow-up, Abbott employees are dedicated to product quality and patient safety.

In keeping with this commitment, we publish the Product Performance Report (PPR) semi-annually to ensure that the healthcare community and the patients it serves are informed about the performance of our cardiac devices, which include, implantable cardioverter defibrillators (ICDs), implantable pacemakers, and implantable pacing and defibrillation leads. Abbott recognizes that such performance data must be transparent and consistent.

To meet these goals, we continue our commitment to the reporting methods described in the 2009 AdvaMed document “Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads”, which set standards for lead and pulse generator performance reporting. Determined to provide the highest level of transparency, Abbott goes beyond the AdvaMed recommendations by identifying the root cause of each ICM, ICD, and pacemaker malfunction and providing subcategories of lead malfunctions.

At Abbott, we adapt quickly to changes in the world around us, harnessing leading-edge science and technology to deliver the best possible solutions for some of the world’s most important health challenges. We are proud to continue to provide our Leadless Pacemaker and Focus on Clinical Performance sections in this PPR beginning on page 163 containing the performance of our three AVEIR™ Leadless Pacemaker models.

As we continually strive to provide unbiased and reliable information on the performance of our products, Abbott is pleased to release the second of the 2025 Product Performance Report containing the latest performance information on our ICDs, pacemakers and lead systems.

Sincerely,

A handwritten signature in black ink that reads "B. Blunt". The signature is written in a cursive, flowing style.

Robert Blunt
Divisional Vice President, Quality

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Serving Our Mission

Abbott is advancing the treatment of heart and vascular disease through breakthrough medical technologies, allowing people to restore their health and get on with their lives. We focus on improving treatment options for coronary artery disease, cardiac rhythm management, atrial fibrillation, heart failure, structural heart and peripheral artery disease. We are here for the people we serve in their pursuit of healthy lives. This has been the way of Abbott for more than a century—passionately and thoughtfully translating science into lasting contributions to health.

Toward this mission, we maintain a rigorous approach to ensuring the quality of our products. The key elements of this effort include:

- Compliance with U.S. and International quality system standards, such as the U.S. FDA Quality Systems Regulation (21 CFR Part 820) and ISO 13485 (an international standard for the Quality Management System for medical devices)
- Thorough evaluation of product design, including extensive design verification and validation, as well as product qualification testing
- Rigorous control of the design and manufacturing processes
- Inspection and qualification of externally supplied components and materials
- Timely analysis of returned products, including extensive malfunction investigation
- Extensive and frequent internal auditing
- Post market surveillance
- Continuous improvement programs
- Ensuring the highest ethical standards

We continue to be committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Abbott Representative or Abbott Technical Services at 1-800-722-3774. Thank you for your input and continued support, allowing Abbott to positively impact the lives of thousands of patients every year.

What's New in This Report

AVEIR™ LEADLESS PACEMAKER PERFORMANCE

Commercial implants of the AVEIR™ VR leadless pacemaker commenced in April 2022 and the DR system became available in November 2023. With the publication of the 2025 Second Edition Product Performance Report, Abbott has continued expanded monitoring and assessment for over three years. The ISO 5841-2:2014(E) criteria for reporting Pulse Generator performance have been applied to the AVEIR™ atrial and ventricular pacemakers, including assessment of returned product analysis and calculation of the survival probability. In addition, the category of 'Extrinsic Factors' has been added to the standard list of pulse generator malfunctions. This category currently exists for cardiac leads and has been adapted by Abbott for the AVEIR™ leadless pacemakers to acknowledge their unique functionality and design characteristics. Additional updates on the AVEIR leadless pacemakers can be found in the Focus on Clinical Performance section on page 184.

UPDATE ON THE MERLIN PATIENT CARE SYSTEM AND MERLIN.NET SOFTWARE FOR LONGEVITY ESTIMATION

In June 2022, Abbott notified customers of an update to the programmer and remote care software to improve the accuracy of the predicted battery longevity in certain pacemaker families. Previous software versions had the potential to display overestimated predicted longevity, even though the pacemaker functionality, therapy delivery, and overall longevity remained normal and within specifications. Further details including patient management recommendations and updated worldwide incidence rates can be found on page 195 and also on the Product Advisories web page at <https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html>

STATUS FOR THE FORTIFY™, FORTIFY ASSURA™, QUADRA ASSURA™, QUADRA ASSURA MP™, UNIFY™, UNIFY ASSURA™ AND UNIFY QUADRA™ ICD PREMATURE BATTERY DEPLETION ADVISORY (2016)

In order to provide the most up-to-date information, Abbott continues to include an update on the Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ ICD premature battery depletion advisory (October 2016) in the Focus on Clinical Performance section (see pages 185-186). This section includes an overview on the analysis of products returned to Abbott. Additionally, for advisory models with at least 500 active devices in service, Abbott provides a separate product performance data page per model number.

Performance Data

Product performance data is derived from customer-initiated complaints and returned products. Abbott strongly encourages the submission of any relevant complaints and product returns. Underreporting of events is recognized throughout our industry. Abbott is constantly improving the accuracy and utility of the data within this Product Performance Report.

SUMMARY INFORMATION

The Performance Data page for each product model or model group includes a table of model-specific information. Several terms from this table that are relevant to performance data calculations are defined below:

Registered U.S. Implants - The total number of U.S. implanted devices for which patient and device information has been provided to Abbott. This total includes devices which have been explanted or are otherwise out of service.

Estimated Active U.S. Implants - The total number of U.S. registered implants that have not been identified to Abbott as explanted or otherwise out of service. An adjustment is made to account for the underreporting of patient mortality. Abbott performed an analysis of the data gathered from multiple clinical studies including some Abbott sponsored studies to determine the mortality rate within the pacemaker and ICD patient population and has factored this into the estimation of the number of active U.S. implants.

Estimated Longevity - The estimated number of years in which a device is expected to reach its Elective Replacement Indicator (ERI), as stated in the product literature. The estimate is based on battery life approximations and empirical battery performance distributions. It is strongly affected by many factors such as programmed parameters, percentage of time paced, internal impedance, etc. For example, the 9.2 year estimated longevity of an Accent™ DR model PM2110 pacemaker is based on the mean longevity (or 50%) value in the product literature corresponding to pacing at 60 ppm, 2.5V dual-chamber output at 0.4 ms pulse width, 500 ohm lead impedance, 100% DDD pacing, and Stored EGMs On. Actual performance can vary considerably, depending on the actual programmed settings and operations.

Normal Battery Depletion - The condition where a returned device met its electrical specification and reached its elective replacement indicator voltage (1) with an implant duration meeting or exceeding the nominal predicted longevity at default shipped settings, or (2) with an implant duration exceeding 75% of its estimated longevity, based on longevity calculations using information from device usage and the actual device settings. The quantity of normal battery depletions reported is determined directly from laboratory analysis and does not represent any adjustment to account for underreporting.

Introduction and Overview

SURVIVAL CALCULATION GENERAL METHODS

For ICDs, pacemakers, ICMs, and leads, we compile cumulative survival data based on the actuarial (or life-table) method of survival analysis, consistent with ISO 5841-2:2014(E) “Reporting of Clinical Performance of Populations of Pulse Generators and Leads” and the 2009 AdvaMed document “Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads”. Product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report, and a minimum sample size for each reported time period of 200 devices. “Survival” refers to the proper function of the device, not the survival of the patient, and is intended to illustrate the calculated probability of device survival at a given point in time. A survival probability of 99% at five years, for example, indicates that at five years after implant, the system has a 1% risk of incurring a malfunction and/or normal battery depletion. All domestically implanted devices within each model family are included in the calculations.

With the large size of the U.S. data pool, and the same products are generally used both in the U.S. and internationally, we consider the data in this report to accurately represent each device’s performance, regardless of where in the world it was implanted.

The ISO 5841-2:2014(E) “Reporting of Clinical Performance of Populations of Pulse Generators and Leads” was revised in August 2014. The revision clarified survivor definitions and reporting methods, further standardizing product performance reporting across the cardiac rhythm management implantable device and lead manufacturers.

This revision of the ISO standard specifically excludes lead malfunctions confirmed through returned product analysis which were received with no accompanying complaint from the survival probability calculations. However, to provide the highest level of transparency, Abbott continues to include malfunctions not associated with a complaint in the survival probability calculations and in the tabular display of laboratory-confirmed malfunctions.

ICD AND PACEMAKER SURVIVAL ANALYSIS

The data used for the analysis of ICDs and pacemakers includes up-to-date device registration information and the laboratory analysis of all domestically implanted devices returned to Abbott. The analysis measures device performance to specification, and does not reflect medical complications, such as infection, erosion, muscle stimulation or inhibition, or units implanted for fewer than 24 hours.

In accordance with ISO 5841-2:2014(E), the survival calculations for ICDs and pacemakers are adjusted to reduce the bias caused by underreporting of malfunctions and normal battery depletions. Abbott compared the malfunctions and normal battery depletion rates calculated from our actively monitored populations to the rates calculated from our passively monitored populations and have adjusted the survival calculations accordingly.

Survival data are presented in a single table and graph. The survival data is separated into “Including Normal Battery Depletion” and “Excluding Normal Battery Depletion” categories. The “Including Normal Battery Depletion” data reflects the frequency of device removal due to normal battery depletion and malfunction of any type. The “Excluding Normal Battery Depletion” category reflects the frequency of device removal due to malfunctions only.

Introduction and Overview

ICD, PACEMAKER, AND ICM MALFUNCTION REPORTING

The quantity and rate of malfunctions recorded for each ICD, pacemaker, and ICM model are presented in a tabular format. The root cause of all laboratory-confirmed malfunctions is classified into one of eight categories: Electrical Component, Electrical Interconnect, Battery, High Voltage Capacitor (ICDs and CRT-Ds only), Software/Firmware, Mechanical, Possible Early Battery Depletion, or Other. Note that in the rare cases where multiple malfunctions are identified in a single device, a single malfunction category will be selected with priority given in the order of the list above. Consistent with previous performance reports, ICD and Pacemaker malfunctions are further classified as with or without compromised therapy.

ISO 5841-2 (E) was revised in August 2014. This version of the standard (ISO 5841-2:2014 (E)) modified the definitions of device malfunctions with compromised therapy and device malfunctions without compromised therapy from the previous version of the standard (ISO 5841-2:2000 (E)). In Product Performance Reports (PPRs) published prior to July 2021, Abbott used the definitions of these terms included in ISO 5841-2:2000 (E). Since the July 2021 PPR, Abbott has used the revised definitions in ISO 5841-2:2014 (E) to classify device malfunctions. Abbott maintains its commitment to provide the highest level of transparency in reporting.

Malfunction Definitions

Malfunction - Failure of a device to meet its performance specifications or otherwise perform as intended.

Malfunction with Compromised Therapy - Device malfunction causing compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

Malfunction without Compromised Therapy - Pulse generator malfunction that did not compromise pacing or defibrillation therapy while implanted and in service.

Note: Therapy is not compromised as long as the critical patient-protective pacing and defibrillation therapies are available. This includes changes in device settings that occur as intended by the design and do not result in loss of critical patient protective therapies but are the reported reasons for explant. Examples include (but are not limited to): reversion to a designed “safe mode”, “backup mode”, “power-on reset” or other manufacturer specific terminology, error-affecting diagnostic functions, telemetry function, data storage, malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Malfunction Root Cause Category Definitions

Electrical Component - Findings linked to electrical components such as integrated circuits, resistors, low voltage capacitors, diodes, etc. Does not include high voltage capacitors or batteries as those are separately listed.

Electrical Interconnect - Findings linked to the connections between electrical components such as wires, solder joints, wire bonds, feedthroughs, etc.

Battery - Findings linked to the battery and its components.

High Voltage Capacitor - Findings linked to the high voltage capacitor and its components.

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Software/Firmware - Findings linked to software or firmware function.

Mechanical - Findings linked to mechanical components such as headers, setscrews, fluid seals, internal supports, the hermetic case, etc.

Possible Early Battery Depletion - Findings where the actual reported implant time is less than 75% of the expected longevity calculated using the available device setting information and no root cause was able to be identified. Additionally, in the absence of a specific root cause finding, returned devices with insufficient device setting information to determine conclusively if battery depletion was normal or premature are conservatively classified as Possible Early Battery Depletion malfunctions.

Other - Findings linked to other components such as packaging and accessories, and findings where analysis is inconclusive, as well as other complications not included above.

Extrinsic Factors - The device was implanted greater than 30 days, removed from service with an associated complaint and returned for analysis, however analysis was inconclusive because (1) the returned device was damaged by the explantation process, or (2) lab analysis could not determine an out of specification condition (typically with complaints such as dislodgements, perforations, or failure to capture).

LEADS SURVIVAL ANALYSIS

Implanted cardiac leads are subjected to constant, complex flexural and torsional forces, interactions with other leads and/or the pulse generator device, plus other forces associated with cardiac contractions, patient physical activity, posture, and anatomy. Therefore, the functional lifetime of cardiac leads is limited and cannot be predicted with a high degree of confidence. Understanding these limitations, survival estimates are provided for all leads included in this report.

The data used for the survival analysis of leads includes up-to-date lead registration information, chronic complications (>30 days) reported by the field, and the laboratory analysis of all domestically implanted leads returned to Abbott. Complaints reported within 30 days of implant (acute observations), are considered to be related to factors other than lead malfunction, such as patient specific characteristics or implant technique, and are therefore excluded from the survival calculations, consistent with industry practice. If there is laboratory data that determines the lead to have exhibited a malfunction, and the lead is known to have been implanted for more than 24 hours, the lead is counted as a non-survivor. If a lead is the subject of a complaint report and was implanted for more than 30 days (chronic complication), then the lead is counted as a non-survivor. These criteria are also followed for partial lead returns. This method for non-returned complications is used to ensure a conservative failure estimate for lead performance. Chronic complications commonly associated with non-returned leads and partial lead returns include, but are not limited to reports of sensing, pacing, and capture anomalies, perforation, and dislodgement.

Introduction and Overview

LEADS OBSERVATION AND COMPLICATION REPORTING

Reporting for recently released lead models provides detail on specific chronic complications (more than 30 days implant), as well as acute observations (post implant to 30 days), that are reported to Abbott as complaints. Each complication and observation is categorized into one of the eleven categories below, irrespective of whether the lead has been returned for analysis. The quantity and rate of each complication and observation type is provided in a tabular format on the Performance Data page. Note that in the rare cases where multiple complaints are identified for a single lead, a single category will be selected with priority given in the order of the list below.

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 (high thresholds), chest pain, or tamponade.

Conductor Fracture - A mechanical break within a lead conductor (includes connectors, coils, cables and/or electrodes) 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.

Failure to Capture - Intermittent or complete failure to achieve cardiac stimulation (atrial or ventricular) at programmed output delivered outside of the cardiac refractory period. A sudden and significant increase in the pacing threshold value (elevated thresholds compared to previous measured value) at which 2:1 safety margin can no longer be achieved.

Oversensing - Misinterpretation of cardiac or non-cardiac events as cardiac depolarization, e.g. T-waves, skeletal muscle potentials, and extracardiac electromagnetic interference (EMI).

Failure to Sense (undersensing) - Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals (atrial or ventricular) during non-refractory periods at programmed sensitivity settings.

Insulation Breach - A disruption or break in lead insulation observed visually, electrically, or radiographically.

Abnormal Pacing Impedance - Pacing impedance is typically considered abnormal if a measurement is $< 200 \Omega$ or $> 2000 \Omega$ (based on lead model and measurement range of the device).

Abnormal Defibrillation Impedance - Defibrillation impedance is typically considered abnormal if a measurement is $< 20 \Omega$ or $> 200 \Omega$ (based on lead model and measurement range of the device).

Extracardiac Stimulation - Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle.

Other - Specific proprietary lead mechanical attributes such as lead incorporated sensors, connectors or seal rings which affect a lead's ability to perform as designed or remain in service, as well as other complications not included above.

Introduction and Overview

LEADS MALFUNCTION REPORTING

As a supplement to the survival estimates, the categorization of lead malfunctions emphasizes the root cause of malfunction rather than a functional longevity prediction. In accordance with AdvaMed guidelines, laboratory analysis results of returned leads are categorized into one of the following five categories of malfunctions. The quantity and rate of each malfunction type is provided in a tabular format on the Performance Data pages.

Note that in the rare cases where multiple malfunctions are identified in a single lead, a single malfunction category will be selected with priority given in the order of the list below. The definition for each malfunction type is provided below:

Conductor Fracture - Conductor break with complete or intermittent loss of continuity that could interrupt current flow. This type of malfunction includes any conductor fracture such as those associated with flex-fatigue or clavicular crush damage.

In an effort to further increase customer understanding of Abbott defibrillation and left-heart lead performance, subcategories of conductor fracture are also provided. The definitions of these subcategories are provided below:

Clavicular Crush - Conductor fracture due to strong compression and bending at the approximation of the first rib and clavicle.

In the Pocket - Conductor fracture not within the vascular or cardiac systems, typically within the subcutaneous pocket or associated with the suture sleeve, excluding the mechanism of clavicular crush.

Intravascular - Conductor fracture within the vascular or cardiac systems.

Insulation Breach - Any lead insulation breach, such as: 1) proximal abrasion associated with lead-to-lead or lead-to-can contact in the pocket, 2) mid-lead insulation damage caused by clavicular crush or insulation wear in the region of vein insertion, 3) distal abrasion due to lead-to-lead interactions or contact with anatomic structures, and 4) externalized conductors in the distal region.

Subcategories of insulation breach for defibrillation and left-heart leads are also provided. The definitions of these subcategories are provided below:

Lead-to-Can Contact - Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) combined with repetitive skeletal movement caused abrasion that resulted in a full thickness outer insulation breach.

Lead-to-Lead Contact - Repetitive contact between two leads caused abrasion that resulted in a full thickness outer insulation breach.

Clavicular Crush - Damage due to strong compression between the first rib and clavicle resulted in a full thickness outer insulation breach.

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Externalized Conductors - Abrasion resulted in an outer insulation breach within the vascular or cardiac systems allowing the normally contained conductors to become visible outside the lead body. Externalized conductors were described in our December 2010 and November 2011 communications regarding insulation abrasion failures on silicone Riata™ and Riata™ ST lead families (summary on pages 199-200) and in our April 2012 communication regarding insulation abrasion failures on QuickSite™ and QuickFlex™ lead families. Additional information regarding externalized conductors on Riata™ and Riata™ ST leads can be found at <https://www.cardiovascular.abbott/us/en/hcp/product-advisories/riata.html>.

Other (Insulation Breach) - Insulation breaches that resulted from a failure mode not represented by the other four categories. This includes a variety of failure modes, such as damage at the suture sleeve and contact with patient anatomy. Also includes insulation breaches for which analysis was unable to isolate a specific cause.

Crimps, Welds and Bonds - Any interruption in the conductor or lead body associated with a point of connection.

Other - Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, and seal rings, as well as other analysis results not included in the alternate categories.

Extrinsic Factors - The lead was implanted greater than 30 days, removed from service with an associated complaint and returned for analysis, however analysis was inconclusive because (1) only portions of the lead were available, or (2) the returned lead was damaged by the explantation process, or (3) lab analysis could not determine an out of specification condition (typically with complaints such as dislodgements, perforations, or failure to capture).

Medical Advisory Board Review

Abbott has an established and independent Medical Advisory Board (MAB) focused on cardiac rhythm management systems, including pulse generators and leads. One of the important tasks assigned to the MAB is the review of the performance data contained in this report prior to its release and publication on a semi-annual basis. MAB members and their location of practice include:

Dr. Rajesh Banker, Newport Beach, California

Dr. Larry Chinitz, New York, New York

Dr. Anne Curtis, Buffalo, New York

Dr. Derek Exner, Calgary Alberta, Canada

Dr. Roger Freedman, Salt Lake City, Utah

Dr. Reinoud Knops, Amsterdam, Netherlands

Dr. Devi Nair, Jonesboro, Arkansas

Dr. Raymond Schaefer, Los Angeles, California

Returning Devices to Abbott

To maintain the continued accuracy of our performance reporting, Abbott strongly encourages physicians to notify our Patient Records department (800-550-1648) each time a device is removed from service for any reason. Additionally, all explanted products are requested to be returned to Abbott for laboratory evaluation whether or not a malfunction is suspected. To facilitate the return of explanted devices, Abbott offers a no-cost Returned Products Kit comprised of a postage paid explant box with a shipping address label, a removed device information form, a biohazard bag, and biohazard labels to seal the explant box. This kit, #N0004, can be ordered free of charge by contacting Abbott Customer Service (800-681-9293).

Contact Us

The Abbott team is always ready to respond to questions, comments or suggestions as well as receive product performance feedback. You can reach us by phone at 651-756-2000, on the web at www.abbott.com, or by contacting your local Abbott representative.

Cardiac Resynchronization Therapy (CRT) ICDs

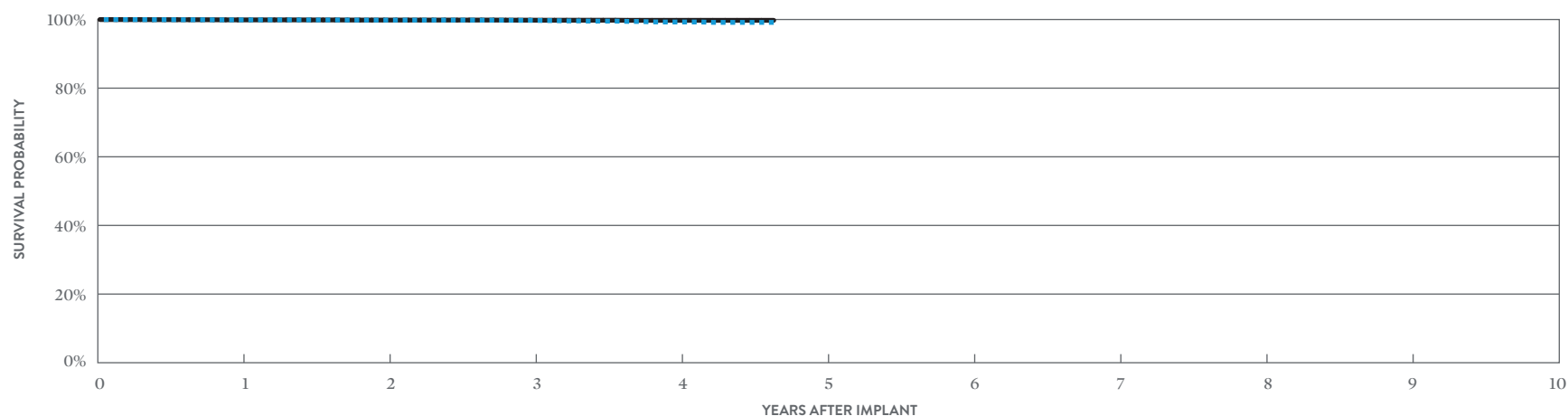
Cardiac Resynchronization Therapy (CRT) ICDs

Gallant™ HF CRT-D

MODEL CDHFA500Q*

US Regulatory Approval	July 2020
Registered US Implants	53,224
Estimated Active US Implants	41,503
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	18
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 189)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	17	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	2	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	3	<0.01%	4	<0.01%
Total	3	<0.01%	28	0.05%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.89%	99.83%	99.75%	99.27%	99.16%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.09%	0.12%
SAMPLE SIZE	45,530	31,130	18,490	7,970	300

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.89%	99.84%	99.81%	99.76%	99.76%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.04%

*DF4-LLHH connector type.

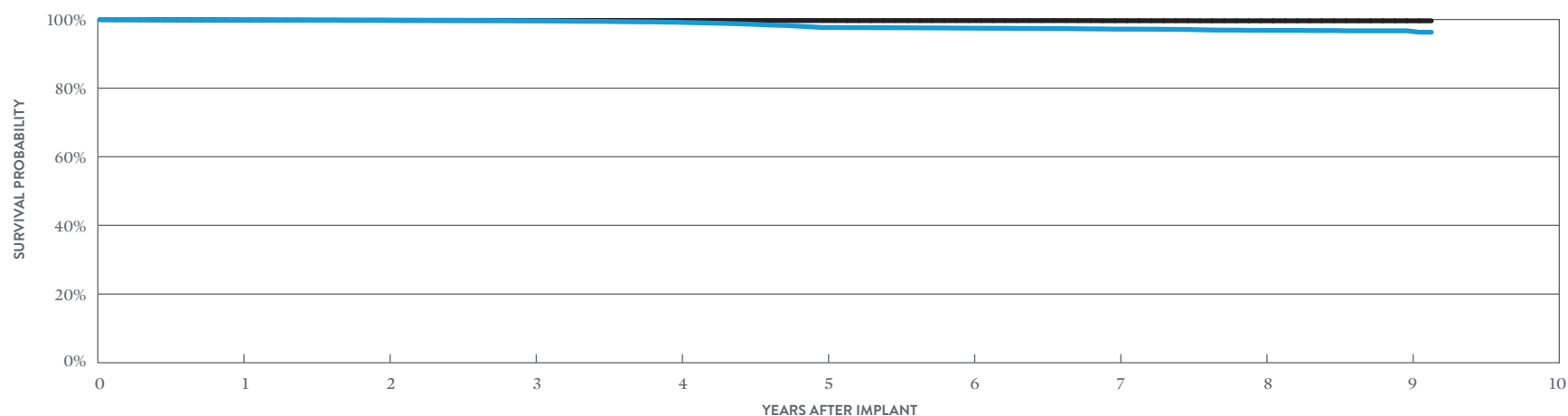
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura MP™ CRT-D

MODEL CD3369-40Q*

US Regulatory Approval	February 2016
Registered US Implants	80,096
Estimated Active US Implants	40,870
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	433
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	8	<0.01%	33	0.04%
Electrical Interconnect	10	0.01%	1	<0.01%
Battery	0	0.00%	3	<0.01%
High Voltage Capacitor	0	0.00%	2	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	6	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	4	<0.01%	23	0.03%
Total	23	0.03%	70	0.09%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 110 MONTHS
SURVIVAL PROBABILITY	99.84%	99.75%	99.62%	99.20%	97.67%	97.48%	97.19%	96.84%	96.71%	96.30%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.04%	0.07%	0.07%	0.08%	0.10%	0.12%	0.31%
SAMPLE SIZE	75,730	67,700	60,400	52,900	43,430	31,850	20,610	11,170	3,800	330

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 110 MONTHS
SURVIVAL PROBABILITY	99.85%	99.78%	99.73%	99.70%	99.69%	99.68%	99.65%	99.62%	99.62%	99.62%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.02%	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%

*DF4-LLHH connector type.

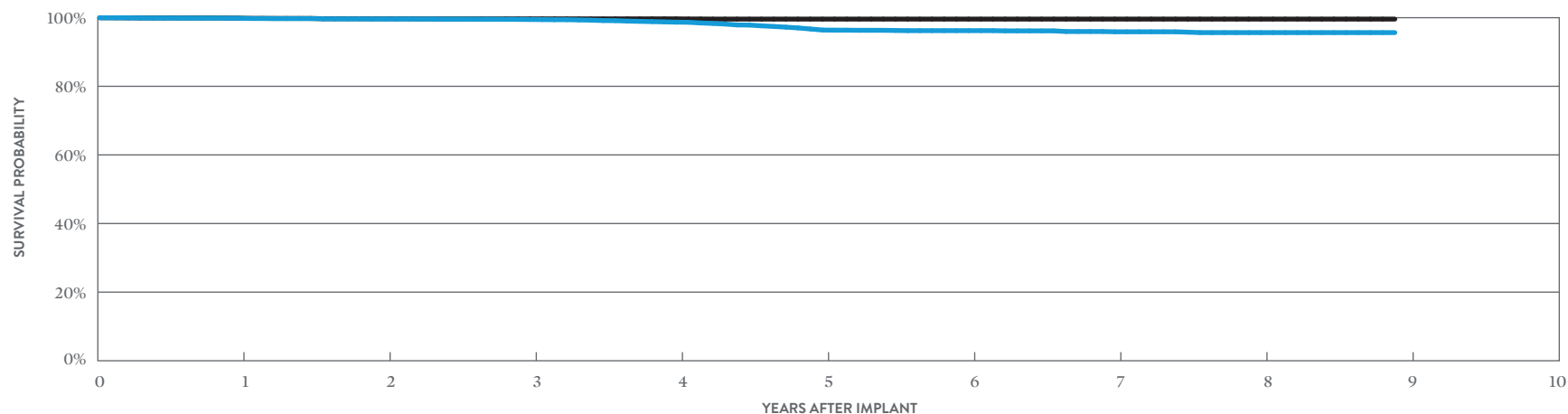
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura MP™ CRT-D

MODEL CD3369-40C*

US Regulatory Approval	February 2016
Registered US Implants	12,482
Estimated Active US Implants	6,598
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	87
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.02%	3	0.02%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	<0.01%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	0.02%
Possible Early Battery Depletion	0	0.00%	2	0.02%
Other	1	<0.01%	4	0.03%
Total	6	0.05%	12	0.10%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.84%	99.62%	99.47%	98.69%	96.40%	96.22%	95.89%	95.65%	95.65%
± 1 STANDARD ERROR	0.03%	0.06%	0.07%	0.12%	0.23%	0.25%	0.27%	0.30%	0.30%
SAMPLE SIZE	11,580	9,840	8,250	6,770	5,360	4,040	2,770	1,630	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.88%	99.68%	99.66%	99.66%	99.59%	99.59%	99.59%	99.59%	99.59%
± 1 STANDARD ERROR	0.03%	0.05%	0.06%	0.06%	0.07%	0.07%	0.07%	0.07%	0.07%

*Parylene coating.

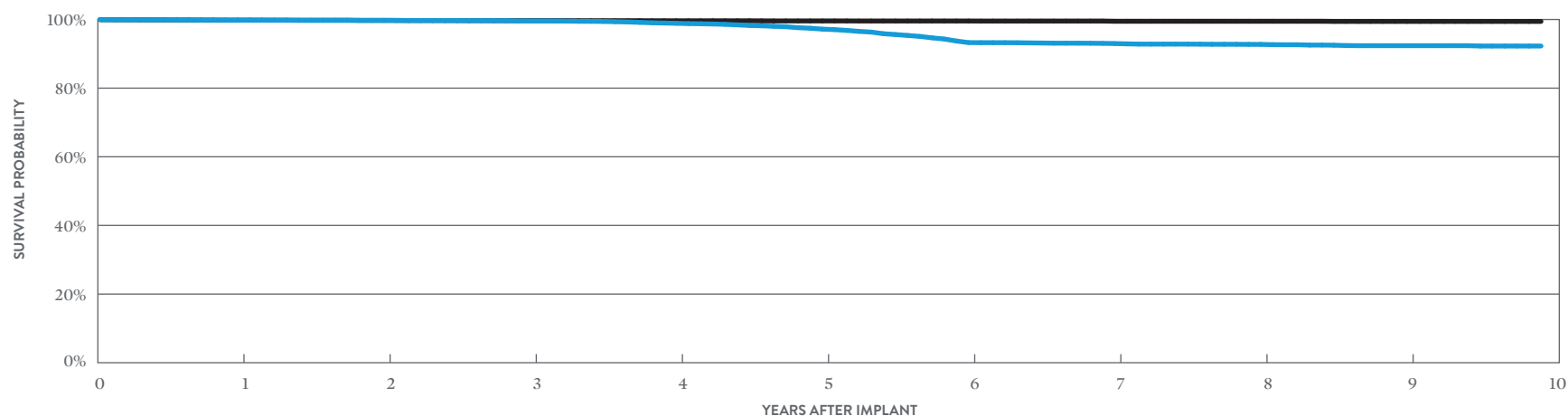
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3365-40Q* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	16,839
Estimated Active US Implants	5,732
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	294
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.01%	8	0.05%
Electrical Interconnect	3	0.02%	0	0.00%
Battery	1	<0.01%	1	<0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	4	0.02%
Possible Early Battery Depletion	1	<0.01%	3	0.02%
Other	2	0.01%	7	0.04%
Total	10	0.06%	23	0.14%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.81%	99.74%	99.58%	98.89%	97.19%	93.27%	92.99%	92.75%	92.37%	92.27%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.09%	0.14%	0.23%	0.25%	0.25%	0.26%	0.27%
SAMPLE SIZE	16,020	14,630	13,530	12,440	11,200	9,850	8,470	6,830	4,770	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.81%	99.74%	99.67%	99.62%	99.58%	99.56%	99.48%	99.48%	99.44%	99.44%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.05%	0.05%	0.06%	0.06%	0.06%	0.07%	0.07%

*DF4-LLHH connector type.

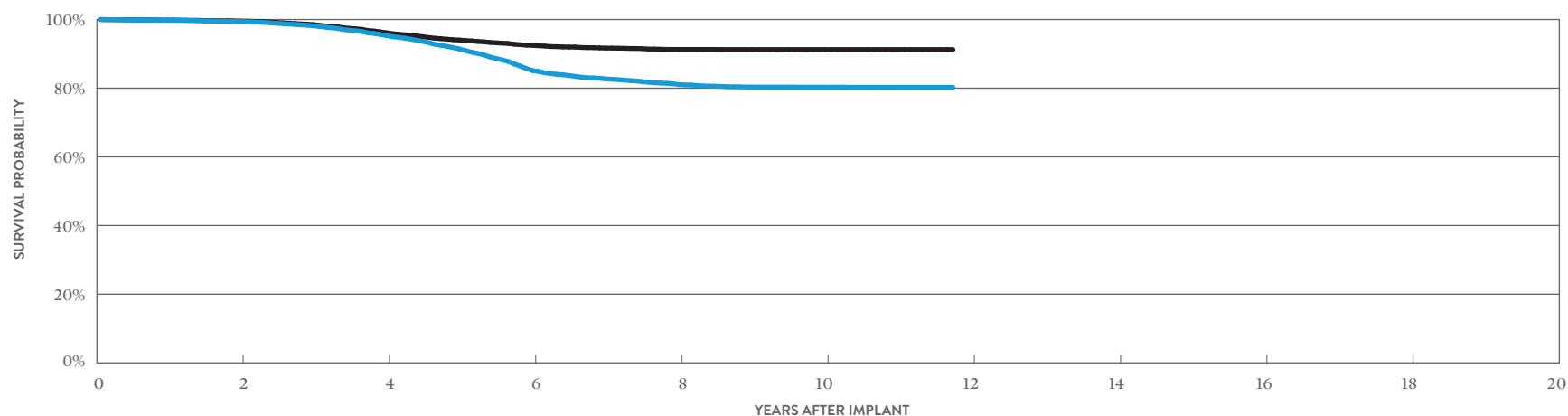
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3365-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	24,249
Estimated Active US Implants	5,645
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	630
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.02%	17	0.07%
Electrical Interconnect	10	0.04%	1	<0.01%
Battery	3	0.01%	19	0.08%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	1	<0.01%	3	0.01%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	43	0.18%	421	1.74%
Other	6	0.02%	7	0.03%
Total	70	0.29%	470	1.94%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 141 MONTHS
SURVIVAL PROBABILITY	99.39%	95.32%	85.11%	81.04%	80.28%	80.25%
± 1 STANDARD ERROR	0.05%	0.16%	0.28%	0.32%	0.33%	0.34%
SAMPLE SIZE	20,050	15,880	12,970	9,240	6,040	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 141 MONTHS
SURVIVAL PROBABILITY	99.55%	96.13%	92.46%	91.27%	91.24%	91.24%
± 1 STANDARD ERROR	0.04%	0.14%	0.21%	0.23%	0.23%	0.23%

*DF4-LLHH connector type.

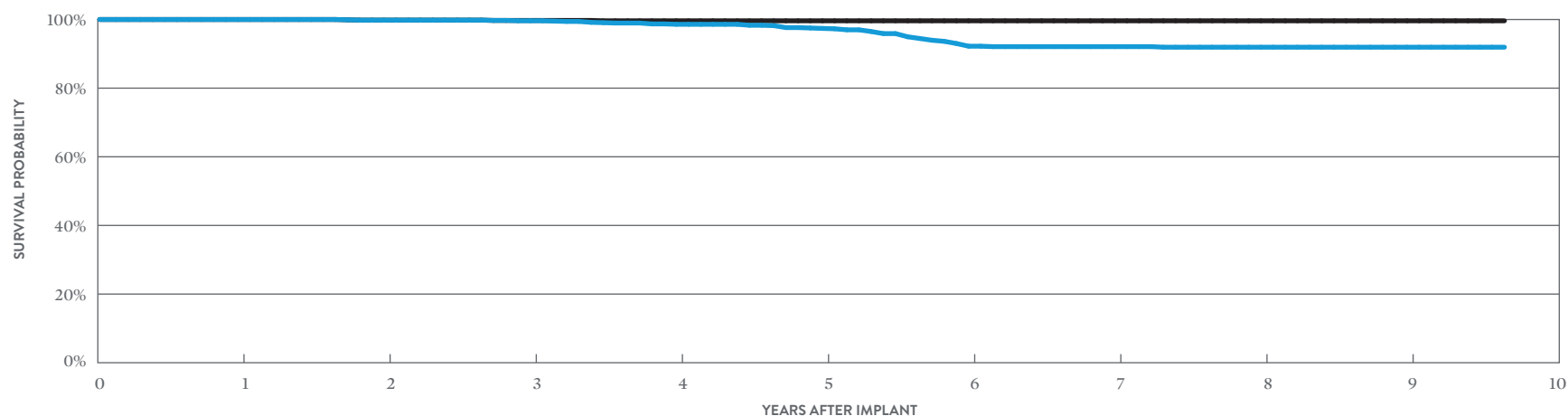
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3365-40C* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	2,705
Estimated Active US Implants	1,019
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	53
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	1	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	2	0.07%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.04%	0	0.00%
Total	3	0.11%	1	0.04%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	100.00%	99.82%	99.63%	98.60%	97.40%	92.22%	92.09%	91.93%	91.93%	91.93%
± 1 STANDARD ERROR	0.00%	0.09%	0.13%	0.25%	0.36%	0.62%	0.66%	0.67%	0.67%	0.67%
SAMPLE SIZE	2,550	2,290	2,100	1,930	1,750	1,550	1,320	1,070	730	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	100.00%	99.82%	99.73%	99.62%	99.62%	99.62%	99.62%	99.62%	99.62%	99.62%
± 1 STANDARD ERROR	0.00%	0.09%	0.11%	0.13%	0.13%	0.13%	0.13%	0.13%	0.13%	0.13%

*Parylene coating.

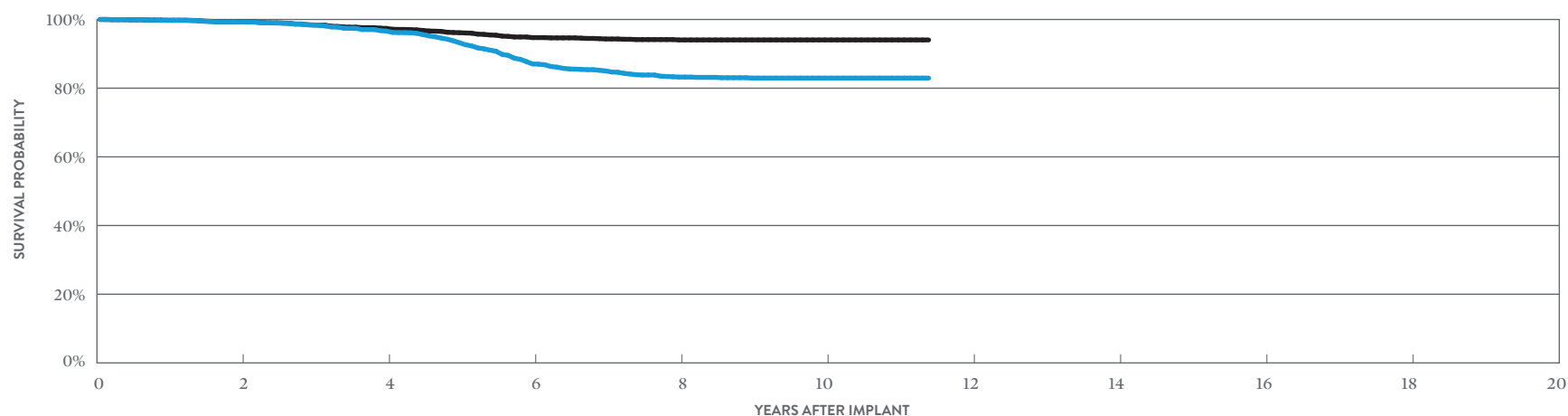
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3365-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,626
Estimated Active US Implants	1,451
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	132
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.11%	2	0.04%
Electrical Interconnect	2	0.04%	0	0.00%
Battery	1	0.02%	1	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	8	0.14%	59	1.05%
Other	3	0.05%	2	0.04%
Total	20	0.36%	65	1.16%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.27%	96.61%	87.05%	83.23%	82.94%	82.94%
± 1 STANDARD ERROR	0.12%	0.29%	0.58%	0.68%	0.69%	0.69%
SAMPLE SIZE	4,450	3,370	2,760	2,060	1,430	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.31%	97.40%	94.72%	94.04%	94.04%	94.04%
± 1 STANDARD ERROR	0.12%	0.25%	0.38%	0.41%	0.42%	0.42%

*Parylene coating.

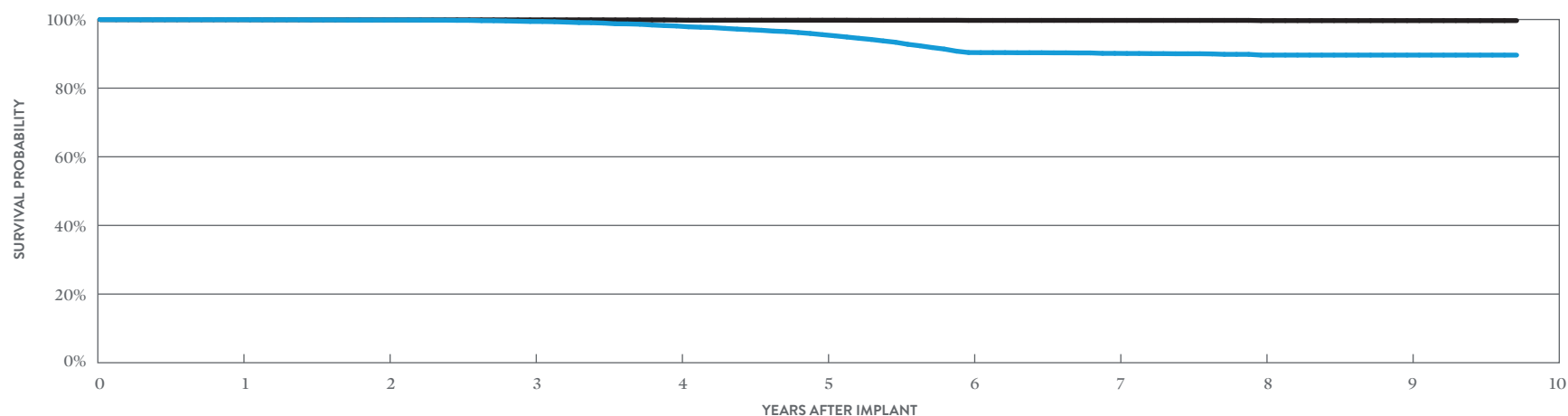
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40Q* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	26,025
Estimated Active US Implants	13,117
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	426
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	7	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	<0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	1	<0.01%	6	0.02%
Total	2	<0.01%	17	0.07%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 117 MONTHS
SURVIVAL PROBABILITY	99.95%	99.85%	99.42%	98.11%	95.58%	90.37%	90.13%	89.63%	89.63%	89.63%
± 1 STANDARD ERROR	0.01%	0.03%	0.05%	0.11%	0.17%	0.28%	0.29%	0.30%	0.31%	0.31%
SAMPLE SIZE	23,490	19,220	16,140	13,640	11,360	9,040	6,540	4,220	2,060	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 117 MONTHS
SURVIVAL PROBABILITY	99.95%	99.90%	99.90%	99.83%	99.79%	99.74%	99.74%	99.68%	99.68%	99.68%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.03%	0.04%	0.04%	0.04%	0.04%	0.06%	0.06%

*DF4-LLHH connector type.

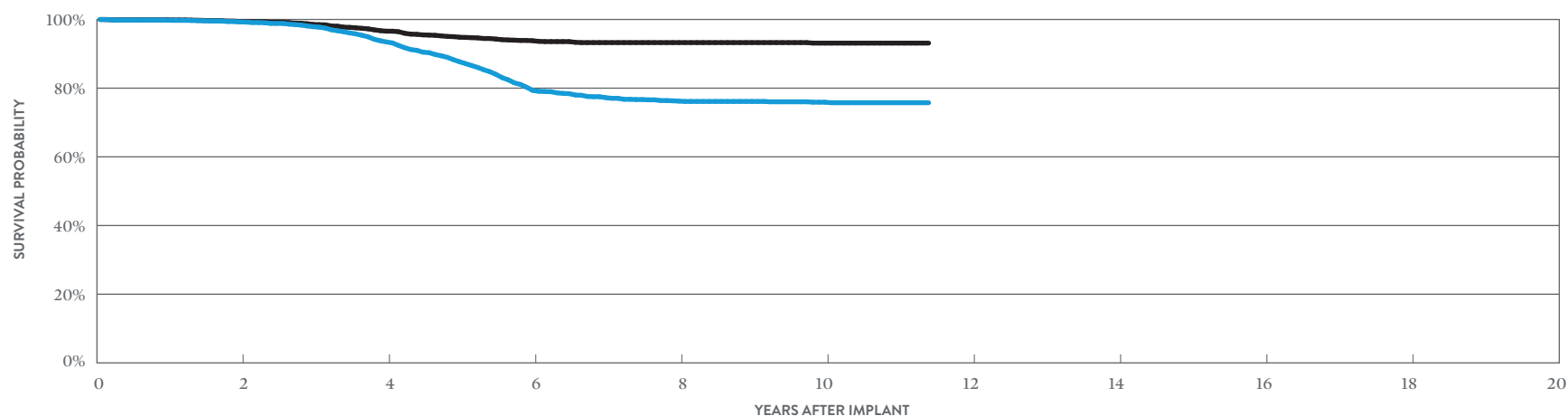
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,458
Estimated Active US Implants	1,300
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	227
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.02%	2	0.04%
Electrical Interconnect	2	0.04%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	2	0.04%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	11	0.20%	75	1.37%
Other	0	0.00%	3	0.05%
Total	16	0.29%	80	1.47%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.28%	93.45%	79.34%	76.22%	75.91%	75.76%
± 1 STANDARD ERROR	0.11%	0.40%	0.69%	0.74%	0.75%	0.76%
SAMPLE SIZE	4,390	3,410	2,690	1,960	1,300	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.39%	96.59%	93.82%	93.27%	93.12%	93.12%
± 1 STANDARD ERROR	0.10%	0.29%	0.41%	0.44%	0.45%	0.45%

*DF4-LLHH connector type.

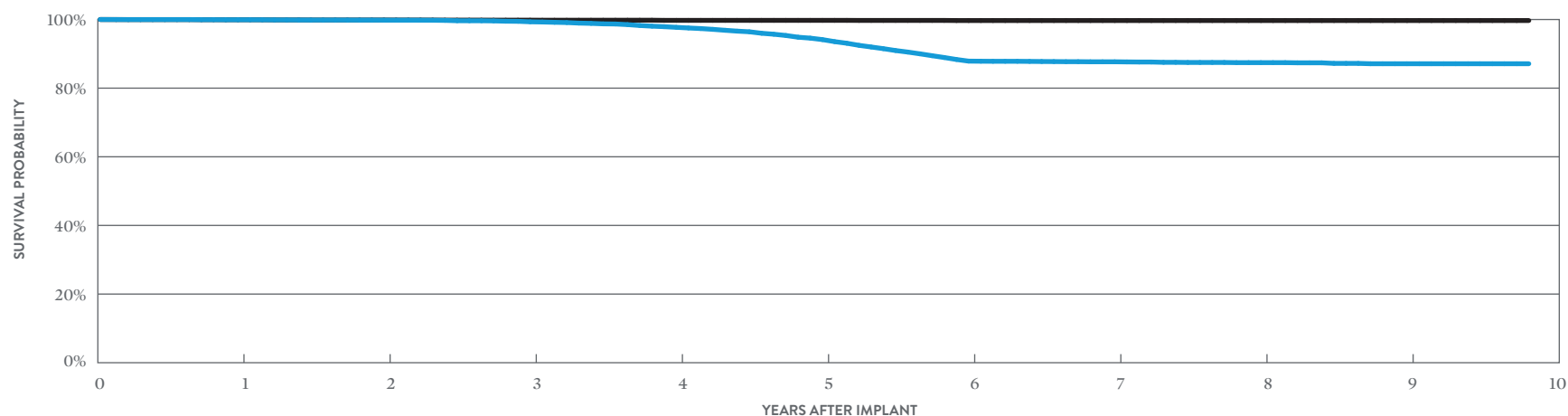
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40C* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	21,179
Estimated Active US Implants	9,968
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	487
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	5	0.02%
Electrical Interconnect	2	<0.01%	1	<0.01%
Battery	0	0.00%	2	<0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	1	<0.01%	6	0.03%
Total	3	0.01%	17	0.08%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 118 MONTHS
SURVIVAL PROBABILITY	99.93%	99.81%	99.33%	97.72%	94.14%	87.87%	87.68%	87.43%	87.11%	87.11%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.12%	0.21%	0.32%	0.33%	0.34%	0.35%	0.35%
SAMPLE SIZE	19,630	16,860	14,510	12,370	10,310	8,250	6,270	4,460	2,440	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 118 MONTHS
SURVIVAL PROBABILITY	99.93%	99.86%	99.81%	99.75%	99.75%	99.70%	99.70%	99.70%	99.70%	99.70%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.04%	0.04%	0.05%	0.05%	0.05%	0.05%	0.05%

*Parylene coating.

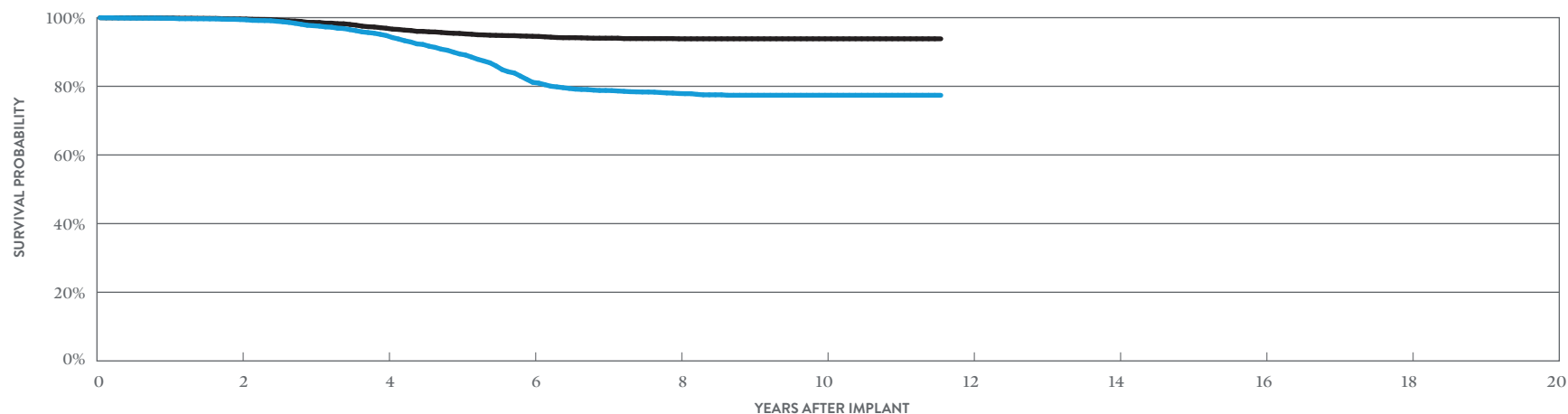
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	9,711
Estimated Active US Implants	2,437
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	377
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.02%	3	0.03%
Electrical Interconnect	2	0.02%	1	0.01%
Battery	0	0.00%	6	0.06%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	2	0.02%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	19	0.20%	109	1.12%
Other	1	0.01%	3	0.03%
Total	25	0.26%	125	1.29%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.44%	94.78%	81.16%	77.90%	77.39%	77.39%
± 1 STANDARD ERROR	0.08%	0.26%	0.50%	0.55%	0.56%	0.56%
SAMPLE SIZE	7,830	6,030	4,790	3,550	2,500	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.62%	96.91%	94.57%	93.84%	93.84%	93.84%
± 1 STANDARD ERROR	0.07%	0.21%	0.29%	0.32%	0.32%	0.32%

*Parylene coating.

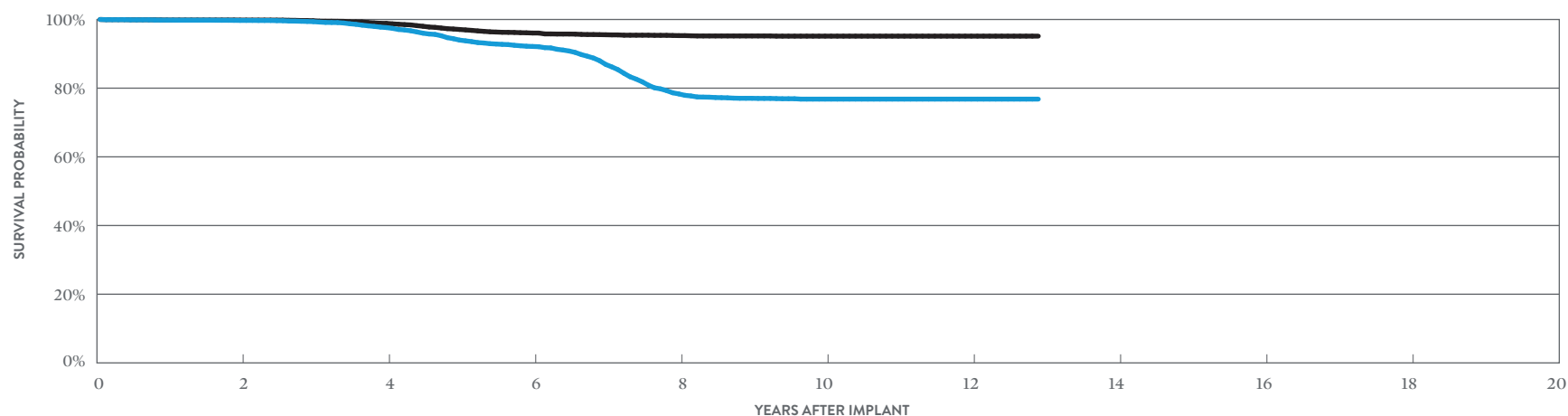
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3265-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	13,959
Estimated Active US Implants	2,901
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	493
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.01%	6	0.04%
Electrical Interconnect	2	0.01%	0	0.00%
Battery	1	<0.01%	7	0.05%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	2	0.01%
Mechanical	0	0.00%	3	0.02%
Possible Early Battery Depletion	24	0.17%	109	0.78%
Other	1	<0.01%	1	<0.01%
Total	31	0.22%	128	0.92%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 155 MONTHS
SURVIVAL PROBABILITY	99.72%	97.64%	92.14%	78.32%	76.81%	76.81%	76.81%
± 1 STANDARD ERROR	0.05%	0.15%	0.29%	0.50%	0.52%	0.52%	0.52%
SAMPLE SIZE	11,590	9,150	7,130	4,940	3,560	2,340	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 155 MONTHS
SURVIVAL PROBABILITY	99.83%	98.87%	96.05%	95.30%	95.15%	95.15%	95.15%
± 1 STANDARD ERROR	0.03%	0.11%	0.21%	0.24%	0.25%	0.25%	0.25%

*DF4-LLHH connector type.

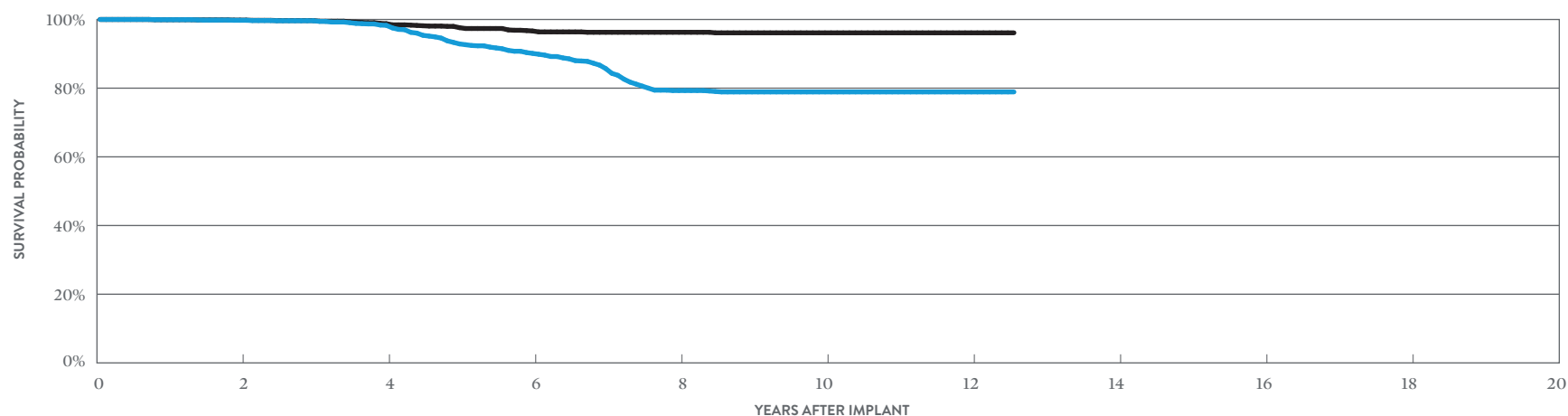
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3265-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	4,026
Estimated Active US Implants	908
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	135
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	0	0.00%	2	0.05%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	6	0.15%	19	0.47%
Other	7	0.17%	2	0.05%
Total	14	0.35%	24	0.60%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 151 MONTHS
SURVIVAL PROBABILITY	99.76%	98.29%	90.12%	79.30%	78.90%	78.90%	78.90%
± 1 STANDARD ERROR	0.09%	0.25%	0.62%	0.91%	0.92%	0.92%	0.92%
SAMPLE SIZE	3,280	2,540	1,940	1,410	1,100	720	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 151 MONTHS
SURVIVAL PROBABILITY	99.82%	98.78%	96.65%	96.27%	96.11%	96.11%	96.11%
± 1 STANDARD ERROR	0.07%	0.21%	0.37%	0.40%	0.42%	0.42%	0.42%

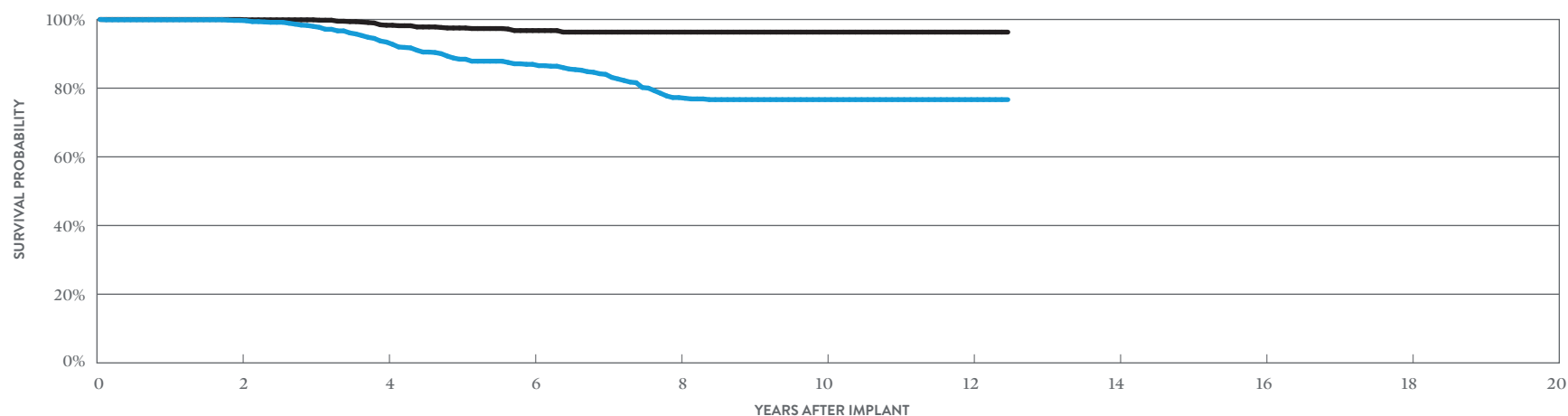
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,716
Estimated Active US Implants	590
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	109
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	2	0.07%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	0.04%	0	0.00%
Mechanical	0	0.00%	1	0.04%
Possible Early Battery Depletion	5	0.18%	12	0.44%
Other	2	0.07%	0	0.00%
Total	8	0.29%	15	0.55%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 150 MONTHS
SURVIVAL PROBABILITY	99.73%	93.42%	86.94%	77.26%	76.66%	76.66%	76.66%
± 1 STANDARD ERROR	0.11%	0.58%	0.85%	1.16%	1.18%	1.18%	1.18%
SAMPLE SIZE	2,170	1,610	1,180	870	690	500	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 150 MONTHS
SURVIVAL PROBABILITY	100.00%	98.32%	96.77%	96.32%	96.32%	96.32%	96.32%
± 1 STANDARD ERROR	0.00%	0.31%	0.47%	0.51%	0.51%	0.51%	0.51%

*DF4-LLHH connector type.

