Boston Scientific
Advancing science for life™

2026

Rhythm Management Product Performance Report

Second Edition

RESONATE™
Family of ICDs AND CRT-Ds

ACCOLADE™
Family of Pacemakers

INGEVITY™ +
Pacing 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 2026 Second Edition report includes data through July 14th, 2026.

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,

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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 both the U.S. Registered Implant population and for leads enrolled in the Longitude Surveillance Registry, 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 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. Performance data for Intermedics products may also be found on www.bostonscientific.com/ppr. Specific inclusion criteria for pulse generator and lead survival probability datasets are described here. Not all products may be approved for use in all geographies, as product approval is geography specific.

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

To convey implant experience for a product family, 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, manufacturing and supplier process modifications, software updates, educational communications, or labeling changes to preceding, existing, or subsequent generations. 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. Intermedics co-branded product data are included in corresponding pacemaker and pacing lead malfunction counts and details. Information presented is based on malfunctions reported to and analyzed by Boston Scientific. Each table contains malfunction counts listed by category, pattern and therapy availability.

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

Patterns
Patients and physicians have asked for more access to Quality System details; therefore, we provide information on patterns of product performance. Patterns listed are informational and do not represent actions that need to be taken. Boston Scientific is committed to direct communication when predicted product performance fails to achieve design or performance expectations or when actions may be taken to improve patient outcomes. Malfunctions associated with product advisories are denoted. Refer to the Product Advisories section for more information. In cases where more than one malfunction pattern could be applied to a device, a single malfunction pattern is reported, with priority given to patterns associated with an advisory, patterns associated with an existing investigation, and malfunctions that resulted in compromised therapy.

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 report to report; 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.

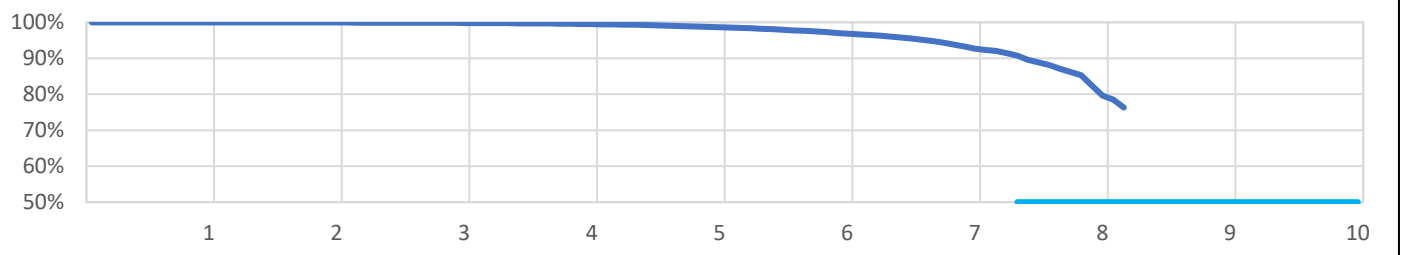
RESONATE/MOMENTUM/CHARISMA/VIGILANT CRT-D

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

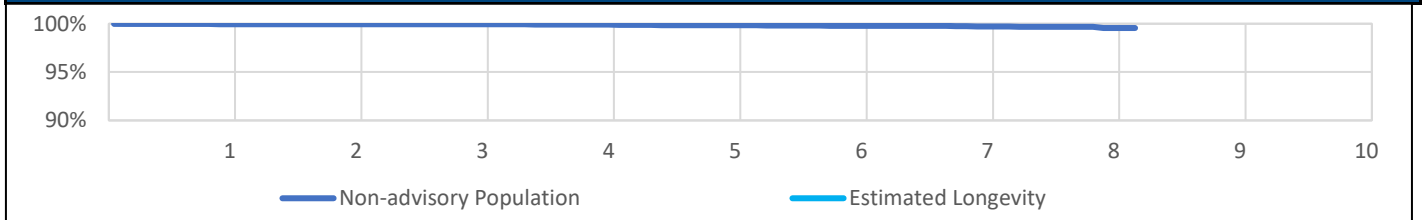
US Summary

US Registered Implants:	123,000	US Normal Battery Depletions:	1,227
US Approval Date:	September 2017	US Malfunctions:	104
US Estimated Active Implants:	109,000	Without Compromised Therapy:	82
		With Compromised Therapy:	22

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%	98.7%	97.1%	93.3%	82.4%	76.3%	--	
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	--	
123,000	Effective Sample Size	93963	70762	51219	35060	22342	12315	5178	804	209	--	@ 99 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	**188**
Worldwide Distribution	**210,000**

US Approval Date: September 2017	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
Integrated circuit (63)	12	24	36
Low-voltage capacitor (69)	0	20	20
Battery (53)	4	45	49
High voltage capacitor (75)	4	0	4
Software			
Memory errors (51)	3	35	38
Other			
Non-patterned, other	12	29	41
Grand Total	**35**	**153**	**188**

References cited in table above (link)

AUTOGEN CRT-D

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

Worldwide Confirmed Malfunctions	**51**
Worldwide Distribution	**25,000**

US Approval Date: April 2014	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	7	7
Battery (53)	3	17	20
High voltage capacitor (75)	1	0	1
Software			
Safety Core-unintended biventricular pacing (64)	0	1	1
Memory errors (51)	0	1	1
Other			
Non-patterned, other	1	7	8
Grand Total	**7**	**44**	**51**

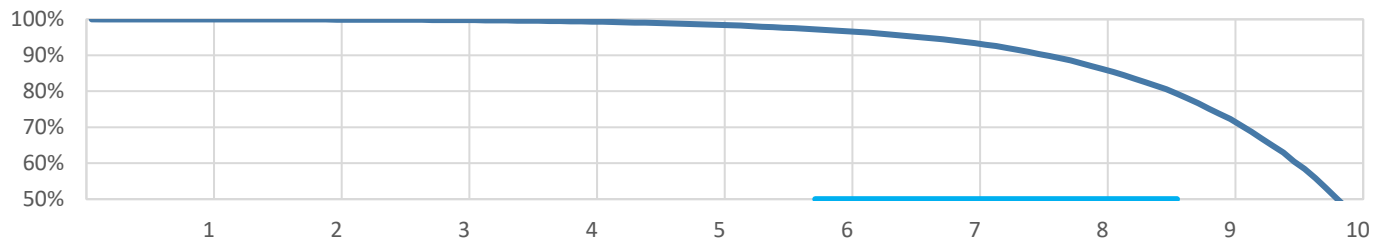
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN CRT-D

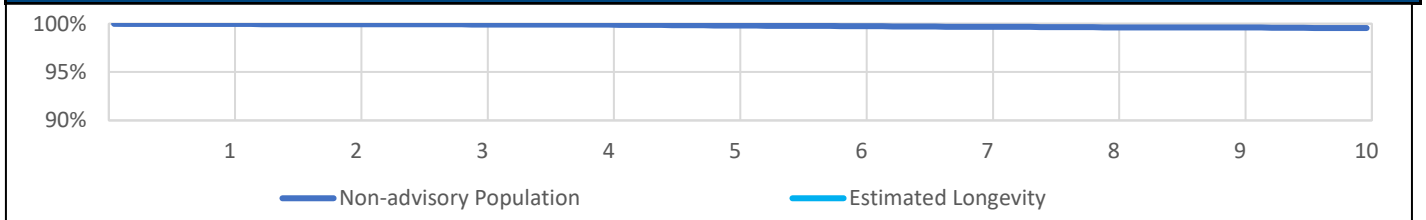
Models: G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158

US Summary			
US Registered Implants:	78,000	US Normal Battery Depletions:	9,191
US Approval Date:	April 2014	US Malfunctions:	156
US Estimated Active Implants:	49,000	Without Compromised Therapy:	141
		With Compromised Therapy:	15

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%	98.5%	96.9%	93.7%	87.0%	73.7%	47.5%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.6%	99.6%	99.6%
78,000	Effective Sample Size	67748	59890	52735	46034	39376	32625	25724	17847	9643	2843

DYNAGEN/INOGEN/ORIGEN CRT-D

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

Worldwide Confirmed Malfunctions	**218**
Worldwide Distribution	**148,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	19	19
Integrated circuit (63)	4	12	16
Low-voltage capacitor (69)	1	37	38
High voltage capacitor (75)	5	1	6
Battery (53)	2	56	58
Low-voltage capacitors (47)	0	1	1
Software			
Memory errors (51)	2	37	39
Safety Core-unintended biventricular pacing (64)	0	3	3
Other			
Non-patterned, other	16	22	38
Grand Total	**30**	**188**	**218**

References cited in table above (link)

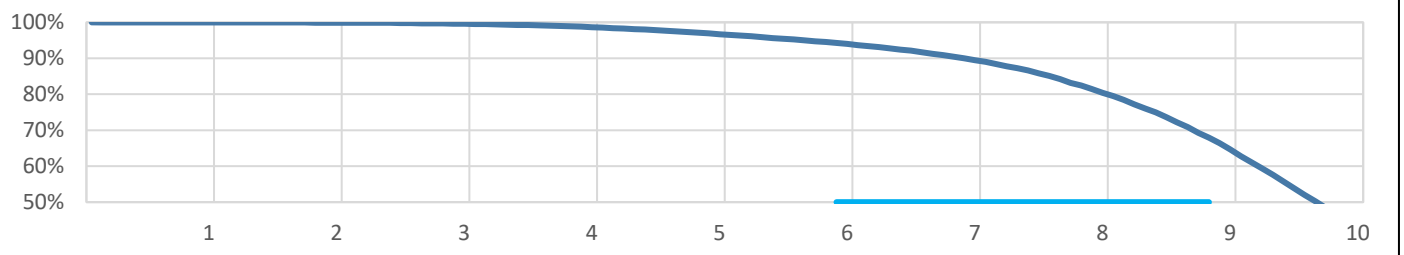
INCEPTA/ENERGEN/PUNCTUA CRT-D

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

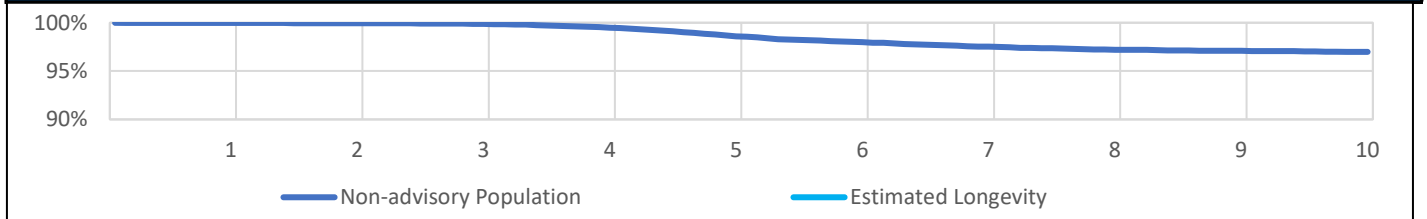
US Summary

US Registered Implants:	53,000	US Normal Battery Depletions:	13,231
US Approval Date:	November 2011	US Malfunctions:	815
US Estimated Active Implants:	16,000	Without Compromised Therapy:	791
		With Compromised Therapy:	24

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%	90.0%	81.5%	66.4%	44.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.5%	98.7%	98.0%	97.5%	97.2%	97.1%	97.0%
53,000	Effective Sample Size	46244	41394	36928	32774	28713	24894	21200	17110	12411	7321

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	**1,302**
Worldwide Distribution	**81,000**

US Approval Date: November 2011	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Safety Core-electrocautery (42)	1	6	7
High-voltage capacitor (43)	5	0	5
Low-voltage capacitors (47)	0	1	1
Integrated circuit (50)	7	2	9
Battery (53)	2	11	13
Low-voltage capacitor (54)	8	1206	1214
Low-voltage capacitor (69)	0	12	12
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	8	18	26
Grand Total	**37**	**1265**	**1302**

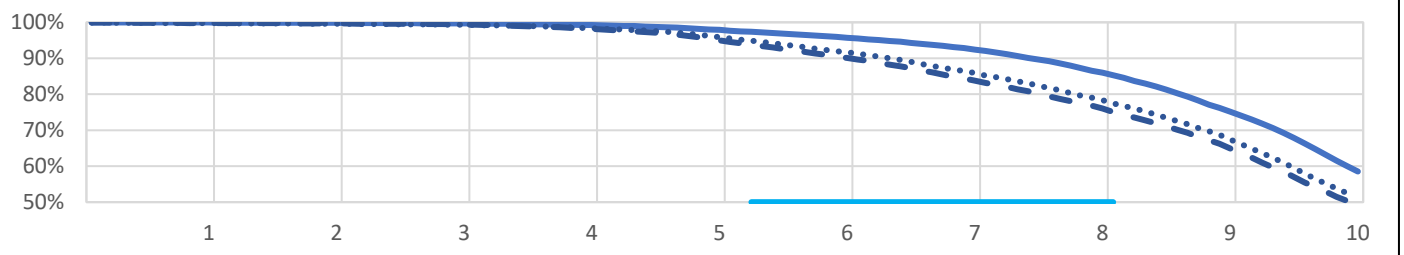
References cited in table above (link)

COGNIS CRT-D

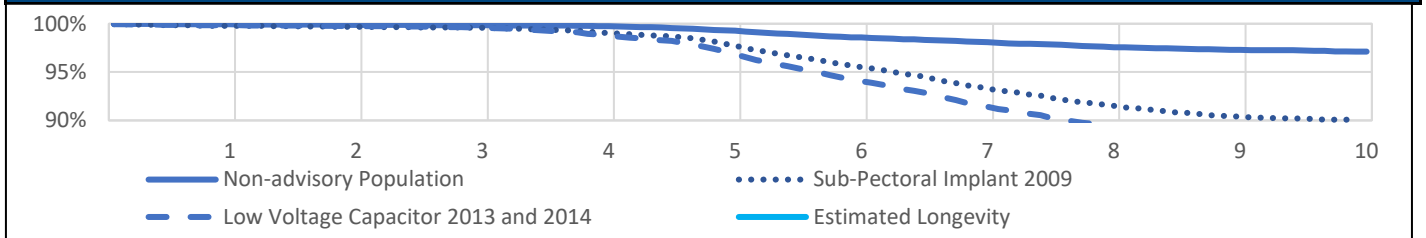
Models: N106/N107/N108/N118/N119/N120/P106/P107/P108

US Summary			
US Registered Implants:	75,000	US Normal Battery Depletions:	16,001
US Approval Date:	March 2008	US Malfunctions:	2,099
US Estimated Active Implants:	14,000	Without Compromised Therapy:	1,906
		With Compromised Therapy:	193

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%	98.0%	95.9%	92.8%	86.6%	76.2%	60.1%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.3%	98.6%	98.1%	97.6%	97.3%	97.1%
36,000	Effective Sample Size	31128	27909	24974	22256	19707	17230	14853	12336	9633	6708

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	Depletions and Malfunctions	99.8%	99.6%	99.3%	98.5%	96.2%	92.0%	86.4%	79.1%	68.7%	52.5%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.6%	99.1%	97.9%	95.7%	93.5%	91.6%	90.4%	90.1%
32,000	Effective Sample Size	26753	23644	21073	18677	16277	13846	11567	9375	7217	4854
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.4%	98.3%	95.4%	90.5%	84.4%	76.8%	66.2%	50.3%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.6%	98.9%	97.1%	94.2%	91.7%	89.5%	88.1%	87.8%
26,000	Effective Sample Size	22077	19559	17471	15442	13411	11304	9355	7537	5757	3829

*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	2,963
Worldwide Distribution	109,000

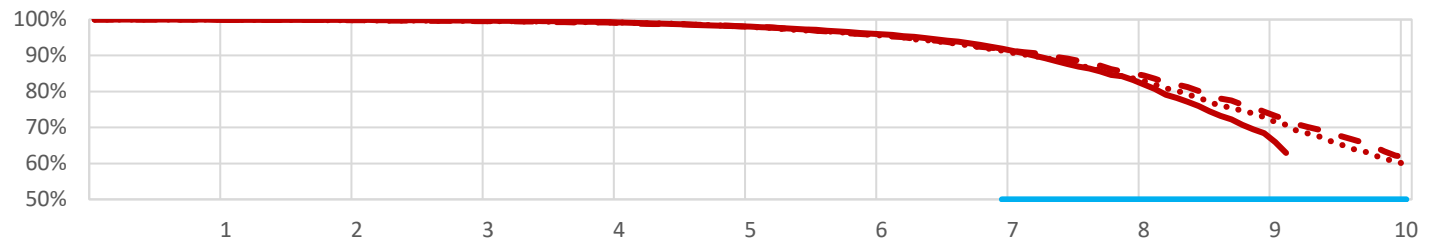
US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	83	1617	1700
Safety Core-electrocautery (42)	25	54	79
High-voltage capacitor (43)	6	1	7
Low-voltage capacitors (47)	0	7	7
Integrated circuit (50)	21	8	29
High voltage circuit (52)	1	0	1
Battery (53)	10	51	61
Low-voltage capacitor (54)	12	851	863
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)	49	20	69
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	11	37	48
Grand Total	**270**	**2693**	**2963**

VISIONIST/VALITUDE

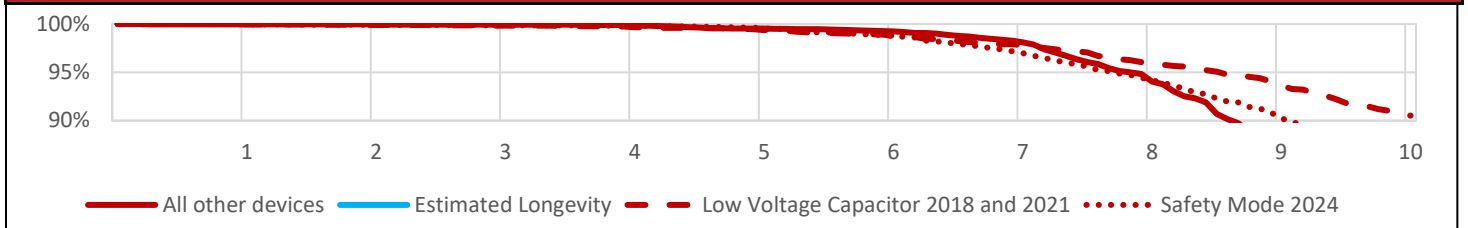
Models: U125/U128/U225/U226/U228

US Summary			
US Registered Implants:	73,000	US Normal Battery Depletions:	2,164
US Approval Date:	October 2014	US Malfunctions:	770
US Estimated Active Implants:	56,000	Without Compromised Therapy:	727
		With Compromised Therapy:	43

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
All other devices	Depletions and Malfunctions	99.9%	99.9%	99.7%	99.3%	98.1%	96.1%	91.9%	83.2%	68.4%	62.9%	
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.5%	99.3%	98.3%	94.8%	88.3%	87.0%	
48,000	Effective Sample Size	47115	35530	26534	19202	12973	8121	4416	1657	399	238	@ 110 months

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

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018 and 2021	Depletions and Malfunctions	100.0%	99.8%	99.6%	99.2%	98.1%	95.8%	91.8%	85.0%	74.4%	62.2%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.8%	99.7%	99.5%	98.9%	97.9%	96.1%	94.1%	90.5%
7,000	Effective Sample Size	6045	5397	4815	4280	3781	3303	2792	2228	1428	529
Safety Mode 2024	Depletions and Malfunctions	100.0%	99.8%	99.6%	99.2%	98.1%	95.8%	91.4%	83.6%	72.9%	60.7%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	99.6%	98.8%	97.2%	94.4%	90.9%	87.6%
11,000	Effective Sample Size	9020	8045	7163	6353	5611	4899	4083	2902	1413	319

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

VISIONIST/VALITUDE

Models: U125/U128/U225/U226/U228

Worldwide Confirmed Malfunctions	**1,163**
Worldwide Distribution	**150,000**

US Approval Date: October 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
Integrated circuit (63)	5	30	35
Telemetry (68)	0	1	1
High battery impedance (89)	6	137	143
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	2	110	112
High battery impedance initiating safety mode - December 2024 (90)	20	345	365
Battery impedance test performance (93)	0	314	314
Software			
Memory errors (51)	0	31	31
Unintended software behavior (92)	0	3	3
Mechanical			
Battery liner (91)	2	0	2
Other			
Non-patterned, other	39	116	155
Grand Total	**74**	**1089**	**1163**

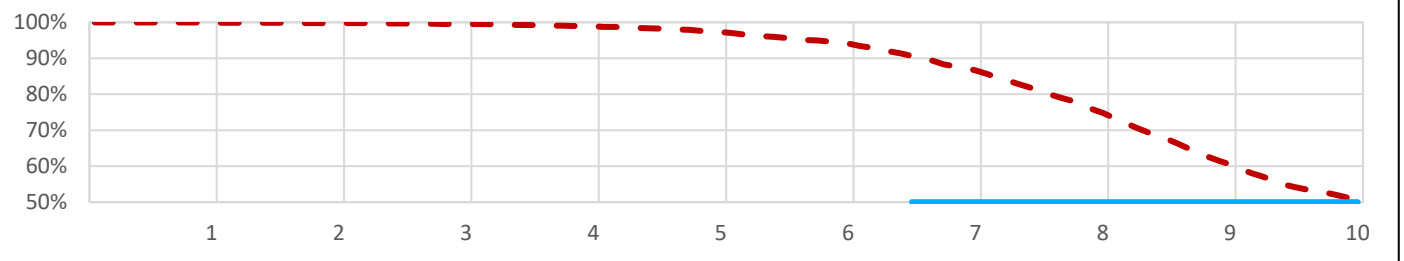
References cited in table above (link)

INTUA/INVIVE/INLIVEN

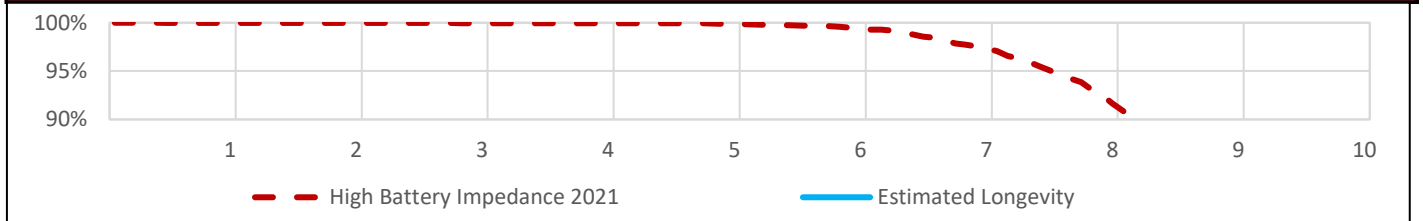
Models: V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/W173/V274/V275/V284/V285/W275

US Summary			
US Registered Implants:	10,000	US Normal Battery Depletions:	1,321
US Approval Date:	May 2013	US Malfunctions:	644
US Estimated Active Implants:	3,000	Without Compromised Therapy:	606
		With Compromised Therapy:	38

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	99.9%	99.8%	99.5%	99.0%	97.5%	94.3%	87.3%	75.8%	61.4%	51.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.5%	97.6%	92.5%	83.8%	78.2%
10,000	Effective Sample Size	8931	7960	7080	6274	5524	4735	3761	2762	1834	1271

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

INTUA/INVIVE/INLIVEN

Models: V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/W173/V274/V275/V284/V285/W275

Worldwide Confirmed Malfunctions	**987**
Worldwide Distribution	**24,000**

US Approval Date: May 2013	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
High battery impedance initiating safety mode 2021 (82)	22	842	864
Low-voltage capacitors (47)	1	0	1
Other			
Non-patterned, other	56	66	122
Grand Total	**79**	**908**	**987**

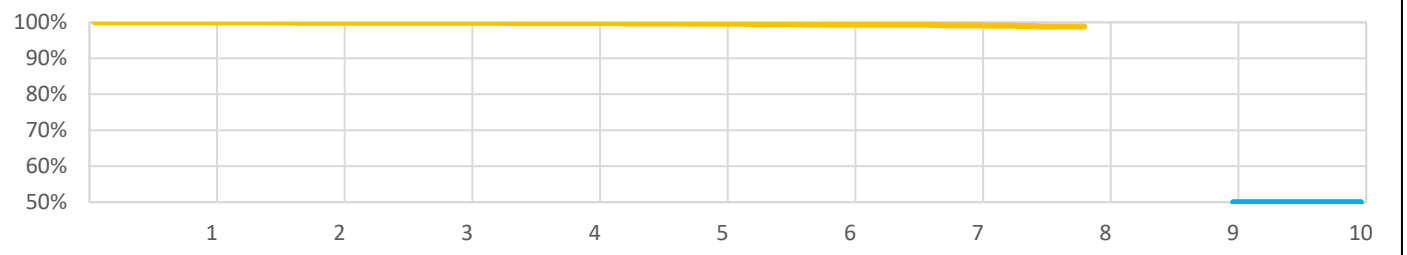
References cited in table above (link)

