Boston Scientific
Advancing science for life™

2016

Rhythm Management Product Performance Report

Q2 Edition

CRM Quality Pledge

I improve

the quality

of patient care

and all things

Boston Scientific

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2016 report includes data through April 14, 2016.

Boston Scientific provides performance data for pulse generators and leads that meets or exceeds the 2014 revision of ISO 5841-2: 2014 (E), the AdvaMed Industry Guidance for Uniform Reporting of Clinical Performance, and addresses recommendations from the Heart Rhythm Society Task Force.

This report provides the most comprehensive presentation of rhythm management product performance data available, including:

- ✓ U.S. lead and pulse generator survival probability
- ✓ Worldwide malfunction counts and patterns
- ✓ Worldwide malfunctions during an implant procedure
- ✓ Longitudinal Surveillance Registry lead survival probability
- ✓ Acute (first month) lead observations
- ✓ Chronic (after first month) lead complications
- ✓ Reasons for out of service
- ✓ Return rates

Your feedback is always welcome, and plays a vital role in our effort to continuously improve our products and services, advancing science to transform the lives of our patients.

Sincerely,

Renold J. Russie
Vice President, Quality Assurance

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Statistical Methodology

What Is Device Survival Probability?
Medical journals have traditionally used patient survival probability to display information on treatment option effectiveness. In the report, **pulse generator and lead** survival probabilities convey information about long-term performance of implantable cardiac rhythm management products.

Survival probability shows the percentage of implanted devices that remain implanted and in service at various points in a product's service life, in the absence of competing risks, such as natural mortality or voluntary explants. Conceptually, a pulse generator of high reliability and large battery capacity or low current drain remains near 100% survival until eventually, normal battery depletion begins to cause significant numbers of devices to be removed, and the device survival probability drops rapidly. For example, a device survival probability of 99% indicates that within the stated implant duration, the pulse generator had a 1% risk of removal for battery depletion or for incurring a malfunction that required replacement. Survival probabilities are provided with and without normal battery depletions, depicted as “Battery Depletions and Malfunctions” and “Malfunctions Only,” respectively.

Boston Scientific estimates survival probability in compliance with the 2014 revision of international standard ISO 5841-2: 2014 (E). Survival probability is calculated at a given time by separately estimating the probability of surviving each interval and multiplying the survival probabilities of all intervals through which a device has passed. To estimate the probability of surviving any interval, the number of units that successfully functioned during the interval is divided by the number of units exposed to malfunction/depletion during the interval. The number of units exposed is calculated using the actuarial method, where device suspensions in an interval are distributed uniformly across the interval. Reasons for device suspension from survival probability statistics are detailed in the report section entitled U.S. Reason for Out of Service.

Survival probabilities are statistical estimates subject to uncertainty. To quantify this uncertainty, 95% confidence intervals of survival probabilities are computed. Greenwood's formula is used to estimate the standard error of the calculated survival probabilities, and confidence intervals are constructed using a logit transformation, assuming the transformed values are normally distributed. For example, 99.36% (-0.3/+0.2) represents an interval of 99.06% to 99.56%, and these intervals are constructed such that 95% of the time they will contain the true survival probability. These confidence intervals are not symmetric due to the transformation method described previously.

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets
Pulse generator survival probability is reported for U.S. implanted devices in product families which meet inclusion criteria described below. Lead survival probability is reported for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry, for product families which meet inclusion criteria described below.

To be included in survival probability statistics, a device must first be successfully implanted (defined in this report as occurring upon pocket closure). Prophylactic device removals are tracked as part of the active population up until the time the device is removed from service; devices removed prophylactically which are not identified as malfunctions at the time of explant do not contribute to a reduction in survival probability. Reasons for device explant or out of service, if known, are provided in this report for each pulse generator product/product grouping.

Survival probabilities are based on devices registered as implanted in the United States. Privacy laws in many other geographies preclude manufacturers from obtaining specific patient implant and explant information, thus device survival probabilities cannot be constructed from these data. Boston Scientific believes, however, that U.S. experience is generally representative of worldwide performance. The Malfunction Details for leads and pulse generators reflect worldwide malfunctions, inclusive of U.S. data.

Criteria for inclusion of product families in this report are in compliance with the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*. Survival estimates are provided for product families once they have at least 10,000 cumulative U.S. implant months. The minimum interval sample size is 200 U.S. implanted units. Pulse generator product families with less than 500 total remaining estimated active U.S. devices are not included in this report. Lead product families that received original U.S. market release approval twenty or more years ago are not included in this report. Survival estimates for leads enrolled in the Longitude Surveillance Registry are provided for product families once they have at least 200 enrolled leads. The minimum interval sample size is 50 leads which have been followed for at least 6 months.

Estimated Longevity information is provided for pulse generator products in the U.S. Survival Probability - Battery Depletions and Malfunctions graphs, depicted as a blue bar on the x axis for Years Implanted. The estimated longevity values from the Instructions for Use for each product family are used to construct the blue longevity bars on their U.S. Survival Probability graph. They represent the range of estimated longevity based on a variety of programmed settings and therapy usage.

Survival probability data are presented in tabular and graphical formats online at www.bostonscientific.com/ppr. Performance data for Intermedics products may also be found on www.bostonscientific.com/ppr. Specific inclusion criteria for pulse generator and lead survival probability datasets are described here. Not all products may be approved for use in all geographies, as product approval is geography specific.

Worldwide distribution, U.S. registered implant and U.S. estimated active implant numbers have been rounded to provide population size context.

To convey implant experience for a product family, average device age and U.S. approval date are provided. The U.S. approval date listed is the earliest date Boston Scientific received approval for one or more of the models in the family. For Longitude Surveillance Registry data, the number of enrolled leads and their cumulative followup months are also provided for context.

Survival Probability – Battery Depletions and Malfunctions (Pulse Generators)
Reduction in survival probability for **pulse generators** is due to:

- Devices removed for normal battery depletion
- Device malfunctions occurring while implanted, as confirmed by returned product analysis
- Devices removed from service and reported to have exhibited premature battery depletion, but not confirmed by laboratory analysis, whether returned or not—also known as “unconfirmed reports of premature battery depletions.”

Survival Probability – Malfunctions Only (Pulse Generators)
Reduction in survival probability for **pulse generators** is due only to:

- Device malfunctions occurring while implanted, as confirmed by returned product analysis; premature battery depletions are considered device malfunctions.

In this case, normal battery depletions do not contribute to the reduction in survival probability; rather, reduction in survival probability is due only to confirmed pulse generator malfunctions. Furthermore, unconfirmed reports of premature battery depletions do not reduce “Malfunctions Only” survival probability. Put another way, this information depicts the percentage of confirmed malfunction-free devices remaining in service at various intervals in the product's service life, based on returned product analysis.

Survival Probability — Complications and Malfunctions (Leads)
The 2014 version of ISO 5841-2: 2014(E) outlines a methodology for lead survival probability inclusion. Boston Scientific has applied this methodology for survival probability to all lead families being implanted as of May 2009 and forward. Worldwide malfunctions are not included for older lead families.

Reduction in survival probability is due to:

- Leads and lead segments returned for analysis and determined to be non-compliant in form, fit, or function at any time while implanted
- Leads removed from service with reported complications 30 days or more post-implant, whether returned or not. See the Chronic Lead Complications Table in this report for the observations which are included.

Further Adjustments for Device and Lead Survival
Because underreporting of patient deaths unrelated to device function would result in overestimation of pulse generator or lead survival by overstating the number of devices in service, Boston Scientific addresses this underreporting in two ways. First, regular updates are obtained from the Social Security Administration about deceased persons and compared to Boston Scientific patient data to learn about patients who have died but whose deaths had not been reported to Boston Scientific. Second, Boston Scientific uses 10% annual patient mortality as a baseline and adjusts reported patient deaths in any interval for which reports are less than the baseline rate. No adjustment is applied to account for underreporting of malfunctions, as the rate of underreporting is unknown.

Boston Scientific does not make statistical adjustments to account for underreporting of battery depletion. However, as mentioned earlier, Boston Scientific includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions.

Categorization of Malfunctions for Survival Probability Reporting
Malfunctions represent pulse generators and leads removed from service and confirmed through laboratory analysis to have operated outside the specified performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (such as ionizing therapeutic radiation), are not reported as device malfunctions in survival data. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction. Malfunctions are further classified according to their impact on therapy, as follows:

Malfunction With Compromised Therapy —
The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

Malfunction Without Compromised Therapy —
The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here.

Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in 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.

Categorization of Normal Battery Depletion for Survival Probability Reporting
Per the AdvaMed *Industry Guidance for Uniform Reporting of Clinical Performance of Pulse Generators and Leads*, **Normal Battery Depletion** is defined as the condition when

a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using actual device settings and therapeutic use.

Boston Scientific includes within this count both returned *and non-returned* devices removed from service for battery depletion with no associated complaint. In conformance with the AdvaMed guidance document, Boston Scientific performs battery usage analysis, including battery status verification, on all devices returned without a complaint. We continue to include non-returned devices reported by our customers as being removed from service due to normal battery depletion within this count.

Boston Scientific CRM's Corrective and Preventive Actions (CAPA) System

Boston Scientific strives to provide implantable devices of high quality and reliability. However, these devices are not perfect and may exhibit malfunctions at a low rate of occurrence. Device performance information is received from many sources through various channels. Boston Scientific monitors information from many sources including suppliers, testing, manufacturing and field performance to identify opportunities for improvement.

When a device is returned to Boston Scientific, laboratory technicians and engineers assess overall device function and perform analysis using specific tests related to the clinical observation(s). Test results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause of the clinical observation(s). Each discrete event is then compared to other similar-appearing events. If a pattern is detected, actions are taken to identify a common root cause, and improvements intended to improve product reliability and/or performance may be implemented. Observations from supplier data and internal manufacturing operations also lead to opportunities for improvement. Improvements, when made, may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes as examples. Improvement implementation may vary by geography due to various factors including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not mitigate or eliminate the potential for additional malfunctions. In cases where an improvement is made to an approved product line, devices made without the improvement may continue to be distributed where such products meet our high reliability and performance standards, particularly when changes are incremental and in accordance with our overall philosophy of continuous product improvement.

Improvements are closely monitored for effectiveness. Boston Scientific informs regulatory bodies of each significant event that poses potential risk to patient health to meet regulatory obligations, and shares returned product investigation findings with physicians. The malfunction details section for pulse generators and leads includes a summary of these findings.

In summary, thorough investigation of internal and external data coupled with low trigger levels for improvements creates a continuous product improvement system that is very responsive to patient and physician needs. Boston Scientific is committed to characterizing and presenting to our customers an accurate picture of product performance and addressing identified issues in a timely fashion.

Malfunction Details: Overview

Boston Scientific CRM pursues product quality and reliability with a passion. We therefore continuously monitor product performance to make improvements whenever possible. Worldwide Malfunction tables provide a count and description of malfunctions associated with the majority of actively in-service Boston Scientific products. Intermedics co-branded product data are included in corresponding pacemaker and pacing lead malfunction counts and details. Information presented is based on malfunctions reported to and analyzed by Boston Scientific. Each table contains malfunction counts listed by category, pattern and therapy availability.

Category
Malfunctions are categorized by the nature of their root cause. For example, a malfunction due to the software within a pulse generator is listed in the Software category. There are four pulse generator malfunction categories and four malfunction categories for leads (described below).

Patterns
Patients and physicians have asked for more access to Quality System details; therefore, we provide information on patterns of product performance. Patterns listed are informational and do not represent actions that need to be taken. Boston Scientific is committed to direct communication when predicted product performance fails to achieve design or performance expectations or when actions may be taken to improve patient outcomes. Malfunctions associated with product advisories are denoted. Refer to the Product Advisories section for more information.

Each pattern description includes:

- ***Clinical Manifestation and Root Cause*** – Malfunctions for each product are characterized according to root cause. Descriptions provide clinical observations and/or analysis findings associated with each malfunction pattern listed in this report. Malfunctions listed within “Other” either do not yet have an identified root cause, or are related to a proprietary product feature, such as connectors or seal rings.

- ***Improvement Implementation*** – All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, improvements have been or will be implemented in response to identified malfunction patterns. Improvements may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications or labeling changes. Improvement implementation may vary by geography due to various factors, including regulatory review timing. They may not be applied to every product susceptible to the malfunction pattern, and may not completely mitigate or eliminate the potential for additional malfunctions.

Pattern information in this report is dynamic. Pattern names, superscript number assignments and descriptions may all change from quarter to quarter; as Boston Scientific's investigations progress and improvements are implemented, updated information is provided.

Therapy Availability

Malfunctions are further classified according to their impact on therapy, as follows:

- ***Malfunction With Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted therapy delivery; intermittent malfunction in which therapy is compromised while in the malfunction state.

- ***Malfunction Without Compromised Therapy*** – The condition when a device is confirmed through laboratory analysis to have malfunctioned in a manner that did not compromise pacing or defibrillation therapy while implanted and in service. Malfunctions in which critical patient-protective pacing and defibrillation therapies remain available are included here. Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes the battery to lose power quickly enough to result in 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.

Pulse Generator Malfunctions

Pulse generator malfunctions represent devices removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. Device damage occurring during or after explant, or caused by external factors including those warned against in product labeling (e.g. therapeutic radiation), are not considered device malfunctions. Damage to a pulse generator caused by a lead malfunction is reported as a lead malfunction.

Lead Confirmed Malfunctions

Lead confirmed malfunctions represent leads removed from service and confirmed through laboratory analysis to have operated outside the performance limits established by Boston Scientific while implanted and in service. The Boston Scientific Product Performance Report is in compliance with the 2014 version of ISO 5841-2: 2 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. This version categorizes leads with reported complications which are taken out of service and returned, but for which no malfunction can be confirmed, as Chronic Lead Complications. This methodology also addresses the Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines.

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Supporting Greater Return of Explanted Devices

The Heart Rhythm Society (HRS) Task Force on Device Performance Policies and Guidelines stated that knowledge, confidence, and trust in cardiac rhythm management devices can be strengthened through enhancing systems that increase the return of devices to the manufacturer. Boston Scientific CRM shares in this belief and supports the HRS-specified actions geared toward achieving the goal of greater device return to the manufacturer, including post-mortem device interrogation, explantation and return to the manufacturer.[1]

In this section of the report, Boston Scientific provides device return rate data with the goal of raising awareness and improving current device explant and return rates. Figure 1 on the following page depicts the percentage of devices reported to have been explanted and then returned to Boston Scientific for various product therapy types.

Help Us Provide You With More Complete Product Performance Data

Reporting Adverse Events

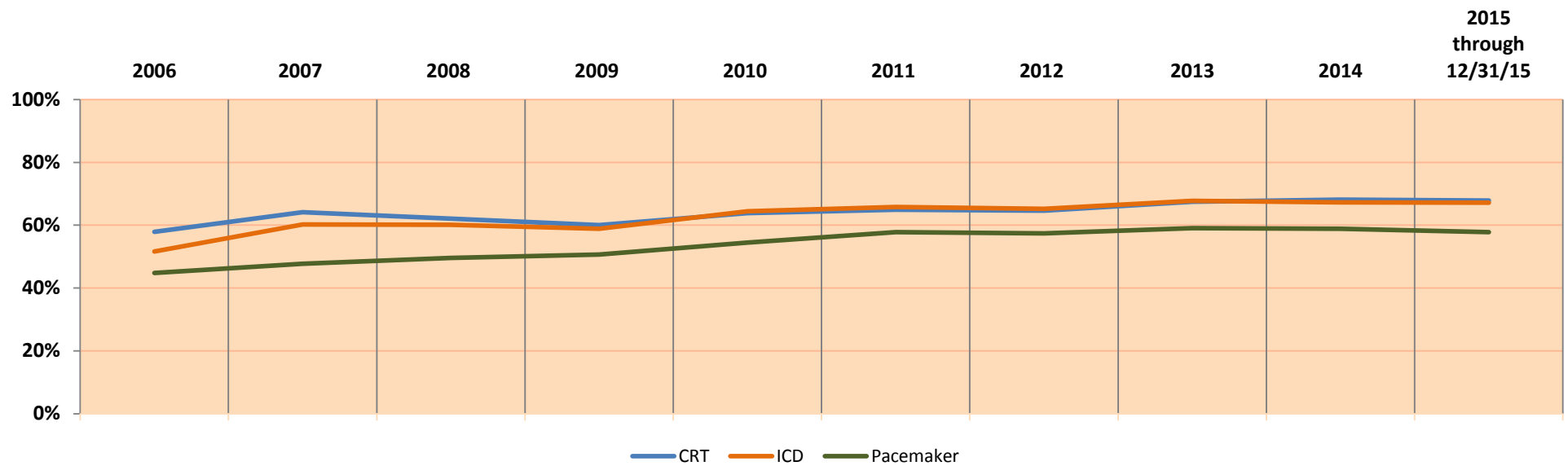
The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department at:

United States: Phone 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698.
International: Please refer to the Country Offices List for local contact information.
E-mail: crmevent@bsci.com

Returning Products to Boston Scientific

Boston Scientific provides a Returned Products Kit (Model 6499) that includes proper forms, shipping/packaging (biohazard bags), and a prepaid shipping label. It can be ordered at no charge through Boston Scientific's Customer Service department at 1.800.CARDIAC (1.800.227.3422) or 1.651.582.2698, or you can order a Returned Products Kit online at www.bostonscientific.com/ppr.

[1]Carlson et al. Recommendations from the Heart Rhythm Society Task Force. Heart Rhythm. October 2006; 3(special issue):1251 — 1252.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015 through 12/31/15
Explants	3350	4245	5676	9257	10451	9295	8014	8271	6851	4910
Returns	1939	2722	3526	5556	6670	6036	5177	5580	4669	3330
% Returned	**58%**	**64%**	**62%**	**60%**	**64%**	**65%**	**65%**	**67%**	**68%**	**68%**
Explants	10180	11530	15543	19480	19880	16531	11926	11841	11190	9863
Returns	5254	6946	9342	11462	12804	10874	7782	8025	7528	6630
% Returned	**52%**	**60%**	**60%**	**59%**	**64%**	**66%**	**65%**	**68%**	**67%**	**67%**
Explants	16945	18378	20421	20973	21052	19937	18610	18674	19135	19253
Returns	7585	8777	10122	10616	11470	11522	10679	11021	11263	11119
% Returned	**45%**	**48%**	**50%**	**51%**	**54%**	**58%**	**57%**	**59%**	**59%**	**58%**

Figure 1. Percentage of U.S .explanted devices as reported and returned to Boston Scientic CRM.

AUTOGEN CRT-D

Models G160/G161/G164/G166/G168/
G172/G173/G175/G177/G179

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

AUTOGEN CRT-D
Models G160/G161/G164/G166/G168/ G172/G173/G175/G177/G179

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[101] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**0**	**2**	**2**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN CRT-D

Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

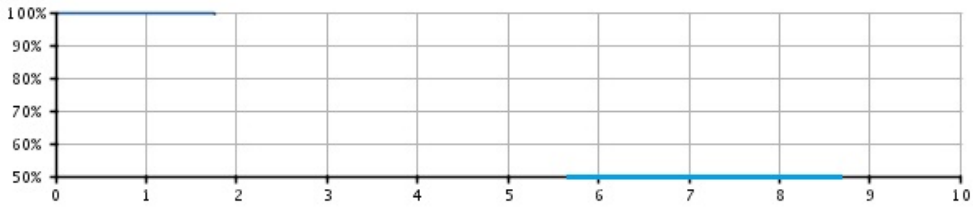
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

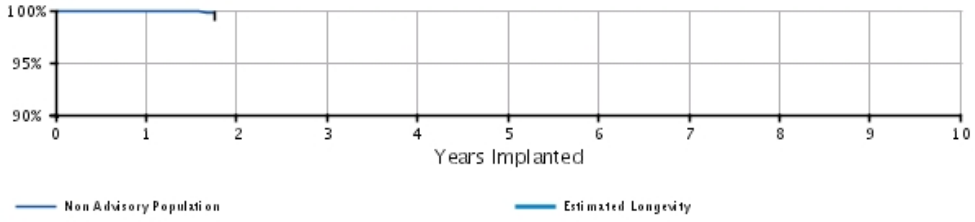
U.S. Registered Implants: 18,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:6
Without Compromised Therapy:6
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.76 @ 21 mo. (-0.7/+0.2)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.79 @ 21 mo. (-0.8/+0.2)	–	–	–	–	–	–	–	–
	Effective Sample Size	4732	349	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN CRT-D

Models G050/G051/G056/G058/G140/
G141/G146/G148/G150/G151/
G154/G156/G158

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

DYNAGEN/INOGEN/ORIGEN CRT-D Models G050/G051/G056/G058/G140/ G141/G146/G148/G150/G151/ G154/G156/G158

Worldwide Distribution: 28,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**-**	**5**
[100] High voltage circuit component	3	-	
[101] Integrated circuit	2	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**1**	**2**
[89] Memory errors	1	1	
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**7**	**2**	**9**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA CRT-D

Models N050/N051/N052/N053/N140/
N141/N142/N143/N160/N161/
N162/N163/N164/N165/P052/
P053/P142/P143/P162/P163/
P165

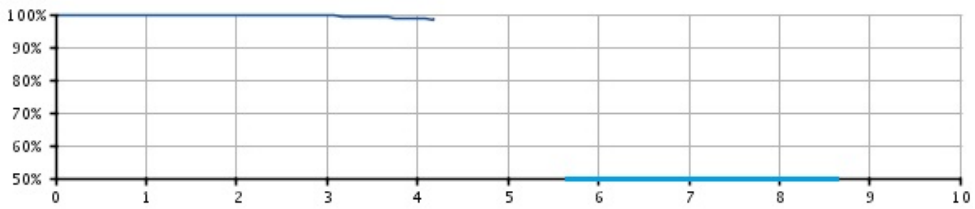
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

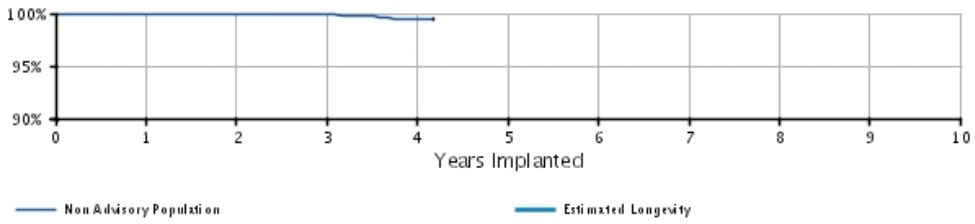
U.S. Registered Implants: 52,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 43,000

U.S. Normal Battery Depletions: 78
U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Malfunctions:58
Without Compromised Therapy:47
With Compromised Therapy:11

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.65 (-0.1/+0.1)	98.83 (-0.3/+0.2)	98.48 @ 50 mo. (-0.7/+0.5)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.88 (-0.1/+0.0)	99.49 (-0.2/+0.1)	99.49 @ 50 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	43657	29108	13407	1644	398	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA CRT-D

Models N050/N051/N052/N053/N140/
N141/N142/N143/N160/N161/
N162/N163/N164/N165/P052/
P053/P142/P143/P162/P163/
P165

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA CRT-D
Models N050/N051/N052/N053/N140/ N141/N142/N143/N160/N161/ N162/N163/N164/N165/P052/ P053/P142/P143/P162/P163/ P165

Worldwide Distribution: 80,000
Worldwide Confirmed Malfunctions: 80

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**54**	**7**	**61**
[78] Safety Core-electrocautery	5	1	
[79] High-voltage capacitor	-	2	
[84] Low-voltage capacitors	1	-	
[88] Integrated circuit	1	4	
[92] Low-voltage capacitor	47	-	
Mechanical	**-**	**6**	**6**
[72] Transformer	-	6	
Software	**5**	**-**	**5**
[89] Memory errors	5	-	
Other	**7**	**1**	**8**
Non-patterned	7	1	
WW Confirmed Malfunctions	**66**	**14**	**80**

More details about malfunctions

References cited in table above

COGNIS

Models N106/N107/N108/N118/N119/
N120/P106/P107/P108

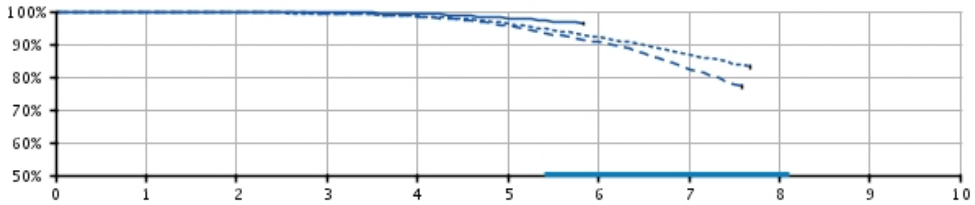
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

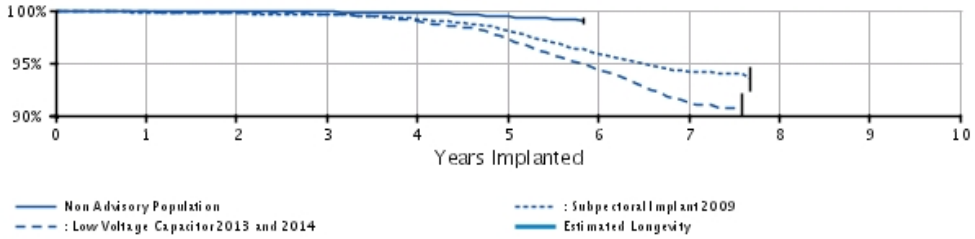
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 41,000

U.S. Normal Battery Depletions: 1,505
U.S. Unconfirmed Reports of Premature Battery Depletion : 87
U.S. Malfunctions:1206
Without Compromised Therapy:1050
With Compromised Therapy:156

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 36000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.84 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.21 (-0.1/+0.1)	97.96 (-0.2/+0.2)	96.31 @ 70 mo. (-0.7/+0.6)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.40 (-0.1/+0.1)	99.04 @ 70 mo. (-0.4/+0.3)	–	–	–	–
	Effective Sample Size	31521	28131	24919	21407	9520	614	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	98.55 (-0.2/+0.1)	96.37 (-0.3/+0.3)	92.12 (-0.3/+0.2)	86.68 (-0.3/+0.2)	83.24 @ 92 mo. (-1.6/+1.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.0/+0.1)	99.70 (-0.0/+0.1)	99.61 (-0.1/+0.1)	99.17 (-0.1/+0.1)	98.11 (-0.1/+0.1)	95.86 (-0.2/+0.3)	94.13 (-0.3/+0.3)	93.57 @ 92 mo. (-1.3/+1.0)	–	–
	Effective Sample Size	27500	24377	21680	19190	16728	14199	4771	231	–	–
Low Voltage Capacitor 2013 and 2014* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.70 (-0.1/+0.1)	99.46 (-0.1/+0.1)	98.40 (-0.1/+0.2)	95.55 (-0.1/+0.2)	90.53 (-0.3/+0.2)	82.36 (-0.3/+0.3)	77.07 @ 91 mo. (-1.3/+1.3)	–	–

26,000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.32 (-0.1/+0.1)	94.34 (-0.2/+0.1)	91.11 (-0.8/+0.7)	90.72 @ 91 mo. (-1.2/+1.4)	–	–
	Effective Sample Size	22620	20034	17839	15761	13662	9468	1664	211	–	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

COGNIS

Models N106/N107/N108/N118/N119/ N120/P106/P107/P108

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

COGNIS
Models N106/N107/N108/N118/N119/ N120/P106/P107/P108

Worldwide Distribution: 109,000
Worldwide Confirmed Malfunctions: 1558

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1256**	**117**	**1373**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1019	61	
[78] Safety Core-electrocautery	47	20	
[79] High-voltage capacitor	1	4	
[84] Low-voltage capacitors	7	-	
[88] Integrated circuit	7	19	
[90] High voltage circuit	-	1	
[91] Battery	36	4	
[92] Low-voltage capacitor	139	8	
Mechanical	**39**	**89**	**128**
[5] Subpectoral implant 2009 (Advisory issued)	16	46	
[72] Transformer	-	9	
[76] Difficulty securing lead	9	9	
[82] Header contacts	8	8	
[102] Header	6	17	
Software	**14**	**-**	**14**
[83] Safety Core-programming	1	-	
[86] Alert messages not displayed post-EOL	2	-	
[89] Memory errors	11	-	
Other	**34**	**9**	**43**
Non-patterned	34	9	
WW Confirmed Malfunctions	**1343**	**215**	**1558**

More details about malfunctions

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

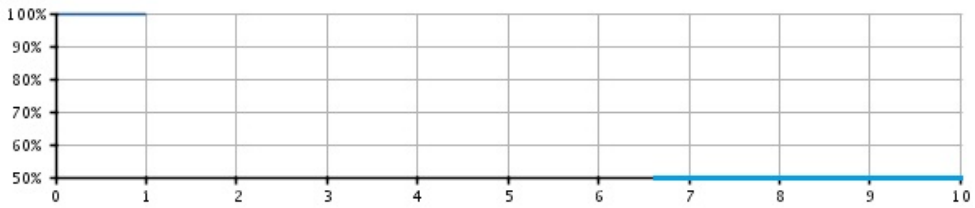
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

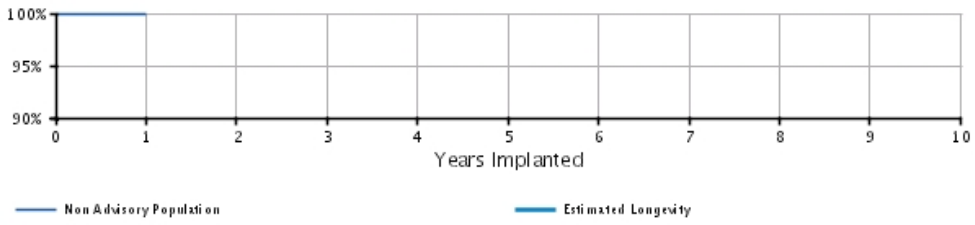
U.S. Registered Implants: 4,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	232	–	–	–	–	–	–	–	–	–

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

VISIONIST/VALITUDE Models U125/U128/U225/U226/U228

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

INTUA

Models V272/V273/V282/V283/W272/
W273

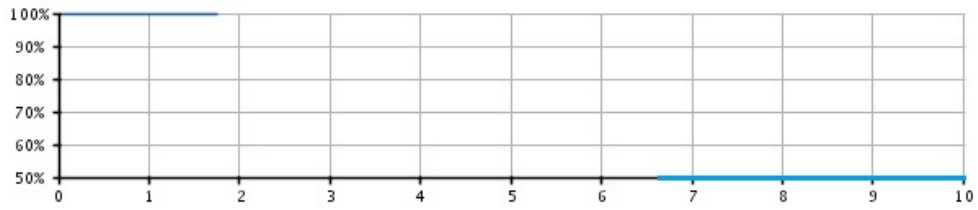
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

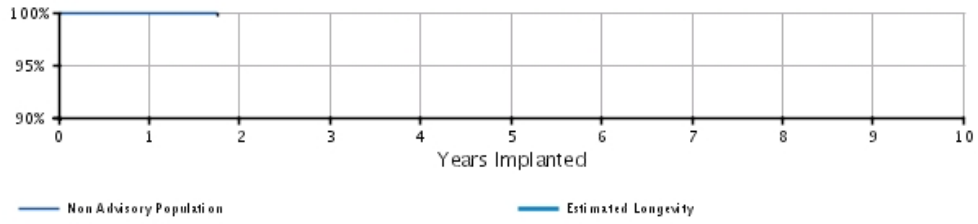
U.S. Registered Implants: 2,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.84 (-0.3/+0.1)	99.84 @ 21 mo. (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 @ 21 mo. (-0.3/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	1286	231	–	–	–	–	–	–	–	–

INTUA

Models V272/V273/V282/V283/W272/ W273

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

INTUA Models V272/V273/V282/V283/W272/ W273

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

INVIVE

Models V172/V173/V182/V183/W172/
W173

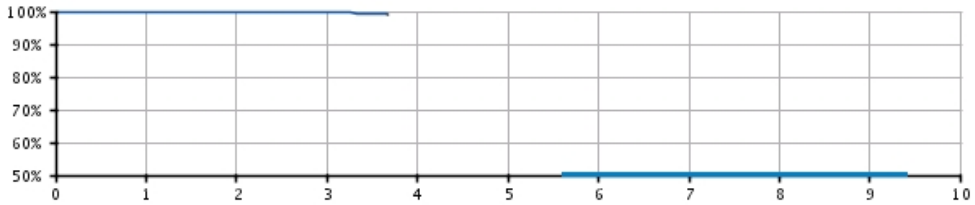
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

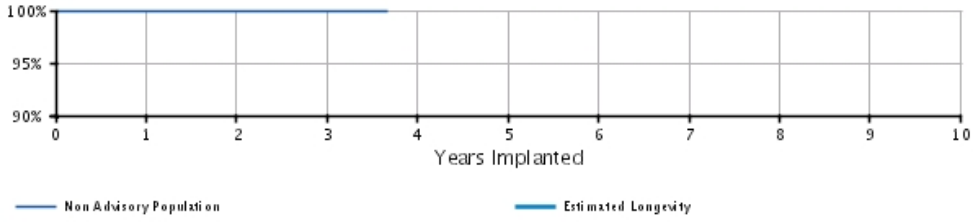
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 16
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.84 (-0.2/+0.1)	99.56 (-0.3/+0.2)	99.28 @ 44 mo. (-0.6/+0.3)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 44 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	6203	4089	1378	239	–	–	–	–	–	–

INVIVE

Models V172/V173/V182/V183/W172/ W173

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

INVIVE
Models V172/V173/V182/V183/W172/ W173

Worldwide Distribution: 17,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[84] Low-voltage capacitors	-	1	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[89] Memory errors	2	-	
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR 2

Models H140/H145

CONTAK RENEWAL TR 2 Models H140/H145

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 30

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[26] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[34] Seal plug	1	-	
[48] Setscrew block	2	-	
[64] Seal plug	1	-	
Software	**13**	**-**	**13**
[41] Memory error	1	-	
[53] Stored EGMs	12	-	
Other	**11**	**1**	**12**
Non-patterned	10	1	
[61] Alert messages	1	-	
WW Confirmed Malfunctions	**29**	**1**	**30**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

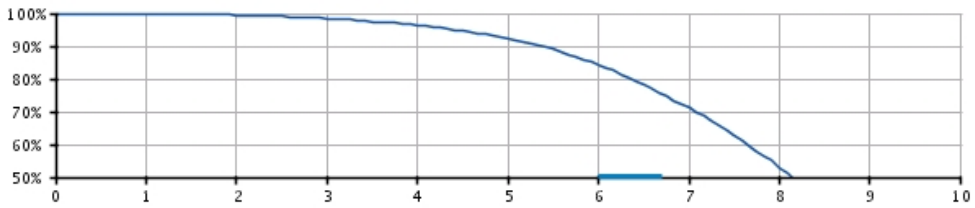
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

