Medtronic

Overview

Introduction

Medtronic uses a prospective, long-term multi-center registry to monitor the performance of certain products at selected centers. The registry is currently conducted utilizing two protocols titled the Implantable Systems Performance Registry (ISPR) and the Product Surveillance Registry (PSR). Both protocols collect data on the performance of Medtronic products; however, PSR captures further information on select patient reported outcomes. Active patients enrolled under the ISPR protocol are in the process of transitioning to the PSR protocol. This 2016 Product Performance Report 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 Medtronic's 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.

Registry Background

The registry was created by Medtronic to monitor the performance of commercially available infusion and spinal cord stimulation systems. These systems were initiated into the registry in August 2003 and June 2004, respectively. Prior to the development of the registry, Medtronic Neuromodulation typically evaluated patient and product outcomes by retrospectively analyzing data from Returned Product Analysis (RPA) and complaints data. The registry allows Medtronic to prospectively capture valuable real-world information that can be used in conjunction with these retrospective and passive data sources. This information is used to guide future product development efforts aimed at improving product reliability and quality. The data are also used to measure progress toward improving product performance to fulfill regulatory requirements. In addition, data from the registry provide information about the treatment practices of physicians using these therapies.

This registry was initially designed to track performance of Medtronic's implantable targeted drug delivery systems (infusion pumps and catheters). These surgically-placed devices deliver prescribed medication directly to the fluid around the spinal cord for the treatment of chronic pain or severe spasticity.

Medtronic's spinal cord stimulation systems (spinal cord neurostimulators, leads, and extensions) for pain indications were later added to the registry. Implanted spinal cord neurostimulators send electrical impulses to the spinal cord.

In July 2009, Medtronic’s deep brain stimulation systems (deep brain neurostimulators, leads, and extensions) were included in the registry. Deep brain stimulation (DBS) uses a surgically implanted neurostimulator to deliver electrical stimulation to targeted areas in the brain.

In April 2010, Medtronic’s sacral neuromodulation systems (neurostimulator, leads, and extensions) were added to the registry. This implantable system sends electrical pulses through a lead to the sacral nerves to modulate the neural activity that influences the behavior of the pelvic floor, lower urinary tract, urinary and anal sphincters, and

colon.

The registry has collected data from centers across the United States, Europe, and South America. There have been 60 centers that have contributed data for targeted drug delivery systems, 75 centers for spinal cord stimulation systems, 36 centers for deep brain stimulation, and 19 centers for sacral neuromodulation. There are 37, 41, 30, and 11 sites currently active for targeted drug delivery, spinal cord stimulation, deep brain stimulation, and sacral neuromodulation, respectively. 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.

Commitment to Quality

Medtronic's 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 9th Annual Medtronic Neurostimulation and Targeted Drug Delivery Systems 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 Systems therapies, we believe that performance reporting is even more important. We strive for better performance with every new product 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 over 14,600 patients in our ongoing post-market registry. The registry has enrolled over 43,900 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 stimulation also involves neurostimulation, the performance of these systems is not included in the registry.

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 on the next page.

Thank you for your support.

Andrina Hougham
Vice President, Clinical Research and Regulatory Affairs
Medtronic

Contact Information

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

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RestoreAdvanced® SureScan® MRI neurostimulator	Vectris® SureScan® leads

2016 Medtronic Product Performance Report: Data through July 31, 2016.

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Percutaneous Tibial Neuromodulation
- Targeted Drug Delivery for Chronic Pain
- Sacral Neuromodulation
- Spinal Cord Stimulation

Resources

- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines
- Clinical Trials Registry
- Clinical Research Investigator Guidance

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Methodology

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
- Implant procedure
- Infusion or stimulation therapy

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

In early versions of the protocol for infusion and spinal cord stimulation systems, an event was reportable only if it required a surgical intervention, led to therapy abandonment, or resulted in death. This event threshold was expanded for infusion and spinal cord stimulation systems in April 2010 in order to capture additional adverse event data.

Additionally, since the protocol expansion, the seriousness (per ISO 14155-1) of adverse events has been assessed and reported by the registry investigators.

For centers participating in the PSR protocol of the registry, specific therapy relevant events are also collected and include:

- Urinary tract infection for sacral neuromodulation
- Negative changes in behavior from baseline for deep brain stimulation
- New or worsening depression from baseline for deep brain stimulation
- New or worsened suicidal ideation from baseline, attempted suicide or completed suicide for deep brain stimulation

By design, not all adverse events experienced by patients during participation were reported in the registry because the registry is primarily focused on understanding the long term reliability and performance of Medtronic implanted systems.

All events reported in the registry are coded using version 17.0 of the Medical Dictionary for Regulatory Activities (MedDRA). Medtronic's own coding system for events related to implanted neuromodulation systems, which do not exist in the MedDRA dictionary, was integrated with the MedDRA dictionary.

Registry Definitions

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, implant procedure, and/or therapy.

Device Event - an issue with any of the implantable or external system components.

Therapy Relevant Event - a specific event type for sacral neuromodulation and deep brain stimulation therapies which are collected regardless of relatedness to the device, procedure, or therapy.

Adverse Event/Device Event Flowchart

View Larger Image

Product-Performance or Non-Product Performance Categorization

For analysis purposes, events collected were collapsed into 2 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 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, that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as product performance-related.

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
- Center personnel initiated corrections or additions

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 are not different between models. When confidence intervals do not overlap, estimates of survival from product performance-related events are different between models.

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 2 or more devices.

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).

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.

2016 Medtronic Product Performance Report: Data through July 31, 2016.

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- Spinal Cord Stimulation

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Targeted Drug Delivery Systems

- Study Participants
- Event Summary
- Pumps
- Catheters

Study Participants

Centers

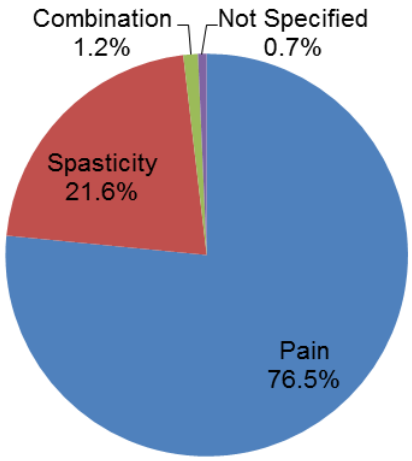
The following tables and graphs were generated based on data collected between August 7, 2003 and the report cut-off date of July 31, 2016. Sixty centers enrolled and contributed patients to the targeted drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 7,459 total targeted drug delivery system patients enrolled through July 31, 2016. As indicated, 58.1% 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 21.6% for treatment of spasticity, and 18.5% for treatment of malignant pain (pain related to cancer). Primary treatment indication is provided by the physician.

Targeted Drug Delivery System Primary Treatment Indications

Targeted Drug Delivery System Primary Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Pain	**5,709 (76.5%)**
Non-Malignant Pain	4.332 (58.1%)
Malignant Pain	1,377 (18.5%)
Spasticity	**1,611 (21.6%)**
Combination	**87 (1.2%)**

Non-Malignant Pain & Spasticity	87 (1.2%)
Not Specified	**52 (0.7%)**
Total Subjects	**7,459**

[a] Refer to product labeling for approved indications.

Malignant Pain Sub-Indications	**Total Enrolled Patients (Percent)[a]**
Location of Pain	
Spine/Back	441 (32.0%)
Abdominal/Visceral	296 (21.5%)
Extremity	189 (13.7%)
Pelvic	183 (13.3%)
Thoracic	156 (11.3%)
Head/Neck	80 (5.8%)
Other	76 (5.5%)
Not Specified	441 (32.0%)
Total Patients	**1,377**

[a] Percent is based on the number of total patients.

Non-Malignant Pain Sub-Indications	**Total Enrolled Patients (Percent)**
Back Pain without Leg Pain	1,376 (31.1%)
Back Pain with Leg Pain	1,225 (27.7%)
General Neuropathic Condition	176 (4.0%)
CRPS I[a]	136 (3.1%)
Peripheral Neuropathy	74 (1.7%)
Joint Pain/Arthritis	63 (1.4%)

CRPS II[a]	34 (0.8%)
General Nociceptive Condition	32 (0.7%)
Osteoporosis	20 (0.5%)
Other	322 (7.3%)
Not Specified	961 (21.7%)
Total Patients[b]	**4,419**

[a] CRPS is complex regional pain syndrome. CRPS I rarely includes detectable peripheral nerve injury. CRPS II includes detectable peripheral nerve or plexus injury.
[b] Includes patients with indications of non-malignant pain and a combination of non-malignant pain and spasticity.

Spasticity Sub-Indications	**Total Enrolled Patients (Percent)**
Cerebral Palsy	450 (26.5%)
Multiple Sclerosis	446 (26.3%)
Spinal Cord Injury	241 (14.2%)
Brain Injury	125 (7.4%)
Stroke	68 (4.0%)
Other	94 (5.5%)
Not Specified	274 (16.1%)
Total Patients[a]	**1,698**

[a] Includes patients with indications of spasticity and a combination of non-malignant pain and spasticity.

Event Summary

There were 4,934 events reported between August 2003 and July 31, 2016 in patients with targeted drug delivery systems. Approximately 28% of these events (1,393/4,934) were categorized as product performance-related events and are presented graphically within this report. The 1,393 product performance events occurred in 982 of the 7,459 total patients (13.17%) enrolled. In addition, there were 3,541 non-product performance events reported. There were also 1,784 deaths reported for patients with targeted drug delivery systems. 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. The event tables provided below include combined data from these versions of the protocol.

Targeted Drug Delivery System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event[b]	Percent of Patients with Event (n=7,459)
Catheter occlusion[c]	280	257	3.45%
Catheter dislodgement	273	236	3.16%
Catheter break/cut	188	169	2.27%
Pump motor stall	132	112	1.50%
Catheter kink	124	113	1.51%
Catheter related complication[d]	56	52	0.70%
Device malfunction[e]	44	41	0.55%
Catheter disconnection at pump	41	41	0.55%
Catheter leakage	39	38	0.51%
Pump reservoir volume discrepancy	33	28	0.38%

Targeted Drug Delivery System Product Performance Events			
Corrosion and/or gear wear	28	28	0.38%
Pump unable to enter/withdraw from catheter access port	22	19	0.25%
Pump underinfusion	20	17	0.23%
Overinfusion[f]	18	12	0.16%
Pump connector break/cut	17	16	0.21%
Medical device complication[g]	12	10	0.13%
Reduced battery performance	9	9	0.12%
Deformed pump tube	7	6	0.08%
Device breakage	5	5	0.07%
Catheter access port issue	4	4	0.05%
Device use error	4	4	0.05%
Catheter	3	3	0.04%

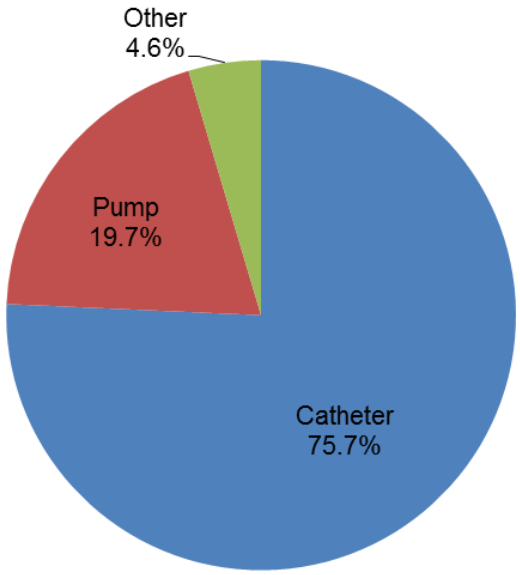
Targeted Drug Delivery System Product Performance Events			
disconnection between catheter segments			
Device alarm issue	3	3	0.04%
Motor feedthrough anomaly	3	3	0.04%
Pump not infusing	3	3	0.04%
Reservoir access issues due to residue	3	2	0.03%
Catheter damage	2	2	0.03%
Device connection issue	2	2	0.03%
Device difficult to use	2	2	0.03%
Device issue	2	2	0.03%
Alarm and/or resonator anomaly	1	1	0.01%
Coil shorted to case	1	1	0.01%
Concave pump shield	1	1	0.01%

Targeted Drug Delivery System Product Performance Events			
Connector block problem	1	1	0.01%
Cracked rotor magnet holder	1	1	0.01%
Device component issue[h]	1	1	0.01%
Device deployment issue	1	1	0.01%
Device infusion issue[j]	1	1	0.01%
Device telemetry issue	1	1	0.01%
Gear or bridging residue	1	1	0.01%
Leaky capacitor	1	1	0.01%
Product sedimentation present	1	1	0.01%
Pump inversion	1	1	0.01%
Not Coded[j]	1	1	0.01%
Totals	**1,393**	**982**	**13.17%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred 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] Includes events reported as catheter occlusion and catheter kink/occlusion.
[d] Includes 18 catheter malfunctions, 15 inability to aspirate from catheter, 4 suspected catheter malfunctions, 4 coiled catheters, 2 difficulty aspirating catheter, 2 non-functioning distal catheter, 1 inability to aspirate CSF, 1 poor CSF flow, 1 aneurysm in catheter, 1 catheter wrapped in coils and knots, 1 catheter wrapped around pump, 1 evidence of catheter wear, 1 catheter failure, 1 no free flow of CSF from spinal segment of catheter, 1 patency issues of catheter, 1 slight loop in catheter, and 1 catheter occlusion.
[e] Includes 25 PTM malfunctions, 8 suspected catheter malfunctions, 6 pump malfunctions, 1 clinician programmer malfunction, 1 catheter dysfunction, 1 possible pump malfunction, 1 suspected rotor problem, and 1 catheter anchor malfunction.
[f] There were a total of 24 pumps with overinfusion (physician reported or confirmed by returned product analysis). The events for 15 of these pumps are reported in the table above. The remaining 9 pumps had no reported events associated with explant but had returned product analysis confirmed overinfusion (not reflected in the table above but included in the occurrence rate of overinfusion indicated in the Pump Events section of this report). The 15 pumps represented in the above table had 21 events; 18 events for overinfusion, and 3 events for pump motor stall.
[g] Includes 1 pump connector appeared somewhat worn, 1 pump unable to interrogate, 1 sutureless connector failure, 1 roller arm seized to ball bearing, 1 pump beeped, 1 pump in safe state, 1 possible corrosion of pump due to concentration of drug, 1 possible corrosion of catheter due to concentration of drug, 1 worn catheter connector, 1 metal clips on sutureless connector bent, 1 prescription table corruption, and 1 pump absorption of drug.
[h] Includes 1 event reported as broken anchor.
[i] Includes 1 event reported as slow dosing at refills.
[j] Event that had not been MedDRA-coded at the time of the report cut-off.

A total of 1,054 (75.7%) of the 1,393 product performance events were related to the catheter, 274 (19.7%) were related to the pump, 38 (2.7%) were reported as related to an external device, 17 (1.2%) were related to "multiple etiologies," which includes events where at least one device and one non-device etiology was indicated, 3 (0.2%) were related to surgery/anesthesia, 2 (0.1%) were related to incisional site/device tract, 2 (0.1%) were related to MRI, 1 (0.1%) was related to programming/refill, 1 (0.1%) was related to medication, and 1 (0.1%) was related to some "other" etiology. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a] Each event could have more than one etiology.

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Event[b]	**Number of Non-Product Performance Events**
Therapeutic and nontherapeutic effects (excluding toxicity)	**998**
Adverse drug reaction	725
Drug withdrawal syndrome	121
Therapeutic product ineffective	99
Therapeutic response decreased	40
No therapeutic response	10
Other[c]	3
Administration site reactions	**622**
Implant site pain	251
Implant site extravasation	157

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Implant site erosion	34
Implant site erythema	29
Catheter site pain	22
Inflammatory mass (Possible)	18
Catheter site fibrosis	17
Implant site haematoma	16
Implant site swelling	14
Inflammatory mass (Confirmed)	13
Implant site inflammation	6
Other[c]	45
Infections - pathogen unspecified	**322**
Inplant site infection	218
Wound infection	35
Meningitis	22
Infection	18
Incision site infection	14
Other[c]	15
Device issues	**317**
Pump inversion	158
Pump migration	74
Device difficult to use	26
Device malfunction	19
Pump reservoir volume discrepancy	6

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Device use error	5
Catheter break/cut	5
Pump unable to enter/withdraw from catheter access port	5
Other[c]	19
Complications associated with device	**226**
Pump motor stall[d]	186
Medical device discomfort	27
Medical device complication[e]	5
Drug-related pump anomaly	5
Other[c]	3
General system disorders Not Elsewhere Classified (NEC)	**214**
Pain	132
No anomaly found by RPA[f]	40
Oedema peripheral	18
Asthenia	5
Other[c]	19
Neurological disorders (NEC)	**212**
Cerebrospinal fluid leakage	102
Hypoaesthesia	43
Sedation	16
Somnolence	15
Paraesthesia	10

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Hyperaesthesia	8
Other[c]	18
Procedural related injuries and complications NEC	**195**
Wound dehiscence	67
Seroma	35
Post lumbar puncture syndrome	27
Procedural complication	8
Anaesthetic complication	5
Other[c]	53
Medication errors	**44**
Overdose	41
Other[c]	3
Muscle disorders	**38**
Muscular weakness	30
Muscle spasms	8
Headaches	**37**
Headache	37
Urinary tract signs and symptoms	**34**
Urinary retention	25
Dysuria	7
Other[c]	2
Neuromuscular disorders	**31**
Muscle spasticity	27

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other[c]	4
Epidermal and dermal conditions	**26**
Erythema	9
Pruritus	6
Other[c]	11
Gastrointestinal signs and symptoms	**22**
Nausea	11
Vomiting	7
Other [c]	4
Musculoskeletal and connective tissue disorders NEC	**21**
Back pain	12
Other[c]	9
Exposures, chemical injuries and poisoning	**19**
Toxicity to various agents	19
Psychiatric disorders NEC	**18**
Mental status changes	15
Other[c]	3
Bacterial infectious disorders	**16**
Inmplant site cellulitis	7
Cellulitis	5
Other[c]	4
Tissue disorders NEC	**16**

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Impaired healing	15
Other[c]	1
Vascular haemorrhagic disorders	**9**
Haematoma	9
Therapeutic procedures and supportive care NEC	**8**
Incisional drainage	5
Other[c]	3
Gastrointestinal motility and defaecation conditions	**6**
Constipation	6
Mental impairment disorders	**6**
Memory impairment	5
Other[c]	1
Skin and subcutaneous tissue disorders NEC	**6**
Skin erosion	6
Other[c]	78
Total	3,541

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Composed of event codes with fewer than 5 events each.
[d] 186 pump motor stalls occurred due to MRI and recovered in less than 24 hours with no pump issues.
[e] Includes events reported as 1 pump poorly positioned,1 difficulty locating pump port due to patient weight gain, 1 possible catheter sheath, 1 inadvertent overfilling of the pump at refill, and 1 mis-filling of pump into pocket.
[f] For products that are returned with a suspected device issue, and RPA establishes a root cause or finds no anomaly, results reported herein reflect the finding from Returned Product Analysis (RPA).

There were 1,784 deaths reported for patients with targeted drug delivery systems. None of the deaths were reported as a direct result of a product performance event. One death was reported by the physician as possibly related to the intrathecal medications in a patient who expired due to pulmonary embolism. A second death was reported by the physician as due to acute respiratory failure following a device procedure, and was reported as

possibly related to the device and implant procedure. A total of 1,086 (60.9%) of deaths occurred in patients receiving therapy for malignant pain, 528 (29.6%) for non-malignant pain, 164 (9.2%) for spasticity, 4 (0.2%) for non-malignant pain and spasticity, and 2 (0.1%) for patients whose primary indication was not specified.

Deaths by Primary Indication	
Primary Indication[a]	**N (%)**
Malignant pain	1,086 (60.9%)
Non-malignant pain	528 (29.6%)
Spasticity	164 (9.2%)
Non-Malignant Pain & Spasticity	4 (0.02%)
Not specified	2 (0.1%)
Total	**1,784**

[a] Refer to product labeling for approved indications.

Pumps

From August 2003 to the report cut-off date of July 31, 2016, there were 9,014 pumps followed in the registry. The difference between the total number of patients (n=7,459) versus 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 237,699 months (19,808 years). The table below provides the number and percentage of pumps by model.

Pumps by Model	
Model Name	**Number of Pumps (%)**
SynchroMed II	7,825 (86.8%)
Unspecified	2 (<0.1%)
Pumps No Longer Manufactured	
SynchroMed EL	1,182 (13.1%)
SynchroMed	5 (<0.1%)
Total	**9,014 (100%)**

Pump Events

There were 279 product performance-related events with an underlying reported etiology related to pump function.

- 274 events had a pump etiology, and 5 events had both a pump

and other etiology (including device and non-device).
    - 138 pumps were analyzed by Medtronic Returned Product Analysis (RPA) with the following analysis findings: 66 motor stalls, 28 corrosion and/or gear wear, 17 overinfusion, 9 reduced battery performance, 6 deformed pump tube, 3 motor feedthrough anomaly, 2 reservoir access issue due to residue, 1 alarm and/or resonator anomaly, 1 coil shorted to case, 1 concave pump shield, 1 cracked rotor magnet holder, 1 leaky capacitor, 1 gear or bridging residue, and 1 medical device complication. Of these 138 pumps with RPA-confirmed malfunction events, 26 were originally reported as non-product performance-related battery depletions by the physician.
        - The current return rate of pumps to Medtronic RPA was 1067/3,980 (26.8%). The proportion was based upon the number of registry pumps received by RPA, divided by the total number of explanted pumps plus the total number of pumps in patients who expired.
    - 141 events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 63 events due to physician-reported motor stalls, 28 pump reservoir discrepancies, 17 pump underinfusion, 9 device malfunctions, 6 medical device complications, 5 pump unable to enter/withdraw from catheter access port, 3 pump not infusing, 3 device alarm issues, 2 catheter occlusions, 2 pump connector break/cut, 1 catheter break/cut, 1 device telemetry issue, and 1 overinfusion.
- 224 were the initial product performance event that affected pump survival estimates.

In addition to the 279 product performance-related events, there were 12 pump events reported as normal battery depletion by the physician, which were returned to Medtronic and had a RPA observation of high battery resistance. For this analysis, these pumps were categorized as having non-product performance-related battery depletion events, because they represented normal implant duration (ranging from 5.6-6.8 years) with no associated physician or patient complaint.

Medtronic executed a field action in March 2014 informing healthcare professionals of overinfusion associated with the SynchroMed II Infusion System. In September 2016, an updated customer letter was provided which stated an overinfusion occurrence rate for registry patients. This rate was based on pumps which had both laboratory overinfusion through returned product analysis and an in-vivo complaint of either clinical overinfusion symptoms or lower than expected residual volume. This definition was used because environmental factors during shipping may impact the results of returned product testing. There were 5 pumps in the registry that met this definition as stated in the customer letter. The 5 pumps with overinfusion provided 95% confidence that the occurrence rate is less than 0.0014 (0.14%).

The laboratory overinfusion rate for all registry pumps with overinfusion found through returned product analysis was also assessed. As of July 31, 2016, this included the 5 pumps described above in the customer

letter, and 18 additional pumps for a total of 23 pumps from registry patients with laboratory overinfusion. Of these 23 pumps with laboratory overinfusion, 14 had an event reported in the registry, and the remaining 9 had no reported events associated with the pump. The 23 findings of laboratory overinfusion occurred in 7,825 SynchroMed II pumps included in the registry at the time of analysis, providing 95% confidence that the occurrence rate is less than 0.0042 (0.42%).

In addition to the 23 pumps with laboratory overinfusion after returned product analysis, there was 1 pump with physician reported overinfusion that was not returned for analysis. Combining the physician reported and laboratory overinfusion (n=24) provided 95% confidence that the total occurrence rate is less than 0.0043 (0.43%). Medtronic continues to monitor pump performance relative to overinfusion.

Overinfusion Rate

	In Vivo & Laboratory Overinfusion[a]	Laboratory Overinfusion[b]	Laboratory or Physician Reported[c] Overinfusion
Number of Pumps	5	23	24
Occurrence Rate[d]	0.14%	0.42%	0.43%

[a] From September 2016 Field Action letter. Rate based on total of 7,505 pumps (January 31, 2016 data cut-off).
[b] Laboratory overinfusion by Returned Product Analysis. Rate based on a total of 7,825 pumps (July 31, 2016 data cut-off).
[c] There was one pump with physician reported overinfusion which was not returned for analysis. Rate based on a total of 7,825 pumps (July 31, 2016 data cut-off).
[d] Upper one-sided exact 95% confidence interval.

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 non-product performance-related or 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:

- 224 were cut-off due to product performance-related events.
- 6,412 were censored in the survival analysis for the following reasons: patient expired, pump explanted, site termination, patient discontinued, patient lost to follow-up, other pump modification, therapy suspended, or non-product performance pump-related event with no associated intervention.
- 2,378 were free from product performance-related events and

censoring events, were censored at the last follow-up visit prior to the report cut-off.

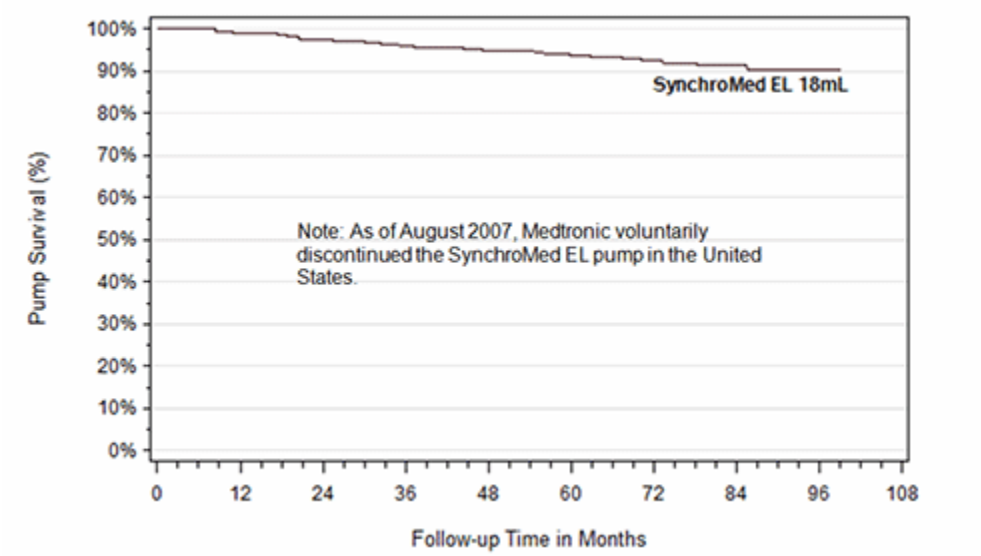
Pump Survival

The figures and tables below represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each 3-month interval. Medtronic chose to voluntarily discontinue the SynchroMed EL pump in August 2007 in the United States.

Choose a model Go

Model 8627-18 SynchroMed EL 18mL: Survival from Pump Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Pump Characteristics	
Model Name	SynchroMed II (18 mL)
FDA Approval Date	Mar 1999
Pumps Enrolled	1,148
Pumps Currently Active in Study	1
Device Events	34
Cumulative Months of Follow-up	31,052

Summary Table Pump Event	Total
Corrosion and/or gear wear	17
Pump underinfusion	6
Pump motor stall	5
Medical device complication[a]	2
Cracked rotor magnet holder	1
Gear or bridging residue	1
Motor feedthrough anomaly	1
Reduced battery performance	1
Total Pump Events	**34**

[a] Includes 1 event for unable to interrogate/program pump and 1 roller arm seized to ball bearing.

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**98.8%** (95.3%, 99.7%)	181
2 yrs	**97.4%** (94.2%, 98.9%)	374
3 yrs	**95.8%** (92.6%, 97.6%)	535
4 yrs	**94.9%** (91.8%, 96.9%)	590
5 yrs	**93.7%** (90.5%, 95.8%)	468
6 yrs	**92.3%** (88.9%, 94.7%)	245
7 yrs	**91.3%** (87.6%, 94.0%)	108
8 yrs	**90.4%** (86.1%, 93.4%)	36
at 99 mo	**90.4%** (86.1%, 93.4%)	23

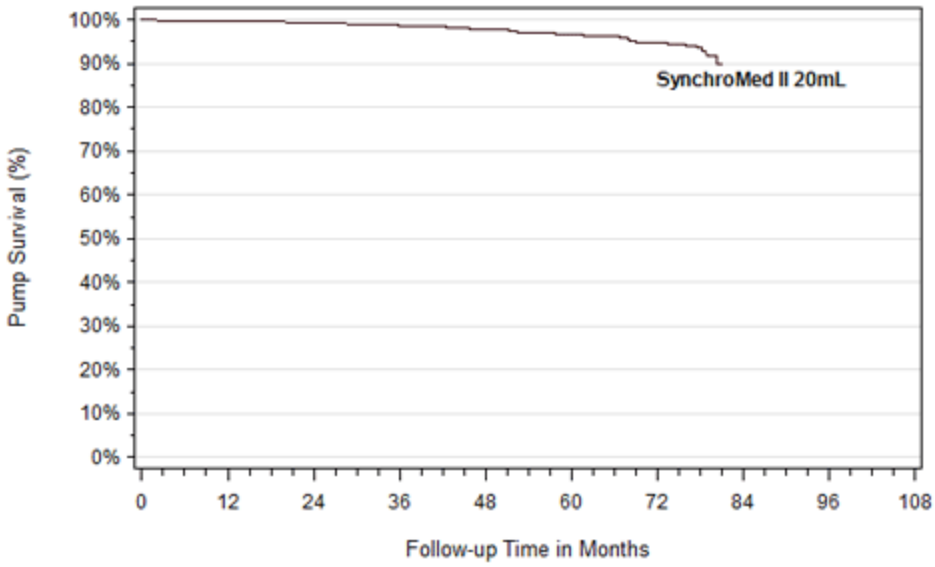
Model 8627-18 SynchroMed EL 18mL: Specifications

Expected battery life[a]	3-7 years
Thickness	1.08 in (27.5 mm)
Diameter (with integral access port)	3.35 in (85.2 mm)
Capacity	18.0 mL
Minimal Programmable Flow Rate[b]	0.048 mL/day
Maximum Programmable Flow Rate[b]	21.6 mL/day

[a] Dependent on flow rate
[b] Actual limits depend on pump calibration constant and selected infusion mode.

Model 8637-20 SynchroMed II 20mL: Survival from Pump Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Pump Characteristics	
Model Name	SynchroMed II (20 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	3,049
Pumps Currently Active in Study	1,167

Device Events	62
Cumulative Months of Follow-up	94,287

SynchroMed II 20mL Event Summary Table Pump Event	Total
Pump motor stall	25
Pump reservoir volume discrepancy	8
Corrosion and/or gear wear	4
Device malfunction[a]	4
Overinfusion	3
Pump unable to enter/withdraw from catheter access port	3
Medical device complication [b]	2
Motor feedthrough anomaly	2
Reduced battery performance	2
Alarm and/or resonator anomaly	1
Catheter occlusion	1
Deformed pump tube	1
Device alarm issue	1
Device telemetry issue	1
Pump connector break/cut	1
Pump not infusing	1
Pump underinfusion	1
Reservoir access issues due to residue	1
Total Pump Events	**62**

[a] Includes 3 events for pump malfunction and 1 event for suspected rotor problem.
[b]Includes 1 event for pump beeped and 1 event for pump in safe state.

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.8%** (99.5%, 99.9%)	2,027
2 yrs	**99.4%** (99.0%, 99.7%)	1,623
3 yrs	**98.7%** (98.1%, 99.2%)	1,196
4 yrs	**97.9%** (97.0%, 98.6%)	869
5 yrs	**96.6%** (95.2%, 97.5%)	612
6 yrs	**93.9%** (91.8%, 95.4%)	391
at 81 mo	**89.2%** (84.3%, 92.6%)	43

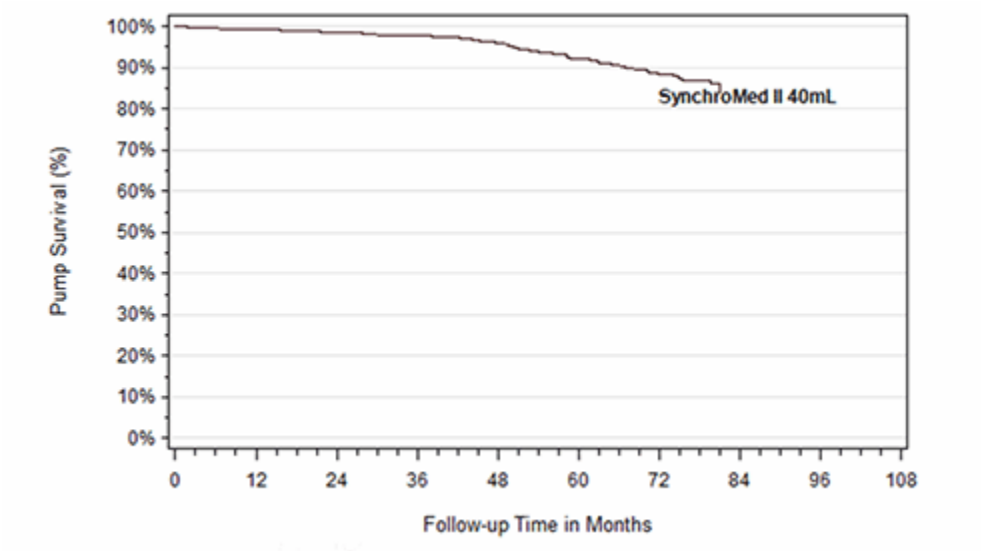
Model 8637-20 SynchroMed II 20mL: Specifications

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
[b] Actual limits depend on pump calibration constant and selected infusion mode.
[c] Nontherapeutic (if therapy is to be temporarily discontinued)

Model 8637-40 SynchroMed II 40mL: Survival from Pump Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Pump Characteristics	
Model Name	SynchroMed II (40 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	4,776
Pumps Currently Active in Study	1,393
Device Events	127
Cumulative Months of Follow-up	111,401

SynchroMed II 40mL Event Summary Table Pump Event	Total
Pump motor stall	67
Pump reservoir volume discrepancy	11
Pump underinfusion	8
Overinfusion	8
Corrosion and/or gear wear	6
Reduced battery performance	5
Deformed pump tube	4

Device malfunction [a]	4
Device alarm issue	2
Medical device complication [b]	2
Pump not infusing	2
Pump unable to enter/withdraw from catheter access port	2
Catheter occlusion [c]	1
Coil shorted to case	1
Concave pump shield	1
Leaky capacitor	1
Pump connector break/cut	1
Reservoir access issues due to residue	1
Total Pump Events	**127**

[a] Includes 2 events for pump malfunction, 1 event for suspected pump malfunction, and 1 event for suspected catheter dysfunction attributed to both pump and catheter.
[b] Includes 1 event for under medicated event that was attributed to the pump and 1 possible corrosion of pump due to concentration of drug.
[c] Includes 1 event for catheter occlusion that was attributed to the pump and catheter.