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

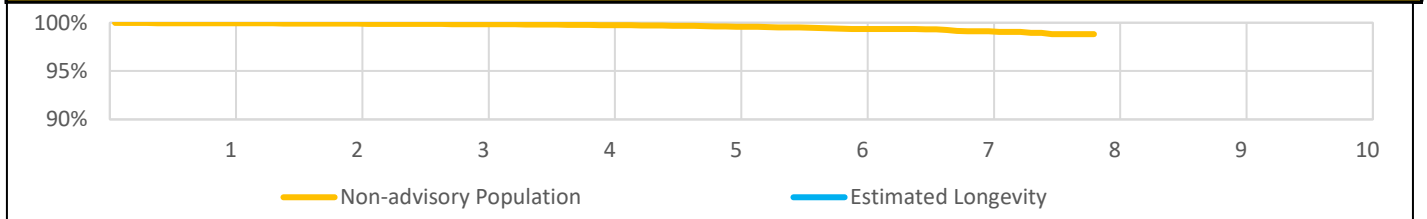
Models: D121/D221/D233/D321/D333/D421/D433/D521/D533

US Summary			
US Registered Implants:	86,000	US Normal Battery Depletions:	85
US Approval Date:	July 2017	US Malfunctions:	68
US Estimated Active Implants:	77,000	Without Compromised Therapy:	57
		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	99.9%	99.9%	99.9%	99.8%	99.6%	99.4%	99.1%	98.8%	--	--	
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.6%	99.4%	99.1%	98.8%	--	--	
86,000	Effective Sample Size	63212	45243	30815	19980	11569	5536	1988	267	--	--	@ 95 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD DR

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

Worldwide Confirmed Malfunctions	**127**
Worldwide Distribution	**156,000**

US Approval Date: July 2017	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
High voltage capacitor (75)	3	0	3
Integrated circuit (63)	5	9	14
Low-voltage capacitor (69)	0	11	11
Battery (53)	1	45	46
Low-voltage capacitors (47)	0	1	1
Software			
Memory errors (51)	1	27	28
Mechanical			
Solder joint (88)	1	0	1
Other			
Non-patterned, other	5	18	23
Grand Total	**16**	**111**	**127**

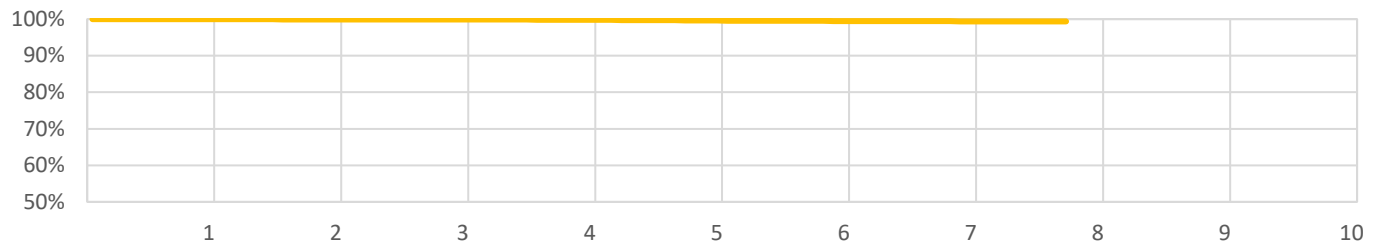
References cited in table above (link)

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

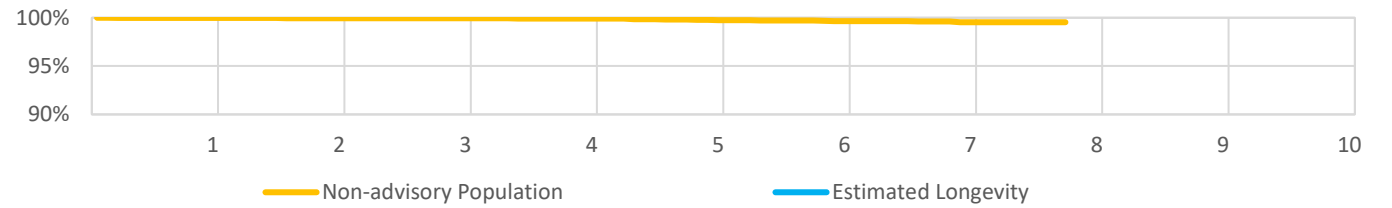
Models: D120/D220/D232/D320/D332/D420/D432/D520/D532

US Summary			
US Registered Implants:	45,000	US Normal Battery Depletions:	28
US Approval Date:	July 2017	US Malfunctions:	40
US Estimated Active Implants:	41,000	Without Compromised Therapy:	37
		With Compromised Therapy:	3

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

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%	99.6%	99.5%	99.4%	99.4%	--	--	
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.5%	--	--	
45,000	Effective Sample Size	34122	24853	17089	11116	6884	3643	1439	268	--	--	@ 94 months

RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR

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

Worldwide Confirmed Malfunctions	**93**
Worldwide Distribution	**112,000**

US Approval Date: July 2017	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
High voltage capacitor (75)	4	0	4
Integrated circuit (63)	1	1	2
Low-voltage capacitor (69)	0	2	2
Low-voltage capacitors (47)	0	1	1
Battery (53)	1	45	46
Software			
Memory errors (51)	0	18	18
Other			
Non-patterned, other	7	13	20
Grand Total	**13**	**80**	**93**

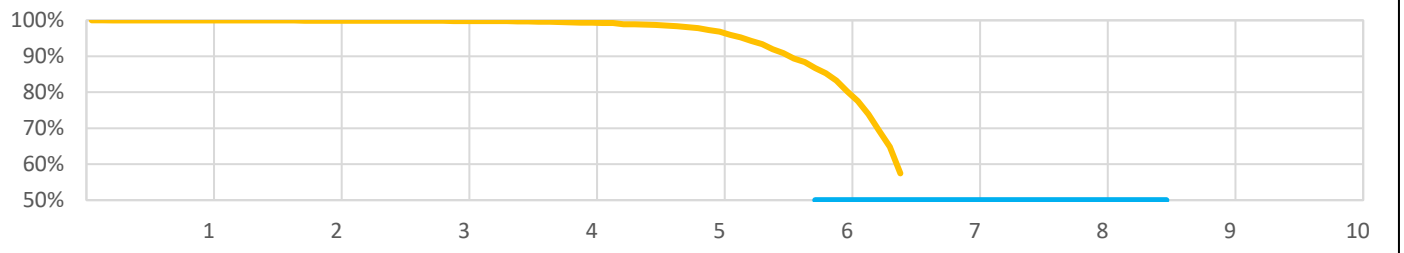
References cited in table above (link)

PERCIVA DR

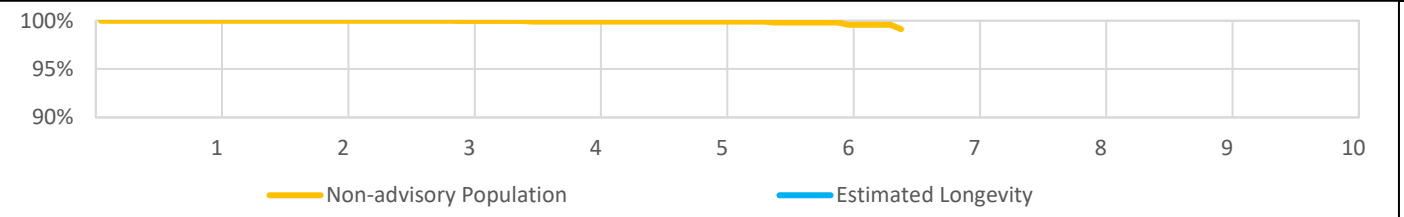
Models: D401/D413/D501/D513

US Summary			
US Registered Implants:	8,000	US Normal Battery Depletions:	408
US Approval Date:	July 2017	US Malfunctions:	5
US Estimated Active Implants:	6,000	Without Compromised Therapy:	5
		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%	99.8%	99.4%	97.3%	83.2%	57.4%	--	--	--	
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.1%	--	--	--	
8,000	Effective Sample Size	5808	4273	3089	2087	1201	482	224	--	--	--	@ 78 months

PERCIVA DR

Models: D401/D413/D501/D513

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**14,000**

US Approval Date: July 2017	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
Battery (53)	0	4	4
Software			
Memory errors (51)	0	1	1
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**7**	**7**

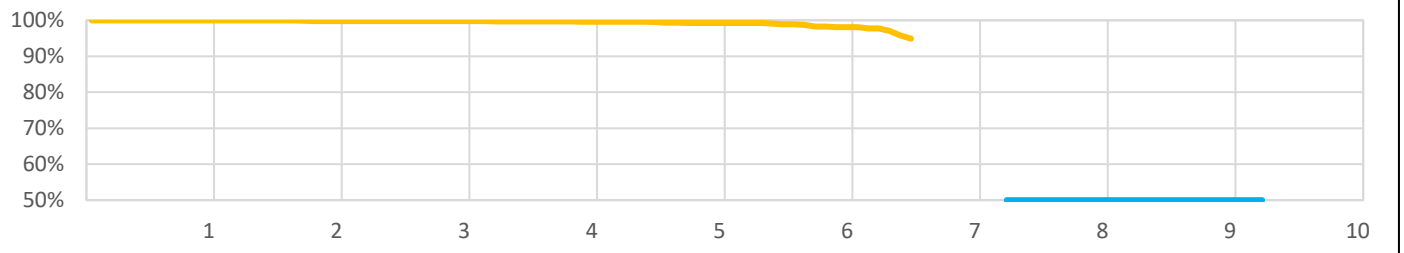
References cited in table above (link)

PERCIVA VR

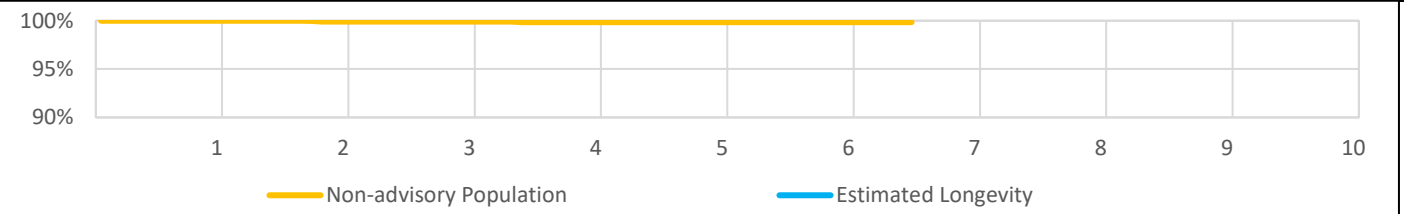
Models: D400/D412/D500/D512

US Summary			
US Registered Implants:	6,000	US Normal Battery Depletions:	88
US Approval Date:	July 2017	US Malfunctions:	4
US Estimated Active Implants:	5,000	Without Compromised Therapy:	2
		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%	99.8%	99.8%	99.6%	99.3%	98.1%	94.9%	--	--	--	
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%	--	--	--	
6,000	Effective Sample Size	4299	3136	2197	1360	787	404	208	--	--	--	@ 79 months

PERCIVA VR

Models: D400/D412/D500/D512

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**11,000**

US Approval Date: July 2017	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Software			
Memory errors (51)	0	2	2
Electrical			
Integrated circuit (63)	1	0	1
High voltage capacitor (75)	1	0	1
Battery (53)	0	2	2
Other			
Non-patterned, other	1	2	3
Grand Total	**3**	**6**	**9**

References cited in table above (link)

AUTOGEN ICD EL DR

Models: D162/D163/D176/D177

Worldwide Confirmed Malfunctions	**112**
Worldwide Distribution	**17,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	2	0	2
Low-voltage capacitor (69)	0	23	23
Battery (53)	3	65	68
High voltage capacitor (75)	2	0	2
Software			
Memory errors (51)	0	8	8
Other			
Non-patterned, other	1	4	5
Grand Total	**8**	**104**	**112**

References cited in table above (link)

AUTOGEN ICD EL VR

Models: D160/D161/D174/D175

Worldwide Confirmed Malfunctions	**108**
Worldwide Distribution	**17,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High voltage capacitor (75)	2	0	2
Low-voltage capacitor (69)	0	11	11
Battery (53)	7	76	83
Integrated circuit (63)	1	1	2
Software			
Memory errors (51)	2	2	4
Other			
Non-patterned, other	0	6	6
Grand Total	**12**	**96**	**108**

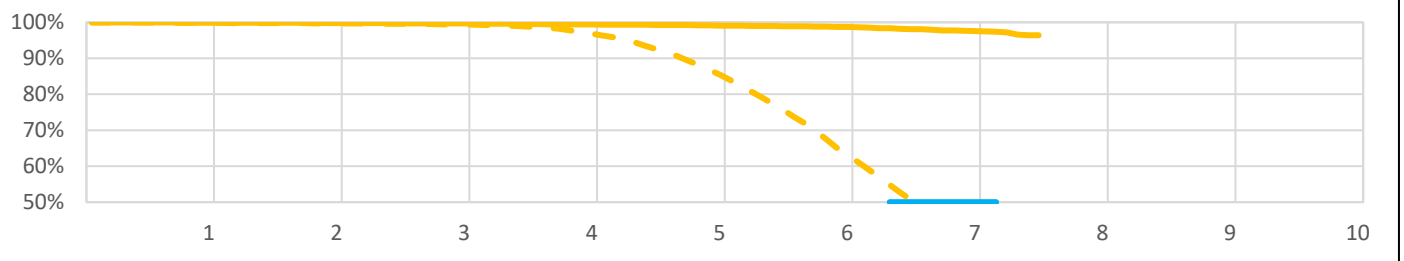
References cited in table above (link)

EMBLEM S-ICD

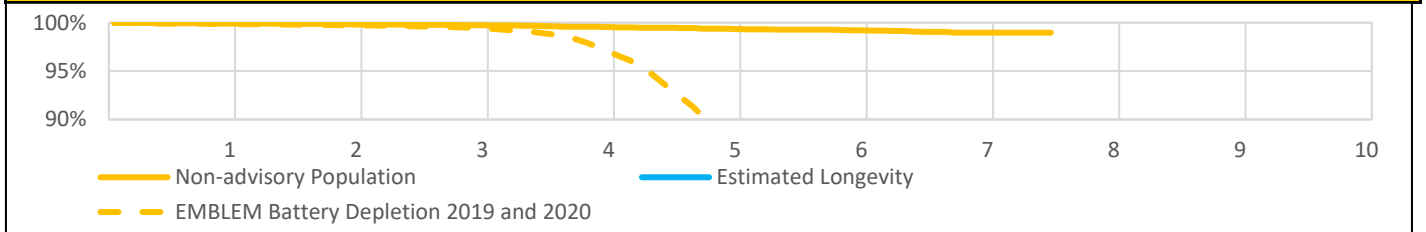
Models: A209/A219

US Summary			
US Registered Implants:	78,000	US Normal Battery Depletions:	2,654
US Approval Date:	March 2015	US Malfunctions:	6,087
US Estimated Active Implants:	58,000	Without Compromised Therapy:	5,854
		With Compromised Therapy:	233

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%	99.4%	99.1%	98.7%	97.7%	96.4%	--	--	
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.6%	99.4%	99.2%	99.0%	99.0%	--	--	
52,000	Effective Sample Size	43052	32578	23630	15784	9513	4969	1757	256	--	--	@ 91 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

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Battery Depletion 2019 and 2020	Depletions and Malfunctions	99.9%	99.7%	99.4%	97.3%	86.9%	65.1%	42.0%	22.6%	13.0%	--
Registered Implants: 22,000	Malfunctions Only	99.9%	99.7%	99.5%	97.5%	88.1%	69.3%	49.8%	35.7%	30.8%	--
	Effective Sample Size	18414	16342	14484	12617	10026	6652	3617	1157	305	--

@ 100 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	**12,282**
Worldwide Distribution	**190,000**

US Approval Date: March 2015	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	4	1	5
Capacitor (72)	0	6	6
S-ICD battery depletion 2019 and 2020 (77)	221	11471	11692
Battery depletion (84)	1	3	4
Low-voltage capacitors (47)	1	0	1
Software			
Memory corruption (65)	1	0	1
Misaligned markers (73)	1	4	5
Memory corruption (85)	4	21	25
Mechanical			
Solder joint (78)	16	2	18
EMBLEM S-ICD electrical overstress 2020 (80)	8	0	8
RF antenna (81)	1	0	1
Cracked case (86)	27	1	28
Header (87)	1	0	1
Other			
Telemetry (56)	20	44	64
Non-patterned, other	64	359	423
Grand Total	**370**	**11912**	**12282**

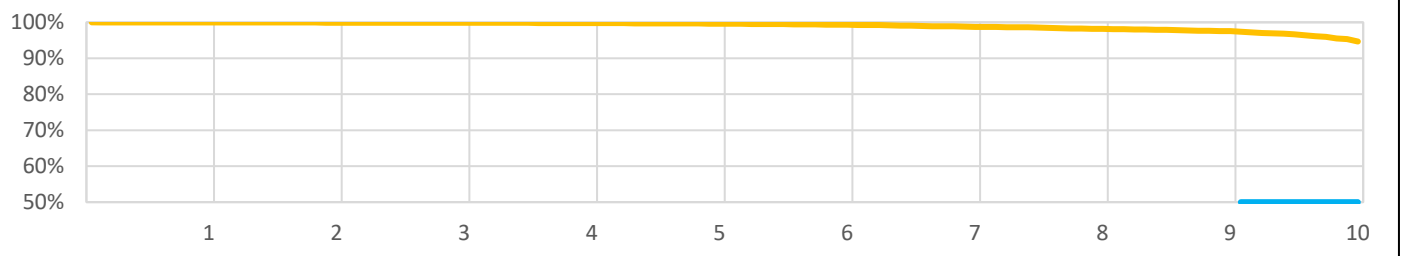
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL DR

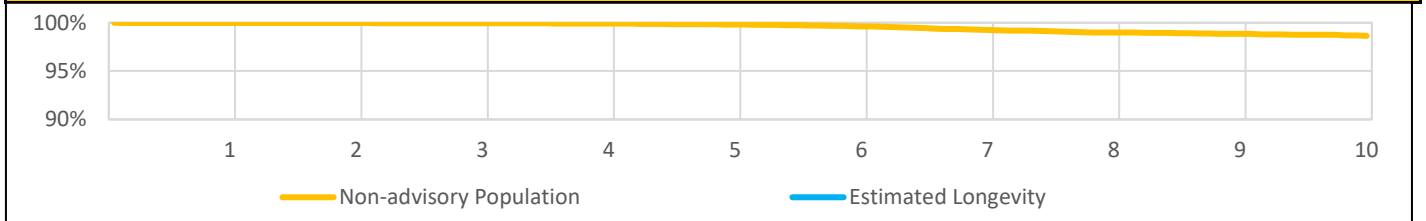
Models: D052/D053/D142/D143/D152/D153

US Summary			
US Registered Implants:	52,000	US Normal Battery Depletions:	327
US Approval Date:	April 2014	US Malfunctions:	204
US Estimated Active Implants:	39,000	Without Compromised Therapy:	182
		With Compromised Therapy:	22

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%	99.6%	99.3%	98.8%	98.2%	97.6%	95.3%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.3%	99.0%	98.9%	98.7%
52,000	Effective Sample Size	44956	39049	33625	28475	23627	18882	14586	9945	5387	1986

DYNAGEN/INOGEN/ORIGEN ICD EL DR

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

Worldwide Confirmed Malfunctions	**261**
Worldwide Distribution	**98,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	3	3
High voltage circuit component (62)	0	4	4
Integrated circuit (63)	4	2	6
Low-voltage capacitor (69)	0	44	44
High voltage capacitor (75)	8	0	8
Battery (53)	14	147	161
Software			
Memory errors (51)	0	2	2
Other			
Non-patterned, other	8	25	33
Grand Total	**34**	**227**	**261**

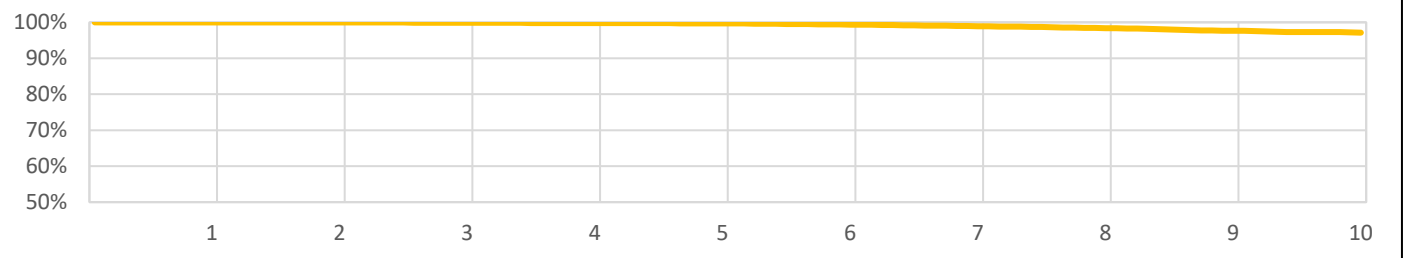
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD EL VR

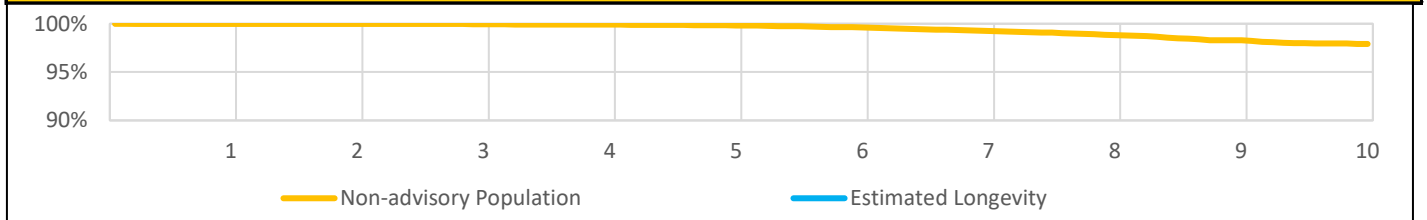
Models: D050/D051/D140/D141/D150/D151

US Summary			
US Registered Implants:	40,000	US Normal Battery Depletions:	101
US Approval Date:	April 2014	US Malfunctions:	221
US Estimated Active Implants:	30,000	Without Compromised Therapy:	202
		With Compromised Therapy:	19

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

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%	99.4%	99.0%	98.4%	97.7%	97.2%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.6%	99.3%	98.9%	98.3%	97.9%
40,000	Effective Sample Size	34537	30216	26212	22535	19136	15814	12409	8764	4961	2058

DYNAGEN/INOGEN/ORIGEN ICD EL VR

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

Worldwide Confirmed Malfunctions	**307**
Worldwide Distribution	**84,000**

US Approval Date: April 2014	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)	2	2	4
Low-voltage capacitor (69)	1	56	57
Battery (53)	20	175	195
High voltage capacitor (75)	1	0	1
Software			
Memory errors (51)	2	12	14
Other			
Non-patterned, other	7	26	33
Grand Total	**33**	**274**	**307**

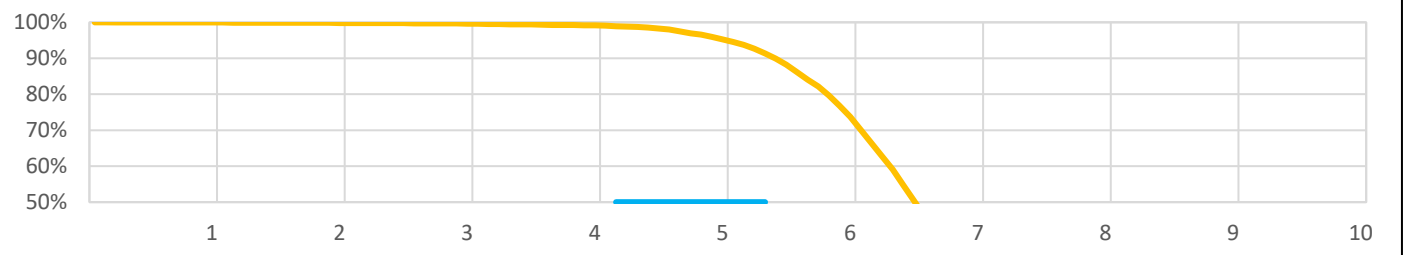
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

