Boston Scientific
Advancing science for life™

2020

Rhythm Management Product Performance Report

Q2 Edition

RESONATE™
FAMILY OF ICDs AND CRT-Ds

Emblem™ MRI S-ICD
System

ACUITY™ X4
Quadripolar LV Lead

CRM Quality Pledge

I improve the quality of patient care and all things Boston Scientific

Advancing Science for Life.

For over forty years, meaningful innovation at Boston Scientific Rhythm Management has helped patients live healthier, longer lives. We are committed to providing performance data which are accurate, transparent and responsive to topics of contemporary clinical interest. This Q2 2020 report includes data through April 8, 2020.

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
- ✓ 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,

Alexandra Naughton
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.

Device 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.

Inclusion Criteria for Pulse Generator and Lead Survival Probability Datasets
Pulse generator survival probability is reported for U.S. implanted devices in product families that meet inclusion criteria described below. Lead survival probability is reported for the U.S. Registered Implant population for product families that 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 and 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 U.S. 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 considers U.S. experience 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 fewer 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.

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. 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, U.S. approval dates 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.

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

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 implanted as of May 2009 and forward. Worldwide malfunctions are not included for previous 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 identify 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 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 sharing an accurate picture of product performance and addressing identified opportunities for improvement in a timely fashion for our customers.

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. Information presented is based on malfunctions reported to and analyzed by Boston Scientific. Each table contains malfunction counts listed by category, pattern and therapy availability.

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

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

Each pattern description includes:

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

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

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

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

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

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

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

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

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Supporting Greater Return of Explanted Devices

The Heart Rhythm Society (HRS) Task Force on Device Performance Policies and Guidelines stated that knowledge, confidence, and trust in cardiac rhythm management devices can be strengthened through enhancing systems that increase the return of devices to the manufacturer. Boston Scientific CRM shares in this belief and supports the HRS-specified actions geared toward achieving the goal of greater device return to the manufacturer, including post-mortem device interrogation, explantation and return to the manufacturer.[1] Approximately 60% of ICD, CRT-D, and PM pulse generators are returned for analysis.

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.

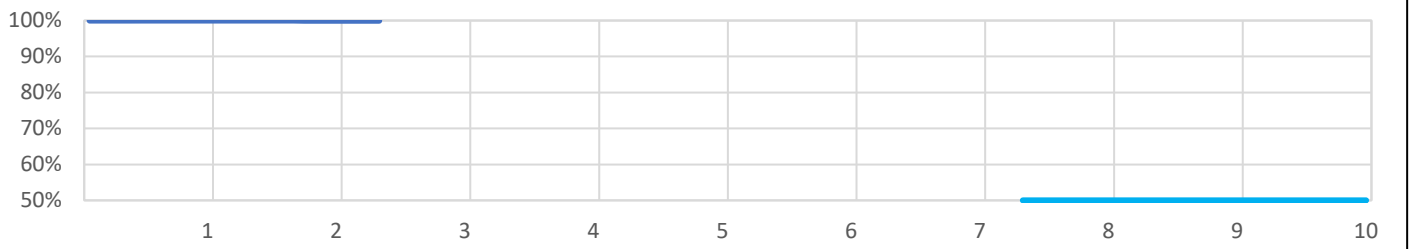
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/ G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

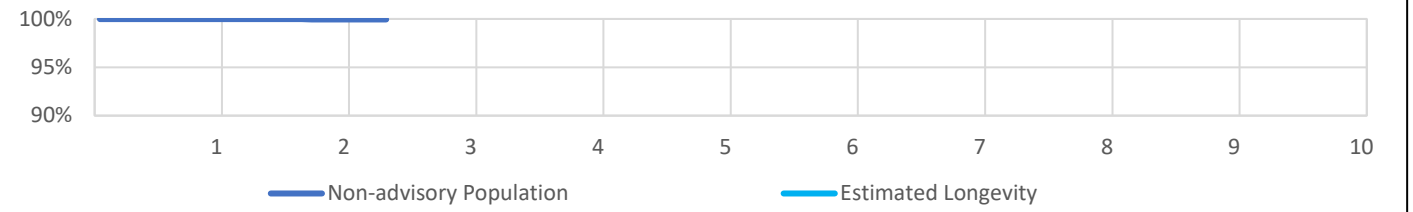
US Summary

US Registered Implants:	23,000	US Normal Battery Depletions:	1
US Approval Date:	September 2017	US Malfunctions:	4
US Estimated Active Implants:	22,000	Without Compromised Therapy:	4
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	--	--	--	--	--	--	--
23,000	Effective Sample Size	10003	1632	218	--	--	--	--	--	--	--

@ 29 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

Models: G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/ G348/G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**48,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (63)	0	2	2
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**5**	**5**

References cited in table above (link)

AUTOGEN CRT-D

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

Worldwide Confirmed Malfunctions	**18**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	7	7
Integrated circuit (63)	2	4	6
Low-voltage capacitor (69)	0	1	1
Software			
Safety Core-unintended biventricular pacing (64)	0	1	1
Other			
Non-patterned, other	1	2	3
Grand Total	**3**	**15**	**18**

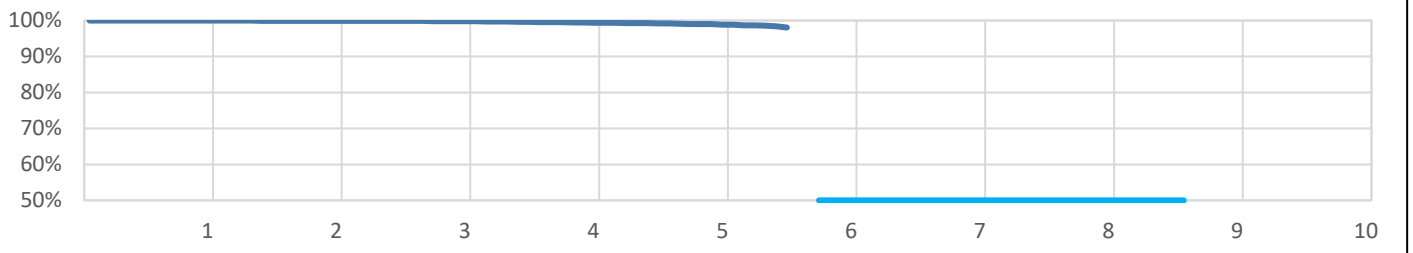
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN CRT-D

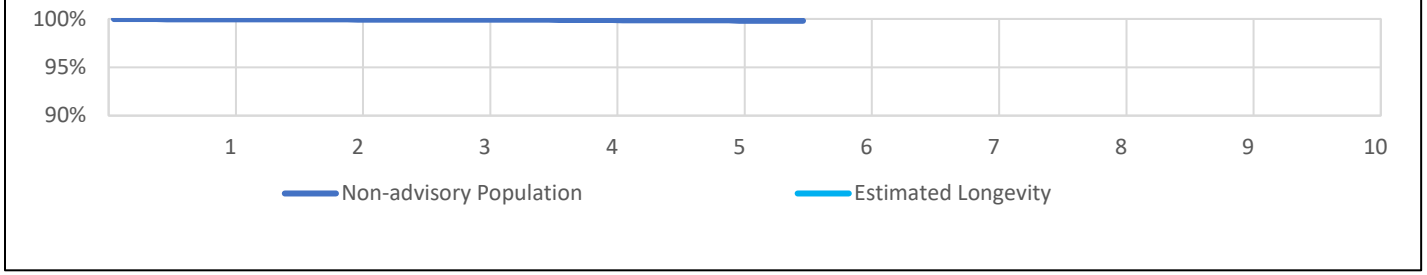
Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	126
US Approval Date:	April 2014	US Malfunctions:	45
US Estimated Active Implants:	57,000	Without Compromised Therapy:	38
		With Compromised Therapy:	7

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	99.0%	98.1%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	--	--	--	--
66,000	Effective Sample Size	52955	39053	24035	11271	2533	328	--	--	--	--

@ 67 months

DYNAGEN/INOGEN/ORIGEN CRT-D

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

Worldwide Confirmed Malfunctions	**68**
Worldwide Distribution	**102,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	16	16
Integrated circuit (63)	3	11	14
Low-voltage capacitor (69)	0	6	6
High voltage capacitor (75)	1	1	2
Battery (53)	0	1	1
Software			
Memory errors (51)	2	18	20
Safety Core-unintended biventricular pacing (64)	0	2	2
Other			
Non-patterned, other	5	2	7
Grand Total	**11**	**57**	**68**

References cited in table above (link)

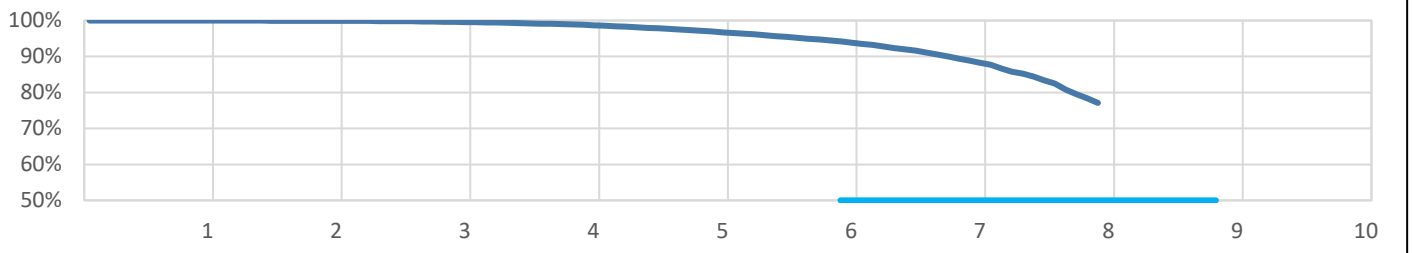
INCEPTA/ENERGEN/PUNCTUA CRT-D

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

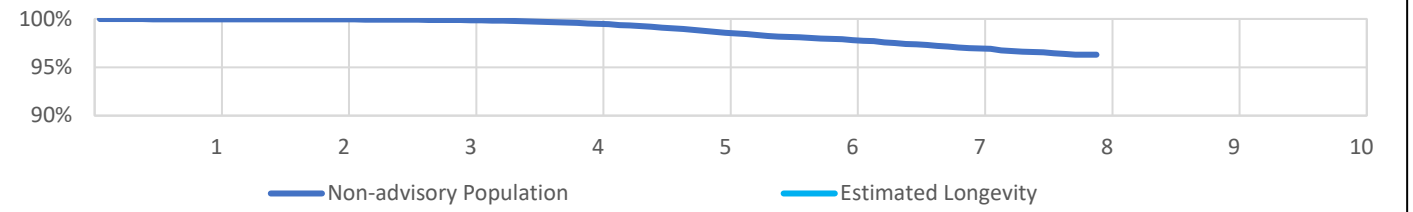
US Summary

US Registered Implants:	53,000	US Normal Battery Depletions:	1,836
US Approval Date:	November 2011	US Malfunctions:	726
US Estimated Active Implants:	33,000	Without Compromised Therapy:	707
		With Compromised Therapy:	19

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.6%	98.8%	96.9%	94.2%	88.9%	77.1%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.7%	97.9%	97.0%	96.3%	--	--
53,000	Effective Sample Size	46319	41474	37017	32530	26754	16721	6711	419	--	--

@ 96 months

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 Confirmed Malfunctions	**1,175**
Worldwide Distribution	**81,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Safety Core-electrocautery (42)	1	5	6
High-voltage capacitor (43)	5	0	5
Low-voltage capacitors (47)	0	1	1
Integrated circuit (50)	7	2	9
Battery (53)	1	9	10
Low-voltage capacitor (54)	5	1101	1106
Low-voltage capacitor (69)	0	5	5
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	5	14	19
Grand Total	**30**	**1145**	**1175**

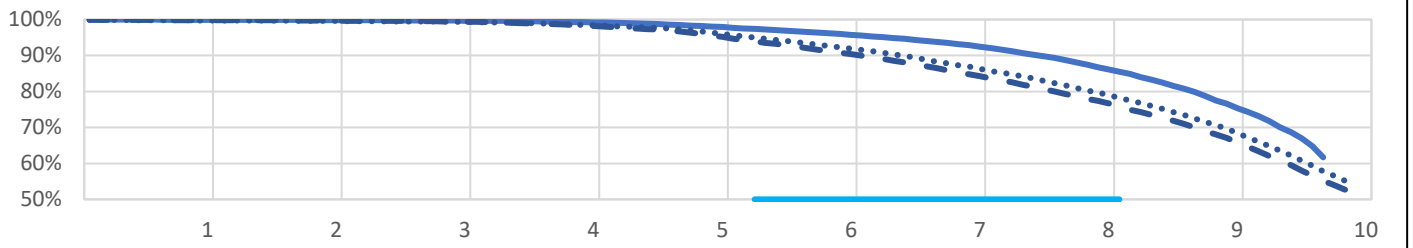
References cited in table above (link)

COGNIS CRT-D

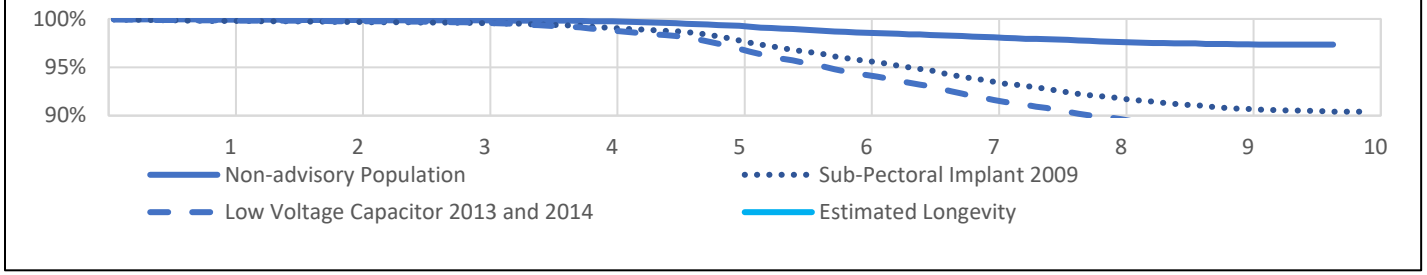
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	9,608
US Approval Date:	March 2008	US Malfunctions:	2,054
US Estimated Active Implants:	23,000	Without Compromised Therapy:	1,865
		With Compromised Therapy:	189

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.1%	96.0%	92.9%	86.7%	76.6%	61.7%	
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.2%	97.7%	97.4%	97.3%	
36,000	Effective Sample Size	31295	28068	25134	22416	19865	17380	14891	11952	4368	227	@ 117 months

COGNIS CRT-D

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

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009 Registered Implants: 32,000	Depletions and Malfunctions	99.8%	99.6%	99.4%	98.5%	96.3%	92.2%	86.9%	79.7%	69.7%	54.0%
	Malfunctions Only	99.8%	99.7%	99.6%	99.1%	98.0%	95.8%	93.7%	91.9%	90.7%	90.4%
	Effective Sample Size	27335	24229	21630	19205	16779	14303	11983	9758	7565	5173
Low Voltage Capacitor 2013 and 2014 Registered Implants: 26,000	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.4%	95.6%	90.8%	84.8%	77.4%	67.1%	51.7%
	Malfunctions Only	99.8%	99.8%	99.6%	98.9%	97.2%	94.4%	91.9%	89.8%	88.4%	88.1%
	Effective Sample Size	22473	19953	17842	15798	13752	11615	9638	7798	5994	3059

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

COGNIS CRT-D

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

Worldwide Confirmed Malfunctions	**2,885**
Worldwide Distribution	**109,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	80	1612	1692
Safety Core-electrocautery (42)	25	54	79
High-voltage capacitor (43)	6	1	7
Low-voltage capacitors (47)	0	7	7
Integrated circuit (50)	21	8	29
High voltage circuit (52)	1	0	1
Battery (53)	8	48	56
Low-voltage capacitor (54)	12	794	806
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	9	0	9
Difficulty securing lead (41)	8	8	16
Header contacts (45)	8	10	18
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	47	19	66
Header (74)	25	9	34
Software			
Safety Core-programming (46)	0	1	1
Alert messages not displayed post-EOL (48)	0	2	2
Memory errors (51)	2	15	17
Other			
Non-patterned, other	10	33	43
Grand Total	**262**	**2623**	**2885**

References cited in table above (link)

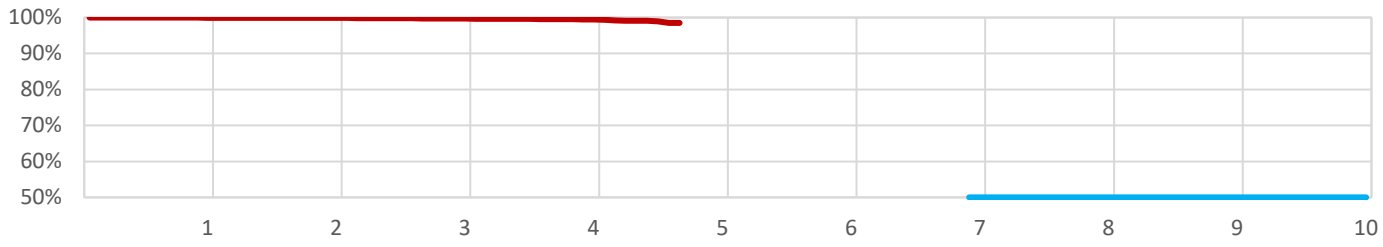
VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

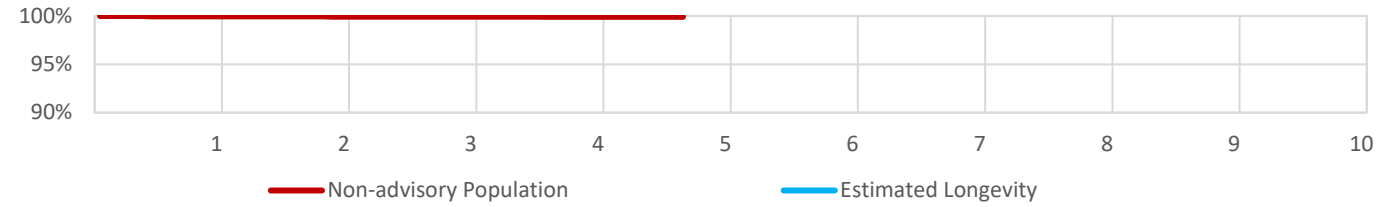
US Summary

US Registered Implants:	30,000	US Normal Battery Depletions:	43
US Approval Date:	October 2014	US Malfunctions:	23
US Estimated Active Implants:	26,000	Without Compromised Therapy:	22
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.5%	98.5%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	--	--	--	--	--
30,000	Effective Sample Size	20506	13143	7054	2166	323	--	--	--	--	--

@ 57 months

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

Worldwide Confirmed Malfunctions	**31**
Worldwide Distribution	**62,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	1	5	6
Telemetry (68)	0	1	1
Hydrogen induced premature depletion - September 2018 (70)	0	11	11
Capacitor (67)	0	1	1
Software			
Memory errors (51)	0	4	4
Other			
Non-patterned, other	0	6	6
Grand Total	**1**	**30**	**31**

References cited in table above (link)

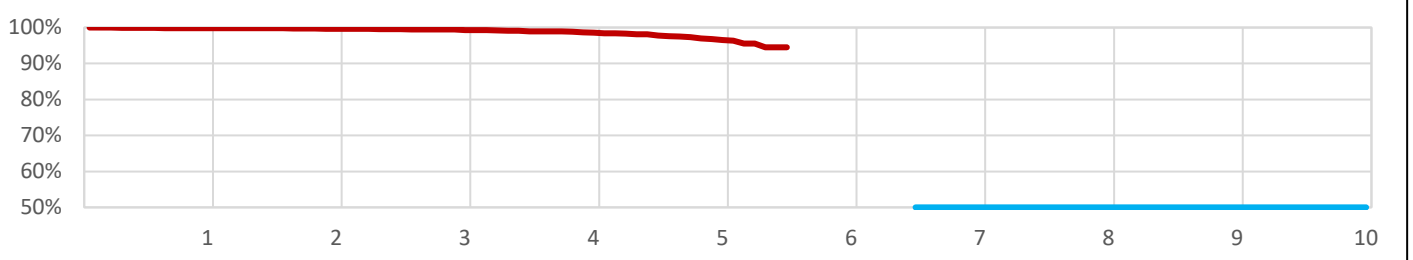
INTUA

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

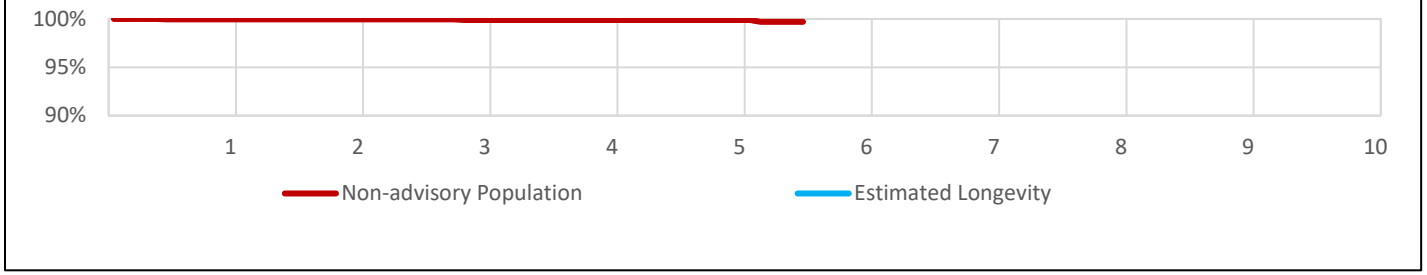
US Summary

US Registered Implants:	3,000	US Normal Battery Depletions:	55
US Approval Date:	May 2013	US Malfunctions:	3
US Estimated Active Implants:	2,000	Without Compromised Therapy:	2
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.6%	99.4%	98.7%	96.8%	94.5%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	--	--	--	--
3,000	Effective Sample Size	2271	2012	1777	1455	743	204	--	--	--	--

@ 67 months

INTUA

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

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**3,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	1	2	3
Grand Total	**1**	**2**	**3**

References cited in table above (link)

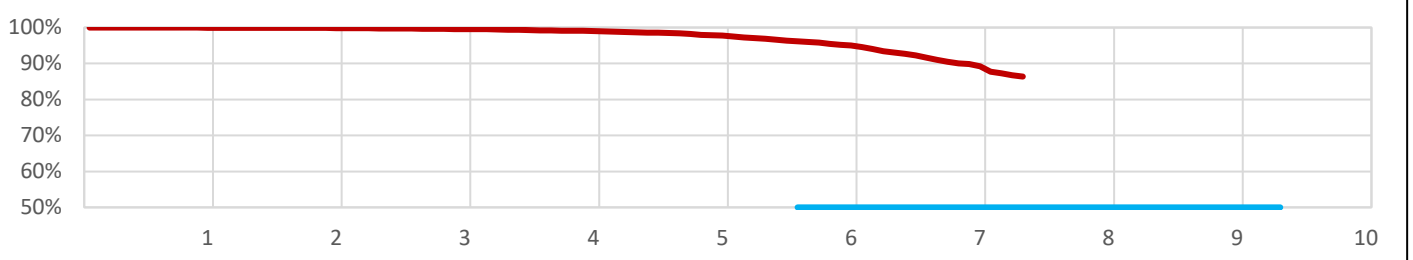
INVIVE

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

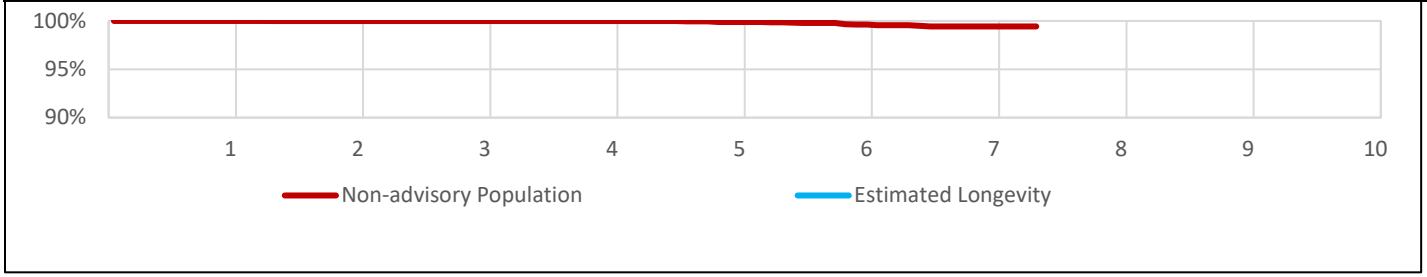
US Summary

US Registered Implants:	8,000	US Normal Battery Depletions:	268
US Approval Date:	May 2012	US Malfunctions:	15
US Estimated Active Implants:	5,000	Without Compromised Therapy:	14
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.6%	99.1%	97.8%	95.1%	89.9%	86.4%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.6%	99.4%	99.4%	--	--
8,000	Effective Sample Size	6718	5997	5337	4690	3781	2348	681	254	--	--

@ 89 months

INVIVE

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

Worldwide Confirmed Malfunctions	**19**
Worldwide Distribution	**18,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	0	1
Software			
Memory errors (51)	0	3	3
Other			
Non-patterned, other	2	13	15
Grand Total	**3**	**16**	**19**

References cited in table above (link)

CONTAK RENEWAL TR 2

Models: H140/H145

Worldwide Confirmed Malfunctions	**38**
Worldwide Distribution	**31,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Mechanical			
Seal plug (19)	0	2	2
Setscrew block (25)	0	2	2
Seal plug (33)	0	1	1
Software			
Memory error (23)	0	1	1
Stored EGMs (28)	0	20	20
Other			
Non-patterned, other	1	10	11
Grand Total	**1**	**37**	**38**

References cited in table above (link)

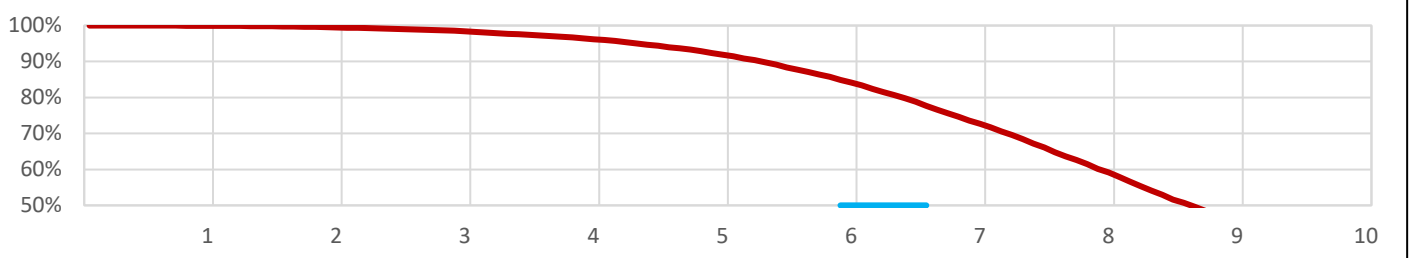
CONTAK RENEWAL TR

Models: H120/H125

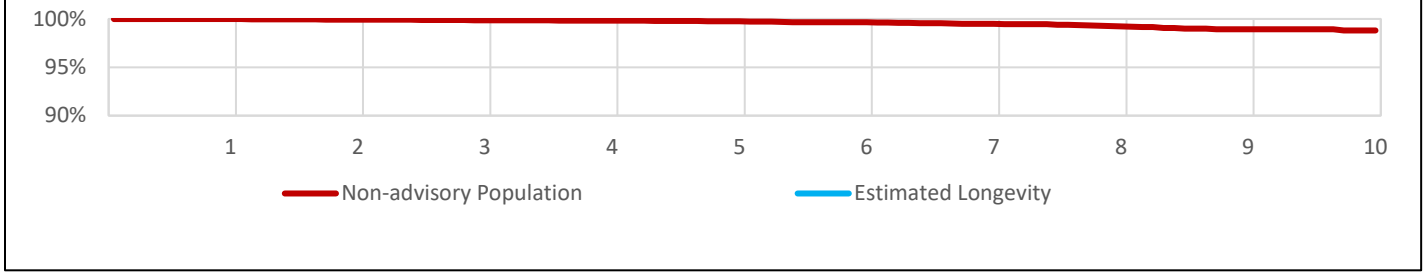
US Summary

US Registered Implants:	19,000	US Normal Battery Depletions:	4,073
US Approval Date:	January 2004	US Malfunctions:	67
US Estimated Active Implants:	3,000	Without Compromised Therapy:	66
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.5%	98.5%	96.4%	92.4%	84.9%	73.6%	60.1%	46.7%	36.5%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	99.8%	99.6%	99.5%	99.3%	98.9%	98.8%
19,000	Effective Sample Size	15214	13191	11494	9957	8463	6881	5241	3490	1753	612

