Boston Scientific

Advancing science for life™

2017

Rhythm Management Product Performance Report

Q1 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 Q1 2017 report includes data through January 11, 2017.

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.

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

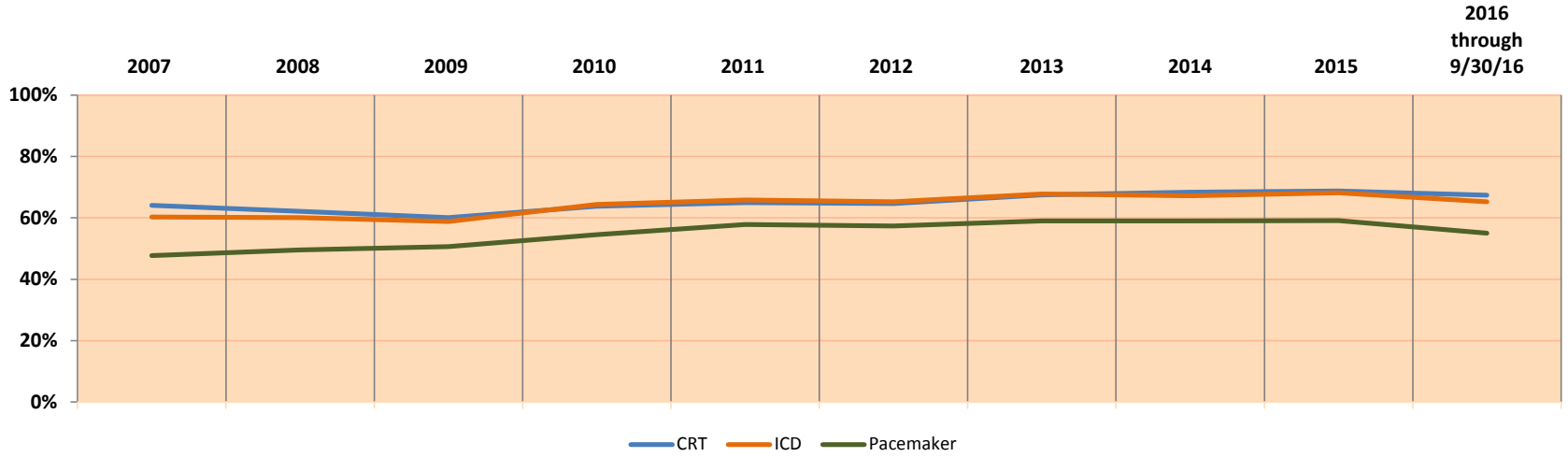
The data in this report reflect Boston Scientific's understanding of product performance. We acknowledge that there is underreporting. If you have product performance observations to report, please contact your local Boston Scientific sales representative or Boston Scientific's Technical Services department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



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016 through 9/30/16
Explants	4247	5678	9264	10472	9311	8033	8296	6885	4988	3366
Returns	2723	3528	5563	6681	6043	5193	5595	4706	3427	2269
% Returned	**64%**	**62%**	**60%**	**64%**	**65%**	**65%**	**67%**	**68%**	**69%**	**67%**
Explants	11535	15550	19490	19918	16563	11950	11878	11249	9943	6288
Returns	6947	9344	11465	12826	10898	7800	8048	7561	6774	4100
% Returned	**60%**	**60%**	**59%**	**64%**	**66%**	**65%**	**68%**	**67%**	**68%**	**65%**
Explants	18397	20440	21003	21106	19994	18674	18757	19240	19507	14512
Returns	8780	10133	10633	11509	11567	10713	11075	11352	11528	7988
% Returned	**48%**	**50%**	**51%**	**55%**	**58%**	**57%**	**59%**	**59%**	**59%**	**55%**

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: 17,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**1**	**5**
[80] High voltage circuit component	3	-	
[81] Integrated circuit	1	1	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**5**	**2**	**7**

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

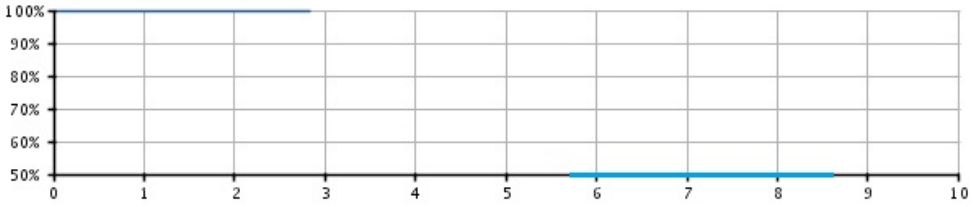
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

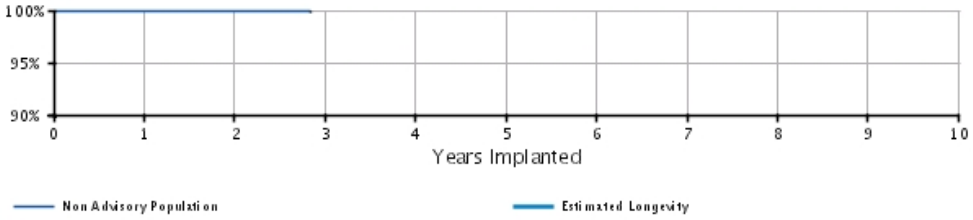
U.S. Registered Implants: 30,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 28,000

U.S. Normal Battery Depletions: 3
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: 30000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.92 (-0.1/+0.0)	99.87 @ 30 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.94 (-0.1/+0.0)	99.89 @ 30 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Effective Sample Size	13514	2436	298	–	–	–	–	–	–	–

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: 47,000
Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**9**	**2**	**11**
[80] High voltage circuit component	4	-	
[81] Integrated circuit	5	1	
[82] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**4**	**1**	**5**
[69] Memory errors	4	1	
Other	**1**	**-**	**1**
Non-patterned	1	-	
WW Confirmed Malfunctions	**14**	**3**	**17**

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

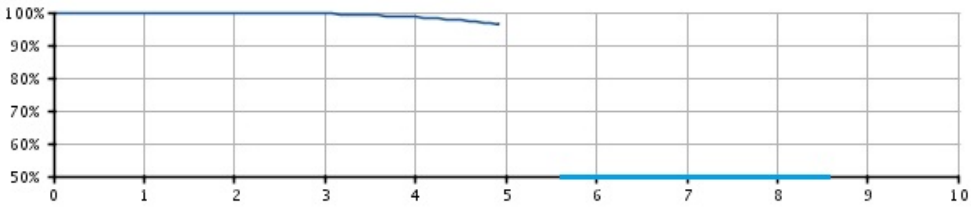
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

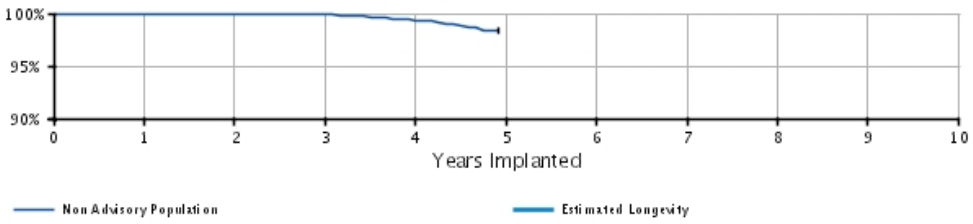
U.S. Registered Implants: 52,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 42,000

U.S. Normal Battery Depletions: 159
U.S. Unconfirmed Reports of Premature Battery Depletion : 34
U.S. Malfunctions:151
Without Compromised Therapy:140
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)	99.89 (-0.0/+0.0)	99.64 (-0.1/+0.1)	98.61 (-0.2/+0.2)	96.49 @ 59 mo. (-0.9/+0.7)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.88 (-0.0/+0.0)	99.36 (-0.1/+0.1)	98.43 @ 59 mo. (-0.4/+0.3)	–	–	–	–	–
	Effective Sample Size	45664	36969	22533	8775	306	–	–	–	–	–

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: 81,000
Worldwide Confirmed Malfunctions: 220

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**188**	**9**	**197**
[60] Safety Core-electrocautery	5	1	
[61] High-voltage capacitor	-	2	
[65] Low-voltage capacitors	1	-	
[68] Integrated circuit	1	6	
[71] Battery	2	-	
[72] Low-voltage capacitor	179	-	
Mechanical	**-**	**6**	**6**
[54] Transformer	-	6	
Software	**8**	**-**	**8**
[69] Memory errors	8	-	
Other	**8**	**1**	**9**
Non-patterned	8	1	
WW Confirmed Malfunctions	**204**	**16**	**220**

More details about malfunctions

References cited in table above

COGNIS

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

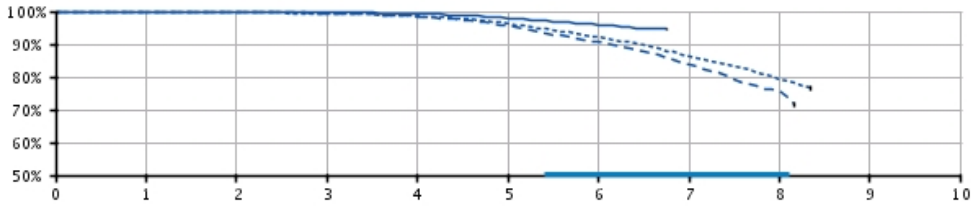
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

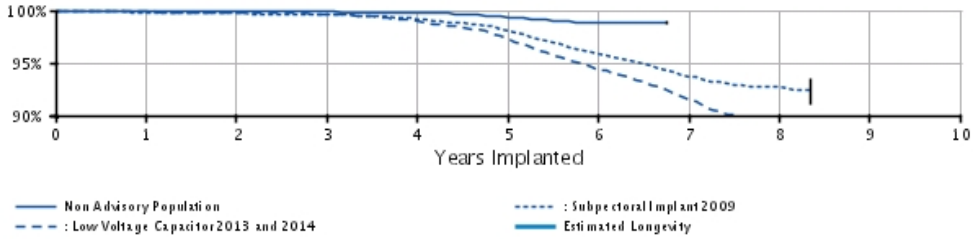
U.S. Registered Implants: 75,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 38,000

U.S. Normal Battery Depletions: 2,243
U.S. Unconfirmed Reports of Premature Battery Depletion : 116
U.S. Malfunctions:1501
Without Compromised Therapy:1334
With Compromised Therapy:167

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)	97.97 (-0.2/+0.2)	95.97 (-0.3/+0.3)	94.59 @ 79 mo. (-0.6/+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)	99.37 (-0.1/+0.1)	98.80 (-0.2/+0.2)	98.80 @ 79 mo. (-0.2/+0.2)	–	–	–
	Effective Sample Size	31510	28118	25056	22036	17495	5546	487	–	–	–
Subpectoral Implant 2009* Registered Implants: 32,000	Depletions and Malfunctions(%) (Confidence Interval)	99.77 (-0.1/+0.0)	99.63 (-0.1/+0.0)	99.37 (-0.1/+0.0)	98.55 (-0.1/+0.0)	96.37 (-0.1/+0.0)	92.09 (-0.1/+0.1)	86.45 (-0.1/+0.1)	79.50 (-0.4/+0.5)	76.59 @ 100 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)	95.83 (-0.2/+0.3)	93.73 (-0.3/+0.3)	92.66 (-0.4/+0.5)	92.49 @ 100 mo. (-1.4/+1.0)	–
	Effective Sample Size	27495	24364	21668	19179	16717	14190	11293	2398	496	–
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)	98.41 (-0.1/+0.1)	95.54 (-0.1/+0.1)	90.51 (-0.1/+0.1)	83.80 (-0.3/+0.1)	75.60 (-0.3/+0.2)	71.55 @ 98 mo. (-1.4/+1.0)	–

26,000											
	Malfunctions Only(%) (Confidence Interval)	99.85 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.65 (-0.1/+0.1)	98.96 (-0.1/+0.1)	97.31 (-0.1/+0.1)	94.37 (-0.1/+0.1)	91.51 (-0.3/+0.1)	89.38 (-0.4/+0.2)	88.95 @ 98 mo. (-1.4/+1.0)	–
	Effective Sample Size	22617	20025	17831	15753	13654	11467	6109	325	213	–

*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: 1966

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1648**	**129**	**1777**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1262	66	
[60] Safety Core-electrocautery	48	21	
[61] High-voltage capacitor	1	6	
[65] Low-voltage capacitors	7	-	
[68] Integrated circuit	7	20	
[70] High voltage circuit	-	1	
[71] Battery	41	5	
[72] Low-voltage capacitor	282	10	
Mechanical	**40**	**90**	**130**
[4] Subpectoral implant 2009 (Advisory issued)	17	47	
[54] Transformer	-	9	
[58] Difficulty securing lead	9	9	
[63] Header contacts	8	8	
[84] Header	6	17	
Software	**15**	**1**	**16**
[64] Safety Core-programming	1	-	
[66] Alert messages not displayed post-EOL	2	-	
[69] Memory errors	12	1	
Other	**34**	**9**	**43**
Non-patterned	34	9	
WW Confirmed Malfunctions	**1737**	**229**	**1966**

More details about malfunctions

References cited in table above

VISIONIST/VALITUDE

Models U125/U128/U225/U226/U228

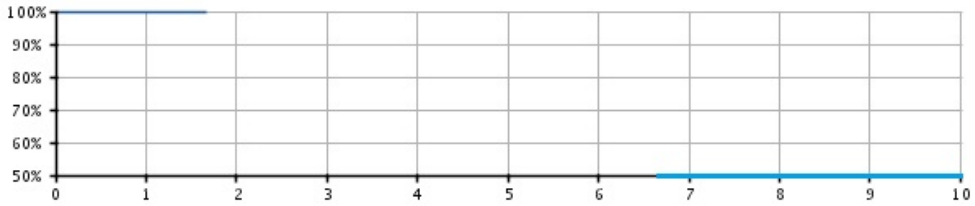
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

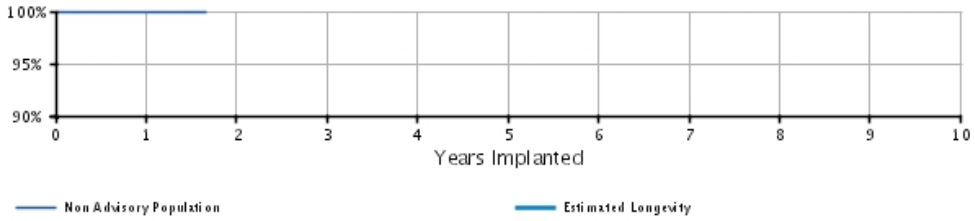
U.S. Registered Implants: 9,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 8,000

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: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.2/+0.0)	99.97 @ 20 mo. (-0.2/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	100.00 @ 20 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2414	347	–	–	–	–	–	–	–	–

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: 19,000
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

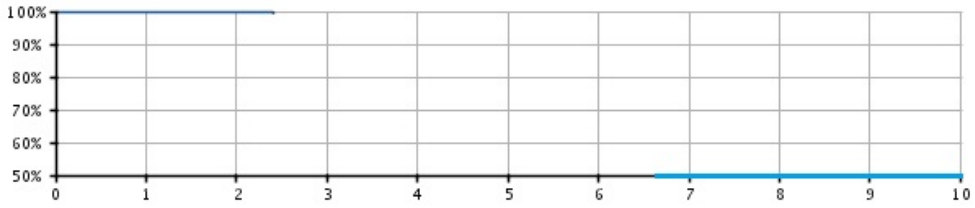
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

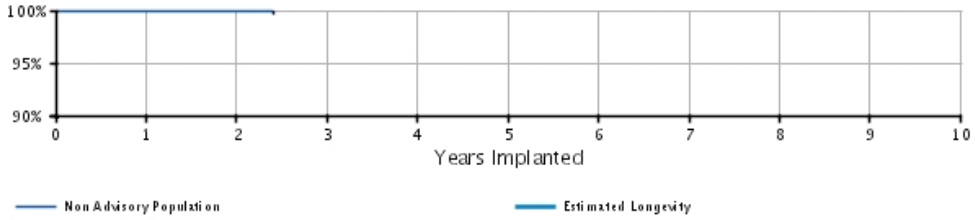
U.S. Registered Implants: 3,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 5
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: 3000	Depletions and Malfunctions(%) (Confidence Interval)	99.82 (-0.3/+0.1)	99.59 (-0.6/+0.2)	99.59 @ 29 mo. (-0.6/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.3/+0.0)	99.96 (-0.3/+0.0)	99.96 @ 29 mo. (-0.3/+0.0)	–	–	–	–	–	–	–
	Effective Sample Size	2009	795	269	–	–	–	–	–	–	–

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: 3,000
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

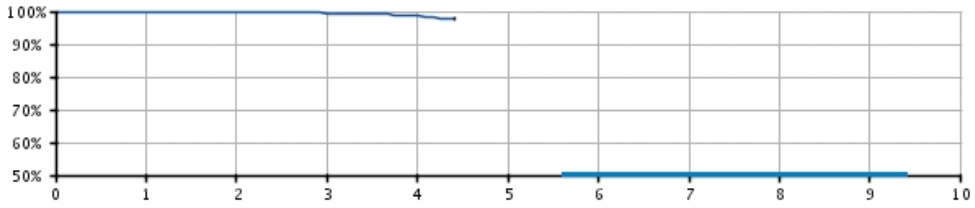
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

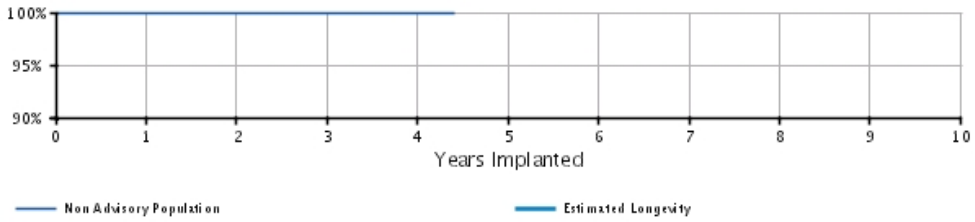
U.S. Registered Implants: 8,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 39
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)	99.85 (-0.1/+0.1)	99.44 (-0.3/+0.2)	98.71 (-0.6/+0.4)	97.93 @ 53 mo. (-1.2/+0.8)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.98 @ 53 mo. (-0.1/+0.0)	–	–	–	–	–
	Effective Sample Size	6644	5250	3014	758	206	–	–	–	–	–

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: 18,000
Worldwide Confirmed Malfunctions: 3

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**1**	**1**
[65] Low-voltage capacitors	-	1	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[69] 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

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

CONTAK RENEWAL TR 2 Models H140/H145

Worldwide Distribution: 31,000
Worldwide Confirmed Malfunctions: 31

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[20] Capacitor	1	-	
Mechanical	**4**	**-**	**4**
[26] Seal plug	1	-	
[36] Setscrew block	2	-	
[49] Seal plug	1	-	
Software	**14**	**-**	**14**
[30] Memory error	1	-	
[40] Stored EGMs	13	-	
Other	**11**	**1**	**12**
Non-patterned	10	1	
[47] Alert messages	1	-	
WW Confirmed Malfunctions	**30**	**1**	**31**

More details about malfunctions

References cited in table above

CONTAK RENEWAL TR

Models H120/H125

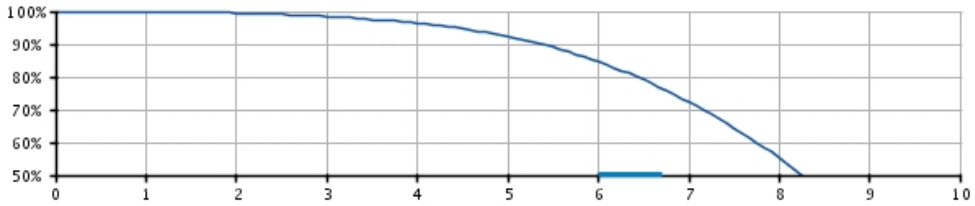
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

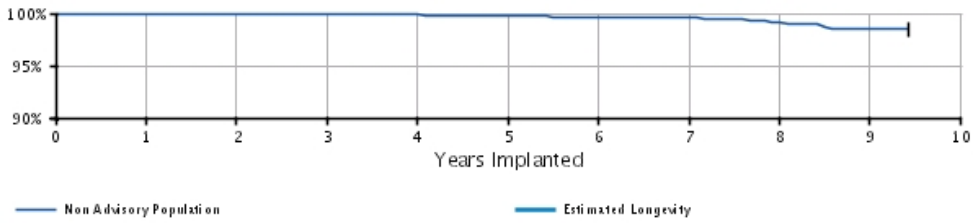
U.S. Registered Implants: 19,000
U.S. Approval Date: January 2004
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 2,794
U.S. Unconfirmed Reports of Premature Battery Depletion : 16
U.S. Malfunctions:52
Without Compromised Therapy:50
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)	99.90 (-0.1/+0.0)	99.47 (-0.1/+0.1)	98.48 (-0.2/+0.2)	96.35 (-0.4/+0.3)	92.37 (-0.5/+0.5)	84.67 (-0.8/+0.8)	72.39 (-1.2/+1.1)	55.09 (-1.7/+1.6)	36.53 (-2.1/+2.2)	28.48 @ 113 mo. (-2.3/+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)	99.77 (-0.1/+0.1)	99.66 (-0.1/+0.1)	99.56 (-0.2/+0.1)	99.20 (-0.4/+0.3)	98.57 (-0.8/+0.5)	98.57 @ 113 mo. (-0.8/+0.5)
	Effective Sample Size	15573	13567	11827	10215	7923	5050	2694	1183	380	208
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: 52

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[8] Low-voltage capacitor (Advisory issued)	1	-	
[20] Capacitor	-	1	
Mechanical	**5**	**-**	**5**
[26] Seal plug	5	-	
Software	**29**	**-**	**29**
[40] Stored EGMs	29	-	
Other	**15**	**1**	**16**
Non-patterned	9	1	
[47] Alert messages	5	-	
[62] Magnet rate	1	-	
WW Confirmed Malfunctions	**50**	**2**	**52**

More details about malfunctions

References cited in table above

EMBLEM S-ICD

Models A209/A219

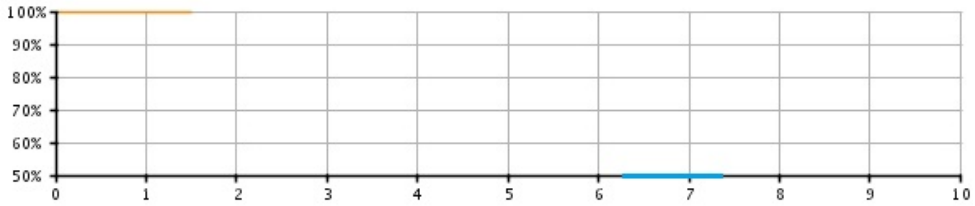
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

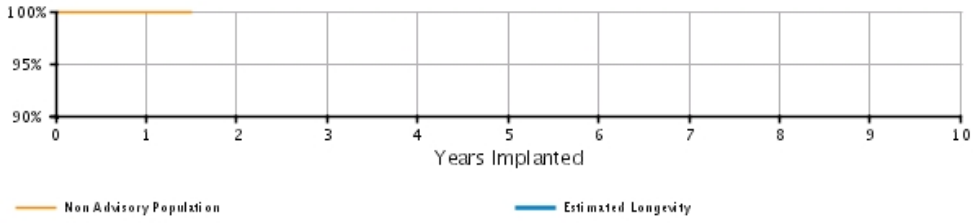
U.S. Registered Implants: 9,000
U.S. Approval Date: March 2015
U.S. Estimated Active Implants: 9,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:3
Without Compromised Therapy:1
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: 9000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.1/+0.0)	99.94 @ 18 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.96 (-0.1/+0.0)	99.96 @ 18 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	2872	324	–	–	–	–	–	–	–	–

