PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA FROM THE MEDTRONIC POST-MARKET REGISTRY

2024

Medtronic
Further, Together

Contents

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 2024 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 77centers that have contributed data for TDD systems, 87 centers for SCS systems, 66 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 receipt of 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 17th 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 23,323 patients in our ongoing post-market registry. The registry has enrolled 73,309 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.

Thank you for your support.

Todd Weaver, PhD, MPH
Clinical Research Director, Post Approval Clinical Surveillance Clinical Research, Medical Science and Regulatory Affairs (CMRA)

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.

MEDTRONIC, PLC.
PHONE: (800) 328-0810

WRITTEN REQUESTS OR SUGGESTIONS CAN BE MAILED TO:

MEDTRONIC, PLC.
ATTN: Todd Weaver, PhD, MPH
8200 Coral Sea Street NE
MVS33
Mounds View, MN 55112

1.4 Editorial Staff

Authors

Todd Weaver, PhD, MPH, Clinical Research Director
Isabelle Buffin, Clinical Research Program Manager
Heidi Vander Velden, Clinical Research Manager
Carrie Bahl, Clinical Research Program Manager
Naomi Pires-Barracosa, Pr. Clinical Research Specialist
Gregory Hilleren, Principal Statistician
Manali Kapadia, Statistical Programmer

External Medical Reviews

Aaron Calodney, MD, Tyler, Texas, USA
Peter Konrad, MD, PhD, Morgantown, West Virginia, USA
Karl Kreder, MD, Iowa City, Iowa, USA
Gobi Paramanandam, MD, Scottsdale, Arizona, USA

Medtronic Review Board

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Bethany Dimaculangan, Principal Medical Affairs Specialist
Cari Herman, Quality
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Ellen Mathelus, Paralegal Program Manager
Glen Smythe, Regulatory Director, Pain Therapies
Gregory Hilleren, Statistician
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Kristie Wallace, Statistics Manager
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Scott Lindfors, Senior Quality Engineering Manager
Tricia Braun, Senior Clinical Research Manager
Vuong Nguyen, Quality Director, Pelvic Health

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
HLGT	High Level Group Terms
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
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/ortherapy.
- **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.

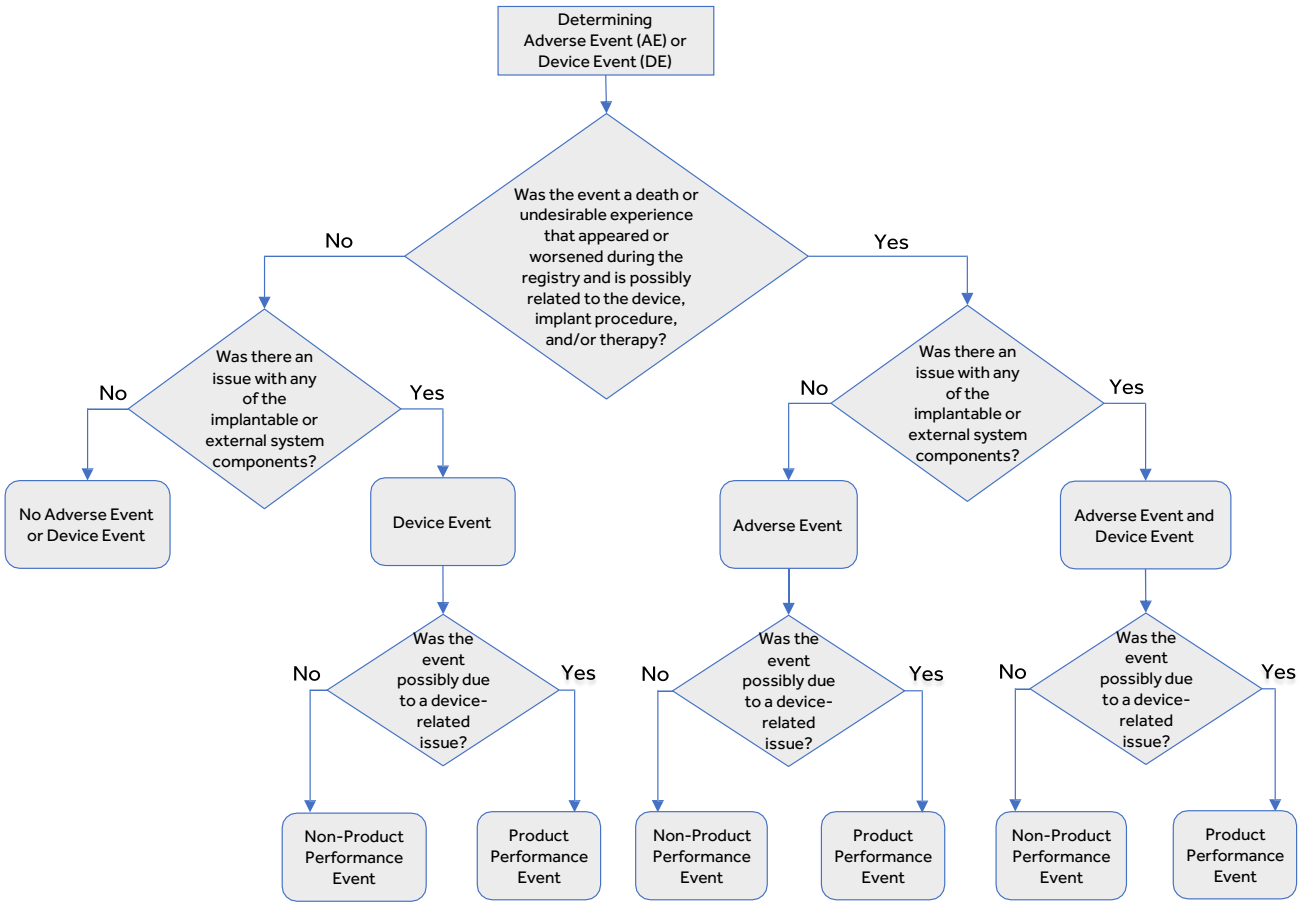


Figure 2.1: Adverse Event/Device Event Flowchart

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, 2024. 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 World Map, in which the countries that enrolled TDD patients are highlighted.

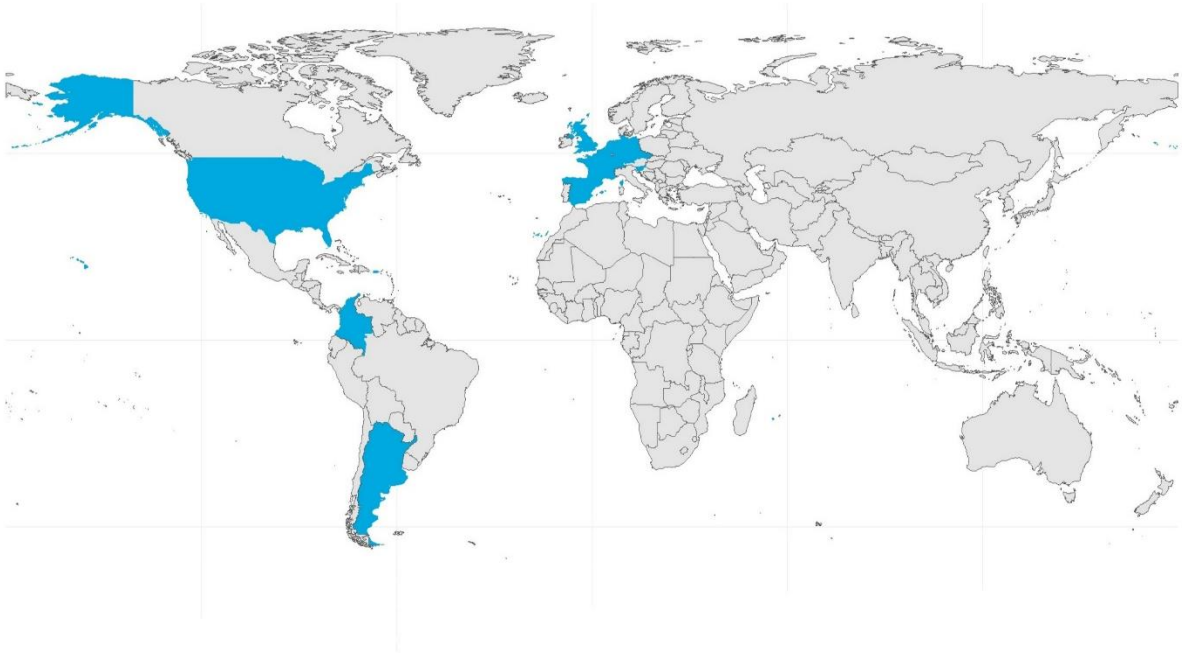


Figure 3.1: Countries with Targeted Drug Delivery Therapy Patients in Registry (Highlighted)

3.1.2 Patients

There were 10,793 total targeted drug delivery system patients enrolled through October 31, 2024. In Table 3.1 and Figure 3.2, 59.5% 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 21.2% for treatment of spasticity, and 17.0% 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.

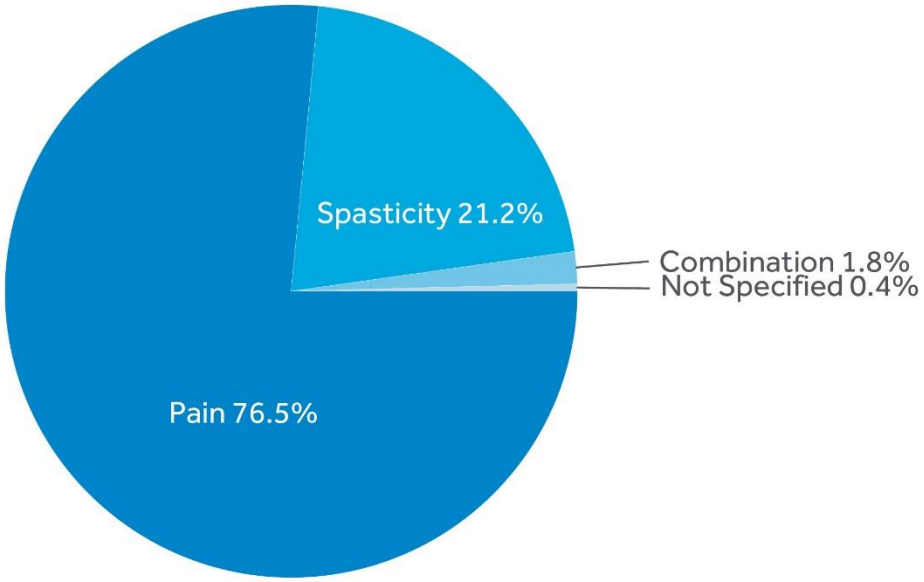


Figure 3.2: Targeted Drug Delivery Primary Treatment Indications

Table 3.1: Targeted Drug Delivery Primary Treatment Indications

Primary Treatment Indication[a]	Enrolled Patients (%)
Pain	**8259 (76.5%)**
Non-malignant pain	6419 (59.5%)
Malignant pain	1839 (17.0%)
Pain not specified	1 (<0.1%)
Spasticity	**2293 (21.2%)**
Combination	**196 (1.8%)**
Non-malignant pain & Spasticity	193 (1.8%)
Malignant pain & Chemotherapy	1 (<0.1%)
Malignant pain & Spasticity	1 (<0.1%)
Non-malignant pain & Chemotherapy	1 (<0.1%)
Not Specified[b]	**45 (0.4%)**
Total Patients	**10793**

[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	761 (41.3%)
Abdominal/Visceral	451 (24.5%)
Extremity	341 (18.5%)
Pelvic	251 (13.6%)
Thoracic	206 (11.2%)
Head/Neck	128 (7.0%)
Other	207 (11.2%)
Not Specified	439 (23.8%)
Total Patients[a]	**1841**

[a] 2784 sites of pain in 1,841 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	2352 (35.6%)
Back Pain without Leg Pain	1715 (25.9%)
General Neuropathic Condition	251 (3.8%)
CRPS I[a]	205 (3.1%)
Peripheral Neuropathy	85 (1.3%)
Joint Pain/Arthritis	74 (1.1%)
General Nociceptive Condition	59 (0.9%)
CRPS II[a]	39 (0.6%)

Non-Malignant Pain: Sub-Indications	Enrolled Patients (%)
Osteoporosis	20 (0.3%)
Abdominal pain	13 (0.2%)
Pelvic pain	9 (0.1%)
Other	836 (12.6%)
Not Specified	955 (14.4%)
Total Patients[b]	**6613**

[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	388 (77.1%)	287 (14.5%)	675 (27.1%)
Multiple Sclerosis	0 (0.0%)	597 (30.1%)	597 (24.0%)
Spinal Cord Injury	9 (1.8%)	394 (19.9%)	403 (16.2%)
Brain Injury	39 (7.8%)	130 (6.6%)	169 (6.8%)
Stroke	1 (0.2%)	103 (5.2%)	104 (4.2%)
Other	22 (4.4%)	243 (12.2%)	265 (10.7%)
Not Specified	44 (8.7%)	230 (11.6%)	274 (11.0%)
Total Patients[a]	**503**	**1984**	**2487**

[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 2,632 product performance events reported between August 7, 2003 and October 31, 2024, in 1,691 patients with targeted drug delivery systems. These events represent 13.1% (2632/20,034) 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=884).

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 2,933 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=10793[b]
RPA Determination	**359**	**0.9**	**327 (3.0%)**
Pump Motor Stall	197	0.5	190 (1.8%)
Laboratory Overinfusion Finding[d]	40	0.1	39 (0.4%)
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[l]	11	<0.1	10 (0.1%)
Reduced Battery Performance	10	<0.1	10 (0.1%)
Deformed Pump Tube	9	<0.1	8 (0.1%)
Reservoir Access Issues Due To Residue	9	<0.1	8 (0.1%)
Motor Feedthrough Anomaly	8	<0.1	8 (0.1%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=10793[b]
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[f]	17	<0.1	17 (0.2%)
Physician's Determination	**2,273**	**5.6**	**1509 (14.0%)**
Catheter Occlusion	539	1.3	471 (4.4%)
Catheter Dislodgement	431	1.0	346 (3.2%)
Catheter Kink	281	0.7	240 (2.2%)
Catheter Break/Cut	273	0.7	244 (2.3%)
Device Malfunction[g]	127	0.3	109 (1.0%)
Pump Motor Stall[h]	97	0.2	79 (0.7%)
Catheter Leakage	89	0.2	82 (0.8%)
Catheter Disconnection At Pump	54	0.1	52 (0.5%)
Pump Reservoir Volume Discrepancy	49	0.1	38 (0.4%)
Pump Unable To Enter/Withdraw From Catheter Access Port	49	0.1	42 (0.4%)
Catheter Dysfunction	48	0.1	43 (0.4%)
Device Difficult To Use	27	0.1	26 (0.2%)
Pump Underinfusion	23	0.1	19 (0.2%)
Catheter Related Complication	22	<0.1	21 (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[i]	15	<0.1	15 (0.1%)
Catheter Disconnection Between Catheter Segments	13	<0.1	12 (0.1%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=10793[b]
Device Connection Issue	10	<0.1	10 (0.1%)
Device Damage	10	<0.1	8 (0.1%)
Catheter Access Port Issue	6	<0.1	6 (0.1%)
Device Breakage	6	<0.1	6 (0.1%)
Device Charging 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[j]	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[k]	2	<0.1	2 (<0.1%)
Pump Infusion Issue	2	<0.1	1 (<0.1%)
Pump Inversion	2	<0.1	2 (<0.1%)
Other[f]	15	<0.1	14 (0.1%)
Total	**2,632**	**6.4**	**1691 (15.7%)**

[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 other 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 and Synchromed III pumps are designed to temporarily stop 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] Composed of event codes with 1 event each.

[g] The majority of these events were attributed to the Patient Therapy Manager (PTM).

[h] 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 and Synchromed III pumps are designed to temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure for patient safety.

[i] Of the 16 device issues, 12 have an etiology of catheter or other component. The 16 device issues include 8 unable to aspirate catheter, 4 PTM Error Codes, 2 pump alarms, and 1 pump in safe state.

[j] Includes1 where metal clips on connector appear bent, 1 pump beeping, and 1 roller arm seized to ball bearing.

[k] Patient had clinical signs and symptoms of overinfusion, but pump not returned and analyzed.

[l] 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.

A total of 1,862 of the 2,632 product performance events were related to the catheter only. There were 541 events related to the pump only. There were 175 related to other components (e.g. PTM malfunction) and 54 (2.1%) related to other etiologies (e.g. bend in catheter anchor). Relatedness is reported by the physician.

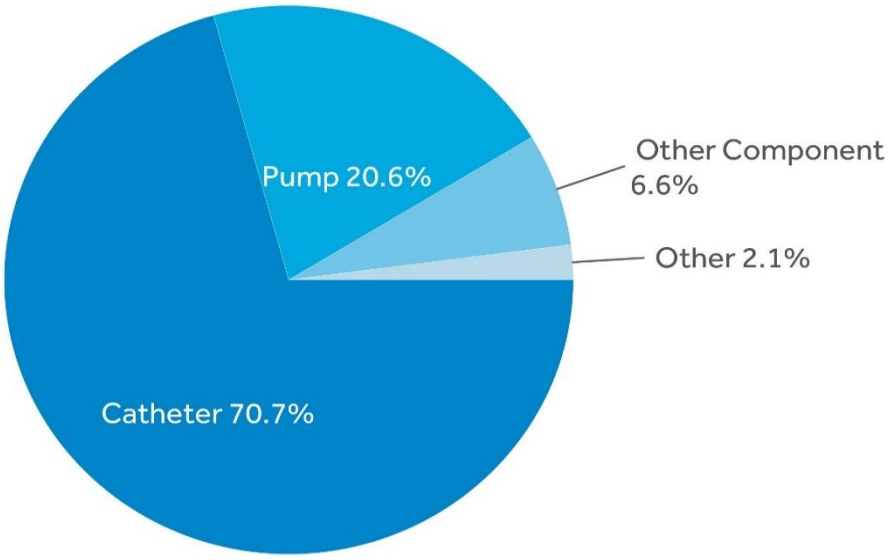


Figure 3.3: Targeted Drug Delivery System Product Performance Events by Relatedness

Table 3.6 describes the interventions 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 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	494 (91.7%)	12 (2.2%)	17 (3.2%)	7 (1.3%)	9 (1.7%)	**539**
Catheter Dislodgement	380 (88.2%)	9 (2.1%)	8 (1.9%)	2 (0.5%)	32 (7.4%)	**431**
Catheter Kink	256 (91.1%)	6 (2.1%)	14 (5%)	1 (0.4%)	4 (1.4%)	**281**
Catheter Break/Cut	259 (94.9%)	1 (0.4%)	6 (2.2%)	1 (0.4%)	6 (2.2%)	**273**
Pump Motor Stall	167 (69%)	15 (6.2%)	4 (1.7%)	9 (3.7%)	47 (19.4%)	**242**
Other[b]	494 (63.3%)	31 (4.0%)	152 (19.5%)	5 (0.6%)	98 (12.6%)	**780**
Total	**2050 (80.5%)**	**74 (2.9%)**	**201 (7.9%)**	**25 (1.0%)**	**196 (7.7%)**	**2546[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=4,217)
- Categorized as serious adverse events (SAEs, n=551)
- Occurred with a System Organ Class (SOC) threshold ≥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 (e.g., Inflammatory Mass, Cerebrospinal Fluid Leaks)

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

Event Type	Number of SAEs	Patients with SAE n (%) N=4,217	SAEs Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4,217
General disorders and administration site conditions	**238**	**212 (5.0%)**	**0.17**	**53 (1.3%)**
Therapeutic and nontherapeutic effects (excl toxicity)	174	156 (3.7%)	0.13	20 (0.5%)
Complications associated with device	42	41 (1.0%)	0.03	26 (0.6%)
General system disorders NEC[a]	12	12 (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	**116**	**108 (2.6%)**	**0.09**	**92 (2.2%)**
Infections - pathogen unspecified	95	90 (2.1%)	0.07	80 (1.9%)
Bacterial infectious disorders	20	19 (0.5%)	0.01	12 (0.3%)
Other[b]	1	1 (<0.1%)	<0.01	1 (<0.1%)
Injury, poisoning and procedural complications	**78**	**74 (1.8%)**	**0.06**	**20 (0.5%)**
Procedural related injuries and complications NEC[a]	38	37 (0.9%)	0.03	15 (0.4%)
Overdoses and underdoses NEC[a]	30	28 (0.7%)	0.02	2 (<0.1%)

Event Type	Number of SAEs	Patients with SAE n (%) N=4,217	SAEs Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=4,217
Injuries NEC[a]	5	5 (0.1%)	<0.01	3 (0.1%)
Other[b]	5	5 (0.1%)	<0.01	0 (0.0%)
Nervous system disorders	**68**	**62 (1.5%)**	**0.05**	**29 (0.7%)**
Neurological disorders NEC[a]	31	29 (0.7%)	0.02	15 (0.4%)
Neuromuscular disorders	22	21 (0.5%)	0.02	10 (0.2%)
Other[b]	15	15 (0.4%)	0.01	6 (0.1%)
Other SOC Terms (<1.0% Threshold)	**51**	**49 (1.2%)**	**0.04**	**15 (0.4%)**
Total	**551**	**442 (10.5%)**	**0.40**	**189 (4.5%)**

[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=520) at the time of this analysis is presented in Table 3.9 with a definitive and probable CSF leak rate of 1.5% (167/10,793). 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]
520	145	22	32	215	106

[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), also sometimes 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 data cut-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 2024 indicates an incidence of 0.22% (18/8,259) for pain patients and 0.00% (0/2,293) 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
2018	4	1	0	0	3
2019	5	1	0	0	4
2020	3	1	0	1	1

Year of Event	Cases Reviewed	Definitive IM	Probable IM	Possible IM	Not IM
2021	2	0	1	0	1
2022	0	0	0	0	0
2023	0	0	0	0	0
2024	0	0	0	0	0
Total	**136**	**10**	**8**	**24**	**94**

3.2.4 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 2,933 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 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, difficulties swallowing 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 1,476 (50.3%) deaths have been reported in this patient registry study based upon patients receiving therapy for malignant pain, 1,098 (37.4%) for non-malignant pain, 329 (11.2%) for spasticity, 26 (0.9%) 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	1476 (50.3%)
Non-malignant pain	1098 (37.4%)
Spasticity	329 (11.2%)
Non-malignant pain & Spasticity	26 (0.9%)
Malignant pain & Chemotherapy	1 (<0.1%)
Not Specified	3 (0.1%)
Total	**2933**

[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, 2024, there were 13,848 pumps followed in the registry. The difference between the total number of patients (n=10,793) 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 479,590 months (39,966 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 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	**145 (1.0%)**
GW3/FT/DLC Enhancements	145 (1.0%)
SynchroMed III 20 mL	**45 (0.3%)**
GW3/FT/DLC Enhancements	45 (0.3%)
SynchroMed II 40 mL	**7832 (56.6%)**
Pre-Enhancements[a]	4630 (33.4%)
GW3/FT/DLC Enhancements[a]	2664 (19.2%)
GW3/FT Enhancements[a]	538 (3.9%)
SynchroMed II 20 mL	**4640 (33.5%)**
Pre-Enhancements[a]	2963 (21.4%)

Model Name	N (%)
GW3/FT/DLC Enhancements[a]	1315 (9.5%)
GW3/FT Enhancements[a]	362 (2.6%)
SynchroMed EL 18 mL[a]	**1146 (8.3%)**
SynchroMed EL 10 mL[a]	**34 (0.2%)**
SynchroMed Classic[a]	**5 (<0.1%)**
Other/Unspecified	**1 (<0.1%)**
Total	**13848**

[a] No longer manufactured.

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

3.3.2 Pump Events

There were 546 product performance-related events with an underlying reported etiology related to pump function. This includes 541 events with a pump etiology and 5 events with both a pump and other etiology (including device and non-device etiologies). Of these, 467 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 26.5% (1,951/7,363). 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 546 pump events, 35.5% (194/546) 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:

- 467 had follow up time cut-off due to product performance-related events.
- 11,196 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.
- 2,185 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 shown due to small sample size 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.

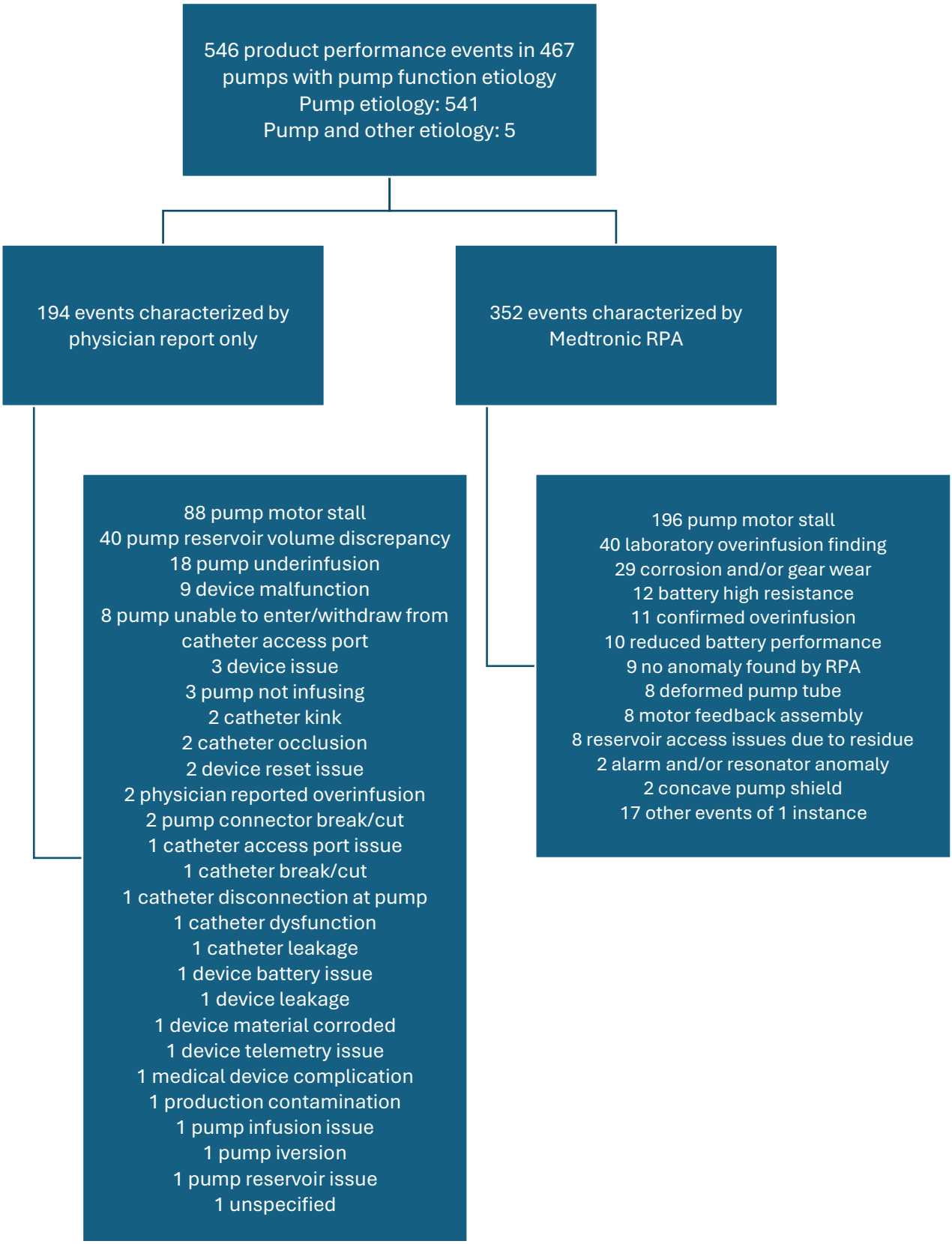
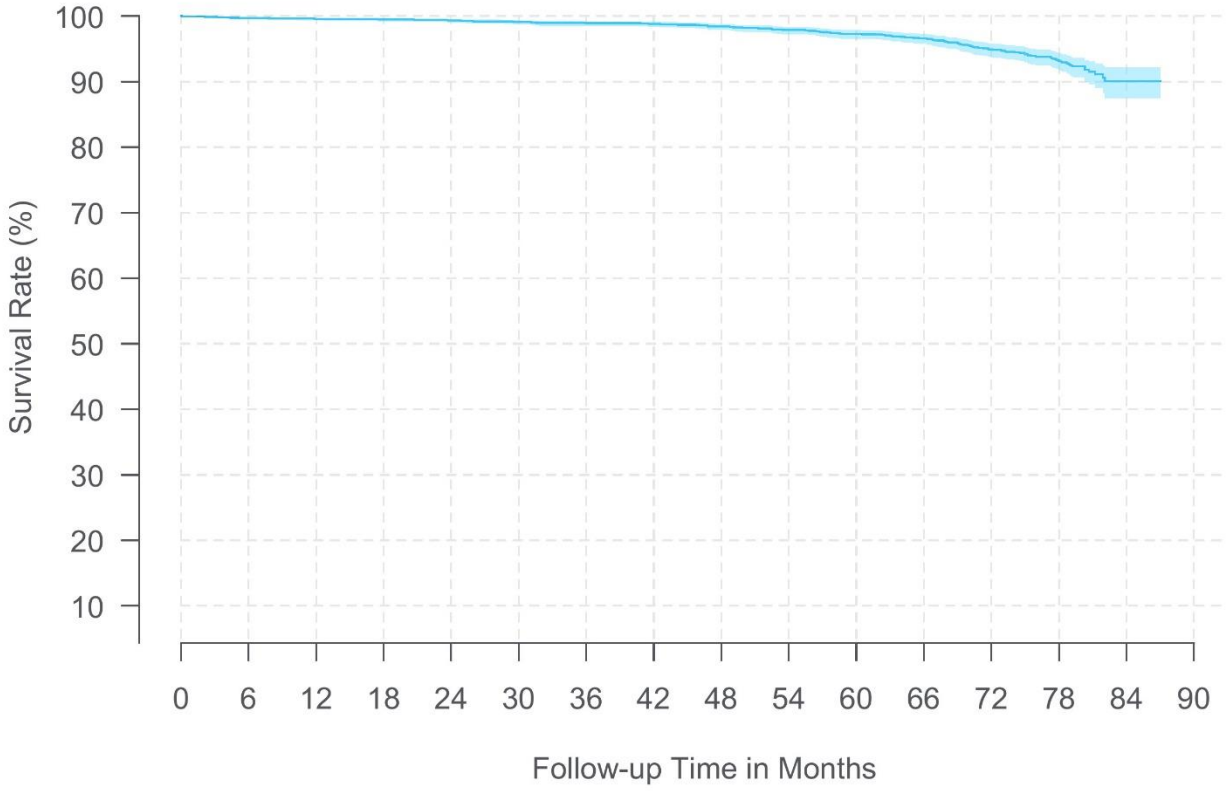


Figure 3.4: Distribution of Pump Function Etiology Product Performance Events

3.3.3.1 Model 8637-20

Model/Name	SynchroMed II 20 mL
FDA Approval Date	September 2003
Pumps Enrolled	4,640
Pumps Currently Active in Study	714
Initial Product Performance Events	129
Median Follow-up Time (Months)	39.0
Cumulative Follow-up Time (Months)	190,651



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (99.3%, 99.8%)	99.4% (99.0%, 99.6%)	98.9% (98.5%, 99.2%)	98.4% (97.9%, 98.8%)	97.3% (96.6%, 97.9%)
Sample Size	3519	2995	2477	2002	1598

Time Interval	6 Years	7 Years	At 87 Months
Survival (95% CI)	94.9% (93.8%, 95.8%)	90.1% (87.5%, 92.2%)	90.1% (87.5%, 92.2%)
Sample Size	1178	44	21

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).

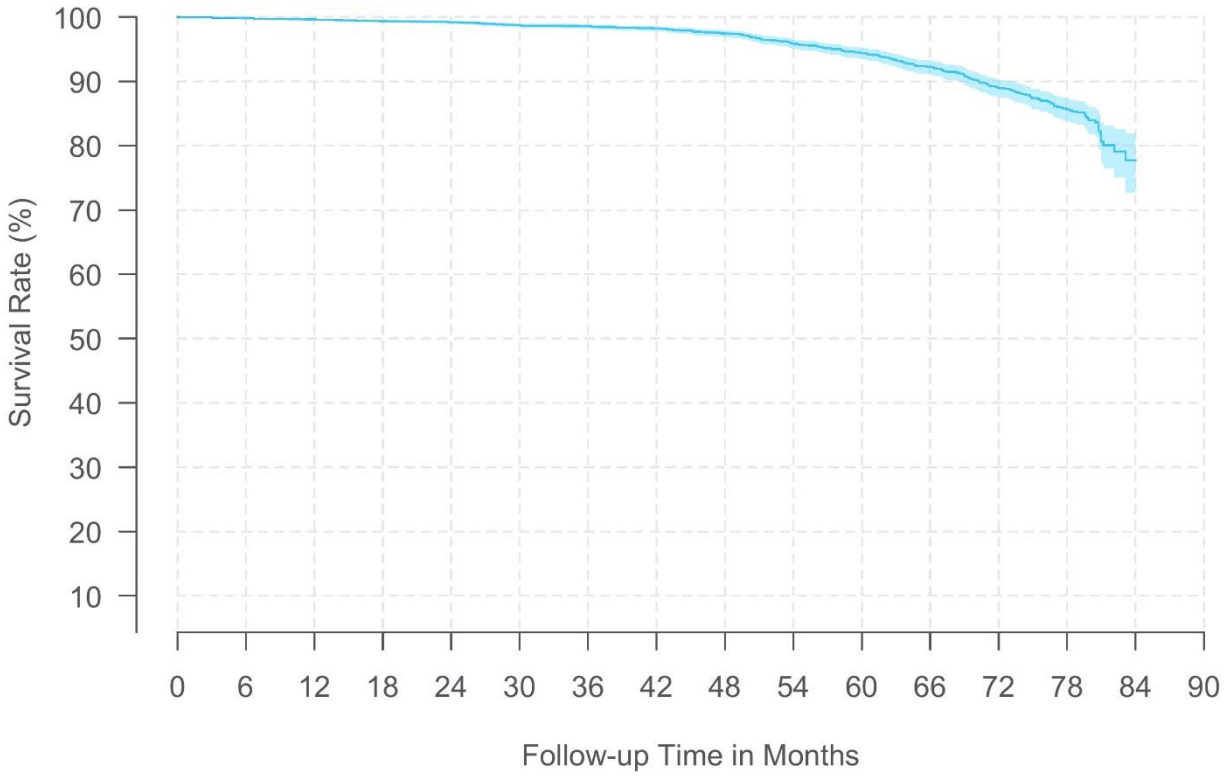
Pump Event Summary: SynchroMed II 20 mL	N
RPA Determination	**78**
Pump Motor Stall	39
Laboratory overinfusion finding	8
Battery High Resistance	7
Corrosion And/Or Gear Wear	4
Motor Feedthrough Anomaly	3
Deformed Pump Tube	2
No Anomaly Found By RPA	2
Reduced Battery Performance	2
Reservoir Access Issues Due To Residue	2
Other[a]	9
Physician's Determination	**51**
Pump Motor Stall	21
Pump Reservoir Volume Discrepancy	10
Device Malfunction	5
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	**129**

[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	7,832
Pumps Currently Active in Study	1,303
Initial Product Performance Events	304
Median Follow-up Time (Months)	26.3
Cumulative Follow-up Time (Months)	256,470



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.6% (99.4%, 99.7%)	99.2% (98.9%, 99.4%)	98.6% (98.2%, 98.9%)	97.4% (96.9%, 97.9%)	94.4% (93.5%, 95.2%)
Sample Size	5169	4102	3225	2487	1819

Time Interval	6 Years	7 Years
Survival (95% CI)	89.0% (87.5%, 90.3%)	77.7% (72.7%, 81.9%)
Sample Size	1166	23

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	**92**

Pump Event Summary: SynchroMed II 40 mL	N
Pump Motor Stall	37
Pump Reservoir Volume Discrepancy	22
Pump Underinfusion	10
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Device Malfunction	2
Pump Not Infusing	2
Other[a]	15
Total	**304**

[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	45
Pumps Currently Active in Study	39
Initial Product Performance Events	0
Median Follow-up Time (Months)	0
Cumulative Follow-up Time (Months)	44

There is not sufficient data to report on SynchroMed III 20 mL (model 8667-20) 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: 8637-40	
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).

3.3.3.4 Model 8667-40

Model/Name	SynchroMed III 40 mL
FDA Approval Date	October 2023
Pumps Enrolled	145
Pumps Currently Active in Study	130
Initial Product Performance Events	0
Median Follow-up Time (Months)	0.4
Cumulative Follow-up Time (Months)	165

There is not sufficient data to report on SynchroMed III 40 mL (model 8667-40) 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: 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

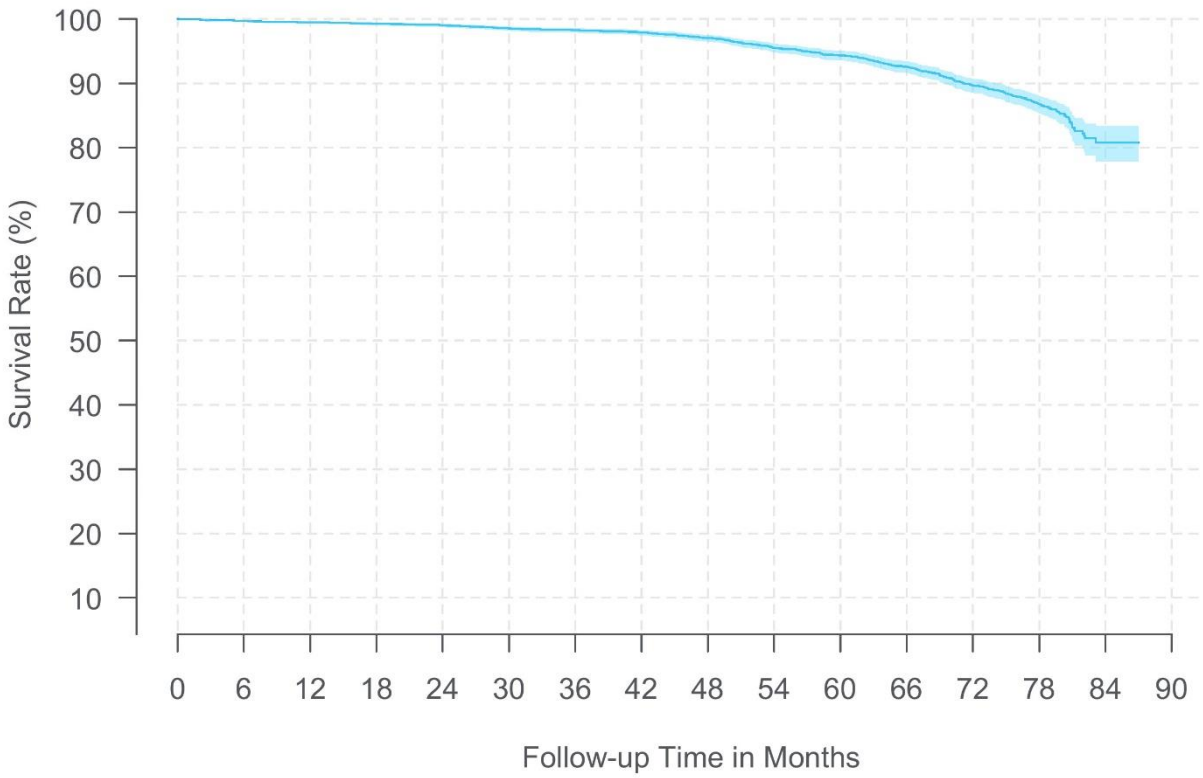
[a] Dependent on flow rate. Designed to shut off at 84 months.

