

PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA
FROM THE MEDTRONIC
POST-MARKET
REGISTRY

2025

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1 Overview

1.1 Registry Background

Medtronic uses a prospective, long-term multi-center registry to monitor the performance of certain products at selected centers titled the Product Surveillance Registry (PSR). This registry was initially created by Medtronic to monitor the performance of commercially available targeted drug delivery (TDD) and spinal cord stimulation (SCS) systems. Later on, deep brain stimulation (DBS) and sacral neuromodulation (SNM) were added to the registry. This 2025 Product Performance Report (PPR) provides data on the devices followed in the registry. Medtronic also incorporates the findings of Returned Product Analysis (RPA) for devices followed in the registry that are returned to Medtronic.

Depending upon geography, this report may contain information outside approved labeling for the Medtronic commercially available devices. It is recognized that healthcare providers prescribe approved therapies to meet specific patient needs; however, Medtronic only directs the use of its products according to geography-specific, approved labeling.

The registry has collected data from centers across North America, Europe, South America, and Asia. There have been 77 centers that have contributed data for TDD systems, 99 centers for SCS systems, 67 centers for DBS systems, and 24 centers for SNM systems. Each registry center received Institutional Review Board or Medical Ethics Committee approval of the registry protocol and associated Informed Consent Forms (ICF). Registry patients signed an ICF prior to enrollment. Each registry center followed its standard clinical practice for device system implantation including patient selection, implant methods, and post-implant therapy management. Centers were activated after receiving the necessary documentation, completion of training, and approval to access the web-based registry system.

1.2 Commitment to Quality

The Medtronic commitment to quality has long been stated in our Mission, "To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

In line with this commitment, we remain focused on sharing information and appropriate updates with customers on a regular basis. Thus, we are pleased to share the 18th Annual Medtronic Neuromodulation Product Performance Report.

We are proud of our pioneering history at Medtronic and we realize the responsibility that comes with driving innovation in technology. As the first and only company to offer a full line of Spinal Cord Stimulation, Deep Brain Stimulation, Sacral Neuromodulation and Targeted Drug Delivery therapies, we believe that performance reporting is of critical importance as we strive for better performance with every new product and therapy we develop. This report shows the evolution of product performance over time and also reveals advances in therapies that come with this experience and knowledge. Through this sharing of information, we can enable physicians to best leverage state-of-the-art therapy delivery and also understand the performance of our devices to best manage patients.

We have tracked 24,269 patients in our ongoing post-market registry. The registry has enrolled 76,634 Neuromodulation system components. Components include pumps, catheters, neurostimulators, leads, and extensions. Data on other events not directly attributed to product performance are also included to provide additional information that may be important for patient management. Although gastric electrical stimulation also involves neurostimulation, the performance of these systems is not included in this report. We welcome your suggestions on content, format, and any information you may have regarding the performance of Medtronic products. If you have questions or comments, please contact us through the information provided below.

1.3 Contact Information

We invite our customers to use this telephone number to call with suggestions, inquiries, or specific problems related to our products or this report.

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1.5 Trademarks of Medtronic, Inc.

Therapy	Trademarks
Targeted Drug Delivery	Ascenda™ intrathecal catheter SynchroMed™ implantable drug pump
Spinal Cord Stimulation	AnkerStim™ Intellis™ neurostimulator Itrel™ 3 neurostimulator Pisces-Octad™ lead Pisces-Quad™ lead PrimeAdvanced™ neurostimulator PrimeAdvanced™ SureScan™ MRI neurostimulator Restore™ implantable neurostimulator RestoreAdvanced™ neurostimulator RestoreAdvanced™ SureScan™ MRI neurostimulator RestoreSensor™ neurostimulator RestoreSensor™ SureScan™ MRI neurostimulator RestoreUltra™ neurostimulator RestoreUltra™ SureScan™ MRI neurostimulator Resume™ TL lead Specify™ lead Synergy Versitrel™ neurostimulator Synergy™ neurostimulator SynergyCompact™ neurostimulator SynergyPlus+™ neurostimulator Vectris™ SureScan™ lead Vanta™ neurostimulator
Deep Brain Stimulation	Activa™ neurostimulator Kinetra™ neurostimulator Percept™ neurostimulator Soletra™ neurostimulator
Sacral Neuromodulation	InterStim™ neurostimulator InterStim™ Micro neurostimulator InterStim™ SureScan™ MRI Lead InterStim X™ neurostimulator

1.6 Glossary

Acronym	Term/Definition
AE	Adverse Event
CEC	Clinical Event Committee
CSF	CerebroSpinal Fluid
CRPS	Complex Regional Pain Syndrome
DBS	Deep Brain Stimulation
FBSS	Failed Back Surgery Syndrome
FDA	Food and Drug Administration
HLGT	High Level Group Terms
ICF	Informed Consent Form
IM	Inflammatory Mass
INS	Implanted Neuro Stimulator
MedDRA	Medical Dictionary for Regulatory Activities
MRI	Magnetic Resonance Imaging
NEC	Not Elsewhere Classified
OCD	Obsessive Compulsive Disorder
PPE	Product Performance Events
PPR	Product Performance Report
PSR	Product Surveillance Registry
PTM	Personal Therapy Manager (TDD Therapy)
RPA	Returned Product Analysis
SAE	Serious Adverse Event
SCS	Spinal Cord Stimulation
SNM	Sacral Neuromodulation
SOC	System Organ Class
TDD	Targeted Drug Delivery

2 Methodology

2.1 Event Classification

Events currently collected in the registry include all events that appear or worsen during the registry and are a result of:

- Implanted or external components (device related),
- Implant or modification procedure (procedure related), or
- Infusion or stimulation therapy (therapy related).

Information on all deaths is also collected regardless of their relatedness to the device, implant procedure, and/or therapy.

For centers participating in the PSR protocol, specific therapy relevant events for deep brain stimulation are also collected and include:

- Negative changes in behavior from baseline,
- New or worsening depression from baseline, and
- New or worsened suicidal ideation from baseline, attempted suicide or completed suicide.

For some events related to implanted neuromodulation systems that did not exist in the MedDRA dictionary, Medtronic used their own coding system, and all results were integrated for reporting purposes.

2.1.1 Registry Definitions

In the registry, the events are defined as follows (see [Figure 2.1](#) for the procedure to determine the event types):

- **Adverse Event:** any death or undesirable experience (associated with signs, symptoms, illnesses, or other medical events) occurring to the patient that appears or worsens during the clinical study and is possibly related to the device, procedure, and/or therapy.
- **Device Event:** an issue with any of the implantable or external system components.
- **Therapy Relevant Event:** a therapy specific event type that may or may not be related to the device, procedure, or therapy.

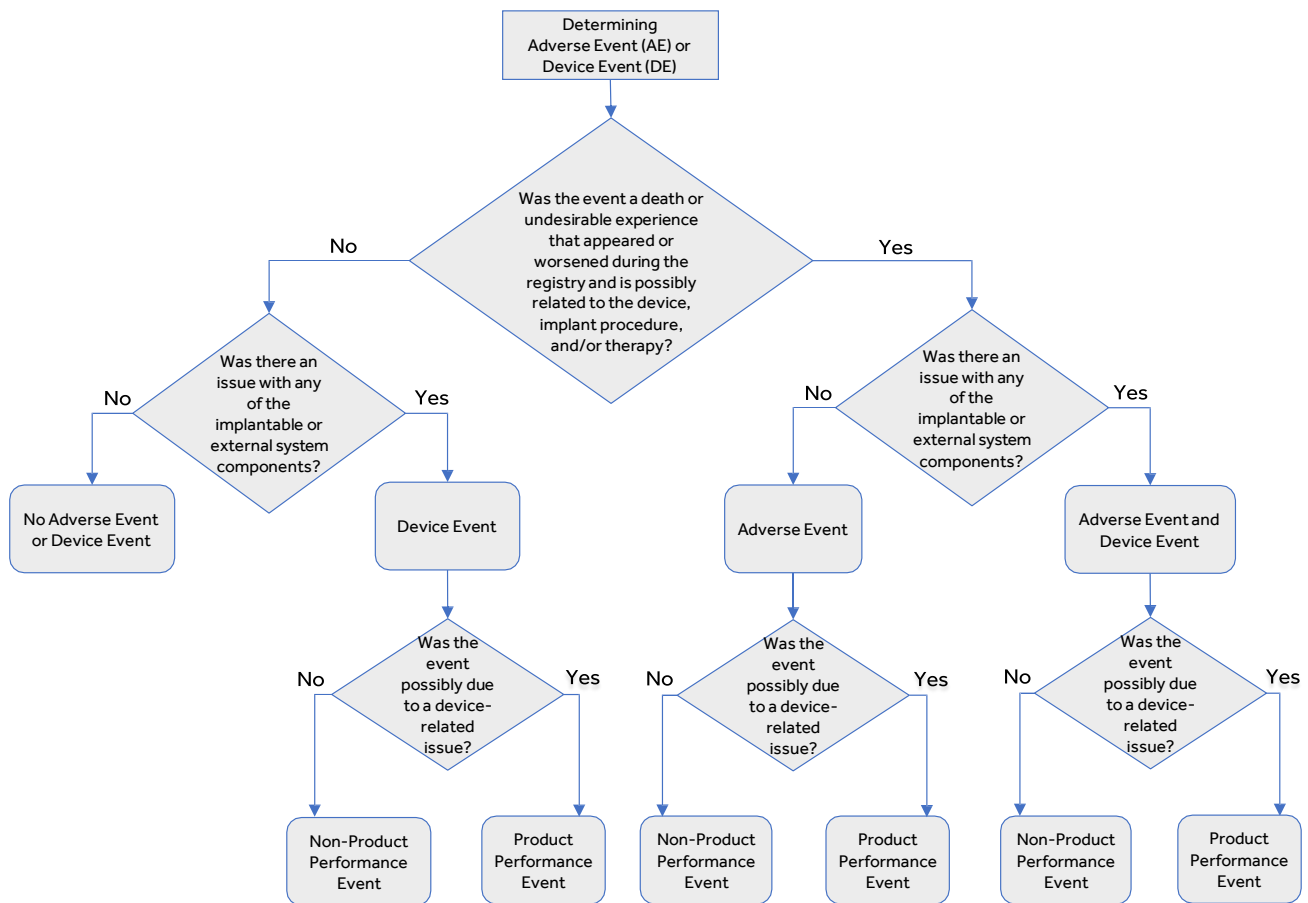


Figure 2.1: Adverse Event/Device Event Flowchart

2.1.2 Product Performance and Non-Product Performance Categorization

For analysis purposes, events collected were collapsed into two categories: product performance events and non-product performance events. All events were reviewed by Medtronic to determine if they were product performance-related (product performance events are events that are possibly due to a device-related issue). A non-product performance related event, or a clinical event not related to product performance, was any undesirable experience (associated with signs, symptoms, illnesses, or other medical events) occurring to the patient, and that appears or worsens during the clinical study. These clinical events not related to product performance possibly resulted from or were related to the implant procedure, or modification between implant and procedure, therapy, or delivery of therapy, and cannot be classified as product performance-related. All clinical events not related to a product performance and reported as a serious adverse event were summarized by MedDRA System Organ Class (SOC) if the event met a patient percentage threshold (0.5% to 1.0%).

2.1.3 Consistency and Accuracy

Consistency and accuracy of event reporting is monitored at four levels: through logic checks built into the study database as center personnel enter information; through review of each event by the study team as it is received by Medtronic; review by the Medical Advisor when necessary; and through routine monitoring at each center per Medtronic standard operating procedures. Monitoring is accomplished through a risk-based approach that aligns with the current FDA guidance on monitoring. Through this approach not every data field is monitored but an emphasis is placed on data related to the primary objective (e.g., events). Clarification and subsequent adjudication of events may be required for, but is not limited to, the following reasons:

- Inconsistency with the protocols,
- Inconsistency with the instructions provided to the centers through training materials,
- Incomplete or inaccurate event description that makes a reported event reason, event reason detail, and the clinical data appear inadequate or inconsistent,
- Medtronic Customer Support and Vigilance Complaint management requirement for additional information, or
- Center personnel initiated corrections or additions.

2.2 Device Survival Analyses

Device performance is expressed in terms of device survival estimates, where “survival” refers to freedom from a product performance event, not the survival of the patient. These survival probabilities are estimated using the Kaplan-Meier method [1]. The estimates are intended to illustrate the probability that a device will survive for a given number of years without a product performance related event.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases, in the registry, active surveillance of a device starts after the device was implanted, which is called left truncation [1]. The survival probability of such a device is conditional on survival to the time when the device enters the registry. For the PPR analysis, a statistical method to incorporate data from these retrospectively enrolled devices was applied. Left truncation provides a statistical technique that uses data from existing devices while appropriately adjusting the device survival curves for the time the device was not actively followed in the registry. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

Throughout this report, cumulative device survival plots are presented. These figures show the percentage of implanted devices that remain free from product performance-related events at various time points. This survival estimate is a good representation of the probability a device will survive a period of time without a product performance event. For example, a device survival probability of 90% indicates that through the stated follow-up time, the device had a 10% risk of incurring a product performance event since the time of implant.

The survival curves are statistical estimates. As performance experience accumulates, the accuracy of the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds [2]. This can be roughly interpreted as meaning that the true survival of the device will fall somewhere in the interval, with 95% probability. When confidence intervals for device models overlap, estimates of survival from product performance-related events may not be different between models. When confidence intervals do not overlap, estimates of survival from product performance-related events may be different between models. Statistical significance may be further evaluated using the Log-rank test or Wilcoxon test as appropriate.

The device survival curves are presented through all continuous time points where there are at least 20 devices and are cut off at the last 3-month time point where at least 20 total devices were still being followed. Since the survival estimate can become very imprecise with small sample sizes, a minimum of 20 devices must have at least 12 months of follow-up as of the report cut-off date to present a survival curve in this report. Device survival estimates are presented at the device level, not at the system level which involves the combination of two or more devices.

2.3 Returned Product Analysis

Registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process following protocols to confirm proper functioning or identification of root cause for any failure or deficiency. For registry pumps and neurostimulators that are returned, and for which RPA establishes a root cause or finds no anomaly, results reported herein reflect the RPA finding unless otherwise indicated in this report. When available, RPA findings are also used as one of the sources to identify the root cause of failure or deficiency for catheters and leads. In cases where the center does not explant and/or return a device, the physician-reported event reason is used for classification and analysis purposes.

Medtronic uses data from RPA as well as complaint reports from non-returned product for ongoing quality monitoring and improvement efforts. This report presents data from the registry including the results of RPA for returned devices from registry centers and patients. Data from RPA outside the registry centers and patients are not presented in this report.

REFERENCES

1. Klein, John P., Moeschberger, Melvin L. Survival Analysis Techniques for Censored and Truncated Data, New York: Springer-Verlag New York, Inc., 1997.
2. Lee, Elisa T. (2003) Statistical Methods for Survival Data Analysis — 3rd Edition (Wiley Series in Probability and Statistics).

3 Targeted Drug Delivery Systems

3.1 Study Participants

3.1.1 Centers

The Targeted Drug Delivery (TDD) tables and graphs were generated based on data collected between August 7, 2003, and the report cut-off date of October 31, 2025. Seventy-seven centers spanning 13 countries/territories in North America, Europe and South America, enrolled patients and contributed patient data to the targeted drug delivery systems section of this report. [Figure 3.1](#) shows a map of the world, in which the countries that enrolled TDD patients are highlighted.

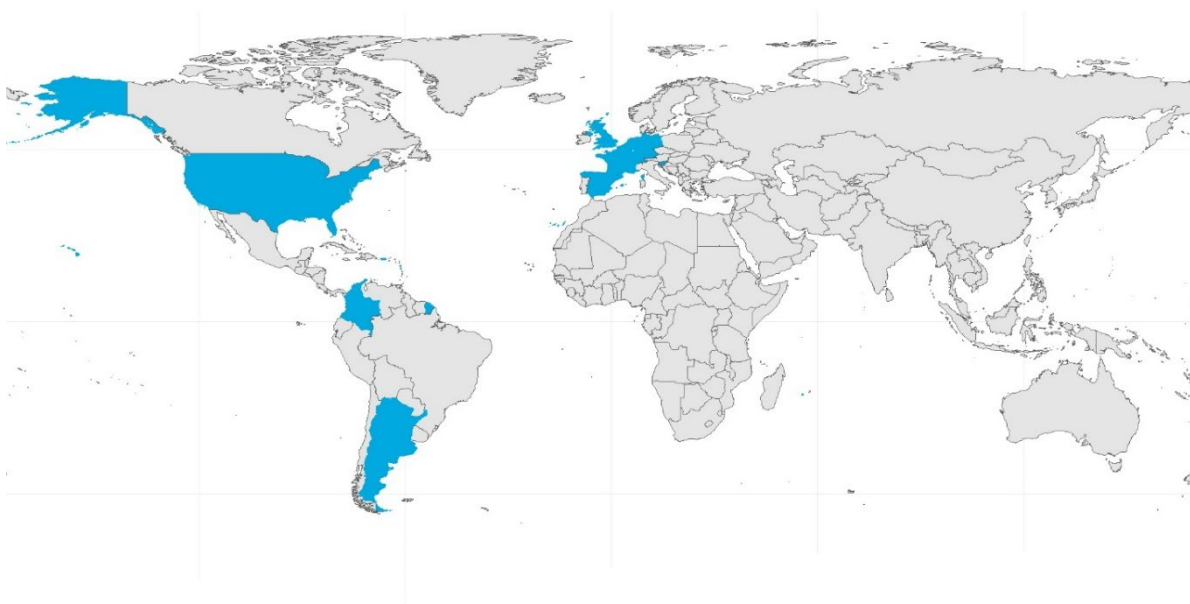


Figure 3.1: Countries with Targeted Drug Delivery Therapy Patients in Registry (Highlighted)

3.1.2 Patients

There were 11,146 total targeted drug delivery system patients enrolled through October 31, 2025. In [Table 3.1](#) and [Figure 3.2](#), 59.8% of patients were implanted with a targeted drug delivery system for treatment of non-malignant pain (pain not related to cancer and its treatment), followed by 20.9% for treatment of spasticity, and 16.9% for treatment of malignant pain (pain related to cancer). Primary treatment indication is provided by the physician. The sites of pain for the malignant pain patients are presented in [Table 3.2](#), while the sub-indications for the non-malignant pain and the spasticity patients are presented in [Table 3.3](#) and [Table 3.4](#), respectively.

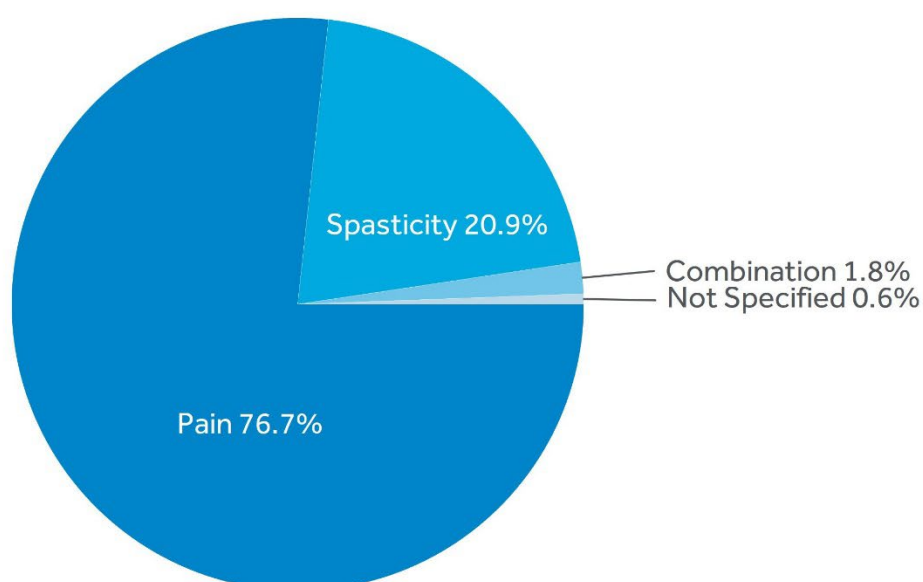


Figure 3.2: Targeted Drug Delivery Primary Treatment Indications

Table 3.1: Targeted Drug Delivery Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Pain	8551 (76.7%)
Non-malignant pain	6669 (59.8%)
Malignant pain	1881 (16.9%)
Pain not specified	1 (<0.1%)
Spasticity	2331 (20.9%)
Combination	199 (1.8%)
Non-malignant pain & Spasticity	197 (1.8%)
Malignant pain & Chemotherapy	1 (<0.1%)
Malignant pain & Spasticity	1 (<0.1%)
Not Specified^b	65 (0.6%)
Total Patients	11146

^a For approved indications refer to product labeling for your geography.

^b Includes incomplete data forms at the time of the data snapshot and exited patients where indication was never provided.

Table 3.2: Targeted Drug Delivery Malignant Pain: Site of Pain

Malignant Pain: Site of Pain	N (%)
Spine/Back	781 (41.5%)
Abdominal/Visceral	465 (24.7%)
Extremity	342 (18.2%)
Pelvic	259 (13.8%)
Thoracic	211 (11.2%)
Head/Neck	129 (6.9%)
Other	210 (11.2%)
Not Specified	439 (23.3%)
Total Patients^a	1883

^a 2,836 sites of pain in 1,883 patients with indications of malignant pain, malignant pain & chemotherapy, and malignant pain & spasticity. Total number of patients is not equal to number of reported sites of pain as patients may have multiple sites of pain.

Table 3.3: Targeted Drug Delivery Non-Malignant Pain: Sub-Indications

Non-Malignant Pain: Sub-Indications	Enrolled Patients (%)
Back Pain with Leg Pain	2469 (36.0%)
Back Pain without Leg Pain	1767 (25.7%)
General Neuropathic Condition	253 (3.7%)
CRPS I ^a	220 (3.2%)
Peripheral Neuropathy	87 (1.3%)
Joint Pain/Arthritis	74 (1.1%)
General Nociceptive Condition	59 (0.9%)
CRPS II ^a	42 (0.6%)
Abdominal pain	23 (0.3%)
Osteoporosis	20 (0.3%)
Pelvic pain	11 (0.2%)
Other	886 (12.9%)
Not Specified	955 (13.9%)
Total Patients^b	6866

^a CRPS is complex regional pain syndrome.

^b Includes patients with indications of non-malignant pain, non-malignant pain & spasticity, and non-malignant pain & chemotherapy.

Table 3.4: Targeted Drug Delivery Spasticity: Sub-Indications

Spasticity: Sub-Indications	Pediatrics (%) (<18 years)	Adults (%) (>=18 years)	All Patients (%)
Cerebral Palsy	395 (77.3%)	293 (14.5%)	688 (27.2%)
Multiple Sclerosis	0 (0.0%)	604 (29.9%)	604 (23.9%)
Spinal Cord Injury	9 (1.8%)	404 (20.0%)	413 (16.3%)
Brain Injury	39 (7.6%)	131 (6.5%)	170 (6.7%)
Stroke	1 (0.2%)	106 (5.3%)	107 (4.2%)
Other	23 (4.5%)	250 (12.4%)	273 (10.8%)
Not Specified	44 (8.6%)	230 (11.4%)	274 (10.8%)
Total Patients^a	511	2018	2529

^a Includes patients with indications of spasticity, non-malignant pain & spasticity, and malignant pain & spasticity.

It is recognized that health care providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved labeling. Product labeling varies by geography. Contact a local Medtronic representative for region-specific product labeling - <https://www.medtronic.com/us-en/our-company/locations.html>.

3.2 Event Summary

Events are reported via database by physicians trained in the PSR. Events are reviewed internally and coded as either a product performance event (e.g. catheter kink, motor stall) or a non-product performance event (e.g. adverse drug reaction and incision site swelling). There were 2,733 product performance events reported between August 7, 2003 and October 31, 2025, in 1,758 patients with targeted drug delivery systems. These events represent 12.68% (2,733/21,547) of the total reported events and are presented graphically within this report (e.g. events per patient years as well as survival curves). As an ongoing registry, events not coded at the time of the data snapshot (waiting for further information) will be included in future reports (n=8).

All registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings assist in the classification of the events. Within this report, [Table 3.5](#) and the event tables in the pump and catheter sections differentiate the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 3,036 deaths reported in patients with targeted drug delivery systems (see [Table 3.12](#)). None of these deaths were reported as a direct result of a product performance event. Early versions of the protocol required events to be reported only when the event required a surgical intervention, resulted in therapy abandonment, or resulted in death. The required event reporting definition was expanded in April 2010 to include all adverse events related to the device, implant procedure, and/or therapy. [Table 3.5](#) includes combined data from these versions of the protocol.

3.2.1 Product Performance Events

Table 3.5: Targeted Drug Delivery System Product Performance Events

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=11146 ^b
RPA Determination	359	0.8	327 (2.9%)
Pump Motor Stall ^c	197	0.5	190 (1.7%)
Laboratory Overinfusion Finding ^d	40	0.1	39 (0.3%)
Corrosion And/Or Gear Wear	29	0.1	29 (0.3%)
Battery High Resistance	12	<0.1	12 (0.1%)
Confirmed overinfusion ^e	11	<0.1	5 (<0.1%)
No Anomaly Found By RPA ^f	11	<0.1	10 (0.1%)
Reduced Battery Performance	10	<0.1	10 (0.1%)
Deformed Pump Tube	9	<0.1	8 (0.1%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=11146 ^b
Reservoir Access Issues Due To Residue	9	<0.1	8 (0.1%)
Motor Feedthrough Anomaly	8	<0.1	8 (0.1%)
Alarm And/Or Resonator Anomaly	2	<0.1	2 (<0.1%)
Concave Pump Shield	2	<0.1	2 (<0.1%)
Hole In Pump Tube	2	<0.1	1 (<0.1%)
Other ^g	17	<0.1	17 (0.2%)
Physician's Determination	2,374	5.5	1576 (14.1%)
Catheter Occlusion	574	1.3	499 (4.5%)
Catheter Dislodgement	434	1.0	348 (3.1%)
Catheter Kink	311	0.7	261 (2.3%)
Catheter Break/Cut	276	0.6	247 (2.2%)
Device Malfunction ^h	129	0.3	111 (1.0%)
Pump Motor Stall ⁱ	97	0.2	79 (0.7%)
Catheter Leakage	95	0.2	86 (0.8%)
Catheter Disconnection At Pump	57	0.1	55 (0.5%)
Pump Unable To Enter/Withdraw From Catheter Access Port	55	0.1	47 (0.4%)
Pump Reservoir Volume Discrepancy	50	0.1	39 (0.3%)
Catheter Dysfunction	48	0.1	43 (0.4%)
Device Difficult To Use	27	0.1	26 (0.2%)
Catheter Related Complication	23	<0.1	22 (0.2%)
Pump Underinfusion	23	<0.1	19 (0.2%)
Device Component Migration	21	<0.1	21 (0.2%)
Pump Connector Break/Cut	19	<0.1	18 (0.2%)
Catheter Damage	17	<0.1	17 (0.2%)
Device Issue ^j	15	<0.1	15 (0.1%)
Catheter Disconnection Between Catheter Segments	13	<0.1	12 (0.1%)
Device Connection Issue	11	<0.1	11 (0.1%)
Device Damage	11	<0.1	9 (0.1%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=11146 ^b
Device Breakage	7	<0.1	7 (0.1%)
Catheter Access Port Issue	6	<0.1	6 (0.1%)
Device Charging Issue	5	<0.1	5 (<0.1%)
Pump Reservoir Issue	5	<0.1	5 (<0.1%)
Device Displays Incorrect Message	4	<0.1	4 (<0.1%)
Device Reset Issue	3	<0.1	3 (<0.1%)
Medical Device Complication ^k	3	<0.1	3 (<0.1%)
Pump Not Infusing	3	<0.1	3 (<0.1%)
Catheter Disconnection Issue	2	<0.1	2 (<0.1%)
Device Infusion Issue	2	<0.1	2 (<0.1%)
Device Kink	2	<0.1	2 (<0.1%)
Device Material Corroded	2	<0.1	1 (<0.1%)
Physician reported overinfusion ^l	2	<0.1	2 (<0.1%)
Pump Infusion Issue	2	<0.1	1 (<0.1%)
Pump Inversion	2	<0.1	2 (<0.1%)
Other ^g	18	<0.1	17 (0.2%)
Total	2,733	6.3	1758 (15.8%)

^a Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.

^b The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.

^c Of the 197 RPA-determined motor stalls, 196 had a pump etiology and 1 had a catheter etiology. Motor stall count does not include temporary motor stalls that may be expected (e.g. due to MRI) and recovered within a 24-hour period. The SynchroMed II pump temporarily stops the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure for patient safety.

^d Includes pumps that had a laboratory finding but the patient did not have clinical signs or symptoms consistent with pump overinfusion.

^e Patient had clinical signs and symptoms consistent with pump overinfusion, pump returned and positive laboratory test.

^f Return Product Analysis (RPA) found no anomaly with the pump but physician initially reported an issue with the device. Events remain reported as PPE for transparency.

^g Composed of event codes with 1 event each.

^h The majority of these events were attributed to the Patient Therapy Manager (PTM).

ⁱ Of the 97 physician-determined motor stalls, 88 had a pump etiology and 9 had an MRI etiology. Of the 9 physician-determined motor stalls with an MRI etiology, 3 pumps were reprogrammed and 6 had no action taken. Motor stall count does not include temporary motor stalls that may be expected (e.g. due to MRI) and recovered within a 24-hour period. The SynchroMed II pump is designed to temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure for patient safety.

^j Of the 15 device issues, 12 have an etiology of catheter or other component. The 15 device issues include 8 unable to aspirate catheter, 4 PTM Error Codes, 2 pump alarms, and 1 pump in safe state.

^k Includes 1 where metal clips on connector appear bent, 1 pump beeping, and 1 roller arm seized to ball bearing.

^l Patient had clinical signs and symptoms of Overinfusion, but pump not returned and analyzed.

A total of 1,944 of the 2,733 product performance events were related to the catheter only. There were 546 events related to the pump only. There were 187 related to other component (e.g. PTM malfunction) and 56 related to other etiologies (e.g. bend in catheter anchor). Relatedness is reported by the physician.

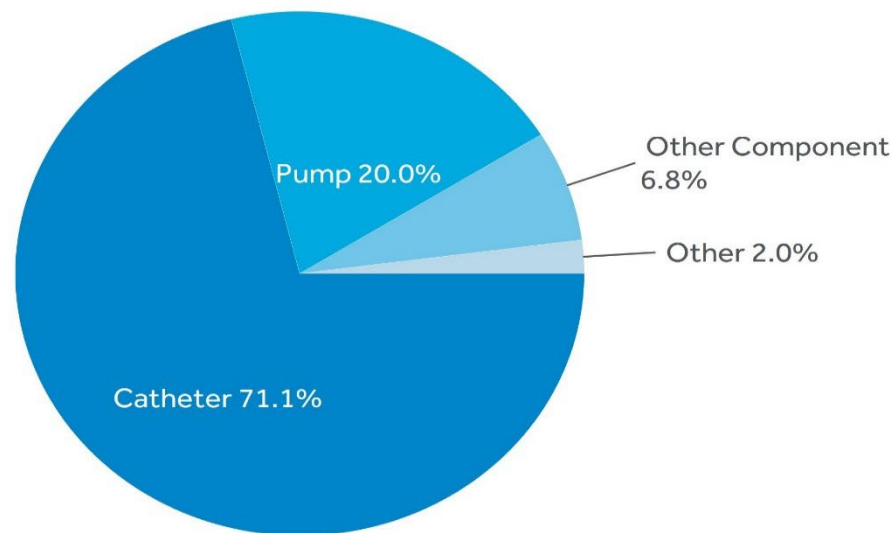


Figure 3.3: Targeted Drug Delivery System Product Performance Events by Relatedness

Table 3.6 describes the interventions implemented for product performance events that required action from the health care provider and thereby may have resulted in an incremental impact to the patient. Survival estimates presented in previous product performance reports included events where no action was taken. To present survival estimates that may better correlate with patient impact, events where no action was taken have been removed from the device survival estimates presented in this report. The far-left column lists the top five reported PPEs as determined by the physician, and all other reported PPEs are listed under Other. The subsequent columns represent the actions taken by the reporting physician.

Table 3.6: TDD Product Performance Events by Intervention

Events by Intervention	Surgical Intervention	Reprogramming	Medical or Non-Surgical Intervention ^a	Therapy Suspension	No Action Taken	Total Events
Catheter Occlusion	522 (90.9%)	19 (3.3%)	17 (3.0%)	7 (1.2%)	9 (1.6%)	574
Catheter Dislodgement	382 (88.0%)	9 (2.1%)	8 (1.8%)	3 (0.7%)	32 (7.4%)	434

Events by Intervention	Surgical Intervention	Reprogramming	Medical or Non-Surgical Intervention ^a	Therapy Suspension	No Action Taken	Total Events
Catheter Kink	276 (88.7%)	13 (4.2%)	15 (4.8%)	1 (0.3%)	6 (1.9%)	311
Catheter Break/Cut	262 (94.9%)	1 (0.4%)	6 (2.2%)	1 (0.4%)	6 (2.2%)	276
Pump Motor Stall	167 (69.0%)	15 (6.2%)	4 (1.7%)	9 (3.7%)	47 (19.4%)	242
Other ^b	512 (63.2%)	35 (4.3%)	157 (19.4%)	5 (0.6%)	101 (12.5%)	810
Total	2121 (80.1%)	92 (3.5%)	207 (7.8%)	26 (1.0%)	201 (7.6%)	2647^c

^a Medical or Non-Surgical Therapy contains but is not limited to the following actions: medication adjustment based on disease symptoms, imaging (e.g. MRI or X-ray), other specialist referral.

^b Other represents all reported PPEs that were not in the top five of occurrence.

^c The total number of events in this table differs from the total number of PPEs overall due to 86 events with an unknown intervention, which are excluded.

3.2.2 Clinical Events Not Related To Product Performance

The clinical events not related to product performance are summarized if:

- The patient was enrolled in the PSR at the time in which the clinical event collection was initiated (n=4,570)
- Occurred with a System Organ Class (SOC) threshold $\geq 1\%$ of patients
- Other Considerations:
 - Some events are described in high level group terms (HLGT) to provide more specificity, if needed
 - Therapy relevant events (e.g., Inflammatory Mass, Cerebrospinal Fluid Leaks) are included for Targeted Drug Delivery therapy

Table 3.7: Targeted Drug Delivery Clinical Events Not Related To Product Performance

Event Type	Number of SAEs	Patients with SAE n (%) N=4,570	SAEs Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4,570
General disorders and administration site conditions	265	235 (5.1%)	0.17	57 (1.2%)
Therapeutic and nontherapeutic effects (excl toxicity)	196	174 (3.8%)	0.13	22 (0.5%)
Complications associated with device	46	45 (1.0%)	0.03	28 (0.6%)

Event Type	Number of SAEs	Patients with SAE n (%) N=4,570	SAEs Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4,570
General system disorders NEC ^a	13	13 (0.3%)	0.01	1 (<0.1%)
Administration site reactions	5	5 (0.1%)	<0.01	4 (0.1%)
Other ^b	5	5 (0.1%)	<0.01	4 (0.1%)
Infections and infestations	129	121 (2.6%)	0.08	105 (2.3%)
Infections - pathogen unspecified	107	102 (2.2%)	0.07	92 (2.0%)
Bacterial infectious disorders	21	20 (0.4%)	0.01	13 (0.3%)
Other ^b	1	1 (<0.1%)	<0.01	1 (<0.1%)
Injury, poisoning and procedural complications	84	79 (1.7%)	0.05	22 (0.5%)
Procedural related injuries and complications NEC ^a	41	39 (0.9%)	0.03	16 (0.4%)
Overdoses and underdoses NEC ^a	32	30 (0.7%)	0.02	3 (0.1%)
Injuries NEC ^a	6	6 (0.1%)	<0.01	3 (0.1%)
Other ^b	5	5 (0.1%)	<0.01	0 (0.0%)
Nervous system disorders	79	72 (1.6%)	0.05	35 (0.8%)
Neurological disorders NEC ^a	37	34 (0.7%)	0.02	17 (0.4%)
Neuromuscular disorders	27	26 (0.6%)	0.02	14 (0.3%)
Other ^b	15	15 (0.3%)	0.01	6 (0.1%)
Other SOC Terms (<1.0% Threshold)	57	55 (1.2%)	0.04	16 (0.4%)
Total	614	491 (10.7%)	0.39	214 (4.7%)

^a Not Elsewhere Classified.

^b Composed of high-level group term event codes with fewer than 5 events each.

3.2.3 Therapy Relevant Events

3.2.3.1 Cerebrospinal Fluid Leaks

Potential cerebrospinal fluid (CSF) leak events are identified and assessed by Medtronic personnel and the site physician for the case to ascertain the case definition using [Table 3.8](#).

Table 3.8: Cerebrospinal Fluid Leak Event Definition

Case Definition	Ascertainment
Definitive CSF Leak	Observation of clear fluid leaking from the wound, or Contrast study demonstrates extravasation of dye outside dura, or Patient with persistent post-operative positional headache, plus one of the following: – Blood patch or suturing relieves headaches, or – Subcutaneous persistent fluid collection on the catheter tract, or – Meningeal enhancement on MRI with contrast.
Probable CSF Leak	Reproducible post-operative positional headache for >14 days with or without report of subcutaneous fluid collection. No contrast study performed or contrast study result inconclusive.
Possible CSF Leak	Intermittent post-operative positional headache for >14 days without report of subcutaneous fluid collection. No contrast study performed or contrast study result inconclusive.
Not CSF Leak	Acute post-operative non-positional headache lasting less than 14 days.

The potential CSF leak status (N=556) at the time of this analysis is presented in [Table 3.9](#) with a definitive and probable CSF leak rate of 1.6% (177/11,146). The causality of the CSF leak event is dependent on the individual case.

Table 3.9: Summary of Cerebrospinal Fluid Leak Adjudication

Cases Reviewed	Definitive CSF Leak	Probable CSF Leak	Possible CSF Leak	Not CSF Leak	Unspecified ^a
556	154	23	38	216	125

^a Unadjudicated due to the timing of the data or due to the site no longer being active.

3.2.3.2 Inflammatory Masses

Inflammatory mass (IM), which may also be reported as catheter-tip inflammatory mass or an intrathecal granuloma, is a potential complication of intrathecal opioid drug therapy. In order to better quantify the incidence of inflammatory mass, all events were evaluated for a report of inflammatory mass. For these identified cases, the medical records were reviewed by Medtronic personnel together with radiographic images when available. The radiographic images were reviewed to determine if there was evidence of an intradural extramedullary enhancing lesion. The adjudication team assessed each case based upon the case definition and ascertainment guideline presented in [Table 3.10](#). A summary of cases evaluated for IM through the datacut-off is shown in [Table 3.11](#).

Table 3.10: Case Definition and Ascertainment of Inflammatory Mass

Case Definition	Ascertainment
Definitive IM	Surgical and histological verification or clinical symptoms plus contrast enhanced MRI or CT myelogram and resolution of lesion following cessation of drug exposure
Probable IM	No surgical or histological verification, but clinical criteria and enhanced MRI or CT myelogram criteria are present
Possible IM	Medical records document IM, but there is no surgical or histological verification, there are no clinical criteria, and no radiographic data are available
Not IM	Surgical and histological verification that lesion is another disease process rather than IM, or radiographic data do not show an intrathecal lesion

There were a total of 136 suspected cases of inflammatory mass ([Table 3.11](#)) that were discerned from evaluation of patient records and reviewed by the adjudication team. Medtronic will continue to evaluate reports of inflammatory mass. Any previously classified case of IM will be re-evaluated if new evidence is received after this report. An analysis of the adjudicated definitive and probable inflammatory mass cases in the PSR from 2003 through October 31, 2025 indicates an incidence of 0.21% (18/8,551) for pain patients and 0.00% (0/2,331) for spasticity patients.

Table 3.11: Summary of Inflammatory Mass Adjudication

Year of Event	Cases Reviewed	Definitive IM	Probable IM	Possible IM	Not IM
2004	4	0	0	0	4
2005	4	1	0	1	2
2006	7	1	1	2	3
2007	9	1	1	2	5
2008	4	0	1	0	3
2009	3	1	0	0	2
2010	11	0	1	1	9
2011	11	1	2	1	7
2012	13	0	0	1	12
2013	6	0	0	4	2
2014	10	0	0	2	8
2015	21	1	0	6	14
2016	10	1	1	2	6
2017	9	0	0	1	8

Year of Event	Cases Reviewed	Definitive IM	Probable IM	Possible IM	Not IM
2018	4	1	0	0	3
2019	5	1	0	0	4
2020	3	1	0	1	1
2021	2	0	1	0	1
2022	0	0	0	0	0
2023	0	0	0	0	0
2024	0	0	0	0	0
2025	0	0	0	0	0
Total	136	10	8	24	94

3.2.4 Patient Deaths

In versions of the protocol prior to 2010, deaths were only assessed for the relatedness to the device product performance. After 2010, death assessments were expanded to also include the relationship to the implant procedure and/or therapy. As of the report cut-off, a total of 3,036 patients in the registry had expired. No deaths were reported as a direct result of a product performance event. Although three deaths were assigned by the physician as possibly related to the implant procedure and/or therapy.

Of the three deaths possibly related to the procedure and/or therapy, one death was due to a pulmonary embolism where the treating physician stated that the event could be possibly related to the withdrawal of the intrathecal medications. The patient had experienced a lack of therapy due to a missed refill visit leading to the withdrawal and not to the device malfunctioning. Medtronic Medical Safety assessed this death event as possibly related to the lack of therapy. A second death was reported by the treating physician as due to acute respiratory failure possibly related to the procedure and/or therapy. This patient had a history of persistent upper respiratory tract problems, swallowing difficulties, and chronic aspiration as the result of cancer-related treatments. Medtronic Medical Safety assessed this death event as possibly related to the surgery/anesthesia during the implant procedure and therapy. The third death was reported by the physician as due to respiratory distress possibly related to the intrathecal medication. This patient had multiple comorbidities with multiple concomitant medications and a decreased level of physical activity. The death records state the cause of death as probable arteriosclerotic cardiovascular disease. Medtronic Medical Safety determined this event as not assessable due to incomplete information.

Since 2003, a total of 1,502 (49.5%) deaths have been reported in this patient registry study based upon patients receiving therapy for malignant pain, 1,143 (37.6%) for non-malignant pain, 354 (11.7%) for spasticity, 33 (1.1%) for non-malignant pain & spasticity, 1 (<0.1%) for malignant pain & chemotherapy, and 3 (0.1%) for not specified primary indication (see [Table 3.12](#)). The percentage is based upon the total patient death events and not based upon the rate of occurrence. **All tables depicted without a patient denominator should not be interpreted using**

other numbers within this report to calculate event rates.

Table 3.12: Targeted Drug Delivery System Patient Deaths by Primary Indication

Number of Reports of Death by Primary Indication ^a	N (%) of Deaths
Malignant pain	1502 (49.5%)
Non-malignant pain	1143 (37.6%)
Spasticity	354 (11.7%)
Non-malignant pain & Spasticity	33 (1.1%)
Malignant pain & Chemotherapy	1 (<0.1%)
Not Specified	3 (0.1%)
Total	3036

^a For approved indications refer to product labeling for your geography.

3.3 Pumps

From August 7, 2003, to the report cut-off date of October 31, 2025, there were 14,424 pumps followed in the registry. The difference between the total number of patients (n=11,146) versus the total number of pumps is due to the fact that some patients were subsequently re-implanted with a pump multiple times. The aggregate prospective follow-up time for all pumps was 504,908 months (42,076 years). [Table 3.13](#) provides the number and percentage of pumps by model number.

3.3.1 SynchroMed II Design Change: Pump Enhancements; SynchroMed III

Design changes to the SynchroMed II 20 mL and 40 mL pump models were implemented to reduce the likelihood of non-recoverable motor stalls. These changes were released incrementally, allowing for the pumps to be considered in three groups: 1) Pre-Enhancements (prior to 2016), 2) the Modified Gear Wheel Material and Encapsulated Feedthroughs (GW3/FT) enhancements (released January 2016) and 3) the Applied Diamond Like Coating (GW3/FT/DLC) enhancement (released July 2017). All enhancements were communicated in the August 2017 Medical Device Safety Notification: SynchroMed II Implantable Drug Infusion Pump Design Change Model Numbers 8637-20, 8637-40. For details, please visit <https://www.medtronic.com/content/dam/medtronic-com/professional/documents/product-advisories/tdd/synchromed-pump-design-change-august-2017-hcp-letter.pdf>. [Table 3.13](#) provides the number and percentage of pumps by model and pump enhancement.

The SynchroMed III pump was released in 2023 and includes the same enhancements as the GW3/FT/DLC pump as well as additional enhancements.

Table 3.13: Targeted Drug Delivery Pump Counts by Model and Pump Enhancement

Model Name	N (%)
SynchroMed III 40 mL	496 (3.4%)
GW3/FT/DLC Enhancements	496 (3.4%)
SynchroMed III 20 mL	206 (1.4%)
GW3/FT/DLC Enhancements	206 (1.4%)
SynchroMed II 40 mL	7859 (54.5%)
Pre-Enhancements ^a	4631 (32.1%)
GW3/FT/DLC Enhancements	2691 (18.7%)
GW3/FT Enhancements ^a	537 (3.7%)
SynchroMed II 20 mL	4675 (32.4%)
Pre-Enhancements ^a	2964 (20.5%)
GW3/FT/DLC Enhancements	1349 (9.4%)
GW3/FT Enhancements ^a	362 (2.5%)

Model Name	N (%)
SynchroMed EL 18 mL ^a	1146 (7.9%)
SynchroMed EL 10 mL ^a	34 (0.2%)
SynchroMed Classic ^a	5 (<0.1%)
Other/Unspecified	3 (<0.1%)
Total	14424

^a No longer manufactured.

The pump product performance-related events by model, including pre-SynchroMed II enhancements and post-SynchroMed II enhancements, are summarized in the pump models section.

3.3.2 Pump Events

There were 551 product performance-related events with an underlying reported etiology related to pump function. This includes 546 events with a pump etiology and 5 events with both a pump and other etiology (including device and non-device etiologies). Of these, 472 were the initial product performance event that affected pump survival estimates. For pumps in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 25.1% (1,952/7,769). The proportion was based upon the number of registry pumps received by RPA, divided by the sum of the total number of explanted devices and the total number of pumps in patients who have expired. In the 551 pump events, 36.1% (199/551) were assigned as device-related by the physician, not returned to Medtronic RPA (see [Figure 3.4](#)). For the purposes of survival analysis, a device's follow-up time is cut off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For pumps:

- 472 had follow up time cut-off due to product performance-related events.
- 11,910 were censored in the survival analysis for the following reasons: patient expired, pump explanted, site termination, patient discontinued, patient lost to follow-up, or therapy suspended.
- 2,042 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

3.3.3 Pump Models

The following figures and tables represent the SynchroMed II pump characteristics, survival (including 95% confidence intervals), specifications and events by model. Since the survival estimate may become very imprecise with smaller sample sizes, the device survival curves below are truncated when the sample size is less than 20 active devices for each 3-month interval. The SynchroMed III pump survival is not yet shown due to the small number of enrolled and tracked devices. The survival of SynchroMed EL model was not shown since it has no active devices in the PSR. For information on this model, please refer to the 2017 or earlier reports.

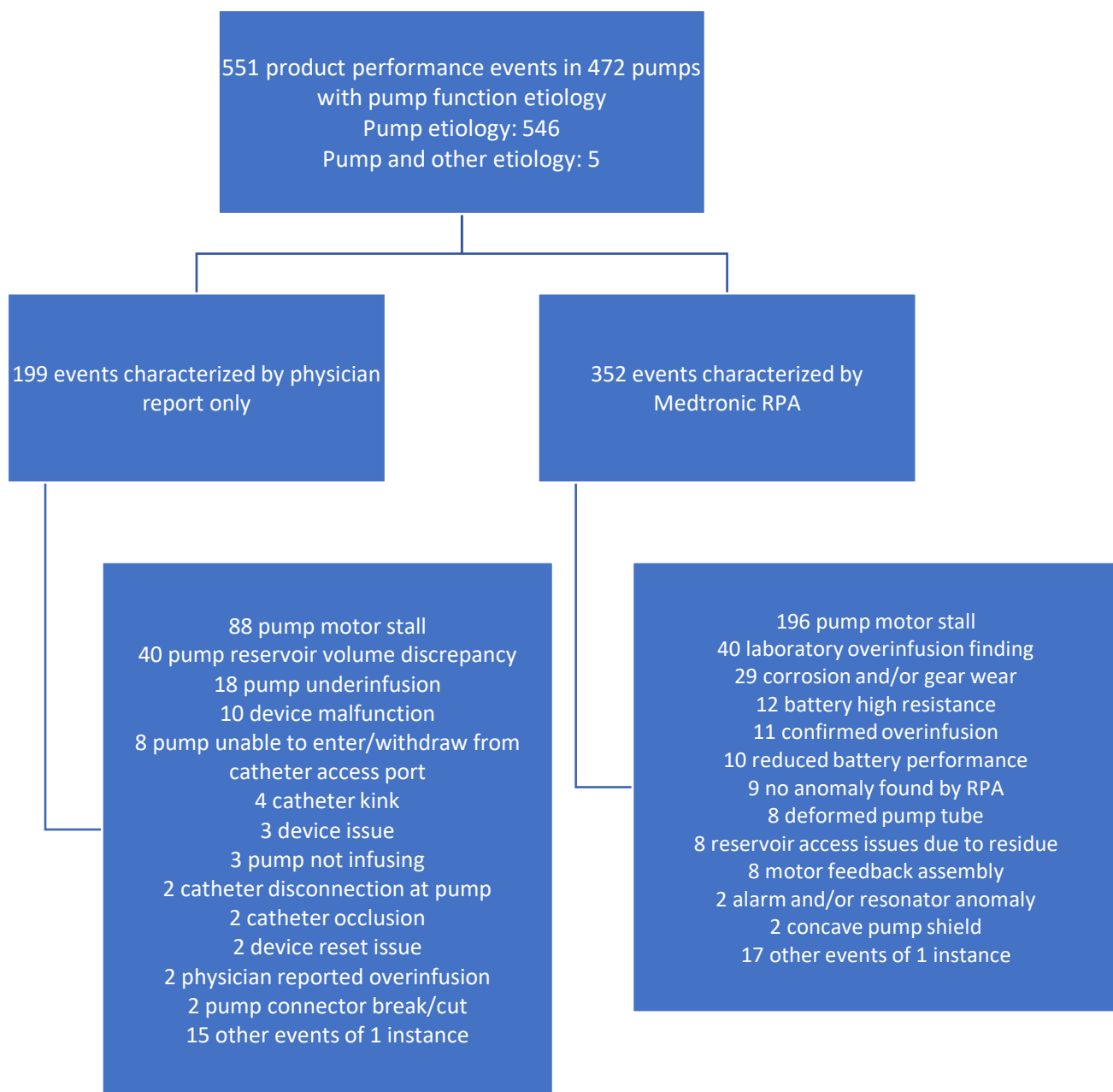
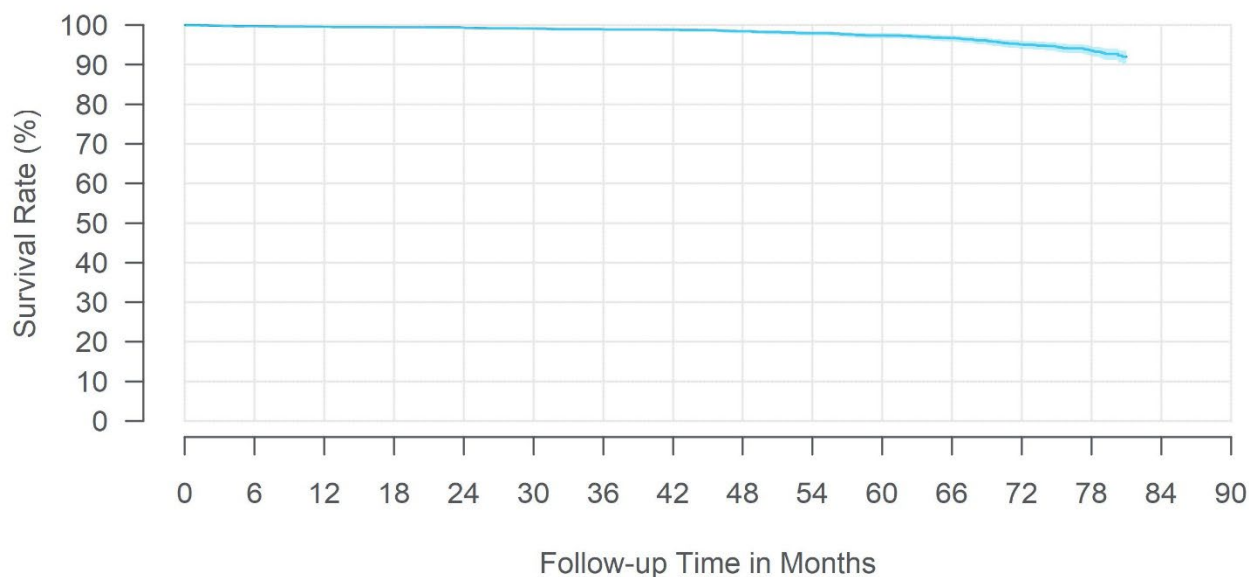


Figure 3.4: Distribution of Pump Function Etiology Product Performance Events

3.3.3.1 Model 8637-20

Model/Name	SynchroMed II 20 mL
FDA Approval Date	September 2003
Pumps Enrolled	4,675
Pumps Currently Active in Study	565
Initial Product Performance Events	130
Median Follow-up Time (Months)	41.7
Cumulative Follow-up Time (Months)	199,270



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (99.3%, 99.7%)	99.3% (99.0%, 99.6%)	98.9% (98.5%, 99.2%)	98.4% (97.9%, 98.8%)	97.4% (96.7%, 98.0%)
Sample Size	3655	3113	2595	2102	1694

Time Interval	6 Years	At 81 Months
Survival (95% CI)	95.2% (94.1%, 96.0%)	92.0% (90.2%, 93.5%)
Sample Size	1272	280

Specification: 8637-20	
Expected battery life^a	6-7 years
Thickness	0.77 in (19.5 mm)
Diameter	3.4 in (87.5 mm)
Capacity	20.0 mL
Minimal Programmable Flow Rate^b	0.048 mL/day
Maximum Programmable Flow Rate^b	24 mL/day
Minimum Rate Infusion Mode^c	0.006 mL/day

^a Dependent on flow rate. Designed to shut off at 84 months.