EMBLEM S-ICD

Models A209/A219

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

EMBLEM S-ICD Models A209/A219

Worldwide Distribution: 18,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	-	-	0
Other	2	5	7
Non-patterned	2	3	
[74] Telemetry	-	2	
WW Confirmed Malfunctions	2	5	7

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: 8,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**1**	**2**
[81] Integrated circuit	-	1	
[82] High voltage capacitor	1	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**1**	**2**
Non-patterned	1	1	
WW Confirmed Malfunctions	**2**	**2**	**4**

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: 9,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	-	-	0
Mechanical	-	-	0
Software	1	1	2
[69] Memory errors	1	1	
Other	-	-	0
Non-patterned	-	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

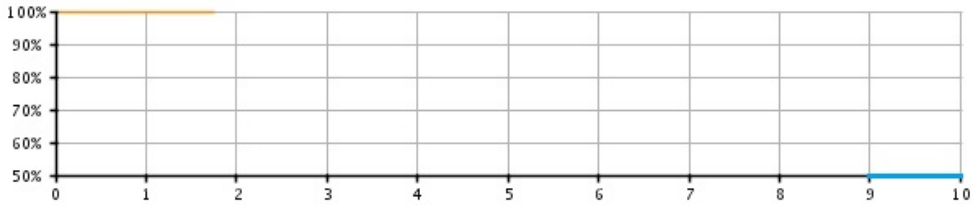
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

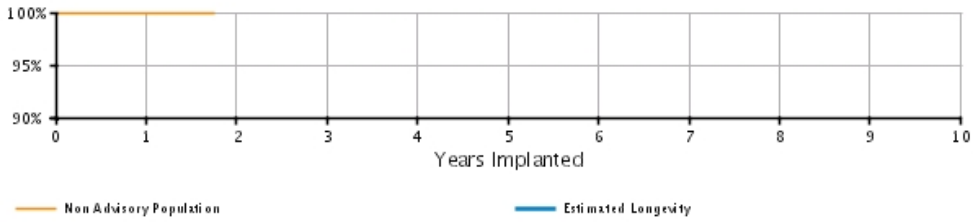
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 14,000

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: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 21 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.99 @ 21 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	5212	341	–	–	–	–	–	–	–	–

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: 21,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[65] Low-voltage capacitors	1	-	
[80] High voltage circuit component	3	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**-**	**0**
Non-patterned	-	-	
WW Confirmed Malfunctions	**4**	**0**	**4**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

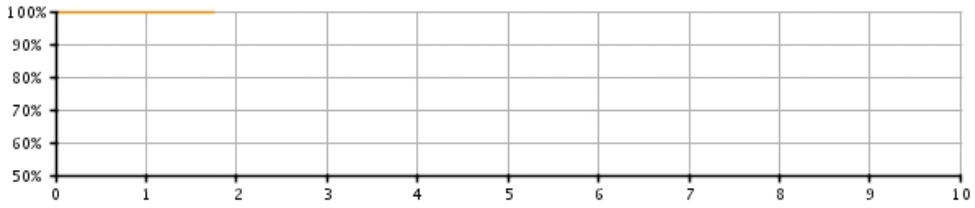
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

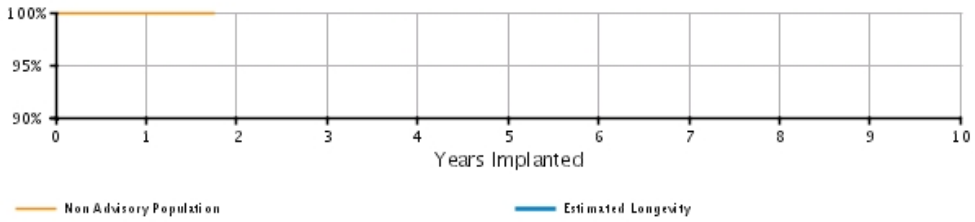
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 13,000

U.S. Normal Battery Depletions: 1
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: 14000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 @ 21 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.98 @ 21 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	5204	330	–	–	–	–	–	–	–	–

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: 23,000
Worldwide Confirmed Malfunctions: 4

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

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

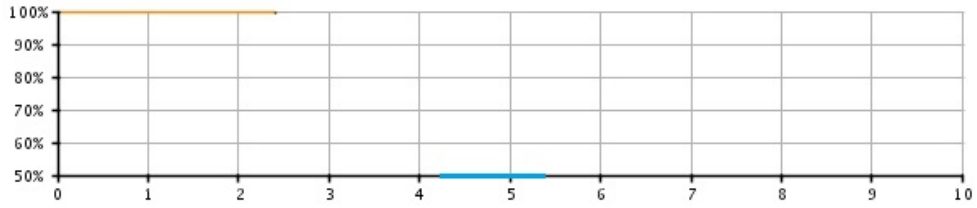
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

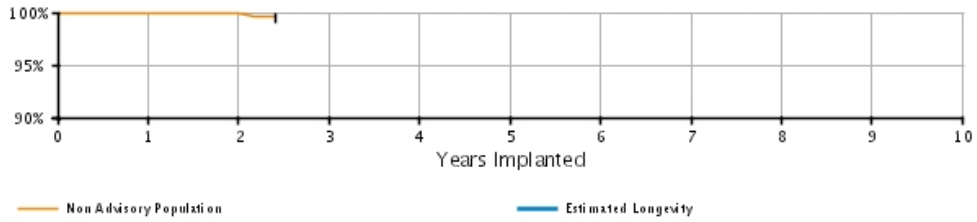
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 1
U.S. Unconfirmed Reports of Premature Battery Depletion : 1
U.S. Malfunctions:4
Without Compromised Therapy:4
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 (-0.1/+0.0)	99.88 (-0.2/+0.1)	99.63 @ 29 mo. (-0.6/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.93 (-0.2/+0.1)	99.68 @ 29 mo. (-0.7/+0.2)	–	–	–	–	–	–	–
	Effective Sample Size	3132	1014	315	–	–	–	–	–	–	–

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: 11,000
Worldwide Confirmed Malfunctions: 6

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[80] High voltage circuit component	4	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**6**	**0**	**6**

More details about malfunctions

References cited in table above

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

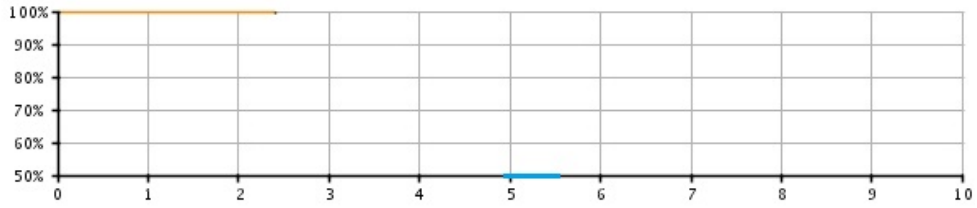
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

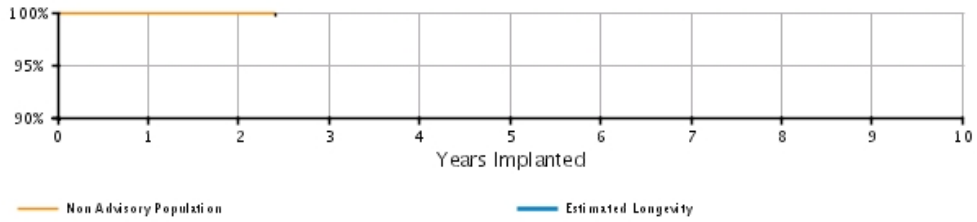
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2014
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 2
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:4
Without Compromised Therapy:3
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: 5000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.2/+0.0)	99.85 (-0.2/+0.1)	99.72 @ 29 mo. (-0.5/+0.2)	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.95 (-0.2/+0.0)	99.87 (-0.2/+0.1)	99.87 @ 29 mo. (-0.2/+0.1)	–	–	–	–	–	–	–
	Effective Sample Size	3156	914	241	–	–	–	–	–	–	–

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: 12,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**1**	**4**
[80] High voltage circuit component	3	-	
[82] High voltage capacitor	-	1	
Mechanical	**-**	**-**	**0**
Software	**1**	**1**	**2**
[69] Memory errors	1	1	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**6**	**2**	**8**

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

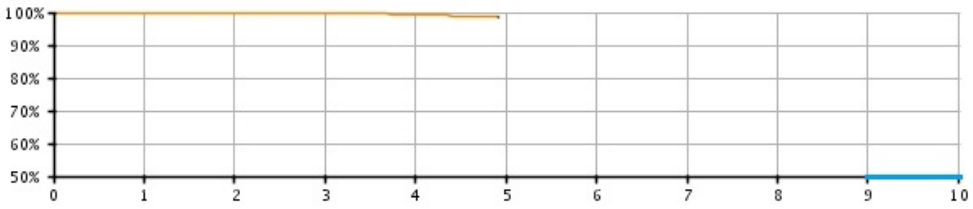
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

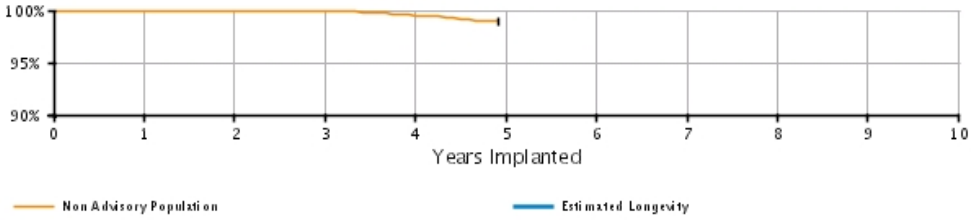
U.S. Registered Implants: 47,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 39,000

U.S. Normal Battery Depletions: 42
U.S. Unconfirmed Reports of Premature Battery Depletion : 13
U.S. Malfunctions:90
Without Compromised Therapy:83
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: 47000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.89 (-0.0/+0.0)	99.79 (-0.1/+0.0)	99.32 (-0.2/+0.1)	98.51 @ 59 mo. (-0.4/+0.3)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.52 (-0.1/+0.1)	98.96 @ 59 mo. (-0.4/+0.3)	–	–	–	–	–
	Effective Sample Size	40624	31924	18651	7143	267	–	–	–	–	–

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: 72,000
Worldwide Confirmed Malfunctions: 139

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**114**	**7**	**121**
[61] High-voltage capacitor	1	2	
[65] Low-voltage capacitors	3	-	
[68] Integrated circuit	5	3	
[71] Battery	6	1	
[72] Low-voltage capacitor	98	1	
[76] High voltage circuit	1	-	
Mechanical	**-**	**2**	**2**
[54] Transformer	-	2	
Software	**3**	**-**	**3**
[69] Memory errors	3	-	
Other	**9**	**4**	**13**
Non-patterned	9	4	
WW Confirmed Malfunctions	**126**	**13**	**139**

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

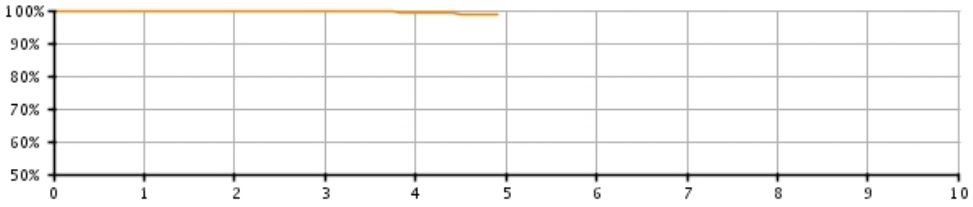
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

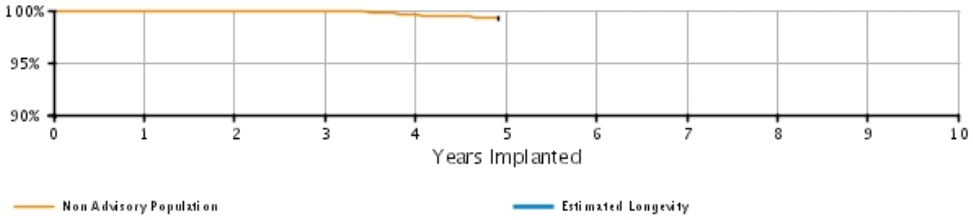
U.S. Registered Implants: 39,000
U.S. Approval Date: November 2011
U.S. Estimated Active Implants: 33,000

U.S. Normal Battery Depletions: 47
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:62
Without Compromised Therapy:49
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: 39000	Depletions and Malfunctions(%) (Confidence Interval)	99.93 (-0.0/+0.0)	99.87 (-0.0/+0.0)	99.77 (-0.1/+0.1)	99.30 (-0.2/+0.1)	98.82 @ 59 mo. (-0.4/+0.3)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.0/+0.0)	99.95 (-0.0/+0.0)	99.90 (-0.0/+0.0)	99.57 (-0.2/+0.1)	99.32 @ 59 mo. (-0.3/+0.2)	–	–	–	–	–
	Effective Sample Size	34241	26709	15317	5870	236	–	–	–	–	–

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: 68,000
Worldwide Confirmed Malfunctions: 98

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**70**	**7**	**77**
[61] High-voltage capacitor	1	1	
[68] Integrated circuit	1	4	
[71] Battery	7	1	
[72] Low-voltage capacitor	61	-	
[76] High voltage circuit	-	1	
Mechanical	**-**	**5**	**5**
[54] Transformer	-	5	
Software	**5**	**-**	**5**
[69] Memory errors	5	-	
Other	**6**	**5**	**11**
Non-patterned	6	5	
WW Confirmed Malfunctions	**81**	**17**	**98**

More details about malfunctions

References cited in table above

SQ-RX S-ICD

Model 1010

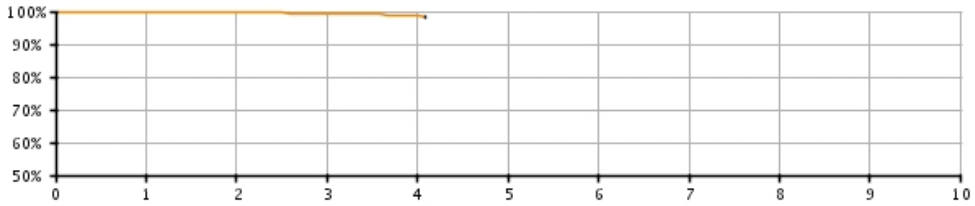
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

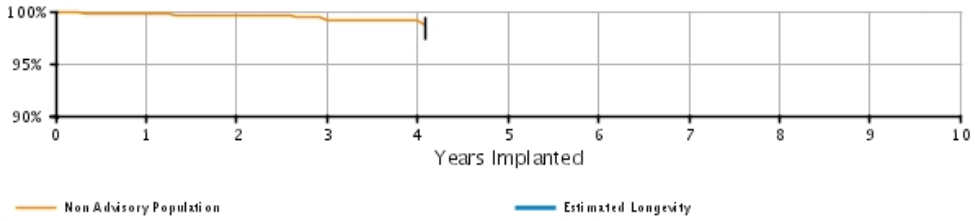
U.S. Registered Implants: 8,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 80
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:37
Without Compromised Therapy:14
With Compromised Therapy:23

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)	99.55 (-0.2/+0.1)	99.05 (-0.6/+0.4)	98.76 (-1.0/+0.6)	98.32 @ 49 mo. (-1.6/+0.8)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.77 (-0.1/+0.1)	99.60 (-0.2/+0.1)	99.12 (-0.6/+0.4)	99.12 (-0.6/+0.4)	98.68 @ 49 mo. (-1.4/+0.7)	–	–	–	–	–
	Effective Sample Size	6526	3882	706	266	224	–	–	–	–	–

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: 94

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**8**	**3**	**11**
[2] Unintended Fuse Activation 2013	-	3	
[79] Charge Timeout Alert	8	-	
Mechanical	**14**	**20**	**34**
[3] High cathode condition	1	2	
[73] Battery depletion	13	18	
Software	**2**	**-**	**2**
[75] Unintended Battery Depletion Alert	2	-	
Other	**16**	**31**	**47**
Non-patterned	13	22	
[74] Telemetry	3	9	
WW Confirmed Malfunctions	**40**	**54**	**94**

More details about malfunctions

References cited in table above

TELIGEN DR

Models E110/E111/F110/F111

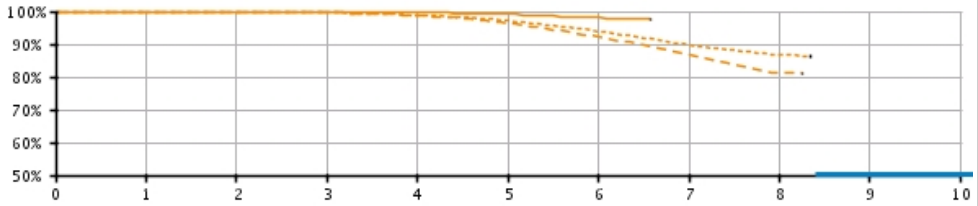
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

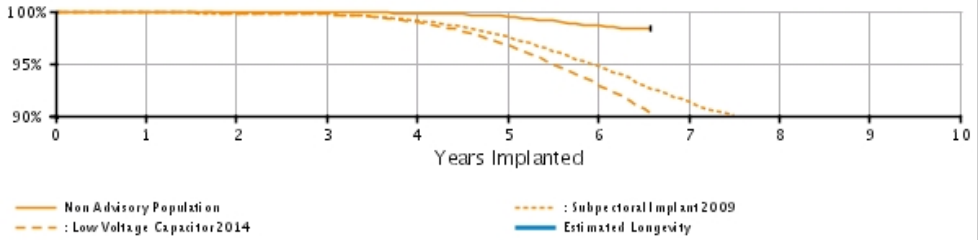
U.S. Registered Implants: 66,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 39,000

U.S. Normal Battery Depletions: 285
U.S. Unconfirmed Reports of Premature Battery Depletion : 153
U.S. Malfunctions:1760
Without Compromised Therapy:1636
With Compromised Therapy:124

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)	99.18 (-0.1/+0.1)	98.13 (-0.3/+0.2)	97.56 @ 79 mo. (-0.4/+0.4)	–	–	–
	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)	99.49 (-0.1/+0.1)	98.69 (-0.2/+0.2)	98.39 @ 79 mo. (-0.3/+0.3)	–	–	–
	Effective Sample Size	26439	23336	20591	18093	14573	5228	543	–	–	–
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)	98.88 (-0.1/+0.1)	97.19 (-0.1/+0.1)	93.95 (-0.1/+0.1)	89.80 (-0.2/+0.1)	86.85 (-0.2/+0.3)	86.41 @ 100 mo. (-1.2/+0.5)	–
	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 (-0.1/+0.1)	94.69 (-0.1/+0.1)	91.28 (-0.2/+0.3)	89.60 (-0.2/+0.3)	89.51 @ 100 mo. (-0.4/+0.3)	–
	Effective Sample Size	26748	23500	20671	18053	15610	13223	10531	2448	508	–
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)	96.37 (-0.1/+0.1)	92.14 (-0.1/+0.1)	86.58 (-0.1/+0.2)	81.46 (-0.3/+0.3)	81.09 @ 99 mo. (-0.4/+0.3)	–
	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)	96.76 (-0.1/+0.1)	92.93 (-0.1/+0.1)	88.28 (-0.1/+0.1)	85.04 (-0.2/+0.1)	84.64 @ 99 mo.	–

									(-0.4/+0.3)	
	Effective Sample Size	20715	18218	16009	13975	11986	10027	5674	336	217	–

*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: 2297

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2077**	**92**	**2169**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1639	40	
[60] Safety Core-electrocautery	3	-	
[61] High-voltage capacitor	1	7	
[65] Low-voltage capacitors	6	-	
[68] Integrated circuit	20	20	
[71] Battery	165	24	
[72] Low-voltage capacitor	243	1	
Mechanical	**20**	**52**	**72**
[4] Subpectoral implant 2009 (Advisory issued)	3	10	
[54] Transformer	-	20	
[57] Seal plug	3	-	
[58] Difficulty securing lead	9	8	
[63] Header contacts	3	11	
[84] Header	2	3	
Software	**16**	**-**	**16**
[66] Alert messages not displayed post-EOL	3	-	
[69] Memory errors	13	-	
Other	**29**	**11**	**40**
Non-patterned	29	11	
WW Confirmed Malfunctions	**2142**	**155**	**2297**

More details about malfunctions

References cited in table above

TELIGEN VR

Models E102/E103/F102/F103

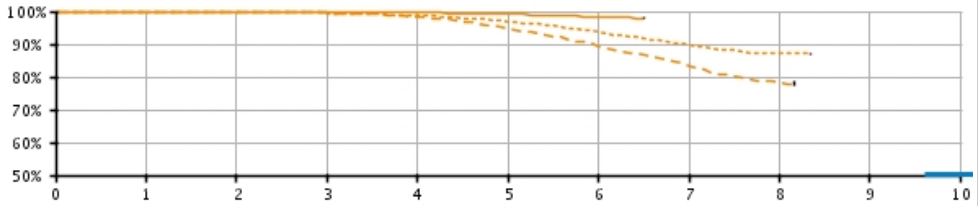
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

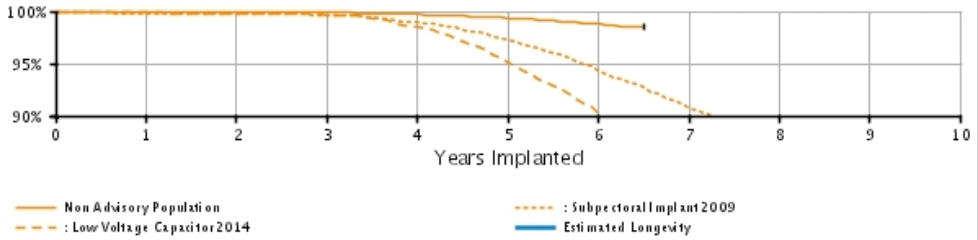
U.S. Registered Implants: 38,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 23,000

U.S. Normal Battery Depletions: 90
U.S. Unconfirmed Reports of Premature Battery Depletion : 102
U.S. Malfunctions:1167
Without Compromised Therapy:1079
With Compromised Therapy:88

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)	99.16 (-0.2/+0.2)	98.27 (-0.4/+0.3)	97.86 @ 78 mo. (-0.6/+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/+0.1)	98.78 (-0.3/+0.2)	98.59 @ 78 mo. (-0.4/+0.3)	–	–	–
	Effective Sample Size	16276	14328	12585	11033	8724	2250	345	–	–	–
Subpectoral Implant 2009* Registered Implants: 16,000	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-0.0/+0.0)	99.66 (-0.1/+0.1)	99.50 (-0.1/+0.1)	98.68 (-0.1/+0.1)	96.93 (-0.1/+0.1)	93.70 (-0.1/+0.1)	89.68 (-0.1/+0.1)	87.10 (-0.2/+0.1)	87.02 @ 100 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)	94.37 (-0.1/+0.2)	90.76 (-0.4/+0.3)	88.81 (-0.5/+0.6)	89.72 @ 100 mo. (-0.6/+0.9)	–
	Effective Sample Size	13680	11994	10512	9149	7863	6663	5295	1283	287	–
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)	89.46 (-0.3/+0.2)	83.29 (-0.4/+0.2)	78.21 (-1.5/+1.6)	77.87 @ 97 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)	90.27 (-0.1/+0.1)	84.83 (-0.3/+0.2)	80.70 (-0.5/+0.6)	80.34 @ 97 mo.	–

									(-1.5/+1.6)	
	Effective Sample Size	10903	9577	8400	7289	6169	5086	2631	267	226	–