CONTAK RENEWAL TR

Models: H120/H125

Worldwide Confirmed Malfunctions	**67**
Worldwide Distribution	**19,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	1	0	1
	0	1	1
Low-voltage capacitor - June 23, 2006 Voluntary Physician Advisory (8)			
Mechanical			
Seal plug (19)	0	5	5
Software			
Stored EGMs (28)	0	39	39
Other			
Non-patterned, other	0	12	12
Alert messages (31)	0	8	8
Magnet rate (44)	0	1	1
Grand Total	**1**	**66**	**67**

References cited in table above (link)

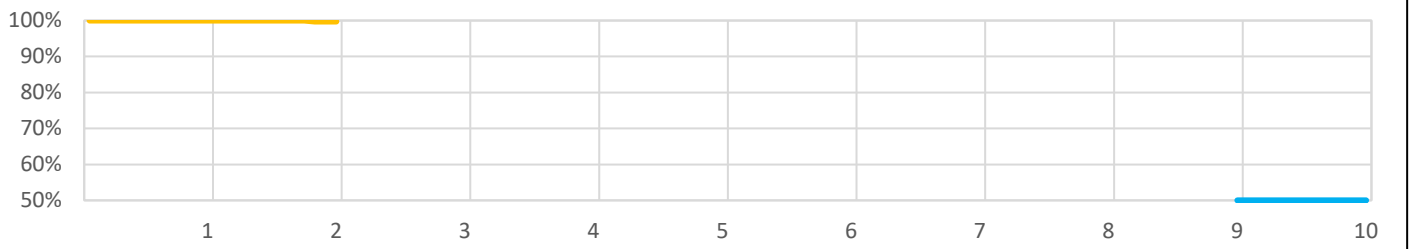
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

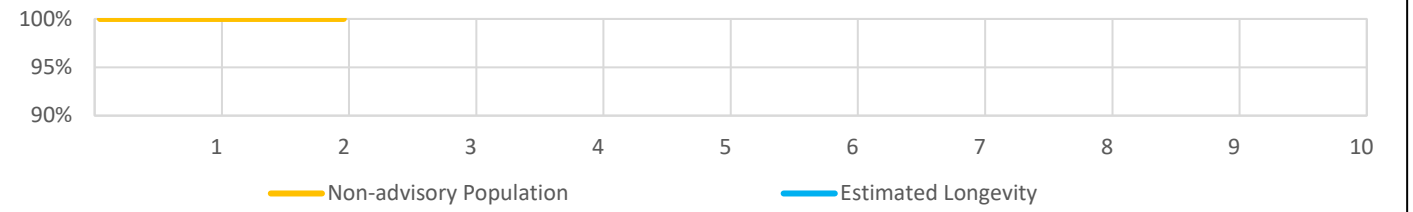
US Summary

US Registered Implants:	7,000	US Normal Battery Depletions:	3
US Approval Date:	July 2017	US Malfunctions:	-
US Estimated Active Implants:	7,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.7%	99.7%	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	--	--	--	--	--	--	--
7,000	Effective Sample Size	2887	314	204	--	--	--	--	--	--	--

@ 25 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**21,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

References cited in table above (link)

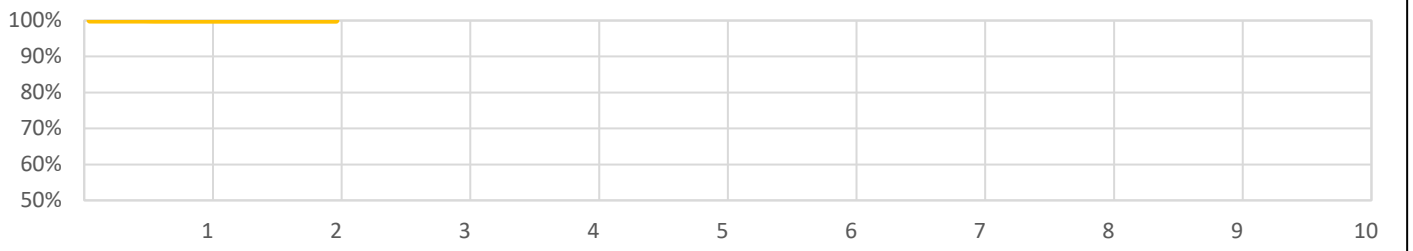
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

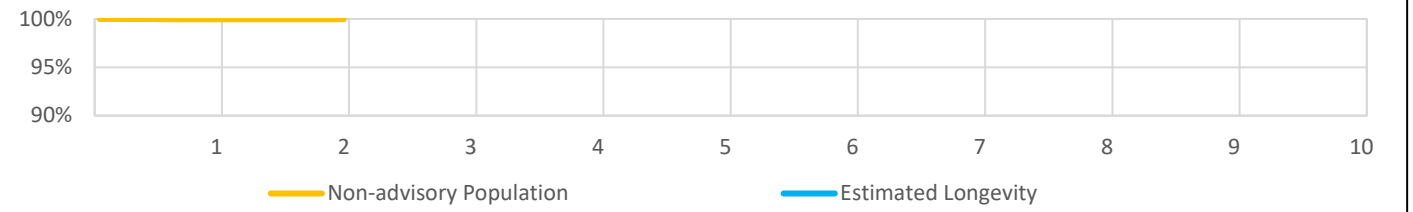
US Summary

US Registered Implants:	11,000	US Normal Battery Depletions:	1
US Approval Date:	July 2017	US Malfunctions:	2
US Estimated Active Implants:	10,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	100.0%	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	--	--	--	--	--	--	--
11,000	Effective Sample Size	3957	444	285	--	--	--	--	--	--	--

@ 25 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

Worldwide Confirmed Malfunctions	**2**
Worldwide Distribution	**18,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**2**	**2**

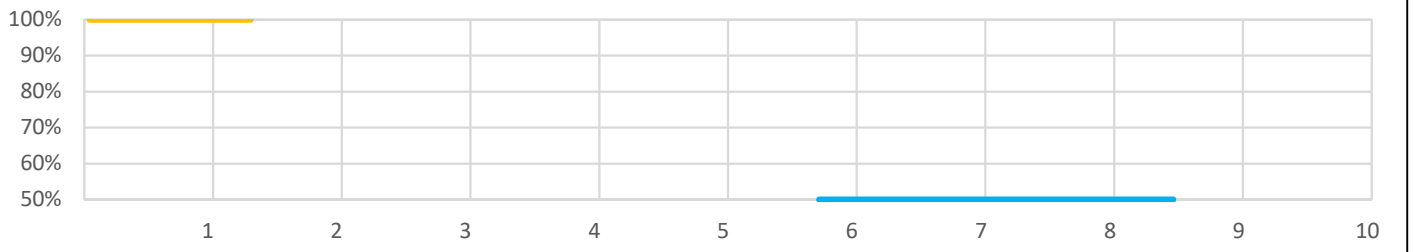
References cited in table above (link)

PERCIVA ICD DR

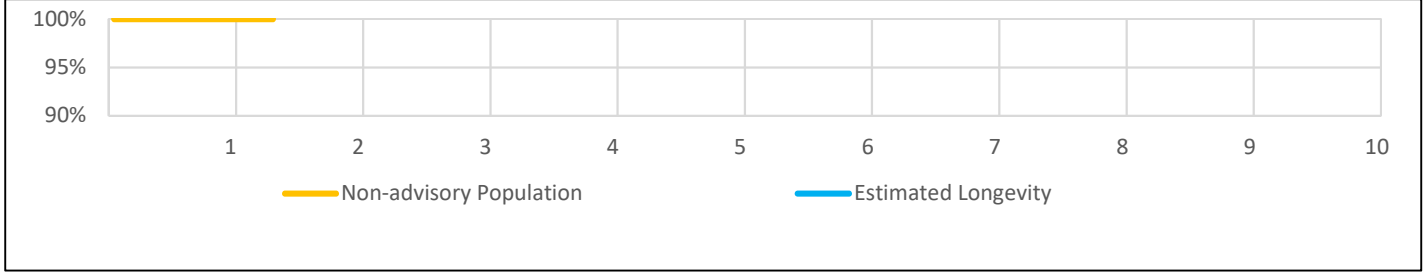
Models: D401/D413/D501/D513

US Summary			
US Registered Implants:	1,000	US Normal Battery Depletions:	-
US Approval Date:	July 2017	US Malfunctions:	-
US Estimated Active Implants:	1,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	--	--	--	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	--	--	--	--	--	--	--	--
1,000	Effective Sample Size	424	217	--	--	--	--	--	--	--	--

@ 17 months

PERCIVA DR

Models: D401/D413/D501/D513

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**2,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

PERCIVA VR

Models: D400/D412/D500/D512

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**2,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

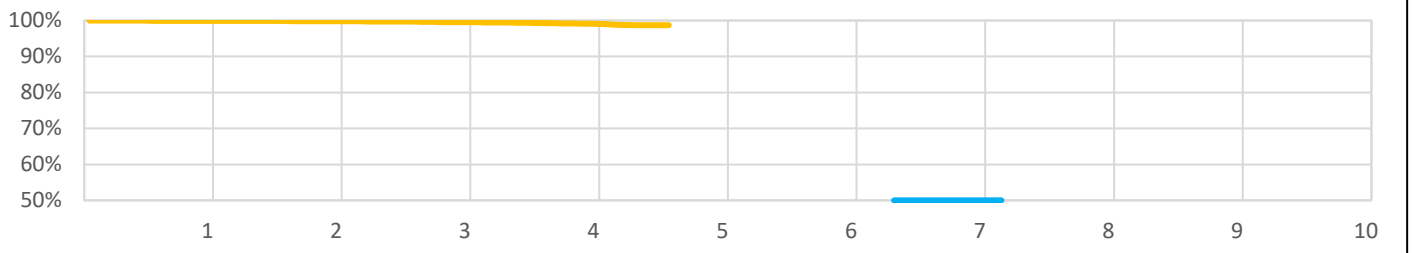
References cited in table above (link)

EMBLEM S-ICD

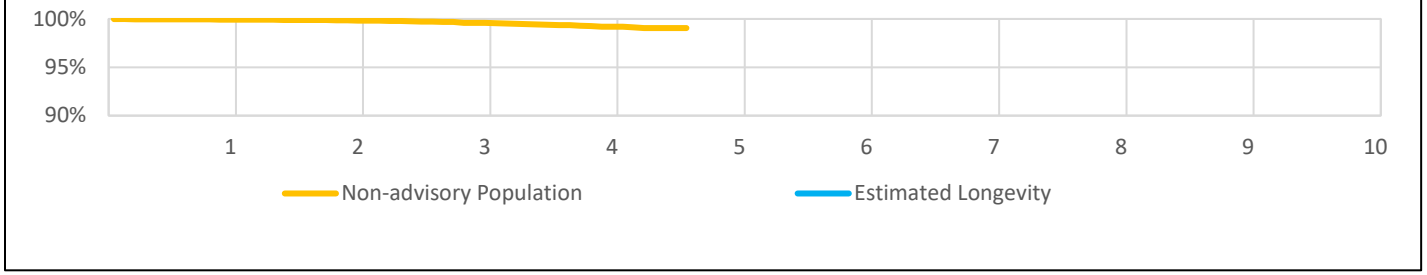
Models: A209/A219

US Summary			
US Registered Implants:	32,000	US Normal Battery Depletions:	14
US Approval Date:	March 2015	US Malfunctions:	93
US Estimated Active Implants:	29,000	Without Compromised Therapy:	73
		With Compromised Therapy:	20

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.6%	99.1%	98.7%	--	--	--	--	--
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.6%	99.2%	99.1%	--	--	--	--	--
32,000	Effective Sample Size	21257	13505	7470	2721	281	--	--	--	--	--

@ 56 months

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

EMBLEM S-ICD

Models: A209/A219

Worldwide Confirmed Malfunctions	**183**
Worldwide Distribution	**68,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	1	0	1
Capacitor (72)	1	68	69
S-ICD battery depletion 2019 (77)	3	24	27
Software			
Memory corruption (65)	1	0	1
Misaligned markers (73)	1	2	3
Mechanical			
Internal insulation (76)	3	0	3
Solder joint (78)	5	0	5
Other			
Non-patterned, other	24	25	49
Telemetry (56)	11	14	25
Grand Total	**50**	**133**	**183**

References cited in table above (link)

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions	**12**
Worldwide Distribution	**16,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	3	3
Integrated circuit (63)	2	0	2
Low-voltage capacitor (69)	0	3	3
Battery (53)	0	1	1
High voltage capacitor (75)	1	0	1
Other			
Non-patterned, other	1	1	2
Grand Total	**4**	**8**	**12**

References cited in table above (link)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions	**6**
Worldwide Distribution	**17,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	1	0	1
Low-voltage capacitor (69)	0	1	1
Other			
Non-patterned, other	0	1	1
Software			
Memory errors (51)	2	1	3
Grand Total	**3**	**3**	**6**

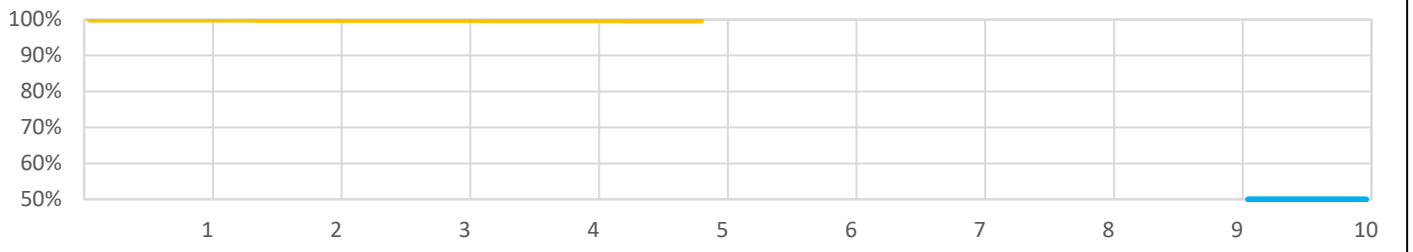
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

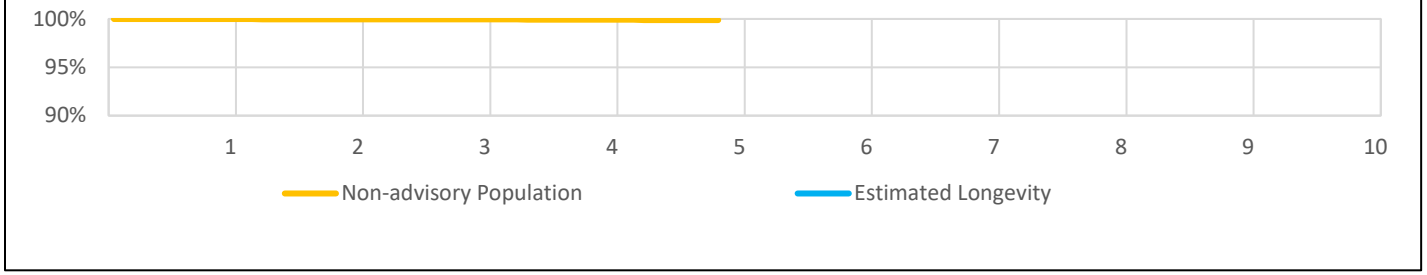
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	40,000	US Normal Battery Depletions:	20
US Approval Date:	April 2014	US Malfunctions:	16
US Estimated Active Implants:	35,000	Without Compromised Therapy:	10
		With Compromised Therapy:	6

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.7%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	--	--	--	--	--
40,000	Effective Sample Size	30928	21127	11500	4455	243	--	--	--	--	--

@ 59 months

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**58,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	1	1
High voltage circuit component (62)	0	3	3
Integrated circuit (63)	1	1	2
Low-voltage capacitor (69)	1	3	4
High voltage capacitor (75)	4	0	4
Software			
Memory errors (51)	0	1	1
Other			
Non-patterned, other	1	4	5
Grand Total	**7**	**13**	**20**

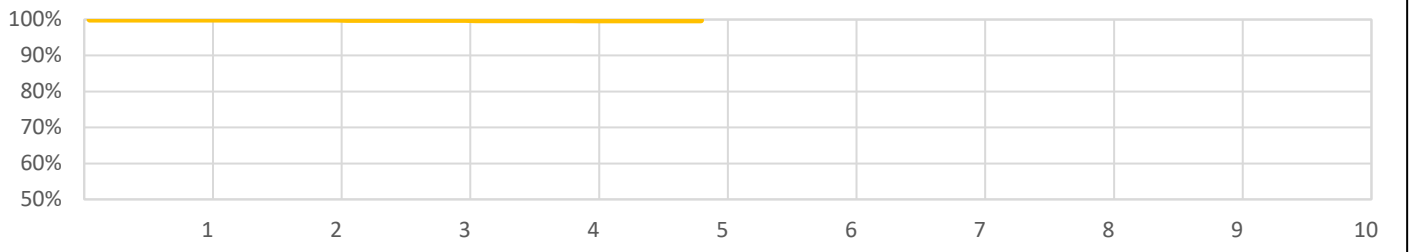
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL VR

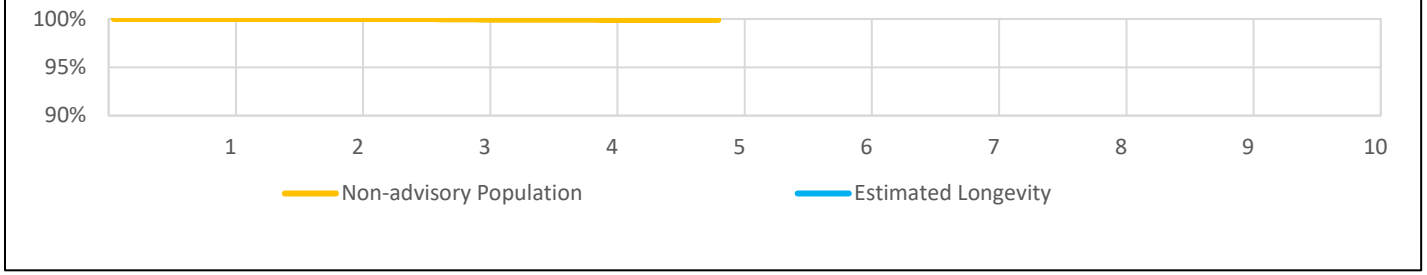
Models: D050/D051/D140/D141/D150/D151

US Summary			
US Registered Implants:	34,000	US Normal Battery Depletions:	16
US Approval Date:	April 2014	US Malfunctions:	13
US Estimated Active Implants:	30,000	Without Compromised Therapy:	13
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.8%	99.8%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	--	--	--	--	--
34,000	Effective Sample Size	26341	18498	10689	4413	222	--	--	--	--	--

@ 59 months

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

Worldwide Confirmed Malfunctions	**23**
Worldwide Distribution	**55,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	1	1
High voltage circuit component (62)	0	2	2
Integrated circuit (63)	0	1	1
Low-voltage capacitor (69)	0	9	9
Software			
Memory errors (51)	0	4	4
Other			
Non-patterned, other	2	4	6
Grand Total	**2**	**21**	**23**

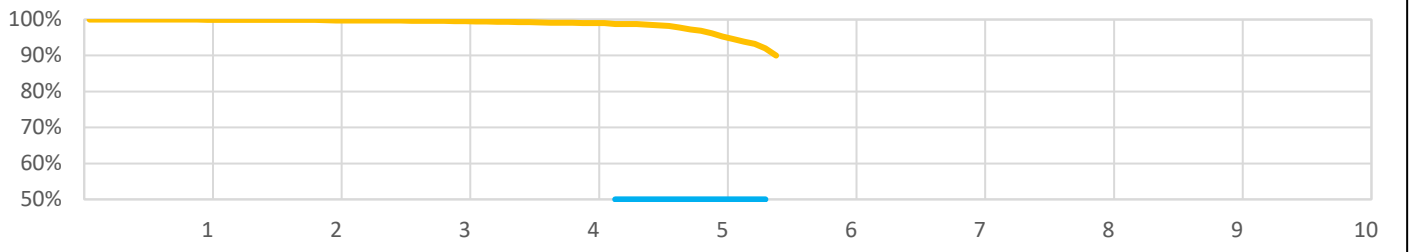
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

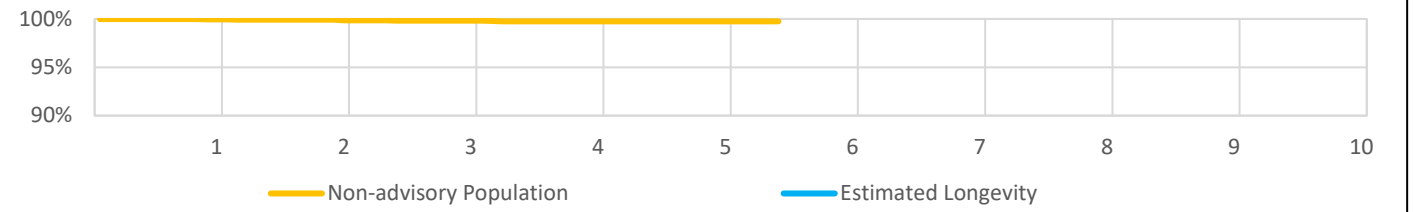
Models: D002/D003/D012/D013/D022/D023

US Summary			
US Registered Implants:	9,000	US Normal Battery Depletions:	99
US Approval Date:	April 2014	US Malfunctions:	13
US Estimated Active Implants:	7,000	Without Compromised Therapy:	10
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.8%	99.6%	99.0%	96.1%	90.0%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.8%	99.8%	99.8%	--	--	--	--
9,000	Effective Sample Size	7290	5445	3765	2360	916	277	--	--	--	--

@ 66 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

Worldwide Confirmed Malfunctions	**18**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	11	11
High voltage capacitor (75)	2	0	2
Other			
Non-patterned, other	2	3	5
Grand Total	**4**	**14**	**18**

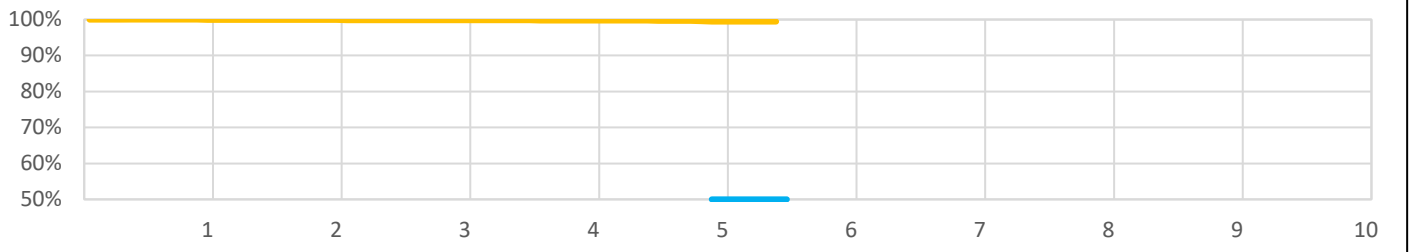
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

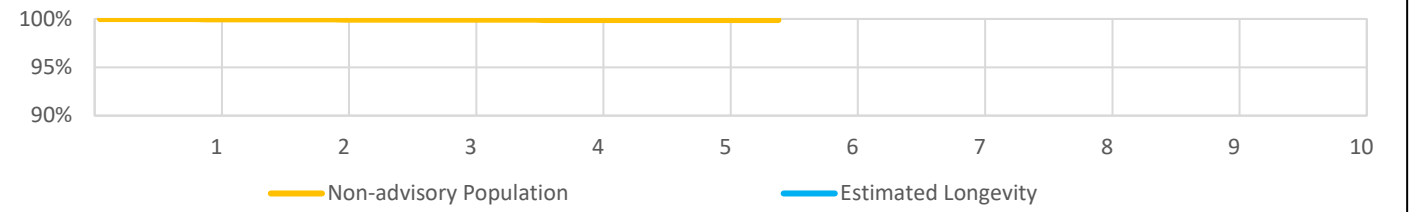
Models: D000/D001/D010/D011/D020/D021

US Summary			
US Registered Implants:	9,000	US Normal Battery Depletions:	11
US Approval Date:	April 2014	US Malfunctions:	6
US Estimated Active Implants:	7,000	Without Compromised Therapy:	5
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.7%	99.4%	99.4%	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--	--	--
9,000	Effective Sample Size	6907	5248	3736	2351	852	258	--	--	--	--

@ 66 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

Worldwide Confirmed Malfunctions	**16**
Worldwide Distribution	**26,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	4	4
High voltage capacitor (75)	4	0	4
Low-voltage capacitor (69)	0	1	1
Software			
Memory errors (51)	1	2	3
Other			
Non-patterned, other	0	2	2
Grand Total	**5**	**11**	**16**

References cited in table above (link)

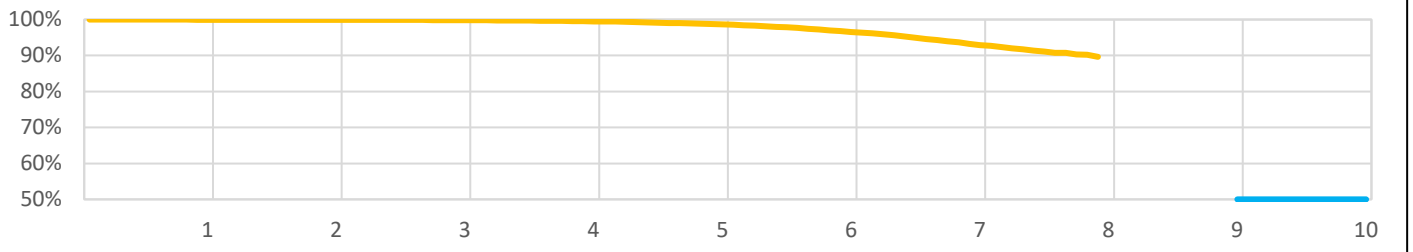
INCEPTA/ENERGEN/PUNCTUA ICD DR

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

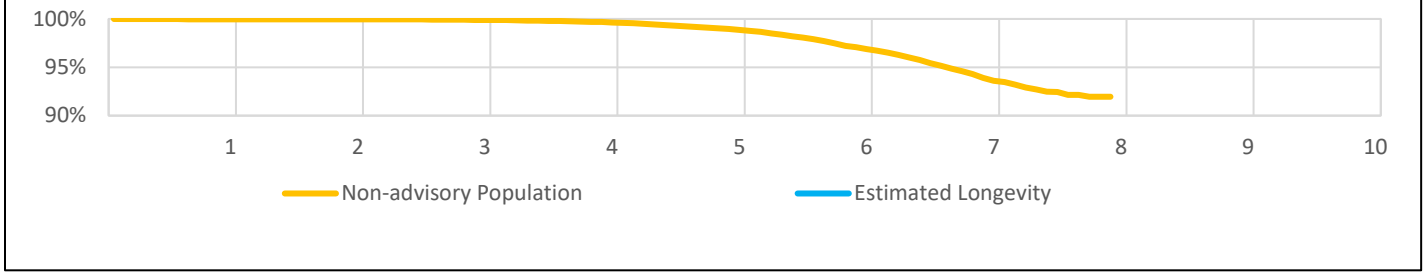
US Summary

US Registered Implants:	47,000	US Normal Battery Depletions:	150
US Approval Date:	November 2011	US Malfunctions:	961
US Estimated Active Implants:	32,000	Without Compromised Therapy:	944
		With Compromised Therapy:	17