^b Actual limits depend on pump calibration constant and selected infusion mode.

^c Nontherapeutic (if therapy is to be temporarily discontinued).



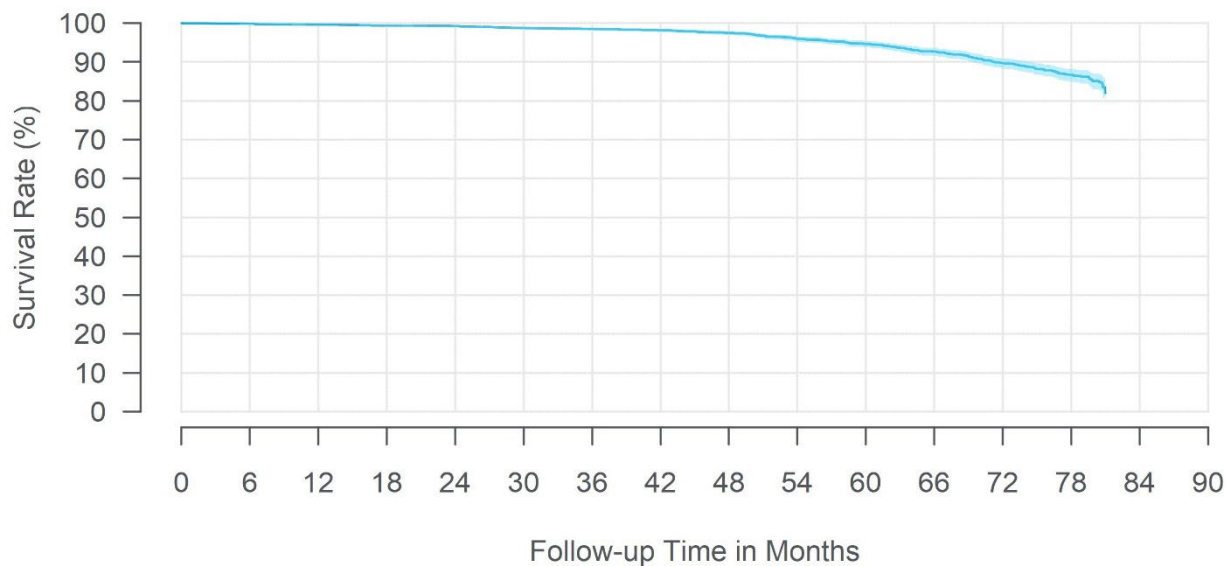
Pump Event Summary: SynchroMed II 20 mL	N
RPA Determination	78
Pump Motor Stall	39
Laboratory overinfusion finding	8
Battery High Resistance	7
Corrosion And/Or Gear Wear	4
Motor Feedthrough Anomaly	3
Deformed Pump Tube	2
No Anomaly Found By RPA	2
Reduced Battery Performance	2
Reservoir Access Issues Due To Residue	2
Other ^a	9
Physician's Determination	52
Pump Motor Stall	21
Pump Reservoir Volume Discrepancy	10
Device Malfunction	6
Pump Unable To Enter/Withdraw From Catheter Access Port	4

Pump Event Summary: SynchroMed II 20 mL	N
Device Issue	3
Other ^a	8
Total	130

^a Composed of event codes with 1 event each.

3.3.3.2 Model 8637-40

Model/Name	SynchroMed II 40 mL
FDA Approval Date	September 2003
Pumps Enrolled	7,859
Pumps Currently Active in Study	881
Initial Product Performance Events	308
Median Follow-up Time (Months)	28.9
Cumulative Follow-up Time (Months)	270,368



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (99.4%, 99.7%)	99.2% (99.0%, 99.4%)	98.5% (98.1%, 98.8%)	97.5% (96.9%, 97.9%)	94.6% (93.8%, 95.4%)
Sample Size	5398	4341	3431	2643	1991

Time Interval	6 Years	At 81 Months
Survival (95% CI)	89.7% (88.4%, 90.9%)	82.0% (78.9%, 84.7%)
Sample Size	1273	162

Specification: 8637-40	
Expected battery life ^a	6-7 years
Thickness	1.0 in (26 mm)
Diameter	3.4 in (87.5 mm)
Capacity	40.0 mL
Minimal Programmable Flow Rate ^b	0.048 mL/day
Maximum Programmable Flow Rate ^b	24 mL/day
Minimum Rate Infusion Mode ^c	0.006 mL/day

^a Dependent on flow rate. Designed to shut off at 84 months.

^b Actual limits depend on pump calibration constant and selected infusion mode.

^c Nontherapeutic (if therapy is to be temporarily discontinued).



Pump Event Summary: SynchroMed II 40 mL	N
RPA Determination	212
Pump Motor Stall	134
Laboratory overinfusion finding	29
Corrosion And/Or Gear Wear	7
No Anomaly Found By RPA	7
Reduced Battery Performance	7
Deformed Pump Tube	5
Confirmed overinfusion	4
Reservoir Access Issues Due To Residue	4
Battery High Resistance	3
Motor Feedthrough Anomaly	3
Concave Pump Shield	2
Other ^a	7
Physician's Determination	96
Pump Motor Stall	37

Pump Event Summary: SynchroMed II 40 mL	N
Pump Reservoir Volume Discrepancy	22
Pump Underinfusion	10
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Kink	3
Device Malfunction	2
Pump Not Infusing	2
Other ^a	16
Total	308

^a Composed of event codes with 1 event each.

3.3.3.3 Model 8667-20

Model/Name	SynchroMed III 20 mL
FDA Approval Date	October 2023
Pumps Enrolled	206
Pumps Currently Active in Study	180
Initial Product Performance Events	0
Median Follow-up Time (Months)	3.4
Cumulative Follow-up Time (Months)	844

There is not sufficient data to report on SynchroMed III 20 mL (model 8667-20) survival rates at 1 year or later (=9).

Specification: 8667-20	
Expected battery life^a	6-7 years
Thickness	1.0 in (26 mm)
Diameter	3.4 in (87.5 mm)
Capacity	20.0 mL
Minimal Programmable Flow Rate^b	0.048 mL/day
Maximum Programmable Flow Rate^b	24 mL/day
Minimum Rate Infusion Mode^c	0.006 mL/day

^a Dependent on flow rate. Designed to shut off at 84 months.

^b Actual limits depend on pump calibration constant and selected infusion mode.

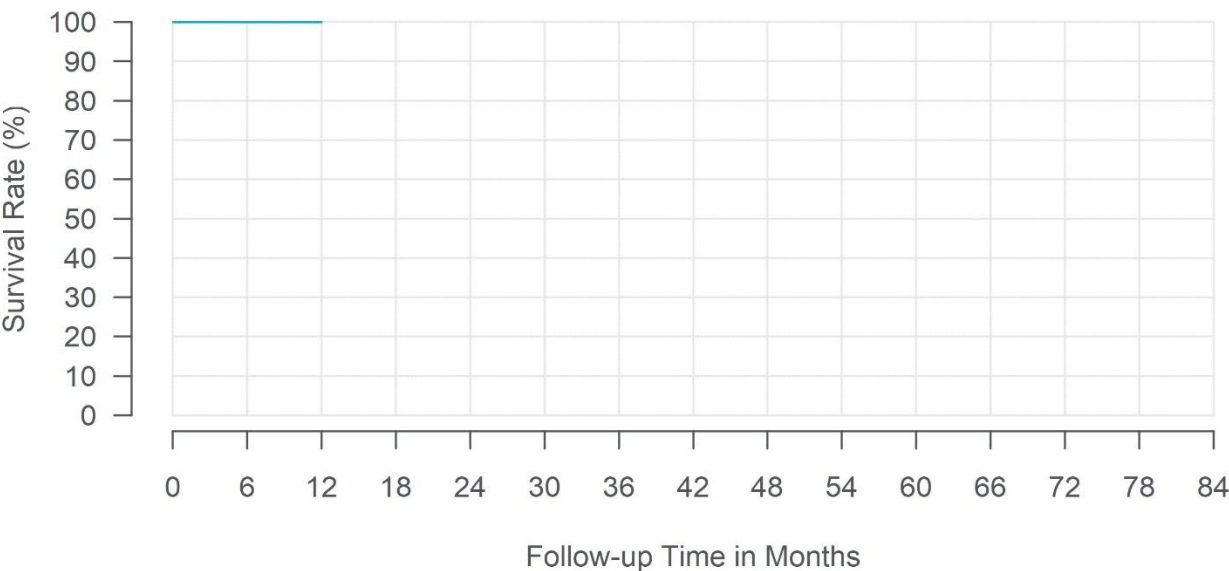
^c Nontherapeutic (if therapy is to be temporarily discontinued).



No product performance events for this model have been reported as of the data cut-off date.

3.3.3.4 Model 8667-40

Model/Name	SynchroMed III 40 mL
FDA Approval Date	October 2023
Pumps Enrolled	496
Pumps Currently Active in Study	418
Initial Product Performance Events	0
Median Follow-up Time (Months)	3.2
Cumulative Follow-up Time (Months)	2,145



Time Interval	1 Year
Survival (95% CI)	100.0% (NA)
Sample Size	28

Specification: 8667-40	
Expected battery life^a	6-7 years
Thickness	1.0 in (26 mm)
Diameter	3.4 in (87.5 mm)
Capacity	40.0 mL
Minimal Programmable Flow Rate^b	0.048 mL/day
Maximum Programmable Flow Rate^b	24 mL/day
Minimum Rate Infusion Mode^c	0.006 mL/day

^a Dependent on flow rate. Designed to shut off at 84 months.

^b Actual limits depend on pump calibration constant and selected infusion mode.

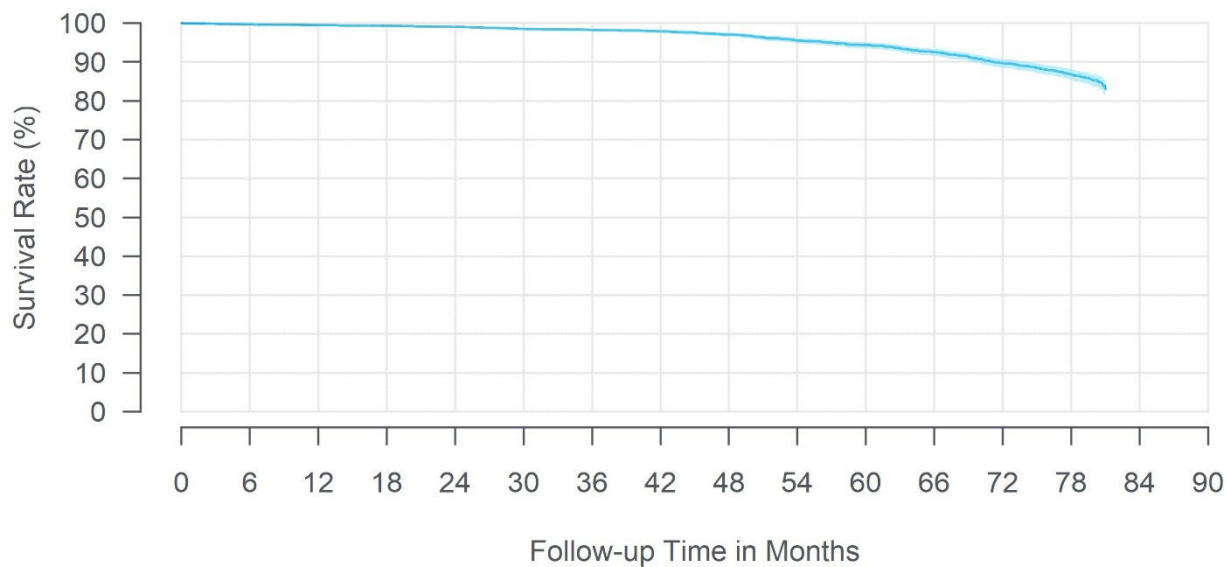
^c Nontherapeutic (if therapy is to be temporarily discontinued).



There have been no reported product performance events for this model as of the data cut-off date.

3.3.3.5 SynchroMed II 20 mL and 40 mL: Pre-enhancements

Model/Name	Pre-Enhancements
FDA Approval Date	September 2003
Pumps Enrolled	7,595
Pumps Currently Active in Study	1
Initial Product Performance Events	399
Median Follow-up Time (Months)	34.7
Cumulative Follow-up Time (Months)	294,523



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.5% (99.3%, 99.7%)	99.0% (98.7%, 99.3%)	98.3% (97.9%, 98.6%)	97.0% (96.5%, 97.5%)	94.4% (93.5%, 95.1%)
Sample Size	5296	4576	3819	3160	2570

Time Interval	6 Years	At 81 Months
Survival (95% CI)	89.7% (88.5%, 90.8%)	83.2% (81.0%, 85.1%)

Time Interval	6 Years	At 81 Months
Sample Size	1894	334

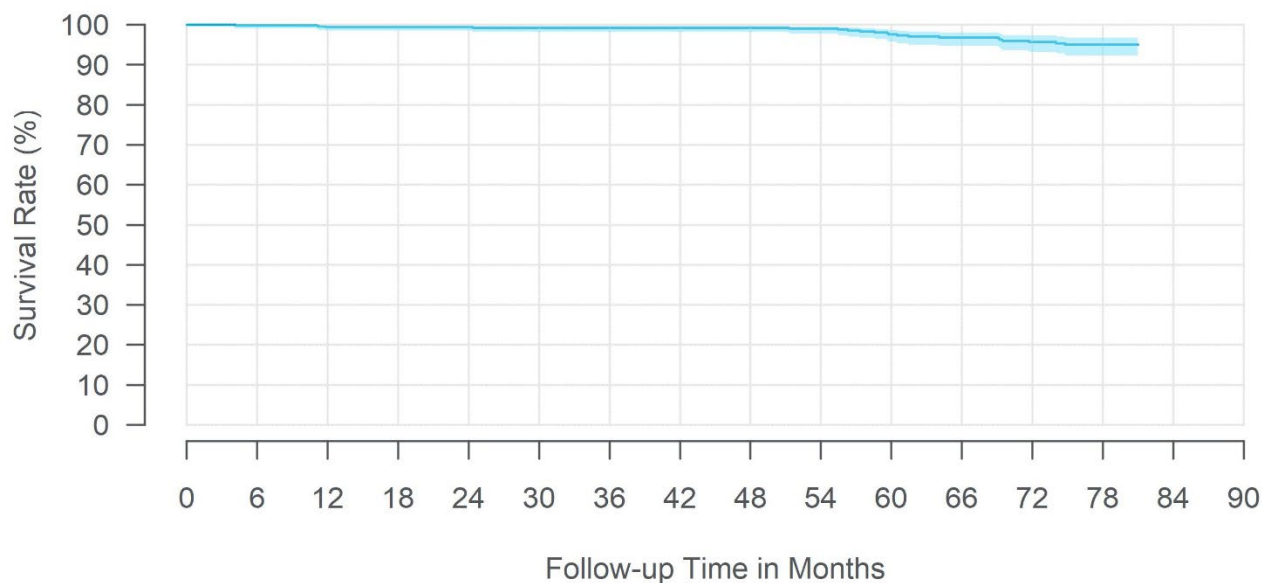
Pump Event Summary: SynchroMed II Pre-enhancements	Total
RPA Determination	269
Pump Motor Stall	165
Laboratory overinfusion finding	35
Battery High Resistance	10
Corrosion And/Or Gear Wear	10
Reduced Battery Performance	9
Deformed Pump Tube	6
Motor Feedthrough Anomaly	6
No Anomaly Found By RPA	6
Confirmed overinfusion	5
Reservoir Access Issues Due To Residue	4
Alarm And/Or Resonator Anomaly	2
Concave Pump Shield	2
Other ^a	9
Physician's Determination	130
Pump Motor Stall	57
Pump Reservoir Volume Discrepancy	28
Pump Unable To Enter/Withdraw From Catheter Access Port	8
Pump Underinfusion	8
Device Malfunction	6
Device Issue	3
Pump Not Infusing	3
Catheter Occlusion	2

Pump Event Summary: SynchroMed II Pre-enhancements	Total
Physician reported overinfusion	2
Pump Connector Break/Cut	2
Other ^a	11
Total	399

^a Composed of event codes with 1 event each.

3.3.3.6 SynchroMed II 20 mL and 40 mL: GW3/FT Enhancements

Model/Name	GW3/FT Enhancements
FDA Approval Date	September 2015 (GW3)/November 2015 (FT)
Pumps Enrolled	899
Pumps Currently Active in Study	1
Initial Product Performance Events	21
Median Follow-up Time (Months)	48.9
Cumulative Follow-up Time (Months)	40,834



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.4% (98.5%, 99.8%)	99.4% (98.5%, 99.8%)	99.3% (98.2%, 99.7%)	99.3% (98.2%, 99.7%)	97.6% (95.8%, 98.7%)
Sample Size	686	575	509	456	398

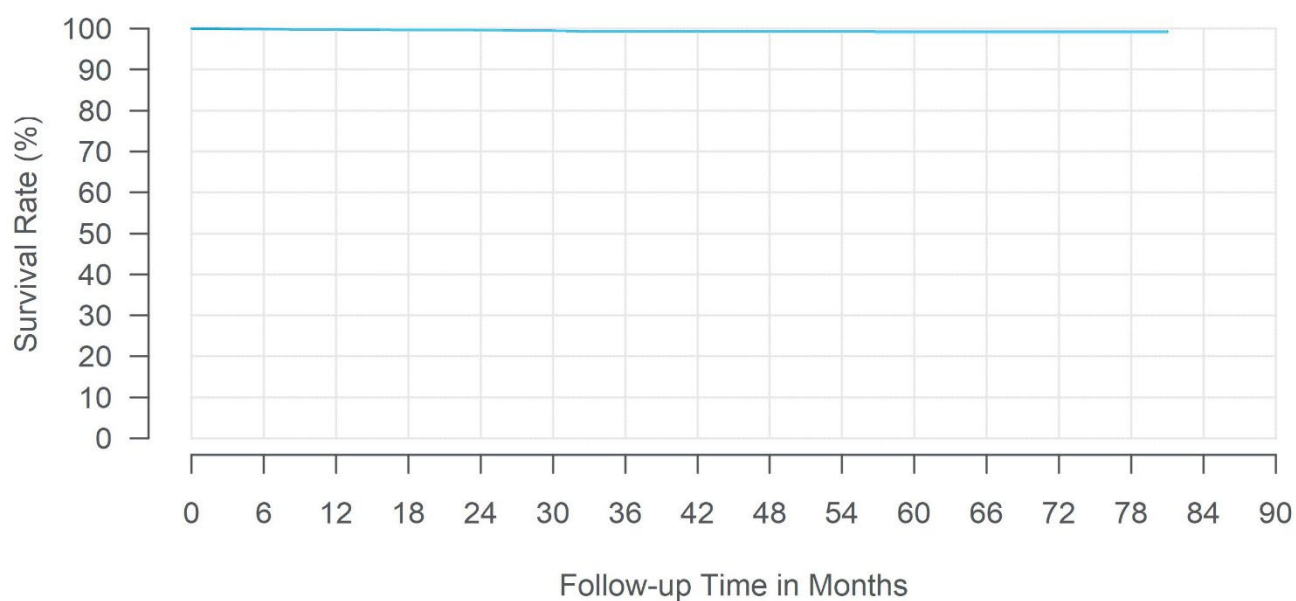
Time Interval	6 Years	At 81 Months
Survival (95% CI)	95.7% (93.3%, 98.1%)	95.1% (92.4%, 97.8%)

Time Interval	6 Years	At 81 Months
CI)	97.3%)	96.8%)
Sample Size	325	66

Pump Event Summary: SynchroMed II GW3/FT Enhancements	Total
RPA Determination	14
Pump Motor Stall	6
No Anomaly Found By RPA	2
Reservoir Access Issues Due To Residue	2
Laboratory overinfusion finding	1
Corrosion And/Or Gear Wear	1
Failed Lab Dispense Test	1
Unknown Root Cause. Battery And Hybrid Tested, No Anomalies Found. The Pump May Have Been Exposed To Some Extreme Condition.	1
Physician's Determination	7
Pump Reservoir Volume Discrepancy	2
Pump Motor Stall	1
Catheter Access Port Issue	1
Catheter Disconnection At Pump	1
Pump Infusion Issue	1
Pump Reservoir Issue	1
Total	21

3.3.3.7 SynchroMed II 20 mL and 40 mL: GW3/FT/DLC Enhancements

Model/Name	GW3/FT/DLC Enhancements
FDA Approval Date	April 2017 (DLC)
Pumps Enrolled	4,040
Pumps Currently Active in Study	1,444
Initial Product Performance Events	18
Median Follow-up Time (Months)	29.4
Cumulative Follow-up Time (Months)	134,281



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.8% (99.6%, 99.9%)	99.7% (99.4%, 99.8%)	99.4% (99.0%, 99.6%)	99.4% (99.0%, 99.6%)	99.2% (98.7%, 99.5%)
Sample Size	3071	2303	1698	1129	717

Time Interval	6 Years	At 81 Months
Survival (95% CI)	99.2% (98.7%, 99.5%)	99.2% (98.7%, 99.5%)
Sample Size	326	42

Pump Event Summary: SynchroMed II GW3/FT/DLC Enhancements	Total
RPA Determination	7
Pump Motor Stall ^a	2
Laboratory overinfusion finding	1
Deformed Pump Tube	1
No Anomaly Found By RPA	1
Pump Leak Due To Damage Or Missing O-Ring	1
Reservoir Septum Damage	1
Physician's Determination	11
Catheter Kink	3
Pump Reservoir Volume Discrepancy	2
Pump Underinfusion	2
Device Malfunction	2
Catheter Disconnection At Pump	1
Pump Migration	1
Total	18

^a One motor stall occurred within one year of implant due to unknown cause.

3.3.4 Pump Summary

Table 3.14: Targeted Drug Delivery Pump Characteristics

Model/Name	FDA Approval Date	Pumps Enrolled	Pumps Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
SynchroMed II 20 mL	September 2003	4,675	565	130	41.7	199,270
SynchroMed II 40 mL	September 2003	7,859	881	308	28.9	270,368
SynchroMed II Pre-enhancements ^a	September 2003	7,595	1	399	34.7	294,523
SynchroMed II GW3/FT enhancements ^a	September 2015 (GW3) November 2015 (FT)	899	1	21	48.9	40,834
SynchroMed II GW3/FT/DLC enhancements ^a	April 2017 (DLC)	4,040	1,444	18	29.4	134,281
SynchroMed III 20 mL	October 2023	206	180	0	3.4	844
SynchroMed III 40 mL	October 2023	496	418	0	3.2	2,145

^a For explanation of enhancements see [Section 3.3.1](#).

Table 3.15: Targeted Drug Delivery Pump Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
SynchroMed II 20 mL	99.6%	99.3%	98.9%	98.4%	97.4%
	(99.3%, 99.7%)	(99.0%, 99.6%)	(98.5%, 99.2%)	(97.9%, 98.8%)	(96.7%, 98.0%)
SynchroMed II 40 mL	99.6%	99.2%	98.5%	97.5%	94.6%
	(99.4%, 99.7%)	(99.0%, 99.4%)	(98.1%, 98.8%)	(96.9%, 97.9%)	(93.8%, 95.4%)
SynchroMed II Pre-	99.5%	99.0%	98.3%	97.0%	94.4%

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Enhancements					
	(99.3%, 99.7%)	(98.7%, 99.3%)	(97.9%, 98.6%)	(96.5%, 97.5%)	(93.5%, 95.1%)
SynchroMed II GW3/FT Enhancements	99.4%	99.4%	99.3%	99.3%	97.6%
	(98.5%, 99.8%)	(98.5%, 99.8%)	(98.2%, 99.7%)	(98.2%, 99.7%)	(95.8%, 98.7%)
SynchroMed II GW3/FT/DLC Enhancements	99.8%	99.7%	99.4%	99.4%	99.2%
	(99.6%, 99.9%)	(99.4%, 99.8%)	(99.0%, 99.6%)	(99.0%, 99.6%)	(98.7%, 99.5%)

Model Name	6 Years	At 81 Months
SynchroMed II 20 mL	95.2%	92.0%
	(94.1%, 96.0%)	(90.2%, 93.5%)
SynchroMed II 40 mL	89.7%	82.0%
	(88.4%, 90.9%)	(78.9%, 84.7%)
SynchroMed II Pre-Enhancements	89.7%	83.2%
	(88.5%, 90.8%)	(81.0%, 85.1%)
SynchroMed II GW3/FT Enhancements	95.7%	95.1%
	(93.3%, 97.3%)	(92.4%, 96.8%)
SynchroMed II GW3/FT/DLC Enhancements	99.2%	99.2%
	(98.7%, 99.5%)	(98.7%, 99.5%)

Table 3.16: Targeted Drug Delivery SynchroMed II Pump Events by Enhancements

Pump Event	Pre-Enhancements	GW3/FT Enhancements	GW3/FT/DLC Enhancements
RPA Determination	269	14	7
Pump Motor Stall	165	6	2
Laboratory overinfusion finding	35	1	1
Battery High Resistance	10	0	0
Corrosion And/Or Gear Wear	10	1	0
Reduced Battery Performance	9	0	0
Deformed Pump Tube	6	0	1
Motor Feedthrough Anomaly	6	0	0
No Anomaly Found By RPA	6	2	1
Confirmed overinfusion	5	0	0
Reservoir Access Issues Due To Residue	4	2	0
Alarm And/Or Resonator Anomaly	2	0	0
Concave Pump Shield	2	0	0
Failed Lab Dispense Test	0	1	0
Pump Leak Due To Damage Or Missing O-Ring	0	0	1
Reservoir Septum Damage	0	0	1
Unknown Root Cause. Battery And Hybrid Tested, No Anomalies Found. The Pump May Have Been Exposed To Some Extreme Condition.	0	1	0
Other ^a	9	0	0
Physician's Determination	130	7	11
Pump Motor Stall	57	1	0
Pump Reservoir Volume Discrepancy	28	2	2
Pump Unable To Enter/Withdraw From Catheter Access Port	8	0	0

Pump Event	Pre-Enhancements	GW3/FT Enhancements	GW3/FT/DLC Enhancements
Pump Underinfusion	8	0	2
Device Malfunction	6	0	2
Device Issue	3	0	0
Pump Not Infusing	3	0	0
Catheter Occlusion	2	0	0
Physician reported overinfusion	2	0	0
Pump Connector Break/Cut	2	0	0
Catheter Kink	1	0	3
Catheter Access Port Issue	0	1	0
Catheter Disconnection At Pump	0	1	1
Pump Infusion Issue	0	1	0
Pump Migration	0	0	1
Pump Reservoir Issue	0	1	0
Other ^a	10	0	0
Total	399	21	18

^a Composed of event codes with 1 event each for SynchroMed II Pre-Enhancements.

3.4 SynchronMed II and SynchronMed III Pumps Exposed to On-Label and Off-Label Medications

The purpose of this analysis is to provide additional information regarding the product performance of SynchronMed II and SynchronMed III pumps exposed to On-Label and Off-Label medications. This report contains information related to uses outside the FDA-approved labeling for the Medtronic SynchronMed II Infusion System. The long-term drug stability/compatibility and safety and/or efficacy of drugs not listed in the SynchronMed II Infusion System product labeling have not been established in the United States. It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved regulatory labeling. For the purposes of this report, On-Label and Off-Label determinations have been made based on the United States FDA-approved labeling. However, product labeling varies by geography, so please contact your local Medtronic representative by going to the [SynchronMed™ III Intrathecal Pump | Medtronic](#) website and clicking on “Contact and Support” for region-specific product labeling.

In this registry, patient status updates were obtained at least annually, until discontinuation of therapy, or until the patient was lost to follow-up. Medications within the pump were recorded at least annually. The interim data collection provided a snapshot of medication use at these points in time.

3.4.1 Pump Groups On/Off-Label Categorization

Through October 31, 2025, 9,558 patients (56.0% female, mean/SD age 54.2/17.5 years) have enrolled in the registry and have been implanted with 12,534 SynchronMed II pumps. At least one drug record was available on each of 11,939 pumps; if no drug records were available (n=595 pumps), the pump was excluded from this analysis. 11,939 pumps were categorized as being On- or Off-Label using the following criteria:

- **On-Label:** If a pump has at least one drug record in the registry, and none of the records show Off-Label drug exposure, that pump is considered On-Label even if the complete drug history of that pump is unknown.
 - For pumps used for pain patients, if the drug record has only one drug and it was morphine or ziconotide (or their brand names), and it was not specified as a compounded drug, these pumps were considered On-Label. Note: The classification was based on the name of the drug only, not the reported concentration of the drug.
 - For pumps used for spasticity patients, if the drug record has only one drug, and it is either Lioresal[®] (baclofen injection) or Gablofen[®] (baclofen injection), that drug record was considered On-Label. Note: The classification was based on the name of the drug only, not the reported concentration of the drug. For this analysis, if only the generic chemical classification, such as baclofen, was entered then the assumption was that the drug was On-Label.
 - Pumps with an On-Label drug history and currently containing preservative free water

or preservative free saline, or if previously contained preservative free water/saline and currently containing On-Label drug were considered On-Label.

- **Off-Label:** Any drugs not within the approved indications specified above are considered Off-Label. Additionally, any drug record with more than one drug at a time in the pump (admixture) was considered Off-Label.
 - If a pump had any known exposure to Off-Label drugs (i.e., the Off-Label data have been collected in the registry), that pump was considered Off-Label, regardless of the amount of exposure time.
 - If a pump is filled with a medication that was reported as compounded, that pump was considered Off-Label.

3.4.2 Data Analysis

Survival estimates were calculated using the methods described in the Methodology section of this report. Statistical testing that compared survival curves was performed using a Cox proportional-hazards model. Since the survival estimate may become very imprecise with small sample sizes, Medtronic Neuromodulation's registry truncates device survival curves when the sample size is less than 20 active devices. At this threshold, one device failure yields a 5% decrease in cumulative survival. Additionally, the standard error for this survival estimate is approximately 5% (depending on previous conditional survival estimates), with 95% confidence intervals of approximately $\pm 10\%$. Overall, this large variability of 20% around the cumulative survival estimate would greatly reduce the precision for the point estimate.

Pump survival from product performance-related events was calculated and compared for the following groups:

- Total study population: On-Label vs. Off-Label Drugs (including all indications)
- Pain study population: On-Label vs. Off-Label Drugs (including all pain indications)
- Spasticity study population: On-Label vs. Off-Label Drugs (including all spasticity indications)

Additionally, the cumulative failure rate (i.e., the estimated probability that a pump will have a product performance-related event by a given time point) is presented in table and graph formats for each of the sub-groups listed above.

3.4.3 SynchroMed II Results

A total of 3,617 (30.3%) SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total 8,322 (69.7%) of pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. Primary indications by on/off label pump groups are shown in table [3.17](#). There were a total of 438 reported SynchroMed II pump product performance events during the study observation period. Of the 438 pump product performance events, 435 of those were the first event and included as failures in the survival analysis. In addition to the 435 pump failures, there were 15

SynchroMed II pumps explanted due to normal battery depletion by the physician, which were returned to Medtronic and had an RPA observation of high battery resistance. For this analysis, these pumps were not considered failures, because they represented normal implant duration (ranging from 5.6 to 6.8 years) with no associated physician or patient complaint.

Three of the 438 pump failure events occurred in pumps with no drug records available. Of the remaining 435 SynchroMed II pump failures, 231 were classified as pump failure due to motor stall (with or without documented motor corrosion). The remaining pump failures were due to events such as inconsistent pump reservoir volume, overinfusion, corrosion and/or gear wear, device malfunction, reduced battery performance, pump underinfusion, and other non-conforming reasons. Overall, the rate of pump failures in this cohort was 3.6% (435/11939) with a median follow-up of 35.3 months.

For the 231 pump failures due to motor stall, 99 of the events were associated with the patient presenting clinical signs or symptoms of possible drug withdrawal or increasing pain or spasticity. The other 132 events had no patient reported signs or symptoms associated with the event but had a physician report of a motor stall occurrence.

Table 3.17: Targeted Drug Delivery Primary Indications by On/Off-Label Pump Groups

Primary Indication ^a	On-Label N=3617	Off-Label N=8322
Non-Malignant Pain	1030 (14.0%)	6305 (86.0%)
Malignant Pain	48 (3.0%)	1558 (97.0%)
Spasticity	2539 (90.7%)	259 (9.3%)
Multiple/Unknown	0 (0.0%)	200 (100%)

^a For approved indications refer to product labeling for your geography.

3.4.3.1 Total Study Population

A total of 3,617 SynchroMed II pumps were classified as On-Label for all therapies, where there was no evidence of Off-Label drug/admixture exposure. A total of 8,322 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. The cumulative survival and failure of the SynchroMed II pump for all indications, stratified by the On-Label or Off-Label pump group, are shown in [Figure 3.5](#) and [Figure 3.6](#) respectively.

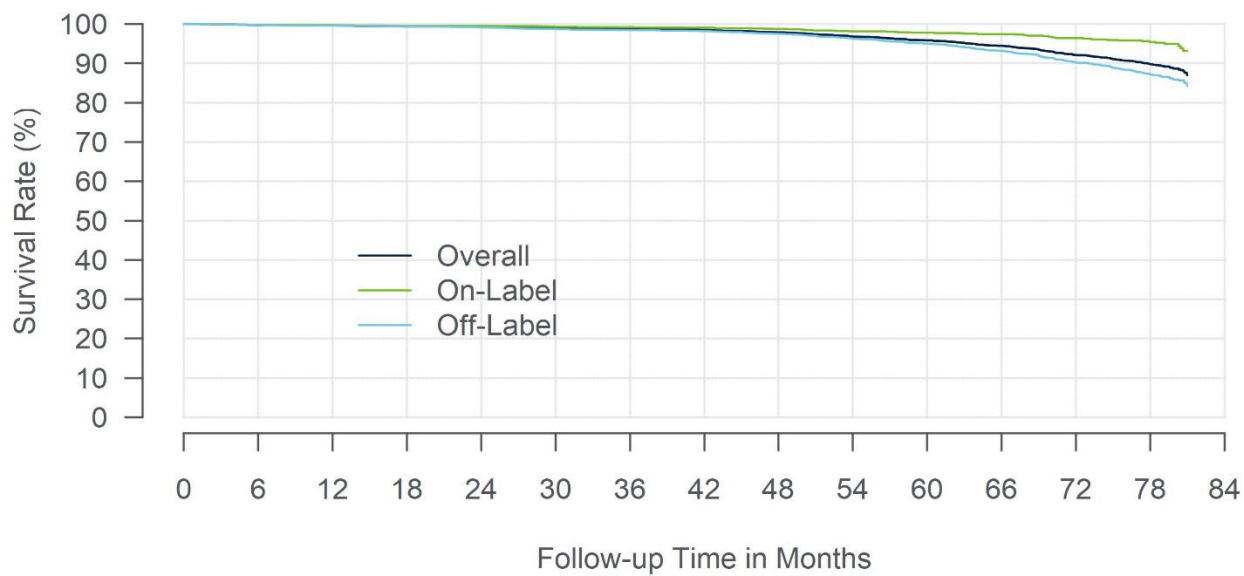


Figure 3.5: SynchroMed II Cumulative Survival (All Therapies)

Table 3.18: Survival Summary Table: All Therapies Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Overall	Survival	99.6%	99.3%	98.7%	97.9%	95.8%	92.2%	87.0%
	Sample Size	8812	7321	5965	4706	3663	2536	440
On-Label	Survival	99.7%	99.5%	99.2%	98.7%	97.8%	96.4%	93.2%
	Sample Size	2713	2243	1805	1390	1124	875	112
Off-Label	Survival	99.6%	99.2%	98.5%	97.5%	95.0%	90.3%	84.3%
	Sample Size	6099	5078	4160	3316	2539	1661	328

	72 Months (6 Years)		81 Months	
Pump Type	On Label	Off Label	On Label	Off Label
Pre-Enhanced SynchroMed II Pumps	95.6% (94.2%, 96.7%),746	88.2% (86.8%, 89.5%), 1465	91.9% (88.6%, 94.3%), 99	81.7% (79.4%, 83.8%), 299
SynchroMed II Fully Enhanced Pumps	99.3% (97.6%, 99.8%), 129	99.2% (98.6%, 99.5%), 196	NA, NA*	99.2% (98.6%, 99.5%), 29

*Fully enhanced On Label Pumps not shown at 81 months because only 13 pumps remain at that timepoint.

There was an additional need to look at these overall numbers specifically at 72 and 81 months due to the lifecycle of the device.

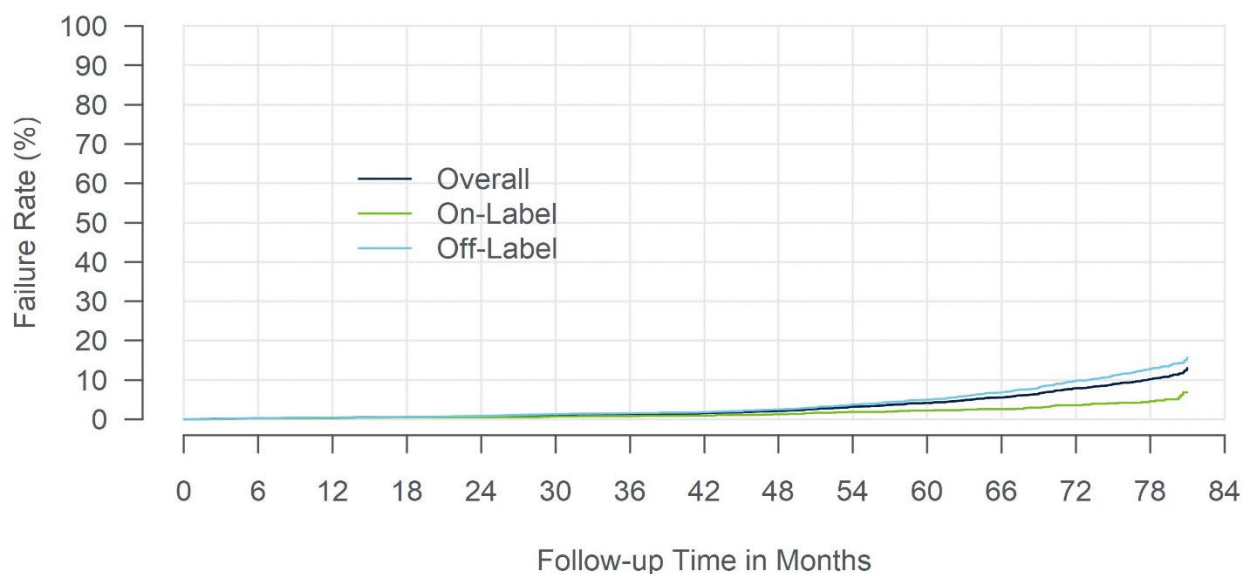


Figure 3.6: SynchroMed II Cumulative Failure (All Therapies)

Table 3.19: Failure Summary Table: All Therapies

Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Overall	Failure	0.4%	0.7%	1.3%	2.1%	4.2%	7.8%	13.0%
	Sample Size	8812	7321	5965	4706	3663	2536	440
On-Label	Failure	0.3%	0.5%	0.8%	1.3%	2.2%	3.6%	6.8%
	Sample Size	2713	2243	1805	1390	1124	875	112
Off-Label	Failure	0.4%	0.8%	1.5%	2.5%	5.0%	9.7%	15.7%
	Sample Size	6099	5078	4160	3316	2539	1661	328

3.4.3.2 Pain Study Population

A total of 1,078 SynchroMed II pumps were classified as On-Label for pain therapies, where there was no evidence of Off-Label drug/admixture exposure. A total of 7,863 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. The cumulative survival and failure of the SynchroMed II pump for pain indications, stratified by the On-Label or Off-Label pump group, are shown in [Figure 3.7](#) and [Figure 3.8](#) respectively.

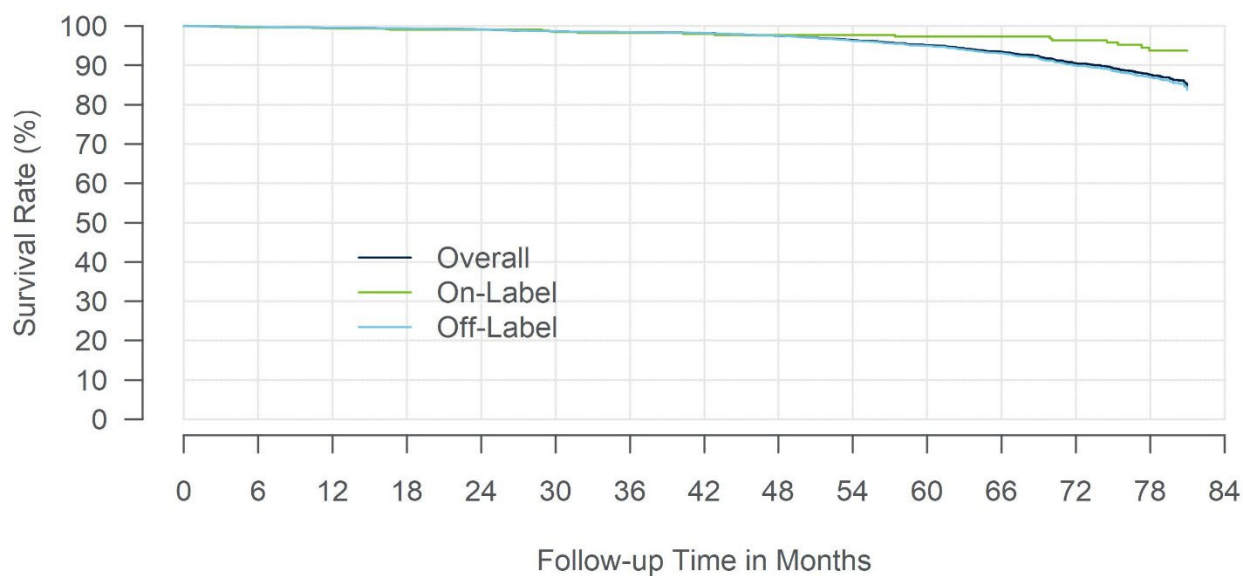


Figure 3.7: SynchroMed II Cumulative Survival (Pain Therapies)

Table 3.20: Survival Summary Table: Pain Therapies

Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Pain Overall	Survival	99.5%	99.1%	98.4%	97.5%	95.1%	90.5%	84.8%
	Sample Size	6469	5321	4316	3390	2602	1724	346
On Label	Survival	99.5%	99.1%	98.3%	97.7%	97.3%	96.4%	93.8%
	Sample Size	744	564	428	297	239	192	43
Off Label	Survival	99.6%	99.1%	98.5%	97.5%	94.9%	90.0%	83.8%
	Sample Size	5725	4757	3888	3093	2363	1532	303

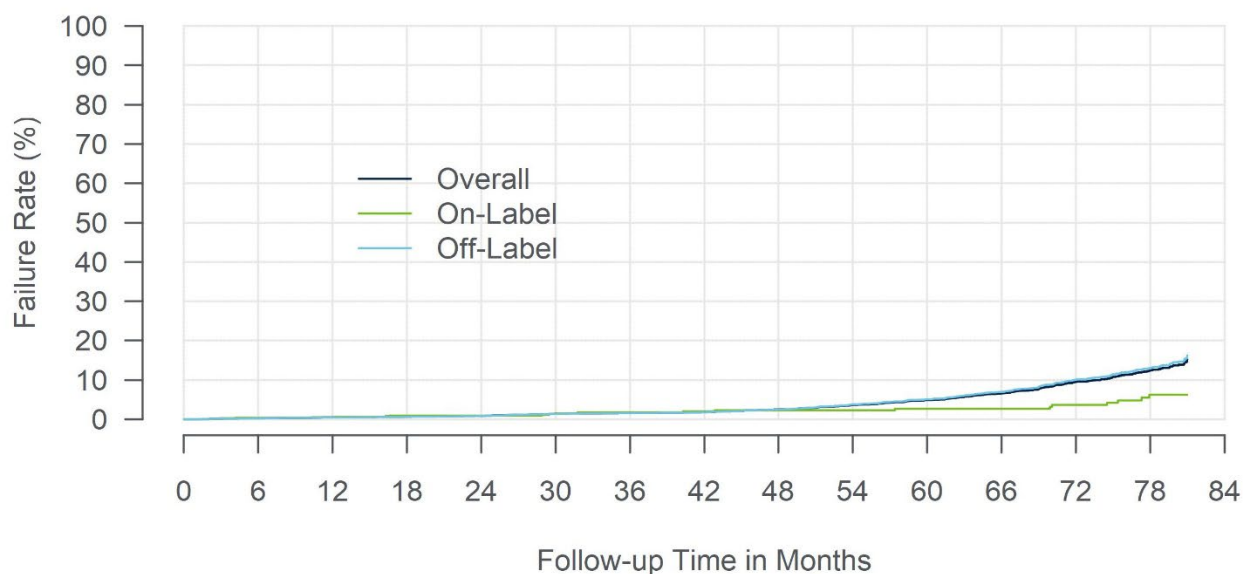


Figure 3.8: SynchroMed II Cumulative Failure (Pain Therapies)

Table 3.21: Failure Summary Table: Pain Therapies

Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Overall	Failure	0.5%	0.9%	1.6%	2.5%	4.9%	9.5%	15.2%
	Sample Size	6469	5321	4316	3390	2602	1724	346
On-Label	Failure	0.5%	0.9%	1.7%	2.3%	2.7%	3.6%	6.2%
	Sample Size	744	564	428	297	239	192	43
Off-Label	Failure	0.4%	0.9%	1.5%	2.5%	5.1%	10%	16.2%
	Sample Size	5725	4757	3888	3093	2363	1532	303

3.4.3.3 Spasticity Study Population

A total of 2,539 SynchroMed II pumps were classified as On-Label for spasticity therapies, where there was no evidence of Off-Label drug/admixture exposure. A total of 259 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. The cumulative survival and failure of the SynchroMed II pump for spasticity indications, stratified by the On-Label or Off-Label pump group, are shown in [Figure 3.9](#) and [Figure 3.10](#) respectively.

