Overview

Introduction

Medtronic uses a prospective, long-term multi-center registry study, titled the Implantable Systems Performance Registry (ISPR) to monitor the performance of certain products at selected centers. This 2013 Product Performance Report provides data on the devices followed in this Registry. Medtronic also incorporates the findings of Returned Product Analysis (RPA) for ISPR devices 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.

Implantable Systems Performance Registry (ISPR) Background

The Implantable Systems Performance Registry (ISPR) was created by Medtronic to monitor the performance of commercially available infusion and spinal cord stimulation systems. These systems were initiated into the ISPR in August 2003 and June 2004, respectively. Prior to the development of the ISPR, Medtronic Neuromodulation typically evaluated patient and product outcomes by retrospectively analyzing data from Returned Product Analysis (RPA) and complaints data. The ISPR 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 ISPR provide information about the treatment practices of physicians using these therapies.

This registry was initially designed to track performance of Medtronic's implantable intrathecal drug delivery systems (infusion pumps and catheters). They are surgically placed devices that deliver pain or spasticity medication directly to the fluid around the spinal cord, providing relief with a small fraction of the medication needed if taken orally.

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 mild electrical impulses to the spinal cord. These impulses replace the perception of pain with a tingling sensation.

In July 2009, Medtronic's deep brain stimulation systems (deep brain neurostimulators, leads, and extensions) were included in the ISPR. Deep brain stimulation (DBS) uses a surgically implanted neurostimulator to deliver carefully controlled electrical stimulation to precisely 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 mild 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 ISPR has collected data from 50 centers across the United States for intrathecal drug delivery systems, 44 centers for spinal cord stimulation systems, 18 centers for deep brain stimulation (both United States and Europe), and 5 centers for sacral neuromodulation. Each ISPR 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 ISPR center followed its standard clinical practice for implant 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.

After enrollment and initial data collection, all patients were followed prospectively for adverse events. Participating investigators reported patient symptoms and patient outcomes for each event. Events were categorized as either product performance events or non-product performance events as described in the event classification section of this report. Patient status updates were obtained every 6 months or until discontinuation from the registry.

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 6th Annual Medtronic Neurostimulation and Intrathecal 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 Intrathecal 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 ensure that physicians are able 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 9,300 patients in our ongoing surveillance study: the Implantable Systems Performance Registry (ISPR). The Registry now includes over 27,000 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 ISPR 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.

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

E-MAIL

Written requests or suggestions can be mailed to:

MEDTRONIC
ATTN: Todd Weaver, PhD, MPH or Michelle Wells, PhD
MAIL STOP: LS380
710 Medtronic Parkway NE, LS380
Minneapolis, MN 55432-5604

RestoreSensor® neurostimulator	Kinetra® neurostimulator
InterStim® neurostimulator	Activa® neurostimulator

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

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

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Methodology

- Event Classification
- Device Survival Analyses
- Returned Product Analysis

Event Classification

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

- Implanted or external components
- Implant procedure
- Infusion or stimulation therapy

In early versions of the protocol for infusion and spinal cord stimulation systems, an event was reportable in the ISPR 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 reported in the ISPR has been assessed and reported by the study investigators.

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

All events reported in the ISPR are coded using version 8.0 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.

ISPR 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. All deaths are reported regardless of their relatedness 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.

Adverse Event/Device Event Flowchart

View Larger Image

Product-Performance or Non-Product Performance Categorization

For analysis purposes, events collected through the Implantable Systems Performance Registry (ISPR) 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 ISPR 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 ISPR 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:

- Inconsistent with the ISPR protocol
- Inconsistent 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 requiring additional information
- Center personnel initiated corrections or additions

Device Survival Analyses

Device Survival Estimates

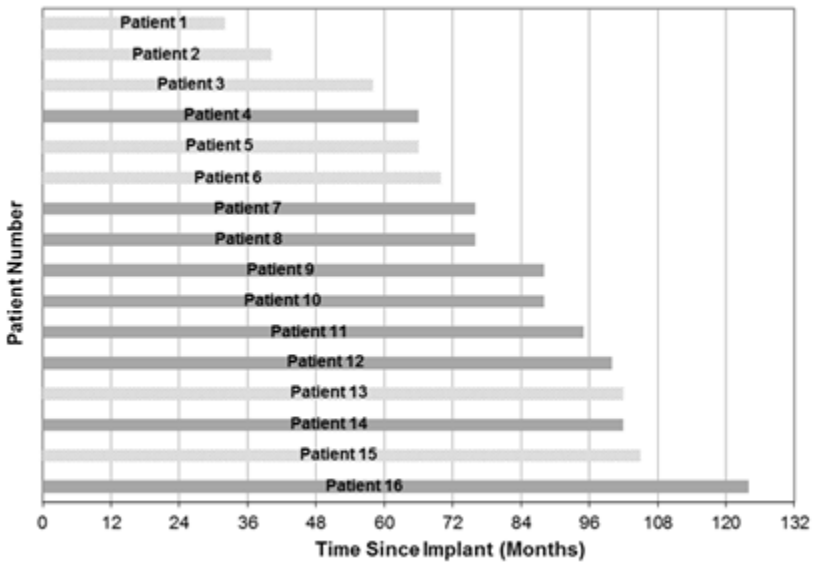
Throughout this report, cumulative device survival plots are presented. These figures show the percentage of implanted devices that remain free from product performance-related events at various time points. For example, a device survival probability of 90% indicates that through the stated follow-up time, the device had a 10% risk of incurring a product performance event since the time of implant.

The Product Performance Report uses actuarial life table methods to estimate device performance over time.[1] The actuarial life table method includes experience for each device up until a product performance-related event occurs, or until the device is removed or therapy is abandoned for non-product performance reasons (including normal battery depletion, patient expired, patient lost to follow-up), or for as long as the device has been followed, whichever occurs first. A minimum of 20 devices must have at least 24 months of follow-up as of the report cut-off date to present a survival curve in this report.

Right Censoring

For each right censored event, the device has performed for a period of time, after which its performance is unknown. Thus, only the time the device has undergone active surveillance is incorporated into the analyses. The following example is intended to provide an overview of the analysis process.

In Figure 1, the first patient's device (patient 1) operated for 32 months. At that time a product performance-related event occurred. The fourth patient's device (patient 4) did not have an event but is censored because it was still in service and without product performance-related events at the time of the last observation of that patient. This patient's device had 66 months of implant experience. In this example, Figure 1 shows that 7 of the 16 devices had product performance events (hashed bars), and 9 devices (solid bars) are censored.



View Larger Image

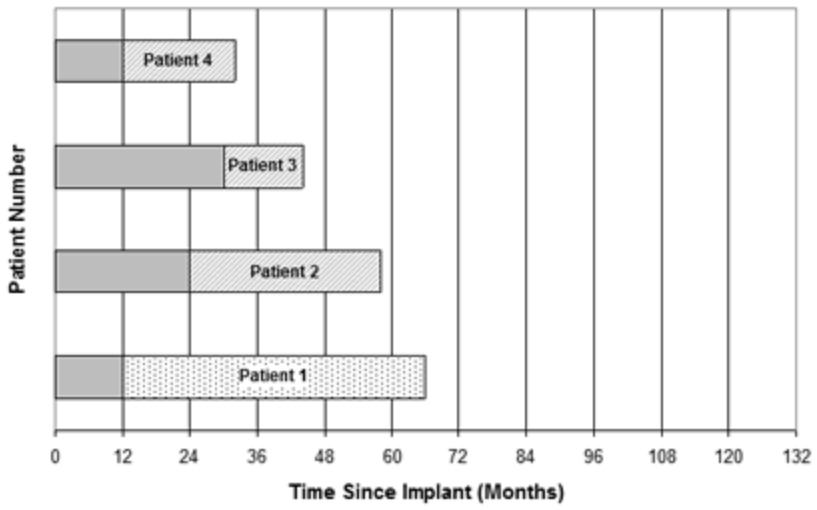
Figure 1. Implant times for an individual device in 16 patients. Hashed bars indicate devices removed from service due to a product performance event. Solid bars indicate right censored devices.

The first step in the life table method is to divide the time since implant into intervals of a specific length and determine how many devices entered each interval, how many were censored in each interval, and how many devices had events in each interval. This example will use 12-month intervals and determine a 60-month, or 5-year cumulative device survival estimate. For the first two 12-month intervals, all 16 devices survived and none were removed. In the 24-36 month interval, the device for patient 1 was removed due to an event. Therefore the table entries show that 16 entered the interval, none were censored, and 1 was removed due to a product performance event. For the 36-48 month interval, only 15 devices entered the interval and 1 was removed for a product performance event (patient 2). For the 48-60 month interval, 14 devices entered the interval and 1 was removed for a product performance event (patient 3). The device survival estimate for the first interval would be 16/16 = 100%. Likewise, the second interval would have a device survival estimate of 16/16 = 100%. The third interval would have a device survival estimate of 15/16 = 94%. The fourth interval from 36-48 months would have a device survival estimate of 14/15 = 93%. The fifth interval from 48-60 months would have a device survival estimate of 13/14 = 93%. In order to determine the overall risk after the first 5 intervals (also known as the cumulative device survival at 60 months), the interval specific estimates must be multiplied. The result of this multiplication is 100% * 100% * 94% * 93% * 93% = 81% cumulative device survival at 5 years.

Effective sample size or the number of devices at risk for each interval is defined as the number of devices with full opportunity to experience a product performance event in the interval. Since censored devices are not fully followed throughout the interval, an adjustment must be made from the total number of devices that enter the interval. This is computed by subtracting one half the number censored in the interval from the number that entered the interval. This adjustment more accurately reflects the number of devices that could have experienced a product performance event than simply using the number that entered the interval. Using the number that enter an interval would over-estimate the sample size because the censored devices do not complete the interval. Completely ignoring the censored devices in the interval would under-estimate the sample size because censored devices would not be credited with their full service time. Using one half the number of censored devices effectively splits the difference. Expanding the example above to determine a 72-month, or 6-year device survival estimate, involves a censored device and adjusting the effective sample size. For the 60-72 month interval, 13 devices entered the interval and 1 was right censored (patient 4) and 2 were removed for a product performance event (patients 5 and 6). The sixth interval from 60-72 months would have a device survival estimate of [13 – (0.5 * 1 censored event) – 2 total events] / [13 – (0.5 * 1 censored device)], or 10.5/12.5 = 84%. The 6-year cumulative device survival would be the 5-year cumulative device survival multiplied by the sixth interval device survival estimate, or 81% * 84% = 68%.

Left Censoring

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases in the Implantable Systems Performance Registry (ISPR) and more predominately in older device models, active surveillance of a device started after the device was implanted. Because the device was not actively followed for some time after implant and before enrollment, this time should not be included in the analysis. For the ISPR, a method to incorporate data from these previously implanted devices was required that would appropriately adjust the follow up time. This method is called left censoring.[2] Left censoring 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.



View Larger Image

Figure 2. Implant times for devices in 4 patients that were implanted prior to the device being enrolled in the ISPR. Solid bars represent the time from implant to enrollment in the ISPR, or the time interval that is left censored. Dotted bars represent the time since enrollment into the ISPR, or the time interval when active surveillance occurred. Hashed bars indicate devices removed from service due to a product performance event.

For example, the first patient's device (patient 1) was implanted for 12 months prior to being enrolled in the ISPR. That period of time is left censored and is not included in the device survival analysis from 0 to 12 months. The period of active surveillance began at 12 months and the device enters the device survival curve at the 12-month time point. Thus, in some cases sample sizes may get larger from one time interval to the next interval.

Device Survival

Device survival for this report is evaluated over discrete 3-month intervals. For each interval, the effective number of devices that successfully functioned throughout the interval is divided by the number of devices that were at risk during the interval. Cumulative device survival probability at any time point is obtained by multiplying the device survival probabilities of all intervals occurring prior to the time point of interest. A cumulative device survival curve is generated by plotting the cumulative device survival probability of all discrete intervals for which an adequate amount of data are present. The device survival curves shown are only presented where at least 20 total devices were still being followed in any given interval, except where otherwise noted. Device survival estimates are presented at the device level, not at the system level which involves the combination of 2 or more devices.

Confidence Intervals

Since device survival curves are derived from a sample of the total implanted population, they are only estimates of device survival. The larger the effective sample size, the more confident the estimate. A confidence interval can be calculated to assess the confidence in an estimate. Confidence intervals for 1-year device survival estimates, constructed using Greenwood's variance estimate,[1] are shown at the end of each section. 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, survival estimates for product performance-related events are not statistically significantly different between models. When confidence intervals do not overlap, survival estimates for product performance-related events are statistically significantly different between models.

References

1. Lee, Elisa T. (2003) Statistical Methods for Survival Data Analysis – 3rd Edition (Wiley Series in Probability and Statistics)
2. Broste SK, Kim JS. Extension of life-table methodology to allow for left-censoring in survival studies of pacing devices followed by commercial monitoring services. *Pacing Clin Electrophysiol.* 1987 Jul;10(4 Pt 1):853-61.

Returned Product Analysis

Implantable Systems Performance Registry (ISPR) devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process following protocols to confirm proper functioning or identification of root cause for any failure or deficiency. For ISPR pumps and neurostimulators that are returned, and for which RPA establishes a root cause or finds no anomaly, results reported herein default to 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 ISPR study including the results of RPA for returned devices from ISPR centers and patients. Data from RPA outside the ISPR study centers and patients are not presented in this report primarily for two reasons: (1) the ISPR study uses a prospective data collection methodology that provides a representative sample of the implanted device population; and (2) the ISPR study represents active surveillance of registered devices with a high level of ascertainment of device problems within the scope of the study as compared to RPA data collected outside of the ISPR.

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

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

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Intrathecal Drug Delivery Systems

- Study Participants
- Event Summary

- Pumps
- Catheters

Study Participants

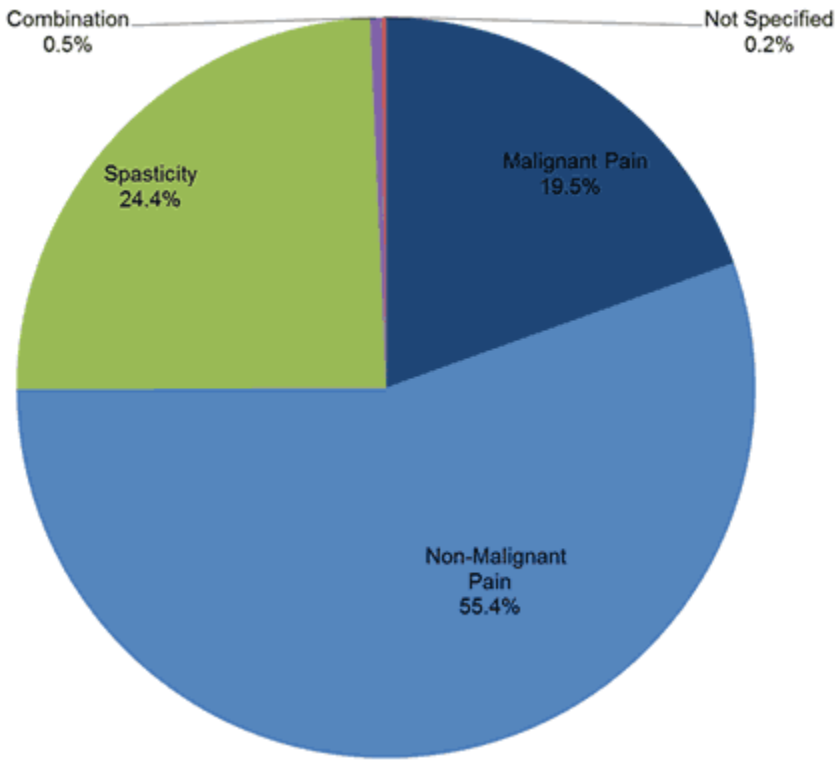
Centers

The following tables and graphs were generated based on data collected between the date of initiation of the Implantable Systems Performance Registry (ISPR) for intrathecal drug delivery systems on August 7, 2003 and the report cut-off date of July 31, 2013. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 5,854 total intrathecal drug delivery system patients enrolled in the ISPR through July 31, 2013. As indicated, 55.4% of patients were implanted with an intrathecal drug delivery system for treatment of non malignant pain (pain not related to cancer and its treatment), followed by 24.4% for treatment of intractable spasticity, and 19.5% for treatment of malignant pain (pain related to cancer). The ISPR is 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-representative in the ISPR (ISPR = 19.5% versus U.S. population = 14.3% - data based on Device and Registration Tracking).

Primary IDD System Treatment Indications



Primary Treatment Indication[a]	N (Percent)
Pain	**4,384 (74.9%)**
Malignant pain	1,143 (19.5%)

Non-malignant pain	3,244 (55.4%)
Spasticity	**1,426 (24.4%)**
Combination	**30 (0.5%)**
Non-malignant pain & spasticity	30 (0.5%)
Not Specified	**11 (0.2%)**
Total Patients	**5,854**

[a] Refer to product labeling for approved indications.

Malignant Pain Sub-Indications[a]	N (Percent) [b]
Location of Pain	
Spine/back	303 (26.5%)
Abdominal/visceral	215 (18.8%)
Pelvic	123 (10.8%)
Extremity	111 (9.7%)
Thoracic	103 (9.0%)
Head/neck	54 (4.7%)
Other	42 (3.7%)
Unknown	439 (38.4%)
Total Patients	**1,143**

[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	N (Percent)
Back pain without leg pain	1,201 (36.7%)
Back pain with leg pain	644 (19.7%)
CRPS I[a]	107 (3.3%)
Peripheral neuropathy	62 (1.9%)
Joint pain/arthritis	45 (1.4%)

A general neuropathic condition	41 (1.3%)
CRPS II[a]	22 (0.7%)
Osteoporosis	19 (0.6%)
A general nociceptive condition	10 (0.3%)
Other	161 (4.9%)
Unknown	962 (29.4%)
Total Patients	**3,274**

[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	N (Percent)
Cerebral palsy	416 (28.6%)
Multiple sclerosis	364 (25.0%)
Spinal cord injury	188 (12.9%)
Brain injury	114 (7.8%)
Stroke	54 (3.7%)
Other	46 (3.2%)
Unknown	274 (18.8%)
Total Patients	**1,456**

Event Summary

There were 4,322 events reported between August 2003 and July 31, 2013 in patients with intrathecal drug delivery systems. Nineteen percent of these events (839/4,322) were categorized as product performance-related events and are presented graphically within this report. The 839 product performance events occurred in 664 of the 5,854 total patients (11.3%) enrolled. In addition, there were 2,109 non-product performance events and 1,374 deaths, none of which were reported as a direct result of a device-related event or the infusion therapy during this timeframe. 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.

Intrathecal 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=5,854)
Catheter kink/occlusion	227	203	3.47%
Catheter dislodgment from intrathecal space	197	178	3.04%
Catheter break/cut	143	131	2.24%
Motor stall	50	50	0.85%
Catheter related complication[c]	44	41	0.70%
Medical device complication[d]	37	35	0.60%
Corrosion and/or gear wear	24	24	0.41%
Unable to enter/withdraw from catheter access port	21	21	0.36%
Catheter disconnection at pump	20	20	0.34%
Catheter leakage	18	18	0.31%
Catheter disconnection at distal connection	13	13	0.22%
Pump underinfusion	13	13	0.22%
Catheter blockage	4	3	0.05%
Deformed pump tube	4	4	0.07%
Device malfunction[e]	4	4	0.07%

Intrathecal Drug Delivery System Product Performance Events			
Reduced battery performance	4	4	0.07%
Pump no infusion	3	3	0.05%
Alarm and/or resonator anomaly	1	1	0.02%
CSF abnormal[f]	1	1	0.02%
Coil shorted to case	1	1	0.02%
Concave pump shield	1	1	0.02%
Cracked rotor magnet holder	1	1	0.02%
Hole in pump tube	1	1	0.02%
Leaky capacitor	1	1	0.02%
Motor feedthrough anomaly	1	1	0.02%
Pump inversion[g]	1	1	0.02%
Pump overinfusion[h]	1	1	0.02%
Roller arm seized to ball bearing	1	1	0.02%
Unable to withdraw fluid from reservoir	1	1	0.02%
Not coded[i]	1	1	0.02%
Total	**839**	**664**	**11.34%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term or Lower Level Term
[b] The total number of patients with event may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[c] Includes 17 events reported as catheter malfunction, 15 difficulty aspirating catheter, 3 coiled catheters, 1 suspected catheter failure, 1 catheter wear, 1 patency issue with catheter, 1 catheter aneurysm, 1 unraveling catheter, 1 catheter wrapped around pump, 1 catheter with sediment, 1 slight loop in catheter, and 1 suspected catheter issue
[d] Includes 14 events reported as pump connector break or cut, 11 events reported as inconsistency in pump reservoir volume, 5 pump malfunctions, 1 pump unable to interrogate/program, 1 possible corrosion of pump, 1 telemetry stopped secondary to error code, 1 non-functioning catheter, 1 sutureless connector

failure, 1 pump in safe state, and 1 under medicated event attributed to the pump

[e] Includes 2 PTM malfunctioning, 1 pump beeped, and 1 fluctuating over and under medication distribution

[f] Poor CSF flow

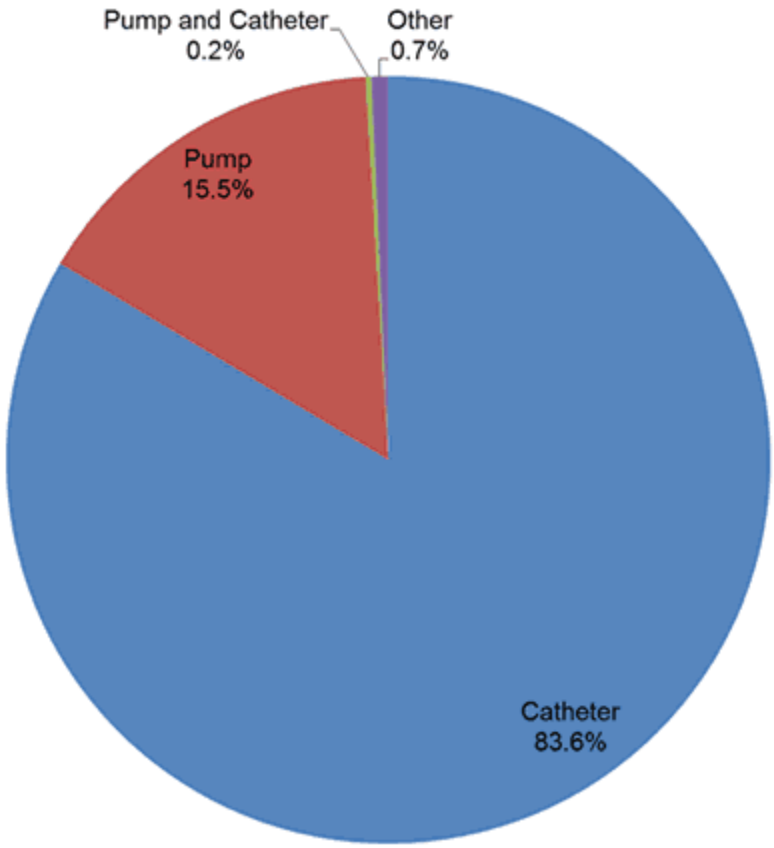
[g] Reported as flipping pump caused catheter to coil and knot

[h] There was 1 event reported as pump overinfusion by the physician, but the pump was not returned for analysis. There were 4 additional pumps confirmed to have overinfusion after returned product analysis. Two were initially reported by the physician as reservoir volume discrepancies (coded in the table above by the returned product analysis - root cause finding of deformed pump tube), 1 as a pump battery end of life (coded in the table above by the returned product analysis - root cause finding of corrosion or gear/wear), and 1 had no reported event associated with its explant (not reflected in the table above).

