CARDIAC RHYTHM MANAGEMENT

Product Performance Report

2024 First Edition

Abbott

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 include a new section in this PPR beginning on page 169 containing the performance of our AVEIR™ VR Leadless Pacemaker.

As we continually strive to provide unbiased and reliable information on the performance of our products, Abbott is pleased to release the first edition of the 2024 Product Performance Report containing the latest performance information on our ICDs, pacemakers and lead systems.

Sincerely,

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™ VR PERFORMANCE

Commercial implants of the Aveir™ VR leadless pacemaker commenced in April 2022, and with the publication of the 2024 First Edition Product Performance Report, Abbott has now completed monitoring and assessment for over one year. The ISO 5841-2:2014(E) criteria for reporting Pulse Generator performance have been applied to the Aveir™ VR pacemaker, 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™ VR leadless pacemaker to acknowledge its unique functionality and design characteristics.

Commercial implants of the Aveir DR leadless pacemaker system commenced in November 2023. At the time of data processing for the 2024 First Edition Product Performance Report, an insufficient quantity (<500 devices) had been implanted to qualify for inclusion. Abbott anticipates that the Aveir DR system will be included in the 2024 Second Edition.

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 215 and also on the Product Advisories web page at https://www.cardiovascular.abbott/us/en/hcp/product-advisories.html

UPDATE ON FORTIFY™, FORTIFY ASSURA™, QUADRA ASSURA™, QUADRA ASSURA MP™, UNIFY™, UNIFY ASSURA™ AND UNIFY QUADRA™ ICD PREMATURE BATTERY DEPLETION ADVISORY

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 198-200). 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.

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.

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). Beginning with the July 2021 PPR, Abbott is using 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.

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.

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 Ω or > 2000 Ω (based on lead model and measurement range of the device).

Abnormal Defibrillation Impedance - Defibrillation impedance is typically considered abnormal if a measurement is < 20 Ω or > 200 Ω (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.

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.

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 224-225) 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 Schaerf, 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

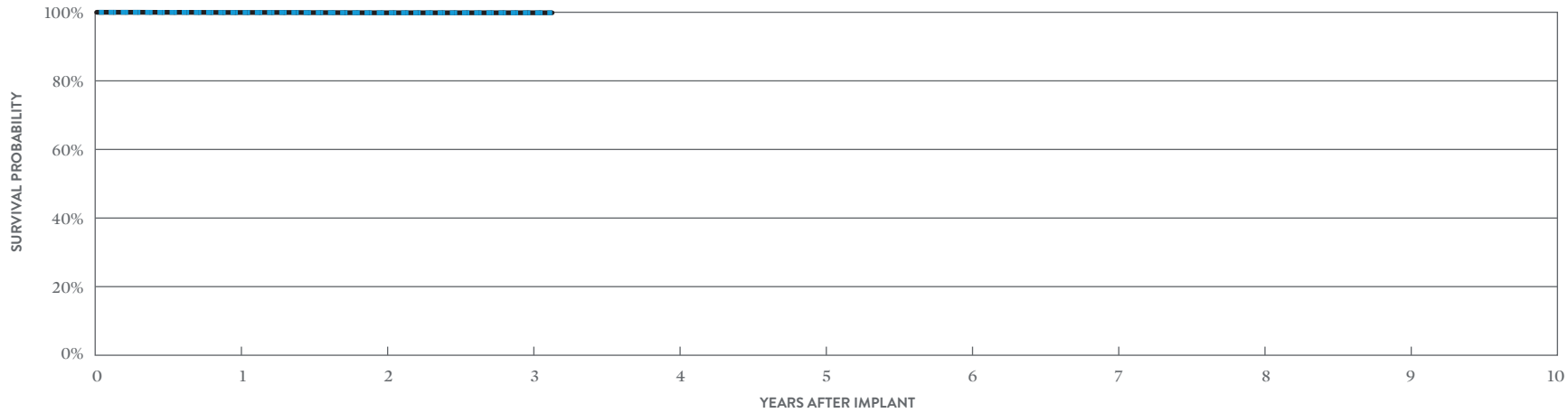
Cardiac Resynchronization Therapy (CRT) ICDs

Gallant™ HF CRT-D

MODEL CDHFA500Q*

US Regulatory Approval	July 2020
Registered US Implants	35,389
Estimated Active US Implants	29,752
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 204)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	6	0.02%
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%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	2	<0.01%	1	<0.01%
Total	**2**	**<0.01%**	**11**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 38 MONTHS
SURVIVAL PROBABILITY	99.92%	99.84%	99.84%	99.84%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%
SAMPLE SIZE	27,700	14,080	4,380	320

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 38 MONTHS
SURVIVAL PROBABILITY	99.93%	99.85%	99.85%	99.85%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%

**DF4-LLHH connector type.*

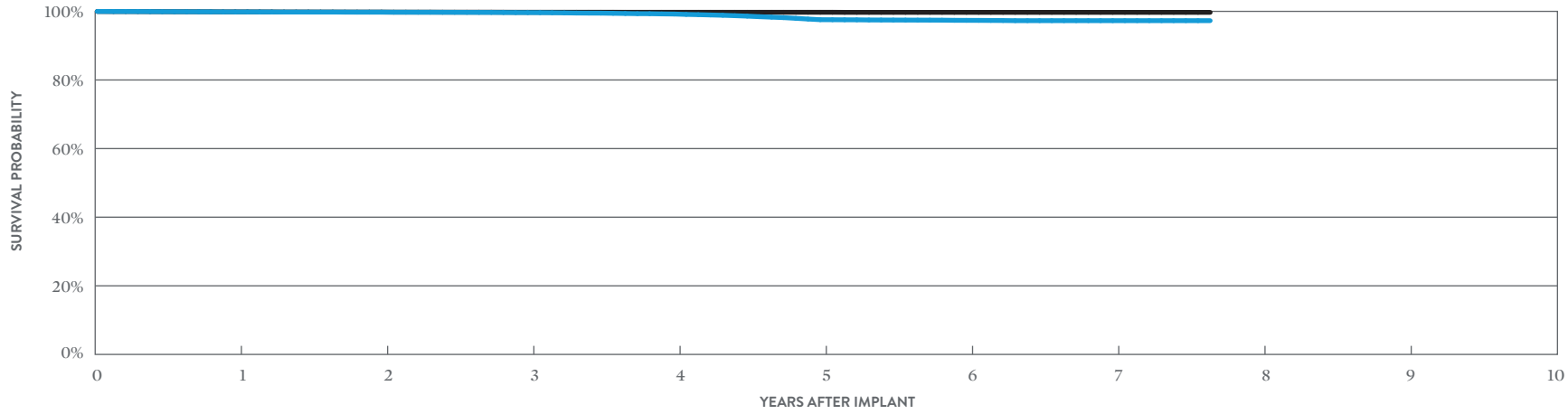
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura MP™ CRT-D

MODEL CD3369-40Q*

US Regulatory Approval	February 2016
Registered US Implants	77,783
Estimated Active US Implants	47,431
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	308
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	7	<0.01%	21	0.03%
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%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	4	<0.01%	19	0.02%
Total	**22**	**0.03%**	**53**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 92 MONTHS
SURVIVAL PROBABILITY	99.84%	99.77%	99.64%	99.22%	97.57%	97.38%	97.29%	97.29%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.04%	0.08%	0.09%	0.09%	0.09%
SAMPLE SIZE	72,660	63,460	54,650	43,320	30,460	18,980	9,180	450

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 92 MONTHS
SURVIVAL PROBABILITY	99.85%	99.79%	99.74%	99.73%	99.73%	99.71%	99.71%	99.71%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%

**DF4-LLHH connector type.*

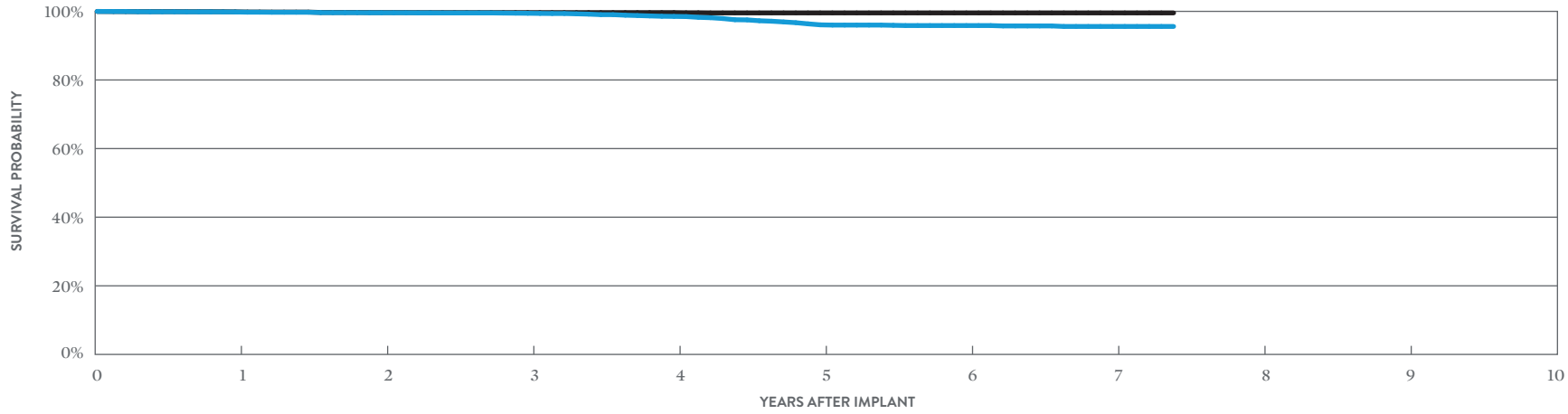
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura MP™ CRT-D

MODEL CD3369-40C*

US Regulatory Approval	February 2016
Registered US Implants	11,593
Estimated Active US Implants	7,095
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	68
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	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%	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%	3	0.03%
Total	**6**	**0.05%**	**11**	**0.09%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 89 MONTHS
SURVIVAL PROBABILITY	99.82%	99.59%	99.44%	98.53%	96.07%	95.86%	95.60%	95.60%
± 1 STANDARD ERROR	0.04%	0.07%	0.08%	0.15%	0.28%	0.30%	0.33%	0.33%
SAMPLE SIZE	10,390	8,330	6,700	5,250	3,910	2,630	1,380	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 89 MONTHS
SURVIVAL PROBABILITY	99.86%	99.66%	99.64%	99.64%	99.55%	99.55%	99.55%	99.55%
± 1 STANDARD ERROR	0.03%	0.06%	0.06%	0.06%	0.08%	0.08%	0.08%	0.08%

**Parylene coating.*

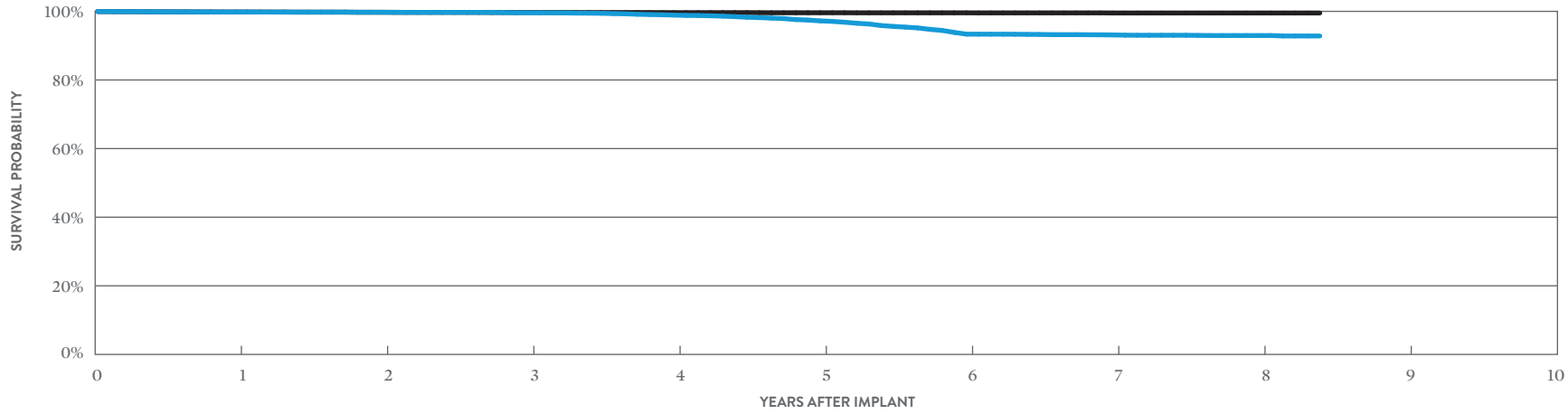
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	16,837
Estimated Active US Implants	7,478
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	267
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.01%	7	0.04%
Electrical Interconnect	3	0.02%	0	0.00%
Battery	1	<0.01%	0	0.00%
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%	6	0.04%
Total	**10**	**0.06%**	**20**	**0.12%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.81%	99.74%	99.59%	98.91%	97.22%	93.36%	93.13%	92.95%	92.82%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.09%	0.15%	0.24%	0.25%	0.26%	0.27%
SAMPLE SIZE	16,000	14,540	13,250	11,950	10,680	9,330	7,640	4,390	440

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.81%	99.74%	99.68%	99.63%	99.59%	99.57%	99.52%	99.52%	99.52%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.05%	0.05%	0.06%	0.06%	0.06%	0.06%

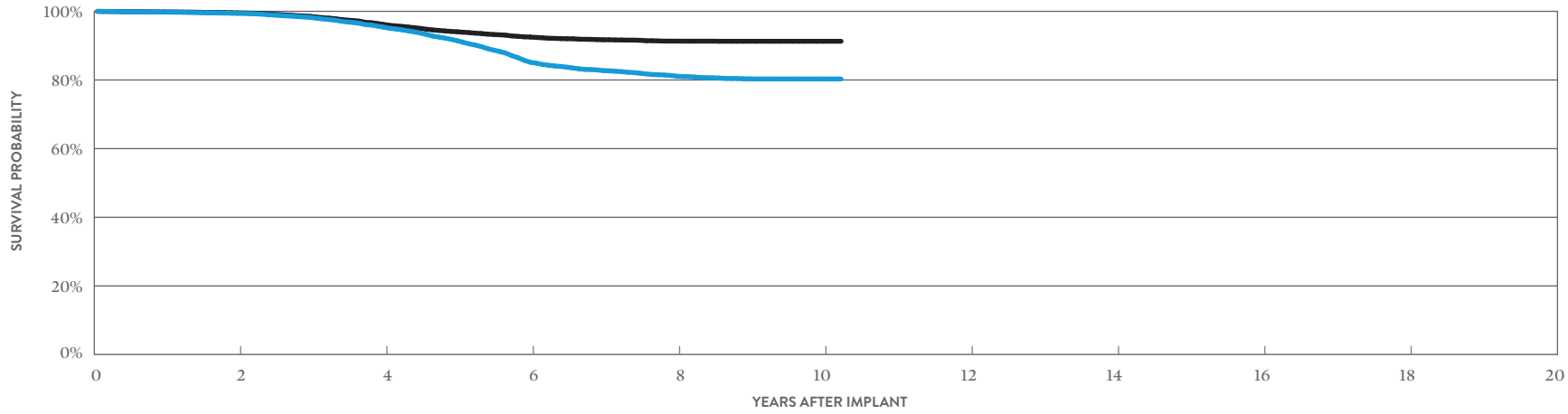
**DF4-LLHH connector type.*

Quadra Assura™ CRT-D

MODEL CD3365-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	24,249
Estimated Active US Implants	6,253
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	626
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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%	18	0.07%
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%	422	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 123 MONTHS
SURVIVAL PROBABILITY	99.40%	95.37%	85.16%	81.11%	80.29%	80.29%
± 1 STANDARD ERROR	0.05%	0.15%	0.28%	0.32%	0.34%	0.34%
SAMPLE SIZE	20,120	16,020	12,990	9,110	2,210	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 123 MONTHS
SURVIVAL PROBABILITY	99.55%	96.16%	92.51%	91.31%	91.28%	91.28%
± 1 STANDARD ERROR	0.04%	0.14%	0.21%	0.23%	0.23%	0.23%

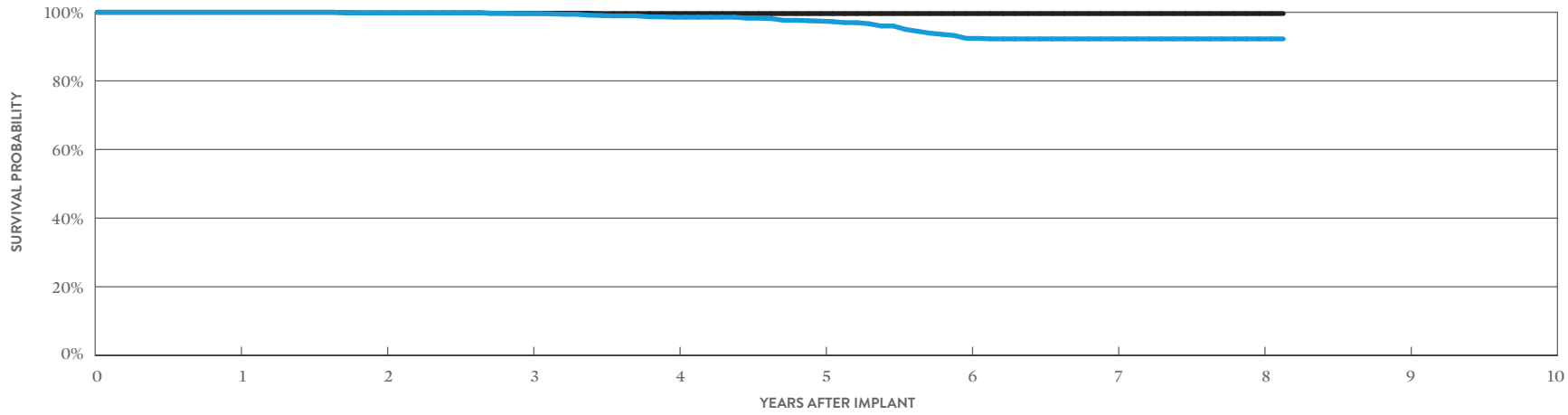
**DF4-LLHH connector type.*

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	1,245
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	48
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	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	AT 98 MONTHS
SURVIVAL PROBABILITY	100.00%	99.82%	99.62%	98.56%	97.42%	92.38%	92.24%	92.24%	92.24%
± 1 STANDARD ERROR	0.00%	0.09%	0.13%	0.26%	0.36%	0.63%	0.68%	0.68%	0.68%
SAMPLE SIZE	2,550	2,290	2,080	1,870	1,660	1,440	1,130	620	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	100.00%	99.82%	99.72%	99.62%	99.62%	99.62%	99.62%	99.62%	99.62%
± 1 STANDARD ERROR	0.00%	0.09%	0.11%	0.14%	0.14%	0.14%	0.14%	0.14%	0.14%

**Parylene coating.*

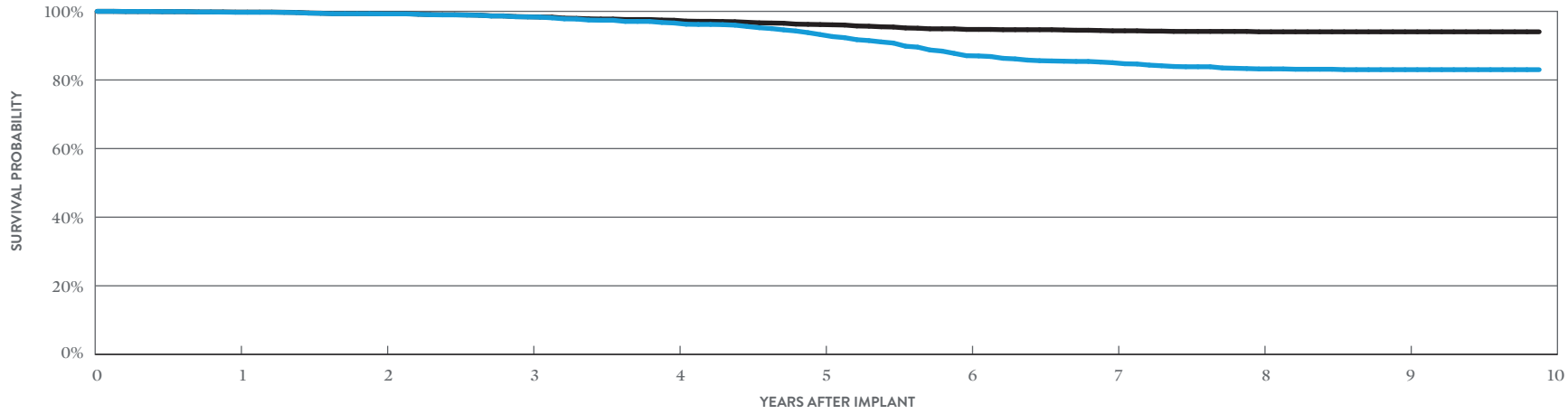
Cardiac Resynchronization Therapy (CRT) ICDs

Quadra Assura™ CRT-D

MODEL CD3365-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,626
Estimated Active US Implants	1,614
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	131
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.74%	99.27%	98.38%	96.61%	93.23%	87.07%	85.03%	83.22%	83.00%	83.00%
± 1 STANDARD ERROR	0.07%	0.12%	0.19%	0.29%	0.41%	0.58%	0.63%	0.68%	0.69%	0.69%
SAMPLE SIZE	5,210	4,460	3,840	3,390	3,070	2,750	2,420	1,990	1,320	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.78%	99.31%	98.42%	97.41%	96.15%	94.73%	94.33%	94.04%	94.04%	94.04%
± 1 STANDARD ERROR	0.06%	0.12%	0.19%	0.25%	0.32%	0.38%	0.40%	0.41%	0.42%	0.42%

**Parylene coating.*

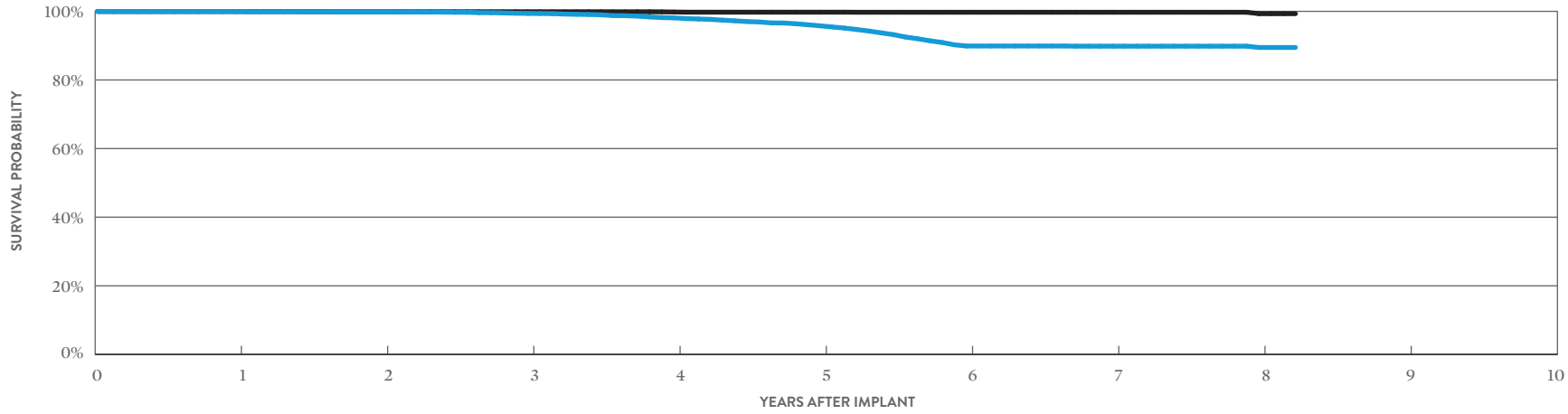
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	22,480
Estimated Active US Implants	12,896
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	329
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	6	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%	5	0.02%
Total	**2**	**<0.01%**	**15**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 99 MONTHS
SURVIVAL PROBABILITY	99.96%	99.84%	99.39%	98.10%	95.78%	89.90%	89.85%	89.47%	89.47%
± 1 STANDARD ERROR	0.01%	0.03%	0.06%	0.12%	0.19%	0.33%	0.34%	0.34%	0.43%
SAMPLE SIZE	20,250	16,600	13,980	11,650	9,170	6,450	3,840	1,510	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 99 MONTHS
SURVIVAL PROBABILITY	99.96%	99.89%	99.89%	99.81%	99.76%	99.74%	99.74%	99.32%	99.32%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.03%	0.04%	0.05%	0.05%	0.05%	0.30%

**DF4-LLHH connector type.*

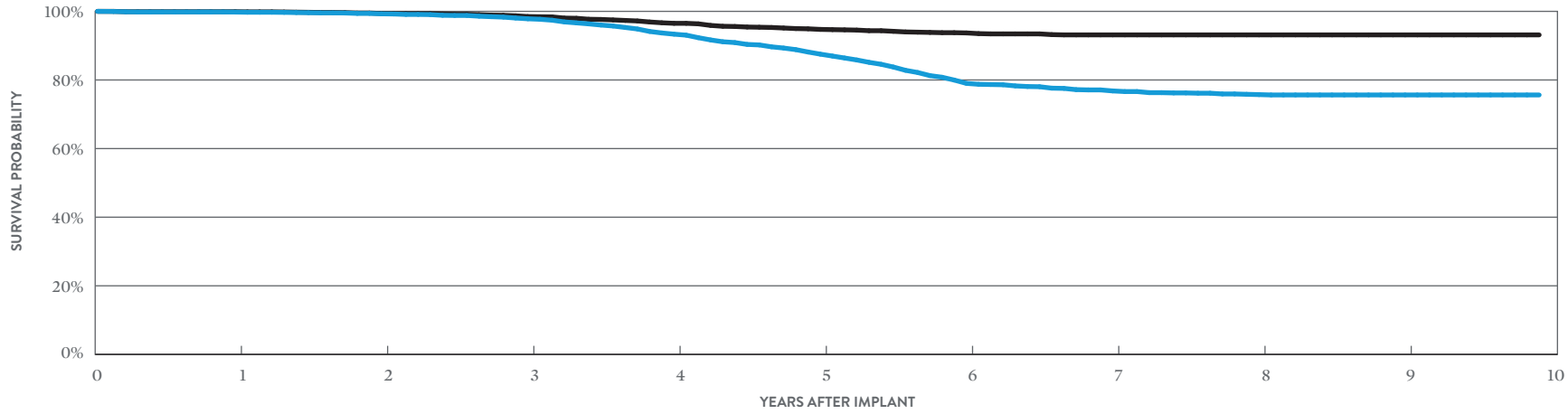
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,458
Estimated Active US Implants	1,406
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	225
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.79%	99.28%	97.83%	93.35%	87.53%	79.00%	76.80%	75.73%	75.63%	75.63%
± 1 STANDARD ERROR	0.06%	0.11%	0.22%	0.40%	0.55%	0.69%	0.74%	0.76%	0.76%	0.76%
SAMPLE SIZE	5,070	4,380	3,820	3,390	3,000	2,620	2,230	1,800	1,150	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.90%	99.39%	98.49%	96.51%	94.74%	93.71%	93.14%	93.14%	93.14%	93.14%
± 1 STANDARD ERROR	0.04%	0.10%	0.18%	0.30%	0.37%	0.42%	0.45%	0.45%	0.45%	0.45%

**DF4-LLHH connector type.*

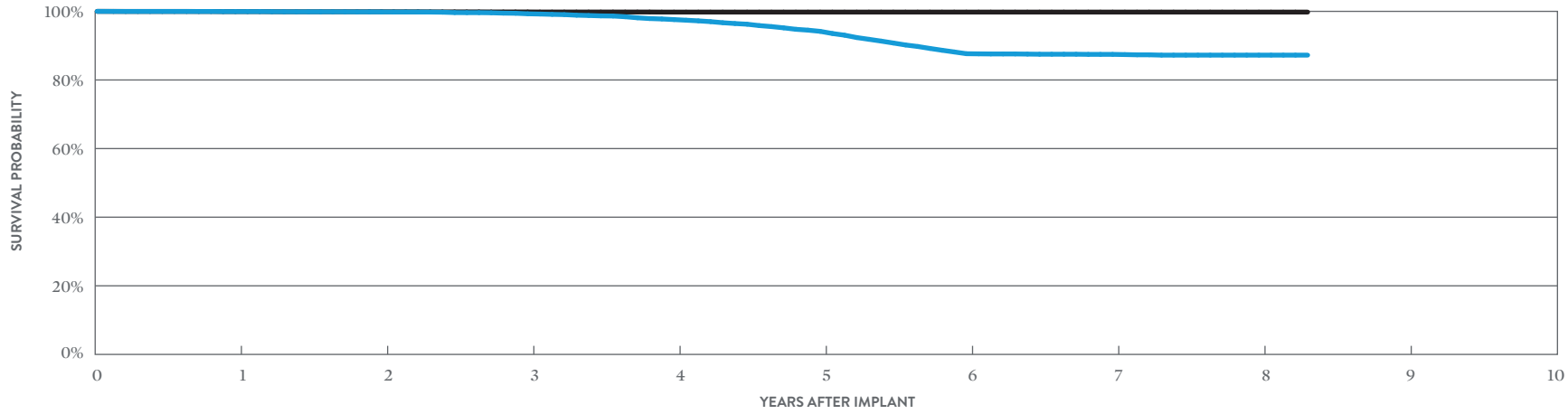
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	19,739
Estimated Active US Implants	10,749
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	411
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	0.01%
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%	1	<0.01%
Other	0	0.00%	5	0.03%
Total	**2**	**0.01%**	**12**	**0.06%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 100 MONTHS
SURVIVAL PROBABILITY	99.94%	99.84%	99.29%	97.60%	94.17%	87.65%	87.46%	87.24%	87.24%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.14%	0.23%	0.36%	0.37%	0.38%	0.38%
SAMPLE SIZE	18,040	15,070	12,730	10,620	8,540	6,450	4,260	1,930	310

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 100 MONTHS
SURVIVAL PROBABILITY	99.94%	99.89%	99.83%	99.79%	99.79%	99.79%	99.79%	99.79%	99.79%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%	0.04%	0.04%

**Parylene coating.*

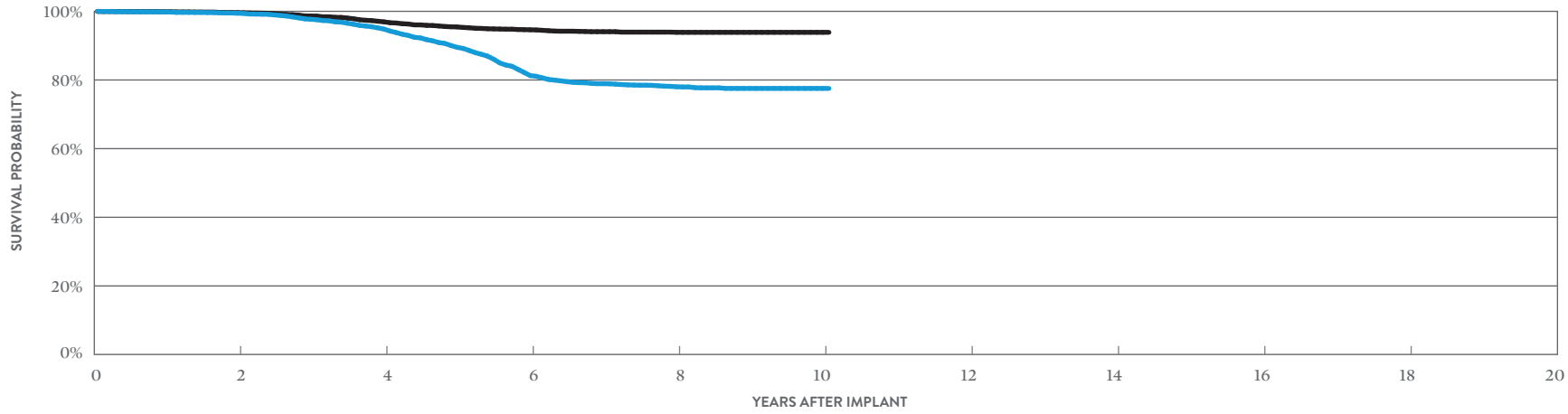
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	9,711
Estimated Active US Implants	2,748
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	376
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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 121 MONTHS
SURVIVAL PROBABILITY	99.45%	94.83%	81.28%	78.02%	77.54%	77.54%
± 1 STANDARD ERROR	0.08%	0.26%	0.50%	0.55%	0.56%	0.56%
SAMPLE SIZE	7,910	6,090	4,820	3,490	880	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 121 MONTHS
SURVIVAL PROBABILITY	99.62%	96.94%	94.62%	93.88%	93.88%	93.88%
± 1 STANDARD ERROR	0.07%	0.21%	0.29%	0.31%	0.32%	0.32%

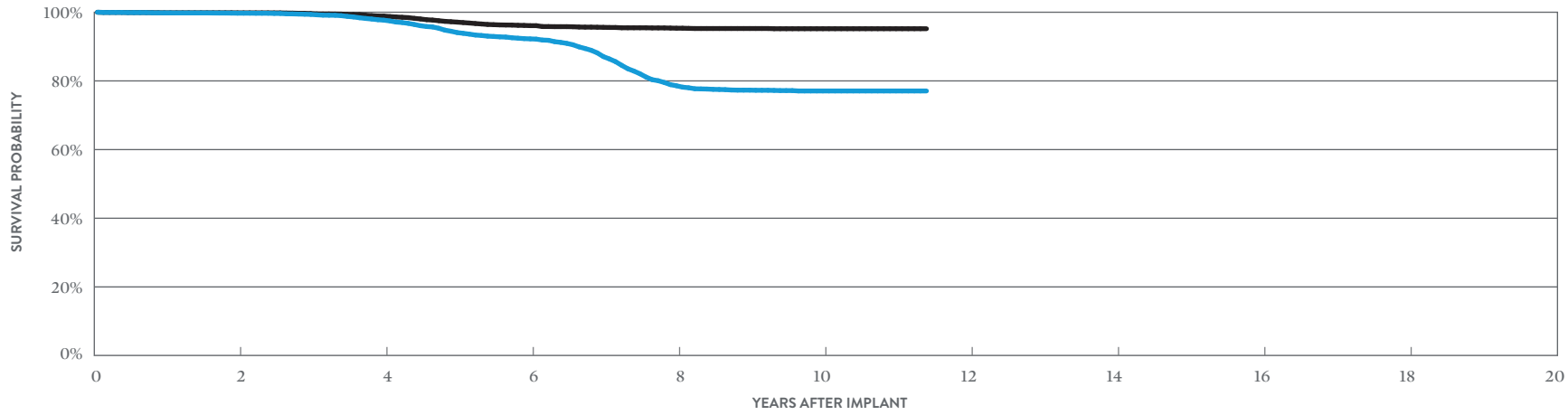
**Parylene coating.*

Quadra Assura™ CRT-D

MODEL CD3265-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	13,959
Estimated Active US Implants	3,246
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	492
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 137 MONTHS
SURVIVAL PROBABILITY	99.72%	97.69%	92.24%	78.58%	77.07%	77.07%
± 1 STANDARD ERROR	0.05%	0.15%	0.29%	0.49%	0.51%	0.51%
SAMPLE SIZE	11,670	9,250	7,230	5,010	3,300	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 137 MONTHS
SURVIVAL PROBABILITY	99.83%	98.88%	96.09%	95.35%	95.20%	95.20%
± 1 STANDARD ERROR	0.03%	0.11%	0.21%	0.24%	0.24%	0.24%

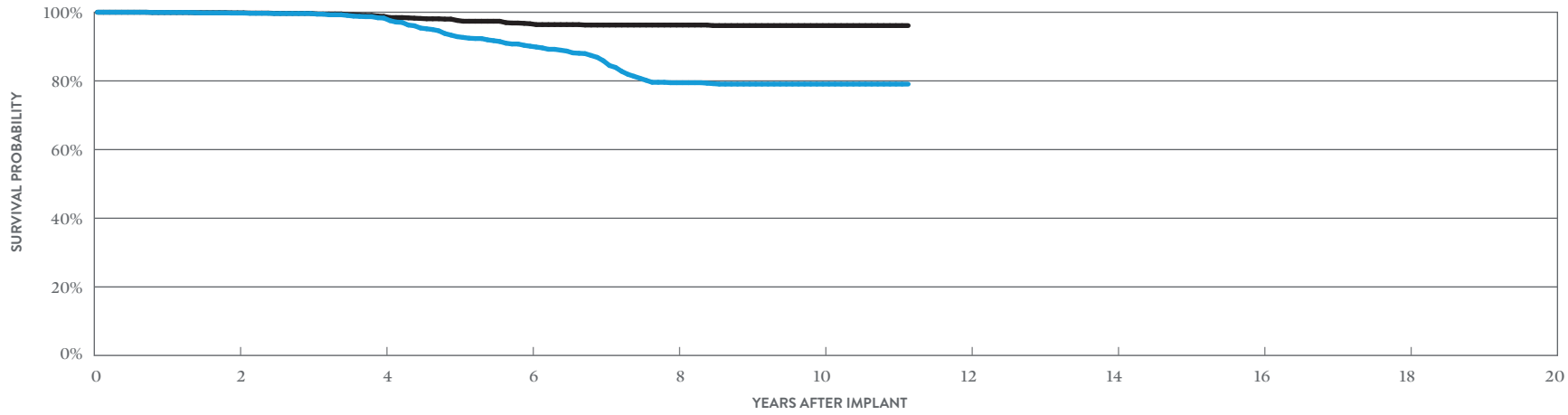
**DF4-LLHH connector type.*

Quadra Assura™ CRT-D

MODEL CD3265-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	4,026
Estimated Active US Implants	997
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	134
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 134 MONTHS
SURVIVAL PROBABILITY	99.76%	98.30%	90.11%	79.47%	79.07%	79.07%
± 1 STANDARD ERROR	0.08%	0.24%	0.62%	0.91%	0.92%	0.92%
SAMPLE SIZE	3,310	2,560	1,930	1,410	1,000	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.82%	98.79%	96.65%	96.27%	96.11%	96.11%
± 1 STANDARD ERROR	0.07%	0.20%	0.37%	0.40%	0.42%	0.42%

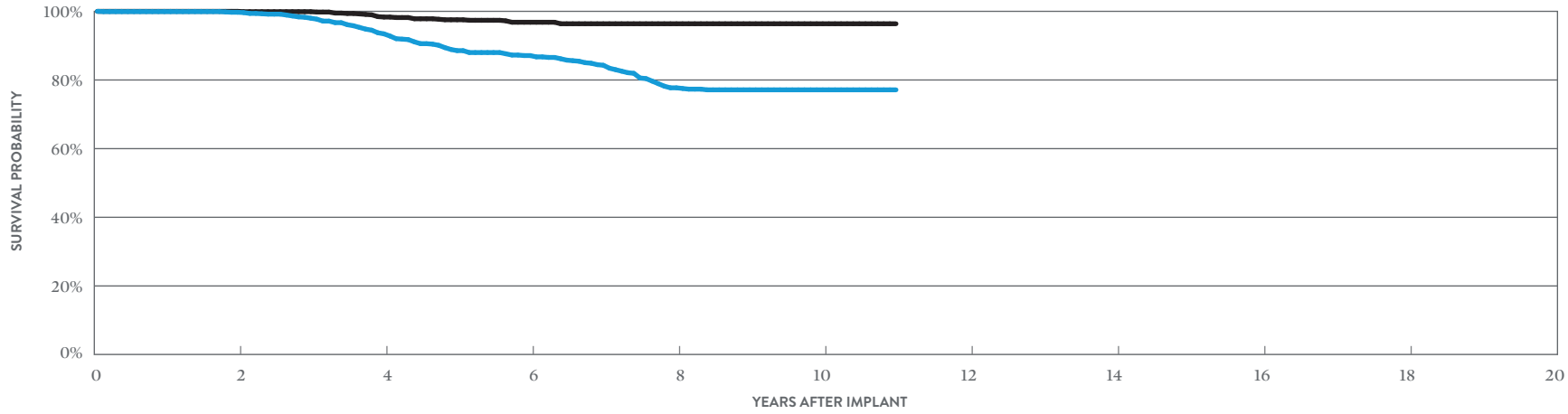
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,716
Estimated Active US Implants	636
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	109
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 132 MONTHS
SURVIVAL PROBABILITY	99.73%	93.44%	87.11%	77.72%	77.13%	77.13%
± 1 STANDARD ERROR	0.11%	0.58%	0.84%	1.14%	1.15%	1.15%
SAMPLE SIZE	2,180	1,620	1,220	900	660	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	100.00%	98.33%	96.82%	96.38%	96.38%	96.38%
± 1 STANDARD ERROR	0.00%	0.31%	0.46%	0.50%	0.50%	0.50%

**DF4-LLHH connector type.*

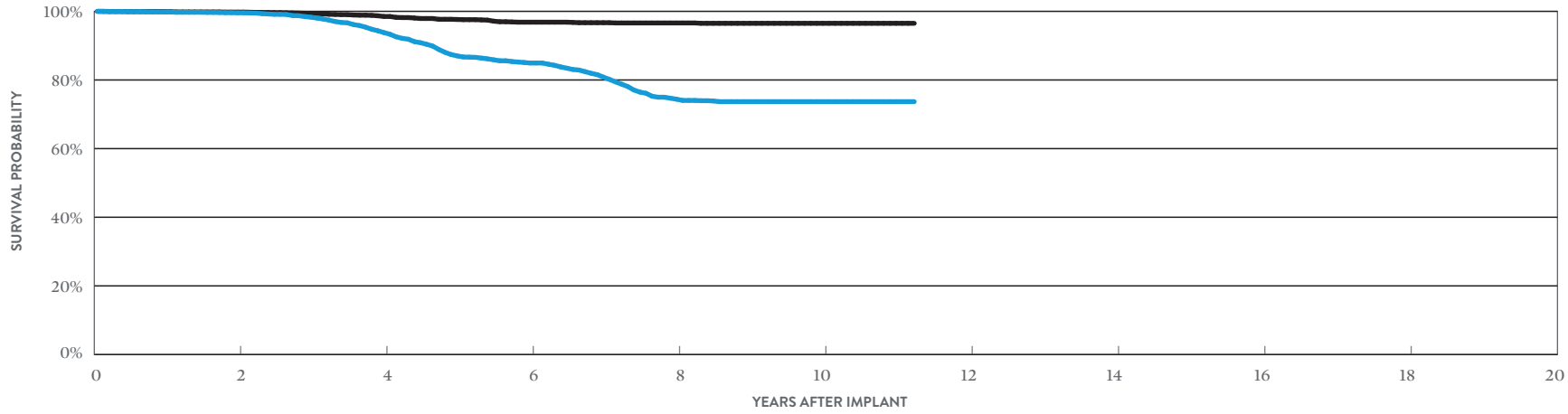
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Assura™ CRT-D

MODEL CD3257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,744
Estimated Active US Implants	1,615
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	328
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 135 MONTHS
SURVIVAL PROBABILITY	99.57%	93.81%	84.94%	74.40%	73.69%	73.69%
± 1 STANDARD ERROR	0.08%	0.34%	0.56%	0.74%	0.75%	0.75%
SAMPLE SIZE	5,510	4,180	3,100	2,260	1,630	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.78%	98.50%	96.84%	96.61%	96.51%	96.51%
± 1 STANDARD ERROR	0.06%	0.17%	0.28%	0.30%	0.30%	0.30%

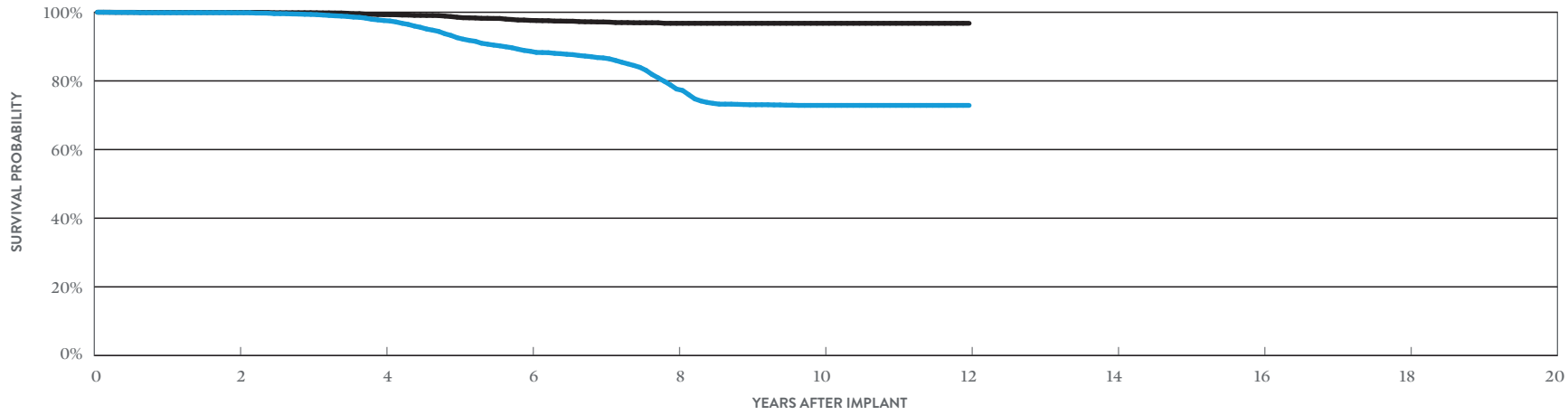
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Quadra™ CRT-D

MODEL CD3249-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	9,940
Estimated Active US Implants	2,041
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	457
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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
SURVIVAL PROBABILITY	99.86%	97.58%	88.64%	77.63%	72.87%	72.87%
± 1 STANDARD ERROR	0.04%	0.18%	0.41%	0.59%	0.67%	0.67%
SAMPLE SIZE	8,270	6,670	5,000	3,390	2,350	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12
SURVIVAL PROBABILITY	99.96%	99.29%	97.62%	96.78%	96.78%	96.78%
± 1 STANDARD ERROR	0.02%	0.10%	0.20%	0.25%	0.25%	0.25%

**DF4-LLHH connector type.*

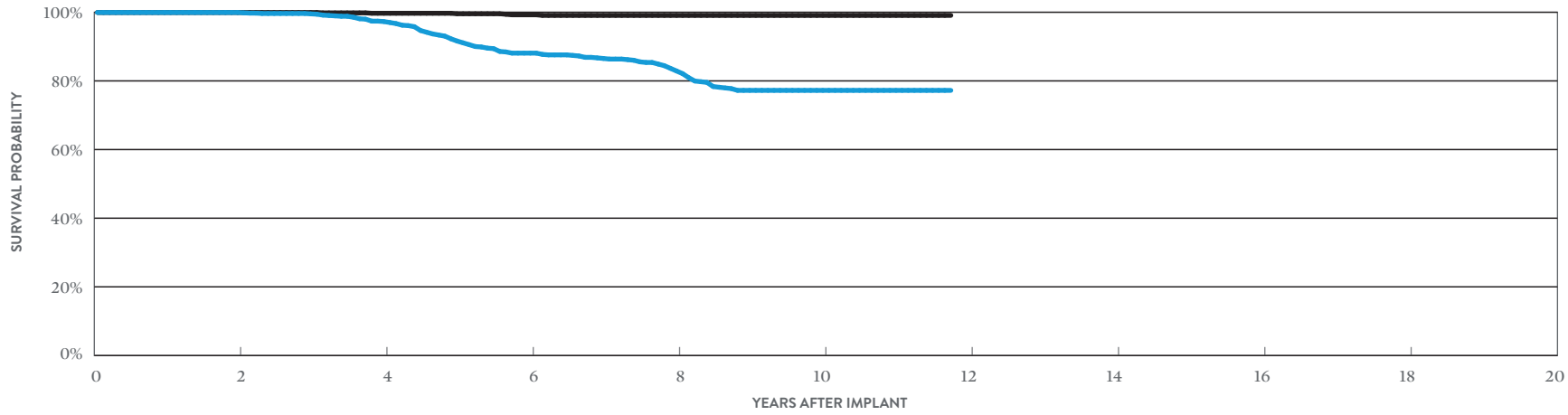
Cardiac Resynchronization Therapy (CRT) ICDs

Unify Quadra™ CRT-D

MODEL CD3249-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	2,767
Estimated Active US Implants	630
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	121
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 141 MONTHS
SURVIVAL PROBABILITY	99.93%	97.29%	88.09%	82.89%	77.24%	77.24%
± 1 STANDARD ERROR	0.05%	0.37%	0.81%	0.98%	1.19%	1.19%
SAMPLE SIZE	2,250	1,780	1,310	940	720	240

EXCLUDING NORMAL BATTERY DEPLETION

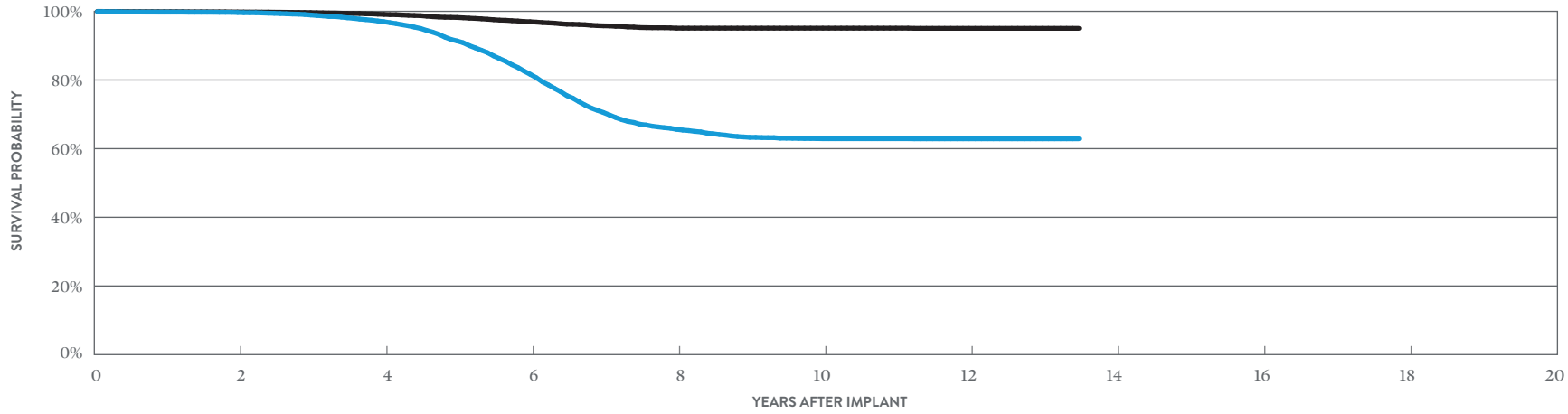
YEAR	2	4	6	8	10	AT 141 MONTHS
SURVIVAL PROBABILITY	99.93%	99.70%	99.25%	99.08%	99.08%	99.08%
± 1 STANDARD ERROR	0.05%	0.12%	0.22%	0.25%	0.25%	0.25%

Unify™ CRT-D

MODEL CD3231-40Q (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	20,709
Estimated Active US Implants	3,533
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,425
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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%	10	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	68	0.33%	62	0.30%
Other	10	0.05%	7	0.03%
Total	**114**	**0.55%**	**96**	**0.46%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	99.65%	96.98%	81.66%	65.62%	62.90%	62.87%	62.87%
± 1 STANDARD ERROR	0.04%	0.14%	0.35%	0.45%	0.48%	0.48%	0.48%
SAMPLE SIZE	16,940	13,510	9,970	6,230	4,360	3,430	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	99.81%	99.11%	96.97%	95.10%	95.10%	95.05%	95.05%
± 1 STANDARD ERROR	0.03%	0.07%	0.16%	0.22%	0.22%	0.22%	0.22%

**DF4-LLHH connector type.*

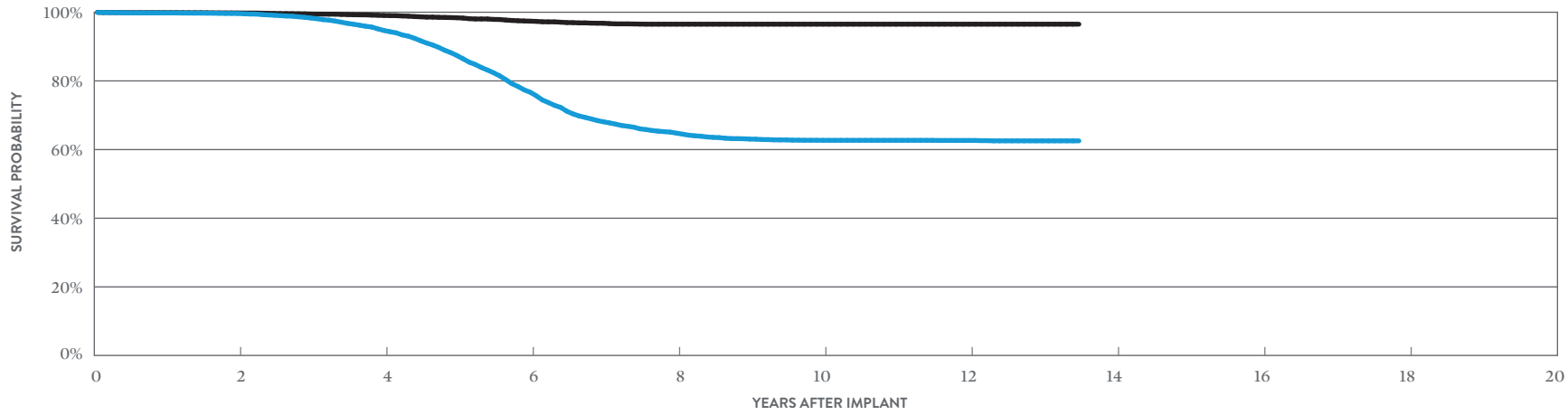
Cardiac Resynchronization Therapy (CRT) ICDs

Unify™ CRT-D

MODEL CD3231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	21,185
Estimated Active US Implants	3,996
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,527
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	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	AT 162 MONTHS
SURVIVAL PROBABILITY	99.63%	94.69%	76.69%	64.78%	62.69%	62.65%	62.54%
± 1 STANDARD ERROR	0.04%	0.18%	0.38%	0.46%	0.47%	0.47%	0.47%
SAMPLE SIZE	17,020	13,000	9,190	6,120	4,790	3,400	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	99.79%	99.06%	97.40%	96.52%	96.52%	96.52%	96.52%
± 1 STANDARD ERROR	0.03%	0.08%	0.15%	0.18%	0.18%	0.18%	0.18%

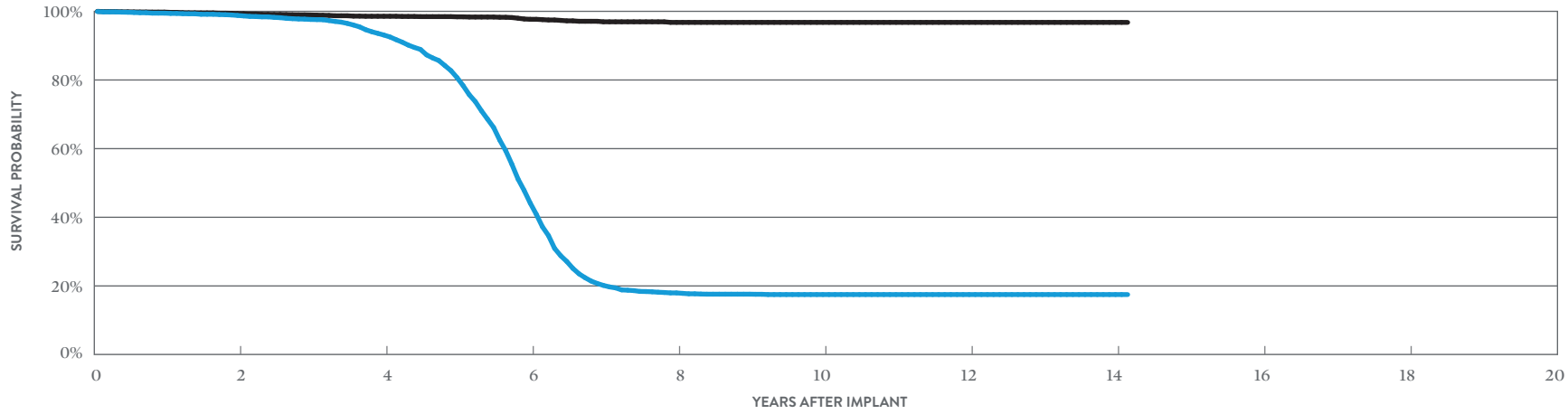
Cardiac Resynchronization Therapy (CRT) ICDs

Promote™ + CRT-D

MODEL CD3211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	7,755
Estimated Active US Implants	839
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,506
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.06%	4	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	10	0.13%	6	0.08%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	11	0.14%
Mechanical	1	0.01%	1	0.01%
Possible Early Battery Depletion	4	0.05%	0	0.00%
Other	5	0.06%	6	0.08%
Total	**26**	**0.34%**	**28**	**0.36%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 170 MONTHS
SURVIVAL PROBABILITY	98.80%	93.09%	44.15%	17.97%	17.49%	17.49%	17.49%	17.49%
± 1 STANDARD ERROR	0.13%	0.34%	0.76%	0.53%	0.53%	0.53%	0.53%	0.53%
SAMPLE SIZE	6,030	4,570	2,750	1,210	1,060	960	550	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 170 MONTHS
SURVIVAL PROBABILITY	99.34%	98.56%	97.68%	96.78%	96.78%	96.78%	96.78%	96.78%
± 1 STANDARD ERROR	0.09%	0.16%	0.23%	0.34%	0.34%	0.34%	0.34%	0.34%

**DF4-LLHH connector type.*

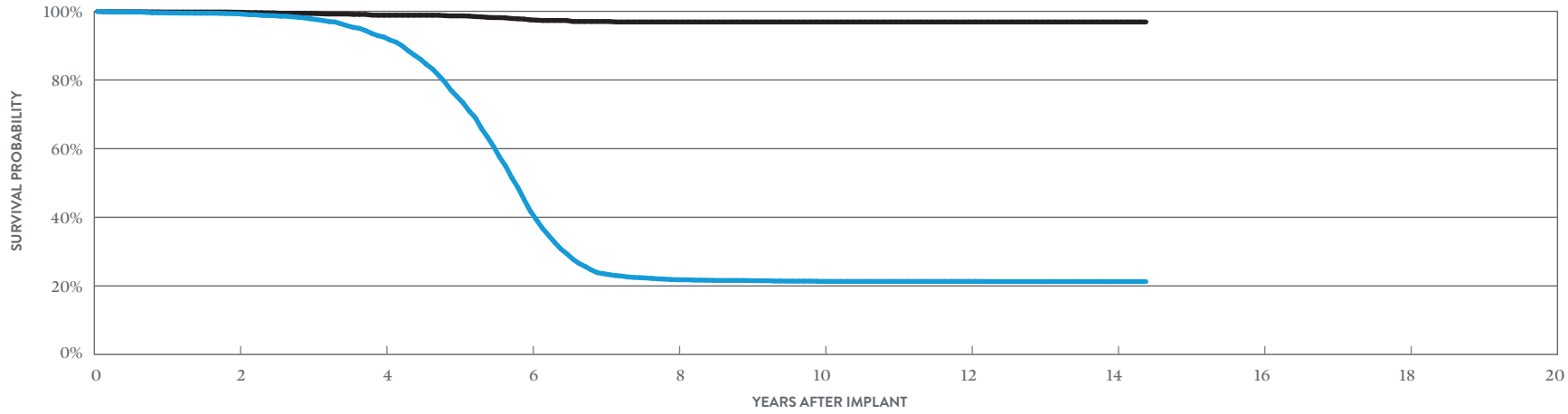
Cardiac Resynchronization Therapy (CRT) ICDs