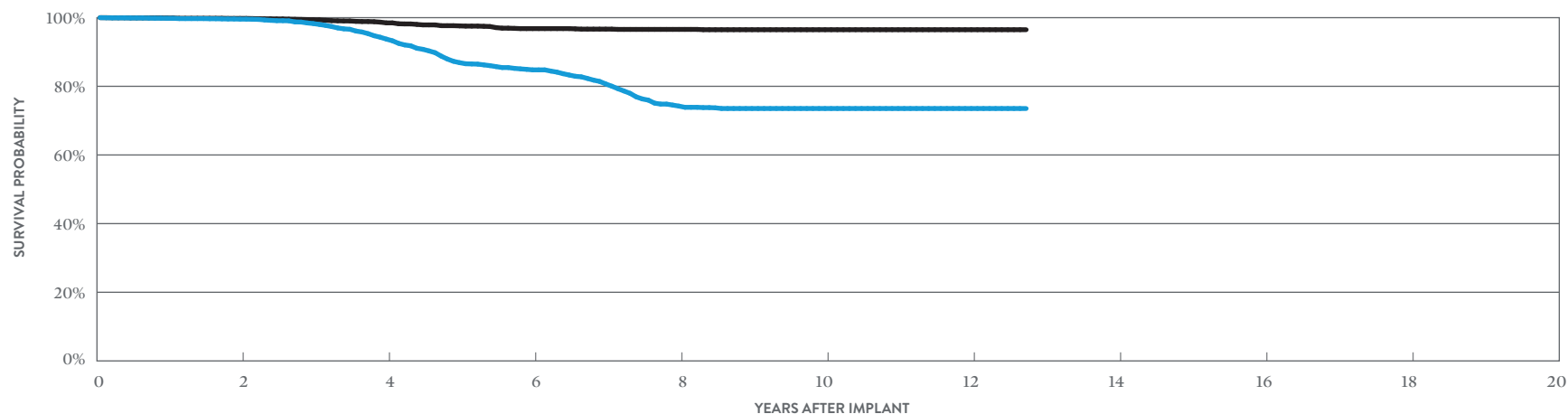
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,744
Estimated Active US Implants	1,474
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	328
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.09%	3	0.04%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	1	0.01%	1	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	4	0.06%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	10	0.15%	30	0.44%
Other	1	0.01%	2	0.03%
Total	19	0.28%	40	0.59%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	99.57%	93.75%	84.79%	74.24%	73.53%	73.53%	73.53%
± 1 STANDARD ERROR	0.08%	0.35%	0.56%	0.74%	0.75%	0.75%	0.75%
SAMPLE SIZE	5,460	4,150	3,070	2,250	1,780	1,190	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	99.78%	98.48%	96.81%	96.58%	96.49%	96.49%	96.49%
± 1 STANDARD ERROR	0.06%	0.17%	0.28%	0.30%	0.31%	0.31%	0.31%

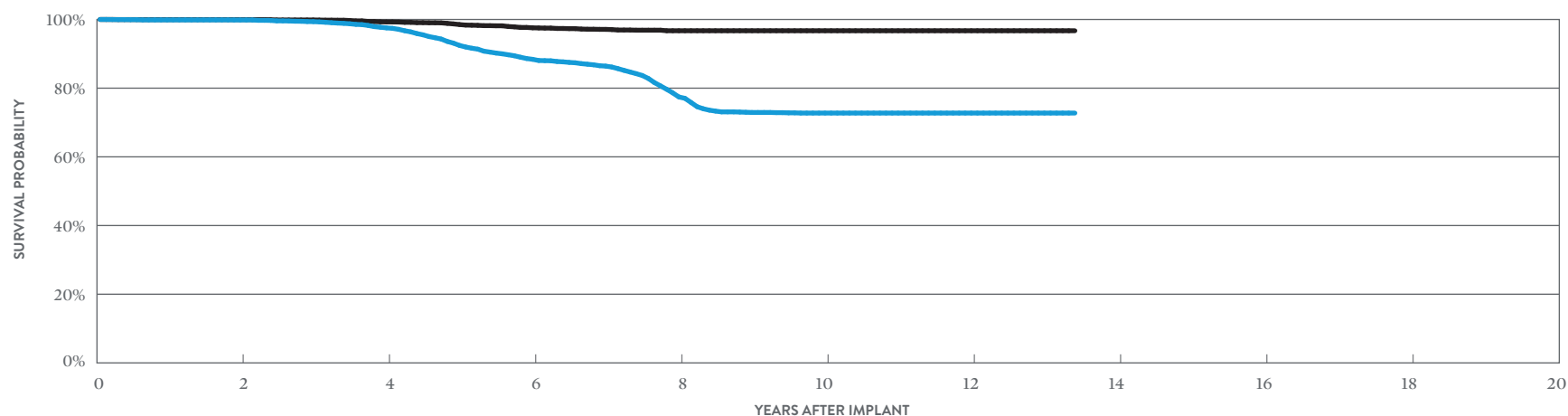
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Quadra™ CRT-D

MODEL CD3249-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	9,940
Estimated Active US Implants	1,927
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	457
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	4	0.04%	3	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.01%	1	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	17	0.17%	40	0.40%
Other	4	0.04%	1	0.01%
Total	26	0.26%	46	0.46%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.86%	97.55%	88.40%	77.44%	72.75%	72.75%	72.75%
± 1 STANDARD ERROR	0.04%	0.18%	0.41%	0.59%	0.67%	0.67%	0.67%
SAMPLE SIZE	8,210	6,560	4,880	3,390	2,450	2,060	320

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.96%	99.28%	97.57%	96.72%	96.72%	96.72%	96.72%
± 1 STANDARD ERROR	0.02%	0.10%	0.20%	0.25%	0.25%	0.25%	0.25%

*DF4-LLHH connector type.

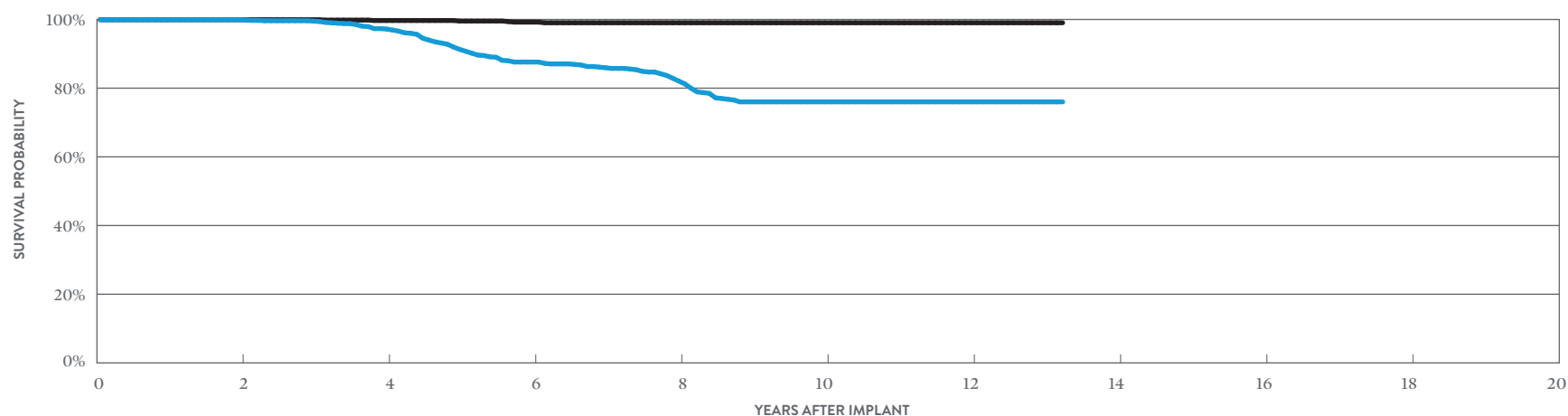
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Quadra™ CRT-D

MODEL CD3249-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	2,767
Estimated Active US Implants	549
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	121
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.04%
Possible Early Battery Depletion	0	0.00%	5	0.18%
Other	1	0.04%	0	0.00%
Total	1	0.04%	6	0.22%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	99.93%	97.22%	87.60%	82.05%	76.01%	76.01%	76.01%
± 1 STANDARD ERROR	0.05%	0.38%	0.84%	1.03%	1.25%	1.25%	1.25%
SAMPLE SIZE	2,220	1,720	1,240	880	670	580	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	99.93%	99.70%	99.22%	99.04%	99.04%	99.04%	99.04%
± 1 STANDARD ERROR	0.05%	0.13%	0.23%	0.26%	0.26%	0.26%	0.26%

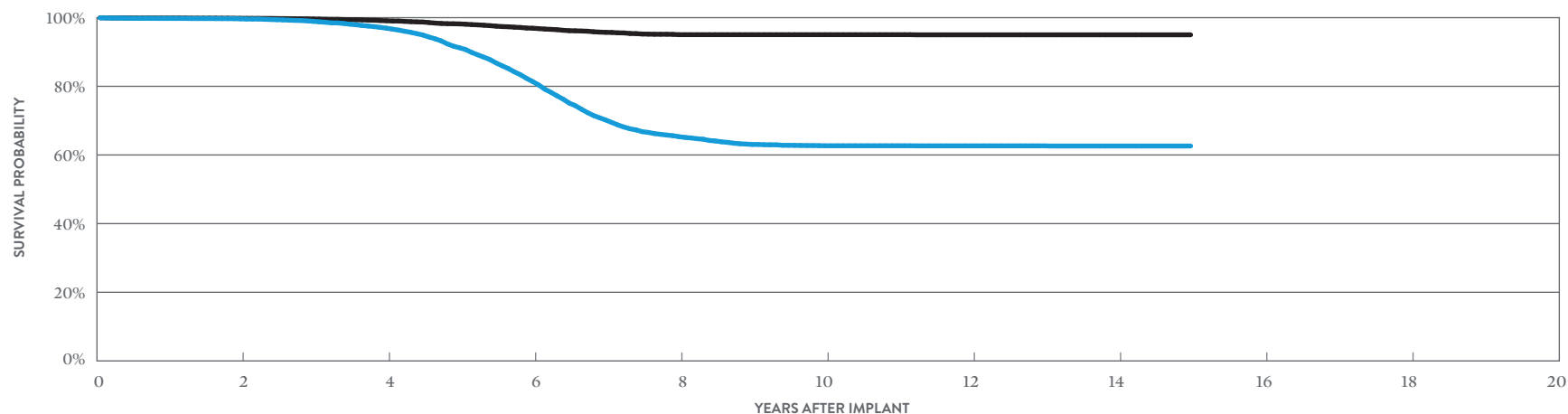
Cardiac Resynchronization Therapy (CRT) ICDs

Unify™ CRT-D

MODEL CD3231-40Q (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	20,709
Estimated Active US Implants	3,272
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,426
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	6	0.03%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	15	0.07%	11	0.05%
High Voltage Capacitor	17	0.08%	6	0.03%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	1	<0.01%	3	0.01%
Possible Early Battery Depletion	67	0.32%	62	0.30%
Other	10	0.05%	7	0.03%
Total	113	0.55%	97	0.47%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.65%	96.94%	81.39%	65.33%	62.68%	62.65%	62.61%	62.61%
± 1 STANDARD ERROR	0.04%	0.14%	0.35%	0.46%	0.48%	0.48%	0.48%	0.48%
SAMPLE SIZE	16,850	13,300	9,810	6,270	4,500	3,920	2,560	290

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.81%	99.10%	96.93%	95.04%	95.04%	95.00%	95.00%	95.00%
± 1 STANDARD ERROR	0.03%	0.08%	0.16%	0.22%	0.22%	0.22%	0.22%	0.22%

*DF4-LLHH connector type.

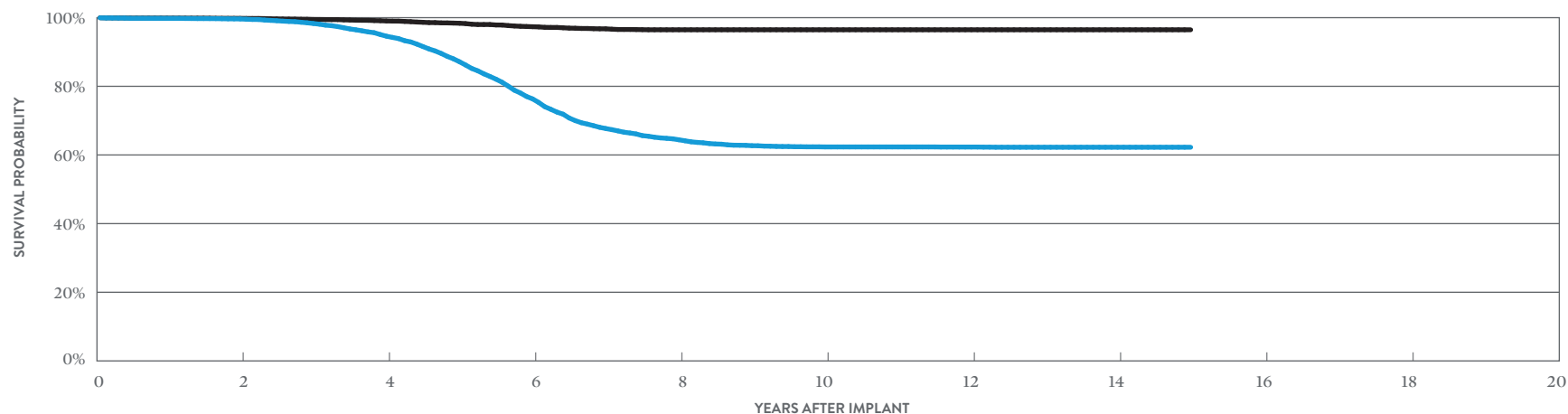
Cardiac Resynchronization Therapy (CRT) ICDs

Unify™ CRT-D

MODEL CD3231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	21,185
Estimated Active US Implants	3,647
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,527
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	11	0.05%	5	0.02%
Electrical Interconnect	4	0.02%	0	0.00%
Battery	10	0.05%	5	0.02%
High Voltage Capacitor	7	0.03%	0	0.00%
Software/Firmware	0	0.00%	3	0.01%
Mechanical	1	<0.01%	1	<0.01%
Possible Early Battery Depletion	33	0.16%	50	0.24%
Other	11	0.05%	12	0.06%
Total	77	0.36%	76	0.36%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.62%	94.60%	76.33%	64.42%	62.34%	62.31%	62.25%	62.25%
± 1 STANDARD ERROR	0.04%	0.18%	0.39%	0.46%	0.47%	0.47%	0.47%	0.47%
SAMPLE SIZE	16,900	12,770	9,040	6,150	4,820	4,230	2,410	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.79%	99.04%	97.36%	96.47%	96.47%	96.47%	96.47%	96.47%
± 1 STANDARD ERROR	0.03%	0.08%	0.15%	0.19%	0.19%	0.19%	0.19%	0.19%

BATTERY LONGEVITY SUMMARY
**Cardiac Resynchronization
Therapy (CRT) ICDs**

Cardiac Resynchronization Therapy (CRT) ICDs

Battery Longevity (years)

MODELS	FAMILY	NO PACING	25% PACING	50% PACING	100% PACING
CDHFA500Q	Gallant™ HF CRT-D***	10.6	9.5	8.7	7.4
CD3369-40Q	Quadra Assura MP™ CRT-D*	11.1	9.9	8.9	7.4
CD3369-40C	Quadra Assura MP™ CRT-D*	11.1	9.9	8.9	7.4
CD3365-40Q	Quadra Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3365-40C	Quadra Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3357-40Q	Unify Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3357-40C	Unify Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3265-40Q	Quadra Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3265-40	Quadra Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3257-40Q	Unify Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3257-40	Unify Assura™ CRT-D*	11.1	9.9	8.9	7.4
CD3249-40Q	Unify Quadra™ CRT-D*	10.2	9.0	8.1	6.7
CD3249-40	Unify Quadra™ CRT-D*	10.2	9.0	8.1	6.7
CD3231-40Q	Unify™ CRT-D*	10.1	9.0	8.1	6.7
CD3231-40	Unify™ CRT-D*	10.1	9.0	8.1	6.7

Pacing parameters: DDD-BiV, RV 2.5V, LV 2.5V, A 2.5V, 0.5 ms, 60 ppm, 500 ohms

*Battery voltage range: 3.20-2.59. Three maximum charges per year.

**Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.

***Capacitor maintenance interval: 1 charge per every 9 months.

SUMMARY INFORMATION

Cardiac Resynchronization
Therapy (CRT) ICDs

Cardiac Resynchronization Therapy (CRT) ICDs Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDHFA500Q	Gallant™ HF CRT-D	99.89%	99.83%	99.75%	99.27%						
CD3369-40Q	Quadra Assura MP™ CRT-D	99.84%	99.75%	99.62%	99.20%	97.67%	97.48%	97.19%	96.84%	96.71%	
CD3369-40C	Quadra Assura MP™ CRT-D	99.84%	99.62%	99.47%	98.69%	96.40%	96.22%	95.89%	95.65%		
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.74%	99.58%	98.89%	97.19%	93.27%	92.99%	92.75%	92.37%	
CD3365-40Q	Quadra Assura™ CRT-D†	99.78%	99.39%	98.18%	95.32%	91.40%	85.11%	82.67%	81.04%	80.33%	80.28%
CD3365-40C	Quadra Assura™ CRT-D	100.00%	99.82%	99.63%	98.60%	97.40%	92.22%	92.09%	91.93%	91.93%	
CD3365-40C	Quadra Assura™ CRT-D†	99.74%	99.27%	98.38%	96.61%	93.21%	87.05%	85.01%	83.23%	82.94%	82.94%
CD3357-40Q	Unify Assura™ CRT-D	99.95%	99.85%	99.42%	98.11%	95.58%	90.37%	90.13%	89.63%	89.63%	
CD3357-40Q	Unify Assura™ CRT-D†	99.79%	99.28%	97.89%	93.45%	87.69%	79.34%	77.23%	76.22%	76.13%	75.91%
CD3357-40C	Unify Assura™ CRT-D	99.93%	99.81%	99.33%	97.72%	94.14%	87.87%	87.68%	87.43%	87.11%	
CD3357-40C	Unify Assura™ CRT-D†	99.81%	99.44%	97.66%	94.78%	89.43%	81.16%	78.79%	77.90%	77.39%	77.39%
CD3265-40Q	Quadra Assura™ CRT-D†	99.81%	99.72%	99.37%	97.64%	94.00%	92.14%	86.90%	78.32%	77.05%	76.81%
CD3265-40	Quadra Assura™ CRT-D†	99.94%	99.76%	99.63%	98.29%	92.88%	90.12%	85.70%	79.30%	78.90%	78.90%
CD3257-40Q	Unify Assura™ CRT-D†	99.92%	99.73%	97.99%	93.42%	88.43%	86.94%	84.02%	77.26%	76.66%	76.66%
CD3257-40	Unify Assura™ CRT-D†	99.81%	99.57%	98.28%	93.75%	86.89%	84.79%	80.69%	74.24%	73.53%	73.53%
CD3249-40Q	Unify Quadra™ CRT-D†	99.88%	99.86%	99.37%	97.55%	92.44%	88.40%	86.42%	77.44%	72.92%	72.75%
CD3249-40	Unify Quadra™ CRT-D†	99.93%	99.93%	99.52%	97.22%	91.31%	87.60%	85.94%	82.05%	76.01%	76.01%
CD3231-40Q	Unify™ CRT-D†	99.77%	99.65%	98.92%	96.94%	91.23%	81.39%	70.18%	65.33%	63.06%	62.68%
CD3231-40	Unify™ CRT-D†	99.79%	99.62%	98.30%	94.60%	87.15%	76.33%	67.70%	64.42%	62.70%	62.34%

†Premature battery depletion advisory population.

Cardiac Resynchronization Therapy (CRT) ICDs Survival Probability Summary

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDHFA500Q	Gallant™ HF CRT-D	99.89%	99.84%	99.81%	99.76%						
CD3369-40Q	Quadra Assura MP™ CRT-D	99.85%	99.78%	99.73%	99.70%	99.69%	99.68%	99.65%	99.62%	99.62%	
CD3369-40C	Quadra Assura MP™ CRT-D	99.88%	99.68%	99.66%	99.66%	99.59%	99.59%	99.59%	99.59%		
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.74%	99.67%	99.62%	99.58%	99.56%	99.48%	99.48%	99.44%	
CD3365-40Q	Quadra Assura™ CRT-D†	99.83%	99.55%	98.51%	96.13%	94.01%	92.46%	91.67%	91.27%	91.24%	91.24%
CD3365-40C	Quadra Assura™ CRT-D	100.00%	99.82%	99.73%	99.62%	99.62%	99.62%	99.62%	99.62%	99.62%	
CD3365-40C	Quadra Assura™ CRT-D†	99.78%	99.31%	98.42%	97.40%	96.14%	94.72%	94.32%	94.04%	94.04%	94.04%
CD3357-40Q	Unify Assura™ CRT-D	99.95%	99.90%	99.90%	99.83%	99.79%	99.74%	99.74%	99.68%	99.68%	
CD3357-40Q	Unify Assura™ CRT-D†	99.90%	99.39%	98.55%	96.59%	94.83%	93.82%	93.27%	93.27%	93.27%	93.12%
CD3357-40C	Unify Assura™ CRT-D	99.93%	99.86%	99.81%	99.75%	99.75%	99.70%	99.70%	99.70%	99.70%	
CD3357-40C	Unify Assura™ CRT-D†	99.89%	99.62%	98.63%	96.91%	95.41%	94.57%	94.02%	93.84%	93.84%	93.84%
CD3265-40Q	Quadra Assura™ CRT-D†	99.85%	99.83%	99.63%	98.87%	97.09%	96.05%	95.55%	95.30%	95.20%	95.15%
CD3265-40	Quadra Assura™ CRT-D†	99.94%	99.82%	99.69%	98.78%	97.61%	96.65%	96.27%	96.27%	96.11%	96.11%
CD3257-40Q	Unify Assura™ CRT-D†	100.00%	100.00%	99.90%	98.32%	97.52%	96.77%	96.32%	96.32%	96.32%	96.32%
CD3257-40	Unify Assura™ CRT-D†	99.90%	99.78%	99.40%	98.48%	97.60%	96.81%	96.66%	96.58%	96.49%	96.49%
CD3249-40Q	Unify Quadra™ CRT-D†	99.96%	99.96%	99.86%	99.28%	98.52%	97.57%	97.12%	96.72%	96.72%	96.72%
CD3249-40	Unify Quadra™ CRT-D†	99.93%	99.93%	99.93%	99.70%	99.55%	99.22%	99.04%	99.04%	99.04%	99.04%
CD3231-40Q	Unify™ CRT-D†	99.88%	99.81%	99.62%	99.10%	98.18%	96.93%	95.72%	95.04%	95.04%	95.04%
CD3231-40	Unify™ CRT-D†	99.87%	99.79%	99.47%	99.04%	98.37%	97.36%	96.75%	96.47%	96.47%	96.47%

†Premature battery depletion advisory population.

Cardiac Resynchronization Therapy (CRT) ICDs

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDHFA500Q	Gallant [™] HF CRT-D	53,224	1.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	3	<0.01%
CD3369-40Q	Quadra Assura MP [™] CRT-D	80,096	4.20%	8	<0.01%	10	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	4	<0.01%	23	0.03%
CD3369-40C	Quadra Assura MP [™] CRT-D	12,482	5.40%	2	0.02%	2	0.02%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	6	0.05%
CD3365-40Q	Quadra Assura [™] CRT-D	16,839	6.60%	2	0.01%	3	0.02%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	2	0.01%	10	0.06%
CD3365-40Q	Quadra Assura [™] CRT-D [†]	24,249	18.30%	6	0.02%	10	0.04%	3	0.01%	1	<0.01%	1	<0.01%	0	0.00%	43	0.18%	6	0.02%	70	0.29%
CD3365-40C	Quadra Assura [™] CRT-D	2,705	8.30%	0	0.00%	0	0.00%	0	0.00%	2	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	3	0.11%
CD3365-40C	Quadra Assura [™] CRT-D [†]	5,626	22.00%	6	0.11%	2	0.04%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	8	0.14%	3	0.05%	20	0.36%
CD3357-40Q	Unify Assura [™] CRT-D	26,025	6.20%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%
CD3357-40Q	Unify Assura [™] CRT-D [†]	5,458	22.70%	1	0.02%	2	0.04%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	11	0.20%	0	0.00%	16	0.29%
CD3357-40C	Unify Assura [™] CRT-D	21,179	7.60%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	3	0.01%
CD3357-40C	Unify Assura [™] CRT-D [†]	9,711	22.50%	2	0.02%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	19	0.20%	1	0.01%	25	0.26%
CD3265-40Q	Quadra Assura [™] CRT-D [†]	13,959	17.90%	2	0.01%	2	0.01%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	24	0.17%	1	<0.01%	31	0.22%
CD3265-40	Quadra Assura [™] CRT-D [†]	4,026	19.80%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.15%	7	0.17%	14	0.35%
CD3257-40Q	Unify Assura [™] CRT-D [†]	2,716	21.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	5	0.18%	2	0.07%	8	0.29%
CD3257-40	Unify Assura [™] CRT-D [†]	6,744	20.90%	6	0.09%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	10	0.15%	1	0.01%	19	0.28%
CD3249-40Q	Unify Quadra [™] CRT-D [†]	9,940	18.00%	4	0.04%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	17	0.17%	4	0.04%	26	0.26%
CD3249-40	Unify Quadra [™] CRT-D [†]	2,767	19.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	1	0.04%
CD3231-40Q	Unify [™] CRT-D [†]	20,709	20.20%	2	<0.01%	1	<0.01%	15	0.07%	17	0.08%	0	0.00%	1	<0.01%	67	0.32%	10	0.05%	113	0.55%
CD3231-40	Unify [™] CRT-D [†]	21,185	21.30%	11	0.05%	4	0.02%	10	0.05%	7	0.03%	0	0.00%	1	<0.01%	33	0.16%	11	0.05%	77	0.36%

Definitions of malfunction categories can be found on [pages 5-6](#).

[†]Premature battery depletion advisory population.

Cardiac Resynchronization Therapy (CRT) ICDs

US Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDHFA500Q	Gallant [™] HF CRT-D	53,224	1.90%	17	0.03%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	5	<0.01%	0	0.00%	4	<0.01%	28	0.05%
CD3369-40Q	Quadra Assura MP [™] CRT-D	80,096	4.20%	33	0.04%	1	<0.01%	3	<0.01%	2	<0.01%	0	0.00%	6	<0.01%	2	<0.01%	23	0.03%	70	0.09%
CD3369-40C	Quadra Assura MP [™] CRT-D	12,482	5.40%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.02%	2	0.02%	4	0.03%	12	0.10%
CD3365-40Q	Quadra Assura [™] CRT-D	16,839	6.60%	8	0.05%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	4	0.02%	3	0.02%	7	0.04%	23	0.14%
CD3365-40Q	Quadra Assura [™] CRT-D [†]	24,249	18.30%	17	0.07%	1	<0.01%	19	0.08%	0	0.00%	3	0.01%	2	<0.01%	421	1.74%	7	0.03%	470	1.94%
CD3365-40C	Quadra Assura [™] CRT-D	2,705	8.30%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%
CD3365-40C	Quadra Assura [™] CRT-D [†]	5,626	22.00%	2	0.04%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	0	0.00%	59	1.05%	2	0.04%	65	1.16%
CD3357-40Q	Unify Assura [™] CRT-D	26,025	6.20%	7	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	6	0.02%	17	0.07%
CD3357-40Q	Unify Assura [™] CRT-D [†]	5,458	22.70%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	75	1.37%	3	0.05%	80	1.47%
CD3357-40C	Unify Assura [™] CRT-D	21,179	7.60%	5	0.02%	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	6	0.03%	17	0.08%
CD3357-40C	Unify Assura [™] CRT-D [†]	9,711	22.50%	3	0.03%	1	0.01%	6	0.06%	0	0.00%	2	0.02%	1	0.01%	109	1.12%	3	0.03%	125	1.29%
CD3265-40Q	Quadra Assura [™] CRT-D [†]	13,959	17.90%	6	0.04%	0	0.00%	7	0.05%	0	0.00%	2	0.01%	3	0.02%	109	0.78%	1	<0.01%	128	0.92%
CD3265-40	Quadra Assura [™] CRT-D [†]	4,026	19.80%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	1	0.02%	0	0.00%	19	0.47%	2	0.05%	24	0.60%
CD3257-40Q	Unify Assura [™] CRT-D [†]	2,716	21.80%	0	0.00%	0	0.00%	2	0.07%	0	0.00%	0	0.00%	1	0.04%	12	0.44%	0	0.00%	15	0.55%
CD3257-40	Unify Assura [™] CRT-D [†]	6,744	20.90%	3	0.04%	0	0.00%	1	0.01%	0	0.00%	4	0.06%	0	0.00%	30	0.44%	2	0.03%	40	0.59%
CD3249-40Q	Unify Quadra [™] CRT-D [†]	9,940	18.00%	3	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	40	0.40%	1	0.01%	46	0.46%
CD3249-40	Unify Quadra [™] CRT-D [†]	2,767	19.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	5	0.18%	0	0.00%	6	0.22%
CD3231-40Q	Unify [™] CRT-D [†]	20,709	20.20%	6	0.03%	0	0.00%	11	0.05%	6	0.03%	2	<0.01%	3	0.01%	62	0.30%	7	0.03%	97	0.47%
CD3231-40	Unify [™] CRT-D [†]	21,185	21.30%	5	0.02%	0	0.00%	5	0.02%	0	0.00%	3	0.01%	1	<0.01%	50	0.24%	12	0.06%	76	0.36%

Definitions of malfunction categories can be found on [pages 5-6](#).

†Premature battery depletion advisory population.

Cardiac Resynchronization Therapy (CRT) ICDs

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDHFA500Q	Gallant™ HF CRT-D	83,532	1.51%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	<0.01%	6	<0.01%
CD3369-40Q	Quadra Assura MP™ CRT-D	80,657	4.39%	16	0.02%	20	0.02%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	8	<0.01%	46	0.06%
CD3369-40C	Quadra Assura MP™ CRT-D	12,661	5.84%	4	0.03%	4	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	11	0.09%
CD3365-40Q	Quadra Assura™ CRT-D	42,062	13.56%	16	0.04%	26	0.06%	8	0.02%	1	<0.01%	4	<0.01%	0	0.00%	88	0.21%	16	0.04%	159	0.38%
CD3365-40C	Quadra Assura™ CRT-D	8,382	18.29%	12	0.14%	4	0.05%	2	0.02%	2	0.02%	0	0.00%	0	0.00%	16	0.19%	8	0.10%	44	0.52%
CD3357-40Q	Unify Assura™ CRT-D	32,140	9.26%	2	<0.01%	4	0.01%	0	0.00%	3	<0.01%	0	0.00%	0	0.00%	22	0.07%	2	<0.01%	33	0.10%
CD3357-40C	Unify Assura™ CRT-D	31,271	12.65%	4	0.01%	8	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	38	0.12%	4	0.01%	55	0.18%
CD3265-40Q	Quadra Assura™ CRT-D	13,955	18.26%	4	0.03%	4	0.03%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	48	0.34%	2	0.01%	62	0.44%
CD3265-40	Quadra Assura™ CRT-D	4,046	20.54%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	12	0.30%	14	0.35%	28	0.69%
CD3257-40Q	Unify Assura™ CRT-D	2,727	22.66%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.07%	0	0.00%	10	0.37%	4	0.15%	16	0.59%
CD3257-40	Unify Assura™ CRT-D	6,723	21.45%	12	0.18%	2	0.03%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	20	0.30%	2	0.03%	38	0.57%
CD3249-40Q	Unify Quadra™ CRT-D	12,592	14.72%	10	0.08%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	34	0.27%	8	0.06%	54	0.43%
CD3249-40	Unify Quadra™ CRT-D	5,828	10.55%	6	0.10%	4	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	2	0.03%	14	0.24%
CD3231-40Q	Unify™ CRT-D	20,973	20.49%	6	0.03%	2	<0.01%	30	0.14%	17	0.08%	0	0.00%	2	<0.01%	134	0.64%	20	0.10%	211	1.01%
CD3231-40	Unify™ CRT-D	25,076	18.52%	22	0.09%	8	0.03%	20	0.08%	7	0.03%	0	0.00%	2	<0.01%	68	0.27%	22	0.09%	149	0.59%

Definitions of malfunction categories can be found on [pages 5-6](#).

Cardiac Resynchronization Therapy (CRT) ICDs

Worldwide Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDHFA500Q	Gallant™ HF CRT-D	83,532	1.51%	48	0.06%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	14	0.02%	0	0.00%	12	0.01%	76	0.09%
CD3369-40Q	Quadra Assura MP™ CRT-D	80,657	4.39%	66	0.08%	2	<0.01%	6	<0.01%	2	<0.01%	0	0.00%	12	0.01%	4	<0.01%	46	0.06%	138	0.17%
CD3369-40C	Quadra Assura MP™ CRT-D	12,661	5.84%	6	0.05%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	4	0.03%	4	0.03%	8	0.06%	23	0.18%
CD3365-40Q	Quadra Assura™ CRT-D	42,062	13.56%	50	0.12%	2	<0.01%	40	0.10%	0	0.00%	6	0.01%	12	0.03%	850	2.02%	28	0.07%	988	2.35%
CD3365-40C	Quadra Assura™ CRT-D	8,382	18.29%	6	0.07%	0	0.00%	2	0.02%	0	0.00%	2	0.02%	0	0.00%	118	1.41%	4	0.05%	132	1.57%
CD3357-40Q	Unify Assura™ CRT-D	32,140	9.26%	18	0.06%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	4	0.01%	156	0.49%	18	0.06%	198	0.62%
CD3357-40C	Unify Assura™ CRT-D	31,271	12.65%	16	0.05%	4	0.01%	16	0.05%	0	0.00%	4	0.01%	4	0.01%	222	0.71%	18	0.06%	284	0.91%
CD3265-40Q	Quadra Assura™ CRT-D	13,955	18.26%	12	0.09%	0	0.00%	14	0.10%	0	0.00%	4	0.03%	6	0.04%	218	1.56%	2	0.01%	256	1.83%
CD3265-40	Quadra Assura™ CRT-D	4,046	20.54%	0	0.00%	0	0.00%	4	0.10%	0	0.00%	2	0.05%	0	0.00%	38	0.94%	4	0.10%	48	1.19%
CD3257-40Q	Unify Assura™ CRT-D	2,727	22.66%	0	0.00%	0	0.00%	4	0.15%	0	0.00%	0	0.00%	2	0.07%	24	0.88%	0	0.00%	30	1.10%
CD3257-40	Unify Assura™ CRT-D	6,723	21.45%	6	0.09%	0	0.00%	2	0.03%	0	0.00%	8	0.12%	0	0.00%	60	0.89%	4	0.06%	80	1.19%
CD3249-40Q	Unify Quadra™ CRT-D	12,592	14.72%	6	0.05%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	2	0.02%	86	0.68%	8	0.06%	104	0.83%
CD3249-40	Unify Quadra™ CRT-D	5,828	10.55%	6	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	14	0.24%	0	0.00%	22	0.38%
CD3231-40Q	Unify™ CRT-D	20,973	20.49%	12	0.06%	0	0.00%	22	0.10%	6	0.03%	4	0.02%	6	0.03%	124	0.59%	14	0.07%	188	0.90%
CD3231-40	Unify™ CRT-D	25,076	18.52%	16	0.06%	0	0.00%	10	0.04%	0	0.00%	6	0.02%	2	<0.01%	106	0.42%	28	0.11%	168	0.67%

Definitions of malfunction categories can be found on [pages 5-6](#).

Cardiac Resynchronization Therapy (CRT) Pacemakers

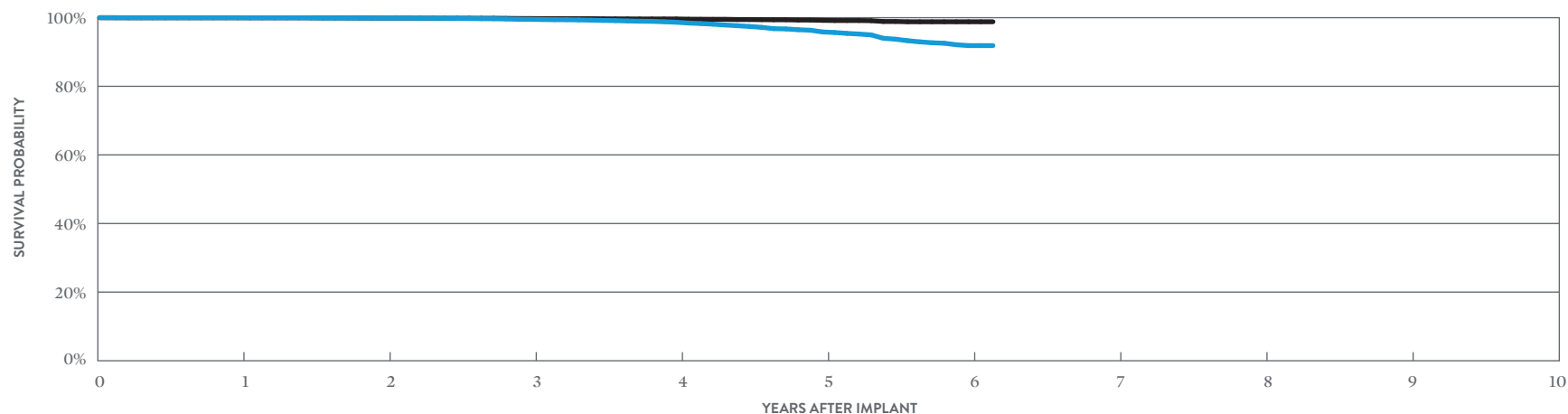
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra MP™ CRT-P

MODEL PM3562

US Regulatory Approval	January 2019
Registered US Implants	45,929
Estimated Active US Implants	32,285
Estimated Longevity	8 Years
Normal Battery Depletion	170
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	1	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	<0.01%	51	0.11%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	2	<0.01%	53	0.12%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 74 MONTHS
SURVIVAL PROBABILITY	99.98%	99.87%	99.51%	98.67%	95.84%	91.86%	91.86%
± 1 STANDARD ERROR	0.01%	0.02%	0.05%	0.09%	0.19%	0.43%	0.47%
SAMPLE SIZE	40,450	30,310	21,620	14,240	7,950	2,790	300

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 74 MONTHS
SURVIVAL PROBABILITY	99.98%	99.87%	99.75%	99.62%	99.22%	98.81%	98.81%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.08%	0.14%	0.14%

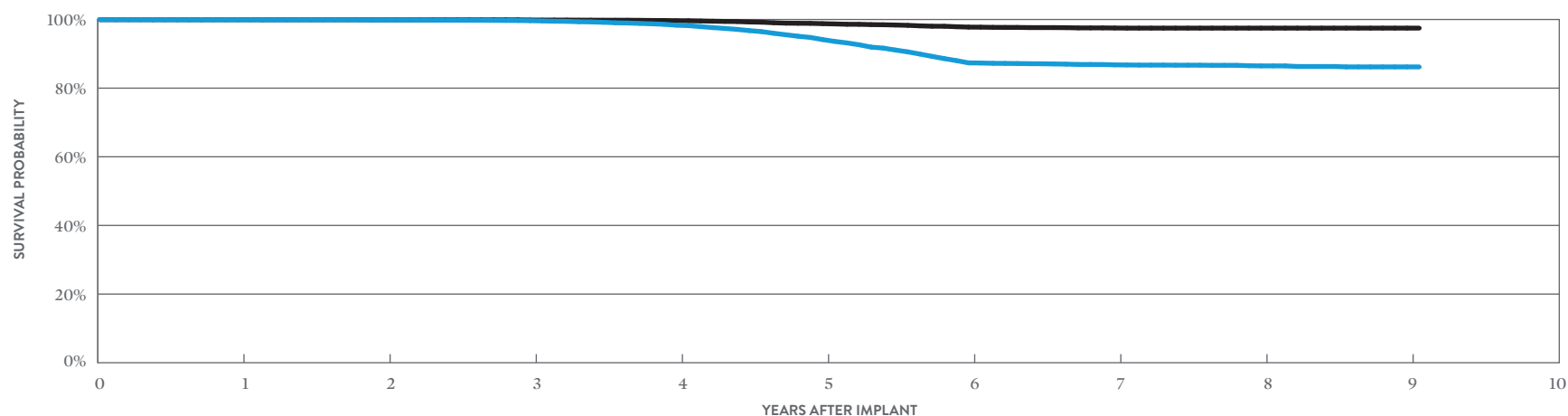
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra MP™ CRT-P

MODEL PM3262

US Regulatory Approval	February 2016
Registered US Implants	19,961
Estimated Active US Implants	8,205
Estimated Longevity	8 Years
Normal Battery Depletion	583
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	1	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	4	0.02%
Mechanical	6	0.03%	116	0.58%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	6	0.03%	122	0.61%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.93%	99.85%	99.65%	98.34%	94.16%	87.36%	86.78%	86.48%	86.19%	86.19%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.09%	0.19%	0.28%	0.29%	0.30%	0.33%	0.33%
SAMPLE SIZE	19,040	17,450	16,180	14,900	13,400	11,580	8,590	4,930	1,800	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.94%	99.90%	99.85%	99.65%	98.79%	97.78%	97.52%	97.49%	97.49%	97.49%
± 1 STANDARD ERROR	0.02%	0.02%	0.02%	0.04%	0.09%	0.13%	0.14%	0.14%	0.14%	0.14%

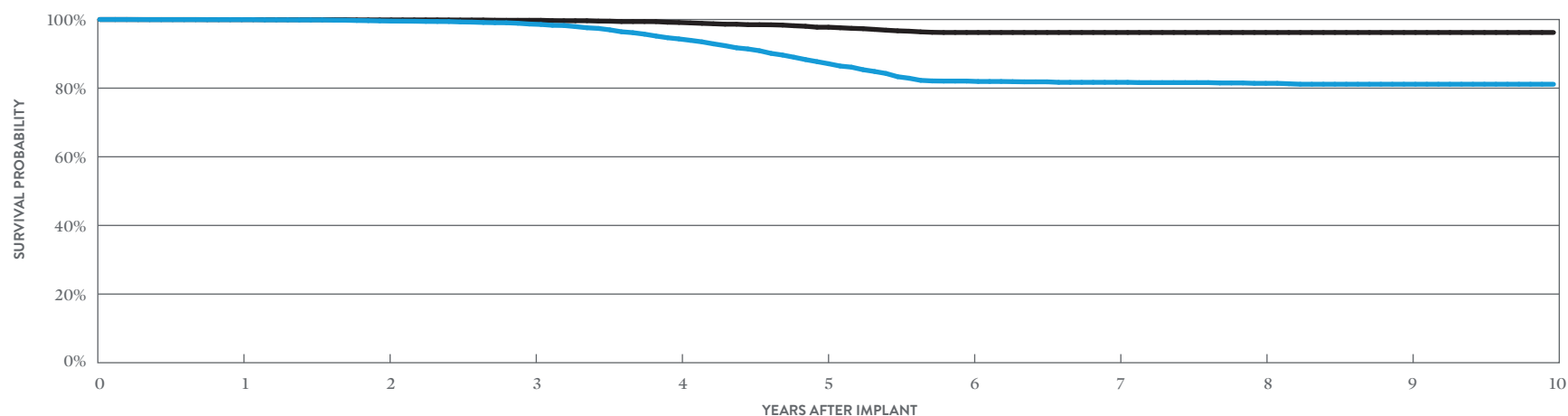
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure™ RF CRT-P

MODEL PM3222

US Regulatory Approval	March 2014
Registered US Implants	15,226
Estimated Active US Implants	7,349
Estimated Longevity	8 Years
Normal Battery Depletion	394
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	85	0.56%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	2	0.01%	85	0.56%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 127 MONTHS
SURVIVAL PROBABILITY	99.66%	95.73%	82.27%	81.61%	81.14%	81.14%
± 1 STANDARD ERROR	0.05%	0.21%	0.47%	0.50%	0.52%	0.52%
SAMPLE SIZE	11,350	7,820	4,700	2,240	720	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 127 MONTHS
SURVIVAL PROBABILITY	99.89%	99.40%	96.40%	96.22%	96.22%	96.22%
± 1 STANDARD ERROR	0.03%	0.08%	0.24%	0.26%	0.26%	0.26%

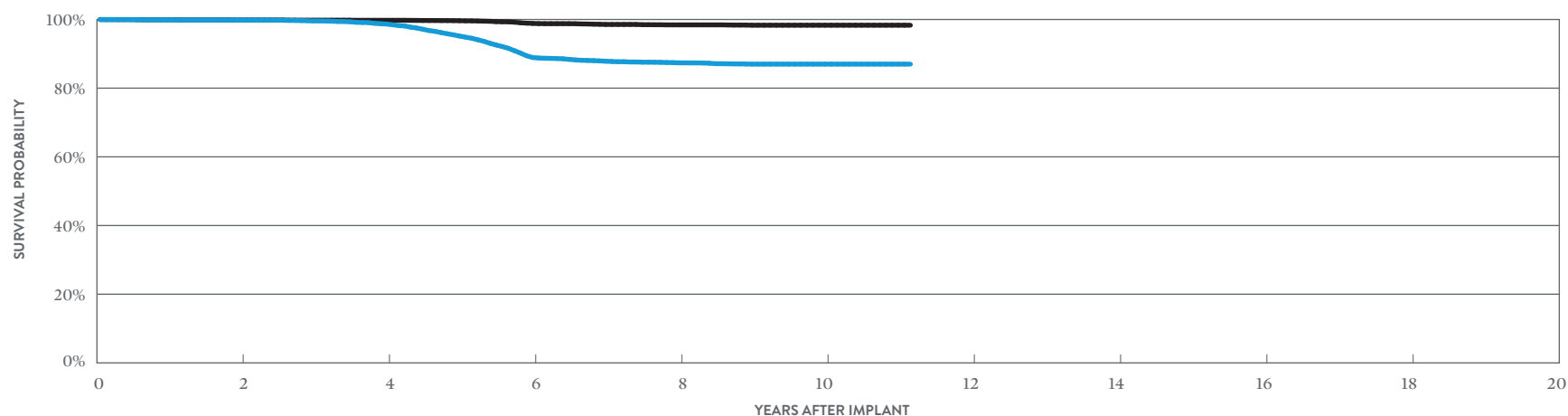
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra™ RF CRT-P

MODEL PM3242

US Regulatory Approval	March 2014
Registered US Implants	18,522
Estimated Active US Implants	5,809
Estimated Longevity	8 Years
Normal Battery Depletion	536
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	2	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	0.01%	71	0.38%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	3	0.02%	73	0.39%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.82%	98.68%	88.92%	87.37%	87.00%	87.00%
± 1 STANDARD ERROR	0.03%	0.09%	0.28%	0.31%	0.31%	0.31%
SAMPLE SIZE	15,620	13,250	10,760	7,870	4,100	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.86%	99.76%	98.85%	98.43%	98.33%	98.33%
± 1 STANDARD ERROR	0.03%	0.04%	0.10%	0.12%	0.13%	0.13%

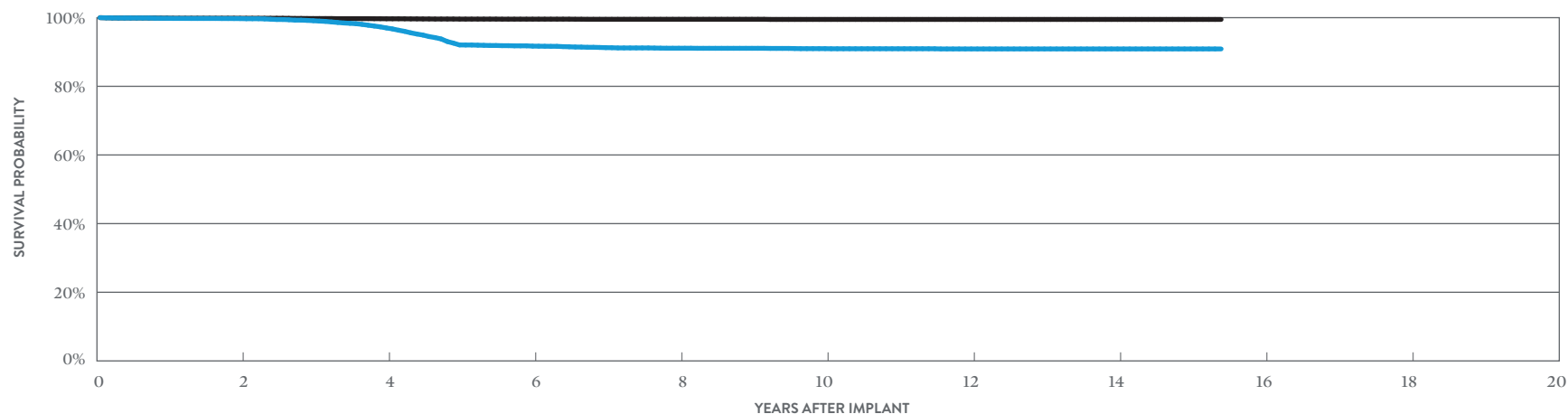
Cardiac Resynchronization Therapy (CRT) Pacemakers

Anthem™ RF CRT-P

MODEL PM3210

US Regulatory Approval	July 2009
Registered US Implants	20,647
Estimated Active US Implants	4,270
Estimated Longevity	8 Years
Normal Battery Depletion	405
Number of US Advisories (see pgs. 195, 197.)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.01%	3	0.01%
Electrical Interconnect	3	0.01%	1	<0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	7	0.03%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	<0.01%	3	0.01%
Other	0	0.00%	9	0.04%
Total	7	0.03%	24	0.12%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	99.72%	97.00%	91.71%	91.10%	90.97%	90.89%	90.89%	90.89%
± 1 STANDARD ERROR	0.04%	0.14%	0.25%	0.26%	0.27%	0.27%	0.27%	0.27%
SAMPLE SIZE	16,160	12,610	9,650	7,210	5,630	3,930	1,570	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	99.83%	99.67%	99.56%	99.52%	99.48%	99.48%	99.48%	99.48%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.06%	0.07%	0.07%	0.07%	0.07%

SUMMARY INFORMATION

Cardiac Resynchronization
Therapy (CRT) Pacemakers

Cardiac Resynchronization Therapy (CRT) Pacemakers

Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM3562	Allure Quadra MP [™] CRT-P	99.98%	99.87%	99.51%	98.67%	95.84%	91.86%				
PM3262	Allure Quadra MP [™] CRT-P	99.93%	99.85%	99.65%	98.34%	94.16%	87.36%	86.78%	86.48%	86.19%	
PM3222	Allure [™] RF CRT-P	99.96%	99.66%	99.05%	95.73%	89.64%	82.27%	81.69%	81.61%	81.14%	81.14%
PM3242	Allure Quadra [™] RF CRT-P	99.90%	99.82%	99.57%	98.68%	95.18%	88.92%	87.84%	87.37%	87.00%	87.00%
PM3210	Anthem [™] RF CRT-P	99.81%	99.72%	99.11%	97.00%	92.05%	91.71%	91.26%	91.10%	91.07%	90.97%

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM3562	Allure Quadra MP [™] CRT-P	99.98%	99.87%	99.75%	99.62%	99.22%	98.81%				
PM3262	Allure Quadra MP [™] CRT-P	99.94%	99.90%	99.85%	99.65%	98.79%	97.78%	97.52%	97.49%	97.49%	
PM3222	Allure [™] RF CRT-P	99.97%	99.89%	99.77%	99.40%	98.37%	96.40%	96.22%	96.22%	96.22%	96.22%
PM3242	Allure Quadra [™] RF CRT-P	99.92%	99.86%	99.80%	99.76%	99.64%	98.85%	98.55%	98.43%	98.33%	98.33%
PM3210	Anthem [™] RF CRT-P	99.87%	99.83%	99.75%	99.67%	99.58%	99.56%	99.52%	99.52%	99.52%	99.48%

Cardiac Resynchronization Therapy (CRT) Pacemakers

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM3562	Allure Quadra MP [™] CRT-P	45,929	3.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	2	<0.01%
PM3262	Allure Quadra MP [™] CRT-P	19,961	9.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.03%	0	0.00%	0	0.00%	6	0.03%
PM3222	Allure [™] RF CRT-P	15,226	8.80%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	2	0.01%
PM3242	Allure Quadra [™] RF CRT-P	18,522	10.60%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	3	0.02%
PM3210	Anthem [™] RF CRT-P	20,647	19.60%	3	0.01%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	7	0.03%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM3562	Allure Quadra MP [™] CRT-P	45,929	3.40%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	51	0.11%	0	0.00%	1	<0.01%	53	0.12%
PM3262	Allure Quadra MP [™] CRT-P	19,961	9.50%	1	<0.01%	0	0.00%	0	0.00%	4	0.02%	116	0.58%	0	0.00%	1	<0.01%	122	0.61%
PM3222	Allure [™] RF CRT-P	15,226	8.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	85	0.56%	0	0.00%	0	0.00%	85	0.56%
PM3242	Allure Quadra [™] RF CRT-P	18,522	10.60%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	71	0.38%	0	0.00%	0	0.00%	73	0.39%
PM3210	Anthem [™] RF CRT-P	20,647	19.60%	3	0.01%	1	<0.01%	1	<0.01%	7	0.03%	0	0.00%	3	0.01%	9	0.04%	24	0.12%

Definitions of malfunction categories can be found on [pages 5-6](#).

Cardiac Resynchronization Therapy (CRT) Pacemakers

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM3562	Allure Quadra MP [™] CRT-P	108,377	1.52%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	0	0.00%	6	<0.01%
PM3262	Allure Quadra MP [™] CRT-P	36,815	5.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	14	0.04%	2	<0.01%	0	0.00%	16	0.04%
PM3222	Allure [™] RF CRT-P	53,661	2.61%	2	<0.01%	2	<0.01%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	0	0.00%	8	0.01%
PM3242	Allure Quadra [™] RF CRT-P	38,087	5.35%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	10	0.03%	0	0.00%	0	0.00%	12	0.03%
PM3210	Anthem [™] RF CRT-P	21,093	18.76%	6	0.03%	6	0.03%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	14	0.07%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM3562	Allure Quadra MP [™] CRT-P	108,377	1.52%	6	<0.01%	0	0.00%	0	0.00%	2	<0.01%	104	0.10%	0	0.00%	10	<0.01%	122	0.11%
PM3262	Allure Quadra MP [™] CRT-P	36,815	5.22%	0	0.00%	0	0.00%	0	0.00%	8	0.02%	226	0.61%	0	0.00%	2	<0.01%	236	0.64%
PM3222	Allure [™] RF CRT-P	53,661	2.61%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	172	0.32%	0	0.00%	4	<0.01%	178	0.33%
PM3242	Allure Quadra [™] RF CRT-P	38,087	5.35%	8	0.02%	0	0.00%	0	0.00%	0	0.00%	164	0.43%	2	<0.01%	2	<0.01%	176	0.46%
PM3210	Anthem [™] RF CRT-P	21,093	18.76%	6	0.03%	2	<0.01%	2	<0.01%	14	0.07%	0	0.00%	6	0.03%	18	0.09%	48	0.23%

Definitions of malfunction categories can be found on [pages 5-6](#).