[i] Possible small fractures in catheter or partial catheter blockage

A total of 701 (83.6%) of the 839 product performance events were related to the catheter, 130 (15.5%) were related to the pump, 2 (0.2%) were related to both the pump and catheter, 3 (0.4%) were reported as "Other/Unspecified Device," 1 (0.1%) was related to incisional site/device tract, 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 Etiology



Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)

Event[b]	Number of Non-Product Performance Events
Pump end of service (EOS)	844
Implant site infection	151
Pump inversion	77
Therapeutic product ineffective	76
Drug toxicity	70
Implant site pain	67
Drug withdrawal syndrome	51
Pain	46
Cerebrospinal fluid leakage	45
Implant site effusion	39
Wound dehiscence	39
Pump migration	38
Implant site erosion	27
Hypoaesthesia	24
Infection	21
Somnolence	19
Muscle spasticity	18
No anomaly found by RPA[c]	15
Implant site fibrosis	14
Overdose	14
Seroma	14
Therapy non-responder	14

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)	
Wound infection	14
Meningitis	13
Medical device complication[d]	13
Asthenia	11
Inflammatory mass (Confirmed)	11
Sedation	11
Inflammatory mass (Possible)	10
Implant site erythema	9
Implant site haematoma	9
Lumbar puncture headache	9
Medical device discomfort	9
Mental status changes	9
Oedema peripheral	9
Impaired fealing	7
Erythema	6
Nausea	6
Back pain	5
Drug related pump anomaly	5
Implant site inflammation	5
Memory impairment	5
Urinary retention	5
Other[e]	206
Total Events	**2,109**

[a] Adverse events associated with product performance events are not included in this table
[b] MedDRA Preferred Term
[c] For products that are returned with a suspected device issue, and RPA establishes a root cause or finds no anomaly, results reported herein default to the RPA finding
[d] Includes 4 malpositioned catheters, 1 event reported as unable to fill/refill pump not caused by the pump,1 empty pump reservoir secondary to patient failure to keep refill appointments, 1 scar tissue contorting the catheter, 1 possible corrosion of the catheter due to drug concentration, 1 intraspinal infusate contamination, 1 elective replacement indicator occurrence, 1 unable to adequately dose patient not caused by the device, and 1 pseudocyst with pooling identified by diagnostic tests.
[e] Composed of 131 event codes that include fewer than 5 patients each and events that had not been MedDRA coded at the time of the report cut-off (n=2)

There were 1,374 deaths reported in the ISPR for patients with intrathecal drug delivery systems, none of which were reported as a direct result of a device-related event or the infusion therapy. A total of 65.9% of patient deaths occurred in patients receiving therapy for malignant pain, 25.6% for non-malignant pain, and 8.4% for intractable spasticity.

Deaths by Primary Indication

Primary Indication	Count (%)
Malignant pain	906 (65.9%)
Non-malignant pain	352 (25.6%)
Spasticity	116 (8.4%)
Total	**1,374 (100.0%)**

Pumps

From August 2003 to the report cut-off date of July 31, 2013, 6,954 pumps were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=5,854) versus pumps is due to the fact that some patients were subsequently re-implanted with a pump multiple times.

Most of the pumps followed in the registry were either SynchroMed II (82.9%) or SynchroMed EL (17.1%), and a small number of pumps were SynchroMed Classic (0.1%). The aggregate prospective follow-up time for all pumps was 182,195 months (15,183 years).

Pump Events

There were 132 product performance-related events with an underlying reported etiology related to pump function. Of these, 122 were the first event attributable to an enrolled pump. The current return rate of pumps to Medtronic Returned Product Analysis (RPA) was 686/2,887 (24%). The proportion was based upon the number of pumps received by RPA, divided by the total number of explanted pumps plus the total number of pumps in patients who expired.

Of the 132 product performance-related events related to the pump, 68 were analyzed by Medtronic RPA with the following analysis findings: 28 motor stalls, 24 corrosion and/or gear wear, 4 with deformed pump tube, 4 reduced battery performance, 1 alarm and/or resonator anomaly, 1 with coil shorted to case, 1 concave pump shield, 1 cracked rotor magnet holder, 1 hole in pump tube, 1 leaky capacitor, 1 motor feedthrough anomaly, and 1 roller arm seized to ball bearing. Of these 68 pumps with RPA-confirmed malfunction events, 14 were originally reported as non-product performance-related battery depletions by the physician.

In addition to the 132 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.

Within the 132 product performance-related events related to the pump, 64 events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 22 events due to physician-reported motor stalls, 19 events due to a medical device complication, 13 events due to underinfusion, 4 events due to an inability to enter/withdraw from the catheter access port, 3 events due to no infusion, 2 events due to device malfunction, and 1 event due to pump overinfusion.

Of the 132 product performance-related events with an underlying reported etiology related to pump function, 95 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 37 pumps, the complete drug history and exposure to admixtures could not be confirmed.

Medtronic is executing a field action informing healthcare professionals of overinfusion associated with the SynchroMed II infusion system. As indicated in the communication, four pumps from ISPR patients were found to have confirmed overinfusion after returned product analysis. Two were initially reported by the physician as reservoir volume discrepancies, one as a pump battery end of life, and one had no reported event associated with its explant. The four reports of overinfusion occurred in 5,765 SynchroMed II pumps included in ISPR at the time of analysis, providing a 95% confidence that the occurrence rate is less than 0.0016 (0.16%). Medtronic will continue 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. In addition to the 122 pumps which were cut-off due to product performance-related events, there were 4,590 pumps 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. The remaining 2,242 pumps, which were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

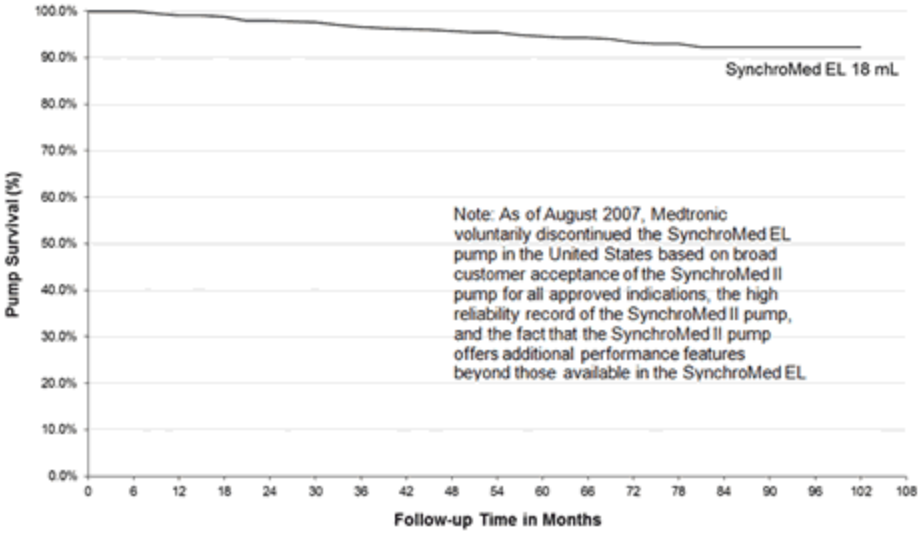
Pump Survival

The figures and tables below represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each 3-month interval. Currently, the 95% confidence intervals for all pump models overlap, indicating that survival from pump-related events is not significantly different between the pump models across various applicable follow-up time points. Medtronic chose to voluntarily discontinue the SynchroMed EL pump in August 2007 in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact that the SynchroMed II pump offers additional performance features beyond those available in the SynchroMed EL pump.

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.



View Larger Image

Note: As of August 2007, Medtronic voluntarily discontinued the SynchroMed EL pump in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact that the SynchroMed II pump offers additional performance features beyond those available in the SynchroMed EL

Pump Characteristics	
Model Name	SynchroMed EL (18 mL)
FDA Approval Date	Mar 1999
Pumps Enrolled	1,151
Pumps Currently Active in Study	2
Device Events	34
Cumulative Months of Follow-up	36,260

Pump Event	Total
Corrosion and/or gear wear	17
Motor stall	6
Pump underinfusion	7
Medical device complication[a]	1
Cracked rotor magnet holder	1
Motor feedthrough anomoly	1

Roller arm seized to ball bearing	1
Total Pump Events	**34**

[a] Reported as unable to interrogate/program pump

Time Interval	Survival	Effective Sample Size
1 yr	99.0%	219
2 yrs	97.9%	448
3 yrs	96.7%	649
4 yrs	95.8%	663
5 yrs	94.6%	521
6 yrs	93.3%	286
7 yrs	92.3%	119
8 yrs	92.3%	41
at 102 mo	92.3%	20

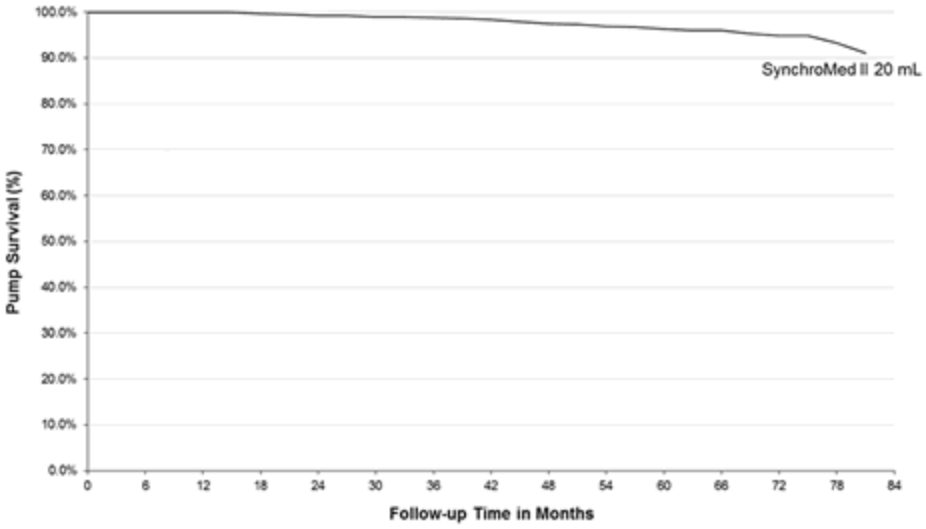
Model 8627-18 SynchroMed EL 18mL: Specifications

Expected battery life	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 Flow Rate*	0.048 mL/day
Maximum Flow Rate**	21.6 mL/day

* At rates less than 0.048 mL/day, the flow accuracy may exceed the ± 15% specification.
** Actual limits depend on pump calibration constant and selected infusion mode. The programmer may further narrow these limits.

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.



View Larger Image

Pump Characteristics	
Model Name	SynchroMed II (20 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	2,237
Pumps Currently Active in Study	1,022
Device Events	35
Cumulative Months of Follow-up	63,317

Pump Event	Total
Motor stall	13
Medical device complication[a]	8
Corrosion and/or gear wear	4
Unable to enter/withdraw from catheter access port	3
Device malfunction[b]	2
Deformed pump tube	2
Pump no infusion	1
Hole in pump tube	1

Alarm and/or resonator anomaly	1
Total Pump Events	**35**

[a] Includes 3 events for excess reservoir volume, 2 events for reservoir volume discrepancy, 1 event reported as pump malfunction, 1 event indicating telemetry was stopped secondary to error code, and 1 event indicating pump was in safe state
[b] Includes 1 event for pump beeped and 1 fluctuating over and under medication distribution

Time Interval	Survival	Effective Sample Size
1 yr	99.9%	1,498
2 yrs	99.3%	1,093
3 yrs	98.7%	796
4 yrs	97.5%	589
5 yrs	96.2%	401
6 yrs	94.9%	236
at 81 mo	91.1%	44

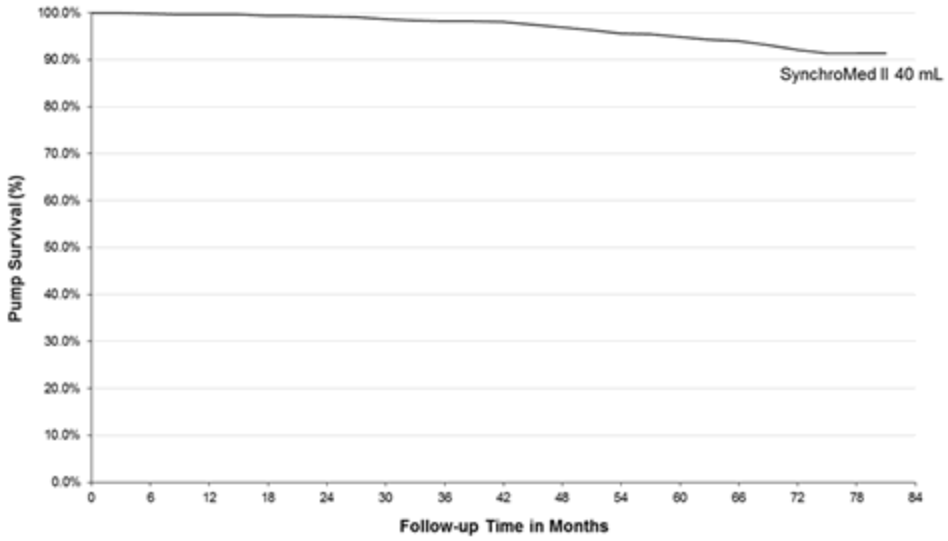
Model 8637-20 SynchroMed II 20mL: Specifications

Expected battery life*	6-7 years
Thickness	0.78 in (19.5 mm)
Diameter	3.4 in (87.5 mm)
Capacity	20.0 mL
Minimal Flow Rate**	0.048 mL/day
Maximum Flow Rate**	24 mL/day

* Dependent on flow rate
** Actual limits depend on pump calibration constant and selected infusion mode.

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.



View Larger Image

Pump Characteristics	
Model Name	SynchroMed II (40 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	3,528
Pumps Currently Active in Study	1,095
Device Events	52
Cumulative Months of Follow-up	76,828

Pump Event	Total
Motor stall	25
Medical device complication[a]	7
Pump underinfusion	5
Reduced battery performance	3
Corrosion and/or gear wear	3
Deformed pump tube	2
Pump no infusion	2
Coil shorted to case	1

Concave pump shield	1
Leaky capacitor	1
Pump overinfusion	1
Unable to enter/withdraw from catheter access port	1
Total Pump Events	**52**

[a] Includes 2 events reported as pump malfunction, 2 events for excess reservoir volume, 1 possible corrosion of the pump due to drug concentration, 1 erroneous empty reservoir alarm, and 1 under medicated event attributed to the pump

Time Interval	Survival	Effective Sample Size
1 yr	99.7%	1,952
2 yrs	99.3%	1,351
3 yrs	98.3%	926
4 yrs	97.0%	604
5 yrs	94.9%	362
6 yrs	92.1%	185
at 81 mo	91.4%	29

Model 8637-40 SynchroMed II 40mL: Specifications

Expected battery life*	6-7 years
Thickness	1.0 in (26 mm)
Diameter	3.4 in (87.5 mm)
Capacity	40.0 mL
Minimal Flow Rate**	0.048 mL/day
Maximum Flow Rate**	24 mL/day

* Dependent on flow rate
** Actual limits depend on pump calibration constant and selected infusion mode.

Pump Survival Summary

Currently, survival from pump-related events is not significantly different between the pump models across all applicable follow-up time points. Medtronic chose to voluntarily discontinue the SynchroMed EL in August 2007 in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact that the SynchroMed II pump offers additional performance features beyond those available in the SynchroMed EL pump.

Pump Characteristics					
Model Name	**FDA Approval Date**	**Pumps Enrolled**	**Pumps Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**
SynchroMed EL (18 mL)	Mar 1999	1,151	2	34	36,260
SynchroMed II (20 mL)	Sep 2003	2,237	1,022	35	63,317
SynchroMed II (40 mL)	Sep 2003	3,528	1,095	52	76,828

[a] There were a total of 132 pump-related events reported to the ISPR, but only 121 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)	**99.0%** (97.7%, 100.0%)	**97.9%** (96.2%, 99.7%)	**96.7%** (94.7%, 98.6%)	**95.8%** (93.8%, 97.8%)
SynchroMed II (20 mL)	**99.9%** (99.7%, 100.0%)	**99.3%** (98.8%, 99.8%)	**98.7%** (98.1%, 99.4%)	**97.5%** (96.4%, 98.6%)
SynchroMed II (40 mL)	**99.7%** (99.5%, 99.9%)	**99.3%** (98.9%, 99.7%)	**98.3%** (97.5%, 99.0%)	**97.0%** (95.8%, 98.1%)

Device Survival Probability (95% Confidence Intervals) –*Table 2 of 2*				
Model Name	**5 yrs**	**6 yrs**	**7 yrs**	**8 yrs**
SynchroMed EL (18 mL)	**94.6%** (92.5%, 96.8%)	**93.3%** (90.8%, 95.8%)	**92.3%** (89.4%, 95.1%)	**92.3%** (89.4%, 95.1%)
SynchroMed II (20 mL)	**96.2%** (94.7%, 97.7%)	**94.9%** (92.9%, 96.9%)	-	-
SynchroMed II (40 mL)	**94.9%** (93.2%, 96.6%)	**92.1%** (89.4%, 94.8%)	-	-

Pump Survival by ON/OFF Label Medication Use

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

The purpose of this section of the report is to provide additional information regarding the product performance of SynchroMed II pumps exposed to On-Label and Off-Label medication. 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® or 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 snap shot 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

Of the 5,765 SynchroMed II pumps enrolled into the ISPR through July 31, 2013, 5478 had at least one available drug record. If a pump had no drug records in the ISPR, the pump was not classified, and was excluded from any 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 ISPR, 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, 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 ISPR), 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 for each 3-month interval were calculated using life-table methods (for more details, see the Methodology section of this report). Statistical testing comparing survival curves was performed using a Cox proportional-hazards model. Since the survival estimate may become very imprecise with small effective sample sizes, Medtronic Neuromodulation's ISPR truncates device survival curves when the effective 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:

1. All pumps: On-Label vs. Off-Label Drugs (including All Indications)
2. Pain: On-Label vs. Off-Label Drugs (including All Pain)
3. 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.

Choose a result Go

Total Study Population: A total of 1,849 SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 3,629 pumps were classified as Off-Label whereby there is evidence of pump exposure to an Off-Label drug/admixture.

Demographic table

Characteristic	On-Label N=1,849	Off-Label N=3,629
Age (years) at enrollment: Mean (SD)	42.7 (21.6)	56.5 (13.4)
Female: N (%)	923 (49.9%)	2,125 (58.6%)
Indication: N (Row %)		
Non-Malignant Pain	597 (19.5%)	2,458 (80.5%)
Malignant Pain	37 (3.6%)	998 (96.4%)
Spasticity	1,215 (89.1%)	149 (10.9%)
Multiple/Unknown	NA	24 (100.0%)

There were a total of 87 reported SynchroMed II pump failures (i.e. had product performance event) during the study observation period. In addition to the 87 pump failures, there were 13 pump events reported as normal battery depletion, but had a returned product analysis observation of high battery resistance. For this analysis, these pumps were not considered failures because they represent normal implant duration ranging from 5.6 – 6.8 years with no associated physician or patient complaint. Two of the 87 pump failure events occurred in pumps with no drug records available. Of the remaining 85 SynchroMed II pump failures, 38 pumps were classified as pump failure due to motor stall (with or without documented motor corrosion). The remaining classified failures were due to events such as premature battery depletion, inconsistent pump reservoir volume, pump under infusion and other non-conforming reasons.

For the 38 pump failures due to motor stall, 27 of the pumps were associated with the patient presenting clinical signs and symptoms of possible drug withdrawal or increasing pain or spasticity. The other 11 pumps had no patient reported patient 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 1.6% (85/5,478) at a median follow up of 17.4 months.