*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

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

TELIGEN VR
Models E102/E103/F102/F103

Worldwide Distribution: 66,000
Worldwide Confirmed Malfunctions: 1842

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1653**	**62**	**1715**
[1] Low Voltage Capacitor 2014 (Advisory issued)	1255	27	
[60] Safety Core-electrocautery	1	1	
[61] High-voltage capacitor	-	3	
[65] Low-voltage capacitors	5	-	
[68] Integrated circuit	10	14	
[71] Battery	234	17	
[72] Low-voltage capacitor	148	-	
Mechanical	**23**	**69**	**92**
[4] Subpectoral implant 2009 (Advisory issued)	7	17	
[34] Transformer	-	2	
[54] Transformer	-	14	
[57] Seal plug	1	-	
[58] Difficulty securing lead	-	10	
[63] Header contacts	13	18	
[84] Header	2	8	
Software	**16**	**-**	**16**
[5] Respiratory Sensor Oversensing	1	-	
[66] Alert messages not displayed post-EOL	4	-	
[69] Memory errors	11	-	
Other	**9**	**10**	**19**
Non-patterned	9	10	
WW Confirmed Malfunctions	**1701**	**141**	**1842**

More details about malfunctions

References cited in table above

CONFIENT DR

Models E030/F030

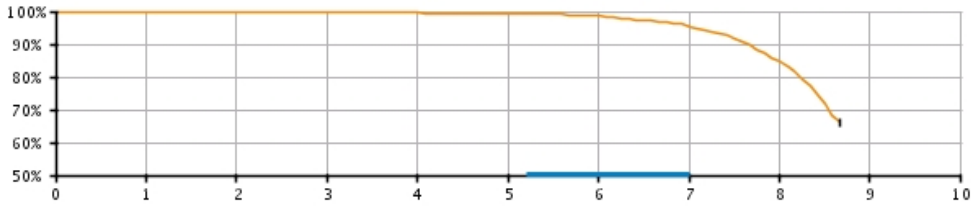
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

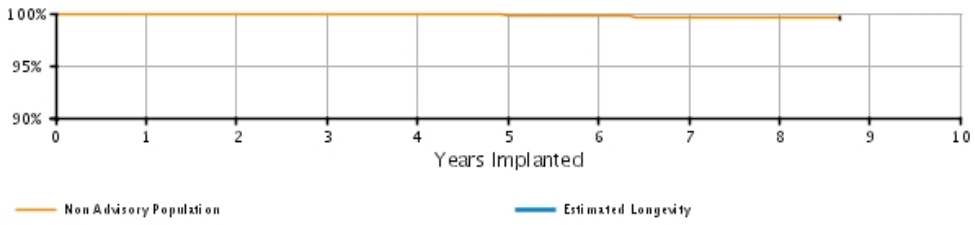
U.S. Registered Implants: 7,000
U.S. Approval Date: February 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 536
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)	98.54 (-0.4/+0.3)	95.49 (-0.8/+0.7)	84.52 (-1.6/+1.5)	66.13 @ 104 mo. (-2.8/+2.7)	–
	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)	99.78 (-0.2/+0.1)	99.63 (-0.3/+0.2)	99.59 (-0.3/+0.2)	99.59 @ 104 mo. (-0.3/+0.2)	–
	Effective Sample Size	6163	5395	4698	4115	3598	3022	2370	1363	308	–

CONFIENT DR

Models E030/F030

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

CONFIENT DR Models E030/F030

Worldwide Distribution: 8,000
Worldwide Confirmed Malfunctions: 14

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

More details about malfunctions

References cited in table above

VITALITY 2 EL VR

Model T177

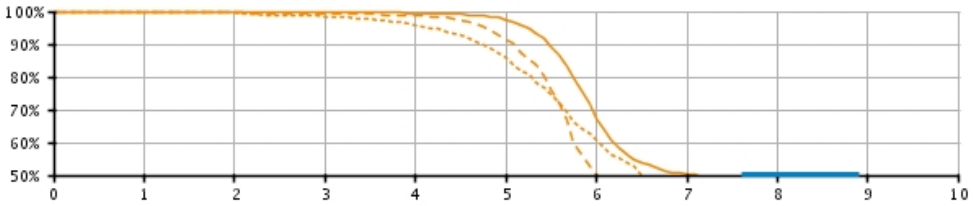
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

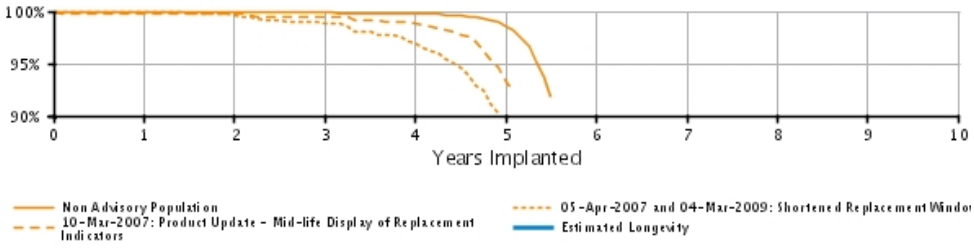
U.S. Registered Implants: 7,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 1,330
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:1276
Without Compromised Therapy:1263
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)	67.12 (-2.1/+2.1)	50.25 (-2.3/+2.3)	44.15 (-2.4/+2.4)	33.05 @ 104 mo. (-2.6/+2.7)	–
	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)	73.46 (-2.1/+2.0)	60.02 (-2.4/+2.3)	59.11 (-2.4/+2.4)	58.67 @ 104 mo. (-2.5/+2.4)	–
	Effective Sample Size	3631	3177	2775	2408	2065	1281	754	506	215	–
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)	85.70 (-2.2/+2.0)	60.76 (-3.3/+3.2)	41.21 (-3.4/+3.5)	33.67 @ 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)	68.24 (-3.2/+3.1)	60.85 (-3.5/+3.4)	60.32 @ 88 mo. (-3.6/+3.5)	–	–
	Effective Sample Size	1687	1474	1279	1087	819	492	273	204	–	–
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: 1929

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1888**	**8**	**1896**
[7] Shortened replacement window (Advisory issued)	139	1	
[8] Low-voltage capacitor (Advisory issued)	2	1	
[12] Extended charge time post-mid-life	21	2	
[23] Integrated circuit	-	3	
[32] Capacitor	1	-	
[35] Capacitor	2	-	
[42] Mid-life display of replacement indicators	1656	1	
[43] High-voltage capacitor	2	-	
[59] Low-voltage capacitor	65	-	
Mechanical	**3**	**8**	**11**
[6] Subpectoral implant (Advisory issued)	-	5	
[19] Header	-	1	
[26] Seal plug	1	-	
[45] Sensing	2	-	
[54] Transformer	-	2	
Software	**-**	**2**	**2**
[39] Memory location	-	1	
[41] Memory location	-	1	
Other	**11**	**9**	**20**
Non-patterned	11	7	
[21] Battery depletion	-	2	
WW Confirmed Malfunctions	**1902**	**27**	**1929**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR EL

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

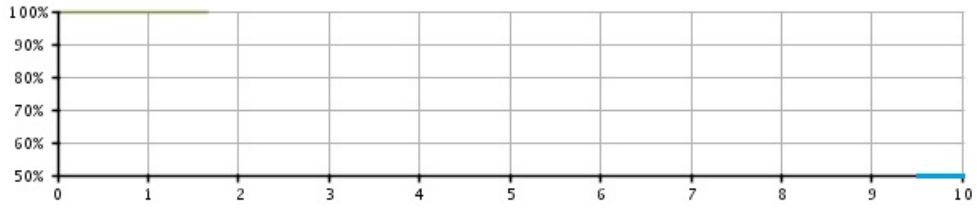
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

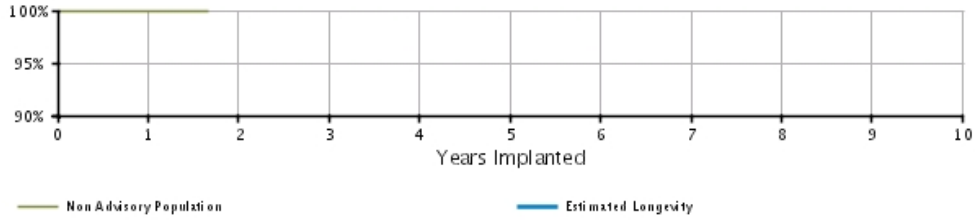
U.S. Registered Implants: 20,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 20,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
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: 20000	Depletions and Malfunctions(%) (Confidence Interval)	99.95 (-0.1/+0.0)	99.85 @ 20 mo. (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.97 @ 20 mo. (-0.1/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	5589	443	–	–	–	–	–	–	–	–

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: 50,000
Worldwide Confirmed Malfunctions: 11

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**-**	**7**
[65] Low-voltage capacitors	1	-	
[81] Integrated circuit	1	-	
[83] Capacitor	5	-	
Mechanical	**-**	**-**	**0**
Software	**2**	**-**	**2**
[69] Memory errors	2	-	
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**11**	**0**	**11**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO DR

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

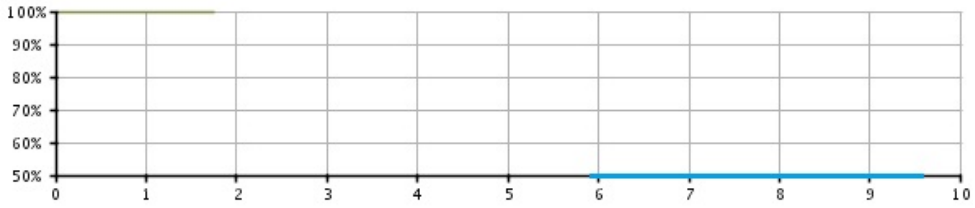
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

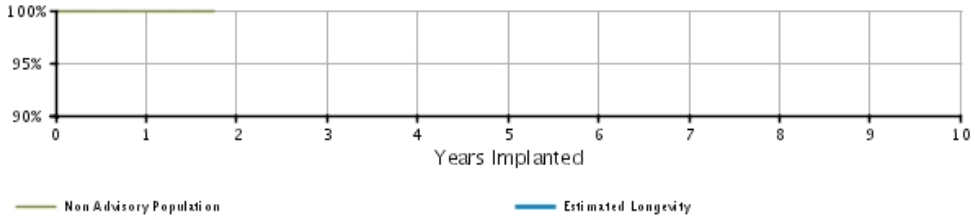
U.S. Registered Implants: 58,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 56,000

U.S. Normal Battery Depletions: 9
U.S. Unconfirmed Reports of Premature Battery Depletion : 5
U.S. Malfunctions:8
Without Compromised Therapy:4
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: 58000	Depletions and Malfunctions(%) (Confidence Interval)	99.94 (-0.0/+0.0)	99.84 @ 21 mo. (-0.3/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.98 @ 21 mo. (-0.0/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	18920	493	–	–	–	–	–	–	–	–

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: 111,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**3**	**8**
[65] Low-voltage capacitors	1	-	
[81] Integrated circuit	2	3	
[83] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**3**	**5**
Non-patterned	2	3	
WW Confirmed Malfunctions	**7**	**6**	**13**

More details about malfunctions

References cited in table above

ACCOLADE/PROPONENT/ESSENTIO SR

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

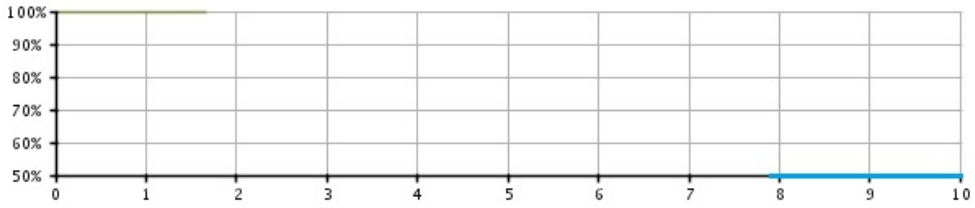
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

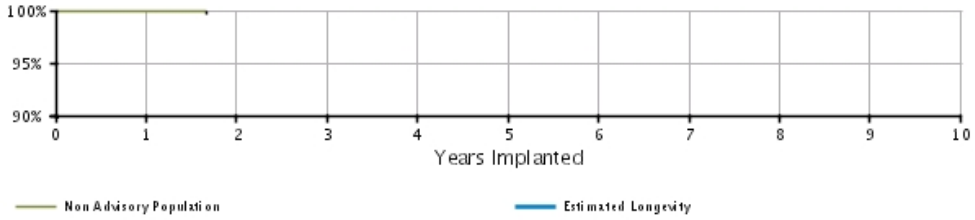
U.S. Registered Implants: 12,000
U.S. Approval Date: October 2014
U.S. Estimated Active Implants: 11,000

U.S. Normal Battery Depletions: 4
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: 12000	Depletions and Malfunctions(%) (Confidence Interval)	99.97 (-0.1/+0.0)	99.84 @ 20 mo. (-0.2/+0.1)	–	–	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.94 @ 20 mo. (-0.3/+0.0)	–	–	–	–	–	–	–	–
	Effective Sample Size	3396	239	–	–	–	–	–	–	–	–

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: 38,000
Worldwide Confirmed Malfunctions: 5

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**2**	**3**
[65] Low-voltage capacitors	1	-	
[81] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	2	-	
WW Confirmed Malfunctions	**3**	**2**	**5**

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

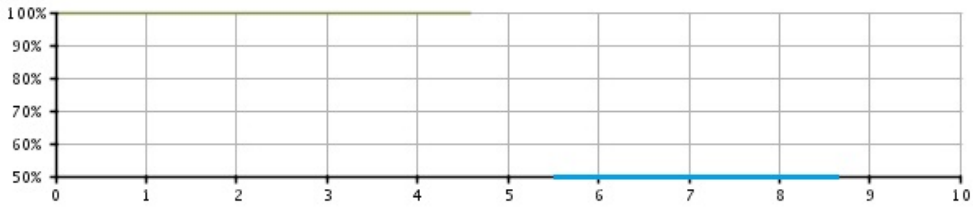
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

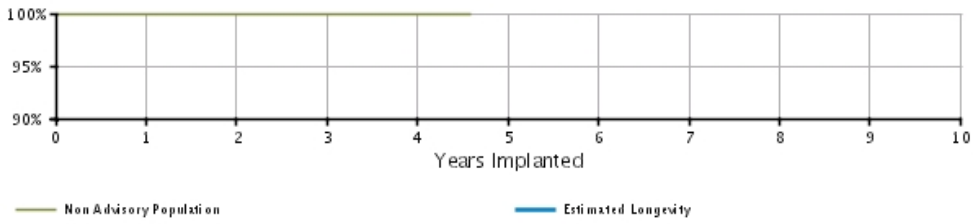
U.S. Registered Implants: 121,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 104,000

U.S. Normal Battery Depletions: 115
U.S. Unconfirmed Reports of Premature Battery Depletion : 12
U.S. Malfunctions:36
Without Compromised Therapy:25
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: 121000	Depletions and Malfunctions(%) (Confidence Interval)	99.96 (-0.0/+0.0)	99.92 (-0.0/+0.0)	99.85 (-0.0/+0.0)	99.73 (-0.1/+0.1)	99.61 @ 55 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)	99.95 (-0.0/+0.0)	99.95 @ 55 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	107533	82562	42690	11433	428	–	–	–	–	–

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: 215,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**8**	**8**	**16**
[65] Low-voltage capacitors	5	-	
[68] Integrated circuit	3	6	
[78] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**13**	**1**	**14**
[69] Memory errors	13	1	
Other	**20**	**4**	**24**
Non-patterned	20	4	
WW Confirmed Malfunctions	**41**	**13**	**54**

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

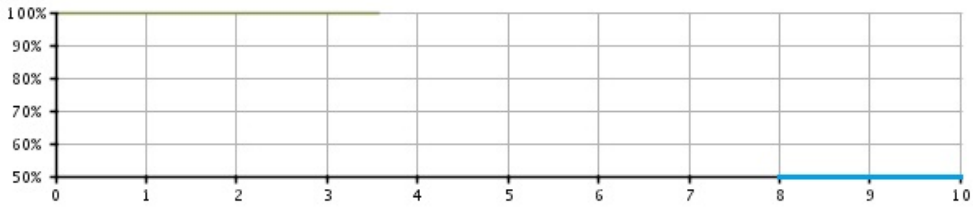
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

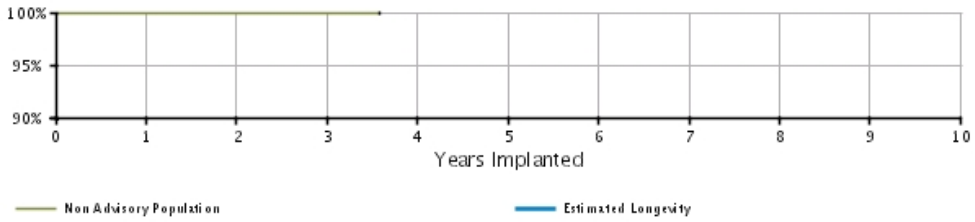
U.S. Registered Implants: 11,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 10,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletion : 0
U.S. Malfunctions:4
Without Compromised Therapy:3
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: 11000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.87 (-0.2/+0.1)	99.87 @ 43 mo. (-0.2/+0.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.91 (-0.2/+0.1)	99.91 @ 43 mo. (-0.2/+0.1)	–	–	–	–	–	–
	Effective Sample Size	9446	6114	1371	225	–	–	–	–	–	–

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: 71,000
Worldwide Confirmed Malfunctions: 21

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[65] Low-voltage capacitors	4	1	
[68] Integrated circuit	-	2	
[78] Titanium case material	-	2	
Mechanical	**-**	**-**	**0**
Software	**4**	**-**	**4**
[69] Memory errors	3	-	
[77] Respiratory sensor	1	-	
Other	**7**	**1**	**8**
Non-patterned	7	1	
WW Confirmed Malfunctions	**15**	**6**	**21**

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

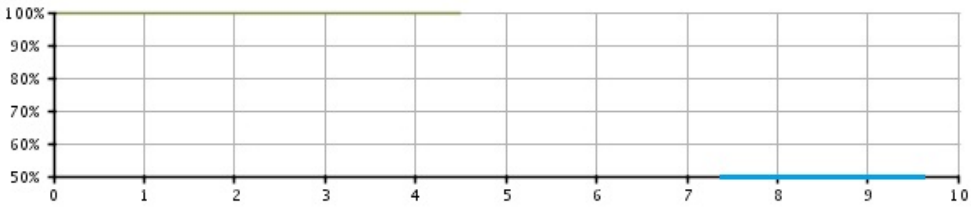
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

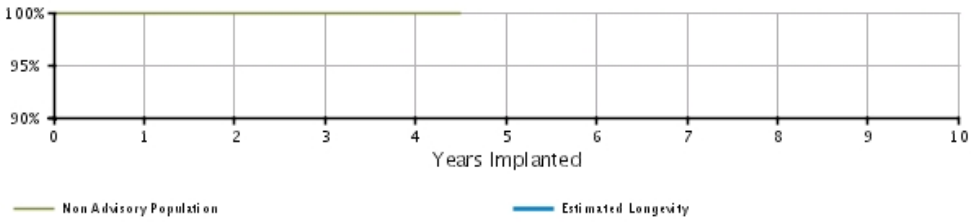
U.S. Registered Implants: 27,000
U.S. Approval Date: May 2012
U.S. Estimated Active Implants: 21,000

U.S. Normal Battery Depletions: 14
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: 27000	Depletions and Malfunctions(%) (Confidence Interval)	99.98 (-0.0/+0.0)	99.94 (-0.0/+0.0)	99.89 (-0.1/+0.0)	99.87 (-0.1/+0.0)	99.87 @ 54 mo. (-0.1/+0.0)	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.99 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.96 @ 54 mo. (-0.0/+0.0)	–	–	–	–	–
	Effective Sample Size	22622	16401	8106	2045	201	–	–	–	–	–

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: 84,000
Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[65] Low-voltage capacitors	3	1	
[68] Integrated circuit	1	3	
[78] Titanium case material	-	1	
Mechanical	**-**	**-**	**0**
Software	**5**	**-**	**5**
[69] Memory errors	5	-	
Other	**1**	**2**	**3**
Non-patterned	1	2	
WW Confirmed Malfunctions	**10**	**7**	**17**

More details about malfunctions

References cited in table above

ALTRUA 60 DR

Model S602

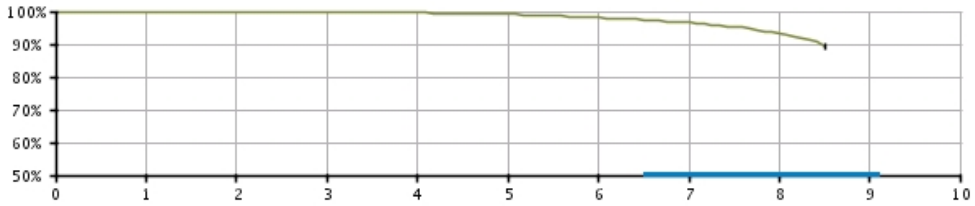
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

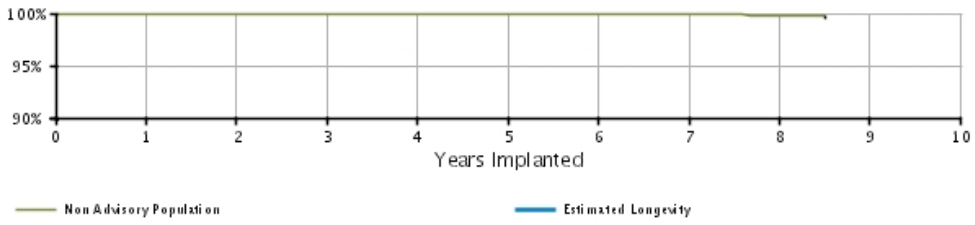
U.S. Registered Implants: 22,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 517
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
U.S. Malfunctions:16
Without Compromised Therapy:15
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)	99.53 (-0.1/+0.1)	99.03 (-0.2/+0.2)	98.04 (-0.3/+0.2)	96.54 (-0.4/+0.4)	93.13 (-0.7/+0.6)	89.30 @ 102 mo. (-2.1/+1.8)	–
	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)	99.91 (-0.1/+0.0)	99.78 (-0.2/+0.1)	99.69 @ 102 mo. (-0.3/+0.1)	–
	Effective Sample Size	19530	17284	15194	13219	11153	8835	6556	2431	&ndash;	–

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: 24

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[20] Capacitor	1	-	
Mechanical	**1**	**1**	**2**
[22] Capacitor array	1	-	
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**19**	**2**	**21**
Non-patterned	2	1	
[37] Battery depletion	1	1	
[67] Battery status	16	-	
WW Confirmed Malfunctions	**21**	**3**	**24**

More details about malfunctions

References cited in table above

ALTRUA 60 DR (Downsize)

Model S603

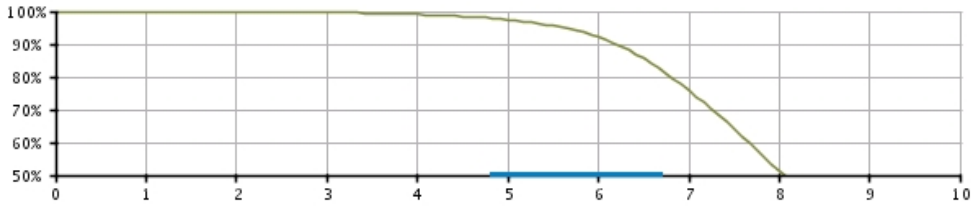
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

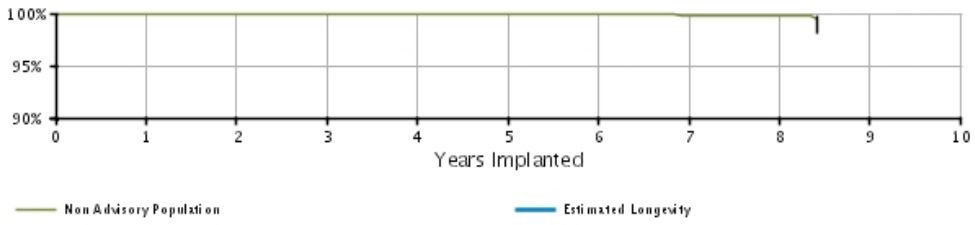
U.S. Registered Implants: 90,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 49,000