Promote™ + CRT-D

MODEL CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,865
Estimated Active US Implants	962
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1,524
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.03%	3	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	11	0.12%	3	0.03%
High Voltage Capacitor	2	0.02%	0	0.00%
Software/Firmware	1	0.01%	14	0.16%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	5	0.06%	1	0.01%
Other	5	0.06%	3	0.03%
Total	**27**	**0.30%**	**25**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 MONTHS
SURVIVAL PROBABILITY	99.29%	92.51%	41.88%	21.81%	21.32%	21.32%	21.28%	21.28%
± 1 STANDARD ERROR	0.09%	0.35%	0.72%	0.57%	0.56%	0.56%	0.56%	0.56%
SAMPLE SIZE	6,860	5,000	2,820	1,370	1,190	1,050	660	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 MONTHS
SURVIVAL PROBABILITY	99.73%	98.86%	97.52%	96.90%	96.90%	96.90%	96.90%	96.90%
± 1 STANDARD ERROR	0.06%	0.14%	0.24%	0.32%	0.32%	0.32%	0.32%	0.32%

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*	9.5	9.9	8.9	7.4
CD3369-40C	Quadra Assura MP™ CRT-D*	8.7	9.9	8.9	7.4
CD3365-40Q	Quadra Assura™ CRT-D*	7.4	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
CD3211-36Q	Promote™ + CRT-D**	8.2	7.2	6.5	5.4
CD3211-36	Promote™ + CRT-D**	8.2	7.2	6.5	5.4
3207-36	Promote™ RF CRT-D**	8.2	7.2	6.5	5.4
V-343	Atlas™ + HF CRT-D**	7.9	7.1	6.4	5.4

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	99.92%	99.84%	99.84%							
CD3369-40Q	Quadra Assura MP™ CRT-D	99.84%	99.77%	99.64%	99.22%	97.57%	97.38%	97.29%			
CD3369-40C	Quadra Assura MP™ CRT-D	99.82%	99.59%	99.44%	98.53%	96.07%	95.86%	95.60%			
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.74%	99.59%	98.91%	97.22%	93.36%	93.13%	92.95%		
CD3365-40Q	Quadra Assura™ CRT-D†	99.78%	99.40%	98.20%	95.37%	91.45%	85.16%	82.72%	81.11%	80.34%	80.29%
CD3365-40C	Quadra Assura™ CRT-D	100.00%	99.82%	99.62%	98.56%	97.42%	92.38%	92.24%	92.24%		
CD3365-40C	Quadra Assura™ CRT-D†	99.74%	99.27%	98.38%	96.61%	93.23%	87.07%	85.03%	83.22%	83.00%	
CD3357-40Q	Unify Assura™ CRT-D	99.96%	99.84%	99.39%	98.10%	95.78%	89.90%	89.85%	89.47%		
CD3357-40Q	Unify Assura™ CRT-D†	99.79%	99.28%	97.83%	93.35%	87.53%	79.00%	76.80%	75.73%	75.63%	
CD3357-40C	Unify Assura™ CRT-D	99.94%	99.84%	99.29%	97.60%	94.17%	87.65%	87.46%	87.24%		
CD3357-40C	Unify Assura™ CRT-D†	99.81%	99.45%	97.68%	94.83%	89.51%	81.28%	78.92%	78.02%	77.54%	77.54%
CD3265-40Q	Quadra Assura™ CRT-D†	99.81%	99.72%	99.37%	97.69%	94.08%	92.24%	87.08%	78.58%	77.31%	77.07%
CD3265-40	Quadra Assura™ CRT-D†	99.94%	99.76%	99.63%	98.30%	92.89%	90.11%	85.87%	79.47%	79.07%	79.07%
CD3257-40Q	Unify Assura™ CRT-D†	99.92%	99.73%	98.00%	93.44%	88.55%	87.11%	84.29%	77.72%	77.13%	77.13%
CD3257-40	Unify Assura™ CRT-D†	99.81%	99.57%	98.30%	93.81%	87.02%	84.94%	80.83%	74.40%	73.69%	73.69%
CD3249-40Q	Unify Quadra™ CRT-D†	99.88%	99.86%	99.37%	97.58%	92.59%	88.64%	86.69%	77.63%	73.06%	72.87%
CD3249-40	Unify Quadra™ CRT-D†	99.93%	99.93%	99.53%	97.29%	91.61%	88.09%	86.53%	82.89%	77.24%	77.24%
CD3231-40Q	Unify™ CRT-D†	99.77%	99.65%	98.93%	96.98%	91.37%	81.66%	70.52%	65.62%	63.29%	62.90%
CD3231-40	Unify™ CRT-D†	99.79%	99.63%	98.32%	94.69%	87.37%	76.69%	68.10%	64.78%	63.05%	62.69%
CD3211-36Q	Promote™ + CRT-D	99.47%	98.80%	97.63%	93.09%	80.69%	44.15%	20.16%	17.97%	17.60%	17.49%
CD3211-36	Promote™ + CRT-D	99.54%	99.29%	97.82%	92.51%	75.18%	41.88%	23.58%	21.81%	21.55%	21.32%

†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	99.93%	99.85%	99.85%							
CD3369-40Q	Quadra Assura MP™ CRT-D	99.85%	99.79%	99.74%	99.73%	99.73%	99.71%	99.71%			
CD3369-40C	Quadra Assura MP™ CRT-D	99.86%	99.66%	99.64%	99.64%	99.55%	99.55%	99.55%			
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.74%	99.68%	99.63%	99.59%	99.57%	99.52%	99.52%		
CD3365-40Q	Quadra Assura™ CRT-D†	99.83%	99.55%	98.52%	96.16%	94.05%	92.51%	91.72%	91.31%	91.28%	91.28%
CD3365-40C	Quadra Assura™ CRT-D	100.00%	99.82%	99.72%	99.62%	99.62%	99.62%	99.62%	99.62%		
CD3365-40C	Quadra Assura™ CRT-D†	99.78%	99.31%	98.42%	97.41%	96.15%	94.73%	94.33%	94.04%	94.04%	
CD3357-40Q	Unify Assura™ CRT-D	99.96%	99.89%	99.89%	99.81%	99.76%	99.74%	99.74%	99.32%		
CD3357-40Q	Unify Assura™ CRT-D†	99.90%	99.39%	98.49%	96.51%	94.74%	93.71%	93.14%	93.14%	93.14%	
CD3357-40C	Unify Assura™ CRT-D	99.94%	99.89%	99.83%	99.79%	99.79%	99.79%	99.79%	99.79%		
CD3357-40C	Unify Assura™ CRT-D†	99.89%	99.62%	98.64%	96.94%	95.45%	94.62%	94.07%	93.88%	93.88%	93.88%
CD3265-40Q	Quadra Assura™ CRT-D†	99.85%	99.83%	99.63%	98.88%	97.12%	96.09%	95.60%	95.35%	95.26%	95.20%
CD3265-40	Quadra Assura™ CRT-D†	99.94%	99.82%	99.69%	98.79%	97.62%	96.65%	96.27%	96.27%	96.11%	96.11%
CD3257-40Q	Unify Assura™ CRT-D†	100.00%	100.00%	99.90%	98.33%	97.54%	96.82%	96.38%	96.38%	96.38%	96.38%
CD3257-40	Unify Assura™ CRT-D†	99.90%	99.78%	99.41%	98.50%	97.63%	96.84%	96.69%	96.61%	96.51%	96.51%
CD3249-40Q	Unify Quadra™ CRT-D†	99.96%	99.96%	99.86%	99.29%	98.55%	97.62%	97.17%	96.78%	96.78%	96.78%
CD3249-40	Unify Quadra™ CRT-D†	99.93%	99.93%	99.93%	99.70%	99.56%	99.25%	99.08%	99.08%	99.08%	99.08%
CD3231-40Q	Unify™ CRT-D†	99.88%	99.81%	99.62%	99.11%	98.21%	96.97%	95.78%	95.10%	95.10%	95.10%
CD3231-40	Unify™ CRT-D†	99.87%	99.79%	99.48%	99.06%	98.39%	97.40%	96.80%	96.52%	96.52%	96.52%
CD3211-36Q	Promote™ + CRT-D	99.78%	99.34%	98.94%	98.56%	98.40%	97.68%	96.95%	96.78%	96.78%	96.78%
CD3211-36	Promote™ + CRT-D	99.79%	99.73%	99.38%	98.86%	98.67%	97.52%	97.04%	96.90%	96.90%	96.90%

†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	35,389	1.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**2**	**<0.01%**
CD3369-40Q	Quadra Assura MP™ CRT-D	77,783	3.70%	7	<0.01%	10	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	4	<0.01%	**22**	**0.03%**
CD3369-40C	Quadra Assura MP™ CRT-D	11,593	4.60%	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	16,837	6.40%	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	8.00%	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	21.90%	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	22,480	5.80%	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	22.60%	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	19,739	6.90%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**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%	68	0.33%	10	0.05%	**114**	**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%**
CD3211-36Q	Promote™ + CRT-D	7,755	28.70%	5	0.06%	0	0.00%	10	0.13%	1	0.01%	0	0.00%	1	0.01%	4	0.05%	5	0.06%	**26**	**0.34%**
CD3211-36	Promote™ + CRT-D	8,865	28.30%	3	0.03%	0	0.00%	11	0.12%	2	0.02%	1	0.01%	0	0.00%	5	0.06%	5	0.06%	**27**	**0.30%**

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	35,389	1.30%	6	0.02%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**11**	**0.03%**
CD3369-40Q	Quadra Assura MP™ CRT-D	77,783	3.70%	21	0.03%	1	<0.01%	3	<0.01%	2	<0.01%	0	0.00%	5	<0.01%	2	<0.01%	19	0.02%	**53**	**0.07%**
CD3369-40C	Quadra Assura MP™ CRT-D	11,593	4.60%	3	0.03%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.02%	2	0.02%	3	0.03%	**11**	**0.09%**
CD3365-40Q	Quadra Assura™ CRT-D	16,837	6.40%	7	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.02%	3	0.02%	6	0.04%	**20**	**0.12%**
CD3365-40Q	Quadra Assura™ CRT-D†	24,249	18.30%	17	0.07%	1	<0.01%	18	0.07%	0	0.00%	3	0.01%	2	<0.01%	422	1.74%	7	0.03%	**470**	**1.94%**
CD3365-40C	Quadra Assura™ CRT-D	2,705	8.00%	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	21.90%	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	22,480	5.80%	6	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	5	0.02%	**15**	**0.07%**
CD3357-40Q	Unify Assura™ CRT-D†	5,458	22.60%	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	19,739	6.90%	2	0.01%	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	5	0.03%	**12**	**0.06%**
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%	10	0.05%	6	0.03%	2	<0.01%	3	0.01%	62	0.30%	7	0.03%	**96**	**0.46%**
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%**
CD3211-36Q	Promote™ + CRT-D	7,755	28.70%	4	0.05%	0	0.00%	6	0.08%	0	0.00%	11	0.14%	1	0.01%	0	0.00%	6	0.08%	**28**	**0.36%**
CD3211-36	Promote™ + CRT-D	8,865	28.30%	3	0.03%	0	0.00%	3	0.03%	0	0.00%	14	0.16%	1	0.01%	1	0.01%	3	0.03%	**25**	**0.28%**

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	53,779	1.12%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	**4**	**<0.01%**
CD3369-40Q	Quadra Assura MP™ CRT-D	78,337	3.88%	14	0.02%	20	0.03%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	8	0.01%	**44**	**0.06%**
CD3369-40C	Quadra Assura MP™ CRT-D	11,755	5.10%	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	41,617	13.58%	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	18.18%	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	28,309	9.44%	2	<0.01%	4	0.01%	0	0.00%	3	0.01%	0	0.00%	0	0.00%	22	0.08%	2	<0.01%	**33**	**0.12%**
CD3357-40C	Unify Assura™ CRT-D	29,738	12.43%	4	0.01%	8	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	38	0.13%	2	<0.01%	**53**	**0.18%**
CD3265-40Q	Quadra Assura™ CRT-D	13,955	18.25%	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	20.51%	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	12,197	15.16%	10	0.08%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	34	0.28%	8	0.07%	**54**	**0.44%**
CD3249-40	Unify Quadra™ CRT-D	5,418	11.30%	6	0.11%	4	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	2	0.04%	**14**	**0.26%**
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%	136	0.65%	20	0.10%	**213**	**1.02%**
CD3231-40	Unify™ CRT-D	24,621	18.84%	22	0.09%	8	0.03%	20	0.08%	7	0.03%	0	0.00%	2	<0.01%	68	0.28%	22	0.09%	**149**	**0.61%**
CD3211-36Q	Promote™ + CRT-D	16,097	14.91%	30	0.19%	0	0.00%	28	0.17%	8	0.05%	2	0.01%	4	0.02%	16	0.10%	12	0.07%	**100**	**0.62%**
CD3211-36	Promote™ + CRT-D	21,011	12.84%	28	0.13%	4	0.02%	30	0.14%	6	0.03%	2	<0.01%	0	0.00%	18	0.09%	28	0.13%	**116**	**0.55%**

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	53,779	1.12%	24	0.04%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	6	0.01%	0	0.00%	2	<0.01%	**34**	**0.06%**
CD3369-40Q	Quadra Assura MP™ CRT-D	78,337	3.88%	42	0.05%	2	<0.01%	6	<0.01%	2	<0.01%	0	0.00%	10	0.01%	4	<0.01%	38	0.05%	**104**	**0.13%**
CD3369-40C	Quadra Assura MP™ CRT-D	11,755	5.10%	6	0.05%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	4	0.03%	4	0.03%	6	0.05%	**21**	**0.18%**
CD3365-40Q	Quadra Assura™ CRT-D	41,617	13.58%	48	0.12%	2	<0.01%	36	0.09%	0	0.00%	6	0.01%	12	0.03%	852	2.05%	26	0.06%	**982**	**2.36%**
CD3365-40C	Quadra Assura™ CRT-D	8,382	18.18%	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	28,309	9.44%	16	0.06%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	4	0.01%	156	0.55%	16	0.06%	**194**	**0.69%**
CD3357-40C	Unify Assura™ CRT-D	29,738	12.43%	10	0.03%	4	0.01%	16	0.05%	0	0.00%	4	0.01%	4	0.01%	220	0.74%	16	0.05%	**274**	**0.92%**
CD3265-40Q	Quadra Assura™ CRT-D	13,955	18.25%	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	20.51%	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	12,197	15.16%	6	0.05%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	2	0.02%	86	0.71%	8	0.07%	**104**	**0.85%**
CD3249-40	Unify Quadra™ CRT-D	5,418	11.30%	4	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	14	0.26%	0	0.00%	**20**	**0.37%**
CD3231-40Q	Unify™ CRT-D	20,973	20.49%	12	0.06%	0	0.00%	20	0.10%	6	0.03%	4	0.02%	6	0.03%	124	0.59%	14	0.07%	**186**	**0.89%**
CD3231-40	Unify™ CRT-D	24,621	18.84%	14	0.06%	0	0.00%	10	0.04%	0	0.00%	6	0.02%	2	<0.01%	106	0.43%	28	0.11%	**166**	**0.67%**
CD3211-36Q	Promote™ + CRT-D	16,097	14.91%	12	0.07%	0	0.00%	14	0.09%	0	0.00%	32	0.20%	6	0.04%	8	0.05%	18	0.11%	**90**	**0.56%**
CD3211-36	Promote™ + CRT-D	21,011	12.84%	16	0.08%	0	0.00%	8	0.04%	0	0.00%	38	0.18%	4	0.02%	4	0.02%	18	0.09%	**88**	**0.42%**

Definitions of malfunction categories can be found on pages 5-6.

Cardiac Resynchronization Therapy (CRT) Pacemakers

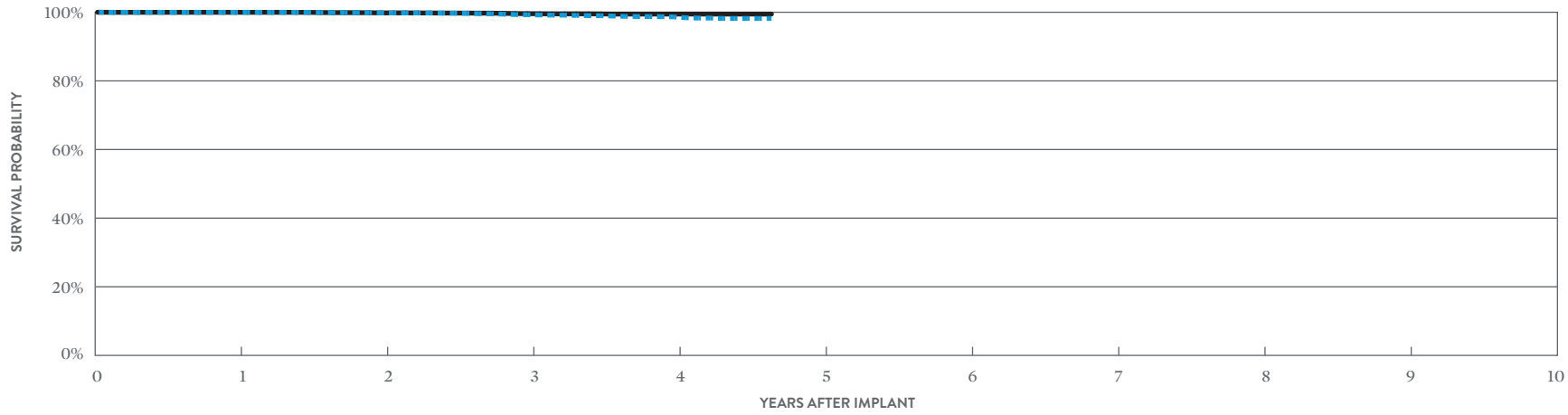
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra MP™ CRT-P

MODEL PM3562

US Regulatory Approval	January 2019
Registered US Implants	34,990
Estimated Active US Implants	27,047
Estimated Longevity	8 Years
Normal Battery Depletion	31
Number of US Advisories (see pgs. 215, 218)	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%	30	0.09%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**30**	**0.09%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.98%	99.82%	99.27%	98.65%	98.19%
± 1 STANDARD ERROR	0.01%	0.03%	0.07%	0.12%	0.19%
SAMPLE SIZE	29,430	19,820	12,380	6,110	360

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.98%	99.82%	99.59%	99.47%	99.47%
± 1 STANDARD ERROR	0.01%	0.03%	0.05%	0.07%	0.07%

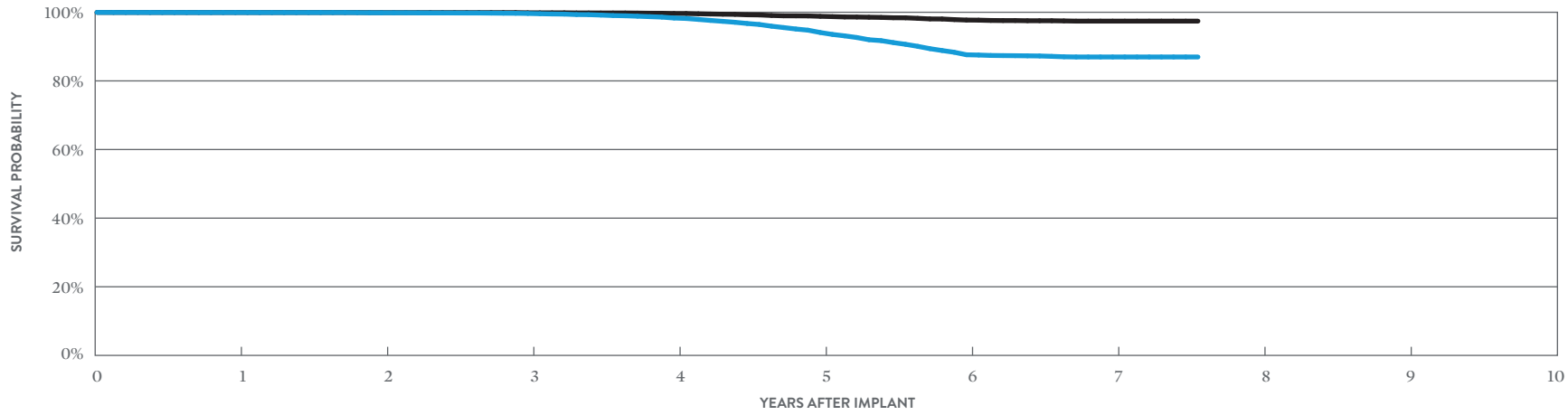
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra MP™ CRT-P

MODEL PM3262

US Regulatory Approval	February 2016
Registered US Implants	19,960
Estimated Active US Implants	10,372
Estimated Longevity	8 Years
Normal Battery Depletion	458
Number of US Advisories (see pgs. 215, 218)	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	4	0.02%	98	0.49%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**4**	**0.02%**	**104**	**0.52%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 91 MONTHS
SURVIVAL PROBABILITY	99.93%	99.85%	99.65%	98.32%	94.10%	87.61%	86.97%	86.97%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.10%	0.19%	0.31%	0.34%	0.34%
SAMPLE SIZE	19,040	17,410	16,080	14,700	12,290	8,340	3,990	360

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 91 MONTHS
SURVIVAL PROBABILITY	99.94%	99.90%	99.85%	99.65%	98.82%	97.73%	97.42%	97.42%
± 1 STANDARD ERROR	0.02%	0.02%	0.02%	0.04%	0.09%	0.14%	0.17%	0.17%

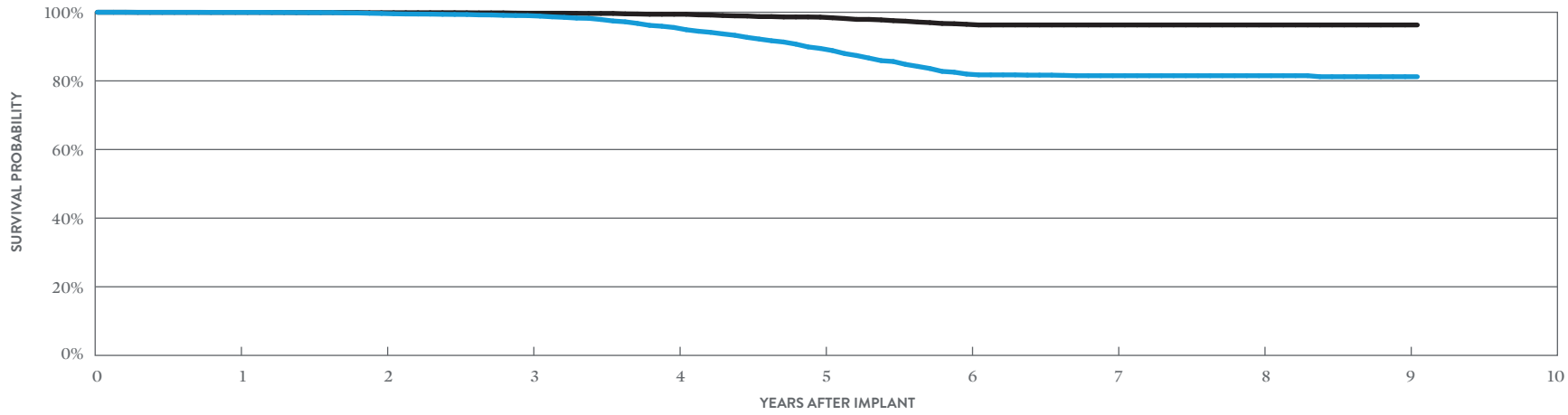
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure™ RF CRT-P

MODEL PM3222

US Regulatory Approval	March 2014
Registered US Implants	13,493
Estimated Active US Implants	7,201
Estimated Longevity	8 Years
Normal Battery Depletion	308
Number of US Advisories (see pgs. 215, 218)	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	0	0.00%	65	0.48%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**65**	**0.48%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.97%	99.65%	99.02%	95.56%	89.46%	81.99%	81.51%	81.51%	81.22%	81.22%
± 1 STANDARD ERROR	0.02%	0.06%	0.11%	0.24%	0.40%	0.55%	0.57%	0.57%	0.61%	0.61%
SAMPLE SIZE	12,050	9,710	8,000	6,410	4,840	3,380	2,190	1,250	530	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.97%	99.87%	99.72%	99.42%	98.58%	96.49%	96.30%	96.30%	96.30%	96.30%
± 1 STANDARD ERROR	0.02%	0.04%	0.05%	0.09%	0.15%	0.28%	0.30%	0.30%	0.30%	0.30%

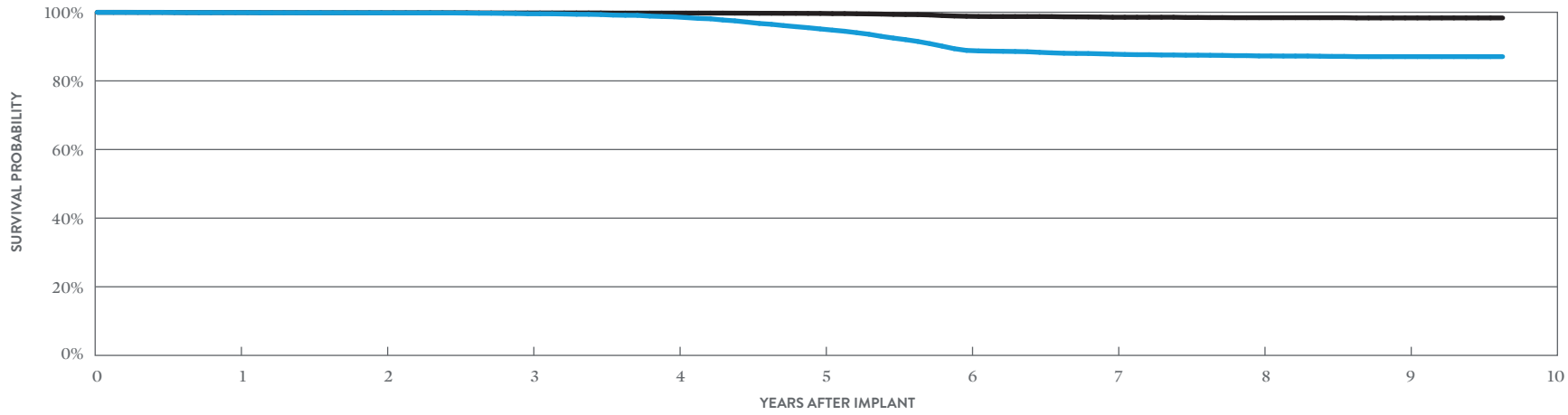
Cardiac Resynchronization Therapy (CRT) Pacemakers

Allure Quadra™ RF CRT-P

MODEL PM3242

US Regulatory Approval	March 2014
Registered US Implants	18,479
Estimated Active US Implants	6,881
Estimated Longevity	8 Years
Normal Battery Depletion	519
Number of US Advisories (see pgs. 215, 218)	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%	67	0.36%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.02%**	**69**	**0.37%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.90%	99.82%	99.56%	98.67%	95.14%	88.88%	87.79%	87.27%	87.07%	87.07%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.09%	0.19%	0.28%	0.30%	0.31%	0.32%	0.32%
SAMPLE SIZE	17,330	15,470	14,160	13,000	11,790	10,440	8,890	6,550	3,290	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.92%	99.86%	99.80%	99.76%	99.66%	98.83%	98.55%	98.42%	98.35%	98.35%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.04%	0.05%	0.10%	0.11%	0.12%	0.13%	0.13%

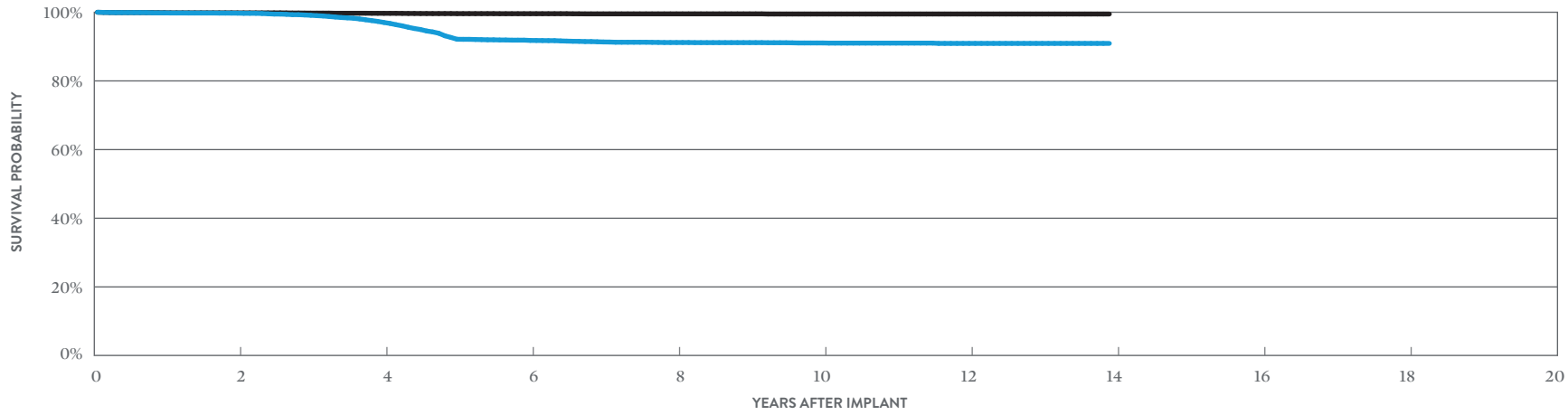
Cardiac Resynchronization Therapy (CRT) Pacemakers

Anthem™ RF CRT-P

MODEL PM3210

US Regulatory Approval	July 2009
Registered US Implants	20,647
Estimated Active US Implants	4,676
Estimated Longevity	8 Years
Normal Battery Depletion	405
Number of US Advisories (see pgs. 215, 218, 220)	Three

	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	AT 167 MONTHS
SURVIVAL PROBABILITY	99.72%	97.02%	91.79%	91.18%	91.05%	90.92%	90.92%
± 1 STANDARD ERROR	0.04%	0.14%	0.25%	0.26%	0.26%	0.27%	0.27%
SAMPLE SIZE	16,230	12,710	9,760	7,200	5,060	2,220	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 167 MONTHS
SURVIVAL PROBABILITY	99.83%	99.68%	99.57%	99.52%	99.48%	99.48%	99.48%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.06%	0.07%	0.07%	0.07%

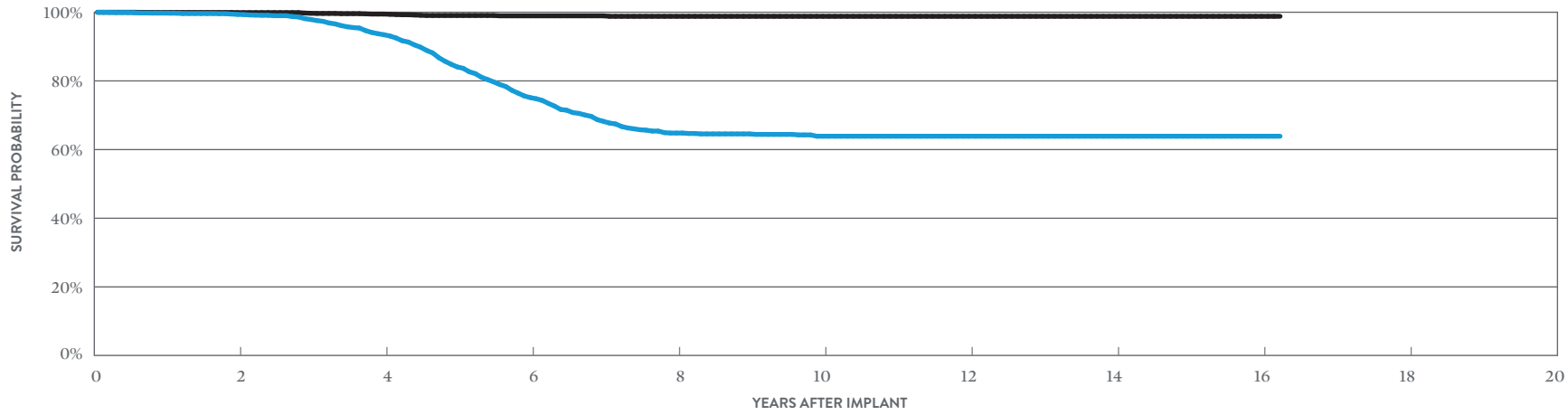
Cardiac Resynchronization Therapy (CRT) Pacemakers

Frontier™ II CRT-P

MODEL 5586

US Regulatory Approval	August 2004
Registered US Implants	6,911
Estimated Active US Implants	690
Estimated Longevity	6.5 Years
Normal Battery Depletion	381
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	7	0.10%
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%	0	0.00%
Possible Early Battery Depletion	0	0.00%	7	0.10%
Other	1	0.01%	3	0.04%
Total	**1**	**0.01%**	**17**	**0.25%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 195 MONTHS
SURVIVAL PROBABILITY	99.36%	93.45%	75.14%	64.81%	63.89%	63.89%	63.89%	63.89%	63.89%
± 1 STANDARD ERROR	0.10%	0.40%	0.79%	0.95%	0.97%	0.97%	0.97%	0.97%	0.97%
SAMPLE SIZE	4,960	3,380	2,100	1,230	880	770	700	330	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 195 MONTHS
SURVIVAL PROBABILITY	99.89%	99.47%	98.95%	98.81%	98.81%	98.81%	98.81%	98.81%	98.81%
± 1 STANDARD ERROR	0.03%	0.12%	0.18%	0.21%	0.21%	0.21%	0.21%	0.21%	0.21%

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%	99.82%	99.27%	98.65%						
PM3262	Allure Quadra MP™ CRT-P	99.93%	99.85%	99.65%	98.32%	94.10%	87.61%	86.97%			
PM3222	Allure™ RF CRT-P	99.97%	99.65%	99.02%	95.56%	89.46%	81.99%	81.51%	81.51%	81.22%	
PM3242	Allure Quadra™ RF CRT-P	99.90%	99.82%	99.56%	98.67%	95.14%	88.88%	87.79%	87.27%	87.07%	
PM3210	Anthem™ RF CRT-P	99.81%	99.72%	99.11%	97.02%	92.13%	91.79%	91.34%	91.18%	91.15%	91.05%
5586	Frontier™ II CRT-P	99.75%	99.36%	97.89%	93.45%	84.09%	75.14%	68.22%	64.81%	64.56%	63.89%

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%	99.82%	99.59%	99.47%						
PM3262	Allure Quadra MP™ CRT-P	99.94%	99.90%	99.85%	99.65%	98.82%	97.73%	97.42%			
PM3222	Allure™ RF CRT-P	99.97%	99.87%	99.72%	99.42%	98.58%	96.49%	96.30%	96.30%	96.30%	
PM3242	Allure Quadra™ RF CRT-P	99.92%	99.86%	99.80%	99.76%	99.66%	98.83%	98.55%	98.42%	98.35%	
PM3210	Anthem™ RF CRT-P	99.87%	99.83%	99.75%	99.68%	99.59%	99.57%	99.52%	99.52%	99.52%	99.48%
5586	Frontier™ II CRT-P	99.93%	99.89%	99.70%	99.47%	99.05%	98.95%	98.95%	98.81%	98.81%	98.81%

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	34,990	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%**
PM3262	Allure Quadra MP™ CRT-P	19,960	8.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	**4**	**0.02%**
PM3222	Allure™ RF CRT-P	13,493	8.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3242	Allure Quadra™ RF CRT-P	18,479	10.30%	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%**
5586	Frontier™ II CRT-P	6,911	20.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**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
PM3562	Allure Quadra MP™ CRT-P	34,990	2.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	30	0.09%	0	0.00%	0	0.00%	**30**	**0.09%**
PM3262	Allure Quadra MP™ CRT-P	19,960	8.40%	1	<0.01%	0	0.00%	0	0.00%	4	0.02%	98	0.49%	0	0.00%	1	<0.01%	**104**	**0.52%**
PM3222	Allure™ RF CRT-P	13,493	8.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	65	0.48%	0	0.00%	0	0.00%	**65**	**0.48%**
PM3242	Allure Quadra™ RF CRT-P	18,479	10.30%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	67	0.36%	0	0.00%	0	0.00%	**69**	**0.37%**
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%**
5586	Frontier™ II CRT-P	6,911	20.00%	7	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	3	0.04%	**17**	**0.25%**

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	80,541	1.09%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
PM3262	Allure Quadra MP™ CRT-P	36,619	4.64%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.02%	2	<0.01%	0	0.00%	**10**	**0.03%**
PM3222	Allure™ RF CRT-P	45,665	2.48%	2	<0.01%	2	<0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**6**	**0.01%**
PM3242	Allure Quadra™ RF CRT-P	37,636	5.26%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	8	0.02%	0	0.00%	0	0.00%	**10**	**0.03%**
PM3210	Anthem™ RF CRT-P	21,093	18.73%	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	80,541	1.09%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	60	0.07%	0	0.00%	4	<0.01%	**68**	**0.08%**
PM3262	Allure Quadra MP™ CRT-P	36,619	4.64%	0	0.00%	0	0.00%	0	0.00%	8	0.02%	190	0.52%	0	0.00%	2	<0.01%	**200**	**0.55%**
PM3222	Allure™ RF CRT-P	45,665	2.48%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	130	0.28%	0	0.00%	4	<0.01%	**136**	**0.30%**
PM3242	Allure Quadra™ RF CRT-P	37,636	5.26%	6	0.02%	0	0.00%	0	0.00%	0	0.00%	154	0.41%	2	<0.01%	2	<0.01%	**164**	**0.44%**
PM3210	Anthem™ RF CRT-P	21,093	18.73%	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

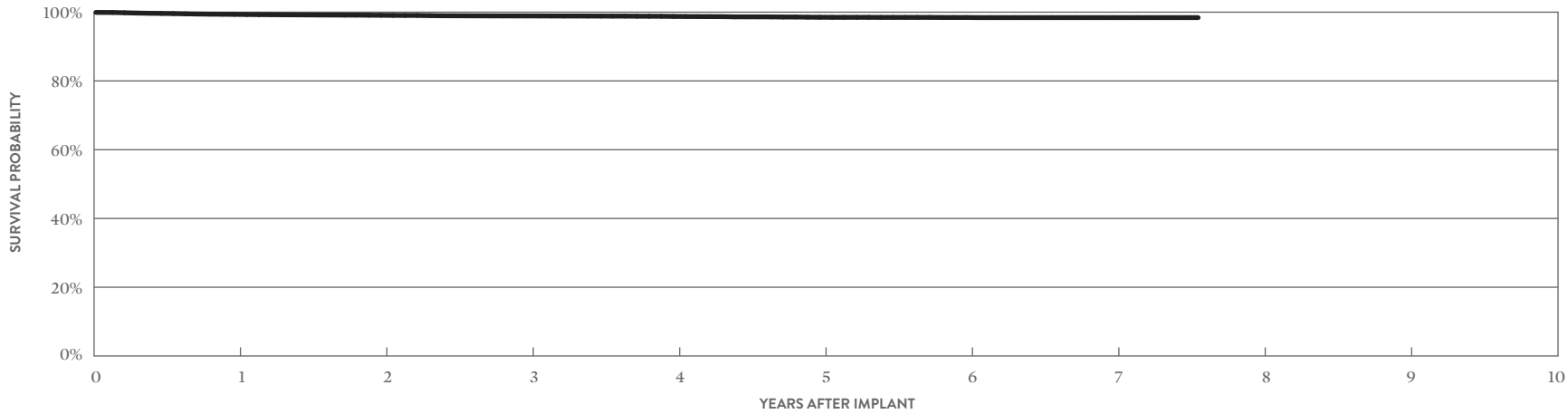
Quartet™

MODEL 1458QL

US Regulatory Approval	October 2015
Registered US Implants	20,567
Estimated Active US Implants	13,399
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	0.18%	136	0.66%
Failure to Capture	23	0.11%	66	0.32%
Oversensing	0	0.00%	2	<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%	20	0.10%
Extracardiac Stimulation	30	0.15%	40	0.19%
Other	6	0.03%	7	0.03%
Total	**104**	**0.51%**	**277**	**1.35%**
Total Returned for Analysis	**23**		**77**	

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	71	0.35%
Total	**72**	**0.35%**



YEAR	1	2	3	4	5	6	7	AT 91 MONTHS
SURVIVAL PROBABILITY	99.36%	99.10%	98.91%	98.76%	98.52%	98.45%	98.42%	98.42%
± 1 STANDARD ERROR	0.06%	0.07%	0.08%	0.09%	0.11%	0.12%	0.12%	0.12%
SAMPLE SIZE	18,480	14,840	11,840	9,130	6,550	4,230	2,190	220

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

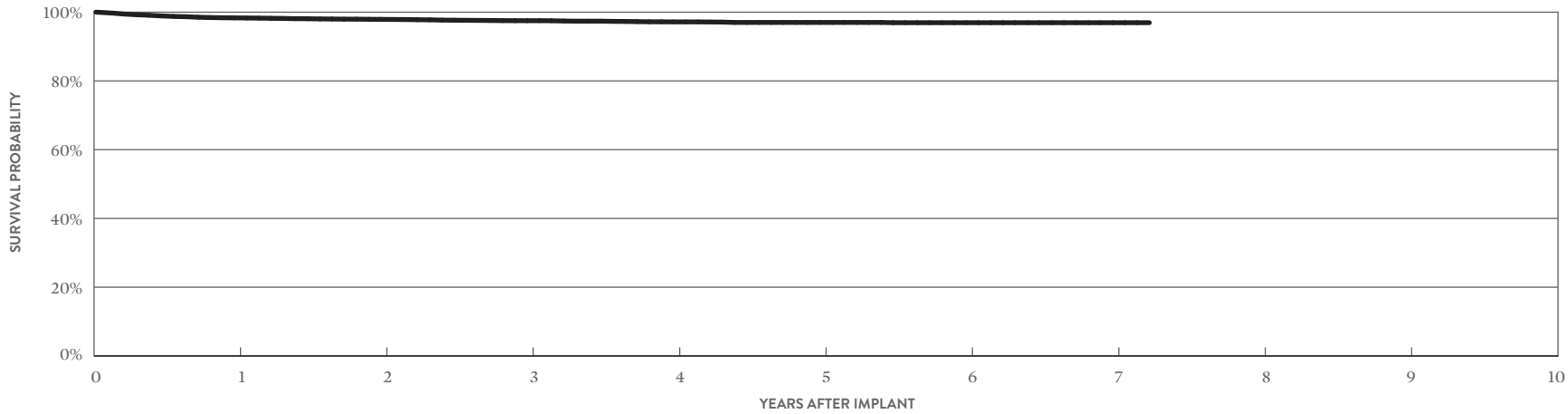
Quartet™

MODEL 1457Q

US Regulatory Approval	March 2017
Registered US Implants	12,756
Estimated Active US Implants	8,326
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%	0	0.00%
Conductor Fracture	1	<0.01%	0	0.00%
Lead Dislodgement	63	0.49%	194	1.52%
Failure to Capture	14	0.11%	59	0.46%
Oversensing	1	<0.01%	2	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	0.04%
Extracardiac Stimulation	17	0.13%	18	0.14%
Other	7	0.05%	6	0.05%
Total	**103**	**0.81%**	**287**	**2.25%**
Total Returned for Analysis	**30**		**115**	

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	117	0.92%
Total	**117**	**0.92%**



YEAR	1	2	3	4	5	6	7	AT 87 MONTHS
SURVIVAL PROBABILITY	98.34%	97.91%	97.52%	97.17%	97.01%	96.94%	96.94%	96.94%
± 1 STANDARD ERROR	0.12%	0.14%	0.16%	0.18%	0.20%	0.21%	0.21%	0.21%
SAMPLE SIZE	11,000	8,110	6,010	4,230	2,720	1,460	570	220

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

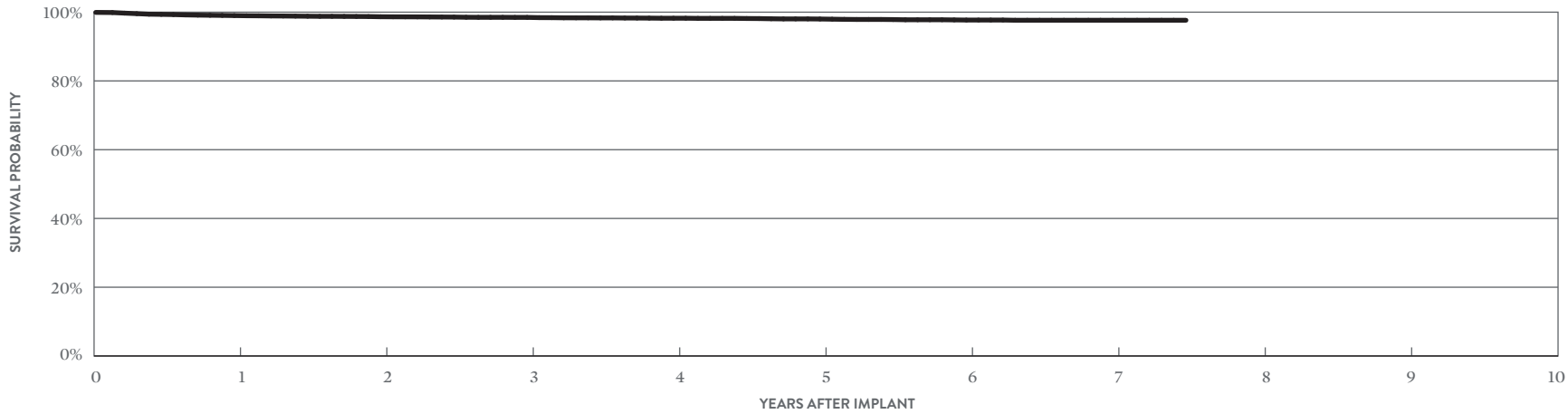
Quartet™

MODEL 1456Q

US Regulatory Approval	October 2015
Registered US Implants	17,034
Estimated Active US Implants	11,291
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	2	0.01%	1	<0.01%
Conductor Fracture	2	0.01%	1	<0.01%
Lead Dislodgement	47	0.28%	168	0.99%
Failure to Capture	15	0.09%	69	0.41%
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%	5	0.03%
Extracardiac Stimulation	17	0.10%	23	0.14%
Other	6	0.04%	4	0.02%
Total	**95**	**0.56%**	**273**	**1.60%**
Total Returned for Analysis	**29**		**117**	

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	5	0.03%
Extrinsic Factors	113	0.66%
Total	**120**	**0.70%**



YEAR	1	2	3	4	5	6	7	AT 90 MONTHS
SURVIVAL PROBABILITY	99.01%	98.67%	98.48%	98.24%	98.01%	97.71%	97.65%	97.65%
± 1 STANDARD ERROR	0.08%	0.09%	0.11%	0.12%	0.14%	0.16%	0.18%	0.18%
SAMPLE SIZE	15,020	11,600	9,000	6,840	4,920	3,120	1,540	250

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

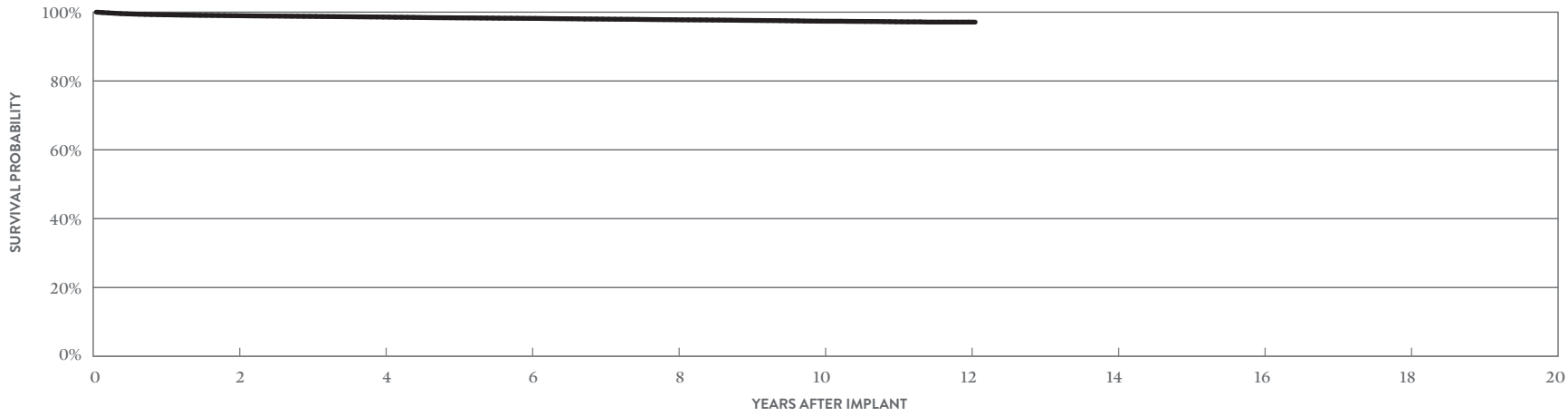
Quartet™

MODEL 1458Q

US Regulatory Approval	November 2011
Registered US Implants	199,758
Estimated Active US Implants	101,616
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%	5	<0.01%
Conductor Fracture	0	0.00%	53	0.03%
Lead Dislodgement	339	0.17%	1644	0.82%
Failure to Capture	155	0.08%	917	0.46%
Oversensing	4	<0.01%	40	0.02%
Failure to Sense	0	0.00%	2	<0.01%
Insulation Breach	2	<0.01%	24	0.01%
Abnormal Pacing Impedance	7	<0.01%	198	0.10%
Extracardiac Stimulation	126	0.06%	275	0.14%
Other	123	0.06%	95	0.05%
Total	**764**	**0.38%**	**3253**	**1.63%**
Total Returned for Analysis	**270**		**1073**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	14	<0.01%
Clavicular Crush	2	<0.01%
In the Pocket	4	<0.01%
Intravascular	8	<0.01%
Insulation Breach	3	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	2	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	15	<0.01%
Extrinsic Factors	1031	0.52%
Total	**1074**	**0.54%**



YEAR	2	4	6	8	10	12	AT 145 MONTHS
SURVIVAL PROBABILITY	98.97%	98.58%	98.19%	97.79%	97.37%	97.11%	97.11%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.04%	0.06%	0.09%	0.09%
SAMPLE SIZE	151,910	113,140	82,570	53,210	20,750	3,000	230

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

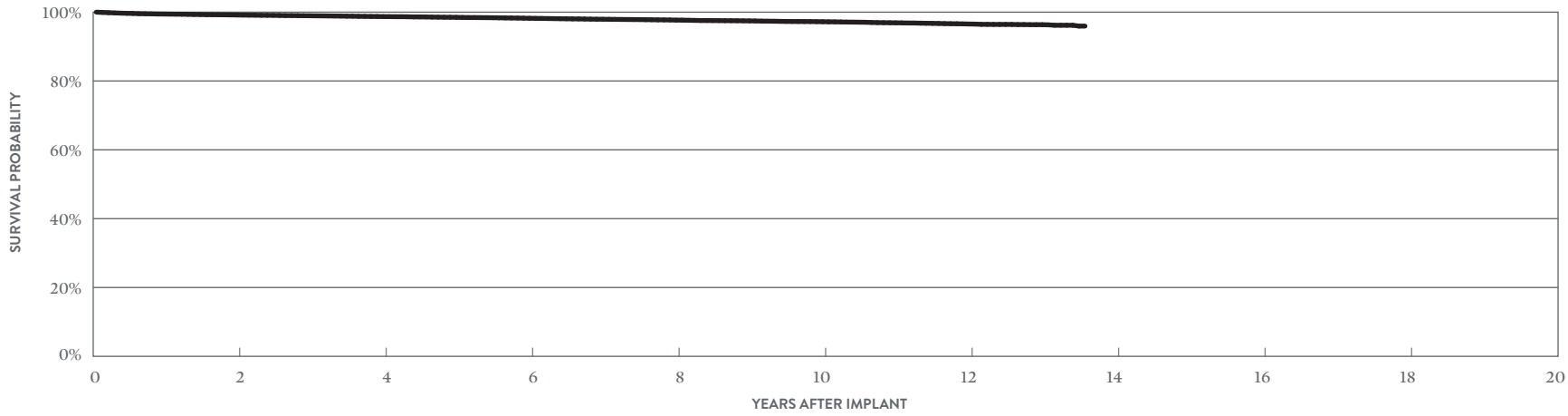
QuickFlex™ µ

MODEL 1258T

US Regulatory Approval	May 2010
Registered US Implants	51,335
Estimated Active US Implants	19,183
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%	53	0.10%
Lead Dislodgement	68	0.13%	317	0.62%
Failure to Capture	30	0.06%	476	0.93%
Oversensing	0	0.00%	32	0.06%
Failure to Sense	1	<0.01%	3	<0.01%
Insulation Breach	0	0.00%	21	0.04%
Abnormal Pacing Impedance	5	<0.01%	116	0.23%
Extracardiac Stimulation	40	0.08%	170	0.33%
Other	16	0.03%	26	0.05%
Total	**160**	**0.31%**	**1215**	**2.37%**
Total Returned for Analysis	**71**		**304**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	12	0.02%
Clavicular Crush	4	<0.01%
In the Pocket	3	<0.01%
Intravascular	5	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	302	0.59%
Total	**323**	**0.63%**



YEAR	2	4	6	8	10	12	AT 163 MONTHS
SURVIVAL PROBABILITY	99.18%	98.71%	98.22%	97.69%	97.22%	96.55%	95.95%
± 1 STANDARD ERROR	0.04%	0.05%	0.07%	0.08%	0.09%	0.12%	0.29%
SAMPLE SIZE	41,280	33,550	27,910	23,390	17,770	9,480	290

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

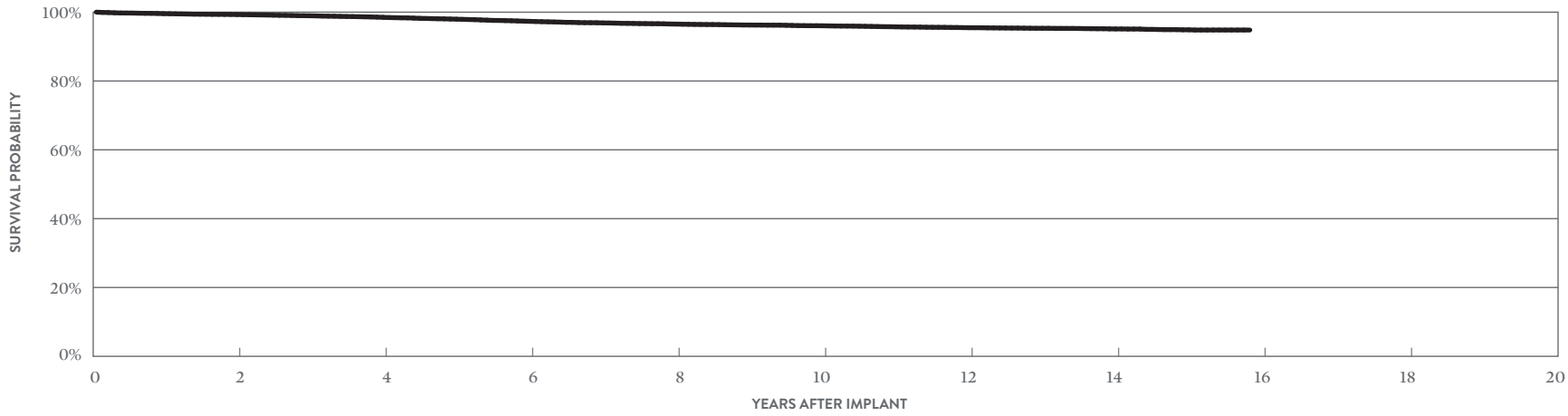
QuickFlex™

MODEL 1156T

US Regulatory Approval	July 2007
Registered US Implants	28,630
Estimated Active US Implants	7,601
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 222)	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	11	0.04%	148	0.52%
Failure to Capture	5	0.02%	262	0.92%
Oversensing	0	0.00%	20	0.07%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	55	0.19%
Abnormal Pacing Impedance	1	<0.01%	71	0.25%
Extracardiac Stimulation	14	0.05%	99	0.35%
Other	9	0.03%	13	0.05%
Total	**40**	**0.14%**	**680**	**2.38%**
Total Returned for Analysis	**14**		**179**	

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	7	0.02%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	1	<0.01%
Other	5	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	157	0.55%
Total	**267**	**0.93%**



YEAR	2	4	6	8	10	12	14	AT 190 MONTHS
SURVIVAL PROBABILITY	99.30%	98.49%	97.33%	96.53%	96.04%	95.48%	95.12%	94.81%
± 1 STANDARD ERROR	0.05%	0.08%	0.12%	0.14%	0.16%	0.17%	0.19%	0.22%
SAMPLE SIZE	22,080	17,230	13,880	11,710	10,280	8,960	5,500	270

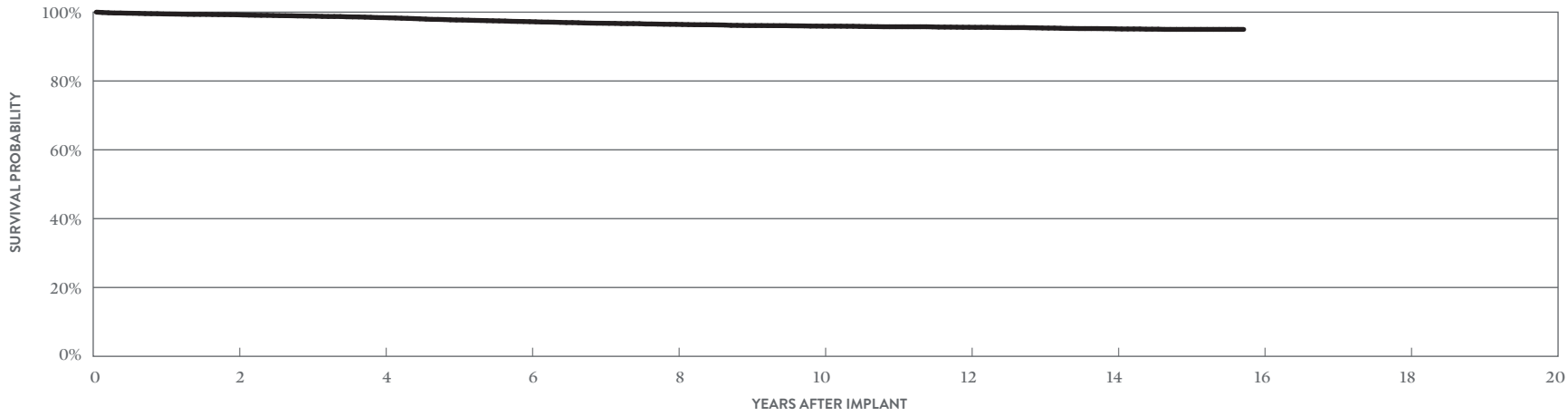
QuickFlex™ XL

MODEL 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,884
Estimated Active US Implants	4,313
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 222)	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	9	0.06%	103	0.65%
Failure to Capture	2	0.01%	165	1.04%
Oversensing	0	0.00%	5	0.03%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	0	0.00%	35	0.22%
Abnormal Pacing Impedance	2	0.01%	29	0.18%
Extracardiac Stimulation	6	0.04%	35	0.22%
Other	6	0.04%	11	0.07%
Total	**25**	**0.16%**	**392**	**2.47%**
Total Returned for Analysis	**13**		**132**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	5	0.03%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	4	0.03%
Insulation Breach	1	<0.01%
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	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	99	0.62%
Total	**168**	**1.06%**



YEAR	2	4	6	8	10	12	14	AT 189 MONTHS
SURVIVAL PROBABILITY	99.24%	98.40%	97.24%	96.46%	95.93%	95.61%	95.15%	94.99%
± 1 STANDARD ERROR	0.07%	0.12%	0.16%	0.19%	0.21%	0.22%	0.25%	0.27%
SAMPLE SIZE	12,300	9,690	7,870	6,640	5,790	5,070	2,970	270