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

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

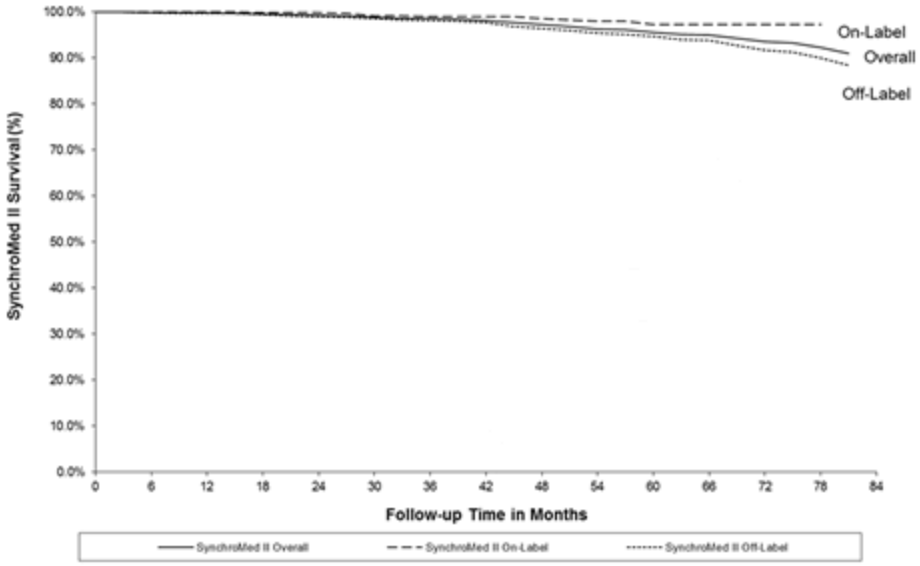
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo
All Pumps	Survival	99.8%	99.3%	98.5%	97.2%	95.5%	93.5%	91.0%
	Number of pumps	3,450	2,444	1,722	1,194	763	421	73
On-Label Drugs	Survival	100.0%	99.8%	99.0%	98.5%	97.2%	97.2%	97.2%[a]
	Number of pumps	1,240	910	635	412	251	137	51
Off-Label Drugs	Survival	99.7%	99.0%	98.2%	96.4%	94.7%	91.7%	88.4%
	Number of pumps	2,120	1,491	1,060	760	504	283	56

[a] Survival for On-Label SynchroMed II pumps through 78 months.

The cumulative survival curve of the SynchroMed II pump for the **entire population**, and stratified by 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.



View Larger Image

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 2.8 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.0005).

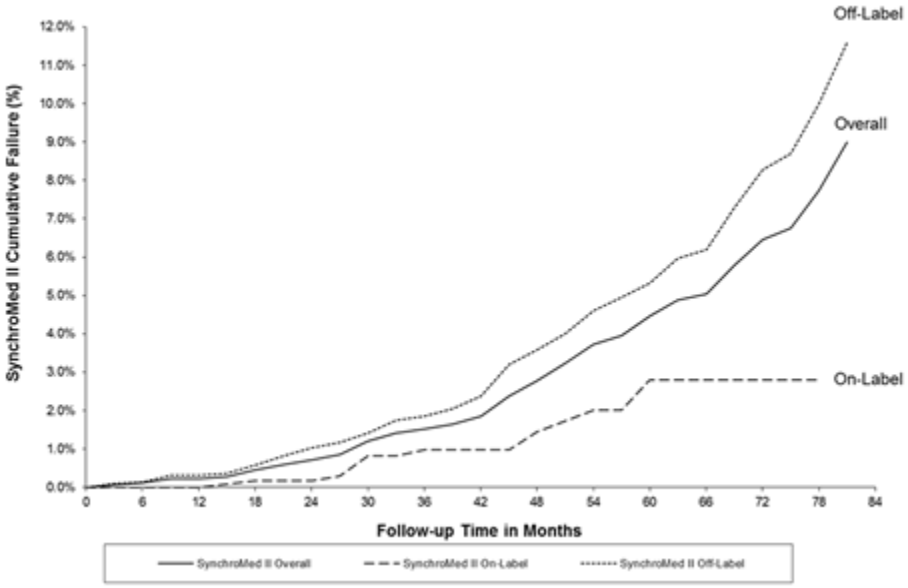
Total study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for all indications, by On/Off-Label drug exposure

Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo
All Pumps	Failure	0.2%	0.7%	1.5%	2.8%	4.5%	6.5%	9.0%
	Number of pumps	3,450	2,444	1,722	1,194	763	421	73
On-Label Drugs	Failure	0.0%	0.2%	1.0%	1.5%	2.8%	2.8%	2.8%[a]
	Number of pumps	1,240	910	635	412	251	137	51
Off-Label Drugs	Failure	0.3%	1.0%	1.8%	3.6%	5.3%	8.3%	11.6%
	Number of pumps	2,120	1,491	1,060	760	504	283	56

[a] Failure for On-Label SynchroMed II pumps through 78 months.

SynchroMed II cumulative failure (All therapies)

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



View Larger Image

Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medication use over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.8 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 97.2%, compared to a survival of 90.0% for Off-Label pumps.
- The data represents reported ISPR experience with a median follow up time of 17.4 months. The longer term data is based on a lower number of pumps and is subject to change as more follow up data is 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.
- On-Label pump group consisted of 66% spasticity therapy (1,215 vs. 634: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 96% pain therapy (3,456 vs. 149: 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 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 received multiple medications over the pump life span. This limits the ability to associate a specific drug, drug concentration, or drug combination with increased pump failure risk.

Pain Study Population: A total of 634 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 3,456 pumps were classified as Off-Label whereby there is evidence of pump exposure to an Off-Label pain drug/admixture.

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

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

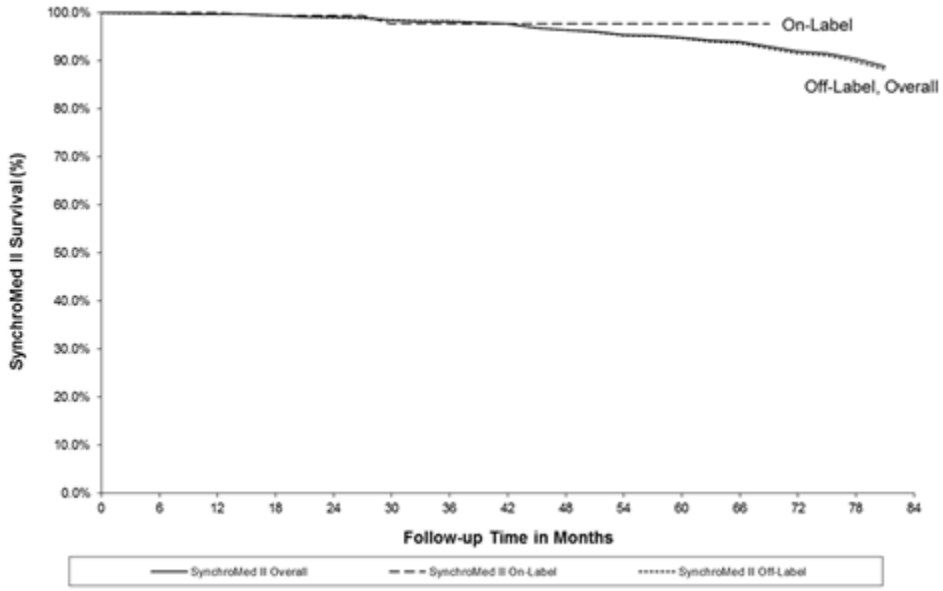
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo
Pain Overall	Survival	99.7%	99.0%	98.1%	96.5%	94.9%	92.0%	88.8%
	Number of pumps	2,408	1,632	1,126	775	506	290	60
Pain On-Label	Survival	100.0%	99.4%	97.6%	97.6%	97.6%	97.6%[a]	-
	Number of pumps	369	222	129	59	30	22	-
Pain Off-Label	Survival	99.7%	99.0%	98.2%	96.4%	94.7%	91.6%	88.2%
	Number of pumps	1,999	1,400	994	714	475	271	55

[a] Survival for On-Label SynchroMed II pumps (pain) through 69 months.

The cumulative survival of the SynchroMed II pump for the **Pain** indication, and stratified by 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.



View Larger Image

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=30) and beyond.

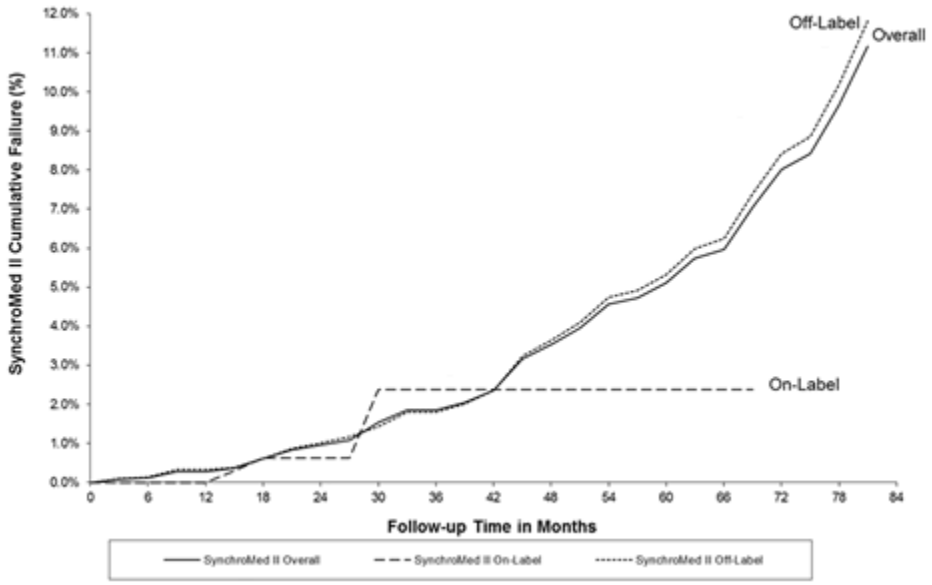
Pain study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Pain indication, by On/Off-Label drug exposure

Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	81 mo
Pain Overall	Failure	0.3%	1.0%	1.9%	3.5%	5.1%	8.0%	11.2%
	Number of pumps	2,408	1,632	1,126	775	506	290	60
Pain On -Label	Failure	0.0%	0.6%	2.4%	2.4%	2.4%	2.4%[a]	-
	Number of pumps	369	222	129	59	30	22	-
Pain Off -Label	Failure	0.3%	1.0%	1.8%	3.6%	5.3%	8.4%	11.8%
	Number of pumps	1,999	1,400	994	714	475	271	55

[a] Failure for On-Label SynchroMed II pumps (pain) through 69 months.

SynchroMed II cumulative failure (Pain)

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



View Larger Image

Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medication use over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.8 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 97.2%, compared to a survival of 90.0% for Off-Label pumps.
- The data represents reported ISPR experience with a median follow up time of 17.4 months. The longer term data is based on a lower number of pumps and is subject to change as more follow up data is 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.
- On-Label pump group consisted of 66% spasticity therapy (1,215 vs. 634: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 96% pain therapy (3,456 vs. 149: 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 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 received multiple medications over the pump life span. This limits the ability to associate a specific drug, drug concentration, or drug combination with increased pump failure risk.

Spasticity Study Population: A total of 1,215 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 149 pumps were classified as Off-Label whereby there is 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 On-Label pump group and 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

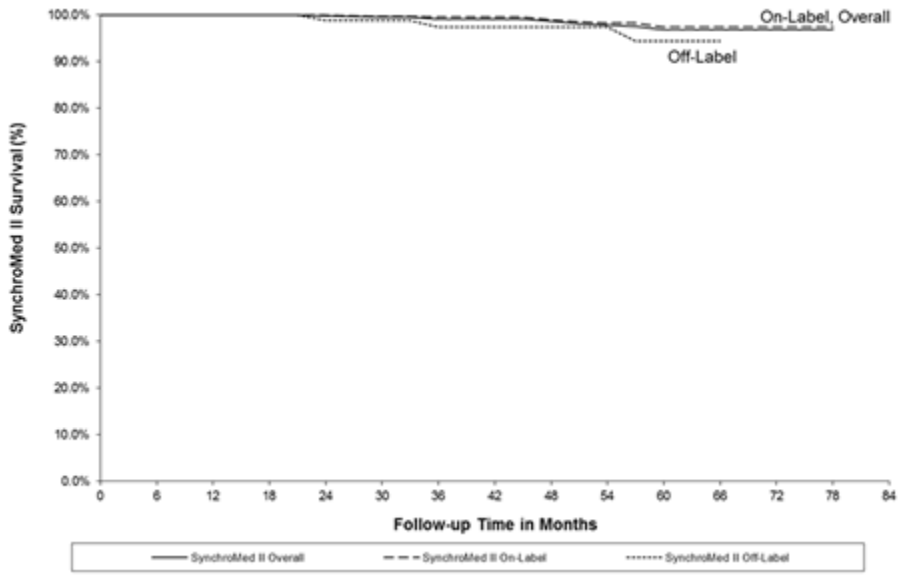
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo
Spasticity Overall	Survival	99.9%	99.8%	99.2%	98.7%	96.8%	96.8%	96.8%
	Number of pumps	1,033	809	595	419	257	131	45
Spasticity On-Label	Survival	100.0%	100.0%	99.5%	98.9%	97.4%	97.4%	97.4%
	Number of pumps	871	687	506	353	221	118	40
Spasticity Off-Label	Survival	100.0%	98.9%	97.4%	97.4%	94.5%	94.5%[a]	-
	Number of pumps	111	88	65	46	29	20	-

[a] Survival for Off-Label SynchroMed II pumps (spasticity) through 66 months.

The cumulative survival of the SynchroMed II pump for the **Spasticity** indication, and stratified by 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.



View Larger Image

The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. Overall the survival for the On-Label pumps was similar to the entire pump population (all therapies). There were too few pumps in the Off-Label group to assess long term survival beyond five years (60 months). Statistical testing was not performed due to low sample size in the Off-Label group at the 60-month follow-up (n=29) 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

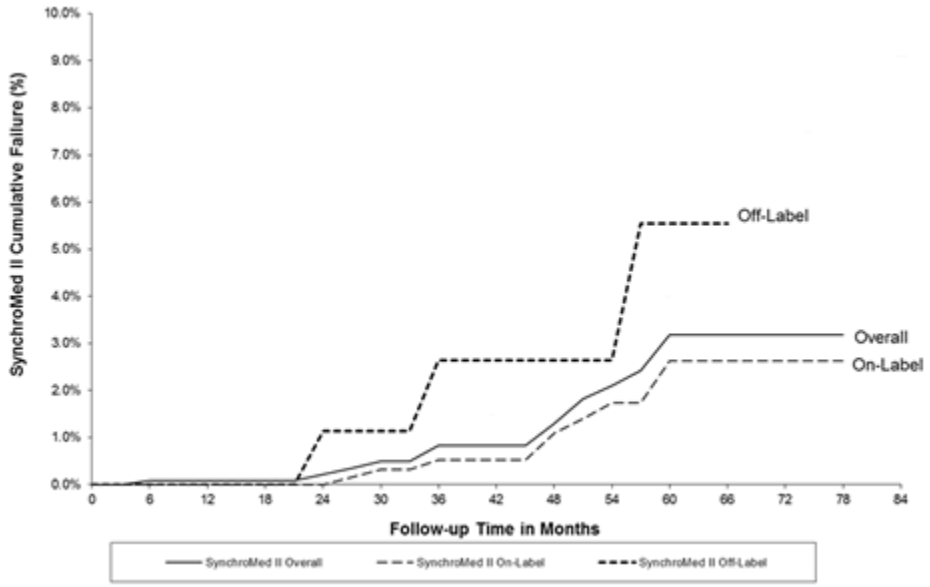
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo
Spasticity Overall	Failure	0.1%	0.2%	0.8%	1.3%	3.2%	3.2%	3.2%
	Number of pumps	1,033	809	595	419	257	131	45
Spasticity On-Label	Failure	0.0%	0.0%	0.5%	1.1%	2.6%	2.6%	2.6%
	Number of pumps	871	687	506	353	221	118	40
Spasticity Off-Label	Failure	0.0%	1.1%	2.6%	2.6%	5.5%	5.5%[a]	-

Number of pumps	111	88	65	46	29	20	-

[a] Failure for Off-Label SynchroMed II pumps (spasticity) through 66 months.

SynchroMed II cumulative failure (Spasticity)

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



View Larger Image

Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medication use over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.8 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 97.2%, compared to a survival of 90.0% for Off-Label pumps.
- The data represents reported ISPR experience with a median follow up time of 17.4 months. The longer term data is based on a lower number of pumps and is subject to change as more follow up data is 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.
- On-Label pump group consisted of 66% spasticity therapy (1,215 vs. 634: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 96% pain therapy (3,456 vs. 149: 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 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 received multiple medications over the pump life span. This limits the ability to associate a specific drug, drug concentration, or drug combination with increased pump failure risk.

Catheters

From August 2003 to the report cut-off date of July 31, 2013, 6,545 catheters were followed in the Implantable Systems Performance Registry (ISPR). The total number of catheters was not equal to the total number of pumps (n=6,954) because a patient may have undergone a pump replacement but used the same catheter, 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 192,423 months (16,035 years).

A total of 42.3% of the catheters were Model 8709 catheters, 15.1% were Model 8709SC catheters, 9.5% were Model 8711 catheters, 7.5% were Model 8731 catheters, 3.2% were Ascenda catheters, 2.9% were Model 8703W catheters, 2.6% were Model 8731SC catheters, and 0.6% were other or unspecified catheters. An additional 3.0% were considered catheters revised as designed, (8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); 0.5% were Ascenda revised as designed (8780 or 8781 catheters repaired with the 8782 or 8784 revision kit); 7.3% were considered catheters revised not as designed (Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); and 5.5% were catheters grafted not as designed (catheters that involve the ad-hoc assembly of components other than a Medtronic repair kit or brand new catheter).

Catheter Events

There were 703 product performance events reported related to the catheter. Of these events, the majority were catheter kink or occlusion (n=226), catheter dislodgement (n=196), or break or cut in the catheter (n=142). Of the 703 events, 630 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. A total of 630 catheters had follow-up time cut-off due to product performance-related events. There were 3,704 catheters 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. The remaining 2,211 catheters, which 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

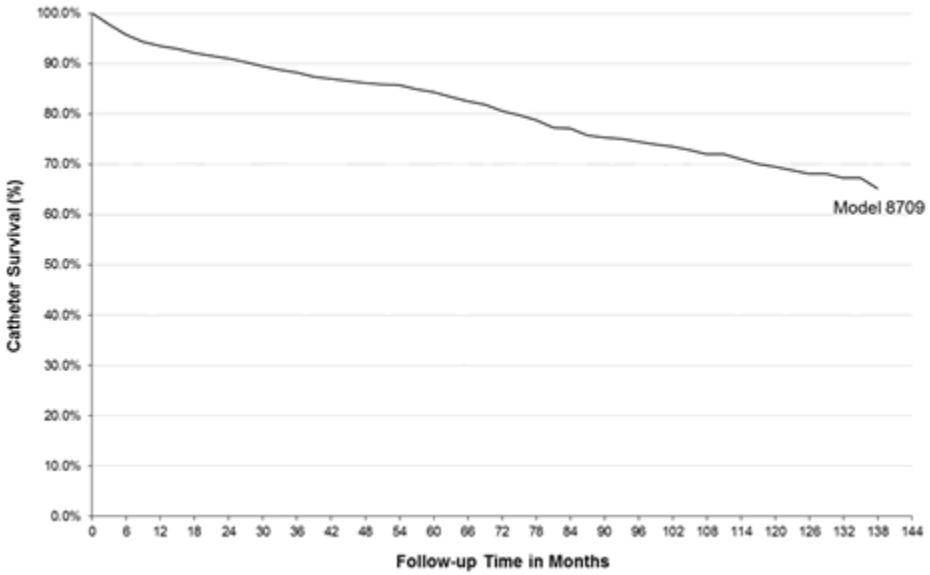
The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. Currently at 1 through 5 years of follow-up, the 95% confidence interval for grafted not as designed catheters does not overlap with Models 8709 and 8731 catheters. In addition, at 4 and 5 years of follow-up, the 95% confidence interval for revised not as designed catheters does not overlap with Model 8731.

The survival estimates suggest that the survival of catheters revised not as designed (Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit) and 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 a Medtronic repair kit or brand new catheter. Medtronic recommends following the labeling for the Model 8596 and 8598 revision kits.

Choose a model Go

Model 8709: Survival from Catheter Events

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



View Larger Image

Catheter Characteristics	
Model Number	8709
FDA Approval Date	May 1998
Catheters Enrolled	2,769
Catheters Currently Active in Study	458
Device Events	253
Cumulative Months of Follow-up	78,978

Catheter Events	Total
Catheter dislodgment from intrathecal space	77
Catheter kink/occlusion	73
Catheter break/cut	62
Catheter disconnection at pump	11

Medical device complication[a]	9
Catheter related complication[b]	6
Catheter disconnection at distal connection	6
Catheter leakage	6
Unable to enter/withdraw from catheter access port	2
Catheter blockage	1
Total Catheter Events	**253**

[a] Includes 9 events reported as pump connector break/cut
[b] Includes 4 events reported as difficulty aspirating catheter, 1 catheter aneurysm, and 1 coiled catheter

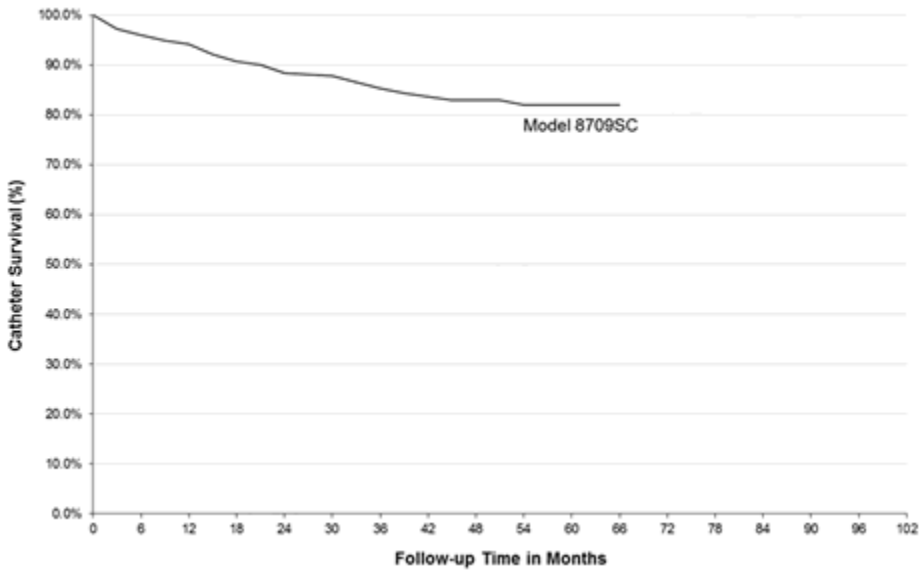
Time Interval	Survival	Effective Sample Size
1 yr	93.5%	1,087
2 yrs	91.0%	967
3 yrs	88.3%	905
4 yrs	86.2%	782
5 yrs	84.3%	659
6 yrs	80.6%	542
7 yrs	77.1%	381
8 yrs	74.5%	259
9 yrs	72.0%	179
10 yrs	69.5%	125
11 yrs	67.3%	79
at 138 mo	65.3%	33

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.