U.S. Normal Battery Depletions: 8,653
U.S. Unconfirmed Reports of Premature Battery Depletion : 45
U.S. Malfunctions:62
Without Compromised Therapy:54
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)	97.45 (-0.1/+0.1)	92.09 (-0.3/+0.3)	75.78 (-0.6/+0.6)	51.14 (-1.0/+1.0)	40.58 @ 101 mo. (-1.8/+1.8)	–
	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)	99.89 (-0.0/+0.0)	99.83 (-0.1/+0.0)	99.78 (-0.1/+0.1)	99.41 @ 101 mo. (-1.4/+0.4)	–
	Effective Sample Size	79406	70667	62731	54633	41591	26003	11473	2132	273	–

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: 76

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**5**	**7**	**12**
[20] Capacitor	4	6	
[46] Integrated circuit	1	1	
Mechanical	**2**	**-**	**2**
[55] Connector block	1	-	
[58] Difficulty securing lead	1	-	
Software	**1**	**-**	**1**
[30] Memory error	1	-	
Other	**58**	**3**	**61**
Non-patterned	3	2	
[37] Battery depletion	3	1	
[67] Battery status	52	-	
WW Confirmed Malfunctions	**66**	**10**	**76**

More details about malfunctions

References cited in table above

ALTRUA 60 DR EL

Model S606

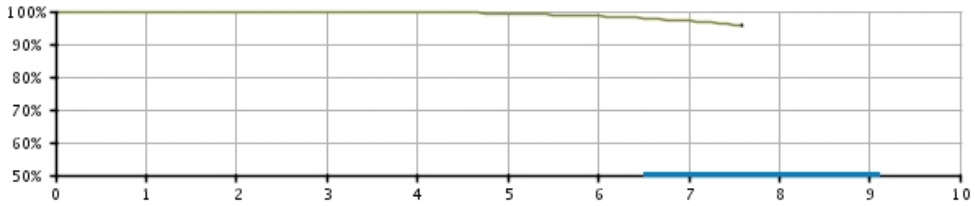
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

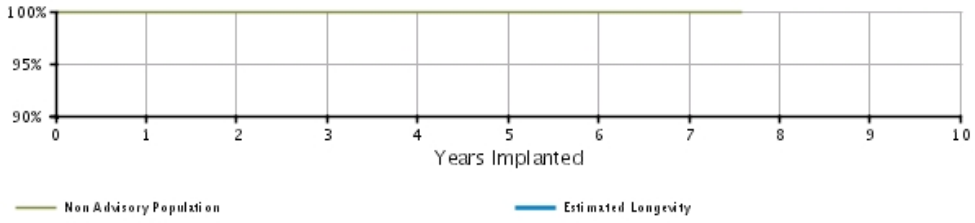
U.S. Registered Implants: 59,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 42,000

U.S. Normal Battery Depletions: 486
U.S. Unconfirmed Reports of Premature Battery Depletion : 10
U.S. Malfunctions:10
Without Compromised Therapy:8
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)	99.35 (-0.1/+0.1)	98.53 (-0.2/+0.1)	97.10 (-0.4/+0.3)	95.63 @ 91 mo. (-1.0/+0.8)	–	–
	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)	99.98 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.97 @ 91 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	52723	46895	41573	36103	25630	13003	3486	290	–	–

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: 12

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**-**	**4**
[20] Capacitor	3	-	
[23] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**6**	**1**	**7**
Non-patterned	1	-	
[37] Battery depletion	-	1	
[67] Battery status	5	-	
WW Confirmed Malfunctions	**10**	**2**	**12**

More details about malfunctions

References cited in table above

ALTRUA 60 SR

Model S601

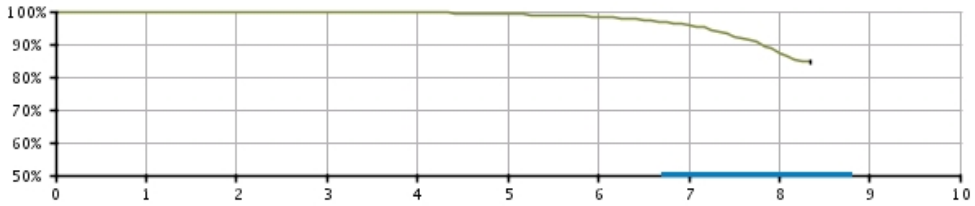
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

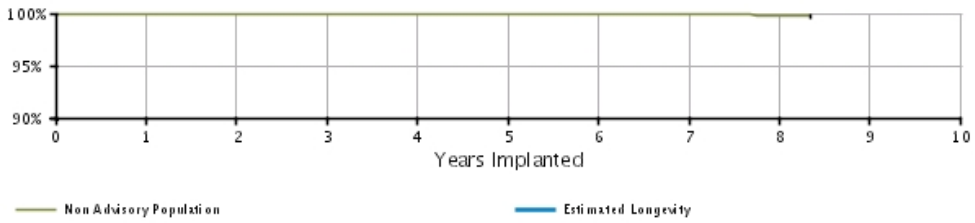
U.S. Registered Implants: 32,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 583
U.S. Unconfirmed Reports of Premature Battery Depletion : 4
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: 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)	99.15 (-0.1/+0.1)	98.31 (-0.2/+0.2)	95.94 (-0.5/+0.4)	87.50 (-1.4/+1.3)	84.58 @ 100 mo. (-1.9/+1.7)	–
	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)	99.94 (-0.1/+0.0)	99.81 (-0.3/+0.1)	99.81 @ 100 mo. (-0.3/+0.1)	–
	Effective Sample Size	26758	23585	20896	18090	13468	8330	4086	959	310	–

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: 18

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[20] Capacitor	1	2	
[46] Integrated circuit	-	2	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**10**	**3**	**13**
Non-patterned	1	2	
[37] Battery depletion	-	1	
[67] Battery status	9	-	
WW Confirmed Malfunctions	**11**	**7**	**18**

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: 48,000
Worldwide Confirmed Malfunctions: 20

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**1**	**4**
[20] Capacitor	2	1	
[46] Integrated circuit	1	-	
Mechanical	**-**	**1**	**1**
[58] Difficulty securing lead	-	1	
Software	**-**	**-**	**0**
Other	**15**	**-**	**15**
Non-patterned	1	-	
[37] Battery depletion	2	-	
[67] Battery status	12	-	
WW Confirmed Malfunctions	**18**	**2**	**20**

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: 25,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[20] Capacitor	1	4	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**1**	**3**	**4**
Non-patterned	-	1	
[37] Battery depletion	-	2	
[67] Battery status	1	-	
WW Confirmed Malfunctions	**2**	**7**	**9**

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: 12,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**-**	**0**
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**4**	**3**	**7**
Non-patterned	-	-	
[37] Battery depletion	-	3	
[67] 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	-	-	
[67] 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	-	-	
[37] Battery depletion	-	1	
[67] Battery status	1	-	
WW Confirmed Malfunctions	1	1	2

More details about malfunctions

References cited in table above

ALTRUA 40 DR

Model S402

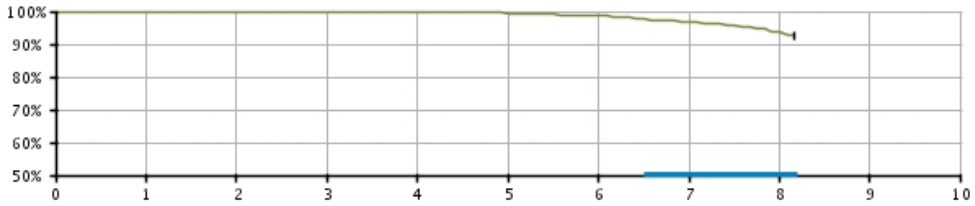
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

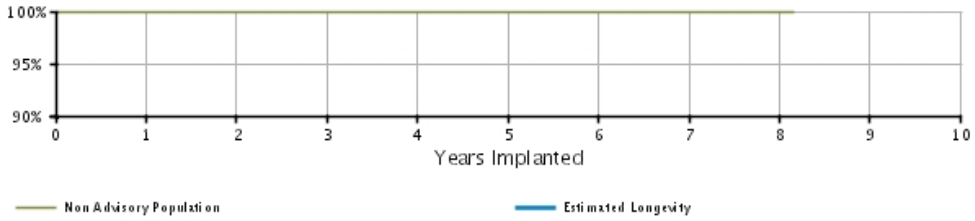
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 49
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)	96.77 (-1.4/+1.0)	93.93 (-2.0/+1.6)	92.64 @ 98 mo. (-2.5/+1.9)	–
	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)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 98 mo. (-0.0/+0.0)	–
	Effective Sample Size	1517	1346	1194	1064	945	835	719	345	244	–

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	-	-	
[37] Battery depletion	-	1	
WW Confirmed Malfunctions	0	1	1

More details about malfunctions

References cited in table above

ALTRUA 40 DR (downsize)

Model S403

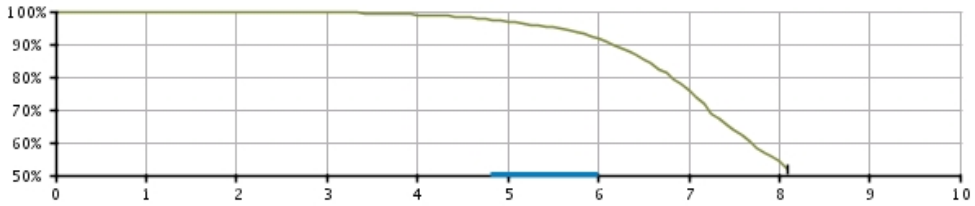
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

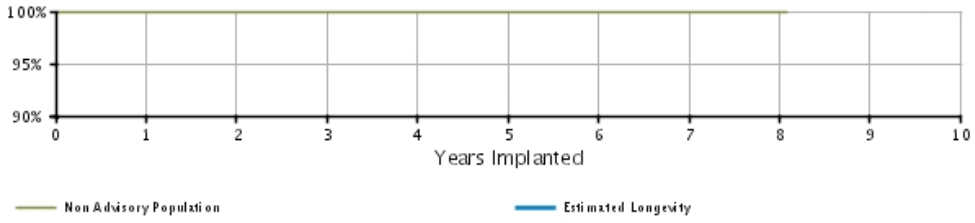
U.S. Registered Implants: 14,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 1,333
U.S. Unconfirmed Reports of Premature Battery Depletion : 3
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)	98.95 (-0.2/+0.2)	96.89 (-0.4/+0.4)	91.64 (-0.7/+0.7)	75.85 (-1.5/+1.4)	54.19 (-2.6/+2.6)	51.60 @ 97 mo. (-2.9/+2.9)	–
	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 (-0.1/+0.0)	99.97 @ 97 mo. (-0.1/+0.0)	–
	Effective Sample Size	12513	11156	9912	8766	6833	4087	1663	299	244	–

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**
[57] Seal plug	1	-	
[58] Difficulty securing lead	1	-	
Software	**-**	**-**	**0**
Other	**2**	**-**	**2**
Non-patterned	-	-	
[67] Battery status	2	-	
WW Confirmed Malfunctions	**4**	**0**	**4**

More details about malfunctions

References cited in table above

ALTRUA 40 DR EL

Model S404

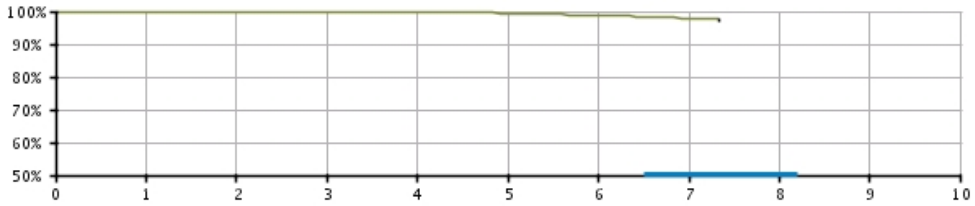
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

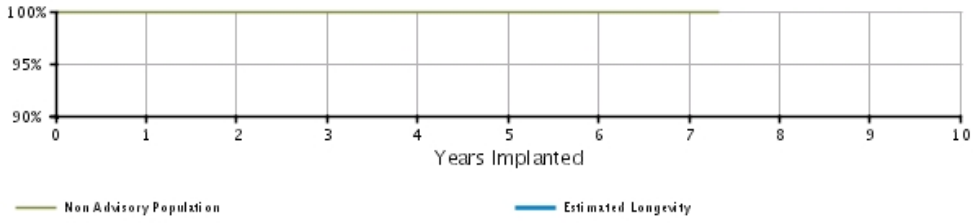
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 39
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)	99.38 (-0.4/+0.2)	98.60 (-0.6/+0.4)	97.85 (-0.9/+0.7)	97.56 @ 88 mo. (-1.2/+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 (-0.0/+0.0)	100.00 @ 88 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	4475	3986	3559	3144	2426	1380	472	202	–	–

ALTRUA 40 DR EL

Model S404

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

ALTRUA 40 DR EL
Model S404

Worldwide Distribution: 11,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**-**	**1**
[20] 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

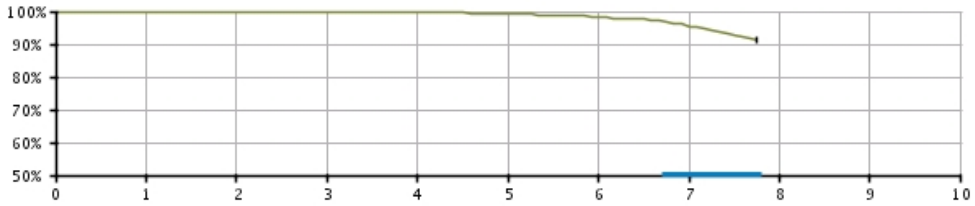
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

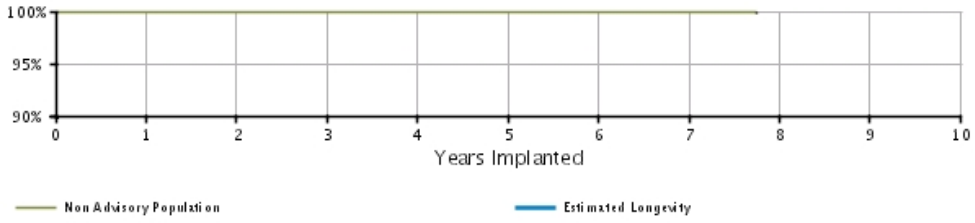
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 84
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)	99.66 (-0.3/+0.2)	99.33 (-0.4/+0.2)	98.23 (-0.7/+0.5)	95.37 (-1.5/+1.1)	91.50 @ 93 mo. (-2.5/+2.0)	–	–
	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 @ 93 mo. (-0.2/+0.0)	–	–
	Effective Sample Size	3954	3461	3039	2693	2089	1281	631	237	–	–

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**
[20] Capacitor	2	-	
[46] 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

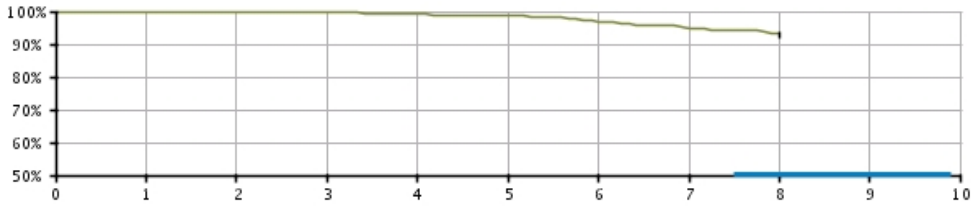
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

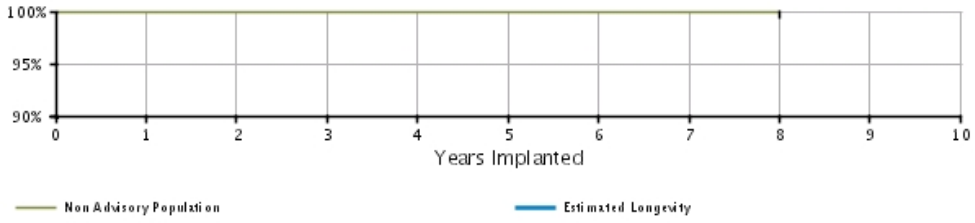
U.S. Registered Implants: 2,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 48
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)	99.30 (-0.7/+0.3)	98.67 (-0.9/+0.5)	96.95 (-1.4/+1.0)	94.85 (-1.9/+1.4)	93.07 (-2.4/+1.8)	–	–
	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 (-0.6/+0.1)	–	–
	Effective Sample Size	1532	1337	1143	980	840	687	538	233	–	–

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	-	-	
[62] Magnet rate	1	-	
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ALTRUA 20 DR (downsize)

Model S203

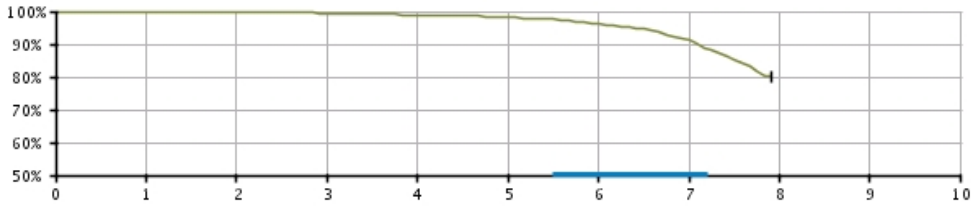
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

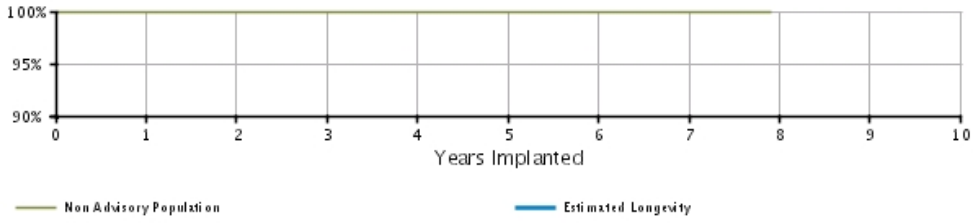
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 222
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)	99.42 (-0.3/+0.2)	98.87 (-0.4/+0.3)	98.15 (-0.5/+0.4)	96.18 (-0.9/+0.7)	91.11 (-1.6/+1.4)	80.02 @ 95 mo. (-3.4/+3.0)	–	–
	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 @ 95 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	4406	3892	3459	3057	2448	1574	764	205	–	–

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**
[20] Capacitor	2	-	
Mechanical	**-**	**-**	**0**
Software	**-**	**-**	**0**
Other	**-**	**1**	**1**
Non-patterned	-	-	
[37] Battery depletion	-	1	
WW Confirmed Malfunctions	**2**	**1**	**3**

More details about malfunctions

References cited in table above

ALTRUA 20 DR EL

Model S208

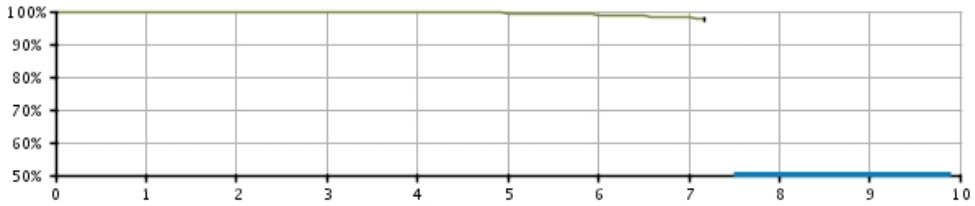
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

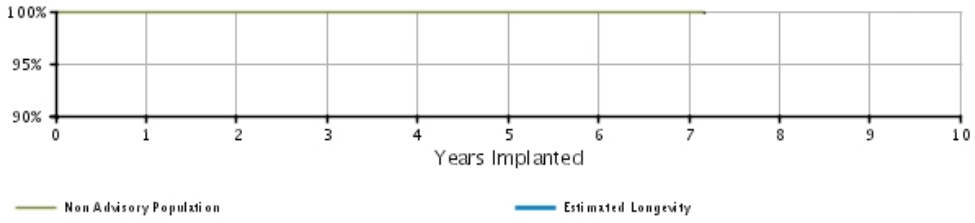
U.S. Registered Implants: 3,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 23
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)	99.63 (-0.3/+0.2)	99.45 (-0.4/+0.2)	98.96 (-0.7/+0.4)	98.08 (-1.2/+0.7)	97.69 @ 86 mo. (-1.6/+0.9)	–	–
	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 (-0.2/+0.0)	99.97 @ 86 mo. (-0.2/+0.0)	–	–
	Effective Sample Size	2773	2467	2190	1954	1476	830	293	224	–	–

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: 3

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

More details about malfunctions

References cited in table above

ALTRUA 20 SR

Models S201/S204

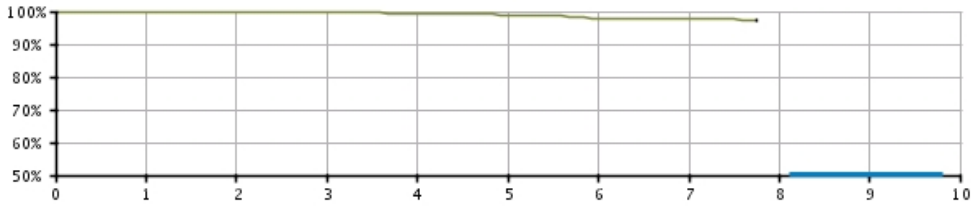
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

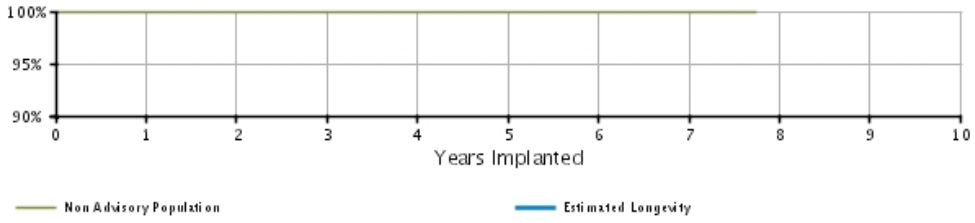
U.S. Registered Implants: 5,000
U.S. Approval Date: April 2008
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 44
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)	99.92 (-0.2/+0.1)	99.70 (-0.3/+0.1)	99.37 (-0.4/+0.2)	98.75 (-0.6/+0.4)	97.98 (-0.8/+0.6)	97.71 (-0.9/+0.7)	97.36 @ 93 mo. (-1.2/+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 (-0.0/+0.0)	100.00 @ 93 mo. (-0.0/+0.0)	–	–
	Effective Sample Size	3605	3057	2609	2242	1743	1079	522	224	–	–

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**
[20] 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

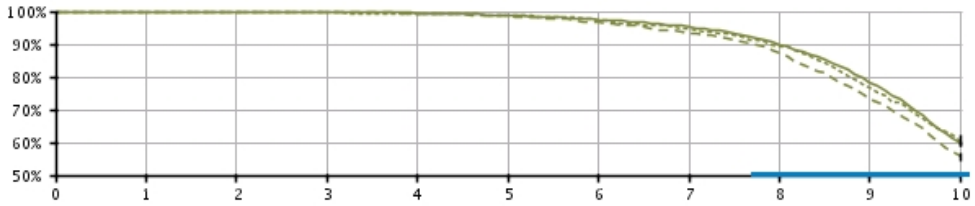
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

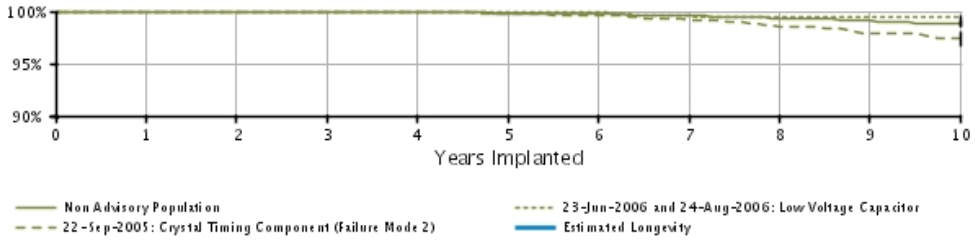
U.S. Registered Implants: 32,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 11,000