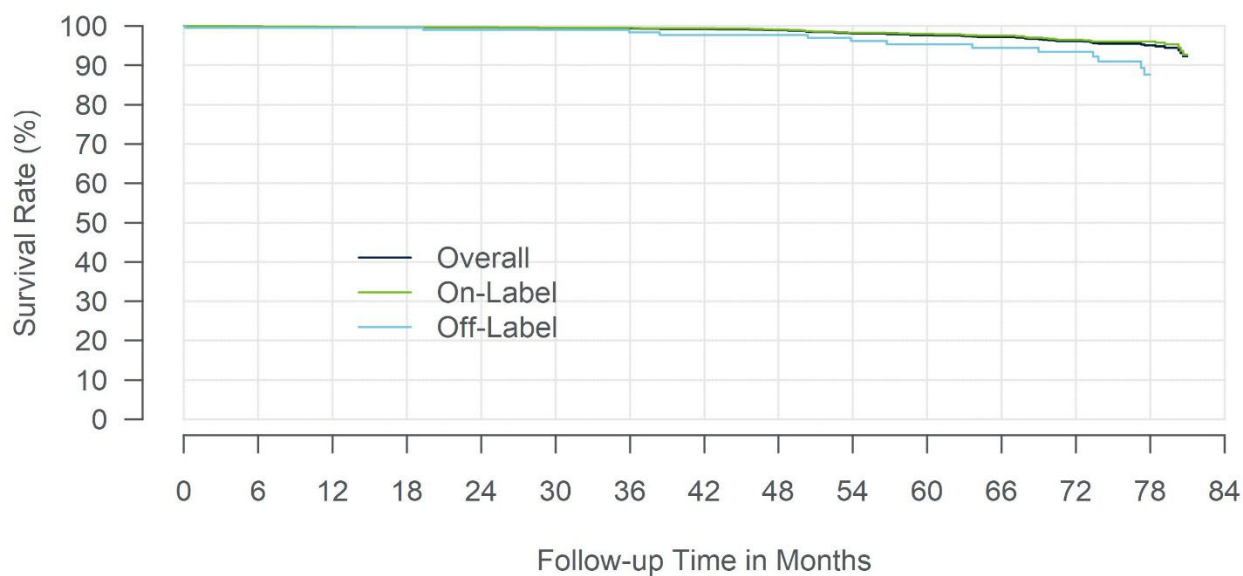


Figure 3.9: SynchroMed II Cumulative Survival (Spasticity Therapies)

Table 3.22: Survival Summary Table: Spasticity Therapies

Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Overall	Survival	99.8%	99.6%	99.5%	99.0%	97.7%	96.2%	92.3%
	Sample Size	2178	1860	1531	1227	993	766	86
On-Label	Survival	99.8%	99.7%	99.6%	99.1%	98.0%	96.5%	92.7%
	Sample Size	1969	1679	1377	1093	885	683	69
Off-Label	Survival	99.5%	99.0%	98.4%	97.7%	95.4%	93.4%	
	Sample Size	209	181	154	134	108	83	

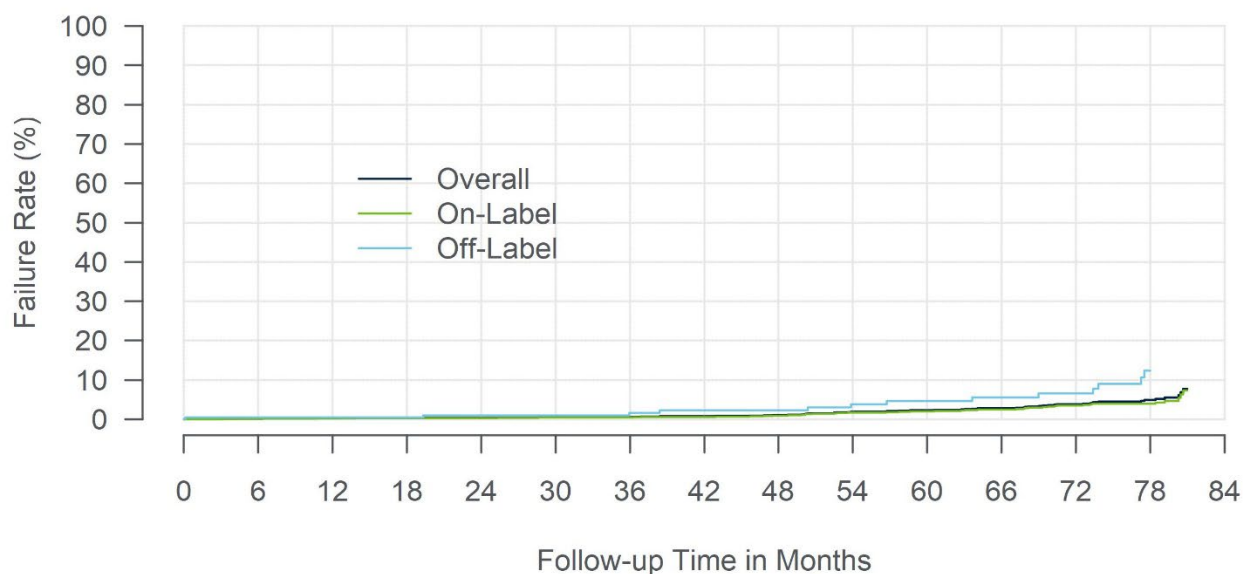


Figure 3.10: SynchroMed II Cumulative Failure (Spasticity Therapies)

Table 3.23: Failure Summary Table: Spasticity Therapies

Category	Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	At 81 Months
Overall	Failure	0.2%	0.4%	0.5%	1.0%	2.3%	3.8%	7.7%
	Sample Size	2178	1860	1531	1227	993	766	86
On-Label	Failure	0.2%	0.3%	0.4%	0.9%	2.0%	3.5%	7.3%
	Sample Size	1969	1679	1377	1093	885	683	69
Off-Label	Failure	0.5%	1.0%	1.6%	2.3%	4.6%	6.6%	
	Sample Size	209	181	154	134	108	83	

3.4.4 SynchroMed III Results

3.4.4.1 Total Study Population

A total of 101 SynchroMed III pumps were classified as On-Label for all therapies, where there was no evidence of Off-Label drug/admixture exposure. A total of 427 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. At 1 year of follow-up, the survival probability and failure rate for SynchroMed III pump for overall indications were 100% and 0%, respectively as shown on Table 3.2.4 and Table 3.2.5.

Table 3.24: Survival Summary Table: All Therapies

Category	Time Interval	1 Year
Overall	Survival	100.0%
	Sample Size	24

Table 3.25: Failure Summary Table: All Therapies

Category	Time Interval	1 Year
Overall	Failure	0%
	Sample Size	24

3.4.4.2 Pain Study Population

A total of 46 SynchroMed III pumps were classified as On-Label for pain therapies, where there was no evidence of Off-Label drug/admixture exposure. A total of 413 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. The cumulative survival and failure of the SynchroMed III pump for overall pain indications are shown in [Table 3.26](#) and [Table 3.27](#) respectively.

Table 3.26: Survival Summary Table: Pain Therapies

Category	Time Interval	1 Year
Pain Overall	Survival	100.0%
	Sample Size	20

Table 3.27: Failure Summary Table: Pain Therapies

Category	Time Interval	1 Year
Pain Overall	Failure	0%
	Sample Size	20

3.4.4.3 Spasticity Study Population

A total of 55 SynchroMed III pumps were classified as On-Label for spasticity therapies; there was no evidence of Off-Label drug/admixture exposure in SynchroMed III pumps. The cumulative

survival and failure of the SynchroMed III pump for spasticity, overall and for on- Label are shown in [Table 3.28](#) and [Table 3.29](#) respectively.

Table 3.28: Survival Summary Table: Spasticity Therapies

Category	Time Interval	At 3 Months
Overall	Survival	100.0%
	Sample Size	25
On-Label	Survival	100.0%
	Sample Size	25

Table 3.29: Failure Summary Table: Spasticity Therapies

On-label Category	Time Interval	At 3 Months
Overall	Failure	0%
	Sample Size	25
On-Label	Failure	0%
	Sample Size	25

3.4.5 Overall Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medications used for all indications over the follow-up period.
- Among pre-enhanced devices (n = 7,595), Off-Label medication exposure is associated with an overall 2.6 times greater risk of pump failures (95% confidence interval [1.965, 3.371]) compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 48 months of follow-up. At 81 months of follow-up the survival from pump failure for On-Label pumps was 91.9% compared to a survival of 81.7% for Off-Label pumps.
- Among fully enhanced devices (n = 4,040), Off-Label medication exposure is associated with a slightly higher, but not statistically significant different risk of pump failures (hazard ratio = 1.5, 95% confidence interval [0.498, 4.597]) compared to On-Label medication exposure for the entire pump population. At 6 years of follow-up the survival from pump failure for On-Label pumps was 99.3% compared to a survival of 99.2% for Off-Label pumps.

- The data represent the reported registry experience with a median follow-up time of 34.7 months for pre-enhanced devices and 29.4 months for fully enhanced devices. The longer-term data are based on a lower number of pumps and are subject to change as more follow-up data are obtained via the registry. Survival curve truncation or plateaus do not imply that the implanted devices will not be adversely impacted beyond the time points of the current data.
- The On-Label pump group for all devices (pre-enhanced and fully enhanced) was comprised of 70.2% of pumps with Spasticity as the indication (2,539/2,798 total spasticity pumps vs. 1,078/8,941 total pain pumps: Spasticity versus Pain pumps respectively). While the Off-Label group consisted of 96.8% of pumps with pain indications (7,863 vs. 259: Pain versus Spasticity pumps respectively).
- Medication use was recorded as a snapshot at the time of follow-up. It is possible that some On-Label pumps received Off-Label medications in between follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent but was not designated as such in the registry database. The time a pump was exposed to an Off-Label medication was not assessed. It is possible that some Off-Label pumps were exposed only for a brief period of time (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

3.5 Catheters

From August 7, 2003, to the report cut-off date of October 31, 2025, there were 12,601 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=14,424) because patients may have undergone pump replacements but used the same catheters, or patients may have been implanted with Medtronic pumps and non-Medtronic catheters which were not registered with Medtronic Device And Registrant Tracking (DART) system. The use of a non-Medtronic catheter with a Medtronic pump is considered off-label. The aggregate prospective follow-up time for all catheters was 498,201 months (41,517 years). [Table 3.30](#) provides the number and percentage of catheters by model.

Table 3.30: Targeted Drug Delivery Catheter Counts by Model

Model Name	N (%)
Currently Manufactured^a	3753 (29.8%)
8780 (US & OUS)	1821 (14.5%)
8781 (US & OUS)	1646 (13.1%)
8731SC (OUS)	286 (2.3%)
Revised Catheters	2938 (23.3%)
Revised As Designed ^b	924 (7.3%)
Revised Not As Designed ^c	749 (5.9%)
Ascenda Revised As Designed ^d	733 (5.8%)
Grafted Not As Designed ^e	532 (4.2%)
No Longer Manufactured	5429 (43.1%)
8709	2928 (23.2%)
8709SC	1111 (8.8%)
8711	665 (5.3%)
8731	538 (4.3%)
8703W	187 (1.5%)
Other/Unspecified	481 (3.8%)
Total	12601 (100%)

^a Manufactured for designated region; US=United States; OUS=Outside United States.

^b 8731 catheters repaired with an 8596 proximal or 8598 distal revision kit.

^c Medtronic non-Ascenda catheters repaired with a Medtronic revision kit, but not for the model it

- was intended.
- ^d 8780 or 8781 Ascenda catheters repaired with the 8782 or 8784 revision kit.
- ^e Catheters that involve the ad-hoc assembly of components other than a Medtronic repair kit or brand-new catheter.

3.5.1 Catheter Events

There were 1,958 product performance-related events with an underlying reported etiology related to catheter function. This includes 1,944 events with a catheter etiology and 14 events with both a catheter and other etiology (including device and non-device etiologies). The majority of the events were catheter occlusion (n=565), catheter dislodgement (n=427), catheter kink (n=304), or catheter break/cut (n=274). Of the 1,958 events, 1,666 were the initial product performance event that affected catheter survival estimates.

The catheter product performance-related events are summarized by model in the catheter models section.

For the purposes of survival analysis, a device's follow-up time is cut off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For catheters:

- 1,666 had follow-up time cut-off due to product performance-related events.
- 9,049 were censored in the survival analysis for the following reasons: patient expired, catheter explanted/capped, site termination, patient discontinued, patient lost to follow-up, or therapy suspended.
- 1,886 were free from product performance-related events and censoring events and were censored at the last follow-up visit prior to the report cut-off.

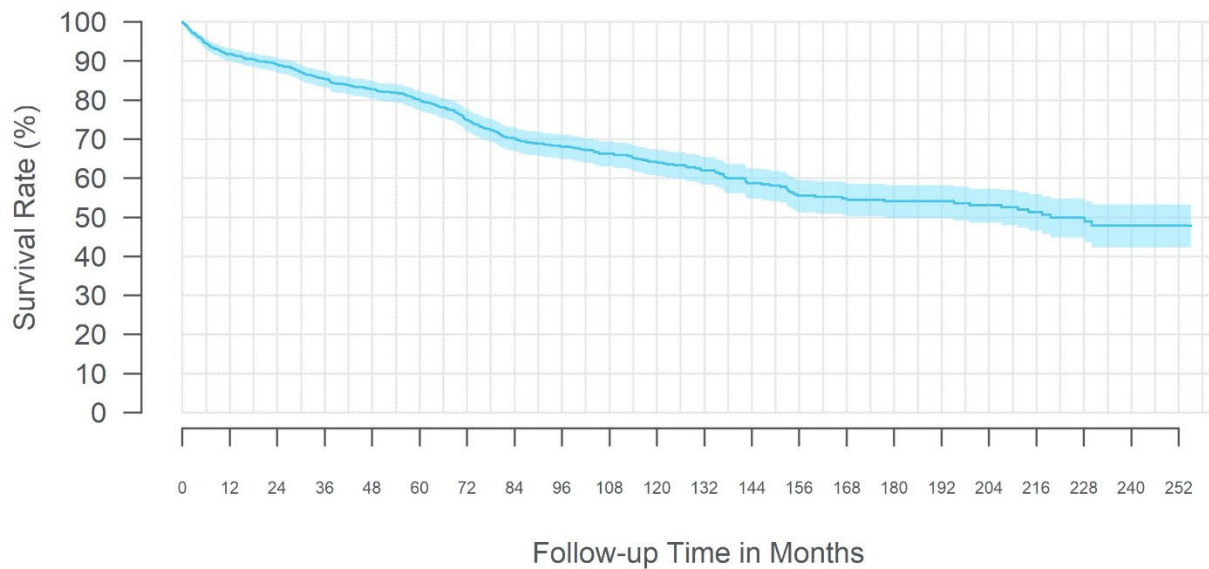
3.5.2 Catheter Models

The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 12 months of follow-up at the time of the report cut-off for each model.

Medtronic catheter repair kits and 2-piece catheters include specially designed connector pins and strain relief sleeves to splice the catheter segments together. Catheters grafted not as designed, by definition, involve the ad-hoc assembly of components other than those from a Medtronic repair kit or brand-new catheter. Medtronic recommends that clinicians follow the labeling for the catheter revision kits.

3.5.2.1 Model 8709

Model/Name	8709/InDura
FDA Approval Date	May 1998
Catheters Enrolled	2,928
Catheters Currently Active in Study	84
Initial Product Performance Events	369
Median Follow-up Time (Months)	18.1
Cumulative Follow-up Time (Months)	103,870



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.8% (90.1%, 93.3%)	89.1% (87.2%, 90.8%)	85.5% (83.3%, 87.4%)	82.7% (80.3%, 84.8%)	80.1% (77.5%, 82.4%)
Sample Size	998	945	882	783	672

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	75.0% (72.1%, 77.6%)	70.3% (67.2%, 73.1%)	68.1% (64.9%, 71.0%)	66.3% (63.0%, 69.4%)	64.2% (60.8%, 67.5%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	579	507	423	338	286

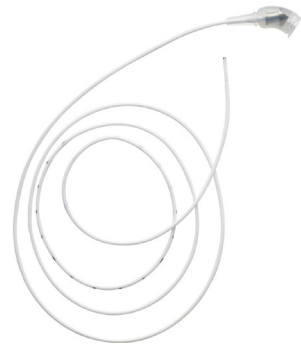
Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	62.0% (58.4%, 65.4%)	58.7% (54.8%, 62.5%)	55.5% (51.3%, 59.5%)	54.5% (50.2%, 58.6%)	54.1% (49.8%, 58.2%)
Sample Size	233	186	166	154	139

Time Interval	16 Years	17 Years	18 Years	19 Years	20 Years
Survival (95% CI)	54.1% (49.8%, 58.2%)	53.1% (48.6%, 57.4%)	51.3% (46.6%, 55.9%)	49.9% (44.9%, 54.7%)	47.9% (42.3%, 53.2%)
Sample Size	117	98	74	50	37

Time Interval	21 Years	At 255 Months
Survival (95% CI)	47.9% (42.3%, 53.2%)	47.9% (42.3%, 53.2%)
Sample Size	25	20

Specification: 8709

Total Length	89 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Pump end

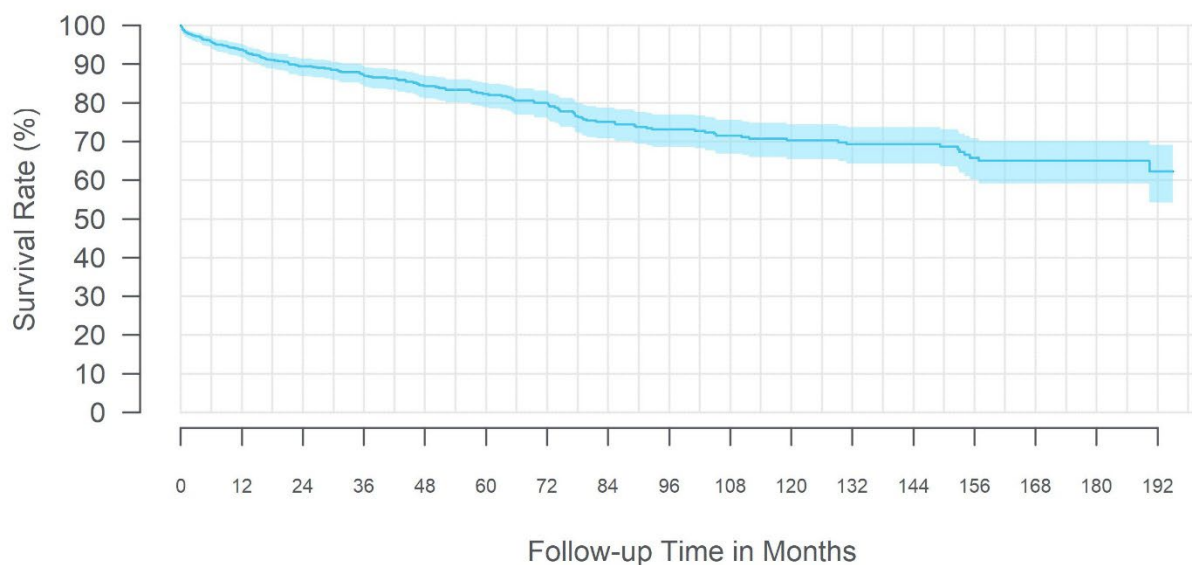


Catheter Event Summary: 8709	N
Catheter Dislodgement	95
Catheter Occlusion	88
Catheter Break/Cut	80
Catheter Kink	32
Catheter Disconnection At Pump	20
Catheter Leakage	17
Pump Connector Break/Cut	10
Catheter Dysfunction	6
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Related Complication	3
Device Issue	2
Device Malfunction	2
Other ^a	10
Total	369

^a Composed of event codes with 1 event each.

3.5.2.2 Model 8709SC

Model/Name	8709SC/InDura 1P
FDA Approval Date	March 2006
Catheters Enrolled	1,111
Catheters Currently Active in Study	88
Initial Product Performance Events	157
Median Follow-up Time (Months)	28.5
Cumulative Follow-up Time (Months)	52,141



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.8% (91.9%, 95.3%)	89.4% (87.0%, 91.5%)	87.2% (84.4%, 89.5%)	84.3% (81.2%, 87.0%)	82.3% (78.9%, 85.2%)
Sample Size	668	520	439	362	300

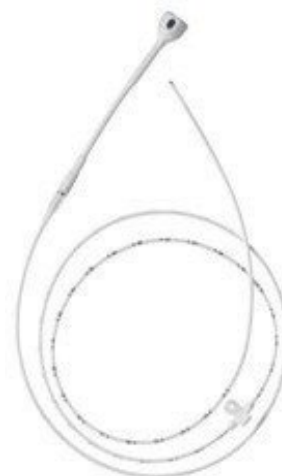
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.0% (76.3%, 83.2%)	75.1% (70.9%, 78.8%)	73.1% (68.7%, 77.0%)	71.6% (66.9%, 75.7%)	70.3% (65.5%, 74.5%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	261	243	200	174	156

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	69.3% (64.4%, 73.7%)	69.3% (64.4%, 73.7%)	65.8% (60.2%, 70.8%)	65.0% (59.2%, 70.2%)	65.0% (59.2%, 70.2%)
Sample Size	139	123	86	61	45

Time Interval	16 Years	At 195 Months
Survival (95% CI)	62.3% (54.3%, 69.2%)	62.3% (54.3%, 69.2%)
Sample Size	21	21

Specification: 8709SC	
Total Length	89 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed tip, radiopaque, titanium with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Pump end

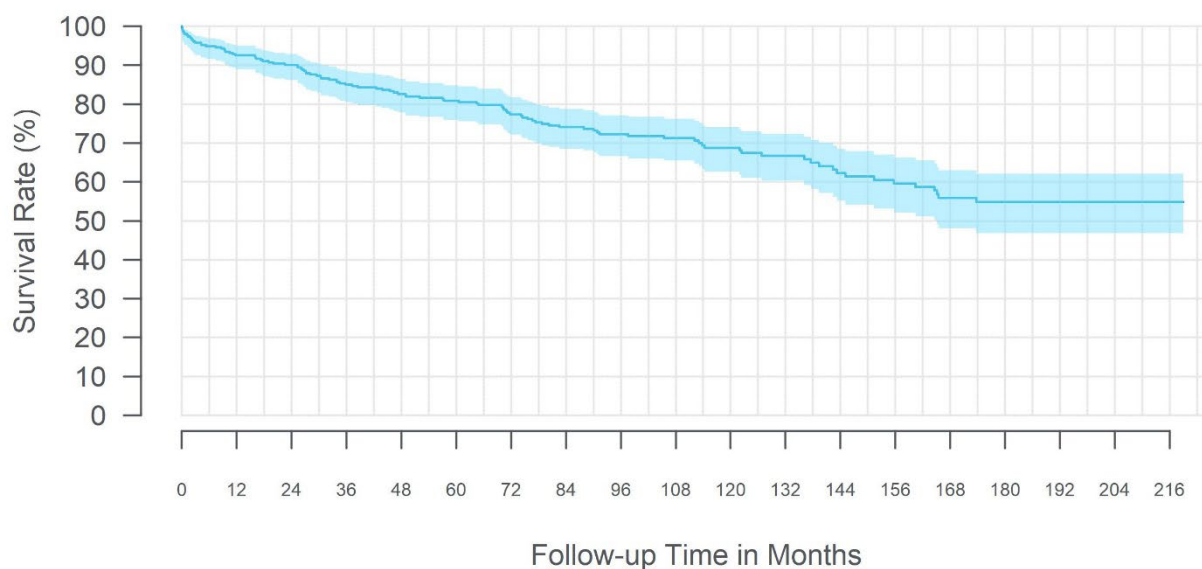


Catheter Event Summary: 8709SC	N
Catheter Occlusion	42
Catheter Break/Cut	36
Catheter Dislodgement	34
Catheter Leakage	10
Catheter Disconnection At Pump	7
Catheter Kink	6
Catheter Dysfunction	5
Catheter Related Complication	3
Pump Unable To Enter/Withdraw From Catheter Access Port	3
Catheter Damage	2
Device Damage	2
Device Malfunction	2
Other ^a	5
Total	157

^a Composed of event codes with 1 event each.

3.5.2.3 Model 8711

Model/Name	8711/InDura
FDA Approval Date	October 1999
Catheters Enrolled	665
Catheters Currently Active in Study	35
Initial Product Performance Events	104
Median Follow-up Time (Months)	31.9
Cumulative Follow-up Time (Months)	33,710



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (89.0%, 95.0%)	90.1% (86.2%, 92.9%)	85.0% (80.5%, 88.5%)	82.6% (77.9%, 86.4%)	80.9% (76.0%, 84.9%)
Sample Size	310	289	259	239	225

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	77.4% (72.2%, 81.7%)	74.1% (68.6%, 78.8%)	72.3% (66.6%, 77.2%)	71.2% (65.5%, 76.2%)	68.8% (62.7%, 74.1%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	189	179	148	124	105

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	66.7% (60.3%, 72.3%)	62.3% (55.1%, 68.6%)	59.6% (52.1%, 66.3%)	55.9% (48.1%, 63.1%)	54.8% (46.8%, 62.1%)
Sample Size	82	70	68	55	43

Time Interval	16 Years	17 Years	18 Years	At 219 Months
Survival (95% CI)	54.8% (46.8%, 62.1%)	54.8% (46.8%, 62.1%)	54.8% (46.8%, 62.1%)	54.8% (46.8%, 62.1%)
Sample Size	37	26	21	20

Specification: 8711	
Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Spinal and pump ends

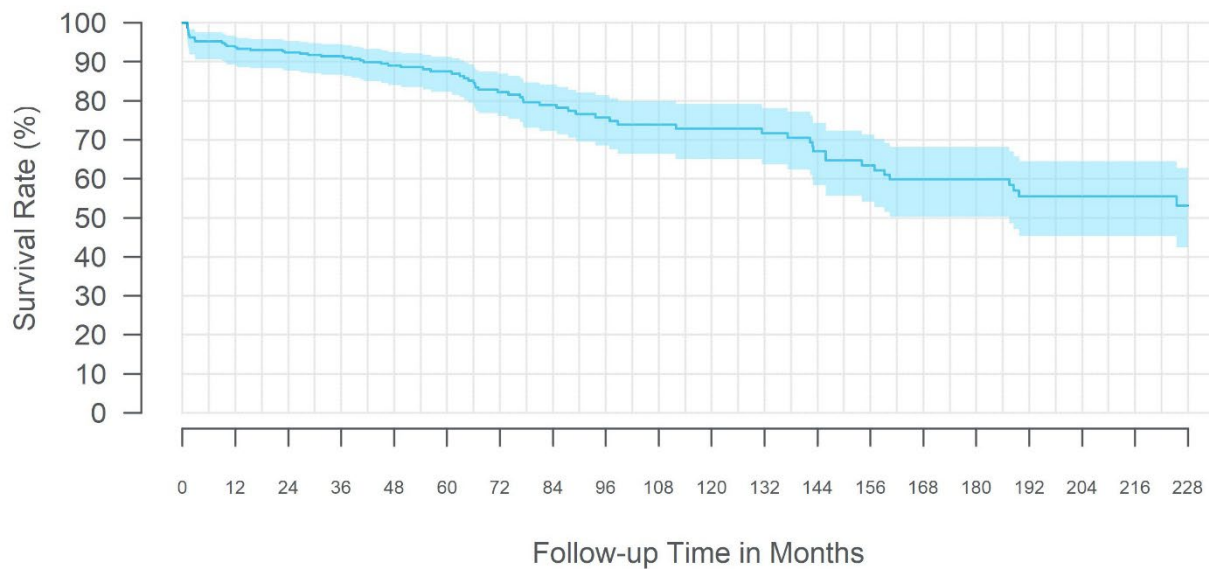


Catheter Event Summary: 8711	N
Catheter Occlusion	34
Catheter Break/Cut	20
Catheter Dislodgement	13
Catheter Dysfunction	9
Catheter Kink	9
Catheter Leakage	4
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Disconnection At Pump	2
Catheter Related Complication	2
Device Issue	2
Other ^a	5
Total	104

^a Composed of event codes with 1 event each.

3.5.2.4 Model 8731

Model/Name	8731
FDA Approval Date	October 2002
Catheters Enrolled	538
Catheters Currently Active in Study	24
Initial Product Performance Events	67
Median Follow-up Time (Months)	33.0
Cumulative Follow-up Time (Months)	25,649



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.7% (89.0%, 96.4%)	92.4% (87.7%, 95.3%)	91.4% (86.7%, 94.5%)	89.1% (84.1%, 92.6%)	87.5% (82.3%, 91.3%)
Sample Size	264	306	256	198	150

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	82.2% (76.1%, 86.9%)	78.9% (72.3%, 84.1%)	75.7% (68.6%, 81.5%)	73.9% (66.4%, 79.9%)	72.9% (65.2%, 79.1%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	134	108	84	73	66

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	71.7% (63.7%, 78.2%)	67.1% (58.3%, 74.4%)	63.4% (54.2%, 71.3%)	59.9% (50.3%, 68.2%)	59.9% (50.3%, 68.2%)
Sample Size	61	56	49	48	42

Time Interval	16 Years	17 Years	18 Years	19 Years
Survival (95% CI)	55.5% (45.3%, 64.5%)	55.5% (45.3%, 64.5%)	55.5% (45.3%, 64.5%)	53.1% (42.4%, 62.7%)
Sample Size	35	33	30	20

Specification: 8731	
Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed tip, radiopaque, titanium with 6 side holes
Catheter Volume	2.22 mL/cm
Trimnable Segments	Spinal end

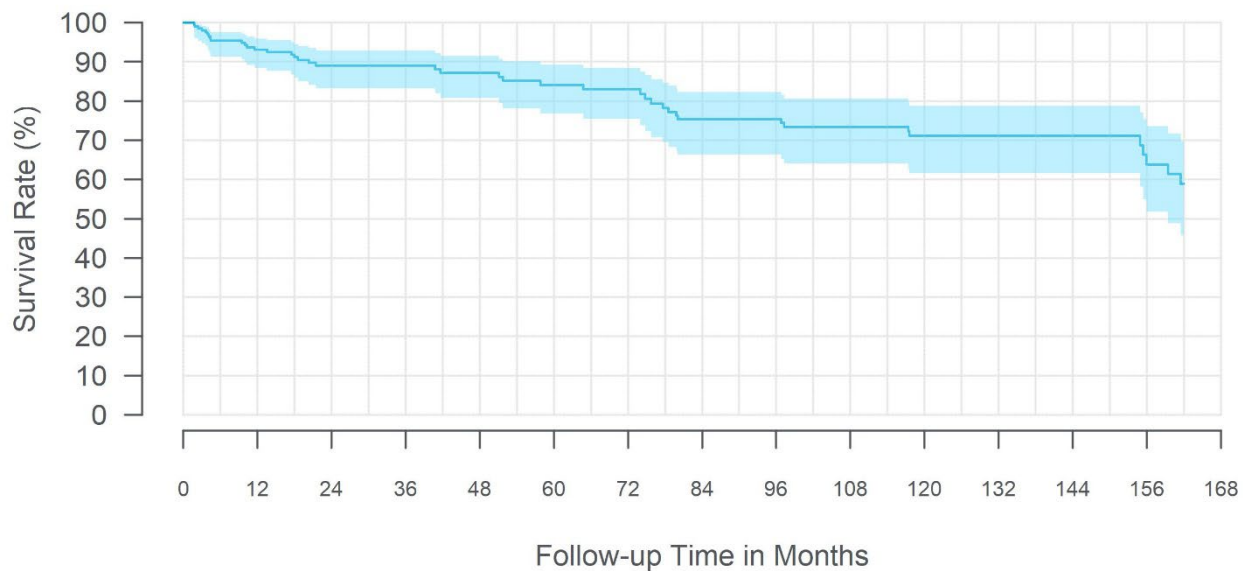


Catheter Event Summary: 8731	N
Catheter Occlusion	25
Catheter Dislodgement	19
Catheter Kink	6
Catheter Break/Cut	5
Catheter Disconnection At Pump	3
Catheter Related Complication	3
Catheter Dysfunction	2
Other ^a	4
Total	67

^a Composed of event codes with 1 event each.

3.5.2.5 Model 8731SC

Model/Name	8731SC
FDA Approval Date	March 2006
Catheters Enrolled	286
Catheters Currently Active in Study	43
Initial Product Performance Events	43
Median Follow-up Time (Months)	39.0
Cumulative Follow-up Time (Months)	14,605



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.1% (88.5%, 96.0%)	89.1% (83.3%, 92.9%)	89.1% (83.3%, 92.9%)	87.2% (80.8%, 91.5%)	84.1% (76.8%, 89.3%)
Sample Size	155	117	100	89	79

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	83.0% (75.5%, 88.4%)	75.4% (66.4%, 82.3%)	75.4% (66.4%, 82.3%)	73.4% (64.2%, 80.6%)	71.1% (61.6%, 78.7%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	69	85	78	68	62

Time Interval	11 Years	12 Years	13 Years	At 162 Months
Survival (95% CI)	71.1% (61.6%, 78.7%)	71.1% (61.6%, 78.7%)	63.8% (51.8%, 73.6%)	58.9% (45.9%, 69.8%)
Sample Size	53	42	26	23

Specification: 8731SC

Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Spinal and pump ends

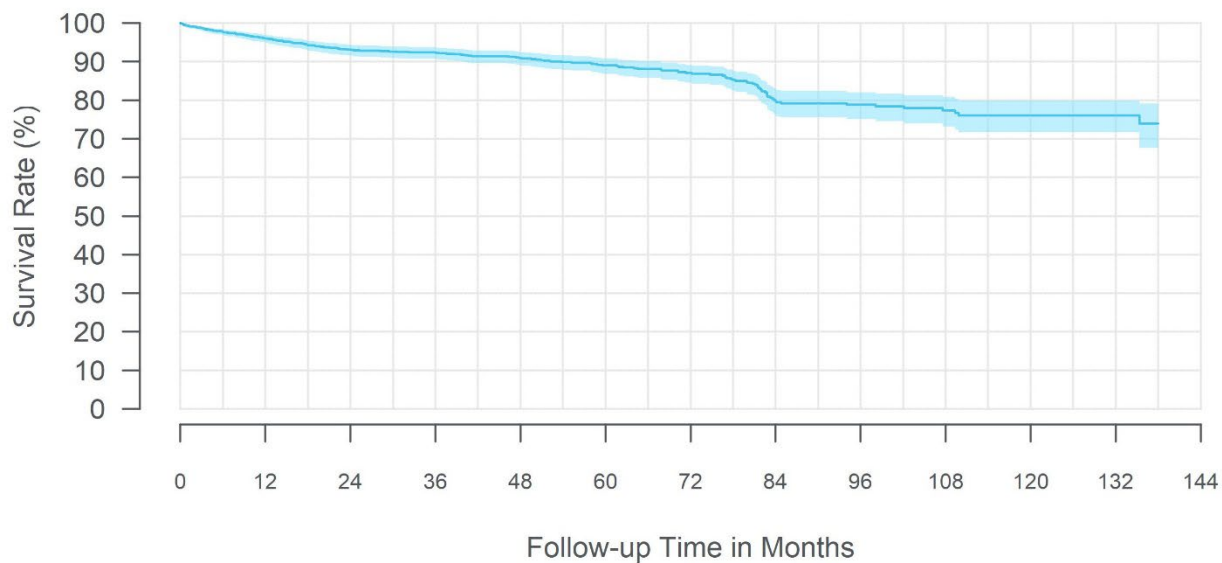


Catheter Event Summary: 8731SC	N
Catheter Occlusion	18
Catheter Dislodgement	8
Pump Unable To Enter/Withdraw From Catheter Access Port	5
Catheter Kink	4
Catheter Dysfunction	3
Catheter Leakage	2
Other ^a	3
Total	43

^a Composed of event codes with 1 event each.

3.5.2.6 Model 8780

Model/Name	8780/Ascenda
FDA Approval Date	May 2012
Catheters Enrolled	1,821
Catheters Currently Active in Study	600
Initial Product Performance Events	169
Median Follow-up Time (Months)	29.0
Cumulative Follow-up Time (Months)	74,247



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	96.0% (94.9%, 96.9%)	93.2% (91.6%, 94.4%)	92.4% (90.8%, 93.8%)	91.0% (89.1%, 92.5%)	89.0% (86.9%, 90.8%)
Sample Size	1176	921	764	614	501

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	87.1% (84.6%, 89.2%)	79.8% (76.2%, 82.9%)	78.8% (75.1%, 82.1%)	77.3% (73.3%, 80.9%)	76.1% (71.7%, 79.9%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	401	276	198	129	92

Time Interval	11 Years	At 138 Months
Survival (95% CI)	76.1% (71.7%, 79.9%)	73.9% (67.7%, 79.2%)
Sample Size	46	29

Specification: 8780	
Total Length	114 cm
Outer Diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Connector end of the spinal segment

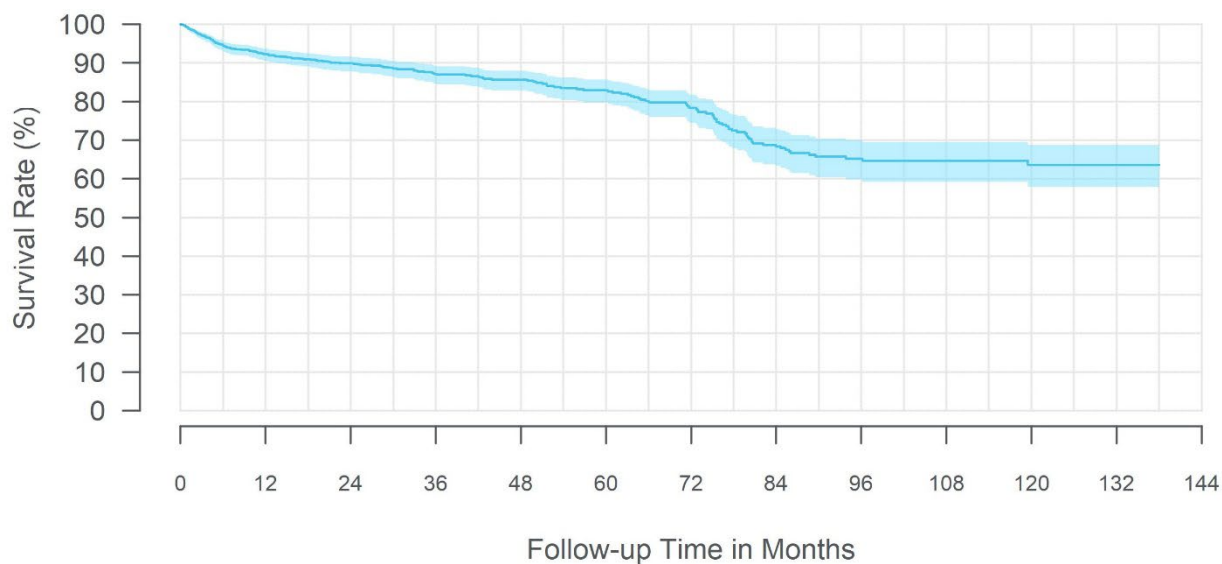


Catheter Event Summary: 8780	N
Catheter Occlusion	65
Catheter Kink	39
Catheter Break/Cut	18
Catheter Dislodgement	18
Catheter Damage	6
Catheter Leakage	6
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Disconnection At Pump	2
Catheter Dysfunction	2
Device Damage	2
Other ^a	7
Total	169

^a Composed of event codes with 1 event each.

3.5.2.7 Model 8781

Model/Name	8781/Ascenda
FDA Approval Date	May 2012
Catheters Enrolled	1,646
Catheters Currently Active in Study	424
Initial Product Performance Events	192
Median Follow-up Time (Months)	14.4
Cumulative Follow-up Time (Months)	48,016



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.3% (90.6%, 93.7%)	89.9% (87.9%, 91.6%)	87.2% (84.7%, 89.3%)	85.6% (82.9%, 87.9%)	82.9% (79.8%, 85.7%)
Sample Size	798	562	428	343	272

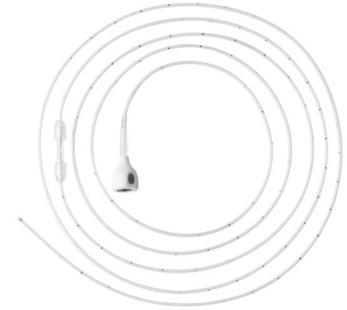
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	78.4% (74.5%, 81.7%)	68.4% (63.4%, 72.8%)	65.2% (59.9%, 70.0%)	64.6% (59.3%, 69.5%)	63.6% (57.9%, 68.8%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	216	168	119	88	59

Time Interval	11 Years	At 138 Months
Survival (95% CI)	63.6% (57.9%, 68.8%)	63.6% (57.9%, 68.8%)
Sample Size	29	25

Specification: 8781

Total Length	140 cm
Outer Diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimnable Segments	Catheter connector ends of the spinal and pump segments

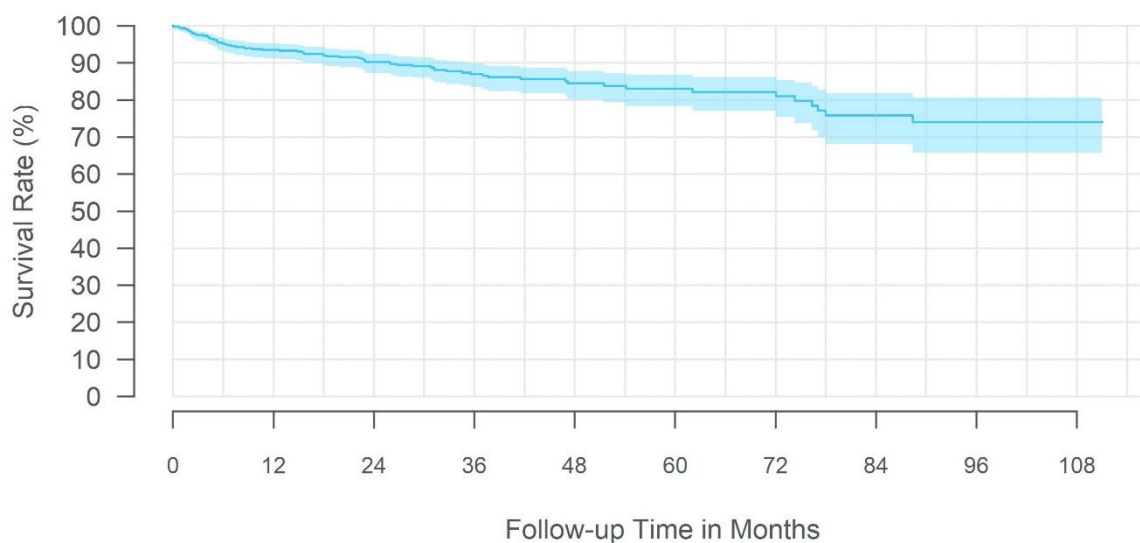


Catheter Event Summary: 8781	N
Catheter Kink	68
Catheter Occlusion	56
Catheter Dislodgement	36
Catheter Break/Cut	9
Catheter Leakage	5
Catheter Dysfunction	4
Catheter Disconnection At Pump	3
Pump Reservoir Volume Discrepancy	3
Device Malfunction	2
Other ^a	6
Total	192

^a Composed of event codes with 1 event each.

3.5.2.8 Ascenda Revised As Designed

Model/Name	Ascenda Revised As Designed
FDA Approval Date	May 2012
Catheters Enrolled	733
Catheters Currently Active in Study	222
Initial Product Performance Events	77
Median Follow-up Time (Months)	23.9
Cumulative Follow-up Time (Months)	21,978



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.5% (91.3%, 95.2%)	90.3% (87.4%, 92.5%)	87.0% (83.4%, 89.8%)	84.5% (80.3%, 87.9%)	83.1% (78.4%, 86.8%)
Sample Size	473	341	222	136	95

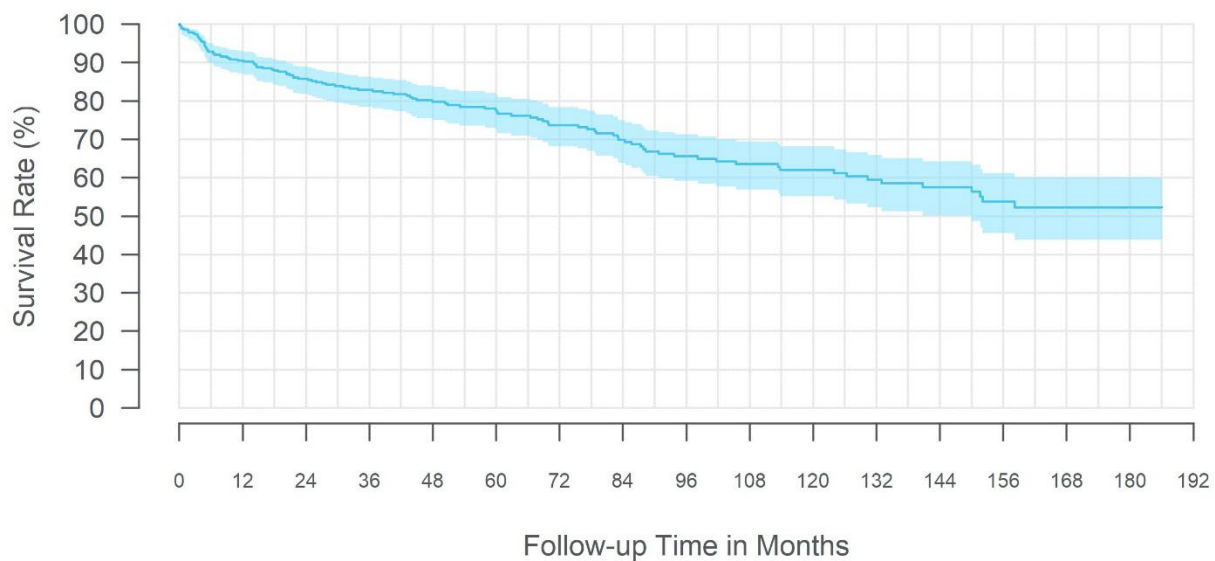
Time Interval	6 Years	7 Years	8 Years	9 Years	At 111 Months
Survival (95% CI)	82.1% (77.1%, 86.2%)	75.8% (68.2%, 81.8%)	74.1% (65.8%, 80.7%)	74.1% (65.8%, 80.7%)	74.1% (65.8%, 80.7%)
Sample Size	72	54	33	25	21

Catheter Event Summary: Ascenda RAD	N
Catheter Occlusion	30
Catheter Kink	20
Catheter Dislodgement	15
Catheter Break/Cut	3
Device Component Migration	3
Other ^a	6
Total	77

^a Composed of event codes with 1 event each.

3.5.2.9 Grafted Not As Designed

Model/Name	Grafted Not As Designed
FDA Approval Date	NA
Catheters Enrolled	532
Catheters Currently Active in Study	59
Initial Product Performance Events	116
Median Follow-up Time (Months)	38.3
Cumulative Follow-up Time (Months)	27,832



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	90.5% (87.2%, 93.0%)	85.8% (81.9%, 89.0%)	82.9% (78.6%, 86.4%)	79.8% (75.1%, 83.7%)	77.6% (72.5%, 81.8%)
Sample Size	327	274	232	191	170

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	73.7% (68.2%, 78.4%)	69.9% (63.9%, 75.0%)	65.6% (59.2%, 71.3%)	63.6% (56.9%, 69.5%)	62.0% (55.2%, 68.1%)
Sample Size	144	120	100	90	78

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	59.5% (52.3%, 65.9%)	57.5% (50.1%, 64.3%)	53.8% (45.6%, 61.2%)	52.2% (43.8%, 60.0%)	52.2% (43.8%, 60.0%)
Sample Size	65	54	37	26	22

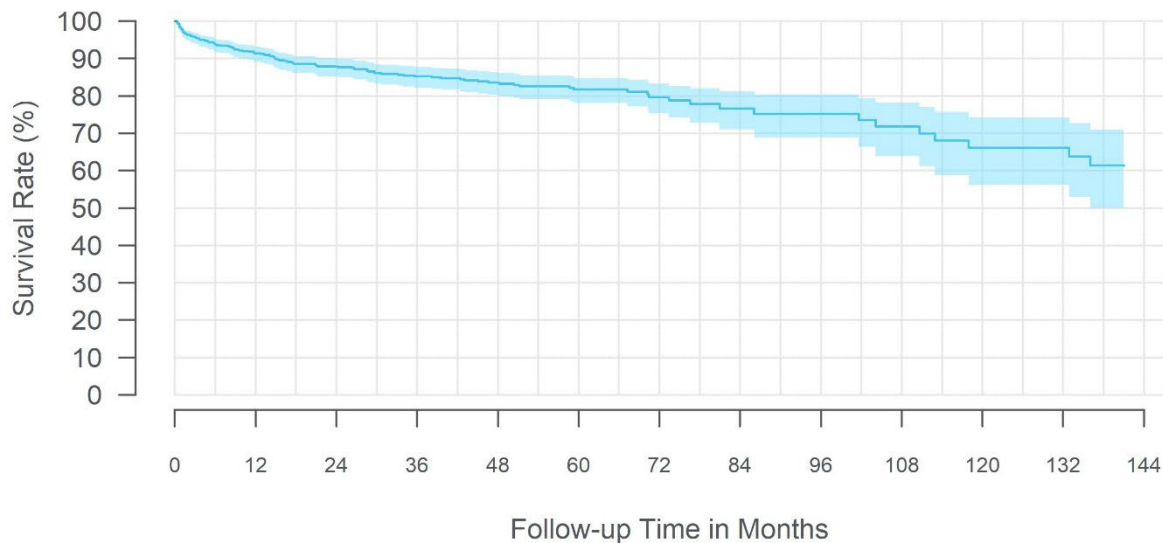
Time Interval	At 186 Months
Survival (95% CI)	52.2% (43.8%, 60.0%)
Sample Size	21

Catheter Event Summary: Grafted Not As Designed	N
Catheter Occlusion	35
Catheter Dislodgement	28
Catheter Break/Cut	15
Catheter Kink	9
Catheter Leakage	7
Catheter Related Complication	4
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Dysfunction	3
Catheter Damage	2
Catheter Disconnection At Pump	2
Device Malfunction	2
Other ^a	5
Total	116

^a Composed of event codes with 1 event each.

3.5.2.10 Revised As Designed

Model/Name	Revised As Designed
FDA Approval Date	October 2002
Catheters Enrolled	924
Catheters Currently Active in Study	236
Initial Product Performance Events	127
Median Follow-up Time (Months)	28.1
Cumulative Follow-up Time (Months)	32,614



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.4% (89.2%, 93.2%)	87.9% (85.2%, 90.1%)	85.2% (82.2%, 87.7%)	83.6% (80.3%, 86.3%)	81.7% (78.1%, 84.8%)
Sample Size	610	479	359	265	179

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	79.7% (75.3%, 83.3%)	76.6% (71.0%, 81.3%)	75.2% (68.9%, 80.4%)	71.8% (63.9%, 78.3%)	66.1% (56.2%, 74.3%)
Sample Size	99	57	48	38	31

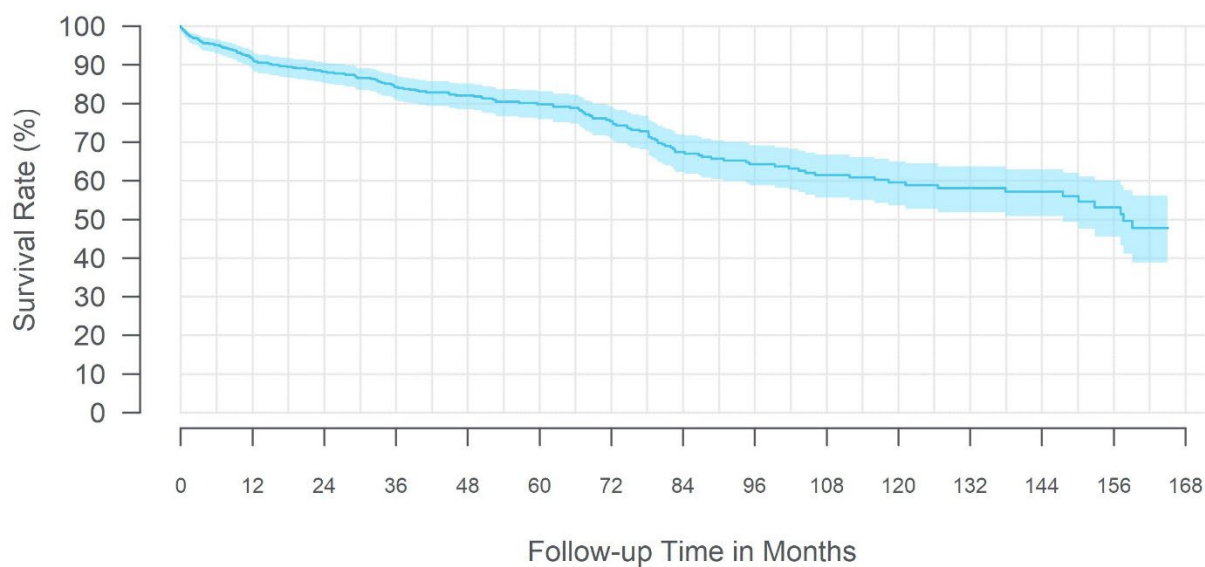
Time Interval	11 Years	At 141 Months
Survival (95% CI)	66.1% (56.2%, 74.3%)	61.4% (50.0%, 70.9%)
Sample Size	28	20

Catheter Event Summary: Revised As Designed	N
Catheter Dislodgement	58
Catheter Occlusion	33
Catheter Kink	11
Catheter Break/Cut	7
Device Component Migration	6
Catheter Leakage	4
Pump Unable To Enter/Withdraw From Catheter Access Port	3
Catheter Dysfunction	2
Other ^a	3
Total	127

^a Composed of event codes with 1 event each.