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

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

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

Model/Name	Pre-Enhancements
FDA Approval Date	September 2003
Pumps Enrolled	7,593
Pumps Currently Active in Study	2
Initial Product Performance Events	399
Median Follow-up Time (Months)	34.7
Cumulative Follow-up Time (Months)	294,382



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	5294	4575	3818	3159	2567

Time Interval	6 Years	7 Years	At 87 Months
Survival (95% CI)	89.7% (88.5%, 90.8%)	80.8% (77.8%, 83.4%)	80.8% (77.8%, 83.4%)
Sample Size	1891	54	28

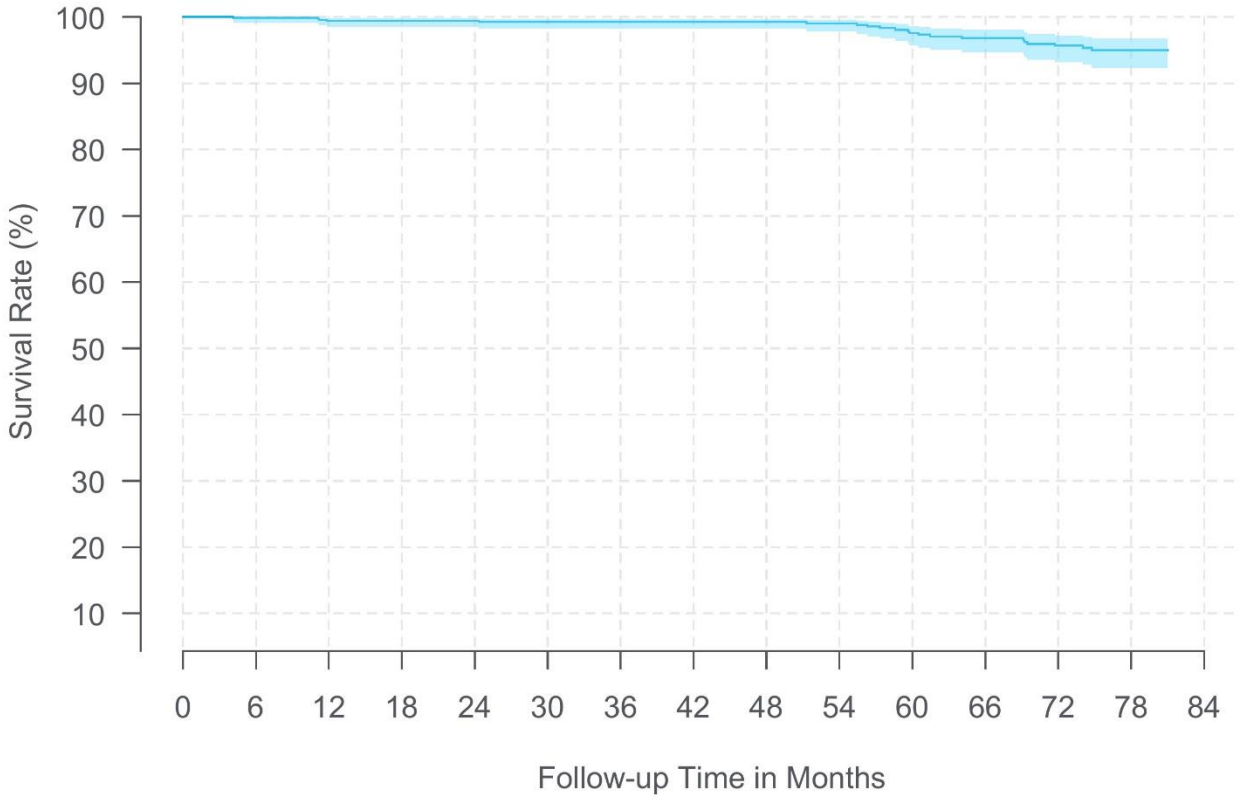
Pump Event Summary: SynchroMed II Pre-enhancements	Total
RPA Determination	**269**
Pump Motor Stall	165
Laboratory overinfusion finding	35
Battery High Resistance	10
Corrosion And/Or Gear Wear	10
Reduced Battery Performance	9
Deformed Pump Tube	6
Motor Feedthrough Anomaly	6
No Anomaly Found By RPA	6
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 Event Summary: SynchroMed II Pre-enhancements	Total
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
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	900
Pumps Currently Active in Study	27
Initial Product Performance Events	21
Median Follow-up Time (Months)	48.5
Cumulative Follow-up Time (Months)	40,572



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% (95.7%, 98.6%)
Sample Size	686	575	507	453	393

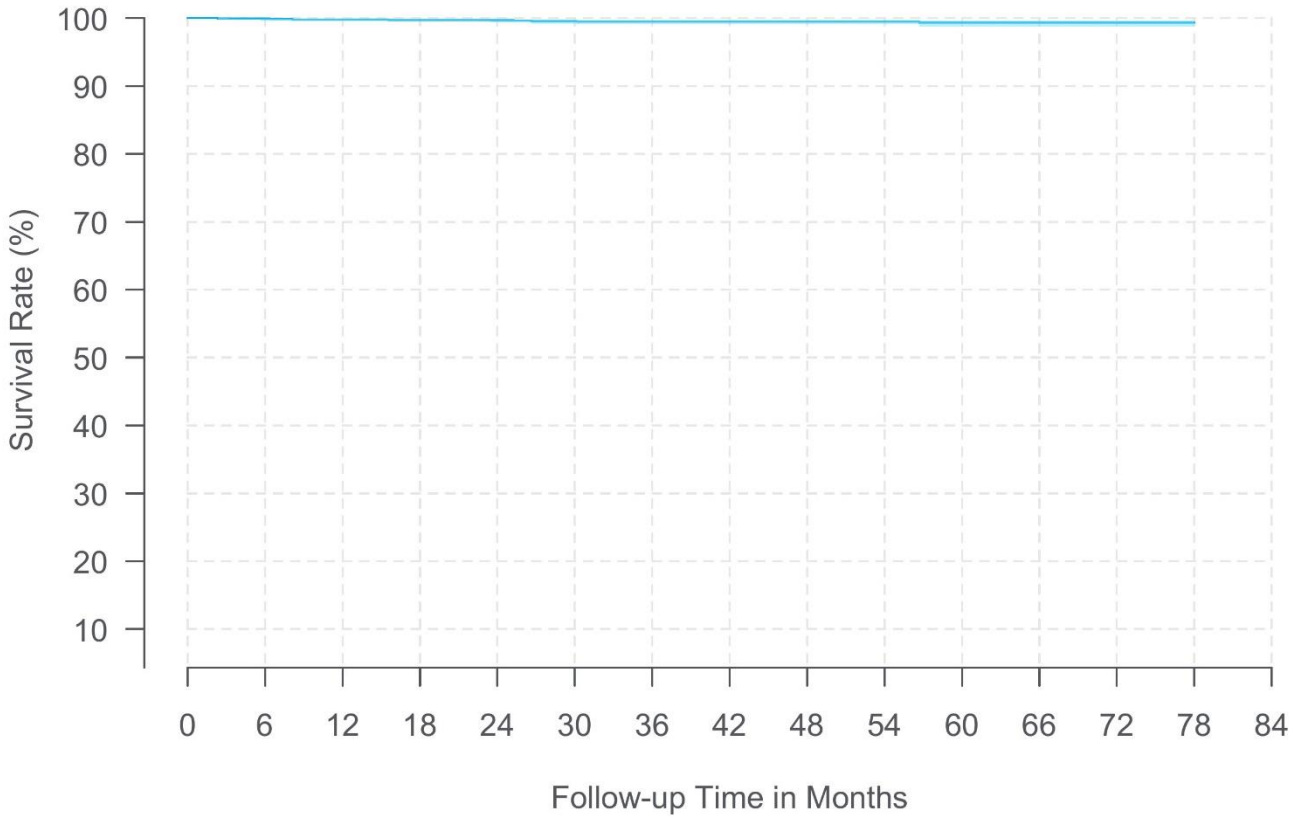
Time Interval	6 Years	At 81 Months
Survival (95% CI)	95.7% (93.2%, 97.2%)	95.0% (92.3%, 96.8%)
Sample Size	320	64

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

Pump Event Summary: SynchroMed II GW3/FT Enhancements	Total
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	3,979
Pumps Currently Active in Study	1,988
Initial Product Performance Events	13
Median Follow-up Time (Months)	23.2
Cumulative Follow-up Time (Months)	112,166



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%)	99.5% (99.1%, 99.7%)	99.5% (99.1%, 99.7%)	99.3% (98.7%, 99.7%)
Sample Size	2708	1947	1377	877	457

Time Interval	6 Years	At 78 Months
Survival (95% CI)	99.3% (98.7%, 99.7%)	99.3% (98.7%, 99.7%)
Sample Size	133	50

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	**6**
Pump Reservoir Volume Discrepancy	2
Pump Underinfusion	2
Device Malfunction	1
Catheter Kink	1
Total	**13**

[a] Motor stall that occurred within 7 months 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	4,640	714	129	39.0	190,651
SynchroMed II 40 mL	September 2003	7,832	1,303	304	26.3	256,470
SynchroMed II Pre-enhancements[a]	September 2003	7,593	2	399	34.7	294,382
SynchroMed II GW3/FT enhancements[a]	September 2015 (GW3) November 2015 (FT)	900	27	21	48.5	40,572
SynchroMed II GW3/FT/DLC enhancements[a]	April 2017 (DLC)	3,979	1,988	13	23.2	112,166
SynchroMed III 20 mL	October 2023	45	39	0	0.0	44
SynchroMed III 40 mL	October 2023	145	130	0	0.4	165

[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%	99.4%	98.9%	98.4%	97.3%
	(99.3%, 99.8%)	(99.0%, 99.6%)	(98.5%, 99.2%)	(97.9%, 98.8%)	(96.6%, 97.9%)
SynchroMed II 40 mL	99.6%	99.2%	98.6%	97.4%	94.4%
	(99.4%, 99.7%)	(98.9%, 99.4%)	(98.2%, 98.9%)	(96.9%, 97.9%)	(93.5%, 95.2%)
SynchroMed II Pre-Enhancements	99.5%	99.0%	98.3%	97.0%	94.4%
	(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%)	(95.7%, 98.6%)
SynchroMed II GW3/FT/DLC Enhancements	99.8%	99.7%	99.5%	99.5%	99.3%
	(99.6%, 99.9%)	(99.4%, 99.8%)	(99.1%, 99.7%)	(99.1%, 99.7%)	(98.7%, 99.7%)

Model Name	6 Years	7 Years
SynchroMed II 20 mL	94.9%	90.1%
	(93.8%, 95.8%)	(87.5%, 92.2%)
SynchroMed II 40 mL	89.0%	77.7%
	(87.5%, 90.3%)	(72.7%, 81.9%)
SynchroMed II Pre-Enhancements	89.7%	80.8%
	(88.5%, 90.8%)	(77.8%, 83.4%)
SynchroMed II GW3/FT Enhancements	95.7%	
	(93.2%, 97.2%)	
SynchroMed II GW3/FT/DLC Enhancements	99.3%	
	(98.7%, 99.7%)	

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

Pump Event	Pre-Enhancements	GW3/FT Enhancements	GW3/FT/DLC Enhancements
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**	**6**
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 Underinfusion	8	0	2
Device Malfunction	6	0	1
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 Access Port Issue	0	1	0
Catheter Disconnection At Pump	0	1	0
Pump Infusion Issue	0	1	0
Pump Reservoir Issue	0	1	0

Pump Event	Pre-Enhancements	GW3/FT Enhancements	GW3/FT/DLC Enhancements
Other[a]	11	0	0
Total	**399**	**21**	**13**

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

3.4 SynchroMed II Pumps Exposed to On-Label and Off-Label Medications

The purpose of this analysis is to provide additional information regarding the product performance of SynchroMed II pumps exposed to On-Label and Off-Label medications. This report contains information outside the FDA approved labeling for the Medtronic SynchroMed II Infusion System. The long-term drug stability/compatibility and safety and/or efficacy of drugs not listed in the SynchroMed 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 SynchroMed™ 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. This data is only for SynchroMed II pumps and does not include SynchroMed III pumps.

3.4.1 Pump Groups On/Off-Label Categorization

Through October 31, 2024, 9,543 patients (56.0% female, mean/SD age 54.2/17.5 years) have enrolled in the registry and have been implanted with 12,472 SynchroMed II pumps. At least one drug record was available on each of 11,786 pumps; if no drug records were available (n=686 pumps), the pump was excluded from this analysis. 11,786 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 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 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 Results

A total of 3,564 (30.2%) SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 8,222 (69.8%) pumps wereclassified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture. There were a total of 433 reported SynchroMed II pump product performance events during the study observation period. Of the 433 pump product performance events, 430 of those were the first event and included as failures in the survival analysis. In addition to the 430 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 433 pump failure events occurred in pumps with no drug records available. Of the remaining 430 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% (430/11,786) with a median follow-up of 33.0 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=3564	Off-Label N=8222
Non-Malignant Pain	1026 (14.2%)	6212 (85.8%)
Malignant Pain	47 (2.9%)	1557 (97.1%)
Spasticity	2491 (90.7%)	255 (9.3%)
Multiple/Unknown	0 (0.0%)	198 (100%)

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

3.4.3.1 Total Study Population

A total of 3,564 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 8,222 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.

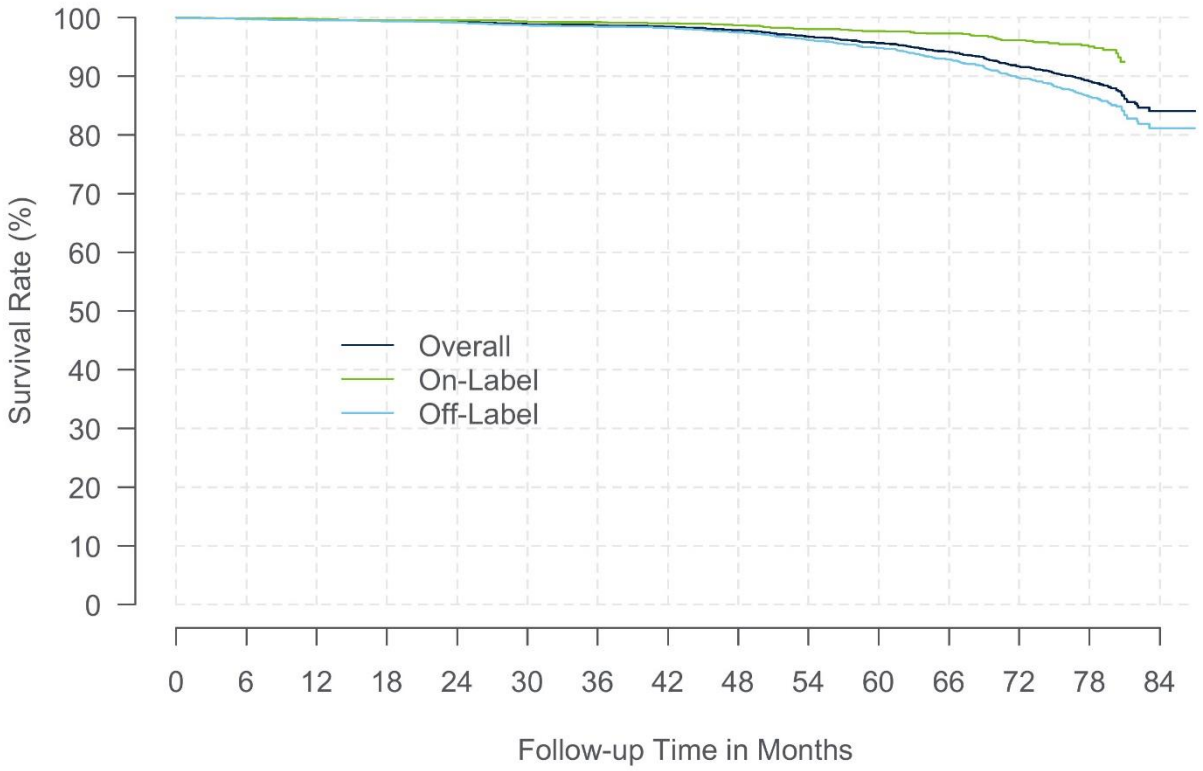


Figure 3.5: SynchroMed II Cumulative Survival (All Therapies)

Table 3.18: Survival Summary Table: All Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	At 87 Mos
Overall	Survival	99.6%	99.3%	98.7%	97.8%	95.7%	91.7%	84.1%	84.1%
	Sample Size	8468	7002	5658	4454	3397	2335	66	31
On-Label	Survival	99.7%	99.5%	99.2%	98.7%	97.7%	96.2%	-	-
	Sample Size	2598	2145	1704	1311	1024	783	-	-
Off-Label	Survival	99.6%	99.2%	98.5%	97.5%	94.8%	89.8%	81.2%	81.2%
	Sample Size	5870	4857	3954	3143	2373	1552	48	24

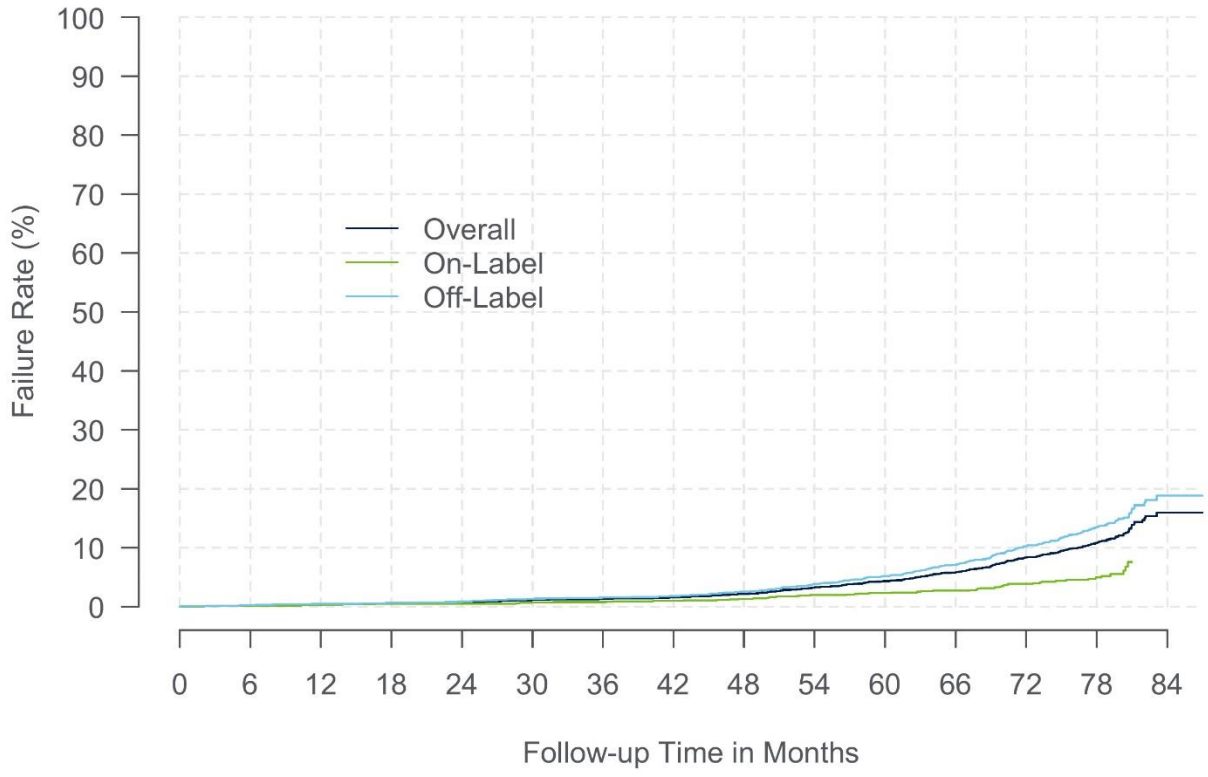


Figure 3.6: SynchroMed II Cumulative Failure (All Therapies)

Table 3.19: Failure Summary Table: All Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	At 87 Mos
Overall	Failure	0.4%	0.7%	1.3%	2.2%	4.3%	8.3%	15.9%	15.9%
	Sample Size	8468	7002	5658	4454	3397	2335	66	31
On-Label	Failure	0.3%	0.5%	0.8%	1.3%	2.3%	3.8%	-	-
	Sample Size	2598	2145	1704	1311	1024	783	-	-
Off-Label	Failure	0.4%	0.8%	1.5%	2.5%	5.2%	10.2%	18.8%	18.8%
	Sample Size	5870	4857	3954	3143	2373	1552	48	24

3.4.3.2 Pain Study Population

A total of 1,073 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 7,769 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.

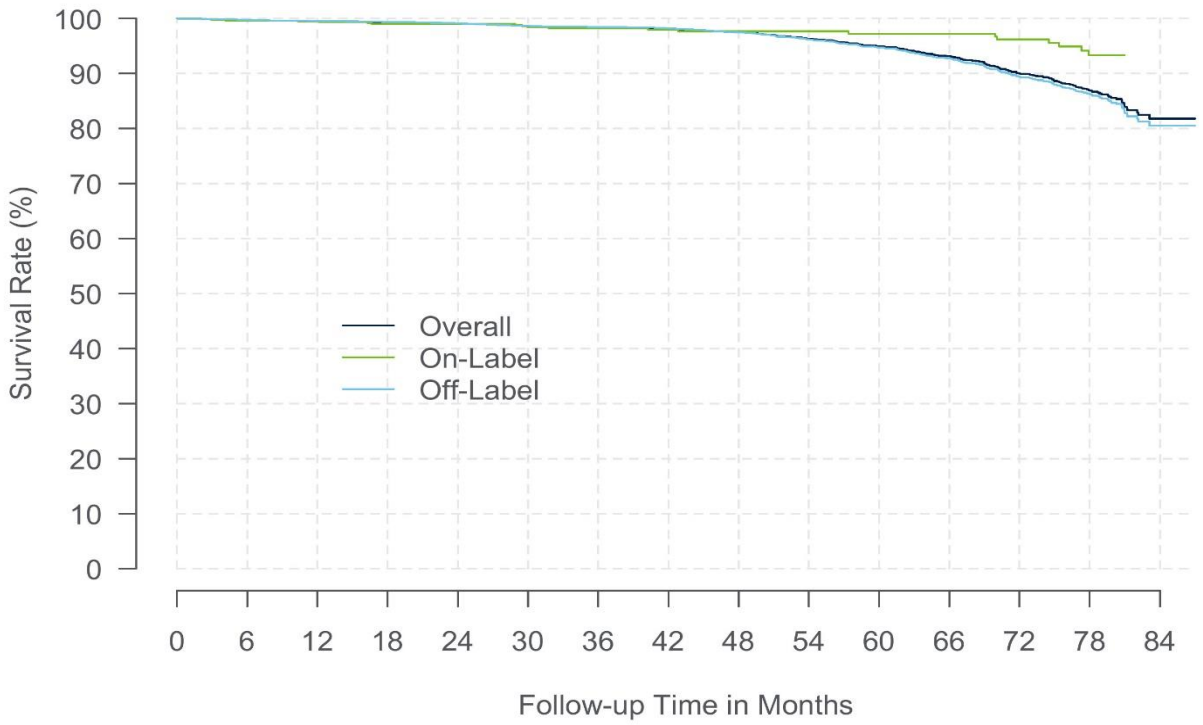


Figure 3.7: SynchroMed II Cumulative Survival (Pain Therapies)

Table 3.20: Survival Summary Table: Pain Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	At 87 Mos
Pain Overall	Survival	99.5%	99.1%	98.5%	97.5%	95.0%	90.0%	81.8%	81.8%
	Sample Size	6228	5108	4107	3214	2431	1605	52	25
On Label	Survival	99.5%	99.1%	98.2%	97.7%	97.3%	96.2%	-	-
	Sample Size	727	556	408	286	225	175	-	-
Off Label	Survival	99.5%	99.1%	98.5%	97.5%	94.8%	89.4%	80.5%	80.5%
	Sample Size	5501	4552	3699	2928	2206	1430	45	22

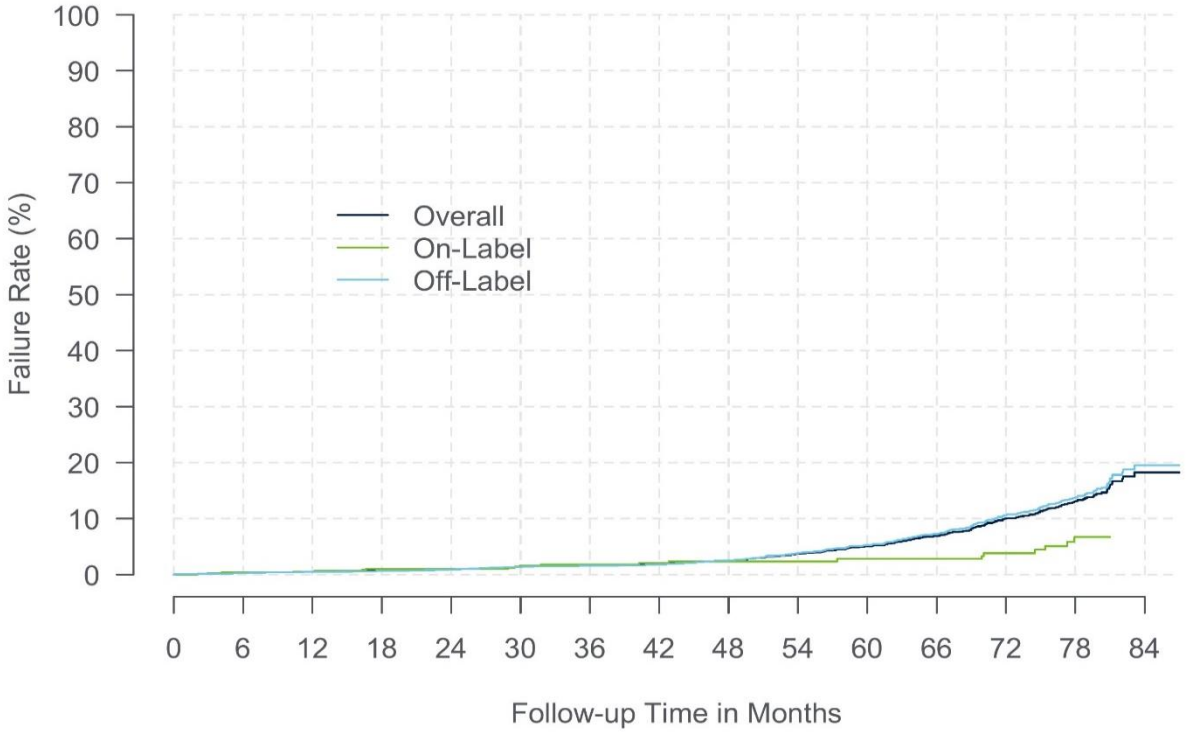


Figure 3.8: SynchroMed II Cumulative Failure (Pain Therapies)

Table 3.21: Failure Summary Table: Pain Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	At 87 Mos
Overall	Failure	0.5%	0.9%	1.5%	2.5%	5%	10%	18.2%	18.2%
	Sample Size	6228	5108	4107	3214	2431	1605	52	25

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	At 87 Mos
On-Label	Failure	0.5%	0.9%	1.8%	2.3%	2.7%	3.8%	-	-
	Sample Size	727	556	408	286	225	175	-	-
Off-Label	Failure	0.5%	0.9%	1.5%	2.5%	5.2%	10.6%	19.5%	19.5%
	Sample Size	5501	4552	3699	2928	2206	1430	45	22

3.4.3.3 Spasticity Study Population

A total of 2,491 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 255 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.

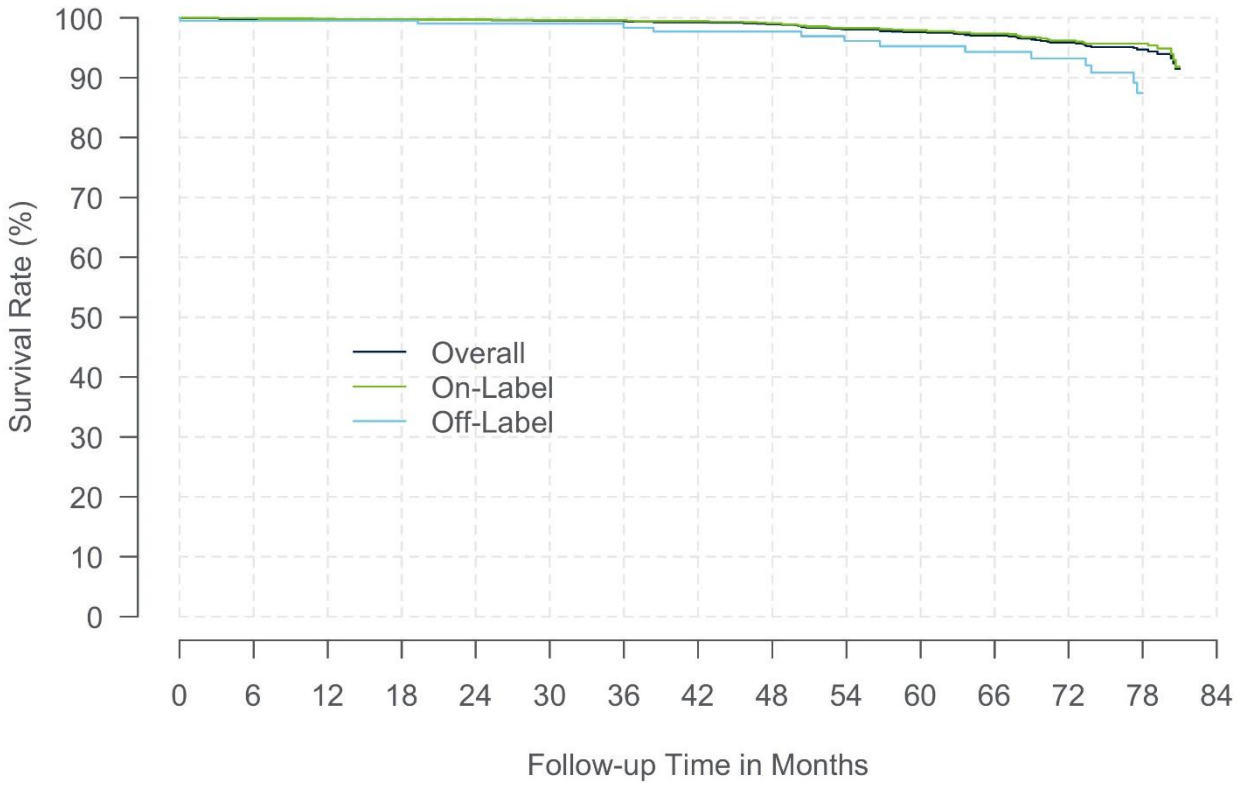


Figure 3.9: SynchroMed II Cumulative Survival (Spasticity Therapies)

Table 3.22: Survival Summary Table: Spasticity Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	At 81 Mos
Overall	Survival	99.8%	99.7%	99.5%	98.9%	97.6%	95.9%	91.5%
	Sample Size	2078	1766	1445	1157	904	690	77
On-Label	Survival	99.8%	99.7%	99.6%	99.1%	97.9%	96.2%	91.8%
	Sample Size	1871	1589	1296	1025	799	608	60
Off-Label	Survival	99.5%	99.0%	98.4%	97.7%	95.3%	93.3%	-
	Sample Size	207	177	149	132	105	82	-

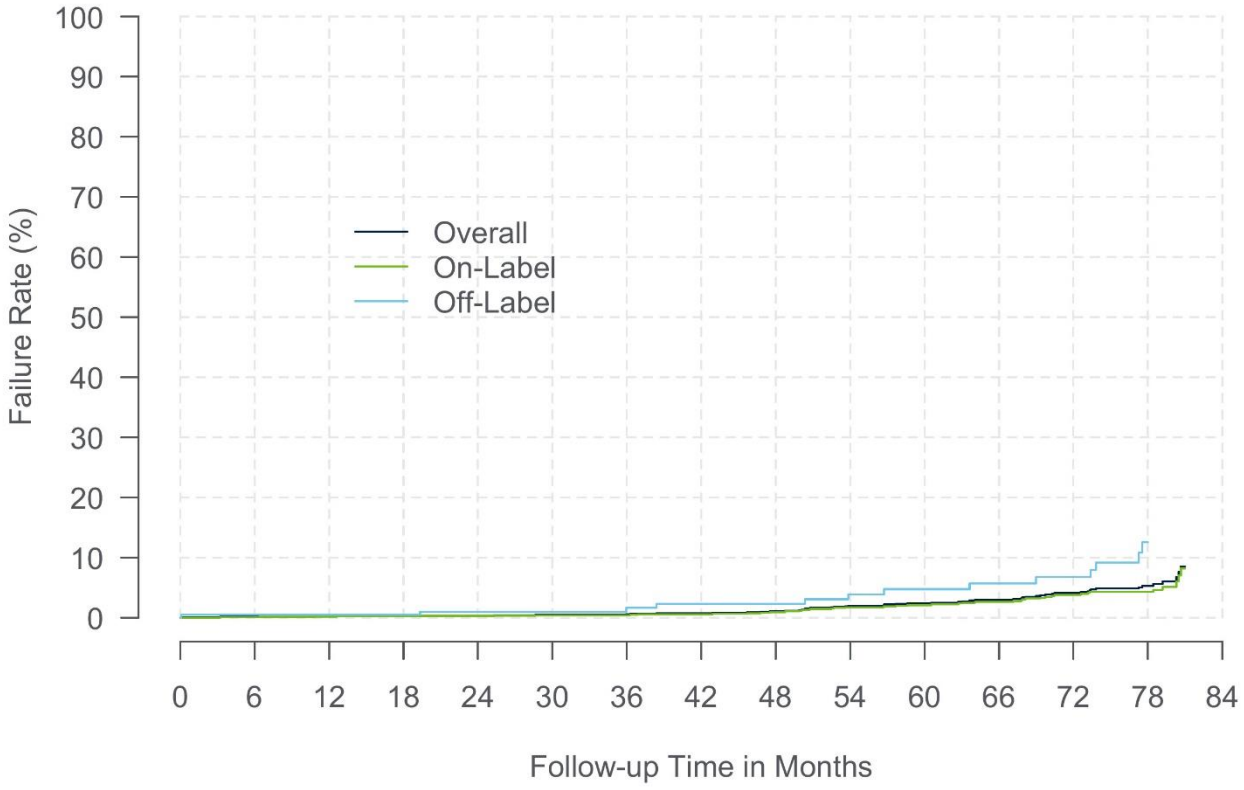


Figure 3.10: SynchroMed II Cumulative Failure (Spasticity Therapies)

Table 3.23: Failure Summary Table: Spasticity Therapies

Category	Time Interval	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	At 81 Mos
Overall	Failure	0.2%	0.3%	0.5%	1.1%	2.4%	4.1%	8.5%
	Sample Size	2078	1766	1445	1157	904	690	77
On-Label	Failure	0.2%	0.3%	0.4%	0.9%	2.1%	3.8%	8.2%
	Sample Size	1871	1589	1296	1025	799	608	60
Off-Label	Failure	0.5%	1%	1.6%	2.3%	4.7%	6.7%	-
	Sample Size	207	177	149	132	105	82	-

3.4.4 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 = 7,593), Off-Label medication exposure is associated with an overall 2.6 times greater risk of pump failures (95% confidence interval [1.963, 3.367]) 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 = 3,583), Off-Label medication exposure is associated with an overall 1.4 times greater risk of pump failures (95% confidence interval [0.384, 5.075]) 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 99.1% compared to a survival of 99.4% 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 19.8 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 69.9% of pumps with Spasticity as the indication (2,491/2,746 total spasticity pumps vs. 1,073/8,842 total pain pumps: Spasticity versus Pain pumps respectively). While the Off-Label group consisted of 94.5% of pumps with pain indications (7,769 vs. 255: 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 Off-Label 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, 2024, there were 12,199 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=13,848) 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 473,340 months (39,445 years). Table 3.24 provides the number and percentage of catheters by model.

Table 3.24: Targeted Drug Delivery Catheter Counts by Model

Model Name	N (%)
Currently Manufactured[a]	**3495 (28.6%)**
8780 (US & OUS)	1659 (13.6%)
8781 (US & OUS)	1552 (12.7%)
8731SC (OUS)	284 (2.3%)
Revised Catheters	**2816 (23.1%)**
Revised As Designed[b]	872 (7.1%)
Revised Not As Designed[c]	742 (6.1%)
Ascenda Revised As Designed[d]	681 (5.6%)
Grafted Not As Designed[e]	521 (4.3%)
No Longer Manufactured	**5425 (44.5%)**
8709	2925 (24%)
8709SC	1110 (9.1%)
8711	665 (5.5%)
8731	538 (4.4%)
8703W	187 (1.5%)
Other/Unspecified	**463 (3.8%)**

Model Name	N (%)
Total	**12199 (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 1,876 product performance-related events with an underlying reported etiology related to catheter function. This includes 1,862 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=531), catheter dislodgement (n=424), catheter kink (n=277), or catheter break/cut (n=271). Of the 1,876 events, 1,599 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:

- 1,599 had follow-up time cut-off due to product performance-related events.
- 8,577 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.
- 2,023 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

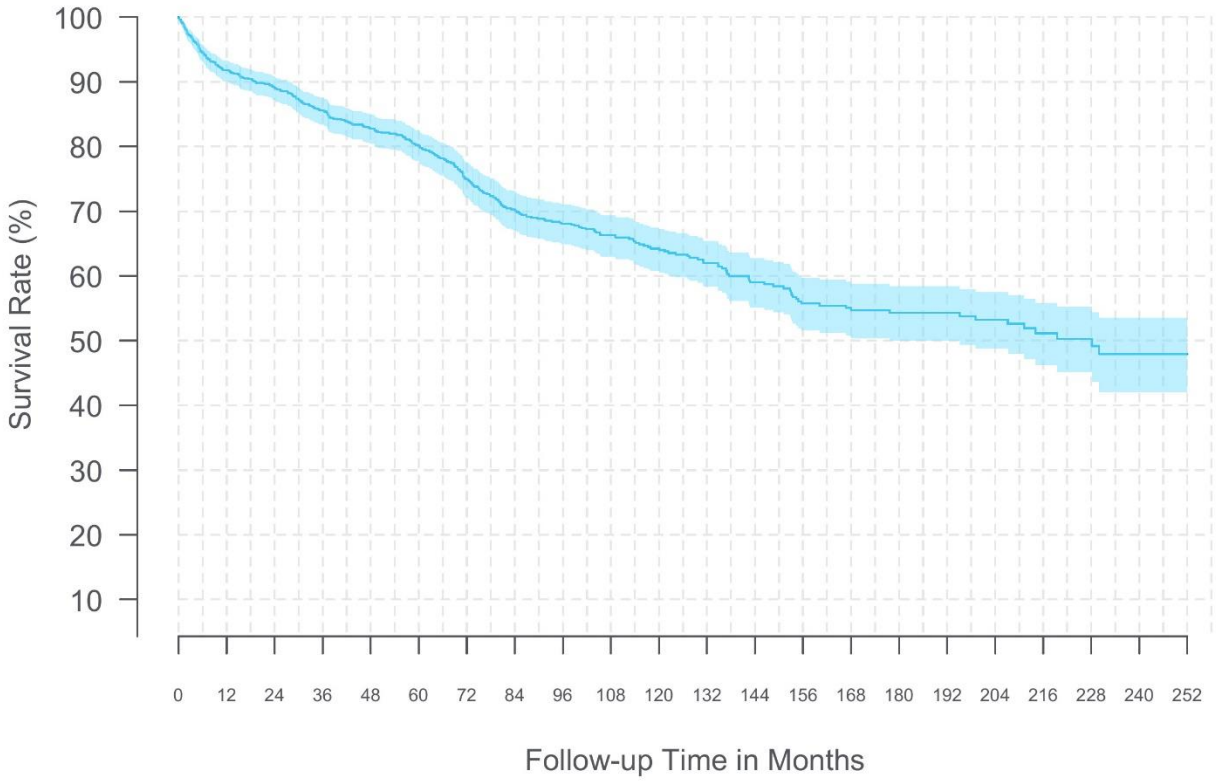
The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 12 months of follow-up at the time of the report cut-off for each model.

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	2,925
Catheters Currently Active in Study	92
Initial Product Performance Events	366
Median Follow-up Time (Months)	18.0
Cumulative Follow-up Time (Months)	102,675



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.8% (90.1%, 93.3%)	89.1% (87.1%, 90.8%)	85.6% (83.4%, 87.5%)	82.8% (80.4%, 84.9%)	80.1% (77.6%, 82.4%)
Sample Size	996	943	876	781	670

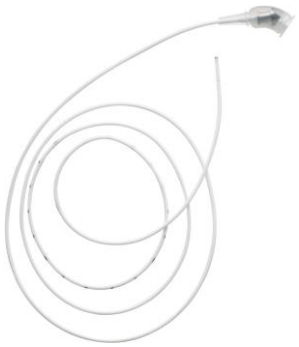
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	75.0% (72.1%, 77.6%)	70.3% (67.2%, 73.1%)	68.1% (64.9%, 71.0%)	66.3% (63.0%, 69.4%)	64.2% (60.8%, 67.5%)
Sample Size	577	505	422	338	286

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	62.0% (58.4%, 65.4%)	59.0% (55.1%, 62.7%)	55.7% (51.5%, 59.7%)	54.7% (50.4%, 58.8%)	54.3% (50.0%, 58.4%)
Sample Size	232	185	163	150	137

Time Interval	16 Years	17 Years	18 Years	19 Years	20 Years
Survival (95% CI)	54.3% (50.0%, 58.4%)	53.2% (48.7%, 57.5%)	51.1% (46.2%, 55.9%)	50.3% (45.1%, 55.2%)	47.9% (42.0%, 53.5%)
Sample Size	114	87	61	45	27

Time Interval	21 Years
Survival (95% CI)	47.9% (42.0%, 53.5%)
Sample Size	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
Trimmable Segments	Pump end

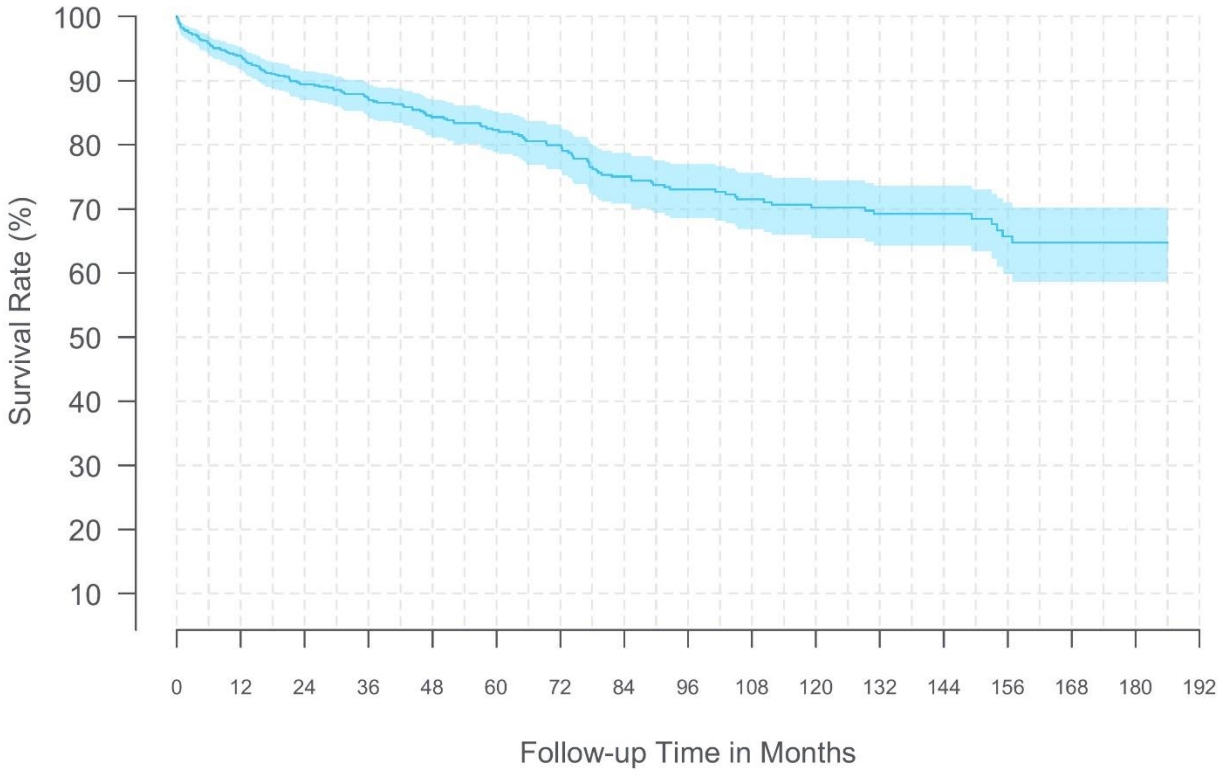


Catheter Event Summary: 8709	N
Catheter Dislodgement	95
Catheter Occlusion	88
Catheter Break/Cut	79
Catheter Kink	31
Catheter Disconnection At Pump	20
Catheter Leakage	16
Pump Connector Break/Cut	10
Catheter Dysfunction	6
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Related Complication	3
Device Issue	2
Device Malfunction	2
Other[a]	10
Total	**366**

[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	1,110
Catheters Currently Active in Study	106
Initial Product Performance Events	155
Median Follow-up Time (Months)	28.3
Cumulative Follow-up Time (Months)	50,935



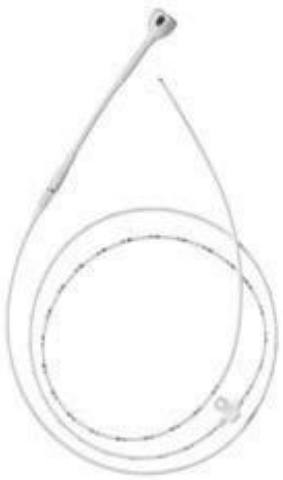
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.8% (91.9%, 95.3%)	89.4% (87.0%, 91.5%)	87.2% (84.4%, 89.5%)	84.3% (81.2%, 87.0%)	82.3% (78.9%, 85.2%)
Sample Size	668	520	437	361	298

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.0% (76.3%, 83.1%)	75.0% (70.8%, 78.8%)	73.0% (68.6%, 77.0%)	71.5% (66.9%, 75.6%)	70.2% (65.4%, 74.5%)
Sample Size	259	242	199	174	155

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	69.2% (64.3%, 73.6%)	69.2% (64.3%, 73.6%)	65.7% (59.9%, 70.9%)	64.7% (58.6%, 70.2%)	64.7% (58.6%, 70.2%)
Sample Size	135	103	68	43	26

Time Interval	At 186 Months
Survival (95% CI)	64.7% (58.6%, 70.2%)
Sample Size	23

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
Trimmable Segments	Pump end

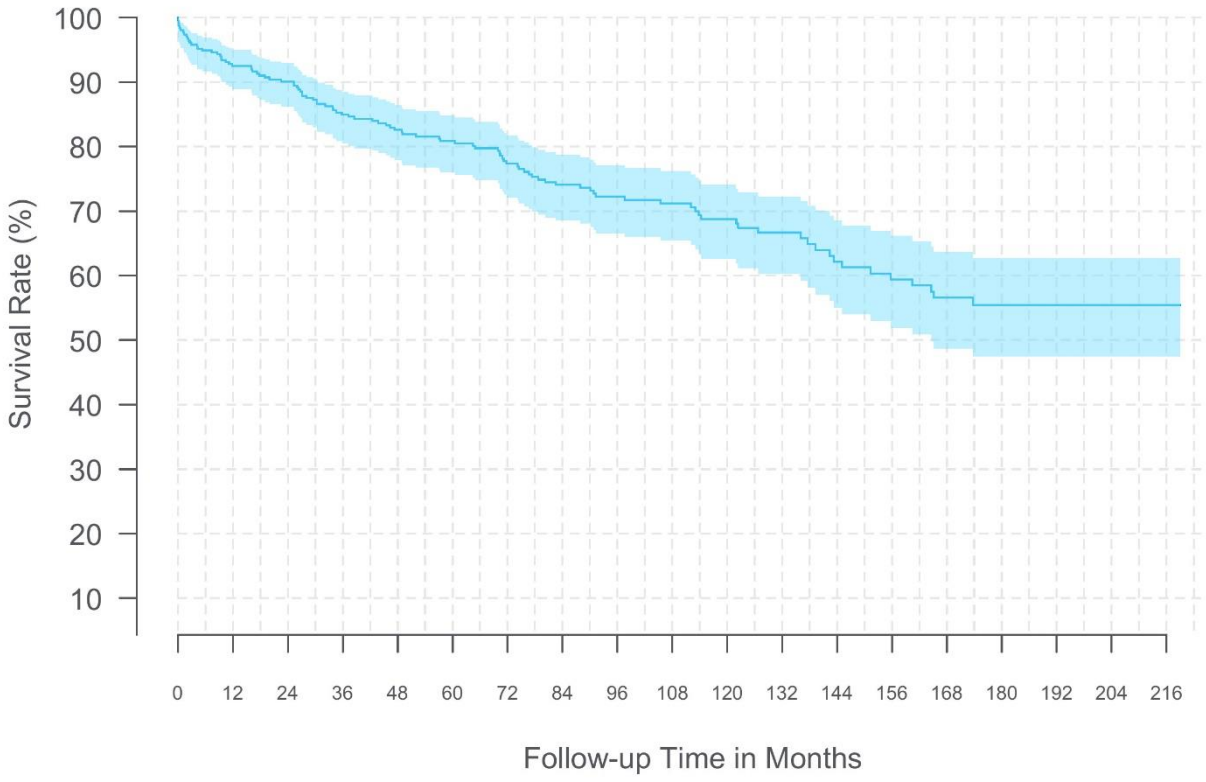


Catheter Event Summary: 8709SC	N
Catheter Occlusion	42
Catheter Break/Cut	36
Catheter Dislodgement	34
Catheter Leakage	9
Catheter Disconnection At Pump	6
Catheter Kink	6
Catheter Dysfunction	5
Catheter Related Complication	3
Pump Unable To Enter/Withdraw From Catheter Access Port	3
Catheter Damage	2
Device Damage	2
Device Malfunction	2
Other[a]	5
Total	**155**