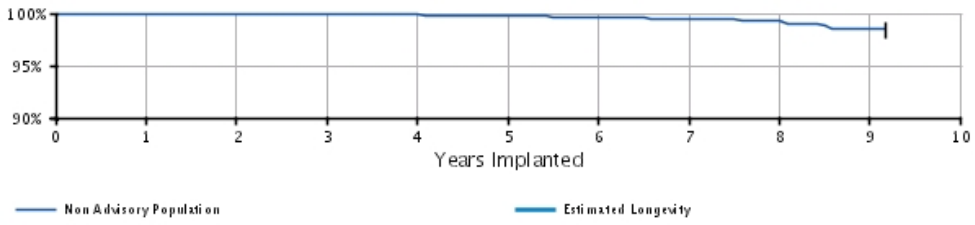
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 2,409
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:48
Without Compromised Therapy:46
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.35 (-0.4/+0.3)	92.29 (-0.5/+0.5)	84.35 (-0.9/+0.8)	71.18 (-1.3/+1.3)	52.83 (-1.9/+1.9)	34.17 (-2.3/+2.4)	30.62 @ 110 mo. (-2.4/+2.5)
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.64 (-0.2/+0.1)	99.52 (-0.2/+0.1)	99.25 (-0.4/+0.3)	98.59 (-1.0/+0.6)	98.59 @ 110 mo. (-1.0/+0.6)
	Effective Sample Size	15589	13595	11855	9816	6921	4029	2084	896	282	225
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

CONTAK RENEWAL TR

Models H120/H125

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

CONTAK RENEWAL TR Models H120/H125

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 48

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[9] Low-voltage capacitor (Advisory issued)	1	-	
[26] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[34] Seal plug	5	-	
Software	**28**	**-**	**28**
[53] Stored EGMs	28	-	
Other	**12**	**1**	**13**
Non-patterned	8	1	
[61] Alert messages	3	-	
[80] Magnet rate	1	-	
WW Confirmed Malfunctions	**46**	**2**	**48**

More details about malfunctions

References cited in table above

EMBLEM S-ICD

Model A209

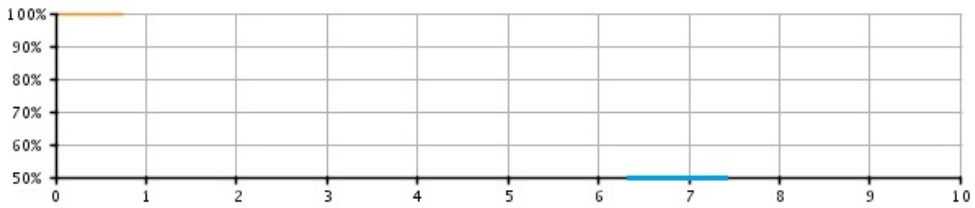
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

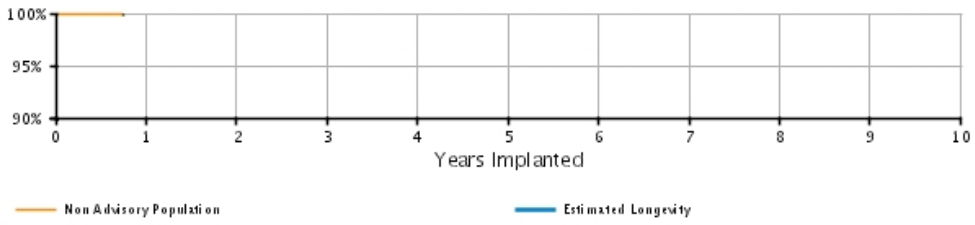
U.S. Registered Implants: 5,000
U.S. Approval Date: March 2015
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:0
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 @ 9 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 @ 9 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	388	–	–	–	–	–	–	–	–	–

EMBLEM S-ICD

Model A209

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

EMBLEM S-ICD Model A209

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	3	3
Non-patterned	-	-	
[94] Telemetry	-	3	
WW Confirmed Malfunctions	0	3	3

More details about malfunctions

References cited in table above

AUTOGEN ICD EL DR

Models D162/D163/D176/D177

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

AUTOGEN ICD EL DR
Models D162/D163/D176/D177

Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

AUTOGEN ICD EL VR

Models D160/D161/D174/D175

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

AUTOGEN ICD EL VR
Models D160/D161/D174/D175

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL DR

Models D052/D053/D142/D143/D152/
D153

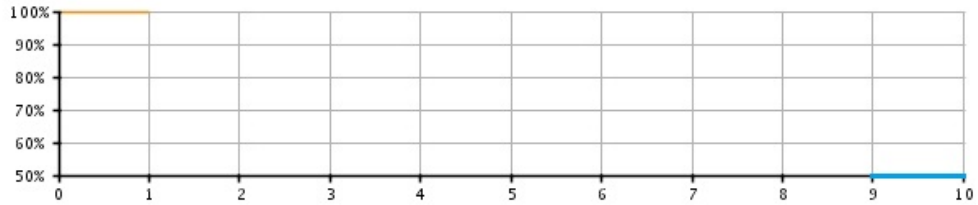
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

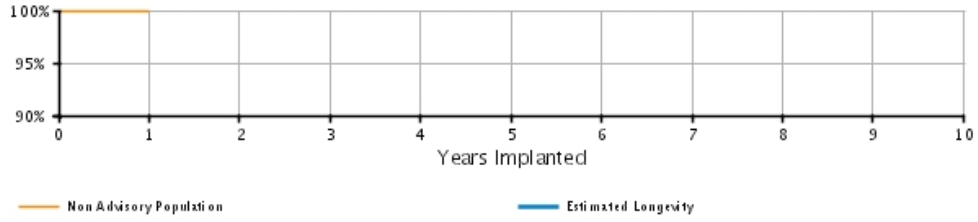
U.S. Registered Implants: 8,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	404	–	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL DR

Models D052/D053/D142/D143/D152/ D153

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD EL DR Models D052/D053/D142/D143/D152/ D153

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[100] High voltage circuit component	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**0**	**1**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

Models D050/D051/D140/D141/D150/
D151

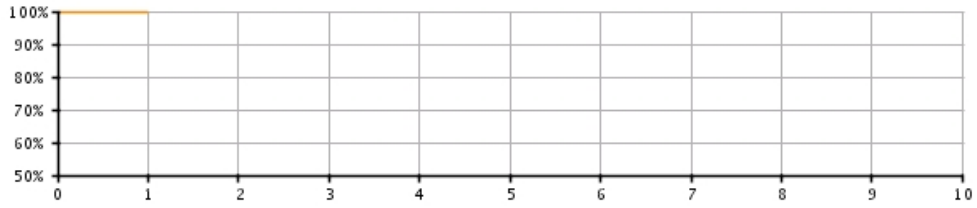
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

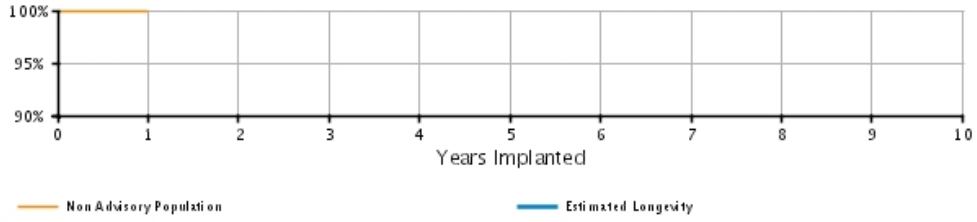
U.S. Registered Implants: 7,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	391	–	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD EL VR

Models D050/D051/D140/D141/D150/ D151

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD EL VR Models D050/D051/D140/D141/D150/ D151

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models D002/D003/D012/D013/D022/
D023

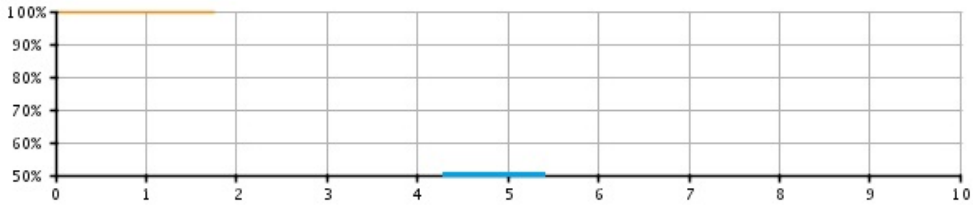
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

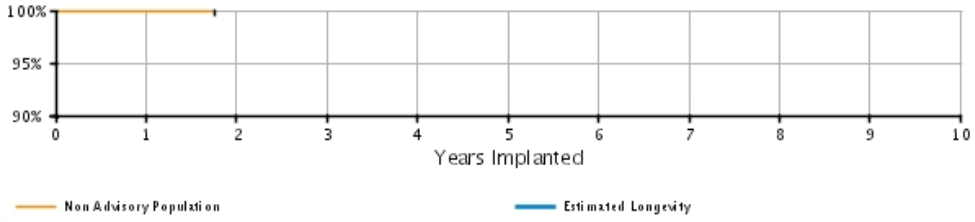
U.S. Registered Implants: 4,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.89 @ 21 mo. (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 @ 21 mo. (-0.4/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	1748	218	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

Models D002/D003/D012/D013/D022/ D023

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD MINI DR Models D002/D003/D012/D013/D022/ D023

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[100] High voltage circuit component	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**3**	**0**	**3**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

Models D000/D001/D010/D011/D020/
D021

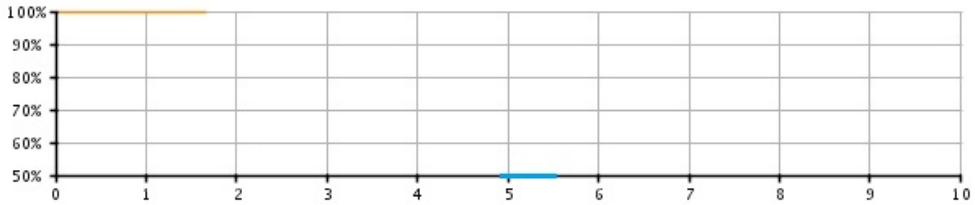
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

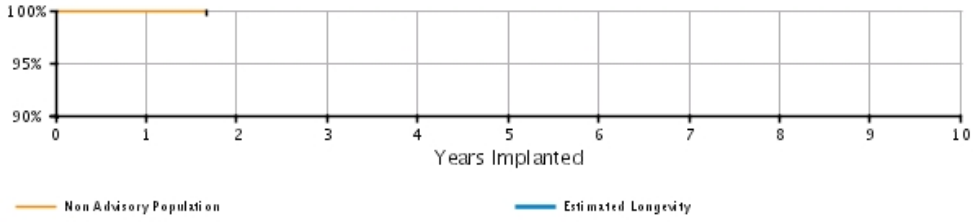
U.S. Registered Implants: 4,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.79 @ 20 mo. (-0.5/+0.2)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 @ 20 mo. (-0.4/+0.1)	–	–	–	–	–	–	–	–
	Effective Sample Size	1616	287	–	–	–	–	–	–	–	–

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

Models D000/D001/D010/D011/D020/ D021

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

DYNAGEN/INOGEN/ORIGEN ICD MINI VR Models D000/D001/D010/D011/D020/ D021

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[100] High voltage circuit component	1	-	
Mechanical	**-**	**-**	**0**
Software	**1**	**-**	**1**
[89] Memory errors	1	-	
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**3**	**1**	**4**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD DR

Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

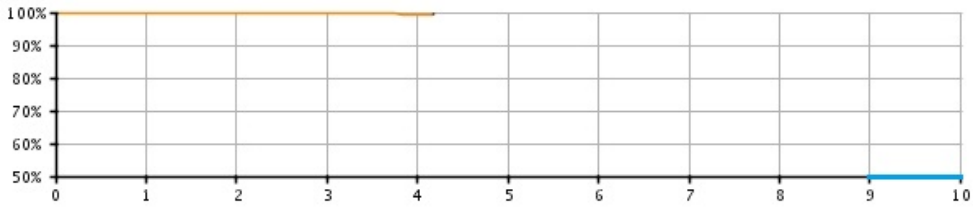
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

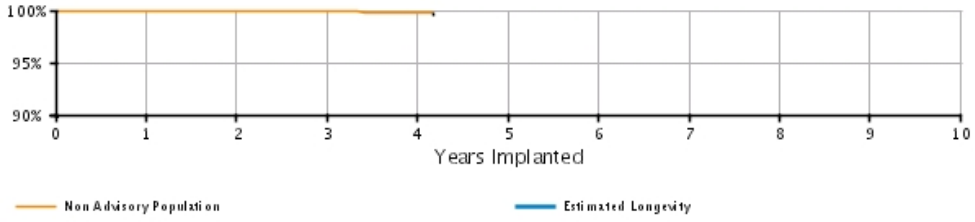
U.S. Registered Implants: 46,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 40,000

U.S. Normal Battery Depletions: 33
U.S. Unconfirmed Reports of Premature Battery Depletion : 5
U.S. Malfunctions:34
Without Compromised Therapy:28
With Compromised Therapy:6

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 46000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.80 (-0.1/+0.1)	99.49 (-0.2/+0.1)	99.49 @ 50 mo. (-0.2/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.73 (-0.2/+0.1)	99.73 @ 50 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	38645	24319	11082	1329	344	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD DR

Models E052/E053/E142/E143/E162/
E163/F052/F053/F142/F143/
F162/F163

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA ICD DR
Models E052/E053/E142/E143/E162/ E163/F052/F053/F142/F143/ F162/F163

Worldwide Distribution: 71,000
Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**30**	**6**	**36**
[79] High-voltage capacitor	1	2	
[84] Low-voltage capacitors	3	-	
[88] Integrated circuit	5	3	
[91] Battery	2	1	
[92] Low-voltage capacitor	18	-	
[96] High voltage circuit	1	-	
Mechanical	**-**	**2**	**2**
[72] Transformer	-	2	
Software	**2**	**-**	**2**
[89] Memory errors	2	-	
Other	**8**	**3**	**11**
Non-patterned	8	3	
WW Confirmed Malfunctions	**40**	**11**	**51**

More details about malfunctions

References cited in table above

INCEPTA/ENERGEN/PUNCTUA ICD VR

Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

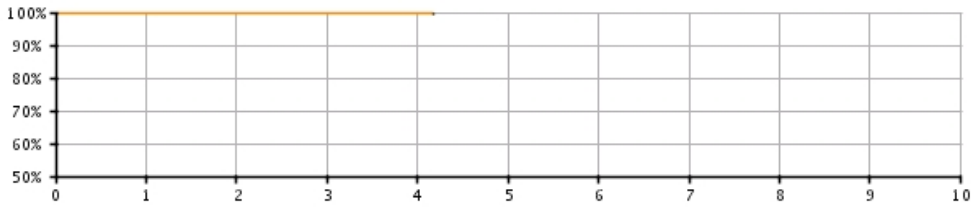
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

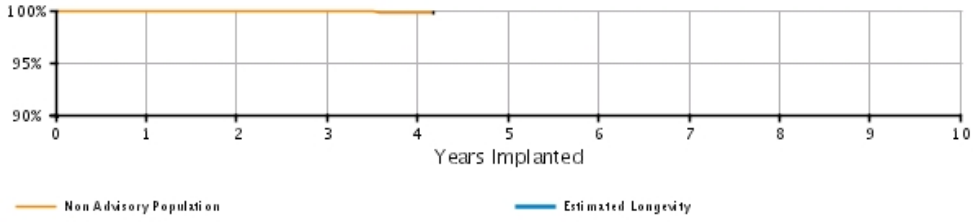
U.S. Registered Implants: 39,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 34,000

U.S. Normal Battery Depletions: 34
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:25
Without Compromised Therapy:14
With Compromised Therapy:11

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 39000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.80 (-0.1/+0.1)	99.54 (-0.2/+0.1)	99.54 @ 50 mo. (-0.2/+0.1)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.77 (-0.2/+0.1)	99.77 @ 50 mo. (-0.2/+0.1)	–	–	–	–	–
	Effective Sample Size	32417	20131	8969	1137	300	–	–	–	–	–

INCEPTA/ENERGEN/PUNCTUA ICD VR

Models E050/E051/E140/E141/E160/
E161/F050/F051/F140/F141/
F160/F161

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INCEPTA/ENERGEN/PUNCTUA ICD VR
Models E050/E051/E140/E141/E160/ E161/F050/F051/F140/F141/ F160/F161

Worldwide Distribution: 67,000
Worldwide Confirmed Malfunctions: 38

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**14**	**6**	**20**
[79] High-voltage capacitor	1	1	
[88] Integrated circuit	1	3	
[91] Battery	1	1	
[92] Low-voltage capacitor	11	-	
[96] High voltage circuit	-	1	
Mechanical	**-**	**5**	**5**
[72] Transformer	-	5	
Software	**4**	**-**	**4**
[89] Memory errors	4	-	
Other	**5**	**4**	**9**
Non-patterned	5	4	
WW Confirmed Malfunctions	**23**	**15**	**38**

More details about malfunctions

References cited in table above

SQ-RX S-ICD

Model 1010

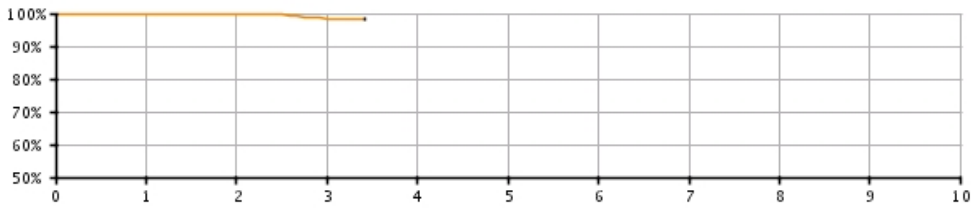
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

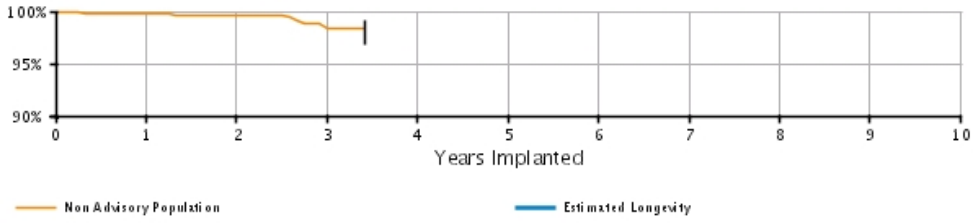
U.S. Registered Implants: 8,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 23
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:32
Without Compromised Therapy:14
With Compromised Therapy:18

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.75 (-0.1/+0.1)	99.59 (-0.2/+0.1)	98.36 (-1.5/+0.8)	98.36 @ 41 mo. (-1.5/+0.8)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.76 (-0.1/+0.1)	99.60 (-0.2/+0.1)	98.37 (-1.5/+0.8)	98.37 @ 41 mo. (-1.5/+0.8)	–	–	–	–	–	–
	Effective Sample Size	5526	1499	375	210	–	–	–	–	–	–

SQ-RX S-ICD

Model 1010

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

SQ-RX S-ICD Model 1010

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 81

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**3**	**10**
[2] Unintended Fuse Activation 2013	-	3	
[99] Charge Timeout Alert	7	-	
Mechanical	**14**	**18**	**32**
[3] High cathode condition	1	2	
[93] Battery depletion	13	16	
Software	**2**	**1**	**3**
[95] Unintended Battery Depletion Alert	2	1	
Other	**12**	**24**	**36**
Non-patterned	9	15	
[94] Telemetry	3	9	
WW Confirmed Malfunctions	**35**	**46**	**81**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

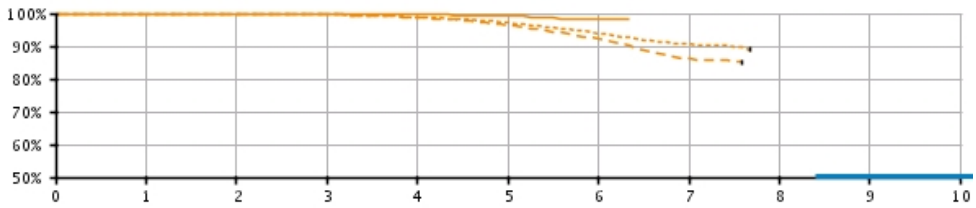
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

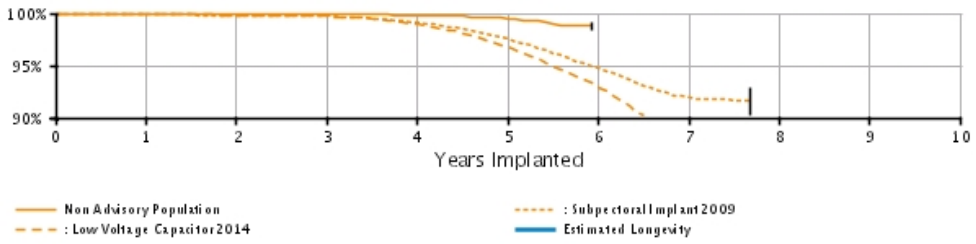
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 41,000

U.S. Normal Battery Depletions: 202
U.S. Unconfirmed Reports of Premature Battery Depletion : 98
U.S. Malfunctions:1378
Without Compromised Therapy:1272
With Compromised Therapy:106

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.86 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.20 (-0.2/+0.1)	98.35 @ 71 mo. (-0.4/+0.3)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.79 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.80 @ 71 mo. (-0.4/+0.3)	–	–	–	–
	Effective Sample Size	26441	23338	20594	17739	8493	246	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 30,000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.1/+0.0)	99.77 (-0.1/+0.1)	99.61 (-0.1/+0.1)	98.89 (-0.1/+0.1)	97.19 (-0.2/+0.1)	93.96 (-0.2/+0.1)	90.54 (-0.3/+0.4)	88.93 @ 92 mo. (-1.8/+1.8)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.12 (-0.1/+0.1)	97.56 (-0.2/+0.2)	94.72 (-0.2/+0.3)	92.44 (-0.4/+0.3)	92.40 @ 89 mo. (-1.4/+1.3)	–	–
	Effective Sample Size	26747	23501	20671	18056	15614	13221	4770	215	–	–
Low Voltage Capacitor 2014* Registered Implants: 23,000	Depletions and Malfunctions(%) (Confidence Interval)	99.89 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.58 (-0.1/+0.1)	98.74 (-0.1/+0.1)	96.38 (-0.1/+0.1)	92.06 (-0.3/+0.3)	86.21 (-0.5/+0.7)	85.98 @ 91 mo. (-1.5/+1.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.0/+0.0)	99.82 (-0.1/+0.1)	99.69 (-0.1/+0.1)	98.95 (-0.1/+0.1)	96.77 (-0.2/+0.1)	92.89 (-0.4/+0.3)	88.06 (-0.6/+1.0)	87.42 @ 91 mo.	–	–

								(-1.2/+1.5)		
Effective Sample Size	20716	18220	16011	13979	11991	8693	1758	219	–	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN DR

Models E110/E111/F110/F111

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

TELIGEN DR
Models E110/E111/F110/F111

Worldwide Distribution: 91,000
Worldwide Confirmed Malfunctions: 1804

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1609**	**77**	**1686**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1309	31	
[78] Safety Core-electrocautery	3	-	
[79] High-voltage capacitor	1	6	
[84] Low-voltage capacitors	6	-	
[88] Integrated circuit	20	20	
[91] Battery	137	19	
[92] Low-voltage capacitor	133	1	
Mechanical	**19**	**51**	**70**
[5] Subpectoral implant 2009 (Advisory issued)	3	9	
[72] Transformer	-	20	
[75] Seal plug	3	-	
[76] Difficulty securing lead	9	8	
[82] Header contacts	2	11	
[102] Header	2	3	
Software	**16**	**-**	**16**
[86] Alert messages not displayed post-EOL	3	-	
[89] Memory errors	13	-	
Other	**24**	**8**	**32**
Non-patterned	24	8	
WW Confirmed Malfunctions	**1668**	**136**	**1804**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

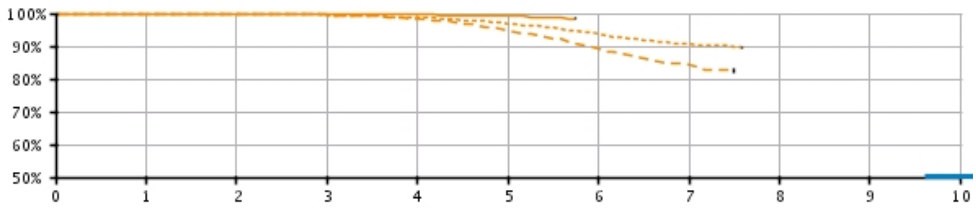
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

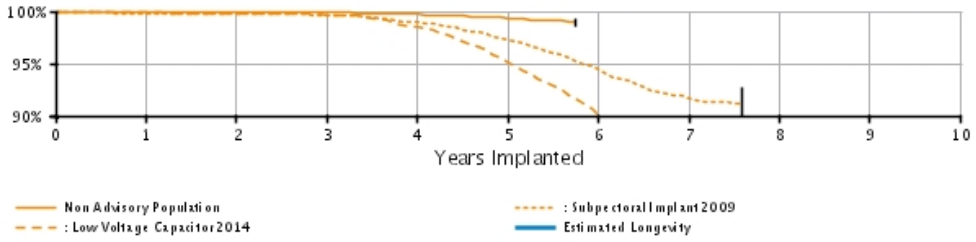
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 24,000

U.S. Normal Battery Depletions: 80
U.S. Unconfirmed Reports of Premature Battery Depletion : 59
U.S. Malfunctions:922
Without Compromised Therapy:843
With Compromised Therapy:79

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 18000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.19 (-0.2/+0.2)	98.44 @ 69 mo. (-0.7/+0.5)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.69 (-0.1/+0.1)	99.36 (-0.2/+0.2)	98.95 @ 69 mo. (-0.5/+0.3)	–	–	–	–
	Effective Sample Size	16276	14329	12589	10831	4160	395	–	–	–	–
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.2/+0.2)	96.93 (-0.4/+0.3)	93.70 (-0.6/+0.5)	90.58 (-0.6/+0.5)	89.73 @ 91 mo. (-0.6/+0.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.80 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.63 (-0.1/+0.1)	98.93 (-0.1/+0.1)	97.32 (-0.1/+0.1)	94.38 (-0.1/+0.2)	91.63 (-0.4/+0.3)	91.19 @ 91 mo. (-1.5/+1.6)	–	–
	Effective Sample Size	13682	11997	10516	9151	7865	6662	2481	339	–	–
Low Voltage Capacitor 2014* Registered Implants: 12,000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.1/+0.1)	99.72 (-0.0/+0.1)	99.51 (-0.0/+0.1)	98.23 (-0.1/+0.1)	94.78 (-0.2/+0.1)	89.26 (-0.3/+0.2)	84.02 (-0.4/+0.2)	82.55 @ 90 mo. (-1.5/+1.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.64 (-0.1/+0.1)	98.45 (-0.1/+0.1)	95.14 (-0.1/+0.1)	90.14 (-0.1/+0.1)	85.39 (-0.3/+0.2)	84.23 @ 90 mo.	–	–

								(-1.2/+1.1)		
Effective Sample Size	10905	9579	8403	7291	6172	4037	848	205	–	–

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

TELIGEN VR

Models E102/E103/F102/F103

TELIGEN VR
Models E102/E103/F102/F103

Worldwide Distribution: 66,000
Worldwide Confirmed Malfunctions: 1434

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1264**	**51**	**1315**
[1] Low Voltage Capacitor 2014 (Advisory issued)	983	22	
[78] Safety Core-electrocautery	1	1	
[79] High-voltage capacitor	-	3	
[84] Low-voltage capacitors	5	-	
[88] Integrated circuit	9	14	
[91] Battery	187	11	
[92] Low-voltage capacitor	79	-	
Mechanical	**21**	**64**	**85**
[5] Subpectoral implant 2009	6	15	
[45] Transformer	-	1	
[72] Transformer	-	14	
[75] Seal plug	1	-	
[76] Difficulty securing lead	-	10	
[82] Header contacts	12	16	
[102] Header	2	8	
Software	**15**	**-**	**15**
[6] Respiratory Sensor Oversensing	1	-	
[86] Alert messages not displayed post-EOL	4	-	
[89] Memory errors	10	-	
Other	**8**	**11**	**19**
Non-patterned	8	11	
WW Confirmed Malfunctions	**1308**	**126**	**1434**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

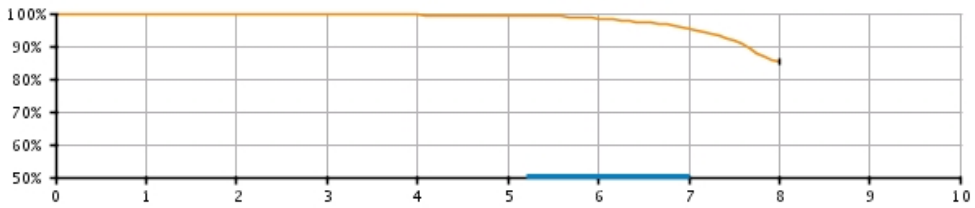
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

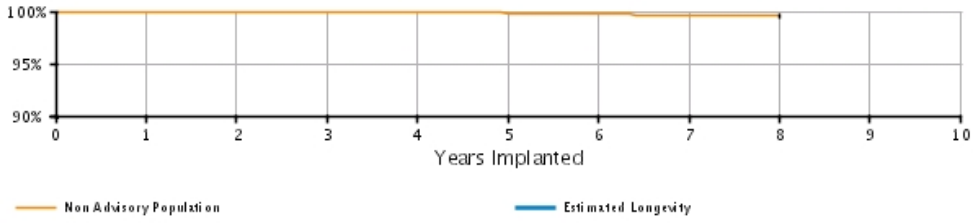
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 251
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:14
Without Compromised Therapy:11
With Compromised Therapy:3

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.54 (-0.2/+0.2)	99.34 (-0.3/+0.2)	98.50 (-0.5/+0.4)	95.35 (-0.9/+0.7)	85.20 (-2.2/+1.9)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.92 (-0.1/+0.1)	99.84 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.57 (-0.3/+0.2)	–	–
	Effective Sample Size	6164	5397	4700	4116	3537	2863	2034	240	–	–

CONFIENT DR

Models E030/F030

CONFIENT DR
Models E030/F030

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 14

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**10**	**-**	**10**
[26] Capacitor	1	-	
[30] Integrated circuit	2	-	
[92] Low-voltage capacitor	7	-	
Mechanical	**-**	**1**	**1**
[72] Transformer	-	1	
Software	**-**	**-**	**0**
Other	**1**	**2**	**3**
Non-patterned	1	1	
[39] Battery depletion	-	1	
WW Confirmed Malfunctions	**11**	**3**	**14**

More details about malfunctions

References cited in table above

VITALITY 2 EL DR

Model T167

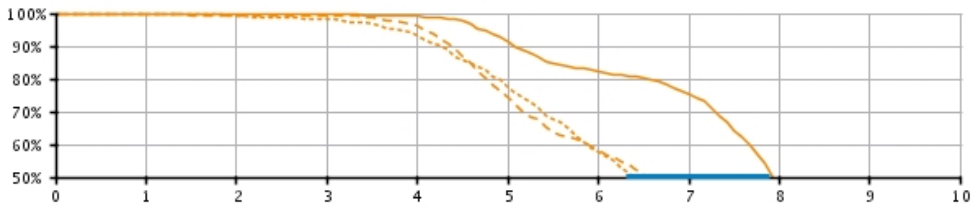
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

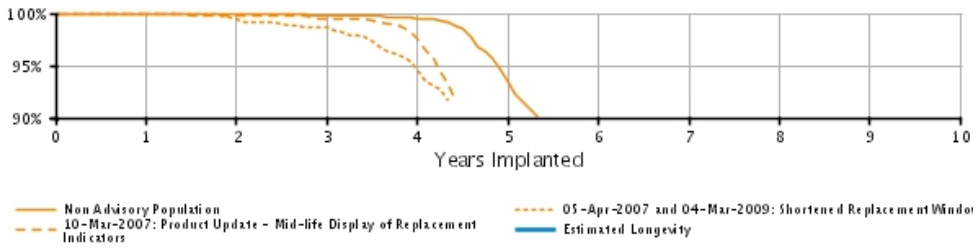
U.S. Registered Implants: 8,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 2,137
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:766
Without Compromised Therapy:752
With Compromised Therapy:14

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.85 (-0.2/+0.1)	99.66 (-0.2/+0.1)	99.01 (-0.4/+0.3)	91.29 (-1.1/+1.0)	82.28 (-1.5/+1.4)	75.35 (-1.8/+1.7)	47.51 (-2.4/+2.4)	29.23 @ 100 mo. (-2.6/+2.8)	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.90 (-0.2/+0.1)	99.82 (-0.2/+0.1)	99.50 (-0.3/+0.2)	93.40 (-1.0/+0.9)	87.35 (-1.4/+1.3)	86.77 (-1.4/+1.3)	86.56 (-1.4/+1.3)	86.56 @ 100 mo. (-1.4/+1.3)	–
	Effective Sample Size	4362	3831	3361	2919	2362	1811	1423	597	241	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.22 (-0.6/+0.3)	98.37 (-0.8/+0.5)	93.31 (-1.5/+1.3)	77.40 (-2.6/+2.4)	57.79 (-3.2/+3.1)	31.54 (-3.2/+3.4)	28.45 @ 85 mo. (-3.1/+3.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.4/+0.1)	99.41 (-0.5/+0.3)	98.63 (-0.7/+0.5)	94.61 (-1.4/+1.1)	83.49 (-2.4/+2.1)	75.79 (-2.9/+2.6)	73.66 (-3.1/+2.9)	73.66 @ 85 mo. (-3.1/+2.9)	–	–
	Effective Sample Size	1699	1489	1289	1076	782	474	218	203	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.68 (-0.5/+0.2)	99.49 (-0.6/+0.3)	99.17 (-0.8/+0.4)	96.22 (-1.5/+1.1)	74.28 (-3.3/+3.1)	58.03 (-3.8/+3.7)	42.53 @ 82 mo. (-4.0/+4.1)	–	–	–

Registered Implants: 1000											
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.5/+0.1)	99.74 (-0.6/+0.2)	99.52 (-0.7/+0.3)	97.51 (-1.3/+0.9)	80.99 (-3.1/+2.8)	70.76 (-3.7/+3.5)	70.52 @ 82 mo. (-3.7/+3.5)	–	–	–
	Effective Sample Size	1171	1024	898	762	500	317	205	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