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	98.8%	96.8%	93.2%	89.6%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.1%	93.9%	92.0%	--	--
47,000	Effective Sample Size	41225	36538	32295	28075	22986	13553	5377	334	--	--

@ 96 months

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

Worldwide Confirmed Malfunctions	**1,492**
Worldwide Distribution	**72,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Mechanical			
Transformer (38)	2	0	2
Header contacts (45)	1	0	1
Electrical			
High-voltage capacitor (43)	4	1	5
Low-voltage capacitors (47)	0	4	4
Integrated circuit (50)	4	7	11
Battery (53)	6	64	70
Low-voltage capacitor (54)	6	1358	1364
High voltage circuit (58)	0	1	1
Low-voltage capacitor (69)	0	6	6
Software			
Memory errors (51)	0	6	6
Other			
Non-patterned, other	6	16	22
Grand Total	**29**	**1463**	**1492**

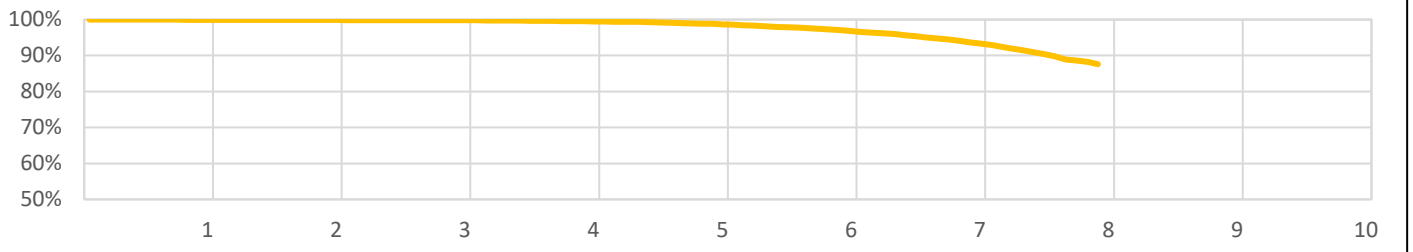
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD VR

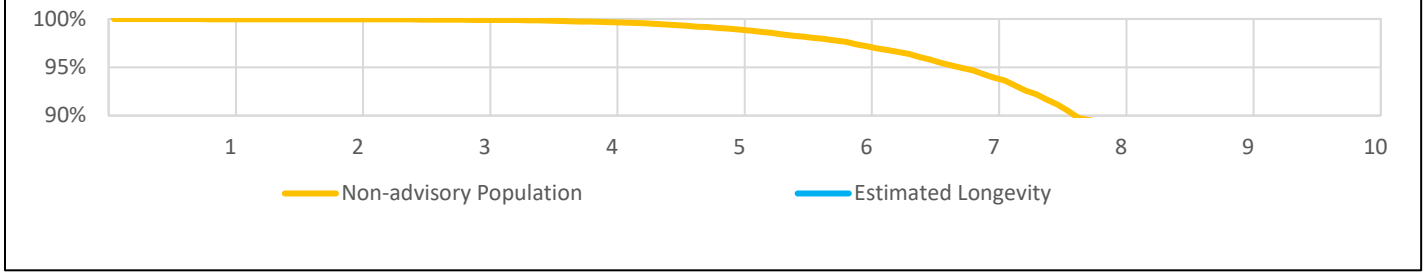
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	109
US Approval Date:	November 2011	US Malfunctions:	807
US Estimated Active Implants:	28,000	Without Compromised Therapy:	779
		With Compromised Therapy:	28

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.5%	98.8%	97.0%	93.7%	87.6%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.4%	94.3%	88.7%	--	--
39,000	Effective Sample Size	34702	30728	27153	23693	19247	11229	4373	264	--	--

@ 96 months

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

Worldwide Confirmed Malfunctions	**1,353**
Worldwide Distribution	**68,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	3	1	4
Integrated circuit (50)	5	3	8
Battery (53)	12	79	91
Low-voltage capacitor (54)	8	1203	1211
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	1	7	8
Other			
Non-patterned, other	10	12	22
Grand Total	**46**	**1307**	**1353**

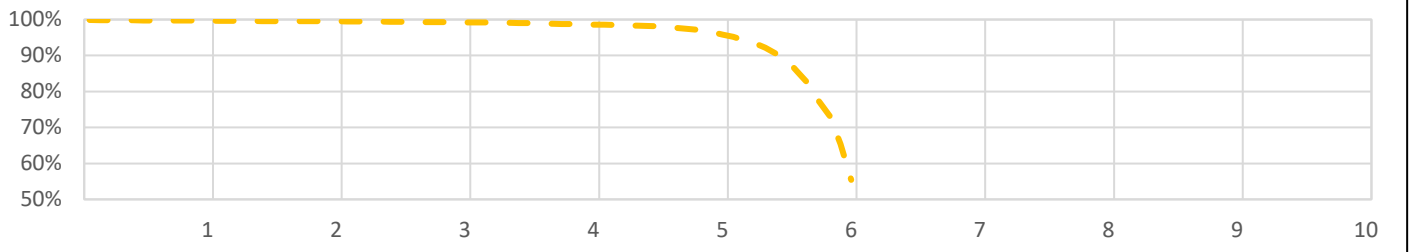
References cited in table above (link)

SQ-RX S-ICD

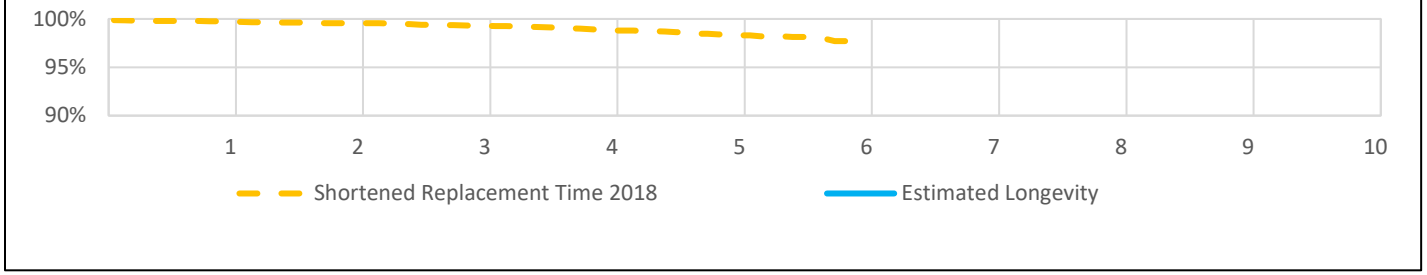
Models: 1010

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	614
US Approval Date:	September 2012	US Malfunctions:	93
US Estimated Active Implants:	5,000	Without Compromised Therapy:	40
		With Compromised Therapy:	53

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Shortened Replacement Time 2018	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.6%	96.5%	65.4%	55.4%	--	--	--
Registered Implants:	Malfunctions Only	99.7%	99.6%	99.3%	98.9%	98.4%	97.7%	97.3%	--	--	--
8,000	Effective Sample Size	6451	5684	5023	4411	3011	429	243	--	--	--

@ 73 months

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

SQ-RX S-ICD

Models: 1010

Worldwide Confirmed Malfunctions	**200**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Unintended Fuse Activation 2013 (4)	3	0	3
Charge Timeout Alert (61)	0	11	11
Mechanical			
High cathode condition (5)	1	1	2
Shortened replacement time 2018 (55)	56	40	96
Software			
Unintended Battery Depletion Alert (57)	0	10	10
Other			
Telemetry (56)	10	4	14
Non-patterned, other	39	25	64
Grand Total	**109**	**91**	**200**

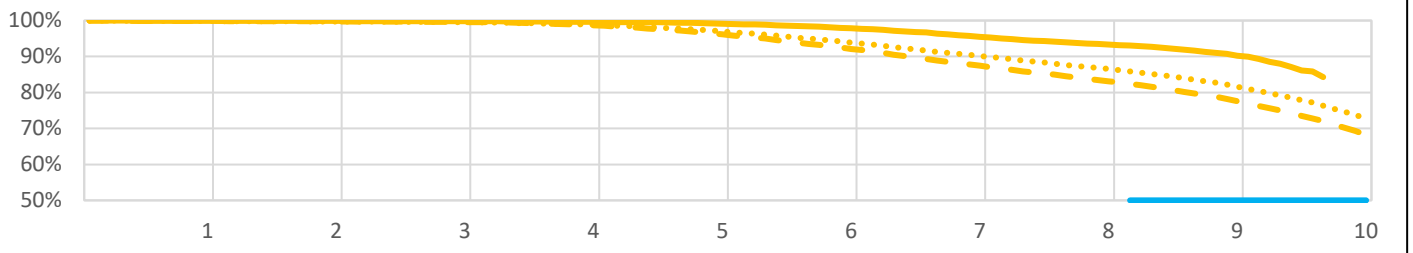
References cited in table above (link)

TELIGEN DR

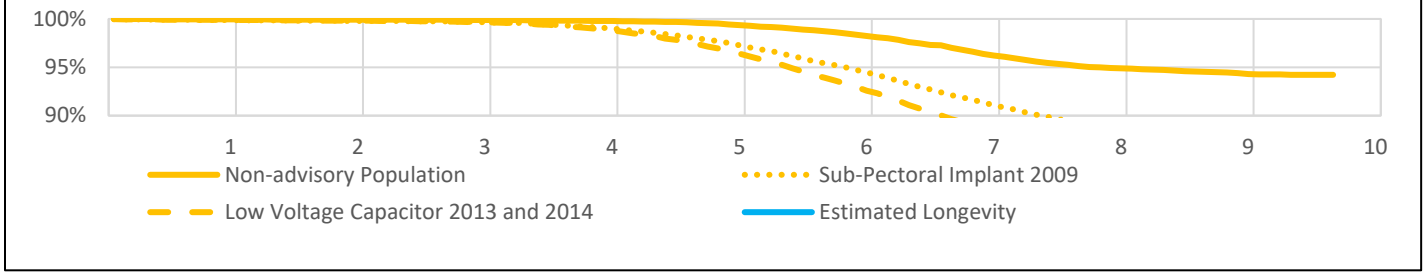
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	2,721
US Approval Date:	March 2008	US Malfunctions:	2,889
US Estimated Active Implants:	29,000	Without Compromised Therapy:	2,740
		With Compromised Therapy:	149

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	99.2%	98.0%	95.7%	93.5%	90.7%	84.3%	
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.4%	94.9%	94.4%	94.2%	
30000	Effective Sample Size	26329	23354	20707	18286	16084	13987	11982	9978	4328	267	@ 117 months

TELIGEN DR

Models: E110/E111/F110/F111

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.9%	97.2%	94.2%	90.4%	86.8%	82.2%	73.8%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.7%	91.3%	88.7%	86.7%	85.4%
30000	Effective Sample Size	26629	23511	20787	18250	15860	13511	11366	9507	7814	6057
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.5%	92.5%	87.8%	83.4%	78.2%	69.3%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	98.9%	96.7%	93.0%	88.7%	85.3%	82.9%	81.3%
23000	Effective Sample Size	20614	18221	16099	14123	12171	10249	8518	7042	5719	3444

*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

Worldwide Confirmed Malfunctions	**3,930**
Worldwide Distribution	**91,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	49	2272	2321
Safety Core-electrocautery (42)	1	4	5
High-voltage capacitor (43)	8	1	9
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	21	22	43
Battery (53)	37	249	286
Low-voltage capacitor (54)	6	1115	1121
Low-voltage capacitor (69)	0	2	2
Mechanical			
Transformer (38)	20	0	20
Seal plug (40)	0	3	3
Difficulty securing lead (41)	7	7	14
Header contacts (45)	13	3	16
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	9	5	14
Header (74)	8	3	11
Software			
Alert messages not displayed post-EOL (48)	0	3	3
Memory errors (51)	0	16	16
Other			
Non-patterned, other	10	28	38
Grand Total	**189**	**3741**	**3930**

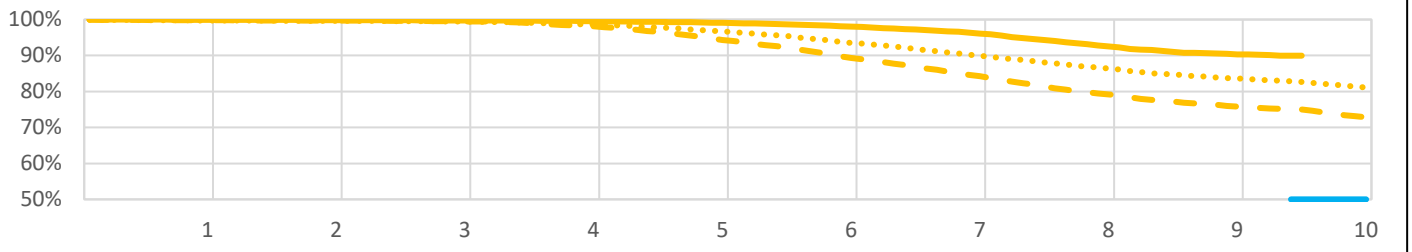
References cited in table above (link)

TELIGEN VR

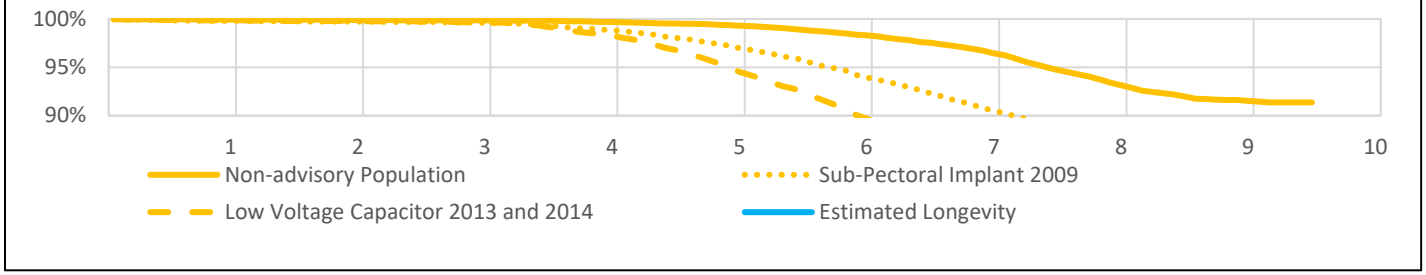
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	311
US Approval Date:	March 2008	US Malfunctions:	2,147
US Estimated Active Implants:	18,000	Without Compromised Therapy:	2,025
		With Compromised Therapy:	122

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.6%	99.1%	98.1%	96.3%	92.8%	90.5%	89.9%	
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.7%	99.3%	98.4%	96.7%	93.4%	91.6%	91.4%	
18000	Effective Sample Size	16201	14332	12650	11155	9789	8517	7305	5943	1989	334	@ 115 months

TELIGEN VR

Models: E102/E103/F102/F103

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Subpectoral Implant 2009	Depletions and Malfunctions	99.8%	99.6%	99.5%	98.7%	96.9%	93.8%	90.2%	86.6%	83.7%	81.4%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.6%	98.9%	97.2%	94.2%	90.7%	87.4%	84.8%	83.4%
16000	Effective Sample Size	13615	11998	10575	9245	7989	6799	5707	4754	3994	3357
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.2%	94.8%	89.7%	84.6%	79.5%	76.0%	73.1%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.6%	98.4%	95.0%	90.0%	85.1%	80.2%	77.1%	75.5%
12000	Effective Sample Size	10850	9580	8447	7365	6263	5195	4246	3443	2855	1677

*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

Worldwide Confirmed Malfunctions	**3,600**
Worldwide Distribution	**66,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	42	1844	1886
Safety Core-electrocautery (42)	1	1	2
High-voltage capacitor (43)	3	0	3
Low-voltage capacitors (47)	0	5	5
Integrated circuit (50)	17	11	28
Battery (53)	49	397	446
Low-voltage capacitor (54)	4	1081	1085
Low-voltage capacitor (69)	0	3	3
Mechanical			
Transformer (24)	1	0	1
Transformer (38)	14	0	14
Seal plug (40)	0	1	1
Difficulty securing lead (41)	9	0	9
Header contacts (45)	22	16	38
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	16	6	22
Header (74)	13	4	17
Software			
Alert messages not displayed post-EOL (48)	0	4	4
Memory errors (51)	0	12	12
Respiratory Sensor Oversensing - March 23, 2009 Voluntary Physician Advisory (7)	0	2	2
Other			
Non-patterned, other	11	11	22
Grand Total	**202**	**3398**	**3600**

References cited in table above (link)

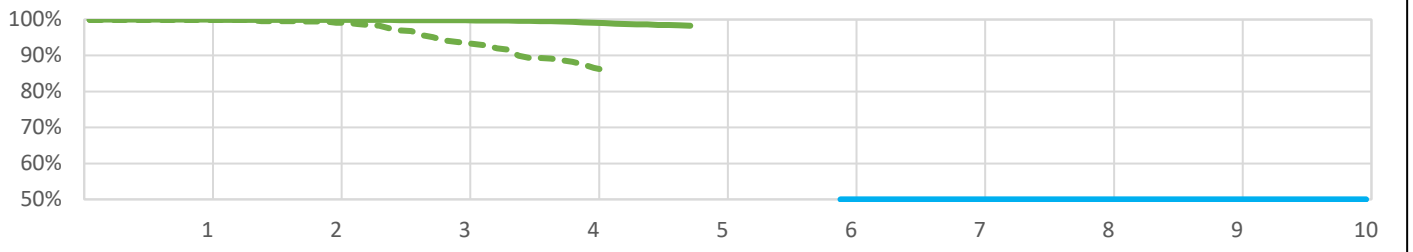
ACCOLADE/PROPONENT/ESSENTIO DR

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

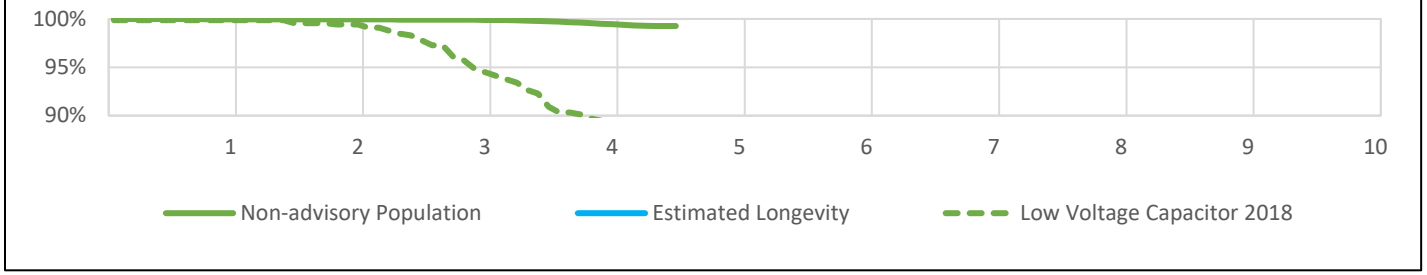
US Summary

US Registered Implants:	173,000	US Normal Battery Depletions:	205
US Approval Date:	October 2014	US Malfunctions:	269
US Estimated Active Implants:	154,000	Without Compromised Therapy:	259
		With Compromised Therapy:	10

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.2%	98.3%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	99.3%	--	--	--	--	--
24000	Effective Sample Size	125458	83789	47120	16275	877	--	--	--	--	--

@ 58 months

ACCOLADE/PROPONENT/ESSENTIO DR

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

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018	Depletions and Malfunctions	99.9%	99.4%	94.2%	88.3%	85.9%	--	--	--	--	--
Registered Implants: 800	Malfunctions Only	99.9%	99.4%	94.9%	89.5%	88.7%	--	--	--	--	--
	Effective Sample Size	712	639	543	406	286	--	--	--	--	--

@ 51 months

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

ACCOLADE/PROPONENT/ESSENTIO DR

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

Worldwide Confirmed Malfunctions	**481**
Worldwide Distribution	**356,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	3	3
Integrated circuit (63)	8	19	27
Capacitor (67)	0	258	258
Telemetry (68)	2	10	12
Hydrogen induced premature depletion - September 2018 (70)	0	110	110
Software			
Memory errors (51)	0	28	28
Mechanical			
Battery cathode (79)	1	0	1
Other			
Non-patterned, other	9	33	42
Grand Total	**20**	**461**	**481**

References cited in table above (link)

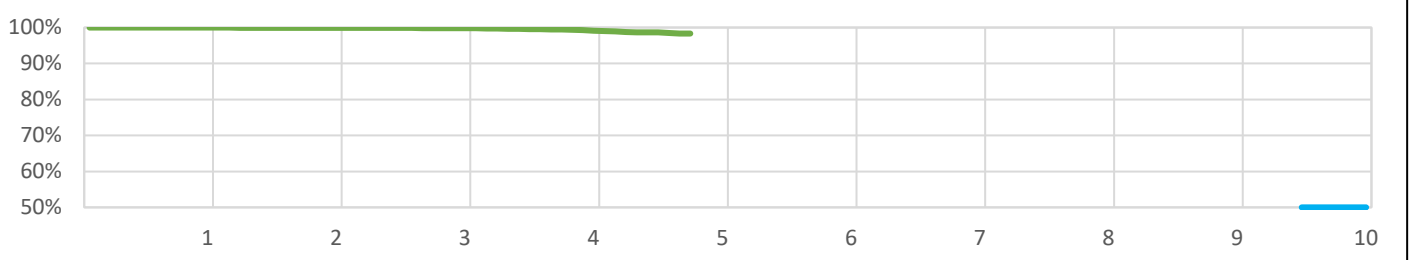
ACCOLADE/PROPONENT/ESSENTIO EL DR

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

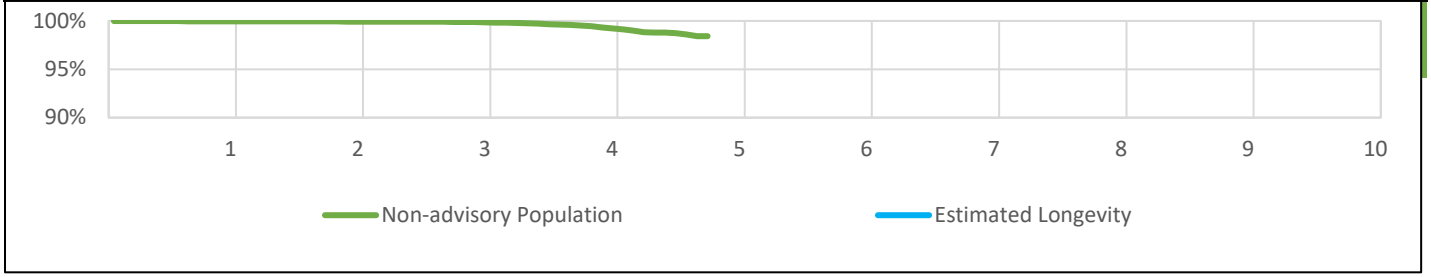
US Summary

US Registered Implants:	82,000	US Normal Battery Depletions:	33
US Approval Date:	October 2014	US Malfunctions:	126
US Estimated Active Implants:	76,000	Without Compromised Therapy:	122
		With Compromised Therapy:	4

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.2%	98.3%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.3%	98.4%	--	--	--	--	--
82,000	Effective Sample Size	54810	33755	16784	4805	206	--	--	--	--	--

@ 58 months

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

ACCOLADE/PROPONENT/ESSENTIO EL DR

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

Worldwide Confirmed Malfunctions	**279**
Worldwide Distribution	**197,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	5	5
Integrated circuit (63)	1	9	10
Capacitor (67)	0	167	167
Telemetry (68)	1	11	12
Hydrogen induced premature depletion - September 2018 (70)	2	39	41
Software			
Memory errors (51)	0	24	24
Mechanical			
Battery cathode (79)	1	0	1
Other			
Non-patterned, other	1	18	19
Grand Total	**6**	**273**	**279**

References cited in table above (link)

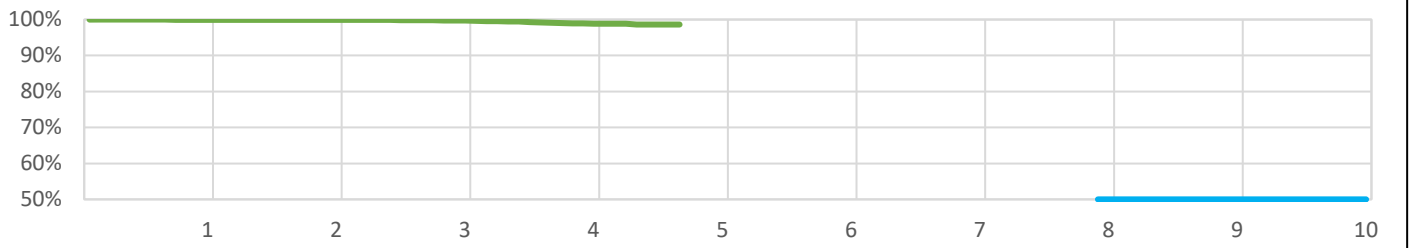
ACCOLADE/PROPONENT/ESSENTIO SR

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

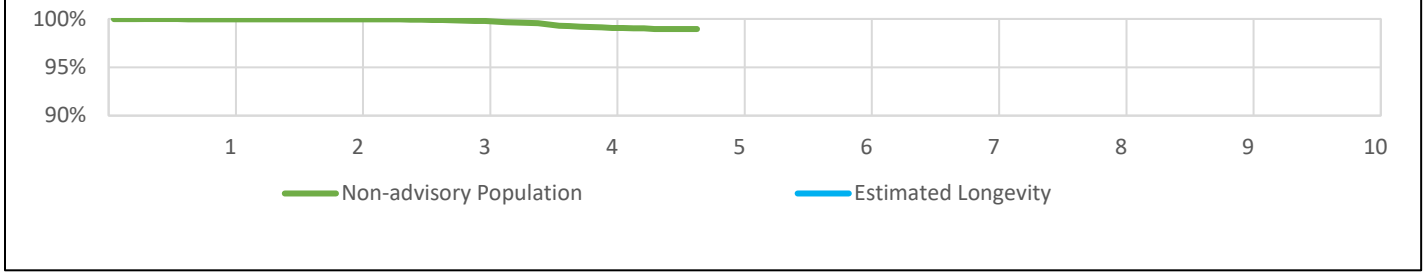
US Summary

US Registered Implants:	34,000	US Normal Battery Depletions:	28
US Approval Date:	October 2014	US Malfunctions:	82
US Estimated Active Implants:	28,000	Without Compromised Therapy:	80
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.7%	98.9%	98.6%	--	--	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.8%	99.1%	99.0%	--	--	--	--	--
34,000	Effective Sample Size	24219	16251	9017	2933	353	--	--	--	--	--