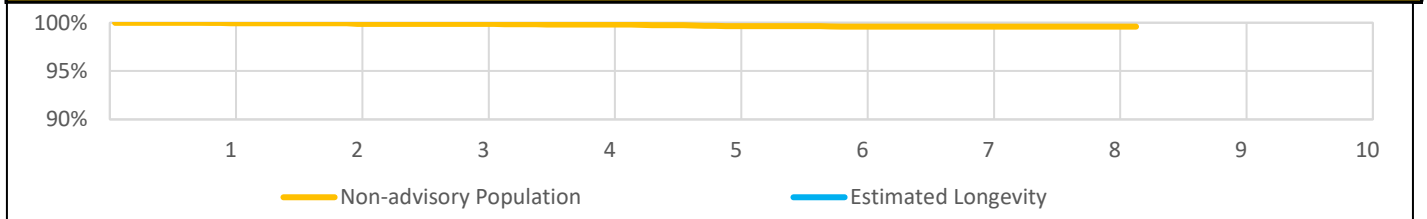
Models: D002/D003/D012/D013/D022/D023

US Summary			
US Registered Implants:	12,000	US Normal Battery Depletions:	3,211
US Approval Date:	April 2014	US Malfunctions:	27
US Estimated Active Implants:	6,000	Without Compromised Therapy:	24
		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 Registered Implants:	Depletions and Malfunctions	99.9%	99.9%	99.7%	99.2%	95.9%	76.8%	30.1%	14.2%	14.0%	--	
	Malfunctions Only	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.6%	--	
12,000	Effective Sample Size	10226	8833	7534	6347	5147	3321	967	249	212	--	@ 99 months

DYNAGEN/INOGEN/ORIGEN ICD MINI DR

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

Worldwide Confirmed Malfunctions	**42**
Worldwide Distribution	**37,000**

US Approval Date: April 2014	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Electrical			
High voltage circuit component (62)	0	12	12
High voltage capacitor (75)	3	0	3
Integrated circuit (63)	0	2	2
Low-voltage capacitors (47)	1	0	1
Battery (53)	0	6	6
Low-voltage capacitor (69)	0	7	7
Other			
Non-patterned, other	4	7	11
Grand Total	**8**	**34**	**42**

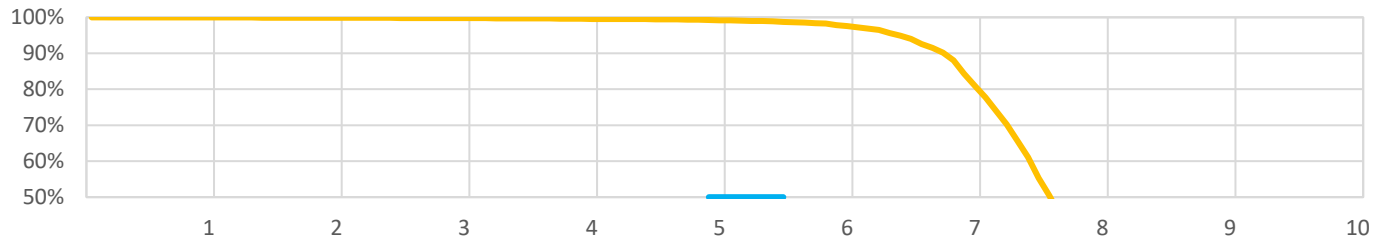
References cited in table above (link)

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

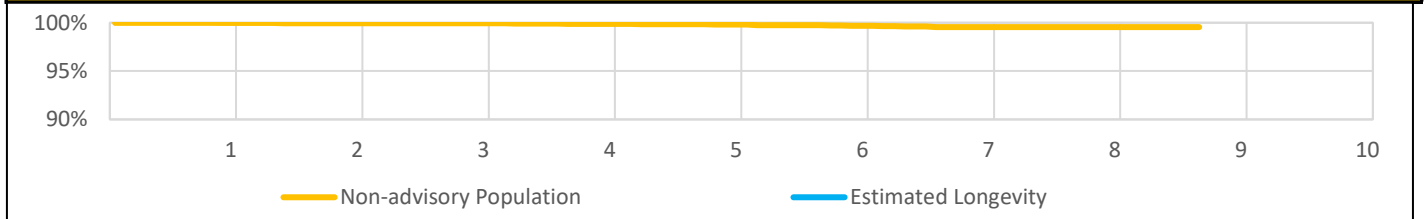
Models: D000/D001/D010/D011/D020/D021

US Summary			
US Registered Implants:	10,000	US Normal Battery Depletions:	2,271
US Approval Date:	April 2014	US Malfunctions:	22
US Estimated Active Implants:	5,000	Without Compromised Therapy:	21
		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%	99.2%	97.8%	84.3%	30.0%	15.4%	--	
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.8%	99.7%	99.5%	99.5%	99.5%	--	
10,000	Effective Sample Size	8378	7326	6381	5513	4713	3954	2776	705	207	--	@ 105 months

DYNAGEN/INOGEN/ORIGEN ICD MINI VR

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

Worldwide Confirmed Malfunctions	**49**
Worldwide Distribution	**37,000**

US Approval Date: April 2014	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	2	2
High voltage circuit component (62)	0	7	7
High voltage capacitor (75)	7	0	7
Low-voltage capacitor (69)	0	7	7
Battery (53)	1	11	12
Integrated circuit (63)	0	1	1
Software			
Memory errors (51)	1	3	4
Other			
Non-patterned, other	2	7	9
Grand Total	**11**	**38**	**49**

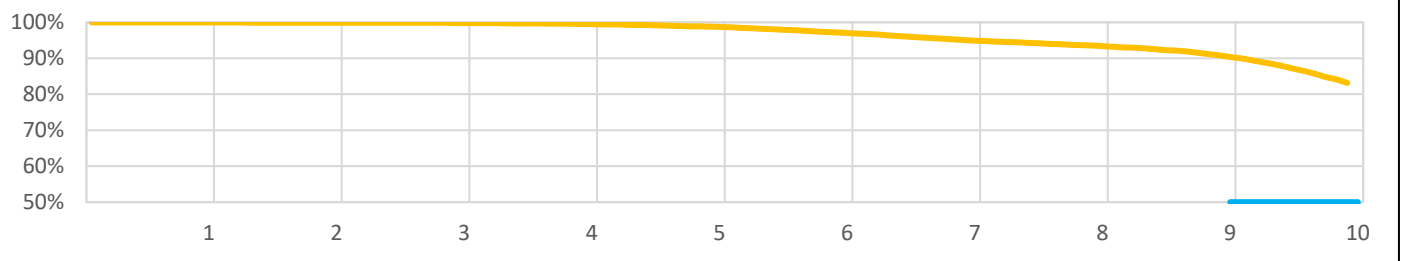
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD DR

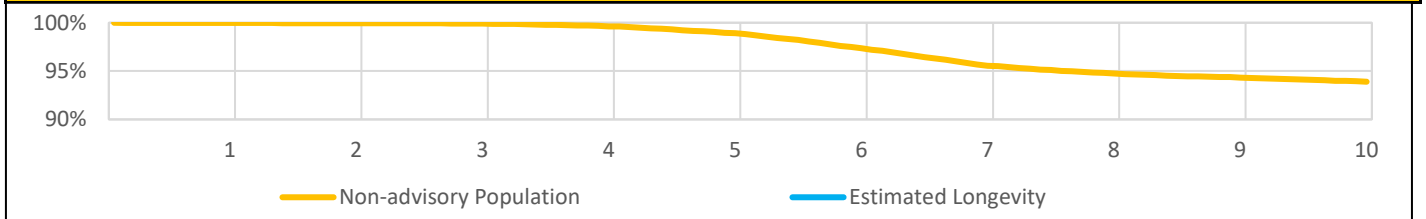
Models: E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163

US Summary			
US Registered Implants:	47,000	US Normal Battery Depletions:	7,844
US Approval Date:	November 2011	US Malfunctions:	1,306
US Estimated Active Implants:	18,000	Without Compromised Therapy:	1,270
		With Compromised Therapy:	36

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%	97.2%	95.1%	93.5%	90.8%	83.1%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.5%	95.7%	94.8%	94.4%	93.9%
47,000	Effective Sample Size	41159	36475	32232	28361	24829	21459	18434	15869	13503	10702

INCEPTA/ENERGEN/PUNCTUA ICD DR

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

Worldwide Confirmed Malfunctions	**2,025**
Worldwide Distribution	**72,000**

US Approval Date: November 2011	**With Compromised Therapy**	**Without Compromised Therapy**	**Total**
Mechanical			
Transformer (38)	2	0	2
Electrical			
High-voltage capacitor (43)	5	1	6
Low-voltage capacitors (47)	0	5	5
Integrated circuit (50)	6	7	13
Battery (53)	17	96	113
Low-voltage capacitor (54)	14	1789	1803
High voltage circuit (58)	0	1	1
Low-voltage capacitor (69)	0	44	44
Software			
Memory errors (51)	0	9	9
Other			
Non-patterned, other	12	17	29
Grand Total	**56**	**1969**	**2025**

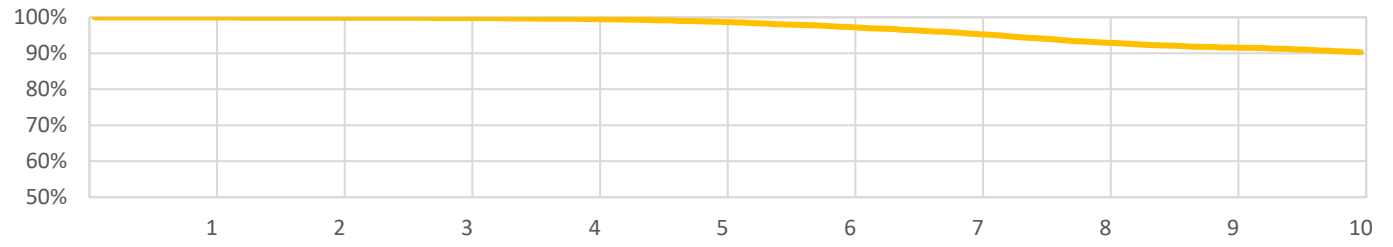
References cited in table above (link)

INCEPTA/ENERGEN/PUNCTUA ICD VR

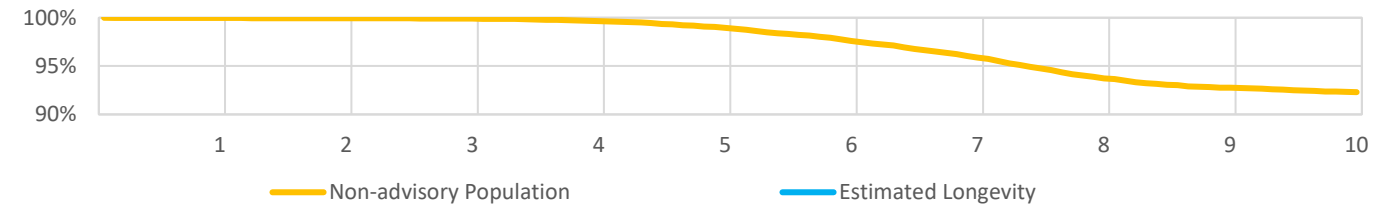
Models: E050/E051/E140/E141/E160/E161/F050/F051/F140/F141/F160/F161

US Summary			
US Registered Implants:	39,000	US Normal Battery Depletions:	1,950
US Approval Date:	November 2011	US Malfunctions:	1,356
US Estimated Active Implants:	20,000	Without Compromised Therapy:	1,309
		With Compromised Therapy:	47

Battery Depletions and Malfunctions



Malfunctions Only



Note: Minimum estimated longevity exceeds 10 years.

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%	97.4%	95.6%	93.1%	91.6%	90.4%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.7%	99.0%	97.8%	96.1%	93.9%	92.8%	92.3%
39,000	Effective Sample Size	34676	30699	27122	23873	20885	18117	15516	13218	11393	9720

INCEPTA/ENERGEN/PUNCTUA ICD VR

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

Worldwide Confirmed Malfunctions	**2,263**
Worldwide Distribution	**68,000**

US Approval Date: November 2011	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
High-voltage capacitor (43)	4	1	5
Integrated circuit (50)	5	5	10
Battery (53)	33	158	191
Low-voltage capacitor (54)	19	1948	1967
High voltage circuit (58)	1	0	1
Low-voltage capacitor (69)	0	41	41
Mechanical			
Transformer (38)	6	0	6
Software			
Memory errors (51)	1	10	11
Other			
Non-patterned, other	12	19	31
Grand Total	**81**	**2182**	**2263**

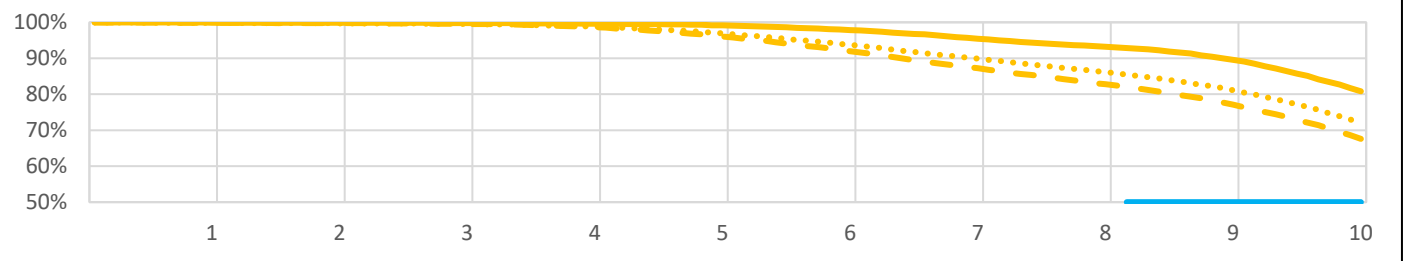
References cited in table above (link)

TELIGEN DR

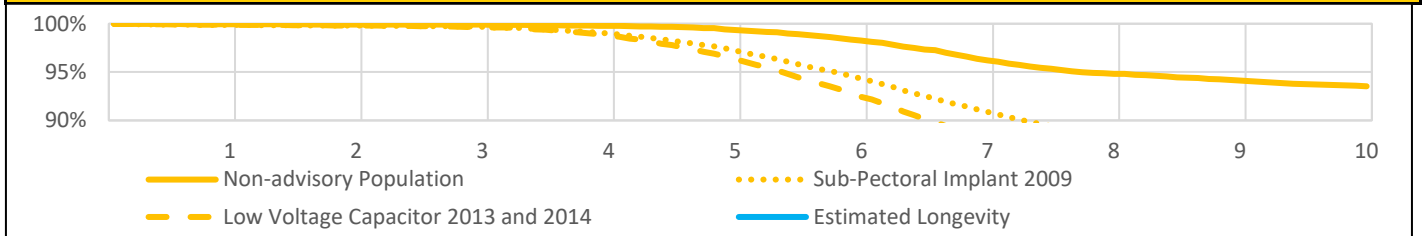
Models: E110/E111/F110/F111

US Summary			
US Registered Implants:	66,000	US Normal Battery Depletions:	13,379
US Approval Date:	March 2008	US Malfunctions:	3,048
US Estimated Active Implants:	13,000	Without Compromised Therapy:	2,879
		With Compromised Therapy:	169

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%	93.4%	90.0%	81.8%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.8%	99.4%	98.4%	96.4%	94.9%	94.2%	93.6%
30000	Effective Sample Size	26333	23353	20706	18280	16075	13977	11968	10206	8592	6796

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%	99.7%	99.6%	98.9%	97.2%	94.0%	90.2%	86.4%	81.7%	73.0%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	99.1%	97.5%	94.6%	91.1%	88.4%	86.3%	84.9%
30000	Effective Sample Size	26089	23016	20331	17838	15480	13166	11053	9216	7544	5811
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.9%	99.8%	99.6%	98.8%	96.4%	92.4%	87.6%	83.1%	77.7%	68.7%
Registered Implants:	Malfunctions Only	99.9%	99.8%	99.7%	98.9%	96.6%	92.8%	88.5%	85.0%	82.5%	80.8%
23000	Effective Sample Size	20266	17903	15806	13858	11929	10028	8317	6859	5550	4215

*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	**4,190**
Worldwide Distribution	**91,000**

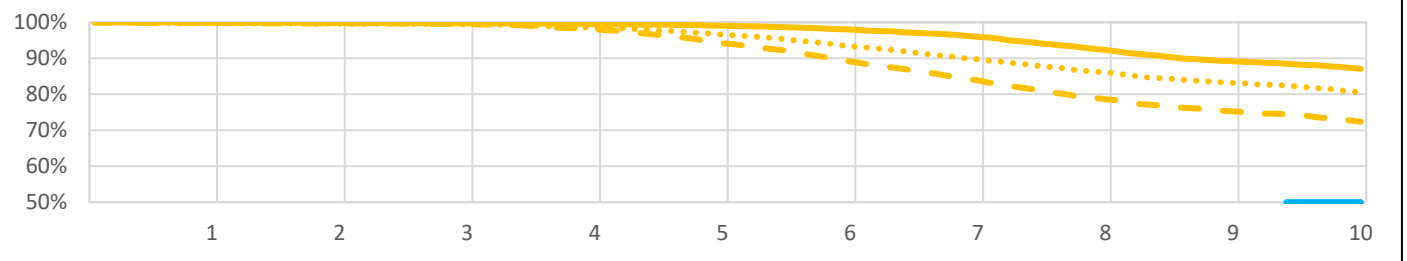
US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	54	2300	2354
Safety Core-electrocautery (42)	1	4	5
High-voltage capacitor (43)	8	1	9
Low-voltage capacitors (47)	0	8	8
Integrated circuit (50)	22	22	44
Battery (53)	43	256	299
Low-voltage capacitor (54)	15	1300	1315
Low-voltage capacitor (69)	1	7	8
Mechanical			
Transformer (38)	20	0	20
Seal plug (40)	0	3	3
Difficulty securing lead (41)	8	7	15
Header contacts (45)	12	3	15
Subpectoral implant 2009 - December 01, 2009 Voluntary Physician Advisory (6)	13	9	22
Header (74)	9	3	12
Software			
Alert messages not displayed post-EOL (48)	0	3	3
Memory errors (51)	0	19	19
Other			
Non-patterned, other	11	28	39
Grand Total	**217**	**3973**	**4190**

TELIGEN VR

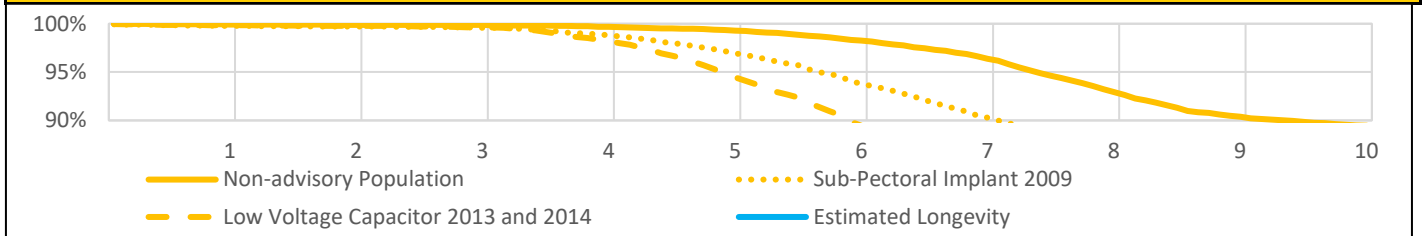
Models: E102/E103/F102/F103

US Summary			
US Registered Implants:	38,000	US Normal Battery Depletions:	6,089
US Approval Date:	March 2008	US Malfunctions:	2,424
US Estimated Active Implants:	9,000	Without Compromised Therapy:	2,286
		With Compromised Therapy:	138

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%	99.5%	99.1%	98.1%	96.3%	92.6%	89.3%	87.4%
Registered Implants:	Malfunctions Only	99.9%	99.9%	99.9%	99.7%	99.3%	98.3%	96.6%	93.2%	90.5%	89.5%
18000	Effective Sample Size	15902	14061	12408	10931	9586	8332	7135	5951	4980	4271

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%	93.6%	89.9%	86.3%	83.3%	80.9%
Registered Implants:	Malfunctions Only	99.8%	99.7%	99.6%	98.9%	97.2%	94.1%	90.5%	87.1%	84.4%	82.9%
16000	Effective Sample Size	13340	11747	10344	9037	7800	6628	5551	4611	3862	3237
Low Voltage Capacitor 2013 and 2014	Depletions and Malfunctions	99.8%	99.7%	99.5%	98.2%	94.7%	89.5%	84.2%	79.0%	75.4%	72.7%
Registered Implants:	Malfunctions Only	99.8%	99.8%	99.6%	98.4%	94.9%	89.8%	84.7%	79.7%	76.6%	74.9%
12000	Effective Sample Size	10645	9392	8274	7207	6122	5066	4129	3335	2756	2294

*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	**4,112**
Worldwide Distribution	**66,000**

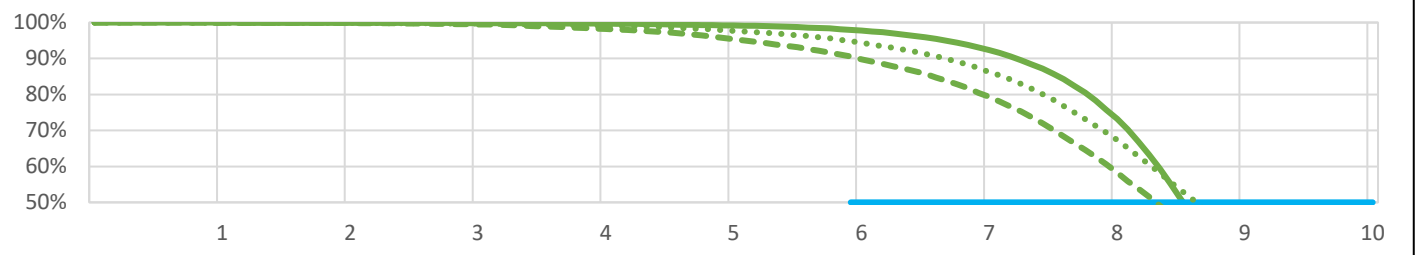
US Approval Date: March 2008	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low Voltage Capacitor 2014 - August 29, 2013 and September 17, 2014 Voluntary Physician Advisory (3)	46	1925	1971
Safety Core-electrocautery (42)	1	1	2
High-voltage capacitor (43)	3	0	3
Low-voltage capacitors (47)	0	5	5
Integrated circuit (50)	17	11	28
Battery (53)	55	423	478
Low-voltage capacitor (54)	13	1449	1462
Low-voltage capacitor (69)	0	5	5
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)	19	12	31
Header (74)	13	4	17
Header (6)	0	1	1
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	15	13	28
Grand Total	**228**	**3884**	**4112**

ACCOLADE/PROPONENT/ESSENTIO DR

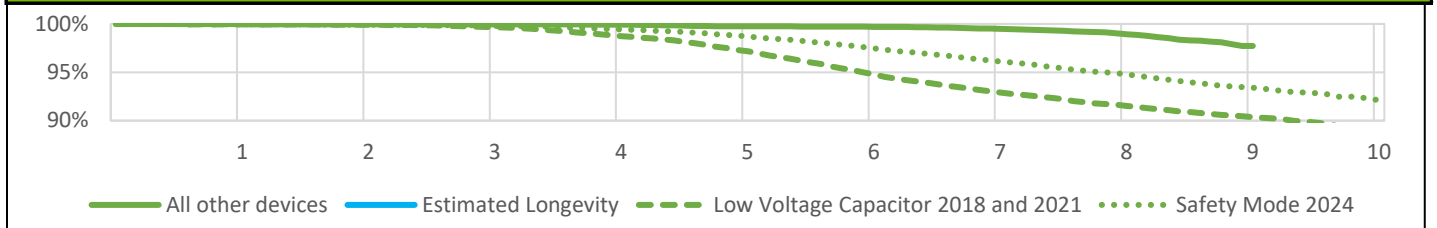
Models: L101/L111/L201/L211/L301/L311

US Summary			
US Registered Implants:	343,000	US Normal Battery Depletions:	21,678
US Approval Date:	April 2016	US Malfunctions:	2,477
US Estimated Active Implants:	254,000	Without Compromised Therapy:	2,311
		With Compromised Therapy:	166

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
All other devices	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.7%	99.2%	98.0%	93.1%	75.7%	22.8%	13.7%	
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.5%	99.0%	97.7%	97.7%	
234000	Effective Sample Size	225090	176562	135513	100263	71018	47449	27882	10116	575	277	@ 109 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