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.2%** (98.9%, 99.5%)	2,564
2 yrs	**98.7%** (98.2%, 99.1%)	1,857
3 yrs	**97.7%** (96.9%, 98.2%)	1,313
4 yrs	**95.9%** (94.7%, 96.8%)	902
5 yrs	**92.2%** (90.4%, 93.7%)	591
6 yrs	**88.4%** (85.9%, 90.5%)	351

at 81 mo	**83.7%** (77.4%, 88.4%)	37

Model 8637-40 SynchroMed II 40mL: Specifications

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
[b] Actual limits depend on pump calibration constant and selected infusion mode.
[c] Nontherapeutic (if therapy is to be temporarily discontinued)

Pump Survival Summary

Pump Characteristics

Model Name	Family	FDA Approval Date	Pumps Enrolled	Pumps Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
SynchroMed EL (18 mL)	SynchroMed EL	Mar 1999	1,148	1	34	31,052
SynchroMed II (20 mL)	SynchroMed II	Sep 2003	3,049	1,167	62	94,287
SynchroMed II (40 mL)	SynchroMed II	Sep 2003	4,776	1,393	127	111,401

[a] There were a total of 279 pump-related events reported to the registry, but only 223 events included in this summary table. The remaining events either occurred in pump models for which no device survival curves are presented due to an insufficient number of enrolled devices (i.e., SynchroMed EL 10 mL[n=1]) or were subsequent events (ie additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Intervals) –*Table 1 of 2*

Model Name	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs

SynchroMed EL (18 mL)	**98.8%** (95.3%, 99.7%)	**97.4%** (94.2%, 98.9%)	**95.8%** (92.6%, 97.6%)	**94.9%** (91.8%, 96.9%)	**93.7%** (90.5%, 95.8%)	**92.3%** (88.9%, 94.7%)	**91.3%** (87.6%, 94.0%)	**90.4%** (86.1%, 93.4%)
SynchroMed II (20 mL)	**99.8%** (99.5%, 99.9%)	**99.4%** (99.0%, 99.7%)	**98.7%** (98.1%, 99.2%)	**97.9%** (97.0%, 98.6%)	**96.6%** (95.2%, 97.5%)	**93.9%** (91.8%, 95.4%)	-	-
SynchroMed II (40 mL)	**99.2%** (98.9%, 99.5%)	**98.7%** (98.2%, 99.1%)	**97.7%** (96.9%, 98.2%)	**95.9%** (94.7%, 96.8%)	**92.2%** (90.4%, 93.7%)	**88.4%** (85.9%, 90.5%)	-	-

Device Survival Probability (95% Confidence Intervals) –*Table 2 of 2*

Model Name	5 yrs	6 yrs	7 yrs	8 yrs
SynchroMed EL (18 mL)	**93.7%** (90.5%, 95.8%)	**92.3%** (88.9%, 94.7%)	**91.3%** (87.6%, 94.0%)	**91.3%** (87.6%, 94.0%)
SynchroMed II (20 mL)	**96.6%** (95.2%, 97.6%)	**94.7%** (92.7%, 96.2%)	-	-
SynchroMed II (40 mL)	**93.4%** (91.5%, 94.9%)	**90.0%** (87.4%, 92.10%)	-	-

Product Performance of SynchroMed II Pumps Exposed to On-Label and Off-Label Medications

The purpose of this section of the report is to provide additional information regarding the product performance of SynchroMed II pumps exposed to On-Label and Off-Label medications. This section contains information outside the FDA approved labeling for Medtronic's SynchroMed II Infusion System. It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products according to FDA approved labeling. Medtronic does not market its products for Off-Label indications and makes no representations regarding the efficacy for Off-Label uses. Infumorph®, Prialt®, Lioresal® and Gablofen® are the only intrathecal FDA approved formulations for the Medtronic SynchroMed II Infusion System. The long term drug stability/compatibility and safety and/or efficacy of drugs not FDA approved for use with the SynchroMed II Infusion System has not been established.

Patient status updates were obtained every 6 months or until discontinuation of therapy or the patient was lost to follow-up. Medications within the pump were recorded at each 6-month follow-up. This provided a snapshot of medication use at these points in time. The registry did not capture every medication or medication concentration used in the pump since any medication or concentration changes that occurred between follow-up visits were not recorded.

Pump Groups – On/Off Label Categorization

There were 6,666 patients enrolled in the registry that had SynchroMed II pumps implanted. Of these patients, 56% were female and 44% were male with a mean age of 54.0 (SD = 17.3). Of the 7,825 SynchroMed II pumps enrolled through July 31, 2016, at least one drug record was available for 7,519 pumps. If a pump had no drug records, the pump was not classified, and was excluded from analyses comparing On-Label to Off-Label. Pumps were categorized as being On7ndash; 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 is morphine sulfate or ziconotide these pumps are considered On-Label.

- o For pumps used for spasticity patients, if the drug record has only one drug, and it is baclofen, Lioresal® or Gablofen®, that drug record is considered On-Label. Note: The classification was based on the name of the drug only, not the reported concentration of the drug.
- 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 specified above within the approved indications are considered Off-Label. Additionally, any drug record with more than one drug at a time in the pump (admixture) is 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 is 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 is considered Off-Label.

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:

- All pumps: On-Label vs. Off-Label Drugs (including all indications)
- Pain: On-Label vs. Off-Label Drugs (including all pain)
- Spasticity: On-Label vs. Off-Label Drugs (including all spasticity)

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.

Results

Choose a result Go

Total Study Population: A total of 2,330 SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 5,189 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture.

Demographic table

Indication [a]: N (Row %)	On-Label N=2,330	Off-Label N=5,189
Non-Malignant Pain	748 (16.9%)	3,685 (83.1%)
Malignant Pain	38 (3.0%)	1,225 (97.0%)

[a] Refer to product labeling for approved indications.

There were a total of 189 reported SynchroMed II pump failures (i.e. had product performance event) during the study observation period. In addition to the 189 pump failures, there were 12 pump events reported as normal battery depletion, but had a Returned Product Analysis (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 – 6.8 years with no associated physician or patient complaint. Three of the 189 pump failure events occurred in pumps with no drug records available. Of the remaining 186 SynchroMed II pump failures, 92 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 corrosion and/or gear wear, inconsistent pump reservoir volume, pump under infusion, and other non-conforming reasons. Overall, the rate of pump failures in this cohort was 2.5% (186/7,519) with a median follow-up of 19.8 months.

For the 92 pump failures due to motor stall, 44 of the events were associated with the patient presenting clinical signs and symptoms of possible drug withdrawal or increasing pain or spasticity. The other 48 events had no patient reported signs and symptoms associated with the event, but had a physician report of a motor stall occurrence. There were no issues reported when pumps were replaced and/or re-started, such as drug overdose. None of the pump failures resulted in patient death.

The table below presents SynchroMed II pump survival for the **entire population** and is stratified by the On-Label or Off-Label pump group.

Total study population: Survival from product performance-related pump events for all indications, by On/Off-Label drug exposure for SynchroMed II pumps

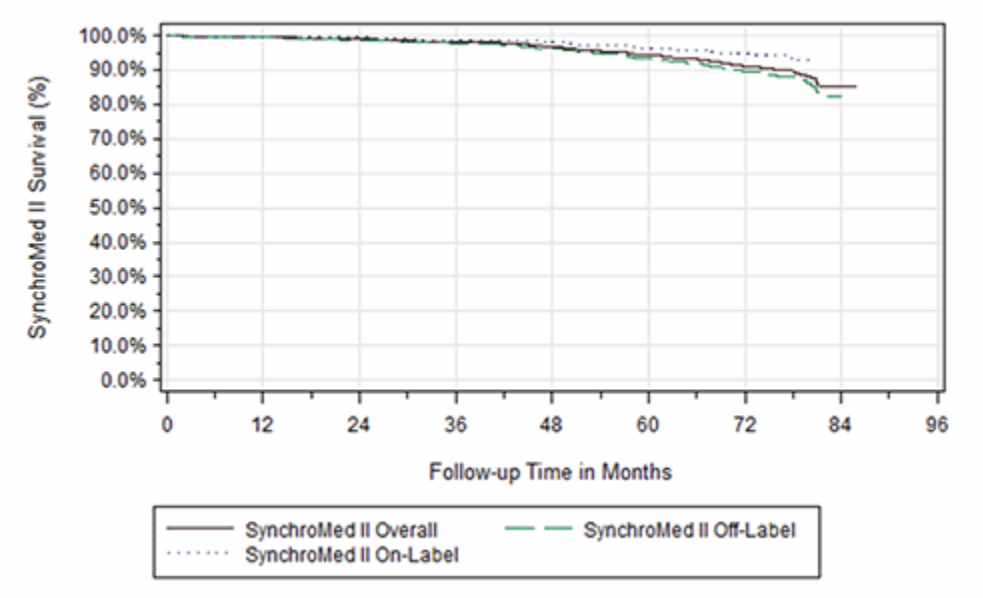
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo	7 yrs	87 mo
All Pumps	Survival	99.5%	99.0%	98.1%	96.8%	94.3%	91.1%	86.3%	85.1%	85.1%
	Number of pumps	4,511	3,433	2,482	1,747	1,192	740	80	30	21
On-Label Drugs	Survival	99.7%	99.5%	98.8%	98.1%	96.3%	94.5%	92.6%	-	-
	Number of pumps	1,481	1,131	811	563	398	233	20	- [a]	- [a]
Off-Label Drugs	Survival	99.4%	98.8%	97.8%	96.2%	93.4%	89.5%	84.0%	82.4%	-
	Number of pumps	3,030	2,302	1,671	1,184	794	507	60	21	- [a]

[a] Sample size is less than 20 active devices at 7 years for On-Label pump group, and at 87 months for both On and Off-Label pump groups.

The cumulative survival curve of the SynchroMed II pump for the **entire population**, and stratified by the On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (All therapies)

Data are shown if there are at least 20 devices in each 3-month interval.



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The table and graph depict the cumulative failure rate over time and estimate the risk of pump failure for specific implant durations (i.e. time period from pump implant). Overall, the pumps with known Off-Label drug exposure had a 1.9 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.0004).

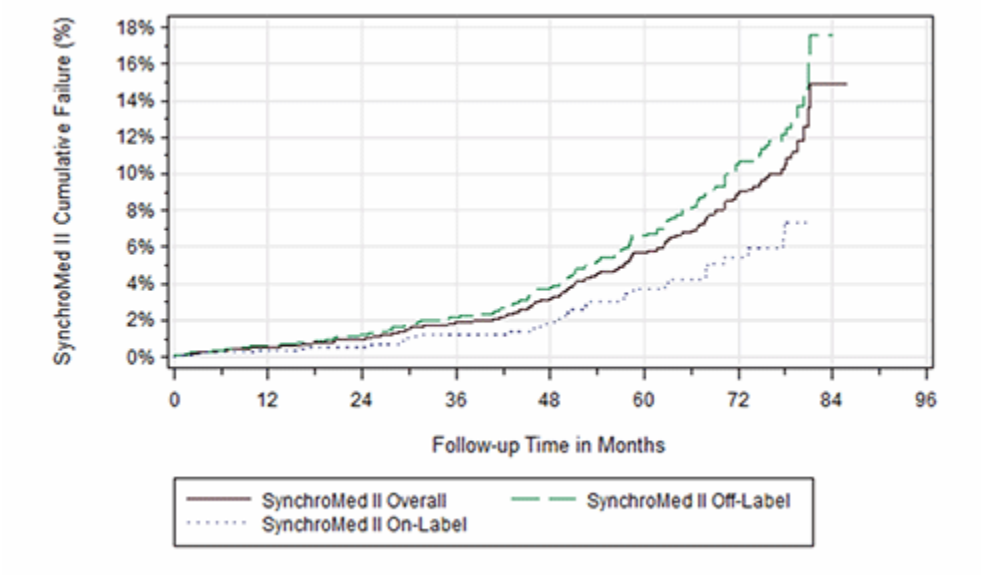
Total study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for all indications, by On/Off-Label drug exposure

Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo	7 yrs	87 mo
All Pumps	Failure	0.5%	1.0%	1.9%	3.2%	5.7%	8.9%	13.7%	14.9%	14.9%
	Number of pumps	4,511	3,433	2,482	1,747	1,192	740	80	30	21
On-Label Drugs	Failure	0.3%	0.5%	1.2%	1.9%	3.7%	5.5%	7.4%	-	-
	Number of pumps	1,481	1,131	811	563	398	233	20	-[a]	-[a]
Off-Label Drugs	Failure	0.6%	1.2%	2.2%	3.8%	6.6%	10.5%	16.0%	17.6%	-
	Number of pumps	3,030	2,302	1,671	1,184	794	507	60	21	-[a]

[a] Sample size is less than 20 active devices at 7 years for On-Label pump group, and at 87 months for both On and Off-Label pump groups.

SynchroMed II cumulative failure (All therapies)

Data are shown if there are at least 20 devices in each 3-month interval.



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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.
- Off-Label medication exposure is associated with an overall 1.9 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 81 months of follow-up, the survival from pump failure for On-Label pumps was 92.6%, compared to a survival of 84.0% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 19.8 months. 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 was comprised of 66% spasticity as the indication (1,544 vs. 786: Spasticity versus Pain pumps respectively). On the other hand, the Off-Label group consisted of 95% pain indications (4,910 vs. 187: 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 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) 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 time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Pain Study Population: A total of 786 SynchroMed II pumps were classified as On-Label for pain therapy, where there was no evidence of Off-Label drug/admixture exposure. A total of 4,910 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label pain drug/admixture.

The table below presents SynchroMed II pump survival for the **Pain** indications and is stratified by the On-Label or Off-Label pump group.

Pain study population: Survival from product performance-related pump events for Pain indications, by On/Off-Label drug exposure for SynchroMed II pumps

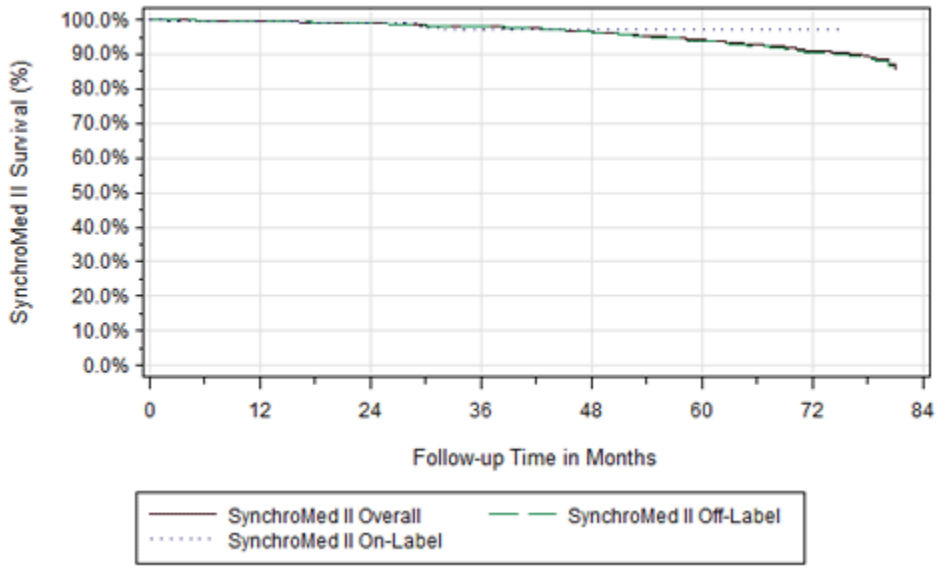
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Survival	99.4%	98.8%	97.8%	96.2%	93.4%	89.6%	88.8%	83.7%
	Number of pumps	3,290	2,446	1,748	1,202	805	514	414	59
Pain On-Label	Survival	99.6%	98.9%	97.2%	97.2%	95.7%	95.7%	95.7%	-
	Number of pumps	444	285	178	97	61	37	31	-[b]
Pain Off-Label	Survival	99.4%	98.8%	97.9%	96.1%	93.2%	89.1%	88.2%	83.2%
	Number of pumps	2,846	2,161	1,570	1,105	744	477	383	54

[a] Refer to product labeling for approved Pain indications.
[b] Sample size is less than 20 active devices at 81 months for Pain On-Label pump group

The cumulative survival of the SynchroMed II pump for the **Pain** indications, and stratified by the On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (Pain)

Data are shown if there are at least 20 devices in each 3-month interval.



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The difference in survival between the On-Label and Off-Label groups for the pumps in the pain population was similar to what was observed for the entire population (all therapies). There was no statistically significant difference in the risk of failure

between the On-Label and Off-Label pumps implanted for the treatment of pain (p=0.31); however, the limited number of On-Label pumps may be insufficient to detect a difference.

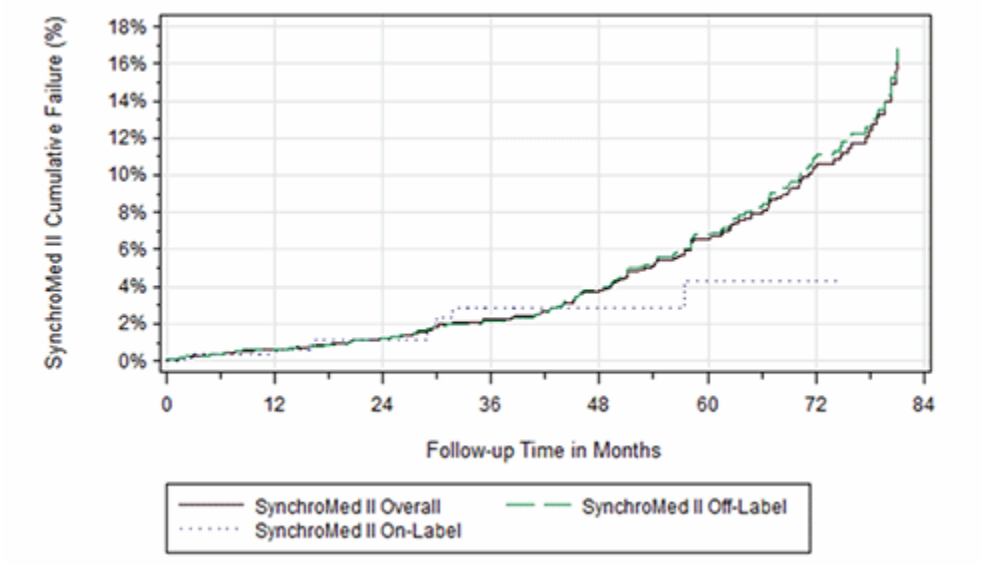
Pain study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Pain indications, by On/Off-Label drug exposure

Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Failure	0.6%	1.2%	2.2%	3.8%	6.6%	10.4%	11.2%	16.3%
	Number of pumps	3,290	2,446	1,748	1,202	805	514	414	59
Pain On-Label	Failure	0.4%	1.1%	2.8%	2.8%	4.3%	4.3%	4.3%	-
	Number of pumps	444	285	178	97	61	37	31	-[b]
Pain Off-Label	Failure	0.6%	1.2%	2.1%	3.9%	6.8%	10.9%	11.8%	16.8%
	Number of pumps	2,846	2,161	1,570	1,105	744	477	383	54

[a] Refer to product labeling for approved Pain indications.
[b] Sample size is less than 20 active devices at 81 months for Pain On-Label pump group.

SynchroMed II cumulative failure (Pain)

Data are shown if there are at least 20 devices in each 3-month interval.



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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.
- Off-Label medication exposure is associated with an overall 1.9 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 81 months of follow-up, the survival from pump failure for On-Label pumps was 92.6%, compared to a survival of 84.0% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 19.8 months. 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 was comprised of 66% spasticity as the indication (1,544 vs. 786: Spasticity versus Pain pumps respectively). On the other hand, the Off-Label group consisted of 95% pain indications (4,910 vs. 187: 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 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) 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 time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Spasticity Study Population: A total of 1,544 SynchroMed II pumps were classified as On-Label for spasticity therapy, where there was no evidence of Off-Label drug/admixture exposure. A total of 187 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label spasticity drug/admixture.

The table below presents SynchroMed II pump survival for the **Spasticity** indication and is stratified by the On-Label or Off-Label pump group.

Spasticity study population: Survival from product performance-related pump events for Spasticity indication, by On/Off-Label drug exposure for SynchroMed II pumps

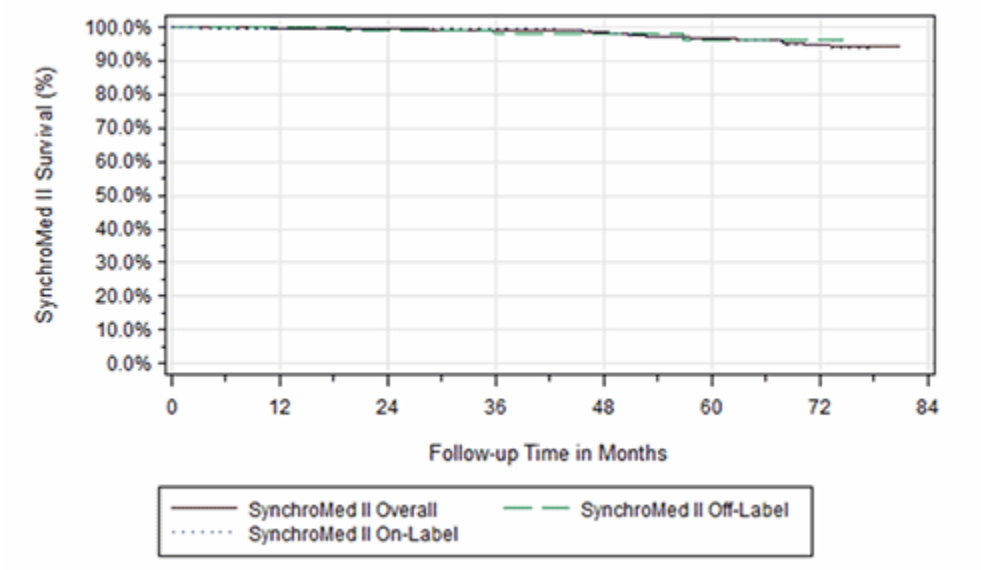
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo	81 mo
Spasticity Overall	Survival	99.7%	99.7%	99.2%	98.5%	96.6%	94.8%	94.3%	94.3%	94.3%
	Number of pumps	1,176	960	720	537	386	226	141	59	21
Spasticity On-Label	Survival	99.7%	99.7%	99.3%	98.5%	96.6%	94.6%	94.0%	94.0%	-
	Number of pumps	1,037	846	633	466	337	196	118	46	-[b]
Spasticity Off-Label	Survival	100.0%	99.2%	98.1%	98.1%	96.4%	96.4%	96.4%	-	-
	Number of pumps	139	114	87	71	49	30	23	-[b]	-[b]

[a] Refer to product labeling for approved Spasticity indication.
[b] Sample size is less than 20 active devices at 78 months for Spasticity Off-Label pump group, and at 81 months for both on-label and off-label pump groups.

The cumulative survival curve of the SynchroMed II pump for the **Spasticity** indication, and stratified by the On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (Spasticity)

Data are shown if there are at least 20 devices in each 3-month interval.



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. Overall the survival for the On-Label pumps was similar to the entire pump population (all therapies). There was no statistically significant difference in the risk of failure between the On-Label and Off-Label pumps implanted for the treatment of Spasticity (p=0.75); however, the limited number of Off-Label pumps may be insufficient to detect a difference.

Spasticity study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Spasticity indication, by On/Off-Label drug exposure

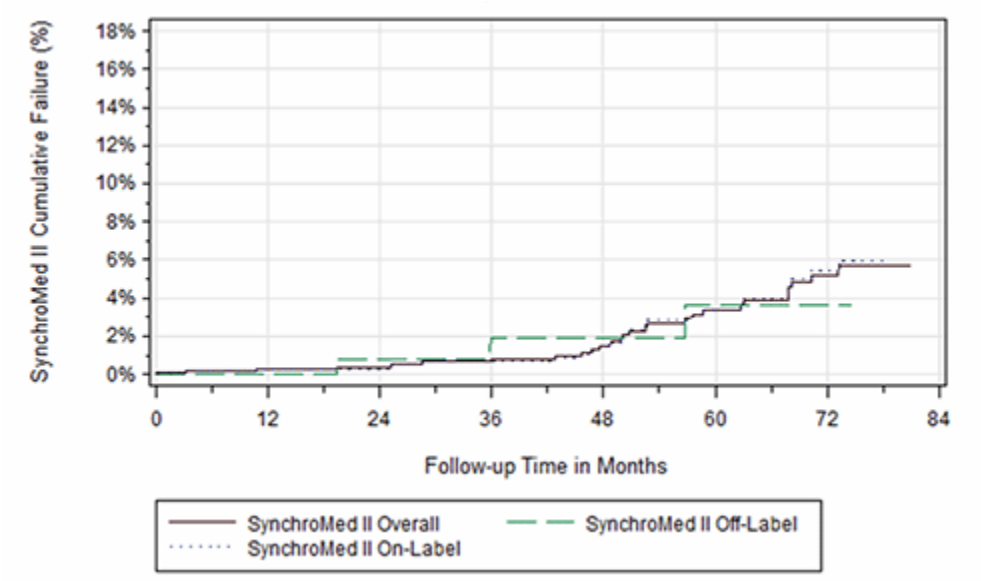
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo	81 mo
Spasticity Overall	Failure	0.3%	0.3%	0.8%	1.5%	3.4%	5.2%	5.7%	5.7%	5.7%
	Number of pumps	1,176	960	720	537	386	226	141	59	21
Spasticity On-Label	Failure	0.3%	0.3%	0.7%	1.5%	3.4%	5.4%	6.0%	6.0%	-
	Number of pumps	1,037	846	633	466	337	196	118	46	-[b]

Spasticity Off-Label	Failure	0.0%	0.8%	1.9%	1.9%	3.6%	3.6%	3.6%	-	-
	Number of pumps	139	114	87	71	49	30	23	-[b]	-[b]

[a] Refer to product labeling for approved Spasticity indication
[b] Sample size is less than 20 active devices at 78 months for Spasticity Off-Label pump group, and at 81 months for Spasticity On-Label and Off-Label groups.

SynchroMed II cumulative failure (Spasticity)

Data are shown if there are at least 20 devices in each 3-month interval.



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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.
- Off-Label medication exposure is associated with an overall 1.9 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 81 months of follow-up, the survival from pump failure for On-Label pumps was 92.6%, compared to a survival of 84.0% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 19.8 months. 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 was comprised of 66% spasticity as the indication (1,544 vs. 786: Spasticity versus Pain pumps respectively). On the other hand, the Off-Label group consisted of 95% pain indications (4,910 vs. 187: 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 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) 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 time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Catheters

From August 2003 to the report cut-off date of July 31, 2016, there were 8,463 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=9,014) 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 system (DART). The aggregate prospective follow-up time for all catheters was 236,702 months (19,725 years). The table below provides the number and percentage of catheters by model.

Catheters by Model	
Model	**Number of Catheters (%)**
8709 (InDura)	2,833 (33.5%)
8709SC (InDura 1P)	1,036 (12.2%)
8780 (Ascenda)	701 (8.3%)
8711 (InDura)	652 (7.7%)
8781 (Ascenda)	607 (7.2%)
8731SC (w/ sutureless connector)	222 (2.6%)
Revised Not As Designed[a]	645 (7.6%)
Grafted Not As Designed[b]	445 (5.3%)
Other	252 (3.0%)
Revised As Designed[c]	217 (2.6%)
Ascenda RAD[d]	166 (2.0%)
Catheters No Longer Manufactured	
8731	503 (5.9%)
8703W	184 (2.2%)
Total	**8,463 (100%)**

[a] Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit.
[b] Catheters that involve the ad-hoc assembly of components other than a Medtronic repair kit or brand new catheter.
[c] 8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit.
[d] 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit.

Catheter Events

There were 1,064 product performance events reported to the registry that were related to the catheter. This includes 1,054 events with a catheter etiology, and 10 events with both a catheter and other etiology (including device and non-device etiologies). The majority of the events were catheter occlusion (n=276), catheter dislodgement (n=241), break or cut in the catheter (n=186), or catheter kink (124). Of the 1,064 events, 925 were the initial product performance event that affected catheter 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 non-product performance-related or 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:

- 925 had follow-up time cut-off due to product performance-related events.
- 5,142 were censored in the survival analysis for the following reasons: patient expired, catheter explanted/capped, site termination, patient discontinued, patient lost to follow-up, other catheter modification, therapy suspended, or non-product performance catheter-related event without an associated intervention.
- 2,396 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

Catheter Survival

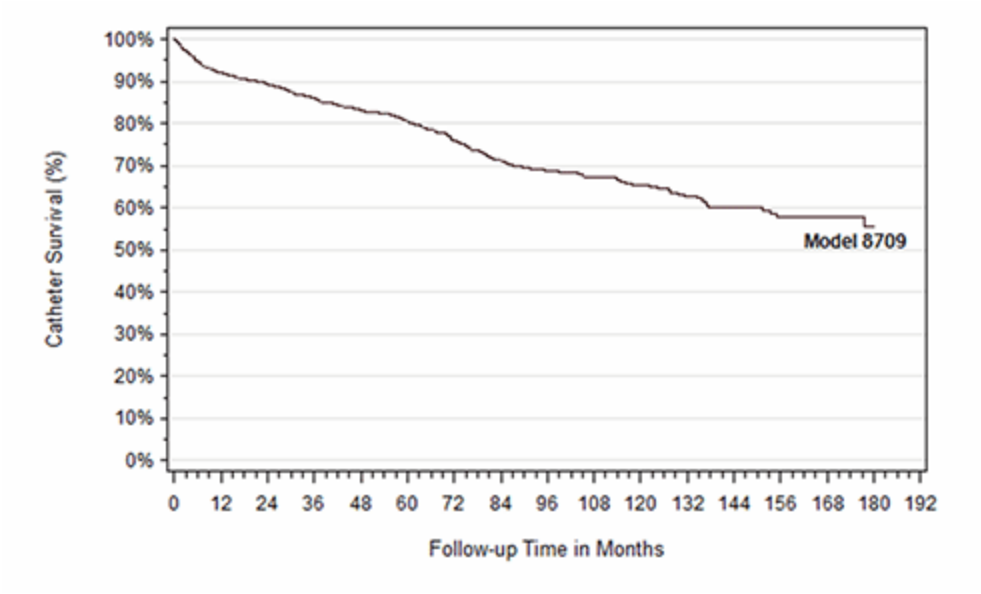
The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 12 months of follow-up at the time of the report cut-off for each model.

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.

Choose a model Go

Model 8709: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8709
FDA Approval Date	May 1998
Catheters Enrolled	2,833
Catheters Currently Active in Study	288
Device Events	309
Cumulative Months of Follow-up	81,797

Model 8709: Event Summary Table

Catheter Event	Total
Catheter dislodgement	85
Catheter occlusion	72
Catheter break/cut	70
Catheter kink	22
Catheter disconnection at pump	18
Catheter leakage	10
Catheter related complication[a]	10
Pump connector break/cut	9

Device malfunction	2
Medical device complication[b]	2
Pump unable to enter/withdraw from catheter access port	2
Pump underinfusion	2
Catheter disconnection between catheter segments	1
Deformed pump tube	1
Device infusion issue[c]	1
Motor stall	1
Reservoir access issues due to residue	1
Total Catheter Events	**309**

[a] Includes 3 events reported as unable to aspirate catheter, 2 catheter malfunctions, 1 coiled catheter, 1 aneurysm in catheter,1 possible catheter malfunction, 1 unable to aspirate CSF, and 1 difficulty aspirating catheter.
[b] Includes 1 event for pump connector appeared somewhat worn, and 1 for possible catheter corrosion due to concentration of drug.
[c] Reported as slow dosing at refills.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.1%** (90.4%, 93.5%)	963
2 yrs	**89.4%** (87.4%, 91.1%)	908
3 yrs	**86.1%** (83.9%, 88.0%)	847
4 yrs	**83.2%** (80.8%, 85.3%)	752
5 yrs	**80.6%** (78.0%, 82.9%)	626
6 yrs	**76.0%** (73.1%, 78.6%)	533
7 yrs	**71.3%** (68.2%, 74.2%)	440

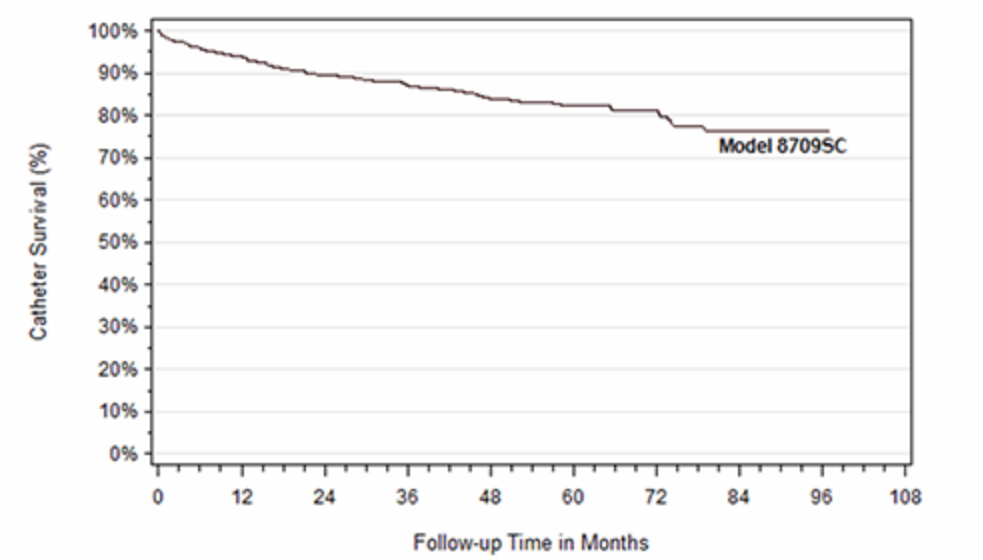
8 yrs	**68.9%** (65.6%, 72.0%)	350
9 yrs	**67.4%** (63.9%, 70.6%)	259
10 yrs	**65.2%** (61.5%, 68.7%)	192
11 yrs	**62.7%** (58.6%, 66.5%)	135
12 yrs	**60.1%** (55.5%, 64.3%)	95
13 yrs	**57.7%** (52.5%, 62.5%)	64
14 yrs	**57.7%** (52.5%, 62.5%)	40
15 yrs	**55.7%** (49.4%, 61.6%)	26

Model 8709: Specifications

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

Model 8709SC: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8709SC
FDA Approval Date	Mar 2006
Catheters Enrolled	1,036
Catheters Currently Active in Study	291
Device Events	115
Cumulative Months of Follow-up	32,258

Model 8709SC: Event Summary Table

Catheter Event	Total
Catheter dislodgement	32
Catheter break/cut	27
Catheter occlusion	24
Catheter related complication[a]	8
Catheter kink	6
Catheter leakage	6
Catheter disconnection at pump	3
Pump unable to enter/withdraw from catheter access port	2

Catheter damage	1
Catheter disconnection between catheter segments	1
Device connection issue	1
Device malfunction	1
Medical device complication[b]	1
Product sedimentation present	1
Pump inversion	1
Total Catheter Events	**115**

[a] Includes 3 events reported as catheter malfunction, 1 coiled catheter, 1 catheter occlusion, 1 catheter unable to aspirate, 1 catheter wrapped around pump, and 1 slight loop in catheter.
[b] Reported as sutureless connector failure.

