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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. In addition, PSR captures further information on select patient reported outcomes. This 2015 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 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 stimulators, leads, and extensions) for pain indications were later added to the registry. Implanted spinal cord stimulators 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 58 centers that have contributed data for targeted drug delivery systems, 72 centers for spinal cord stimulation systems, 32 centers for deep brain stimulation, and 19 centers for sacral neuromodulation. There are 29, 36, 24, and 13 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 8th 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 12,900 patients in our ongoing post-market registry. The registry now includes over 38,700 pumps, catheters, neurostimulators, leads, and extensions. Data on other events not directly attributed to product performance are also included in an effort 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 at this time.

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, Reimbursement and Regulatory Affairs
Medtronic, Inc.

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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RestoreUltra® neurostimulator	Soletra® neurostimulator
RestoreSensor® neurostimulator	Kinetra® neurostimulator
InterStim® neurostimulator	Activa® neurostimulator
RestoreSensor® SureScan® MRI neurostimulator	RestoreUltra® SureScan® MRI neurostimulator
PrimeAdvanced® SureScan® MRI neurostimulator	SynergyCompact® neurostimulator
RestoreAdvanced® SureScan® MRI neurostimulator	Vectris® SureScan® leads

2015 Medtronic Product Performance Report: Data through July 31, 2015

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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Methodology

- Event Classification
- Device Survival Analyses
- Returned Product Analysis

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

All deaths are 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. An issue is defined as: the device is not functioning within specifications or programmed settings, whether or not it is associated with an adverse event.

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 the last 3-month time point where at least 20 total devices were still being followed, except where otherwise noted. 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 an 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.

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Targeted Drug Delivery Systems

Study Participants

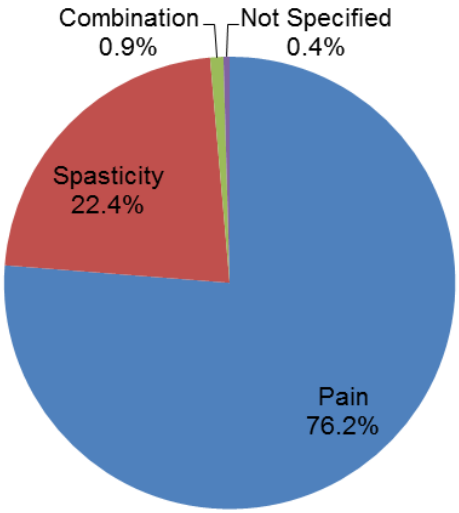
Centers

The following tables and graphs were generated based on data collected between August 7, 2003 and the report cut-off date of July 31, 2015. Fifty-eight centers enrolled and contributed patients to the targeted drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 6,953 total targeted drug delivery system patients enrolled through July 31, 2015. As indicated, 57.4% 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 22.4% for treatment of spasticity, and 18.9% for treatment of malignant pain (pain related to cancer). Primary treatment indication is provided by the physician. The data are representative of the overall population of patients receiving new pump implants in the United States, with the minor exception of malignant pain, which is slightly over-represented (Registry = 18.9% versus U.S. population = 13.9% - data based on Device and Registrant Tracking).

TDD System Primary Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Pain	**5,301 (76.2%)**
Malignant Pain	1,313 (18.9%)
Non-Malignant Pain	3,988 (57.4%)

Spasticity	**1,555 (22.4%)**
Combination	**66 (0.9%)**
Non-Malignant Pain & Spasticity	66 (0.9%)
Not Specified	**31 (0.4%)**
Total Subjects	**6,953**

[a] Refer to product labeling for approved indications.

Malignant Pain Sub-Indications[a]	**Total Enrolled Patients (Percent)[b]**
Location of Pain	
Spine/Back	406 (30.9%)
Abdominal/Visceral	278 (21.2%)
Extremity	176 (13.4%)
Pelvic	168 (12.8%)
Thoracic	147 (11.2%)
Head/Neck	75 (5.7%)
Other	54 (4.1%)
Not Specified	441 (33.6%)
Total Patients	**1,313**

[a] Patients may have more than one location of pain
[b] Percent is based on the number of total patients

Non-Malignant Pain Sub-Indications	**Total Enrolled Patients (Percent)**
Back Pain without Leg Pain	1,316 (32.5%)
Back Pain with Leg Pain	1,010 (24.9%)
General Neuropathic Condition	162 (4.0%)
CRPS I[a]	126 (3.1%)

Peripheral Neuropathy	66 (1.6%)
Joint Pain/Arthritis	60 (1.5%)
CRPS II[a]	33 (0.8%)
General Nociceptive Condition	31 (0.8%)
Osteoporosis	20 (0.5%)
Other	269 (6.6%)
Not Specified	961 (23.7%)
Total Patients	**4,054**

[a] CRPS is complex regional pain syndrome. CRPS I rarely includes detectable peripheral nerve injury. CRPS II includes detectable peripheral nerve or plexus injury.

Spasticity Sub-Indications	**Total Enrolled Patients (Percent)**
Cerebral Palsy	426 (26.3%)
Multiple Sclerosis	425 (26.2%)
Spinal Cord Injury	221 (13.6%)
Brain Injury	123 (7.6%)
Stroke	67 (4.1%)
Other	85 (5.2%)
Not Specified	274 (16.9%)
Total Patients	**1,621**

Event Summary

There were 3,659 events reported between August 2003 and July 31, 2015 in patients with targeted drug delivery systems. Approximately 33% of these events (1,212/3,659) were categorized as product performance-related events and are presented graphically within this report. The 1,212 product performance events occurred in 872 of the 6,953 total patients (12.54%) enrolled. In addition, there were 2,447 non-product performance events reported. There were also 1,661 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a device-related event or the infusion therapy. 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=6,953)
Catheter dislodgment from intrathecal space	255	222	3.19%
Catheter occlusion[c]	242	225	3.24%
Catheter break/cut	180	162	2.33%
Catheter kink	99	91	1.31%
Pump motor stall	89	82	1.18%
Catheter related complication[d]	62	58	0.83%
Catheter disconnection at pump	39	39	0.56%
Device malfunction[e]	34	32	0.46%
Catheter leakage	32	31	0.45%
Pump reservoir volume discrepancy	29	20	0.29%
Corrosion and/or gear wear	28	28	0.40%
Pump unable to enter/withdraw from catheter access port	20	18	0.26%
Pump underinfusion	18	14	0.20%
Pump connector break/cut	16	15	0.22%
Overinfusion[f]	15	9	0.13%
Medical device complication[g]	9	8	0.12%
Deformed pump tube	6	5	0.07%
Reduced battery performance	5	5	0.07%
Device breakage	3	3	0.04%
Device complication[h]	3	3	0.04%
Pump not infusing	3	3	0.04%

Reservoir access issues due to residue	3	2	0.03%
Catheter access port issue	2	2	0.03%
Catheter damage	2	2	0.03%
Catheter disconnection between catheter segments	2	2	0.03%
Device connection issue	2	2	0.03%
Motor feedthrough anomaly	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%
Connector block problem	1	1	0.01%
Cracked rotor magnet holder	1	1	0.01%
Device alarm issue	1	1	0.01%
Device component issue[i]	1	1	0.01%
Device infusion issue[j]	1	1	0.01%
Device use error	1	1	0.01%
Leaky capacitor	1	1	0.01%
Product sedimentation present	1	1	0.01%
Pump inversion	1	1	0.01%
Totals	**1,212**	**872**	**12.54%**

[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 17 catheter malfunctions, 15 inability to aspirate from catheter, 6 suspected catheter malfunctions, 4 coiled catheters, 2 inability to aspirate CSF, 2 difficulty aspirating catheter, 2 non-functioning distal catheter, 2 poor CSF flow, 1 aneurysm in catheter, 1 catheter dysfunction, 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, 1 catheter occlusion, 1 poor aspiration, and 1 suspected catheter issue.

[e] Includes 20 PTM malfunctions, 3 pump malfunctions, 3 suspected catheter malfunctions, 3 unable to activate PTM, 2 catheter dysfunctions, 1 possible pump malfunction, 1 suspected rotor problem, and 1 catheter anchor malfunction.

[f] There were a total of 18 pumps with overinfusion (physician reported or confirmed by returned product analysis). The events for 11 of these pumps are reported in the table above. The remaining 7 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 11 pumps represented in the above table had 17 events; 15 events for overinfusion , 1 event for corrosion and/or gear wear, and 1 event for motor stall.

[g] Includes 1 pump connector appeared somewhat worn, 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 worn catheter connector, 1 metal clips on sutureless connector bent, and 1 prescription table corruption.

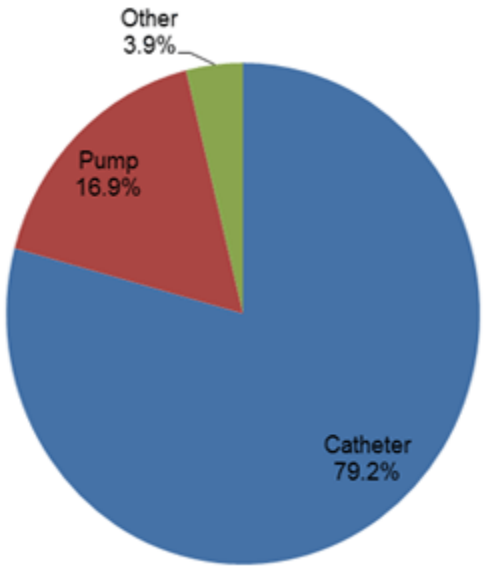
[h] Includes 1 pump unable to interrogate/program, 1 telemetry stopped secondary to error code, 1 under medicated event attributed to the pump.

[i] Includes 1 broken anchor.

[j] Includes 1 event reported as slow dosing at refills.

A total of 960 (79.2%) of the 1,212 product performance events were related to the catheter, 205 (16.9%) were related to the pump, 20 (1.7%) were reported as related to “other device”, 16 (1.3%) were related to “multiple etiologies”, which includes events where at least one device and one non-device etiology was indicated, 6 (0.5%) were related to an external study device, 1 (0.1%) was related to incisional site/device tract, 1 (0.1%) was related to procedure, 1 (0.1%) was related to programming/refill, 1 (0.1%) was related to surgery/anesthesia, and 1 (0.1%) was related to medication. Relatedness is determined by the physician.

Product Performance Events by Relatedness



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)	**560**
Adverse drug reaction	363
Therapeutic product ineffective	86
Drug withdrawal syndrome	73
Therapeutic response decreased	27
No therapeutic response	10
Other[c]	1
Administration site reactions	**420**
Implant site pain	167
Implant site extravasation	99
Implant site erosion	35
Implant site erythema	26
Implant site fibrosis	14
Implant site haematoma	12
Inflammatory mass (Possible)	12
Inflammatory mass (Confirmed)	11
Implant site swelling	7
Implant site inflammation	6
Other[c]	31
Infections - pathogen unspecified	**293**

Inplant site infection	195
Wound infection	32
Meningitis	20
Infection	19
Incision site infection	13
Other[c]	14
Device issues	**221**
Pump inversion	129
Pump migration	59
Other[c]	33
Neurological disorders not elsewhere classified (NEC)	**176**
Cerebrospinal fluid leakage	82
Hypoaesthesia	38
Sedation	17
Somnolence	12
Paraesthesia	6
Other[c]	21
General system disorders NEC	**160**
Pain	97
No anomaly found by RPA[d]	27
Oedema peripheral	14
Oedema	5
Other[c]	17

Procedural related injuries and complications NEC	**153**
Wound dehiscence	60
Seroma	35
Post lumbar puncture syndrome	18
Other[c]	40
Complications associated with device	**86**
Pump motor stall[e]	67
Medical device complication[f]	7
Drug-related pump anomaly	5
Other[c]	7
Psychiatric disorders NEC	**41**
Withdrawal syndrome	27
Mental status changes	14
Medication errors	**34**
Overdose	33
Other[c]	1
Muscle disorders	**30**
Muscular weakness	26
Other[c]	4
Neuromuscular disorders	**31**
Muscle spasticity	24
Other[c]	7
Urinary tract signs and symptoms	**24**

Urinary retention	18
Dysuria	5
Other[c]	1
Exposures, chemical injuries and poisoning	**20**
Toxicity to various agents	20
Gastrointestinal signs and symptoms	**19**
Nausea	10
Vomiting	5
Other [c]	4
Musculoskeletal and connective tissue disorders NEC	**16**
Back pain	9
Other[c]	7
Epidermal and dermal conditions	**15**
Erythema	5
Other[c]	10
Headaches	**14**
Headaches	14
Tissue disorders NEC	**13**
Impaired healing	11
Other[c]	2
Bacterial infectious disorders	**11**
Cellulitis	5
Inmplant site cellulitis	5

Other[c]	1
Vascular haemorrhagic disorders	**7**
Haematoma	7
Mental impairment disorders	**6**
Memory impairment	5
Other[c]	1
Skin and subcutaneous tissue disorders NEC	**6**
Skin erosion	6
Not coded[g]	**14**
Other[c]	**77**
Total	**2,447**

[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] 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).
[e] 67 pump motor stalls occurred due to MRI and recovered in less than 24 hours with no pump issues.
[f] 1 pumps poorly positioned,1 possible corrosion of the catheter due to drug concentration, 1 intraspinal infusate contamination, 1 inadvertent overfilling of the pump at refill, 1 mis-filling of pump into pocket, 1 difficulty locating pump port due to weight gain, and 1 increased back pain.
[g] Events that had not been MedDRA-coded at the time of the report cut-off.

In addition, there were 1,661 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a device-related event or the infusion therapy. A total of 1,038 (62.5%) of deaths occurred in patients receiving therapy for malignant pain, 469 (28.2%) for non-malignant pain, 151 (9.1%) for spasticity, 1 (0.06%) 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	1,038 (62.5%)
Non-malignant pain	469 (28.2%)
Spasticity	151 (9.1%)

Non-Malignant Pain & Spasticity	1 (0.06%)
Not specified	2 (0.1%)
Total	**1,661**

[a] Refer to product labeling for approved indications.

Pumps

From August 2003 to the report cut-off date of July 31, 2015, there were 8,372 pumps followed in the registry. The difference between the total number of patients (n=6,953) 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 213,219 months (17,768 years). The table below provides the number and percentage of pumps by model.

Pumps by Model

Model Name	Number of Pumps (%)
SynchroMed II	7,185 (85.8%)
SynchroMed EL	1,181 (14.1%)
SynchroMed	5 (0.06%)
Unspecified	1 (0.01%)
Total	**8,372 (100%)**

Pump Events

There were 211 product performance-related events with an underlying reported etiology related to pump function. This includes 205 events with a pump etiology, and 6 events with both a pump and other etiology (including device and non-device). Of these 211 events, 175 were the first event attributable to an enrolled pump. The current return rate of pumps to Medtronic Returned Product Analysis (RPA) was 963/3,630 (26.5%). 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.

Of the 211 product performance-related events related to the pump, 106 were analyzed by Medtronic RPA with the following analysis findings: 44 motor stalls, 28 corrosion and/or gear wear,14 overinfusion, 5 reduced battery performance, 5 with deformed pump tube, 2 reservoir access issue due to residue, 2 motor feedthrough anomaly, 1 alarm and/or resonator anomaly, 1 with coil shorted to case, 1 concave pump shield, 1 cracked rotor magnet holder, 1 leaky capacitor, and 1 medical device complication. Of these 106 pumps with RPA-confirmed malfunction events, 21 were originally reported as non-product performance-related battery depletions by the physician.

Within the 211 product performance-related events related to the pump, 105 events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 45 events due to physician-reported motor stalls, 22 pump reservoir discrepancy, 14 pump underinfusion, 6 device malfunction, 4 pump unable to enter/withdraw from catheter access port, 4 medical device complication, 3

device complication, 3 pump not infusing, 1 overinfusion, 1 pump connector break/cut, 1 catheter related complication, and 1 device alarm issue.

In addition to the 211 product performance-related events, there were 13 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.

Of the 211 product performance-related events with an underlying reported etiology related to pump function, 160 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 51 pumps, the complete drug history and exposure to admixtures could not be confirmed.

Medtronic executed a field action in March 2014 informing healthcare professionals of overinfusion associated with the SynchroMed II Infusion System. As of July 31, 2015, 17 pumps from registry patients were found to have confirmed overinfusion after returned product analysis. Of these 17 pumps, 10 had an event reported in the registry, and the remaining 7 had no reported events associated with the pump. The 17 reports of overinfusion occurred in 7,185 SynchroMed II pumps included in the registry at the time of analysis, providing 95% confidence that the occurrence rate is less than 0.0035 (0.35%).

In addition to the 17 pumps with confirmed overinfusion after returned product analysis, there was 1 pump with physician reported overinfusion that was not returned for analysis. Combining the physician reported and confirmed pump overinfusion (n=18) provided 95% confidence that the occurrence rate is less than 0.0037 (0.37%). Medtronic continues to monitor pump performance relative to overinfusion.

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:

- 175 were cut-off due to product performance-related events.
- 5,889 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.
- 2,308 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

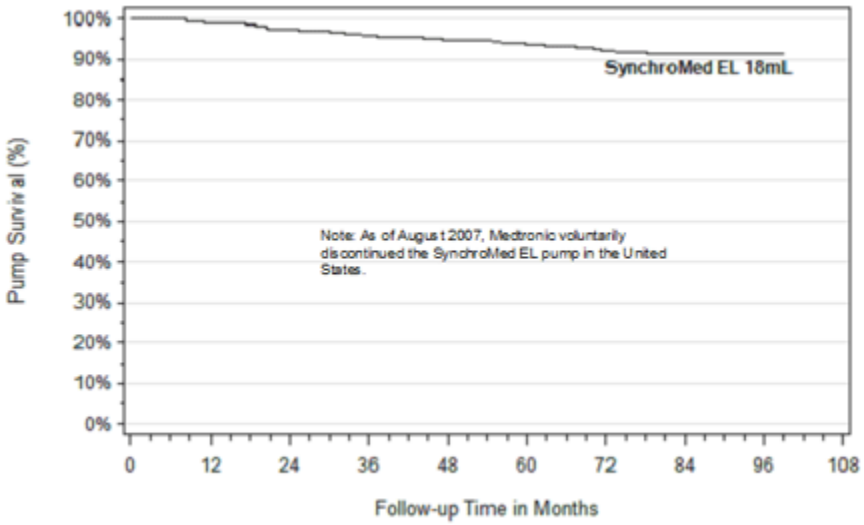
Pump Survival

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 EL (18 mL)
FDA Approval Date	Mar 1999
Pumps Enrolled	1,147
Pumps Currently Active in Study	1
Device Events	33
Cumulative Months of Follow-up	31,026

SynchroMed EL 18mL Event Summary Table

Pump Event	Total
Corrosion and/or gear wear	17
Pump underinfusion	6
Pump motor stall	6
Cracked rotor magnet holder	1
Device complication [a]	1
Medical device complication[b]	1
Motor feedthrough anomaly	1
Total Pump Events	**33**

[a] Reported as unable to interrogate/program pump
[b] Reported as 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%)	467
6 yrs	**92.3%** (88.9%, 94.7%)	244
7 yrs	**91.3%** (87.6%, 94.0%)	108
8 yrs	**91.3%** (87.6%, 94.0%)	36
at 99 mo	**91.3%** (87.6%, 94.0%)	23

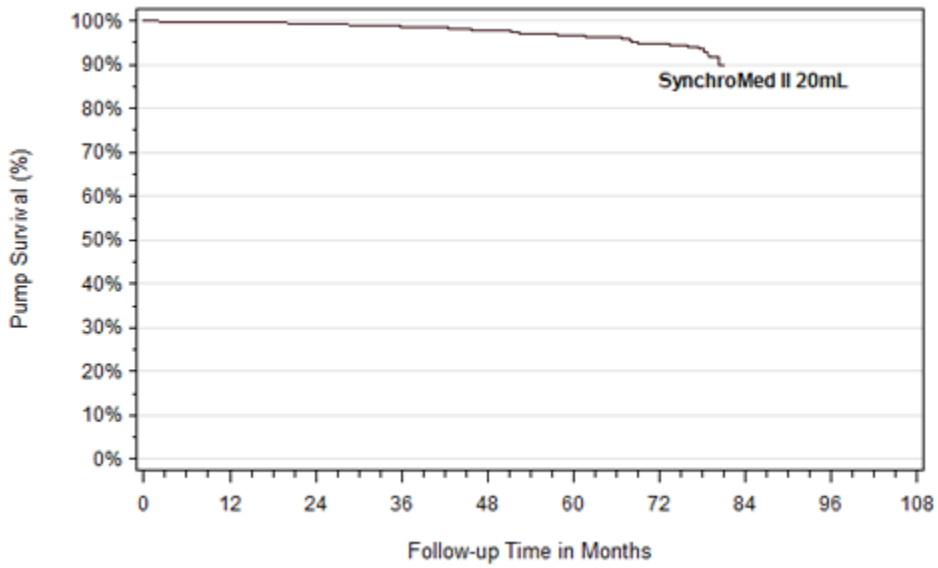
Model 8627-18 SynchroMed EL 18mL: Specifications

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	2,805
Pumps Currently Active in Study	1,192
Device Events	50
Cumulative Months of Follow-up	82,997

SynchroMed II 20mL Event Summary Table

Pump Event	Total
Pump motor stall	24
Pump reservoir volume discrepancy	5
Corrosion and/or gear wear	4

Device malfunction[a]	3
Pump unable to enter/withdraw from catheter access port	3
Medical device complication [b]	2
Pump overinfusion	2
Alarm and/or resonator anomaly	1
Deformed pump tube	1
Device complication [c]	1
Motor feedthrough anomaly	1
Pump connector break/cut	1
Pump not infusing	1
Reservoir access issues due to residue	1
Total Pump Events	**50**

[a] Includes 2 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
[c] Reported as telemetry stopped secondary to error code

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.7%** (99.3%, 99.9%)	1,828
2 yrs	**99.3%** (98.7%, 99.6%)	1,432
3 yrs	**98.7%** (98.0%, 99.2%)	1,017
4 yrs	**97.8%** (96.7%, 98.5%)	713
5 yrs	**96.6%** (95.2%, 97.6%)	523
6 yrs	**94.7%** (92.7%, 96.2%)	349

at 81 mo	**90.0%** (84.1%, 93.8%)	36

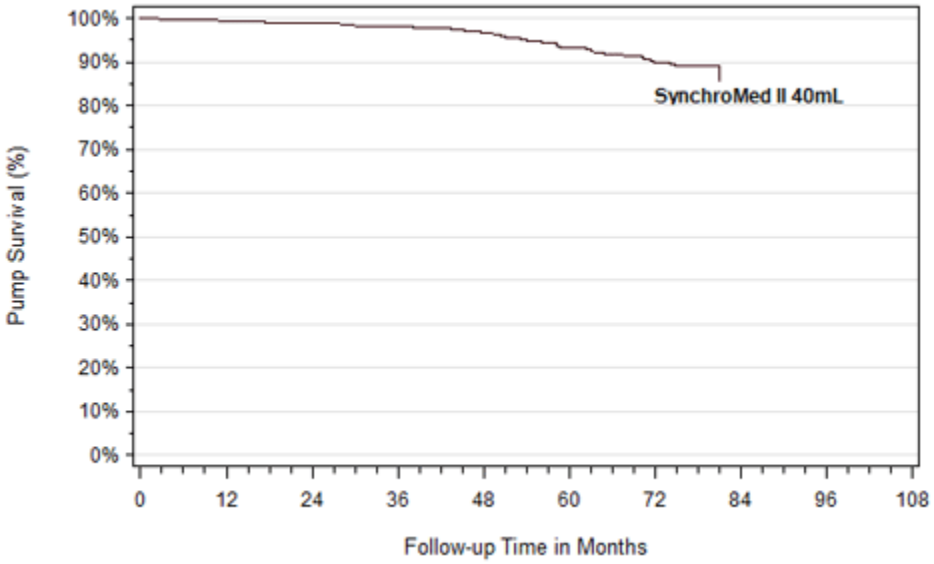
Model 8637-20 SynchroMed II 20mL: Specifications

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	4,380
Pumps Currently Active in Study	1,301
Device Events	91
Cumulative Months of Follow-up	98,248

SynchroMed II 40mL Event Summary Table

Pump Event	Total
Pump motor stall	41
Pump reservoir volume discrepancy	10
Pump underinfusion	7
Corrosion and/or gear wear	6
Overinfusion	6
Reduced battery performance	4
Deformed pump tube	3
Device malfunction [a]	3
Pump not infusing	2
Coil shorted to case	1
Concave pump shield	1
Device alarm issue	1
Device complication [b]	1
Leaky capacitor	1
Medical device complication [c]	1

Pump overinfusion	1
Pump unable to enter/withdraw from catheter access port	1
Reservoir access issues due to residue	1
Total Pump Events	**91**

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

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.5%** (99.1%, 99.7%)	2,275
2 yrs	**98.9%** (98.4%, 99.2%)	1,649
3 yrs	**98.1%** (97.4%, 98.6%)	1,124
4 yrs	**96.7%** (95.5%, 97.5%)	774
5 yrs	**93.4%** (91.5%, 94.9%)	515
6 yrs	**90.0%** (87.4%, 92.1%)	300
at 81 mo	**85.8%** (77.2%, 91.4%)	25

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	1,147	1	33	31,026
SynchroMed II (20 mL)	SynchroMed II	Sep 2003	2,805	1,192	50	82,997
SynchroMed II (40 mL)	SynchroMed II	Sep 2003	4,380	1,301	91	98,248

[a] There were a total of 211 pump-related events reported to the registry, but only 174 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 (ie, SynchroMed EL 10 mL[n=1]) or were subsequent events 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
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%)
SynchroMed II (20 mL)	**99.7%** (99.3%, 99.9%)	**99.3%** (98.7%, 99.6%)	**98.7%** (98.0%, 99.2%)	**97.8%** (96.7%, 98.5%)
SynchroMed II (40 mL)	**99.5%** (99.1%, 99.7%)	**98.9%** (98.4%, 99.2%)	**98.1%** (97.4%, 98.6%)	**96.7%** (95.5%, 97.5%)

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%)	-	-

Pump Survival by On/Off Label Medication Use

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 6,206 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 53.5 (SD = 17.7). Of the 7,185 SynchroMed II pumps enrolled through July 31, 2015, at least one drug record was available for 6,797 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 On- or Off-Label using the following criteria:

- On-Label: If a pump has at least one drug record in the registry, and none of the records show Off-Label drug exposure, that pump is considered On-Label even if the complete drug history of that pump is unknown.
    - For pumps used for pain patients, if the drug record has only one drug and it is morphine sulfate or ziconotide these pumps are considered On-Label.
    - For pumps used for spasticity patients, if the drug record has only one drug, and it is baclofen 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 2,154 SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 4,643 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=2,154	Off-Label N=4,643
Non-Malignant Pain	697 (17.7%)	3,248 (82.3%)
Malignant Pain	41 (3.4%)	1,158 (96.6%)
Spasticity	1,416 (89.3%)	170 (10.7%)
Multiple/Unknown	NA	67

[a] Refer to product labeling for approved indications.

There were a total of 141 reported SynchroMed II pump failures (i.e. had product performance event) during the study observation period. In addition to the 141 pump failures, there were 13 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. Four of the 141 pump failure events occurred in pumps with no drug records available. Of the remaining 137 SynchroMed II pump failures, 64 pumps 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.

For the 64 pump failures due to motor stall, 38 of the pumps were associated with the patient presenting clinical signs and symptoms of possible drug withdrawal or increasing pain or spasticity. The other 26 pumps 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. Overall, the rate of pump failures in this cohort was 2.0% (137/6,797) with a median follow-up of 19.3 months.