3.5.2.11 Revised Not As Designed

Model/Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	749
Catheters Currently Active in Study	70
Initial Product Performance Events	163
Median Follow-up Time (Months)	41.2
Cumulative Follow-up Time (Months)	39,260



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.4% (88.9%, 93.4%)	88.2% (85.3%, 90.6%)	84.2% (80.9%, 87.0%)	82.1% (78.6%, 85.1%)	79.8% (76.0%, 83.1%)
Sample Size	533	466	382	316	256

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival	75.4% (71.1%,	67.4% (62.3%,	64.3% (58.8%,	61.5% (55.7%,	59.6% (53.6%,

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
(95% CI)	79.2%)	72.1%)	69.2%)	66.7%)	65.1%)
Sample Size	207	163	127	102	86

Time Interval	11 Years	12 Years	13 Years	At 165 Months
Survival (95% CI)	58.1% (51.9%, 63.8%)	57.2% (50.8%, 63.1%)	53.1% (45.6%, 60.0%)	47.8% (39.0%, 56.1%)
Sample Size	66	51	32	21

Catheter Event Summary: Revised Not As Designed	N
Catheter Occlusion	63
Catheter Dislodgement	24
Catheter Break/Cut	18
Catheter Kink	18
Catheter Leakage	12
Pump Unable To Enter/Withdraw From Catheter Access Port	5
Catheter Disconnection At Pump	4
Device Component Migration	4
Catheter Dysfunction	3
Catheter Related Complication	2
Other ^a	10
Total	163

^a Composed of event codes with 1 event each.

3.5.3 Catheter Summary

Table 3.31: Targeted Drug Delivery Catheter Characteristics

Model/Name	FDA Approval Date	Catheters Enrolled	Catheters Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
8709	May 1998	2,928	84	369	18.1	103,870
8709SC	March 2006	1,111	88	157	28.5	52,141
8711	October 1999	665	35	104	31.9	33,710
8731	October 2002	538	24	67	33.0	25,649
8731SC	March 2006	286	43	43	39.0	14,605
8780	May 2012	1,821	600	169	29.0	74,247
8781	May 2012	1,646	424	192	14.4	48,016
Ascenda Revised As Designed	May 2012	733	222	77	23.9	21,978
Grafted Not As Designed	NA	532	59	116	38.3	27,832
Revised As Designed	October 2002	924	236	127	28.1	32,614
Revised Not As Designed	NA	749	70	163	41.2	39,260

Table 3.32: Targeted Drug Delivery Catheter Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
8709	91.8%	89.1%	85.5%	82.7%	80.1%
	(90.1%, 93.3%)	(87.2%, 90.8%)	(83.3%, 87.4%)	(80.3%, 84.8%)	(77.5%, 82.4%)
8709SC	93.8%	89.4%	87.2%	84.3%	82.3%
	(91.9%, 95.3%)	(87.0%, 91.5%)	(84.4%, 89.5%)	(81.2%, 87.0%)	(78.9%, 85.2%)
8711	92.5%	90.1%	85.0%	82.6%	80.9%

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
	(89.0%, 95.0%)	(86.2%, 92.9%)	(80.5%, 88.5%)	(77.9%, 86.4%)	(76.0%, 84.9%)
8731	93.7%	92.4%	91.4%	89.1%	87.5%
	(89.0%, 96.4%)	(87.7%, 95.3%)	(86.7%, 94.5%)	(84.1%, 92.6%)	(82.3%, 91.3%)
8731SC	93.1%	89.1%	89.1%	87.2%	84.1%
	(88.5%, 96.0%)	(83.3%, 92.9%)	(83.3%, 92.9%)	(80.8%, 91.5%)	(76.8%, 89.3%)
8780	96.0%	93.2%	92.4%	91.0%	89.0%
	(94.9%, 96.9%)	(91.6%, 94.4%)	(90.8%, 93.8%)	(89.1%, 92.5%)	(86.9%, 90.8%)
8781	92.3%	89.9%	87.2%	85.6%	82.9%
	(90.6%, 93.7%)	(87.9%, 91.6%)	(84.7%, 89.3%)	(82.9%, 87.9%)	(79.8%, 85.7%)
Ascenda RAD	93.5%	90.3%	87.0%	84.5%	83.1%
	(91.3%, 95.2%)	(87.4%, 92.5%)	(83.4%, 89.8%)	(80.3%, 87.9%)	(78.4%, 86.8%)
Grafted Not As Designed	90.5%	85.8%	82.9%	79.8%	77.6%
	(87.2%, 93.0%)	(81.9%, 89.0%)	(78.6%, 86.4%)	(75.1%, 83.7%)	(72.5%, 81.8%)
Revised As Designed	91.4%	87.9%	85.2%	83.6%	81.7%
	(89.2%, 93.2%)	(85.2%, 90.1%)	(82.2%, 87.7%)	(80.3%, 86.3%)	(78.1%, 84.8%)
Revised Not As Designed	91.4%	88.2%	84.2%	82.1%	79.8%
	(88.9%, 93.4%)	(85.3%, 90.6%)	(80.9%, 87.0%)	(78.6%, 85.1%)	(76.0%, 83.1%)
Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
8709	75.0%	70.3%	68.1%	66.3%	64.2%
	(72.1%, 77.6%)	(67.2%, 73.1%)	(64.9%, 71.0%)	(63.0%, 69.4%)	(60.8%, 67.5%)
8709SC	80.0%	75.1%	73.1%	71.6%	70.3%
	(76.3%, 83.2%)	(70.9%, 78.8%)	(68.7%, 77.0%)	(66.9%, 75.7%)	(65.5%, 74.5%)
8711	77.4%	74.1%	72.3%	71.2%	68.8%
	(72.2%, 81.7%)	(68.6%, 78.8%)	(66.6%, 77.2%)	(65.5%, 76.2%)	(62.7%, 74.1%)
8731	82.2%	78.9%	75.7%	73.9%	72.9%
	(76.1%, 86.9%)	(72.3%, 84.1%)	(68.6%, 81.5%)	(66.4%, 79.9%)	(65.2%, 79.1%)
8731SC	83.0%	75.4%	75.4%	73.4%	71.1%

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
	(75.5%, 88.4%)	(66.4%, 82.3%)	(66.4%, 82.3%)	(64.2%, 80.6%)	(61.6%, 78.7%)
8780	87.1%	79.8%	78.8%	77.3%	76.1%
	(84.6%, 89.2%)	(76.2%, 82.9%)	(75.1%, 82.1%)	(73.3%, 80.9%)	(71.7%, 79.9%)
8781	78.4%	68.4%	65.2%	64.6%	63.6%
	(74.5%, 81.7%)	(63.4%, 72.8%)	(59.9%, 70.0%)	(59.3%, 69.5%)	(57.9%, 68.8%)
Ascenda RAD	82.1%	75.8%	74.1%	74.1%	
	(77.1%, 86.2%)	(68.2%, 81.8%)	(65.8%, 80.7%)	(65.8%, 80.7%)	
Grafted Not As Designed	73.7%	69.9%	65.6%	63.6%	62.0%
	(68.2%, 78.4%)	(63.9%, 75.0%)	(59.2%, 71.3%)	(56.9%, 69.5%)	(55.2%, 68.1%)
Revised As Designed	79.7%	76.6%	75.2%	71.8%	66.1%
	(75.3%, 83.3%)	(71.0%, 81.3%)	(68.9%, 80.4%)	(63.9%, 78.3%)	(56.2%, 74.3%)
Revised Not As Designed	75.4%	67.4%	64.3%	61.5%	59.6%
	(71.1%, 79.2%)	(62.3%, 72.1%)	(58.8%, 69.2%)	(55.7%, 66.7%)	(53.6%, 65.1%)

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
8709	62.0%	58.7%	55.5%	54.5%	54.1%
	(58.4%, 65.4%)	(54.8%, 62.5%)	(51.3%, 59.5%)	(50.2%, 58.6%)	(49.8%, 58.2%)
8709SC	69.3%	69.3%	65.8%	65.0%	65.0%
	(64.4%, 73.7%)	(64.4%, 73.7%)	(60.2%, 70.8%)	(59.2%, 70.2%)	(59.2%, 70.2%)
8711	66.7%	62.3%	59.6%	55.9%	54.8%
	(60.3%, 72.3%)	(55.1%, 68.6%)	(52.1%, 66.3%)	(48.1%, 63.1%)	(46.8%, 62.1%)
8731	71.7%	67.1%	63.4%	59.9%	59.9%
	(63.7%, 78.2%)	(58.3%, 74.4%)	(54.2%, 71.3%)	(50.3%, 68.2%)	(50.3%, 68.2%)
8731SC	71.1%	71.1%	63.8%		
	(61.6%, 78.7%)	(61.6%, 78.7%)	(51.8%, 73.6%)		
8780	76.1%				
	(71.7%, 79.9%)				
8781	63.6%				

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
	(57.9%, 68.8%)				
Ascenda RAD					
Grafted Not As Designed	59.5%	57.5%	53.8%	52.2%	52.2%
	(52.3%, 65.9%)	(50.1%, 64.3%)	(45.6%, 61.2%)	(43.8%, 60.0%)	(43.8%, 60.0%)
Revised As Designed	66.1%				
	(56.2%, 74.3%)				
Revised Not As Designed	58.1%	57.2%	53.1%		
	(51.9%, 63.8%)	(50.8%, 63.1%)	(45.6%, 60.0%)		

Model Name	16 Years	17 Years	18 Years	19 Years	20 Years
8709	54.1%	53.1%	51.3%	49.9%	47.9%
	(49.8%, 58.2%)	(48.6%, 57.4%)	(46.6%, 55.9%)	(44.9%, 54.7%)	(42.3%, 53.2%)
8709SC	62.3%				
	(54.3%, 69.2%)				
8711	54.8%	54.8%	54.8%		
	(46.8%, 62.1%)	(46.8%, 62.1%)	(46.8%, 62.1%)		
8731	55.5%	55.5%	55.5%	53.1%	
	(45.3%, 64.5%)	(45.3%, 64.5%)	(45.3%, 64.5%)	(42.4%, 62.7%)	
8731SC					
8780					
8781					
Ascenda RAD					
Grafted Not As Designed					

Model Name	16 Years	17 Years	18 Years	19 Years	20 Years
Revised As Designed					
Revised Not As Designed					

Model Name	21 Years
8709	47.9%
	(42.3%, 53.2%)
8709SC	
8711	
8731	
8731SC	
8780	
8781	
Ascenda RAD	
Grafted Not As Designed	
Revised As Designed	
Revised Not As Designed	

4 Spinal Cord Stimulation Systems

4.1 Study Participants

4.1.1 Centers

The spinal cord stimulation tables and graphs were generated based on data collected between June 2004 and the report cut-off date of October 31, 2025. Ninety-nine centers, in North America, Europe and South America, enrolled patients and contributed patient data to the Spinal Cord Stimulation Systems section of this report. [Figure 4.1](#) shows a map of the world, highlighting the countries that enrolled spinal cord stimulation patients.

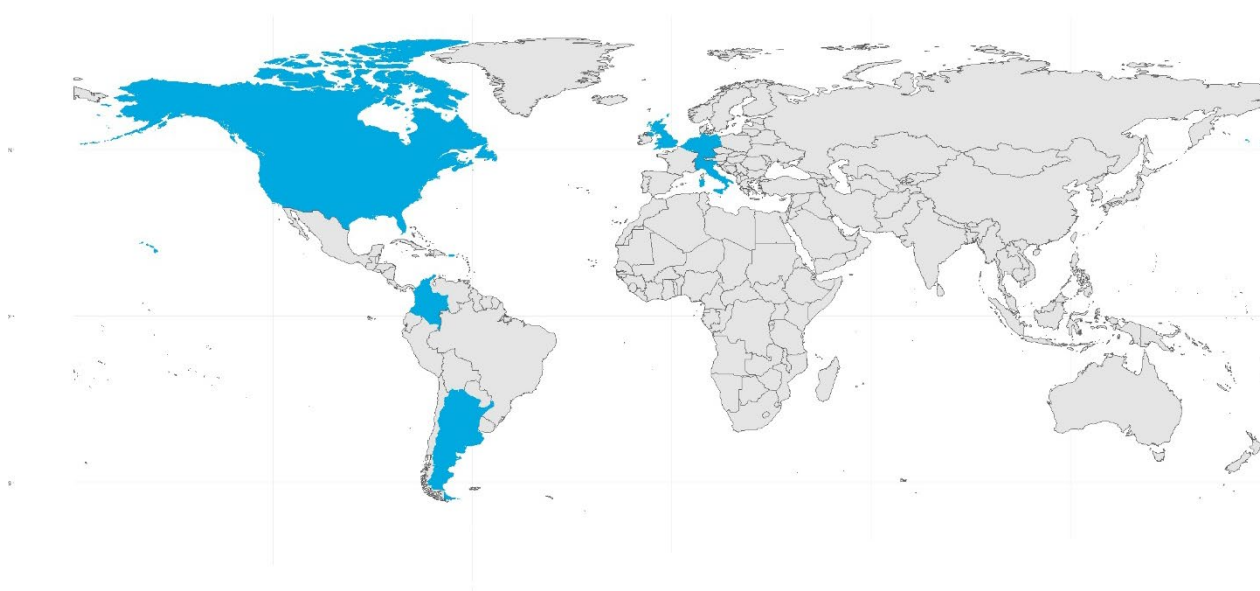


Figure 4.1: Countries with Spinal Cord Stimulation Patients in Registry (Highlighted)

4.1.2 Patients

Of the 7,091 spinal cord stimulation patients enrolled, 44.7% were implanted for the treatment of chronic back and leg pain, 26.4% were implanted for the treatment of other primary indications, 18.2% were implanted for the treatment of trunk and limb pain, 10.1% were implanted for the treatment of complex regional pain syndrome (CRPS), and 0.7% were implanted for indications that were not specified in the database (see [Figure 4.2](#) and [Table 4.1](#)).

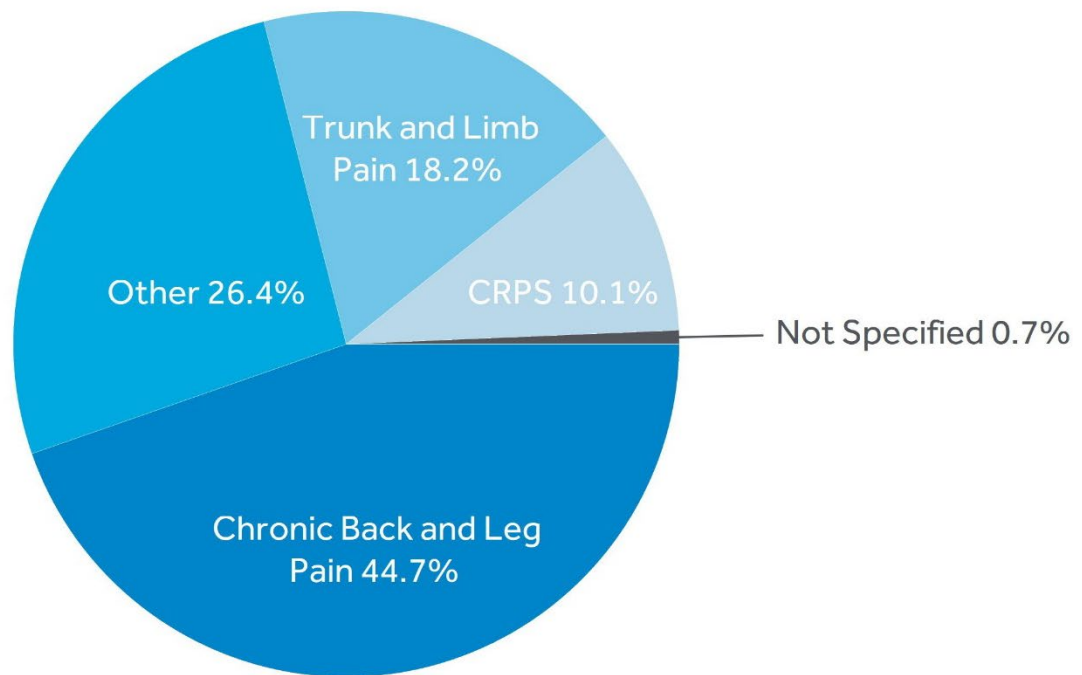


Figure 4.2: Spinal Cord Stimulation Primary Treatment Indications

Table 4.1: Spinal Cord Stimulation Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Chronic Back and Leg Pain	3167 (44.7%)
Post Surgical Back and/or Leg Pain ^b	2359 (33.3%)
Combination Back and Leg Pain	786 (11.1%)
Arachnoiditis	22 (0.3%)
Other Primary Indication	1869 (26.4%)
Other Chronic Pain	893 (12.6%)
Cervical Pain	112 (1.6%)
Chronic Cluster Headache	108 (1.5%)
Diabetic Neuropathy	79 (1.1%)
Traumatic Nerve Injury	67 (0.9%)
Post Herpetic Neuralgia	19 (0.3%)
Facial Pain	16 (0.2%)

Primary Treatment Indication ^a	Enrolled Patients (%)
Angina	12 (0.2%)
Epidural Fibrosis	4 (0.1%)
Post Herniorrhaphy Pain	3 (<0.1%)
Other	556 (7.8%)
Trunk and Limb Pain	1294 (18.2%)
Radicular Pain Syndrome	975 (13.7%)
Degenerative Disc Disease	319 (4.5%)
CRPS	714 (10.1%)
CRPS I	552 (7.8%)
CRPS II	162 (2.3%)
Not Specified	47 (0.7%)
Total Patients	7091 (100.0%)

^a For approved indications refer to product labeling for your geography.

^b Contains Failed Back Surgery Syndrome (FBSS), Post Laminectomy Pain, Multiple Back Operations and Unsuccessful Disc Surgery.

It is recognized that health care providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved labeling. Product labeling varies by geography. Contact a local Medtronic representative (<http://www.medtronic.com/us-en/about/locations.html>) for region-specific product labeling.

4.2 Event Summary

Adverse and device events were reported by the investigational site, where the principal investigator determined the suspected etiology. For device-related events, etiology could be attributed to one or more system components (e.g., neurostimulator, lead, and/or extension). If multiple components were identified as contributing to a single event, a separate product performance event (PPE) was recorded for each implicated component. For example, an event attributed to both the neurostimulator and the lead would be counted as one PPE for the neurostimulator and an additional PPE for the lead. As a result, the total number of PPEs may exceed the number of unique PPEs.

For PSTM, there were 2,274 PPEs (1665 unique events) reported in 1,108 patients between June 2004 and October 31, 2025, with spinal cord stimulation systems. These events represent 35.8% of the total reported events (2,274/6,353), occurred in 1,108 (15.6%) of the 7,091 total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves). In addition, there were 4,020 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the spinal cord stimulation systems. As an ongoing registry, events not coded at the time of the data snapshot (waiting on further information) will be included in future reports (n=59).

Any registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings assist in the classification of the events. Within this report, [Table 4.2](#) differentiates the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 331 deaths reported for patients followed in the PSR with spinal cord stimulation systems, none of which were reported as a direct result of a product performance event.

4.2.1 Product Performance Events

Table 4.2: Spinal Cord Stimulation System Product Performance Events

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=7091 ^b
RPA Determination	3	<0.1	3 (<0.1%)
Other ^c	3	<0.1	3 (<0.1%)
Physician's Determination	2,271	11.2	1105 (15.6%)
Lead Migration/Dislodgement	887	4.4	467 (6.6%)
High Impedance	599	2.9	291 (4.1%)
Neurostimulator Unable To Recharge ^d	131	0.6	121 (1.7%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=7091 ^b
Device Malfunction ^e	127	0.6	113 (1.6%)
Lead Fracture	113	0.6	72 (1.0%)
Unspecified ^f	63	0.3	39 (0.5%)
Low Impedance	56	0.3	26 (0.4%)
Device Charging Issue	52	0.3	45 (0.6%)
Device Breakage ^g	49	0.2	44 (0.6%)
Device Electrical Impedance Issue	25	0.1	14 (0.2%)
Extension Fracture	20	0.1	14 (0.2%)
Device Connection Issue	13	0.1	10 (0.1%)
Device Overheating	12	0.1	11 (0.2%)
Extension Migration	12	0.1	8 (0.1%)
Device Issue	11	0.1	10 (0.1%)
Neurostimulator Migration	9	<0.1	9 (0.1%)
Device Lead Damage	7	<0.1	5 (0.1%)
Antenna Cable Breakage	6	<0.1	6 (0.1%)
Device Battery Issue	6	<0.1	5 (0.1%)
Medical Device Complication ^h	6	<0.1	2 (<0.1%)
Device Damage	4	<0.1	4 (0.1%)
Device Difficult To Program	4	<0.1	4 (0.1%)
Device Failure ⁱ	4	<0.1	3 (<0.1%)
Device Inappropriate Shock Delivery	4	<0.1	1 (<0.1%)
Device Stimulation Issue ^j	4	<0.1	3 (<0.1%)
Device Use Issue	4	<0.1	3 (<0.1%)
Inadequate Lead Connection	4	<0.1	2 (<0.1%)
Premature Battery Depletion	4	<0.1	4 (0.1%)
Device Computer Software Issue	3	<0.1	3 (<0.1%)
Device Telemetry Issue	3	<0.1	3 (<0.1%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=7091 ^b
Internal Device Exposed	3	<0.1	3 (<0.1%)
Device Image Display Error	2	<0.1	2 (<0.1%)
Device Lead Issue	2	<0.1	1 (<0.1%)
Device Loosening	2	<0.1	2 (<0.1%)
Device Positioned Inappropriately	2	<0.1	1 (<0.1%)
Medical Device Site Pain	2	<0.1	1 (<0.1%)
Other ^c	16	0.1	16 (0.2%)
Total	2,274	11.2	1108 (15.6%)

- a Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
- b The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.
- c Consists of events with one count each.
- d There were 4,839 patients that used rechargeable SCS neurostimulators in the registry. A total of 2.50% (121/4,839) of patients with a rechargeable SCS neurostimulator experienced a neurostimulator unable to recharge event.
- e Includes recharging components, charging and other technical related issues.
- f Includes product performance events that were reported as adverse events rather than device events (e.g. Device Stimulation Issue, Pain, and Medical Device Erosion).
- g Includes external components.
- h Includes a combination of mechanical and electrical observations.
- i Device failure includes 3 events for lead failure, and 1 extension failure.
- j Device stimulation issue reported by physician as being caused by lead (n=2) and neurostimulator (n=2).

A total of 1,614 (71.0%) of the 2,274 product performance events were related to the Lead only, 138 (6.1%) were related to the Neurostimulator only, 58 (2.6%) were related to Multiple Etiologies (which includes events where at least one device and one non-device etiology was indicated), 51 (2.2%) were related to the Extension only, and 413 (18.2%) were related to Other Etiologies, including: 327 (14.4%) were related to other component, 41 (1.8%) were related to recharging process, 17 (0.7%) were related to programming/stimulation, 14 (0.6%) were related to incisional site/device tract, 7 (0.3%) were related to surgery/anesthesia, 1 (<0.1%) was related to MRI, and 6 (0.3%) were related to other etiology. Relatedness is determined by the physician.

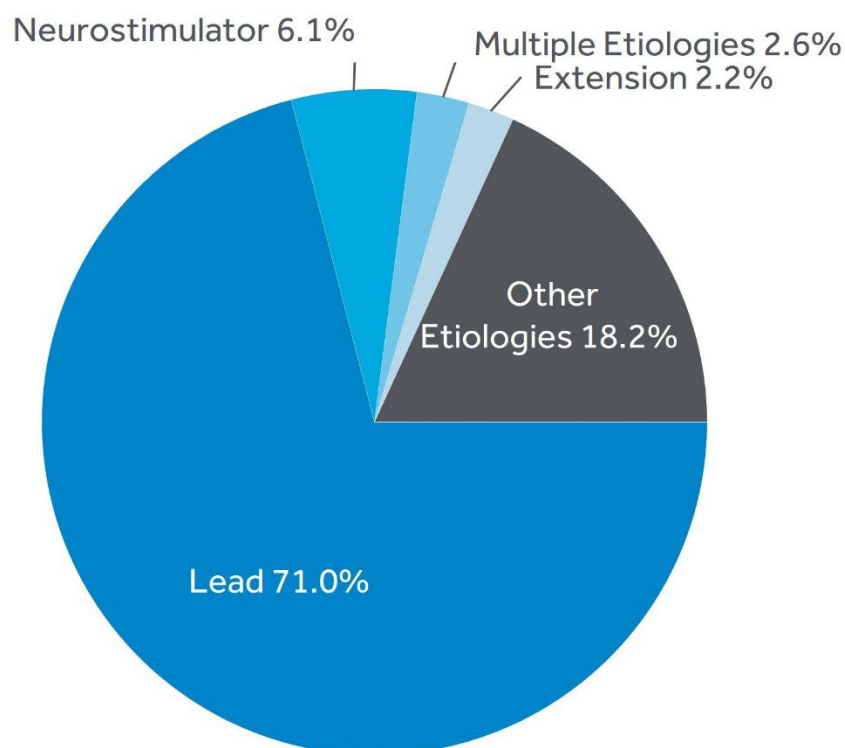


Figure 4.3: Spinal Cord Stimulation System Product Performance Events by Relatedness

Table 4.3 and Table 4.4 describe the interventions taken for reported impedance events. In 28.5% and 21.4% of the high and low impedance events, respectively, the action taken was a surgical intervention. However, impedance could be used as a diagnostic measurement and may not result in any intervention or clinical impact. The majority of events required no intervention or device reprogramming only (68.9% for high impedance and 76.8% for low impedance).

Table 4.3: Spinal Cord Stimulation System High Impedance Events by Intervention

Intervention	N (%) of High Impedance Events
Reprogramming	263 (43.9%)
Device Surgical Intervention	169 (28.2%)
Therapy Suspension	9 (1.5%)
Other Intervention	6 (1.0%)
Other Surgical Intervention	2 (0.3%)
No Action Taken	150 (25.0%)
Total	599 (100.0%)

Table 4.4: Spinal Cord Stimulation System Low Impedance Events by Intervention

Intervention	N (%) of Low Impedance Events
Reprogramming	26 (46.4%)
Device Surgical Intervention	11 (19.6%)
Other Intervention	1 (1.8%)
Other Surgical Intervention	1 (1.8%)
No Action Taken	17 (30.4%)
Total	56 (100.0%)

Table 4.5 describes the interventions taken for reported lead migration/dislodgement events; 77.6% of events led to a surgical intervention, and 11.4% of events led to reprogramming.

Table 4.5: Spinal Cord Stimulation System Lead Migration/Dislodgement Events by Intervention

Intervention	N (%) of Lead Migration/Dislodgement Events
Device Surgical Intervention	642 (72.4%)
Reprogramming	101 (11.4%)
Other Surgical Intervention	46 (5.2%)
Therapy Suspension	19 (2.1%)
Other Intervention	15 (1.7%)
Medical or Non-Surgical Therapy	3 (0.3%)
Medication	2 (0.2%)
No Action Taken	59 (6.7%)
Total	887 (100.0%)

Table 4.6 describes the interventions completed for product performance events that required action from the health care provider and thereby may have resulted in an incremental impact to the patient. Survival estimates presented in previous product performance reports included events where no action was taken. To present survival estimates that may better correlate with patient impact, events where no action was taken have been removed from the device survival estimates presented in this report. The far-left column lists the top five reported product performance events (PPEs), and all other reported PPEs are listed under Other. The subsequent columns represent the actions taken by the reporting physician.

Table 4.6: Spinal Cord Stimulation System Product Performance Events by Intervention

Events by Intervention ^a	Surgical Intervention	Reprogramming	Medical or Non-Surgical Intervention	Therapy Suspension	Recharge	No Action Taken	Total Events
Lead Migration/Dislodgement	688 (77.6%)	101 (11.4%)	20 (2.3%)	19 (2.1%)	0 (0.0%)	59 (6.7%)	887
High Impedance	171 (28.5%)	263 (43.9%)	6 (1.0%)	9 (1.5%)	0 (0.0%)	150 (25.0%)	599
Neurostimulator Unable To Recharge	41 (31.3%)	9 (6.9%)	69 (52.7%)	4 (3.1%)	2 (1.5%)	6 (4.6%)	131
Device Malfunction	22 (17.3%)	12 (9.4%)	76 (59.8%)	5 (3.9%)	1 (0.8%)	11 (8.7%)	127
Lead Fracture	105 (92.9%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	0 (0.0%)	6 (5.3%)	113
Other/Unspecified ^b	171 (41.0%)	52 (12.5%)	141 (33.8%)	11 (2.6%)	1 (0.2%)	41 (9.8%)	417
Total	1198 (52.7%)	437 (19.2%)	312 (13.7%)	50 (2.2%)	4 (0.2%)	273 (12.0%)	2274

^a Medical or Non-Surgical Therapy contains but is not limited to the following actions: medication adjustment based on disease symptoms, imaging (e.g. MRI or X-ray), other specialist referral.

^b Other represents all reported PPEs that were not in the top five of occurrence.

4.2.2 Clinical Events Not Related To Product Performance

The clinical events not related to product performance are summarized if:

- The patient was enrolled in the PSR since 2013, the year in which the clinical event collection was initiated (N=4,200)
- Categorized as serious adverse events (SAEs, N=160)
- Occurred with a System Organ Class (SOC) threshold $\geq 1\%$ of patients
- Other Considerations
 - Some events are described in high level group terms (HLGT) to provide more specificity, if needed
 - Some therapies will provide therapy relevant events

Table 4.7: Spinal Cord Stimulation System Clinically Relevant Serious Adverse Events

Event Type	Number of SAE	Patients with SAE n (%) N=4200	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4200
Infections and infestations	70	65 (1.5%)	0.05	48 (1.1%)
Infections - pathogen unspecified	61	56 (1.3%)	0.04	45 (1.1%)
Bacterial infectious disorders	7	7 (0.2%)	<0.01	3 (0.1%)
Other ^a	2	2 (<0.1%)	<0.01	0 (0.0%)
General disorders and administration site conditions	44	40 (1.0%)	0.03	32 (0.8%)
Complications associated with device	24	23 (0.5%)	0.02	21 (0.5%)
Therapeutic and nontherapeutic effects (excl toxicity)	10	10 (0.2%)	0.01	8 (0.2%)
General system disorders NEC	8	8 (0.2%)	0.01	5 (0.1%)
Other ^a	2	2 (<0.1%)	<0.01	1 (<0.1%)
Injury, poisoning and procedural complications	19	19 (0.5%)	0.01	7 (0.2%)
Procedural related injuries and complications NEC	15	15 (0.4%)	0.01	6 (0.1%)
Other ^a	4	4 (0.1%)	<0.01	1 (<0.1%)
Musculoskeletal and connective tissue disorders	8	7 (0.2%)	0.01	7 (0.2%)
Musculoskeletal and connective tissue disorders NEC	7	6 (0.1%)	<0.01	6 (0.1%)
Other ^a	1	1 (<0.1%)	<0.01	1 (<0.1%)
Product issues	8	8 (0.2%)	0.01	6 (0.1%)
Device issues	8	8 (0.2%)	0.01	6 (0.1%)
Nervous system disorders	6	6 (0.1%)	<0.01	3 (0.1%)
Other ^a	6	6 (0.1%)	<0.01	3 (0.1%)
Other SOC Terms (<1.0%)	5	4 (0.1%)	<0.01	1 (<0.1%)

Event Type	Number of SAE	Patients with SAE n (%) N=4200	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4200
Threshold)				
Total	160	129 (3.1%)	0.11	92 (2.2%)

^a Composed of high level group term event codes with fewer than 5 events each.

4.2.3 Patient Deaths

In earlier versions of the protocol, deaths were only assessed for the relatedness to the device product performance. After 2010, death assessments were expanded to also include the relationship to the implant procedure and/or therapy. As of the report cut-off, a total of 331 patients in the registry had expired. No deaths were reported as a direct result of a product performance event.

A total of 104 (31.4%) deaths have been reported in this patient registry study based upon patients receiving therapy for post-surgical back and/or leg pain, 63 (19.0%) for other chronic pain, 43 (13.0%) for radicular pain syndrome, 40 (12.1%) for combination back and leg pain, 22 (6.6%) for CRPS I, 14 (4.2%) for degenerative disc disease, 4 (1.2%) for CRPS II, 4 (1.2%) for post herpetic neuralgia, 3 (0.9%) for diabetic neuropathy, 2 (0.6%) for cervical pain, 2 (0.6%) for traumatic nerve injury, 1 (0.3%) for angina, 1 (0.3%) for chronic cluster headache, and 28 (8.5%) for other indications. The percentage is based upon the total patient death events and not based upon the rate of occurrence. **All tables depicted without a patient denominator should not be interpreted using other numbers within this report to calculate event rates.**

Table 4.8: Spinal Cord Stimulation System Patient Deaths by Primary Indication

Number of Reports of Death by Primary Indication ^a	N (%) of Deaths
Post Surgical Back and/or Leg Pain ^b	104 (31.4%)
Other Chronic Pain	63 (19.0%)
Radicular Pain Syndrome	43 (13.0%)
Combination Back and Leg Pain	40 (12.1%)
CRPS I	22 (6.6%)
Degenerative Disc Disease	14 (4.2%)
CRPS II	4 (1.2%)
Post Herpetic Neuralgia	4 (1.2%)
Diabetic Neuropathy	3 (0.9%)
Cervical Pain	2 (0.6%)

Number of Reports of Death by Primary Indication^a	N (%) of Deaths
Traumatic Nerve Injury	2 (0.6%)
Angina	1 (0.3%)
Chronic Cluster Headache	1 (0.3%)
Other ^c	28 (8.5%)
Total	331 (100.0%)

^a For approved indications refer to product labeling for your geography.

^b Contains Failed Back Surgery Syndrome (FBSS), Post Laminectomy Pain and Multiple Back Operations.

^c Includes specific free-text entries of the following nature: Radiculopathy, Lumbosacral Neuritis, Peripheral Neuropathy, Occipital Neuralgia, Raynaud's Disease, Bilateral Lower Legs and Feet, Post Hemangioma Surgery Complication, Headache, Arteriopathie, Vascular Pain, Leg Pain after Accident.

4.3 Neurostimulators

From June 2004 to the report cut-off date of October 31, 2025, there were 7,839 neurostimulators followed in the registry. The difference between the total number of patients (n=7,091) versus neurostimulators is due to the fact that some patients were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord neurostimulators was 237,507 months (19,792 years) [Table 4.9](#) provides the number and percentage of neurostimulators by model.

Table 4.9: Spinal Cord Stimulation Neurostimulator Counts by Model

Model Name	N (%)
Currently manufactured	2177 (27.8%)
Intellis with AdaptiveStim (97715)	1693 (21.6%)
Inceptiv (977119)	216 (2.8%)
Vanta (977006)	207 (2.6%)
Intellis LT (97716)	47 (0.6%)
Intellis Pro (977118)	14 (0.2%)
No longer manufactured	5652 (72.1%)
RestoreSensor SureScan MRI (97714)	1385 (17.7%)
PrimeAdvanced SureScan MRI (97702)	796 (10.2%)
PrimeAdvanced (37702)	667 (8.5%)
RestoreULTRA (37712)	581 (7.4%)
Synergy (7427)	460 (5.9%)
Restore (37711)	448 (5.7%)
RestoreSensor (37714)	377 (4.8%)
RestoreAdvanced (37713)	357 (4.6%)
Itrel 4 (37703)	140 (1.8%)
RestoreAdvanced SureScan MRI (97713)	116 (1.5%)
Itrel 3 (7425)	96 (1.2%)
RestoreUltra SureScan MRI (97712)	93 (1.2%)
RestorePrime (37701)	56 (0.7%)

Model Name	N (%)
Synergy Versitrel (7427V)	53 (0.7%)
SynergyPlus (7479)	17 (0.2%)
SynergyCompact (7479B)	7 (0.1%)
Itrel 4 (37704)	3 (<0.1%)
Other/Unspecified	10 (0.1%)
Total	7839 (100.0%)

4.3.1 Neurostimulator Events

There were 152 product performance-related events with an underlying reported etiology related to spinal cord neurostimulator function. This includes 138 events with a neurostimulator etiology and 14 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 115 were the initial product performance event that affected neurostimulator survival estimates. For spinal cord neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 15.9% (401/2,529). The proportion was based upon the number of registry spinal cord neurostimulators received by RPA, divided by the sum of the total number of explanted devices and the total number of neurostimulators in patients who have expired. In the 152 spinal cord neurostimulator events, 98.03% (149/152) were assigned as device related by the physician, not returned to Medtronic RPA (see [Table 4.10](#)).

Table 4.10: Spinal Cord Stimulation Neurostimulator Product Performance Events by Determination

Product Performance Events	N (%)
RPA Determination	3 (2.0%)
Broken Bond Wire	1 (0.7%)
Medical Device Complication	1 (0.7%)
No Anomaly Found By RPA ^a	1 (0.7%)
Physician's Determination	149 (98.0%)
High Impedance	34 (22.4%)
Neurostimulator Unable To Recharge	32 (21.1%)
Device Malfunction	29 (19.1%)

Product Performance Events	N (%)
Lead Migration/Dislodgement	12 (7.9%)
Device Charging Issue	7 (4.6%)
Unspecified	6 (3.9%)
Neurostimulator Migration	5 (3.3%)
Device Overheating	3 (2.0%)
Low Impedance	3 (2.0%)
Premature Battery Depletion	3 (2.0%)
Device Breakage	2 (1.3%)
Device Stimulation Issue	2 (1.3%)
Device Battery Issue	1 (0.7%)
Device Connection Issue	1 (0.7%)
Device Electrical Impedance Issue	1 (0.7%)
Device Image Display Error	1 (0.7%)
Device Inappropriate Shock Delivery	1 (0.7%)
Device Issue	1 (0.7%)
Device Telemetry Issue	1 (0.7%)
Extension Migration	1 (0.7%)
Internal Device Exposed	1 (0.7%)
Medical Device Site Warmth	1 (0.7%)
Neurostimulator Inversion	1 (0.7%)
Total	152 (100.0%)

^a The physician's determination for this event was Neurostimulator Unable to Recharge

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

- 115 had follow-up time cut-off due to product performance-related events.
- 6,304 were censored in the survival analysis for the following reasons: patient

expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.

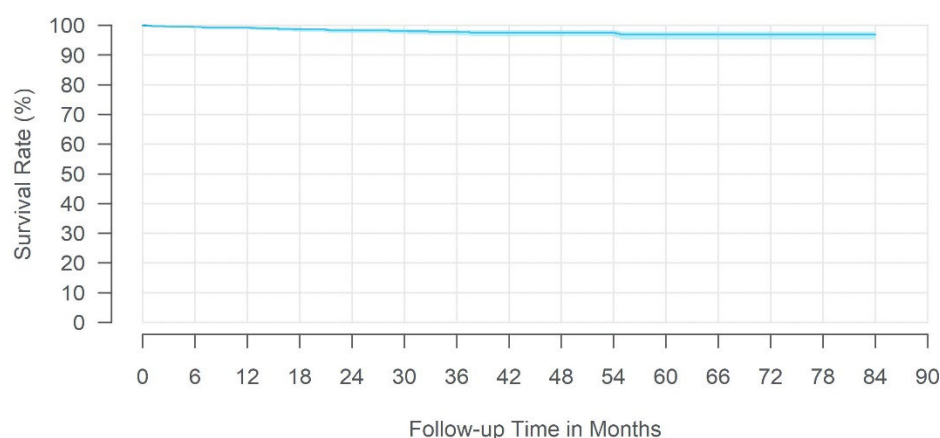
- 1,420 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

4.3.2 Neurostimulator Models

The following figures and tables represent spinal cord neurostimulator survival and 95% confidence intervals where at least 20 spinal cord neurostimulators contributed to each 3-month interval.

4.3.2.1 Model Intellis with AdaptiveStim

Model Name	Intellis with AdaptiveStim (model 97715)
FDA Approval Date	September 2017
Neurostimulators Enrolled	1,693
Neurostimulators Currently Active in Study	801
Initial Product Performance Events	28
Median Follow-up Time (Months)	24.8
Cumulative Follow-up Time (Months)	50,853



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (98.7%, 99.6%)	98.3% (97.4%, 98.9%)	97.9% (96.8%, 98.6%)	97.5% (96.3%, 98.4%)	96.9% (95.3%, 98.0%)
Sample Size	1218	862	574	394	238

Time Interval	6 Years	7 Years
Survival (95% CI)	96.9% (95.3%, 98.0%)	96.9% (95.3%, 98.0%)
Sample Size	119	26

Specification: Intellis with AdaptiveStim

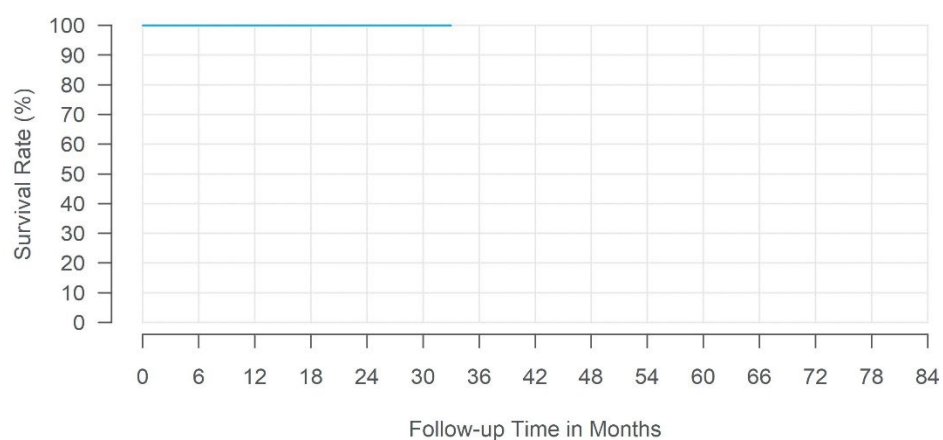
Height	57.1mm (2.2in)
Width	47.2mm (1.9in)
Thickness Case	6.3 mm (0.2 in)
Thickness Connector	9.1 mm (0.4 in)
Volume	13.9 cc
Battery Type	Rechargeable
Expected Battery Life	9 years before ERI
Maximum Electrodes	16
Amplitude	0 - 100 mA
Rate Range	40 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	1 - 3
Programs	12
Implant Depth	≤3 cm



Neurostimulator Event Summary: Intellis with AdaptiveStim	N
High Impedance	8
Device Malfunction	5
Neurostimulator Migration	3
Neurostimulator Unable To Recharge	3
Device Charging Issue	2
Device Electrical Impedance Issue	1
Device Inappropriate Shock Delivery	1
Device Overheating	1
Internal Device Exposed	1
Lead Migration/Dislodgement	1
Neurostimulator Inversion	1
Unspecified	1
Total	28

4.3.2.2 Model Intellis LT

Model Name	Intellis LT (model 97716)
FDA Approval Date	July 2017
Neurostimulators Enrolled	47
Neurostimulators Currently Active in Study	26
Initial Product Performance Events	0
Median Follow-up Time (Months)	28.4
Cumulative Follow-up Time (Months)	1,201



Time Interval	1 Year	2 Years	At 33 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	30	24	20

Specification: Intellis LT

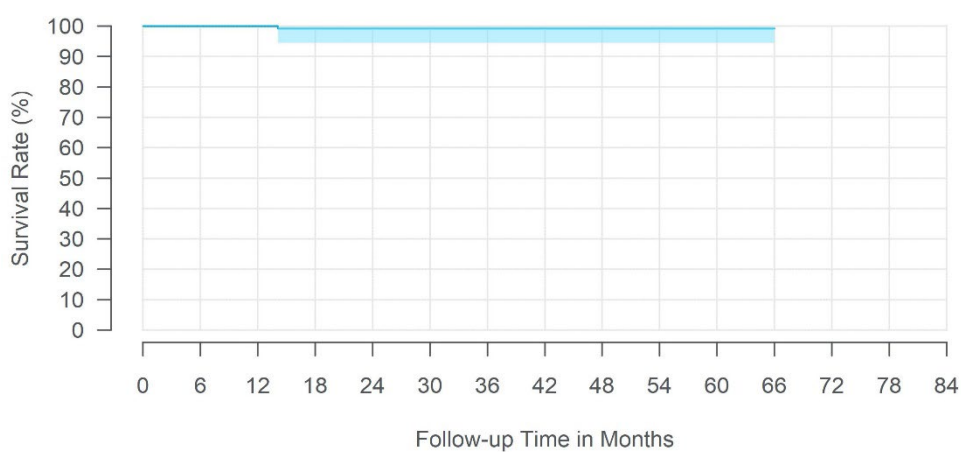
Height	57.1mm (2.2in)
Width	47.2mm (1.9in)
Thickness Case	6.3 mm (0.2 in)
Thickness Connector	9.1 mm (0.4 in)
Volume	13.9 cc
Battery Type	Rechargeable
Expected Battery Life	9 years before ERI
Maximum Electrodes	16
Amplitude	0 - 100 mA
Rate Range	40 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	1 - 3
Programs	12
Implant Depth	≤3 cm



Neurostimulator Event Summary: Intellis LT	Total
N	0

4.3.2.3 Model Itrel 4

Model Name	Itrel 4 (model 37703)
FDA Approval Date	May 2012
Neurostimulators Enrolled	140
Neurostimulators Currently Active in Study	19
Initial Product Performance Events	2
Median Follow-up Time (Months)	36.3
Cumulative Follow-up Time (Months)	5,747



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	99.2% (94.5%, 99.9%)	99.2% (94.5%, 99.9%)	99.2% (94.5%, 99.9%)	99.2% (94.5%, 99.9%)
Sample Size	128	96	72	48	28

Time Interval	At 66 Months
Survival (95% CI)	99.2% (94.5%, 99.9%)
Sample Size	20

Specification: Itrel 4	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

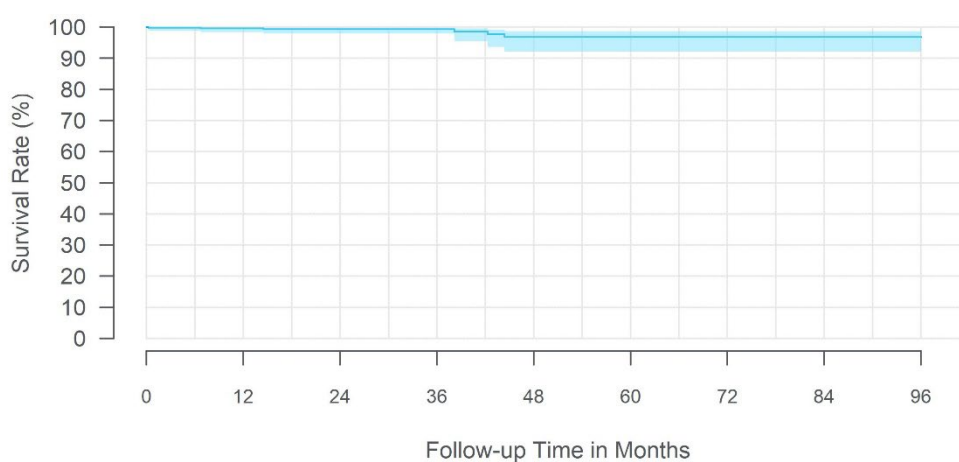


Neurostimulator Event Summary: Itrel 4	N
High Impedance	1
Neurostimulator Unable To Recharge*	1
Total	2

*Incorrect reporting of Event as this is a primary cell INS device. Will be rectified in the next PPR.