View Larger Image

Catheter Characteristics	
Model Number	8709SC
FDA Approval Date	Mar 2006
Catheters Enrolled	987
Catheters Currently Active in Study	487
Device Events	87

Cumulative Months of Follow-up	19,123

Catheter Events	Total
Catheter dislodgment from intrathecal space	27
Catheter kink/occlusion	21
Catheter break/cut	19
Catheter related complication[a]	9
Catheter leakage	4
Medical device complication[b]	2
Catheter disconnection at distal connection	2
Unable to enter/withdraw from catheter access port	1
Catheter disconnection at pump	1
Unable to withdraw fluid from reservoir	1
Total Catheter Events	**87**

[a] Includes 4 events reported as catheter malfunction, 1 coiled catheter, 1 catheter unable to aspirate, 1 catheter wrapped around pump, 1 sediment in infusion catheter, and 1 slight loop in catheter
[b] Includes 1 event reported as leak at pump and 1 sutureless connector failure

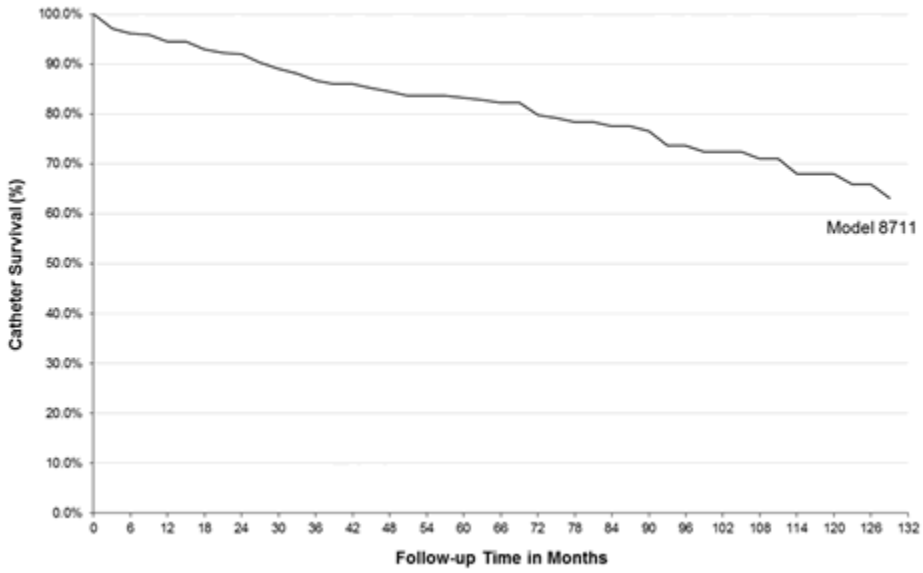
Time Interval	Survival	Effective Sample Size
1 yr	94.2%	603
2 yrs	88.4%	333
3 yrs	85.3%	200
4 yrs	83.0%	102
5 yrs	82.0%	49
at 66 mo	82.0%	20

Model 8709SC: Specifications

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

Model 8711: Survival from Catheter Events

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



View Larger Image

Catheter Characteristics	
Model Number	8711
FDA Approval Date	Oct 1999
Catheters Enrolled	622
Catheters Currently Active in Study	185

Device Events	75
Cumulative Months of Follow-up	22,228

Catheter Events	Total
Catheter kink/occlusion	27
Catheter break/cut	14
Catheter dislodgment from intrathecal space	14
Catheter related complication[a]	9
Unable to enter/withdraw from catheter access port	5
Catheter disconnection at pump	2
Medical device complication[b]	2
Catheter blockage	1
Catheter leakage	1
Total Catheter Events	**75**

[a] Includes 5 events reported as catheter malfunction and 4 difficulty aspirating catheter
[b] Includes 1 event reported as nonfunctioning catheter and 1 event reported as pump connector break/cut

Time Interval	Survival	Effective Sample Size
1 yr	94.5%	340
2 yrs	92.0%	293
3 yrs	86.7%	253
4 yrs	84.5%	227
5 yrs	83.3%	190
6 yrs	79.8%	135
7 yrs	77.6%	91
8 yrs	73.6%	68
9 yrs	71.1%	53

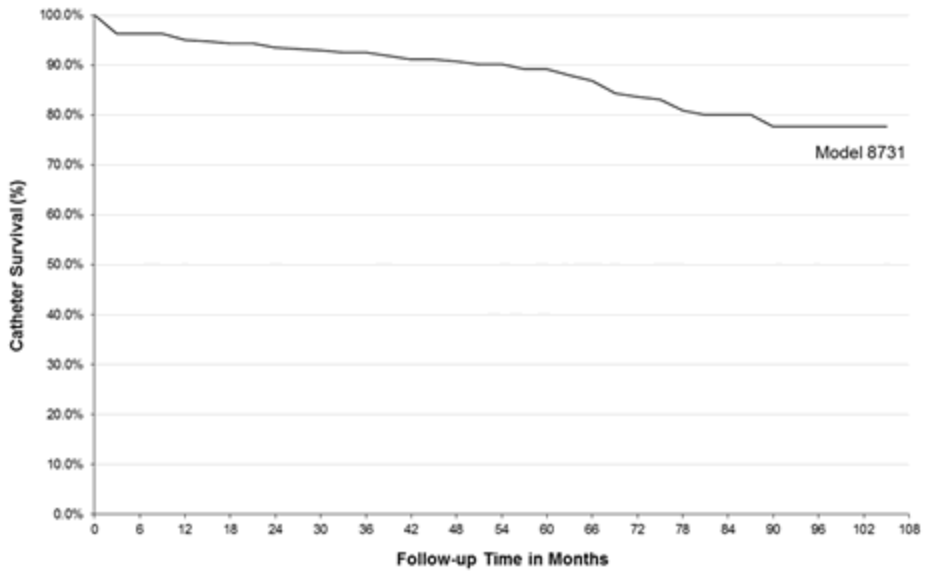
10 yrs	68.0%	35
at 129 mo	63.1%	24

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.



View Larger Image

Catheter Characteristics	
Model Number	8731
FDA Approval Date	Oct 2002

Catheters Enrolled	493
Catheters Currently Active in Study	92
Device Events	44
Cumulative Months of Follow-up	19,390

Catheter Events	Total
Catheter kink/occlusion	18
Catheter dislodgment from intrathecal space	18
Catheter related complication[a]	3
Catheter break/cut	2
Catheter disconnection at distal connection	2
Medical device complication[b]	1
Total Catheter Events	**44**

[a] Includes 1 event reported as patency issue with catheter, 1 coiled catheter, and 1 catheter malfunction
[b] Reported as pump connector break/cut

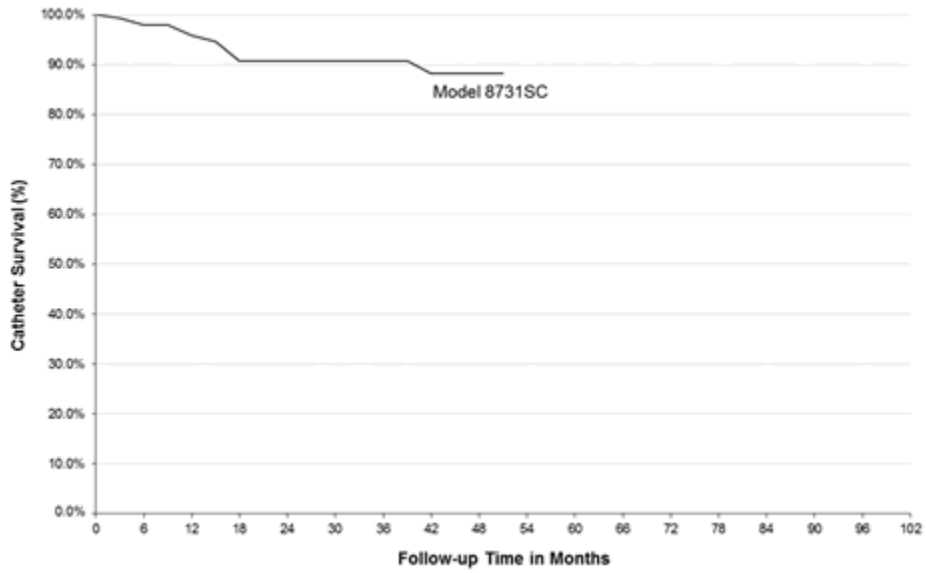
Time Interval	Survival	Effective Sample Size
1 yr	95.0%	293
2 yrs	93.5%	317
3 yrs	92.6%	275
4 yrs	90.7%	213
5 yrs	89.2%	157
6 yrs	83.7%	133
7 yrs	80.1%	88
8 yrs	77.7%	48
at 105 mo	77.7%	23

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	2.22µl/cm
Trimmable Segments	Spinal end

Model 8731SC: Survival from Catheter Events

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



View Larger Image

Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	168
Catheters Currently Active in Study	89

Device Events	10
Cumulative Months of Follow-up	3,493

Catheter Events	Total
Catheter kink/occlusion	4
Catheter dislodgment from intrathecal space	4
Catheter disconnection at distal connection	1
Unable to enter/withdraw from catheter access port	1
Total Catheter Events	**10**

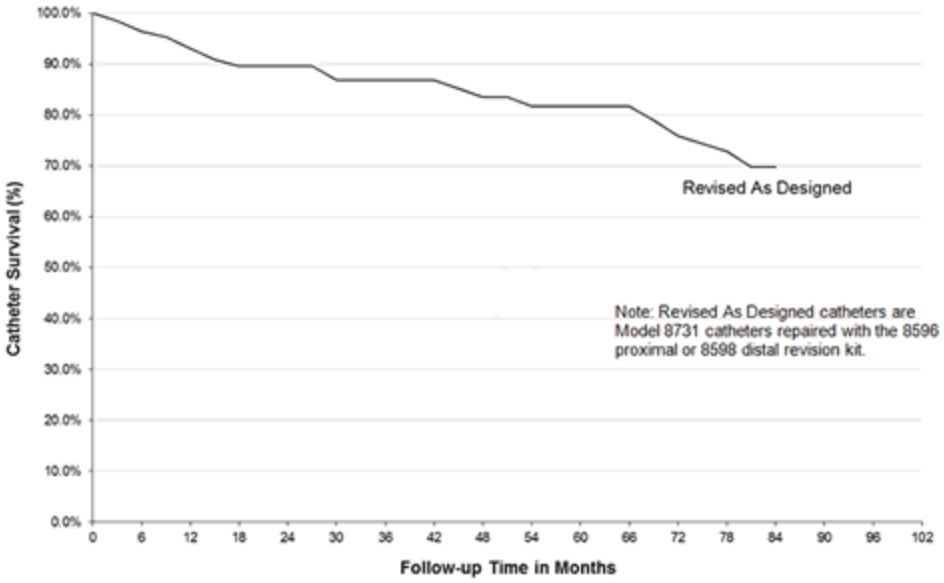
Time Interval	Survival	Effective Sample Size
1 yr	95.9%	96
2 yrs	90.7%	56
3 yrs	90.7%	45
4 yrs	88.2%	25
at 51 mo	88.2%	20

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

Revised As Designed: Survival from Catheter Events

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



View Larger Image

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	194
Catheters Currently Active in Study	89
Device Events	20
Cumulative Months of Follow-up	4,842

Catheter Events	Total
Catheter kink/occlusion	13
Catheter related complication[a]	3
Catheter dislodgment from intrathecal space	2
Catheter break/cut	1
Unable to enter/withdraw from catheter access port	1
Total Catheter Events	**20**

[a] 2 events reported as catheter malfunction and 1 reported as catheter inability to aspirate

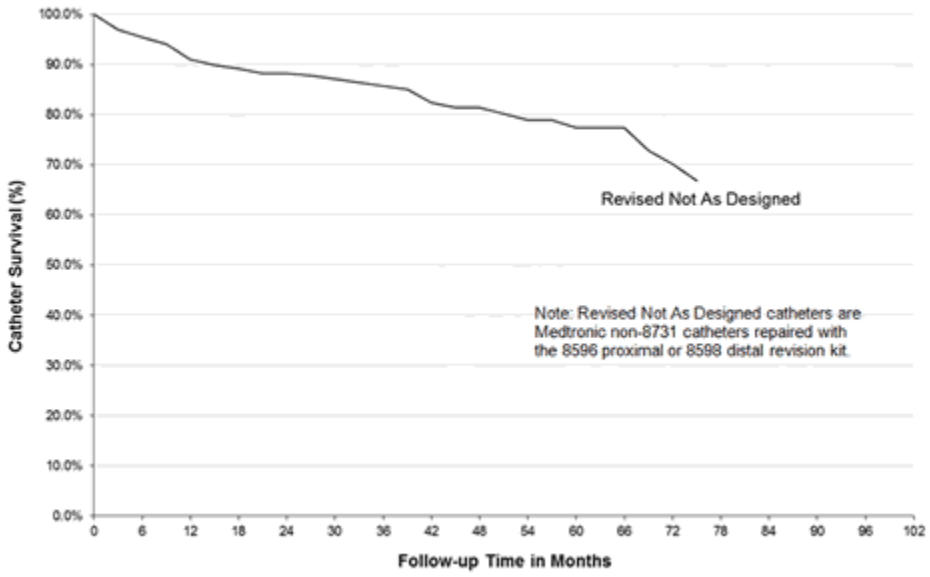
Time Interval	Survival	Effective Sample Size
1 yr	93.1%	85
2 yrs	89.7%	68
3 yrs	86.8%	56
4 yrs	83.6%	51
5 yrs	81.7%	37
6 yrs	75.9%	26
7 yrs	69.8%	20

Revised As Designed: Specifications

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

Revised Not As Designed: Survival from Catheter Events

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



View Larger Image

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	480
Catheters Currently Active in Study	270
Device Events	60
Cumulative Months of Follow-up	11,097

Catheter Events	Total
Catheter kink/occlusion	18
Catheter break/cut	13
Catheter dislodgment from intrathecal space	13
Unable to enter/withdraw from catheter access port	5
Catheter related complication[a]	3
Catheter disconnection at distal connection	2
Catheter leakage	1
Pump inversion[b]	1
Catheter disconnection at pump	1
CSF abnormal	1
Medical device complication	1
Device malfunction	1
Total Catheter Events	**60**

[a] Includes 2 events reported as catheter malfunction and 1 inability to aspirate catheter
[b] Reported as flipping pump caused catheter to coil and knot

Time Interval	Survival	Effective Sample Size
1 yr	91.0%	309
2 yrs	88.3%	189
3 yrs	85.8%	119

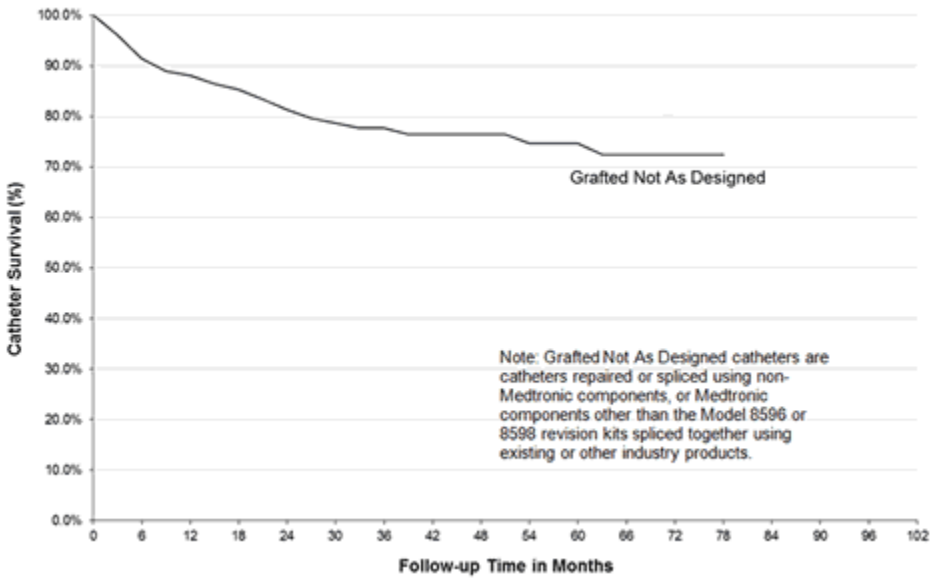
4 yrs	81.5%	71
5 yrs	77.4%	52
6 yrs	70.2%	27
at 75 mo	66.8%	20

Revised Not As Designed: Specifications

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

Grafted Not As Designed: Survival from Catheter Events

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



View Larger Image

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	360
Catheters Currently Active in Study	174

Device Events	54
Cumulative Months of Follow-up	7,801

Catheter Events	Total
Catheter dislodgment from intrathecal space	24
Catheter kink/occlusion	13
Catheter break/cut	5
Catheter related complication[a]	4
Catheter leakage	3
Unable to enter/withdraw from catheter access port	2
Catheter disconnection at pump	1
Medical device complication[b]	1
Catheter blockage	1
Total Catheter Events	**54**

[a] Includes 3 inability to aspirate catheter, 1 event reported as catheter malfunction
[b] Reported as pump connector break/cut

Time Interval	Survival	Effective Sample Size
1 yr	88.0%	196
2 yrs	81.3%	115
3 yrs	77.6%	68
4 yrs	76.4%	44
5 yrs	74.6%	36
6 yrs	72.4%	28
at 78 mo	72.8%	23

Grafted Not As Designed: Specifications

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 Survival Summary

Currently at 1 through 5 years of follow-up, the 95% confidence interval for grafted not as designed catheters does not overlap with Models 8709 and 8731 catheters. In addition, at 4 and 5 years of follow-up, the 95% confidence interval for revised not as designed catheters does not overlap with Model 8731.

The survival estimates suggest that the survival of catheters revised not as designed (Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit) and 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.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**
8709[b]	May 1998	2,769	458	253	78,978
8709SC	Mar 2006	987	487	87	19,123
8711	Oct 1999	622	185	75	22,228
8731	Oct 2002	493	92	44	19,390
8731SC	Mar 2006	168	89	10	3,493
Revised As Designed	Oct 2002	194	89	20	4,842
Revised Not As Designed	NA	480	270	60	11,097
Grafted Not As Designed	NA	360	174	54	7,801

[a] There were a total of 703 catheter-related events reported to the ISPR, but only 603 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=27) 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 2*					
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**
8709	**93.5%** (92.1%, 94.8%)	**91.0%** (89.3%, 92.6%)	**88.3%** (86.4%, 90.1%)	**86.2%** (84.1%, 88.2%)	**84.3%** (82.1%, 86.5%)

8709SC	**94.2%** (92.5%, 95.8%)	**88.4%** (85.8%, 91.1%)	**85.3%** (81.9%, 88.7%)	**83.0%** (79.0%, 87.0%)	**82.0%** (77.5%, 86.4%)
8711	**94.5%** (92.2%, 96.8%)	**92.0%** (89.2%, 94.8%)	**86.7%** (82.9%, 90.4%)	**84.5%** (80.4%, 88.5%)	**83.3%** (79.0%, 87.5%)
8731	**95.0%** (92.2%, 97.9%)	**93.5%** (90.4%, 96.6%)	**92.6%** (89.4%, 95.8%)	**90.7%** (87.1%, 94.3%)	**89.2%** (85.2%, 93.1%)
8731SC	**95.9%** (92.2%, 99.6%)	**90.7%** (84.6%, 96.8%)	**90.7%** (84.6%, 96.8%)	**88.2%** (80.5%, 95.9%)	-
Revised As Designed	**93.1%** (87.9%, 98.2%)	**89.7%** (83.4%, 95.9%)	**86.8%** (79.5%, 94.1%)	**83.6%** (75.2%, 91.9%)	**81.7%** (72.7%, 90.6%)
Revised Not As Designed	**91.0%** (88.0%, 94.0%)	**88.3%** (84.8%, 91.8%)	**85.8%** (81.5%, 90.0%)	**81.5%** (75.9%, 87.0%)	**77.4%** (70.4%, 84.4%)
Grafted Not As Designed	**88.0%** (84.1%, 92.0%)	**81.3%** (75.9%, 86.7%)	**77.6%** (71.4%, 83.9%)	**76.4%** (69.8%, 83.0%)	**74.6%** (67.2%, 82.0%)

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

Model Number	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs
8709	**80.6%** (78.1%, 83.2%)	**77.1%** (74.2%, 80.0%)	**74.5%** (71.3%, 77.7%)	**72.0%** (68.4%, 75.6%)	**69.5%** (65.3%, 73.6%)	**67.3%** (62.5%, 72.0%)
8709SC	-	-	-	-	-	-
8711	**79.8%** (74.9%, 84.7%)	**77.6%** (72.2%, 83.0%)	**73.6%** (67.2%, 80.0%)	**71.1%** (63.9%, 78.2%)	**68.0%** (59.9%, 76.0%)	-
8731	**83.7%** (78.6%, 88.8%)	**80.1%** (74.2%, 85.9%)	**77.7%** (71.1%, 84.2%)	-	-	-
8731SC	-	-	-	-	-	-
Revised As Designed	**75.9%** (64.5%, 87.3%)	**69.8%** (56.4%, 83.2%)	-	-	-	-

Revised Not As Designed	**70.2%** (60.1%, 80.4%)	-	-	-	-	-
Grafted Not As Designed	**72.4%** (64.1%, 80.8%)	-	-	-	-	-

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

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

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Spinal Cord Stimulation Systems

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

Study Participants

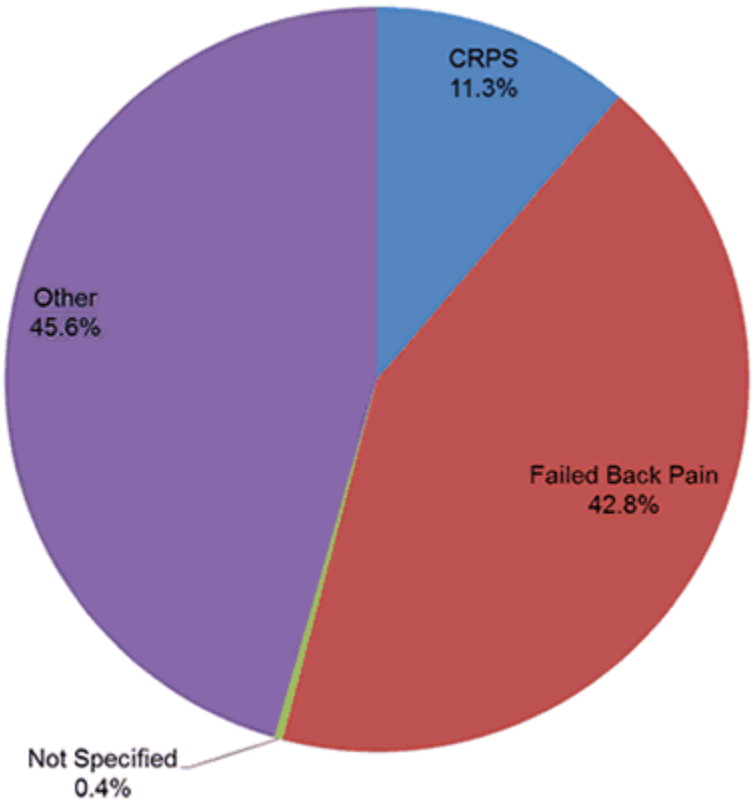
Centers

The following spinal cord stimulation tables and graphs were generated based on data collected between the date of initiation of the Implantable Systems Performance Registry (ISPR) for spinal cord stimulation systems in June 2004 and the report cut-off date of July 31, 2013. Forty-four centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Patients

Of the 2,472 total spinal cord stimulation patients enrolled in the ISPR, 45.6% were implanted for the treatment of other pain indications, 42.8% were implanted for the treatment of failed back pain, 11.3% were implanted for the treatment of complex regional pain syndrome (CRPS), and 0.4% were implanted for indications that were not specified in the database.