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

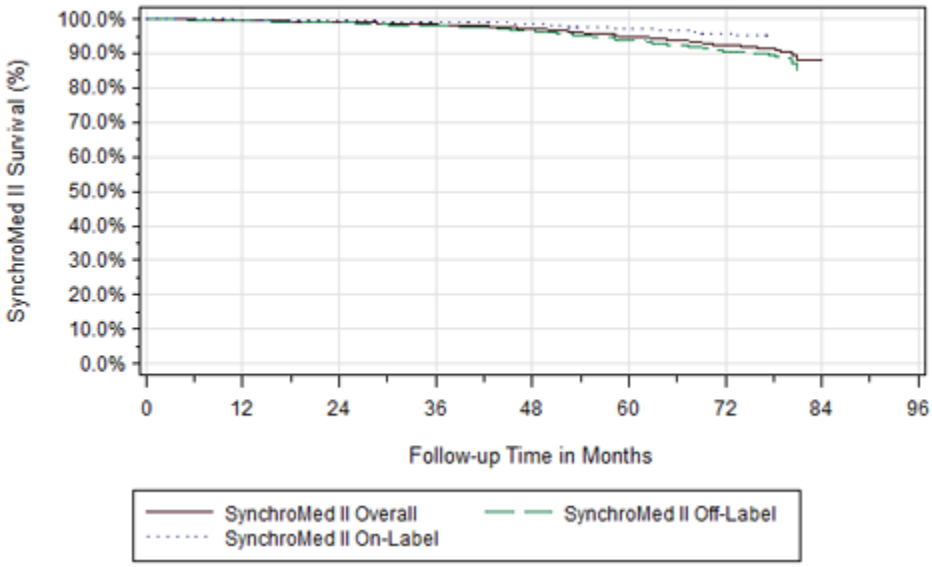
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo	81 mo	7 yrs
All Pumps	Survival	99.6%	99.1%	98.4%	97.2%	95.0%	92.3%	91.3%	87.9%	87.9%
	Number of pumps	4,013	3,028	2,110	1,463	1,028	647	251	61	20
On-Label Drugs	Survival	99.8%	99.5%	98.9%	98.5%	97.1%	95.8%	95.2%	-	-
	Number of pumps	1,347	1,030	721	489	351	201	53	- [a]	- [a]
Off-Label Drugs	Survival	99.5%	98.9%	98.2%	96.5%	93.9%	90.6%	89.4%	85.0%	-
	Number of pumps	2,666	1,998	1,389	974	677	446	198	42	- [a]

[a] Sample size is less than 20 active devices at 81 months for On-Label pump group, and 7 years 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 2.2 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.0003).

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

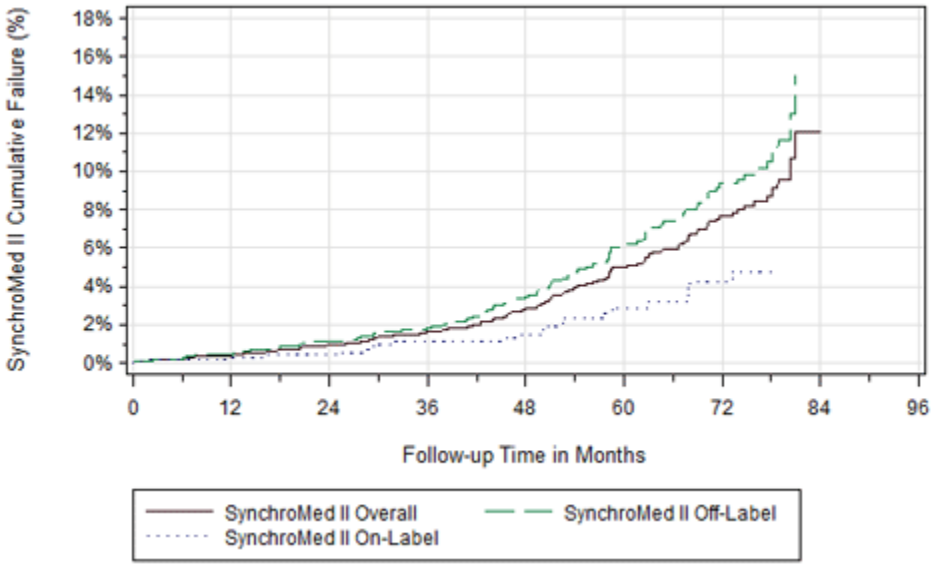
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo	81 mo	7 yrs
All Pumps	Failure	0.4%	0.9%	1.6%	2.8%	5.0%	7.7%	8.7%	12.1%	12.1%
	Number of pumps	4,013	3,028	2,110	1,463	1,028	647	251	61	20
On-Label Drugs	Failure	0.2%	0.5%	1.1%	1.5%	2.9%	4.2%	4.8%	-	-
	Number of pumps	1,347	1,030	721	489	351	201	53	-[a]	-[a]
Off-Label Drugs	Failure	0.5%	1.1%	1.8%	3.5%	6.1%	9.4%	10.6%	15.0%	-
	Number of	2,666	1,998	1,389	974	677	446	198	42	-[a]

pumps

[a] Sample size is less than 20 active devices at 81 months for On-Label pump group, and 7 years 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 2.4 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 78 months of follow-up, the survival from pump failure for On-Label pumps was 96.4%, compared to a survival of 88.9% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 17.5 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 consisted of 65% spasticity indication (1,249 vs. 687: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 95% pain indications (3,929 vs. 205: 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 738 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 4,405 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

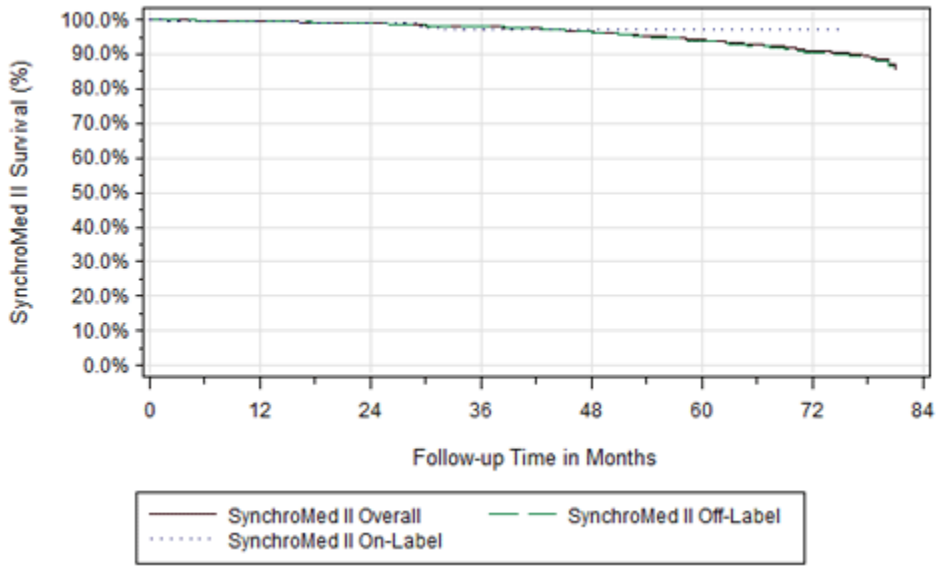
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Survival	99.5%	98.9%	98.1%	96.5%	94.2%	90.9%	90.4%	85.5%
	Number of pumps	2,921	2,145	1,462	991	685	452	343	45
Pain On-Label	Survival	99.8%	99.0%	97.2%	97.2%	97.2%	97.2%	97.2%	-
	Number of pumps	414	269	158	76	48	32	26	-[b]
Pain Off-Label	Survival	99.5%	98.9%	98.2%	96.5%	94.0%	90.5%	89.9%	84.5%
	Number of pumps	2,507	1,876	1,304	915	637	420	317	39

[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 **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). Statistical testing, however, was not performed due to low sample size in the On-Label group at the five-year (60-month) follow-up (n=48) and beyond.

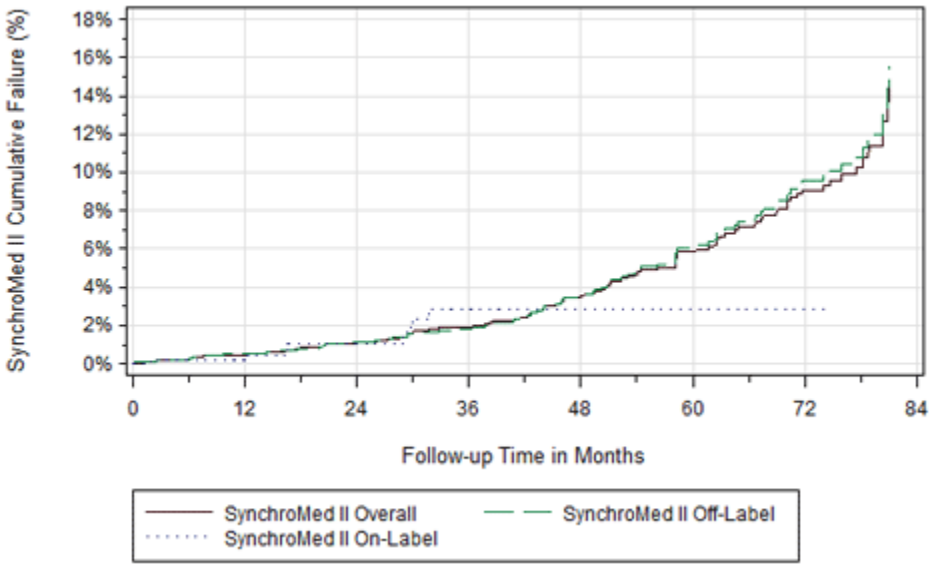
Pain study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Pain indications, by On/Off-Label drug exposure

Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Failure	0.5%	1.1%	1.9%	3.5%	5.8%	9.1%	9.6%	14.5%
	Number of pumps	2,921	2,145	1,462	991	685	452	343	45
Pain On-Label	Failure	0.2%	1.0%	2.8%	2.8%	2.8%	2.8%	2.8%	-
	Number of pumps	414	269	158	76	48	32	26	-[b]
Pain Off-Label	Failure	0.5%	1.1%	1.8%	3.5%	6.0%	9.5%	10.1%	15.5%
	Number of pumps	2,507	1,876	1,304	915	637	420	317	39

[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 2.4 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 78 months of follow-up, the survival from pump failure for On-Label pumps was 96.4%, compared to a survival of 88.9% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 17.5 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 consisted of 65% spasticity indication (1,249 vs. 687: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 95% pain indications (3,929 vs. 205: 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 1,416 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 170 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

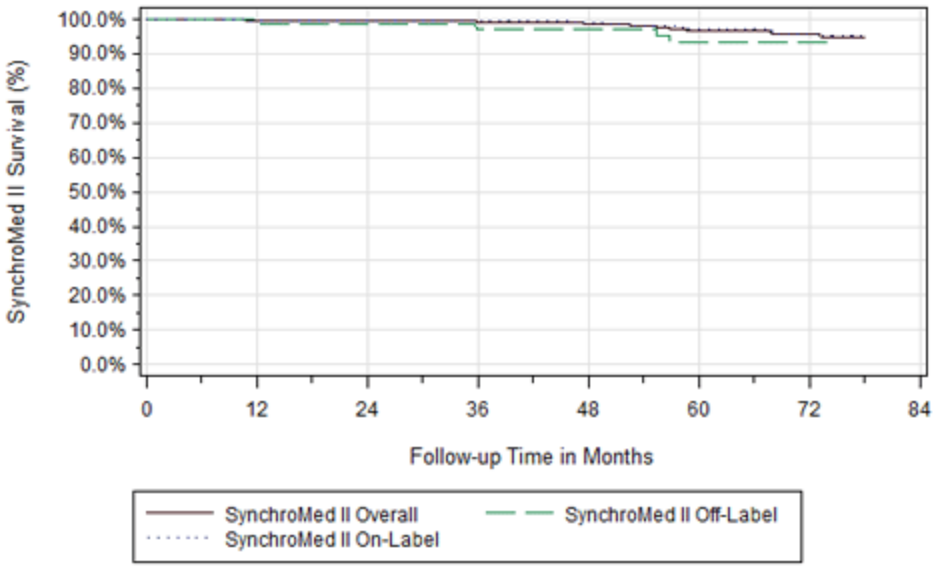
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo
Spasticity Overall	Survival	99.8%	99.6%	99.2%	98.8%	96.9%	95.5%	95.0%	95.0%
	Number of pumps	1,057	867	642	470	343	195	121	49
Spasticity On-Label	Survival	99.8%	99.8%	99.5%	99.0%	97.4%	95.9%	95.2%	95.2%
	Number of pumps	933	761	563	413	303	169	101	39
Spasticity Off-Label	Survival	100.0%	98.4%	97.2%	97.2%	93.3%	93.3%	93.3%	-
	Number of pumps	124	106	79	57	40	26	20	-[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.

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). Statistical testing, however, was not performed due to low sample size in the Off-Label group at the 60-month follow-up (n=40) and beyond.

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

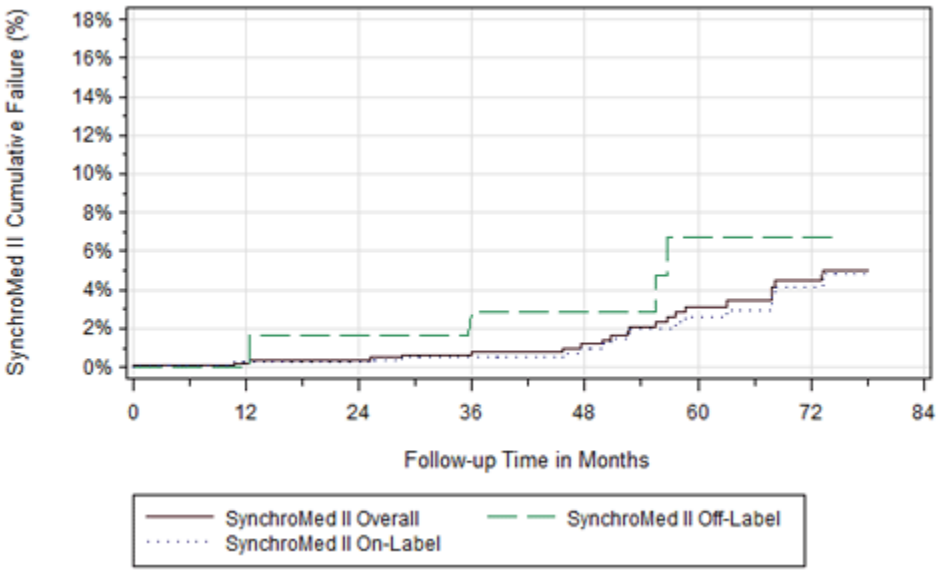
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo
Spasticity Overall	Failure	0.2%	0.4%	0.8%	1.2%	3.1%	4.5%	5.0%	5.0%
	Number of pumps	1,057	867	642	470	343	195	121	49
Spasticity On-Label	Failure	0.2%	0.2%	0.5%	1.0%	2.6%	4.1%	4.8%	4.8%
	Number of pumps	933	761	563	413	303	169	101	39
Spasticity Off-Label	Failure	0.0%	1.6%	2.8%	2.8%	6.7%	6.7%	6.7%	-
	Number of pumps	124	106	79	57	40	26	20	-[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

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 2.2 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 78 months of follow-up, the survival from pump failure for On-Label pumps was 95.2%, compared to a survival of 89.4% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 19.3 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 consisted of 65% spasticity indication (1,416 vs. 738: Spasticity versus Pain pumps respectively). On the other hand, the Off-Label group consisted of 96% pain indications (4,406 vs. 170: 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, 2015, there were 7,888 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=8,372) 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 211,551 months (17,629 years). The table below provides the number and percentage of catheters by model.

Catheters by Model	
Model Number	**Number of Catheters (%)**
8709	2,806 (35.6%)
8709SC	1,017 (12.9%)
8711	640 (8.1%)
8780	514 (6.5%)
8731	500 (6.3%)
8781	455 (5.8%)
8731SC	209 (2.6%)
8703W	190 (2.4%)
Revised Not as Designed[a]	581 (7.4%)
Grafted Not As Designed[b]	421 (5.3%)
Revised as Designed (RAD)[c]	217 (2.8%)
Other	204 (2.6%)
Ascenda RAD[d]	134 (1.7%)
Total	**7,888 (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 967 product performance events reported to the registry that were related to the catheter. This includes 960 events with a catheter etiology, and 7 events with both a catheter and other etiology (including device and non-device etiologies). The majority of the events were catheter dislodgement (n=253), catheter

occlusion (n=241), or break or cut in the catheter (n=179). Of the 967 events, 843 were the first event attributable to an enrolled catheter.

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:

- 843 had follow-up time cut-off due to product performance-related events.
- 4,723 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.
- 2,322 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.

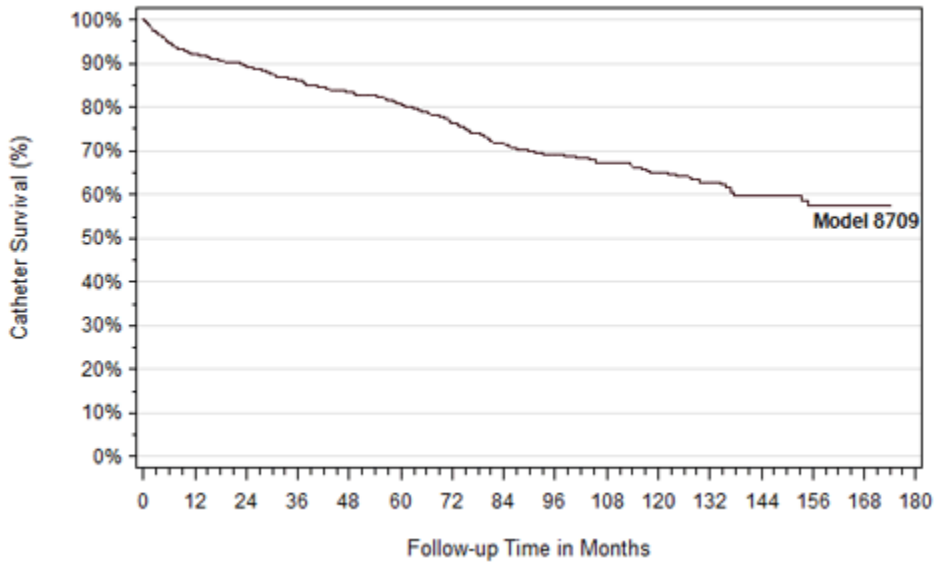
The survival estimates suggest that the survival of catheters grafted not as designed (those catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits) have a lower probability of survival across various applicable follow-up time points than some other catheter models. 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 Model 8596 and 8598 revision kits.

In addition, although the survival estimate for the Ascenda model 8781 catheter may appear to demonstrate lower performance than the 8731SC predicate catheter at early follow-up time points, these results are reflective of limited cumulative follow-up months. This catheter will continue to be monitored closely as we enroll more patients and follow devices for longer periods of time.

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	2,806
Catheters Currently Active in Study	326
Device Events	300
Cumulative Months of Follow-up	79,003

Model 8709: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	82
Catheter occlusion	71
Catheter break/cut	70
Catheter kink	20
Catheter disconnection at pump	18
Catheter related complication[a]	10
Catheter leakage	9

Pump connector break/cut	9
Pump reservoir volume discrepancy	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[b]	1
Medical device complication[c]	1
Reservoir access issues due to residue	1
Total Catheter Events	**300**

[a] Includes 3 events reported as unable to aspirate catheter, 1 catheter malfunction, 1 coiled catheter, 1 aneurysm in catheter, 1 catheter dysfunction, 1 possible catheter malfunction, 1 unable to aspirate CSF, 1 difficulty aspirating catheter

[b] Reported as slow dosing at refills

[c] Reported as pump connector appeared somewhat worn

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.2% (90.4%, 93.6%)	966
2 yrs	89.5% (87.5%, 91.1%)	911
3 yrs	86.2% (84.0%, 88.1%)	844
4 yrs	83.3% (80.9%, 85.5%)	740
5 yrs	80.7% (78.1%, 83.1%)	616
6 yrs	76.3% (73.4%, 78.9%)	523
7 yrs	71.6% (68.4%, 74.5%)	428

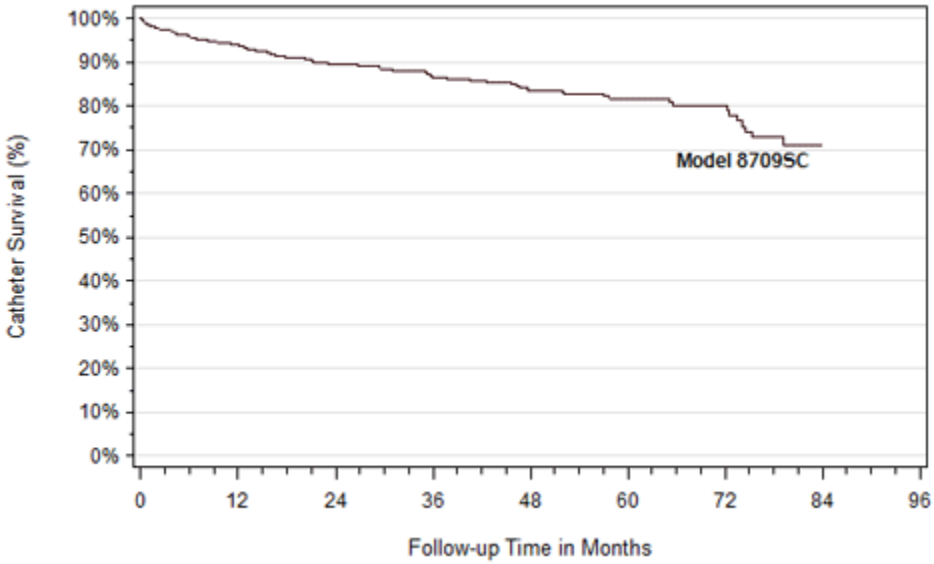
8 yrs	69.1% (65.7%, 72.2%)	332
9 yrs	67.3% (63.8%, 70.6%)	220
10 yrs	65.1% (61.3%, 68.7%)	160
11 yrs	62.8% (58.5%, 66.7%)	116
12 yrs	59.7% (54.7%, 64.2%)	76
13 yrs	57.4% (51.6%, 62.7%)	41
14 yrs	57.4% (51.6%, 62.7%)	26
at 174 mo	57.4% (51.6%, 62.7%)	21

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	1,017
Catheters Currently Active in Study	356
Device Events	112
Cumulative Months of Follow-up	28,384

Model 8709SC: Event Summary Table Catheter Event	Total
Catheter dislodgment from intrathecal space	31
Catheter break/cut	27
Catheter occlusion	23
Catheter related complication[a]	9
Catheter kink	6
Catheter leakage	5
Catheter disconnection at pump	3

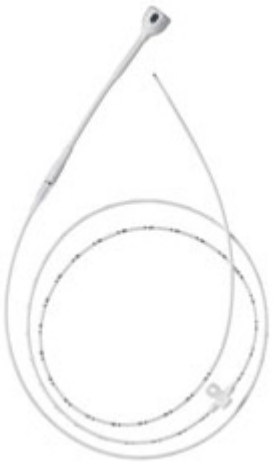
Pump unable to enter/withdraw from catheter access port	2
Catheter damage	1
Catheter disconnection between catheter segments	1
Device connection issue	1
Medical device complication[b]	1
Product sedimentation present	1
Pump inversion	1
Total Catheter Events	**112**

[a] Includes 3 events reported as catheter malfunction, 1 coiled catheter, 1 catheter occlusion, 1 suspected catheter malfunction, 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	94.0% (92.1%, 95.4%)	665
2 yrs	89.5% (87.0%, 91.5%)	499
3 yrs	86.7% (83.7%, 89.1%)	348
4 yrs	83.6% (80.1%, 86.6%)	206
5 yrs	81.7% (77.6%, 85.0%)	127
6 yrs	80.1% (75.4%, 83.9%)	71
7 yrs	71.1% (63.0%, 77.7%)	20

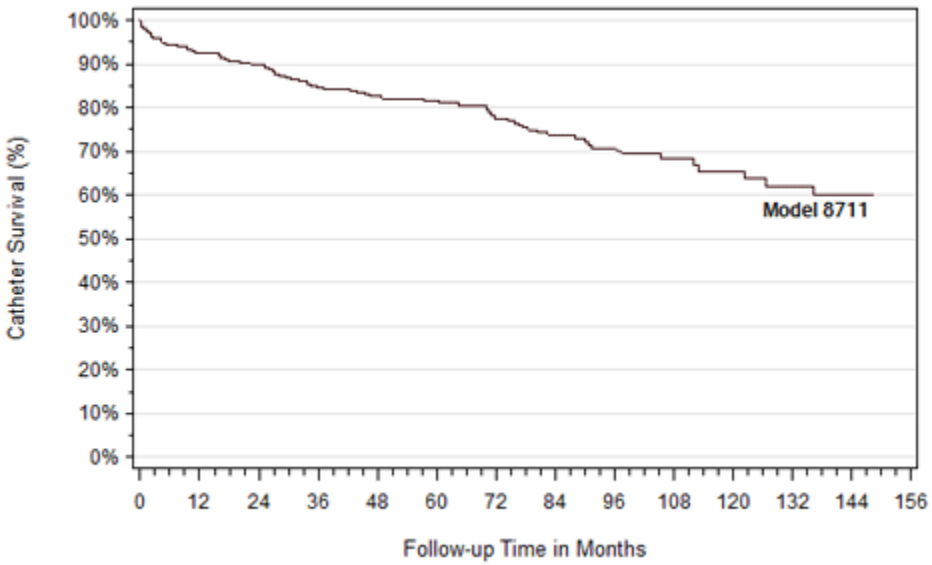
Model 8709SC: Specifications

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	640
Catheters Currently Active in Study	159

Device Events	82
Cumulative Months of Follow-up	22,860

Model 8711: Event Summary Table **Catheter Event**	**Total**
Catheter occlusion	26
Catheter break/cut	18
Catheter dislodgment from intrathecal space	14
Catheter related complication[a]	14
Catheter kink	4
Pump unable to enter/withdraw from catheter access port	3
Catheter disconnection at pump	2
Pump connector break/cut	1
Total Catheter Events	**82**

[a] Includes 4 events reported as catheter malfunction, 3 unable to aspirate catheter, 2 non-functioning spinal catheters, 2 could not aspirate pump, 1 no free flow of CSF from spinal segment of catheter, 1 difficulty aspirating catheter, 1 suspected catheter malfunction

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	92.5% (88.9%, 94.9%)	308
2 yrs	90.0% (86.1%, 92.9%)	286
3 yrs	84.8% (80.3%, 88.4%)	247
4 yrs	83.0% (78.2%, 86.7%)	212
5 yrs	81.7% (76.9%, 85.7%)	189
6 yrs	77.9% (72.4%, 82.4%)	151

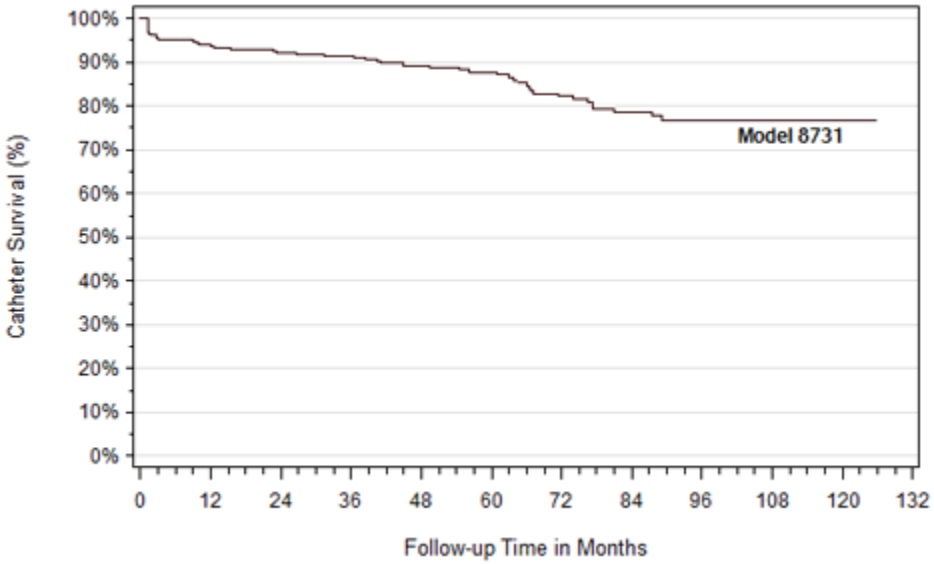
7 yrs	73.9% (68.0%, 79.0%)	108
8 yrs	70.9% (64.4%, 76.5%)	76
9 yrs	68.8% (61.7%, 74.8%)	53
10 yrs	65.9% (58.0%, 72.7%)	41
11 yrs	62.6% (53.7%, 70.3%)	30
12 yrs	60.4% (50.8%, 68.8%)	23
at 150 mo	60.4% (50.8%, 68.8%)	20

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	500
Catheters Currently Active in Study	79
Device Events	46
Cumulative Months of Follow-up	19,333

Model 8731: Event Summary Table Catheter Event	Total
Catheter dislodgment from intrathecal space	18
Catheter occlusion	16
Catheter related complication[a]	4
Catheter kink	3
Catheter break/cut	2
Catheter disconnection at pump	2
Pump connector break/cut	1

Total Catheter Events	**46**

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

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	93.5% (88.8%, 96.3%)	261
2 yrs	92.2% (87.5%, 95.2%)	300
3 yrs	91.3% (86.4%, 94.4%)	249
4 yrs	89.3% (84.3%, 92.8%)	193
5 yrs	87.7% (82.4%, 91.5%)	145
6 yrs	82.2% (76.0%, 86.9%)	129
7 yrs	78.6% (71.8%, 84.0%)	93
8 yrs	76.7% (69.5%, 82.4%)	70
9 yrs	76.7% (69.5%, 82.4%)	52
10 yrs	76.7% (69.5%, 82.4%)	34
at 126 mo	76.7% (69.5%, 82.4%)	20

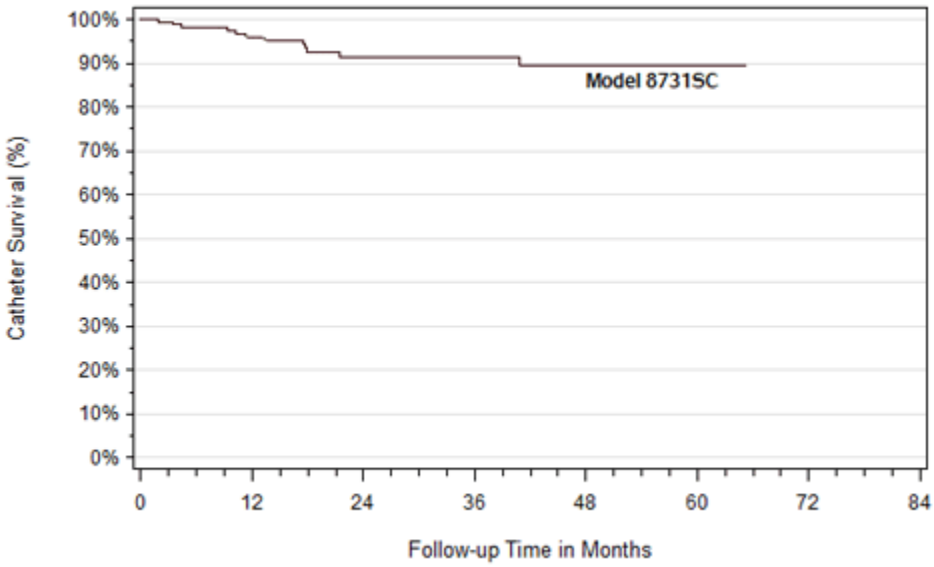
Model 8731: Specifications

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.