@ 57 months

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

ACCOLADE/PROPONENT/ESSENTIO SR

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

Worldwide Confirmed Malfunctions	**225**
Worldwide Distribution	**129,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	4	3	7
Capacitor (67)	0	159	159
Telemetry (68)	0	4	4
Hydrogen induced premature depletion - September 2018 (70)	2	35	37
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	0	7	7
Grand Total	**6**	**219**	**225**

References cited in table above (link)

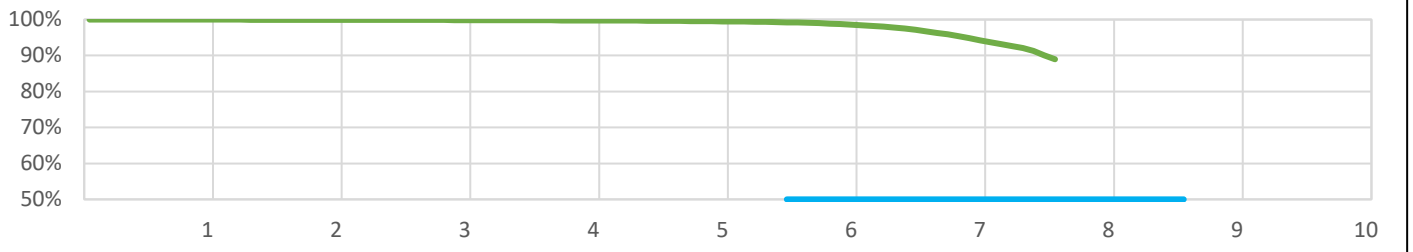
ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

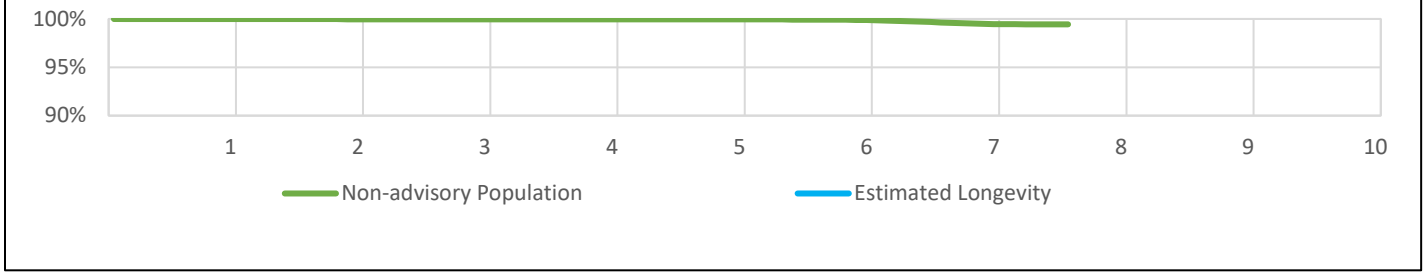
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	1,575
US Approval Date:	May 2012	US Malfunctions:	154
US Estimated Active Implants:	87,000	Without Compromised Therapy:	143
		With Compromised Therapy:	11

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.5%	98.8%	94.9%	89.0%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.5%	99.4%	--	--
121,000	Effective Sample Size	107351	95771	85405	76098	62927	34138	10749	824	--	--

@ 92 months

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 Confirmed Malfunctions	**191**
Worldwide Distribution	**219,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	7	3	10
Titanium case material (60)	3	0	3
Software			
Memory errors (51)	1	25	26
Other			
Non-patterned, other	8	136	144
Grand Total	**19**	**172**	**191**

References cited in table above (link)

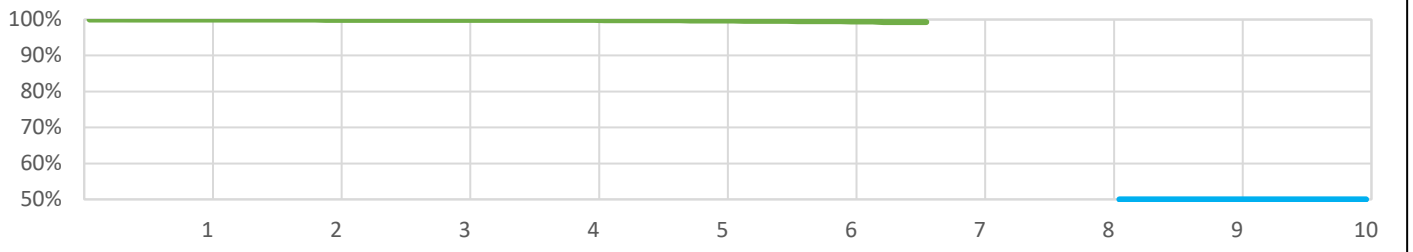
ADVANTIO/INGENIO/VITALIO EL DR

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

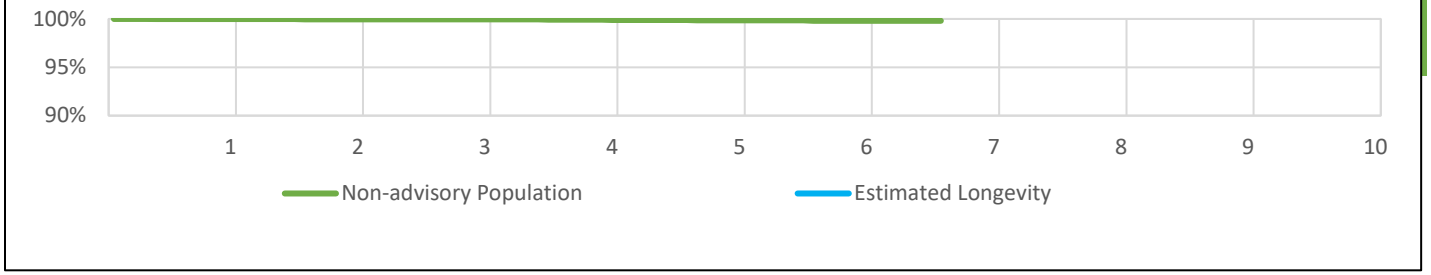
US Summary

US Registered Implants:	11,000	US Normal Battery Depletions:	15
US Approval Date:	May 2012	US Malfunctions:	12
US Estimated Active Implants:	9,000	Without Compromised Therapy:	10
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	99.7%	99.5%	99.3%	--	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.8%	--	--	--
11,000	Effective Sample Size	9676	8589	7640	6698	5090	1360	219	--	--	--

@ 80 months

ADVANTIO/INGENIO/VITALIO/FORMIO EL DR

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

Worldwide Confirmed Malfunctions	**80**
Worldwide Distribution	**76,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	5	6
Integrated circuit (50)	2	0	2
Titanium case material (60)	2	0	2
Software			
Memory errors (51)	1	4	5
Respiratory sensor (59)	0	1	1
Other			
Non-patterned, other	4	60	64
Grand Total	**10**	**70**	**80**

References cited in table above (link)

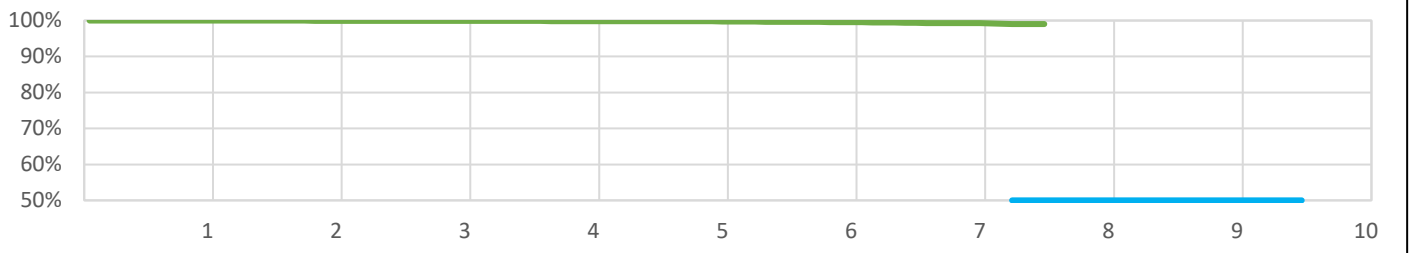
ADVANTIO/INGENIO/VITALIO/FORMIO SR

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

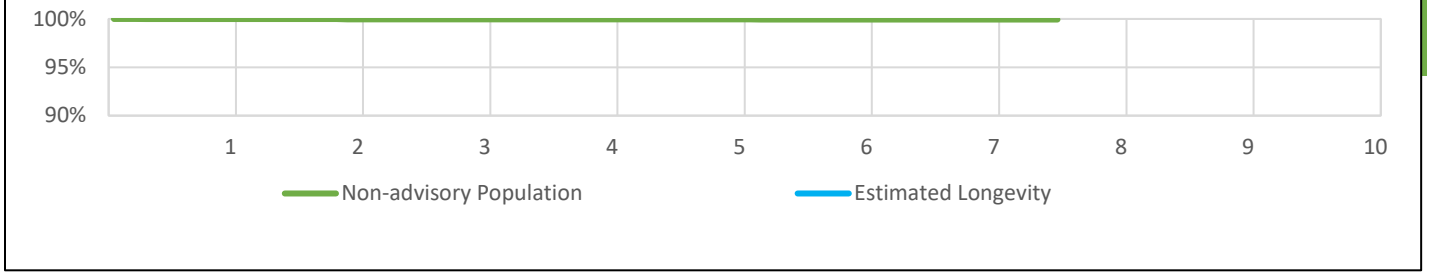
US Summary

US Registered Implants:	27,000	US Normal Battery Depletions:	67
US Approval Date:	May 2012	US Malfunctions:	11
US Estimated Active Implants:	16,000	Without Compromised Therapy:	10
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.8%	99.5%	99.3%	99.0%	--	--
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	--	--
27,000	Effective Sample Size	22871	20344	18146	16004	12559	6644	2041	307	--	--

@ 91 months

ADVANTIO/INGENIO/VITALIO SR

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

Worldwide Confirmed Malfunctions	**24**
Worldwide Distribution	**86,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (50)	3	2	5
Titanium case material (60)	1	0	1
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	3	2	5
Grand Total	**8**	**16**	**24**

References cited in table above (link)

ALTRUA 2 DR

Models: S702

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	1	1
Electrical			
Capacitor (67)	0	2	2
Grand Total	**0**	**3**	**3**

References cited in table above (link)

ALTRUA 2 EL DR

Models: S722

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**4,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

ALTRUA 2 SR

Models: S701

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (67)	0	3	3
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**4**	**4**

References cited in table above (link)

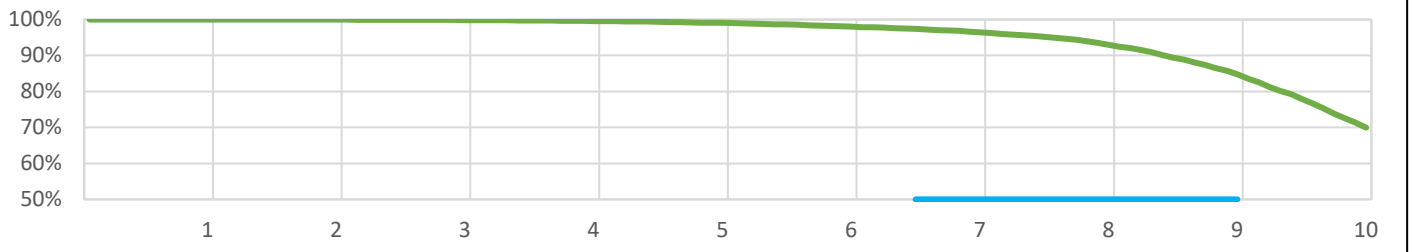
ALTRUA 60 DR

Model: S602

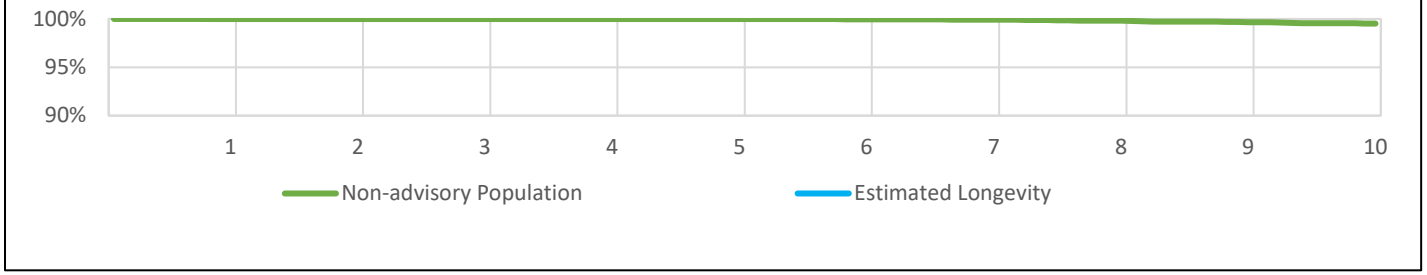
US Summary

US Registered Implants:	22,000	US Normal Battery Depletions:	2,744
US Approval Date:	April 2008	US Malfunctions:	38
US Estimated Active Implants:	9,000	Without Compromised Therapy:	35
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.6%	99.1%	98.2%	96.6%	93.5%	85.7%	71.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%
22,000	Effective Sample Size	19599	17526	15594	13820	12188	10664	9227	7628	5595	3444

ALTRUA 60 DR

Models: S602

Worldwide Confirmed Malfunctions	**64**
Worldwide Distribution	**56,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Mechanical			
Capacitor array (16)	0	1	1
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	1	1	2
Battery status (49)	0	52	52
Non-patterned, other	3	4	7
Grand Total	**5**	**59**	**64**

References cited in table above (link)

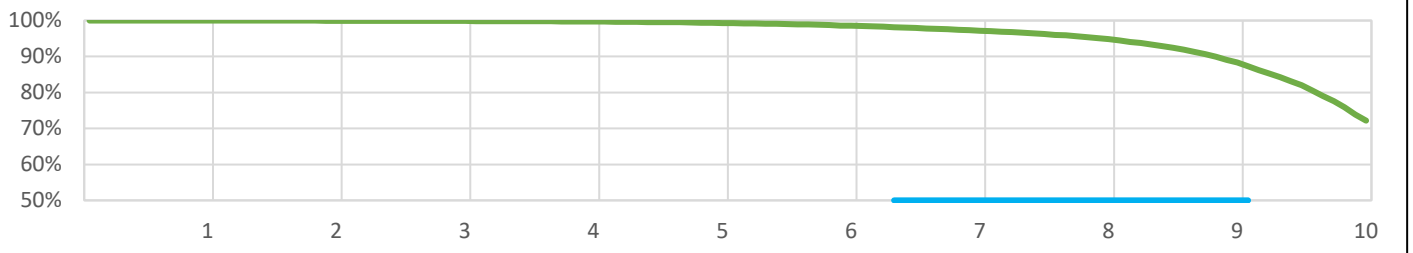
ALTRUA 60 EL DR

Model: S606

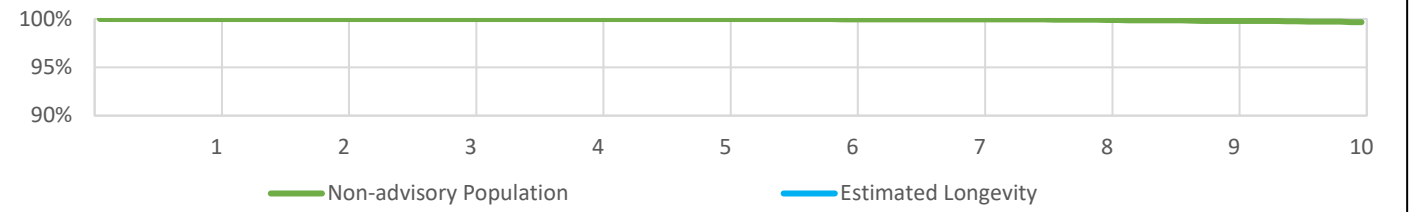
US Summary

US Registered Implants:	59,000	US Normal Battery Depletions:	3,220
US Approval Date:	April 2008	US Malfunctions:	47
US Estimated Active Implants:	33,000	Without Compromised Therapy:	42
		With Compromised Therapy:	5

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.7%	99.4%	98.6%	97.3%	95.1%	89.1%	73.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%
59,000	Effective Sample Size	52529	46947	41902	37354	33260	29388	25458	19027	9249	2120

ALTRUA 60 EL DR

Models: S606

Worldwide Confirmed Malfunctions	**60**
Worldwide Distribution	**90,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	3	3
Integrated circuit (17)	0	1	1
Mechanical			
Difficulty securing lead (41)	1	0	1
Other			
Battery depletion (26)	2	0	2
Battery status (49)	1	46	47
Magnet rate (44)	0	1	1
Non-patterned, other	2	3	5
Grand Total	**6**	**54**	**60**

References cited in table above (link)

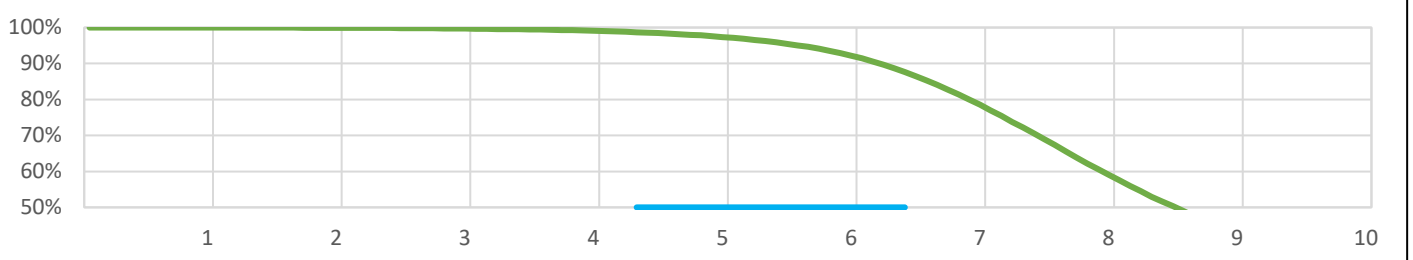
ALTRUA 60 DR (Downsize)

Model: S603

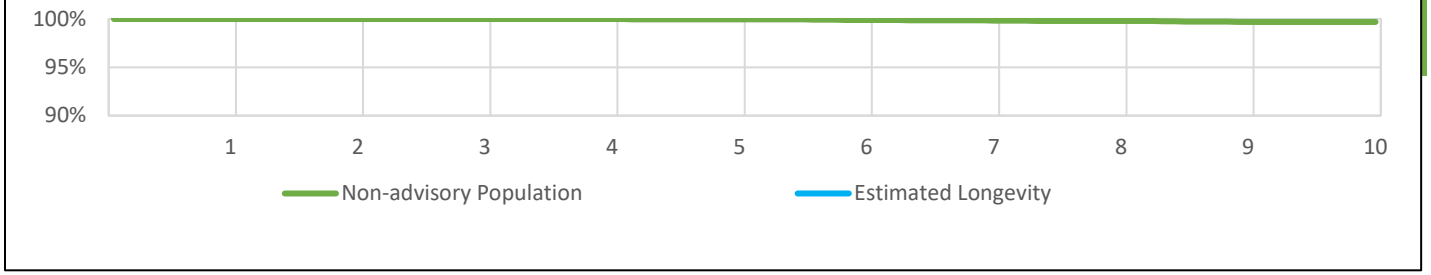
US Summary

US Registered Implants:	90,000	US Normal Battery Depletions:	21,870
US Approval Date:	April 2008	US Malfunctions:	97
US Estimated Active Implants:	28,000	Without Compromised Therapy:	87
		With Compromised Therapy:	10

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.7%	99.2%	97.6%	92.9%	79.9%	60.7%	43.5%	25.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%	99.7%	99.7%
90,000	Effective Sample Size	78696	70389	62862	55937	49239	41828	31702	18533	7665	1601

ALTRUA 60 DR (Downsize)

Models: S603

Worldwide Confirmed Malfunctions	**126**
Worldwide Distribution	**132,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	7	4	11
Integrated circuit (30)	1	1	2
Mechanical			
Difficulty securing lead (41)	0	1	1
Connector block (39)	0	1	1
Software			
Underestimation of battery status (34)	0	1	1
Other			
Battery depletion (26)	1	3	4
Battery status (49)	0	96	96
Magnet response (21)	0	2	2
Non-patterned, other	4	4	8
Grand Total	**13**	**113**	**126**

References cited in table above (link)

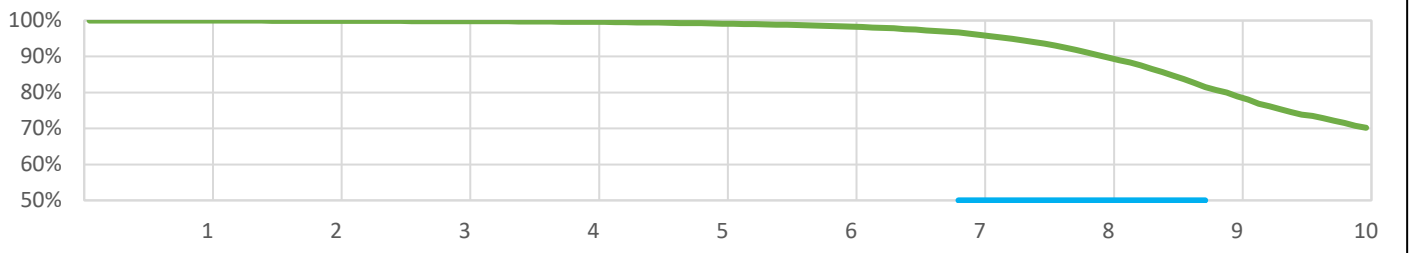
ALTRUA 60 SR

Model: S601

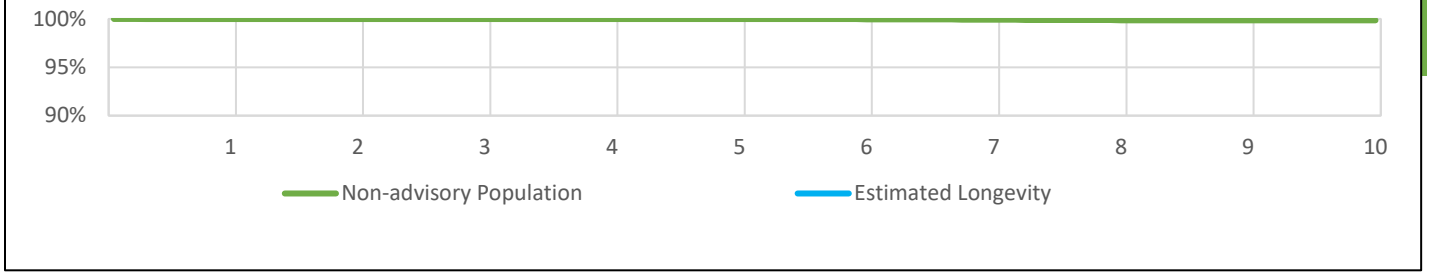
US Summary

US Registered Implants:	32,000	US Normal Battery Depletions:	2,569
US Approval Date:	April 2008	US Malfunctions:	18
US Estimated Active Implants:	11,000	Without Compromised Therapy:	16
		With Compromised Therapy:	2

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.6%	99.2%	98.4%	96.3%	90.4%	79.9%	70.8%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
32,000	Effective Sample Size	26349	23132	20542	18313	16313	14420	12396	9102	4816	2049

ALTRUA 60 SR

Models: S601

Worldwide Confirmed Malfunctions	**35**
Worldwide Distribution	**68,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	1	3
Integrated circuit (30)	2	0	2
Other			
Battery depletion (26)	1	0	1
Battery status (49)	0	26	26
Non-patterned, other	2	1	3
Grand Total	**7**	**28**	**35**

References cited in table above (link)

ALTRUA 50 DR (Downsize)

Models: S502

Worldwide Confirmed Malfunctions	**36**
Worldwide Distribution	**48,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	1	2	3
Integrated circuit (30)	0	1	1
Other			
Battery depletion (26)	0	2	2
Battery status (49)	0	28	28
Non-patterned, other	0	2	2
Grand Total	**1**	**35**	**36**

References cited in table above (link)

ALTRUA 50 SR

Models: S501

Worldwide Confirmed Malfunctions	**14**
Worldwide Distribution	**25,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	4	1	5
Other			
Battery depletion (26)	2	0	2
Battery status (49)	0	6	6
Non-patterned, other	1	0	1
Grand Total	**7**	**7**	**14**

References cited in table above (link)

ALTRUA 50 DDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**12,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	3	0	3
Battery status (49)	0	6	6
Grand Total	**3**	**6**	**9**

References cited in table above (link)

ALTRUA 50 SSI

Models: S508

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery depletion (26)	1	0	1
Battery status (49)	0	3	3
Grand Total	**1**	**3**	**4**

References cited in table above (link)

ALTRUA 50 VDD (Downsize)

Models: S504

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Battery status (49)	0	7	7
Grand Total	**0**	**7**	**7**

References cited in table above (link)

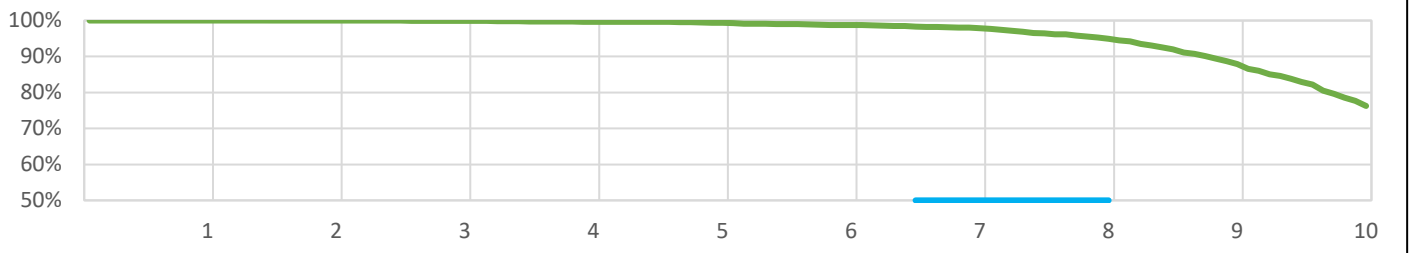
ALTRUA 40 EL DR

Model: S404

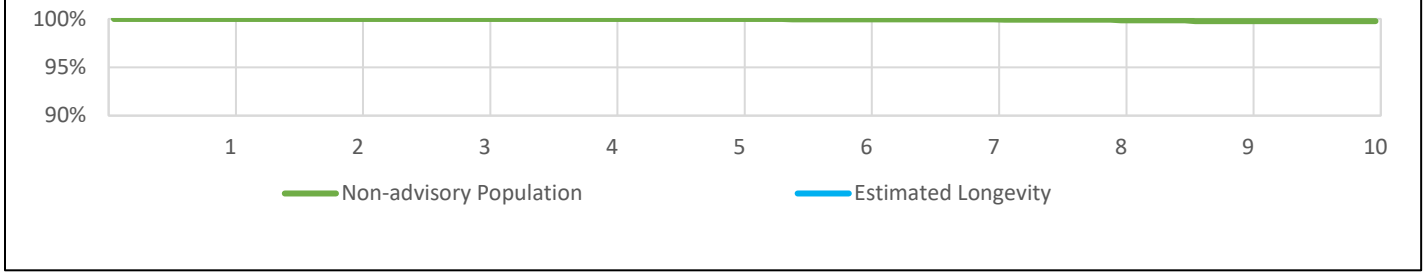
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	295
US Approval Date:	April 2008	US Malfunctions:	4
US Estimated Active Implants:	2,000	Without Compromised Therapy:	4
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.7%	99.4%	98.8%	98.0%	95.2%	88.7%	77.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.8%
5,000	Effective Sample Size	4435	3966	3561	3181	2842	2518	2222	1756	946	332