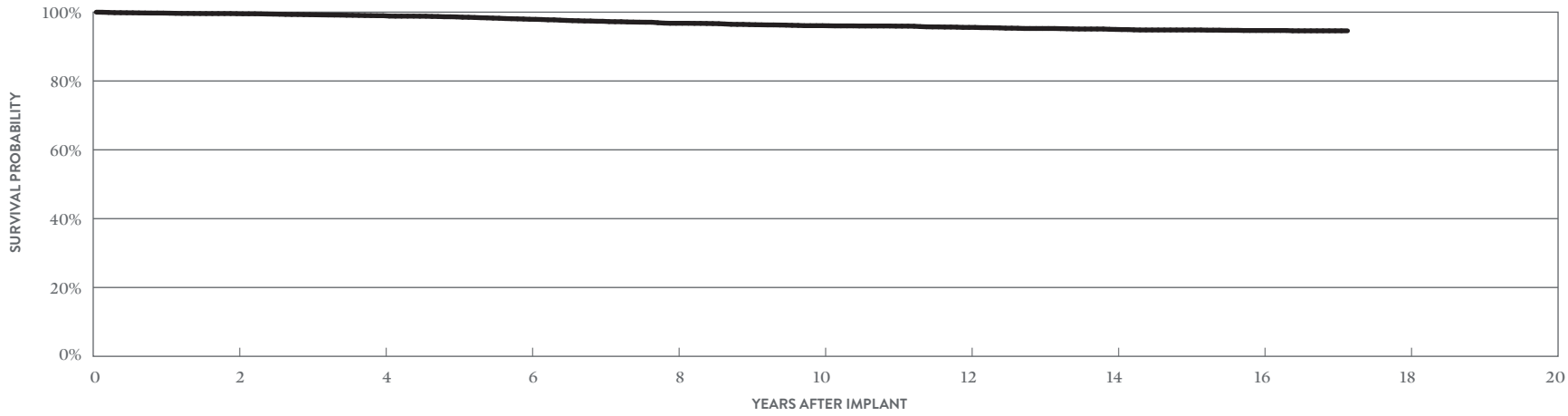
QuickSite™ XL

MODEL 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,049
Estimated Active US Implants	2,204
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 222)	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%	8	0.08%
Lead Dislodgement	10	0.10%	36	0.36%
Failure to Capture	3	0.03%	101	1.01%
Oversensing	1	<0.01%	4	0.04%
Failure to Sense	0	0.00%	2	0.02%
Insulation Breach	0	0.00%	32	0.32%
Abnormal Pacing Impedance	2	0.02%	22	0.22%
Extracardiac Stimulation	9	0.09%	25	0.25%
Other	1	<0.01%	6	0.06%
Total	**26**	**0.26%**	**237**	**2.36%**
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	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	1	<0.01%
Extrinsic Factors	32	0.32%
Total	**61**	**0.61%**



YEAR	2	4	6	8	10	12	14	16	AT 206 MONTHS
SURVIVAL PROBABILITY	99.56%	98.97%	97.93%	96.77%	96.07%	95.57%	94.98%	94.67%	94.58%
± 1 STANDARD ERROR	0.07%	0.12%	0.19%	0.25%	0.29%	0.32%	0.35%	0.37%	0.38%
SAMPLE SIZE	7,720	5,780	4,480	3,640	3,110	2,800	2,490	1,810	230

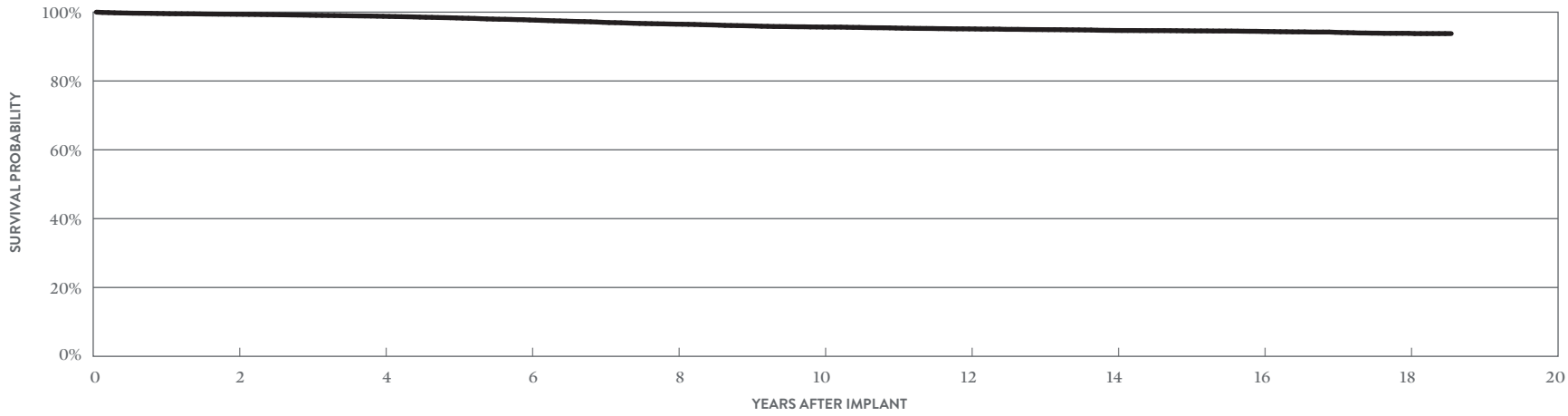
QuickSite™

MODEL 1056T

US Regulatory Approval	April 2005
Registered US Implants	32,639
Estimated Active US Implants	6,388
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 222)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	13	0.04%
Lead Dislodgement	32	0.10%	176	0.54%
Failure to Capture	15	0.05%	302	0.93%
Oversensing	2	<0.01%	28	0.09%
Failure to Sense	0	0.00%	2	<0.01%
Insulation Breach	1	<0.01%	114	0.35%
Abnormal Pacing Impedance	3	<0.01%	69	0.21%
Extracardiac Stimulation	22	0.07%	112	0.34%
Other	9	0.03%	30	0.09%
Total	**84**	**0.26%**	**846**	**2.59%**
Total Returned for Analysis	**28**		**222**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	6	0.02%
Clavicular Crush	0	0.00%
In the Pocket	2	<0.01%
Intravascular	4	0.01%
Insulation Breach	5	0.02%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	4	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	169	0.52%
Total	**274**	**0.84%**



YEAR	2	4	6	8	10	12	14	16	18	AT 223 MONTHS
SURVIVAL PROBABILITY	99.38%	98.80%	97.72%	96.51%	95.67%	95.13%	94.68%	94.40%	93.85%	93.77%
± 1 STANDARD ERROR	0.05%	0.07%	0.11%	0.15%	0.17%	0.19%	0.20%	0.21%	0.25%	0.26%
SAMPLE SIZE	25,200	18,880	14,100	11,150	9,270	8,240	7,370	5,880	2,180	240

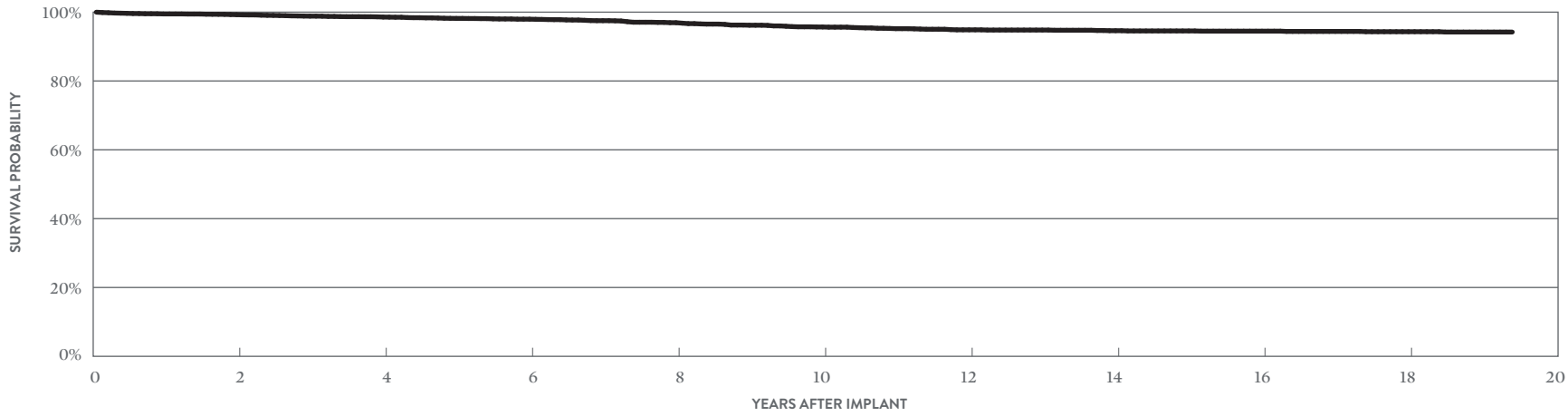
QuickSite™

MODEL 1056K

US Regulatory Approval	June 2004
Registered US Implants	7,874
Estimated Active US Implants	1,299
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
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%	0	0.00%
Conductor Fracture	0	0.00%	8	0.10%
Lead Dislodgement	10	0.13%	36	0.46%
Failure to Capture	3	0.04%	78	0.99%
Oversensing	0	0.00%	2	0.03%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	6	0.08%
Abnormal Pacing Impedance	0	0.00%	9	0.11%
Extracardiac Stimulation	10	0.13%	32	0.41%
Other	2	0.03%	12	0.15%
Total	**25**	**0.32%**	**183**	**2.32%**
Total Returned for Analysis	**13**		**52**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	3	0.04%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	3	0.04%
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	53	0.67%
Total	**59**	**0.75%**



YEAR	2	4	6	8	10	12	14	16	18	AT 233 MONTHS
SURVIVAL PROBABILITY	99.26%	98.57%	97.96%	96.94%	95.69%	94.86%	94.61%	94.48%	94.32%	94.22%
± 1 STANDARD ERROR	0.10%	0.15%	0.20%	0.28%	0.37%	0.43%	0.44%	0.45%	0.46%	0.47%
SAMPLE SIZE	6,050	4,420	3,160	2,340	1,900	1,650	1,510	1,350	1,080	260

SUMMARY INFORMATION

Left-Heart Leads

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%	99.10%	98.91%	98.76%	98.52%	98.45%	98.42%			
1457Q	QuickFlex™ µ	98.34%	97.91%	97.52%	97.17%	97.01%	96.94%	96.94%			
1456Q	QuickFlex™ µ	99.01%	98.67%	98.48%	98.24%	98.01%	97.71%	97.65%			
1458Q	Quartet™	99.24%	98.97%	98.78%	98.58%	98.35%	98.19%	97.98%	97.79%	97.61%	97.37%
1258T	QuickFlex™ µ	99.45%	99.18%	98.95%	98.71%	98.49%	98.22%	97.94%	97.69%	97.46%	97.22%
1156T	QuickFlex™	99.56%	99.30%	98.95%	98.49%	97.96%	97.33%	96.87%	96.53%	96.26%	96.04%
1158T	QuickFlex™ XL	99.48%	99.24%	98.85%	98.40%	97.72%	97.24%	96.78%	96.46%	96.10%	95.93%
1058T	QuickSite™ XL	99.73%	99.56%	99.26%	98.97%	98.62%	97.93%	97.35%	96.77%	96.38%	96.07%
1056T	QuickSite™	99.59%	99.38%	99.11%	98.80%	98.32%	97.72%	97.05%	96.51%	96.02%	95.67%
1056K	QuickSite™	99.48%	99.26%	98.84%	98.57%	98.18%	97.96%	97.52%	96.94%	96.20%	95.69%

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	20,567	13,399	1	<0.01%	0	0.00%	37	0.18%	23	0.11%	0	0.00%	0	0.00%	2	<0.01%	5	0.02%	30	0.15%	6	0.03%	**104**	**0.51%**	**23**
1457Q	Oct-15	12,756	8,326	0	0.00%	1	<0.01%	63	0.49%	14	0.11%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	17	0.13%	7	0.05%	**103**	**0.81%**	**30**
1456Q	Oct-15	17,034	11,291	2	0.01%	2	0.01%	47	0.28%	15	0.09%	1	<0.01%	0	0.00%	1	<0.01%	4	0.02%	17	0.10%	6	0.04%	**95**	**0.56%**	**29**
1458Q	Nov-11	199,758	101,616	8	<0.01%	0	0.00%	339	0.17%	155	0.08%	4	<0.01%	0	0.00%	2	<0.01%	7	<0.01%	126	0.06%	123	0.06%	**764**	**0.38%**	**270**
1258T	May-10	51,335	19,183	0	0.00%	0	0.00%	68	0.13%	30	0.06%	0	0.00%	1	<0.01%	0	0.00%	5	<0.01%	40	0.08%	16	0.03%	**160**	**0.31%**	**71**
1156T	Jul-07	28,630	7,601	0	0.00%	0	0.00%	11	0.04%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	14	0.05%	9	0.03%	**40**	**0.14%**	**14**
1158T	Jul-07	15,884	4,313	0	0.00%	0	0.00%	9	0.06%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	6	0.04%	6	0.04%	**25**	**0.16%**	**13**
1058T	Feb-06	10,049	2,204	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**	**0.26%**	**11**
1056T	Apr-05	32,639	6,388	0	0.00%	0	0.00%	32	0.10%	15	0.05%	2	<0.01%	0	0.00%	1	<0.01%	3	<0.01%	22	0.07%	9	0.03%	**84**	**0.26%**	**28**
1056K	Jun-04	7,874	1,299	0	0.00%	0	0.00%	10	0.13%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	10	0.13%	2	0.03%	**25**	**0.32%**	**13**

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	20,567	13,399	1	<0.01%	3	0.01%	136	0.66%	66	0.32%	2	<0.01%	0	0.00%	2	<0.01%	20	0.10%	40	0.19%	7	0.03%	**277**	**1.35%**	**77**
1457Q	Oct-15	12,756	8,326	0	0.00%	0	0.00%	194	1.52%	59	0.46%	2	0.02%	0	0.00%	3	0.02%	5	0.04%	18	0.14%	6	0.05%	**287**	**2.25%**	**115**
1456Q	Oct-15	17,034	11,291	1	<0.01%	1	<0.01%	168	0.99%	69	0.41%	2	0.01%	0	0.00%	0	0.00%	5	0.03%	23	0.14%	4	0.02%	**273**	**1.60%**	**117**
1458Q	Nov-11	199,758	101,616	5	<0.01%	53	0.03%	1644	0.82%	917	0.46%	40	0.02%	2	<0.01%	24	0.01%	198	0.10%	275	0.14%	95	0.05%	**3253**	**1.63%**	**1073**
1258T	May-10	51,335	19,183	1	<0.01%	53	0.10%	317	0.62%	476	0.93%	32	0.06%	3	<0.01%	21	0.04%	116	0.23%	170	0.33%	26	0.05%	**1215**	**2.37%**	**304**
1156T	Jul-07	28,630	7,601	1	<0.01%	11	0.04%	148	0.52%	262	0.92%	20	0.07%	0	0.00%	55	0.19%	71	0.25%	99	0.35%	13	0.05%	**680**	**2.38%**	**179**
1158T	Jul-07	15,884	4,313	2	0.01%	6	0.04%	103	0.65%	165	1.04%	5	0.03%	1	<0.01%	35	0.22%	29	0.18%	35	0.22%	11	0.07%	**392**	**2.47%**	**132**
1058T	Feb-06	10,049	2,204	1	<0.01%	8	0.08%	36	0.36%	101	1.01%	4	0.04%	2	0.02%	32	0.32%	22	0.22%	25	0.25%	6	0.06%	**237**	**2.36%**	**43**
1056T	Apr-05	32,639	6,388	0	0.00%	13	0.04%	176	0.54%	302	0.93%	28	0.09%	2	<0.01%	114	0.35%	69	0.21%	112	0.34%	30	0.09%	**846**	**2.59%**	**222**
1056K	Jun-04	7,874	1,299	0	0.00%	8	0.10%	36	0.46%	78	0.99%	2	0.03%	0	0.00%	6	0.08%	9	0.11%	32	0.41%	12	0.15%	**183**	**2.32%**	**52**

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	20,567	5.50%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	71	0.35%	**72**	**0.35%**
1457Q	12,756	6.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	117	0.92%	**117**	**0.92%**
1456Q	17,034	9.30%	0	0.00%	0	0.00%	0	0.00%	5	0.03%	113	0.66%	**118**	**0.69%**
1458Q	199,758	7.70%	14	<0.01%	3	<0.01%	0	0.00%	15	<0.01%	1031	0.52%	**1063**	**0.53%**
1258T	51,335	13.20%	12	0.02%	2	<0.01%	0	0.00%	1	<0.01%	302	0.59%	**317**	**0.62%**
1156T	28,630	10.20%	7	0.02%	7	0.02%	0	0.00%	0	0.00%	157	0.55%	**171**	**0.60%**
1158T	15,884	11.20%	5	0.03%	1	<0.01%	1	<0.01%	0	0.00%	99	0.62%	**106**	**0.67%**
1058T	10,049	10.80%	2	0.02%	0	0.00%	0	0.00%	1	<0.01%	32	0.32%	**35**	**0.35%**
1056T	32,639	10.30%	6	0.02%	5	0.02%	0	0.00%	1	<0.01%	169	0.52%	**181**	**0.55%**
1056K	7,874	15.90%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	53	0.67%	**56**	**0.71%**

Definitions of malfunction categories can be found on pages 8-9.

Left-Heart Leads

Worldwide Malfunction Summary

MODELS	WORLWIDE 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	45,963	2.46%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	88	0.19%	**90**	**0.20%**
1457Q	34,162	2.58%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	133	0.39%	**133**	**0.39%**
1456Q	50,911	3.10%	0	0.00%	3	0.01%	0	0.00%	9	0.02%	147	0.29%	**159**	**0.31%**
1458Q	448,290	3.62%	39	0.01%	24	0.01%	0	0.00%	32	0.01%	1438	0.32%	**1533**	**0.34%**
1258T	199,584	3.93%	53	0.03%	15	0.01%	0	0.00%	5	<0.01%	462	0.23%	**535**	**0.27%**

Definitions of malfunction categories can be found on pages 8-9.

DUAL-CHAMBER

Implantable Cardioverter Defibrillator (ICD) Devices

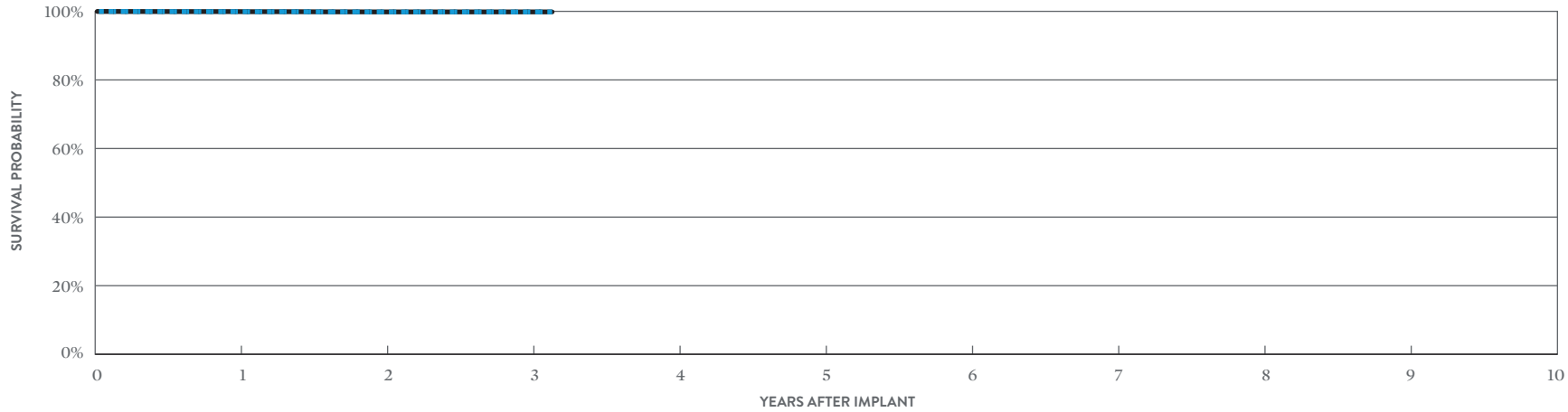
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Gallant™ DR

MODEL CDDRA500Q*

US Regulatory Approval	June 2020
Registered US Implants	29,048
Estimated Active US Implants	24,352
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories (see page 204)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	6	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%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	<0.01%
Total	**0**	**0.00%**	**9**	**0.04%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 38 MONTHS
SURVIVAL PROBABILITY	99.92%	99.83%	99.83%	99.83%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%
SAMPLE SIZE	22,740	11,580	3,610	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 38 MONTHS
SURVIVAL PROBABILITY	99.93%	99.84%	99.84%	99.84%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%

**DF4-LLHH connector type.*

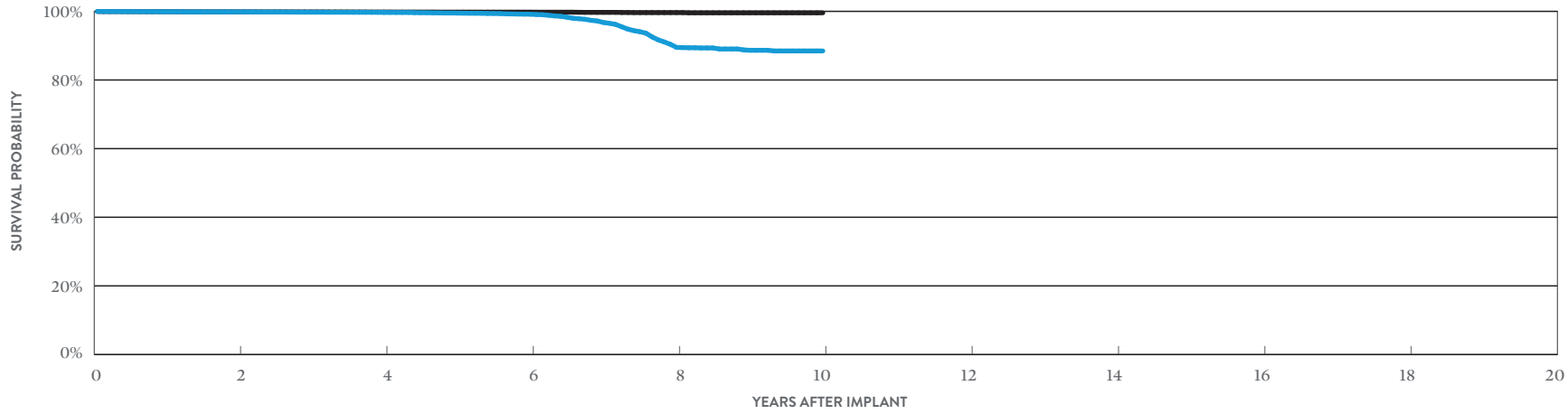
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	33,978
Estimated Active US Implants	17,686
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	266
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 205, 206, 208)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	<0.01%	12	0.04%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	2	<0.01%	2	<0.01%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	1	<0.01%	4	0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	2	<0.01%	6	0.02%
Total	**10**	**0.03%**	**25**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10
SURVIVAL PROBABILITY	99.85%	99.68%	99.16%	89.49%	88.46%
± 1 STANDARD ERROR	0.02%	0.03%	0.07%	0.38%	0.46%
SAMPLE SIZE	27,390	19,470	11,560	5,040	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10
SURVIVAL PROBABILITY	99.86%	99.80%	99.77%	99.63%	99.57%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.06%	0.07%

**DF4-LLHH connector type.*

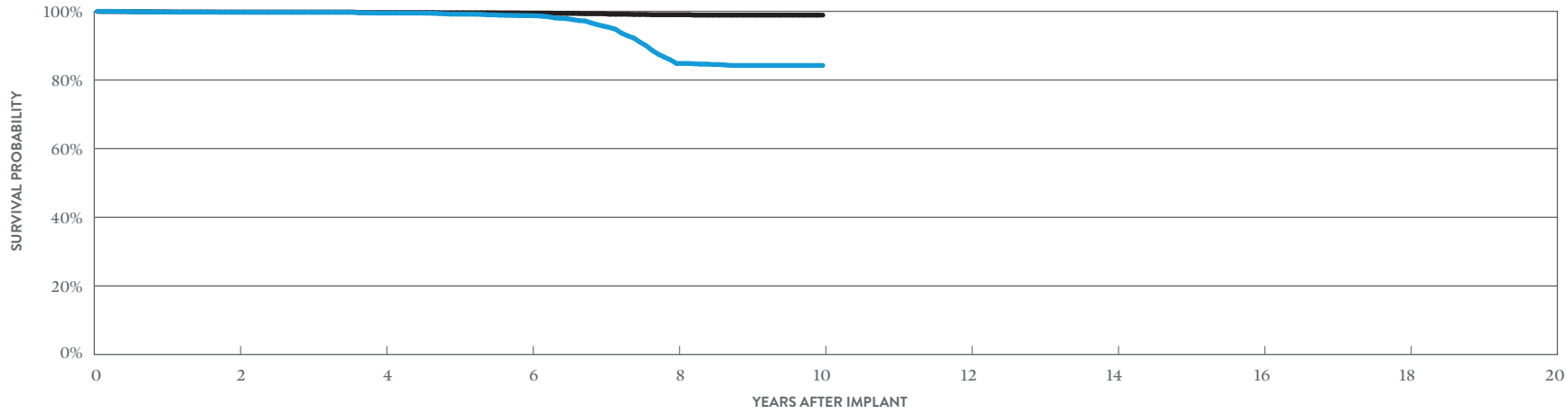
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2411-36C*

US Regulatory Approval	June 2013
Registered US Implants	12,267
Estimated Active US Implants	5,693
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	193
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 205, 206, 208)	Four

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.02%	8	0.07%
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%**	**17**	**0.14%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10
SURVIVAL PROBABILITY	99.74%	99.50%	98.74%	84.81%	84.23%
± 1 STANDARD ERROR	0.05%	0.08%	0.14%	0.61%	0.66%
SAMPLE SIZE	9,600	7,220	5,390	2,740	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10
SURVIVAL PROBABILITY	99.78%	99.63%	99.49%	99.01%	98.90%
± 1 STANDARD ERROR	0.05%	0.06%	0.08%	0.14%	0.16%

**Parylene coating.*

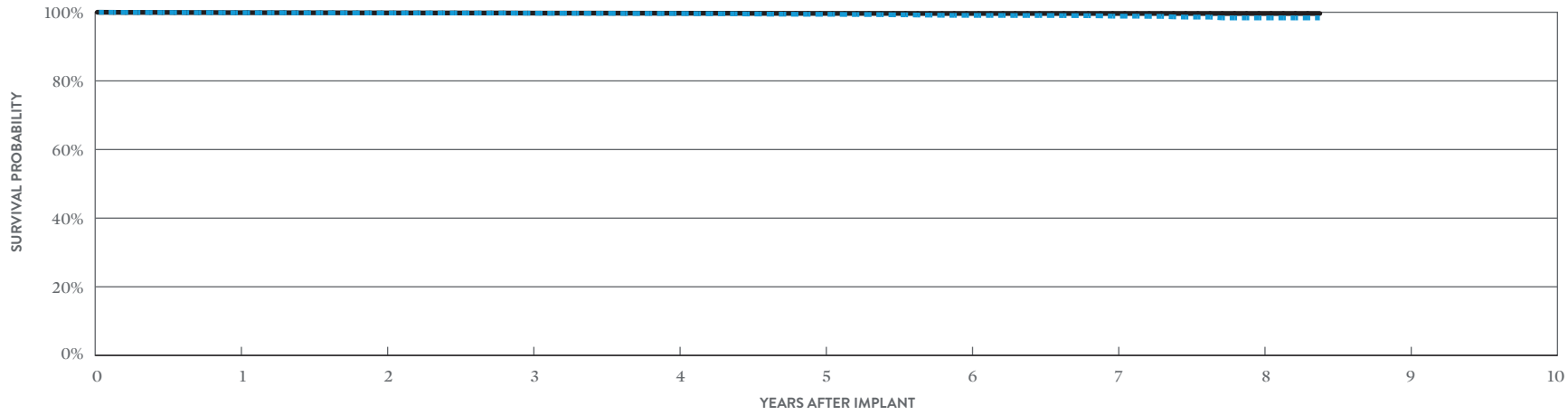
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

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

US Regulatory Approval	June 2013
Registered US Implants	43,189
Estimated Active US Implants	25,468
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	49
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	<0.01%	16	0.04%
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%	3	<0.01%
Other	7	0.02%	4	<0.01%
Total	**15**	**0.03%**	**31**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.86%	99.79%	99.74%	99.64%	99.40%	99.10%	98.86%	98.35%	98.35%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.05%	0.07%	0.09%	0.17%	0.17%
SAMPLE SIZE	40,270	34,880	29,620	23,480	17,150	11,730	7,070	2,980	290

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.88%	99.82%	99.76%	99.72%	99.67%	99.65%	99.65%	99.65%	99.65%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%

**DF4-LLHH connector type.*

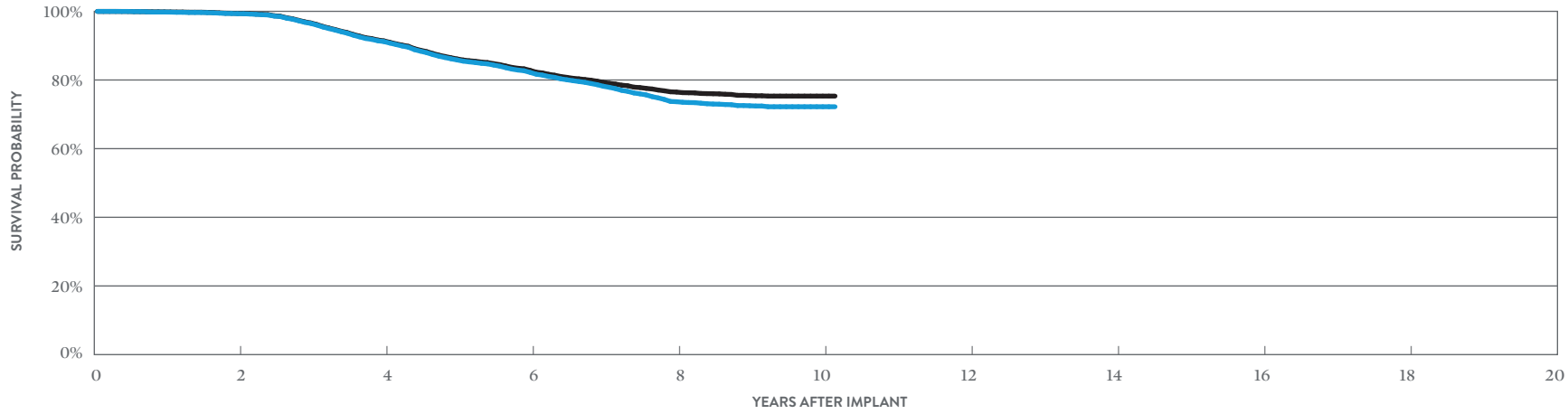
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	12,263
Estimated Active US Implants	4,104
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	90
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	19	0.15%
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	73	0.60%	673	5.49%
Other	1	<0.01%	6	0.05%
Total	**78**	**0.64%**	**709**	**5.78%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 122 MONTHS
SURVIVAL PROBABILITY	99.32%	91.19%	82.20%	73.67%	72.21%	72.21%
± 1 STANDARD ERROR	0.08%	0.30%	0.41%	0.50%	0.52%	0.52%
SAMPLE SIZE	10,150	8,140	6,630	5,150	1,280	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 122 MONTHS
SURVIVAL PROBABILITY	99.40%	91.40%	82.79%	76.48%	75.31%	75.31%
± 1 STANDARD ERROR	0.07%	0.29%	0.41%	0.48%	0.50%	0.50%

**DF4-LLHH connector type.*

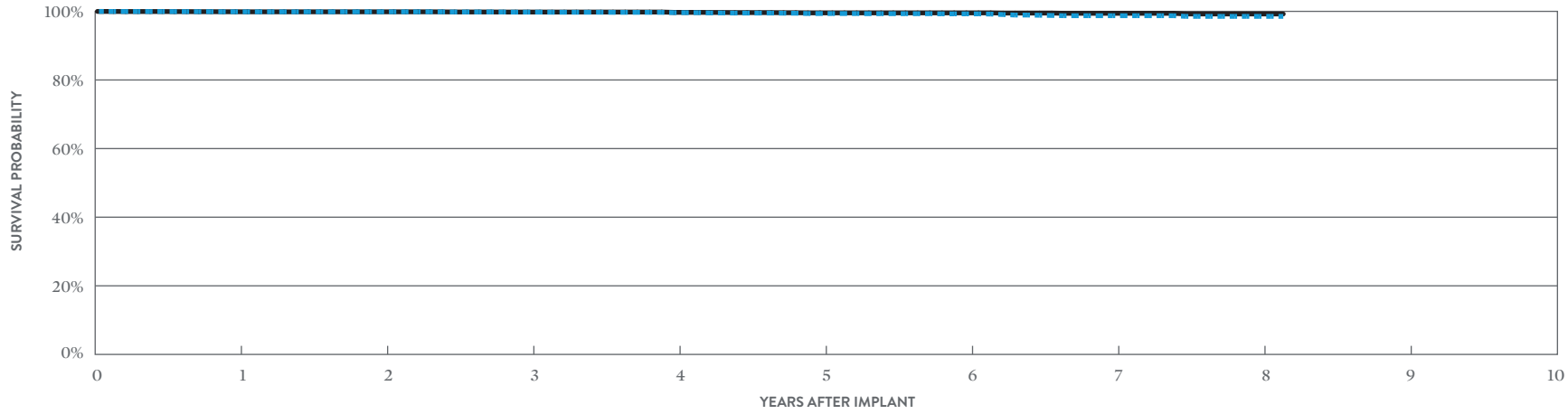
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

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

US Regulatory Approval	June 2013
Registered US Implants	12,313
Estimated Active US Implants	7,051
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	13
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.02%	7	0.06%
Electrical Interconnect	0	0.00%	1	<0.01%
Battery	0	0.00%	1	<0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	2	0.02%
Mechanical	0	0.00%	2	0.02%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	2	0.02%
Total	**3**	**0.02%**	**16**	**0.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.89%	99.87%	99.77%	99.62%	99.36%	99.27%	98.73%	98.54%	98.54%
± 1 STANDARD ERROR	0.03%	0.03%	0.05%	0.06%	0.10%	0.11%	0.17%	0.21%	0.21%
SAMPLE SIZE	11,250	9,360	7,800	6,450	5,350	4,320	2,920	1,180	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.89%	99.87%	99.80%	99.71%	99.56%	99.56%	99.43%	99.24%	99.24%
± 1 STANDARD ERROR	0.03%	0.03%	0.05%	0.05%	0.08%	0.08%	0.10%	0.17%	0.17%

**Parylene coating.*

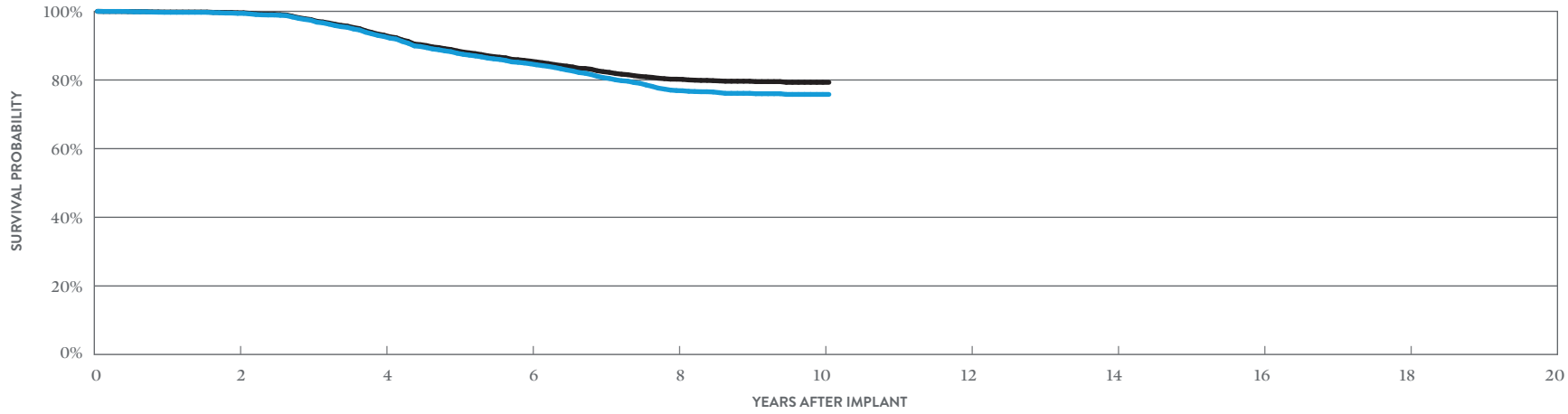
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	6,956
Estimated Active US Implants	2,355
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	60
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.04%	2	0.03%
Electrical Interconnect	2	0.03%	1	0.01%
Battery	1	0.01%	6	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	33	0.47%	309	4.44%
Other	2	0.03%	2	0.03%
Total	**41**	**0.59%**	**320**	**4.60%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 121 MONTHS
SURVIVAL PROBABILITY	99.41%	92.67%	84.72%	76.92%	75.80%	75.80%
± 1 STANDARD ERROR	0.09%	0.36%	0.52%	0.64%	0.68%	0.68%
SAMPLE SIZE	5,740	4,570	3,720	2,870	820	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 121 MONTHS
SURVIVAL PROBABILITY	99.58%	93.06%	85.51%	80.24%	79.31%	79.31%
± 1 STANDARD ERROR	0.07%	0.35%	0.51%	0.60%	0.64%	0.64%

**Parylene coating.*

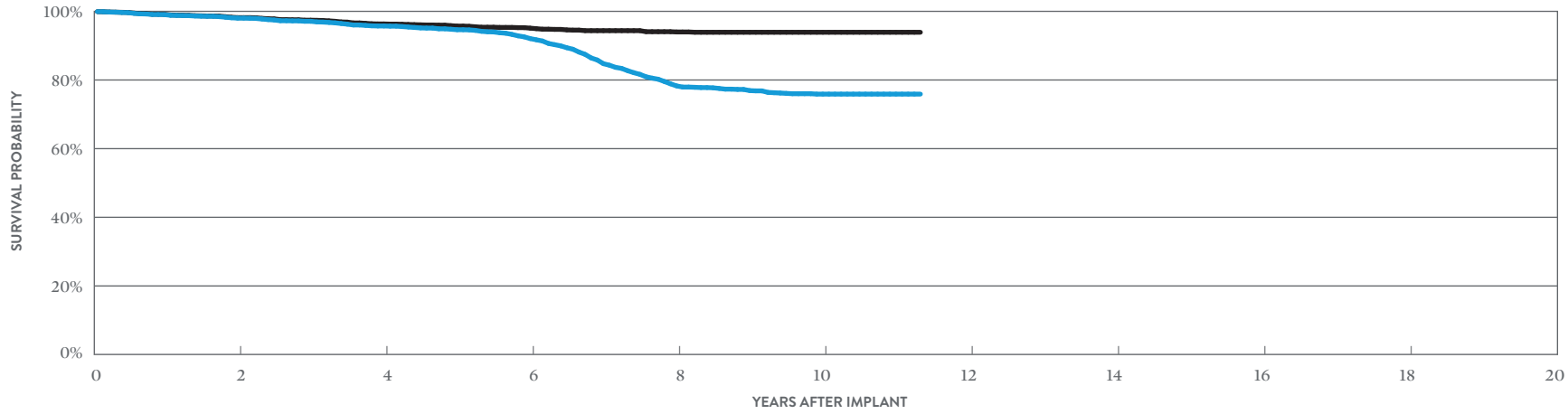
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	5,900
Estimated Active US Implants	1,347
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	234
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 206, 208)	Two

	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	AT 136 MONTHS
SURVIVAL PROBABILITY	98.02%	95.73%	92.06%	78.28%	75.89%	75.89%
± 1 STANDARD ERROR	0.19%	0.29%	0.41%	0.69%	0.75%	0.75%
SAMPLE SIZE	4,940	4,060	3,380	2,550	1,550	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	98.17%	96.33%	95.10%	93.99%	93.90%	93.90%
± 1 STANDARD ERROR	0.18%	0.27%	0.32%	0.37%	0.38%	0.38%

**DF4-LLHH connector type.*

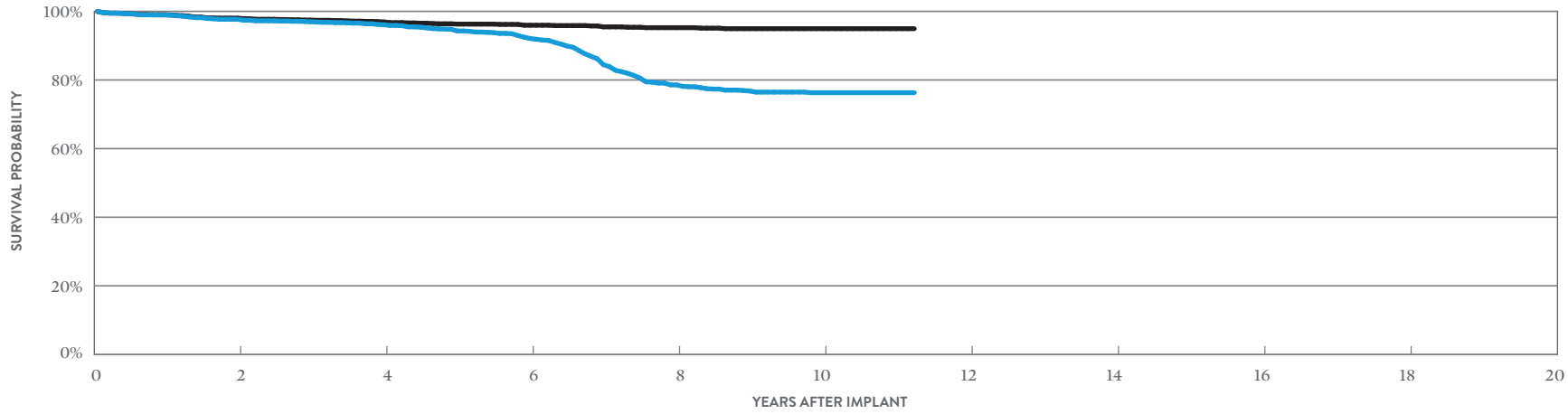
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ DR

MODEL CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	3,748
Estimated Active US Implants	943
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	157
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 206, 208)	Two

	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	AT 135 MONTHS
SURVIVAL PROBABILITY	97.68%	96.09%	92.09%	78.57%	76.30%	76.30%
± 1 STANDARD ERROR	0.26%	0.35%	0.52%	0.88%	0.93%	0.93%
SAMPLE SIZE	3,100	2,480	2,080	1,610	1,020	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	98.02%	96.91%	95.95%	95.24%	94.95%	94.95%
± 1 STANDARD ERROR	0.24%	0.31%	0.37%	0.42%	0.44%	0.44%

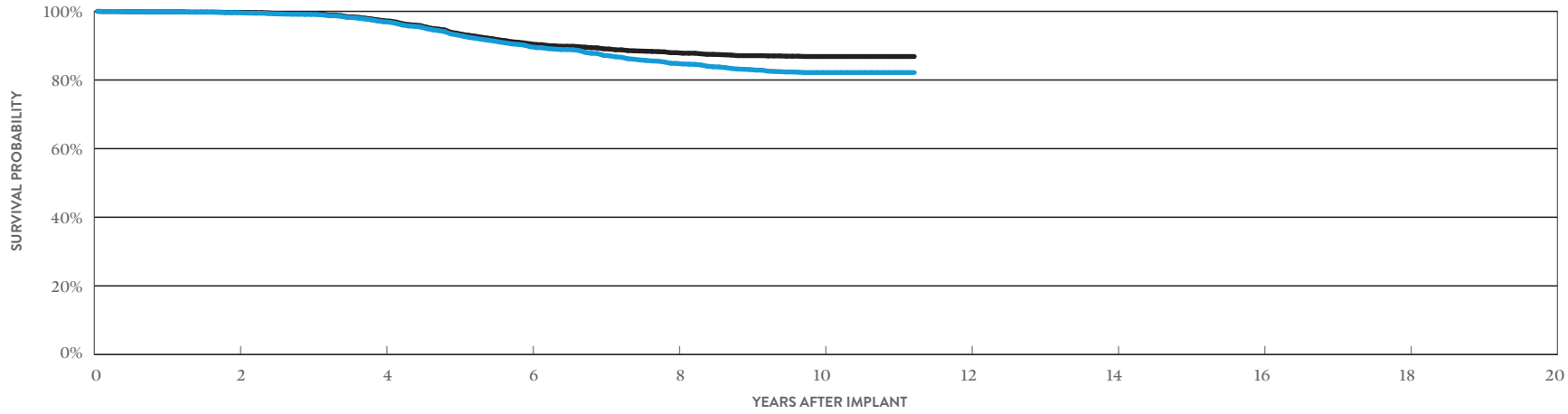
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,797
Estimated Active US Implants	1,704
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	68
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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	AT 135 MONTHS
SURVIVAL PROBABILITY	99.63%	96.95%	89.70%	84.82%	82.17%	82.17%
± 1 STANDARD ERROR	0.08%	0.24%	0.45%	0.57%	0.62%	0.62%
SAMPLE SIZE	5,680	4,550	3,660	2,990	2,000	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.72%	97.27%	90.54%	87.95%	86.84%	86.84%
± 1 STANDARD ERROR	0.07%	0.23%	0.44%	0.51%	0.54%	0.54%

**DF4-LLHH connector type.*

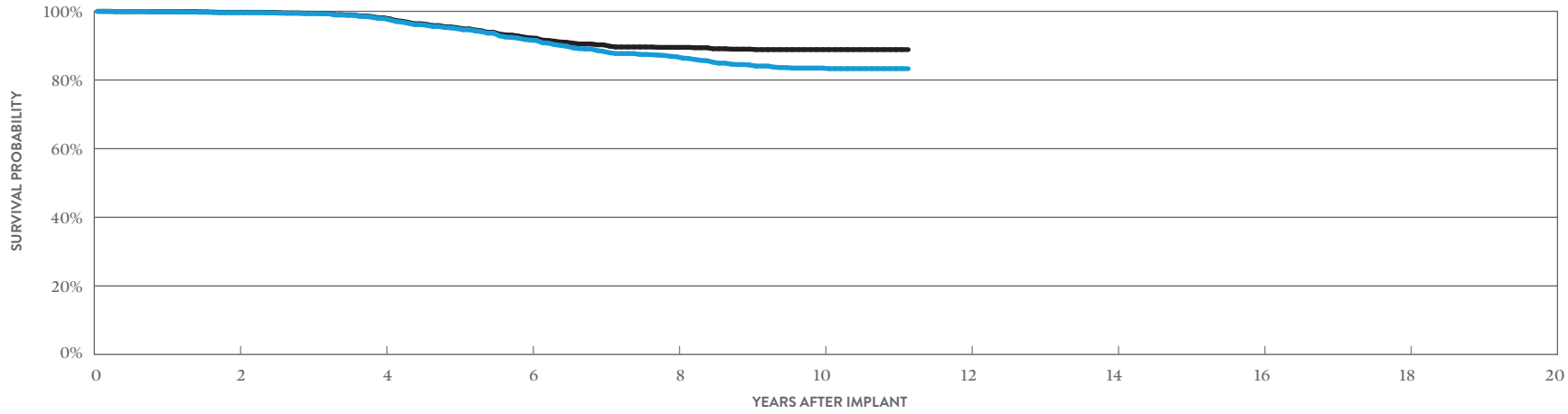
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ DR

MODEL CD2257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	4,235
Estimated Active US Implants	1,077
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	45
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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	AT 134 MONTHS
SURVIVAL PROBABILITY	99.61%	97.91%	91.61%	86.79%	83.47%	83.30%
± 1 STANDARD ERROR	0.10%	0.26%	0.55%	0.70%	0.80%	0.81%
SAMPLE SIZE	3,470	2,710	2,150	1,750	1,200	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.72%	98.09%	92.25%	89.50%	88.85%	88.85%
± 1 STANDARD ERROR	0.09%	0.25%	0.53%	0.63%	0.66%	0.66%

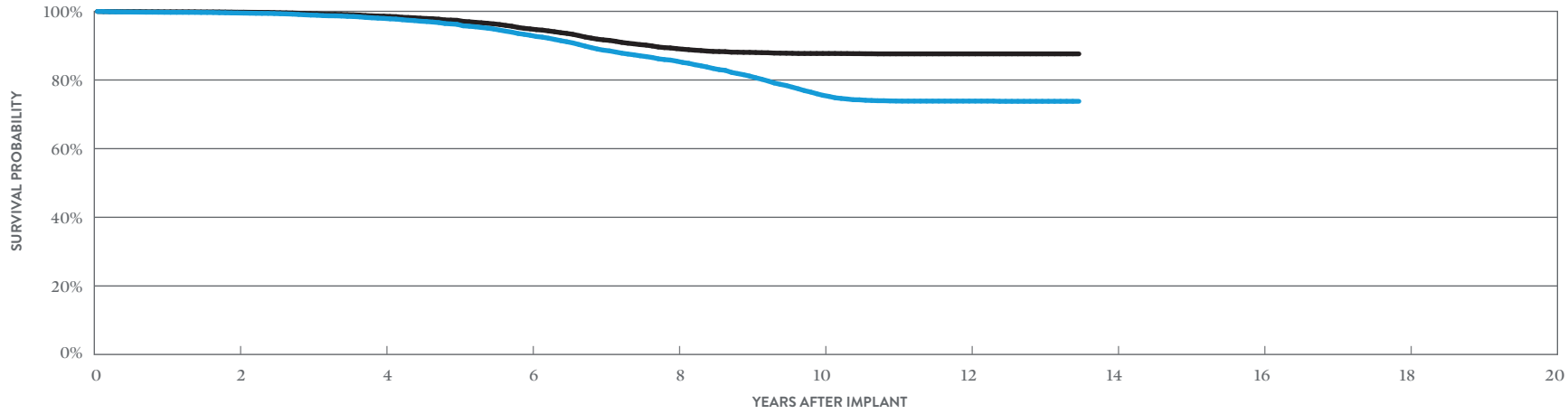
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ DR

MODEL CD2231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	27,257
Estimated Active US Implants	4,987
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	689
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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	AT 162 MONTHS
SURVIVAL PROBABILITY	99.52%	97.94%	93.02%	85.49%	75.53%	73.85%	73.79%
± 1 STANDARD ERROR	0.04%	0.10%	0.19%	0.28%	0.37%	0.39%	0.40%
SAMPLE SIZE	22,470	18,270	14,640	11,680	8,360	4,480	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	99.75%	98.60%	94.88%	89.14%	87.72%	87.61%	87.61%
± 1 STANDARD ERROR	0.03%	0.08%	0.17%	0.25%	0.28%	0.28%	0.28%

**DF4-LLHH connector type.*

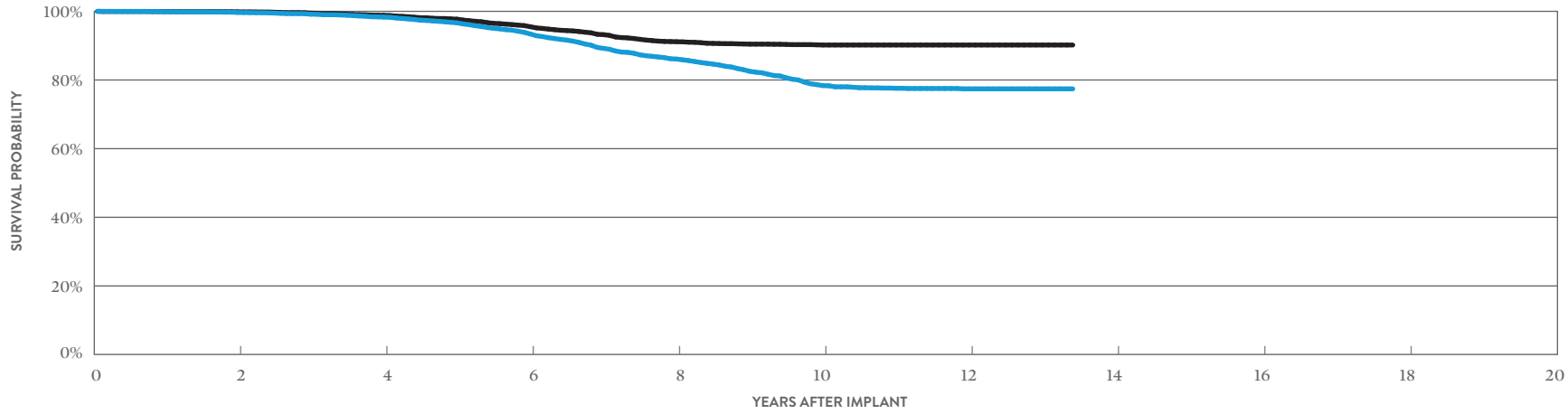
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ DR

MODEL CD2231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	12,267
Estimated Active US Implants	2,416
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	277
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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	AT 161 MONTHS
SURVIVAL PROBABILITY	99.67%	98.32%	93.41%	86.10%	78.36%	77.42%	77.42%
± 1 STANDARD ERROR	0.05%	0.14%	0.28%	0.43%	0.55%	0.57%	0.57%
SAMPLE SIZE	9,920	7,840	6,190	4,910	3,610	2,040	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.86%	98.84%	95.52%	91.15%	90.19%	90.19%	90.19%
± 1 STANDARD ERROR	0.03%	0.12%	0.24%	0.36%	0.38%	0.39%	0.39%

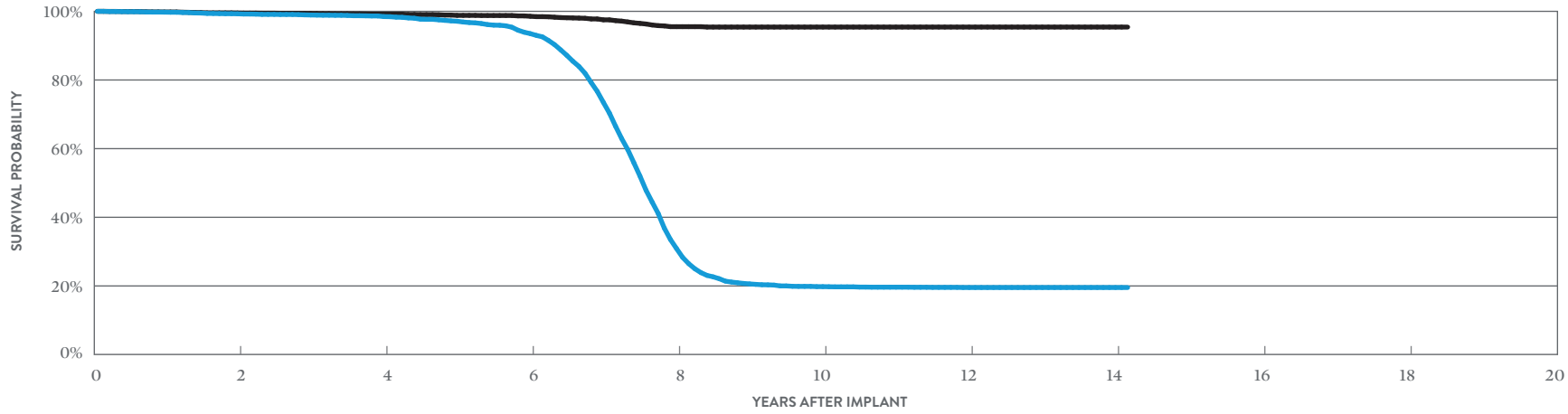
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Current™ + DR

MODEL CD2211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	8,981
Estimated Active US Implants	1,026
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	1,695
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.07%	7	0.08%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	7	0.08%	10	0.11%
High Voltage Capacitor	3	0.03%	0	0.00%
Software/Firmware	1	0.01%	25	0.28%
Mechanical	0	0.00%	2	0.02%
Possible Early Battery Depletion	4	0.04%	4	0.04%
Other	6	0.07%	7	0.08%
Total	**27**	**0.30%**	**55**	**0.61%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 170 MONTHS
SURVIVAL PROBABILITY	99.28%	98.47%	93.51%	30.89%	19.80%	19.54%	19.54%	19.54%
± 1 STANDARD ERROR	0.09%	0.14%	0.33%	0.64%	0.51%	0.51%	0.51%	0.51%
SAMPLE SIZE	7,330	5,900	4,770	2,840	1,460	1,220	660	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 170 MONTHS
SURVIVAL PROBABILITY	99.53%	99.18%	98.56%	95.53%	95.42%	95.42%	95.42%	95.42%
± 1 STANDARD ERROR	0.08%	0.11%	0.15%	0.34%	0.35%	0.35%	0.35%	0.35%

**DF4-LLHH connector type.*

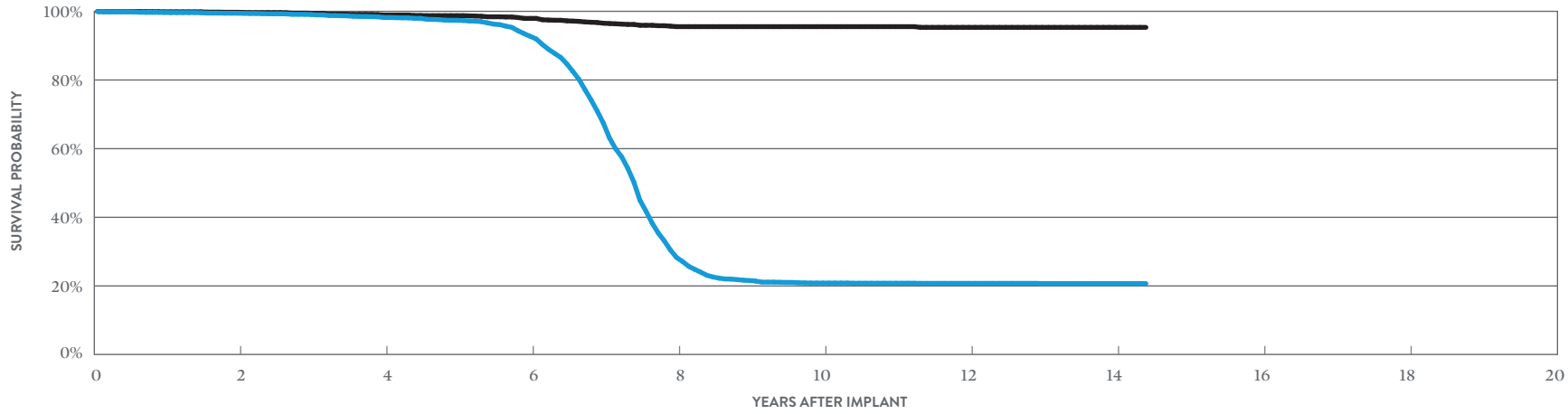
Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Current™ + DR

MODEL CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,387
Estimated Active US Implants	763
Estimated Longevity	(see table on page 86)
Normal Battery Depletion	1,145
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.05%	2	0.03%
Electrical Interconnect	2	0.03%	0	0.00%
Battery	8	0.13%	4	0.06%
High Voltage Capacitor	1	0.02%	0	0.00%
Software/Firmware	1	0.02%	18	0.28%
Mechanical	0	0.00%	1	0.02%
Possible Early Battery Depletion	9	0.14%	4	0.06%
Other	7	0.11%	3	0.05%
Total	**31**	**0.49%**	**32**	**0.50%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 MONTHS
SURVIVAL PROBABILITY	99.45%	98.20%	92.72%	28.30%	20.85%	20.76%	20.70%	20.70%
± 1 STANDARD ERROR	0.10%	0.18%	0.41%	0.74%	0.63%	0.63%	0.62%	0.62%
SAMPLE SIZE	5,140	4,070	3,230	1,860	1,040	870	540	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 MONTHS
SURVIVAL PROBABILITY	99.73%	98.93%	97.94%	95.54%	95.54%	95.33%	95.33%	95.33%
± 1 STANDARD ERROR	0.07%	0.14%	0.23%	0.38%	0.39%	0.42%	0.42%	0.42%

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
CD2211-36Q	Current™ + DR***	8.2	7.5	7.0	6.1
CD2211-36	Current™ + DR***	8.2	7.5	7.0	6.1