US Survival Probability (cont.)											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018 and 2021	Depletions and Malfunctions	100.0%	99.9%	99.6%	98.4%	96.1%	91.1%	81.7%	62.6%	36.9%	22.1%
Registered Implants: 42000	Malfunctions Only	100.0%	99.9%	99.7%	98.8%	97.3%	95.0%	93.0%	91.7%	90.5%	89.1%
	Effective Sample Size	37798	33693	29911	26393	22944	19345	15350	10221	4569	652
Safety Mode 2024	Depletions and Malfunctions	99.9%	99.9%	99.7%	99.2%	97.9%	94.9%	87.3%	69.4%	41.9%	23.8%
Registered Implants: 64000	Malfunctions Only	100.0%	99.9%	99.8%	99.5%	98.8%	97.6%	96.2%	94.9%	93.5%	92.3%
	Effective Sample Size	57568	51272	45582	40423	35603	30703	24965	16516	6594	809

*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	**4,459**
Worldwide Distribution	**848,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	2	7	9
Integrated circuit (63)	21	89	110
Capacitor (67)	0	6	6
Telemetry (68)	2	14	16
High battery impedance (89)	16	194	210
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	72	2534	2606
High battery impedance initiating safety mode - December 2024 (90)	45	638	683
Battery impedance test performance (93)	0	282	282
Software			
Memory errors (51)	1	107	108
Unintended software behavior (92)	0	1	1
Mechanical			
Battery cathode (79)	12	7	19
Other			
Non-patterned, other	173	236	409
Grand Total	**344**	**4115**	**4459**

References cited in table above (link)

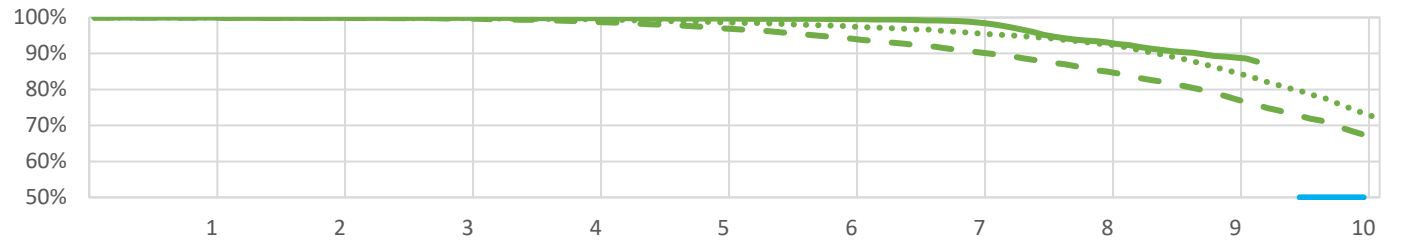
ACCOLADE/PROPONENT/ESSENTIO EL DR

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

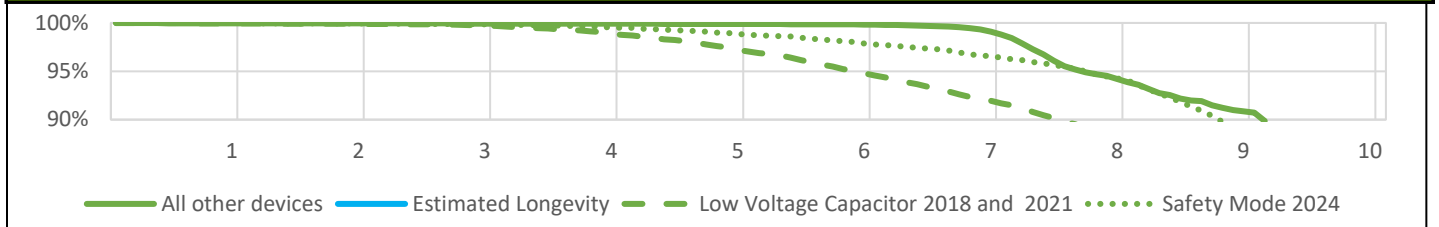
US Summary

US Registered Implants:	250,000	US Normal Battery Depletions:	1,090
US Approval Date:	April 2016	US Malfunctions:	2,596
US Estimated Active Implants:	212,000	Without Compromised Therapy:	2,544
		With Compromised Therapy:	52

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
All other devices	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.8%	99.7%	99.6%	98.8%	93.4%	89.1%	87.7%	
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.9%	99.9%	99.8%	99.3%	94.5%	91.0%	89.9%	
181,000	Effective Sample Size	171413	127522	92269	64163	42293	26207	14700	5835	1123	321	@ 111 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

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018 and 2021	Depletions and Malfunctions	100.0%	99.9%	99.7%	98.8%	97.0%	94.1%	90.3%	84.9%	77.3%	67.4%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.7%	98.9%	97.2%	94.8%	91.9%	88.0%	83.5%	77.8%
17,000	Effective Sample Size	15121	13447	11950	10556	9199	7904	6691	5477	3714	957
Safety Mode 2024	Depletions and Malfunctions	100.0%	99.9%	99.8%	99.4%	98.6%	97.5%	95.6%	92.5%	84.7%	73.4%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.9%	99.5%	98.9%	97.9%	96.5%	94.3%	88.8%	81.5%
24,000	Effective Sample Size	21305	18941	16827	14934	13170	11540	9990	8198	4580	702

*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	**4,240**
Worldwide Distribution	**645,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	0	11	11
Integrated circuit (63)	12	85	97
Capacitor (67)	0	2	2
Telemetry (68)	1	14	15
High battery impedance (89)	5	50	55
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	55	2274	2329
High battery impedance initiating safety mode - December 2024 (90)	18	169	187
Battery impedance test performance (93)	1	1124	1125
Software			
Memory errors (51)	0	104	104
Unintended software behavior (92)	0	2	2
Mechanical			
Battery cathode (79)	3	1	4
Battery liner (91)	10	3	13
Other			
Non-patterned, other	24	272	296
Grand Total	**129**	**4111**	**4240**

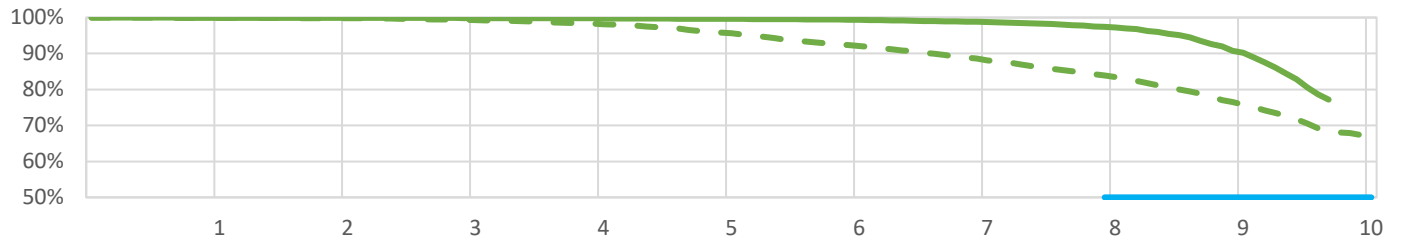
References cited in table above (link)

ACCOLADE/PROPONENT/ESSENTIO SR

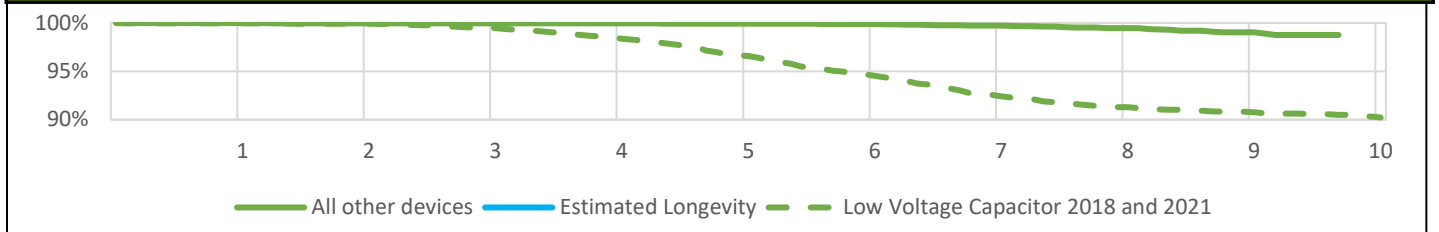
Models: L100/L110/L200/L210/L300/L310

US Summary			
US Registered Implants:	64,000	US Normal Battery Depletions:	1,427
US Approval Date:	April 2016	US Malfunctions:	641
US Estimated Active Implants:	44,000	Without Compromised Therapy:	618
		With Compromised Therapy:	23

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10	
All other devices	Depletions and Malfunctions	99.9%	99.9%	99.9%	99.8%	99.6%	99.4%	98.8%	97.4%	90.8%	77.2%	
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.5%	99.0%	98.8%	
33,000	Effective Sample Size	40504	32206	25160	19447	14447	10271	6807	3631	1139	213	@ 117 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

US Survival Probability											
	Year	1	2	3	4	5	6	7	8	9	10
Low Voltage Capacitor 2018 and 2021	Depletions and Malfunctions	99.9%	99.8%	99.3%	98.3%	95.8%	92.3%	88.6%	83.9%	76.5%	67.3%
Registered Implants:	Malfunctions Only	100.0%	99.9%	99.5%	98.5%	96.7%	94.7%	92.6%	91.3%	90.8%	90.3%
12,000	Effective Sample Size	10483	9299	8237	7270	6334	5445	4656	3887	2838	1015

*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	**1,459**
Worldwide Distribution	**298,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Low-voltage capacitors (47)	1	3	4
Integrated circuit (63)	8	12	20
Capacitor (67)	0	4	4
Telemetry (68)	0	5	5
High battery impedance (89)	5	72	77
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	43	1184	1227
Battery impedance test performance (93)	0	42	42
Software			
Memory errors (51)	0	23	23
Other			
Non-patterned, other	19	31	50
Mechanical			
Battery cathode (79)	5	1	6
Battery liner (91)	1	0	1
Grand Total	**82**	**1377**	**1459**

References cited in table above (link)

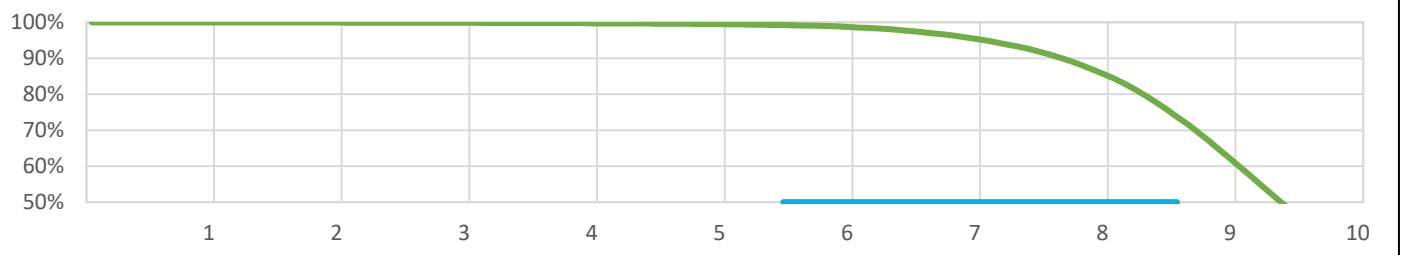
ADVANTIO/INGENIO/VITALIO/FORMIO DR

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

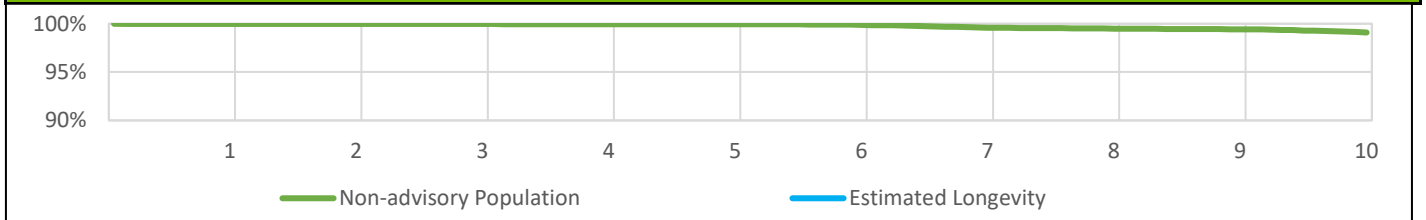
US Summary

US Registered Implants:	121,000	US Normal Battery Depletions:	32,603
US Approval Date:	May 2012	US Malfunctions:	421
US Estimated Active Implants:	41,000	Without Compromised Therapy:	375
		With Compromised Therapy:	46

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%	98.9%	95.9%	87.0%	64.6%	36.1%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.6%	99.5%	99.4%	99.2%
121,000	Effective Sample Size	107070	95500	85146	75887	67459	59734	51565	41507	27104	12976

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	**510**
Worldwide Distribution	**218,000**

US Approval Date: May 2012	**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
High battery impedance initiating safety mode 2021 (82)	0	1	1
Software			
Memory errors (51)	1	29	30
Other			
Non-patterned, other	44	414	458
Grand Total	**55**	**455**	**510**

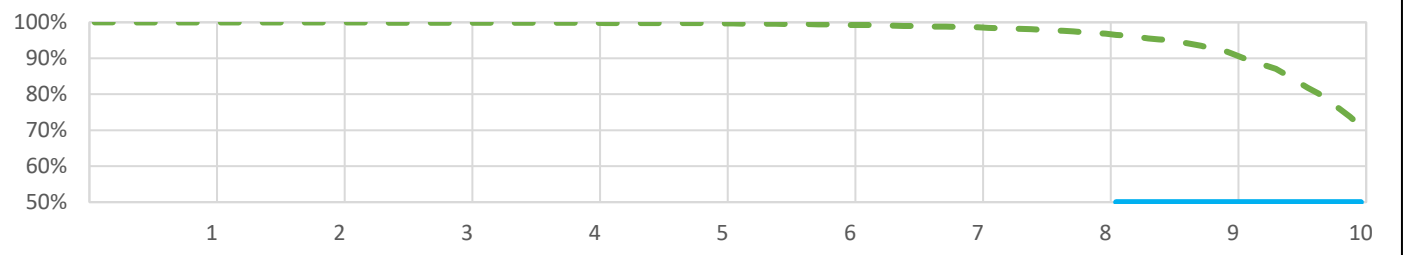
References cited in table above (link)

ADVANTIO/INGENIO/VITALIO EL DR

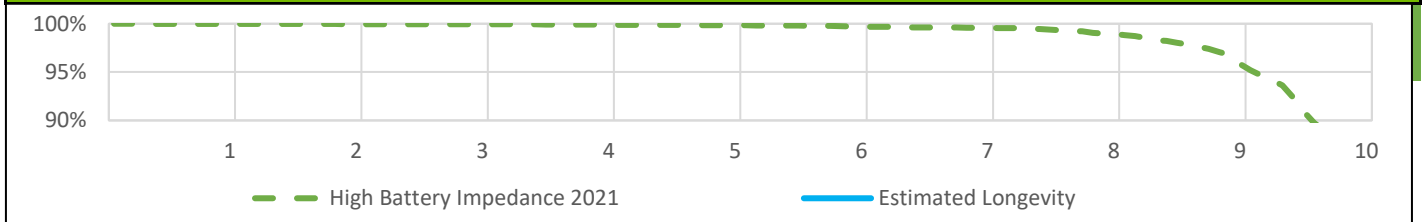
Models: J064/J067/J174/J177/J274/J277/K064/K067/K084/K087/K174/K177/K184/K187/K274/K277/K284/K287

US Summary			
US Registered Implants:	11,000	US Normal Battery Depletions:	586
US Approval Date:	May 2012	US Malfunctions:	866
US Estimated Active Implants:	4,000	Without Compromised Therapy:	805
		With Compromised Therapy:	61

Battery Depletions and Malfunctions



Malfunctions Only



US Survival Probability

	Year	1	2	3	4	5	6	7	8	9	10
High Battery Impedance 2021	Depletions and Malfunctions	100.0%	99.9%	99.9%	99.9%	99.7%	99.3%	98.7%	97.0%	92.3%	73.7%
Registered Implants:	Malfunctions Only	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.0%	96.8%	83.6%
11,000	Effective Sample Size	9675	8588	7639	6792	6038	5329	4604	3789	2852	1567

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

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	**2,048**
Worldwide Distribution	**75,000**

US Approval Date: May 2012	**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
High battery impedance initiating safety mode 2021 (82)	89	1390	1479
Software			
Memory errors (51)	1	11	12
Respiratory sensor (59)	0	1	1
Other			
Non-patterned, other	156	390	546
Grand Total	**251**	**1797**	**2048**

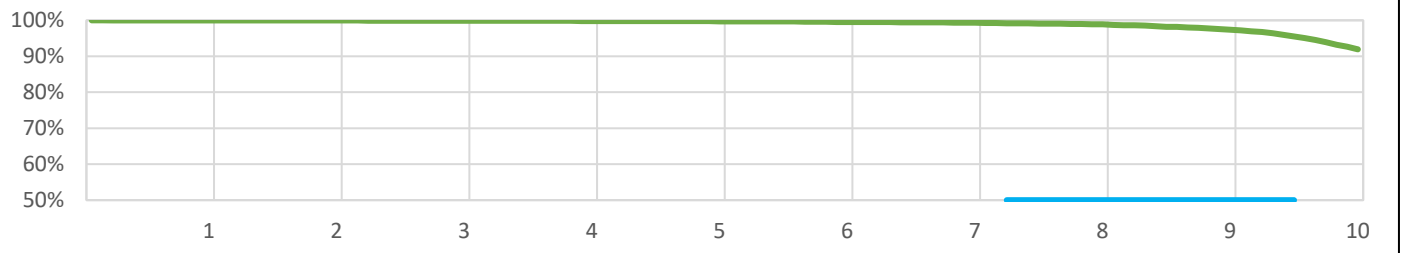
References cited in table above (link)

ADVANTIO/INGENIO/VITALIO/FORMIO SR

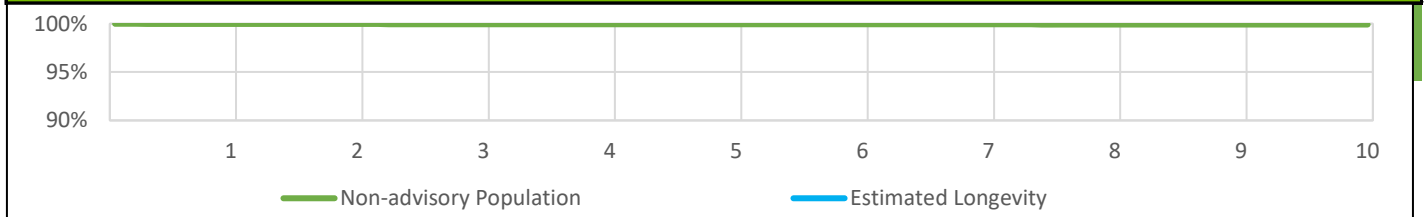
Models: J062/J065/J172/J175/J272/J275/K062/K065/K082/K085/K172/K175/K182/K185/K272/K275/K282/K285

US Summary			
US Registered Implants:	27,000	US Normal Battery Depletions:	2,180
US Approval Date:	May 2012	US Malfunctions:	20
US Estimated Active Implants:	11,000	Without Compromised Therapy:	18
		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%	99.8%	99.8%	99.6%	99.4%	98.9%	97.5%	92.6%
Registered Implants:	Malfunctions Only	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
27,000	Effective Sample Size	22729	20203	18016	16079	14332	12766	11390	10147	8954	7572

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	**40**
Worldwide Distribution	**86,000**

US Approval Date: May 2012	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	4	17	21
Grand Total	**9**	**31**	**40**

References cited in table above (link)

ALTRUA 2 DR

Models: S702

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

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Software			
Memory errors (51)	0	2	2
Electrical			
High battery impedance (89)	0	1	1
Integrated circuit (63)	0	1	1
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	0	11	11
High battery impedance initiating safety mode - December 2024 (90)	0	1	1
Grand Total	**0**	**16**	**16**

References cited in table above (link)

ALTRUA 2 EL DR

Models: S722

Worldwide Confirmed Malfunctions	**6**
Worldwide Distribution	**9,000**

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	0	3	3
Integrated circuit (63)	0	1	1
Other			
Non-patterned, other	1	1	2
Grand Total	**1**	**5**	**6**

References cited in table above (link)

ALTRUA 2 SR

Models: S701

Worldwide Confirmed Malfunctions	**17**
Worldwide Distribution	**12,000**

CE Mark Date: December 2018	With Compromised Therapy	Without Compromised Therapy	Total
Electrical			
Integrated circuit (63)	0	1	1
Hydrogen induced premature depletion - September 2018 and June 2021 (70)	2	12	14
Other			
Non-patterned, other	1	1	2
Grand Total	**3**	**14**	**17**

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 and June 2021 -** *September 2018 and June 2021 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 and 2020 –** *August 2019 and December 2020 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. Improvement implemented.
80. **EMBLEM S-ICD electrical overstress 2020—** *December 2020 Voluntary Physician Advisory.* Beeping tones, loss of telemetry, loss of sensing, premature battery depletion, loss of tachy therapy.
81. **RF antenna—** Beeping tones, loss of telemetry, loss of sensing, premature battery depletion, loss of tachy therapy. Exposed antenna issue.
82. **High battery impedance initiating safety mode 2021—** *June 2021 Voluntary Physician Advisory.* Safety mode operation, system resets. Temporary reduction in battery voltage later in device life.
84. **Battery depletion—** Beeping tones, device errors, premature battery depletion.
85. **Memory corruption**— Inability to interrogate, error messages upon interrogation, inappropriate shocks, loss of tachy therapy, and/or inaccurate patient information. Product returned with evidence of transient memory corruption.
86. **Cracked case**— Error messages upon interrogation, inability to interrogate, inappropriate shocks, loss of tachy therapy. Cracked outer case.
87. **Header**— Inability to interrogate, loss of tachy therapy. Header insulation issue.
88. **Solder joint**— Error messages upon interrogation, low impedance measurements, loss of tachy therapy. Fractured solder joint.
89. **High battery impedance**— Safety mode operation, system resets. Battery performance not as intended.
90. **High battery impedance initiating safety mode December 2024**— *December 2024 Voluntary Physician Advisory.* Safety mode operation, system resets. Battery performance not as intended.
91. **Battery liner—** High impedance, muscle stimulation, loss of capture, loss of pacing therapy. Battery liner issue.
92. **Unintended software behavior**— Software issue resulting in unintended device behavior.
93. **Battery impedance test performance**— Early replacement due to Code 1003 and/or ZIP Disablement from Brady SMR5 or SMR6 battery impedance test.