ALTRUA 40 EL DR

Models: S404

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Other			
Battery status (49)	0	4	4
Grand Total	**0**	**5**	**5**

References cited in table above (link)

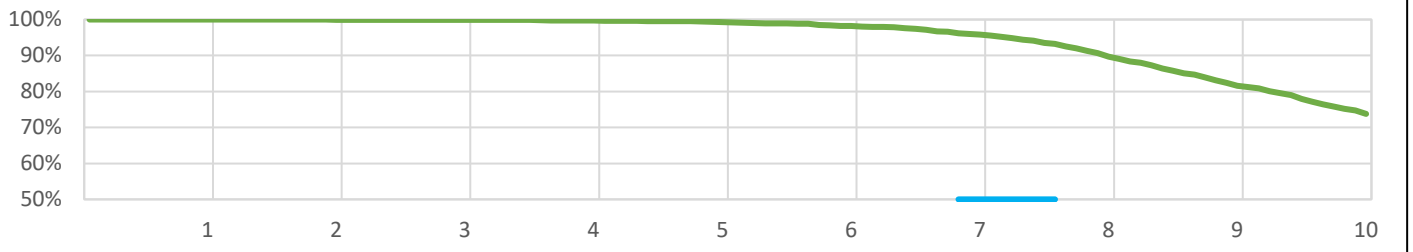
ALTRUA 40 SR

Model: S401

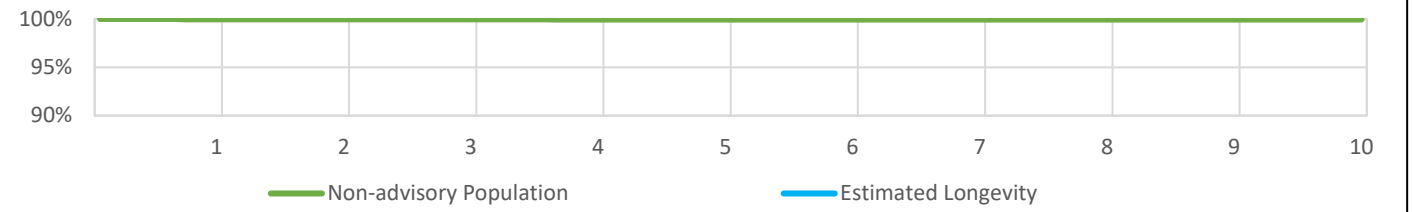
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	362
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	1,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	100.0%	99.9%	99.7%	99.4%	98.2%	96.0%	90.7%	82.4%	74.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
5,000	Effective Sample Size	3889	3406	2972	2636	2327	2056	1785	1395	791	334

ALTRUA 40 SR

Models: S401

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**9,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	2	2
Integrated circuit (30)	1	0	1
Grand Total	**1**	**2**	**3**

References cited in table above (link)

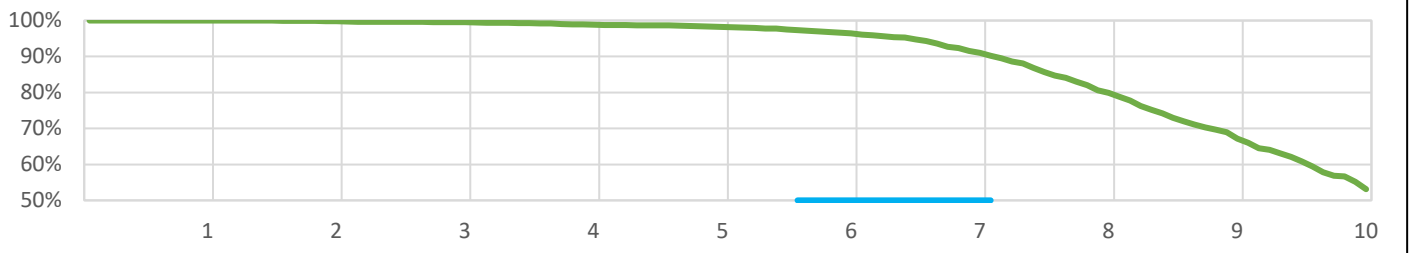
ALTRUA 20 DR (downsize)

Model: S203

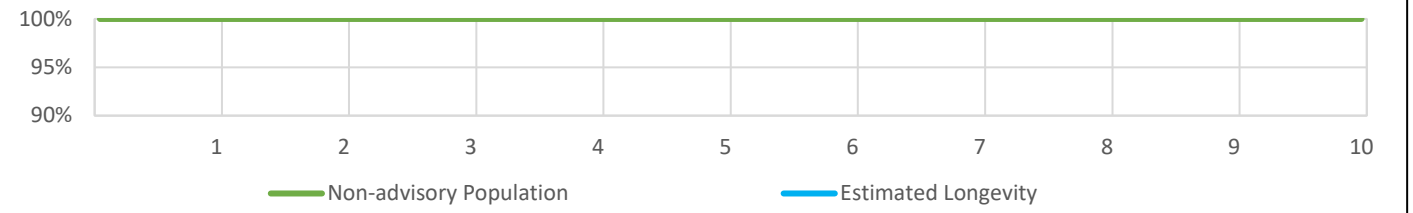
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	723
US Approval Date:	April 2008	US Malfunctions:	-
US Estimated Active Implants:	2,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.8%	99.5%	98.9%	98.3%	96.6%	91.6%	80.6%	68.9%	55.2%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
5,000	Effective Sample Size	4317	3818	3397	3017	2684	2355	1994	1459	747	238

@ 121 months

ALTRUA 20 DR (downsize)

Models: S203

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**16,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	2	2
Other			
Battery depletion (26)	1	0	1
Battery status (49)	0	1	1
Grand Total	**1**	**3**	**4**

References cited in table above (link)

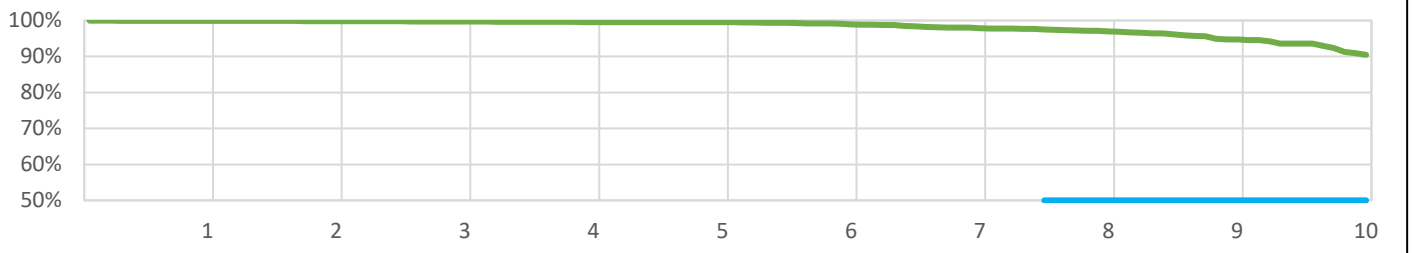
ALTRUA 20 EL DR

Model: S208

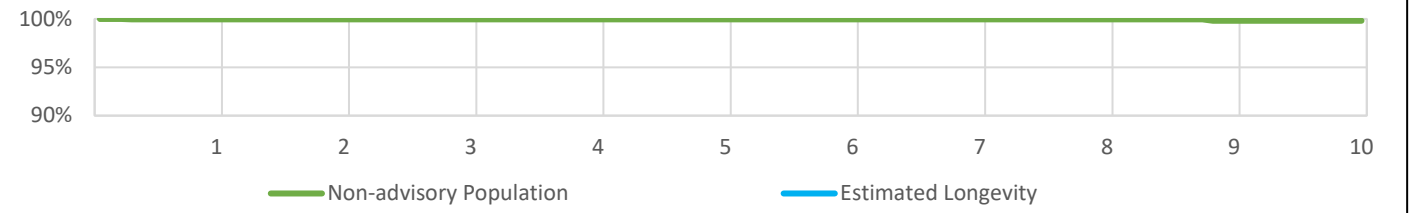
US Summary

US Registered Implants:	3,000	US Normal Battery Depletions:	86
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		With Compromised Therapy:	1

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.8%	99.6%	99.5%	99.1%	98.0%	97.2%	94.7%	90.9%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.8%
3,000	Effective Sample Size	2763	2473	2200	1972	1751	1560	1373	1096	619	228

ALTRUA 20 EL DR

Models: S208

Worldwide Confirmed Malfunctions	**5**
Worldwide Distribution	**11,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	2	0	2
Other			
Non-patterned, other	1	0	1
Battery status (49)	0	2	2
Grand Total	**3**	**2**	**5**

References cited in table above (link)

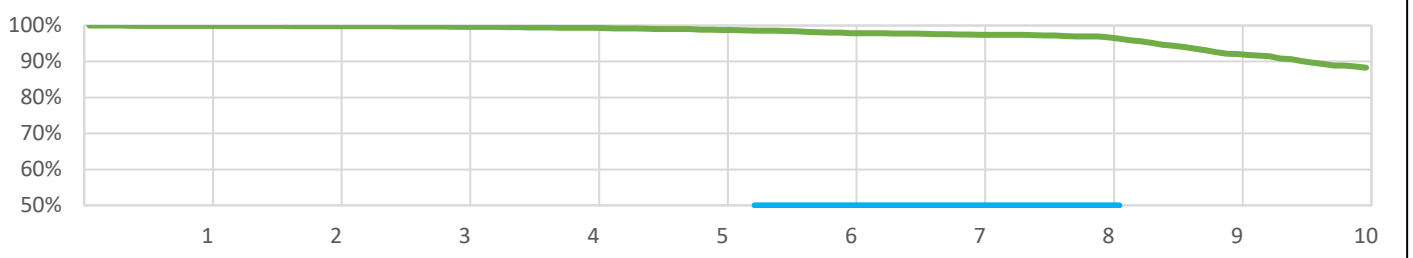
ALTRUA 20 SR

Model: S201/S204

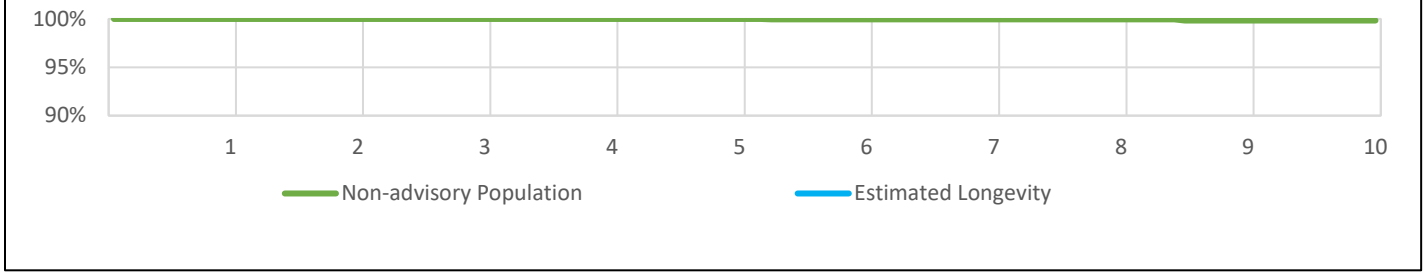
US Summary

US Registered Implants:	5,000	US Normal Battery Depletions:	142
US Approval Date:	April 2008	US Malfunctions:	2
US Estimated Active Implants:	1,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.7%	99.3%	98.8%	98.0%	97.5%	96.9%	92.2%	88.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%
5,000	Effective Sample Size	3569	3042	2615	2287	1992	1726	1498	1204	705	330

ALTRUA 20 SR

Models: S201/S204

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**24,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Capacitor (15)	0	1	1
Other			
Non-patterned, other	1	0	1
Battery status (49)	0	2	2
Grand Total	**1**	**3**	**4**

References cited in table above (link)

ALTRUA 20 DDD

Models: S207

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**1,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

ALTRUA 20 SSI

Models: S206

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterend, other	0	0	0
Grand Total	**0**	**0**	**0**

References cited in table above (link)

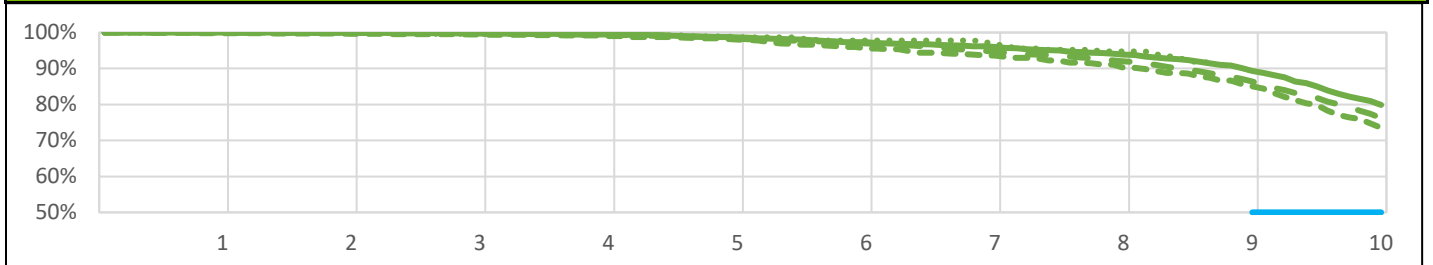
INSIGNIA Entra DR

Model: 1294/1295

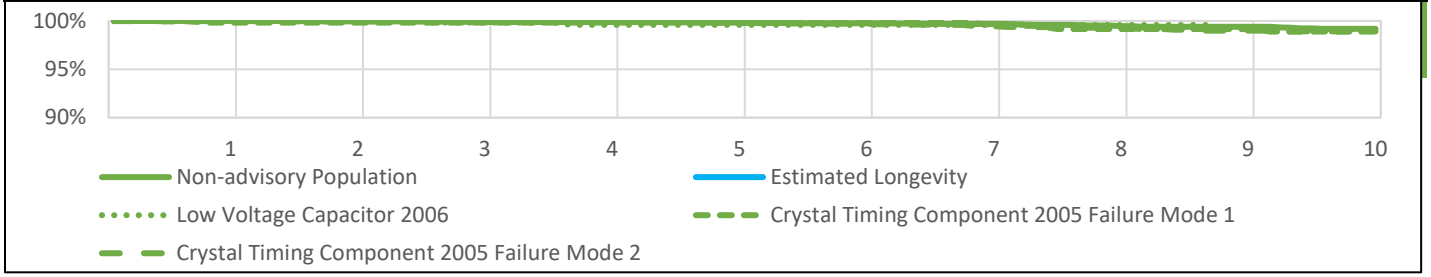
US Summary

US Registered Implants:	17,000	US Normal Battery Depletions:	2,578
US Approval Date:	March 2002	US Malfunctions:	74
US Estimated Active Implants:	2,000	Without Compromised Therapy:	64
		With Compromised Therapy:	10

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.5%	98.7%	97.3%	96.1%	94.1%	90.1%	81.0%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.5%	99.4%	99.2%
7000	Effective Sample Size	6116	5427	4810	4265	3726	3241	2842	2492	2122	1677

INSIGNIA Entra DR

Model: 1294/1295

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2006	Depletions and Malfunctions	100.0%	100.0%	99.6%	99.4%	98.9%	97.7%	97.4%	94.8%	91.7%	--
Registered Implants: 1000	Malfunctions Only	100.0%	100.0%	99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	--
	Effective Sample Size	669	582	505	433	374	317	276	231	201	--
Crystal Timing Component 2005 Failure Mode 1	Depletions and Malfunctions	99.8%	99.7%	99.5%	99.2%	98.3%	96.0%	93.7%	91.1%	85.6%	74.7%
Registered Implants: 2000	Malfunctions Only	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%	99.2%	99.2%	98.9%
	Effective Sample Size	1611	1401	1172	1029	896	753	633	526	428	311
Crystal Timing Component 2005 Failure Mode 2	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.5%	97.1%	95.0%	92.3%	87.1%	77.4%
Registered Implants: 7000	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	99.0%	98.9%
	Effective Sample Size	6147	5448	4796	4225	3696	3187	2684	2277	1854	1409

@ 105 months

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

INSIGNIA Entra DR

Models: 1294/1295

Worldwide Confirmed Malfunctions	**92**
Worldwide Distribution	**37,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (13)	1	0	1
Capacitor (15)	1	0	1
Integrated circuit (30)	1	0	1
Mechanical			
Seal plug (19)	0	3	3
Header (20)	2	0	2
Seal plug (33)	0	1	1
Crystal timing component Failure Mode 1 - September 22, 2005 Voluntary Physician Advisory (9)	5	0	5
Software			
Underestimation of battery status (34)	0	2	2
Other			
Longevity labeling (11)	0	50	50
Battery status (49)	0	15	15
Battery depletion (26)	1	0	1
Non-patterned, other	7	3	10
Grand Total	**18**	**74**	**92**

References cited in table above (link)

Confirmed Malfunction Details: Pulse Generator 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.

3. **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.
4. **Unintended Fuse Activation 2013**— *March 1, 2013 Voluntary Physician Advisory*.Inability to interrogate, no magnet response, permanent loss of therapy without warning. Improvement implemented.
5. **High cathode condition**— *June 1, 2011 Voluntary Physician Advisory*.Premature battery depletion. Misaligned battery component. Improvement implemented.
6. **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.
7. **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.
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. **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.
10. **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.
11. **Longevity labeling**— Battery longevity inconsistent with longevity labeling. Device battery status indicators are accurate and no loss of therapy has been reported.
12. **Solder bond**— Loss of device output, loss of sensing. Separation of component solder from substrate. Improvement implemented.
13. **Integrated circuit**— Power on Reset state, loss of telemetry, safety mode operation or loss of output. Failed digital integrated circuit.
14. **Capacitor**— Premature battery depletion, inability to interrogate. Damage to low-voltage capacitor.
15. **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.
16. **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.
17. **Integrated circuit**— No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor.
18. **Battery depletion**— Premature battery depletion and loss of capture.
19. **Seal plug**— Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.
20. **Header**— High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.
21. **Magnet response**— No magnet response. Particulate material in component. Improvement implemented.
22. **Battery depletion**— Premature battery depletion.
23. **Memory error**— Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.
24. **Transformer**— Charge time alert message and/or end of life (EOL) indicator displayed, loss of shock therapy. Damaged transformer. Improvement implemented.
25. **Setscrew block**— No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.
26. **Battery depletion**— Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.

27. **Solder bond**— Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.
28. **Stored EGMs**— Inability to view stored EGMs. Incorrect EGM index location.
29. **Battery post**— Inability to interrogate, no pacing output. Bent battery post. Improvement implemented.
30. **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.
31. **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.
32. **Setscrew**— Inability to tighten or loosen setscrews during implant or replacement procedure due to process variability. Improvement implemented.
33. **Seal plug**— Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented
34. **Underestimation of battery status**— Underestimation of remaining longevity due to invalid charge time measurement. Improvement implemented.
35. **Interrupted telemetry**— Early appearance of Elective Replacement Time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade. Improvement implemented.
36. **Pacing rate limit**— Inability to interrogate. Inappropriate pacing due to feature interaction. Improvement implemented.
37. **Solder joint**— Inappropriate shocks, beeping, fallback mode, errors or inability to interrogate or program. Cracked solder joint due to repetitive mechanical stress-induced component damage, only when implanted subpectorally with serial number facing the ribs.
38. **Transformer**— Inability to interrogate, loss of pacing and shock therapy. Failed transformer.
39. **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.
40. **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.
41. **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.
42. S**afety Core-electrocautery**— During electrocautery, device may enter Safety Core. Circuitry response to noise caused by electrocautery. Improvement implemented.
43. **High-voltage capacitor**— Alert message upon interrogation, extended charge time. Damaged high voltage capacitor.
44. **Magnet rate**— During interrogation, magnet rate remains after removal of magnet. Reed switch stuck in closed position. Improvement implemented.
45. **Header contacts**— Noise, oversensing, inappropriate shock, high pacing impedance, possible loss of pacing and sensing. Poor header connection with lead terminals due to contacts.
46. **Safety Core-programming**— Device enters Safety Core after three consecutive invalid programming attempts, due to firmware issue. Improvement implemented.
47. **Low-voltage capacitors**— Premature battery depletion, voltage alert during followup, device beeping. Capacitor failure.
48. **Alert messages not displayed post-EOL**— No alert message display after EOL declaration. Improvement implemented.
49. **Battery status**— Longevity remaining, battery status, gas gauge and/or magnet rate do not align or are inconsistent.
50. **Integrated circuit**— Loss of telemetry, premature battery depletion, alert message during followup. Integrated circuit issue. Improvement implemented.
51. **Memory errors**— Safety mode operation, inaccurately labeled pacing data. Errors in device memory
52. **High voltage circuit**— Alert message after implant, loss of shock therapy. Failed output module.
53. **Battery**— Beeping tones and alert message upon interrogation. Reduced battery voltage. Improvement implemented.
54. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion. Diminished low voltage capacitor performance. Improvement implemented.
55. **Shortened replacement time 2018** *November 2018 Voluntary Physician Advisory.* Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
56. **Telemetry**— Inability to interrogate, premature battery depletion.
57. **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.
58. **High voltage circuit**— Long charge time at implant, inability to interrogate, loss of pacing and shock therapy. Improvement implemented.
59. **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.
60. **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.
61. **Charge Timeout Alert**— Beeping tones, programmer warning screen, abnormal shock impedance. Charge timeout alert.
62. **High voltage circuit component**— Charge time alert message and/or Elective Replacement indicator (ERI) displayed, beeping tones. High voltage circuit component. Improvement implemented.
63. **Integrated circuit**— Abnormal lead impedance, no telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor Improvement implemented

64. **Safety Core-unintended biventricular pacing**— *Dec 2017 Voluntary Physician Advisory.* Device enters Safety Core after detecting unintended asynchronous biventricular pacing due to software issue.
65. **Memory corruption** - *Jun 2017 Voluntary Physician Advisory.* Atypical energy delivery, error messages upon interrogation, loss of tachy therapy. Memory corruption. Improvement implemented.
67. **Capacitor**— Premature battery depletion. Diminished low voltage capacitor performance.
68. **Telemetry**— Alert message during followup, inability to interrogate, premature battery depletion, loss of pacing therapy. Telemetry component.
69. **Low-voltage capacitor**— Alert message during followup, beeping tones, premature battery depletion.
70. **Hydrogen induced premature depletion - September 2018 -** *September 2018 Voluntary Physician Advisory*. Premature battery depletion. Diminished low voltage capacitor performance.
71. **Battery –** Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available. Improvement implemented.
72. **Capacitor**— Premature battery depletion. Diminished capacitor performance
73. **Misaligned markers**— Stored episode markers do not match recorded EGM.
74. **Header**— Noise, oversensing, inappropriate shocks, pacing inhibition, high impedance when implanted subcutaneously. Weakened bond between header and titanium case. Improvement Implemented.
75. **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.
76. **Internal insulation**— Beeping tones, loss of telemetry, premature battery depletion, loss of tachy therapy. Internal insulation issue.
77. **S-ICD battery depletion 2019 –** *August 2019 Voluntary Physician Advisory.* Premature battery depletion. Diminished capacitor performance.
78. **Solder joint**— Beeping tones, device errors, loss of tachy therapy. Cracked solder joint.
79. **Battery cathode –** Safety mode operation, inability to interrogate, loss of brady therapy. Internal battery cathode issue.

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
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/ G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/ G447/G448/G524/G525/G526/G528/G537/G547/G548	48,000	1	2	2	5	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	24,000	3	0	0	3	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	102,000	3	4	5	14	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	62,000	5	0	1	2	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	3	0	0
CONTAK RENEWAL TR 2 H140/H145	31,000	1	7	0	5	0	0

ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	21,000	0	1	2	1	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	18,000	0	3	1	0	0	0
AUTOGEN ICD EL VR D160/D161/D174/D175	17,000	1	0	0	0	0	0
AUTOGEN ICD EL DR D162/D163/D176/D177	16,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D020/D021/D010/D011/D000/D001	55,000	1	0	3	4	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D020/D021/D010/D011/D000/D001	58,000	0	2	2	1	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D020/D021/D010/D011/D000/D001	26,000	1	0	3	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D022/D023/D012/D013/D002/D003	24,000	2	0	0	2	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	68,000	1	0	5	47	0	0
SQ-RX S-ICD 1010	11,000	11	0	21	27	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL J064/K064/K067/K084	197,000	7	3	4	11	0	0
ACCOLADE/PROPONENT/ESSENTIO DR J064/K064/K067/K084	356,000	5	0	5	18	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	129,000	1	1	1	13	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	77,000	1	1	0	4	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	219,000	4	0	1	15	0	0
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	86,000	0	0	1	5	0	0

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	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D G124/G125/G126/G128/G138/G224/G225/G228/G237/G247/G248/G324/G325/G347/G348/G424/G425/G426/G428/G437/G447/G448/G524/G525/G526/G528/G537/G547/G548	23000	0	57	4	227	856
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158	66000	124	259	48	905	7293
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	53000	1830	335	736	872	16114
COGNIS N118/N119/N120/P106/P107/P108	75000	9588	362	2066	1644	37631

CRT-P/Model	U.S. Registered Implants	Normal 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	30000	42	522	23	187	2911
INTUA V272/V273/V282/V283/W272/W273	3000	55	58	3	25	601
INVIVE V172/V173/V182/V183/W172/W173	8000	267	129	15	45	2526
CONTAK RENEWAL TR H120/H125	19000	4067	202	67	207	11139

S-ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
EMBLEM S-ICD A209, A219	32000	13	228	93	641	2160
SQ-RX S-ICD 1010	8000	612	145	93	241	1660

ICD/Model	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR D121/D221/D233/D321/D333/D421/D433/D521/D533	11000	1	105	2	82	256
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	7000	3	76	0	53	158
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	40000	20	1119	16	450	2842
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	34000	15	1005	13	345	2168
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	9000	98	238	13	102	1168
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	9000	11	268	6	103	980
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	105	1649	810	502	8604
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	143	1922	965	603	10850

ICD/Model, continued…	U.S. Registered Implants	Normal 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	308	1497	2154	643	15495
TELIGEN DR E110/E111/F110/F111	66000	2709	2323	2899	1105	28223

Pacemaker/Model	U.S. Registered Implants	Normal 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	82000	33	1585	126	361	4005
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	173000	201	3049	270	841	14324
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	34000	27	801	82	162	4849
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	15	339	12	49	1780
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	1569	2842	156	514	29456
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	67	554	12	106	9665

Pacemaker/Model, continued…	U.S. Registered Implants	Normal Battery Depletion	Device Upgrade	Device Malfunction[1]	Complication related to another system component or clinical condition[2]	Other[3]
ALTRUA 60 SR S601	32000	2565	438	18	144	17572
ALTRUA 60 DR (Downsize) S603	90000	21852	1190	97	465	38375
ALTRUA 60 DR S602	22000	2741	421	38	157	9454
ALTRUA 60 DR EL S606	59000	3209	1128	47	344	21750
ALTRUA 40 SR S401	5000	361	46	2	17	2839
ALTRUA 40 DR (downsize) S403	14000	3490	153	4	62	6443
ALTRUA 40 DR S402	2000	216	32	1	7	908
ALTRUA 40 DR EL S404	5000	292	77	4	32	2299
ALTRUA 20 SR S201/S204	5000	140	34	2	31	2866
ALTRUA 20 DR (downsize) S203	5000	721	41	0	30	2708
ALTRUA 20 DR EL S208	3000	85	42	2	10	1531
INSIGNIA Ultra SR 1190 [4]	24000	2990	230	47	147	17037
INSIGNIA Ultra DR 1291 [4]	32000	7596	472	214	252	17999
INSIGNIA Entra SR 1195/1198 [4]	14000	1216	92	8	53	11044
INSIGNIA Entra DR 1294/1295 [4]	17000	2574	167	74	134	12054

[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.