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Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	209
Catheters Currently Active in Study	112
Device Events	12

Cumulative Months of Follow-up	5,180

Model 8731SC: Event Summary Table **Catheter Event**	**Total**
Catheter dislodgment from intrathecal space	4
Catheter occlusion	4
Catheter disconnection at pump	1
Catheter kink	1
Catheter related complication [a]	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**12**

[a] Reported as poor aspiration of catheter

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	96.0% (91.3%, 98.2%)	125
2 yrs	91.6% (85.1%, 95.3%)	86
3 yrs	91.6% (85.1%, 95.3%)	49
4 yrs	89.3% (80.9%, 94.2%)	36
5 yrs	89.3% (80.9%, 94.2%)	22
at 66 mo	89.3% (80.9%, 94.2%)	21

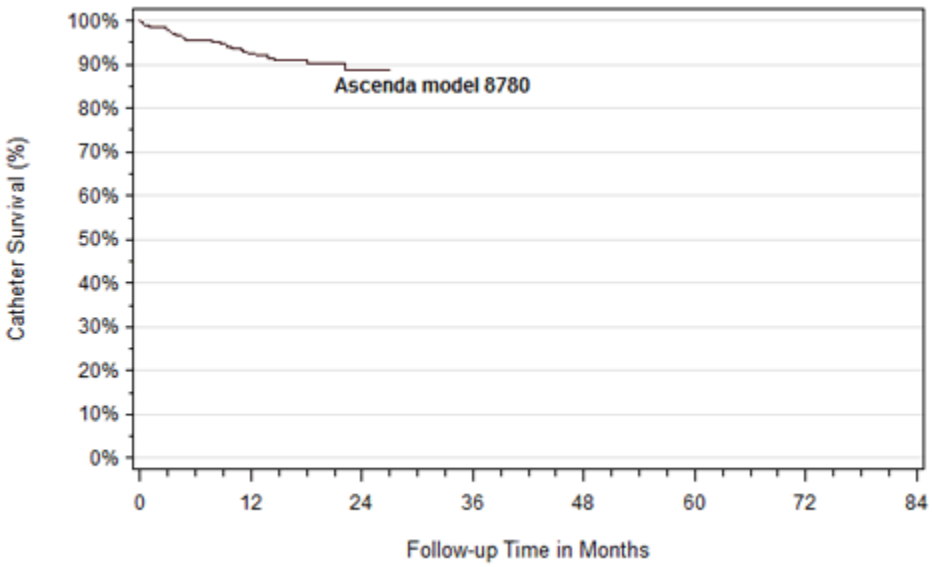
Model 8731SC: Specifications

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	514
Catheters Currently Active in Study	399
Device Events	32

Cumulative Months of Follow-up	5,582

Model 8780: Event Summary Table **Catheter Event**	**Total**
Catheter occlusion	12
Catheter dislodgment from intrathecal space	6
Catheter kink	6
Catheter break/cut	2
Catheter disconnection at pump	2
Catheter leakage	1
Catheter related complication[a]	1
Pump connector break/cut	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**32**

[a] Reported as unable to aspirate catheter

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.4% (89.0%, 94.8%)	218
2 yrs	88.9% (83.6%, 92.5%)	50
at 27 mo	88.9% (83.6%, 92.5%)	40

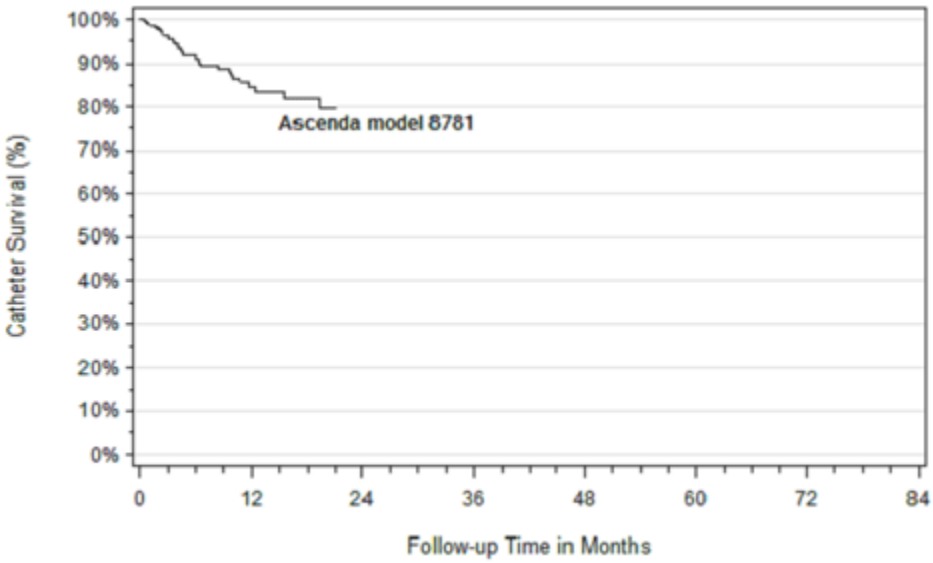
Model 8780: Specifications

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	455
Catheters Currently Active in Study	271
Device Events	34
Cumulative Months of Follow-up	2,808

Model 8781: Event Summary Table	
Catheter Event	**Total**

Catheter dislodgment from intrathecal space	12
Catheter kink	12
Catheter occlusion	3
Pump underinfusion	2
Catheter break/cut	1
Catheter disconnection at pump	1
Catheter leakage	1
Device malfunction[a]	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**34**

[a] Reported as possible catheter malfunction

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	84.6% (78.2%, 89.2%)	78
at 21 mo	79.6% (70.6%, 86.2%)	31

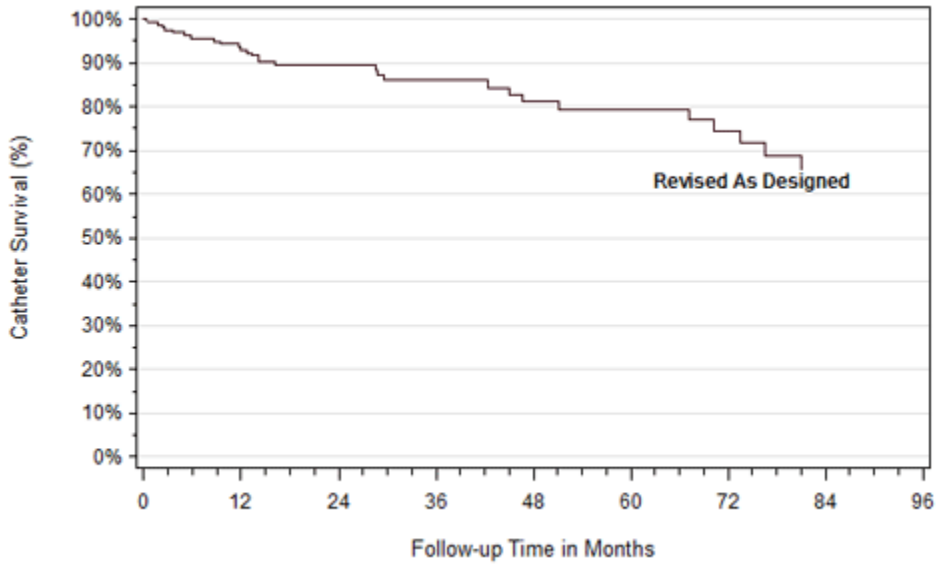
Model 8781: Specifications

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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Note: Revised As Designed catheters are Model 8731 catheters repaired with the 8596 proximal or 8598 distal revision kit.

Catheter Characteristics	
Model Name	Revised As Designed
FDA Approval Date	Oct 2002
Catheters Enrolled	217
Catheters Currently Active in Study	88
Device Events	30
Cumulative Months of Follow-up	6,549

Revised As Designed Catheters: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	12
Catheter dislodgment from intrathecal space	7

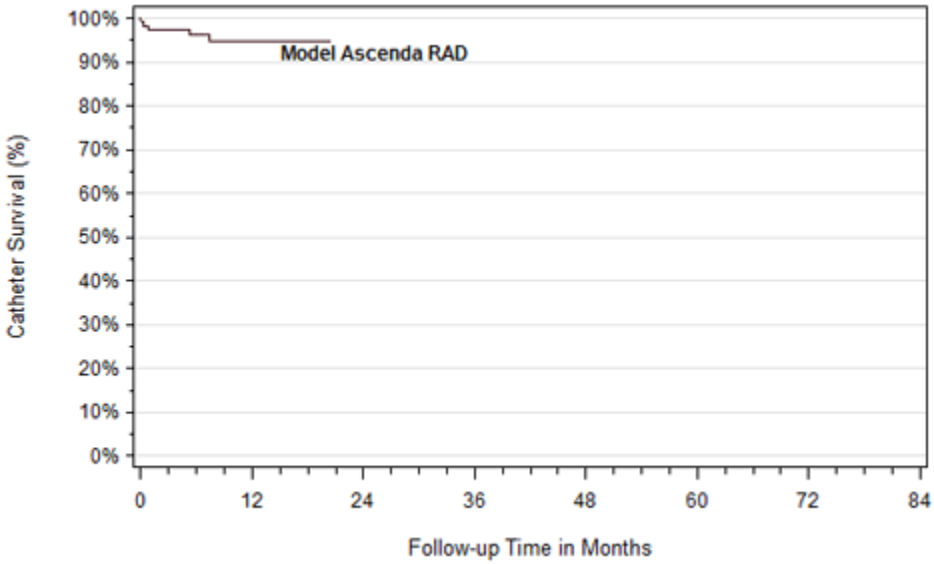
Catheter kink	4
Catheter related complication[a]	3
Catheter break/cut	2
Device connection issue	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**30**

[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	92.9% (87.6%, 96.0%)	143
2 yrs	89.6% (83.6%, 93.5%)	91
3 yrs	85.9% (78.4%, 91.0%)	57
4 yrs	81.2% (71.8%, 87.7%)	46
5 yrs	79.3% (69.2%, 86.4%)	37
6 yrs	74.3% (62.2%, 83.1%)	27
at 81 mo	65.8% (51.3%, 77.0%)	21

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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Note: Ascenda Revised As Designed catheters are Medtronic 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit.

Catheter Characteristics	
Model Name	Ascenda Revised As Designed[a]
FDA Approval Date	Sept 2012
Catheters Enrolled	134
Catheters Currently Active in Study	104
Device Events	5
Cumulative Months of Follow-up	1,319

Ascenda Revised As Designed Catheters: Event Summary Table

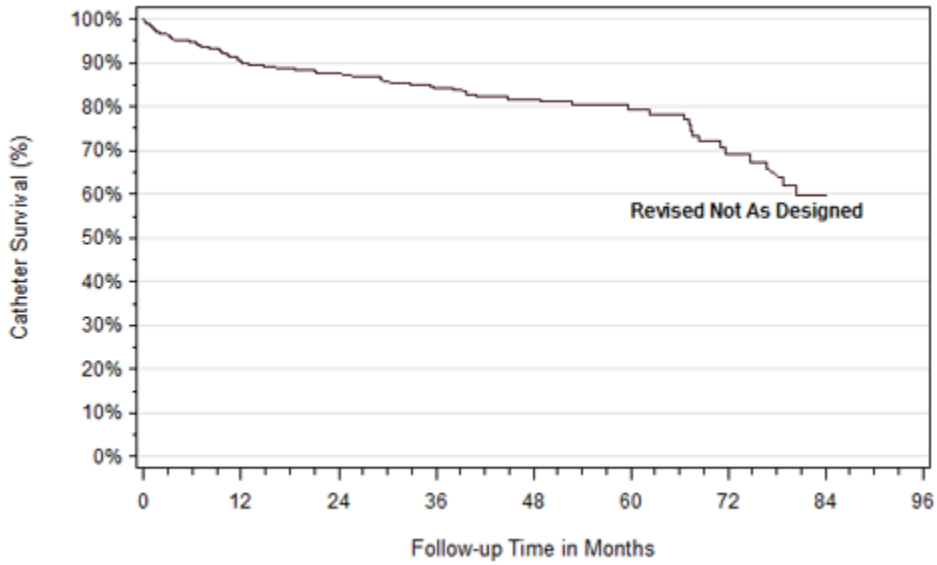
Catheter Event	Total
Catheter leakage	2
Catheter dislodgment from intrathecal space	1
Catheter kink	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**5**

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	94.8% (87.6%, 97.9%)	49
at 21 mo	94.8% (87.6%, 97.9%)	20

Revised Not As Designed: Survival from Catheter Events

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



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Note: Revised Not As Designed catheters are Medtronic non-8731 catheters repaired with the 8596 proximal or 8598 distal revision kit.

Catheter Characteristics	
Model Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	581
Catheters Currently Active in Study	277
Device Events	87
Cumulative Months of Follow-up	16,957

Revised Not As Designed Catheters: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	25

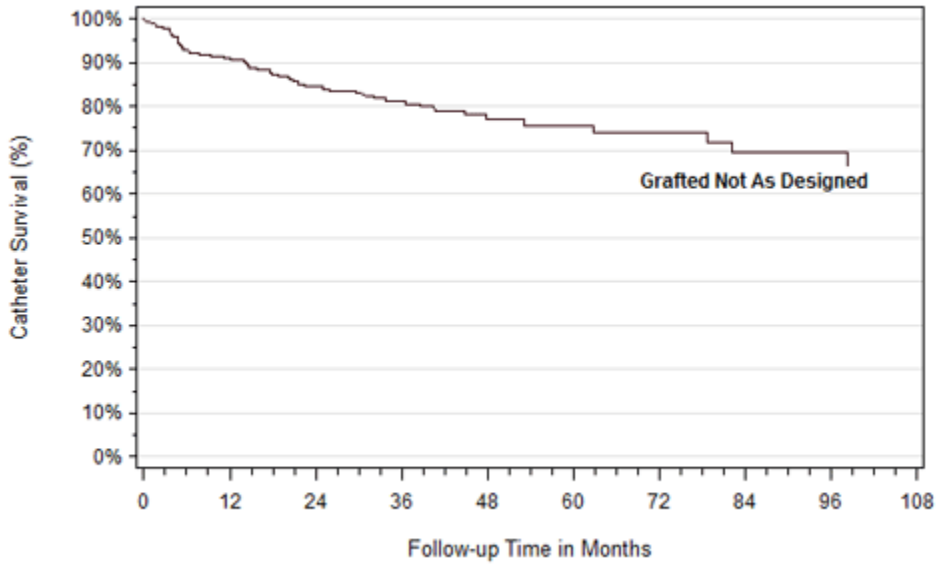
Catheter dislodgment from intrathecal space	20
Catheter break/cut	14
Catheter kink	9
Catheter related complication[a]	5
Catheter disconnection at pump	4
Catheter leakage	4
Pump unable to enter/withdraw from catheter access port	3
Catheter access port issue	1
Connector block problem	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**87**

[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	90.2% (87.1%, 92.6%)	394
2 yrs	87.5% (84.0%, 90.2%)	306
3 yrs	84.3% (80.2%, 87.5%)	195
4 yrs	81.7% (77.1%, 85.5%)	121
5 yrs	79.2% (73.8%, 83.7%)	77
6 yrs	69.1% (60.4%, 76.2%)	47
7 yrs	59.8% (48.8%, 69.2%)	23

Grafted Not As Designed: Survival from Catheter Events

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



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Note: Grafted Not As Designed catheters are catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits spliced together using existing or other industry products.

Catheter Characteristics	
Model Name	Grafted Not As Designed
FDA Approval Date	NA
Catheters Enrolled	421
Catheters Currently Active in Study	183
Device Events	63
Cumulative Months of Follow-up	11,579

Grafted Not As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter dislodgment from intrathecal space	24
Catheter occlusion	15
Catheter break/cut	8
Catheter related complication[a]	5

Catheter leakage	3
Catheter kink	2
Pump unable to enter/withdraw from catheter access port	2
Catheter access port issue	1
Catheter disconnection at pump	1
Device component issue[b]	1
Pump connector break/cut	1
Total Catheter Events	**63**

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

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	90.9% (87.1%, 93.6%)	243
2 yrs	84.5% (79.7%, 88.2%)	181
3 yrs	81.3% (76.0%, 85.6%)	119
4 yrs	77.1% (70.6%, 82.3%)	70
5 yrs	75.7% (68.6%, 81.4%)	43
6 yrs	73.9% (66.0%, 80.2%)	37
7 yrs	69.6% (59.8%, 77.5%)	27
8 yrs	69.6% (59.8%, 77.5%)	23
at 99 mo	66.4% (54.8%, 75.6%)	20

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	2,806	326	300	79,003
8709SC	8709	Mar 2006	1,017	356	112	28,384
8711	8711	Oct 1999	640	159	82	22,860
8731	8731	Oct 2002	500	79	46	19,333
8731SC	8731	Mar 2006	209	112	12	5,180
8780	Ascenda	Sept 2012	514	399	32	5,582
8781	Ascenda	Sept 2012	455	271	34	2,808
Revised As Designed	NA	Oct 2002	217	88	30	6,549
Ascenda Revised As Designed	NA	Sept 2012	134	104	5	1,319
Revised Not As Designed	NA	NA	581	277	87	16,957
Grafted Not As Designed	NA	NA	421	183	63	11,579

[a] There were a total of 967 catheter-related events reported to the registry, but only 803 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=18), or were subsequent events 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[b]	**92.2%** (90.4%, 93.6%)	**89.5%** (87.5%, 91.1%)	**86.2%** (84.0%, 88.1%)	**83.3%** (80.9%, 85.5%)	**80.7%** (78.1%, 83.1%)
8709SC	**94.0%** (92.1%, 95.4%)	**89.5%** (87.0%, 91.5%)	**86.7%** (83.7%, 89.1%)	**83.6%** (80.1%, 86.6%)	**81.7%** (77.6%, 85.0%)
8711	**92.5%** (88.9%, 94.9%)	**90.0%** (86.1%, 92.9%)	**84.8%** (80.3%, 88.4%)	**83.0%** (78.2%, 86.7%)	**81.7%** (76.9%, 85.7%)
8731	**93.5%** (88.8%, 96.3%)	**92.2%** (87.5%, 95.2%)	**91.3%** (86.4%, 94.4%)	**89.3%** (84.3%, 92.8%)	**87.7%** (82.4%, 91.5%)
8731SC	**96.0%** (91.3%, 98.2%)	**91.6%** (85.1%, 95.3%)	**91.6%** (85.1%, 95.3%)	**89.3%** (80.9%, 94.2%)	**89.3%** (80.9%, 94.2%)
8780	**92.4%** (89.0%, 94.8%)	**88.9%** (83.6%, 92.5%)	-	-	-
8781	**84.6%** (78.2%, 89.2%)	-	-	-	-
Revised As Designed	**92.9%** (87.6%, 96.0%)	**89.6%** (83.6%, 93.5%)	**85.9%** (78.4%, 91.0%)	**81.2%** (71.8%, 87.7%)	**79.3%** (69.2%, 86.4%)
Ascenda Revised As Designed	**94.8%** (87.6%, 97.9%)	-	-	-	-
Revised Not As Designed	**90.2%** (87.1%, 92.6%)	**87.5%** (84.0%, 90.2%)	**84.3%** (80.2%, 87.5%)	**81.7%** (77.1%, 85.5%)	**79.2%** (73.8%, 83.7%)
Grafted Not As Designed	**90.9%** (87.1%, 93.6%)	**84.5%** (79.7%, 88.2%)	**81.3%** (76.0%, 85.6%)	**77.1%** (70.6%, 82.3%)	**75.7%** (68.6%, 81.4%)

[a] There were a total of 967 catheter-related events reported to the registry, but only 803 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=18), or were subsequent events that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models

Device Survival Probability (95% Confidence Intervals) – *Table 2 of 3*					
Model Number	**6 yrs**	**7 yrs**	**8 yrs**	**9 yrs**	**10 yrs**
8709[b]	**76.3%** (73.4%, 78.9%)	**71.6%** (68.4%, 74.5%)	**69.1%** (65.7%, 72.2%)	**67.3%** (63.8%, 70.6%)	**65.1%** (61.3%, 68.7%)
8709SC	**80.1%** (75.4%, 83.9%)	**71.1%** (63.0%, 77.7%)	-	-	-
8711	**77.9%** (72.4%, 82.4%)	**73.9%** (68.0%, 79.0%)	**70.9%** (64.4%, 76.5%)	**68.8%** (61.7%, 74.8%)	**65.9%** (58.0%, 72.7%)
8731	**82.2%** (76.0%, 86.9%)	**78.6%** (71.8%, 84.0%)	**76.7%** (69.5%, 82.4%)	**76.7%** (69.5%, 82.4%)	**76.7%** (69.5%, 82.4%)
8731SC	-	-	-	-	-
8780	-	-	-	-	-
8781	-	-	-	-	-
Revised As Designed	**74.3%** (62.2%, 83.1%)	-	-	-	-
Ascenda Revised As Designed	-	-	-	-	-
Revised Not As Designed	**69.1%** (60.4%, 76.2%)	**59.8%** (48.8%, 69.2%)	-	-	-
Grafted Not As Designed	**73.9%** (66.0%, 80.2%)	**69.6%** (59.8%, 77.5%)	**69.6%** (59.8%, 77.5%)	-	-

[a] There were a total of 967 catheter-related events reported to the registry, but only 803 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=18), or were subsequent events that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models

Device Survival Probability (95% Confidence Intervals) – *Table 3 of 3*				
Model Number	**11 yrs**	**12 yrs**	**13 yrs**	**14 yrs**
8709[b]	**62.8%** (58.5%, 66.7%)	**59.7%** (54.7%, 64.2%)	**57.4%** (51.6%, 62.7%)	**57.4%** (51.6%, 62.7%)
8709SC	-	-	-	-
8711	**62.6%** (53.7%, 70.3%)	**60.4%** (50.8%, 68.8%)	-	-
8731	-	-	-	-
8731SC	-	-	-	-
8780	-	-	-	-
8781	-	-	-	-
Revised As Designed	-	-	-	-
Ascenda Revised As Designed	-	-	-	-
Revised Not As Designed	-	-	-	-
Grafted Not As Designed	-	-	-	-

[a] There were a total of 967 catheter-related events reported to the registry, but only 803 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=18), or were subsequent events that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models

Catheter Survival Summary

The survival estimates suggest that the survival of catheters grafted not as designed (those catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits) have a lower probability of survival across various applicable follow-up time points than some other catheter models.

In addition, although the survival estimate for the Ascenda model 8781 catheter may appear to demonstrate

lower performance than the 8731SC predicate catheter at early follow-up time points, these results are reflective of limited cumulative follow-up months. This catheter will continue to be monitored closely as we enroll more patients and follow devices for longer periods of time.

2015 Medtronic Product Performance Report: Data through July 31, 2015

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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Spinal Cord Stimulation Systems

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

Study Participants

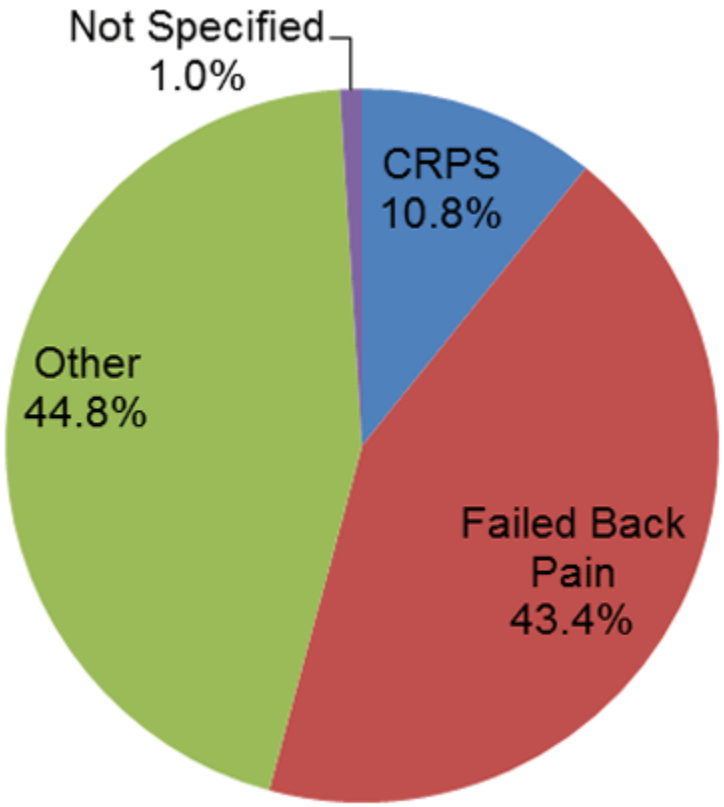
Centers

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, 2015. Seventy-two centers enrolled and contributed patients.