Left-Heart Leads

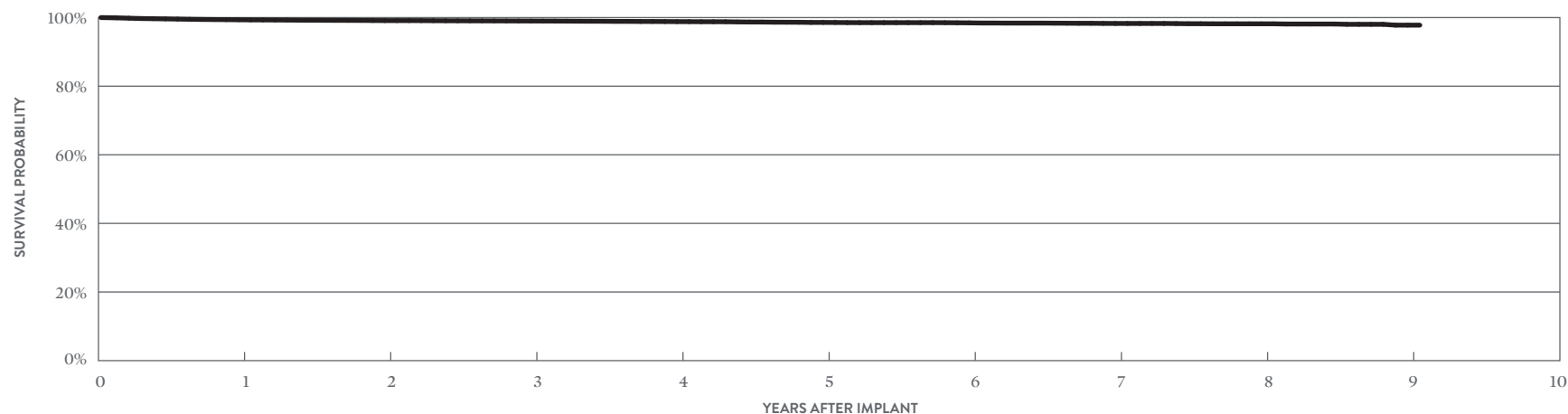
Quartet™

MODEL 1458QL

US Regulatory Approval	October 2015
Registered US Implants	24,440
Estimated Active US Implants	13,812
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	<0.01%	1	<0.01%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	37	0.15%	147	0.60%
Failure to Capture	23	0.09%	84	0.34%
Oversensing	0	0.00%	3	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	2	<0.01%	2	<0.01%
Abnormal Pacing Impedance	5	0.02%	23	0.09%
Extracardiac Stimulation	30	0.12%	45	0.18%
Other	6	0.02%	9	0.04%
Total	104	0.43%	317	1.30%
Total Returned for Analysis	23		86	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	1	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	83	0.34%
Total	84	0.34%



YEAR	1	2	3	4	5	6	7	8	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.36%	99.12%	99.00%	98.82%	98.58%	98.46%	98.28%	98.18%	97.79%	97.79%
± 1 STANDARD ERROR	0.05%	0.06%	0.07%	0.08%	0.10%	0.10%	0.12%	0.13%	0.29%	0.29%
SAMPLE SIZE	21,000	17,580	14,760	12,090	9,530	7,150	4,940	2,970	1,140	200

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Left-Heart Leads

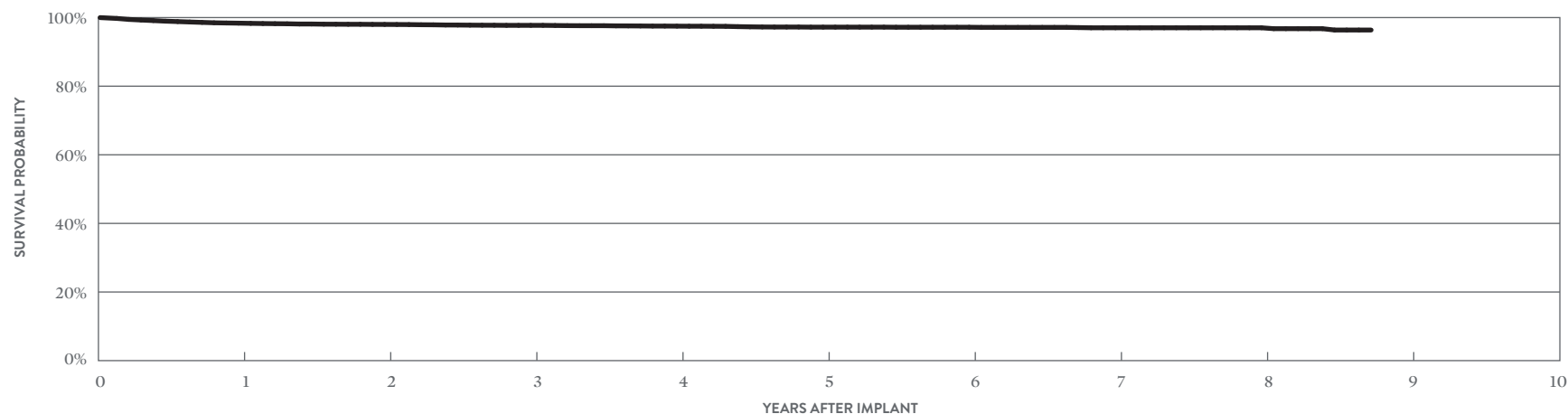
Quartet™

MODEL 1457Q

US Regulatory Approval	March 2017
Registered US Implants	16,260
Estimated Active US Implants	8,961
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	1	<0.01%	0	0.00%
Lead Dislodgement	70	0.43%	224	1.38%
Failure to Capture	14	0.09%	73	0.45%
Oversensing	1	<0.01%	3	0.02%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	0	0.00%	5	0.03%
Extracardiac Stimulation	19	0.12%	19	0.12%
Other	8	0.05%	6	0.04%
Total	113	0.69%	334	2.05%
Total Returned for Analysis	33		126	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	134	0.82%
Total	134	0.82%



YEAR	1	2	3	4	5	6	7	8	AT 105 MONTHS
SURVIVAL PROBABILITY	98.37%	98.00%	97.73%	97.50%	97.21%	97.18%	97.02%	97.02%	96.37%
± 1 STANDARD ERROR	0.11%	0.12%	0.14%	0.15%	0.17%	0.17%	0.19%	0.19%	0.51%
SAMPLE SIZE	13,260	10,460	8,280	6,380	4,660	3,150	1,910	880	210

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Left-Heart Leads

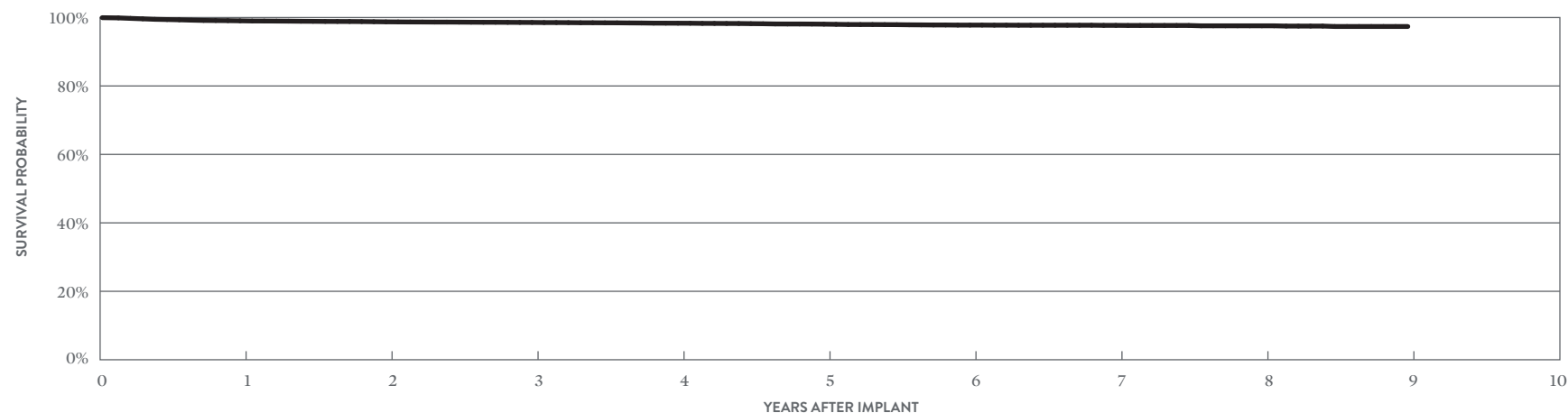
Quartet™

MODEL 1456Q

US Regulatory Approval	October 2015
Registered US Implants	21,834
Estimated Active US Implants	12,130
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	3	0.01%	1	<0.01%
Conductor Fracture	2	<0.01%	4	0.02%
Lead Dislodgement	52	0.24%	191	0.87%
Failure to Capture	18	0.08%	93	0.43%
Oversensing	1	<0.01%	2	<0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	4	0.02%	9	0.04%
Extracardiac Stimulation	19	0.09%	28	0.13%
Other	6	0.03%	4	0.02%
Total	106	0.49%	332	1.52%
Total Returned for Analysis	33		124	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	2	<0.01%
Lead-to-Can Contact	2	<0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	5	0.02%
Extrinsic Factors	125	0.57%
Total	132	0.60%



YEAR	1	2	3	4	5	6	7	8	9
SURVIVAL PROBABILITY	99.04%	98.74%	98.56%	98.34%	98.06%	97.79%	97.71%	97.58%	97.38%
± 1 STANDARD ERROR	0.07%	0.08%	0.09%	0.10%	0.12%	0.14%	0.15%	0.17%	0.22%
SAMPLE SIZE	17,940	14,380	11,670	9,270	7,110	5,260	3,640	2,150	210

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Left-Heart Leads

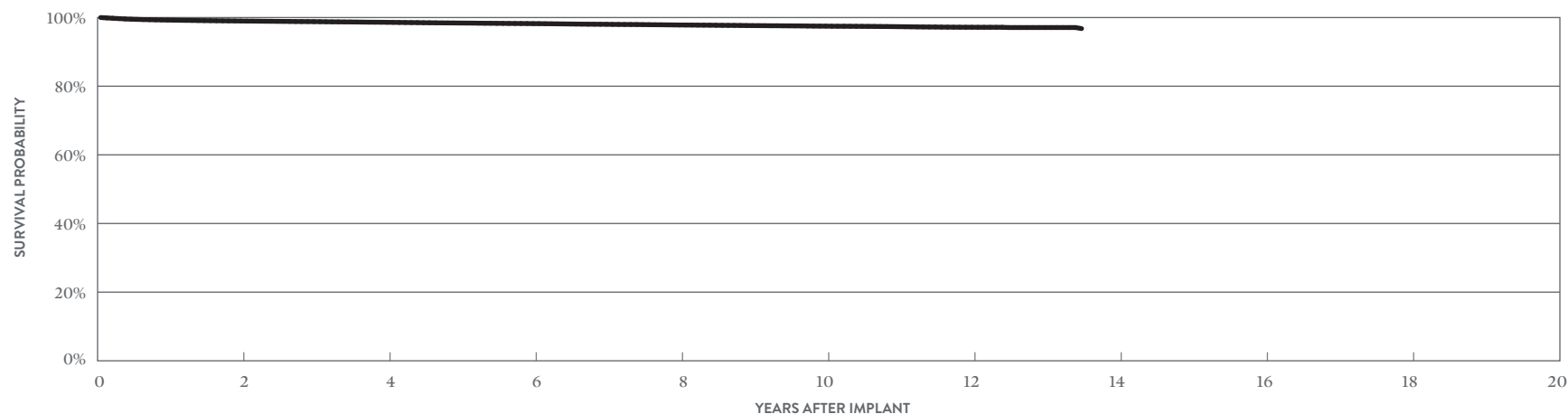
Quartet™

MODEL 1458Q

US Regulatory Approval	November 2011
Registered US Implants	227,420
Estimated Active US Implants	100,530
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	8	<0.01%	6	<0.01%
Conductor Fracture	0	0.00%	59	0.03%
Lead Dislodgement	362	0.16%	1808	0.80%
Failure to Capture	169	0.07%	1086	0.48%
Oversensing	4	<0.01%	46	0.02%
Failure to Sense	0	0.00%	2	<0.01%
Insulation Breach	3	<0.01%	27	0.01%
Abnormal Pacing Impedance	8	<0.01%	224	0.10%
Extracardiac Stimulation	146	0.06%	342	0.15%
Other	126	0.06%	113	0.05%
Total	826	0.36%	3713	1.63%
Total Returned for Analysis	285		1176	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	16	<0.01%
Clavicular Crush	3	<0.01%
In the Pocket	4	<0.01%
Intravascular	9	<0.01%
Insulation Breach	17	<0.01%
Lead-to-Can Contact	6	<0.01%
Lead-to-Lead Contact	9	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	2	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	17	<0.01%
Extrinsic Factors	1121	0.49%
Total	1171	0.51%



YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	98.99%	98.61%	98.23%	97.83%	97.49%	97.17%	96.78%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.07%
SAMPLE SIZE	166,510	126,540	95,920	69,520	41,160	13,630	440

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Left-Heart Leads

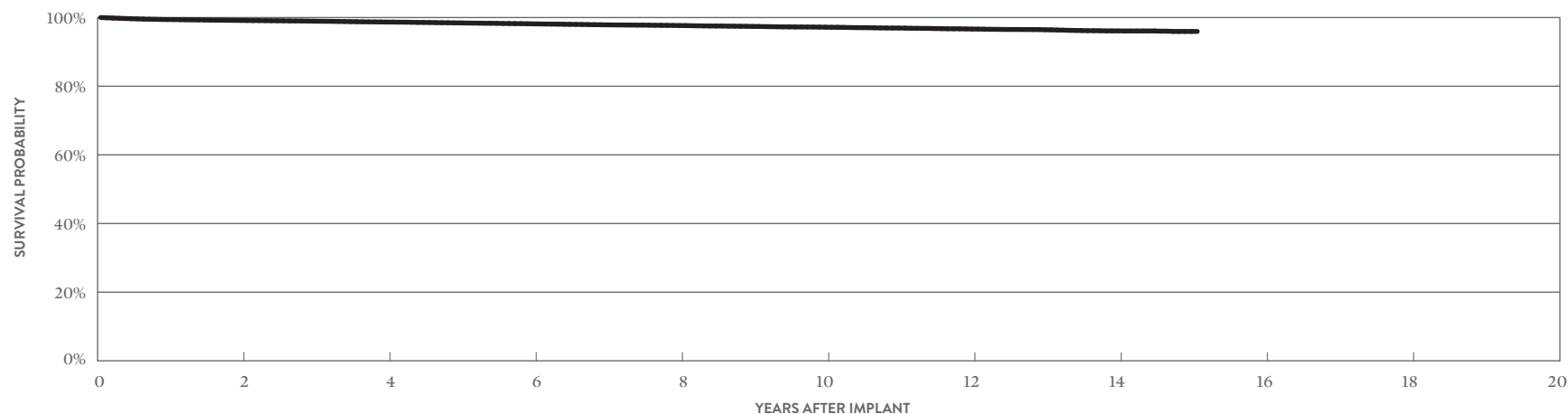
QuickFlex™ μ

MODEL 1258T

US Regulatory Approval	May 2010
Registered US Implants	56,677
Estimated Active US Implants	16,991
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	55	0.10%
Lead Dislodgement	69	0.12%	324	0.57%
Failure to Capture	30	0.05%	494	0.87%
Oversensing	0	0.00%	33	0.06%
Failure to Sense	1	<0.01%	3	<0.01%
Insulation Breach	0	0.00%	23	0.04%
Abnormal Pacing Impedance	5	<0.01%	119	0.21%
Extracardiac Stimulation	40	0.07%	173	0.31%
Other	16	0.03%	27	0.05%
Total	161	0.28%	1252	2.21%
Total Returned for Analysis	71		318	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	13	0.02%
Clavicular Crush	4	<0.01%
In the Pocket	3	<0.01%
Intravascular	6	0.01%
Insulation Breach	8	0.01%
Lead-to-Can Contact	2	<0.01%
Lead-to-Lead Contact	5	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	320	0.56%
Total	342	0.60%



YEAR	2	4	6	8	10	12	14	AT 181 MONTHS
SURVIVAL PROBABILITY	99.16%	98.68%	98.16%	97.67%	97.19%	96.65%	96.11%	95.95%
± 1 STANDARD ERROR	0.04%	0.06%	0.07%	0.08%	0.09%	0.11%	0.14%	0.17%
SAMPLE SIZE	41,590	33,990	28,500	24,300	20,050	14,110	6,320	280

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Left-Heart Leads

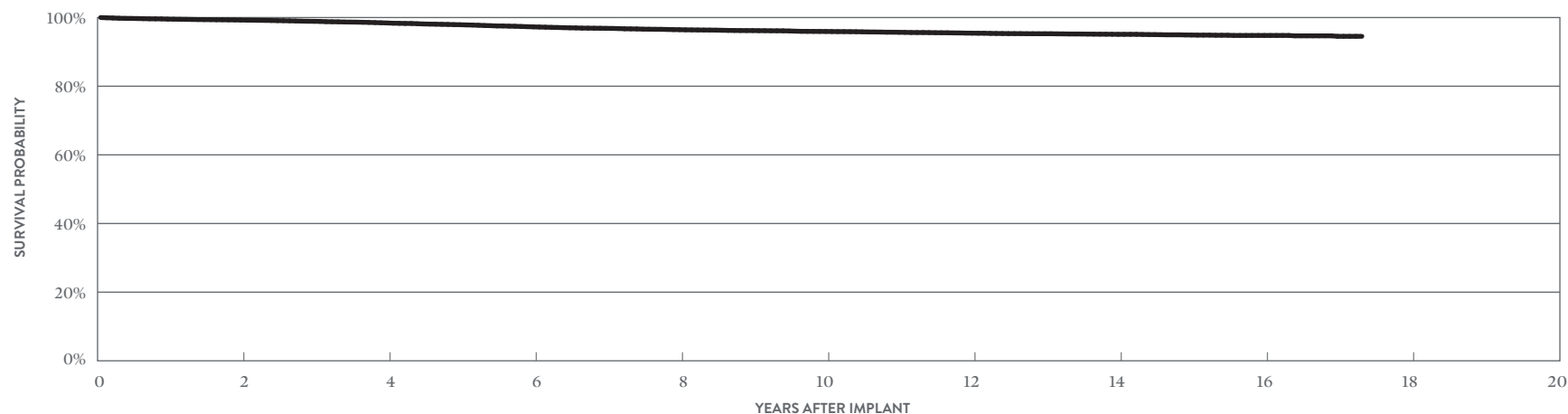
QuickFlex™

MODEL 1156T

US Regulatory Approval	July 2007
Registered US Implants	29,741
Estimated Active US Implants	7,003
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	11	0.04%
Lead Dislodgement	21	0.07%	175	0.59%
Failure to Capture	7	0.02%	304	1.02%
Oversensing	0	0.00%	20	0.07%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	55	0.18%
Abnormal Pacing Impedance	1	<0.01%	79	0.27%
Extracardiac Stimulation	20	0.07%	121	0.41%
Other	9	0.03%	16	0.05%
Total	58	0.20%	782	2.63%
Total Returned for Analysis	20		208	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	7	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	7	0.02%
Insulation Breach	104	0.35%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	5	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	15	0.05%
Other	84	0.28%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	159	0.53%
Total	270	0.91%



YEAR	2	4	6	8	10	12	14	16	AT 208 MONTHS
SURVIVAL PROBABILITY	99.27%	98.42%	97.28%	96.46%	95.94%	95.45%	95.11%	94.78%	94.53%
± 1 STANDARD ERROR	0.05%	0.08%	0.12%	0.14%	0.16%	0.17%	0.18%	0.20%	0.26%
SAMPLE SIZE	22,060	17,250	13,970	11,780	10,310	9,160	7,750	3,960	230

Left-Heart Leads

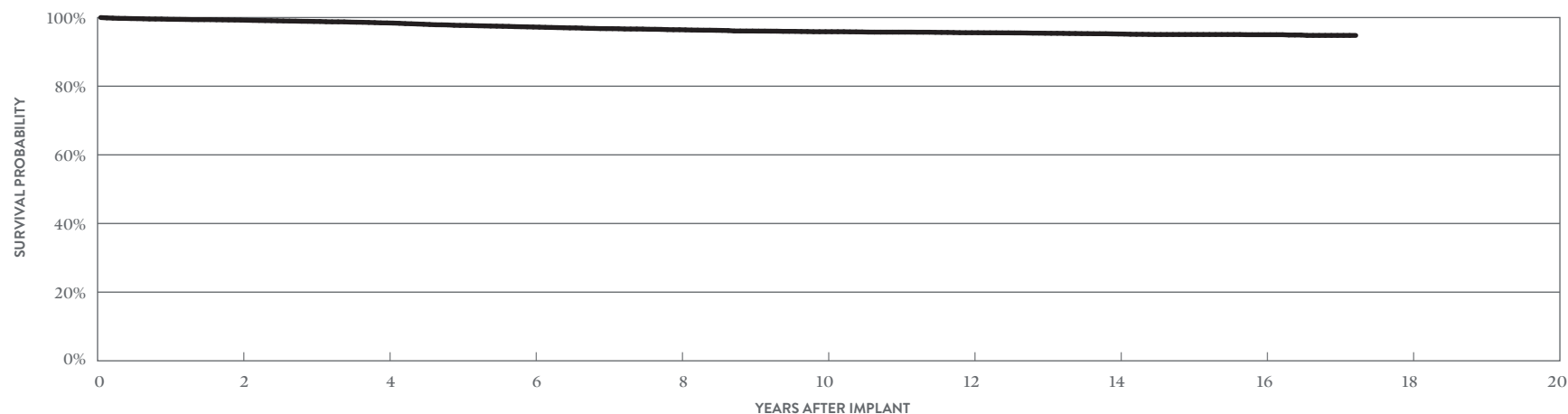
QuickFlex™ XL

MODEL 1158T

US Regulatory Approval	July 2007
Registered US Implants	16,624
Estimated Active US Implants	3,845
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	2	0.01%
Conductor Fracture	0	0.00%	6	0.04%
Lead Dislodgement	16	0.10%	111	0.67%
Failure to Capture	3	0.02%	178	1.07%
Oversensing	1	<0.01%	8	0.05%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	0	0.00%	37	0.22%
Abnormal Pacing Impedance	2	0.01%	31	0.19%
Extracardiac Stimulation	8	0.05%	46	0.28%
Other	6	0.04%	11	0.07%
Total	36	0.22%	431	2.59%
Total Returned for Analysis	16		141	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	5	0.03%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	4	0.02%
Insulation Breach	63	0.38%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	3	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	10	0.06%
Other	50	0.30%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	100	0.60%
Total	169	1.02%



YEAR	2	4	6	8	10	12	14	16	AT 207 MONTHS
SURVIVAL PROBABILITY	99.26%	98.43%	97.24%	96.45%	95.87%	95.58%	95.21%	95.00%	94.79%
± 1 STANDARD ERROR	0.07%	0.11%	0.16%	0.19%	0.21%	0.23%	0.24%	0.26%	0.29%
SAMPLE SIZE	12,300	9,690	7,830	6,670	5,840	5,120	4,220	2,100	240

Left-Heart Leads

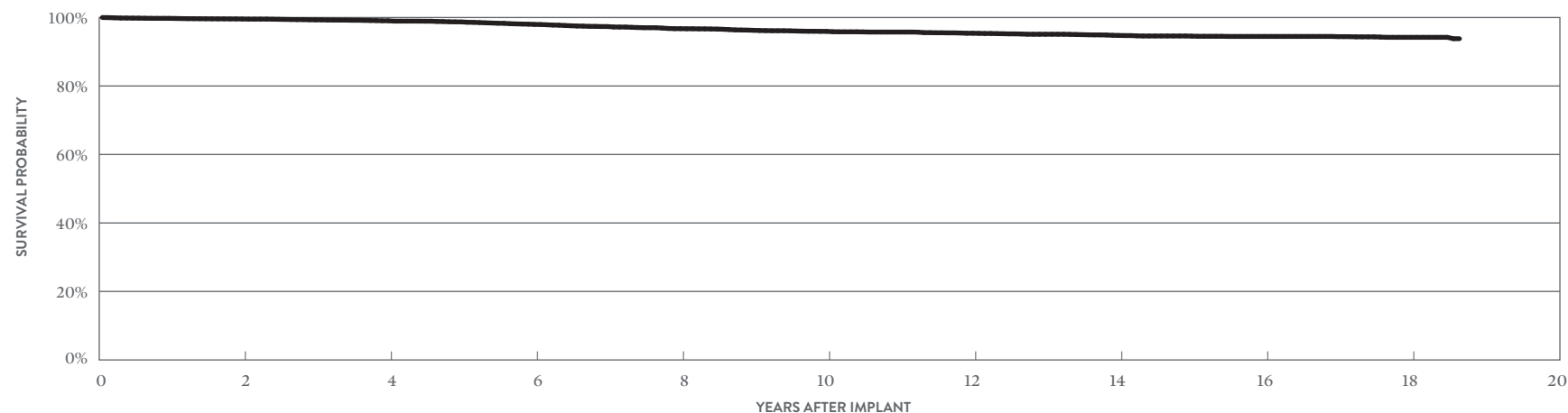
QuickSite™ XL

MODEL 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,507
Estimated Active US Implants	1,962
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	9	0.09%
Lead Dislodgement	10	0.10%	37	0.35%
Failure to Capture	3	0.03%	106	1.01%
Oversensing	1	<0.01%	5	0.05%
Failure to Sense	0	0.00%	2	0.02%
Insulation Breach	0	0.00%	32	0.30%
Abnormal Pacing Impedance	2	0.02%	22	0.21%
Extracardiac Stimulation	9	0.09%	26	0.25%
Other	1	<0.01%	6	0.06%
Total	26	0.25%	246	2.34%
Total Returned for Analysis	11		43	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.02%
Insulation Breach	26	0.25%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	6	0.06%
Other	19	0.18%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	32	0.30%
Total	61	0.58%



YEAR	2	4	6	8	10	12	14	16	18	AT 224 MONTHS
SURVIVAL PROBABILITY	99.56%	99.05%	97.98%	96.74%	95.95%	95.40%	94.76%	94.47%	94.21%	93.81%
± 1 STANDARD ERROR	0.07%	0.12%	0.19%	0.26%	0.30%	0.33%	0.36%	0.38%	0.40%	0.56%
SAMPLE SIZE	7,670	5,720	4,420	3,580	3,050	2,730	2,460	2,120	1,240	210

Left-Heart Leads

Survival Probability Summary

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
1458QL	Quartet™	99.36%	99.12%	99.00%	98.82%	98.58%	98.46%	98.28%	98.18%	97.79%	
1457Q	QuickFlex™ μ	98.37%	98.00%	97.73%	97.50%	97.21%	97.18%	97.02%	97.02%		
1456Q	QuickFlex™ μ	99.04%	98.74%	98.56%	98.34%	98.06%	97.79%	97.71%	97.58%	97.38%	
1458Q	Quartet™	99.26%	98.99%	98.81%	98.61%	98.40%	98.23%	98.03%	97.83%	97.65%	97.49%
1258T	QuickFlex™ μ	99.42%	99.16%	98.94%	98.68%	98.44%	98.16%	97.88%	97.67%	97.41%	97.19%
1156T	QuickFlex™	99.54%	99.27%	98.90%	98.42%	97.91%	97.28%	96.85%	96.46%	96.20%	95.94%
1158T	QuickFlex™ XL	99.50%	99.26%	98.86%	98.43%	97.71%	97.24%	96.77%	96.45%	96.07%	95.87%
1058T	QuickSite™ XL	99.75%	99.56%	99.31%	99.05%	98.71%	97.98%	97.36%	96.74%	96.26%	95.95%

Left-Heart Leads

Acute Observation Summary

POST IMPLANT ≤30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLODGEMENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
1458QL	Oct-15	24,440	13,812	1	<0.01%	0	0.00%	37	0.15%	23	0.09%	0	0.00%	0	0.00%	2	<0.01%	5	0.02%	30	0.12%	6	0.02%	104	0.43%	23
1457Q	Oct-15	16,260	8,961	0	0.00%	1	<0.01%	70	0.43%	14	0.09%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	19	0.12%	8	0.05%	113	0.69%	33
1456Q	Oct-15	21,834	12,130	3	0.01%	2	<0.01%	52	0.24%	18	0.08%	1	<0.01%	0	0.00%	1	<0.01%	4	0.02%	19	0.09%	6	0.03%	106	0.49%	33
1458Q	Nov-11	227,420	100,530	8	<0.01%	0	0.00%	362	0.16%	169	0.07%	4	<0.01%	0	0.00%	3	<0.01%	8	<0.01%	146	0.06%	126	0.06%	826	0.36%	285
1258T	May-10	56,677	16,991	0	0.00%	0	0.00%	69	0.12%	30	0.05%	0	0.00%	1	<0.01%	0	0.00%	5	<0.01%	40	0.07%	16	0.03%	161	0.28%	71
1156T	Jul-07	29,741	7,003	0	0.00%	0	0.00%	21	0.07%	7	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	20	0.07%	9	0.03%	58	0.20%	20
1158T	Jul-07	16,624	3,845	0	0.00%	0	0.00%	16	0.10%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	2	0.01%	8	0.05%	6	0.04%	36	0.22%	16
1058T	Feb-06	10,507	1,962	0	0.00%	0	0.00%	10	0.10%	3	0.03%	1	<0.01%	0	0.00%	0	0.00%	2	0.02%	9	0.09%	1	<0.01%	26	0.25%	11

Chronic Complication Summary

>30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLODGEMENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
1458QL	Oct-15	24,440	13,812	1	<0.01%	3	0.01%	147	0.60%	84	0.34%	3	0.01%	0	0.00%	2	<0.01%	23	0.09%	45	0.18%	9	0.04%	317	1.30%	86
1457Q	Oct-15	16,260	8,961	1	<0.01%	0	0.00%	224	1.38%	73	0.45%	3	0.02%	0	0.00%	3	0.02%	5	0.03%	19	0.12%	6	0.04%	334	2.05%	126
1456Q	Oct-15	21,834	12,130	1	<0.01%	4	0.02%	191	0.87%	93	0.43%	2	<0.01%	0	0.00%	0	0.00%	9	0.04%	28	0.13%	4	0.02%	332	1.52%	124
1458Q	Nov-11	227,420	100,530	6	<0.01%	59	0.03%	1808	0.80%	1086	0.48%	46	0.02%	2	<0.01%	27	0.01%	224	0.10%	342	0.15%	113	0.05%	3713	1.63%	1176
1258T	May-10	56,677	16,991	1	<0.01%	55	0.10%	324	0.57%	494	0.87%	33	0.06%	3	<0.01%	23	0.04%	119	0.21%	173	0.31%	27	0.05%	1252	2.21%	318
1156T	Jul-07	29,741	7,003	1	<0.01%	11	0.04%	175	0.59%	304	1.02%	20	0.07%	0	0.00%	55	0.18%	79	0.27%	121	0.41%	16	0.05%	782	2.63%	208
1158T	Jul-07	16,624	3,845	2	0.01%	6	0.04%	111	0.67%	178	1.07%	8	0.05%	1	<0.01%	37	0.22%	31	0.19%	46	0.28%	11	0.07%	431	2.59%	141
1058T	Feb-06	10,507	1,962	1	<0.01%	9	0.09%	37	0.35%	106	1.01%	5	0.05%	2	0.02%	32	0.30%	22	0.21%	26	0.25%	6	0.06%	246	2.34%	43

Definitions of observations and complications can be found on [page 7](#).

Left-Heart Leads

US Malfunction Summary

MODELS	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
1458QL	24,440	5.50%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	83	0.34%	84	0.34%
1457Q	16,260	6.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	134	0.82%	134	0.82%
1456Q	21,834	8.70%	0	0.00%	2	<0.01%	0	0.00%	5	0.02%	125	0.57%	132	0.60%
1458Q	227,420	7.50%	16	<0.01%	17	<0.01%	0	0.00%	17	<0.01%	1121	0.49%	1171	0.51%
1258T	56,677	12.50%	13	0.02%	8	0.01%	0	0.00%	1	<0.01%	320	0.56%	342	0.60%
1156T	29,741	10.00%	7	0.02%	104	0.35%	0	0.00%	0	0.00%	159	0.53%	270	0.91%
1158T	16,624	10.90%	5	0.03%	63	0.38%	1	<0.01%	0	0.00%	100	0.60%	169	1.02%
1058T	10,507	10.40%	2	0.02%	26	0.25%	0	0.00%	1	<0.01%	32	0.30%	61	0.58%
1056T	34,826	9.70%	6	0.02%	98	0.28%	0	0.00%	1	<0.01%	169	0.49%	274	0.79%

Definitions of malfunction categories can be found on [pages 8-9](#).

Left-Heart Leads

Worldwide Malfunction Summary

MODELS	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
1458QL	53,520	2.51%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	102	0.19%	104	0.19%
1457Q	40,644	2.71%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	151	0.37%	151	0.37%
1456Q	62,365	3.04%	0	0.00%	3	<0.01%	0	0.00%	10	0.02%	160	0.26%	173	0.28%
1458Q	495,282	3.64%	44	0.01%	27	0.01%	0	0.00%	35	0.01%	1560	0.31%	1666	0.34%
1258T	208,892	3.90%	54	0.03%	15	0.01%	0	0.00%	5	<0.01%	485	0.23%	559	0.27%

Definitions of malfunction categories can be found on [pages 8-9](#).

DUAL-CHAMBER
Implantable Cardioverter
Defibrillator (ICD) Devices

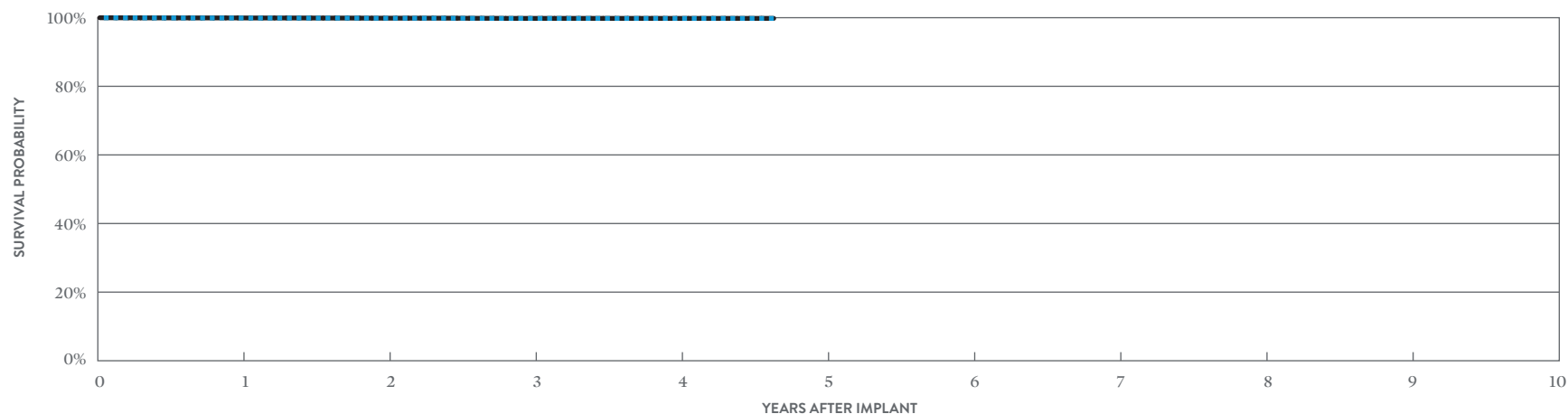
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Gallant™ DR

MODEL CDDRA500Q*

US Regulatory Approval	June 2020
Registered US Implants	43,588
Estimated Active US Implants	33,574
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories (see page 189)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	15	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	3	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	5	0.01%
Total	0	0.00%	24	0.06%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.91%	99.84%	99.78%	99.78%	99.78%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.03%
SAMPLE SIZE	37,210	25,290	15,010	6,470	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.93%	99.86%	99.80%	99.80%	99.80%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.03%	0.03%

*DF4-LLHH connector type.

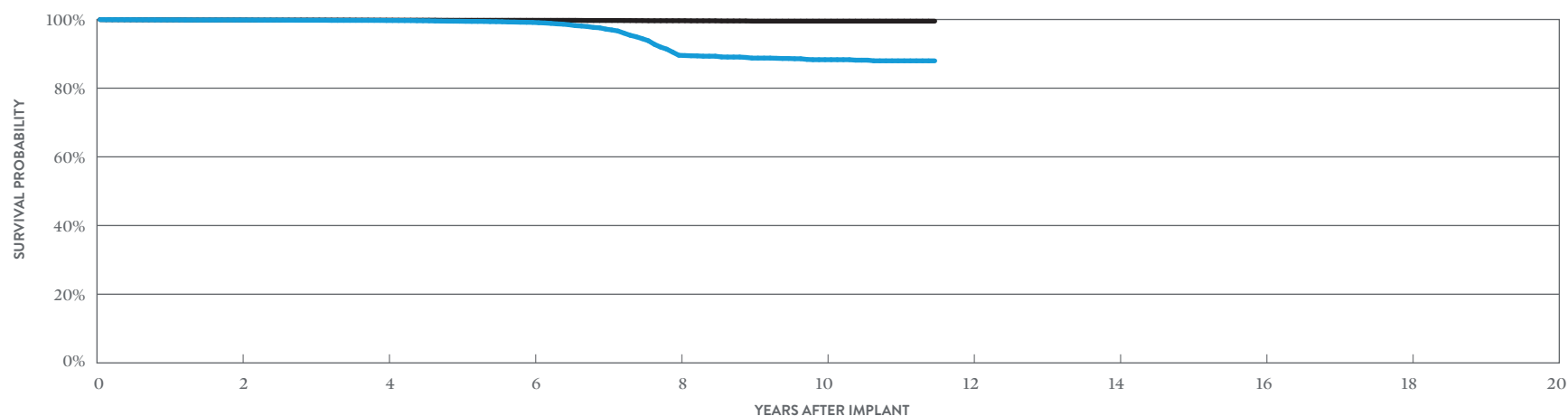
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	34,533
Estimated Active US Implants	14,920
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	410
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 190, 191)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	<0.01%	14	0.04%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	1	<0.01%
High Voltage Capacitor	2	<0.01%	2	<0.01%
Software/Firmware	1	<0.01%	1	<0.01%
Mechanical	1	<0.01%	4	0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	2	<0.01%	7	0.02%
Total	10	0.03%	30	0.09%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.85%	99.70%	99.15%	89.57%	88.29%	87.96%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.30%	0.36%	0.40%
SAMPLE SIZE	28,830	22,600	15,330	8,220	2,760	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.87%	99.81%	99.76%	99.64%	99.52%	99.52%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.05%	0.07%	0.07%

*DF4-LLHH connector type.

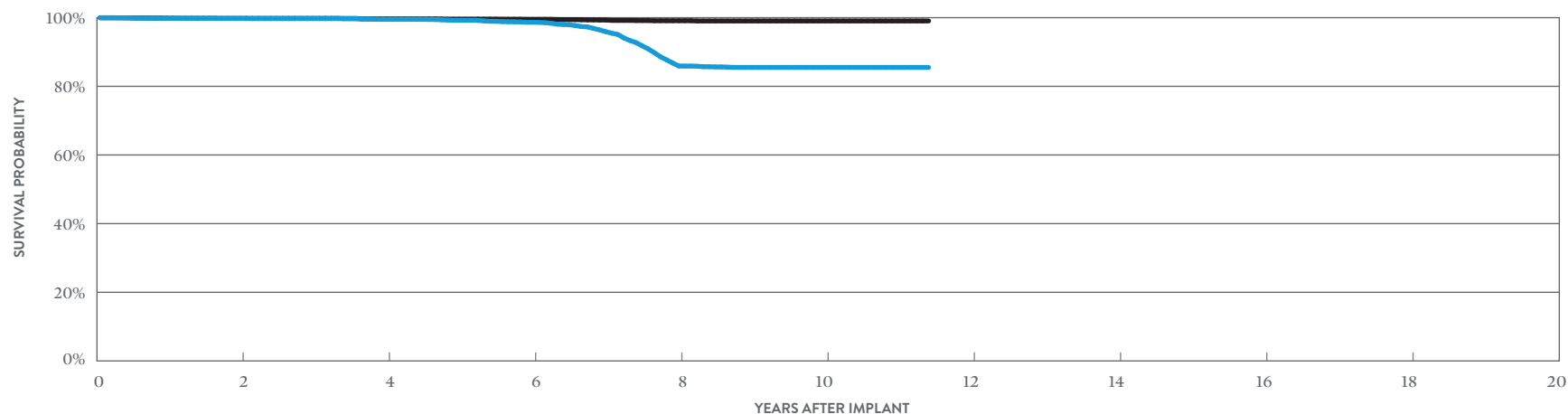
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2411-36C*

US Regulatory Approval	June 2013
Registered US Implants	12,718
Estimated Active US Implants	4,983
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	252
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 190, 191)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.02%	10	0.08%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	7	0.06%	2	0.02%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	5	0.04%
Total	11	0.09%	19	0.15%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.76%	99.51%	98.66%	85.90%	85.51%	85.51%
± 1 STANDARD ERROR	0.05%	0.07%	0.14%	0.49%	0.52%	0.52%
SAMPLE SIZE	10,300	7,870	5,980	4,070	1,520	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.79%	99.64%	99.51%	99.11%	99.04%	99.04%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.12%	0.13%	0.13%

*Parylene coating.

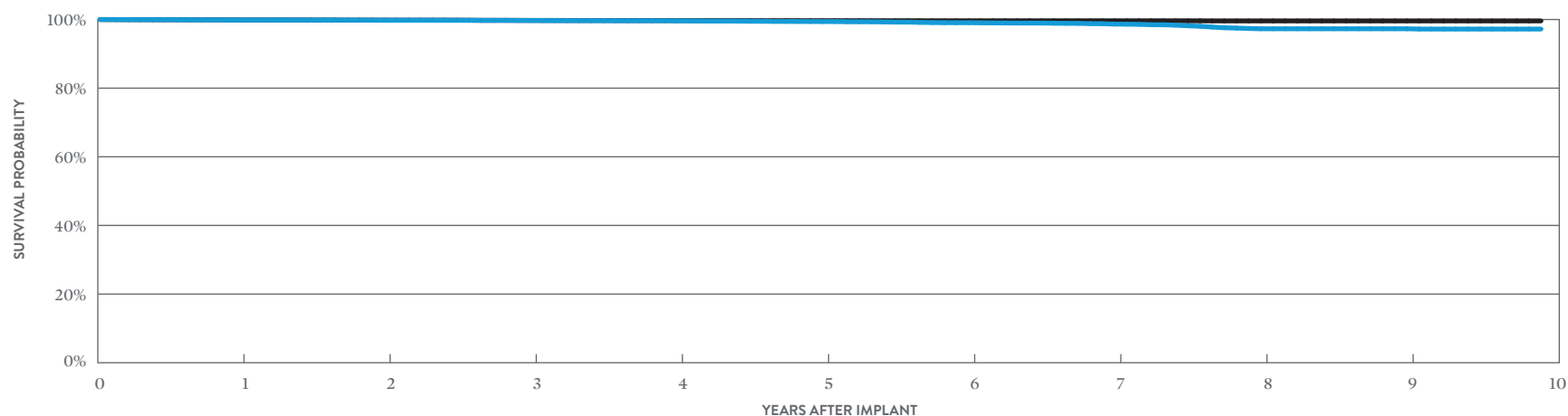
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40Q* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	44,156
Estimated Active US Implants	22,967
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	113
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	<0.01%	20	0.05%
Electrical Interconnect	0	0.00%	1	<0.01%
Battery	2	<0.01%	4	<0.01%
High Voltage Capacitor	3	<0.01%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	5	0.01%
Other	7	0.02%	8	0.02%
Total	15	0.03%	41	0.09%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.86%	99.79%	99.71%	99.62%	99.40%	99.07%	98.66%	97.30%	97.30%	97.22%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.04%	0.06%	0.08%	0.15%	0.15%	0.17%
SAMPLE SIZE	41,650	37,020	32,880	28,730	23,650	17,850	12,690	8,360	4,370	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.88%	99.82%	99.74%	99.69%	99.65%	99.62%	99.62%	99.59%	99.59%	99.59%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%

*DF4-LLHH connector type.

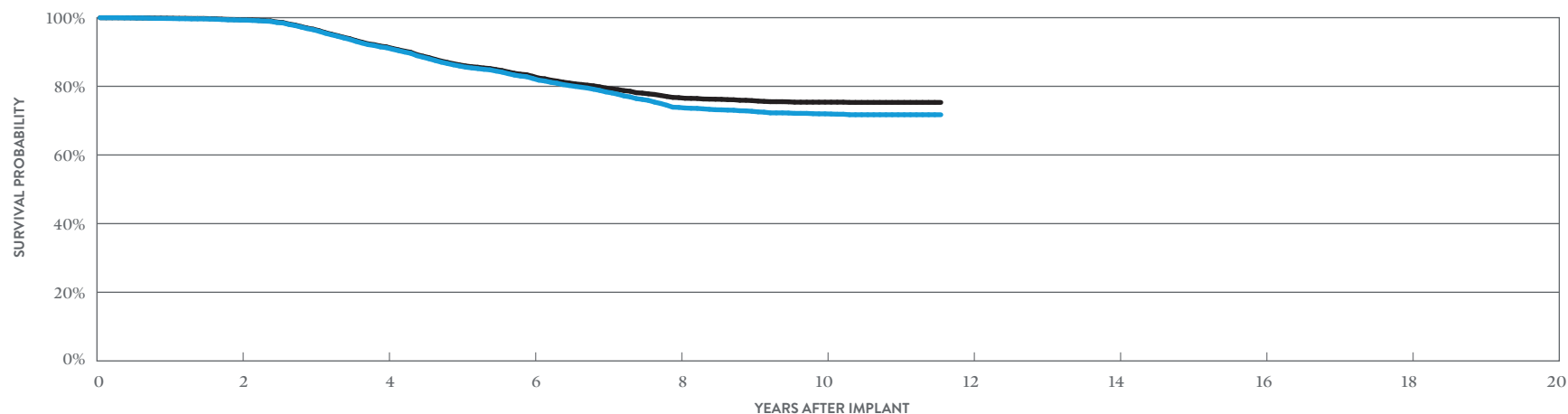
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	12,263
Estimated Active US Implants	3,129
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	105
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.02%	10	0.08%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	20	0.16%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	72	0.59%	687	5.60%
Other	1	<0.01%	6	0.05%
Total	77	0.63%	724	5.90%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.30%	91.25%	82.31%	73.85%	71.98%	71.72%
± 1 STANDARD ERROR	0.08%	0.29%	0.41%	0.49%	0.51%	0.52%
SAMPLE SIZE	10,210	8,230	6,690	5,410	3,720	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.40%	91.49%	82.92%	76.70%	75.38%	75.31%
± 1 STANDARD ERROR	0.07%	0.29%	0.40%	0.47%	0.49%	0.49%

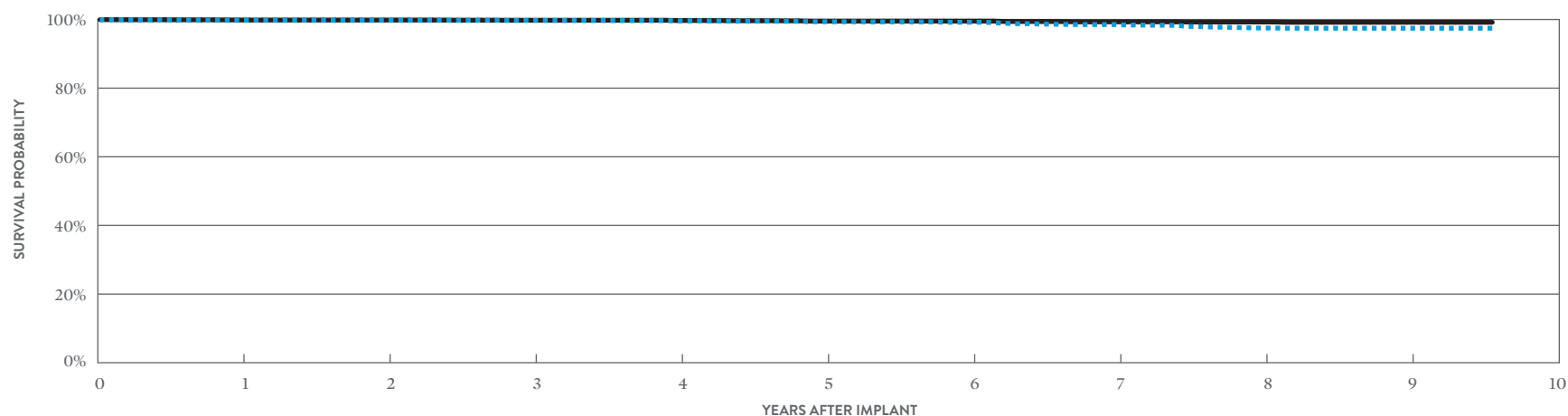
*DF4-LLHH connector type.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40C* (NON-BATTERY ADVISORY POPULATION)

		MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY		
		QTY	RATE	QTY	RATE	
US Regulatory Approval	June 2013	Electrical Component	2	0.02%	8	0.06%
Registered US Implants	13,034	Electrical Interconnect	0	0.00%	1	<0.01%
Estimated Active US Implants	6,653	Battery	0	0.00%	4	0.03%
Estimated Longevity	(see table on page 84)	High Voltage Capacitor	1	<0.01%	0	0.00%
Normal Battery Depletion	32	Software/Firmware	0	0.00%	2	0.02%
Max. Delivered Energy	40 joules	Mechanical	0	0.00%	3	0.02%
Number of US Advisories (see pg. 191)	One	Possible Early Battery Depletion	0	0.00%	1	<0.01%
		Other	0	0.00%	3	0.02%
		Total	3	0.02%	22	0.17%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 115 MONTHS
SURVIVAL PROBABILITY	99.85%	99.83%	99.74%	99.61%	99.34%	99.20%	98.52%	97.52%	97.45%	97.45%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.06%	0.09%	0.11%	0.16%	0.23%	0.24%	0.24%
SAMPLE SIZE	12,160	10,480	8,990	7,620	6,340	5,260	4,350	3,320	1,780	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 115 MONTHS
SURVIVAL PROBABILITY	99.86%	99.84%	99.78%	99.71%	99.53%	99.53%	99.32%	99.27%	99.19%	99.19%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.05%	0.08%	0.08%	0.10%	0.11%	0.12%	0.12%

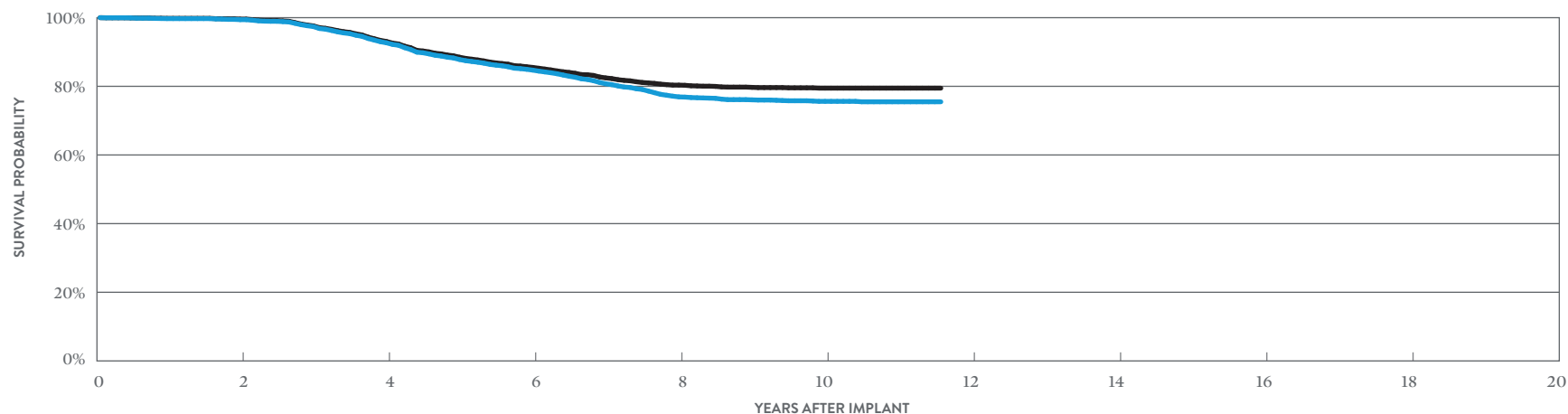
*Parylene coating.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40C* (BATTERY ADVISORY POPULATION)

		MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY		
		QTY	RATE	QTY	RATE	
US Regulatory Approval	June 2013	Electrical Component	3	0.04%	2	0.03%
Registered US Implants	6,956	Electrical Interconnect	2	0.03%	1	0.01%
Estimated Active US Implants	1,882	Battery	1	0.01%	8	0.12%
Estimated Longevity	(see table on page 84)	High Voltage Capacitor	0	0.00%	0	0.00%
Normal Battery Depletion	68	Software/Firmware	0	0.00%	0	0.00%
Max. Delivered Energy	40 joules	Mechanical	0	0.00%	0	0.00%
Number of US Advisories (see pgs. 191, 192)	Two	Possible Early Battery Depletion	33	0.47%	310	4.46%
		Other	2	0.03%	2	0.03%
		Total	41	0.59%	323	4.64%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.41%	92.68%	84.72%	76.92%	75.62%	75.49%
± 1 STANDARD ERROR	0.09%	0.36%	0.52%	0.64%	0.66%	0.67%
SAMPLE SIZE	5,730	4,580	3,720	3,030	2,040	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.58%	93.07%	85.51%	80.35%	79.47%	79.47%
± 1 STANDARD ERROR	0.07%	0.35%	0.51%	0.60%	0.62%	0.62%

*Parylene coating.

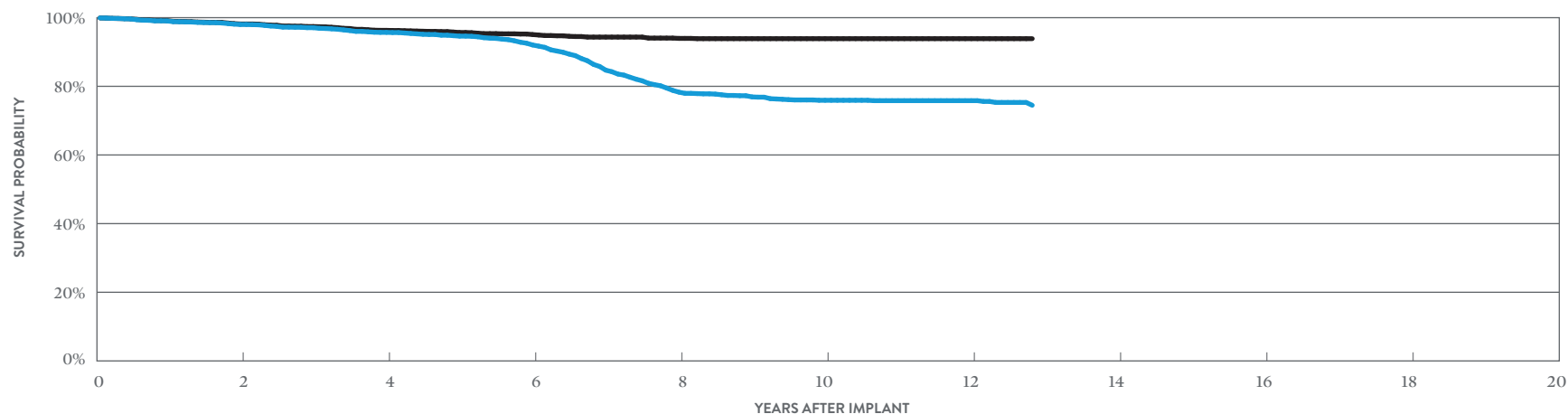
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	5,900
Estimated Active US Implants	1,224
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	237
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.05%	11	0.19%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.02%
High Voltage Capacitor	65	1.10%	14	0.24%
Software/Firmware	1	0.02%	0	0.00%
Mechanical	2	0.03%	3	0.05%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	5	0.08%	3	0.05%
Total	76	1.29%	32	0.54%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 154 MONTHS
SURVIVAL PROBABILITY	98.01%	95.71%	92.04%	78.30%	75.93%	75.82%	74.48%
± 1 STANDARD ERROR	0.19%	0.30%	0.41%	0.69%	0.75%	0.75%	0.79%
SAMPLE SIZE	4,900	4,040	3,370	2,530	1,650	1,040	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 154 MONTHS
SURVIVAL PROBABILITY	98.16%	96.31%	95.08%	93.96%	93.88%	93.88%	93.88%
± 1 STANDARD ERROR	0.18%	0.28%	0.32%	0.37%	0.38%	0.38%	0.38%

*DF4-LLHH connector type.

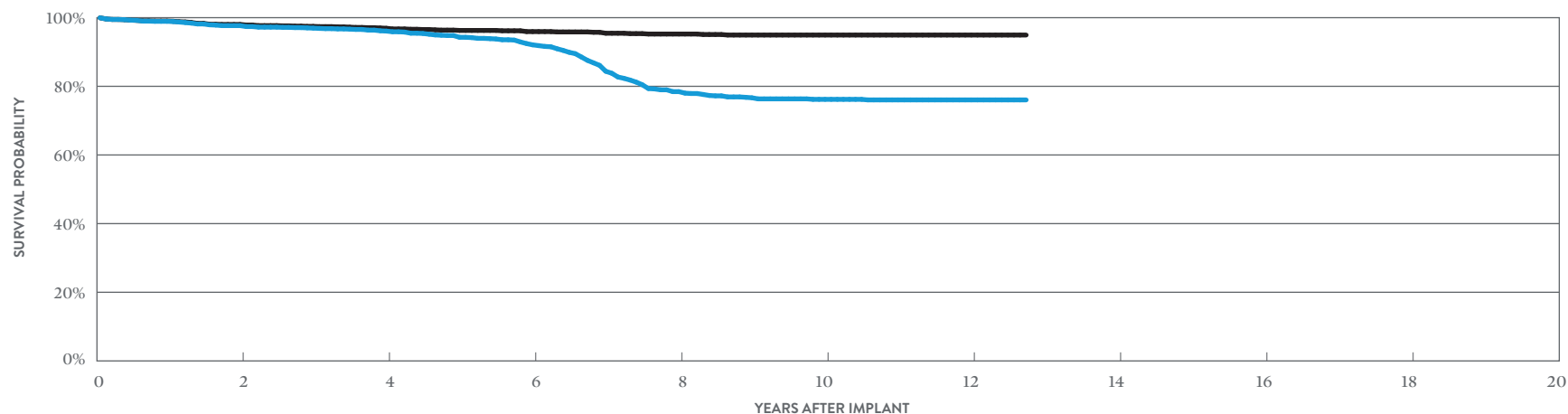
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	3,748
Estimated Active US Implants	863
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	158
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.13%	9	0.24%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	22	0.59%	8	0.21%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	4	0.11%	3	0.08%
Possible Early Battery Depletion	0	0.00%	2	0.05%
Other	5	0.13%	2	0.05%
Total	36	0.96%	24	0.64%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	97.68%	96.09%	92.08%	78.45%	76.20%	76.04%	76.04%
± 1 STANDARD ERROR	0.26%	0.35%	0.52%	0.88%	0.93%	0.93%	0.93%
SAMPLE SIZE	3,100	2,500	2,080	1,590	1,130	720	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	98.02%	96.91%	95.94%	95.23%	94.94%	94.94%	94.94%
± 1 STANDARD ERROR	0.24%	0.31%	0.37%	0.42%	0.44%	0.44%	0.44%

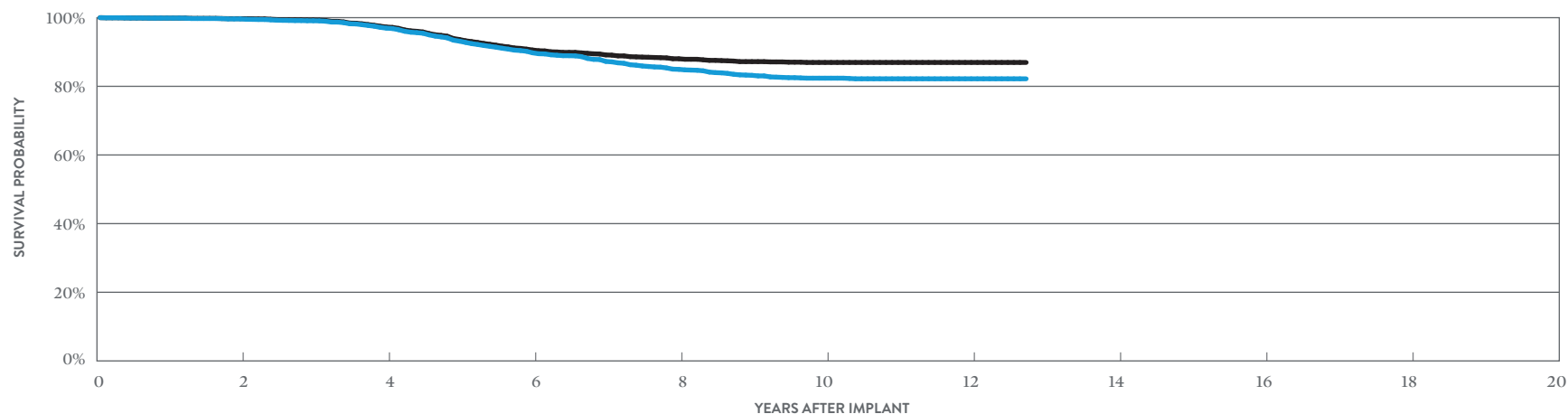
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,797
Estimated Active US Implants	1,491
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	70
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.07%	3	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.01%	2	0.03%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	27	0.40%	174	2.56%
Other	3	0.04%	1	0.01%
Total	36	0.53%	182	2.68%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	99.63%	96.94%	89.75%	84.94%	82.37%	82.19%	82.19%
± 1 STANDARD ERROR	0.08%	0.24%	0.45%	0.56%	0.62%	0.62%	0.62%
SAMPLE SIZE	5,650	4,560	3,690	3,040	2,200	1,200	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 153 MONTHS
SURVIVAL PROBABILITY	99.72%	97.27%	90.58%	88.03%	86.95%	86.95%	86.95%
± 1 STANDARD ERROR	0.07%	0.23%	0.44%	0.51%	0.54%	0.54%	0.54%

*DF4-LLHH connector type.

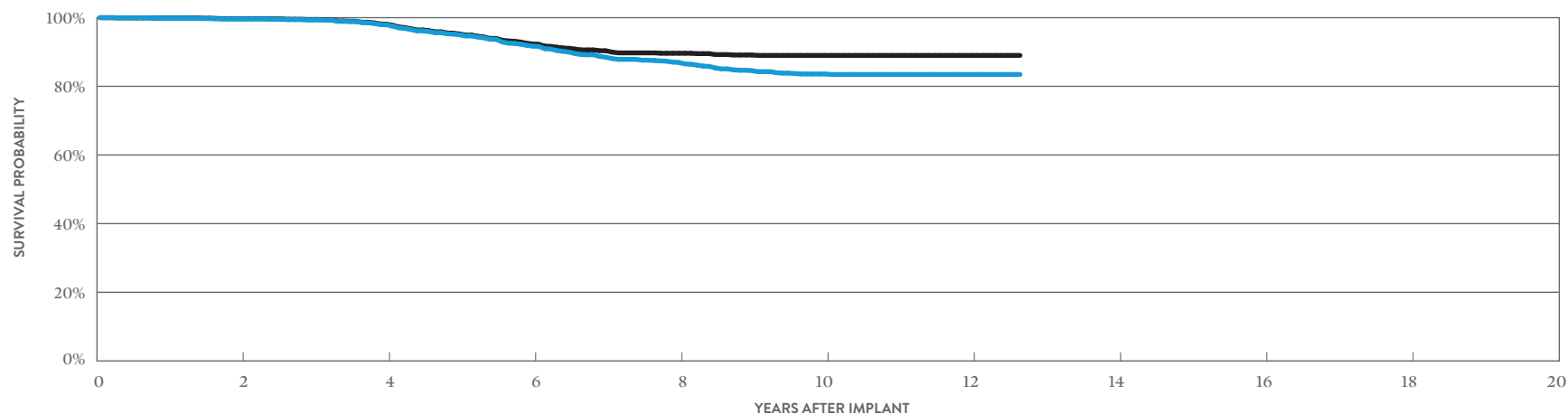
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	4,235
Estimated Active US Implants	989
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	46
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.05%	1	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.02%	4	0.09%
High Voltage Capacitor	1	0.02%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	13	0.31%	81	1.91%
Other	0	0.00%	4	0.09%
Total	17	0.40%	91	2.15%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 152 MONTHS
SURVIVAL PROBABILITY	99.61%	97.92%	91.71%	86.95%	83.59%	83.45%	83.45%
± 1 STANDARD ERROR	0.10%	0.26%	0.54%	0.69%	0.79%	0.80%	0.80%
SAMPLE SIZE	3,480	2,720	2,190	1,770	1,340	820	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 152 MONTHS
SURVIVAL PROBABILITY	99.72%	98.10%	92.33%	89.63%	89.00%	89.00%	89.00%
± 1 STANDARD ERROR	0.09%	0.25%	0.52%	0.62%	0.65%	0.65%	0.65%

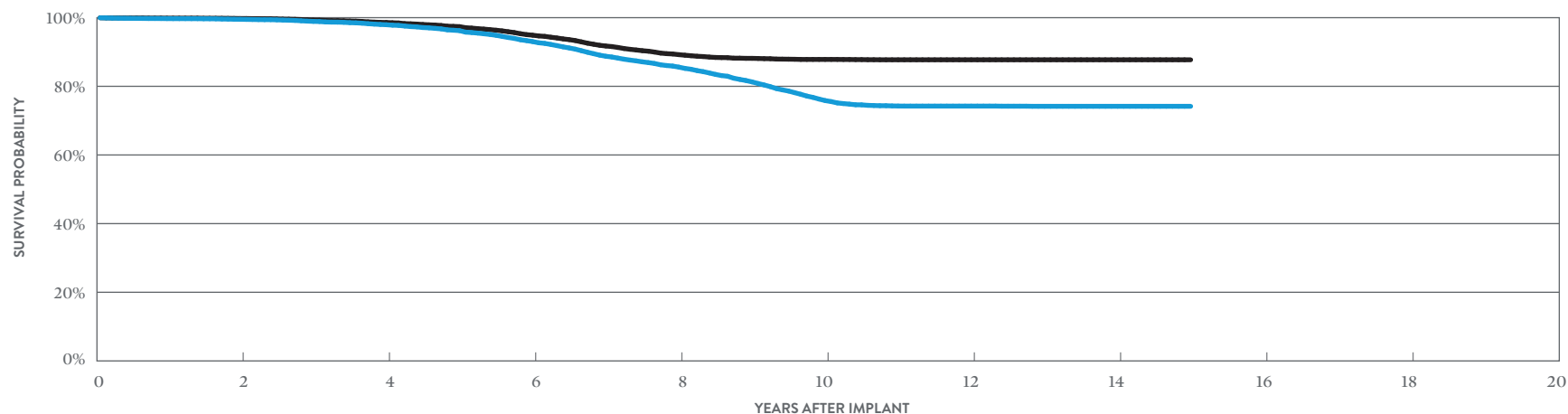
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ DR

MODEL CD2231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	27,257
Estimated Active US Implants	4,677
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	691
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	10	0.04%	11	0.04%
Electrical Interconnect	3	0.01%	2	<0.01%
Battery	29	0.11%	55	0.20%
High Voltage Capacitor	5	0.02%	2	<0.01%
Software/Firmware	1	<0.01%	2	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	166	0.61%	408	1.50%
Other	17	0.06%	13	0.05%
Total	231	0.85%	493	1.81%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.52%	97.94%	93.03%	85.59%	75.85%	74.24%	74.18%	74.18%
± 1 STANDARD ERROR	0.04%	0.10%	0.19%	0.28%	0.37%	0.39%	0.39%	0.39%
SAMPLE SIZE	22,500	18,270	14,710	11,820	8,610	5,760	3,280	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.75%	98.60%	94.89%	89.22%	87.83%	87.73%	87.73%	87.73%
± 1 STANDARD ERROR	0.03%	0.08%	0.17%	0.25%	0.27%	0.28%	0.28%	0.28%

*DF4-LLHH connector type.