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*	99.92%	99.83%	99.83%							
CD2411-36Q	Ellipse™ DR	99.88%	99.85%	99.75%	99.68%	99.49%	99.16%	96.75%	89.49%	88.65%	88.46%
CD2411-36C	Ellipse™ DR	99.80%	99.74%	99.72%	99.50%	99.19%	98.74%	95.70%	84.81%	84.23%	84.23%
CD2357-40Q	Fortify Assura™ DR	99.86%	99.79%	99.74%	99.64%	99.40%	99.10%	98.86%	98.35%		
CD2357-40Q	Fortify Assura™ DR†	99.79%	99.32%	96.48%	91.19%	85.84%	82.20%	78.17%	73.67%	72.49%	72.21%
CD2357-40C	Fortify Assura™ DR	99.89%	99.87%	99.77%	99.62%	99.36%	99.27%	98.73%	98.54%		
CD2357-40C	Fortify Assura™ DR†	99.72%	99.41%	97.41%	92.67%	87.80%	84.72%	80.69%	76.92%	76.11%	75.80%
CD2311-36Q	Ellipse™ DR	99.04%	98.02%	97.10%	95.73%	94.64%	92.06%	84.75%	78.28%	76.91%	75.89%
CD2311-36	Ellipse™ DR	98.94%	97.68%	96.95%	96.09%	94.28%	92.09%	84.46%	78.57%	76.79%	76.30%
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.63%	99.11%	96.95%	93.13%	89.70%	87.18%	84.82%	83.05%	82.17%
CD2257-40	Fortify Assura™ DR†	99.84%	99.61%	99.35%	97.91%	94.97%	91.61%	88.33%	86.79%	84.37%	83.47%
CD2231-40Q	Fortify™ DR†	99.72%	99.52%	98.91%	97.94%	96.22%	93.02%	88.69%	85.49%	81.13%	75.53%
CD2231-40	Fortify™ DR†	99.88%	99.67%	99.16%	98.32%	96.65%	93.41%	89.22%	86.10%	82.52%	78.36%
CD2211-36Q	Current™ + DR	99.76%	99.28%	98.93%	98.47%	97.12%	93.51%	73.48%	30.89%	20.59%	19.80%
CD2211-36	Current™ + DR	99.66%	99.45%	99.08%	98.20%	97.39%	92.72%	67.42%	28.30%	21.57%	20.85%

†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%	99.84%	99.84%							
CD2411-36Q	Ellipse™ DR	99.90%	99.86%	99.83%	99.80%	99.77%	99.77%	99.70%	99.63%	99.57%	99.57%
CD2411-36C	Ellipse™ DR	99.84%	99.78%	99.78%	99.63%	99.57%	99.49%	99.31%	99.01%	98.90%	98.90%
CD2357-40Q	Fortify Assura™ DR	99.88%	99.82%	99.76%	99.72%	99.67%	99.65%	99.65%	99.65%		
CD2357-40Q	Fortify Assura™ DR†	99.84%	99.40%	96.62%	91.40%	86.13%	82.79%	79.28%	76.48%	75.47%	75.31%
CD2357-40C	Fortify Assura™ DR	99.89%	99.87%	99.80%	99.71%	99.56%	99.56%	99.43%	99.24%		
CD2357-40C	Fortify Assura™ DR†	99.80%	99.58%	97.61%	93.06%	88.48%	85.51%	82.42%	80.24%	79.64%	79.31%
CD2311-36Q	Ellipse™ DR	99.13%	98.17%	97.42%	96.33%	95.70%	95.10%	94.37%	93.99%	93.90%	93.90%
CD2311-36	Ellipse™ DR	99.02%	98.02%	97.46%	96.91%	96.28%	95.95%	95.47%	95.24%	94.95%	94.95%
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.72%	99.33%	97.27%	93.60%	90.54%	89.08%	87.95%	87.09%	86.84%
CD2257-40	Fortify Assura™ DR†	99.90%	99.72%	99.46%	98.09%	95.23%	92.25%	90.25%	89.50%	88.98%	88.85%
CD2231-40Q	Fortify™ DR†	99.86%	99.75%	99.31%	98.60%	97.39%	94.88%	91.69%	89.14%	88.05%	87.72%
CD2231-40	Fortify™ DR†	99.95%	99.86%	99.48%	98.84%	97.72%	95.52%	93.21%	91.15%	90.44%	90.19%
CD2211-36Q	Current™ + DR	99.82%	99.53%	99.38%	99.18%	98.82%	98.56%	97.52%	95.53%	95.42%	95.42%
CD2211-36	Current™ + DR	99.86%	99.73%	99.44%	98.93%	98.74%	97.94%	96.54%	95.54%	95.54%	95.54%

†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
CDDRA500Q	Gallant™ DR	29,048	1.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2411-36Q	Ellipse™ DR	33,978	6.50%	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	12,267	9.00%	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	43,189	5.40%	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	19.90%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	73	0.60%	1	<0.01%	**78**	**0.64%**
CD2357-40C	Fortify Assura™ DR	12,313	6.50%	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	21.20%	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	17.50%	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	19.20%	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%**
CD2211-36Q	Current™ + DR	8,981	29.70%	6	0.07%	0	0.00%	7	0.08%	3	0.03%	1	0.01%	0	0.00%	4	0.04%	6	0.07%	**27**	**0.30%**
CD2211-36	Current™ + DR	6,387	30.10%	3	0.05%	2	0.03%	8	0.13%	1	0.02%	1	0.02%	0	0.00%	9	0.14%	7	0.11%	**31**	**0.49%**

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	29,048	1.50%	6	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	**13**	**0.04%**
CD2411-36Q	Ellipse™ DR	33,978	6.50%	12	0.04%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	4	0.01%	1	<0.01%	6	0.02%	**25**	**0.07%**
CD2411-36C	Ellipse™ DR	12,267	9.00%	8	0.07%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	1	<0.01%	1	<0.01%	5	0.04%	**17**	**0.14%**
CD2357-40Q	Fortify Assura™ DR	43,189	5.40%	16	0.04%	1	<0.01%	4	<0.01%	1	<0.01%	0	0.00%	2	<0.01%	3	<0.01%	4	<0.01%	**31**	**0.07%**
CD2357-40Q	Fortify Assura™ DR†	12,263	19.90%	10	0.08%	0	0.00%	19	0.15%	0	0.00%	0	0.00%	1	<0.01%	673	5.49%	6	0.05%	**709**	**5.78%**
CD2357-40C	Fortify Assura™ DR	12,313	6.50%	7	0.06%	1	<0.01%	1	<0.01%	0	0.00%	2	0.02%	2	0.02%	1	<0.01%	2	0.02%	**16**	**0.13%**
CD2357-40C	Fortify Assura™ DR†	6,956	21.20%	2	0.03%	1	0.01%	6	0.09%	0	0.00%	0	0.00%	0	0.00%	309	4.44%	2	0.03%	**320**	**4.60%**
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	17.50%	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	19.20%	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%**
CD2211-36Q	Current™ + DR	8,981	29.70%	7	0.08%	0	0.00%	10	0.11%	0	0.00%	25	0.28%	2	0.02%	4	0.04%	7	0.08%	**55**	**0.61%**
CD2211-36	Current™ + DR	6,387	30.10%	2	0.03%	0	0.00%	4	0.06%	0	0.00%	18	0.28%	1	0.02%	4	0.06%	3	0.05%	**32**	**0.50%**

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
CDDRA500Q	Gallant™ DR	44,833	1.22%	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	34,585	6.60%	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	12,396	9.45%	6	0.05%	0	0.00%	0	0.00%	7	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**15**	**0.12%**
CD2357-40Q	Fortify Assura™ DR	56,748	8.68%	12	0.02%	2	<0.01%	4	<0.01%	3	<0.01%	0	0.00%	0	0.00%	146	0.26%	16	0.03%	**183**	**0.32%**
CD2357-40C	Fortify Assura™ DR	19,458	12.22%	10	0.05%	4	0.02%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	66	0.34%	4	0.02%	**87**	**0.45%**
CD2311-36Q	Ellipse™ DR	5,881	16.20%	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	16.40%	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	17.92%	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	20.22%	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	29,172	16.80%	22	0.08%	6	0.02%	58	0.20%	5	0.02%	2	<0.01%	0	0.00%	344	1.18%	34	0.12%	**471**	**1.61%**
CD2231-40	Fortify™ DR	18,121	13.83%	18	0.10%	4	0.02%	10	0.06%	8	0.04%	0	0.00%	0	0.00%	126	0.70%	12	0.07%	**178**	**0.98%**
CD2211-36Q	Current™ + DR	15,224	18.36%	18	0.12%	2	0.01%	18	0.12%	8	0.05%	2	0.01%	0	0.00%	16	0.11%	32	0.21%	**96**	**0.63%**
CD2211-36	Current™ + DR	13,483	15.20%	16	0.12%	10	0.07%	22	0.16%	4	0.03%	2	0.01%	0	0.00%	24	0.18%	20	0.15%	**98**	**0.73%**

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	44,833	1.22%	14	0.03%	2	<0.01%	0	0.00%	1	<0.01%	0	0.00%	6	0.01%	0	0.00%	6	0.01%	**29**	**0.06%**
CD2411-36Q	Ellipse™ DR	34,585	6.60%	24	0.07%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	8	0.02%	2	<0.01%	12	0.03%	**48**	**0.14%**
CD2411-36C	Ellipse™ DR	12,396	9.45%	16	0.13%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	2	0.02%	2	0.02%	10	0.08%	**32**	**0.26%**
CD2357-40Q	Fortify Assura™ DR	56,748	8.68%	52	0.09%	2	<0.01%	46	0.08%	2	<0.01%	0	0.00%	6	0.01%	1352	2.38%	20	0.04%	**1480**	**2.61%**
CD2357-40C	Fortify Assura™ DR	19,458	12.22%	18	0.09%	4	0.02%	14	0.07%	0	0.00%	4	0.02%	4	0.02%	620	3.19%	10	0.05%	**674**	**3.46%**
CD2311-36Q	Ellipse™ DR	5,881	16.20%	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	16.40%	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	17.92%	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	20.22%	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	29,172	16.80%	28	0.10%	4	0.01%	112	0.38%	2	<0.01%	4	0.01%	0	0.00%	862	2.95%	26	0.09%	**1038**	**3.56%**
CD2231-40	Fortify™ DR	18,121	13.83%	10	0.06%	0	0.00%	18	0.10%	2	0.01%	2	0.01%	4	0.02%	314	1.73%	10	0.06%	**360**	**1.99%**
CD2211-36Q	Current™ + DR	15,224	18.36%	24	0.16%	0	0.00%	22	0.14%	2	0.01%	54	0.35%	6	0.04%	18	0.12%	20	0.13%	**146**	**0.96%**
CD2211-36	Current™ + DR	13,483	15.20%	4	0.03%	2	0.01%	8	0.06%	1	<0.01%	40	0.30%	4	0.03%	10	0.07%	14	0.10%	**83**	**0.62%**

Definitions of malfunction categories can be found on pages 5-6.

SINGLE-CHAMBER

Implantable Cardioverter Defibrillator (ICD) Devices

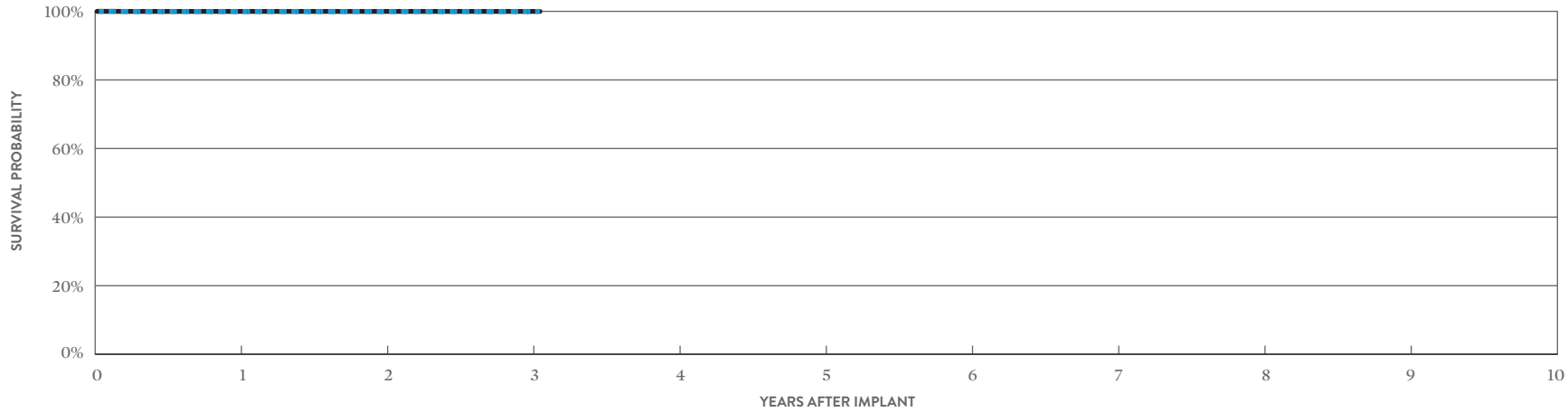
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Gallant™ VR

MODEL CDVRA500Q*

US Regulatory Approval	June 2020
Registered US Implants	14,267
Estimated Active US Implants	11,983
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories (page 204)	One

	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	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**<0.01%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 37 MONTHS
SURVIVAL PROBABILITY	99.98%	99.98%	99.98%	99.98%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%
SAMPLE SIZE	11,000	5,470	1,710	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 37 MONTHS
SURVIVAL PROBABILITY	99.98%	99.98%	99.98%	99.98%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%

**DF4-LLHH connector type.*

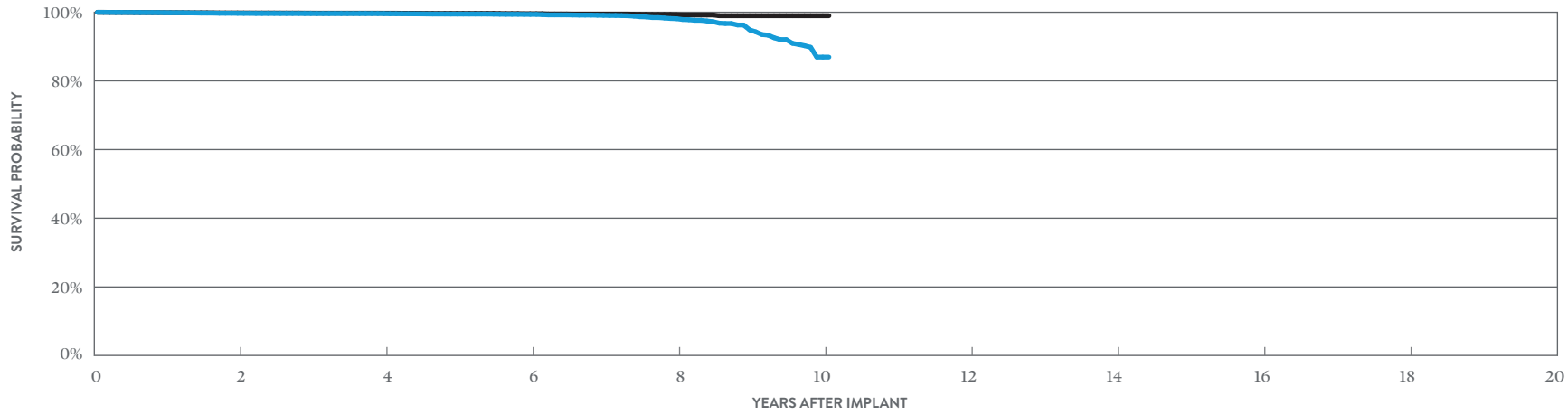
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	24,130
Estimated Active US Implants	12,627
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	78
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 205, 206, 208)	Three

	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%	6	0.02%
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	2	<0.01%	5	0.02%
Total	**17**	**0.07%**	**27**	**0.11%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 121 MONTHS
SURVIVAL PROBABILITY	99.68%	99.60%	99.37%	98.12%	86.93%	86.93%
± 1 STANDARD ERROR	0.04%	0.04%	0.06%	0.17%	1.23%	1.23%
SAMPLE SIZE	19,850	14,780	9,040	4,320	810	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 121 MONTHS
SURVIVAL PROBABILITY	99.79%	99.72%	99.56%	99.27%	98.98%	98.98%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.09%	0.15%	0.15%

**DF4-LLHH connector type.*

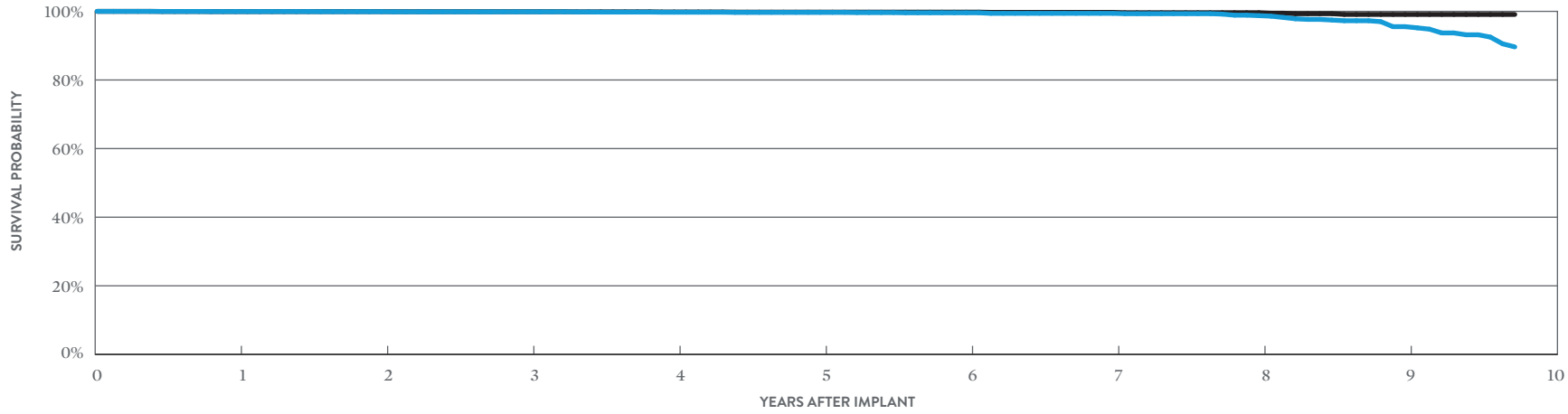
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1411-36C*

US Regulatory Approval	June 2013
Registered US Implants	7,486
Estimated Active US Implants	3,717
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	29
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 205, 206, 208)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	6	0.08%
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%	1	0.01%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	2	0.03%
Total	**0**	**0.00%**	**11**	**0.15%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 117 MONTHS
SURVIVAL PROBABILITY	99.94%	99.91%	99.87%	99.75%	99.70%	99.59%	99.42%	98.75%	95.54%	89.64%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%	0.07%	0.07%	0.09%	0.12%	0.21%	0.64%	1.35%
SAMPLE SIZE	6,980	6,120	5,440	4,850	4,230	3,420	2,550	1,780	990	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 117 MONTHS
SURVIVAL PROBABILITY	99.94%	99.94%	99.91%	99.82%	99.78%	99.78%	99.71%	99.61%	99.10%	99.10%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.06%	0.07%	0.07%	0.08%	0.11%	0.24%	0.24%

**Parylene coating.*

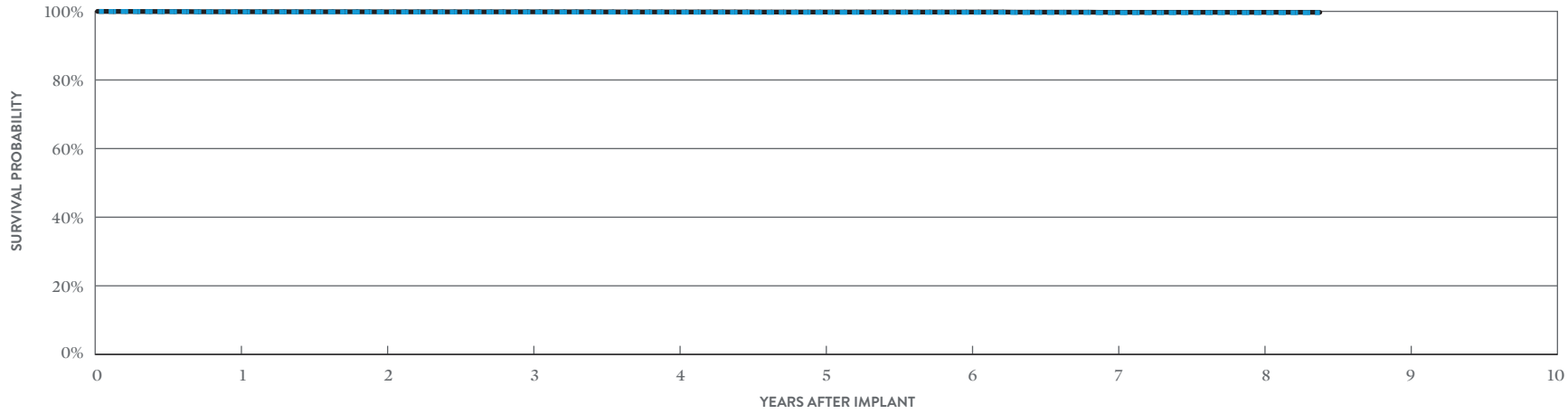
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

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

US Regulatory Approval	June 2013
Registered US Implants	26,154
Estimated Active US Implants	15,033
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	8
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	7	0.03%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	1	<0.01%
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%	1	<0.01%
Other	3	0.01%	3	0.01%
Total	**7**	**0.03%**	**14**	**0.05%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.86%	99.79%	99.78%	99.73%	99.70%	99.70%	99.62%	99.62%	99.62%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.06%	0.06%	0.06%
SAMPLE SIZE	24,450	21,350	18,540	15,370	11,730	8,200	5,210	2,450	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 101 MONTHS
SURVIVAL PROBABILITY	99.89%	99.86%	99.86%	99.82%	99.80%	99.80%	99.72%	99.72%	99.72%
± 1 STANDARD ERROR	0.02%	0.02%	0.02%	0.03%	0.03%	0.03%	0.05%	0.05%	0.05%

**DF4-LLHH connector type.*

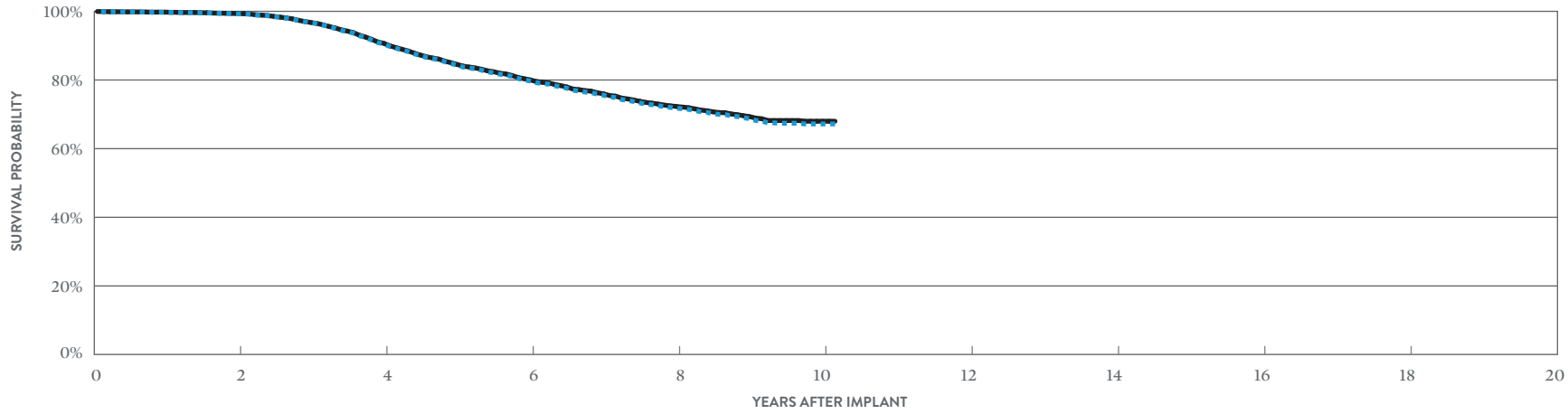
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	10,214
Estimated Active US Implants	3,581
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	19
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	735	7.20%
Other	4	0.04%	6	0.06%
Total	**81**	**0.79%**	**758**	**7.42%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 122 MONTHS
SURVIVAL PROBABILITY	99.25%	90.48%	79.70%	71.79%	67.20%	67.20%
± 1 STANDARD ERROR	0.09%	0.33%	0.47%	0.54%	0.63%	0.63%
SAMPLE SIZE	8,560	6,930	5,580	4,380	1,170	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 122 MONTHS
SURVIVAL PROBABILITY	99.32%	90.67%	80.03%	72.28%	67.99%	67.99%
± 1 STANDARD ERROR	0.08%	0.33%	0.47%	0.54%	0.62%	0.62%

**DF4-LLHH connector type.*

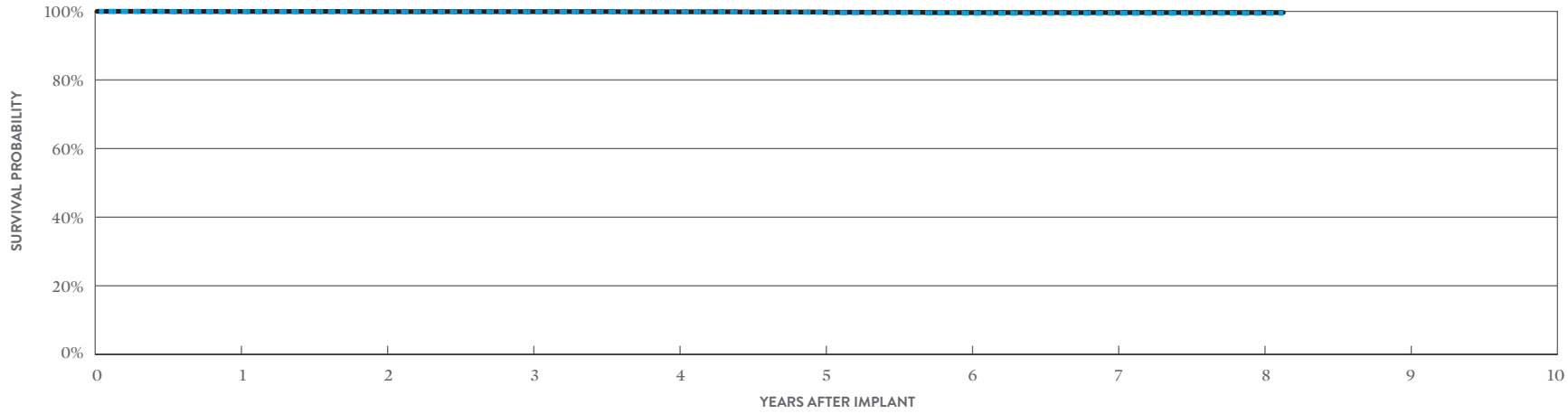
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

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

US Regulatory Approval	June 2013
Registered US Implants	6,379
Estimated Active US Implants	3,560
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	0.03%
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	0.02%
Possible Early Battery Depletion	0	0.00%	2	0.03%
Other	0	0.00%	1	0.02%
Total	**0**	**0.00%**	**6**	**0.09%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.96%	99.88%	99.88%	99.83%	99.70%	99.43%	99.43%	99.43%	99.43%
± 1 STANDARD ERROR	0.02%	0.05%	0.05%	0.06%	0.09%	0.12%	0.14%	0.14%	0.14%
SAMPLE SIZE	5,830	4,900	4,250	3,710	3,150	2,370	1,420	630	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.96%	99.92%	99.92%	99.87%	99.80%	99.64%	99.64%	99.64%	99.64%
± 1 STANDARD ERROR	0.02%	0.04%	0.04%	0.06%	0.07%	0.11%	0.11%	0.11%	0.11%

**Parylene coating.*

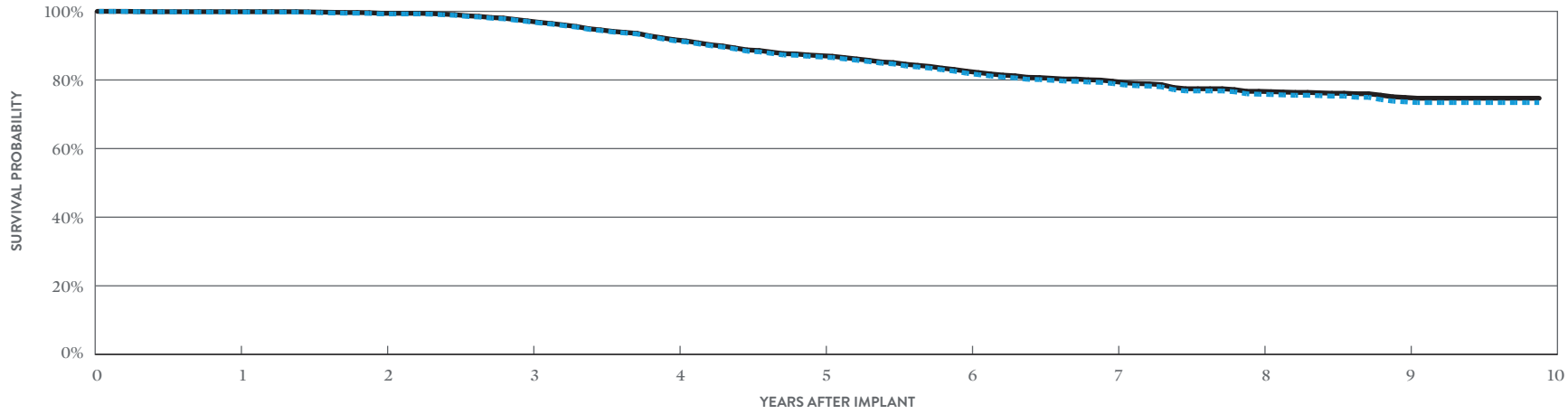
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	4,131
Estimated Active US Implants	1,424
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	12
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.07%	2	0.05%
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%	232	5.62%
Other	0	0.00%	2	0.05%
Total	**15**	**0.36%**	**243**	**5.88%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.79%	99.25%	97.01%	91.45%	86.71%	81.96%	78.96%	75.85%	73.62%	73.41%
± 1 STANDARD ERROR	0.07%	0.13%	0.28%	0.51%	0.64%	0.73%	0.79%	0.85%	0.91%	0.93%
SAMPLE SIZE	3,860	3,380	2,980	2,650	2,380	2,140	1,920	1,650	1,100	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.90%	99.44%	97.20%	91.74%	87.09%	82.56%	79.62%	76.69%	74.90%	74.68%
± 1 STANDARD ERROR	0.05%	0.11%	0.28%	0.50%	0.63%	0.72%	0.78%	0.84%	0.89%	0.91%

**Parylene coating.*

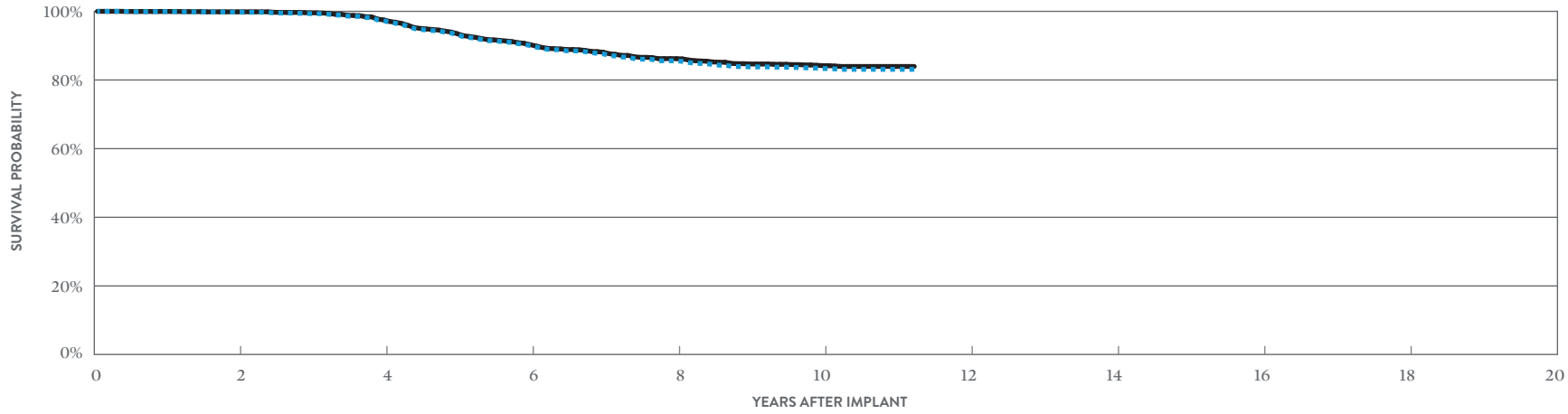
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	5,079
Estimated Active US Implants	1,621
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	12
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	166	3.27%
Other	1	0.02%	1	0.02%
Total	**23**	**0.45%**	**173**	**3.41%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.77%	97.24%	90.00%	85.59%	83.33%	83.10%
± 1 STANDARD ERROR	0.07%	0.26%	0.52%	0.63%	0.69%	0.70%
SAMPLE SIZE	4,230	3,410	2,790	2,310	1,750	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.86%	97.49%	90.28%	86.22%	84.17%	83.94%
± 1 STANDARD ERROR	0.06%	0.25%	0.51%	0.62%	0.67%	0.68%

**DF4-LLHH connector type.*

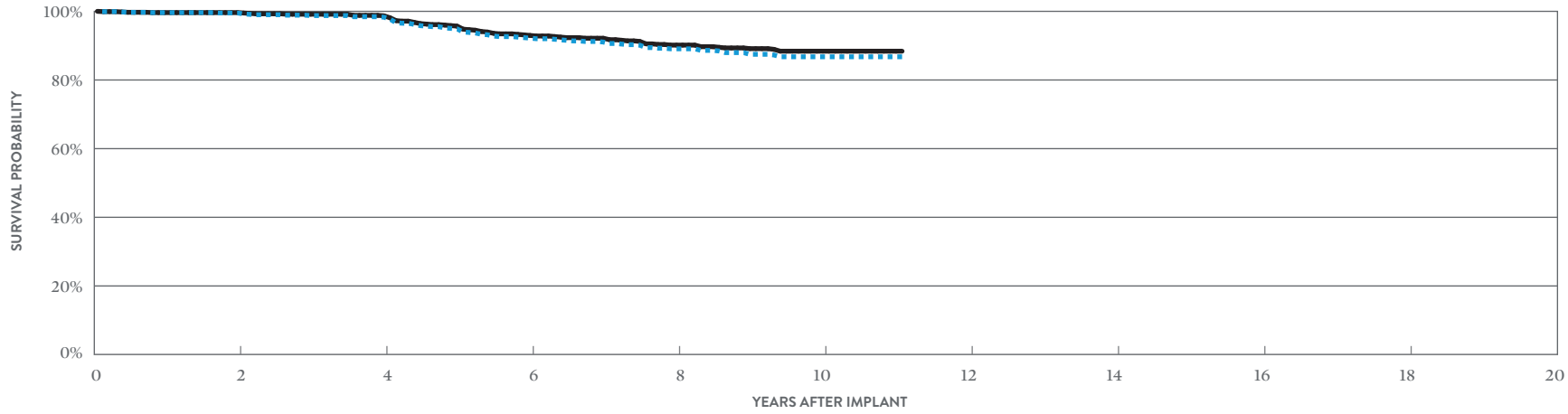
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify Assura™ VR

MODEL CD1257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,294
Estimated Active US Implants	772
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	9
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	51	2.22%
Other	2	0.09%	1	0.04%
Total	**14**	**0.61%**	**54**	**2.35%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 133 MONTHS
SURVIVAL PROBABILITY	99.52%	98.29%	92.18%	89.08%	86.76%	86.76%
± 1 STANDARD ERROR	0.15%	0.30%	0.70%	0.85%	0.95%	0.95%
SAMPLE SIZE	1,890	1,490	1,240	1,040	770	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 133 MONTHS
SURVIVAL PROBABILITY	99.63%	98.69%	92.97%	90.16%	88.39%	88.39%
± 1 STANDARD ERROR	0.13%	0.26%	0.67%	0.82%	0.90%	0.90%

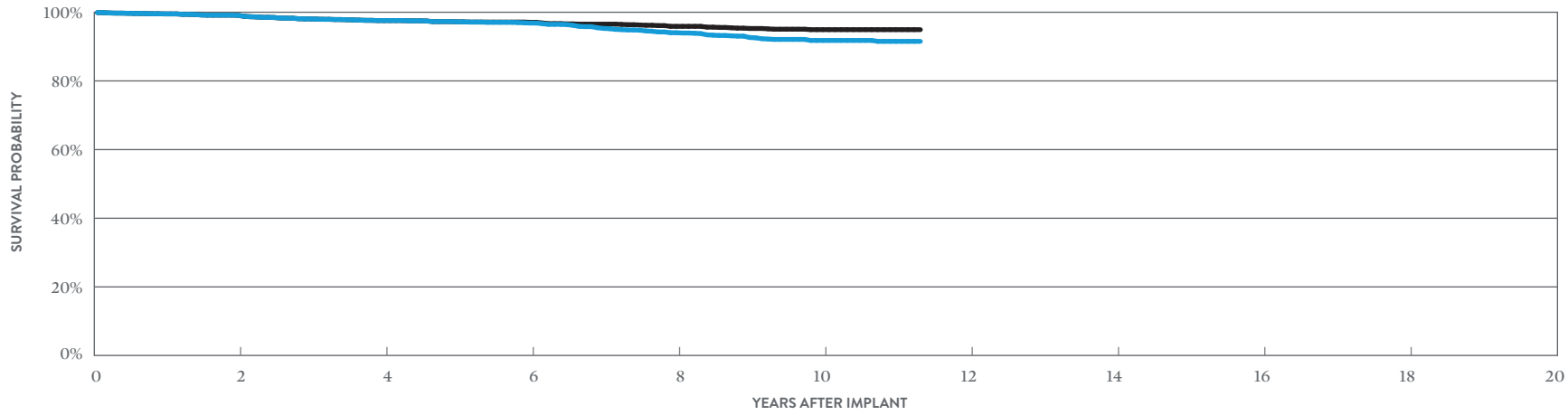
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	4,743
Estimated Active US Implants	1,332
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	31
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 206, 208)	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	AT 136 MONTHS
SURVIVAL PROBABILITY	99.11%	97.58%	96.85%	94.04%	91.79%	91.52%
± 1 STANDARD ERROR	0.14%	0.25%	0.29%	0.44%	0.54%	0.57%
SAMPLE SIZE	3,940	3,220	2,720	2,260	1,630	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	99.11%	97.58%	97.07%	95.89%	94.93%	94.93%
± 1 STANDARD ERROR	0.14%	0.25%	0.28%	0.35%	0.41%	0.41%

**DF4-LLHH connector type.*

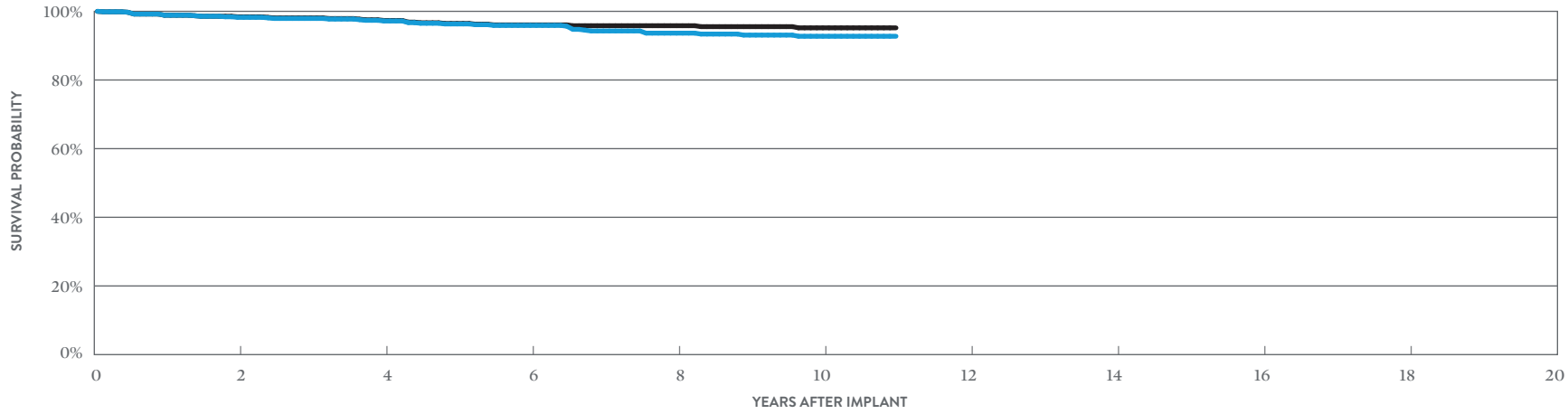
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Ellipse™ VR

MODEL CD1311-36

US Regulatory Approval	May 2012
Registered US Implants	1,621
Estimated Active US Implants	471
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	9
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 206, 208)	Two

	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	AT 132 MONTHS
SURVIVAL PROBABILITY	98.25%	97.19%	95.90%	93.65%	92.74%	92.74%
± 1 STANDARD ERROR	0.33%	0.44%	0.58%	0.76%	0.84%	0.84%
SAMPLE SIZE	1,330	1,090	910	760	540	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	98.41%	97.34%	96.05%	95.81%	95.19%	95.19%
± 1 STANDARD ERROR	0.31%	0.43%	0.57%	0.59%	0.67%	0.67%

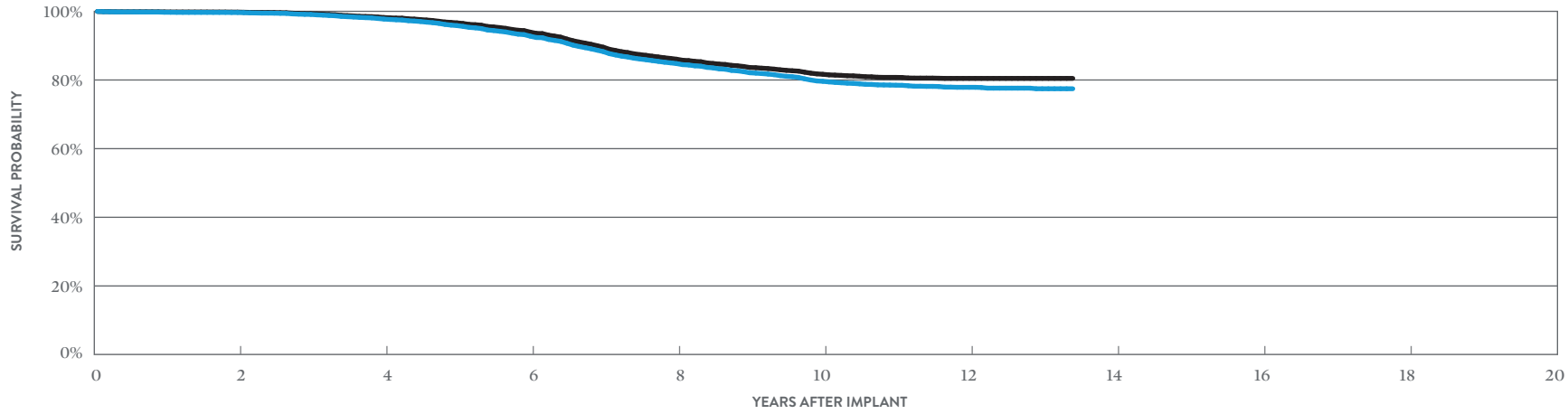
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ VR

MODEL CD1231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	16,341
Estimated Active US Implants	3,780
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	101
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	49	0.30%
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	132	0.81%	443	2.71%
Other	9	0.06%	7	0.04%
Total	**170**	**1.04%**	**511**	**3.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.66%	97.75%	92.76%	84.78%	79.61%	77.87%	77.45%
± 1 STANDARD ERROR	0.05%	0.13%	0.25%	0.37%	0.43%	0.45%	0.48%
SAMPLE SIZE	13,410	10,930	8,890	7,280	6,020	3,690	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.78%	98.20%	93.94%	86.06%	81.66%	80.47%	80.47%
± 1 STANDARD ERROR	0.04%	0.12%	0.23%	0.36%	0.42%	0.43%	0.43%

**DF4-LLHH connector type.*

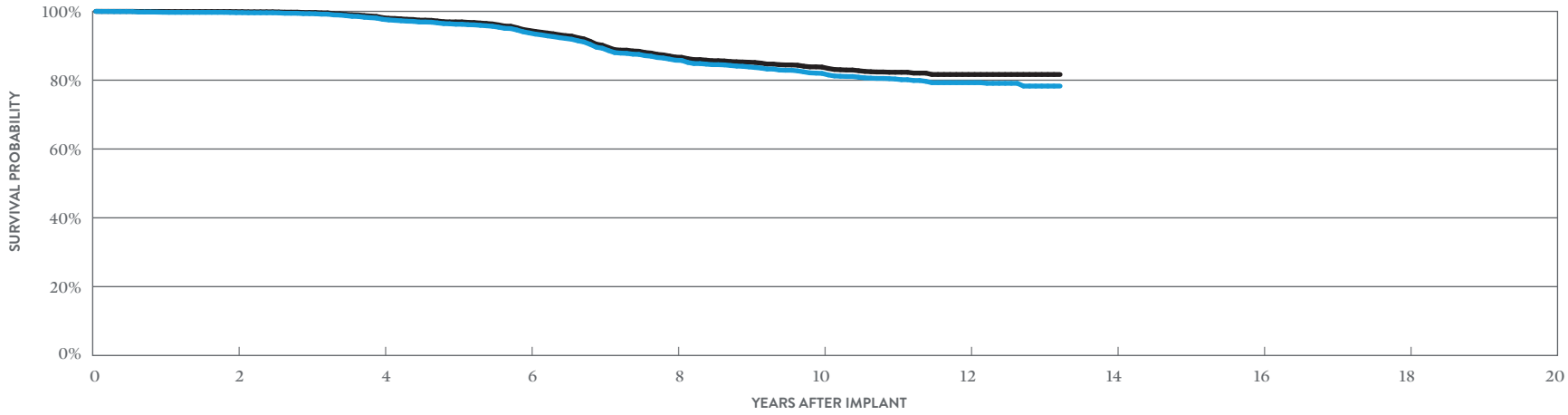
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Fortify™ VR

MODEL CD1231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	6,782
Estimated Active US Implants	1,525
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	38
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 206, 207)	Three

	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%	148	2.18%
Other	6	0.09%	6	0.09%
Total	**69**	**1.02%**	**179**	**2.64%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	99.63%	97.70%	93.74%	85.80%	81.98%	79.27%	78.29%
± 1 STANDARD ERROR	0.07%	0.20%	0.37%	0.58%	0.66%	0.72%	0.81%
SAMPLE SIZE	5,530	4,390	3,510	2,830	2,320	1,460	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	99.90%	98.17%	94.45%	86.70%	83.80%	81.65%	81.65%
± 1 STANDARD ERROR	0.03%	0.18%	0.36%	0.57%	0.63%	0.69%	0.69%

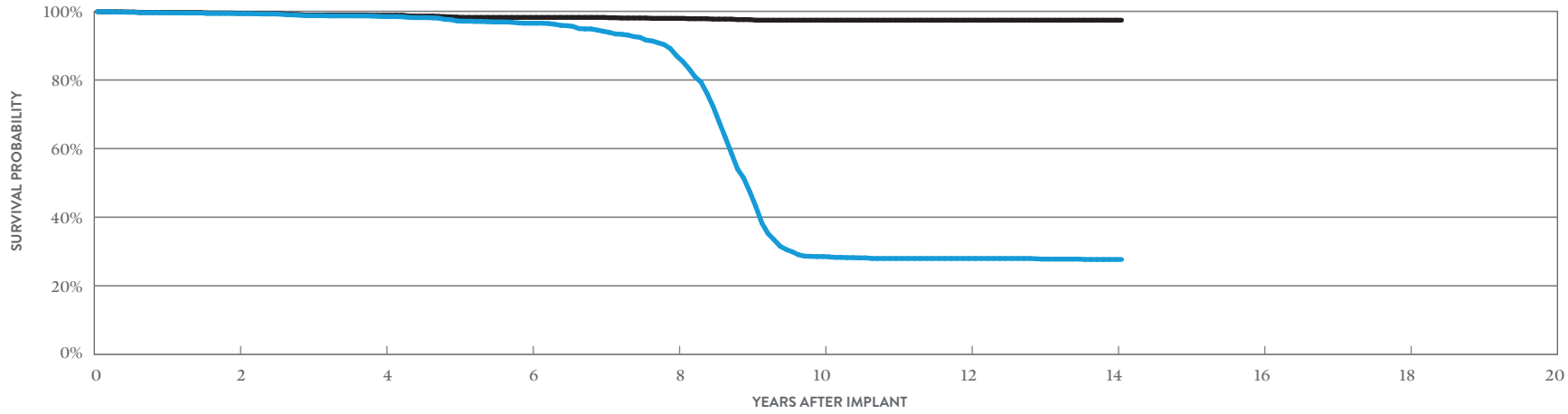
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Current™ + VR

MODEL CD1211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	4,792
Estimated Active US Implants	648
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	682
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	4	0.08%	3	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	6	0.13%	3	0.06%
High Voltage Capacitor	1	0.02%	0	0.00%
Software/Firmware	0	0.00%	3	0.06%
Mechanical	0	0.00%	1	0.02%
Possible Early Battery Depletion	6	0.13%	2	0.04%
Other	3	0.06%	2	0.04%
Total	**20**	**0.42%**	**14**	**0.29%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 169 MONTHS
SURVIVAL PROBABILITY	99.34%	98.48%	96.54%	87.04%	28.56%	28.00%	27.71%	27.71%
± 1 STANDARD ERROR	0.12%	0.20%	0.33%	0.63%	0.89%	0.88%	0.88%	0.88%
SAMPLE SIZE	3,850	3,050	2,470	2,030	1,040	730	420	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 169 MONTHS
SURVIVAL PROBABILITY	99.45%	98.85%	98.23%	97.95%	97.42%	97.42%	97.42%	97.42%
± 1 STANDARD ERROR	0.11%	0.18%	0.23%	0.26%	0.32%	0.32%	0.32%	0.32%

**DF4-LLHH connector type.*

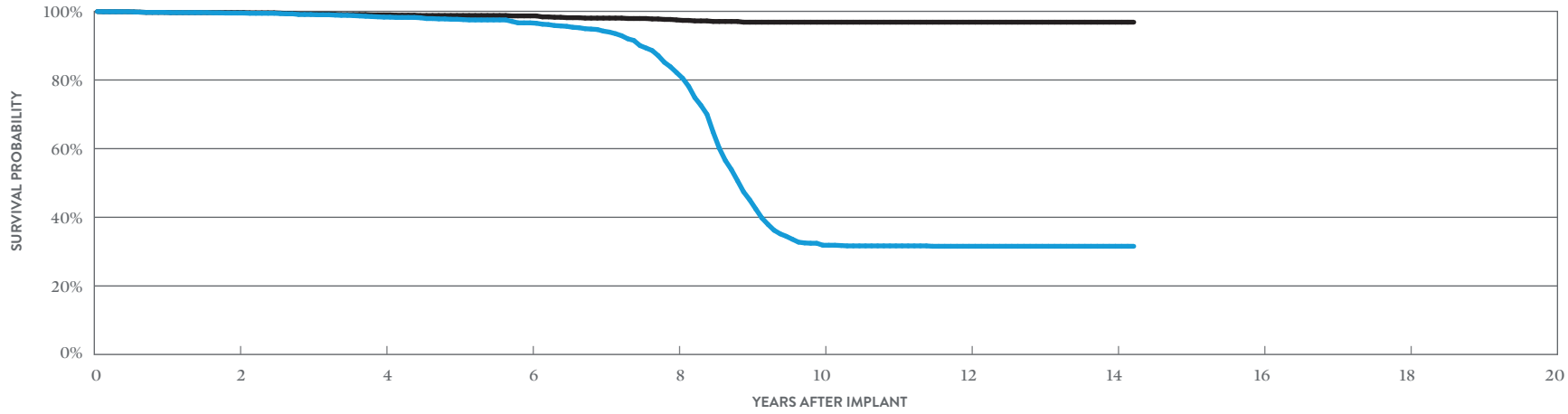
Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Current™ + VR

MODEL CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,641
Estimated Active US Implants	516
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	480
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 206)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.08%	3	0.08%
Electrical Interconnect	2	0.05%	0	0.00%
Battery	5	0.14%	0	0.00%
High Voltage Capacitor	2	0.05%	0	0.00%
Software/Firmware	0	0.00%	5	0.14%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	5	0.14%	2	0.05%
Other	2	0.05%	1	0.03%
Total	**19**	**0.52%**	**11**	**0.30%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 171 MONTHS
SURVIVAL PROBABILITY	99.50%	98.31%	96.64%	82.18%	31.86%	31.56%	31.56%	31.56%
± 1 STANDARD ERROR	0.12%	0.25%	0.38%	0.88%	1.08%	1.07%	1.07%	1.07%
SAMPLE SIZE	2,940	2,330	1,860	1,500	780	580	370	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 171 MONTHS
SURVIVAL PROBABILITY	99.64%	98.96%	98.67%	97.50%	96.84%	96.84%	96.84%	96.84%
± 1 STANDARD ERROR	0.10%	0.19%	0.23%	0.34%	0.42%	0.42%	0.42%	0.42%

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
CD1211-36Q	Current™ + VR***	8.4	8.0	7.6	7.0
CD1211-36	Current™ + VR***	8.4	8.0	7.6	7.0

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%	99.98%	99.98%							
CD1411-36Q	Ellipse™ VR	99.86%	99.68%	99.63%	99.60%	99.47%	99.37%	99.10%	98.12%	94.86%	86.93%
CD1411-36C	Ellipse™ VR	99.94%	99.91%	99.87%	99.75%	99.70%	99.59%	99.42%	98.75%	95.54%	
CD1357-40Q	Fortify Assura™ VR	99.86%	99.79%	99.78%	99.73%	99.70%	99.70%	99.62%	99.62%		
CD1357-40Q	Fortify Assura™ VR†	99.74%	99.25%	96.69%	90.48%	84.31%	79.70%	75.58%	71.79%	68.73%	67.20%
CD1357-40C	Fortify Assura™ VR	99.96%	99.88%	99.88%	99.83%	99.70%	99.43%	99.43%	99.43%		
CD1357-40C	Fortify Assura™ VR†	99.79%	99.25%	97.01%	91.45%	86.71%	81.96%	78.96%	75.85%	73.62%	
CD1257-40Q	Fortify Assura™ VR†	99.92%	99.77%	99.32%	97.24%	93.21%	90.00%	87.59%	85.59%	83.81%	83.33%
CD1257-40	Fortify Assura™ VR†	99.63%	99.52%	98.76%	98.29%	94.88%	92.18%	91.05%	89.08%	87.48%	86.76%
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.06%	97.58%	97.21%	96.85%	95.29%	94.04%	92.64%	91.79%
CD1311-36	Ellipse™ VR	98.86%	98.25%	97.92%	97.19%	96.32%	95.90%	94.28%	93.65%	93.08%	92.74%
CD1231-40Q	Fortify™ VR†	99.73%	99.66%	99.10%	97.75%	95.84%	92.76%	88.26%	84.78%	82.10%	79.61%
CD1231-40	Fortify™ VR†	99.74%	99.63%	99.34%	97.70%	96.26%	93.74%	89.29%	85.80%	83.86%	81.98%
CD1211-36Q	Current™ + VR	99.57%	99.34%	98.75%	98.48%	97.21%	96.54%	94.19%	87.04%	47.52%	28.56%
CD1211-36	Current™ + VR	99.70%	99.50%	99.08%	98.31%	97.69%	96.64%	94.24%	82.18%	45.09%	31.86%

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

†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%	99.98%	99.98%							
CD1411-36Q	Ellipse™ VR	99.88%	99.79%	99.74%	99.72%	99.64%	99.56%	99.46%	99.27%	98.98%	98.98%
CD1411-36C	Ellipse™ VR	99.94%	99.94%	99.91%	99.82%	99.78%	99.78%	99.71%	99.61%	99.10%	
CD1357-40Q	Fortify Assura™ VR	99.89%	99.86%	99.86%	99.82%	99.80%	99.80%	99.72%	99.72%		
CD1357-40Q	Fortify Assura™ VR†	99.77%	99.32%	96.76%	90.67%	84.53%	80.03%	75.98%	72.28%	69.32%	67.99%
CD1357-40C	Fortify Assura™ VR	99.96%	99.92%	99.92%	99.87%	99.80%	99.64%	99.64%	99.64%		
CD1357-40C	Fortify Assura™ VR†	99.90%	99.44%	97.20%	91.74%	87.09%	82.56%	79.62%	76.69%	74.90%	
CD1257-40Q	Fortify Assura™ VR†	99.96%	99.86%	99.57%	97.49%	93.50%	90.28%	88.08%	86.22%	84.66%	84.17%
CD1257-40	Fortify Assura™ VR†	99.63%	99.63%	99.16%	98.69%	95.69%	92.97%	92.16%	90.16%	89.13%	88.39%
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.06%	97.58%	97.21%	97.07%	96.53%	95.89%	95.27%	94.93%
CD1311-36	Ellipse™ VR	98.86%	98.41%	98.08%	97.34%	96.47%	96.05%	95.81%	95.81%	95.54%	95.19%
CD1231-40Q	Fortify™ VR†	99.83%	99.78%	99.33%	98.20%	96.64%	93.94%	89.55%	86.06%	83.64%	81.66%
CD1231-40	Fortify™ VR†	99.97%	99.90%	99.67%	98.17%	96.93%	94.45%	90.16%	86.70%	85.21%	83.80%
CD1211-36Q	Current™ + VR	99.69%	99.45%	98.92%	98.85%	98.31%	98.23%	98.23%	97.95%	97.59%	97.42%
CD1211-36	Current™ + VR	99.70%	99.64%	99.22%	98.96%	98.78%	98.67%	98.03%	97.50%	96.84%	96.84%

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

†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	14,267	1.40%	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%**
CD1411-36Q	Ellipse™ VR	24,130	6.10%	5	0.02%	0	0.00%	0	0.00%	10	0.04%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**17**	**0.07%**
CD1411-36C	Ellipse™ VR	7,486	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%	**0**	**0.00%**
CD1357-40Q	Fortify Assura™ VR	26,154	5.50%	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	19.20%	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	6,379	6.90%	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†	4,131	20.80%	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	15.20%	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†	2,294	17.70%	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†	16,341	16.70%	7	0.04%	2	0.01%	18	0.11%	2	0.01%	0	0.00%	0	0.00%	132	0.81%	9	0.06%	**170**	**1.04%**
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%**
CD1211-36Q	Current™ + VR	4,792	25.60%	4	0.08%	0	0.00%	6	0.13%	1	0.02%	0	0.00%	0	0.00%	6	0.13%	3	0.06%	**20**	**0.42%**
CD1211-36	Current™ + VR	3,641	24.30%	3	0.08%	2	0.05%	5	0.14%	2	0.05%	0	0.00%	0	0.00%	5	0.14%	2	0.05%	**19**	**0.52%**

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	14,267	1.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
CD1411-36Q	Ellipse™ VR	24,130	6.10%	8	0.03%	0	0.00%	2	<0.01%	6	0.02%	1	<0.01%	3	0.01%	2	<0.01%	5	0.02%	**27**	**0.11%**
CD1411-36C	Ellipse™ VR	7,486	8.10%	6	0.08%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	2	0.03%	**11**	**0.15%**
CD1357-40Q	Fortify Assura™ VR	26,154	5.50%	7	0.03%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	3	0.01%	**14**	**0.05%**
CD1357-40Q	Fortify Assura™ VR†	10,214	19.20%	8	0.08%	0	0.00%	9	0.09%	0	0.00%	0	0.00%	0	0.00%	735	7.20%	6	0.06%	**758**	**7.42%**
CD1357-40C	Fortify Assura™ VR	6,379	6.90%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	2	0.03%	1	0.02%	**6**	**0.09%**
CD1357-40C	Fortify Assura™ VR†	4,131	20.80%	2	0.05%	0	0.00%	6	0.15%	0	0.00%	1	0.02%	0	0.00%	232	5.62%	2	0.05%	**243**	**5.88%**
CD1257-40Q	Fortify Assura™ VR†	5,079	15.20%	2	0.04%	0	0.00%	4	0.08%	0	0.00%	0	0.00%	0	0.00%	166	3.27%	1	0.02%	**173**	**3.41%**
CD1257-40	Fortify Assura™ VR†	2,294	17.70%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	51	2.22%	1	0.04%	**54**	**2.35%**
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†	16,341	16.70%	10	0.06%	0	0.00%	49	0.30%	1	<0.01%	1	<0.01%	0	0.00%	443	2.71%	7	0.04%	**511**	**3.13%**
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%	148	2.18%	6	0.09%	**179**	**2.64%**
CD1211-36Q	Current™ + VR	4,792	25.60%	3	0.06%	0	0.00%	3	0.06%	0	0.00%	3	0.06%	1	0.02%	2	0.04%	2	0.04%	**14**	**0.29%**
CD1211-36	Current™ + VR	3,641	24.30%	3	0.08%	0	0.00%	0	0.00%	0	0.00%	5	0.14%	0	0.00%	2	0.05%	1	0.03%	**11**	**0.30%**

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	WORLWIDE 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	25,663	1.00%	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%**
CD1411-36Q	Ellipse™ VR	24,821	6.19%	10	0.04%	0	0.00%	0	0.00%	10	0.04%	0	0.00%	0	0.00%	0	0.00%	4	0.02%	**24**	**0.10%**
CD1411-36C	Ellipse™ VR	7,590	8.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1357-40Q	Fortify Assura™ VR	37,201	9.42%	14	0.04%	6	0.02%	0	0.00%	2	<0.01%	2	<0.01%	0	0.00%	136	0.37%	14	0.04%	**174**	**0.47%**
CD1357-40C	Fortify Assura™ VR	10,631	12.94%	6	0.06%	2	0.02%	0	0.00%	1	<0.01%	0	0.00%	2	0.02%	18	0.17%	0	0.00%	**29**	**0.27%**
CD1257-40Q	Fortify Assura™ VR	5,038	15.74%	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	18.41%	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	11.36%	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†	18,627	15.45%	16	0.09%	4	0.02%	36	0.19%	2	0.01%	0	0.00%	0	0.00%	290	1.56%	18	0.10%	**366**	**1.96%**
CD1231-40	Fortify™ VR†	11,859	11.45%	18	0.15%	0	0.00%	10	0.08%	10	0.08%	0	0.00%	0	0.00%	96	0.81%	12	0.10%	**146**	**1.23%**
CD1211-36Q	Current™ + VR	16,551	8.38%	30	0.18%	6	0.04%	18	0.11%	7	0.04%	0	0.00%	0	0.00%	16	0.10%	16	0.10%	**93**	**0.56%**
CD1211-36	Current™ + VR	14,877	6.83%	10	0.07%	8	0.05%	10	0.07%	6	0.04%	0	0.00%	0	0.00%	22	0.15%	22	0.15%	**78**	**0.52%**

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	WORLWIDE 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	25,663	1.00%	8	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**10**	**0.04%**
CD1411-36Q	Ellipse™ VR	24,821	6.19%	16	0.06%	0	0.00%	4	0.02%	6	0.02%	2	<0.01%	6	0.02%	4	0.02%	10	0.04%	**48**	**0.19%**
CD1411-36C	Ellipse™ VR	7,590	8.70%	12	0.16%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	2	0.03%	2	0.03%	4	0.05%	**21**	**0.28%**
CD1357-40Q	Fortify Assura™ VR	37,201	9.42%	30	0.08%	0	0.00%	20	0.05%	0	0.00%	2	<0.01%	2	<0.01%	1472	3.96%	18	0.05%	**1544**	**4.15%**
CD1357-40C	Fortify Assura™ VR	10,631	12.94%	10	0.09%	0	0.00%	12	0.11%	0	0.00%	2	0.02%	2	0.02%	468	4.40%	6	0.06%	**500**	**4.70%**
CD1257-40Q	Fortify Assura™ VR	5,038	15.74%	4	0.08%	0	0.00%	8	0.16%	0	0.00%	0	0.00%	0	0.00%	332	6.59%	2	0.04%	**346**	**6.87%**
CD1257-40	Fortify Assura™ VR	2,298	18.41%	0	0.00%	0	0.00%	4	0.17%	0	0.00%	0	0.00%	0	0.00%	102	4.44%	2	0.09%	**108**	**4.70%**
CD1311-36Q	Ellipse™ VR	4,912	11.36%	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†	18,627	15.45%	26	0.14%	2	0.01%	98	0.53%	1	<0.01%	2	0.01%	0	0.00%	976	5.24%	14	0.08%	**1119**	**6.01%**
CD1231-40	Fortify™ VR†	11,859	11.45%	14	0.12%	0	0.00%	30	0.25%	4	0.03%	0	0.00%	2	0.02%	326	2.75%	12	0.10%	**388**	**3.27%**
CD1211-36Q	Current™ + VR	16,551	8.38%	20	0.12%	0	0.00%	16	0.10%	3	0.02%	6	0.04%	2	0.01%	18	0.11%	28	0.17%	**93**	**0.56%**
CD1211-36	Current™ + VR	14,877	6.83%	16	0.11%	0	0.00%	6	0.04%	0	0.00%	18	0.12%	0	0.00%	12	0.08%	16	0.11%	**68**	**0.46%**

Definitions of malfunction categories can be found on pages 5-6.