[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	43
Initial Product Performance Events	103
Median Follow-up Time (Months)	31.9
Cumulative Follow-up Time (Months)	33,220



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (88.9%, 95.0%)	90.1% (86.2%, 92.9%)	85.0% (80.5%, 88.5%)	82.6% (77.9%, 86.4%)	80.8% (76.0%, 84.8%)
Sample Size	308	287	259	238	225

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	77.3% (72.1%, 81.7%)	74.1% (68.6%, 78.7%)	72.3% (66.6%, 77.1%)	71.2% (65.4%, 76.2%)	68.7% (62.6%, 74.1%)
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%)	62.2% (55.0%, 68.5%)	59.4% (51.9%, 66.2%)	56.6% (48.7%, 63.7%)	55.4% (47.4%, 62.7%)
Sample Size	82	69	64	53	41

Time Interval	16 Years	17 Years	18 Years	At 219 Months
Survival (95% CI)	55.4% (47.4%, 62.7%)	55.4% (47.4%, 62.7%)	55.4% (47.4%, 62.7%)	55.4% (47.4%, 62.7%)
Sample Size	32	21	21	20

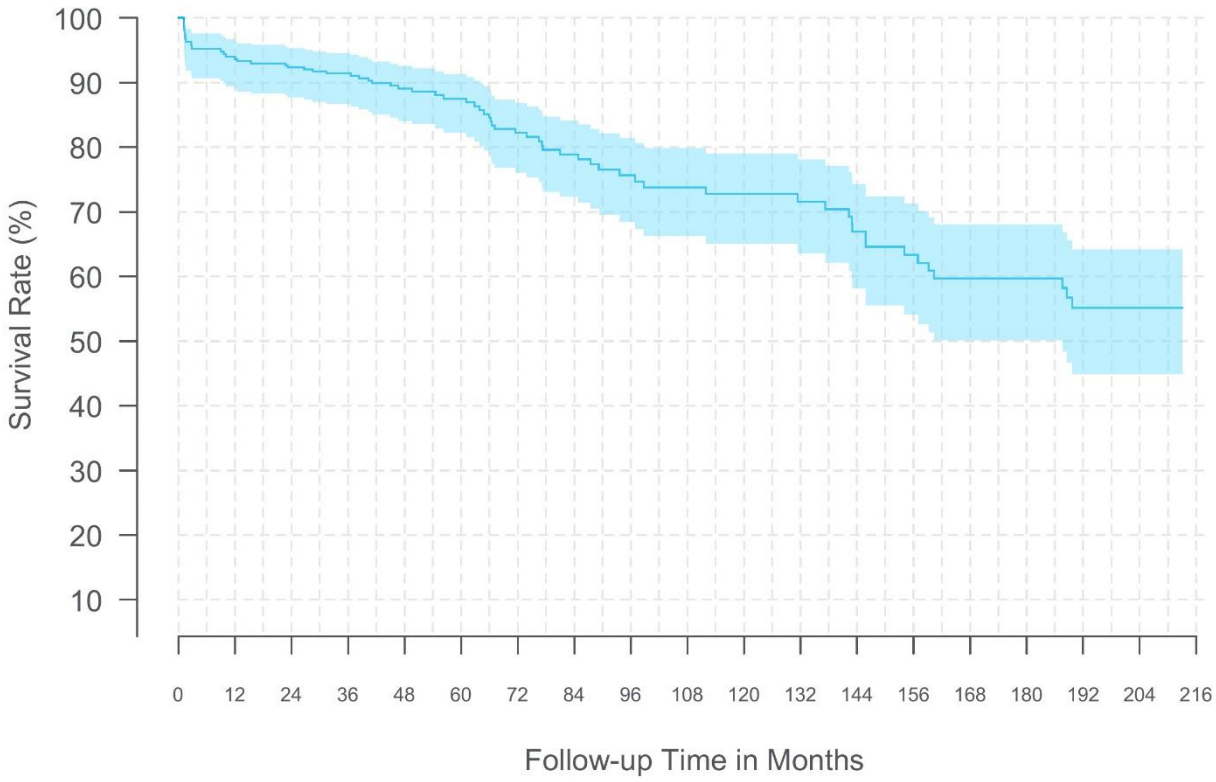
Specification: 8711	
Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Spinal and pump ends

Catheter Event Summary: 8711	N
Catheter Occlusion	33
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	**103**

[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	34
Initial Product Performance Events	66
Median Follow-up Time (Months)	33.0
Cumulative Follow-up Time (Months)	25,141



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%, 92.5%)	87.5% (82.3%, 91.3%)
Sample Size	262	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%)	75.6% (68.5%, 81.4%)	73.8% (66.3%, 79.9%)	72.8% (65.1%, 79.0%)
Sample Size	134	107	83	72	66

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	71.6% (63.6%, 78.1%)	67.0% (58.2%, 74.3%)	63.4% (54.1%, 71.3%)	59.7% (50.1%, 68.1%)	59.7% (50.1%, 68.1%)
Sample Size	61	56	49	47	41

Time Interval	16 Years	17 Years	At 213 Months
Survival (95% CI)	55.1% (44.9%, 64.2%)	55.1% (44.9%, 64.2%)	55.1% (44.9%, 64.2%)
Sample Size	32	27	21

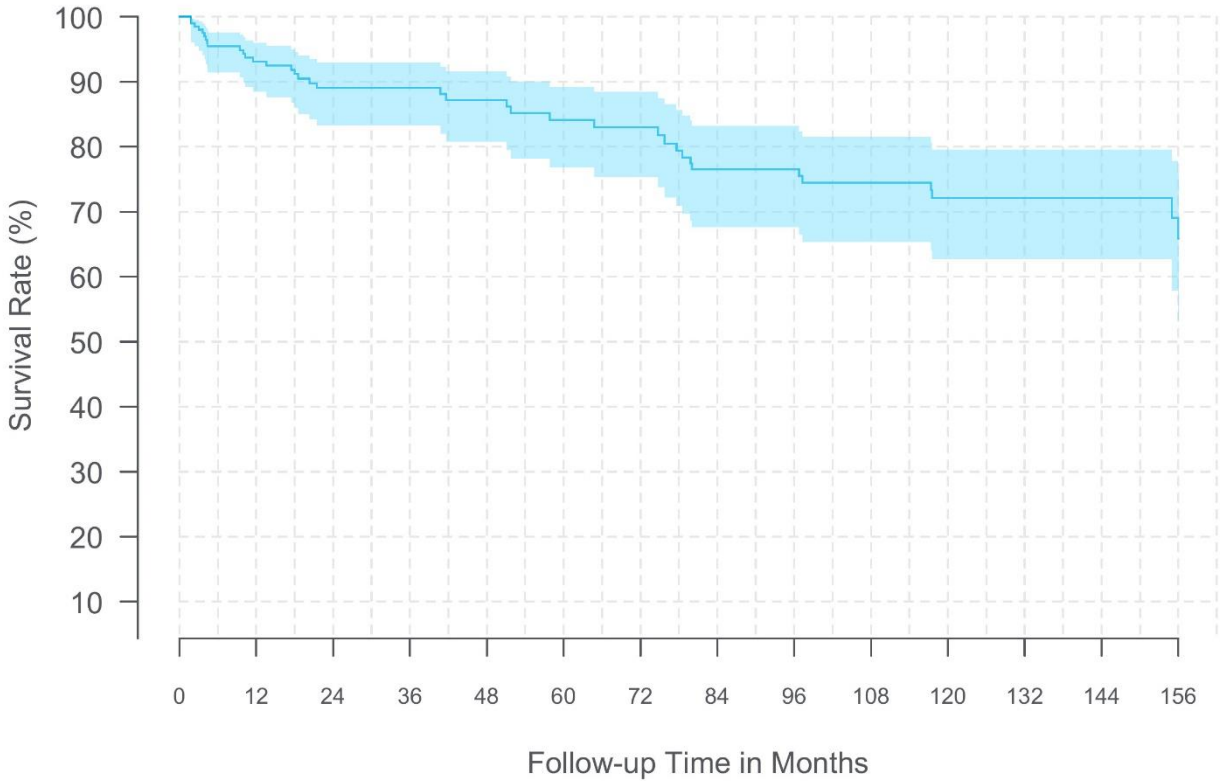
Specification: 8731	
Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed tip, radiopaque, titanium with 6 side holes
Catheter Volume	2.22 mL/cm
Trimmable Segments	Spinal end

Catheter Event Summary: 8731	N
Catheter Occlusion	25
Catheter Dislodgement	19
Catheter Break/Cut	5
Catheter Kink	5
Catheter Disconnection At Pump	3
Catheter Related Complication	3
Catheter Dysfunction	2
Other[a]	4
Total	**66**

[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	284
Catheters Currently Active in Study	52
Initial Product Performance Events	39
Median Follow-up Time (Months)	38.9
Cumulative Follow-up Time (Months)	14,071



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	78

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	83.0% (75.4%, 88.4%)	76.5% (67.6%, 83.2%)	76.5% (67.6%, 83.2%)	74.5% (65.4%, 81.5%)	72.1% (62.7%, 79.6%)
Sample Size	68	82	77	67	61

Time Interval	11 Years	12 Years	13 Years
Survival (95% CI)	72.1% (62.7%, 79.6%)	72.1% (62.7%, 79.6%)	65.9% (53.2%, 75.8%)
Sample Size	49	37	21

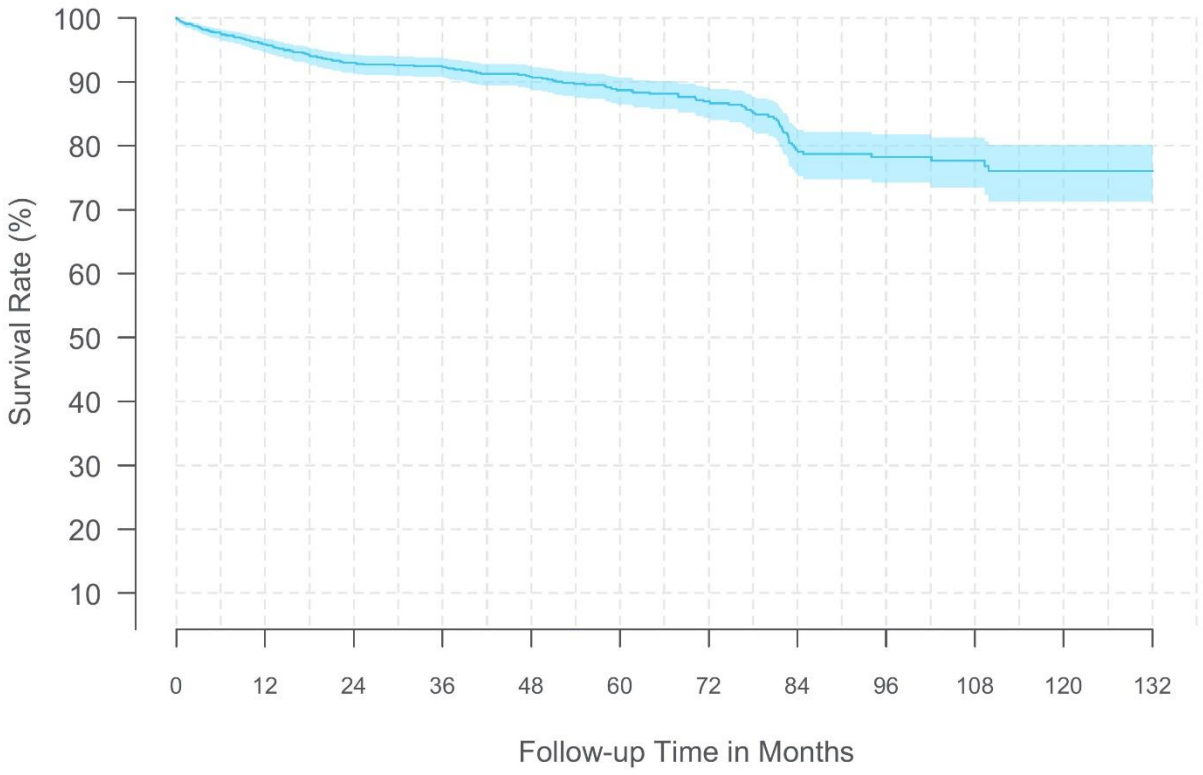
Specification: 8731SC	
Total Length	104.1 cm
Outer Diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Spinal and pump ends

Catheter Event Summary: 8731SC	N
Catheter Occlusion	15
Catheter Dislodgement	8
Catheter Kink	4
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Dysfunction	3
Catheter Leakage	2
Other[a]	3
Total	**39**

[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	1,659
Catheters Currently Active in Study	574
Initial Product Performance Events	156
Median Follow-up Time (Months)	30.3
Cumulative Follow-up Time (Months)	67,308



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	95.8% (94.6%, 96.8%)	93.0% (91.4%, 94.3%)	92.5% (90.8%, 93.9%)	90.8% (88.9%, 92.4%)	88.7% (86.5%, 90.6%)
Sample Size	1115	873	719	580	450

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	86.9% (84.3%, 89.1%)	79.1% (75.2%, 82.4%)	78.3% (74.2%, 81.8%)	77.7% (73.4%, 81.3%)	76.0% (71.2%, 80.1%)
Sample Size	351	232	156	100	60

Time Interval	11 Years
Survival (95% CI)	76.0% (71.2%, 80.1%)
Sample Size	20

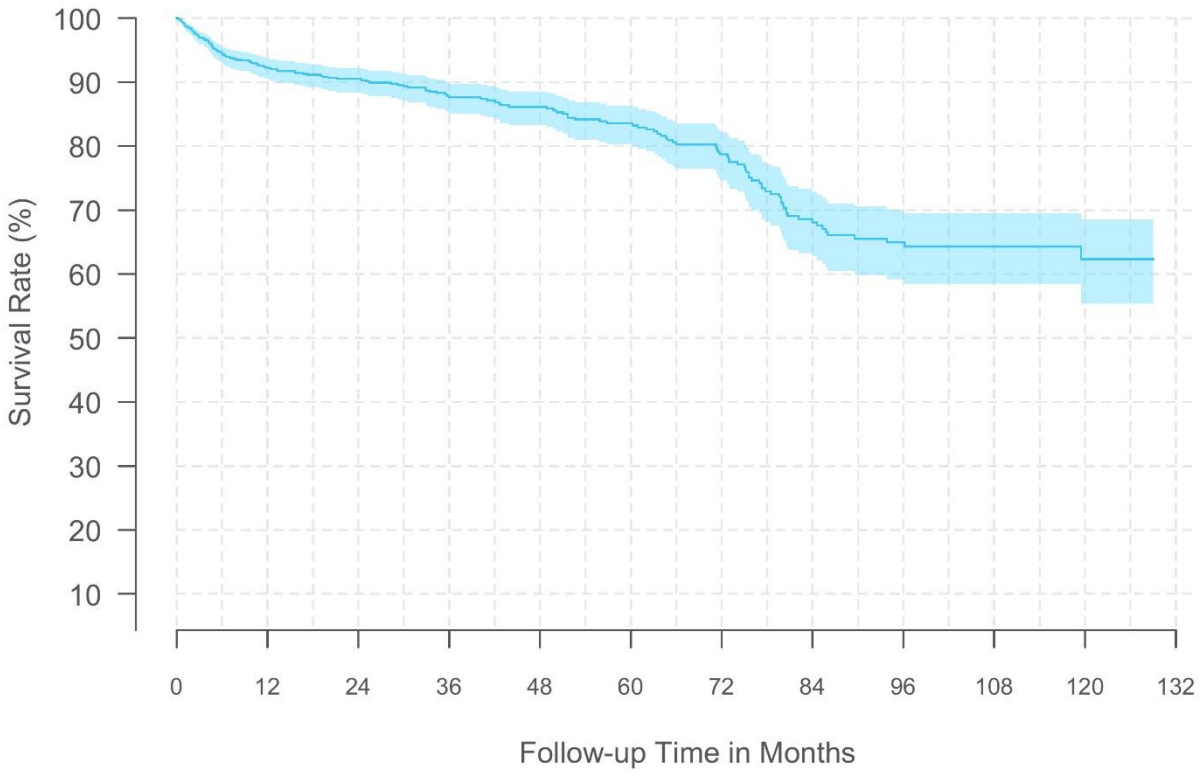
Specification: 8780	
Total Length	114 cm
Outer Diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Connector end of the spinal segment

Catheter Event Summary: 8780	N
Catheter Occlusion	57
Catheter Kink	36
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]	5
Total	**156**

[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	1,552
Catheters Currently Active in Study	439
Initial Product Performance Events	174
Median Follow-up Time (Months)	12.4
Cumulative Follow-up Time (Months)	43,084



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.3% (90.5%, 93.8%)	90.5% (88.4%, 92.2%)	87.8% (85.3%, 90.0%)	86.1% (83.3%, 88.5%)	83.6% (80.3%, 86.3%)
Sample Size	698	497	396	318	260

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	78.7% (74.7%, 82.2%)	68.1% (62.7%, 72.9%)	64.9% (59.2%, 70.1%)	64.3% (58.5%, 69.5%)	62.3% (55.4%, 68.5%)
Sample Size	203	138	104	72	30

Time Interval	At 129 Months
Survival (95% CI)	62.3% (55.4%, 68.5%)
Sample Size	20

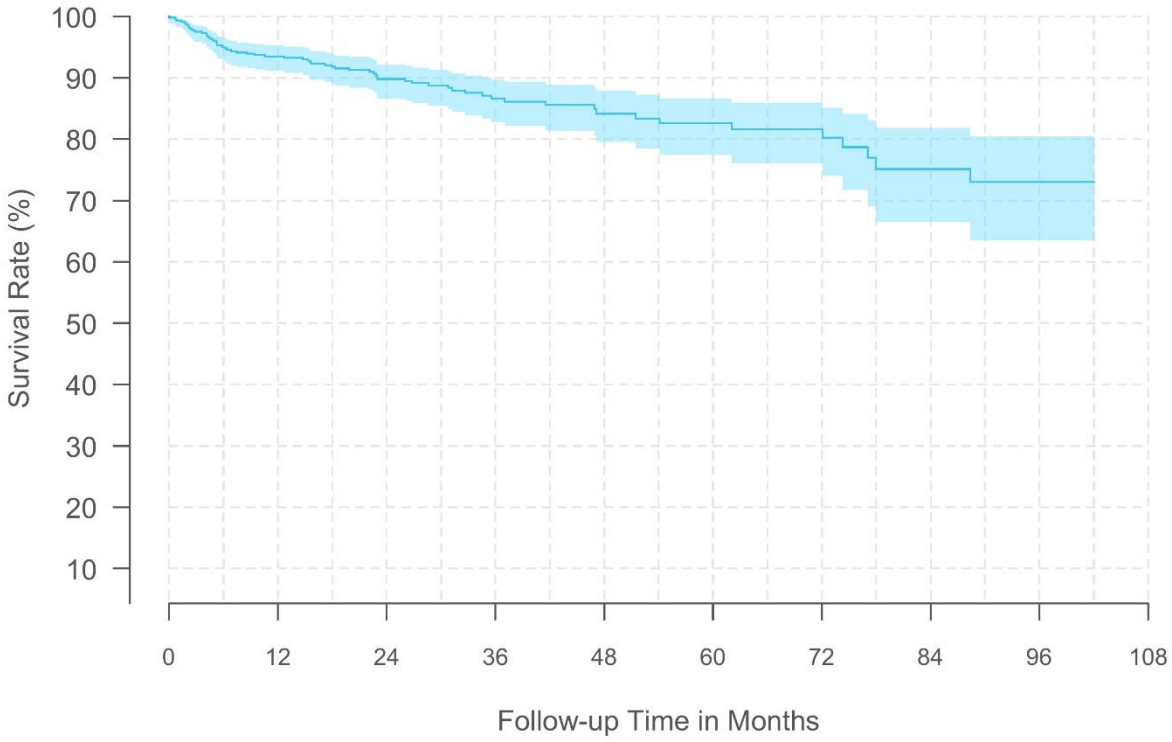
Specification: 8781	
Total Length	140 cm
Outer Diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Catheter connector ends of the spinal and pump segments

Catheter Event Summary: 8781	N
Catheter Kink	61
Catheter Occlusion	47
Catheter Dislodgement	34
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	**174**

[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	681
Catheters Currently Active in Study	240
Initial Product Performance Events	70
Median Follow-up Time (Months)	21.1
Cumulative Follow-up Time (Months)	19,094



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	93.5% (91.1%, 95.3%)	89.8% (86.7%, 92.2%)	86.6% (82.7%, 89.7%)	84.2% (79.5%, 87.8%)	82.6% (77.5%, 86.7%)
Sample Size	424	295	184	117	89

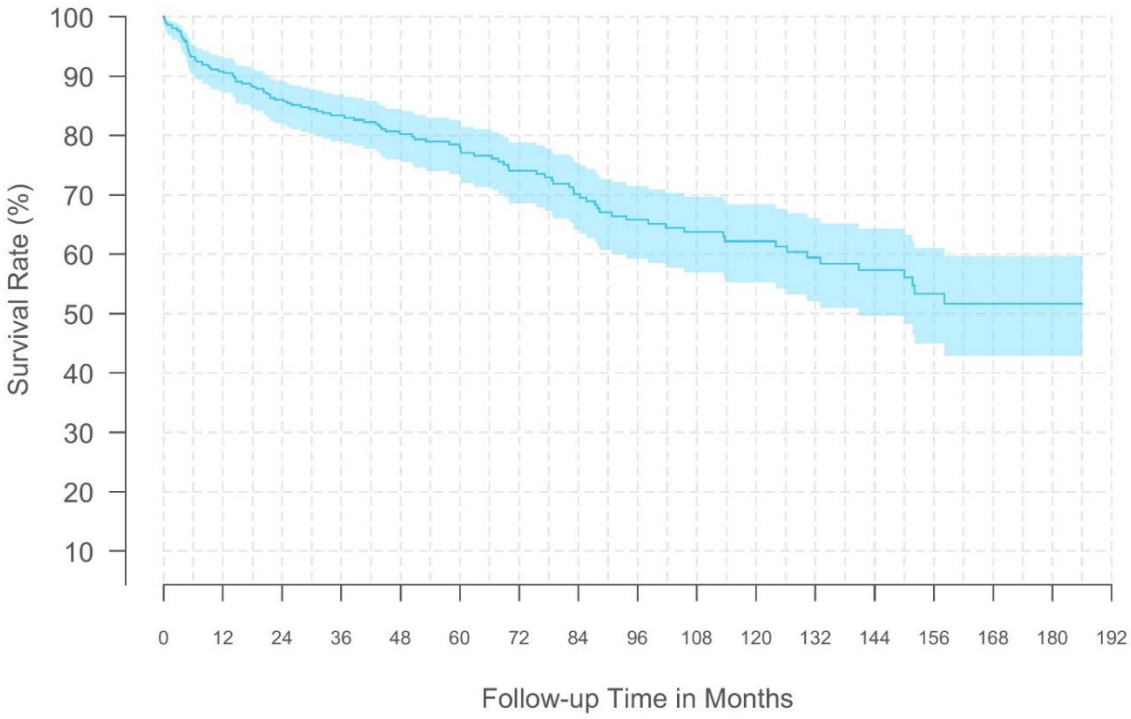
Time Interval	6 Years	7 Years	8 Years	At 102 Months
Survival (95% CI)	81.6% (76.1%, 86.0%)	75.1% (66.5%, 81.8%)	73.0% (63.5%, 80.5%)	73.0% (63.5%, 80.5%)
Sample Size	58	38	30	21

Catheter Event Summary: Ascenda RAD	N
Catheter Occlusion	25
Catheter Kink	18
Catheter Dislodgement	15
Catheter Break/Cut	3
Device Component Migration	3
Other[a]	6
Total	**70**

[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	521
Catheters Currently Active in Study	69
Initial Product Performance Events	113
Median Follow-up Time (Months)	39.0
Cumulative Follow-up Time (Months)	27,080



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	90.8% (87.5%, 93.3%)	86.0% (82.1%, 89.2%)	83.4% (79.1%, 86.9%)	80.2% (75.5%, 84.2%)	78.0% (73.0%, 82.2%)
Sample Size	323	270	231	191	168

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	74.1% (68.5%, 78.8%)	70.1% (64.1%, 75.3%)	65.8% (59.3%, 71.5%)	63.7% (57.0%, 69.7%)	62.2% (55.2%, 68.3%)

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Sample Size	142	118	98	89	75

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	59.4% (52.1%, 66.0%)	57.3% (49.7%, 64.3%)	53.3% (44.9%, 61.0%)	51.6% (42.9%, 59.7%)	51.6% (42.9%, 59.7%)
Sample Size	59	49	32	24	21

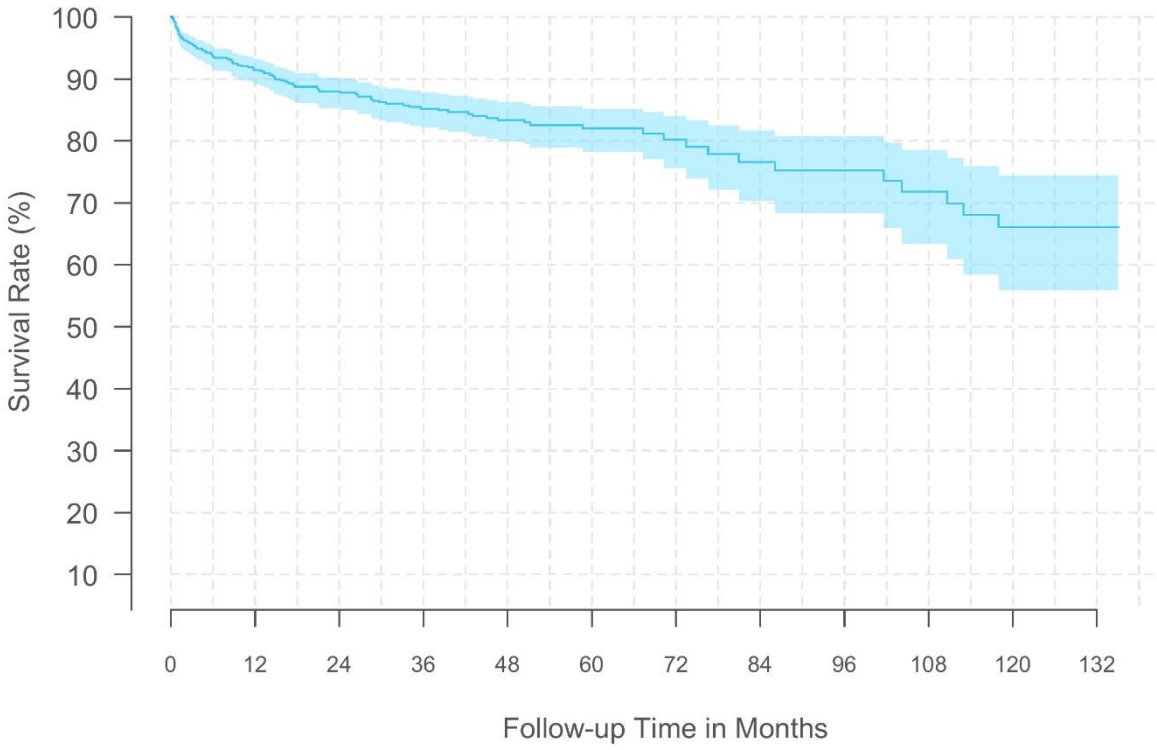
Time Interval	At 186 Months
Survival (95% CI)	51.6% (42.9%, 59.7%)
Sample Size	20

Catheter Event Summary: Grafted Not As Designed	N
Catheter Occlusion	34
Catheter Dislodgement	28
Catheter Break/Cut	15
Catheter Kink	8
Catheter Leakage	7
Catheter Related Complication	4
Pump Unable To Enter/Withdraw From Catheter Access Port	4
Catheter Dysfunction	3
Catheter Damage	2
Device Malfunction	2
Other[a]	6
Total	**113**

[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	872
Catheters Currently Active in Study	274
Initial Product Performance Events	117
Median Follow-up Time (Months)	25.6
Cumulative Follow-up Time (Months)	29,499



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.4% (89.1%, 93.2%)	88.0% (85.3%, 90.2%)	85.2% (82.1%, 87.8%)	83.3% (79.9%, 86.2%)	82.0% (78.3%, 85.2%)
Sample Size	578	435	311	228	146

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.2% (75.6%, 84.0%)	76.6% (70.4%, 81.7%)	75.2% (68.4%, 80.8%)	71.8% (63.5%, 78.5%)	66.1% (55.9%, 74.4%)
Sample Size	74	55	48	38	31

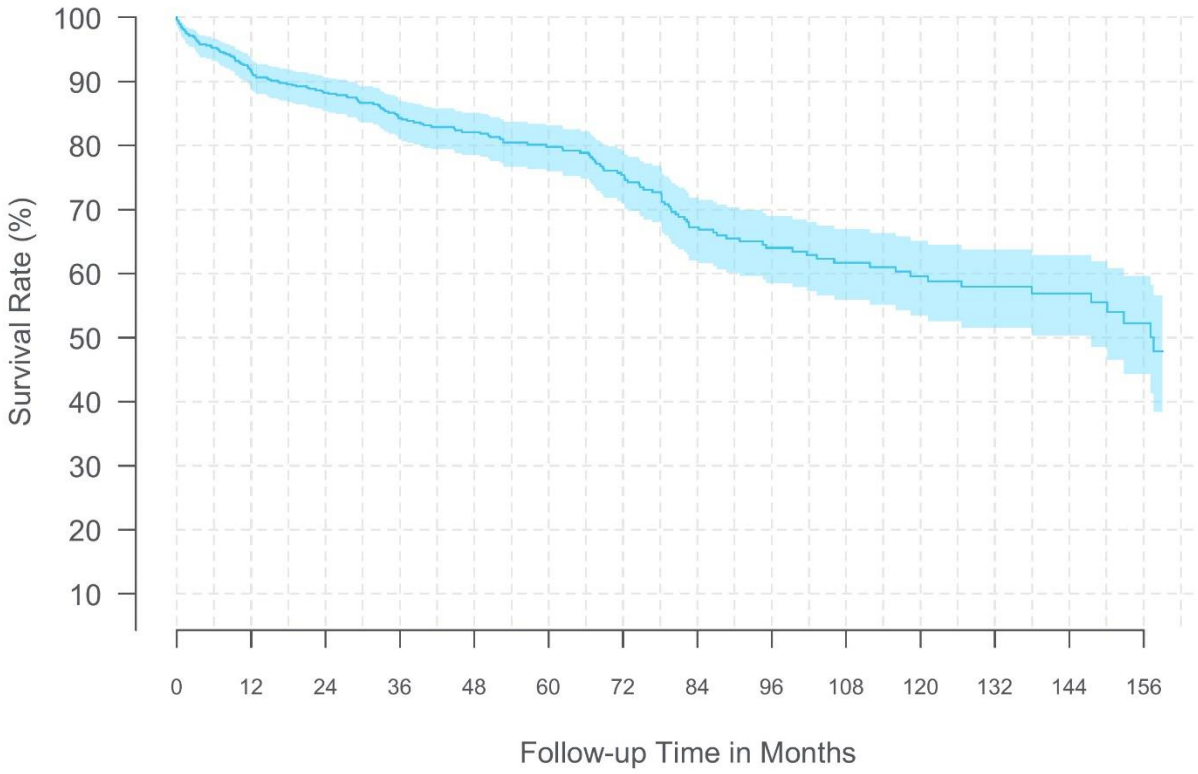
Time Interval	11 Years	At 135 Months
Survival (95% CI)	66.1% (55.9%, 74.4%)	66.1% (55.9%, 74.4%)
Sample Size	23	21

Catheter Event Summary: Revised As Designed	N
Catheter Dislodgement	57
Catheter Occlusion	30
Catheter Kink	8
Catheter Break/Cut	6
Device Component Migration	6
Catheter Leakage	3
Catheter Dysfunction	2
Pump Unable To Enter/Withdraw From Catheter Access Port	2
Other[a]	3
Total	**117**

[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	742
Catheters Currently Active in Study	86
Initial Product Performance Events	161
Median Follow-up Time (Months)	41.4
Cumulative Follow-up Time (Months)	38,246



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.5% (88.9%, 93.5%)	88.3% (85.3%, 90.6%)	84.2% (80.9%, 87.1%)	82.1% (78.5%, 85.1%)	79.8% (76.0%, 83.1%)
Sample Size	527	462	378	315	254

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	75.4% (71.0%, 79.2%)	67.3% (62.1%, 71.9%)	64.0% (58.5%, 69.0%)	61.7% (55.9%, 66.9%)	59.6% (53.5%, 65.1%)
Sample Size	205	161	120	99	77

Time Interval	11 Years	12 Years	13 Years	At 159 Months
Survival (95% CI)	57.9% (51.6%, 63.8%)	56.9% (50.3%, 62.9%)	52.3% (44.3%, 59.6%)	47.8% (38.4%, 56.6%)
Sample Size	61	41	25	21

Catheter Event Summary: Revised Not As Designed	N
Catheter Occlusion	62
Catheter Dislodgement	24
Catheter Break/Cut	18
Catheter Kink	18
Catheter Leakage	11
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

Catheter Event Summary: Revised Not As Designed	N
Total	**161**

[a] Composed of event codes with 1 event each.

3.5.3 Catheter Summary

Table 3.25: 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	2,925	92	366	18.0	102,675
8709SC	March 2006	1,110	106	155	28.3	50,935
8711	October 1999	665	43	103	31.9	33,220
8731	October 2002	538	34	66	33.0	25,141
8731SC	March 2006	284	52	39	38.9	14,071
8780	May 2012	1,659	574	156	30.3	67,308
8781	May 2012	1,552	439	174	12.4	43,084
Ascenda Revised As Designed	May 2012	681	240	70	21.1	19,094
Grafted Not As Designed	NA	521	69	113	39.0	27,080
Revised As Designed	October 2002	872	274	117	25.6	29,499
Revised Not As Designed	NA	742	86	161	41.4	38,246

Table 3.26: 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%	85.6%	82.8%	80.1%
	(90.1%, 93.3%)	(87.1%, 90.8%)	(83.4%, 87.5%)	(80.4%, 84.9%)	(77.6%, 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%	80.8%
	(88.9%, 95.0%)	(86.2%, 92.9%)	(80.5%, 88.5%)	(77.9%, 86.4%)	(76.0%, 84.8%)
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%, 92.5%)	(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	95.8%	93.0%	92.5%	90.8%	88.7%
	(94.6%, 96.8%)	(91.4%, 94.3%)	(90.8%, 93.9%)	(88.9%, 92.4%)	(86.5%, 90.6%)
8781	92.3%	90.5%	87.8%	86.1%	83.6%
	(90.5%, 93.8%)	(88.4%, 92.2%)	(85.3%, 90.0%)	(83.3%, 88.5%)	(80.3%, 86.3%)
Ascenda RAD	93.5%	89.8%	86.6%	84.2%	82.6%
	(91.1%, 95.3%)	(86.7%, 92.2%)	(82.7%, 89.7%)	(79.5%, 87.8%)	(77.5%, 86.7%)
Grafted Not As Designed	90.8%	86.0%	83.4%	80.2%	78.0%
	(87.5%, 93.3%)	(82.1%, 89.2%)	(79.1%, 86.9%)	(75.5%, 84.2%)	(73.0%, 82.2%)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Revised As Designed	91.4%	88.0%	85.2%	83.3%	82.0%
	(89.1%, 93.2%)	(85.3%, 90.2%)	(82.1%, 87.8%)	(79.9%, 86.2%)	(78.3%, 85.2%)
Revised Not As Designed	91.5%	88.3%	84.2%	82.1%	79.8%
	(88.9%, 93.5%)	(85.3%, 90.6%)	(80.9%, 87.1%)	(78.5%, 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%	75.0%	73.0%	71.5%	70.2%
	(76.3%, 83.1%)	(70.8%, 78.8%)	(68.6%, 77.0%)	(66.9%, 75.6%)	(65.4%, 74.5%)
8711	77.3%	74.1%	72.3%	71.2%	68.7%
	(72.1%, 81.7%)	(68.6%, 78.7%)	(66.6%, 77.1%)	(65.4%, 76.2%)	(62.6%, 74.1%)
8731	82.2%	78.9%	75.6%	73.8%	72.8%
	(76.1%, 86.9%)	(72.3%, 84.1%)	(68.5%, 81.4%)	(66.3%, 79.9%)	(65.1%, 79.0%)
8731SC	83.0%	76.5%	76.5%	74.5%	72.1%
	(75.4%, 88.4%)	(67.6%, 83.2%)	(67.6%, 83.2%)	(65.4%, 81.5%)	(62.7%, 79.6%)
8780	86.9%	79.1%	78.3%	77.7%	76.0%
	(84.3%, 89.1%)	(75.2%, 82.4%)	(74.2%, 81.8%)	(73.4%, 81.3%)	(71.2%, 80.1%)
8781	78.7%	68.1%	64.9%	64.3%	62.3%

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
	(74.7%, 82.2%)	(62.7%, 72.9%)	(59.2%, 70.1%)	(58.5%, 69.5%)	(55.4%, 68.5%)
Ascenda RAD	81.6%	75.1%	73.0%	-	-
	(76.1%, 86.0%)	(66.5%, 81.8%)	(63.5%, 80.5%)	-	-
Grafted Not As Designed	74.1%	70.1%	65.8%	63.7%	62.2%
	(68.5%, 78.8%)	(64.1%, 75.3%)	(59.3%, 71.5%)	(57.0%, 69.7%)	(55.2%, 68.3%)
Revised As Designed	80.2%	76.6%	75.2%	71.8%	66.1%
	(75.6%, 84.0%)	(70.4%, 81.7%)	(68.4%, 80.8%)	(63.5%, 78.5%)	(55.9%, 74.4%)
Revised Not As Designed	75.4%	67.3%	64.0%	61.7%	59.6%
	(71.0%, 79.2%)	(62.1%, 71.9%)	(58.5%, 69.0%)	(55.9%, 66.9%)	(53.5%, 65.1%)

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
8709	62.0%	59.0%	55.7%	54.7%	54.3%
	(58.4%, 65.4%)	(55.1%, 62.7%)	(51.5%, 59.7%)	(50.4%, 58.8%)	(50.0%, 58.4%)
8709SC	69.2%	69.2%	65.7%	64.7%	64.7%
	(64.3%, 73.6%)	(64.3%, 73.6%)	(59.9%, 70.9%)	(58.6%, 70.2%)	(58.6%, 70.2%)
8711	66.7%	62.2%	59.4%	56.6%	55.4%
	(60.3%, 72.3%)	(55.0%, 68.5%)	(51.9%, 66.2%)	(48.7%, 63.7%)	(47.4%, 62.7%)
8731	71.6%	67.0%	63.4%	59.7%	59.7%

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
	(63.6%, 78.1%)	(58.2%, 74.3%)	(54.1%, 71.3%)	(50.1%, 68.1%)	(50.1%, 68.1%)
8731SC	72.1%	72.1%	65.9%	-	-
	(62.7%, 79.6%)	(62.7%, 79.6%)	(53.2%, 75.8%)	-	-
8780	76.0%	-	-	-	-
	(71.2%, 80.1%)	-	-	-	-
8781	-	-	-	-	-
	-	-	-	-	-
Ascenda RAD	-	-	-	-	-
	-	-	-	-	-
Grafted Not As Designed	59.4%	57.3%	53.3%	51.6%	51.6%
	(52.1%, 66.0%)	(49.7%, 64.3%)	(44.9%, 61.0%)	(42.9%, 59.7%)	(42.9%, 59.7%)
Revised As Designed	66.1%	-	-	-	-
	(55.9%, 74.4%)	-	-	-	-
Revised Not As Designed	57.9%	56.9%	52.3%	-	-
	(51.6%, 63.8%)	(50.3%, 62.9%)	(44.3%, 59.6%)	-	-

Model Name	16 Years	17 Years	18 Years	19 Years	20 Years
8709	54.3%	53.2%	51.1%	50.3%	47.9%
	(50.0%, 58.4%)	(48.7%, 57.5%)	(46.2%, 55.9%)	(45.1%, 55.2%)	(42.0%, 53.5%)
8709SC	-	-	-	-	-
	-	-	-	-	-
8711	55.4%	55.4%	55.4%	-	-
	(47.4%, 62.7%)	(47.4%, 62.7%)	(47.4%, 62.7%)	-	-
8731	55.1%	55.1%	-	-	-
	(44.9%, 64.2%)	(44.9%, 64.2%)	-	-	-
8731SC	-	-	-	-	-
	-	-	-	-	-
8780	-	-	-	-	-
	-	-	-	-	-
8781	-	-	-	-	-
	-	-	-	-	-
Ascenda RAD	-	-	-	-	-
	-	-	-	-	-
Grafted Not As Designed	-	-	-	-	-
	-	-	-	-	-
Revised As Designed	-	-	-	-	-
	-	-	-	-	-
Revised Not As Designed	-	-	-	-	-
	-	-	-	-	-

Model Name	21 Years
8709	47.9%
	(42.0%, 53.5%)
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, 2024. Eighty-seven 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 World Map and highlights the countries that enrolled spinal cord stimulation patients.

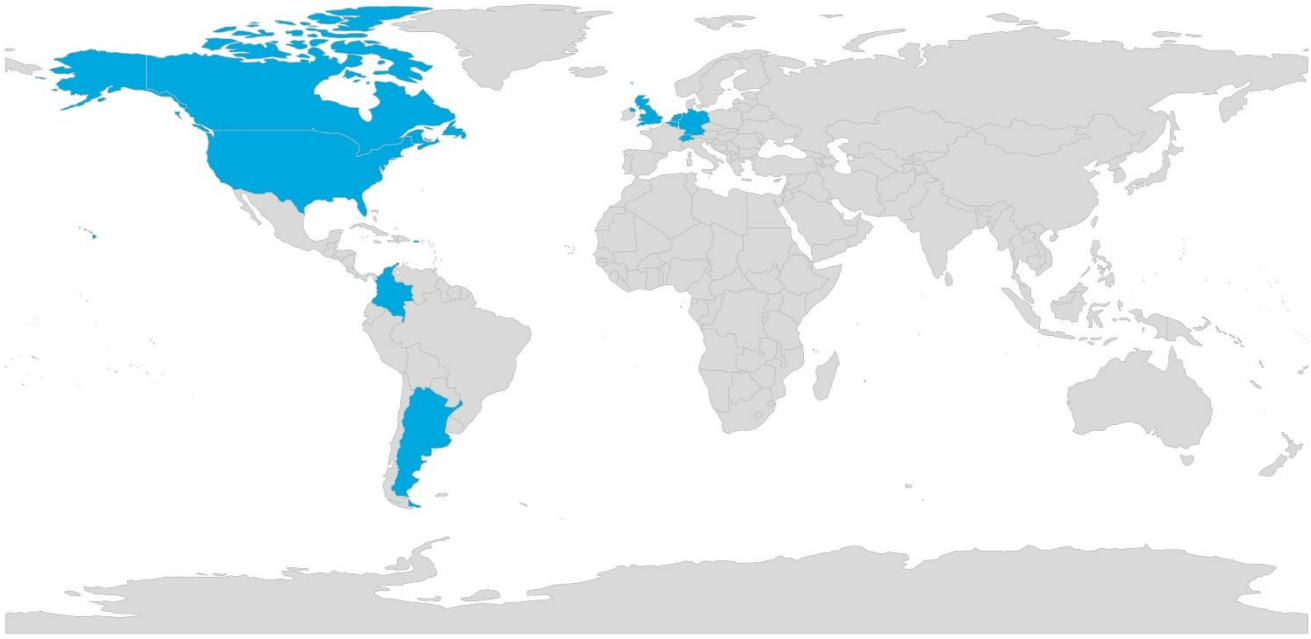


Figure 4.1: Countries with Spinal Cord Stimulation Patients in Registry (Highlighted)

4.1.2 Patients

Of the 6,791 spinal cord stimulation patients enrolled, 44.8% were implanted for the treatment of chronic back and leg pain, 26.2% were implanted for the treatment of other primary indications, 18.3% were implanted for the treatment of trunk and limb pain, 10.0% 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).