4.3.2.4 Model PrimeAdvanced

Model Name	PrimeAdvanced (model 37702)
FDA Approval Date	July 2006
Neurostimulators Enrolled	667
Neurostimulators Currently Active in Study	7
Initial Product Performance Events	6
Median Follow-up Time (Months)	16.0
Cumulative Follow-up Time (Months)	16,121



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (98.5%, 99.9%)	99.3% (97.9%, 99.8%)	99.3% (97.9%, 99.8%)	96.8% (92.1%, 98.7%)	96.8% (92.1%, 98.7%)
Sample Size	393	238	144	96	68

Time Interval	6 Years	7 Years	8 Years
Survival (95% CI)	96.8% (92.1%, 98.7%)	96.8% (92.1%, 98.7%)	96.8% (92.1%, 98.7%)
Sample Size	41	26	20

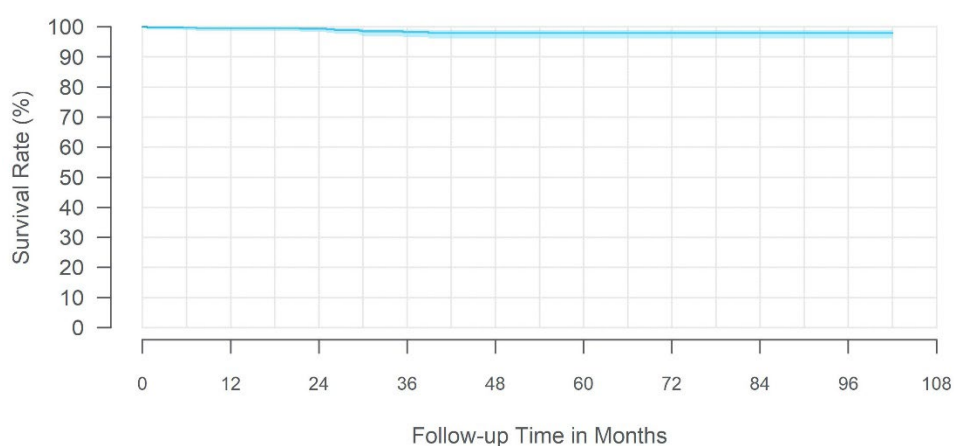
Specification: PrimeAdvanced	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 μ sec
Groups	26
Programs	32
Implant Depth	$\leq$ 4 cm



Neurostimulator Event Summary: PrimeAdvanced	N
Device Malfunction	2
High Impedance	2
Low Impedance	1
Unspecified	1
Total	6

4.3.2.5 Model PrimeAdvanced SureScan MRI

Model Name	PrimeAdvanced SureScan MRI (model 97702)
FDA Approval Date	March 2013
Neurostimulators Enrolled	796
Neurostimulators Currently Active in Study	86
Initial Product Performance Events	11
Median Follow-up Time (Months)	32.3
Cumulative Follow-up Time (Months)	30,217



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (98.7%, 99.9%)	99.4% (98.4%, 99.8%)	98.2% (96.6%, 99.1%)	97.9% (96.1%, 98.9%)	97.9% (96.1%, 98.9%)
Sample Size	654	500	362	238	155

Time Interval	6 Years	7 Years	8 Years	At 102 Months
Survival (95% CI)	97.9% (96.1%, 98.9%)	97.9% (96.1%, 98.9%)	97.9% (96.1%, 98.9%)	97.9% (96.1%, 98.9%)
Sample Size	102	66	41	29

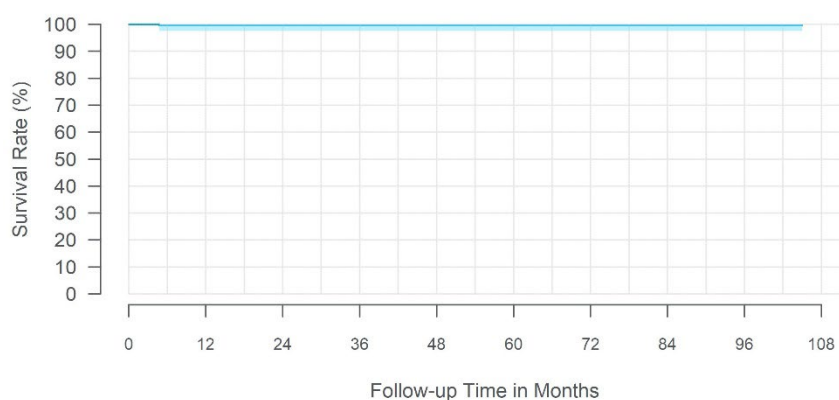
Specification: PrimeAdvanced SureScan MRI	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	3 - 130 Hz
Pulse Width	60 - 450 μ sec
Groups	26
Programs	32
Implant Depth	$\leq$ 4 cm



Neurostimulator Event Summary: PrimeAdvanced SureScan MRI	N
High Impedance	6
Lead Migration/Dislodgement	2
Premature Battery Depletion	2
Unspecified	1
Total	11

4.3.2.6 Model RestoreAdvanced

Model Name	RestoreAdvanced (model 37713)
FDA Approval Date	July 2006
Neurostimulators Enrolled	357
Neurostimulators Currently Active in Study	1
Initial Product Performance Events	1
Median Follow-up Time (Months)	22.0
Cumulative Follow-up Time (Months)	11,363



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)
Sample Size	238	170	115	84	62

Time Interval	6 Years	7 Years	8 Years	At 105 Months
Survival (95% CI)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)
Sample Size	49	35	29	20

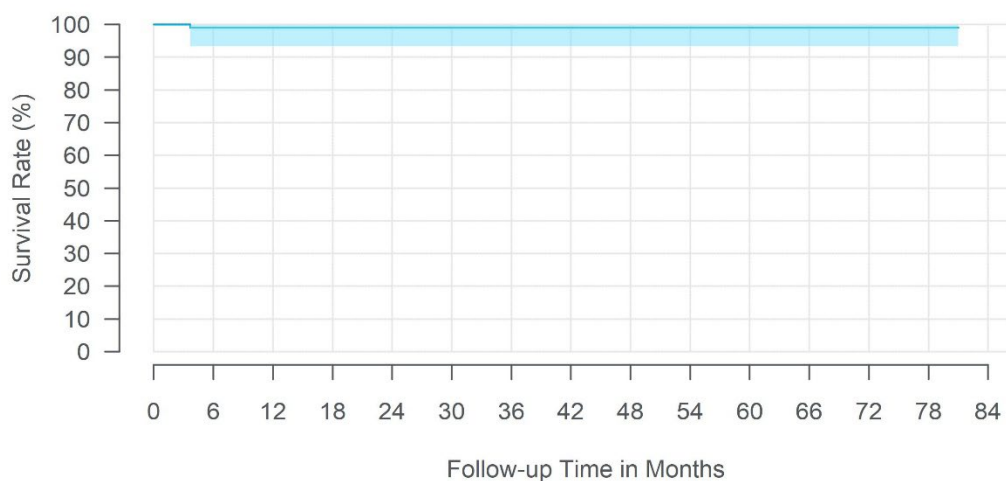
Specification: RestoreAdvanced	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 μ sec
Groups	26
Programs	32
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreAdvanced	N
Medical Device Complication	1
Total	1

4.3.2.7 Model RestoreAdvanced SureScan MRI

Model Name	RestoreAdvanced SureScan MRI (model 97713)
FDA Approval Date	March 2013
Neurostimulators Enrolled	116
Neurostimulators Currently Active in Study	10
Initial Product Performance Events	2
Median Follow-up Time (Months)	33.0
Cumulative Follow-up Time (Months)	4,690



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)
Sample Size	89	71	54	36	31

Time Interval	6 Years	At 81 Months
Survival (95% CI)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)
Sample Size	28	20

**Specification:
RestoreAdvanced SureScan MRI**

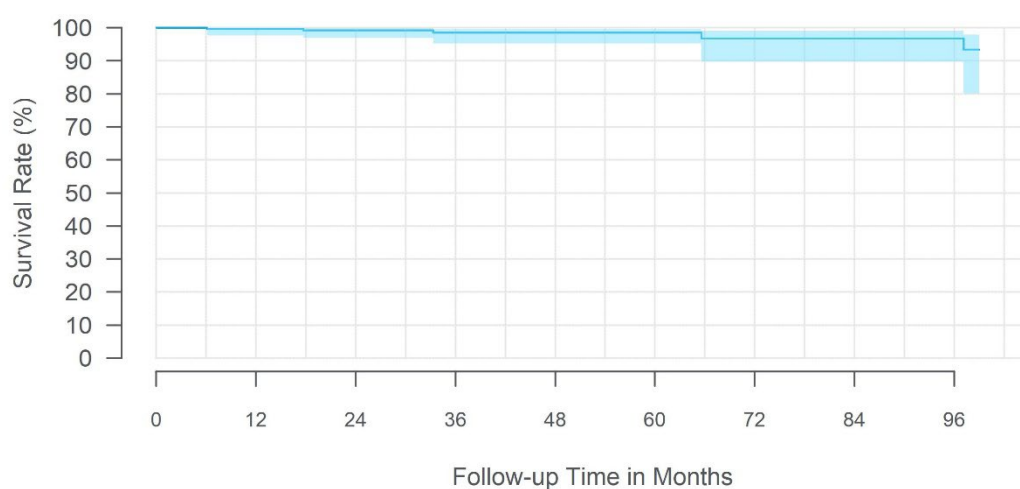
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 μ sec
Groups	26
Programs	32
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreAdvanced SureScan MRI	N
Device Malfunction	1
Neurostimulator Unable To Recharge	1
Total	2

4.3.2.8 Model RestoreSensor

Model Name	RestoreSensor (model 37714)
FDA Approval Date	November 2011
Neurostimulators Enrolled	377
Neurostimulators Currently Active in Study	8
Initial Product Performance Events	5
Median Follow-up Time (Months)	23.2
Cumulative Follow-up Time (Months)	12,513



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (97.7%, 100.0%)	99.2% (96.9%, 99.8%)	98.5% (95.3%, 99.6%)	98.5% (95.3%, 99.6%)	98.5% (95.3%, 99.6%)
Sample Size	258	185	135	93	66

Time Interval	6 Years	7 Years	8 Years	At 99 Months
Survival (95% CI)	96.8% (89.8%, 99.0%)	96.8% (89.8%, 99.0%)	96.8% (89.8%, 99.0%)	93.4% (80.2%, 97.9%)
Sample Size	45	36	29	25

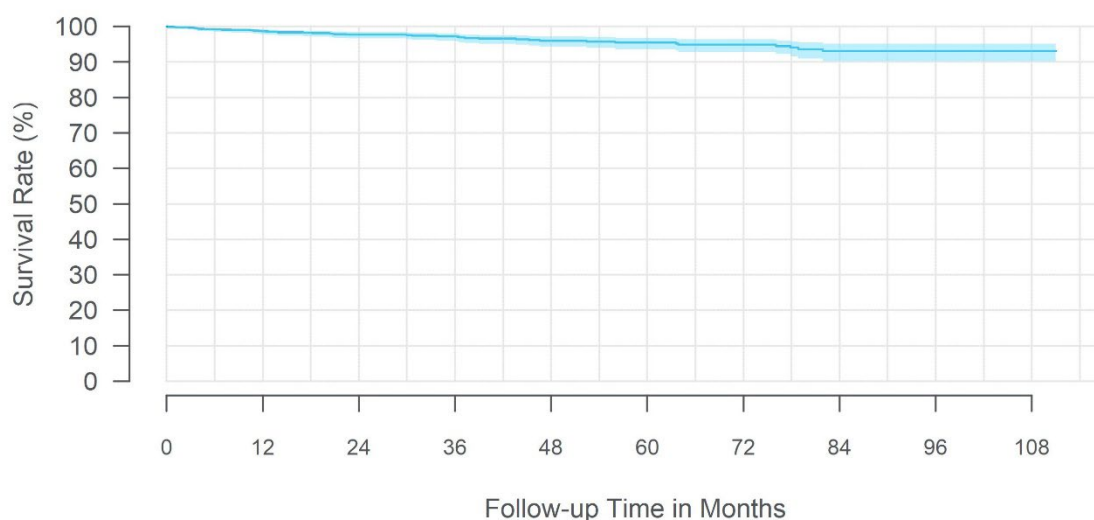
Specification: RestoreSensor	
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 μ sec
Groups	8
Programs	16
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreSensor		N
Neurostimulator Unable To Recharge		3
Device Issue		1
Device Malfunction		1
Total		5

4.3.2.9 Model RestoreSensor SureScan MRI

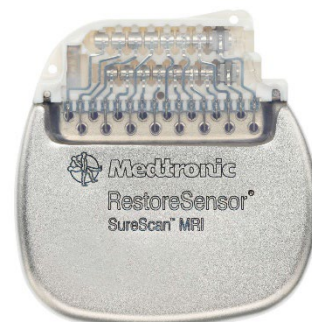
Model Name	RestoreSensor SureScan MRI (model 97714)
FDA Approval Date	March 2013
Neurostimulators Enrolled	1,385
Neurostimulators Currently Active in Study	78
Initial Product Performance Events	43
Median Follow-up Time (Months)	30.0
Cumulative Follow-up Time (Months)	54,658



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.7% (97.8%, 99.2%)	97.7% (96.6%, 98.5%)	97.3% (96.0%, 98.1%)	96.0% (94.4%, 97.2%)	95.5% (93.7%, 96.8%)
Sample Size	1047	802	598	452	339

Time Interval	6 Years	7 Years	8 Years	9 Years	At 111 Months
Survival (95% CI)	94.9% (92.9%, 96.4%)	93.1% (90.2%, 95.2%)	93.1% (90.2%, 95.2%)	93.1% (90.2%, 95.2%)	93.1% (90.2%, 95.2%)
Sample Size	250	180	117	36	23

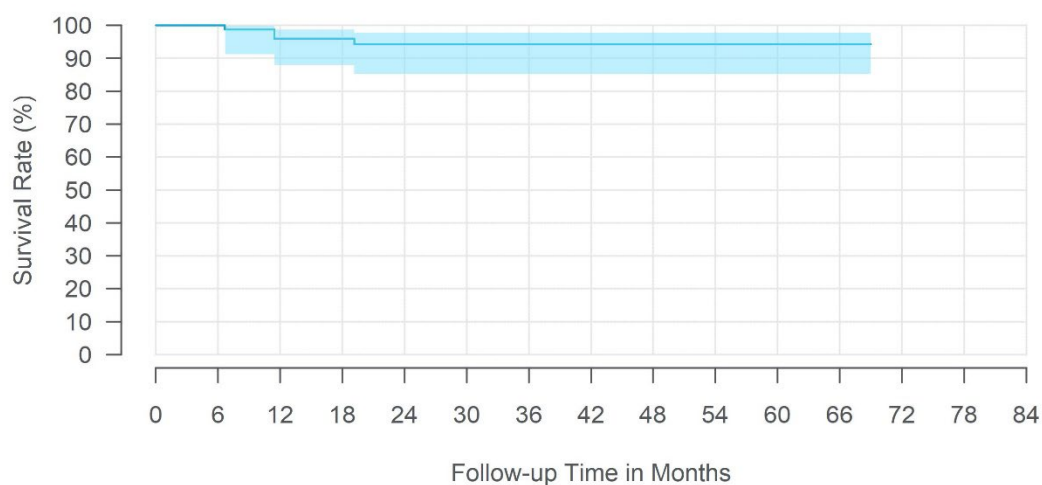
Specification: RestoreSensor SureScan MRI	
Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thickness	9 mm (0.4 in)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 μ sec
Groups	8
Programs	16
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreSensor SureScan MRI	N
Neurostimulator Unable To Recharge	14
Device Malfunction	9
Lead Migration/Dislodgement	7
Device Overheating	2
High Impedance	2
Low Impedance	2
Neurostimulator Migration	2
Device Battery Issue	1
Device Breakage	1
Device Connection Issue	1
Device Image Display Error	1
Device Stimulation Issue	1
Total	43

4.3.2.10 Model RestoreUltra SureScan MRI

Model Name	RestoreUltra SureScan MRI (model 97712)
FDA Approval Date	March 2013
Neurostimulators Enrolled	93
Neurostimulators Currently Active in Study	10
Initial Product Performance Events	4
Median Follow-up Time (Months)	28.5
Cumulative Follow-up Time (Months)	3,767



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	95.9% (87.9%, 98.7%)	94.3% (85.4%, 97.8%)	94.3% (85.4%, 97.8%)	94.3% (85.4%, 97.8%)	94.3% (85.4%, 97.8%)
Sample Size	66	50	42	33	25

Time Interval	At 69 Months
Survival (95% CI)	94.3% (85.4%, 97.8%)
Sample Size	21

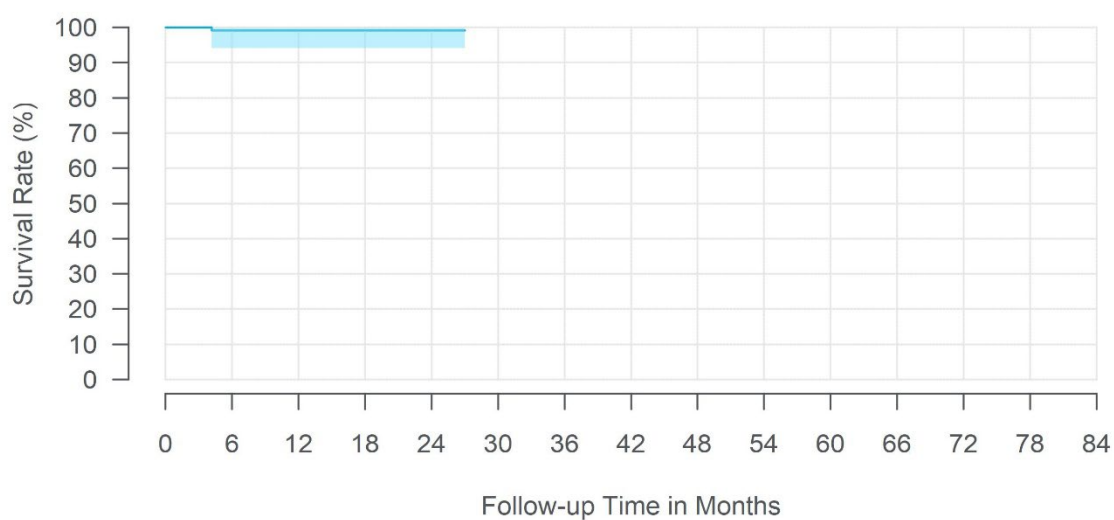
Specification: RestoreUltra SureScan MRI	
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 μ sec
Groups	8
Programs	16
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreUltra SureScan MRI		N
Neurostimulator Unable To Recharge		2
Extension Migration		1
No Anomaly Found By RPA		1
Total		4

4.3.2.11 Model Vanta

Model Name	Vanta (model 977006)
FDA Approval Date	June 2021
Neurostimulators Enrolled	207
Neurostimulators Currently Active in Study	167
Initial Product Performance Events	1
Median Follow-up Time (Months)	6.3
Cumulative Follow-up Time (Months)	2,022



Time Interval	1 Year	2 Years	At 27 Months
Survival (95% CI)	99.2% (94.2%, 99.9%)	99.2% (94.2%, 99.9%)	99.2% (94.2%, 99.9%)
Sample Size	76	30	22

Specification: Vanta with Adaptive Stim

Height	68 mm (2.7in)
Width	51 mm (2.0in)
Thickness Case	11 mm (0.43in)
Thickness Connector	13 mm (0.51 in)
Volume	33 cc
Battery Type	Non- Rechargeable
Expected Battery Life	Up to 11 years
Maximum Electrodes	16
Amplitude	0 - 100 mA
Rate Range	40 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	8
Programs	32
Implant Depth	≤4 cm



Neurostimulator Event Summary: Vanta	N
Premature Battery Depletion	1
Total	1

4.3.2.12 Model Inceptiv

Model Name	Inceptiv (model 977119)
FDA Approval Date	April 2024
Neurostimulators Enrolled	216
Neurostimulators Currently Active in Study	200
Initial Product Performance Events	0
Median Follow-up Time (Months)	0.1
Cumulative Follow-up Time (Months)	582

As of October 31, 2025, there was not sufficient data available to evaluate Inceptiv survival.

Specification: Inceptiv 977119

Height	57mm (2.2in)
Width	47mm (1.9in)
Thickness Case	6 mm (0.2 in)
Thickness Connector	9 mm (0.4 in)
Volume	13.77 cc
Battery Type	Rechargeable
Expected Battery Life	15 years before ERI
Maximum Electrodes	16
Amplitude	0 - 100 mA
Rate Range	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	32
Implant Depth	≤3 cm



As of October 31, 2025, there were no product performance events reported among Inceptiv neurostimulators.

4.3.3 Neurostimulator Summary

Table 4.11: Spinal Cord Stimulation Primary Cell Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Itrel 4 (model 37703)	May 2012	140	19	2	36.3	5,747
PrimeAdvanced (model 37702)	July 2006	667	7	6	16.0	16,121
PrimeAdvanced SureScan MRI (model 97702)	March 2013	796	86	11	32.3	30,217
Vanta (model 977006)	July 2021	207	167	1	6.3	2,022

Table 4.12: Spinal Cord Stimulation Primary Cell Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Itrel 4 (model 37703)	100.0%	99.2%	99.2%	99.2%	99.2%
	(NA)	(94.5%, 99.9%)	(94.5%, 99.9%)	(94.5%, 99.9%)	(94.5%, 99.9%)
PrimeAdvanced (model 37702)	99.6%	99.3%	99.3%	96.8%	96.8%
	(98.5%, 99.9%)	(97.9%, 99.8%)	(97.9%, 99.8%)	(92.1%, 98.7%)	(92.1%, 98.7%)
PrimeAdvanced SureScan MRI (model 97702)	99.6%	99.4%	98.2%	97.9%	97.9%
	(98.7%, 99.9%)	(98.4%, 99.8%)	(96.6%, 99.1%)	(96.1%, 98.9%)	(96.1%, 98.9%)
Vanta (model 977006)	99.2%	99.2%			
	(94.2%, 99.9%)	(94.2%, 99.9%)			

Model Name	6 Years	7 Years	8 Years
ltrel 4 (model 37703)			
PrimeAdvanced (model 37702)	96.8%	96.8%	96.8%
	(92.1%, 98.7%)	(92.1%, 98.7%)	(92.1%, 98.7%)
PrimeAdvanced SureScan MRI (model 97702)	97.9%	97.9%	97.9%
	(96.1%, 98.9%)	(96.1%, 98.9%)	(96.1%, 98.9%)
Vanta (model 977006)			

Table 4.13: Spinal Cord Stimulation Rechargeable Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Inceptiv (model 977119)	April 2024	216	200	0	0.1	582
Intellis LT (model 97716)	September 2017	47	26	0	28.4	1,201
Intellis with AdaptiveStim (model 97715)	July 2017	1,693	801	28	24.8	50,853
RestoreAdvanced (model 37713)	July 2006	357	1	1	22.0	11,363
RestoreAdvanced SureScan MRI (model 97713)	March 2013	116	10	2	33.0	4,690
RestoreSensor (model 37714)	November 2011	377	8	5	23.2	12,513
RestoreSensor SureScan MRI (model 97714)	March 2013	1,385	78	43	30.0	54,658
RestoreUltra SureScan MRI (model 97712)	March 2013	93	10	4	28.5	3,767

Table 4.14: Spinal Cord Stimulation Rechargeable Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Inceptiv (model 977119)					
Intellis LT (model 97716)	100.0%	100.0%			
	(NA)	(NA)			
Intellis with AdaptiveStim (model 97715)	99.3%	98.3%	97.9%	97.5%	96.9%
	(98.7%, 99.6%)	(97.4%, 98.9%)	(96.8%, 98.6%)	(96.3%, 98.4%)	(95.3%, 98.0%)
RestoreAdvanced (model 37713)	99.7%	99.7%	99.7%	99.7%	99.7%
	(97.6%, 100.0%)	(97.6%, 100.0%)	(97.6%, 100.0%)	(97.6%, 100.0%)	(97.6%, 100.0%)
RestoreAdvanced SureScan MRI (model 97713)	99.0%	99.0%	99.0%	99.0%	99.0%
	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)
RestoreSensor (model 37714)	99.7%	99.2%	98.5%	98.5%	98.5%
	(97.7%, 100.0%)	(96.9%, 99.8%)	(95.3%, 99.6%)	(95.3%, 99.6%)	(95.3%, 99.6%)
RestoreSensor SureScan MRI (model 97714)	98.7%	97.7%	97.3%	96.0%	95.5%
	(97.8%, 99.2%)	(96.6%, 98.5%)	(96.0%, 98.1%)	(94.4%, 97.2%)	(93.7%, 96.8%)
RestoreUltra SureScan MRI (model 97712)	95.9%	94.3%	94.3%	94.3%	94.3%
	(87.9%, 98.7%)	(85.4%, 97.8%)	(85.4%, 97.8%)	(85.4%, 97.8%)	(85.4%, 97.8%)
RestoreUltra SureScan MRI (model 97712)	95.9%	94.3%	94.3%	94.3%	94.3%
	(87.9%, 98.7%)	(85.4%, 97.8%)	(85.4%, 97.8%)	(85.4%, 97.8%)	(85.4%, 97.8%)

Model Name	6 Years	7 Years	8 Years	9 Years
Inceptiv (model 977119)				
Intellis LT (model 97716)				
Intellis with AdaptiveStim (model 97715)	96.9%	96.9%		
	(95.3%, 98.0%)	(95.3%, 98.0%)		
RestoreAdvanced (model 37713)	99.7%	99.7%	99.7%	
	(97.6%, 100.0%)	(97.6%, 100.0%)	(97.6%, 100.0%)	
RestoreAdvanced SureScan MRI (model 97713)	99.0%			
	(93.4%, 99.9%)			
RestoreSensor (model 37714)	96.8%	96.8%	96.8%	
	(89.8%, 99.0%)	(89.8%, 99.0%)	(89.8%, 99.0%)	
RestoreSensor SureScan MRI (model 97714)	94.9%	93.1%	93.1%	93.1%
	(92.9%, 96.4%)	(90.2%, 95.2%)	(90.2%, 95.2%)	(90.2%, 95.2%)
RestoreUltra SureScan MRI (model 97712)				
RestoreUltra SureScan MRI (model 97712)				

4.4 Leads

From June 2004 to the report cut-off date of October 31, 2025, there were 12,411 leads followed in the registry. The difference between the total number of leads (n=12,411) versus the number of neurostimulators (n=7,839) is due to the fact that some patients were subsequently re-implanted with a lead or were implanted with more than one lead. The aggregate prospective follow-up time for all leads was 418,315 months (34,860 years). A lead is a set of thin wires with a protective coating and electrodes near the tip (percutaneous lead) or on a paddle (surgical lead). [Table 4.15](#) provides the number and percentage of leads by model.

Table 4.15: Spinal Cord Stimulation Lead Counts by Model

Model Name	N (%)
Currently manufactured	7241 (58.0%)
Vectris SureScan MRI 1x8 Compact (977A2)	5644 (45.5%)
Pisces Standard (3487A)	994 (8.0%)
AnkerStim (09100)	296 (2.4%)
Vectris SureScan MRI 1x8 Subcompact (977A1)	164 (1.3%)
Specify SureScan MRI 5-6-5 (977C1)	96 (0.8%)
Specify SureScan MRI 2x8 (977C2)	47 (0.4%)
No longer manufactured	4927 (40.0%)
1x8 Compact (3778)	2170 (17.5%)
1x8 Standard (3777)	840 (6.8%)
Pisces Plus (3888)	460 (3.7%)
Specify 5-6-5 (39565)	295 (2.4%)
Pisces Compact (3887)	202 (1.6%)
1x8 SC (3776)	188 (1.5%)
Specify (3998)	158 (1.3%)
Pisces Z Standard (3890)	143 (1.2%)
Pisces Z Compact (3891)	132 (1.1%)
Resume TL (3986A)	108 (0.9%)
Resume II (3587A)	60 (0.5%)
2x4 Hinged Specify (3999)	54 (0.4%)

Model Name	N (%)
Octopolar	49 (0.4%)
Pisces Z Plus (3892)	25 (0.2%)
On-Point (3987A)	9 (0.1%)
SymMix (3982A)	2 (<0.1%)
Specify 2x8 (39286)	32 (0.3%)
Other/Unspecified	243 (2.0%)
Total	12411 (100.0%)

Percutaneous leads composed 88.3% (10,962/12,411) of leads in the registry, including 46.8% (5,808/12,411) in the Vectris SureScan lead family, 25.8% (3,198/12,411) in the Pisces-Octad lead family, 13.3% (1,656/12,411) in the Pisces-Quad lead family, and 2.4% (300/12,411) in the Pisces-Quad LZ lead family; 6.9% (861/12,411) of leads were surgical leads; and 4.7% (588/12,411) of leads were designated as “Other” or were unspecified in the database.

4.4.1 Lead Events

There were 1,644 product performance-related events with an underlying reported etiology related to lead function. This includes 1,614 events with a lead etiology only and 30 events with both a lead and other etiology (including device and non-device etiologies). Of these, 1,204 were the initial product performance event that affected lead survival estimates; the majority were lead migration/dislodgement (n=704), high impedance (n=298), lead fracture (n=90), unspecified (n=45), and low impedance (n=29).

There were 1,097 events in 10,962 (10.0%) percutaneous leads, 50 events in 861 (5.8%) surgical leads, and 57 events occurred in leads with unknown/other model numbers.

For the purposes of survival analysis, a device’s follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient’s last follow-up prior to the data cut-off. For leads:

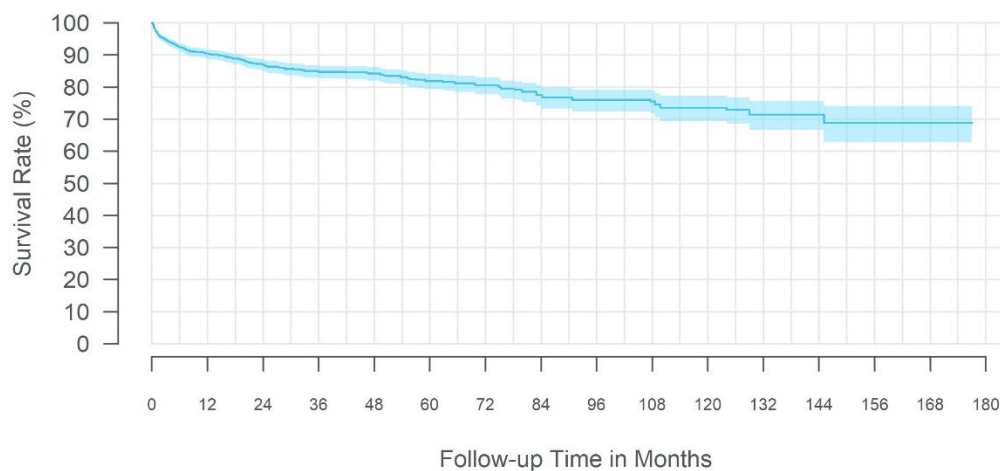
- 1,204 had follow-up time cut-off due to product performance-related events.
- 8,957 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,250 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

4.4.2 Lead Models

The following figures and tables represent spinal cord stimulation lead survival and 95% confidence intervals where at least 20 spinal cord stimulation leads contributed to each 3-month interval.

4.4.2.1 Model 1x8 Compact

Model Name	1x8 Compact (model 3778)
FDA Approval Date	April 2005
Leads Enrolled	2,170
Leads Currently Active in Study	39
Initial Product Performance Events	268
Median Follow-up Time (Months)	18.0
Cumulative Follow-up Time (Months)	70,391



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	90.4% (88.9%, 91.8%)	87.0% (85.2%, 88.7%)	84.8% (82.7%, 86.6%)	84.2% (82.1%, 86.2%)	81.9% (79.3%, 84.1%)
Sample Size	1214	805	602	460	379

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.6% (77.9%, 83.1%)	77.5% (74.2%, 80.5%)	76.0% (72.4%, 79.2%)	75.5% (71.8%, 78.8%)	73.6% (69.4%, 77.3%)
Sample Size	292	219	178	157	131

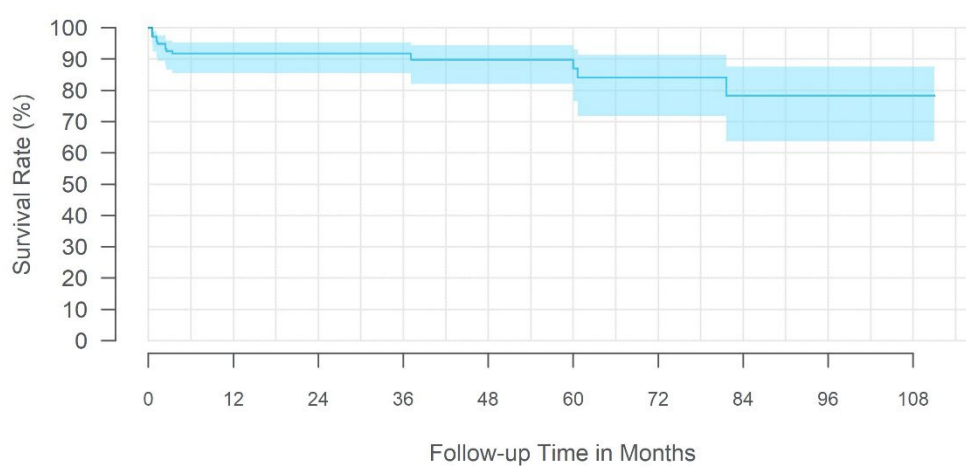
Time Interval	11 Years	12 Years	13 Years	14 Years	At 177 Months
Survival (95% CI)	71.4% (66.6%, 75.6%)	71.4% (66.6%, 75.6%)	68.8% (62.9%, 74.0%)	68.8% (62.9%, 74.0%)	68.8% (62.9%, 74.0%)

Time Interval	11 Years	12 Years	13 Years	14 Years	At 177 Months	
Sample Size	86	57	44	33	21	
Specification: 1x8 Compact						
Lead Type						Percutaneous
Lead						
Length (cm)						45, 60, 75
Diameter (mm)						1.3
Electrode						
Number						8
Shape						Cylindrical
Length (mm)						3.0
Individual Surface Area (mm ²)						12.0
Inter-Electrode Spacing: Edge to Edge (mm)						4.0
Array Length (mm)						52.0

Lead Event Summary: 1x8 Compact	N
Lead Migration/Dislodgement	205
High Impedance	27
Lead Fracture	22
Unspecified	8
Device Malfunction	2
Low Impedance	2
Medical Device Complication	2
Total	268

4.4.2.2 Model 1x8 SC

Model Name	1x8 SC (model 3776)
FDA Approval Date	November 2005
Leads Enrolled	188
Leads Currently Active in Study	9
Initial Product Performance Events	17
Median Follow-up Time (Months)	15.0
Cumulative Follow-up Time (Months)	5,859



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.8% (85.6%, 95.4%)	91.8% (85.6%, 95.4%)	91.8% (85.6%, 95.4%)	89.8% (82.0%, 94.4%)	87.0% (76.5%, 93.0%)
Sample Size	86	64	49	39	30

Time Interval	6 Years	7 Years	8 Years	9 Years	At 111 Months
Survival (95% CI)	84.1% (71.8%, 91.4%)	78.3% (63.7%, 87.6%)	78.3% (63.7%, 87.6%)	78.3% (63.7%, 87.6%)	78.3% (63.7%, 87.6%)
Sample Size	23	24	25	21	20

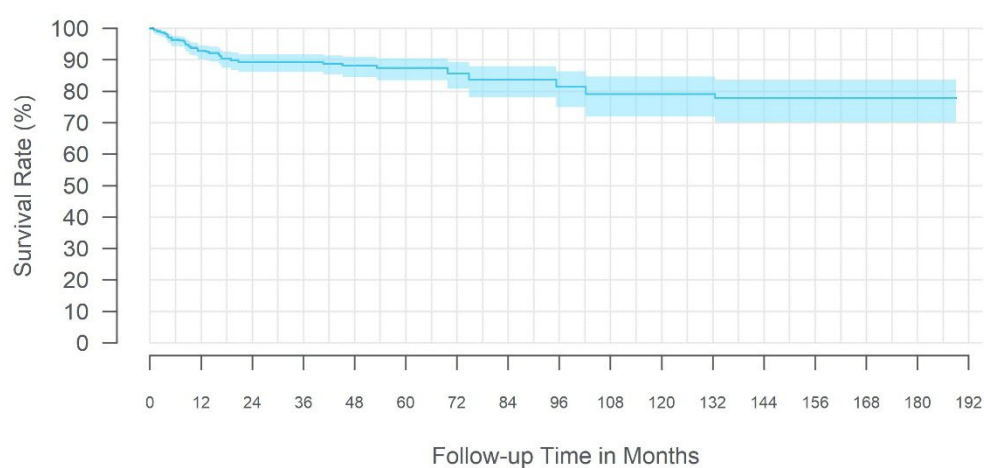
Specification: 1x8 SC	
Lead Type	Percutaneous
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	35.0



Lead Event Summary: 1x8 SC	N
Lead Migration/Dislodgement	12
High Impedance	3
Lead Fracture	1
Unspecified	1
Total	17

4.4.2.3 Model 1x8 Standard

Model Name	1x8 Standard (model 3777)
FDA Approval Date	April 2005
Leads Enrolled	840
Leads Currently Active in Study	34
Initial Product Performance Events	71
Median Follow-up Time (Months)	16.4
Cumulative Follow-up Time (Months)	26,359



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.8% (90.3%, 94.7%)	89.3% (86.2%, 91.8%)	89.3% (86.2%, 91.8%)	88.2% (84.5%, 91.0%)	87.4% (83.5%, 90.5%)
Sample Size	443	288	187	132	108

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	85.7% (80.9%, 89.3%)	83.7% (78.2%, 88.0%)	81.4% (74.9%, 86.4%)	79.1% (71.9%, 84.7%)	79.1% (71.9%, 84.7%)
Sample Size	91	75	70	85	81

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	79.1% (71.9%, 84.7%)	77.8% (70.2%, 83.7%)	77.8% (70.2%, 83.7%)	77.8% (70.2%, 83.7%)	77.8% (70.2%, 83.7%)
Sample Size	63	55	48	35	27

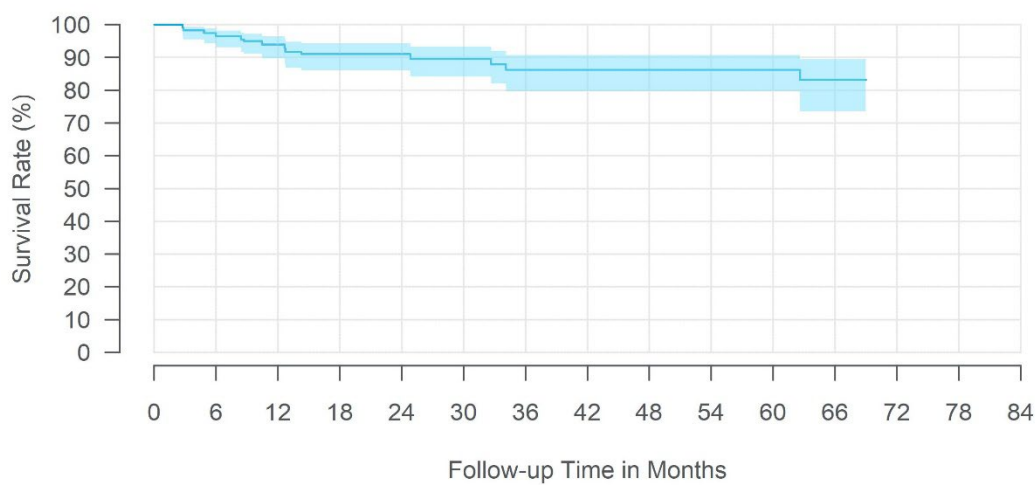
Time Interval	At 189 Months
Survival (95% CI)	77.8% (70.2%, 83.7%)
Sample Size	20

Specification: 1x8 Standard	
Lead Type	Percutaneous
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	66.0

Lead Event Summary: 1x8 Standard	N
Lead Migration/Dislodgement	41
High Impedance	14
Unspecified	7
Lead Fracture	3
Device Lead Damage	2
Device Malfunction	2
Low Impedance	2
Total	71

4.4.2.4 Model AnkerStim

Model Name	AnkerStim (model09100)
FDA Approval Date	NA
Leads Enrolled	296
Leads Currently Active in Study	180
Initial Product Performance Events	25
Median Follow-up Time (Months)	17.5
Cumulative Follow-up Time (Months)	7,795



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.9% (89.8%, 96.4%)	91.1% (86.1%, 94.3%)	86.2% (79.8%, 90.7%)	86.2% (79.8%, 90.7%)	86.2% (79.8%, 90.7%)
Sample Size	170	127	94	54	30

Time Interval	At 69 Months
Survival (95% CI)	83.2% (73.6%, 89.5%)
Sample Size	20

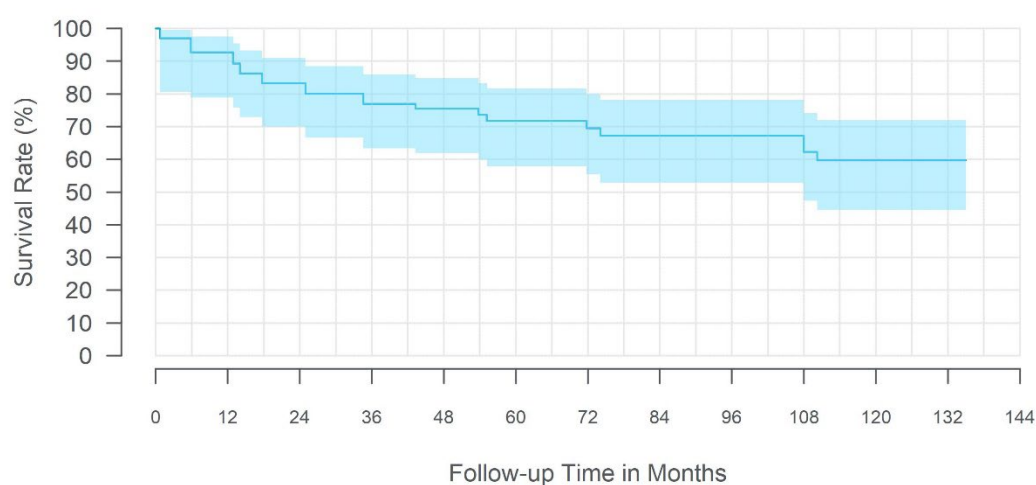
Specification: AnkerStim	
Lead Type	Percutaneous
Lead	
Length (cm)	60
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	6.0
Individual Surface Area (mm)	24.5
Inter-Electrode Spacing: Edge to Edge (mm)	12.0
Array Length (mm)	60.0



Lead Event Summary: AnkerStim	N
High Impedance	14
Lead Migration/Dislodgement	5
Lead Fracture	2
Medical Device Complication	2
Medical Device Site Pain	2
Total	25

4.4.2.5 Model Pisces Compact

Model Name	Pisces Compact (model 3887)
FDA Approval Date	January 1997
Leads Enrolled	202
Leads Currently Active in Study	12
Initial Product Performance Events	25
Median Follow-up Time (Months)	23.7
Cumulative Follow-up Time (Months)	8,303



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.7% (78.9%, 97.6%)	83.3% (70.0%, 91.0%)	76.9% (63.4%, 86.0%)	75.5% (62.0%, 84.8%)	71.7% (57.9%, 81.7%)
Sample Size	51	54	49	43	37

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	69.5% (55.4%, 79.9%)	67.2% (52.9%, 78.1%)	67.2% (52.9%, 78.1%)	62.3% (47.3%, 74.1%)	59.7% (44.6%, 71.9%)
Sample Size	31	26	25	24	24

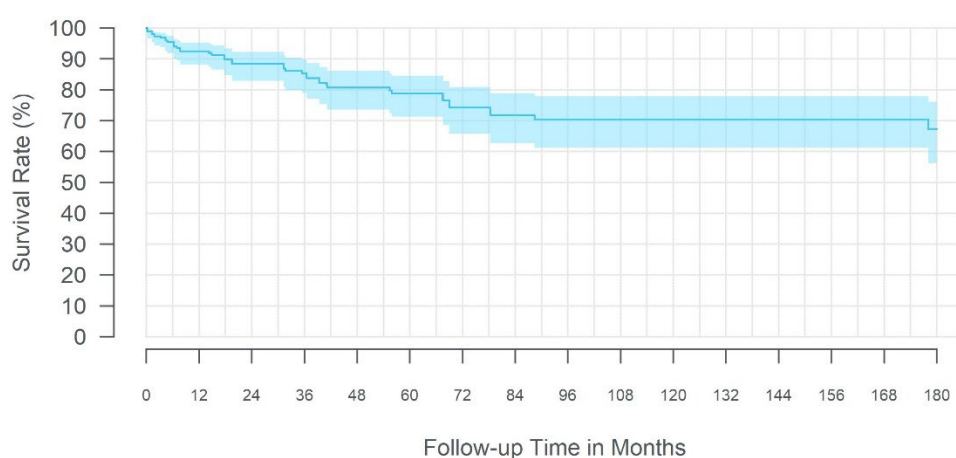
Time Interval	11 Years	At 135 Months
Survival (95% CI)	59.7% (44.6%, 71.9%)	59.7% (44.6%, 71.9%)
Sample Size	20	20

Specification: Pisces Compact	
Lead Type	Percutaneous
Lead	
Length (cm)	28, 33, 45, 56
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	24.0

Lead Event Summary: Pisces Compact	N
Lead Fracture	9
Lead Migration/Dislodgement	9
High Impedance	4
Unspecified	2
Device Lead Damage	1
Total	25

4.4.2.6 Model Pisces Plus

Model Name	Pisces Plus (model 3888)
FDA Approval Date	November 1992
Leads Enrolled	460
Leads Currently Active in Study	29
Initial Product Performance Events	47
Median Follow-up Time (Months)	15.4
Cumulative Follow-up Time (Months)	13,986



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (88.2%, 95.3%)	88.5% (82.9%, 92.3%)	85.3% (79.0%, 89.9%)	80.7% (73.6%, 86.1%)	78.8% (71.3%, 84.6%)
Sample Size	164	118	111	91	76

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	74.2% (65.7%, 80.9%)	71.8% (62.8%, 78.9%)	70.4% (61.2%, 77.9%)	70.4% (61.2%, 77.9%)	70.4% (61.2%, 77.9%)
Sample Size	59	52	49	44	41

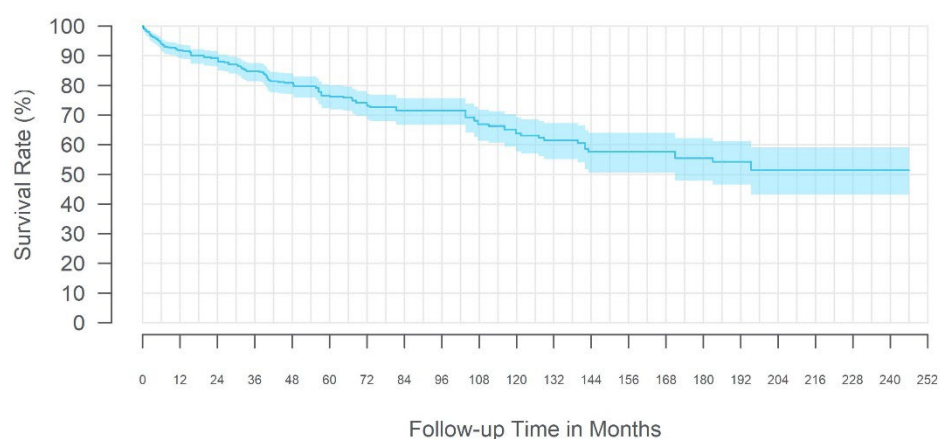
Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	70.4% (61.2%, 77.9%)	70.4% (61.2%, 77.9%)	70.4% (61.2%, 77.9%)	70.4% (61.2%, 77.9%)	67.3% (56.2%, 76.1%)
Sample Size	35	31	27	25	21

Specification: Pisces Plus	
Lead Type	Percutaneous
Lead	
Length (cm)	28, 33, 45, 56
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	6.0
Individual Surface Area (mm ²)	24.0
Inter-Electrode Spacing: Edge to Edge (mm)	12.0
Array Length (mm)	60.0

Lead Event Summary: Pisces Plus	N
Lead Migration/Dislodgement	32
High Impedance	12
Unspecified	2
Lead Fracture	1
Total	47

4.4.2.7 Model Pisces Standard

Model Name	Pisces Standard (model 3487A)
FDA Approval Date	May 1988
Leads Enrolled	994
Leads Currently Active in Study	43
Initial Product Performance Events	167
Median Follow-up Time (Months)	31.6
Cumulative Follow-up Time (Months)	43,803



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.8% (89.2%, 93.8%)	89.3% (86.4%, 91.6%)	84.8% (81.4%, 87.7%)	80.9% (77.1%, 84.1%)	76.6% (72.3%, 80.3%)
Sample Size	512	424	359	283	235

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	73.5% (68.9%, 77.5%)	71.5% (66.7%, 75.8%)	71.5% (66.7%, 75.8%)	66.9% (61.4%, 71.9%)	63.8% (57.8%, 69.2%)
Sample Size	201	169	133	114	95

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	61.5% (55.2%, 67.2%)	57.6% (50.6%, 64.0%)	57.6% (50.6%, 64.0%)	57.6% (50.6%, 64.0%)	55.5% (48.0%, 62.3%)
Sample Size	68	58	57	52	50

Time Interval	16 Years	17 Years	18 Years	19 Years	20 Years
Survival (95% CI)	54.3% (46.6%, 61.3%)	51.4% (43.2%, 59.0%)	51.4% (43.2%, 59.0%)	51.4% (43.2%, 59.0%)	51.4% (43.2%, 59.0%)
Sample Size	40	34	26	24	21

Time Interval	At 246 Months
Survival (95% CI)	51.4% (43.2%, 59.0%)
Sample Size	20

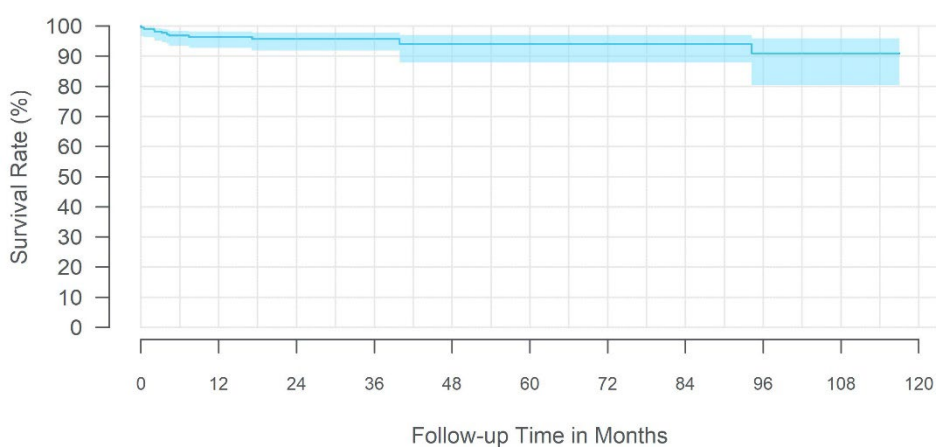
Specification: Pisces Standard

Lead Type	Percutaneous
Lead	
Length (cm)	28, 33, 45, 56
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	30.0

Lead Event Summary: Pisces Standard	N
High Impedance	70
Lead Migration/Dislodgement	53
Unspecified	17
Low Impedance	15
Lead Fracture	9
Inadequate Lead Connection	2
Device Lead Damage	1
Total	167

4.4.2.8 Model Specify 5-6-5

Model Name	Specify 5-6-5 (model 39565)
FDA Approval Date	June 2007
Leads Enrolled	295
Leads Currently Active in Study	22
Initial Product Performance Events	11
Median Follow-up Time (Months)	22.8
Cumulative Follow-up Time (Months)	9,402



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	96.4% (92.8%, 98.2%)	95.7% (91.9%, 97.8%)	95.7% (91.9%, 97.8%)	94.0% (88.0%, 97.1%)	94.0% (88.0%, 97.1%)
Sample Size	164	117	72	47	37

Time Interval	6 Years	7 Years	8 Years	9 Years	At 117 Months
Survival (95% CI)	94.0% (88.0%, 97.1%)	94.0% (88.0%, 97.1%)	91.0% (80.3%, 96.0%)	91.0% (80.3%, 96.0%)	91.0% (80.3%, 96.0%)
Sample Size	35	31	27	23	21

Specification: Specify 5-6-5

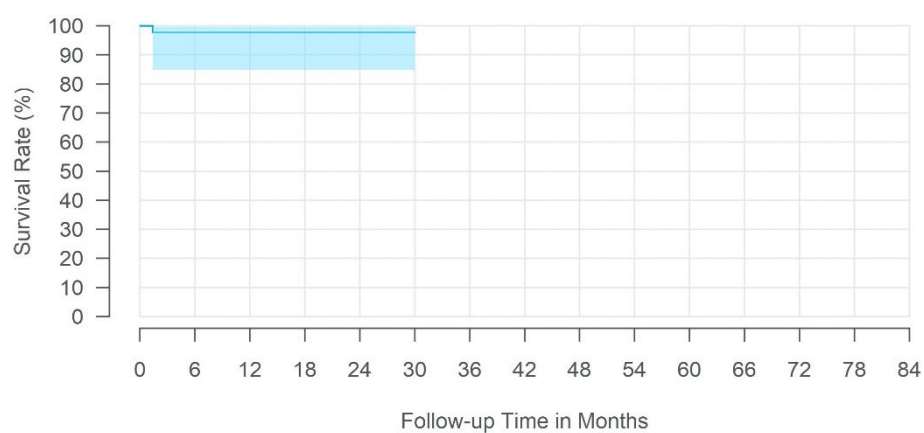
Lead Type	Surgical
Lead	
Length (cm)	30, 65
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Length (mm)	4.0
Width (mm)	1.5
Individual Surface Area (mm ²)	6.0
Longitudinal Spacing: Edge to Edge (mm)	4.5
Lateral Spacing: Edge to Edge (mm)	1.0
Array Length (mm)	49.0
Array Width (mm)	7.5
Paddle	
Length (mm)	64.2
Width (mm)	10.0
Thickness (mm)	7.5



Lead Event Summary: Specify 5-6-5	N
Lead Migration/Dislodgement	9
Lead Fracture	1
Lead Insulation Failure	1
Total	11

4.4.2.9 Model Specify SureScan MRI 2x8

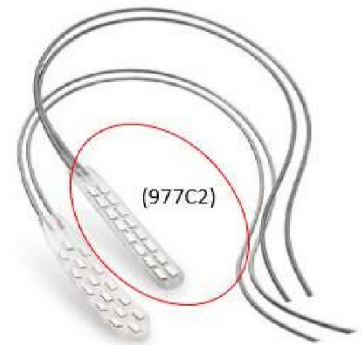
Model Name	Specify SureScan MRI 2x8 (model 977C2)
FDA Approval Date	February 2016
Leads Enrolled	47
Leads Currently Active in Study	11
Initial Product Performance Events	2
Median Follow-up Time (Months)	24.8
Cumulative Follow-up Time (Months)	1,518



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)
Sample Size	34	24	21

Specification: Specify SureScan MRI 2x8

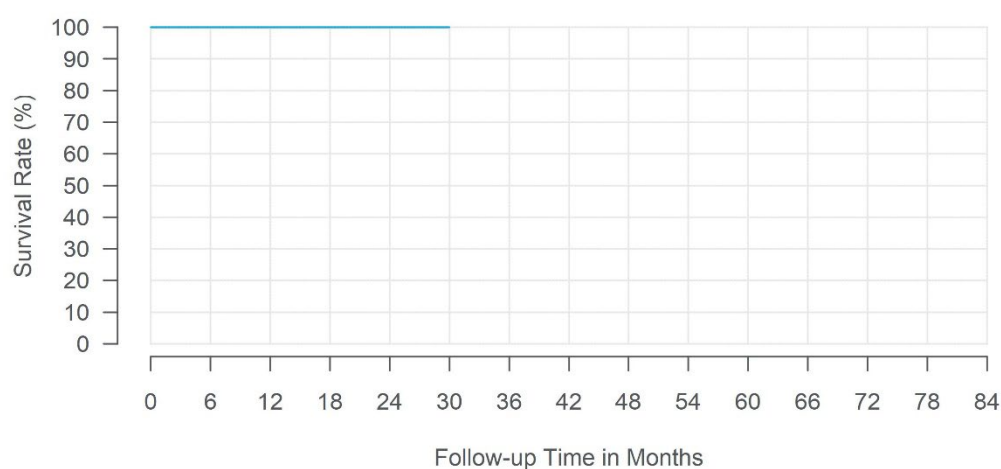
Lead	
Length (cm)	65, 90
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Size (width x length)	1.5 mm x 4.0 mm
Stimulating area (mm ²)	6.0
Inter-Electrode Spacing: Edge to Edge	
In-line spacing (mm)	1.0
Row spacing (mm)	1.0
Lead paddle length (mm)	56.4



Lead Event Summary: Specify SureScan MRI 2x8		N
High Impedance		1
Lead Migration/Dislodgement		1
Total		2

4.4.2.10 Model Specify SureScan MRI 5-6-5

Model Name	Specify SureScan MRI 5-6-5 (model 977C1)
FDA Approval Date	February 2016
Leads Enrolled	96
Leads Currently Active in Study	33
Initial Product Performance Events	3
Median Follow-up Time (Months)	15.0
Cumulative Follow-up Time (Months)	2,103



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI) ^a	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	53	29	23

^aDevices with at least one day of follow-up in the registry are included in the analysis. One lead had an event on the day of implant (follow-up time = 0), one lead had an event at 31 months post-implant, and another lead had an event at 44 months post-implant, when fewer than 20 devices were at risk. These three events did not impact the survival probability estimates shown in this table.