VITALITY 2 EL DR

Model T167

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

VITALITY 2 EL DR Model T167

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 1065

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1026**	**10**	**1036**
[8] Shortened replacement window (Advisory issued)	143	2	
[15] Extended charge time post-mid-life	15	-	
[26] Capacitor	1	-	
[30] Integrated circuit	-	4	
[43] Capacitor	1	-	
[55] Mid-life display of replacement indicators	824	-	
[56] High-voltage capacitor	-	2	
[60] Integrated circuit	-	1	
[77] Low-voltage capacitor	42	1	
Mechanical	**8**	**3**	**11**
[7] Subpectoral implant (Advisory issued)	1	1	
[25] Header	1	-	
[34] Seal plug	5	1	
[64] Seal plug	1	-	
[72] Transformer	-	1	
Software	**7**	**1**	**8**
[54] Memory location	1	1	
[74] Misaligned markers	6	-	
Other	**3**	**7**	**10**
Non-patterned	2	3	
[20] Firmware error	1	4	
WW Confirmed Malfunctions	**1044**	**21**	**1065**

More details about malfunctions

References cited in table above

VITALITY 2 EL VR

Model T177

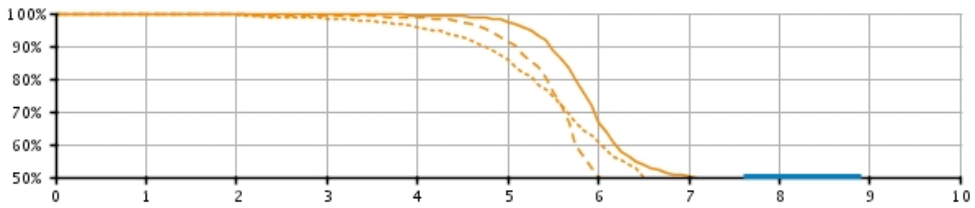
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

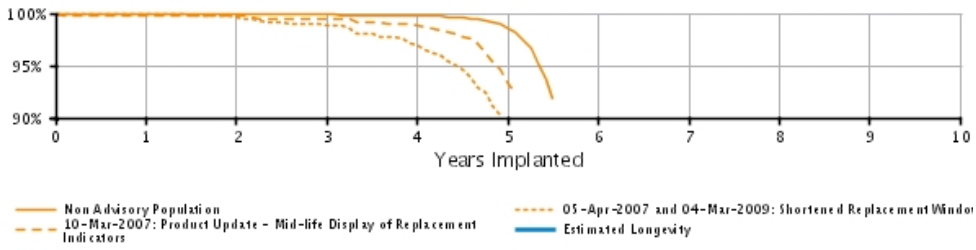
U.S. Registered Implants: 7,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 1,197
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:1273
Without Compromised Therapy:1260
With Compromised Therapy:13

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.39 (-0.4/+0.2)	97.37 (-0.7/+0.6)	67.04 (-2.1/+2.1)	50.12 (-2.3/+2.3)	43.01 (-2.5/+2.5)	37.65 @ 99 mo. (-2.8/+2.9)	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.85 (-0.2/+0.1)	99.73 (-0.3/+0.1)	98.48 (-0.6/+0.4)	73.39 (-2.1/+2.0)	59.99 (-2.4/+2.4)	58.98 (-2.4/+2.4)	58.45 @ 99 mo. (-2.5/+2.5)	–
	Effective Sample Size	3631	3176	2774	2409	2062	1278	731	335	201	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.48 (-0.8/+0.5)	95.88 (-1.2/+1.0)	85.71 (-2.2/+2.0)	60.80 (-3.3/+3.2)	41.29 (-3.4/+3.5)	33.79 @ 88 mo. (-3.4/+3.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.56 (-0.5/+0.2)	98.84 (-0.7/+0.4)	97.00 (-1.1/+0.8)	88.93 (-2.1/+1.8)	68.27 (-3.2/+3.1)	60.90 (-3.5/+3.4)	60.37 @ 88 mo. (-3.6/+3.5)	–	–
	Effective Sample Size	1687	1474	1279	1087	820	493	275	206	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.61 (-0.6/+0.2)	99.61 (-0.6/+0.2)	99.38 (-0.8/+0.3)	98.80 (-1.0/+0.6)	91.14 (-2.5/+2.0)	50.22 (-4.4/+4.4)	45.00 @ 74 mo. (-4.4/+4.5)	–	–	–

Registered Implants: 1000											
	Malfunctions Only (%) (Confidence Interval)	99.72 (-0.6/+0.2)	99.72 (-0.6/+0.2)	99.48 (-0.7/+0.3)	98.90 (-1.0/+0.5)	93.22 (-2.3/+1.8)	59.60 (-4.6/+4.4)	54.40 @ 74 mo. (-4.7/+4.6)	–	–	–
	Effective Sample Size	975	854	747	647	526	237	206	–	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

VITALITY 2 EL VR

Model T177

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

VITALITY 2 EL VR Model T177

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 1914

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1873**	**8**	**1881**
[8] Shortened replacement window (Advisory issued)	139	1	
[9] Low-voltage capacitor (Advisory issued)	2	1	
[15] Extended charge time post-mid-life	20	2	
[30] Integrated circuit	-	3	
[43] Capacitor	1	-	
[46] Capacitor	2	-	
[55] Mid-life display of replacement indicators	1642	1	
[56] High-voltage capacitor	2	-	
[77] Low-voltage capacitor	65	-	
Mechanical	**3**	**8**	**11**
[7] Subpectoral implant (Advisory issued)	-	5	
[25] Header	-	1	
[34] Seal plug	1	-	
[58] Sensing	2	-	
[72] Transformer	-	2	
Software	**-**	**2**	**2**
[52] Memory location	-	1	
[54] Memory location	-	1	
Other	**11**	**9**	**20**
Non-patterned	11	7	
[28] Battery depletion	-	2	
WW Confirmed Malfunctions	**1887**	**27**	**1914**

More details about malfunctions

References cited in table above

VITALITY 2 VR

Model T175

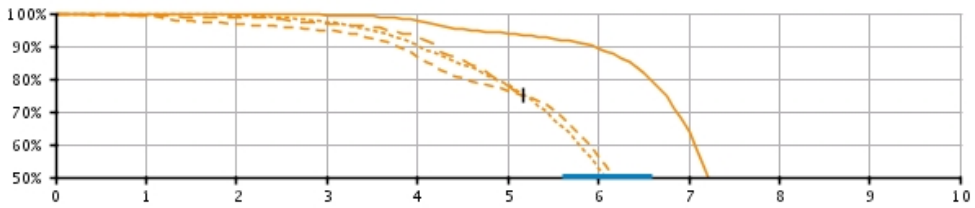
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

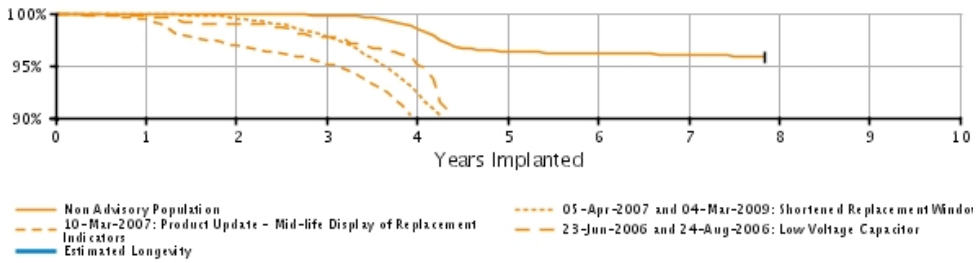
U.S. Registered Implants: 21,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 6,547
U.S. Unconfirmed Reports of Premature Battery Depletion : 36
U.S. Malfunctions:1243
Without Compromised Therapy:1218
With Compromised Therapy:25

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.49 (-0.2/+0.1)	97.64 (-0.4/+0.3)	93.84 (-0.6/+0.6)	89.30 (-0.8/+0.8)	63.78 (-1.4/+1.4)	10.27 @ 94 mo. (-1.1/+1.2)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.92 (-0.1/+0.0)	99.80 (-0.1/+0.1)	98.47 (-0.3/+0.3)	96.34 (-0.5/+0.4)	96.16 (-0.5/+0.5)	96.00 (-0.5/+0.5)	95.91 @ 94 mo. (-0.6/+0.5)	–	–
	Effective Sample Size	9498	8338	7262	6251	5121	4145	2535	283	–	–
05-Apr-07 and 04-Mar-09 Shortened Replacement Window* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.43 (-0.3/+0.2)	97.47 (-0.5/+0.4)	90.30 (-1.0/+0.9)	78.07 (-1.4/+1.3)	52.52 (-1.8/+1.8)	16.82 (-1.5/+1.6)	8.95 @ 87 mo. (-1.2/+1.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.50 (-0.2/+0.2)	97.79 (-0.5/+0.4)	92.40 (-0.9/+0.8)	86.39 (-1.2/+1.1)	84.86 (-1.3/+1.2)	83.18 (-1.6/+1.4)	83.18 @ 87 mo. (-1.6/+1.4)	–	–
	Effective Sample Size	5391	4691	4022	3235	2374	1372	359	243	–	–
10-Mar-07 Product Update - Mid-life Display of Replacement Indicators*	Depletions and Malfunctions(%) (Confidence Interval)	99.34 (-0.3/+0.2)	96.85 (-0.6/+0.5)	94.72 (-0.8/+0.7)	86.62 (-1.3/+1.2)	76.42 (-1.7/+1.6)	56.28 (-2.1/+2.1)	15.94 (-1.7/+1.9)	13.61 @ 85 mo. (-1.6/+1.8)	–	–

Registered Implants: 4000											
	Malfunctions Only(%) (Confidence Interval)	99.39 (-0.3/+0.2)	96.95 (-0.6/+0.5)	95.13 (-0.8/+0.7)	89.21 (-1.2/+1.1)	84.05 (-1.4/+1.3)	83.38 (-1.5/+1.4)	81.60 (-1.8/+1.7)	81.60 @ 85 mo. (-1.8/+1.7)	–	–
	Effective Sample Size	3907	3331	2852	2262	1679	1058	245	203	–	–
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.47 (-1.1/+0.4)	98.64 (-1.5/+0.7)	96.87 (-2.1/+1.3)	92.76 (-3.1/+2.2)	77.80 (-5.0/+4.3)	75.17 @ 62 mo. (-5.2/+4.5)	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.82 (-1.1/+0.2)	98.99 (-1.4/+0.6)	97.72 (-1.9/+1.1)	95.06 (-2.7/+1.8)	84.87 (-4.5/+3.6)	84.87 @ 62 mo. (-4.5/+3.6)	–	–	–	–
	Effective Sample Size	503	430	364	305	214	201	–	–	–	–
12-May-06 Premature Battery Depletion*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

VITALITY 2 VR

Model T175

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

VITALITY 2 VR Model T175

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 1587

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1533**	**26**	**1559**
[8] Shortened replacement window (Advisory issued)	347	9	
[9] Low-voltage capacitor (Advisory issued)	-	1	
[10] Premature battery depletion (Advisory issued)	219	6	
[15] Extended charge time post-mid-life	64	-	
[21] Integrated circuit	-	1	
[26] Capacitor	1	-	
[30] Integrated circuit	4	7	
[43] Capacitor	1	-	
[46] Capacitor	4	-	
[55] Mid-life display of replacement indicators	773	-	
[56] High-voltage capacitor	-	1	
[77] Low-voltage capacitor	120	1	
Mechanical	**2**	**1**	**3**
[34] Seal plug	2	1	
Software	**-**	**1**	**1**
[54] Memory location	-	1	
Other	**18**	**6**	**24**
Non-patterned	16	6	
[28] Battery depletion	2	-	
WW Confirmed Malfunctions	**1553**	**34**	**1587**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

Models L121/L131/L221/L231/L321/
L331

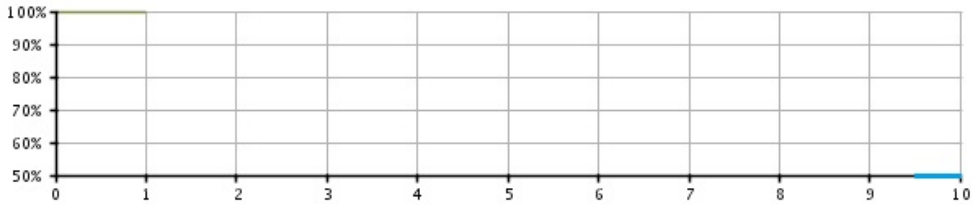
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

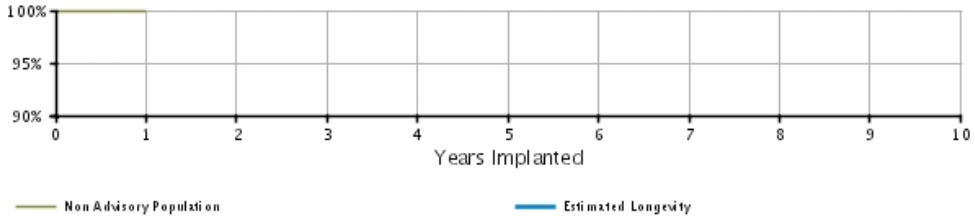
U.S. Registered Implants: 8,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	204	–	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR EL

Models L121/L131/L221/L231/L321/
L331

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO DR EL
Models L121/L131/L221/L231/L321/ L331

Worldwide Distribution: 21,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR

Models L101/L111/L201/L211/L301/
L311

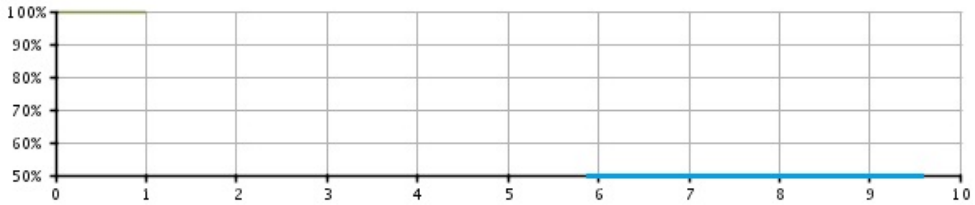
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

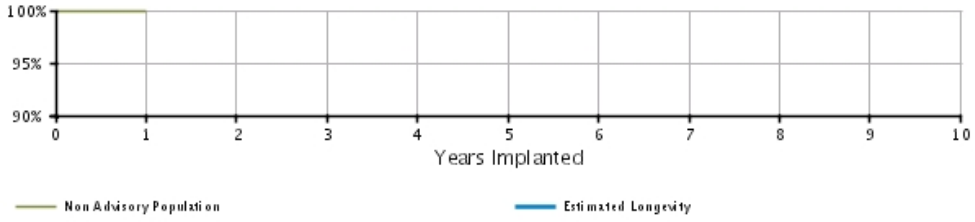
U.S. Registered Implants: 28,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 27,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:1
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 28000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	608	–	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO DR

Models L101/L111/L201/L211/L301/ L311

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO DR Models L101/L111/L201/L211/L301/ L311

Worldwide Distribution: 50,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**2**	**2**
[101] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**1**	**2**	**3**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

Models L100/L110/L200/L210/L300/
L310

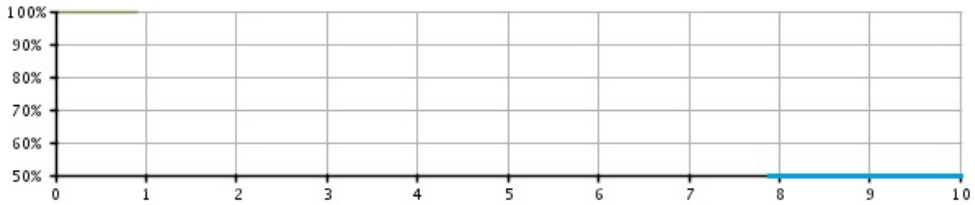
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

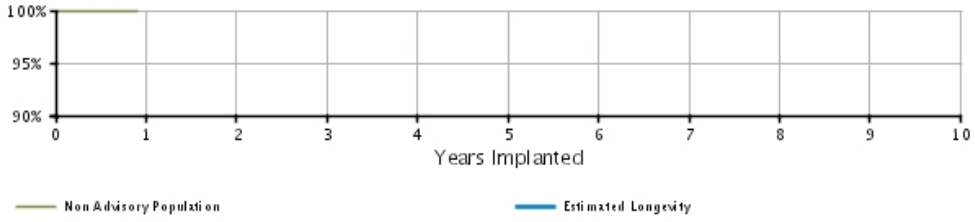
U.S. Registered Implants: 5,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 0
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 @ 11 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 @ 11 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–	–
	Effective Sample Size	284	–	–	–	–	–	–	–	–	–

ACCOLADE/PROPONENT/ESSENTIO SR

Models L100/L110/L200/L210/L300/
L310

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACCOLADE/PROPONENT/ESSENTIO SR Models L100/L110/L200/L210/L300/ L310

Worldwide Distribution: 17,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models J063/J066/J173/J176/J273/
J276/J278/J279/K063/K066/
K083/K086/K173/K176/K183/
K186/K273/K276/K278/K279/
K283/K286/K288/K289

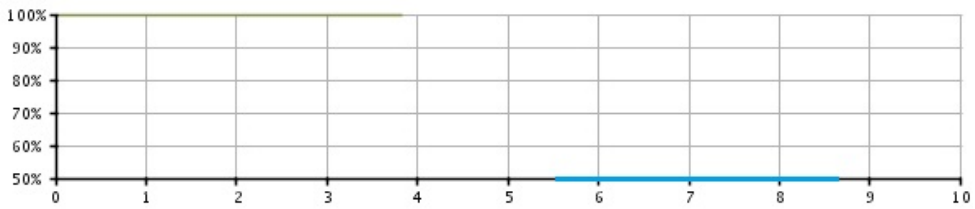
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

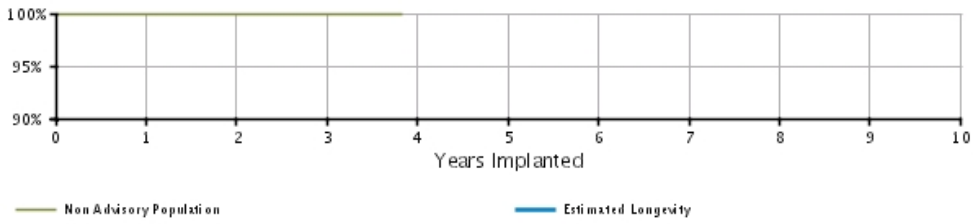
U.S. Registered Implants: 121,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 108,000

U.S. Normal Battery Depletions: 72
U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Malfunctions:25
Without Compromised Therapy:18
With Compromised Therapy:7

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 121000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.78 @ 46 mo. (-0.1/+0.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 46 mo. (-0.0/+0.0)	–	–	–	–	–	–
	Effective Sample Size	101520	57121	20225	491	–	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO/FORMIO DR

Models J063/J066/J173/J176/J273/
J276/J278/J279/K063/K066/
K083/K086/K173/K176/K183/
K186/K273/K276/K278/K279/
K283/K286/K288/K289

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO/FORMIO DR
Models J063/J066/J173/J176/J273/ J276/J278/J279/K063/K066/ K083/K086/K173/K176/K183/ K186/K273/K276/K278/K279/ K283/K286/K288/K289

Worldwide Distribution: 210,000
Worldwide Confirmed Malfunctions: 40

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**6**	**13**
[84] Low-voltage capacitors	4	-	
[88] Integrated circuit	3	4	
[98] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**9**	**1**	**10**
[89] Memory errors	9	1	
Other	**15**	**2**	**17**
Non-patterned	15	2	
WW Confirmed Malfunctions	**31**	**9**	**40**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO EL DR

Models J064/J067/J174/J177/J274/
J277/K064/K067/K084/K087/
K174/K177/K184/K187/K274/
K277/K284/K287

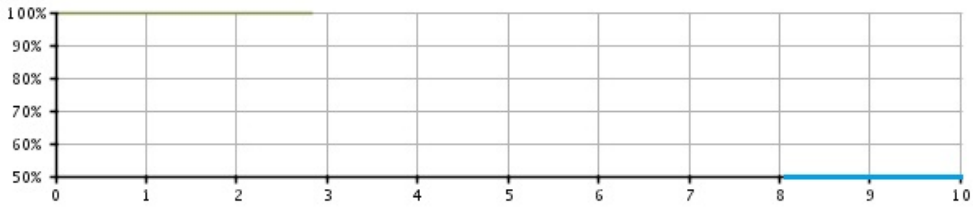
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

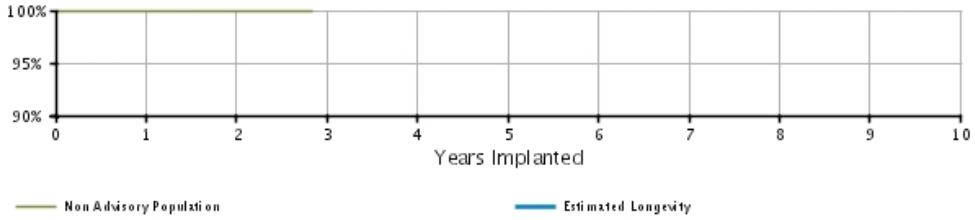
U.S. Registered Implants: 11,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 34 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 34 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	8325	2456	255	–	–	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO EL DR

Models J064/J067/J174/J177/J274/
J277/K064/K067/K084/K087/
K174/K177/K184/K187/K274/
K277/K284/K287

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO EL DR
Models J064/J067/J174/J177/J274/ J277/K064/K067/K084/K087/ K174/K177/K184/K187/K274/ K277/K284/K287

Worldwide Distribution: 64,000
Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**4**	**8**
[84] Low-voltage capacitors	4	1	
[88] Integrated circuit	-	1	
[98] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**4**	**-**	**4**
[89] Memory errors	3	-	
[97] Respiratory sensor	1	-	
Other	**4**	**1**	**5**
Non-patterned	4	1	
WW Confirmed Malfunctions	**12**	**5**	**17**

More details about malfunctions

References cited in table above

ADVANTIO/INGENIO/VITALIO SR

Models J062/J065/J172/J175/J272/
J275/K062/K065/K082/K085/
K172/K175/K182/K185/K272/
K275/K282/K285

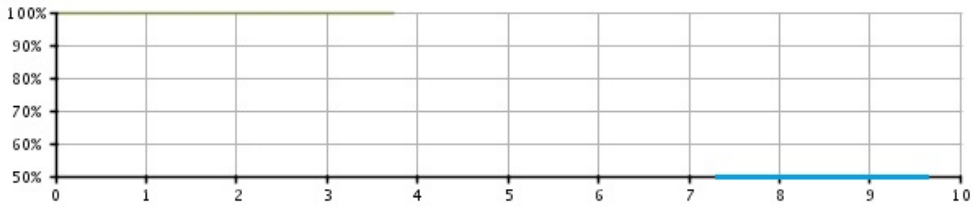
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

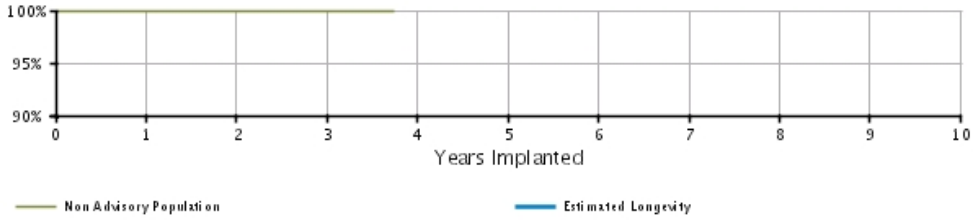
U.S. Registered Implants: 26,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 22,000

U.S. Normal Battery Depletions: 12
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:7
Without Compromised Therapy:6
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 26000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.86 (-0.1/+0.1)	99.86 @ 45 mo. (-0.1/+0.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 45 mo. (-0.1/+0.0)	–	–	–	–	–	–
	Effective Sample Size	20587	11140	3700	237	–	–	–	–	–	–

ADVANTIO/INGENIO/VITALIO SR

Models J062/J065/J172/J175/J272/
J275/K062/K065/K082/K085/
K172/K175/K182/K185/K272/
K275/K282/K285

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ADVANTIO/INGENIO/VITALIO SR
Models J062/J065/J172/J175/J272/ J275/K062/K065/K082/K085/ K172/K175/K182/K185/K272/ K275/K282/K285

Worldwide Distribution: 79,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[84] Low-voltage capacitors	3	1	
[88] Integrated circuit	1	3	
[98] Titanium case material	-	1	
Mechanical	**-**	**-**	**0**
Software	**4**	**-**	**4**
[89] Memory errors	4	-	
Other	**1**	**2**	**3**
Non-patterned	1	2	
WW Confirmed Malfunctions	**9**	**7**	**16**

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

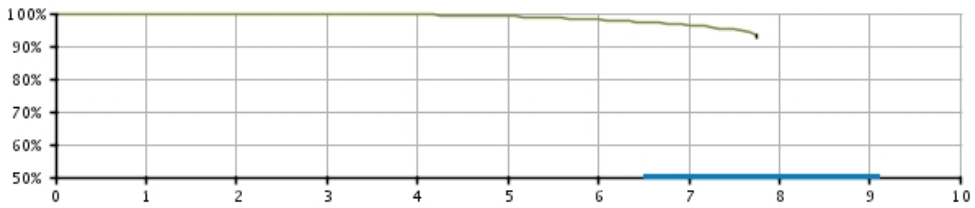
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

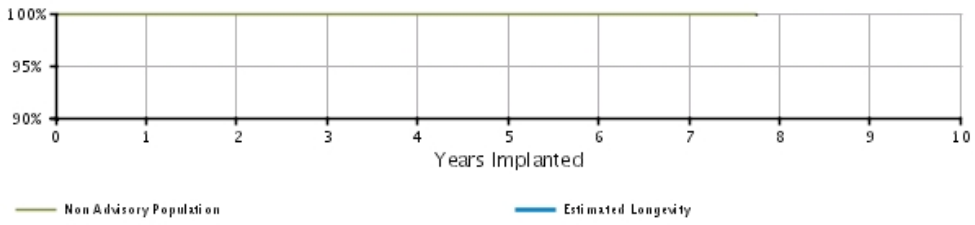
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 353
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:10
Without Compromised Therapy:9
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 22000	Depletions and Malfunctions(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.54 (-0.1/+0.1)	99.04 (-0.2/+0.2)	98.04 (-0.3/+0.2)	96.42 (-0.4/+0.4)	93.29 @ 93 mo. (-1.6/+1.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.86 @ 93 mo. (-0.1/+0.1)	–	–
	Effective Sample Size	19461	17170	15005	12861	10347	7974	4381	274	–	–

ALTRUA 60 DR

Model S602

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

ALTRUA 60 DR
Model S602

Worldwide Distribution: 56,000
Worldwide Confirmed Malfunctions: 15

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[26] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[29] Capacitor array	1	-	
[76] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**11**	**1**	**12**
Non-patterned	2	1	
[49] Battery depletion	1	-	
[87] Battery status	8	-	
WW Confirmed Malfunctions	**13**	**2**	**15**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

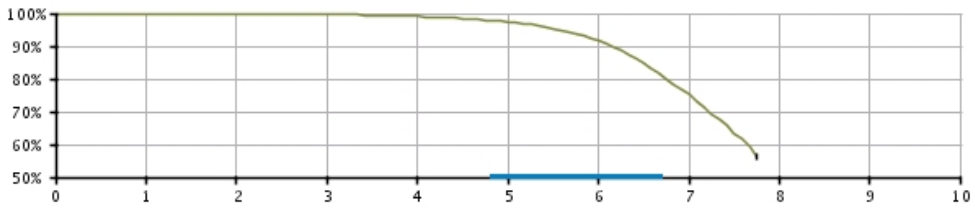
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

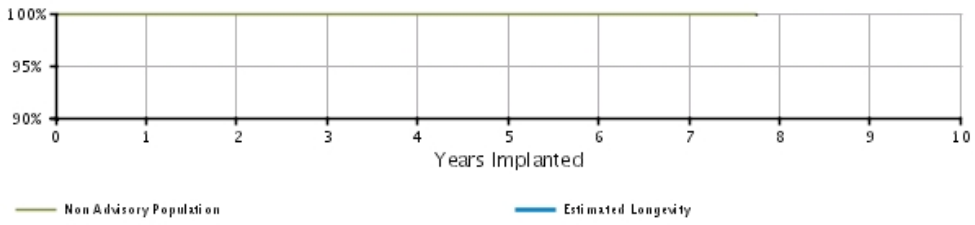
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 55,000

U.S. Normal Battery Depletions: 5,372
U.S. Unconfirmed Reports of Premature Battery Depletion : 39
U.S. Malfunctions:42
Without Compromised Therapy:34
With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 90000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.0/+0.0)	99.67 (-0.0/+0.0)	99.09 (-0.1/+0.1)	97.40 (-0.2/+0.1)	91.63 (-0.3/+0.3)	75.16 (-0.7/+0.7)	56.47 @ 93 mo. (-2.1/+2.0)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.85 (-0.1/+0.0)	99.85 @ 93 mo. (-0.1/+0.0)	–	–
	Effective Sample Size	79415	70633	62168	50647	34061	18841	5949	272	–	–

ALTRUA 60 DR (Downsize)

Model S603

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 60 DR (Downsize) Model S603

Worldwide Distribution: 132,000
Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**7**	**12**
[26] Capacitor	4	6	
[60] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[73] Connector block	1	-	
[76] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**34**	**3**	**37**
Non-patterned	-	2	
[49] Battery depletion	3	1	
[87] Battery status	31	-	
WW Confirmed Malfunctions	**41**	**10**	**51**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

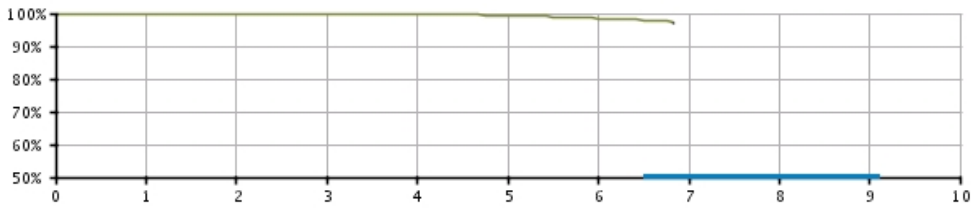
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

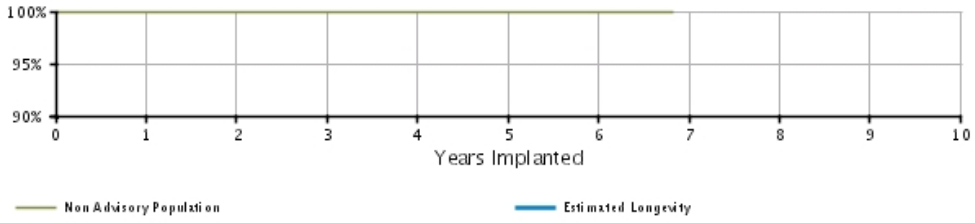
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 44,000

U.S. Normal Battery Depletions: 300
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:9
Without Compromised Therapy:7
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 59000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.71 (-0.1/+0.0)	99.37 (-0.1/+0.1)	98.50 (-0.2/+0.2)	97.09 @ 82 mo. (-1.0/+0.7)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.95 @ 82 mo. (-0.1/+0.0)	–	–	–
	Effective Sample Size	52728	46869	41060	32164	17538	6251	363	–	–	–

ALTRUA 60 DR EL

Model S606

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 60 DR EL
Model S606

Worldwide Distribution: 90,000
Worldwide Confirmed Malfunctions: 11

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[26] Capacitor	3	-	
[30] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[76] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**5**	**1**	**6**
Non-patterned	1	-	
[49] Battery depletion	-	1	
[87] Battery status	4	-	
WW Confirmed Malfunctions	**9**	**2**	**11**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

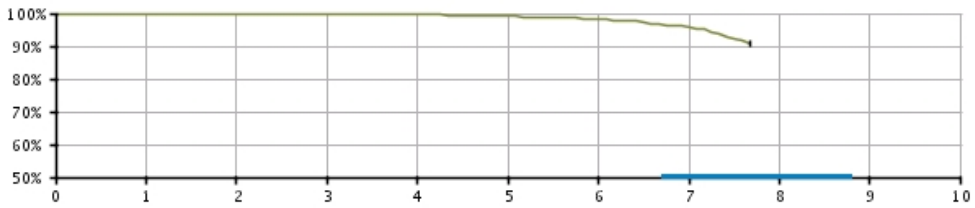
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

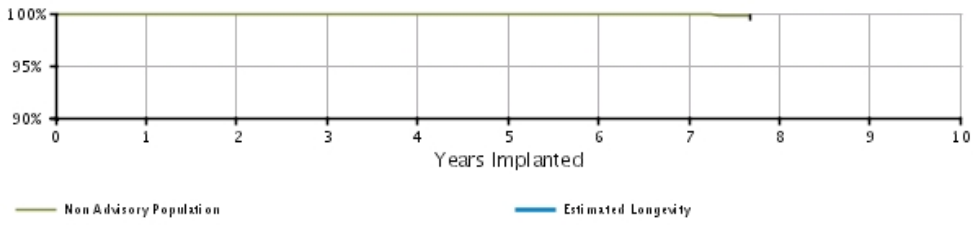
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 335
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:6
Without Compromised Therapy:4
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 32000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.80 (-0.1/+0.0)	99.61 (-0.1/+0.1)	99.10 (-0.2/+0.1)	98.25 (-0.3/+0.2)	95.71 (-0.7/+0.6)	90.92 @ 92 mo. (-2.0/+1.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.2/+0.0)	99.78 @ 92 mo. (-0.5/+0.1)	–	–
	Effective Sample Size	26811	23633	20655	16502	10526	5780	1884	234	–	–

ALTRUA 60 SR

Model S601

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 60 SR
Model S601

Worldwide Distribution: 68,000
Worldwide Confirmed Malfunctions: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**3**	**5**
[26] Capacitor	2	1	
[60] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**4**	**3**	**7**
Non-patterned	-	2	
[49] Battery depletion	-	1	
[87] Battery status	4	-	
WW Confirmed Malfunctions	**6**	**6**	**12**

More details about malfunctions

References cited in table above

ALTRUA 50 DR (Downsize)

Model S502

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 DR (Downsize) Model S502

Worldwide Distribution: 46,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**-**	**3**
[26] Capacitor	2	-	
[60] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[76] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**9**	**-**	**9**
Non-patterned	1	-	
[49] Battery depletion	1	-	
[87] Battery status	7	-	
WW Confirmed Malfunctions	**12**	**1**	**13**

More details about malfunctions

References cited in table above

ALTRUA 50 SR

Model S501

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 50 SR
Model S501

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**3**	**4**
[26] Capacitor	1	3	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**3**	**3**
Non-patterned	-	1	
[49] Battery depletion	-	2	
WW Confirmed Malfunctions	**1**	**6**	**7**