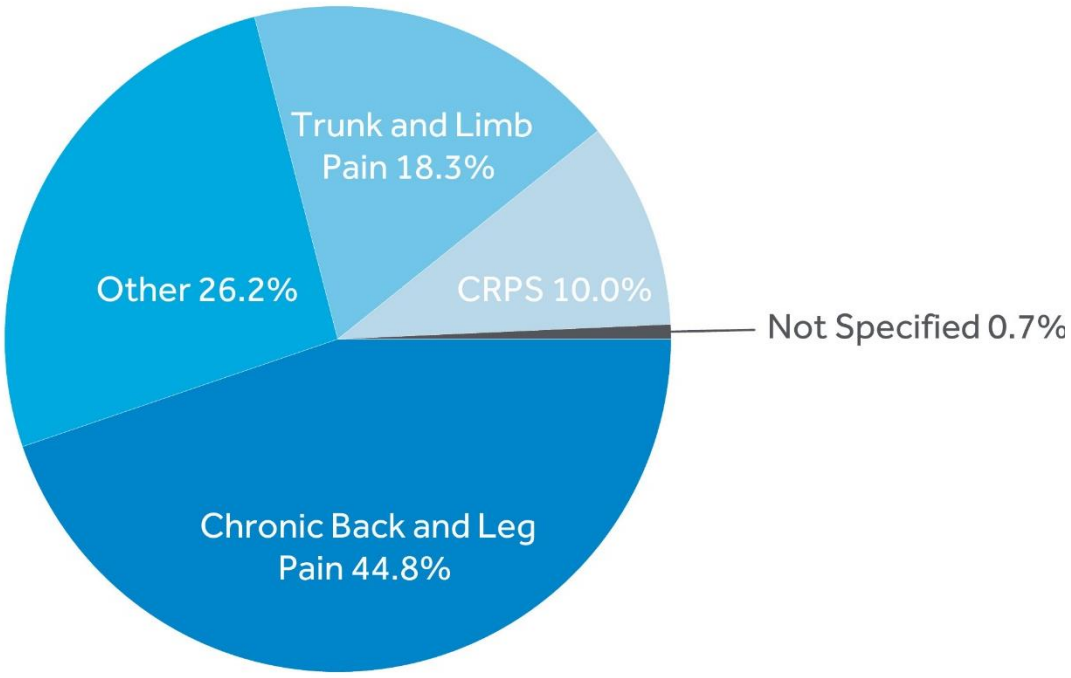


Figure 4.2: Spinal Cord Stimulation Primary Treatment Indications

Table 4.1: Spinal Cord Stimulation Primary Treatment Indications

Primary Treatment Indication[a]	Enrolled Patients (%)
Chronic Back and Leg Pain	**3040 (44.8%)**
Post Surgical Back and/or Leg Pain[b]	2254 (33.2%)
Combination Back and Leg Pain	764 (11.3%)
Arachnoiditis	22 (0.3%)
Other Primary Indication	**1780 (26.2%)**
Other Chronic Pain	888 (13.1%)
Cervical Pain	107 (1.6%)
Chronic Cluster Headache	78 (1.1%)
Diabetic Neuropathy	67 (1.0%)
Traumatic Nerve Injury	63 (0.9%)

Primary Treatment Indication[a]	Enrolled Patients (%)
Post Herpetic Neuralgia	19 (0.3%)
Facial Pain	16 (0.2%)
Angina	12 (0.2%)
Epidural Fibrosis	4 (0.1%)
Post Herniorrhaphy Pain	3 (<0.1%)
Other	523 (7.7%)
Trunk and Limb Pain	**1241 (18.3%)**
Radicular Pain Syndrome	929 (13.7%)
Degenerative Disc Disease	312 (4.6%)
CRPS	**682 (10.0%)**
CRPS I	530 (7.8%)
CRPS II	152 (2.2%)
Not Specified	48 (0.7%)
Total Patients	**6791 (100%)**

[a] For approved indications refer to product labeling for your geography.
[b] Contains Failed Back Surgery Syndrome (FBSS), Post Laminectomy Pain, Multiple Back Operation, 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

There were 2,190 product performance events reported between June 2004 and October 31, 2024, in 1,060 patients with spinal cord stimulation systems. These events represent 35.8% of the total reported events (2,190/6,114), occurred in 1,060 (15.6%) of the 6,791 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 3,837 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=87).

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 314 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=6791[b]
RPA Determination	**3**	**<0.1**	**3 (<0.1%)**
Other[c]	3	<0.1	3 (<0.1%)
Physician's Determination	**2,187**	**11.4**	**1057 (15.6%)**
Lead Migration/Dislodgement	877	4.6	462 (6.8%)
High Impedance	569	3.0	270 (4.0%)
Device Malfunction[d]	124	0.6	110 (1.6%)
Neurostimulator Unable To Recharge[e]	123	0.6	114 (1.7%)
Lead Fracture	109	0.6	70 (1.0%)
Unspecified[f]	58	0.3	34 (0.5%)
Low Impedance	56	0.3	26 (0.4%)
Device Breakage[g]	46	0.2	41 (0.6%)
Device Charging Issue	42	0.2	36 (0.5%)
Device Electrical Impedance Issue	25	0.1	14 (0.2%)
Extension Fracture	20	0.1	14 (0.2%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=6791[b]
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	8	<0.1	7 (0.1%)
Neurostimulator Migration	8	<0.1	8 (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%)
Internal Device Exposed	5	<0.1	3 (<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 Use Issue	4	<0.1	3 (<0.1%)
Inadequate Lead Connection	4	<0.1	2 (<0.1%)
Device Computer Software Issue	3	<0.1	3 (<0.1%)
Device Stimulation Issue[j]	3	<0.1	2 (<0.1%)
Device Telemetry Issue	3	<0.1	3 (<0.1%)
Premature Battery Depletion	3	<0.1	3 (<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%)
Neurostimulator Inversion	2	<0.1	2 (<0.1%)
Other[c]	15	0.1	15 (0.2%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=6791[b]
Total	**2,190**	**11.4**	**1060 (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 4,638 patients that used rechargeable SCS neurostimulators in the registry. A total of 2.5% (114/4,638) 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 Site 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=1).

A total of 1,570 (71.7%) of the 2,190 product performance events were related to the Lead only, 127 (5.8%) were related to the Neurostimulator only, 51 (2.3%) were related to the Extension only, 59 (2.7%) were related to Multiple Etiologies (which includes events where at least one device and one non-device etiology was indicated), and 383 (17.5%) were related to Other Etiologies, including: 304 (13.9%) were related to other component, 38 (1.7%) were related to recharging process, 15 (0.7%) were related to programming/stimulation, 13 (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 5 (0.2%) were related to other etiology. Relatedness is determined by the physician.

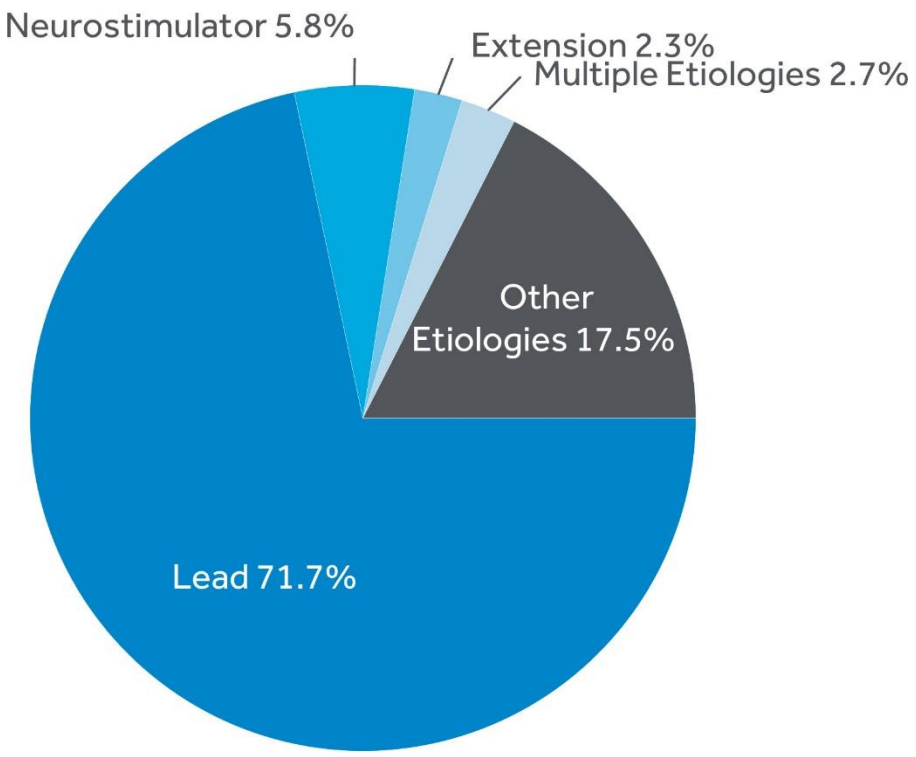


Figure 4.3: Spinal Cord Stimulation System Product Performance Events by Relatedness

Table 4.3 and Table 4.4 describe the interventions taken for reported impedance events. In 28.1% 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 (69.4% 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	251 (44.11%)
Device Surgical Intervention	158 (27.77%)
Therapy Suspension	8 (1.41%)
Other Intervention	6 (1.05%)
Other Surgical Intervention	2 (0.35%)
No Action Taken	144 (25.31%)
Total	**569 (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; 77.5% of them led to a surgical intervention, and 11.3% 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	634 (72.3%)
Reprogramming	99 (11.3%)
Other Surgical Intervention	46 (5.2%)
Therapy Suspension	19 (2.2%)
Other Intervention	15 (1.7%)
Medical or Non-Surgical Therapy	3 (0.3%)
Medication	2 (0.2%)
No Action Taken	59 (6.7%)
Total	**877 (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	680 (77.5%)	99 (11.3%)	20 (2.3%)	19 (2.2%)	0 (0.0%)	59 (6.7%)	877
High Impedance	160 (28.1%)	251 (44.1%)	6 (1.1%)	8 (1.4%)	0 (0.0%)	144 (25.3%)	569
Device Malfunction	22 (17.7%)	12 (9.7%)	75 (60.5%)	4 (3.2%)	1 (0.8%)	10 (8.1%)	124
Neurostimulator Unable To Recharge	40 (32.5%)	8 (6.5%)	65 (52.8%)	4 (3.3%)	2 (1.6%)	4 (3.3%)	123
Lead Fracture	103 (94.5%)	0 (0.0%)	0 (0.0%)	2 (1.8%)	0 (0.0%)	4 (3.7%)	109
Other/Unspecified[b]	164 (42.3%)	49 (12.6%)	124 (32%)	11 (2.8%)	1 (0.3%)	39 (10.1%)	388
Total	**1169 (53.4%)**	**419 (19.1%)**	**290 (13.2%)**	**48 (2.2%)**	**4 (0.2%)**	**260 (11.9%)**	**2190**

[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=3,900)
- Categorized as serious adverse events (SAEs, N=153)
- Occurred with a System Organ Class (SOC) threshold ≥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=3900	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=3900
Infections and infestations	**68**	**63 (1.6%)**	**0.05**	**46 (1.2%)**
Infections - pathogen unspecified	59	54 (1.4%)	0.05	43 (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	**42**	**38 (1.0%)**	**0.03**	**30 (0.8%)**
Complications associated with device	22	21 (0.5%)	0.02	19 (0.5%)
Therapeutic and nontherapeutic effects (excl toxicity)	10	10 (0.3%)	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	**18**	**18 (0.5%)**	**0.01**	**7 (0.2%)**
Procedural related injuries and complications NEC	14	14 (0.4%)	0.01	6 (0.2%)
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 (0.2%)	0.01	6 (0.2%)
Other[a]	1	1 (<0.1%)	<0.01	1 (<0.1%)

Event Type	Number of SAE	Patients with SAE n (%) N=3900	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=3900
Product issues	**7**	**7 (0.2%)**	**0.01**	**5 (0.1%)**
Device issues	7	7 (0.2%)	0.01	5 (0.1%)
Nervous system disorders	**5**	**5 (0.1%)**	**<0.01**	**3 (0.1%)**
Other[a]	5	5 (0.1%)	<0.01	3 (0.1%)
Other SOC Terms (<1.0% Threshold)	**5**	**4 (0.1%)**	**<0.01**	**1 (<0.1%)**
Total	**153**	**124 (3.2%)**	**0.12**	**88 (2.3%)**

[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 314 patients in the registry had expired. No deaths were reported as a direct result of a product performance event.

Since 2006, a total of 97 (30.9%) deaths have been reported in this patient registry study based upon patients receiving therapy for post-surgical back and/or leg pain, 61 (19.4%) for other chronic pain, 42 (13.4%) for radicular pain syndrome, 40 (12.7%) for combination back and leg pain, 19 (6.1%) for CRPS I, 14 (4.5%) for degenerative disc disease, 3 (1.0%) for CRPS II, 3 (1.0%) for diabetic neuropathy, 3 (1.0%) for post herpetic neuralgia, 2 (0.6%) for traumatic nerve injury, 1 (0.3%) for angina, 1 (0.3%) for cervical pain, 1 (0.3%) for chronic cluster headache, and 27 (8.6%) 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]	97 (30.9%)
Other Chronic Pain	61 (19.4%)
Radicular Pain Syndrome	42 (13.4%)

Number of Reports of Death by Primary Indication[a]	N (%) of Deaths
Combination Back and Leg Pain	40 (12.7%)
CRPS I	19 (6.1%)
Degenerative Disc Disease	14 (4.5%)
CRPS II	3 (1.0%)
Diabetic Neuropathy	3 (1.0%)
Post Herpetic Neuralgia	3 (1.0%)
Traumatic Nerve Injury	2 (0.6%)
Angina	1 (0.3%)
Cervical Pain	1 (0.3%)
Chronic Cluster Headache	1 (0.3%)
Other[c]	27 (8.6%)
Total	**314 (100%)**

[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, 2024, there were 7,529 neurostimulators followed in the registry. The difference between the total number of patients (n=6,791) 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 223,841 months (18,653 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	**5801 (77.05%)**
Intellis with AdaptiveStim (97715)	1652 (21.9%)
RestoreSensor SureScan MRI (97714)	1383 (18.4%)
PrimeAdvanced SureScan MRI (97702)	795 (10.6%)
PrimeAdvanced (37702)	667 (8.9%)
RestoreSensor (37714)	377 (5%)
RestoreAdvanced (37713)	357 (4.7%)
Itrel 4 (37703)	139 (1.8%)
Vanta (977006)	129 (1.7%)
RestoreAdvanced SureScan MRI (97713)	116 (1.5%)
RestoreUltra SureScan MRI (97712)	93 (1.2%)
Inceptiv (977119)	46 (0.6%)
Intellis LT (97716)	44 (0.6%)
Itrel 4 (37704)	3 (<0.1%)
No longer manufactured	**1718 (22.82%)**
RestoreULTRA (37712)	581 (7.7%)
Synergy (7427)	460 (6.1%)
Restore (37711)	448 (6%)
Itrel 3 (7425)	96 (1.3%)

Model Name	N (%)
RestorePrime (37701)	56 (0.7%)
Synergy Versitrel (7427V)	53 (0.7%)
SynergyPlus (7479)	17 (0.2%)
SynergyCompact (7479B)	7 (0.1%)
Other/Unspecified	**10 (0.1%)**
Total	**7529 (100%)**

4.3.1 Neurostimulator Events

There were 140 product performance-related events with an underlying reported etiology related to spinal cord neurostimulator function. This includes 127 events with a neurostimulator etiology and 13 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 107 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 16.6% (401/2,420). 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 140 spinal cord neurostimulator events, 97.9% (137/140) 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 (2.1%)**
Broken Bond Wire	1 (0.7%)
Medical Device Complication	1 (0.7%)
No Anomaly Found By RPA[a]	1 (0.7%)
Physician's Determination	**137 (97.9%)**
High Impedance	31 (22.1%)
Neurostimulator Unable To Recharge	31 (22.1%)
Device Malfunction	27 (19.3%)

Product Performance Events	N (%)
Lead Migration/Dislodgement	12 (8.6%)
Device Charging Issue	5 (3.6%)
Neurostimulator Migration	5 (3.6%)
Unspecified	4 (2.9%)
Device Overheating	3 (2.1%)
Low Impedance	3 (2.1%)
Device Breakage	2 (1.4%)
Neurostimulator Inversion	2 (1.4%)
Premature Battery Depletion	2 (1.4%)
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 Issue	1 (0.7%)
Device Stimulation 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%)
Total	**140 (100%)**

[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:

- 107 had follow-up time cut-off due to product performance-related events.
- 5,955 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.

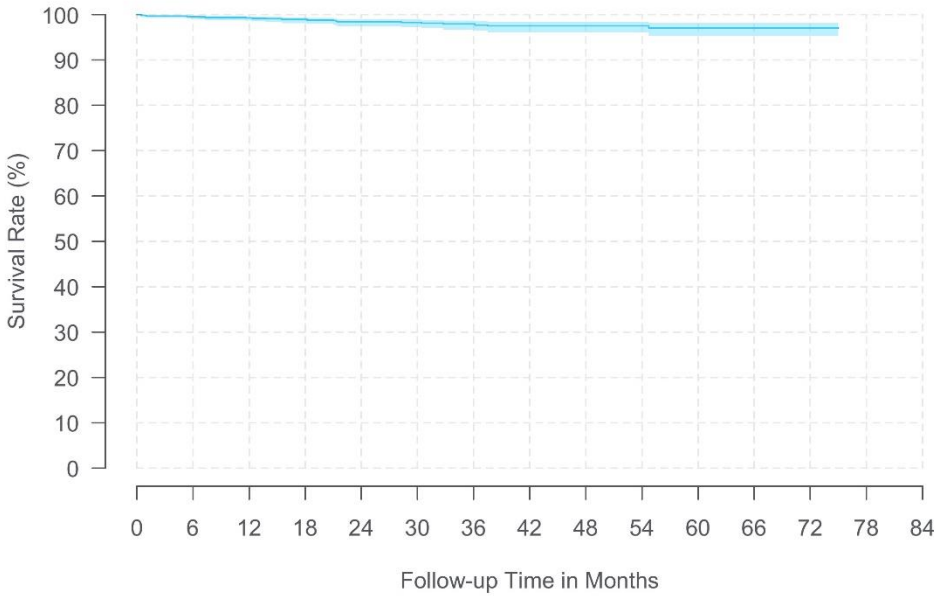
- 1,467 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

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	1,652
Neurostimulators Currently Active in Study	984
Initial Product Performance Events	23
Median Follow-up Time (Months)	21.0
Cumulative Follow-up Time (Months)	42,213



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (98.7%, 99.6%)	98.4% (97.5%, 99.0%)	97.9% (96.8%, 98.7%)	97.5% (96.1%, 98.4%)	97.1% (95.3%, 98.2%)
Sample Size	1064	731	482	309	150

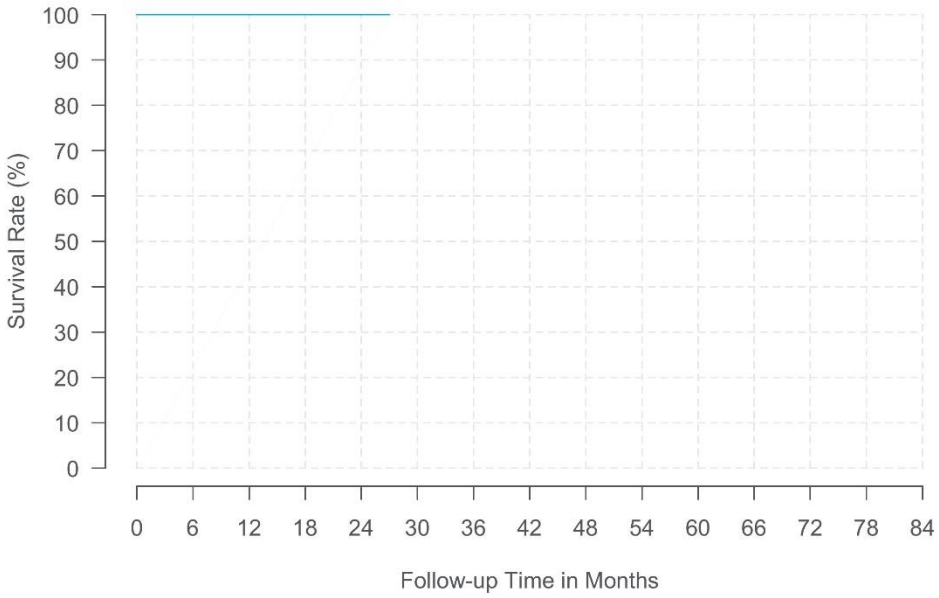
Time Interval	6 Years	At 75 Months
Survival (95% CI)	97.1% (95.3%, 98.2%)	97.1% (95.3%, 98.2%)
Sample Size	33	24

Specification: Intellis with	
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	≤3 cm

Neurostimulator Event Summary: Intellis with AdaptiveStim	N
High Impedance	6
Device Malfunction	5
Neurostimulator Unable To Recharge	3
Neurostimulator Migration	2
Device Charging Issue	1
Device Electrical Impedance Issue	1
Device Overheating	1
Internal Device Exposed	1
Lead Migration/Dislodgement	1
Neurostimulator Inversion	1
Unspecified	1
Total	**23**

4.3.2.2 Model Intellis LT

Model Name	Intellis LT (model 97716)
FDA Approval Date	July 2017
Neurostimulators Enrolled	44
Neurostimulators Currently Active in Study	30
Initial Product Performance Events	0
Median Follow-up Time (Months)	25.4
Cumulative Follow-up Time (Months)	980



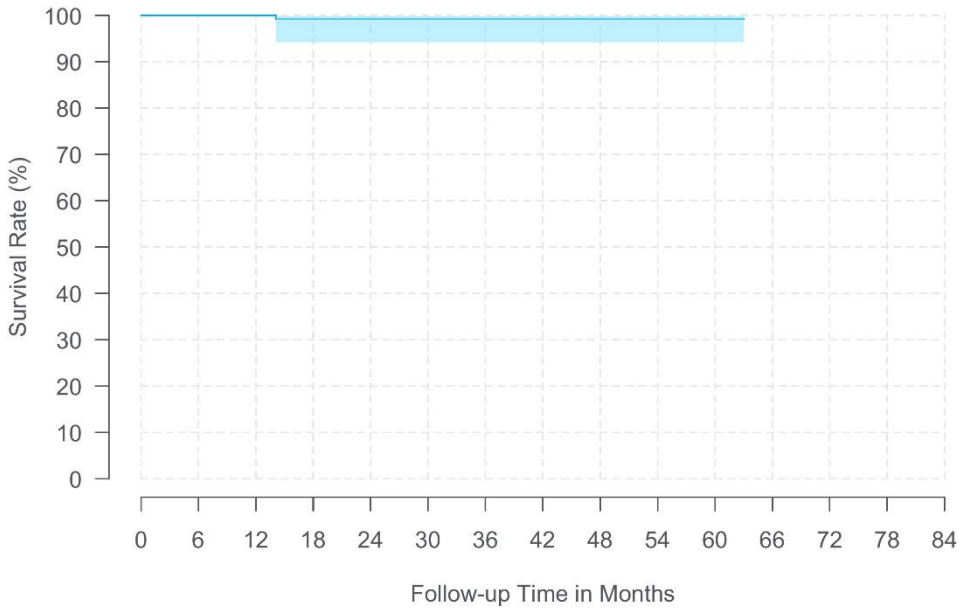
Time Interval	1 Year	2 Years	At 27 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	29	23	20

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	≤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	139
Neurostimulators Currently Active in Study	26
Initial Product Performance Events	1
Median Follow-up Time (Months)	35.8
Cumulative Follow-up Time (Months)	5,517



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	99.2% (94.3%, 99.9%)	99.2% (94.3%, 99.9%)	99.2% (94.3%, 99.9%)	99.2% (94.3%, 99.9%)
Sample Size	124	92	68	47	28

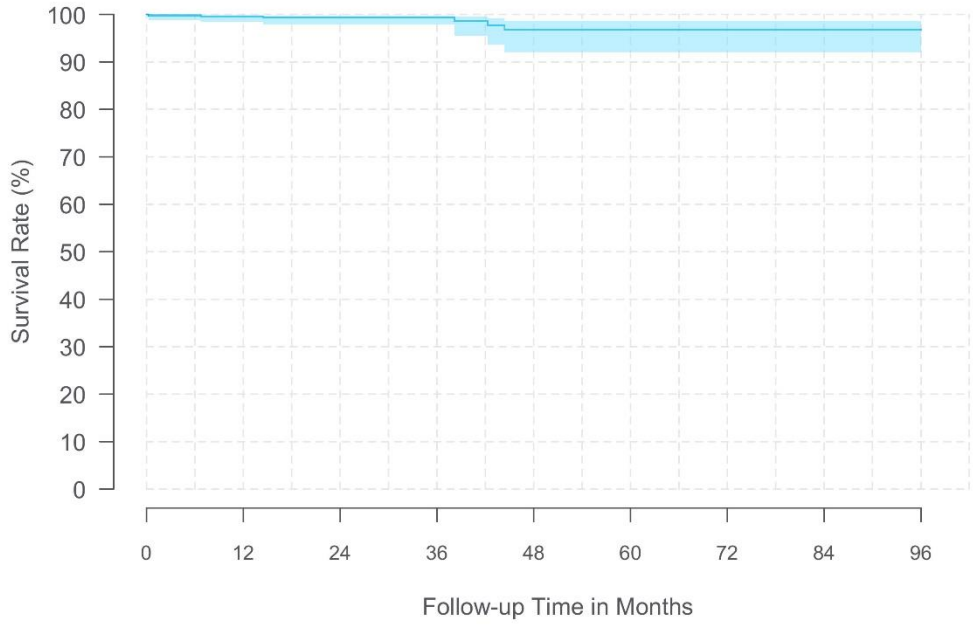
Time Interval	At 63 Months
Survival (95% CI)	99.2% (94.3%, 99.9%)
Sample Size	24

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
Total	**1**

4.3.2.4 Model PrimeAdvanced

Model Name	PrimeAdvanced (model 37702)
FDA Approval Date	July 2006
Neurostimulators Enrolled	667
Neurostimulators Currently Active in Study	10
Initial Product Performance Events	6
Median Follow-up Time (Months)	16.0
Cumulative Follow-up Time (Months)	16,052



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%)

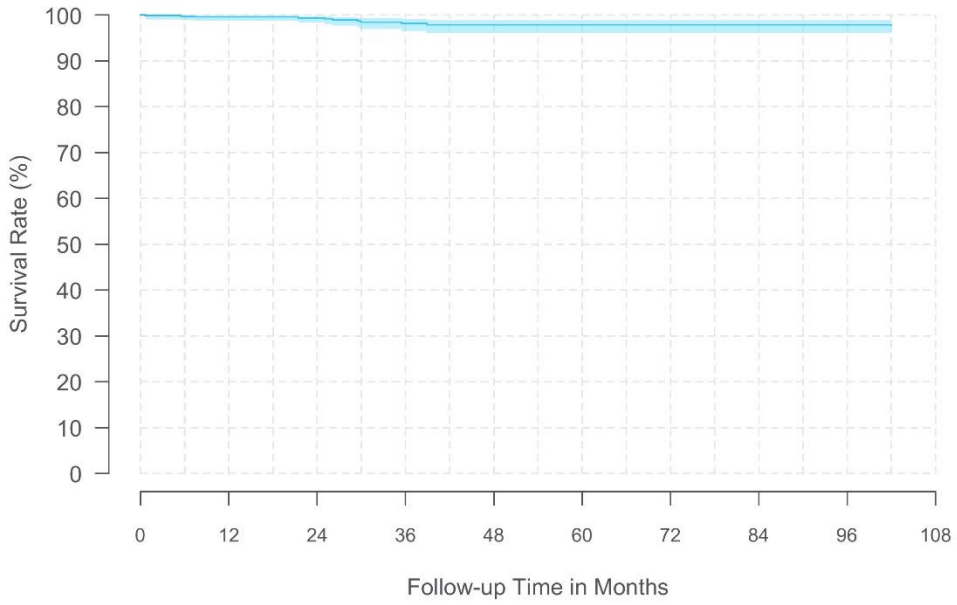
Time Interval	6 Years	7 Years	8 Years
Sample Size	41	26	20

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 µsec
Groups	26
Programs	32
Implant Depth	≤ 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	795
Neurostimulators Currently Active in Study	122
Initial Product Performance Events	11
Median Follow-up Time (Months)	31.4
Cumulative Follow-up Time (Months)	29,150



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% (96.5%, 99.1%)	97.9% (96.0%, 98.9%)	97.9% (96.0%, 98.9%)
Sample Size	644	489	347	225	149

Time Interval	6 Years	7 Years	8 Years	At 102 Months
Survival (95% CI)	97.9% (96.0%, 98.9%)	97.9% (96.0%, 98.9%)	97.9% (96.0%, 98.9%)	97.9% (96.0%, 98.9%)

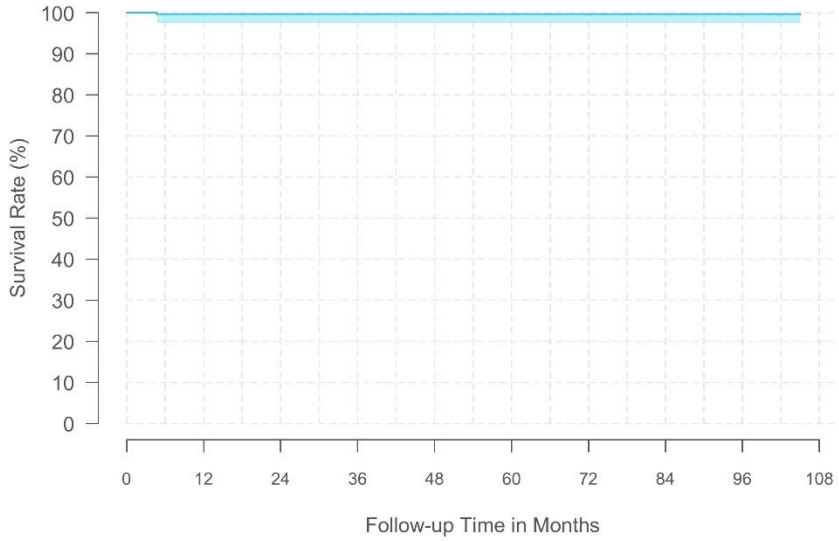
Time Interval	6 Years	7 Years	8 Years	At 102 Months
Sample Size	92	60	35	20

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 µsec
Groups	26
Programs	32
Implant Depth	≤ 4 cm

Neurostimulator Event Summary: PrimeAdvanced SureScan MRI	N
High Impedance	6
Lead Migration/Dislodgement	2
Premature Battery Depletion	2
Neurostimulator Unable To Recharge	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)	11,347



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

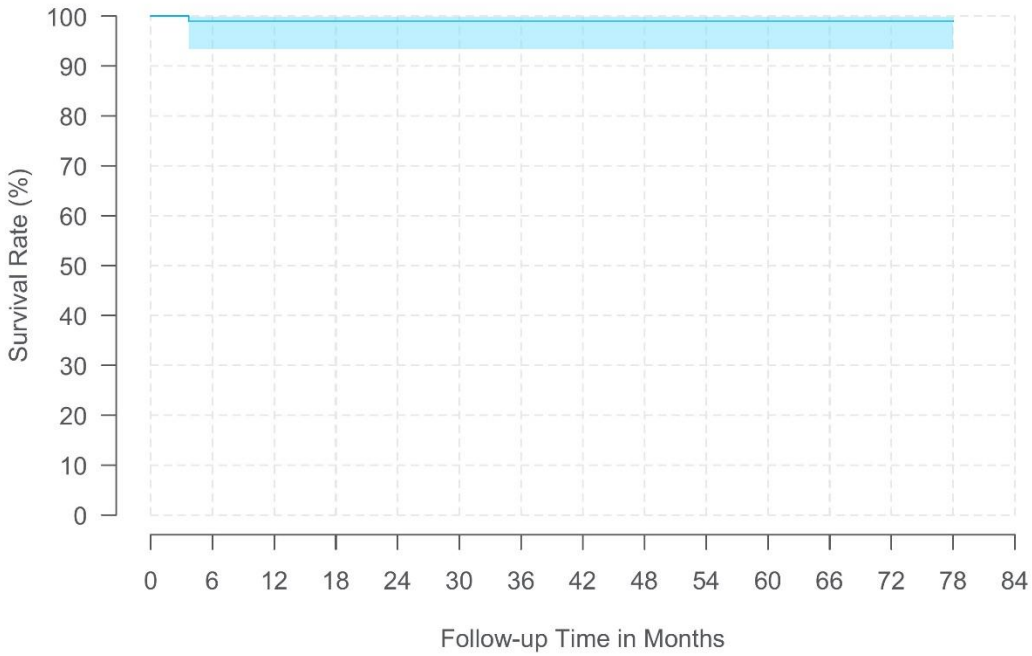
Time Interval	6 Years	7 Years	8 Years	At 105 Months
Survival (95% CI)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)	99.7% (97.6%, 100.0%)
Sample Size	49	35	29	20

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 µsec
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

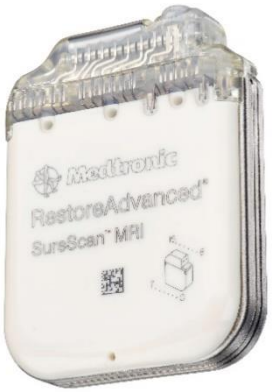
Model Name	RestoreAdvanced SureScan MRI (model 97713)
FDA Approval Date	March 2013
Neurostimulators Enrolled	116
Neurostimulators Currently Active in Study	10
Initial Product Performance Events	2
Median Follow-up Time (Months)	33.0
Cumulative Follow-up Time (Months)	4,659



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 78 Months
Survival (95% CI)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)
Sample Size	28	21

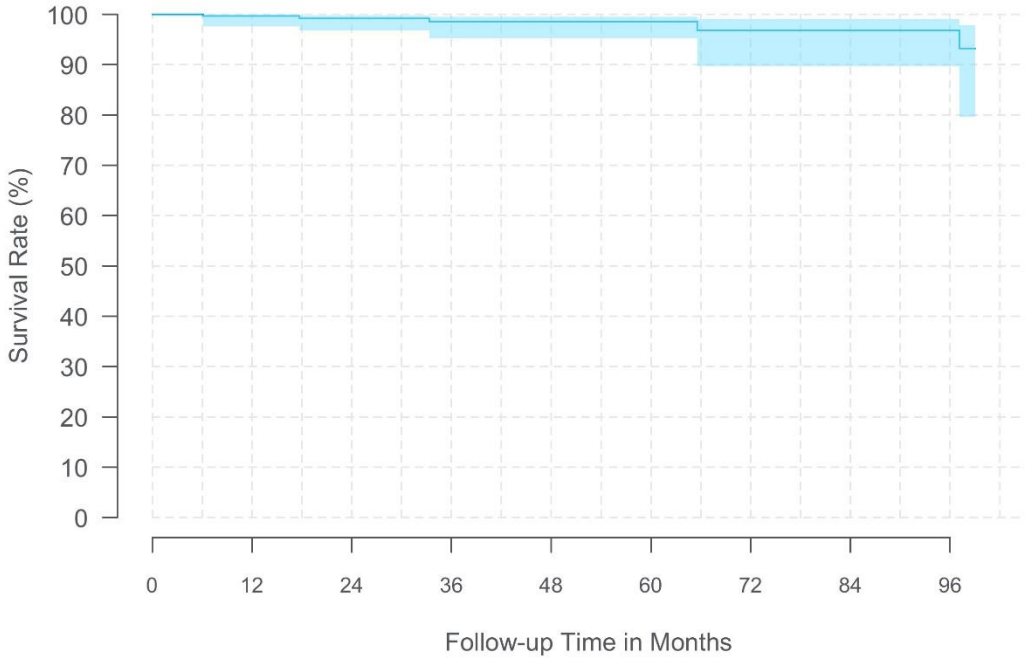
Specification: RestoreAdvanced SureScan MRI	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 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)	12,438



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

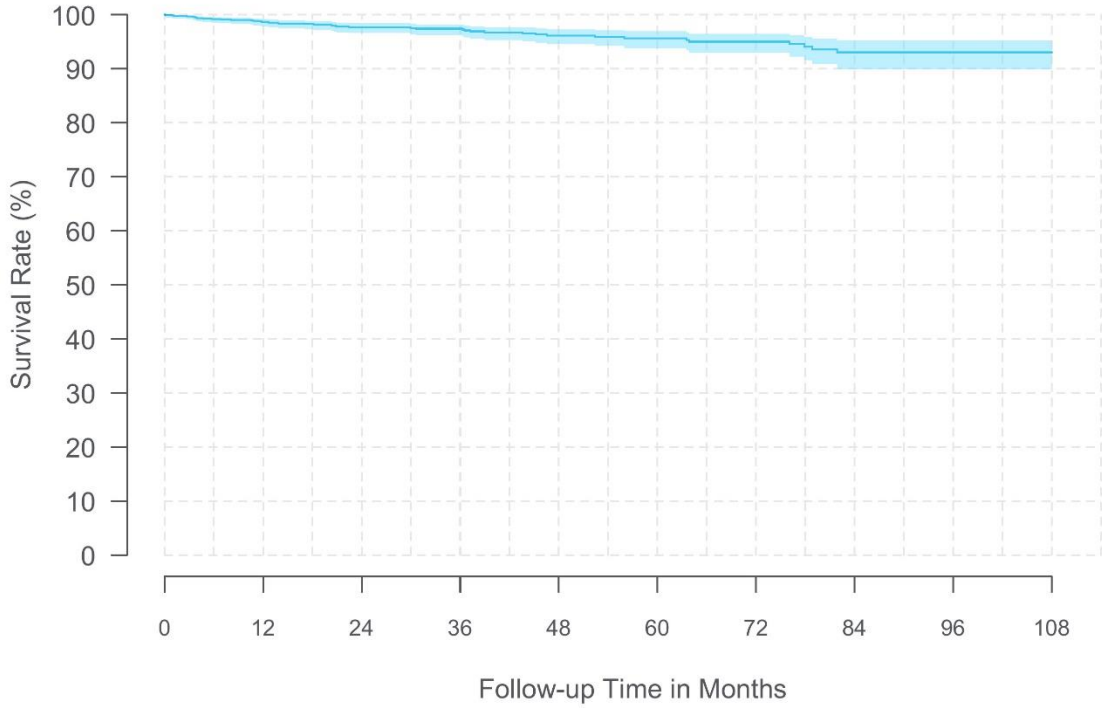
Time Interval	6 Years	7 Years	8 Years	At 99 Months
Survival (95% CI)	96.8% (89.8%, 99.0%)	96.8% (89.8%, 99.0%)	96.8% (89.8%, 99.0%)	93.3% (79.7%, 97.9%)
Sample Size	45	36	28	24

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 µsec
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

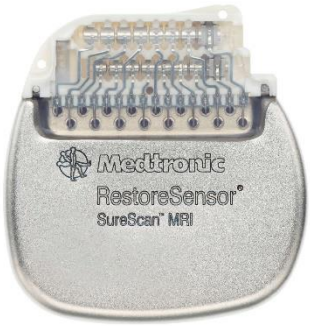
Model Name	RestoreSensor SureScan MRI (model 97714)
FDA Approval Date	March 2013
Neurostimulators Enrolled	1,383
Neurostimulators Currently Active in Study	114
Initial Product Performance Events	42
Median Follow-up Time (Months)	30.0
Cumulative Follow-up Time (Months)	53,356



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%)	97.4% (96.2%, 98.2%)	96.2% (94.5%, 97.3%)	95.7% (93.9%, 96.9%)
Sample Size	1045	799	595	450	331

Time Interval	6 Years	7 Years	8 Years	9 Years
Survival (95% CI)	95.0% (93.0%, 96.5%)	93.1% (90.0%, 95.2%)	93.1% (90.0%, 95.2%)	93.1% (90.0%, 95.2%)
Sample Size	235	154	92	20

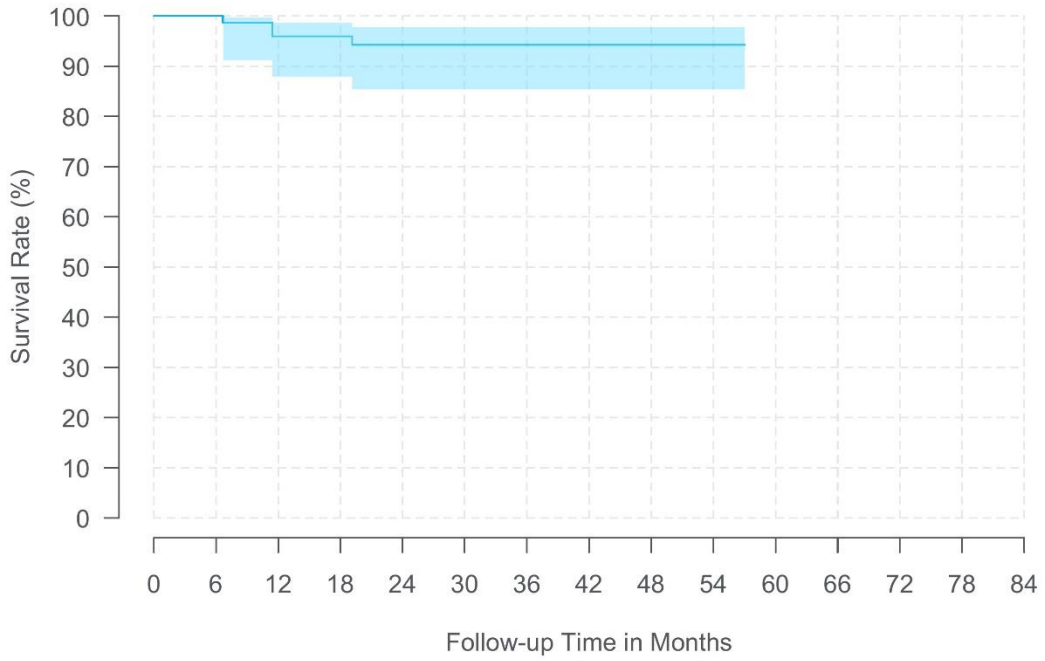
Specification: RestoreSensor SureScan MRI	
Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thickness	9 mm (0.4 in)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth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



Neurostimulator Event Summary: RestoreSensor SureScan MRI	N
Neurostimulator Unable To Recharge	14
Device Malfunction	8
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	**42**

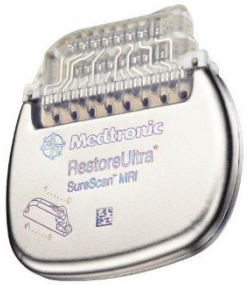
4.3.2.10 Model RestoreUltra SureScan MRI

Model Name	RestoreUltra SureScan MRI (model 97712)
FDA Approval Date	March 2013
Neurostimulators Enrolled	93
Neurostimulators Currently Active in Study	15
Initial Product Performance Events	4
Median Follow-up Time (Months)	28.5
Cumulative Follow-up Time (Months)	3,395



Time Interval	1 Year	2 Years	3 Years	4 Years	At 57 Months
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	41	28	20

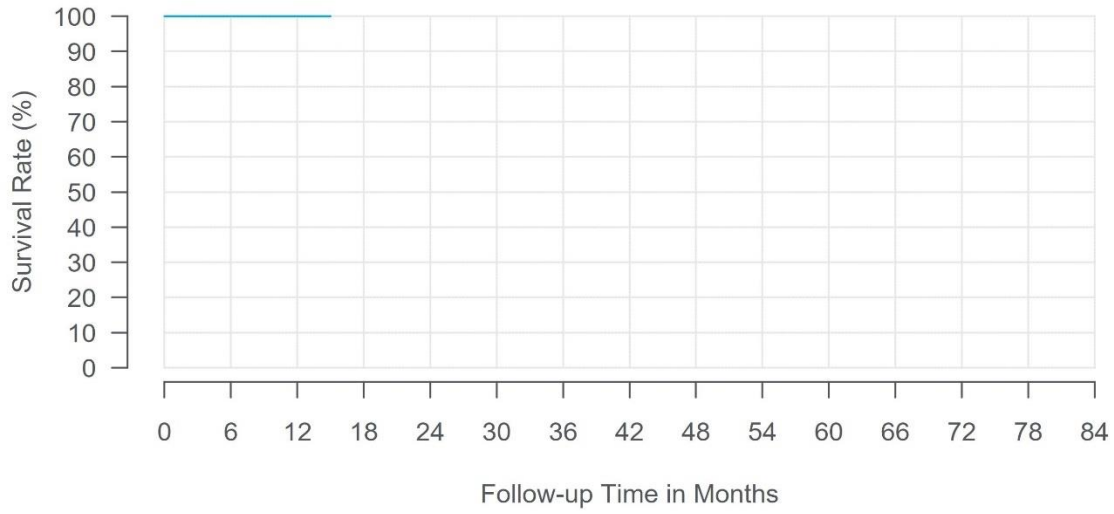
Specification: RestoreUltra SureScan MRI	
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 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	129
Neurostimulators Currently Active in Study	109
Initial Product Performance Events	0
Median Follow-up Time (Months)	6.7
Cumulative Follow-up Time (Months)	1035



Time Interval	1 Year	At 15 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)
Sample Size	42	23

As of October 31, 2024, there were no product performance events reported among Vanta neurostimulators.