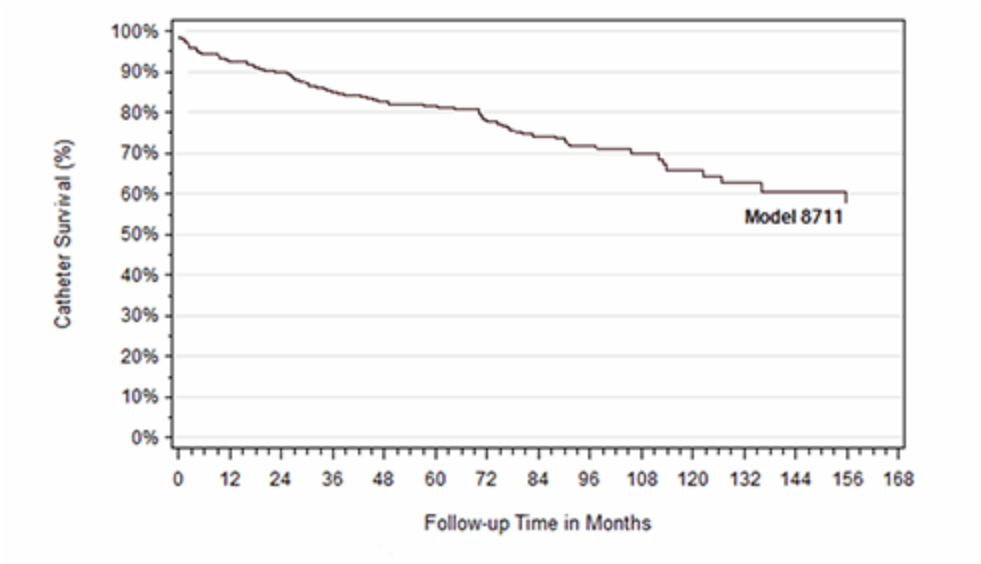
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**93.9%** (92.0%, 95.4%)	659
2 yrs	**89.4%** (86.9%, 91.5%)	511
3 yrs	**87.1%** (84.3%, 89.4%)	419
4 yrs	**83.9%** (80.7%, 86.7%)	299
5 yrs	**82.2%** (78.6%, 85.2%)	186
6 yrs	**81.1%** (77.2%, 84.4%)	112
7 yrs	**76.4%** (71.0%, 81.0%)	67
8 yrs	**76.4%** (71.0%, 81.0%)	23
at 99 mo	**76.4%** (71.0%, 81.0%)	20

Model 8709SC: Specifications

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

Model 8711: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8711
FDA Approval Date	Oct 1999
Catheters Enrolled	652
Catheters Currently Active in Study	156

Device Events	86
Cumulative Months of Follow-up	23,973

Model 8711: Event Summary Table

Catheter Event	Total
Catheter occlusion	27
Catheter break/cut	18
Catheter dislodgement	14
Catheter related complication[a]	13
Catheter kink	5
Pump unable to enter/withdraw from catheter access port	3
Catheter disconnection at pump	2
Catheter access port issue	1
Catheter leakage	1
Device malfunction	1
Pump connector break/cut	1
Total Catheter Events	**86**

[a] Includes 6 events reported as catheter malfunction, 3 unable to aspirate catheter, 2 non-functioning spinal catheters, 1 no free flow of CSF from spinal segment of catheter, and 1 difficulty aspirating catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.5%** (88.9%, 94.9%)	309
2 yrs	**90.0%** (86.1%, 92.9%)	286
3 yrs	**84.9%** (80.4%, 88.4%)	252
4 yrs	**82.7%** (78.0%, 86.5%)	219

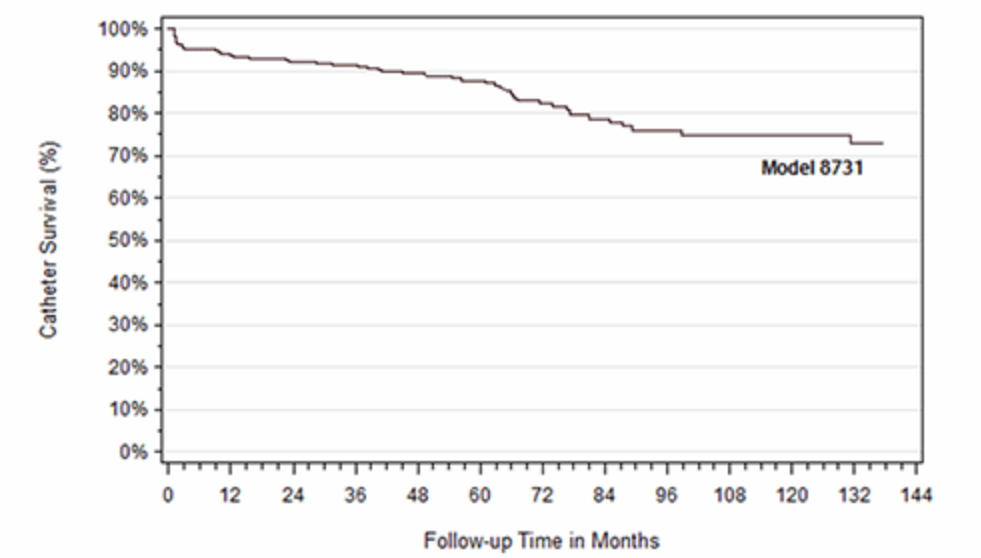
5 yrs	**81.6%** (76.7%, 85.5%)	195
6 yrs	**77.7%** (72.3%, 82.2%)	154
7 yrs	**74.1%** (68.3%, 79.1%)	135
8 yrs	**71.7%** (65.5%, 76.9%)	89
9 yrs	**69.8%** (63.2%, 75.5%)	57
10 yrs	**65.9%** (58.1%, 72.5%)	45
11 yrs	**62.6%** (53.9%, 70.2%)	31
12 yrs	**60.6%** (51.1%, 68.7%)	29
13 yrs	**57.9%** (47.3%, 67.0%)	21

Model 8711: Specifications

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

Model 8731: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8731
FDA Approval Date	Oct 2002
Catheters Enrolled	503
Catheters Currently Active in Study	71
Device Events	50
Cumulative Months of Follow-up	20,109

Model 8731: Event Summary Table

Catheter Event	Total
Catheter occlusion	19
Catheter dislodgement	19
Catheter kink	3
Catheter related complication[a]	3
Catheter break/cut	2
Catheter disconnection at pump	2
Device malfunction	1
Pump connector break/cut	1

Total Catheter Events	**50**

[a] Includes 1 event reported as patency issue with catheter, 1 coiled catheter, and 1 catheter malfunction.

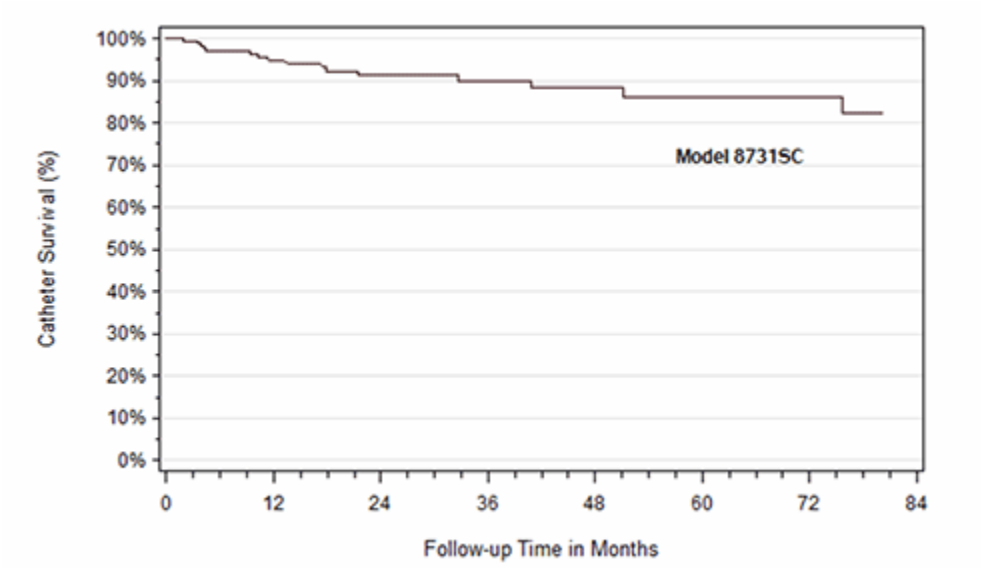
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**93.6%** (88.8%, 96.3%)	260
2 yrs	**92.3%** (87.5%, 95.3%)	302
3 yrs	**91.3%** (86.5%, 94.4%)	251
4 yrs	**89.3%** (84.3%, 92.8%)	193
5 yrs	**87.7%** (82.4%, 91.5%)	145
6 yrs	**82.3%** (76.1%, 87.0%)	129
7 yrs	**78.7%** (71.9%, 84.0%)	93
8 yrs	**76.0%** (68.6%, 81.8%)	71
9 yrs	**74.8%** (67.2%, 80.9%)	61
10 yrs	**74.8%** (67.2%, 80.9%)	48
11 yrs	**72.8%** (64.2%, 79.7%)	35
at 138 mo	**72.8%** (64.2%, 79.7%)	22

Model 8731: Specifications

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, with 6 side holes
Catheter Volume	2.22mL/cm
Trimmable Segments	Spinal end

Model 8731SC: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	222
Catheters Currently Active in Study	110
Device Events	16
Cumulative Months of Follow-up	5,786

Model 8731SC: Event Summary Table

Catheter Event	Total

Catheter occlusion	8
Catheter dislodgment	5
Catheter disconnection at pump	1
Catheter leakage	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**16**

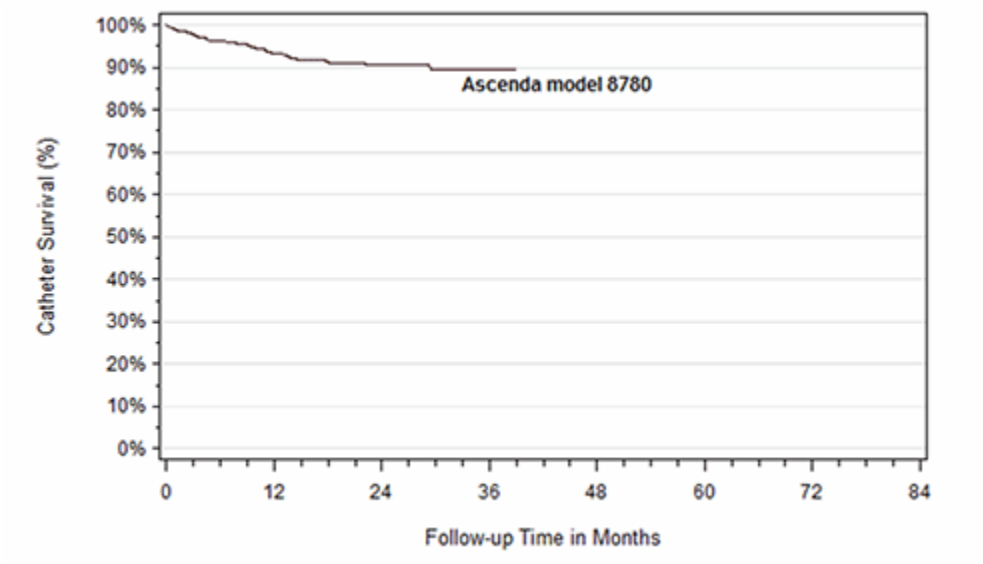
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.8%** (89.9%, 97.4%)	122
2 yrs	**91.3%** (85.0%, 95.0%)	87
3 yrs	**90.0%** (83.0%, 94.2%)	64
4 yrs	**88.3%** (80.4%, 93.2%)	42
5 yrs	**86.2%** (76.9%, 91.9%)	32
6 yrs	**86.2%** (76.9%, 91.9%)	21
at 81 mo	**82.2%** (68.9%, 90.2%)	23

Model 8731SC: Specifications

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 end

Model 8780: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8780
FDA Approval Date	Sept 2012
Catheters Enrolled	701
Catheters Currently Active in Study	500
Device Events	44
Cumulative Months of Follow-up	9,810

Model 8780: Event Summary Table	
Catheter Event	**Total**

Catheter occlusion	19
Catheter dislodgement	9
Catheter kink	8
Catheter break/cut	3
Catheter disconnection at pump	2
Catheter leakage	2
Catheter related complication[a]	1
Total Catheter Events	**44**

[a] Reported as unable to aspirate catheter.

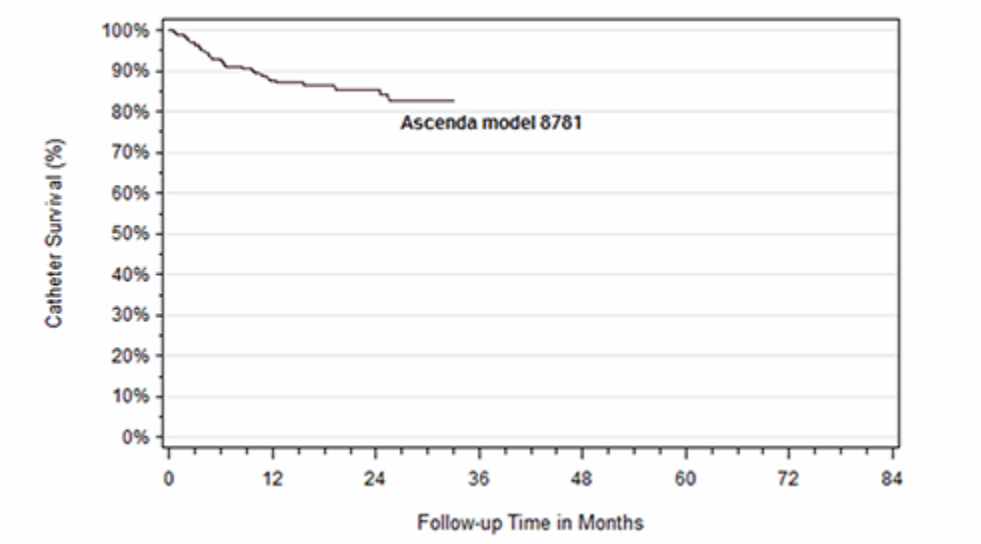
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**93.4%** (90.8%, 95.3%)	348
2 yrs	**90.5%** (87.1%, 93.0%)	172
3 yrs	**89.6%** (85.7%, 92.5%)	34
at 39 mo	**89.6%** (85.7%, 92.5%)	22

Model 8780: Specifications

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

Model 8781: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Number	8781
FDA Approval Date	Sept 2012
Catheters Enrolled	607
Catheters Currently Active in Study	346
Device Events	50
Cumulative Months of Follow-up	5,479

Model 8781: Event Summary Table

Catheter Event	Total
Catheter kink	21
Catheter dislodgement	14
Catheter occlusion	7
Catheter disconnection at pump	2
Catheter break/cut	1
Catheter leakage	1
Catheter related complication[a]	1

Device issue	1
Pump reservoir volume discrepancy	1
Pump underinfusion	1
Total Catheter Events	**50**

[a] Reported as possible catheter malfunction.

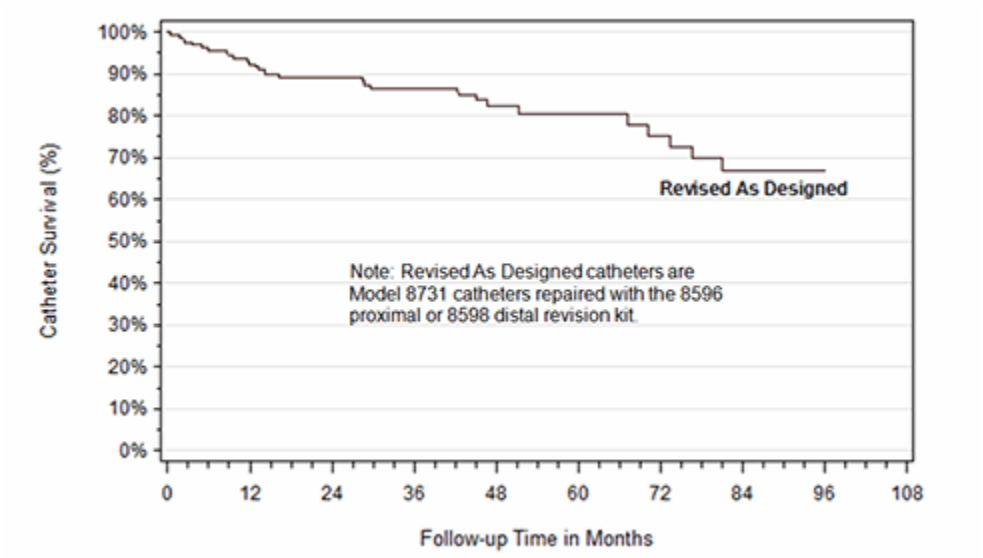
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**87.6%** (83.4%, 90.8%)	169
2 yrs	**85.5%** (80.5%, 89.3%)	60
at 33 mo	**82.5%** (75.8%, 87.5%)	28

Model 8781: Specifications

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

Revised As Designed Catheters: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Name	Revised As Designed
FDA Approval Date	Oct 2002
Catheters Enrolled	217
Catheters Currently Active in Study	75
Device Events	33
Cumulative Months of Follow-up	7,323

Revised As Designed Catheters: Event Summary Table

Catheter Event	Total
Catheter occlusion	14
Catheter dislodgement	8
Catheter kink	4
Catheter related complication[a]	3
Catheter break/cut	2
Device connection issue	1
Pump unable to enter/withdraw from catheter access port	1

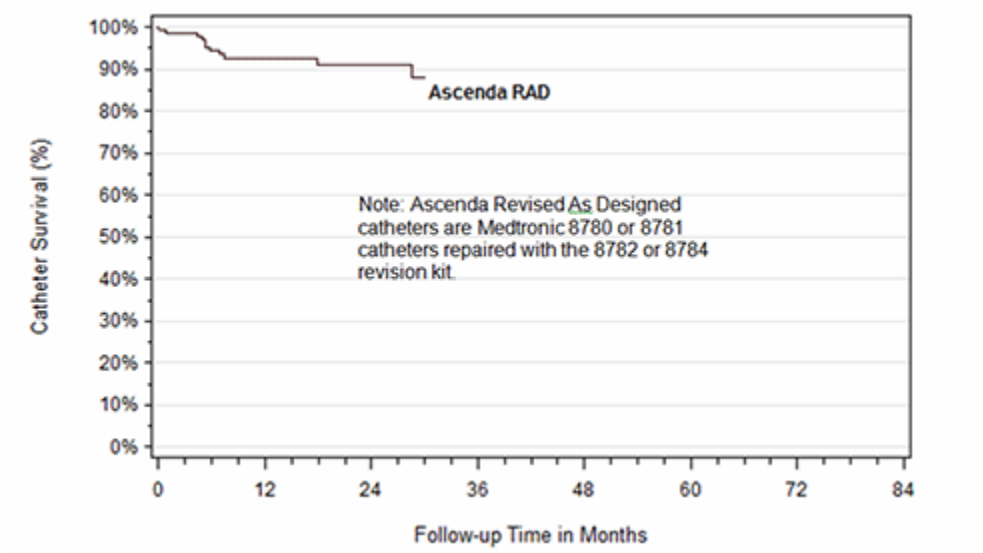
Total Catheter Events	**33**

[a] Includes 1 event reported as catheter malfunction, 1 possible catheter malfunction, and 1 inability to aspirate catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.3%** (86.8%, 95.5%)	144
2 yrs	**89.0%** (82.9%, 93.0%)	123
3 yrs	**86.5%** (79.8%, 91.1%)	78
4 yrs	**82.2%** (73.7%, 88.1%)	48
5 yrs	**80.4%** (71.2%, 86.9%)	37
6 yrs	**75.3%** (63.7%, 83.7%)	27
7 yrs	**67.0%** (52.8%, 77.8%)	22
8 yrs	**67.0%** (52.8%, 77.8%)	20

Ascenda Revised As Designed Catheters: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Name	Ascenda Revised As Designed
FDA Approval Date	Sept 2012
Catheters Enrolled	166
Catheters Currently Active in Study	118
Device Events	11
Cumulative Months of Follow-up	2,410

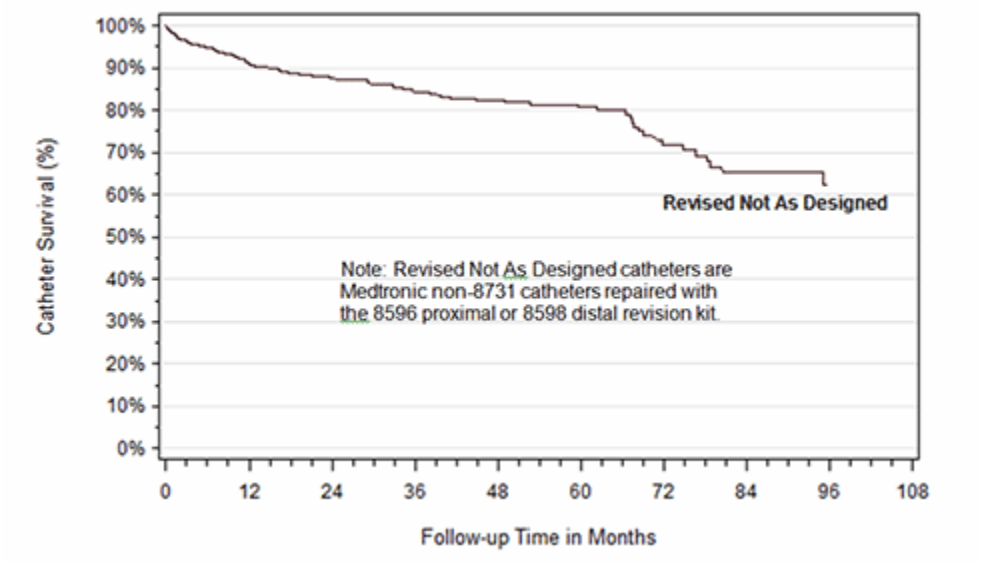
Ascenda Revised As Designed Catheters: Event Summary Table

Catheter Event	Total
Catheter occlusion	3
Catheter dislodgement	2
Catheter break/cut	1
Catheter disconnection at pump	1
Catheter kink	1
Catheter leakage	1
Pump connector break/cut	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**11**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.6%** (86.2%, 96.1%)	90
2 yrs	**91.1%** (83.7%, 95.2%)	41
at 30 mo	**88.1%** (77.5%, 93.9%)	23

Revised Not As Designed Catheters: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	645
Catheters Currently Active in Study	286
Device Events	95
Cumulative Months of Follow-up	20,944

Revised Not As Designed Catheters: Event Summary Table

Catheter Event	Total
Catheter occlusion	29
Catheter dislodgement	22
Catheter break/cut	14
Catheter kink	12
Catheter related complication[a]	5
Catheter disconnection at pump	4
Catheter leakage	3

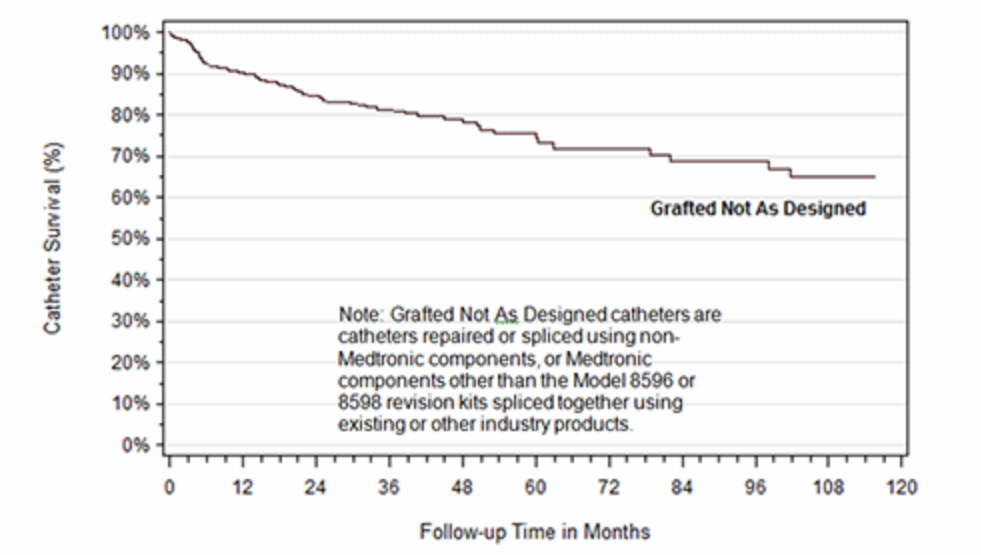
Pump unable to enter/withdraw from catheter access port	3
Catheter access port issue	1
Connector block problem	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**95**

[a] Includes 2 events reported as catheter malfunction, 1 inability to aspirate catheter, 1 poor CSF flow, and 1 catheter wrapped in coils and knots.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.0%** (88.1%, 93.2%)	441
2 yrs	**87.6%** (84.4%, 90.3%)	356
3 yrs	**84.2%** (80.4%, 87.3%)	263
4 yrs	**82.4%** (78.3%, 85.7%)	186
5 yrs	**80.7%** (76.2%, 84.4%)	115
6 yrs	**71.8%** (64.6%, 77.8%)	63
7 yrs	**65.2%** (56.4%, 72.7%)	37
8 yrs	**62.5%** (52.4%, 71.1%)	21

Grafted Not As Designed Catheters: Survival from Catheter Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Catheter Characteristics	
Model Name	Grafted Not As Designed
FDA Approval Date	NA
Catheters Enrolled	445
Catheters Currently Active in Study	180
Device Events	72
Cumulative Months of Follow-up	14,426

Grafted Not As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter dislodgement	25
Catheter occlusion	18
Catheter break/cut	10
Catheter leakage	4
Catheter related complication[a]	4
Catheter kink	3
Pump unable to enter/withdraw from catheter access port	3

Catheter access port issue	1
Catheter disconnection at pump	1
Device component issue[b]	1
Device malfunction	1
Pump connector break/cut	1
Total Catheter Events	**72**

[a] Includes 3 events reported as inability to aspirate catheter, and 1 catheter malfunction.
[b] Reported as broken anchor attributed to the catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**90.3%** (86.6%, 93.0%)	267
2 yrs	**84.5%** (79.9%, 88.1%)	207
3 yrs	**81.4%** (76.3%, 85.4%)	158
4 yrs	**78.2%** (72.5%, 82.9%)	97
5 yrs	**75.5%** (69.2%, 80.8%)	64
6 yrs	**71.9%** (64.5%, 78.1%)	47
7 yrs	**68.8%** (60.2%, 75.8%)	43
8 yrs	**68.8%** (60.2%, 75.8%)	37
9 yrs	**65.0%** (55.3%, 73.1%)	28
at 117 mo	**65.0%** (55.3%, 73.1%)	21

Catheter Survival Summary Table

Catheter Characteristics						
Model Number	Family	FDA Approval Date	Catheters Enrolled	Catheters Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
8709[b]	8709	May 1998	2,833	288	309	81,797
8709SC	8709	Mar 2006	1,036	291	115	32,258
8711	8711	Oct 1999	652	156	86	23,973
8731	8731	Oct 2002	503	71	50	20,109
8731SC	8731	Mar 2006	222	110	16	5,786
8780	Ascenda	Sept 2012	701	500	44	9,810
8781	Ascenda	Sept 2012	607	346	50	5,749
Revised As Designed	NA	Oct 2002	217	75	33	7,323
Ascenda Revised As Designed	NA	Sept 2012	166	118	11	2,410
Revised Not As Designed	NA	NA	645	286	95	20,944
Grafted Not As Designed	NA	NA	445	180	72	14,426

[a] There were a total of 1,064 catheter-related events reported to the registry, but only 881 events included in this summary table. The remaining catheter-related events either occurred in catheter models for which no device survival curves are presented due to an insufficient number of enrolled devices (n=22), or in catheters for which no model information was provided (n=22), or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models.

Device Survival Probability (95% Confidence Intervals) – *Table 1 of 3*					
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**
8709	**92.1%** (90.4%,	**89.4%** (87.4%,	**86.1%** (83.9%,	**83.2%** (80.8%,	**80.6%** (78.0%,

	93.5%)	91.1%)	88.0%)	85.3%)	82.9%)
8709SC	**93.9%** (92.0%, 95.4%)	**89.4%** (86.9%, 91.5%)	**87.1%** (84.3%, 89.4%)	**83.9%** (80.7%, 86.7%)	**82.2%** (78.6%, 85.2%)
8711	**92.5%** (88.9%, 94.9%)	**90.0%** (86.1%, 92.9%)	**84.9%** (80.4%, 88.4%)	**82.7%** (78.0%, 86.5%)	**81.6%** (76.7%, 85.5%)
8731	**93.6%** (88.8%, 96.3%)	**92.3%** (87.5%, 95.3%)	**91.3%** (86.5%, 94.4%)	**89.3%** (84.3%, 92.8%)	**87.7%** (82.4%, 91.5%)
8731SC	**94.8%** (89.9%, 97.4%)	**91.3%** (85.0%, 95.0%)	**90.0%** (83.0%, 94.2%)	**88.3%** (80.4%, 93.2%)	**86.2%** (76.9%, 91.9%)
8780	**93.4%** (90.8%, 95.3%)	**90.5%** (87.1%, 93.0%)	**89.6%** (85.7%, 92.5%)	**-**	**-**
8781	**87.6%** (83.4%, 90.8%)	**85.5%** (80.5%, 89.3%)	**-**	**-**	**-**
Revised As Designed	**92.3%** (86.8%, 95.5%)	**89.0%** (82.9%, 93.0%)	**86.5%** (79.8%, 91.1%)	**82.2%** (73.7%, 88.1%)	**80.4%** (71.2%, 86.9%)
Ascenda Revised As Designed	**92.6%** (86.2%, 96.1%)	**91.1%** (83.7%, 95.2%)	**-**	**-**	**-**
Revised Not As Designed	**91.0%** (88.1%, 93.2%)	**87.6%** (84.4%, 90.3%)	**84.2%** (80.4%, 87.3%)	**82.4%** (78.3%, 85.7%)	**80.7%** (76.2%, 84.4%)
Grafted Not As Designed	**90.3%** (86.6%, 93.0%)	**84.5%** (79.9%, 88.1%)	**81.4%** (76.3%, 85.4%)	**78.2%** (72.5%, 82.9%)	**75.5%** (69.2%, 80.8%)

Device Survival Probability (95% Confidence Intervals) – *Table 2 of 3*

Model Number	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs
8709	**76.0%** (73.1%, 78.6%)	**71.3%** (68.2%, 74.2%)	**68.9%** (65.6%, 72.0%)	**67.4%** (63.9%, 70.6%)	**65.2%** (61.5%, 68.7%)

8709SC	**81.1%** (77.2%, 82.2%)	**76.4%** (71.0%, 81.0%)	**76.4%** (71.0%, 81.0%)	-	-
8711	**77.7%** (72.3%, 82.2%)	**74.1%** (68.3%, 79.1%)	**71.7%** (65.5%, 76.9%)	**69.8%** (63.2%, 75.5%)	**65.9%** (58.1%, 72.5%)
8731	**82.3%** (76.1%, 87.0%)	**78.7%** (71.9%, 84.0%)	**76.0%** (68.6%, 81.8%)	**74.8%** (67.2%, 80.9%)	**74.8%** (67.2%, 80.9%)
8731SC	**86.2%** (76.9%, 91.9%)	-	-	-	-
8780	-	-	-	-	-
8781	-	-	-	-	-
Revised As Designed	**75.3%** (63.7%, 83.7%)	**67.0%** (52.8%, 77.8%)	**67.0%** (52.8%, 77.8%)	-	-
Ascenda Revised As Designed	-	-	-	-	-
Revised Not As Designed	**71.8%** (64.6%, 77.8%)	**65.2%** (56.4%, 72.7%)	**62.5%** (52.4%, 71.1%)	-	-
Grafted Not As Designed	**71.9%** (64.5%, 78.1%)	**68.8%** (60.2%, 75.8%)	**68.8%** (60.2%, 75.8%)	**65.0%** (55.3%, 73.1%)	-

Device Survival Probability (95% Confidence Intervals) – *Table 3 of 3*

Model Number	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs
8709	**62.7%** (58.6%, 66.5%)	**60.1%** (55.5%, 64.3%)	**57.7%** (52.5%, 62.5%)	**57.7%** (52.5%, 62.5%)	**55.7%** (49.4%, 61.6%)
8709SC	-	-	-	-	-
8711	**62.6%** (53.9%, 70.2%)	**60.6%** (51.1%, 68.7%)	**57.9%** (47.3%, 67.0%)	-	-
8731	**72.8%** (64.2%,	-	-	-	-

	79.7%)				
8731SC	-	-	-	-	-
8780	-	-	-	-	-
8781	-	-	-	-	-
Revised As Designed	-	-	-	-	-
Ascenda Revised As Designed	-	-	-	-	-
Revised Not As Designed	-	-	-	-	-
Grafted Not As Designed	-	-	-	-	-

2016 Medtronic Product Performance Report: Data through July 31, 2016.

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Percutaneous Tibial Neuromodulation
- Targeted Drug Delivery for Chronic Pain
- Sacral Neuromodulation
- Spinal Cord Stimulation

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- Research Proposal Contacts and Guidelines
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Spinal Cord Stimulation Systems

- Study Participants
- Event Summary
- Spinal Cord Neurostimulators
- Leads
- Extensions

Study Participants

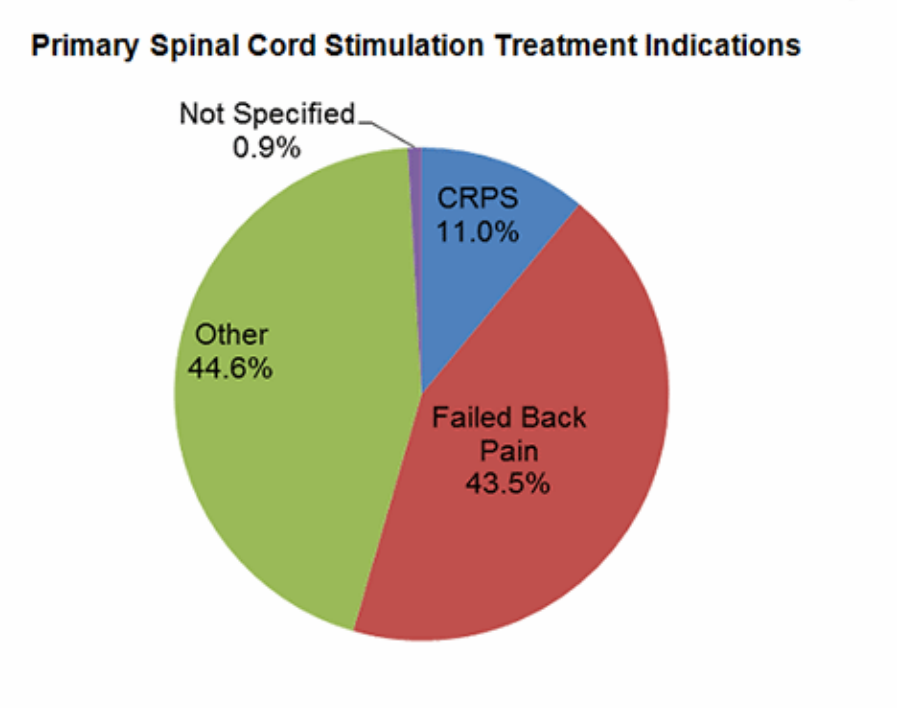
Centers

The following spinal cord stimulation tables and graphs were generated based on data collected between June 2004 and the report cut-off date of July 31, 2016. Seventy-five centers enrolled and contributed patients.