More details about malfunctions

References cited in table above

ALTRUA 50 DDD (Downsize)

Model S503

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ALTRUA 50 DDD (Downsize) Model S503

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	4	3	7
Non-patterned	-	-	
[49] Battery depletion	-	3	
[87] Battery status	4	-	
WW Confirmed Malfunctions	4	3	7

More details about malfunctions

References cited in table above

ALTRUA 50 VDD (Downsize)

Model S504

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 50 VDD (Downsize) Model S504

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
[87] Battery status	2	-	
WW Confirmed Malfunctions	2	0	2

More details about malfunctions

References cited in table above

ALTRUA 50 SSI

Model S508

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 50 SSI
Model S508

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	1	2
Non-patterned	-	-	
[49] Battery depletion	-	1	
[87] Battery status	1	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

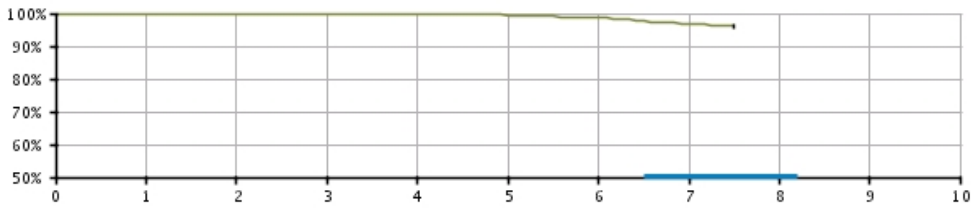
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

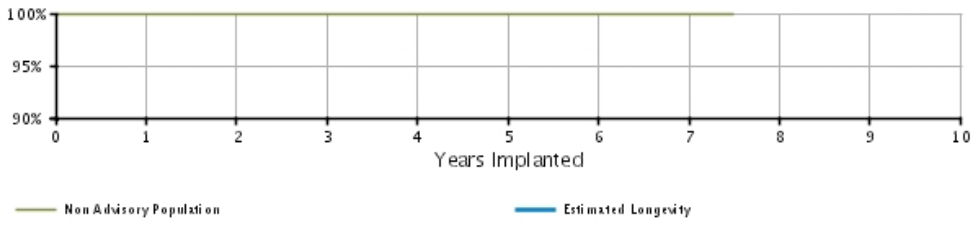
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 29
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.93 (-0.4/+0.1)	99.66 (-0.6/+0.2)	99.45 (-0.7/+0.3)	98.66 (-1.0/+0.6)	96.72 (-1.4/+1.0)	96.19 @ 90 mo. (-1.7/+1.2)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 90 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	1517	1346	1194	1064	945	832	614	218	–	–

ALTRUA 40 DR

Model S402

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

ALTRUA 40 DR
Model S402

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	-	1	1
Non-patterned	-	-	
[49] Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

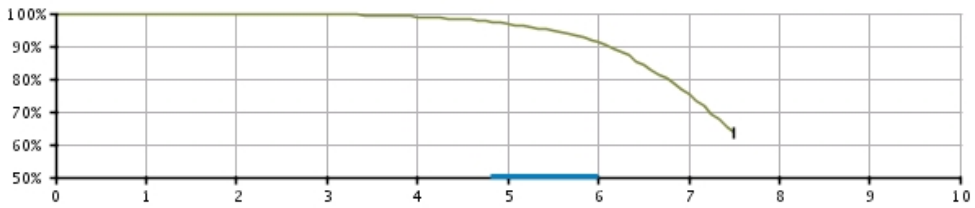
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

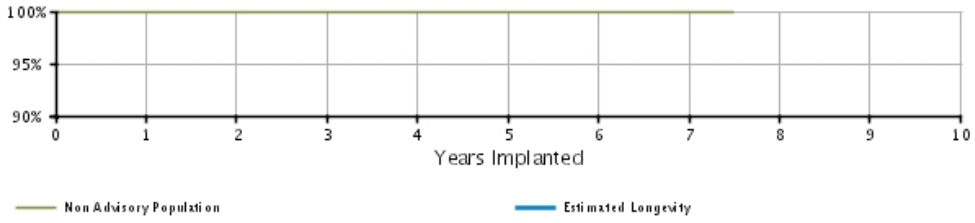
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 823
U.S. Unconfirmed Reports of Premature Battery Depletion : 2
U.S. Malfunctions:3
Without Compromised Therapy:3
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.69 (-0.1/+0.1)	98.94 (-0.2/+0.2)	96.77 (-0.4/+0.4)	91.25 (-0.9/+0.8)	75.34 (-2.0/+1.9)	63.55 @ 90 mo. (-3.3/+3.1)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 90 mo. (-0.1/+0.0)	–	–
	Effective Sample Size	12515	11156	9907	8330	5436	2746	753	203	–	–

ALTRUA 40 DR (downsize)

Model S403

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 40 DR (downsize) Model S403

Worldwide Distribution: 22,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	2	-	2
[75] Seal plug	1	-	
[76] Difficulty securing lead	1	-	
Software	-	-	0
Other	2	-	2
Non-patterned	-	-	
[87] Battery status	2	-	
WW Confirmed Malfunctions	4	0	4

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

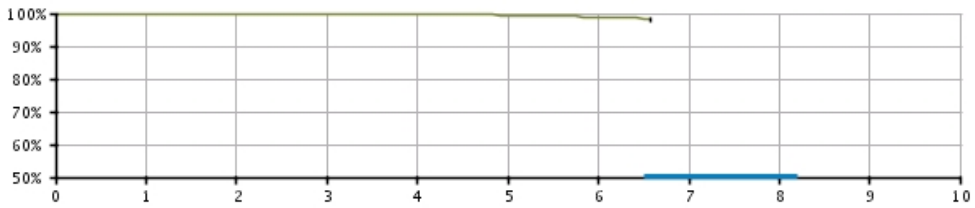
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

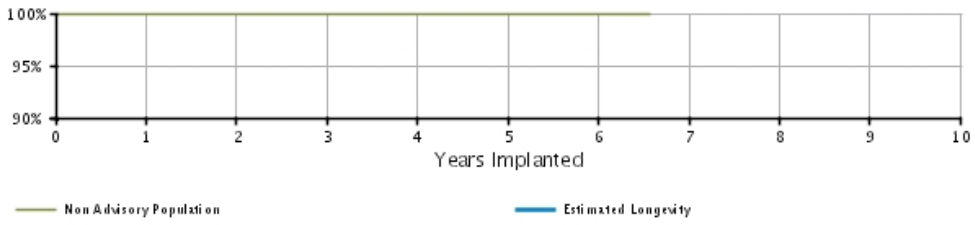
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 25
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.92 (-0.2/+0.1)	99.68 (-0.3/+0.1)	99.32 (-0.4/+0.3)	98.81 (-0.7/+0.4)	98.15 @ 79 mo. (-1.4/+0.8)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 79 mo. (-0.0/+0.0)	–	–	–
	Effective Sample Size	4475	3987	3551	2949	1773	806	234	–	–	–

ALTRUA 40 DR EL

Model S404

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[26] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**1**	**0**	**1**

More details about malfunctions

References cited in table above

ALTRUA 40 SR

Model S401

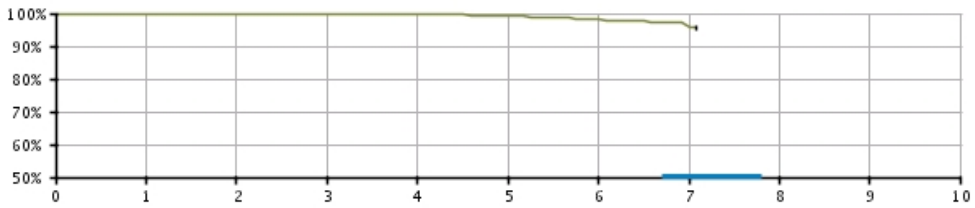
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

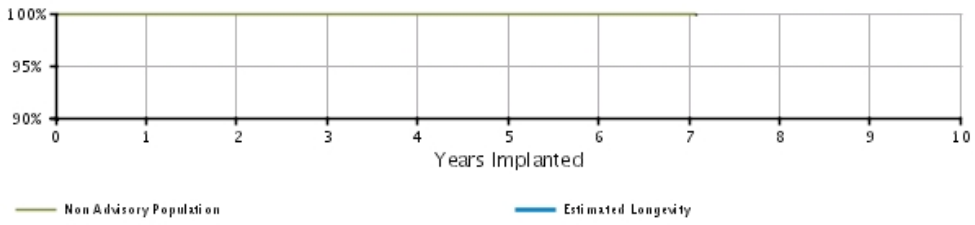
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 45
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:2
Without Compromised Therapy:2
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.91 (-0.2/+0.1)	99.91 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.70 (-0.3/+0.1)	99.30 (-0.4/+0.3)	98.08 (-0.9/+0.6)	95.79 (-2.0/+1.4)	95.79 @ 85 mo. (-2.0/+1.4)	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.98 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 85 mo. (-0.2/+0.0)	–	–
	Effective Sample Size	3960	3472	3050	2536	1650	870	286	234	–	–

ALTRUA 40 SR

Model S401

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 40 SR
Model S401

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**1**	**3**
[26] Capacitor	2	-	
[60] Integrated circuit	-	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR

Models S202/S205

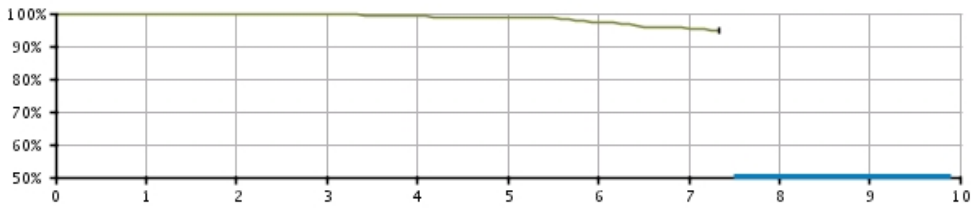
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

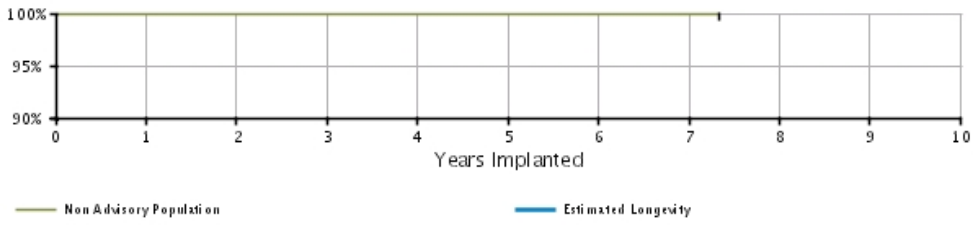
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 36
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:1
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 (-0.4/+0.1)	99.68 (-0.5/+0.2)	99.29 (-0.7/+0.4)	98.64 (-0.9/+0.6)	97.25 (-1.4/+0.9)	95.38 (-1.8/+1.3)	94.77 @ 88 mo. (-2.1/+1.5)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 (-0.6/+0.1)	99.91 @ 88 mo. (-0.6/+0.1)	–	–
	Effective Sample Size	1517	1318	1129	972	818	661	442	220	–	–

ALTRUA 20 DR

Models S202/S205

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 20 DR
Models S202/S205

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	1	-	1
Non-patterned	-	-	
[80] Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

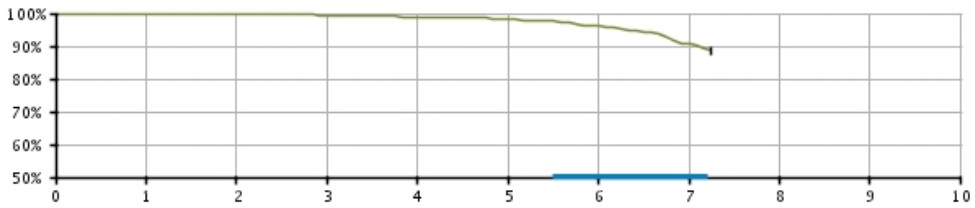
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

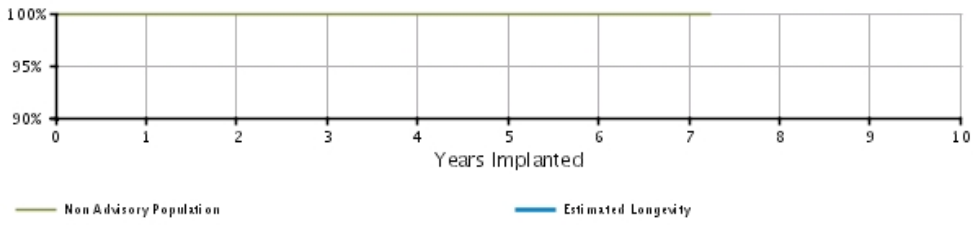
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 131
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.93 (-0.4/+0.3)	98.21 (-0.5/+0.4)	96.02 (-1.0/+0.8)	90.72 (-2.2/+1.8)	88.64 @ 87 mo. (-2.8/+2.3)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 87 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	4415	3906	3471	2925	1976	1091	348	218	–	–

ALTRUA 20 DR (downsize)

Model S203

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 20 DR (downsize) Model S203

Worldwide Distribution: 16,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**-**	**2**
[26] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	-	
[49] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

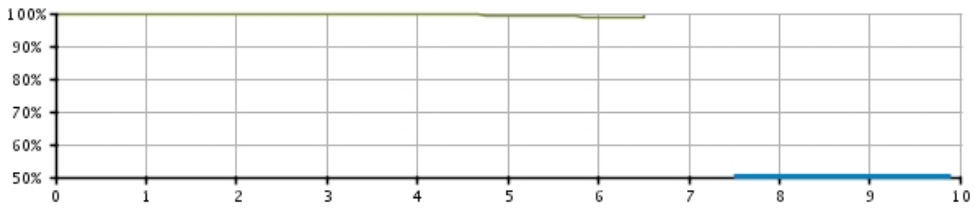
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

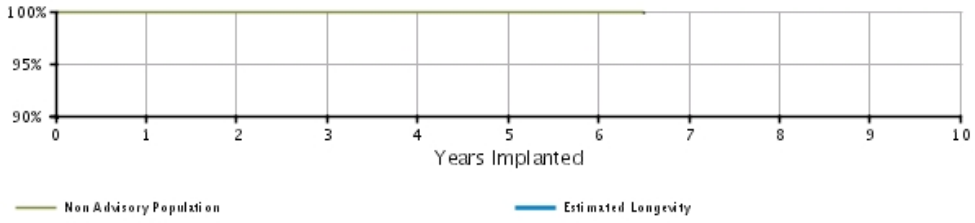
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 14
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.86 (-0.2/+0.1)	99.77 (-0.3/+0.1)	99.62 (-0.4/+0.2)	99.39 (-0.5/+0.3)	98.98 (-0.8/+0.5)	98.98 @ 78 mo. (-0.8/+0.5)	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 78 mo. (-0.2/+0.0)	–	–	–
	Effective Sample Size	2774	2468	2190	1795	1073	459	216	–	–	–

ALTRUA 20 DR EL

Model S208

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

ALTRUA 20 DR EL
Model S208

Worldwide Distribution: 10,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**2**	**2**
[26] Capacitor	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**2**	**2**

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

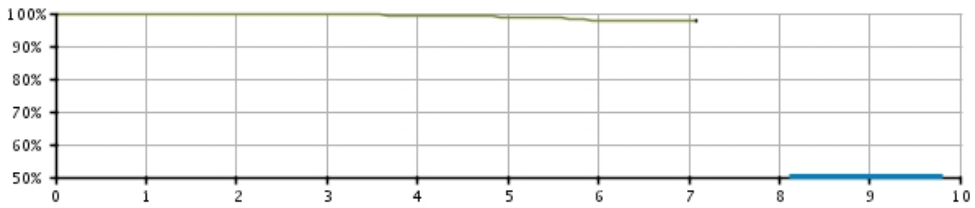
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

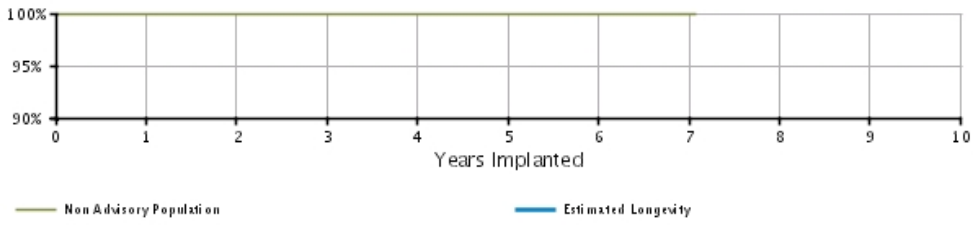
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 35
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.67 (-0.3/+0.2)	99.37 (-0.4/+0.2)	98.83 (-0.6/+0.4)	97.90 (-0.9/+0.6)	97.90 (-0.9/+0.6)	97.90 @ 85 mo. (-0.9/+0.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 85 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	3595	3057	2597	2123	1376	722	256	228	–	–

ALTRUA 20 SR

Models S201/S204

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 20 SR
Models S201/S204

Worldwide Distribution: 24,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[26] Capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	1	
WW Confirmed Malfunctions	**1**	**1**	**2**

More details about malfunctions

References cited in table above

ALTRUA 20 SSI

Model S206

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 20 SSI
Model S206

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

ALTRUA 20 DDD

Model S207

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ALTRUA 20 DDD
Model S207

Worldwide Distribution: 1,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	**0**
Mechanical	-	-	**0**
Software	-	-	**0**
Other	-	-	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**0**	**0**	**0**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR

Model 1291

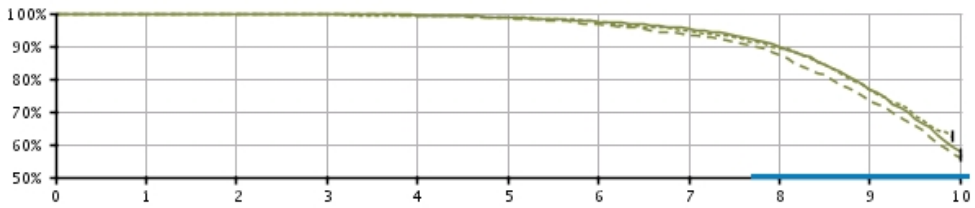
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

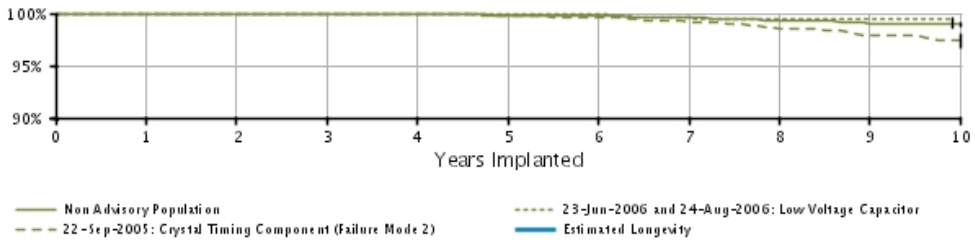
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 3,549
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:164
Without Compromised Therapy:154
With Compromised Therapy:10

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 24000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.50 (-0.1/+0.1)	98.71 (-0.2/+0.2)	97.43 (-0.3/+0.3)	95.30 (-0.4/+0.4)	89.71 (-0.6/+0.6)	76.78 (-1.1/+1.1)	57.62 (-2.3/+2.3)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.73 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.36 (-0.2/+0.1)	99.02 (-0.3/+0.2)	98.91 (-0.3/+0.3)
	Effective Sample Size	21002	18657	16559	14648	12904	11299	9789	6981	2335	459
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.3/+0.1)	99.79 (-0.3/+0.1)	99.59 (-0.5/+0.2)	99.30 (-0.6/+0.3)	98.80 (-0.7/+0.5)	97.47 (-1.1/+0.8)	94.62 (-1.5/+1.2)	89.39 (-2.2/+1.8)	76.98 (-3.1/+2.8)	62.42 @ 119 mo. (-3.7/+3.6)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.95 (-0.3/+0.0)	99.63 (-0.6/+0.2)	99.38 (-0.8/+0.3)	99.38 (-0.8/+0.3)	99.38 @ 119 mo. (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	844	692	521	276
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.35 (-0.3/+0.2)	98.51 (-0.4/+0.3)	96.58 (-0.7/+0.6)	93.41 (-0.9/+0.8)	87.17 (-1.3/+1.2)	73.45 (-1.8/+1.7)	55.60 (-2.1/+2.1)

	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.89 (-0.2/+0.1)	99.78 (-0.2/+0.1)	99.62 (-0.3/+0.2)	99.15 (-0.4/+0.3)	98.58 (-0.5/+0.4)	97.96 (-0.7/+0.5)	97.39 (-0.8/+0.6)
	Effective Sample Size	5703	5046	4468	3939	3451	2978	2553	2094	1553	1006

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR

Model 1291

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Ultra DR Model 1291

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 199

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[9] Low-voltage capacitor (Advisory issued)	-	2	
[22] Capacitor	1	-	
[26] Capacitor	4	2	
[60] Integrated circuit	2	1	
Mechanical	**7**	**5**	**12**
[34] Seal plug	5	4	
[35] Header	1	1	
[62] Setscrew	1	-	
Software	**4**	**-**	**4**
[66] Underestimation of battery status	3	-	
[68] Pacing rate limit	1	-	
Other	**166**	**5**	**171**
Non-patterned	8	4	
[16] Longevity labeling	74	-	
[36] Magnet response	1	-	
[49] Battery depletion	3	1	
[87] Battery status	80	-	
WW Confirmed Malfunctions	**184**	**15**	**199**

More details about malfunctions

References cited in table above

INSIGNIA Ultra DR (downsize)

Model 1290

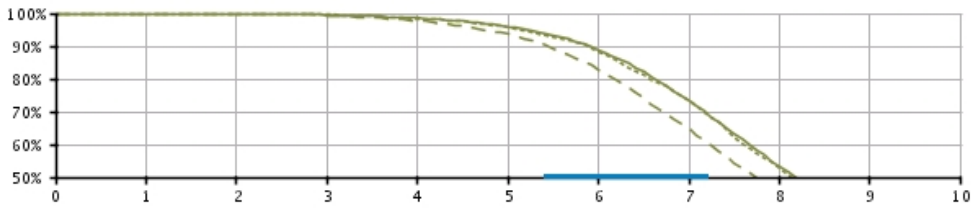
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

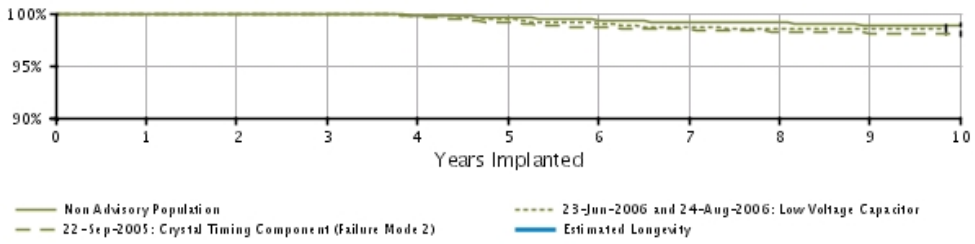
U.S. Registered Implants: 76,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 20,149
U.S. Unconfirmed Reports of Premature Battery Depletion : 115
U.S. Malfunctions:425
Without Compromised Therapy:411
With Compromised Therapy:14

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.86 (-0.0/+0.0)	99.48 (-0.1/+0.1)	98.54 (-0.1/+0.1)	95.94 (-0.2/+0.2)	88.92 (-0.4/+0.4)	73.24 (-0.5/+0.5)	53.34 (-0.7/+0.7)	35.44 (-0.8/+0.8)	20.49 (-1.2/+1.3)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.17 (-0.1/+0.1)	99.07 (-0.1/+0.1)	98.90 (-0.2/+0.2)	98.90 (-0.2/+0.2)
	Effective Sample Size	47638	42289	37443	32971	28507	23424	16880	9297	2443	333
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.88 (-0.2/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.3/+0.2)	98.41 (-0.5/+0.4)	95.67 (-0.8/+0.7)	88.15 (-1.4/+1.2)	73.15 (-1.9/+1.9)	52.82 (-2.3/+2.3)	34.57 (-2.3/+2.4)	24.21 @ 118 mo. (-2.1/+2.3)
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.38 (-0.4/+0.2)	99.06 (-0.5/+0.3)	98.66 (-0.6/+0.4)	98.48 (-0.6/+0.5)	98.48 (-0.6/+0.5)	98.48 @ 118 mo. (-0.6/+0.5)
	Effective Sample Size	4024	3553	3142	2732	2337	1903	1371	849	475	271
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.0/+0.0)	99.87 (-0.1/+0.0)	99.38 (-0.2/+0.1)	97.77 (-0.3/+0.3)	93.65 (-0.5/+0.5)	82.83 (-0.8/+0.8)	64.51 (-1.1/+1.1)	44.52 (-1.2/+1.2)	27.78 (-1.1/+1.2)	18.07 (-1.0/+1.1)

Component (Failure Mode 2)* Registered Implants: 17000	(Confidence Interval)										
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.95 (-0.1/+0.0)	99.73 (-0.1/+0.1)	99.09 (-0.2/+0.2)	98.67 (-0.3/+0.2)	98.45 (-0.3/+0.2)	98.25 (-0.3/+0.3)	98.12 (-0.4/+0.3)	98.12 (-0.4/+0.3)
	Effective Sample Size	14973	13294	11729	10221	8605	6631	4399	2572	1319	710

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR (downsize)

Model 1290

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Ultra DR (downsize) Model 1290

Worldwide Distribution: 124,000
Worldwide Confirmed Malfunctions: 578

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**9**	**18**
[9] Low-voltage capacitor (Advisory issued)	1	5	
[26] Capacitor	7	3	
[60] Integrated circuit	1	1	
Mechanical	**6**	**2**	**8**
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[23] Setscrew thread depth	1	-	
[34] Seal plug	4	1	
[44] Circuit connection	1	-	
Software	**12**	**-**	**12**
[41] Memory error	2	-	
[42] Rate fault declaration	1	-	
[66] Underestimation of battery status	8	-	
[68] Pacing rate limit	1	-	
Other	**529**	**11**	**540**
Non-patterned	23	7	
[16] Longevity labeling	398	-	
[49] Battery depletion	6	4	
[87] Battery status	102	-	
WW Confirmed Malfunctions	**556**	**22**	**578**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

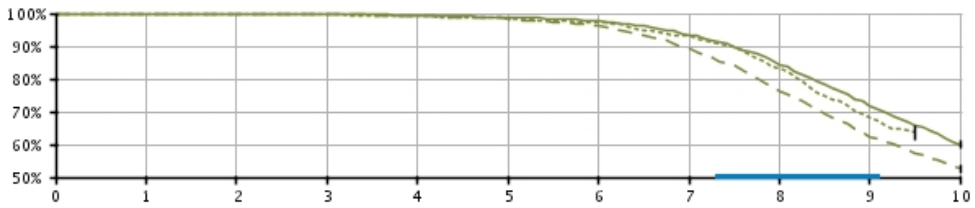
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

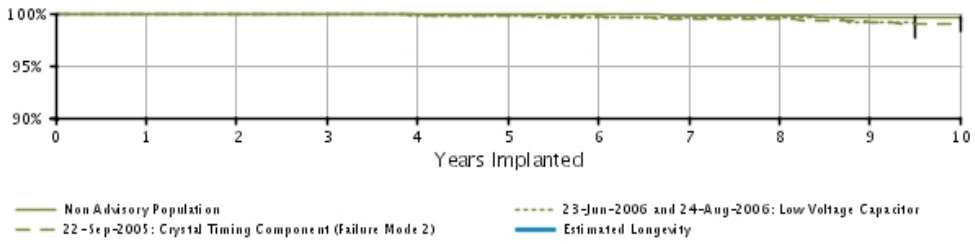
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 2,329
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:40
Without Compromised Therapy:36
With Compromised Therapy:4

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.91 (-0.1/+0.0)	99.71 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.54 (-0.4/+0.3)	93.47 (-0.6/+0.6)	84.44 (-1.0/+0.9)	71.96 (-1.5/+1.4)	59.94 (-2.5/+2.5)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.70 (-0.2/+0.1)	99.66 (-0.2/+0.1)	99.58 (-0.3/+0.2)
	Effective Sample Size	14142	12080	10294	8834	7704	6754	5720	3934	1348	306
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.5/+0.1)	99.73 (-0.6/+0.2)	99.51 (-0.7/+0.3)	99.10 (-0.9/+0.5)	98.46 (-1.2/+0.7)	97.21 (-1.6/+1.0)	93.23 (-2.5/+1.8)	83.13 (-3.7/+3.2)	68.18 (-4.7/+4.4)	63.61 @ 114 mo. (-4.9/+4.7)
	Malfunctions Only(%) (Confidence Interval)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.91 (-0.5/+0.1)	99.77 (-0.7/+0.2)	99.77 (-0.7/+0.2)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.59 (-0.9/+0.3)	99.20 (-1.6/+0.5)	99.20 @ 114 mo. (-1.6/+0.5)
	Effective Sample Size	1147	962	811	698	587	500	418	331	233	200
22-Sep-05 Crystal Timing Component (Failure Mode 1)*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.98 (-0.1/+0.0)	99.93 (-0.1/+0.0)	99.81 (-0.2/+0.1)	99.23 (-0.4/+0.3)	98.27 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.33 (-1.5/+1.3)	76.25 (-2.2/+2.1)	62.44 (-2.6/+2.5)	52.65 (-2.8/+2.7)

Component (Failure Mode 2)* Registered Implants: 5000	(Confidence Interval)										
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.78 (-0.3/+0.1)	99.47 (-0.4/+0.2)	99.40 (-0.5/+0.3)	99.16 (-0.7/+0.4)	99.01 (-0.8/+0.4)
	Effective Sample Size	4142	3555	2998	2526	2109	1766	1415	1030	732	531

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra SR

Model 1190

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Ultra SR Model 1190

Worldwide Distribution: 48,000
Worldwide Confirmed Malfunctions: 67

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[9] Low-voltage capacitor (Advisory issued)	1	3	
[26] Capacitor	1	-	
[60] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[34] Seal plug	3	-	
[35] Header	-	1	
Software	**1**	**-**	**1**
[41] Memory error	1	-	
Other	**55**	**-**	**55**
Non-patterned	1	-	
[16] Longevity labeling	23	-	
[49] Battery depletion	2	-	
[87] Battery status	29	-	
WW Confirmed Malfunctions	**61**	**6**	**67**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

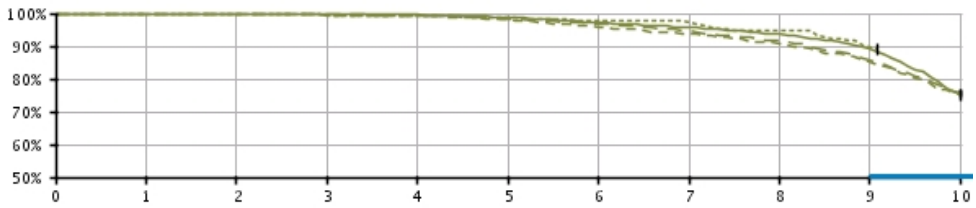
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

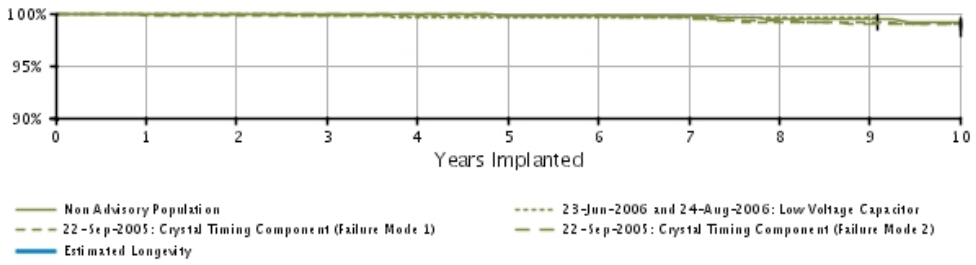
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1,653
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:64
Without Compromised Therapy:57
With Compromised Therapy:7

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.87 (-0.1/+0.1)	99.75 (-0.2/+0.1)	99.51 (-0.2/+0.2)	98.72 (-0.4/+0.3)	97.05 (-0.6/+0.5)	95.69 (-0.7/+0.6)	93.57 (-0.9/+0.8)	89.42 (-1.3/+1.2)	75.65 (-3.0/+2.7)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.46 (-0.3/+0.2)	99.20 (-0.6/+0.3)
	Effective Sample Size	6260	5548	4914	4354	3807	3314	2883	2214	1110	321
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.45 (-1.1/+0.4)	99.23 (-1.3/+0.5)	98.75 (-1.5/+0.7)	97.65 (-2.0/+1.1)	97.31 (-2.2/+1.2)	94.51 (-3.1/+2.0)	89.86 (-4.2/+3.0)	89.41 @ 109 mo. (-4.2/+3.1)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 (-1.2/+0.3)	99.60 @ 109 mo. (-1.2/+0.3)
	Effective Sample Size	692	606	527	450	392	335	292	245	203	201
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.69 (-0.4/+0.2)	99.46 (-0.5/+0.3)	99.19 (-0.7/+0.4)	98.09 (-1.0/+0.7)	95.93 (-1.4/+1.1)	93.69 (-1.8/+1.4)	90.92 (-2.2/+1.8)	85.21 (-2.9/+2.5)	75.07 (-3.7/+3.4)

	Malfunctions Only(%) (Confidence Interval)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.83 (-0.4/+0.1)	99.67 (-0.6/+0.2)	99.19 (-1.0/+0.5)	99.19 (-1.0/+0.5)	98.95 (-1.2/+0.6)
	Effective Sample Size	1676	1454	1213	1063	922	785	662	554	451	335
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.71 (-0.2/+0.1)	99.31 (-0.3/+0.2)	98.40 (-0.4/+0.3)	96.91 (-0.6/+0.5)	94.59 (-0.8/+0.7)	91.55 (-1.0/+0.9)	85.58 (-1.4/+1.3)	75.46 (-1.8/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.83 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.47 (-0.3/+0.2)	99.31 (-0.4/+0.2)	98.97 (-0.5/+0.3)	98.91 (-0.5/+0.3)
	Effective Sample Size	6207	5479	4821	4227	3691	3185	2675	2259	1851	1405