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	225,000	2	2	8	21	0	0
AUTOGEN CRT-D G160/G161/G164/G166/G168/G172/G173/G175/ G177/G179	25,000	3	0	0	4	0	0
DYNAGEN/INOGEN/ORIGEN CRT-D G150/G151/G154/G156/G158/G140/G141/ G146/G148/G050/G051/G056/G058	148,000	4	4	5	17	0	0

CRT-P/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
VISIONIST/VALITUDE U125/U128//U225/U226/U228	150,000	6	1	4	15	0	0
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	24,000	0	0	1	6	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	156,000	1	2	8	14	0	0
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	112,000	1	7	2	6	0	0
PERCIVA ICD DR D401/D413/D501/D513	14,000	0	0	0	1	0	0
PERCIVA ICD VR D400/D412/D500/D512	11,000	0	0	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	17,000	1	0	1	0	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	84,000	1	0	3	5	0	0
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	98,000	0	3	2	4	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	37,000	1	0	4	2	0	0
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	37,000	2	0	0	3	0	0

S-ICD/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
EMBLEM S-ICD A209/A219	190,000	4	0	5	161	0	0

Pacemaker/Model	Worldwide Distribution	Electrical	Mechanical	Software	Other	Labeling	Packaging
ACCOLADE/PROPONENT/ESSENTIO DR EL L121/L131/L221/L231/L321/L331	645,000	14	3	16	46	0	0
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	848,000	7	1	18	37	0	0
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	298,000	5	1	8	19	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	75,000	1	1	0	8	0	0
ADVANTIO/INGENIO/VITALIO/FORMIO DR J063/J066/J173/J176/J273/J276/J278/ J279/K063/K066/K083/K086/K173/ K176/K183/K186/K273/K276/K278/K279/	218,000	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	123000	1224	739	105	1738	10441
DYNAGEN/INOGEN/ORIGEN CRT-D G050/G051/G056/G058/G140/G141/G146/G148/G150/G151/G154/G156/G158	78000	9171	719	160	1453	17222
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	13227	544	825	964	20833
COGNIS N118/N119/N120/P106/P107/P108	75000	15990	447	2111	1693	40502

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	73000	2161	1843	771	592	12362
INTUA/INVIVE/INLIVEN V272/V273/V282/V283/W272/W273/V172/V173/V182/V183/W172/ W173	10000	1321	232	646	78	5057

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	78000	2648	1366	6097	1516	8324

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	86000	85	2722	68	981	4649
RESONATE/MOMENTUM/CHARISMA/VIGILANT ICD VR D120/D220/D232/D320/D332/D420/D432/D520/D532	45000	27	1719	40	525	2291
DYNAGEN/INOGEN/ORIGEN ICD EL DR D052/D053/D142/D143/D152/D153	52000	326	3366	205	839	8180
DYNAGEN/INOGEN/ORIGEN ICD EL VR D050/D051/D140/D141/D150/D151	40000	100	3020	221	640	5968
DYNAGEN/INOGEN/ORIGEN ICD MINI DR D002/D003/D012/D013/D022/D023	12000	3209	574	28	158	2431
DYNAGEN/INOGEN/ORIGEN ICD MINI VR D000/D001/D010/D011/D020/D021	10000	2268	616	22	146	1947
INCEPTA/ENERGEN/PUNCTUA ICD VR E050/E051/E140/E141/E160/E160/ F050/F051/F140/F141/F160/F161	39000	1935	3237	1361	619	11913
INCEPTA/ENERGEN/PUNCTUA ICD DR E052/E053/E142/E143/E162/E163/F052/F053/F142/F143/F162/F163	47000	7822	3490	1310	761	15313
TELIGEN VR E102/E103/F102/F103	38000	6086	2292	2432	691	17764
TELIGEN DR E110/E111/F110/F111	66000	13374	3083	3059	1167	31903

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	250000	1084	8791	2598	1461	23583
ACCOLADE/PROPONENT/ESSENTIO DR L101/L111/L201/L211/L301/L311	359000	26458	11395	2847	1934	55286
ACCOLADE/PROPONENT/ESSENTIO SR L100/L110/L200/L210/L300/L310	64000	1422	2579	644	310	14661
ADVANTIO/INGENIO/VITALIO EL DR J064/J067/K064/K067/K084/K087/ J174/J177/K174/K177/K184/K187/ J274/J277/K274/K277/K284/K287	11000	585	549	867	62	4923
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	32595	4336	423	585	42258
ADVANTIO/INGENIO/VITALIO SR J062/J065/K062/K065/K082/K085/ J172/J175/K172/K175/K182/K185/ J272/J275/K272/K275/K282/K285	27000	2178	827	21	116	12613

[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.

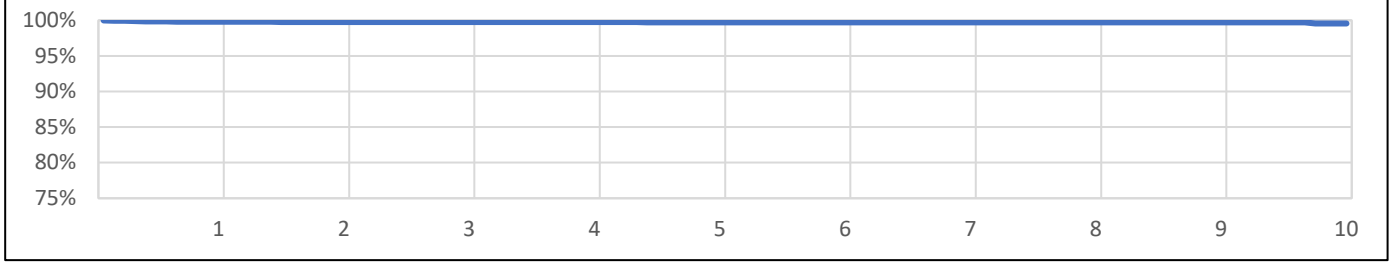
[3] Other consists of: patient death, elective replacement, general product dissatisfaction, other observation/complication, unspecifed, or unknown.

ACUITY X4 Spiral L

Models: 4677/4678

US Summary			
US Registered Implants:	27,000	US Chronic Complications	64
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	23,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.6%
Registered Implants: 27000	Effective Sample Size	21922	17733	14190	11211	8655	6479	4661	2901	1492	482

ACUITY X4 Spiral L

Models: 4677/4678

Worldwide Confirmed Malfunctions	**2**
Worldwide Distribution	**65,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	2	2
Grand Total	**0**	**2**	**2**

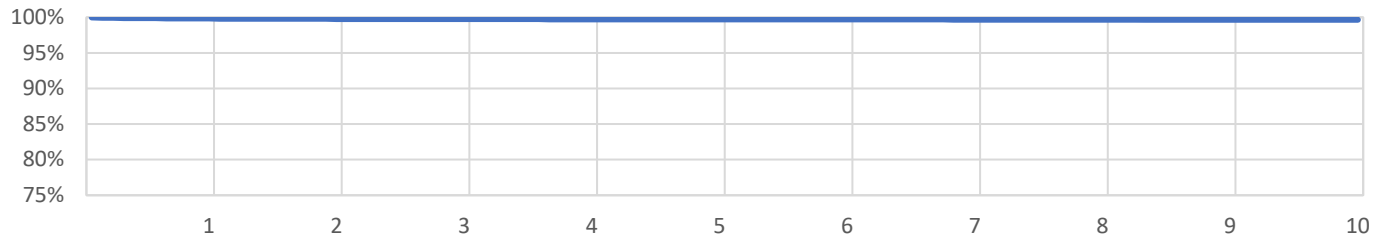
References cited in table above (link)

ACUITY X4 Spiral S

Models: 4674/4675

US Summary			
US Registered Implants:	82,000	US Chronic Complications	189
US Approval Date:	February 2016	US Malfunctions:	1
US Estimated Active Implants:	70,000	Without Compromised Therapy:	1
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%
Registered Implants: 82000	Effective Sample Size	66141	53253	42088	32519	24477	17763	12083	7279	3656	897

ACUITY X4 Spiral S

Models: 4674/4675

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**176,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	1	1
Grand Total	**0**	**1**	**1**

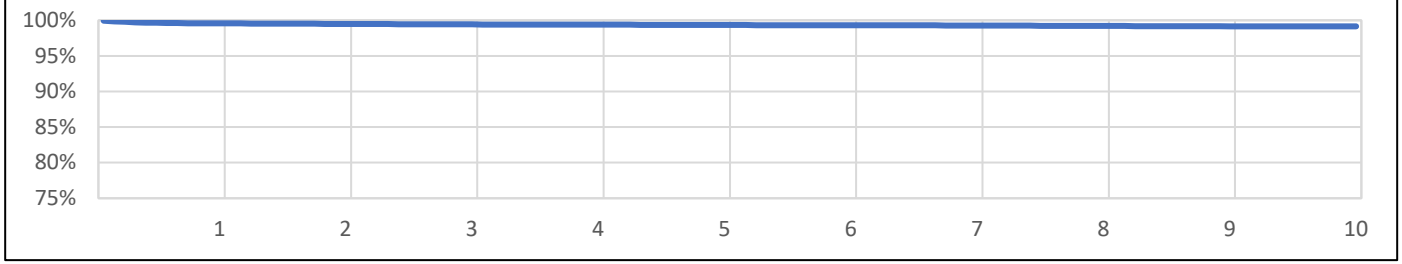
References cited in table above (link)

ACUITY X4 Straight

Models: 4671/4672

US Summary			
US Registered Implants:	61,000	US Chronic Complications	335
US Approval Date:	February 2016	US Malfunctions:	2
US Estimated Active Implants:	51,000	Without Compromised Therapy:	2
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.6%	99.5%	99.4%	99.4%	99.3%	99.3%	99.3%	99.2%	99.2%	99.2%
Registered Implants: 61000	Effective Sample Size	48890	39664	31503	24439	18373	13094	8808	5152	2576	644

ACUITY X4 Straight

Models: 4671/4672

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**136,000**

US Approval Date: February 2016	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	4	4
Grand Total	**0**	**4**	**4**

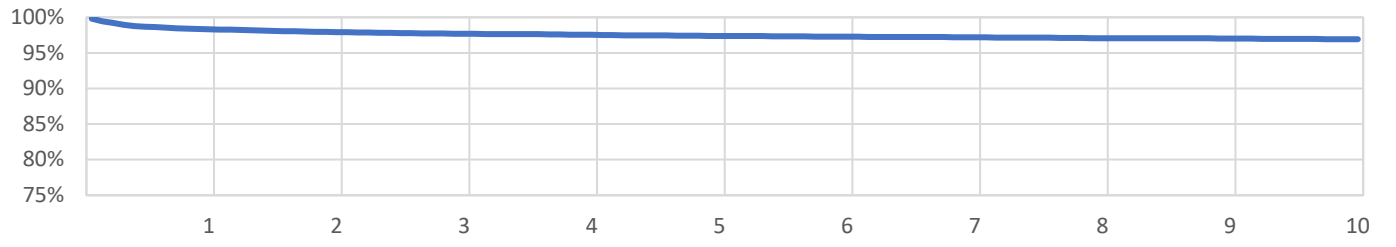
References cited in table above (link)

ACUITY Spiral

Models: 4591/4592/4593

US Summary			
US Registered Implants:	24,000	US Chronic Complications	590
US Approval Date:	May 2008	US Malfunctions:	9
US Estimated Active Implants:	11,000	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	Complications and Malfunctions	98.3%	97.9%	97.7%	97.5%	97.4%	97.3%	97.2%	97.1%	97.0%	96.9%
Registered Implants: 24000	Effective Sample Size	20092	17910	15996	14284	12732	11300	10028	8816	7742	6768

ACUITY Spiral

Models: 4591/4592/4593

Worldwide Confirmed Malfunctions	**9**
Worldwide Distribution	**47,000**

US Approval Date: May 2008	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	4	5	9
Grand Total	**4**	**5**	**9**

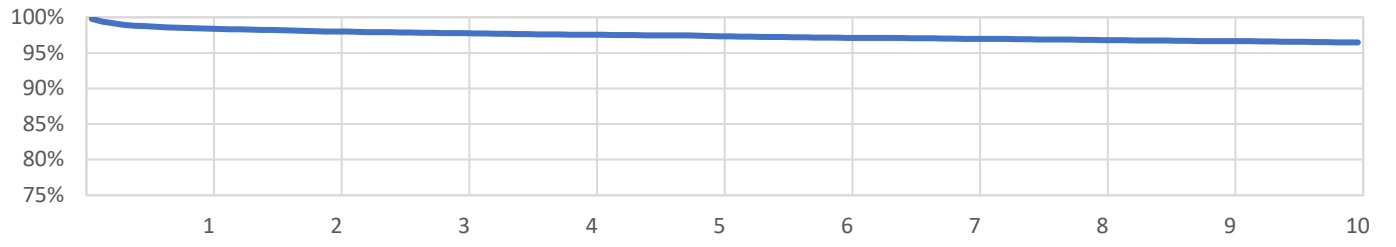
References cited in table above (link)

ACUITY Steerable

Models: 4554/4555/4556

US Summary			
US Registered Implants:	29,000	US Chronic Complications	766
US Approval Date:	May 2008	US Malfunctions:	33
US Estimated Active Implants:	11,000	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	Complications and Malfunctions	98.4%	98.0%	97.8%	97.5%	97.3%	97.1%	97.0%	96.8%	96.6%	96.5%
Registered Implants: 29000	Effective Sample Size	24424	21825	19555	17556	15761	14127	12648	11339	10154	9045

ACUITY Steerable

Models: 4554/4555/4556

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

US Approval Date: May 2008	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**

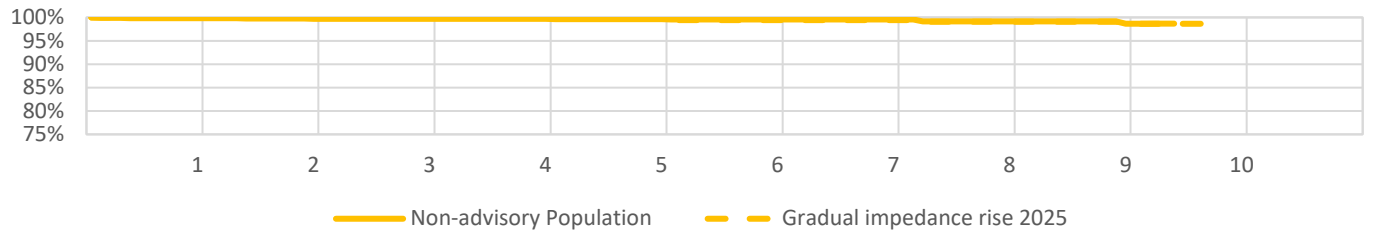
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

US Summary			
US Registered Implants:	17,000	US Chronic Complications	50
US Approval Date:	May 2018	US Malfunctions:	1
US Estimated Active Implants:	15,000	Without Compromised Therapy:	-
		With Compromised Therapy:	1

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.7%	99.7%	99.6%	99.5%	99.5%	99.1%	98.7%	98.7%
Registered Implants: 17000	Effective Sample Size	12376	9451	6886	4731	2797	1269	285	229	205	206

@ 113 month

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

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

US Survival Probability (cont.)												
Year		1	2	3	4	5	6	7	8	9	10	
Gradual Rise in Impedance 2025	Complications and Malfunctions	100.0%	100.0%	100.0%	100.0%	99.7%	99.5%	99.5%	99.1%	98.6%	98.6%	
Registered Implants: 1000	Effective Sample Size	535	479	433	389	348	311	280	248	223	203	@ 116 month

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

ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation

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

Worldwide Confirmed Malfunctions	**7**
Worldwide Distribution	**42,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	7	0	7
Grand Total	**7**	**0**	**7**

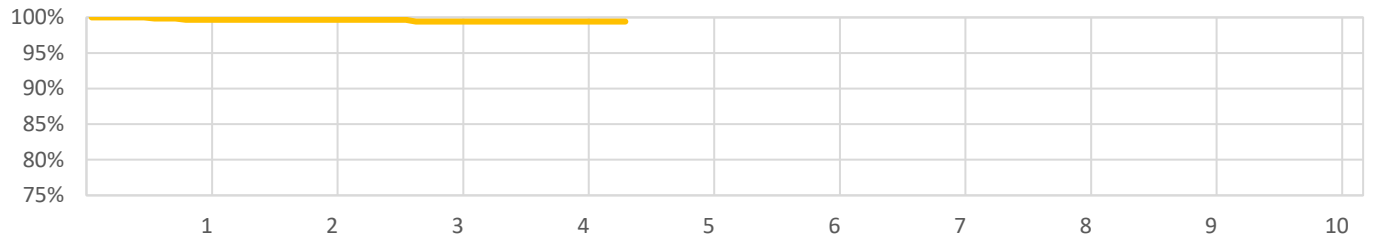
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

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

US Summary			
US Registered Implants:	1,000	US Chronic Complications	3
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	1,000	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	Complications and Malfunctions	99.7%	99.7%	99.4%	99.4%	99.4%	--	--	--	--	--
Registered Implants: 1000	Effective Sample Size	586	455	336	229	201	--	--	--	--	--

@ 52 months

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

ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation

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

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

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	0	0	0
Grand Total	**0**	**0**	**0**

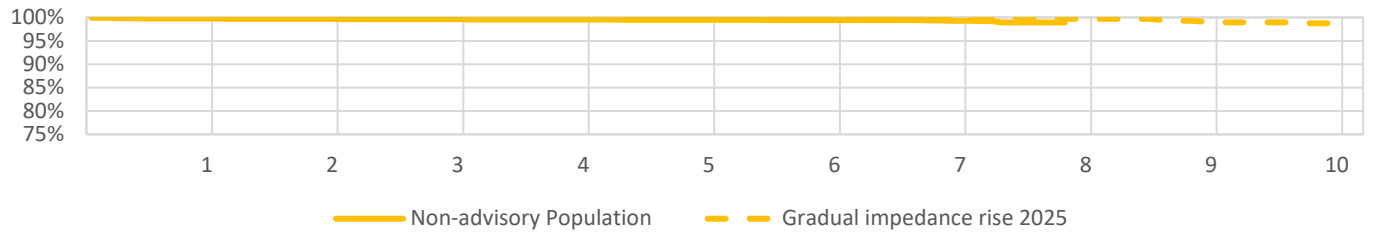
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Summary			
US Registered Implants:	148,000	US Chronic Complications	490
US Approval Date:	May 2018	US Malfunctions:	30
US Estimated Active Implants:	137,000	Without Compromised Therapy:	6
		With Compromised Therapy:	24

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.7%	99.6%	99.5%	99.5%	99.4%	99.3%	98.9%	--	--
Registered Implants: 147000	Effective Sample Size	108496	77967	53806	36192	22337	10762	2610	205	--	--

@ 94 months

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

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

Models: 0657/0672/0673/0692/0693

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	100.0%	100.0%	100.0%	99.9%	99.7%	99.7%	99.7%	99.7%	99.1%	98.7%
Registered Implants: 1000	Effective Sample Size	1270	1142	1024	926	831	745	670	598	533	476

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

ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation

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

Worldwide Confirmed Malfunctions	**132**
Worldwide Distribution	**419,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	30	0	30
Other			
Gradual rise in shock impedance 2025 (45)	0	7	7
Non-patterned, other	76	19	95
Grand Total	**106**	**26**	**132**

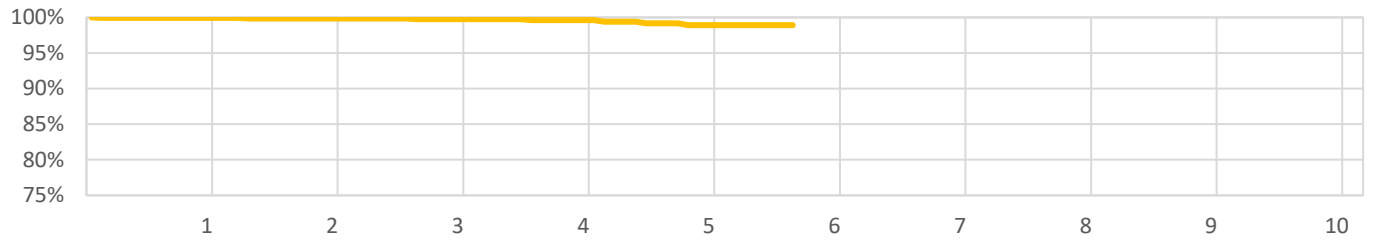
References cited in table above (link)

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

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

US Summary			
US Registered Implants:	3,000	US Chronic Complications	8
US Approval Date:	May 2018	US Malfunctions:	-
US Estimated Active Implants:	2,000	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	Complications and Malfunctions	99.9%	99.9%	99.8%	99.6%	98.9%	98.9%	--	--	--	--
	Effective Sample Size	1878	1342	888	550	327	202	--	--	--	--
Registered Implants: 3000											

@ 68 months

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

ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation

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

Worldwide Confirmed Malfunctions	**1**
Worldwide Distribution	**11,000**

US Approval Date: May 2018	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor cable fracture (38)	1	0	1
Grand Total	**1**	**0**	**1**

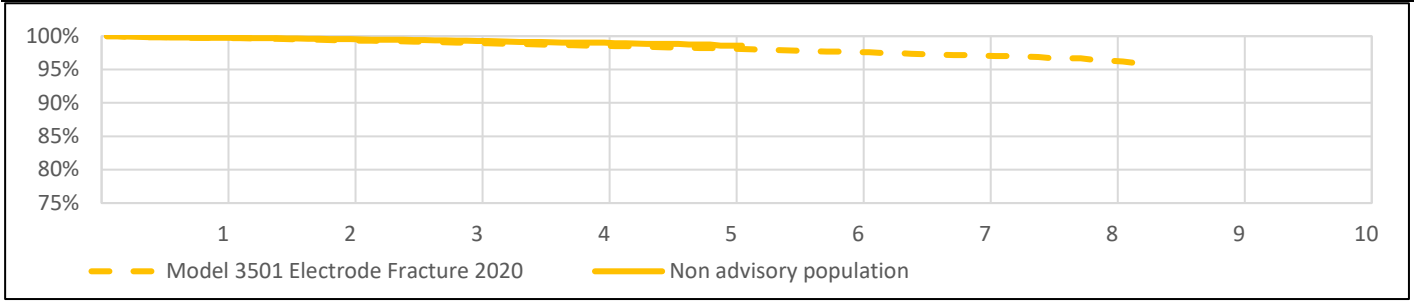
References cited in table above (link)

EMBLEM S-ICD Electrode

Models: 3501

US Summary			
US Registered Implants:	49,000	US Chronic Complications	359
US Approval Date:	September 2017	US Malfunctions:	153
US Estimated Active Implants:	43,000	Without Compromised Therapy:	19
		With Compromised Therapy:	134

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non advisory population	Complications and Malfunctions	99.8%	99.6%	99.3%	99.0%	98.6%	98.1%	--	--	--	--
Registered Implants: 20000	Effective Sample Size	20209	13518	7971	3541	316	234	--	--	--	--

@ 61 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 Electrode

Models: 3501

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Model 3501 Electrode Fracture 2020	Complications and Malfunctions	99.7%	99.4%	99.0%	98.5%	98.1%	97.6%	97.1%	96.3%	95.8%	--
Registered Implants: 21000	Effective Sample Size	17544	15526	13773	12226	10843	7001	3674	938	283	--

@ 100 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 Electrode

Models: 3501

Worldwide Confirmed Malfunctions	**380**
Worldwide Distribution	**132,000**

US Approval Date: September 2017	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Model 3501 electrode fracture 2020 (42)	110	3	113
Electrode conductor fracture in or near the pocket (44)	212	31	243
Other			
Non-patterned, other	15	9	24
Grand Total	**337**	**43**	**380**

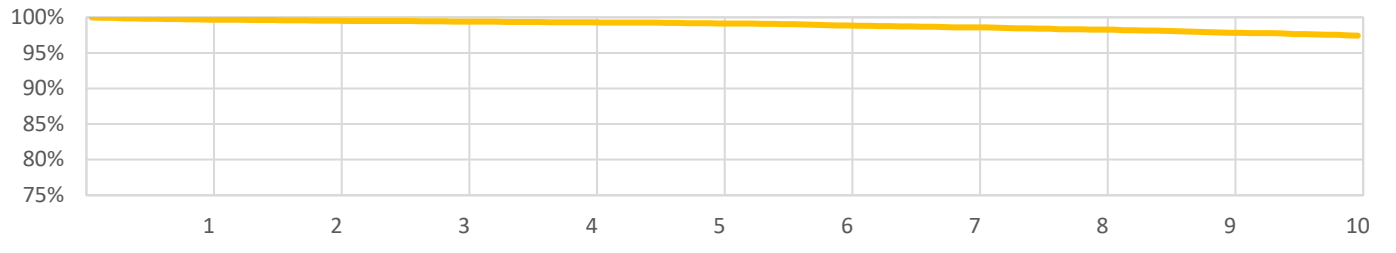
References cited in table above (link)

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

US Summary			
US Registered Implants:	24,000	US Chronic Complications	278
US Approval Date:	September 2012	US Malfunctions:	49
US Estimated Active Implants:	17,000	Without Compromised Therapy:	18
		With Compromised Therapy:	31

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.5%	99.4%	99.3%	99.1%	98.8%	98.6%	98.3%	97.8%	97.4%
Registered Implants: 24000	Effective Sample Size	21000	18670	16613	14764	13027	11377	9900	8501	5996	3412

EMBLEM/Q-TRAK S-ICD Electrode

Models: 3010/3401

Worldwide Confirmed Malfunctions	**123**
Worldwide Distribution	**43,000**

US Approval Date: September 2012	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Electrode conductor fracture in or near the pocket (44)	51	10	61
Crimp/Weld/Bond			
Weld fracture (37)	3	0	3
Other			
Non-patterned, other	34	25	59
Grand Total	**88**	**35**	**123**