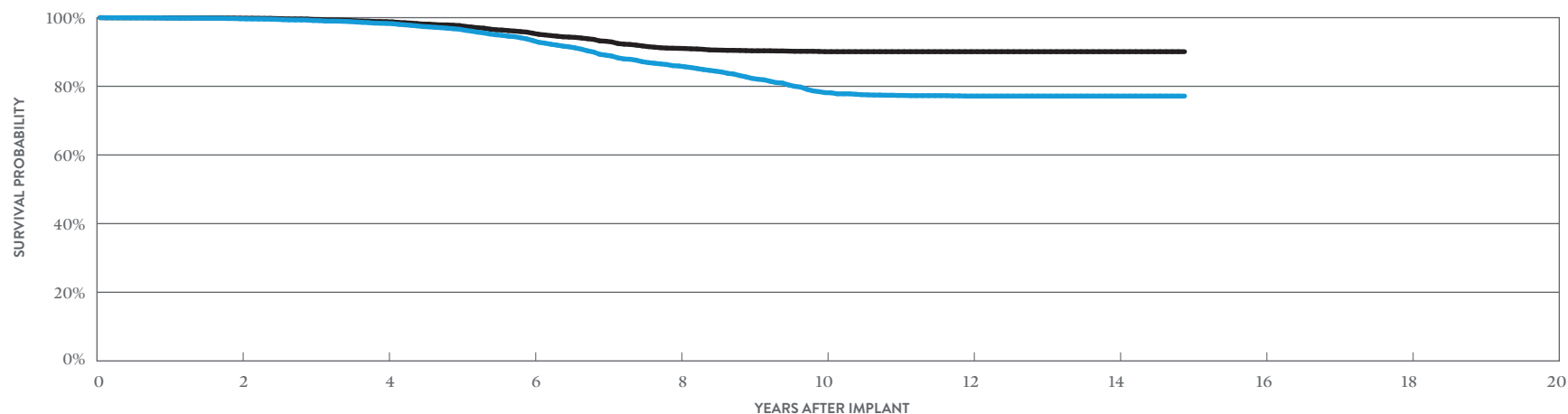
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ DR

MODEL CD2231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	12,267
Estimated Active US Implants	2,215
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	280
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	9	0.07%	3	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	5	0.04%	9	0.07%
High Voltage Capacitor	8	0.07%	2	0.02%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	60	0.49%	140	1.14%
Other	5	0.04%	5	0.04%
Total	88	0.72%	161	1.31%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	99.67%	98.32%	93.35%	85.92%	78.15%	77.16%	77.16%	77.16%
± 1 STANDARD ERROR	0.05%	0.14%	0.29%	0.44%	0.55%	0.57%	0.57%	0.57%
SAMPLE SIZE	9,940	7,800	6,120	4,850	3,620	2,620	1,440	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	99.86%	98.83%	95.47%	91.06%	90.09%	90.09%	90.09%	90.09%
± 1 STANDARD ERROR	0.03%	0.12%	0.24%	0.36%	0.39%	0.39%	0.39%	0.39%

BATTERY LONGEVITY SUMMARY

**Dual-Chamber
Implantable Cardioverter
Defibrillator (ICD) Devices**

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Battery Longevity (years)

MODELS	FAMILY	NO PACING	25% PACING	50% PACING	100% PACING
CDDRA500Q	Gallant™ DR†	10.6	9.9	9.3	8.2
CD2411-36Q	Ellipse™ DR*	10.4	9.6	8.9	7.7
CD2411-36C	Ellipse™ DR*	10.4	9.6	8.9	7.7
CD2357-40Q	Fortify Assura™ DR**	11.1	10.2	9.5	8.3
CD2357-40C	Fortify Assura™ DR**	11.1	10.2	9.5	8.3
CD2311-36Q	Ellipse™ DR*	10.4	9.6	8.9	7.7
CD2311-36	Ellipse™ DR*	10.4	9.6	8.9	7.7
CD2257-40Q	Fortify Assura™ DR**	11.1	10.2	9.5	8.3
CD2257-40	Fortify Assura™ DR**	11.1	10.2	9.5	8.3
CD2231-40Q	Fortify™ DR**	10.1	9.3	8.6	7.5
CD2231-40	Fortify™ DR**	10.1	9.3	8.6	7.5

Pacing parameters: DDD, 2.5V, 0.5 ms, 60 ppm, 500 ohms

* Battery voltage range 3.20-2.59. Two maximum charges per year.

** Battery voltage range 3.20-2.59. Three maximum charges per year.

*** Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.

†Capacitor maintenance interval: 1 charge per every 9 months

SUMMARY INFORMATION

**Dual-Chamber
Implantable Cardioverter
Defibrillator (ICD) Devices**

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDDRA500Q	Gallant™ DR*	99.91%	99.84%	99.78%	99.78%						
CD2411-36Q	Ellipse™ DR	99.89%	99.85%	99.77%	99.70%	99.49%	99.15%	97.20%	89.57%	88.76%	88.29%
CD2411-36C	Ellipse™ DR	99.81%	99.76%	99.73%	99.51%	99.23%	98.66%	95.92%	85.90%	85.51%	85.51%
CD2357-40Q	Fortify Assura™ DR	99.86%	99.79%	99.71%	99.62%	99.40%	99.07%	98.66%	97.30%	97.30%	
CD2357-40Q	Fortify Assura™ DR†	99.76%	99.30%	96.48%	91.25%	85.92%	82.31%	78.37%	73.85%	72.72%	71.98%
CD2357-40C	Fortify Assura™ DR	99.85%	99.83%	99.74%	99.61%	99.34%	99.20%	98.52%	97.52%	97.45%	
CD2357-40C	Fortify Assura™ DR†	99.72%	99.41%	97.41%	92.68%	87.81%	84.72%	80.74%	76.92%	76.06%	75.62%
CD2311-36Q	Ellipse™ DR	99.04%	98.01%	97.08%	95.71%	94.62%	92.04%	84.71%	78.30%	76.92%	75.93%
CD2311-36	Ellipse™ DR	98.93%	97.68%	96.95%	96.09%	94.28%	92.08%	84.38%	78.45%	76.66%	76.20%
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.63%	99.10%	96.94%	93.15%	89.75%	87.25%	84.94%	83.20%	82.37%
CD2257-40	Fortify Assura™ DR†	99.84%	99.61%	99.35%	97.92%	95.01%	91.71%	88.48%	86.95%	84.56%	83.59%
CD2231-40Q	Fortify™ DR†	99.72%	99.52%	98.91%	97.94%	96.22%	93.03%	88.76%	85.59%	81.29%	75.85%
CD2231-40	Fortify™ DR†	99.88%	99.67%	99.16%	98.32%	96.62%	93.35%	89.07%	85.92%	82.31%	78.15%

†Premature battery depletion advisory population.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices Survival Probability Summary

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDDRA500Q	Gallant™ DR*	99.93%	99.86%	99.80%	99.80%						
CD2411-36Q	Ellipse™ DR	99.90%	99.87%	99.84%	99.81%	99.76%	99.76%	99.71%	99.64%	99.52%	99.52%
CD2411-36C	Ellipse™ DR	99.85%	99.79%	99.79%	99.64%	99.57%	99.51%	99.31%	99.11%	99.04%	99.04%
CD2357-40Q	Fortify Assura™ DR	99.88%	99.82%	99.74%	99.69%	99.65%	99.62%	99.62%	99.59%	99.59%	
CD2357-40Q	Fortify Assura™ DR†	99.84%	99.40%	96.65%	91.49%	86.24%	82.92%	79.51%	76.70%	75.84%	75.38%
CD2357-40C	Fortify Assura™ DR	99.86%	99.84%	99.78%	99.71%	99.53%	99.53%	99.32%	99.27%	99.19%	
CD2357-40C	Fortify Assura™ DR†	99.80%	99.58%	97.61%	93.07%	88.48%	85.51%	82.45%	80.35%	79.70%	79.47%
CD2311-36Q	Ellipse™ DR	99.13%	98.16%	97.41%	96.31%	95.68%	95.08%	94.34%	93.96%	93.88%	93.88%
CD2311-36	Ellipse™ DR	99.02%	98.02%	97.46%	96.91%	96.28%	95.94%	95.46%	95.23%	94.94%	94.94%
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.72%	99.33%	97.27%	93.63%	90.58%	89.14%	88.03%	87.19%	86.95%
CD2257-40	Fortify Assura™ DR†	99.90%	99.72%	99.46%	98.10%	95.26%	92.33%	90.37%	89.63%	89.12%	89.00%
CD2231-40Q	Fortify™ DR†	99.86%	99.75%	99.31%	98.60%	97.39%	94.89%	91.74%	89.22%	88.15%	87.83%
CD2231-40	Fortify™ DR†	99.95%	99.86%	99.48%	98.83%	97.70%	95.47%	93.14%	91.06%	90.35%	90.09%

†Premature battery depletion advisory population.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/ FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL			
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDDRA500Q	Gallant™ DR	43,588	2.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2411-36Q	Ellipse™ DR	34,533	7.40%	3	<0.01%	1	<0.01%	0	0.00%	2	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	2	<0.01%	10	0.03%		
CD2411-36C	Ellipse™ DR	12,718	9.80%	3	0.02%	0	0.00%	0	0.00%	7	0.06%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	11	0.09%		
CD2357-40Q	Fortify Assura™ DR	44,156	6.40%	3	<0.01%	0	0.00%	2	<0.01%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	0.02%	15	0.03%		
CD2357-40Q	Fortify Assura™ DR†	12,263	20.20%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	72	0.59%	1	<0.01%	77	0.63%		
CD2357-40C	Fortify Assura™ DR	13,034	7.50%	2	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%		
CD2357-40C	Fortify Assura™ DR†	6,956	21.40%	3	0.04%	2	0.03%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	33	0.47%	2	0.03%	41	0.59%		
CD2311-36Q	Ellipse™ DR	5,900	14.70%	3	0.05%	0	0.00%	0	0.00%	65	1.10%	1	0.02%	2	0.03%	0	0.00%	5	0.08%	76	1.29%		
CD2311-36	Ellipse™ DR	3,748	15.50%	5	0.13%	0	0.00%	0	0.00%	22	0.59%	0	0.00%	4	0.11%	0	0.00%	5	0.13%	36	0.96%		
CD2257-40Q	Fortify Assura™ DR†	6,797	17.60%	5	0.07%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	27	0.40%	3	0.04%	36	0.53%		
CD2257-40	Fortify Assura™ DR†	4,235	19.70%	2	0.05%	0	0.00%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	13	0.31%	0	0.00%	17	0.40%		
CD2231-40Q	Fortify™ DR†	27,257	17.40%	10	0.04%	3	0.01%	29	0.11%	5	0.02%	1	<0.01%	0	0.00%	166	0.61%	17	0.06%	231	0.85%		
CD2231-40	Fortify™ DR†	12,267	19.30%	9	0.07%	1	<0.01%	5	0.04%	8	0.07%	0	0.00%	0	0.00%	60	0.49%	5	0.04%	88	0.72%		

Definitions of malfunction categories can be found on [pages 5-6](#).

†Premature battery depletion advisory population.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

US Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/ FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDDRA500Q	Gallant™ DR	43,588	2.30%	15	0.03%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	3	<0.01%	0	0.00%	5	0.01%	24	0.06%
CD2411-36Q	Ellipse™ DR	34,533	7.40%	14	0.04%	0	0.00%	1	<0.01%	2	<0.01%	1	<0.01%	4	0.01%	1	<0.01%	7	0.02%	30	0.09%
CD2411-36C	Ellipse™ DR	12,718	9.80%	10	0.08%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	1	<0.01%	1	<0.01%	5	0.04%	19	0.15%
CD2357-40Q	Fortify Assura™ DR	44,156	6.40%	20	0.05%	1	<0.01%	4	<0.01%	1	<0.01%	0	0.00%	2	<0.01%	5	0.01%	8	0.02%	41	0.09%
CD2357-40Q	Fortify Assura™ DR†	12,263	20.20%	10	0.08%	0	0.00%	20	0.16%	0	0.00%	0	0.00%	1	<0.01%	687	5.60%	6	0.05%	724	5.90%
CD2357-40C	Fortify Assura™ DR	13,034	7.50%	8	0.06%	1	<0.01%	4	0.03%	0	0.00%	2	0.02%	3	0.02%	1	<0.01%	3	0.02%	22	0.17%
CD2357-40C	Fortify Assura™ DR†	6,956	21.40%	2	0.03%	1	0.01%	8	0.12%	0	0.00%	0	0.00%	0	0.00%	310	4.46%	2	0.03%	323	4.64%
CD2311-36Q	Ellipse™ DR	5,900	14.70%	11	0.19%	0	0.00%	1	0.02%	14	0.24%	0	0.00%	3	0.05%	0	0.00%	3	0.05%	32	0.54%
CD2311-36	Ellipse™ DR	3,748	15.50%	9	0.24%	0	0.00%	0	0.00%	8	0.21%	0	0.00%	3	0.08%	2	0.05%	2	0.05%	24	0.64%
CD2257-40Q	Fortify Assura™ DR†	6,797	17.60%	3	0.04%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	1	0.01%	174	2.56%	1	0.01%	182	2.68%
CD2257-40	Fortify Assura™ DR†	4,235	19.70%	1	0.02%	0	0.00%	4	0.09%	0	0.00%	1	0.02%	0	0.00%	81	1.91%	4	0.09%	91	2.15%
CD2231-40Q	Fortify™ DR†	27,257	17.40%	11	0.04%	2	<0.01%	55	0.20%	2	<0.01%	2	<0.01%	0	0.00%	408	1.50%	13	0.05%	493	1.81%
CD2231-40	Fortify™ DR†	12,267	19.30%	3	0.02%	0	0.00%	9	0.07%	2	0.02%	1	<0.01%	1	<0.01%	140	1.14%	5	0.04%	161	1.31%

Definitions of malfunction categories can be found on [pages 5-6](#).

†Premature battery depletion advisory population.

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL			
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDDRA500Q	Gallant™ DR	70,177	1.68%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2411-36Q	Ellipse™ DR	35,246	7.54%	6	0.02%	2	<0.01%	0	0.00%	2	<0.01%	2	<0.01%	2	<0.01%	0	0.00%	4	0.01%	18	0.05%		
CD2411-36C	Ellipse™ DR	12,853	10.32%	6	0.05%	0	0.00%	0	0.00%	7	0.05%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	15	0.12%		
CD2357-40Q	Fortify Assura™ DR	58,933	9.24%	12	0.02%	2	<0.01%	4	<0.01%	3	<0.01%	0	0.00%	0	0.00%	144	0.24%	16	0.03%	181	0.31%		
CD2357-40C	Fortify Assura™ DR	20,209	12.73%	10	0.05%	4	0.02%	2	<0.01%	1	<0.01%	0	0.00%	0	0.00%	66	0.33%	4	0.02%	87	0.43%		
CD2311-36Q	Ellipse™ DR	5,881	16.26%	6	0.10%	0	0.00%	0	0.00%	65	1.11%	2	0.03%	4	0.07%	0	0.00%	10	0.17%	87	1.48%		
CD2311-36	Ellipse™ DR	3,749	16.43%	10	0.27%	0	0.00%	0	0.00%	22	0.59%	0	0.00%	8	0.21%	0	0.00%	10	0.27%	50	1.33%		
CD2257-40Q	Fortify Assura™ DR	6,780	17.96%	10	0.15%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	54	0.80%	6	0.09%	72	1.06%		
CD2257-40	Fortify Assura™ DR	4,234	20.26%	4	0.09%	0	0.00%	2	0.05%	1	0.02%	0	0.00%	0	0.00%	26	0.61%	0	0.00%	33	0.78%		
CD2231-40Q	Fortify™ DR	29,369	16.69%	22	0.07%	6	0.02%	58	0.20%	5	0.02%	2	<0.01%	0	0.00%	344	1.17%	34	0.12%	471	1.60%		
CD2231-40	Fortify™ DR	18,808	13.41%	20	0.11%	4	0.02%	10	0.05%	8	0.04%	0	0.00%	0	0.00%	126	0.67%	14	0.07%	182	0.97%		

Definitions of malfunction categories can be found on [pages 5-6](#).

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Worldwide Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDDRA500Q	Gallant™ DR	70,177	1.68%	36	0.05%	2	<0.01%	2	<0.01%	2	<0.01%	0	0.00%	6	<0.01%	0	0.00%	14	0.02%	62	0.09%
CD2411-36Q	Ellipse™ DR	35,246	7.54%	28	0.08%	0	0.00%	2	<0.01%	2	<0.01%	2	<0.01%	8	0.02%	2	<0.01%	14	0.04%	58	0.16%
CD2411-36C	Ellipse™ DR	12,853	10.32%	20	0.16%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	2	0.02%	2	0.02%	10	0.08%	36	0.28%
CD2357-40Q	Fortify Assura™ DR	58,933	9.24%	60	0.10%	2	<0.01%	48	0.08%	2	<0.01%	0	0.00%	6	0.01%	1384	2.35%	28	0.05%	1530	2.60%
CD2357-40C	Fortify Assura™ DR	20,209	12.73%	20	0.10%	4	0.02%	24	0.12%	0	0.00%	4	0.02%	6	0.03%	622	3.08%	12	0.06%	692	3.42%
CD2311-36Q	Ellipse™ DR	5,881	16.26%	22	0.37%	0	0.00%	2	0.03%	14	0.24%	0	0.00%	6	0.10%	0	0.00%	6	0.10%	50	0.85%
CD2311-36	Ellipse™ DR	3,749	16.43%	18	0.48%	0	0.00%	0	0.00%	8	0.21%	0	0.00%	6	0.16%	4	0.11%	4	0.11%	40	1.07%
CD2257-40Q	Fortify Assura™ DR	6,780	17.96%	6	0.09%	0	0.00%	4	0.06%	0	0.00%	2	0.03%	2	0.03%	348	5.13%	2	0.03%	364	5.37%
CD2257-40	Fortify Assura™ DR	4,234	20.26%	2	0.05%	0	0.00%	8	0.19%	0	0.00%	2	0.05%	0	0.00%	162	3.83%	8	0.19%	182	4.30%
CD2231-40Q	Fortify™ DR	29,369	16.69%	28	0.10%	4	0.01%	112	0.38%	2	<0.01%	4	0.01%	0	0.00%	862	2.94%	26	0.09%	1038	3.53%
CD2231-40	Fortify™ DR	18,808	13.41%	16	0.09%	0	0.00%	18	0.10%	2	0.01%	2	0.01%	4	0.02%	316	1.68%	16	0.09%	374	1.99%

Definitions of malfunction categories can be found on [pages 5-6](#).

SINGLE-CHAMBER
**Implantable Cardioverter
Defibrillator (ICD) Devices**

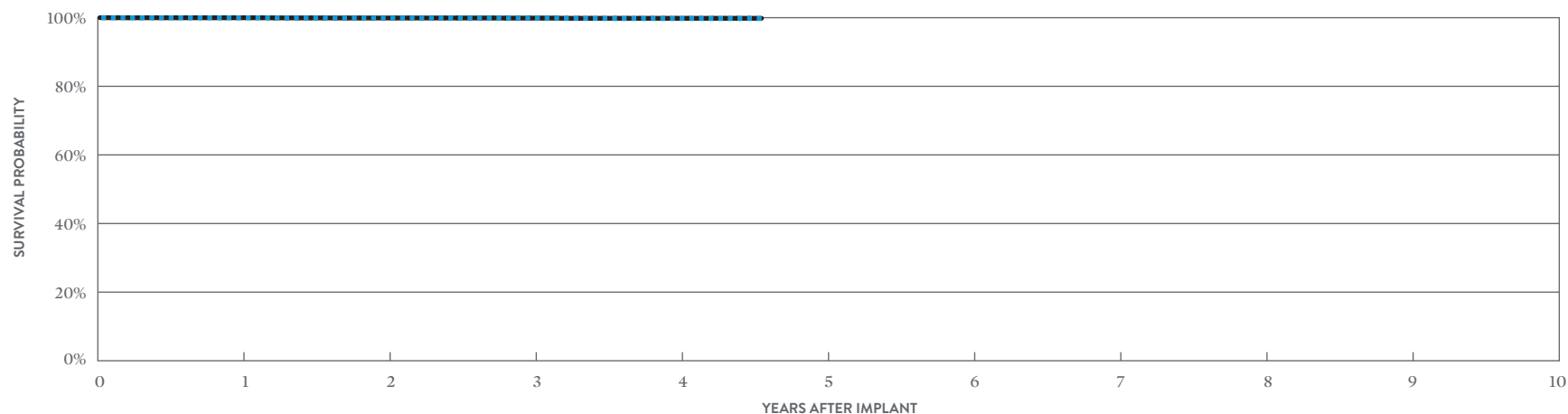
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Gallant™ VR

MODEL CDVRA500Q*

US Regulatory Approval	June 2020
Registered US Implants	21,030
Estimated Active US Implants	16,224
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories (page 189)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	5	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	0	0.00%	8	0.04%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.98%	99.89%	99.86%	99.74%	99.74%
± 1 STANDARD ERROR	0.01%	0.03%	0.04%	0.07%	0.07%
SAMPLE SIZE	18,120	12,340	7,080	3,000	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.98%	99.91%	99.88%	99.82%	99.82%
± 1 STANDARD ERROR	0.01%	0.02%	0.04%	0.05%	0.05%

*DF4-LLHH connector type.

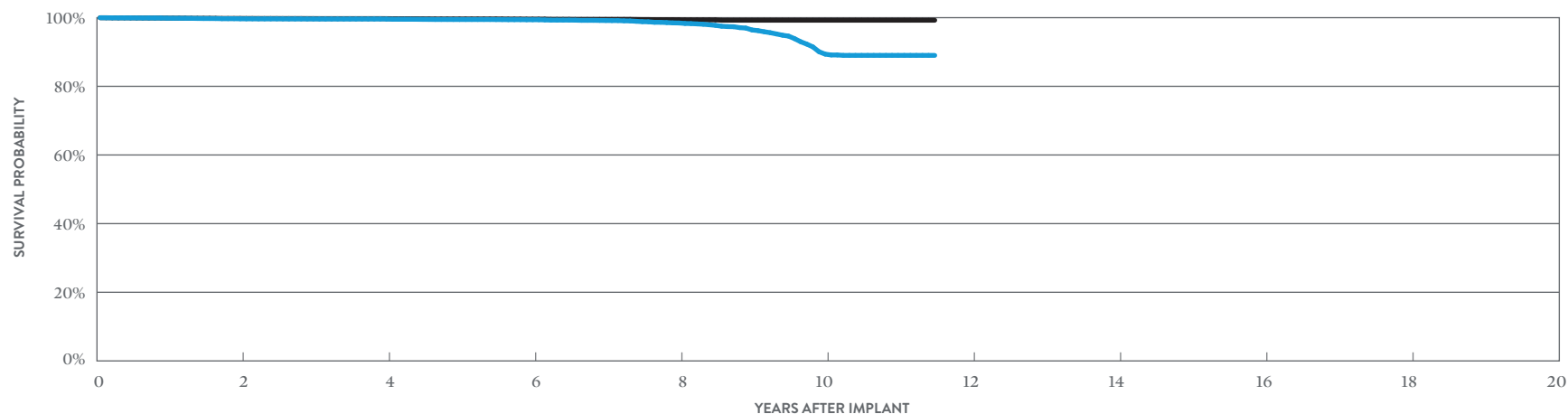
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	24,339
Estimated Active US Implants	11,063
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	152
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 190, 191)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.02%	8	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	2	<0.01%
High Voltage Capacitor	10	0.04%	7	0.03%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	3	0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	3	0.01%	5	0.02%
Total	18	0.07%	28	0.12%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.67%	99.59%	99.39%	98.45%	89.38%	89.01%
± 1 STANDARD ERROR	0.04%	0.04%	0.06%	0.13%	0.52%	0.56%
SAMPLE SIZE	20,610	16,520	11,950	6,890	2,840	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.78%	99.72%	99.58%	99.39%	99.25%	99.25%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.07%	0.09%	0.09%

*DF4-LLHH connector type.

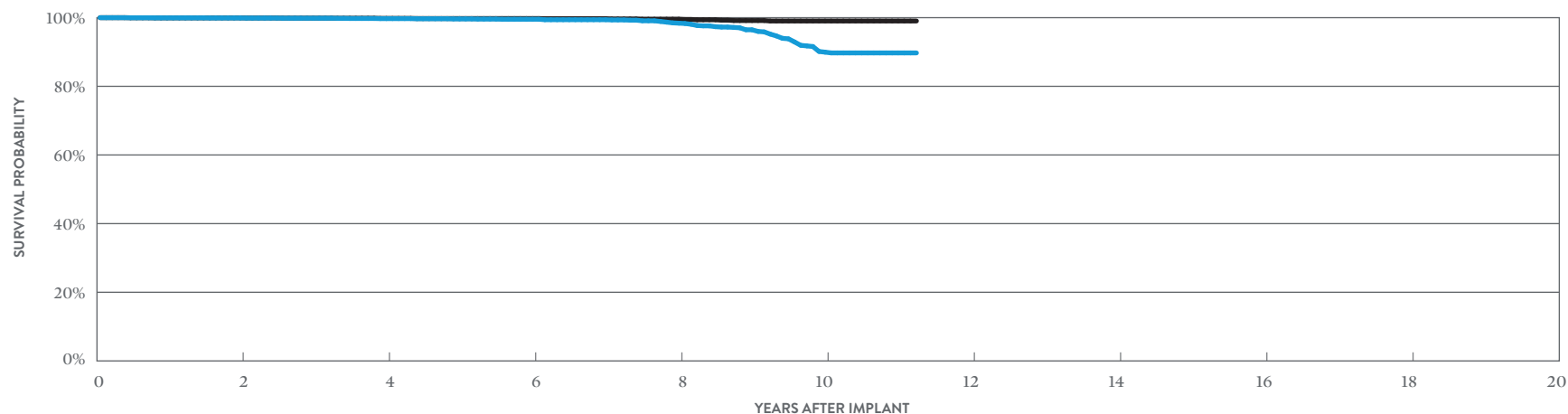
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1411-36C*

US Regulatory Approval	June 2013
Registered US Implants	7,646
Estimated Active US Implants	3,291
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	62
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 190, 191)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	9	0.12%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	0.01%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	2	0.03%
Total	0	0.00%	15	0.20%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.91%	99.72%	99.54%	98.39%	89.95%	89.73%
± 1 STANDARD ERROR	0.04%	0.07%	0.10%	0.22%	0.77%	0.79%
SAMPLE SIZE	6,350	5,080	4,050	2,690	1,240	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.94%	99.79%	99.75%	99.56%	99.03%	99.03%
± 1 STANDARD ERROR	0.03%	0.06%	0.07%	0.10%	0.20%	0.20%

*Parylene coating.

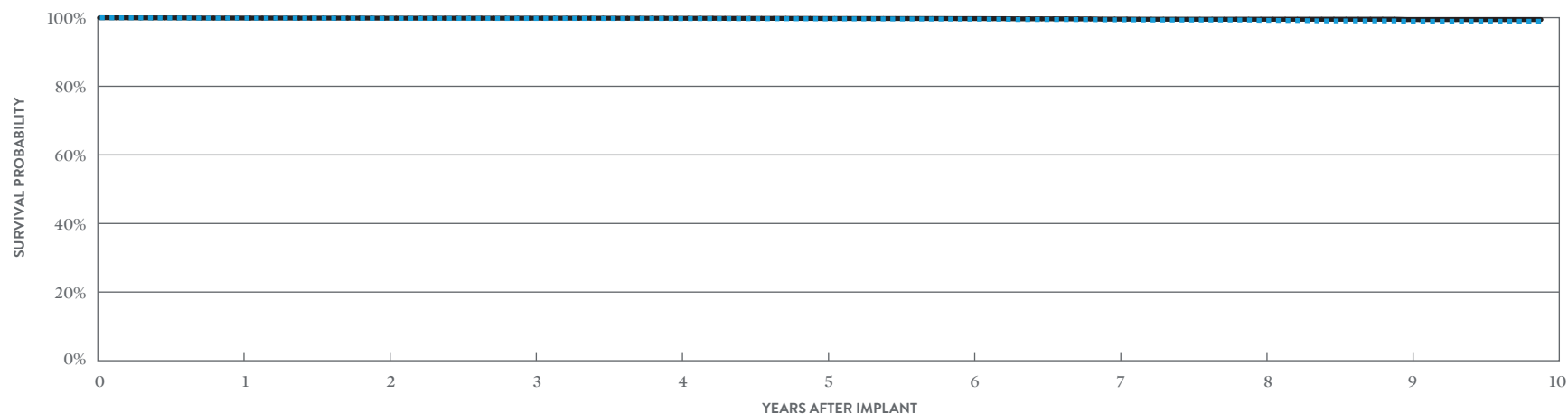
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40Q* (NON-BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	26,664
Estimated Active US Implants	13,718
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	19
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	11	0.04%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	6	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	3	0.01%	4	0.02%
Total	7	0.03%	25	0.09%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.87%	99.79%	99.78%	99.73%	99.66%	99.58%	99.38%	99.22%	98.98%	98.98%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%	0.04%	0.05%	0.07%	0.07%	0.11%	0.12%
SAMPLE SIZE	25,180	22,460	20,050	17,740	15,100	11,970	8,810	5,980	3,400	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.90%	99.86%	99.86%	99.83%	99.77%	99.74%	99.58%	99.55%	99.46%	99.46%
± 1 STANDARD ERROR	0.02%	0.02%	0.02%	0.03%	0.03%	0.04%	0.06%	0.06%	0.06%	0.09%

*DF4-LLHH connector type.

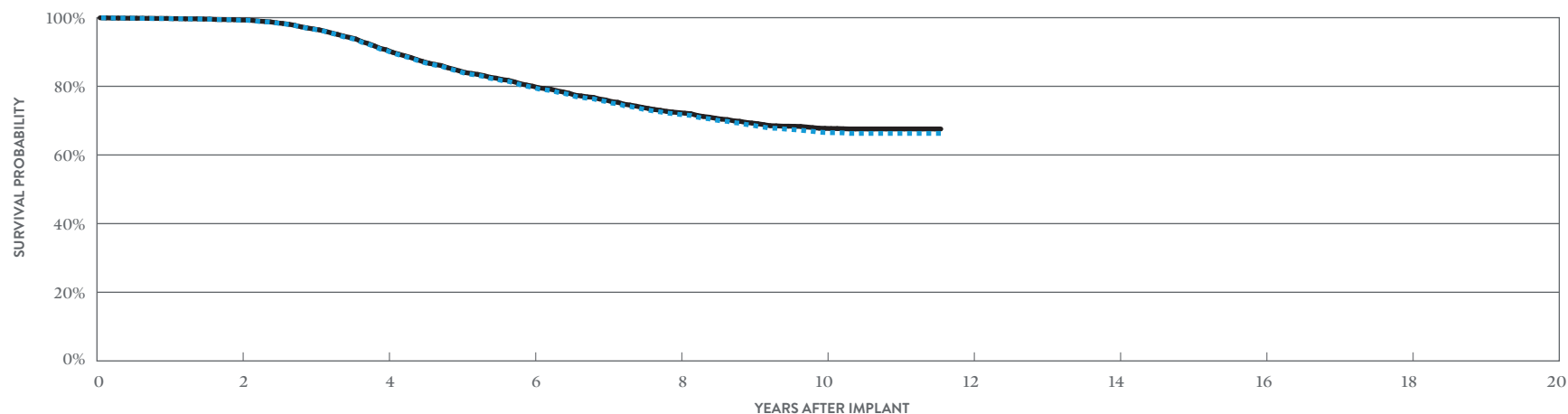
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	10,214
Estimated Active US Implants	3,114
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	31
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.05%	8	0.08%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	9	0.09%
High Voltage Capacitor	2	0.02%	0	0.00%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	68	0.67%	776	7.60%
Other	4	0.04%	6	0.06%
Total	81	0.79%	799	7.82%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.25%	90.43%	79.70%	71.83%	66.54%	66.28%
± 1 STANDARD ERROR	0.09%	0.33%	0.47%	0.54%	0.58%	0.59%
SAMPLE SIZE	8,530	6,920	5,630	4,560	3,340	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.31%	90.63%	80.04%	72.33%	67.75%	67.58%
± 1 STANDARD ERROR	0.08%	0.33%	0.47%	0.54%	0.58%	0.58%

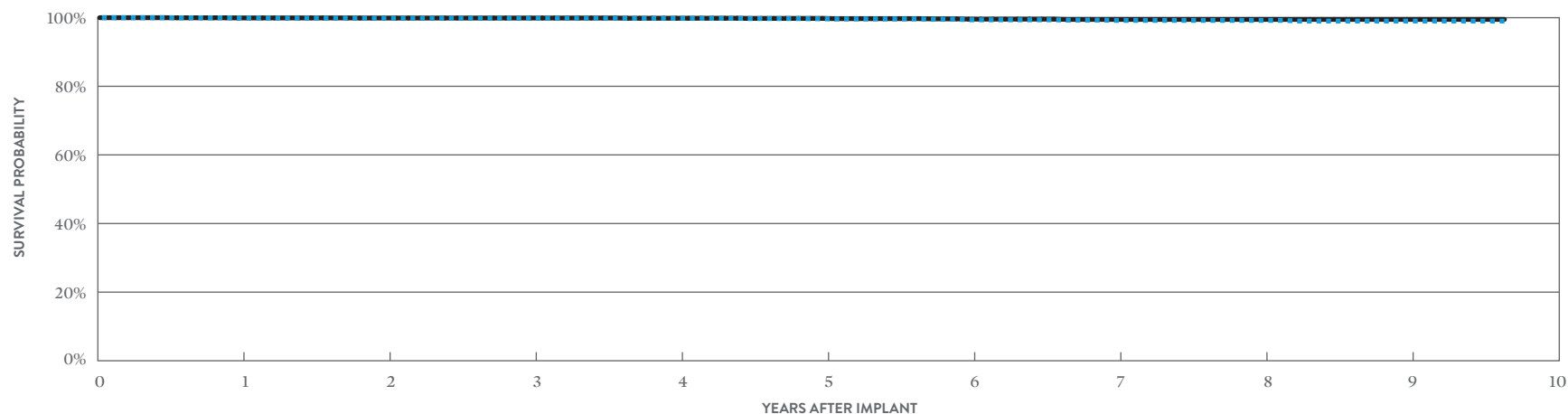
*DF4-LLHH connector type.

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40C* (NON-BATTERY ADVISORY POPULATION)

		MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY		
		QTY	RATE	QTY	RATE	
US Regulatory Approval	June 2013	Electrical Component	0	0.00%	4	0.06%
Registered US Implants	6,748	Electrical Interconnect	0	0.00%	0	0.00%
Estimated Active US Implants	3,345	Battery	0	0.00%	0	0.00%
Estimated Longevity	(see table on page 109)	High Voltage Capacitor	0	0.00%	0	0.00%
Normal Battery Depletion	5	Software/Firmware	0	0.00%	0	0.00%
Max. Delivered Energy	40 joules	Mechanical	0	0.00%	1	0.01%
Number of US Advisories (see pg. 191)	One	Possible Early Battery Depletion	0	0.00%	2	0.03%
		Other	0	0.00%	2	0.03%
		Total	0	0.00%	9	0.13%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.93%	99.86%	99.86%	99.81%	99.69%	99.38%	99.21%	99.21%	99.02%	99.02%
± 1 STANDARD ERROR	0.02%	0.05%	0.05%	0.06%	0.09%	0.11%	0.15%	0.16%	0.21%	0.21%
SAMPLE SIZE	6,300	5,410	4,610	3,990	3,480	3,000	2,440	1,660	890	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.93%	99.90%	99.90%	99.84%	99.79%	99.59%	99.50%	99.50%	99.50%	99.50%
± 1 STANDARD ERROR	0.02%	0.04%	0.04%	0.06%	0.07%	0.09%	0.12%	0.12%	0.12%	0.12%

*Parylene coating.

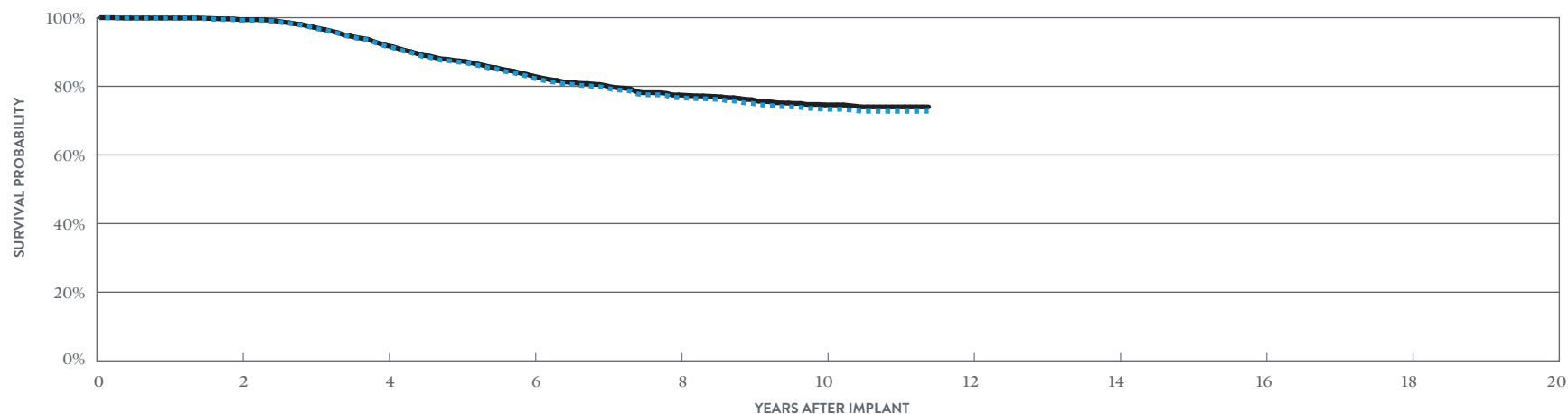
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	4,130
Estimated Active US Implants	1,293
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	14
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.07%	3	0.07%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	0	0.00%	6	0.15%
High Voltage Capacitor	1	0.02%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	1	0.02%	0	0.00%
Possible Early Battery Depletion	9	0.22%	247	5.98%
Other	0	0.00%	2	0.05%
Total	15	0.36%	259	6.27%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.25%	91.63%	82.42%	76.68%	73.30%	72.73%
± 1 STANDARD ERROR	0.13%	0.50%	0.71%	0.82%	0.88%	0.91%
SAMPLE SIZE	3,390	2,720	2,220	1,820	1,310	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.44%	91.91%	83.01%	77.49%	74.59%	74.01%
± 1 STANDARD ERROR	0.11%	0.49%	0.70%	0.81%	0.86%	0.89%

*Parylene coating.

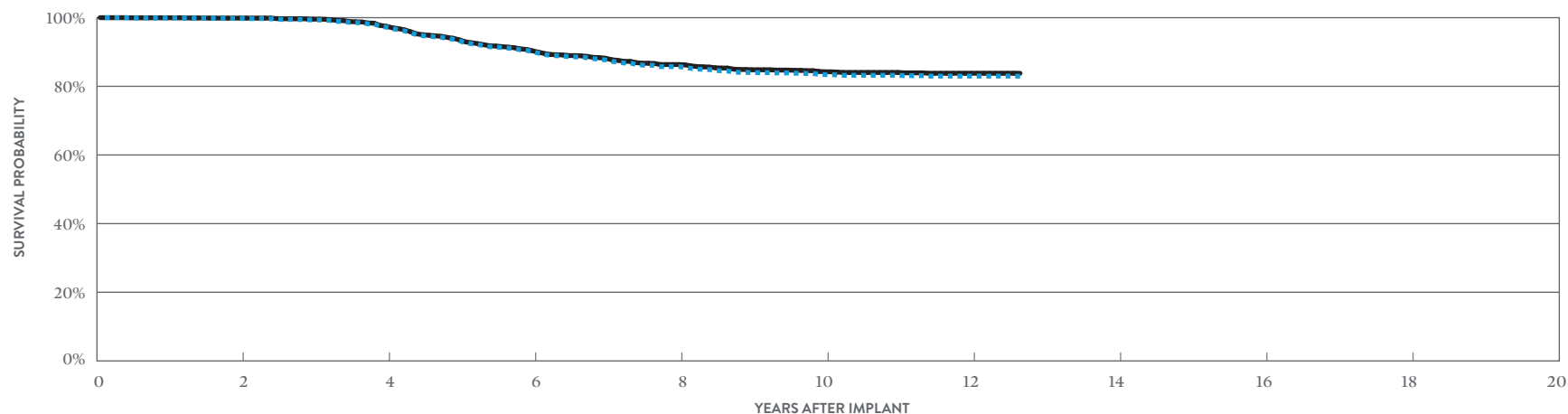
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	5,079
Estimated Active US Implants	1,239
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	12
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.02%	2	0.04%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	0	0.00%	4	0.08%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	20	0.39%	168	3.31%
Other	1	0.02%	2	0.04%
Total	23	0.45%	176	3.47%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 152 MONTHS
SURVIVAL PROBABILITY	99.77%	97.25%	90.06%	85.72%	83.40%	82.97%	82.97%
± 1 STANDARD ERROR	0.07%	0.26%	0.51%	0.63%	0.68%	0.70%	0.70%
SAMPLE SIZE	4,250	3,420	2,830	2,350	1,920	1,120	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 152 MONTHS
SURVIVAL PROBABILITY	99.87%	97.49%	90.33%	86.34%	84.23%	83.80%	83.80%
± 1 STANDARD ERROR	0.06%	0.25%	0.51%	0.62%	0.67%	0.68%	0.68%

*DF4-LLHH connector type.

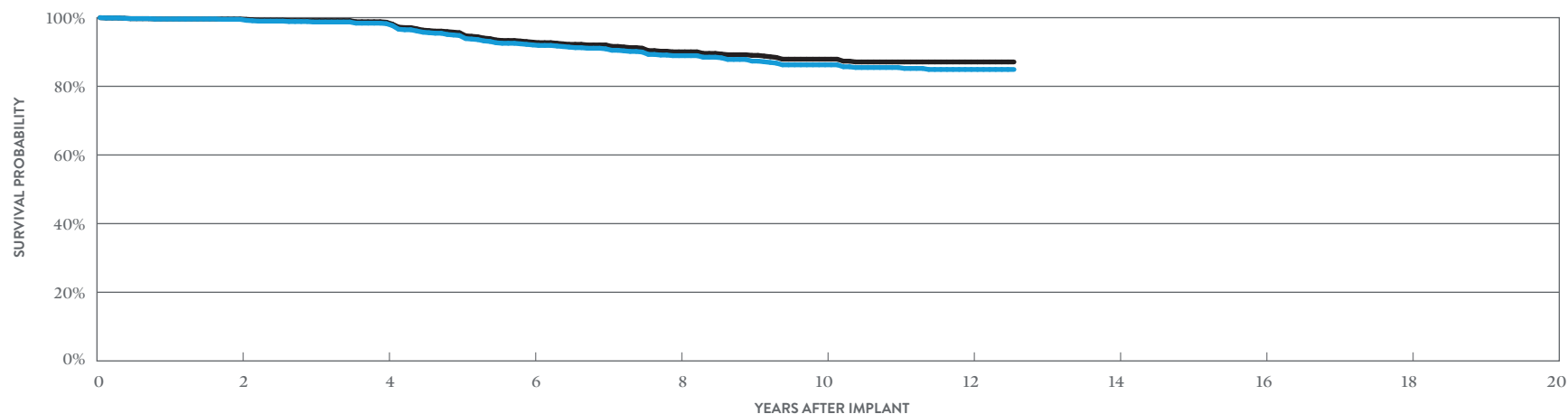
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,293
Estimated Active US Implants	616
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	11
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.09%	0	0.00%
Electrical Interconnect	2	0.09%	0	0.00%
Battery	1	0.04%	2	0.09%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	7	0.31%	56	2.44%
Other	2	0.09%	1	0.04%
Total	14	0.61%	59	2.57%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 151 MONTHS
SURVIVAL PROBABILITY	99.51%	98.26%	92.06%	88.93%	86.26%	84.91%	84.91%
± 1 STANDARD ERROR	0.15%	0.30%	0.71%	0.86%	0.97%	1.04%	1.04%
SAMPLE SIZE	1,850	1,470	1,220	1,040	850	520	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 151 MONTHS
SURVIVAL PROBABILITY	99.62%	98.67%	92.87%	90.04%	87.90%	87.10%	87.10%
± 1 STANDARD ERROR	0.13%	0.26%	0.68%	0.83%	0.92%	0.96%	0.96%

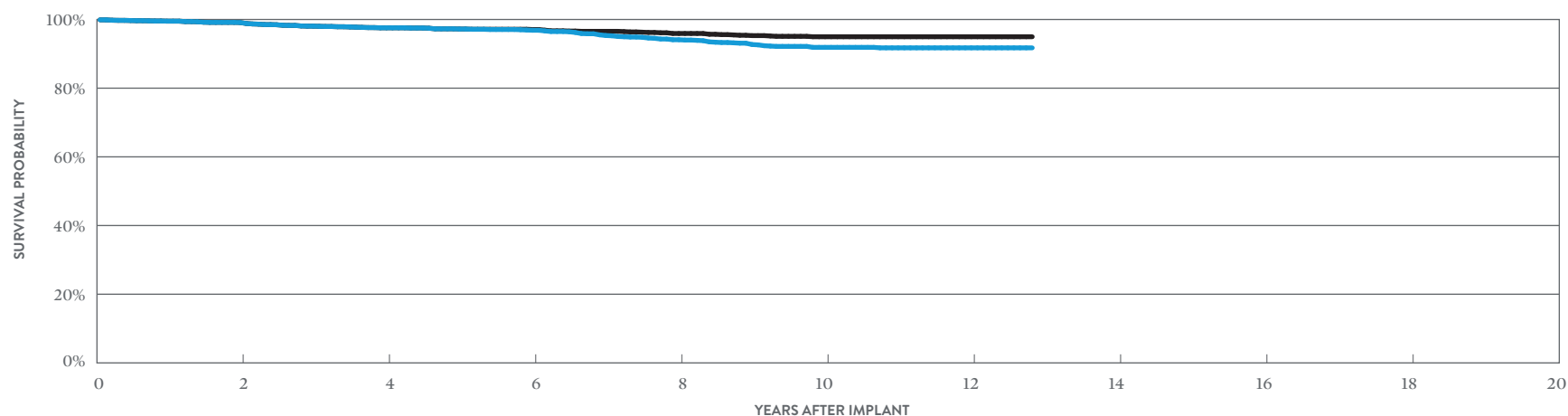
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	4,743
Estimated Active US Implants	1,085
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	31
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 191)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.06%	4	0.08%
Electrical Interconnect	0	0.00%	1	0.02%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	38	0.80%	16	0.34%
Software/Firmware	1	0.02%	0	0.00%
Mechanical	1	0.02%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.02%	5	0.11%
Total	44	0.93%	26	0.55%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 154 MONTHS
SURVIVAL PROBABILITY	99.11%	97.58%	96.86%	94.10%	91.88%	91.74%	91.74%
± 1 STANDARD ERROR	0.14%	0.25%	0.29%	0.43%	0.53%	0.54%	0.54%
SAMPLE SIZE	3,940	3,240	2,750	2,300	1,720	970	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 154 MONTHS
SURVIVAL PROBABILITY	99.11%	97.58%	97.07%	95.92%	94.97%	94.97%	94.97%
± 1 STANDARD ERROR	0.14%	0.25%	0.28%	0.35%	0.41%	0.41%	0.41%

*DF4-LLHH connector type.

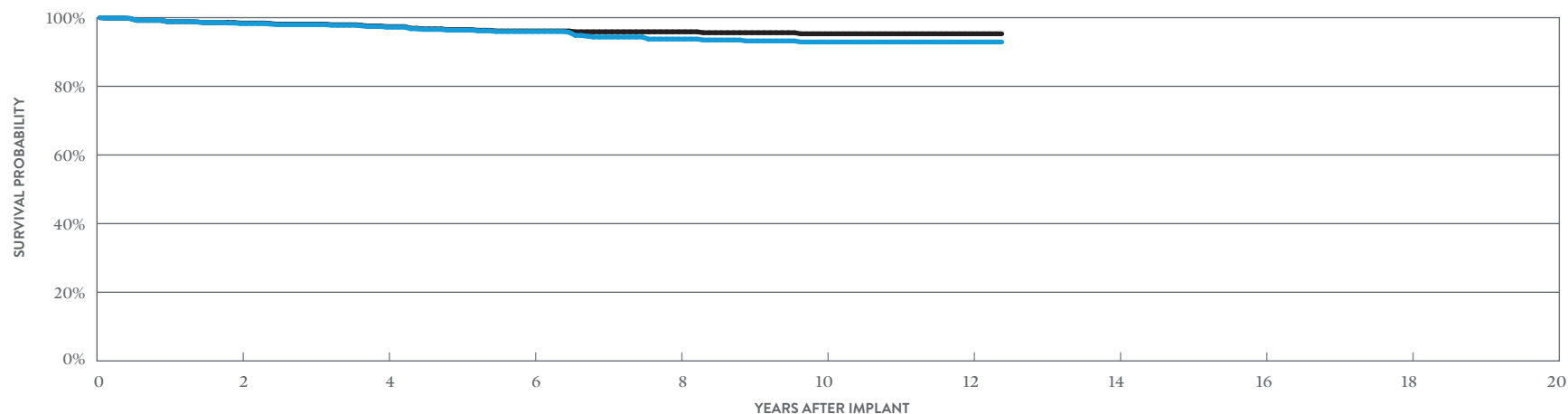
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1311-36*

US Regulatory Approval	May 2012
Registered US Implants	1,621
Estimated Active US Implants	450
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	9
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 191)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	4	0.25%	2	0.12%
Electrical Interconnect	1	0.06%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	8	0.49%	4	0.25%
Software/Firmware	0	0.00%	1	0.06%
Mechanical	2	0.12%	1	0.06%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	2	0.12%	0	0.00%
Total	17	1.05%	8	0.49%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 149 MONTHS
SURVIVAL PROBABILITY	98.28%	97.24%	95.96%	93.76%	92.91%	92.91%	92.91%
± 1 STANDARD ERROR	0.32%	0.43%	0.57%	0.75%	0.82%	0.82%	0.82%
SAMPLE SIZE	1,350	1,110	930	780	620	390	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 149 MONTHS
SURVIVAL PROBABILITY	98.43%	97.39%	96.11%	95.88%	95.30%	95.30%	95.30%
± 1 STANDARD ERROR	0.31%	0.42%	0.56%	0.58%	0.65%	0.65%	0.65%

*DF4-LLHH connector type.

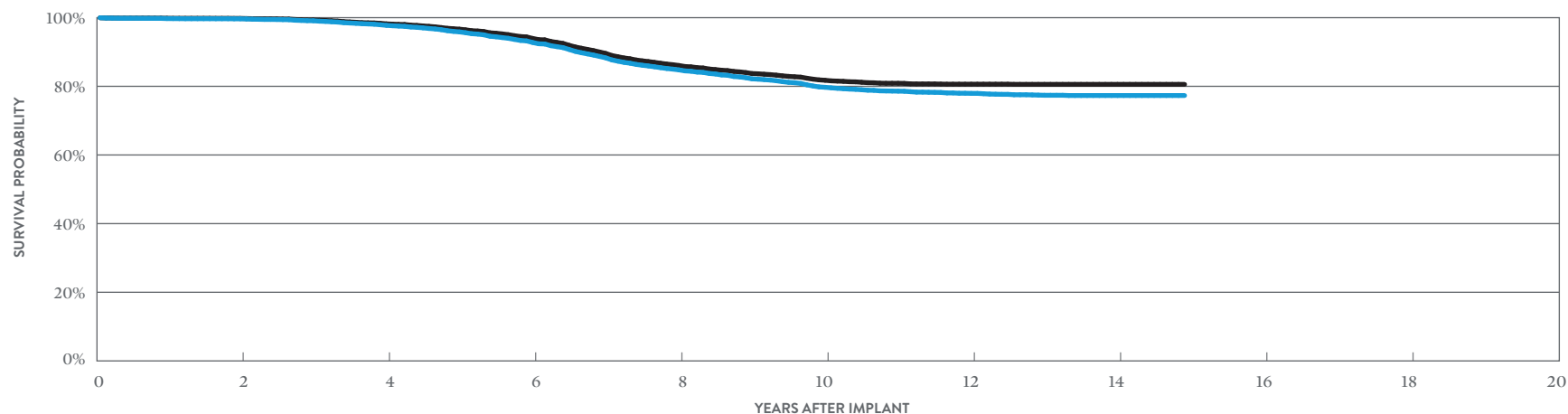
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ VR

MODEL CD1231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	16,339
Estimated Active US Implants	3,047
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	112
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	7	0.04%	10	0.06%
Electrical Interconnect	2	0.01%	0	0.00%
Battery	18	0.11%	50	0.31%
High Voltage Capacitor	2	0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	131	0.80%	444	2.72%
Other	9	0.06%	7	0.04%
Total	169	1.03%	513	3.14%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	99.66%	97.76%	92.77%	84.79%	79.72%	77.94%	77.32%	77.32%
± 1 STANDARD ERROR	0.05%	0.13%	0.25%	0.37%	0.43%	0.45%	0.46%	0.46%
SAMPLE SIZE	13,460	10,960	8,910	7,320	6,090	4,600	2,000	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	99.78%	98.20%	93.95%	86.07%	81.76%	80.62%	80.57%	80.57%
± 1 STANDARD ERROR	0.04%	0.12%	0.23%	0.36%	0.41%	0.43%	0.43%	0.43%

*DF4-LLHH connector type.

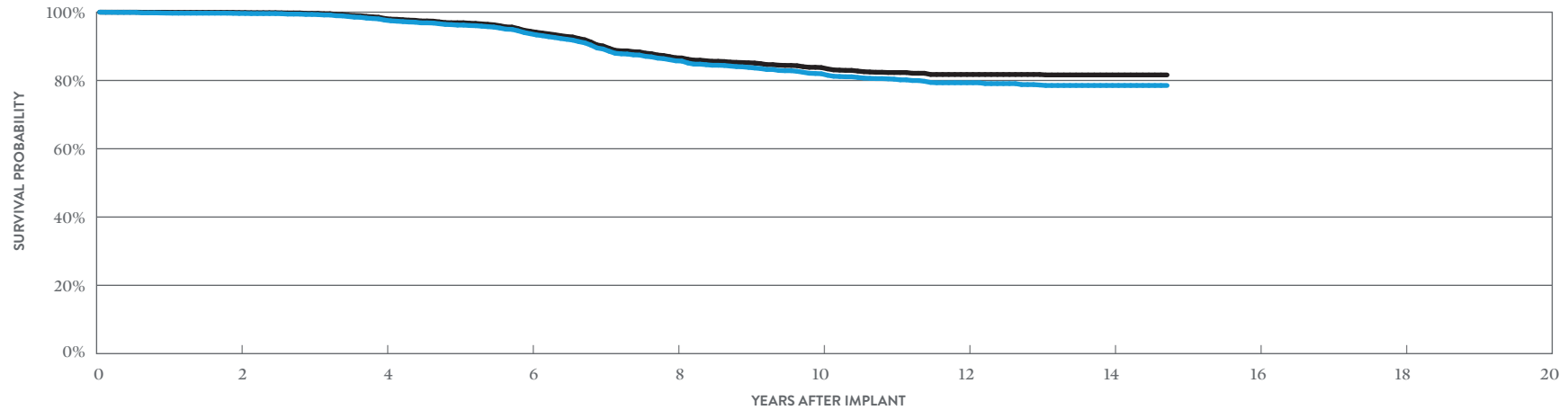
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ VR

MODEL CD1231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	6,782
Estimated Active US Implants	1,312
Estimated Longevity	(see table on page 109)
Normal Battery Depletion	41
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 191, 192)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.07%	6	0.09%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.06%	14	0.21%
High Voltage Capacitor	10	0.15%	4	0.06%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	44	0.65%	149	2.20%
Other	6	0.09%	6	0.09%
Total	69	1.02%	180	2.65%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 177 MONTHS
SURVIVAL PROBABILITY	99.63%	97.68%	93.69%	85.75%	81.97%	79.33%	78.53%	78.53%
± 1 STANDARD ERROR	0.07%	0.20%	0.37%	0.58%	0.66%	0.71%	0.74%	0.74%
SAMPLE SIZE	5,480	4,340	3,470	2,830	2,360	1,820	880	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 177 MONTHS
SURVIVAL PROBABILITY	99.89%	98.16%	94.40%	86.65%	83.78%	81.75%	81.62%	81.62%
± 1 STANDARD ERROR	0.03%	0.18%	0.36%	0.57%	0.63%	0.68%	0.69%	0.69%

BATTERY LONGEVITY SUMMARY

**Single-Chamber
Implantable Cardioverter
Defibrillator (ICD) Devices**

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Battery Longevity (years)

MODELS	FAMILY	NO PACING	25% PACING	50% PACING	100% PACING
CDVRA500Q	Gallant [™] VR*	11.2	10.8	10.4	9.8
CD1411-36Q	Ellipse [™] VR*	11.1	10.6	10.1	9.4
CD1411-36C	Ellipse [™] VR*	11.1	10.6	10.1	9.4
CD1357-40Q	Fortify Assura [™] VR**	11.7	11.3	10.8	10.1
CD1357-40C	Fortify Assura [™] VR**	11.7	11.3	10.8	10.1
CD1257-40Q	Fortify Assura [™] VR**	11.7	11.3	10.8	10.1
CD1257-40	Fortify Assura [™] VR**	11.7	11.3	10.8	10.1
CD1311-36Q	Ellipse [™] VR*	11.1	10.6	10.1	9.4
CD1311-36	Ellipse [™] VR*	11.1	10.6	10.1	9.4
CD1231-40Q	Fortify [™] VR**	10.8	10.3	9.9	9.1
CD1231-40	Fortify [™] VR**	10.8	10.3	9.9	9.1

Pacing parameters: VVI, 2.5V, 0.5 ms, 60 ppm, 500 ohms

* Battery voltage range 3.20-2.59. Two maximum charges per year.