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR

Models 1294/1295

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

INSIGNIA Entra DR Models 1294/1295

Worldwide Distribution: 37,000
Worldwide Confirmed Malfunctions: 79

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[21] Integrated circuit	-	1	
[26] Capacitor	-	1	
[60] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[34] Seal plug	3	-	
[35] Header	-	2	
Software	**-**	**-**	**0**
Other	**62**	**4**	**66**
Non-patterned	4	4	
[16] Longevity labeling	49	-	
[87] Battery status	9	-	
WW Confirmed Malfunctions	**65**	**14**	**79**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

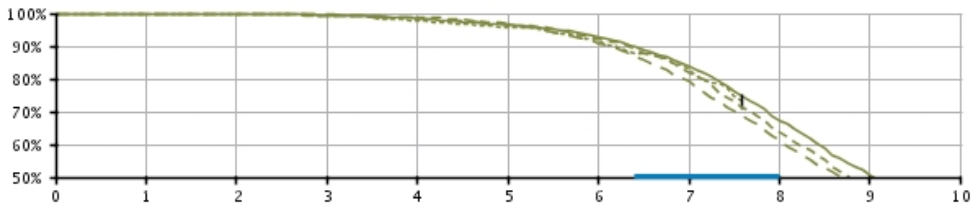
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

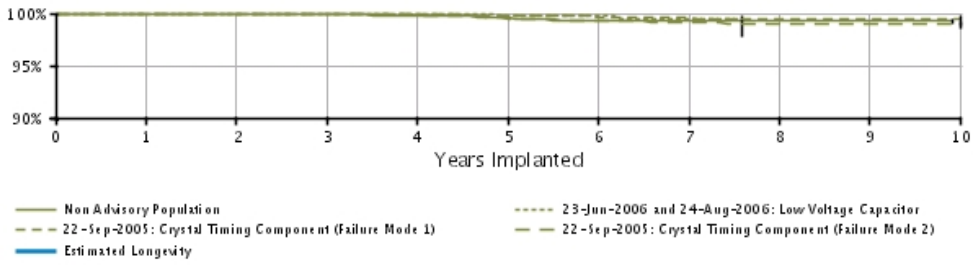
U.S. Registered Implants: 24,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 4,942
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:96
Without Compromised Therapy:90
With Compromised Therapy:6

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 8000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.85 (-0.1/+0.1)	99.43 (-0.2/+0.2)	98.41 (-0.4/+0.3)	96.58 (-0.5/+0.5)	92.99 (-0.8/+0.7)	83.74 (-1.2/+1.1)	67.49 (-1.6/+1.6)	50.72 (-2.1/+2.1)	39.33 @ 119 mo. (-2.6/+2.7)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.99 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.57 (-0.2/+0.2)	99.37 (-0.3/+0.2)	99.31 (-0.3/+0.2)	99.23 (-0.3/+0.2)	99.23 (-0.3/+0.2)	99.23 @ 119 mo. (-0.3/+0.2)
	Effective Sample Size	7138	6278	5494	4776	4109	3506	2763	1728	683	201
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.70 (-0.9/+0.2)	99.20 (-1.1/+0.5)	97.84 (-1.6/+0.9)	95.61 (-2.2/+1.5)	91.90 (-3.0/+2.2)	82.98 (-4.2/+3.5)	73.13 @ 91 mo. (-5.1/+4.6)	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.75 (-1.5/+0.2)	99.75 (-1.5/+0.2)	99.43 (-1.7/+0.4)	99.43 @ 91 mo. (-1.7/+0.4)	–	–
	Effective Sample Size	763	657	563	476	402	329	250	202	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants:	Depletions and Malfunctions(%) (Confidence Interval)	99.83 (-0.2/+0.1)	99.79 (-0.3/+0.1)	99.34 (-0.4/+0.3)	98.82 (-0.6/+0.4)	96.71 (-0.9/+0.7)	92.03 (-1.5/+1.3)	81.78 (-2.2/+2.0)	63.95 (-2.9/+2.8)	45.71 (-3.2/+3.2)	31.88 (-3.1/+3.3)

3000											
	Malfunctions Only(%) (Confidence Interval)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.90 (-0.2/+0.1)	99.84 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.59 (-0.5/+0.2)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)	99.48 (-0.6/+0.3)
	Effective Sample Size	2736	2405	2071	1813	1515	1227	933	597	359	204
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.86 (-0.1/+0.1)	99.56 (-0.2/+0.1)	98.52 (-0.3/+0.3)	96.46 (-0.5/+0.4)	90.84 (-0.8/+0.7)	79.01 (-1.2/+1.1)	61.17 (-1.5/+1.5)	44.84 (-1.6/+1.6)	35.81 (-1.6/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.52 (-0.2/+0.1)	99.26 (-0.3/+0.2)	99.14 (-0.3/+0.2)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)	98.91 (-0.4/+0.3)
	Effective Sample Size	9583	8451	7364	6364	5502	4508	3329	2159	1318	899

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR (downsize)

Model 1296

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Entra DR (downsize) Model 1296

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 119

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[9] Low-voltage capacitor (Advisory issued)	-	1	
[26] Capacitor	1	-	
[60] Integrated circuit	-	3	
Mechanical	**-**	**3**	**3**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
[17] Solder bond	-	1	
Software	**4**	**-**	**4**
[33] Memory error	1	-	
[66] Underestimation of battery status	1	-	
[67] Interrupted telemetry	2	-	
Other	**105**	**2**	**107**
Non-patterned	5	2	
[16] Longevity labeling	95	-	
[49] Battery depletion	1	-	
[87] Battery status	4	-	
WW Confirmed Malfunctions	**110**	**9**	**119**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

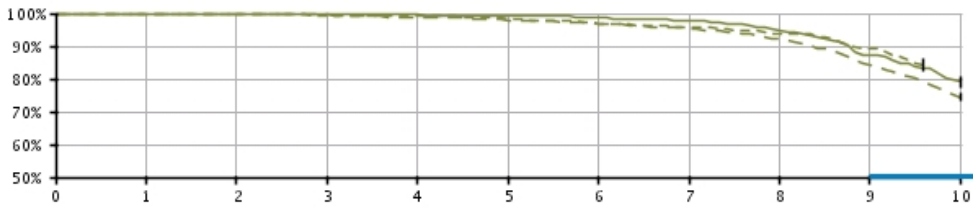
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

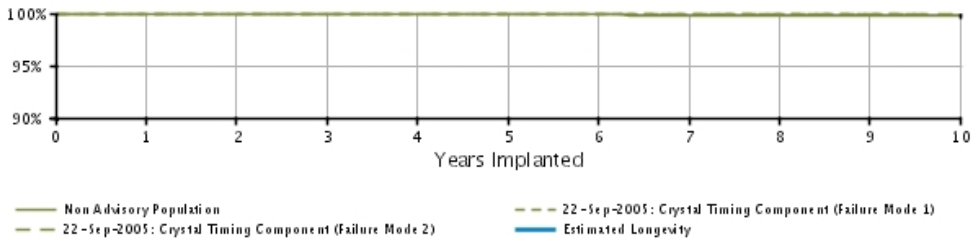
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 860
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:9
Without Compromised Therapy:7
With Compromised Therapy:2

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.1)	99.85 (-0.2/+0.1)	99.77 (-0.2/+0.1)	99.52 (-0.3/+0.2)	99.36 (-0.4/+0.2)	98.74 (-0.5/+0.4)	97.89 (-0.7/+0.5)	94.79 (-1.2/+1.0)	87.35 (-2.1/+1.9)	79.17 (-3.6/+3.2)
	Malfunctions Only(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.91 (-0.1/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)	99.81 (-0.3/+0.1)
	Effective Sample Size	4707	3871	3248	2734	2308	1982	1713	1245	598	203
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.84 (-0.5/+0.1)	99.50 (-0.7/+0.3)	99.20 (-0.9/+0.4)	98.19 (-1.3/+0.8)	96.95 (-1.8/+1.1)	95.72 (-2.1/+1.4)	93.94 (-2.6/+1.9)	89.43 (-3.6/+2.8)	84.33 @ 115 mo. (-4.5/+3.6)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 115 mo. (-0.0/+0.0)
	Effective Sample Size	1215	998	806	661	549	446	355	297	244	203
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.96 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.58 (-0.3/+0.2)	98.79 (-0.4/+0.3)	97.94 (-0.6/+0.5)	96.94 (-0.8/+0.6)	95.25 (-1.0/+0.8)	92.16 (-1.3/+1.2)	84.04 (-2.0/+1.8)	74.36 (-2.5/+2.3)

Component (Failure Mode 2)* Registered Implants: 6000	(Confidence Interval)										
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.2/+0.0)	99.96 (-0.2/+0.0)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)
	Effective Sample Size	4576	3825	3172	2632	2175	1819	1530	1276	1012	780

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra SR

Models 1195/1198

INSIGNIA Entra SR Models 1195/1198

Worldwide Distribution: 52,000
Worldwide Confirmed Malfunctions: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[9] Low-voltage capacitor (Advisory issued)	-	2	
[26] Capacitor	2	2	
[60] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[29] Capacitor array	-	2	
[34] Seal plug	-	2	
[64] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**12**	**1**	**13**
Non-patterned	1	1	
[16] Longevity labeling	6	-	
[87] Battery status	5	-	
WW Confirmed Malfunctions	**16**	**11**	**27**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

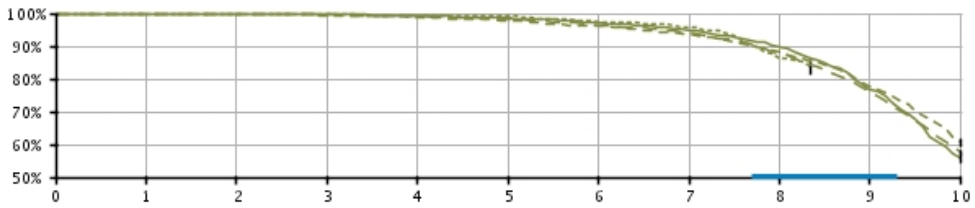
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

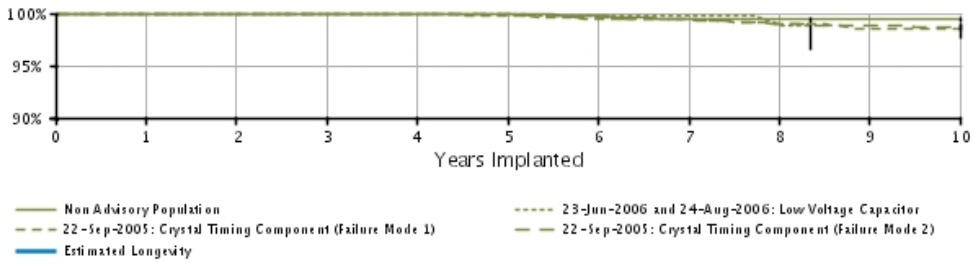
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 4,862
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:127
Without Compromised Therapy:118
With Compromised Therapy:9

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 7000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.75 (-0.2/+0.1)	99.26 (-0.3/+0.2)	98.51 (-0.4/+0.3)	97.16 (-0.6/+0.5)	94.98 (-0.7/+0.7)	89.78 (-1.1/+1.0)	76.76 (-1.9/+1.8)	55.81 (-3.3/+3.2)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.73 (-0.2/+0.1)	99.49 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)	99.38 (-0.3/+0.2)
	Effective Sample Size	6561	5832	5161	4547	3998	3497	3025	2260	945	287
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 1000	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.19 (-1.3/+0.5)	99.19 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.95 (-2.6/+1.6)	86.24 (-4.5/+3.5)	83.77 @ 100 mo. (-4.8/+3.9)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.73 (-1.6/+0.2)	99.73 (-1.6/+0.2)	98.86 (-2.4/+0.8)	98.86 @ 100 mo. (-2.4/+0.8)	–
	Effective Sample Size	664	580	510	442	386	333	285	222	203	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.89 (-0.5/+0.3)	97.87 (-0.7/+0.5)	96.19 (-0.9/+0.7)	93.52 (-1.2/+1.0)	88.09 (-1.7/+1.5)	77.80 (-2.2/+2.1)	60.58 (-2.8/+2.7)

	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.90 (-0.2/+0.1)	99.81 (-0.3/+0.1)	99.48 (-0.4/+0.2)	99.42 (-0.5/+0.3)	99.04 (-0.6/+0.4)	98.57 (-0.8/+0.5)	98.45 (-0.8/+0.5)
	Effective Sample Size	3514	3072	2597	2280	1971	1704	1456	1208	928	612
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.89 (-0.1/+0.0)	99.55 (-0.1/+0.1)	99.10 (-0.2/+0.2)	98.16 (-0.3/+0.3)	96.48 (-0.4/+0.4)	94.04 (-0.6/+0.5)	87.78 (-0.8/+0.8)	76.07 (-1.2/+1.1)	57.64 (-1.4/+1.4)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.88 (-0.1/+0.1)	99.58 (-0.2/+0.1)	99.38 (-0.2/+0.2)	99.05 (-0.3/+0.2)	98.80 (-0.3/+0.3)	98.70 (-0.3/+0.3)
	Effective Sample Size	12755	11251	9911	8722	7618	6594	5628	4611	3472	2255

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus DR

Model 1297

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Plus DR Model 1297

Worldwide Distribution: 47,000
Worldwide Confirmed Malfunctions: 160

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[9] Low-voltage capacitor (Advisory issued)	1	1	
[26] Capacitor	2	1	
[60] Integrated circuit	-	1	
Mechanical	**16**	**8**	**24**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[17] Solder bond	1	-	
[29] Capacitor array	1	-	
[34] Seal plug	5	-	
[35] Header	8	5	
Software	**7**	**-**	**7**
[66] Underestimation of battery status	4	-	
[67] Interrupted telemetry	2	-	
[68] Pacing rate limit	1	-	
Other	**119**	**4**	**123**
Non-patterned	7	4	
[16] Longevity labeling	88	-	
[49] Battery depletion	2	-	
[87] Battery status	22	-	
WW Confirmed Malfunctions	**145**	**15**	**160**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR (downsize)

Model 1298

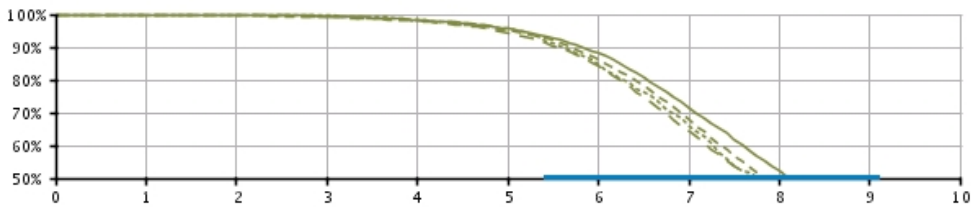
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

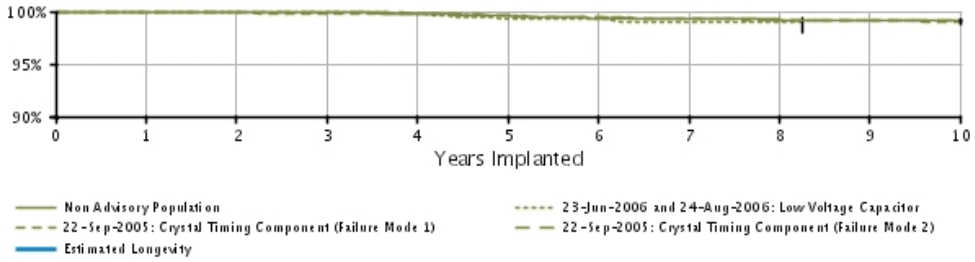
U.S. Registered Implants: 90,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 26,789
U.S. Unconfirmed Reports of Premature Battery Depletion : 114
U.S. Malfunctions:371

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 19000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.41 (-0.1/+0.1)	98.27 (-0.2/+0.2)	95.60 (-0.4/+0.4)	88.23 (-0.6/+0.6)	71.49 (-0.9/+0.9)	52.08 (-1.1/+1.1)	34.52 (-1.3/+1.3)	21.15 (-1.6/+1.7)
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.90 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.35 (-0.2/+0.1)	99.26 (-0.2/+0.1)	99.17 (-0.2/+0.2)	99.07 (-0.3/+0.2)	99.07 (-0.3/+0.2)
	Effective Sample Size	16866	14982	13240	11652	10060	8186	5790	3261	1042	231
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 2000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.4/+0.1)	99.86 (-0.4/+0.1)	99.77 (-0.5/+0.2)	98.12 (-1.0/+0.7)	95.80 (-1.5/+1.1)	84.84 (-2.6/+2.3)	65.83 (-3.5/+3.4)	45.28 (-3.8/+3.9)	38.68 @ 99 mo. (-3.8/+4.0)	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.70 (-0.6/+0.2)	99.37 (-0.8/+0.3)	99.25 (-0.8/+0.4)	98.91 (-1.0/+0.5)	98.91 (-1.0/+0.5)	98.91 @ 99 mo. (-1.0/+0.5)	–
	Effective Sample Size	1419	1249	1111	963	824	640	432	250	202	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 16000	Depletions and Malfunctions(%) (Confidence Interval)	99.90 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.13 (-0.2/+0.2)	98.03 (-0.3/+0.2)	95.05 (-0.5/+0.4)	86.19 (-0.8/+0.7)	67.65 (-1.1/+1.1)	46.92 (-1.3/+1.3)	31.72 (-1.3/+1.3)	21.70 (-1.2/+1.3)
	Malfunctions Only(%) (Confidence Interval)	99.93 (-0.1/+0.0)	99.88 (-0.1/+0.0)	99.81 (-0.1/+0.1)	99.79 (-0.1/+0.1)	99.57 (-0.2/+0.1)	99.38 (-0.2/+0.1)	99.32 (-0.2/+0.2)	99.19 (-0.2/+0.2)	99.13 (-0.3/+0.2)	99.02 (-0.4/+0.3)

	Effective Sample Size	13681	12071	10372	9051	7723	6109	4087	2332	1283	717
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 54000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.0/+0.0)	99.80 (-0.0/+0.0)	99.26 (-0.1/+0.1)	97.91 (-0.2/+0.1)	94.47 (-0.3/+0.2)	84.12 (-0.4/+0.4)	64.17 (-0.6/+0.6)	44.06 (-0.7/+0.7)	29.71 (-0.7/+0.7)	20.55 (-0.6/+0.6)
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.83 (-0.0/+0.0)	99.61 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.30 (-0.1/+0.1)	99.22 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.14 (-0.1/+0.1)
	Effective Sample Size	47024	41684	36742	32064	27279	21092	13644	7726	4282	2442

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus DR (downsize)

Model 1298

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA Plus DR (downsize) Model 1298

Worldwide Distribution: 140,000
Worldwide Confirmed Malfunctions: 447

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**11**	**10**	**21**
[9] Low-voltage capacitor (Advisory issued)	-	3	
[22] Capacitor	-	1	
[26] Capacitor	6	2	
[30] Integrated circuit	-	1	
[60] Integrated circuit	5	3	
Mechanical	**21**	**22**	**43**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	5	20	
[12] Crystal timing component Failure Mode 2 (Advisory issued)	3	-	
[17] Solder bond	1	-	
[29] Capacitor array	3	1	
[34] Seal plug	3	1	
[35] Header	5	-	
[64] Seal plug	1	-	
Software	**11**	**-**	**11**
[41] Memory error	1	-	
[65] Interrogation at EOL	2	-	
[66] Underestimation of battery status	6	-	
[67] Interrupted telemetry	1	-	
[68] Pacing rate limit	1	-	
Other	**361**	**11**	**372**
Non-patterned	28	9	
[16] Longevity labeling	310	-	
[32] Battery depletion	2	1	
[36] Magnet response	1	-	
[49] Battery depletion	11	1	
[87] Battery status	9	-	
WW Confirmed Malfunctions	**404**	**43**	**447**

More details about malfunctions

References cited in table above

INSIGNIA Plus SR

Model 1194

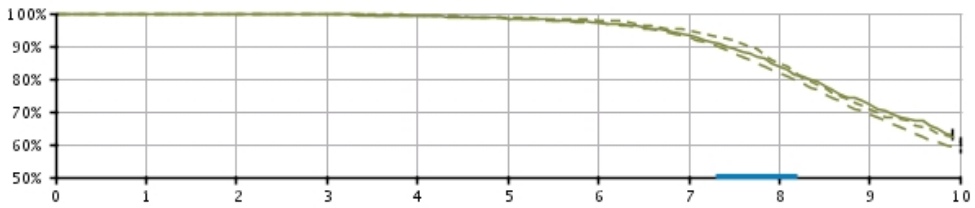
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

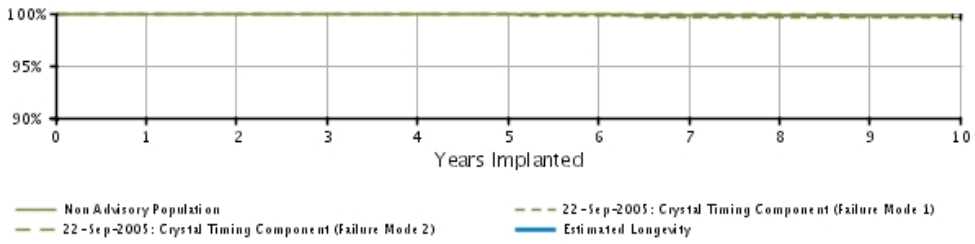
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 3,314
U.S. Unconfirmed Reports of Premature Battery Depletion : 8
U.S. Malfunctions:27
Without Compromised Therapy:19
With Compromised Therapy:8

Battery Depletions and Malfunctions



Malfunctions Only



U.S. Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.90 (-0.1/+0.1)	99.59 (-0.3/+0.2)	99.31 (-0.3/+0.2)	98.45 (-0.5/+0.4)	97.27 (-0.7/+0.6)	93.25 (-1.1/+1.0)	83.67 (-1.8/+1.6)	72.06 (-2.5/+2.4)	62.89 @ 119 mo. (-3.4/+3.3)
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 (-0.2/+0.0)	99.89 (-0.2/+0.1)	99.85 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 (-0.3/+0.1)	99.75 @ 119 mo. (-0.3/+0.1)
	Effective Sample Size	4724	4029	3446	2882	2467	2125	1786	1243	543	213
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor*	Survival probability data not provided because this population does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Product Advisories for more information.										
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 4000	Depletions and Malfunctions(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.89 (-0.2/+0.1)	99.73 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.74 (-0.6/+0.4)	98.00 (-0.7/+0.5)	94.84 (-1.2/+1.0)	84.82 (-2.2/+1.9)	70.89 (-2.9/+2.7)	60.69 (-3.2/+3.1)
	Malfunctions Only(%) (Confidence Interval)	99.92 (-0.2/+0.1)	99.92 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.88 (-0.2/+0.1)	99.76 (-0.3/+0.1)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)	99.68 (-0.4/+0.2)
	Effective Sample Size	3452	2916	2417	2064	1738	1432	1166	871	615	453
22-Sep-05 Crystal Timing	Depletions and Malfunctions(%)	99.94 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.24 (-0.2/+0.2)	98.49 (-0.3/+0.2)	97.08 (-0.4/+0.4)	92.84 (-0.7/+0.6)	81.75 (-1.1/+1.0)	69.45 (-1.4/+1.3)	58.11 (-1.5/+1.5)

Component (Failure Mode 2)* Registered Implants: 17000	(Confidence Interval)										
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.99 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.94 (-0.1/+0.0)	99.91 (-0.1/+0.0)	99.89 (-0.1/+0.1)	99.89 (-0.1/+0.1)	99.82 (-0.2/+0.1)	99.82 (-0.2/+0.1)
	Effective Sample Size	13682	11685	10054	8508	7144	6002	4891	3613	2594	1877

*Devices subject to an advisory. Refer to the Advisories for more details. Devices may be part of more than one advisory.

Data are representative of Boston Scientific INSIGNIA Plus and Intermedics NEXUS Plus device performance.

INSIGNIA Plus SR

Model 1194

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

INSIGNIA Plus SR Model 1194

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 36

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[9] Low-voltage capacitor (Advisory issued)	1	2	
[26] Capacitor	2	2	
[30] Integrated circuit	-	1	
[60] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[11] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[29] Capacitor array	1	-	
[34] Seal plug	-	1	
Software	**1**	**-**	**1**
[68] Pacing rate limit	1	-	
Other	**18**	**1**	**19**
Non-patterned	4	-	
[16] Longevity labeling	10	-	
[32] Battery depletion	-	1	
[49] Battery depletion	1	-	
[87] Battery status	3	-	
WW Confirmed Malfunctions	**24**	**12**	**36**

More details about malfunctions

References cited in table above

INSIGNIA AVT

Models 0482/0882/0982/1192/1292

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INSIGNIA AVT
Models 0482/0882/0982/1192/1292

Worldwide Distribution: 51,000
Worldwide Confirmed Malfunctions: 95

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[9] Low-voltage capacitor (Advisory issued)	-	3	
[26] Capacitor	-	1	
[60] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[34] Seal plug	1	-	
[35] Header	1	-	
Software	**-**	**-**	**0**
Other	**86**	**2**	**88**
Non-patterned	3	1	
[16] Longevity labeling	42	-	
[49] Battery depletion	-	1	
[87] Battery status	41	-	
WW Confirmed Malfunctions	**88**	**7**	**95**

More details about malfunctions

References cited in table above

References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each pulse generator confirmed malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

1. **Low Voltage Capacitor 2014**— *Aug 2013 and Sep 2014 Voluntary Physician Advisory.* Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
2. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory.* Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
3. **High cathode condition 2011**— *June 1, 2011 Voluntary Physician Advisory.* Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **Magnetic reed switch 2010**— *July 21, 2010 Voluntary Physician Advisory.* Upon magnet removal, magnetic reed switch remains closed and device tones do not cease. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON.
5. **Subpectoral implant 2009**— *December 01, 2009 Voluntary Physician Advisory.* Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subpectorally. Weakened bond between header and titanium case. Improvement implemented.
6. **Respiratory Sensor Oversensing**— *March 23, 2009 Voluntary Physician Advisory.* Oversensing, noise, inappropriate shock, pacing inhibition. When Respiratory Sensor is ON, RV lead or system complications may cause oversensing or noise. Improvement implemented.
7. **Subpectoral implant**— *May 12, 2006 and January 04, 2008 Voluntary Physician Advisory.* Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications, loss of pacing (intermittent or permanent) and/or loss of shock therapy. Repetitive mechanical stress-induced component damage, only when implanted subpectorally with the serial number facing the ribs. Improvement implemented.
8. **Shortened replacement window**— *April 05, 2007 and March 04, 2009 Voluntary Physician Advisory.* Accelerated battery depletion may reduce time between elective replacement (ERI) and end of life (EOL) indicators to less than three months. Device replacement indicators continue to function normally. Degradation of low-voltage capacitor. Improvement implemented.
9. **Low-voltage capacitor**— *June 23, 2006 and August 24, 2006 Voluntary Physician Advisory.* Premature battery depletion, no output, no interrogation. Failed low-voltage capacitor. Improvement implemented.
10. **Premature battery depletion**— *May 12, 2006 Voluntary Physician Advisory.* Premature battery depletion, significantly shortened longevity and duration between elective replacement (ERI) and end of life (EOL) indicators. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
11. **Crystal timing component Failure Mode 1**— *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.
12. **Crystal timing component Failure Mode 2**— *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a crystal timing component. Three failures have been reported following confirmation of successful implantation. No currently distributed devices are subject to this peri-implant failure mode. Improvement implemented.
13. **Magnetic switch**— *June 23, 2005 Voluntary Physician Advisory.* Inhibition of tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. Magnetic switch stuck in closed position. Improvement implemented.
14. **Hermetic sealing component Original Population**— Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.
15. **Extended charge time post-mid-life**— Extended charge time post-mid-life resulting in decreased longevity, shortened ERI to EOL or no time stamp, due to increased battery impedance. Improvement implemented.
16. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
17. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate.

Improvement implemented.

18. **Longevity Remaining error**— When near ERT, Longevity Remaining Estimate is incorrect when amplitude is reprogrammed to a higher value. Gas gauge display is not affected.
19. **Parameter errors**— During RF interrogation, parameter errors occur, requiring manual parameter correction. Corruption in telemetry logic. Improvement implemented.
20. **Firmware error**— Device beeping unaffected by magnet application, missing EGMs, loss of telemetry, loss of tachy therapy. Multiple resets due to firmware error. Improvement implemented.
21. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
22. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
23. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
24. **Reconfirmation after charge**— Tachy therapy delayed. Redetection and therapy occur after lack of reconfirmation after initial charge. Timing conflict involving specific features. Improvement implemented.
25. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.
26. **Capacitor**— No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.
27. **Feedthrough wires**— High impedance and/or loss of pacing therapy. Broken wire connecting header to internal circuitry. Improvement implemented.
28. **Battery depletion**— Premature battery depletion.
29. **Capacitor array**— Loss of device output, loss of capture, inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.
30. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
31. **Impedance measurements**— High impedance value (generally >3000 ohms) recorded and displayed as weekly average impedance. Low daily impedance recordings cause error in calculating weekly average impedance due to memory storage limitations. Device fully capable of therapy delivery as programmed. Improvement implemented.
32. **Battery depletion**— Premature battery depletion and loss of capture.
33. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
34. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
35. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
36. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
37. **Overestimation of battery status**— Improvement in battery status between follow-up visits and/or overestimation of remaining longevity. Very specific conditions involving the use of an atrial tachycardia response feature. Software upgrade distributed late November 2003 eliminated the possibility of battery status overestimation. Improvement implemented.
38. **Telemetry or atrial noise**— Noise during telemetry and/or atrial sensing. Inappropriate contact between telemetry coil and device case. Improvement implemented.
39. **Battery depletion**— Premature battery depletion.
40. **Reset during charge**— Power on reset state during therapeutic shock charging attempt due to firmware issue. Improvement implemented.
41. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
42. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
43. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
44. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
45. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
46. **Capacitor**— Premature battery depletion, significantly shortened ERI to EOL time. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor. Improvement implemented.
47. **Device tones**— Inappropriately sustained device tone. Magnet removal or initialization of programming event during specific timing window. Device fully capable of therapy delivery as programmed. Improvement implemented.
48. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
49. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
50. **Internal device connection**— Intermittent or no telemetry. Telemetry coil connection. Improvement implemented.
51. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
52. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.

53. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.

54. **Memory location**— Loss of pacing and/or shock therapy, premature battery depletion, inability to perform diagnostic testing, loss of telemetry, and/or incorrect diagnostic information. Incorrect data within a specific memory location.

55. **Mid-life display of replacement indicators**— Extended charge time resulting in early occurrence of ERI or EOL, or shortened ERI to EOL time. Please reference the ERI Charge Time Limit Extended During Mid-Life Product Update for more details. Improvement implemented.

56. **High-voltage capacitor**— In most cases, temporary long capform charge time; in some cases delayed therapy or loss of tachy therapy. Extended charge time could prompt EOL declaration. High-voltage capacitor issue.

57. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.

58. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.

59. **Software download**— Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available. Improvement implemented.

60. **Integrated circuit**— Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing, loss of shock therapy. Damage to integrated circuit. Improvement implemented.

61. **Alert messages**— During programmer interactions, alert messages appear which are able to be cleared. In one case, an alert message occurred with two memory errors after multiple device resets.

62. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.

63. **Charge time limit**— Early appearance of elective replacement indicator (ERI). Incorrect extended charge time limit. Improvement implemented.

64. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented

65. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.

66. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.

67. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.

68. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.

69. **Logic errors**— Unable to complete diagnostic, cap reform or daily shock lead measurement processes; loss of pacing output, loss of shock therapy. Logic errors when device is performing capacitor reforms or shock impedance measurements.

70. **Reed switch**— While implanted, continuous device tone or beeping occurs. During interrogation, magnet presence dialog box appears. Tachy therapy unavailable if the Enable Magnet Use feature is programmed ON. Reed switch stuck in closed position. Improvement implemented.

71. **Cracked solder joint**— Safety mode operation, beeping tones. Cracked solder joint.

72. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.

73. **Connector block**— Connector block can be moved out of alignment or displaced from header. Prolonged implant procedure, high impedance, no pacing, no sensing. Improvement implemented.

74. **Misaligned markers**— Stored episode markers do not match recorded EGM. Software error when ventricular episode begins during ATR episode. New software was released in 2006 which prevents misaligned markers. Improvement implemented.

75. **Seal plug**— Non-cardiac signals on electrograms may result in loss of pacing or inappropriate shocks. Seal plug allows air in lead port to escape.

76. **Difficulty securing lead**— Noise, high impedance, inappropriate shocks or loss of therapy due to crossthreaded setscrews, intermittent or lack of contact between lead and header. Improvement implemented.

77. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.

78. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.

79. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.

80. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.

81. **Battery status**— Battery status readings below BOL at or soon after implant caused by exposure to below room temperatures before implant. Actual battery status and longevity are not affected. Improvement implemented.

82. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.

83. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.

84. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.

85. **Bent flex circuit**— Charge time-out and/or EOL declaration, due to bent flex circuit. Improvement implemented.

86. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.

87. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.

88. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated

circuit issue. Improvement implemented.

89. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
90. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
91. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
92. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
93. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
94. **Telemetry**— Inability to interrogate, premature battery depletion.
95. **Unintended Battery Depletion Alert**— Beeping tones, Battery Depletion alert during followup despite normal battery depletion. Alert may be cleared without impact to battery status or therapy availability. Improvement implemented.
96. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
97. **Respiratory sensor**— Temporary increase or decrease in pacing rate as a result of respiratory sensor response to non-respiratory signals. No loss of pacing output.
98. **Titanium case material**— Noise, oversensing, abnormal pacing impedance, loss of capture, premature battery depletion. Titanium case material creating a higher than normal current drain condition. Improvement implemented.
99. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
100. **High voltage circuit component**— Charge time alert message and/or end of life (EOL) indicator displayed, beeping tones. High voltage circuit component.
101. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor
102. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement Implemented.

Before/During Implant Procedure - Worldwide Malfunctions: Pulse Generators

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling (e.g. radiation) is not reported as device malfunction here.
The Electrical category is comprised of confirmed malfunctions involving electrical components such as batteries and capacitors, and also includes fault codes encountered at implant. The majority of before/during implant pulse generator confirmed malfunctions in the Mechanical category are issues occurring within the connector block (e.g. stuck setscrews, seal plug/ring issues). The Software category consists primarily of confirmed malfunctions that result in telemetry issues. Confirmed malfunctions in the Labeling and Packaging categories include product labeling/identification issues and damage to sterile packaging, respectively. The Other category is comprised of non-patterned confirmed malfunctions.