Primary SCS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Other	**1,126 (45.6%)**
Radicular pain syndrome	318 (12.9%)
Degenerative disc disease	79 (3.2%)
Cervical pain	12 (0.5%)
Diabetic neuropathy	5 (0.2%)
Post Herpetic Neuralgia	5 (0.2%)
Traumatic nerve injury	5 (0.2%)
Facial pain	3 (0.1%)

Epidural Fibrosis	2 (0.1%)
Post herniorrhaphy pain	1 (0.1%)
Other chronic pain	605 (24.5%)
Other	91 (3.7%)
Failed Back Pain	**1,058 (42.8%)**
Postlaminectomy pain	495 (20.0%)
Failed Back Syndrome (FBS)	351 (14.2%)
Combination back and leg pain	121 (4.9%)
Multiple Back Operations	64 (2.6%)
Arachnoiditis	21 (0.8%)
Unsuccessful Disc Surgery	6 (0.2%)
CRPS	**279 (11.3%)**
CRPS I	213 (8.6%)
CRPS II	66 (2.7%)
Not Specified	**9 (0.4%)**
Total Patients	**2,472**

[a] Refer to product labeling for approved indications.

Event Summary

There were 1,696 events reported between June 2004 and July 31, 2013 in patients with spinal cord stimulation systems. Thirty-five percent of these events (597/1,696) were categorized as product performance-related and are presented graphically within this report. The 597 product performance events occurred in 278 of the 2,472 total patients (11.2%) enrolled. In addition, there were 1,024 non-product performance events and 75 deaths, none of which were reported as a direct result of a device-related event or the stimulation therapy during this timeframe. 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=2,472)**
Lead migration/dislodgment	316	164	6.63%
High impedance	80	36	1.46%
Lead fracture	46	31	1.25%
Undesirable change in stimulation[c]	45	25	1.01%
Medical device complication[d]	38	21	0.85%
Low impedance	17	5	0.20%
Device malfunction[e]	14	7	0.28%
Recharging unable to recharge[f]	14	14	0.57%[g]
Extension fracture	13	8	0.32%
Device failure[h]	6	5	0.20%
Impedance NOS	3	3	0.12%
Paraesthesia	2	2	0.08%
Therapeutic productive ineffective	2	1	0.04%
Broken bond wire	1	1	0.04%
Total	**597**	**278**	**11.25%**

[a] MedDRA Preferred Term

[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] Undesirable change in stimulation reported by the physician as being caused by the neurostimulator (n=2) or lead (n=43)

[d] Includes 6 events reported as electrodes out of range, 4 leads no longer provided stimulation, 3 error messages on patient programmer, 2 broken recharging units, 2 events reported as damaged leads, 2 damaged electrodes, 2 lead electrodes not functional, 2 lead malfunction secondary to open circuit, 2 events reported as unable to pass stylet into lead, 2 lead failures, 2 broken recharge belts, 1 lead with pinched outer insulation, 1 separation of the material on the end of the neuroelectrode, 1 broken recharger strap, 1

broken antenna cord, 1 broken patient programmer, 1 neurostimulator losing charge, 1 faulty antenna, 1 lead damaged contacts, and 1 unknown problem with an extension

[e] Includes 8 events reported as electrodes out of range too high, 2 event for impedance not measureable, 2 neurostimulator malfunctions, 1 increased lead impedance, and 1 antenna malfunction

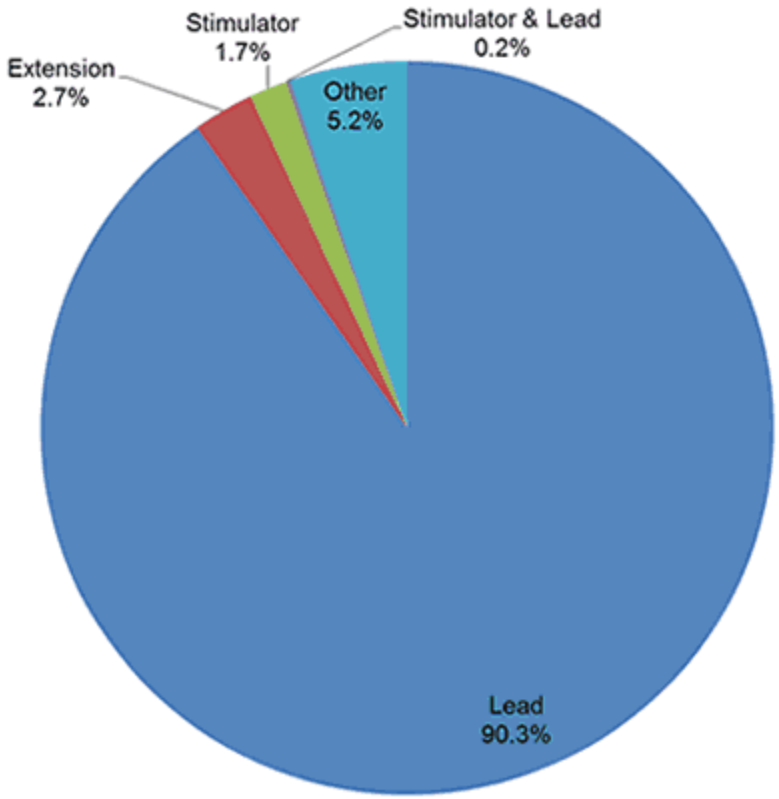
[f] Patient was unable to recharge due to device related issue (includes issues with external devices)

[g] There were a total of 1480 patients that used rechargeable SCS neurostimulators in the ISPR. A total of 0.9% (14/1480) of patients with a rechargeable SCS neurostimulator experienced a recharging unable to recharge event

[h] Includes 1 broken jack and antenna, 1 failure of lead electrodes, 1 extension failure, 1 defective patient programmer, 1 frayed wire to recharger, and 1 broken antenna

A total of 539 (90.3%) of the 597 product performance events were related to the lead, 21 (3.5%) were related to an external device, 16 (2.7%) were related to the extension, 10 (1.7%) were related to the stimulator, 2 (0.3%) were related to programming/stimulation, 6 (1.0%) were related to recharging process, 1 (0.2%) was related to both the stimulator and the lead, 1 (0.2%) was related to incisional site/device tract, and 1 (0.2%) was related to other etiology. Relatedness is determined by the physician.

Product Performance Events by Etiology



Neurostimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)

Events[b]	Number of Non-Product Performance Events
Neurostimulator battery depletion	310

Neurostimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)	
Implant site pain	108
Undesirable change in stimulation[c]	70
Therapeutic product ineffective	67
Recharging unable to recharge[d]	62
Therapy non-responder	60
Implant site infection	58
Change in sensation of stimulation[c]	40
Pain	29
Neurostimulator migration	27
Paraesthesia	20
Implant site erosion	14
Implant site erythema	14
Medical device complication[e]	13
Implant site effusion	9
Incision site complication	8
Infection	8
Wound dehiscence	7
Pain in extremity	6
Back pain	5
Other[f]	89
Total	**1,024**

[a] Adverse events associated with product performance events are not included in this table
[b] MedDRA Preferred Term
[c] Event reported by the physician with an etiology that was not device related
[d] Patient was unable to recharge due to an issue not related to the device

[e] Includes 4 events reported as inability to activate neurostimulation not due to neurostimulator, 1 'POR' alarm noted on patient's programmer that resolved after POR, 1 prominent protrusion of the neuroelectrodes and bifurcated connectors in the left flank, 1 lead tip protruding against the skin, 1 patient unable to work neurostimulator, 1 battery depletes too quickly not due to a device issue, 1 inability to interrogate the pulse generator due to patient usability issues, 1 punctured IPG wall during surgery, 1 spinal cord stimulator not working due to patient difficulties turning device on and off, 1 protruding generator
[f] Composed of 58 event codes that include fewer than 5 patients each and one event that had not been MedDRA coded at the time of the report cut-off

There were 75 deaths reported in the ISPR 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, 50.7% of patient deaths occurred in patients receiving therapy for pain indications in the unspecified "other" category, 42.7% for failed back, and 6.7% for CRPS.

Death by Primary Indication	
Primary Indication	**N (%)**
CRPS	5 (6.67%)
Failed Back	32 (42.67%)
Other	38 (50.67%)
Total	**75 (100%)**

Spinal Cord Stimulators

From June 2004 to the report cut-off date of July 31, 2013, 2,841 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=2,472) versus spinal cord stimulators is due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted.

Twenty-one percent (21.0%) of the spinal cord stimulators were PrimeAdvanced, 19.6% were RestoreUltra, 16.2% were Synergy, 15.7% were Restore, 12.1% were RestoreAdvanced, 7.7% were RestoreSensor, 3.6% were Itrel 3, and a smaller number were RestorePrime (2.0%), Synergy Versitrel (1.3%), SynergyPlus+ (0.8%), and there was 1 other unspecified model. The aggregate prospective follow-up time for all spinal cord stimulators was 56,536 months (4,711 years).

Spinal Cord Stimulator Events

There were 11 product performance-related events with an underlying reported etiology related to spinal cord stimulator function. Of these, 9 were the first event attributable to an enrolled stimulator. For spinal cord stimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 179/720 (25%). The proportion was based upon the number of ISPR 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 11 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 10 spinal cord stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device related by the physician as medical device complication (n=3), device malfunction (n=2), undesirable change in stimulation (n=2), high impedance (n=1), paraesthesia (n=1), or recharging unable to recharge (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. A total of 9 stimulators had follow-up time cut-off due to product performance-related events. There were 1,819 spinal cord stimulators censored in the survival analysis for the following reasons: patient

expired, stimulator explanted, site termination, patient discontinued, patient lost to follow-up, other stimulator modification, therapy suspended, or non-product performance stimulator-related event without an associated intervention. The remaining 1,013 spinal cord stimulators, which were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

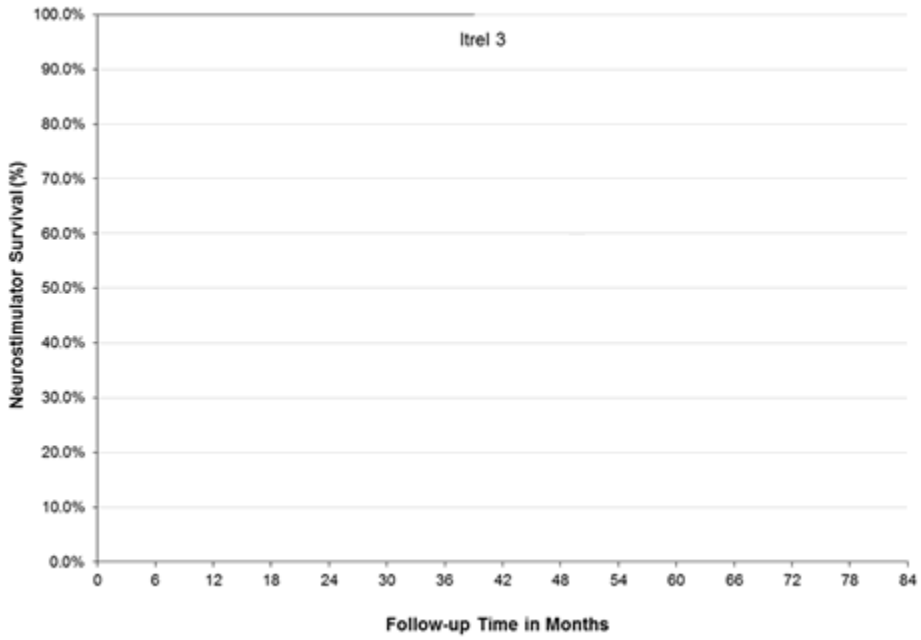
Spinal Cord Stimulator Survival

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. Survival curves are only shown if more than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. Currently, the 95% confidence intervals for all neurostimulator models overlap, indicating that survival from neurostimulator-related events is not significantly different between the neurostimulator models across various applicable follow-up time points.

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.



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	102

Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	2,039

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	59
2 yrs	100.0%	44
3 yrs	100.0%	26
at 39 mo	100.0%	22

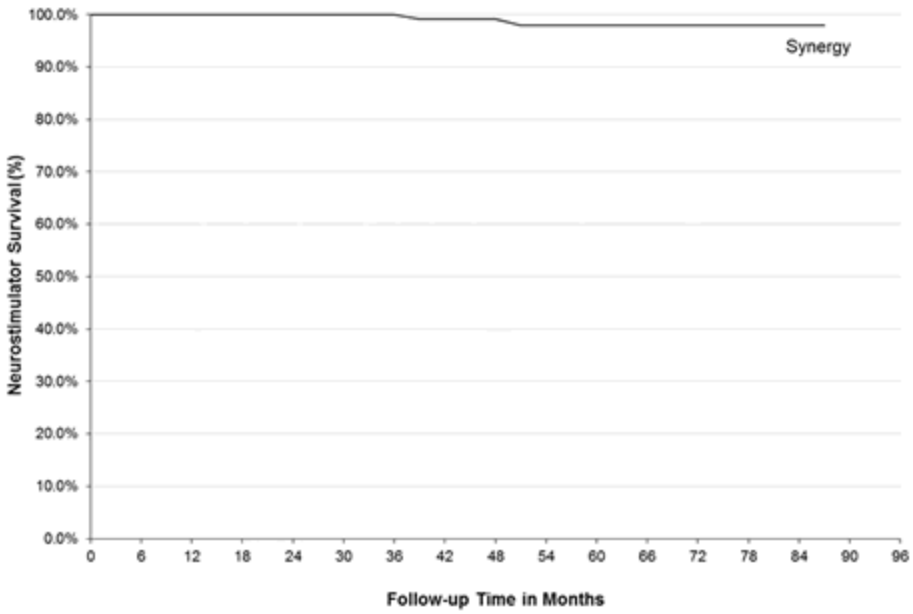
Model 7425 Itrel 3: Specifications

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.



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	459
Neurostimulators Currently Active in Study	21
Device Events	2
Cumulative Months of Follow-up	10,878

Neurostimulator Event	Total
Undesirable change in stimulation	1
Broken bond wire	1
Total Neurostimulator Events	**2**

Time Interval	Survival	Effective Sample Size

1 yr	100.0%	270
2 yrs	100.0%	215
3 yrs	100.0%	143
4 yrs	99.2%	88
5 yrs	97.9%	47
6 yrs	97.9%	31
7 yrs	97.9%	21
at 87 mo	97.9%	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	38
Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	737

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	21
at 15 mo	100.0%	20

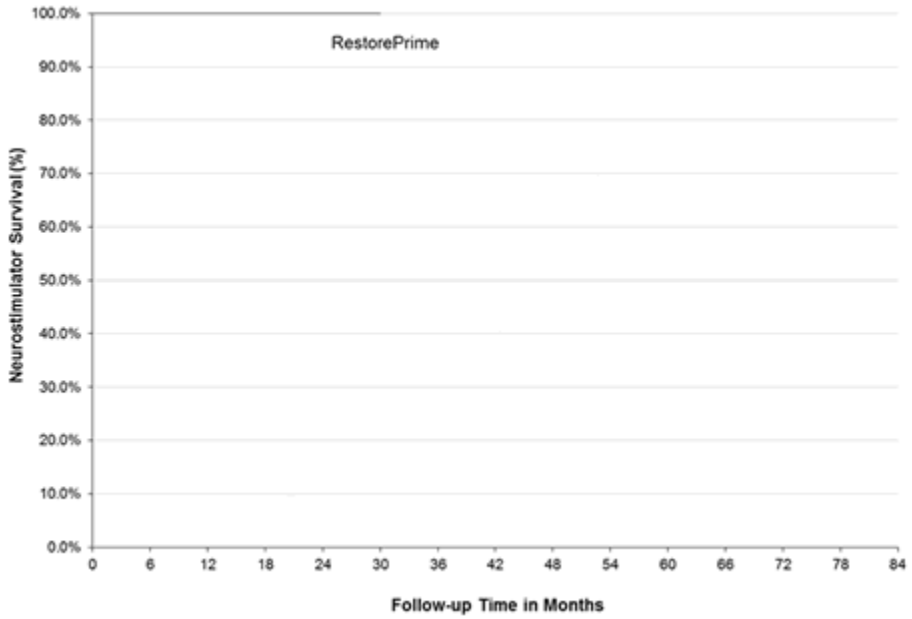
Model 7427V Synergy Versitrel: Specifications

Height	2.4 in (61 mm)
Width	2.4 in (61 mm)
Thinness	0.6 in (15 mm)
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.



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	57
Neurostimulators Currently Active in Study	8
Device Events	0
Cumulative Months of Follow-up	1,353

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size

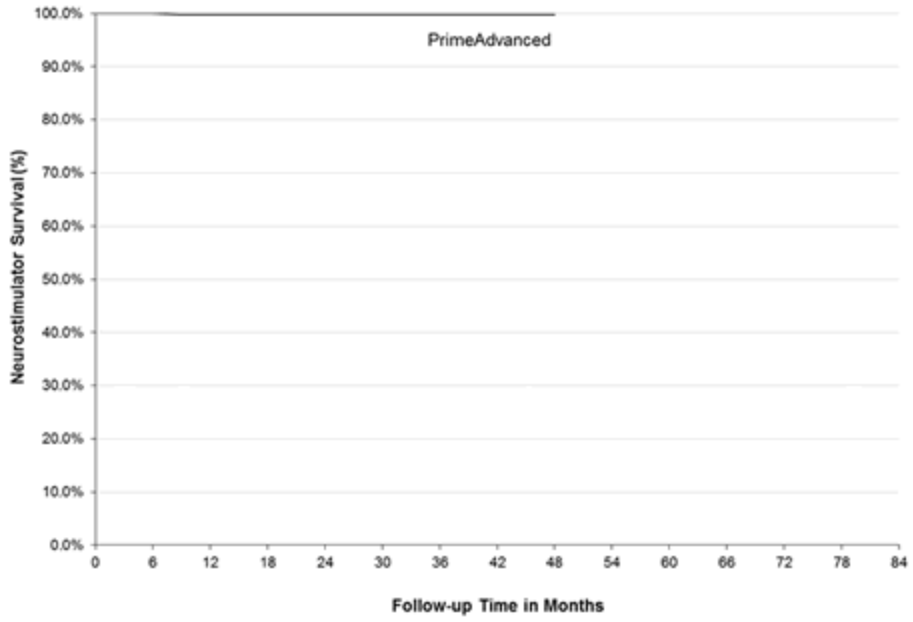
1 yr	100.0%	43
2 yrs	100.0%	25
at 30 mo	100.0%	21

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.



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	596
Neurostimulators Currently Active in Study	195
Device Events	1
Cumulative Months of Follow-up	8,070

Neurostimulator Event	Total
Undesirable change in stimulation	1
Total Neurostimulator Events	**1**

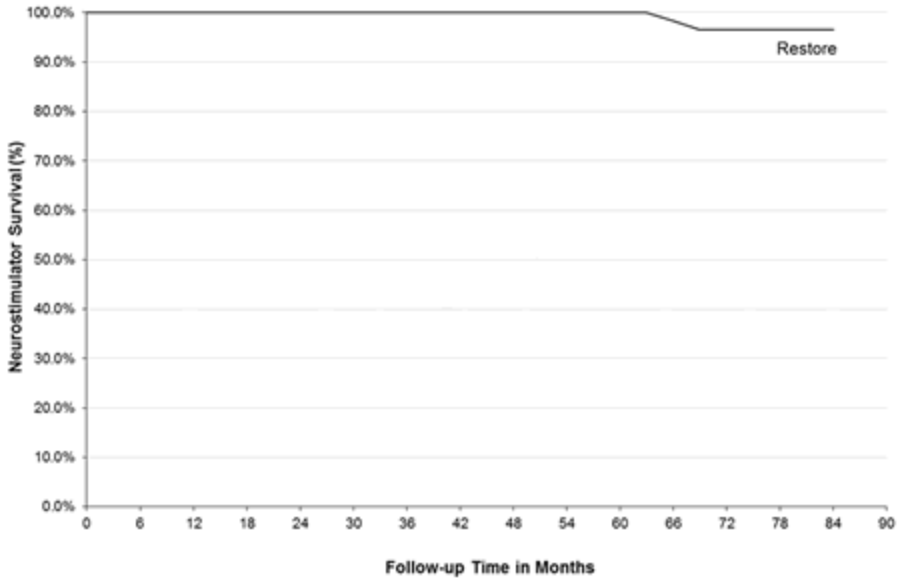
Time Interval	Survival	Effective Sample Size
1 yr	99.7%	293
2 yrs	99.7%	130
3 yrs	99.7%	47
4 yrs	99.7%	20

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.