** Battery voltage range 3.20-2.59. Three maximum charges per year.

*** Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.

SUMMARY INFORMATION

**Single-Chamber
Implantable Cardioverter
Defibrillator (ICD) Devices**

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDVRA500Q	Gallant™ VR*	99.98%	99.89%	99.86%	99.74%						
CDI411-36Q	Ellipse™ VR	99.85%	99.67%	99.62%	99.59%	99.46%	99.39%	99.17%	98.45%	96.42%	89.38%
CDI411-36C	Ellipse™ VR	99.94%	99.91%	99.84%	99.72%	99.63%	99.54%	99.40%	98.39%	96.47%	89.95%
CDI357-40Q	Fortify Assura™ VR	99.87%	99.79%	99.78%	99.73%	99.66%	99.58%	99.38%	99.22%	98.98%	
CDI357-40Q	Fortify Assura™ VR†	99.74%	99.25%	96.64%	90.43%	84.27%	79.70%	75.60%	71.83%	68.69%	66.54%
CDI357-40C	Fortify Assura™ VR	99.93%	99.86%	99.86%	99.81%	99.69%	99.38%	99.21%	99.21%	99.02%	
CDI357-40C	Fortify Assura™ VR†	99.79%	99.25%	97.05%	91.63%	87.02%	82.42%	79.55%	76.68%	75.04%	73.30%
CDI257-40Q	Fortify Assura™ VR†	99.92%	99.77%	99.33%	97.25%	93.23%	90.06%	87.69%	85.72%	83.98%	83.40%
CDI257-40	Fortify Assura™ VR†	99.62%	99.51%	98.74%	98.26%	94.80%	92.06%	90.92%	88.93%	87.35%	86.26%
CDI311-36Q	Ellipse™ VR	99.51%	99.11%	98.06%	97.58%	97.22%	96.86%	95.33%	94.10%	92.71%	91.88%
CDI311-36	Ellipse™ VR	98.87%	98.28%	97.96%	97.24%	96.37%	95.96%	94.36%	93.76%	93.22%	92.91%
CDI231-40Q	Fortify™ VR†	99.73%	99.66%	99.10%	97.76%	95.85%	92.77%	88.29%	84.79%	82.18%	79.72%
CDI231-40	Fortify™ VR†	99.74%	99.63%	99.34%	97.68%	96.22%	93.69%	89.22%	85.75%	83.82%	81.97%

†Premature battery depletion advisory population.

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices Survival Probability Summary

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
CDVRA500Q	Gallant™ VR*	99.98%	99.91%	99.88%	99.82%						
CDI411-36Q	Ellipse™ VR	99.87%	99.78%	99.74%	99.72%	99.63%	99.58%	99.51%	99.39%	99.25%	99.25%
CDI411-36C	Ellipse™ VR	99.94%	99.94%	99.87%	99.79%	99.75%	99.75%	99.70%	99.56%	99.16%	99.03%
CDI357-40Q	Fortify Assura™ VR	99.90%	99.86%	99.86%	99.83%	99.77%	99.74%	99.58%	99.55%	99.46%	
CDI357-40Q	Fortify Assura™ VR†	99.77%	99.31%	96.71%	90.63%	84.49%	80.04%	76.01%	72.33%	69.30%	67.75%
CDI357-40C	Fortify Assura™ VR	99.93%	99.90%	99.90%	99.84%	99.79%	99.59%	99.50%	99.50%	99.50%	
CDI357-40C	Fortify Assura™ VR†	99.90%	99.44%	97.24%	91.91%	87.40%	83.01%	80.20%	77.49%	76.11%	74.59%
CDI257-40Q	Fortify Assura™ VR†	99.96%	99.87%	99.57%	97.49%	93.52%	90.33%	88.17%	86.34%	84.82%	84.23%
CDI257-40	Fortify Assura™ VR†	99.62%	99.62%	99.15%	98.67%	95.63%	92.87%	92.05%	90.04%	89.01%	87.90%
CDI311-36Q	Ellipse™ VR	99.51%	99.11%	98.06%	97.58%	97.22%	97.07%	96.55%	95.92%	95.30%	94.97%
CDI311-36	Ellipse™ VR	98.87%	98.43%	98.11%	97.39%	96.52%	96.11%	95.88%	95.88%	95.62%	95.30%
CDI231-40Q	Fortify™ VR†	99.83%	99.78%	99.33%	98.20%	96.65%	93.95%	89.58%	86.07%	83.72%	81.76%
CDI231-40	Fortify™ VR†	99.97%	99.89%	99.66%	98.16%	96.90%	94.40%	90.10%	86.65%	85.17%	83.78%

†Premature battery depletion advisory population.

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/ FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDVRA500Q	Gallant [™] VR	21,030	2.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1411-36Q	Ellipse [™] VR	24,339	7.10%	5	0.02%	0	0.00%	0	0.00%	10	0.04%	0	0.00%	0	0.00%	0	0.00%	3	0.01%	18	0.07%
CD1411-36C	Ellipse [™] VR	7,646	9.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1357-40Q	Fortify Assura [™] VR	26,664	6.50%	2	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.01%	7	0.03%
CD1357-40Q	Fortify Assura [™] VR [†]	10,214	20.10%	5	0.05%	1	<0.01%	0	0.00%	2	0.02%	1	<0.01%	0	0.00%	68	0.67%	4	0.04%	81	0.79%
CD1357-40C	Fortify Assura [™] VR	6,748	7.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1357-40C	Fortify Assura [™] VR [†]	4,130	21.60%	3	0.07%	1	0.02%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	9	0.22%	0	0.00%	15	0.36%
CD1257-40Q	Fortify Assura [™] VR [†]	5,079	15.30%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	20	0.39%	1	0.02%	23	0.45%
CD1257-40	Fortify Assura [™] VR [†]	2,293	18.00%	2	0.09%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	7	0.31%	2	0.09%	14	0.61%
CD1311-36Q	Ellipse [™] VR	4,743	11.10%	3	0.06%	0	0.00%	0	0.00%	38	0.80%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	44	0.93%
CD1311-36	Ellipse [™] VR	1,621	13.40%	4	0.25%	1	0.06%	0	0.00%	8	0.49%	0	0.00%	2	0.12%	0	0.00%	2	0.12%	17	1.05%
CD1231-40Q	Fortify [™] VR [†]	16,339	16.80%	7	0.04%	2	0.01%	18	0.11%	2	0.01%	0	0.00%	0	0.00%	131	0.80%	9	0.06%	169	1.03%
CD1231-40	Fortify [™] VR [†]	6,782	18.00%	5	0.07%	0	0.00%	4	0.06%	10	0.15%	0	0.00%	0	0.00%	44	0.65%	6	0.09%	69	1.02%

Definitions of malfunction categories can be found on [pages 5-6](#).

†Premature battery depletion advisory population.

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

US Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDVRA500Q	Gallant [™] VR	21,030	2.30%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	8	0.04%
CD1411-36Q	Ellipse [™] VR	24,339	7.10%	8	0.03%	0	0.00%	2	<0.01%	7	0.03%	1	<0.01%	3	0.01%	2	<0.01%	5	0.02%	28	0.12%
CD1411-36C	Ellipse [™] VR	7,646	9.40%	9	0.12%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	1	0.01%	2	0.03%	15	0.20%
CD1357-40Q	Fortify Assura [™] VR	26,664	6.50%	11	0.04%	0	0.00%	6	0.02%	0	0.00%	1	<0.01%	1	<0.01%	2	<0.01%	4	0.02%	25	0.09%
CD1357-40Q	Fortify Assura [™] VR [†]	10,214	20.10%	8	0.08%	0	0.00%	9	0.09%	0	0.00%	0	0.00%	0	0.00%	776	7.60%	6	0.06%	799	7.82%
CD1357-40C	Fortify Assura [™] VR	6,748	7.80%	4	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	2	0.03%	9	0.13%
CD1357-40C	Fortify Assura [™] VR [†]	4,130	21.60%	3	0.07%	0	0.00%	6	0.15%	0	0.00%	1	0.02%	0	0.00%	247	5.98%	2	0.05%	259	6.27%
CD1257-40Q	Fortify Assura [™] VR [†]	5,079	15.30%	2	0.04%	0	0.00%	4	0.08%	0	0.00%	0	0.00%	0	0.00%	168	3.31%	2	0.04%	176	3.47%
CD1257-40	Fortify Assura [™] VR [†]	2,293	18.00%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	56	2.44%	1	0.04%	59	2.57%
CD1311-36Q	Ellipse [™] VR	4,743	11.10%	4	0.08%	1	0.02%	0	0.00%	16	0.34%	0	0.00%	0	0.00%	0	0.00%	5	0.11%	26	0.55%
CD1311-36	Ellipse [™] VR	1,621	13.40%	2	0.12%	0	0.00%	0	0.00%	4	0.25%	1	0.06%	1	0.06%	0	0.00%	0	0.00%	8	0.49%
CD1231-40Q	Fortify [™] VR [†]	16,339	16.80%	10	0.06%	0	0.00%	50	0.31%	1	<0.01%	1	<0.01%	0	0.00%	444	2.72%	7	0.04%	513	3.14%
CD1231-40	Fortify [™] VR [†]	6,782	18.00%	6	0.09%	0	0.00%	14	0.21%	4	0.06%	0	0.00%	1	0.01%	149	2.20%	6	0.09%	180	2.65%

Definitions of malfunction categories can be found on [pages 5-6](#).

†Premature battery depletion advisory population.

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDVRA500Q	Gallant™ VR	40,361	1.41%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1411-36Q	Ellipse™ VR	25,155	7.17%	10	0.04%	0	0.00%	0	0.00%	10	0.04%	0	0.00%	0	0.00%	0	0.00%	6	0.02%	26	0.10%
CD1411-36C	Ellipse™ VR	7,757	9.95%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1357-40Q	Fortify Assura™ VR	38,105	10.21%	14	0.04%	6	0.02%	0	0.00%	2	<0.01%	2	<0.01%	0	0.00%	136	0.36%	14	0.04%	174	0.46%
CD1357-40C	Fortify Assura™ VR	11,009	13.63%	6	0.05%	2	0.02%	0	0.00%	1	<0.01%	0	0.00%	2	0.02%	18	0.16%	0	0.00%	29	0.26%
CD1257-40Q	Fortify Assura™ VR	5,038	15.84%	2	0.04%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	40	0.79%	2	0.04%	46	0.91%
CD1257-40	Fortify Assura™ VR	2,298	18.71%	4	0.17%	4	0.17%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	14	0.61%	4	0.17%	28	1.22%
CD1311-36Q	Ellipse™ VR	4,912	11.38%	6	0.12%	0	0.00%	0	0.00%	38	0.77%	2	0.04%	2	0.04%	0	0.00%	2	0.04%	50	1.02%
CD1311-36	Ellipse™ VR	1,628	15.23%	8	0.49%	2	0.12%	0	0.00%	9	0.55%	0	0.00%	4	0.25%	0	0.00%	4	0.25%	27	1.66%
CD1231-40Q	Fortify™ VR†	18,772	15.42%	16	0.09%	4	0.02%	36	0.19%	2	0.01%	0	0.00%	0	0.00%	288	1.53%	18	0.10%	364	1.94%
CD1231-40	Fortify™ VR†	12,353	11.13%	18	0.15%	0	0.00%	10	0.08%	10	0.08%	0	0.00%	0	0.00%	96	0.78%	12	0.10%	146	1.18%

Definitions of malfunction categories can be found on [pages 5-6](#).

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Worldwide Malfunction Summary

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		HIGH VOLTAGE CAPACITOR		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
CDVRA500Q	Gallant™ VR	40,361	1.41%	28	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.01%	0	0.00%	2	<0.01%	36	0.09%
CD1411-36Q	Ellipse™ VR	25,155	7.17%	16	0.06%	0	0.00%	4	0.02%	7	0.03%	2	<0.01%	6	0.02%	4	0.02%	10	0.04%	49	0.19%
CD1411-36C	Ellipse™ VR	7,757	9.95%	18	0.23%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	2	0.03%	2	0.03%	4	0.05%	29	0.37%
CD1357-40Q	Fortify Assura™ VR	38,105	10.21%	38	0.10%	0	0.00%	30	0.08%	0	0.00%	2	<0.01%	2	<0.01%	1556	4.08%	20	0.05%	1648	4.32%
CD1357-40C	Fortify Assura™ VR	11,009	13.63%	16	0.15%	0	0.00%	12	0.11%	0	0.00%	2	0.02%	2	0.02%	498	4.52%	8	0.07%	538	4.89%
CD1257-40Q	Fortify Assura™ VR	5,038	15.84%	4	0.08%	0	0.00%	8	0.16%	0	0.00%	0	0.00%	0	0.00%	336	6.67%	4	0.08%	352	6.99%
CD1257-40	Fortify Assura™ VR	2,298	18.71%	0	0.00%	0	0.00%	4	0.17%	0	0.00%	0	0.00%	0	0.00%	112	4.87%	2	0.09%	118	5.13%
CD1311-36Q	Ellipse™ VR	4,912	11.38%	8	0.16%	2	0.04%	0	0.00%	16	0.33%	0	0.00%	0	0.00%	0	0.00%	10	0.20%	36	0.73%
CD1311-36	Ellipse™ VR	1,628	15.23%	4	0.25%	0	0.00%	0	0.00%	4	0.25%	2	0.12%	2	0.12%	0	0.00%	0	0.00%	12	0.74%
CD1231-40Q	Fortify™ VR†	18,772	15.42%	26	0.14%	2	0.01%	100	0.53%	1	<0.01%	2	0.01%	0	0.00%	980	5.22%	14	0.07%	1125	5.99%
CD1231-40	Fortify™ VR†	12,353	11.13%	16	0.13%	0	0.00%	32	0.26%	4	0.03%	0	0.00%	2	0.02%	328	2.66%	14	0.11%	396	3.21%

Definitions of malfunction categories can be found on [pages 5-6](#).

Defibrillation Leads

Defibrillation Leads

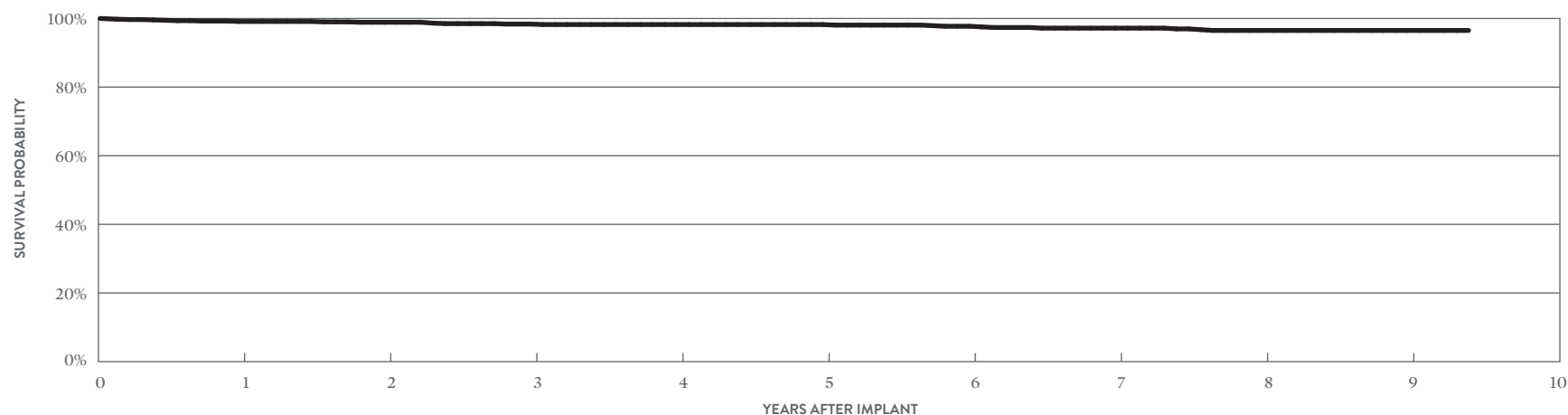
Optisure™ DF4

MODEL LDA230Q

US Regulatory Approval	February 2014
Registered US Implants	1,092
Estimated Active US Implants	479
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 199)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	0.09%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.09%	3	0.27%
Failure to Capture	0	0.00%	7	0.64%
Oversensing	0	0.00%	8	0.73%
Failure to Sense	0	0.00%	1	0.09%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.09%	3	0.27%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	1	0.09%	0	0.00%
Other	0	0.00%	0	0.00%
Total	4	0.37%	22	2.01%
Total Returned for Analysis	1		8	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	0.09%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.09%
Insulation Breach	3	0.27%
Lead-to-Can Contact	1	0.09%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	0.09%
Externalized Conductors	0	0.00%
Other	1	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.73%
Total	12	1.10%



YEAR	1	2	3	4	5	6	7	8	9	AT 113 MONTHS
SURVIVAL PROBABILITY	99.13%	98.89%	98.37%	98.23%	98.23%	97.73%	97.18%	96.51%	96.51%	96.51%
± 1 STANDARD ERROR	0.28%	0.35%	0.43%	0.45%	0.45%	0.54%	0.62%	0.73%	0.73%	0.73%
SAMPLE SIZE	970	830	750	690	640	580	510	430	320	200

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

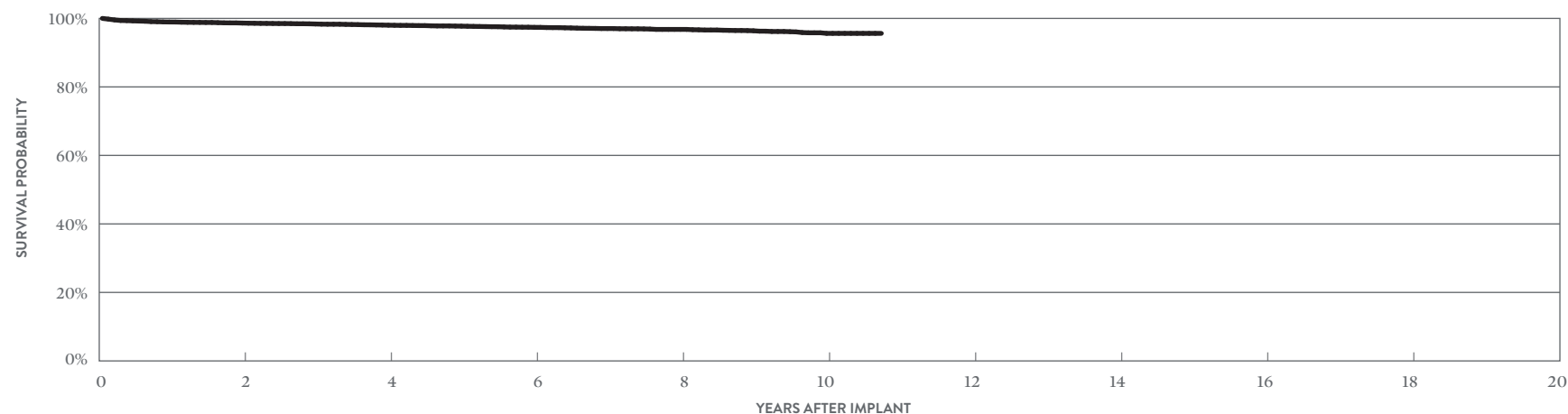
Optisure™ DF4

MODEL LDA220Q

US Regulatory Approval	February 2014
Registered US Implants	14,993
Estimated Active US Implants	7,501
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 199)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	16	0.11%	5	0.03%
Conductor Fracture	0	0.00%	9	0.06%
Lead Dislodgement	65	0.43%	100	0.67%
Failure to Capture	31	0.21%	114	0.76%
Oversensing	7	0.05%	102	0.68%
Failure to Sense	3	0.02%	11	0.07%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	0	0.00%	24	0.16%
Abnormal Defibrillation Impedance	5	0.03%	29	0.19%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	8	0.05%	11	0.07%
Total	136	0.91%	408	2.72%
Total Returned for Analysis	49		103	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	<0.01%
Insulation Breach	10	0.07%
Lead-to-Can Contact	4	0.03%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	2	0.01%
Externalized Conductors	0	0.00%
Other	3	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	92	0.61%
Total	103	0.69%



YEAR	2	4	6	8	10	AT 129 MONTHS
SURVIVAL PROBABILITY	98.64%	98.02%	97.39%	96.79%	95.63%	95.63%
± 1 STANDARD ERROR	0.10%	0.13%	0.16%	0.19%	0.29%	0.31%
SAMPLE SIZE	11,580	8,840	6,410	4,100	1,690	270

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

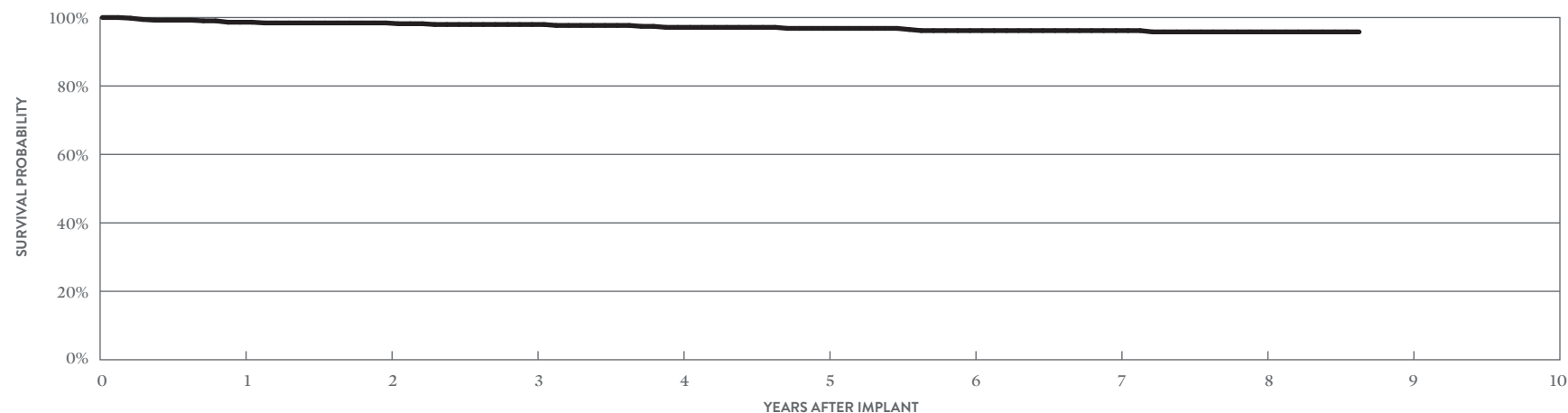
Optisure™

MODEL LDA220

US Regulatory Approval	February 2014
Registered US Implants	670
Estimated Active US Implants	282
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 199)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	0.15%	0	0.00%
Conductor Fracture	0	0.00%	1	0.15%
Lead Dislodgement	0	0.00%	5	0.75%
Failure to Capture	0	0.00%	5	0.75%
Oversensing	0	0.00%	7	1.05%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	3	0.45%
Abnormal Defibrillation Impedance	0	0.00%	1	0.15%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	1	0.15%	22	3.30%
Total Returned for Analysis	0		4	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.90%
Total	6	0.90%



YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	98.63%	98.42%	97.96%	97.13%	96.83%	96.18%	96.18%	95.80%	95.80%
± 1 STANDARD ERROR	0.51%	0.55%	0.64%	0.79%	0.85%	0.96%	0.96%	1.03%	1.03%
SAMPLE SIZE	570	450	410	360	320	300	270	240	210

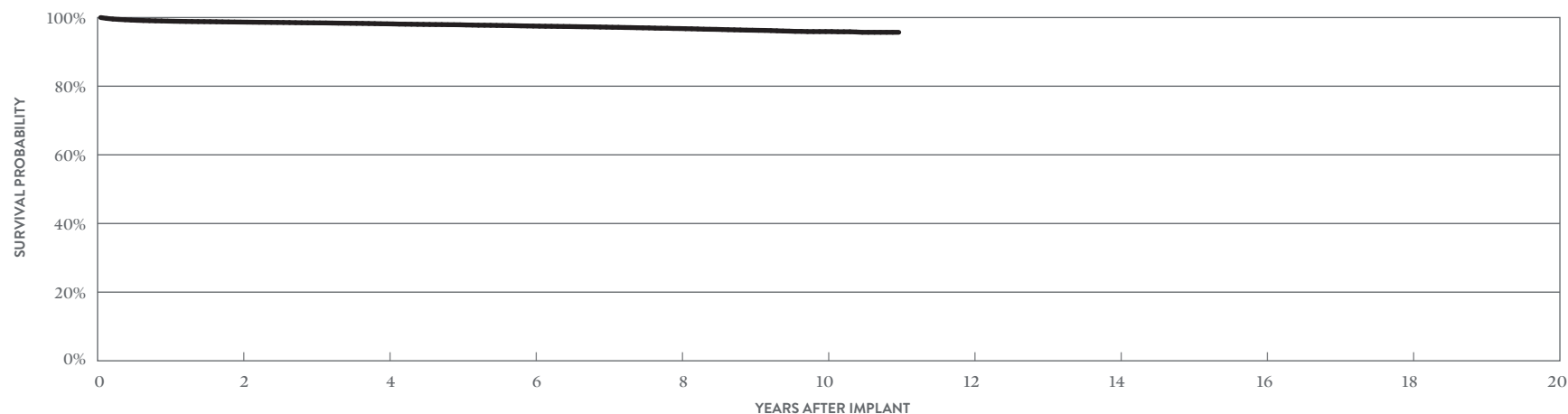
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Optisure™ DF4

MODEL LDA210Q

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)		MALFUNCTIONS			
		QTY	RATE	QTY	RATE		QTY	RATE	
US Regulatory Approval	February 2014	Cardiac Perforation	162	0.19%	46	0.05%	Conductor Fracture	9	0.01%
Registered US Implants	84,049	Conductor Fracture	3	<0.01%	45	0.05%	Clavicular Crush	1	<0.01%
Estimated Active US Implants	45,690	Lead Dislodgement	257	0.31%	514	0.61%	In the Pocket	2	<0.01%
Insulation	Optim*	Failure to Capture	159	0.19%	442	0.53%	Intravascular	6	<0.01%
Type and/or Fixation	Single Coil, Active	Oversensing	52	0.06%	377	0.45%	Insulation Breach	37	0.04%
Polarity	Bipolar	Failure to Sense	18	0.02%	39	0.05%	Lead-to-Can Contact	20	0.02%
Steroid	Yes	Insulation Breach	5	<0.01%	3	<0.01%	Lead-to-Lead Contact	12	0.01%
Number of US Advisories	None	Abnormal Pacing Impedance	10	0.01%	94	0.11%	Clavicular Crush	1	<0.01%
		Abnormal Defibrillation Impedance	12	0.01%	80	0.10%	Externalized Conductors	0	0.00%
		Extracardiac Stimulation	7	<0.01%	8	<0.01%	Other	4	<0.01%
		Other	22	0.03%	64	0.08%	Crimps, Welds & Bonds	0	0.00%
		Total	707	0.84%	1712	2.04%	Other	6	<0.01%
		Total Returned for Analysis	256		527		Extrinsic Factors	494	0.59%
							Total	546	0.65%



YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	98.68%	98.17%	97.52%	96.80%	95.91%	95.70%
± 1 STANDARD ERROR	0.04%	0.05%	0.07%	0.10%	0.15%	0.20%
SAMPLE SIZE	59,820	39,870	24,910	13,180	4,390	210

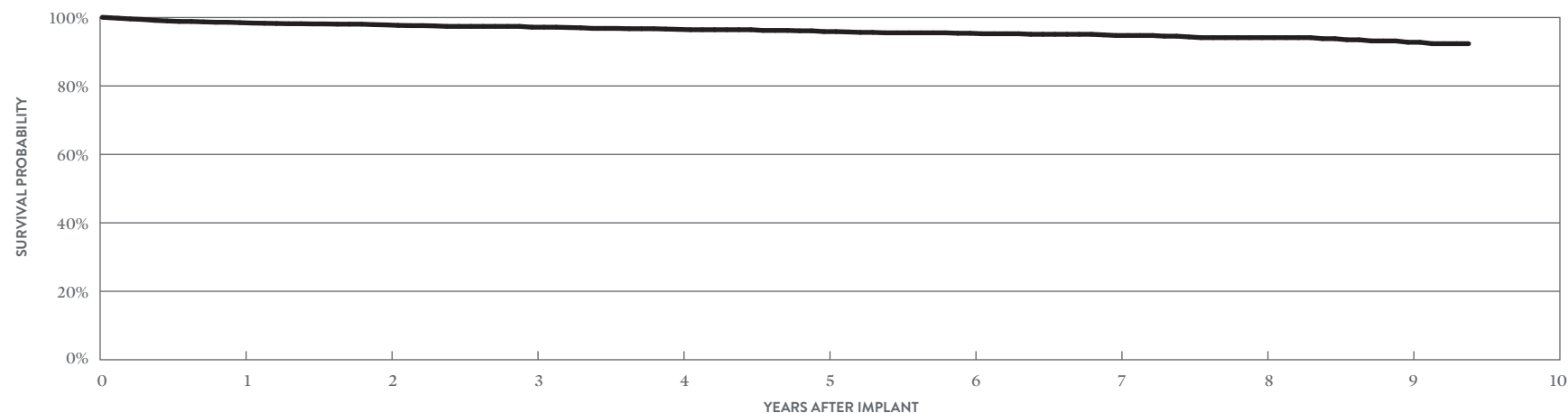
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Optisure™

MODEL LDA210

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)		MALFUNCTIONS			
		QTY	RATE	QTY	RATE	QTY	RATE		
US Regulatory Approval	February 2014	Cardiac Perforation	3	0.14%	1	0.05%	Conductor Fracture	0	0.00%
Registered US Implants	2,191	Conductor Fracture	0	0.00%	5	0.23%	Clavicular Crush	0	0.00%
Estimated Active US Implants	1,091	Lead Dislodgement	9	0.41%	13	0.59%	In the Pocket	0	0.00%
Insulation	Optim™*	Failure to Capture	4	0.18%	16	0.73%	Intravascular	0	0.00%
Type and/or Fixation	Single Coil, Active	Oversensing	4	0.18%	42	1.92%	Insulation Breach	3	0.14%
Polarity	Bipolar	Failure to Sense	0	0.00%	0	0.00%	Lead-to-Can Contact	0	0.00%
Steroid	Yes	Insulation Breach	0	0.00%	0	0.00%	Lead-to-Lead Contact	2	0.09%
Number of US Advisories	None	Abnormal Pacing Impedance	0	0.00%	12	0.55%	Clavicular Crush	1	0.05%
		Abnormal Defibrillation Impedance	0	0.00%	3	0.14%	Externalized Conductors	0	0.00%
		Extracardiac Stimulation	0	0.00%	2	0.09%	Other	0	0.00%
		Other	1	0.05%	2	0.09%	Crimps, Welds & Bonds	0	0.00%
		Total	21	0.96%	96	4.38%	Other	0	0.00%
		Total Returned for Analysis	8		24		Extrinsic Factors	23	1.05%
							Total	26	1.19%



YEAR	1	2	3	4	5	6	7	8	9	AT 113 MONTHS
SURVIVAL PROBABILITY	98.50%	97.85%	97.17%	96.54%	95.89%	95.40%	94.75%	94.12%	92.77%	92.36%
± 1 STANDARD ERROR	0.27%	0.34%	0.39%	0.46%	0.52%	0.59%	0.65%	0.76%	0.93%	1.08%
SAMPLE SIZE	1,880	1,510	1,280	1,090	920	760	600	440	300	200

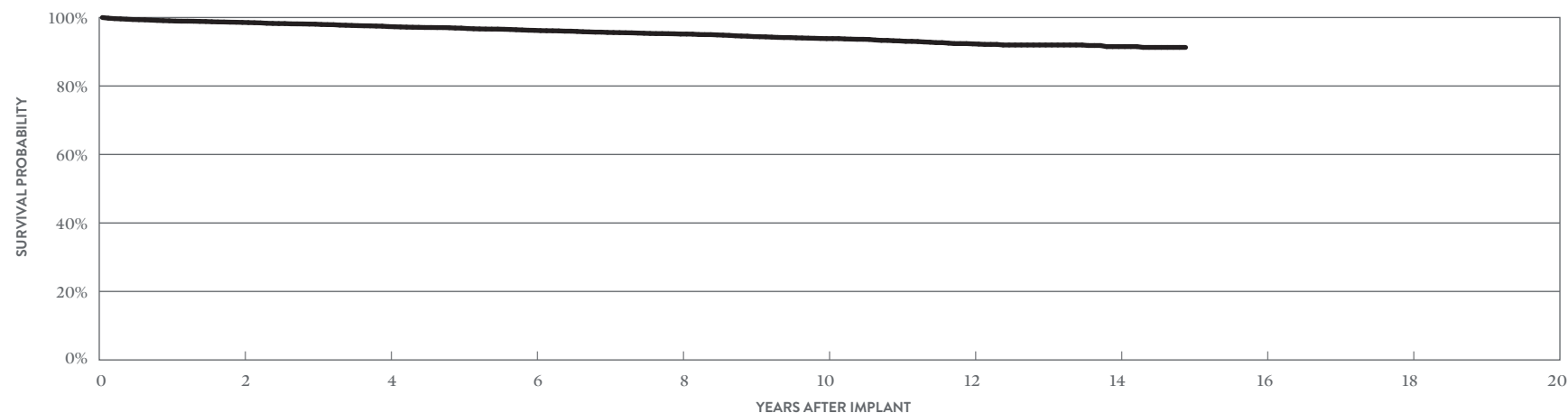
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Durata™ DF4

MODELS 7170Q & 7171Q

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)		MALFUNCTIONS			
		QTY	RATE	QTY	RATE	QTY	RATE		
US Regulatory Approval	July 2009	Cardiac Perforation	6	0.08%	8	0.10%	Conductor Fracture	6	0.08%
Registered US Implants	7,632	Conductor Fracture	1	0.01%	36	0.47%	Clavicular Crush	0	0.00%
Estimated Active US Implants	2,542	Lead Dislodgement	26	0.34%	42	0.55%	In the Pocket	3	0.04%
Insulation	Optim™*	Failure to Capture	14	0.18%	100	1.31%	Intravascular	3	0.04%
Type and/or Fixation	Dual Coil, Passive	Oversensing	4	0.05%	90	1.18%	Insulation Breach	20	0.26%
Polarity	Bipolar	Failure to Sense	0	0.00%	2	0.03%	Lead-to-Can Contact	12	0.16%
Steroid	Yes	Insulation Breach	0	0.00%	6	0.08%	Lead-to-Lead Contact	5	0.07%
Number of US Advisories	None	Abnormal Pacing Impedance	1	0.01%	32	0.42%	Clavicular Crush	1	0.01%
		Abnormal Defibrillation Impedance	0	0.00%	26	0.34%	Externalized Conductors	0	0.00%
		Extracardiac Stimulation	1	0.01%	0	0.00%	Other	2	0.03%
		Other	1	0.01%	5	0.07%	Crimps, Welds & Bonds	0	0.00%
		Total	54	0.71%	347	4.55%	Other	0	0.00%
		Total Returned for Analysis	23		82		Extrinsic Factors	61	0.80%
							Total	87	1.14%



YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	98.57%	97.35%	96.25%	95.17%	93.84%	92.30%	91.50%	91.27%
± 1 STANDARD ERROR	0.14%	0.21%	0.26%	0.31%	0.38%	0.48%	0.58%	0.62%
SAMPLE SIZE	5,930	4,800	3,880	3,050	2,220	1,410	660	210

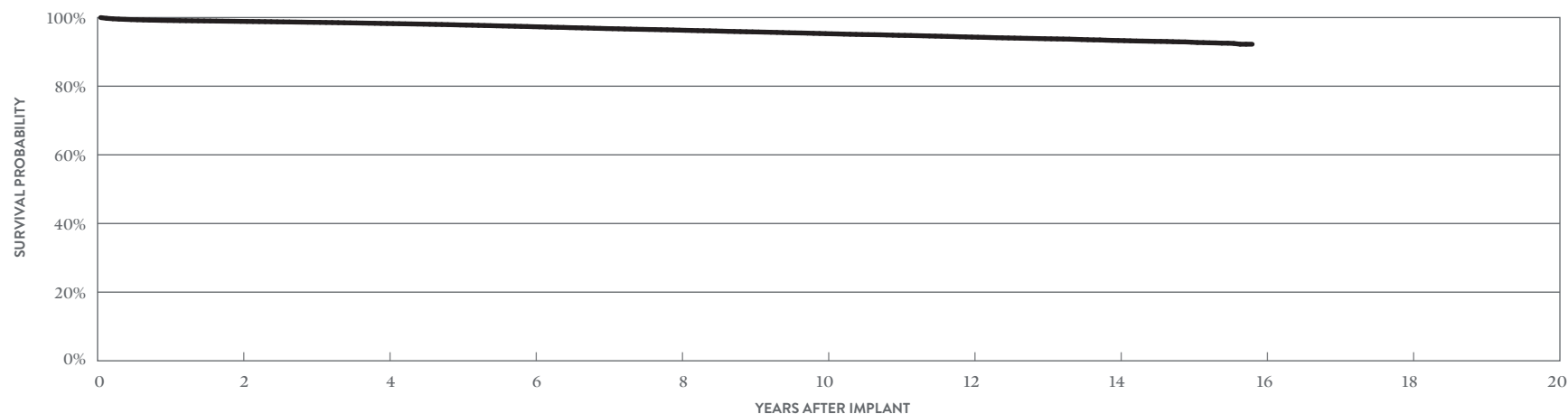
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Durata™ DF4

MODELS 7120Q & 7121Q

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)					
		QTY	RATE	QTY	RATE	MALFUNCTIONS	QTY	RATE	
US Regulatory Approval	January 2009	Cardiac Perforation	116	0.08%	58	0.04%	Conductor Fracture	44	0.03%
Registered US Implants	152,226	Conductor Fracture	2	<0.01%	336	0.22%	Clavicular Crush	7	<0.01%
Estimated Active US Implants	52,425	Lead Dislodgement	347	0.23%	818	0.54%	In the Pocket	13	<0.01%
Insulation	Optim™*	Failure to Capture	164	0.11%	1403	0.92%	Intravascular	24	0.02%
Type and/or Fixation	Dual Coil, Active	Oversensing	59	0.04%	1552	1.02%	Insulation Breach	465	0.31%
Polarity	Bipolar	Failure to Sense	17	0.01%	125	0.08%	Lead-to-Can Contact	282	0.19%
Steroid	Yes	Insulation Breach	0	0.00%	102	0.07%	Lead-to-Lead Contact	50	0.03%
Number of US Advisories	None	Abnormal Pacing Impedance	7	<0.01%	331	0.22%	Clavicular Crush	38	0.02%
		Abnormal Defibrillation Impedance	11	<0.01%	748	0.49%	Externalized Conductors	0	0.00%
		Extracardiac Stimulation	8	<0.01%	11	<0.01%	Other	95	0.06%
		Other	50	0.03%	138	0.09%	Crimps, Welds & Bonds	2	<0.01%
		Total	781	0.51%	5622	3.69%	Other	39	0.03%
		Total Returned for Analysis	369		1469		Extrinsic Factors	1074	0.71%
							Total	1624	1.07%



YEAR	2	4	6	8	10	12	14	AT 190 MONTHS
SURVIVAL PROBABILITY	98.88%	98.26%	97.33%	96.33%	95.31%	94.31%	93.31%	92.23%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.06%	0.07%	0.09%	0.11%	0.24%
SAMPLE SIZE	122,970	100,390	82,180	66,810	52,110	35,680	18,140	340

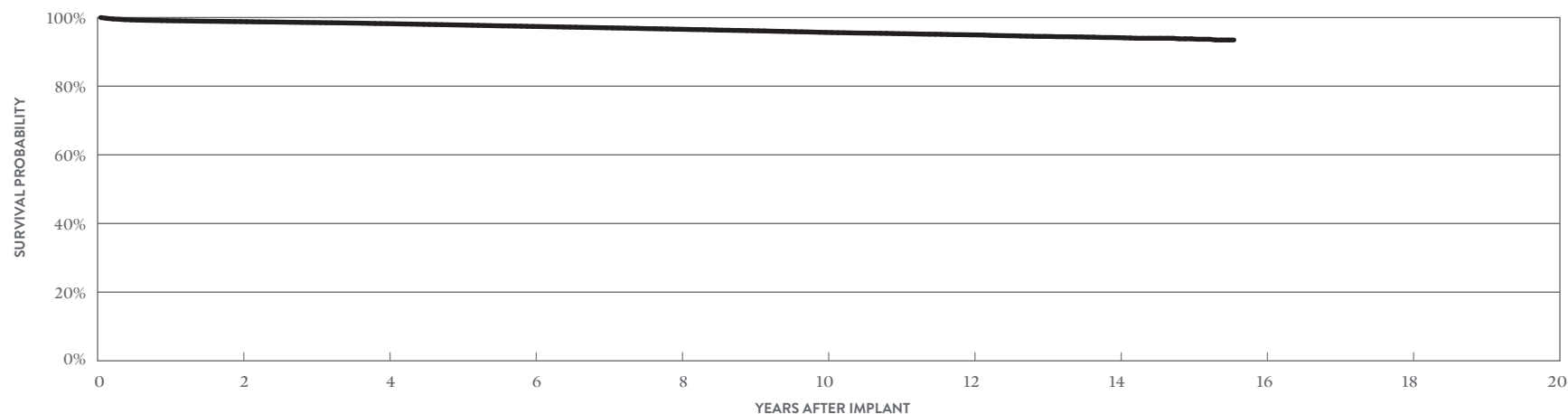
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Durata™ DF4

MODEL 7122Q

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)		MALFUNCTIONS			
		QTY	RATE	QTY	RATE		QTY	RATE	
US Regulatory Approval	January 2009	Cardiac Perforation	258	0.13%	90	0.05%	Conductor Fracture	30	0.02%
Registered US Implants	196,577	Conductor Fracture	4	<0.01%	171	0.09%	Clavicular Crush	6	<0.01%
Estimated Active US Implants	90,141	Lead Dislodgement	519	0.26%	1112	0.57%	In the Pocket	11	<0.01%
Insulation	Optim™*	Failure to Capture	304	0.15%	1239	0.63%	Intravascular	13	<0.01%
Type and/or Fixation	Single Coil, Active	Oversensing	94	0.05%	1151	0.59%	Insulation Breach	340	0.17%
Polarity	Bipolar	Failure to Sense	18	<0.01%	107	0.05%	Lead-to-Can Contact	219	0.11%
Steroid	Yes	Insulation Breach	2	<0.01%	67	0.03%	Lead-to-Lead Contact	48	0.02%
Number of US Advisories	None	Abnormal Pacing Impedance	20	0.01%	276	0.14%	Clavicular Crush	25	0.01%
		Abnormal Defibrillation Impedance	16	<0.01%	264	0.13%	Externalized Conductors	0	0.00%
		Extracardiac Stimulation	6	<0.01%	18	<0.01%	Other	48	0.02%
		Other	64	0.03%	157	0.08%	Crimps, Welds & Bonds	1	<0.01%
		Total	1305	0.66%	4652	2.37%	Other	23	0.01%
		Total Returned for Analysis	499		1426		Extrinsic Factors	1178	0.60%
							Total	1572	0.80%



YEAR	2	4	6	8	10	12	14	AT 187 MONTHS
SURVIVAL PROBABILITY	98.81%	98.22%	97.41%	96.59%	95.67%	94.95%	94.15%	93.46%
± 1 STANDARD ERROR	0.03%	0.03%	0.05%	0.06%	0.08%	0.10%	0.15%	0.33%
SAMPLE SIZE	144,230	102,890	72,150	48,460	29,830	13,810	4,220	220

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

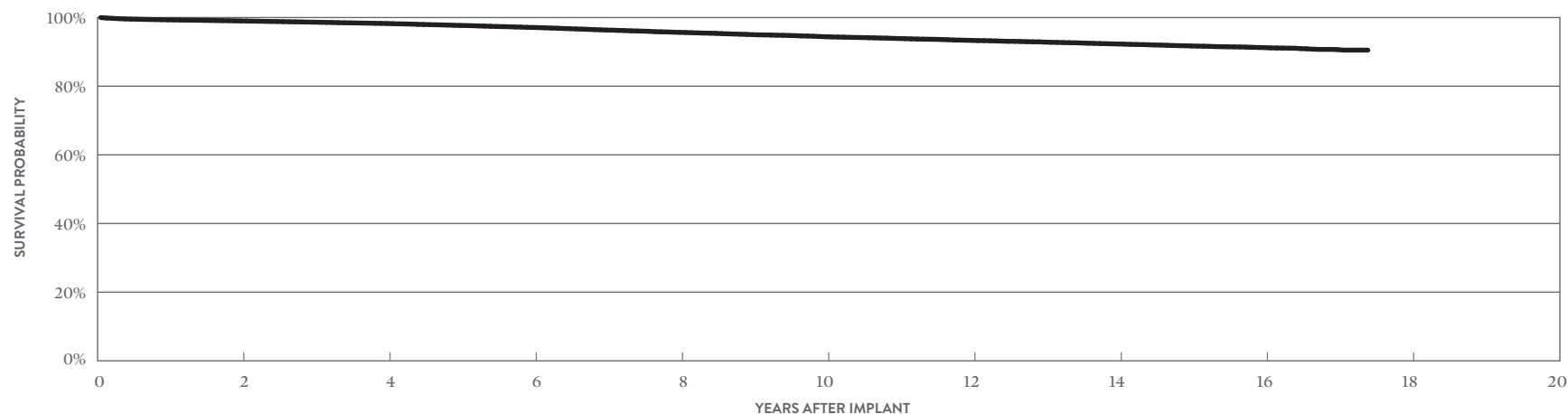
Durata™

MODELS 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	64,445
Estimated Active US Implants	15,651
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	42	0.07%	19	0.03%
Conductor Fracture	3	<0.01%	218	0.34%
Lead Dislodgement	82	0.13%	217	0.34%
Failure to Capture	29	0.04%	511	0.79%
Oversensing	52	0.08%	1124	1.74%
Failure to Sense	5	<0.01%	81	0.13%
Insulation Breach	0	0.00%	82	0.13%
Abnormal Pacing Impedance	2	<0.01%	268	0.42%
Abnormal Defibrillation Impedance	23	0.04%	447	0.69%
Extracardiac Stimulation	1	<0.01%	4	<0.01%
Other	22	0.03%	73	0.11%
Total	261	0.40%	3044	4.72%
Total Returned for Analysis	98		716	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	35	0.05%
Clavicular Crush	2	<0.01%
In the Pocket	24	0.04%
Intravascular	9	0.01%
Insulation Breach	256	0.40%
Lead-to-Can Contact	136	0.21%
Lead-to-Lead Contact	50	0.08%
Clavicular Crush	19	0.03%
Externalized Conductors	0	0.00%
Other	51	0.08%
Crimps, Welds & Bonds	1	<0.01%
Other	10	0.02%
Extrinsic Factors	499	0.77%
Total	801	1.24%



YEAR	2	4	6	8	10	12	14	16	AT 209 MONTHS
SURVIVAL PROBABILITY	99.01%	98.26%	97.11%	95.68%	94.41%	93.34%	92.30%	91.24%	90.51%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.10%	0.12%	0.14%	0.16%	0.18%	0.24%
SAMPLE SIZE	51,220	41,520	34,220	28,700	24,680	20,910	16,650	9,960	220

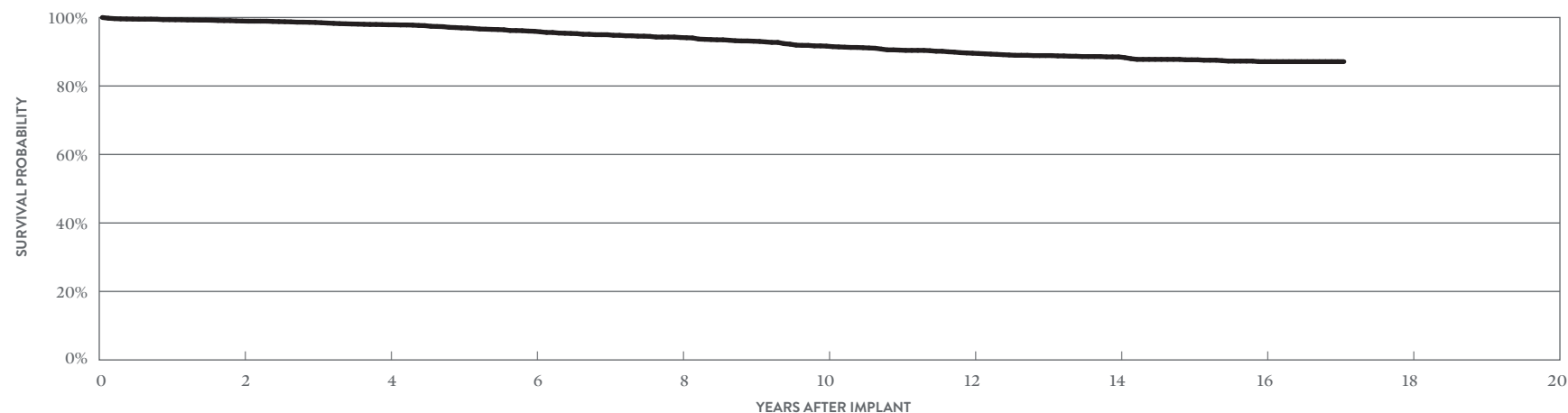
*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Riata™ ST Optim™

MODELS 7070 & 7071

		ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)		MALFUNCTIONS		QTY	RATE
		QTY	RATE	QTY	RATE			QTY	RATE
US Regulatory Approval	July 2006	Cardiac Perforation	3	0.08%	3	0.08%	Conductor Fracture	4	0.11%
Registered US Implants	3,660	Conductor Fracture	1	0.03%	32	0.87%	Clavicular Crush	0	0.00%
Estimated Active US Implants	725	Lead Dislodgement	4	0.11%	16	0.44%	In the Pocket	0	0.00%
Insulation	Optim™*	Failure to Capture	6	0.16%	48	1.31%	Intravascular	4	0.11%
Type and/or Fixation	Dual Coil, Passive	Oversensing	4	0.11%	81	2.21%	Insulation Breach	25	0.68%
Polarity	Bipolar	Failure to Sense	4	0.11%	3	0.08%	Lead-to-Can Contact	11	0.30%
Steroid	Yes	Insulation Breach	0	0.00%	9	0.25%	Lead-to-Lead Contact	4	0.11%
Number of US Advisories	None	Abnormal Pacing Impedance	0	0.00%	18	0.49%	Clavicular Crush	2	0.05%
		Abnormal Defibrillation Impedance	0	0.00%	27	0.74%	Externalized Conductors	1	0.03%
		Extracardiac Stimulation	0	0.00%	1	0.03%	Other	7	0.19%
		Other	0	0.00%	3	0.08%	Crimps, Welds & Bonds	0	0.00%
		Total	22	0.60%	241	6.58%	Other	0	0.00%
		Total Returned for Analysis	6		56		Extrinsic Factors	25	0.68%
							Total	54	1.48%



YEAR	2	4	6	8	10	12	14	16	AT 205 MONTHS
SURVIVAL PROBABILITY	98.97%	97.88%	95.98%	94.16%	91.64%	89.57%	88.50%	87.11%	87.11%
± 1 STANDARD ERROR	0.18%	0.28%	0.42%	0.52%	0.66%	0.76%	0.81%	0.89%	0.89%
SAMPLE SIZE	2,730	2,160	1,760	1,490	1,280	1,100	930	630	210

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

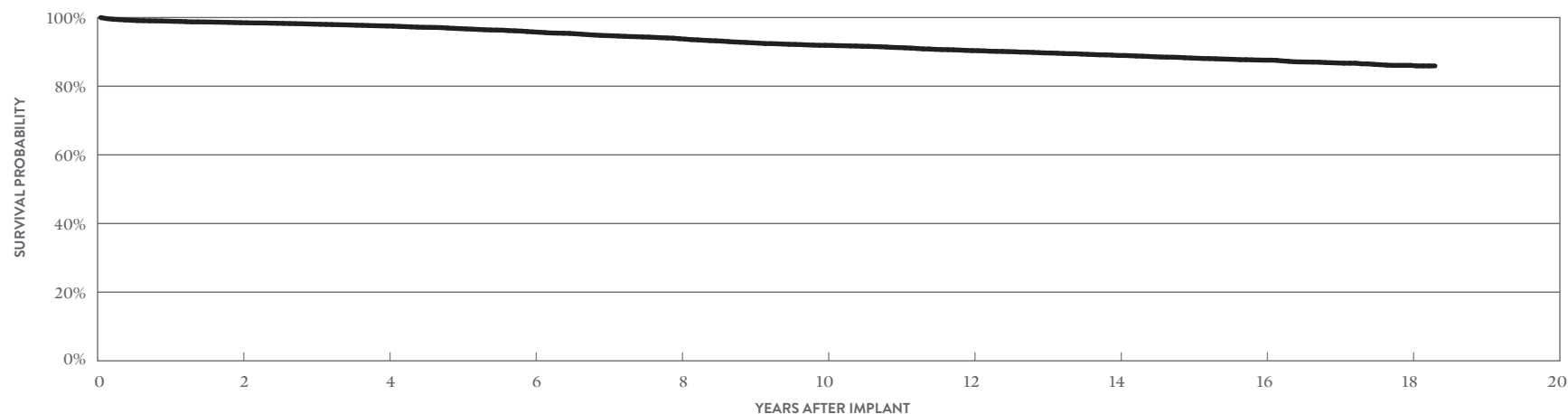
Riata™ ST Optim™

MODELS 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,876
Estimated Active US Implants	3,080
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	39	0.25%	21	0.13%
Conductor Fracture	0	0.00%	87	0.55%
Lead Dislodgement	37	0.23%	76	0.48%
Failure to Capture	20	0.13%	214	1.35%
Oversensing	20	0.13%	360	2.27%
Failure to Sense	8	0.05%	27	0.17%
Insulation Breach	0	0.00%	35	0.22%
Abnormal Pacing Impedance	2	0.01%	72	0.45%
Abnormal Defibrillation Impedance	5	0.03%	144	0.91%
Extracardiac Stimulation	5	0.03%	2	0.01%
Other	0	0.00%	34	0.21%
Total	136	0.86%	1072	6.75%
Total Returned for Analysis	61		277	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	14	0.09%
Clavicular Crush	1	<0.01%
In the Pocket	8	0.05%
Intravascular	5	0.03%
Insulation Breach	84	0.53%
Lead-to-Can Contact	40	0.25%
Lead-to-Lead Contact	12	0.08%
Clavicular Crush	7	0.04%
Externalized Conductors	0	0.00%
Other	25	0.16%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	203	1.28%
Total	301	1.90%



YEAR	2	4	6	8	10	12	14	16	18	AT 220 MONTHS
SURVIVAL PROBABILITY	98.50%	97.53%	95.81%	93.83%	91.91%	90.37%	88.95%	87.59%	86.07%	85.91%
± 1 STANDARD ERROR	0.10%	0.14%	0.19%	0.25%	0.30%	0.34%	0.38%	0.41%	0.47%	0.49%
SAMPLE SIZE	12,280	9,640	7,810	6,440	5,480	4,820	4,240	3,560	1,650	250

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

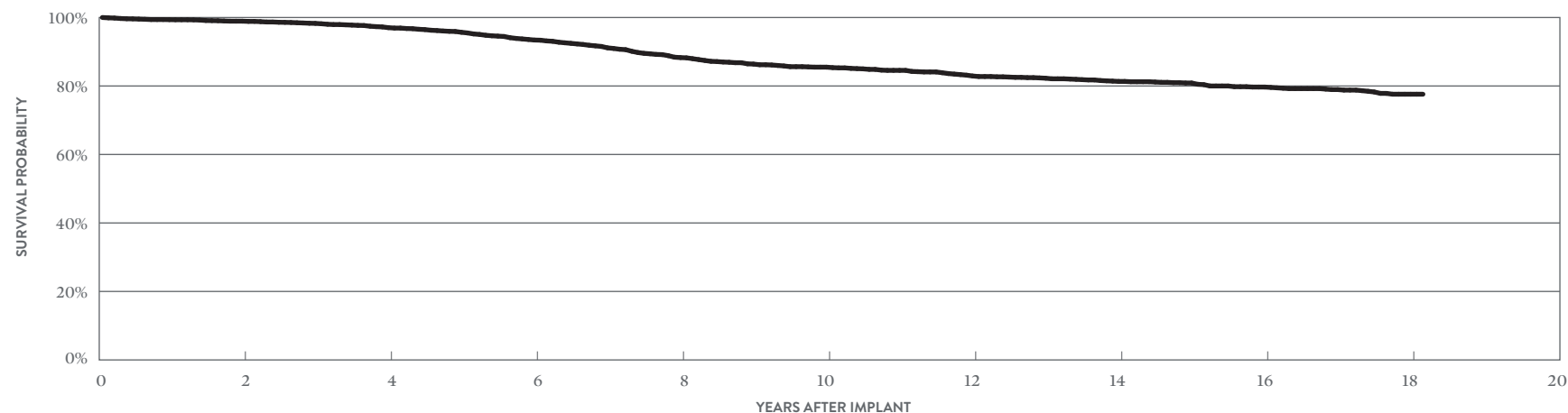
Riata™ ST

MODELS 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,133
Estimated Active US Implants	698
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 200)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	4	0.10%	4	0.10%
Conductor Fracture	0	0.00%	41	0.99%
Lead Dislodgement	5	0.12%	5	0.12%
Failure to Capture	1	0.02%	59	1.43%
Oversensing	4	0.10%	133	3.22%
Failure to Sense	0	0.00%	16	0.39%
Insulation Breach	0	0.00%	67	1.62%
Abnormal Pacing Impedance	2	0.05%	23	0.56%
Abnormal Defibrillation Impedance	0	0.00%	40	0.97%
Extracardiac Stimulation	0	0.00%	1	0.02%
Other	1	0.02%	13	0.31%
Total	17	0.41%	402	9.73%
Total Returned for Analysis	3		90	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	4	0.10%
Clavicular Crush	0	0.00%
In the Pocket	1	0.02%
Intravascular	3	0.07%
Insulation Breach	75	1.81%
Lead-to-Can Contact	36	0.87%
Lead-to-Lead Contact	22	0.53%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.05%
Other	15	0.36%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	33	0.80%
Total	113	2.73%



YEAR	2	4	6	8	10	12	14	16	18	AT 218 MONTHS
SURVIVAL PROBABILITY	98.93%	97.03%	93.42%	88.29%	85.50%	82.92%	81.33%	79.69%	77.60%	77.60%
± 1 STANDARD ERROR	0.18%	0.31%	0.51%	0.72%	0.82%	0.90%	0.95%	1.02%	1.15%	1.15%
SAMPLE SIZE	3,140	2,440	1,890	1,480	1,240	1,090	950	790	390	230

Defibrillation Leads

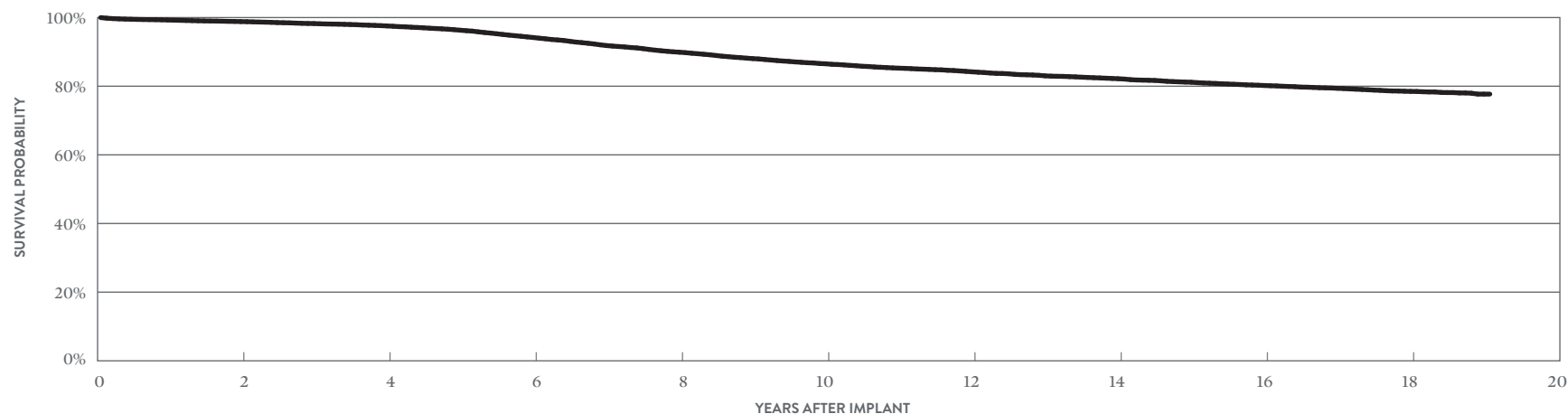
Riata™ ST

MODELS 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	35,583
Estimated Active US Implants	5,829
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 200)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	42	0.12%	35	0.10%
Conductor Fracture	0	0.00%	197	0.55%
Lead Dislodgement	39	0.11%	62	0.17%
Failure to Capture	43	0.12%	421	1.18%
Oversensing	40	0.11%	1111	3.12%
Failure to Sense	7	0.02%	66	0.19%
Insulation Breach	2	<0.01%	825	2.32%
Abnormal Pacing Impedance	8	0.02%	152	0.43%
Abnormal Defibrillation Impedance	4	0.01%	306	0.86%
Extracardiac Stimulation	3	<0.01%	7	0.02%
Other	11	0.03%	107	0.30%
Total	199	0.56%	3289	9.24%
Total Returned for Analysis	97		876	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	26	0.07%
Clavicular Crush	4	0.01%
In the Pocket	8	0.02%
Intravascular	14	0.04%
Insulation Breach	707	1.99%
Lead-to-Can Contact	370	1.04%
Lead-to-Lead Contact	185	0.52%
Clavicular Crush	12	0.03%
Externalized Conductors	46	0.13%
Other	94	0.26%
Crimps, Welds & Bonds	2	<0.01%
Other	1	<0.01%
Extrinsic Factors	349	0.98%
Total	1085	3.05%



YEAR	2	4	6	8	10	12	14	16	18	AT 229 MONTHS
SURVIVAL PROBABILITY	98.82%	97.55%	94.18%	89.90%	86.53%	84.19%	82.18%	80.20%	78.48%	77.70%
± 1 STANDARD ERROR	0.06%	0.09%	0.16%	0.22%	0.27%	0.30%	0.32%	0.35%	0.37%	0.44%
SAMPLE SIZE	28,100	21,800	16,880	13,180	10,720	9,310	8,190	7,050	4,560	360

SUMMARY INFORMATION
Defibrillation Leads

Defibrillation Leads

Survival Probability Summary

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
LDA230Q	Optisure™ DF4	99.13%	98.89%	98.37%	98.23%	98.23%	97.73%	97.18%	96.51%	96.51%	
LDA220Q	Optisure™ DF4	98.95%	98.64%	98.37%	98.02%	97.74%	97.39%	97.04%	96.79%	96.39%	95.63%
LDA220	Optisure™	98.63%	98.42%	97.96%	97.13%	96.83%	96.18%	96.18%	95.80%		
LDA210Q	Optisure™ DF4	98.96%	98.68%	98.46%	98.17%	97.89%	97.52%	97.21%	96.80%	96.31%	95.91%
LDA210	Optisure™	98.50%	97.85%	97.17%	96.54%	95.89%	95.40%	94.75%	94.12%	92.77%	
7170Q/7171Q	Durata™ DF4	99.04%	98.57%	98.06%	97.35%	96.90%	96.25%	95.64%	95.17%	94.43%	93.84%
7120Q/7121Q	Durata™ DF4	99.15%	98.88%	98.61%	98.26%	97.84%	97.33%	96.79%	96.33%	95.83%	95.31%
7122Q	Durata™ DF4	99.09%	98.81%	98.54%	98.22%	97.83%	97.41%	97.02%	96.59%	96.16%	95.67%
7120/7121	Durata™	99.33%	99.01%	98.65%	98.26%	97.70%	97.11%	96.36%	95.68%	95.01%	94.41%
7070/7071	Riata™ ST Optim™	99.37%	98.97%	98.56%	97.88%	96.96%	95.98%	94.98%	94.16%	93.08%	91.64%
7020/7021	Riata™ ST Optim™	98.94%	98.50%	98.09%	97.53%	96.77%	95.81%	94.73%	93.83%	92.63%	91.91%
7040/7041	Riata™ ST	99.37%	98.93%	98.28%	97.03%	95.68%	93.42%	91.14%	88.29%	86.40%	85.50%
7000/7001	Riata™ ST	99.28%	98.82%	98.25%	97.55%	96.31%	94.18%	91.84%	89.90%	88.04%	86.53%

Defibrillation Leads

Acute Observation Summary

POST IMPLANT ≤30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLODGE MENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		ABNORMAL DEFIBRILLATION IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
LDA230Q	Feb-14	1,092	479	1	0.09%	0	0.00%	1	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.09%	0	0.00%	1	0.09%	0	0.00%	4	0.37%	1
LDA220Q	Feb-14	14,993	7,501	16	0.11%	0	0.00%	65	0.43%	31	0.21%	7	0.05%	3	0.02%	0	0.00%	0	0.00%	5	0.03%	1	<0.01%	8	0.05%	136	0.91%	49
LDA220	Feb-14	670	282	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	0
LDA210Q	Feb-14	84,049	45,690	162	0.19%	3	<0.01%	257	0.31%	159	0.19%	52	0.06%	18	0.02%	5	<0.01%	10	0.01%	12	0.01%	7	<0.01%	22	0.03%	707	0.84%	256
LDA210	Feb-14	2,191	1,091	3	0.14%	0	0.00%	9	0.41%	4	0.18%	4	0.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.05%	21	0.96%	8
7170Q/7171Q	Jul-09	7,632	2,542	6	0.08%	1	0.01%	26	0.34%	14	0.18%	4	0.05%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	54	0.71%	23
7120Q/7121Q	Jan-09	152,226	52,425	116	0.08%	2	<0.01%	347	0.23%	164	0.11%	59	0.04%	17	0.01%	0	0.00%	7	<0.01%	11	<0.01%	8	<0.01%	50	0.03%	781	0.51%	369
7122Q	Jan-09	196,577	90,141	258	0.13%	4	<0.01%	519	0.26%	304	0.15%	94	0.05%	18	<0.01%	2	<0.01%	20	0.01%	16	<0.01%	6	<0.01%	64	0.03%	1305	0.66%	499
7120/7121	Sep-07	64,445	15,651	42	0.07%	3	<0.01%	82	0.13%	29	0.04%	52	0.08%	5	<0.01%	0	0.00%	2	<0.01%	23	0.04%	1	<0.01%	22	0.03%	261	0.40%	98
7070/7071	Jul-06	3,660	785	3	0.08%	1	0.03%	4	0.11%	6	0.16%	4	0.11%	4	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	22	0.60%	6
7020/7021	Jul-06	15,876	3,080	39	0.25%	0	0.00%	37	0.23%	20	0.13%	20	0.13%	8	0.05%	0	0.00%	2	0.01%	5	0.03%	5	0.03%	0	0.00%	136	0.86%	61
7040/7041	Mar-06	4,133	698	4	0.10%	0	0.00%	5	0.12%	1	0.02%	4	0.10%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	17	0.41%	3
7000/7001	Jun-05	35,583	5,829	42	0.12%	0	0.00%	39	0.11%	43	0.12%	40	0.11%	7	0.02%	2	<0.01%	8	0.02%	4	0.01%	3	<0.01%	11	0.03%	199	0.56%	97

Definitions of observations and complications can be found on [page 7](#).