Defibrillation Leads

Defibrillation Leads

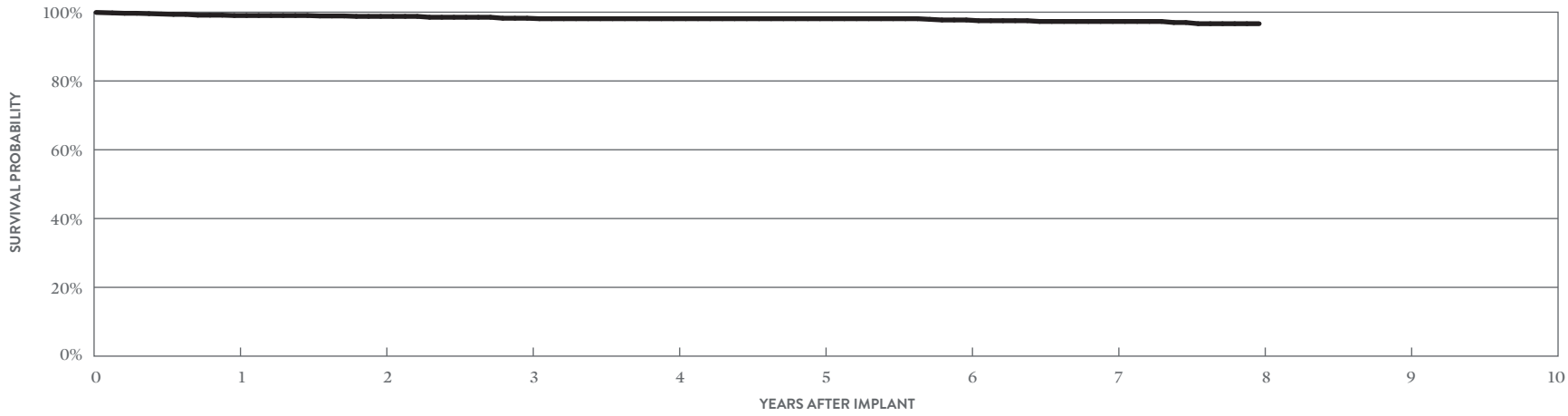
Optisure™ DF4

MODEL LDA230Q

US Regulatory Approval	February 2014
Registered US Implants	1,063
Estimated Active US Implants	541
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 223)	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	0.28%
Failure to Capture	0	0.00%	7	0.66%
Oversensing	0	0.00%	8	0.75%
Failure to Sense	0	0.00%	1	0.09%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.09%	1	0.09%
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**	**0.38%**	**20**	**1.88%**
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	0.28%
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	0.75%
Total	**12**	**1.13%**



YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.02%	98.78%	98.24%	98.10%	98.10%	97.73%	97.30%	96.65%
± 1 STANDARD ERROR	0.30%	0.37%	0.45%	0.47%	0.47%	0.54%	0.62%	0.77%
SAMPLE SIZE	960	820	740	670	610	530	430	210

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

Defibrillation Leads

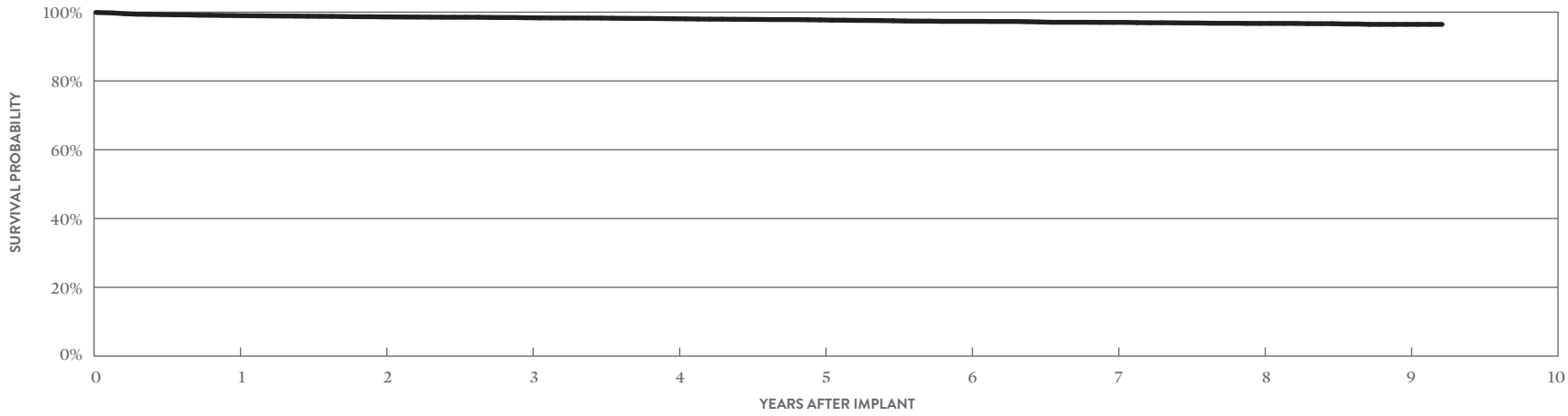
Optisure™ DF4

MODEL LDA220Q

US Regulatory Approval	February 2014
Registered US Implants	13,811
Estimated Active US Implants	7,824
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 223)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	15	0.11%	5	0.04%
Conductor Fracture	0	0.00%	8	0.06%
Lead Dislodgement	59	0.43%	88	0.64%
Failure to Capture	28	0.20%	96	0.70%
Oversensing	5	0.04%	83	0.60%
Failure to Sense	2	0.01%	10	0.07%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	0	0.00%	17	0.12%
Abnormal Defibrillation Impedance	5	0.04%	23	0.17%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	6	0.04%	8	0.06%
Total	**121**	**0.88%**	**340**	**2.46%**
Total Returned for Analysis	**46**		**89**	

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	7	0.05%
Lead-to-Can Contact	2	0.01%
Lead-to-Lead Contact	0	0.00%
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	83	0.60%
Total	**91**	**0.66%**



YEAR	1	2	3	4	5	6	7	8	9	AT 111 MONTHS
SURVIVAL PROBABILITY	99.01%	98.64%	98.38%	98.09%	97.75%	97.33%	97.03%	96.73%	96.45%	96.45%
± 1 STANDARD ERROR	0.09%	0.10%	0.11%	0.13%	0.15%	0.17%	0.19%	0.22%	0.28%	0.28%
SAMPLE SIZE	12,580	10,590	9,150	7,770	6,420	5,140	3,880	2,530	1,130	260

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

Defibrillation Leads

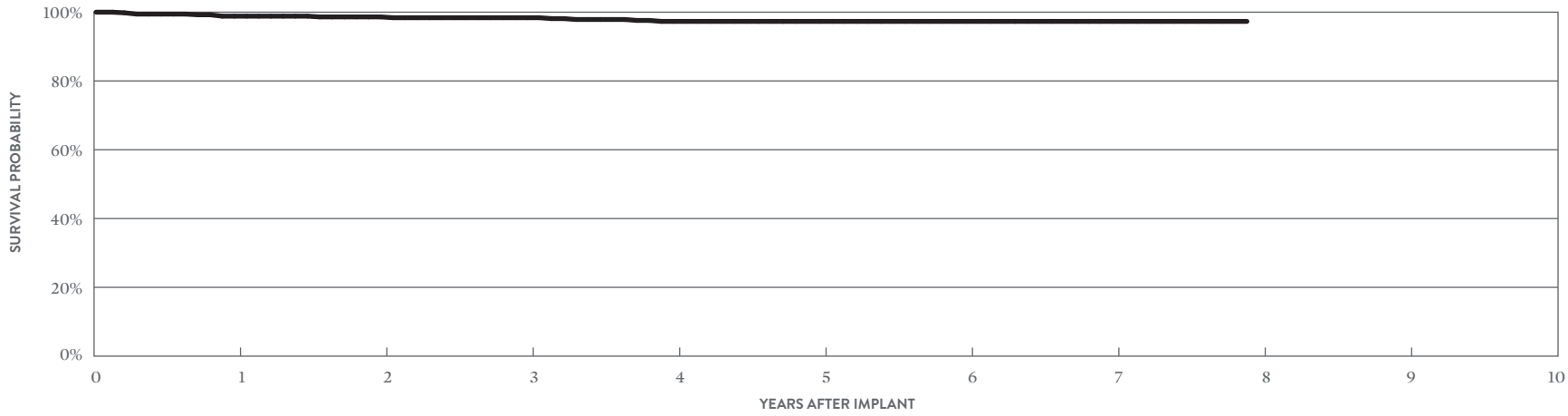
Optisure™

MODEL LDA220

US Regulatory Approval	February 2014
Registered US Implants	637
Estimated Active US Implants	314
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 223)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	0.16%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	0	0.00%	5	0.78%
Failure to Capture	0	0.00%	3	0.47%
Oversensing	0	0.00%	6	0.94%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	3	0.47%
Abnormal Defibrillation Impedance	0	0.00%	1	0.16%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.16%**	**18**	**2.83%**
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	0.94%
Total	**6**	**0.94%**



YEAR	1	2	3	4	5	6	7	AT 95 MONTHS
SURVIVAL PROBABILITY	98.84%	98.62%	98.39%	97.32%	97.32%	97.32%	97.32%	97.32%
± 1 STANDARD ERROR	0.47%	0.52%	0.57%	0.77%	0.77%	0.77%	0.77%	0.77%
SAMPLE SIZE	560	460	410	370	340	310	270	200

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

Defibrillation Leads

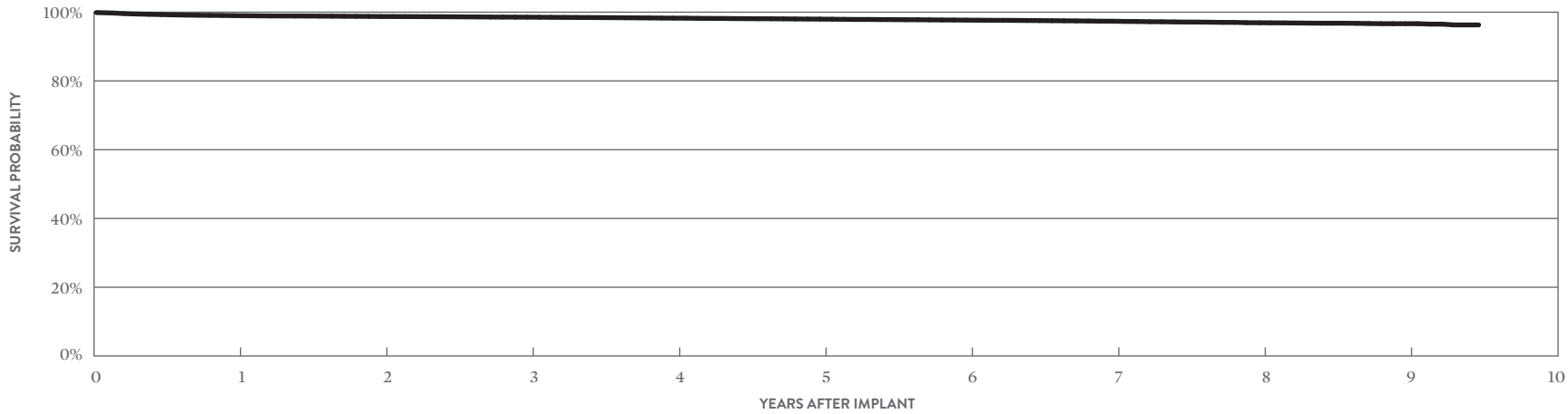
Optisure™ DF4

MODEL LDA210Q

US Regulatory Approval	February 2014
Registered US Implants	71,740
Estimated Active US Implants	43,528
Insulation	Optim™*
Type and/or Fixation	Single 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	135	0.19%	37	0.05%
Conductor Fracture	2	<0.01%	33	0.05%
Lead Dislodgement	235	0.33%	423	0.59%
Failure to Capture	134	0.19%	343	0.48%
Oversensing	49	0.07%	291	0.41%
Failure to Sense	17	0.02%	32	0.04%
Insulation Breach	5	<0.01%	2	<0.01%
Abnormal Pacing Impedance	9	0.01%	66	0.09%
Abnormal Defibrillation Impedance	12	0.02%	60	0.08%
Extracardiac Stimulation	6	<0.01%	6	<0.01%
Other	20	0.03%	47	0.07%
Total	**624**	**0.87%**	**1340**	**1.87%**
Total Returned for Analysis	**218**		**442**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	8	0.01%
Clavicular Crush	1	<0.01%
In the Pocket	2	<0.01%
Intravascular	5	<0.01%
Insulation Breach	25	0.03%
Lead-to-Can Contact	14	0.02%
Lead-to-Lead Contact	9	0.01%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	5	<0.01%
Extrinsic Factors	425	0.59%
Total	**463**	**0.65%**



YEAR	1	2	3	4	5	6	7	8	9	AT 114 MONTHS
SURVIVAL PROBABILITY	98.99%	98.74%	98.54%	98.26%	97.98%	97.69%	97.37%	96.92%	96.65%	96.29%
± 1 STANDARD ERROR	0.04%	0.04%	0.05%	0.06%	0.07%	0.08%	0.09%	0.12%	0.16%	0.31%
SAMPLE SIZE	63,280	49,440	39,570	31,330	24,020	17,470	11,960	7,150	2,950	230

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

Defibrillation Leads

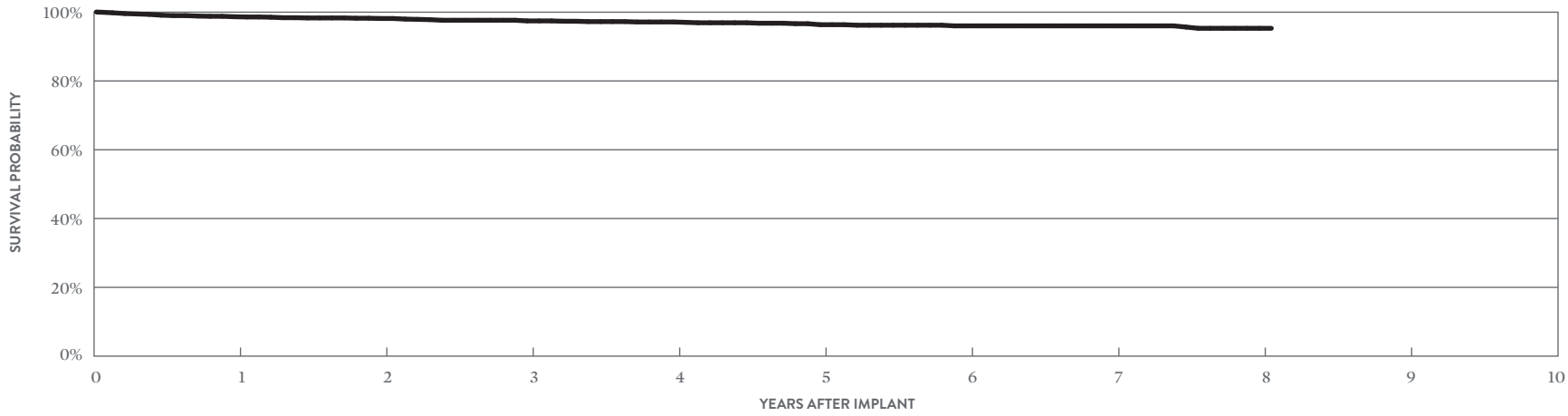
Optisure™

MODEL LDA210

US Regulatory Approval	February 2014
Registered US Implants	1,907
Estimated Active US Implants	1,075
Insulation	Optim™*
Type and/or Fixation	Single 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	3	0.16%	0	0.00%
Conductor Fracture	0	0.00%	5	0.26%
Lead Dislodgement	7	0.37%	10	0.52%
Failure to Capture	3	0.16%	14	0.73%
Oversensing	3	0.16%	27	1.42%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	6	0.31%
Abnormal Defibrillation Impedance	0	0.00%	2	0.10%
Extracardiac Stimulation	0	0.00%	2	0.10%
Other	1	0.05%	2	0.10%
Total	**17**	**0.89%**	**68**	**3.57%**
Total Returned for Analysis	**6**		**15**	

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	0.05%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	0.05%
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	16	0.84%
Total	**17**	**0.89%**



YEAR	1	2	3	4	5	6	7	8	AT 97 MONTHS
SURVIVAL PROBABILITY	98.67%	98.16%	97.46%	97.15%	96.36%	96.02%	96.02%	95.31%	95.31%
± 1 STANDARD ERROR	0.27%	0.33%	0.40%	0.45%	0.52%	0.60%	0.60%	0.78%	0.78%
SAMPLE SIZE	1,680	1,340	1,120	930	750	580	420	280	210

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

Defibrillation Leads

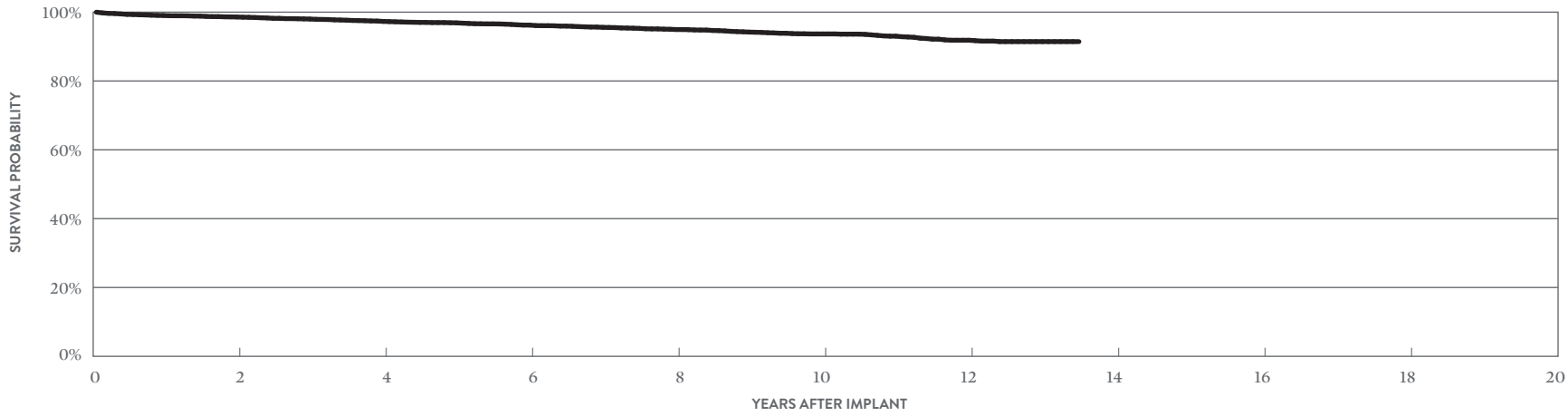
Durata™ DF4

MODELS 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	7,317
Estimated Active US Implants	2,862
Insulation	Optim™*
Type and/or Fixation	Dual Coil, 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	0.08%	8	0.11%
Conductor Fracture	1	0.01%	34	0.46%
Lead Dislodgement	22	0.30%	38	0.52%
Failure to Capture	14	0.19%	92	1.26%
Oversensing	3	0.04%	83	1.13%
Failure to Sense	0	0.00%	2	0.03%
Insulation Breach	0	0.00%	6	0.08%
Abnormal Pacing Impedance	1	0.01%	31	0.42%
Abnormal Defibrillation Impedance	0	0.00%	24	0.33%
Extracardiac Stimulation	1	0.01%	0	0.00%
Other	1	0.01%	4	0.05%
Total	**49**	**0.67%**	**322**	**4.40%**
Total Returned for Analysis	**22**		**78**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	6	0.08%
Clavicular Crush	0	0.00%
In the Pocket	3	0.04%
Intravascular	3	0.04%
Insulation Breach	17	0.23%
Lead-to-Can Contact	9	0.12%
Lead-to-Lead Contact	5	0.07%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Other	2	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	60	0.82%
Total	**83**	**1.13%**



YEAR	2	4	6	8	10	12	AT 162 MONTHS
SURVIVAL PROBABILITY	98.59%	97.31%	96.24%	94.95%	93.67%	91.84%	91.44%
± 1 STANDARD ERROR	0.15%	0.21%	0.27%	0.33%	0.41%	0.56%	0.60%
SAMPLE SIZE	5,830	4,660	3,660	2,740	1,870	960	210

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

Defibrillation Leads

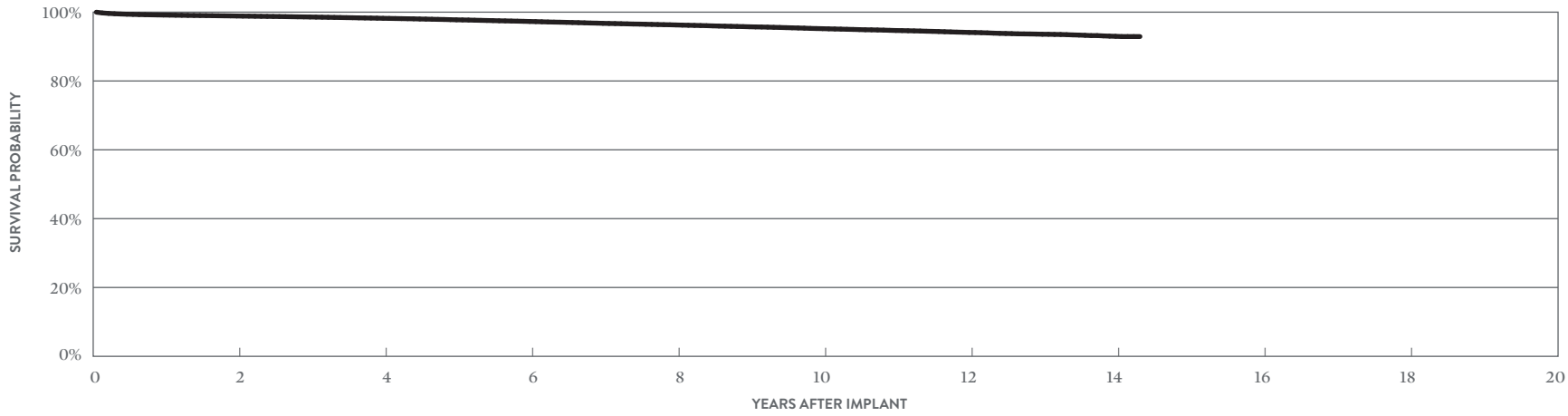
Durata™ DF4

MODELS 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	147,605
Estimated Active US Implants	56,992
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	109	0.07%	52	0.04%
Conductor Fracture	2	<0.01%	302	0.20%
Lead Dislodgement	310	0.21%	749	0.51%
Failure to Capture	147	0.10%	1258	0.85%
Oversensing	55	0.04%	1341	0.91%
Failure to Sense	17	0.01%	117	0.08%
Insulation Breach	0	0.00%	85	0.06%
Abnormal Pacing Impedance	7	<0.01%	290	0.20%
Abnormal Defibrillation Impedance	11	<0.01%	622	0.42%
Extracardiac Stimulation	7	<0.01%	10	<0.01%
Other	45	0.03%	117	0.08%
Total	**710**	**0.48%**	**4943**	**3.35%**
Total Returned for Analysis	**345**		**1335**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	41	0.03%
Clavicular Crush	7	<0.01%
In the Pocket	13	<0.01%
Intravascular	21	0.01%
Insulation Breach	422	0.29%
Lead-to-Can Contact	253	0.17%
Lead-to-Lead Contact	45	0.03%
Clavicular Crush	37	0.03%
Externalized Conductors	0	0.00%
Other	87	0.06%
Crimps, Welds & Bonds	2	<0.01%
Other	39	0.03%
Extrinsic Factors	1045	0.71%
Total	**1549**	**1.05%**



YEAR	2	4	6	8	10	12	14	AT 172 MONTHS
SURVIVAL PROBABILITY	98.88%	98.21%	97.29%	96.28%	95.20%	94.10%	92.98%	92.91%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.06%	0.08%	0.10%	0.15%	0.17%
SAMPLE SIZE	120,150	96,930	77,680	61,120	43,740	24,720	5,950	400

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

Defibrillation Leads

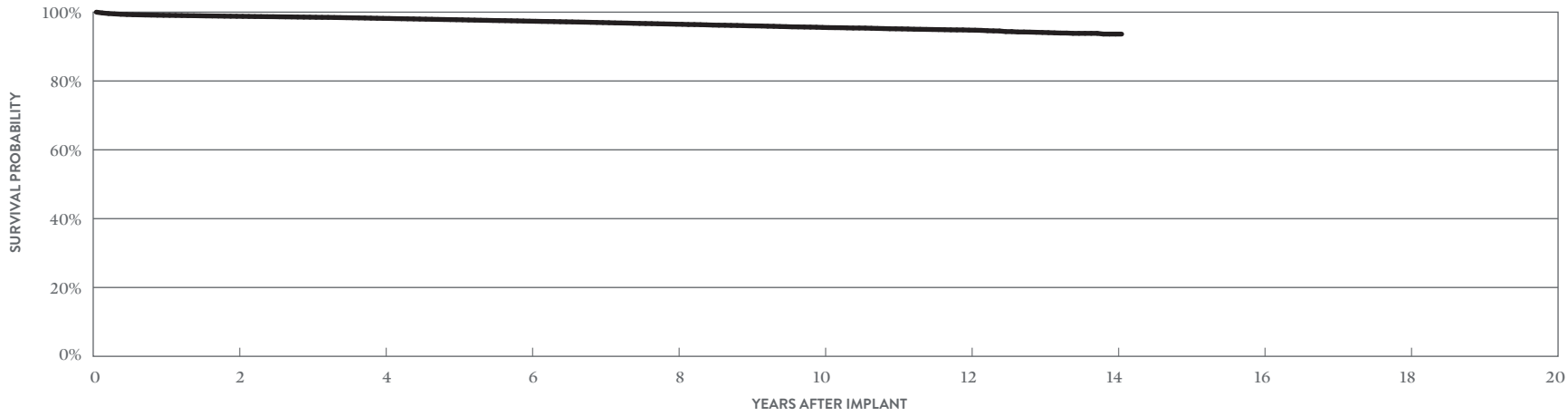
Durata™ DF4

MODEL 7122Q

US Regulatory Approval	January 2009
Registered US Implants	174,733
Estimated Active US Implants	87,746
Insulation	Optim™*
Type and/or Fixation	Single 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	233	0.13%	78	0.04%
Conductor Fracture	4	<0.01%	146	0.08%
Lead Dislodgement	452	0.26%	944	0.54%
Failure to Capture	254	0.15%	1041	0.60%
Oversensing	79	0.05%	959	0.55%
Failure to Sense	17	<0.01%	90	0.05%
Insulation Breach	2	<0.01%	54	0.03%
Abnormal Pacing Impedance	18	0.01%	225	0.13%
Abnormal Defibrillation Impedance	14	<0.01%	209	0.12%
Extracardiac Stimulation	5	<0.01%	15	<0.01%
Other	57	0.03%	134	0.08%
Total	**1135**	**0.65%**	**3895**	**2.23%**
Total Returned for Analysis	**457**		**1264**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	26	0.01%
Clavicular Crush	4	<0.01%
In the Pocket	10	<0.01%
Intravascular	12	<0.01%
Insulation Breach	289	0.17%
Lead-to-Can Contact	180	0.10%
Lead-to-Lead Contact	43	0.02%
Clavicular Crush	22	0.01%
Externalized Conductors	0	0.00%
Other	44	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	22	0.01%
Extrinsic Factors	1075	0.62%
Total	**1413**	**0.81%**



YEAR	2	4	6	8	10	12	14	AT 169 MONTHS
SURVIVAL PROBABILITY	98.80%	98.19%	97.38%	96.50%	95.56%	94.78%	93.63%	93.63%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.07%	0.09%	0.13%	0.32%	0.32%
SAMPLE SIZE	125,860	87,080	58,660	37,280	18,980	6,340	1,040	240

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

Defibrillation Leads

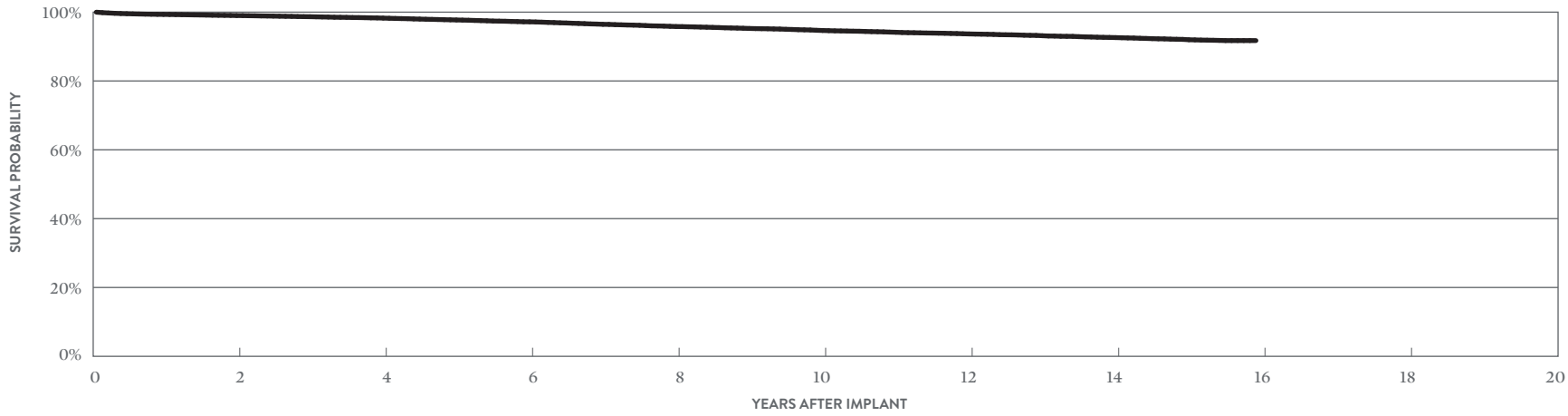
Durata™

MODELS 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	63,479
Estimated Active US Implants	17,832
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	41	0.06%	19	0.03%
Conductor Fracture	2	<0.01%	192	0.30%
Lead Dislodgement	70	0.11%	192	0.30%
Failure to Capture	26	0.04%	465	0.73%
Oversensing	51	0.08%	999	1.57%
Failure to Sense	5	<0.01%	73	0.11%
Insulation Breach	0	0.00%	79	0.12%
Abnormal Pacing Impedance	2	<0.01%	249	0.39%
Abnormal Defibrillation Impedance	21	0.03%	406	0.64%
Extracardiac Stimulation	0	0.00%	3	<0.01%
Other	21	0.03%	65	0.10%
Total	**239**	**0.38%**	**2742**	**4.32%**
Total Returned for Analysis	**93**		**657**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	35	0.06%
Clavicular Crush	2	<0.01%
In the Pocket	24	0.04%
Intravascular	9	0.01%
Insulation Breach	246	0.39%
Lead-to-Can Contact	130	0.20%
Lead-to-Lead Contact	48	0.08%
Clavicular Crush	19	0.03%
Externalized Conductors	0	0.00%
Other	49	0.08%
Crimps, Welds & Bonds	1	<0.01%
Other	10	0.02%
Extrinsic Factors	493	0.78%
Total	**785**	**1.24%**



YEAR	2	4	6	8	10	12	14	AT 191 MONTHS
SURVIVAL PROBABILITY	99.01%	98.27%	97.19%	95.82%	94.67%	93.67%	92.61%	91.74%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.10%	0.12%	0.14%	0.16%	0.20%
SAMPLE SIZE	51,160	41,490	34,140	28,570	24,290	20,010	13,780	260

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

Defibrillation Leads

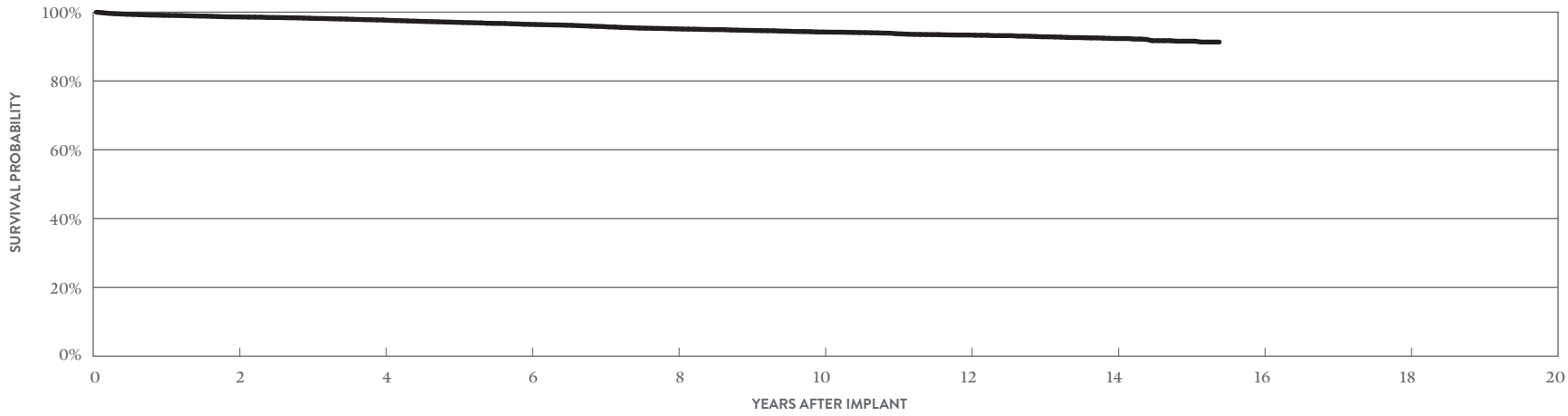
Durata™

MODEL 7122

US Regulatory Approval	September 2007
Registered US Implants	16,845
Estimated Active US Implants	5,599
Insulation	Optim™*
Type and/or Fixation	Single 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	12	0.07%	5	0.03%
Conductor Fracture	1	<0.01%	52	0.31%
Lead Dislodgement	24	0.14%	80	0.47%
Failure to Capture	19	0.11%	128	0.76%
Oversensing	13	0.08%	241	1.43%
Failure to Sense	0	0.00%	13	0.08%
Insulation Breach	2	0.01%	27	0.16%
Abnormal Pacing Impedance	3	0.02%	61	0.36%
Abnormal Defibrillation Impedance	3	0.02%	53	0.31%
Extracardiac Stimulation	2	0.01%	2	0.01%
Other	4	0.02%	16	0.09%
Total	**83**	**0.49%**	**678**	**4.02%**
Total Returned for Analysis	**38**		**214**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	18	0.11%
Clavicular Crush	1	<0.01%
In the Pocket	13	0.08%
Intravascular	4	0.02%
Insulation Breach	87	0.52%
Lead-to-Can Contact	47	0.28%
Lead-to-Lead Contact	27	0.16%
Clavicular Crush	2	0.01%
Externalized Conductors	1	<0.01%
Other	10	0.06%
Crimps, Welds & Bonds	0	0.00%
Other	4	0.02%
Extrinsic Factors	163	0.97%
Total	**272**	**1.61%**



YEAR	2	4	6	8	10	12	14	AT 185 MONTHS
SURVIVAL PROBABILITY	98.62%	97.72%	96.45%	95.15%	94.23%	93.36%	92.33%	91.31%
± 1 STANDARD ERROR	0.10%	0.13%	0.17%	0.21%	0.25%	0.28%	0.35%	0.51%
SAMPLE SIZE	13,560	10,740	8,570	6,740	5,040	3,520	1,860	210

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

Defibrillation Leads

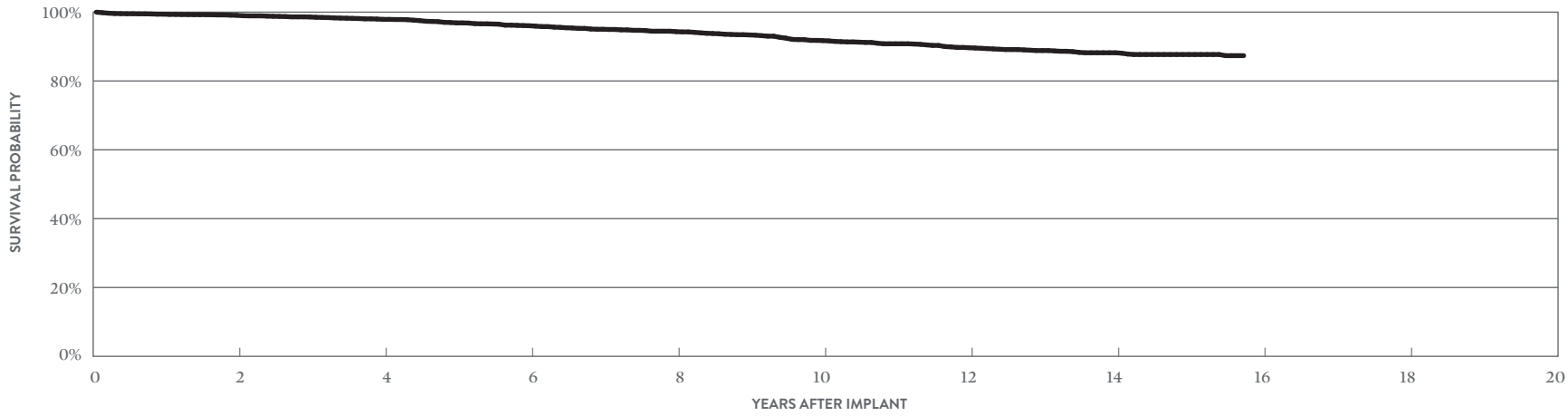
Riata™ ST Optim™

MODELS 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,583
Estimated Active US Implants	875
Insulation	Optim™*
Type and/or Fixation	Dual Coil, 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	3	0.08%	2	0.06%
Conductor Fracture	1	0.03%	29	0.81%
Lead Dislodgement	3	0.08%	13	0.36%
Failure to Capture	6	0.17%	44	1.23%
Oversensing	4	0.11%	75	2.09%
Failure to Sense	4	0.11%	3	0.08%
Insulation Breach	0	0.00%	9	0.25%
Abnormal Pacing Impedance	0	0.00%	18	0.50%
Abnormal Defibrillation Impedance	0	0.00%	22	0.61%
Extracardiac Stimulation	0	0.00%	1	0.03%
Other	0	0.00%	3	0.08%
Total	**21**	**0.59%**	**219**	**6.11%**
Total Returned for Analysis	**6**		**50**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	4	0.11%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	4	0.11%
Insulation Breach	24	0.67%
Lead-to-Can Contact	10	0.28%
Lead-to-Lead Contact	4	0.11%
Clavicular Crush	2	0.06%
Externalized Conductors	1	0.03%
Other	7	0.20%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	25	0.70%
Total	**53**	**1.48%**



YEAR	2	4	6	8	10	12	14	AT 189 MONTHS
SURVIVAL PROBABILITY	99.08%	97.90%	96.05%	94.33%	91.73%	89.66%	88.20%	87.36%
± 1 STANDARD ERROR	0.17%	0.28%	0.41%	0.51%	0.66%	0.76%	0.84%	0.93%
SAMPLE SIZE	2,730	2,150	1,740	1,480	1,290	1,100	800	200

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

Defibrillation Leads

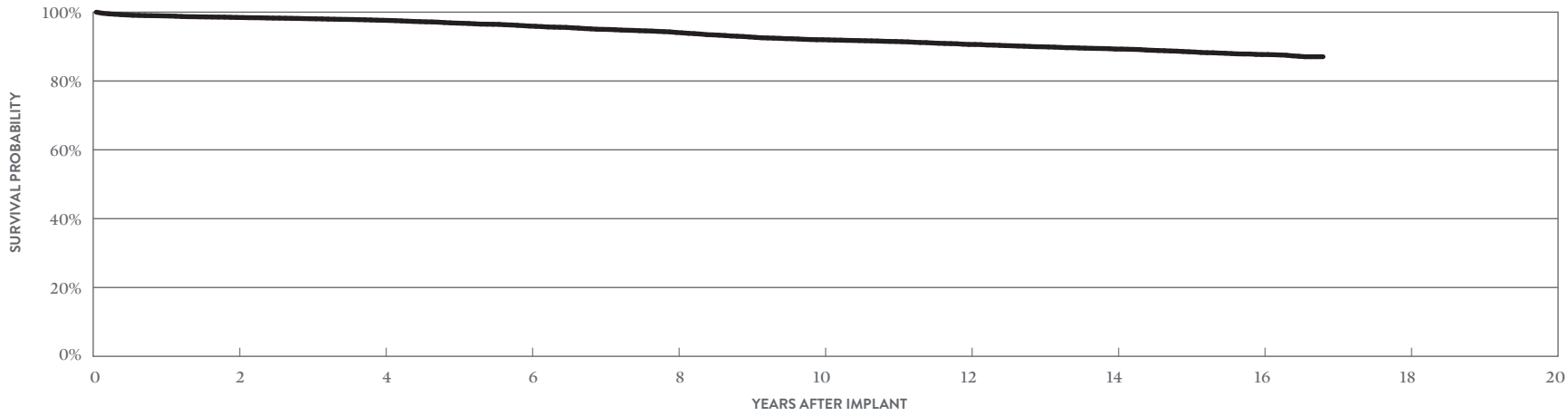
Riata™ ST Optim™

MODELS 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,622
Estimated Active US Implants	3,453
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	33	0.21%	17	0.11%
Conductor Fracture	0	0.00%	76	0.49%
Lead Dislodgement	27	0.17%	67	0.43%
Failure to Capture	17	0.11%	192	1.23%
Oversensing	19	0.12%	319	2.04%
Failure to Sense	8	0.05%	23	0.15%
Insulation Breach	0	0.00%	30	0.19%
Abnormal Pacing Impedance	2	0.01%	65	0.42%
Abnormal Defibrillation Impedance	4	0.03%	126	0.81%
Extracardiac Stimulation	3	0.02%	2	0.01%
Other	0	0.00%	30	0.19%
Total	**113**	**0.72%**	**947**	**6.06%**
Total Returned for Analysis	**53**		**248**	

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	78	0.50%
Lead-to-Can Contact	37	0.24%
Lead-to-Lead Contact	9	0.06%
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	202	1.29%
Total	**294**	**1.88%**



YEAR	2	4	6	8	10	12	14	16	AT 202 MONTHS
SURVIVAL PROBABILITY	98.46%	97.63%	95.95%	94.10%	91.99%	90.61%	89.27%	87.68%	87.05%
± 1 STANDARD ERROR	0.10%	0.14%	0.19%	0.24%	0.30%	0.34%	0.37%	0.42%	0.49%
SAMPLE SIZE	12,280	9,670	7,840	6,480	5,450	4,770	4,130	2,670	260

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

Defibrillation Leads

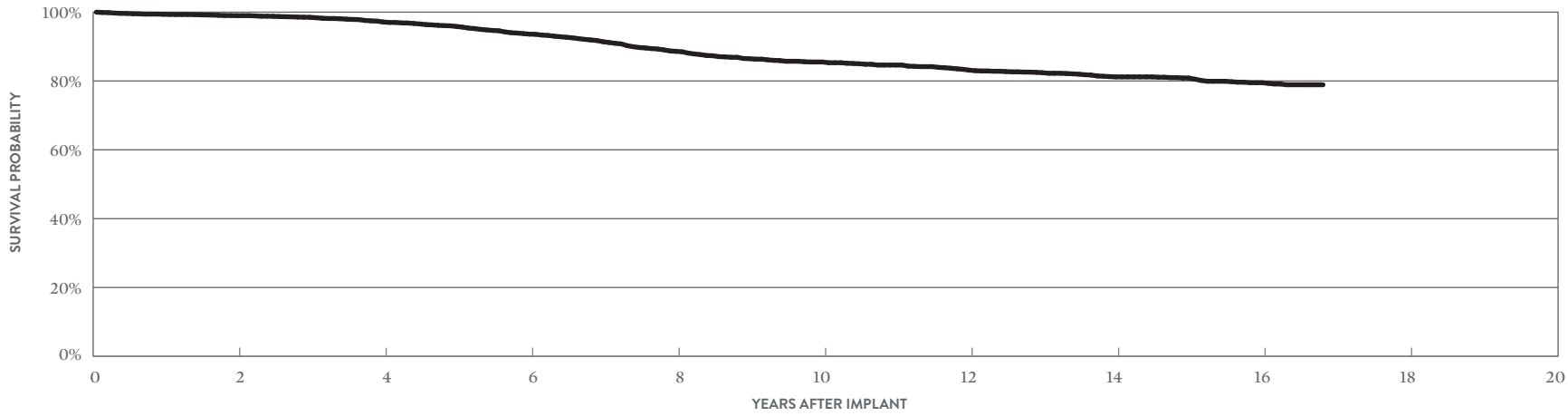
Riata™ ST

MODELS 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,057
Estimated Active US Implants	802
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 224)	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%	39	0.96%
Lead Dislodgement	5	0.12%	5	0.12%
Failure to Capture	1	0.02%	58	1.43%
Oversensing	4	0.10%	126	3.11%
Failure to Sense	0	0.00%	16	0.39%
Insulation Breach	0	0.00%	66	1.63%
Abnormal Pacing Impedance	2	0.05%	22	0.54%
Abnormal Defibrillation Impedance	0	0.00%	37	0.91%
Extracardiac Stimulation	0	0.00%	1	0.02%
Other	1	0.02%	12	0.30%
Total	**17**	**0.42%**	**386**	**9.51%**
Total Returned for Analysis	**3**		**88**	

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	72	1.77%
Lead-to-Can Contact	35	0.86%
Lead-to-Lead Contact	22	0.54%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.05%
Other	13	0.32%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	33	0.81%
Total	**110**	**2.71%**



YEAR	2	4	6	8	10	12	14	16	AT 202 MONTHS
SURVIVAL PROBABILITY	98.99%	97.14%	93.61%	88.61%	85.52%	83.15%	81.19%	79.50%	78.90%
± 1 STANDARD ERROR	0.17%	0.30%	0.50%	0.70%	0.81%	0.89%	0.96%	1.05%	1.09%
SAMPLE SIZE	3,170	2,470	1,910	1,510	1,240	1,080	940	580	210

Defibrillation Leads

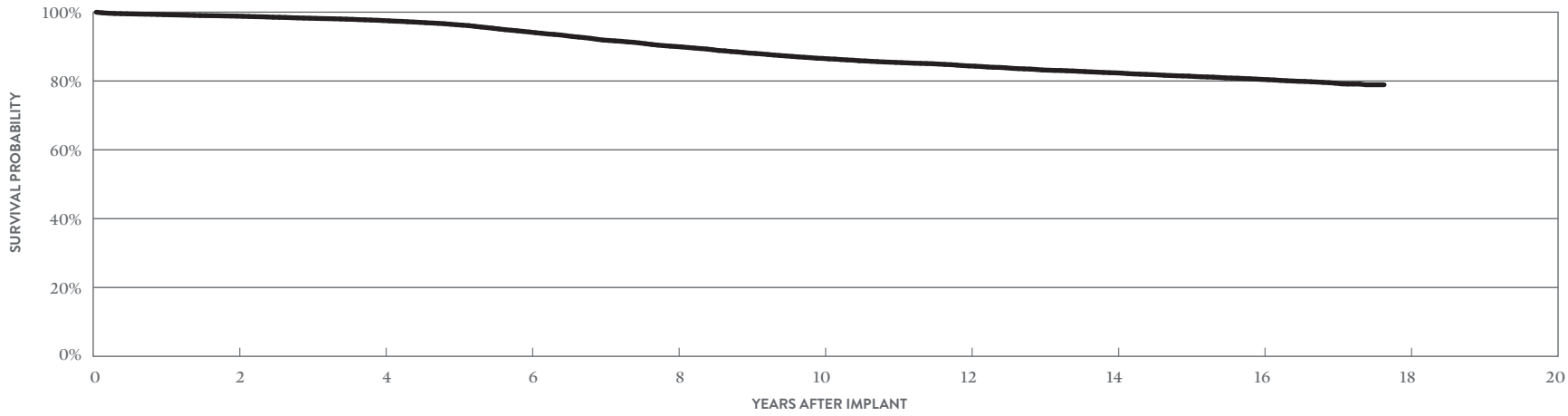
Riata™ ST

MODELS 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	35,059
Estimated Active US Implants	6,582
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 224)	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%	193	0.55%
Lead Dislodgement	38	0.11%	61	0.17%
Failure to Capture	43	0.12%	412	1.18%
Oversensing	40	0.11%	1078	3.07%
Failure to Sense	7	0.02%	66	0.19%
Insulation Breach	2	<0.01%	809	2.31%
Abnormal Pacing Impedance	8	0.02%	146	0.42%
Abnormal Defibrillation Impedance	4	0.01%	290	0.83%
Extracardiac Stimulation	3	<0.01%	7	0.02%
Other	11	0.03%	107	0.31%
Total	**198**	**0.56%**	**3204**	**9.14%**
Total Returned for Analysis	**97**		**848**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	25	0.07%
Clavicular Crush	4	0.01%
In the Pocket	7	0.02%
Intravascular	14	0.04%
Insulation Breach	698	1.99%
Lead-to-Can Contact	364	1.04%
Lead-to-Lead Contact	185	0.53%
Clavicular Crush	12	0.03%
Externalized Conductors	45	0.13%
Other	92	0.26%
Crimps, Welds & Bonds	2	<0.01%
Other	1	<0.01%
Extrinsic Factors	342	0.98%
Total	**1068**	**3.05%**



YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	98.85%	97.56%	94.22%	90.01%	86.56%	84.37%	82.36%	80.46%	78.90%
± 1 STANDARD ERROR	0.06%	0.09%	0.16%	0.22%	0.27%	0.29%	0.32%	0.34%	0.41%
SAMPLE SIZE	28,150	21,880	16,990	13,230	10,800	9,360	8,230	6,220	220

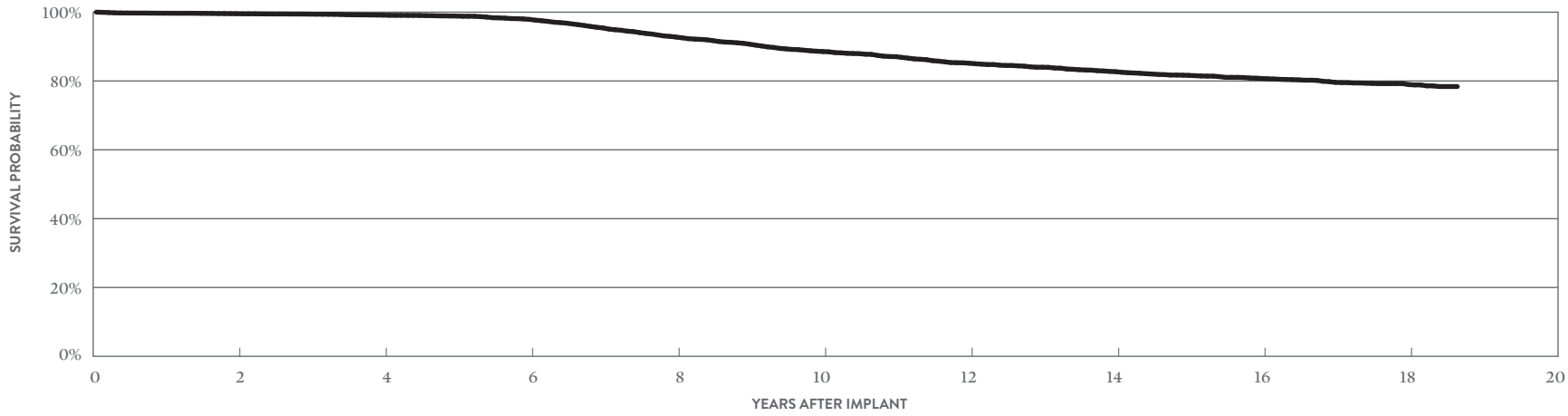
Defibrillation Leads

Riata™ i

MODELS 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,700
Estimated Active US Implants	1,578
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 224)	One

MALFUNCTIONS	QTY	RATE
Conductor Fracture	8	0.08%
Clavicular Crush	1	0.01%
In the Pocket	1	0.01%
Intravascular	6	0.06%
Insulation Breach	217	2.24%
Lead-to-Can Contact	92	0.95%
Lead-to-Lead Contact	59	0.61%
Clavicular Crush	2	0.02%
Externalized Conductors	21	0.22%
Other	43	0.44%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	60	0.62%
Total	**286**	**2.95%**



YEAR	2	4	6	8	10	12	14	16	18	AT 224 MONTHS
SURVIVAL PROBABILITY	99.55%	99.13%	97.89%	92.76%	88.55%	85.16%	82.70%	80.72%	78.95%	78.39%
± 1 STANDARD ERROR	0.07%	0.11%	0.18%	0.39%	0.51%	0.60%	0.66%	0.70%	0.75%	0.81%
SAMPLE SIZE	7,860	6,130	4,680	3,570	2,830	2,350	2,050	1,780	1,120	230

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	99.02%	98.78%	98.24%	98.10%	98.10%	97.73%	97.30%	96.65%		
LDA220Q	Optisure™ DF4	99.01%	98.64%	98.38%	98.09%	97.75%	97.33%	97.03%	96.73%	96.45%	
LDA220	Optisure™	98.84%	98.62%	98.39%	97.32%	97.32%	97.32%	97.32%			
LDA210Q	Optisure™ DF4	98.99%	98.74%	98.54%	98.26%	97.98%	97.69%	97.37%	96.92%	96.65%	
LDA210	Optisure™	98.67%	98.16%	97.46%	97.15%	96.36%	96.02%	96.02%	95.31%		
7170Q/7171Q	Durata™ DF4	99.03%	98.59%	98.00%	97.31%	96.89%	96.24%	95.58%	94.95%	94.20%	93.67%
7120Q/7121Q	Durata™ DF4	99.16%	98.88%	98.59%	98.21%	97.77%	97.29%	96.75%	96.28%	95.75%	95.20%
7122Q	Durata™ DF4	99.09%	98.80%	98.54%	98.19%	97.80%	97.38%	96.97%	96.50%	96.03%	95.56%
7120/7121	Durata™	99.34%	99.01%	98.68%	98.27%	97.73%	97.19%	96.46%	95.82%	95.26%	94.67%
7122	Durata™	99.09%	98.62%	98.23%	97.72%	97.05%	96.45%	95.82%	95.15%	94.71%	94.23%
7070/7071	Riata™ ST Optim™	99.41%	99.08%	98.59%	97.90%	96.88%	96.05%	95.03%	94.33%	93.38%	91.73%
7020/7021	Riata™ ST Optim™	98.91%	98.46%	98.09%	97.63%	96.82%	95.95%	95.00%	94.10%	92.80%	91.99%
7040/7041	Riata™ ST	99.37%	98.99%	98.50%	97.14%	95.84%	93.61%	91.41%	88.61%	86.48%	85.52%
7000/7001	Riata™ ST	99.28%	98.85%	98.24%	97.56%	96.34%	94.22%	91.90%	90.01%	88.10%	86.56%
1590/1591	Riata™ i	99.69%	99.55%	99.42%	99.13%	98.87%	97.89%	95.42%	92.76%	90.70%	88.55%