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

4.3.2.12 Model Inceptiv

Model Name	Inceptiv (model 977119)
FDA Approval Date	April 2024
Neurostimulators Enrolled	46
Neurostimulators Currently Active in Study	45
Initial Product Performance Events	0
Median Follow-up Time (Months)	0.0
Cumulative Follow-up Time (Months)	48

As of October 31, 2024, there was not sufficient data available to evaluate Inceptiv survival.

Specification: Inceptiv	
Height	2.2 in (57 mm)
Width	1.9 in (27 mm)
Thickness Case	0.2 in (6 mm)
Thickness Connector	0.4 in (9 mm)
Volume	13.77 cc
Battery type	Rechargeable
Expected Battery life	15 years before ERI
Maximum Electrodes	16
Amplitude	0 – 100 mA
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	32
Implant Depth	≤ 3 cm

As of October 31, 2024, 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	139	26	1	35.8	5,517
PrimeAdvanced (model 37702)	July 2006	667	10	6	16.0	16,052
PrimeAdvanced SureScan MRI (model 97702)	March 2013	795	122	11	31.4	29,150
Vanta (model 977006)	July 2021	129	109	0	6.7	1,035

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)	(94.3%, 99.9%)	(94.3%, 99.9%)	(94.3%, 99.9%)	(94.3%, 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%)	(96.5%, 99.1%)	(96.0%, 98.9%)	(96.0%, 98.9%)
Vanta (model 977006)	100.0%				
	(NA)				

Model Name	6 Years	7 Years	8 Years
Itrel 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%
	(96.0%, 98.9%)	(96.0%, 98.9%)	(96.0%, 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	46	45	0	0.0	48
Intellis LT (model 97716)	September 2017	44	30	0	25.4	980
Intellis with AdaptiveStim (model 97715)	July 2017	1,652	984	23	21.0	42,213
RestoreAdvanced (model 37713)	July 2006	357	1	1	22.0	11,347
RestoreAdvanced SureScan MRI (model 97713)	March 2013	116	10	2	33.0	4,659
RestoreSensor (model 37714)	November 2011	377	8	5	23.2	12,438

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
RestoreSensor SureScan MRI (model 97714)	March 2013	1,383	114	42	30.0	53,356
RestoreUltra SureScan MRI (model 97712)	March 2013	93	15	4	28.5	3,395

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
Intellis LT (model 97716)	100.0%	100.0%			
	(NA)	(NA)			
Intellis with AdaptiveStim (model 97715)	99.3%	98.4%	97.9%	97.5%	97.1%
	(98.7%, 99.6%)	(97.5%, 99.0%)	(96.8%, 98.7%)	(96.1%, 98.4%)	(95.3%, 98.2%)
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%	97.4%	96.2%	95.7%
	(97.8%, 99.2%)	(96.6%, 98.5%)	(96.2%, 98.2%)	(94.5%, 97.3%)	(93.9%, 96.9%)
RestoreUltra SureScan MRI (model 97712)	95.9%	94.3%	94.3%	94.3%	
	(87.9%, 98.7%)	(85.4%, 97.8%)	(85.4%, 97.8%)	(85.4%, 97.8%)	

Model Name	6 Years	7 Years	8 Years	9 Years
Intellis LT (model 97716)				
Intellis with AdaptiveStim (model 97715)	97.1%			
	(95.3%, 98.2%)			
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)	95.0%	93.1%	93.1%	93.1%
	(93.0%, 96.5%)	(90.0%, 95.2%)	(90.0%, 95.2%)	(90.0%, 95.2%)
RestoreUltra SureScan MRI (model 97712)				

4.4 Leads

From June 2004 to the report cut-off date of October 31, 2024, there were 11,935 leads followed in the registry. The difference between the total number of leads (n=11,935) versus the number of neurostimulators (n=7,529) 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 395,649 months (32,971 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	**10707 (90.0%)**
Vectris SureScan MRI 1x8 Compact (977A2)	5243 (43.9%)
1x8 Compact (3778)	2170 (18.2%)
Pisces Standard (3487A)	993 (8.3%)
1x8 Standard (3777)	840 (7.0%)
Pisces Plus (3888)	458 (3.8%)
Specify 5-6-5 (39565)	294 (2.5%)
Pisces Compact (3887)	202 (1.7%)
1x8 SC (3776)	188 (1.6%)
Vectris SureScan MRI 1x8 Subcompact (977A1)	147 (1.2%)
Specify SureScan MRI 5-6-5 (977C1)	94 (0.8%)
Specify SureScan MRI 2x8 (977C2)	46 (0.4%)
Specify 2x8 (39286)	32 (0.3%)
No longer manufactured	**690 (6.0%)**
Specify (3998)	158 (1.3%)
Pisces Z Standard (3890)	143 (1.2%)
Pisces Z Compact (3891)	132 (1.1%)

Model Name	N (%)
Resume TL (3986A)	108 (0.9%)
Resume II (3587A)	59 (0.5%)
2x4 Hinged Specify (3999)	54 (0.5%)
Pisces Z Plus (3892)	25 (0.2%)
On-Point (3987A)	9 (0.1%)
SymMix (3982A)	2 (<0.1%)
Other/Unspecified	**245 (2.1%)**
Total	**11935 (100.0%)**

Percutaneous leads composed 88.3% (10,541/11,935) of leads in the registry, including 45.2% (5,390/11,935) in the Vectris SureScan lead family, 26.8% (3,198/11,935) in the Pisces-Octad lead family, 13.9% (1653/11,935) in the Pisces-Quad lead family, and 2.5% (300/11,935) in the Pisces-Quad LZ lead family; 7.2% (856/11,935) of leads were surgical leads; and 4.5% (538/11,935)of leads were designated as "Other" or were unspecified in the database.

4.4.1 Lead Events

There were 1,602 product performance-related events with an underlying reported etiology related to lead function. This includes 1,570 events with a lead etiology only and 32 events with both a lead and other etiology (including device and non-device etiologies). Of these, 1,178 were the initial product performance event that affected lead survival estimates; the majority were lead migration/dislodgement (n=694), high impedance (n=284), lead fracture (n=88), unspecified (n=45), and low impedance (n=29). There were 1,075 events in 10,541 (10.2%) percutaneous leads, 49 events in 856 (5.7%) surgical leads, and 54 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:

- 1,178 had follow-up time cut-off due to product performance-related events.
- 8,429 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.

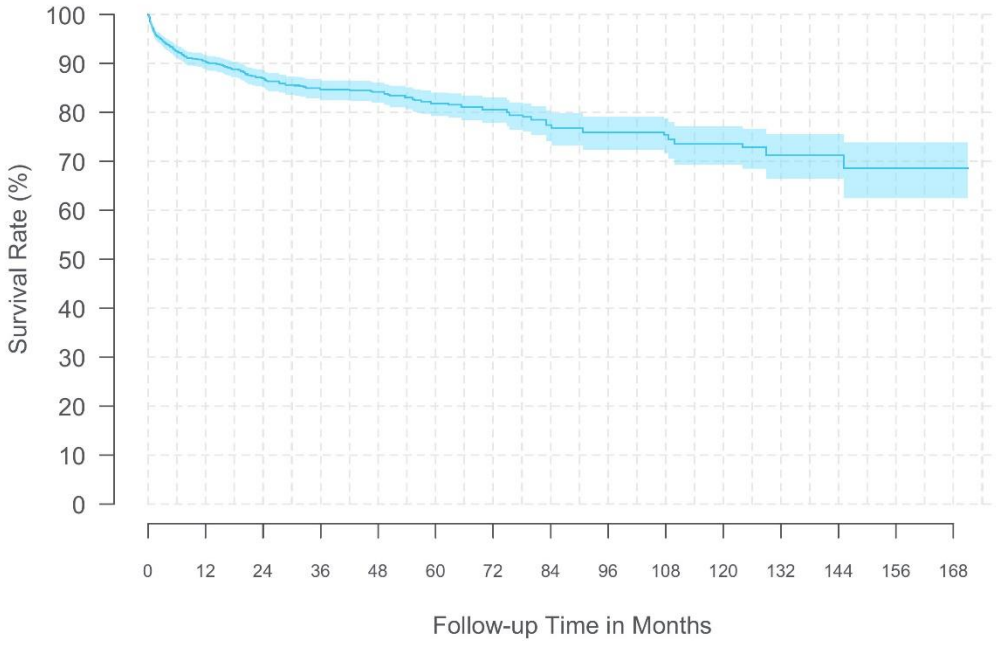
- 2,328 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

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	53
Initial Product Performance Events	267
Median Follow-up Time (Months)	17.9
Cumulative Follow-up Time (Months)	69,868



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%)	84.7% (82.6%, 86.6%)	84.2% (82.0%, 86.1%)	81.8% (79.3%, 84.1%)
Sample Size	1212	801	600	458	379

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.6% (77.9%, 83.0%)	77.5% (74.1%, 80.4%)	76.0% (72.4%, 79.2%)	75.5% (71.8%, 78.8%)	73.5% (69.4%, 77.2%)
Sample Size	292	219	178	157	126

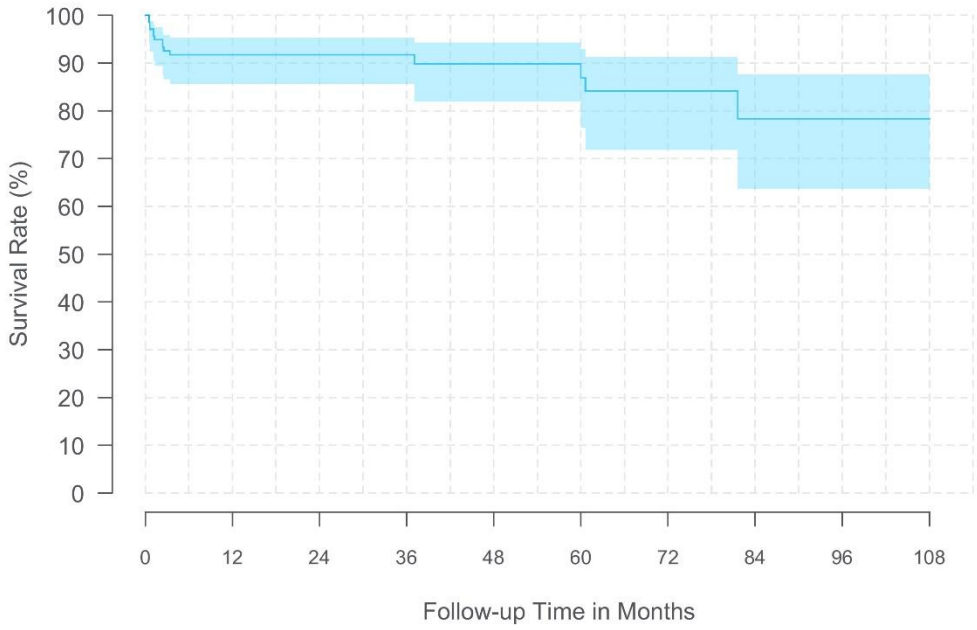
Time Interval	11 Years	12 Years	13 Years	14 Years	At 171 Months
Survival (95% CI)	71.3% (66.4%, 75.6%)	71.3% (66.4%, 75.6%)	68.6% (62.5%, 73.9%)	68.6% (62.5%, 73.9%)	68.6% (62.5%, 73.9%)
Sample Size	83	55	38	24	24

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	21
Unspecified	8
Device Malfunction	2
Low Impedance	2
Medical Device Complication	2
Total	**267**

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	10
Initial Product Performance Events	17
Median Follow-up Time (Months)	15.0
Cumulative Follow-up Time (Months)	5,773



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
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%)

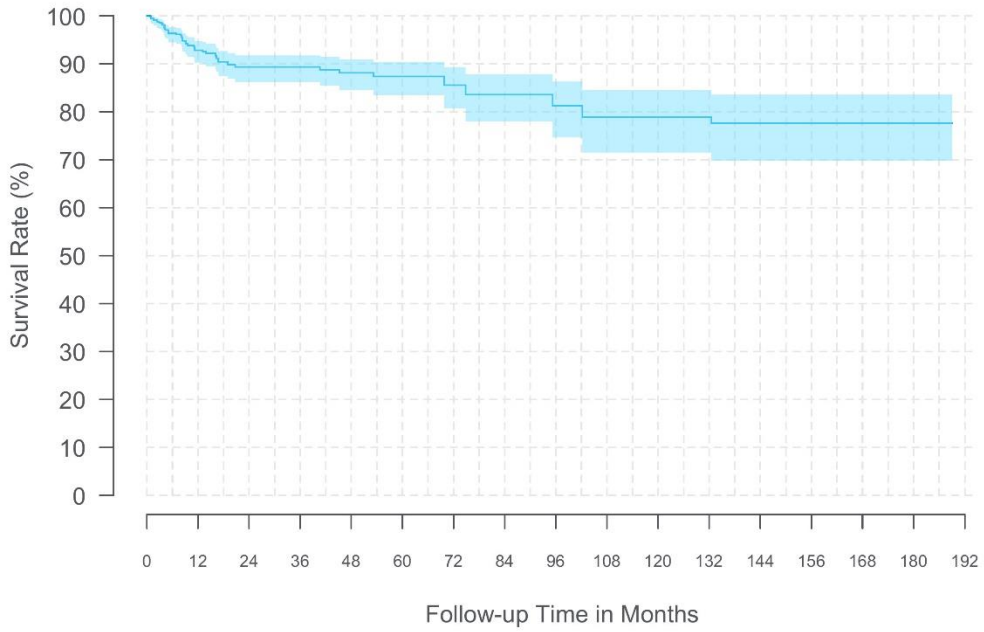
Time Interval	6 Years	7 Years	8 Years	9 Years
Sample Size	23	24	25	20

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	44
Initial Product Performance Events	71
Median Follow-up Time (Months)	16.4
Cumulative Follow-up Time (Months)	25,899



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%)	88.1% (84.5%, 91.0%)	87.4% (83.5%, 90.5%)
Sample Size	443	288	187	130	105

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	85.6% (80.8%, 89.3%)	83.6% (77.9%, 87.9%)	81.2% (74.6%, 86.3%)	78.9% (71.5%, 84.5%)	78.9% (71.5%, 84.5%)
Sample Size	89	73	68	83	78

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	78.9% (71.5%, 84.5%)	77.6% (69.9%, 83.6%)	77.6% (69.9%, 83.6%)	77.6% (69.9%, 83.6%)	77.6% (69.9%, 83.6%)
Sample Size	63	52	46	33	26

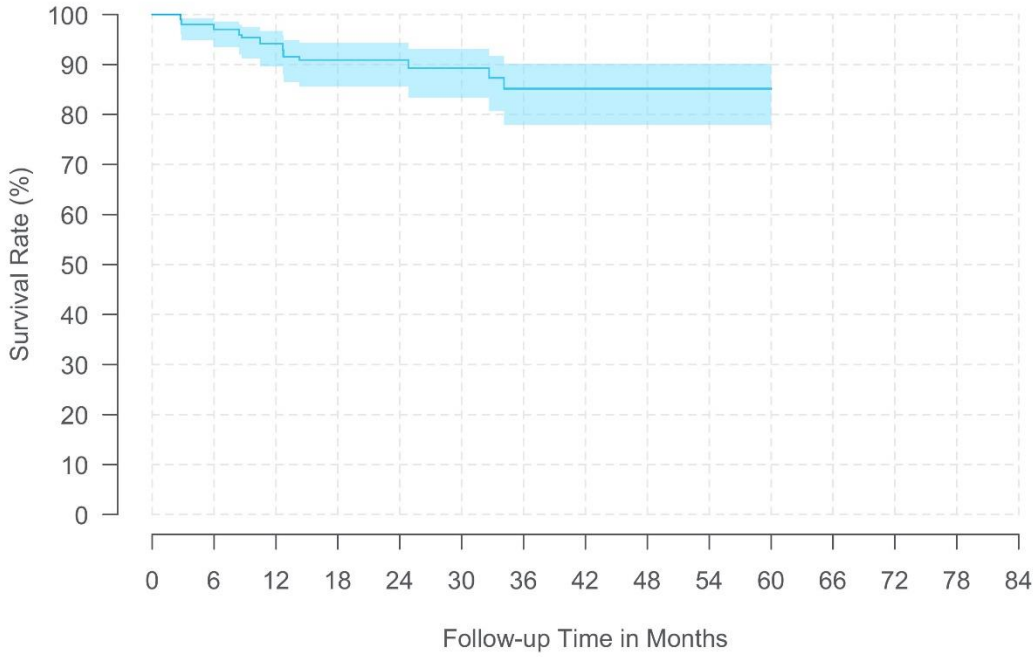
Time Interval	At 189 Months
Survival (95% CI)	77.6% (69.9%, 83.6%)
Sample Size	20

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 (model 09100)
FDA Approval Date	NA
Leads Enrolled	244
Leads Currently Active in Study	158
Initial Product Performance Events	23
Median Follow-up Time (Months)	22.1
Cumulative Follow-up Time (Months)	6,277



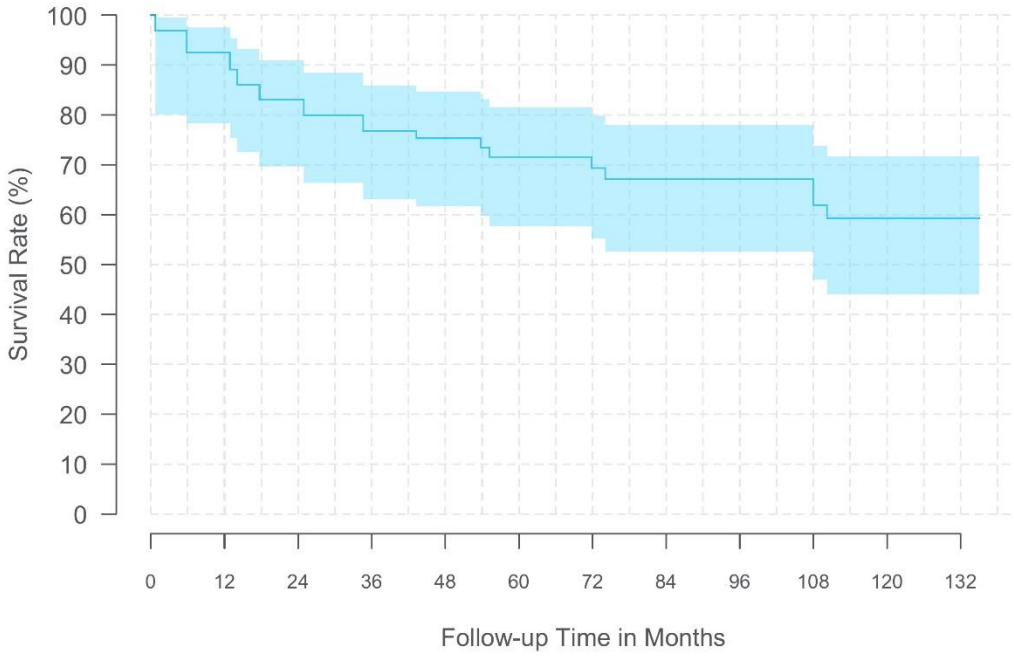
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	94.2% (89.7%, 96.7%)	91.0% (85.6%, 94.4%)	85.2% (77.9%, 90.2%)	85.2% (77.9%, 90.2%)	85.2% (77.9%, 90.2%)
Sample Size	151	111	74	34	20

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	12
Lead Migration/Dislodgement	5
Lead Fracture	2
Medical Device Complication	2
Medical Device Site Pain	2
Total	**23**

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	14
Initial Product Performance Events	25
Median Follow-up Time (Months)	23.7
Cumulative Follow-up Time (Months)	8,199



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (78.3%, 97.6%)	83.1% (69.7%, 90.9%)	76.8% (63.2%, 85.9%)	75.3% (61.8%, 84.7%)	71.6% (57.7%, 81.6%)
Sample Size	51	54	49	43	37

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	69.4% (55.2%, 79.8%)	67.1% (52.7%, 78.0%)	67.1% (52.7%, 78.0%)	61.9% (46.9%, 73.8%)	59.3% (44.1%, 71.7%)
Sample Size	31	26	25	23	24

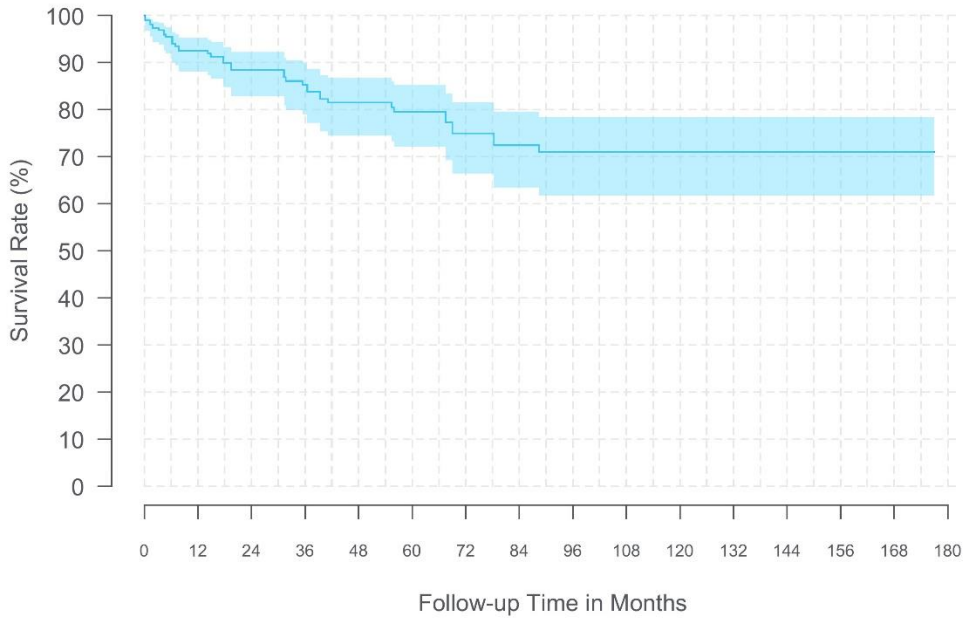
Time Interval	11 Years	At 135 Months
Survival (95% CI)	59.3% (44.1%, 71.7%)	59.3% (44.1%, 71.7%)
Sample Size	20	20

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	458
Leads Currently Active in Study	32
Initial Product Performance Events	46
Median Follow-up Time (Months)	15.1
Cumulative Follow-up Time (Months)	13,616



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%)	81.5% (74.5%, 86.7%)	79.6% (72.1%, 85.2%)
Sample Size	164	118	111	91	76

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	74.9% (66.5%, 81.6%)	72.5% (63.5%, 79.6%)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)
Sample Size	59	49	48	44	39

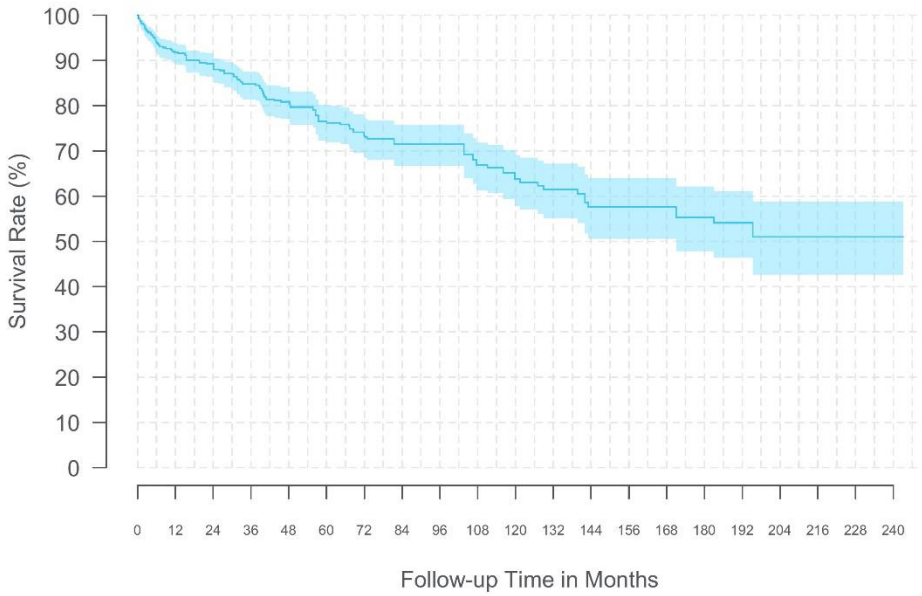
Time Interval	11 Years	12 Years	13 Years	14 Years	At 177 Months
Survival (95% CI)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)	71.0% (61.7%, 78.4%)
Sample Size	33	27	25	22	20

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	11
Unspecified	2
Lead Fracture	1
Total	**46**

4.4.2.7 Model Pisces Standard

Model Name	Pisces Standard (model 3487A)
FDA Approval Date	May 1988
Leads Enrolled	993
Leads Currently Active in Study	46
Initial Product Performance Events	167
Median Follow-up Time (Months)	31.7
Cumulative Follow-up Time (Months)	43,345



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	234

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	73.4% (68.8%, 77.5%)	71.5% (66.7%, 75.7%)	71.5% (66.7%, 75.7%)	66.9% (61.4%, 71.8%)	63.8% (57.8%, 69.1%)
Sample Size	201	167	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% (50.5%, 64.0%)	57.6% (50.5%, 64.0%)	57.6% (50.5%, 64.0%)	55.3% (47.9%, 62.2%)
Sample Size	67	58	56	51	47

Time Interval	16 Years	17 Years	18 Years	19 Years	20 Years
Survival (95% CI)	54.1% (46.4%, 61.2%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)
Sample Size	37	31	25	21	20

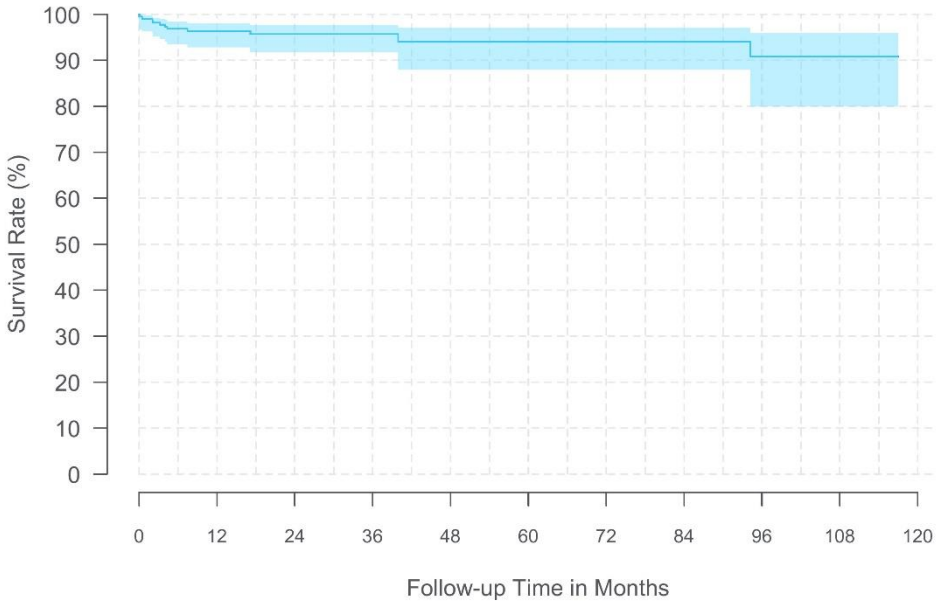
Time Interval	At 243 Months
Survival (95% CI)	51.0% (42.6%, 58.8%)
Sample Size	20

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	294
Leads Currently Active in Study	27
Initial Product Performance Events	11
Median Follow-up Time (Months)	22.9
Cumulative Follow-up Time (Months)	9,210



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	36

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%)	90.9% (80.0%, 96.0%)	90.9% (80.0%, 96.0%)	90.9% (80.0%, 96.0%)

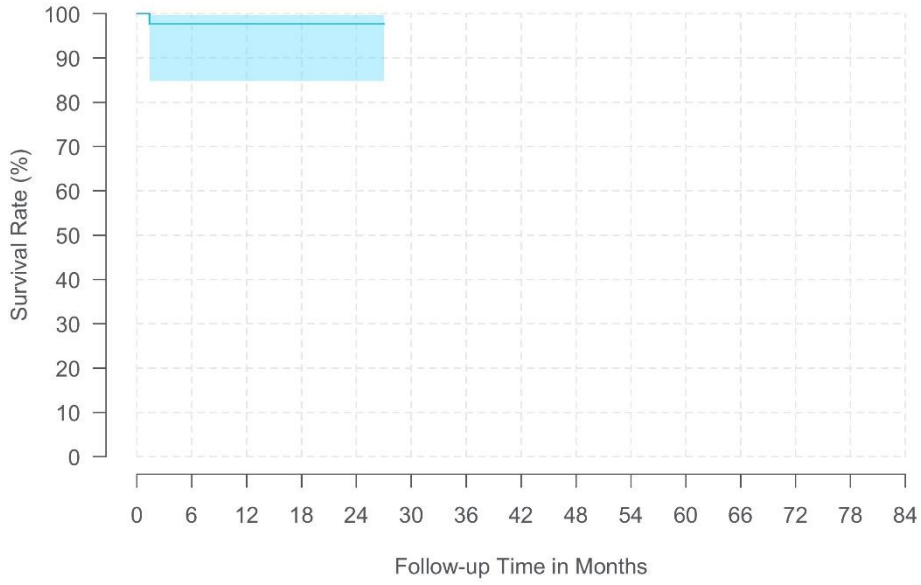
Time Interval	6 Years	7 Years	8 Years	9 Years	At 117 Months
Sample Size	35	31	27	22	21

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	46
Leads Currently Active in Study	17
Initial Product Performance Events	2
Median Follow-up Time (Months)	21.1
Cumulative Follow-up Time (Months)	1,339



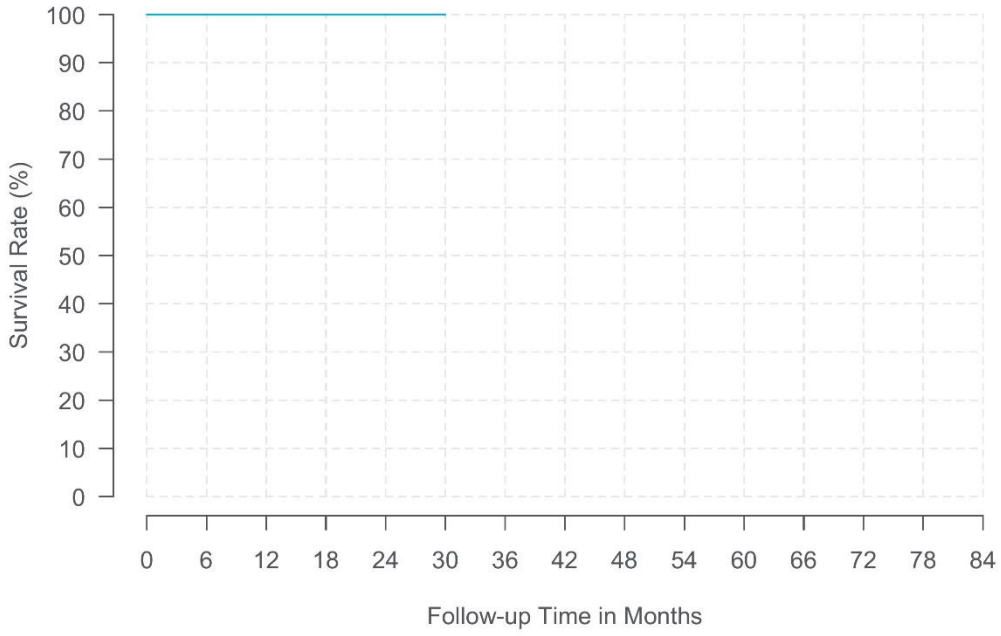
Time Interval	1 Year	2 Years	At 27 Months
Survival (95% CI)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)
Sample Size	32	22	21

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	NA
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	94
Leads Currently Active in Study	36
Initial Product Performance Events	3
Median Follow-up Time (Months)	12.2
Cumulative Follow-up Time (Months)	1,801



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)[a]	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	48	26	21

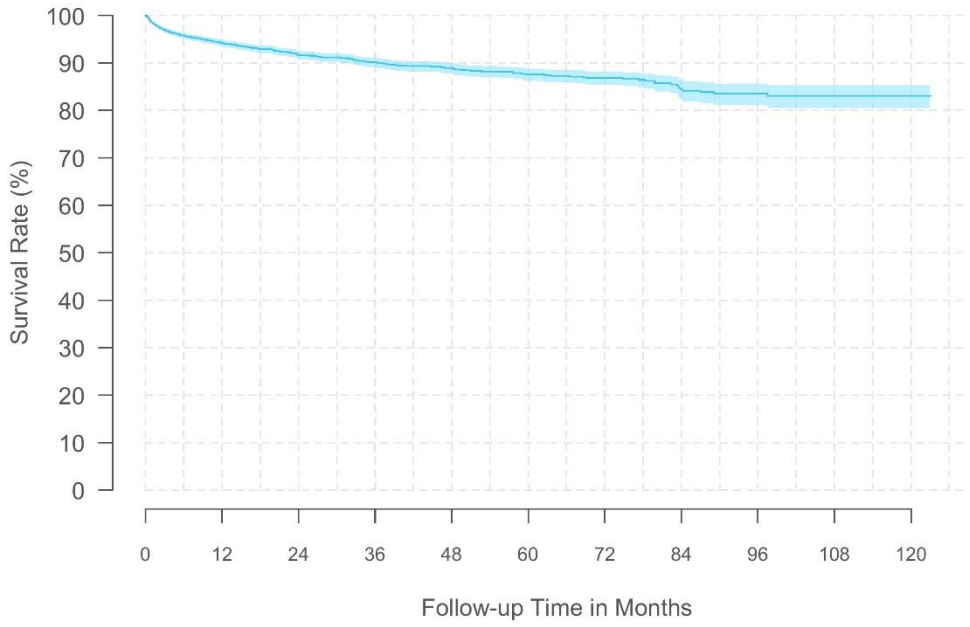
[a]Devices with at least 1 day of follow-up in the registry are included in analysis. One lead had an event on the day of implant (follow-up time = 0), one lead had an event at 31 months post-implant, and another lead had an event at 44 months post-implant, when fewer than 20 leads were at risk. These 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	NA
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	5,243
Leads Currently Active in Study	1,801
Initial Product Performance Events	427
Median Follow-up Time (Months)	24.2
Cumulative Follow-up Time (Months)	165,736



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	94.2% (93.5%, 94.9%)	91.6% (90.7%, 92.5%)	90.2% (89.2%, 91.1%)	88.9% (87.8%, 90.0%)	87.6% (86.3%, 88.8%)
Sample Size	3421	2474	1756	1254	843

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	86.8% (85.4%, 88.2%)	84.4% (82.3%, 86.3%)	83.5% (81.2%, 85.6%)	83.1% (80.6%, 85.3%)	83.1% (80.6%, 85.3%)
Sample Size	514	313	200	110	31

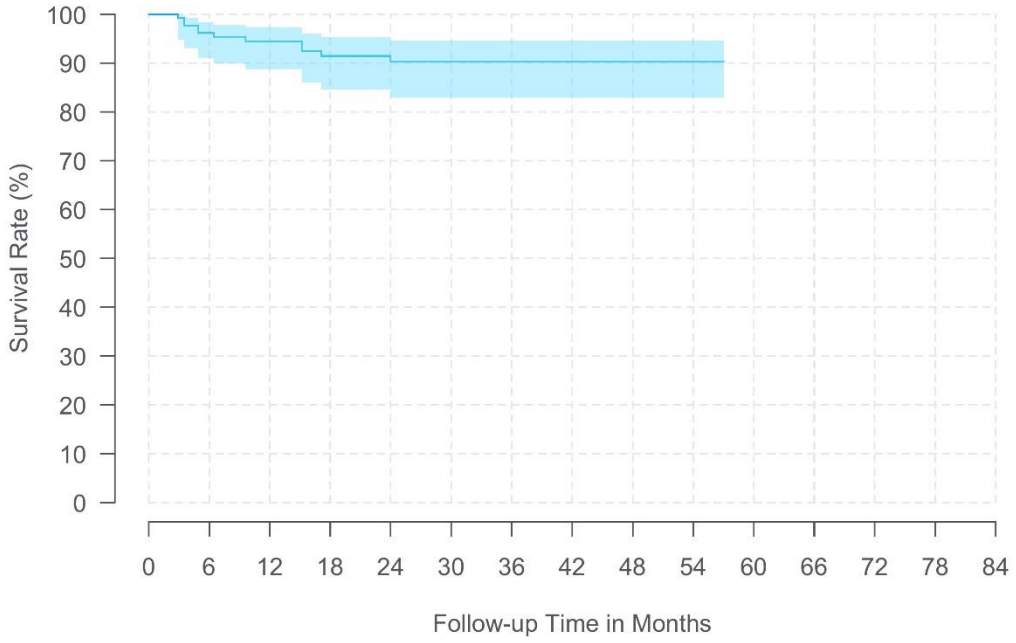
Time Interval	At 123 Months
Survival (95% CI)	83.1% (80.6%, 85.3%)
Sample Size	20

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	288
High Impedance	94
Lead Fracture	24
Device Electrical Impedance Issue	10
Low Impedance	3
Device Charging Issue	2
Device Positioned Inappropriately	2
Internal Device Exposed	2
Device Malfunction	1
Unspecified	1
Total	**427**

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	147
Leads Currently Active in Study	20
Initial Product Performance Events	11
Median Follow-up Time (Months)	28.5
Cumulative Follow-up Time (Months)	4,755



Time Interval	1 Year	2 Years	3 Years	4 Years	At 57 Months
Survival (95% CI)	94.5% (88.8%, 97.3%)	90.3% (82.9%, 94.5%)	90.3% (82.9%, 94.5%)	90.3% (82.9%, 94.5%)	90.3% (82.9%, 94.5%)
Sample Size	96	74	58	37	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	1
Total	**11**

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	53	267	17.9	69,868
1x8 SC (model 3776)	November 2005	188	10	17	15.0	5,773
1x8 Standard (model 3777)	April 2005	840	44	71	16.4	25,899
AnkerStim (model 09100)	NA	244	158	23	22.1	6,277
Pisces Compact (model 3887)	January 1997	202	14	25	23.7	8,199

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Pisces Plus (model 3888)	November 1992	458	32	46	15.1	13,616
Pisces Standard (model 3487A)	May 1988	993	46	167	31.7	43,345
Vectris SureScan MRI 1x8 Compact (model 977A2)	March 2013	5,243	1,801	427	24.2	165,736
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	March 2013	147	20	11	28.5	4,755

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%	84.7%	84.2%	81.8%
	(88.9%, 91.8%)	(85.2%, 88.7%)	(82.6%, 86.6%)	(82.0%, 86.1%)	(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%	88.1%	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)	94.2%	91.0%	85.2%	85.2%	85.2%
	(89.7%, 96.7%)	(85.6%, 94.4%)	(77.9%, 90.2%)	(77.9%, 90.2%)	(77.9%, 90.2%)
Pisces Compact (model 3887)	92.5%	83.1%	76.8%	75.3%	71.6%
	(78.3%, 97.6%)	(69.7%, 90.9%)	(63.2%, 85.9%)	(61.8%, 84.7%)	(57.7%, 81.6%)
Pisces Plus (model 3888)	92.5%	88.5%	85.3%	81.5%	79.6%
	(88.2%, 95.3%)	(82.9%, 92.3%)	(79.0%, 89.9%)	(74.5%, 86.7%)	(72.1%, 85.2%)
Pisces Standard (model 3487A)	91.8%	89.3%	84.8%	80.9%	76.6%
	(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)	94.2%	91.6%	90.2%	88.9%	87.6%
	(93.5%, 94.9%)	(90.7%, 92.5%)	(89.2%, 91.1%)	(87.8%, 90.0%)	(86.3%, 88.8%)
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	94.5%	90.3%	90.3%	90.3%	
	(88.8%, 97.3%)	(82.9%, 94.5%)	(82.9%, 94.5%)	(82.9%, 94.5%)	

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 Compact (model 3778)	80.6%	77.5%	76.0%	75.5%	73.5%
	(77.9%, 83.0%)	(74.1%, 80.4%)	(72.4%, 79.2%)	(71.8%, 78.8%)	(69.4%, 77.2%)
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)	85.6%	83.6%	81.2%	78.9%	78.9%
	(80.8%, 89.3%)	(77.9%, 87.9%)	(74.6%, 86.3%)	(71.5%, 84.5%)	(71.5%, 84.5%)
AnkerStim (model 09100)					
Pisces Compact (model 3887)	69.4%	67.1%	67.1%	61.9%	59.3%
	(55.2%, 79.8%)	(52.7%, 78.0%)	(52.7%, 78.0%)	(46.9%, 73.8%)	(44.1%, 71.7%)
Pisces Plus (model 3888)	74.9%	72.5%	71.0%	71.0%	71.0%
	(66.5%, 81.6%)	(63.5%, 79.6%)	(61.7%, 78.4%)	(61.7%, 78.4%)	(61.7%, 78.4%)
Pisces Standard (model 3487A)	73.4%	71.5%	71.5%	66.9%	63.8%
	(68.8%, 77.5%)	(66.7%, 75.7%)	(66.7%, 75.7%)	(61.4%, 71.8%)	(57.8%, 69.1%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	86.8%	84.4%	83.5%	83.1%	83.1%
	(85.4%, 88.2%)	(82.3%, 86.3%)	(81.2%, 85.6%)	(80.6%, 85.3%)	(80.6%, 85.3%)
Vectris SureScan MRI 1x8 Subcompact (model 977A1)					

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
1x8 Compact (model 3778)	71.3%	71.3%	68.6%	68.6%	
	(66.4%, 75.6%)	(66.4%, 75.6%)	(62.5%, 73.9%)	(62.5%, 73.9%)	
1x8 SC (model 3776)					
1x8 Standard (model 3777)	78.9%	77.6%	77.6%	77.6%	77.6%
	(71.5%, 84.5%)	(69.9%, 83.6%)	(69.9%, 83.6%)	(69.9%, 83.6%)	(69.9%, 83.6%)
AnkerStim (model 09100)					
Pisces Compact (model 3887)	59.3%				
	(44.1%, 71.7%)				
Pisces Plus (model 3888)	71.0%	71.0%	71.0%	71.0%	
	(61.7%, 78.4%)	(61.7%, 78.4%)	(61.7%, 78.4%)	(61.7%, 78.4%)	
Pisces Standard (model 3487A)	61.5%	57.6%	57.6%	57.6%	55.3%
	(55.2%, 67.2%)	(50.5%, 64.0%)	(50.5%, 64.0%)	(50.5%, 64.0%)	(47.9%, 62.2%)
Vectris SureScan MRI 1x8 Compact (model 977A2)					
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)	54.1% (46.4%, 61.2%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)	51.0% (42.6%, 58.8%)
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	294	27	11	22.9	9,210
Specify SureScan MRI 2x8 (model 977C2)	February 2016	46	17	2	21.1	1,339
Specify SureScan MRI 5-6-5 (model 977C1)	February 2016	94	36	3	12.2	1,801

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%	95.7%	95.7%	94.0%	94.0%
	(92.8%, 98.2%)	(91.9%, 97.8%)	(91.9%, 97.8%)	(88.0%, 97.1%)	(88.0%, 97.1%)
Specify SureScan MRI 2x8 (model 977C2)	97.7%	97.7%			
	(84.8%, 99.7%)	(84.8%, 99.7%)			
Specify SureScan MRI 5-6-5 (model 977C1)	100.0%	100.0%			
	(NA)	(NA)			

Model Name	6 Years	7 Years	8 Years	9 Years
Specify 5-6-5 (model 39565)	94.0%	94.0%	90.9%	90.9%