Patients

Of the 3,797 total spinal cord stimulation patients enrolled, 44.8% were implanted for the treatment of other pain indications, 43.4% were implanted for the treatment of failed back pain, 10.8% were implanted for the treatment of complex regional pain syndrome (CRPS), and 1.0% were implanted for indications that were not specified in the database.

Primary SCS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Other	**1,701 (44.8%)**
Other chronic pain	716 (18.9%)

Radicular pain syndrome	533 (14.0%)
Other	219 (5.8%)
Degenerative disc disease	144 (3.8%)
Cervical pain	28 (0.7%)
Traumatic nerve injury	24 (0.6%)
Diabetic neuropathy	18 (0.5%)
Post Herpetic Neuralgia	9 (0.2%)
Facial pain	6 (0.2%)
Epidural Fibrosis	3 (0.1%)
Post herniorrhaphy pain	1 (<0.1%)
Failed Back Pain	**1,648 (43.4%)**
Postlaminectomy pain	685 (18.0%)
Failed Back Syndrome (FBS)	554 (14.6%)
Combination back and leg pain	308 (8.1%)
Multiple Back Operations	74 (1.9%)
Arachnoiditis	21 (0.6%)
Unsuccessful Disc Surgery	6 (0.2%)
CRPS	**410 (10.8%)**
CRPS I	308 (8.1%)
CRPS II	102 (2.7%)
Not Specified	**38 (1.0%)**
Total Patients	**3,797**

[a] Refer to product labeling for approved indications.

Event Summary

There were 2,213 events reported between June 2004 and July 31, 2015 in patients with spinal cord

stimulation systems. Of these events, 38.9% (860/2,213) were categorized as product performance-related and are presented within this report. The 860 product performance events occurred in 405 of the 3,797 total patients (10.7%) enrolled. In addition, there were 1,353 non-product performance events. There were also 103 deaths reported for patients with neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. 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.

Neurostimulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event[b]	Percent of Patients with Event (n=3,797)
Lead migration/dislodgment	425	222	5.9%
Lead high impedance	176	79	2.1%
Lead fracture	56	37	1.0%
Device stimulation issue[c]	47	26	0.7%
Lead low impedance	31	10	0.3%
Neurostimulator unable to recharge[d]	26	24	0.6%
Medical device complication[e]	17	12	0.3%
Device malfunction[f]	15	13	0.3%
Extension fracture	14	9	0.2%
Device breakage[g]	12	12	0.3%
Device lead damage	7	5	0.1%
Battery recharge issue[d]	5	5	0.1%
Device component issue[h]	4	3	0.1%
Device failure[i]	4	3	0.1%
Extension migration	4	2	0.1%
Therapeutic product ineffective	3	2	0.1%

Device battery issue	2	2	0.1%
Device connection issue	2	2	0.1%
Device lead issue	2	1	<0.1%
Inadequate lead connection	2	1	<0.1%
Paraesthesia[j]	2	2	0.1%
Antenna cable breakage	1	1	<0.1%
Broken bond wire	1	1	<0.1%
Device kink	1	1	<0.1%
Device telemetry issue	1	1	<0.1%
Totals	**860**	**405**	**10.7%**

[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 2,489 patients that used rechargeable SCS neurostimulators in the registry. A total of 1.2% (29/2,489) of patients with a rechargeable SCS neurostimulator experienced a recharging unable to recharge or battery recharge issue product performance event.

[e] Includes 4 leads no longer providing stimulation, 3 error messages on patient programmer, 2 events reported as unable to pass stylet into lead, 2 leads with open circuits, 1 hybrid anomaly, 1 loose anchor, 1 programmer error message, 1 unknown problem with extension, 1 defective patient programmer, 1 excessive heating of charging unit.

[f] Includes 2 events for charger malfunction, 2 events for impedance not measurable, 2 events for non-functional lead electrodes, 2 patient programmer malfunctions, 2 antenna malfunctions, 1 malfunctioning programmer, 1 neurostimulator malfunction, 1 event for lead impedance changes, 1 event for neurostimulator stopped working abruptly, and 1 event for error message on programmer.

[g] Includes 6 broken recharger belts, 1 broken antenna, 1 broken antenna and jack, 1 broken charger, 1 broken patient programmer, 1 frayed cord to recharge antenna, and 1 frayed wire to recharger.

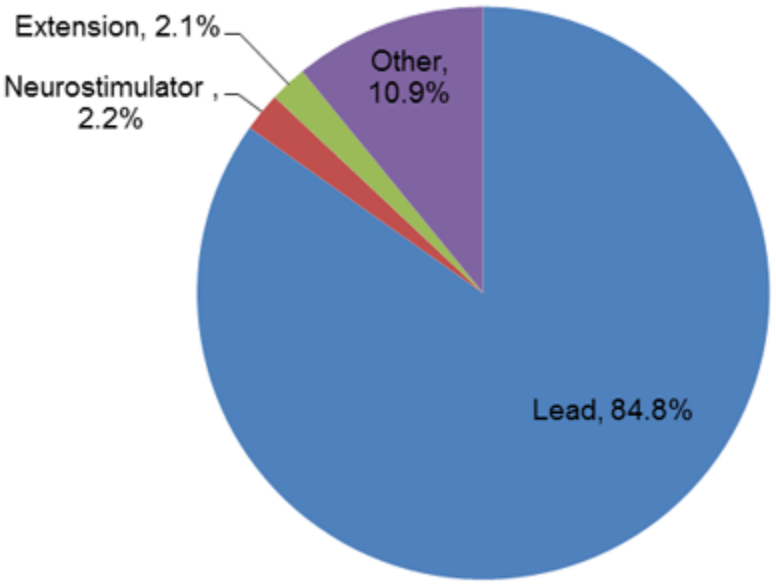
[h] Includes 2 events for lead fractures and migration, 1 damaged antenna cord, and 1 faulty antenna.

[i] Includes 2 events for lead failure, 1 event for failure of lead electrodes, and 1 extension failure.

[j] Includes 1 event for shocking sensation at battery site and 1 shocking sensation at battery/extension connection.

A total of 729 (84.8%) of the 860 product performance events were related to the lead, 37 (4.3%) were related to "other device", 34 (4.0%) were related to “multiple etiologies”, which includes events where at least one device and one non-device etiology was indicated, 19 (2.2%) were related to the neurostimulator, 18 (2.1%) were related to the extension, 13 (1.5%) were related to recharging process, 5 (0.6%) were related to programming/stimulation, 2 (0.2%) were related to incisional site/device tract, 2 (0.2%) were related to other etiology, and 1 (0.1%) was related to the procedure. Relatedness is determined by the physician.

Product Performance Events by Relatedness



Neurostimulation 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	**410**
Device stimulation issue[c]	223
Battery recharge issue[d]	64
Device battery issue[e]	27
Neurostimulator unable to recharge[f]	24
Neurostimulator migration	22
Neurostimulator inversion	17
Device use error	9

Other[g]	24
Therapeutic and nontherapeutic effects (excluding toxicity)	**333**
Therapeutic product ineffective	147
Therapeutic response decreased	124
No therapeutic response	58
Other[g]	4
Administration site reactions	**204**
Implant site pain	139
Implant site erythema	20
Implant site erosion	13
Implant site extravasation	12
Other[g]	20
Infections - pathogen unspecified	**115**
Implant site infection	85
Infection	15
Wound infection	9
Other[g]	6
General system disorders not elsewhere classified (NEC)	**76**
Pain	60
No anomaly found by RPA[h]	9
Other[g]	7
Procedural related injuries and complications NEC	**45**
Wound dehiscence	7
Incision site pain	6

Seroma	6
Incision site erythema	5
Other[g]	21
Musculoskeletal and connective tissue disorders NEC	**40**
Pain in extremity	21
Back pain	14
Other[g]	5
Neurological disorders NEC	**32**
Paraesthesia	19
Other[g]	13
Complications associated with device	**20**
Medical device discomfort	14
Other[g]	6
Muscle disorders	**9**
Muscle spasms	6
Other[g]	3
Headaches	**8**
Headache	7
Other[g]	1
Tissue disorders NEC	**5**
Impaired healing	5
Not Coded[i]	**13**
Other[g]	**43**
Total	**1,353**

[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 or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Event reported by the physician with an etiology that was either not device related or had no associated device event.
[d] Event reported as recharge issues not due to a device malfunction.
[e] Event reported as battery discharge or depletion not due to a device malfunction.
[f] Patient was unable to recharge due to an issue not related to the device.
[g] Composed of event codes with fewer than 5 events each.
[h] 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).
[i] Events that had not been MedDRA-coded at the time of the report cut-off.

There were 103 deaths reported for patients with neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. As indicated, 52 (50.5%) of the deaths occurred in patients receiving therapy for pain indications in the "other" category, 43 (41.8%) for failed back pain, and 8 (7.8%) for CRPS.

Death by Primary Indication

Primary Indication[a]	N (%)
Other	52 (50.5%)
Failed Back Pain	43 (41.8%)
CRPS	8 (7.8%)
Total	**103 (100%)**

[a] Refer to product labeling for approved indications

Spinal Cord Stimulators

From June 2004 to the report cut-off date of July 31, 2015, 4,176 spinal cord stimulators were followed in the registry. The difference between the total number of patients (N=3,797) versus spinal cord stimulators is due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord stimulators was 68,753 months (5,729 years). The table below provides the number and percentage of spinal cord stimulators by model.

Spinal Cord Stimulators by Model

Model Name	Number of Spinal Cord Stimulators (%)
PrimeAdvanced	661 (15.8%)
RestoreSensor SureScan MRI	637 (15.3%)
RestoreUltra	581 (13.9%)
Synergy	461 (11.0%)

Restore	448 (10.7%)
RestoreAdvanced	364 (8.7%)
RestoreSensor	360 (8.6%)
PrimeAdvanced SureScan MRI	267 (6.4%)
Itrel 3	96 (2.3%)
RestoreAdvanced SureScan MRI	70 (1.7%)
RestorePrime	57 (1.4%)
Itrel 4	54 (1.3%)
Synergy Versitrel	52 (1.2%)
RestoreUltra SureScan MRI	29 (0.7%)
SynergyPlus+	16 (0.4%)
SynergyCompact	8 (0.2%)
Other/Unspecified	15 (0.4%)
Total	**4,176 (100%)**

Spinal Cord Stimulator Events

There were 28 product performance-related events with an underlying reported etiology related to spinal cord stimulator function. This includes 19 events with a stimulator etiology and 9 events with both a stimulator and other etiology (including device and non-device etiologies). Of these, 21 were the first event attributable to an enrolled stimulator. For spinal cord stimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 238/927 (25.7%). The proportion was based upon the number of registry spinal cord stimulators received by RPA, divided by the total number of explanted devices plus the total number of spinal cord stimulation devices in patients who have expired. One of the 28 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 27 spinal cord stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device related by the physician as neurostimulator unable to recharge (n=8), lead high impedance (n=6), battery recharge issue (n=3), medical device complication (n=3), device stimulation issue (n=2), device battery issue (n=2), device malfunction (n=1), extension migration (n=1), or lead migration/dislodgement (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 stimulators:

- 21 had follow-up time cut-off due to product performance-related events.
- 2,654 were censored in the survival analysis for the following reasons: patient expired, stimulator explanted, site termination, patient discontinued, other stimulator modification, therapy suspended, or

non-product performance stimulator-related event without an associated intervention.
- 1,501 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

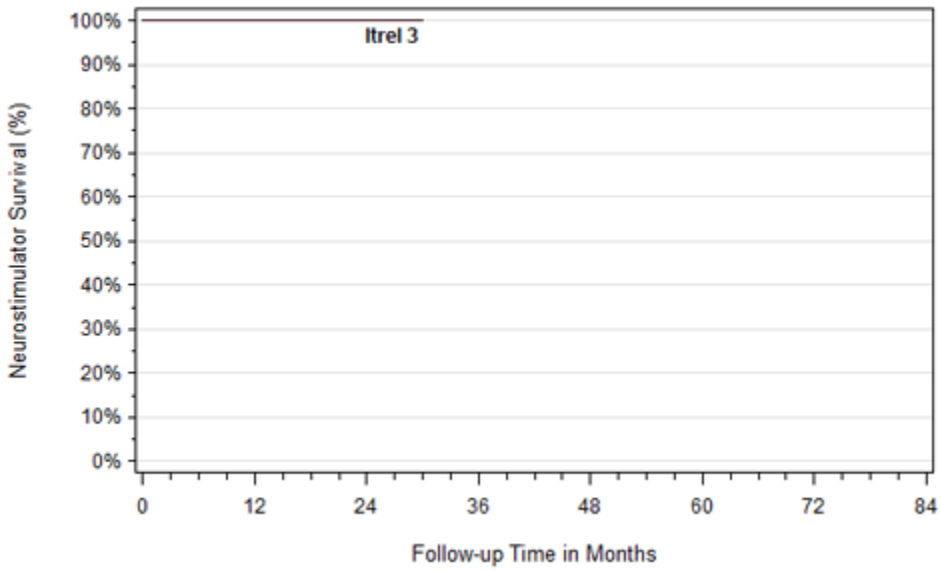
Spinal Cord Stimulator Survival

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

Choose a model Go

Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	96
Neurostimulators Currently Active in Study	0
Device Events	0
Cumulative Months of Follow-up	1,425

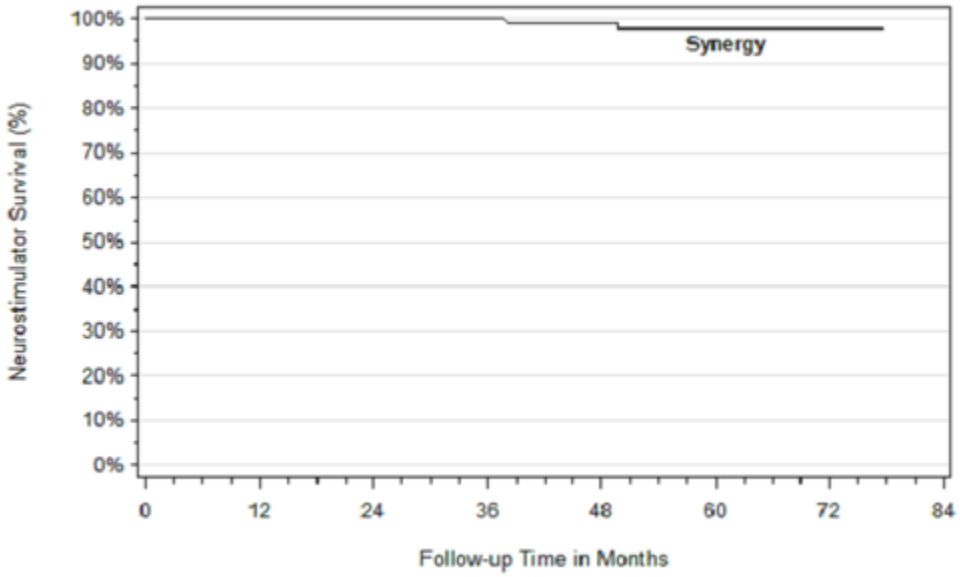
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	35
2 yrs	100.0% (NA)	26
at 30 mo	100.0% (NA)	22

Model 7425 Itrel 3: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	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 7427 Synergy: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	461
Neurostimulators Currently Active in Study	10
Device Events	3
Cumulative Months of Follow-up	9,281

Model 7427 Synergy: Event Summary Table Neurostimulator Event	Total
Device stimulation issue	1
Broken bond wire	1
Lead migration/dislodgment	1
Total Neurostimulator Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	207
2 yrs	100.0% (NA)	174

3 yrs	100.0% (NA)	118
4 yrs	99.1% (93.9%, 99.9%)	78
5 yrs	97.8% (91.3%, 99.5%)	44
6 yrs	97.8% (91.3%, 99.5%)	32
at 81 mo	97.8% (91.3%, 99.5%)	20

Model 7427 Synergy: Specifications

Height	2.4 in (61 mm)
Width	3.0 in (76 mm)
Thinness	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 7427V Synergy Versitrel: Survival from Spinal Cord Stimulator Events

Spinal Cord Stimulator Characteristics	
Model Name	Synergy Versitrel
FDA Approval Date	Dec 2001
Neurostimulators Enrolled	52
Neurostimulators Currently Active in Study	14
Device Events	0
Cumulative Months of Follow-up	724

Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	100.0% (NA)	23
at 9 mo	100.0% (NA)	22

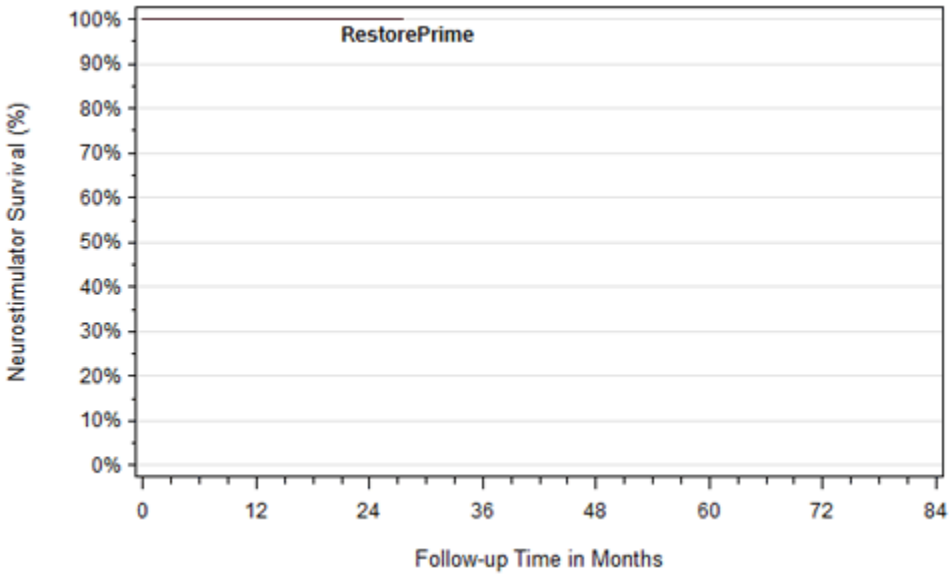
Model 7427V Synergy Versitrel: Specifications

Height	61 mm (2.4 in)
Width	61 mm (2.4 in)
Thinness	15 mm (0.6 in)
Volume	40 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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	57
Neurostimulators Currently Active in Study	2
Device Events	0
Cumulative Months of Follow-up	1,240

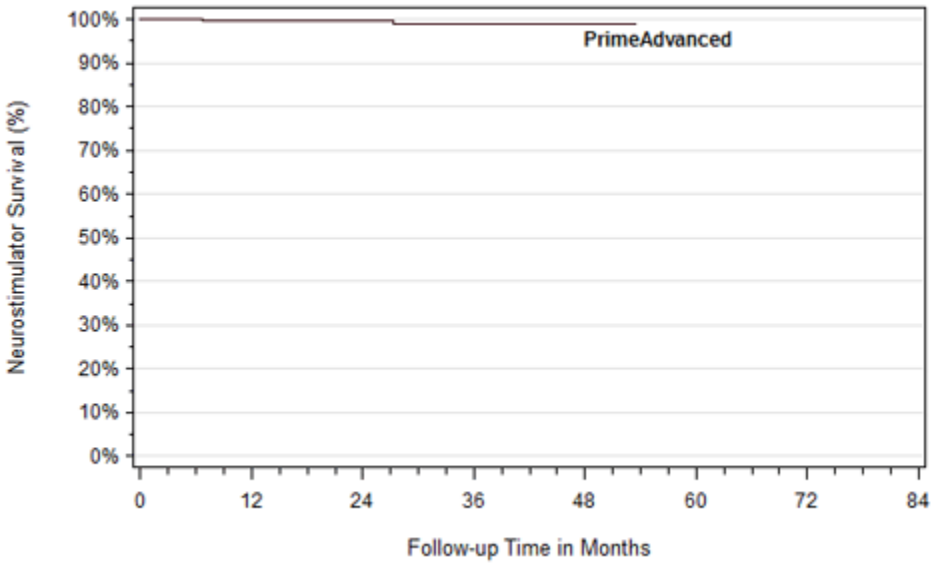
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	37
2 yrs	100.0% (NA)	23
at 27 mo	100.0% (NA)	21

Model 37701 RestorePrime: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	661
Neurostimulators Currently Active in Study	148
Device Events	2
Cumulative Months of Follow-up	10,988

Model 37702 PrimeAdvanced: Event Summary Table Neurostimulator Event	Total
Device stimulation issue	1
Device battery issue	1
Total Neurostimulator Events	**2**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.8% (98.4%,100.0%)	337
2 yrs	99.8% (98.4%,100.0%)	175

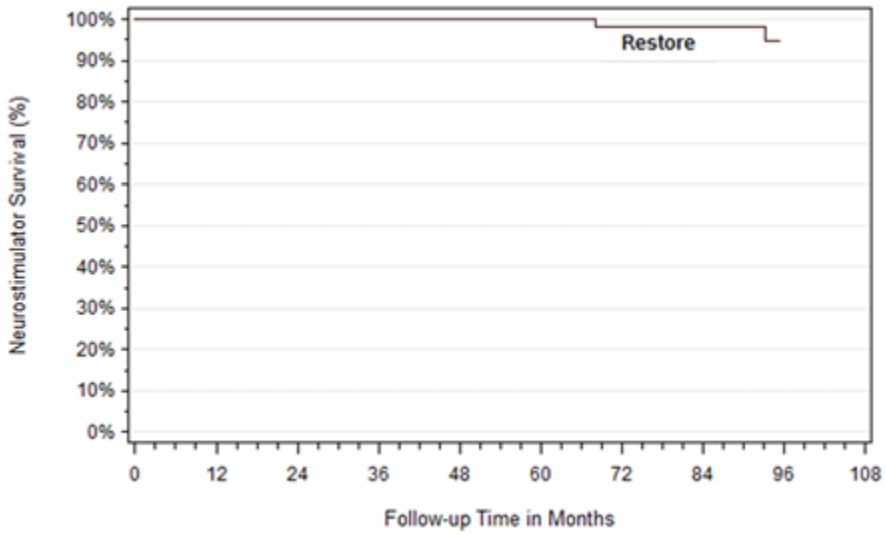
3 yrs	99.0% (95.5%,99.8%)	77
4 yrs	99.0% (95.5%,99.8%)	38
at 54 mo	99.0% (95.5%,99.8%)	22

Model 37702 PrimeAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	448
Neurostimulators Currently Active in Study	21
Device Events	4
Cumulative Months of Follow-up	12,815

Model 37711 Restore: Event Summary Table Neurostimulator Event	Total
Neurostimulator unable to recharge	2
Device battery issue	1
Battery recharge issue	1
Total Neurostimulator Events	**4**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	278
2 yrs	100.0% (NA)	221

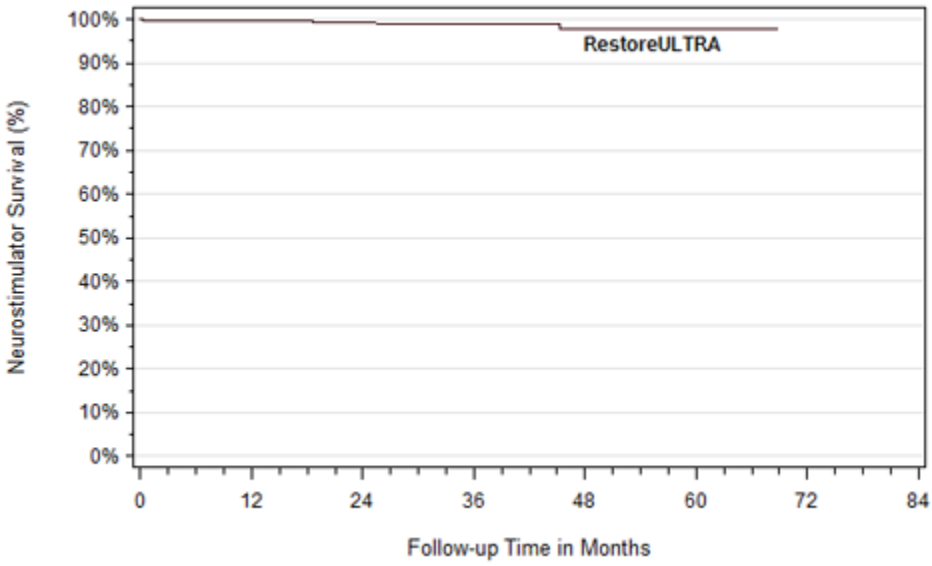
3 yrs	100.0% (NA)	144
4 yrs	100.0% (NA)	91
5 yrs	100.0% (NA)	70
6 yrs	98.3% (88.3%, 99.8%)	53
7 yrs	98.3% (88.3%, 99.8%)	40
8 yrs	94.9% (80.0%, 98.8%)	24

Model 37711 Restore: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	581
Neurostimulators Currently Active in Study	106
Device Events	5
Cumulative Months of Follow-up	12,303

Model 37712 RestoreUltra: Event Summary Table Neurostimulator Event	Total
Neurostimulator unable to recharge	2
Device malfunction[a]	1
Medical device complication[b]	1
Lead high impedance	1
Total Neurostimulator Events	**5**

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

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.8% (98.6%, 100.0%)	325
2 yrs	99.4% (97.3%, 99.9%)	182
3 yrs	98.8% (96.1%, 99.6%)	126
4 yrs	97.8% (93.2%, 99.3%)	80
5 yrs	97.8% (93.2%, 99.3%)	42
at 69 mo	97.8% (93.2%, 99.3%)	23

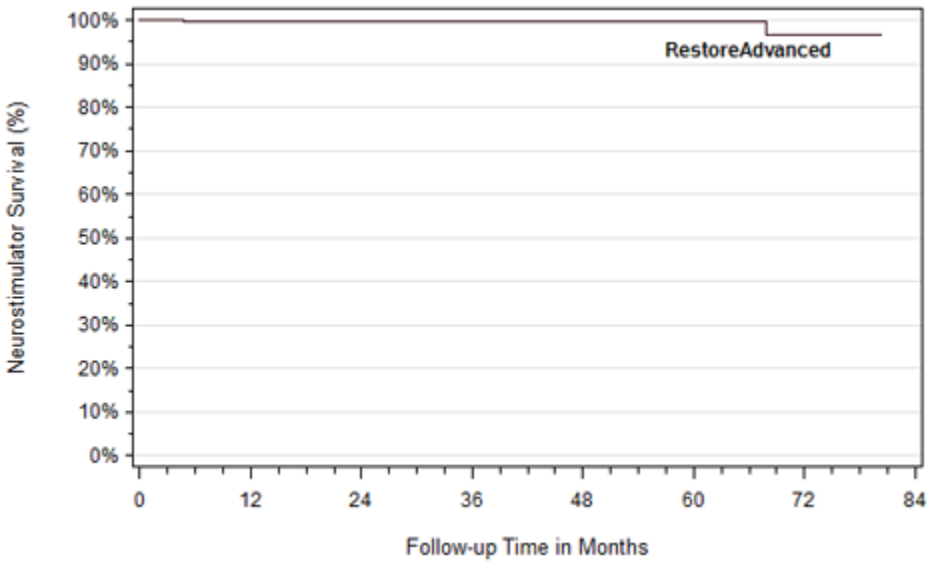
Model 37712 RestoreUltra: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	364
Neurostimulators Currently Active in Study	94
Device Events	2
Cumulative Months of Follow-up	8,940

Model 37713 RestoreAdvanced: Event Summary Table Neurostimulator Event	Total
Medical device complication[a]	1
Battery recharge issue	1
Total Neurostimulator Events	**2**

[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%)	219
2 yrs	99.6% (97.5%, 99.9%)	143
3 yrs	99.6% (97.5%, 99.9%)	88
4 yrs	99.6% (97.5%, 99.9%)	57
5 yrs	99.6% (97.5%, 99.9%)	42
6 yrs	96.8% (83.0%, 99.4%)	28
at 81 mo	96.8% (83.0%, 99.4%)	21