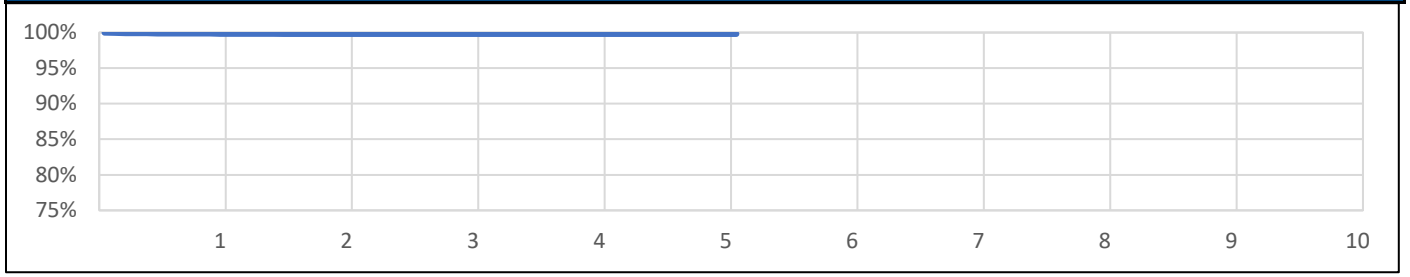
ACUITY X4 Spiral L

Models: 4677/4678

US Summary

US Registered Implants:	12,000	US Chronic Complications	21
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	11,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	--	--	--	--	
Registered Implants: 12000	Effective Sample Size	8773	5333	2687	573	223	204	--	--	--	--	@ 61 months

ACUITY X4 Spiral L

Models: 4677/4678

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**30,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

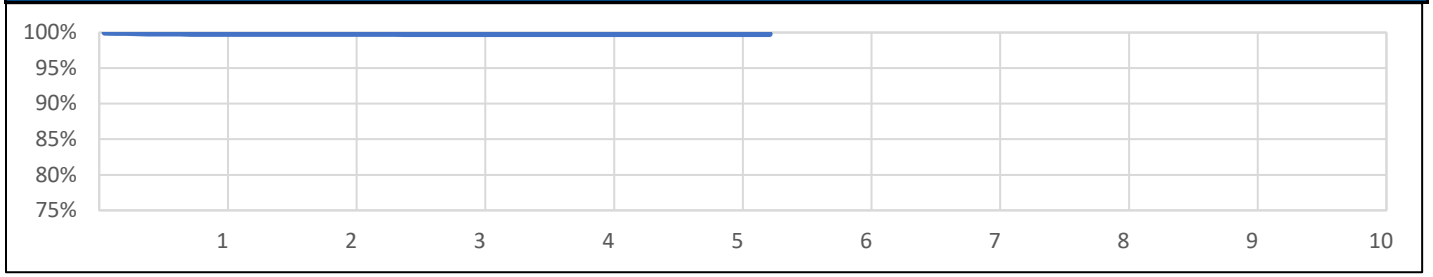
References cited in table above (link)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	34,000	US Chronic Complications	59
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	31,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	--	--	--	--	
Registered Implants: 34000	Effective Sample Size	22899	13705	6477	962	293	208	--	--	--	--	@ 63 months

ACUITY X4 Spiral S

Models: 4674/4675

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**72,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

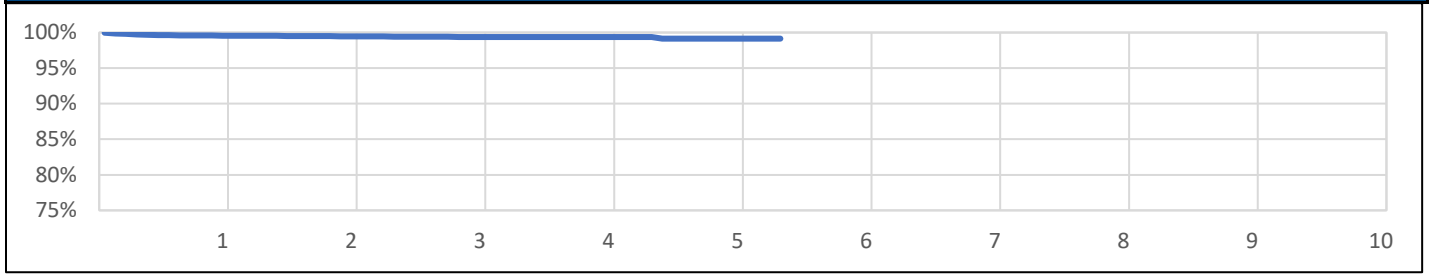
References cited in table above (link)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	26,000	US Chronic Complications	117
US Approval Date:	February 2016	US Malfunctions:	-
US Estimated Active Implants:	23,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.5%	99.4%	99.4%	99.1%	99.1%	--	--	--	--	
Registered Implants: 26000	Effective Sample Size	16673	9576	4379	687	286	208	--	--	--	--	@ 64 months

ACUITY X4 Straight

Models: 4671/4672

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**58,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

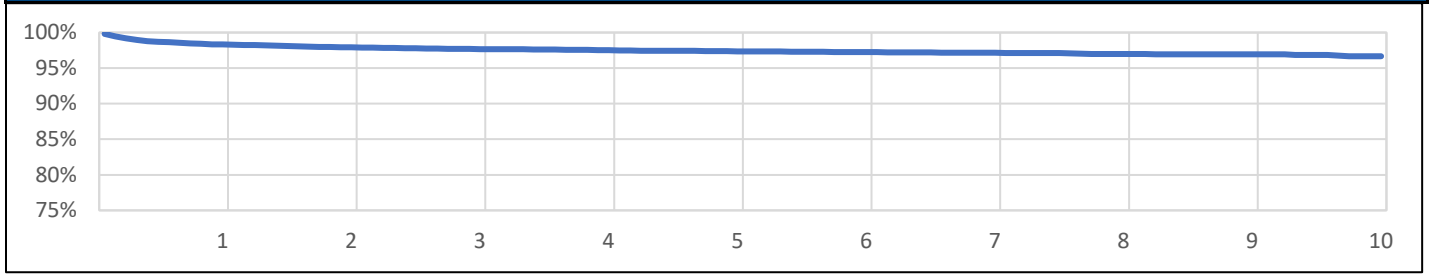
References cited in table above (link)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	24,000	US Chronic Complications	557
US Approval Date:	May 2008	US Malfunctions:	9
US Estimated Active Implants:	13,000	Without Compromised Therapy:	5
		With Compromised Therapy:	4

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.3%	97.9%	97.7%	97.5%	97.4%	97.2%	97.2%	97.0%	96.9%	96.7%
Registered Implants: 24000	Effective Sample Size	19770	17427	15403	13551	11413	9035	6743	4774	3098	1741

ACUITY Spiral

Models: 4591/4592/4593

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**46,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	5	9
Grand Total	**4**	**5**	**9**

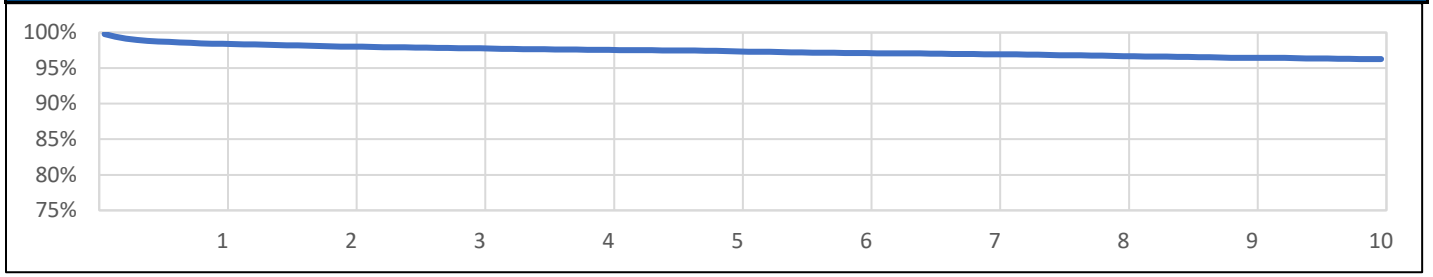
References cited in table above (link)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	723
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	14,000	Without Compromised Therapy:	12
		With Compromised Therapy:	21

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.4%	98.0%	97.8%	97.6%	97.3%	97.1%	96.9%	96.7%	96.4%	96.3%
Registered Implants: 29000	Effective Sample Size	24563	21946	19648	17559	15271	12624	9923	7723	5792	3994

ACUITY Steerable

Models: 4554/4555/4556

Worldwide Confirmed Malfunctions	**57**
Worldwide Distribution	**65,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	8	36
Other			
Non-patterned, other	10	11	21
Grand Total	**38**	**19**	**57**

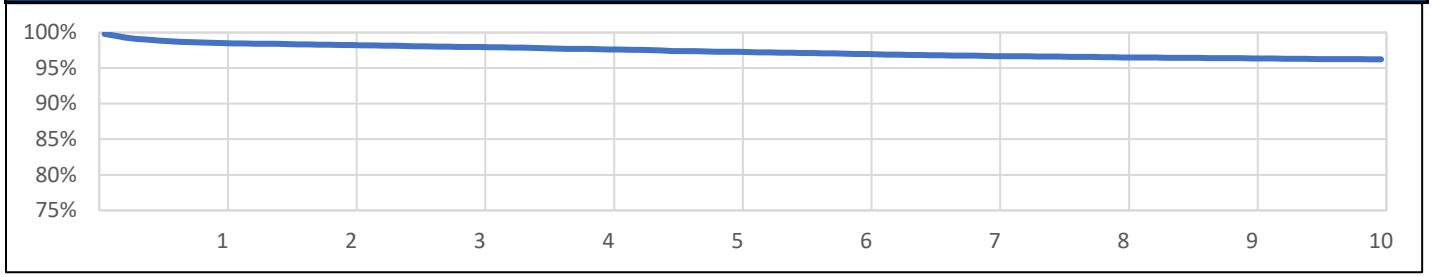
References cited in table above (link)

EASYTRAK 3

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

US Summary			
US Registered Implants:	22,000	US Chronic Complications	552
US Approval Date:	August 2004	US Malfunctions:	32
US Estimated Active Implants:	8,000	Without Compromised Therapy:	9
		With Compromised Therapy:	23

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.5%	98.2%	98.0%	97.6%	97.3%	97.0%	96.7%	96.5%	96.4%	96.2%
Registered Implants: 22000	Effective Sample Size	18461	16493	14759	13168	11488	9692	7890	6403	5188	4155

EASYTRAK 3

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

Worldwide Confirmed Malfunctions	**52**
Worldwide Distribution	**43,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (34)	28	6	34
Other			
Non-patterned, other	7	11	18
Grand Total	**35**	**17**	**52**

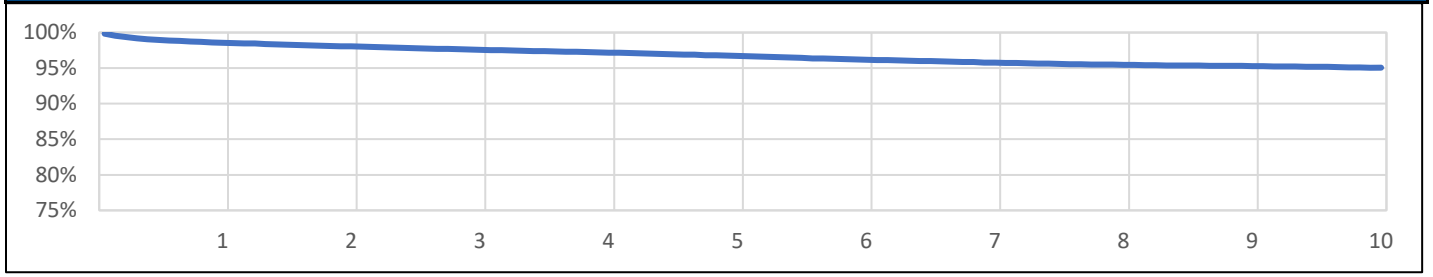
References cited in table above (link)

EASYTRAK 2

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

US Summary			
US Registered Implants:	97,000	US Chronic Complications	2,856
US Approval Date:	August 2004	US Malfunctions:	400
US Estimated Active Implants:	36,000	Without Compromised Therapy:	141
		With Compromised Therapy:	259

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.6%	98.0%	97.6%	97.2%	96.7%	96.2%	95.8%	95.5%	95.3%	95.1%
Registered Implants: 97000	Effective Sample Size	82336	73364	65422	58200	50528	42594	35063	28684	23063	17849

EASYTRAK 2

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

Worldwide Confirmed Malfunctions	**543**
Worldwide Distribution	**180,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (25)	329	145	474
Other			
Non-patterned, other	39	30	69
Grand Total	**368**	**175**	**543**

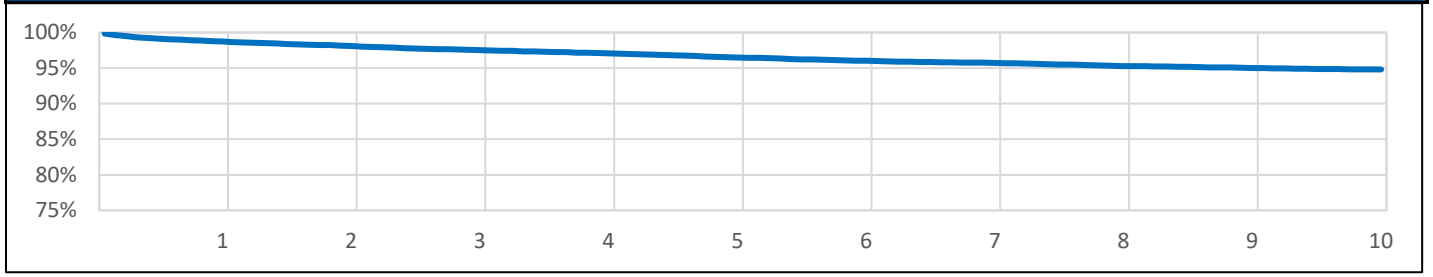
References cited in table above (link)

EASYTRAK

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

US Summary			
US Registered Implants:	38,000	US Chronic Complications	1,126
US Approval Date:	May 2002	US Malfunctions:	94
US Estimated Active Implants:	6,000	Without Compromised Therapy:	9
		With Compromised Therapy:	85

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	98.7%	98.1%	97.5%	97.1%	96.5%	96.0%	95.7%	95.3%	95.0%	94.8%
Registered Implants: 38000	Effective Sample Size	30335	26091	22396	19263	16451	14076	12078	10520	9292	8264

EASYTRAK

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

Worldwide Confirmed Malfunctions	**106**
Worldwide Distribution	**53,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	96	10	106
Grand Total	**96**	**10**	**106**

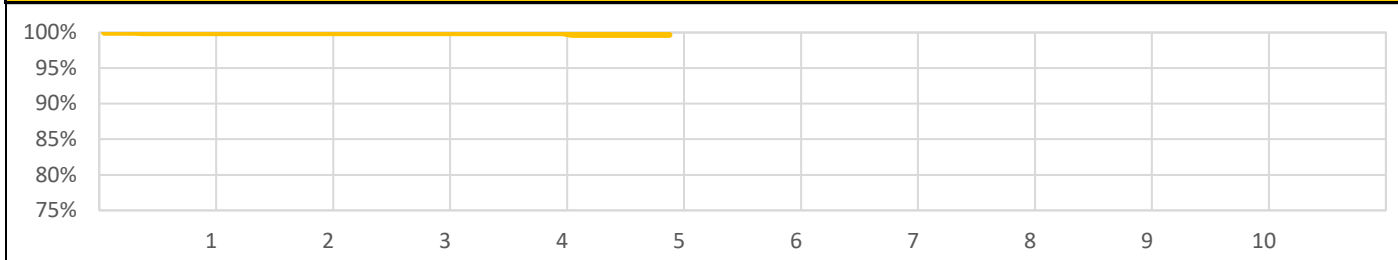
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0653/0658/0675/0676/0695/0696

US Summary			
US Registered Implants:	3,000	US Chronic Complications	3
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	3,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.9%	99.9%	99.9%	99.7%	--	--	--	--	--	
Registered Implants: 3000	Effective Sample Size	841	489	441	396	207	--	--	--	--	--	@ 59 months

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

Models: 0653/0658/0675/0676/0695/0696

Worldwide Confirmed Malfunctions	**3**
Worldwide Distribution	**18,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	3	0	3
Grand Total	**3**	**0**	**3**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

Models: 0636/0651/0655/0665/0685/0686

Worldwide Confirmed Malfunctions	**0**
Worldwide Distribution	**1,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

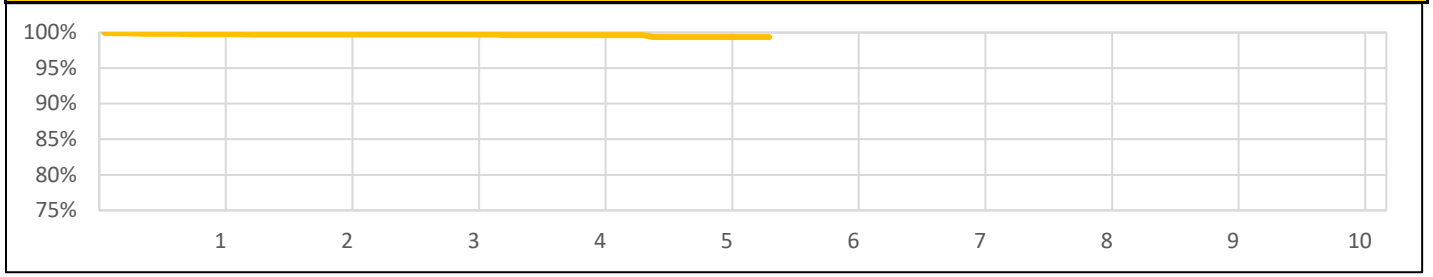
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Summary			
US Registered Implants:	19,000	US Chronic Complications	35
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	19,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.7%	99.7%	99.6%	99.4%	99.4%	--	--	--	--	
	Effective Sample Size	3797	1121	1004	906	403	210	--	--	--	--	@ 64 months
Registered Implants: 19000												

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0652/ 0657/0672/0673/0692/0693

Worldwide Confirmed Malfunctions	**40**
Worldwide Distribution	**103,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	16	0	16
Other			
Non-patterned, other	21	3	24
Grand Total	**37**	**3**	**40**

References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

Models: 0650/0654/0662/0663/0682/0683

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**5,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	1	0	1
Grand Total	**1**	**0**	**1**

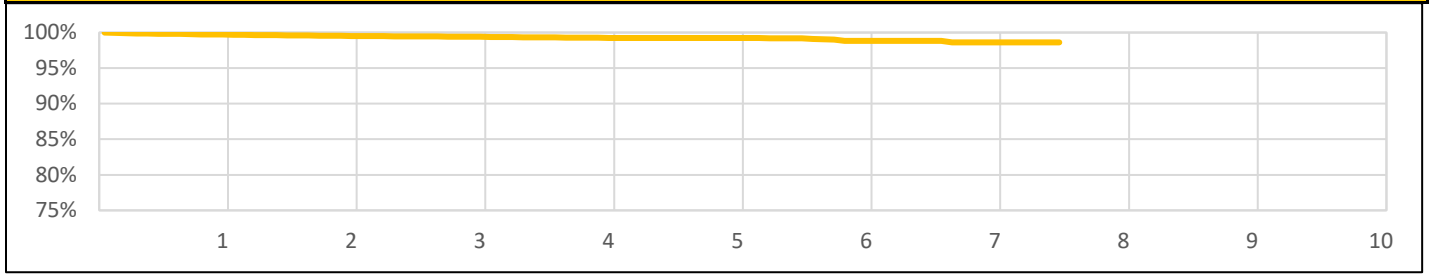
References cited in table above (link)

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401/3501

US Summary			
US Registered Implants:	38,000	US Chronic Complications	167
US Approval Date:	September 2012	US Malfunctions:	15
US Estimated Active Implants:	33,000	Without Compromised Therapy:	-
		With Compromised Therapy:	15

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.5%	99.4%	99.3%	99.2%	98.8%	98.6%	98.6%	--	--	
Registered Implants: 38000	Effective Sample Size	27598	19324	12589	7293	3231	961	426	309	--	--	@ 90 months

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401/3501

Worldwide Confirmed Malfunctions	**42**
Worldwide Distribution	**77,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Electrode conductor fracture (42)	12	0	12
Crimp/Weld/Bond			
Weld fracture (37)	3	0	3
Other			
Non-patterned, other	26	1	27
Grand Total	**41**	**1**	**42**

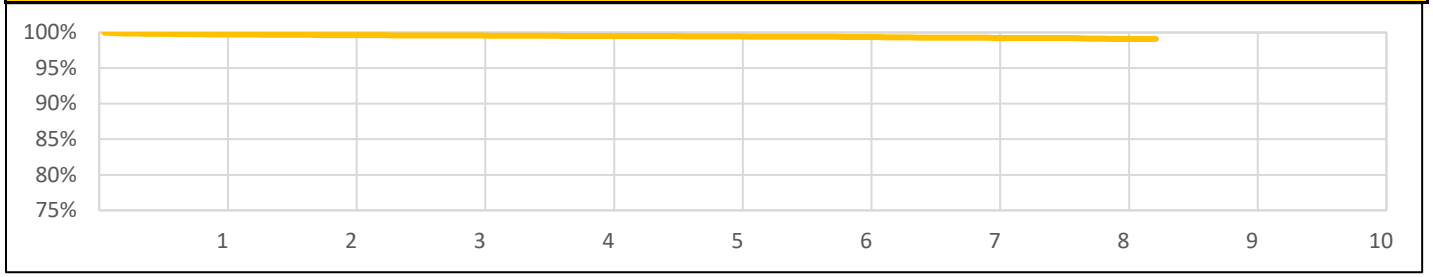
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Summary			
US Registered Implants:	75,000	US Chronic Complications	328
US Approval Date:	November 2010	US Malfunctions:	26
US Estimated Active Implants:	61,000	Without Compromised Therapy:	4
		With Compromised Therapy:	22

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.4%	99.4%	99.2%	99.1%	99.1%	--	
Registered Implants: 75000	Effective Sample Size	64372	52916	42684	33273	24520	16007	7943	1028	241	--	@ 99 months

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

Worldwide Confirmed Malfunctions	**60**
Worldwide Distribution	**122,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	2	0	2
Other			
Non-patterned, other	47	11	58
Grand Total	**49**	**11**	**60**

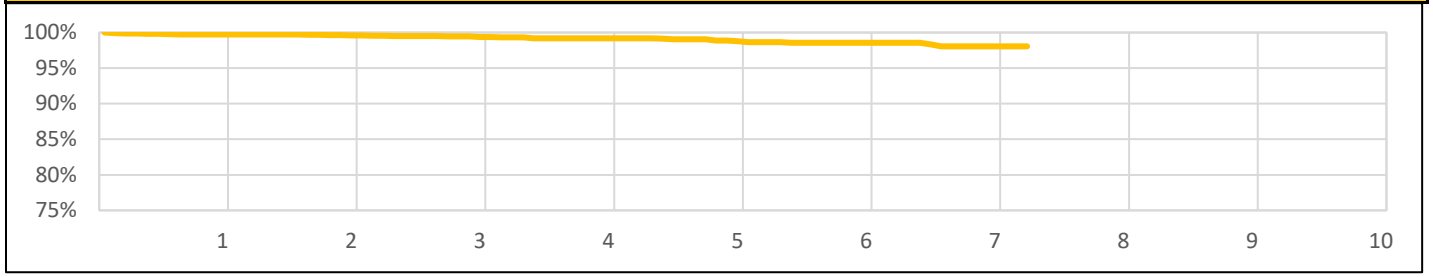
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Summary			
US Registered Implants:	3,000	US Chronic Complications	29
US Approval Date:	Novemeber 2010	US Malfunctions:	-
US Estimated Active Implants:	3,000	Without Compromised Therapy:	-
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.4%	99.2%	98.8%	98.6%	98.1%	98.1%	--	--	
Registered Implants: 3000	Effective Sample Size	2750	2280	1830	1423	1022	591	267	201	--	--	@ 87 months

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**10,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

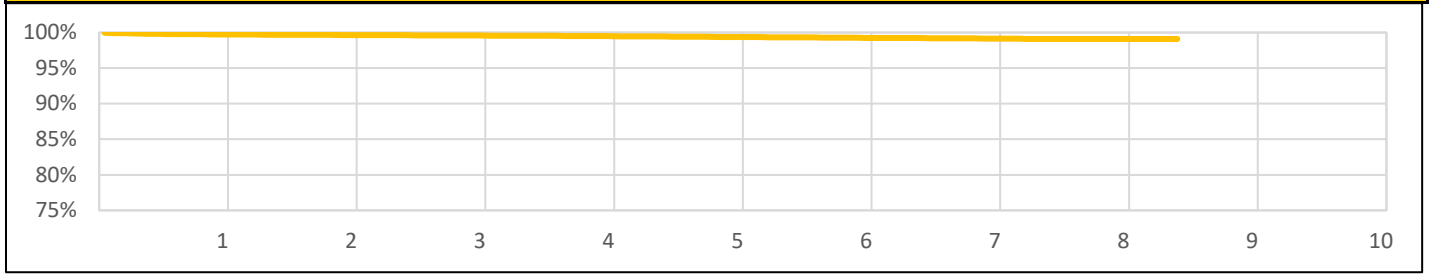
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Summary			
US Registered Implants:	118,000	US Chronic Complications	475
US Approval Date:	November 2010	US Malfunctions:	34
US Estimated Active Implants:	103,000	Without Compromised Therapy:	6
		With Compromised Therapy:	28

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	99.1%	--	
Registered Implants: 118000	Effective Sample Size	101187	73954	50916	33740	20300	10401	4033	665	385	--	@ 101 months

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

Worldwide Confirmed Malfunctions	**67**
Worldwide Distribution	**190,000**

	Without Compromised Therapy	With Compromised Therapy	Total
Conductor			
Conductor fracture (24)	7	0	7
Other			
Non-patterned, other	52	8	60
Grand Total	**59**	**8**	**67**

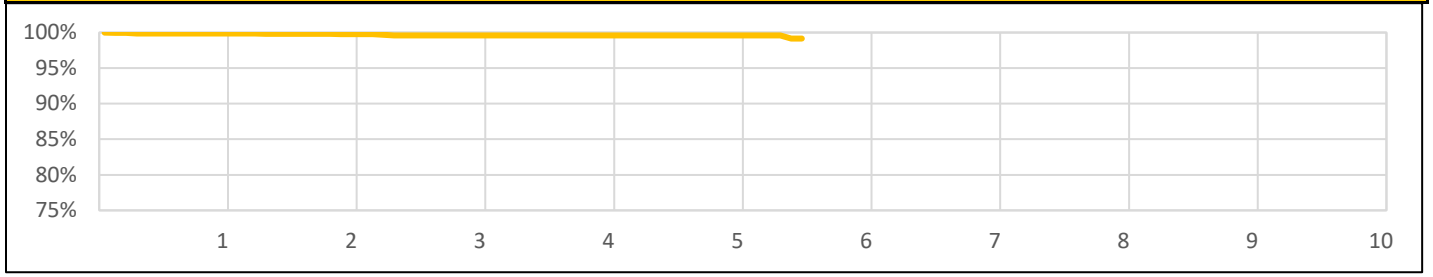
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Summary			
US Registered Implants:	8,000	US Chronic Complications	13
US Approval Date:	November 2010	US Malfunctions:	2
US Estimated Active Implants:	7,000	Without Compromised Therapy:	-
		With Compromised Therapy:	2