Model Name	6 Years	7 Years	8 Years	9 Years
	(88.0%, 97.1%)	(88.0%, 97.1%)	(80.0%, 96.0%)	(80.0%, 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, 2024, there were 3,749 extensions followed in the registry. The difference between the total number of extensions (n=3,749) versus neurostimulators (n=7,529) is due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 135,390 months (11,283 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	**2634 (70.0%)**
1x8 (37081)	1547 (41.3%)
Bifurcated Stretch-Coil (37082)	653 (17.4%)
Single Stretch-Coil (37083)	434 (11.6%)
No longer manufactured	**1085 (29.0%)**
Low Profile Quad (7489)	761 (20.3%)
Quadripolar In-Line (7495)	280 (7.5%)
Synergy bifurcated 1x8 (7472)	26 (0.7%)
Quadripolar (7496)	9 (0.2%)
Synergy 1x8 (7471)	9 (0.2%)
Other/Unspecified	**30 (0.8%)**
Total	**3749 (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:

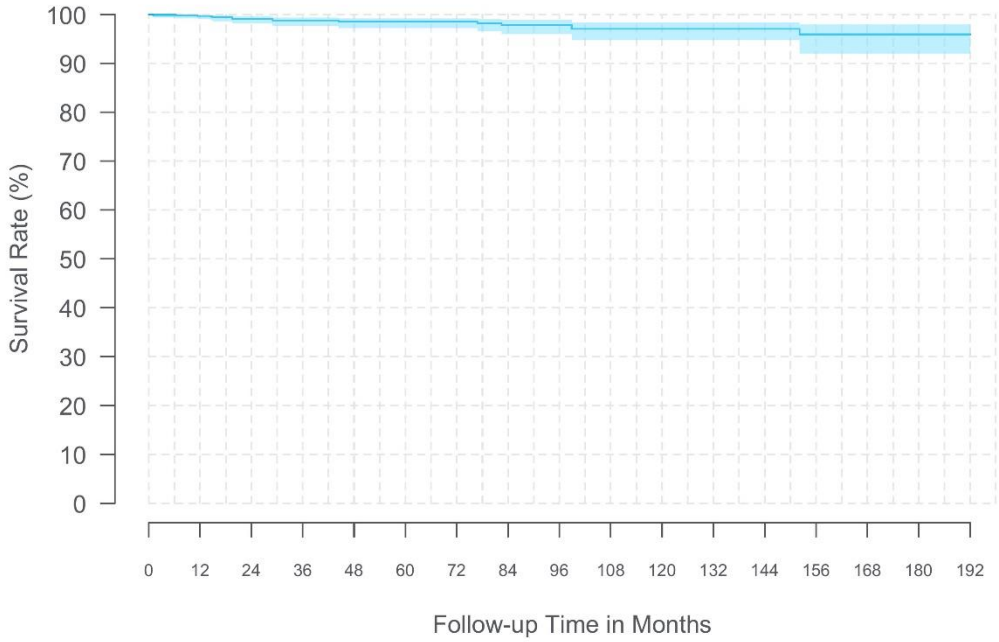
- 47 had follow-up time cut-off due to product performance-related events.
- 3,212 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 490 were free from 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	1,547
Extensions Currently Active in Study	221
Initial Product Performance Events	16
Median Follow-up Time (Months)	22.4
Cumulative Follow-up Time (Months)	59,034



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (99.1%, 99.9%)	99.1% (98.2%, 99.6%)	98.8% (97.6%, 99.4%)	98.5% (97.2%, 99.2%)	98.5% (97.2%, 99.2%)
Sample Size	857	590	439	388	347

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.5% (97.2%, 99.2%)	97.8% (96.0%, 98.8%)	97.8% (96.0%, 98.8%)	97.0% (94.7%, 98.4%)	97.0% (94.7%, 98.4%)
Sample Size	308	271	256	221	192

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	97.0% (94.7%, 98.4%)	97.0% (94.7%, 98.4%)	95.9% (92.0%, 97.9%)	95.9% (92.0%, 97.9%)	95.9% (92.0%, 97.9%)
Sample Size	153	103	77	52	38

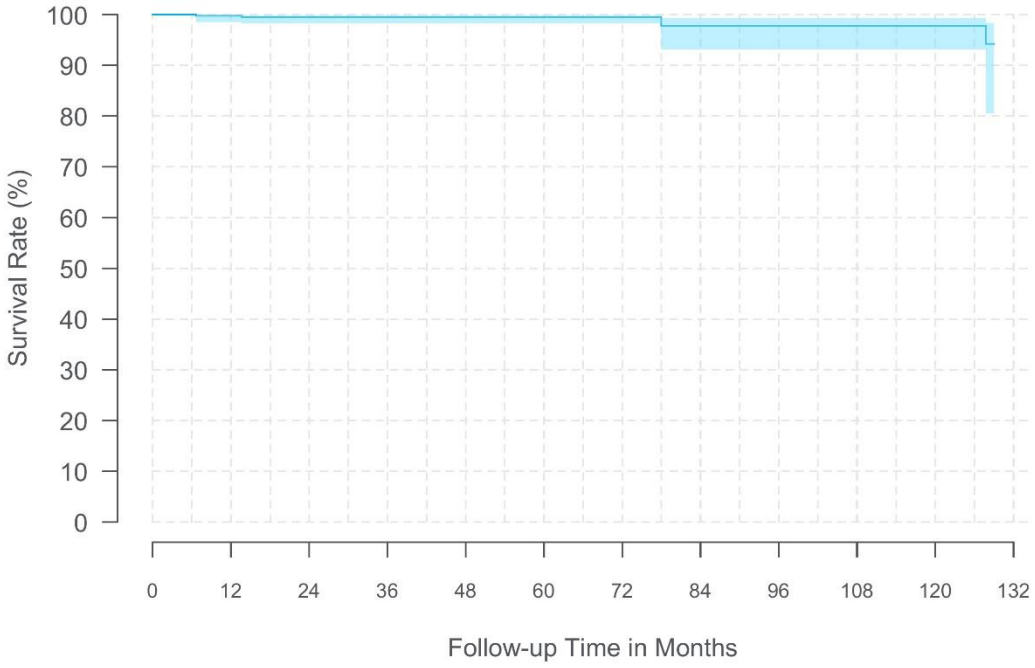
Time Interval	16 Years
Survival (95% CI)	95.9% (92.0%, 97.9%)
Sample Size	20

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	653
Extensions Currently Active in Study	35
Initial Product Performance Events	5
Median Follow-up Time (Months)	23.6
Cumulative Follow-up Time (Months)	24,216



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	440	316	230	177	148

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	96	72	56	40

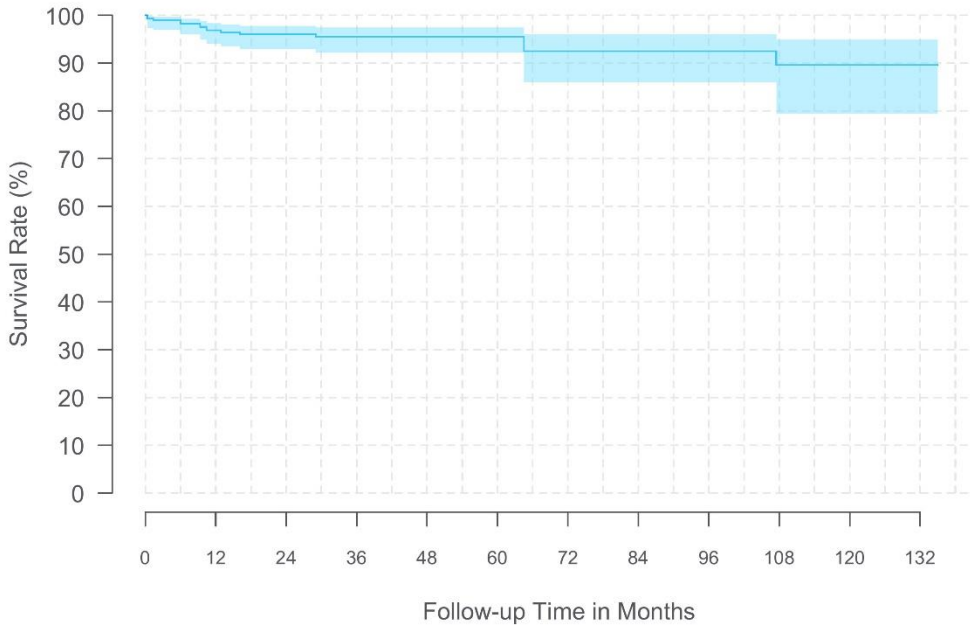
Time Interval	At 129 Months
Survival (95% CI)	94.2% (80.5%, 98.4%)
Sample Size	24

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	434
Extensions Currently Active in Study	146
Initial Product Performance Events	18
Median Follow-up Time (Months)	23.2
Cumulative Follow-up Time (Months)	14,154



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	96.9% (94.1%, 98.4%)	96.1% (93.0%, 97.8%)	95.6% (92.3%, 97.5%)	95.6% (92.3%, 97.5%)	95.6% (92.3%, 97.5%)
Sample Size	268	216	137	89	64

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	92.5% (86.0%, 96.1%)	92.5% (86.0%, 96.1%)	92.5% (86.0%, 96.1%)	89.6% (79.4%, 94.9%)	89.6% (79.4%, 94.9%)
Sample Size	41	41	36	30	25

Time Interval	11 Years	At 135 Months
Survival (95% CI)	89.6% (79.4%, 94.9%)	89.6% (79.4%, 94.9%)
Sample Size	21	21

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	1,547	221	16	22.4	59,034
Bifurcated Stretch-Coil (model 37082)	March 2006	653	35	5	23.6	24,216
Single Stretch-Coil (model 37083)	September 2005	434	146	18	23.2	14,154

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%	99.1%	98.8%	98.5%	98.5%
	(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)	96.9%	96.1%	95.6%	95.6%	95.6%
	(94.1%, 98.4%)	(93.0%, 97.8%)	(92.3%, 97.5%)	(92.3%, 97.5%)	(92.3%, 97.5%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 (model 37081)	98.5%	97.8%	97.8%	97.0%	97.0%
	(97.2%, 99.2%)	(96.0%, 98.8%)	(96.0%, 98.8%)	(94.7%, 98.4%)	(94.7%, 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)	92.5%	92.5%	92.5%	89.6%	89.6%
	(86.0%, 96.1%)	(86.0%, 96.1%)	(86.0%, 96.1%)	(79.4%, 94.9%)	(79.4%, 94.9%)

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
1x8 (model 37081)	97.0%	97.0%	95.9%	95.9%	95.9%
	(94.7%, 98.4%)	(94.7%, 98.4%)	(92.0%, 97.9%)	(92.0%, 97.9%)	(92.0%, 97.9%)
Bifurcated Stretch-Coil (model 37082)					
Single Stretch-Coil (model 37083)	89.6%				
	(79.4%, 94.9%)				

Model Name	16 Years
1x8 (model 37081)	95.9%
	(92.0%, 97.9%)
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, 2024. Sixty-six 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.

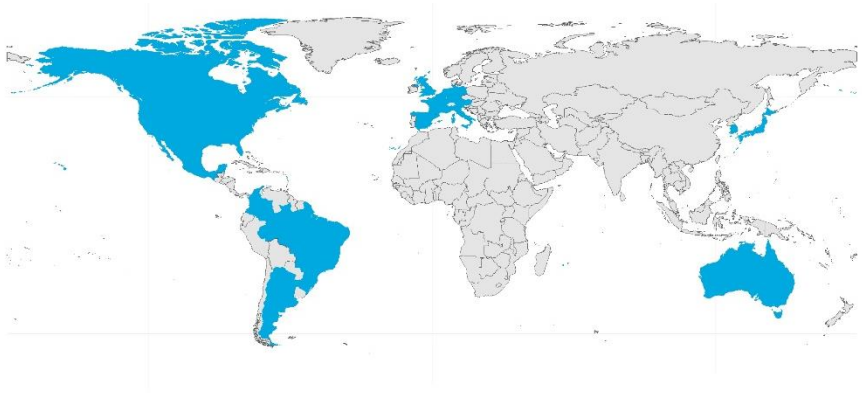


Figure 5.1: Countries with Deep Brain Stimulation Therapy Patients in Registry (Highlighted)

5.1.2 Patients

Of the 4,012 deep brain stimulation patients enrolled, the primary indications for implant were as follows: 63.63% were implanted for the treatment of Parkinson's Disease, 20.56% were implanted for the treatment of essential tremor, 9.35% were implanted for the treatment of dystonia, 1.92% were implanted for the treatment of epilepsy, 1.42% were implanted for the treatment of obsessive compulsive disorder, 2.39% were implanted for the treatment of other indications, and 0.72% 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).

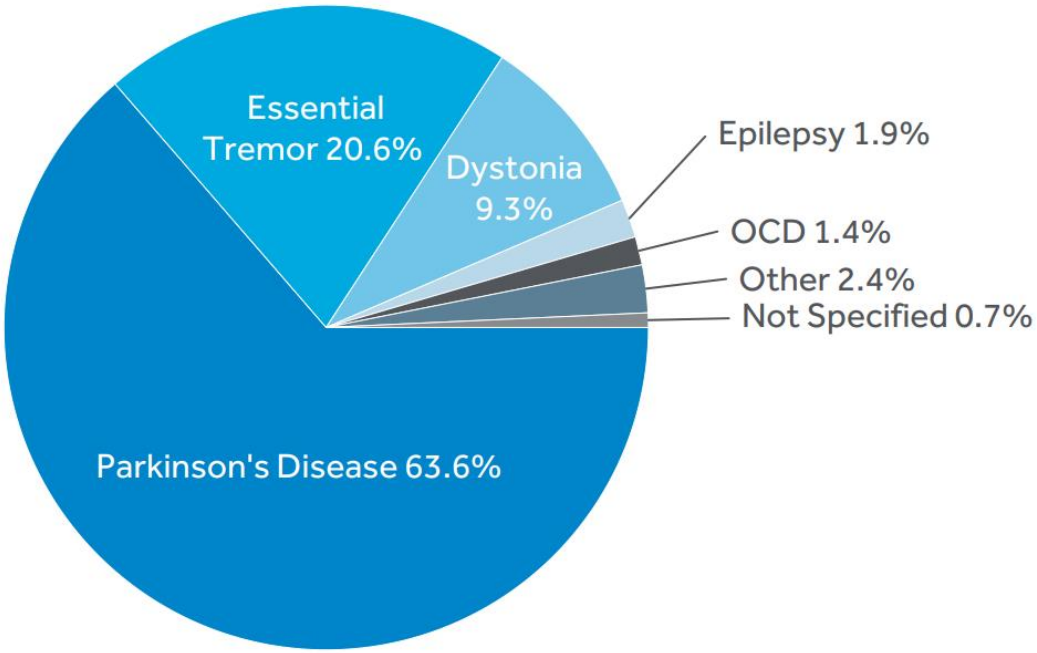


Figure 5.2: Deep Brain Stimulation Primary Treatment Indications

Table 5.1: Deep Brain Stimulation Primary Treatment Indications

Primary Treatment Indication[a]	Enrolled Patients (%)
Parkinson's Disease	2553 (63.63%)
Essential Tremor	825 (20.56%)
Dystonia	375 (9.35%)[b]
Epilepsy	77 (1.92%)
OCD	57 (1.42%)
Other	96 (2.39%)
Not Specified	29 (0.72%)
Total Patients	**4012 (100.00%)**

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

[b] 375/4012 = 0.09347 or 9.347%

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 (http://www.medtronic.com/us-en/about/locations.html).

5.2 Event Summary

There were 576 product performance events reported between July 2009 and October 31, 2024, in patients with deep brain stimulation systems. These events represented 22.4% of the total reported events (576/2,567), occurred in 340 of the 4,012 (8.5%) total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves). Of the remaining 1,991 reported non-product performance related events, 336 were serious and 1,655 were non-serious. Serious non-product performance related events (n=336) are described in Table 5.6. Non-serious non-product performance related (n=1,655) events are not listed in this report.

All 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 510 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=4012
RPA Determination	3	0.0	3 (0.07%)
Premature Battery Depletion	3	0.0	3 (0.07%)
Physician's Determination	573	3.9	338 (8.42%)
High Impedance	279	1.9	166 (4.14%)
Lead Migration/Dislodgement	54	0.4	38 (0.95%)
Low Impedance	40	0.3	25 (0.62%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%)[b] N=4012
Device Malfunction	28	0.2	24 (0.60%)
Lead Fracture	27	0.2	21 (0.52%)
Neurostimulator Unable To Recharge[c]	24	0.2	24 (0.60%)
Extension Migration	23	0.2	12 (0.30%)
Device Electrical Impedance Issue	12	0.1	6 (0.15%)
Extension Fracture	12	0.1	9 (0.22%)
Premature Battery Depletion	11	0.1	11 (0.27%)
Medical Device Complication	9	0.1	6 (0.15%)
Device Breakage	5	0.0	5 (0.12%)
Device Electrical Finding[d]	4	0.0	3 (0.07%)
Device End Of Life	4	0.0	4 (0.10%)
Device Lead Issue	4	0.0	4 (0.10%)
Device Protrusion	4	0.0	2 (0.05%)
Neurostimulator Inversion	4	0.0	4 (0.10%)
Device Charging Issue	3	0.0	3 (0.07%)
Device Connection Issue	3	0.0	3 (0.07%)
Device Lead Damage	2	0.0	1 (0.02%)
Device Material Corroded	2	0.0	1 (0.02%)
Device Short Circuiting	2	0.0	2 (0.05%)
Electromagnetic Interference	2	0.0	2 (0.05%)
Neurostimulator Migration	2	0.0	2 (0.05%)
Unspecified	2	0.0	2 (0.05%)
Other[e]	11	0.1	11 (0.27%)
Total	**576**	**3.9**	**340 (8.47%)**

[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] There were 953 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.5% (24/953) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

[d] Including open circuit contact, electric discharge.

e Composed of event codes with 1 event each.

A total of 277 (48.1%) of the 576 product performance events were related to the lead, 108 (18.8%) were related to the extension, 102 (17.7%) were related to the neurostimulator, 15 (2.6%) were related to multiple etiologies, which includes events where at least one device and one non-device etiology was indicated, and 74 (12.8%) were related to other etiologies. Other etiologies included: 45 (7.8%) related to other component, 10 (1.7%) related to surgery/anesthesia, 7 (1.2%) related to incisional site/device tract, 7 (1.2%) related to recharging process, 3 (0.5%) related to programming/stimulation, and 2 (0.4%) 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.

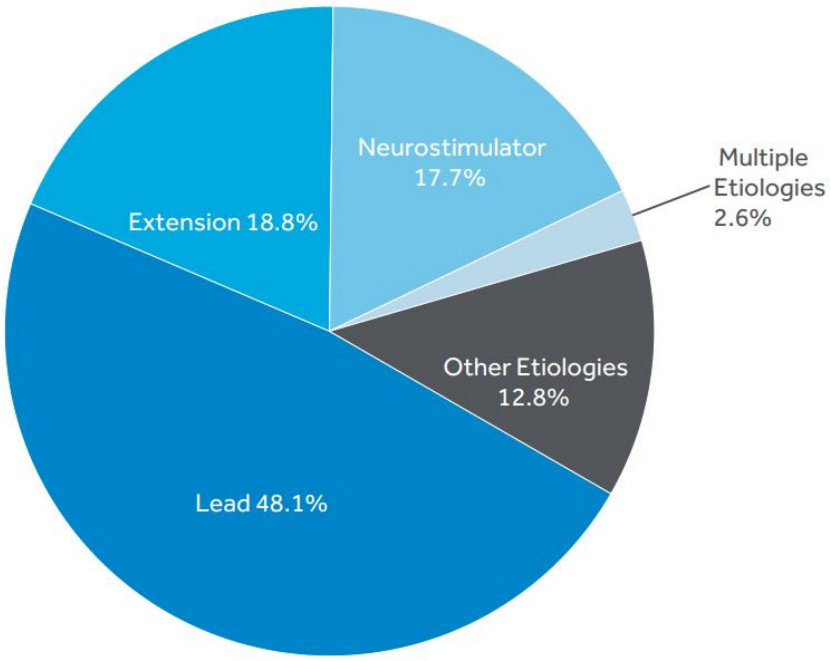


Figure 5.3: Deep Brain Stimulation System Product Performance Events by Relatedness

Table 5.3 and Table 5.4 describe the interventions taken for reported impedance events. In 35.5% and 32.5% 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 (58.4% for high impedance and 60.0% for low impedance).

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

Intervention	N (%) of High impedance Events
Device Surgical Intervention	86 (30.82%)
Reprogramming	64 (22.94%)
Other Surgical Intervention	13 (4.66%)
Other Intervention	8 (2.87%)
Medical or Non-Surgical Therapy	5 (1.79%)
Therapy Suspension	3 (1.08%)
Medication	1 (0.36%)
No Action Taken	99 (35.48%)
Total	**279 (100.00%)**

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

Intervention	N (%) of Low impedance Events
Device Surgical Intervention	13 (32.50%)
Reprogramming	10 (25.00%)
Medication	2 (5.00%)
Other Intervention	1 (2.50%)
No Action Taken	14 (35.00%)
Total	**40 (100.00%)**

Table 5.5 describes the interventions taken for reported lead migration/dislodgement events over the total of 4,012 patients enrolled. 68.5% of reported lead migration/dislodgement events resulted in a surgical intervention and 14.8% 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	35 (64.81%)
Reprogramming	8 (14.81%)
Other Surgical Intervention	2 (3.70%)
Medication	1 (1.85%)
No Action Taken	8 (14.81%)
Total	**54 (100.00%)**

* considering "dislodgment" as an observation, not confirmed by imaging

5.2.2 Clinical Events Not Related ToProduct 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=2,829).
- Categorized as serious adverse events (SAEs, N=336).
- Occurred with a System Organ Class (SOC) threshold ≥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 (e.g. Negative changes in behavior from baseline, new or worsening depression, attempted suicide, etc.)

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=2,829	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=2,829
Infections and infestations	126	103 (3.64%)	0.11	97 (3.43%)
Infections - pathogen unspecified	123	100 (3.53%)	0.11	95 (3.36%)
Other[b]	3	3 (0.11%)	0.00	2 (0.07%)
Nervous system disorders	78	69 (2.44%)	0.07	17 (0.60%)
Movement disorders (incl parkinsonism)	24	21 (0.74%)	0.02	5 (0.18%)
Central nervous system vascular disorders	22	22 (0.78%)	0.02	4 (0.14%)
Neurological disorders NEC	14	13 (0.46%)	0.01	4 (0.14%)
Seizures (incl subtypes)	8	8 (0.28%)	0.01	1 (0.04%)
Other[b]	10	10 (0.35%)	0.01	3 (0.11%)
General disorders and administration site conditions	66	62 (2.19%)	0.06	41 (1.45%)
Complications associated with device	48	46 (1.63%)	0.04	34 (1.2%)
General system disorders NEC	10	10 (0.35%)	0.01	2 (0.07%)
Other[b]	8	8 (0.28%)	0.01	6 (0.21%)
Other SOC Terms (<1.0% Threshold)	66	63 (2.23%)	0.06	27 (0.95%)
Total	**336**	**264 (9.33%)**	**0.31**	**165 (5.83%)**

[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 510 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 4,012 enrolled patients, there have been 407 (deaths reported in this patient registry study based upon patients receiving therapy for Parkinson's Disease, 74) for essential tremor, 16 for dystonia, 4 for epilepsy, 1 (for OCD, and 7 for other indications (see Table 5.7).

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

Number of Reports of Death by Primary Indication[a]	N (%[b]) of Deaths	Mean Age of Death in Years
Parkinson's Disease	407 (79.8%)	74.1
Essential Tremor	74 (14.5%)	78.2
Dystonia	16 (3.1%)	61.3
Epilepsy	4 (0.8%)	29.8
OCD	1 (0.2%)	70.4
Other	7 (1.4%)	66.9
Not Specified	1 (0.2%)	50.0
Total	**510**	**74.1**

[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 (primary 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, 2024, there were 6,349 neurostimulators followed in the registry. The difference between the total number of patients (n=4,012) versus the number of neurostimulators (n=6,349) 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 189,261 months (15,772 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)	2771 (43.6%)
Percept™ PC (model B35200)	1238 (19.5%)
Activa™ RC (model 37612)	974 (15.3%)
Activa™ SC (model 37603)	700 (11.0%)
Activa ™SC (model 37602)	475 (7.5%)
Percept™ RC (model B35300)	78 (1.2%)
No longer manufactured	
Soletra (model 7426)	67 (1.1%)
Kinetra (model 7428)	12 (0.2%)
Other/Unspecified[a]	**34 (0.5%)**
Total	**6349**

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

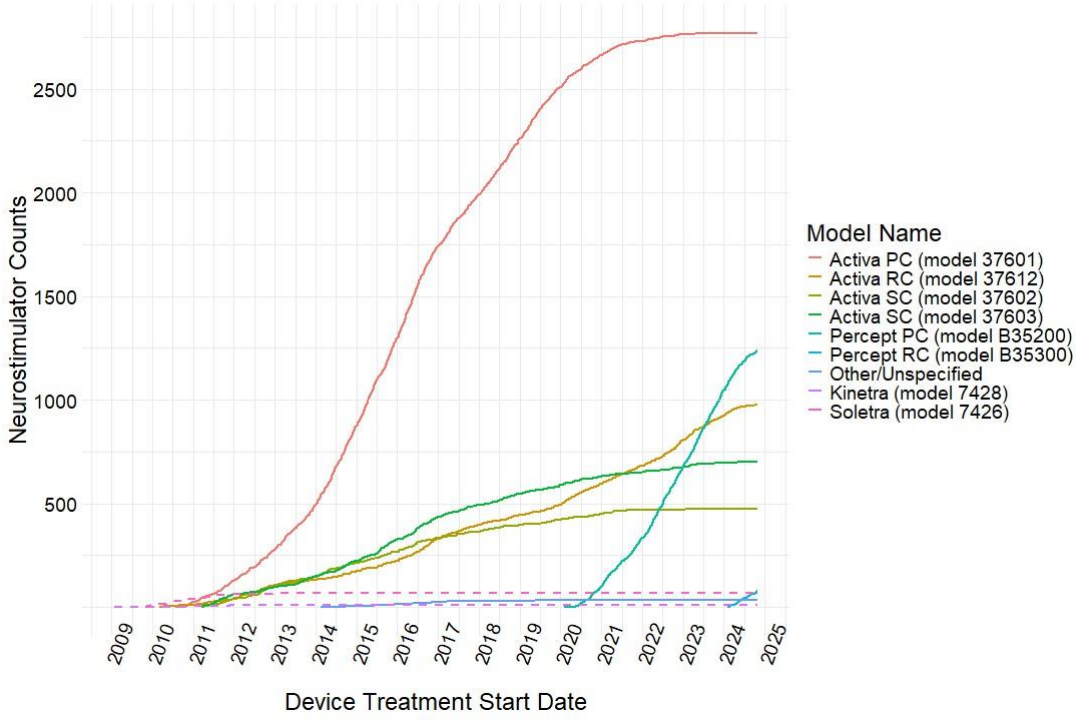


Figure 5.4: Cumulative Neurostimulator Counts by model over time

5.3.1 Neurostimulator Events

Of the total of 576 product performance-related events, there were 104 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 102 events with a neurostimulator etiology and 2 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 77 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 3.7% (106/2,845). 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 104 neurostimulator events, 97.1 % (101/104) 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 (2.9%)
Premature Battery Depletion	3 (2.9%)

Product Performance Events	N (%)
Physician's Determination	101 (97.1%)
High Impedance	49 (47.1%)
Device Malfunction	13 (12.5%)
Premature Battery Depletion	11 (10.6%)
Low Impedance	8 (7.7%)
Device End Of Life[a]	4 (3.8%)
Electromagnetic Interference	2 (1.9%)
Extension Migration	2 (1.9%)
Device Computer Software Issue	1 (1.0%)
Device Electrical Finding[b]	1 (1.0%)
Device Electrical Impedance Issue	1 (1.0%)
Device Protrusion	1 (1.0%)
Device Short Circuiting	1 (1.0%)
Device Temperature Issue	1 (1.0%)
Device Vibration	1 (1.0%)
Neurostimulator Inversion	1 (1.0%)
Neurostimulator Migration	1 (1.0%)
Neurostimulator Unable To Recharge	1 (1.0%)
No Adverse Event	1 (1.0%)
Unspecified	1 (1.0%)
Total	**104 (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:

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

- 4,398 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.
- 1,874 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.

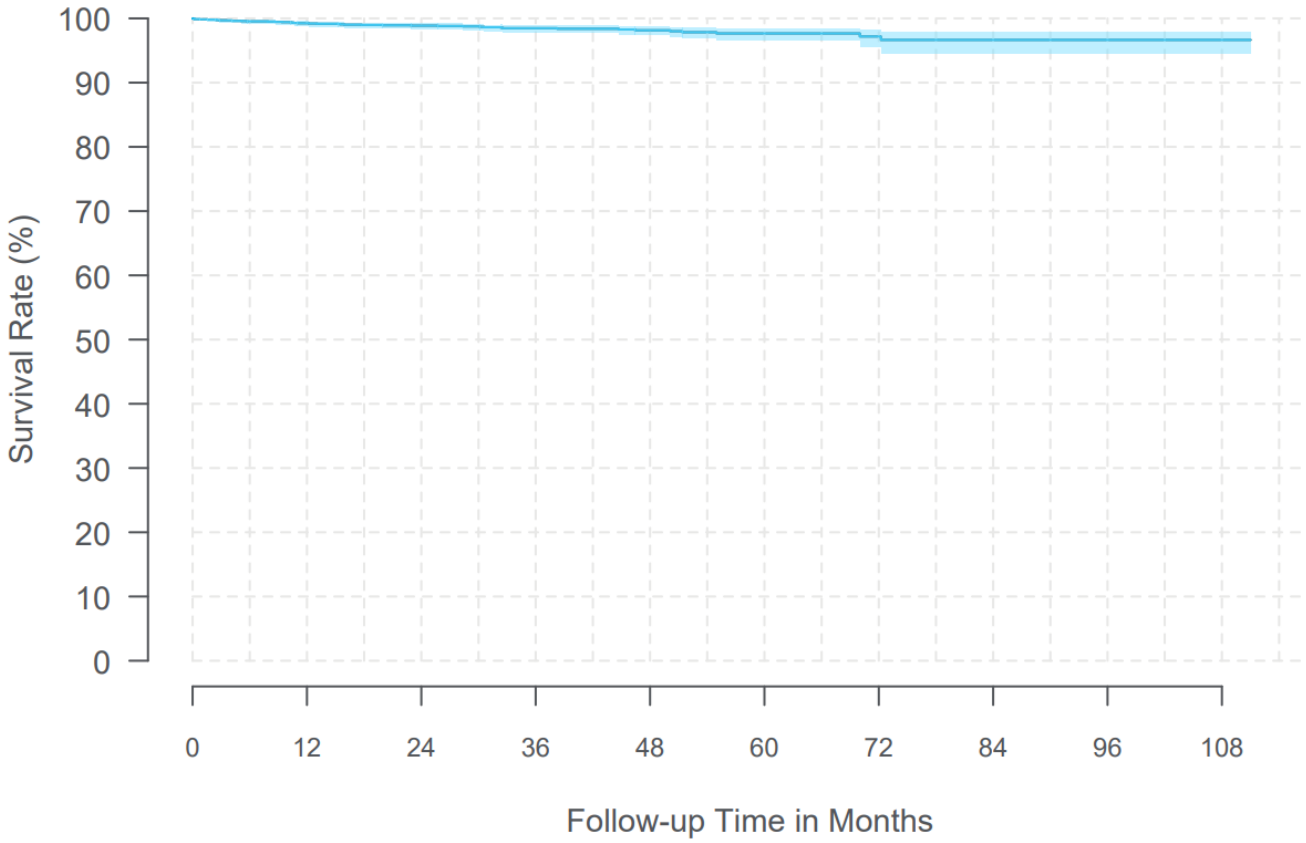
5.3.2 Neurostimulator Models

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	2,771
Neurostimulators Currently Active in Study	270
Initial Product Performance Events	46
Median Follow-up Time (Months)	32.2
Cumulative Follow-up Time (Months)	97,852



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.2% (98.8%, 99.5%)	98.9% (98.4%, 99.2%)	98.5% (97.8%, 98.9%)	98.1% (97.4%, 98.7%)	97.7% (96.6%, 98.4%)
Sample Size	2290	1803	1225	737	393

Time Interval	6 Years	7 Years	8 Years	9 Years	At 111 Months
Survival (95% CI)	97.2% (95.6%, 98.2%)	96.6% (94.6%, 97.9%)	96.6% (94.6%, 97.9%)	96.6% (94.6%, 97.9%)	96.6% (94.6%, 97.9%)
Sample Size	182	91	46	24	21

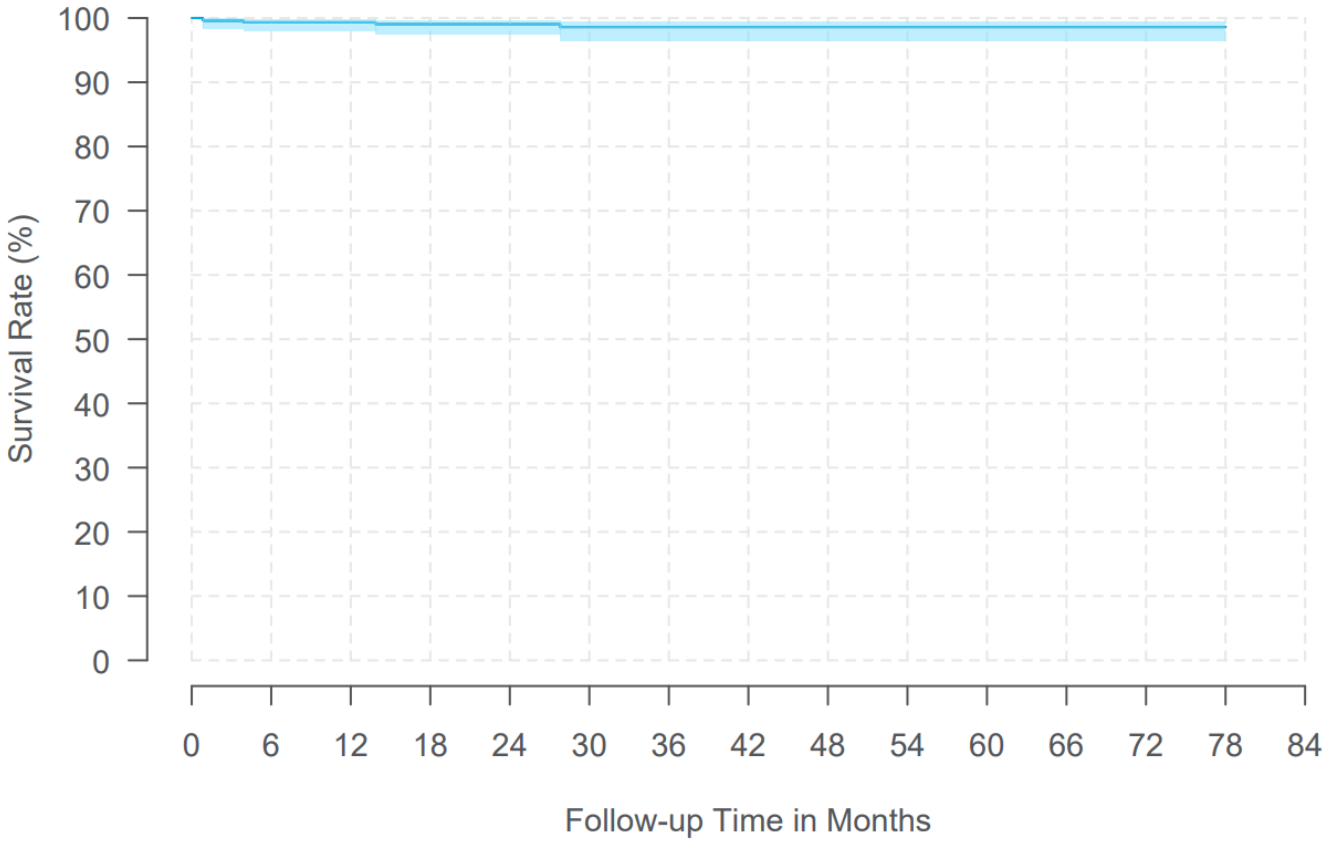
Specification: Activa™ PC (model 37601)	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current 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 (model 37601)	N
High Impedance	18
Premature Battery Depletion	13
Device Malfunction	6
Device End Of Life	3
Device Electrical Finding[a]	1
Device Protrusion	1
Device Temperature Issue	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	475
Neurostimulators Currently Active in Study	34
Initial Product Performance Events	5
Median Follow-up Time (Months)	26.2
Cumulative Follow-up Time (Months)	13,928



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% (96.5%, 99.4%)	98.6% (96.5%, 99.4%)	98.6% (96.5%, 99.4%)

Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Sample Size	361	260	146	77	39

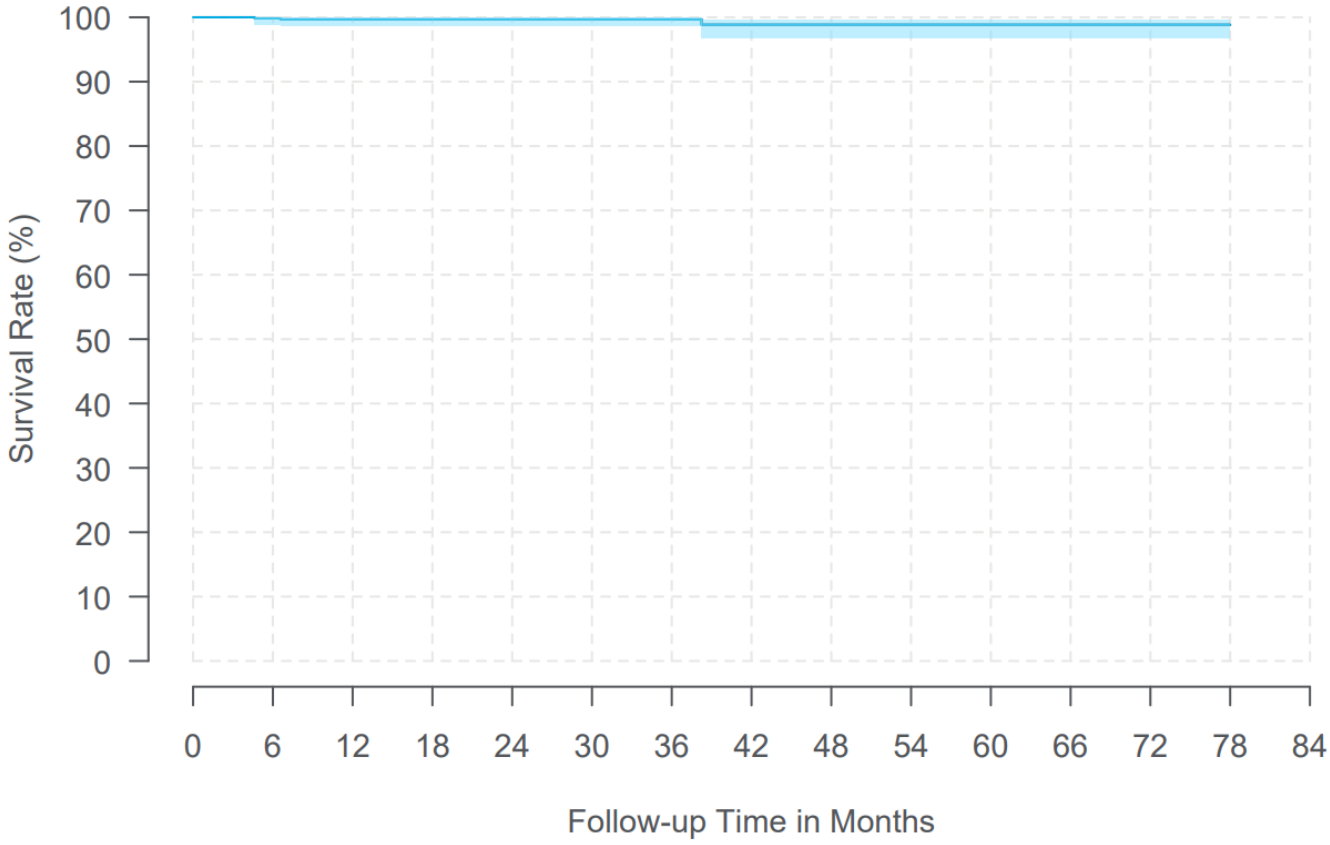
Time Interval	6 Years	At 78 Months
Survival (95% CI)	98.6% (96.5%, 99.4%)	98.6% (96.5%, 99.4%)
Sample Size	27	20

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	700
Neurostimulators Currently Active in Study	78
Initial Product Performance Events	5
Median Follow-up Time (Months)	28.2
Cumulative Follow-up Time (Months)	21,656



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%)	99.7% (98.7%, 99.9%)	98.9% (96.7%, 99.6%)	98.9% (96.7%, 99.6%)

Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Sample Size	552	418	266	137	66

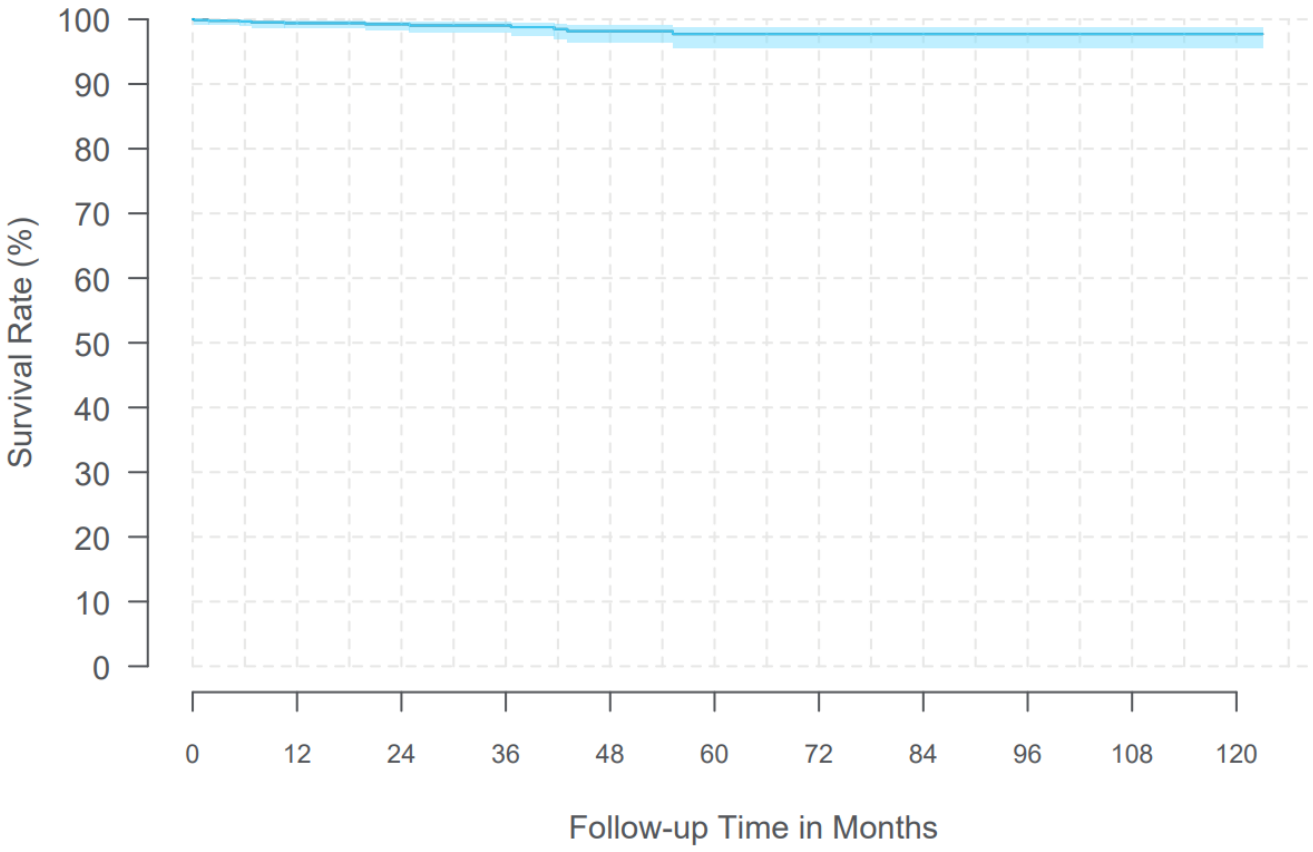
Time Interval	6 Years	At 78 Months
Survival (95% CI)	98.9% (96.7%, 99.6%)	98.9% (96.7%, 99.6%)
Sample Size	36	25