Patients

Of the 4,286 total spinal cord stimulation patients enrolled, 44.6% were implanted for the treatment of “other” pain indications, 43.5% were implanted for the treatment of failed back pain, 11.0% were implanted for the treatment of complex regional pain syndrome (CRPS), and 0.9% were implanted for indications that were not specified in the database.

Primary SCS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Other	**1,912 (44.6%)**
Other chronic pain	765 (17.8%)
Radicular pain syndrome	597 (13.9%)
Other	261 (6.1%)
Degenerative disc disease	168 (3.9%)
Cervical pain	35 (0.8%)
Traumatic nerve injury	31 (0.7%)
Diabetic neuropathy	25 (0.6%)
Post herpetic neuralgia	11 (0.3%)
Facial pain	6 (0.1%)
Angina	4 (0.1%)
Epidural fibrosis	4 (0.1%)
Post herniorrhaphy pain	3 (0.1%)

Chronic cluster headache	2 (<0.1%)
Failed Back Pain	**1,863 (43.5%)**
Postlaminectomy pain	750 (17.5%)
Failed Back Syndrome (FBS)	625 (14.6%)
Combination back and leg pain	376 (8.8%)
Multiple back operations	83 (1.9%)
Arachnoiditis	21 (0.5%)
Unsuccessful disc surgery	8 (0.2%)
CRPS	**472 (11.0%)**
CRPS I	361 (8.4%)
CRPS II	111 (2.6%)
Not Specified	**39 (0.9%)**
Total Patients	**4,286**

[a] Refer to product labeling for approved indications.

Event Summary

There were 2,755 events reported between June 2004 and July 31, 2016 in patients with spinal cord stimulation systems. Over thirty-seven percent of these events (1,034/2,755) were categorized as product performance-related and are presented within this report. The 1,034 product performance events occurred in 490 of the 4,286 total patients (11.4%) enrolled. In addition, there were 1,721 non-product performance events. There were also 123 deaths reported for patients with spinal cord stimulation systems, 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. The event tables provided below include combined data from these versions of the protocol.

Spinal Cord Stimulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event[b]	Percent of Patients with Event (n=4,286)
Lead migration/dislodgement	505	264	6.2%

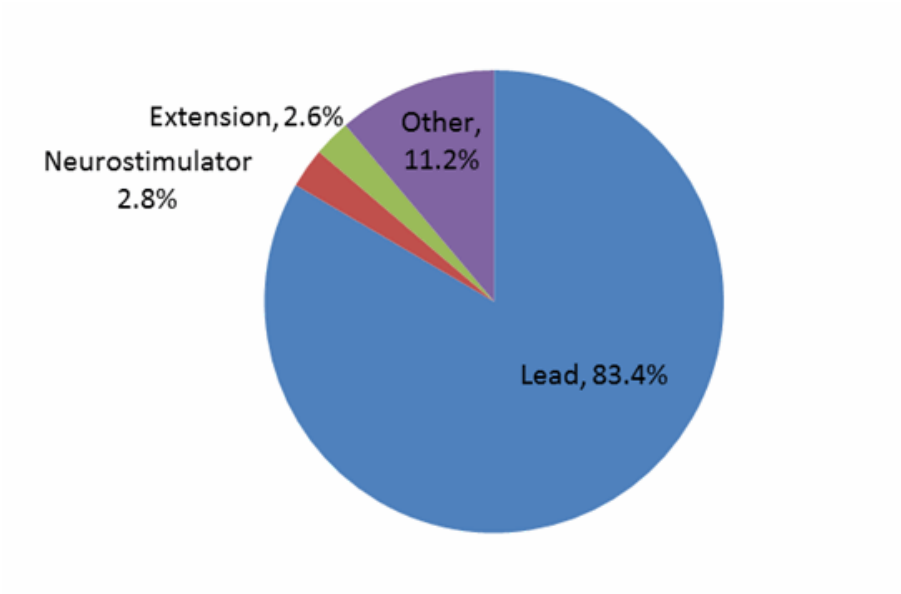
Spinal Cord Stimulation System Product Performance Events			
High impedance	226	107	2.5%
Lead fracture	64	41	1.0%
Device stimulation issue[c]	47	26	0.6%
Low impedance	37	13	0.3%
Neurostimulator unable to recharge[d]	34	32	0.8%
Device malfunction[e]	24	22	0.5%
Medical device complication[f]	17	12	0.3%
Extension fracture	15	10	0.2%
Device breakage[g]	13	13	0.3%
Device lead damage	7	5	0.1%
Device connection issue	5	3	0.1%
Extension migration	5	3	0.1%
Device failure[h]	4	3	0.1%
Device telemetry issue	4	4	0.1%
Impedance increased	4	3	0.1%
Battery recharge issue[d]	3	3	0.1%
Device battery issue	3	3	0.1%
Device issue	3	3	0.1%
Device component issue[i]	2	2	0.1%
Inadequate lead connection	2	1	<0.1%

Spinal Cord Stimulation System Product Performance Events			
Paraesthesia[j]	2	2	0.1%
Therapeutic product ineffective	2	1	<0.1%
Antenna cable breakage	1	1	<0.1%
Broken bond wire	1	1	<0.1%
Device electrical impedance issue	1	1	<0.1%
Device kink	1	1	<0.1%
Device lead issue	1	1	<0.1%
Not Coded[k]	1	1	<0.1%
Totals	**1,034**	**490**	**11.4%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[b] The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[c] Device stimulation issue reported by physician as being caused by neurostimulator (n=2) or lead (n=45).
[d] There were a total of 2,671 patients that used rechargeable SCS neurostimulators in the registry. A total of 1.3% (35/2,671) of patients with a rechargeable SCS neurostimulator experienced a neurostimulator unable to recharge or battery recharge issue product performance event.
[e] Includes 5 charger malfunctions, 4 patient programmer malfunctions, 3 antenna malfunctions, 2 neurostimulator malfunctions, 2 events for impedance not measurable, 2 events for non-functional lead electrodes, 1 event for lead impedance changes, 1 event for error message on programmer, 1 inability to turn neurostimulator on, 1 suspected device malfunction, 1 recharging cable malfunction, and 1 event for neurostimulator stopped working abruptly.
[f] Includes 4 leads no longer providing stimulation, 4 error messages on patient programmer, 2 events reported as unable to pass stylet into lead, 2 leads with open circuits, 1 loose anchor, 1 hybrid anomaly, 1 unknown problem with extension, 1 defective patient programmer, 1 excessive heating of charging unit.
[g] Includes 6 broken charger belts, 1 broken antenna, 1 broken antenna and jack, 1 broken charger, 1 broken patient programmer, 1 frayed cord to charger antenna, 1 broken charger cord, and 1 frayed wire to charger.
[h] Includes 2 events for lead failure, 1 event for failure of lead electrodes, and 1 extension failure.
[i] Includes 1 event for damaged antenna cord, and 1 faulty antenna.
[j] Includes 1 event for shocking sensation at battery site and 1 shocking sensation at battery/extension connection.
[k] Event that had not been MedDRA-coded at the time of the report cut-off.

A total of 862 (83.4%) of the 1,034 product performance events were related to the lead, 46 (4.4%) were related to "other device", 38 (3.7%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 29 (2.8%) were related to the neurostimulator, 27 (2.6%) were related to the extension, 19 (1.8%) were related to the recharging process, 6 (0.6%) were related to programming/stimulation, 3 (0.3%) were related to "other" etiology, 2 (0.2%) were related to the incisional site/device tract, and 2 (0.2%) were related to surgery/anesthesia. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a]Each event could have more than one etiology.

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Device issues	**550**
Device stimulation issue[c]	295
Battery recharge issue[d]	64
Neurostimulator unable to recharge[e]	64
Device battery issue[f]	27
Neurostimulator migration	27
Neurostimulator inversion	19
Device use error	13
Device difficult to use	8
Device malfunction[g]	7
Device extrusion	5

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other[h]	21
Therapeutic and nontherapeutic effects (excluding toxicity)	**394**
Therapeutic product ineffective	182
Therapeutic response decreased	149
No therapeutic response	58
Other[h]	5
Administration site reactions	**249**
Implant site pain	172
Implant site erythema	18
Implant site extravasation	17
Implant site erosion	13
Other[h]	29
Infections - pathogen unspecified	**137**
Implant site infection	74
Device related infection	22
Infection	18
Wound infection	11
Incision site infection	7
Other[h]	5
General system disorders Not Elsewhere Classified (NEC)	**116**
Pain	87
No anomaly found by RPA[i]	19

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other[h]	10
Procedural related injuries and complications NEC	**63**
Incision site erythema	12
Incision site pain	10
Wound dehiscence	10
Seroma	6
Suture related complication	5
Other[h]	20
Neurological disorders NEC	**45**
Paraesthesia	27
Other[h]	18
Musculoskeletal and connective tissue disorders NEC	**44**
Pain in extremity	21
Back pain	17
Other[h]	6
Complications associated with device	**23**
Medical device discomfort	18
Other[h]	5
Spinal cord and nerve root disorders	**15**
Radiculopathy	14
Other[h]	1
Headaches	**10**

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Headache	9
Other[h]	1
Muscle disorders	**9**
Muscle spasms	6
Other[h]	3
Tissue disorders NEC	**8**
Impaired healing	8
Other[h]	**58**
Total	**1,721**

[a] Adverse events associated with product performance events are not included in this table. Related adverse and device events reported on a single event form are represented individually in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms.
[c] Event reported by the physician with an etiology that was either not device related or had no associated device event.
[d] Events reported as recharge issues not due to a device malfunction.
[e] Patients with these events were unable to recharge due to an issue not related to the device.
[f] Events reported as battery discharge or depletion not due to a device malfunction.
[g] Events were device issues due to patient use or other non-device defect etiology.
[h] Composed of event codes with fewer than 5 events each.
[i] For products that are returned with a suspected device issue, and RPA establishes a root cause or finds no anomaly, results reported herein reflect the finding from Returned Product Analysis (RPA).

There were 123 deaths reported for patients with spinal cord stimulation systems. None of these deaths were reported as a direct result of a product performance event. As indicated, 62 (50.4%) of the deaths occurred in patients receiving therapy for pain indications in the "other" category, 51 (41.5%) for failed back, and 10 (8.1%) for CRPS.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Other	62 (50.4%)
Failed Back	51 (41.5%)
CRPS	10 (8.1%)
Total	**123 (100%)**

[a] Refer to product labeling for approved indications

Spinal Cord Neurostimulators

From June 2004 to the report cut-off date of July 31, 2016, 4,731 spinal cord neurostimulators were followed in the registry. The difference between the total number of patients (N=4,286) versus neurostimulators is due to the fact that some patients had multiple neurostimulators or were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord neurostimulators was 81,755 months (6,813 years). The table below provides the number and percentage of spinal cord neurostimulators by model.

Spinal Cord Neurostimulators by Model	
Model	**Number of Neurostimulators (%)**
RestoreSensor SureScan MRI (97714)	936 (19.8%)
PrimeAdvanced (37702)	671 (14.2%)
RestoreSensor (37714)	376 (7.9%)
RestoreAdvanced (37713)	357 (7.5%)
PrimeAdvanced SureScan MRI (97702)	421 (8.9%)
RestoreAdvanced SureScan MRI (97713)	99 (2.1%)
Itrel 4 (37703)	74 (1.6%)
RestoreUltra SureScan MRI (97712)	57 (1.2%)
Other/Unspecified	19 (0.4%)
Neurostimulators No Longer Manufactured	
RestoreUltra (37712)	581 (12.3%)
Synergy (7427)	461 (9.7%)
Restore (37711)	448 (9.5%)
Itrel 3 (7425)	97 (2.1%)
RestorePrime (37701)	57 (1.2%)
Synergy Versitrel (7427V)	53 (1.1%)
Synergy Plus (7479)	16 (0.3%)
Synergy Compact (7479B)	8 (0.2%)
Total	**4,731 (100%)**

Neurostimulator Events

There were 37 product performance-related events with an underlying reported etiology related to spinal cord neurostimulator function. This includes 29 events with a neurostimulator etiology and 8 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 31 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 274/1,118 (25%). The proportion was based upon the number of registry spinal cord neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of neurostimulators in patients who have expired. One of the 37 spinal cord neurostimulator events was confirmed by Medtronic RPA as a broken bond wire. The neurostimulators with the remaining 36 performance-related events were not returned to Medtronic RPA and the events were assigned as device related by the physician. These events included: neurostimulator unable to recharge (n=9), high impedance (n=5), device battery issue (n=3), device malfunction (n=3), lead migration/dislodgement (n=3), medical device complication (n=3), battery recharge issue (n=2), device issue (n=2), device stimulation issue (n=2), device connection issue (n=1), device telemetry issue (n=1), extension migration (n=1), and low impedance (n=1).

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 non-product performance-related or 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 spinal cord neurostimulators:

- 31 had follow-up time cut-off due to product performance-related events.
- 3,092 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, site termination, patient discontinued, other neurostimulator modification, therapy suspended, or non-product performance neurostimulator-related event without an associated intervention.
- 1,608 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

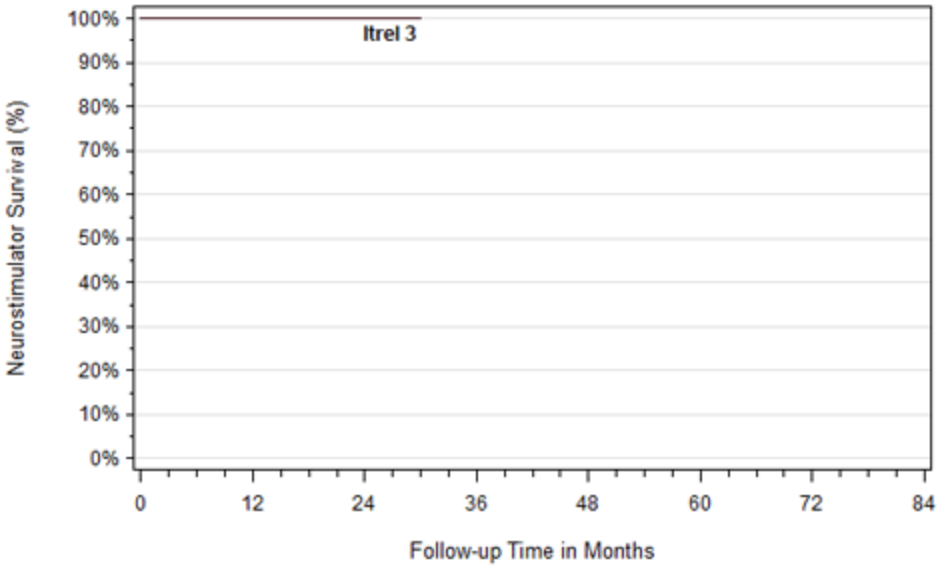
Neurostimulator Survival

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

Choose a model Go

Model 7425 Itrel 3: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	97
Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	1,425

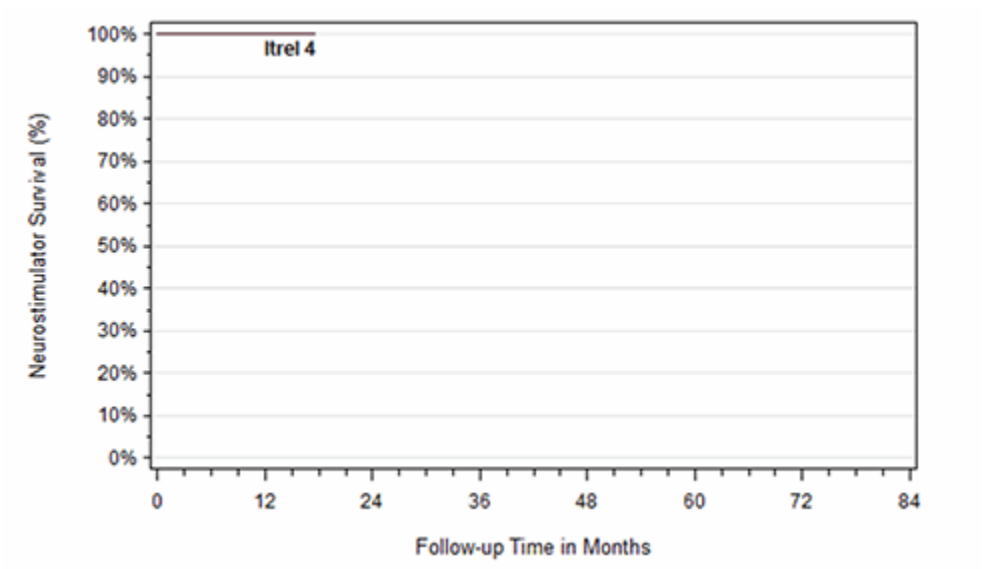
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	35
2 yrs	**100.0%** (NA)	26
at 30 mo	**100.0%** (NA)	22

Model 7425 Itrel 3: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

Model 37703 Itrel 4: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics

Model Name	Itrel 4
FDA Approval Date	May 2012
Neurostimulators Enrolled	74
Neurostimulators Currently Active in Study	64
Device Events	0
Cumulative Months of Follow-up	795

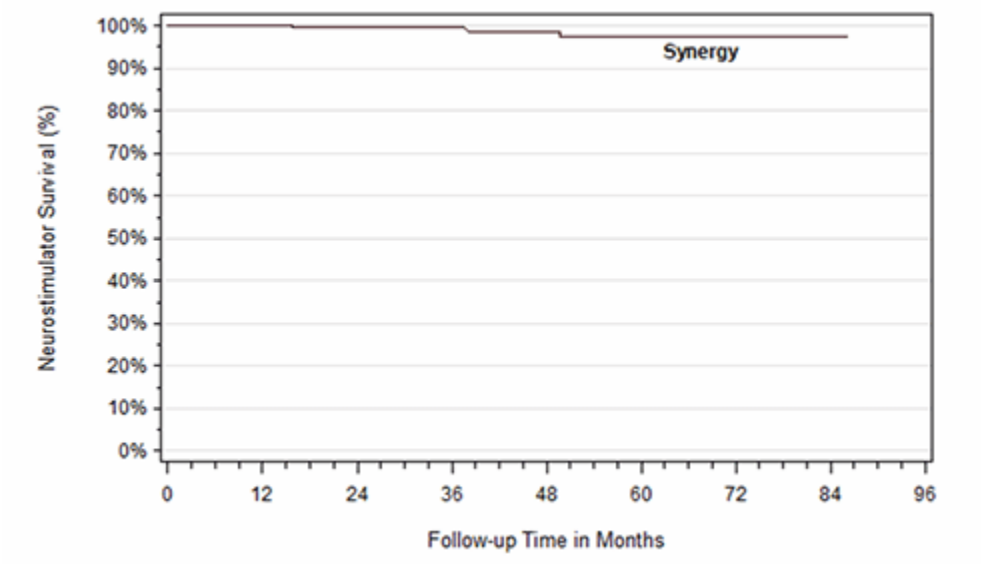
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	37
at 18 mo	**100.0%** (NA)	21

Model 37703 Itrel 4: Specifications

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 (additional Information)
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

Model 7427 Synergy: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	461
Neurostimulators Currently Active in Study	9
Device Events	3
Cumulative Months of Follow-up	9,396

Model 7427 Synergy: Event Summary Table

Neurostimulator Event	Total
Broken bond wire	1
Device stimulation issue	1
Device connection issue	1
Total Neurostimulator Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	208

2 yrs	**99.5%** (96.6%, 99.9%)	176
3 yrs	**99.5%** (96.6%, 99.9%)	119
4 yrs	**98.6%** (94.4%, 99.7%)	79
5 yrs	**97.3%** (91.4%, 99.2%)	44
6 yrs	**97.3%** (91.4%, 99.2%)	32
7 yrs	**97.3%** (91.4%, 99.2%)	21
at 87 mo	**97.3%** (91.4%, 99.2%)	20

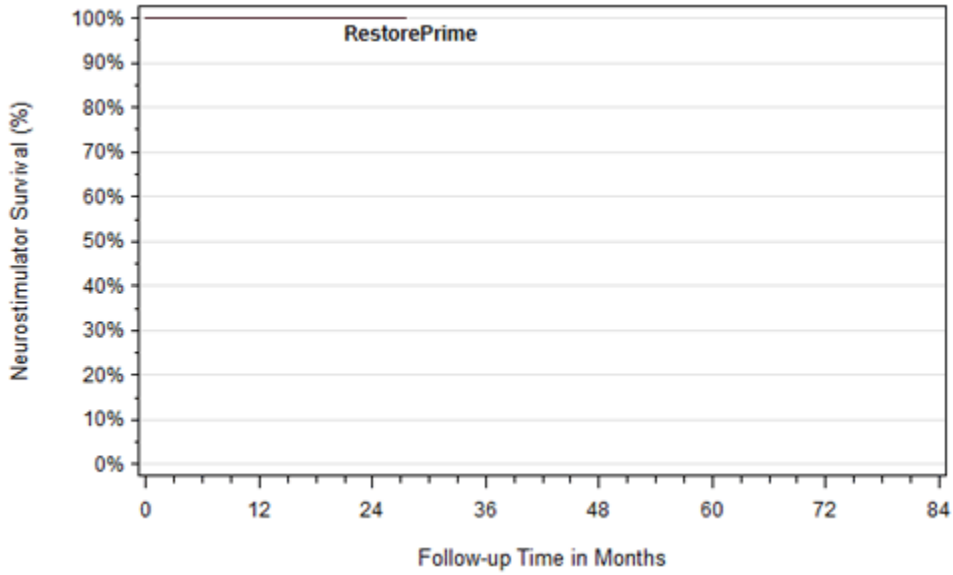
Model 7427 Synergy: Specifications

Height	2.4 in (61 mm)
Width	3.0 in (76 mm)
Thickness	0.6 in (15 mm)
Volume	51 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	8
Amplitude	0 - 10.5 V
Rate	3 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	1
Programs	2

Implant Depth	≤ 4 cm

Model 37701 RestorePrime: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	57
Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	1,249

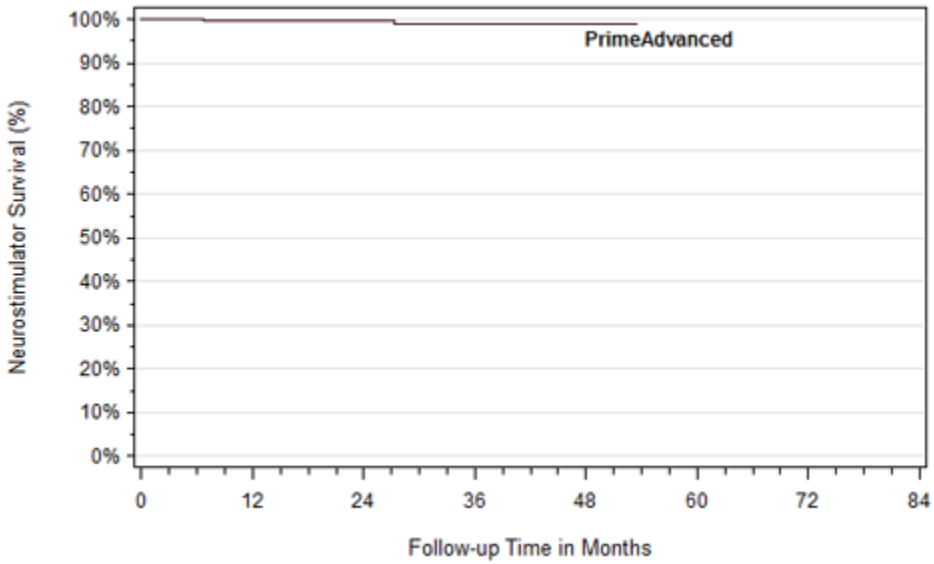
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	38
2 yrs	**100.0%** (NA)	23
at 27 mo	**100.0%** (NA)	21

Model 37701 RestorePrime: Specifications

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 (additional Information)
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	4
Implant Depth	≤ 4 cm

Model 37702 PrimeAdvanced: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	671
Neurostimulators Currently Active in Study	103
Device Events	4
Cumulative Months of Follow-up	12,149

Model 37702 PrimeAdvanced: Event Summary Table

Neurostimulator Event	Total
Device battery issue	1
Device stimulation issue	1
High impedance	1
Low impedance	1
Total Neurostimulator Events	**4**

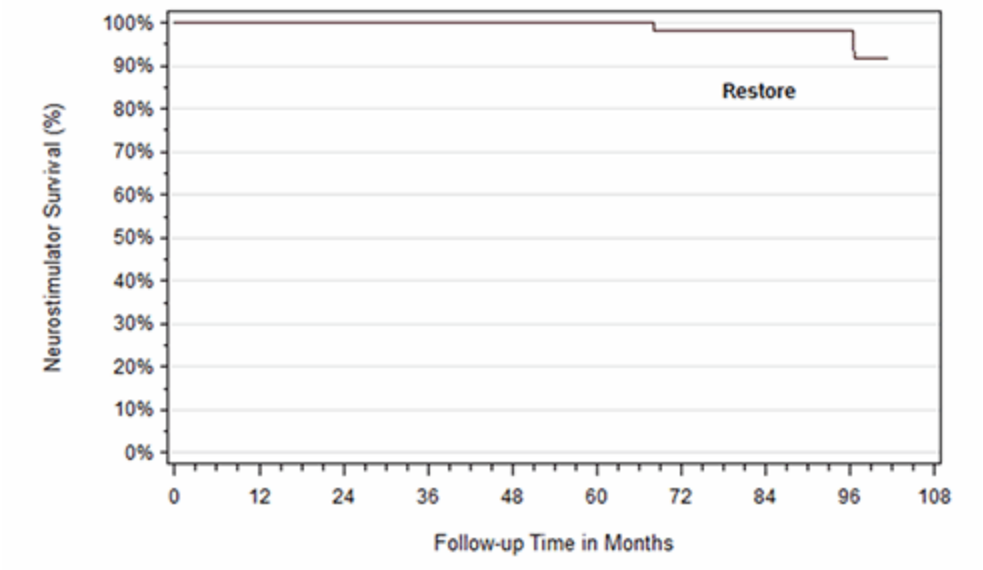
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.8%** (98.5%,100.0%)	366
2 yrs	**99.5%** (97.9%,99.9%)	201
3 yrs	**98.9%** (96.1%,99.7%)	95
4 yrs	**98.9%** (96.1%,99.7%)	47
5 yrs	**98.9%** (96.1%,99.7%)	22

Model 37702 PrimeAdvanced: Specifications

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 (additional Information)
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

Model 37711 Restore: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics

Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	448
Neurostimulators Currently Active in Study	13
Device Events	4
Cumulative Months of Follow-up	12,959

Model 37711 Restore: Event Summary Table

Neurostimulator Event	**Total**
Neurostimulator unable to recharge	2
Battery recharge issue	1
Device malfunction[a]	1
Total Neurostimulator Events	**4**

[a]Reported as suspected device malfunction.

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	**100.0%** (NA)	278
2 yrs	**100.0%** (NA)	221
3 yrs	**100.0%** (NA)	144
4 yrs	**100.0%** (NA)	91
5 yrs	**100.0%** (NA)	71
6 yrs	**98.3%** (88.5%, 99.8%)	53
7 yrs	**98.3%** (88.5%, 99.8%)	41
8 yrs	**98.3%**	29

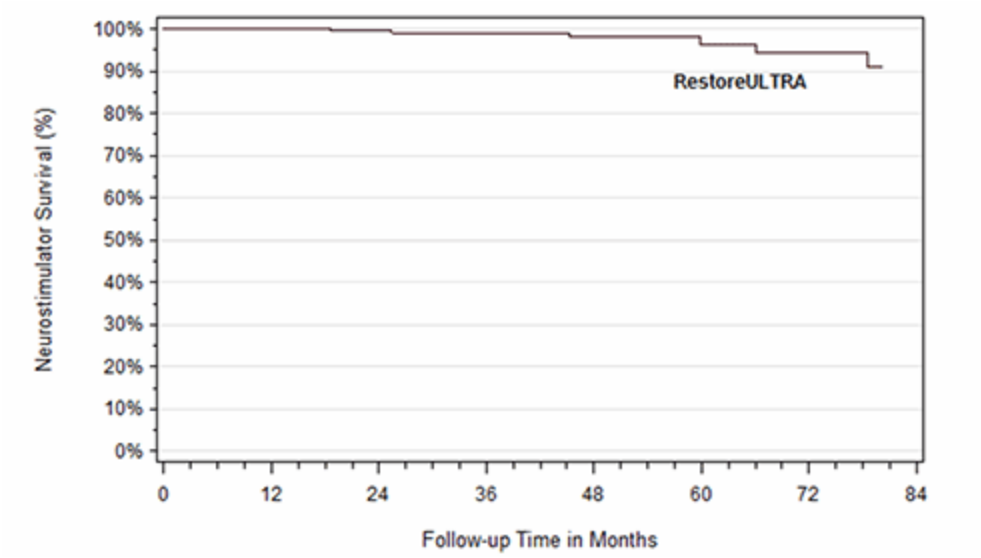
	(88.5%, 99.8%)	
at 102 mo	**91.6%** (75.3%, 97.3%)	24

Model 37711 Restore: Specifications

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

Model 37712 RestoreUltra: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	581
Neurostimulators Currently Active in Study	65
Device Events	7
Cumulative Months of Follow-up	13,240

Model 37712 RestoreUltra: Event Summary Table

Neurostimulator Event	Total
Neurostimulator unable to recharge	3
Device battery issue	1
Device issue	1
Device malfunction[a]	1
Medical device complication[b]	1
Total Neurostimulator Events	**7**

[a] Reported as malfunction of the spinal cord stimulation system.
[b]Reported as error message on patient programmer.

Time Interval	Survival	Sample Size

	(95% Confidence Interval)	
1 yr	**100%** (NA)	334
2 yrs	**99.6%** (97.2%, 99.9%)	195
3 yrs	**99.1%** (96.3%, 99.8%)	130
4 yrs	**98.1%** (93.6%, 99.4%)	88
5 yrs	**96.4%** (89.4%, 98.8%)	58
6 yrs	**94.4%** (85.3%, 97.9%)	31
at 81 mo	**91.0%** (77.6%, 96.5%)	21

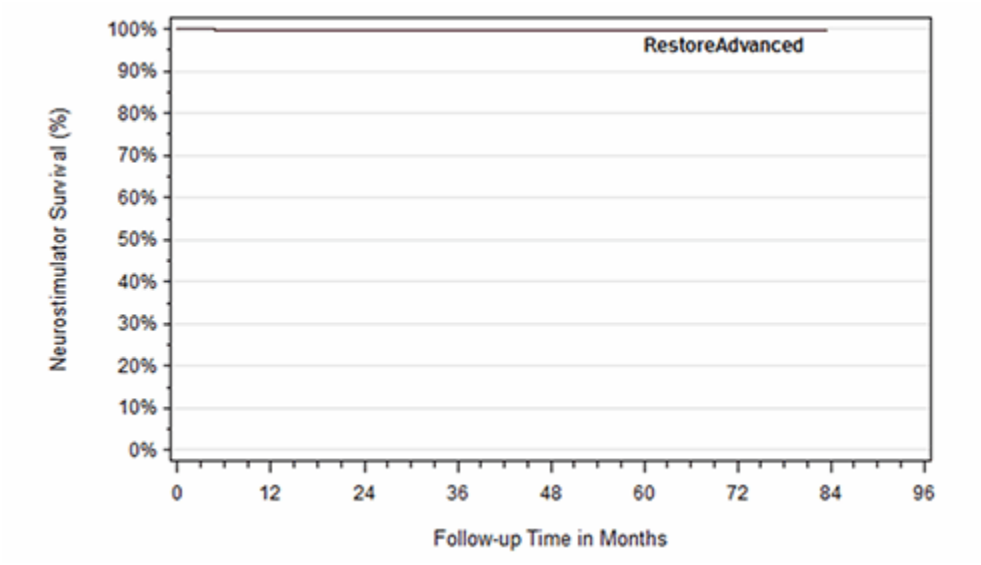
Model 37712 RestoreUltra: Specifications

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

Model 37713 RestoreAdvanced: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	357
Neurostimulators Currently Active in Study	53
Device Events	1
Cumulative Months of Follow-up	9,479

Model 37713 RestoreAdvanced: Event Summary Table

Neurostimulator Event	Total
Medical device complication[a]	1
Total Neurostimulator Events	**1**

[a] Reported as simulation therapy did not meet patient's expectations.