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	447
Neurostimulators Currently Active in Study	61
Device Events	2
Cumulative Months of Follow-up	12,798

Neurostimulator Event	Total
Paraesthesia	1
Recharging unable to recharge	1
Total Neurostimulator Events	**2**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	318
2 yrs	100.0%	231
3 yrs	100.0%	147
4 yrs	100.0%	90

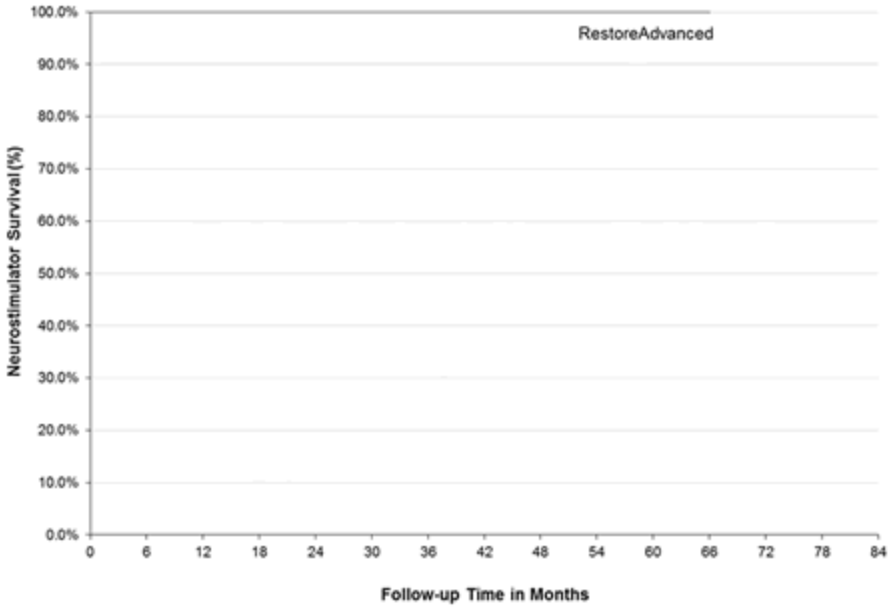
5 yrs	100.0%	69
6 yrs	96.5%	46
7 yrs	96.5%	23

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 37713 RestoreAdvanced: Survival from Spinal Cord Stimulator Events

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



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	343
Neurostimulators Currently Active in Study	142
Device Events	0
Cumulative Months of Follow-up	7,017

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

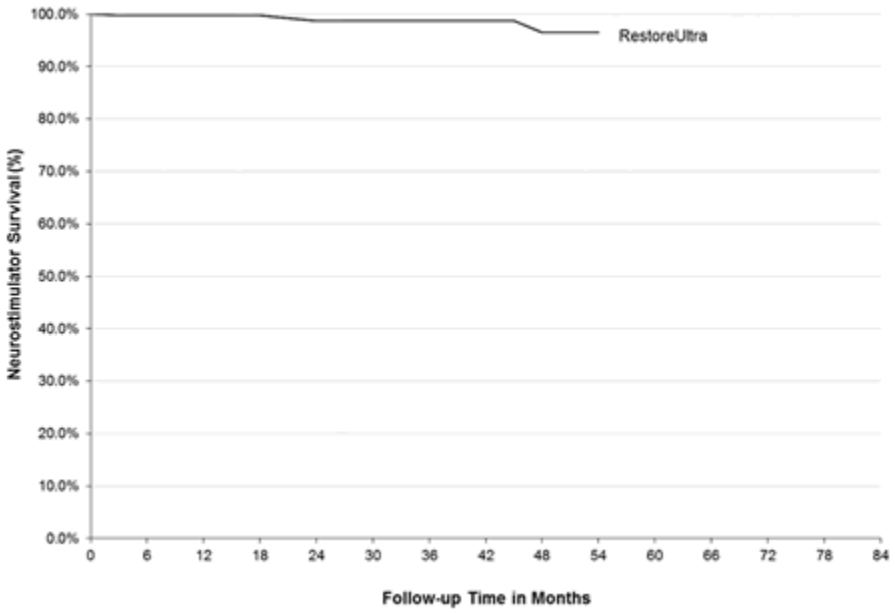
Time Interval	Survival	Effective Sample Size
1 yr	100.0%	196
2 yrs	100.0%	121
3 yrs	100.0%	76
4 yrs	100.0%	44
5 yrs	100.0%	32
at 66 mo	100.0%	22

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 37712 RestoreUltra: Survival from Spinal Cord Stimulator Events

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



View Larger Image

Spinal Cord Stimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	556
Neurostimulators Currently Active in Study	179
Device Events	4
Cumulative Months of Follow-up	9,958

Neurostimulator Event	Total
Device malfunction[a]	2
High impedance	1
Medical device complication[b]	1
Total Neurostimulator Events	**4**

[a] One event reported as malfunction of the spinal cord stimulation system and 1 as problems with reprogramming
[b] Error message on patient programmer

Time Interval Survival Effective Sample Size

1 yr	99.8%	324
2 yrs	98.7%	173
3 yrs	98.7%	99
4 yrs	96.5%	45
at 54 mo	96.5%	24

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 37714 RestoreSensor: Survival from Spinal Cord Stimulator Events

Spinal Cord Stimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011

Neurostimulators Enrolled	218
Neurostimulators Currently Active in Study	201
Device Events	0
Cumulative Months of Follow-up	953

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	90
1 yr	100.0%	37

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

[Spinal Cord Stimulator Survival Summary]

Currently, survival from neurostimulator-related events is not statistically significantly different between the neurostimulator models across all applicable follow-up time points.

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	102	1	0	2,039
Synergy	Synergy	Nov 1999	459	21	2	10,878
Synergy Versitrel	Synergy	Dec 2001	38	1	0	737
Restore Prime	Restore	Mar 2006	57	8	0	1,353
Prime Advanced	Prime Advanced	Jul 2006	596	195	1	8,070
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	447	61	2	12,798
Restore Advanced	Restore	Jul 2006	343	142	0	7,017
Restore Ultra	Restore	Jan 2008	556	179	4	9,958
Restore Sensor	Restore	Nov 2011	218	201	0	953

[a] There were 11 neurostimulator-related events reported to the ISPR, but only 9 events included in this summary table. The remaining neurostimulator-related events were subsequent events that did not affect the device survival estimates.

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	**100.0%** NA	**-**

Synergy	**100.0%** NA	**100.0%** NA	**100.0%** NA	**99.2%** (97.7%, 100.0%)
Synergy Versitrel	**100.0%** NA	**-**	**-**	**-**
RestorePrime	**100.0%** NA	**100.0%** NA	**-**	**-**
PrimeAdvanced	**99.7%** (99.1%, 100.0%)	**99.7%** (99.1%, 100.0%)	**99.7%** (99.1%, 100.0%)	**99.7%** (99.1%, 100.0%)
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA
RestoreAdvanced	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA
RestoreUltra	**99.8%** (99.4%, 100.0%)	**98.7%** (97.2%, 100.0%)	**98.7%** (97.2%, 100.0%)	**96.5%** (91.9%, 100.0%)
RestoreSensor	**100.0%** NA	**-**	**-**	**-**

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

Model Name	5 yrs	6 yrs	7 yrs
Primary Cell Neurostimulators			
Itrel 3	**-**	**-**	**-**
Synergy	**97.9%** (95.0%, 100.0%)	**97.9%** (95.0%, 100.0%)	**97.9%** (95.0%, 100.0%)
Synergy Versitrel	**-**	**-**	**-**
RestorePrime	**-**	**-**	**-**
PrimeAdvanced	**-**	**-**	**-**
Rechargeable Neurostimulators			
Restore	**100.0%** NA	**96.5%** (91.5%, 100.0%)	**96.5%** (91.5%, 100.0%)
RestoreAdvanced	**100.0%** NA	**-**	**-**

RestoreUltra	-	-	-
RestoreSensor	-	-	-

Leads

From June 2004 to the report cut-off date of July 31, 2013, there were 4,963 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=2,841) were due to the fact that some patients were subsequently re-implanted with a new lead or were implanted with more than 1 lead.

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). Nearly ninety percent (89.7%) of leads in the ISPR were percutaneous leads (4,452/4,963) including 57.4% (2,849/4,963) in the Pisces-Octad lead family, 27.4% (1,361/4,963) in the Pisces-Quad lead family, and 4.9% (242/4,963) in the Pisces-Quad LZ lead family. Nine percent (9.2%) of leads (458/4,963) were surgical leads. A small number of leads (53/4,963) were designated as Other (1.1%). The aggregate prospective follow-up time for all leads was 108,193 months (9,016 years).

Lead Events

There were 540 product performance-related events with an underlying reported etiology related to the lead. Of these events, the majority were lead migration/dislodgements (n=314), high impedance (n=78), lead fracture (n=46), undesirable change in stimulation (n=43), medical device complication (n=25), low impedance (n=17), device malfunction (n=11), impedance NOS (n=3), therapeutic product ineffective (n=2), or device failure (n=1). Of the 540 events, 473 were the first event attributable to an enrolled lead. There were 445 events in 4,452 (10.0%) percutaneous leads, 25 events in 458 (5.5%) surgical leads, and 3 events occurred in leads with unknown model numbers.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event, 2) the occurrence of a 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. A total of 473 leads had follow-up time cut-off due to product performance-related events. There were 2,469 leads censored in the survival analysis for the following reasons: patient expired, lead explanted, site termination, patient discontinued, patient lost to follow-up, other lead modification, therapy suspended, or non-product performance lead-related event without an associated intervention. The remaining 2,021 leads, which 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

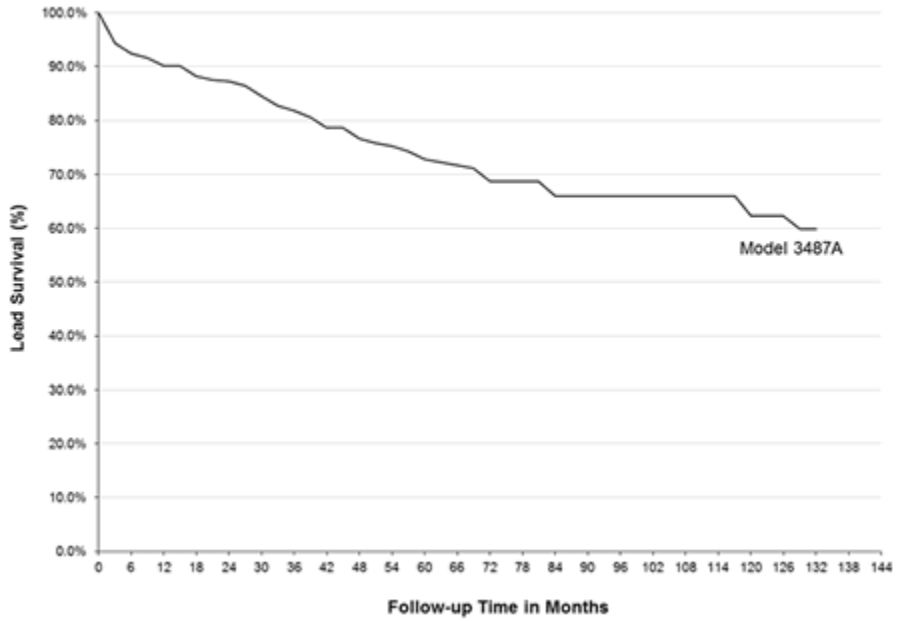
The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. For surgical leads, at 3 years of follow-up the 95% confidence interval for lead Model 3986A does not overlap with Model 39565 indicating that Model 39565 is currently performing better at this time point.

For percutaneous leads, the 95% confidence interval for Pisces-Quad LZ Model 3891 leads does not overlap with several of the other percutaneous lead models at 1 and 2 years of follow-up. 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. In addition, Model 3776 has consistently high device survival probability at 1 through 3 years when compared to several other percutaneous lead models.

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.



View Larger Image

Lead Characteristics	
Model Number	3487A
FDA Approval Date	May 1988
Leads Enrolled	839
Leads Currently Active in Study	358
Device Events	122
Cumulative Months of Follow-up	23,242

Lead Event	Total
High impedance	37
Lead migration/dislodgment	31
Undesirable change in stimulation	17
Low impedance	12
Lead fracture	10

Device malfunction[a]	8
Medical device complication[b]	5
Impedance NOS	2
Total Lead Events	**122**

[a] Reported as electrodes out of range
[b] 3 events were reported as electrodes out of range, 1 event as lead with pinched outer insulation, 1 as separation of the material on the end of the neuroelectrode

Time Interval	Survival	Effective Sample Size
1 yr	90.1%	430
2 yrs	87.2%	342
3 yrs	81.8%	271
4 yrs	76.6%	197
5 yrs	72.8%	146
6 yrs	68.7%	114
7 yrs	66.0%	79
8 yrs	66.0%	57
9 yrs	66.0%	42
10 yrs	62.3%	35
11 yrs	59.8%	22

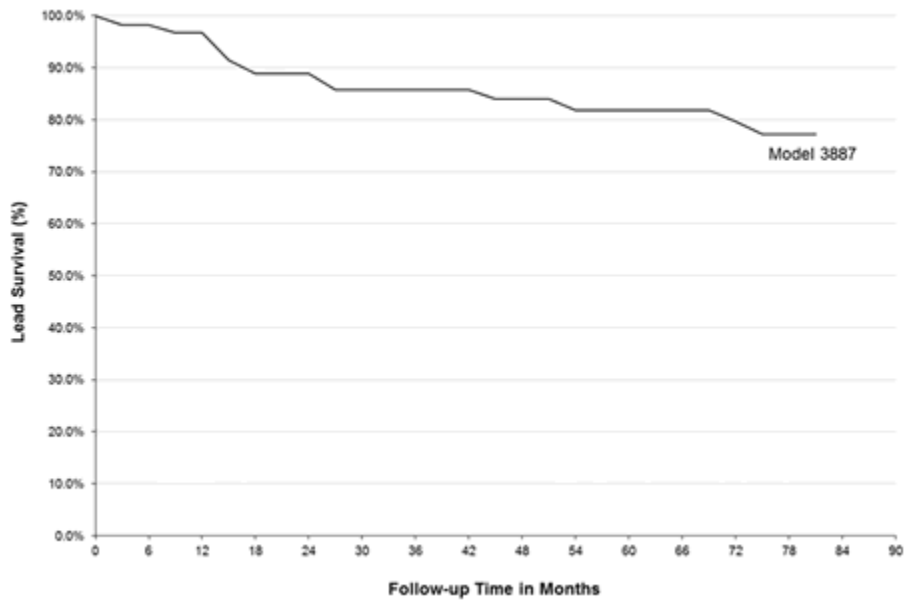
Model 3487A Pisces-Quad: Specifications

Device Name Lead Type	Pisces Standard 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.



View Larger Image

Lead Characteristics	
Model Number	3887
FDA Approval Date	Jan 1997
Leads Enrolled	151
Leads Currently Active in Study	28
Device Events	14

Cumulative Months of Follow-up	4,690

Lead Event	Total
Lead fracture	7
Lead migration/dislodgment	3
Undesirable change in stimulation	2
High impedance	1
Medical device complication[a]	1
Total Lead Events	**14**

[a] Reported as lead damaged contacts

Time Interval	Survival	Effective Sample Size
1 yr	96.8%	72
2 yrs	88.9%	58
3 yrs	85.8%	58
4 yrs	84.0%	43
5 yrs	81.8%	39
6 yrs	79.6%	37
at 81 mo	77.2%	31

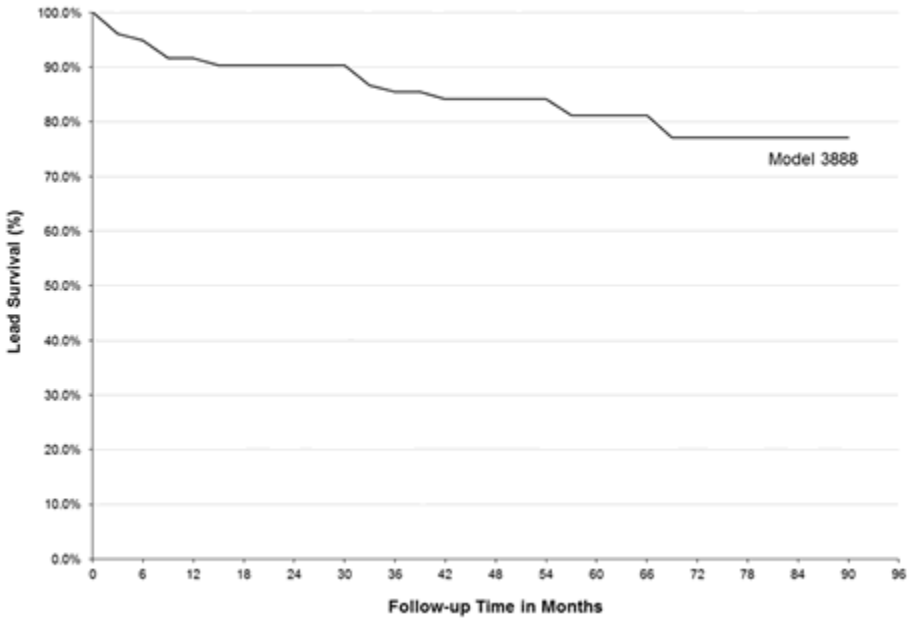
Model 3887 Pisces-Quad: Specifications

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.



View Larger Image

Lead Characteristics	
Model Number	3888
FDA Approval Date	Nov 1992
Leads Enrolled	354
Leads Currently Active in Study	74
Device Events	28

Cumulative Months of Follow-up	7,570

Lead Event	Total
Lead migration/dislodgment	25
Undesirable change in stimulation	2
Lead fracture	1
Total Lead Events	**28**

Time Interval	Survival	Effective Sample Size
1 yr	91.7%	153
2 yrs	90.3%	83
3 yrs	85.5%	72
4 yrs	84.2%	63
5 yrs	81.2%	52
6 yrs	77.1%	36
7 yrs	77.1%	24
at 90 mo	77.1%	24

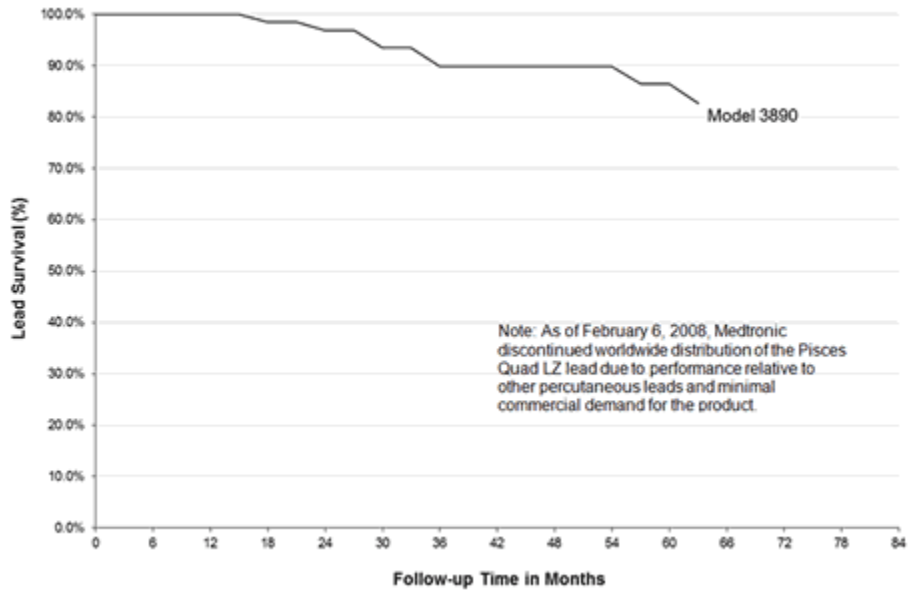
Model 3888 Pisces-Quad: Specifications

Device Name Lead Type	Pisces Plus 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.



View Larger Image

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	128
Leads Currently Active in Study	13
Device Events	10
Cumulative Months of Follow-up	3,123

Lead Event	Total
Lead migration/dislodgment	4

Device malfunction	2
High impedance	2
Lead fracture	2
Total Lead Events	**10**

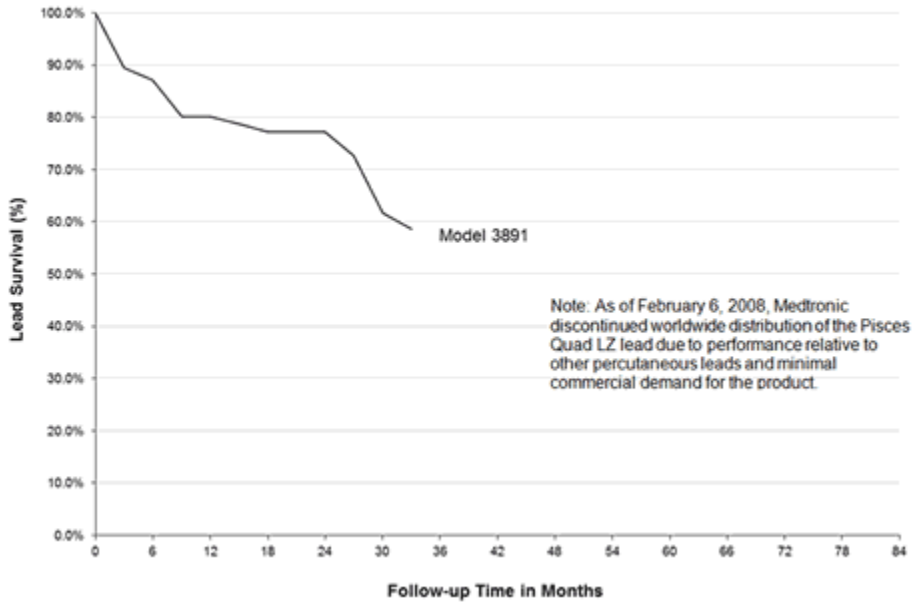
Time Interval	Survival	Effective Sample Size
1 yr	100.0%	53
2 yrs	96.9%	65
3 yrs	89.8%	51
4 yrs	89.8%	33
5 yrs	86.5%	25
at 63 mo	82.6%	22

Model 3890 Pisces-Quad LZ: Specifications

Device name Lead Type	Pisces Z Quad 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.