Defibrillation Leads

Chronic Complication Summary

>30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLODGEMENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		ABNORMAL DEFIBRILLATION IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
LDA230Q	Feb-14	1,092	479	0	0.00%	0	0.00%	3	0.27%	7	0.64%	8	0.73%	1	0.09%	0	0.00%	3	0.27%	0	0.00%	0	0.00%	0	0.00%	22	2.01%	8
LDA220Q	Feb-14	14,993	7,501	5	0.03%	9	0.06%	100	0.67%	114	0.76%	102	0.68%	11	0.07%	3	0.02%	24	0.16%	29	0.19%	0	0.00%	11	0.07%	408	2.72%	103
LDA220	Feb-14	670	282	0	0.00%	1	0.15%	5	0.75%	5	0.75%	7	1.04%	0	0.00%	0	0.00%	3	0.45%	1	0.15%	0	0.00%	0	0.00%	22	3.28%	4
LDA210Q	Feb-14	84,049	45,690	46	0.05%	45	0.05%	514	0.61%	442	0.53%	377	0.45%	39	0.05%	3	<0.01%	94	0.11%	80	0.10%	8	<0.01%	64	0.08%	1712	2.04%	527
LDA210	Feb-14	2,191	1,091	1	0.05%	5	0.23%	13	0.59%	16	0.73%	42	1.92%	0	0.00%	0	0.00%	12	0.55%	3	0.14%	2	0.09%	2	0.09%	96	4.38%	24
7170Q/7171Q	Jul-09	7,632	2,542	8	0.10%	36	0.47%	42	0.55%	100	1.31%	90	1.18%	2	0.03%	6	0.08%	32	0.42%	26	0.34%	0	0.00%	5	0.07%	347	4.55%	82
7120Q/7121Q	Jan-09	152,226	52,425	58	0.04%	336	0.22%	818	0.54%	1403	0.92%	1552	1.02%	125	0.08%	102	0.07%	331	0.22%	748	0.49%	11	<0.01%	138	0.09%	5622	3.69%	1469
7122Q	Jan-09	196,577	90,141	90	0.05%	171	0.09%	1112	0.57%	1239	0.63%	1151	0.59%	107	0.05%	67	0.03%	276	0.14%	264	0.13%	18	<0.01%	157	0.08%	4652	2.37%	1426
7120/7121	Sep-07	64,445	15,651	19	0.03%	218	0.34%	217	0.34%	511	0.79%	1124	1.74%	81	0.13%	82	0.13%	268	0.42%	447	0.69%	4	<0.01%	73	0.11%	3044	4.72%	716
7070/7071	Jul-06	3,660	785	3	0.08%	32	0.87%	16	0.44%	48	1.31%	81	2.21%	3	0.08%	9	0.25%	18	0.49%	27	0.74%	1	0.03%	3	0.08%	241	6.58%	56
7020/7021	Jul-06	15,876	3,080	21	0.13%	87	0.55%	76	0.48%	214	1.35%	360	2.27%	27	0.17%	35	0.22%	72	0.45%	144	0.91%	2	0.01%	34	0.21%	1072	6.75%	277
7040/7041	Mar-06	4,133	698	4	0.10%	41	0.99%	5	0.12%	59	1.43%	133	3.22%	16	0.39%	67	1.62%	23	0.56%	40	0.97%	1	0.02%	13	0.31%	402	9.73%	90
7000/7001	Jun-05	35,583	5,829	35	0.10%	197	0.55%	62	0.17%	421	1.18%	1111	3.12%	66	0.19%	825	2.32%	152	0.43%	306	0.86%	7	0.02%	107	0.30%	3289	9.24%	876

Definitions of observations and complications can be found on [page 7](#).

Defibrillation Leads

U.S. Malfunction Summary

MODELS	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LDA230Q	1,092	4.60%	1	0.09%	3	0.27%	0	0.00%	0	0.00%	8	0.73%	12	1.10%
LDA220Q	14,993	5.20%	1	<0.01%	10	0.07%	0	0.00%	0	0.00%	92	0.61%	103	0.69%
LDA220	670	5.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.90%	6	0.90%
LDA210Q	84,049	4.40%	9	0.01%	37	0.04%	0	0.00%	6	<0.01%	494	0.59%	546	0.65%
LDA210	2,191	5.90%	0	0.00%	3	0.14%	0	0.00%	0	0.00%	23	1.05%	26	1.19%
7170Q/7171Q	7,632	6.70%	6	0.08%	20	0.26%	0	0.00%	0	0.00%	61	0.80%	87	1.14%
7120Q/7121Q	152,226	6.10%	44	0.03%	465	0.31%	2	<0.01%	39	0.03%	1074	0.71%	1624	1.07%
7122Q	196,577	5.70%	30	0.02%	340	0.17%	1	<0.01%	23	0.01%	1178	0.60%	1572	0.80%
7120/7121	64,445	7.30%	35	0.05%	256	0.40%	1	<0.01%	10	0.02%	499	0.77%	801	1.24%
7070/7071	3,660	9.50%	4	0.11%	25	0.68%	0	0.00%	0	0.00%	25	0.68%	54	1.48%
7020/7021	15,876	8.50%	14	0.09%	84	0.53%	0	0.00%	0	0.00%	203	1.28%	301	1.90%
7040/7041	4,133	9.70%	4	0.10%	75	1.81%	0	0.00%	1	0.02%	33	0.80%	113	2.73%
7000/7001	35,583	8.80%	26	0.07%	707	1.99%	2	<0.01%	1	<0.01%	349	0.98%	1085	3.05%

Definitions of malfunction categories can be found on [pages 8-9](#).

Defibrillation Leads

Worldwide Malfunction Summary

MODELS	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LDA230Q	1,020	4.90%	1	0.10%	3	0.29%	0	0.00%	0	0.00%	8	0.78%	12	1.18%
LDA220Q	20,463	3.92%	1	<0.01%	10	0.05%	0	0.00%	1	<0.01%	118	0.58%	130	0.64%
LDA220	1,274	2.75%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.47%	6	0.47%
LDA210Q	152,047	2.48%	18	0.01%	67	0.04%	0	0.00%	12	0.01%	757	0.50%	854	0.56%
LDA210	2,326	5.55%	0	0.00%	3	0.13%	0	0.00%	0	0.00%	23	0.99%	26	1.12%
7170Q/7171Q	19,858	3.34%	12	0.06%	34	0.17%	2	0.01%	0	0.00%	99	0.50%	147	0.74%
7120Q/7121Q	256,712	4.08%	75	0.03%	579	0.23%	3	<0.01%	96	0.04%	1540	0.60%	2293	0.89%
7122Q	620,341	2.04%	82	0.01%	589	0.09%	3	<0.01%	154	0.02%	2564	0.41%	3392	0.55%
7120/7121	149,330	3.75%	119	0.08%	354	0.24%	1	<0.01%	25	0.02%	884	0.59%	1383	0.93%
7122	97,262	2.86%	123	0.13%	219	0.23%	1	<0.01%	24	0.02%	628	0.65%	995	1.02%

Definitions of malfunction categories can be found on [pages 8-9](#).

Dual-Chamber Pacemakers

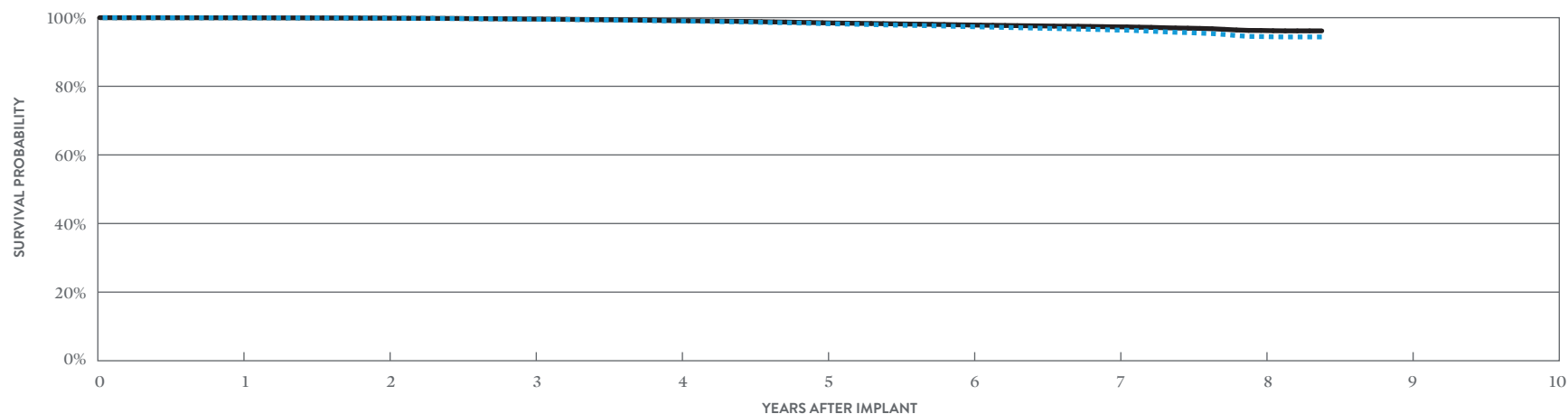
Dual-Chamber Pacemakers

Assurity MRI™

MODEL PM2272

US Regulatory Approval	January 2017
Registered US Implants	500,885
Estimated Active US Implants	321,038
Estimated Longevity	94 Years
Normal Battery Depletion	466
Number of US Advisories (see pgs. 195, 196, 197)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	4	<0.01%	27	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	3	<0.01%	78	0.02%
Mechanical	107	0.02%	1481	0.30%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	3	<0.01%	14	<0.01%
Total	117	0.02%	1601	0.32%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	at 101 months
SURVIVAL PROBABILITY	99.96%	99.86%	99.57%	99.05%	98.28%	97.41%	96.40%	94.50%	94.39%
± 1 STANDARD ERROR	0.00%	0.01%	0.01%	0.02%	0.03%	0.04%	0.06%	0.11%	0.12%
SAMPLE SIZE	450,100	357,500	280,160	213,400	154,040	102,480	58,870	23,280	660

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	at 101 months
SURVIVAL PROBABILITY	99.97%	99.87%	99.61%	99.14%	98.52%	97.88%	97.33%	96.27%	96.16%
± 1 STANDARD ERROR	0.00%	0.01%	0.01%	0.02%	0.03%	0.04%	0.05%	0.09%	0.10%

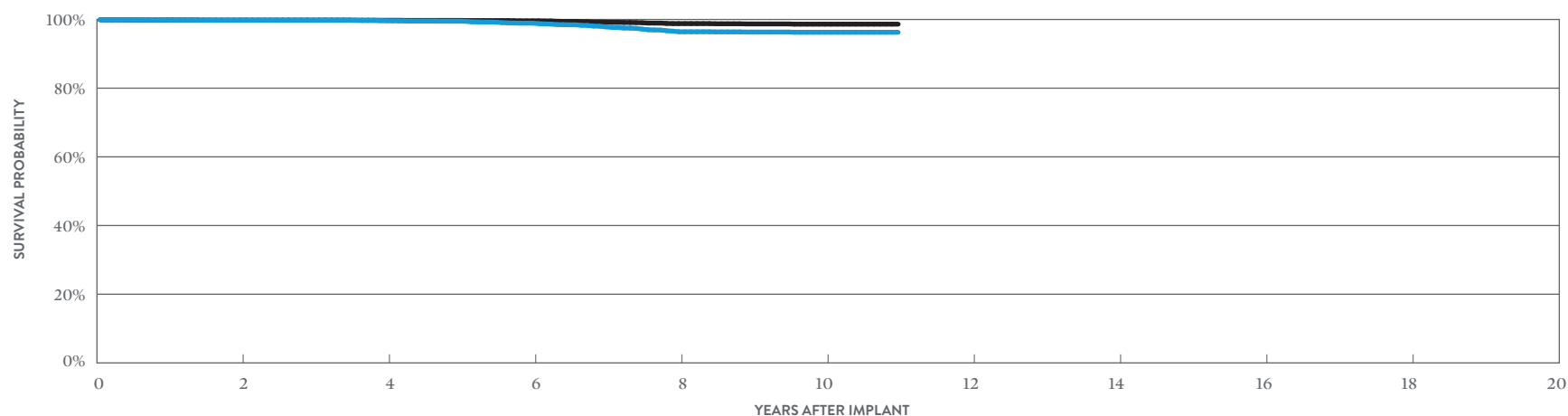
Dual-Chamber Pacemakers

Endurity™ DR

MODEL PM2160

US Regulatory Approval	March 2014
Registered US Implants	9,414
Estimated Active US Implants	3,692
Estimated Longevity	9.7 Years
Normal Battery Depletion	53
Number of US Advisories (see pg. 195, 196)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	33	0.35%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	0	0.00%	35	0.37%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.77%	99.63%	98.93%	96.43%	96.27%	96.27%
± 1 STANDARD ERROR	0.05%	0.06%	0.13%	0.24%	0.26%	0.26%
SAMPLE SIZE	8,120	6,970	5,920	4,800	2,960	320

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.82%	99.76%	99.60%	98.80%	98.64%	98.64%
± 1 STANDARD ERROR	0.04%	0.05%	0.07%	0.14%	0.16%	0.16%

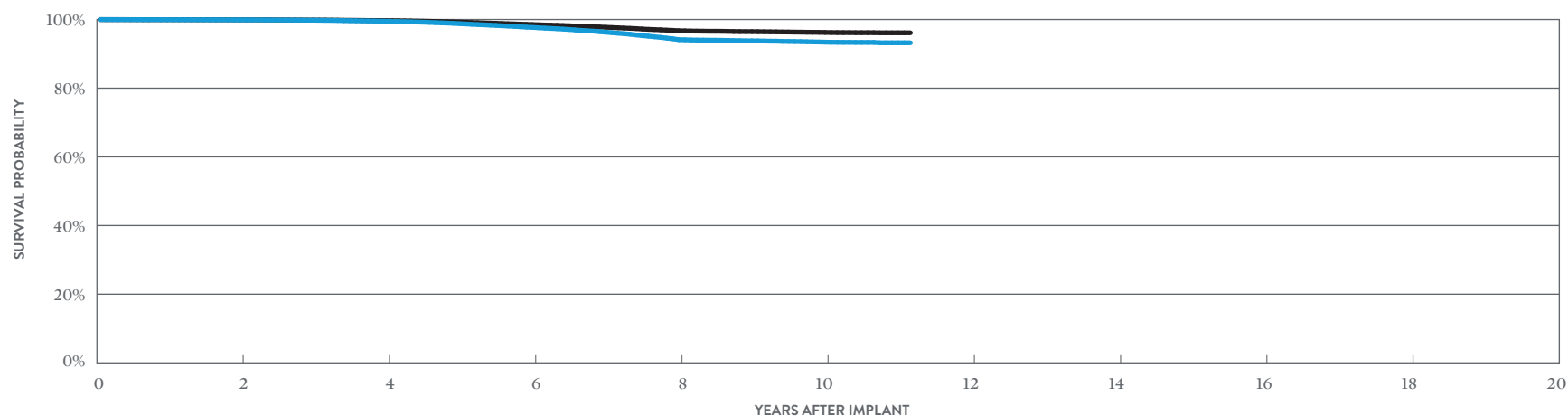
Dual-Chamber Pacemakers

Assurity™ DR RF

MODEL PM2240

US Regulatory Approval	March 2014
Registered US Implants	186,273
Estimated Active US Implants	76,739
Estimated Longevity	9.4 Years
Normal Battery Depletion	1,166
Number of US Advisories (see pgs. 195, 196, 197)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	<0.01%	25	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	38	0.02%
Mechanical	121	0.06%	1344	0.72%
Possible Early Battery Depletion	3	<0.01%	3	<0.01%
Other	0	0.00%	11	<0.01%
Total	131	0.07%	1421	0.76%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.90%	99.50%	97.69%	94.13%	93.41%	93.22%
± 1 STANDARD ERROR	0.01%	0.02%	0.04%	0.07%	0.08%	0.10%
SAMPLE SIZE	161,870	138,290	115,820	88,670	36,050	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.92%	99.67%	98.52%	96.72%	96.23%	96.12%
± 1 STANDARD ERROR	0.01%	0.01%	0.03%	0.05%	0.06%	0.07%

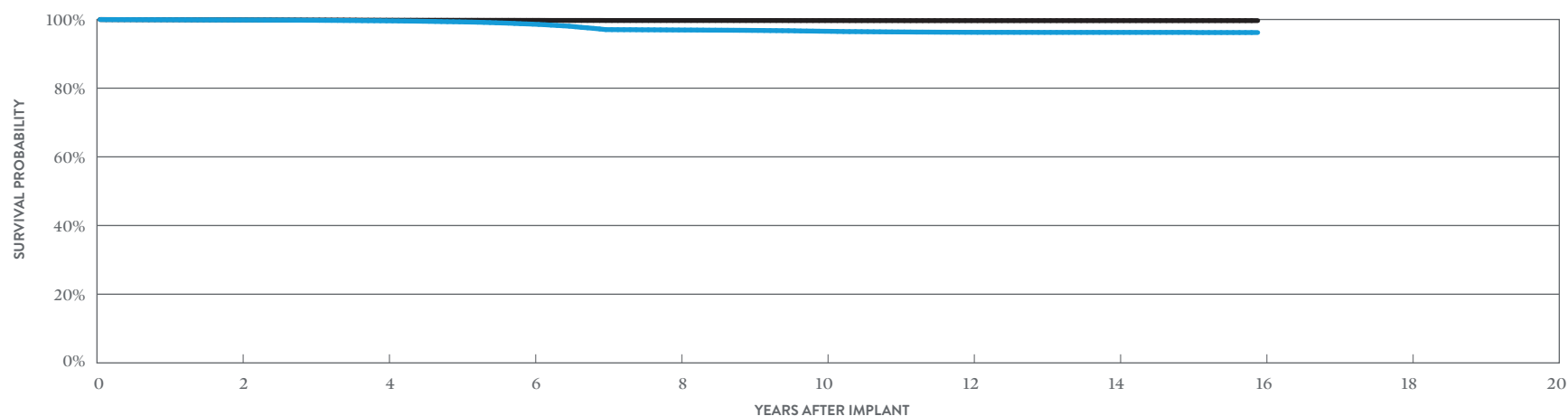
Dual-Chamber Pacemakers

Accent™ DR RF

MODEL PM2210

US Regulatory Approval	July 2009
Registered US Implants	244,871
Estimated Active US Implants	54,204
Estimated Longevity	8 Years
Normal Battery Depletion	1,766
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	17	<0.01%	55	0.02%
Electrical Interconnect	8	<0.01%	33	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	5	<0.01%
Mechanical	1	<0.01%	22	<0.01%
Possible Early Battery Depletion	7	<0.01%	24	<0.01%
Other	5	<0.01%	49	0.02%
Total	38	0.02%	188	0.08%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 191 MONTHS
SURVIVAL PROBABILITY	99.86%	99.60%	98.64%	96.94%	96.57%	96.27%	96.24%	96.20%
± 1 STANDARD ERROR	0.01%	0.01%	0.03%	0.05%	0.05%	0.05%	0.05%	0.06%
SAMPLE SIZE	204,870	168,790	141,610	118,020	89,200	55,190	22,400	260

EXCLUDING NORMAL BATTERY DEPLETION

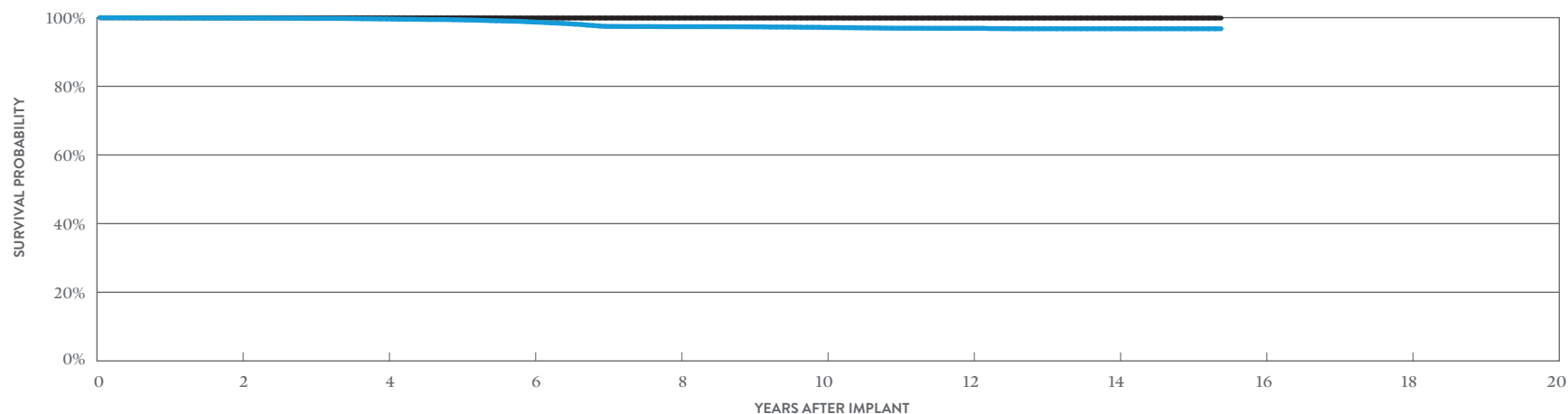
YEAR	2	4	6	8	10	12	14	AT 191 MONTHS
SURVIVAL PROBABILITY	99.90%	99.79%	99.74%	99.71%	99.69%	99.67%	99.67%	99.67%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%

Dual-Chamber Pacemakers

Accent™ DR MODEL PM2110

US Regulatory Approval	July 2009
Registered US Implants	49,135
Estimated Active US Implants	12,254
Estimated Longevity	9.2 Years
Normal Battery Depletion	330
Number of US Advisories (see pg. 195)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	3	<0.01%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	4	<0.01%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	0	0.00%	0	0.00%
Total	4	<0.01%	14	0.03%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	99.89%	99.62%	98.74%	97.38%	97.14%	96.90%	96.77%	96.77%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.09%	0.10%	0.11%	0.11%	0.11%
SAMPLE SIZE	41,020	33,660	28,360	24,100	19,190	12,500	4,680	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	99.95%	99.93%	99.90%	99.90%	99.90%	99.89%	99.89%	99.89%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

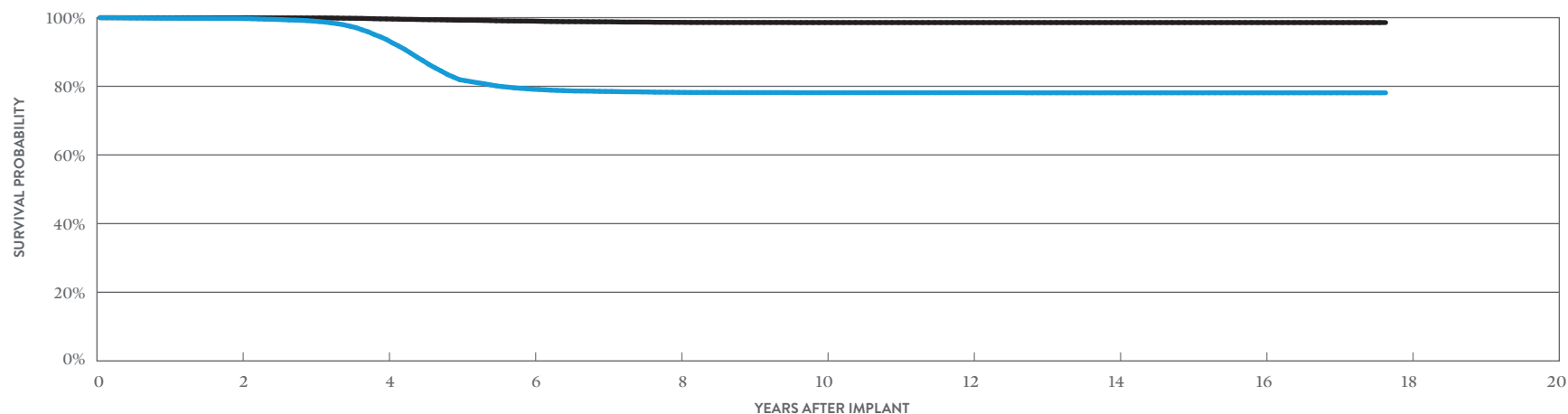
Dual-Chamber Pacemakers

Zephyr™ DR

MODEL 5820

US Regulatory Approval	March 2007
Registered US Implants	54,739
Estimated Active US Implants	9,081
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,473
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	36	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	9	0.02%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	93	0.17%
Total	2	<0.01%	141	0.26%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	99.75%	93.65%	79.16%	78.24%	78.14%	78.14%	78.11%	78.11%	78.11%
± 1 STANDARD ERROR	0.02%	0.13%	0.23%	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
SAMPLE SIZE	42,540	31,580	21,050	14,350	11,440	8,880	5,480	2,520	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	99.96%	99.63%	98.99%	98.63%	98.57%	98.57%	98.57%	98.57%	98.57%
± 1 STANDARD ERROR	0.01%	0.03%	0.06%	0.08%	0.08%	0.08%	0.08%	0.08%	0.08%

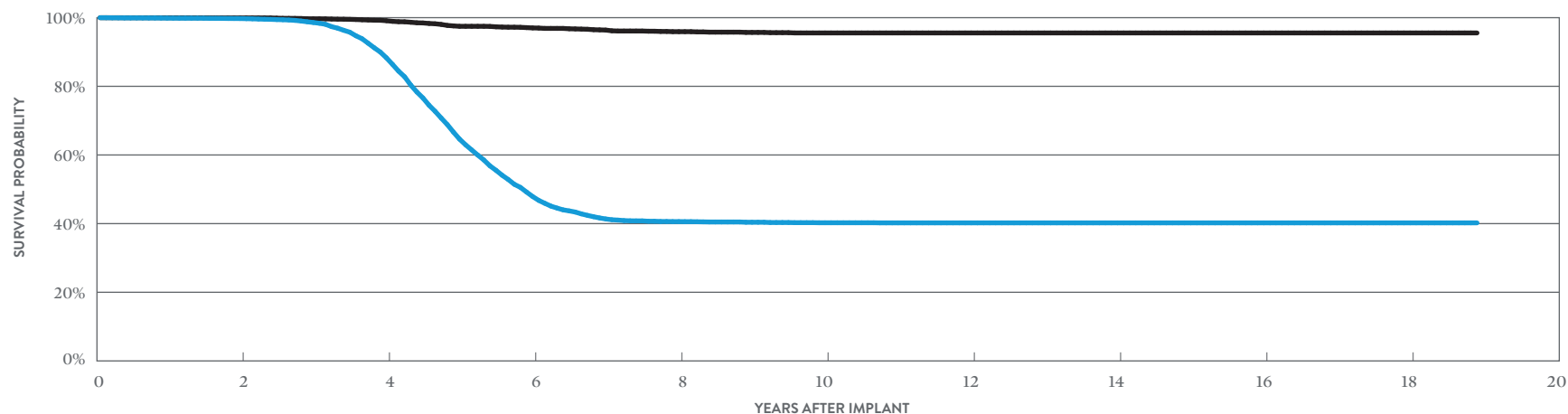
Dual-Chamber Pacemakers

Victory™ DR

MODEL 5810

US Regulatory Approval	December 2005
Registered US Implants	26,314
Estimated Active US Implants	1,794
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,779
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	89	0.34%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	8	0.03%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	17	0.06%
Other	0	0.00%	37	0.14%
Total	1	<0.01%	153	0.58%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 227 MONTHS
SURVIVAL PROBABILITY	99.74%	88.31%	47.90%	40.59%	40.25%	40.22%	40.22%	40.22%	40.22%	40.22%
± 1 STANDARD ERROR	0.03%	0.25%	0.45%	0.46%	0.46%	0.46%	0.46%	0.46%	0.46%	0.46%
SAMPLE SIZE	20,160	13,530	6,550	3,200	2,480	2,270	2,120	1,800	1,020	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 227 MONTHS
SURVIVAL PROBABILITY	99.93%	99.11%	97.01%	95.92%	95.55%	95.55%	95.55%	95.55%	95.55%	95.55%
± 1 STANDARD ERROR	0.02%	0.07%	0.17%	0.24%	0.27%	0.27%	0.27%	0.27%	0.27%	0.27%

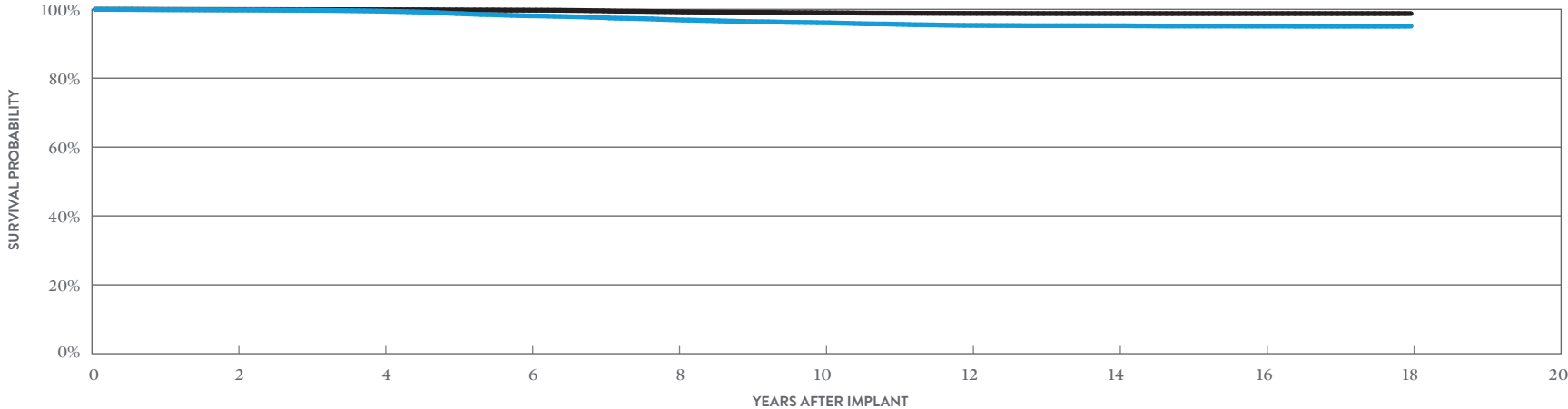
Dual-Chamber Pacemakers

Zephyr™ XL DR

MODEL 5826

US Regulatory Approval	March 2007
Registered US Implants	113,833
Estimated Active US Implants	16,866
Estimated Longevity	11.7 Years
Normal Battery Depletion	703
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	25	0.02%
Electrical Interconnect	4	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	16	0.01%
Mechanical	1	<0.01%	9	<0.01%
Possible Early Battery Depletion	0	0.00%	3	<0.01%
Other	2	<0.01%	160	0.14%
Total	8	<0.01%	213	0.19%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18
SURVIVAL PROBABILITY	99.83%	99.47%	98.10%	96.95%	96.09%	95.32%	95.23%	95.12%	95.09%
± 1 STANDARD ERROR	0.01%	0.02%	0.05%	0.07%	0.09%	0.10%	0.11%	0.11%	0.11%
SAMPLE SIZE	92,280	71,850	56,070	40,430	29,380	22,870	17,690	11,640	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18
SURVIVAL PROBABILITY	99.93%	99.88%	99.75%	99.28%	99.01%	98.81%	98.78%	98.77%	98.77%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.04%	0.05%	0.06%	0.06%	0.06%	0.06%

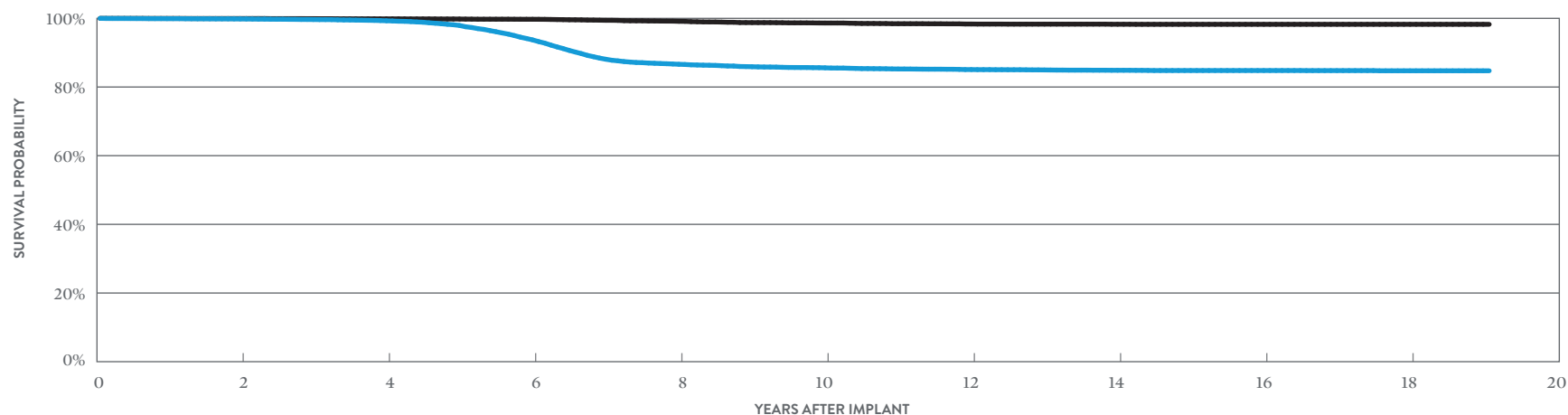
Dual-Chamber Pacemakers

Victory™ XL DR

MODEL 5816

US Regulatory Approval	December 2005
Registered US Implants	63,053
Estimated Active US Implants	6,585
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,524
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	31	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	8	0.01%
Mechanical	0	0.00%	9	0.01%
Possible Early Battery Depletion	0	0.00%	5	<0.01%
Other	1	<0.01%	92	0.15%
Total	3	<0.01%	145	0.23%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 229 MONTHS
SURVIVAL PROBABILITY	99.83%	99.29%	93.72%	86.62%	85.59%	85.08%	84.87%	84.80%	84.73%	84.73%
± 1 STANDARD ERROR	0.02%	0.04%	0.13%	0.20%	0.22%	0.22%	0.23%	0.23%	0.23%	0.23%
SAMPLE SIZE	51,090	38,840	29,270	18,970	12,630	9,970	8,470	6,990	3,780	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 229 MONTHS
SURVIVAL PROBABILITY	99.95%	99.85%	99.73%	99.13%	98.64%	98.35%	98.28%	98.26%	98.26%	98.26%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.06%	0.08%	0.10%	0.10%	0.10%	0.10%	0.10%

SUMMARY INFORMATION
Dual-Chamber
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Dual-Chamber Pacemakers

Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM2272	Assurity MRI™	99.96%	99.86%	99.57%	99.05%	98.28%	97.41%	96.40%	94.50%		
PM2160	Endurity™ DR	99.82%	99.77%	99.75%	99.63%	99.51%	98.93%	97.85%	96.43%	96.34%	96.27%
PM2240	Assurity™ DR RF	99.95%	99.90%	99.79%	99.50%	98.79%	97.69%	96.30%	94.13%	93.79%	93.41%
PM2210	Accent™ DR RF	99.92%	99.86%	99.77%	99.60%	99.31%	98.64%	97.05%	96.94%	96.82%	96.57%
PM2110	Accent™ DR	99.94%	99.89%	99.81%	99.62%	99.38%	98.74%	97.46%	97.38%	97.32%	97.14%
5820	Zephyr™ DR	99.85%	99.75%	99.00%	93.65%	81.94%	79.16%	78.51%	78.24%	78.17%	78.14%
5810	Victory™ DR	99.87%	99.74%	98.59%	88.31%	64.63%	47.90%	41.36%	40.59%	40.40%	40.25%
5826	Zephyr™ XL DR	99.91%	99.83%	99.74%	99.47%	98.77%	98.10%	97.61%	96.95%	96.42%	96.09%
5816	Victory™ XL DR	99.91%	99.83%	99.65%	99.29%	97.93%	93.72%	88.09%	86.62%	85.91%	85.59%

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM2272	Assurity MRI™	99.96%	99.86%	99.57%	99.05%	98.28%	97.41%	96.40%	94.50%		
PM2160	Endurity™ DR	99.82%	99.77%	99.75%	99.63%	99.51%	98.93%	97.85%	96.43%	96.34%	96.27%
PM2240	Assurity™ DR RF	99.95%	99.90%	99.79%	99.50%	98.79%	97.69%	96.30%	94.13%	93.79%	93.41%
PM2210	Accent™ DR RF	99.92%	99.86%	99.77%	99.60%	99.31%	98.64%	97.05%	96.94%	96.82%	96.57%
PM2110	Accent™ DR	99.94%	99.89%	99.81%	99.62%	99.38%	98.74%	97.46%	97.38%	97.32%	97.14%
5820	Zephyr™ DR	99.85%	99.75%	99.00%	93.65%	81.94%	79.16%	78.51%	78.24%	78.17%	78.14%
5810	Victory™ DR	99.87%	99.74%	98.59%	88.31%	64.63%	47.90%	41.36%	40.59%	40.40%	40.25%
5826	Zephyr™ XL DR	99.91%	99.83%	99.74%	99.47%	98.77%	98.10%	97.61%	96.95%	96.42%	96.09%
5816	Victory™ XL DR	99.91%	99.83%	99.65%	99.29%	97.93%	93.72%	88.09%	86.62%	85.91%	85.59%

Dual-Chamber Pacemakers

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM2272	Assurity MRI	500,885	3.40%	4	<0.01%	0	0.00%	0	0.00%	3	<0.01%	107	0.02%	0	0.00%	3	<0.01%	117	0.02%
PM2160	Endurity DR	9,414	5.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM2240	Assurity DR RF	186,273	7.10%	6	<0.01%	0	0.00%	0	0.00%	1	<0.01%	121	0.06%	3	<0.01%	0	0.00%	131	0.07%
PM2210	Accent DR RF	244,871	12.50%	17	<0.01%	8	<0.01%	0	0.00%	0	0.00%	1	<0.01%	7	<0.01%	5	<0.01%	38	0.02%
PM2110	Accent DR	49,135	10.60%	2	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%
5820	Zephyr DR	54,739	16.40%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%
5810	Victory DR	26,314	19.20%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%
5826	Zephyr XL DR	113,833	19.20%	1	<0.01%	4	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	<0.01%	8	<0.01%
5816	Victory XL DR	63,053	20.90%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	3	<0.01%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM2272	Assurity MRI	500,885	3.40%	27	<0.01%	0	0.00%	0	0.00%	78	0.02%	1481	0.30%	1	<0.01%	14	<0.01%	1601	0.32%
PM2160	Endurity DR	9,414	5.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	33	0.35%	0	0.00%	2	0.02%	35	0.37%
PM2240	Assurity DR RF	186,273	7.10%	25	0.01%	0	0.00%	0	0.00%	38	0.02%	1344	0.72%	3	<0.01%	11	<0.01%	1421	0.76%
PM2210	Accent DR RF	244,871	12.50%	55	0.02%	33	0.01%	0	0.00%	5	<0.01%	22	<0.01%	24	<0.01%	49	0.02%	188	0.08%
PM2110	Accent DR	49,135	10.60%	3	<0.01%	0	0.00%	0	0.00%	4	<0.01%	5	0.01%	2	<0.01%	0	0.00%	14	0.03%
5820	Zephyr DR	54,739	16.40%	36	0.07%	0	0.00%	0	0.00%	9	0.02%	2	<0.01%	1	<0.01%	93	0.17%	141	0.26%
5810	Victory DR	26,314	19.20%	89	0.34%	0	0.00%	0	0.00%	8	0.03%	2	<0.01%	17	0.06%	37	0.14%	153	0.58%
5826	Zephyr XL DR	113,833	19.20%	25	0.02%	0	0.00%	0	0.00%	16	0.01%	9	<0.01%	3	<0.01%	160	0.14%	213	0.19%
5816	Victory XL DR	63,053	20.90%	31	0.05%	0	0.00%	0	0.00%	8	0.01%	9	0.01%	5	<0.01%	92	0.15%	145	0.23%

Definitions of malfunction categories can be found on [pages 5-6](#).

Dual-Chamber Pacemakers

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM2272	Assurity MRI™	1,164,860	1.96%	28	<0.01%	2	<0.01%	0	0.00%	6	<0.01%	682	0.06%	0	0.00%	12	<0.01%	730	0.06%
PM2160	Endurity™ DR	76,004	1.04%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	6	<0.01%	0	0.00%	0	0.00%	10	0.01%
PM2240	Assurity™ DR RF	208,194	6.22%	12	<0.01%	0	0.00%	0	0.00%	2	<0.01%	244	0.12%	6	<0.01%	0	0.00%	264	0.13%
PM2210	Accent™ DR RF	246,721	12.03%	34	0.01%	16	<0.01%	0	0.00%	0	0.00%	2	<0.01%	12	<0.01%	10	<0.01%	74	0.03%
PM2110	Accent™ DR	49,730	10.08%	4	<0.01%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.02%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM2272	Assurity MRI™	1,164,860	1.96%	140	0.01%	0	0.00%	0	0.00%	160	0.01%	4154	0.36%	16	<0.01%	50	<0.01%	4520	0.39%
PM2160	Endurity™ DR	76,004	1.04%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	100	0.13%	0	0.00%	6	<0.01%	108	0.14%
PM2240	Assurity™ DR RF	208,194	6.22%	56	0.03%	0	0.00%	0	0.00%	74	0.04%	2608	1.25%	8	<0.01%	26	0.01%	2772	1.33%
PM2210	Accent™ DR RF	246,721	12.03%	116	0.05%	68	0.03%	0	0.00%	10	<0.01%	44	0.02%	48	0.02%	96	0.04%	382	0.15%
PM2110	Accent™ DR	49,730	10.08%	6	0.01%	0	0.00%	0	0.00%	8	0.02%	10	0.02%	4	<0.01%	0	0.00%	28	0.06%

Definitions of malfunction categories can be found on [pages 5-6](#).

Single-Chamber Pacemakers

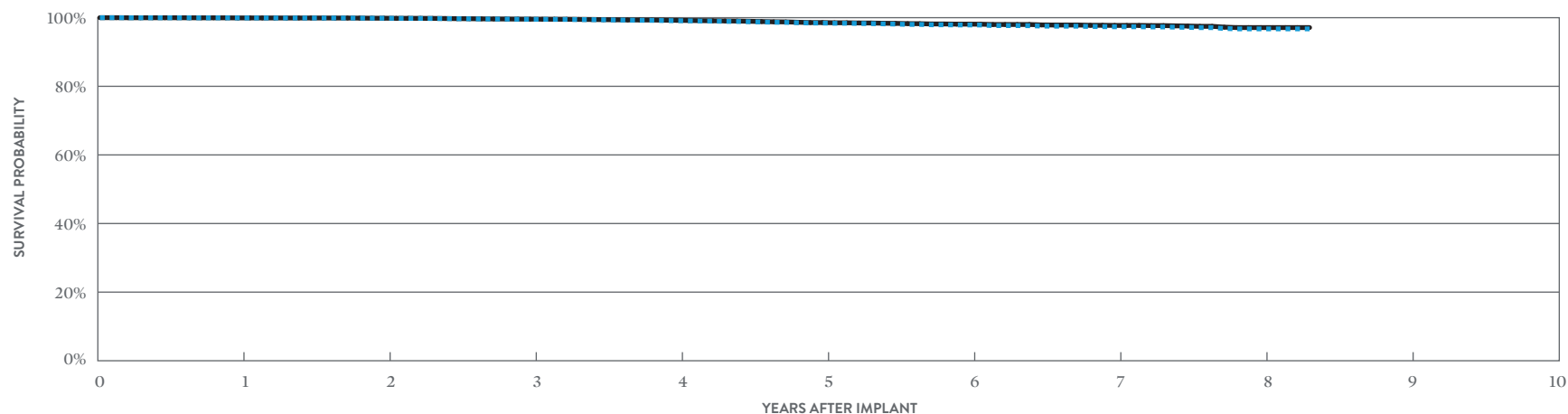
Single-Chamber Pacemakers

Assurity MRI™

MODEL PM1272

US Regulatory Approval	January 2017
Registered US Implants	45299
Estimated Active US Implants	28072
Estimated Longevity	13.7 Years
Normal Battery Depletion	22
Number of US Advisories (see pgs. 195, 196, 197)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	5	0.01%
Mechanical	3	<0.01%	146	0.32%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	4	<0.01%	153	0.34%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 100 MONTHS
SURVIVAL PROBABILITY	99.93%	99.85%	99.54%	99.12%	98.43%	97.88%	97.35%	96.74%	96.74%
± 1 STANDARD ERROR	0.01%	0.02%	0.04%	0.06%	0.09%	0.11%	0.14%	0.21%	0.21%
SAMPLE SIZE	40,760	32,730	26,350	20,910	15,880	11,240	6,880	2,860	320

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 100 MONTHS
SURVIVAL PROBABILITY	99.93%	99.85%	99.58%	99.23%	98.58%	98.12%	97.74%	97.12%	97.12%
± 1 STANDARD ERROR	0.01%	0.02%	0.04%	0.05%	0.08%	0.11%	0.13%	0.21%	0.21%

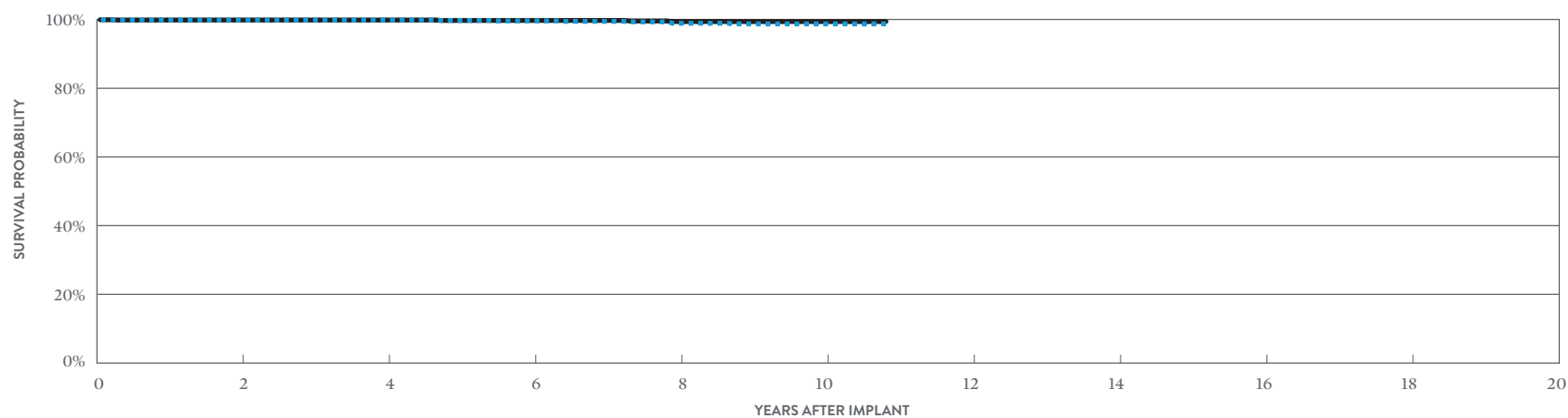
Single-Chamber Pacemakers

Endurity™ VR

MODEL PM1160

US Regulatory Approval	March 2014
Registered US Implants	2,573
Estimated Active US Implants	1,060
Estimated Longevity	14.6 Years
Normal Battery Depletion	4
Number of US Advisories (see pgs. 195, 196)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	4	0.16%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.04%
Total	0	0.00%	5	0.19%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 130 MONTHS
SURVIVAL PROBABILITY	99.84%	99.84%	99.59%	98.89%	98.71%	98.71%
± 1 STANDARD ERROR	0.08%	0.08%	0.15%	0.27%	0.30%	0.30%
SAMPLE SIZE	2,100	1,770	1,540	1,280	780	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 130 MONTHS
SURVIVAL PROBABILITY	99.84%	99.84%	99.72%	99.40%	99.40%	99.40%
± 1 STANDARD ERROR	0.08%	0.08%	0.12%	0.20%	0.20%	0.20%

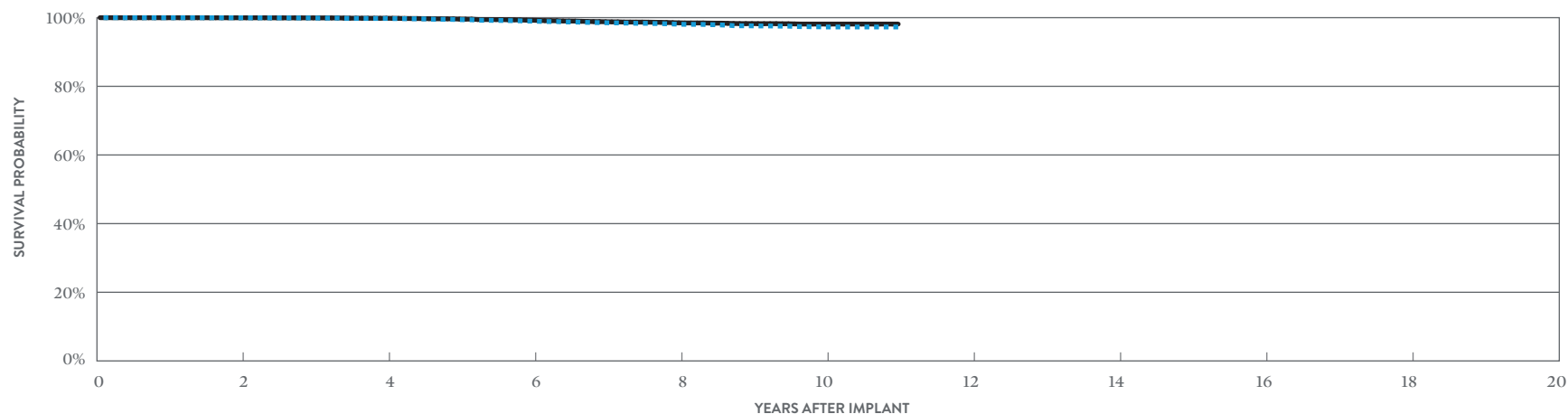
Single-Chamber Pacemakers

Assurity™ VR

MODEL PM1240

US Regulatory Approval	March 2014
Registered US Implants	28,772
Estimated Active US Implants	12,664
Estimated Longevity	14.1 Years
Normal Battery Depletion	43
Number of US Advisories (see pgs. 195, 196, 197)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	4	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	3	0.01%
Mechanical	3	0.01%	106	0.37%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	3	0.01%	114	0.40%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.96%	99.77%	98.98%	98.09%	97.29%	97.29%
± 1 STANDARD ERROR	0.01%	0.03%	0.07%	0.10%	0.14%	0.15%
SAMPLE SIZE	24,260	20,720	17,540	13,610	5,640	240

EXCLUDING NORMAL BATTERY DEPLETION

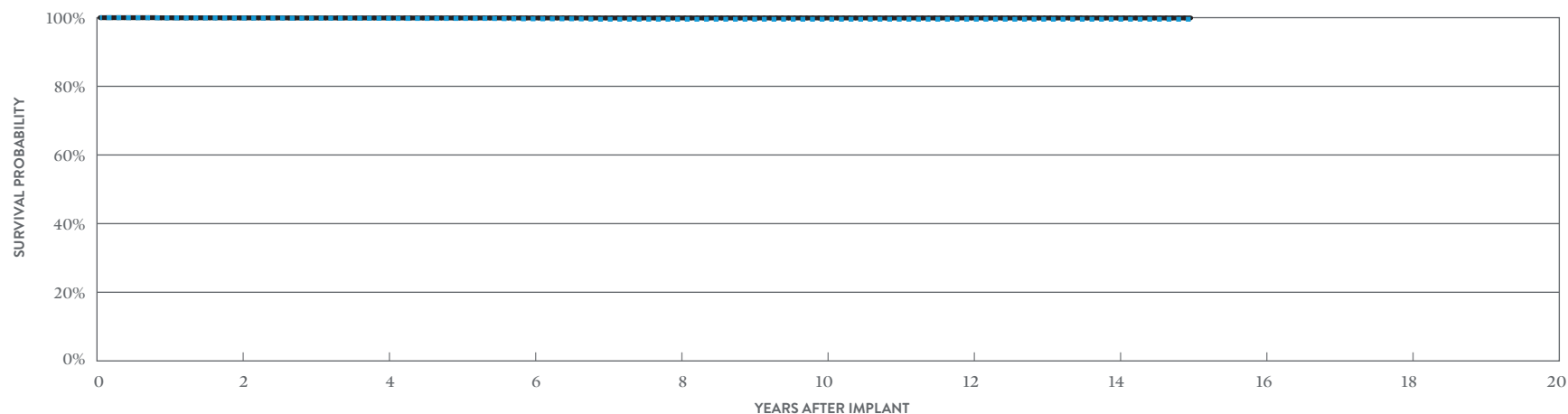
YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.96%	99.83%	99.24%	98.50%	98.14%	98.14%
± 1 STANDARD ERROR	0.01%	0.03%	0.06%	0.09%	0.12%	0.12%

Single-Chamber Pacemakers

Accent™ SR MODEL PM1110

US Regulatory Approval	July 2009
Registered US Implants	13,596
Estimated Active US Implants	4,167
Estimated Longevity	12.9 Years
Normal Battery Depletion	15
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	0	0.00%	4	0.03%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.87%	99.80%	99.66%	99.54%	99.54%	99.54%	99.54%	99.54%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.07%	0.07%	0.07%	0.07%	0.07%
SAMPLE SIZE	10,670	8,480	7,250	6,390	5,580	4,040	1,440	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 180 MONTHS
SURVIVAL PROBABILITY	99.94%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%