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	**99.6%** (97.5%, 99.9%)	224
2 yrs	**99.6%** (97.5%, 99.9%)	155
3 yrs	**99.6%** (97.5%, 99.9%)	95
4 yrs	**99.6%** (97.5%, 99.9%)	60
5 yrs	**99.6%** (97.5%, 99.9%)	44
6 yrs	**99.6%** (97.5%, 99.9%)	32
7 yrs	**99.6%** (97.5%, 99.9%)	21

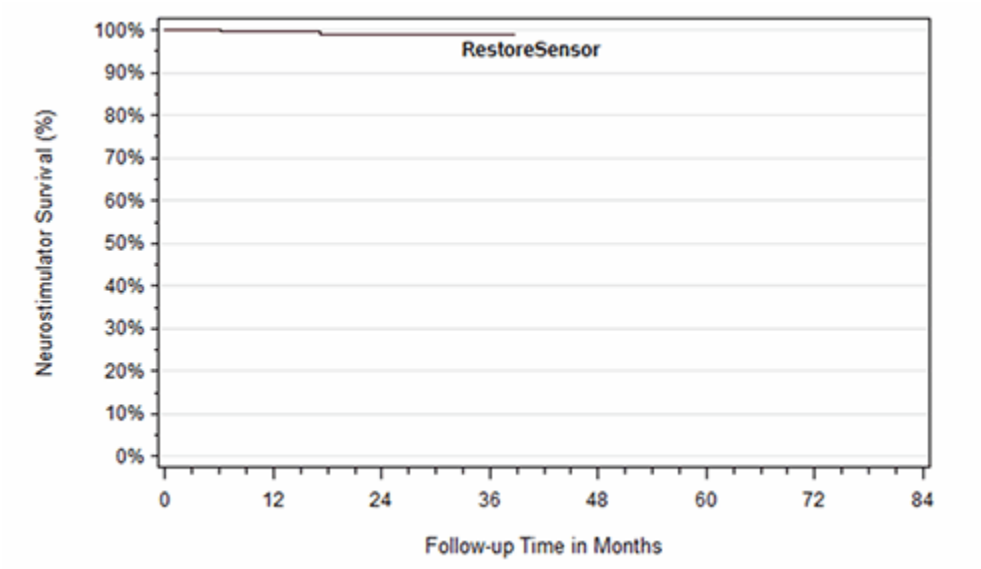
Model 37713 RestoreAdvanced: Specifications

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

Model 37714 RestoreSensor: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011
Neurostimulators Enrolled	376
Neurostimulators Currently Active in Study	197
Device Events	2
Cumulative Months of Follow-up	6,437

Model 37714 RestoreSensor: Event Summary Table

Neurostimulator Event	Total
Battery recharge issue	1
Neurostimulator unable to recharge	1
Total Neurostimulator Events	**2**

Time Interval	Survival (95% Confidence Interval)	Sample Size

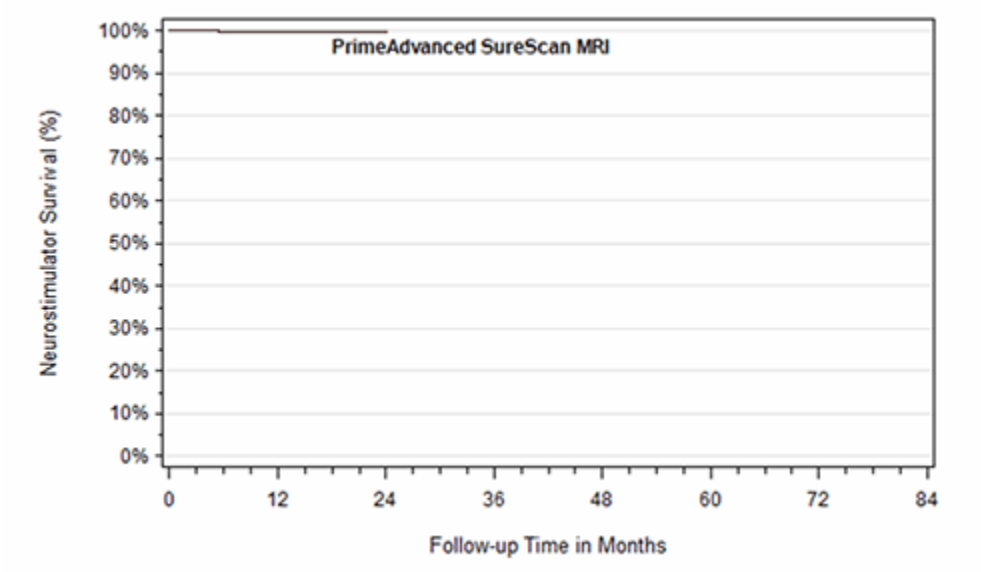
1 yr	99.6% (97.4%, 99.9%)	216
2 yrs	99.1% (96.1%, 99.8%)	119
3 yrs	99.1% (96.1%, 99.8%)	40
at 39 mo	99.1% (96.1%, 99.8%)	23

Model 37714 RestoreSensor: Specifications

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

Model 97702 PrimeAdvanced SureScan MRI: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Spinal Cord Neurostimulator Characteristics	
Model Name	PrimeAdvanced SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	421
Neurostimulators Currently Active in Study	326
Device Events	1
Cumulative Months of Follow-up	3,625

Model 97702 PrimeAdvanced SureScan MRI: Event Summary Table

Neurostimulator Event	Total
Device battery issue	1
Total Neurostimulator Events	**1**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.6% (97.0%, 99.9%)	132
2 yrs	99.6% (97.0%, 99.9%)	29

Model 97702 PrimeAdvanced SureScan MRI: Specifications

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 (additional Information)
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

Model 97712 RestoreUltra SureScan MRI: Survival from Spinal Cord Neurostimulator Events

Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreUltra SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	57
Neurostimulators Currently Active in Study	43
Device Events	0
Cumulative Months of Follow-up	405

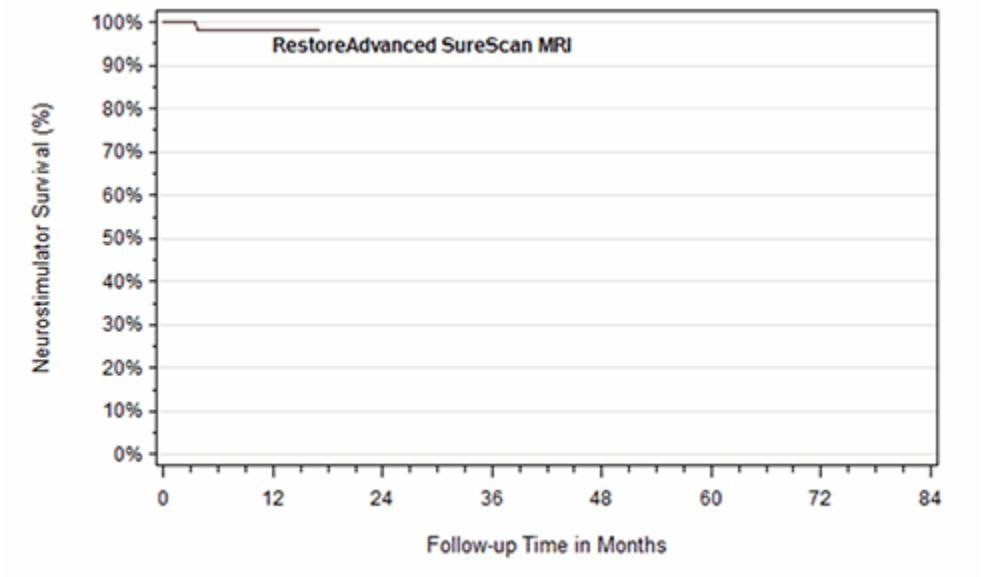
Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	100% (NA)	26

Model 97712 RESTOREULTRA SURESCAN MRI: Specifications

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

Model 97713 RestoreAdvanced SureScan MRI: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreAdvanced SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	99
Neurostimulators Currently Active in Study	76
Device Events	1
Cumulative Months of Follow-up	869

Model 97713 RestoreAdvanced SureScan MRI: Event Summary Table

Neurostimulator Event	Total
Device malfunction[a]	1
Total Neurostimulator Events	**1**

[a]Reported as malfunction of spinal cord neurostimulator.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	98.2% (88.1%, 99.7%)	33
at 18 mo	98.2% (88.1%, 99.7%)	20

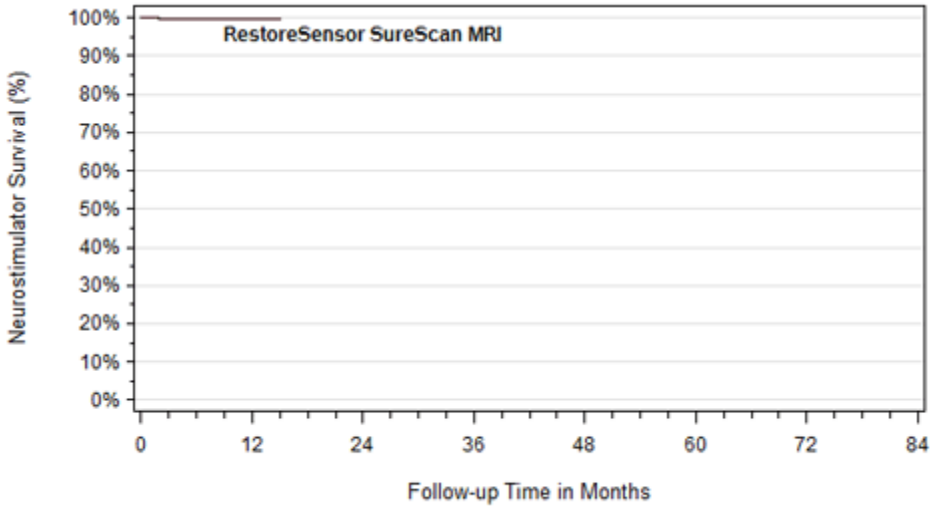
Model 97713 RestoreAdvanced Surescan MRI: Specifications

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

Model 97714 RestoreSensor SureScan MRI: Survival from Spinal Cord Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreSensor SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	936
Neurostimulators Currently Active in Study	720
Device Events	6
Cumulative Months of Follow-up	8,127

Model 97714 RestoreSensor SureScan MRI: Event Summary Table

Neurostimulator Event	Total
Lead migration/dislodgement	3
Device telemetry issue	1
High impedance	1
Neurostimulator unable to recharge	1
Total Neurostimulator Events	**6**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.2% (98.0%, 99.7%)	297
2 yrs	99.2% (98.0%, 99.7%)	54
at 27 mo	99.2% (98.0%, 99.7%)	26

Model 97714 RestoreSensor SureScan MRI: Specifications

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 msec
Groups	8

Programs	16
Implant Depth	≤ 1 cm

Spinal Cord Stimulator Survival Summary

Spinal Cord Neurostimulator Survival Summary Table

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
Primary Cell Neurostimulators						
Itrel 3	Itrel 3	Aug 1995	97	1	0	1,425
Itrel 4	Itrel 4	May 2012	74	64	0	795
Synergy	Synergy	Nov 1999	461	9	3	9,396
Restore Prime	Restore	Mar 2006	57	1	0	1,249
Prime Advanced	Prime Advanced	Jul 2006	671	103	4	12,149
Prime Advanced SureScan MRI	Prime Advanced	Mar 2013	421	326	1	3,625
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	448	13	4	12,959
Restore Ultra	Restore	Jan 2008	581	65	7	13,240
Restore Advanced	Restore	Jul 2006	357	53	1	9,479
Restore Sensor	Restore	Nov 2011	376	197	2	6,437
Restore Ultra	Restore	Mar 2013	57	43	0	405

SureScan MRI						
Restore Advanced SureScan MRI	Restore	Mar 2013	99	76	1	869
Restore Sensor SureScan MRI	Restore	Mar 2013	936	720	6	8,127

[a] There were 37 neurostimulator-related events reported to the registry, but only 29 events included in this summary table. The remaining neurostimulator related events occurred in a model for which no device survival data are presented due to an insufficient number of enrolled devices (n=2), or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.
[b]RestoreUltra SureScan MRI had a device survival probability of 100% at 6 months of follow-up.

Device Survival Probability (95% Confidence Interval)– *Table 1 of 2*				
Model Name	1 yr	2 yrs	3 yrs	4 yrs
Primary Cell Neurostimulators				
Itrel 3	**100.0%** (NA)	**100.0%** (NA)	-	-
Itrel 4	**100.0%** (NA)	-	-	-
Synergy	**100.0%** (NA)	**99.5%** (96.6%, 99.9%)	**99.5%** (96.6%, 99.9%)	**98.6%** (94.4%, 99.7%)
RestorePrime	**100.0%** (NA)	**100.0%** (NA)	-	-
PrimeAdvanced	**99.8%** (98.5%, 100.0%)	**99.5%** (97.9%, 99.9%)	**98.9%** (96.1%, 99.7%)	**98.9%** (96.1%, 99.7%)
PrimeAdvanced SureScan MRI	**99.6%** (97.0%, 99.9%)	**99.6%** (97.0%, 99.9%)	-	-
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA
RestoreUltra	**100.0%** (NA)	**99.6%** (97.2%, 99.9%)	**99.1%** (96.3%, 99.8%)	**98.1%** (93.6%, 99.4%)

RestoreAdvanced	**99.6%** (97.5%, 99.9%)	**99.6%** (97.5%, 99.9%)	**99.6%** (97.5%, 99.9%)	**99.6%** (97.5%, 99.9%)
RestoreSensor	**99.6%** (97.4%, 99.9%)	**99.1%** (96.1%, 99.8%)	**99.1%** (96.1%, 99.8%)	-
RestoreUltra SureScan MRI	-[b]	-	-	-
RestoreAdvanced SureScan MRI	**98.2%** (88.1%, 99.7%)	-	-	-
Restore Sensor SureScan MRI	**99.2%** (98.0%, 99.7%)	**99.2%** (98.0%, 99.7%)	-	-

Device Survival Probability (95% Confidence Interval)– *Table 2 of 2*

Model Name	5 yrs	6 yrs	7 yrs	8 yrs
Primary Cell Neurostimulators				
Itrel 3	-	-	-	-
Itrel 4	-	-	-	-
Synergy	**97.3%** (91.4%, 99.2%)	**97.3%** (91.4%, 99.2%)	**97.3%** (91.4%, 99.2%)	-
RestorePrime	-	-	-	-
PrimeAdvanced	**98.9%** (96.1%, 99.7%)	-	-	-
PrimeAdvanced SureScan MRI	-	-	-	-
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**98.3%** (88.5%, 99.8%)	**98.3%** (88.5%, 99.8%)	**98.3%** (88.5%, 99.8%)
RestoreUltra	**96.4%** (89.4%, 98.8%)	**94.4%** (85.3%, 97.9%)	-	-
RestoreAdvanced	**99.6%** (97.5%, 99.9%)	**99.6%** (97.5%, 99.9%)	**99.6%** (97.5%, 99.9%)	-
RestoreSensor	-	-	-	-
RestoreAdvanced SureScan MRI	-	-	-	-

Restore Sensor SureScan MRI	-	-	-	-
RestoreUltra SureScan MRI	-	-	-	-

Leads

From June 2004 to the report cut-off date of July 31, 2016, there were 7,909 leads followed in the registry. Differences between the total number of leads versus spinal cord neurostimulators (N=4,731) were due to the fact that some patients were subsequently re-implanted with a new lead or were implanted with more than 1 lead. The aggregate prospective follow-up time for all leads was 150,646 months (12,554 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). The table below provides the number and percentage of leads by model.

Leads by Model

Model	**Number of Leads (%)**
Pisces Octad Compact (3778)[a]	2,147 (27.1%)
Vectris SureScan MRI Compact (977A2)[a]	1,917 (24.2%)
Pisces Standard (3487A)[a]	963 (12.2%)
Pisces Octad Standard (3777)[a]	821 (10.4%)
Pisces Plus (3888)[a]	424 (5.4%)
Specify 5-6-5 (39565)[b]	271 (3.4%)
Pisces Compact (3887)[a]	192 (2.4%)
Pisces Octad Subcompact (3776)[a]	184 (2.3%)
Vectris SureScan MRI Subcompact (977A1)[a]	105 (1.3%)
Specify 2x8 (39286)[b]	30 (0.4%)
Specify SureScan MRI 5-6-5 (977C1)[b]	10 (0.1%)
Specify SureScan MRI 2x8 (977C2)[b]	2 (<0.1%)
Other/Unspecified	186 (2.4%)
Leads No Longer Manufactured	

Specify (3998)[b]	149 (1.9%)
Pisces Z Standard (3890)[a]	140 (1.8%)
Pisces Z Compact (3891)[a]	123 (1.6%)
Resume TL (3986A)[b]	104 (1.3%)
Hinged Specify (3999)[b]	54 (0.7%)
Resume II (3587A)[b]	52 (0.7%)
Pisces Z Plus (3892)[a]	24 (0.3%)
On-Point (3987A)[b]	9 (0.1%)
SymMix (3982A)[b]	2 (<0.1%)
Total	**7,909 (100%)**

[a] Percutaneous lead
[b]Surgical lead

Percutaneous leads composed eighty-nine percent (89.0%) of leads in the registry (7,040/7,909), including 39.9% (3,152/7,909) in the Pisces-Octad lead family, 25.6% (2,022/7,909) in the Vectris SureScan MRI lead family, 20.0% (1,579/7,909) in the Pisces-Quad lead family, and 3.6% (287/7,909) in the Pisces-Quad LZ lead family. Over eight percent (8.6%) of leads (683/7,909) were surgical leads. A small percent (2.4%) of leads (186/7,909) were designated as “Other” or were unspecified in the database.

Lead Events

There were 885 product performance-related events with an underlying reported etiology related to the lead. This includes 862 events with a lead etiology and 23 events with both a lead and other etiology (including device and non-device etiologies). Of these events, the majority were lead migration/dislodgements (n=500), high impedance (n=207), and lead fracture (n=64). Of the 885 lead events, 757 were the initial product performance event that affected lead survival estimates. There were 702 events in the 7,040 (10.0%) percutaneous leads, 44 events in the 683 (6.4%) surgical leads, and 11 events occurred in a lead with an unknown/other model number.

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 non-product performance-related or 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:

- 757 had follow-up time cut-off due to product performance-related events.
- 4,404 were censored in the survival analysis for the following reasons: patient expired, lead explanted, site termination, patient discontinued, other lead modification, therapy suspended, or non-product performance lead-related event without an associated intervention.
- 2,748 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

Lead Survival

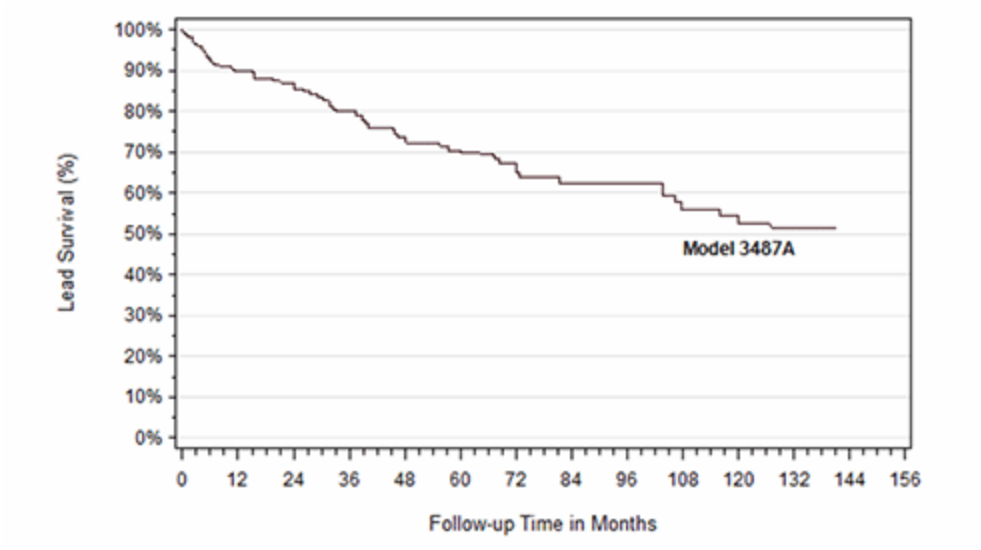
The tables below represent annual lead survival and 95% confidence intervals where at least 20 leads contributed to

each 3-month interval.

Choose a model Go

Model 3487A Pisces-Quad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3487A
FDA Approval Date	May 1988
Leads Enrolled	963
Leads Currently Active in Study	328
Device Events	182
Cumulative Months of Follow-up	28,621

Model 3487A Pisces-Quad: Event Summary Table

Lead Event	Total
High impedance	74
Lead migration/dislodgement	51
Low impedance	25
Device stimulation issue	17

Lead fracture	13
Inadequate lead connection	2
Total Lead Events	**182**

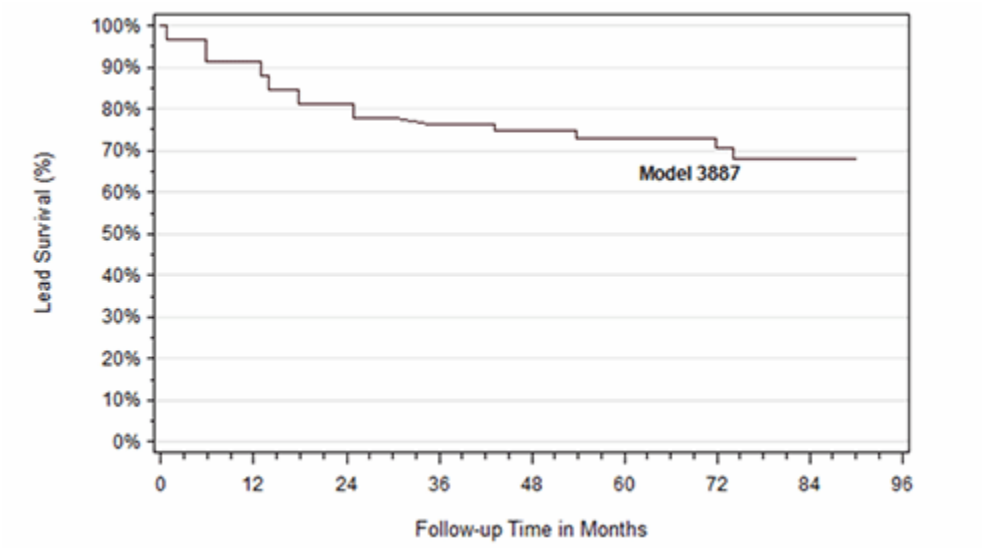
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**89.8%** (86.9%, 92.0%)	464
2 yrs	**86.8%** (83.6%, 89.4%)	380
3 yrs	**80.0%** (76.1%, 83.3%)	311
4 yrs	**73.6%** (69.2%, 77.6%)	224
5 yrs	**70.4%** (65.7%, 74.7%)	184
6 yrs	**65.3%** (60.1%, 70.1%)	145
7 yrs	**62.3%** (56.7%, 67.4%)	107
8 yrs	**62.3%** (56.7%, 67.4%)	93
9 yrs	**56.1%** (49.5%, 62.1%)	70
10 yrs	**52.6%** (45.6%, 59.1%)	59
11 yrs	**51.5%** (44.3%, 58.2%)	40
at 141 mo	**51.5%** (44.3%, 58.2%)	22

Model 3487A Pisces-Quad: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	30.0

Model 3887 Pisces-Quad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3887
FDA Approval Date	Jan 1997

Leads Enrolled	192
Leads Currently Active in Study	56
Device Events	22
Cumulative Months of Follow-up	4,598

Model 3887 Pisces-Quad: Event Summary Table

Lead Event	**Total**
Lead migration/dislodgement	9
Lead fracture	7
High impedance	3
Device stimulation issue	2
Device lead damage	1
Total Lead Events	**22**

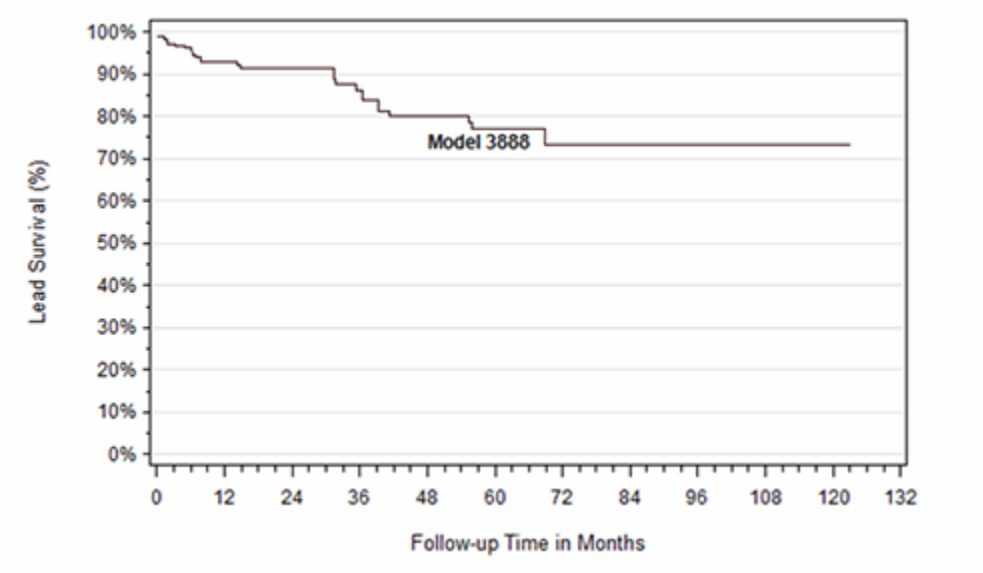
Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	**91.5%** (75.8%, 97.2%)	46
2 yrs	**81.4%** (66.8%, 90.0%)	49
3 yrs	**76.3%** (61.7%, 85.9%)	47
4 yrs	**74.8%** (60.3%, 84.7%)	41
5 yrs	**72.9%** (58.3%, 83.1%)	36
6 yrs	**70.5%** (55.6%, 81.2%)	29
7 yrs	**68.0%** (52.8%, 79.2%)	23
at 90 mo	**68.0%** (52.8%, 79.2%)	21

Model 3887 Pisces-Quad: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	24.0

Model 3888 Pisces-Quad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3888

FDA Approval Date	Nov 1992
Leads Enrolled	424
Leads Currently Active in Study	74
Device Events	34
Cumulative Months of Follow-up	7,935

Model 3888 Pisces-Quad: Event Summary Table

Lead Event	Total
Lead migration/dislodgement	24
High impedance	7
Device stimulation issue	2
Lead fracture	1
Total Lead Events	**34**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.8%** (88.2%, 95.6%)	136
2 yrs	**91.2%** (86.1%, 94.5%)	83
3 yrs	**86.2%** (78.6%, 91.2%)	69
4 yrs	**80.0%** (70.9%, 86.5%)	59
5 yrs	**77.0%** (67.1%, 84.2%)	44
6 yrs	**73.1%** (62.1%, 81.4%)	35
7 yrs	**73.1%** (62.1%, 81.4%)	29
8 yrs	**73.1%** (62.1%, 81.4%)	27

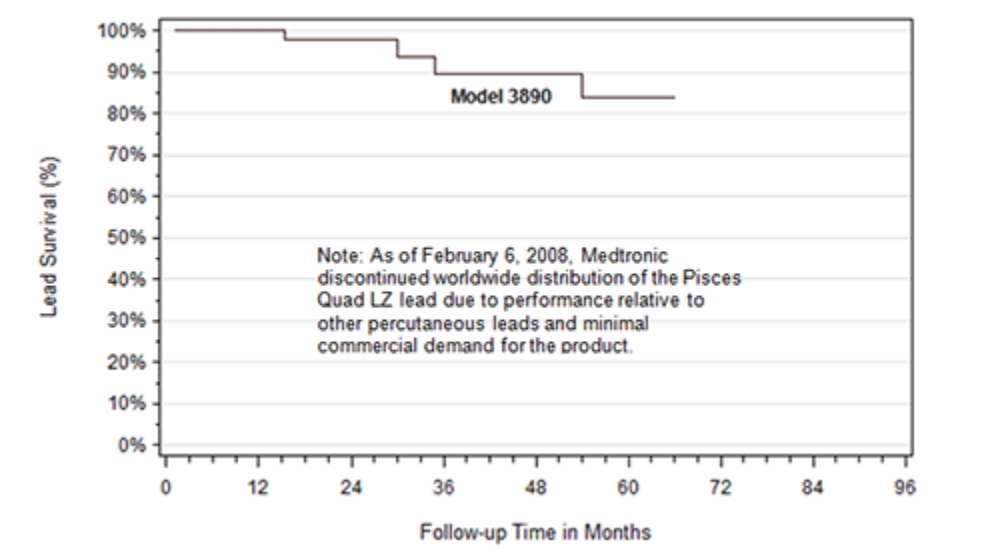
9 yrs	**73.1%** (62.1%, 81.4%)	22
10 yrs	**73.1%** (62.1%, 81.4%)	22
at 123 mo	**73.1%** (62.1%, 81.4%)	22

Model 3888 Pisces-Quad: Specifications

Device Name	**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)	24.0
Inter-Electrode Spacing: Edge to Edge (mm)	12.0
Array Length (mm)	60.0

Model 3890 Pisces-Quad LZ: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3890
FDA Approval Date	Sep 2002
Leads Enrolled	140
Leads Currently Active in Study	18
Device Events	10
Cumulative Months of Follow-up	2,986

Model 3890 Pisces-Quad LZ: Event Summary Table

Lead Event	Total
Lead migration/dislodgement	4
Device malfunction[a]	2
Lead fracture	2
High impedance	2
Total Lead Events	**10**

[a] Includes 2 events reported as impedance not measurable.

Time Interval	Survival (95% Confidence Interval)	Sample Size

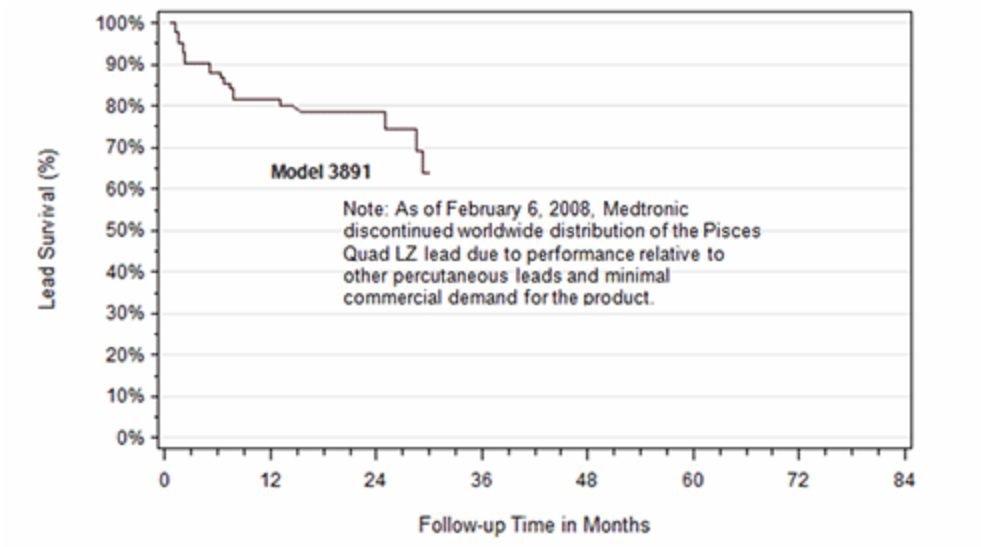
1 yr	**100.0%** (NA)	38
2 yrs	**97.8%** (85.1%, 99.7%)	51
3 yrs	**89.4%** (76.4%, 95.5%)	40
4 yrs	**89.4%** (76.4%, 95.5%)	33
5 yrs	**83.8%** (68.8%, 92.0%)	22
at 66 mo	**83.8%** (68.8%, 92.0%)	20

Model 3890 Pisces-Quad LZ: Specifications

Device name	**Pisces Z Quad**
Lead Type	**Percutaneous**
Lead	
Length (cm)	10 - 100
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	3.0
Array Length (mm)	30.0

Model 3891 Pisces-Quad LZ: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3891
FDA Approval Date	Sep 2002
Leads Enrolled	123
Leads Currently Active in Study	12
Device Events	32
Cumulative Months of Follow-up	2,315

Model 3891 Pisces-Quad LZ: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	18
Lead fracture	6
Device stimulation issue	4
Device lead damage	2
High impedance	2
Total Lead Events	**32**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**81.7%** (71.4%, 88.5%)	56

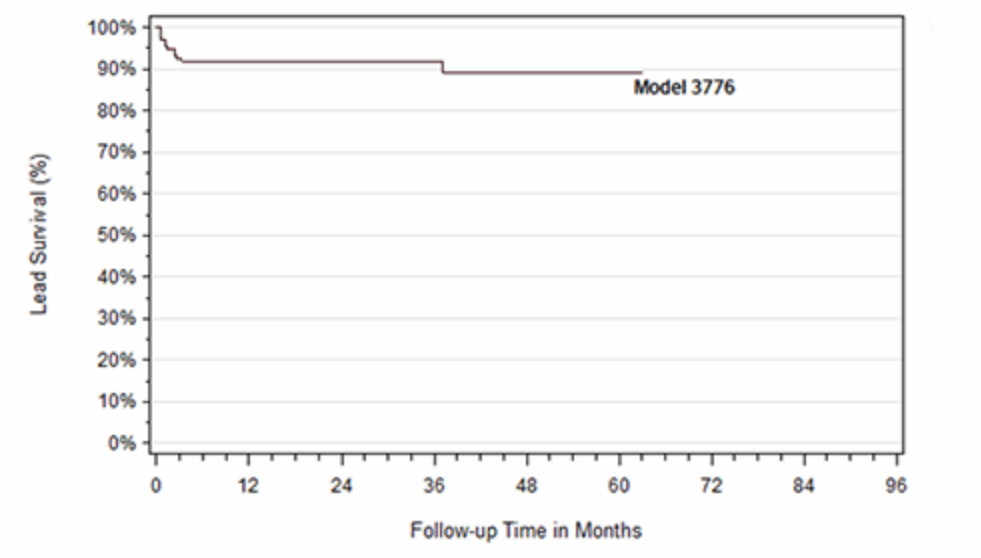
2 yrs	**78.7%** (67.9%, 86.2%)	37
at 30 mo	**63.9%** (49.3%, 75.3%)	21

Model 3891 Pisces-Quad LZ: Specifications

Device Name	**Pisces Z Quad Compact**
Lead Type	**Percutaneous**
Lead	
Length (cm)	10 - 100
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	3.0
Array Length (mm)	24.0

Model 3776 Pisces-Octad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3776
FDA Approval Date	Nov 2005
Leads Enrolled	184
Leads Currently Active in Study	37
Device Events	14
Cumulative Months of Follow-up	3,816

Model 3776 Pisces-Octad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	10
High impedance	2
Device stimulation issue	1
Lead fracture	1
Total Lead Events	**14**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.6%** (85.4%, 95.3%)	83

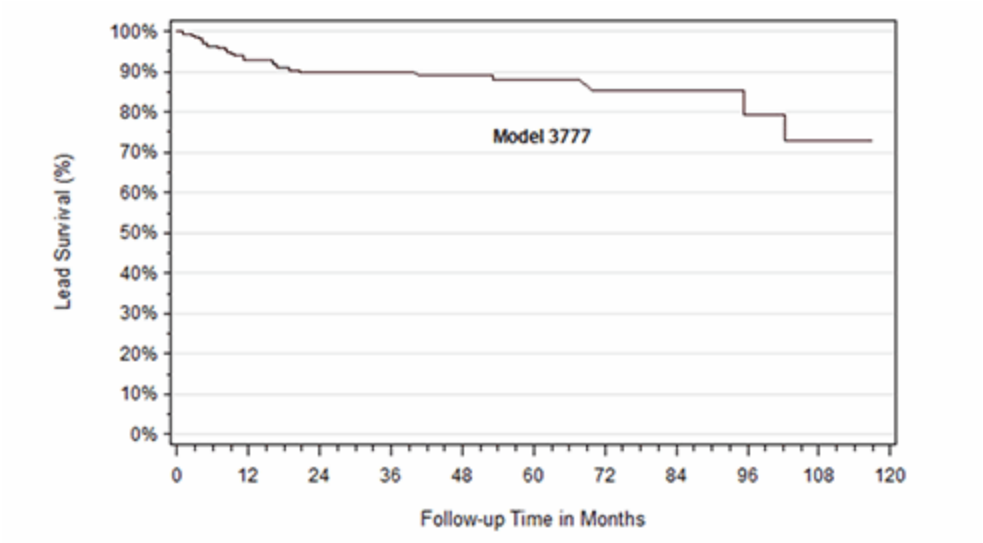
2 yrs	**91.6%** (85.4%, 95.3%)	61
3 yrs	**91.6%** (85.4%, 95.3%)	38
4 yrs	**89.0%** (79.9%, 94.2%)	23
5 yrs	**89.0%** (79.9%, 94.2%)	20
at 63 mo	**89.0%** (79.9%, 94.2%)	20

Model 3776 Pisces-Octad: Specifications

Device Name	**1x8 Sub-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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	35.0

Model 3777 Pisces-Octad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	821
Leads Currently Active in Study	149
Device Events	60
Cumulative Months of Follow-up	17,564

Model 3777 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgement	40
Device stimulation issue	7
High impedance	7
Device lead damage	2
Lead fracture	2
Low impedance	2
Total Lead Events	**60**

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	**93.0%** (90.5%, 94.9%)	423
2 yrs	**89.7%** (86.6%, 92.2%)	265
3 yrs	**89.7%** (86.6%, 92.2%)	157
4 yrs	**89.1%** (85.5%, 91.8%)	100
5 yrs	**88.1%** (83.9%, 91.2%)	72
6 yrs	**85.2%** (79.1%, 89.7%)	55
7 yrs	**85.2%** (79.1%, 89.7%)	36
8 yrs	**79.4%** (68.2%, 87.0%)	25
9 yrs	**73.0%** (58.9%, 83.0%)	32
at 117 mo	**73.0%** (58.9%, 83.0%)	23

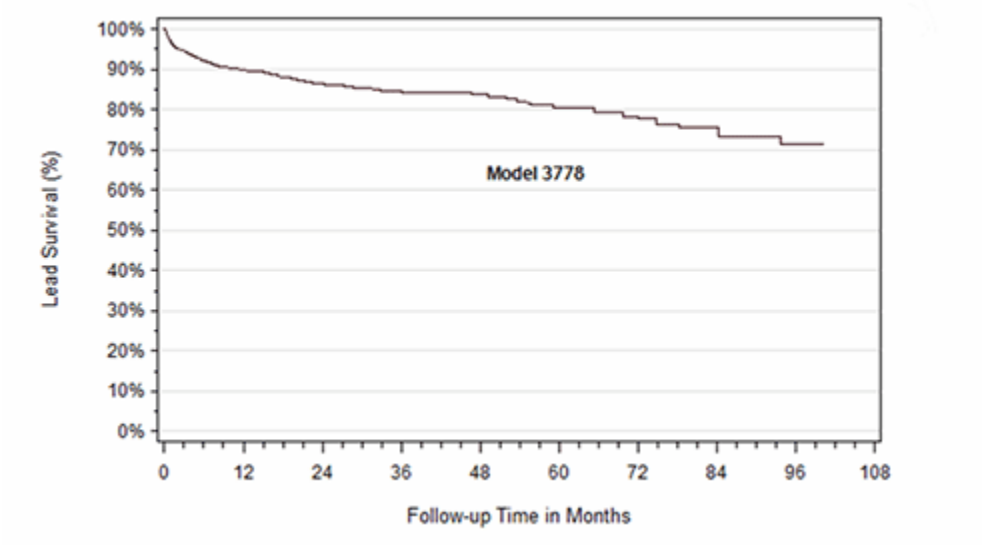
Model 3777 Pisces-Octad: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	66.0

Model 3778 Pisces-Octad: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Lead Characteristics	
Model Number	3778
FDA Approval Date	Apr 2005
Leads Enrolled	2,147
Leads Currently Active in Study	428
Device Events	257
Cumulative Months of Follow-up	48,813

Model 3778 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgement	194
High impedance	34

Lead fracture	15
Device stimulation issue	6
Medical device complication[a]	4
Device malfunction[b]	2
Impedance increased	1
Low impedance	1
Total Lead Events	**257**

[a] Includes 2 events reported as lead lost capability of stimulation and 2 events of open circuit on lead.
[b] Includes 2 events reported as lead electrodes not functional.