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 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	1,063	541	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**	**0.38%**	**1**
LDA220Q	Feb-14	13,811	7,824	15	0.11%	0	0.00%	59	0.43%	28	0.20%	5	0.04%	2	0.01%	0	0.00%	0	0.00%	5	0.04%	1	<0.01%	6	0.04%	**121**	**0.88%**	**46**
LDA220	Feb-14	637	314	1	0.16%	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**	**0.16%**	**0**
LDA210Q	Feb-14	71,740	43,528	135	0.19%	2	<0.01%	235	0.33%	134	0.19%	49	0.07%	17	0.02%	5	<0.01%	9	0.01%	12	0.02%	6	<0.01%	20	0.03%	**624**	**0.87%**	**218**
LDA210	Feb-14	1,907	1,075	3	0.16%	0	0.00%	7	0.37%	3	0.16%	3	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.05%	**17**	**0.89%**	**6**
7170Q/7171Q	Jul-09	7,317	2,862	6	0.08%	1	0.01%	22	0.30%	14	0.19%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	**49**	**0.67%**	**22**
7120Q/7121Q	Jan-09	147,605	56,992	109	0.07%	2	<0.01%	310	0.21%	147	0.10%	55	0.04%	17	0.01%	0	0.00%	7	<0.01%	11	<0.01%	7	<0.01%	45	0.03%	**710**	**0.48%**	**345**
7122Q	Jan-09	174,733	87,746	233	0.13%	4	<0.01%	452	0.26%	254	0.15%	79	0.05%	17	<0.01%	2	<0.01%	18	0.01%	14	<0.01%	5	<0.01%	57	0.03%	**1135**	**0.65%**	**457**
7120/7121	Sep-07	63,479	17,832	41	0.06%	2	<0.01%	70	0.11%	26	0.04%	51	0.08%	5	<0.01%	0	0.00%	2	<0.01%	21	0.03%	0	0.00%	21	0.03%	**239**	**0.38%**	**93**
7122	Sep-07	16,845	5,599	12	0.07%	1	<0.01%	24	0.14%	19	0.11%	13	0.08%	0	0.00%	2	0.01%	3	0.02%	3	0.02%	2	0.01%	4	0.02%	**83**	**0.49%**	**38**
7070/7071	Jul-06	3,583	875	3	0.08%	1	0.03%	3	0.08%	6	0.17%	4	0.11%	4	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**21**	**0.59%**	**6**
7020/7021	Jul-06	15,622	3,453	33	0.21%	0	0.00%	27	0.17%	17	0.11%	19	0.12%	8	0.05%	0	0.00%	2	0.01%	4	0.03%	3	0.02%	0	0.00%	**113**	**0.72%**	**53**
7040/7041	Mar-06	4,057	802	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**	**0.42%**	**3**
7000/7001	Jun-05	35,059	6,582	42	0.12%	0	0.00%	38	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%	**198**	**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	1,063	541	0	0.00%	0	0.00%	3	0.28%	7	0.66%	8	0.75%	1	0.09%	0	0.00%	1	0.09%	0	0.00%	0	0.00%	0	0.00%	**20**	**1.88%**	**8**
LDA220Q	Feb-14	13,811	7,824	5	0.04%	8	0.06%	88	0.64%	96	0.70%	83	0.60%	10	0.07%	2	0.01%	17	0.12%	23	0.17%	0	0.00%	8	0.06%	**340**	**2.46%**	**89**
LDA220	Feb-14	637	314	0	0.00%	0	0.00%	5	0.78%	3	0.47%	6	0.94%	0	0.00%	0	0.00%	3	0.47%	1	0.16%	0	0.00%	0	0.00%	**18**	**2.83%**	**4**
LDA210Q	Feb-14	71,740	43,528	37	0.05%	33	0.05%	423	0.59%	343	0.48%	291	0.41%	32	0.04%	2	<0.01%	66	0.09%	60	0.08%	6	<0.01%	47	0.07%	**1340**	**1.87%**	**442**
LDA210	Feb-14	1,907	1,075	0	0.00%	5	0.26%	10	0.52%	14	0.73%	27	1.42%	0	0.00%	0	0.00%	6	0.31%	2	0.10%	2	0.10%	2	0.10%	**68**	**3.57%**	**15**
7170Q/7171Q	Jul-09	7,317	2,862	8	0.11%	34	0.46%	38	0.52%	92	1.26%	83	1.13%	2	0.03%	6	0.08%	31	0.42%	24	0.33%	0	0.00%	4	0.05%	**322**	**4.40%**	**78**
7120Q/7121Q	Jan-09	147,605	56,992	52	0.04%	302	0.20%	749	0.51%	1258	0.85%	1341	0.91%	117	0.08%	85	0.06%	290	0.20%	622	0.42%	10	<0.01%	117	0.08%	**4943**	**3.35%**	**1335**
7122Q	Jan-09	174,733	87,746	78	0.04%	146	0.08%	944	0.54%	1041	0.60%	959	0.55%	90	0.05%	54	0.03%	225	0.13%	209	0.12%	15	<0.01%	134	0.08%	**3895**	**2.23%**	**1264**
7120/7121	Sep-07	63,479	17,832	19	0.03%	192	0.30%	192	0.30%	465	0.73%	999	1.57%	73	0.11%	79	0.12%	249	0.39%	406	0.64%	3	<0.01%	65	0.10%	**2742**	**4.32%**	**657**
7122	Sep-07	16,845	5,599	5	0.03%	52	0.31%	80	0.47%	128	0.76%	241	1.43%	13	0.08%	27	0.16%	61	0.36%	53	0.31%	2	0.01%	16	0.09%	**678**	**4.02%**	**214**
7070/7071	Jul-06	3,583	875	2	0.06%	29	0.81%	13	0.36%	44	1.23%	75	2.09%	3	0.08%	9	0.25%	18	0.50%	22	0.61%	1	0.03%	3	0.08%	**219**	**6.11%**	**50**
7020/7021	Jul-06	15,622	3,453	17	0.11%	76	0.49%	67	0.43%	192	1.23%	319	2.04%	23	0.15%	30	0.19%	65	0.42%	126	0.81%	2	0.01%	30	0.19%	**947**	**6.06%**	**248**
7040/7041	Mar-06	4,057	802	4	0.10%	39	0.96%	5	0.12%	58	1.43%	126	3.11%	16	0.39%	66	1.63%	22	0.54%	37	0.91%	1	0.02%	12	0.30%	**386**	**9.51%**	**88**
7000/7001	Jun-05	35,059	6,582	35	0.10%	193	0.55%	61	0.17%	412	1.18%	1078	3.07%	66	0.19%	809	2.31%	146	0.42%	290	0.83%	7	0.02%	107	0.31%	**3204**	**9.14%**	**848**

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	1,063	4.50%	1	0.09%	3	0.28%	0	0.00%	0	0.00%	8	0.75%	**12**	**1.13%**
LDA220Q	13,811	5.00%	1	<0.01%	7	0.05%	0	0.00%	0	0.00%	83	0.60%	**91**	**0.66%**
LDA220	637	5.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.94%	**6**	**0.94%**
LDA210Q	71,740	4.10%	8	0.01%	25	0.03%	0	0.00%	5	<0.01%	425	0.59%	**463**	**0.65%**
LDA210	1,907	5.50%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	16	0.84%	**17**	**0.89%**
7170Q/7171Q	7,317	6.20%	6	0.08%	17	0.23%	0	0.00%	0	0.00%	60	0.82%	**83**	**1.13%**
7120Q/7121Q	147,605	6.00%	41	0.03%	422	0.29%	2	<0.01%	39	0.03%	1045	0.71%	**1549**	**1.05%**
7122Q	174,733	5.60%	26	0.01%	289	0.17%	1	<0.01%	22	0.01%	1075	0.62%	**1413**	**0.81%**
7120/7121	63,479	7.20%	35	0.06%	246	0.39%	1	<0.01%	10	0.02%	493	0.78%	**785**	**1.24%**
7122	16,845	11.10%	18	0.11%	87	0.52%	0	0.00%	4	0.02%	163	0.97%	**272**	**1.61%**
7070/7071	3,583	9.30%	4	0.11%	24	0.67%	0	0.00%	0	0.00%	25	0.70%	**53**	**1.48%**
7020/7021	15,622	8.40%	14	0.09%	78	0.50%	0	0.00%	0	0.00%	202	1.29%	**294**	**1.88%**
7040/7041	4,057	9.70%	4	0.10%	72	1.77%	0	0.00%	1	0.02%	33	0.81%	**110**	**2.71%**
7000/7001	35,059	8.70%	25	0.07%	698	1.99%	2	<0.01%	1	<0.01%	342	0.98%	**1068**	**3.05%**
1590/1591	9,700	8.60%	8	0.08%	217	2.24%	0	0.00%	1	0.01%	60	0.62%	**286**	**2.95%**

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	1,100	4.36%	1	0.09%	3	0.27%	0	0.00%	0	0.00%	8	0.73%	**12**	**1.09%**
LDA220Q	19,331	3.65%	1	0.01%	7	0.04%	0	0.00%	1	0.01%	109	0.56%	**118**	**0.61%**
LDA210Q	128,970	2.36%	17	0.01%	47	0.04%	0	0.00%	11	0.01%	652	0.51%	**727**	**0.56%**
LDA210	2,077	5.01%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	16	0.77%	**17**	**0.82%**
7170Q/7171Q	19,692	3.05%	12	0.06%	27	0.14%	2	0.01%	0	0.00%	91	0.46%	**132**	**0.67%**
7120Q/7121Q	251,410	3.98%	72	0.03%	536	0.21%	3	<0.01%	96	0.04%	1508	0.60%	**2215**	**0.88%**
7122Q	528,952	2.11%	73	0.01%	520	0.10%	3	<0.01%	150	0.03%	2337	0.44%	**3083**	**0.58%**
7120/7121	148,858	3.67%	119	0.08%	344	0.23%	1	<0.01%	25	0.02%	877	0.59%	**1366**	**0.92%**
7122	91,660	2.89%	121	0.13%	206	0.22%	1	<0.01%	24	0.03%	609	0.66%	**961**	**1.05%**

Definitions of malfunction categories can be found on pages 8-9.

Dual-Chamber Pacemakers

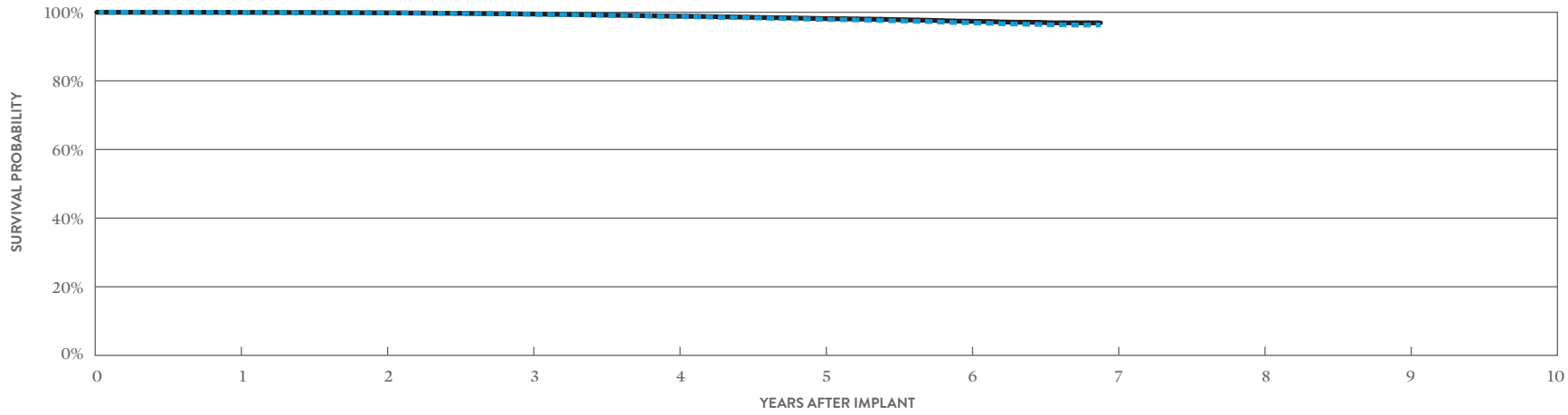
Dual-Chamber Pacemakers

Assurity MRI™

MODEL PM2272

US Regulatory Approval	January 2017
Registered US Implants	416,445
Estimated Active US Implants	290,734
Estimated Longevity	9.4 Years
Normal Battery Depletion	165
Number of US Advisories (see pgs. 215, 216, 218)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	22	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	2	<0.01%	66	0.02%
Mechanical	62	0.01%	1039	0.25%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	3	<0.01%	10	<0.01%
Total	**69**	**0.02%**	**1138**	**0.27%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 83 MONTHS
SURVIVAL PROBABILITY	99.96%	99.82%	99.44%	98.76%	97.94%	96.95%	96.28%
± 1 STANDARD ERROR	0.00%	0.01%	0.02%	0.03%	0.04%	0.06%	0.10%
SAMPLE SIZE	364,290	273,780	202,360	141,850	89,300	44,480	840

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 83 MONTHS
SURVIVAL PROBABILITY	99.96%	99.83%	99.49%	98.86%	98.17%	97.40%	96.92%
± 1 STANDARD ERROR	0.00%	0.01%	0.01%	0.03%	0.04%	0.06%	0.08%

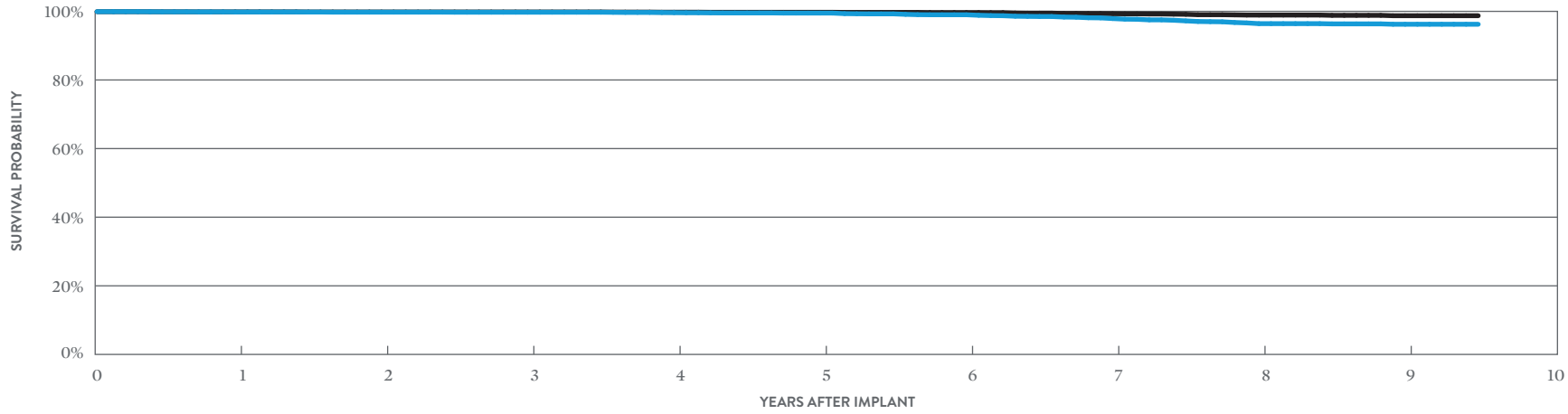
Dual-Chamber Pacemakers

Endurity™ DR

MODEL PM2160

US Regulatory Approval	March 2014
Registered US Implants	9,408
Estimated Active US Implants	4,333
Estimated Longevity	9.7 Years
Normal Battery Depletion	50
Number of US Advisories (see pg. 215, 216)	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%	28	0.30%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	**0**	**0.00%**	**30**	**0.32%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 114 MONTHS
SURVIVAL PROBABILITY	99.82%	99.77%	99.75%	99.63%	99.50%	99.01%	97.90%	96.42%	96.24%	96.24%
± 1 STANDARD ERROR	0.04%	0.05%	0.05%	0.07%	0.08%	0.12%	0.18%	0.25%	0.28%	0.28%
SAMPLE SIZE	8,940	8,110	7,450	6,850	6,290	5,710	5,080	4,180	2,580	410

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 114 MONTHS
SURVIVAL PROBABILITY	99.85%	99.82%	99.82%	99.76%	99.73%	99.66%	99.31%	98.92%	98.73%	98.73%
± 1 STANDARD ERROR	0.04%	0.04%	0.04%	0.05%	0.06%	0.07%	0.10%	0.14%	0.17%	0.17%

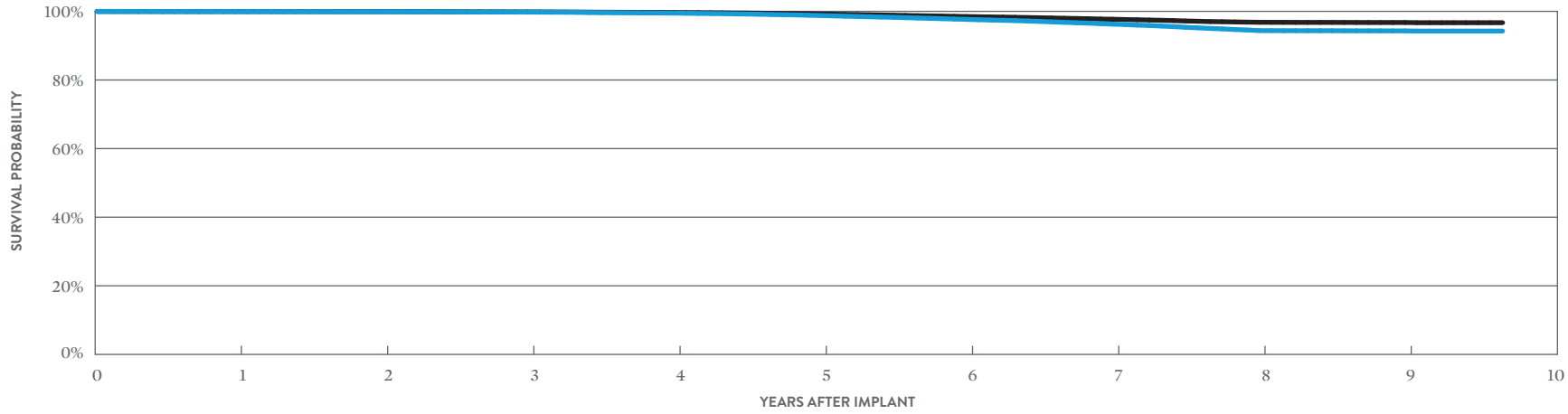
Dual-Chamber Pacemakers

Assurity™ DR RF

MODEL PM2240

US Regulatory Approval	March 2014
Registered US Implants	185,826
Estimated Active US Implants	90,947
Estimated Longevity	9.4 Years
Normal Battery Depletion	879
Number of US Advisories (see pgs. 215, 216, 218)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	<0.01%	24	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	36	0.02%
Mechanical	102	0.05%	1073	0.58%
Possible Early Battery Depletion	3	<0.01%	3	<0.01%
Other	0	0.00%	10	<0.01%
Total	**111**	**0.06%**	**1146**	**0.62%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.95%	99.90%	99.78%	99.49%	98.78%	97.66%	96.28%	94.40%	94.31%	94.26%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.02%	0.03%	0.04%	0.06%	0.08%	0.08%	0.08%
SAMPLE SIZE	176,540	160,400	147,390	135,230	123,000	109,250	90,360	60,660	26,520	450

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 116 MONTHS
SURVIVAL PROBABILITY	99.96%	99.92%	99.84%	99.67%	99.23%	98.49%	97.70%	96.82%	96.75%	96.70%
± 1 STANDARD ERROR	0.00%	0.01%	0.01%	0.01%	0.02%	0.03%	0.04%	0.06%	0.06%	0.06%

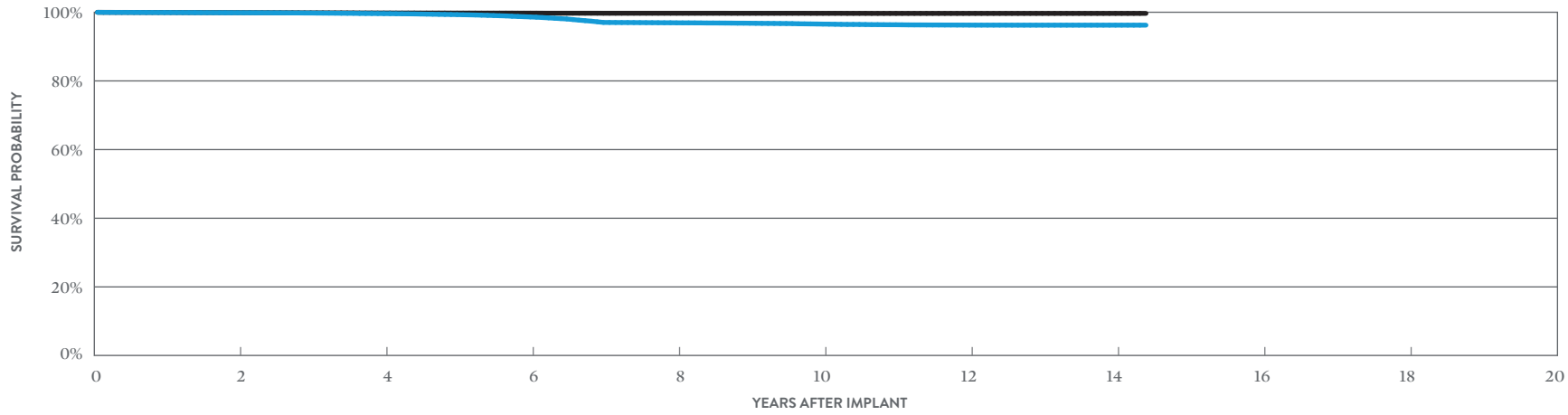
Dual-Chamber Pacemakers

Accent™ DR RF

MODEL PM2210

US Regulatory Approval	July 2009
Registered US Implants	244,866
Estimated Active US Implants	61,814
Estimated Longevity	8 Years
Normal Battery Depletion	1,729
Number of US Advisories (see pgs. 215, 216, 218)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	17	<0.01%	54	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%	48	0.02%
Total	**38**	**0.02%**	**186**	**0.08%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 MONTHS
SURVIVAL PROBABILITY	99.86%	99.60%	98.63%	96.92%	96.55%	96.26%	96.24%	96.24%
± 1 STANDARD ERROR	0.01%	0.01%	0.03%	0.05%	0.05%	0.06%	0.06%	0.06%
SAMPLE SIZE	205,060	168,580	140,720	116,830	81,450	33,290	6,750	290

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 173 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%

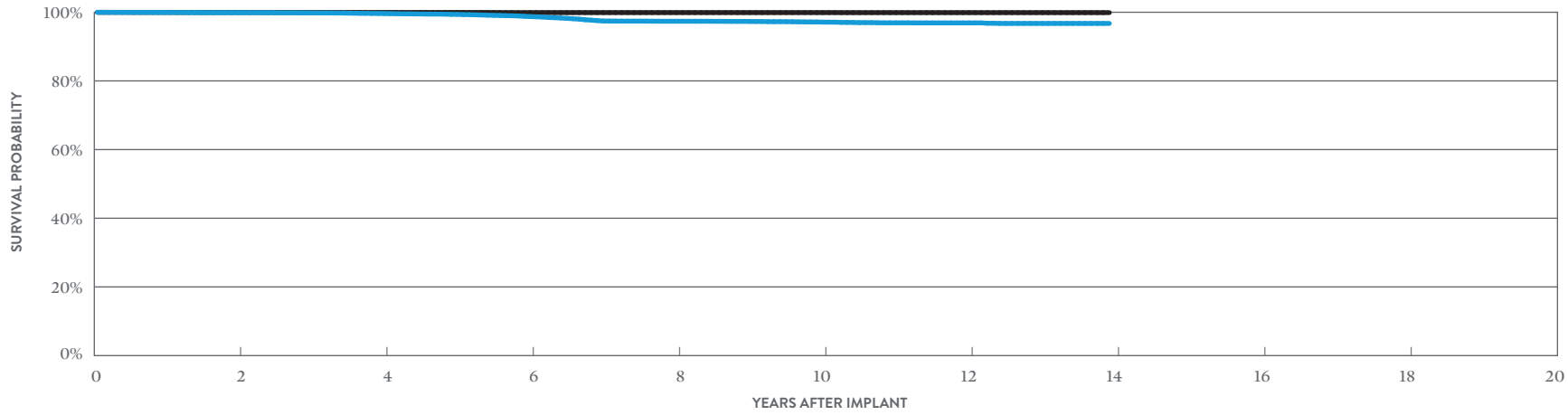
Dual-Chamber Pacemakers

Accent™ DR

MODEL PM2110

US Regulatory Approval	July 2009
Registered US Implants	49,131
Estimated Active US Implants	13,970
Estimated Longevity	9.2 Years
Normal Battery Depletion	323
Number of US Advisories (see pg. 220)	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	AT 167 MONTHS
SURVIVAL PROBABILITY	99.89%	99.62%	98.74%	97.37%	97.12%	96.90%	96.74%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.09%	0.10%	0.11%	0.13%
SAMPLE SIZE	41,120	33,670	28,300	23,930	17,610	7,370	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 167 MONTHS
SURVIVAL PROBABILITY	99.95%	99.93%	99.90%	99.90%	99.90%	99.89%	99.89%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.02%	0.02%	0.02%	0.02%

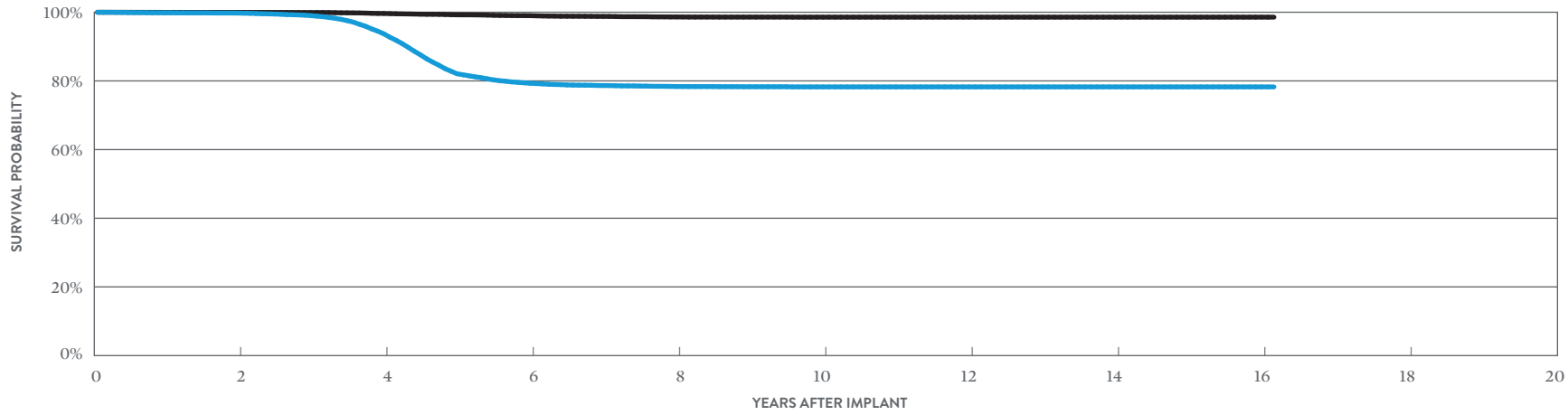
Dual-Chamber Pacemakers

Zephyr™ DR

MODEL 5820

US Regulatory Approval	March 2007
Registered US Implants	54,733
Estimated Active US Implants	9,932
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,471
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 194 MONTHS
SURVIVAL PROBABILITY	99.75%	93.70%	79.31%	78.37%	78.26%	78.26%	78.26%	78.26%	78.26%
± 1 STANDARD ERROR	0.02%	0.13%	0.23%	0.24%	0.24%	0.24%	0.24%	0.24%	0.24%
SAMPLE SIZE	42,650	31,830	21,120	13,960	10,410	6,910	3,490	790	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 194 MONTHS
SURVIVAL PROBABILITY	99.96%	99.64%	99.00%	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%

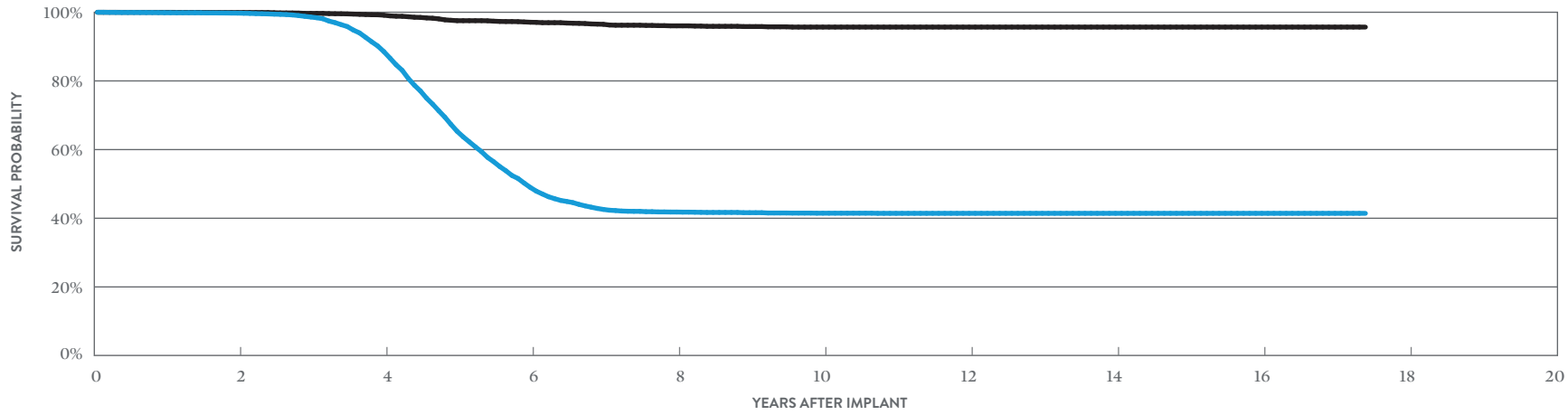
Dual-Chamber Pacemakers

Victory™ DR

MODEL 5810

US Regulatory Approval	December 2005
Registered US Implants	26,314
Estimated Active US Implants	1,969
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	AT 209 MONTHS
SURVIVAL PROBABILITY	99.74%	88.52%	48.99%	41.81%	41.47%	41.43%	41.43%	41.43%	41.43%
± 1 STANDARD ERROR	0.03%	0.25%	0.45%	0.46%	0.46%	0.46%	0.46%	0.46%	0.46%
SAMPLE SIZE	20,250	13,770	6,820	3,310	2,550	2,340	2,090	1,380	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 209 MONTHS
SURVIVAL PROBABILITY	99.93%	99.13%	97.09%	96.04%	95.68%	95.68%	95.68%	95.68%	95.68%
± 1 STANDARD ERROR	0.02%	0.07%	0.16%	0.23%	0.26%	0.26%	0.26%	0.26%	0.26%

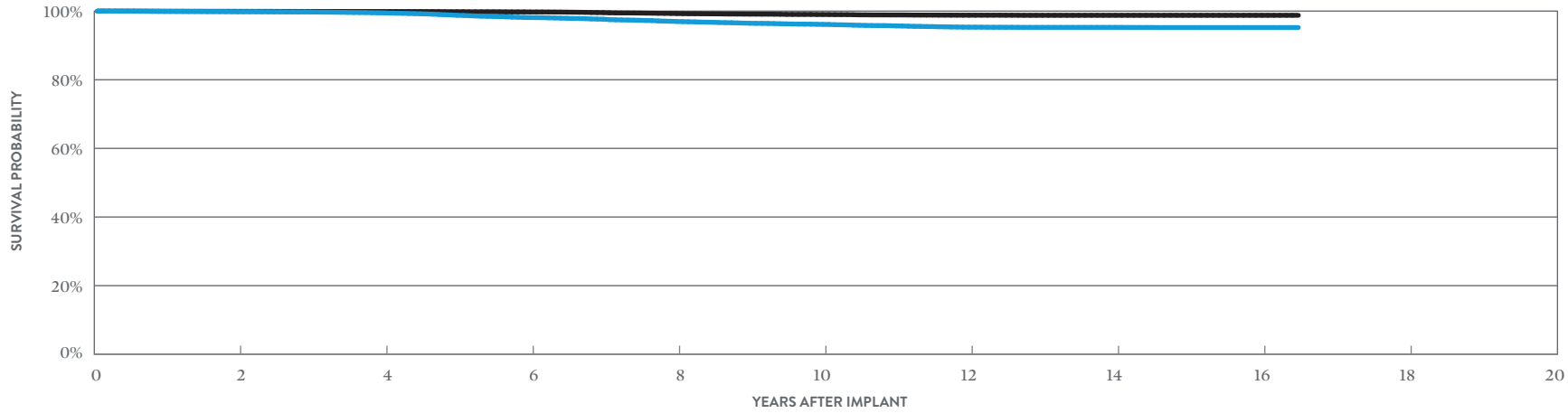
Dual-Chamber Pacemakers

Zephyr™ XL DR

MODEL 5826

US Regulatory Approval	March 2007
Registered US Implants	113,816
Estimated Active US Implants	18,648
Estimated Longevity	11.7 Years
Normal Battery Depletion	693
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%	159	0.14%
Total	**8**	**<0.01%**	**212**	**0.19%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 198 MONTHS
SURVIVAL PROBABILITY	99.83%	99.48%	98.12%	96.98%	96.13%	95.32%	95.26%	95.21%	95.21%
± 1 STANDARD ERROR	0.01%	0.02%	0.05%	0.07%	0.09%	0.10%	0.11%	0.11%	0.11%
SAMPLE SIZE	92,490	72,390	56,890	40,780	28,840	21,310	15,180	3,770	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 198 MONTHS
SURVIVAL PROBABILITY	99.93%	99.88%	99.75%	99.29%	99.01%	98.81%	98.78%	98.78%	98.78%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.04%	0.05%	0.06%	0.06%	0.06%	0.06%

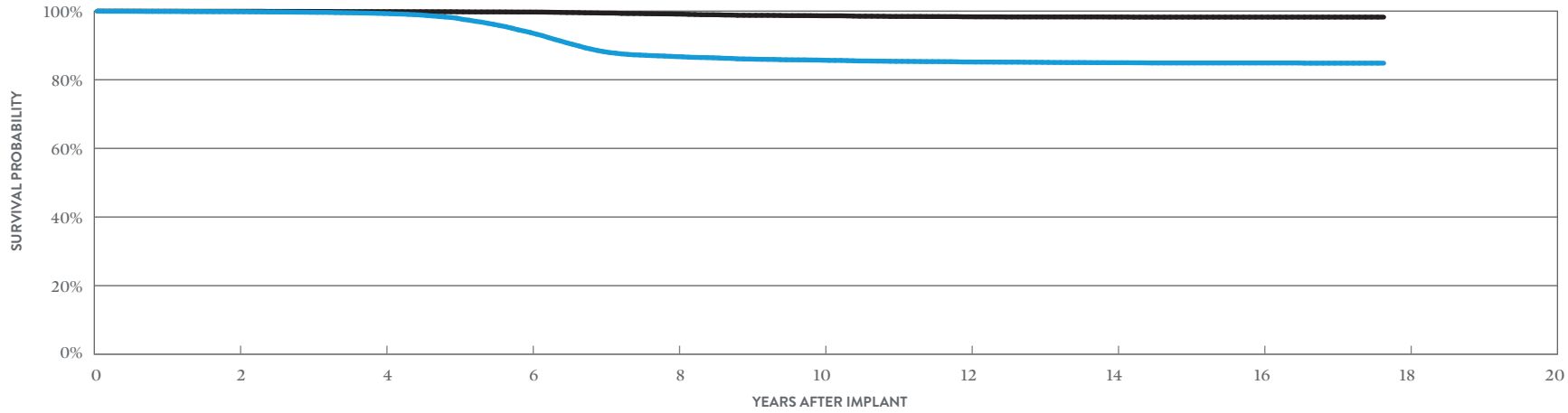
Dual-Chamber Pacemakers

Victory™ XL DR

MODEL 5816

US Regulatory Approval	December 2005
Registered US Implants	63,053
Estimated Active US Implants	7,042
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,523
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	AT 212 MONTHS
SURVIVAL PROBABILITY	99.83%	99.30%	93.78%	86.74%	85.70%	85.18%	84.96%	84.89%	84.83%
± 1 STANDARD ERROR	0.02%	0.04%	0.13%	0.20%	0.21%	0.22%	0.23%	0.23%	0.23%
SAMPLE SIZE	51,250	39,200	29,600	19,060	12,500	9,730	8,070	5,250	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	99.95%	99.85%	99.73%	99.13%	98.64%	98.35%	98.28%	98.25%	98.25%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.06%	0.08%	0.10%	0.10%	0.10%	0.10%

SUMMARY INFORMATION

Dual-Chamber Pacemakers

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%	99.82%	99.44%	98.76%	97.94%	96.95%				
PM2160	Endurity™ DR	99.82%	99.77%	99.75%	99.63%	99.50%	99.01%	97.90%	96.42%	96.24%	
PM2240	Assurity™ DR RF	99.95%	99.90%	99.78%	99.49%	98.78%	97.66%	96.28%	94.40%	94.31%	
PM2210	Accent™ DR RF	99.92%	99.86%	99.77%	99.60%	99.31%	98.63%	97.03%	96.92%	96.80%	96.55%
PM2110	Accent™ DR	99.94%	99.89%	99.81%	99.62%	99.38%	98.74%	97.45%	97.37%	97.31%	97.12%
5820	Zephyr™ DR	99.85%	99.75%	99.01%	93.70%	82.08%	79.31%	78.65%	78.37%	78.30%	78.26%
5810	Victory™ DR	99.87%	99.74%	98.61%	88.52%	65.34%	48.99%	42.57%	41.81%	41.62%	41.47%
5826	Zephyr™ XL DR	99.91%	99.83%	99.74%	99.48%	98.78%	98.12%	97.64%	96.98%	96.46%	96.13%
5816	Victory™ XL DR	99.91%	99.83%	99.65%	99.30%	97.94%	93.78%	88.21%	86.74%	86.03%	85.70%

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	99.96%	99.83%	99.49%	98.86%	98.17%	97.40%					
PM2160	99.85%	99.82%	99.82%	99.76%	99.73%	99.66%	99.31%	98.92%	98.73%		
PM2240	99.96%	99.92%	99.84%	99.67%	99.23%	98.49%	97.70%	96.82%	96.75%		
PM2210	99.95%	99.90%	99.84%	99.79%	99.76%	99.74%	99.71%	99.71%	99.70%	99.69%	99.69%
PM2110	99.97%	99.95%	99.93%	99.93%	99.93%	99.90%	99.90%	99.90%	99.90%	99.90%	99.90%
5820	99.97%	99.96%	99.92%	99.64%	99.25%	99.00%	98.79%	98.63%	98.59%	98.57%	98.57%
5810	99.98%	99.93%	99.67%	99.13%	97.54%	97.09%	96.49%	96.04%	95.83%	95.68%	95.68%
5826	99.96%	99.93%	99.91%	99.88%	99.82%	99.75%	99.56%	99.29%	99.12%	99.01%	99.01%
5816	99.97%	99.95%	99.91%	99.85%	99.80%	99.73%	99.43%	99.13%	98.76%	98.64%	98.65%

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™	416,445	2.80%	2	<0.01%	0	0.00%	0	0.00%	2	<0.01%	62	0.01%	0	0.00%	3	<0.01%	**69**	**0.02%**
PM2160	Endurity™ DR	9,408	5.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2240	Assurity™ DR RF	185,826	6.50%	5	<0.01%	0	0.00%	0	0.00%	1	<0.01%	102	0.05%	3	<0.01%	0	0.00%	**111**	**0.06%**
PM2210	Accent™ DR RF	244,866	12.40%	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	49,131	10.50%	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	54,733	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	113,816	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™	416,445	2.80%	22	<0.01%	0	0.00%	0	0.00%	66	0.02%	1039	0.25%	1	<0.01%	10	<0.01%	**1138**	**0.27%**
PM2160	Endurity™ DR	9,408	5.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	28	0.30%	0	0.00%	2	0.02%	**30**	**0.32%**
PM2240	Assurity™ DR RF	185,826	6.50%	24	0.01%	0	0.00%	0	0.00%	36	0.02%	1073	0.58%	3	<0.01%	10	<0.01%	**1146**	**0.62%**
PM2210	Accent™ DR RF	244,866	12.40%	54	0.02%	33	0.01%	0	0.00%	5	<0.01%	22	<0.01%	24	<0.01%	48	0.02%	**186**	**0.08%**
PM2110	Accent™ DR	49,131	10.50%	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	54,733	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	113,816	19.20%	25	0.02%	0	0.00%	0	0.00%	16	0.01%	9	<0.01%	3	<0.01%	159	0.14%	**212**	**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™	946,648	1.77%	18	<0.01%	2	<0.01%	0	0.00%	4	<0.01%	360	0.04%	0	0.00%	10	<0.01%	**394**	**0.04%**
PM2160	Endurity™ DR	71,541	1.06%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	0	0.00%	**8**	**0.01%**
PM2240	Assurity™ DR RF	206,629	5.71%	10	<0.01%	0	0.00%	0	0.00%	2	<0.01%	206	0.10%	6	<0.01%	0	0.00%	**224**	**0.11%**
PM2210	Accent™ DR RF	246,721	11.93%	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	9.99%	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™	946,648	1.77%	100	0.01%	0	0.00%	0	0.00%	136	0.01%	2810	0.30%	16	<0.01%	34	<0.01%	**3096**	**0.33%**
PM2160	Endurity™ DR	71,541	1.06%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	86	0.12%	0	0.00%	6	<0.01%	**94**	**0.13%**
PM2240	Assurity™ DR RF	206,629	5.71%	54	0.03%	0	0.00%	0	0.00%	70	0.03%	2044	0.99%	8	<0.01%	22	0.01%	**2198**	**1.06%**
PM2210	Accent™ DR RF	246,721	11.93%	114	0.05%	68	0.03%	0	0.00%	10	<0.01%	44	0.02%	48	0.02%	94	0.04%	**378**	**0.15%**
PM2110	Accent™ DR	49,730	9.99%	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

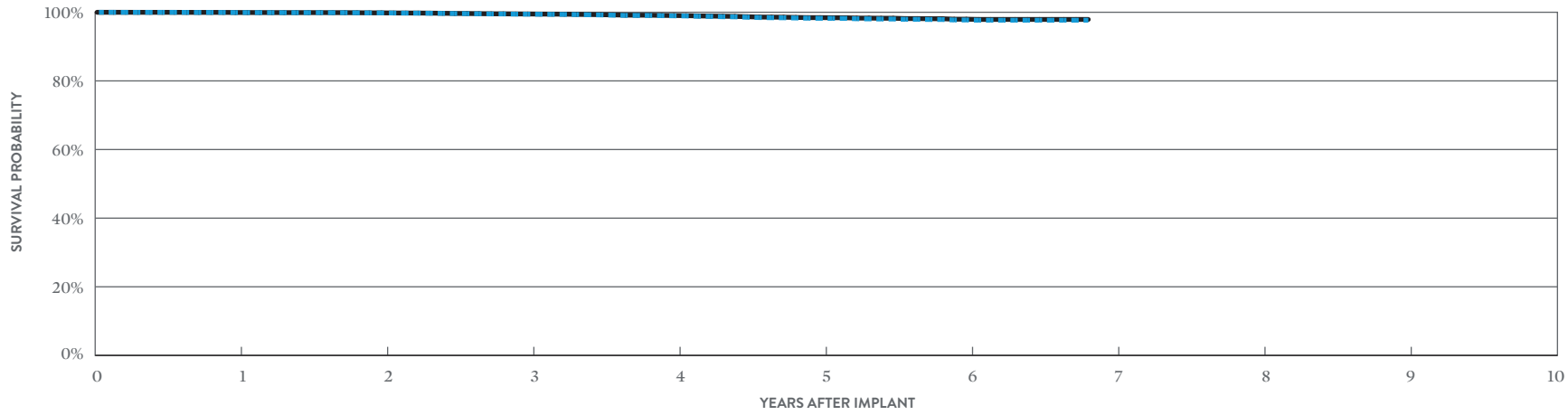
Single-Chamber Pacemakers

Assurity MRI™

MODEL PM1272

US Regulatory Approval	January 2017
Registered US Implants	38,701
Estimated Active US Implants	26,215
Estimated Longevity	13.7 Years
Normal Battery Depletion	12
Number of US Advisories (see pgs. 215, 216, 218)	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	0	0.00%	4	0.01%
Mechanical	1	<0.01%	103	0.27%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**109**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 82 MONTHS
SURVIVAL PROBABILITY	99.92%	99.82%	99.44%	98.96%	98.24%	97.75%	97.68%
± 1 STANDARD ERROR	0.01%	0.03%	0.05%	0.07%	0.11%	0.15%	0.16%
SAMPLE SIZE	34,110	26,340	20,370	15,080	10,040	5,250	350

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 82 MONTHS
SURVIVAL PROBABILITY	99.93%	99.83%	99.50%	99.05%	98.44%	97.98%	97.91%
± 1 STANDARD ERROR	0.01%	0.03%	0.05%	0.07%	0.11%	0.14%	0.15%

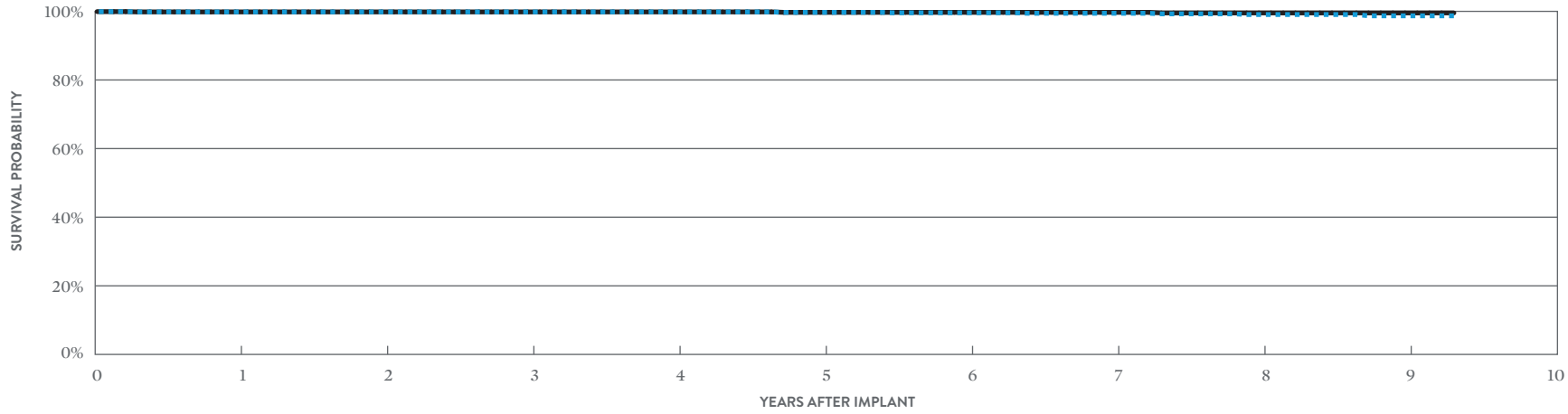
Single-Chamber Pacemakers

Endurity™ VR

MODEL PM1160

US Regulatory Approval	March 2014
Registered US Implants	2,571
Estimated Active US Implants	1,195
Estimated Longevity	14.6 Years
Normal Battery Depletion	4
Number of US Advisories (see pgs. 217, 218)	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%	3	0.12%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.04%
Total	**0**	**0.00%**	**4**	**0.16%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 112 MONTHS
SURVIVAL PROBABILITY	99.84%	99.84%	99.84%	99.84%	99.71%	99.58%	99.44%	99.07%	98.70%	98.70%
± 1 STANDARD ERROR	0.08%	0.08%	0.08%	0.08%	0.12%	0.15%	0.18%	0.26%	0.37%	0.37%
SAMPLE SIZE	2,390	2,110	1,920	1,760	1,650	1,520	1,350	1,090	640	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 112 MONTHS
SURVIVAL PROBABILITY	99.84%	99.84%	99.84%	99.84%	99.71%	99.71%	99.71%	99.55%	99.55%	99.55%
± 1 STANDARD ERROR	0.08%	0.08%	0.08%	0.08%	0.12%	0.12%	0.12%	0.17%	0.17%	0.17%

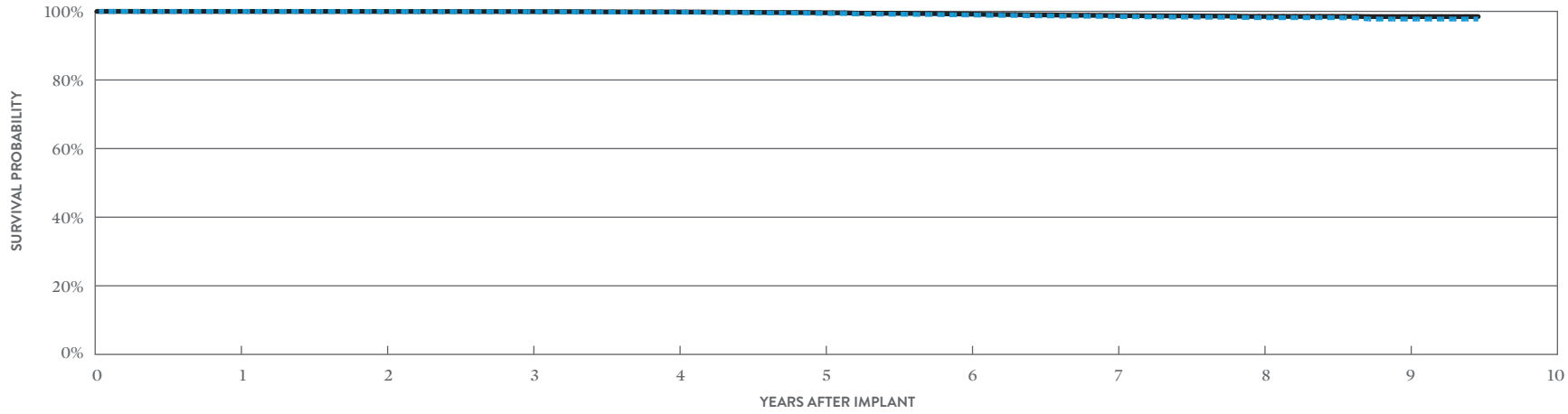
Single-Chamber Pacemakers

Assurity™ VR

MODEL PM1240

US Regulatory Approval	March 2014
Registered US Implants	28,741
Estimated Active US Implants	14,302
Estimated Longevity	14.1 Years
Normal Battery Depletion	29
Number of US Advisories (see pgs. 215, 216, 218)	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%	84	0.29%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**3**	**0.01%**	**92**	**0.32%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 114 MONTHS
SURVIVAL PROBABILITY	99.98%	99.96%	99.91%	99.77%	99.41%	98.96%	98.50%	98.16%	97.76%	97.76%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.03%	0.05%	0.07%	0.09%	0.11%	0.16%	0.16%
SAMPLE SIZE	27,010	24,160	22,150	20,420	18,700	16,630	13,590	8,980	3,890	290

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 114 MONTHS
SURVIVAL PROBABILITY	99.98%	99.96%	99.93%	99.83%	99.59%	99.21%	98.79%	98.53%	98.47%	98.47%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.03%	0.04%	0.06%	0.08%	0.10%	0.11%	0.11%

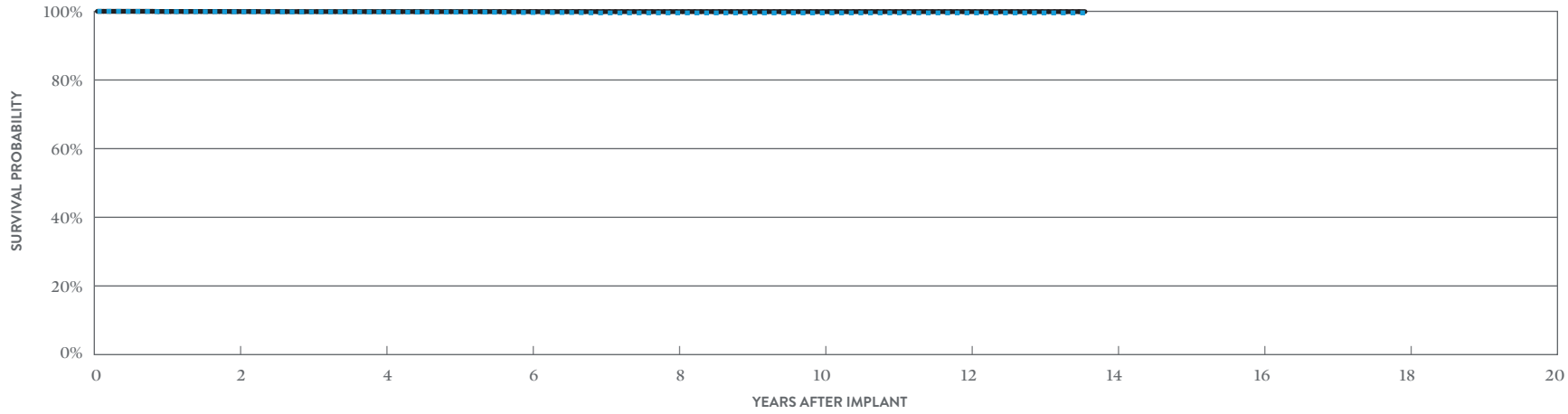
Single-Chamber Pacemakers

Accent™ SR

MODEL PM1110

US Regulatory Approval	July 2009
Registered US Implants	13,595
Estimated Active US Implants	4,642
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	AT 163 MONTHS
SURVIVAL PROBABILITY	99.87%	99.80%	99.66%	99.54%	99.54%	99.54%	99.54%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.08%	0.08%	0.08%	0.08%
SAMPLE SIZE	10,680	8,480	7,200	6,290	4,990	2,220	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 163 MONTHS
SURVIVAL PROBABILITY	99.94%	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%

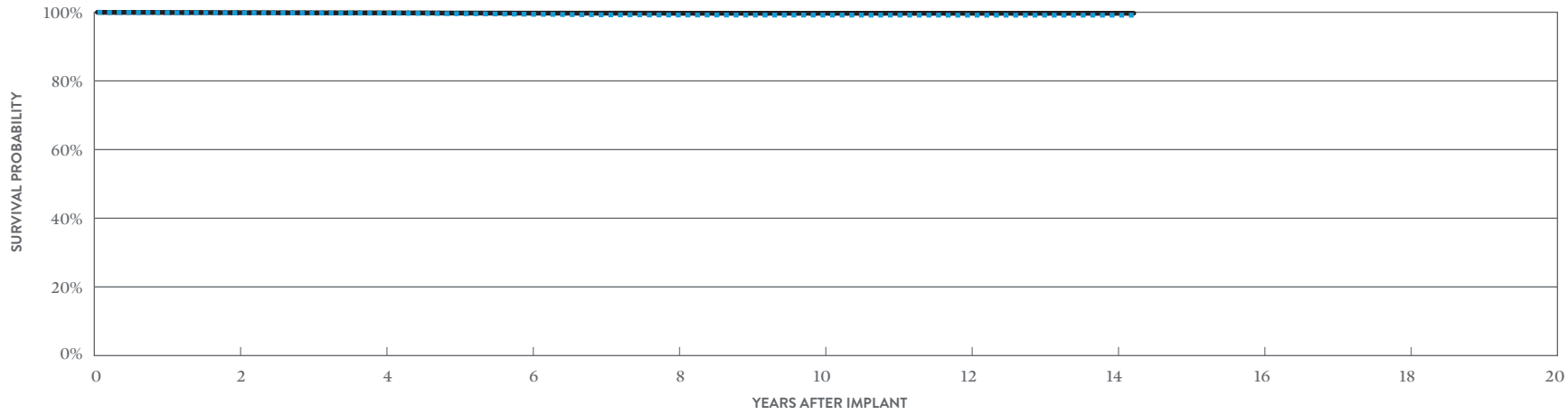
Single-Chamber Pacemakers

Accent™ SR RF

MODEL PM1210

US Regulatory Approval	July 2009
Registered US Implants	40,045
Estimated Active US Implants	12,981
Estimated Longevity	10.9 Years
Normal Battery Depletion	51
Number of US Advisories (see pgs. 215, 218)	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 171 MONTHS
SURVIVAL PROBABILITY	99.80%	99.73%	99.40%	99.20%	99.18%	99.14%	99.14%	99.14%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.06%	0.06%	0.06%	0.06%	0.06%
SAMPLE SIZE	31,340	24,960	20,940	18,140	14,490	6,830	1,380	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 171 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%

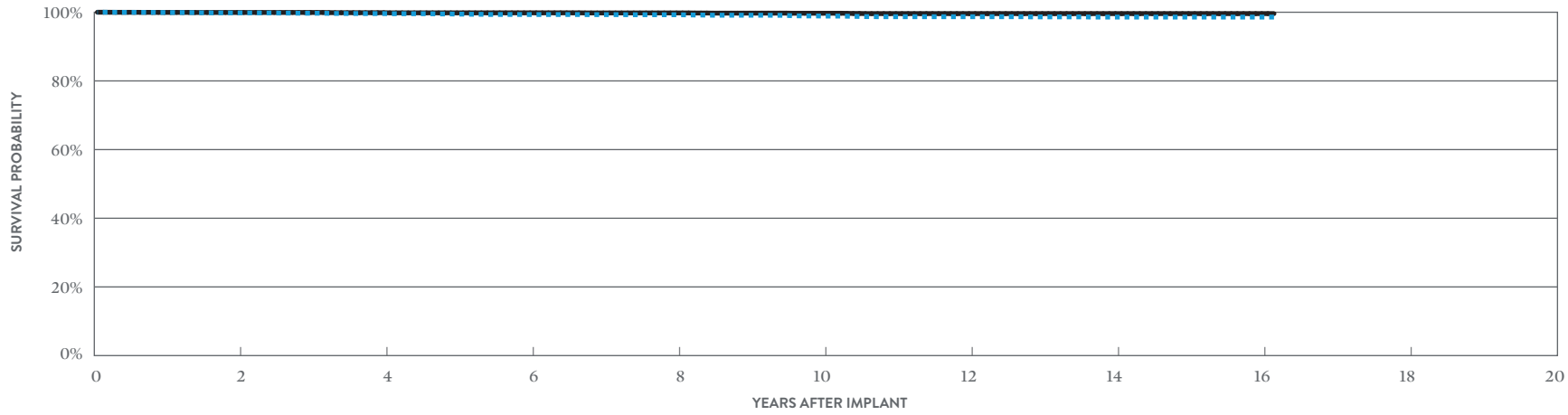
Single-Chamber Pacemakers

Zephyr™ XL SR

MODEL 5626

US Regulatory Approval	May 2007
Registered US Implants	20,881
Estimated Active US Implants	4,402
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 194 MONTHS
SURVIVAL PROBABILITY	99.81%	99.61%	99.33%	99.27%	98.88%	98.70%	98.59%	98.59%	98.59%
± 1 STANDARD ERROR	0.03%	0.05%	0.08%	0.08%	0.11%	0.13%	0.14%	0.14%	0.14%
SAMPLE SIZE	15,590	11,540	8,990	7,420	6,010	4,750	3,420	780	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 194 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%	0.05%	0.07%	0.07%	0.07%	0.07%