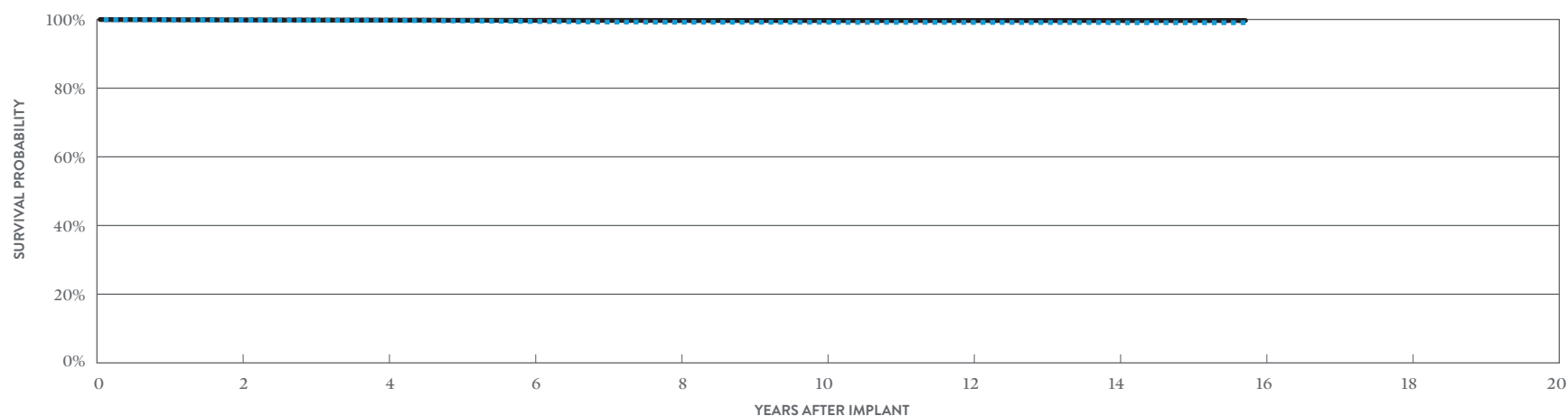
Single-Chamber Pacemakers

Accent™ SR RF

MODEL PM1210

US Regulatory Approval	July 2009
Registered US Implants	40,047
Estimated Active US Implants	11,439
Estimated Longevity	10.9 Years
Normal Battery Depletion	54
Number of US Advisories (see pgs. 195, 197)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	<0.01%	11	0.03%
Electrical Interconnect	1	<0.01%	3	<0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	4	0.01%
Possible Early Battery Depletion	2	<0.01%	3	<0.01%
Other	0	0.00%	8	0.02%
Total	6	0.02%	31	0.08%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 189 MONTHS
SURVIVAL PROBABILITY	99.80%	99.73%	99.41%	99.20%	99.19%	99.14%	99.06%	99.06%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.06%	0.06%	0.06%	0.08%	0.08%
SAMPLE SIZE	31,400	25,060	21,060	18,360	15,900	11,400	4,520	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 189 MONTHS
SURVIVAL PROBABILITY	99.87%	99.81%	99.74%	99.70%	99.70%	99.70%	99.70%	99.70%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%

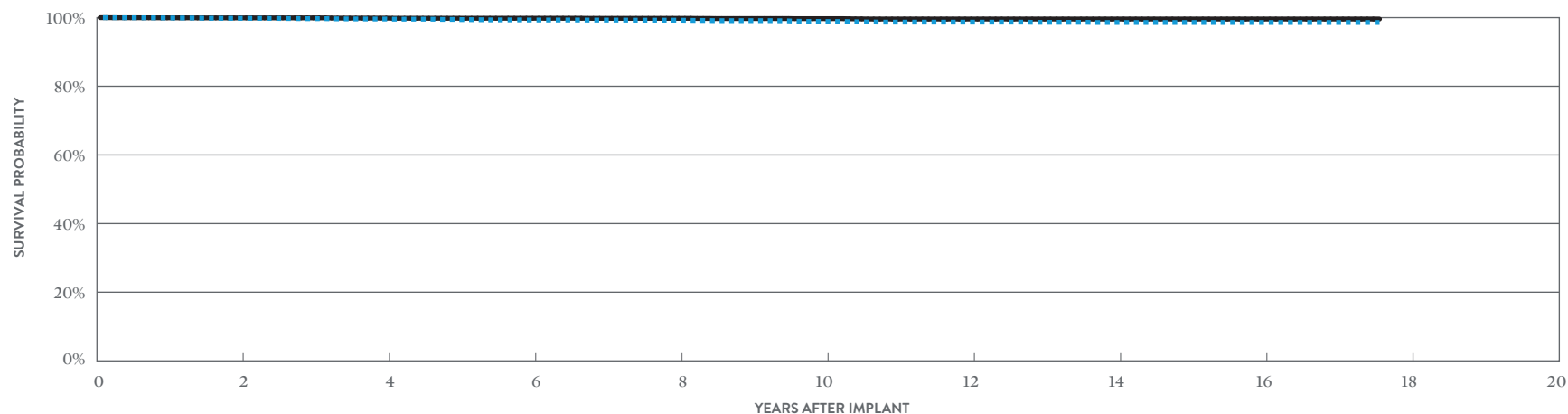
Single-Chamber Pacemakers

Zephyr™ XL SR

MODEL 5626

US Regulatory Approval	May 2007
Registered US Implants	20,883
Estimated Active US Implants	3,972
Estimated Longevity	15.8 Years
Normal Battery Depletion	41
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	4	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	13	0.06%
Total	2	<0.01%	17	0.08%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 211 MONTHS
SURVIVAL PROBABILITY	99.81%	99.61%	99.32%	99.27%	98.88%	98.70%	98.60%	98.60%	98.60%
± 1 STANDARD ERROR	0.03%	0.05%	0.08%	0.08%	0.11%	0.13%	0.13%	0.13%	0.13%
SAMPLE SIZE	15,570	11,500	8,940	7,340	6,050	5,030	4,000	2,550	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 211 MONTHS
SURVIVAL PROBABILITY	99.93%	99.87%	99.83%	99.80%	99.71%	99.60%	99.60%	99.60%	99.60%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.04%	0.06%	0.07%	0.07%	0.07%	0.07%

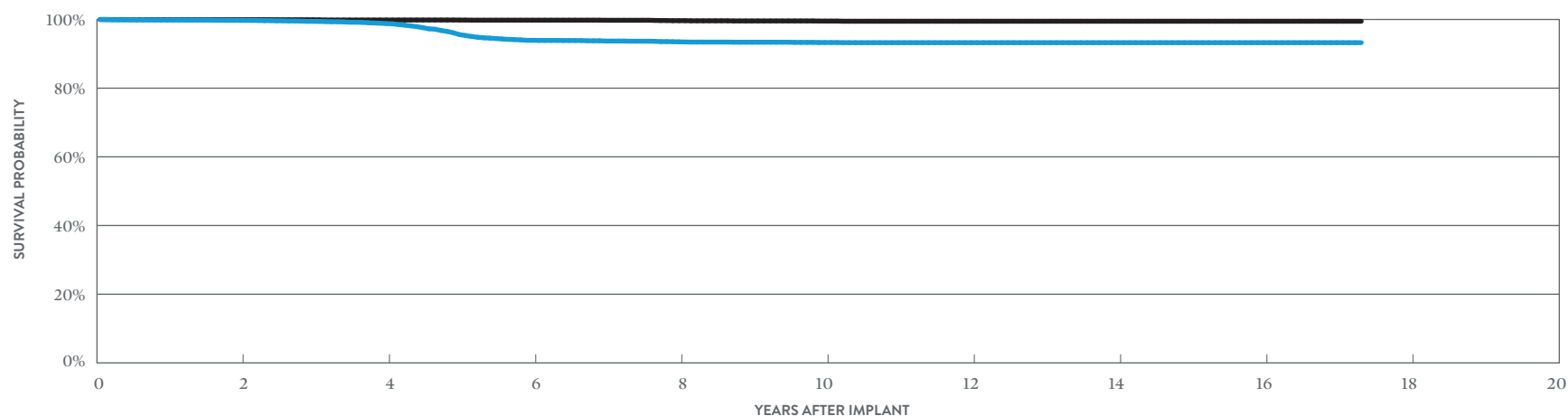
Single-Chamber Pacemakers

Zephyr™ SR

MODEL 5620

US Regulatory Approval	March 2007
Registered US Implants	17,530
Estimated Active US Implants	3,629
Estimated Longevity	8.8 Years
Normal Battery Depletion	209
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	4	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	0.01%
Mechanical	1	<0.01%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	11	0.06%
Total	1	<0.01%	17	0.10%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 208 MONTHS
SURVIVAL PROBABILITY	99.74%	98.80%	93.93%	93.49%	93.29%	93.25%	93.25%	93.25%	93.25%
± 1 STANDARD ERROR	0.04%	0.10%	0.26%	0.27%	0.28%	0.28%	0.28%	0.28%	0.28%
SAMPLE SIZE	12,540	9,270	7,110	5,530	4,420	3,410	2,020	940	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 208 MONTHS
SURVIVAL PROBABILITY	99.94%	99.85%	99.80%	99.65%	99.53%	99.48%	99.48%	99.48%	99.48%
± 1 STANDARD ERROR	0.02%	0.04%	0.05%	0.07%	0.09%	0.09%	0.09%	0.09%	0.09%

SUMMARY INFORMATION
Single-Chamber
Pacemakers

Single-Chamber Pacemakers Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM1272	AssurityMRI™	99.93%	99.85%	99.54%	99.12%	98.43%	97.88%	97.35%	96.74%		
PM1160	Endurity™ SR	99.84%	99.84%	99.84%	99.84%	99.72%	99.59%	99.45%	98.89%	98.71%	98.71%
PM1240	Assurity™ SR	99.98%	99.96%	99.91%	99.77%	99.42%	98.98%	98.52%	98.09%	97.61%	97.29%
PM1110	Accent™ SR	99.92%	99.87%	99.84%	99.80%	99.77%	99.66%	99.54%	99.54%	99.54%	99.54%
PM1210	Accent™ SR RF	99.88%	99.80%	99.76%	99.73%	99.59%	99.41%	99.24%	99.20%	99.19%	99.19%
5626	Zephyr™ XL SR	99.92%	99.81%	99.71%	99.61%	99.44%	99.32%	99.30%	99.27%	99.13%	98.88%
5620	Zephyr™ SR	99.86%	99.74%	99.46%	98.80%	95.59%	93.93%	93.72%	93.49%	93.38%	93.29%

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
PM1272	AssurityMRI™	99.93%	99.85%	99.58%	99.23%	98.58%	98.12%	97.74%	97.12%		
PM1160	Endurity™ SR	99.84%	99.84%	99.84%	99.84%	99.72%	99.72%	99.72%	99.40%	99.40%	99.40%
PM1240	Assurity™ SR	99.98%	99.96%	99.93%	99.83%	99.59%	99.24%	98.81%	98.50%	98.27%	98.14%
PM1110	Accent™ SR	99.96%	99.94%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%
PM1210	Accent™ SR RF	99.93%	99.87%	99.83%	99.81%	99.76%	99.74%	99.73%	99.70%	99.70%	99.70%
5626	Zephyr™ XL SR	99.95%	99.93%	99.93%	99.87%	99.83%	99.83%	99.80%	99.80%	99.74%	99.71%
5620	Zephyr™ SR	99.97%	99.94%	99.92%	99.85%	99.83%	99.80%	99.77%	99.65%	99.57%	99.53%

Single-Chamber Pacemakers

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM1272	Assurity MRI [™]	45,299	4.90%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	4	<0.01%
PM1160	Endurity [™] SR	2,573	6.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM1240	Assurity [™] SR	28,772	7.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.01%	0	0.00%	0	0.00%	3	0.01%
PM1110	Accent [™] SR	13,596	8.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM1210	Accent [™] SR RF	40,047	7.90%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	6	0.01%
5626	Zephyr [™] XL SR	20,883	11.60%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%
5620	Zephyr [™] SR	17,530	12.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM1272	Assurity MRI [™]	45,299	4.90%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	146	0.32%	0	0.00%	0	0.00%	153	0.34%
PM1160	Endurity [™] SR	2,573	6.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.16%	0	0.00%	1	0.04%	5	0.19%
PM1240	Assurity [™] SR	28,772	7.30%	4	0.01%	0	0.00%	0	0.00%	3	0.01%	106	0.37%	1	<0.01%	0	0.00%	114	0.40%
PM1110	Assurity [™] SR	13,596	8.10%	2	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	4	0.03%
PM1210	Accent [™] SR RF	40,047	7.90%	11	0.03%	3	<0.01%	1	<0.01%	1	<0.01%	4	<0.01%	3	<0.01%	8	0.02%	31	0.08%
5626	Zephyr [™] XL SR	20,883	11.60%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	13	0.06%	17	0.08%
5620	Zephyr [™] SR	17,530	12.00%	4	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	11	0.06%	17	0.10%

Definitions of malfunction categories can be found on [pages 5-6](#).

Single-Chamber Pacemakers

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM1272	Assurity MRI™	186,766	1.27%	6	<0.01%	0	0.00%	0	0.00%	2	<0.01%	8	<0.01%	2	<0.01%	0	0.00%	18	<0.01%
PM1160	Endurity™ SR	29,634	0.83%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	0.01%	0	0.00%	0	0.00%	6	0.02%
PM1240	Assurity™ SR	32,593	6.31%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.02%	0	0.00%	0	0.00%	6	0.02%
PM1110	Accent™ SR	59,286	2.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM1210	Accent™ SR RF	49,812	6.43%	12	0.02%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	18	0.04%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM1272	Assurity MRI™	186,766	1.27%	8	<0.01%	0	0.00%	0	0.00%	10	<0.01%	280	0.15%	0	0.00%	6	<0.01%	304	0.16%
PM1160	Endurity™ SR	29,634	0.83%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	14	0.05%	0	0.00%	2	<0.01%	16	0.05%
PM1240	Assurity™ SR	32,593	6.31%	10	0.03%	0	0.00%	0	0.00%	8	0.02%	208	0.64%	2	<0.01%	0	0.00%	228	0.70%
PM1110	Accent™ SR	59,286	2.18%	10	0.02%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	2	<0.01%	10	0.02%	26	0.04%
PM1210	Accent™ SR RF	49,812	6.43%	28	0.06%	8	0.02%	2	<0.01%	2	<0.01%	8	0.02%	6	0.01%	20	0.04%	74	0.15%

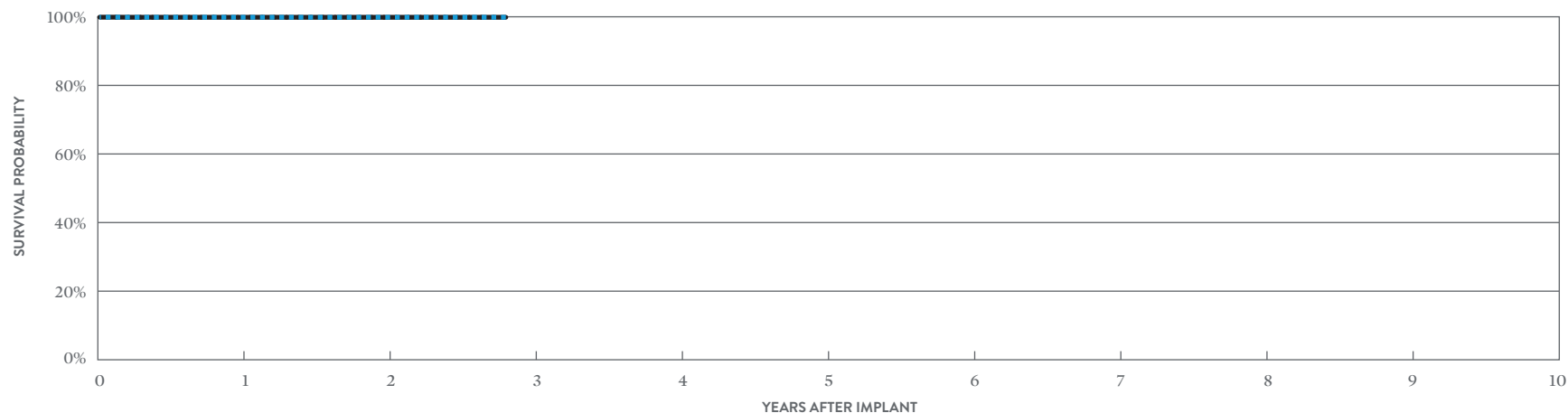
Definitions of malfunction categories can be found on [pages 5-6](#).

Leadless Pacemakers

AVEIR™ DR MODEL LSP202V

US Regulatory Approval	June 2023
Registered US Implants	7,007
Estimated Active US Implants	5,984
Estimated Longevity	10.3 Years
Normal Battery Depletion	0
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Extrinsic Factors	0	0.00%	3	0.04%
Total	0	0.00%	5	0.07%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.85%	99.85%	99.85%
± 1 STANDARD ERROR	0.05%	0.05%	0.05%
SAMPLE SIZE	4,200	810	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.85%	99.85%	99.85%
± 1 STANDARD ERROR	0.05%	0.05%	0.05%

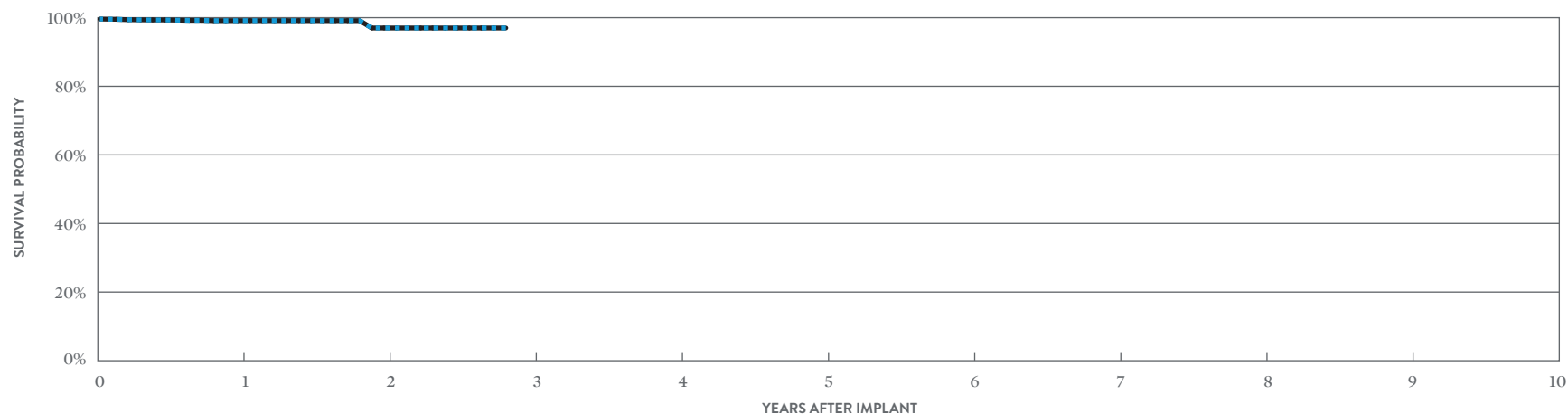
*VVIR 60 bpm, 2.5V @0.4 ms, 600Ω, 100% pacing.

Leadless Pacemakers

AVEIR™ DR MODEL LSP201A

US Regulatory Approval	June 2023
Registered US Implants	7,535
Estimated Active US Implants	6,421
Estimated Longevity	10.3 Years
Normal Battery Depletion	0
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.01%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	0.03%
Mechanical	8	0.11%	10	0.13%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	2	0.03%	0	0.00%
Extrinsic Factors	0	0.00%	2	0.03%
Total	11	0.15%	15	0.20%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.14%	97.00%	97.00%
± 1 STANDARD ERROR	0.13%	0.96%	0.96%
SAMPLE SIZE	4,500	850	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.14%	97.00%	97.00%
± 1 STANDARD ERROR	0.13%	0.96%	0.96%

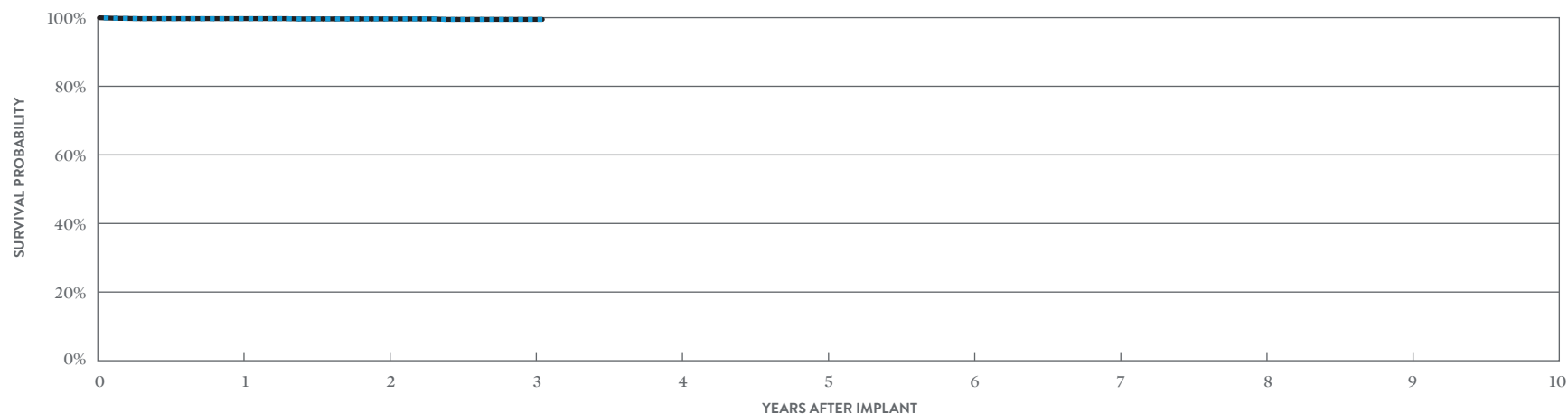
*AAIR 60 bpm, 1.5V @0.4 ms, 600Ω, 100% pacing.

Leadless Pacemakers

AVEIR™ VR MODEL LSP112V

US Regulatory Approval	March 2022
Registered US Implants	11,643
Estimated Active US Implants	9,728
Estimated Longevity	10.3 Years
Normal Battery Depletion	0
Number of US Advisories (see pg. 198)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	10	0.09%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	3	0.03%	0	0.00%
Extrinsic Factors	2	0.02%	24	0.21%
Total	5	0.04%	36	0.31%



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 37 MONTHS
SURVIVAL PROBABILITY	99.73%	99.65%	99.51%	99.51%
± 1 STANDARD ERROR	0.05%	0.06%	0.12%	0.12%
SAMPLE SIZE	9640	5260	1550	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 37 MONTHS
SURVIVAL PROBABILITY	99.73%	99.65%	99.51%	99.51%
± 1 STANDARD ERROR	0.05%	0.06%	0.12%	0.12%

*VVIR 60 bpm, 2.5V @0.4 ms, 600Ω, 100% pacing.

Leadless Pacemakers

Survival Probability Summary

INCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
LSP202V	AVEIR [®] DR	99.85%	99.85%								
LSP201A	AVEIR [®] DR	99.14%	97.00%								
LSP112V	AVEIR [®] VR	99.73%	99.65%	99.51%							

EXCLUDING NORMAL BATTERY DEPLETION

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
LSP202V	AVEIR [®] DR	99.85%	99.85%								
LSP201A	AVEIR [®] DR	99.14%	97.00%								
LSP112V	AVEIR [®] VR	99.73%	99.65%	99.51%							

Leadless Pacemakers

US Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP202V	AVEIR™ DR	7,007	2.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	0	0.00%	3	0.04%
LSP201A	AVEIR™ DR	7,535	3.60%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	8	0.11%	0	0.00%	2	0.03%	0	0.00%	11	0.15%
LSP112V	AVEIR™ VR	11,643	3.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.03%	2	0.02%	5	0.04%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	REGISTERED IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP202V	AVEIR™ DR	7,007	2.70%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	5	0.07%
LSP201A	AVEIR™ DR	7,535	3.60%	1	0.01%	0	0.00%	0	0.00%	2	0.03%	10	0.13%	0	0.00%	0	0.00%	2	0.03%	15	0.20%
LSP112V	AVEIR™ VR	11,643	3.30%	2	0.02%	0	0.00%	0	0.00%	10	0.09%	0	0.00%	0	0.00%	0	0.00%	24	0.21%	36	0.31%

Definitions of malfunction categories can be found on [pages 5-6](#).

Leadless Pacemakers

Worldwide Malfunction Summary

WITH COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP202V	AVEIR™ DR	11,969	1.65%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.03%	0	0.00%	3	0.03%
LSP201A	AVEIR™ DR	12,931	2.44%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	22	0.00%	0	0.00%	3	0.02%	0	0.00%	26	0.20%
LSP112V	AVEIR™ VR	27,227	2.47%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.02%	2	0.01%	9	0.03%

WITHOUT COMPROMISED THERAPY

MODELS	FAMILY	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP202V	AVEIR™ DR	11,969	1.65%	4	0.03%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	10	0.08%
LSP201A	AVEIR™ DR	12,931	2.44%	5	0.04%	0	0.00%	0	0.00%	5	0.04%	46	0.36%	0	0.00%	1	0.01%	8	0.06%	65	0.50%
LSP112V	AVEIR™ VR	27,227	2.47%	5	0.02%	0	0.00%	0	0.00%	29	0.11%	2	0.01%	0	0.00%	4	0.01%	37	0.14%	77	0.28%

Definitions of malfunction categories can be found on [pages 5-6](#).

Pacing Leads

Pacing Leads

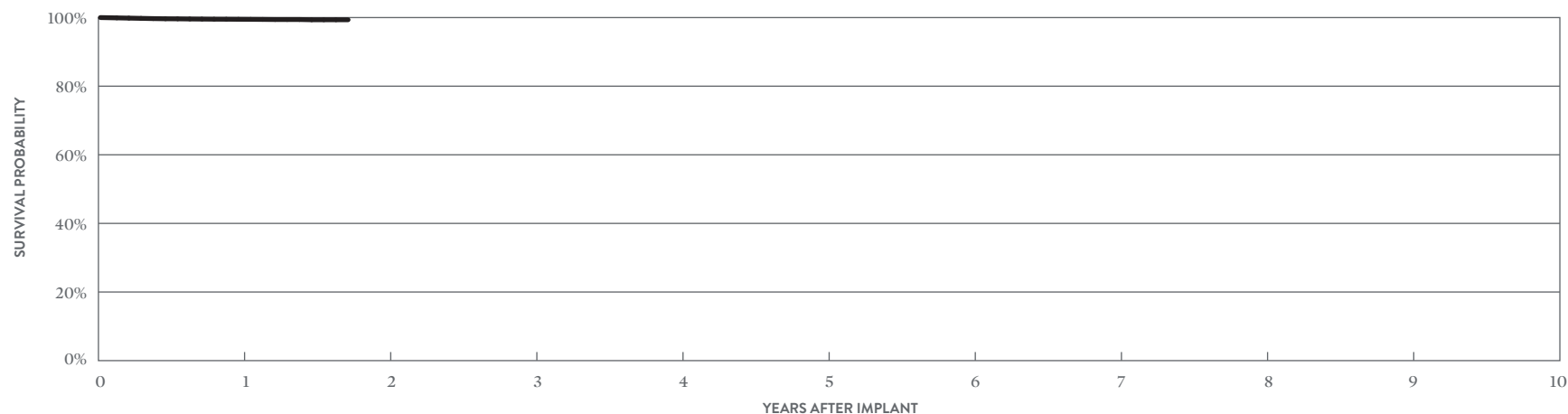
UltiPace™

MODEL LPA1231

US Regulatory Approval	May 2023
Registered US Implants	53,491
Estimated Active US Implants	47,236
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	21	0.04%	10	0.02%
Conductor Fracture	0	0.00%	2	<0.01%
Lead Dislodgement	142	0.27%	134	0.25%
Failure to Capture	39	0.07%	45	0.08%
Oversensing	2	<0.01%	8	0.01%
Failure to Sense	1	<0.01%	2	<0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	3	<0.01%	2	<0.01%
Extracardiac Stimulation	0	0.00%	2	<0.01%
Other	11	0.02%	7	0.01%
Total	219	0.41%	212	0.40%
Total Returned for Analysis	63		58	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	4	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	59	0.11%
Total	63	0.12%



YEAR	1	AT 21 MONTHS
SURVIVAL PROBABILITY	99.50%	99.36%
± 1 STANDARD ERROR	0.04%	0.09%
SAMPLE SIZE	30,210	270

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

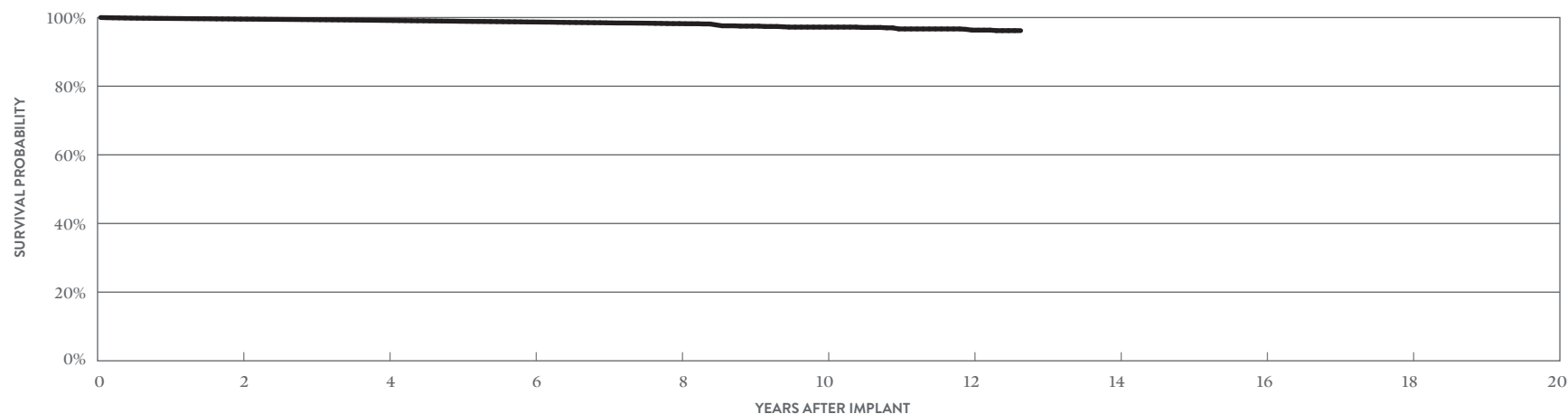
Pacing Leads

Tendril MRI™ MODEL LPA1200M

US Regulatory Approval	January 2017
Registered US Implants	208,396
Estimated Active US Implants	103,216
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	59	0.03%	23	0.01%
Conductor Fracture	3	<0.01%	123	0.06%
Lead Dislodgement	419	0.20%	580	0.28%
Failure to Capture	68	0.03%	432	0.21%
Oversensing	20	<0.01%	905	0.43%
Failure to Sense	27	0.01%	63	0.03%
Insulation Breach	2	<0.01%	45	0.02%
Abnormal Pacing Impedance	2	<0.01%	105	0.05%
Extracardiac Stimulation	8	<0.01%	12	<0.01%
Other	62	0.03%	66	0.03%
Total	670	0.32%	2354	1.13%
Total Returned for Analysis	254		590	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	70	0.03%
Insulation Breach	159	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	7	<0.01%
Extrinsic Factors	390	0.19%
Total	626	0.30%



YEAR	2	4	6	8	10	12	AT 152 MONTHS
SURVIVAL PROBABILITY	99.55%	99.16%	98.70%	98.23%	97.21%	96.34%	96.19%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.05%	0.30%	0.39%	0.45%
SAMPLE SIZE	169,570	126,350	89,140	31,060	1,010	870	200

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

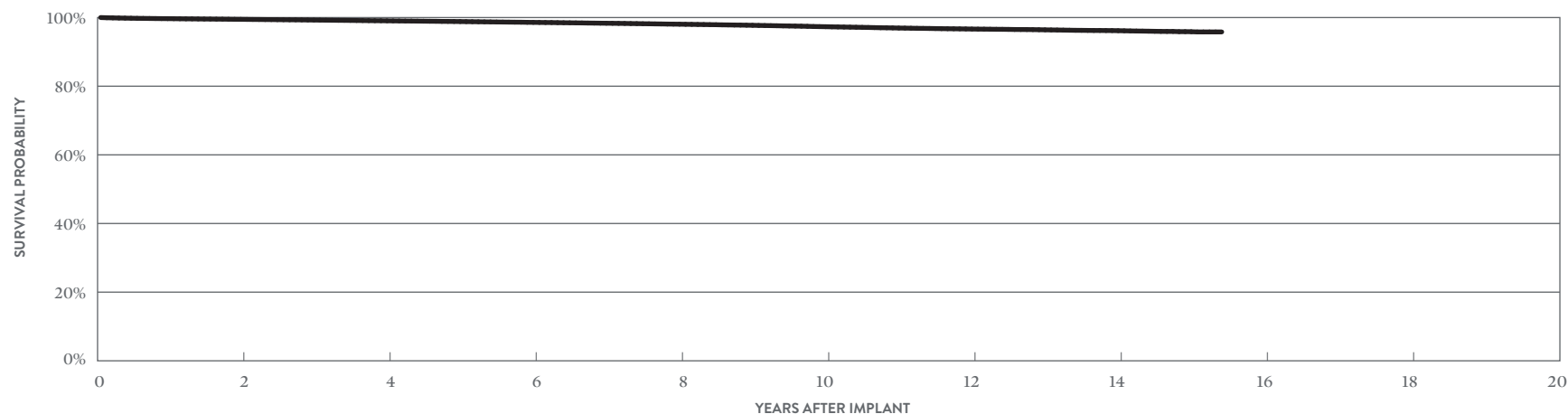
Tendril™ STS

MODEL 2088TC

US Regulatory Approval	May 2009
Registered US Implants	1,349,116
Estimated Active US Implants	615,257
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	317	0.02%	182	0.01%
Conductor Fracture	11	<0.01%	614	0.05%
Lead Dislodgement	1881	0.14%	3234	0.24%
Failure to Capture	573	0.04%	2905	0.22%
Oversensing	141	0.01%	9347	0.69%
Failure to Sense	72	<0.01%	364	0.03%
Insulation Breach	29	<0.01%	620	0.05%
Abnormal Pacing Impedance	71	<0.01%	682	0.05%
Extracardiac Stimulation	19	<0.01%	121	<0.01%
Other	245	0.02%	560	0.04%
Total	3359	0.25%	18629	1.38%
Total Returned for Analysis	1143		4587	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	149	0.01%
Insulation Breach	1952	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	38	<0.01%
Extrinsic Factors	3097	0.23%
Total	5236	0.39%



YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	99.48%	99.05%	98.59%	98.06%	97.33%	96.65%	96.17%	95.81%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.08%
SAMPLE SIZE	994,030	689,400	470,730	328,820	214,500	113,780	39,960	480

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

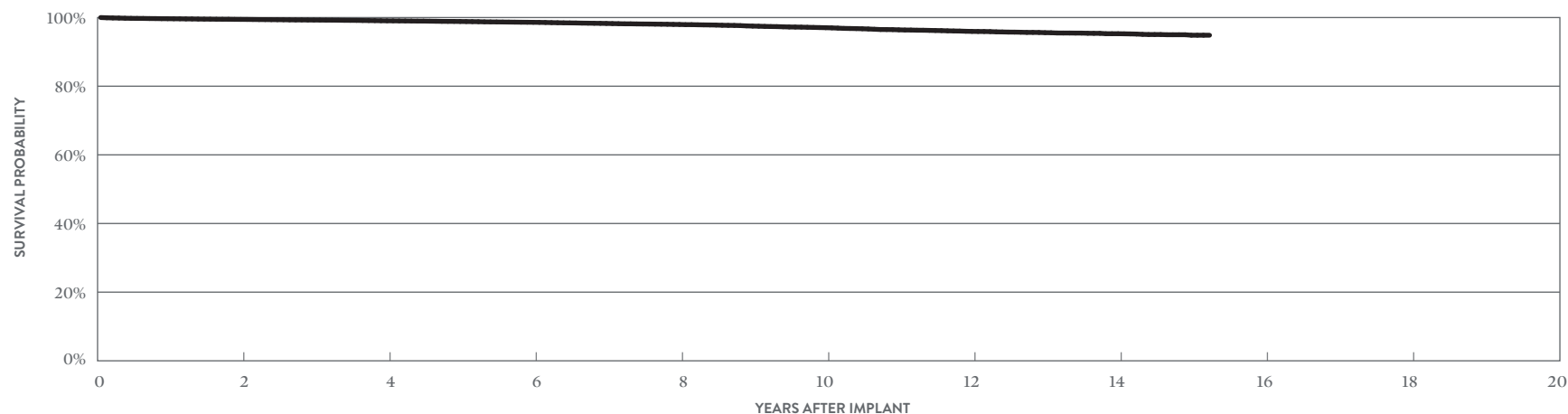
OptiSense™

MODEL 1999

US Regulatory Approval	May 2007
Registered US Implants	49,272
Estimated Active US Implants	17,162
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	5	0.01%	2	<0.01%
Conductor Fracture	0	0.00%	24	0.05%
Lead Dislodgement	69	0.14%	212	0.43%
Failure to Capture	8	0.02%	139	0.28%
Oversensing	11	0.02%	724	1.47%
Failure to Sense	3	<0.01%	57	0.12%
Insulation Breach	1	<0.01%	63	0.13%
Abnormal Pacing Impedance	0	0.00%	30	0.06%
Extracardiac Stimulation	0	0.00%	2	<0.01%
Other	14	0.03%	35	0.07%
Total	111	0.23%	1288	2.61%
Total Returned for Analysis	61		322	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	9	0.02%
Insulation Breach	135	0.27%
Crimps, Welds & Bonds	0	0.00%
Other	7	0.01%
Extrinsic Factors	211	0.43%
Total	362	0.73%



YEAR	2	4	6	8	10	12	14	AT 183 MONTHS
SURVIVAL PROBABILITY	99.46%	99.05%	98.61%	97.98%	97.04%	95.96%	95.29%	94.85%
± 1 STANDARD ERROR	0.03%	0.05%	0.06%	0.08%	0.10%	0.13%	0.17%	0.25%
SAMPLE SIZE	41,380	35,060	29,920	25,230	18,870	11,000	4,480	300

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

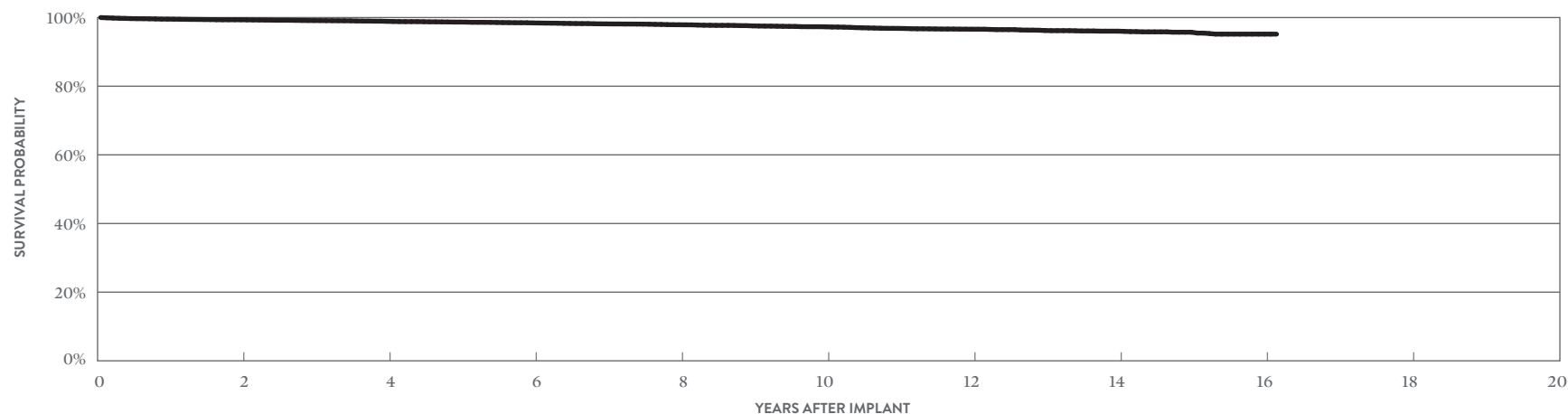
IsoFlex™ Optim™

MODEL 1944

US Regulatory Approval	March 2008
Registered US Implants	23,307
Estimated Active US Implants	8,153
Insulation	Optim™*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	13	0.06%
Lead Dislodgement	131	0.56%	98	0.42%
Failure to Capture	19	0.08%	80	0.34%
Oversensing	1	<0.01%	210	0.90%
Failure to Sense	3	0.01%	12	0.05%
Insulation Breach	0	0.00%	12	0.05%
Abnormal Pacing Impedance	0	0.00%	9	0.04%
Extracardiac Stimulation	3	0.01%	2	<0.01%
Other	4	0.02%	7	0.03%
Total	161	0.69%	444	1.91%
Total Returned for Analysis	75		73	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	29	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	60	0.26%
Total	90	0.39%



YEAR	2	4	6	8	10	12	14	16	AT 194 MONTHS
SURVIVAL PROBABILITY	99.34%	98.89%	98.43%	97.90%	97.30%	96.60%	96.03%	95.17%	95.17%
± 1 STANDARD ERROR	0.06%	0.08%	0.10%	0.13%	0.15%	0.19%	0.24%	0.40%	0.40%
SAMPLE SIZE	17,430	13,740	10,930	8,550	6,310	4,030	1,980	510	220

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

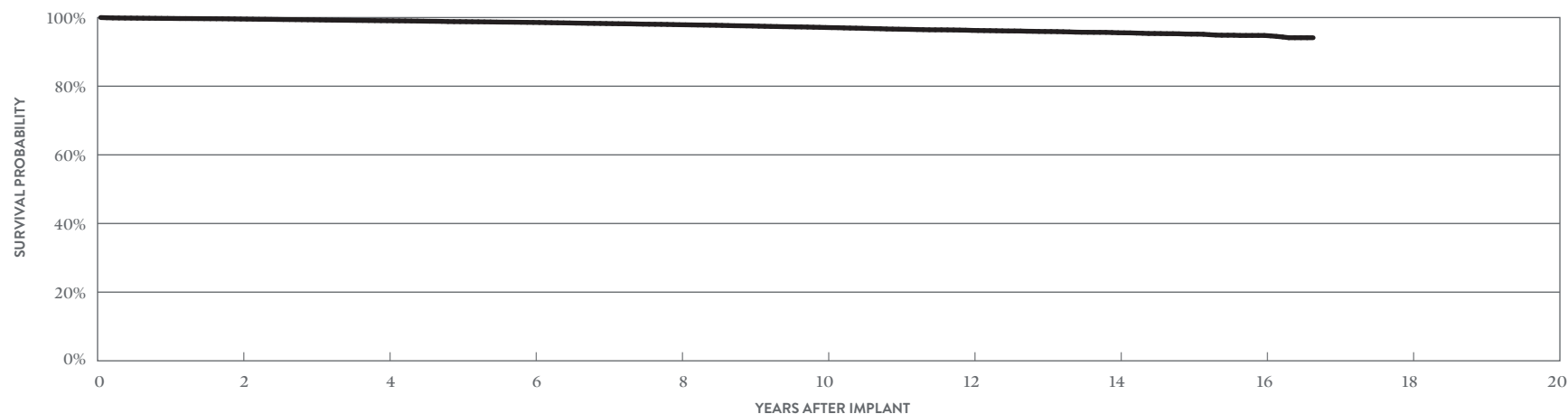
IsoFlex™ Optim™

MODEL 1948

US Regulatory Approval	March 2008
Registered US Implants	84,285
Estimated Active US Implants	29,660
Insulation	Optim™*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	6	<0.01%	13	0.02%
Conductor Fracture	1	<0.01%	132	0.16%
Lead Dislodgement	88	0.10%	106	0.13%
Failure to Capture	58	0.07%	345	0.41%
Oversensing	4	<0.01%	647	0.77%
Failure to Sense	2	<0.01%	7	<0.01%
Insulation Breach	4	<0.01%	134	0.16%
Abnormal Pacing Impedance	1	<0.01%	69	0.08%
Extracardiac Stimulation	2	<0.01%	10	0.01%
Other	9	0.01%	37	0.04%
Total	175	0.21%	1500	1.78%
Total Returned for Analysis	77		221	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	23	0.03%
Insulation Breach	210	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	5	<0.01%
Extrinsic Factors	125	0.15%
Total	363	0.43%



YEAR	2	4	6	8	10	12	14	16	AT 200 MONTHS
SURVIVAL PROBABILITY	99.57%	99.08%	98.58%	97.91%	97.10%	96.26%	95.57%	94.78%	94.12%
± 1 STANDARD ERROR	0.02%	0.04%	0.05%	0.07%	0.09%	0.11%	0.14%	0.22%	0.41%
SAMPLE SIZE	65,050	51,330	41,120	32,430	23,500	14,370	6,620	1,710	220

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

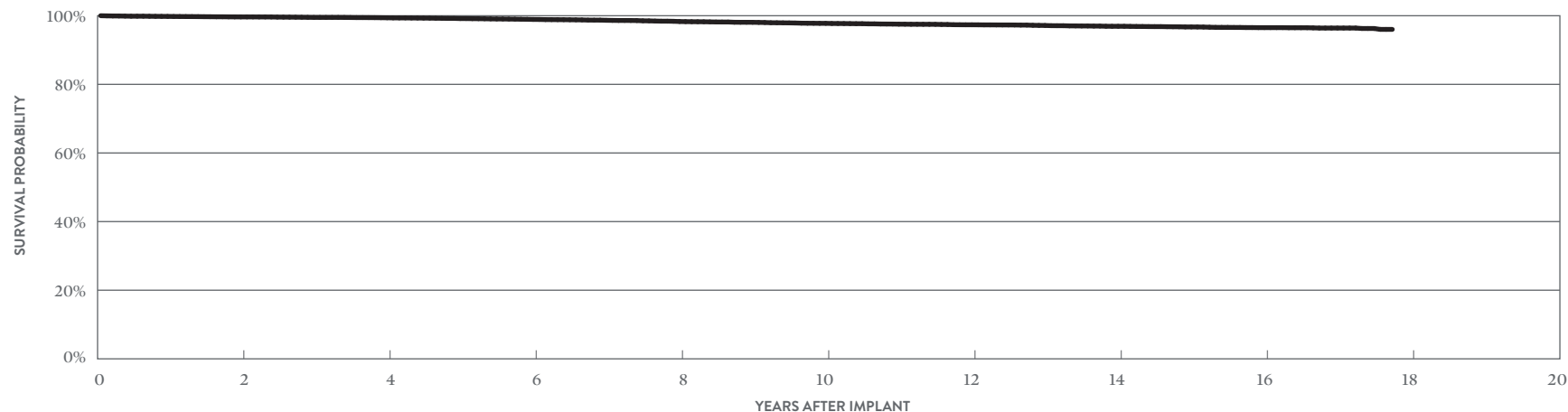
OptiSense™

MODELS 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	24,342
Estimated Active US Implants	5746
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	20	0.08%
Lead Dislodgement	7	0.03%	65	0.27%
Failure to Capture	4	0.02%	72	0.30%
Oversensing	3	0.01%	196	0.81%
Failure to Sense	8	0.03%	35	0.14%
Insulation Breach	0	0.00%	11	0.05%
Abnormal Pacing Impedance	0	0.00%	34	0.14%
Extracardiac Stimulation	0	0.00%	3	0.01%
Other	2	<0.01%	11	0.05%
Total	25	0.10%	447	1.84%
Total Returned for Analysis	16		102	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	14	0.06%
Insulation Breach	57	0.23%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	67	0.28%
Total	138	0.57%



YEAR	2	4	6	8	10	12	14	16	AT 213 MONTHS
SURVIVAL PROBABILITY	99.65%	99.40%	98.92%	98.31%	97.78%	97.36%	96.92%	96.53%	96.02%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.11%	0.13%	0.15%	0.16%	0.18%	0.35%
SAMPLE SIZE	19,430	15,750	13,070	11,040	9,620	8,400	7,210	4,830	230

Pacing Leads

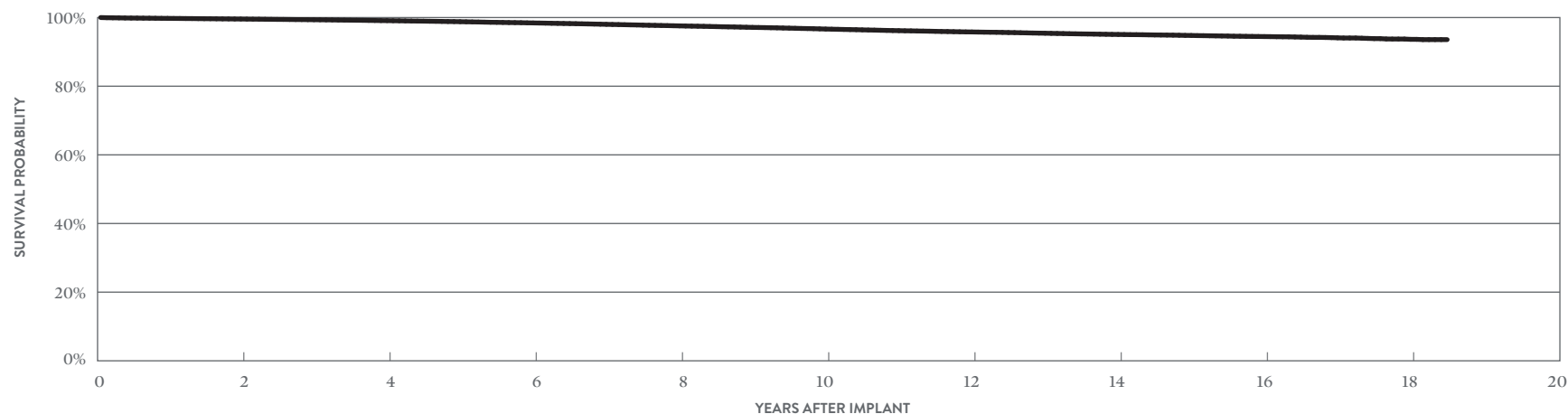
Tendril™ ST Optim™

MODELS 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	320,123
Estimated Active US Implants	82,917
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	43	0.01%	49	0.02%
Conductor Fracture	8	<0.01%	385	0.12%
Lead Dislodgement	187	0.06%	712	0.22%
Failure to Capture	104	0.03%	1340	0.42%
Oversensing	23	<0.01%	4621	1.44%
Failure to Sense	14	<0.01%	176	0.05%
Insulation Breach	7	<0.01%	582	0.18%
Abnormal Pacing Impedance	11	<0.01%	351	0.11%
Extracardiac Stimulation	6	<0.01%	54	0.02%
Other	43	0.01%	235	0.07%
Total	446	0.14%	8505	2.66%
Total Returned for Analysis	217		1864	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	58	0.02%
Insulation Breach	1381	0.43%
Crimps, Welds & Bonds	1	<0.01%
Other	20	<0.01%
Extrinsic Factors	1028	0.32%
Total	2488	0.78%



YEAR	2	4	6	8	10	12	14	16	18	AT 222 MONTHS
SURVIVAL PROBABILITY	99.57%	99.10%	98.43%	97.57%	96.65%	95.80%	95.07%	94.46%	93.65%	93.57%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.04%	0.05%	0.06%	0.07%	0.11%	0.15%
SAMPLE SIZE	256,310	208,100	172,760	146,330	124,740	98,430	70,370	37,100	6,370	200

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

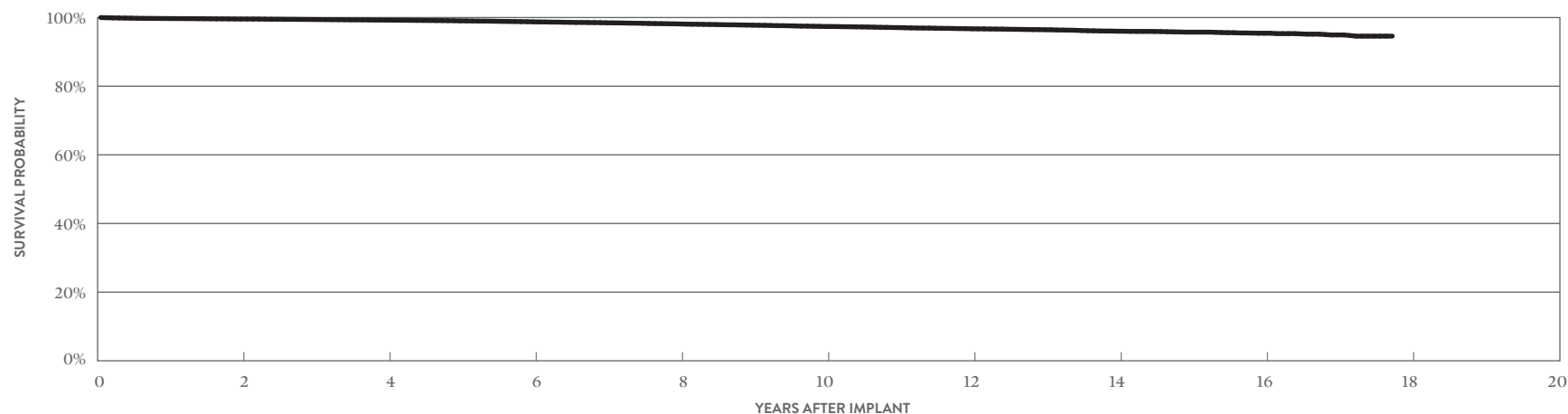
Tendril™ ST Optim™

MODELS 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	51,367
Estimated Active US Implants	15,789
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	6	0.01%	4	<0.01%
Conductor Fracture	0	0.00%	28	0.05%
Lead Dislodgement	54	0.11%	176	0.34%
Failure to Capture	13	0.03%	155	0.30%
Oversensing	7	0.01%	525	1.02%
Failure to Sense	5	<0.01%	34	0.07%
Insulation Breach	0	0.00%	64	0.12%
Abnormal Pacing Impedance	1	<0.01%	39	0.08%
Extracardiac Stimulation	0	0.00%	6	0.01%
Other	15	0.03%	35	0.07%
Total	101	0.20%	1066	2.08%
Total Returned for Analysis	50		227	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	<0.01%
Insulation Breach	128	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	158	0.31%
Total	291	0.57%



YEAR	2	4	6	8	10	12	14	16	AT 213 MONTHS
SURVIVAL PROBABILITY	99.57%	99.25%	98.75%	98.14%	97.39%	96.72%	96.01%	95.43%	94.58%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.07%	0.09%	0.12%	0.15%	0.20%	0.38%
SAMPLE SIZE	42,000	35,100	29,690	24,720	18,840	12,570	7,000	2,790	230

*Optim™ lead insulation is a copolymer of silicone and polyurethane.