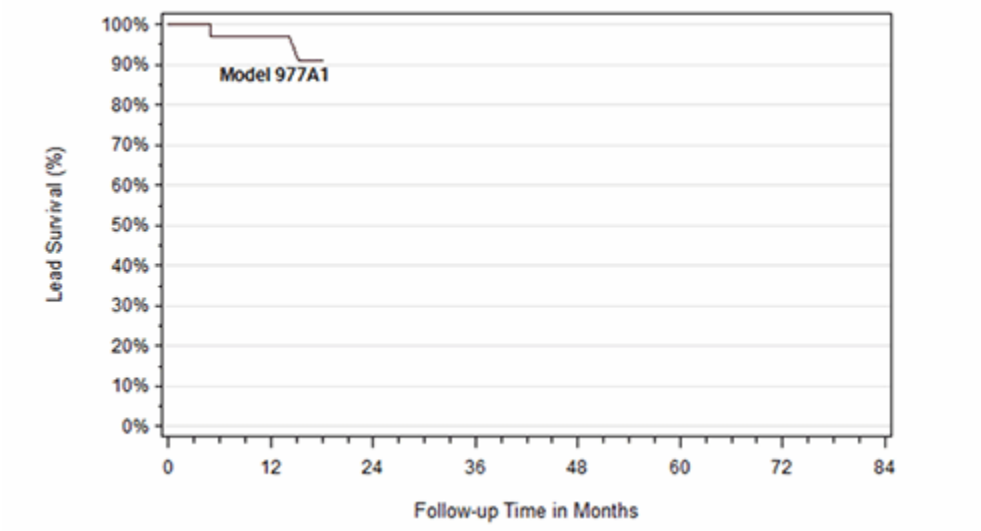
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**89.9%** (88.3%, 91.3%)	1,198
2 yrs	**86.4%** (84.5%, 88.1%)	762
3 yrs	**84.3%** (82.1%, 86.2%)	498
4 yrs	**83.8%** (81.5%, 85.8%)	318
5 yrs	**80.4%** (77.3%, 83.0%)	212
6 yrs	**77.7%** (73.9%, 81.1%)	126
7 yrs	**75.5%** (70.9%, 79.5%)	68
8 yrs	**71.4%** (64.6%, 77.1%)	32
at 102 mo	**71.4%** (64.6%, 77.1%)	24

Model 3778 Pisces-Octad: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Lead Characteristics	
Model Number	977A1
FDA Approval Date	Mar 2013

Leads Enrolled	105
Leads Currently Active in Study	75
Device Events	4
Cumulative Months of Follow-up	1,023

Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Event Summary Table

Lead Event	**Total**
Device lead fracture	2
Lead migration/dislodgement	2
Total Lead Events	**4**

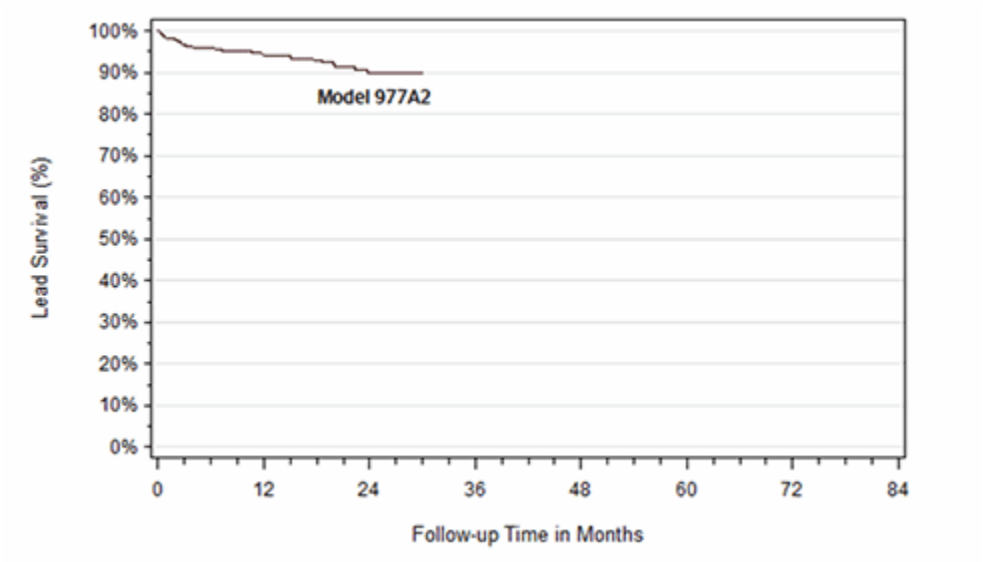
Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	**97.1%** (89.1%, 99.3%)	43
at 18 mo	**91.1%** (76.6%, 96.8%)	22

Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	34.5

Model 977A2 Vectris SureScan MRI 1x8 Compact: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	977A2
FDA Approval Date	Mar 2013
Leads Enrolled	1,917
Leads Currently Active in Study	1,449
Device Events	86
Cumulative Months of Follow-up	16,566

Model 977A2 Vectris SureScan MRI 1x8 Compact: Event Summary Table

Lead Event	Total
Lead migration/dislodgement	68
High impedance	12
Lead fracture	4
Impedance increased	1
Low impedance	1
Total Lead Events	**86**

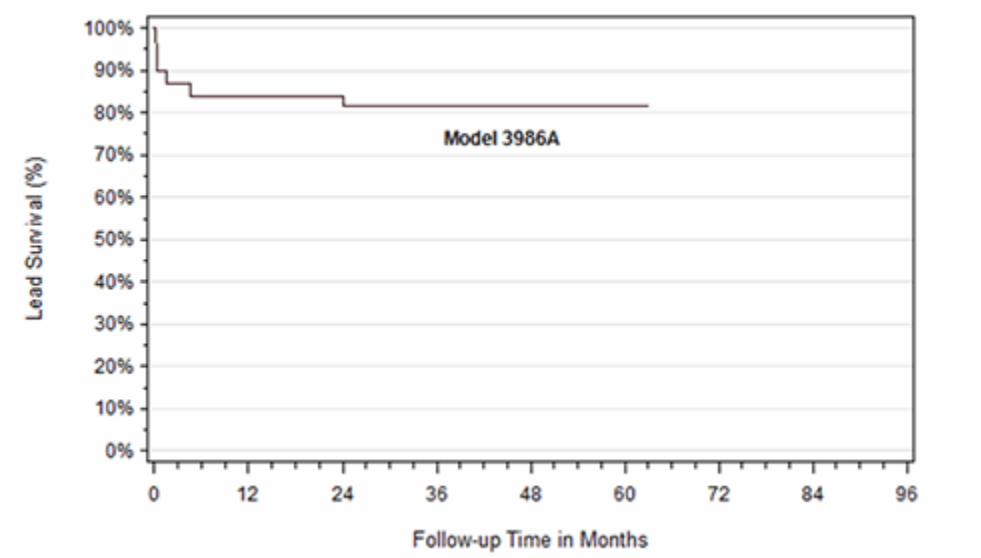
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.2%** (92.6%, 95.4%)	595
2 yrs	**89.9%** (86.8%, 92.4%)	138
at 30 mo	**89.9%** (86.8%, 92.4%)	37

Model 977A2 Vectris SureScan MRI 1x8 Compact: Specifications

Device Name	**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)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

Model 3986A Resume TL: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3986A

FDA Clearance Date	Apr 1995
Leads Enrolled	104
Leads Currently Active in Study	35
Device Events	19
Cumulative Months of Follow-up	2,893

Model 3986A Resume TL: Event Summary Table

Lead Event	Total
High impedance	10
Device connection issue	2
Device stimulation issue	2
Low impedance	2
Lead migration/dislodgement	2
Lead fracture	1
Total Lead Events	**19**

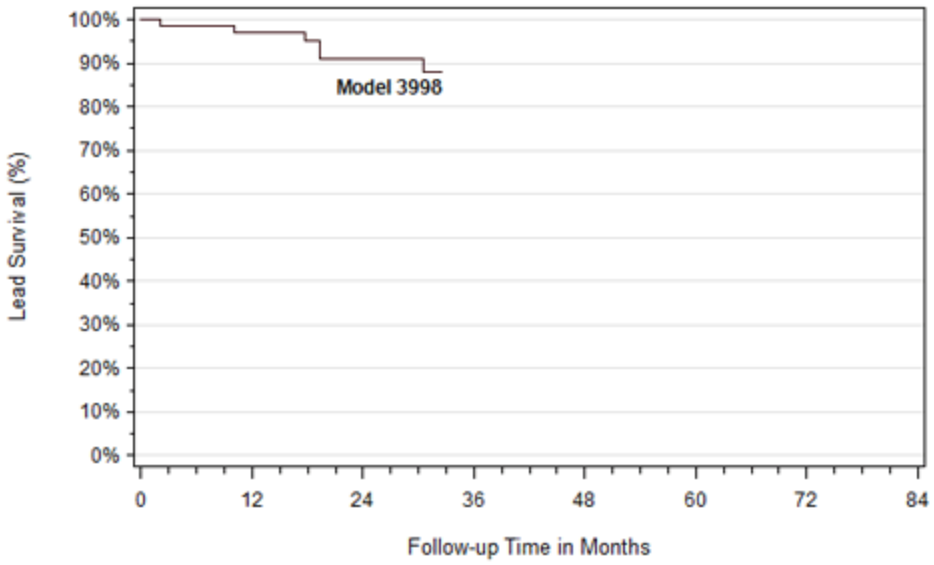
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**84.0%** (72.9%, 90.8%)	47
2 yrs	**84.0%** (72.9%, 90.8%)	36
3 yrs	**81.7%** (69.7%, 89.3%)	29
4 yrs	**81.7%** (69.7%, 89.3%)	26
5 yrs	**81.7%** (69.7%, 89.3%)	20
at 63 mo	**81.7%** (69.7%, 89.3%)	20

Model 3986A Resume TL: Specifications

Device Name	**Resume TL**
Lead Type	**Surgical**
Lead	
Length (cm)	25
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Circle
Length (mm)	4.0
Width (mm)	4.0
Individual Surface Area (mm)	12.6
Longitudinal Spacing: Edge to Edge (mm)	6.2
Lateral Spacing: Edge to Edge (mm)	NA
Array Length (mm)	34.5
Array Width (mm)	4.0
Paddle	
Length (mm)	44.0
Width (mm)	6.6
Thickness (mm)	1.4

Model 3998 Specify: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	149
Leads Currently Active in Study	20
Device Events	10
Cumulative Months of Follow-up	2,992

Model 3998 Specify: Event Summary Table

Lead Event	Total
High impedance	4
Lead fracture	3
Lead migration/dislodgement	2
Device stimulation issue	1
Total Lead Events	**10**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**97.0%** (88.6%, 99.2%)	59

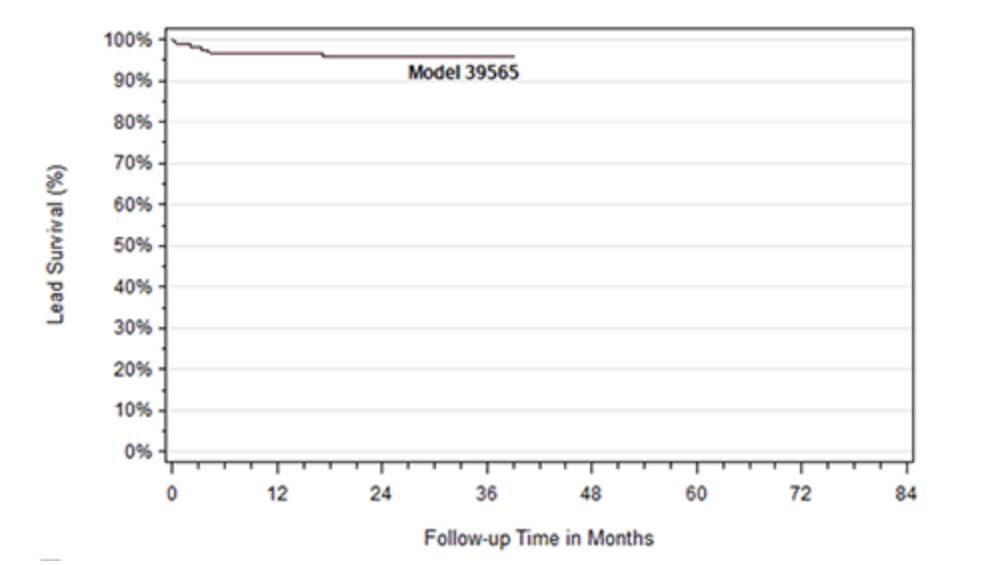
2 yrs	**91.6%** (80.8%, 96.4%)	41
at 33 mo	**88.5%** (75.3%, 94.8%)	26

Model 3998 Specify: Specifications

Device Name	**Specify**
Lead Type	**Surgical**
Lead	
Length (cm)	20
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Rectangular
Length (mm)	3.0
Width (mm)	2.0
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	6.0
Lateral Spacing: Edge to Edge (mm)	2.0
Array Length (mm)	30.0
Array Width (mm)	6.0
Paddle	
Length (mm)	45.0
Width (mm)	7.9
Thickness (mm)	1.8

Model 39565 Specify: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	39565
FDA Approval Date	Jun 2007
Leads Enrolled	271
Leads Currently Active in Study	120
Device Events	11
Cumulative Months of Follow-up	4,441

Model 39565 Specify: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	10
High impedance	1
Total Lead Events	**11**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**96.6%** (93.0%, 98.4%)	136
2 yrs	**95.7%** (91.5%, 97.9%)	74
3 yrs	**95.7%** (91.5%, 97.9%)	29

at 39 mo	**95.7%** (91.5%, 97.9%)	24

Model 39565 Specify: Specifications

Device Name	**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)	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 Survival Summary]

Lead Characteristics						
Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up

Percutaneous Leads						
3487A	**Pisces-Quad**	May 1988	963	328	182	28,621
3887	**Pisces-Quad**	Jan 1997	192	56	22	4,598
3888	**Pisces-Quad**	Nov 1992	424	74	34	7,935
3890	**Pisces-Quad LZ**	Sep 2002	140	18	10	2,986
3891	**Pisces-Quad LZ**	Sep 2002	123	12	32	2,315
3776	**Pisces-Octad**	Nov 2005	184	37	14	3,816
3777	**Pisces-Octad**	Apr 2005	821	149	60	17,564
3778	**Pisces-Octad**	Apr 2005	2,147	428	257	48,813
977A1	**Vectris SureScan**	Mar 2013	105	75	4	1,023
977A2	**Vectris SureScan**	Mar 2013	1,917	1,449	86	16,566
Surgical Leads						
3986A	**Resume TL**	Apr 1995[b]	104	35	19	2,893
3998	**Specify**	Feb 1998	149	20	10	2,992
39565	**Specify**	Jun 2007	271	120	11	4,441

[a] There were a total of 885 lead-related events reported to the registry, but only 741 events included in this summary table. The remaining lead-related events occurred in lead models for which no device survival data are presented due to an insufficient number of enrolled devices (n=5), leads with an unknown model number (n=11), or were subsequent device events (i.e. additional events that occurred after the survival censoring event) that did not affect the survival estimates.
[b] FDA clearance date.

Device Survival Probability (95% Confidence Interval) – *Table 1 of 3*

Model Number	Family	1 yr	2 yrs	3 yrs	4 yrs
Percutaneous Leads					
3487A	**Pisces-Quad**	**89.8%** (86.9%, 92.0%)	**86.8%** (83.6%, 89.4%)	**80.0%** (76.1%, 83.3%)	**73.6%** (69.2%, 77.6%)

3887	**Pisces-Quad**	**91.5%** (75.8%, 97.2%)	**81.4%** (66.8%, 90.0%)	**76.3%** (61.7%, 85.9%)	**74.8%** (60.3%, 84.7%)
3888	**Pisces-Quad**	**92.8%** (88.2%, 95.6%)	**91.2%** (86.1%, 94.5%)	**86.2%** (78.6%, 91.2%)	**80.0%** (70.9%, 86.5%)
3890	**Pisces-Quad LZ**	**100.0%** (NA)	**97.8%** (85.1%, 99.7%)	**89.4%** (76.4%, 95.5%)	**89.4%** (76.4%, 95.5%)
3891	**Pisces-Quad LZ**	**81.7%** (71.4%, 88.5%)	**78.7%** (67.9%, 86.2%)	-	-
3776	**Pisces-Octad**	**91.6%** (85.4%, 95.3%)	**91.6%** (85.4%, 95.3%)	**91.6%** (85.4%, 95.3%)	**89.0%** (79.9%, 94.2%)
3777	**Pisces-Octad**	**93.0%** (90.5%, 94.9%)	**89.7%** (86.6%, 92.2%)	**89.7%** (86.6%, 92.2%)	**89.1%** (85.5%, 91.8%)
3778	**Pisces-Octad**	**89.9%** (88.3%, 91.3%)	**86.4%** (84.5%, 88.1%)	**84.3%** (82.1%, 86.2%)	**83.8%** (81.5%, 85.8%)
977A1	**Vectris SureScan**	**97.1%** (89.1%, 99.3%)	-	-	-
977A2	**Vectris SureScan**	**94.2%** (92.6%, 95.4%)	**89.9%** (86.8%, 92.4%)	-	-
Surgical Leads					
3986A	**Resume TL**	**84.0%** (72.9%, 90.8%)	**84.0%** (72.9%, 90.8%)	**81.7%** (69.7%, 89.3%)	**81.7%** (69.7%, 89.3%)
3998	**Specify**	**97.0%** (88.6%, 99.2%)	**91.6%** (80.8%, 96.4%)	-	-
39565	**Specify**	**96.6%** (93.0%, 98.4%)	**95.7%** (91.5%, 97.9%)	**95.7%** (91.5%, 97.9%)	-

Device Survival Probability (95% Confidence Interval) – *Table 2 of 3*

Model Number	Family	5 yrs	6 yrs	7 yrs	8 yrs
Percutaneous Leads					
3487A	**Pisces-Quad**	**70.4%** (65.7%, 74.7%)	**65.3%** (60.1%, 70.1%)	**62.3%** (56.7%, 67.4%)	**62.3%** (56.7%, 67.4%)

3887	**Pisces-Quad**	**72.9%** (58.3%, 83.1%)	**70.5%** (55.6%, 81.2%)	**68.0%** (52.8%, 79.2%)	-
3888	**Pisces-Quad**	**77.0%** (67.1%, 84.2%)	**73.1%** (62.1%, 81.4%)	**73.1%** (62.1%, 81.4%)	**73.1%** (62.1%, 81.4%)
3890	**Pisces-Quad LZ**	**83.8%** (68.8%, 92.0%)	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
3776	**Pisces-Octad**	**89.0%** (79.9%, 94.2%)	-	-	-
3777	**Pisces-Octad**	**88.1%** (83.9%, 91.2%)	**85.2%** (79.1%, 89.7%)	**85.2%** (79.1%, 89.7%)	**79.4%** (68.2%, 87.0%)
3778	**Pisces-Octad**	**80.4%** (77.3%, 83.0%)	**77.7%** (73.9%, 81.1%)	**75.5%** (70.9%, 79.5%)	**71.4%** (64.6%, 77.1%)
977A1	**Vectris SureScan**	-	-	-	-
977A2	**Vectris SureScan**	-	-	-	-
Surgical Leads					
3986A	**Resume TL**	**81.7%** (69.7%, 89.3%)	-	-	-
3998	**Specify**	-	-	-	-
39565	**Specify**	-	-	-	-

Device Survival Probability (95% Confidence Interval) – *Table 3 of 3*

Model Number	Family	9 yrs	10 yrs	11 yrs
Percutaneous Leads				
3487A	**Pisces-Quad**	**56.1%** (49.5%, 62.1%)	**52.6%** (45.6%, 59.1%)	**51.5%** (44.3%, 58.2%)
3887	**Pisces-Quad**	-	-	-
3888	**Pisces-Quad**	**73.1%** (62.1%, 81.4%)	**73.1%** (62.1%, 81.4%)	-
3890	**Pisces-Quad LZ**	-	-	-

3891	**Pisces-Quad LZ**	-	-	-
3776	**Pisces-Octad**	-	-	-
3777	**Pisces-Octad**	**73.0%** (58.9%, 83.0%)	-	-
3778	**Pisces-Octad**	-	-	-
977A1	**Vectris SureScan**	-	-	-
977A2	**Vectris SureScan**	-	-	-
Surgical Leads				
3986A	**Resume TL**	-	-	-
3998	**Specify**	-	-	-
39565	**Specify**	-	-	-

Extensions

From June 2004 to the report cut-off date of July 31, 2016, there were 3,275 extensions followed in the registry. Differences between the total number of extensions versus spinal cord neurostimulators (N=4,731) were due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 77,026 months (6,419 years).

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. The table below provides the number and percentage of extensions by model.

Extensions by Model

Model	**Number of Extensions (%)**
37081 (1x8)	1,377 (42.0%)
37082 (bifurcated stretch coil)	614 (18.7%)
37083 (single stretch coil)	222 (6.8%)
Other/Unspecified	14 (0.4%)
Extensions No Longer Manufactured	
7489 (Low profile quadripolar)	746 (22.8%)
7495 (quadripolar in-line)	264 (8.1%)

7472 (bifurcated 1x8)	21 (0.6%)
7496 (quadripolar)	9 (0.3%)
7471 (1x8)	8 (0.2%)
Total	**3,275 (100%)**

Extension Events

There were 31 product performance-related events with an underlying reported etiology related to the extension. This includes 27 events with an extension etiology and 4 events with both an extension and other etiology (including device and non-device etiologies). Of these events, the majority were extension fractures (n=15). Of the 31 events, 27 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 non-product performance-related or 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:

- 27 had follow-up time cut-off due to product performance-related events.
- 2,433 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, other extension modification, therapy suspended, or non-product performance extension-related event without an associated intervention.
- 815 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

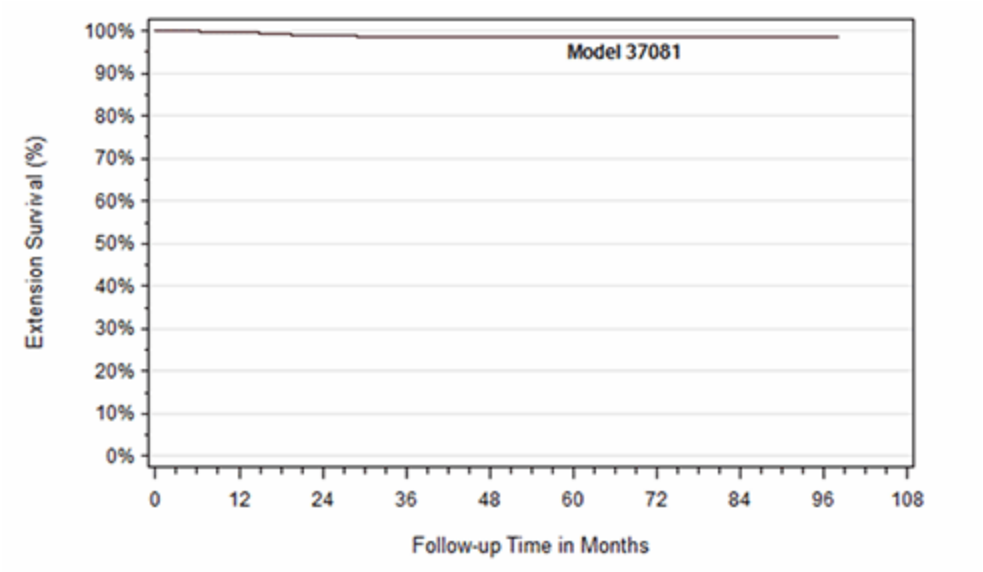
Extension Survival

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

Choose a model Go

Model 37081: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Extension Characteristics	
Model Number	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	1,377
Extensions Currently Active in Study	423
Device Events	9
Cumulative Months of Follow-up	27,730

Model 37081 Extension: Event Summary Table

Extension Event	Total
Extension fracture	6
Extension migration	1
High impedance	1
Low impedance	1
Total Extension Events	**9**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.8%** (99.1%, 99.9%)	707

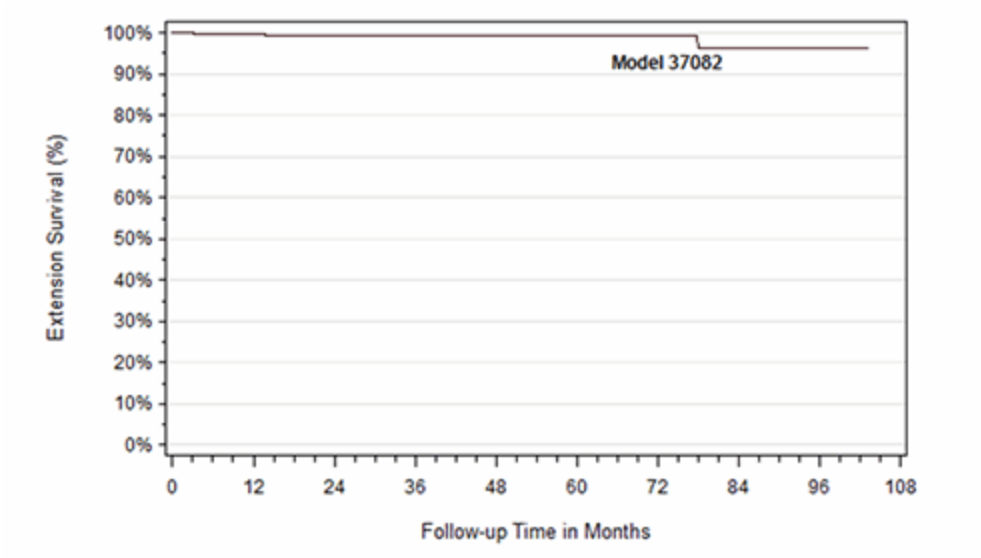
2 yrs	**99.1%** (97.9%, 99.6%)	424
3 yrs	**98.5%** (97.0%, 99.3%)	246
4 yrs	**98.5%** (97.0%, 99.3%)	160
5 yrs	**98.5%** (97.0%, 99.3%)	113
6 yrs	**98.5%** (97.0%, 99.3%)	74
7 yrs	**98.5%** (97.0%, 99.3%)	49
8 yrs	**98.5%** (97.0%, 99.3%)	29
at 99 mo	**98.5%** (97.0%, 99.3%)	25

Model 37081: Specifications

Device Name	**1x8 Extension**
Length (cm)	20, 40, 60
Distal End Compatibility	1 Octad Lead
Distal End Set Screws	1
Proximal End INS Compatibility	Restore Family

Model 37082: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Extension Characteristics	
Model Number	37082
FDA Approval Date	Mar 2006
Extensions Enrolled	614
Extensions Currently Active in Study	178
Device Events	5
Cumulative Months of Follow-up	18,102

Model 37082 Extension: Event Summary Table	
Extension Event	**Total**
Device connection issue	2
Extension fracture	2
Paraesthesia[a]	1
Total Extension Events	**5**

[a] Reported as shocking sensation at battery/extension connection.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.3%, 99.9%)	403

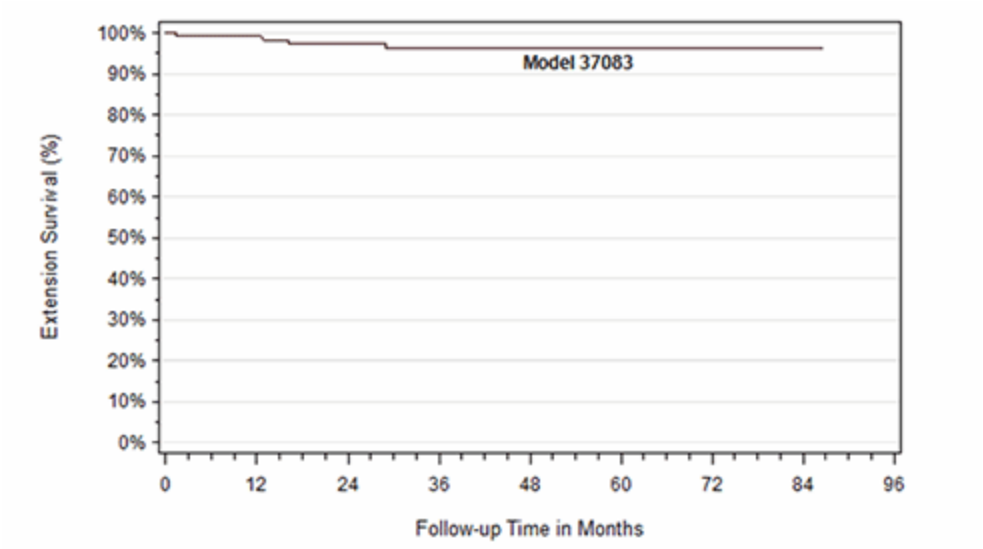
2 yrs	**99.3%** (97.9%, 99.8%)	274
3 yrs	**99.3%** (97.9%, 99.8%)	176
4 yrs	**99.3%** (97.9%, 99.8%)	125
5 yrs	**99.3%** (97.9%, 99.8%)	98
6 yrs	**99.3%** (97.9%, 99.8%)	76
7 yrs	**96.4%** (89.1%, 98.8%)	51
8 yrs	**96.4%** (89.1%, 98.8%)	34
at 105 mo	**96.4%** (89.1%, 98.8%)	21

Model 37082: Specifications

Device Name	**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

Model 37083: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Extension Characteristics	
Model Number	37083
FDA Approval Date	Sep 2005
Extensions Enrolled	222
Extensions Currently Active in Study	51
Device Events	5
Cumulative Months of Follow-up	5,691

Model 37083 Extension: Event Summary Table

Extension Event	Total
Extension fracture	3
Device failure[a]	1
Extension migration	1
Total Extension Events	**5**

[a] Reported as extension failure

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.1%** (94.1%, 99.9%)	122

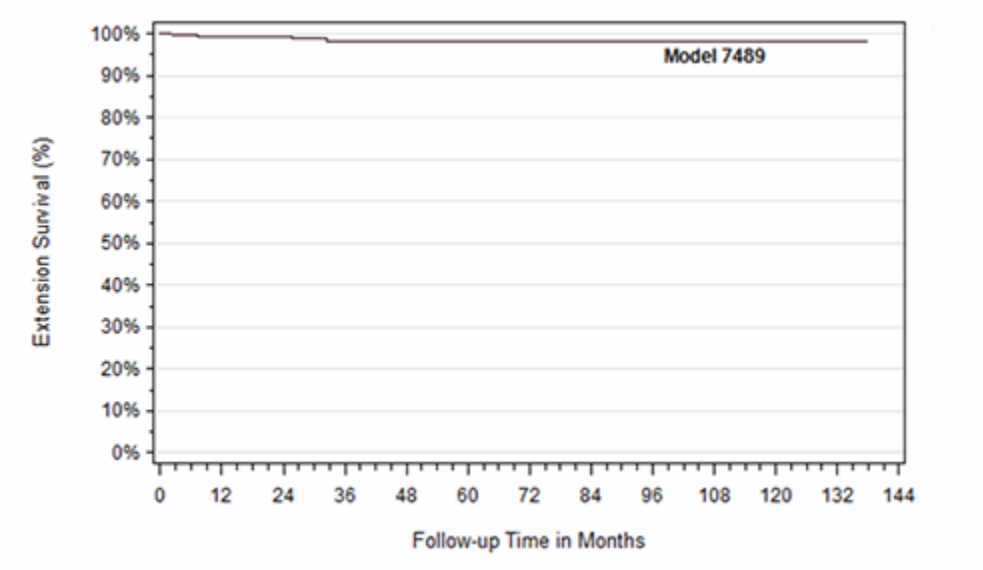
2 yrs	**97.3%** (92.0%, 99.1%)	97
3 yrs	**96.2%** (90.0%, 98.6%)	54
4 yrs	**96.2%** (90.0%, 98.6%)	42
5 yrs	**96.2%** (90.0%, 98.6%)	31
6 yrs	**96.2%** (90.0%, 98.6%)	28
7 yrs	**96.2%** (90.0%, 98.6%)	26
at 87 mo	**96.2%** (90.0%, 98.6%)	21

Model 37083: Specifications

Device Name	**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

Model 7489: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Extension Characteristics	
Model Number	7489
FDA Approval Date	Oct 2002
Extensions Enrolled	746
Extensions Currently Active in Study	97
Device Events	4
Cumulative Months of Follow-up	17,761

Model 7489 Extension: Event Summary Table

Extension Event	Total
Extension fracture	2
Extension migration	1
Medical device complication[a]	1
Total Extension Events	**4**

[a] Reported as unknown problem with extension

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.1%** (96.5%, 99.8%)	294

2 yrs	**99.1%** (96.5%, 99.8%)	290
3 yrs	**98.3%** (95.6%, 99.4%)	205
4 yrs	**98.3%** (95.6%, 99.4%)	138
5 yrs	**98.3%** (95.6%, 99.4%)	103
6 yrs	**98.3%** (95.6%, 99.4%)	80
7 yrs	**98.3%** (95.6%, 99.4%)	63
8 yrs	**98.3%** (95.6%, 99.4%)	61
9 yrs	**98.3%** (95.6%, 99.4%)	60
10 yrs	**98.3%** (95.6%, 99.4%)	53
11 yrs	**98.3%** (95.6%, 99.4%)	42
at 138 mo	**98.3%** (95.6%, 99.4%)	30

Model 7489: Specifications

Device Name	**Low Profile Quad Extension**
Length (cm)	10, 25, 40, 51, 66
Distal End Compatibility	1 Quad Lead
Distal End Set Screws	4
Proximal End INS Compatibility	Itrel 3, Synergy, Versitrel

[Extension Survival Summary]

Extension Characteristics

Model Number	Family	FDA Approval Date	Extensions Enrolled	Extensions Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
37081	37081	Apr 2005	1,377	423	9	27,730
37082	37082	Mar 2006	614	178	5	18,102
37083	37083	Sep 2005	222	51	5	5,691
7489	7489	Oct 2002	746	97	4	17,761

[a] There were a total of 31 extension-related events reported to the registry, but only 23 events are included in this summary table. The remaining extension-related events occurred in an extension model for which no device survival data is presented due to an insufficient number of enrolled devices (n=4), or were subsequent device events (i.e. additional events that occurred after the survival censoring event) that did not affect the survival estimates.