View Larger Image

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	114
Leads Currently Active in Study	12
Device Events	28
Cumulative Months of Follow-up	2,148

Lead Event	Total
Lead migration/dislodgment	16
Lead fracture	6
Undesirable change in stimulation	4
Medical device complication[a]	2
Total Lead Events	**28**

[a] Two events reported as damaged electrodes

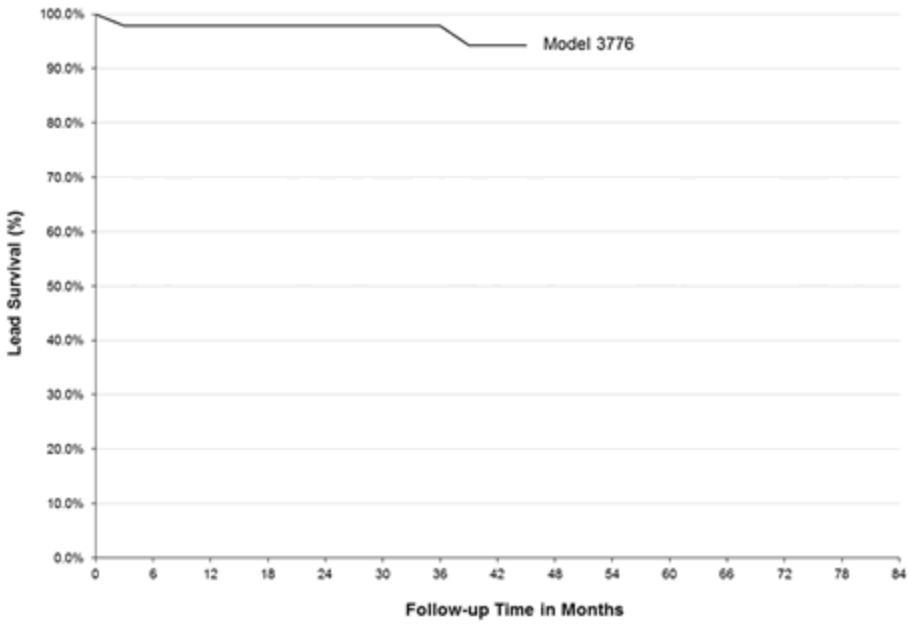
Time Interval	Survival	Effective Sample Size
1 yr	80.1%	66
2 yrs	77.2%	39
at 33 mo	58.6%	20

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.



View Larger Image

Lead Characteristics	
Model Number	3776
FDA Approval Date	Nov 2005
Leads Enrolled	159
Leads Currently Active in Study	62
Device Events	4
Cumulative Months of Follow-up	2,709

Lead Event	Total
Lead migration/dislodgement	2
Lead fracture	1
Undesirable change in stimulation	1
Total Lead Events	**4**

Time Interval	Survival	Effective Sample Size
1 yr	97.8%	70
2 yrs	97.8%	40

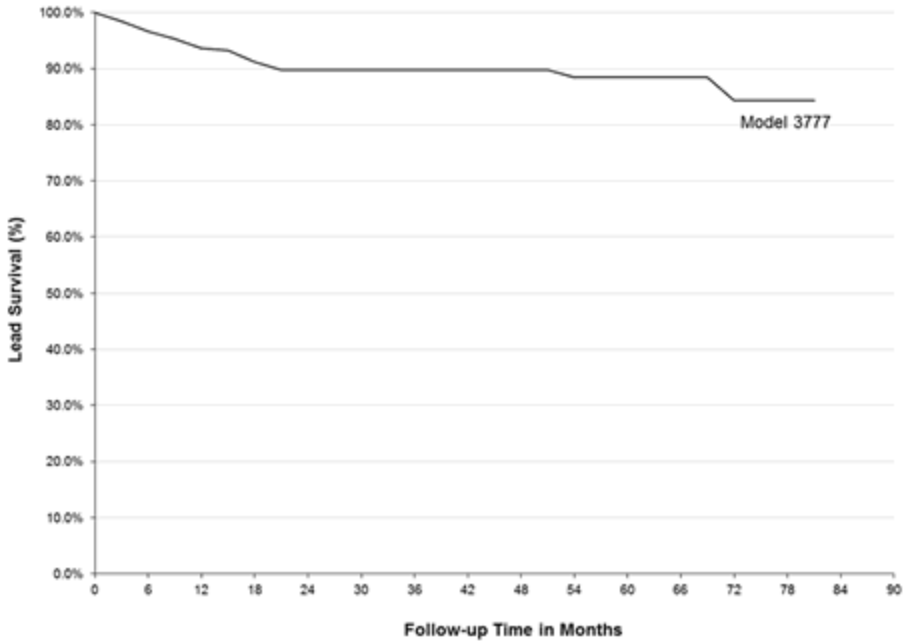
3 yrs	97.8%	31
at 45 mo	94.2%	20

Model 3776 Pisces-Octad: Specifications

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

Model 3777 Pisces-Octad: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	663
Leads Currently Active in Study	123
Device Events	46
Cumulative Months of Follow-up	13,722

Lead Event	Total
Lead migration/dislodgment	33
Undesirable change in stimulation	7
High impedance	3
Medical device complication[a]	2
Lead fracture	1
Total Lead Events	**46**

[a] Two events reported as damaged leads

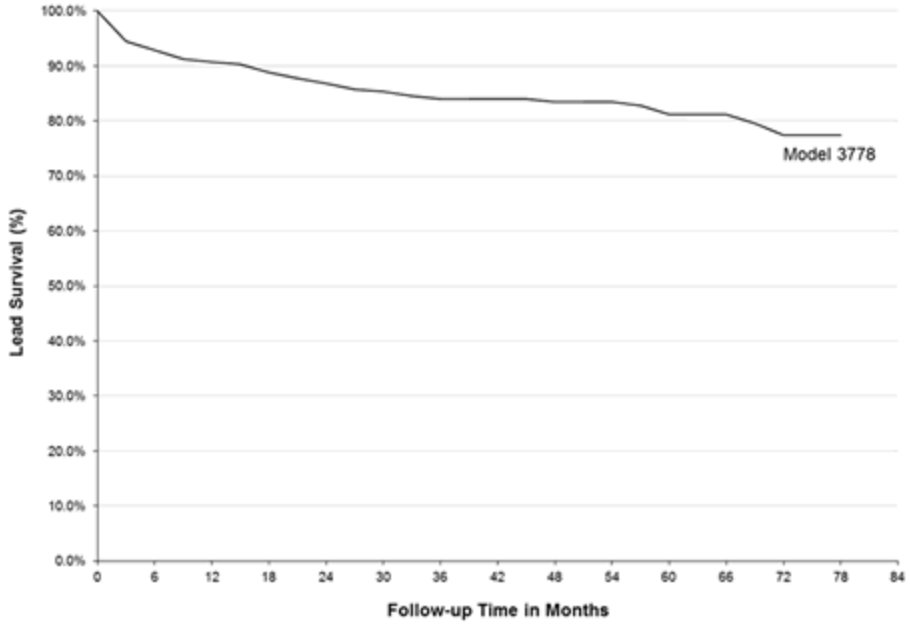
Time Interval	Survival	Effective Sample Size
1 yr	93.6%	399
2 yrs	89.8%	232
3 yrs	89.8%	131
4 yrs	89.8%	77
5 yrs	88.4%	55
6 yrs	84.3%	43
at 81 mo	84.3%	23

Model 3777 Pisces-Octad: Specifications

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

Model 3778 Pisces-Octad: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3778
FDA Approval Date	Apr 2005
Leads Enrolled	2,027
Leads Currently Active in Study	901
Device Events	192
Cumulative Months of Follow-up	32,871

Lead Event	Total
Lead migration/dislodgment	158
High impedance	13
Lead fracture	9
Medical device complication[a]	6
Undesirable change in stimulation	4
Device malfunction[b]	1
Low impedance	1

Total Lead Events	**192**

[a] Two events were reported as lead electrodes not functional, 2 as lead malfunction secondary to open circuit, and 2 as open circuit on lead.
[b] Reported as increased lead impedance

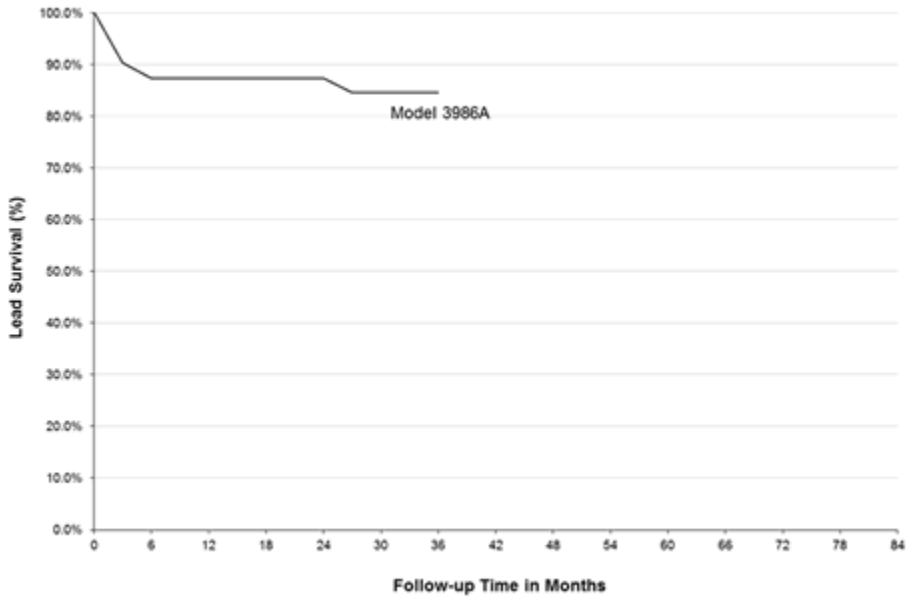
Time Interval	Survival	Effective Sample Size
1 yr	90.7%	994
2 yrs	86.8%	528
3 yrs	84.0%	329
4 yrs	83.5%	182
5 yrs	81.2%	100
6 yrs	77.4%	37
at 78 mo	77.4%	21

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.



View Larger Image

Lead Characteristics	
Model Number	3986A
FDA Approval Date	Apr 1995
Leads Enrolled	91
Leads Currently Active in Study	39
Device Events	10
Cumulative Months of Follow-up	2,156

Lead Event	Total
High impedance	5
Low impedance	2
Undesirable change in stimulation	2
Lead migration/dislodgment	1
Total Lead Events	**10**

Time Interval Survival Effective Sample Size

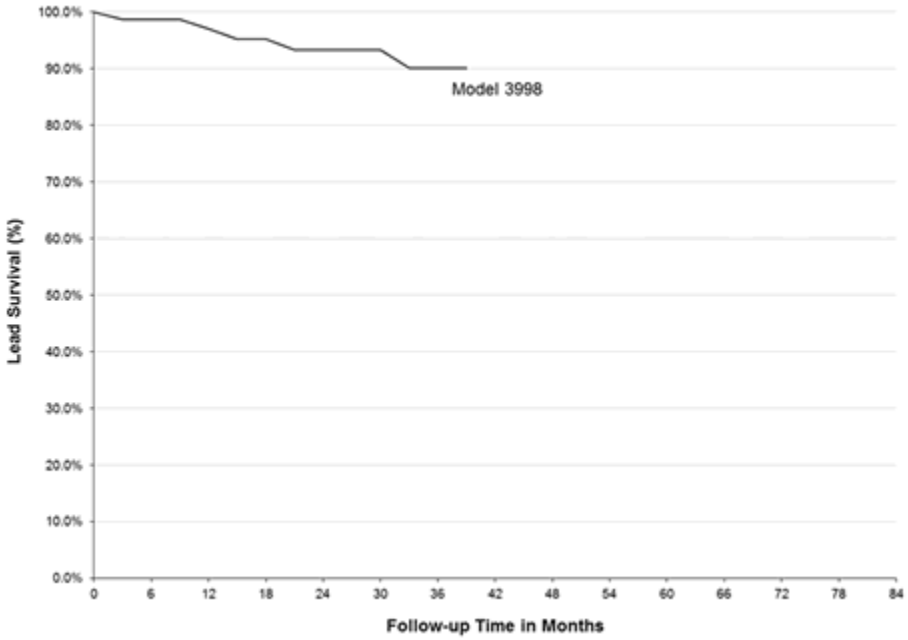
1 yr	87.3%	49
2 yrs	87.3%	35
3 yrs	84.5%	20

Model 3986A Resume TL: Specifications

Device Name Lead Type	Resume TL 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.



View Larger Image

Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	130
Leads Currently Active in Study	13
Device Events	10
Cumulative Months of Follow-up	2,766

Lead Event	Total
Lead fracture	3
High impedance	3
Device failure[a]	1
Impedance NOS	1
Lead migration/dislodgment	1

Undesirable change in stimulation	1
Total Lead Events	**10**

[a] Reported as failure of lead electrodes

Time Interval	Survival	Effective Sample Size
1 yr	97.0%	60
2 yrs	93.3%	42
3 yrs	90.1%	26
at 39 mo	90.1%	22

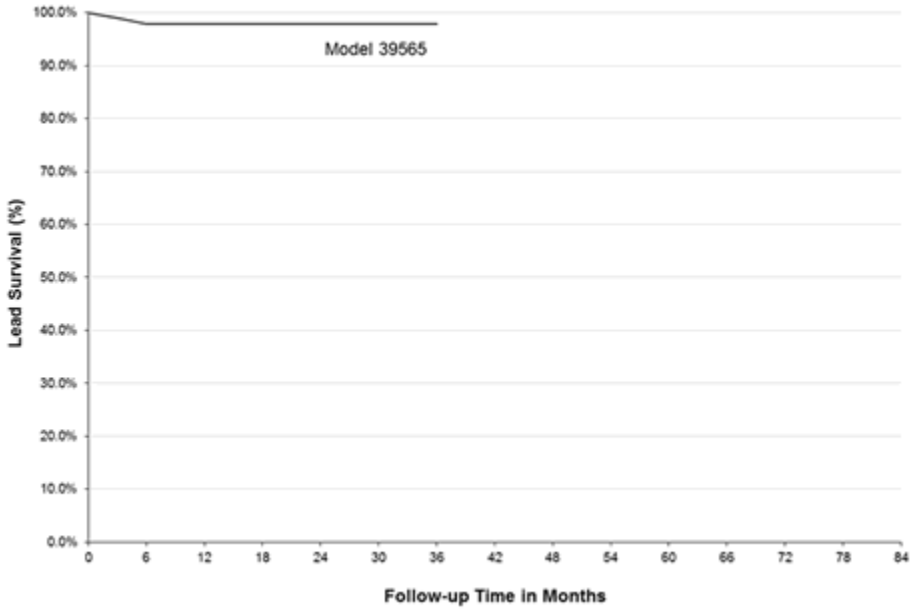
Model 3998 Specify: Specifications

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.



View Larger Image

Lead Characteristics	
Model Number	39565
FDA Approval Date	Jun 2007
Leads Enrolled	123
Leads Currently Active in Study	55
Device Events	2
Cumulative Months of Follow-up	2,106

Lead Event	Total
Lead migration/dislodgment	2

Total Lead Events	2

Time Interval	Survival	Effective Sample Size
1 yr	97.9%	65
2 yrs	97.9%	41
3 yrs	97.9%	21

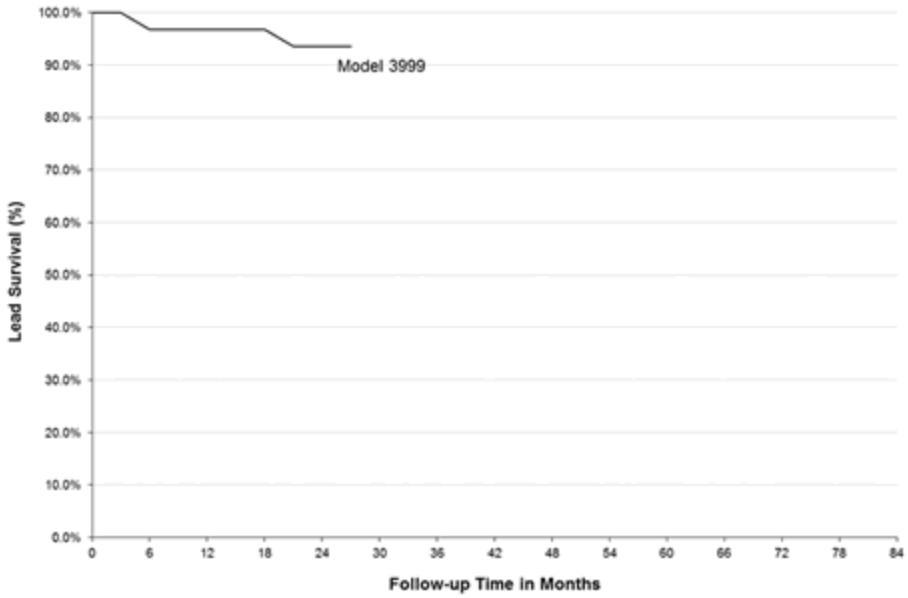
Model 39565 Specify: Specifications

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 3999 2x4 Hinged: 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	3999
FDA Approval Date	Jun 2004
Leads Enrolled	51
Leads Currently Active in Study	1
Device Events	2
Cumulative Months of Follow-up	1,017

Lead Event	Total
Lead migration/dislodgment	2
Total Lead Events	**2**

Time Interval	Survival	Effective Sample Size
1 yr	96.7%	37
2 yrs	93.6%	25

at 27 mo	93.6%	22

Model 3999 2x4 Hinged: Specifications

Device Name Lead Type	2x4 Hinged Specify Surgical
Lead	
Length (cm)	30, 45, 60
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)	3.3
Lateral Spacing: Edge to Edge (mm)	3.5
Array Length (mm)	28.2
Array Width (mm)	7.5
Paddle	
Length (mm)	41.0
Width (mm)	9.9
Thickness (mm)	1.8

Lead Survival Summary

For surgical leads, at 3 years of follow-up the 95% confidence interval for lead Model 3986A does not overlap with Model 39565 indicating that Model 39565 is currently performing better at this time point.

For percutaneous leads, the 95% confidence interval for Pisces-Quad LZ Model 3891 leads does not overlap with several of the other percutaneous lead models at 1 and 2 years of follow-up. 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. In addition, Model 3776 has consistently high device survival probability at 1 through 3 years when compared to several other percutaneous lead models.

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	839	358	122	23,242
3887	**Pisces-Quad**	Jan 1997	151	28	14	4,690
3888	**Pisces-Quad**	Nov 1992	354	74	28	7,570
3890	**Pisces-Quad LZ**	Sep 2002	128	13	10	3,123
3891	**Pisces-Quad LZ**	Sep 2002	114	12	28	2,148
3776	**Pisces-Octad**	Nov 2005	159	62	4	2,709
3777	**Pisces-Octad**	Apr 2005	663	123	46	13,722
3778	**Pisces-Octad**	Apr 2005	2,027	901	192	32,871
Surgical Leads						
3986A	**Resume TL**	Apr 1995	91	39	10	2,156
3998	**Specify**	Feb 1998	130	13	10	2,766
3999	**2 x 4 Hinged Specify**	Jun 2004	51	1	2	1,017
39565	**Specify**	Jun 2007	123	55	2	2,106

[a] There were a total of 540 lead-related events reported to the ISPR, but only 468 events included in this summary table. The remaining lead-related events either occurred in lead models for which no device survival curves are presented due to an insufficient number of enrolled devices (n=5) or were subsequent or unlinked device events that did not affect the survival estimates.

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%** (87.5%, 92.7%)	**87.2%** (84.2%, 90.2%)	**81.8%** (78.1%, 85.5%)	**76.6%** (72.3%, 81.0%)
3887	**Pisces-Quad**	**96.8%** (92.3%, 100.0%)	**88.9%** (81.5%, 96.3%)	**85.8%** (77.4%, 94.2%)	**84.0%** (75.2%, 92.9%)
3888	**Pisces-Quad**	**91.7%** (87.8%, 95.6%)	**90.3%** (86.0%, 94.6%)	**85.5%** (79.3%, 91.7%)	**84.2%** (77.6%, 90.8%)
3890	**Pisces-Quad LZ**	**100.0%** NA	**96.9%** (92.7%, 100.0%)	**89.8%** (81.8%, 97.7%)	**89.8%** (81.8%, 97.7%)
3891	**Pisces-Quad LZ**	**80.1%** (71.5%, 88.7%)	**77.2%** (68.0%, 86.5%)	-	-
3776	**Pisces-Octad**	**97.8%** (95.2%, 100.0%)	**97.8%** (95.2%, 100.0%)	**97.8%** (95.2%, 100.0%)	-
3777	**Pisces-Octad**	**93.6%** (91.3%, 95.8%)	**89.8%** (86.8%, 92.8%)	**89.8%** (86.8%, 92.8%)	**89.8%** (86.8%, 92.8%)
3778	**Pisces-Octad**	**90.7%** (89.2%, 92.2%)	**86.8%** (84.7%, 88.8%)	**84.0%** (81.5%, 86.5%)	**83.5%** (80.9%, 86.2%)
Surgical Leads					
3986A	**Resume TL**	**87.3%** (79.3%, 95.2%)	**87.3%** (79.3%, 95.2%)	**84.5%** (75.0%, 93.9%)	-
3998	**Specify**	**97.0%** (92.8%, 100.0%)	**93.3%** (86.7%, 99.9%)	**90.1%** (81.2%, 99.0%)	-
3999	**2 x 4 Hinged Specify**	**96.7%** (90.3%, 100.0%)	**93.6%** (84.7%, 100.0%)	-	-
39565	**Specify**	**97.9%** (94.9%, 100.0%)	**97.9%** (94.9%, 100.0%)	**97.9%** (94.9%, 100.0%)	-

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**	**72.8%** (67.9%, 77.7%)	**68.7%** (63.1%, 74.2%)	**66.0%** (59.9%, 72.1%)	**66.0%** (59.9%, 72.1%)
3887	**Pisces-Quad**	**81.8%** (72.1%, 91.5%)	**79.6%** (69.1%, 90.0%)	-	-
3888	**Pisces-Quad**	**81.2%** (73.6%, 88.8%)	**77.1%** (67.8%, 86.3%)	**77.1%** (67.8%, 86.3%)	-
3890	**Pisces-Quad LZ**	**86.5%** (76.6%, 96.5%)	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
3776	**Pisces-Octad**	-	-	-	-
3777	**Pisces-Octad**	**88.4%** (84.3%, 92.5%)	**84.3%** (77.4%, 91.2%)	-	-
3778	**Pisces-Octad**	**81.2%** (77.5%, 84.9%)	**77.4%** (71.1%, 83.8%)	-	-
Surgical Leads					
3986A	**Resume TL**	-	-	-	-
3998	**Specify**	-	-	-	-
3999	**2 x 4 Hinged Specify**	-	-	-	-
39565	**Specify**	-	-	-	-

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

Model Number	Family	9 yrs	10 yrs	11 yrs
Percutaneous Leads				
3487A	**Pisces-Quad**	**66.0%** (59.9%, 72.1%)	**62.3%** (54.5%, 70.0%)	**59.8%** (51.0%, 68.7%)

3887	**Pisces-Quad**	-	-	-
3888	**Pisces-Quad**	-	-	-
3890	**Pisces-Quad LZ**	-	-	-
3891	**Pisces-Quad LZ**	-	-	-
3776	**Pisces-Octad**	-	-	-
3777	**Pisces-Octad**	-	-	-
3778	**Pisces-Octad**	-	-	-
Surgical Leads				
3986A	**Resume TL**	-	-	-
3998	**Specify**	-	-	-
3999	**2 x 4 Hinged Specify**	-	-	-
39565	**Specify**	-	-	-

Extensions

From June 2004 to the report cut-off date of July 31, 2013, there were 2,757 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=2,841) were due to the fact that some patients were subsequently re-implanted with an extension or implanted with 2 or more extensions.