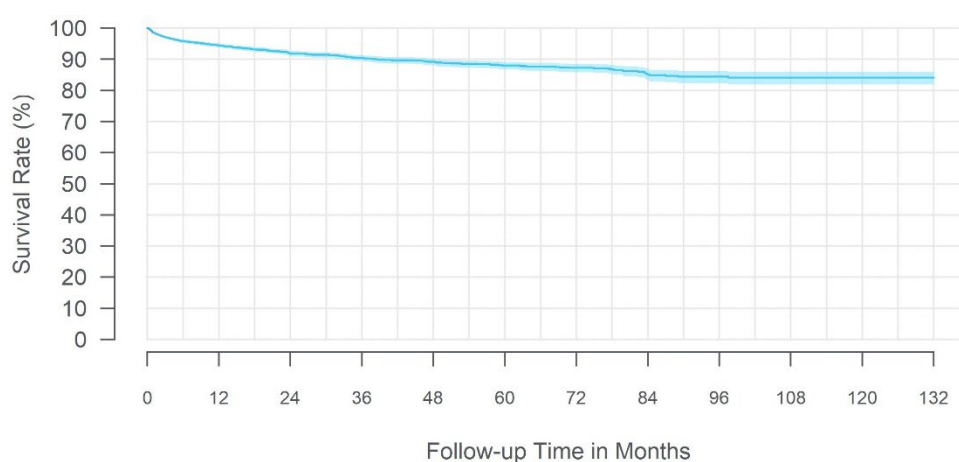
Specification: Specify SureScan MRI 5-6-5	
Lead	
Length (cm)	65, 90
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Size (width x length)	1.5 mm x 4.0 mm
Stimulating area (mm ²)	6.0
Inter-Electrode Spacing: Edge to Edge	
In-line spacing (mm)	4.5
Row spacing (mm)	1.0
Lead paddle length (mm)	64.2



Lead Event Summary: Specify SureScan MRI 5-6-5	N
High Impedance	2
Lead Migration/Dislodgement	1
Total	3

4.4.2.11 Model Vectris SureScan MRI 1x8 Compact

Model Name	Vectris SureScan MRI 1x8 Compact (model 977A2)
FDA Approval Date	March 2013
Leads Enrolled	5,644
Leads Currently Active in Study	1,739
Initial Product Performance Events	446
Median Follow-up Time (Months)	24.1
Cumulative Follow-up Time (Months)	182,725



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	94.4% (93.7%, 95.1%)	91.8% (91.0%, 92.6%)	90.5% (89.5%, 91.4%)	89.2% (88.1%, 90.2%)	88.0% (86.7%, 89.1%)
Sample Size	3678	2655	1878	1366	965

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	87.2% (85.8%, 88.5%)	85.1% (83.2%, 86.8%)	84.4% (82.4%, 86.3%)	84.1% (81.9%, 86.0%)	84.1% (81.9%, 86.0%)
Sample Size	648	390	265	161	85

Time Interval	11 Years
Survival (95% CI)	84.1% (81.9%, 86.0%)
Sample Size	22

Specification: Vectris SureScan MRI 1x8 Compact

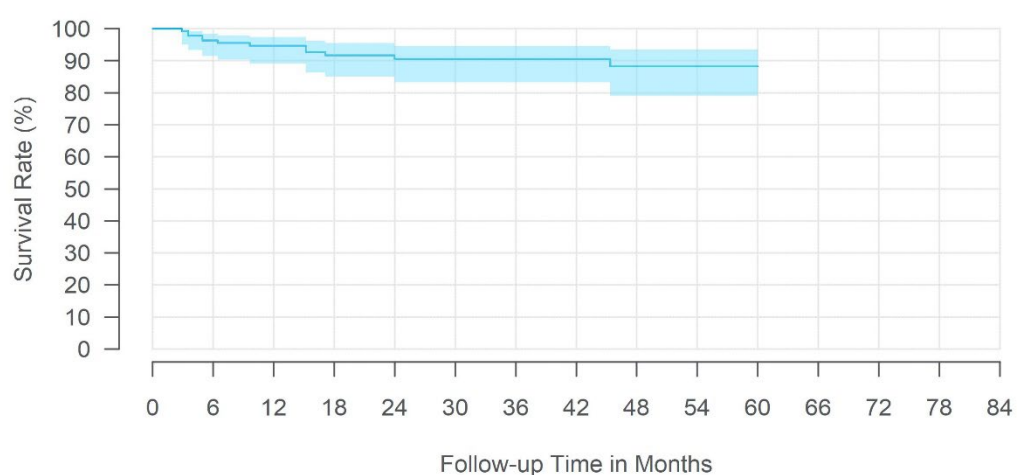
Lead Type	Percutaneous
Lead	
Length (cm)	60, 75, 90
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

Lead Event Summary: Vectris SureScan MRI 1x8 Compact	N
Lead Migration/Dislodgement	297
High Impedance	103
Lead Fracture	25
Device Electrical Impedance Issue	10
Low Impedance	3
Device Charging Issue*	2
Device Inappropriate Shock Delivery	2
Device Positioned Inappropriately	2
Device Malfunction	1
Unspecified	1
Total	446

*Charging performance issue attributable to the neurostimulator rather than the lead. The site has been notified to ensure accurate characterization in subsequent reports.

4.4.2.12 Model Vectris SureScan MRI 1x8 Subcompact

Model Name	Vectris SureScan MRI 1x8 Subcompact (model 977A1)
FDA Approval Date	March 2013
Leads Enrolled	164
Leads Currently Active in Study	29
Initial Product Performance Events	12
Median Follow-up Time (Months)	22.5
Cumulative Follow-up Time (Months)	5,004



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	94.7% (89.1%, 97.4%)	90.5% (83.4%, 94.7%)	90.5% (83.4%, 94.7%)	88.2% (79.1%, 93.5%)	88.2% (79.1%, 93.5%)
Sample Size	98	76	60	38	20

Specification: Vectris SureScan MRI 1x8 Subcompact	
Lead Type	Percutaneous
Lead	
Length (cm)	60, 75, 90
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	34.5



Lead Event Summary: Vectris SureScan MRI 1x8 Subcompact	N
Lead Migration/Dislodgement	7
Lead Fracture	3
High Impedance	2
Total	12

4.4.3 Lead Summary

Table 4.16: Spinal Cord Stimulation Percutaneous Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
1x8 Compact (model 3778)	April 2005	2,170	39	268	18.0	70,391
1x8 SC (model 3776)	November 2005	188	9	17	15.0	5,859
1x8 Standard (model 3777)	April 2005	840	34	71	16.4	26,359
AnkerStim (model 09100)	NA	296	180	25	17.5	7,795
Pisces Compact (model 3887)	January 1997	202	12	25	23.7	8,303
Pisces Plus (model 3888)	November 1992	460	29	47	15.4	13,986

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Pisces Standard (model 3487A)	May 1988	994	43	167	31.6	43,803
Vectris SureScan MRI 1x8 Compact (model 977A2)	March 2013	5,644	1,739	446	24.1	182,725
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	March 2013	164	29	12	22.5	5,004

Table 4.17: Spinal Cord Stimulation Percutaneous Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
1x8 Compact (model 3778)	90.4%	87.0%	84.8%	84.2%	81.9%
	(88.9%, 91.8%)	(85.2%, 88.7%)	(82.7%, 86.6%)	(82.1%, 86.2%)	(79.3%, 84.1%)
1x8 SC (model 3776)	91.8%	91.8%	91.8%	89.8%	87.0%
	(85.6%, 95.4%)	(85.6%, 95.4%)	(85.6%, 95.4%)	(82.0%, 94.4%)	(76.5%, 93.0%)
1x8 Standard (model 3777)	92.8%	89.3%	89.3%	88.2%	87.4%
	(90.3%, 94.7%)	(86.2%, 91.8%)	(86.2%, 91.8%)	(84.5%, 91.0%)	(83.5%, 90.5%)
AnkerStim (model 09100)	93.9%	91.1%	86.2%	86.2%	86.2%
	(89.8%, 96.4%)	(86.1%, 94.3%)	(79.8%, 90.7%)	(79.8%, 90.7%)	(79.8%, 90.7%)
Pisces Compact (model 3887)	92.7%	83.3%	76.9%	75.5%	71.7%
	(78.9%, 97.6%)	(70.0%, 91.0%)	(63.4%, 86.0%)	(62.0%, 84.8%)	(57.9%, 81.7%)
Pisces Plus (model 3888)	92.5%	88.5%	85.3%	80.7%	78.8%
	(88.2%, 95.3%)	(82.9%, 92.3%)	(79.0%, 89.9%)	(73.6%, 86.1%)	(71.3%, 84.6%)
Pisces Standard (model 3487A)	91.8%	89.3%	84.8%	80.9%	76.6%

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
	(89.2%, 93.8%)	(86.4%, 91.6%)	(81.4%, 87.7%)	(77.1%, 84.1%)	(72.3%, 80.3%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	94.4%	91.8%	90.5%	89.2%	88.0%
	(93.7%, 95.1%)	(91.0%, 92.6%)	(89.5%, 91.4%)	(88.1%, 90.2%)	(86.7%, 89.1%)
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	94.7%	90.5%	90.5%	88.2%	88.2%
	(89.1%, 97.4%)	(83.4%, 94.7%)	(83.4%, 94.7%)	(79.1%, 93.5%)	(79.1%, 93.5%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 Compact (model 3778)	80.6%	77.5%	76.0%	75.5%	73.6%
	(77.9%, 83.1%)	(74.2%, 80.5%)	(72.4%, 79.2%)	(71.8%, 78.8%)	(69.4%, 77.3%)
1x8 SC (model 3776)	84.1%	78.3%	78.3%	78.3%	
	(71.8%, 91.4%)	(63.7%, 87.6%)	(63.7%, 87.6%)	(63.7%, 87.6%)	
1x8 Standard (model 3777)	85.7%	83.7%	81.4%	79.1%	79.1%
	(80.9%, 89.3%)	(78.2%, 88.0%)	(74.9%, 86.4%)	(71.9%, 84.7%)	(71.9%, 84.7%)
AnkerStim (model 09100)					
Pisces Compact (model 3887)	69.5%	67.2%	67.2%	62.3%	59.7%
	(55.4%, 79.9%)	(52.9%, 78.1%)	(52.9%, 78.1%)	(47.3%, 74.1%)	(44.6%, 71.9%)
Pisces Plus (model 3888)	74.2%	71.8%	70.4%	70.4%	70.4%
	(65.7%, 80.9%)	(62.8%, 78.9%)	(61.2%, 77.9%)	(61.2%, 77.9%)	(61.2%, 77.9%)
Pisces Standard (model 3487A)	73.5%	71.5%	71.5%	66.9%	63.8%
	(68.9%, 77.5%)	(66.7%, 75.8%)	(66.7%, 75.8%)	(61.4%, 71.9%)	(57.8%, 69.2%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	87.2%	85.1%	84.4%	84.1%	84.1%

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
	(85.8%, 88.5%)	(83.2%, 86.8%)	(82.4%, 86.3%)	(81.9%, 86.0%)	(81.9%, 86.0%)
Vectris SureScan MRI 1x8 Subcompact (model 977A1)					

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
1x8 Compact (model 3778)	71.4%	71.4%	68.8%	68.8%	
	(66.6%, 75.6%)	(66.6%, 75.6%)	(62.9%, 74.0%)	(62.9%, 74.0%)	
1x8 SC (model 3776)					
1x8 Standard (model 3777)	79.1%	77.8%	77.8%	77.8%	77.8%
	(71.9%, 84.7%)	(70.2%, 83.7%)	(70.2%, 83.7%)	(70.2%, 83.7%)	(70.2%, 83.7%)
AnkerStim (model 09100)					
Pisces Compact (model 3887)	59.7%				
	(44.6%, 71.9%)				
Pisces Plus (model 3888)	70.4%	70.4%	70.4%	70.4%	67.3%
	(61.2%, 77.9%)	(61.2%, 77.9%)	(61.2%, 77.9%)	(61.2%, 77.9%)	(56.2%, 76.1%)
Pisces Standard (model 3487A)	61.5%	57.6%	57.6%	57.6%	55.5%
	(55.2%, 67.2%)	(50.6%, 64.0%)	(50.6%, 64.0%)	(50.6%, 64.0%)	(48.0%, 62.3%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	84.1%				
	(81.9%, 86.0%)				
Vectris SureScan MRI 1x8 Subcompact (model 977A1)					

Model Name	16 Years	17 Years	18 Years	19 Years	20 Years
1x8 Compact (model 3778)					
1x8 SC (model 3776)					
1x8 Standard (model 3777)					
AnkerStim (model 09100)					
Pisces Compact (model 3887)					
Pisces Plus (model 3888)					
Pisces Standard (model 3487A)	54.3%	51.4%	51.4%	51.4%	51.4%
	(46.6%, 61.3%)	(43.2%, 59.0%)	(43.2%, 59.0%)	(43.2%, 59.0%)	(43.2%, 59.0%)
Vectris SureScan MRI 1x8 Compact (model 977A2)					
Vectris SureScan MRI 1x8 Subcompact (model 977A1)					

Table 4.18: Spinal Cord Stimulation Surgical Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Specify 5-6-5 (model 39565)	June 2007	295	22	11	22.8	9,402
Specify SureScan MRI 2x8 (model 977C2)	February 2016	47	11	2	24.8	1,518

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Specify SureScan MRI 5-6-5 (model 977C1)	February 2016	96	33	3	15.0	2,103

Table 4.19: Spinal Cord Stimulation Surgical Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Specify 5-6-5 (model 39565)	96.4% (92.8%, 98.2%)	95.7% (91.9%, 97.8%)	95.7% (91.9%, 97.8%)	94.0% (88.0%, 97.1%)	94.0% (88.0%, 97.1%)
Specify SureScan MRI 2x8 (model 977C2)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)			
Specify SureScan MRI 5-6-5 (model 977C1)	100.0% (NA)	100.0% (NA)			

Model Name	6 Years	7 Years	8 Years	9 Years
Specify 5-6-5 (model 39565)	94.0% (88.0%, 97.1%)	94.0% (88.0%, 97.1%)	91.0% (80.3%, 96.0%)	91.0% (80.3%, 96.0%)
Specify SureScan MRI 2x8 (model 977C2)				
Specify SureScan MRI 5-6-5 (model 977C1)				

4.5 Extensions

From June 2004 to the report cut-off date of October 31, 2025, there were 3,816 extensions followed in the registry. The difference between the total number of extensions (n=3,816) versus neurostimulators (n=7,839) is due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 139,887 months (11,657 years). An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. [Table 4.20](#) provides the number and percentage of extensions by model.

Table 4.20: Spinal Cord Stimulation Extension Counts by Model

Model Name	N (%)
Currently manufactured	2700 (70.8%)
1x8 (37081)	1587 (41.6%)
Bifurcated Stretch-Coil (37082)	674 (17.7%)
Single Stretch-Coil (37083)	439 (11.5%)
No longer manufactured	1086 (28.5%)
Low Profile Quad (7489)	761 (19.9%)
Quadripolar In-Line (7495)	281 (7.4%)
Synergy bifurcated 1x8 (7472)	26 (0.7%)
Quadripolar (7496)	9 (0.2%)
Synergy 1x8 (7471)	9 (0.2%)
Other/Unspecified	30 (0.8%)
Total	3816 (100.0%)

4.5.1 Extension Events

There were 61 product performance-related events with an underlying reported etiology related to extension function. This includes 51 events with an extension etiology only and 10 events with both an extension and other etiology (including device and non-device etiologies). Of these, 47 were the initial product performance event that affected extension survival estimates; the majority were extension fracture (n=19) and extension migration (n=10).

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

- 47 had follow-up time cut-off due to product performance-related events.

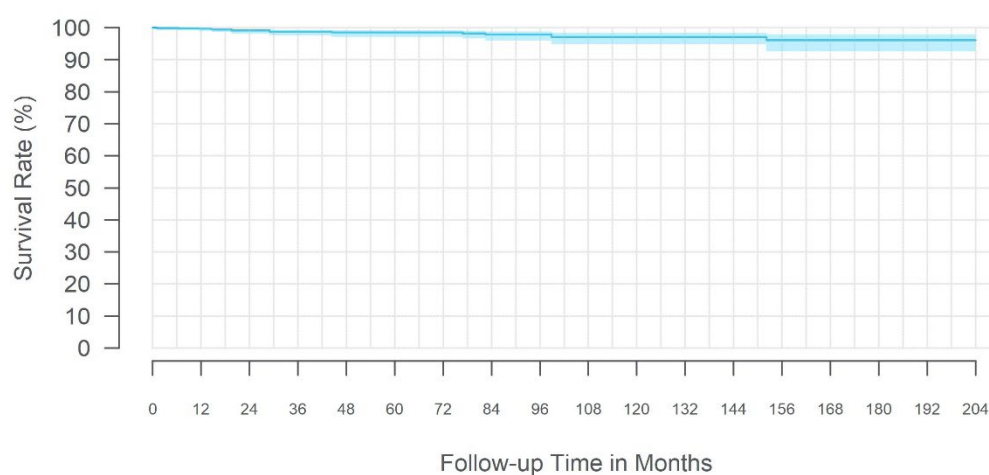
- 3,266 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 503 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

4.5.2 Extension Models

The following figures and tables represent spinal cord stimulation extension survival and 95% confidence intervals where at least 20 spinal cord stimulation extensions contributed to each 3-month interval.

4.5.2.1 Model 1x8 Extension

Model Name	1x8 Extension (model 37081)
FDA Approval Date	April 2005
Extensions Enrolled	1,587
Extensions Currently Active in Study	239
Initial Product Performance Events	16
Median Follow-up Time (Months)	22.0
Cumulative Follow-up Time (Months)	61,003



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (99.1%, 99.9%)	99.2% (98.2%, 99.6%)	98.8% (97.6%, 99.4%)	98.6% (97.2%, 99.2%)	98.6% (97.2%, 99.2%)
Sample Size	864	594	443	390	355

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.6% (97.2%, 99.2%)	97.9% (96.1%, 98.9%)	97.9% (96.1%, 98.9%)	97.1% (94.9%, 98.4%)	97.1% (94.9%, 98.4%)
Sample Size	314	278	264	240	203

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	97.1% (94.9%, 98.4%)	97.1% (94.9%, 98.4%)	96.1% (92.6%, 98.0%)	96.1% (92.6%, 98.0%)	96.1% (92.6%, 98.0%)

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Sample Size	166	122	89	55	41

Time Interval	16 Years	17 Years
Survival (95% CI)	96.1% (92.6%, 98.0%)	96.1% (92.6%, 98.0%)
Sample Size	32	20

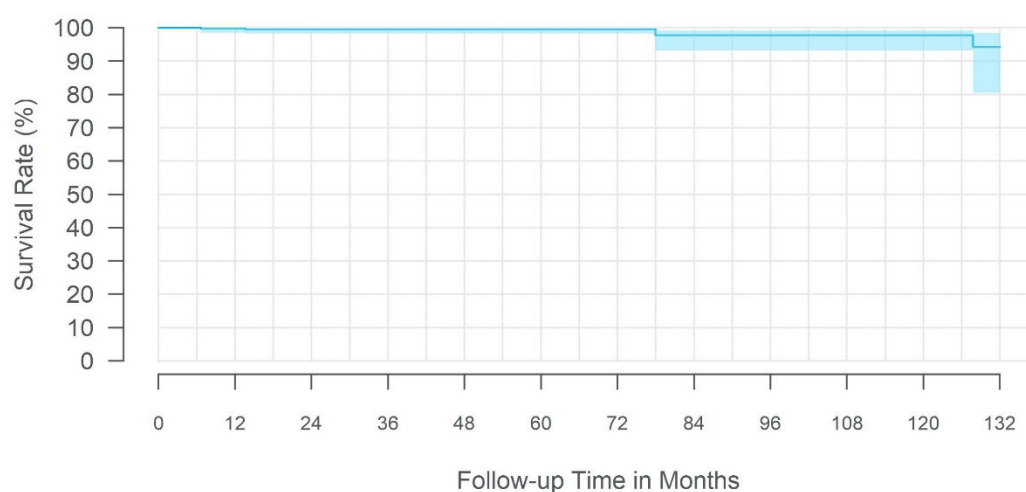
Specification: 1x8 Extension

Length (cm)	20, 40, 60
Distal End Compatibility	1 Octad Lead
Distal End Set Screws	1
Proximal End INS Compatibility	Restore Family

Extension Event Summary: 1x8 Extension	N
Extension Fracture	8
High Impedance	5
Extension Migration	2
Low Impedance	1
Total	16

4.5.2.2 Model Bifurcated Stretch-Coil Extension

Model Name	Bifurcated Stretch-Coil Extension (model 37082)
FDA Approval Date	March 2006
Extensions Enrolled	674
Extensions Currently Active in Study	52
Initial Product Performance Events	5
Median Follow-up Time (Months)	23.2
Cumulative Follow-up Time (Months)	24,651



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.8% (98.6%, 100.0%)	99.6% (98.3%, 99.9%)	99.6% (98.3%, 99.9%)	99.6% (98.3%, 99.9%)	99.6% (98.3%, 99.9%)
Sample Size	444	320	234	179	149

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	99.6% (98.3%, 99.9%)	97.8% (93.2%, 99.3%)	97.8% (93.2%, 99.3%)	97.8% (93.2%, 99.3%)	97.8% (93.2%, 99.3%)
Sample Size	123	99	75	57	42

Time Interval	11 Years
Survival (95% CI)	94.2% (80.5%, 98.4%)
Sample Size	20

Specification: Bifurcated Stretch-Coil Extension

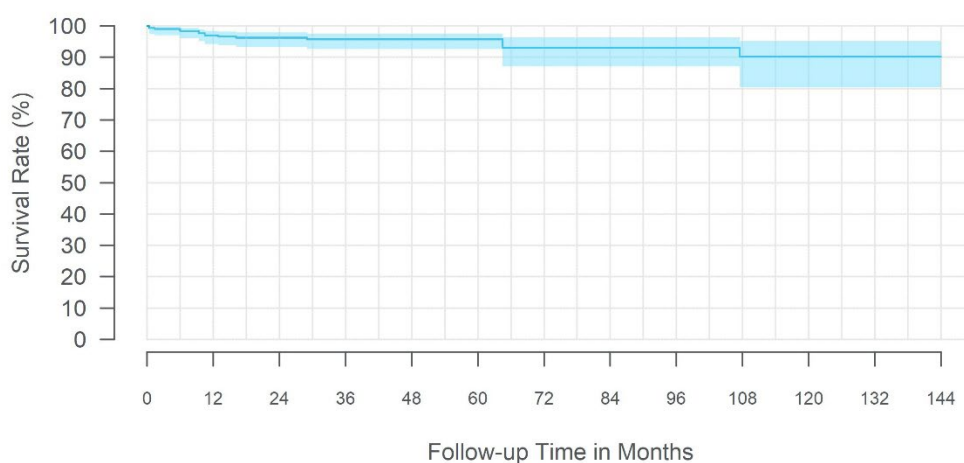
Length (cm)	20, 40, 60
Distal End Compatibility	2 Quad Leads
Distal End Set Screws	8 (4 per Lead)
Proximal End INS Compatibility	Restore Family



Extension Event Summary: Bifurcated Stretch-coil Extension	N
Extension Fracture	3
Device Connection Issue	2
Total	5

4.5.2.3 Model Single Stretch-Coil Extension

Model Name	Single Stretch-Coil Extension (model 37083)
FDA Approval Date	September 2005
Extensions Enrolled	439
Extensions Currently Active in Study	132
Initial Product Performance Events	18
Median Follow-up Time (Months)	24.6
Cumulative Follow-up Time (Months)	15,565



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	97.0% (94.3%, 98.4%)	96.2% (93.3%, 97.9%)	95.8% (92.6%, 97.6%)	95.8% (92.6%, 97.6%)	95.8% (92.6%, 97.6%)
Sample Size	284	226	155	111	72

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	93.1% (87.1%, 96.3%)	93.1% (87.1%, 96.3%)	93.1% (87.1%, 96.3%)	90.2% (80.4%, 95.2%)	90.2% (80.4%, 95.2%)
Sample Size	53	41	36	31	28

Time Interval	11 Years	12 Years
Survival (95% CI)	90.2% (80.4%, 95.2%)	90.2% (80.4%, 95.2%)

Time Interval	11 Years	12 Years
Sample Size	24	20

Specification: Single Stretch-Coil Extension	
Length (cm)	20, 40, 60
Distal End Compatibility	1 Quad Lead
Distal End Set Screws	4
Proximal End INS Compatibility	Restore Family

Extension Event Summary: Single Stretch-coil Extension	N
Extension Migration	6
Extension Fracture	5
Lead Fracture	2
Lead Migration/Dislodgement	2
Medical Device Complication	2
Device Failure	1
Total	18

4.5.3 Extension Summary

Table 4.21: Spinal Cord Stimulation Extension Characteristics

Model Name	FDA Approval Date	Extensions Enrolled	Extensions Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
1x8 (model 37081)	April 2005	1,587	239	16	22.0	61,003
Bifurcated Stretch-Coil (model 37082)	March 2006	674	52	5	23.2	24,651
Single Stretch-Coil (model 37083)	September 2005	439	132	18	24.6	15,565

Table 4.22: Spinal Cord Stimulation Extension Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
1x8 (model 37081)	99.7%	99.2%	98.8%	98.6%	98.6%
	(99.1%, 99.9%)	(98.2%, 99.6%)	(97.6%, 99.4%)	(97.2%, 99.2%)	(97.2%, 99.2%)
Bifurcated Stretch-Coil (model 37082)	99.8%	99.6%	99.6%	99.6%	99.6%
	(98.6%, 100.0%)	(98.3%, 99.9%)	(98.3%, 99.9%)	(98.3%, 99.9%)	(98.3%, 99.9%)
Single Stretch-Coil (model 37083)	97.0%	96.2%	95.8%	95.8%	95.8%
	(94.3%, 98.4%)	(93.3%, 97.9%)	(92.6%, 97.6%)	(92.6%, 97.6%)	(92.6%, 97.6%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 (model 37081)	98.6%	97.9%	97.9%	97.1%	97.1%
	(97.2%, 99.2%)	(96.1%, 98.9%)	(96.1%, 98.9%)	(94.9%, 98.4%)	(94.9%, 98.4%)
Bifurcated Stretch-Coil (model 37082)	99.6%	97.8%	97.8%	97.8%	97.8%
	(98.3%, 99.9%)	(93.2%, 99.3%)	(93.2%, 99.3%)	(93.2%, 99.3%)	(93.2%, 99.3%)
Single Stretch-Coil (model 37083)	93.1%	93.1%	93.1%	90.2%	90.2%
	(87.1%, 96.3%)	(87.1%, 96.3%)	(87.1%, 96.3%)	(80.4%, 95.2%)	(80.4%, 95.2%)

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
1x8 (model 37081)	97.1%	97.1%	96.1%	96.1%	96.1%
	(94.9%, 98.4%)	(94.9%, 98.4%)	(92.6%, 98.0%)	(92.6%, 98.0%)	(92.6%, 98.0%)
Bifurcated Stretch-Coil (model 37082)	94.2%				
	(80.5%, 98.4%)				
Single Stretch-Coil (model 37083)	90.2%	90.2%			

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
	(80.4%, 95.2%)	(80.4%, 95.2%)			

Model Name	16 Years	17 Years
1x8 (model 37081)	96.1%	96.1%
	(92.6%, 98.0%)	(92.6%, 98.0%)
Bifurcated Stretch-Coil (model 37082)		
Single Stretch-Coil (model 37083)		

5 Deep Brain Stimulation Systems

5.1 Study Participants

5.1.1 Centers

In this section, the deep brain stimulation tables and graphs were generated based on data collected between July 2009 and the report cut-off date of October 31, 2025. Sixty-seven centers in North America, Europe, South America, Asia, and Australia have enrolled and contributed patients to the deep brain stimulation systems section of this report. [Figure 5.1](#) shows a World Map, in which the countries that enrolled DBS patients are highlighted.

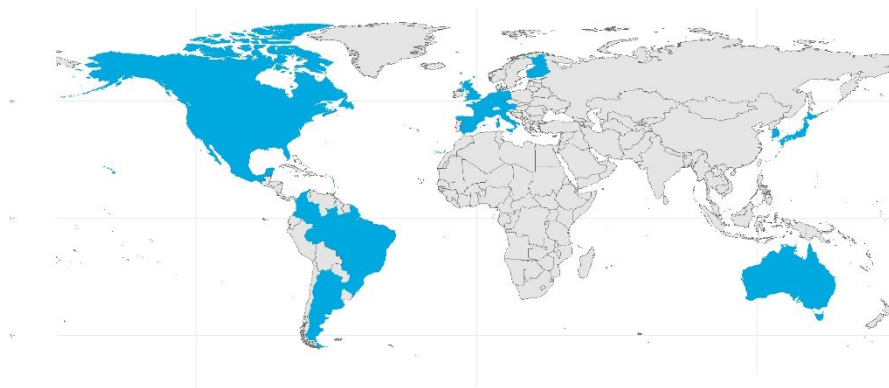


Figure 5.1: Countries with Deep Brain Stimulation Therapy Patients in Registry (Highlighted)

5.1.2 Patients

Of the 4,207 deep brain stimulation patients enrolled, the primary indications for implant were as follows: 64.11% were implanted for the treatment of Parkinson's Disease, 20.11% were implanted for the treatment of essential tremor, 9.29% were implanted for the treatment of dystonia, 1.90% were implanted for the treatment of epilepsy, 1.62% were implanted for the treatment of obsessive compulsive disorder (OCD), 2.47% were implanted for the treatment of other indications, and 0.50% were implanted for indications that were not specified in the database at the time of data cut-off (see [Figure 5.2](#) and [Table 5.1](#)).

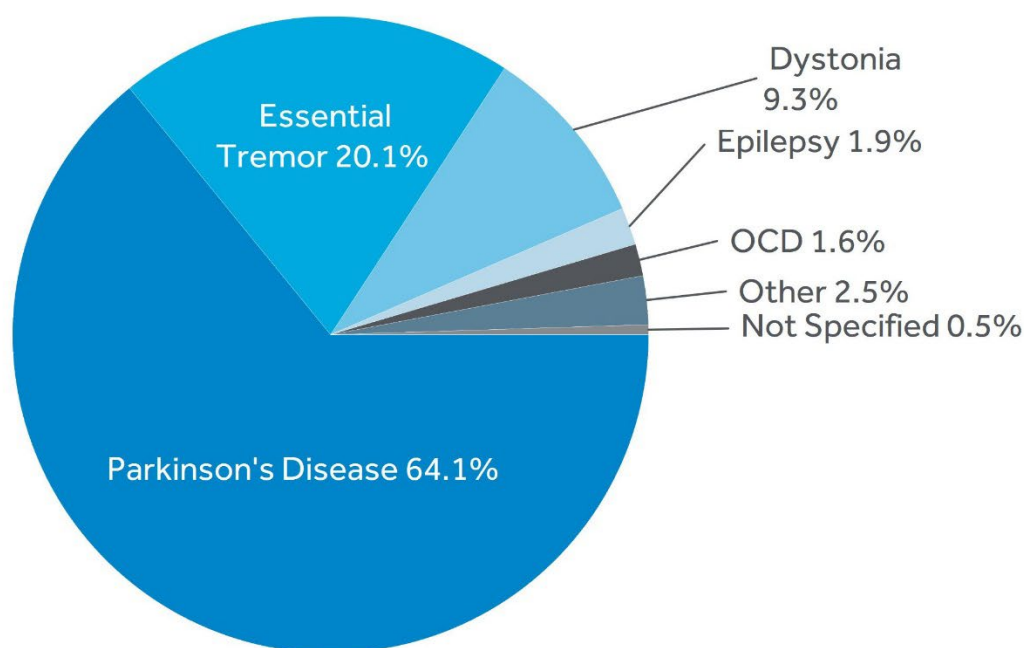


Figure 5.2: Deep Brain Stimulation Primary Treatment Indications

Table 5.1: Deep Brain Stimulation Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Parkinson's Disease	2697 (64.11%)
Essential Tremor	846 (20.11%)
Dystonia	391 (9.29%)
Epilepsy	80 (1.90%)
OCD	68 (1.62%)
Other	104 (2.47%)
Not Specified	21 (0.50%)
Total Patients	4207 (100.0%)

^a For approved indications refer to product labeling for your geography.

It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved labeling, which varies by geography. Please contact your local Medtronic representative for region-specific product labeling (www.medtronic.com/manuals).

5.2 Event Summary

Adverse and device events were reported by the investigational site, where the principal investigator determined the suspected etiology. For device-related events, etiology could be attributed to one or more system components (e.g., neurostimulator, lead, and/or extension). If multiple components were identified as contributing to a single event, a separate product performance event (PPE) was recorded for each implicated component. For example, an event attributed to both the neurostimulator and the lead would be counted as one PPE for the neurostimulator and an additional PPE for the lead. As a result, the total number of PPEs may exceed the number of unique PPEs.

For DBS, there were 636 PPEs (472 unique events) reported in 376 patients between July 2009 and October 31, 2025, in patients with deep brain stimulation systems ([Table 5.2](#)). These events represented 22.8% of the total reported events (636/2,792), occurred in 376 of the 4,207 (8.9%) total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves). Of the remaining 2,156 reported non-product performance related events, 368 were serious and 1,788 were non-serious. Serious non-product performance related events (n=368) are described in [Table 5.6](#). Non-serious non-product performance related (n=1,788) events are not listed in this report.

Any registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings overwrite in the classification of the events. Within this report, [Table 5.2](#) differentiates the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 602 deaths reported for patients followed in the PSR with deep brain stimulation systems (see [Table 5.7](#)), none of which were reported as a direct result of a product performance event. Early versions of the protocol required events to be reported only when the event required a surgical intervention, resulted in therapy abandonment, or resulted in death. The required event reporting definition was expanded in April 2010 to include all adverse events related to the device, implant procedure, and/or therapy.

5.2.1 Product Performance Events

Table 5.2: Deep Brain Stimulation System Product Performance Events

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=4207
RPA Determination	3	<0.1	3 (0.07%)
Premature Battery Depletion	3	<0.1	3 (0.07%)
Physician's Determination	633	3.9	374 (8.89%)
High Impedance	310	1.9	185 (4.40%)
Lead Migration/Dislodgement	56	0.3	40 (0.95%)
Low Impedance	42	0.3	26 (0.62%)
Device Malfunction	33	0.2	29 (0.69%)
Lead Fracture	28	0.2	22 (0.52%)
Neurostimulator Unable To Recharge ^c	28	0.2	28 (0.67%)
Extension Migration	23	0.1	12 (0.29%)
Device Electrical Impedance Issue	16	0.1	7 (0.17%)
Extension Fracture	13	0.1	10 (0.24%)
Premature Battery Depletion	12	0.1	12 (0.29%)
Medical Device Complication	9	0.1	6 (0.14%)
Device Breakage	6	<0.1	6 (0.14%)
Unspecified	6	<0.1	6 (0.14%)
Device Charging Issue	4	<0.1	4 (0.10%)
Device Connection Issue	4	<0.1	4 (0.10%)
Device Electrical Finding ^d	4	<0.1	3 (0.07%)
Device End Of Life	4	<0.1	4 (0.10%)
Device Lead Issue	4	<0.1	4 (0.10%)
Device Protrusion	4	<0.1	2 (0.05%)
Neurostimulator Inversion	4	<0.1	4 (0.10%)
Device Damage	2	<0.1	1 (0.02%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=4207
Device Lead Damage	2	<0.1	1 (0.02%)
Device Material Corroded	2	<0.1	1 (0.02%)
Device Short Circuiting	2	<0.1	2 (0.05%)
Electromagnetic Interference	2	<0.1	2 (0.05%)
Neurostimulator Migration	2	<0.1	2 (0.05%)
Other ^e	11	0.1	11 (0.26%)
Total	636	3.9	376 (8.94%)

^a Medical Dictionary for Regulatory Activities (MedDRA) Lowest-Level Term (LLT) or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.

^b The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.

^c There were 983 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.85% (28/983) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

^d Including open circuit contact and electric discharge.

^e Composed of event codes with 1 event each.

A total of 307 (48.3%) of the 636 product performance events were related to the lead, 119 (18.7%) were related to the extension, 111 (17.5%) were related to the neurostimulator, 15 (2.4%) were related to multiple etiologies, which includes events where at least one device and one non-device etiology was indicated, and 84 (13.2%) were related to other etiologies. Other etiologies included: 54 (8.5%) related to other components, 10 (1.6%) related to surgery/anesthesia, 7 (1.1%) related to incisional site/device tract, 6 (0.9%) related to recharging process, 4 (0.6%) related to programming/stimulation, and 3 (0.5%) related to other etiologies (see [Figure 5.4](#)). Events could have more than one etiology.

Relatedness is reported by the physician. In cases where the Clinical Events Committee (CEC) has adjudicated relatedness differently from the site, the CEC adjudication is used in this report for analysis purposes. However, both the site's reporting and the CEC's adjudication remain in the database.

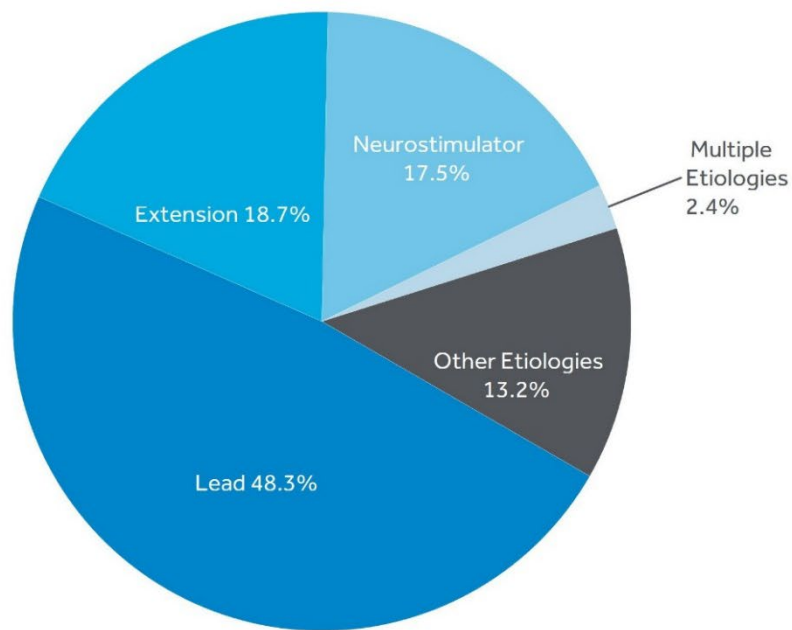


Figure 5.4: Deep Brain Stimulation System Product Performance Events by Relatedness

Table 5.3 and Table 5.4 describe the interventions taken for reported impedance events. In 35.81% and 30.95% of the high and low impedance events, respectively, the action taken was a surgical intervention. However, impedance could be used as a diagnostic measurement and may not result in any intervention or clinical impact. The majority of events required no intervention, or device reprogramming only (58.71% for high impedance and 61.91% for low impedance).

Table 5.3: Deep Brain Stimulation System High Impedance Events by Intervention

Intervention	N (%) of High impedance Events
Device Surgical Intervention	95 (30.65%)
Reprogramming	69 (22.26%)
Other Surgical Intervention	16 (5.16%)
Other Intervention	8 (2.58%)
Medical or Non-Surgical Therapy	5 (1.61%)
Therapy Suspension	3 (0.97%)
Medication	1 (0.32%)
No Action Taken	113 (36.45%)
Total	310 (100.00%)

Table 5.4: Deep Brain Stimulation System Low Impedance Events by Intervention

Intervention	N (%) of Low impedance Events
Device Surgical Intervention	13 (30.95%)
Reprogramming	10 (23.81%)
Medication	2 (4.76%)
Other Intervention	1 (2.38%)
No Action Taken	16 (38.10%)
Total	42 (100.00%)

Table 5.5 describes the interventions taken for reported lead migration/dislodgement events over the total of 4,207 patients enrolled. 76.78% of reported lead migration/dislodgement events resulted in a surgical intervention and 14.29% resulted in reprogramming.

Table 5.5: Deep Brain Stimulation System Lead Migration/Dislodgement* Events by Intervention

Intervention	N (%) of Lead Migration/Dislodgement Events
Device Surgical Intervention	41 (73.21%)
Reprogramming	8 (14.29%)
Other Surgical Intervention	2 (3.57%)
Therapy Suspension	1 (1.79%)
No Action Taken	4 (7.14%)
Total	56 (100.00%)

* Considering "dislodgment" as an observation, not confirmed by imaging.

5.2.2 Clinical Events Not Related to Product Performance

The clinical events not related to product performance (see table 5.6) are summarized if:

- The patient was enrolled in the PSR since 2013, the year in which the clinical event collection was initiated (N=3,024).
- Categorized as serious adverse events (SAEs, N=368).
- Occurred with a System Organ Class (SOC) threshold $\geq 1\%$ of patients.

Other Considerations

- Some events are described in high level group terms (HLGT) to provide more specificity, if needed
- Some DBS therapy relevant events (e.g. Negative changes in behavior from baseline, new or worsening depression, attempted suicide, etc.) are collected to facilitate complete and consistent related event reporting.

Table 5.6: Deep Brain Stimulation System Clinical Events Not Related To Product Performance

Event Type ^a	Number of SAE	Patients with SAE n (%) N=3,024	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=3,024
Infections and infestations	135	112 (3.70%)	0.11	105 (3.47%)
Infections - pathogen unspecified	132	109 (3.60%)	0.10	103 (3.41%)
Other ^b	3	3 (0.10%)	<0.01	2 (0.07%)
Nervous system disorders	81	74 (2.45%)	0.06	20 (0.66%)
Central nervous system vascular disorders	24	24 (0.79%)	0.02	4 (0.13%)
Movement disorders (incl parkinsonism)	21	19 (0.63%)	0.02	5 (0.17%)
Neurological disorders NEC	16	16 (0.53%)	0.01	6 (0.20%)
Seizures (incl subtypes)	10	10 (0.33%)	0.01	2 (0.07%)
Increased intracranial pressure and hydrocephalus	5	5 (0.17%)	<0.01	1 (0.03%)
Other ^b	5	5 (0.17%)	<0.01	2 (0.07%)
General disorders and administration site conditions	72	68 (2.25%)	0.06	49 (1.62%)
Complications associated with device	54	52 (1.72%)	0.04	41 (1.36%)
General system disorders NEC	9	9 (0.30%)	0.01	2 (0.07%)
Other ^b	9	9 (0.30%)	0.01	7 (0.23%)
Other SOC Terms (<1.0% Threshold)	80	78 (2.58%)	0.06	36 (1.19%)
Total	368	296 (9.79%)	0.29	190 (6.28%)

^a The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.

^b Composed of high level group term event codes with fewer than 5 events each.

5.2.3 Patient Deaths

There were 602 deaths reported for patients with deep brain stimulation systems, none of which were reported as a direct result of a product performance event. Since July 2009, of the 4,207 enrolled patients, there have been 477 deaths reported in this patient registry study based upon patients receiving therapy for Parkinson's Disease, 89 for essential tremor, 18 for dystonia, 5 for epilepsy, 2 for OCD, and 11 for other indications (see [Table 5.7](#)).

Table 5.7: Deep Brain Stimulation System Patient Deaths by Primary Indication for Implantation

Primary Indication ^a	N (%) of Deaths ^b	Mean Age of Death in Years
Parkinson's Disease	477 (79.2%)	74.1
Essential Tremor	89 (14.8%)	78.2
Dystonia	18 (3.0%)	61.3
Epilepsy	5 (0.8%)	23.1
OCD	2 (0.3%)	72.4
Other	11 (1.8%)	61.7
Total	602	74.3

^a For approved indications refer to product labeling for your geography.

^b The percentage is based upon the total patient death events per distribution group (indication) and not based upon the rate of occurrence among all enrolled patients

5.3 Neurostimulators

From July 2009 to the report cut-off date of October 31, 2025, there were 6,749 neurostimulators followed in the registry. The difference between the total number of patients (n=4,207) versus the number of neurostimulators (n=6,749) is due to the fact that some patients were implanted with more than one neurostimulator or were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 209,393 months (17,449 years). [Table 5.8](#) provides the number and percentage of neurostimulators by model.

Table 5.8: Deep Brain Stimulation Neurostimulator Counts by Model

Model Name	N (%)
Currently manufactured	
Activa PC™ (model 37601)	2785 (41.3%)
Percept PC™ (model B35200)	1426 (21.1%)
Activa RC™ (model 37612)	1005 (14.9%)
Activa SC™ (model 37603)	708 (10.5%)
Activa SC™ (model 37602)	474 (7.0%)
Percept RC™ (model B35300)	231 (3.4%)
No longer manufactured	
Soletra™ (model 7426)	67 (1.0%)
Kinetra™ (model 7428)	13 (0.2%)
Other/Unspecified^a	40 (0.6%)
Total	6749

^a Other includes Activa™ PC+S and non-Activa™ systems used for DBS.

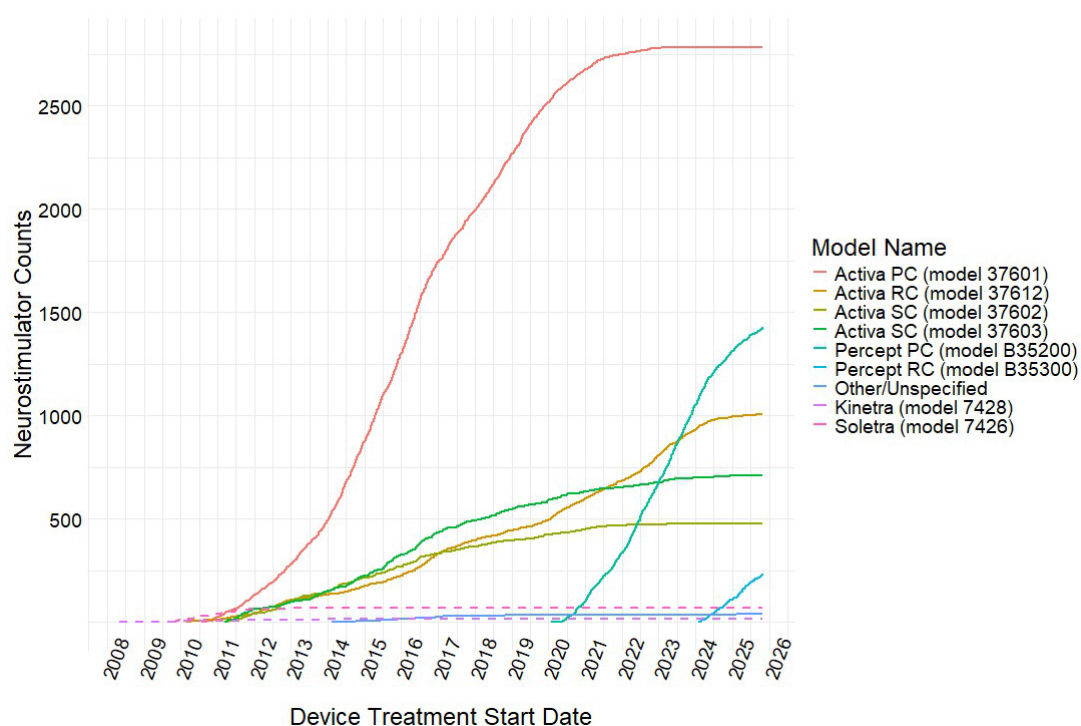


Figure 5.5: Cumulative Neurostimulator Counts by model over time

5.3.1 Neurostimulator Events

Of the total of 636 product performance-related events, there were 113 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 111 events with a neurostimulator etiology and 2 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 80 were the initial product performance events that affected neurostimulator survival estimates.

For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 3.4% (106/3136). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the sum of the total number of explanted devices and the total number of neurostimulators in patients who have expired. In the 113 neurostimulator events, 97.35% (110/113) were assigned as device related by the physician, not returned to Medtronic RPA (see [Table 5.9](#)).

Table 5.9: Deep Brain Stimulation Neurostimulator Product Performance Events by Determination

Product Performance Events	N (%)
RPA Determination	3 (2.7%)
Premature Battery Depletion	3 (2.7%)
Physician's Determination	110 (97.3%)
High Impedance	54 (47.8%)
Device Malfunction	14 (12.4%)
Premature Battery Depletion	12 (10.6%)
Low Impedance	8 (7.1%)
Device End Of Life ^a	4 (3.5%)
Device Electrical Impedance Issue	2 (1.8%)
Electromagnetic Interference	2 (1.8%)
Extension Migration	2 (1.8%)
Device Computer Software Issue	1 (0.9%)
Device Connection Issue	1 (0.9%)
Device Electrical Finding ^b	1 (0.9%)
Device Issue	1 (0.9%)
Device Protrusion	1 (0.9%)

Product Performance Events	N (%)
Device Short Circuiting	1 (0.9%)
Device Vibration	1 (0.9%)
Neurostimulator Inversion	1 (0.9%)
Neurostimulator Migration	1 (0.9%)
Neurostimulator Unable To Recharge	1 (0.9%)
No Adverse Event	1 (0.9%)
Unspecified	1 (0.9%)
Total	113 (100%)

^a Battery's life expectancy

^b Open circuit contact

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

- 80 had follow-up time cut-off due to product performance-related events.
- 4,827 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 1,842 were free from product performance-related events and censoring events and were censored at the last follow-up visit prior to the report cut-off.