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.9%	99.8%	99.6%	99.6%	99.6%	99.2%	--	--	--	--	
Registered Implants: 8000	Effective Sample Size	2583	1420	943	595	310	210	--	--	--	--	@ 66 months

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**6,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	3	1	4
Grand Total	**3**	**1**	**4**

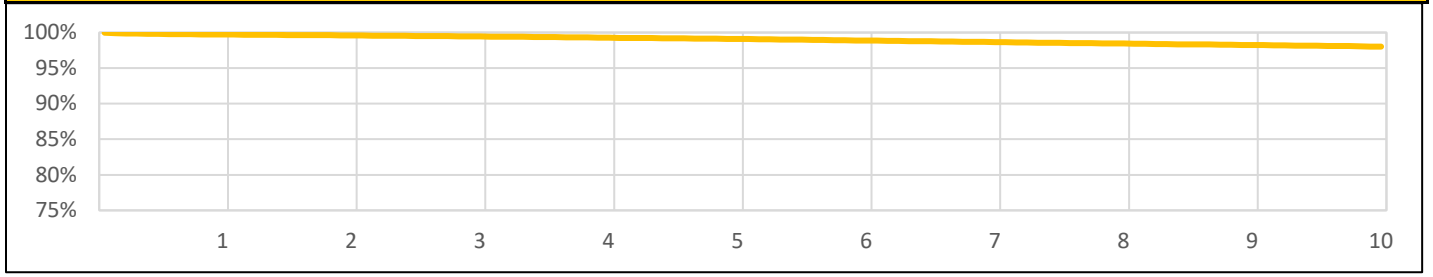
References cited in table above (link)

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

US Summary			
US Registered Implants:	287,000	US Chronic Complications	3,349
US Approval Date:	July 2002	US Malfunctions:	370
US Estimated Active Implants:	117,000	Without Compromised Therapy:	119
		With Compromised Therapy:	251

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.4%	99.3%	99.1%	98.9%	98.6%	98.5%	98.2%	98.0%
Registered Implants: 287000	Effective Sample Size	251927	226001	202899	181928	162688	144947	128418	112777	91467	71505

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**567**
Worldwide Distribution	**380,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	103	0	103
Crimp/Weld/Bond			
Seal rings (5)	2	2	4
Other			
Non-patterned, other	262	198	460
Grand Total	**367**	**200**	**567**

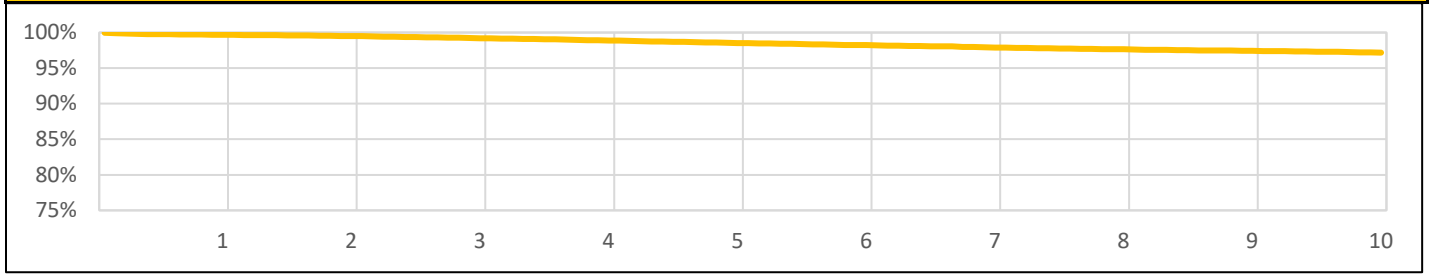
References cited in table above (link)

ENDOTAK RELIANCE Dual Coil, Passive Fixation

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

US Summary			
US Registered Implants:	47,000	US Chronic Complications	866
US Approval Date:	October 2000	US Malfunctions:	59
US Estimated Active Implants:	15,000	Without Compromised Therapy:	13
		With Compromised Therapy:	46

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.9%	98.5%	98.2%	97.9%	97.6%	97.4%	97.2%
Registered Implants: 47000	Effective Sample Size	40550	36387	32642	29212	26086	23275	20663	18186	15698	13377

ENDOTAK RELIANCE Dual Coil, Passive Fixation

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

Worldwide Confirmed Malfunctions	**162**
Worldwide Distribution	**110,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	19	0	19
Crimp/Weld/Bond			
Conductor connection (36)	3	0	3
Other			
Non-patterned, other	86	53	139
Manufacturing material (6)	1	0	1
Grand Total	**109**	**53**	**162**

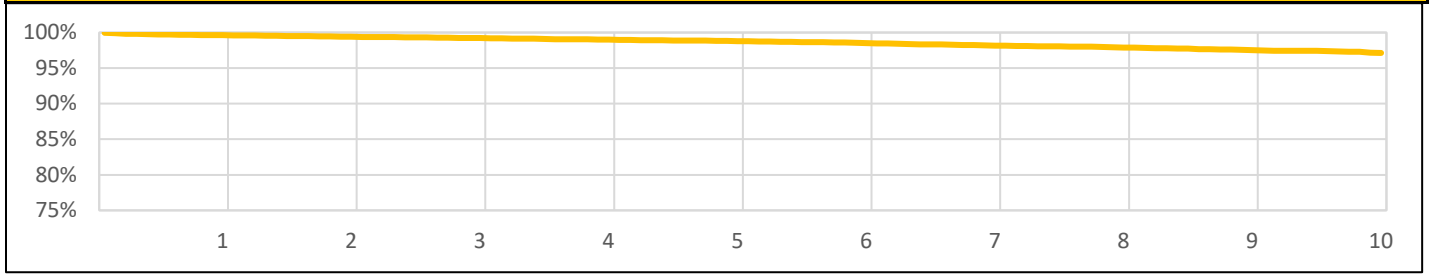
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Active Fixation

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

US Summary			
US Registered Implants:	33,000	US Chronic Complications	400
US Approval Date:	October 2000	US Malfunctions:	81
US Estimated Active Implants:	21,000	Without Compromised Therapy:	22
		With Compromised Therapy:	59

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.4%	99.2%	99.0%	98.8%	98.5%	98.2%	97.9%	97.5%	97.1%
Registered Implants: 33000	Effective Sample Size	28757	25405	22399	19571	16626	13742	11025	8715	5349	3183

ENDOTAK RELIANCE Single Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**197**
Worldwide Distribution	**74,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	62	0	62
Other			
Non-patterned, other	81	54	135
Grand Total	**143**	**54**	**197**

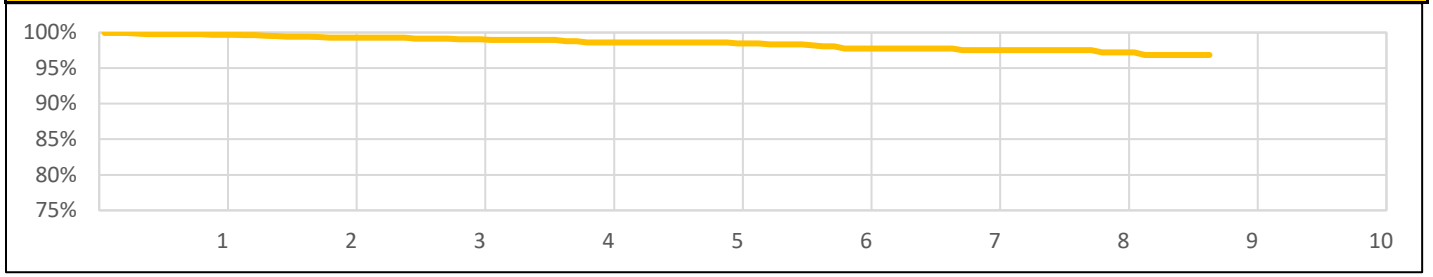
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Passive Fixation

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

US Summary			
US Registered Implants:	2,000	US Chronic Complications	32
US Approval Date:	October 2000	US Malfunctions:	4
US Estimated Active Implants:	1,000	Without Compromised Therapy:	1
		With Compromised Therapy:	3

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.3%	99.0%	98.6%	98.5%	97.7%	97.5%	97.2%	96.8%	--	
Registered Implants: 2000	Effective Sample Size	1539	1356	1188	1003	807	611	427	280	200	--	@ 104 month

ENDOTAK RELIANCE Single Coil, Passive Fixation

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

Worldwide Confirmed Malfunctions	**20**
Worldwide Distribution	**8,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Non-patterned, other	9	8	17
Grand Total	**12**	**8**	**20**

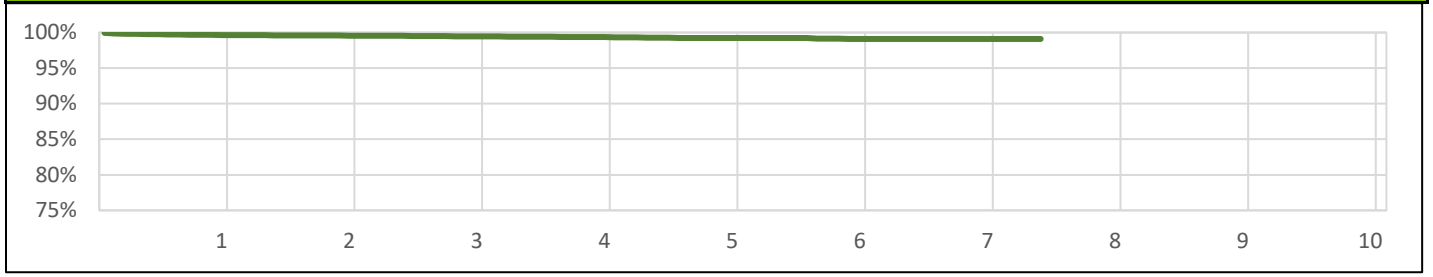
References cited in table above (link)

INGEVITY Positive Fixation

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

US Summary			
US Registered Implants:	355,000	US Chronic Complications	1,213
US Approval Date:	April 2016	US Malfunctions:	148
US Estimated Active Implants:	327,000	Without Compromised Therapy:	72
		With Compromised Therapy:	76

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.5%	99.4%	99.2%	99.1%	99.1%	99.1%	--	--	
Registered Implants: 355000	Effective Sample Size	236425	137764	56671	1848	1726	1472	1174	1181	--	--	@ 89 months

INGEVITY Positive Fixation

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

Worldwide Confirmed Malfunctions	**232**
Worldwide Distribution	**850,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	4	7	11
Extracardiac fracture (41)	63	65	128
Other			
Non-patterned, other	46	47	93
Grand Total	**113**	**119**	**232**

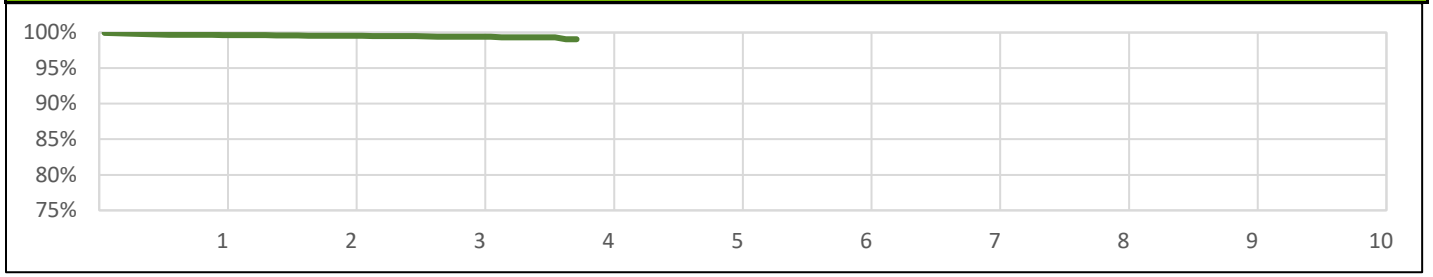
References cited in table above (link)

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	10,000	US Chronic Complications	39
US Approval Date:	April 2016	US Malfunctions:	3
US Estimated Active Implants:	9,000	Without Compromised Therapy:	3
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.5%	99.4%	99.1%	--	--	--	--	--	--	
Registered Implants: 10000	Effective Sample Size	6810	3925	1579	214	--	--	--	--	--	--	@ 45 months

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	**6**
Worldwide Distribution	**75,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	3	3
Crimp/Weld/Bond			
Weld (40)	0	1	1
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**6**	**6**

References cited in table above (link)

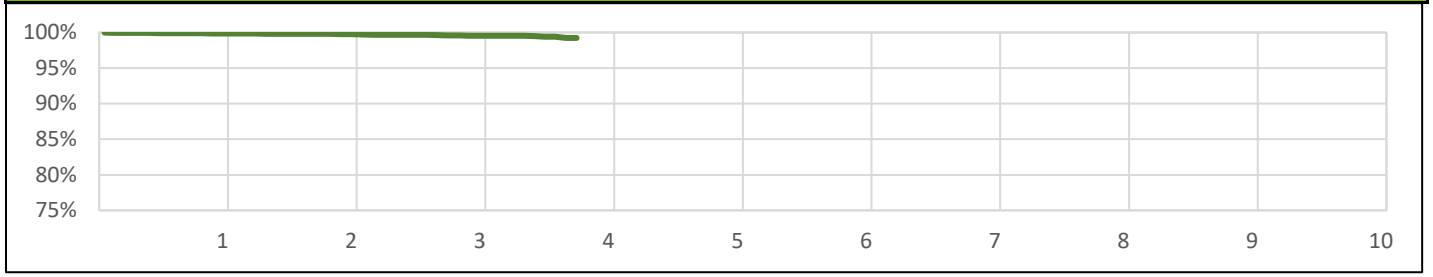
INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary

US Registered Implants:	18,000	US Chronic Complications	37
US Approval Date:	April 2016	US Malfunctions:	6
US Estimated Active Implants:	16,000	Without Compromised Therapy:	-
		With Compromised Therapy:	6

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.8%	99.5%	99.2%	--	--	--	--	--	--	
Registered Implants: 18000	Effective Sample Size	11950	7085	3005	394	--	--	--	--	--	--	@ 45 months

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**89,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	6	0	6
Other			
Non-patterned, other	3	0	3
Grand Total	**9**	**0**	**9**

References cited in table above (link)

FLEXTEND 2 Positive Fixation

Models: 4095/4096/4097

Worldwide Confirmed Malfunctions	**123**
Worldwide Distribution	**185,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	17	5	22
Electrical			
Inner insulation abrasion (2)	2	5	7
Other			
Non-patterned, other	2	9	11
Conductor damage (32)	22	61	83
Grand Total	**43**	**80**	**123**

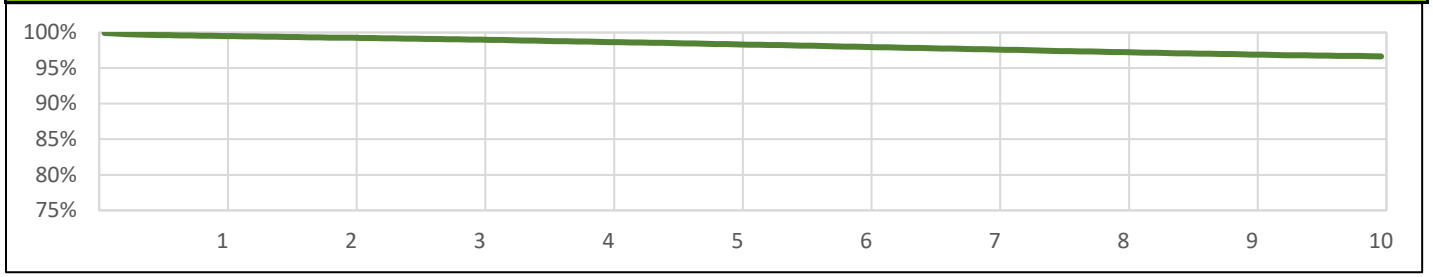
References cited in table above (link)

FLEXTEND Positive Fixation

Models: 4086/4087/4088

US Summary			
US Registered Implants:	235,000	US Chronic Complications	4,637
US Approval Date:	February 2002	US Malfunctions:	367
US Estimated Active Implants:	82,000	Without Compromised Therapy:	147
		With Compromised Therapy:	220

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.5%	99.3%	99.0%	98.7%	98.3%	98.0%	97.6%	97.2%	96.9%	96.6%
Registered Implants: 235000	Effective Sample Size	200486	179514	160678	143034	124881	108392	93259	79633	67289	55866

FLEXTEND Positive Fixation

Models: 4086/4087/4088

Worldwide Confirmed Malfunctions	**397**
Worldwide Distribution	**291,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	88	18	106
Electrical			
Inner insulation abrasion (2)	16	21	37
Other			
Non-patterned, other	11	17	28
Conductor damage (32)	123	103	226
Grand Total	**238**	**159**	**397**

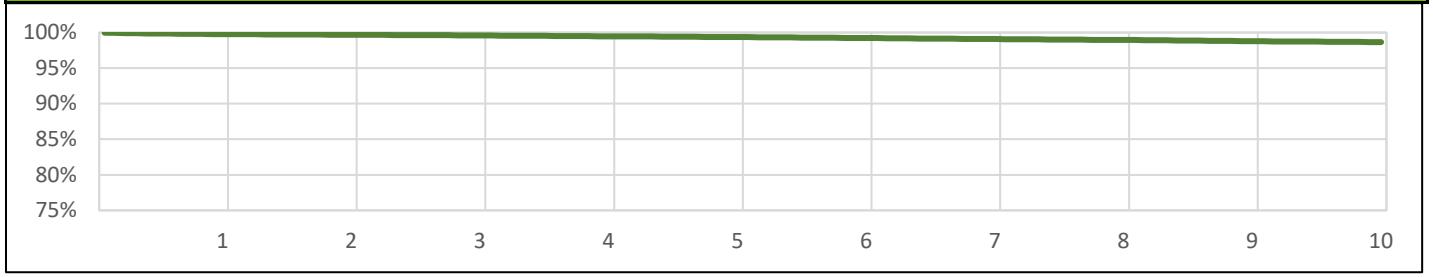
References cited in table above (link)

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

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

US Summary			
US Registered Implants:	490,000	US Chronic Complications	3,552
US Approval Date:	January 2000	US Malfunctions:	160
US Estimated Active Implants:	255,000	Without Compromised Therapy:	43
		With Compromised Therapy:	117

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.4%	99.2%	99.1%	98.9%	98.8%	98.7%
Registered Implants: 490000	Effective Sample Size	422781	369686	323017	281427	237844	198437	163261	132541	105449	81491

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

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

Worldwide Confirmed Malfunctions	**190**
Worldwide Distribution	**769,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	65	16	81
Crimp/Weld/Bond			
Terminal weld (23)	1	0	1
Other			
Lead body (4)	68	26	94
Non-patterned, other	8	6	14
Grand Total	**142**	**48**	**190**

References cited in table above (link)

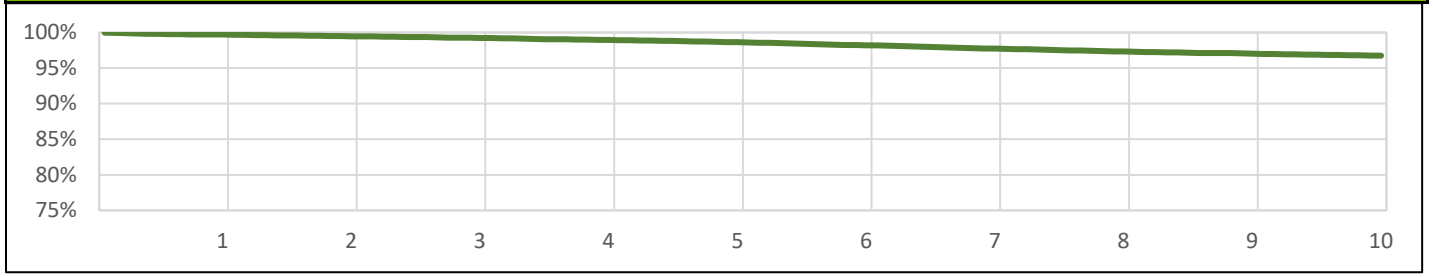
FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)

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

US Summary

US Registered Implants:	52,000	US Chronic Complications	879
US Approval Date:	January 2000	US Malfunctions:	148
US Estimated Active Implants:	22,000	Without Compromised Therapy:	34
		With Compromised Therapy:	114

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.5%	99.2%	98.9%	98.6%	98.2%	97.7%	97.3%	97.0%	96.7%
Registered Implants: 52000	Effective Sample Size	45978	41038	36571	32409	28019	23933	20192	16869	13937	11210

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

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

Worldwide Confirmed Malfunctions	**186**
Worldwide Distribution	**143,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	89	11	100
Other			
Conductor damage (32)	54	22	76
Lead body (4)	0	1	1
Non-patterned, other	3	6	9
Grand Total	**146**	**40**	**186**

References cited in table above (link)

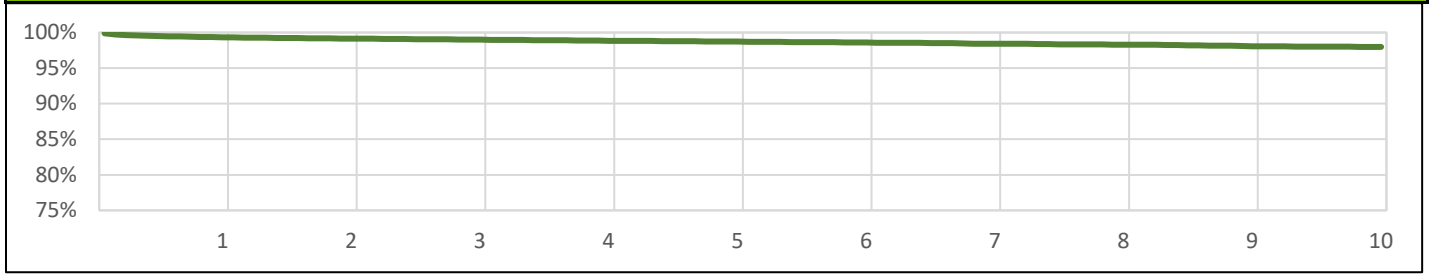
FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary

US Registered Implants:	63,000	US Chronic Complications	824
US Approval Date:	January 2000	US Malfunctions:	38
US Estimated Active Implants:	28,000	Without Compromised Therapy:	19
		With Compromised Therapy:	19

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.3%	99.1%	99.0%	98.8%	98.7%	98.6%	98.4%	98.3%	98.1%	98.0%
Registered Implants: 63000	Effective Sample Size	54440	48606	43249	38216	32653	27525	22861	18788	15238	12064

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	**78**
Worldwide Distribution	**315,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	5	1	6
Other			
J-shape (22)	26	30	56
Lead body (4)	8	3	11
Non-patterned, other	3	2	5
Grand Total	**42**	**36**	**78**

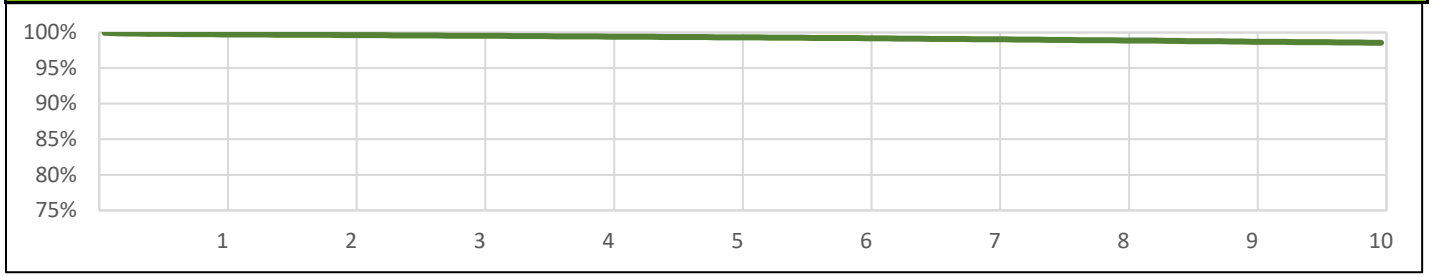
References cited in table above (link)

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

US Summary			
US Registered Implants:	194,000	US Chronic Complications	1,581
US Approval Date:	January 2000	US Malfunctions:	45
US Estimated Active Implants:	80,000	Without Compromised Therapy:	3
		With Compromised Therapy:	42

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.7%	99.6%	99.5%	99.4%	99.3%	99.2%	99.0%	98.9%	98.7%	98.6%
Registered Implants: 194000	Effective Sample Size	166886	148309	131535	115982	99262	83771	69898	57769	47170	37696

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	**68**
Worldwide Distribution	**546,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	18	0	18
Other			
Lead body (4)	41	3	44
Non-patterned, other	5	1	6
Grand Total	**64**	**4**	**68**

References cited in table above (link)

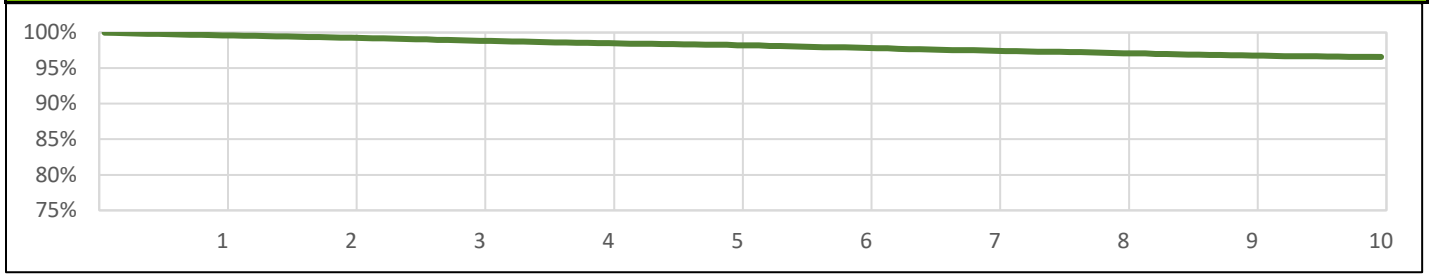
FINELINE II EZ/FINELINE II Sterox Passive Fixation (Silicone)

Models: 4454/4455/4458/4459

US Summary

US Registered Implants:	14,000	US Chronic Complications	299
US Approval Date:	January 2000	US Malfunctions:	23
US Estimated Active Implants:	4,000	Without Compromised Therapy:	-
		With Compromised Therapy:	23

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Depletions and Malfunctions	99.6%	99.3%	98.8%	98.5%	98.2%	97.8%	97.4%	97.1%	96.8%	96.6%
Registered Implants: 14000	Effective Sample Size	12281	10981	9767	8648	7562	6546	5639	4815	4054	3379

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)

Models: 4454/4455/4458/4459

Worldwide Confirmed Malfunctions	**59**
Worldwide Distribution	**105,000**

	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	19	0	19
Other			
Conductor damage (32)	35	3	38
Non-patterned, other	2	0	2
Grand Total	**56**	**3**	**59**

References cited in table above (link)

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. **Lead conductor**— Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing leading to fatigue of lead conductor.
20. **Serial number label**— Loss of sensing, loss of pacing. Broken serial number label due to either sharp bend away from header at implant or repetitive movement during implant.
21. **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.
22. **J-shape**— Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.
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.
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-onlead 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.
40. **Weld -** Out of range impedance measurements, noise, oversensing. Incomplete weld.
41. **Extracardiac fracture**— High impedance, noise, oversensing, loss of capture, loss of pacing. Flex fatigue leading to discontinuity of outer conductor.
42. **Electrode conductor fracture**— High shock impedance, loss of tachy therapy. Fractured electrode conductor.