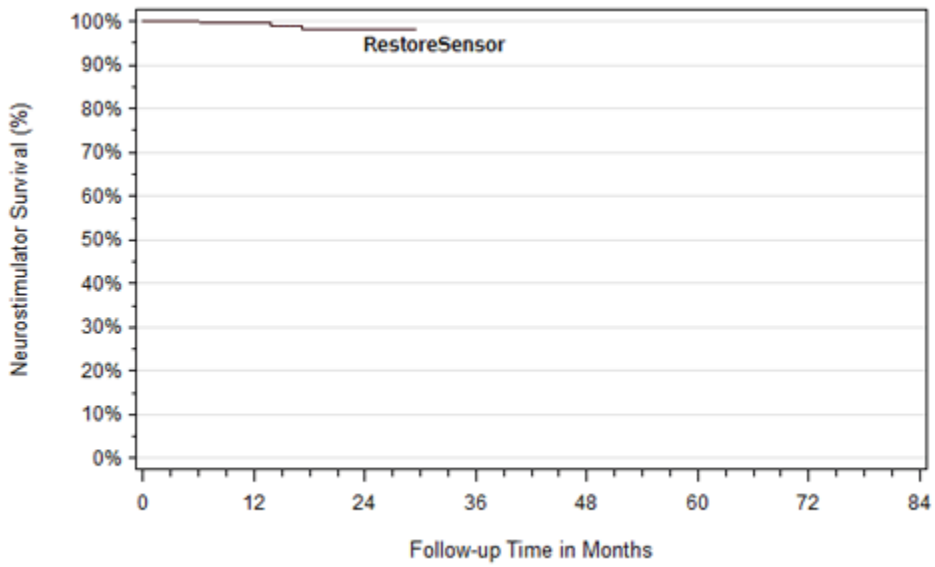
Model 37713 RestoreAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	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 Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011
Neurostimulators Enrolled	360
Neurostimulators Currently Active in Study	238
Device Events	3
Cumulative Months of Follow-up	4,598

Model 37714 RestoreSensor: Event Summary Table	
Neurostimulator Event	**Total**
Neurostimulator unable to recharge	2

Battery recharge issue	1
Total Neurostimulator Events	**3**

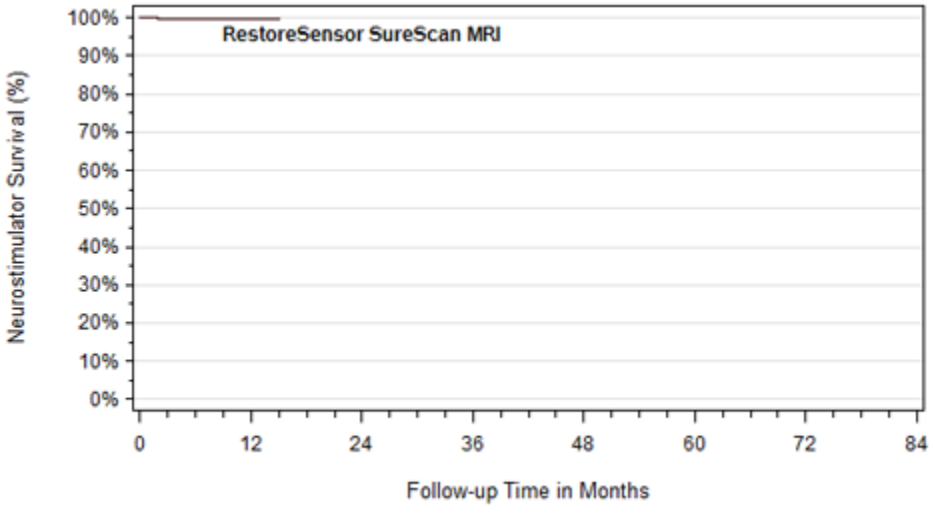
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.6% (96.9%, 99.9%)	171
2 yrs	98.2% (94.3%, 99.4%)	60
at 30 mo	98.2% (94.3%, 99.4%)	28

Model 37714 RestoreSensor: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	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 97714 RestoreSensor SureScan MRI: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreSensor SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	637
Neurostimulators Currently Active in Study	552
Device Events	2
Cumulative Months of Follow-up	3,409

Model 97714 RestoreSensor SureScan MRI: Event Summary Table	
Neurostimulator Event	**Total**
Neurostimulator unable to recharge	2
Total Neurostimulator Events	**2**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.4% (97.7%, 99.9%)	108
at 15 mo	99.4% (97.7%, 99.9%)	56

Model 97714 RestoreSensor SureScan MRI: Specifications

Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thinness	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 Stimulator Characteristics

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	96	0	0	1,425
Synergy	Synergy	Nov 1999	461	10	3	9,281
Synergy Versitrel	Synergy	Dec 2001	52	14	0	724
Restore Prime	Restore	Mar 2006	57	2	0	1,240

Prime Advanced	Prime Advanced	Jul 2006	661	148	2	10,988
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	448	21	4	12,815
Restore Ultra	Restore	Jan 2008	581	106	5	12,303
Restore Advanced	Restore	Jul 2006	364	94	2	8,940
Restore Sensor	Restore	Nov 2011	360	238	3	4,598
Restore Sensor SureScan MRI	Restore	Mar 2013	637	552	2	3,409

[a] There were 28 neurostimulator-related events reported to the registry, but only 21 events included in this summary table. The remaining neurostimulator related events were subsequent events that did not affect the device survival estimates.
[b] Synergy Versitrel had device survival probability of 100% at 9 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	-	-
Synergy	**100.0%** NA	**100.0%** NA	**100.0%** NA	**99.1%** (93.9%, 99.9%)
SynergyVersitrel	-[b]	-	-	-
RestorePrime	**100.0%** NA	**100.0%** NA	-	-
PrimeAdvanced	**99.8%** (98.4%, 100.0%)	**99.8%** (98.4%, 100.0%)	**99.0%** (95.5%, 99.8%)	**99.0%** (95.5%, 99.8%)
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA

RestoreUltra	**99.8%** (98.6%, 100.0%)	**99.4%** (97.3%, 99.9%)	**98.8%** (96.1%, 99.6%)	**97.8%** (93.2%, 99.3%)
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%** (96.9%, 99.9%)	**98.2%** (94.3%, 99.4%)	-	-
RestoreSensor SureScan MRI	**99.4%** (97.7%, 99.9%)	-	-	-

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	-	-	-	-
Synergy	**97.8%** (91.3%, 99.5%)	**97.8%** (91.3%, 99.5%)	-	-
SynergyVersitrel	-	-	-	-
RestorePrime	-	-	-	-
PrimeAdvanced	-	-	-	-
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**98.3%** (88.3%, 99.8%)	**98.3%** (88.3%, 99.8%)	**94.9%** (80.0%, 98.8%)
RestoreUltra	**97.8%** (93.2%, 99.3%)	-	-	-
RestoreAdvanced	**99.6%** (97.5%, 99.9%)	**96.8%** (83.0%, 99.4%)	-	-
RestoreSensor	-	-	-	-
RestoreSensor SureScan MRI	-	-	-	-

[a] There were 28 neurostimulator-related events reported to the registry, but only 21 events included in this summary table. The remaining neurostimulator related events were subsequent events that did not affect the device survival estimates.

[b] Synergy Versitrel had device survival probability of 100% at 9 months of follow-up.

Leads

From June 2004 to the report cut-off date of July 31, 2015, there were 7,054 leads followed in the registry. Differences between the total number of leads versus spinal cord stimulators (N=4,176) 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 127,844 months (10,654 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	**Number of Leads (%)**
3778	2,121 (30.1%)
977A2	1,330 (18.9%)
3487A	937 (13.3%)
3777	792 (11.2%)
3888	408 (5.8%)
39565	236 (3.3%)
3776	183 (2.6%)
3887	176 (2.5%)
3998	148 (2.1%)
3890	137 (1.9%)
3891	119 (1.7%)
3986A	98 (1.4%)
977A1	83 (1.2%)
3999	54 (0.8%)
3587A	50 (0.7%)
39286	23 (0.3%)
3892	22 (0.3%)
3987A	7 (0.1%)
3982A	2 (<0.1%)

Other/Unspecified	128 (1.8%)
Total	**7,054 (100%)**

Over eighty-nine percent (89.4%) of leads in the registry were percutaneous leads (6,308/7,054) including 43.9% (3,096/7,054) in the Pisces-Octad lead family, 21.6% (1,521/7,054) in the Pisces-Quad lead family, 20.0% (1,413/7,054) in the Vectris SureScan MRI lead family, and 3.9% (278/7,054) in the Pisces-Quad LZ lead family. Over eight percent (8.8%) of leads (618/7,054) were surgical leads. A small number of leads (128/7,054) were designated as “other” (1.8%).

Lead Events

There were 748 product performance-related events with an underlying reported etiology related to the lead. This includes 729 events with a lead etiology and 19 events with both a lead and other etiology (including device and non-device etiologies). Of these events, the majority were lead migration/dislodgements (n=421), high impedance (n=161), and lead fracture (n=56). Of the 748 lead events, 644 were the first event attributable to an enrolled lead: 606 events in 6,436 (9.4%) percutaneous leads, 38 events in 618 (6.1%) surgical leads, and 3 events occurred in 128 (2.3%) leads 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:

- 644 had follow-up time cut-off due to product performance-related events.
- 3,818 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.
- 2,592 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

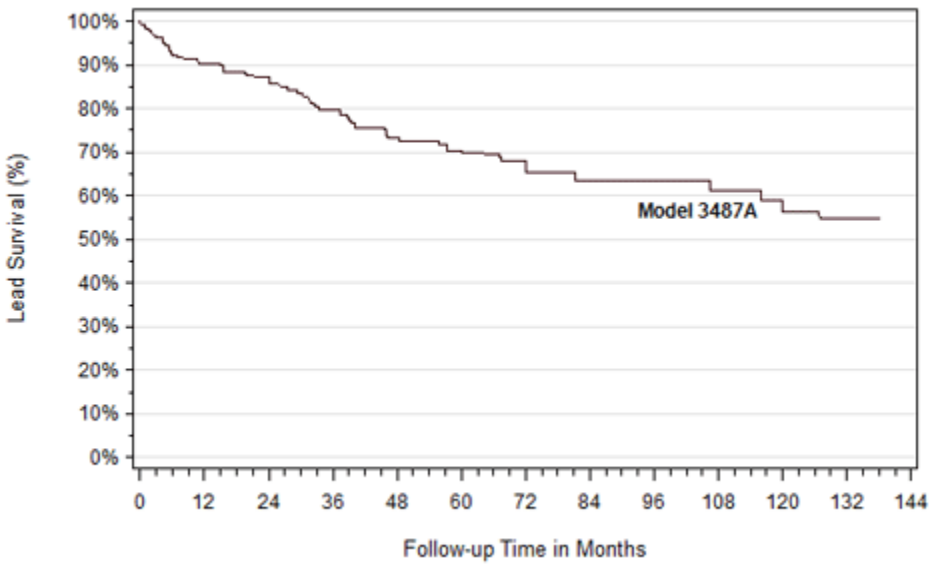
Lead Survival

The table below represents annual lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. As of February 6, 2008, Medtronic has discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

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	937
Leads Currently Active in Study	331
Device Events	162
Cumulative Months of Follow-up	26,143

Model 3487A Pisces-Quad: Event Summary Table

Lead Event	Total
Lead high impedance	60
Lead migration/dislodgment	46
Lead low impedance	23
Device stimulation issue	17
Lead fracture	13
Inadequate lead connection	2
Therapeutic product ineffective	1

Total Lead Events	162

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	90.1% (87.2%, 92.4%)	451
2 yrs	87.0% (83.8%, 89.7%)	364
3 yrs	79.9% (75.8%, 83.3%)	287
4 yrs	73.1% (68.5%, 77.2%)	202
5 yrs	70.4% (65.4%, 74.7%)	163
6 yrs	65.8% (60.3%, 70.7%)	122
7 yrs	63.4% (57.6%, 68.7%)	100
8 yrs	63.4% (57.6%, 68.7%)	70
9 yrs	61.3% (55.0%, 67.1%)	58
10 yrs	56.5% (48.9%, 63.3%)	44
11 yrs	54.9% (47.0%, 62.2%)	31
at 138 mo	54.9% (47.0%, 62.2%)	24

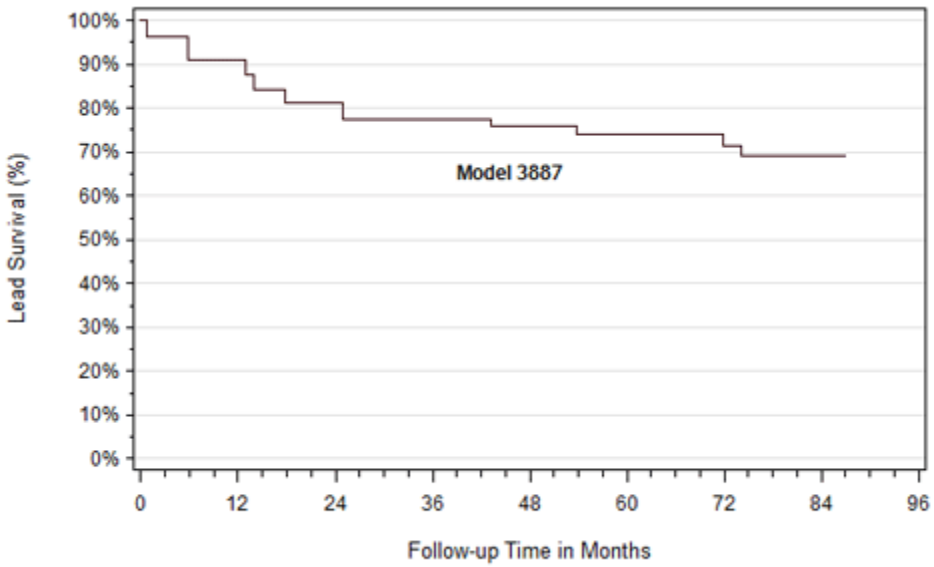
Model 3487A Pisces-Quad: Specifications

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	176

Leads Currently Active in Study	40
Device Events	21
Cumulative Months of Follow-up	4,250

Model 3887 Pisces-Quad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	9
Lead fracture	7
Device stimulation issue	2
Lead high impedance	2
Device lead damage	1
Total Lead Events	**21**

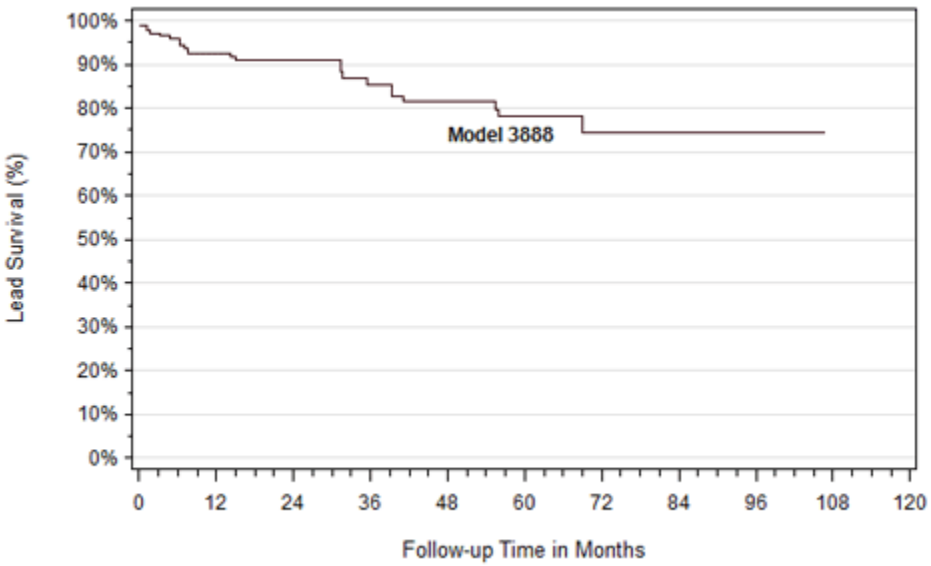
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	91.2% (74.8%, 97.1%)	46
2 yrs	81.0% (66.2%, 89.8%)	47
3 yrs	77.4% (62.5%, 87.0%)	48
4 yrs	75.9% (61.1%, 85.7%)	42
5 yrs	73.9% (59.0%, 84.1%)	36
6 yrs	71.5% (56.3%, 82.2%)	29
7 yrs	69.0% (53.5%, 80.2%)	21
at 87 mo	69.0% (53.5%, 80.2%)	21

Model 3887 Pisces-Quad: Specifications

Device Name **Lead Type**	**Pisces Compact** **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	408
Leads Currently Active in Study	69
Device Events	29
Cumulative Months of Follow-up	7,362

Model 3888 Pisces-Quad: Event Summary Table/strong>

Lead Event	Total
Lead migration/dislodgment	24
Device stimulation issue	2
Lead high impedance	2
Lead fracture	1
Total Lead Events	**29**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.5% (87.8%, 95.5%)	132
2 yrs	91.0% (85.7%, 94.4%)	79
3 yrs	85.5% (77.4%, 90.8%)	63
4 yrs	81.5% (72.3%, 87.8%)	51
5 yrs	78.3% (68.2%, 85.5%)	44
6 yrs	74.2% (62.9%, 82.6%)	34
7 yrs	74.2% (62.9%, 82.6%)	24
8 yrs	74.2% (62.9%, 82.6%)	22

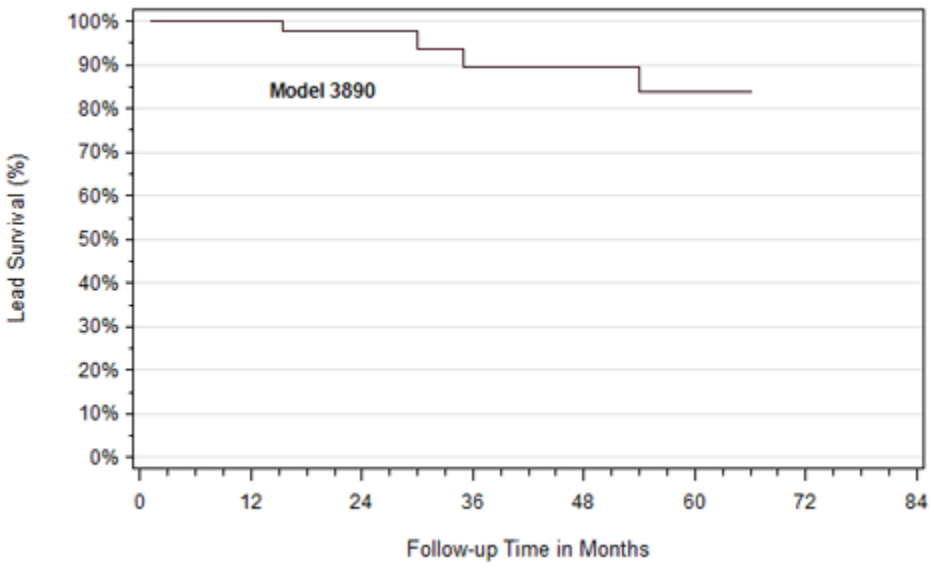
9 yrs	74.2% (62.9%, 82.6%)	21

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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Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics	
Model Number	3890
FDA Approval Date	Sep 2002
Leads Enrolled	137
Leads Currently Active in Study	15
Device Events	10
Cumulative Months of Follow-up	2,885

Model 3890 Pisces-Quad LZ: Event Summary Table

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

[a] Includes 2 events reported as impedance not measurable

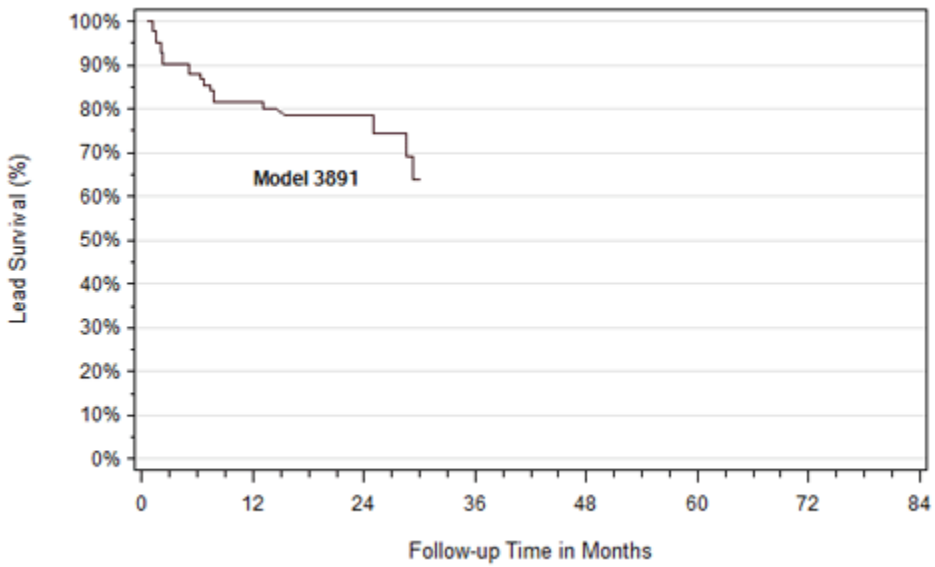
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	38
2 yrs	97.8% (85.1%, 99.7%)	51
3 yrs	89.4% (76.4%, 95.5%)	40
4 yrs	89.4% (76.4%, 95.5%)	33
5 yrs	83.8% (68.8%, 92.0%)	22
at 66 mo	83.8% (68.8%, 92.0%)	20

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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Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics	
Model Number	3891
FDA Approval Date	Sep 2002
Leads Enrolled	119
Leads Currently Active in Study	8
Device Events	30
Cumulative Months of Follow-up	2,217

Model 3891 Pisces-Quad LZ: Event Summary Table

Lead Event	**Total**
Lead migration/dislodgment	18
Lead fracture	6
Device stimulation issue	4
Device lead damage	2
Total Lead Events	**30**

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**

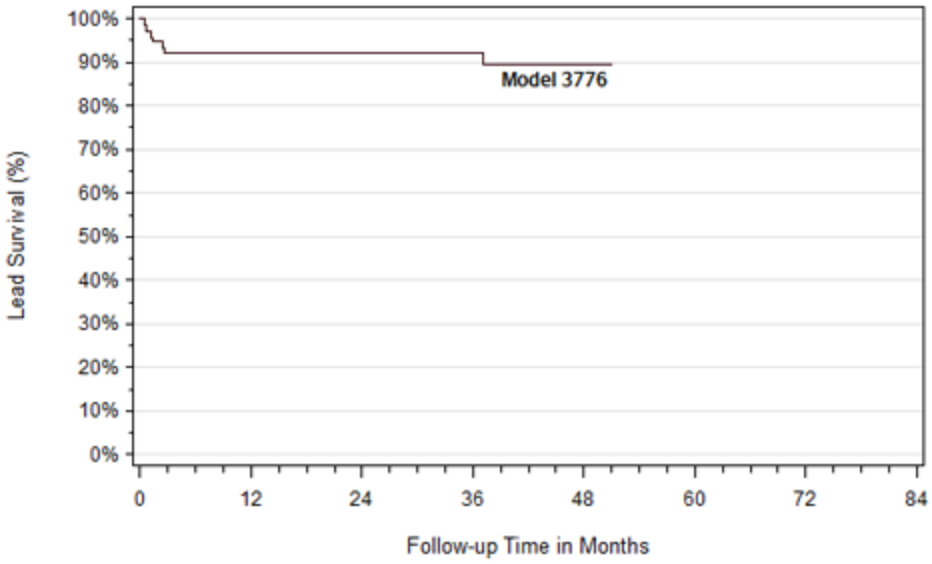
1 yr	81.7% (71.4%, 88.5%)	56
2 yrs	78.7% (67.9%, 86.2%)	37
at 30 mo	63.9% (49.3%, 75.3%)	21

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	183
Leads Currently Active in Study	44
Device Events	13
Cumulative Months of Follow-up	3,427

Model 3776 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	9
Lead high impedance	2
Device stimulation issue	1
Lead fracture	1
Total Lead Events	**13**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.3%	79

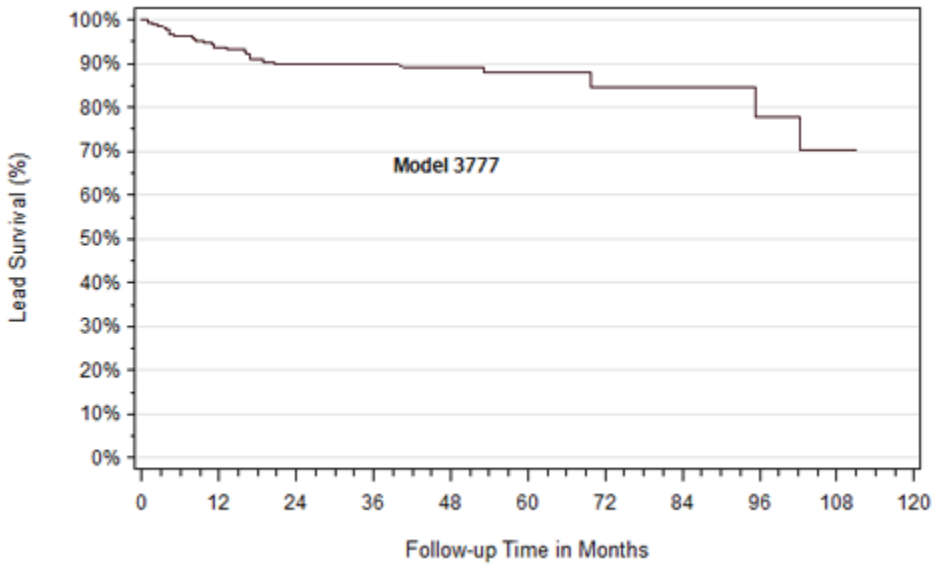
	(86.2%, 95.8%)	
2 yrs	92.3% (86.2%, 95.8%)	53
3 yrs	92.3% (86.2%, 95.8%)	33
4 yrs	89.4% (79.5%, 94.7%)	22
at 51 mo	89.4% (79.5%, 94.7%)	22

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.



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Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	792
Leads Currently Active in Study	187
Device Events	53
Cumulative Months of Follow-up	15,645

Model 3777 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	35
Device stimulation issue	7
Lead high impedance	5
Device lead damage	2
Lead fracture	2
Lead low impedance	2
Total Lead Events	**53**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	93.5% (90.9%, 95.4%)	387
2 yrs	89.7% (86.3%, 92.3%)	233
3 yrs	89.7% (86.3%, 92.3%)	147
4 yrs	89.0% (85.3%, 91.9%)	86
5 yrs	87.9% (83.3%, 91.3%)	61
6 yrs	84.7% (78.0%, 89.6%)	48
7 yrs	84.7% (78.0%, 89.6%)	32
8 yrs	77.7% (64.6%, 86.4%)	21
9 yrs	70.3% (54.1%, 81.7%)	21
at 111 mo	70.3% (54.1%, 81.7%)	21

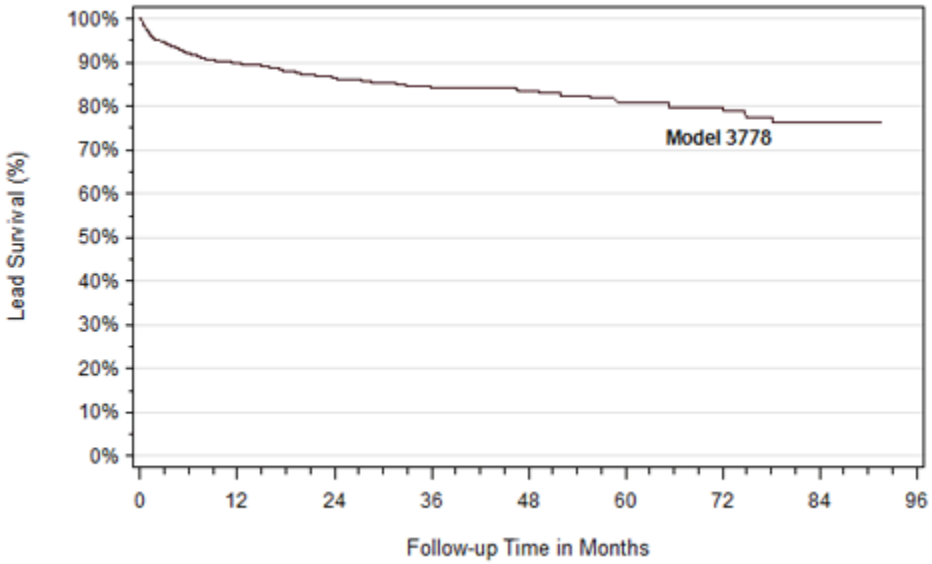
Model 3777 Pisces-Octad: Specifications

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.