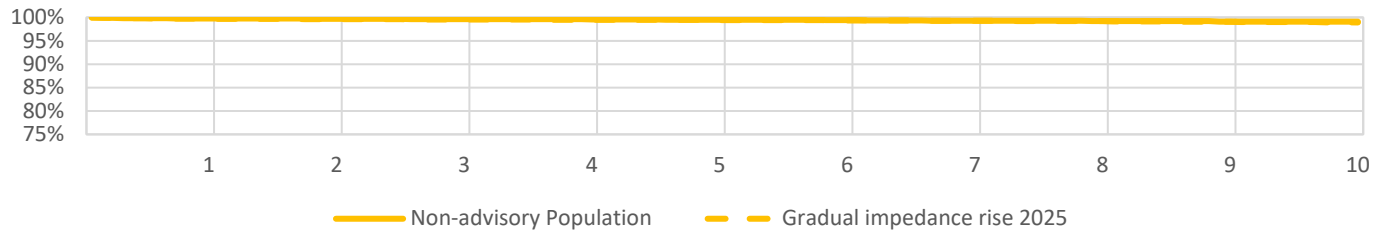
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Summary			
US Registered Implants:	78,000	US Chronic Complications	545
US Approval Date:	November 2010	US Malfunctions:	40
US Estimated Active Implants:	54,000	Without Compromised Therapy:	9
		With Compromised Therapy:	31

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	99.1%
Registered Implants: 9000	Effective Sample Size	6680	5952	5163	4312	3547	2791	2238	1860	1527	1206

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

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%
Registered Implants: 69000	Effective Sample Size	62175	55770	50093	45017	40480	36147	31577	25959	20573	15807

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

ENDOTAK RELIANCE 4-Site Dual Coil, Active Fixation

Models: 0275/0276/0295/0296

Worldwide Confirmed Malfunctions	**77**
Worldwide Distribution	**127,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	3	0	3
Other			
Gradual rise in shock impedance 2025 (45)	3	1	4
Non-patterned, other	55	15	70
Grand Total	**61**	**16**	**77**

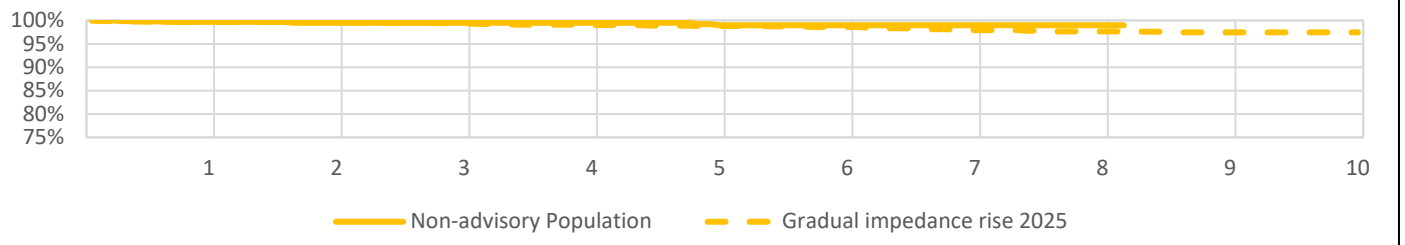
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Summary			
US Registered Implants:	3,000	US Chronic Complications	51
US Approval Date:	November 2010	US Malfunctions:	3
US Estimated Active Implants:	2,000	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	Complications and Malfunctions	99.7%	99.5%	99.5%	99.5%	99.0%	99.0%	99.0%	99.0%	99.0%	--	
Registered Implants: 500	Effective Sample Size	614	550	492	423	351	291	244	207	201	--	@ 98 months

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

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.7%	99.6%	99.3%	99.0%	98.8%	98.6%	98.0%	97.7%	97.5%	97.5%
Registered Implants: 3000	Effective Sample Size	2390	2146	1922	1723	1542	1370	1176	959	762	577

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

ENDOTAK RELIANCE 4-Site Dual Coil, Passive Fixation

Models: 0265/0266/0285/0286

Worldwide Confirmed Malfunctions	**4**
Worldwide Distribution	**11,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Gradual rise in shock impedance 2025 (45)	0	1	1
Non-patterned, other	0	3	3
Grand Total	**0**	**4**	**4**

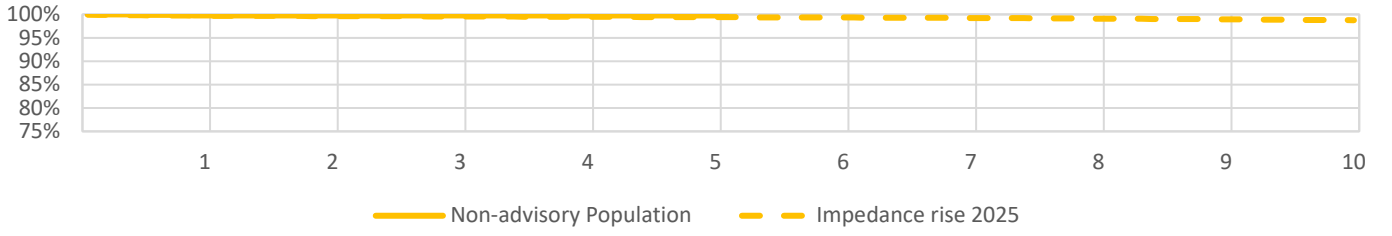
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Summary			
US Registered Implants:	120,000	US Chronic Complications	832
US Approval Date:	November 2010	US Malfunctions:	88
US Estimated Active Implants:	91,000	Without Compromised Therapy:	29
		With Compromised Therapy:	59

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.8%	99.8%	99.8%	99.8%	99.8%	--	--	--	--
Registered Implants: 1000	Effective Sample Size	867	726	561	394	218	205	--	--	--	--

@ 61 months

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

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.7%	99.6%	99.6%	99.5%	99.4%	99.3%	99.2%	99.1%	98.9%	98.8%
Registered Implants: 119000	Effective Sample Size	104951	94210	84644	76039	68302	61070	53461	40031	27044	17613

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

ENDOTAK RELIANCE 4-Site Single Coil, Active Fixation

Models: 0272/0273/0292/0293

Worldwide Confirmed Malfunctions	**143**
Worldwide Distribution	**221,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	12	0	12
Other			
Gradual rise in shock impedance 2025 (45)	3	15	18
Non-patterned, other	86	27	113
Grand Total	**101**	**42**	**143**

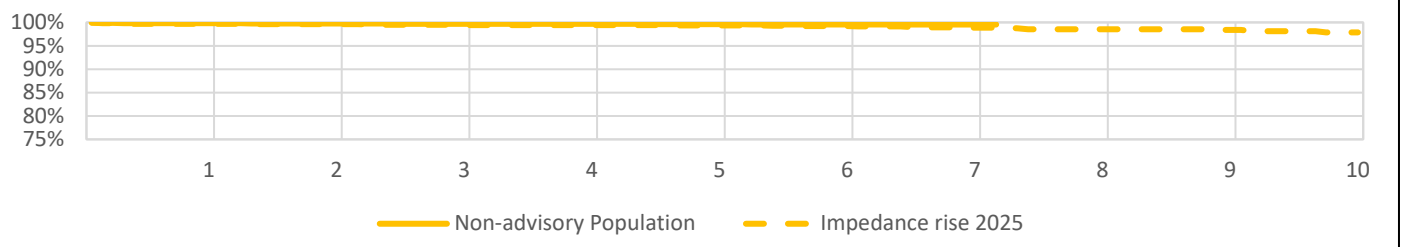
References cited in table above (link)

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Summary			
US Registered Implants:	26,000	US Chronic Complications	88
US Approval Date:	November 2010	US Malfunctions:	9
US Estimated Active Implants:	23,000	Without Compromised Therapy:	3
		With Compromised Therapy:	6

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%	99.5%	99.5%	--	--
Registered Implants: 24000	Effective Sample Size	20420	17882	14399	10069	6395	3157	724	357	--	--

@ 86 mont

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

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.7%	99.6%	99.4%	99.4%	99.4%	99.2%	98.9%	98.6%	98.4%	97.9%
Registered Implants: 2000	Effective Sample Size	2144	1918	1720	1549	1388	1233	1052	774	497	305

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

ENDOTAK RELIANCE 4-Site Single Coil, Passive Fixation

Models: 0262/0263/0282/0283

Worldwide Confirmed Malfunctions	**14**
Worldwide Distribution	**44,000**

US Approval Date: November 2010	With Compromised Therapy	Without Compromised Therapy	Total
Other			
Non-patterned, other	10	4	14
Grand Total	**10**	**4**	**14**

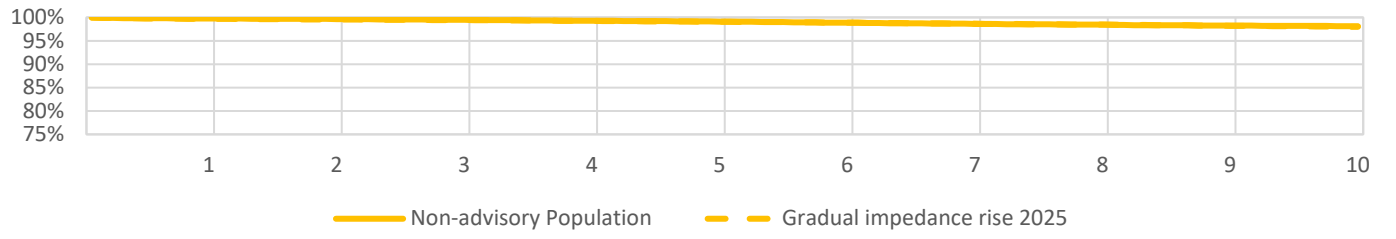
References cited in table above (link)

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	4,010
US Approval Date:	July 2002	US Malfunctions:	414
US Estimated Active Implants:	99,000	Without Compromised Therapy:	138
		With Compromised Therapy:	276

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.5%	99.3%	99.1%	98.9%	98.6%	98.4%	98.3%	98.1%
Registered Implants: 102000	Effective Sample Size	84200	75606	67856	60781	54440	48658	43558	39071	35045	31437

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

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.7%	99.5%	99.4%	99.3%	99.1%	98.9%	98.7%	98.5%	98.2%	98.0%
Registered Implants: 185000	Effective Sample Size	166116	149063	133950	120324	108025	96790	86630	77467	69210	61802

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

ENDOTAK RELIANCE Dual Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**616**
Worldwide Distribution	**383,000**

US Approval Date: July 2002	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	106	0	106
Crimp/Weld/Bond			
Seal rings (5)	2	2	4
Other			
Gradual rise in shock impedance 2025 (45)	3	2	5
Non-patterned, other	283	218	501
Grand Total	**394**	**222**	**616**

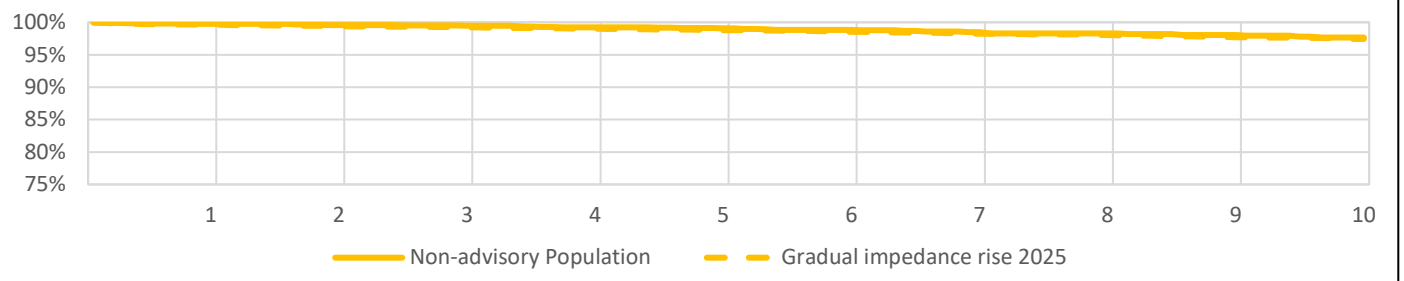
References cited in table above (link)

ENDOTAK RELIANCE Single Coil, Active Fixation

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

US Summary			
US Registered Implants:	36,000	US Chronic Complications	573
US Approval Date:	October 2000	US Malfunctions:	110
US Estimated Active Implants:	21,000	Without Compromised Therapy:	32
		With Compromised Therapy:	78

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.6%	99.5%	99.2%	99.1%	98.8%	98.5%	98.3%	98.0%	97.7%
Registered Implants: 6000	Effective Sample Size	4106	3270	2568	2011	1543	1179	987	881	791	703

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

ENDOTAK RELIANCE Single Coil, Active Fixation

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

US Survival Probability (cont.)											
Year		1	2	3	4	5	6	7	8	9	10
Gradual Rise in Impedance 2025	Complications and Malfunctions	99.6%	99.4%	99.2%	99.0%	98.8%	98.6%	98.3%	98.0%	97.7%	97.4%
Registered Implants: 30000	Effective Sample Size	26853	24061	21592	19355	17344	15469	13656	11980	10445	9031

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

ENDOTAK RELIANCE Single Coil, Active Fixation

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

Worldwide Confirmed Malfunctions	**236**
Worldwide Distribution	**83,000**

US Approval Date: October 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Conductor fracture (24)	62	1	63
Other			
Gradual rise in shock impedance 2025 (45)	6	4	10
Non-patterned, other	99	64	163
Grand Total	**167**	**69**	**236**

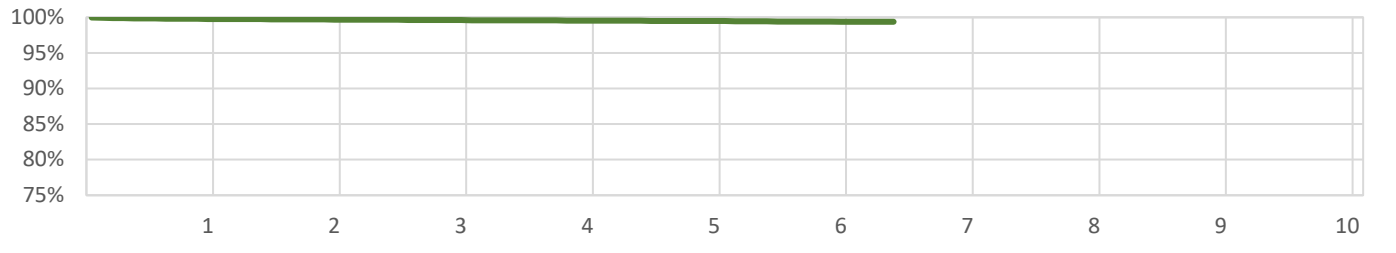
References cited in table above (link)

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

US Summary			
US Registered Implants:	603,000	US Chronic Complications	1,671
US Approval Date:	December 2019	US Malfunctions:	271
US Estimated Active Implants:	556,000	Without Compromised Therapy:	171
		With Compromised Therapy:	100

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.5%	99.4%	99.4%	--	--	--	
Registered Implants: 603000	Effective Sample Size	444816	317440	212000	126849	58837	7043	1096	--	--	--	@ 77 months

INGEVITY+ Positive Fixation

Models: 7840/7841/7842

Worldwide Confirmed Malfunctions	312
Worldwide Distribution	1,260,000

US Approval Date: December 2019	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	0	1	1
Extracardiac fracture (41)	47	78	125
Other			
Insulation (43)	1	17	18
Non-patterned, other	63	105	168
Grand Total	**111**	**201**	**312**

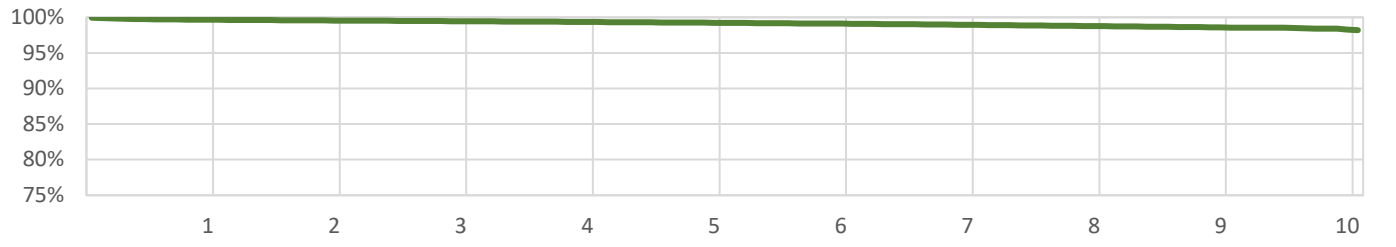
References cited in table above (link)

INGEVITY Positive Fixation

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

US Summary			
US Registered Implants:	365,000	US Chronic Complications	2,707
US Approval Date:	April 2016	US Malfunctions:	407
US Estimated Active Implants:	283,000	Without Compromised Therapy:	240
		With Compromised Therapy:	167

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.5%	99.3%	99.2%	99.1%	98.9%	98.8%	98.6%	98.3%
Registered Implants: 365000	Effective Sample Size	321945	288601	258915	232362	208567	185622	130388	77422	34624	2128

INGEVITY Positive Fixation

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

Worldwide Confirmed Malfunctions	**578**
Worldwide Distribution	**1,154,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Inner conductor break (39)	12	12	24
Extracardiac fracture (41)	128	183	311
Other			
Insulation (43)	3	39	42
Non-patterned, other	94	107	201
Grand Total	**237**	**341**	**578**

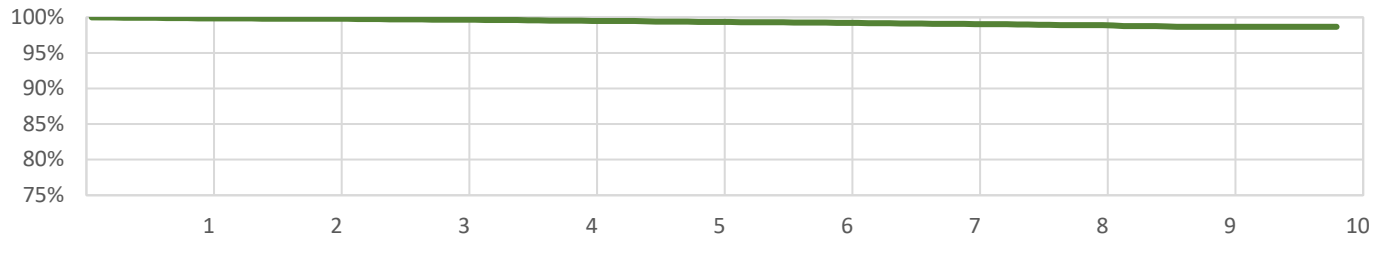
References cited in table above (link)

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

US Summary			
US Registered Implants:	35,000	US Chronic Complications	163
US Approval Date:	April 2016	US Malfunctions:	20
US Estimated Active Implants:	29,000	Without Compromised Therapy:	4
		With Compromised Therapy:	16

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.9%	99.8%	99.7%	99.5%	99.3%	99.2%	99.1%	98.9%	98.7%	98.7%	
Registered Implants: 35000	Effective Sample Size	29193	24542	20132	15977	12292	9029	6152	3696	1649	271	@ 118 month

INGEVITY Passive Fixation

Models: 7631/7632/7731/7732

Worldwide Confirmed Malfunctions	**29**
Worldwide Distribution	**156,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	9	0	9
Other			
Insulation (43)	0	2	2
Non-patterned, other	15	3	18
Grand Total	**24**	**5**	**29**

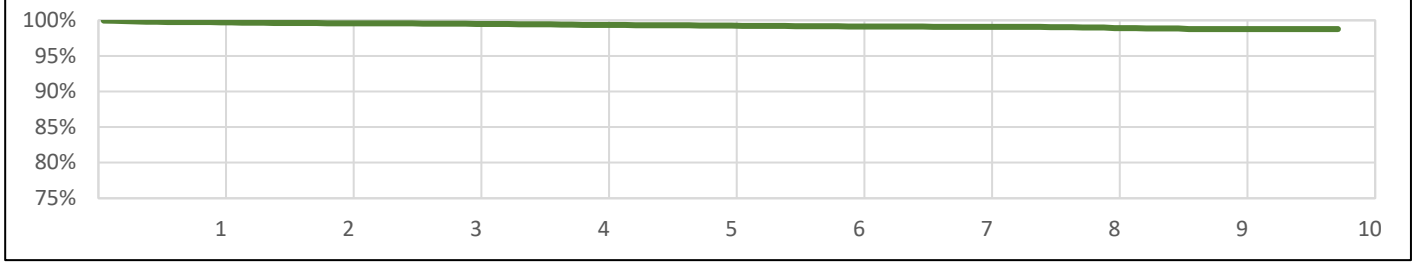
References cited in table above (link)

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

US Summary			
US Registered Implants:	22,000	US Chronic Complications	118
US Approval Date:	April 2016	US Malfunctions:	11
US Estimated Active Implants:	19,000	Without Compromised Therapy:	11
		With Compromised Therapy:	-

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10	
Non-Advisory Population	Complications and Malfunctions	99.7%	99.6%	99.5%	99.3%	99.2%	99.1%	99.1%	98.9%	98.8%	98.8%	
Registered Implants: 22000	Effective Sample Size	17723	14600	11805	9340	7236	5308	3665	2172	910	245	@ 117 month

INGEVITY Atrial J Passive Fixation

Models: 7635/7636/7735/7736

Worldwide Confirmed Malfunctions	**19**
Worldwide Distribution	**162,000**

US Approval Date: April 2016	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Extracardiac fracture (41)	0	9	9
Crimp/Weld/Bond			
Weld (40)	0	1	1
Other			
Non-patterned, other	0	9	9
Grand Total	**0**	**19**	**19**

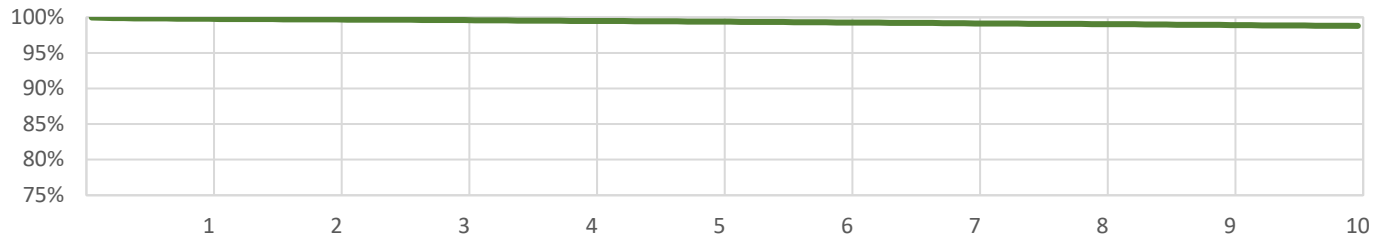
References cited in table above (link)

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

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

US Summary			
US Registered Implants:	542,000	US Chronic Complications	4,127
US Approval Date:	January 2000	US Malfunctions:	187
US Estimated Active Implants:	267,000	Without Compromised Therapy:	67
		With Compromised Therapy:	120

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.5%	99.4%	99.3%	99.1%	99.0%	98.9%	98.8%
Registered Implants: 542000	Effective Sample Size	472676	417981	368864	324403	285104	249670	216804	186795	160517	138273

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

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

Worldwide Confirmed Malfunctions	**222**
Worldwide Distribution	**868,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	66	19	85
Crimp/Weld/Bond			
Terminal weld (23)	1	0	1
Other			
Lead body (4)	72	33	105
Non-patterned, other	10	20	30
Insulation (43)	0	1	1
Grand Total	**149**	**73**	**222**

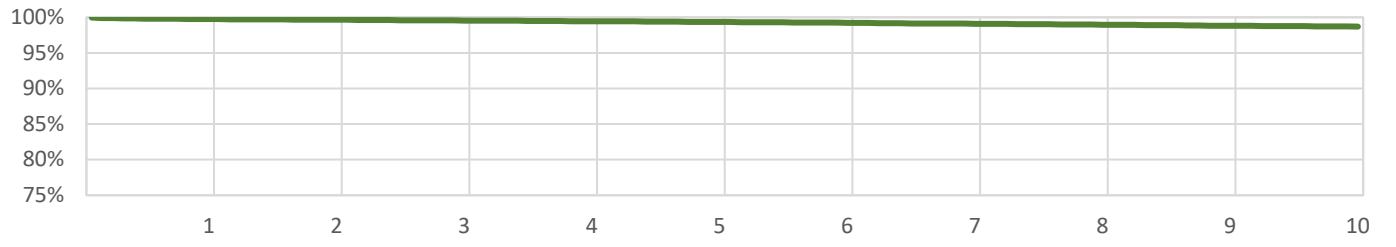
References cited in table above (link)

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

US Summary			
US Registered Implants:	201,000	US Chronic Complications	1,734
US Approval Date:	January 2000	US Malfunctions:	48
US Estimated Active Implants:	73,000	Without Compromised Therapy:	3
		With Compromised Therapy:	45

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.8%	99.7%	99.6%	99.4%	99.3%	99.2%	99.1%	99.0%	98.8%	98.7%
Registered Implants: 201000	Effective Sample Size	173377	155024	138294	123266	109776	97639	86513	76366	67210	59111