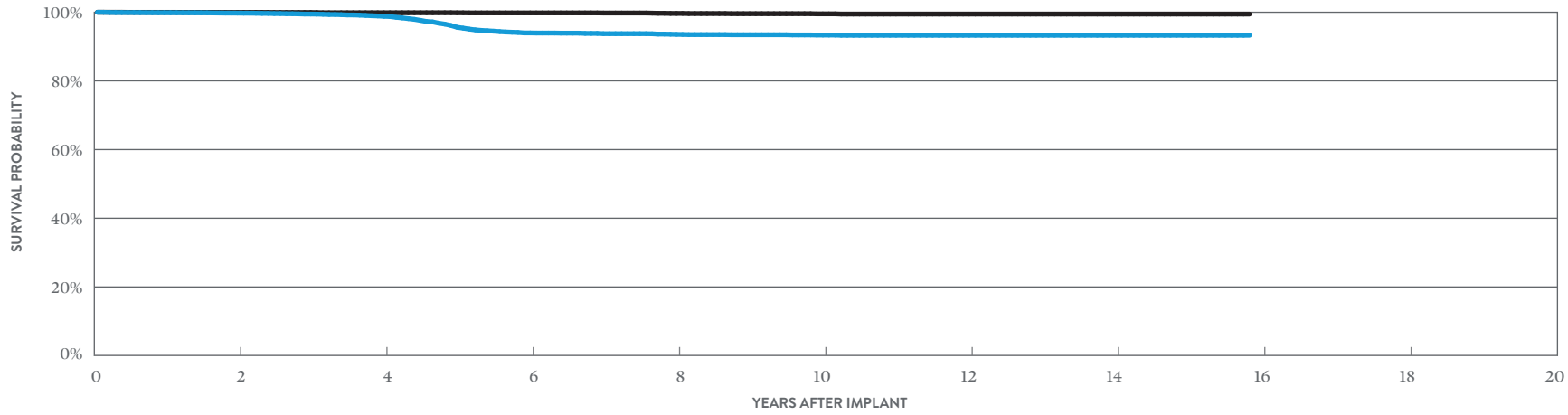
Single-Chamber Pacemakers

Zephyr™ SR

MODEL 5620

US Regulatory Approval	March 2007
Registered US Implants	17,530
Estimated Active US Implants	4,041
Estimated Longevity	8.8 Years
Normal Battery Depletion	208
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	AT 190 MONTHS
SURVIVAL PROBABILITY	99.74%	98.81%	93.98%	93.56%	93.36%	93.30%	93.30%	93.30%
± 1 STANDARD ERROR	0.04%	0.10%	0.26%	0.27%	0.28%	0.28%	0.28%	0.28%
SAMPLE SIZE	12,620	9,350	7,150	5,470	4,110	2,640	1,310	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 190 MONTHS
SURVIVAL PROBABILITY	99.94%	99.85%	99.80%	99.65%	99.52%	99.46%	99.46%	99.46%
± 1 STANDARD ERROR	0.02%	0.04%	0.04%	0.07%	0.09%	0.10%	0.10%	0.10%

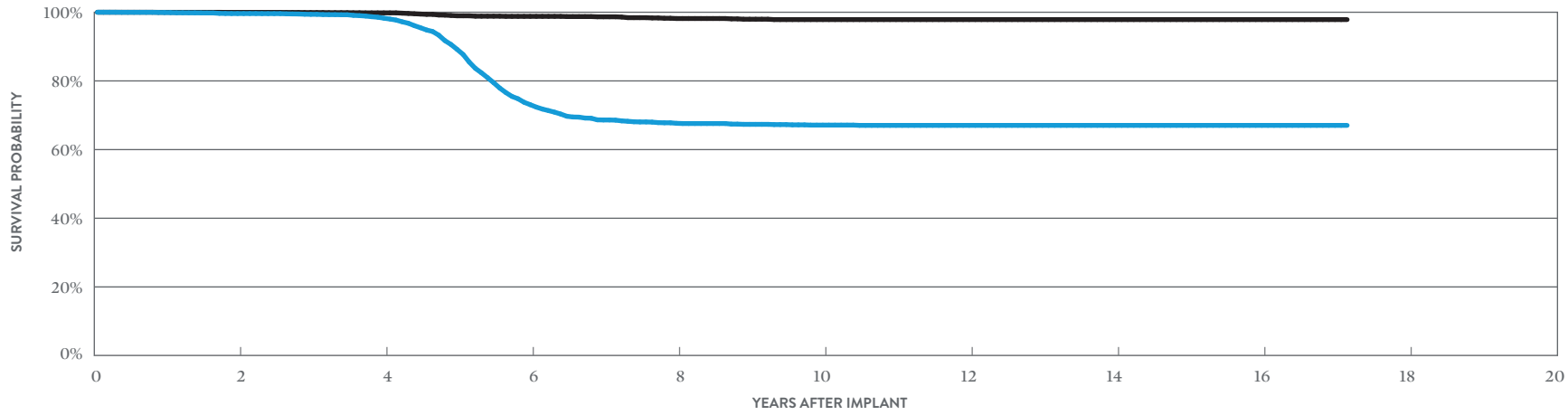
Single-Chamber Pacemakers

Victory™ SR

MODEL 5610

US Regulatory Approval	December 2005
Registered US Implants	13,690
Estimated Active US Implants	1,486
Estimated Longevity	8.8 Years
Normal Battery Depletion	670
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	25	0.18%
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	1	<0.01%	12	0.09%
Total	**1**	**<0.01%**	**39**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 206 MONTHS
SURVIVAL PROBABILITY	99.62%	98.26%	73.08%	67.65%	67.13%	67.05%	67.05%	67.05%	67.05%
± 1 STANDARD ERROR	0.06%	0.14%	0.59%	0.65%	0.66%	0.66%	0.66%	0.66%	0.66%
SAMPLE SIZE	9,840	6,750	4,290	2,560	1,840	1,690	1,520	1,000	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 206 MONTHS
SURVIVAL PROBABILITY	99.96%	99.82%	98.80%	98.17%	97.86%	97.86%	97.86%	97.86%	97.86%
± 1 STANDARD ERROR	0.02%	0.05%	0.15%	0.20%	0.25%	0.25%	0.25%	0.25%	0.25%

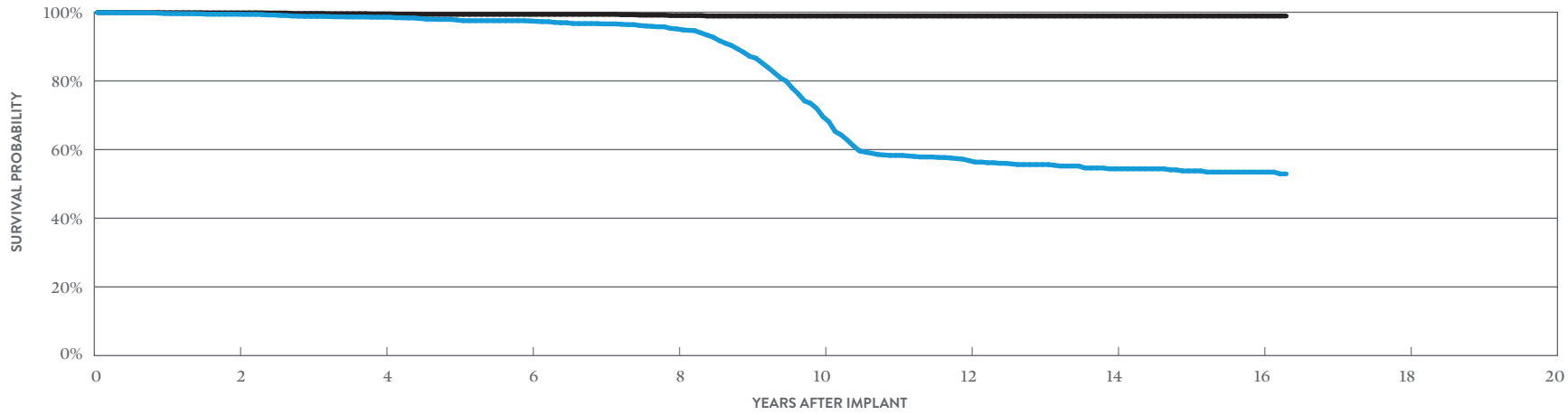
Single-Chamber Pacemakers

Microny™

MODEL 2525T

US Regulatory Approval	April 2001
Registered US Implants	7,394
Estimated Active US Implants	1,331
Estimated Longevity	7.5 Years
Normal Battery Depletion	293
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%	0	0.00%
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%**	**2**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 196 MONTHS
SURVIVAL PROBABILITY	99.42%	98.56%	97.45%	95.17%	69.58%	56.78%	54.39%	53.44%	52.92%
± 1 STANDARD ERROR	0.10%	0.18%	0.26%	0.43%	1.13%	1.27%	1.31%	1.35%	1.38%
SAMPLE SIZE	4,880	3,380	2,400	1,720	1,180	740	490	280	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 196 MONTHS
SURVIVAL PROBABILITY	99.82%	99.52%	99.39%	99.04%	98.90%	98.90%	98.90%	98.90%	98.90%
± 1 STANDARD ERROR	0.06%	0.11%	0.13%	0.19%	0.21%	0.21%	0.21%	0.21%	0.21%

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™	99.92%	99.82%	99.44%	98.96%	98.24%	97.75%				
PM1160	Endurity™ SR	99.84%	99.84%	99.84%	99.84%	99.71%	99.58%	99.44%	99.07%	98.70%	
PM1240	Assurity™ SR	99.98%	99.96%	99.91%	99.77%	99.41%	98.96%	98.50%	98.16%	97.76%	
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%	99.40%	99.24%	99.20%	99.18%	99.18%
5626	Zephyr™ XL SR	99.92%	99.81%	99.71%	99.61%	99.45%	99.33%	99.30%	99.27%	99.13%	98.88%
5620	Zephyr™ SR	99.86%	99.74%	99.47%	98.81%	95.62%	93.98%	93.76%	93.56%	93.45%	93.36%
5610	Victory™ SR	99.92%	99.62%	99.39%	98.26%	89.20%	73.08%	68.62%	67.65%	67.35%	67.13%
2525T	Microny™	99.64%	99.42%	98.80%	98.56%	97.73%	97.45%	96.60%	95.17%	87.15%	69.58%

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%	99.83%	99.50%	99.05%	98.44%	97.98%				
PM1160	Endurity™ SR	99.84%	99.84%	99.84%	99.84%	99.71%	99.71%	99.71%	99.55%	99.55%	
PM1240	Assurity™ SR	99.98%	99.96%	99.93%	99.83%	99.59%	99.21%	98.79%	98.53%	98.47%	
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%	99.52%
5610	Victory™ SR	99.98%	99.96%	99.91%	99.82%	98.96%	98.80%	98.67%	98.17%	97.97%	97.86%
2525T	Microny™	99.86%	99.82%	99.64%	99.52%	99.39%	99.39%	99.39%	99.04%	98.90%	98.90%

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™	38,701	4.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM1160	Endurity™ SR	2,571	6.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1240	Assurity™ SR	28,741	6.90%	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	13,595	8.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent™ SR RF	40,045	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	20,881	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	11.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
5610	Victory™ SR	13,690	15.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**
2525T	Microny™	7,394	7.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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™	38,701	4.40%	2	<0.01%	0	0.00%	0	0.00%	4	0.01%	103	0.27%	0	0.00%	0	0.00%	**109**	**0.28%**
PM1160	Endurity™ SR	2,571	6.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.12%	0	0.00%	1	0.04%	**4**	**0.16%**
PM1240	Assurity™ SR	28,741	6.90%	4	0.01%	0	0.00%	0	0.00%	3	0.01%	84	0.29%	1	<0.01%	0	0.00%	**92**	**0.32%**
PM1110	Accent™ SR	13,595	8.00%	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	40,045	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	20,881	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	11.90%	4	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	11	0.06%	**17**	**0.10%**
5610	Victory™ SR	13,690	15.70%	25	0.18%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	12	0.09%	**39**	**0.28%**
2525T	Microny™	7,394	7.40%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**2**	**0.03%**

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™	157,600	1.15%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	2	<0.01%	0	0.00%	**8**	**<0.01%**
PM1160	Endurity™ SR	28,197	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	32,494	5.92%	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	59,281	2.16%	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	6.39%	10	0.02%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	**16**	**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		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
PM1272	Assurity MRI™	157,600	1.15%	6	<0.01%	0	0.00%	0	0.00%	8	<0.01%	188	0.12%	0	0.00%	2	<0.01%	**204**	**0.13%**
PM1160	Endurity™ SR	28,197	0.83%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	12	0.04%	0	0.00%	2	<0.01%	**14**	**0.05%**
PM1240	Assurity™ SR	32,494	5.92%	10	0.03%	0	0.00%	0	0.00%	8	0.02%	162	0.50%	2	<0.01%	0	0.00%	**182**	**0.56%**
PM1110	Accent™ SR	59,281	2.16%	10	0.02%	0	0.00%	0	0.00%	4	<0.01%	0	0.00%	2	<0.01%	8	0.01%	**24**	**0.04%**
PM1210	Accent™ SR RF	49,812	6.39%	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.

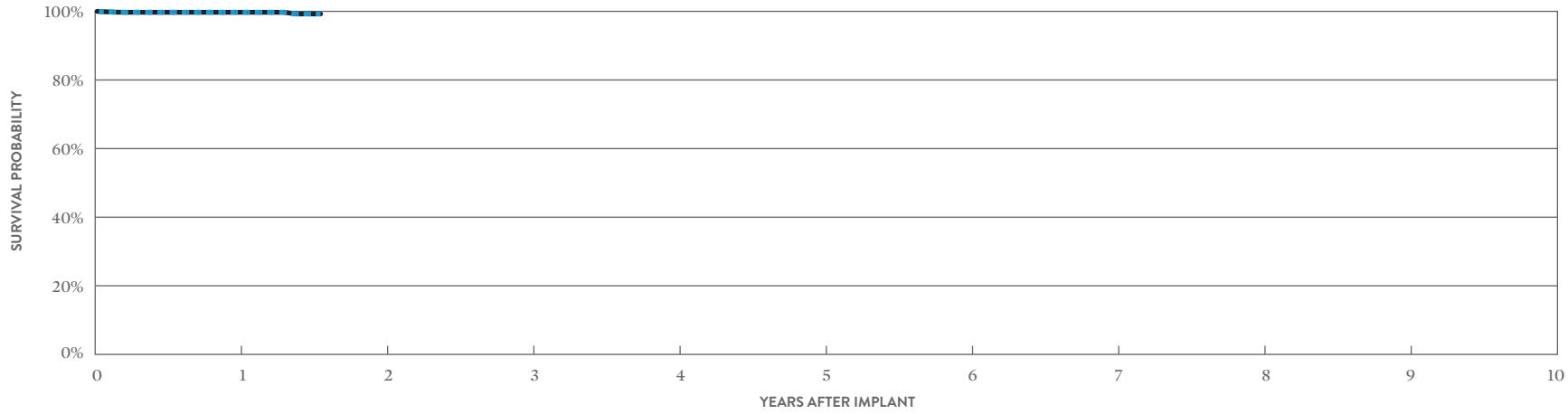
Single-Chamber Leadless Pacemakers

AVEIR™ VR

MODEL LSP112V

US Regulatory Approval	March 2022
Registered US Implants	5,990
Estimated Active US Implants	5,451
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%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	0.03%
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	2	0.06%	6	0.10%
Total	**2**	**0.06%**	**8**	**0.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	AT 19 MONTHS
SURVIVAL PROBABILITY	99.73%	99.25%
± 1 STANDARD ERROR	0.07%	0.35%
SAMPLE SIZE	3,620	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	AT 19 MONTHS
SURVIVAL PROBABILITY	99.73%	99.25%
± 1 STANDARD ERROR	0.07%	0.35%

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

AVEIR™ VR Performance

The Aveir VR leadless pacemaker exhibits 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 from Aveir VR approval to December 31, 2023.

DAY OF IMPLANT OBSERVATIONS (N = 5,990)

REPORTED COMPLICATION	QTY	RATE
Cardiac Perforation	30	0.50%
Dislodgement	36	0.60%
Failure to Capture	4	0.07%
Oversensing	1	0.02%
Failure to Sense	1	0.02%
Abnormal Impedance	4	0.07%

ACUTE OBSERVATIONS: OCCURRING WITHIN THE FIRST 30 DAYS POST-IMPLANT (N = 5,990)

REPORTED COMPLICATION	QTY	RATE
Cardiac Perforation	0	0%
Dislodgement	14	0.23%
Failure to Capture	7	0.12%
Oversensing	0	0%
Failure to Sense	1	0.02%
Abnormal Impedance	1	0.02%

SUMMARY INFORMATION

Single Chamber Leadless Pacemakers

Single-Chamber 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
LSP112V	AVEIR™ VR	99.73%									

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
LSP112V	AVEIR™ VR	99.73%									

Single-Chamber Leadless 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		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP112V	AVEIR™ VR	5,990	3.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	**2**	**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		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP112V	AVEIR™ VR	5,990	3.40%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	6	0.10%	**8**	**0.13%**

Definitions of malfunction categories can be found on pages 5-6.

Single-Chamber 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
LSP112V	AVEIR™ VR	10,059	2.73%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	2	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		EXTRINSIC FACTORS		TOTAL	
				QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE	QTY	RATE
LSP112V	AVEIR™ VR	10,059	2.73%	0	0.00%	0	0.00%	0	0.00%	5	0.00%	0	0.00%	0	0.00%	1	0.00%	8	0.07%	14	0.07%

Definitions of malfunction categories can be found on pages 5-6.

Pacing Leads

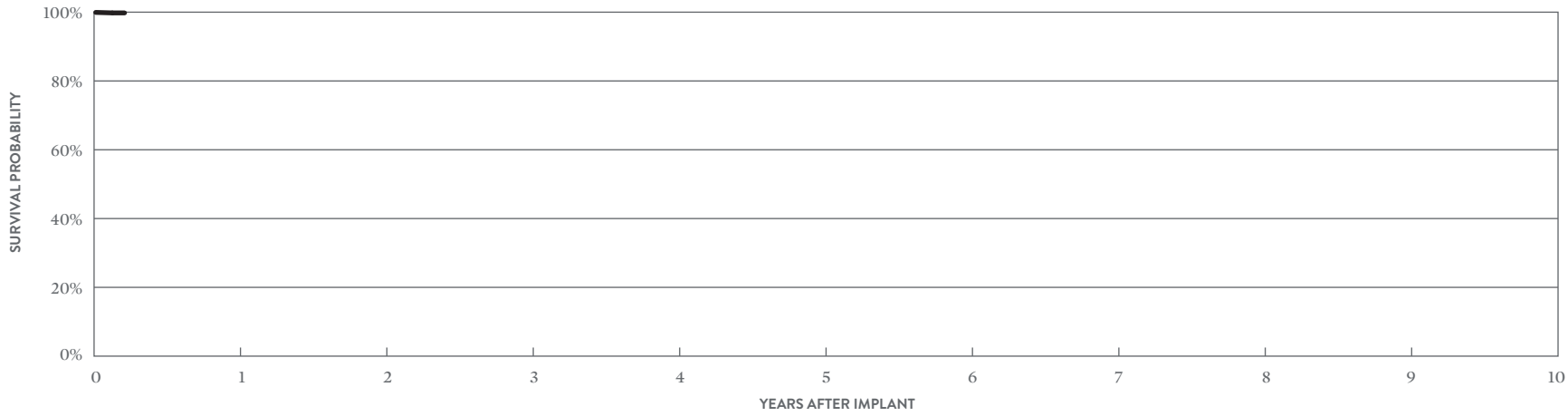
UltiPace™

MODEL LPA1231

US Regulatory Approval	May 2023
Registered US Implants	1,199
Estimated Active US Implants	1,173
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	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.08%	1	0.08%
Failure to Capture	1	0.08%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.08%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.08%	1	0.08%
Total	**3**	**0.25%**	**3**	**0.25%**
Total Returned for Analysis	**0**		**0**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**0**	**0.00%**



YEAR	AT 3 MONTHS
SURVIVAL PROBABILITY	99.79%
± 1 STANDARD ERROR	0.21%
SAMPLE SIZE	300

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

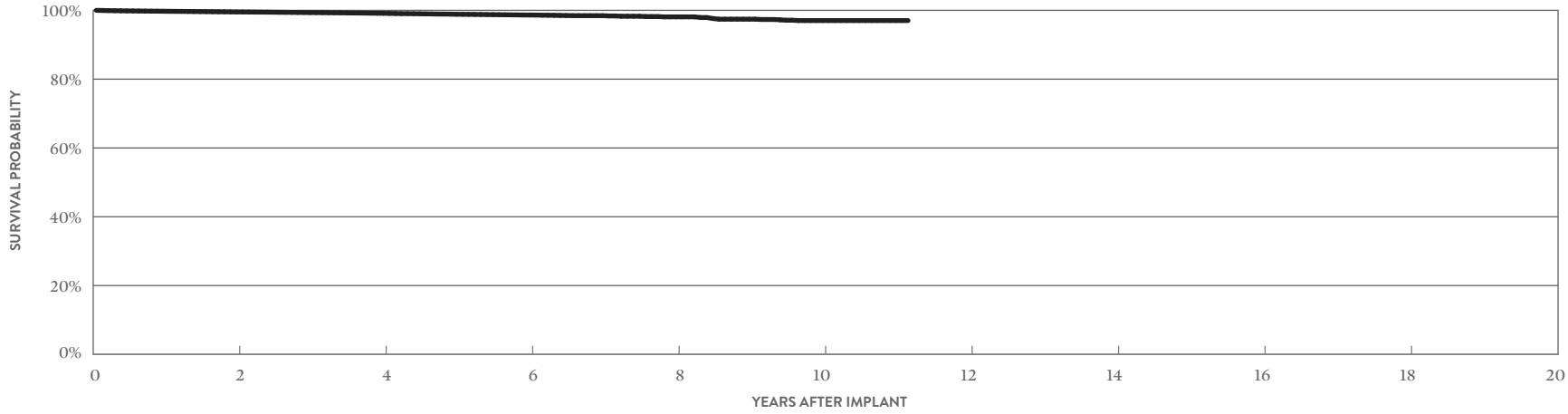
Tendril MRI™

MODEL LPA1200M

US Regulatory Approval	January 2017
Registered US Implants	199,280
Estimated Active US Implants	113,262
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%	22	0.01%
Conductor Fracture	3	<0.01%	112	0.06%
Lead Dislodgement	418	0.21%	541	0.27%
Failure to Capture	68	0.03%	364	0.18%
Oversensing	20	0.01%	753	0.38%
Failure to Sense	27	0.01%	57	0.03%
Insulation Breach	2	<0.01%	38	0.02%
Abnormal Pacing Impedance	2	<0.01%	89	0.04%
Extracardiac Stimulation	8	<0.01%	12	<0.01%
Other	62	0.03%	50	0.03%
Total	**669**	**0.34%**	**2038**	**1.02%**
Total Returned for Analysis	**246**		**538**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	67	0.03%
Insulation Breach	127	0.06%
Crimps, Welds & Bonds	0	0.00%
Other	7	<0.01%
Extrinsic Factors	338	0.17%
Total	**539**	**0.27%**



YEAR	2	4	6	8	10	AT 134 MONTHS
SURVIVAL PROBABILITY	99.53%	99.13%	98.64%	98.10%	97.03%	97.03%
± 1 STANDARD ERROR	0.02%	0.02%	0.04%	0.18%	0.37%	0.37%
SAMPLE SIZE	154,330	110,930	57,270	1,110	960	230

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

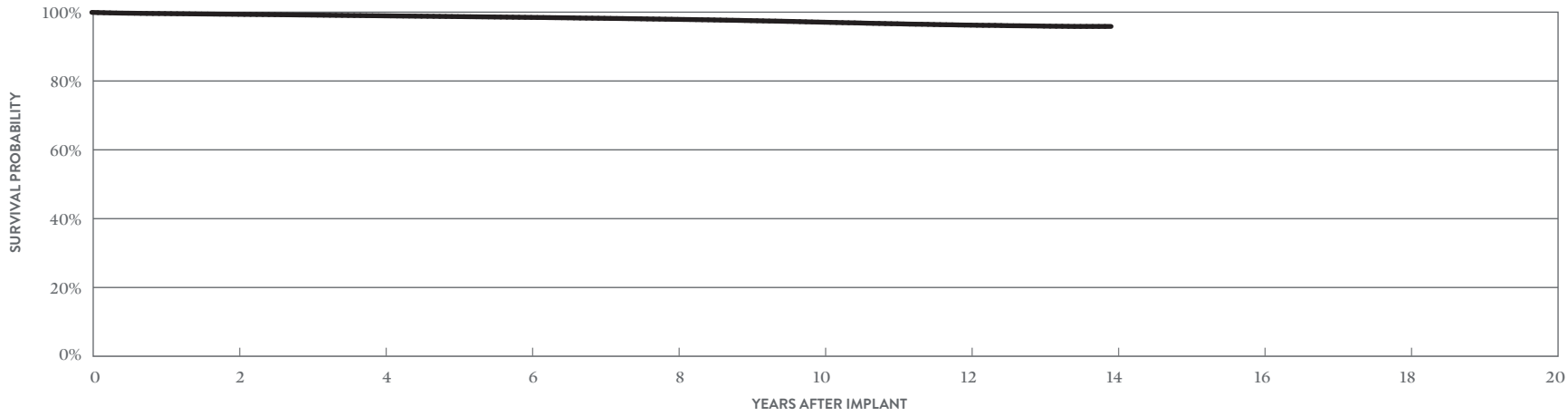
Tendril™ STS

MODEL 2088TC

US Regulatory Approval	May 2009
Registered US Implants	1,210,377
Estimated Active US Implants	609,219
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	299	0.02%	162	0.01%
Conductor Fracture	11	<0.01%	555	0.05%
Lead Dislodgement	1764	0.15%	2895	0.24%
Failure to Capture	540	0.04%	2537	0.21%
Oversensing	138	0.01%	8136	0.67%
Failure to Sense	70	<0.01%	334	0.03%
Insulation Breach	27	<0.01%	554	0.05%
Abnormal Pacing Impedance	67	<0.01%	581	0.05%
Extracardiac Stimulation	18	<0.01%	107	<0.01%
Other	235	0.02%	442	0.04%
Total	**3169**	**0.26%**	**16303**	**1.35%**
Total Returned for Analysis	**1080**		**4069**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	132	0.01%
Insulation Breach	1654	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	35	<0.01%
Extrinsic Factors	2681	0.22%
Total	**4502**	**0.37%**



YEAR	2	4	6	8	10	12	14
SURVIVAL PROBABILITY	99.46%	99.02%	98.56%	98.00%	97.18%	96.32%	95.92%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.07%
SAMPLE SIZE	854,830	575,350	388,250	266,300	148,630	61,400	210

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

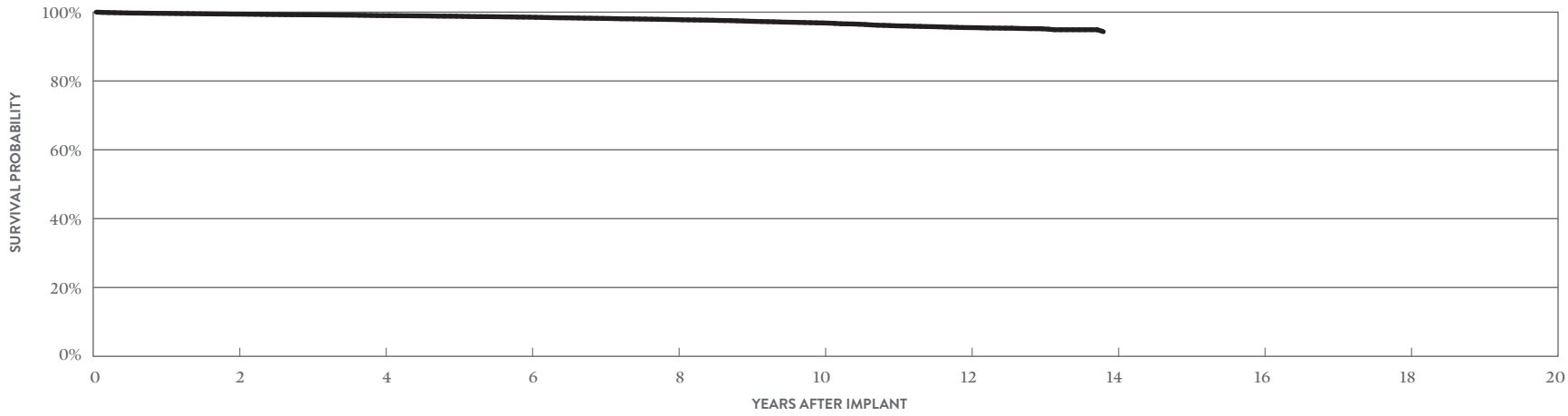
OptiSense™

MODEL 1999

US Regulatory Approval	May 2007
Registered US Implants	48,429
Estimated Active US Implants	18,958
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%	23	0.05%
Lead Dislodgement	64	0.13%	198	0.41%
Failure to Capture	8	0.02%	128	0.26%
Oversensing	10	0.02%	652	1.35%
Failure to Sense	3	<0.01%	56	0.12%
Insulation Breach	1	<0.01%	61	0.13%
Abnormal Pacing Impedance	0	0.00%	25	0.05%
Extracardiac Stimulation	0	0.00%	2	<0.01%
Other	14	0.03%	31	0.06%
Total	**105**	**0.22%**	**1178**	**2.43%**
Total Returned for Analysis	**59**		**291**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	8	0.02%
Insulation Breach	119	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	7	0.01%
Extrinsic Factors	202	0.42%
Total	**336**	**0.69%**



YEAR	2	4	6	8	10	12	AT 166 MONTHS
SURVIVAL PROBABILITY	99.43%	99.00%	98.54%	97.84%	96.87%	95.51%	94.33%
± 1 STANDARD ERROR	0.04%	0.05%	0.06%	0.08%	0.11%	0.16%	0.23%
SAMPLE SIZE	41,160	34,590	29,110	22,910	14,400	6,780	230

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

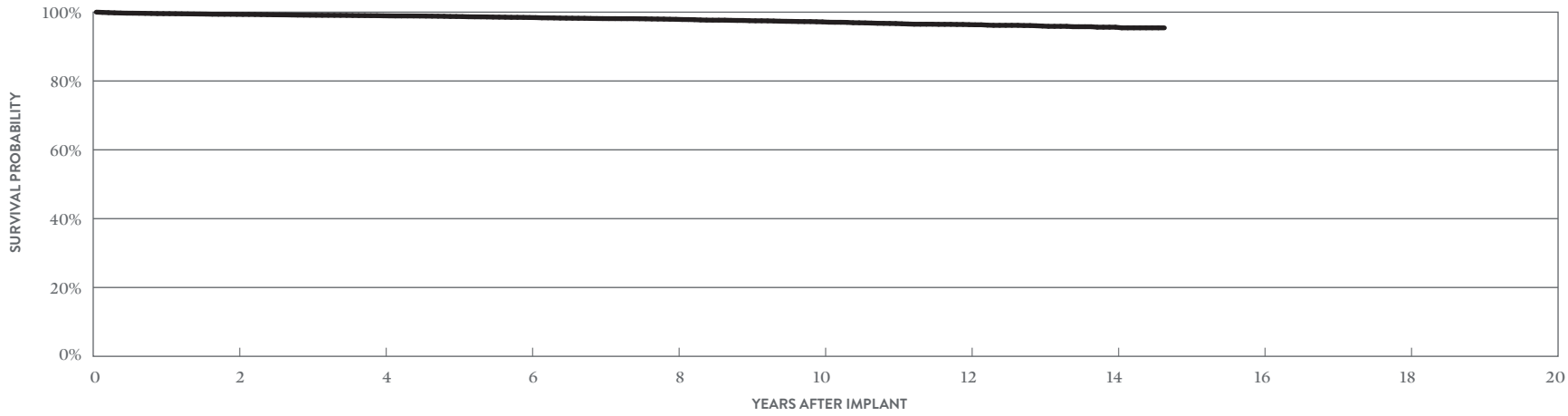
IsoFlex™ Optim™

MODEL 1944

US Regulatory Approval	March 2008
Registered US Implants	21,422
Estimated Active US Implants	8,492
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%	12	0.06%
Lead Dislodgement	124	0.58%	84	0.39%
Failure to Capture	18	0.08%	73	0.34%
Oversensing	1	<0.01%	197	0.92%
Failure to Sense	3	0.01%	11	0.05%
Insulation Breach	0	0.00%	9	0.04%
Abnormal Pacing Impedance	0	0.00%	9	0.04%
Extracardiac Stimulation	3	0.01%	1	<0.01%
Other	4	0.02%	6	0.03%
Total	**153**	**0.71%**	**403**	**1.88%**
Total Returned for Analysis	**73**		**66**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	23	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	51	0.24%
Total	**75**	**0.35%**



YEAR	2	4	6	8	10	12	14	AT 176 MONTHS
SURVIVAL PROBABILITY	99.36%	98.94%	98.44%	97.92%	97.17%	96.37%	95.63%	95.44%
± 1 STANDARD ERROR	0.06%	0.08%	0.10%	0.13%	0.17%	0.23%	0.34%	0.39%
SAMPLE SIZE	16,590	12,940	9,980	7,500	5,020	2,650	870	220

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

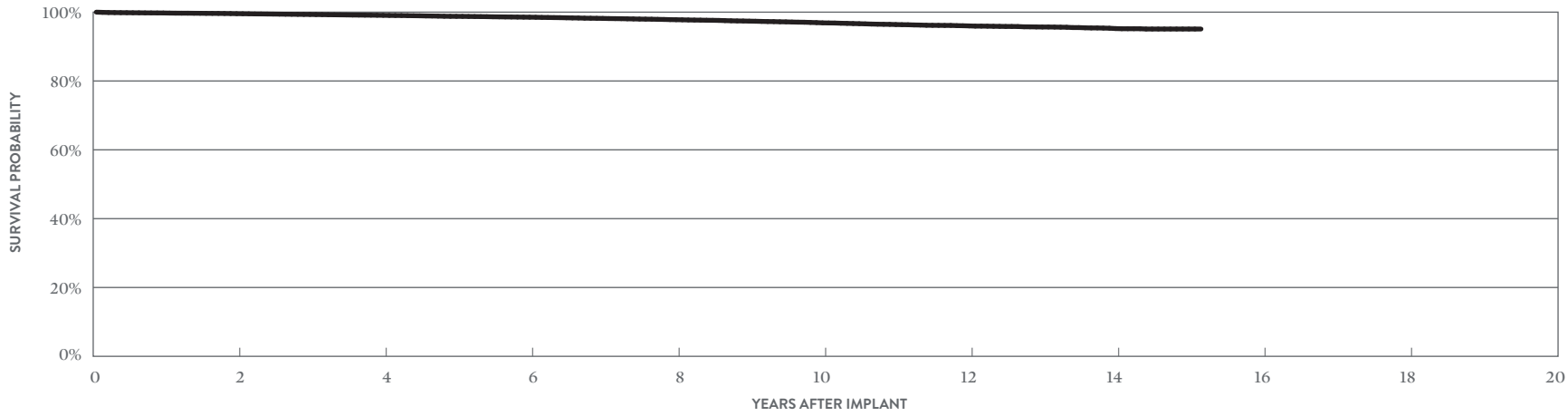
IsoFlex™ Optim™

MODEL 1948

US Regulatory Approval	March 2008
Registered US Implants	79,507
Estimated Active US Implants	31,359
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%	131	0.16%
Lead Dislodgement	86	0.11%	98	0.12%
Failure to Capture	56	0.07%	321	0.40%
Oversensing	4	<0.01%	597	0.75%
Failure to Sense	2	<0.01%	7	<0.01%
Insulation Breach	4	<0.01%	127	0.16%
Abnormal Pacing Impedance	1	<0.01%	61	0.08%
Extracardiac Stimulation	2	<0.01%	9	0.01%
Other	9	0.01%	36	0.05%
Total	**171**	**0.22%**	**1400**	**1.76%**
Total Returned for Analysis	**74**		**213**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	23	0.03%
Insulation Breach	178	0.22%
Crimps, Welds & Bonds	0	0.00%
Other	4	<0.01%
Extrinsic Factors	119	0.15%
Total	**324**	**0.41%**



YEAR	2	4	6	8	10	12	14	AT 182 MONTHS
SURVIVAL PROBABILITY	99.56%	99.08%	98.53%	97.80%	96.89%	96.00%	95.23%	95.10%
± 1 STANDARD ERROR	0.02%	0.04%	0.05%	0.07%	0.10%	0.13%	0.18%	0.22%
SAMPLE SIZE	62,250	48,720	38,030	28,270	18,310	9,240	3,100	260

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

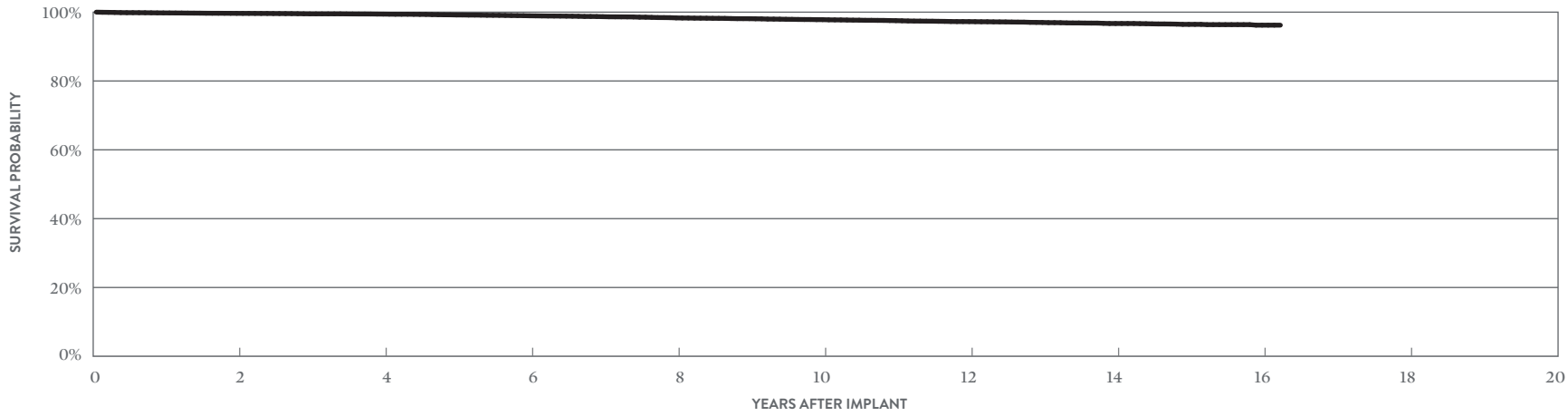
OptiSense™

MODELS 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	23,977
Estimated Active US Implants	6,304
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	4	0.02%	57	0.24%
Failure to Capture	4	0.02%	65	0.27%
Oversensing	3	0.01%	174	0.73%
Failure to Sense	8	0.03%	34	0.14%
Insulation Breach	0	0.00%	11	0.05%
Abnormal Pacing Impedance	0	0.00%	30	0.13%
Extracardiac Stimulation	0	0.00%	3	0.01%
Other	2	<0.01%	11	0.05%
Total	**22**	**0.09%**	**405**	**1.69%**
Total Returned for Analysis	**16**		**92**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	14	0.06%
Insulation Breach	56	0.23%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	67	0.28%
Total	**137**	**0.57%**



YEAR	2	4	6	8	10	12	14	16	AT 195 MONTHS
SURVIVAL PROBABILITY	99.65%	99.43%	98.94%	98.33%	97.82%	97.25%	96.70%	96.22%	96.22%
± 1 STANDARD ERROR	0.04%	0.05%	0.08%	0.11%	0.13%	0.15%	0.17%	0.25%	0.25%
SAMPLE SIZE	19,490	15,720	13,020	10,950	9,500	8,270	6,360	1,620	250

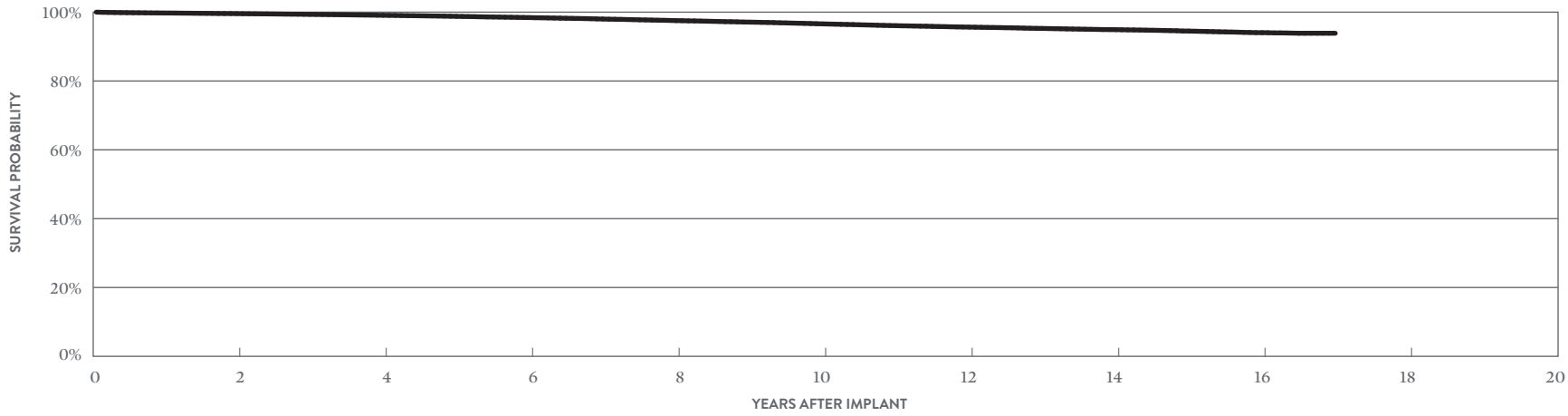
Tendril™ ST Optim™

MODELS 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	315,900
Estimated Active US Implants	91,656
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	41	0.01%	46	0.01%
Conductor Fracture	8	<0.01%	365	0.12%
Lead Dislodgement	158	0.05%	640	0.20%
Failure to Capture	88	0.03%	1248	0.40%
Oversensing	22	<0.01%	4284	1.36%
Failure to Sense	14	<0.01%	162	0.05%
Insulation Breach	7	<0.01%	544	0.17%
Abnormal Pacing Impedance	10	<0.01%	327	0.10%
Extracardiac Stimulation	5	<0.01%	49	0.02%
Other	42	0.01%	208	0.07%
Total	**395**	**0.13%**	**7873**	**2.49%**
Total Returned for Analysis	**207**		**1735**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	56	0.02%
Insulation Breach	1317	0.42%
Crimps, Welds & Bonds	1	<0.01%
Other	18	<0.01%
Extrinsic Factors	1006	0.32%
Total	**2398**	**0.76%**



YEAR	2	4	6	8	10	12	14	16	AT 204 MONTHS
SURVIVAL PROBABILITY	99.57%	99.09%	98.42%	97.54%	96.59%	95.65%	94.91%	94.04%	93.87%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.04%	0.05%	0.06%	0.10%	0.12%
SAMPLE SIZE	256,110	207,530	171,510	144,030	115,740	85,270	51,810	13,110	230

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

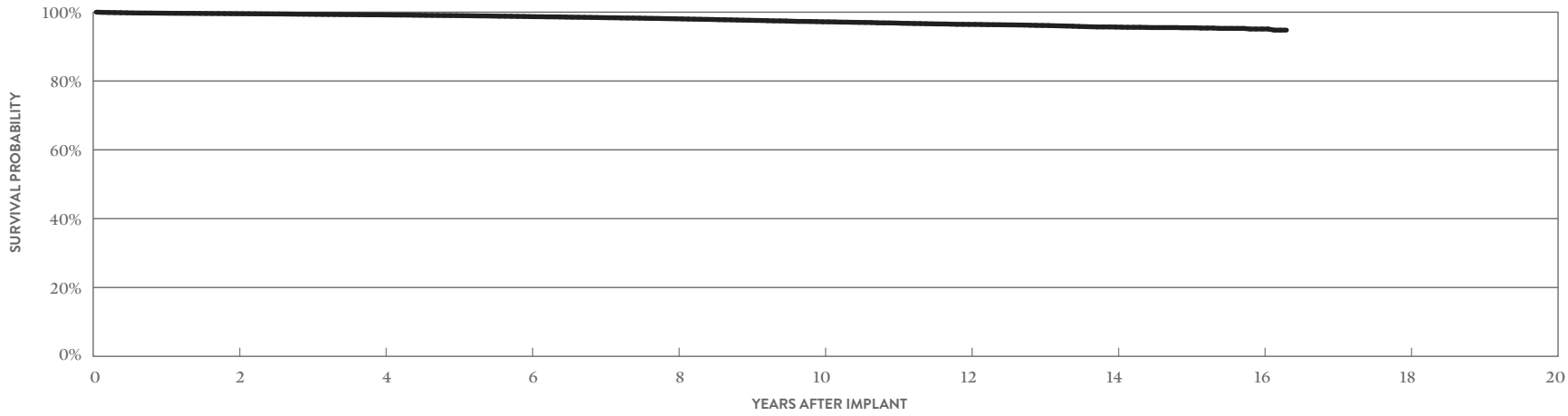
Tendril™ ST Optim™

MODELS 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	50,312
Estimated Active US Implants	17,565
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	4	<0.01%	4	<0.01%
Conductor Fracture	0	0.00%	27	0.05%
Lead Dislodgement	49	0.10%	172	0.34%
Failure to Capture	12	0.02%	148	0.29%
Oversensing	6	0.01%	503	1.00%
Failure to Sense	4	<0.01%	33	0.07%
Insulation Breach	0	0.00%	63	0.13%
Abnormal Pacing Impedance	1	<0.01%	36	0.07%
Extracardiac Stimulation	0	0.00%	4	<0.01%
Other	15	0.03%	34	0.07%
Total	**91**	**0.18%**	**1024**	**2.04%**
Total Returned for Analysis	**49**		**220**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	<0.01%
Insulation Breach	122	0.24%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	154	0.31%
Total	**281**	**0.56%**



YEAR	2	4	6	8	10	12	14	16	AT 196 MONTHS
SURVIVAL PROBABILITY	99.55%	99.21%	98.71%	98.07%	97.20%	96.44%	95.67%	95.10%	94.78%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.08%	0.10%	0.13%	0.18%	0.30%	0.44%
SAMPLE SIZE	41,870	34,660	28,830	22,630	15,670	9,190	4,080	870	220

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

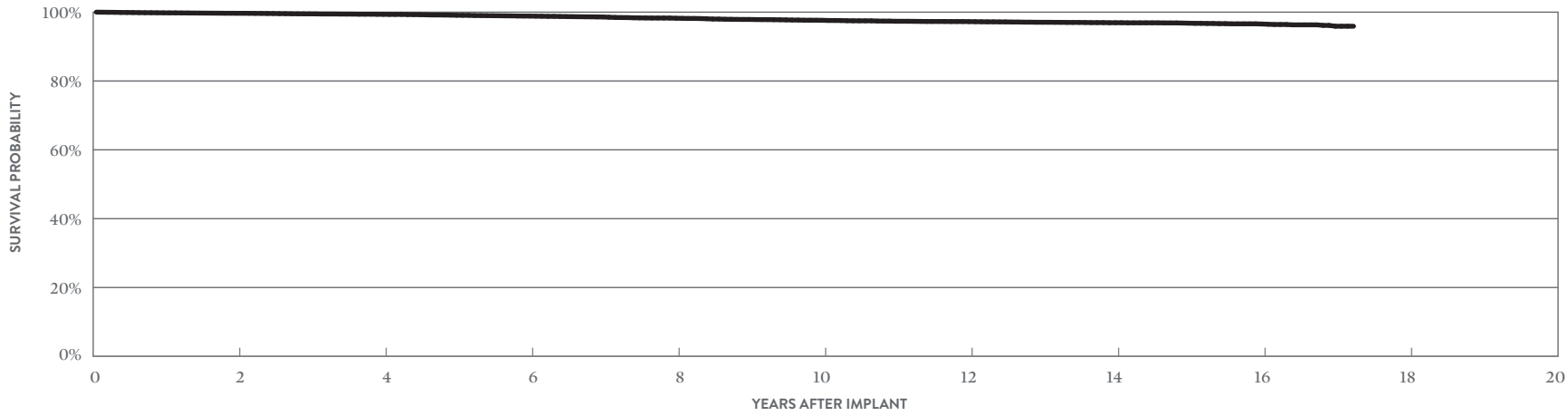
Tendril™

MODELS 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,576
Estimated Active US Implants	4,036
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	0.33%
Failure to Capture	5	0.03%	61	0.37%
Oversensing	0	0.00%	85	0.51%
Failure to Sense	0	0.00%	10	0.06%
Insulation Breach	0	0.00%	7	0.04%
Abnormal Pacing Impedance	2	0.01%	21	0.13%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	6	0.04%
Total	**29**	**0.17%**	**251**	**1.51%**
Total Returned for Analysis	**16**		**73**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	<0.01%
Insulation Breach	52	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	51	0.31%
Total	**104**	**0.63%**



YEAR	2	4	6	8	10	12	14	16	AT 207 MONTHS
SURVIVAL PROBABILITY	99.67%	99.36%	98.86%	98.23%	97.63%	97.25%	96.93%	96.55%	95.91%
± 1 STANDARD ERROR	0.05%	0.07%	0.10%	0.14%	0.17%	0.19%	0.20%	0.23%	0.40%
SAMPLE SIZE	13,380	10,630	8,440	6,910	5,930	5,100	3,760	1,950	230

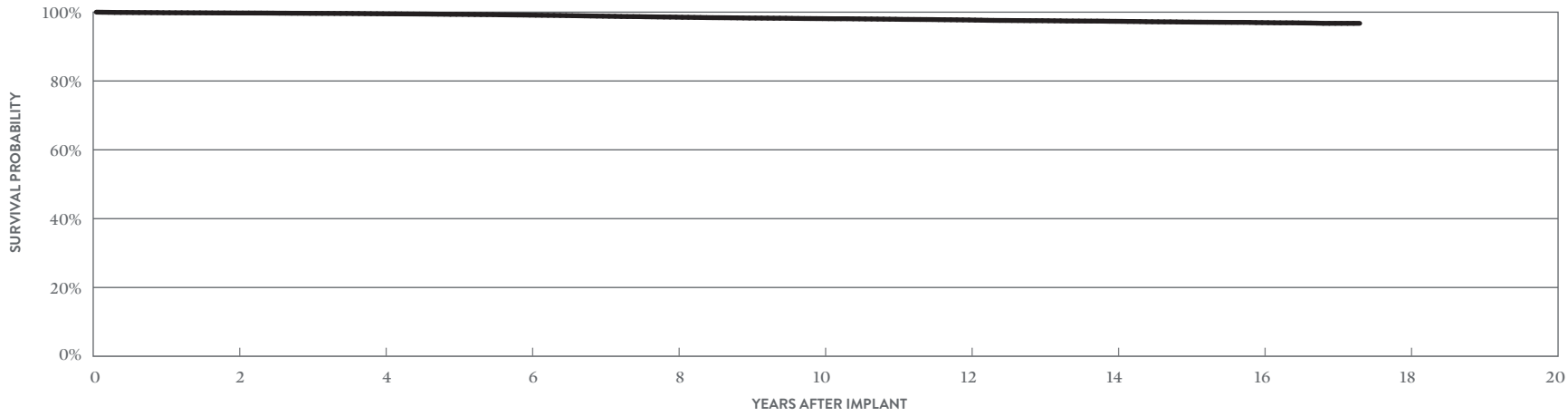
Tendril™

MODELS 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,626
Estimated Active US Implants	15,782
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%	8	0.01%
Conductor Fracture	1	<0.01%	40	0.06%
Lead Dislodgement	31	0.05%	80	0.12%
Failure to Capture	31	0.05%	215	0.33%
Oversensing	4	<0.01%	313	0.48%
Failure to Sense	2	<0.01%	27	0.04%
Insulation Breach	1	<0.01%	37	0.06%
Abnormal Pacing Impedance	9	0.01%	59	0.09%
Extracardiac Stimulation	2	<0.01%	9	0.01%
Other	20	0.03%	37	0.06%
Total	**113**	**0.17%**	**825**	**1.26%**
Total Returned for Analysis	**49**		**180**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	10	0.02%
Insulation Breach	152	0.23%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	111	0.17%
Total	**275**	**0.42%**



YEAR	2	4	6	8	10	12	14	16	AT 208 MONTHS
SURVIVAL PROBABILITY	99.75%	99.53%	99.14%	98.55%	98.12%	97.73%	97.34%	96.96%	96.75%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.06%	0.08%	0.09%	0.10%	0.11%	0.13%
SAMPLE SIZE	52,400	40,940	32,890	27,130	23,450	20,840	17,490	10,780	280

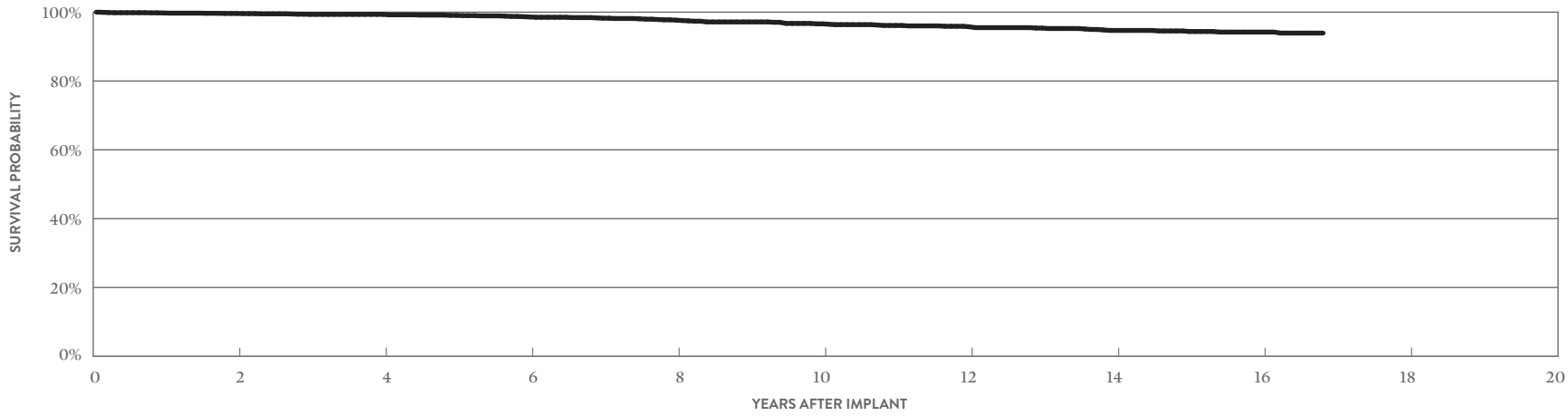
IsoFlex™ P

MODEL 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,836
Estimated Active US Implants	614
Insulation	Polyurethane
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%	0	0.00%
Conductor Fracture	0	0.00%	7	0.25%
Lead Dislodgement	2	0.07%	2	0.07%
Failure to Capture	2	0.07%	17	0.60%
Oversensing	0	0.00%	3	0.11%
Failure to Sense	1	0.04%	1	0.04%
Insulation Breach	0	0.00%	15	0.53%
Abnormal Pacing Impedance	0	0.00%	4	0.14%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	6	0.21%
Total	**6**	**0.21%**	**55**	**1.94%**
Total Returned for Analysis	**1**		**8**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	20	0.71%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.07%
Extrinsic Factors	6	0.21%
Total	**28**	**0.99%**



YEAR	2	4	6	8	10	12	14	16	AT 202 MONTHS
SURVIVAL PROBABILITY	99.62%	99.35%	98.60%	97.67%	96.60%	95.76%	94.69%	94.21%	93.92%
± 1 STANDARD ERROR	0.13%	0.18%	0.28%	0.40%	0.53%	0.60%	0.71%	0.76%	0.81%
SAMPLE SIZE	2,120	1,640	1,260	1,030	870	770	690	500	200

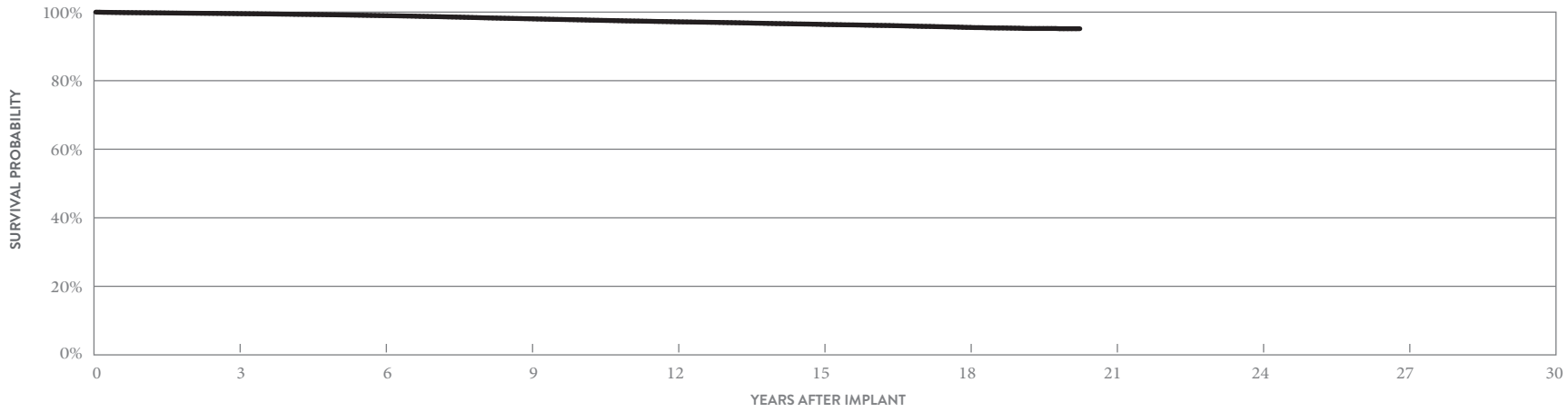
Tendril™ SDX

MODELS 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	494,454
Estimated Active US Implants	121,850
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	81	0.02%	46	<0.01%
Conductor Fracture	6	<0.01%	658	0.13%
Lead Dislodgement	322	0.07%	659	0.13%
Failure to Capture	203	0.04%	2050	0.41%
Oversensing	24	<0.01%	2642	0.53%
Failure to Sense	34	<0.01%	197	0.04%
Insulation Breach	10	<0.01%	276	0.06%
Abnormal Pacing Impedance	30	<0.01%	735	0.15%
Extracardiac Stimulation	8	<0.01%	54	0.01%
Other	68	0.01%	246	0.05%
Total	**786**	**0.16%**	**7563**	**1.53%**
Total Returned for Analysis	**353**		**1738**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	227	0.05%
Insulation Breach	1245	0.25%
Crimps, Welds & Bonds	2	<0.01%
Other	21	<0.01%
Extrinsic Factors	901	0.18%
Total	**2396**	**0.48%**



YEAR	3	6	9	12	15	18	AT 244 MONTHS
SURVIVAL PROBABILITY	99.55%	98.98%	98.06%	97.18%	96.43%	95.54%	95.16%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.05%	0.07%	0.11%
SAMPLE SIZE	358,480	253,660	175,980	114,600	69,080	27,920	230

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™										
LPA1200M	Tendril MRI™	99.73%	99.53%	99.35%	99.13%	98.86%	98.64%	98.45%	98.10%	97.43%	97.03%
2088TC	Tendril™ STS	99.67%	99.46%	99.25%	99.02%	98.80%	98.56%	98.30%	98.00%	97.64%	97.18%
1999	OptiSense™ Optim™	99.65%	99.43%	99.23%	99.00%	98.81%	98.54%	98.18%	97.84%	97.36%	96.87%
1944	IsoFlex™ Optim™	99.57%	99.36%	99.12%	98.94%	98.74%	98.44%	98.13%	97.92%	97.52%	97.17%
1948	IsoFlex™ Optim™	99.76%	99.56%	99.33%	99.08%	98.78%	98.53%	98.18%	97.80%	97.39%	96.89%
1699T/TC	OptiSense™	99.78%	99.65%	99.51%	99.43%	99.18%	98.94%	98.69%	98.33%	98.10%	97.82%
1888T/TC	Tendril™ ST Optim™	99.75%	99.57%	99.35%	99.09%	98.78%	98.42%	98.00%	97.54%	97.10%	96.59%
1882T/TC	Tendril™ ST Optim™	99.70%	99.55%	99.38%	99.21%	99.00%	98.71%	98.40%	98.07%	97.64%	97.20%
1782T/TC	Tendril™	99.80%	99.67%	99.50%	99.36%	99.10%	98.86%	98.60%	98.23%	97.88%	97.63%
1788T/TC	Tendril™	99.83%	99.75%	99.65%	99.53%	99.37%	99.14%	98.84%	98.55%	98.29%	98.12%
1648T	IsoFlex™ P	99.76%	99.62%	99.35%	99.35%	99.07%	98.60%	98.24%	97.67%	97.16%	96.60%
1688T/TC	Tendril™ SDX	99.82%	99.69%	99.55%	99.40%	99.22%	98.98%	98.71%	98.37%	98.06%	97.75%