Device Survival Probability (95% Confidence Interval) – *Table 1 of 2*

Model Number	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
37081	**99.8%** (99.1%, 99.9%)	**99.1%** (97.9%, 99.6%)	**98.5%** (97.0%, 99.3%)	**98.5%** (97.0%, 99.3%)	**98.5%** (97.0%, 99.3%)
37082	**99.6%** (98.3%, 99.9%)	**99.3%** (97.9%, 99.8%)	**99.3%** (97.9%, 99.8%)	**99.3%** (97.9%, 99.8%)	**99.3%** (97.9%, 99.8%)
37083	**99.1%** (94.1%, 99.9%)	**97.3%** (92.0%, 99.1%)	**96.2%** (90.0%, 98.6%)	**96.2%** (90.0%, 98.6%)	**96.2%** (90.0%, 98.6%)
7489	**99.1%** (96.5%, 99.8%)	**99.1%** (96.5%, 99.8%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)

Device Survival Probability (95% Confidence Interval) – *Table 2 of 2*

Model Number	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs
37081	**98.5%** (97.0%, 99.3%)	**98.5%** (97.0%, 99.3%)	**98.5%** (97.0%, 99.3%)	-	-	-
37082	**99.3%** (97.9%, 99.8%)	**96.4%** (89.1%, 98.8%)	**96.4%** (89.1%, 98.8%)	-	-	-
37083	**96.2%** (90.0%, 98.6%)	**96.2%** (90.0%, 98.6%)	-	-	-	-

7489	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)

2016 Medtronic Product Performance Report: Data through July 31, 2016.

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Percutaneous Tibial Neuromodulation
- Targeted Drug Delivery for Chronic Pain
- Sacral Neuromodulation
- Spinal Cord Stimulation

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Deep Brain Stimulation Systems

- Study Participants
- Event Summary
- Deep Brain Neurostimulators
- Leads
- Extensions

Study Participants

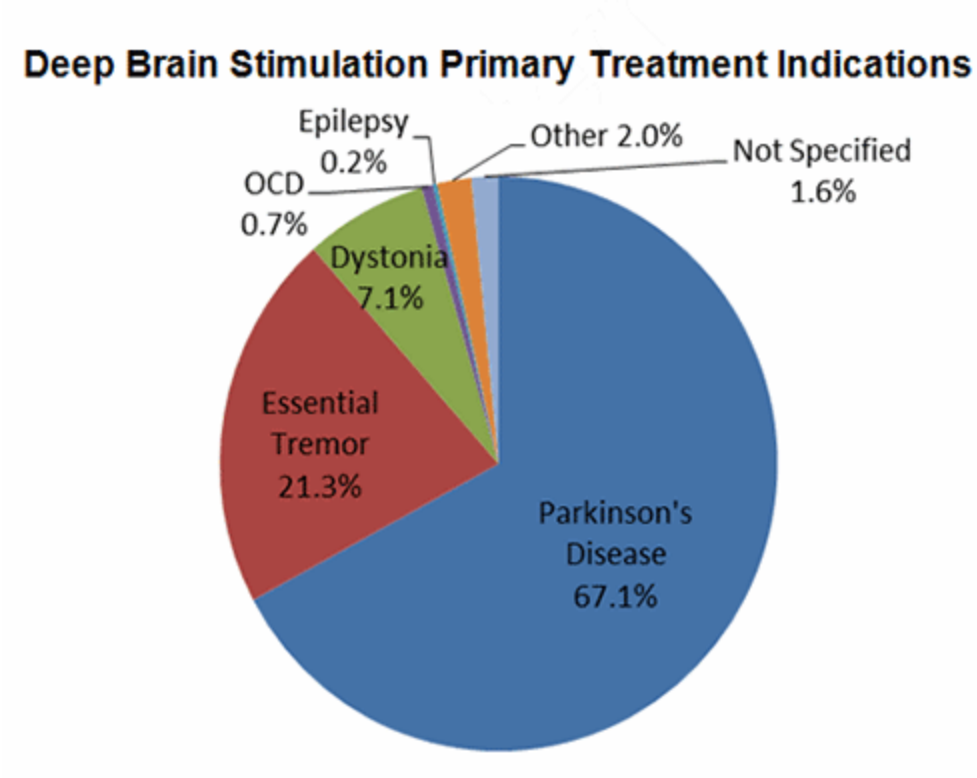
Centers

The following deep brain stimulation tables and graphs were generated based on data collected between July 2009 and the report cut-off date of July 31, 2016. Thirty-six centers enrolled and contributed patients to the deep brain stimulation section of the report.

Patients

Of the 2,109 deep brain stimulation patients enrolled, 67.1% were implanted for the treatment of Parkinson's Disease, 21.3% were implanted for the treatment of Essential Tremor, 7.1% were implanted for the treatment of Dystonia, 2.0% were implanted for the treatment of some other indication, 1.6% were implanted for indications that were not specified in the database, 0.7% were implanted for the treatment of Obsessive Compulsive Disorder, and 0.2% were implanted for the treatment of Epilepsy.

Primary DBS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Parkinson's Disease	1,416 (67.1%)
Essential Tremor	449 (21.3%)
Dystonia	150 (7.1%)
OCD	14 (0.7%)

Epilepsy	5 (0.2%)
Other	42 (2.0%)
Not specified	33 (1.6%)
Total Patients	**2,109**

[a] Refer to product labeling for approved indications.

Event Summary

There were 715 events reported between July 2009 and July 31, 2016 in patients with deep brain stimulation systems. Of these events, 17.3% (124/715) were categorized as product performance-related and are presented graphically within this report. The 124 product performance events occurred in 74 of the 2,109 total patients (3.5%) enrolled. In addition, there were 591 non-product performance events reported. There were also 78 deaths reported for patients with deep brain stimulation systems. None of these deaths were reported as a direct result of a product performance event.

Deep Brain Stimulation System Product Performance Events

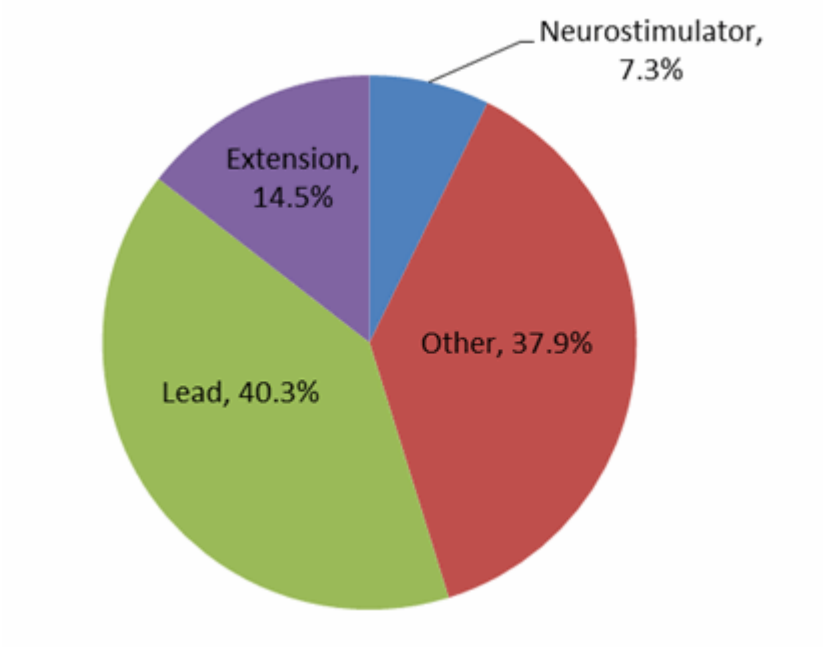
Event[a]	Number of Product Performance Events	Number of Patients with Event[b]	Percent of Patients with Event (N=2,109)
High impedance	57	32	1.5%
Lead fracture	13	9	0.4%
Lead migration/dislodgement	13	7	0.3%
Medical device complication[c]	10	8	0.4%
Device malfunction	6	3	0.1%
Neurostimulator unable to recharge[d]	5	5	0.2%
Extension fracture	3	3	0.1%
Extension migration	3	2	0.1%
Low impedance	3	3	0.1%
Device breakage	2	2	0.1%

Deep Brain Stimulation System Product Performance Events			
Device connection issue	2	1	<0.1%
Impedance increased	2	1	<0.1%
Device defective	1	1	<0.1%
Device failure	1	1	<0.1%
Device migration	1	1	<0.1%
Electromagnetic interference	1	1	<0.1%
Lead insulation breach	1	1	<0.1%
Totals	**124**	**74**	**3.5%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[b] The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[c] Includes 2 events for extension cable loop, 2 events for extension twisting, 1 event reported as open circuit to lead, 1 antenna heating while recharging, 1 suspicion of heating of the antenna while recharging, 1 undesirable interaction with external electronic device, 1 short circuit, and 1 issue with controller not communicating.
[d] There were 254 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.0% (5/254) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

A total of 50 (40.3%) of the 124 product performance events were related to the lead, 26 (21.0%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 18 (14.5%) were related to the extension, 9 (7.3%) were related to the neurostimulator, 6 (4.8%) were related to the recharging process, 6 (4.8%) were related to surgery/anesthesia, 5 (4.0%) were related to other devices, 3 (2.4%) were related to programming/stimulation, and 1 (0.8%) was related to some "other" etiology. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a] Each event could have more than one etiology.

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Movement disorders (including parkinsonism)	**83**
Tremor	37
Dyskinesia	21
Dystonia	12
Bradykinesia	3
Parkinson's disease	3
Other[c]	7
Infections - pathogen unspecified	**79**
Implant site infection	51
Postoperative wound infection	6
Wound infection	6

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Device related infection	4
Infection	4
Other[c]	8
Device issues	**75**
Device stimulation issue	39
Neurostimulator migration	16
Neurostimulator unable to recharge[d]	4
Battery recharge issue	3
Other[c]	13
Neurological disorders Not Elsewhere Classified (NEC)	**56**
Dysarthria	17
Paraesthesia	12
Balance disorder	9
Speech disorder	9
Other[c]	9
Administration site reactions	**42**
Implant site pain	10
Implant site erosion	9
Implant site inflammation	6
Implant site haematoma	4
Other[c]	13
Depressed mood disorders and disturbances	**32**

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Depression	30
Other[c]	2
Procedural related injuries and complications NEC	**25**
Wound dehiscence	14
Other[c]	11
Injuries NEC	**22**
Fall	9
Subdural haematoma	6
Other[c]	7
General system disorders NEC	**17**
Gait disturbance	9
Pain	3
Other[c]	5
Anxiety disorders and symptoms	**11**
Anxiety	8
Other[c]	3
Deliria (including confusion)	**11**
Confusional state	8
Delirium	3
Psychiatric and behavioural symptoms NEC	**11**
Abnormal behaviour	11
Central nervous system vascular disorders	**10**

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Cerebral haematoma	4
Haemorrhage intracranial	4
Other[c]	2
Mental impairment disorders	**8**
Cognitive disorder	4
Other[c]	4
Mood disorders and disturbances NEC	**7**
Apathy	3
Other[c]	4
Physical examination and organ system status topics	**7**
Weight increased	7
Seizures (including subtypes)	**7**
Convulsion	4
Other[c]	3
Suicidal and self-injurious behaviours NEC	**7**
Suicidal ideation	5
Other[c]	2
Musculoskeletal and connective tissue disorders NEC	**5**
Musculoskeletal stiffness	3
Other[c]	2
Disturbances in thinking and perception	**4**
Hallucination	4

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Pulmonary vascular disorders	**3**
Pulmonary embolism	3
Other[c]	**69**
Total	**591**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Composed of event codes with fewer than 3 events each.
[d] Patients were unable to recharge their neurostimulators due to an issue not related to the device.

There were 78 deaths reported for patients with deep brain stimulation systems. None of these deaths were reported as a direct result of a product performance event. A total of 66 (84.6%) deaths occurred in patients receiving therapy for Parkinson's disease and 12 (15.4%) for Essential Tremor.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Parkinson's Disease	66 (84.6%)
Essential Tremor	12 (15.4%)
Total	**78 (100%)**

[a] Refer to product labeling for approved indications

Neurostimulators

From July 2009 to the report cut-off date of July 31, 2016, 2,462 deep brain neurostimulators were followed in the registry. The difference between the total number of patients (N=2,109) versus neurostimulators is due to the fact that some patients have more than one neurostimulator implanted or were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 36,458 months (3,038 years). The table below provides the number and percentage of neurostimulators by model.

Neurostimulators by Model	
Model	**Number of Neurostimulators (%)**
Activa PC (37601)	1,440 (58.5%)
Activa SC (37602/37603)	663 (26.9%)
Activa RC (37612)	257 (10.4%)
Other/Unspecified	22 (0.9%)

Neurostimulators No Longer Manufactured	
Soletra (7426)	68 (2.8%)
Kinetra (7428)	12 (0.5%)
Total	**2,462 (100%)**

Neurostimulator Events

There were 12 product performance-related events with an underlying reported etiology related to deep brain neurostimulator function. This includes 9 events with a neurostimulator etiology, and 3 with both a neurostimulator and other etiology (including device and non-device etiologies). All 12 of these events were the initial product performance event that affected neurostimulator survival estimates. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 28/409 (6.8%). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of deep brain stimulation devices in patients who have expired. There were no anomalies found in the 28 devices that were returned for analysis. The 12 deep brain neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as high impedance (n=5), device malfunction (n=2), medical device complication (n=2), device connection issue (n=1), electromagnetic interference (n=1), and impedance increased (n=1).

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 non-product performance-related or 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:

- 12 had follow-up time cut-off due to a product performance-related event.
- 852 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, other neurostimulator modification, site termination, or non-product performance neurostimulator-related event without an associated intervention.
- 1,598 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

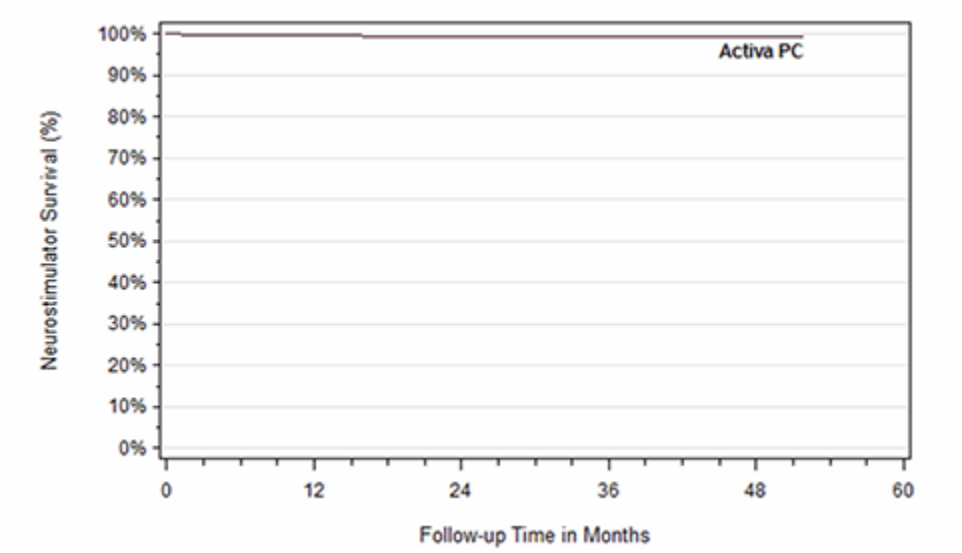
Neurostimulator Survival

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

Choose a model Go

Model 37601 Activa PC: Survival from Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Deep Brain Neurostimulator Characteristics	
Model Name	Activa PC
FDA Approval Date	Apr 2009
Neurostimulators Enrolled	1,440
Neurostimulators Currently Active in Study	1,031
Device Events	7
Cumulative Months of Follow-up	20,638

Model Activa PC: Event Summary Table	
Neurostimulator Event	**Total**
Device malfunction	2
Device connection issuee	1
Electromagnetic interference	1
High impedance[a]	1
Impedance increased[b]	1
Medical device complication[c]	1
Total Neurostimulator Events	**7**

[a] Reported as high impedance attributed to leads, neurostimulator and extensions.
[b]Reported as increased impedance attributed to the neurostimulator and extension.

[c]Reported as undesirable interaction with external electronic device.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (99.0%, 99.9%)	706
2 yrs	**99.3%** (98.3%, 99.7%)	285
3 yrs	**99.3%** (98.3%, 99.7%)	106
4 yrs	**99.3%** (98.3%, 99.7%)	27
at 51 mo	**99.3%** (98.3%, 99.7%)	23

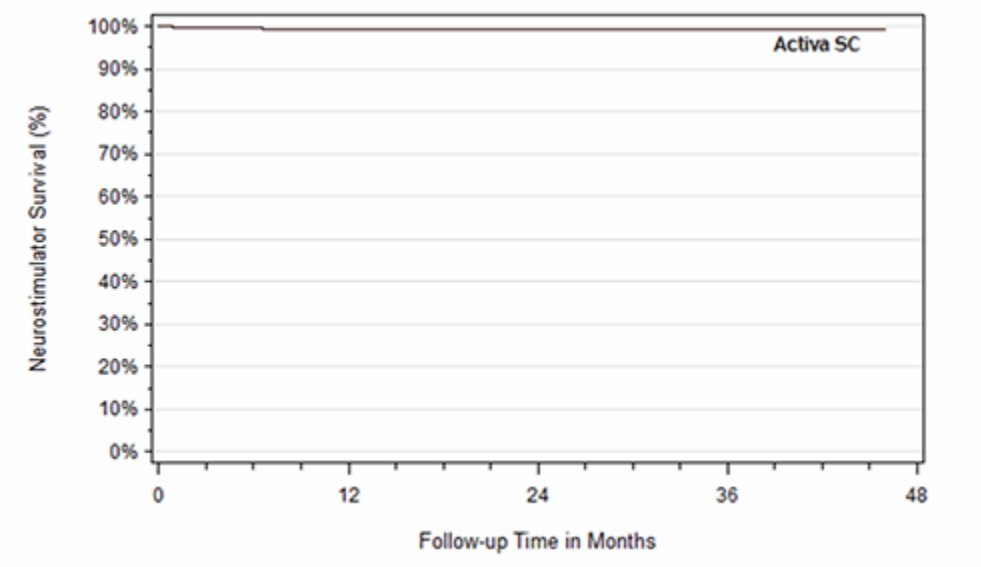
Model 37601 Activa PC: Specifications

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 (additional Information)
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	≤ 4 cm

Models 37602 & 37603 Activa SC: Survival from Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Deep Brain Neurostimulator Characteristics	
Model Name	Activa SC
FDA Approval Date	Jan 2011
Neurostimulators Enrolled	663
Neurostimulators Currently Active in Study	387
Device Events	3
Cumulative Months of Follow-up	9,725

Model Activa SC: Event Summary Table	
Neurostimulator Event	**Total**
High impedance[a]	2
Medical device complication[b]	1
Total Neurostimulator Events	**3**

[a] Includes 2 events reported as high impedance attributed to neurostimulator, leads and extensions.
[b] Reported as short circuit.

Time Interval	Survival	Sample Size

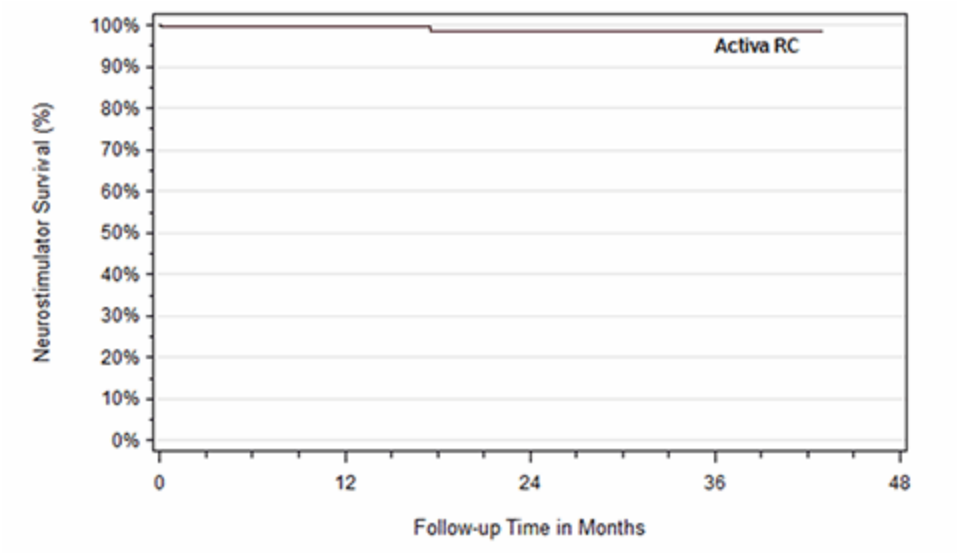
	(95% Confidence Interval)	
1 yr	**99.4%** (98.0%, 99.8%)	327
2 yrs	**99.4%** (98.0%, 99.8%)	159
3 yrs	**99.4%** (98.0%, 99.8%)	54
at 45 mo	**99.4%** (98.0%, 99.8%)	27

Models 37602 & 37603 Activa SC: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc (Model 37602) 27 cc (Model 37603)
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
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)
Implant Depth	≤ 4 cm

Model 37612 Activa RC: Survival from Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Deep Brain Neurostimulator Characteristics	
Model Name	Activa RC
FDA Approval Date	Mar 2009
Neurostimulators Enrolled	257
Neurostimulators Currently Active in Study	175
Device Events	2
Cumulative Months of Follow-up	4,268

Model Activa RC: Event Summary Table	
Neurostimulator Event	**Total**
High impedance[a]	2
Total Neurostimulator Events	**2**

[a]Includes 1 events reported as high impedance attributed to the neurostimulator, extension and lead, and 1 for high impedance attributed to the neurostimulator.

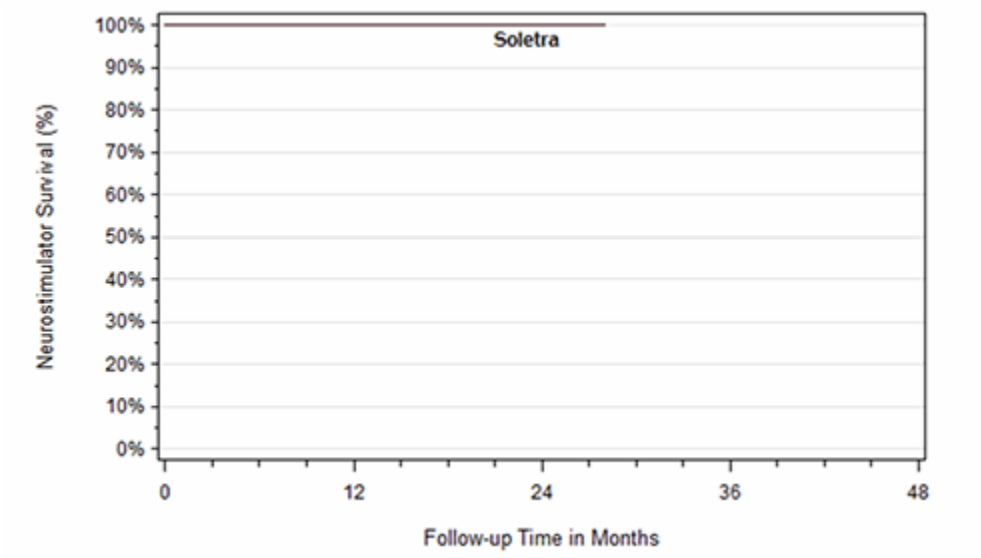
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.5%** (96.8%, 99.9%)	132
2 yrs	**98.6%** (94.0%, 99.7%)	69

3 yrs	**98.6%** (94.0%, 99.7%)	38
at 42 mo	**98.6%** (94.0%, 99.7%)	24

Model 37612 Activa RC: Specifications

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

Model 7426 Soletra: Survival from Neurostimulator Events



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Deep Brain Neurostimulator Characteristics	
Model Name	Soletra
FDA Approval Date	Jan 2002
Neurostimulators Enrolled	68
Neurostimulators Currently Active in Study	4
Device Events	0
Cumulative Months of Follow-up	1,427

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	44
2 yrs	**100.0%** (NA)	27
27 mo	**100.0%** (NA)	20

Model 7426 Soletra: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Non-rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	3 - 185 Hz
Pulse Width	30 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

Deep Brain Neurostimulator Survival Summary

Deep Brain Neurostimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events	Cumulative Months of Follow-up
Activa PC	Activa	Apr 2009	1,440	1,031	7	20,638
Activa SC	Activa	Jan 2011	663	387	3	9,725
Activa RC	Activa	Mar 2009	257	175	2	4,268
Soletra	Soletra	Jan 2002	68	4	0	1,427

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs	3 yrs	4 yrs
Activa PC	**99.6%** (99.0%, 99.9%)	**99.3%** (98.3%, 99.7%)	**99.3%** (98.3%, 99.7%)	**99.3%** (98.3%, 99.7%)
Activa SC	**99.4%** (98.0%, 99.8%)	**99.4%** (98.0%, 99.8%)	**99.4%** (98.0%, 99.8%)	-
Activa RC	**99.5%** (96.8%, 99.9%)	**98.6%** (94.0%, 99.7%)	**98.6%** (94.0%, 99.7%)	-
Soletra	**100.0%** (NA)	**100.0%** (NA)	-	-

Leads

From July 2009 to the report cut-off date of July 31, 2016, there were 3,293 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=2,462) were due to the fact that some patients were implanted with more than 1 lead or were subsequently re-implanted with a new lead. The aggregate prospective follow-up time for all leads was 57,102 months (4,758 years).

A lead is a set of thin wires with a protective coating and electrodes near the tip. The table below provides the number and percentage of leads by model.

Leads by Model	
Model Number	**Number of Leads (%)**
3389 (compact electrode spacing)	1,852 (56.2%)
3387 (standard electrode spacing)	1,408 (42.8%)
3391	22 (0.7%)
Other/Unspecified	11 (0.3%)
Total	**3,293 (100%)**

Lead Events

There were 66 product performance-related events with an underlying reported etiology related to the lead. This includes 50 events with a lead etiology and 16 events with both a lead and other etiology (including device and non-device etiologies). Thirty-seven events were high impedance, 13 were lead fracture, 8 were lead migration/dislodgement, 3 were low impedance, 2 were device malfunction, 1 was medical device complication, 1 was device defective, and 1 was device failure. Of the 66 events, 38 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 non-product performance-related or 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:

- 38 had follow-up time cut-off due to product performance-related events.
- 828 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, site termination, therapy suspended, or other lead modification, or non-product performance

lead-related event without an associated intervention.
- 2,427 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

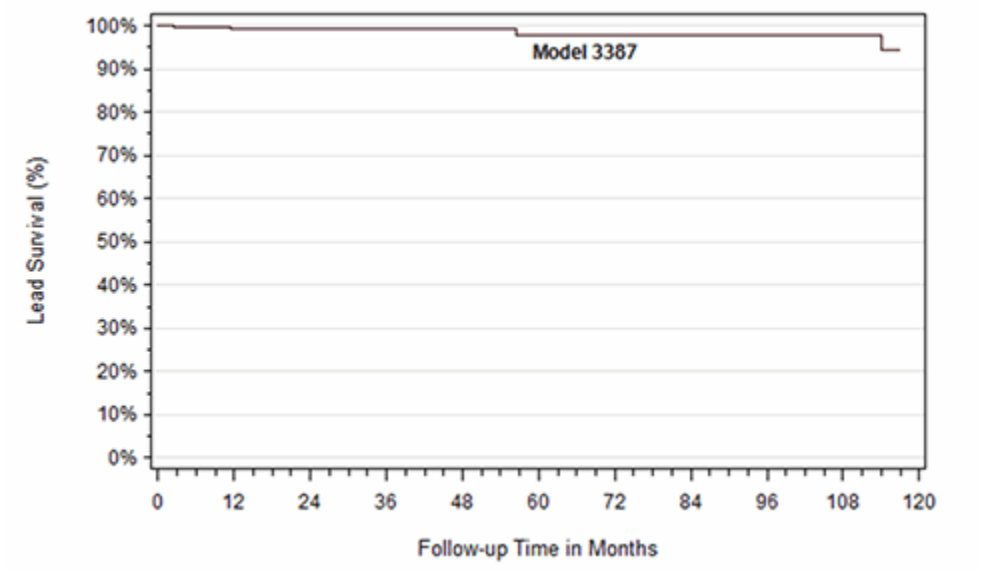
Lead Survival

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

Choose a model Go

Model 3387: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3387
FDA Approval Date	Jan 2002
Leads Enrolled	1,408
Leads Currently Active in Study	994
Device Events	10
Cumulative Months of Follow-up	25,137

Model 3387: Event Summary Table	
Lead Event	**Total**

High impedance	6
Lead fracture	1
Low impedance	1
Lead migration/dislodgement	1
Medical device complication[a]	1
Total Lead Events	**10**

[a] Reported as open circuit of lead.

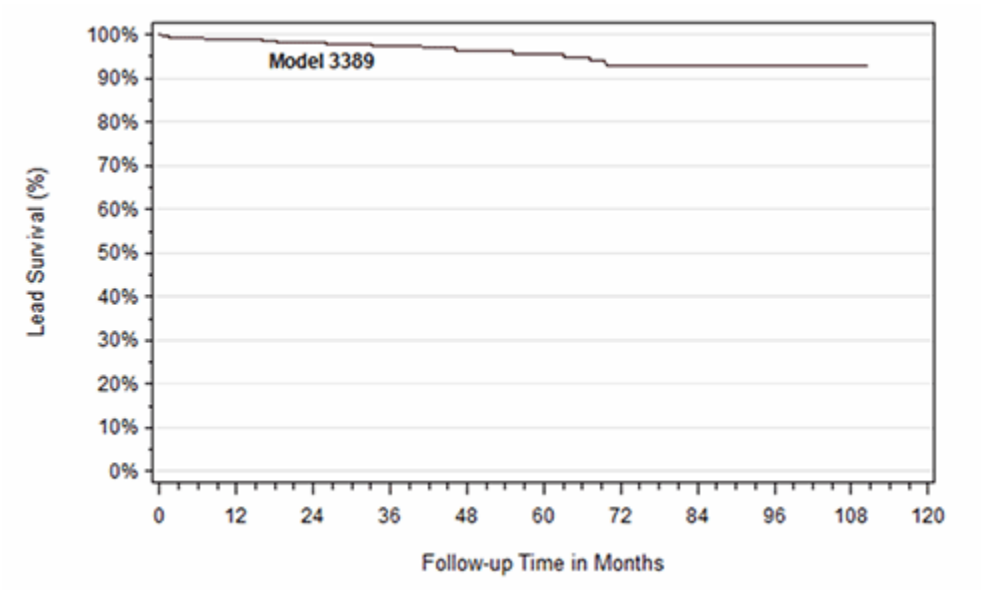
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.3%** (98.5%, 99.7%)	675
2 yrs	**99.1%** (98.0%, 99.6%)	341
3 yrs	**99.1%** (98.0%, 99.6%)	187
4 yrs	**99.1%** (98.0%, 99.6%)	114
5 yrs	**97.8%** (92.9%, 99.3%)	49
6 yrs	**97.8%** (92.9%, 99.3%)	32
7 yrs	**97.8%** (92.9%, 99.3%)	42
8 yrs	**97.8%** (92.9%, 99.3%)	38
9 yrs	**97.8%** (92.9%, 99.3%)	29
at 117 mo	**94.2%** (80.4%, 98.4%)	20

Model 3387: Specifications

Model Number	**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

Model 3389: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3389
FDA Approval Date	Sep 1999
Leads Enrolled	1,852

Leads Currently Active in Study	1,440
Device Events	27
Cumulative Months of Follow-up	31,496

Model 3389: Event Summary Table

Lead Event	Total
High impedance	18
Lead fracture	5
Lead migration/dislodgement	2
Device defective	1
Low impedance	1
Total Lead Events	**27**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.0% (98.2%, 99.4%)	779
2 yrs	98.1% (96.9%, 98.9%)	398
3 yrs	97.5% (95.8%, 98.5%)	234
4 yrs	96.3% (93.7%, 97.9%)	148
5 yrs	95.6% (92.2%, 97.5%)	118
6 yrs	93.0% (88.1%, 95.9%)	95
7 yrs	93.0% (88.1%, 95.9%)	85
8 yrs	93.0% (88.1%, 95.9%)	59
9 yrs	93.0% (88.1%, 95.9%)	28

at 111 mo	93.0% (88.1%, 95.9%)	23

Model 3389: Specifications

Model Number	**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 Survival Summary

Lead Characteristics

Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
3387	**3387**	Jan 2002	1,408	994	10	25,137
3389	**3389**	Sep 1999	1,852	1,440	27	31,496

[a] There were a total of 66 lead-related events reported to the registry, but only 37 events included in this summary table. The remaining lead-related events occurred in a lead model for which no device survival data are presented due to an insufficient number of enrolled devices (n=1) or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval) – ***Table 1 of 2***

Model Number	Family	1 yr	2 yrs	3 yrs	4 yrs
3387	**3387**	**99.3%** (98.5%, 99.7%)	**99.1%** (98.0%, 99.6%)	**99.1%** (98.0%, 99.6%)	**99.1%** (98.0%, 99.6%)

3389	**3389**	**99.0%** (98.2%, 99.4%)	**98.1%** (96.9%, 98.9%)	**97.5%** (95.8%, 98.5%)	**96.3%** (93.7%, 97.9%)

Device Survival Probability (95% Confidence Interval) – ***Table 2 of 2***

Model Number	Family	5 yrs	6 yrs	7 yrs	8 yrs	9 yrs
3387	**3387**	**97.8%** (92.9%, 99.3%)	**97.8%** (92.9%, 99.3%)	**97.8%** (92.9%, 99.3%)	**97.8%** (92.9%, 99.3%)	**97.8%** (92.9%, 99.3%)
3389	**3389**	**95.6%** (92.2%, 97.5%)	**93.0%** (88.1%, 95.9%)	**93.0%** (88.1%, 95.9%)	**93.0%** (88.1%, 95.9%)	**93.0%** (88.1%, 95.9%)

Extensions

From July 2009 to the report cut-off date of July 31, 2016, there were 3,307 extensions followed in the registry. Differences between the total number of extensions versus the total number of neurostimulators (N=2,462) were due to the fact that some patients were implanted with more than 1 extension or subsequently re-implanted with an extension. In addition, the number of extensions does not equal the number of leads (N=3,293) because some patients were re-implanted with a new lead using existing extensions. The aggregate prospective follow-up time for all extensions was 56,121 months (4,677 years).