Initial product performance events of other/unspecified models (n=1) are not summarized in the subsequent sections.

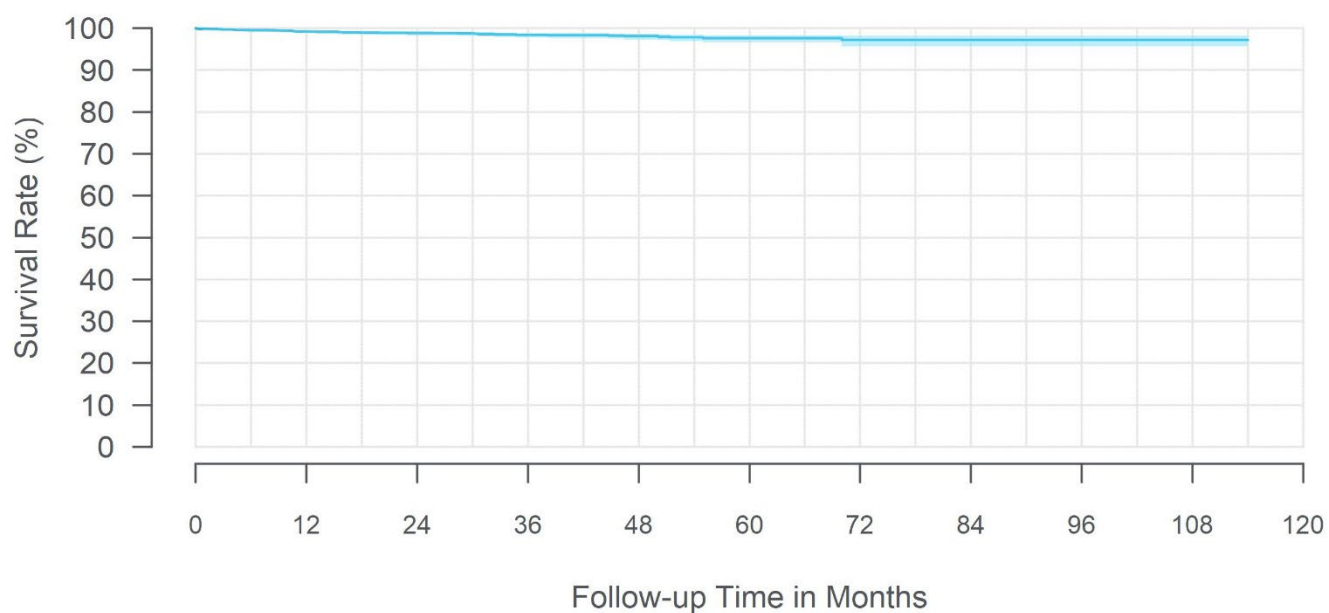
5.3.2 Neurostimulator Models

The following figures and tables represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval.

The Soletra and Kinetra models were removed from the table due to the fact that there are no more active devices in PSR. For information on survival for those models, please refer to past reports.

5.3.2.1 Model Activa™ PC 37601

Model Name	Activa™ PC
FDA Approval Date	April 2009
Neurostimulators Enrolled	2,785
Neurostimulators Currently Active in Study	144
Initial Product Performance Events	46
Median Follow-up Time (Months)	33.6
Cumulative Follow-up Time (Months)	100,691



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (98.8%, 99.5%)	98.9% (98.4%, 99.2%)	98.4% (97.8%, 98.9%)	98.1% (97.4%, 98.7%)	97.7% (96.7%, 98.4%)
Sample Size	2321	1850	1272	775	417

Time Interval	6 Years	7 Years	8 Years	9 Years	At 114 Months
Survival (95% CI)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)
Sample Size	192	98	53	28	22

**Specification: Activa™ PC
(model 37601)**

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	16 (up to 4 per group)



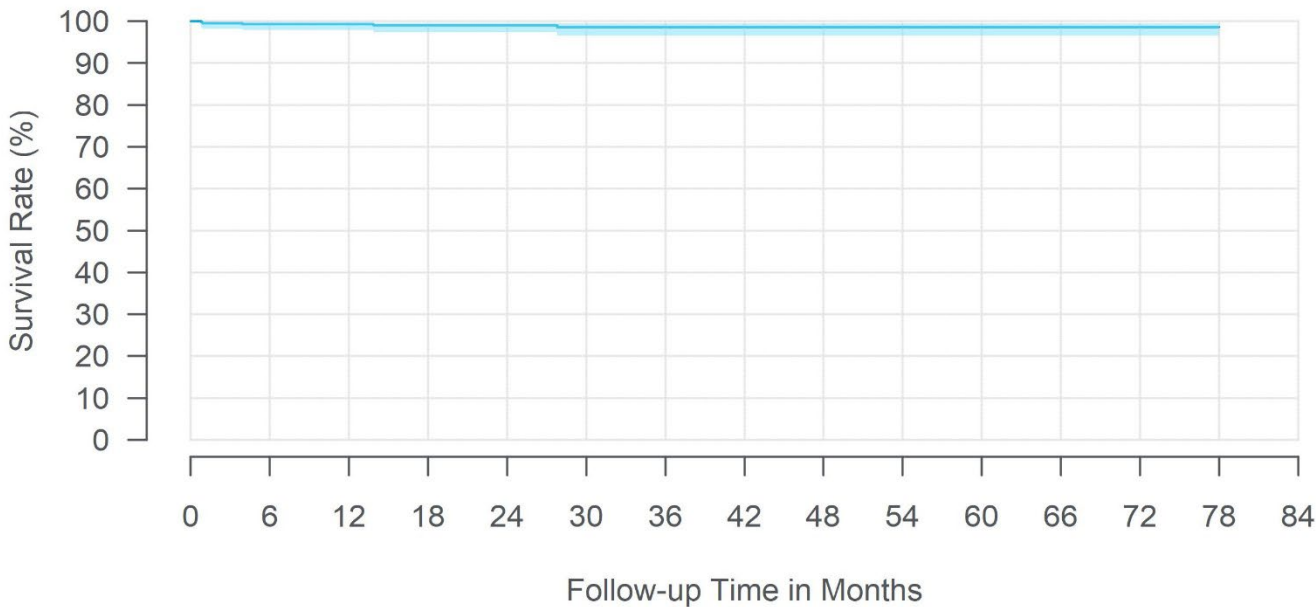
Neurostimulator Event Summary: Activa PC	N
High Impedance	19
Premature Battery Depletion	13
Device Malfunction	6
Device End Of Life	3
Device Electrical Finding ^a	1
Device Protrusion	1
Electromagnetic Interference	1
Low Impedance	1
No Adverse Event	1
Total	46

^a Open circuit contact

5.3.2.2 Model Activa™ SC 37602

Model Name	Activa™ SC (model 37602)
FDA Approval Date	January 2011
Neurostimulators Enrolled	474*
Neurostimulators Currently Active in Study	30
Initial Product Performance Events	5
Median Follow-up Time (Months)	27.2
Cumulative Follow-up Time (Months)	14,458

* Note: there is one less neurostimulator enrolled than reported in the 2024 Product Performance Report. This change is due to a single subject having two procedure forms entered. On October 21, 2025, the site deleted one of the procedure CRFs, citing it as a duplicate entry.



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (97.9%, 99.8%)	99.0% (97.5%, 99.6%)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)
Sample Size	366	265	157	89	49

Time Interval	6 Years	At 78 Months
Survival (95% CI)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)
Sample Size	27	21

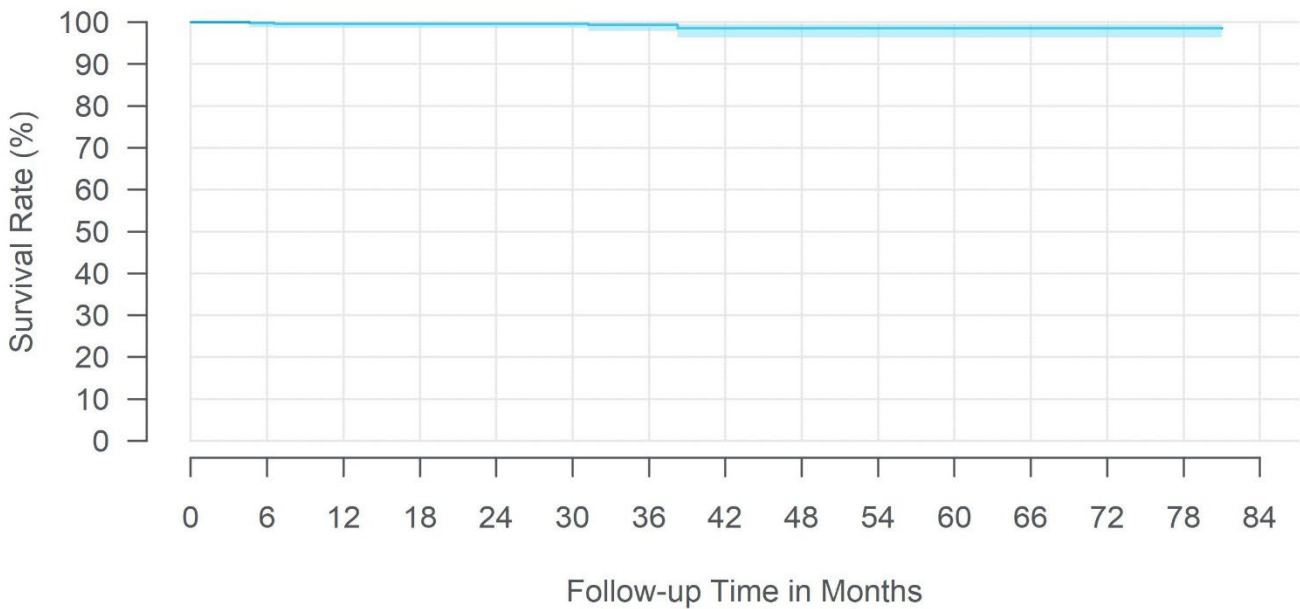
Specification: Activa™ SC (model 37602)	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	4
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	8 (up to 2 per group)



Neurostimulator Event Summary: Activa SC (model 37602)		N
High Impedance		2
Device Short Circuiting		1
Low Impedance		1
Premature Battery Depletion		1
Total		5

5.3.2.3 Model Activa™ SC 37603

Model Name	Activa™ SC (model 37603)
FDA Approval Date	January 2011
Neurostimulators Enrolled	708
Neurostimulators Currently Active in Study	57
Initial Product Performance Events	6
Median Follow-up Time (Months)	28.7
Cumulative Follow-up Time (Months)	22,485



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (98.7%, 99.9%)	99.7% (98.7%, 99.9%)	99.4% (98.0%, 99.8%)	98.6% (96.4%, 99.4%)	98.6% (96.4%, 99.4%)
Sample Size	568	431	275	142	66

Time Interval	6 Years	At 81 Months
Survival (95% CI)	98.6% (96.4%, 99.4%)	98.6% (96.4%, 99.4%)
Sample Size	37	21

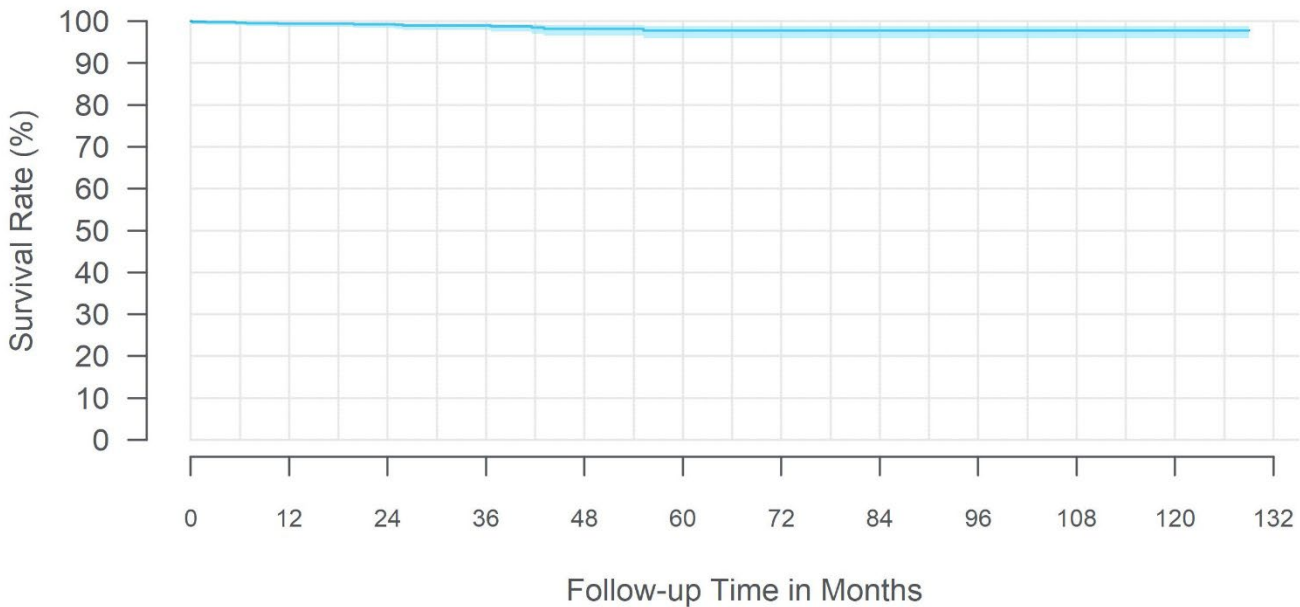
Specification: Aactiva™ SC (model 37603)	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	27 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	4
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	8 (up to 2 per group)



Neurostimulator Event Summary: Aactiva SC (model 37603)		N
High Impedance		5
Low Impedance		1
Total		6

5.3.2.4 Model Activa™ RC 37612

Model Name	Activa™ RC
FDA Approval Date	March 2009
Neurostimulators Enrolled	1005
Neurostimulators Currently Active in Study	486
Initial Product Performance Events	14
Median Follow-up Time (Months)	32.5
Cumulative Follow-up Time (Months)	41,924



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.5% (98.7%, 99.8%)	99.3% (98.5%, 99.7%)	99.0% (98.0%, 99.5%)	98.2% (96.6%, 99.0%)	97.8% (95.9%, 98.8%)
Sample Size	837	634	431	301	224

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)
Sample Size	182	149	102	56	30

Time Interval	At 129 Months
Survival (95% CI)	97.8% (95.9%, 98.8%)
Sample Size	22

Specification: Activa™ RC

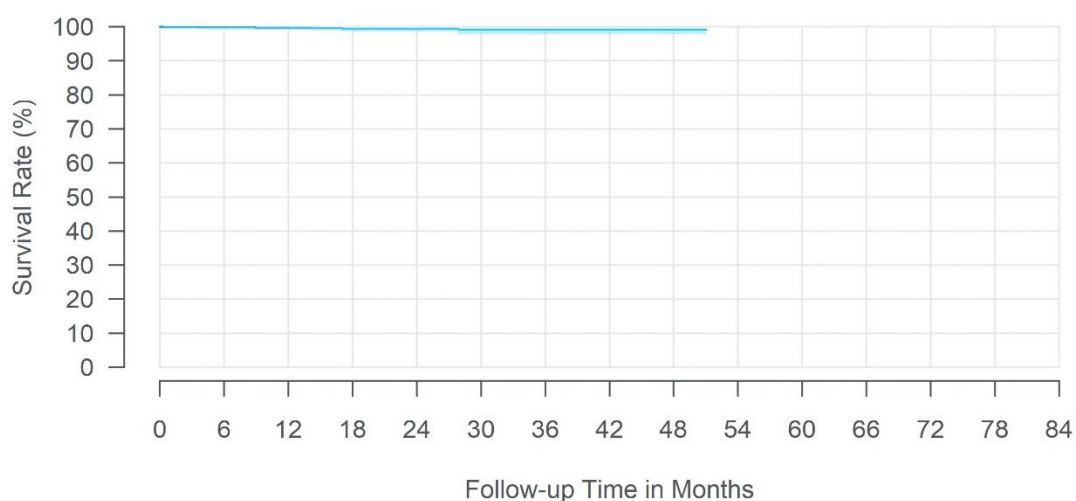
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	16 (up to 4 per group)
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: Activa RC	N
High Impedance	4
Device Malfunction	2
Extension Migration	2
Device Computer Software Issue	1
Device Connection Issue	1
Low Impedance	1
Neurostimulator Inversion	1
Neurostimulator Migration	1
Neurostimulator Unable To Recharge	1
Total	14

5.3.2.5 Model Percept™ PC B35200

Model Name	Percept™ PC
FDA Approval Date	June 2020
Neurostimulators Enrolled	1,426
Neurostimulators Currently Active in Study	902
Initial Product Performance Events	8
Median Follow-up Time (Months)	14.8
Cumulative Follow-up Time (Months)	25,279



Time Interval	1 Year	2 Years	3 Years	4 Years	At 51 Months
Survival (95% CI)	99.7% (99.2%, 99.9%)	99.5% (98.6%, 99.8%)	99.1% (97.8%, 99.7%)	99.1% (97.8%, 99.7%)	99.1% (97.8%, 99.7%)
Sample Size	867	412	164	39	25

Specification: Percept™ PC (model B353200)	
Height	68 mm
Width	2 in (51 mm)
Thickness	0.43 in (11 mm)
Volume	33 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	16 Electrodes (8 per channel)
Amplitude	0 to 25.5 mA
Rate	2 to 250 Hz
Pulse Width	20 to 450 µsec
Groups	4
Programs	16
Implant Depth	≤ 4cm



Neurostimulator Event Summary: Percept PC	N
High Impedance	4
Device Malfunction	2
Premature Battery Depletion	1
Unspecified	1
Total	8

5.3.2.6 Model Percept™ RC B35300

Model Name	Percept™ RC
FDA Approval Date	January 2024
Neurostimulators Enrolled	231
Neurostimulators Currently Active in Study	223
Initial Product Performance Events	0
Median Follow-up Time (Months)	1.2
Cumulative Follow-up Time (Months)	806

There is not sufficient data to report on Percept™ RC (model B35300) survival at 1 year or later and there have been no reported product performance events for this model as of the data cut-off date.

Specification: Percept™ RC (model B35300)	
Height	57 mm
Width	47 mm
Thickness	6 mm
Volume	13.77 cm ³
Battery type	Rechargeable
Expected Battery life	15 years before ERI*
Number of Channels	2
Maximum Electrodes	16 Electrodes (8 per channel)
Amplitude	0 to 25.5 mA
Rate	2 to 250 Hz
Pulse Width	20 to 450 µsec
Groups	4
Programs	16
Implant Depth	≤ 4cm

*ERI: Elective Replacement Indicator



5.3.3 Neurostimulator Summary

Table 5.10: Deep Brain Stimulation Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Activa PC (model 37601)	April 2009	2,785	144	46	33.6	100,691
Activa SC	January	474	30	5	27.2	14,458

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
(model 37602)	2011					
Activa SC (model 37603)	January 2011	708	57	6	28.7	22,485
Activa RC (model 37612)	March 2009	1,005	486	14	32.5	41,924
Percept PC (model B35200)	June 2020	1,426	902	8	14.8	25,279
Percept RC (model B35300)	January 2024	231	223	0	1.2	806

Table 5.11: Deep Brain Stimulation Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Activa PC (model 37601)	99.3%	98.9%	98.4%	98.1%	97.7%
	(98.8%, 99.5%)	(98.4%, 99.2%)	(97.8%, 98.9%)	(97.4%, 98.7%)	(96.7%, 98.4%)
Activa SC (model 37602)	99.3%	99.0%	98.6%	98.6%	98.6%
	(97.9%, 99.8%)	(97.5%, 99.6%)	(96.6%, 99.4%)	(96.6%, 99.4%)	(96.6%, 99.4%)
Activa SC (model 37603)	99.7%	99.7%	99.4%	98.6%	98.6%
	(98.7%, 99.9%)	(98.7%, 99.9%)	(98.0%, 99.8%)	(96.4%, 99.4%)	(96.4%, 99.4%)
Activa RC (model 37612)	99.5%	99.3%	99.0%	98.2%	97.8%
	(98.7%, 99.8%)	(98.5%, 99.7%)	(98.0%, 99.5%)	(96.6%, 99.0%)	(95.9%, 98.8%)
Percept PC (model B35200)	99.7%	99.5%	99.1%	99.1%	
	(99.2%, 99.9%)	(98.6%, 99.8%)	(97.8%, 99.7%)	(97.8%, 99.7%)	

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Activa PC (model 37601)	97.2%	97.2%	97.2%	97.2%	
	(95.7%, 98.2%)	(95.7%, 98.2%)	(95.7%, 98.2%)	(95.7%, 98.2%)	
Activa SC (model 37602)	98.6%				
	(96.6%, 99.4%)				
Activa SC (model 37603)	98.6%				
	(96.4%, 99.4%)				
Activa RC (model 37612)	97.8%	97.8%	97.8%	97.8%	97.8%
	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)
Percept PC (model B35200)					

5.4 Leads

From July 2009 to the report cut-off date of October 31, 2025, there were 7,357 leads followed in the registry. The difference between the total number of leads (n= 7,357) versus neurostimulators (n= 6,749) is due to the fact that some patients were subsequently re-implanted with a lead or were implanted with more than one lead. The aggregate prospective follow-up time for all leads was 343,646 months (28,637 years) [Table 5.12](#) provides the number and percentage of leads by model.

Table 5.12: Deep Brain Stimulation Lead Counts by Model

Model Name	N (%)
Currently manufactured	
3389 (compact electrode spacing)	3242 (44.1%)
3387 (standard electrode spacing)	2456 (33.4%)
SenSight B33005 (compact electrode spacing)	1184 (16.1%)
SenSight B33015 (standard electrode spacing)	381 (5.2%)
No longer manufactured	
3391 (large electrode and wide spacing)	73 (1.0%)
Other/Unspecified^a	21 (0.3%)
Total	7357

^a Includes leads used in other manufacturers' systems.

5.4.1 Lead Events

Of the total of 636 product performance-related events, there were 316 product performance-related events with an underlying reported etiology related to lead function. This includes 307 events with a lead etiology and 9 events with both a lead and other etiology (including device and non-device etiologies). Out of the 316 PPE's, 175 were the initial product performance event that affected lead survival estimates.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

- 175 had follow-up time cut-off due to product performance-related events.
- 3,983 were censored in the survival analysis for the following reasons: patient expired, leads explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.

- 3,199 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

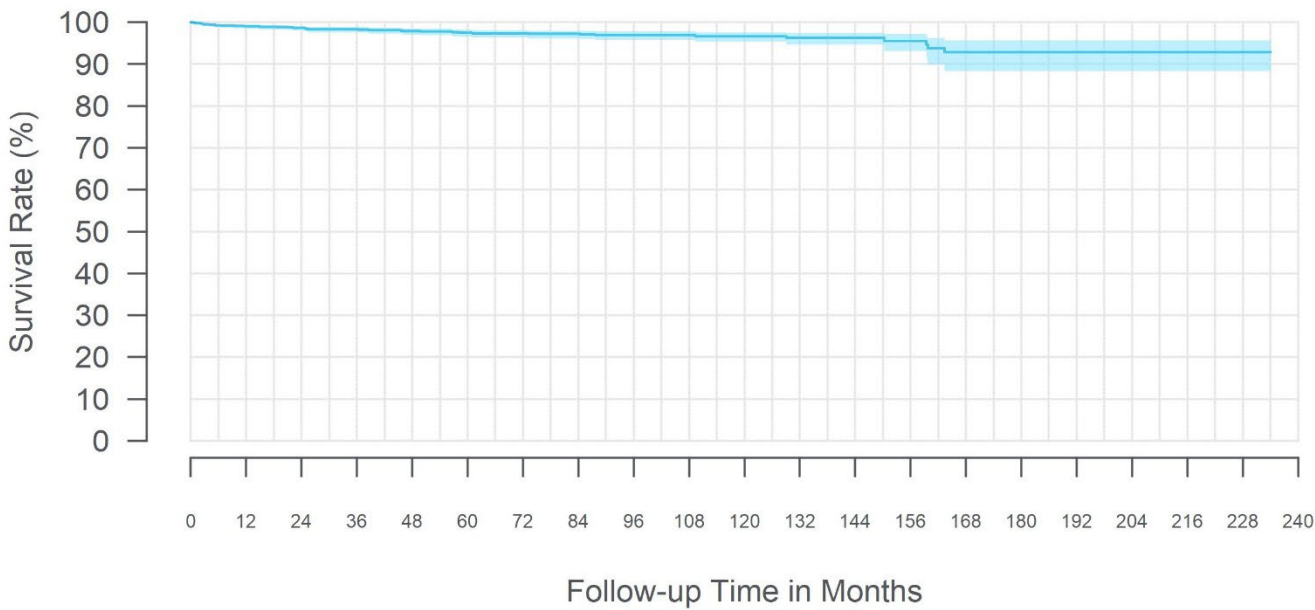
Initial product performance events of other/unspecified models (n=3) are not summarized in the subsequent sections.

5.4.2 Lead Models

The following figures and tables represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Due to enrollment of replacement patients with previously implanted leads, sample size may increase at later timepoints.

5.4.2.1 Model 3387

Model Name	3387
FDA Approval Date	July 1997
Leads Enrolled	2,456
Leads Currently Active in Study	780
Initial Product Performance Events	50
Median Follow-up Time (Months)	41.5
Cumulative Follow-up Time (Months)	130,846



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.1% (98.5%, 99.4%)	98.7% (98.0%, 99.1%)	98.3% (97.6%, 98.8%)	97.9% (97.1%, 98.5%)	97.5% (96.5%, 98.2%)
Sample Size	1767	1463	1202	1017	882

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.4% (96.4%, 98.1%)	97.2% (96.2%, 98.0%)	96.9% (95.8%, 97.8%)	96.9% (95.8%, 97.8%)	96.7% (95.4%, 97.6%)
Sample Size	763	647	533	372	295

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	96.3% (94.7%, 97.4%)	96.3% (94.7%, 97.4%)	95.5% (93.1%, 97.1%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)
Sample Size	224	160	112	84	65

Time Interval	16 Years	17 Years	18 Years	19 Years	At 234 Months
Survival (95% CI)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)
Sample Size	48	35	23	23	20

Specification: 3387

Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm ²)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	10.5

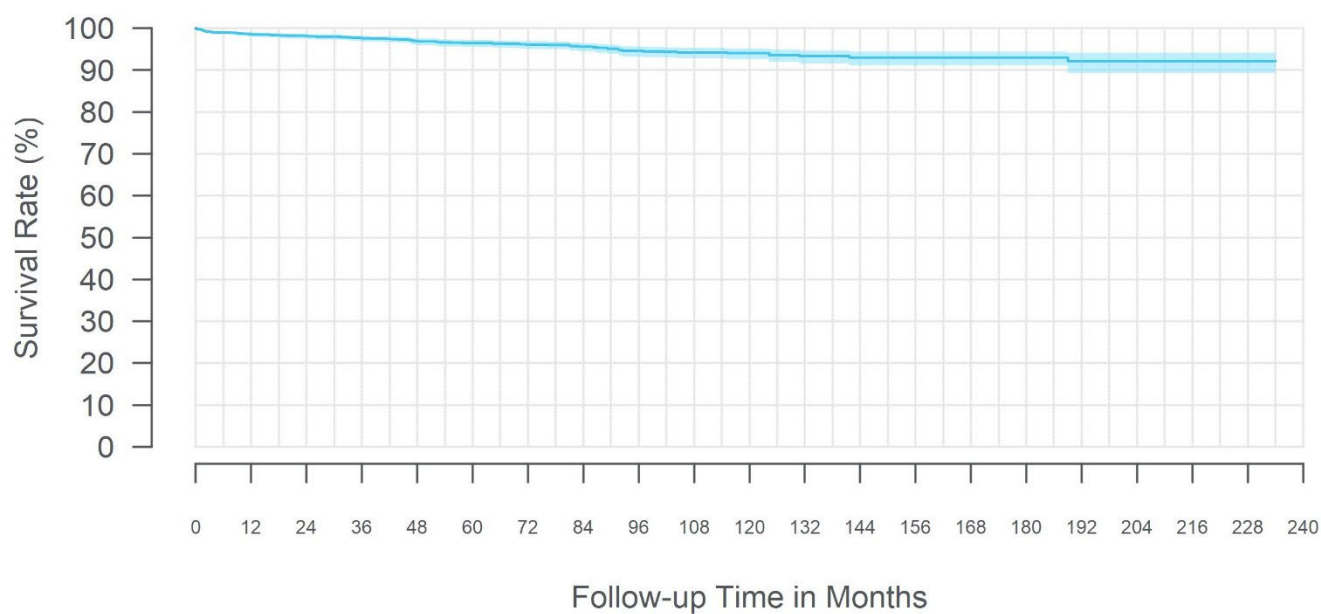


Lead Event Summary: 3387	N
High Impedance	21
Lead Migration/Dislodgement	16
Low Impedance	8
Lead Fracture	3
Device Electrical Finding ^a	1
Device Lead Issue	1
Total	50

^a Open circuit contact

5.4.2.2 Model 3389

Model Name	3389
FDA Approval Date	September 1999
Leads Enrolled	3,242
Leads Currently Active in Study	1,189
Initial Product Performance Events	99
Median Follow-up Time (Months)	48.6
Cumulative Follow-up Time (Months)	187,074



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.6% (98.0%, 99.0%)	98.2% (97.5%, 98.7%)	97.6% (96.9%, 98.2%)	96.9% (96.0%, 97.6%)	96.5% (95.5%, 97.2%)
Sample Size	2175	1870	1611	1464	1355

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	96.1% (95.1%, 96.9%)	95.6% (94.5%, 96.5%)	94.6% (93.3%, 95.6%)	94.2% (92.9%, 95.3%)	94.0% (92.6%, 95.2%)
Sample Size	1222	1060	841	647	460

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	93.3% (91.7%, 94.7%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)
Sample Size	347	258	205	166	140

Time Interval	16 Years	17 Years	18 Years	19 Years	At 234 Months
Survival (95% CI)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)
Sample Size	100	71	39	22	20

Specification: 3389

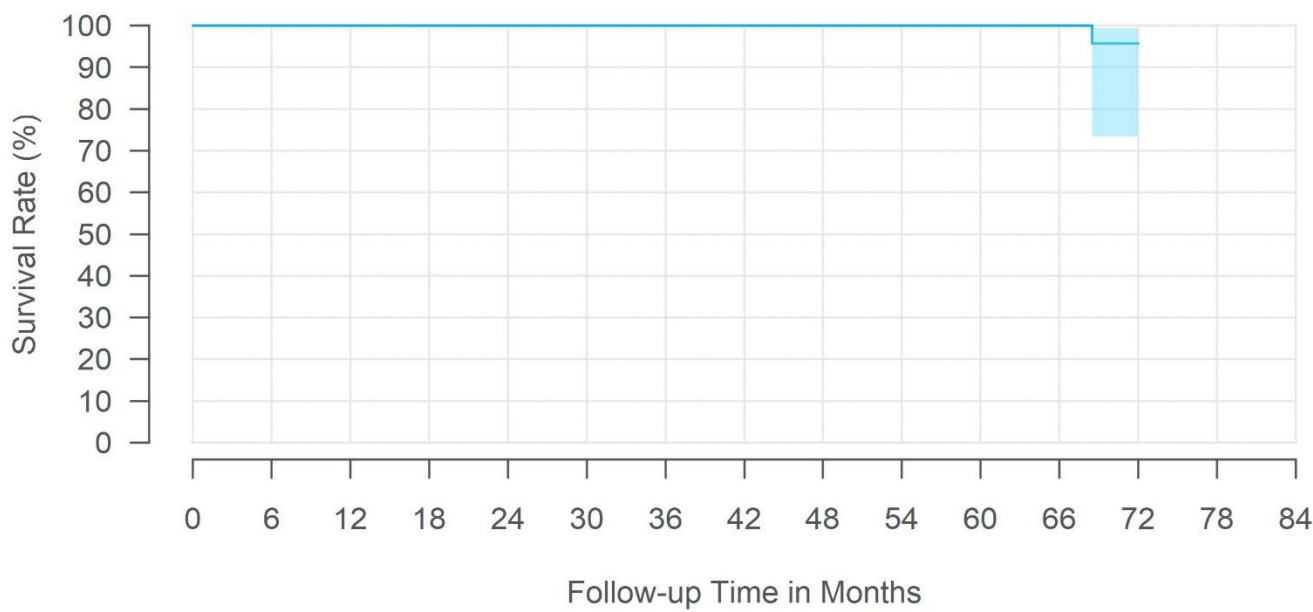
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm ²)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	0.5
Array Length (mm)	7.5



Lead Event Summary: 3389	N
High Impedance	52
Lead Migration/Dislodgement	21
Lead Fracture	13
Low Impedance	4
Device Electrical Impedance Issue	2
Device Material Corroded	2
Medical Device Complication	2
Device Lead Issue	1
Device Malfunction	1
Lead Insulation Failure	1
Total	99

5.4.2.3 Model 3391

Model Name	3391
FDA Approval Date	February 2009
Leads Enrolled	73
Leads Currently Active in Study	16
Initial Product Performance Events	2
Median Follow-up Time (Months)	42.1
Cumulative Follow-up Time (Months)	4,160



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI) ^a	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	51	47	34	30	27

Time Interval	6 Years
Survival (95% CI)	95.7% (73.4%, 99.4%)
Sample Size	20

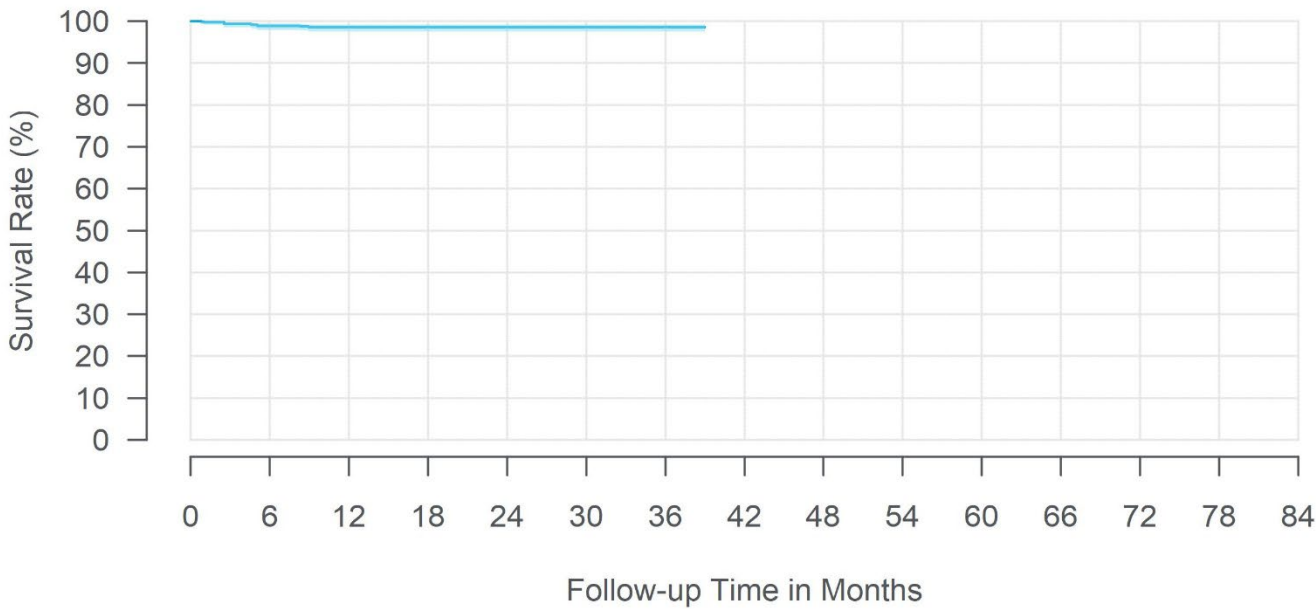
Specification: 3391	
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	24



Lead Event Summary: 3391	N
High Impedance	1
Lead Fracture	1
Total	2

5.4.2.4 Model SenSight™ B33005

Model Name	B33005 (Compact electrode spacing)
FDA Approval Date	May 2021
Leads Enrolled	1,184
Leads Currently Active in Study	968
Initial Product Performance Events	12
Median Follow-up Time (Months)	10.8
Cumulative Follow-up Time (Months)	14,872



Time Interval	1 Year	2 Years	3 Years	At 39 Months
Survival (95% CI)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)
Sample Size	529	178	34	29

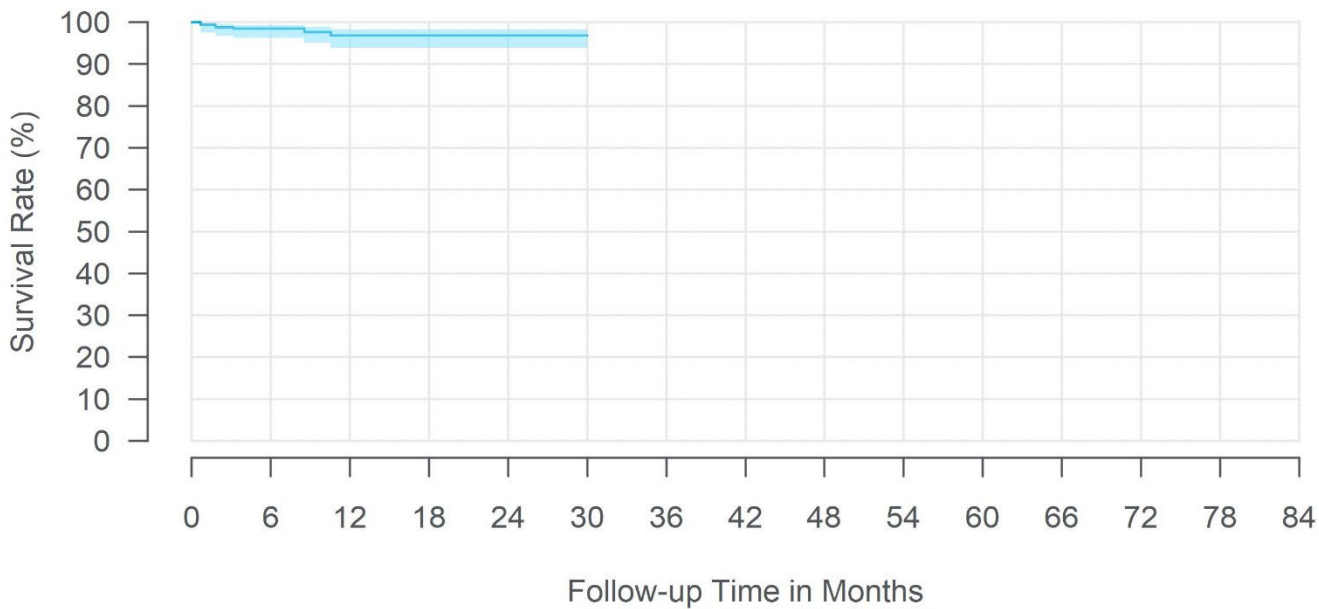
Specification: SenSight™ B33005	
Lead	
Length (cm)	33
Diameter (mm)	1.36
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	0.5
Individual Surface Area (cm ²)	33 cm: 13.55
Proximal end Lead contact spacing, Stylet handle length (mm)	8 contacts, in- line 2.2
Distal end Electrode shape Distal tip distance (mm)	8 electrodes Cylindrical 1.0



Lead Event Summary: B33005	N
High Impedance	8
Device Electrical Impedance Issue	2
Lead Migration/Dislodgement	2
Total	12

5.4.2.5 Model SenSight™ B33015

Model Name	B33015 (Standard electrode spacing)
FDA Approval Date	May 2021
Leads Enrolled	381
Leads Currently Active in Study	300
Initial Product Performance Events	9
Median Follow-up Time (Months)	12.9
Cumulative Follow-up Time (Months)	5,323



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	96.8% (93.9%, 98.3%)	96.8% (93.9%, 98.3%)	96.8% (93.9%, 98.3%)
Sample Size	201	61	29

Specification: SenSight™ B33015	
Lead	
Length (cm)	42
Diameter (mm)	1.36
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (cm ²)	42 cm: 17.26
Proximal end Lead contact spacing, Stylet handle length (mm)	8 contacts, in-line 4.6
Distal end	8 electrodes
Electrode shape	Cylindrical
Distal tip distance (mm)	1.0



Lead Event Summary: B33015	N
High Impedance	7
Lead Fracture	2
Total	9

5.4.3 Lead Summary

Table 5.13: Deep Brain Stimulation Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Model 3387	July 1997	2,456	780	50	41.5	130,846
Model 3389	September 1999	3,242	1,189	99	48.6	187,074
Model 3391	February 2009	73	16	2	42.1	4,160
SenSight (model B33005)	May 2021	1,184	968	12	10.8	14,872
SenSight (model B33015)	May 2021	381	300	9	12.9	5,323

Table 5.14: Deep Brain Stimulation Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Model 3387	99.1%	98.7%	98.3%	97.9%	97.5%
	(98.5%, 99.4%)	(98.0%, 99.1%)	(97.6%, 98.8%)	(97.1%, 98.5%)	(96.5%, 98.2%)
Model 3389	98.6%	98.2%	97.6%	96.9%	96.5%
	(98.0%, 99.0%)	(97.5%, 98.7%)	(96.9%, 98.2%)	(96.0%, 97.6%)	(95.5%, 97.2%)
Model 3391	100.0%	100.0%	100.0%	100.0%	100.0%
	(NA)	(NA)	(NA)	(NA)	(NA)
SenSight (model B33005)	98.6%	98.6%	98.6%		
	(97.6%, 99.2%)	(97.6%, 99.2%)	(97.6%, 99.2%)		
SenSight (model B33015)	96.8%	96.8%			
	(93.9%, 98.3%)	(93.9%, 98.3%)			
Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Model 3387	97.4%	97.2%	96.9%	96.9%	96.7%

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
	(96.4%, 98.1%)	(96.2%, 98.0%)	(95.8%, 97.8%)	(95.8%, 97.8%)	(95.4%, 97.6%)
Model 3389	96.1%	95.6%	94.6%	94.2%	94.0%
	(95.1%, 96.9%)	(94.5%, 96.5%)	(93.3%, 95.6%)	(92.9%, 95.3%)	(92.6%, 95.2%)
Model 3391	95.7%				
	(73.4%, 99.4%)				
SenSight (model B33005)					
SenSight (model B33015)					

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
Model 3387	96.3%	96.3%	95.5%	92.9%	92.9%
	(94.7%, 97.4%)	(94.7%, 97.4%)	(93.1%, 97.1%)	(88.4%, 95.7%)	(88.4%, 95.7%)
Model 3389	93.3%	93.0%	93.0%	93.0%	93.0%
	(91.7%, 94.7%)	(91.2%, 94.5%)	(91.2%, 94.5%)	(91.2%, 94.5%)	(91.2%, 94.5%)
Model 3391					
SenSight (model B33005)					
SenSight (model B33015)					

Model Name	16 Years	17 Years	18 Years	19 Years
Model 3387	92.9%	92.9%	92.9%	92.9%
	(88.4%, 95.7%)	(88.4%, 95.7%)	(88.4%, 95.7%)	(88.4%, 95.7%)
Model 3389	92.1%	92.1%	92.1%	92.1%
	(89.4%, 94.2%)	(89.4%, 94.2%)	(89.4%, 94.2%)	(89.4%, 94.2%)
Model 3391				

Model Name	16 Years	17 Years	18 Years	19 Years
SenSight (model B33005)				
SenSight (model B33015)				

5.5 Extensions

From July 2009 to the report cut-off date of October 31, 2025, there were 7,407 extensions followed in the registry. The difference between the total number of extensions (n=7,407) versus neurostimulators (n=6,749) is due to some patients implanted with more than one extension or subsequently re-implanted with an extension. The aggregate prospective follow-up time for all extensions was 336,655 months (28,055 years). [Table 5.15](#) provides the number and percentage of extensions by model.

Table 5.15: Deep Brain Stimulation Extension Counts by Model

Model Name	N (%)
Currently manufactured	
37085/37086 (quadripolar stretch)	5212 (70.4%)
SenSight B34000/B34000M	1555 (21.0%)
No longer manufactured	
7482 (quadripolar) ^a	510 (6.9%)
7483	1 (<0.1%)
Other/Unspecified^b	129 (1.7%)
Total	7407

^a Includes Models 7482 and 7482a.

^b Includes extensions for other legacy stimulation systems.

5.5.1 Extension Events

Of the total of 636 product performance-related events, there were 123 product performance-related events with an underlying reported etiology related to extension function. This includes 119 events with an extension etiology and 4 events with both an extension and other etiology (including device and non-device etiologies). Of these, 93 were the initial product performance event that affected extension survival estimates.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

- 93 had follow-up time cut-off due to product performance-related events.
- 4,131 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued

participation in the registry.

- 3,183 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

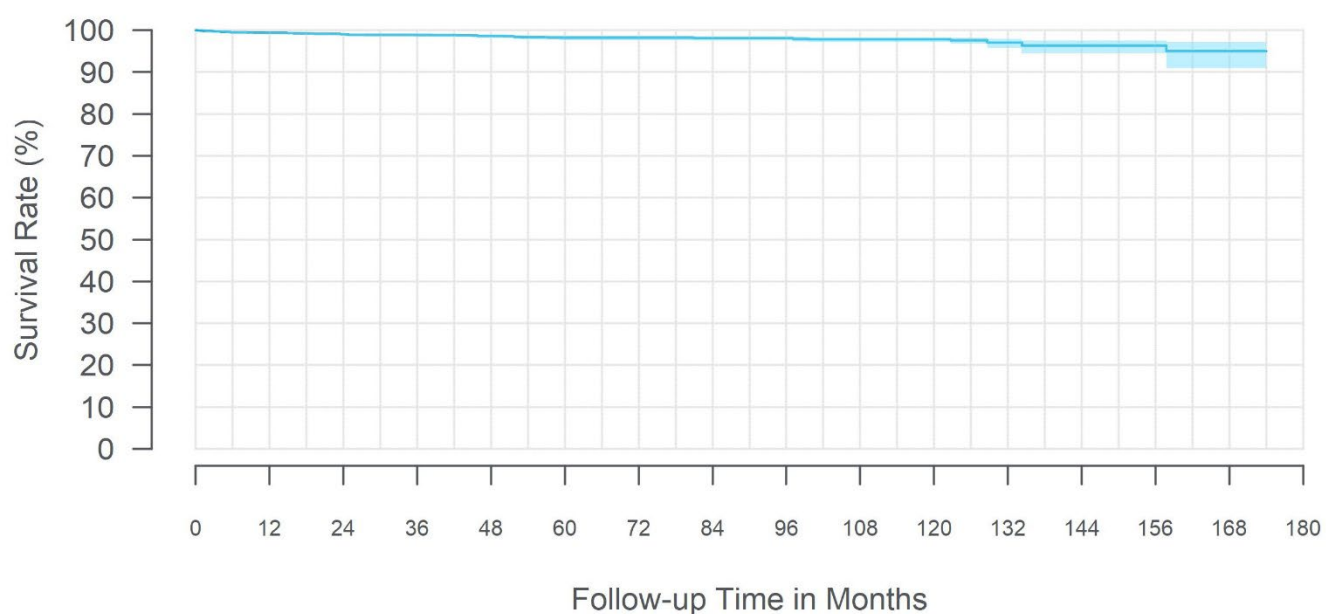
Initial product performance events of Model 7482 (n=7) and other/unspecified models (n=6) are not summarized in the subsequent sections as these models are not manufactured anymore.

5.5.2 Extension Models

The following figures and tables represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval.

5.5.2.1 Model 37085/37086

Model Name	37085/37086
FDA Approval Date	March 2009/February 2012
Extensions Enrolled	5,212
Extensions Currently Active in Study	1,796
Initial Product Performance Events	74
Median Follow-up Time (Months)	42.1
Cumulative Follow-up Time (Months)	277,737



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.4% (99.1%, 99.6%)	99.1% (98.7%, 99.3%)	98.9% (98.5%, 99.2%)	98.7% (98.2%, 99.0%)	98.2% (97.7%, 98.6%)
Sample Size	4005	3363	2805	2405	2059

Time Interval	6 Year	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.2% (97.7%, 98.6%)	98.1% (97.5%, 98.5%)	98.1% (97.5%, 98.5%)	97.8% (97.2%, 98.3%)	97.8% (97.2%, 98.3%)
Sample Size	1782	1460	1110	759	496

Time Interval	11 Years	12 Years	13 Years	14 Years	At 174 Months
Survival (95% CI)	97.1% (95.8%, 97.9%)	96.3% (94.6%, 97.5%)	96.3% (94.6%, 97.5%)	95.0% (91.0%, 97.2%)	95.0% (91.0%, 97.2%)
Sample Size	286	163	78	35	22

Specification: 37085/37086

Device Name	Stretch-Coil Extension
Length (cm)	40, 60, 95
Distal End Compatibility	3387, 3389, or 3391 lead
Distal End Set Screws	4
Proximal End INS Compatibility	Activa™ RC, Activa™ PC, Activa™ SC, Percept™ PC, or Percept™ RC

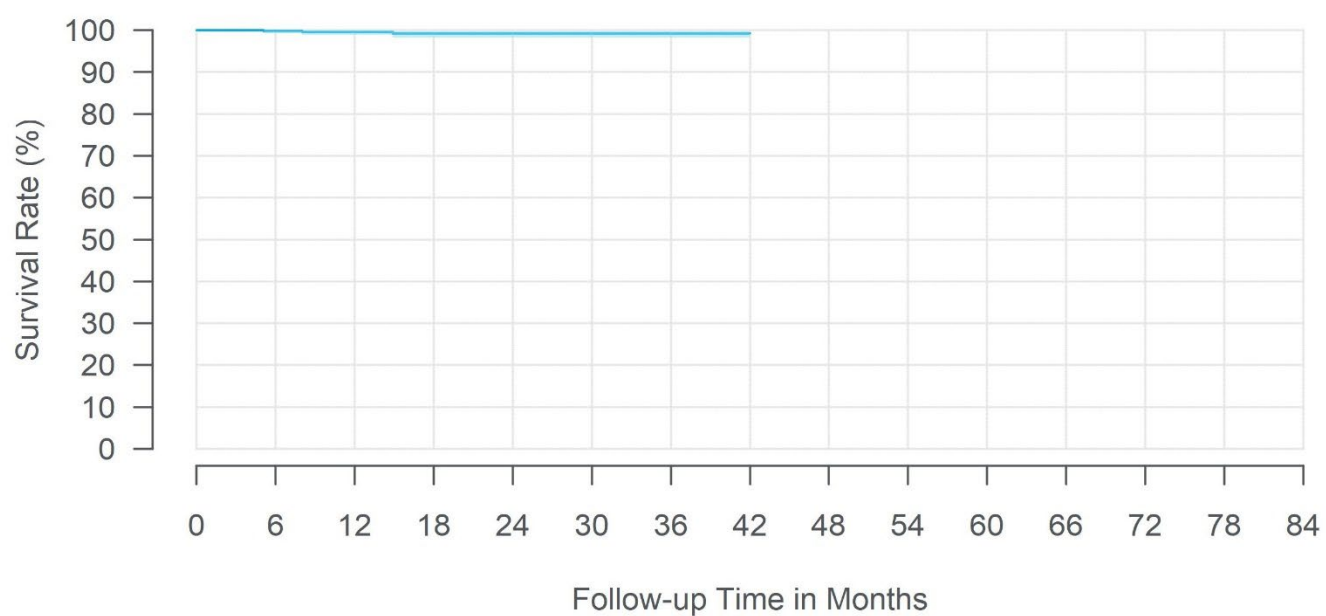


Extension Event Summary: 37085/37086	N
High Impedance	32
Extension Migration	15
Extension Fracture	8
Low Impedance	6
Medical Device Complication	4
Device Protrusion	3
Device Electrical Finding ^a	2
Device Extension Dislodgement	1
Device Malfunction	1
Lead Migration/Dislodgement	1
Unspecified	1
Total	74

^a Open circuit contact

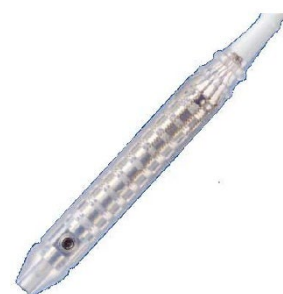
5.5.2.2 Model B34000/B34000M

Model Name	B34000/B34000M
FDA Approval Date	May 2021
Extensions Enrolled	1,555
Extensions Currently Active in Study	1,248
Initial Product Performance Events	6
Median Follow-up Time (Months)	11.3
Cumulative Follow-up Time (Months)	19,605



Time Interval	1 Year	2 Years	3 Years	At 42 Months
Survival (95% CI)	99.6% (99.0%, 99.9%)	99.3% (98.3%, 99.7%)	99.3% (98.3%, 99.7%)	99.3% (98.3%, 99.7%)
Sample Size	727	229	46	29

Specification: B34000/B34000M	
Device Name	SenSight™ Extension Kit
Length (cm)	40, 60, 95
Distal End Compatibility	B33005, or B33015 Lead
Distal End Set Screws	1
Proximal End INS Compatibility	Activa™ RC, Percept™ PC, or Percept™ RC



Extension Event Summary: B34000/B34000M	N
Extension Migration	4
Device Damage	2
Total	6

5.5.3 Extension Summary

Table 5.16: Deep Brain Stimulation Extension Characteristics

Model Name	FDA Approval Date	Extensions Enrolled	Extensions Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
37085/37086	March 2009	5,212	1,796	74	42.1	277,737
B34000/B34000M	May 2021	1,555	1,248	6	11.3	19,605

Table 5.17: Deep Brain Stimulation Extension Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
B34000/B34000M	99.6%	99.3%	99.3%		
	(99.0%, 99.9%)	(98.3%, 99.7%)	(98.3%, 99.7%)		
37085/37086	99.4%	99.1%	98.9%	98.7%	98.2%
	(99.1%, 99.6%)	(98.7%, 99.3%)	(98.5%, 99.2%)	(98.2%, 99.0%)	(97.7%, 98.6%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
B34000/B34000M					

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
37085/37086	98.2%	98.1%	98.1%	97.8%	97.8%
	(97.7%, 98.6%)	(97.5%, 98.5%)	(97.5%, 98.5%)	(97.2%, 98.3%)	(97.2%, 98.3%)

Model Name	11 Years	12 Years	13 Years	14 Years
B34000/B34000M				
37085/37086	97.1%	96.3%	96.3%	95.0%
	(95.8%, 97.9%)	(94.6%, 97.5%)	(94.6%, 97.5%)	(91.0%, 97.2%)

6 Sacral Neuromodulation Systems

6.1 Study Participants

6.1.1 Centers

In this section, the sacral neuromodulation tables and graphs were generated based on data collected between April 2010 and the report cut-off date of October 31, 2025. Twenty-four centers in North America, South America, and Europe have enrolled and contributed patients to the sacral neuromodulation systems section of this report. [Figure 6.1](#) shows a World Map, in which the countries that enrolled SNM patients are highlighted in blue.