Specification: Activa™ 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: Activa ™ SC (model 37603)	N
High Impedance	4
Low Impedance	1
Total	**5**

5.3.2.4 Model Activa™ RC 37612

Model Name	Activa™ RC
FDA Approval Date	March 2009
Neurostimulators Enrolled	974
Neurostimulators Currently Active in Study	533
Initial Product Performance Events	13
Median Follow-up Time (Months)	29.7
Cumulative Follow-up Time (Months)	36,034

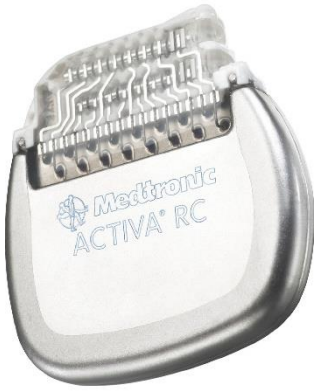


Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.4% (98.6%, 99.8%)	99.2% (98.3%, 99.7%)	99.0% (98.0%, 99.6%)	98.2% (96.4%, 99.1%)	97.7% (95.6%, 98.8%)
Sample Size	729	539	388	266	195

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.7% (95.6%, 98.8%)	97.7% (95.6%, 98.8%)	97.7% (95.6%, 98.8%)	97.7% (95.6%, 98.8%)	97.7% (95.6%, 98.8%)
Sample Size	155	116	67	39	24

Time Interval	At 123 Months
Survival (95% CI)	97.7% (95.6%, 98.8%)
Sample Size	22

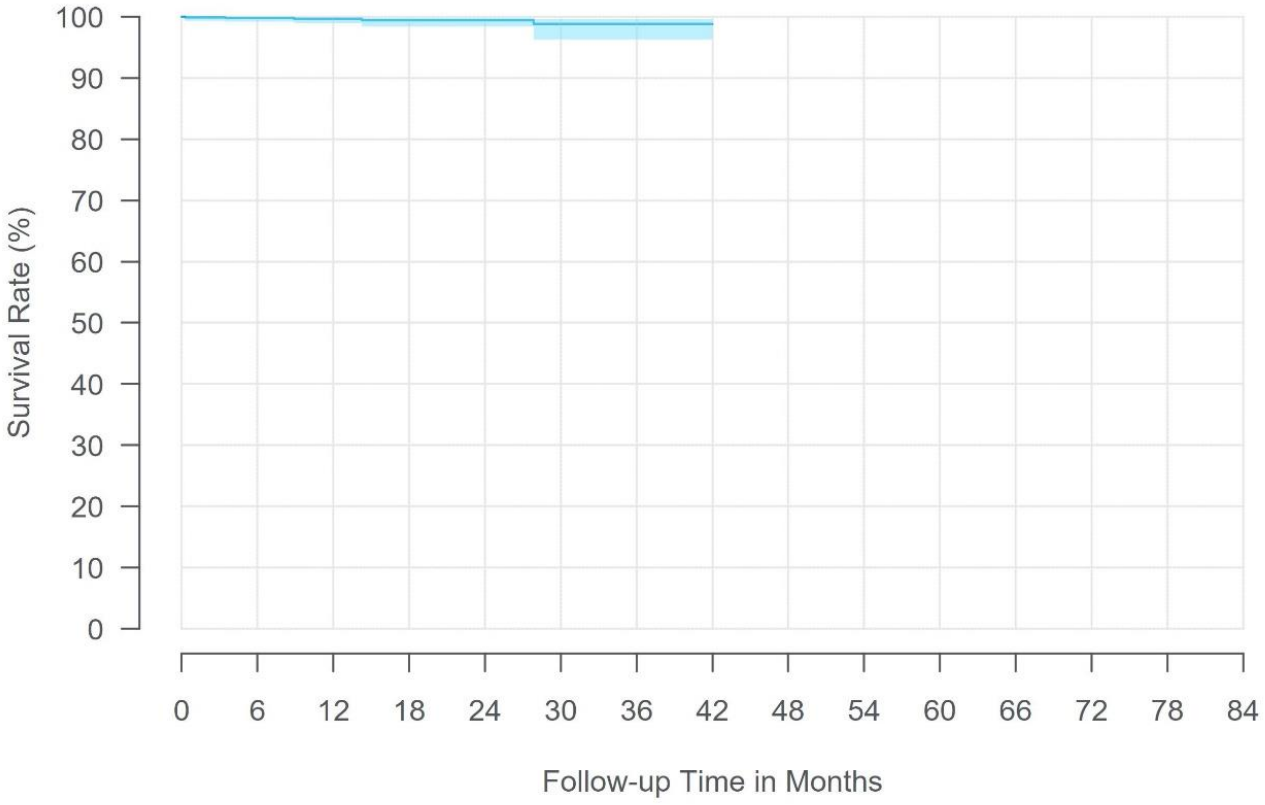
Specification: Activa™ RC (model 37612)	
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 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 (model 37612)	N
High Impedance	4
Device Malfunction	2
Extension Migration	2
Device Computer Software Issue	1
Low Impedance	1
Neurostimulator Inversion	1
Neurostimulator Migration	1
Neurostimulator Unable To Recharge	1
Total	**13**

5.3.2.5 Model Percept™ PC B35200

Model Name	Percept™ PC
FDA Approval Date	June 2020
Neurostimulators Enrolled	1,238
Neurostimulators Currently Active in Study	889
Initial Product Performance Events	7
Median Follow-up Time (Months)	11.3
Cumulative Follow-up Time (Months)	16,292



Time Interval	1 Year	2 Years	3 Years	At 42 Months
Survival (95% CI)	99.7% (99.0%, 99.9%)	99.4% (98.4%, 99.8%)	98.8% (96.3%, 99.6%)	98.8% (96.3%, 99.6%)
Sample Size	569	222	68	20

Specification: Percept™ PC (model B35200)	
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 (model B35200)	N
High Impedance	4
Device Malfunction	2
Unspecified	1
Total	**7**

5.3.2.6 Model Percept™ RC B35300

Model Name	Percept™ RC
FDA Approval Date	January 2024
Neurostimulators Enrolled	78
Neurostimulators Currently Active in Study	76
Initial Product Performance Events	0
Median Follow-up Time (Months)	0
Cumulative Follow-up Time (Months)	88

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 (case) 9 mm (connector block)
Volume	13.77 cm3
Battery type	Rechargeable
Expected Battery life	15years 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 (up to 2 per hemisphere per group)
Implant Depth	≤ 3cm

*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	2,771	270	46	32.2	97,852
Activa™ SC (model 37602)	January 2011	475	34	5	26.2	13,928
Activa™ RC (model 37612)	March 2009	974	533	13	29.7	36,034
Activa™ SC (model 37603)	January 2011	700	78	5	28.2	21,656
Percept™ PC (model B35200)	June 2020	1238	889	7	11.3	16,292
Percept™ RC (model B35300)	January 2024	78	76	0	0	88

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)	99.2%	98.9%	98.5%	98.1%	97.7%
	(98.8%, 99.5%)	(98.4%, 99.2%)	(97.8%, 98.9%)	(97.4%, 98.7%)	(96.6%, 98.4%)
Activa™ SC (model 37602)	99.3%	99.0%	98.6%	98.6%	98.6%
	(97.9%, 99.8%)	(97.5%, 99.6%)	(96.5%, 99.4%)	(96.5%, 99.4%)	(96.5%, 99.4%)
Activa™ RC (model 37612)	99.4%	99.2%	99.0%	98.2%	97.7%
	(98.6%, 99.8%)	(98.3%, 99.7%)	(98.0%, 99.6%)	(96.4%, 99.1%)	(95.6%, 98.8%)
Activa™ SC (model 37603)	99.7%	99.7%	99.7%	98.9%	98.9%
	(98.7%, 99.9%)	(98.7%, 99.9%)	(98.7%, 99.9%)	(96.7%, 99.6%)	(96.7%, 99.6%)
Percept™ PC (model B35200)	99.7%	99.4%	98.8%		
	(99.0%, 99.9%)	(98.4%, 99.8%)	(96.3%, 99.6%)		

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Activa™ PC (model 37601)	97.2%	96.6%	96.6%	96.6%	
	(95.6%, 98.2%)	(94.6%, 97.9%)	(94.6%, 97.9%)	(94.6%, 97.9%)	
Activa™ SC (model 37602)	98.6%				
	(96.5%, 99.4%)				
Activa™ RC (model 37612)	97.7%	97.7%	97.7%	97.7%	97.7%
	(95.6%, 98.8%)	(95.6%, 98.8%)	(95.6%, 98.8%)	(95.6%, 98.8%)	(95.6%, 98.8%)
Activa™ SC (model 37603)	98.9%				
	(96.7%, 99.6%)				
Percept™ PC (model B35200)					

5.4 Leads

From July 2009 to the report cut-off date of October 31, 2024, there were 6,941 leads followed in the registry. The difference between the total number of leads (n=6,941) versus neurostimulators (n=6,349) 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 308,892 months (25,741 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 (%)
3389 (compact electrode spacing)	3203 (46.1%)
3387 (standard electrode spacing)	2452 (35.3%)
SenSight™ B33005 (compact electrode spacing)	876 (12.6%)
SenSight™ B33015 (standard electrode spacing)	318 (4.6%)
3391 (large electrode and wide spacing)	72 (1.0%)
Other/Unspecified[a]	20 (0.3%)
Total	**6941**

[a] Includes leads used in other manufacturer's systems.

5.4.1 Lead Events

Of the total of 576 product performance-related events, there were 286 product performance- related events with an underlying reported etiology related to lead function. This includes 277 events with a lead etiology and 9 events with both a lead and other etiology (including device and non-device etiologies). Of these, 153 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:

- 153 had follow-up time cut-off due to product performance-related events.
- 3,585 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.
- 3,203 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.

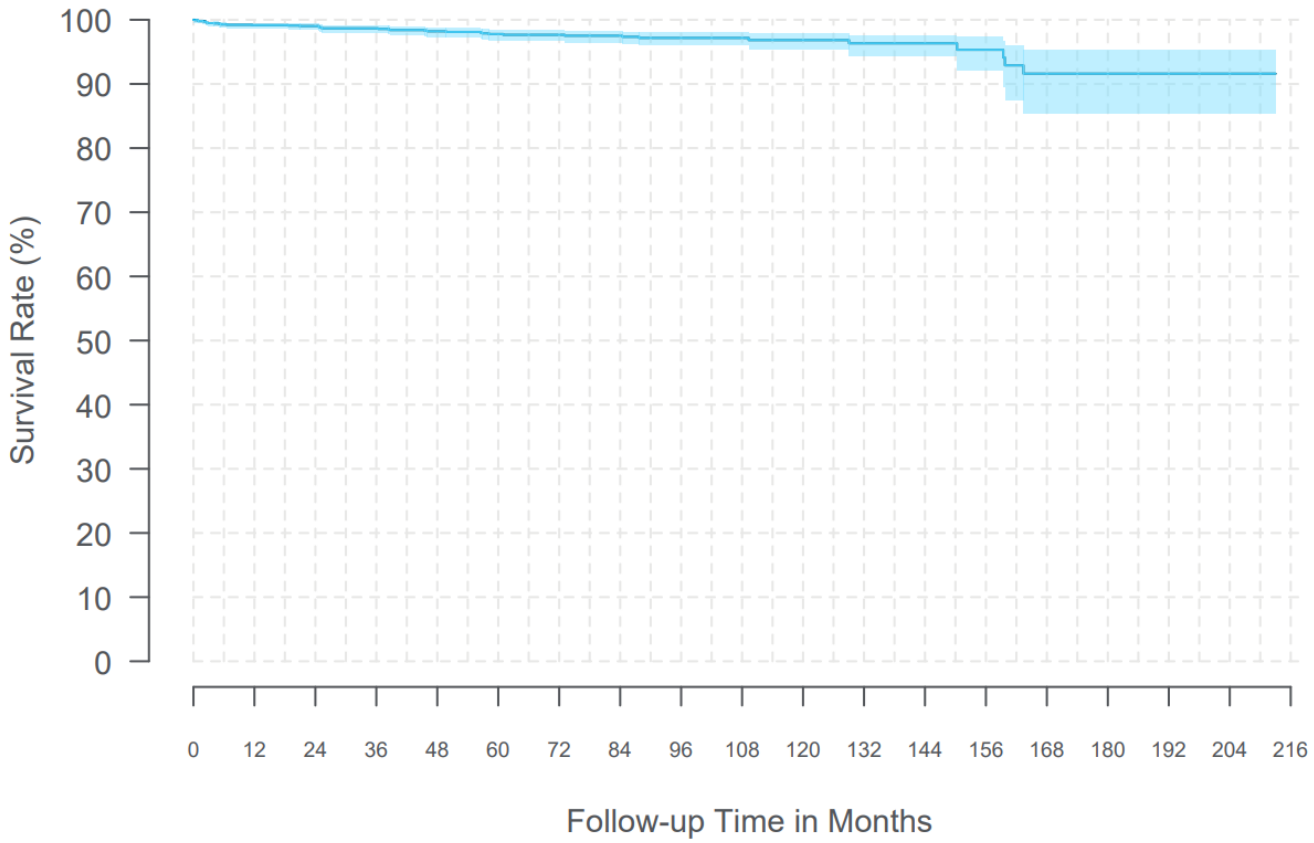
Initial product performance events of other/unspecified models (n=3) are not summarized in the subsequent sections.

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	2,452
Leads Currently Active in Study	930
Initial Product Performance Events	44
Median Follow-up Time (Months)	39.4
Cumulative Follow-up Time (Months)	120,981



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.2% (98.6%, 99.5%)	99.0% (98.5%, 99.4%)	98.7% (98.0%, 99.1%)	98.2% (97.4%, 98.8%)	97.8% (96.8%, 98.4%)
Sample Size	1723	1369	1145	983	849

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.7% (96.7%, 98.4%)	97.5% (96.5%, 98.3%)	97.2% (96.0%, 98.0%)	97.2% (96.0%, 98.0%)	96.8% (95.4%, 97.8%)
Sample Size	709	588	434	292	228

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	96.3% (94.4%, 97.6%)	96.3% (94.4%, 97.6%)	95.3% (92.1%, 97.3%)	91.6% (85.3%, 95.3%)	91.6% (85.3%, 95.3%)
Sample Size	182	114	78	69	54

Time Interval	16 Years	17 Years	At 213 Months
Survival (95% CI)	91.6% (85.3%, 95.3%)	91.6% (85.3%, 95.3%)	91.6% (85.3%, 95.3%)
Sample Size	39	24	20

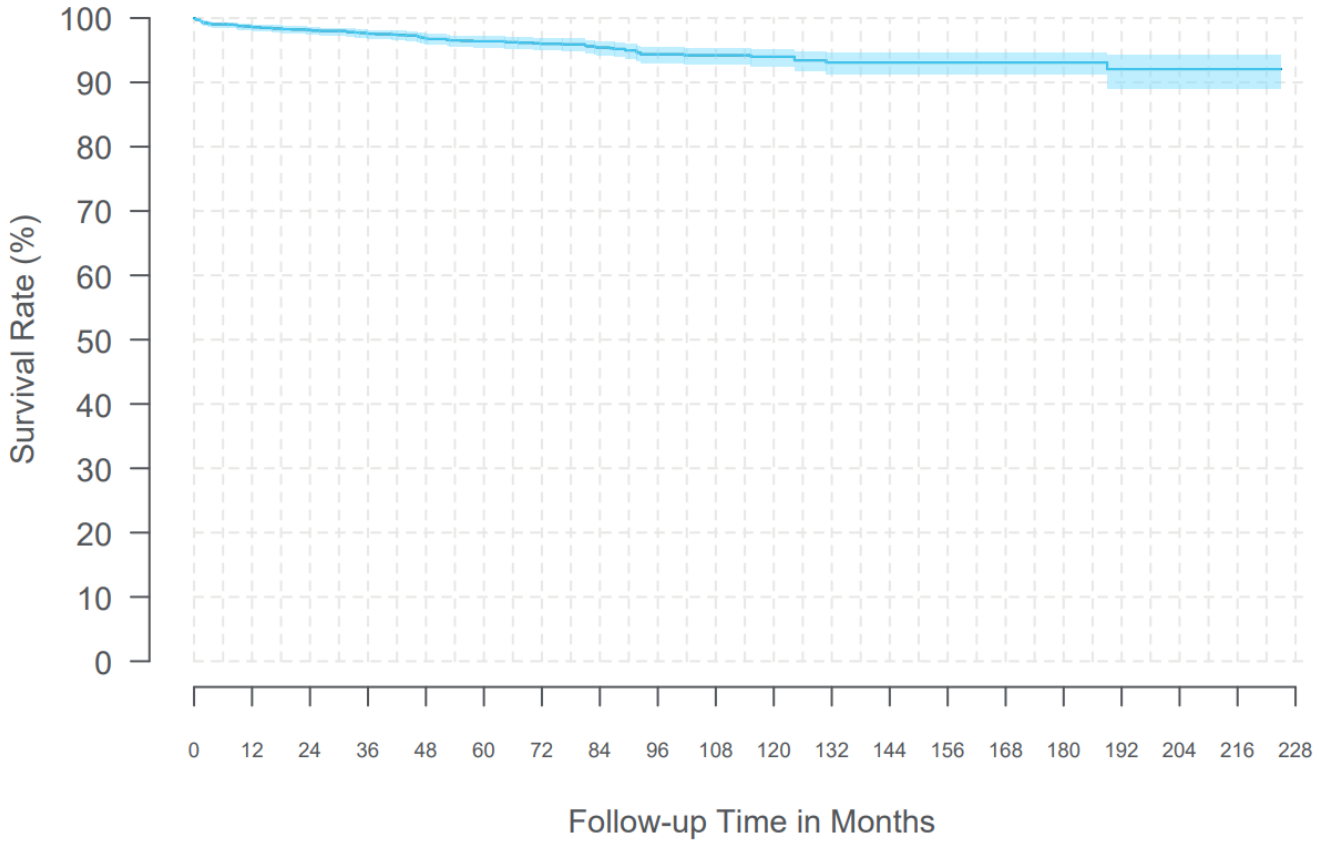
Specification: 3387	
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm^2)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	10.5

Lead Event Summary: 3387	N
High Impedance	21
Lead Migration/Dislodgement	10
Low Impedance	8
Lead Fracture	3
Device Electrical Finding[a]	1
Device Lead Issue	1
Total	**44**

[a] Open circuit contact

5.4.2.2 Model 3389

Model Name	3389
FDA Approval Date	September 1999
Leads Enrolled	3,203
Leads Currently Active in Study	1,297
Initial Product Performance Events	94
Median Follow-up Time (Months)	44.7
Cumulative Follow-up Time (Months)	177,977



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%, 98.6%)	97.6% (96.8%, 98.1%)	96.8% (95.9%, 97.5%)	96.4% (95.4%, 97.2%)
Sample Size	2080	1774	1553	1405	1310

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	96.0% (95.0%, 96.8%)	95.4% (94.3%, 96.3%)	94.4% (93.0%, 95.5%)	94.2% (92.8%, 95.3%)	94.0% (92.5%, 95.2%)
Sample Size	1153	929	690	514	363

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	93.1% (91.2%, 94.6%)	93.1% (91.2%, 94.6%)	93.1% (91.2%, 94.6%)	93.1% (91.2%, 94.6%)	93.1% (91.2%, 94.6%)
Sample Size	274	215	178	143	116

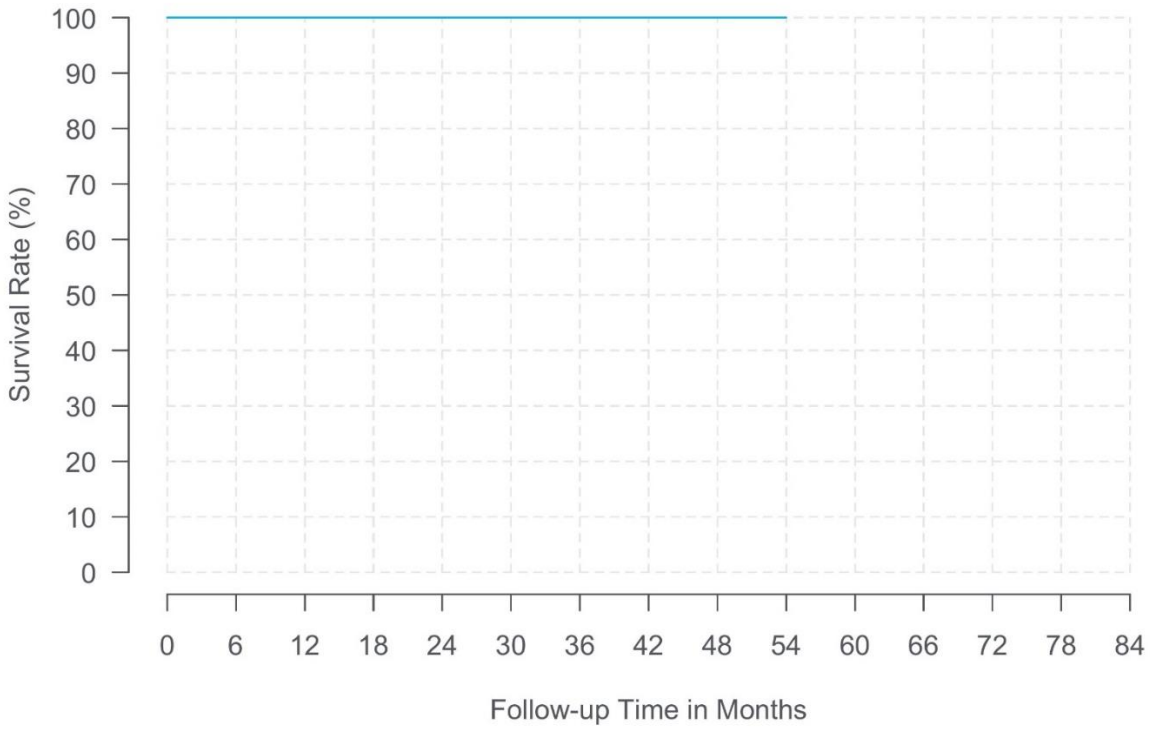
Time Interval	16 Years	17 Years	18 Years	At 225 Months
Survival (95% CI)	92.1% (89.0%, 94.3%)	92.1% (89.0%, 94.3%)	92.1% (89.0%, 94.3%)	92.1% (89.0%, 94.3%)
Sample Size	87	54	33	25

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	49
Lead Migration/Dislodgement	20
Lead Fracture	12
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	**94**

5.4.2.3 Model 3391

Model Name	3391
FDA Approval Date	February 2009
Leads Enrolled	72
Leads Currently Active in Study	46
Initial Product Performance Events	1
Median Follow-up Time (Months)	34.9
Cumulative Follow-up Time (Months)	3,649



Time Interval	1 Year	2 Years	3 Years	4 Years	At 54 Months
Survival (95% CI)[a]	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	49	45	28	22	21

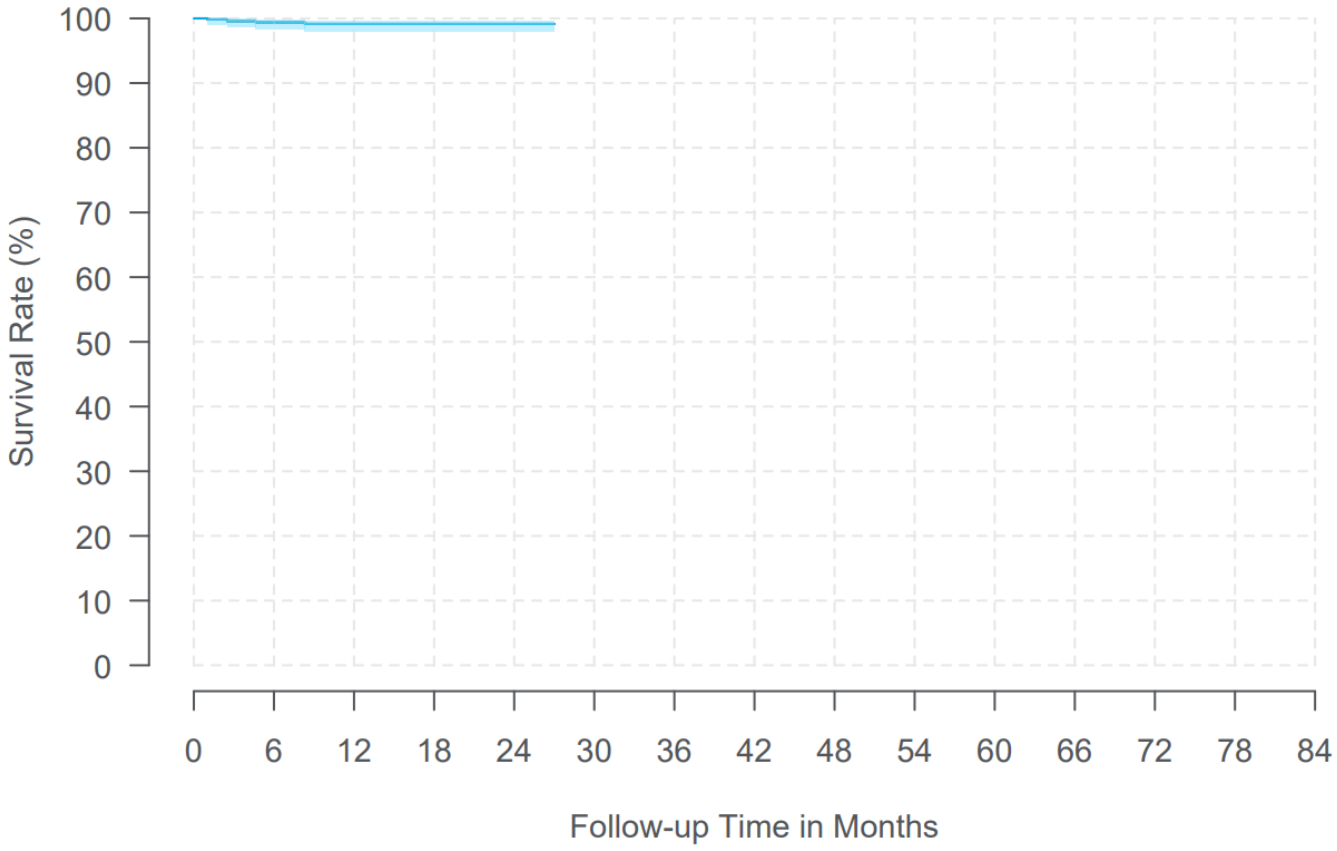
[a]Devices with at least 1 day of follow-up in the registry are included in analysis. One lead had an event at 84 months post-implant.

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
Lead Fracture	1
Total	**1**

5.4.2.4 Model SenSight™ B33005

Model Name	B33005 (Compact electrode spacing)
FDA Approval Date	June 2021
Leads Enrolled	876
Leads Currently Active in Study	717
Initial Product Performance Events	5
Median Follow-up Time (Months)	8.2
Cumulative Follow-up Time (Months)	7,987



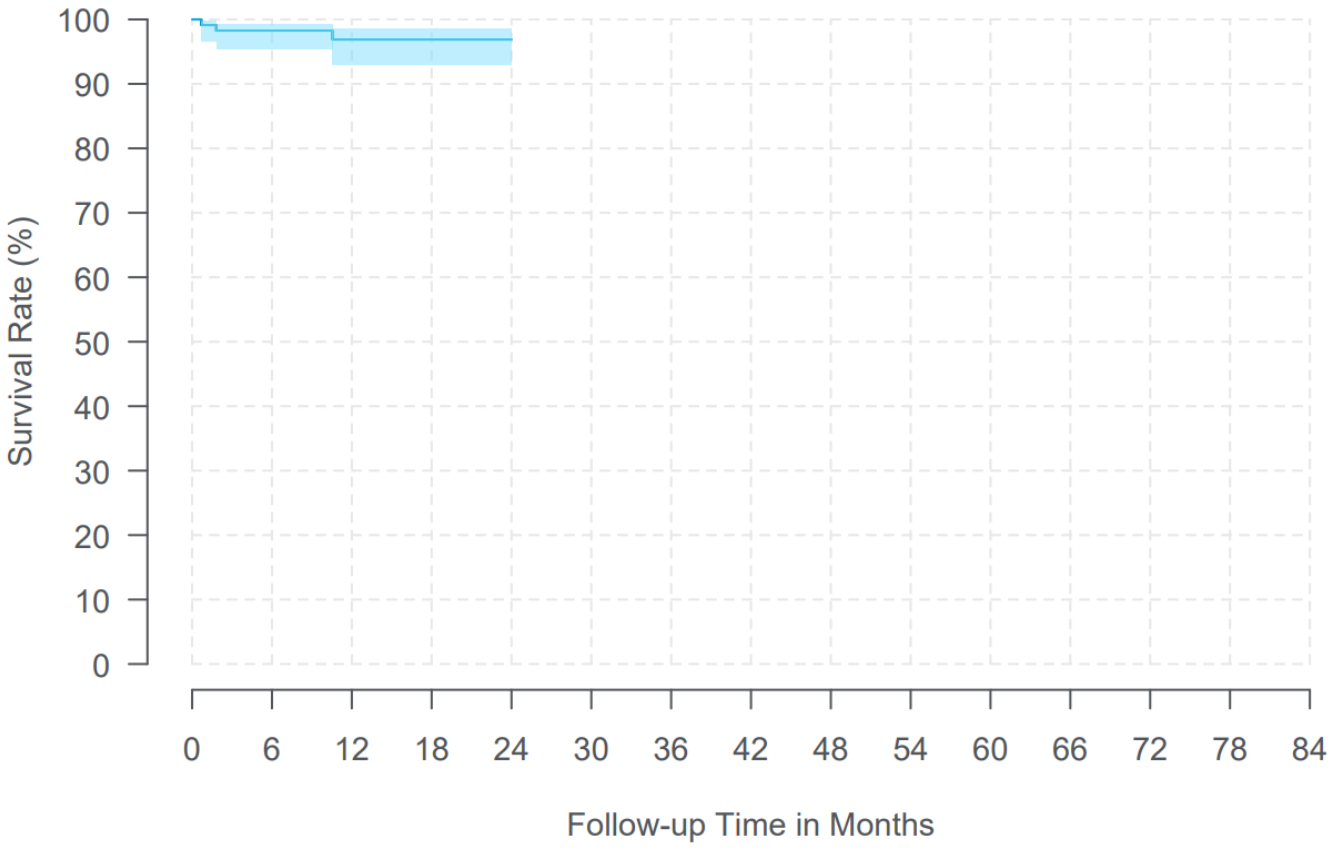
Time Interval	1 Year	2 Years	At 27 Months
Survival (95% CI)	99.1% (97.9%, 99.7%)	99.1% (97.9%, 99.7%)	99.1% (97.9%, 99.7%)
Sample Size	291	45	28

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	4
Lead Migration/Dislodgement	1
Total	**5**

5.4.2.5 Model SenSight™ B33015

Model Name	B33015 (Standard electrode spacing)
FDA Approval Date	June 2021
Leads Enrolled	318
Leads Currently Active in Study	256
Initial Product Performance Events	6
Median Follow-up Time (Months)	8.7
Cumulative Follow-up Time (Months)	3,074



Time Interval	1 Year	2 Years
Survival (95% CI)	96.9% (93.0%, 98.6%)	96.9% (93.0%, 98.6%)
Sample Size	108	21

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 Electrode shape Distal tip distance (mm)	8 electrodes Cylindrical 1.0

Lead Event Summary: B33015	N
High Impedance	4
Lead Fracture	2
Total	**6**

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	2,452	930	44	39.4	120,981
Model 3389	September 1999	3,203	1,297	94	44.7	171,977
Model 3391	February 2009	72	46	1	34.9	3,649
SenSight™ (model B33005)	June 2021	876	717	5	8.2	7,987
SenSight™ (model B33015)	June 2021	318	256	6	8.7	3,074

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	99.2%	99.0%	98.7%	98.2%	97.8%
	(98.6%, 99.5%)	(98.5%, 99.4%)	(98.0%, 99.1%)	(97.4%, 98.8%)	(96.8%, 98.4%)
Model 3389	98.6%	98.2%	97.6%	96.8%	96.4%
	(98.0%, 99.0%)	(97.5%, 98.6%)	(96.8%, 98.1%)	(95.9%, 97.5%)	(95.4%, 97.2%)
Model 3391	100.0%	100.0%	100.0%	100.0%	
	(NA)	(NA)	(NA)	(NA)	
SenSight™ (model B33005)	99.1%	99.1%			

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
	(97.9%, 99.7%)	(97.9%, 99.7%)			
SenSight™ (model B33015)	96.9%	96.9%			
	(93.0%, 98.6%)	(93.0%, 98.6%)			

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Model 3387	97.7%	97.5%	97.2%	97.2%	96.8%
	(96.7%, 98.4%)	(96.5%, 98.3%)	(96.0%, 98.0%)	(96.0%, 98.0%)	(95.4%, 97.8%)
Model 3389	96.0%	95.4%	94.4%	94.2%	94.0%
	(95.0%, 96.8%)	(94.3%, 96.3%)	(93.0%, 95.5%)	(92.8%, 95.3%)	(92.5%, 95.2%)
Model 3391					
SenSight™ (model B33005)					
SenSight™ (model B33015)					

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
Model 3387	96.3%	96.3%	95.3%	91.6%	91.6%
	(94.4%, 97.6%)	(94.4%, 97.6%)	(92.1%, 97.3%)	(85.3%, 95.3%)	(85.3%, 95.3%)
Model 3389	93.1%	93.1%	93.1%	93.1%	93.1%
	(91.2%, 94.6%)	(91.2%, 94.6%)	(91.2%, 94.6%)	(91.2%, 94.6%)	(91.2%, 94.6%)

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
Model 3391					
SenSight™ (model B33005)					
SenSight™ (model B33015)					

Model Name	16 Years	17 Years	18 Years
Model 3387	91.6%	91.6%	
	(85.3%, 95.3%)	(85.3%, 95.3%)	
Model 3389	92.1%	92.1%	92.1%
	(89.0%, 94.3%)	(89.0%, 94.3%)	(89.0%, 94.3%)
Model 3391			
SenSight™ (model B33005)			
SenSight™ (model B33015)			

5.5 Extensions

From July 2009 to the report cut-off date of October 31, 2024, there were 6,981 extensions followed in the registry. The difference between the total number of extensions (n=6,981) versus neurostimulators (n=6,349) 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 302,715 months (25,226 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)	5175 (74.1%)
SenSight™ B34000/B34000M	1169 (16.7%)
No longer manufactured	
7482 (quadripolar)[a]	508 (7.3%)
Other/Unspecified[b]	129 (1.8%)
Total	**6981**

[a] Includes Models 7482 and 7482a.
[b] Includes extensions for other legacy stimulation systems.

5.5.1 Extension Events

Of the total of 576 product performance-related events, there were 112 product performance-related events with an underlying reported etiology related to extension function. This includes 108 events with an extension etiology and 4 events with both an extension and other etiology (including device and non-device etiologies). Of these, 89 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:

- 89 had follow-up time cut-off due to product performance-related events.
- 3,708 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.

- 3,184 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.

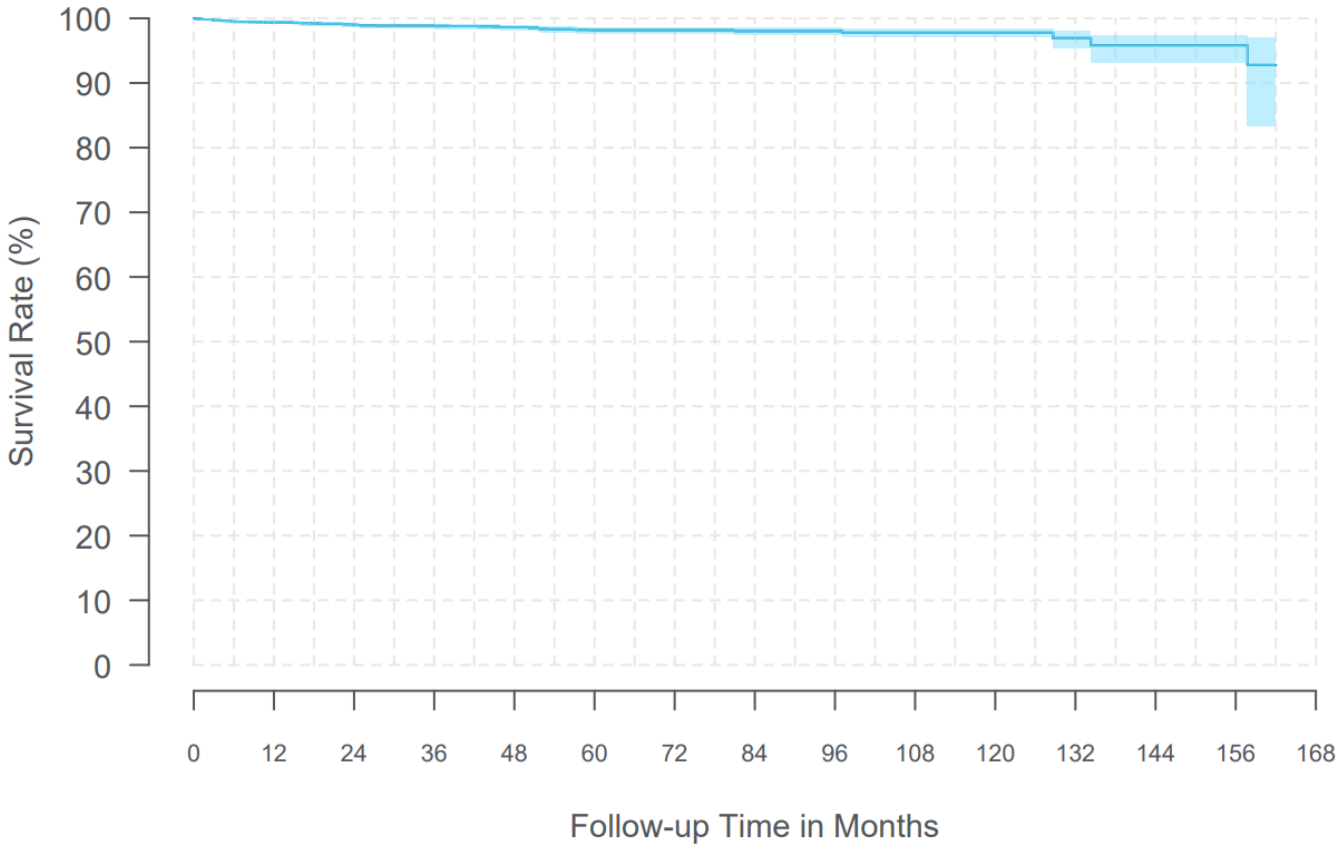
Initial product performance events of other/unspecified models (n=6) are not summarized in the subsequent sections.

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	5,175
Extensions Currently Active in Study	2,079
Initial Product Performance Events	72
Median Follow-up Time (Months)	39.5
Cumulative Follow-up Time (Months)	255,161



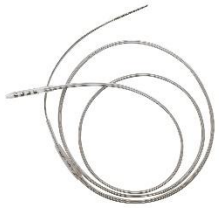
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.4% (99.1%, 99.6%)	99.0% (98.7%, 99.3%)	98.8% (98.4%, 99.1%)	98.6% (98.2%, 99.0%)	98.2% (97.6%, 98.6%)

Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Sample Size	3855	3170	2675	2305	1967

Time Interval	6 Year	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.2% (97.6%, 98.6%)	98.0% (97.4%, 98.5%)	98.0% (97.4%, 98.5%)	97.8% (97.1%, 98.3%)	97.8% (97.1%, 98.3%)
Sample Size	1666	1277	860	550	332

Time Interval	11 Years	12 Years	13 Years	At 162 Months
Survival (95% CI)	96.9% (95.3%, 98.0%)	95.8% (93.3%, 97.4%)	95.8% (93.3%, 97.4%)	92.8% (83.3%, 97.0%)
Sample Size	189	85	36	21

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

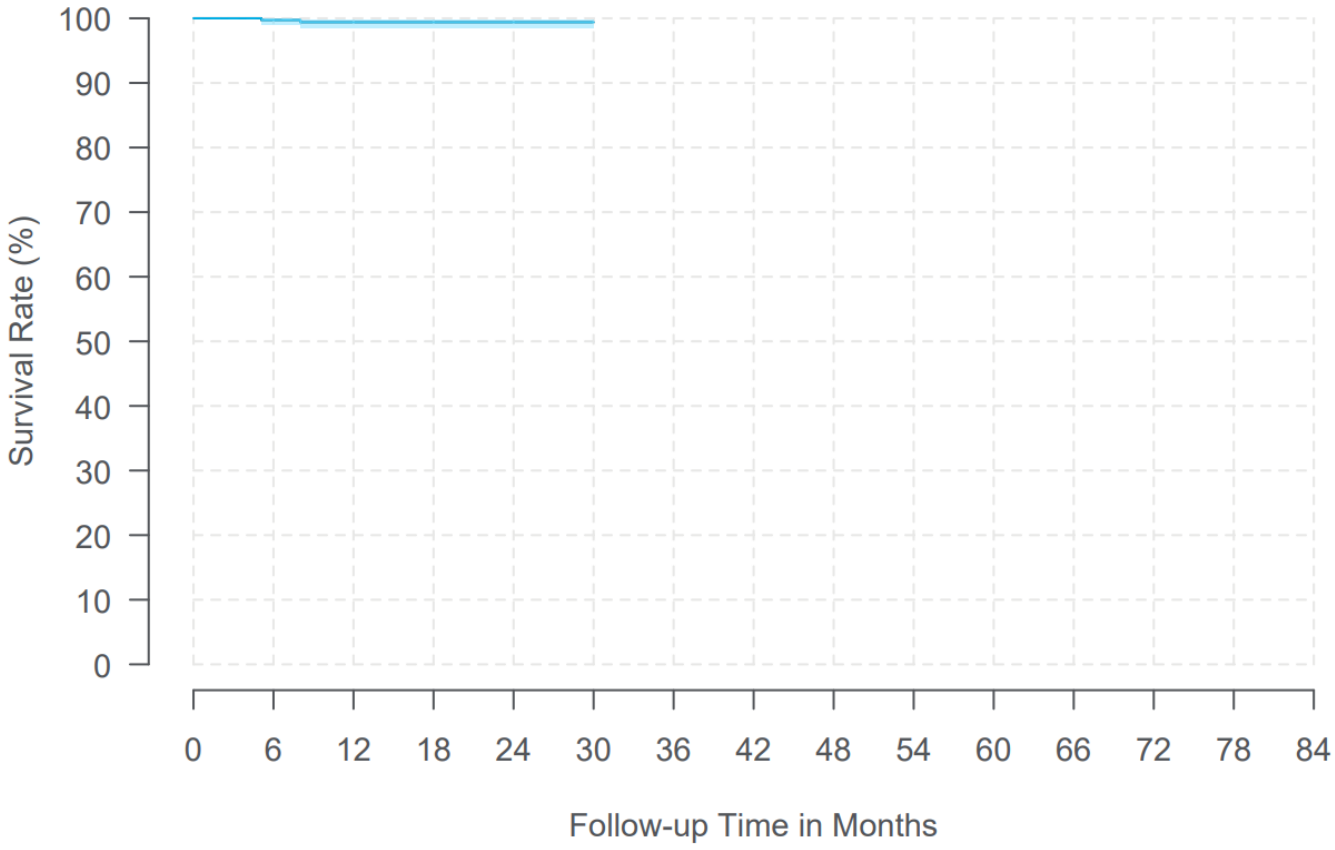


Extension Event Summary: 37085/37086	N
High Impedance	32
Extension Migration	15
Extension Fracture	8
Low Impedance	6
Medical Device Complication	4
Device Protrusion	3
Device Electrical Finding[a]	2
Device Malfunction	1
Lead Migration/Dislodgement	1
Total	**72**

[a] Open circuit contact

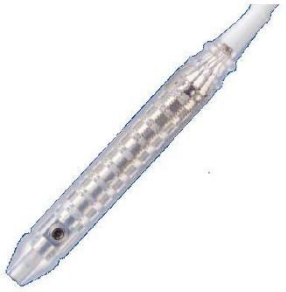
5.5.2.2 Model B34000/B34000M

Model Name	B34000/B34000M
FDA Approval Date	May 2021
Extensions Enrolled	1,169
Extensions Currently Active in Study	943
Initial Product Performance Events	4
Median Follow-up Time (Months)	8.5
Cumulative Follow-up Time (Months)	10,615



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	99.4% (98.4%, 99.8%)	99.4% (98.4%, 99.8%)	99.4% (98.4%, 99.8%)
Sample Size	386	58	22

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
Total	**4**

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	5,175	2,079	72	39.5	255,161
B34000/B34000M	May 2021	1,169	943	4	8.5	10,615

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	99.4%	99.4%			
	(98.4%, 99.8%)	(98.4%, 99.8%)			
37085/37086	99.4%	99.0%	98.8%	98.6%	98.2%
	(99.1%, 99.6%)	(98.7%, 99.3%)	(98.4%, 99.1%)	(98.2%, 99.0%)	(97.6%, 98.6%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
B34000/B34000M					
37085/37086	98.2%	98.0%	98.0%	97.8%	97.8%
	(97.6%, 98.6%)	(97.4%, 98.5%)	(97.4%, 98.5%)	(97.1%, 98.3%)	(97.1%, 98.3%)

Model Name	11 Years	12 Years	13 Years
B34000/B34000M			
37085/37086	96.9%	95.8%	95.8%
	(95.3%, 98.0%)	(93.3%, 97.4%)	(93.3%, 97.4%)

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, 2024. 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.