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane)

Models: 4452/4453/4456/4457

Worldwide Confirmed Malfunctions	**71**
Worldwide Distribution	**564,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	20	0	20
Other			
Lead body (4)	41	3	44
Non-patterned, other	6	1	7
Grand Total	**67**	**4**	**71**

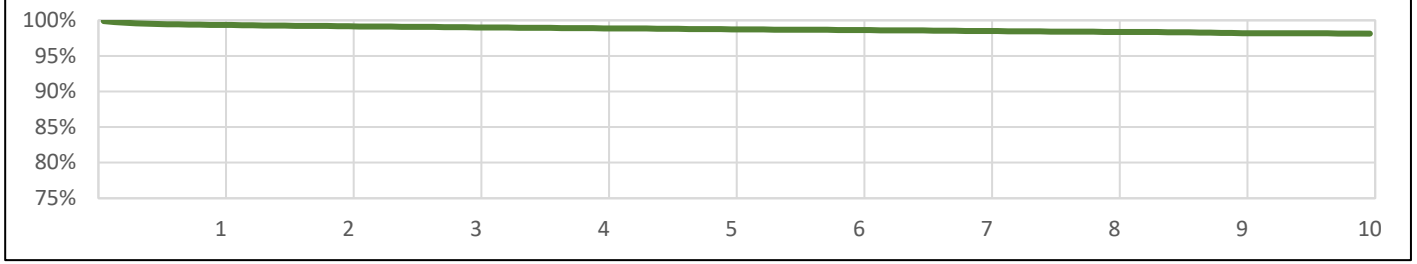
References cited in table above (link)

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

US Summary			
US Registered Implants:	64,000	US Chronic Complications	877
US Approval Date:	January 2000	US Malfunctions:	39
US Estimated Active Implants:	26,000	Without Compromised Therapy:	20
		With Compromised Therapy:	19

Complications and Malfunctions



US Survival Probability

Year		1	2	3	4	5	6	7	8	9	10
Non-Advisory Population	Complications and Malfunctions	99.3%	99.2%	99.0%	98.9%	98.7%	98.6%	98.5%	98.4%	98.2%	98.1%
Registered Implants: 64000	Effective Sample Size	55846	49937	44673	40014	35849	32030	28557	25373	22365	19663

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)

Models: 4477/4478/4479/4480

Worldwide Confirmed Malfunctions	**79**
Worldwide Distribution	**335,000**

US Approval Date: January 2000	With Compromised Therapy	Without Compromised Therapy	Total
Conductor			
Lead conductor (7)	5	2	7
Other			
J-shape (22)	26	30	56
Lead body (4)	8	3	11
Non-patterned, other	3	2	5
Grand Total	**42**	**37**	**79**

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. **Model 3501 electrode fracture 2020**— *December 2020 Voluntary Physician Advisory*. High shock impedance, loss of tachy therapy. Fractured electrode conductor immediately distal to the proximal sense electrode. Note: per ISO 5841-2:2(E), only returned and confirmed failures are included in this table. All failures associated with this pattern – including reports that are not returned - are included in rate calculations and projections updated in the advisory section.
43. **Insulation**— High pacing impedance, noise, undersensing. Insulation issue.
44. **Electrode conductor fracture in or near pocket**— High shock impedance, loss of tachy therapy. Fractured electrode conductor proximal to the proximal sense electrode.
45. **Gradual rise in impedance 2025**— Gradual rise in shock impedance, potential loss of tachy therapy. Calcification on ePTFE

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 7840/7841/7842	603,000	167	305	774	240	48	27	10	98	0	2
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	153	963	637	358	185	33	78	275	0	25
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	22,000	0	31	53	16	4	3	2	9	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	35,000	3	62	24	28	10	4	3	29	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	201,000	6	516	254	318	82	36	220	283	0	19
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	542,000	31	928	959	568	228	171	625	586	0	31
FINELINE II Atrial J (poly) 4477/4478/4479/4480	64,000	2	137	373	147	32	36	84	58	0	8

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	27,000	1	0	40	13	1	0	0	1	0	8
ACUITY X4 Spiral S 4674/4675	82,000	1	4	141	18	3	0	1	2	0	19
ACUITY X4 Straight 4671/4672	61,000	1	2	221	43	1	0	1	9	0	57
ACUITY Steerable 4554/4555/4556	29,000	6	52	467	73	6	2	19	43	0	98
ACUITY Spiral 4591/4592/4593	24,000	0	28	344	60	0	1	5	14	0	138

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 0652/0657/0672/0673/0692/0693	148,000	53	96	190	55	37	10	0	32	14	3
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0663/0682/0683	3,000	0	3	3	1	1	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	17,000	4	6	23	4	5	1	2	1	3	1
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	1,000	0	0	2	0	0	0	0	1	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	17,000	4	6	23	4	5	1	2	1	3	1
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	78,000	27	78	128	46	99	17	24	40	79	7
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	1	5	9	7	9	0	0	16	3	1
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	142,000	42	131	226	82	139	29	19	75	140	12
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	2	5	3	5	1	0	0	8	1	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	36	871	440	264	941	108	173	497	650	30
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	36,000	15	137	64	40	95	4	9	68	137	4

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 S-ICD Electrode 3501	49,000	1	17	19	0	269	15	1	12	25
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	24,000	0	13	27	1	187	21	4	5	20

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 7840/7841/7842	603,000	583	69	1465	378	89	87	6	65	0	7
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	365,000	456	421	944	221	77	52	8	51	0	30
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	22,000	1	0	51	11	1	1	0	1	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	35,000	3	0	50	13	0	3	0	0	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457	201,000	9	11	405	104	7	12	16	15	0	10
FINELINE II Atrial J (poly) 4477/4478/4479/4480	64,000	0	10	399	52	2	16	5	7	0	5
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471	542,000	57	51	741	158	92	74	29	81	0	26

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	27,000	0	0	53	67	13	0	0	11	0	21
ACUITY X4 Spiral S 4674/4675	82,000	0	2	116	109	14	0	0	37	0	57
ACUITY X4 Straight 4671/4672	61,000	2	0	215	66	9	1	0	17	0	60
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	174	29	5	0	3	9	0	167

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 0652/0657/0672/0673/0692/0693	148,000	113	24	314	58	46	6	4	20	11	2
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0663/0682/0683	3,000	0	0	2	1	3	0	0	1	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Active Fixation 0653/0658/0675/0676/0695/0696	17,000	12	2	42	11	3	0	0	3	3	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	1,000	0	0	1	3	0	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	78,000	56	18	252	42	31	3	2	28	7	6
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0285/0286	3,000	2	0	10	1	0	0	0	4	0	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	142,000	101	20	373	72	60	16	6	32	15	21
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	3,000	4	1	6	0	2	1	0	8	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	287,000	81	138	510	130	223	12	17	178	108	44
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	36,000	31	7	72	17	21	4	2	18	25	9

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 S-ICD Electrode 3501	49,000	1	2	38	0	468	19	0	14	14
EMBLEM/Q-TRAK S-ICD Electrode 3010/3401	24,000	1	0	21	0	208	6	1	0	15

Pacing Leads/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
INGEVITY+ Positive Fixation 7840/7841/7842	1,260,000	0	0	0	155	0	0	0
INGEVITY Positive Fixation 7640/7641/7642/7740/7741/7742	1,154,000	2774	0	0	3374	0	0	0
INGEVITY Atrial J Passive Fixation 7635/7636/7735/7736	162,000	0	0	0	0	0	0	0
INGEVITY Passive Fixation 7631/7632/7731/7732	156,000	1	0	1	3	0	0	0
FINELINE II ; Passive Fixation (poly) 4452/4453/4456/4457*	564,000	1	0	3	8	6	26	0
FINELINE II EZ ; Positive Fixation (poly) 4463/4464/4465/4469/4470/4471*	868,000	0	0	6	730	1	52	3
FINELINE II Atrial J (poly) 4477/4478/4479/4480*	335,000	0	0	1	144	6	18	0

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

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	65,000	0	0	0	3	0	0	0
ACUITY X4 Spiral S 4674/4675	176,000	0	0	0	5	0	0	0
ACUITY X4 Straight 4671/4672	136,000	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	47,000	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 0653/0658/0675/0676/0695/0696	42,000	0	0	0	11	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Active Fixation 0652/0657/0672/0673/0692/0693	419,000	3	1	0	180	0	0	0
ENDOTAK RELIANCE 4-FRONT Dual Coil Passive Fixation 0636/0651/0655/0665/0685/0686	2,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE 4-FRONT Single Coil Passive Fixation 0650/0654/0662/0682/0663/0683	11,000	0	1	0	0	0	0	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Active Fixation 0275/0276/0295/0296	127,000	0	0	0	91	0	1	0
ENDOTAK RELIANCE 4-Site ; Dual Coil, Passive Fixation 0265/0266/0285/0286	11,000	0	0	0	7	15	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Active Fixation 0292/0293	217,000	0	0	0	68	0	1	0
ENDOTAK RELIANCE 4-Site ; Single Coil, Passive Fixation 0282/0283	7,000	0	0	0	0	0	0	0
ENDOTAK RELIANCE ; Dual Coil, Active Fixation 0157/0158/0159/0164/0165/0167/ 0184/0185/0186/0187	383,000	0	0	92	571	1	3	10
ENDOTAK RELIANCE ; Single Coil, Active Fixation 0137/0138/0160/0161/0162/0180/0181/0182	83,000	0	0	15	81	0	1	1

S-ICD Electrodes/Model	Worldwide Distribution	Conductor	Insulation	Crimp/Weld/Bond	Other	Labeling	Packaging	Implant Accessory
EMBLEM S-ICD Electrode 3501	132,000	0	0	0	6	0	0	0
EMBLEM/Q-TRAK S-ICD Electrode 3010, 3401	43,000	0	0	1	2	0	0	0

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. Information reported in the Current Status section of each summary represents Boston Scientific's most current understanding of the data presented, but is not necessarily updated in every report. Rates and counts reported in this section may differ from those in other sections of the report due to population, geographical, methodological, or timing differences. 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 **Jul 2025 – RELIANCE ePTFE Potential Calcification/Gradually Rising LVSI**
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 **RELIANCE G and SG Defibrillation Leads** RELIANCE ePTFE Potential Calcification/Gradually Rising LVSI - Physiian Letter, July 2025 RELIANCE ePTFE Potential Calcification/Gradually Rising LVSI, Patient Letter, July 2025	Voluntary Physician Advisory FDA Classification: Pending Management of gradually rising daily subthreshold, low-voltage shock impedance (LVSI) pattern associated with calcification of expanded polytetrafluoroethylene (ePTFE) coated single coil (SC) and dual coil (DC) RELIANCE™ defibrillation leads manufactured by Boston Scientific Corporation (BSC) from 2002 to 2021 that are no longer available for distribution. The association of calcified defibrillation lead coil(s) with a pattern of gradually rising LVSI measurements has been reported. This calcification phenomenon can biologically encapsulate and electrically insulate the defibrillation lead coil(s). BSC has completed a comprehensive investigation of ePTFE RELIANCE lead performance to identify the early signs of this phenomenon, characterize its potential effect on shock efficacy, and provide recommendations to mitigate the associated risk. Details of this investigation are described within Appendix A of the physician letter; key findings include: • While fissuring of calcified ePTFE coating has been observed, calcification of the shock coil(s) does not compromise the physical or electrical integrity of the lead. • A trend of gradually rising LVSI is correlated with shock coil calcification and is more prevalent with BSC RELIANCE ePTFE defibrillation leads compared to non-ePTFE defibrillation leads from BSC and other manufacturers; leads may be implanted for eight (8) or more years prior to manifestation of this trend. • The shock coil encapsulant material may exhibit a polarity bias with Reversed (RV+) polarity having an elevated high voltage shock impedance (HVSI) relative to Initial (RV-) polarity. Reversed (RV+) polarity shocks are 4.5 times more likely to initiate a high, delivered shock impedance alert (Code-1005), and defibrillation systems programmed to Reversed (RV+) polarity exhibiting a gradual rising LVSI have a lower defibrillator-determined shock success rate. • When managing leads with calcified coil(s), delivery of commanded shocks is neither effective at permanently mitigating rising impedance risk nor predictive of future impedance as LVSI may initially decrease but typically returns to pre-shock values in less than six (6) months. *Estimated Rate of Occurrence* The most common harm is early lead replacement (1 in 238 at 10 years). The most serious harm is death or need for cardiac resuscitation due to non-conversion of a sustained ventricular arrhythmia from a reduced shock energy due to high impedance (1 in 47,500 at 10yrs). Advisory Population 354,000 active RELIANCE ePTFE leads. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **14-Jul-26** *Estimated Rate of Occurrence - as of 08/2025* The most common harm is early lead replacement (1 in 238 at 10 years). The most serious harm is death or need for cardiac resuscitation due to non-conversion of a sustained ventricular arrhythmia from a reduced shock energy due to high impedance (1 in 47,500 at 10 years). Advisory Population 354,000 active RELIANCE ePTFE leads.

CURRENT RECOMMENDATION **14-Jul-26**

There are no changes to the scheduled follow-up interval for patients with ePTFE lead models.

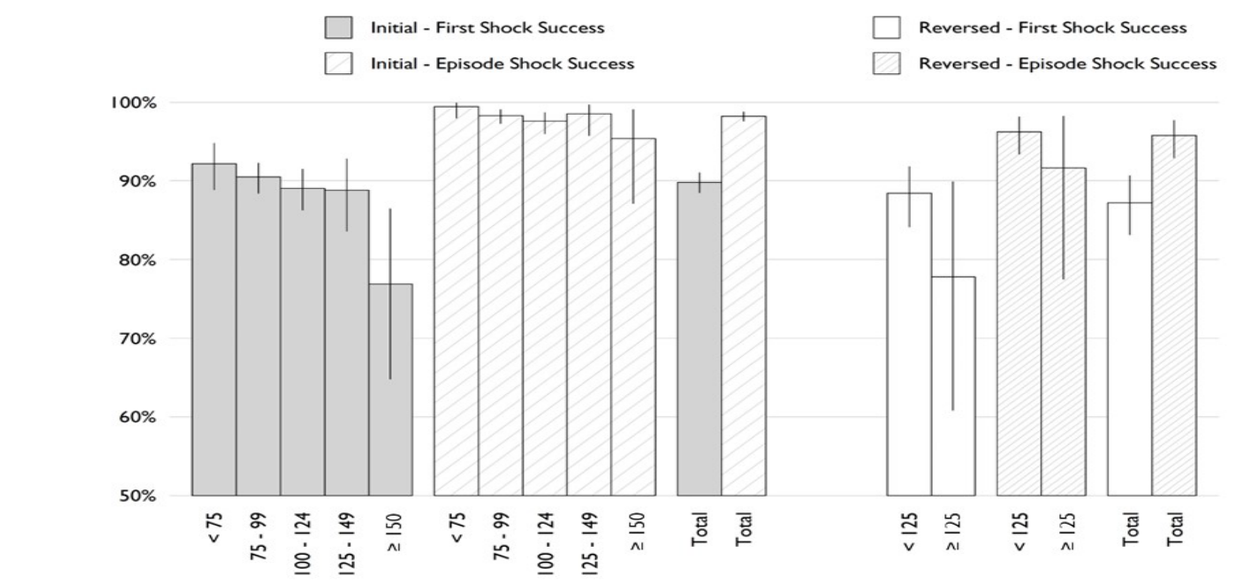
1. Continue routine follow-up of defibrillation systems with ePTFE leads either via in-person or remote monitoring (RM) per labeling or medical guidelines with consideration that RM can facilitate early detection of this pattern.
2. During routine follow-up of affected leads, determine the most recent approximate 28-day average LVSI that has not been influenced by the delivery of a shock (see examples in Appendix C of physician letter) and review HVSI for all shocks from the most recent episode since the last system check using the criteria in the Table below and data provided in Figure 1.
3. If lead replacement is planned, carefully consider the risk/benefit of lead extraction versus abandonment. Based on implant time and likely coil calcification, these leads may pose an increased risk of extraction-related complications.
4. There may be circumstances such as routine defibrillator replacement that merit complex decision making. Contact BSC Technical Services for further assistance if necessary.

Table 1: Guidance for mitigating risk by assessing 28-day average LVSI and Code-1005 alerts of defibrillation systems with ePTFE leads

Criteria	Lead Coil(s)† SC	Lead Coil(s)† DC	Assessment and Recommended Risk Mitigations for Calcifying Defibrillation Lead Coil(s)
Most recent 28-day average LVSI not affected by delivery of a shock (see Appendix C)	>90Ω	>70Ω	• Program Shock Polarity to Initial (RV-) and all shocks to maximum energy. • For patients who cannot be reprogrammed for clinical reasons to Initial (RV-) polarity, further management should be guided by the data in Figure 1 including consideration for lead replacement if LVSI increases.
	≥150Ω		Lead replacement should be considered. • For Initial (RV-) polarity shocks, there is a 24.9% likelihood of an associated Code-1005 and the defibrillator-determined first shock success rate decreases in absolute and relative terms versus other intervals (Figure 1). • Contact BSC Technical Services for additional technical guidance to support informed lead replacement decision-making.
High-Voltage Shock Impedance (HVSI), Code-1005 alert	X	X	Lead replacement should be considered. • Contact Technical Services as directed by alert message to rule out non-invasive options. • The urgency for lead replacement should be commensurate with the likelihood of the patient requiring shock therapy.

If the system includes a DC lead programmed RV2CAN, treat the system as a SC system; if DC lead programmed RV2RA treat as DC; if SC lead connected to SQ array treat as DC.

Figure 1: Defibrillator-determined shock success based on programmed polarity and post-shock Code-1005 likelihood based on polarity of individual shocks for defibrillation systems with ePTFE leads relative to preceding 28-day averaged LVSI. X-axis: LVSI Intervals and Y-axis: Defibrillator-Determined Shock Success Rate.



Impedance (Ω):	< 75	75 – 99	100 – 124	125 – 149	≥ 150	Total	< 75	75 – 99	100 – 124	125 – 149	≥ 150	Total
Likelihood of Post-Shock Code-1005:	0.0%	0.2%	3.7%	6.1%	24.9%	3.5%	3.5%	11.0%	16.9%	32.4%	40.8%	15.9%

PRODUCT	ORIGINAL COMMUNICATION **Dec 2024 – High Battery Impedance Initiating Safety Mode in a Subset of ACCOLADE DR-SLs, DR-ELs, and CRT-Ps**
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 L301, L311, L321, L331 **PROPONENT Pacemaker** Models L201, L209, L211, L221, L231 **ESSENTIO Pacemaker** Models L101, L111, L121, L131 **ALTRUA 2 Pacemaker** Models S702, S722 ACCOLADE Software Correction SMR6 and CRT-P/DR-EL Expansion, March 2026 - Physician Letter ACCOLADE Software Correction SMR6 and CRT-P/DR-EL Expansion, March 2026 - Patient Letter	Voluntary Physician Advisory FDA Classification: Dec 2024 - Class I; Aug 2025 – Class I; Mar 2026 - Class I Dec. 2024 A subset of ACCOLADE devices, produced prior to Sep 2018, have an increased potential of exhibiting a high battery impedance condition because of unanticipated concentration of lithium salts resulting from variability of battery assembly techniques. This may result in a lack of available electrolyte between the battery anode and cathode. At that time, high battery impedance could cause a device to exhibit transient voltage decreases, typically during telemetry operations or, in rare instances, during other normal high power device operations. If the battery voltage dropped below a minimum threshold during a wanded ZIP telemetry, a system reset was automatically performed, and the conditions of the high-power state were interrupted. Subsequent high-power states could result in additional system resets due to the high battery impedance. If three (3) system resets occured within a 48-hour period, the device was designed to enter Safety Mode to maintain backup pacing with pre-defined, non-programmable settings (see labeling or advisory letter for settings). If a device enters Safety Mode, users are directed to contact Boston Scientific via a programmer warning screen and LATITUDE alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode is increased when an affected device reaches approximately four years of remaining battery longevity. Aug. 2025 Update - *Software Maintenance Release 5 (SMR5) Model 3869 v2.04 installed on Model 3300 LATITUDE programmers which updates firmware of the ACCOLADE family of devices (3.10)* Brady SMR5 introduces a new battery impedance test that is designed to detect onset of an elevated battery impedance state and alert healthcare professionals (HCPs) via “Voltage is too low for projected remaining longevity” (Code-1003). If the device remains in service after this alert and the battery impedance advances from elevated to high, the software is designed to disable wandless ZIP™ telemetry in an ambulatory setting before Safety Mode is activated. Subsequent to launching Brady SMR5, unintended behaviors were identified. Device sensing, therapy delivery, and all programmed functions remain unaffected. Despite the possible occurrence of these unintended behaviors, the benefits of implementing Brady SMR5 outweigh the risks associated with previous prophylactic replacement recommendations. Mar. 2026 Update - *Software Maintenance Release 6 (SMR6) launch and CRT-P/DR-EL population expansion* • Brady SMR6 is available. This software includes a battery impedance test that is proven effective at mitigating the risk of Safety Mode in an ambulatory setting due to high battery impedance and corrects all unintended behaviors associated with Brady SMR5. • However, the advisory population has expanded to include all ACCOLADE CRT-P and DR-EL devices because there is a 7.6% probability of early device replacement due to high battery impedance induced wandless ZIP™ telemetry (ZIP) disablement. As a result, some devices may not achieve original, projected longevity. • Prophylactic replacement before confirming high battery impedance is not recommended. • There is a residual risk of in-clinic Safety Mode being induced by wanded telemetry. This risk applies to patients who are not monitored on the LATITUDE™ NXT Remote Patient Management System, are pacemaker dependent, and have a CRT-P or DR-EL device with three years or less longevity time remaining. Availability of Brady SMR5 and SMR6 varies by country, contact your local Boston Scientific representative for the status of software in your country. *Device Longevity Impact* Any ACCOLADE device experiencing ZIP disablement by the battery impedance test due to detection of high battery impedance requires replacement before normal battery replacement is indicated. There is a 7.6% likelihood that an individual CRT-P or DR-EL device will need to be replaced early due to high battery impedance-induced ZIP disablement. For those devices, the projected reduction in longevity is 10.9% ± 9.6%. Most CRT-P and DR-EL devices (92.4%) are not anticipated to experience high battery impedance-induced ZIP disablement; thus the overall weighted longevity impact from the high battery impedance condition to the entire CRT-P/DR-EL device population is 1%. Given this longevity impact, Boston Scientific is expanding the advisory population to include all CRT-P and DR-EL devices until additional battery impedance test refinements and updated longevity projections are available. Single-chamber (SR) and DR standard life (SL) devices are performing within anticipated longevity expectations; therefore, no population expansion is required for these devices. *Clinical Impact of Safety Mode - Effectively Mitigated for Pacemakers Upgraded to Brady SMR5 or SMR6* Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The non-programmable Safety Mode pacing parameters may not provide optimal support of a patient’s cardiac condition; patients at risk of harm for Safety Mode include those with an inadequate underlying escape rhythm, a need for AV/VV pacing for cardiac synchrony, and/or the potential for pacing inhibition due to myopotential oversensing. The most common clinical outcome has been early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure prior to device replacement. The worst-case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. • There have been three (3) patients with pacemakers whose devices activated Safety Mode due to high battery impedance; these patients experienced syncope requiring hospitalization and later died. • There has been one (1) patient whose device activated Safety Mode due to high battery impedance and died after the replacement procedure. Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **24-Aug-26**

Estimated Rate of Occurrence - as of 03/2026

There have been no changes to deaths associated with high battery impedance induced Safety Mode. The battery impedance test introduced with Brady SMR5 effectively mitigates the risks associated with high battery impedance induced Safety Mode in an ambulatory setting. The Safety Mode data below is evaluated for events occurring in devices that did not include the battery impedance test (e.g., devices with software that preceded Brady SMR5):

Population	Device Type	Estimated WW Active Population	Estimated WW Distributed Population	WW Safety Mode Events	Lifetime Safety Mode Occurrence Rate‡
Dec 2024 Advisory Population	CRT-P	7,900	21,300	328	3.7% at 122 months
	DR EL	32,300	58,600	202	3.7% at 165 months*
	DR SL	52,000	123,400	663	0.8% at 102 months
All other devices	CRT-P	95,900	131,900	120	1.2% at 122 months
	DR EL	480,700	580,600	39	1.2% at 165 months*
	DR SL	560,600	723,900	169	0.2% at 102 months
	SR SL	195,400	309,400	75	0.2% at 117 months
Total		1,424,800	1,949,100	1,596	