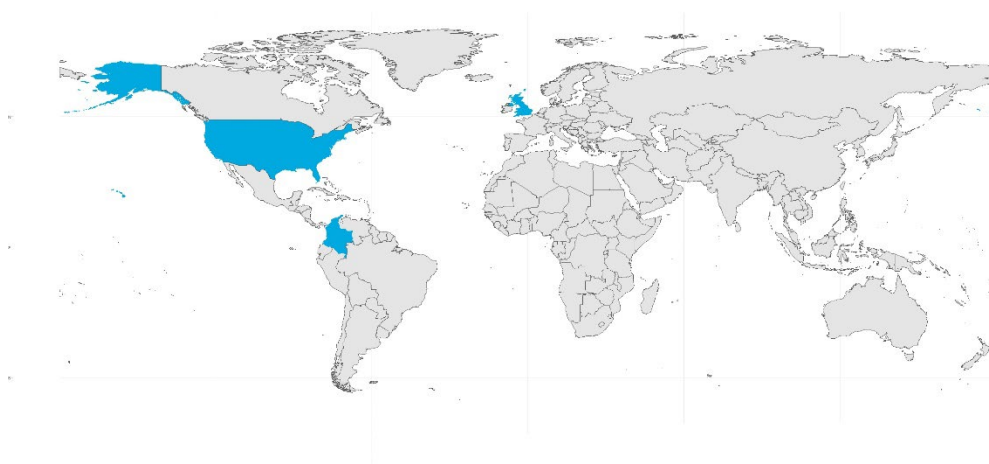


Figure 6.1: Countries with Sacral Neuromodulation Therapy Patients in Registry (Highlighted)

6.1.2 Patients

Of the 1,825 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 44.5% were implanted for the treatment of urinary urge incontinence, 25.8% were implanted for the treatment of urgency-frequency, 13.3% were implanted for the treatment of non-obstructive urinary retention, and 9.8% were implanted for the treatment of fecal incontinence. There were also 2.1% implanted for the treatment of bladder pain syndrome and 0.1% were implanted for the treatment of constipation, which are both considered off-label indications. There were 3.7% patients implanted for the treatment of some other indication, and 0.7% were implanted for indications that were not specified in the database at the time of data cut-off (see [Figure 6.2](#) and [Table 6.1](#)).

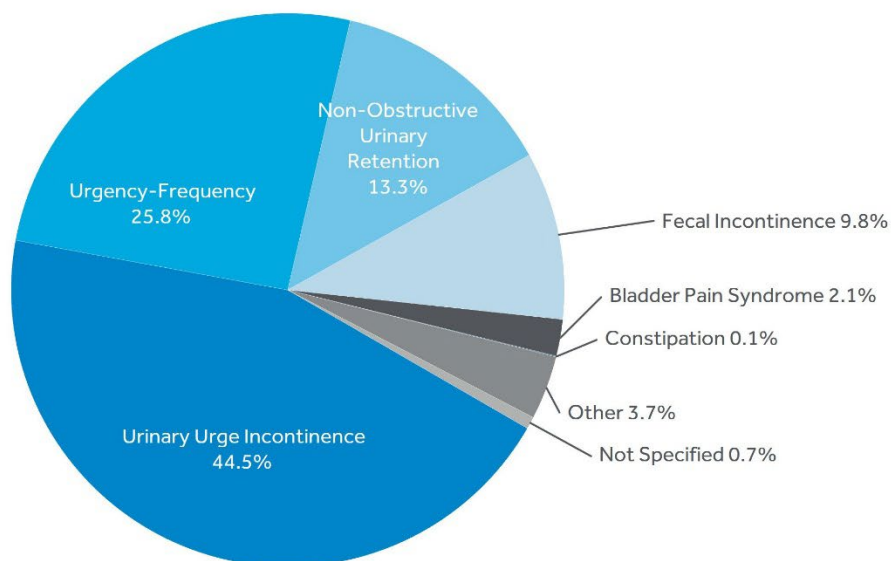


Figure 6.2: Sacral Neuromodulation Primary Treatment Indications

Table 6.1: Sacral Neuromodulation Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Urinary Urge Incontinence	813 (44.5%)
Urgency-Frequency	470 (25.8%)
Non-Obstructive Urinary Retention	242 (13.3%)
Fecal Incontinence	179 (9.8%)
Bladder Pain Syndrome	39 (2.1%)
Constipation	1 (0.1%)
Other	68 (3.7%)
Not Specified	13 (0.7%)
Total Patients	1825 (100.0%)

^a For approved indications refer to product labeling for your geography.

It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved labeling, which varies by geography. Please contact your local Medtronic representative for region- specific product labeling (<https://www.medtronic.com/us-en/our-company/locations.html>).

6.2 Event Summary

Adverse and device events were reported by the investigational site, where the principal investigator determined the suspected etiology. For device-related events, etiology could be attributed to one or more system components (e.g., neurostimulator, lead, and/or extension). If multiple components were identified as contributing to a single event, a separate product performance event (PPE) was recorded for each implicated component. For example, an event attributed to both the neurostimulator and the lead would be counted as one PPE for the neurostimulator and an additional PPE for the lead. As a result, the total number of PPEs may exceed the number of unique PPEs.

For SNM, there were 263 PPEs (224 unique PPEs) reported in 188 patients between April 2010 and October 31, 2025. These events represent 16.6% of the total reported events (263/1,581), occurring in 188 (10.3%) of the 1,825 total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves). In addition, there were 1,318 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the sacral neuromodulation systems.

Any registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings assist in the classification of the events. Within this report, [Table 6.2](#) differentiates the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 97 deaths reported for patients followed in the Product Surveillance Registry (PSR) with sacral neuromodulation systems, none of which were reported as a direct result of a product performance event.

6.2.1 Product Performance Events

Table 6.2: Sacral Neuromodulation System Product Performance Events

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=1825
RPA Determination	0	0	0 (0.00%)
Physician's Determination	263	4.4	188 (10.30%)
High Impedance	101	1.7	76 (4.16%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=1825
Lead Migration/Dislodgement	48	0.8	39 (2.14%)
Device Lead Issue	30	0.5	20 (1.10%)
Lead Fracture	25	0.4	21 (1.15%)
Device Malfunction	15	0.3	13 (0.71%)
Low Impedance	11	0.2	10 (0.55%)
Device Electrical Impedance Issue	6	0.1	4 (0.22%)
Premature Battery Depletion	5	0.1	4 (0.22%)
Device Issue	4	0.1	3 (0.16%)
Unspecified	4	0.1	4 (0.22%)
Device Charging Issue	2	<0.1	2 (0.11%)
Device Failure	2	<0.1	1 (0.05%)
Device Overheating	2	<0.1	2 (0.11%)
Other ^c	8	0.1	8 (0.44%)
Total	263	4.4	188 (10.30%)

^a Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.

^b The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.

^c Composed of event codes with 1 event each.

A total of 173 (65.8%) of 263 product performance events were related to the lead only, 53 (20.2%) related to the neurostimulator only, 2 (0.8%) related to the extension only, 8 (3.0%) related to multiple etiologies (which includes events where at least one device and one non-device etiology was indicated), and 27 (10.3%) related to other/not specified etiologies. Relatedness is determined by the physician.

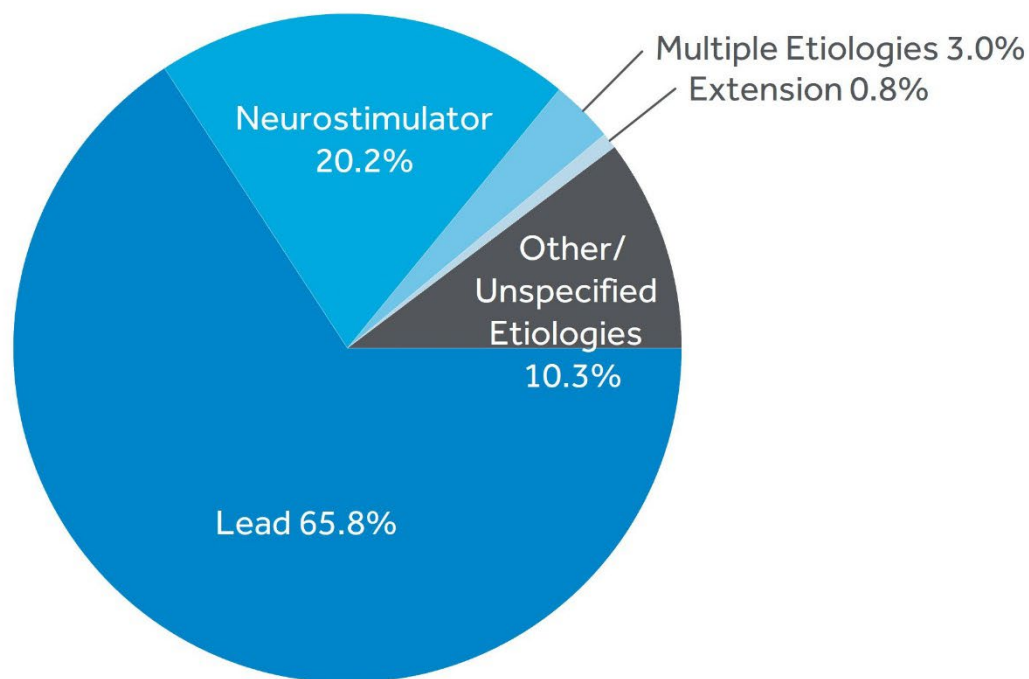


Figure 6.3: Sacral Neuromodulation System Product Performance Events by Relatedness

[Table 6.3](#) describes the interventions completed for product performance events that required action from the health care provider and thereby may have resulted in an incremental impact to the patient. Survival estimates presented in previous product performance reports included events where no action was taken. To present survival estimates that may better correlate with patient impact, events where no action was taken have been removed from the device survival estimates presented in this report. The far-left column lists the top five reported PPEs, and all other reported PPEs are listed under Other. The subsequent columns represent the actions taken by the reporting physician.

Table 6.3: Sacral Neuromodulation System Product Performance Events by Intervention

Events by Intervention ^a	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention	No Action Taken	Total Events
High Impedance	53 (52.5%)	37 (36.6%)	0 (0.0%)	0 (0.0%)	11 (10.9%)	101
Lead Migration/Dislodgement	34 (70.8%)	6 (12.5%)	1 (2.1%)	1 (2.1%)	6 (12.5%)	48
Device Lead Issue	12 (40%)	9 (30.0%)	4 (13.3%)	0 (0.0%)	5 (16.7%)	30

Events by Intervention ^a	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention	No Action Taken	Total Events
Lead Fracture	17 (68%)	2 (8.0%)	1 (4.0%)	3 (12%)	2 (8.0%)	25
Device Malfunction	8 (53.3%)	4 (26.7%)	2 (13.3%)	0 (0.0%)	1 (6.7%)	15
Other ^b	29 (65.9%)	6 (13.6%)	2 (4.5%)	3 (6.8%)	4 (9.1%)	44
Total	153 (58.2%)	64 (24.3%)	10 (3.8%)	7 (2.7%)	29 (11.0%)	263

^a Medical or Non-Surgical Therapy contains but is not limited to the following actions: medication adjustment based on disease symptoms, imaging (e.g. MRI or X-ray), other specialist referral.

^b Other represents all reported PPEs that were not in the top five of occurrence.

6.2.2 Clinical Events Not Related to Product Performance

The clinical events not related to product performance are summarized if:

- The patient was enrolled in the PSR since 2013, the time in which clinical event collection was initiated (n=1,515)
- Categorized as serious adverse events (SAEs, n=23)
- Occurred with a System Organ Class (SOC) threshold $\geq 0.5\%$ of patients
- Other considerations
 - Some events are described in high level group terms (HLGT) to provide more specificity, if needed

Table 6.4: Sacral Neuromodulation System Clinical Events Not Related To Product Performance

Event Type	Number of SAE	Patients with SAE n (%) N=1515	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=1515
Infections and infestations	15	15 (0.99%)	0.026	13 (0.86%)
Infections - pathogen unspecified	15	15 (0.99%)	0.026	13 (0.86%)
Other SOC Terms (<0.5% Threshold)^a	8	8 (0.53%)	0.014	4 (0.26%)
Total	23	23 (1.52%)	0.040	17 (1.12%)

^a Composed of high-level group term event codes with fewer than 5 events each.

6.2.3 Patient Deaths

In earlier versions of the protocol, deaths were only assessed for the relatedness to the device product performance. After 2010, death assessments were expanded to also include the relationship to the implant procedure and/or therapy. As of the report cut-off, a total of 97 patients in the registry had expired. No deaths were reported as a direct result of a product performance event.

The percentage is based upon the total patient death events and not based upon the rate of occurrence. **Tables depicted without a patient denominator should not be interpreted using other numbers within this report to calculate event rates.**

Table 6.5: Sacral Neuromodulation System Patient Deaths by Primary Indication

Number of Reports of Death by Primary Indication ^a	N (%) of Deaths
Urinary Urge Incontinence	42 (43.3%)
Urgency-Frequency	31 (32.0%)
Non-Obstructive Urinary Retention	13 (13.4%)
Fecal Incontinence	6 (6.2%)
Other	5 (5.2%)
Total	97

^a For approved indications refer to product labeling for your geography.

6.3 Neurostimulators

From April 2010 to the report cut-off date of October 31, 2025, there were 1,981 neurostimulators followed in the registry. The difference between the total number of patients (n=1,825) versus the total number of neurostimulators (n=1,981) is due to the fact that some patients were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 69,523 months (5,794 years).

Table 6.6: Sacral Neuromodulation Neurostimulator Counts by Model

Model Name	N (%)
InterStim II (model 3058)	1420 (71.7%)
InterStim X (model 97800)	399 (20.1%)
InterStim (model 3023)	102 (5.1%)
InterStim Micro (model 97810)	60 (3.0%)
Total	1981

6.3.1 Neurostimulator Events

There were 57 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 53 events with a neurostimulator etiology and 4 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 48 were the initial product performance events that affected neurostimulator survival estimates.

For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 9.03% (58/642). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the sum of the total number of explanted devices and the total number of neurostimulators in patients who have expired. In the 57 neurostimulator events, 100.00% (57/57) were assigned as device related by the physician, not returned to Medtronic RPA (see [Table 6.7](#))

Table 6.7: Sacral Neuromodulation Neurostimulator PPE by Determination

Product Performance Events	N (%)
Physician's Determination	57 (100%)
High Impedance	21 (36.8%)
Device Lead Issue	7 (12.3%)
Device Malfunction	7 (12.3%)
Lead Migration/Dislodgement	5 (8.8%)
Premature Battery Depletion	4 (7.0%)
Device Electrical Impedance Issue	2 (3.5%)
Device Issue	2 (3.5%)

Product Performance Events	N (%)
Device Overheating	2 (3.5%)
Lead Fracture	2 (3.5%)
Device Battery Issue	1 (1.8%)
Device Breakage	1 (1.8%)
Device Connection Issue	1 (1.8%)
Device Failure	1 (1.8%)
Unspecified	1 (1.8%)

For the purposes of survival analysis, a device's follow-up time is cut off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

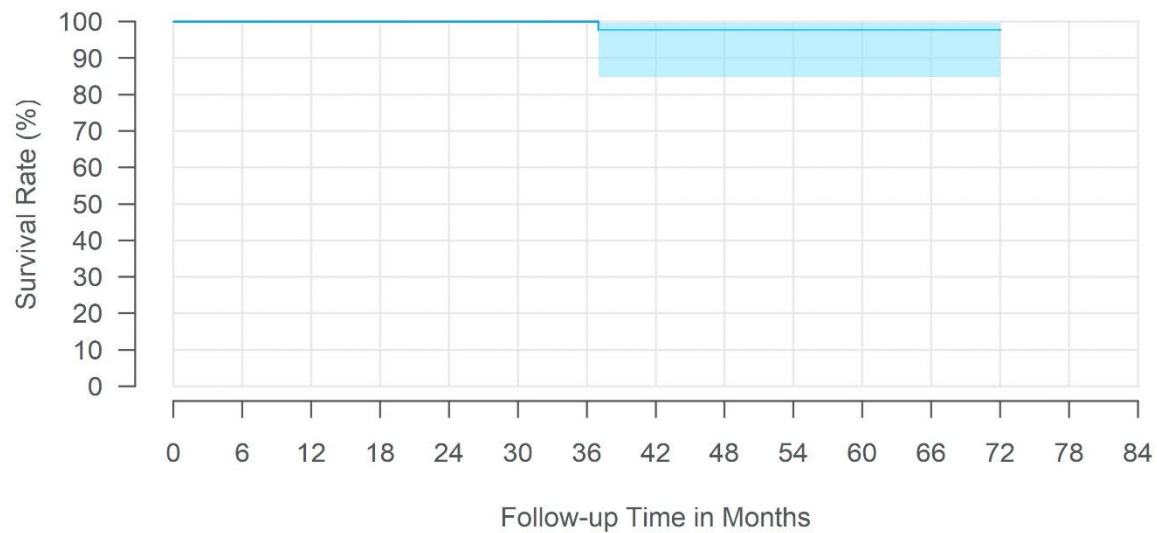
- 48 had follow-up time cut-off due to product performance related-events.
- 1,361 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 572 were free from product performance-related events and censoring events and were censored at the last follow-up visit prior to the report cut-off.

6.3.2 Neurostimulator Models

The following figures and tables represent neurostimulator survival and 95% confidence intervals (CIs) where at least 20 neurostimulators contributed to each 3-month interval.

6.3.2.1 Model 3023

Model Name	InterStim
FDA Approval Date	July 1998
Neurostimulators Enrolled	102
Neurostimulators Currently Active in Study	1
Initial Product Performance Events	2
Median Follow-up Time (Months)	28.8
Cumulative Follow-up Time (Months)	4,118



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)
Sample Size	71	60	43	33	25

Time Interval	6 Years
Survival (95% CI)	97.7% (84.8%, 99.7%)
Sample Size	22

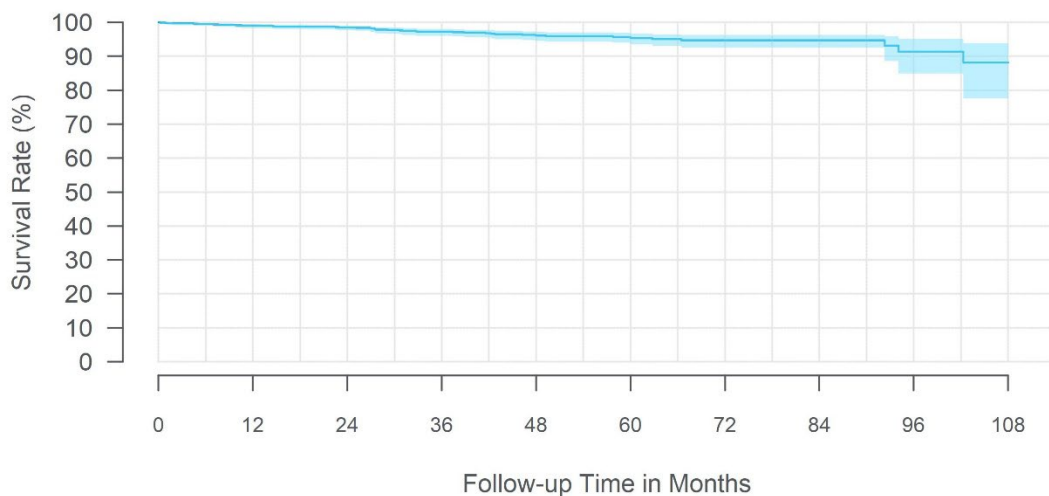
Specification: 3023	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (10 mm)
Volume	25 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 μ sec
Programs	4
Implant Depth	≤ 4 cm



Neurostimulator Event Summary: 3023	N
High Impedance	1
Premature Battery Depletion	1
Total	2

6.3.2.2 Model 3058

Model Name	InterStim II
FDA Approval Date	June 2006
Neurostimulators Enrolled	1,420
Neurostimulators Currently Active in Study	206
Initial Product Performance Events	44
Median Follow-up Time (Months)	37.2
Cumulative Follow-up Time (Months)	57,547



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.1% (98.4%, 99.5%)	98.5% (97.6%, 99.1%)	97.3% (96.0%, 98.1%)	96.1% (94.6%, 97.2%)	95.4% (93.6%, 96.7%)
Sample Size	1174	938	729	516	342

Time Interval	6 Years	7 Years	8 Years	9 Years
Survival (95% CI)	94.7% (92.6%, 96.2%)	94.7% (92.6%, 96.2%)	91.4% (85.0%, 95.1%)	88.2% (77.6%, 93.9%)
Sample Size	200	113	47	21

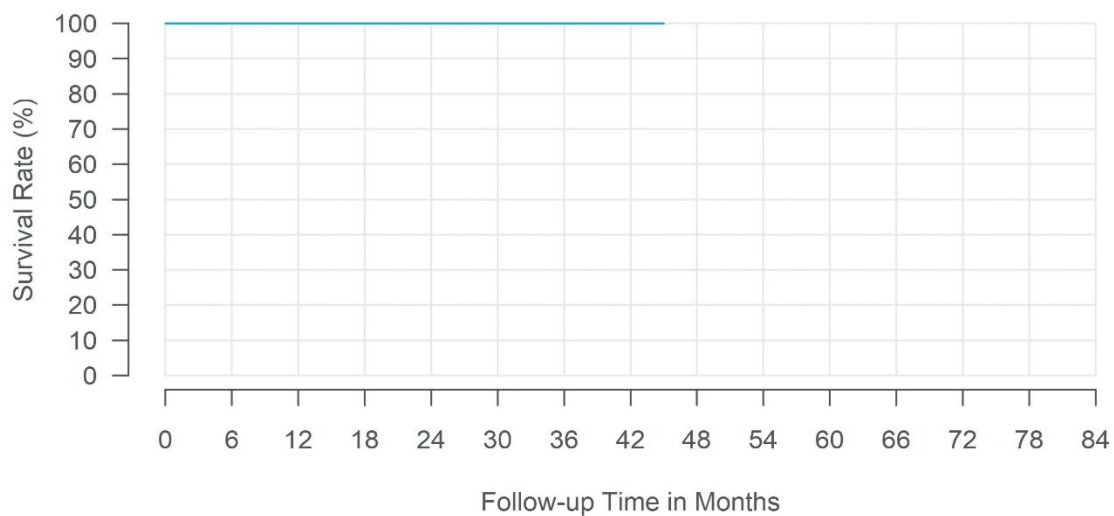
Specification: 3058	
Height	1.7 in (44 mm)
Width	2.0 in (51 mm)
Thickness	0.3 in (7.7 mm)
Volume	14 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 8.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 μ sec
Programs	4
Implant Depth	$\leq$ 2.5 cm



Neurostimulator Event Summary: 3058	N
High Impedance	17
Device Malfunction	6
Lead Migration/Dislodgement	5
Device Lead Issue	4
Premature Battery Depletion	3
Device Electrical Impedance Issue	2
Device Issue	2
Device Breakage	1
Device Failure	1
Device Overheating	1
Lead Fracture	1
Unspecified	1
Total	44

6.3.2.3 Model 97810

Model Name	InterStim Micro
FDA Approval Date	July 2020
Neurostimulators Enrolled	60
Neurostimulators Currently Active in Study	24
Initial Product Performance Events	0
Median Follow-up Time (Months)	34.4
Cumulative Follow-up Time (Months)	1,998



Time Interval	1 Year	2 Years	3 Years	At 45 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	54	39	30	20

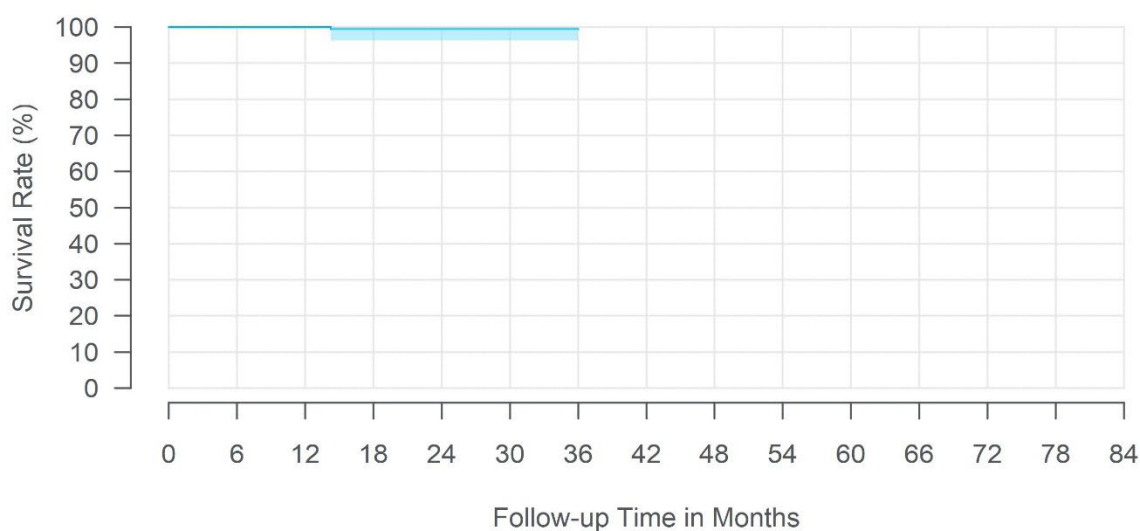
Specification: 97810

Height	0.7 in (17 mm)
Length	1.9 in (47 mm)
Thickness	0.2 in (5 mm)
Volume	2.8 cc
Battery type	Rechargeable
Expected Battery life	15 years
Maximum Electrodes	1
Amplitude	0 to 12.5 mA (0.1 mA increment)
Rate	3 to 130 Hz
Pulse Width	40 to 450 µsec (10 µsec increment)
Programs	11
Implant Depth	≤ 2.5 cm

**Neurostimulator Event Summary: 97810****Total****N****0**

6.3.2.4 Model 97800

Model Name	InterStim X
FDA Approval Date	February 2022
Neurostimulators Enrolled	399
Neurostimulators Currently Active in Study	341
Initial Product Performance Events	2
Median Follow-up Time (Months)	13.2
Cumulative Follow-up Time (Months)	5,859



Time Interval	1 Year	2 Years	3 Years
Survival (95% CI)	100.0% (NA)	99.5% (96.3%, 99.9%)	99.5% (96.3%, 99.9%)
Sample Size	209	99	22

Specification: 97800	
Height	1.7 in (44 mm)
Length	2.0 in (51 mm)
Thickness	0.3 in (7.7 mm)
Volume	12.5 cc
Battery type	Recharge-free
Expected Battery life	10.2 years ^a
Maximum Electrodes	4
Amplitude	0 - 12.5 mA (0.1 mA increment)
Rate	3 - 130 Hz
Pulse Width	40 - 450 µsec (10 µsec increment)
Programs	Up to 7 standard programs (Programs 1-7) and up to 4 custom programs (Programs A-D)
Implant Depth	No deeper than 2.5 cm (1 in) below the skin



^aService life may be up to 15 years depending on device settings and patient impedance. See System Eligibility, Battery Longevity, Specifications (available at manuals.medtronic.com) for details about the impact of programming parameters and patient impedance on battery longevity.

Neurostimulator Event Summary: 97800	N
Device Connection Issue	1
High Impedance	1
Total	2

6.3.3 Neurostimulator Summary

Table 6.8: Sacral Neuromodulation Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
InterStim (model 3023)	July 1998	102	1	2	28.8	4,118
InterStim II (model 3058)	June 2006	1,420	206	44	37.2	57,547
InterStim Micro (model 97810)	July 2020	60	24	0	34.4	1,998

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
InterStim X (model 97800)	February 2022	399	341	2	13.2	5,859

Table 6.9: Sacral Neuromodulation Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
InterStim (model 3023)	100.0%	100.0%	100.0%	97.7%	97.7%
	(NA)	(NA)	(NA)	(84.8%, 99.7%)	(84.8%, 99.7%)
InterStim II (model 3058)	99.1%	98.5%	97.3%	96.1%	95.4%
	(98.4%, 99.5%)	(97.6%, 99.1%)	(96.0%, 98.1%)	(94.6%, 97.2%)	(93.6%, 96.7%)
InterStim Micro (model 97810)	100.0%	100.0%	100.0%		
	(NA)	(NA)	(NA)		
InterStim X (model 97800)	100.0%	99.5%	99.5%		
	(NA)	(96.3%, 99.9%)	(96.3%, 99.9%)		

Model Name	6 Years	7 Years	8 Years	9 Years
InterStim (model 3023)	97.7%			
	(84.8%, 99.7%)			
InterStim II (model 3058)	94.7%	94.7%	91.4%	88.2%
	(92.6%, 96.2%)	(92.6%, 96.2%)	(85.0%, 95.1%)	(77.6%, 93.9%)
InterStim Micro (model 97810)				
InterStim X (model 97800)				

6.4 Leads

From April 2010 to the report cut-off date of October 31, 2025, there were 1,884 leads followed in the registry. The difference between the total number of leads (n=1,884) versus the total number of neurostimulators (n=1,981) is due to the fact that some patients were subsequently re-implanted with a new neurostimulator. The aggregate prospective follow-up time for all leads was 69,988 months (5,832 years). [Table 6.10](#) provides the number and percentage of leads by model.

Table 6.10: Sacral Neuromodulation Lead Counts by Model

Model Name	N (%)
Currently manufactured	551 (29.2%)
InterStim SureScan MRI (model 978B1)	479 (25.4%)
InterStim SureScan MRI (model 978A1)	72 (3.8%)
No longer manufactured	1321 (70.2%)
InterStim Quad Tined (model 3889)	1230 (65.3%)
InterStim Extended Electrode Quad Tined (model 3093)	87 (4.6%)
InterStim Quad (model 3080)	3 (0.2%)
InterStim Extended Electrode Quad (model 3092)	1 (0.1%)
Other/Unspecified	12 (0.6%)
Total	1884 (100.0%)

6.4.1 Lead Events

There were 177 product performance-related events with an underlying reported etiology related to lead function. This includes 173 events with a lead etiology and 4 events with both a lead and other etiology (including device and non-device etiologies). Of these, 137 were the initial product performance event that affected lead survival estimates.

For the purposes of survival analysis, a device's follow-up time is cut off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

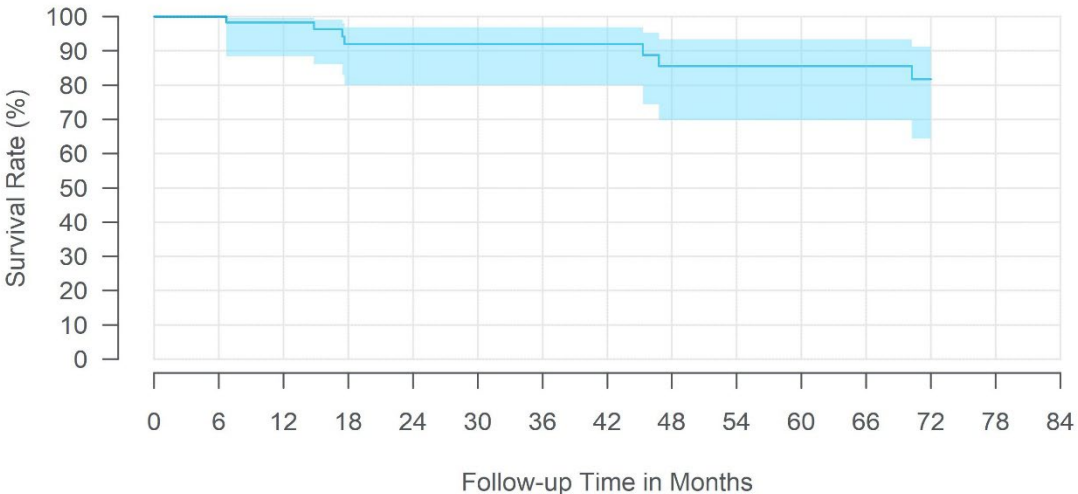
- 137 had follow-up time cut-off due to product performance-related events.
- 1,179 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 568 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

6.4.2 Lead Models

The following figures and tables represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval.

6.4.2.1 Model 3093

Model Name	InterStim Extended Electrode
FDA Approval Date	Quad Lead Tined
Leads Enrolled	September 2002
Leads Currently Active in Study	87
Initial Product Performance Events	2
Median Follow-up Time (Months)	11
Cumulative Follow-up Time (Months)	27.3
	3,626



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.3% (88.5%, 99.8%)	92.0% (80.0%, 96.9%)	92.0% (80.0%, 96.9%)	85.6% (69.8%, 93.4%)	85.6% (69.8%, 93.4%)
Sample Size	50	36	27	26	24

Time Interval	6 Years
Survival (95% CI)	81.8% (64.4%, 91.2%)
Sample Size	20

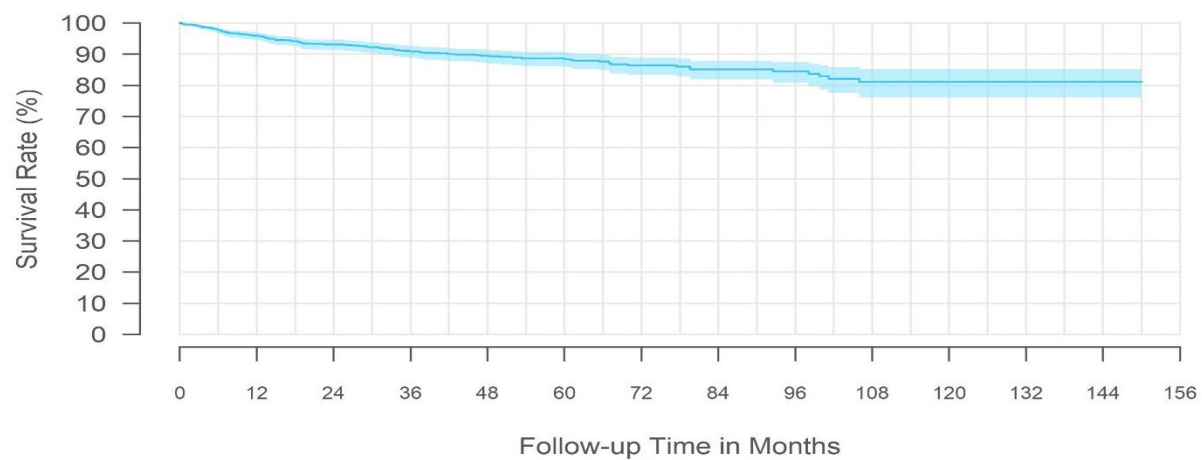
Specification: 3093	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0 (3x) and 10.2 (1x)
Individual Surface Area (mm ²)	12.0 and 40.7
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	23.7



Lead Event Summary: 3093	N
High Impedance	4
Device Lead Issue	3
Device Electrical Impedance Issue	1
Device Lead Damage	1
Lead Fracture	1
Lead Migration/Dislodgement	1
Total	11

6.4.2.2 Model 3889

Model Name	InterStim Quad Lead Tined
FDA Approval Date	September 2002
Leads Enrolled	1,230
Leads Currently Active in Study	190
Initial Product Performance Events	112
Median Follow-up Time (Months)	38.8
Cumulative Follow-up Time (Months)	53,529



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	96.0% (94.6%, 97.0%)	93.2% (91.4%, 94.6%)	90.9% (88.8%, 92.6%)	89.5% (87.2%, 91.5%)	88.5% (86.0%, 90.5%)
Sample Size	907	726	588	462	352

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	86.4% (83.5%, 88.9%)	85.2% (81.9%, 87.9%)	84.5% (81.0%, 87.5%)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)
Sample Size	251	177	116	73	49

Time Interval	11 Years	12 Years	At 150 Months
Survival (95% CI)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)
Sample Size	34	21	22

Specification: 3889

Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0
Individual Surface Area (mm ²)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	3.0
Array Length (mm)	21.0

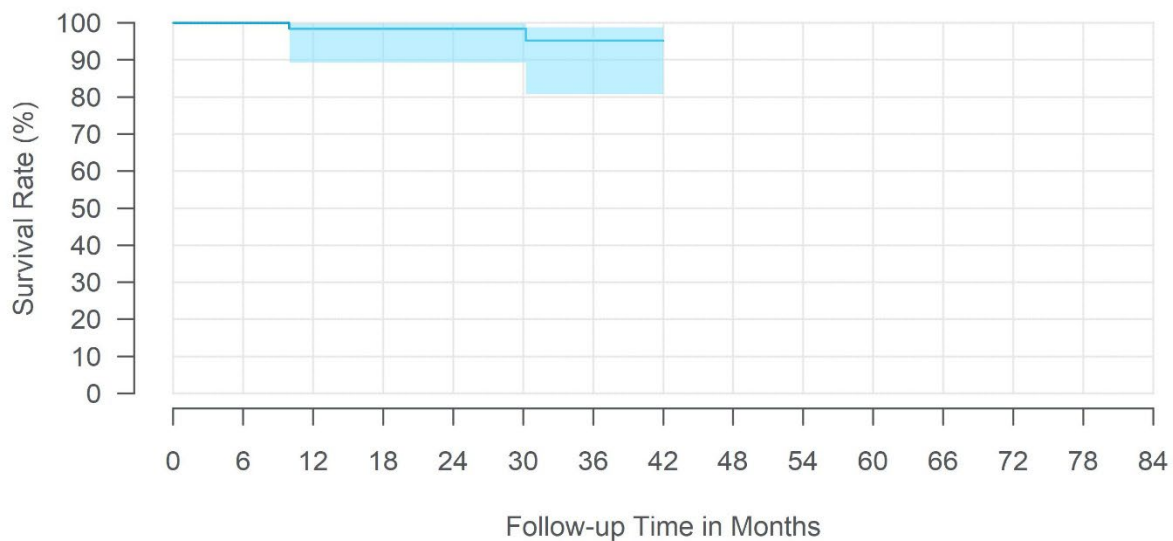


Lead Event Summary: 3889	N
High Impedance	47
Lead Migration/Dislodgement	28
Lead Fracture	14
Device Lead Issue	10
Low Impedance	6
Device Electrical Impedance Issue	2
Device Malfunction	2
Device Failure	1
Device Issue	1
Premature Battery Depletion ^a	1
Total	112

^aSite reported event related to multiple system components.

6.4.2.3 Model 978A1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	72
Leads Currently Active in Study	32
Initial Product Performance Events	2
Median Follow-up Time (Months)	28.2
Cumulative Follow-up Time (Months)	2,203



Time Interval	1 Year	2 Years	3 Years	At 42 Months
Survival (95% CI)	98.4% (89.3%, 99.8%)	98.4% (89.3%, 99.8%)	95.2% (80.7%, 98.9%)	95.2% (80.7%, 98.9%)
Sample Size	61	40	27	23

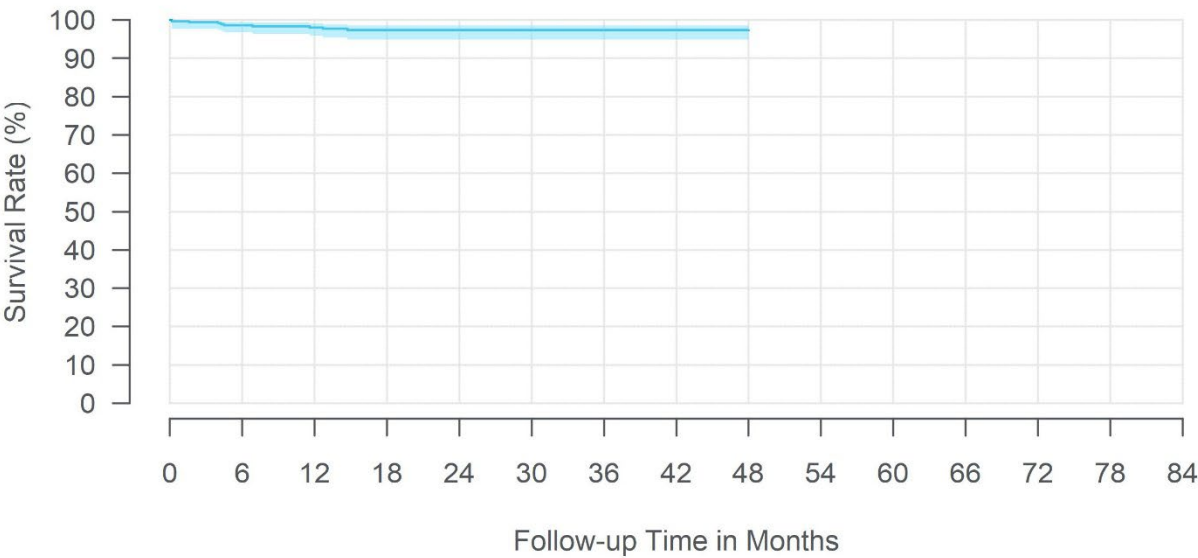
Specification: 978A1	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3 (4x)
Individual Surface Area (mm ²)	11.61
Inter-Electrode Spacing: Edge to Edge (mm)	3
Array Length (mm)	21



Lead Event Summary: 978A1	N
High Impedance	1
Lead Migration/Dislodgement	1
Total	2

6.4.2.4 Model 978B1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	479
Leads Currently Active in Study	340
Initial Product Performance Events	10
Median Follow-up Time (Months)	18.2
Cumulative Follow-up Time (Months)	10,266



Time Interval	1 Year	2 Years	3 Years	4 Years
Survival (95% CI)	98.1% (95.9%, 99.1%)	97.4% (94.9%, 98.6%)	97.4% (94.9%, 98.6%)	97.4% (94.9%, 98.6%)
Sample Size	293	178	84	25

Specification: 978B1	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3 (4x)
Individual Surface Area (mm ²)	11.61
Inter-Electrode Spacing: Edge to Edge (mm)	3
Array Length (mm)	21



Lead Event Summary: 978B1	N
High Impedance	4
Device Lead Issue	2
Device Electrical Impedance Issue	1
Device Kink	1
Device Malfunction	1
Lead Migration/Dislodgement	1
Total	10

6.3.2 Lead Summary

Table 6.11: Sacral Neuromodulation Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
InterStim Extended Electrode Quad Tined (model 3093)	September 2002	87	2	11	27.3	3,626
InterStim Quad Tined (model 3889)	September 2002	1,230	190	112	38.8	53,529
InterStim SureScan MRI (model 978A1)	July 2020	72	32	2	28.2	2,203
InterStim SureScan MRI (model 978B1)	July 2020	479	340	10	18.2	10,266

Table 6.12: Sacral Neuromodulation Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
InterStim Extended Electrode Quad Tined (model 3093)	98.3%	92.0%	92.0%	85.6%	85.6%
	(88.5%, 99.8%)	(80.0%, 96.9%)	(80.0%, 96.9%)	(69.8%, 93.4%)	(69.8%, 93.4%)
InterStim Quad Tined (model 3889)	96.0%	93.2%	90.9%	89.5%	88.5%
	(94.6%, 97.0%)	(91.4%, 94.6%)	(88.8%, 92.6%)	(87.2%, 91.5%)	(86.0%, 90.5%)
InterStim SureScan MRI (model 978A1)	98.4%	98.4%	95.2%		
	(89.3%, 99.8%)	(89.3%, 99.8%)	(80.7%, 98.9%)		
InterStim SureScan MRI (model 978B1)	98.1%	97.4%	97.4%	97.4%	
	(95.9%, 99.1%)	(94.9%, 98.6%)	(94.9%, 98.6%)	(94.9%, 98.6%)	

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Extended Electrode Quad Tined (model 3093)	81.8%				
	(64.4%, 91.2%)				

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Quad Tined (model 3889)	86.4%	85.2%	84.5%	81.1%	81.1%
	(83.5%, 88.9%)	(81.9%, 87.9%)	(81.0%, 87.5%)	(76.1%, 85.2%)	(76.1%, 85.2%)
InterStim SureScan MRI (model 978A1)					
InterStim SureScan MRI (model 978B1)					

Model Name	11 Years	12 Years
InterStim Extended Electrode Quad Tined (model 3093)		
InterStim Quad Tined (model 3889)	81.1%	81.1%
	(76.1%, 85.2%)	(76.1%, 85.2%)
InterStim SureScan MRI (model 978A1)		
InterStim SureScan MRI (model 978B1)		

6.5 Extensions

From April 2010 to the report cut-off date of October 31, 2025, there were 165 extensions followed in the registry, of which 61.8% were Model 3095 102/165. The remaining 63 extensions were Percutaneous Extension Model 3560022 (n=61) or Model 3560030 (n=2) and are not shown in this report due to the sample size at 1 year follow-up not being equal to an n=20. The difference between the total number of extensions (n=165) versus the total number of neurostimulators (n=1,981) is due to the fact that not all systems require an extension, or some patients were subsequently re-implanted with a new neurostimulator. The aggregate prospective follow-up time for all extensions was 5,392 months (449 years).

6.5.1 Extension Events

There were 2 product performance-related events with an underlying reported etiology related to extension function. Of these, 1 was the initial product performance event that affected extension survival estimates.

For the purposes of survival analysis, a device's follow-up time is cut off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

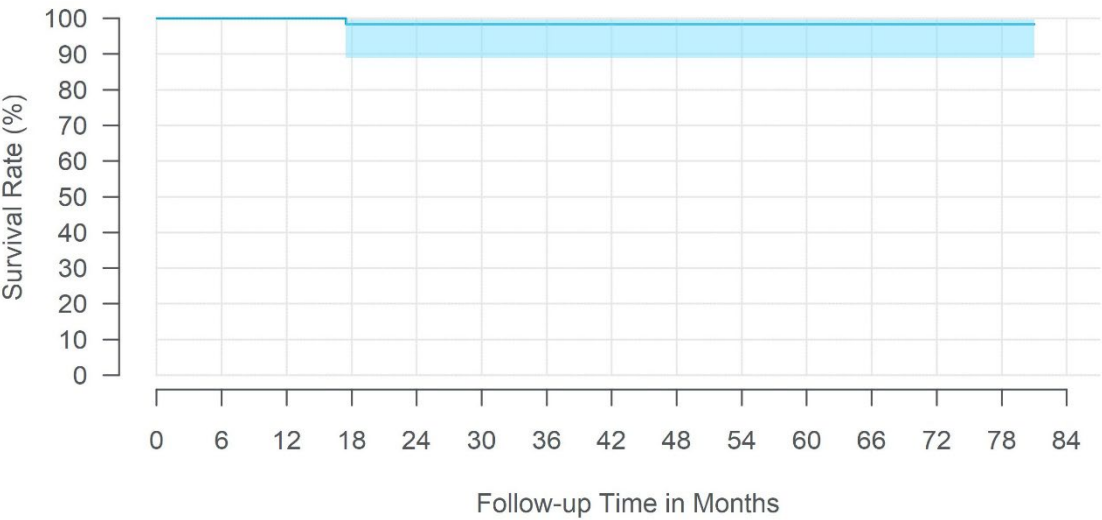
- 1 had follow-up time cut-off due to product performance-related events.
- 105 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 59 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

6.5.2 Extension Models

The following figures and tables represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval.

6.5.2.1 Model 3095

Model Name	Quadripolar Extension
FDA Approval Date	July 1998
Extensions Enrolled	102
Extensions Currently Active in Study	7
Initial Product Performance Events	1
Median Follow-up Time (Months)	28.6
Cumulative Follow-up Time (Months)	4,484



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)
Sample Size	64	52	34	26	24

Time Interval	6 Years	At 81 Months
Survival (95% CI)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)
Sample Size	23	20

Specification: 3095	
Length (cm)	10, 25, 51
Distal End Compatibility	Tined lead models 3889 and 3093
Distal End Set Screws	4
Proximal End INS Compatibility	InterStim Model 3023



Extension Event Summary: 3095	N
Lead Fracture ^a	1
Total	1

^a Site reported event related to multiple system components.

6.5.3 Extension Summary

Table 6.13: Sacral Neuromodulation Extension Characteristics

Model Name	FDA Approval Date	Extensions Enrolled	Extensions Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Quadripolar (model 3095)	July 1998	102	7	1	28.6	4,484

Table 6.14: Sacral Neuromodulation Extension Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years
Quadripolar (model 3095)	100.0%	98.4%	98.4%	98.4%	98.4%	98.4%
	(NA)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)