Pacing Leads

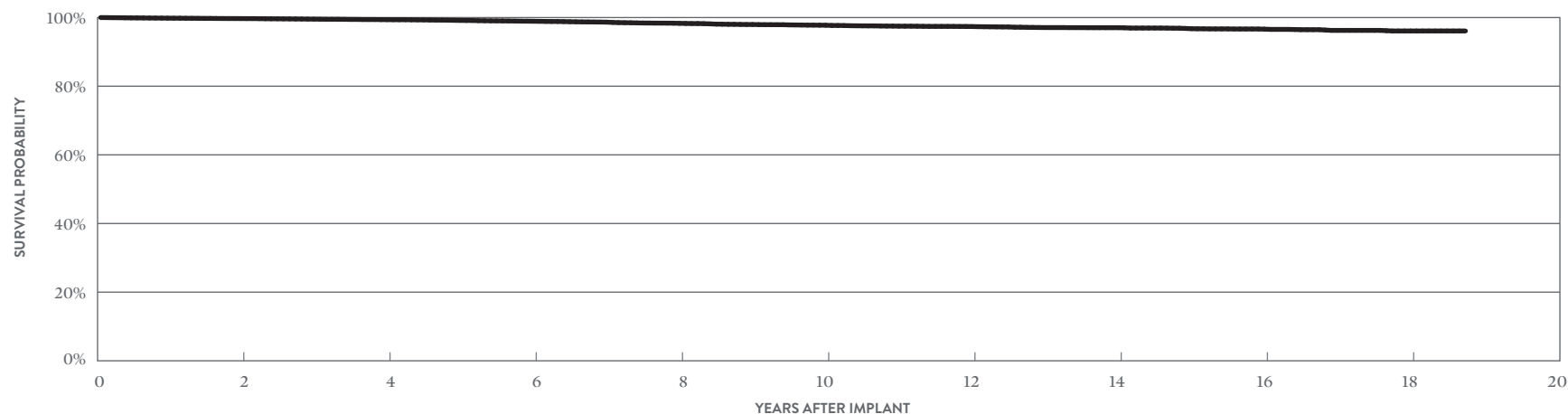
Tendril™

MODELS 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,889
Estimated Active US Implants	3659
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	6	0.04%	0	0.00%
Conductor Fracture	0	0.00%	6	0.04%
Lead Dislodgement	13	0.08%	54	0.32%
Failure to Capture	5	0.03%	63	0.37%
Oversensing	0	0.00%	89	0.53%
Failure to Sense	0	0.00%	10	0.06%
Insulation Breach	0	0.00%	7	0.04%
Abnormal Pacing Impedance	2	0.01%	21	0.12%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	6	0.04%
Total	29	0.17%	257	1.52%
Total Returned for Analysis	16		75	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	<0.01%
Insulation Breach	53	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	52	0.31%
Total	106	0.63%



YEAR	2	4	6	8	10	12	14	16	18	AT 225 MONTHS
SURVIVAL PROBABILITY	99.70%	99.38%	98.92%	98.31%	97.76%	97.38%	97.04%	96.62%	96.09%	96.09%
± 1 STANDARD ERROR	0.04%	0.07%	0.10%	0.13%	0.16%	0.18%	0.20%	0.22%	0.29%	0.29%
SAMPLE SIZE	13,340	10,580	8,410	6,910	5,920	5,200	4,380	3,020	1,260	200

Pacing Leads

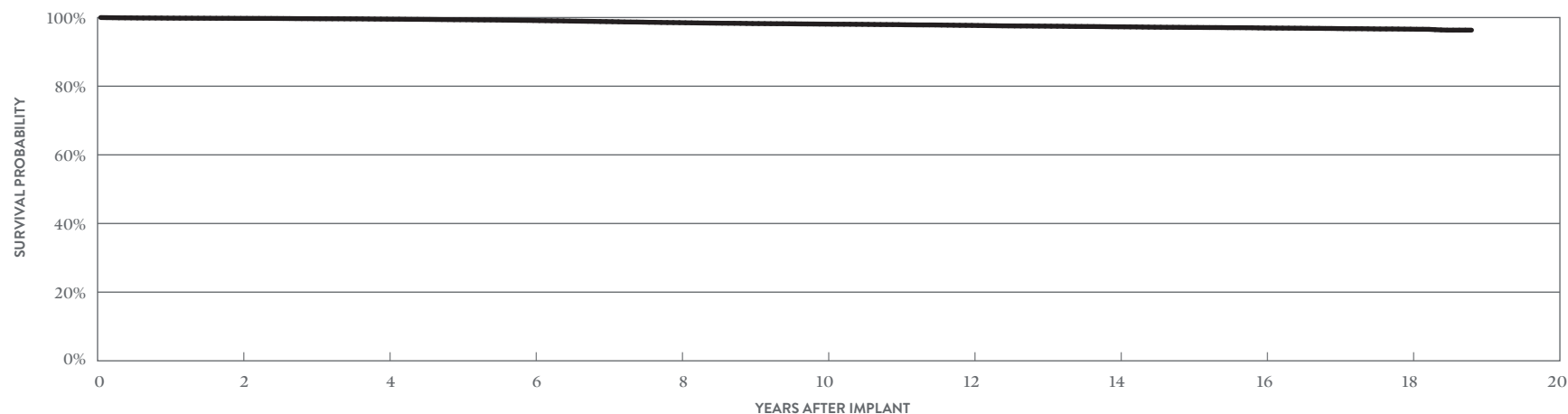
Tendril™

MODELS 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	66,683
Estimated Active US Implants	14,000
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	12	0.02%	10	0.01%
Conductor Fracture	1	<0.01%	42	0.06%
Lead Dislodgement	32	0.05%	88	0.13%
Failure to Capture	32	0.05%	220	0.33%
Oversensing	4	<0.01%	334	0.50%
Failure to Sense	2	<0.01%	29	0.04%
Insulation Breach	1	<0.01%	37	0.06%
Abnormal Pacing Impedance	9	0.01%	60	0.09%
Extracardiac Stimulation	2	<0.01%	10	0.01%
Other	21	0.03%	41	0.06%
Total	116	0.17%	871	1.31%
Total Returned for Analysis	49		188	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	10	0.01%
Insulation Breach	157	0.24%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	114	0.17%
Total	283	0.42%



YEAR	2	4	6	8	10	12	14	16	18	AT 226 MONTHS
SURVIVAL PROBABILITY	99.76%	99.54%	99.14%	98.51%	98.09%	97.71%	97.30%	96.96%	96.62%	96.34%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.06%	0.08%	0.09%	0.10%	0.11%	0.12%	0.16%
SAMPLE SIZE	52,310	40,860	32,820	27,060	23,360	20,840	18,350	14,620	7,340	250

SUMMARY INFORMATION
Pacing Leads

Pacing Leads

Survival Probability Summary

MODELS	FAMILY	1 YEAR	2 YEAR	3 YEAR	4 YEAR	5 YEAR	6 YEAR	7 YEAR	8 YEAR	9 YEAR	10 YEAR
LPA1231	UltiPace™	99.50%									
LPA1200M	Tendril MRI™	99.74%	99.55%	99.38%	99.16%	98.91%	98.70%	98.46%	98.23%	97.50%	97.21%
2088TC	Tendril™ STS	99.68%	99.48%	99.27%	99.05%	98.83%	98.59%	98.34%	98.06%	97.74%	97.33%
1999	OptiSense™ Optim™	99.66%	99.46%	99.27%	99.05%	98.85%	98.61%	98.28%	97.98%	97.51%	97.04%
1944	IsoFlex™ Optim™	99.54%	99.34%	99.12%	98.89%	98.68%	98.43%	98.15%	97.90%	97.57%	97.30%
1948	IsoFlex™ Optim™	99.75%	99.57%	99.33%	99.08%	98.80%	98.58%	98.25%	97.91%	97.54%	97.10%
1699T/TC	OptiSense™	99.80%	99.65%	99.51%	99.40%	99.17%	98.92%	98.67%	98.31%	98.08%	97.78%
1888T/TC	Tendril™ ST Optim™	99.76%	99.57%	99.36%	99.10%	98.79%	98.43%	98.02%	97.57%	97.13%	96.65%
1882T/TC	Tendril™ ST Optim™	99.71%	99.57%	99.43%	99.25%	99.03%	98.75%	98.47%	98.14%	97.78%	97.39%
1782T/TC	Tendril™	99.82%	99.70%	99.54%	99.38%	99.16%	98.92%	98.66%	98.31%	97.97%	97.76%
1788T/TC	Tendril™	99.83%	99.76%	99.66%	99.54%	99.37%	99.14%	98.82%	98.51%	98.25%	98.09%

Pacing Leads

Acute Observation Summary

POST IMPLANT ≤30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLOJEMENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
LPA1231	May-23	53,491	47236	21	0.04%	0	0.00%	142	0.27%	39	0.07%	2	<0.01%	1	<0.01%	0	0.00%	3	<0.01%	0	0.00%	11	0.02%	219	0.41%	63
LPA1200M	Jan-17	208,396	103216	59	0.03%	3	<0.01%	419	0.20%	68	0.03%	20	<0.01%	27	0.01%	2	<0.01%	2	<0.01%	8	<0.01%	62	0.03%	670	0.32%	254
2088TC	May-09	1,349,116	615257	317	0.02%	11	<0.01%	1881	0.14%	573	0.04%	141	0.01%	72	<0.01%	29	<0.01%	71	<0.01%	19	<0.01%	245	0.02%	3359	0.25%	1143
1999	Oct-09	49,272	17162	5	0.01%	0	0.00%	69	0.14%	8	0.02%	11	0.02%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	14	0.03%	111	0.23%	61
1944	Mar-08	23,307	8153	0	0.00%	0	0.00%	131	0.56%	19	0.08%	1	<0.01%	3	0.01%	0	0.00%	0	0.00%	3	0.01%	4	0.02%	161	0.69%	75
1948	Mar-08	84,285	29660	6	<0.01%	1	<0.01%	88	0.10%	58	0.07%	4	<0.01%	2	<0.01%	4	<0.01%	1	<0.01%	2	<0.01%	9	0.01%	175	0.21%	77
1699T/TC	May-07	24,342	5746	1	<0.01%	0	0.00%	7	0.03%	4	0.02%	3	0.01%	8	0.03%	0	0.00%	0	0.00%	2	<0.01%	2	<0.01%	25	0.10%	16
1888T/TC	Jun-06	320,123	82917	43	0.01%	8	<0.01%	187	0.06%	104	0.03%	23	<0.01%	14	<0.01%	7	<0.01%	11	<0.01%	6	<0.01%	43	0.01%	446	0.14%	217
1882T/TC	Jun-06	51,367	15789	6	0.01%	0	0.00%	54	0.11%	13	0.03%	7	0.01%	5	<0.01%	0	0.00%	1	<0.01%	0	0.00%	15	0.03%	101	0.20%	50
1782T/TC	Feb-06	16,889	3659	6	0.04%	0	0.00%	13	0.08%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	29	0.17%	16
1788T/TC	Feb-06	66,683	14000	12	0.02%	1	<0.01%	32	0.05%	32	0.05%	4	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	21	0.03%	116	0.17%	49

Chronic Complication Summary

>30 DAYS

MODELS	US REGULATORY APPROVAL	REGISTERED US IMPLANTS	ESTIMATED ACTIVE US IMPLANTS	CARDIAC PERFORATION		CONDUCTOR FRACTURE		LEAD DISLOJEMENT		FAILURE TO CAPTURE		OVERSENSING		FAILURE TO SENSE		INSULATION BREACH		ABNORMAL PACING IMPEDANCE		EXTRACARDIAC STIMULATION		OTHER		TOTAL		TOTAL RETURNED FOR ANALYSIS
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	
LPA1231	May-23	53,491	47236	10	0.02%	2	<0.01%	134	0.25%	45	0.08%	8	0.01%	2	<0.01%	0	0.00%	2	<0.01%	2	<0.01%	7	0.01%	212	0.40%	58
LPA1200M	Jan-17	208,396	103216	23	0.01%	123	0.06%	580	0.28%	432	0.21%	905	0.43%	63	0.03%	45	0.02%	105	0.05%	12	<0.01%	66	0.03%	2354	1.13%	590
2088TC	May-09	1,349,116	615257	182	0.01%	614	0.05%	3234	0.24%	2905	0.22%	9347	0.69%	364	0.03%	620	0.05%	682	0.05%	121	<0.01%	560	0.04%	18629	1.38%	4587
1999	Oct-09	49,272	17162	2	<0.01%	24	0.05%	212	0.43%	139	0.28%	724	1.47%	57	0.12%	63	0.13%	30	0.06%	2	<0.01%	35	0.07%	1288	2.61%	322
1944	Mar-08	23,307	8153	1	<0.01%	13	0.06%	98	0.42%	80	0.34%	210	0.90%	12	0.05%	12	0.05%	9	0.04%	2	<0.01%	7	0.03%	444	1.91%	73
1948	Mar-08	84,285	29660	13	0.02%	132	0.16%	106	0.13%	345	0.41%	647	0.77%	7	<0.01%	134	0.16%	69	0.08%	10	0.01%	37	0.04%	1500	1.78%	221
1699T/TC	May-07	24,342	5746	0	0.00%	20	0.08%	65	0.27%	72	0.30%	196	0.81%	35	0.14%	11	0.05%	34	0.14%	3	0.01%	11	0.05%	447	1.84%	102
1888T/TC	Jun-06	320,123	82917	49	0.02%	385	0.12%	712	0.22%	1340	0.42%	4621	1.44%	176	0.05%	582	0.18%	351	0.11%	54	0.02%	235	0.07%	8505	2.66%	1864
1882T/TC	Jun-06	51,367	15789	4	<0.01%	28	0.05%	176	0.34%	155	0.30%	525	1.02%	34	0.07%	64	0.12%	39	0.08%	6	0.01%	35	0.07%	1066	2.08%	227
1782T/TC	Feb-06	16,889	3659	0	0.00%	6	0.04%	54	0.32%	63	0.37%	89	0.53%	10	0.06%	7	0.04%	21	0.12%	1	<0.01%	6	0.04%	257	1.52%	75
1788T/TC	Feb-06	66,683	14000	10	0.01%	42	0.06%	88	0.13%	220	0.33%	334	0.50%	29	0.04%	37	0.06%	60	0.09%	10	0.01%	41	0.06%	871	1.31%	188

Definitions of observations and complications can be found on [page 7](#).

Pacing Leads U.S. Malfunction Summary

MODELS	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LPA1231	53,491	1.60%	0	0.00%	4	<0.01%	0	0.00%	0	0.00%	59	0.11%	63	0.12%
LPA1200M	208,396	3.70%	70	0.03%	159	0.08%	0	0.00%	7	<0.01%	390	0.19%	626	0.30%
2088TC	1,349,116	4.50%	149	0.01%	1952	0.14%	0	0.00%	38	<0.01%	3097	0.23%	5236	0.39%
1999	49,272	6.20%	9	0.02%	135	0.27%	0	0.00%	7	0.01%	211	0.43%	362	0.73%
1944	23,307	9.80%	0	0.00%	29	0.12%	0	0.00%	1	<0.01%	60	0.26%	90	0.39%
1948	84,285	5.30%	23	0.03%	210	0.25%	0	0.00%	5	<0.01%	125	0.15%	363	0.43%
1699T/TC	24,342	6.30%	14	0.06%	57	0.23%	0	0.00%	0	0.00%	67	0.28%	138	0.57%
1888T/TC	320,123	5.80%	58	0.02%	1381	0.43%	1	<0.01%	20	<0.01%	1028	0.32%	2488	0.78%
1882T/TC	51,367	5.00%	2	<0.01%	128	0.25%	0	0.00%	3	<0.01%	158	0.31%	291	0.57%
1782T/TC	16,889	6.00%	1	<0.01%	53	0.31%	0	0.00%	0	0.00%	52	0.31%	106	0.63%
1788T/TC	66,683	6.30%	10	0.01%	157	0.24%	1	<0.01%	1	<0.01%	114	0.17%	283	0.42%

Definitions of malfunction categories can be found on [pages 8-9](#).

Pacing Leads

Worldwide Malfunction Summary

MODELS	WORLDWIDE SALES	PERCENT RETURNED FOR ANALYSIS	CONDUCTOR FRACTURE		INSULATION BREACH		CRIMPS, WELDS & BONDS		OTHER		EXTRINSIC FACTORS		TOTAL	
			QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LPA1231	108,699	0.77%	0	0.00%	4	<0.01%	0	0.00%		0.00%	60	0.06%	64	0.06%
LPA1200M	537,726	1.57%	107	0.02%	235	0.04%	0	0.00%	17	<0.01%	519	0.10%	878	0.16%
2088TC	5,202,394	1.21%	199	<0.01%	2409	0.05%	0	0.00%	108	<0.01%	4010	0.08%	6726	0.13%
1888T/TC	1,163,412	1.81%	79	0.01%	1574	0.14%	1	<0.01%	39	<0.01%	1400	0.12%	3093	0.27%

Definitions of malfunction categories can be found on [pages 8-9](#).

Implantable Cardiac Monitors (ICM) Devices

Implantable Cardiac Monitors (ICMs) Devices

US Malfunction Summary

MODELS	FAMILY	REGISTERED US IMPLANTS	PERCENT RETURNED FOR ANALYSIS	ELECTRICAL COMPONENT		ELECTRICAL INTERCONNECT		BATTERY		SOFTWARE/ FIRMWARE		MECHANICAL		POSSIBLE EARLY BATTERY DEPLETION		OTHER		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
DM5500	Assert™ IQ	21,465	1.10%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.02%	8	0.04%
DM5300	Assert™ IQ	16,418	1.10%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	3	0.02%
DM5000	Assert™ IQ	5,870	0.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
DM4500	Jot Dx™ ICM	40,805	3.90%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	5	0.01%
DM3500	SJM Confirm Rx™ ICM	101,776	5.00%	12	0.01%	10	<0.01%	0	0.00%	0	0.00%	2	<0.01%	9	<0.01%	10	<0.01%	43	0.04%

Definitions of malfunction categories can be found on [pages 5-6](#).

Focus on Clinical Performance

Update on AVEIR™ Leadless Pacemaker Performance

The AVEIR leadless pacemakers exhibit characteristics which are similar to both implantable pulse generators and cardiac leads. Device malfunction criteria are reported according to standard pacemaker laboratory-confirmed processes. In addition, Abbott has assessed the events reported in the United States according to the relevant hierarchical criteria listed in ISO 5841-2 (E) for cardiac leads. The tables below provide an overview of the product performance since commercial approval for the AVEIR Atrial and Ventricular Leadless Pacemakers through June 30, 2025.

AVEIR VENTRICULAR PACEMAKERS: MODELS LSP112V AND LSP202V (N = 18,600) DAY OF IMPLANT OBSERVATIONS

REPORTED COMPLICATION	RATE
Cardiac Perforation	0.34%
Dislodgement (Post Tether Mode)	0.47%
Failure to Capture	0.10%
Oversensing	0.01%
Failure to Sense	0.01%

AVEIR ATRIAL PACEMAKER: MODEL LSP201A (N = 7,500) DAY OF IMPLANT OBSERVATIONS

REPORTED COMPLICATION	RATE
Cardiac Perforation	0.36%
Dislodgement (Post Tether Mode)	0.60%
Failure to Capture	0.27%
Oversensing	0.01%
Failure to Sense	0.04%

AVEIR VENTRICULAR PACEMAKERS: MODELS LSP112V AND LSP202V (N = 18,600) ACUTE OBSERVATIONS: OCCURRING WITHIN THE FIRST 30 DAYS POST-IMPLANT

REPORTED COMPLICATION	RATE
Cardiac Perforation	0%
Dislodgement	0.21%
Failure to Capture	0.12%
Oversensing	0.01%
Failure to Sense	0.00%

AVEIR ATRIAL PACEMAKER: MODEL LSP201A (N = 7,500) ACUTE OBSERVATIONS: OCCURRING WITHIN THE FIRST 30 DAYS POST-IMPLANT

REPORTED COMPLICATION	RATE
Cardiac Perforation	0.03%
Dislodgement	0.63%
Failure to Capture	0.11%
Oversensing	0.07%
Failure to Sense	0.03%

ICD Premature Battery Depletion Advisory Update

Since the original October 2016 communication, Abbott has continued to analyze and review the performance data from the affected device population. The rates reported below summarize performance data through August 31, 2025.

Importantly, the information contained in this notice has not altered our previously communicated patient management recommendations. This information is intended to keep you informed of our continuous analysis of all products returned to the company.

RATES

The table below summarizes the updated worldwide experience for the affected devices that were returned for product analysis due to premature battery depletion (PBD). The table includes the updated data through August 31, 2025. Consistent with prior Performance Reports, all events reported since August 31, 2022 were assessed as “No Harm Reported/Additional Surgery Only”; there have been no (0) additional reports of Loss of Pacing or Loss of Defibrillation.

WORLDWIDE PATIENT IMPACT	NUMBER / RATE THROUGH AUGUST 31, 2025
No Harm Reported/Additional Surgery Only*	9,751/2.445%
Loss of Pacing – Minor (Dizziness)	60/0.015%
Loss of Pacing – Major (Syncope)	29/<0.01%
Loss of Defibrillation – Emergency	4/<0.01%
Loss of Defibrillation – Death	2/<0.01%
Grand Total	9,846/2.469%
Total Units Sold	398,740

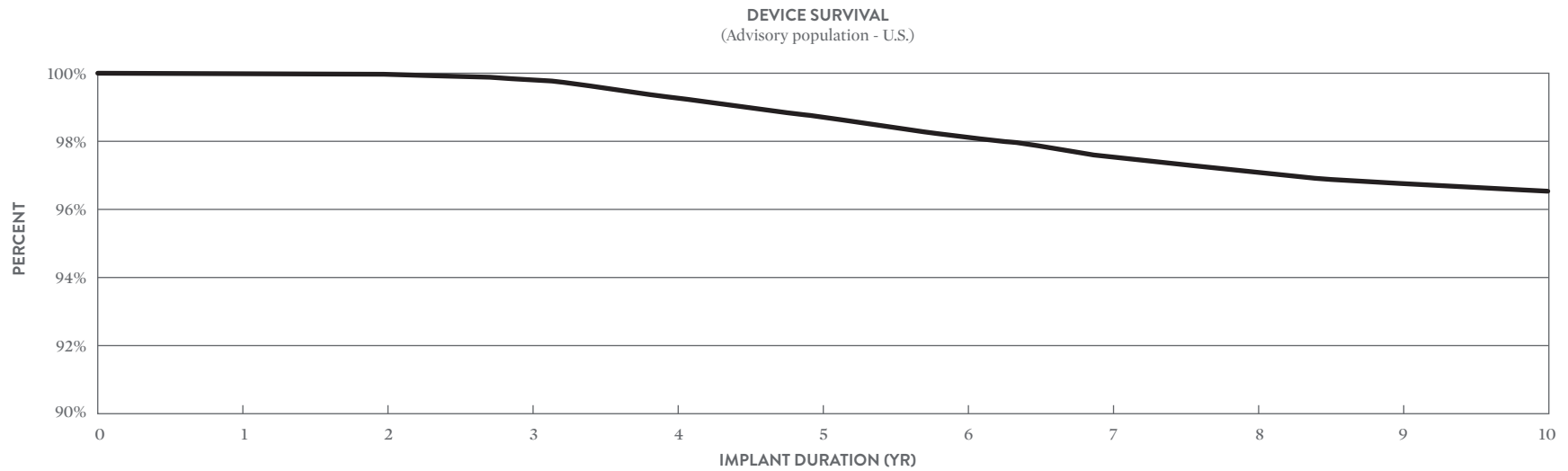
**All impacts in this table were related to a replacement surgery, as the data are from units explanted and returned for analysis. The category “No Harm Reported/Additional Surgery Only” means there was no associated report of patient symptoms in addition to the replacement of the affected unit.*

Note: The calculation also includes investigations associated with the Battery Performance Alert notifications. These are reflected in the “No Harm Reported/Additional Surgery Only” category.

Focus on Clinical Performance

Estimated Performance of Affected Fortify™ Implantable Cardioverter Defibrillator (ICD), Fortify Assura™ ICD, Quadra Assura™ Cardiac Resynchronization Therapy Defibrillator (CRT-D), Unify™ CRT-D, Unify Assura™ CRT-D and Unify Quadra™ CRT-D Devices

TEN-YEAR COMBINED KAPLAN-MEIER SURVIVAL CURVE OF FREEDOM FROM PREMATURE BATTERY DEPLETION ASSOCIATED WITH LITHIUM DEPOSITS IN AFFECTED U.S. ADVISORY DEVICE POPULATION



YEAR	1	2	3	4	5	6	7	8	9	10
SURVIVAL PROBABILITY	99.997%	99.970%	99.750%	99.233%	98.588%	97.947%	97.383%	96.936%	96.697%	96.556%
SAMPLE SIZE	227,000	210,000	197,000	185,000	173,000	165,000	147,000	126,000	114,000	94,000

SURVIVAL CALCULATION GENERAL METHODS

Internal modeling based on an analysis of field returns related to premature battery depletions associated with lithium clusters; updated with data through February 28, 2025.

Non-Advisory Population Update

Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ Devices manufactured after May 23, 2015 were built with an improved battery design with additional insulation and thus not included in the advisory population. Information regarding the performance of the non-advisory devices is provided throughout this Product Performance Report, consistent with previous editions. Please refer to the specific model number and advisory designation in the associated CRT or ICD device sections of the report (beginning with page 11 or page 64 respectively).

Advisories & Safety Alerts

Advisories & Safety Alerts

The following table summarizes advisories and safety alerts regarding Abbott implantable device systems since 2016. These advisories and alerts have been previously communicated to physicians. For more information please access our Product Advisory web page at [Cardiovascular Product Advisories | Abbott](#) or contact Abbott Technical Services at 1-800-722-3774.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>GLOBAL MODELS A subset of Gallant™ VR (Model CDVRA500Q), Gallant™ HF (Model CDHFA500Q), Gallant™ DR (Model CDDRA500Q), Neutrino™ NxT HF (Model CDHFA600Q), Neutrino™ NxT DR (Model CDDRA600Q), Neutrino™ NxT VR (Model CDVRA600Q), Entrant™ HF (Model CDHFA300Q), Entrant™ VR (Model CDVRA300Q), and Entrant™ DR (Model CDDRA300Q)</p>	<p>8/18/2023 Class II</p> <p>Abbott informed customers of a rare potential for a Bluetooth (BLE) circuit component issue on a subset of Gallant™, Neutrino™, and Entrant™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) manufactured prior to April 2022. This issue has been associated with a risk of loss of Bluetooth communication, higher than normal current consumption, and reduced device longevity. A sub-group of approximately 1,500 devices are more likely to manifest this issue as compared to the remaining 65,500 devices.</p>	<p>Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott is providing the following guidelines:</p> <ul style="list-style-type: none"> • Prophylactic device replacement is NOT recommended as the new firmware version pr00.10.87.04 eliminates the potential for loss of therapy between follow-ups due to unrecognized decreased device longevity. • Determine the firmware version of devices followed at your clinic. The device firmware version is visible in the footer of any programmer reports from the Merlin™ PCS 3650 or Merlin™2 PCS. • For patients with firmware version pr00.10.87.00 or with firmware version undetermined, upgrade devices to device firmware version pr00.10.87.04 by interrogating patients in-clinic with Merlin™ PCS 3650 programmer or Merlin™ 2 PCS MER3700 programmer software versions listed below. <ul style="list-style-type: none"> • Prioritize in-clinic firmware upgrade for the specific devices from the 1,500 device sub-group. • For remaining patients, schedule the next follow-up in-clinic to complete the firmware upgrade. • Following firmware upgrade, continue to follow patients routinely at the recommended interval per the device User's Manual. • If a device experiences a loss of Bluetooth communication, contact Abbott Technical Support for troubleshooting to determine whether the loss of Bluetooth communication is related to this issue. <p>Firmware version pr00.10.87.04 is available in:</p> <ul style="list-style-type: none"> • Merlin™ Patient Care System (PCS) Software Model 3330 version 25.4.1 rev 1 (United States), 26.0.4 rev 1 (Canada), or 25.8.# rev 1 (all other countries) or later • Merlin™ 2 Patient Care System (PCS) Software Model MER3400 version 1.8.2 rev 1 or later (Europe) or any other software version in all other countries <p>Current Status (June 30, 2025): 43 devices of the 67,121 devices distributed globally (0.06%) are known to have lost Bluetooth* communication due to this issue.</p>

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
GLOBAL MODELS Subset of Ellipse™ (Models CD2411-36C, CD1277-36, CD1377-36C, CD1377-36QC, CD2277-36Q, CD2377-36QC)	1/22/2020 Class II Abbott is notifying physicians that a small number of Ellipse™ Implantable Cardioverter Defibrillators (ICDs) may lose wireless radiofrequency (RF) communication. Devices will continue to function normally, but remote monitoring and data transmission capabilities may be interrupted.	Abbott has developed a software patch for the Merlin™ PCS Programmer which restores wireless RF communication capability in affected devices. This solution does not present additional risk to patients and device explant is not required for the update. The solution is available in Merlin™ PCS Programmer software Model 3330 v24.6.1 or later and Abbott will assist in updating programmer software and restoring wireless RF communication for these devices. We recommend working with your Abbott representative to help correct affected devices during the patient's next regularly scheduled visit. Current Status (June 30, 2025): No occurrences have been reported following the field communication and correction.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
GLOBAL MODELS Ellipse™ (Models CD1411-36Q, CD2411-36Q, CD2411-36C)	6/21/2019 Class I The potential for electrical failures was identified in implantable cardioverter defibrillators (ICDs) due to a manufacturing error with aluminum wires. The affected ICDs may contain electrical wire connections which may not be completely insulated. The potential patient impact could be the inability to deliver high voltage therapy. There is no available option to verify the vulnerability status for implanted devices.	On June 20, 2019 Abbott began voluntarily recalling a small number (204 devices globally) of Ellipse implantable cardioverter defibrillators (ICDs) from our customers and hospitals to prevent implant of devices that may have a latent vulnerability in the electronics circuitry. We have currently received zero (0) product performance complaints related to this issue. On June 21, 2019, hand-delivery of Urgent Medical Device Recall Notices to physicians supporting implanted patients commenced. Device explant and replacement are recommended. Customers were advised to: 1) Review the device model and serial numbers in the appendix of the customer letter to identify the impacted patients and return the acknowledgement form to the Abbott sales representative; and 2) Device explant and replacement are recommended. A copy of this letter is available on Cardiovascular Product Advisories Abbott . Customers with additional questions are encouraged to call 1-800-727-7846 (Opt3), 8:30am - 5:30pm Central Time, Monday through Friday. Current Status (June 30, 2025): No occurrences of failure to deliver high voltage therapy have been reported following the field communication. Potentially affected devices have been managed per recommendations.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>GLOBAL MODELS</p> <p>Current™ (Models 1207-30, 1207-36, 2207-30, 2207-36, CD1211-36, CD1211-36Q, CD1215-36, CD1215-36Q, CD1217-36, CD1219-36, CD1219-36Q, CD2211-36, CD2211-36Q, CD2215-36, CD2215-36Q, CD2217-36, CD2219-36, CD2219-36Q) Ellipse™ (Models CD1275-36, CD1275-36Q, CD1277-36, CD1277-36Q, CD1293-36Q, CD1309-36, CD1309-36Q, CD1311-36, CD1311-36Q, CD1377-36, CD1377-36Q, CD1377-36QC, CD1393-36C, CD1393-36QC, CD1409-36Q, CD1411-36C, CD1411-36Q, CD1411-36QC, CD2275-36, CD2275-36Q, CD2277-36, CD2277-36Q, CD2293-36, CD2293-36Q, CD2309-36, CD2309-36Q, CD2311-36, CD2311-36Q, CD2377-36, CD2377-36C, CD2377-36Q, CD2377-36QC, CD2393-36C, CD2393-36QC, CD2409-36C, CD2409-36Q, CD2411-36C, CD2411-36Q)</p> <p>Excelis Quadra™ (Models CD3281-40, CD3281-40Q)</p> <p>Excelis™ (Models CD3389-40C, CD3389-40QC)</p> <p>Excelis™ CRT-D (Models CD3297-40, CD3297-40Q)</p> <p>Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC)</p> <p>Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2363-40C, CD2363-40Q)</p> <p>Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q)</p> <p>Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC)</p> <p>Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q)</p> <p>Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q)</p> <p>Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q)</p> <p>Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q)</p> <p>HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC)</p> <p>HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC)</p> <p>HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q)</p> <p>Promote™ (Models 3207-30, 3207-36, 3213-36, CD3211-36, CD3211-36Q, CD3215-36, CD3215-36Q)</p> <p>Promote Quadra™ (Models CD3221-36, CD3223-36P, CD3239-40, CD3239-40Q)</p> <p>Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC, CD3387-40C, CD3387-40QC)</p> <p>Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3369-40C, CD3369-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC)</p> <p>Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC)</p> <p>Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC)</p> <p>Unify Quadra MP™ (Models CD3255-40, CD3255-40Q)</p> <p>Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q)</p> <p>Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q)</p>	<p>4/16/2018</p> <p>Class II</p> <p>Abbott released a planned upgrade to the firmware installed on our implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) devices. The cybersecurity firmware update provides an additional layer of protection against unauthorized device access.</p>	<p>Prophylactic replacement of affected devices is not recommended.</p> <p>Recommendations for Devices Eligible for Firmware Upgrade</p> <p>While not intended to serve as a substitute for your professional judgment, we, along with our Medical Advisory Boards, recommend the firmware upgrade for all eligible patients at the next regularly scheduled visit or when appropriate depending on the preferences of the patient and physician.</p> <p>Please consider the following:</p> <ul style="list-style-type: none"> • Discuss the risks and benefits of the firmware update with your patients. As part of this discussion, it is important to consider patient specific issues such as pacemaker dependence, frequency of high voltage therapy, age of device, and patient preference. • If deemed appropriate, install this firmware update following the instructions on the programmer. • The update should be performed with appropriate monitoring and external defibrillation equipment available. <p>Recommendations for Current™ & Promote™ Devices not Eligible for Cybersecurity Firmware Update</p> <p>If you have any concerns relating to device cybersecurity for those patients implanted with Current™/Promote™ devices, you do have the option to permanently disable the RF communication capability in the device. However, if you choose that option, the patient can no longer be monitored remotely using an RF Merlin@home transmitter. For most patients, permanently disabling RF is not advisable given the proven benefits and improved survival associated with home monitoring. [1,2] Therefore we, along with our Medical Advisory Boards, recommend the following:</p> <ul style="list-style-type: none"> • Discuss the risks of cybersecurity vulnerabilities and proven benefits of remote monitoring with your patients at the next regularly scheduled visit. • If deemed appropriate, RF communication may be permanently disabled during an in-clinic device interrogation with Merlin programmer software version 24.2.x or later by selecting the RF icon in the upper left corner of the FastPath summary screen. <p>Current Status (June 30, 2025): We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.</p> <p>If you have any questions about the cybersecurity firmware update you can contact your Abbott representative or our dedicated customer technical support hotline at 1-800-722-3774 (U.S.).</p> <p>Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories Abbott.</p> <p>¹ Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). Remote monitoring of ICD patients is associated with reduced mortality irrespective of device type. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and had limitations.</p> <p>² Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). Increased adherence to remote monitoring is associated with reduced mortality in both pacemaker and defibrillator patients. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and has limitations.</p>

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>GLOBAL MODELS</p> <p>Excelis Quadra™ (Models CD3281-40, CD3281-40Q) Excelis™ + (Models CD3389-40C, CD3389-40QC) Excelis™ CRT-D (Models CD3297-40, CD3297-40Q) Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC) Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2263-40C, CD2263-40Q) Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q) Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC) Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q) Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q) Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q) Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q) HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC) HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC) HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q) HeartMinder™ ST VR (Models CD1299-40, CD1299-40Q) Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC) Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC) Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC) Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC) Unify Quadra MP™ (Models CD3255-40, CD3255-40Q) Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q) Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q)</p>	<p>10/11/2016 Class I</p> <p>High voltage devices (ICDs and CRT-Ds) that utilize Lithium-based battery chemistries are subject to Lithium cluster formation during high voltage charging. Depending on their location, Lithium clusters may cause a short circuit that can lead to premature battery depletion. Our investigation indicates that if a short circuit occurs, battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy.</p> <p>8/28/2017 Class I</p> <p>Customers were made aware of the availability of a new battery performance management tool for detection of abnormal battery performance in devices subject to the October 2016 advisory.</p> <p>A follow up was provided on April 16, 2018 regarding the availability of a firmware upgrade for devices subject to the October 2016 advisory which provides further detection capability for premature battery depletion.</p>	<p>In consultation with our Medical Advisory Board, we recommend the following:</p> <ul style="list-style-type: none"> • Do not implant unused affected devices. • Conduct patient follow-up per standard practice. • Prophylactic device replacement is NOT recommended because complications following replacement have been reported to occur at a greater rate than the rate of harm associated with premature battery depletion due to lithium cluster induced shorts (see below for selected references). • In the event of an ERI indicator in these devices, immediate device change is recommended. At this time there is no factor, method or test to identify devices with this form of premature battery depletion approaching ERI or to accurately predict remaining battery life once ERI appears. • Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events. • Enroll patients in Merlin.net™ Patient Care Network (PCN) utilizing the “DirectAlerts™” feature to provide you with an immediate alert notification in the event ERI is reached. For patients currently enrolled in Merlin.net PCN, remind them of the importance of using remote monitoring. • Review the most recent Programmed Parameters printout. <ul style="list-style-type: none"> • Ensure that under the “Trigger Alerts When” section, that the “Device at ERI” parameter is ON (it is normally ON) for both “Show on FastPath” and “Notify Patient” selections. • If the “Device at ERI” alert is OFF, we recommend that the patient be seen promptly to program this parameter ON. • Advise patients that an ERI indication triggers a vibratory alert. At the next scheduled office visit: <ul style="list-style-type: none"> • Interrogate the patient’s device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing ERI or more advanced battery depletion. • Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert. • Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness. • Advise the patient to contact your office promptly should they feel a vibratory alert. • In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert. <p>The following additional recommendations were communicated in April 2018 follow up advisory:</p> <ul style="list-style-type: none"> • Patients receiving the firmware update should be advised that the device-based Battery Performance Alert (BPA) will trigger a vibratory alert. • In the absence of a BPA being triggered in a patient’s device, through Merlin.net or the Merlin programmer, we continue to recommend adhering to the original patient management recommendations from the 2016 Premature Battery Depletion advisory. However, if the BPA is triggered, immediate device explant and replacement is recommended. <p>Device Replacement Complication Publications</p> <ol style="list-style-type: none"> 1. John W. Moore III, William Barrington, et. al.; “Complications of replacing implantable devices in response to advisories: A single center experience”; International Journal of Cardiology 134 (2009) 42–46 (5.5% overall, 2.1% major complications) 2. Paul A. Gould, MBBS, PhD, Lorne J. Gula, MD, et. al.; “Outcome of advisory implantable cardioverter- defibrillator replacement: One-year follow-up”; Heart Rhythm, Vol 5, No 12, December 2008 (9.1% overall, 5.9% major complications, including two deaths) 3. Krystina B. Lewis, Dawn Stacey, R.N., Ph.D, et. al.; “Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review; PACE, Vol. 39, July 2016 (7.5% overall, 4.0% major complications) <p>Current Status (August 31, 2025): At the time of the advisory, 841 returned devices (0.21%) of 398,740 devices worldwide had premature depletion in association with lithium clusters, including 549 in the US. As of August 31, 2025, there were additional occurrences reported to Abbott or returned for analysis resulting in a cumulative worldwide total of 9,846 devices. Based on this, the rate is now 2.47%.</p> <p>For additional information and to determine if a device serial number is subject to this advisory, please go to the following website: Cardiovascular Product Advisories Abbott.</p>

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>A subset of Assurity™, Assurity MRI™, Endurity™, and Endurity MRI™ pacemakers (Models PM1140, PM1152, PM1160, PM1162, PM1172, PM1272, PM2140, PM2152, PM2160, PM2162, PM2172, PM2240, PM2272)</p>	<p>February 2025 Outside US Only</p> <p>Abbott informed clinicians of the potential for device malfunction due to a manufacturing issue which may affect a specific subset of serial numbers for pacemakers distributed and implanted outside of the United States. The issue is caused by incomplete mixing of epoxy during manufacturing, which may introduce risk of moisture ingress and interruption of device functionality. The affected devices were manufactured between August 2019 and June 2020; the specific equipment associated with this issue is no longer in use.</p>	<p>Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provided the following guidelines:</p> <p>Prophylactic generator replacement is not recommended due to the low rate of occurrence of this issue. Evaluate the potential for risk in patients who are pacemaker dependent, particularly if they are unable to be reliably followed using remote monitoring.</p> <p>Routine follow-up should remain as per standard of care. Enroll patients on Merlin.net when possible and consider increasing frequency of scheduled interrogations in patients with non-RF enabled pacemakers. Review device function, including measured battery voltage, any unexpected change in battery consumption, and connectivity status on Merlin.net where available.</p> <p>Prompt replacement for devices that demonstrate unexpected depletion to ERI/EOS, trigger an EPI (Electronics Performance Indicator) notification, reach ERI/EOS, or demonstrate one of the clinical impacts listed above. As always, timing of replacements should be appropriate for the patient's underlying clinical condition.</p> <p>The Electronics Performance Indicator (EPI) tool supplements information available on Merlin.net to identify abnormal electrical system behavior resulting from moisture ingress.</p> <p>Current Status (June 30, 2025): The observed rate at the time of the Advisory announcement was 0.18% for devices which have exhibited moisture ingress into the pulse generator, resulting in a loss of functionality. Additional reports have been received and analyzed, and the cumulative worldwide rate is now 0.23%.</p>

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>A subset of Assurity MRI™ (Model PM2272), Endurity™ (Model PM2162), Endurity™ Core (Model PM2152), Endurity MRI™ (Model PM2172) implanted outside of the United States</p>	<p>10/10/23 Outside US Only</p> <p>Abbott is informed clinicians of the potential for device malfunction due to a manufacturing issue which may affect a limited subset of 455 Assurity™ and Endurity™ pacemakers implanted outside of the United States.</p> <p>The issue is caused by a manufacturing process variation within a single piece of equipment resulting in the potential for moisture ingress into the pulse generator. This has been associated with interrupted functionality such as loss of pacing, reduced battery longevity, reverting to back-up mode, loss of telemetry / communication, and/or shortened duration between Elective Replacement Indicator (ERI) and End of Service.</p>	<p>Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following guidelines:</p> <ul style="list-style-type: none"> • Consider generator replacement for patients with significant symptoms or who are at high risk of harm, if pacemaker malfunction were to occur. • When possible, monitor patients using Merlin.net to benefit from compliance and alert monitoring, including Electronics Performance Indicator (EPI) between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI alerts and includes monitoring of the safety notification population by the EPI tool. • Prompt replacement for devices that receive an EPI notification, or reach ERI/EOS, or experience one of the clinical impacts listed above, unless particular patient circumstances preclude this. <p>The Electronics Performance Indicator (EPI) tool supplements information available on Merlin.net to identify abnormal electrical system behavior resulting from moisture ingress.</p> <p>Current Status (June 30, 2025): 24 devices of the 455 devices distributed (5.27%) have exhibited symptoms of moisture ingress through the pulse generator which may result in loss of functionality.</p>

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>A subset of Assurity MRI™ (Model PM2272), Endurity™ (Model PM2162), Endurity™ Core (Model PM2152), Endurity MRI™ (Model PM2172), Zenex MRI™ (Model PM2282) distributed and implanted outside of the United States</p>	<p>7/20/2022 Outside US Only</p> <p>Abbott informed customers of the potential for device malfunction which may affect a specific subset of serial numbers of Zenex™, Assurity™, and Endurity™ pacemakers distributed and implanted outside of the United States. The issue is caused by a manufacturing laser surface preparation subprocess, unique to a single assembly line, which may not have properly prepared the device's metal housing potentially leading to abnormal device-to-header adhesion. This in turn may allow moisture ingress into the pulse generator header result in interrupted device functionality such as loss of pacing, reduced battery longevity, devices reverting to back-up mode, and/or loss of telemetry / communication.</p>	<p>Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following guidelines:</p> <ul style="list-style-type: none"> • Prophylactic generator replacement is NOT generally recommended. • When possible, monitor patients using Merlin.net to benefit from compliance and alert monitoring, including Electronics Performance Indicator (EPI), between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI alerts and will now also include monitoring of the safety notification population by the EPI tool. The EPI tool supplements information available on Merlin.net to identify abnormal electrical system performance resulting from moisture ingress. • Consider individualized therapy up to and including generator replacement for patients who are at high risk if interruption of pacemaker function were to occur, potentially considering <ul style="list-style-type: none"> • Adequacy of intrinsic / underlying rhythm • Individual patient characteristics and circumstance • Ability to adequately monitor patients based on risk • Prompt replacement for devices that receive an EPI notification, reach ERI, or experience one of the clinical impacts listed above, unless particular patient circumstances preclude this. <p>To determine if a device implanted outside of the United States is subject to this advisory, please go to the following website: https://www.cardiovascular.abbott/int/en/hcp/product-advisories/laser-adhesion-safety-lookup.html</p> <p>Current Status (June 30, 2025): The cumulative worldwide incidence rate is now 1.68% for advisory pulse generators exhibiting symptoms of moisture ingress which may result in loss of functionality.</p>

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>GLOBAL MODELS Merlin™ Patient Care System (PCS) Software Model 3330, Merlin™ 2 PCS Software Model MER3400, and Merlin.net™ MN5000 Remote Monitoring Application when used with certain pacemakers:</p> <p>Accent™, Accent MRI™, Assurity™, Assurity MRI™, Endurity™, Endurity MRI™, Nuance™, Zenex MRI™, and Zenus MRI™ IPGs and Allure™, Allure Quadra™, Quadra Allure™, Anthem™, Relieve™, Relieve Quadra™, and Quadra Relieve™ CRT-Ps</p>	<p>6/16/2022 Class II</p> <p>Abbott is notifying customers of the potential for Merlin™ PCS and Merlin™ 2 PCS and Merlin.net remote monitoring software applications to display overestimated predicted battery longevity for certain pacemakers. Pacemaker/battery functionality, therapy delivery, and longevity remain normal and within specifications. Voltage measurements and Elective Replacement Indicator (ERI), which is based on direct voltage measurement, remain accurate.</p>	<p>Abbott has developed updated software for the Merlin™ PCS and Merlin™ 2 PCS Programmer to improve accuracy of predicted battery longevity, which will correct the longevity overestimation displayed during device interrogation. Abbott representatives will assist in updating programmer software.</p> <p>The solution is available in: Merlin™ Patient Care System (PCS) Software Model 3330 version 26.0.1 rev 2 (United States), 26.0.4 rev 1 (Canada), 20.1.5 rev 5 (China), or 25.8.# rev 1 (all other countries) or later Merlin™ 2 Patient Care System (PCS) Software Model MER3400 version 1.8.2 rev 1 (Europe) or later</p> <p>Additionally, Merlin.net was updated globally in June 2022 to improve accuracy of predicted battery longevity displayed on remote transmissions.</p> <p>Abbott provides the following patient management guidance: Prophylactic device replacement is not recommended, as device functionality, actual longevity, and ERI indicator are not impacted (device functionality remains normal and within specifications). Routine follow-up should remain as per local standard of care and clinical protocol, and ERI should continue to serve as an indicator of the need for device replacement scheduling. Please direct any questions about device longevity to Abbott Technical Support.</p> <p>Upon programmer software / remote monitoring software update, the improved longevity estimate will be displayed at the patient's next clinic visit or wireless transmission. Please note that until programmers are updated, a difference in longevity estimates between programmers and remote monitoring (Merlin.net) may be observed.</p> <p>Current Status (June 30, 2024): The worldwide cumulative complaint rate has remained stable at 0.03% regarding longevity overestimates for an estimated 3,400,000 devices worldwide.</p>

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>A subset of Assurity™ (Models PM1240, PM2240), Assurity™ + (Model PM2260), Assurity MRI™ (Models PM1272, PM2272), Endurity™ (Models PM1160, PM2160), Endurity™ Core (Models PM1152, PM2152), Endurity MRI™ (Models PM1172, PM2172)</p>	<p>3/15/2021 Class I</p> <p>Abbott informed customers of an issue which may affect a subset of Assurity™ and Endurity™ pacemakers. The issue is caused by intermittent incomplete mixing of epoxy during manufacture, which may introduce a risk of moisture ingress and interruption of device functionality.</p> <p>Abbott provided a follow up safety notification on October 5, 2021 to communicate additional units in the advisory and the availability of a new Electronics Performance Indicator (EPI) tool to assist in patient management for those pacemakers monitored with Merlin.net. The EPI tool supplements information available on Merlin.net to identify abnormal electrical system performance resulting from moisture ingress.</p>	<p>Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following guidelines:</p> <ul style="list-style-type: none"> • Prophylactic generator replacement is not recommended. This is due to the very low rate of occurrence, and the low potential for patient harm when replacement is performed following an EPI notification or an ERI/EOS alert. • Routine follow-up should remain as per standard of care and clinical protocol. Review device function including measured battery voltage or any unexpected change in battery consumption. Also, evaluate the potential for risk in patients who are pacemaker dependent and are unable to be reliably followed using remote monitoring. • Prompt replacement for devices that receive an EPI notification, reach ERI/EOS, or experience one of these clinical impacts (loss of telemetry, reduced battery longevity, loss of pacing, or reduced ERI to EOS duration), commensurate with the patient's underlying clinical condition. • When possible, monitor patients using Merlin.net to benefit from alert monitoring between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI and EOS alerts and includes monitoring of the safety notification population by the EPI tool. <p>Current Status (June 30, 2025): The cumulative worldwide incidence rate is now 0.31% for advisory pulse generators exhibiting moisture ingress into the pulse generator, resulting in a loss of functionality.</p> <p>To determine if a device serial number is subject to this advisory, please go to the following website: https://www.cardiovascular.abbott/us/en/hcp/product-advisories/pacemaker-lookup.html.</p>

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>Global Models Accent™ MRI™ (Model PM1224) Accent™ DR RF (Models PM2210, PM2212) Accent MRI™ (Models PM2218, PM2224) Accent™ SR RF (Model PM1210) Accent™ ST DR RF (Models PM2216, PM2222) Accent™ ST MRI DR RF (Model PM2226) Accent™ ST MRI SR RF (Model PM1226) Accent™ ST SR RF (Model PM1222) Allure Quadra™ RF CRT-P (Model PM3242) Allure™ RF CRT-P (Model PM3222) Anthem™ RF CRT-P (Models PM3210, PM3212) Assurity™ + DR RF (Model PM2260) Assurity™ + SR RF (Model PM1260) Assurity™ DR RF (Model PM2240) Assurity MRI™ (Model PM2272) Assurity™ SR RF (Model PM1240) Assurity MRI™ (Model PM1272) Nuance™ DR RF (Model PM2214) Nuance™ MRI DR RF (Model PM2230) Nuance™ MRI SR RF (Model PM1230) Nuance™ SR RF (Model PM1214) Nuance™ ST DR RF (Model PM2228) Nuance™ ST SR RF (Model PM1228) Quadra Allure MP™ (Model PM3562) Quadra Allure MP™ RF CRT-P (Model PM3262) Quadra Allure™ (Model PM3542) Quadra Relieve MP™ (Model PM3564) Quadra Relieve MP™ RF CRT-P (Model PM3264) Quadra Relieve™ (Model PM3544) Quadra Relieve™ RF CRT-P (Model PM3244) Relieve™ RF CRT-P (Model PM3224) Zenex™ + DR RF (Model PM2270) Zenex™ + SR RF (Model PM1270) Zenex™ DR RF (Model PM2250) Zenex™ DR RF MRI (Model PM2282) Zenex™ SR RF (Model PM1250) Zenex™ SR RF MRI (Model PM1282)</p>	<p>8/28/2017 Class II</p> <p>New pacemaker firmware was developed to further mitigate the risk of unauthorized access to our pacemakers that utilize radio frequency (RF) communications. The firmware update provides an additional layer of security against unauthorized access to these devices that further reduces the potential for a successful cybersecurity attack.</p>	<p>Patient Management Recommendations</p> <p>Prophylactic replacement of affected devices is not recommended.</p> <p>While not intended to serve as a substitute for your professional judgment as to whether the firmware update is advisable for a particular patient, we, along with our Cyber Security Medical Advisory Board, recommend the following:</p> <ul style="list-style-type: none"> • Discuss the risks and benefits of the cybersecurity vulnerabilities and associated firmware update with your patients at the next regularly scheduled visit. As part of this discussion, it is important to consider patient specific issues such as pacemaker dependence, age of device, and patient preference and provide them with the "Patient Communication". • Determine if the update is appropriate given the risk of update for the patient. If deemed appropriate, install this firmware update following the instructions on the programmer (and listed below). • For pacing dependent patients, consider performing the cybersecurity firmware update in a facility where temporary pacing and pacemaker generator change are readily available, due to the very small estimated risk of firmware update malfunction. <p>Current Status (June 30, 2025): We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.</p> <p>If you have any questions about the cybersecurity firmware update you can contact your Abbott representative or our dedicated customer technical support hotline at 1-800-722-3774 (U.S.).</p> <p>Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories Abbott.</p>

LEADLESS PACEMAKERS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>AVEIR™ VR (Model LSP112V)</p>	<p>4/3/2024 Class II</p> <p>Abbott is informing customers of the potential for electromagnetic interference (EMI) to cause an inadvertent mode change in a subset of AVEIR™ VR LSP112V devices manufactured with firmware version 19.05.00. This issue is corrected through a firmware upgrade.</p> <p>The issue may cause an AVEIR VR device to enter either EVVI or MRI mode. Compared to nominal settings, the increased pacing output and rate of each mode may reduce longevity. If present, the mode change is detected during a Merlin programmer interrogation session.</p>	<p>Abbott has developed updated Merlin™ PCS 3650 programmer software that facilitates the download of AVEIR device firmware version 19.12.00 starting April 2024. Zero (0) devices with firmware 19.12.00 have experienced the reported mode change issue. The firmware download occurs through an automatic prompt to the user during an in-clinic interrogation. All device settings and therapies remain active during the firmware download.</p> <p>The updated firmware is available in: Merlin™ Patient Care System (PCS) Software Model 3330 version v28.1.1 rev1 (United States), v28.1.4 rev 1 (Canada), v28.1.3 rev 1 (Japan), and v28.1.2 rev 1 (other countries supporting AVEIR VR) or later.</p> <p>Additionally, Abbott provides the following patient management guidance: Recognizing that each patient requires individual clinical considerations by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott is providing the following guidelines:</p> <ol style="list-style-type: none"> 1. Prophylactic device replacement is NOT recommended. <ul style="list-style-type: none"> • All currently manufactured LSP112V devices utilize the upgraded firmware. • Following the firmware upgrade, the implanted device will be equivalent to newly manufactured LSP112V devices. 2. As part of follow-up, suggested within 3 months, upgrade the LSP112V firmware. <ul style="list-style-type: none"> • For most devices, the upgrade will execute automatically when interrogated. If required, contact Abbott Technical Support to assist with the upgrade. • If the device presents in MRI or EVVI mode, reprogram the device to the desired mode and settings.

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>Optisure™ Defibrillation Lead (Models LDA220, LDA220Q, LDA230Q, LDP220Q)</p>	<p>11/3/2015 Class I</p> <p>A limited number of dual coil Optisure defibrillation leads may have been compromised during the manufacturing process. A trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.</p> <p>A thorough investigation has determined the probability of a lead malfunction as a result of this trim technique is very low. A total of 447 leads subjected to the trim technique were distributed globally. Of those, 278 were implanted in the United States. Abbott is not aware of any adverse clinical events related to this matter. Furthermore, an analysis of patients implanted with the subject leads that are being actively monitored via Merlin.net™ Patient Care Network has shown that none of these patients have experienced any recorded electrical issues.</p>	<p>Abbott recommends the following actions depending on the device the affected patients have implanted. According to our records the vast majority of patients with the subject leads have devices with the DynamicTx™ feature that provides additional protection to help ensure therapy delivery in the case of a compromised lead.</p> <p>For patients implanted with a potentially-impacted Optisure lead connected to a device WITH DynamicTx™ technology, we recommend:</p> <p>Review the Patient Records:</p> <ol style="list-style-type: none"> 1. Ensure DynamicTx™ technology is programmed "On" 2. Enroll these patients in our Merlin.net™ Patient Care Network 3. Monitor patients as normal, with no additional testing or follow-up needed. <p>For patients implanted with a potentially-impacted Optisure lead connected to a device WITHOUT DynamicTx™ technology we recommend:</p> <ol style="list-style-type: none"> 1. Enroll these patients in our Merlin.net™ Patient Care Network 2. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector) 3. If dual coil shocking configuration is desired, consider performing a high voltage test using maximum energy. <ol style="list-style-type: none"> a. If shock delivery is normal - no additional testing is required b. If shock delivery identifies a short circuit – consider lead replacement <ul style="list-style-type: none"> • DynamicTx™ technology automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur. <p>We recommend at your patient's next follow-up visit an Abbott representative be present to program an alert message into the implanted device. This will provide clinicians following patients with impacted subject lead an alert message on the Merlin™ Programmer upon interrogation, ensuring that future caregivers assessing the diagnostics of these devices receive the latest information and be made aware of this corrective action. We believe such actions will further the ability of our clinician partners to most optimally manage the care of their patients.</p>

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>Riata[™] Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582) Riata[™] i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata[™] ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)</p>	<p>11/28/2011 Class I</p> <p>Externalized conductors occur when an abrasion results in an outer insulation breach, allowing the normally contained conductors to become visible outside the lead body. Even though causality cannot be established, when externalized conductors are accompanied by reports of electrical malfunction, these reports typically include pacing or defibrillation impedance changes, inappropriate therapy, noise and oversensing, and pacing threshold rise. Externalized conductors have not been observed in Riata ST Optim[™] and Durata[™] models due to the presence of an abrasion resistant outer Optim[™] lead insulation sheath.</p>	<p>Abbott and its Medical Advisory Board (MAB) make the following recommendations, which are consistent with standard best practices and our December 2010 product communication.</p> <p>Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. Abbott[™] remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors.</p> <p>Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.</p> <p>Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits.</p> <p>If there is evidence of a lead electrical failure, manage the patient per standard practice.¹ This may include x-ray or fluoroscopy. Additional testing, if necessary, could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem associated with any source of lead electrical failure if one exists.</p> <p>The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time and is therefore not recommended.</p> <p>In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended.</p> <p>Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalized conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances.</p> <p>Based on input from the MAB, Abbott continues to monitor post-market surveillance data to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities.</p> <p>Current Status (June 30, 2025): At the time of the advisory there was a worldwide reported all-cause insulation abrasion rate of 0.63% for Riata silicone leads. The worldwide reported rate for the subcategory of externalized conductors in Riata silicone leads was 0.10%. As of June 30, 2025, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 5.01% and 3.04% respectively. The latest information related to the silicone Riata lead advisory, including the final results of the Cardiac Lead Assessment Study (CLAS) and references to independent studies of Riata lead performance, can be obtained at https://www.cardiovascular.abbott/us/en/hcp/product-advisories/riata.html.</p>
		<p>1 Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." <i>Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy</i>, 4th ed. Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2011. 889-910.</p>

REMOTE MONITORING/TRANSMITTERS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
<p>Merlin@home™ Software Model EX2000 v8.2.2 for Merlin@home™ Transmitter (Models EX1150, EX1150W, EX1100, EX1100W)</p>	<p>4/3/2017 Class II</p> <p>In recognition of the changing cybersecurity landscape, and the increased public attention on medical device cyber risks, we have informed the clinical community about available updates to Merlin@home™ transmitter software. The Merlin@home™ patient transmitter software version 8.2.2 includes security updates that complement the company's existing security measures and further reduce the already extremely low cybersecurity risks.</p>	<ul style="list-style-type: none"> • Patients should ensure that their Merlin@home™ transmitter is plugged in and connected via cellular adapter, wi-fi or landline so the transmitter can receive these and any future updates. • Health Care Providers should continue to conduct patient management using the Merlin.net™ Patient Care Network (PCN) and in-office follow-ups per normal routine with patients who have an implantable cardiac device that is monitored using the Merlin@home™ transmitter. • For further information, health care providers can contact their local sales representative. In addition, both health care providers and patients can visit Connectivity and Remote Care for Cardiac Rhythm Management Abbott (cardiovascular.abbott) for answers to questions and additional information regarding Abbott's implantable cardiac rhythm devices, or the Merlin@home™ transmitter. <p>Current Status (June 30, 2025): We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.</p>

Healthcare Professional Communications

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	COMMUNICATION	DETAILS
<p>Affinity[™], Entity[™], Integrity[™], Identity[™], Sustain[™], Frontier[™], Victory[™] and Zephyr[™] models</p>	<p>1/29/2014 Worldwide</p> <p>As part of Abbott's commitment to communications on device performance, and in consultation with our Medical Advisory Board, we provided Health Care Professionals information regarding possible effects of electrocautery on older generation Abbott pacemakers.</p>	<p>Abbott has reviewed incident reports on specific older generation pacemaker models exposed to electrocautery. When devices from these pacemaker families are exposed to electrocautery (as well as the PEAK PlasmaBlade[™] blade), they may exhibit a temporary change in function that could persist for 30 seconds or longer after the electrocautery exposure has been terminated. The duration of the effect depends on several factors including the battery voltage of the device, the energy of the electrocautery output, and the distance from the electrocautery source to the implanted system. The most clinically significant observation has been loss of capture due to a transient reduction in the pacing output voltage. Placing a magnet over the device or programming to an asynchronous pacing mode will not prevent this temporary reduction in pacing output.</p> <p>The effects of electrocautery on cardiac implantable electronic device operation are well documented in the scientific literature and most, if not all, pacemaker and implantable cardioverter defibrillator (ICD) User's Manuals include labeling about the use of electrosurgery equipment and its possible effects on the operational characteristics and/or internal circuitry of these devices.</p> <p>As is the case with all perioperative assessments in patients with cardiac implantable electronic devices, evaluating the individual patient's dependence on the implanted device should be assessed prior to any procedure that would ordinarily require electrocautery, particularly a pacemaker procedure. If pacemaker dependency is identified, either do not use electrocautery or employ appropriate precautions to ensure that the heart rate will be supported in the presence of electrocautery. Consideration of placing a temporary transvenous pacemaker is appropriate.^{1,2}</p> <p>All Abbott pacemaker and ICD User's Manuals provide Warnings and Precautions regarding the use of electrosurgical devices in the vicinity of an implanted device.</p> <p>Importantly, the more recent families of Abbott pacemakers (Accent and Anthem) and all ICDs are not subject to this temporary change in function from the extended effects of electrocautery.</p> <p>References: ¹ Hayes and Friedman, Cardiac Pacing, Defibrillation and Resynchronization, 2nd Edition, p. 192 ² Ellenbogen and Wood, Cardiac Pacing and ICDs, 4th Edition, p. 227</p>

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Phased-out Models

As stated in the introduction of this Product Performance Report, product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report. As such, models that no longer meet the criteria for inclusion have been phased-out of the Product Performance Report over time. In order to provide our customers with information on these phased-out models, an index including the final edition for each phased-out model has been included. Previous Product Performance Reports can be viewed on the web at [Product Performance Reports | Abbott \(cardiovascular.abbott\)](https://www.abbott.com/products/cardiovascular/performance-reports).

CRT DEVICES

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Atlas™ + HF CRT-D (V-343)
Atlas™ II HF (V-365)
Atlas™ II + HF (V-366)
Epic™ HF (V-337)
Epic™ HF (V-338)
Epic™ II HF (V-355)
Frontier™ (5508)
Frontier™ II CRT-P (5586)
Promote™ (3107-36)
Promote™ RF (3207-30)
Promote™ RF CRT-D (3207-36)
Promote™ + CRT-D (CD3211-36)
Promote™ + CRT-D (CD3211-36Q)

LEFT-HEART LEADS

QuickSite™ (1056K)
QuickSite™ (1056T)

ICDS

Atlas™ DR (V-240)
Atlas™ DR (V-242)
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Atlas™ II DR (V-265)
Atlas™ II + DR (V-268)
Atlas™ II VR (V-168)
Atlas™ VR (V-199)
Atlas™ + VR (V-193)
Contour™ II (V-185, V-185AC, V-185B, V-185C, V-185D)
Contour™ MD (V-175, V-175AC, V-175B, V-175C, V-175D)
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Current™ + DR (CD2211-36)
Current™ + DR (CD2211-36Q)
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Current™ DR RF (2207-36)

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Epic™ II DR (V-258)
Epic™ II VR (V-158)
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Riata ST Optim (7022)
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TVL™ ADX (1559)
TVL™ RV (RV01, RV02, RV03, RV06, RV07)
TVL™ SVC (SV01, SV02, SV03)
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Phased-out Models

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 Identity ADx™ XL DR (5386)
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 Identity™ SR (5172)
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 Integrity™ SR (5142)
 Integrity™ μ SR (5136)
 Integrity ADx™ DR (5360)
 Integrity™ ADx DR (5366)
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 Meta™ DDDR (1256)
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 Paragon™ III (2304, 2314, 2315)
 Phoenix™ II (2005, 2008, 2009)
 Phoenix™ III (2204, 2205)
 Regency™ SC+ (2400L, 2402L)
 Solus™ (2002, 2003)
 Solus™ II (2006, 2007)
 Synchrony™ II (2022, 2023)
 Synchrony™ III (2028, 2029)
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 Trilogy™ DC+ (2318)
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PACEMAKERS

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 Verity ADx™ XL DR (5356)
 Verity ADx™ XL DR M/S (5357M/S)
 Verity ADx™ XL SC (5056)
 Verity ADx™ XL SR (5156)
 Verity ADx™ XL SR M/S (5157M/S)
 Victory™ SR (5610)

PACING LEADS

ACE™ (1015M, 1025M)
 AV Plus™ DX (1368)
 Fast-Pass™ (1018T, 1028T)
 IsoFlex™ P (1644T)
 IsoFlex™ P (1648T)
 IsoFlex™ S (1642)
 IsoFlex™ S (1646)
 Passive Plus™ (1135K, 1143K, 1145K, 1235K, 1243K, 1245K)
 Passive Plus™ (1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T)
 Passive Plus™ DX (1336T, 1342T, 1346T)
 Passive Plus™ DX (1343K, 1345K)
 Permathane™ ACE (1035M)
 Permathane™ ACE (1036T, 1038T)
 Tendril™ (1148T, 1188T)
 Tendril™ (1188K)
 Tendril™ DX (1388K)
 Tendril™ DX (1388T, 1388TC)
 Tendril™ SDX (1488T, 1488TC)
 Tendril™ SDX (1688T, 1688TC)
 Unipolar Lead (1007)

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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