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. The table below provides the number and percentage of extensions by model.

Extensions by Model

Model	Number of Extensions (%)
37086[a] (quadripolar stretch)	2,782 (84.1%)
Other/Unspecified	94 (2.8%)
Extensions No Longer Manufactured	
7482 (quadripolar)	431 (13.0%)
Total	**3,307 (100%)**

[a] Includes Models 37085 and 37086

Extension Events

There were 23 product performance-related events with an underlying reported etiology related to the extension. This includes 18 events with an extension etiology and 5 events with both an extension and other etiology (including device and non-device etiologies). Eleven events were high impedance attributed to the extensions, 4 were medical device complications, 3 were extension fractures, 2 were extension migrations, 1 was device malfunction, 1 was device connection issue, and 1 was impedance increased. Of the 23 events, 15 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 non-product performance-related or 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:

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

- 850 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, therapy suspended, other extension modification, or non-product performance extension-related event without an associated intervention.
- 2,442 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

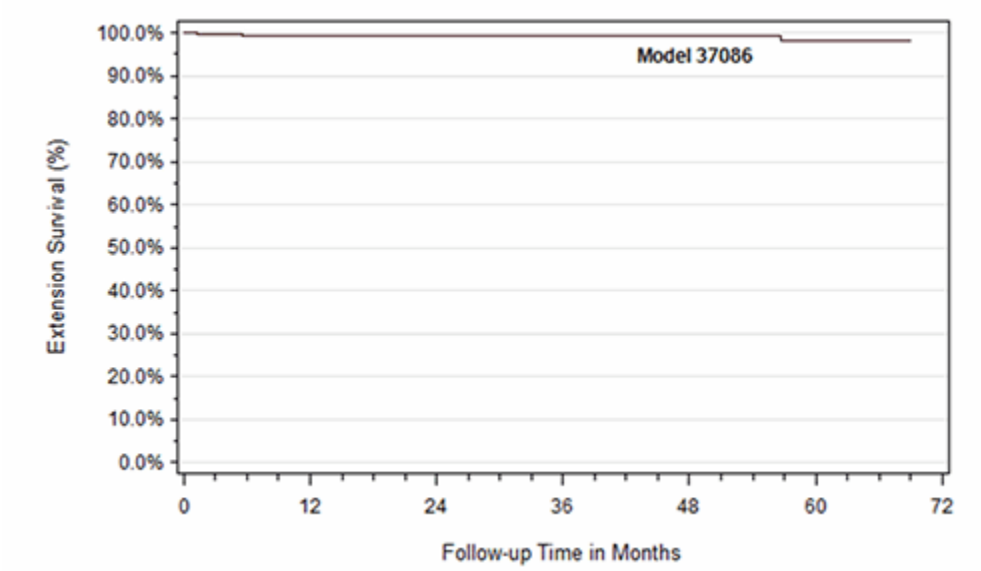
Extension Survival

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

Choose a model Go

Model 37086: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



View Larger Image

Extension Characteristics	
Model Number	37086
FDA Approval Date	Sep 2009
Extensions Enrolled	2,782
Extensions Currently Active in Study	2,063
Device Events	15
Cumulative Months of Follow-up	46,254

Model 37086 Extension: Event Summary Table	
Extension Event	**Total**

High impedance	7
Medical device complication[a]	4
Extension migration	2
Extension fracture	1
Impedance increased[b]	1
Total Extension Events	**15**

[a] Includes 2 events for extension cable loop, and 2 events for twisting of extensions.
[b] Reported as increased impedance attributed to the neurostimulator and extension.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.5% (99.0%, 99.7%)	1,407
2 yrs	99.3% (98.8%, 99.6%)	699
3 yrs	99.3% (98.8%, 99.6%)	378
4 yrs	99.3% (98.8%, 99.6%)	190
5 yrs	98.3% (94.7%, 99.5%)	57
at 69 mo	98.3% (94.7%, 99.5%)	29

Model 37086 Extension: Specifications

Device Name	Stretch-Coil® DBS Extension
Length (cm)	40, 40, 95
Distal End Compatibility	3387, 3389, or 3391 DBS lead
Distal End Set Screws	4
Proximal End INS Compatibility	Activa® RC, Activa PC, or Activa SC 37603

Extension Survival Summary

Extension Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**
37086[b]	37086	Sep 2009	2,782	2,063	15	46,254

Device Survival Probability (95% Confidence Interval)					
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**
37086[b]	**99.5%** (99.0%, 99.7%)	**99.3%** (98.8%, 99.6%)	**99.3%** (98.8%, 99.6%)	**99.3%** (98.8%, 99.6%)	**98.3%** (94.7%, 99.5%)

[a] There were a total of 23 extension-related events reported to the registry, but only 15 events included in this summary table. The remaining events were subsequent events that did not affect the device survival estimates.
[b] Includes Models 37085 and 37086

2016 Medtronic Product Performance Report: Data through July 31, 2016.

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Percutaneous Tibial Neuromodulation
- Targeted Drug Delivery for Chronic Pain
- Sacral Neuromodulation
- Spinal Cord Stimulation

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Sacral Neuromodulation Systems

- Study Participants
- Event Summary
- Neurostimulators
- Leads
- Extensions

Study Participants

Centers

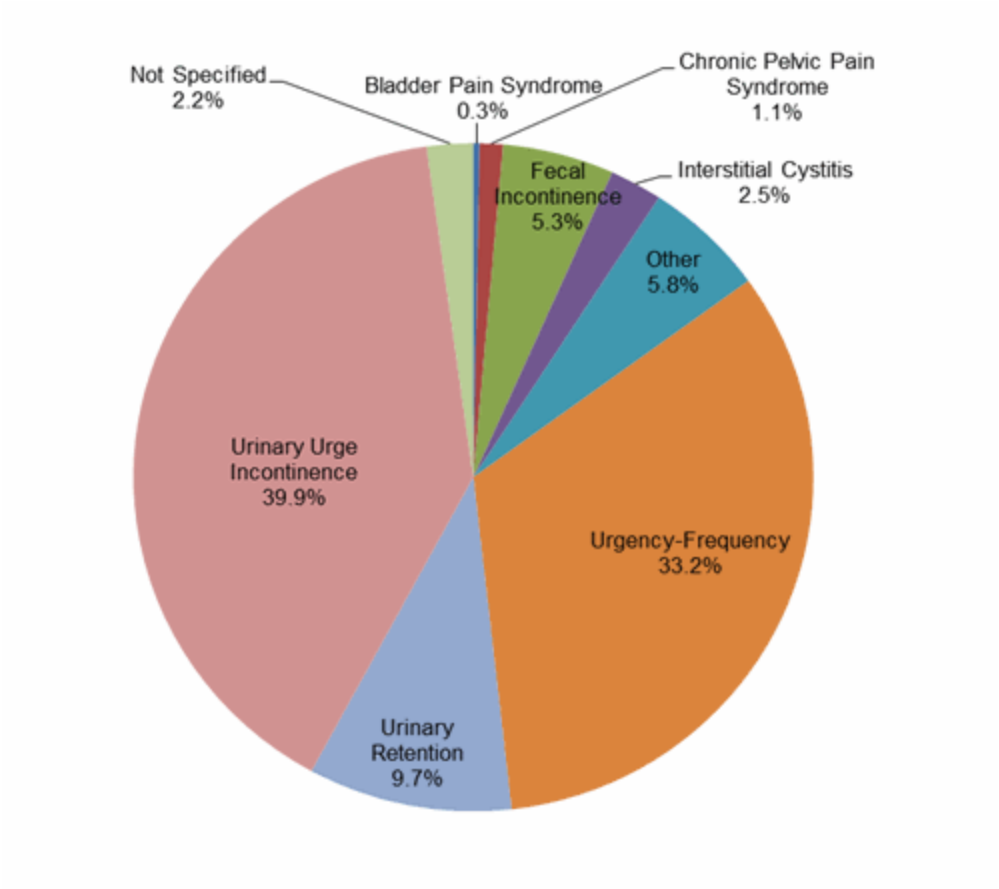
The following sacral neuromodulation tables and graphs were generated based on data collected between April 2010 and the report cut-off date of July 31, 2016. Nineteen centers enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 756 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 39.9% were implanted for the treatment of urinary urge incontinence, 33.2% were implanted for the treatment of urgency-frequency, 9.7% were implanted for the treatment of urinary retention, 5.8% were implanted for the treatment of some other indication, 5.3% were implanted for the treatment of fecal incontinence, 2.5% were implanted for the treatment of interstitial cystitis, 1.1% were implanted for the treatment of chronic pelvic pain syndrome, 0.3% were implanted for the treatment of bladder pain syndrome, and 2.2% were implanted for indications that were not specified in the database.

Primary SNM Treatment Indications

Sacral Neuromodulation Primary Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Urinary Urge Incontinence	302 (39.9%)
Urgency-Frequency	251 (33.2%)
Urinary Retention	73 (9.7%)
Fecal Incontinence	40 (5.3%)
Interstitial Cystitis	19 (2.5%)
Chronic Pelvic Pain Syndrome	8 (1.1%)
Painful Bladder Syndrome	2 (0.3%)
Other	44 (5.8%)
Not specified	17 (2.2%)
Total Patients	**756**

[a] Refer to product labeling for approved indications.

Event Summary

There were 300 events reported between April 2010 and July 31, 2016 in patients with sacral neuromodulation systems. Of these events, 23.0% (69/300) were categorized as product performance-related and are presented graphically within this report. The 69 product performance events occurred in 57 of the 756 total patients (7.5%) enrolled. In addition, there were 231 non-product performance events reported. There were also 16 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a product performance event.

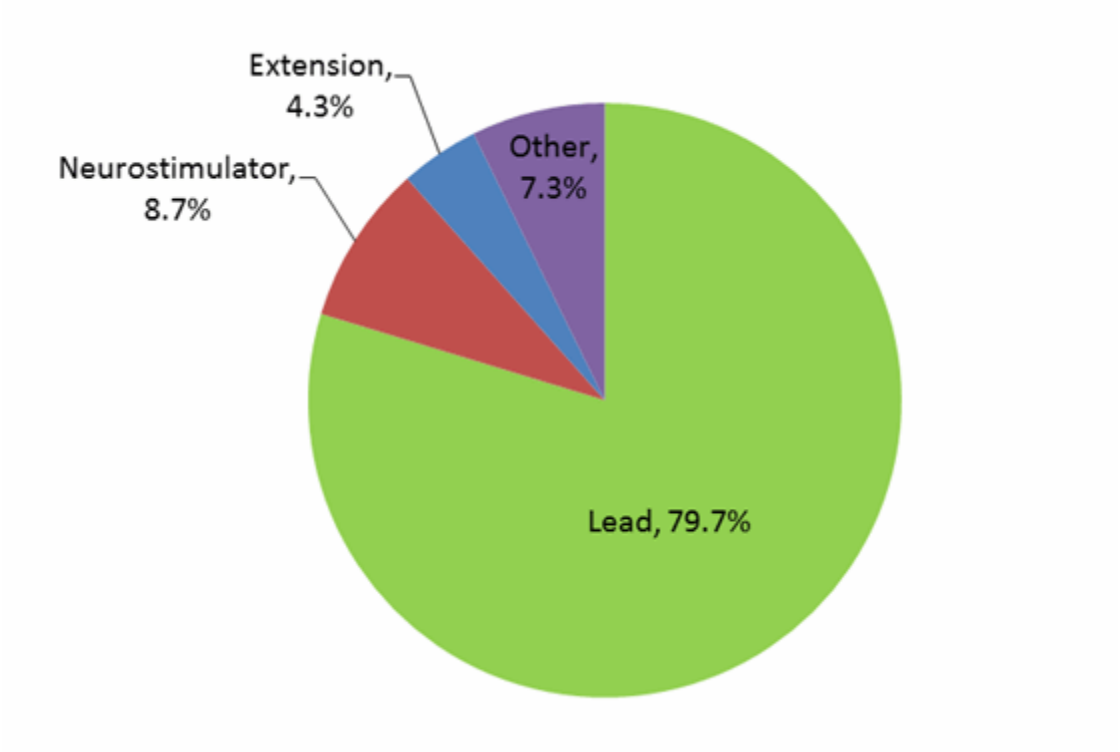
Sacral Neuromodulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event	Percent of Patients with Event (n=756)
High impedance	30	25	3.3%
Lead migration/dislodgement	12	11	1.5%
Lead fracture	9	8	1.0%
Low impedance	6	6	0.8%
Device battery issue	4	1	0.1%
Device electrical impedance issue	2	1	0.1%
Device malfunction[b]	2	2	0.3%
Device lead damage	1	1	0.1%
Device lead issue	1	1	0.1%
Device telemetry issue	1	1	0.1%
Lead migration	1	1	0.1%
Total	**69**	**57**	**7.5%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[b] Includes 1 event reported as device function could not be restored after a fall and 1 neurostimulator malfunction.

A total of 55 (79.7%) of the 69 product performance events were related to the lead, 6 (8.7%) were related to the neurostimulator, 3 (4.3%) were related to the extension, 2 (2.9%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 1 (1.4%) was related to some "other device", 1 (1.4%) was related to some "other etiology", and 1 (1.4%) was related to programming/stimulation. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a]Each event could have more than one etiology.

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Infections - pathogen unspecified	**101**
Urinary tract infection[c]	83
Implant site infection	9
Wound infection	4
Incision site infection	2
Cystitis	1
Infection	1
Postoperative wound infection	1
Therapeutic and nontherapeutic effects (excluding toxicity)	**29**
Therapeutic product ineffective	27

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Therapeutic response decreased	2
Administration site reactions	**26**
Implant site pain	25
Implant site erythema	1
Device issues	**20**
Device stimulation issue	14
Neurostimulator migration	3
Neurostimulator inversion	2
Device extrusion	1
Urinary tract signs and symptoms	**13**
Urinary incontinence	5
Micturition urgency	3
Urge incontinence	2
Bladder pain	1
Incontinence	1
Urinary retention	1
Neurological disorders Not Elsewhere Classified (NEC)	**11**
Paraesthesia	9
Restless legs syndrome	1
Sensory disturbance	1
General system disorders NEC	**9**
Pain	5

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
No anomaly found by RPA[d]	1
Oedema	1
Sensation of pressure	1
Swelling	1
Bacterial infectious disorders	**4**
Staphylococcal infection	2
Cellulitis	1
Implant site cellulitis	1
Therapeutic procedures and supportive care NEC	**4**
Incisional drainage	3
Wound drainage	1
Complications associated with device	**2**
Medical device discomfort	2
Epidermal and dermal conditions	**2**
Rash	1
Skin reaction	1
Musculoskeletal and connective tissue disorders NEC	**2**
Groin pain	1
Pain in extremity	1
Reproductive tract disorders NEC	**2**
Pelvic pain	2
Anal and rectal conditions NEC	**1**

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Proctalgia	1
Bone disorders (excluding congenital and fractures)	**1**
Bone pain	1
Genitourinary tract disorders NEC	**1**
Urinary tract disorder	1
Joint disorders	**1**
Arthralgia	1
Procedural related injuries and complications NEC	**1**
Procedural complication	1
Vulvovaginal disorders (excluding infections and inflammations)	**1**
Vulvovaginal pain	1
Totals	**231**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Therapy relevant event collected per registry protocol but not device related.
[d] For products that are returned with a suspected device issue, and RPA establishes a root cause or finds no anomaly, results reported herein reflect the finding from Returned Product Analysis (RPA).

There were 16 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a product performance event. Eight deaths occurred in patients receiving therapy for urgency-frequency, 4 deaths for other indications, 3 deaths for urinary urge incontinence and 1 for urinary retention.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Urgency-frequency	8 (50.0%)
Other[b]	4 (25.0%)
Urinary urge incontinence	3 (18.8%)

Death by Primary Indication	
Urinary retention	1 (6.3%)
Total	**16 (100%)**

[a] Refer to product labeling for approved indications.
[b] Includes 1 indication of atony of bladder, 1 of neurogenic bladder, 1 of BPH without urinary obstruction, and 1 of urinary tract infection.

Neurostimulators

From April 2010 to the report cut-off date of July 31, 2016, 705 neurostimulators were followed in the registry. The difference between the total number of patients (n=756) versus neurostimulators (n=705) is due to the fact that patients could enroll prior to implant but may not have received an implanted device, or patients were enrolled but not implanted before the data cut-off.

Over eighty-six percent (86.5%) of neurostimulators were InterStim II (n=610), and 13.5% (n=95) were InterStim. The aggregate prospective follow-up time for all neurostimulators was 11,523 months (960 years).

Neurostimulator Events

There were 6 product performance-related events with an underlying reported etiology related to neurostimulator function. All 6 of these events were the initial product performance event that affected neurostimulator survival estimates. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 14/82 (17%). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of stimulation devices in patients who have expired. There were no anomalies found in the 14 devices that were returned for analysis. The 6 neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as high impedance (n=2), device malfunction (n=2), device electrical impedance issue (n=1), and device battery issue (n=1).

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 non-product performance-related or 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:

- 6 had follow-up cut-off due to product performance-related events.
- 292 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, other neurostimulator modification, or non-product performance neurostimulator-related event with no associated intervention.
- 407 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

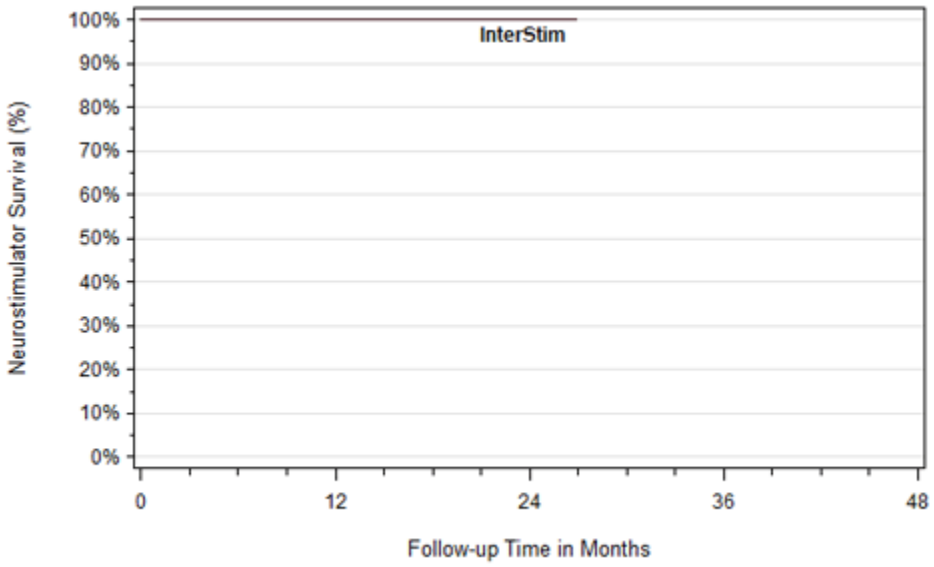
Neurostimulator Survival

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

Choose a model Go

Model 3023 InterStim: Survival from Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Neurostimulator Characteristics	
Model Name	InterStim
FDA Approval Date	Jul 1998
Neurostimulators Enrolled	95
Neurostimulators Currently Active in Study	61
Device Events	1[a]
Cumulative Months of Follow-up	2,115

[a]Event occurred at 37 months of follow-up.

Model 3023 InterStim: Event Summary Table	
Neurostimulator Event	**Total**
Device battery issue	1
Total Neurostimulator Events	**1**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	57
2 yrs	100.0% (NA)	44
3 yrs	100.0% (NA)[a]	24

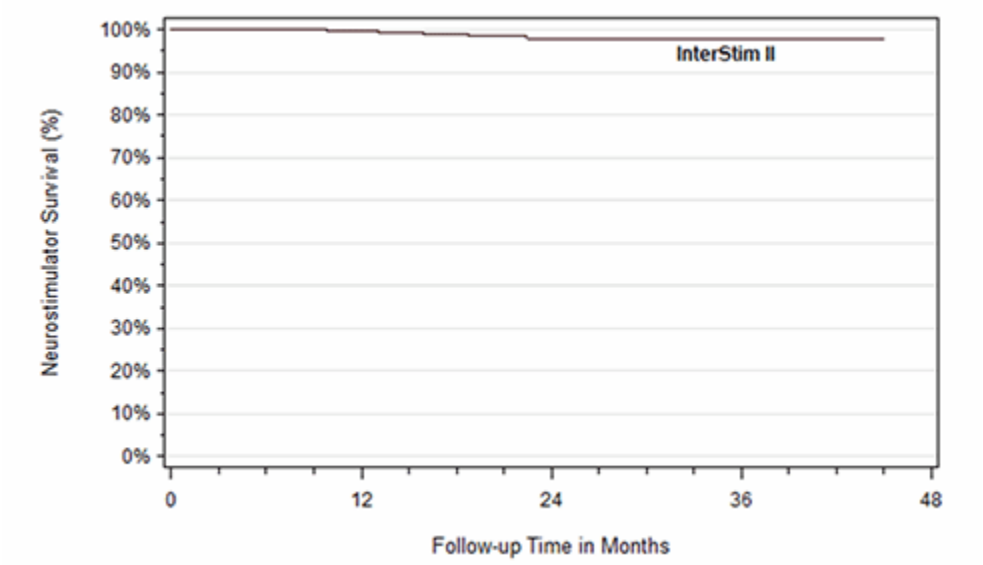
[a]Event occurred at 37 months of follow-up.

Model 3023 InterStim: Specifications

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 (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 µsec
Programs	4
Implant Depth	≤ 4 cm

Model 3058 InterStim II: Survival from Neurostimulator Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Neurostimulator Characteristics	
Model Name	InterStim II
FDA Approval Date	Jun 2006
Neurostimulators Enrolled	610
Neurostimulators Currently Active in Study	362
Device Events	5
Cumulative Months of Follow-up	9,409

Model 3058 InterStim II: Event Summary Table

Neurostimulator Event	Total
High impedance[a]	2
Device malfunction[b]	2
Device electrical impedance issue	1
Total Neurostimulator Events	**5**

[a] Includes 2 events reported as high impedance attributed to both lead and neurostimulator.
[b] Includes 1 event reported as device function could not be restored after a fall and 1 neurostimulator malfunction.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.7% (98.0%, 100.0%)	323
2 yrs	97.9% (94.9%, 99.2%)	145
3 yrs	97.9% (94.9%, 99.2%)	54
45 mo	97.9% (94.9%, 99.2%)	27

Model 3058 InterStim II: Specifications

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 (additional Information)
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 Survival Summary

Neurostimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
InterStim	InterStim	Jul 1998	95	61	1	2,115
InterStim II	InterStim	Jun 2006	610	362	5	9,409

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs	3 yrs
InterStim	**100.0%** NA	**100.0%** NA	**100.0%** NA
InterStim II	**99.7%** (98.0%, 100.0%)	**97.9%** (94.9%, 99.2%)	**97.9%** (94.9%, 99.2%)

[a] The event for the InterStim device occurred at 37 months of follow-up, a point beyond which the survival estimates are provided due to a low number of active devices (less than 20).

Leads

From April 2010 to the report cut-off date of July 31, 2016, there were 695 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=705) were 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 11,314 months (943 years).

A lead is a set of thin wires with a protective coating and electrodes near the tip. The table below provides the number and percentage of leads by model.

Leads by Model

Model	Number of Leads (%)
3889 (tined)	604 (86.9%)
Unspecified	2 (0.3%)
Leads No Longer Manufactured	
3093 (tined)	85 (12.2%)
3080	3 (0.4%)
3092	1 (0.1%)
Total	**695 (100%)**

Lead Events

There were 57 product performance-related events with an underlying reported etiology related to the lead. This includes 55 events with a lead etiology and 2 events with both a lead and other etiology (including device and non-device etiologies). The majority of the events were high impedance (n=28). Of the 57 product performance-related lead events, 49 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 non-product performance-related or 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:

- 49 had follow-up time cut-off due to product performance-related events.
- 249 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, other lead modification, therapy suspended, or non-product performance lead-related event without an associated intervention.
- 397 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

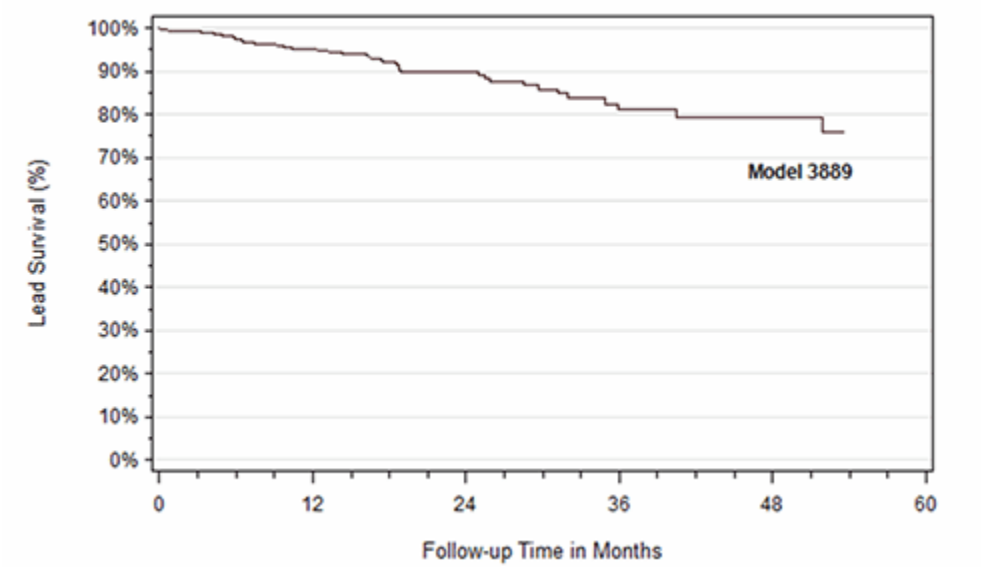
Lead Survival

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

Choose a model Go

Model 3889: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3889
FDA Approval Date	Sep 2002
Leads Enrolled	604
Leads Currently Active in Study	375
Device Events	44
Cumulative Months of Follow-up	9,454

Model 3889: Event Summary Table

Lead Event	Total
High impedance	22
Lead migration/dislodgement	8
Lead fracture	7
Low impedance	6
Device electrical impedance issue	1
Total Lead Events	**44**

Time Interval	Survival (95% Confidence Interval)	Sample Size

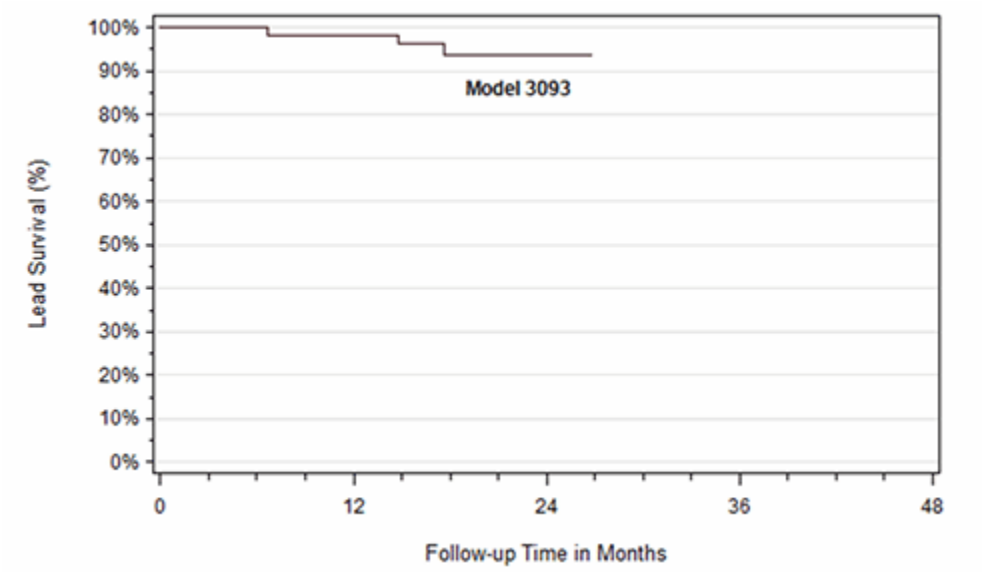
1 yr	**95.2%** (92.6%, 96.9%)	293
2 yrs	**89.8%** (85.6%, 92.8%)	139
3 yrs	**81.0%** (73.5%, 86.6%)	56
4 yrs	**79.4%** (71.1%, 85.5%)	29
at 54 mo	**76.0%** (65.0%, 84.0%)	20

Model 3889 Tined Lead: Specifications

Model Number	**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

Model 3093: Survival from Lead Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Lead Characteristics	
Model Number	3093
FDA Approval Date	Sep 2002
Leads Enrolled	85
Leads Currently Active in Study	41
Device Events	4
Cumulative Months of Follow-up	1,780

Model 3093: Event Summary Table Lead Event	Total
Device lead damage	1
High impedance	1
Lead fracture	1
Lead migration/dislodgement	1
Total Lead Events	**4**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.3%** (88.5%, 99.8%)	48

2 yrs	**93.6%** (81.3%, 97.9%)	29
at 27 mo	**93.6%** (81.3%, 97.9%)	25

Model 3093 Tined Lead: Specifications

Model Number	**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 Survival Summary

Lead Characteristics

Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
3889	**3889**	Sep 2002	604	375	44	9,454
3093	**3093**	Sep 2002	85	41	4	1,780

[a] There were 57 lead-related events reported to the registry, but only 48 events included in this summary table. The remaining events occurred in a lead model for which no device survival curve is presented due to an insufficient number of enrolled devices (i.e., Model 3080) (n=1) or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval)

Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**

3889	**95.2%** (92.6%, 96.9%)	**89.8%** (85.6%, 92.8%)	**81.0%** (73.5%, 86.6%)	**79.4%** (71.1%, 85.5%)
3093	**98.3%** (88.5%, 99.8%)	**93.6%** (81.3%, 97.9%)	**-**	**-**

Extensions

From April 2010 to the report cut-off date of July 31, 2016, there were 94 extensions followed in the registry. Differences between the total number of extensions versus the total neurostimulators (N=705) were due to the fact that not all systems require an extension.

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead (not required for all neurostimulation systems). All the extensions were Model 3095. The aggregate prospective follow-up time for all extensions was 2,185 months (182 years).

Extension Events

There were 3 product performance-related events with an underlying reported etiology related to the extension. Of these 3 events, 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 non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

- 1 had follow-up time cut-off due to product performance-related events.
- 33 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, or therapy suspended.
- 60 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.

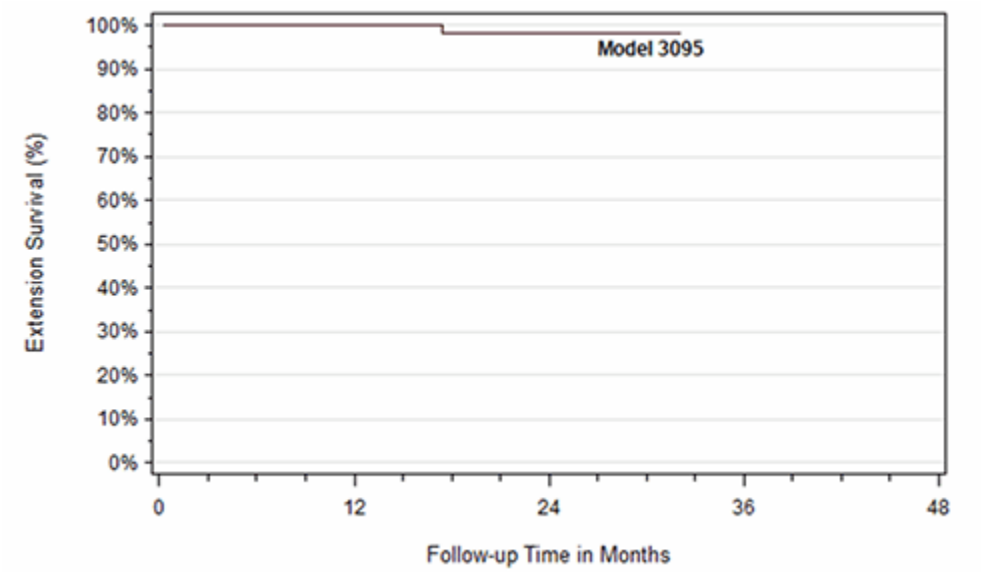
Extension Survival

The figure and table below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval unless otherwise noted.

Choose a model Go

Model 3095: Survival from Extension Events

Data are shown if there are at least 20 devices in each 3-month interval.



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Extension Characteristics	
Model Number	3095
FDA Approval Date	Jul 1998
Extensions Enrolled	94
Extensions Currently Active in Study	61
Device Events	1
Cumulative Months of Follow-up	2,185

Model 3095: Event Summary Table	
Lead fracture[a]	1
Total Extension Events	**1**

[a]Lead fracture attributed to both the lead and extension.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	56
2 yrs	**98.0%** (86.8%, 99.7%)	40
at 33 mo	**98.0%** (86.8%, 99.7%)	24

Model 3095 Extension: Specifications

Device Name	Quadripolar Extension
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 Survival Summary

Extension Characteristics

Model Number	Family	FDA Approval Date	Extensions Enrolled	Extensions Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
3095	3095	Jul 1998	94	61	1	2,185

Device Survival Probability (95% Confidence Interval)

Model Number	1 yr	2 yrs
3095	**100.0%** NA	**98.0%** (86.8%, 99.7%)

[a] There were a total of 3 extension-related events reported to the registry, but only 1 event included in this summary table. The remaining events were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

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Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Percutaneous Tibial Neuromodulation
- Targeted Drug Delivery for Chronic Pain
- Sacral Neuromodulation
- Spinal Cord Stimulation

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