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Lead Characteristics	
Model Number	3778
FDA Approval Date	Apr 2005
Leads Enrolled	2,121
Leads Currently Active in Study	558
Device Events	245
Cumulative Months of Follow-up	44,764

Model 3778 Pisces-Octad: Event Summary Table Lead Event	Total
Lead migration/dislodgment	187
Lead high impedance	31
Lead fracture	14
Device stimulation issue	6
Medical device complication[a]	4
Device malfunction[b]	2
Lead low impedance	1
Total Lead Events	**245**

[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

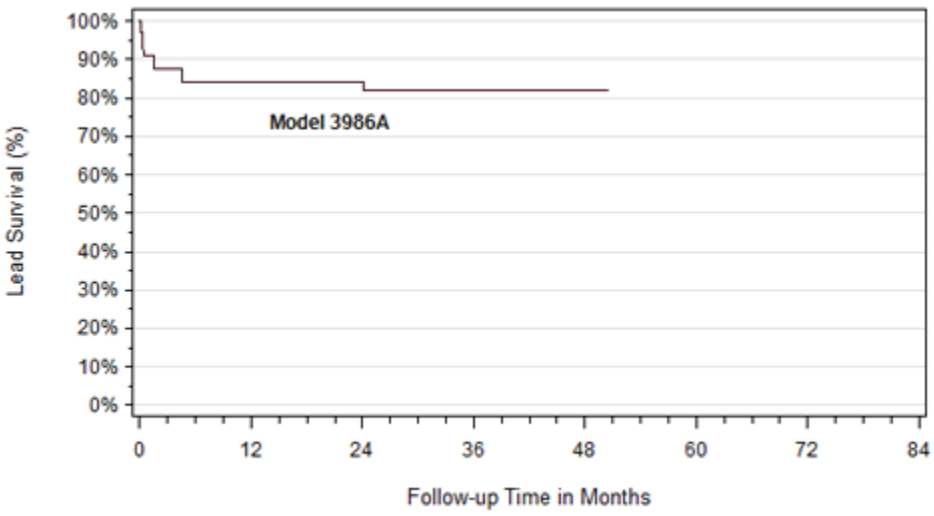
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	89.8% (88.2%, 91.2%)	1,167
2 yrs	86.4% (84.5%, 88.1%)	676
3 yrs	84.1% (81.9%, 86.1%)	429
4 yrs	83.6% (81.2%, 85.7%)	268
5 yrs	80.9% (77.8%, 83.7%)	173
6 yrs	79.1% (75.3%, 82.4%)	107
7 yrs	76.4% (71.5%, 80.6%)	42
at 93 mo	76.4% (71.5%, 80.6%)	23

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 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	98
Leads Currently Active in Study	37
Device Events	17
Cumulative Months of Follow-up	2,658

Model 3986A Resume TL: Event Summary Table

Lead Event	Total
Lead high impedance	9
Device connection issue	2
Device stimulation issue	2
Lead low impedance	2
Lead migration/dislodgment	2
Total Lead Events	**17**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	84.9% (73.8%, 91.6%)	46
2 yrs	84.9% (73.8%, 91.6%)	36
3 yrs	82.6% (70.5%, 90.1%)	25
4 yrs	82.6% (70.5%, 90.1%)	22
at 51 mo	82.6% (70.5%, 90.1%)	21

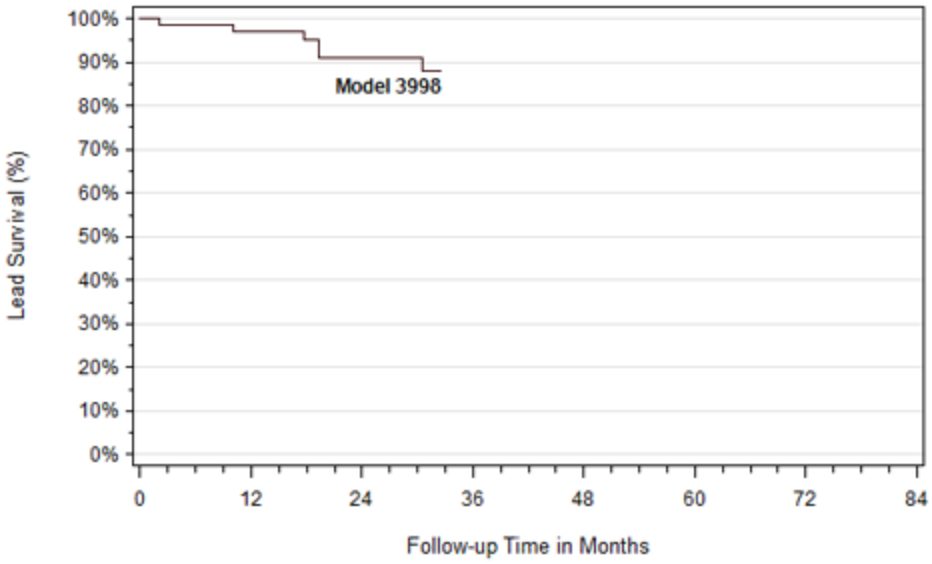
Model 3986A Resume TL: Specifications

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	148
Leads Currently Active in Study	24
Device Events	10
Cumulative Months of Follow-up	2,798

Model 3998 Specify: Event Summary Table

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

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	96.9%	57

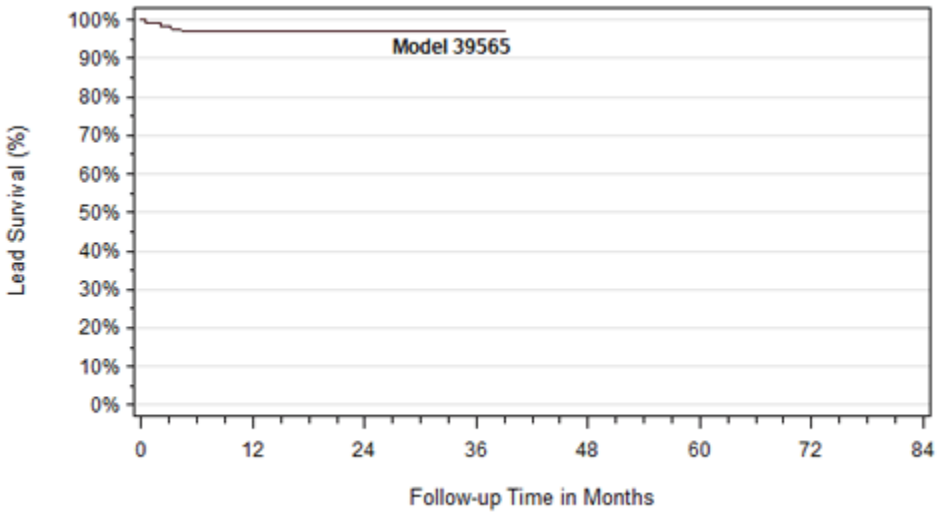
	(88.3%, 99.2%)	
2 yrs	91.2% (79.9%, 96.3%)	38
at 33 mo	87.9% (74.0%, 94.6%)	25

Model 3998 Specify: Specifications

Device Name **Lead Type**	**Specify** **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	236
Leads Currently Active in Study	132
Device Events	7
Cumulative Months of Follow-up	3,290

Model 39565 Specify: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	7
Total Lead Events	**7**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	96.9% (92.8%, 98.7%)	94
2 yrs	96.9%	53

	(92.8%, 98.7%)	
3 yrs	96.9% (92.8%, 98.7%)	25
at 39 mo	96.9% (92.8%, 98.7%)	22

Model 39565 Specify: Specifications

Device Name **Lead Type**	**Specify 5-6-5** **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

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

Lead Characteristics	
Model Number	977A1
FDA Approval Date	Mar 2013
Leads Enrolled	83
Leads Currently Active in Study	66
Device Events	2
Cumulative Months of Follow-up	437

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

Lead Event	Total
Device component issue	2
Total Lead Events	**2**

Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	94.7% (80.6%, 98.7%)	31
at 9 mo	94.7% (80.6%, 98.7%)	21

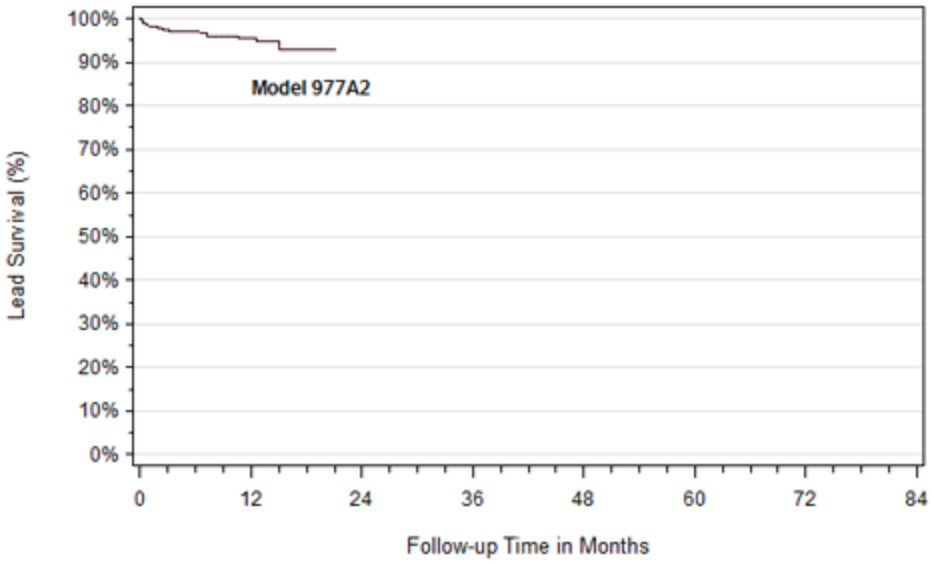
Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Specifications

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.



View Larger Image

Lead Characteristics	
Model Number	977A2
FDA Approval Date	Mar 2013
Leads Enrolled	1,330
Leads Currently Active in Study	1,152
Device Events	37
Cumulative Months of Follow-up	7,073

Model 977A2 Vectris SureScan MRI 1x8 Compact: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgment	27
Lead high impedance	5
Lead fracture	4
Lead low impedance	1
Total Lead Events	**37**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	95.7%	225

	(93.7%, 97.0%)	
at 21 mo	92.9% (88.8%, 95.5%)	20

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

[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	937	331	162	26,143
3887	**Pisces-Quad**	Jan 1997	176	40	21	4,250
	Pisces-					

3888	**Quad**	Nov 1992	408	69	29	7,362
3890	**Pisces-Quad LZ**	Sep 2002	137	15	10	2,885
3891	**Pisces-Quad LZ**	Sep 2002	119	8	30	2,217
3776	**Pisces-Octad**	Nov 2005	183	44	13	3,427
3777	**Pisces-Octad**	Apr 2005	792	187	53	15,645
3778	**Pisces-Octad**	Apr 2005	2,121	558	245	44,764
977A1	**Vectris SureScan**	Mar 2013	83	66	2	437
977A2	**Vectris SureScan**	Mar 2013	1,330	1,152	37	7,073
Surgical Leads						
3986A	**Resume TL**	Apr 1995[b]	98	37	17	2,658
3998	**Specify**	Feb 1998	148	24	10	2,798
39565	**Specify**	Jun 2007	236	132	7	3,290

[a] There were a total of 748 lead-related events reported to the registry, but only 636 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=3), or were subsequent or unlinked device events that did not affect the survival estimates.

[b] Model 977A1 had a device survival probability of 93.8 % (77.3%, 98.4%) at 6 months of follow-up.

[c] 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**	**90.1%** (87.2%, 92.4%)	**87.0%** (83.8%, 89.7%)	**79.9%** (75.8%, 83.3%)	**73.1%** (68.5%, 77.2%)
3887	**Pisces-Quad**	**91.2%** (74.8%, 97.1%)	**81.0%** (66.2%, 89.8%)	**77.4%** (62.5%, 87.0%)	**75.9%** (61.1%, 85.7%)

3888	**Pisces-Quad**	**92.5%** (87.8%, 95.5%)	**91.0%** (85.7%, 94.4%)	**85.5%** (77.4%, 90.8%)	**81.5%** (72.3%, 87.8%)
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**	**92.3%** (86.2%, 95.8%)	**92.3%** (86.2%, 95.8%)	**92.3%** (86.2%, 95.8%)	**89.4%** (79.5%, 94.7%)
3777	**Pisces-Octad**	**93.5%** (90.9%, 95.4%)	**89.7%** (86.3%, 92.3%)	**89.7%** (86.3%, 92.3%)	**89.0%** (85.3%, 91.9%)
3778	**Pisces-Octad**	**89.8%** (88.2%, 91.2%)	**86.4%** (84.5%, 88.1%)	**84.1%** (81.9%, 86.1%)	**83.6%** (81.2%, 85.7%)
977A1	**Vectris SureScan**	[b]	-	-	-
977A2	**Vectris SureScan**	**95.7%** (93.7%, 97.0%)	-	-	-
Surgical Leads					
3986A	**Resume TL**	**84.9%** (73.8%, 91.6%)	**84.9%** (73.8%, 91.6%)	**82.6%** (70.5%, 90.1%)	**82.6%** (70.5%, 90.1%)
3998	**Specify**	**96.9%** (88.3%, 99.2%)	**91.2%** (79.9%, 96.3%)	-	-
39565	**Specify**	**96.9%** (92.8%, 98.7%)	**96.9%** (92.8%, 98.7%)	**96.9%** (92.8%, 98.7%)	-

[a] There were a total of 748 lead-related events reported to the registry, but only 636 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=3), or were subsequent or unlinked device events that did not affect the survival estimates.

[b] Model 977A1 had a device survival probability of 93.8 % (77.3%, 98.4%) at 6 months of follow-up.

[c] FDA clearance date.

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%** (65.4%, 74.7%)	**65.8%** (60.3%, 70.7%)	**63.4%** (57.6%, 68.7%)	**63.4%** (57.6%, 68.7%)

3887	**Pisces-Quad**	**73.9%** (59.0%, 84.1%)	**71.5%** (56.3%, 82.2%)	**69.0%** (53.5%, 80.2%)	-
3888	**Pisces-Quad**	**78.3%** (68.2%, 85.5%)	**74.2%** (62.9%, 82.6%)	**74.2%** (62.9%, 82.6%)	**74.2%** (62.9%, 82.6%)
3890	**Pisces-Quad LZ**	**83.8%** (68.8%, 92.0%)	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
3776	**Pisces-Octad**	-	-	-	-
3777	**Pisces-Octad**	**87.9%** (83.3%, 91.3%)	**84.7%** (78.0%, 89.6%)	**84.7%** (78.0%, 89.6%)	**77.7%** (64.6%, 86.4%)
3778	**Pisces-Octad**	**80.9%** (77.8%, 83.7%)	**79.1%** (75.3%, 82.4%)	**76.4%** (71.5%, 80.6%)	-
977A1	**Vectris SureScan**	-	-	-	-
977A2	**Vectris SureScan**	-	-	-	-
Surgical Leads					
3986A	**Resume TL**	-	-	-	-
3998	**Specify**	-	-	-	-
39565	**Specify**	-	-	-	-

[a] There were a total of 748 lead-related events reported to the registry, but only 636 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=3), or were subsequent or unlinked device events that did not affect the survival estimates.

[b] Model 977A1 had a device survival probability of 93.8 % (77.3%, 98.4%) at 6 months of follow-up.

[c] FDA clearance date.

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

Model Number	Family	9 yrs	10 yrs	11 yrs
Percutaneous Leads				
3487A	**Pisces-Quad**	**61.3%** (55.0%, 67.1%)	**56.5%** (48.9%, 63.3%)	**54.9%** (47.0%, 62.2%)

3887	**Pisces-Quad**	-	-	-
3888	**Pisces-Quad**	**74.2%** (62.9%, 82.6%)	-	-
3890	**Pisces-Quad LZ**	-	-	-
3891	**Pisces-Quad LZ**	-	-	-
3776	**Pisces-Octad**	-	-	-
3777	**Pisces-Octad**	**70.3%** (54.1%, 81.7%)	-	-
3778	**Pisces-Octad**	-	-	-
977A1	**Vectris SureScan**	-	-	-
977A2	**Vectris SureScan**	-	-	-
Surgical Leads				
3986A	**Resume TL**	-	-	-
3998	**Specify**	-	-	-
39565	**Specify**	-	-	-

[a] There were a total of 748 lead-related events reported to the registry, but only 636 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=3), or were subsequent or unlinked device events that did not affect the survival estimates.
[b] Model 977A1 had a device survival probability of 93.8 % (77.3%, 98.4%) at 6 months of follow-up.
[c] FDA clearance date.

Extensions

From June 2004 to the report cut-off date of July 31, 2015, there were 3,093 extensions followed in the registry. Differences between the total number of extensions versus spinal cord stimulators (N=4,176) were due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 70,468 months (5,872 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 Mode	
Model Number	**Number of Extensions (%)**
37081	1,256 (40.6%)

7489	731 (23.6%)
37082	596 (19.3%)
7495	252 (8.1%)
37083	209 (6.8%)
7472	20 (0.6%)
7496	9 (0.3%)
7471	8 (0.3%)
Other/Unspecified	12 (0.4%)
Total	**3,093 (100%)**

Extension Events

There were 22 product performance-related events with an underlying reported etiology related to the extension. This includes 18 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=14). Of the 22 events, 18 were the first event attributable to an enrolled extension.

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:

- 18 had follow-up time cut-off due to product performance-related events
- 2,290 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.
- 785 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

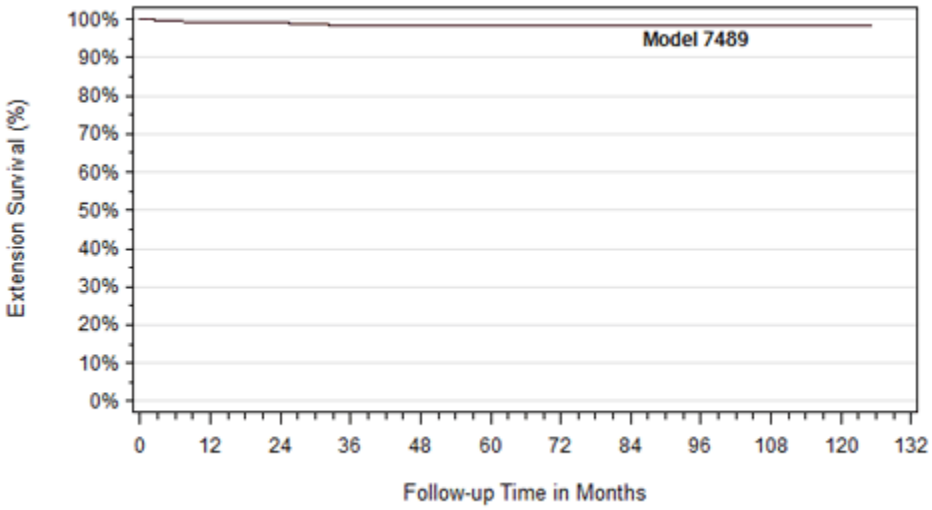
Extension Survival

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 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	731
Extensions Currently Active in Study	81
Device Events	4
Cumulative Months of Follow-up	16,903

Model 7489 Extension: Event Summary Table

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

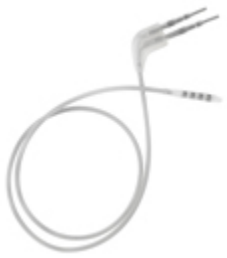
[a] Reported as unknown problem with extension

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%)	204
4 yrs	98.3% (95.6%, 99.4%)	136
5 yrs	98.3% (95.6%, 99.4%)	103
6 yrs	98.3% (95.6%, 99.4%)	78
7 yrs	98.3% (95.6%, 99.4%)	59
8 yrs	98.3% (95.6%, 99.4%)	59
9 yrs	98.3% (95.6%, 99.4%)	55
10 yrs	98.3% (95.6%, 99.4%)	40
at 126 mo	98.3% (95.6%, 99.4%)	24

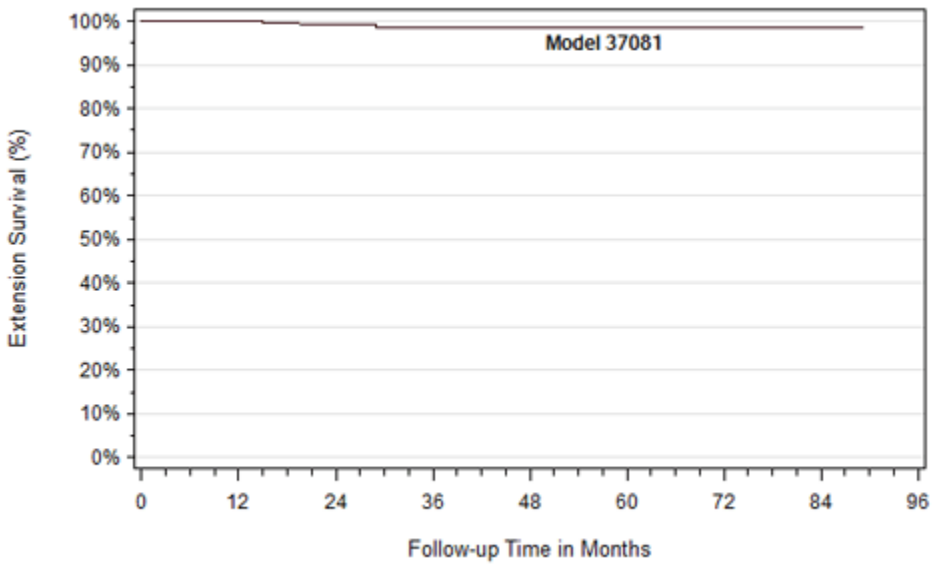
Model 7489: Specifications

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



Model 37081: 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	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	1,256
Extensions Currently Active in Study	413
Device Events	6
Cumulative Months of Follow-up	24,785

Model 37081 Extension: Event Summary Table

Extension Event	Total
Extension fracture	5
Extension migration	1
Total Extension Events	**6**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.9% (99.2%, 100.0%)	653
2 yrs	99.3% (98.1%, 99.7%)	374

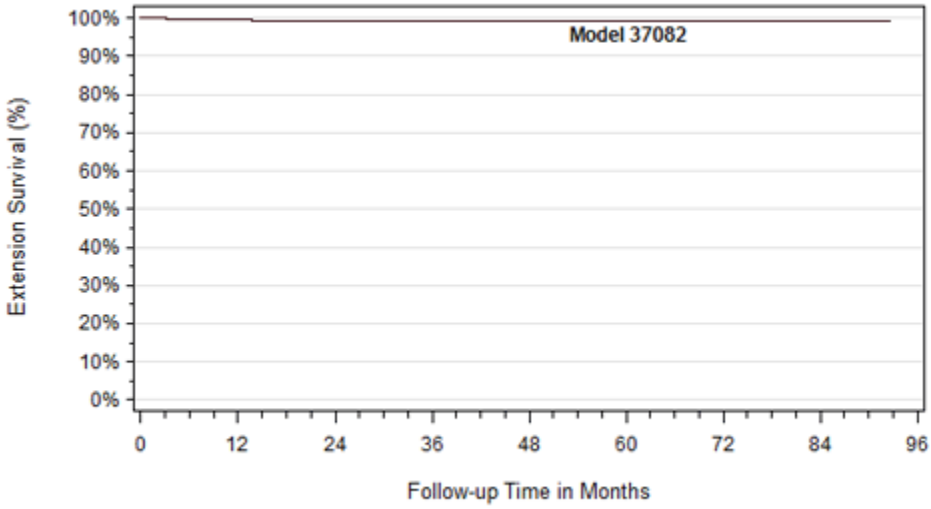
3 yrs	98.7% (96.9%, 99.4%)	204
4 yrs	98.7% (96.9%, 99.4%)	141
5 yrs	98.7% (96.9%, 99.4%)	98
6 yrs	98.7% (96.9%, 99.4%)	65
7 yrs	98.7% (96.9%, 99.4%)	36
at 90 mo	98.7% (96.9%, 99.4%)	28

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	596
Extensions Currently Active in Study	182
Device Events	3
Cumulative Months of Follow-up	16,397

Model 37082 Extension: Event Summary Table

Extension Event	Total
Extension fracture	2
Paraesthesia[a]	1
Total Extension Events	**3**

[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%)	393

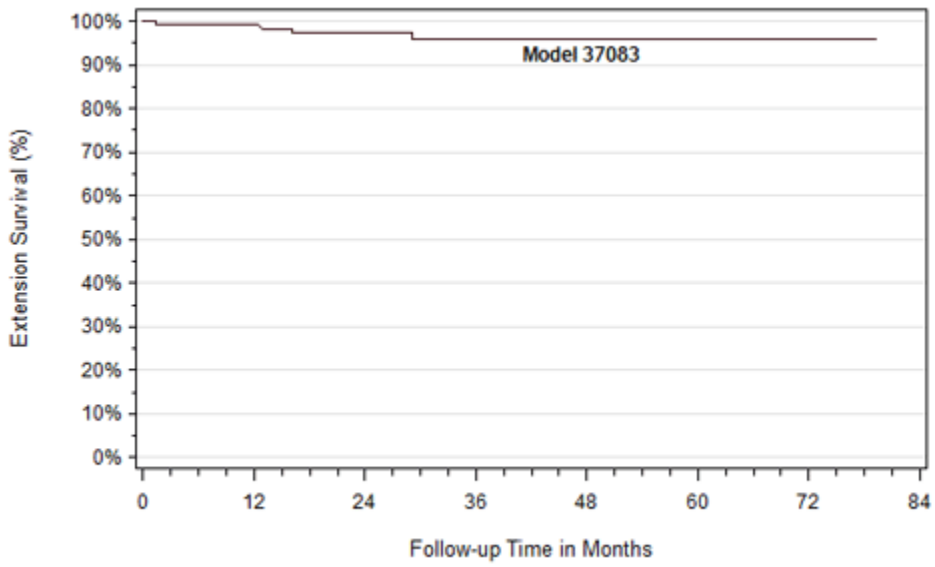
2 yrs	99.3% (97.9%, 99.8%)	254
3 yrs	99.3% (97.9%, 99.8%)	160
4 yrs	99.3% (97.9%, 99.8%)	107
5 yrs	99.3% (97.9%, 99.8%)	85
6 yrs	99.3% (97.9%, 99.8%)	60
7 yrs	99.3% (97.9%, 99.8%)	38
at 93 mo	99.3% (97.9%, 99.8%)	22

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.



View Larger Image

Extension Characteristics	
Model Number	37083
FDA Approval Date	Sep 2005
Extensions Enrolled	209
Extensions Currently Active in Study	45
Device Events	4
Cumulative Months of Follow-up	5,315

Model 37083 Extension: Event Summary Table

Extension Event	Total
Extension fracture	3
Device failure[a]	1
Total Extension Events	**4**

[a] Reported as extension failure

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.1% (93.9%, 99.9%)	119

2 yrs	97.3% (91.8%, 99.1%)	96
3 yrs	96.1% (89.8%, 98.5%)	56
4 yrs	96.1% (89.8%, 98.5%)	44
5 yrs	96.1% (89.8%, 98.5%)	31
6 yrs	96.1% (89.8%, 98.5%)	25
at 81 mo	96.1% (89.8%, 98.5%)	20

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

[Extension Survival Summary]

Currently, estimates of device survival from extension-related events exceed 95% (confidence intervals exceed 89%) for all extension models at the applicable follow-up time points that include at least 20 active devices.