‡Safety Mode rate describes the occurrence rate for Safety Mode for a device without Brady SMR5 or SMR6

*DR-EL rate is projected based on the experience of CRT-P, which uses the same EL battery

There have been two (2) reported devices with Brady SMR5 that disabled wandless ZIP telemetry and later initiated Safety Mode. These devices were replaced with no permanent injury beyond the procedure to replace the device

The table below provides further categorization of the harms relating to the WW Safety Mode Events described in the table above:

Safety Mode Harms in Descending Order of Severity	% Harms
Death resulting from injuries from prolonged pacing pause	0.2%
Death resulting from complications from replacement procedure	0.1%
Pacing pause causing syncope resulting in injury	1.5%
Replacement	100.0%
Pacing pause causing syncope requiring medical intervention (e.g., temporary pacing, Rx support, or seizure)	2.9%
Additional Intervention	0.1%
Pacing pause causing syncope without medical intervention.	8.9%
Muscle stimulation	10.3%
Heart failure related to symptoms such as shortness of breath or fatigue.	4.6%
Pacing pauses causing pre-syncope/dizziness	5.0%

CURRENT RECOMMENDATION **14-Jul-26**

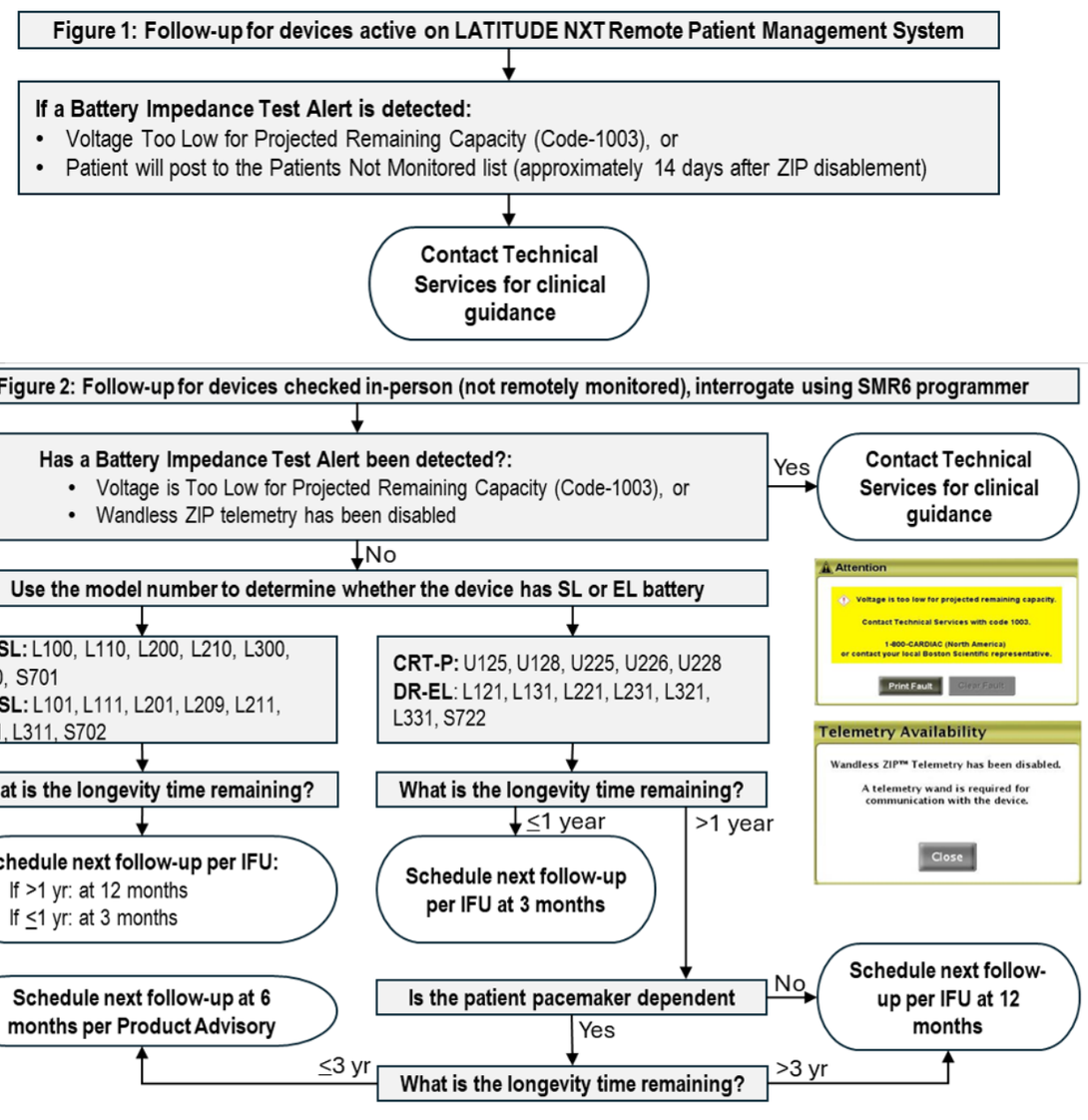
- Upgrade LATITUDE Model 3300 programmers with Model 3869 v2.05 software (Brady SMR6).
- Upgrade pacemaker software in-clinic by interrogating the device with a programmer upgraded with Brady SMR6 (Model 3869 v2.05).

– Patients at risk of harm from Safety Mode who haven't already received Brady SMR5: Promptly schedule an in-person follow-up if four (4) or less years of longevity time remaining. Note, the footer of the device follow-up report identifies the device firmware version. If the parenthetical at the end of the reported Firmware Version is "(3.10)" or greater, the device has been updated to either Brady SMR5 or SMR6. ↕

– All other patients: Schedule the next in-person follow up at a frequency described in the IFU: every 12 months or every 3 months if the battery status reaches One-Year-Remaining.

- Follow devices using the applicable flow chart below, based on the remote monitoring status (Figure 1 and 2).
- Update the medical record for each patient with an affected device by appending this letter to ensure continuous awareness throughout the device's remaining service life.

↕Brady SMR6 Model 3869 v2.05 includes firmware revision "(3.24)" and Brady SMR5 Model 3869 v2.04 includes firmware revision "(3.10)"



PRODUCT	ORIGINAL COMMUNICATION **Jun 2021 – High Battery Impedance Initiating Safety Mode in INGENIO EL Pacemakers and CRT-Ps**
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 **INLIVEN CRT-P** Models: V284, V285, W274, W275 **INTUA CRT-P** Models: V272, V273, W273 **INVIVE CRT-P** Models: V172, V173, V182, V183, W172, W173 **VITALIO DR EL Pacemaker** Models: J274, J277, K274, K277, K284 **INGENIO DR EL Pacemaker** Models: J174, J177, K174, K184, K187 **ADVANTIO DR EL Pacemaker** Models: J064, J067, K064, K084, K087 Safety Mode, Physician Letter, June 2021 Safety Mode, Patient Letter, June 2021 Safety Mode, Physician Letter, December 2023 Update Safety Mode, Patient Letter, December 2023 Update	Voluntary Physician Advisory FDA Classification: June 2021 - Class I; Advisory update issued in Nov 2023 Affected devices built with the extended life (EL) battery have the potential to transition to Safety Mode during periods of high-power consumption (e.g., interrogation by a programmer). If the battery voltage drops below a minimum threshold during a high-power state, a system reset is automatically performed, and the conditions of the high-power state are interrupted. Subsequent high-power states may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to enter Safety Mode to maintain back-up pacing with pre-defined non-programmable settings. When a device is in Safety Mode, users are directed to contact Boston Scientific via a programmer warning screen and LATITUDE alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode is increased when an affected device reaches approximately three (CRT-P) or four (DR EL) years of remaining battery longevity. Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The non-programmable Safety Mode pacing parameters may not provide optimal support of a patient's cardiac condition (e.g., adequacy of underlying escape rhythm, the need for AV/VV pacing for cardiac synchrony, and/or the potential for pacing inhibition due to myopotential oversensing). The most common clinical outcome has been early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure prior to device replacement. The worst-case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. No affected devices remain available for implant. Estimated Rate It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator. The potential for life-threatening harm due to loss of pacing (occurring because of prolonged inhibition) over a device's lifetime is estimated to be less than 1 in 15,000. November 2023 update: Since June 2021, the affected device population has aged, and additional post-market surveillance data has been collected. Most Safety Mode reports continue to be associated with telemetry operations involving an external device. However, approximately 3.5% of reports are unrelated to telemetry operations with an external device and may occur in an ambulatory setting by transient voltage drops during normal, higher power device operations such as automatic radio frequency telemetry circuit enablement and automatic memory checks. There have been 15 reports of a pause in pacing for older devices with less battery capacity experiencing extended transitions into Safety Mode (up to approximately 20 seconds) during telemetry operations with an external device. Thirteen (13) were associated with in-person programmer/Consult interrogations, and two (2) were associated with a LATITUDE patient initiated interrogation (PII). When Safety Mode is initiated due to this behavior, previously reported battery time remaining estimates are invalid because they were determined without accounting for Safety Mode's increased outputs or the battery's high impedance state. There have been three (3) deaths in pacemaker-dependent patients associated with this behavior; all were within the recommended replacement interval. Estimated Rate The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years. The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below. Standard Warranty program available, please contact your local representative for terms and conditions.

CURRENT STATUS **14-Jul-26**

Estimated Rate of Occurrence - as of 11/2023

The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years.

The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below.

CURRENT RECOMMENDATION **14-Jul-26**

Identify patients who are at risk of harm due to Safety Mode's non-programmable parameters.

If a device enters Safety Mode, perform emergent replacement for patients who are at risk of harm. For other patients, non-emergent replacement is recommended. When choosing a replacement interval, do not rely on previously reported battery time remaining estimates which do not account for Safety Mode's increased outputs nor the battery's high impedance state.

General prophylactic replacement is not recommended. For patients who are at risk of harm, device replacement is recommended as follows:
–For DR EL pacemakers, schedule replacement when the longevity remaining is 4 years or less.
–For CRT-Ps, schedule replacement when the longevity remaining is 3 years or less.

Note: There is a potential for pacing pauses during in-person checks and LATITUDE PII in patients at risk of harm who remain implanted beyond the recommended replacement interval. During in-person device checks, consider patient recumbency and availability of resuscitation equipment with qualified personnel. Consider disabling PII for patients on LATITUDE.

Follow-up interval. Per instructions for use, perform a system follow-up via remote or in-office interrogation at least every 12 months. When longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated.

For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT	ORIGINAL COMMUNICATION **Sep 2018 and Jun 2021 – Hydrogen-Induced 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 **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, **ALTRUA 2 Pacemaker** Models S701, S702, S722 Hydrogen Induced Premature Depletion, Physician Letter, September 2018 Hydrogen Induced Premature Depletion, Patient Letter, September 2018 Hydrogen Induced Premature Depletion, Physician Letter, June 2021 Hydrogen Induced Premature Depletion, Patient Letter, June 2021	Voluntary Physician Advisory FDA Classification: Sep 2018 – Class II; Jun 2021 - Class II This advisory discusses two separate, distinct subsets of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) with a potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion. The 2018 advisory population included approximately 2,900 active pacemakers, and the 2021 advisory population included approximately 125,000 active pacemakers. Latent release of small amounts of hydrogen within the pacemaker may compromise electrical function of a low voltage capacitor over time, resulting in accelerated depletion of the battery. The susceptibility of a pacemaker to this hydrogen-induced accelerated battery depletion mechanism is dependent upon the amount of hydrogen accumulation within the device and the susceptibility of the low voltage capacitors to hydrogen. The 2018 population is composed of pacemakers built with specific batches/lots of a liner component exhibiting a higher likelihood for this behavior. The 2021 population is composed of pacemakers built with a discontinued/original low voltage capacitor that is susceptible to compromised electrical performance in the presence of hydrogen. The use of the original low voltage capacitor in pacemaker and production of pacemakers from these advisory populations ceased in Nov 2017, and therefore they are no longer available for implantation. The most common clinical outcome has been device replacement. There have been no reported deaths associated with this behavior. *Estimated Rate of Occurrence* In June 2021 Boston Scientific identified an additional population of devices and the rate of occurrence at that time is described for each population below. • The 2018 advisory subset was composed of approximately 2,100 active pacemakers. The observed malfunction rate for this behavior was 11.0% at 5 years with a potential for life-threatening harm of 1 in 500,000 (0.0002%) at 5 years. • The 2021 advisory subset was composed of approximately 125,000 active pacemakers. The observed malfunction rate for this behavior was 1.3% at 5 years with a potential for life-threatening harm of 1 in 5,000,000 (0.00002%) at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **14-Jul-26**
	Estimated Rate of Occurrence - as of 06/2025 The combined 2018 and 2021 advisories subset is composed of approximately 80,000 active pacemakers. The observed malfunction rate for this behavior is 2.3% at 5 years, and 5.1% at approximately 10 years. The observed potential for life-threatening harm is 1 in 1,000,000 (0.0001%) at 5 years. More than 98% of hydrogen-induced confirmed events have been replaced before the battery reached a depleted state; therefore, normal battery assessment during labeled 12-month follow-ups is effective and recommended for both advisory populations. 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 battery depletion due to the low voltage capacitors. Additionally, improvements were implemented in the liner component starting in May 2021 intended to further reduce the device's overall capacity to generate hydrogen.
	CURRENT RECOMMENDATION **14-Jul-26**
	• Per labeling, perform a system follow-up via remote or in-office interrogation every 12 months until One-Year-Remaining and then every three (3) months thereafter until replacement is indicated. • Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. • Replace any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery depletion. • For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

PRODUCT	ORIGINAL COMMUNICATION **Dec 2020 — Model 3501 Electrode Fracture**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool **EMBLEM Subcutaneous Electrode** Model 3501 Model 3501 Electrode Fracture, Physician Letter, December 2020 Model 3501 Electrode Fracture, Patient Letter, December 2020	Voluntary Physician Advisory FDA Classification: Class I This advisory discusses the performance of approximately 47,000 EMBLEM S-ICD Subcutaneous Electrodes (Model 3501). During assembly of the EMBLEM S-ICD Subcutaneous Electrode, a small amount of adhesive is applied to a location just distal to the proximal sense ring. Over time, mechanical stresses on the electrode body at this location may create the potential for a fatigue crack to initiate from the outer lumen. This crack then propagates inward toward the center-oriented distal sense conductor, eventually resulting in a fracture of the two high voltage conductors. The cumulative occurrence rate for this specific electrode body fracture location is 0.2% at 41 months with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years. The physician letter (link provided) details device programming considerations and troubleshooting and detection techniques. Standard Warranty program available, please contact your local representative for terms and conditions. CURRENT STATUS **14-Jul-26** *Estimated Rate of Occurrence - as of 01/2026* The occurrence rate for EMBLEM S-ICD Subcutaneous Electrode (Model 3501) body fractures at a location just distal to the proximal sense ring is 0.34% at 103 months and the potential for life-threatening harm is 1 in 14,000 (0.0069%) at 10 years. This rate was derived by including all reports of this failure mode, whether or not the product was returned. An enhanced version of the EMBLEM Electrode has been developed to address the risks associated with this device behavior. Based on accelerated, extreme laboratory test, the enhanced EMBLEM Electrode design has demonstrated statistical survival of the electrode body around the sense ring to 10 implant years. Contact your local Boston Scientific sales professionals for availability. CURRENT RECOMMENDATION **14-Jul-26** 1. Remote monitoring. Enroll and monitor patients through LATITUDE remote monitoring to facilitate detection of high electrode impedance alert or non-physiologic, mechanical artifacts on stored S-ECGs during the interval between in-office device checks. Instruct patients to comply with weekly remote interrogations. 2. Follow-up interval. Perform a system follow-up every three months via remote or in-office interrogation. 3. During follow-ups. For every remote or in-office follow-up: 3.1. Promptly investigate any high impedance alerts in-clinic, as this may indicate an electrode body fracture and an inability of the system to provide therapy. 3.2. Review stored episode S-ECGs for non-physiologic, mechanical artifacts, as this may indicate onset of electrode body fracture. 3.3. During in-clinic follow-up, capture all sensing vectors, and review for the following conditions, any of which may indicate onset of electrode body fracture: 3.3.1. cardiac signals on the S-ECGs of the Primary and Secondary sensing vector look nearly identical; or 3.3.2. flatline S-ECGs in the Alternate sensing vector. 3.4. Assess sensing performance in-clinic during isometrics and/or posture changes if any of the following is observed: non-physiologic, mechanical artifacts and/or high electrode impedance alerts. If isometrics and/or posture changes provoke non-physiologic, mechanical artifacts, this may indicate onset of an electrode body fracture. 4. Imaging. If an electrode body fracture is suspected, perform chest radiography in PA and left lateral viewprojections, ensuring the entire electrode length can be visualized to enable differential diagnosis of competing causes of high impedance or artifact signals. Portable X-ray images typically provide insufficient clarity to evaluate electrode integrity. In the absence of any indications of electrode fracture, surveillance X-rays are not recommended. 5. Shocks and beeping tones. During the next in-office follow-up visit, demonstrate the device beeper tothe patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu. - 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; and - Remind all patients to promptly contact their physician if beeping tones are heard from their device or if a shock is delivered. 6. Evaluate risk. The potential for life-threatening harm due to an electrode body fracture is greatest for: - patients with a history of life-threatening ventricular arrhythmias such as secondary preventionindication or previous appropriate shock for VT/VF; - patients who are unable to be reliably followed remotely or in person every three months; or - patients who are not monitored via LATITUDE and are unable to hear beeping tones 7. Replacement. Following consultation with Boston Scientific Technical Services, promptly replace any electrode that is indicated to have compromised integrity as evidenced by non-physiologic, mechanical artifacts, high impedance alert, and/or X-ray. Routine prophylactic replacement of an electrode without evidence of fracture is not recommended. Return explanted devices to Boston Scientific. 8. De novo and replacement S-ICD candidates. Consider overall S-ICD performance with respect to the competing risks for transvenous ICDs. The Product Performance Report includes up-to-date performance data on Boston Scientific transvenous leads and subcutaneous electrodes.

PRODUCT	ORIGINAL COMMUNICATION **Dec 2020 — EMBLEM S-ICD Electrical Overstress**
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 Electrical Overstress, Physician Letter, December 2020 EMBLEM Electrical Overstress, Patient Letter, December 2020	Voluntary Physician Advisory FDA Classification: Class I This advisory discusses the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress (i.e., damage to the device caused by electrical shorting). Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations. *Estimated Rate of Occurrence* • Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported. • The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide needed defibrillation therapy, as it is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years Standard Warranty program available, please contact your local representative for terms and conditions.
CURRENT STATUS **14-Jul-26**	
Estimated Rate of Occurrence - as of 08/2021 • The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. • We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years	
CURRENT RECOMMENDATION **14-Jul-26**	
1. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations. 2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation. 3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed. 4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu. - 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; and - Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI. 5. 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 secondary prevention indication or previous appropriate shock for ventricular arrhythmias; - Patients who are unable to be reliably followed remotely or in person every 3 months; or - Patients who are not monitored via LATITUDE and are unable to hear beeping tones. 6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. - In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making. - Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.	

PRODUCT	ORIGINAL COMMUNICATION **Aug 2019 and Dec 2020 — 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 EMBLEM Premature Battery Depletion Physician Letter Update, December 2020 EMBLEM Premature Depletion, Patient Letter Update, December 2020 EMBLEM Premature Battery Depletion Physician Letter Update, February 2022 EMBLEM Premature Depletion, Patient Letter Update, February 2022	Voluntary Physician Advisory FDA Classification August 2019: Class II FDA Classification December 2020: Class II In August 2019, a physician communication discussed a subset of 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. In December 2020, the advisory population was expanded to a total of approximately 42,000 distributed EMBLEM S-ICDs with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion. This behavior 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. In August 2018, Boston Scientific transitioned S-ICDs to an alternative low voltage capacitor. All EMBLEM S-ICDs with the original low voltage capacitor are included in either the original or the expanded advisory population and none are available for implantation. *Estimated Rate of Occurrence* • The August 2019 advisory subset is comprised of approximately 400 distributed worldwide devices manufactured in July 2017. The August 2019 advisory subset has a projected rate of accelerated depletion of 15.1% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 50,000 at 5 years. • The December 2020 advisory subset is comprised of approximately 42,000 distributed worldwide devices manufactured before August 2018. The December 2020 advisory subset has a projected rate of accelerated depletion of 3.7% at 5 years with a projected potential for life-threatening harm in this subset of approximately 1 in 250,000 at 5 years. Standard Warranty program available, please contact your local representative for terms and conditions.
	CURRENT STATUS **14-Jul-26**
	The existing Battery Depletion (BD) alert has been enhanced to enable detection of hydrogen-induced accelerated battery depletion in Model A209 and A219 EMBLEM S-ICDs. Affected devices must be interrogated by a programmer with updated software. *Estimated Rate of Occurrence - as of 06/2025* Because the 5-year malfunction rate for the August 2019 and December 2020 populations has converged, a single malfunction rate is reported for the combined populations. There are approximately 13,000 active worldwide devices. The malfunction rate is 10.3% at 5 years, 23.2% at 6 years, and 33.5% at 7 years. The projected potential for life-threatening harm is approximately 1 in 110,000 at 5 years.

CURRENT RECOMMENDATION **14-Jul-26**

Recommendations for countries where enhanced BD alert software upgrade is available. Contact your local Boston Scientific sales representative to determine availability of software in your country.

1. Programmer Software Upgrade. Confirm programmers at your center have been upgraded.
- Model 3300 LATITUDE Programmers are supported with Model 3877 v1.03 application
- Model 3200 EMBLEM Programmers are supported with Model 2877 v4.09 application
2. Next Follow-up. Boston Scientific continues to recommend 3-month follow-ups per labeling. Bearing in mind the risk versus benefits of in-person visits in the setting of the global COVID-19 pandemic, consider an in-person visit at the next scheduled follow-up, so the enhanced BD alert can be enabled in each affected device.
- When an EMBLEM S-ICD is first interrogated by an upgraded programmer, an S-ICD software update will be performed. Per labeling, monitor the patient and have external defibrillation equipment available as tachycardia therapy is suspended during a S-ICD software update.
- If a BD alert occurs, follow screen prompts and contact Technical Services. Using device data, Technical Services can provide a replacement interval.
3. Update Records. For each patient with an affected EMBLEM S-ICD, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

Follow-up Recommendations:

1. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations.
2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation.
3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed.
4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
- 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; and
- Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI.
5. 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 secondary prevention indication or previous appropriate shock for ventricular arrhythmias;
- Patients who are unable to be reliably followed remotely or in person every 3 months; or
- Patients who are not monitored via LATITUDE and are unable to hear beeping tones.
6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE.
- In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
- Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

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 **COGNIS** Models N106/N107/N108/N118/ N119/N120/P106/P107/P108 **TELIGEN VR** Models E102/E103/F102/F103 **TELIGEN DR** Models E110/E111/F110/F111 Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014 Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014 Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013	Voluntary Physician Advisory FDA Classification August 2013: Class II FDA Classification September 2014: Class II In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. 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. 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. <u>Advisory population</u> 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 **14-Jul-26**

Estimated Rate of Occurrence - as of 01/2022

• COGNIS CRT-D and TELIGEN ICD advisory population - The rate of occurrence is 2.8% at 60 months, 5.8% at 72 months, 8.6% at 84 months, 10.9% at 96 months, 12.2% at 108 months, and 12.9% at 120 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, 2.4% at 72 months, 3.9% at 84 months, 5.2% at 96 months, 6.0% at 108 months, and 6.2% at 120 months . Since notifying customers of this behavior in September 2014 and improving the Safety Architecture voltage alert, the portion of malfunctions with compromised therapy is approximately 2.2%. 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 1.1% at 60 months, 2.0% at 72 months, 3.0% at 84 months, 3.8% at 96 months, 4.3% at 108 months, and 4.5% at 120 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 2,500,000 (0.00004%) at 60 months.

CURRENT RECOMMENDATION **14-Jul-26**

<u>Updated Software</u>

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.

<u>LATITUDE Patient Management System</u>

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”.

<u>Additional Recommendations</u>

- 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 Subpectoral Implant 2009 Patient Letter, Dec 01, 2009	*Rate of Occurrence* The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location. The following factors may also impact the risk of failure if implanted in a subpectoral location: – Exact location of the patient's ribs relative to the device – Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients) – Activity level and/or occupation of the patient (risk may increase for more active patients)

CURRENT STATUS **14-Jul-26**

Reported events (worldwide)

106 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.

CURRENT RECOMMENDATION **14-Jul-26**

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.

Trademarks

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