CRT-D/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN CRT-D G160/G161/G164/G166/G172/G173/G175/ G177/G179	12,000	2	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	28,000	2	1	0	5	0	0
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/ N143/N160/N161/N162/N163/N164/N165/ P052/P053/P142/P143/P162/P163/P165	80,000	10	0	0	10	0	0
COGNIS N118/N119/N120/P106/P107/P108	109,000	24	50	4	26	0	0
CONTAK RENEWAL 4 H190/H195	18,000	1	13	1	2	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE V172/V173/V182/V183/W172/W173	8,000	0	0	0	0	0	0
INTUA V272/V273/V282/V283/W272/W273	2,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	17,000	0	0	1	2	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	8	0	2	0	0
CONTAK RENEWAL TR H120/H125	19,000	0	11	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
AUTOGEN ICD EL VR D160/D161/D174/D175	6,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	5,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	12,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	11,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	8,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	7,000	1	0	0	2	0	0

ICD/Model, continued…	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	67,000	3	1	0	9	0	0
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	71,000	5	1	0	4	0	0
TELIGEN VR E102/E103/F102/F103	66,000	8	32	2	18	0	0
TELIGEN DR E110/E111/F110/F111	91,000	6	42	1	24	0	0
CONFIENT DR E030/F030	8,000	1	3	0	0	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209	8,000	0	0	0	10	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	23	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	21,000	0	0	0	1	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	50,000	0	0	0	3	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	17,000	0	0	0	2	0	0
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	64,000	1	1	0	3	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	210,000	4	2	1	13	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	79,000	0	0	1	3	0	0
INGENIO VDD J178/J179/K188	2,000	0	0	0	21	0	0
ALTRUA 60 SR S601	68,000	1	6	0	2	0	0
ALTRUA 60 DR EL S606	90,000	0	8	0	2	0	0
ALTRUA 60 DR (Downsize) S603	132,000	1	22	0	4	0	0
ALTRUA 60 DR S602	56,000	1	11	0	2	0	0
ALTRUA 50 SR S501	24,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	46,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	11,000	1	1	0	0	0	0
ALTRUA 50 VDD (Downsize) S504	6,000	0	0	0	0	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ALTRUA 50 SSI S508	6,000	0	0	0	1	0	0
ALTRUA 40 SR S401	9,000	0	2	0	0	0	0
ALTRUA 40 DR (Downsize) S403	22,000	0	4	0	2	0	0
ALTRUA 40 DR S402	3,000	1	3	0	0	0	0
ALTRUA 40 DR EL S404	10,000	0	0	0	0	0	0
ALTRUA 20 SR S201/S204	24,000	0	2	0	0	0	0
ALTRUA 20 DR (Downsize) S203	16,000	0	1	0	0	0	0
ALTRUA 20 DR S202/S205	3,000	1	0	0	1	0	0
ALTRUA 20 DR EL S208	10,000	0	0	0	0	0	0
ALTRUA 20 DDD S207	1,000	0	0	0	0	0	0
ALTRUA 20 SSI S206	8,000	0	0	0	0	0	0
INSIGNIA Ultra SR 1190*	48,000	3	3	1	4	0	0
INSIGNIA Ultra DR (Downsize) 1290*	124,000	3	3	1	6	0	0
INSIGNIA Ultra DR 1291*	51,000	1	8	1	4	0	0

Pacemaker/Model (cont.)	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
INSIGNIA Entra SR 1195/1198*	52,000	1	0	3	5	0	0
INSIGNIA Entra DR (Downsize) 1296*	47,000	1	7	6	3	0	0
INSIGNIA Entra DR 1294/1295*	37,000	0	6	3	9	0	0
INSIGNIA Plus SR 1194*	51,000	1	5	13	5	0	0
INSIGNIA Plus DR (Downsize) 1298*	140,000	3	16	30	7	0	1
INSIGNIA Plus DR 1297*	47,000	0	7	8	6	0	1
INSIGNIA AVT 0482/0882/0982/1192/1292*	51,000	1	1	0	3	0	0

*Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

U.S. Reason for Out of Service

As requested by the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, Boston Scientific provides reasons for device explant or out of service, if known. The reasons consist of normal battery depletion, unconfirmed premature battery depletion, device upgrade, device malfunction (which includes devices under advisory that have experienced a malfunction), complication related to another system component or clinical condition, (such as infection), or "other," a category consisting of patient death, prophylactic device explant, elective replacement, general product dissatisfaction, other observation/complication, unspecified, or unknown.

The counts for normal battery depletion, unconfirmed premature battery depletion, and device malfunction are reflected in the U.S. survival probability data. Reason for device explant or out of service may either be confirmed through laboratory analysis (as in the case of device malfunction) or it may be reported to Boston Scientific with no associated device return or laboratory analysis. Although a device may be indicated by the health care provider to have been taken out of service for more than one reason, the table below indicates only one reason per device in category counts.

CRT-D/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/ G148/G150/G151/G154/G156/G158	18000	1	3	5	6	154	568
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/N161/N162/N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	52000	78	13	34	58	791	7582
COGNIS N118/N119/N120/P106/P107/P108	75000	1505	87	46	1206	1667	28673

CRT-P/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
VISIONIST/VALITUDE U125/U128/U225/U226/U228	4000	0	0	18	0	15	91
INTUA V272/V273/V282/V283/W272/W273	2000	2	0	12	1	15	166
INVIVE V172/V173/V182/V183/W172/W173	8000	16	0	29	1	52	1204
CONTAK RENEWAL TR H120/H125	19000	2409	16	146	48	256	9623

S-ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
EMBLEM S-ICD A209	5000	0	0	2	2	66	73
SQ-RX S-ICD 1010	8000	23	0	12	32	235	531

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	8000	0	0	20	0	49	122
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	7000	1	0	23	0	35	101
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	4000	1	0	11	1	40	190
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	4000	2	0	20	1	35	179
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	34	2	176	25	412	4058
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	46000	33	5	211	34	508	5138

ICD/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
TELIGEN VR E102/E103/F102/F103	38000	80	59	487	922	622	11567
TELIGEN DR E110/E111/F110/F111	66000	202	98	670	1378	1108	20954
CONFIENT DR E030/F030	7000	251	2	120	14	153	2973
VITALITY 2 EL VR T177	7000	1197	9	154	1273	113	2731
VITALITY 2 EL DR T167	8000	2137	14	152	768	133	3377
VITALITY 2 VR T175	21000	6547	36	394	1243	304	9471

Pacemaker/Model	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	8000	0	0	16	1	21	107
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	28000	0	0	71	2	107	464

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	5000	0	0	17	0	22	185
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	2	0	58	2	43	536
ADVANTIO/INGENIO/VITALIO/FORMIO DR J064/J067/K064/K067/K084/K087/J174/J177/ K174/K177/K184/K187/J274/J277/K274/K277/ K284/K287/J278/J279/K278/K279/K288/K289	121000	72	8	399	25	636	11768
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	26000	12	0	100	7	133	4328
ALTRUA 60 SR S601	32000	335	3	206	6	164	13516
ALTRUA 60 DR (Downsize) S603	90000	5372	39	462	42	552	27893
ALTRUA 60 DR S602	22000	353	3	148	10	188	6859
ALTRUA 60 DR EL S606	59000	300	10	313	9	407	14031
ALTRUA 40 SR S401	5000	45	0	17	2	21	2198
ALTRUA 40 DR (downsize) S403	14000	823	2	52	3	77	4638
ALTRUA 40 DR S402	2000	29	1	14	0	7	687
ALTRUA 40 DR EL S404	5000	25	1	28	0	41	1586
ALTRUA 20 SR S201/S204	5000	35	1	16	0	36	2312
ALTRUA 20 DR (downsize) S203	5000	131	3	23	0	36	2061

Pacemaker/Model (cont.)	U.S. Registered Implants	Normal Battery Depletion	Unconfirmed Premature Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 20 DR S202/S205	2000	36	0	7	1	12	765
ALTRUA 20 DR EL S208	3000	14	0	16	1	10	1098
INSIGNIA Ultra SR 1190 [4]	24000	2329	9	205	42	144	16210
INSIGNIA Ultra DR (Downsize) 1290 [4]	76000	20149	115	554	438	600	39480
INSIGNIA Ultra DR 1291 [4]	32000	3549	20	314	165	305	15359
INSIGNIA Entra SR 1195/1198 [4]	14000	860	10	87	9	74	10517
INSIGNIA Entra DR (Downsize) 1296 [4]	24000	4942	25	128	97	152	15446
INSIGNIA Entra DR 1294/1295 [4]	17000	1653	14	126	64	183	10790
INSIGNIA Plus SR 1194 [4]	27000	3314	8	224	27	155	20593
INSIGNIA Plus DR (Downsize) 1298 [4]	90000	26789	114	540	374	697	52269
INSIGNIA Plus DR 1297 [4]	27000	4862	20	262	131	260	15041

[1] Device malfunction consists of all U.S. confirmed malfunctions for a product/product grouping. These include confirmed malfunctions for advisory populations, as well as any other type of malfunction in which a device was returned and confirmed by laboratory analysis to have malfunctioned.. U.S. confirmed malfunction counts are reflected in U.S. survival probability.

[2] System component and/or clinical condition complications may include, for example: infection, erosion, lead-to-PG interface.

[3] Other consists of: patient death, electrive replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

[4] Counts consist of Boston Scientific and Intermedics co-branded pacemaker data.

ACUITY X4 Spiral L

Models 4677/4678

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ACUITY X4 Spiral L
Models 4677/4678

Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ACUITY X4 Spiral S

Models 4674/4675

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ACUITY X4 Spiral S
Models 4674/4675

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ACUITY X4 Straight

Models 4671/4672

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ACUITY X4 Straight Models 4671/4672

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ACUITY Spiral

Models 4591/4592/4593

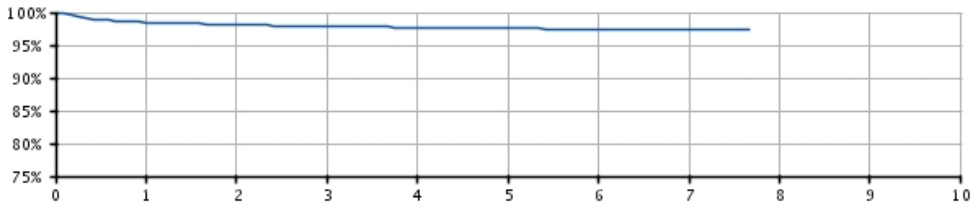
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 23,000
U.S. Approval Date: May 2006
U.S. Estimated Active Implants: 15,000

U.S. Chronic Lead Complications: 438
U.S. Malfunctions:8
Without Compromised Therapy:4
With Compromised Therapy:4

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 21000	98.49 (-0.2/+0.2)	98.12 (-0.2/+0.2)	97.87 (-0.2/+0.2)	97.68 (-0.2/+0.2)	97.54 (-0.3/+0.2)	97.41 (-0.3/+0.3)	97.35 (-0.3/+0.3)	97.35 @ 92 mo. (-0.3/+0.3)	–	–
Effective Sample Size	18114	14481	10999	7976	5319	2971	1154	233	–	–

ACUITY Spiral

Models 4591/4592/4593

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

ACUITY Spiral
Models 4591/4592/4593

Worldwide Distribution: 42,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**3**	**4**
[28] Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**1**	**1**	**2**
[29] Non-patterned, Insulation	1	1	
Other	**2**	**-**	**2**
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**4**	**4**	**8**

More details about malfunctions

References cited in table above

ACUITY Spiral Longitude*

Models 4591/4592/4593

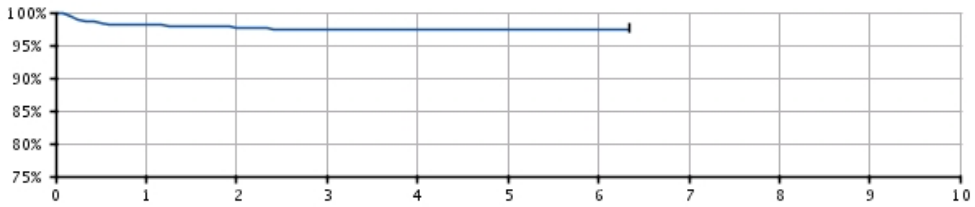
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1323
Leads Active: 916
Cumulative Followup Months : 42,912

Chronic Lead Complications: 31
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 1375	98.09 (-1.6/+1.6)	97.71 (-1.7/+1.7)	97.37 (-1.9/+1.9)	97.37 (-1.9/+1.9)	97.37 (-1.9/+1.9)	97.37 (-1.9/+3.8)	97.37 @ 76 mo. (-1.9/+3.8)	–	–	–
Effective Sample Size	1123	925	726	555	339	119	64	–	–	–

ACUITY Steerable

Models 4554/4555/4556

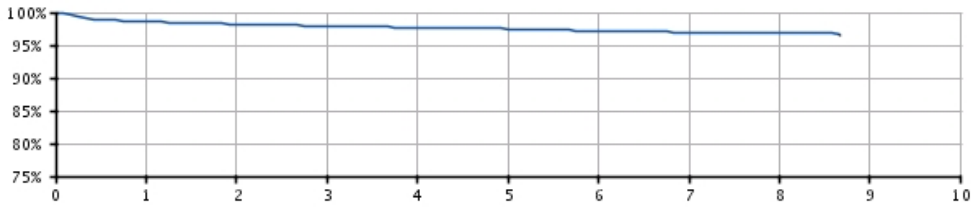
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 17,000

U.S. Chronic Lead Complications: 607
U.S. Malfunctions:32
Without Compromised Therapy:11
With Compromised Therapy:21

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 29000	98.58 (-0.2/+0.1)	98.21 (-0.2/+0.2)	97.94 (-0.2/+0.2)	97.72 (-0.2/+0.2)	97.45 (-0.2/+0.2)	97.17 (-0.3/+0.2)	96.93 (-0.3/+0.3)	96.89 (-0.3/+0.3)	96.58 @ 104 mo. (-0.7/+0.6)	–
Effective Sample Size	23670	19695	15726	12421	9396	6498	3872	1591	311	–

ACUITY Steerable

Models 4554/4555/4556

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 63,000
Worldwide Confirmed Malfunctions: 53

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**35**	**45**
[26] Conductor fracture	1	-	
[28] Non-patterned, Conductor	6	9	
[35] Extracardiac fracture	3	26	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**6**	**1**	**7**
[27] Non-patterned, Other	6	1	
WW Confirmed Malfunctions	**16**	**37**	**53**

More details about malfunctions

References cited in table above

EASYTRAK 3

Models 4522/4524/4525/4527/4548/
4549/4550

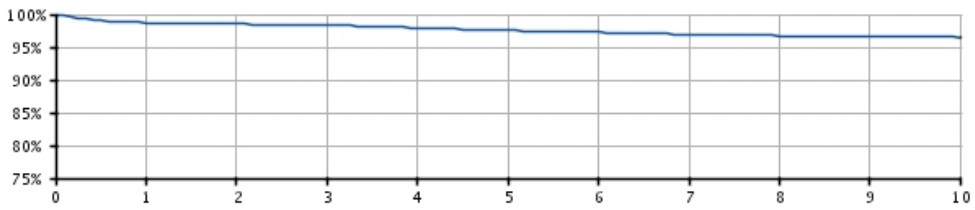
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 22,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 10,000

U.S. Chronic Lead Complications: 437
U.S. Malfunctions:30
Without Compromised Therapy:7
With Compromised Therapy:23

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	98.72 (-0.2/+0.1)	98.54 (-0.2/+0.2)	98.31 (-0.2/+0.2)	97.97 (-0.2/+0.2)	97.57 (-0.3/+0.2)	97.27 (-0.3/+0.3)	96.90 (-0.3/+0.3)	96.75 (-0.3/+0.3)	96.58 (-0.4/+0.3)	96.47 (-0.4/+0.4)
Registered Implants: 22000										
Effective Sample Size	18051	15336	12651	10350	8421	6727	5235	3936	2777	1513

EASYTRAK 3

Models 4522/4524/4525/4527/4548/
4549/4550

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

EASYTRAK 3
Models 4522/4524/4525/4527/4548/ 4549/4550

Worldwide Distribution: 42,000
Worldwide Confirmed Malfunctions: 48

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**9**	**34**	**43**
[28] Non-patterned, Conductor	6	5	
[35] Extracardiac fracture	3	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**1**	**4**
[29] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**13**	**35**	**48**

More details about malfunctions

References cited in table above

EASYTRAK 2

Models 4515/4517/4518/4520/4542/
4543/4544

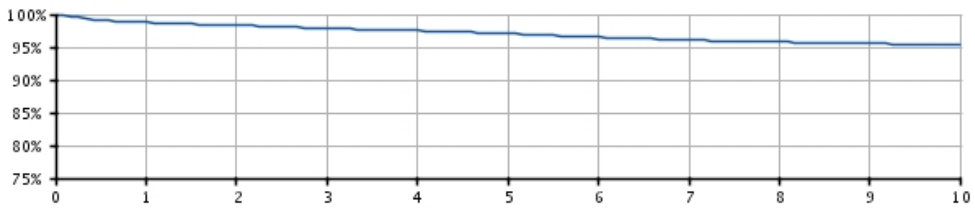
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 96,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 45,000

U.S. Chronic Lead Complications: 2,172
U.S. Malfunctions:342
Without Compromised Therapy:85
With Compromised Therapy:257

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 96000	98.78 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.90 (-0.1/+0.1)	97.52 (-0.1/+0.1)	97.06 (-0.1/+0.1)	96.51 (-0.2/+0.1)	96.07 (-0.2/+0.2)	95.77 (-0.2/+0.2)	95.59 (-0.2/+0.2)	95.32 (-0.2/+0.2)
Effective Sample Size	79689	67564	56124	46280	37534	29226	21895	15831	10678	5945

EASYTRAK 2

Models 4515/4517/4518/4520/4542/
4543/4544

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EASYTRAK 2
Models 4515/4517/4518/4520/4542/ 4543/4544

Worldwide Distribution: 175,000
Worldwide Confirmed Malfunctions: 477

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**93**	**358**	**451**
[26] Conductor fracture	87	311	
[28] Non-patterned, Conductor	6	47	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**11**	**2**	**13**
[29] Non-patterned, Insulation	11	2	
Other	**8**	**5**	**13**
[27] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**112**	**365**	**477**

More details about malfunctions

References cited in table above

EASYTRAK

Models 4510/4511/4512/4513/4535/
4536/4537/4538

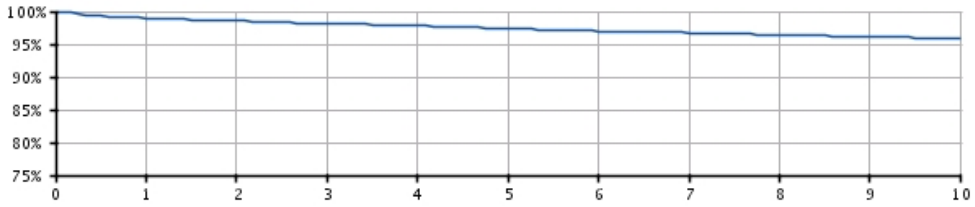
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 38,000
U.S. Approval Date: May 2002
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 898
U.S. Malfunctions:24
Without Compromised Therapy:10
With Compromised Therapy:14

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 38000	98.94 (-0.1/+0.1)	98.57 (-0.1/+0.1)	98.15 (-0.2/+0.1)	97.84 (-0.2/+0.2)	97.36 (-0.2/+0.2)	97.00 (-0.2/+0.2)	96.75 (-0.2/+0.2)	96.36 (-0.3/+0.2)	96.11 (-0.3/+0.3)	95.92 (-0.3/+0.3)
Effective Sample Size	30533	26247	22512	19341	16507	14115	12109	10451	8899	7570

EASYTRAK

Models 4510/4511/4512/4513/4535/
4536/4537/4538

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

EASYTRAK
Models 4510/4511/4512/4513/4535/ 4536/4537/4538

Worldwide Distribution: 53,000
Worldwide Confirmed Malfunctions: 26

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**12**	**12**
[28] Non-patterned, Conductor	-	12	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**3**	**6**
[29] Non-patterned, Insulation	3	3	
Other	**7**	**1**	**8**
[27] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**16**	**26**

More details about malfunctions

References cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

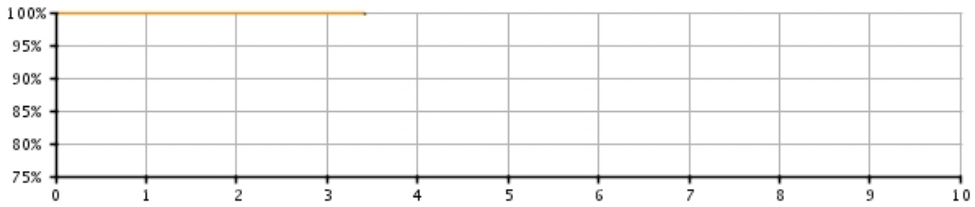
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 12,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 6
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 12000	99.87 (-0.1/+0.1)	99.76 (-0.2/+0.1)	99.76 (-0.2/+0.1)	99.76 @ 41 mo. (-0.2/+0.1)	–	–	–	–	–	–
Effective Sample Size	5506	1497	378	217	–	–	–	–	–	–

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

EMBLEM/Q-TRAK S-ICD Electrode Models 3010/3401

Worldwide Distribution: 19,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	**1**	**1**
[37] Weld fracture	-	1	
Insulation	-	-	**0**
Other	-	**2**	**2**
Non-patterned, Other	-	2	
WW Confirmed Malfunctions	**0**	**3**	**3**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation

Models 0658/0695/0696

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation Models 0658/0695/0696

Worldwide Distribution: 8,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation

Models 0657/0692/0693

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation Models 0657/0692/0693

Worldwide Distribution: 24,000

Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**4**	**4**
[28] Non-patterned, Conductor	-	1	
[38] Conductor cable fracture	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**-**	**-**	**0**
WW Confirmed Malfunctions	**0**	**5**	**5**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation

Models 0655/0685/0686

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation Models 0655/0685/0686

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation

Models 0654/0682/0683

U.S. Survival Probability | **Worldwide Malfunction Details** | Product Advisories

ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation Models 0654/0682/0683

Worldwide Distribution: 2,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models 0275/0276/0295/0296

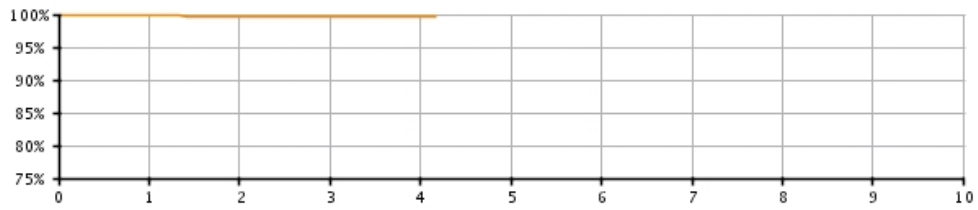
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 53,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 47,000

U.S. Chronic Lead Complications: 128
U.S. Malfunctions:8
Without Compromised Therapy:0
With Compromised Therapy:8

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 52000	99.79 (-0.0/+0.0)	99.70 (-0.1/+0.0)	99.67 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.62 @ 50 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	39207	25998	13387	1921	533	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models 0275/0276/0295/0296

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation Models 0275/0276/0295/0296

Worldwide Distribution: 86,000

Worldwide Confirmed Malfunctions: 35

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[28] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**7**	**23**	**30**
[29] Non-patterned, Insulation	7	23	
Other	**2**	**-**	**2**
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**9**	**26**	**35**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation Longitude*

Models 0275/0276/0295/0296

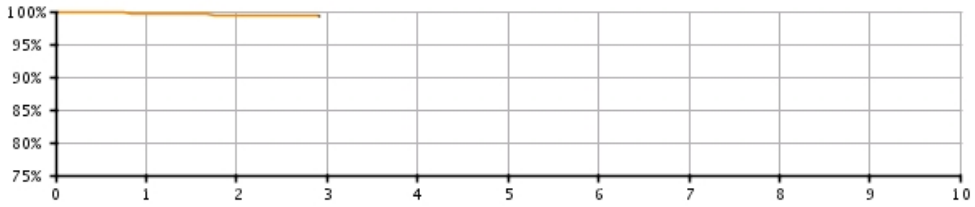
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 846
Leads Active: 661
Cumulative Followup Months: 18,035

U.S. Chronic Lead Complications: 2
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 846	99.74 (-0.8/+0.1)	99.40 (-1.3/+0.3)	99.40 @ 35 mo. (-1.3/+0.3)	–	–	–	–	–	–	–
Effective Sample Size	733	357	53	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

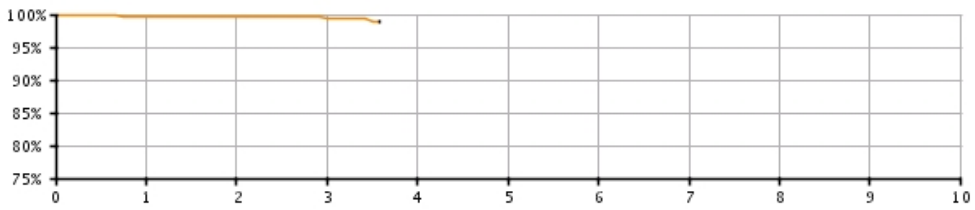
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 2,000

U.S. Chronic Lead Complications: 10
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.71 (-0.4/+0.2)	99.53 (-0.5/+0.2)	99.32 (-0.8/+0.4)	98.93 @ 43 mo. (-1.5/+0.6)	–	–	–	–	–	–
Effective Sample Size	1648	994	476	216	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation Models 0265/0266/0285/0286

Worldwide Distribution: 8,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models 0292/0293

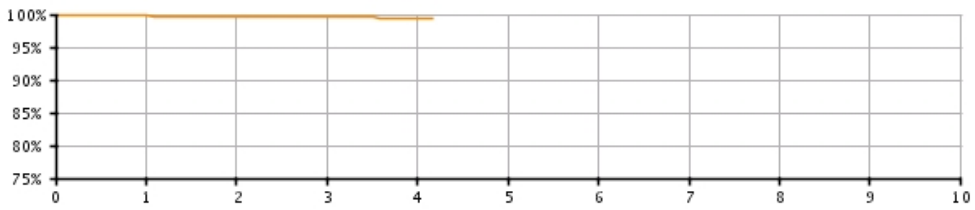
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 54,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 50,000

U.S. Chronic Lead Complications: 136
U.S. Malfunctions:8
Without Compromised Therapy:1
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 53000	99.77 (-0.0/+0.0)	99.65 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.47 (-0.1/+0.1)	99.47 @ 50 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	33001	17044	6609	787	231	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models 0292/0293

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation Models 0292/0293

Worldwide Distribution: 89,000

Worldwide Confirmed Malfunctions: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[25] Conductor fracture	-	1	
[28] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**21**	**23**
[29] Non-patterned, Insulation	2	21	
Other	**-**	**2**	**2**
[27] Non-patterned, Other	-	2	
WW Confirmed Malfunctions	**2**	**25**	**27**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Single Coil, Active Fixation Longitude

Models 0292/0293

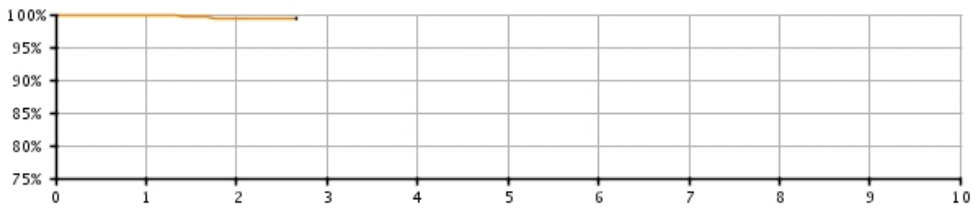
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1103
Leads Active: 955
Cumulative Followup Months : 22,892

Chronic Lead Complications: 3
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 1103	99.89 (-0.6/+0.1)	99.49 (-1.7/+0.6)	99.49 @ 32 mo. (-1.7/+0.6)	–	–	–	–	–	–	–
Effective Sample Size	854	404	60	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

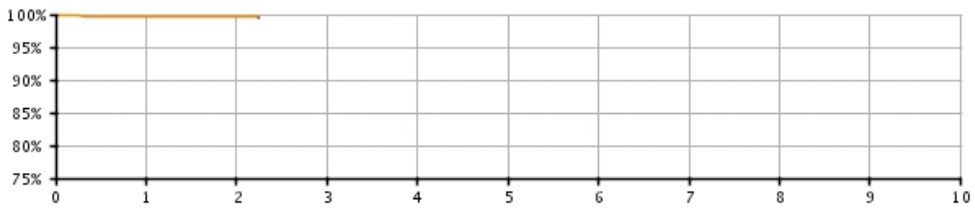
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 1,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 3
U.S. Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 1000	99.66 (-0.7/+0.2)	99.66 (-0.7/+0.2)	99.66 @ 27 mo. (-0.7/+0.2)	–	–	–	–	–	–	–
Effective Sample Size	527	251	209	–	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models 0282/0283

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation Models 0282/0283

Worldwide Distribution: 4,000

Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	1	1
[29] Non-patterned, Insulation	-	1	
Other	-	-	0
WW Confirmed Malfunctions	0	1	1

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

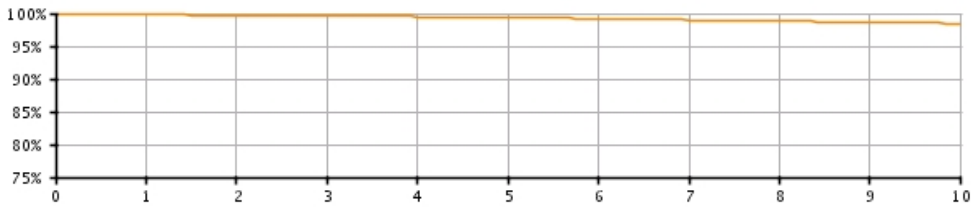
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 286,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 141,000

U.S. Chronic Lead Complications: 1,843
U.S. Malfunctions:281
Without Compromised Therapy:110
With Compromised Therapy:171

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.80 (-0.0/+0.0)	99.70 (-0.0/+0.0)	99.61 (-0.0/+0.0)	99.50 (-0.0/+0.0)	99.37 (-0.0/+0.0)	99.20 (-0.0/+0.0)	99.00 (-0.1/+0.0)	98.84 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.47 (-0.1/+0.1)
Registered Implants: 285000										
Effective Sample Size	251016	223030	197473	173498	142966	113724	86953	63051	44364	30181

ENDOTAK RELIANCE
Dual Coil, Active Fixation

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Dual Coil, Active Fixation
Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

Worldwide Distribution: 371,000
Worldwide Confirmed Malfunctions: 438

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**123**	**125**
[25] Conductor fracture	-	80	
[28] Non-patterned, Conductor	2	43	
Crimp/Weld/Bond	**5**	**1**	**6**
[3] Seal rings	2	1	
[32] Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	**145**	**116**	**261**
[29] Non-patterned, Insulation	145	116	
Other	**28**	**18**	**46**
[27] Non-patterned, Other	28	18	
WW Confirmed Malfunctions	**180**	**258**	**438**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Dual Coil, Active Fixation Longitude

Models 0157/0158/0159/0164/0165/
0166/0167/0184/0185/0186/
0187

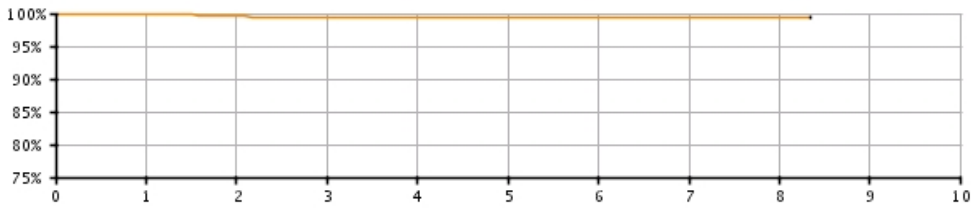
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 741
Leads Active: 409
Cumulative Followup Months: 25,754

U.S. Chronic Lead Complications: 3
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 741	100.00 (-0.0/+0.0)	99.67 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 (-1.2/+0.3)	99.49 @ 100 mo. (-1.2/+0.3)	–
Effective Sample Size	644	568	500	422	308	157	70	56	50	–

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149/0174/0175/
0176/0177

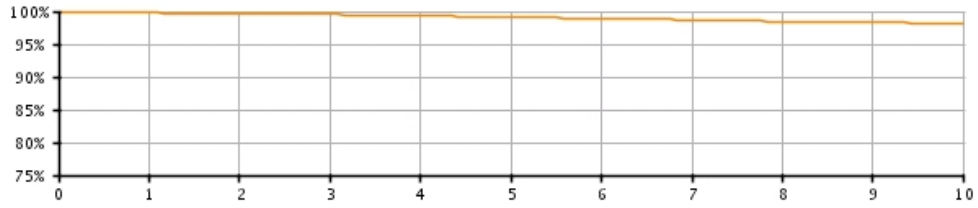
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 46,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 17,000

U.S. Chronic Lead Complications: 479
U.S. Malfunctions:38
Without Compromised Therapy:10
With Compromised Therapy:28

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.77 (-0.0/+0.0)	99.69 (-0.1/+0.0)	99.53 (-0.1/+0.1)	99.34 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.70 (-0.1/+0.1)	98.47 (-0.2/+0.1)	98.31 (-0.2/+0.2)	98.11 (-0.2/+0.2)
Registered Implants: 46000										
Effective Sample Size	40525	36064	31986	28117	24303	20760	17595	14696	12139	9946

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

Models 0147/0148/0149/0174/0175/
0176/0177

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Dual Coil, Passive Fixation
Models 0147/0148/0149/0174/0175/
0176/0177

Worldwide Distribution: 107,000
Worldwide Confirmed Malfunctions: 124

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**30**	**30**
[25] Conductor fracture	-	17	
[28] Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	**-**	**3**	**3**
[36] Conductor connection	-	3	
Insulation	**38**	**43**	**81**
[29] Non-patterned, Insulation	38	43	
Other	**7**	**3**	**10**
[4] Manufacturing material	-	1	
[27] Non-patterned, Other	7	3	
WW Confirmed Malfunctions	**45**	**79**	**124**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

Models 0137/0138/0160/0161/0162/
0180/0181/0182

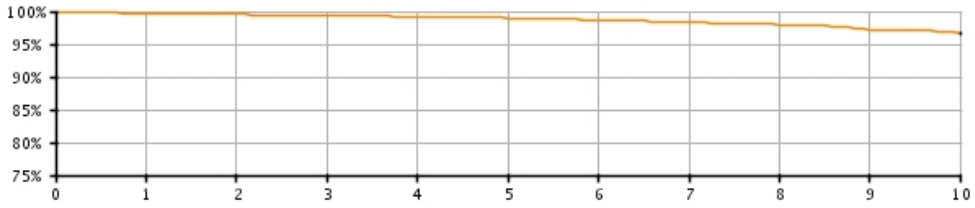
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 31,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 22,000