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

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 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	
LPA1231	May-23	1,199	1,173	0	0.00%	0	0.00%	1	0.08%	1	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.08%	**3**	**0.25%**	**0**
LPA1200M	Jan-17	199,280	113,262	59	0.03%	3	<0.01%	418	0.21%	68	0.03%	20	0.01%	27	0.01%	2	<0.01%	2	<0.01%	8	<0.01%	62	0.03%	**669**	**0.34%**	**246**
2088TC	May-09	1,210,377	609,219	299	0.02%	11	<0.01%	1764	0.15%	540	0.04%	138	0.01%	70	<0.01%	27	<0.01%	67	<0.01%	18	<0.01%	235	0.02%	**3169**	**0.26%**	**1080**
1999	Oct-09	48,429	18,958	5	0.01%	0	0.00%	64	0.13%	8	0.02%	10	0.02%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	14	0.03%	**105**	**0.22%**	**59**
1944	Mar-08	21,422	8,492	0	0.00%	0	0.00%	124	0.58%	18	0.08%	1	<0.01%	3	0.01%	0	0.00%	0	0.00%	3	0.01%	4	0.02%	**153**	**0.71%**	**73**
1948	Mar-08	79,507	31,359	6	<0.01%	1	<0.01%	86	0.11%	56	0.07%	4	<0.01%	2	<0.01%	4	<0.01%	1	<0.01%	2	<0.01%	9	0.01%	**171**	**0.22%**	**74**
1699T/TC	May-07	23,977	6,304	1	<0.01%	0	0.00%	4	0.02%	4	0.02%	3	0.01%	8	0.03%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**22**	**0.09%**	**16**
1888T/TC	Jun-06	315,900	91,656	41	0.01%	8	<0.01%	158	0.05%	88	0.03%	22	<0.01%	14	<0.01%	7	<0.01%	10	<0.01%	5	<0.01%	42	0.01%	**395**	**0.13%**	**207**
1882T/TC	Jun-06	50,312	17,565	4	<0.01%	0	0.00%	49	0.10%	12	0.02%	6	0.01%	4	<0.01%	0	0.00%	1	<0.01%	0	0.00%	15	0.03%	**91**	**0.18%**	**49**
1782T/TC	Feb-06	16,576	4,036	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	65,626	15,782	12	0.02%	1	<0.01%	31	0.05%	31	0.05%	4	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**113**	**0.17%**	**49**
1648T	Apr-05	2,836	614	0	0.00%	0	0.00%	2	0.07%	2	0.07%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	**6**	**0.21%**	**1**
1688T/TC	Jun-03	494,454	121,850	81	0.02%	6	<0.01%	322	0.07%	203	0.04%	24	<0.01%	34	<0.01%	10	<0.01%	30	<0.01%	8	<0.01%	68	0.01%	**786**	**0.16%**	**353**

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	
LPA1231	May-23	1,199	1,173	0	0.00%	0	0.00%	1	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.08%	0	0.00%	1	0.08%	**3**	**0.25%**	**0**
LPA1200M	Jan-17	199,280	113,262	22	0.01%	112	0.06%	541	0.27%	364	0.18%	753	0.38%	57	0.03%	38	0.02%	89	0.04%	12	<0.01%	50	0.03%	**2038**	**1.02%**	**538**
2088TC	May-09	1,210,377	609,219	162	0.01%	555	0.05%	2895	0.24%	2537	0.21%	8136	0.67%	334	0.03%	554	0.05%	581	0.05%	107	<0.01%	442	0.04%	**16303**	**1.35%**	**4069**
1999	Oct-09	48,429	18,958	2	<0.01%	23	0.05%	198	0.41%	128	0.26%	652	1.35%	56	0.12%	61	0.13%	25	0.05%	2	<0.01%	31	0.06%	**1178**	**2.43%**	**291**
1944	Mar-08	21,422	8,492	1	<0.01%	12	0.06%	84	0.39%	73	0.34%	197	0.92%	11	0.05%	9	0.04%	9	0.04%	1	<0.01%	6	0.03%	**403**	**1.88%**	**66**
1948	Mar-08	79,507	31,359	13	0.02%	131	0.16%	98	0.12%	321	0.40%	597	0.75%	7	<0.01%	127	0.16%	61	0.08%	9	0.01%	36	0.05%	**1400**	**1.76%**	**213**
1699T/TC	May-07	23,977	6,304	0	0.00%	20	0.08%	57	0.24%	65	0.27%	174	0.73%	34	0.14%	11	0.05%	30	0.13%	3	0.01%	11	0.05%	**405**	**1.69%**	**92**
1888T/TC	Jun-06	315,900	91,656	46	0.01%	365	0.12%	640	0.20%	1248	0.40%	4284	1.36%	162	0.05%	544	0.17%	327	0.10%	49	0.02%	208	0.07%	**7873**	**2.49%**	**1735**
1882T/TC	Jun-06	50,312	17,565	4	<0.01%	27	0.05%	172	0.34%	148	0.29%	503	1.00%	33	0.07%	63	0.13%	36	0.07%	4	<0.01%	34	0.07%	**1024**	**2.04%**	**220**
1782T/TC	Feb-06	16,576	4,036	0	0.00%	6	0.04%	54	0.33%	61	0.37%	85	0.51%	10	0.06%	7	0.04%	21	0.13%	1	<0.01%	6	0.04%	**251**	**1.51%**	**73**
1788T/TC	Feb-06	65,626	15,782	8	0.01%	40	0.06%	80	0.12%	215	0.33%	313	0.48%	27	0.04%	37	0.06%	59	0.09%	9	0.01%	37	0.06%	**825**	**1.26%**	**180**
1648T	Apr-05	2,836	614	0	0.00%	7	0.25%	2	0.07%	17	0.60%	3	0.11%	1	0.04%	15	0.53%	4	0.14%	0	0.00%	6	0.21%	**55**	**1.94%**	**8**
1688T/TC	Jun-03	494,454	121,850	46	<0.01%	658	0.13%	659	0.13%	2050	0.41%	2642	0.53%	197	0.04%	276	0.06%	735	0.15%	54	0.01%	246	0.05%	**7563**	**1.53%**	**1738**

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	1,199	1.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
LPA1200M	199,280	3.20%	67	0.03%	127	0.06%	0	0.00%	7	<0.01%	338	0.17%	**539**	**0.27%**
2088TC	1,210,377	4.20%	132	0.01%	1654	0.14%	0	0.00%	35	<0.01%	2681	0.22%	**4502**	**0.37%**
1999	48,429	5.90%	8	0.02%	119	0.25%	0	0.00%	7	0.01%	202	0.42%	**336**	**0.69%**
1944	21,422	9.30%	0	0.00%	23	0.11%	0	0.00%	1	<0.01%	51	0.24%	**75**	**0.35%**
1948	79,507	5.10%	23	0.03%	178	0.22%	0	0.00%	4	<0.01%	119	0.15%	**324**	**0.41%**
1699T/TC	23,977	6.10%	14	0.06%	56	0.23%	0	0.00%	0	0.00%	67	0.28%	**137**	**0.57%**
1888T/TC	315,900	5.70%	56	0.02%	1317	0.42%	1	<0.01%	18	<0.01%	1006	0.32%	**2398**	**0.76%**
1882T/TC	50,312	4.90%	2	<0.01%	122	0.24%	0	0.00%	3	<0.01%	154	0.31%	**281**	**0.56%**
1782T/TC	16,576	5.90%	1	<0.01%	52	0.31%	0	0.00%	0	0.00%	51	0.31%	**104**	**0.63%**
1788T/TC	65,626	6.20%	10	0.02%	152	0.23%	1	<0.01%	1	<0.01%	111	0.17%	**275**	**0.42%**
1648T	2,836	6.60%	0	0.00%	20	0.71%	0	0.00%	2	0.07%	6	0.21%	**28**	**0.99%**
1688T/TC	494,454	5.90%	227	0.05%	1245	0.25%	2	<0.01%	21	<0.01%	901	0.18%	**2396**	**0.48%**

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	1,180	1.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
LPA1200M	531,903	1.35%	103	0.02%	196	0.04%	0	0.00%	17	<0.01%	461	0.09%	**777**	**0.15%**
2088TC	4,410,158	1.21%	177	<0.01%	2032	0.05%	0	0.00%	99	<0.01%	3476	0.08%	**5784**	**0.13%**
1888T/TC	1,162,670	1.75%	77	0.01%	1506	0.13%	1	<0.01%	37	<0.01%	1375	0.12%	**2996**	**0.26%**

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	3,542	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%**
DM5300	Assert™ IQ	3,649	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
DM4500	Jot Dx™ ICM	29,161	1.60%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**2**	**<0.01%**
DM3500	Confirm Rx™ ICM	100,574	4.90%	11	0.01%	10	<0.01%	0	0.00%	0	0.00%	2	<0.01%	9	<0.01%	7	<0.01%	**39**	**0.04%**
DM2102	SJM Confirm™ ICM	5,873	15.00%	19	0.32%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	5	0.09%	**26**	**0.44%**
DM2100	SJM Confirm™ ICM	18,687	17.90%	15	0.08%	1	<0.01%	20	0.11%	10	0.05%	0	0.00%	7	0.04%	42	0.22%	**95**	**0.51%**

Definitions of malfunction categories can be found on pages 5-6.

Focus on Clinical Performance

ICD Premature Battery Depletion Advisory Update – June 2024

Since the original October 2016 communication, Abbott (formerly St. Jude Medical) has continued to analyze and review the performance data from the affected device population. The rates reported below summarize performance data through February, 29, 2024.

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 February 29, 2024. All events reported since August 31, 2022 were classified as "No Harm Reported/Additional Surgery Only"; there were no (0) reports of Loss of Pacing or Loss of Defibrillation.

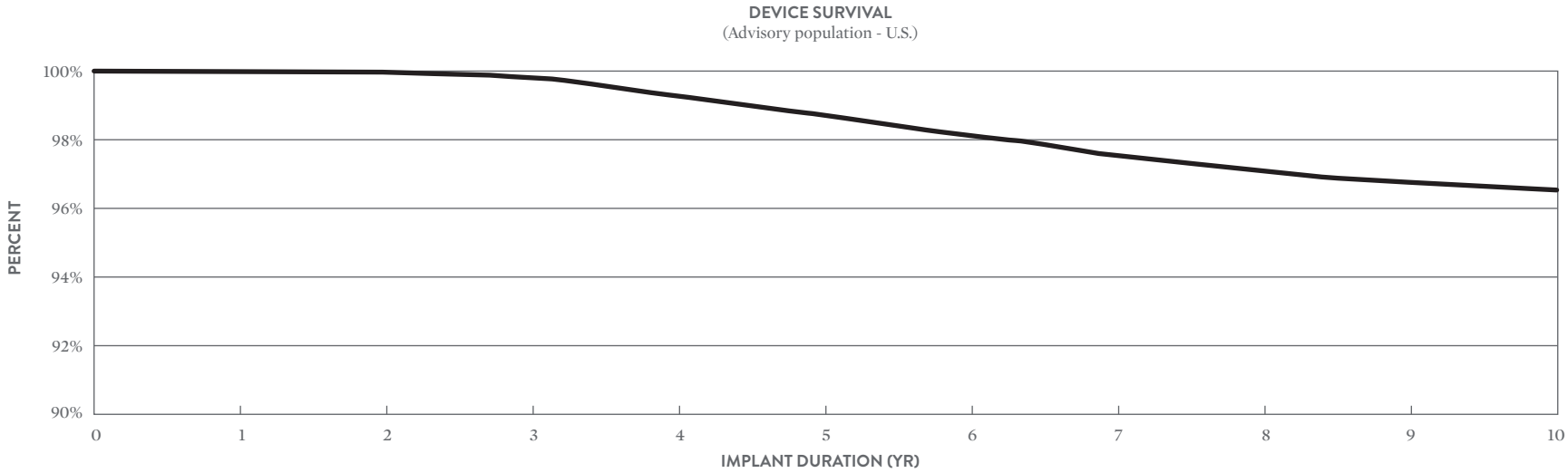
WORLDWIDE PATIENT IMPACT	NUMBER / RATE THROUGH FEBRUARY 29, 2024
No Harm Reported/Additional Surgery Only*	9,621/2.413%
Loss of Pacing – Minor (Dizziness)	60/0.015%
Loss of Pacing – Major (Syncope)	29/<0.01%
Loss of Defibrillation – Emergency	4/<0.01%
Loss of Defibrillation – Death	2/<0.01%
Grand Total	**9,716/2.437%**
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.

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%	96.937%	96.700%	96.555%
SAMPLE SIZE	227,000	210,000	197,000	185,000	173,000	165,000	147,000	124,000	100,000	71,000

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 29, 2024.

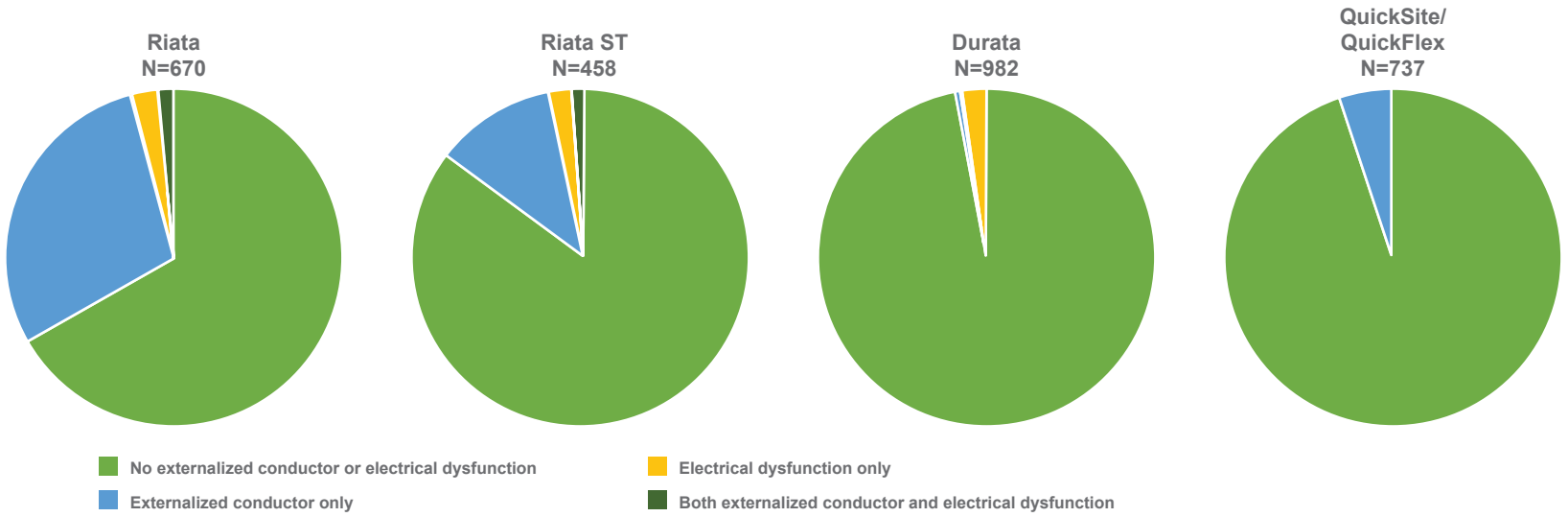
Non-Advisory Population Update

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 69 respectively).

Update on Riata™ Lead Performance

REGISTRY AND POST-MARKET STUDIES

Prospective, monitored registries provide the best data to support clinical decision making. In December 2011, Abbott initiated the Riata Lead Evaluation Study (RLES) and enrolled 782 patients with Riata leads at sites in the U.S., Canada, and Japan. In 2013, Abbott expanded the RLES to include Durata and QuickSite/QuickFlex leads and to increase the quantity of monitored Riata and Riata ST leads. The expanded study, known as the "St. Jude Medical Cardiac Lead Assessment Study" (CLAS) began enrollment in February 2013 to ensure inclusion of at least 500 leads in each of those lead families. Under the CLAS protocol, patients were followed every six months for three years with cinefluoroscopy performed at yearly follow-up visits. The main objective of the study was to determine the prevalence and incidence of lead compromise evidenced by imaging and electrical dysfunction in Riata, Riata ST, QuickSite/QuickFlex, and Durata leads. Since initiation, Abbott provided biannual updates in the Product Performance Report (PPR) regarding the progress of the Cardiac Lead Assessment Study (CLAS) and Kaplan-Meier analysis of the leads which had been enrolled. In April 2022, the final assessment of each lead family's performance was published in the Heart Rhythm O2 journal[1] and is available online as an open access manuscript. The conclusion stated that "*a high prevalence of externalized conductors was found in Riata and Riata ST defibrillator leads, with a higher risk of externalization for 8F Riata lead than for 7F Riata ST leads. The 98% reduction in prevalence of externalized conductors in Durata leads compared to Riata/Riata ST leads confirms that the design improvements culminating in Durata leads significantly improved abrasion resistance and durability.*" These findings are consistent with the data and analysis published in prior versions of the PPR. The excerpt below provides the 10-year survival probability for "Externalized Conductors" and the "Freedom from Electrical Dysfunction":



[1] *Heart Rhythm O2 2022; Volume 3, Issue 2, pgs. 160-168*

CUSTOMER REPORTED PERFORMANCE DATA

As in prior publications, Abbott provides externalized conductor rates from the passive data system to maintain continuity with previously published data and to provide full disclosure of the data available to Abbott. As of February 29, 2024, there were 6,750 cases of externalized conductors reported to Abbott worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 3.61% (5,642/156,000) incidence rate for Riata (8F) and 1.57% (1,108/70,600) for Riata ST (7F) leads. Of these 6,750 leads, 4,927 were not returned and 1,823 were returned for analysis.

Advisories & Safety Alerts

Advisories & Safety Alerts

The following table summarizes advisories and safety alerts regarding Abbott implantable device systems since 2005. 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

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 (CDVRA600Q), Entrant™ HF (Model CDHFA300Q), Entrant™ VR (Model CDVRA300Q), and Entrant™ DR (Model CDDRA300Q)
	8/18/2023
	Class II
	
	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.
		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:
		• 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.
		  • 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.
		
		Firmware version pr00.10.87.04 is available in:
		• 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
		
		Current Status (December 31, 2023): 41 devices of the 67,121 devices distributed globally (0.06%) are known to have lost Bluetooth communication due to this issue.

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 (December 31, 2023):** 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 thru Friday. **Current Status (December 31, 2023):** No occurrences of failure to deliver high voltage therapy have been reported following the field communication. Potentially affected devices have been or are planned for explant per recommendations.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
GLOBAL MODELS 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, CD1377-36C, 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) 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, CD2363-40C, CD2363-40Q) 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) Promote™ (Models 3207-30, 3207-36, 3213-36, CD3211-36, CD3211-36Q, CD3215-36, CD3215-36Q) Promote Quadra™ (Models CD3221-36, CD3223-36P, CD3239-40, CD3239-40Q) Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC, CD3387-40C, CD3387-40QC) Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3369-40C, CD3369-40Q, 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)	**4/16/2018** **Class II** 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.	Prophylactic replacement of affected devices is not recommended. **Recommendations for Devices Eligible for Firmware Upgrade** 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. Please consider the following: • 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. **Recommendations for Current™ & Promote™ Devices not Eligible for Cybersecurity Firmware Update** 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: • 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. **Current Status (December 31, 2023):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication. 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.). Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories | Abbott. [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. [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.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY

GLOBAL MODELS
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, CD2363-40C, CD2363-40Q)
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)
	10/11/2016
	Class I
	
	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.
	
	8/28/2017
	Class I
	
	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.
	
	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.
		In consultation with our Medical Advisory Board, we recommend the following:
		
		• 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.
		  • 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:
		  • 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.
		
		The following additional recommendations were communicated in April 2018 follow up advisory:
		• 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.**
		
		Device Replacement Complication Publications
		
		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)
		
		Current Status (February 29, 2024): 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 February 29, 2024, there were additional occurrences reported to Abbott or returned for analysis resulting in a cumulative worldwide total of 9,716 devices. Based on this, the rate is now 2.44%.
		
		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.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Ellipse™ and Ellipse ST VR/DR US: CD1309, CD1311*, CD1409, CD1411*, CD2309, CD2311*, CD2409, CD2411* (all -36, -36Q, -36C and -36QC suffixes). *Denotes models also sold OUS. OUS: CD1277, CD1279, CD1293, CD1295, CD1377, CD1393, CD2277, CD2279, CD2293, CD2295, CD2377, CD2393 (all -36, -36Q, -36C and -36QC suffixes).	**8/19/2014** **Class II** Extended Charge Time may result in delayed delivery of high voltage therapy or prevent delivery of part or all of a programmed high voltage therapy shock. The anomaly most commonly presents as a vibratory patient notification and upon interrogation, a programmer or Merlin.net™ Patient Care Network (PCN) alert indicating a "Capacitor Charge Time Limit reached" message. This may occur during a capacitor maintenance or charging for high voltage therapy. The anomaly occurs as a result of internal damage to the capacitors used in the high voltage charging circuitry of the subject devices, which may result in an extended charge time. As designed, the device will deliver the available energy on the capacitors once the charge time limit of 32 seconds is reached, even if the energy is less than the programmed value. This condition is detectable as the device will initiate a vibratory patient alert and, for patients enrolled and actively being followed, a Merlin.net PCN notification. Additionally, upon device interrogation, an alert message will indicate "Capacitor Charge Time Limit reached" on a specific date. Approximately 97% of Ellipse ICD extended charge time events reported to Abbott have been detected during capacitor maintenance with the remainder detected during defibrillation threshold (DFT) testing. There have been no reported cases of an Ellipse device failing to deliver high voltage therapy to a patient when needed.	Abbott recommends that patients with affected devices be enrolled in Merlin.net Patient Care Network (PCN) so that any extended charge time alert ("Capacitor Charge Time Limit reached" message) will be transmitted to Merlin.net PCN for patients being actively monitored and can be viewed by your clinic staff. If your patient has received a vibratory notification and/or if a programmer or Merlin.net alert for an extended charge time has been observed: • Schedule your Ellipse ICD patient for an in-office follow-up evaluation as soon as possible. • Interrogate the Ellipse ICD and perform a manual capacitor maintenance charge. Note the charge time to full charge; it should be approximately 15 seconds or less. • Contact Abbott CRM Technical Services Department at 800-722-3774 to review the results of the capacitor maintenance test and discuss if additional evaluation is required. • A device that has experienced repeated extended charge time out warnings should be considered for replacement. As the large majority of the extended charge time events have presented at the routine 6 month automatic capacitor maintenance interval, programming the interval to every 4 months at your patient's next scheduled follow up visit may provide an earlier indication of this potential anomaly. It should be noted that changing the device programming to a 4 month capacitor maintenance interval will reduce device longevity by approximately 9%. Device replacement is not recommended for an Ellipse device exhibiting normal charge times, and patients should continue to be followed at routine follow up intervals, per HRS/EHRA Expert Consensus on Monitoring Cardiovascular Implantable Electronic Devices (CIED), April 2008. **Current Status (December 31, 2023):** At the time of the advisory, the worldwide event rate of extended charge time on the affected population was 0.42%, based on 179 extended charge time events out of 43,000 worldwide sales. Through December 31, 2023, the rate remains stable at 1.52%. There have been no reports of serious injury or death within this population.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
AnalyST Accel™ DR RF (Models CD2219-36, CD2219-36Q) AnalyST Accel™ VR RF (Models CD1219-36, CD1219-36Q) Current Accel™ DR RF (Models CD2215-36, CD2215-36Q) Current Accel™ VR RF (Models CD1215-36, CD1215-36Q) Current™ DR (Model 2207-36) Current™ VR (Model 1207-36) Ellipse™ DR (Models CD2277-36, CD2277-36Q, CD2377-36, CD2377-36Q, CD2377-36C, CD2377-36QC) Ellipse™ VR (Models CD1277-36, CD1277-36Q, CD1377-36, CD1377-36Q, CD1377-36C, CD1377-36QC) Fortify Assura™ DR (Models CD2259-40, CD2259-40Q, CD2359-40, CD2359-40Q, CD2359-40C, CD2359-40QC) Fortify Assura™ VR (Models CD1259-40, CD1259-40Q, CD1359-40, CD1359-40Q, CD1359-40C, CD1359-40QC) Fortify™ ST DR (Models CD2235-40, CD2235-40Q) Fortify™ ST VR (Models CD1235-40, CD1235-40Q) Promote Accel™ RF (Models CD3215-36, CD3215-36Q) Promote Quadra™ (Models CD3239-40, CD3239-40Q) Promote™ (Model 3213-36) Quadra Assura™ (Models CD3267-40, CD3267-40Q, CD3367-40, CD3367-40Q, CD3367-40C, CD3367-40QC) Quadra Assura MP™ (Models CD3371-40, CD3371-40Q, CD3371-40C, CD3371-40QC) Unify Assura™ (Models CD3261-40, CD3261-40Q, CD3361-40, CD3361-40Q, CD3361-40C, CD3361-40QC) Unify Quadra™ (Models CD3251-40, CD3251-40Q) Unify™ (Models CD3235-40, CD3235-40Q)	**1/23/2014** **Outside US only** In November 2013, Abbott released the Merlin™ Programmer Software version 17.2.2 rev. 0 (herein after referred to as 17.2.2) as an upgrade to existing programmers. Testing has shown that, when using a programmer with the 17.2.2 software, an incorrect value for sinus redetection, potentially affecting the high voltage therapy delivery sequence can occur when a device is programmed to a single VF detection zone. The issue can be introduced during programming of certain families of Abbott ICD/CRTD devices. The issue is not present when a device is programmed to a two or three zone configuration. When using the 17.2.2 software and any parameter is programmed as part of a single VF detection zone configuration, the sinus redetection value will be inappropriately set to zero milliseconds. As a result, any intrinsic activity following the first shock will be considered a "sinus rate" and the device will diagnose "return to sinus". Therefore, if the arrhythmia was not terminated by the initial high voltage therapy, the ongoing arrhythmia would be considered a new episode causing the next high voltage therapy to also be delivered at the first programmed energy level. For example, if the first shock is programmed to 20 joules and subsequent shocks are programmed to higher energy values, the only HV therapy the patient would receive if the arrhythmia continues and is redetected, would be 20 joules, rather than the increasing HV energy levels as programmed.	Immediate Resolution Steps: • Review your SJM™ ICD/CRT-D patient records for patients with affected devices implanted or seen in clinic starting in September 2013 and programmed to a single VF detection zone with the 17.2.2 software. For patients identified during this review we recommend that you schedule an immediate follow-up visit. The programmer software version is printed on the bottom of each report page. • For patient devices programmed as described above with 17.2.2 software, a new software version 17.2.3 will correct this issue and is expected to be available by February 2014. Your Abbott representative will assist you with obtaining and installing the 17.2.3 software on your programmer. Using this software, programming any parameter will reset the return to sinus criteria to normal function. • If a patient is seen before the 17.2.3 software is installed, then program the device to a two or three zone configuration, even if one of the zones is strictly a monitor zone. This will resolve the issue when using a programmer with 17.2.2 software. **Current Status (December 31, 2023):** Software version 17.2.3 which corrected the issue was released in early 2014. No occurrences have been reported or are expected following the field communication and correction.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Fortify™ ST (Models CD1235-40, CD1235-40Q, CD2235-40, CD2235-40Q)	**4/18/2013** **Outside US only** The Merlin™ PCS programmer software Model 3330 versions 14.2.2, 16.2.1 and 17.2.1.1 provide new features for Abbott ICDs, including an option to enhance the ST diagnostic features in Abbott Fortify™ ST ICD models CD1235-40, CD1235-40Q, CD2235-40 and CD2235-40Q via a device software upgrade. During a device software upgrade, implanted devices are temporarily placed into the back-up pacing (BVVI) and back-up defibrillation only (BDFO) mode. The back-up mode parameter settings will be in effect for the two minute upgrade process. Once the upgrade successfully completes, the device will revert to the previously programmed parameter settings. Depending on the individual patient, this temporary change in parameter values while in back-up defibrillation only mode could make the device susceptible to oversensing and potentially deliver high voltage therapy during the upgrade procedure.	In order to prevent the potential for inappropriate therapy during the software upgrade process, consider programming the "Tachy Therapy Enabled/Disabled" function to Disabled prior to proceeding with the software upgrade. It is imperative to re-interrogate the device and program the "Tachy Therapy Enabled/Disabled" function to Enabled after the upgrade has been successfully completed. As with any device evaluation and programming, ECG monitoring and availability of back up external defibrillation equipment is recommended during the entire software upgrade process. **Current Status (December 31, 2023):** At the time of the advisory there were 20 devices confirmed to be affected by this issue. As of December 31, 2023 there were an additional 52 devices confirmed with this issue. There have been no reports of serious injury or death.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Convert™+ (Model V-195)	**5/6/2010** **Outside US only** A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin™ Patient Care System (PCS) programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful.	If a patient's device is already programmed to a two zone configuration with a Merlin™ PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below: A permanent correction is available in the new release of the Merlin™ PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin™ programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (December 31, 2023):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of December 31, 2023 there have been no additional reports associated with this advisory.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Epic™ ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic™ + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic™ II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas™ + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas™ II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	**1/16/2008** **Class II** A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic™ and Atlas™ family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window.	A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin™ Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available. Abbott, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (December 31, 2023):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2023 there have been no additional devices confirmed to have this issue since the time of the advisory.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Photon™ DR (V-230HV) (certain serial numbers), Photon™ Micro VR/DR (Models V-194, V-232), Atlas™ VR/DR (Models V-199, V-240)	**10/7/2005** **Class II** A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, Abbott recommends: If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (December 31, 2023):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2023 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue. This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Epic™ DR/HF (V-233, V-337, V-338), Epic™ Plus DR/VR/HF (V-236, V-239, V-196, V-239T, V-196T, V-350), Atlas™ DR (V-242), and Atlas™ Plus DR/VR/HF (V-243, V-193, V-193C, V-340, V-341, V-343)	**6/13/2005** **Class II** Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to Abbott. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic™ DR/HF (V-233/V-337/V-338), Epic™ Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas™ DR (V-242), and Atlas™ Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to Abbott by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. Abbott has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), Abbott recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, Abbott defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (December 31, 2023):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Epic™ (V-197, V-235), Epic™+ (V-196, V-236), Epic™ HF CRT-D (V-338), Epic™+ HF CRT-D (V-350), Atlas™+ (V-193, V-243), Atlas™+ HF CRT-D (V-340), or Atlas™ (model V-242) ICDs	**3/10/2005** **Class II** A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, Abbott Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, Abbott Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (December 31, 2023):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
A subset of Assurity MRI™ (Model PM2272), Endurity™ (Model PM2162), Endurity™ Core (Model PM2152), Endurity MRI™ (Model PM2172) implanted outside of the United States	**10/10/23** **Outside US Only** Abbott is informing 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. 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.	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: • 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. The Electronics Performance Indicator (EPI) tool supplements information available on Merlin.net to identify abnormal electrical system behavior resulting from moisture ingress. **Current Status (December 31, 2023):** 13 devices of the 455 devices distributed (2.86%) have exhibited symptoms of moisture ingress through the pulse generator which may result in loss of functionality.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY

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	**7/20/2022**
	Outside US Only
	
	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.
		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:
		• 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
		  • 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.
		
		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
		
		Current Status (December 31, 2023): 1001 devices of the 81,925 distributed (1.22%) have exhibited symptoms of moisture ingress into the pulse generator which may result in loss of functionality.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
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: 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	**6/16/2022** **Class II** 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.	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. 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 Additionally, Merlin.net was updated globally in June 2022 to improve accuracy of predicted battery longevity displayed on remote transmissions. 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. 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. **Current Status (December 31, 2023):** 984 complaints (0.03%) regarding longevity overestimates were received out of an estimated 2,900,000 devices worldwide.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
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)	**3/15/2021** **Class I** 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. 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.	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: • 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. **Current Status (December 31, 2023):** 783 devices of the 337,990 worldwide (0.23%) have exhibited moisture ingress into the pulse generator, resulting in a loss of functionality. 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.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP)	**11/17/2017** **Outside US and US Investigational Device Exemption (IDE) only** Abbott was made aware of docking button detachments that have occurred following implant or during attempted retrieval of Nanostim™ Leadless Cardiac Pacemaker (LCP) devices. The docking button is a small component (3.6 mm diameter) and is connected to the end of the LCP by two cables. This component is necessary for docking the LCP to the retrieval catheter during a retrieval procedure.	The following patient management recommendations have been developed in consultation with our Leadless Steering Committee members after discussions detailing the occurrences and the potential clinical impact associated with detached docking buttons: • Continue following patients as per recommendations of the October 2016 Battery Malfunction for Nanostim™ LCP advisory. • Retrieval of an implanted Nanostim™ LCP with an intact docking button confirmed radiographically remains an option, but should only be considered if the procedure can be performed as per the specifications contained in the instructions for use. • If a detached docking button has been identified, Nanostim™ LCP retrieval is not recommended. In the rare situation where retrieval is the only management option, Abbott recommends the procedure be performed by physicians experienced in foreign body removal, including using the femoral approach. Please contact the Abbott Clinical Study Team for further guidance. • Prophylactic imaging for the sole purpose of determining if the docking button is intact is not recommended due to the effects of radiation and lack of any clear clinical actions based on results of imaging alone. If the option of Nanostim™ LCP retrieval is being considered, final imaging decisions should take into account the individual patient circumstances and preferences. • If a detached docking button is identified, continue to follow the patient as per the Clinical Study Protocol and report the incident to Abbott and relevant Competent Authority, as appropriate. **Current Status: (December 31, 2023):** At the time of advisory, three (0.21%) of 1,423 devices implanted worldwide have been reported to have a detached docking button. As of December 31, 2023, a total of 8 have been reported and the rate is now at 0.6% (8/1,423). There have been no reports of serious injury or death.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
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)	**8/28/2017** **Class II** 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.	**Patient Management Recommendations** Prophylactic replacement of affected devices is not recommended. 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: • 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. **Current Status (December 31, 2023):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication. 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.). Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories | Abbott.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY

Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP)	**10/28/2016**
	Outside US and US Investigational Device Exemption (IDE) only
	
	Abbott was made aware of seven (7) reports worldwide of lost telemetry and pacing output as a result of a battery malfunction associated with Nanostim Leadless Cardiac Pacemaker (LCP) devices. Due to these events, we have decided to pause Nanostim LCP implants in the Leadless II IDE/CAP study.
	
	Analysis of returned units has found decreased battery capacity due to reduced electrolyte, resulting in high internal battery resistance. This disrupts the required capacity for proper device function and reduces device longevity.
	
	Referring to a previously measured battery voltage may not provide an indication of continued normal operation as battery voltage remains normal under these circumstances. The Recommended Replacement Time (RRT) indicator will not be triggered as the battery voltage will remain above RRT in these devices. Battery malfunction may be indicated with a loss of telemetry/communication with the implanted device and/or loss of pacing and magnet mode operation.
		In consultation with our Leadless II IDE and our Leadless Postmarket Study Steering Committees we recommend the following:
		
		• Do not implant unused devices and return them to Abbott.
		• Do not rely on the RRT indicator to identify a battery that may potentially malfunction. However, if the RRT indicator does trigger, replace the device per standard practice.
		• Do not perform AV Node ablation in patients with an existing Nanostim LCP without another functional pacing system implanted.
		• For patients who have not previously been documented to be pacemaker dependent, re-assess patients in-office for pacemaker dependence.
		• **For non-pacemaker dependent patients with devices of implant duration ≥ 24 months, more intensive follow-up and monitoring is recommended.**
		  • Implant Duration ≥ 24 months: Request follow-up as soon as possible to assess the status of the battery. Then, monthly follow-up is recommended through in-office visits or a reliable method of tele-monitoring of heart rate and electrocardiogram.
		  • Implant Duration < 24 months: Continue follow up per protocol.
		• **For pacemaker dependent patients, device replacement is recommended (priority should be for patients with implants of longer duration).**
		  • Identify and treat patients as quickly as possible.
		  • Interrogate the device and identify the ability to communicate with the device and the patient's underlying rhythm.
		  • Determine the strategy for management, including a decision whether to retrieve or abandon the Nanostim LCP, based on the individual patient's clinical history and overall medical condition. Use a temporary pacemaker for backup pacing while replacing the Nanostim device where clinically indicated.
		  • If the device is to be retrieved, use the Nanostim retrieval system as per the standard procedure described in the instructions for use.
		  • If the device will not be retrieved or if retrieval was attempted and not possible, implant a new pacemaker lead (bipolar) at a distance from the existing LCP to prevent long-term mechanical and electrical interactions. Confirm the location using multiple radiographic views.
		  • After implantation of the new pacing system, if it is possible to communicate with the LCP, turn "OFF" the abandoned LCP system. If the LCP device cannot be turned "OFF", consider programming the newly implanted system a minimum of 5 bpm faster than the LCP in order to inhibit the Nanostim device.
		
		Current Status: (December 31, 2023): At the time of advisory, seven (7) reported devices (0.5%) of 1,423 implanted devices worldwide have exhibited battery malfunction at 29-37 months after implant. As of December 31, 2023, there were additional reports and the rate is now 26.8%. There have been no reports of serious injury or death.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Accent™ SR (Model PM1110) Accent™ DR (Model PM2112)	**12/7/2012** **Outside US Only** Due to an incorrect software setting, a specific subset of the Accent™ SR and Accent™ DR devices shipped to certain countries outside the US will not provide a change in the sensor driven (rate responsive) pacing rates in response to patient physical activity. All other programmed parameters, features and functions operate as designed, e.g. an Accent DR device programmed to DDDR will appropriately track atrial activity and properly function in the DDD mode. A non-invasive programmer software solution that will correct the issue in all affected, implanted devices will be available once regulatory approval has been completed.	Abbott makes the following recommendations: Identify affected patient • Review your patient's clinical indications for pacing and determine the clinical need for rate responsive, sensor driven pacing. • In the event that a patient requires rate responsive sensor driven activity pacing and exhibits clinical symptoms due to the lack of increased pacing rates with exercise, please contact your local Sales Representative or our Technical Support • Continue to follow patients on their standard follow-up schedule. **Current Status (December 31, 2023):** The programmer software update was released in April 2013. At the time of the advisory, approximately 6,000 affected devices were implanted. There have been no additional devices confirmed to have this issue since the time of the software release in April 2013.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Accent™ DR (Models PM2110, PM2112, PM2210, PM2212), Anthem™ CRT-P (Models PM3110, PM3112, PM3210, PM3212)	**9/22/2011** **Class II** A small amount of electrical charge may accumulate within an internal capacitor which results in a low or varying pacing lead impedance (PLI) value during the automatic daily measurements. An out of range lead impedance measurement may result in a patient notifier alert, a remote monitoring Merlin.net™ Patient Care Network alert, or a prior alert message to be displayed on the programmer screen at the next in-clinic follow-up.	In order to prevent a false reading, a new Merlin™ Patient Care System programmer software version is available. When used to interrogate an Accent DR or Anthem CRT-P pacemaker this software will eliminate the potential for this anomaly to occur. With the new software, the programmer will automatically activate circuitry in the pacemaker during the interrogation process to ensure that any residual charge on the capacitor is discharged prior to performing the daily PLI measurement. The onetime upgrade is performed automatically on affected devices and will not change the operation of the implanted device. Your Abbott Sales Representative will assist you in loading the new programmer software onto your Merlin programmer. If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, Abbott makes the following recommendations, which are consistent with standard best practices: • Ensure that the new programmer software version is loaded on your programmers as soon as practical. • Continue to follow patients on their standard follow-up schedule. Since the likelihood of the low lead impedance measurement is low, the device interrogation can be performed at the patient's next regular scheduled follow-up visit. • In the event that a patient receives a low lead impedance alert before the new programmer software has been loaded, we suggest that you evaluate the device as you normally would for any such instance. If the daily pacing lead impedance value is out-of range, re-interrogate the device's measured data and look at the lead impedance values. This "in-clinic" measurement is not affected by the aforementioned capacitor charge build-up and will provide an accurate lead impedance measurement. **Current Status (December 31, 2023):** Worldwide, 13 Accent DR (<0.01%) and 225 Anthem CRT-P (1.6%) devices have exhibited this diagnostic anomaly.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Identity™ SR (Model 5172) Identity™ DR (Model 5370) Identity™ XL DR (Model 5376)	**10/12/2006** **Class II** A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in Abbott Identity™ pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the Abbott Identity™ family of pacemakers when programmed by the Abbott APS™ III Model 3500/3510 or Merlin™ Patient Care System Model 3650 programmers.	No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process. **Current Status (December 31, 2023):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2023 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.

LEFT-HEART LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
QuickSite™ (Models 1056T, 1058T) QuickFlex™ (Models 1156T, 1158T)	**4/3/2012** **Class II** Abrasion of the silicone insulation in the distal portion of QuickSite and QuickFlex leads has led to visual observations of externalized conductors. There have been no reports of death or serious injury associated with the externalized conductors; likewise there have been no electrical dysfunctions attributable to the externalized conductors. The reported rate of externalized conductors in the QuickSite and QuickFlex leads is 0.023%, based on 39 confirmed cases of externalized conductors in a population of approximately 82,000 QuickSite and 89,000 QuickFlex leads sold worldwide. This issue is under-detected because these cases are visual observations without any signs of electrical dysfunction and fluoroscopic/xray imaging is not routine. Based on a review of returned leads and available fluoroscopic and x-ray images of patients with QuickSite and QuickFlex leads (1,219 leads), it is estimated that the incidence of conductor externalization on these leads may be 3% to 4%.	Abbott and its Medical Advisory Board recommend that physicians continue to monitor their patient's implanted system at regularly scheduled intervals with attention paid to diagnostic information related to LV pacing performance, in particular LV lead impedance and capture thresholds. Programming of alerts that monitor lead impedance changes outside of the nominal range and enabling the patient notifier should be considered. A special X-ray or fluoroscopic imaging is not recommended for LV CRT leads with normal electrical function. CRT pacing functionality should be evaluated during routine device checks and only leads exhibiting electrical anomalies that cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement. **Current Status (December 31, 2023):** At the time of the advisory there was a worldwide reported externalized conductor rate of 0.023% in QuickSite and QuickFlex leads. As of December 31, 2023, the cumulative worldwide reported externalized conductor rate (based on both returns and non-returns) for QuickSite and QuickFlex leads remained stable at 0.28%.

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Optisure™ Defibrillation Lead (Models LDA220, LDA220Q, LDA230Q, LDP220Q)	**11/3/2015** **Class I** 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. 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.	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. For patients implanted with a potentially-impacted Optisure lead connected to a device WITH DynamicTx™* technology, we recommend: Review the Patient Records: 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. For patients implanted with a potentially-impacted Optisure lead connected to a device WITHOUT DynamicTx™* technology we recommend: 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. a. If shock delivery is normal - no additional testing is required b. If shock delivery identifies a short circuit – consider lead replacement • DynamicTx™ technology automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur. 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.

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
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)	**11/28/2011** **Class I** 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.	Abbott and its Medical Advisory Board (MAB) make the following recommendations, which are consistent with standard best practices and our December 2010 product communication. 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. 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. 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. 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. 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. In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended. 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. 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. **Current Status (February 29, 2024):** 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 February 29, 2024, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 4.96% and 3.01% respectively. The latest information related to the silicone Riata lead advisory, including the final results of the Cardiac Lead Assesment 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.

1 Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." *Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 4th ed.* Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2011. 889-910.

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
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)	**12/15/2010** **Outside US Only** Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10%. After more than 9 years of clinical use and approximately 227,000 implants, silicone insulated Riata™, Riata™ i, and Riata™ ST defibrillation leads have exhibited an insulation abrasion rate of 0.47% (inclusive of confirmed returns and complaints/observations with no associated return). There are several factors that can contribute to lead abrasion in implanted pacing and defibrillation systems, including physiological stresses placed on the lead due to patient anatomy, implant orientation, and mechanical stresses applied from concomitant devices in the body.	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 or remote monitoring are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedure in particular looking for significant changes from the patient's previous follow-up visits. 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 if one exists. Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events. **Current Status (February 29, 2024):** At the time of the advisory there was a worldwide insulation abrasion rate of 0.47% for Riata silicone leads. As of February 29, 2024, there have been additional reports and the worldwide reported insulation abrasion rate is 4.96%.

1 Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." *Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 4th ed.* Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2011. 889-910.

ICM DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Confirm Rx™ (Model DM3500)	**5/18/2018** **Class II** **US Only** Abbott advised physicians that exposure to sub-freezing temperatures during our supply chain process caused a transient battery voltage drop for a small number of Confirm Rx™ Model DM3500 Insertable Cardiac Monitoring (ICM) devices.	Prophylactic replacement of affected devices is not recommended. To correct implanted devices or detect affected units before implant, it is required to update to Merlin™ programmer software version 24.2.x or later. If you do not yet have this software version, you may contact your Abbott representative to facilitate in upgrading your programmer(s). **Recommendations for Patients with Implanted Devices** Abbott reviewed data in Merlin.net™ Patient Care Network to identify implanted devices with an incorrect low battery indicator. Patients confirmed to be impacted can be found in the enclosed Patient List. Additionally, implanted patients who could not be assessed for this condition through data available in Merlin.net™ PCN are included in this list. We recommend performing the following actions at the patient's next regularly scheduled visit: • For patients confirmed to be impacted, contact Abbott Technical Services to assist in correcting the battery indicator. • For Confirm Rx™ device patients requiring further assessment to determine potential impact, review post-implant programmer printouts or session records to determine whether a low battery indicator is present. • If a low battery indicator is observed, contact Abbott Technical Services to assist in confirmation and correction of the battery indicator display. **Recommendations for Devices not yet Implanted** For new implants, Merlin™ programmer software version 24.2.x or later will detect this incorrect low battery indicator condition. Interrogate all new Confirm Rx devices prior to implant. If the notification pop-up is displayed, follow the on-screen instructions to proceed with contacting Abbott Technical Services and select an alternate device for the implant. **Current Status (December 31, 2023):** At the time of the advisory, 0.41% devices distributed worldwide have been reported to have experienced incorrect display of low battery indicator. As of June 30, 2023 there have been no additional reports of low battery indicator and the rate remains at 0.283%. There have been no reports of serious injury or death. If you have any questions about this communication or the patient management recommendations, please contact your Abbott representative or Abbott Technical Support at 1-800-722-3774 (U.S.). Additional materials, can be found on Cardiovascular Product Advisories | Abbott.

ICM DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
SJM Confirm™ ICM (Models DM2100, DM2102)	**3/11/2011** **Class II** **US and Germany** A product firmware upgrade using the Merlin™ Patient Care System (PCS) programmer running software versions 10.1.1.3, 10.1.1.2, or 11.2.2 leaves the implantable cardiac monitor device in a state which results in increased current usage. If not corrected this state could result in premature battery depletion.	If you are following any patients implanted with the SJM Confirm ICM Models DM2100 or DM2102 and their device was upgraded using the Merlin programmer with the above mentioned software versions it is recommended to determine the patient's clinical reason for the implant and their continued need for the device: • If the device has previously been used to record and assist in the diagnosis of an arrhythmia and is no longer needed, no further action is required. The device will exhaust its battery capacity prior to the 3 year expected longevity. • If the unit is still indicated for diagnosing a potential clinical arrhythmia, contact your Field Clinical Engineer and he/she will assist in calculating the projected remaining longevity. If appropriate, the microprocessor operation can be reset to the nominal current drain. • If the device is no longer indicated it can be left implanted until such time that a routine explant is desired. If the device is determined to be necessary and is experiencing increased current usage as described above, it can be corrected with assistance from your Sales Representative or Abbott Technical Services. **Current Status (December 31, 2023):** At the time of the advisory, 83 implanted devices world-wide were identified as having undergone the problematic firmware upgrade. All of these devices have been corrected using the Merlin PCS programmer or were determined by the clinician to not require further action because the device had already provided the necessary diagnostic information and was no longer required. There have been no additional implanted devices confirmed to have been affected by this issue. Updated Merlin PCS programmer software has been implemented which prevents this issue from occurring in the future.

REMOTE MONITORING/TRANSMITTERS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Merlin@home™ Software Model EX2000 v8.2.2 for Merlin@home™ Transmitter (Models EX1150, EX1150W, EX1100, EX1100W)	**4/3/2017** **Class II** 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.	• 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. **Current Status (December 31, 2023):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.

REMOTE MONITORING/TRANSMITTERS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Merlin@home™ RF Remote Monitoring Transmitter EX1150	**12/18/2014** **Class II** A low incidence of Merlin@home transmitters initiating a software reset resulting in backup operation in some implanted Abbott Radio Frequency (RF) enabled Implantable Cardioverter Defibrillators (ICDs) and Pacemakers. Potentially affected RF devices include the Abbott Ellipse™, Fortify Assura™, Unify Assura™, and Quadra Assura™ ICDs and Assurity™ and Allure™ Pacemakers. In the event that an Ellipse, Fortify Assura, Unify Assura, or Quadra Assura ICD enters backup mode, the nominal operational settings will be VVI pacing mode, 67 ppm, 5.0v/0.6ms with bipolar pacing output and defibrillation settings of a VF detection rate of 146 bpm and 36J high voltage therapy. In the event an Assurity or Allure pacemaker enters backup mode, it will have output settings of VVI pacing mode, 67 ppm, 5.0v/0.6ms with unipolar pacing. This issue can only occur when the patient is being actively monitored by a Merlin@home™ RF bedside transmitter. If a device enters backup mode, the Merlin@home system will detect it and an alert will be provided to the clinic. Additionally, the ICD will deliver a patient vibratory alert and the pacemaker will deliver a patient audible alert. For Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs, the rate of occurrence is 0.25% based on 55,000 devices followed via Merlin.net™ remote monitoring. For Assurity and Allure pacemakers, the rate of occurrence is 0.016% based on 12,000 devices followed remotely. All pacemakers and the vast majority (approximately 90%) of ICDs reported to exhibit backup operation as a result of this anomaly were non-invasively restored to normal operation. In approximately 10% of the ICD cases, software was unable to be successfully restored and a device replacement was performed. The software download procedure was revised to ensure a successful download if an incident of a software reset were to occur in the future. There have been no reported cases of serious injury or death associated with this anomaly. The issue will be resolved with a software update of the Merlin@home transmitter that will be performed automatically over its telephone, broadband, or cellular connection without requiring any action from you or your patients. **9/19/2015** An additional software upgrade was implemented to address a second software anomaly which coexisted in the Merlin@home transmitter system that also had the potential to cause software resets for potentially affected Abbott devices.	The Merlin@home transmitter software has been modified to prevent this issue from occurring and has received FDA approval. A Merlin@home software update will be performed automatically over its telephone, broadband, or cellular connection without requiring any action from you or your patients. No changes to your patient's remote or in-clinic follow up schedules are required. Patients with implanted devices not mentioned above, patients who are being remotely followed with inductive telemetry (wand directly over the device) and patients not being followed remotely are not affected by this issue. **Current Status (December 31, 2023):** In December 2014, the worldwide event rate of Merlin@home transmitters initiating a software reset resulting in backup operation for Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs was 0.30% based on 83,000 devices followed via Merlin.net Patient Care Network (Merlin remote monitoring). For Assurity and Allure pacemakers, the rate of occurrence was 0.06% in 2014, based on 12,000 devices followed remotely. With the subsequent software updates, the incidence rates have been significantly reduced. As of December 31, 2023, the average monthly incidence rate based on the worldwide quantity of remotely monitored Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs declined to 0.0004%. For Assurity and Allure pacemakers, the average monthly rate of occurrence continued to decline and was stable at 0.0001% throughout 2023, based on the worldwide quantity of remotely monitored devices.

Healthcare Professional Communications

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	COMMUNICATION	DETAILS
Affinity™, Entity™, Integrity™, Identity™, Sustain™, Frontier™, Victory™ and Zephyr™ models	**1/29/2014** **Worldwide** 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.	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. 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. 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] 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. 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. 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

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Index of Phased-out Models

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).

CRT DEVICES	FINAL EDITION
Atlas™ + HF (V-340)	First Edition 2011
Atlas™ + HF CRT-D (V-343)	Second Edition 2023
Atlas™ II HF (V-365)	Second Edition 2015
Atlas™ II + HF (V-366)	Second Edition 2015
Epic™ HF (V-337)	First Edition 2011
Epic™ HF (V-338)	First Edition 2010
Epic™ II HF (V-355)	First Edition 2011
Frontier™ (5508)	First Edition 2010
Promote™ (3107-36)	Second Edition 2010
Promote™ RF (3207-30)	First Edition 2014
Promote™ RF CRT-D (3207-36)	Second Edition 2023

ICDS	FINAL EDITION
Atlas™ DR (V-240)	First Edition 2010
Atlas™ DR (V-242)	Second Edition 2014
Atlas™ + DR (V-243)	Second Edition 2023
Atlas™ II DR (V-265)	First Edition 2010
Atlas™ II + DR (V-268)	Second Edition 2023
Atlas™ II VR (V-168)	Second Edition 2023
Atlas™ VR (V-199)	Second Edition 2010
Atlas™ + VR (V-193)	Second Edition 2023
Contour™ II (V-185, V-185AC, V-185B, V-185C, V-185D)	First Edition 2008
Contour™ MD (V-175, V-175AC, V-175B, V-175C, V-175D)	First Edition 2010
Current™ DR (2107-36)	Second Edition 2010
Current™ DR RF (2207-30)	Second Edition 2015
Current™ DR RF (2207-36)	Second Edition 2023
Current™ VR (1107-36)	First Edition 2010
Current™ VR (1207-30)	Second Edition 2013
Current™ VR RF (1207-36)	Second Edition 2023
Epic™ + DR (V-236)	First Edition 2010
Epic™ + DR (V-239)	First Edition 2014
Epic™ DR (V-233)	First Edition 2011
Epic™ DR (V-235)	Second Edition 2010

ICDS	FINAL EDITION
Epic™ II DR (V-255)	First Edition 2010
Epic™ II DR (V-258)	Second Edition 2013
Epic™ II VR (V-158)	Second Edition 2013
Epic™ + VR (V-196)	Second Edition 2015
Epic™ VR (V-197)	Second Edition 2010
Photon™ DR (V-230HV)	Second Edition 2007
Photon™ µ DR (V-232)	Second Edition 2009
Photon™ µ VR (V-194)	First Edition 2010
Profile™ (V-186F, V-186HV3)	Second Edition 2007

DEFIBRILLATION LEADS	FINAL EDITION
Riata (1570, 1571)	First Edition 2023
Riata (1580, 1581)	First Edition 2023
Riata (1582)	First Edition 2023
Riata™ i (1560, 1561)	Second Edition 2016
Riata™ ST (7002)	First Edition 2023
Riata ST (7010, 7011)	First Edition 2023
Riata ST Optim (7022)	First Edition 2023
Riata™ ST Optim™ (7030, 7031)	Second Edition 2013
TVL™ ADX (1559)	Second Edition 2019
TVL™ RV (RV01, RV02, RV03, RV06, RV07)	First Edition 2010
TVL™ SVC (SV01, SV02, SV03)	First Edition 2010
SPL™ (SP01, SP02, SP03 & SP04)	First Edition 2018

PACEMAKERS	FINAL EDITION
AddVent™ (2060)	First Edition 2010
Affinity™ DC (5230)	First Edition 2019
Affinity™ DR (5330, 5331)	First Edition 2019
Affinity™ SR (5130, 5131)	First Edition 2019
Affinity™ VDR (5430)	First Edition 2010
Entity™ DC (5226)	First Edition 2019
Entity™ DR (5326)	First Edition 2019
Identity™ (5370)	Second Edition 2021
Identity ADx™ DR (5380)	Second Edition 2023

Phased-out Models

PACEMAKERS	FINAL EDITION
Identity ADx™ XL DC (5286)	Second Edition 2023
Identity ADx™ XL DR (5386)	Second Edition 2023
Identity ADx™ SR (5180)	Second Edition 2023
Identity™ SR (5172)	Second Edition 2021
Identity™ XL (5376)	Second Edition 2021
Integrity™ SR (5142)	First Edition 2020
Integrity™ µ SR (5136)	Second Edition 2013
Integrity ADx™ DR (5360)	Second Edition 2013
Integrity™ ADx DR (5366)	Second Edition 2023
Integrity ADx™ SR (5160)	Second Edition 2013
Integrity™ AFx DR (5342, 5346)	First Edition 2020
Integrity™ µ DR (5336)	Second Edition 2010
Meta™ DDDR (1256)	Second Edition 2008
Meta™ DDDR (1256D)	Second Edition 2008
Paragon™ (2010, 2011, 2012)	Second Edition 2010
Paragon™ II (2016)	Second Edition 2010
Paragon™ III (2304, 2314, 2315)	First Edition 2010
Phoenix™ II (2005, 2008, 2009)	Second Edition 2010
Phoenix™ III (2204, 2205)	First Edition 2009
Regency™ SC+ (2400L, 2402L)	First Edition 2010
Solus™ (2002, 2003)	Second Edition 2010
Solus™ II (2006, 2007)	Second Edition 2010
Synchrony™ II (2022, 2023)	Second Edition 2009
Synchrony™ III (2028, 2029)	First Edition 2010
Tempo™ D (2902)	Second Edition 2008
Tempo™ DR (2102)	Second Edition 2008
Tempo™ V (1102)	First Edition 2010
Tempo™ VR (1902)	First Edition 2010
Trilogy™ DC (2308)	Second Edition 2006
Trilogy™ DC+ (2318)	Second Edition 2009
Trilogy™ DR (2350)	First Edition 2007
Trilogy™ DR+ (2360, 2364)	First Edition 2010
Trilogy™ SR (2250)	Second Edition 2009
Trilogy™ SR+ (2260, 2264)	Second Edition 2010
Verity ADx™ XL DC (5256)	Second Edition 2023
Verity ADx™ XL DR (5356)	Second Edition 2023
Verity ADx™ XL DR M/S (5357M/S)	Second Edition 2023
Verity ADx™ XL SC (5056)	Second Edition 2023
Verity ADx™ XL SR (5156)	Second Edition 2023
Verity ADx™ XL SR M/S (5157M/S)	Second Edition 2023

PACING LEADS	FINAL EDITION
ACE™ (1015M, 1025M)	Second Edition 2009
AV Plus™ DX (1368)	First Edition 2019
Fast-Pass™ (1018T, 1028T)	Second Edition 2009
IsoFlex™ P (1644T)	First Edition 2011
IsoFlex™ S (1642)	Second Edition 2022
IsoFlex™ S (1646)	Second Edition 2022
Passive Plus™ (1135K, 1143K, 1145K,1235K, 1243K, 1245K)	First Edition 2010
Passive Plus™ (1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T)	Second Edition 2014
Passive Plus™ DX (1336T, 1342T, 1346T)	First Edition 2018
Passive Plus™ DX (1343K, 1345K)	First Edition 2010
Permathane™ ACE (1035M)	First Edition 2010
Permathane™ ACE (1036T, 1038T)	First Edition 2010
Tendril™ (1148T, 1188T)	Second Edition 2015
Tendril™ (1188K)	First Edition 2010
Tendril™ DX (1388K)	First Edition 2010
Tendril™ DX (1388T, 1388TC)	First Edition 2017
Tendril™ SDX (1488T, 1488TC)	First Edition 2020
Unipolar Lead (1007)	First Edition 2010

Abbott
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Rx Only
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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