U.S. Normal Battery Depletions: 4,572
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:180
Without Compromised Therapy:167
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: 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)	89.76 (-0.6/+0.6)	78.45 (-0.9/+0.9)	59.57 (-1.6/+1.5)
	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)	99.08 (-0.2/+0.2)	98.82 (-0.3/+0.3)
	Effective Sample Size	21001	18656	16557	14647	12904	11296	9794	8140	4393	1141
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)	89.38 (-2.2/+1.8)	76.93 (-3.1/+2.8)	60.37 (-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 (-0.8/+0.3)
	Effective Sample Size	1877	1658	1459	1286	1131	984	843	691	518	350
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)	73.44 (-1.8/+1.7)	55.51 (-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)	97.95 (-0.7/+0.5)	97.39 (-0.8/+0.6)
	Effective Sample Size	5702	5046	4467	3938	3451	2978	2553	2094	1551	997

*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: 226

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**7**	**5**	**12**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[17] Capacitor	1	-	
[20] Capacitor	4	2	
[46] Integrated circuit	2	1	
Mechanical	**8**	**5**	**13**
[26] Seal plug	5	4	
[27] Header	2	1	
[48] Setscrew	1	-	
Software	**4**	**-**	**4**
[51] Underestimation of battery status	3	-	
[53] Pacing rate limit	1	-	
Other	**189**	**8**	**197**
Non-patterned	9	7	
[13] Longevity labeling	74	-	
[28] Magnet response	1	-	
[37] Battery depletion	3	1	
[67] Battery status	102	-	
WW Confirmed Malfunctions	**208**	**18**	**226**

More details about malfunctions

References cited in table above

INSIGNIA Ultra SR

Model 1190

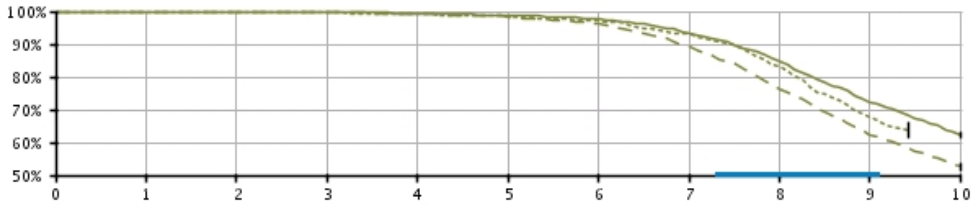
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

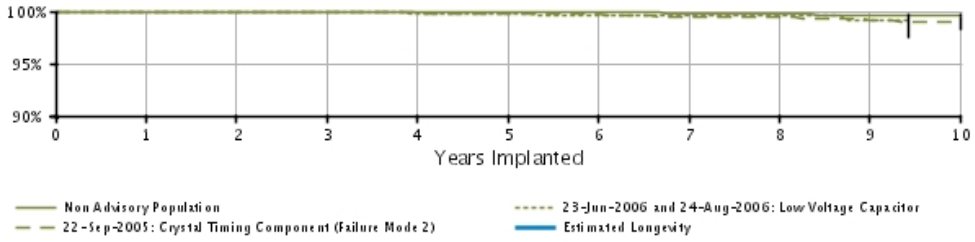
U.S. Registered Implants: 24,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 2,718
U.S. Unconfirmed Reports of Premature Battery Depletion : 9
U.S. Malfunctions:41
Without Compromised Therapy:37
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)	99.70 (-0.1/+0.1)	99.40 (-0.2/+0.1)	98.72 (-0.3/+0.2)	97.53 (-0.4/+0.3)	93.46 (-0.6/+0.6)	84.61 (-0.9/+0.9)	72.43 (-1.2/+1.2)	62.33 (-1.7/+1.7)
	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)	99.65 (-0.2/+0.1)	99.60 (-0.2/+0.1)
	Effective Sample Size	14141	12075	10288	8821	7686	6728	5726	4530	2474	763
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)	97.20 (-1.6/+1.0)	93.20 (-2.5/+1.9)	83.03 (-3.8/+3.2)	67.90 (-4.8/+4.4)	63.91 @ 113 mo. (-5.0/+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 (-1.7/+0.5)	99.20 @ 113 mo. (-1.7/+0.5)
	Effective Sample Size	1146	961	810	696	585	497	415	328	229	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)	99.22 (-0.4/+0.3)	98.27 (-0.6/+0.4)	96.24 (-0.9/+0.7)	89.33 (-1.5/+1.3)	76.24 (-2.2/+2.1)	62.39 (-2.6/+2.5)	52.56 (-2.8/+2.8)

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	4143	3555	2997	2525	2108	1765	1414	1029	730	527

*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: 73

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**2**	**5**	**7**
[8] Low-voltage capacitor (Advisory issued)	1	3	
[20] Capacitor	1	-	
[46] Integrated circuit	-	2	
Mechanical	**3**	**1**	**4**
[26] Seal plug	3	-	
[27] Header	-	1	
Software	**1**	**-**	**1**
[30] Memory error	1	-	
Other	**61**	**-**	**61**
Non-patterned	2	-	
[13] Longevity labeling	23	-	
[37] Battery depletion	2	-	
[67] Battery status	34	-	
WW Confirmed Malfunctions	**67**	**6**	**73**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR

Models 1294/1295

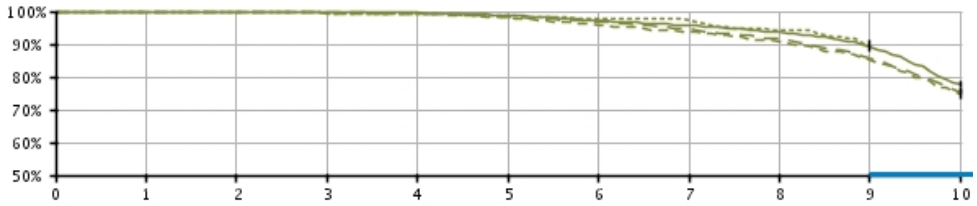
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

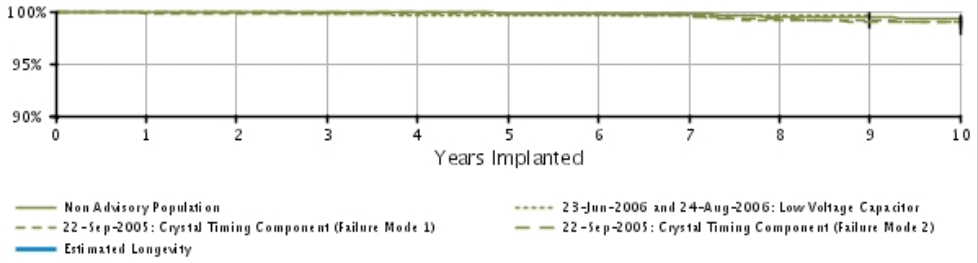
U.S. Registered Implants: 17,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1,957
U.S. Unconfirmed Reports of Premature Battery Depletion : 14
U.S. Malfunctions:65
Without Compromised Therapy:58
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)	95.66 (-0.7/+0.6)	93.53 (-0.9/+0.8)	89.40 (-1.2/+1.1)	77.60 (-2.1/+2.0)
	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)	99.44 (-0.3/+0.2)	99.28 (-0.4/+0.3)
	Effective Sample Size	6262	5549	4915	4355	3806	3311	2897	2490	1666	675
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)	94.50 (-3.1/+2.0)	89.84 (-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)	–
	Effective Sample Size	692	606	527	450	392	335	292	245	202	–
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)	90.91 (-2.2/+1.8)	85.18 (-2.9/+2.5)	74.96 (-3.8/+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)	99.18 (-1.0/+0.5)	99.18 (-1.0/+0.5)	98.94 (-1.2/+0.6)
	Effective Sample Size	1676	1454	1213	1063	922	784	660	552	449	331
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)	98.37 (-0.4/+0.3)	96.89 (-0.6/+0.5)	94.56 (-0.8/+0.7)	91.52 (-1.0/+0.9)	85.55 (-1.4/+1.3)	75.41 (-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	3690	3184	2674	2259	1848	1400

*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: 81

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**3**	**3**
[16] Integrated circuit	-	1	
[20] Capacitor	-	1	
[46] Integrated circuit	-	1	
Mechanical	**3**	**7**	**10**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[26] Seal plug	3	-	
[27] Header	-	2	
Software	**-**	**-**	**0**
Other	**64**	**4**	**68**
Non-patterned	4	4	
[13] Longevity labeling	49	-	
[67] Battery status	11	-	
WW Confirmed Malfunctions	**67**	**14**	**81**

More details about malfunctions

References cited in table above

INSIGNIA Entra DR (downsize)

Model 1296

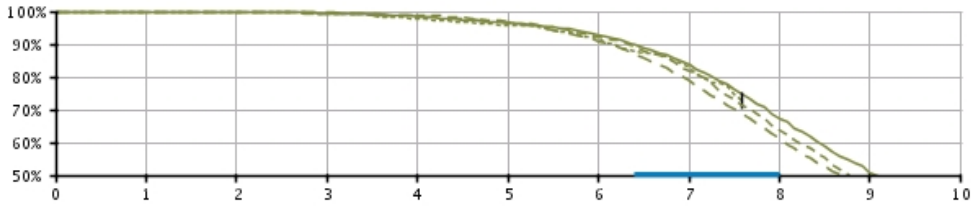
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

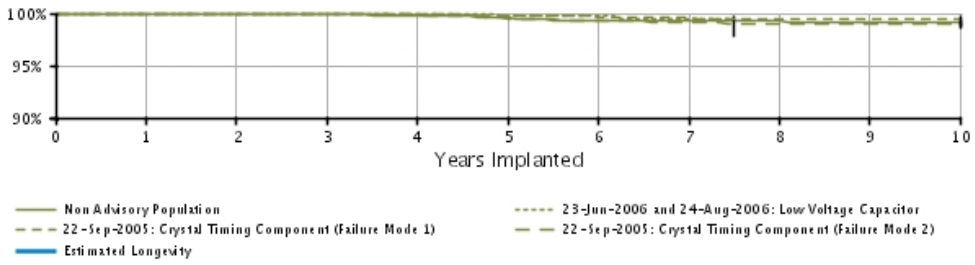
U.S. Registered Implants: 24,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 5,160
U.S. Unconfirmed Reports of Premature Battery Depletion : 25
U.S. Malfunctions:98
Without Compromised Therapy:92
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)	92.98 (-0.8/+0.7)	83.67 (-1.2/+1.1)	67.43 (-1.6/+1.6)	51.00 (-1.9/+1.9)	39.98 (-2.1/+2.2)
	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)	99.11 (-0.4/+0.3)	99.11 (-0.4/+0.3)
	Effective Sample Size	7136	6276	5492	4773	4102	3498	2768	1927	985	388
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)	91.88 (-3.0/+2.2)	82.91 (-4.3/+3.6)	72.97 @ 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	401	327	248	NaN	–	–
22-Sep-05 Crystal Timing Component (Failure Mode 1)* Registered Implants: 3000	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)	92.02 (-1.5/+1.3)	81.76 (-2.2/+2.0)	63.88 (-2.9/+2.8)	45.56 (-3.2/+3.2)	31.63 (-3.1/+3.3)

	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	2735	2404	2070	1812	1513	1225	932	594	356	200
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)	78.99 (-1.2/+1.1)	61.10 (-1.5/+1.5)	44.68 (-1.6/+1.6)	35.56 (-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	8450	7363	6362	5499	4505	3325	2151	1302	883

*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: 121

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**1**	**4**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	1	
[20] Capacitor	1	-	
[46] Integrated circuit	-	3	
Mechanical	**-**	**3**	**3**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	-	2	
[14] Solder bond	-	1	
Software	**4**	**-**	**4**
[25] Memory error	1	-	
[51] Underestimation of battery status	1	-	
[52] Interrupted telemetry	2	-	
Other	**107**	**2**	**109**
Non-patterned	5	2	
[13] Longevity labeling	95	-	
[37] Battery depletion	1	-	
[67] Battery status	6	-	
WW Confirmed Malfunctions	**112**	**9**	**121**

More details about malfunctions

References cited in table above

INSIGNIA Entra SR

Models 1195/1198

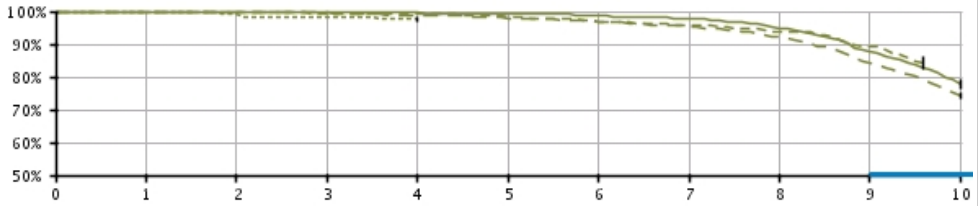
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

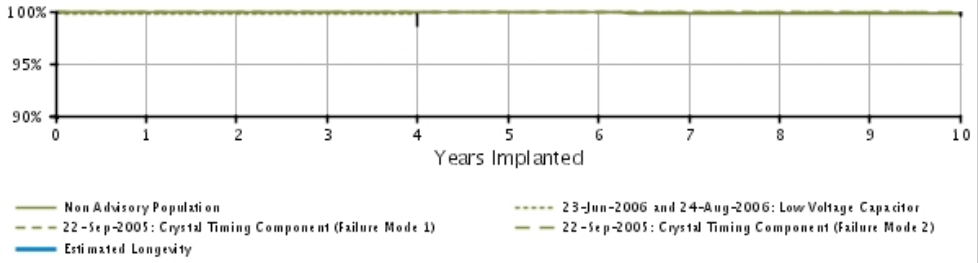
U.S. Registered Implants: 14,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 989
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)	94.84 (-1.1/+0.9)	87.59 (-1.8/+1.6)	77.68 (-2.9/+2.7)
	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	2733	2305	1975	1723	1447	879	371
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 500	Depletions and Malfunctions(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.10 (-1.9/+0.6)	98.39 (-2.2/+0.9)	97.94 (-2.5/+1.1)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	99.78 (-1.3/+0.2)	–	–	–	–	–	–
	Effective Sample Size	348	284	237	204	–	–	–	–	–	–
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)	95.71 (-2.1/+1.5)	93.92 (-2.7/+1.9)	89.40 (-3.7/+2.8)	84.27 @ 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	997	805	660	548	445	354	296	242	202
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 6000	Depletions and Malfunctions(%) (Confidence Interval)	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)	92.15 (-1.3/+1.2)	84.02 (-2.0/+1.8)	74.30 (-2.5/+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)	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	4575	3824	3171	2631	2174	1818	1528	1273	1009	775

*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

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

INSIGNIA Entra SR Models 1195/1198

Worldwide Distribution: 52,000
Worldwide Confirmed Malfunctions: 28

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**4**	**7**
[8] Low-voltage capacitor (Advisory issued)	-	2	
[20] Capacitor	2	2	
[46] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	1	-	
[11] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[22] Capacitor array	-	2	
[26] Seal plug	-	2	
[49] Seal plug	-	1	
Software	**-**	**-**	**0**
Other	**12**	**2**	**14**
Non-patterned	1	2	
[13] Longevity labeling	6	-	
[67] Battery status	5	-	
WW Confirmed Malfunctions	**16**	**12**	**28**

More details about malfunctions

References cited in table above

INSIGNIA Plus DR

Model 1297

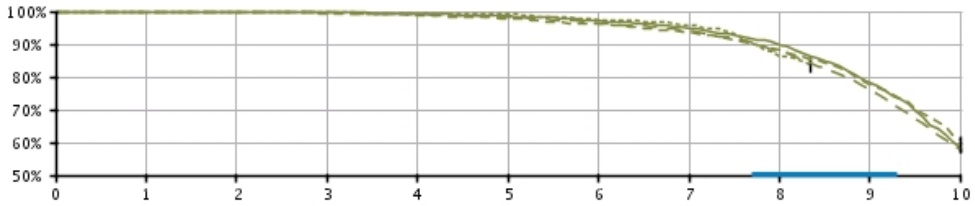
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

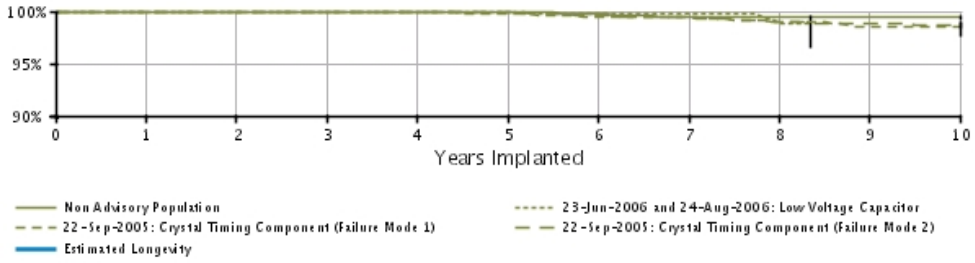
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 5,444
U.S. Unconfirmed Reports of Premature Battery Depletion : 20
U.S. Malfunctions:129
Without Compromised Therapy:120
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)	89.80 (-1.1/+1.0)	78.10 (-1.6/+1.5)	58.27 (-2.6/+2.5)
	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	6560	5831	5160	4545	3996	3495	3029	2521	1527	484
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)	99.18 (-1.3/+0.5)	99.18 (-1.3/+0.5)	97.24 (-2.2/+1.2)	95.94 (-2.6/+1.6)	86.19 (-4.5/+3.5)	83.71 @ 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)	98.85 (-2.4/+0.8)	98.85 @ 100 mo. (-2.4/+0.8)	–
	Effective Sample Size	664	580	510	441	385	333	284	220	201	–
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)	57.62 (-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	3470	2252

*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: 164

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**3**	**3**	**6**
[8] Low-voltage capacitor (Advisory issued)	1	1	
[20] Capacitor	2	1	
[46] Integrated circuit	-	1	
Mechanical	**16**	**8**	**24**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	1	2	
[11] Crystal timing component Failure Mode 2 (Advisory issued)	-	1	
[14] Solder bond	1	-	
[22] Capacitor array	1	-	
[26] Seal plug	5	-	
[27] Header	8	5	
Software	**7**	**-**	**7**
[51] Underestimation of battery status	4	-	
[52] Interrupted telemetry	2	-	
[53] Pacing rate limit	1	-	
Other	**122**	**5**	**127**
Non-patterned	7	5	
[13] Longevity labeling	87	-	
[37] Battery depletion	2	-	
[67] Battery status	26	-	
WW Confirmed Malfunctions	**148**	**16**	**164**

More details about malfunctions

References cited in table above

INSIGNIA Plus SR

Model 1194

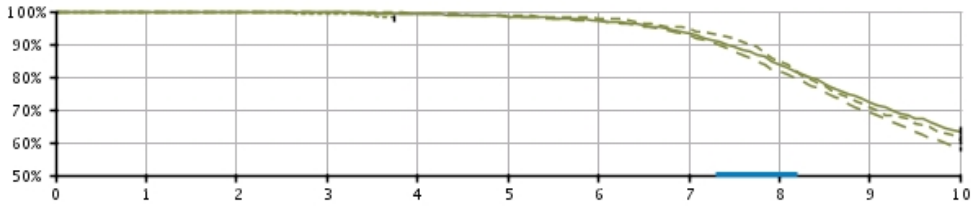
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

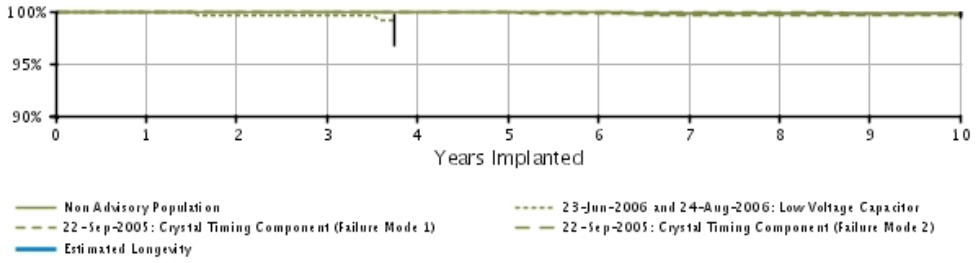
U.S. Registered Implants: 27,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 3,479
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)	99.30 (-0.3/+0.2)	98.44 (-0.5/+0.4)	97.26 (-0.7/+0.6)	93.23 (-1.1/+1.0)	83.54 (-1.7/+1.6)	72.24 (-2.2/+2.1)	63.41 (-2.8/+2.7)
	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 (-0.3/+0.1)
	Effective Sample Size	4724	4028	3444	2880	2463	2116	1784	1394	800	341
23-Jun-06 and 24-Aug-06 Low Voltage Capacitor* Registered Implants: 400	Depletions and Malfunctions(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.27 (-2.2/+0.6)	98.33 @ 45 mo. (-2.7/+1.0)	–	–	–	–	–	–
	Malfunctions Only(%) (Confidence Interval)	100.00 (-0.0/+0.0)	99.66 (-2.0/+0.3)	99.66 (-2.0/+0.3)	99.18 @ 45 mo. (-2.5/+0.6)	–	–	–	–	–	–
	Effective Sample Size	326	277	240	201	–	–	–	–	–	–
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)	94.83 (-1.2/+1.0)	84.81 (-2.2/+1.9)	70.86 (-2.9/+2.7)	60.66 (-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	2416	2063	1737	1431	1165	870	614	452
22-Sep-05 Crystal Timing Component (Failure Mode 2)* Registered Implants: 17000	Depletions and Malfunctions(%) (Confidence Interval)	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)	92.83 (-0.7/+0.6)	81.73 (-1.1/+1.0)	69.41 (-1.4/+1.3)	58.03 (-1.5/+1.5)
	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	13681	11683	10052	8506	7140	5999	4887	3606	2584	1867

*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: 37

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**4**	**5**	**9**
[8] Low-voltage capacitor (Advisory issued)	1	2	
[20] Capacitor	2	2	
[23] Integrated circuit	-	1	
[46] Integrated circuit	1	-	
Mechanical	**1**	**6**	**7**
[10] Crystal timing component Failure Mode 1 (Advisory issued)	-	5	
[22] Capacitor array	1	-	
[26] Seal plug	-	1	
Software	**1**	**-**	**1**
[53] Pacing rate limit	1	-	
Other	**19**	**1**	**20**
Non-patterned	4	-	
[13] Longevity labeling	10	-	
[24] Battery depletion	-	1	
[37] Battery depletion	1	-	
[67] Battery status	4	-	
WW Confirmed Malfunctions	**25**	**12**	**37**

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: 101

	Without Compromised Therapy	With Compromised Therapy	Total
Electrical	**-**	**5**	**5**
[8] Low-voltage capacitor (Advisory issued)	-	3	
[20] Capacitor	-	1	
[46] Integrated circuit	-	1	
Mechanical	**2**	**-**	**2**
[26] Seal plug	1	-	
[27] Header	1	-	
Software	**-**	**-**	**0**
Other	**92**	**2**	**94**
Non-patterned	3	1	
[13] Longevity labeling	42	-	
[37] Battery depletion	-	1	
[67] Battery status	47	-	
WW Confirmed Malfunctions	**94**	**7**	**101**

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**— *June 1, 2011 Voluntary Physician Advisory.* Premature battery depletion. Misaligned battery component. Improvement implemented.
4. **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.
5. **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.
6. **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.
7. **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.
8. **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.
9. **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.
10. **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.
11. **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.
12. **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.
13. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
14. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
15. **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.
16. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
17. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
18. **Setscrew thread depth**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew thread depth. Improvement implemented.
19. **Header**— Loosened header at pulse generator replacement or lead revision due to process variability. Improvement implemented.