U.S. Chronic Lead Complications: 206
U.S. Malfunctions:53
Without Compromised Therapy:20
With Compromised Therapy:33

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 31000	99.70 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.00 (-0.2/+0.1)	98.71 (-0.2/+0.2)	98.38 (-0.3/+0.2)	97.91 (-0.4/+0.3)	97.17 (-0.7/+0.6)	96.72 (-0.9/+0.7)
Effective Sample Size	26092	21692	17650	14141	9173	5643	3320	1748	908	535

ENDOTAK RELIANCE
Single Coil, Active Fixation

Models 0137/0138/0160/0161/0162/
0180/0181/0182

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Single Coil, Active Fixation
Models 0137/0138/0160/0161/0162/
0180/0181/0182

Worldwide Distribution: 66,000
Worldwide Confirmed Malfunctions: 147

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**54**	**55**
[25] Conductor fracture	1	46	
[28] Non-patterned, Conductor	-	8	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**48**	**30**	**78**
[29] Non-patterned, Insulation	48	30	
Other	**8**	**6**	**14**
[27] Non-patterned, Other	8	6	
WW Confirmed Malfunctions	**57**	**90**	**147**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

Models 0127/0128/0170/0171/0172/
0173

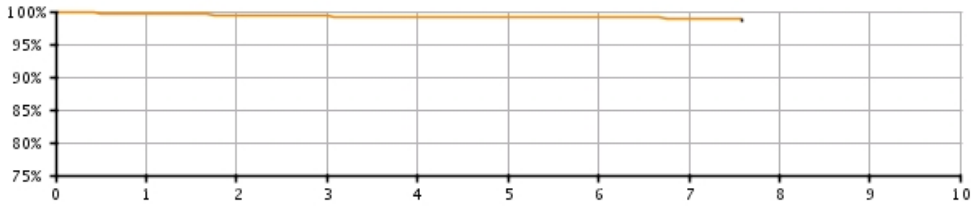
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 2,000
U.S. Approval Date: October 2000
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 16
U.S. Malfunctions:1
Without Compromised Therapy:0
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 2000	99.74 (-0.4/+0.2)	99.40 (-0.6/+0.3)	99.29 (-0.7/+0.3)	99.16 (-0.7/+0.4)	99.16 (-0.7/+0.4)	99.16 (-0.7/+0.4)	98.77 (-1.4/+0.7)	98.77 @ 91 mo. (-1.4/+0.7)	–	–
Effective Sample Size	1326	1057	807	593	445	307	232	203	–	–

ENDOTAK RELIANCE
Single Coil, Passive Fixation

Models 0127/0128/0170/0171/0172/
0173

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

ENDOTAK RELIANCE
Single Coil, Passive Fixation
Models 0127/0128/0170/0171/0172/
0173

Worldwide Distribution: 7,000
Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**4**	**5**
[25] Conductor fracture	1	2	
[28] Non-patterned, Conductor	-	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**6**	**4**	**10**
[29] Non-patterned, Insulation	6	4	
Other	**1**	**-**	**1**
[27] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**8**	**8**	**16**

More details about malfunctions

References cited in table above

ENDOTAK ENDURANCE
Passive Fixation

Models 0134/0135/0136

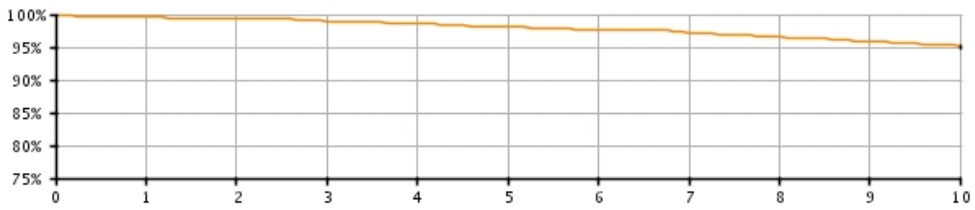
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: August 1998
U.S. Estimated Active Implants: 1,000

U.S. Chronic Lead Complications: 112
U.S. Malfunctions:3
Without Compromised Therapy:2
With Compromised Therapy:1

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.53 (-0.4/+0.2)	99.35 (-0.4/+0.3)	98.98 (-0.5/+0.3)	98.57 (-0.6/+0.4)	98.12 (-0.7/+0.5)	97.68 (-0.8/+0.6)	97.17 (-0.9/+0.7)	96.60 (-1.1/+0.8)	95.95 (-1.2/+0.9)	95.08 (-1.4/+1.1)
Registered Implants: 3000										
Effective Sample Size	2332	2067	1830	1609	1426	1251	1103	961	831	728

ENDOTAK ENDURANCE EZ
Active Fixation

Models 0154/0155/0156

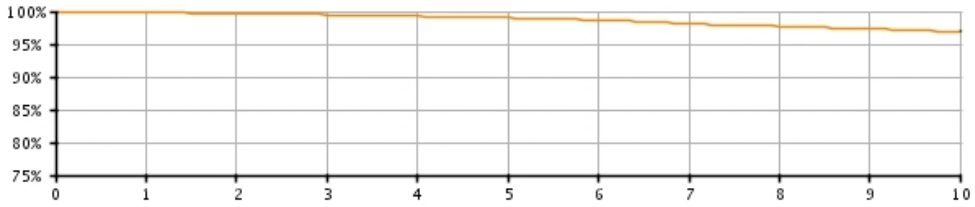
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 571
U.S. Malfunctions:24
Without Compromised Therapy:11
With Compromised Therapy:13

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.01 (-0.1/+0.1)	98.66 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.73 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.96 (-0.3/+0.3)
Registered Implants: 29000										
Effective Sample Size	24453	21794	19399	17263	15330	13600	12053	10714	9493	8403

ENDOTAK ENDURANCE Rx
Passive Fixation Steroid Eluting

Models 0144/0145/0146

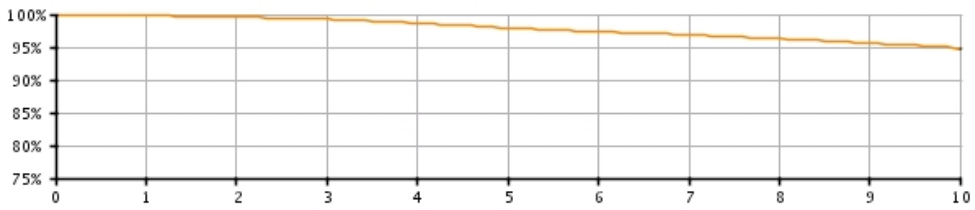
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 18,000
U.S. Approval Date: January 1999
U.S. Estimated Active Implants: 4,000

U.S. Chronic Lead Complications: 682
U.S. Malfunctions:24
Without Compromised Therapy:6
With Compromised Therapy:18

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.26 (-0.2/+0.1)	98.65 (-0.2/+0.2)	97.92 (-0.3/+0.2)	97.39 (-0.3/+0.3)	96.85 (-0.3/+0.3)	96.26 (-0.4/+0.4)	95.65 (-0.4/+0.4)	94.69 (-0.5/+0.5)
Registered Implants: 18000										
Effective Sample Size	15628	13937	12418	10989	9679	8564	7597	6723	5920	5202

INGEVITY Positive Fixation

Models 7640/7641/7642/7740/7741/
7742

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

INGEVITY Positive Fixation Models 7640/7641/7642/7740/7741/ 7742

Worldwide Distribution: 98,000
Worldwide Confirmed Malfunctions: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**4**	**10**
[28] Non-patterned, Conductor	4	2	
[39] Inner conductor break	2	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[29] Non-patterned, Insulation	-	1	
Other	**-**	**1**	**1**
[27] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**6**	**6**	**12**

More details about malfunctions

References cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INGEVITY Passive Fixation Models 7631/7632/7731/7732

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

INGEVITY Atrial J Passive Fixation

Models 7635/7636/7735/7736

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

INGEVITY Atrial J Passive Fixation Models 7635/7636/7735/7736

Worldwide Distribution: 12,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	-	-	0
WW Confirmed Malfunctions	0	0	0

More details about malfunctions

References cited in table above

FLEXTEND 2 Active Fixation

Models 4095/4096/4097

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FLEXTEND 2 Active Fixation Models 4095/4096/4097

Worldwide Distribution: 178,000
Worldwide Confirmed Malfunctions: 111

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**6**	**32**	**38**
[7] Lead conductor	3	18	
[33] Conductor damage	3	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**52**	**10**	**62**
[2] Inner insulation abrasion	3	1	
[29] Non-patterned, Insulation	4	-	
[34] Insulation damage	45	9	
Other	**11**	**-**	**11**
[27] Non-patterned, Other	11	-	
WW Confirmed Malfunctions	**69**	**42**	**111**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

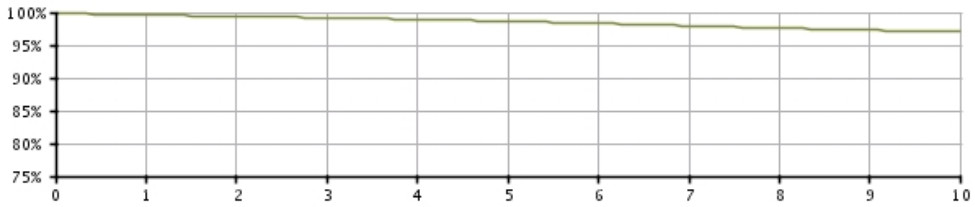
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 234,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 101,000

U.S. Chronic Lead Complications: 3,224
U.S. Malfunctions:308
Without Compromised Therapy:123
With Compromised Therapy:185

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.93 (-0.0/+0.0)	98.65 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.97 (-0.1/+0.1)	97.61 (-0.1/+0.1)	97.30 (-0.1/+0.1)	97.05 (-0.1/+0.1)
Registered Implants: 234000										
Effective Sample Size	197374	171615	148483	127569	108655	90983	75000	61302	48096	33520

FLEXTEND Active Fixation

Models 4086/4087/4088

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FLEXTEND Active Fixation Models 4086/4087/4088

Worldwide Distribution: 286,000
Worldwide Confirmed Malfunctions: 331

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**13**	**171**	**184**
[7] Lead conductor	7	80	
[28] Non-patterned, Conductor	-	7	
[33] Conductor damage	6	84	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**103**	**26**	**129**
[2] Inner insulation abrasion	19	6	
[29] Non-patterned, Insulation	8	-	
[34] Insulation damage	76	20	
Other	**16**	**2**	**18**
[27] Non-patterned, Other	16	2	
WW Confirmed Malfunctions	**132**	**199**	**331**

More details about malfunctions

References cited in table above

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models 4463/4464/4465/4469/4470/ 4471

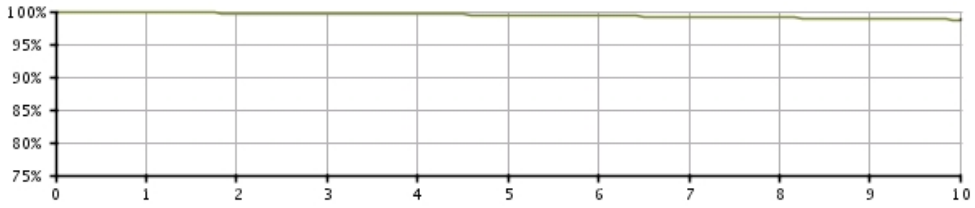
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 443,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 253,000

U.S. Chronic Lead Complications: 2,334
U.S. Malfunctions:132
Without Compromised Therapy:26
With Compromised Therapy:106

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.0/+0.0)	99.74 (-0.0/+0.0)	99.66 (-0.0/+0.0)	99.56 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.32 (-0.0/+0.0)	99.16 (-0.0/+0.0)	99.03 (-0.0/+0.0)	98.87 (-0.1/+0.1)	98.73 (-0.1/+0.1)
Registered Implants: 442000										
Effective Sample Size	372898	313879	261952	216170	175575	139219	106480	80516	59841	42569

Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane)

Models 4463/4464/4465/4469/4470/ 4471

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) Models 4463/4464/4465/4469/4470/ 4471

Worldwide Distribution: 1,000

Worldwide Confirmed Malfunctions: 158

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**118**	**129**
[7] Lead conductor	6	55	
[28] Non-patterned, Conductor	-	5	
[33] Conductor damage	5	58	
Crimp/Weld/Bond	**1**	**2**	**3**
[24] Terminal weld	-	1	
[32] Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	**12**	**6**	**18**
[34] Insulation damage	12	6	
Other	**6**	**2**	**8**
[27] Non-patterned, Other	6	2	
WW Confirmed Malfunctions	**30**	**128**	**158**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

Models 4463/4464/4465/4469/4470/
4471

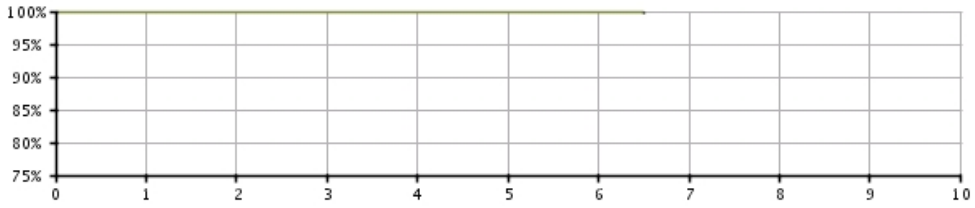
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories	Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 922
Leads Active: 705
Cumulative Followup Months : 26,618

Chronic Lead Complications: 0
Malfunctions:0
Without Compromised Therapy:0
With Compromised Therapy:0

Complications and Malfunctions



Longitude Registry Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Longitude Registered Implants: 922	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 (-0.7/+0.1)	99.88 @ 78 mo. (-0.7/+0.1)	–	–	–	–
Effective Sample Size	773	541	312	252	169	92	56	–	–	–

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

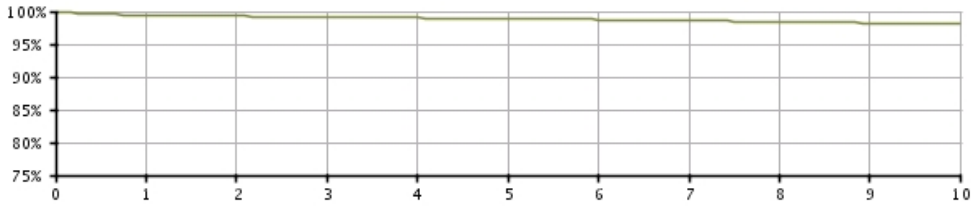
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 60,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 31,000

U.S. Chronic Lead Complications: 620
U.S. Malfunctions:25
Without Compromised Therapy:18
With Compromised Therapy:7

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 60000	99.43 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.14 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.92 (-0.1/+0.1)	98.75 (-0.1/+0.1)	98.59 (-0.1/+0.1)	98.45 (-0.1/+0.1)	98.21 (-0.2/+0.2)	98.13 (-0.2/+0.2)
Effective Sample Size	50371	42761	35946	29991	24808	20128	15848	12410	9540	7173

Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)
Models 4477/4478/4479/4480

Worldwide Distribution: 285,000

Worldwide Confirmed Malfunctions: 16

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**3**	**10**	**13**
[7] Lead conductor	-	3	
[33] Conductor damage	3	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[34] Insulation damage	-	1	
Other	**2**	**-**	**2**
[23] J-shape	30	4	
[27] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**5**	**11**	**16**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

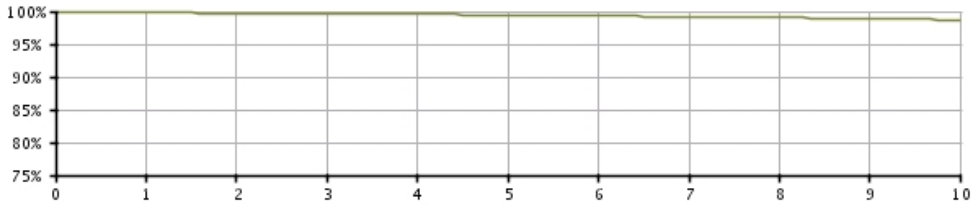
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 185,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 89,000

U.S. Chronic Lead Complications: 1,057
U.S. Malfunctions:42
Without Compromised Therapy:5
With Compromised Therapy:37

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.81 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.45 (-0.0/+0.0)	99.34 (-0.1/+0.0)	99.18 (-0.1/+0.1)	99.04 (-0.1/+0.1)	98.85 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 185000										
Effective Sample Size	154937	131527	110685	92514	76607	62326	49309	38679	30129	22871

Data are representative of Boston Scientific FINELINE II (poly) and Intermedics Thinline II (poly) lead performance.

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) Models 4452/4453/4456/4457

Worldwide Distribution: 508,000

Worldwide Confirmed Malfunctions: 60

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**45**	**46**
[7] Lead conductor	-	15	
[28] Non-patterned, Conductor	-	2	
[33] Conductor damage	1	28	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**7**	**9**
[34] Insulation damage	2	7	
Other	**4**	**-**	**4**
[27] Non-patterned, Other	4	-	
WW Confirmed Malfunctions	**7**	**53**	**60**

More details about malfunctions

References cited in table above

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models 4466/4467/4468/4472/4473/ 4474

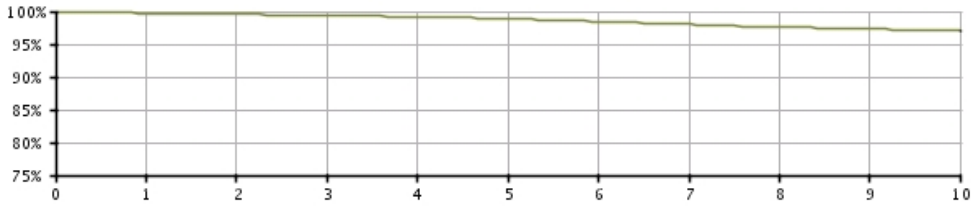
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 51,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 24,000

U.S. Chronic Lead Complications: 583
U.S. Malfunctions:122
Without Compromised Therapy:20
With Compromised Therapy:102

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.74 (-0.1/+0.0)	99.57 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.89 (-0.1/+0.1)	98.47 (-0.1/+0.1)	98.02 (-0.2/+0.2)	97.59 (-0.2/+0.2)	97.38 (-0.2/+0.2)	97.07 (-0.3/+0.2)
Registered Implants: 51000										
Effective Sample Size	44108	38006	32472	27525	23085	18913	15296	12194	9628	7317

Data are representative of Boston Scientific FINELINE II (silicone) and Intermedics Thinline II (silicone) lead performance.

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

Models 4466/4467/4468/4472/4473/ 4474

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone) Models 4466/4467/4468/4472/4473/ 4474

Worldwide Distribution: 137,000

Worldwide Confirmed Malfunctions: 160

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**8**	**122**	**130**
[7] Lead conductor	3	75	
[28] Non-patterned, Conductor	-	2	
[33] Conductor damage	5	45	
Crimp/Weld/Bond	**1**	**-**	**1**
[32] Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	**9**	**9**	**18**
[29] Non-patterned, Insulation	2	-	
[34] Insulation damage	7	9	
Other	**5**	**3**	**8**
[27] Non-patterned, Other	5	3	
WW Confirmed Malfunctions	**23**	**137**	**160**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

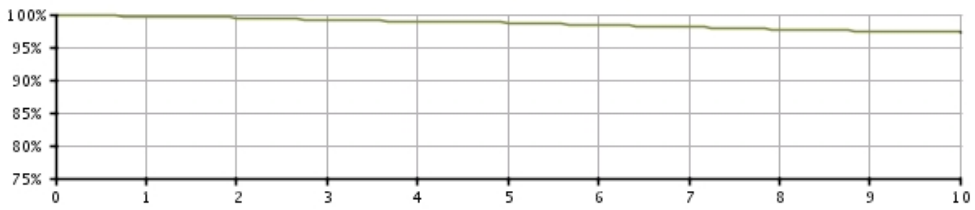
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 186
U.S. Malfunctions:22
Without Compromised Therapy:0
With Compromised Therapy:22

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.67 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.19 (-0.2/+0.1)	98.92 (-0.2/+0.2)	98.75 (-0.2/+0.2)	98.42 (-0.3/+0.2)	98.05 (-0.3/+0.3)	97.70 (-0.4/+0.3)	97.44 (-0.4/+0.4)	97.32 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12237	10656	9226	7912	6710	5593	4649	3861	3230	2620

Data are representative of Boston Scientific FINELINE II (silicone) and Intermedics Thinline II (silicone) lead performance.

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) Models 4454/4455/4458/4459

Worldwide Distribution: 102,000

Worldwide Confirmed Malfunctions: 51

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**42**	**42**
[7] Lead conductor	-	16	
[33] Conductor damage	-	26	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**4**	**6**
[34] Insulation damage	2	4	
Other	**-**	**3**	**3**
[27] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**49**	**51**

More details about malfunctions

References cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

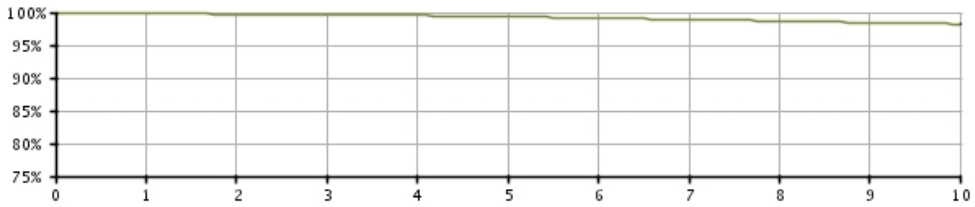
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 24,000
U.S. Approval Date: July 1999
U.S. Estimated Active Implants: 5,000

U.S. Chronic Lead Complications: 290
U.S. Malfunctions:10
Without Compromised Therapy:1
With Compromised Therapy:9

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	99.82 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.64 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.36 (-0.1/+0.1)	99.14 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.70 (-0.2/+0.2)	98.45 (-0.2/+0.2)	98.23 (-0.3/+0.2)
Registered Implants: 24000										
Effective Sample Size	20913	18710	16691	14867	13217	11629	10248	9037	7930	6997

Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

FINELINE Passive Fixation

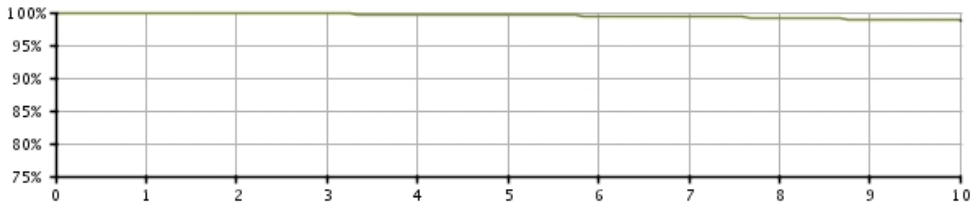
Models 4450/4451

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 42,000
U.S. Approval Date: November 1996
U.S. Estimated Active Implants: 7,000
U.S. Chronic Lead Complications: 327
U.S. Malfunctions:11

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 42000	99.91 (-0.0/+0.0)	99.84 (-0.0/+0.0)	99.79 (-0.1/+0.0)	99.72 (-0.1/+0.1)	99.62 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.35 (-0.1/+0.1)	99.18 (-0.1/+0.1)	98.97 (-0.1/+0.1)	98.79 (-0.2/+0.1)
Effective Sample Size	35803	32045	28628	25412	22463	19765	17327	15290	13466	11870

Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

FINELINE Atrial J

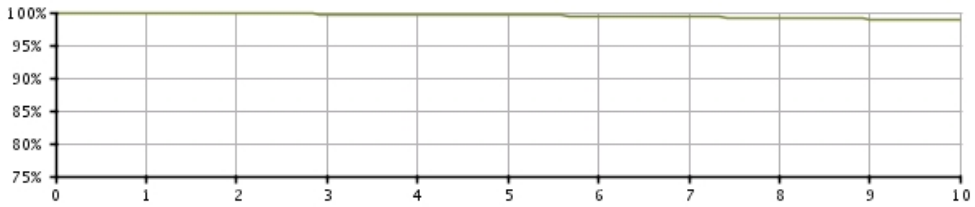
Models 4475/4476

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 14,000
U.S. Approval Date: November 1996
U.S. Estimated Active Implants: 3,000
U.S. Chronic Lead Complications: 104
U.S. Malfunctions:6

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 14000	99.87 (-0.1/+0.0)	99.83 (-0.1/+0.1)	99.75 (-0.1/+0.1)	99.68 (-0.1/+0.1)	99.61 (-0.1/+0.1)	99.45 (-0.2/+0.1)	99.31 (-0.2/+0.2)	99.16 (-0.2/+0.2)	98.98 (-0.3/+0.2)	98.89 (-0.3/+0.2)
Effective Sample Size	12441	11148	9968	8891	7907	6971	6147	5430	4756	4160

Data are representative of Boston Scientific FINELINE and Intermedics Thinline lead performance.

SELUTE
Passive Fixation

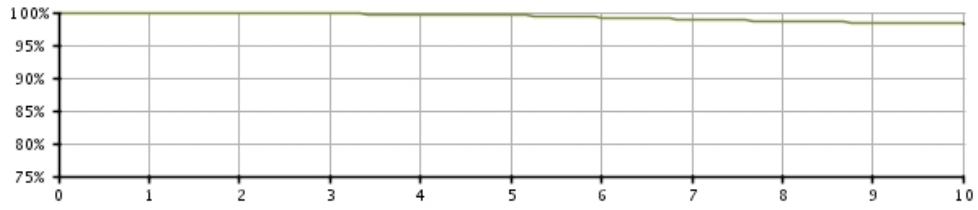
Models 4185/4285

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 48,000
U.S. Approval Date: May 1996
U.S. Estimated Active Implants: 7,000
U.S. Chronic Lead Complications: 468
U.S. Malfunctions:26

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 48000	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.78 (-0.1/+0.0)	99.68 (-0.1/+0.1)	99.54 (-0.1/+0.1)	99.25 (-0.1/+0.1)	98.94 (-0.1/+0.1)	98.66 (-0.2/+0.1)	98.43 (-0.2/+0.2)	98.29 (-0.2/+0.2)
Effective Sample Size	40966	36601	32643	28926	25573	22373	19638	17170	14978	13048

SELUTE PICOTIP
Passive Fixation

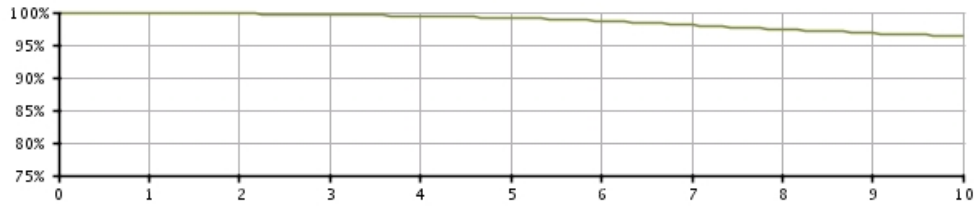
Models 4030/4031/4032/4033/4034/
4035

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 13,000
U.S. Chronic Lead Complications: 1,102
U.S. Malfunctions:35

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 58000	99.86 (-0.0/+0.0)	99.78 (-0.0/+0.0)	99.64 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.15 (-0.1/+0.1)	98.67 (-0.1/+0.1)	98.05 (-0.2/+0.1)	97.37 (-0.2/+0.2)	96.77 (-0.2/+0.2)	96.38 (-0.2/+0.2)
Effective Sample Size	49277	43965	39177	34805	30802	27100	23737	20661	17809	15318

SELUTE PICOTIP Atrial J

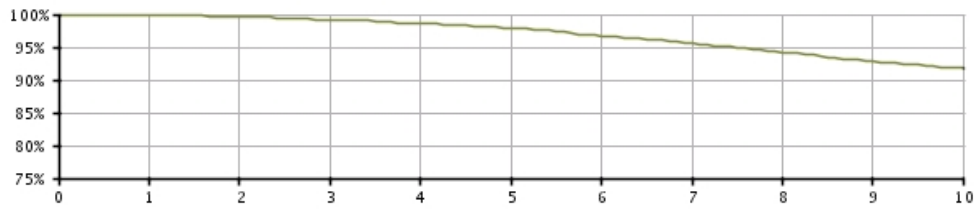
Models 4040/4041/4042/4043/4044/
4045/4063/4064

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 10,000
U.S. Approval Date: May 2000
U.S. Estimated Active Implants: 3,000
U.S. Chronic Lead Complications: 423
U.S. Malfunctions:21

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 10000	99.87 (-0.1/+0.1)	99.65 (-0.2/+0.1)	99.19 (-0.2/+0.2)	98.61 (-0.3/+0.2)	97.89 (-0.4/+0.3)	96.67 (-0.5/+0.4)	95.57 (-0.6/+0.5)	94.21 (-0.7/+0.6)	92.87 (-0.8/+0.7)	91.79 (-0.9/+0.8)
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3435	2901	2451

SWEET PICOTIP Rx
Positive Fixation

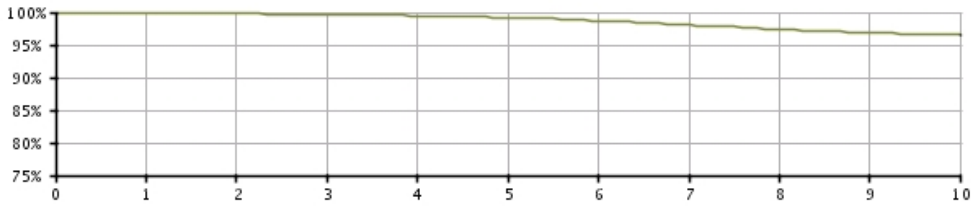
Models 4050/4051/4052/4053/4054/
4055

U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 41,000
U.S. Approval Date: April 1999
U.S. Estimated Active Implants: 12,000
U.S. Chronic Lead Complications: 685
U.S. Malfunctions:56

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 41000	99.91 (-0.0/+0.0)	99.81 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.21 (-0.1/+0.1)	98.68 (-0.2/+0.1)	98.05 (-0.2/+0.2)	97.43 (-0.2/+0.2)	96.91 (-0.3/+0.2)	96.54 (-0.3/+0.3)
Effective Sample Size	35764	31933	28497	25357	22470	19820	17275	14597	12058	9963

SWEET TIP
Positive Fixation

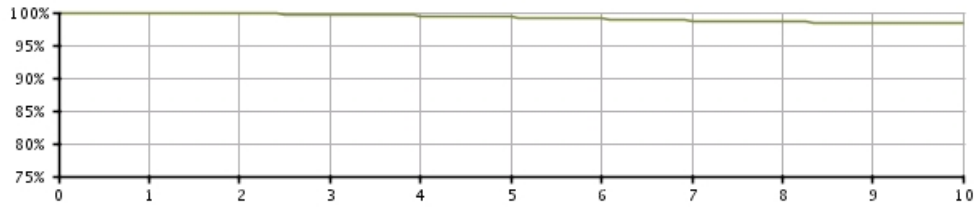
Models 4165/4168/4169/4268/4269

U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 89,000
U.S. Approval Date:
U.S. Estimated Active Implants: 15,000
U.S. Chronic Lead Complications: 956
U.S. Malfunctions:161

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 89000	99.88 (-0.0/+0.0)	99.79 (-0.0/+0.0)	99.68 (-0.0/+0.0)	99.50 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.72 (-0.1/+0.1)	98.54 (-0.1/+0.1)	98.41 (-0.1/+0.1)	98.28 (-0.1/+0.1)
Effective Sample Size	77716	69454	62065	55311	49106	43278	38074	33561	29653	26155

SWEET TIP RX
Positive Fixation

Models 4143/4144/4145/4243/4244/
4245

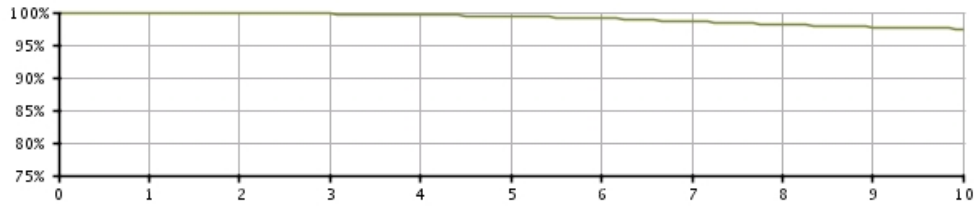
U.S. Survival Probability	Worldwide Malfunction Details	Product Advisories

U.S. Summary

U.S. Registered Implants: 34,000
U.S. Approval Date: October 1998
U.S. Estimated Active Implants: 7,000

U.S. Chronic Lead Complications: 485
U.S. Malfunctions:28

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 34000	99.90 (-0.0/+0.0)	99.82 (-0.1/+0.0)	99.76 (-0.1/+0.1)	99.63 (-0.1/+0.1)	99.37 (-0.1/+0.1)	99.10 (-0.1/+0.1)	98.58 (-0.2/+0.2)	98.11 (-0.2/+0.2)	97.75 (-0.2/+0.2)	97.44 (-0.3/+0.2)
Effective Sample Size	29682	26536	23705	21101	18665	16404	14399	12492	10721	9119

Confirmed Malfunction Details: Leads

References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each confirmed lead malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

1. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
2. **Inner insulation abrasion**— Loss of capture, decreasing impedance, increased pacing thresholds, noisy signals, oversensing. Abrasion of inner insulation.
3. **Seal rings**— Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.
4. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
5. **Lead body**— Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.
6. **Terminal leg insulation**— Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.
7. **Lead conductor**— Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.
8. **Lead body**— Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.
9. **Lead conductor**— Loss of sensing, loss of pacing. Physical damage to lead body due to repeated flexing.
10. **Lead conductor**— Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component may lead to fatigue of high-voltage lead conductor. Improvement implemented.
11. **Lead connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
12. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
13. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
14. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.
15. **Electrode tip**— Separation between electrode tip and lead body.
16. **Lead body**— Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.
17. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.
18. **IS-1 terminal pin**— Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.
19. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
22. **DF-1 terminal pin**— Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.
23. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
24. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
25. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.

26. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.

27. **Non-patterned, Other**— Confirmed malfunction for which the root cause does not fit within other categories and is not associated with other malfunctions, or has not yet been identified.

28. **Non-patterned, Conductor**— Conductor malfunction (including clavicle fatigue or crush damage) where the root cause is not associated with other malfunctions.

29. **Non-patterned, Insulation**— Lead insulation breach (including damage due to lead-on-lead or lead-on-anatomy contact, clavicle fatigue or crush) where the root cause is not associated with other malfunctions.

32. **Non-patterned, Crimp, Weld, Bond**— Interruption in conductor or lead body associated with a point of connection where the root cause is not associated with other malfunctions.

33. **Conductor damage**— Noise, oversensing, inappropriate shocks, possible loss of therapy. Conductor damage attributed to application of compressive or torsional loads which may be due to clavicle-first rib entrapment.