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	1,256	413	6	24,785
37082	37082	Mar 2006	596	182	3	16,397
		Sep				

37083	37083	2005	209	45	4	5,315
7489	7489	Oct 2002	731	81	4	16,903

[a] There were a total of 22 extension-related events reported to the registry, but only 17 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=1), or were subsequent events 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	**99.9%** (99.2%, 100.0%)	**99.3%** (98.1%, 99.7%)	**98.7%** (96.9%, 99.4%)	**98.7%** (96.9%, 99.4%)	**98.7%** (96.9%, 99.4%)
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%** (93.9%, 99.9%)	**97.3%** (91.8%, 99.1%)	**96.1%** (89.8%, 98.5%)	**96.1%** (89.8%, 98.5%)	**96.1%** (89.8%, 98.5%)
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
37081	**98.7%** (96.9%, 99.4%)	**98.7%** (96.9%, 99.4%)	-	-	-
37082	**99.3%** (97.9%, 99.8%)	**99.3%** (97.9%, 99.8%)	-	-	-
37083	**96.1%** (89.8%, 98.5%)	-	-	-	-
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%)

2015 Medtronic Product Performance Report: Data through July 31, 2015

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

- Education and Training
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- Clinical Trials Registry
- Clinical Research Investigator Guidance

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Deep Brain Stimulation Systems

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

Study Participants

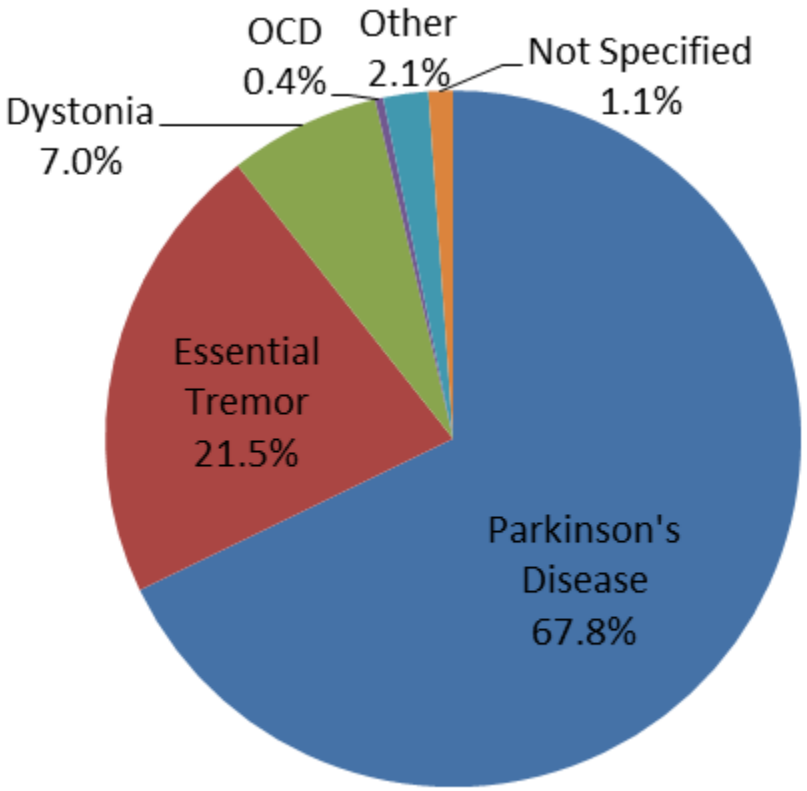
Centers

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, 2015. Thirty-two centers enrolled and contributed patients to the deep brain stimulation section of the report.

Patients

Of the 1,580 deep brain stimulation patients enrolled, 67.8% were implanted for the treatment of Parkinson's Disease, 21.5% were implanted for the treatment of Essential Tremor, 7.0% were implanted for the treatment of Dystonia, 0.4% were implanted for the treatment of Obsessive Compulsive Disorder, 2.1% were implanted for the treatment of some other indication, and 1.1% were implanted for indications that were not specified in the database.

Primary DBS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Parkinson's Disease	1,072 (67.8%)
Essential Tremor	340 (21.5%)
Dystonia	111 (7.0%)
Obsessive Compulsive Disorder	6 (0.4%)
Other	33 (2.1%)
Not specified	18 (1.1%)
Total Patients	**1,580**

[a] Refer to product labeling for approved indications.

Event Summary

There were 468 events reported between July 2009 and July 31, 2015 in patients with deep brain stimulation systems. Of these events, 18.6% (87/468) were categorized as product performance-related and are presented graphically within this report. The 87 product performance events occurred in 48 of the 1,580 total patients (3.04%) enrolled. In addition, there were 381 non-product performance events reported. There were also 49 deaths reported for patients with deep brain neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy.

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=1,580)
Lead high impedance	38	19	1.2%
Lead fracture	12	8	0.5%
Medical device complication[c]	10	8	0.5%
Device malfunction	6	1	<0.1%
Neurostimulator unable to recharge[d]	4	4	0.3%
Device migration	3	2	0.1%
Lead low impedance	3	3	0.2%
Lead migration/dislodgment	3	1	<0.1%
Extension fracture	2	2	0.1%
Increased impedance	2	1	<0.1%
Device breakage	1	1	<0.1%
Device dislocation	1	1	<0.1%
Device issue	1	1	<0.1%
Electromagnetic interference	1	1	<0.1%
Totals	**87**	**48**	**3.04%**

[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.

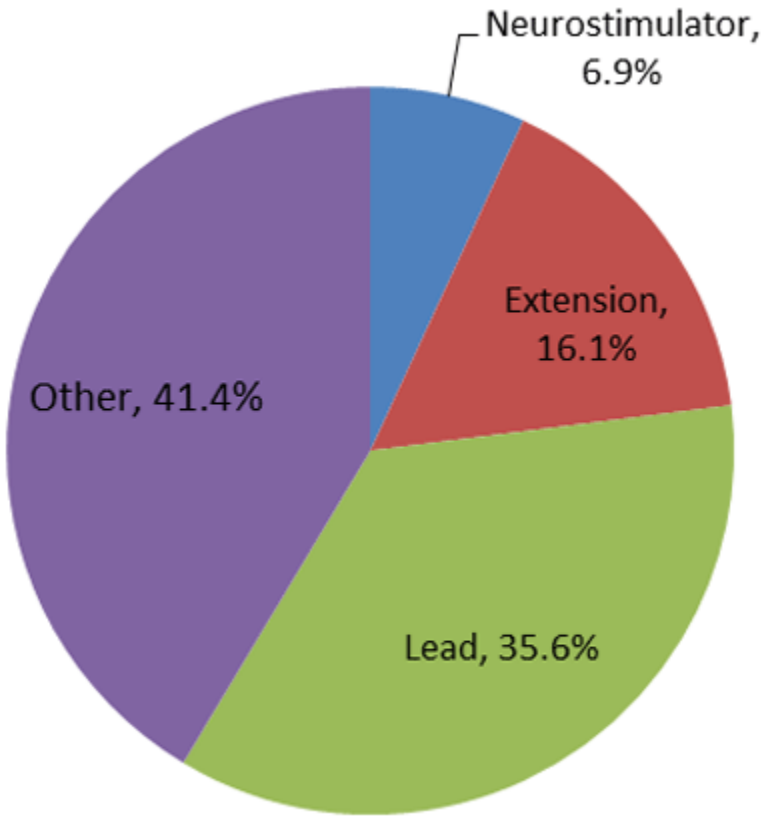
[b] The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.

[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 185 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.2% (4/185) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

A total of 31 (35.6%) of the 87 product performance events were related to the lead, 24 (27.6%) were related to “multiple etiologies”, which includes events where at least one device and one non-device etiology was indicated, 14 (16.1%) were related to the extension, 6 (6.9%) were related to the neurostimulator, 4 (4.6%) were related to other devices, 4 (4.6%) were related to the recharging process, 2 (2.3%) were related to the procedure, and 2 (2.3%) were related to programming/stimulation. Relatedness is determined by the physician.

Product Performance Events by Relatedness



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**
Device issues	**57**
Device stimulation issue	25
Neurostimulator migration	13
Neurostimulator unable to recharge[c]	4
Battery recharge issue	3
Other[d]	12
Infections - pathogen unspecified	**51**
Implant site infection	42
Wound infection	4
Infection	3
Other[d]	2
Movement disorders (including parkinsonism)	**36**
Tremor	13
Dyskinesia	8
Dystonia	5
Other[d]	10
Administration site reactions	**31**
Implant site erosion	10
Implant site haematoma	4
Implant site pain	4
Other[d]	13

Neurological disorders not elsewhere classified (NEC)	**30**
Dysarthria	8
Paraesthesia	8
Speech disorder	7
Other[d]	7
Injuries NEC	**20**
Fall	8
Subdural haematoma	6
Other[d]	6
Procedural related injuries and complications NEC	**19**
Wound dehiscence	9
Other[d]	10
Depressed mood disorders and disturbances	**12**
Depression	11
Other[d]	1
General system disorders NEC	**10**
Gait disturbance	4
Other[d]	6
Complications associated with device	**8**
Medical device complication[e]	3
Medical device discomfort	3
Other[d]	2
Central nervous system vascular disorders	**7**
Haemorrhage intracranial	4

Other[d]	3
Anxiety disorders and symptoms	**6**
Anxiety	5
Other[d]	1
Physical examination and organ system status topics	**6**
Weight increased	6
Seizures (including subtypes)	**6**
Convulsion	4
Other[d]	2
Psychiatric and behavioural symptoms NEC	**4**
Abnormal behaviour	4
Not coded[f]	**11**
Other[d]	**67**
Total	**381**

[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] Patients were unable to recharge their neurostimulators due to an issue not related to the device.
[d] Composed of event codes with fewer than 3 events each.
[e] Includes 1 event reported as charge icon missing from patient programmer, 1 cortical bleeding secondary to penetration of right lead, and 1 DBS system turned off by airport security.
[f] Events that had not been MedDRA-coded at the time of the report cut-off.

There were 49 deaths reported for patients with deep brain neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. A total of 40 (81.6%) deaths occurred in patients receiving therapy for Parkinson's disease and 9 (18.4%) for Essential Tremor.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Parkinson's Disease	40 (81.6%)
Essential Tremor	9 (18.4%)

Total	**49 (100%)**

[a] Refer to product labeling for approved indications

Deep Brain Neurostimulators

From July 2009 to the report cut-off date of July 31, 2015, 1,830 deep brain neurostimulators were followed in the registry. The difference between the total number of patients (N=1,580) 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 23,726 months (1,977 years). The table below provides the number and percentage of neurostimulators by model.

Neurostimulators by Model	
Model Name	**Number of Neurostimulators (%)**
Activa PC	1,062 (58.0%)
Activa SC	492 (26.9%)
Activa RC	186 (10.2%)
Soletra	68 (3.7%)
Kinetra	12 (0.7%)
Other/Unspecified	10 (0.5%)
Total	**1,830 (100%)**

Deep Brain Neurostimulator Events

There were 11 product performance-related events with an underlying reported etiology related to deep brain neurostimulator function. This includes 6 events with a neurostimulator etiology and 5 with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 8 were the first event attributable to an enrolled stimulator. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 19/257 (7.4%). 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 19 devices that were returned for analysis; however, 1 of these stimulators had a physician reported performance-related event of lead high impedance which was reported as related to the neurostimulator. The 10 remaining deep brain stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as lead high impedance (n=3), medical device complication (n=2), electromagnetic interference (n=1), neurostimulator unable to recharge (n=1), device issue (n=1), device malfunction (n=1) and increased 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 neurostimulators:

- 8 had follow-up time cut-off due to a product performance-related event.
- 602 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.
- 1220 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

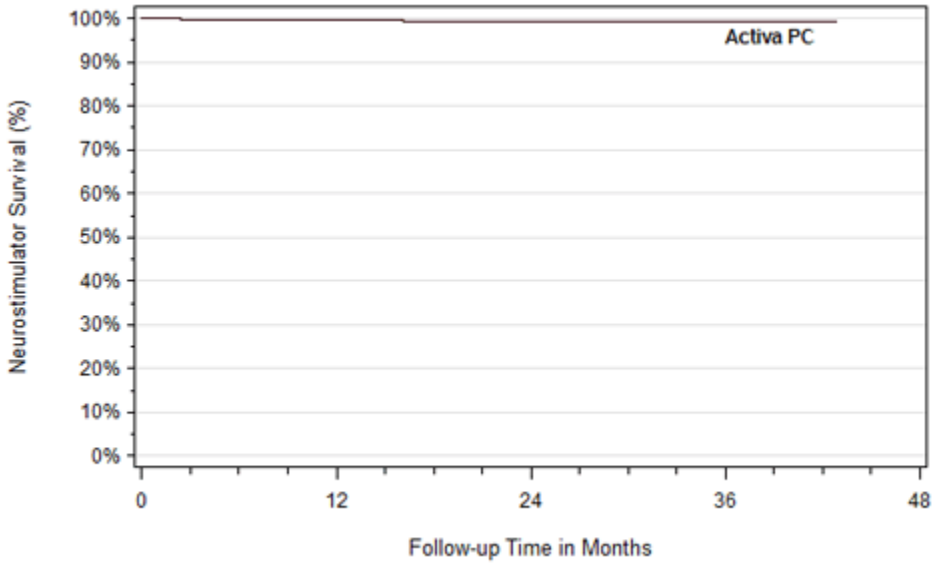
Deep Brain Neurostimulator Survival

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.



View Larger Image

Deep Brain Neurostimulator Characteristics	
Model Name	Activa PC
FDA Approval Date	Apr 2009
Neurostimulators Enrolled	1,062
Neurostimulators Currently Active in Study	796
Device Events	4

Cumulative Months of Follow-up	12,569

Model Activa PC: Event Summary Table **Neurostimulator Event**	**Total**
Lead high impedance[a]	2
Electromagnetic interference	1
Medical device complication[b]	1
Total Neurostimulator Events	**4**

[a] Two events for high impedance >40000 attributed to the neurostimulator
[b] Undesirable interaction with external electronic device

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.7%, 99.9%)	436
2 yrs	**99.3%** (97.9%, 99.8%)	161
3 yrs	**99.3%** (97.9%, 99.8%)	52
at 42 mo	**99.3%** (97.9%, 99.8%)	23

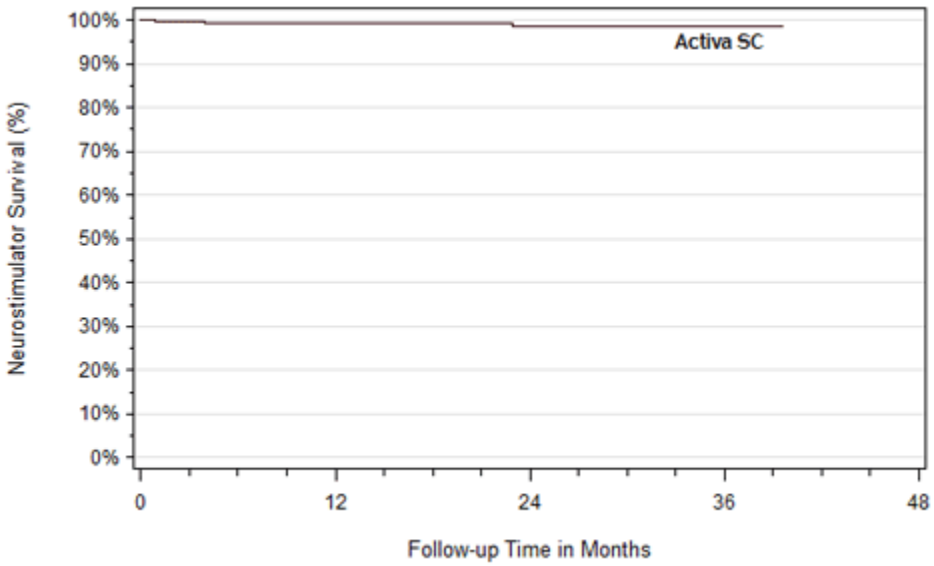
Model 37601 Activa PC: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	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	492

Neurostimulators Currently Active in Study	304
Device Events	3
Cumulative Months of Follow-up	6,590

Model Activa SC: Event Summary Table **Neurostimulator Event**	**Total**
Device issue[a]	1
Lead high impedance[b]	1
Medical device complication[c]	1
Total Neurostimulator Events	**3**

[a] Reported as ERI indicator error
[b] Reported as high impedance attributed to neurostimulator, lead and extension
[c] Reported as short circuit

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.4%** (97.8%, 99.9%)	219
2 yrs	**98.6%** (94.7%, 99.6%)	105
3 yrs	**98.6%** (94.7%, 99.6%)	26
at 39 mo	**98.6%** (94.7%, 99.6%)	24

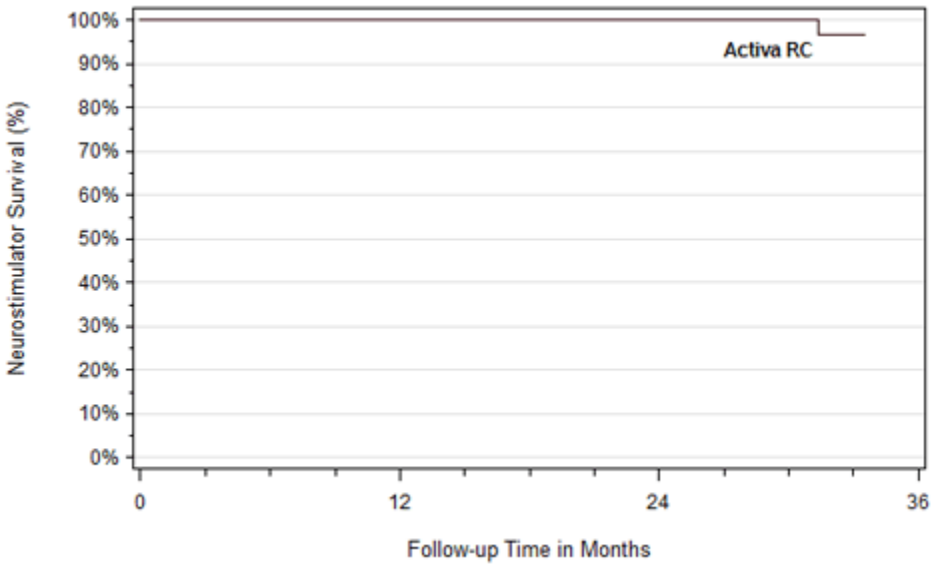
Models 37602 & 37603 Activa SC: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	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	186
Neurostimulators Currently Active in Study	118
Device Events	1
Cumulative Months of Follow-up	2,979

Model Activa RC: Event Summary Table

Neurostimulator Event	Total
Neurostimulator unable to recharge	1
Total Neurostimulator Events	**1**

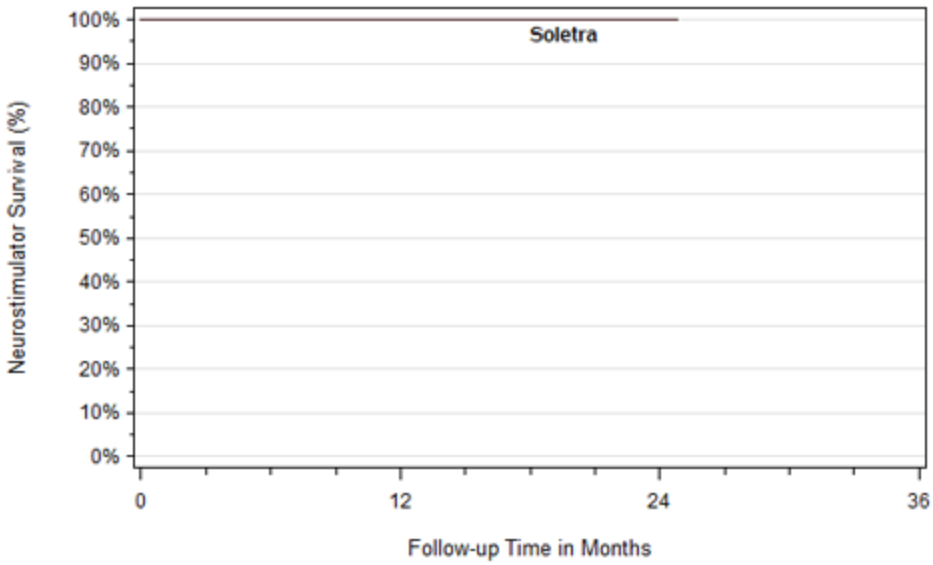
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	99
2 yrs	100.0% (NA)	54
at 33 mo	**96.6%** (78.3%, 99.5%)	26

Model 37612 Activa RC: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	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)
	2 - 250 Hz (voltage mode)

Rate	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	6
Device Events	0
Cumulative Months of Follow-up	1,364

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	**100.0%** (NA)	44
2 yrs	**100.0%** (NA)	25

Model 7426 Soletra: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	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[a]	Cumulative Months of Follow-up
Activa PC	Activa	Apr	1,062	796	4	12,569

		2009				
Activa SC	Activa	Jan 2011	492	304	3	6,590
Activa RC	Activa	Mar 2009	186	118	1	2,979
Soletra	Soletra	Jan 2002	68	6	0	1,364

[a] There were a total of 11 neurostimulator-related events reported to the registry, but only 8 events are included in this summary table. The remaining 3 events were subsequent events that did not affect the survival estimates.

Device Survival Probability (95% Confidence Interval)			
Model Name	**1 yr**	**2 yrs**	**3 yrs**
Activa PC	**99.6%** (98.7%, 99.9%)	**99.3%** (97.9%, 99.8%)	**99.3%** (97.9%, 99.8%)
Activa SC	**99.4%** (97.8%, 99.9%)	**98.6%** (94.7%, 99.6%)	**98.6%** (94.7%, 99.6%)
Activa RC	**100.0%** NA	**100.0%** NA	-
Soletra	**100.0%** NA	**100.0%** NA	-

Leads

From July 2009 to the report cut-off date of July 31, 2015, there were 2,525 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=1,830) 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 36,905 months (3,075 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	1,388 (55.0%)
3387	1,118 (44.3%)
3391	14 (0.6%)

Other/Unspecified	5 (0.2%)
Total	**2,525 (100%)**

Lead Events

There were 43 product performance-related events with an underlying reported etiology related to the lead. This includes 31 events with a lead etiology and 12 events with both a lead and other etiology (including device and non-device etiologies). Twenty-three events were lead high impedance, 11 were lead fracture, 3 were lead low impedance, 2 were device malfunction, 2 were lead migration/dislodgment, 1 was medical device complication, and 1 was device dislocation. Of the 43 events, 25 were the first event attributable to an enrolled lead.

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:

- 25 had follow-up time cut-off due to product performance-related events.
- 599 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.
- 1,901 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

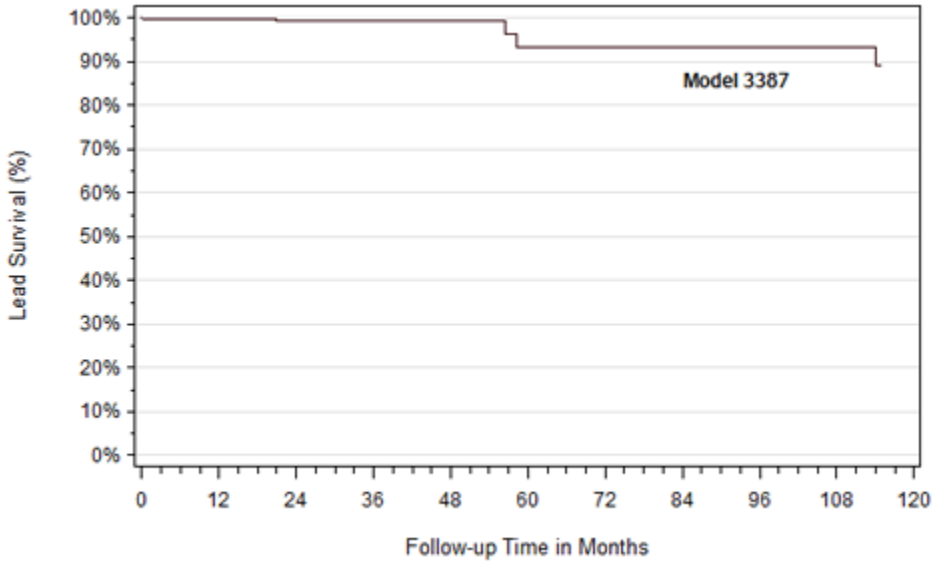
Lead Survival

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	1,118
Leads Currently Active in Study	822
Device Events	7
Cumulative Months of Follow-up	16,576

Model 3387: Event Summary Table Lead Event	Total
Lead high impedance	3
Lead fracture	1
Lead low impedance	1
Lead migration/dislodgment	1
Medical device complication[a]	1
Total Lead Events	**7**

[a] Reported as open circuit of lead

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.6%, 99.9%)	465
2 yrs	**99.2%** (97.6%, 99.7%)	193
3 yrs	**99.2%** (97.6%, 99.7%)	106
4 yrs	**99.2%** (97.6%, 99.7%)	51
5 yrs	**93.8%** (80.4%, 98.1%)	34
6 yrs	**93.8%** (80.4%, 98.1%)	23
7 yrs	**93.8%** (80.4%, 98.1%)	29
8 yrs	**93.8%** (80.4%, 98.1%)	31
9 yrs	**93.8%** (80.4%, 98.1%)	22
at 114 mo	89.4% (71.7%, 96.3%)	20

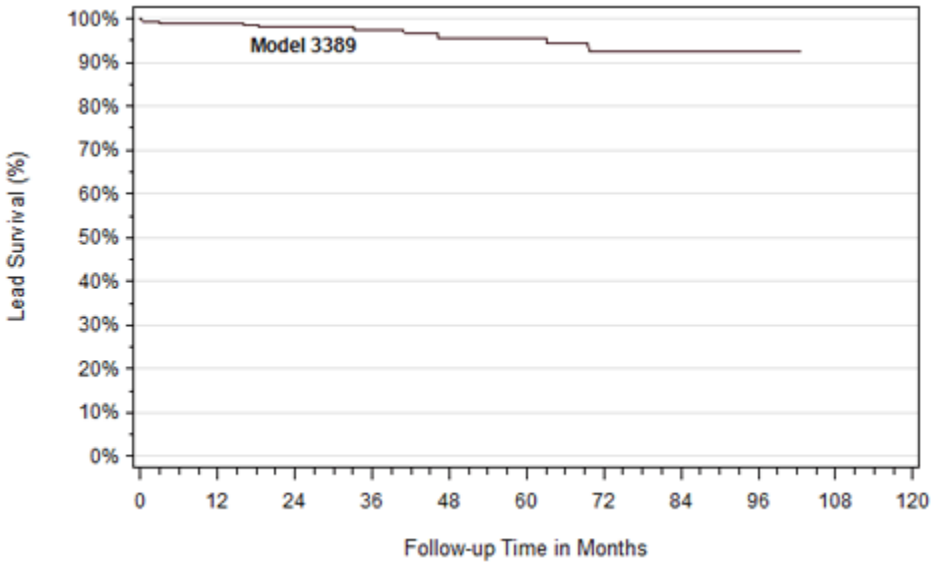
Model 3387: Specifications

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	1,388
Leads Currently Active in Study	1,081
Device Events	18
Cumulative Months of Follow-up	20,074

Model 3389: Event Summary Table Lead Event	Total
Lead high impedance	14
Lead fracture	3
Lead low impedance	1
Total Lead Events	**18**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	98.9% (98.0%, 99.4%)	509
2 yrs	98.2% (96.7%, 99.0%)	241
3 yrs	97.6% (95.3%, 98.8%)	134
4 yrs	95.7% (91.3%, 97.9%)	82
5 yrs	95.7% (91.3%, 97.9%)	80
6 yrs	92.8% (85.9%, 96.4%)	55
7 yrs	92.8% (85.9%, 96.4%)	50
8 yrs	92.8% (85.9%, 96.4%)	37
at 102 mo	92.8% (85.9%, 96.4%)	21

Model 3389: Specifications

Model Number Lead	3389
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
Percutaneous Leads						
3387	**3387**	Jan 2002	1,118	822	7	16,576
3389	**3389**	Sep 1999	1,388	1,081	18	20,074

[a] There were a total of 43 lead-related events reported to the registry, but only 25 events included in this summary table. The remaining events were subsequent events 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**	**99.6%** (98.6%, 99.9%)	**99.2%** (97.6%, 99.7%)	**99.2%** (97.6%, 99.7%)	**99.2%** (97.6%, 99.7%)
3389	**3389**	**98.9%** (98.0%, 99.4%)	**98.2%** (96.7%, 99.0%)	**97.6%** (95.3%, 98.8%)	**95.7%** (91.3%, 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**	**93.8%** (80.4%, 98.1%)	**93.8%** (80.4%, 98.1%)	**93.8%** (80.4%, 98.1%)	**93.8%** (80.4%, 98.1%)	**93.8%** (80.4%, 98.1%)

3389	**3389**	**95.7%** (91.3%, 97.9%)	**92.8%** (85.9%, 96.4%)	**92.8%** (85.9%, 96.4%)	**92.8%** (85.9%, 96.4%)	-

Extensions

From July 2009 to the report cut-off date of July 31, 2015, there were 2,507 extensions followed in the registry. Differences between the total number of extensions versus the total number of neurostimulators (N=1,830) 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=2,525) because some patients were re-implanted with a new lead using existing extensions. The aggregate prospective follow-up time for all extensions was 36,043 months (3,004 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	Number of Extensions (%)
37086[a]	2,097 (83.6%)
7482	349 (13.9%)
Other/Unspecified	61 (2.4%)
Total	**2,507 (100%)**

[a] Includes Models 37085 and 37086

Extension Events

There were 20 product performance-related events with an underlying reported etiology related to the extension. This includes 14 events with an extension etiology and 6 events with both an extension and other etiology (including device and non-device etiologies). Nine events were lead high impedance attributed to the extensions, 4 were medical device complications, 2 were device migrations attributed to the extensions, 2 were device malfunctions, 2 were extension fractures, and 1 was increased impedance attributed to an extension. Of the 20 events, 13 were the first event attributable to an enrolled extension.