20. **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.
21. **Battery depletion**— Premature battery depletion.
22. **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.
23. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
24. **Battery depletion**— Premature battery depletion and loss of capture.
25. **Memory error**— Pacing not as expected. Memory map error. Improvement implemented.
26. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
27. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
28. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
29. **Battery depletion**— Premature battery depletion.
30. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
31. **Rate fault declaration**— Inappropriate pacing due to timing interaction when autocapture is programmed on. Improvement implemented.
32. **Capacitor**— Premature battery depletion, no telemetry. Damage to capacitor. Improvement implemented.
33. **Circuit connection**— Loss of telemetry, no magnet tones, loss of pacing, loss of shock therapy. Damaged internal circuit connection. Improvement implemented.
34. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
35. **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.
36. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
37. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.
38. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
39. **Memory location**— Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location. Improvement implemented.
40. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
41. **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.
42. **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.
43. **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.
44. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
45. **Sensing**— Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.
46. **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.
47. **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.
48. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
49. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
50. **Interrogation at EOL**— No interrogation at end of life (EOL). Improvement implemented.
51. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
52. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
53. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
54. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
55. **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.
56. **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.
57. **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.

58. **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.
59. **Low-voltage capacitor**— Premature battery depletion, early appearance of elective replacement indicator (ERI). Failed low-voltage capacitor. Improvement implemented.
60. **Safety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
61. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
62. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
63. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
64. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
65. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
66. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
67. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
68. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
69. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
70. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
71. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
72. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
73. **Battery depletion**— Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
74. **Telemetry**— Inability to interrogate, premature battery depletion.
75. **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.
76. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
77. **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.
78. **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.
79. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
80. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
81. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented.
82. **High voltage capacitor**— Charge time alert message, end of life (EOL) indicator displayed, beeping tones. Loss of tachy therapy without loss of brady therapy. Internal high-voltage capacitor issue. Improvement implemented.
83. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.
84. **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	17,000	2	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	47,000	3	1	0	7	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	81,000	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	19,000	0	0	0	1	0	0
INTUA V272/V273/V282/V283/W272/W273	3,000	0	0	0	0	0	0
INVIVE V172/V173/V182/V183/W172/W173	18,000	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	9,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	8,000	1	0	0	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	23,000	1	0	1	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	21,000	0	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	12,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	11,000	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	68,000	3	1	0	9	0	0
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	72,000	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/A219	18,000	0	0	2	16	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	50,000	0	0	0	1	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	111,000	0	0	0	5	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	38,000	0	0	0	5	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	71,000	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	215,000	4	0	1	15	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	84,000	0	0	1	4	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	25,000	0	1	0	0	0	0
ALTRUA 50 DR (Downsize) S502	48,000	0	2	0	1	0	0
ALTRUA 50 DDD (Downsize) S503	12,000	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	11,000	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 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 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	30000	3	3	27	10	291	1232
INCEPTA/ENERGEN/PUNCTUA CRT-D N050/N051/N052/N053/N140/N141/N142/N143/N160/N1 61/N162/N163/N164/N165/P052/P053/P142/P143/ P162/P163/P165	52000	159	34	89	151	888	9251
COGNIS N118/N119/N120/P106/P107/P108	75000	2243	116	86	1501	1733	30469

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	9000	1	0	68	0	54	308
INTUA V272/V273/V282/V283/W272/W273	3000	5	0	23	1	19	243
INVIVE V172/V173/V182/V183/W172/W173	8000	39	0	51	1	59	1496
CONTAK RENEWAL TR H120/H125	19000	2794	16	163	52	257	9925

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, A219	9000	1	0	12	3	172	237
SQ-RX S-ICD 1010	8000	80	0	35	37	258	696

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	14000	1	0	98	1	98	330
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	14000	1	0	111	2	82	272
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	5000	1	1	45	4	61	312
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	5000	2	0	49	4	54	309
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	47	10	441	62	478	4875
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/ F052/F053/F142/F143/F162/F163	47000	42	13	546	90	583	6148

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	90	102	702	1167	649	12289
TELIGEN DR E110/E111/F110/F111	66000	285	153	1017	1760	1156	22263
CONFIENT DR E030/F030	7000	536	2	165	14	156	3098
VITALITY 2 EL VR T177	7000	1330	9	166	1276	114	2792

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	20000	4	0	109	3	71	319
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	58000	9	5	299	8	232	1450

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	12000	4	0	91	2	52	576
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	3	0	123	4	50	739
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	115	12	944	36	696	15022
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	14	0	219	7	142	5423
ALTRUA 60 SR S601	32000	583	4	263	9	171	14423
ALTRUA 60 DR (Downsize) S603	90000	8653	45	651	62	562	30024
ALTRUA 60 DR S602	22000	517	3	212	16	197	7344
ALTRUA 60 DR EL S606	59000	486	10	501	10	418	15624
ALTRUA 40 SR S401	5000	84	0	28	2	23	2340
ALTRUA 40 DR (downsize) S403	14000	1333	3	71	3	79	4960
ALTRUA 40 DR S402	2000	49	1	17	0	8	731
ALTRUA 40 DR EL S404	5000	39	1	34	0	43	1738
ALTRUA 20 SR S201/S204	5000	44	1	22	0	36	2464
ALTRUA 20 DR (downsize) S203	5000	222	3	29	0	38	2226

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	48	0	10	1	15	815
ALTRUA 20 DR EL S208	3000	23	0	24	1	10	1218
INSIGNIA Ultra SR 1190 [4]	24000	2718	9	222	43	146	16526
INSIGNIA Ultra DR 1291 [4]	32000	4572	20	355	181	314	15848
INSIGNIA Entra SR 1195/1198 [4]	14000	989	10	93	9	75	10640
INSIGNIA Entra DR (Downsize) 1296 [4]	24000	5160	25	130	99	152	15604
INSIGNIA Entra DR 1294/1295 [4]	17000	1957	14	141	65	183	11033
INSIGNIA Plus SR 1194 [4]	27000	3479	8	228	27	155	20739
INSIGNIA Plus DR 1297 [4]	27000	5444	20	268	131	261	15301

[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

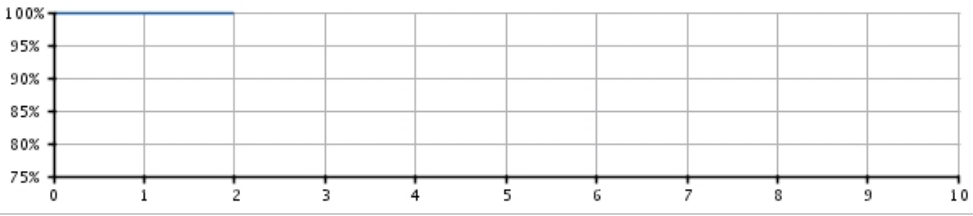
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 3,000

U.S. Chronic Lead Complications: 0
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: 3000	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	–	–	–	–	–	–	–	–
Effective Sample Size	502	203	–	–	–	–	–	–	–	–

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: 9,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	-	0
Insulation	-	-	0
Other	1	-	1
WW Confirmed Malfunctions	1	0	1

More details about malfunctions

References cited in table above

ACUITY X4 Spiral S

Models 4674/4675

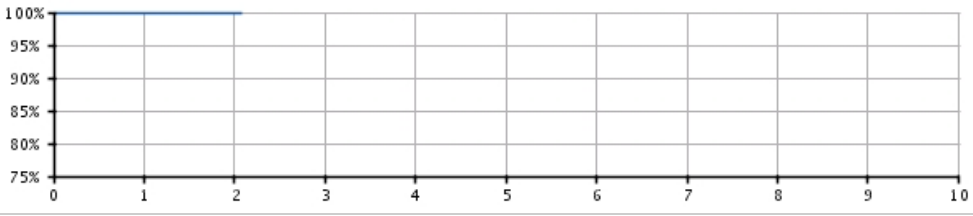
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 7,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 7,000

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: 7000	99.95 (-0.1/+0.0)	99.95 (-0.1/+0.0)	99.95 @ 25 mo. (-0.1/+0.0)	–	–	–	–	–	–	–
Effective Sample Size	741	253	205	–	–	–	–	–	–	–

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: 19,000
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

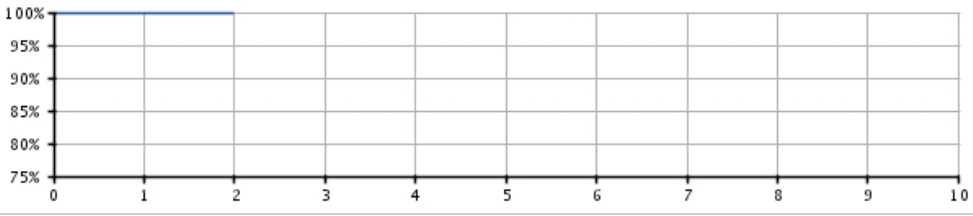
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 5,000
U.S. Approval Date: February 2016
U.S. Estimated Active Implants: 4,000

U.S. Chronic Lead Complications: 4
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: 5000	99.87 (-0.2/+0.1)	99.87 (-0.2/+0.1)	–	–	–	–	–	–	–	–
Effective Sample Size	577	204	–	–	–	–	–	–	–	–

ACUITY X4 Straight

Models 4671/4672

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

ACUITY X4 Straight Models 4671/4672

Worldwide Distribution: 17,000
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

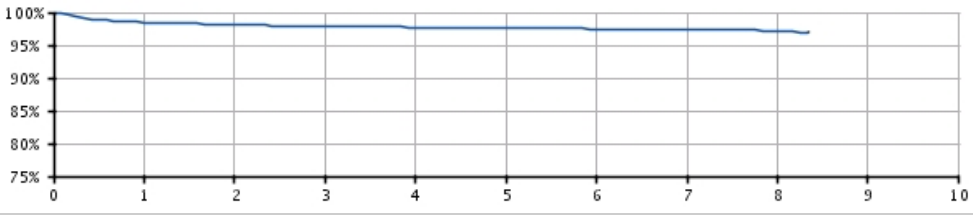
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 23,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 15,000

U.S. Chronic Lead Complications: 446
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: 22000	98.49 (-0.2/+0.2)	98.14 (-0.2/+0.2)	97.89 (-0.2/+0.2)	97.72 (-0.2/+0.2)	97.58 (-0.2/+0.2)	97.49 (-0.3/+0.2)	97.45 (-0.3/+0.2)	97.25 (-0.4/+0.4)	96.99 @ 100 mo. (-0.7/+0.6)	–
Effective Sample Size	18883	15722	12375	9219	6571	4144	2232	650	275	–

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: 43,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**3**	**4**
[27] Non-patterned, Conductor	1	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**1**	**1**	**2**
[28] Non-patterned, Insulation	1	1	
Other	**2**	**-**	**2**
[26] 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

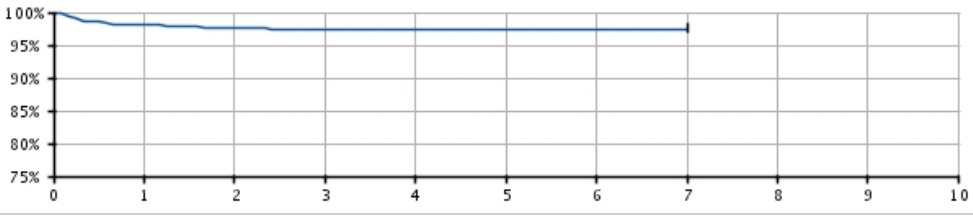
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 1383
Leads Active: 891
Cumulative Followup Months : 45,772

Chronic Lead Complications: 33
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: 1383	98.01 (-1.6/+1.6)	97.64 (-1.7/+1.7)	97.32 (-1.9/+1.9)	97.32 (-1.9/+1.9)	97.32 (-1.9/+1.9)	97.32 (-1.9/+1.9)	97.32 (-1.9/+3.8)	–	–	–
Effective Sample Size	1124	971	775	613	429	237	59	–	–	–

ACUITY Steerable

Models 4554/4555/4556

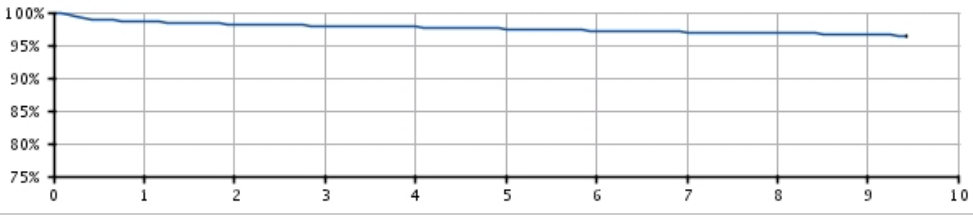
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2008
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 591
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	98.59 (-0.1/+0.1)	98.22 (-0.2/+0.2)	97.96 (-0.2/+0.2)	97.76 (-0.2/+0.2)	97.50 (-0.2/+0.2)	97.23 (-0.2/+0.2)	97.00 (-0.3/+0.3)	96.90 (-0.3/+0.3)	96.67 (-0.4/+0.3)	96.42 @ 113 mo. (-0.7/+0.6)
Effective Sample Size	24184	20749	16998	13491	10501	7729	5249	2849	887	257

ACUITY Steerable

Models 4554/4555/4556

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

ACUITY Steerable Models 4554/4555/4556

Worldwide Distribution: 64,000
Worldwide Confirmed Malfunctions: 54

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**35**	**46**
[25] Conductor fracture	1	-	
[27] Non-patterned, Conductor	7	9	
[34] Extracardiac fracture	3	26	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**6**	**1**	**7**
[26] Non-patterned, Other	6	1	
WW Confirmed Malfunctions	**17**	**37**	**54**

More details about malfunctions

References cited in table above

EASYTRAK 3

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

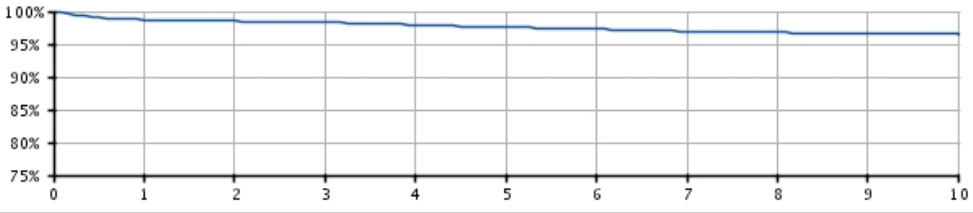
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 440
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 Registered Implants: 22000	98.70 (-0.2/+0.1)	98.52 (-0.2/+0.2)	98.30 (-0.2/+0.2)	97.98 (-0.2/+0.2)	97.60 (-0.3/+0.2)	97.31 (-0.3/+0.3)	96.94 (-0.3/+0.3)	96.80 (-0.3/+0.3)	96.65 (-0.4/+0.3)	96.57 (-0.4/+0.3)
Effective Sample Size	18324	15875	13337	10916	8862	7191	5735	4392	3275	2161

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: 49

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**34**	**44**
[27] Non-patterned, Conductor	6	5	
[34] Extracardiac fracture	4	29	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**1**	**4**
[28] Non-patterned, Insulation	3	1	
Other	**1**	**-**	**1**
[26] Non-patterned, Other	1	-	
WW Confirmed Malfunctions	**14**	**35**	**49**

More details about malfunctions

References cited in table above

EASYTRAK 2

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

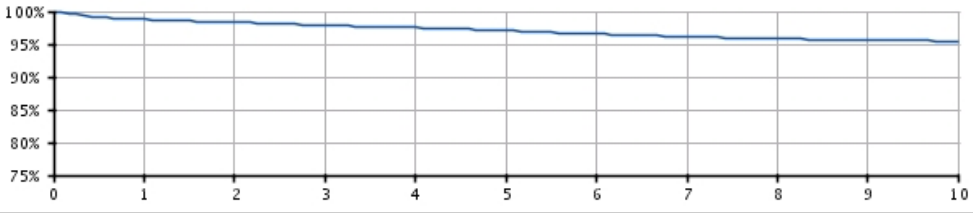
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 97,000
U.S. Approval Date: August 2004
U.S. Estimated Active Implants: 43,000

U.S. Chronic Lead Complications: 2,220
U.S. Malfunctions:353
Without Compromised Therapy:97
With Compromised Therapy:256

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 97000	98.77 (-0.1/+0.1)	98.32 (-0.1/+0.1)	97.90 (-0.1/+0.1)	97.53 (-0.1/+0.1)	97.08 (-0.1/+0.1)	96.56 (-0.1/+0.1)	96.13 (-0.2/+0.2)	95.84 (-0.2/+0.2)	95.64 (-0.2/+0.2)	95.41 (-0.2/+0.2)
Effective Sample Size	81034	69856	58756	48537	39722	31750	24561	17976	12749	NaN

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: 177,000
Worldwide Confirmed Malfunctions: 489

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**106**	**357**	**463**
[25] Conductor fracture	100	310	
[27] Non-patterned, Conductor	6	47	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**11**	**2**	**13**
[28] Non-patterned, Insulation	11	2	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**125**	**364**	**489**

More details about malfunctions

References cited in table above

EASYTRAK

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

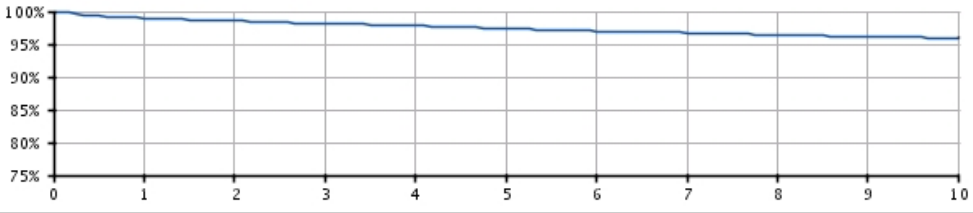
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 904
U.S. Malfunctions:25
Without Compromised Therapy:10
With Compromised Therapy:15

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)	96.12 (-0.3/+0.3)	95.93 (-0.3/+0.3)
Effective Sample Size	30531	26244	22510	19337	16502	14104	12099	10522	9137	7789

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: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**13**	**13**
[27] Non-patterned, Conductor	-	13	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**3**	**3**	**6**
[28] Non-patterned, Insulation	3	3	
Other	**7**	**1**	**8**
[26] Non-patterned, Other	7	1	
WW Confirmed Malfunctions	**10**	**17**	**27**

More details about malfunctions

References cited in table above

EMBLEM/Q-TRAK S-ICD Electrode

Models 3010/3401

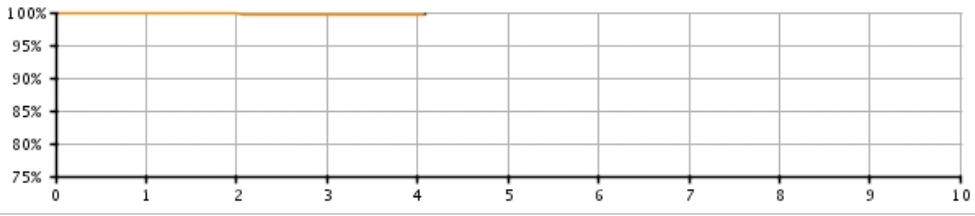
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 17,000
U.S. Approval Date: September 2012
U.S. Estimated Active Implants: 16,000

U.S. Chronic Lead Complications: 11
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: 17000	99.86 (-0.1/+0.1)	99.77 (-0.1/+0.1)	99.74 (-0.1/+0.1)	99.74 (-0.1/+0.1)	99.74 @ 49 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	9340	3852	708	270	228	–	–	–	–	–

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: 29,000
Worldwide Confirmed Malfunctions: 4

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	0
Crimp/Weld/Bond	-	2	2
[37] Weld fracture	-	2	
Insulation	-	-	0
Other	-	2	2
WW Confirmed Malfunctions	0	4	4

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: 10,000

Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	-	-	**0**
Crimp/Weld/Bond	-	-	**0**
Insulation	-	-	**0**
[28] Non-patterned, Insulation	-	-	
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: 35,000

Worldwide Confirmed Malfunctions: 10

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**7**	**7**
[27] Non-patterned, Conductor	-	1	
[38] Conductor cable fracture	-	6	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**2**	**2**
[28] Non-patterned, Insulation	-	2	
Other	**-**	**1**	**1**
[26] Non-patterned, Other	-	1	
WW Confirmed Malfunctions	**0**	**10**	**10**

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: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**1**	**1**
[38] Conductor cable fracture	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**-**	**0**
Other	**-**	**-**	**0**
WW Confirmed Malfunctions	**0**	**1**	**1**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE 4-Site
Dual Coil, Active Fixation

Models 0275/0276/0295/0296

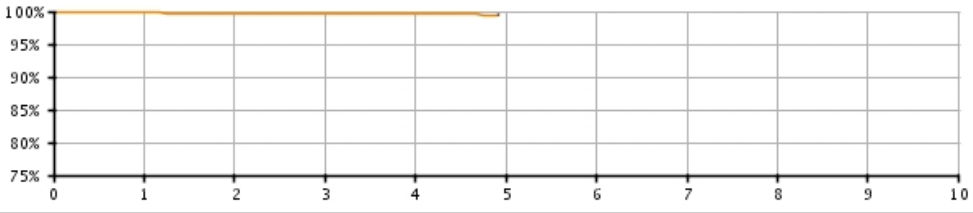
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 51,000

U.S. Chronic Lead Complications: 162
U.S. Malfunctions:10
Without Compromised Therapy:0
With Compromised Therapy:10

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 58000	99.78 (-0.0/+0.0)	99.69 (-0.1/+0.0)	99.65 (-0.1/+0.1)	99.59 (-0.1/+0.1)	99.50 @ 59 mo. (-0.2/+0.1)	–	–	–	–	–
Effective Sample Size	45145	32662	20736	9157	422	–	–	–	–	–

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: 95,000

Worldwide Confirmed Malfunctions: 37

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**3**	**3**
[27] Non-patterned, Conductor	-	3	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**7**	**25**	**32**
[28] Non-patterned, Insulation	7	25	
Other	**2**	**-**	**2**
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**9**	**28**	**37**

More details about malfunctions

References cited in table above

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

Models 0275/0276/0295/0296

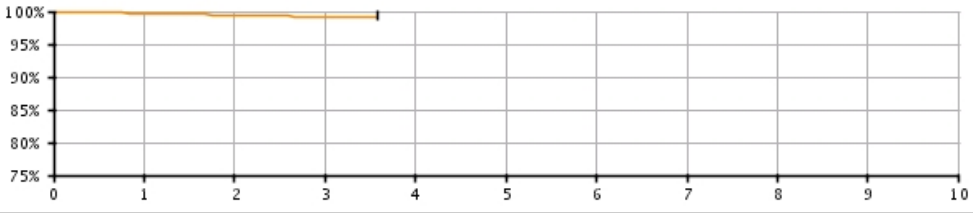
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 851
Leads Active: 638
Cumulative Followup Months : 23,260

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: 1104	99.75 (-1.6/+1.6)	99.46 (-1.7/+1.7)	99.19 (-1.9/+1.9)	99.19 @ 43 mo. (-1.9/+3.8)	–	–	–	–	–	–
Effective Sample Size	738	653	200	51	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Dual Coil, Passive Fixation

Models 0265/0266/0285/0286

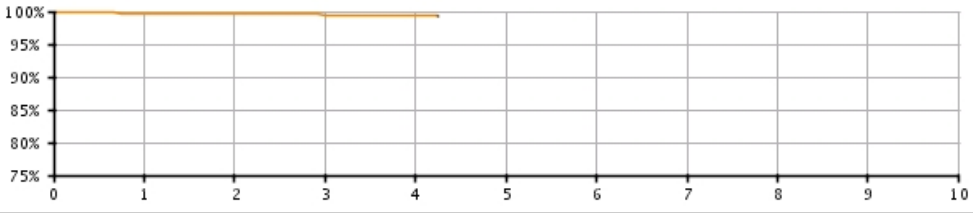
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
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: 3000	99.74 (-0.3/+0.1)	99.61 (-0.4/+0.2)	99.47 (-0.6/+0.3)	99.28 (-0.8/+0.4)	99.28 @ 51 mo. (-0.8/+0.4)	–	–	–	–	–
Effective Sample Size	1929	1367	762	318	227	–	–	–	–	–