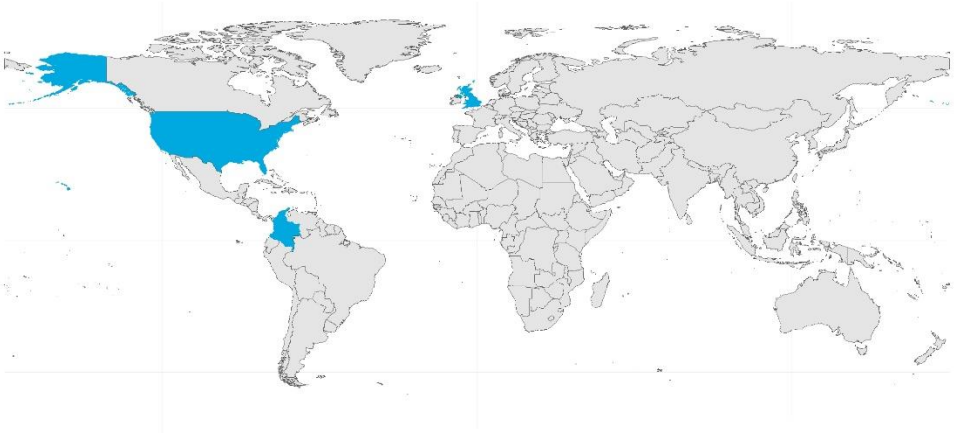


Figure 6.1: Countries with Sacral Neuromodulation Therapy Patients in Registry (Highlighted)

6.1.2 Patients

Of the 1,727 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 44.1% were implanted for the treatment of urinary urge incontinence, 25.9% were implanted for the treatment of urgency-frequency, 13.0% were implanted for the treatment of non-obstructive urinary retention, 10.2% were implanted for the treatment of fecal incontinence, 2.1% were implanted for the treatment of bladder pain syndrome, 3.5% were implanted for the treatment of some other indication, and 1.0% were implanted for indications that were not specified in the database at the time of data cut-off (see Figure 6.2 and Table6.1).

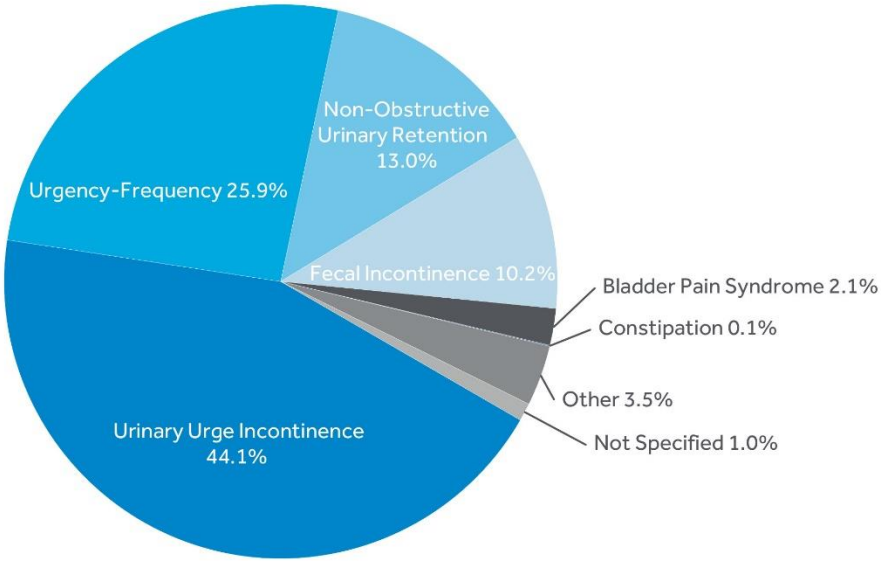


Figure 6.2: Sacral Neuromodulation Primary Treatment Indications

Table 6.1: Sacral Neuromodulation Primary Treatment Indications

Primary Treatment Indication[a]	Enrolled Patients (%)
Urinary Urge Incontinence	761 (44.1%)
Urgency-Frequency	448 (25.9%)
Non-Obstructive Urinary Retention	224 (13.0%)
Fecal Incontinence	177 (10.2%)
Bladder Pain Syndrome	37 (2.1%)
Constipation	1 (0.1%)
Other	61 (3.5%)
Not Specified	18 (1.0%)
Total Patients	**1727 (100.00%)**

[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

There were 258 product performance events (PPE) reported between April 2010 and October 31, 2024, in patients with sacral neuromodulation systems. These events represent 17.3% of the total reported events (258/1,494), occurred in 184 (10.7%) of the 1,727 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 1,171 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the sacral neuromodulation 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=65).

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 89 deaths reported for patients followed in the 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=1727
RPA Determination	**0**	**0.0**	**0 (0.00%)**
Physician's Determination	**258**	**4.8**	**184 (10.65%)**
High Impedance	99	1.8	74 (4.28%)
Lead Migration/Dislodgement	48	0.9	39 (2.26%)
Device Lead Issue	30	0.6	20 (1.16%)

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events[b] (%) N=1727
Lead Fracture	25	0.5	21 (1.22%)
Device Malfunction	15	0.3	13 (0.75%)
Low Impedance	11	0.2	10 (0.58%)
Device Electrical Impedance Issue	6	0.1	4 (0.23%)
Premature Battery Depletion	5	0.1	4 (0.23%)
Device Issue	4	0.1	3 (0.17%)
Device Charging Issue	2	0.0	2 (0.12%)
Device Failure	2	0.0	1 (0.06%)
Device Overheating	2	0.0	2 (0.12%)
Unspecified	2	0.0	2 (0.12%)
Other	7	0.1	7 (0.41%)
Total	**258**	**4.8**	**184 (10.65%)**

[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.

A total of 170 (65.9%) of 258 product performance events were related to the lead only, 53 (20.5%) related to the neurostimulator only, 2 (0.8%) related to the extension only, 8 (3.1%) related to multiple etiologies (which includes events where at least one device and one non-device etiology was indicated), and 25 (9.7%) related to other/not specified etiologies. Relatedness is determined by the physician.

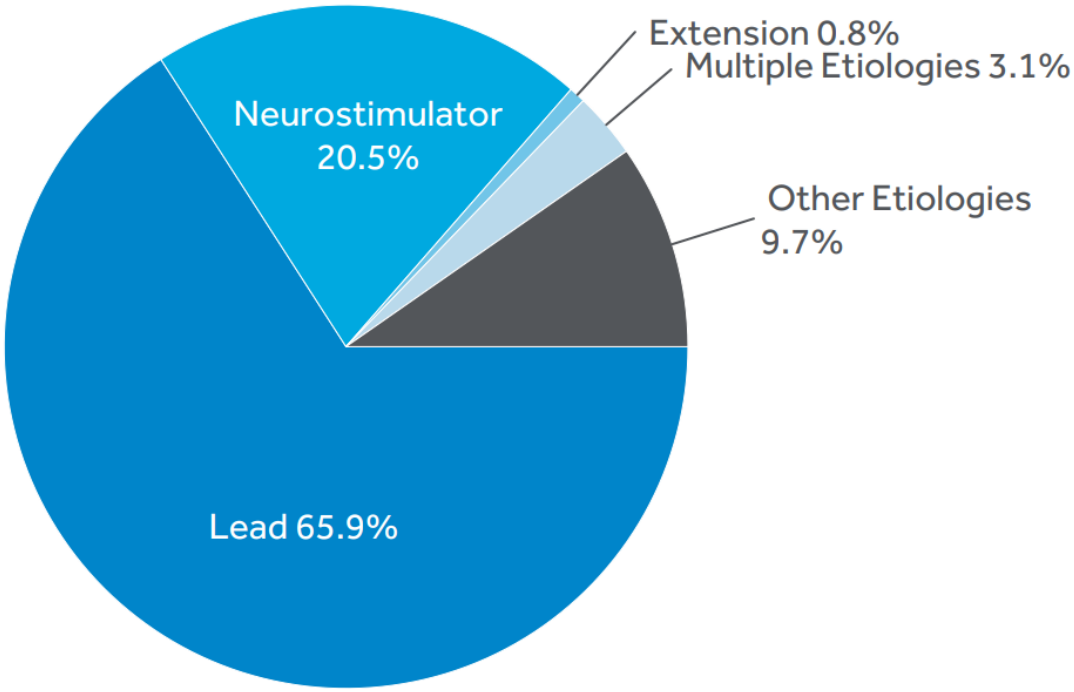


Figure 6.3: Sacral Neuromodulation System Product Performance Events by Relatedness

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 (53.5%)	35 (35.4%)	0 (0.0%)	0 (0.0%)	11 (11.1%)	99

Events by Intervention[a]	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention	No Action Taken	Total Events
Lead Migration/Dislodgement	34 (70.8%)	6 (12.5%)	1 (2.1%)	1 (2.1%)	6 (12.5%)	48
Device Lead Issue	12 (40.0%)	9 (30.0%)	4 (13.3%)	0 (0.0%)	5 (16.7%)	30
Lead Fracture	17 (68.0%)	2 (8.0%)	1 (4.0%)	3 (12.0%)	2 (8.0%)	25
Device Malfunction	8 (53.3%)	4 (26.7%)	2 (13.3%)	0 (0.0%)	1 (6.7%)	15
Other[b]	27 (65.9%)	6 (14.6%)	1 (2.4%)	3 (7.3%)	4 (9.8%)	41
Total	**151 (58.5%)**	**62 (24.0%)**	**9 (3.5%)**	**7 (2.7%)**	**29 (11.2%)**	**258**

[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=1,417)
- Categorized as serious adverse events (SAEs, n=12)
- Occurred with a System Organ Class (SOC) threshold ≥ 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=1417	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=1417
Infections and infestations	**9**	**9 (0.64%)**	**0.018**	**7 (0.49%)**
Infections - pathogen unspecified	9	9 (0.64%)	0.018	7 (0.49%)
Other SOC Terms (<0.5% Threshold)[a]	**3**	**3 (0.21%)**	**0.006**	**1 (0.07%)**
Total	**12**	**12 (0.85%)**	**0.024**	**8 (0.56%)**

[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 89 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	37 (41.6%)
Urgency-Frequency	30 (33.7%)
Urinary Retention	12 (13.5%)
Fecal Incontinence	5 (5.6%)
Other	5 (5.6%)
Total	**89 (100.0%)**

[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, 2024, there were 1,859 neurostimulators followed in the registry. The difference between the total number of patients (n=1,727) versus the total number of neurostimulators (n=1,859) is due to the fact that some patients were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 63,025 months (5,252 years).

Table 6.6: Sacral Neuromodulation Neurostimulator Counts by Model

Model Name	N (%)
InterStim II (model 3058)	1415 (76.1%)
InterStim X (model 97800)	282 (15.2%)
InterStim (model 3023)	102 (5.5%)
InterStim Micro (model 97810)	60 (3.2%)
Total	**1859 (100.0%)**

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 9.76% (58/594). 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, 100.0% (57/57) were assigned as device related by the physician, not returned to Medtronic RPA (see Table6.7)

Table 6.7: Sacral Neuromodulation Neurostimulator PPE by Determination

Product Performance Events	N (%)
Physician's Determination	**57 (100.0%)**
High Impedance	21 (36.8%)
Device Lead Issue	7 (12.3%)

Product Performance Events	N (%)
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%)
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:

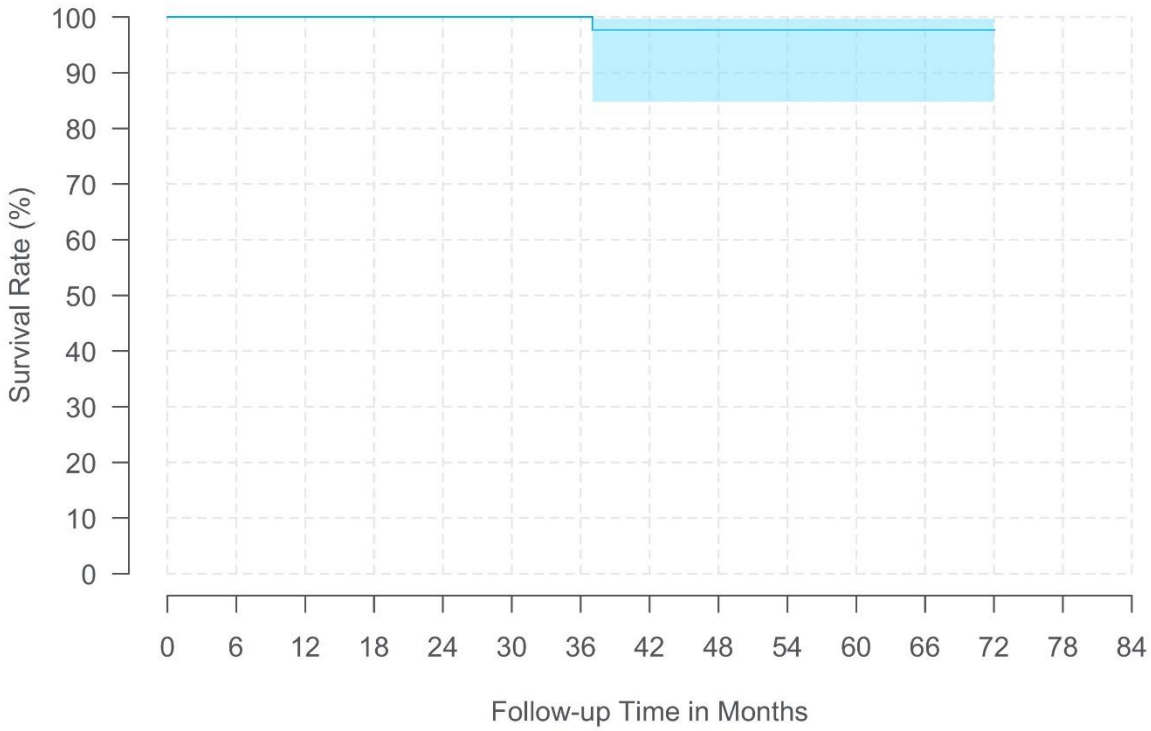
- 48 had follow-up time cut-off due to product performance-related events.
- 1,219 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 592 were free 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)	4,104



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	70	60	43	33	25

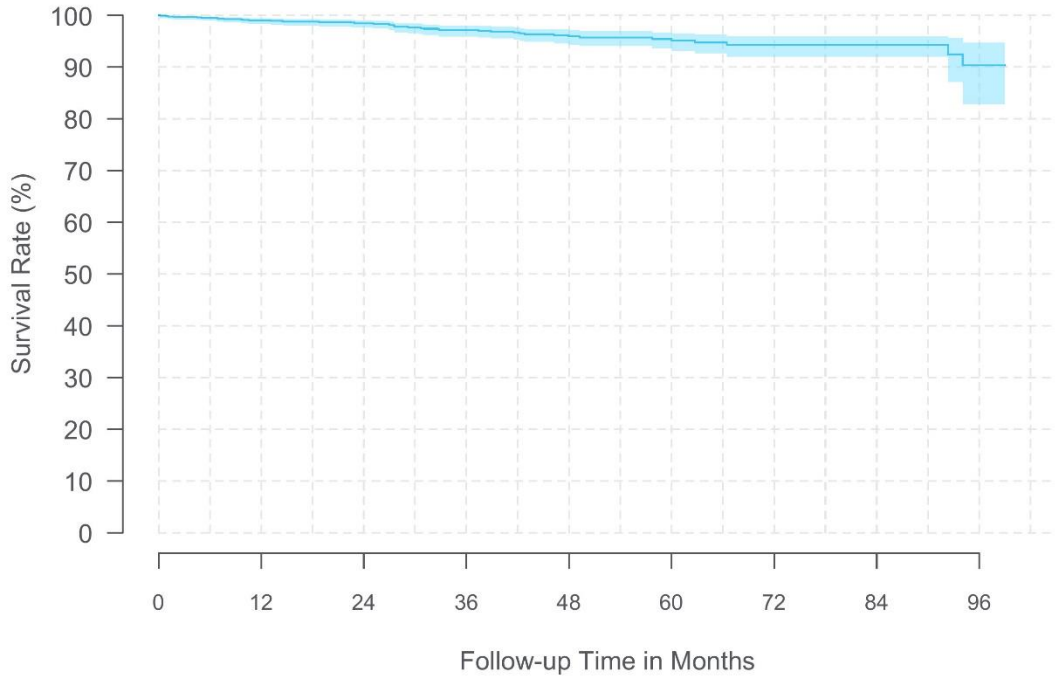
Time Interval	6 Years
Survival (95% CI)	97.7% (84.8%, 99.7%)
Sample Size	22

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 µsec
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	1,415
Neurostimulators Currently Active in Study	295
Initial Product Performance Events	44
Median Follow-up Time (Months)	34.7
Cumulative Follow-up Time (Months)	54,392



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%, 99.0%)	97.2% (95.9%, 98.0%)	96.0% (94.3%, 97.1%)	95.1% (93.2%, 96.5%)
Sample Size	1157	902	686	475	299

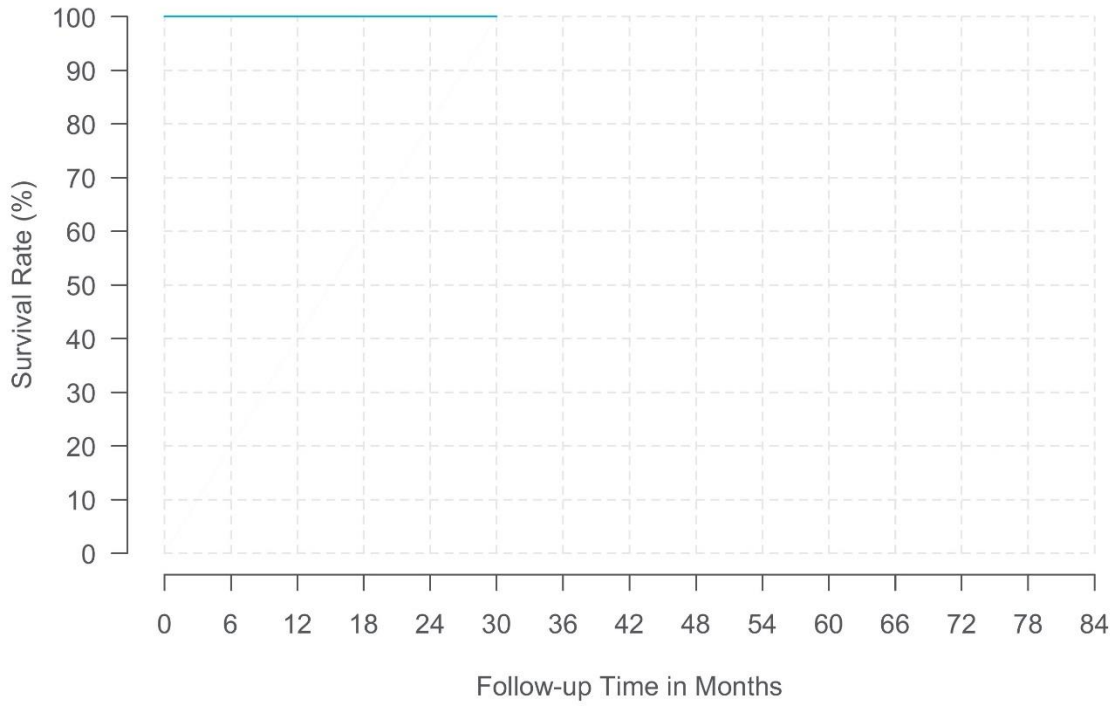
Time Interval	6 Years	7 Years	8 Years	At 99 Months
Survival (95% CI)	94.3% (92.0%, 96.0%)	94.3% (92.0%, 96.0%)	90.4% (82.8%, 94.7%)	90.4% (82.8%, 94.7%)
Sample Size	170	98	37	26

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 μsec
Programs	4
Implant Depth	≤ 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	38
Initial Product Performance Events	0
Median Follow-up Time (Months)	25.8
Cumulative Follow-up Time (Months)	1,582



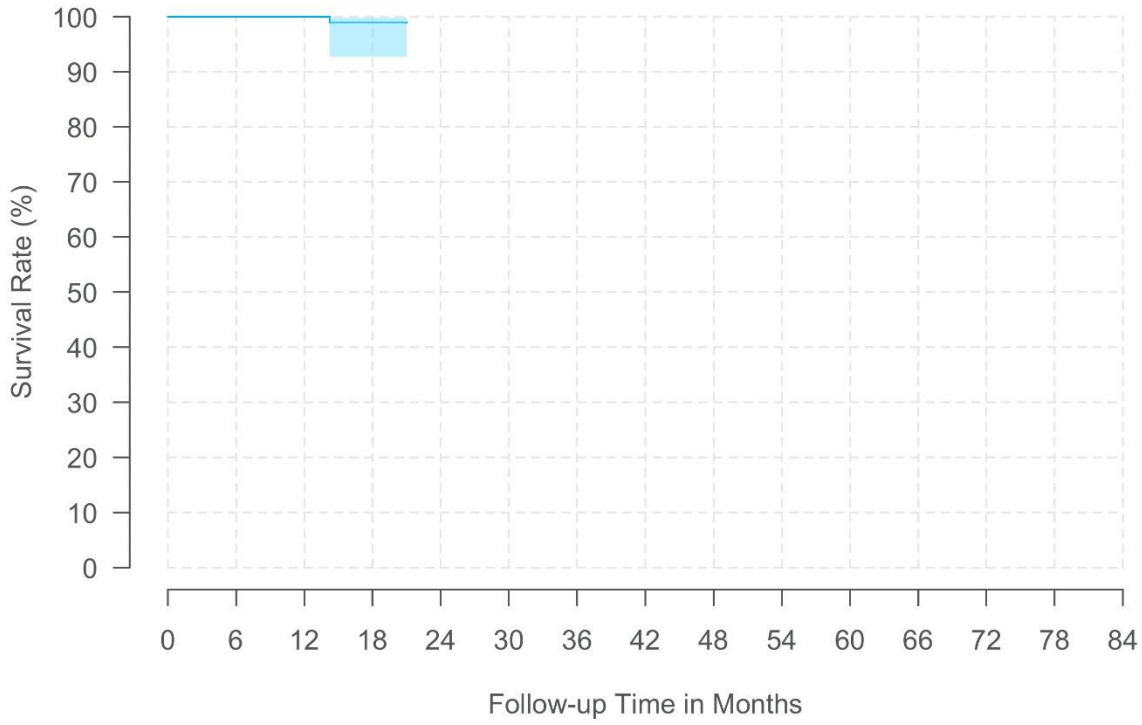
Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	54	35	22

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	282
Neurostimulators Currently Active in Study	258
Initial Product Performance Events	2
Median Follow-up Time (Months)	10.0
Cumulative Follow-up Time (Months)	2,947



Time Interval	1 Year	At 21 Months
Survival (95% CI)	100.0% (NA)	98.9% (92.7%, 99.9%)
Sample Size	125	33

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

[a]Service 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; manual document number M988757A016) 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	4,104
InterStim II (model 3058)	June 2006	1,415	295	44	34.7	54,392
InterStim Micro (model 97810)	July 2020	60	38	0	25.8	1,582
InterStim X (model 97800)	February 2022	282	258	2	10.0	2,947

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%	97.2%	96.0%	95.1%
	(98.4%, 99.5%)	(97.6%, 99.0%)	(95.9%, 98.0%)	(94.3%, 97.1%)	(93.2%, 96.5%)
InterStim Micro (model 97810)	100.0%	100.0%			
	(NA)	(NA)			
InterStim X (model 97800)	100.0%				

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
	(NA)				

Model Name	6 Years	7 Years	8 Years
InterStim (model 3023)	97.7%		
	(84.8%, 99.7%)		
InterStim II (model 3058)	94.3%	94.3%	90.4%
	(92.0%, 96.0%)	(92.0%, 96.0%)	(82.8%, 94.7%)
InterStim Micro (model 97810)			
InterStim X (model 97800)			

6.4 Leads

From April 2010 to the report cut-off date of October 31, 2024 there were 1,768 leads followed in the registry. The difference between the total number of leads (n=1,768) versus the total number of neurostimulators (n=1,859) 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 63,407 months (5,284 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	**450 (25.4%)**
InterStim SureScan MRI (model 978B1)	379 (21.4%)
InterStim SureScan MRI (model 978A1)	71 (4.0%)
No longer manufactured	**1306 (73.9%)**
InterStim Quad Tined (model 3889)	1201 (67.9%)
InterStim Extended Electrode Quad Tined (model 3093)	100 (5.7%)
InterStim Quad (model 3080)	3 (0.2%)
InterStim Extended Electrode Quad (model 3092)	2 (0.1%)
Other/Unspecified	**12 (0.7%)**
Total	**1768 (100.0%)**

6.4.1 Lead Events

There were 174 product performance-related events with an underlying reported etiology related to lead function. This includes 170 events with a lead etiology and 4 events with both a lead and other etiology (including device and non-device etiologies). Of these, 134 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:

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

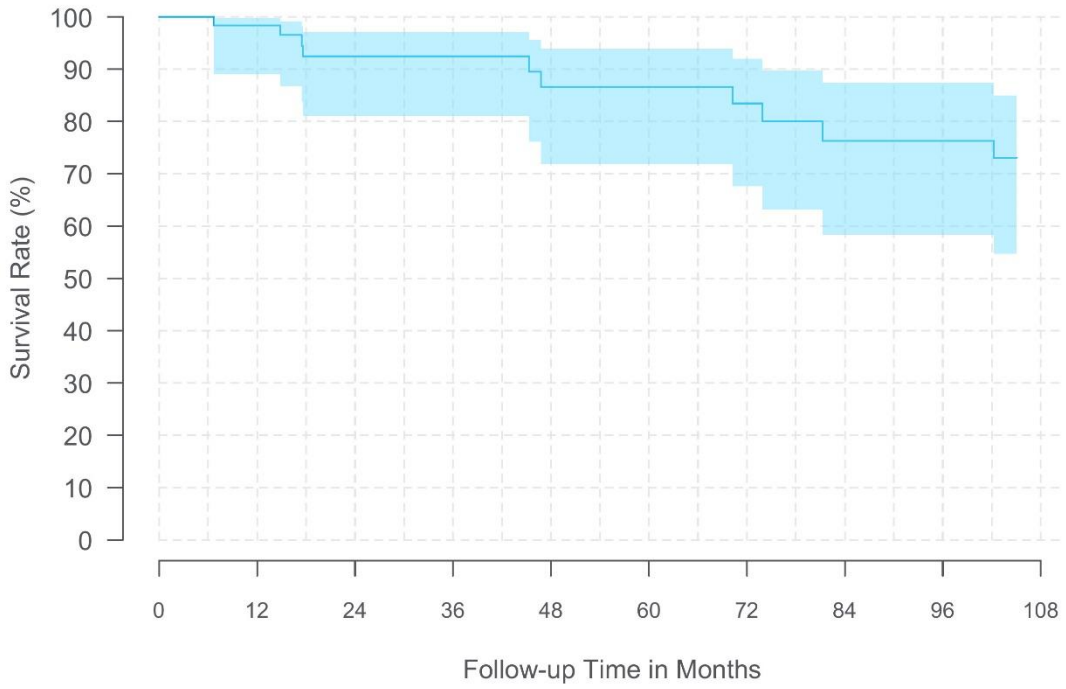
- 1045 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 589 were free from product performance-related events and censoring events, and were censored at the 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 Quad Lead Tined
FDA Approval Date	September 2002
Leads Enrolled	100
Leads Currently Active in Study	12
Initial Product Performance Events	12
Median Follow-up Time (Months)	31.5
Cumulative Follow-up Time (Months)	4,462



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.4% (89.0%, 99.8%)	92.5% (81.1%, 97.1%)	92.5% (81.1%, 97.1%)	86.6% (71.9%, 93.9%)	86.6% (71.9%, 93.9%)
Sample Size	53	39	30	29	26

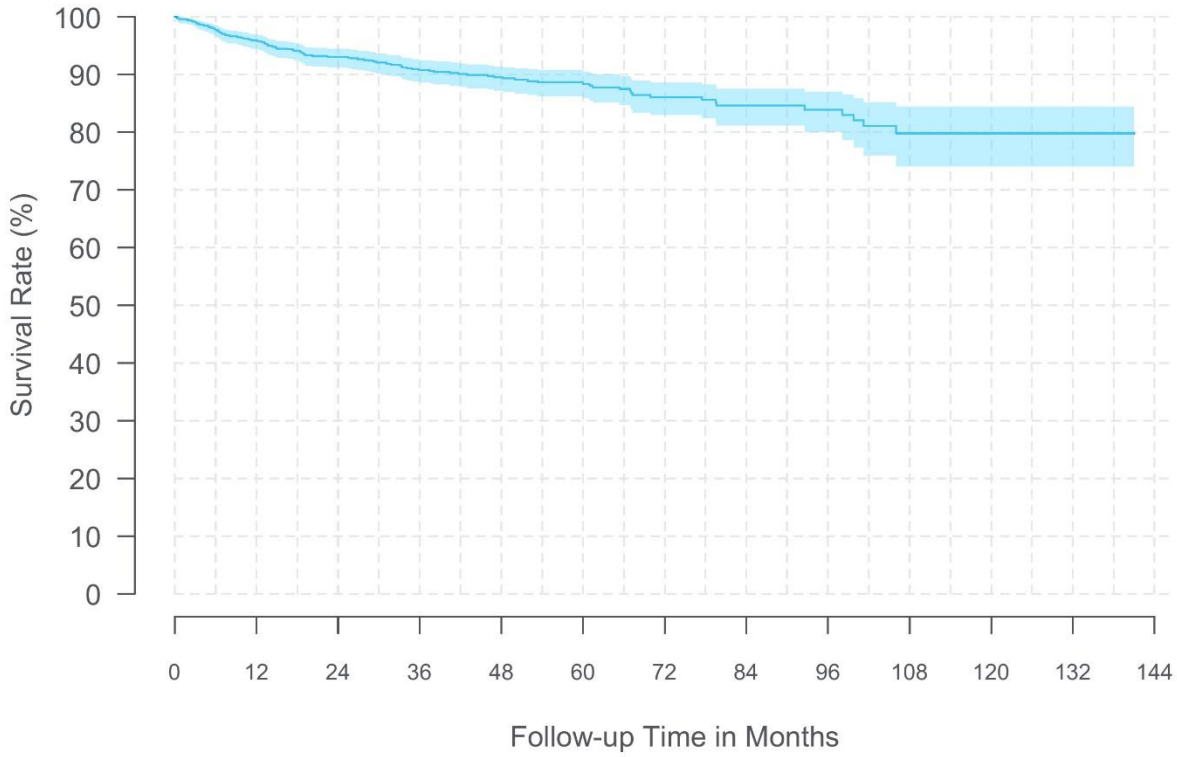
Time Interval	6 Years	7 Years	8 Years	At 105 Months
Survival (95% CI)	83.5% (67.6%, 92.0%)	76.3% (58.3%, 87.3%)	76.3% (58.3%, 87.3%)	73.1% (54.7%, 85.0%)
Sample Size	25	21	25	21

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	5
Device Lead Issue	3
Device Electrical Impedance Issue	1
Device Lead Damage	1
Lead Fracture	1
Lead Migration/Dislodgement	1
Total	**12**

6.4.2.2 Model 3889

Model Name	InterStim Quad Lead Tined
FDA Approval Date	September 2002
Leads Enrolled	1,201
Leads Currently Active in Study	220
Initial Product Performance Events	111
Median Follow-up Time (Months)	38.8
Cumulative Follow-up Time (Months)	51,005



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	95.9% (94.5%, 97.0%)	93.1% (91.3%, 94.5%)	90.8% (88.6%, 92.5%)	89.5% (87.2%, 91.5%)	88.4% (85.8%, 90.5%)
Sample Size	895	711	581	448	318

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	86.1% (83.0%, 88.7%)	84.7% (81.2%, 87.6%)	83.9% (80.0%, 87.1%)	79.8% (74.0%, 84.4%)	79.8% (74.0%, 84.4%)
Sample Size	222	155	99	57	40

Time Interval	11 Years	At 141 Months
Survival (95% CI)	79.8% (74.0%, 84.4%)	79.8% (74.0%, 84.4%)
Sample Size	29	21

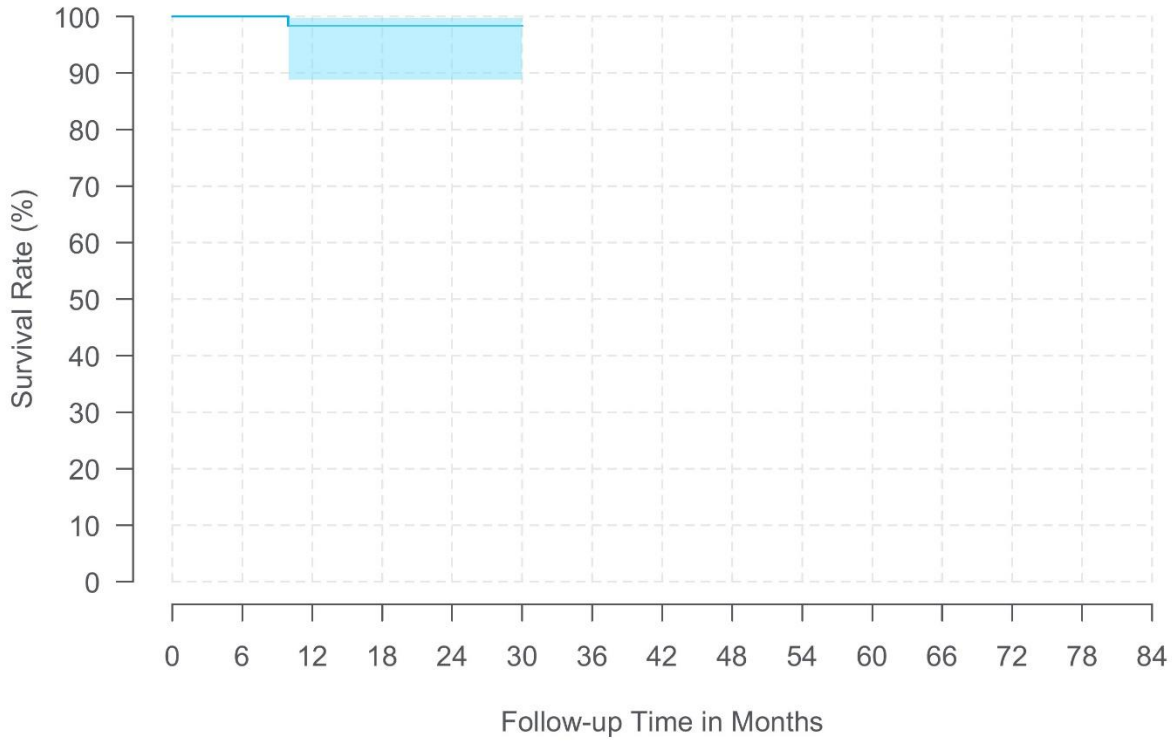
Specification: 3889	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0
Individual Surface Area (mm^2)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	3.0
Array Length (mm)	21.0

Lead Event Summary: 3889	N
High Impedance	46
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	**111**

[a]Site 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	71
Leads Currently Active in Study	46
Initial Product Performance Events	2
Median Follow-up Time (Months)	23.4
Cumulative Follow-up Time (Months)	1,709



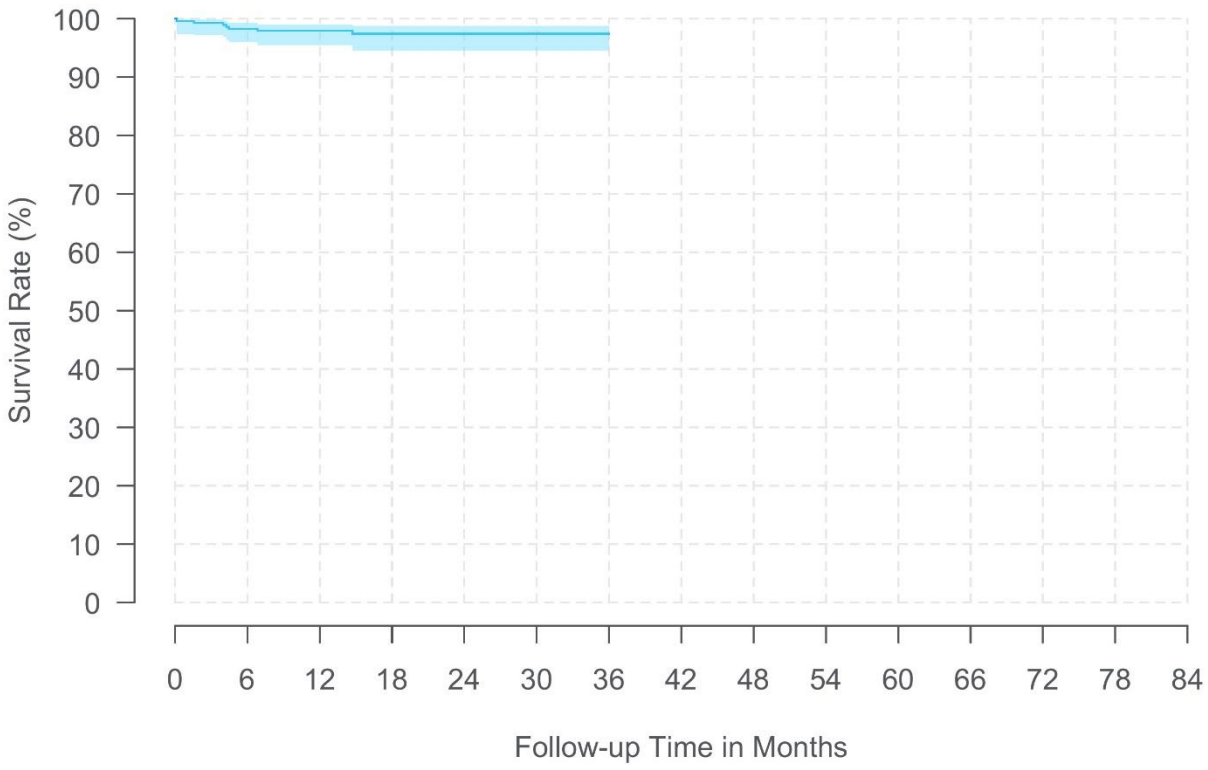
Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	98.3% (88.8%, 99.8%)	98.3% (88.8%, 99.8%)	98.3% (88.8%, 99.8%)
Sample Size	58	34	23

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	379
Leads Currently Active in Study	304
Initial Product Performance Events	7
Median Follow-up Time (Months)	14.4
Cumulative Follow-up Time (Months)	5,886



Time Interval	1 Year	2 Years	3 Years
Survival (95% CI)	97.9% (95.5%, 99.1%)	97.4% (94.6%, 98.8%)	97.4% (94.6%, 98.8%)
Sample Size	218	92	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
Device Lead Issue	2
High Impedance	2
Device Electrical Impedance Issue	1
Device Malfunction	1
Lead Migration/Dislodgement	1
Total	**7**

6.4.3 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	100	12	12	31.5	4,462
InterStim Quad Tined (model 3889)	September 2002	1,201	220	111	38.8	51,005
InterStim SureScan MRI (model 978A1)	July 2020	71	46	2	23.4	1,709
InterStim SureScan MRI (model 978B1)	July 2020	379	304	7	14.4	5,886

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)	98.4%	92.5%	92.5%	86.6%	86.6%
	(89.0%, 99.8%)	(81.1%, 97.1%)	(81.1%, 97.1%)	(71.9%, 93.9%)	(71.9%, 93.9%)
InterStim Quad Tined (model 3889)	95.9%	93.1%	90.8%	89.5%	88.4%
	(94.5%, 97.0%)	(91.3%, 94.5%)	(88.6%, 92.5%)	(87.2%, 91.5%)	(85.8%, 90.5%)
InterStim SureScan MRI (model 978A1)	98.3%	98.3%			
	(88.8%, 99.8%)	(88.8%, 99.8%)			
InterStim SureScan MRI (model 978B1)	97.9%	97.4%	97.4%		
	(95.5%, 99.1%)	(94.6%, 98.8%)	(94.6%, 98.8%)		

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Extended Electrode Quad Tined (model 3093)	83.5%	76.3%	76.3%		
	(67.6%, 92.0%)	(58.3%, 87.3%)	(58.3%, 87.3%)		
InterStim Quad Tined (model 3889)	86.1%	84.7%	83.9%	79.8%	79.8%
	(83.0%, 88.7%)	(81.2%, 87.6%)	(80.0%, 87.1%)	(74.0%, 84.4%)	(74.0%, 84.4%)
InterStim SureScan MRI (model 978A1)					
InterStim SureScan MRI (model 978B1)					

Model Name	11 Years
InterStim Extended Electrode Quad Tined (model 3093)	
InterStim Quad Tined (model 3889)	79.8%
	(74.0%, 84.4%)
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, 2024, there were 151 extensions followed in the registry, of which 67.5% were Model 3095 (102/151). The difference between the total number of extensions (n=151) versus the total number of neurostimulators (n=1,859) 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 4,740 months (395 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:

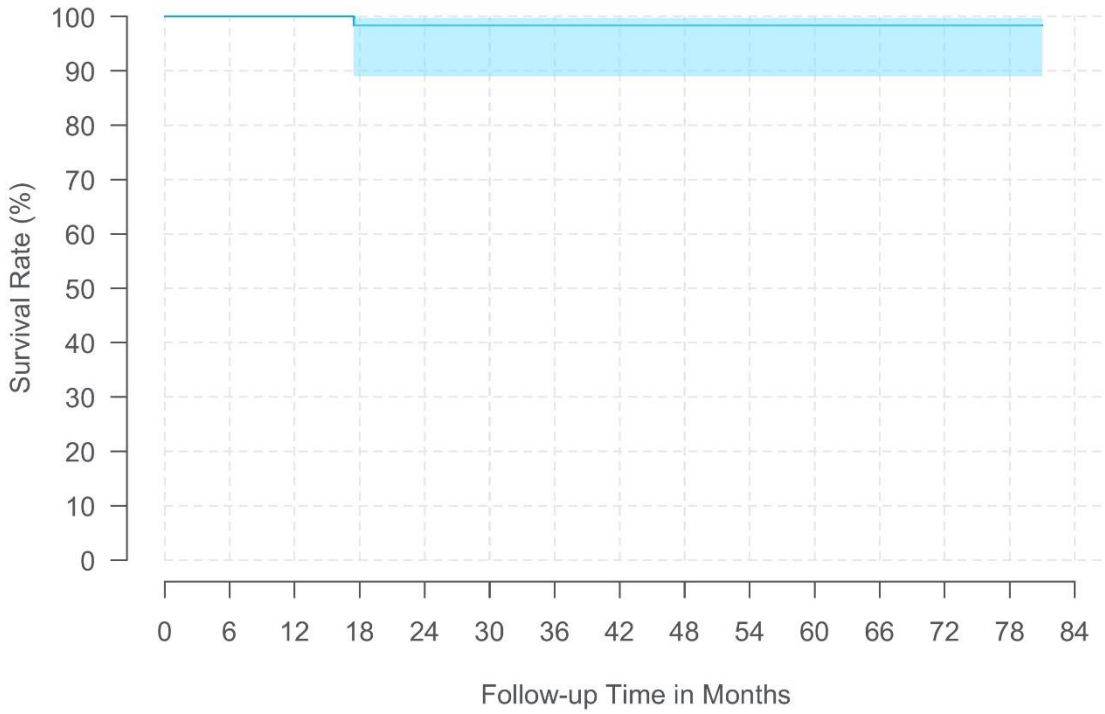
- 1 had follow-up time cut-off due to a product performance-related event.
- 96 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 54 were free from product 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.

6.4.2.5 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)	4,362



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	Quadripolar (model 3095)
FDA Approval Date	July 1998
Extensions Enrolled	102
Extensions Active	7
Initial Product Performance Events	1
Median Follow-up Time (Months)	28.6
Cumulative Follow-up Time (Months)	4,362

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%)