34. **Insulation damage**— Low pacing impedance, noise, possible loss of therapy. Insulation abrasion due to lead-on-lead or lead-on-can contact, or due to application of compressive or torsional loads which may be due to clavicle-first rib entrapment. Damage to lead body may expose conductor.

35. **Extracardiac fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue near suture sleeve, not including clavicle-first rib damage, leading to discontinuity of conductor.

36. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.

37. **Weld fracture**— Noise, loss of sensing. Fractured weld.

38. **Conductor cable fracture**— High impedance, potential loss of pacing and defibrillation therapy. Fractured high-voltage cable.

39. **Inner conductor break**— High impedance, loss of capture, loss of sensing. Inner conductor break. Commonly associated with helix extension/retraction difficulties at implant.

U.S. Chronic Lead Complications (Occurring After the First Month of Service)

Boston Scientific strives to provide meaningful detail in describing the performance of our products. U.S. Chronic Lead Complications are reported in compliance with ISO 5841-2: 2014 (E), Reporting of Clinical Performance of Populations of Pulse Generators or Leads. To be included in the Chronic Lead Complications table, a lead must be successfully implanted, with clinical observations (as listed in the table) occurring after the first month of implant, and have been removed from service surgically or electronically. The lead either was not returned for analysis, or was returned but had no confirmation of a malfunction.

While multiple complications are possible for any given lead, only one complication is reported per lead. The complication reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Chronic Lead Complications are included in the calculation of survival probability. Complications for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are provided.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	234000	72	740	825	668	254	81	155	366	0	63
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	185000	4	308	191	169	31	19	148	167	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	443000	21	495	628	316	66	75	394	306	0	33
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	60000	1	91	298	104	8	18	59	35	0	6
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	85	19	36	11	3	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	51000	0	214	73	73	49	15	68	87	0	4

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	29000	2	25	415	39	2	1	9	22	0	92
ACUITY Spiral 4591/4592/4593	23000	0	13	253	25	1	1	2	5	0	138

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	28	256	38	4	1	9	10	0	89
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	96000	1	259	1088	230	5	7	60	74	0	448
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	63	397	102	2	0	46	30	0	257

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	53000	10	15	61	13	8	7	3	4	4	3
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	0	1	4	0	2	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	54000	13	14	53	19	11	7	2	6	8	3
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	0	0	1	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	27	386	341	121	440	63	92	194	155	24
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	87	63	45	73	7	34	129	31	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	6	44	42	16	36	1	7	27	24	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	2	5	1	3	0	1	2	2	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	12000	0	0	0	0	0	0	0	0	0

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1375	0	0	21	2	0	0	0	0	0	8
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	741	0	0	0	0	0	0	0	1	1	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	846	0	0	1	1	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	0	1	0	0	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	922	0	1	0	0	0	0	0	0	0	0

U.S. Acute Lead Observations

Boston Scientific strives to provide meaningful detail reflective of real-world product experience. In the first weeks following lead implantation, physiologic responses and lead performance can vary until chronic lead stability is attained. Acute lead performance may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques.

Because acute implant time contributes to overall clinical experience. Boston Scientific provides specific information regarding acute llead performance. To be included in the Acute Lead Observations table, a lead must first be successfully implanted, with clinical observations occurring within the first month of implant. These reports may or may not have resulted in clinical action and/or product return to Boston Scientific. The categories are consistent with the AdvaMed guidance for *Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads* . Although multiple observations are possible for any given lead, only one observation is reported per lead. The observation reported is determined by an observation hierarchy, indicated by the order of the categories from left to right in the table. The number of U.S. Registered Implants is also provided as context for the data. Acute Lead Observations are not included in calculation of lead survival probability. Observations for both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry (bottom of table) are included.

Pacing Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
FLEXTEND Active Fixation 4086/4087/4088	234000	236	195	1356	428	76	89	55	214	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	185000	15	13	440	174	7	27	24	38	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	443000	80	80	696	244	110	95	57	244	0	42
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	60000	1	18	446	92	7	30	17	21	0	10
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	33	17	1	2	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	51000	3	18	104	27	9	10	21	13	0	6

CRT Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Steerable 4554/4555/4556	29000	1	3	329	46	24	2	7	134	0	242
ACUITY Spiral 4591/4592/4593	23000	5	4	208	67	9	1	10	39	0	241

CRT Leads/Model (cont.)	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	270	39	12	2	8	48	0	186
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	96000	13	7	929	132	45	9	27	200	0	729
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	18	34	0	186

Defibrillation Leads/Model	U.S. Registered Implants	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	53000	43	29	153	75	52	11	7	79	17	10
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	2000	2	0	8	1	3	0	0	17	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	54000	54	39	136	51	65	18	5	73	65	20
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	1	1	2	2	1	1	0	15	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	150	189	647	169	366	54	69	360	234	81
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	8	2	107	46	57	8	5	177	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	28	16	76	29	31	14	3	57	118	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	2	1	1	2	0	11	1	0

S-ICD Electrodes/Model	U.S. Registered Implants	Perforation	Conductor fracture	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal defibrillation impedance	Extracardiac stimulation
EMBLEM/Q-TRAK S-ICD Electrode 3010/3011	12000	1	0	16	0	130	9	1	38	1

Longitude Surveillance Registry	Leads Enrolled	Cardiac Perforation	Conductor fracture/ helix damage	Lead dislodgement	Failure to capture	Oversensing	Failure to sense	Insulation breach	Abnormal pacing impedance	Abnormal defibrillation impedance	Extracardiac stimulation
ACUITY Spiral 4591/4592/4593	1375	0	0	12	10	1	0	0	3	0	48
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	846	0	2	12	0	0	0	1	2	0	3
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1103	6	1	10	5	5	3	0	2	1	2
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	741	0	0	1	0	1	0	1	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	922	0	0	1	1	0	0	0	0	0	0

Before/During Implant Procedure - Worldwide Malfunctions: Leads

This section of the report depicts the number of product malfunctions that occurred worldwide either before implant (prior to opening the sterile product packaging) or during implant (once the sterile product packaging has been opened). In all cases, the product in question must be returned to Boston Scientific CRM and confirmed through laboratory analysis to have operated or exhibited a problem outside the specified performance limits established by Boston Scientific. Damage incurred during shipping/transit or due to external factors warned against in labeling is not reported as device malfunction here.
The Conductor category includes any conductor break or damage with complete or intermittent loss of continuity that could interrupt current flow, including clavicle fatigue or crush damage. The Insulation category includes any lead insulation breach, such as damage due to lead-on-lead or lead-on-anatomy contact, or clavicle fatigue or crush. The Crimp/Weld/Bond category includes any interruption in the conductor or lead body associated with a point of connection. The Other category includes malfunctions for which the root cause does not fit within other categories or has not yet been determined. The Labeling and Packaging categories include product identification issues and damage to sterile packaging, respectively. The Implant Accessory category includes lead malfunctions due to catheter, guidewire or sheath issues.

CRT Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ACUITY X4 Spiral L 4677/4678	5,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	8,000	0	0	0	0	0	0	0
ACUITY X4 Straight 4671/4672	8,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	63,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	42,000	0	0	0	2	1	0	0
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	42,000	0	2	0	17	0	0	2
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	175,000	0	5	0	7	1	1	1
EASYTRAK 4510/4511/4512/4513/4535/4536/4537/4538	53,000	0	0	0	4	0	0	3

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE G 4-FRONT Dual Coil Active Fixation 0658/0695/0696	8,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	24,000	2	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Passive Fixation 0654/0682/0683	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil Active Fixation 0275/0276/0295/0296	86,000	0	0	0	61	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	8,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	89,000	0	0	0	21	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Passive Fixation 0282/0283	4,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE Dual Coil Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	371,000	0	0	44	486	0	3	14
ENDOTAK RELIANCE Dual Coil Passive Fixation 0147/0148/0149/0174/0175/0176/0177	107,000	0	1	3	87	0	3	0
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	66,000	0	0	7	62	0	1	3
ENDOTAK RELIANCE Single Coil Passive Fixation 0127/0128/0170/0171/0172/0173	7,000	0	0	0	2	0	0	0

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	19,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Passive Fixation 7631/7632/7731/7732	14,000	0	0	0	0	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	98,000	261	0	0	343	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	12,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	178,000	0	0	10	121	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	286,000	0	0	55	599	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	508,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	675,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	285,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	102,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	137,000	0	1	1	25	1	6	0

*Counts consist of Boston Scientific and Intermedics co-branded pacing leads data.

Product Advisories

A Product Advisory is a voluntary letter issued to inform physicians of an anomalous device behavior identified by Boston Scientific's Quality System. A Product Advisory is issued when there is a material elevation in risk to patient safety with potential for compromised lifesaving therapy, or when Boston Scientific can provide meaningful guidance to improve patient outcomes or device performance. Boston Scientific considers many perspectives in the decision to issue a Product Advisory, including internal expertise and guidance from an independent Patient Safety Advisory Board (PSAB). The Board includes cardiac electrophysiology, engineering, statistics, risk management and bioethics experts.

This report section includes summaries of Product Advisories for which significant, active U.S. device populations exist. In general, this includes advisories for which the estimated active U.S. advisory population is at least 200. Physician and patient letters, as well as Advisory Updates, are available at www.bostonscientific.com. With respect to the number of reported events listed in the summaries below, Boston Scientific recognizes that the actual number of clinical malfunctions may be greater than the number actually reported. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION **17-Nov-2014 - AUTOGEN RVAT November 2014**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **AUTOGEN CRT-D** Models G172/G173/G175/ G177/G179 **AUTOGEN ICD MINI DR** Models D046/D047 **AUTOGEN ICD EL DR** Models D176/D177	Voluntary Physician Advisory AUTOGEN DR ICD and CRT-D devices include the option of enabling a Right Ventricular Automatic Threshold (RVAT) test to determine the RV pacing threshold and adjust amplitude in an ambulatory setting. If the RVAT test feature is enabled and noise signals are continuously sensed within a brief RV noise window following an Atrial pace, a patient may not receive effective pacing support until the RVAT test ends (i.e., up to 20 cardiac cycles). Although no patients have been harmed in the cases reported to date, brief periods of dizziness were reported in one case. Note that there is no additional risk for patients in whom the RVAT feature is disabled. Single-chamber AUTOGEN ICDs (VR models) have not demonstrated this behavior. The Left Ventricular Auto Threshold (LVAT) test (for AUTOGEN CRT-Ds) and the Right Atrial Auto Threshold (RAAT) test (for AUTOGEN CRT-Ds and dual-chamber ICDs) are not subject to this device behavior and are performing as intended. In addition, Boston Scientific pacemaker and CRT-P models with similar automatic pacing threshold test features are performing as intended and thus are not subject to this device behavior. Boston Scientific is developing a software solution that will prevent this device behavior from occurring when the RVAT test feature is enabled. Following geography-specific regulatory approval, this software solution will be implemented via a non-invasive download from the programmer.
AUTOGEN RVAT November 2014 Physician Letter, Nov 17, 2014 AUTOGEN RVAT November 2014 Patient Letter, Nov 17, 2014	CURRENT STATUS **08-Apr-16** *Reported events (worldwide)* Four (4) reports have been received worldwide of ineffective pacing support during an RVAT test. There have been no reported patient deaths associated with this advisory.
	CURRENT RECOMMENDATION **08-Apr-16** Updated software is available in the U.S. and most geographies which provides effective pacing support with the RVAT test feature enabled for ambulatory use. If the software update has not been performed, Boston Scientific recommends the following: 1. For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use: • Select the SETTINGS tab • Select the SETTINGS SUMMARY tab • In the BRADY section, select the NORMAL SETTINGS details icon • In the PACING and SENSING section, select the desired pacing RV Amplitude (do not select Auto) • Ensure that DAILY TREND is not selected • Press PROGRAM to implement the selected fixed amplitude pacing output. 2. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilizing the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude).
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.
COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108 **TELIGEN VR** Models E102/E103/F102/F103 **TELIGEN DR** Models E110/E111/F110/F111	The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping. The most common alert is a yellow programmer screen that states, “Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003”. LATITUDE issues a corresponding yellow alert (nominally configured “On”). In other instances, diminished LV capacitor performance can result in an early “Explant” battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry. Advisory population Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.
Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014 Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014 Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013	CURRENT STATUS **08-Apr-16** Advisory devices have not been available for implant for more than three years. *Confirmed Malfunctions (worldwide)* 3,404 malfunctions have been confirmed from the advisory population. Approximately 41,000 devices from the advisory population remain in service. There has been one reported patient death associated with this advisory. *Projected Rate of Occurrence* The rate of occurrence for advisory population devices is 5.7% at 72 months. The projected rate of occurrence at 84 months is approximately 9.6%.
	CURRENT RECOMMENDATION **08-Apr-16** Updated Software In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted. LATITUDE Patient Management System Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if/when scheduled checkups have not occurred. Verify that the yellow alert “Voltage was too low for projected remaining capacity” is configured “On”. Additional Recommendations - After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling. - Device replacement is not recommended for advisory devices displaying normal behavior. - Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages. - Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that “Approximate time to Explant” and “Time Remaining” estimates displayed on the programmer are not accurate following a low voltage alert.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **01-Jun-11 — High Cathode Condition**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **SQ-RX S-ICD** Model1010 High Cathode Condition Physician Letter, Jun 01, 2011 High Cathode Condition Patient Letter, Jun 01, 2011	Voluntary Physician Advisory Boston Scientific has determined that a specific subset of SQ-RX pulse generators may not achieve the five (5) year typical longevity due to premature battery depletion. Although the longevity of these devices may be shortened, therapy remains available through the onset of the Elective Replacement Indicator (ERI). This subset of devices also has the potential for the time between the onset of the ERI and End of Life (EOL) indicators to be less than the nominal three (3) months. The risk for premature battery depletion is due to a specific condition within an individual battery cell. No affected devices remain available for implant. *Rate of Occurrence* Cameron Health has confirmed one (1) occurrence of a device experiencing premature battery depletion due to this condition. Cameron Health conducted a systematic analysis of all implanted devices worldwide and identified two populations at risk for premature battery depletion due to this condition: – Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date. – Population II consists of 386 devices for which manufacturing records cannot exclude the possibility of the condition existing within a battery cell. Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There have been zero (0) confirmed occurrences in this population to date.
	CURRENT STATUS **08-Apr-16**
	No devices in the advisory population remain available for implant. *Confirmed Malfunctions (worldwide)* Three (3) malfunctions have been confirmed worldwide of devices experiencing High Cathode Condition. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* – Population I – Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. – Population II - Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity.
	CURRENT RECOMMENDATION **08-Apr-16**
	– If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible. – Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone. For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **July 2010— Magnetic Reed Switch 2010**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II Some Boston Scientific defibrillators include a component referred to as a “magnetic reed switch,” designed to sense the presence of a magnet. If Enable Magnet Use is programmed to On (nominally On) and a magnet is applied in emergent situations or during a medical/surgical procedure, the switch is designed to close and temporarily prevent delivery of undesired tachy therapy. When the magnet is removed, the magnetic switch is designed to open and thereby restore ability to deliver programmed tachy therapy.
CONTAK RENEWAL 3 Models H170/H175 **CONTAK RENEWAL 3 HE** Models H177/H179	Magnetic reed switch technology has historically demonstrated a very low but non-zero rate of failing to open upon magnet removal. However, certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007 have exhibited a somewhat higher rate of magnetic reed switch failure. Approximately 34,000 of these devices remain actively implanted; no devices in this population are available for implant. Devices manufactured after November of 2007 have returned to historic performance rates and are not included in this advisory
CONTAK RENEWAL 3 RF Models H210/H215 **CONTAK RENEWAL 3 RF HE** Models H217/H219	No patient deaths or injuries have been reported as a result of this issue, although some devices have been replaced. Most devices with a magnetic reed switch confirmed to be stuck in a closed position have remained implanted after “Enable Magnet Use” was programmed to Off (see Recommendations).
CONTAK RENEWAL 4 Models H190/H195/H197/H199	Rate of Occurrence A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.
CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179 **CONTAK RENEWAL 4 RF** Models H230/H235/H239	CURRENT STATUS **08-Apr-16** There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.
VITALITY DR HE Model T180	CURRENT RECOMMENDATION **08-Apr-16** Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device. In addition, Boston Scientific recommends:
Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010	1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.
Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010	2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. [NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]

July 2010— Magnetic Reed Switch 2010, continued…

CURRENT RECOMMENDATION, continued…

3) If a stuck magnetic switch is confirmed, program the Enable Magnet Use feature to Off, which ensures that programmed therapy will be provided to treat tachyarrhythmias. However, if Enable Magnet Use is programmed Off:

– A magnet will no longer inhibit tachy therapy.
– The Patient Triggered Monitor feature will no longer be available.

Contact Boston Scientific Technical Services (1-800-CARDIAC) for assistance to re-activate Daily Measurements for devices with a stuck magnetic switch.

4) After consultation with our Independent Patient Safety Advisory Board, **Boston Scientific does not recommend prophylactic explant**. We further advise that physicians **do not routinely program Enable Magnet Use to Off in the absence of a confirmed stuck magnetic reed switch** because the benefits of magnet use to disable tachy therapy in emergent situations outweigh the probability of patient harm associated with a stuck reed switch.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant 2009**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.
This advisory is limited to those models listed below implanted subpectorally.	Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.
COGNIS Models N106/N107/N108/N118/N119 P106/P107/P108 **TELIGEN VR** Models E102/F102 **TELIGEN DR** Models E110/E111/F110/F111	A weakened header bond can result in one or more of the following device behaviors: – Significant changes in measured lead impedance – Noise on real-time or stored electrograms – Intermittent inhibition of pacing – Inappropriate anti-tachy pacing or shock therapy – Loss of pacing therapy – Loss of anti-tachy pacing and shock therapy No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.
Subpectoral Implant 2009 Physician Letter, Dec 01, 2009 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)
	CURRENT STATUS **08-Apr-16**
	COGNIS and TELIGEN devices are available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired. *Reported events (worldwide)* Ninety-four (94) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. There have been no reported patient deaths associated with this advisory. *Rate of Occurrence* An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.

01-Dec-09 — Subpectoral Implant 2009, continued…

CURRENT RECOMMENDATION **08-Apr-16**

If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended.

For affected devices implanted in a subpectoral location:
– Follow patient at least once every three months as recommended in device instructions for use.
– Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.
– Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

COGNIS and TELIGEN devices are now available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **05-Apr-07 and 04-Mar-09— Shortened Replacement Window**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool	Voluntary Physician Advisory FDA Classification: Class II Low-voltage capacitors may be subject to degradation. These capacitors may cause accelerated battery depletion and may reduce the time between Elective Replacement Indicator (ERI) and End Of Life (EOL) to less than three months. Device replacement indicators continue to function normally.
CONTAK RENEWAL 4 RF HE Model H239	In April 2007, Boston Scientific CRM communicated with physicians regarding a population of devices subject to this failure mechanism. As of March 2009, the April 2007 advisory population has not experienced any clinically significant changes to either the rate of occurrence or patient management recommendations.
CONTAK RENEWAL 4 RF Models H230/H235	
CONTAK RENEWAL 4 HE Models H197/H199	In March 2009, a second population was identified of 856 active ICDs and CRT-Ds manufactured with capacitors from the same supplier that may be subject to the same failure mechanism. The cumulative failure rate for accelerated depletion within this population is approximately 6% at 42 months and is projected to increase. Recommendations described in April 2007 have been 99.9% successful in identifying susceptible devices and ensuring replacement at ERI in the original population, and will minimize patient risk associated with a shortened replacement window when applied to this second population. No devices from this population have been registered as implanted after April 2007. No devices in this subset remain available for implant.
CONTAK RENEWAL 4 Models H190/H195	
CONTAK RENEWAL 4 AVT / AVT HE Models M170/M175/M177/M179	CURRENT STATUS **08-Apr-16**
CONTAK RENEWAL 3 RF HE Models H217/H219	*Confirmed Malfunctions (worldwide)* **April 2007 Population** 2,566 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices.
CONTAK RENEWAL 3 RF Models H210/H215	115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).
CONTAK RENEWAL 3 HE Models H177/H179	**March 2009 Population** 117 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).
CONTAK RENEWAL 3 Models H170/H175	
CONTAK RENEWAL 3 AVT / AVT HE Models M155/M159	There have been no reported patient deaths associated with either advisory population. No devices currently being distributed are susceptible to this malfunction mode.
VITALITY 2 EL VR/DR Models T177/T167	*Rate of Occurrence* **April 2007 Population** The cumulative rate of occurrence for accelerated battery depletion for the April 2007 advisory population is approximately 5.0% at 60 months.
VITALITY 2 VR/DR Models T175/T165	**March 2009 Population** The cumulative rate of occurrence for accelerated battery depletion for the March 2009 advisory population is approximately 15.8% at 60 months.
VITALITY DR HE Model T180	
VITALITY DS VR/DR Model T135/T125	Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.

VITALITY EL
Model T127

VITALITY AVT A155
Model A155

Shortened Replacement Window Physician Letter, Mar 04, 2009

Shortened Replacement Window Patient Letter, Mar 04, 2009

Shortened Replacement Window Physician Letter, Apr 5, 2007

Shortened Replacement Window Patient Letter, Apr 5, 2007

05-Apr-07 and 04-Mar-09— Shortened Replacement Window, continued…

CURRENT RECOMMENDATION **08-Apr-16**

Patient management recommendations from the April 5, 2007 physician communication remain unchanged.

If a patient has a device with a degraded capacitor, the time from implant to 2.65 volts (Middle of Life 2 / MOL2) will be reduced.

To determine whether a patient may be at risk for a reduced ERI to EOL time, note when 2.65 volts (MOL2) was observed. For each patient:

1. Review patient records to assess battery voltage.
2. If battery voltage is ***above*** 2.65 volts (MOL2), continue to follow patient every three months per device labeling.

3. If battery voltage is ***at or below*** 2.65 volts (MOL2), determine the time between device implant and this observation.
4. If the time from implant to 2.65 volts (MOL2) is greater than 27 months (32 months for VITALITY® EL / 2 EL / HE devices), the patient is not at risk for a shortened ERI to EOL time, and **this advisory no longer applies.**
5. If the time from implant to 2.65 volts (MOL2) is 27 months or less (32 months for VITALITY® EL / 2 EL / HE devices), **the patient should be followed monthly until ERI.** For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed as ERI to EOL time may be shortened.

NOTE: If it is not clear when a battery voltage of less than 2.65 volts (MOL2) was reached, conduct a memory “Save to Disk” and return (mail or e-mail) to Boston Scientific CRM for prompt analysis. Contact your local Boston Scientific representative or Technical Services for further assistance

In geographies where available, the LATITUDE® Patient Management System can facilitate remote patient monitoring and provide automatic notification when the device reaches a battery status of ERI.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **CONTAK RENEWAL 4 RF HE** Model H239 **CONTAK RENEWAL 4 RF / HE** Models H230/H235/H197/H199 **CONTAK RENEWAL 4 and 4 AVT / AVT HE** Models H190/H195/M170/M175/ M177/M179 **CONTAK RENEWAL 3 RF HE** Models H217/H219 **CONTAK RENEWAL 3 RF / HE** Models H210/H215/H177/H179 **CONTAK RENEWAL 3 and 3 AVT / AVT HE** Models H170/H175/M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE and EL** Model T180 and Model T127 **VITALITY DS VR/DR** Model T135/T125 **VITALITY AVT A135 / A155** Models A135/A155 **VITALITY VR/DR and DR+** Models 1871/1870/1872 **ASSURE** Model B301 Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007 Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007	FDA Classification: Devices in Table 1, Column 1 of this *Product Update* were classified as Class II (27-November-07) Certain devices may display ERI or EOL during mid-life (typically 24–48 months), even though battery voltage (typically greater than or equal to 2.65 volts) and capacity remain available. This behavior is caused by high battery impedance rather than low battery voltage. Devices that have triggered charge time-based ERI or EOL during mid-life have several months, and in most cases more than one year of remaining battery voltage and capacity, which allows the devices to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled. *Rate Projection* Certain devices, typically implanted prior to July 2005 (Table 1, Column 1 of the Product Update) are projected to exhibit Mid-Life Display of Replacement Indicators as indicated below: – VITALITY AVT (Model A135), VITALITY VR/DR, VITALITY DR+ (**Projected rate: 8–10%**) – VITALITY AVT (Model A155), VITALITY DS VR/DR, VITALITY 2 VR/DR, ASSURE (**Projected rate: 4–7%**) – VITALITY EL; VITALITY 2 EL DR/VR; VITALITY DR HE; CONTAK RENEWAL 3/4/3HE/4HE; CONTAK RENEWAL 3 RF/4RF/3RF HE/4RF HE; CONTAK RENEWAL 3 AVT/4AVT/3AVT HE/4AVT HE (**Projected rate: 1–2%**) Continuous manufacturing improvements intended to reduce variability in battery performance have been implemented by our battery supplier, which mitigate the occurrence of mid-life display of replacement indicators. CURRENT STATUS **08-Apr-16** *Confirmed Malfunctions (worldwide)* For confirmed malfunction counts related to a specific product family, refer to the Confirmed Malfunction Details section of the Product Performance Report and see pattern titled “Mid-life display of replacement indicators.” *Projected Rate of Occurrence* For projected rates of occurrence see device-specific ranges listed above. Some performance differences have been observed between product families. For example, dual chamber devices have generally performed better than single chamber devices within the same product family. For current performance of a specific product family, refer to the U.S. Survival Probability section of the Product Performance Report and see population titled “10–Mar-07 Product Update — Mid-Life Display of Replacement Indicators.” CURRENT RECOMMENDATION **08-Apr-16** Patient management recommendations from the March 10, 2007 Product Update remain unchanged. *Patient Management Considerations* – Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled. – Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL. – Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI. – Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding a manual capacitor reform may be helpful in characterizing the current charge time. Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **23-Jun-06 and 24-Aug-06— Low Voltage Capacitor**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492 **CONTAK RENEWAL TR / TR2** Models H120/H125/H140/H145 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY 2 VR/DR** Models T175/T165 **VITALITY DR HE** Model T180 **VITALITY DS VR/DR** Models T135/T125 **VITALITY VR/DR and EL** Models 1870/1871/T127	Voluntary Physician Advisory FDA Classification: Class II Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue. *Reported Events (worldwide)* At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing. *Projected Rate of Occurrence* While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future. CURRENT STATUS **08-Apr-16** *Confirmed Malfunctions (worldwide)* 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation. There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* The rate of occurrence is projected to range between 0.10% and 0.22%. CURRENT RECOMMENDATION **08-Apr-16** Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged. – Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients whenmaking medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation. **Device Behavior** **Pacemakers: INSIGNIA/NEXUS** – Intermittent or permanent loss of pacing output – Inability to interrogate – Erased values in Daily Measurements – ERT or EOL indicator message displayed earlier than expected – A gas gauge less than BOL within six months of implant

	23-Jun-06 and 24-Aug-06— Low Voltage Capacitor, continued…
VENTAK PRIZM 2 VR/DR Models 1860/1861	CURRENT RECOMMENDATION, continued…
Low Voltage Capacitor, Physician Letter, Aug 24, 2006 Low Voltage Capacitor, Patient Letter, Aug 24, 2006 Low Voltage Capacitor, Physician Letter, Jun 23, 2006	**CRT-Ps: RENEWAL TR/TR2** – ERI or EOL indicator message displayed earlier than expected – Fault Code 11 message (high current indicator) – A gas gauge less than BOL within six months of implant **ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2** – ERI or EOL indicator message displayed earlier than expected – A battery voltage **less than 3.10V** within six months of implant
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **12-May-06 and 04-Jan-08 Subpectoral Implant**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool *This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs..*	Voluntary Physician Advisory FDA Classification: Class II Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this subpectoral failure mode will not occur in a subcutaneous position or in a position with the serial number facing up.
CONTAK RENEWAL 4 HE Models H197/H199 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 AVT / AVT HE** Models M170/M175/M177/M179 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 AVT / AVT HE** Models M155/M159 **VITALITY 2 EL VR/DR** Models T177/T167 **VITALITY DR HE** Model T180 **VITALITY EL** Model T127 **VITALITY DR+** Model 1872	This failure mechanism can result in one or more of the following device behaviors: – Loss of shock therapy – Loss of pacing therapy (intermittent or permanent) – Loss of telemetry communications – Beeping (16 tones every six hours), and a programmer warning screen upon interrogation *Reported Events* Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism. *Rate of Occurrence* The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.
	CURRENT STATUS **08-Apr-16**
	Confirmed Malfunctions (worldwide) May 12, 2006 Population Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation. January 4, 2008 Population Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation. There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence* The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.
	CURRENT RECOMMENDATION **08-Apr-16**
Subpectoral Implant, Physician Letter, Jan 04, 2008 Subpectoral Implant, Patient Letter, Jan 04, 2008	Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication. – For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. – For subpectoral implants, use an AP radiograph to determine specific device orientation. - If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary.

12-May-06 and 04-Jan-08 Subpectoral Implant, continued…

CURRENT RECOMMENDATION, continued…

If the device is in a susceptible orientation (serial number facing the ribs):

– Advise patient of the potential for device failure.

– Follow patient at 3 month intervals in accordance with device labeling.

– Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

– For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **22-Sep-05 — Crystal Timing Component**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **INSIGNIA Ultra SR** Models 1190/1390 **INSIGNIA Ultra DR and Ultra DR Downsize** Models 1291/1491/1290/1490 **INSIGNIA Entra SR** Models 1195/1198/1395/1398 **INSIGNIA Entra DR (downsize)** Models 1296/1466 **INSIGNIA Entra DR** Models 1294/1295/1494/1495 **INSIGNIA Entra SSI** Models 0484/0485/1325/1326 **INSIGNIA Entra DDD** Models 0985/0986/1426 **INSIGNIA Plus SR** Models 1194/1394 **INSIGNIA Plus DR and Plus DR Downsize** Models 1297/1467/1298/1468 **INSIGNIA AVT** Models 0482/0882/0982 1192/12921392/1428/1432/1492	Voluntary Physician Advisory FDA Classification: Class II Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of September 22, 2005, the root cause of the second failure mode had not yet been determined and analysis was ongoing. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component. *Reported Events* Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004. Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths. *Rate Projection* Failure Mode 1—As of the September 22, 2005 communication, Guidant's modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
	CURRENT STATUS **08-Apr-16**
	Confirmed Malfunctions (worldwide) Failure Mode 1— 62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory. Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory. None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 4,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **08-Apr-16**
Crystal Timing Component, Physician Letter, Dec 12, 2005 Crystal Timing Component, Patient Letter, Oct 03, 2005 Crystal Timing Component, Physician Letter, Sep 22, 2005	Failure Mode 1— Patient management recommendations from the September 22, 2005 physician communication remain unchanged. Failure Mode 2— Patient management recommendations supersede those originally communicated on September 22, 2005. – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
	Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION **18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **CONTAK TR** Model 1241 **DISCOVERY II SR (downsize)** Models 1184/1384 **DISCOVERY II SR** Models 1186/1187/1385 **DISCOVERY II DR (downsize)** Models 1283/1483 **DISCOVERY II DR** Models 1284/1286/1484/1485 **DISCOVERY II SSI (downsize)** Models 0481/1349 **DISCOVERY II DDD** Models 0981/1285/1499 **PULSAR MAX II SR (downsize)** Models 1180/1380 **PULSAR MAX II SR / DR** Models 1181/1290/1480 **DISCOVERY SR/SR (downsize)** Models 1174/1175 **DISCOVERY DR/DR (downsize)** Models 1274/1275/1273 **PULSAR MAX SR (downsize)** Model 1170 **PULSAR MAX SR / DR** Model 1171/1270 **PULSAR** Models 1272/0470/0870/0970/0972/1172 **MERIDIAN SSI / DDD** Models 0476/0976 **MERIDIAN SR / DR** Models 1176/1276	Voluntary Physician Advisory (18-Jul-05) FDA Classification: Class I Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I A hermetic sealing component utilized in a subset of pacemakers may experience a gradual degradation, resulting in higher than normal moisture content within the pacemaker case late in the device's service life; this could lead to a variety of inappropriate clinical behaviors. The original July 18, 2005 physician communication bounded the population to approximately 78,000 devices manufactured between November 25, 1997 and October 26, 2000; this number was further refined to 77,500 devices manufactured between October 27, 1997 and October 26, 2000. The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated at that time to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis. A Second Population of 54,000 devices was subsequently identified to be at risk of hermetic seal degradation (but at a much lower rate than the original population). This was communicated in the January 21, 2006 letter. Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below). Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence. *Rate Projection* Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 had increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and was projected to range between 0.31% and 0.88% over the remaining device lifetime. Second Population—For the remaining lifetime of the estimated worldwide 19,300 active devices, the projected rate of occurrence for reported events was estimated to be between 0.02% and 0.06%.
	CURRENT STATUS **08-Apr-16**
	Reported Events (worldwide) Refined Original Population— 342 malfunctions have been confirmed out of the 77,500 advisory population devices. Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices. *Projected Rate of Occurrence* Refined Original Population—The rate of occurrence for the estimated worldwide active device population of 3,000 is projected to range between 0.31% and 0.88% over the remaining device lifetime, as communicated in the January 21, 2006 Advisory Update letter. Second Population—The rate of occurrence for the estimated worldwide active device population of 2,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.

18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component, continued…

CURRENT RECOMMENDATION **08-Apr-16**

Hermetic Sealing Component, Physician Letter, Jan 21, 2006

Original Population— **Patient management recommendations from the July 18, 2005 physician letter remain unchanged**; however, physicians should reassess patients in light of the increased projected rate of occurrence communicated in the January 21, 2006 Advisory Update letter.

Hermetic Sealing Component, Patient Letter, Jan 21, 2006

Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.

Hermetic Sealing Component, Physician Letter, Jul 18, 2005

– Consider replacing devices for pacemaker-dependent patients.
– Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure.

– Select a suitable Maximum Sensor Rate (MSR) setting, given the rare possibility that inappropriate sustained pacing at MSR can occur

OR
– Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR.
– Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a malfunction that has already occurred, but does not guarantee that the device will not exhibit this malfunction mode in the future. At each patient follow-up:

- Evaluate for the clinical behaviors described in the July 18, 2005 letter.
- Evaluate battery status for signs of early or rapid depletion between sequential follow-up visits.
- Evaluate the accelerometer rate response (for devices with this feature).
  - — Accelerometer ON:
    - Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit (LRL) while the patient is at rest.
    - Look for lack of rate response with activity (i.e., isometrics, short hall walk).
  - — Accelerometer OFF:
    - *Temporarily* program the accelerometer ON and evaluate as described above

– Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.

– If any of these device behaviors are observed, contact your local representative or Technical Services for troubleshooting and recommendations.

Standard Warranty program available, please contact your local representative for terms and conditions.

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300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
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