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: 9,000

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

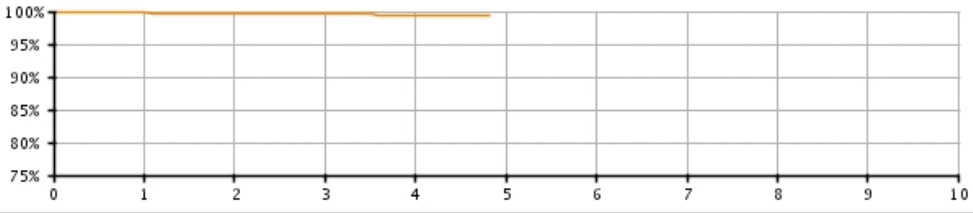
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 67,000
U.S. Approval Date: November 2010
U.S. Estimated Active Implants: 62,000

U.S. Chronic Lead Complications: 186
U.S. Malfunctions:11
Without Compromised Therapy:1
With Compromised Therapy:10

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 66000	99.76 (-0.0/+0.0)	99.65 (-0.1/+0.0)	99.57 (-0.1/+0.1)	99.50 (-0.1/+0.1)	99.45 @ 58 mo. (-0.1/+0.1)	–	–	–	–	–
Effective Sample Size	44204	25841	12635	4171	421	–	–	–	–	–

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: 110,000

Worldwide Confirmed Malfunctions: 30

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**2**	**2**
[24] Conductor fracture	-	1	
[27] Non-patterned, Conductor	-	1	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**23**	**25**
[28] Non-patterned, Insulation	2	23	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**28**	**30**

More details about malfunctions

References cited in table above

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

Models 0292/0293

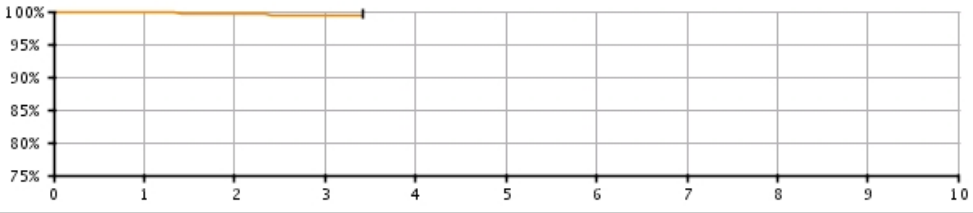
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 1,104
Leads Active: 910
Cumulative Followup Months : 30,060

Chronic Lead Complications: 4
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: 1104	99.89 (-1.6/+1.6)	99.52 (-1.7/+1.7)	99.36 (-1.9/+1.9)	99.36 @ 41 mo. (-1.9/+3.8)	–	–	–	–	–	–
Effective Sample Size	854	756	206	52	–	–	–	–	–	–

ENDOTAK RELIANCE 4-Site
Single Coil, Passive Fixation

Models 0282/0283

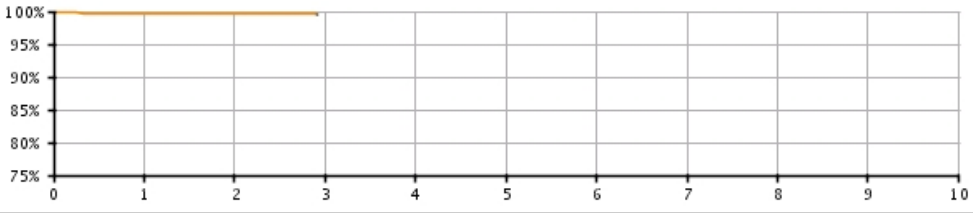
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 4
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	99.64 (-0.6/+0.2)	99.64 (-0.6/+0.2)	99.64 @ 35 mo. (-0.6/+0.2)	–	–	–	–	–	–	–
Effective Sample Size	768	391	201	–	–	–	–	–	–	–

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: 2

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

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

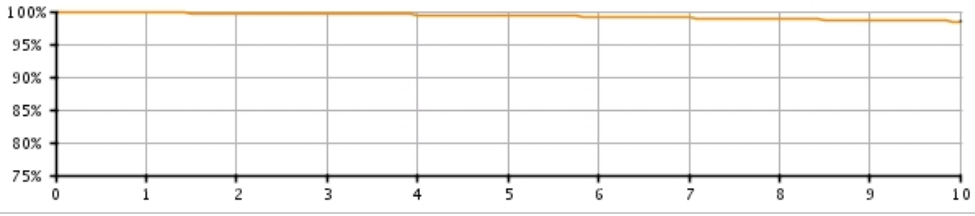
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 286,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 136,000

U.S. Chronic Lead Complications: 1,954
U.S. Malfunctions:294
Without Compromised Therapy:111
With Compromised Therapy:183

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 286000	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)	99.21 (-0.0/+0.0)	99.01 (-0.0/+0.0)	98.85 (-0.1/+0.1)	98.68 (-0.1/+0.1)	98.48 (-0.1/+0.1)
Effective Sample Size	251619	223861	198900	175532	152732	123406	97548	72410	51422	35793

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: 373,000
Worldwide Confirmed Malfunctions: 461

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**2**	**128**	**130**
[24] Conductor fracture	-	84	
[27] Non-patterned, Conductor	2	44	
Crimp/Weld/Bond	**6**	**1**	**7**
[5] Seal rings	3	1	
[31] Non-patterned, Crimp, Weld, Bond	3	-	
Insulation	**146**	**126**	**272**
[28] Non-patterned, Insulation	146	126	
Other	**30**	**22**	**52**
[26] Non-patterned, Other	30	22	
WW Confirmed Malfunctions	**184**	**277**	**461**

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

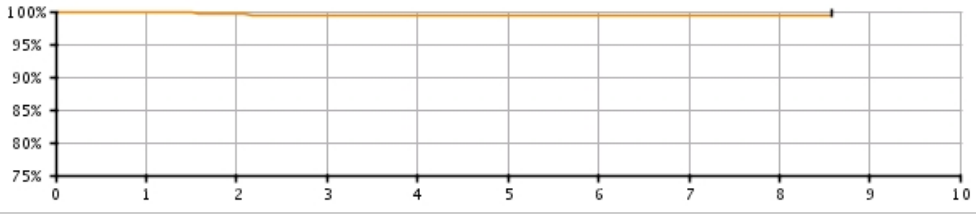
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

Longitude Registry Summary Data

Leads Enrolled: 743
Leads Active: 395
Cumulative Followup Months : 26,494

Chronic Lead Complications: 2
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: 743	100 (-1.6/+1.6)	99.67 (-1.7/+1.7)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+1.9)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 (-1.9/+3.8)	99.49 @ 103 mo. (-1.9/+3.8)	–
Effective Sample Size	645	571	505	435	366	247	121	59	50	–

ENDOTAK RELIANCE
Dual Coil, Passive Fixation

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

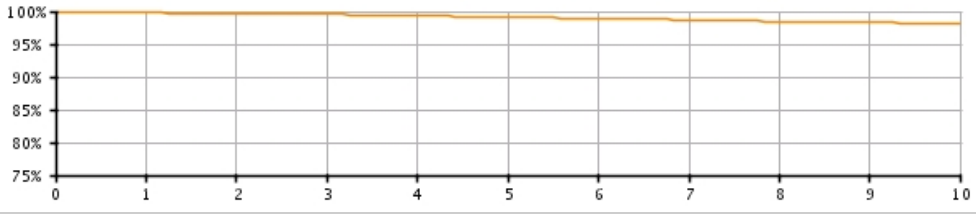
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 500
U.S. Malfunctions:38
Without Compromised Therapy:9
With Compromised Therapy:29

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 46000	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)	98.69 (-0.1/+0.1)	98.46 (-0.2/+0.1)	98.30 (-0.2/+0.2)	98.10 (-0.2/+0.2)
Effective Sample Size	40569	36122	32128	28369	24831	21350	18205	15297	12690	10453

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: 108,000

Worldwide Confirmed Malfunctions: 127

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**31**	**31**
[24] Conductor fracture	-	17	
[27] Non-patterned, Conductor	-	14	
Crimp/Weld/Bond	**-**	**3**	**3**
[36] Conductor connection	-	3	
Insulation	**37**	**45**	**82**
[28] Non-patterned, Insulation	37	45	
Other	**8**	**3**	**11**
[6] Manufacturing material	-	1	
[26] Non-patterned, Other	8	3	
WW Confirmed Malfunctions	**45**	**82**	**127**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Active Fixation

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

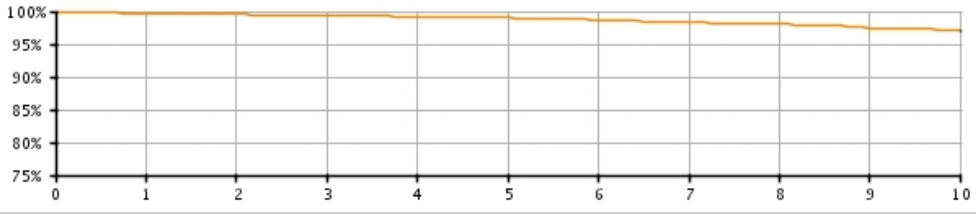
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 222
U.S. Malfunctions:59
Without Compromised Therapy:20
With Compromised Therapy:39

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 31000	99.69 (-0.1/+0.1)	99.52 (-0.1/+0.1)	99.41 (-0.1/+0.1)	99.21 (-0.1/+0.1)	99.02 (-0.1/+0.1)	98.72 (-0.2/+0.2)	98.35 (-0.3/+0.2)	98.01 (-0.3/+0.3)	97.43 (-0.5/+0.4)	97.06 (-0.7/+0.6)
Effective Sample Size	27038	22838	18871	15207	11842	7231	4510	2478	1209	645

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: 68,000

Worldwide Confirmed Malfunctions: 157

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**60**	**61**
[24] Conductor fracture	1	51	
[27] Non-patterned, Conductor	-	9	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**48**	**35**	**83**
[28] Non-patterned, Insulation	48	35	
Other	**8**	**5**	**13**
[26] Non-patterned, Other	8	5	
WW Confirmed Malfunctions	**57**	**100**	**157**

More details about malfunctions

References cited in table above

ENDOTAK RELIANCE
Single Coil, Passive Fixation

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

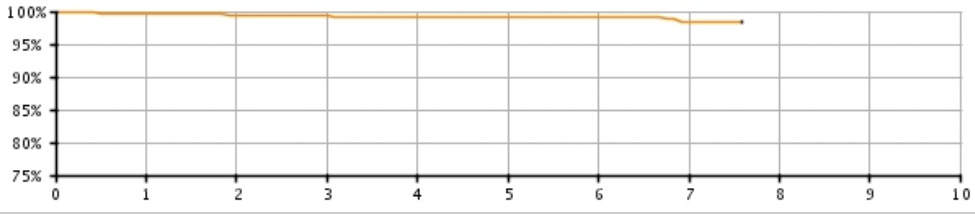
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 17
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	99.75 (-0.4/+0.2)	99.44 (-0.6/+0.3)	99.34 (-0.6/+0.3)	99.22 (-0.7/+0.4)	99.22 (-0.7/+0.4)	99.22 (-0.7/+0.4)	98.44 (-1.7/+0.8)	98.44 @ 91 mo. (-1.7/+0.8)	–	–
Effective Sample Size	1421	1138	907	669	497	342	237	201	–	–

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: 8,000

Worldwide Confirmed Malfunctions: 16

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

More details about malfunctions

References cited in table above

ENDOTAK ENDURANCE EZ
Active Fixation

Models 0154/0155/0156

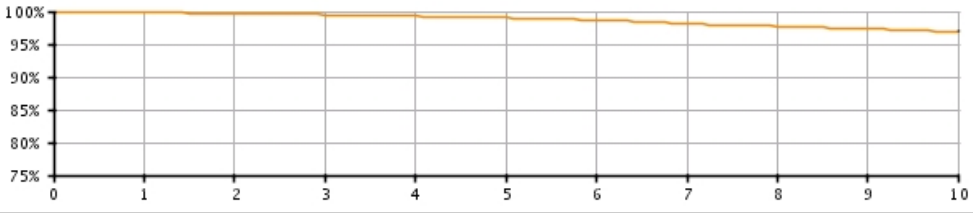
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 587
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	24452	21793	19399	17262	15330	13599	12052	10712	9491	8402

ENDOTAK ENDURANCE Rx
Passive Fixation Steroid Eluting

Models 0144/0145/0146

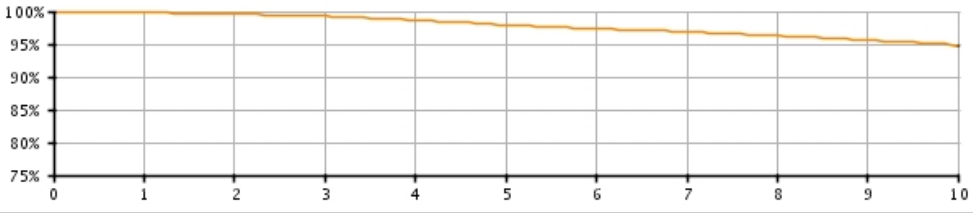
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 694
U.S. Malfunctions:25
Without Compromised Therapy:6
With Compromised Therapy:19

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	5203

INGEVITY Positive Fixation

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

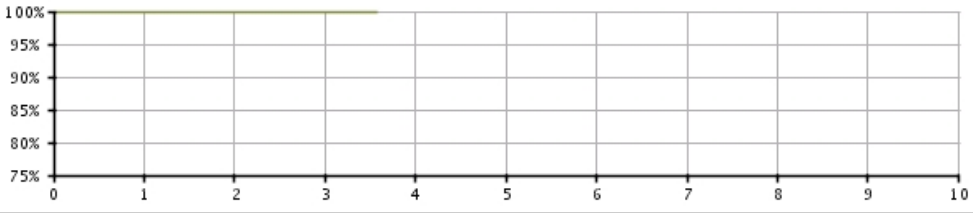
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 54,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 52,000

U.S. Chronic Lead Complications: 55
U.S. Malfunctions:5
Without Compromised Therapy:3
With Compromised Therapy:2

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 54000	99.78 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.78 @ 43 mo. (-0.1/+0.1)	–	–	–	–	–	–
Effective Sample Size	1058	931	635	251	–	–	–	–	–	–

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: 224,000
Worldwide Confirmed Malfunctions: 19

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**10**	**6**	**16**
[27] Non-patterned, Conductor	8	4	
[39] Inner conductor break	2	2	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[28] Non-patterned, Insulation	-	1	
Other	**1**	**1**	**2**
[26] Non-patterned, Other	1	1	
WW Confirmed Malfunctions	**11**	**8**	**19**

More details about malfunctions

References cited in table above

INGEVITY Passive Fixation

Models 7631/7632/7731/7732

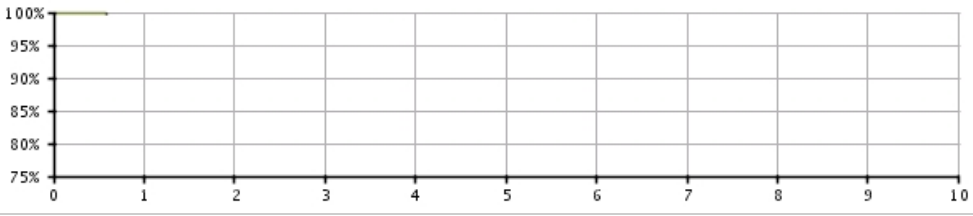
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 3,000
U.S. Approval Date: April 2016
U.S. Estimated Active Implants: 3,000

U.S. Chronic Lead Complications: 0
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: 3000	99.81 @ 7 mo. (-0.7/+0.2)	–	–	–	–	–	–	–	–	–
Effective Sample Size	396	–	–	–	–	–	–	–	–	–

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: 29,000
Worldwide Confirmed Malfunctions: 2

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

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: 24,000
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: 182,000
Worldwide Confirmed Malfunctions: 114

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**5**	**32**	**37**
[7] Lead conductor	2	18	
[32] Conductor damage	3	14	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**53**	**10**	**63**
[2] Inner insulation abrasion	3	1	
[28] Non-patterned, Insulation	4	-	
[33] Insulation damage	46	9	
Other	**14**	**-**	**14**
[26] Non-patterned, Other	14	-	
WW Confirmed Malfunctions	**72**	**42**	**114**

More details about malfunctions

References cited in table above

FLEXTEND Active Fixation

Models 4086/4087/4088

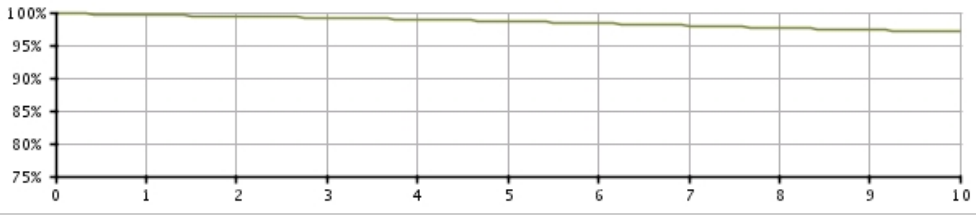
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 235,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 98,000

U.S. Chronic Lead Complications: 3,356
U.S. Malfunctions:324
Without Compromised Therapy:131
With Compromised Therapy:193

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population Registered Implants: 235000	99.60 (-0.0/+0.0)	99.40 (-0.0/+0.0)	99.20 (-0.0/+0.0)	98.93 (-0.0/+0.0)	98.66 (-0.1/+0.1)	98.33 (-0.1/+0.1)	97.98 (-0.1/+0.1)	97.63 (-0.1/+0.1)	97.31 (-0.1/+0.1)	97.07 (-0.1/+0.1)
Effective Sample Size	200079	174363	151266	130325	111558	94352	78333	64197	52208	39388

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: 289,000
Worldwide Confirmed Malfunctions: 348

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**16**	**174**	**190**
[7] Lead conductor	9	83	
[27] Non-patterned, Conductor	-	7	
[32] Conductor damage	7	84	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**106**	**29**	**135**
[2] Inner insulation abrasion	19	8	
[28] Non-patterned, Insulation	9	-	
[33] Insulation damage	78	21	
Other	**18**	**5**	**23**
[26] Non-patterned, Other	18	5	
WW Confirmed Malfunctions	**140**	**208**	**348**

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

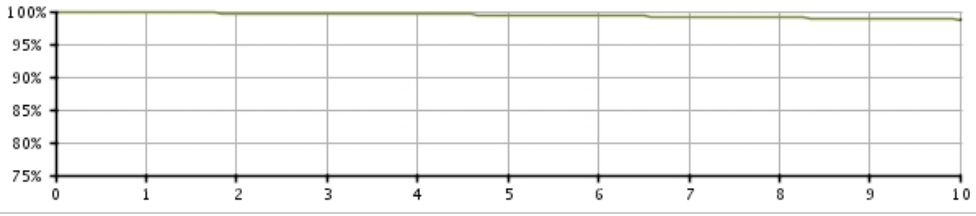
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

U.S. Summary

U.S. Registered Implants: 453,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 254,000

U.S. Chronic Lead Complications: 2,457
U.S. Malfunctions:134
Without Compromised Therapy:28
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)	99.57 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.33 (-0.0/+0.0)	99.18 (-0.0/+0.0)	99.05 (-0.0/+0.0)	98.89 (-0.1/+0.1)	98.75 (-0.1/+0.1)
Registered Implants: 452000										
Effective Sample Size	386953	327465	274596	227755	186650	150052	117387	88279	66068	48271

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: 696,000

Worldwide Confirmed Malfunctions: 161

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**12**	**118**	**130**
[7] Lead conductor	6	54	
[27] Non-patterned, Conductor	1	5	
[32] Conductor damage	5	59	
Crimp/Weld/Bond	**1**	**2**	**3**
[23] Terminal weld	-	1	
[31] Non-patterned, Crimp, Weld, Bond	1	1	
Insulation	**12**	**6**	**18**
[33] Insulation damage	12	6	
Other	**8**	**2**	**10**
[26] Non-patterned, Other	8	2	
WW Confirmed Malfunctions	**33**	**128**	**161**

More details about malfunctions

References cited in table above

FINELINE II EZ
Positive Fixation (poly) Longitude*

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

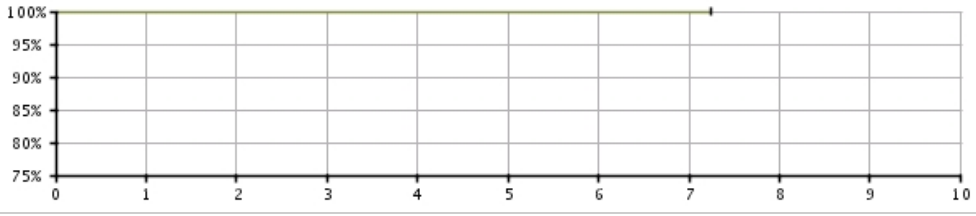
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories | Longitude Survival Probability

Longitude Registry Summary Data

Leads Enrolled: 924
Leads Active: 676
Cumulative Followup Months : 28,636

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: 924	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.1)	99.76 (-0.7/+0.5)	99.76 @ 87 mo. (-1.9/+3.4)	–	–
Effective Sample Size	730	566	302	241	175	104	74	54	–	–

FINELINE II/FINELINE II
Sterox Atrial J (Polyurethane)

Models 4477/4478/4479/4480

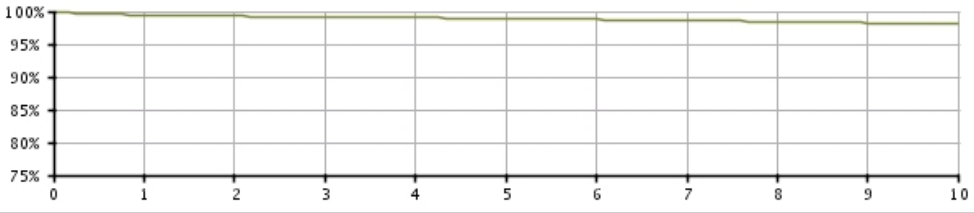
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 61,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 31,000

U.S. Chronic Lead Complications: 641
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	99.43 (-0.1/+0.1)	99.27 (-0.1/+0.1)	99.15 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.76 (-0.1/+0.1)	98.61 (-0.1/+0.1)	98.48 (-0.1/+0.1)	98.24 (-0.2/+0.2)	98.16 (-0.2/+0.2)
Registered Implants: 61000										
Effective Sample Size	52004	44384	37544	31408	26046	21367	17079	13299	10321	7869

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: 293,000

Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**4**	**10**	**14**
[7] Lead conductor	1	3	
[32] Conductor damage	3	7	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**-**	**1**	**1**
[33] Insulation damage	-	1	
Other	**2**	**-**	**2**
[21] J-shape	30	4	
[26] Non-patterned, Other	2	-	
WW Confirmed Malfunctions	**6**	**11**	**17**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models 4452/4453/4456/4457

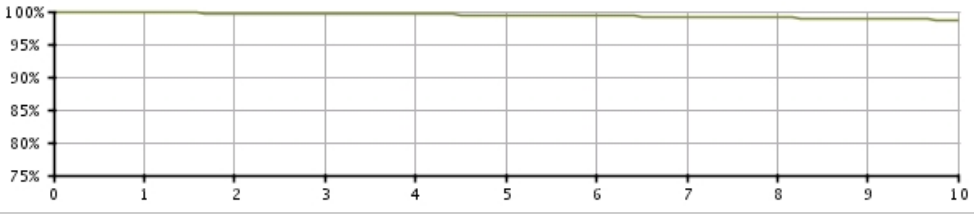
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 188,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 87,000