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:

- 13 extensions had follow-up time cut-off due to product performance-related events.
- 617 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.
- 1,877 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

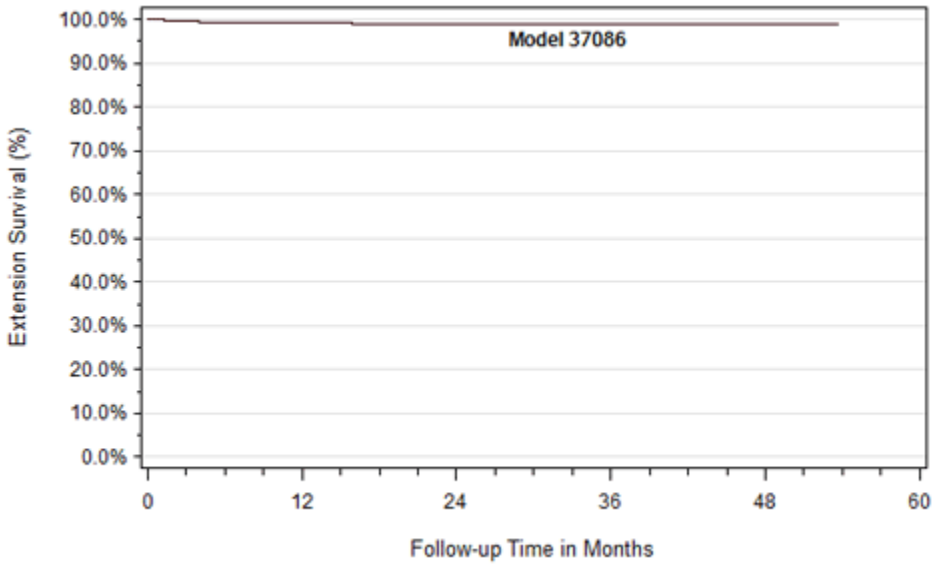
Extension Survival

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.



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Extension Characteristics	
Model Number	37086
FDA Approval Date	Sep 2009
Extensions Enrolled	2,097
Extensions Currently Active in Study	1,574
Device Events	13
Cumulative Months of Follow-up	29,433

Model 37086 Extension: Event Summary Table

Extension Event	Total
Lead high impedance	6

Medical device complication[a]	4
Device migration	2
Extension fracture	1
Total Extension Events	**13**

[a] Includes 2 events for extension cable loop, and 2 events for twisting of extensions

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.3% (98.6%, 99.6%)	930
2 yrs	99.0% (98.2%, 99.4%)	412
3 yrs	99.0% (98.2%, 99.4%)	209
4 yrs	99.0% (98.2%, 99.4%)	67
at 54 mo	99.0% (98.2%, 99.4%)	22

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**	**Extensions Enrolled**	**Extensions Currently Active in**	**Device**	**Cumulative Months of Follow-up**

		Date		Study	Events[a]	
37086[b]	37086	Sep 2009	2,097	1,574	13	29,433

Device Survival Probability (95% Confidence Interval)				
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**
37086[b]	**99.3%** (98.6%, 99.6%)	**99.0%** (98.2%, 99.4%)	**99.0%** (98.2%, 99.4%)	**99.0%** (98.2%, 99.4%)

[a] There were a total of 20 extension-related events reported to the registry, but only 13 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

2015 Medtronic Product Performance Report: Data through July 31, 2015

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

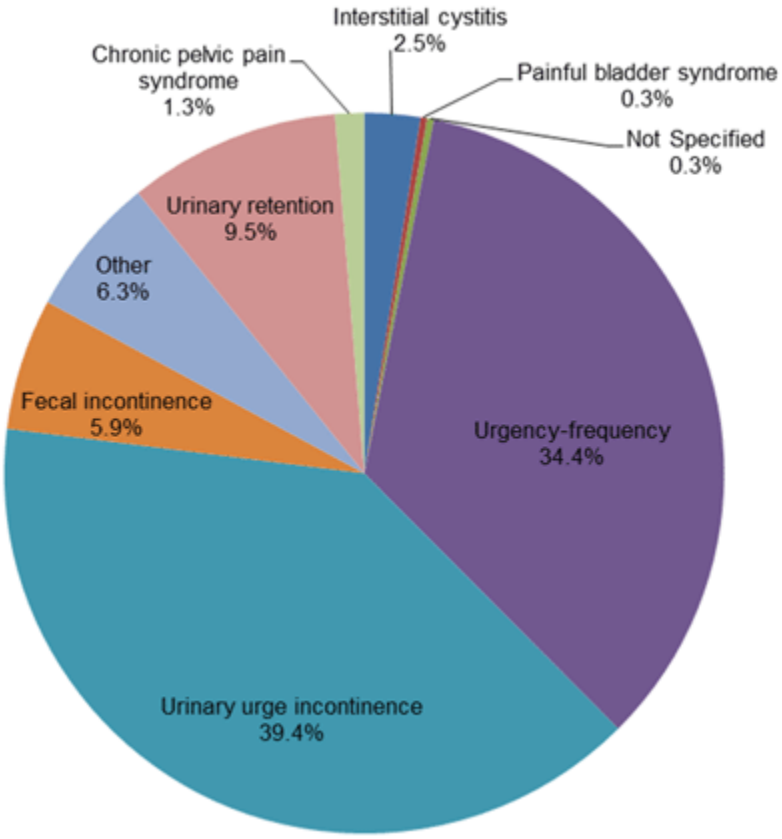
Centers

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, 2015. Nineteen centers enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 639 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 39.4% were implanted for the treatment of urinary urge incontinence, 34.4% were implanted for the treatment of urgency-frequency, 9.5% were implanted for the treatment of urinary retention, 6.3% were implanted for the treatment of some other indication, 5.9% were implanted for the treatment of fecal incontinence, 2.5% were implanted for the treatment of interstitial cystitis, 1.3% were implanted for the treatment of chronic pelvic pain syndrome, 0.3% were implanted for the treatment of painful bladder syndrome, and 0.3% were implanted for indications that were not specified in the database.

Primary SNM Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Urinary urge incontinence	252 (39.4%)
Urgency-frequency	220 (34.4%)
Urinary retention	61 (9.5%)
Fecal incontinence	38 (5.9%)
Interstitial cystitis	16 (2.5%)
Chronic pelvic pain syndrome	8 (1.3%)
Painful bladder syndrome	2 (0.3%)
Other	40 (6.3%)
Not specified	2 (0.3%)
Total Patients	**639**

[a] Refer to product labeling for approved indications.

Event Summary

There were 245 events reported between April 2010 and July 31, 2015 in patients with sacral neuromodulation systems. Of these events, 26.1% (64/245) were categorized as product performance-related and are presented graphically within this report. The 64 product performance events occurred in 43 of the 639 total patients (6.73%) enrolled. In addition, there were 181 non-product performance events reported. There were also 11 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy.

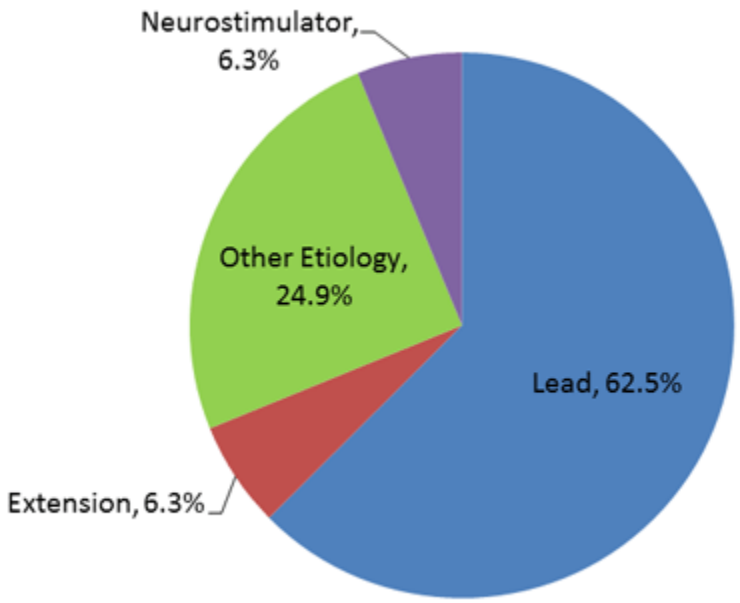
Sacral Neuromodulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event	Percent of Patients with Event (n=639)
Lead high impedance	31	21	3.29%
Lead migration/dislodgment	13	9	1.41%
Lead fracture	6	6	0.94%
Device battery issue	4	1	0.16%
Lead low impedance	3	3	0.47%
Device electrical impedance issue	2	1	0.16%
Device lead issue	2	1	0.16%
Device lead damage	1	1	0.16%
Device malfunction[b]	1	1	0.16%
Device telemetry issue	1	1	0.16%
Total	**64**	**43**	**6.73%**

[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] Reported as device function could not be recovered after a fall.

A total of 40 (62.5%) of the 64 product performance events were related to the lead, 12 (18.8%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 4 (6.3%) were related to the extension, 4 (6.3%) were related to the neurostimulator, 2 (3.1%) were related to other devices, 1 (1.6%) was related to other etiology, and 1 (1.6%) was related to programming/stimulation. Relatedness is determined by the physician.

Product Performance Events by Relatedness



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	**65**
Urinary tract infection[c]	51
Implant site infection	8
Incision site infection	2
Wound infection	2
Infection	1
Postoperative wound infection	1
Administration site reactions	**23**

Implant site pain	22
Implant site erythema	1
Therapeutic and nontherapeutic effects (excluding toxicity)	**25**
Therapeutic product ineffective	24
Therapeutic response decreased	1
Device issues	**18**
Device stimulation issue	12
Neurostimulator migration	3
Neurostimulator inversion	2
Device extrusion	1
Neurological disorders not elsewhere classified (NEC)	**9**
Paraesthesia	7
Restless legs syndrome	1
Sensory disturbance	1
Urinary tract signs and symptoms	**8**
Urinary incontinence	3
Bladder pain	1
Micturition urgency	1
Nocturia	1
Urge incontinence	1
Urinary retention	1
General system disorders NEC	**7**
Pain	3
No anomaly found by RPA[d]	2

Oedema	1
Sensation of pressure	1
Therapeutic procedures and supportive care NEC	**4**
Incisional drainage	3
Wound drainage	1
Injuries NEC	**2**
Electric shock	1
Wound	1
Bacterial infectious disorders	**4**
Cellulitis	1
Implant site cellulitis	1
Staphylococcal infection	2
Reproductive tract disorders NEC	**2**
Pelvic pain	2
Anal and rectal conditions NEC	**1**
Proctalgia	1
Bladder and bladder neck disorders (excluding calculi)	**1**
Cystitis	1
Bone disorders (excluding congenital and fractures)	**1**
Bone pain	1
Complications associated with device	**1**
Medical device discomfort	1
Epidermal and dermal conditions	**1**
Skin reaction	1
Genitourinary tract disorders NEC	

	1
Urinary tract disorder	1
Joint disorders	**1**
Arthralgia	1
Musculoskeletal and connective tissue disorders NEC	**1**
Pain in extremity	1
Procedural related injuries and complications NEC	**1**
Procedural complication	1
Vulvovaginal disorders (excluding infections and inflammations)	**1**
Vulvovaginal pain	1
Not Coded[e]	**4**
Totals	**181**

[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.
[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).
[e] Events that had not been MedDRA-coded at the time of the report cut-off.

There were 11 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. Five deaths occurred in patients receiving therapy for urgency-frequency, 3 deaths for other indications, 2 deaths for urinary urge incontinence and 1 for urinary retention.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Urgency-frequency	5 (45.5%)
Other[b]	3 (27.3%)
Urinary urge incontinence	2 (18.2%)
Urinary retention	1 (9.1%)
Total	**11 (100%)**

[a] Refer to product labeling for approved indications
[b] Includes 1 indication of atony of bladder, 1 of neurogenic bladder and 1 of urinary tract infection

Neurostimulators

From April 2010 to the report cut-off date of July 31, 2015, 598 neurostimulators were followed in the registry. The difference between the total number of patients (n=639) versus neurostimulators (n=598) 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-four percent (84.8%) of neurostimulators were InterStim II (n=507), and 15.2% (n=91) were InterStim. The aggregate prospective follow-up time for all neurostimulators was 8,003 months (667 years).

Neurostimulator Events

There were 6 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 4 events with a neurostimulator etiology and 2 events with both a stimulator and other etiology (including device and non-device etiologies). Of these 6 product performance events, 5 were the first event attributable to an enrolled neurostimulator. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 10/55 (18%). 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 10 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 lead high impedance (n=3), device malfunction (n=1), 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:

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

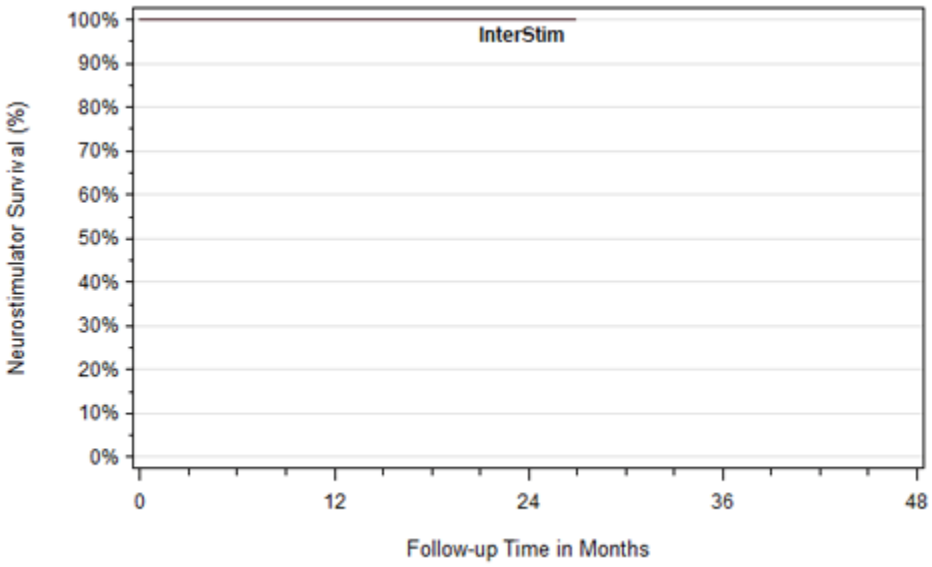
Neurostimulator Survival

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	91
Neurostimulators Currently Active in Study	60
Device Events	1[a]
Cumulative Months of Follow-up	1,625

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)	49
2 yrs	100.0% (NA)	29
at 27 mo	100.0% (NA)[a]	24

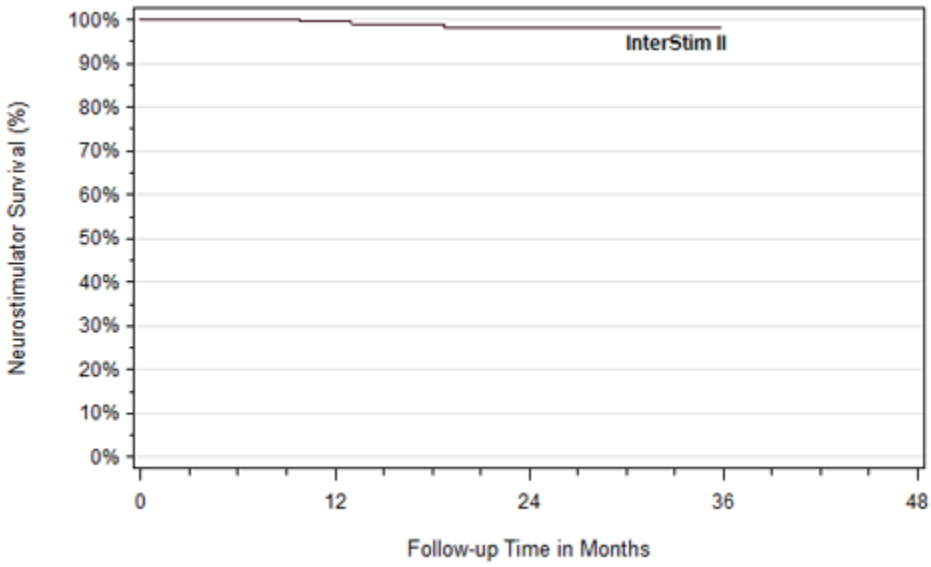
[a]Event occurred at 37 months of follow-up.

Model 3023 InterStim: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	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	507
Neurostimulators Currently Active in Study	337
Device Events	4
Cumulative Months of Follow-up	6,378

Model 3058 InterStim II: Event Summary Table Neurostimulator Event	Total
Lead high impedance[a]	2
Device malfunction[b]	1
Device electrical impedance issue	1
Total Neurostimulator Events	**4**

[a] Includes 2 events reported as high impedance of both lead and neurostimulator
[b] Reported as device function could not be restored after a fall

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.5% (96.7%, 99.9%)	182
2 yrs	98.1% (93.9%, 99.4%)	77
3 yrs	98.1% (93.9%, 99.4%)	25

Model 3058 InterStim II: Specifications

Height	1.7 in (44 mm)
Width	2.0 in (51 mm)

Thinness	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	91	60	1	1,625
InterStim II	InterStim	Jun 2006	507	337	4	6,378

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs	3 yrs
InterStim	**100.0%** NA	**100.0%** NA	-
InterStim II	**99.5%** (96.7%, 99.9%)	**98.1%** (93.9%, 99.4%)	**98.1%** (93.9%, 99.4%)

[a] There were a total of 6 neurostimulator-related events reported to the registry, but only 5 events included in this summary table. The remaining event was a subsequent device event that did not affect the survival estimates.

Leads

From April 2010 to the report cut-off date of July 31, 2015, there were 595 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=598) 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 7,856 months (655 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 (%)**
3889	507 (85.2%)
3093	83 (13.9%)
3080	3 (0.5%)
3092	1 (0.2%)
Unspecified	1 (0.2%)
Total	**595 (100%)**

Lead Events

There were 44 product performance-related events with an underlying reported etiology related to the lead. This includes 40 events with a lead etiology and 4 events with both a lead and other etiology (including device and non-device etiologies). The majority of the events were lead high impedance (n=23). Of the 44 product performance-related lead events, 36 were the first event attributable to an enrolled lead.

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:

- 36 had follow-up time cut-off due to product performance-related events.
- 179 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.
- 380 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

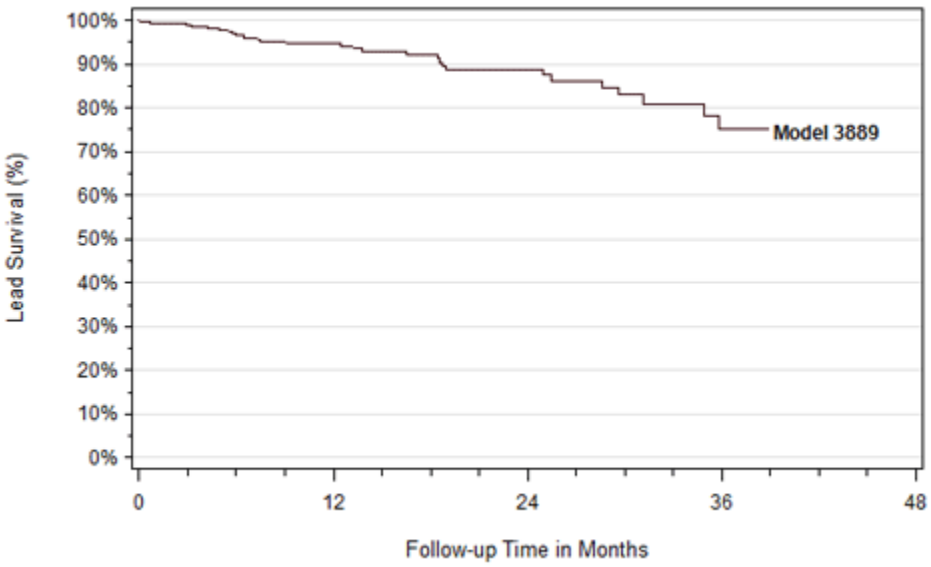
Lead Survival

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	507
Leads Currently Active in Study	345
Device Events	32
Cumulative Months of Follow-up	6,412

Model 3889: Event Summary Table

Lead Event	Total
Lead high impedance	18
Lead fracture	5
Lead migration/dislodgment	5
Lead low impedance	3
Device electrical impedance issue	1
Total Lead Events	**32**

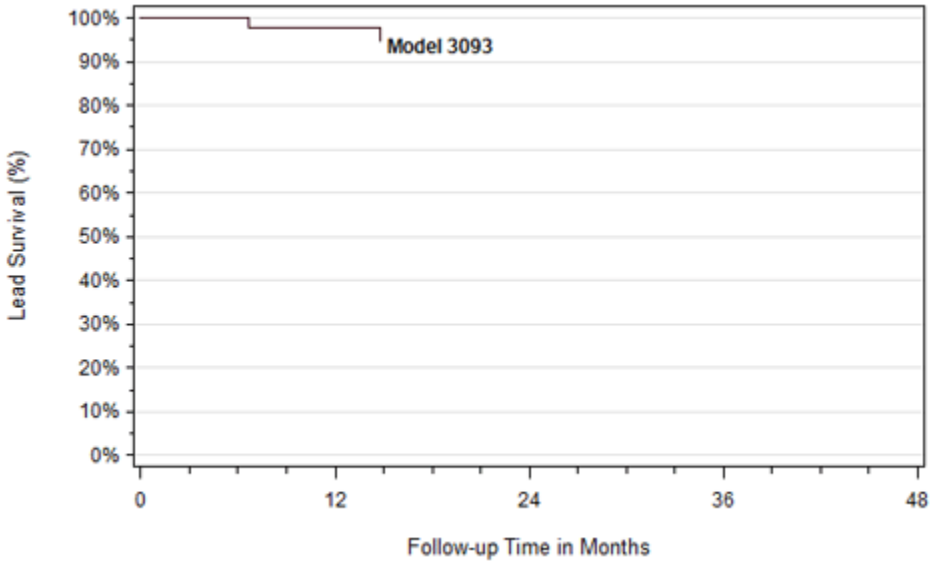
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.7%** (91.2%, 96.9%)	171
2 yrs	**88.7%** (82.8%, 92.7%)	79
3 yrs	**75.2%** (62.6%, 84.1%)	25
at 39 mo	**75.2%** (62.6%, 84.1%)	20

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	83
Leads Currently Active in Study	47
Device Events	3
Cumulative Months of Follow-up	1,387

Model 3093: Event Summary Table Lead Event	Total
Lead migration/dislodgment	1
Lead fracture	1
Device lead damage	1
Total Lead Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**97.9%** (86.0%, 99.7%)	34

at 15 mo	**94.7%** (79.8%, 98.7%)	29

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	507	345	32	6,412
3093	**3093**	Sep 2002	83	47	3	1,387

[a] There were 44 lead-related events reported to the registry, but only 35 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 (ie, Model 3080) (n=1) or were subsequent events that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval)				
Model Number	**Family**	**1 yr**	**2 yrs**	**3 yrs**

3889	**3889**	**94.7%** (91.2%, 96.9%)	**88.7%** (82.8%, 92.7%)	**75.2%** (62.6%, 84.1%)
3093	**3093**	**97.9%** (86.0%, 99.7%)	-	-

Extensions

From April 2010 to the report cut-off date of July 31, 2015, there were 92 extensions followed in the registry. Differences between the total number of extensions versus the total neurostimulators (N=598) 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 1,656 months (138 years).

Extension Events

There were 7 product performance-related events with an underlying reported etiology related to the extension, however, none of these could be attributed to an extension model because data needed to associate the event to the model was missing at the time of the data cut-off for this report. Of these 7 events, 4 had an extension etiology, and 3 had both an extension and other etiology (including device and non-device).

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:

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

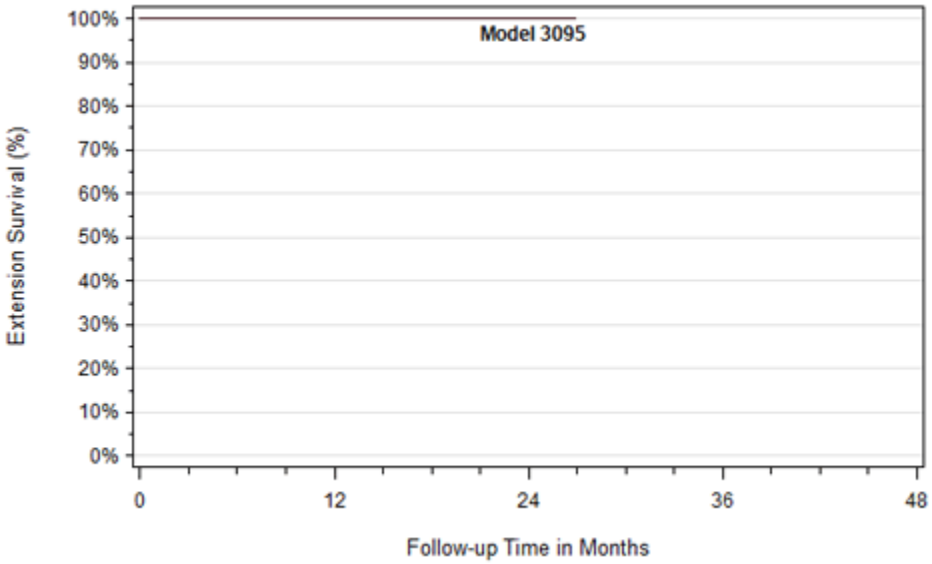
Extension Survival

The figure and 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	92
Extensions Currently Active in Study	61
Device Events	0
Cumulative Months of Follow-up	1,656

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	45
2 yrs	**100.0%** (NA)	26
at 27 mo	**100.0%** (NA)	20

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	92	61	0	1,656

Device Survival Probability (95% Confidence Interval)

Model Number	1 yr	2 yrs
3095	**100.0%** NA	**100.0%** NA

[a] There were 7 product performance-related events with an underlying reported etiology related to the extension, however, none of these could be attributed to an extension model because data needed to associate the event to the model was missing at the time of the data cut-off for this report.

2015 Medtronic Product Performance Report: Data through July 31, 2015

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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