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.

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	355,000	86	375	449	137	43	17	30	47	0	25
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	10,000	0	10	19	5	0	1	2	2	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	18,000	1	11	8	4	2	1	1	9	0	0
FLEXTEND Active Fixation 4086/4087/4088	235,000	82	1038	1012	988	554	132	220	555	0	54
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	194,000	5	464	242	285	65	34	211	254	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	490,000	21	764	847	490	168	140	583	507	0	30
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	1	123	364	138	26	33	79	53	0	7
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	2	125	19	65	27	4	23	34	0	1
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474	52,000	0	295	96	112	105	23	101	144	0	2

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	12,000	0	0	15	2	1	0	0	0	0	3
ACUITY X4 Spiral S 4674/4675	34,000	1	0	45	2	1	0	0	0	0	10

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	26,000	0	1	71	11	0	0	1	4	0	29
ACUITY Steerable 4554/4555/4556	29,000	3	38	460	63	5	2	17	38	0	95
ACUITY Spiral 4591/4592/4593	24,000	0	22	335	51	0	1	5	11	0	132
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	2	40	312	60	5	2	16	22	0	95
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	1	399	1359	356	10	8	116	163	0	441
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	2	89	488	149	4	1	76	53	0	267

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-FRONT Single Coil Active Fixation 0657/0692/0693	19,000	7	2	17	3	2	1	0	1	2	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0675/0676/0658/0695/0696	3,000	0	1	1	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	75,000	19	46	117	32	45	11	13	20	20	4
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	0	3	8	1	5	0	0	11	0	1
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	123,000	28	56	187	50	61	20	11	25	28	9
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	1	3	1	2	1	0	0	2	1	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	32	717	425	219	823	99	164	419	421	30
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	4	154	75	81	150	13	48	261	73	7
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	33,000	13	88	60	34	74	2	9	46	70	4
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	5	5	3	7	0	1	9	3	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, 3501	38,000	0	4	19	0	119	10	4	0	9

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.

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	355,000	352	419	916	235	75	48	8	51	0	31
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	10,000	0	0	23	3	1	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	18,000	0	0	28	8	0	2	0	0	0	0
FLEXTEND Active Fixation 4086/4087/4088	235,000	170	265	1011	292	46	55	25	92	0	30
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	194,000	9	10	392	101	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4477/4478/4479/4480	63,000	0	10	396	50	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	490,000	54	49	642	143	84	64	28	79	0	26
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459	14,000	0	1	28	9	0	0	3	4	0	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/4473/4474	52,000	2	13	89	13	3	8	6	4	0	3

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	12,000	0	0	22	21	7	0	0	4	0	18
ACUITY X4 Spiral S 4674/4675	34,000	0	1	40	24	6	0	0	17	0	42

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	26,000	1	0	89	15	3	0	0	9	0	43
ACUITY Steerable 4554/4555/4556	29,000	1	1	291	22	13	1	1	21	0	162
ACUITY Spiral 4591/4592/4593	24,000	1	2	172	28	5	0	3	9	0	168
EASYTRAK 3 4522/4524/4525/4527/4548/4549/4550	22,000	0	1	240	23	8	1	3	17	0	128
EASYTRAK 2 4515/4517/4518/4520/4542/4543/4544	97,000	7	4	806	84	30	4	14	63	0	512
EASYTRAK 4510/4511/4512/4513/4535/4536/ 4537/4538	38,000	4	4	168	23	11	1	10	20	0	141

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-FRONT Single Coil Active Fixation 0657/0692/0693	19,000	17	1	39	6	4	0	1	1	1	1
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0675/0676/0658/0695/0696	3,000	1	0	5	3	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	75,000	55	18	249	41	27	3	2	26	6	6
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	2	0	10	1	0	0	0	5	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	123,000	90	19	338	63	47	13	6	30	13	18
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	2	1	6	1	2	1	0	7	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	83	137	510	130	223	12	17	178	108	44
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	47,000	5	4	92	36	41	4	3	47	5	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	33,000	30	7	67	14	19	3	2	18	23	9

ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	2,000	0	0	3	1	2	0	0	1	0	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 3010/3401/3501	38,000	1	0	32	0	309	7	1	0	19

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	30,000	0	0	0	1	0	0	0
ACUITY X4 Spiral S 4674/4675	72,000	0	0	0	4	0	0	0
ACUITY X4 Straight 4671/4672	58,000	0	0	0	0	0	0	0
ACUITY Steerable 4554/4555/4556	65,000	0	0	0	5	0	2	0
ACUITY Spiral 4591/4592/4593	46,000	0	0	0	2	1	0	0

Defibrillation Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0658/0695/0696	18,000	0	0	0	1	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0657/0692/0693	103,000	3	1	0	8	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0655/0685/0686	1,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0654/0682/0683	5,000	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	122,000	0	0	0	84	0	1	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0265/0266/0285/0286	10,000	0	0	0	7	15	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	190,000	0	0	0	45	0	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	6,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	380,000	0	0	92	571	1	3	10
ENDOTAK RELIANCE ; Dual Coil, Passive Fixation 0147/0148/0149/0174/0175/0176/0177	110,000	1	0	20	108	0	3	0
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	74,000	0	0	15	73	0	1	1
ENDOTAK RELIANCE ; Single Coil, Passive Fixation 0127/0128/0170/0171/0172/0173	8,000	0	0	1	6	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, 3501	77,000	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	850,000	2144	0	0	3189	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	75,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	89,000	1	0	1	0	0	0	0
FLEXTEND 2 Active Fixation 4095/4096/4097	185,000	0	0	11	136	1	0	0
FLEXTEND Active Fixation 4086/4087/4088	291,000	0	0	66	636	1	1	4
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457*	546,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	769,000	0	0	6	726	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	315,000	0	0	1	144	6	18	0
FINELINE II/THINLINE II ; Passive Fixation (silicone) 4454/4455/4458/4459*	105,000	0	0	2	2	1	1	0
FINELINE II/THINLINE II EZ ; Positive Fixation (silicone) 4466/4467/4468/4472/5573/4474*	143,000	0	0	0	233	4	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).

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 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 **August 2019 — EMBLEM S-ICD Premature Depletion**
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 **EMBLEM S-ICD** Models A209, A219 EMBLEM Premature Depletion, Physician Letter, August 2019 EMBLEM Premature Depletion, Patient Letter, August 2019	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the performance of approximately 400 active worldwide EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) that may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion. Accelerated depletion can be detected if an unexpected decrease in remaining battery capacity is observed between remote/in-clinic follow-ups. Progression of accelerated depletion eventually produces a battery status replacement indicator (ERI) which is detectable through ambulatory beeping tones, remote monitoring, or in-clinic follow-up. Devices exhibiting this accelerated depletion behavior are capable of providing therapy for a minimum of 21 days after ERI independent of when EOL is initiated. The most common clinical outcome associated with this device behavior is early replacement with a potential for life-threatening harm due to an inability to provide defibrillation therapy. *Estimated Rate of Occurrence* The advisory subset is comprised of approximately 400 active worldwide devices manufactured in July 2017. The advisory subset has a projected rate of accelerated depletion of 19% at 3 years. Because this behavior is detectable through regular follow-up care, the projected potential for life-threatening harm in this subset is approximately 1 in 20,000 at 3 years. The projected potential for life-threatening harm for all other devices (non-advisory) is approximately 1 in 5,000,000 at 3 years. There are no devices within this advisory subset available for implant. Standard Warranty program available, please contact your local representative for terms and conditions. CURRENT STATUS **08-Apr-20** *Estimated Rate of Occurrence* The advisory subset is comprised of approximately 400 active worldwide devices manufactured in July 2017. The advisory subset has an projected rate of accelerated depletion of 20% at 5 years. The observed malfunction rate for the non-advisory population is projected to be 1.6% at 5 years. Because this behavior is detectable through regular follow-up care, the projected potential for life-threatening harm in the advisory subset is approximately 1 in 15,000 at 5 years. The projected potential for life-threatening harm for the non-advisory population is approximately 1 in 200,000 at 5 years. There are no devices within this advisory subset available for implant. Devices built since July 2018 include a low voltage capacitor that is less susceptible to hydrogen induced compromises in electrical performance. CURRENT RECOMMENDATION **08-Apr-20** • Follow-Up. − Enroll and monitor patients in LATITUDE to facilitate prompt detection of ERI/EOL during the interval between in-office device checks. − Perform a device follow-up every 3 months via remote or in-office interrogation. o During the next in-office follow-up visit, demonstrate the beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu; o For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan as strong magnetic fields may cause permanent loss of beeper volume; o Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI/EOL; and − Promptly investigate any suspected indication of accelerated depletion, contact Boston Scientific Technical Services for assistance as needed. − Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of the device. • Evaluate Risk. The potential for life-threatening harm due to accelerated depletion is greatest for patients: − with a history of life-threatening ventricular arrhythmias such as a secondary prevention indication or previous appropriate shock for VT/VF2 . − who are unable to be reliably followed every 3 months (via LATITUDE and/or in-clinic interrogation). − who are not monitored via LATITUDE and are unable to hear beeping tones. • Replace As Needed. − Replace device within 21 days of ERI. − Prophylactically replace devices in high risk patients as indicated by the factors listed above.

PRODUCT	ORIGINAL COMMUNICATION **November 2018 — SQ-RX 1010 Shortened Replacement Time**
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 **S-ICD** Model 1010 SQ-RX 1010 Shortened Replacement Time, Physician Letter, November 2018 SQ-RX 1010 Shortened Replacement Time, Patient Letter, November 2018	Voluntary Physician Advisory FDA Classification: Unclassified This advisory discusses the potential for a shortened replacement interval after a Charge Time (CT) / Battery Depletion (BD) alert has occurred or after the battery status reaches Elective Replacement Indicator (ERI) in the first-generation Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) system's SQ-RX™ Model 1010 Pulse Generator (PG). The SQ-RX Model 1010 PG provides an Elective Replacement Indicator (ERI) as the PG approaches the end of its expected battery service life. When the battery reaches ERI through normal use, there is sufficient capacity to support up to 90 days of continued operation, including up to 6 maximum energy charges/shocks before fully depleting. However, if the PG experiences a latent battery malfunction resulting in accelerated battery depletion, the reserve battery capacity available beyond ERI may not be sufficient to support the full 90-day interval or additional shock therapy before depleting. The rate of depletion for a latent battery malfunctions varies. The SQ-RX model 1010 PGs include separate monitors for charging and battery performance. The Charge Time (CT) alert is designed to detect unsuccessful charging of the high voltage capacitors within 44 seconds. The Battery Depletion (BD) alert is designed to detect higher rates of accelerated battery depletion. When an alert condition occurs, the patient is notified through beeping tones and the clinician user is notified through programmer messages. Most battery malfunctions exhibit a sufficient rate of accelerated depletion to be detected by one of these alerts. Some battery malfunctions exhibit a slower rate of accelerated depletion, which is not detected as an alert condition. Based on an analysis of accelerated battery depletion events where only ERI presented (no alert condition), at least one maximum energy shock has been determined to be available for at least 20 days after ERI. *Estimated Rate of Occurrence* The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years. There have been no reports of injuries or deaths associated with this behavior. Laboratory analysis of returned PGs with latent battery malfunctions has shown some depletions to a level at which therapy would not have been available if not replaced in accordance with the recommendations above. Based on a 3-month follow-up interval, the potential for life threatening harm for this behavior is 0.006% (1 in 16,667) at 5 years. However, the potential for life-threatening harm is greater for secondary prevention patients or those who have received appropriate therapy previously, patients with longer follow-up intervals, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **08-Apr-20**
	Estimated Rate of Occurrence The projected occurrence rate for latent battery malfunctions for SQ-RX Model 1010 PGs is up to 2% at 5 years. There have been no reports of injuries or deaths associated with this behavior.
	CURRENT RECOMMENDATION **08-Apr-20**
	• Follow-Up. Consistent with the SQ-RX Model 1010 PG User Manual: - Perform in-clinic checks every 3 months as the PG is not capable of remote patient management; - If it has been more than 3 months since a patient's last in-clinic follow-up, schedule a follow-up within the next month and every 3 months thereafter; - During the next follow-up visit, demonstrate the beeper by applying a magnet over the PG to elicit beeping tones; and - Remind patients to promptly contact their physician if beeping tones are heard from their PG as this may be an indication of a CT / BD alert or ERI. - Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of their PG • Evaluate Risk. The potential for life-threatening harm is greater for patients who have experienced life-threatening ventricular arrhythmias, patients not followed every 3 months, and/or patients who are unable to hear beeping tones. For these patients, the benefit associated with prophylactically replacing the PG may outweigh the risks associated with a shortened replacement interval due to latent battery malfunction • CT / BD Alerts. Promptly investigate any beeping tones, CT alerts, or BD alerts and report them to Boston Scientific Technical Services. Using saved PG data, Technical Services can determine if an accelerated battery depletion exists and provide guidance for replacement. • ERI. To mitigate the rare potential for undetected accelerated battery depletion, replace SQ-RX Model 1010 PGs within 20 days of ERI. If a longer replacement interval is desired, save PG data and contact Technical Service to determine a recommended replacement interval. Note: CT / BD Alerts appearing before or after ERI should always be reported to Technical Services for evaluation

PRODUCT

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

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

ACCOLADE Pacemaker
Models L300, L301, L310, L311, L321, L331

PROPONENT Pacemaker
Models L200, L201, L209, L210, L211, L221, L231

ESSENTIO Pacemaker
Models L100, L101, L110, L111, L121, L131

Hydrogen Induced Premature Depletion, Physician Letter, September 2018

Hydrogen Induced Premature Depletion, Patient Letter, September 2018

ORIGINAL COMMUNICATION **September 2018 — Hydrogen Induced Premature Depletion**

Voluntary Physician Advisory
FDA Classification: Unclassified

This advisory discusses a subset of 2900 pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) with an elevated potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion.

The pacemaker manual describes how increases in pacing requirements or changes in programmed parameters may result in an expected longevity reduction and are considered normal battery depletion. However, hydrogen exposure within the pacemaker's circuitry may compromise the electrical performance of low voltage capacitors causing current leakage and a moderate acceleration in the rate of battery depletion.

Because this accelerated depletion does not occur rapidly, a follow-up interval of no more than six months is recommended. Boston Scientific has determined a liner component to be the source of hydrogen and identified a subset of 2900 previously distributed pacemakers that have an elevated potential for exhibiting this behavior. Boston Scientific pacemakers include automated diagnostic tools, including battery status assessment and estimated longevity predictions, that dynamically adjust based on power consumption. It is important to emphasize that the accuracy of battery status and longevity estimates are not affected by this behavior.

Estimated Rate of Occurrence
The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is 1.4% at 2.5 years which is 233 times higher than the non-advisory population. Because this behavior is highly detectable through regular pacemaker follow-up care, the projected potential for life-threatening harm is 0.0003% (1 in 333,333) at 5 years. There are no devices within this advisory subset that are still available for implant.

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

CURRENT STATUS **08-Apr-20**

Estimated Rate of Occurrence
The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is projected to be 10% at 5 years. The observed malfunction rate for the non-advisory population is projected to be 1.5% at 5 years.

Over 90% of confirmed malfunctions within the advisory and non-advisory populations were detected before the battery status indicated elective replacement (e.g., Battery Status = Explant). Based on the rate of battery depletion, devices would have been able to support device therapy for approximately 100 days after the battery status indicated Explant.

Because this behavior is highly detectable through regular pacemaker follow-up care, the projected potential for life-threatening harm is 0.0002% (1 in 500,000) at 5 years in the advisory population and is 0.00002% (1 in 5,000,000) at 5 years in the non-advisory population. There are no devices within this advisory subset that are still available for implant.

Approximately 116,000 devices were built with the original low voltage capacitor. All devices built since November 2017 include a low voltage capacitor that is less susceptible to hydrogen induced compromises in electrical performance. A polymer material, designed to remove excess hydrogen within the pulse generator, was added to this device family in March 2018 and is intended to mitigate hydrogen induced accelerated depletion of the low voltage capacitors. To date there have been no confirmed occurrences of hydrogen induced accelerated battery depletion in the ACCOLADE family of devices that include the contemporary low voltage capacitor and this polymer material.

CURRENT RECOMMENDATION **08-Apr-20**

• Boston Scientific recommends following patients implanted with any affected pacemaker from the advisory subset at intervals no greater than every six (6) months either in-clinic or via LATITUDE in accordance with the best practices outlined in international societal guidelines
• Promptly investigate any suspected indication of accelerated depletion. Before surgical intervention, contact Boston Scientific Technical Services for verification of accelerated depletion and to determine an appropriate timeframe for pacemaker replacement. Please note, if accelerated depletion is identified, the Save to Disk feature or LATITUDE is necessary to perform an engineering assessment.
• Prophylactic replacement is NOT recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated depletion.

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

ACCOLADE Pacemaker
Models L300, L301, L310, L311, L321, L331

PROPONENT Pacemaker
Models L200, L201, L209, L210, L211, L221, L231

ESSENTIO Pacemaker
Models L100, L101, L110, L111, L121, L131

ALTRUA 2 Pacemaker
Models S701, S702, S722

Minute Ventialtion Signal Oversensing, Physician Letter,

Minute Ventialtion Signal Oversensing, Patient Letter, December 2017

Minute Ventialtion Signal Oversensing, Update letter, January 2019

ORIGINAL COMMUNICATION **December 2017 — Minute Ventilation Signal Oversensing**

Voluntary Physician Advisory

This advisory discusses intermittent oversensing of the Minute Ventilation (MV) sensor signal with certain Boston Scientific pacemaker and cardiac resynchronization therapy pacemaker systems (pacemakers). MV sensor signal oversensing may cause pre-syncope or syncope due to periods of pacing inhibition. This MV behavior may occur with any manufacturer's pacing lead system, but Boston Scientific has determined it to be more likely for affected Boston Scientific pacemakers using Medtronic or Abbott/St. Jude (Abbott) leads implanted in either the right atrium (RA) or right ventricle (RV).

The MV sensor in Boston Scientific pacemakers can be used for RightRate™ (rate adaptive pacing), Respiratory Rate Trend, or AP Scan. When the RA/RV pacing leads and lead terminal connections are operating as intended, the MV sensor signal is appropriately filtered and therefore is not detected by the pacemaker or displayed on electrograms (EGMs). However, intermittency related to the lead or pacemaker-lead connection has the potential to create a transient high impedance condition. A high impedance condition may subsequently alter the MV sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels. For a technical description of the Boston Scientific's MV sensor, please refer to Appendix A in the December 2017 physician letter.

Engineering analysis and testing, as well as evaluation of post-market surveillance data, demonstrates an elevated potential for oversensing of the MV sensor signal in certain pacemaker systems connected to Medtronic or Abbott pacing leads. Although all leads evaluated in simulated testing environments comply with appropriate connector standards, we have discovered subtle differences amongst lead manufacturers in the surface finish of the lead terminal ring and amount of axial and radial terminal ring motion within the pacemaker header. These factors may result in intermittent increases in impedance leading to oversensing of the MV sensor signal or changes in daily impedance test measurements.

Estimated Rate of Occurrence

Boston Scientific investigation has shown that the probability of harm associated with MV sensor signal oversensing behavior is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

Affected pacemaker systems connected to the following RA/RV pacing leads[4]:	Probability of Injury at 5 years	Probability of Life Threatening Harm at 5 years
Medtronic or Abbott pacing leads	0.0005 (1 in 2,000)	0.00001 (1 in 100,000)
Boston Scientific pacing leads (including DEXTRUS)	0.00003 (1 in 33,333)	0.0000008 (1 in 1,250,000)
All pacing leads combined[5]	0.00008 (1 in 12,500)	0.000002 (1 in 500,000)

CURRENT STATUS **08-Apr-20**

Estimated Rate of Occurrence

Boston Scientific investigation has shown that the probability of harm associated with MV sensor signal oversensing behavior is significantly greater when affected pacemakers are connected to Medtronic or Abbott pacing leads.

Affected pacemaker systems connected to the following RA/RV pacing leads[4]:	Probability of Injury at 5 years	Probability of Life Threatening Harm at 5 years
Medtronic or Abbott pacing leads	0.0005 (1 in 2,000)	0.00001 (1 in 100,000)
Boston Scientific pacing leads (including DEXTRUS)	0.00003 (1 in 33,333)	0.0000008 (1 in 1,250,000)
All pacing leads combined[5]	0.00008 (1 in 12,500)	0.000002 (1 in 500,000)

CURRENT RECOMMENDATION **08-Apr-20**

Software is available in most countries to address the potential for pacing inhibition due to MV sensor signal oversensing in affected pacemakers. The software adds the Signal Artifact Monitor (SAM) to Boston Scientific's proprietary suite of Safety Architecture diagnostics. When enabled, the SAM continuously monitors electrograms for MV sensor signal artifacts and measures MV vector lead impedance values. If artifacts are detected or the MV vector lead impedance is out of range, the monitor either switches to the right ventricular vector or disables the MV sensor in approximately one second. In this manner, the SAM promptly eliminates the clinical risk of pacing inhibition associated with MV sensor signal oversensing.

Programmer	Software Model	Software Version
Model 3120 ZOOM Programmer	2869	2.06
Model 3300 LATITUDE Programmer	3869	1.05

If software is not available in your country, continue to follow advisory recommendations.

PRODUCT

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

VALITUDE CRT-P
Models U125, U128

VISIONIST CRT-P
Models U225, U226, U228

RESONATE CRT-D
Models G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548

VIGILANT CRT-D
Models G224, G225, G228, G237, G247, G248

MOMENTUM CRT-D
Models G124, G125, G126, G128, G138

CHARISMA CRT-D
Models G324, G325, G328, G337, G347, G348

AUTOGEN CRT-D
Models G172, G173, G175, G177, G179

DYNAGEN CRT-D
Models G150, G151, G156, G158

INOGEN CRT-D
Models G140, G141, G146, G148

ORIGEN CRT-D
Models G050, G051, G056, G058

CRT Positive LV Offset and TPP Interaction, Physician Letter, Dec 2017

CRT Positive LV Offset and TPP Interaction, Patient Letter, December 2017

CRT Positive LV Offset and TPP Interaction, Update Letter, January 2019

ORIGINAL COMMUNICATION **December 2017 — CRT Positive LV Offset and TPP Interaction**

Voluntary Physician Advisory
FDA Classification: Unclassified

This advisory discusses unintended asynchronous biventricular (BiV) pacing behavior when tracking elevated atrial intrinsic rhythms in certain Boston Scientific Cardiac Resynchronization Therapy (CRT) pacemakers (CRT-Ps) and defibrillators (CRT-Ds). Repeated detection of this unintended asynchronous BiV pacing behavior may result in the implanted device reverting to a permanent Safety Mode (Safety Core™) status thus requiring early replacement. The unintended asynchronous BiV pacing behavior can only occur when an infrequent combination of parameters are programmed, specifically:

• Left Ventricular (LV) Offset programmed to a positive value which exceeds the Atrial Blank after Ventricular Pace (A-Blank after V-Pace) interval; and
• Tracking Preference = ON (nominal).

Observed Rate
Of the 60,500 CRT devices distributed worldwide, Boston Scientific estimates approximately 300 CRT devices are programmed with the combination of parameters which may lead to this device behavior. There have been two confirmed instances of early device replacement due to this device behavior (0.7%). Of the two cases, a single patient death occurred due to complications related to the replacement procedure.

CURRENT STATUS **08-Apr-20**

Confirmed Malfunctions (worldwide)
There have been four confirmed instances of early device replacement due to this device behavior.

CURRENT RECOMMENDATION **09-Oct-19**

Software is available in most countries to addresses the rare potential for early replacement due to permanent Safety Mode status. The software imposes an interactive limit which prevents programming the device into a susceptible manner. Affected devices interrogated by an updated programmer are no longer susceptible to this issue.

Programmer	Device Therapy	Software Model	Software Version
Model 3120 ZOOM Programmer	CRT-Ps	2869	2.06
Model 3300 LATITUDE Programmer	CRT-Ps	3869	1.05
Model 3120 ZOOM Programmer	CRT-Ds	2868	4.07
Model 3300 LATITUDE Programmer	CRT-Ds	3868	1.07

If software is not available in your country, continue to follow advisory recommendations.

PRODUCT	ORIGINAL COMMUNICATION **Aug 2013 and Sep 2014 — 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	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. It also informed physicians how to identify and respond to a Safety Architecture low voltage alert. In September 2014, a second subset of devices was identified that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset. The second communication also discussed improvements to Safety Architecture's low voltage alert, which were released through a programmer software update.
COGNIS Models N106/N107/N108/N118/ N119/N120/P106/P107/P108 **TELIGEN VR** Models E102/E103/F102/F103 **TELIGEN DR** Models E110/E111/F110/F111	The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping. The most common alert is a yellow programmer screen that states, "Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003". LATITUDE issues a corresponding yellow alert (nominally configured "On"). In other instances, diminished LV capacitor performance can result in an early "Explant" battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.
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	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 **08-Apr-20**

Advisory devices have not been available for implant for more than seven years.

Projected Rate of Occurrence

• COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.9% at 60 months, 6.0% at 72 months, 8.9% at 84 months and 11.2% at 96 months. The potential for life-threatening harm from loss of therapy is approximately 1 in 200,000 (0.0005%) at 60 months.

• COGNIS CRT-D and TELIGEN ICD populations (advisory and non-advisory) - The overall rate of occurrence is approximately 1.1% at 60 months, 2.5% at 72 months and 3.7% at 84 months. The projected rate of occurrence is 5.0% at 96 months. Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy has decreased to approximately 1.6%. The potential for life-threatening harm from loss of therapy is approximately 1 in 500,000 (0.0002%) at 60 months.

• INCEPTA, ENERGEN and PUNCTUA CRT-Ds and ICDs - The rate of occurrence is 1% at 60 months. The projected rate of occurrence is 1.8% at 72 months. The portion of malfunctions with compromised therapy is approximately 0.3%. The potential for life-threatening harm from loss of therapy is approximately 1 in 5,000,000 (0.00002%) at 60 months.

CURRENT RECOMMENDATION **08-Apr-20**

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.

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

PRODUCT	ORIGINAL COMMUNICATION **01-Dec-09 — Subpectoral Implant**
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 **08-Apr-20**
	Reported events (worldwide) 102 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.
	CURRENT RECOMMENDATION **08-Apr-20**
	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.
	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	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.
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	CURRENT STATUS **08-Apr-20**
INSIGNIA Plus SR Models 1194/1394	*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%.
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	CURRENT RECOMMENDATION **08-Apr-20** 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 when making 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** – 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 Standard Warranty program available, please contact your local representative for terms and conditions.
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	
VENTAK PRIZM 2 VR/DR Models 1860/1861	
Low Voltage Capacitor, Physician	
Low Voltage Capacitor, Patient Letter,	
Low Voltage Capacitor, Physician Letter, Jun 23, 2006	

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 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, Modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.
	CURRENT STATUS **08-Apr-20**
	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. *Projected Rate of Occurrence* Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 3,000 is projected to range between 0.027% and 0.038%.
	CURRENT RECOMMENDATION **08-Apr-20**
Crystal Timing Component, Physician Letter, Dec 12, 2005 Crystal Timing Component, Patient Letter, Oct 03, 2005 Crystal Timing Component, Physician Letter, Sep 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.

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