U.S. Chronic Lead Complications: 1,106
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)	99.73 (-0.0/+0.0)	99.64 (-0.0/+0.0)	99.55 (-0.0/+0.0)	99.46 (-0.0/+0.0)	99.35 (-0.0/+0.0)	99.18 (-0.1/+0.1)	99.03 (-0.1/+0.1)	98.85 (-0.1/+0.1)	98.72 (-0.1/+0.1)
Registered Implants: 188000										
Effective Sample Size	159512	136284	115118	96484	80365	66030	53020	41556	32459	25075

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: 521,000

Worldwide Confirmed Malfunctions: 60

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**1**	**45**	**46**
[7] Lead conductor	-	15	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	1	28	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**7**	**9**
[33] Insulation damage	2	7	
Other	**4**	**-**	**4**
[26] 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

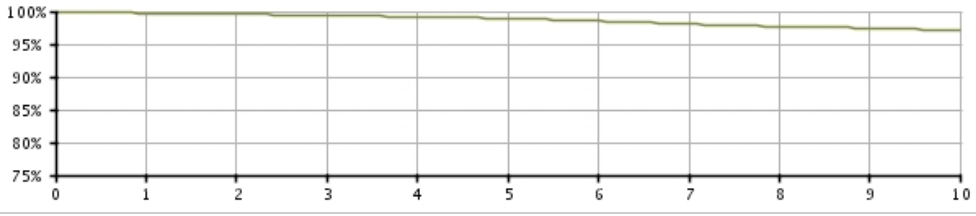
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 52,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 24,000

U.S. Chronic Lead Complications: 611
U.S. Malfunctions:124
Without Compromised Therapy:22
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 Registered Implants: 52000	99.74 (-0.0/+0.0)	99.58 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.19 (-0.1/+0.1)	98.91 (-0.1/+0.1)	98.51 (-0.1/+0.1)	98.06 (-0.2/+0.2)	97.65 (-0.2/+0.2)	97.42 (-0.2/+0.2)	97.13 (-0.3/+0.2)
Effective Sample Size	45054	38979	33495	28443	23999	19861	16141	12909	10227	7967

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: 139,000

Worldwide Confirmed Malfunctions: 163

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**11**	**124**	**135**
[7] Lead conductor	4	74	
[27] Non-patterned, Conductor	-	2	
[32] Conductor damage	7	45	
[35] Lead conductor	-	3	
Crimp/Weld/Bond	**1**	**-**	**1**
[31] Non-patterned, Crimp, Weld, Bond	1	-	
Insulation	**9**	**9**	**18**
[28] Non-patterned, Insulation	2	-	
[33] Insulation damage	7	9	
Other	**5**	**4**	**9**
[26] Non-patterned, Other	5	4	
WW Confirmed Malfunctions	**26**	**137**	**163**

More details about malfunctions

References cited in table above

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models 4454/4455/4458/4459

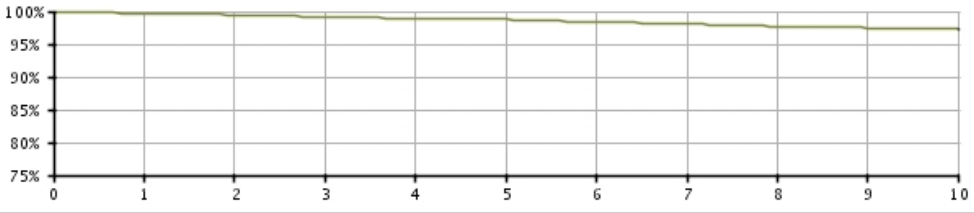
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 191
U.S. Malfunctions:23
Without Compromised Therapy:0
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	99.67 (-0.1/+0.1)	99.49 (-0.1/+0.1)	99.19 (-0.2/+0.1)	98.93 (-0.2/+0.2)	98.76 (-0.2/+0.2)	98.44 (-0.3/+0.2)	98.07 (-0.3/+0.3)	97.73 (-0.4/+0.3)	97.48 (-0.4/+0.4)	97.35 (-0.4/+0.4)
Registered Implants: 14000										
Effective Sample Size	12392	10824	9383	8078	6911	5805	4797	3982	3320	2749

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: 103,000

Worldwide Confirmed Malfunctions: 53

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor	**-**	**44**	**44**
[7] Lead conductor	-	16	
[32] Conductor damage	-	28	
Crimp/Weld/Bond	**-**	**-**	**0**
Insulation	**2**	**4**	**6**
[33] Insulation damage	2	4	
Other	**-**	**3**	**3**
[26] Non-patterned, Other	-	3	
WW Confirmed Malfunctions	**2**	**51**	**53**

More details about malfunctions

References cited in table above

FINELINE EZ Positive Fixation

Models 4460/4461/4462

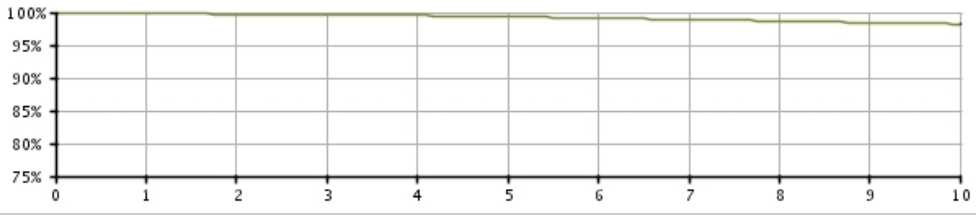
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 298
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 Registered Implants: 24000	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)
Effective Sample Size	20914	18711	16691	14868	13217	11627	10246	9034	7926	6992

SELUTE PICOTIP
Passive Fixation

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

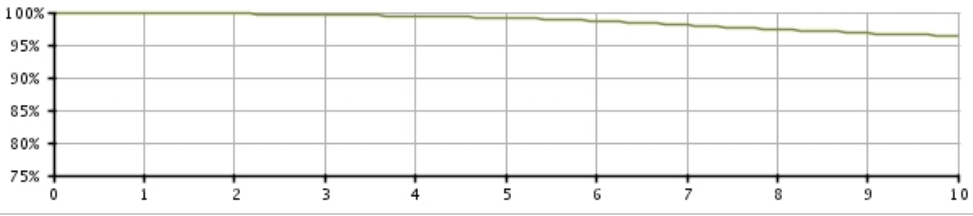
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 58,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 12,000

U.S. Chronic Lead Complications: 1,112
U.S. Malfunctions:36

Complications and Malfunctions



U.S. Survival Probability

Year	1	2	3	4	5	6	7	8	9	10
Non Advisory Population	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)	97.38 (-0.2/+0.2)	96.78 (-0.2/+0.2)	96.39 (-0.2/+0.2)
Registered Implants: 58000										
Effective Sample Size	49277	43965	39177	34805	30802	27098	23786	20849	18063	15667

SELUTE PICOTIP Atrial J

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

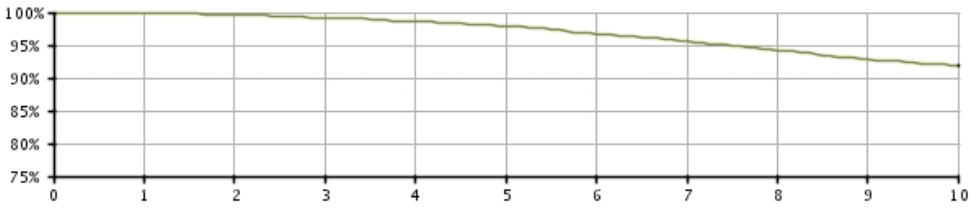
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 435
U.S. Malfunctions:22

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)	94.22 (-0.7/+0.6)	92.89 (-0.8/+0.7)	91.83 (-0.9/+0.8)
Effective Sample Size	8577	7643	6793	6022	5318	4666	4029	3474	2935	2508

SWEET PICOTIP Rx
Positive Fixation

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

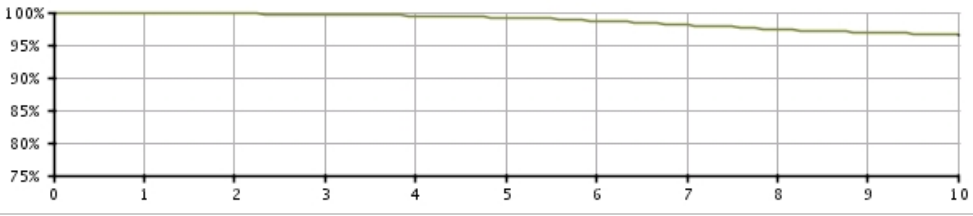
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

U.S. Summary

U.S. Registered Implants: 41,000
U.S. Approval Date: April 1999
U.S. Estimated Active Implants: 11,000

U.S. Chronic Lead Complications: 696
U.S. Malfunctions:58

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)	96.56 (-0.3/+0.3)
Effective Sample Size	35767	31936	28499	25357	22466	19812	17403	15086	12642	10478

SWEET TIP
Positive Fixation

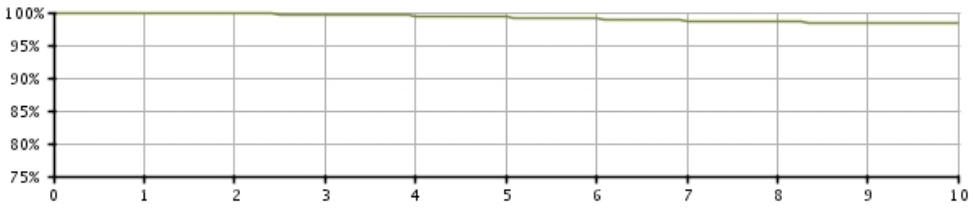
Models 4165/4168/4169/4268/4269

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

U.S. Summary

U.S. Registered Implants: 89,000
U.S. Estimated Active Implants: 15,000
U.S. Chronic Lead Complications: 966
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	43279	38075	33560	29652	26155

SWEET TIP RX
Positive Fixation

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

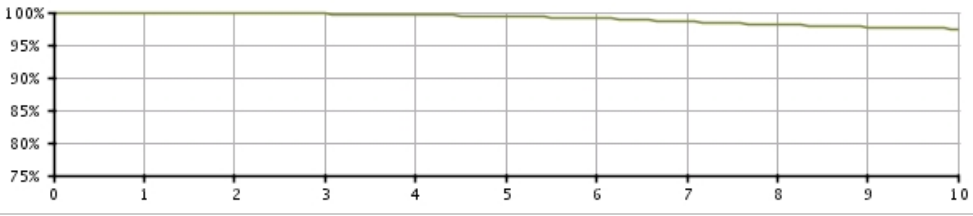
U.S. Survival Probability | Worldwide Malfunction Details | Product Advisories

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: 503
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	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)	98.57 (-0.2/+0.2)	98.09 (-0.2/+0.2)	97.74 (-0.2/+0.2)	97.43 (-0.3/+0.2)
Registered Implants: 34000										
Effective Sample Size	29684	26538	23707	21102	18667	16404	14409	12618	10960	9354

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. **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.
4. **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.
5. **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.
6. **Manufacturing material**— Loss of sensing, loss of pacing, noisy signals. Manufacturing material embedded in lead body.
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 connector**— Insulation damage resulting from bending or tension at the terminal connector. May lead to inappropriate shocks, oversensing.
11. **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.
12. **Conductor connection**— Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.
13. **Serial number label**— Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.
14. **Terminal component**— Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. 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. **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.
18. **Yoke component**— Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.
19. **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.
20. **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.
21. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
22. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
23. **Terminal weld**— Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.
24. **Conductor fracture**— High impedance, loss of capture, loss of pacing, inappropriate shocks. Flex fatigue leading to discontinuity of pace/sense conductor.
25. **Conductor fracture**— High impedance, loss of LV capture, loss of LV pacing. Flex fatigue leading to discontinuity of conductor.

26. **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.

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

28. **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.

31. **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.

32. **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.

33. **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.

34. **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.

35. **Lead conductor**— High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.

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. Improvement implemented.

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
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	54000	6	16	25	4	2	0	0	1	0	1
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	2000	0	0	0	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	3000	0	0	0	0	0	0	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	72	763	841	694	289	90	159	383	0	65
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	188000	4	322	201	177	36	19	154	173	0	20
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	453000	21	522	655	336	81	83	402	321	0	36
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	95	308	108	9	19	59	35	0	7
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	88	19	36	12	4	14	16	0	1
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/5573/4474	52000	0	221	73	78	55	15	72	93	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 X4 Spiral L 4677/4678	3000	0	0	0	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	7000	0	0	3	0	0	0	0	0	0	0

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
ACUITY X4 Straight 4671/4672	5000	0	0	4	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	29000	2	25	394	39	3	2	7	24	0	95
ACUITY Spiral 4591/4592/4593	23000	0	15	250	27	1	1	2	5	0	145
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	2	27	253	41	3	2	10	11	0	91
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	1	271	1087	238	8	6	61	81	0	467
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	1	64	397	100	3	1	47	31	0	260

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	58000	14	22	70	15	11	7	5	6	8	4
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	0	1	4	0	2	0	0	3	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	67000	16	19	80	24	15	7	4	7	10	4
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	0	0	2	0	1	0	0	1	0	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	28	407	348	122	481	64	97	211	169	27
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	4	89	64	47	80	7	34	138	31	6
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	8	45	43	19	41	1	7	27	28	3
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	2	5	1	3	0	1	3	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	17000	0	0	2	0	7	0	2	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	1383	0	0	22	2	0	0	0	0	0	9
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	743	0	0	0	0	0	0	0	1	1	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	851	0	0	1	1	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1104	0	1	0	1	1	1	0	0	0	0
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	0	1	1	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 lead 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
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	54000	67	113	131	59	13	9	6	52	0	7
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	2000	0	0	2	1	0	0	0	0	0	1
INGEVITY Passive Fixation 7631/7632/7731/7732	3000	1	1	3	4	0	1	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235000	239	196	1360	429	75	91	57	214	0	51
FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) 4452/4453/4456/4457	188000	15	13	447	176	8	27	25	41	0	21
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	453000	84	84	700	260	111	99	61	249	0	44
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) 4477/4478/4479/4480	61000	1	18	451	92	8	29	17	22	0	11
FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) 4454/4455/4458/4459	14000	1	4	34	17	1	2	6	6	0	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (Silicone) 4466/4467/4468/4472/4473/4474	52000	3	18	106	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 X4 Spiral L 4677/4678	3000	1	0	6	6	1	0	0	3	0	9
ACUITY X4 Spiral S 4674/4675	7000	1	0	11	6	0	0	0	11	0	18

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
ACUITY X4 Straight 4671/4672	5000	1	0	12	5	0	0	0	10	0	5
ACUITY Steerable 4554/4555/4556	29000	1	3	329	47	25	2	7	134	0	240
ACUITY Spiral 4591/4592/4593	23000	5	4	210	72	9	1	9	38	0	242
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22000	4	2	275	38	12	2	8	47	0	187
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97000	13	8	934	134	46	9	27	201	0	729
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38000	7	8	196	38	15	1	19	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	58000	54	32	173	77	62	12	7	83	21	12
ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation 0285/0286	3000	2	0	9	1	3	0	0	17	2	0
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	67000	63	40	164	67	78	20	7	82	71	25
ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation 0282/0283	1000	1	1	3	2	1	1	0	17	1	0
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	286000	149	188	652	168	366	54	69	361	234	80
ENDOTAK RELIANCE Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	46000	8	3	107	45	57	8	5	177	17	2
ENDOTAK RELIANCE Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	31000	29	17	78	29	31	14	3	56	120	9
ENDOTAK RELIANCE Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2000	0	0	3	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 3010/3401	17000	1	0	15	0	176	12	1	55	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	1383	0	0	11	11	1	0	0	3	0	48
ENDOTAK RELIANCE Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	743	0	0	1	0	1	0	1	0	0	0
ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation 0275/0276/0295/0296	851	0	2	12	0	0	0	1	2	0	3
ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation 0292/0293	1104	6	1	11	5	5	3	0	2	1	2
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) 4463/4464/4465/4469/4470/4471	924	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	9,000	0	0	0	0	0	0	0
ACUITY X4 Spiral S 4674/4675	19,000	0	0	0	1	0	0	0
ACUITY X4 Straight 4671/4672	17,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	64,000	0	0	0	4	0	2	0
ACUITY Spiral 4591/4592/4593	43,000	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	177,000	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	10,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE SG 4-FRONT Single Coil Active Fixation 0657/0692/0693	35,000	3	0	0	1	0	0	0
ENDOTAK RELIANCE G 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	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	95,000	0	0	0	65	0	1	0
ENDOTAK RELIANCE 4-Site Dual Coil Passive Fixation 0265/0266/0285/0286	9,000	0	0	0	4	0	1	0
ENDOTAK RELIANCE 4-Site Single Coil Active Fixation 0292/0293	110,000	0	0	0	22	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	373,000	0	0	44	487	0	3	14
ENDOTAK RELIANCE Dual Coil Passive Fixation 0147/0148/0149/0174/0175/0176/0177	108,000	0	1	3	87	0	3	0
ENDOTAK RELIANCE Single Coil Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	68,000	0	0	7	63	0	1	3
ENDOTAK RELIANCE Single Coil Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	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	29,000	0	0	1	0	0	0	0

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	224,000	567	0	0	1016	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	24,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	29,000	0	0	0	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	182,000	0	0	10	122	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	289,000	0	0	55	604	0	1	4
FINELINE II/FINELINE II Sterox Passive Fixation (polyurethane) 4452/4453/4456/4457*	521,000	1	0	2	7	3	25	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (polyurethane) 4463/4464/4465/4469/4470/4471*	696,000	0	0	7	56	1	44	2
FINELINE II/FINELINE II Sterox Atrial J (poly) 4477/4478/4479/4480*	293,000	0	3	1	129	6	19	0
FINELINE II/FINELINE II Sterox Passive Fixation (silicone) 4454/4455/4458/4459*	103,000	0	0	2	1	1	1	0
FINELINE II/FINELINE II Sterox EZ Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	139,000	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 **January 2017 — S-ICD Programmer Commands**
S-ICD Programmer Model 3200 S-ICD Programmer Commands, Physician Letter, Jan 12, 2017 S-ICD Programmer Commands, Patient Letter, Jan 12, 2017	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the potential for radio frequency (RF) interference to alter wireless communication from a Model 3200 S-ICD programmer, which in rare instances may cause an S-ICD to perform an unintended command. This behavior can only occur during an active, in-clinic interrogation/programming session with the Model 3200 S-ICD programmer. There is no risk of this behavior occurring when the LATITUDE Patient Management System communicates with an S-ICD in an ambulatory setting. Both the programmer and the S-ICD check the validity of telemetry commands using an algorithm intended to detect whether these commands have been altered. In nearly all instances, invalid commands are rejected. In rare instances, interference may go undetected and alter communications from the programmer. This can potentially result in the S-ICD performing an induction, utilizing temporary parameters that impair the S-ICD from detecting or treating a tachyarrhythmia during the active telemetry session, or disabling therapy in the permanent programming mode such that therapy will be unavailable after the telemetry session is ended. Because the programmer display may not match device programming when this behavior occurs, ending the session and re-interrogating the S-ICD is an effective means to check the permanently programmed device parameters. The potential for this behavior to occur during this brief re-interrogation is extremely remote. All communications between the programmer and S-ICD remain secure. This behavior is not related to a cybersecurity vulnerability. The LATITUDE Patient Management System (remote monitoring) is not subject to this behavior and is a reliable way to check S-ICD settings and performance. *Estimated Rate of Occurrence* For the EMBLEM S-ICD, the probability of serious adverse consequence is estimated to be 1 in 25,000 at 5 years. For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.
	CURRENT STATUS **12-Jan-17**
	Seven observations of unintended programming commands or data changes have been observed within the population of approximately 16,400 EMBLEM and EMBLEM MRI S-ICDs. Three observations of unintended programming commands or data changes have occurred with the SQ-RX™ S-ICD. There have been no reported patient deaths associated with this advisory. *Estimated Rate of Occurrence* For the EMBLEM S-ICD, the probability of serious adverse consequence is estimated to be 1 in 25,000 at 5 years. For the SQ-RX S-ICD, the probability of serious adverse consequences is estimated to be 1 in 200,000 at 5 years.

January 2017 — S-ICD Programmer Commands, continued…

CURRENT RECOMMENDATION **12-Jan-17**

Boston Scientific is developing software to mitigate this behavior. Until updated software is available, the recommendations below mitigate the risks associated with this behavior:

• Using the LATITUDE Patient Management System for routine S-ICD assessments will minimize the number of programmer interactions with an S-ICD.
• If the LATITUDE Patient Management System is not available, consider reducing the frequency of in-clinic checks while following medical society guidelines.
• When performing any S-ICD programming or check using a Model 3200 S-ICD Programmer:
  - Ensure external defibrillation equipment and medical personnel skilled in CPR are available during implant and in-office follow-up testing and do not leave the patient unattended.
  - Place the telemetry wand directly over the S-ICD at all times and increase the distance between any source of interference and the programmer and S-ICD as much as possible.
  - Minimize the duration of programmer communications and end the programmer telemetry session promptly after completion.
• When the programmer is communicating with an S-ICD, it is possible that this behavior may alter temporary parameters without the user's knowledge. Altering of temporary parameters may result in an inability for the S-ICD to detect a tachyarrhythmia or an inappropriate detection of a heart rhythm.
  - To initiate a defibrillation therapy, press the Rescue Shock icon and follow screen prompts.
  - To abort an inappropriate shock, press the Abort button while the S-ICD is charging.
• When the S-ICD programming or check is complete, confirm S-ICD settings by performing the following steps:
  1. End the original telemetry session
  2. Initiate a new telemetry session
  3. Print a device Summary Report (see Appendix A)
  4. End the telemetry session
  5. Confirm device settings: if any settings have been altered from intended programming, contact Technical Services
  6. Instruct the patient to contact their physician if the device emits beeping tones

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 **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 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	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. 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.
	CURRENT STATUS **10-Jan-17**
	Advisory devices have not been available for implant for more than six years. *Confirmed Malfunctions (worldwide)* 4,266 malfunctions have been confirmed from the advisory population. Approximately 37,000 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 6.0% at 72 months. The projected rate of occurrence at 84 months is approximately 8.5%.
	CURRENT RECOMMENDATION **10-Jan-17**
	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 **10-Jan-17** 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 **10-Jan-17** – 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	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 3 RF HE Models H217/H219	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 Models H190/H195/H197/H199	
CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179	CURRENT STATUS **10-Jan-17** There have been no reported patient deaths associated with this advisory. *Projected Rate of Occurrence*
CONTAK RENEWAL 4 RF Models H230/H235/H239	The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.
VITALITY DR HE Model T180	CURRENT RECOMMENDATION **10-Jan-17** 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	*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.
Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	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 **10-Jan-17**
	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-five (95) 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 **10-Jan-17**

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 **10-Jan-17**
	Confirmed Malfunctions (worldwide)
CONTAK RENEWAL 3 RF HE Models H217/H219	**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 originally active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).
CONTAK RENEWAL 3 Models H170/H175	
	There have been no reported patient deaths associated with either advisory population.
CONTAK RENEWAL 3 **AVT / AVT HE** Models M155/M159	No devices currently being distributed are susceptible to this malfunction mode.
	Rate of Occurrence
VITALITY 2 EL VR/DR Models T177/T167	**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.

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

CURRENT RECOMMENDATION **10-Jan-17**

VITALITY EL
Model T127

VITALITY AVT A155
Model A155

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:

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

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 **10-Jan-17** *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 **10-Jan-17** 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 **10-Jan-17** *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 **10-Jan-17** 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 Low Voltage Capacitor, Physician Letter, Aug 24, 2006 Low Voltage Capacitor, Patient Letter, Aug 24, 2006 Low Voltage Capacitor, Physician Letter, Jun 23, 2006	CURRENT RECOMMENDATION, continued… **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..* **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	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. 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 **10-Jan-17**
	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 **10-Jan-17**
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 **10-Jan-17**
	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 **10-Jan-17**
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	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 **10-Jan-17**
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	*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 **10-Jan-17**

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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