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). Over thirty-nine percent (39.5%) of the extensions were Model 37081 extensions, 24.7% were Model 7489 extensions, 19.8% were Model 37082 extensions, 7.6% were Model 7495 extensions, 6.8% were Model 37083 extensions, and less than 1.0% were Model 7471, Model 7472, Model 7496 and other models. The aggregate prospective follow-up time for all extensions was 57,897 months (4,825 years).

Extension Events

There were 16 product performance-related events with an underlying reported etiology related to the extension. Of these events, the majority were extension fractures (n=13). Of the 16 events, 15 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. A total of 15 extensions had follow-up time cut-off due to product performance-related events. There were 1,771 extensions censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, patient lost to follow-up, other extension modification, therapy suspended, or non-product performance extension-related event without an associated intervention. The remaining 971 extensions, which were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

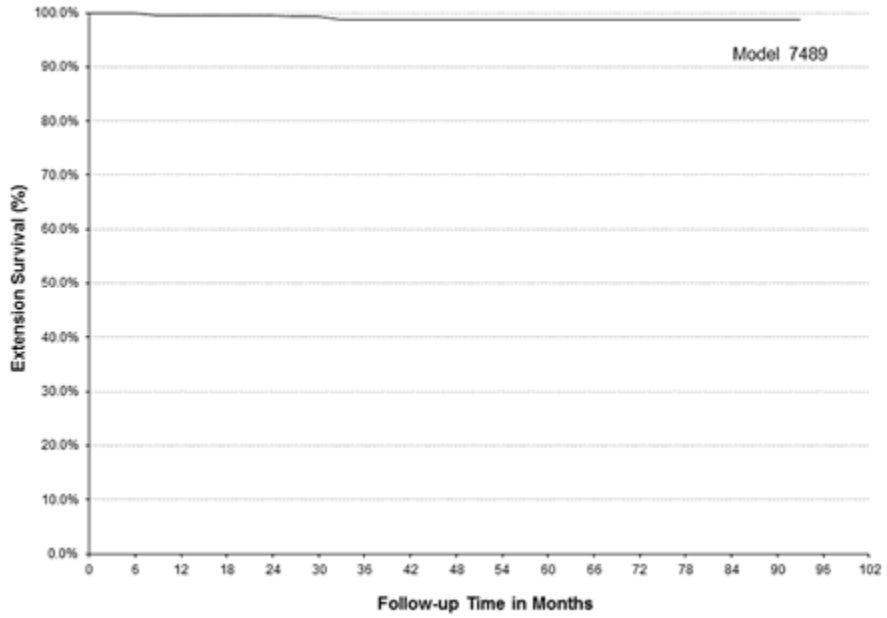
Extension Survival

The figures and tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval. Currently, the 95% confidence intervals for all extension models overlap at all-time intervals, indicating that survival from extension-related events is not significantly different between the extension models across various applicable follow-up time points.

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.



View Larger Image

Extension Characteristics	
Model Number	7489
FDA Approval Date	Oct 2002
Extensions Enrolled	681
Extensions Currently Active in Study	58
Device Events	3
Cumulative Months of Follow-up	15,709

Extension Event	Total

Extension fracture	2
Medical device complication[a]	1
Total Extension Events	**3**

[a] Reported as unknown problem with extension

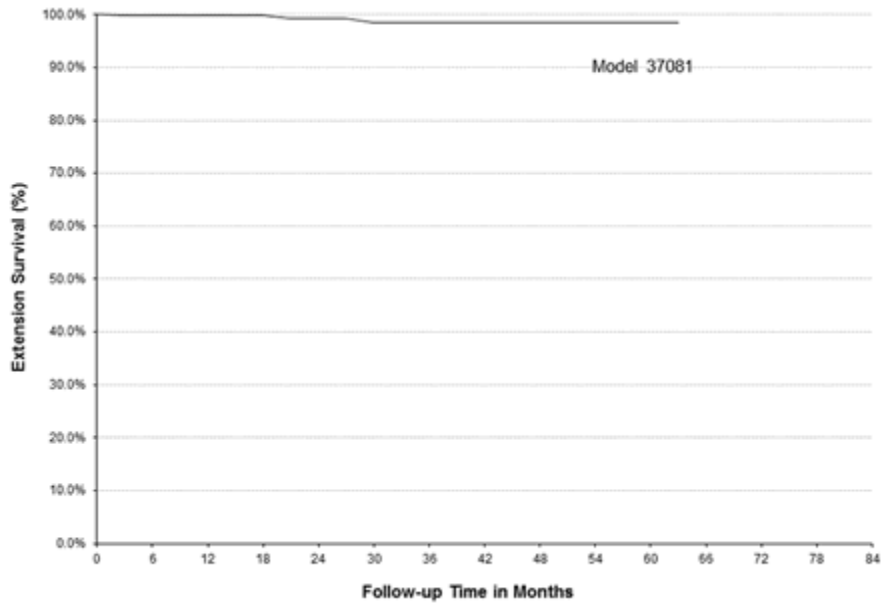
Time Interval	Survival	Effective Sample Size
1 yr	99.6%	286
2 yrs	99.6%	292
3 yrs	98.8%	214
4 yrs	98.8%	140
5 yrs	98.8%	103
6 yrs	98.8%	76
7 yrs	98.8%	60
8 yrs	98.8%	50
at 105 mo	98.8%	21

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.



View Larger Image

Extension Characteristics	
Model Number	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	1,090
Extensions Currently Active in Study	410
Device Events	5
Cumulative Months of Follow-up	18,591

Extension Event	Total
Extension fracture	5
Total Extension Events	**5**

Time Interval	Survival	Effective Sample Size
1 yr	99.9%	555
2 yrs	99.4%	333
3 yrs	98.6%	189
4 yrs	98.6%	102
5 yrs	98.6%	55

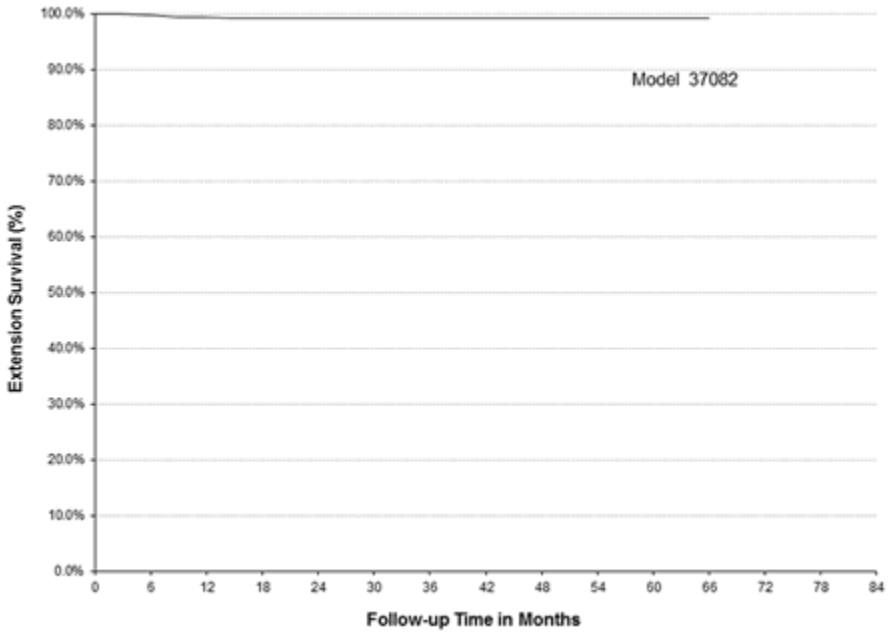
6 yrs	98.6%	21

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.



View Larger Image

Extension Characteristics	
Model Number	37082
FDA Approval Date	Mar 2006
Extensions Enrolled	545
Extensions Currently Active in Study	209

Device Events	3
Cumulative Months of Follow-up	12,256

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

[a] Physician reported shocking sensation at battery/extension connection

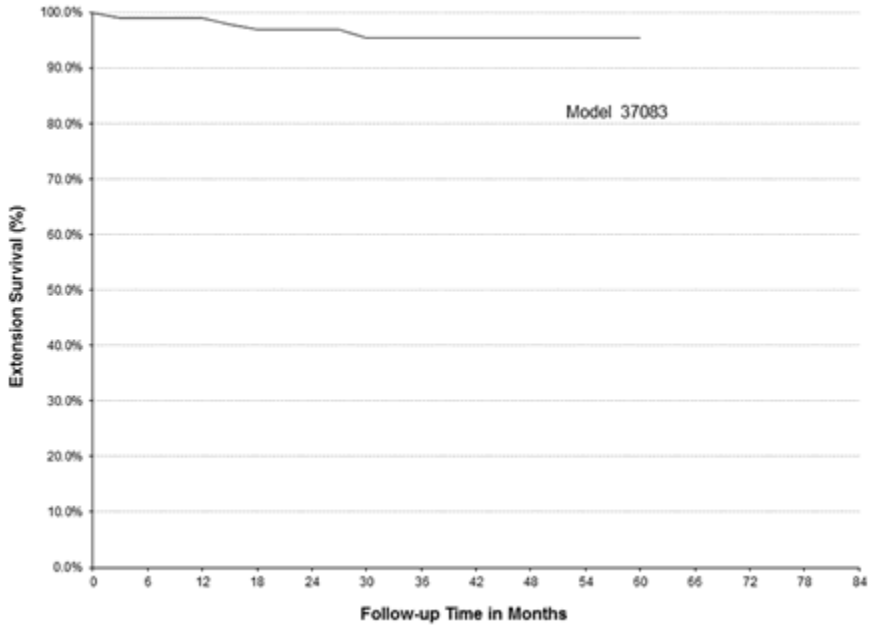
Time Interval	Survival	Effective Sample Size
1 yr	99.5%	346
2 yrs	99.2%	218
3 yrs	99.2%	127
4 yrs	99.2%	79
5 yrs	99.2%	54
6 yrs	99.2%	30
at 75 mo	99.2%	22

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	187
Extensions Currently Active in Study	31
Device Events	4
Cumulative Months of Follow-up	4,365

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

[a] Reported as extension failure

Time Interval	Survival	Effective Sample Size
1 yr	99.0%	105
2 yrs	97.0%	86

3 yrs	95.7%	54
4 yrs	95.7%	40
5 yrs	95.7%	23
at 63 mo	95.7%	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, survival from extension-related events is not statistically significantly different between the extension models across all applicable follow-up time points.

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	1,090	410	5	18,591
37082	37082	Mar 2006	545	209	3	12,256
37083	37083	Sep 2005	187	31	4	4,365
7489	7489	Oct 2002	681	58	3	15,709

[a] There were a total of 16 extension-related events reported to the ISPR, but only 15 events included in this summary table. The remaining 1 event was a subsequent event that did not affect the device 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%** (99.6%, 100.0%)	**99.4%** (98.6%, 100.0%)	**98.6%** (97.3%, 99.9%)	**98.6%** (97.3%, 99.9%)	**98.6%** (97.3%, 99.9%)
37082	**99.5%** (98.8%, 100.0%)	**99.2%** (98.2%, 100.0%)	**99.2%** (98.2%, 100.0%)	**99.2%** (98.2%, 100.0%)	**99.2%** (98.2%, 100.0%)
37083	**99.0%** (97.0%, 100.0%)	**97.0%** (93.6%, 100.0%)	**95.7%** (91.4%, 99.9%)	**95.7%** (91.4%, 99.9%)	**95.7%** (91.4%, 99.9%)
7489	**99.6%** (98.9%, 100.0%)	**99.6%** (98.9%, 100.0%)	**98.8%** (97.5%, 100.0%)	**98.8%** (97.5%, 100.0%)	**98.8%** (97.5%, 100.0%)

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

Model Number	6 yrs	7 yrs	8 yrs
37081	**98.6%** (97.3%, 99.9%)	-	-
37082	**99.2%** (98.2%, 100.0%)	-	-
37083	-	-	-
7489	**98.8%** (97.5%, 100.0%)	**98.8%** (97.5%, 100.0%)	**98.8%** (97.5%, 100.0%)

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

- Education and Training
- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines
- Clinical Trials Registry

- Clinical Research Investigator Guidance

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Deep Brain Stimulation Systems

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

Study Participants

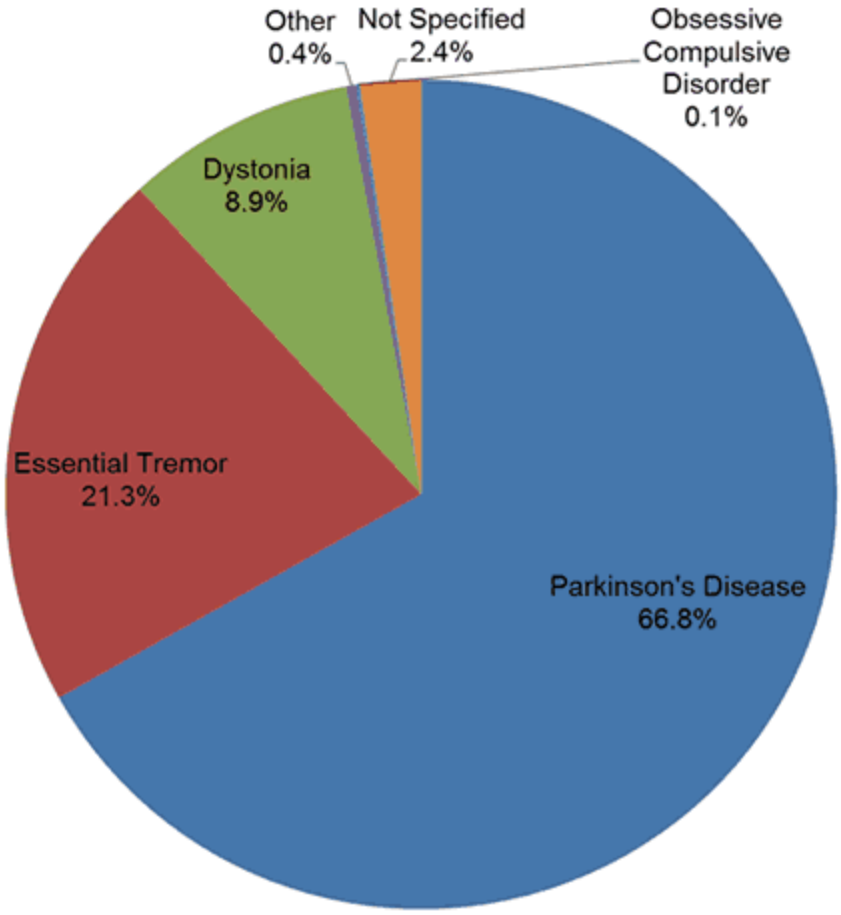
Centers

The following deep brain stimulation tables and graphs were generated based on data collected between the date of initiation of the Implantable Systems Performance Registry (ISPR) for deep brain stimulation systems in July 2009 and the report cut-off date of July 31, 2013. Eighteen centers enrolled and contributed patients to the deep brain stimulation section of the report.

Patients

Of the 760 deep brain stimulation patients enrolled in the ISPR, 66.8% were implanted for the treatment of Parkinson's Disease, 21.3% were implanted for the treatment of Essential Tremor, 8.9% were implanted for the treatment of Dystonia, 0.1% were implanted for the treatment of Obsessive Compulsive Disorder, 0.4% were implanted for the treatment of some other indication and 2.4% 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	508 (66.8%)
Essential Tremor	162 (21.3%)
Dystonia	68 (8.9%)
Obsessive Compulsive Disorder	1 (0.1%)
Other	3 (0.4%)
Not specified	18 (2.4%)
Total Patients	**760**

[a] Refer to product labeling for approved indications.

Event Summary

There were 172 events reported between July 2009 and July 31, 2013 in patients with deep brain stimulation systems. Fifteen percent of these events (25/172) were categorized as product performance-related and are

presented graphically within this report. The 25 product performance events occurred in 18 of the 760 total patients (2.4%) enrolled. In addition, there were 128 non-product performance events and 19 deaths, none of which were reported as a direct result of a device-related event or the stimulation therapy during this timeframe.

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=760)
Lead fracture	6	3	0.39%
High impedance	5	4	0.53%
Medical device complication[c]	5	5	0.66%
Low impedance	2	2	0.26%
Migration of implant[d]	2	1	0.13%
Recharging unable to recharge	2	2	0.26%[e]
Device malfunction[f]	1	1	0.13%
Extension fracture	1	1	0.13%
Lead migration/dislodgement	1	1	0.13%
Total	**25**	**18**	**2.37%**

[a] MedDRA Preferred Term

[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 reported as open circuits to lead, 1 suspicion of heating of the antenna while recharging, 1 undesirable interaction with external electronic device, and 1 issue with controller not communicating

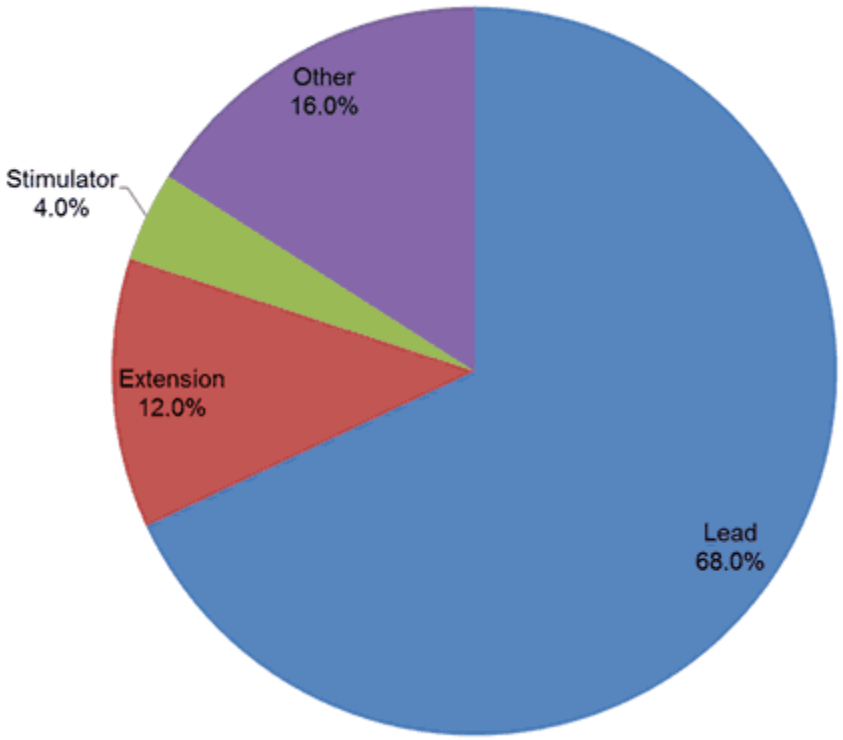
[d] Migration was attributed to the extensions

[e] There were a total of 111 patients that used rechargeable neurostimulators for DBS in the ISPR. A total of 1.8% (2/111) of patients with a rechargeable neurostimulator experienced a recharging unable to recharge event.

[f] Reported as increased impedance

A total of 17 (68.0%) of the 25 product performance events were related to the lead, 3 (12.0%) were related to the extension, 3 (12.0%) were related to the recharging process, 1(4.0%) was related to an external device, and 1 (4.0%) was related to neurostimulator. Relatedness is determined by the physician.

Product Performance Events by Etiology



Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)

Events[b]	Number of Non-Product Performance Events
Neurostimulator battery depletion	16
Implant site infection	15
Implant site pain	5
Weight increased	5
Dyskinesia	4
Recharging unable to recharge[c]	4
Speech disorder	4
Dystonia	3
Fall	3

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)	
Implant site erosion	3
Medical device complication[d]	3
Neurostimulator migration	3
Wound infection	3
Dysarthria	2
Dysphonia	2
Hemorrhage intracranial	2
Lead(s) not within target	2
Migraine	2
Muscle spasticity	2
Paraesthesia	2
Staphylococcal infection	2
Wound dehiscence	2
Other[e]	39
Total	**128**

[a] Adverse events associated with product performance events are not included in this table
[b] MedDRA Preferred Term
[c] Patient was unable to recharge due to an issue not related to the device
[d] Includes 1 event reported as increased charging time not due to the device, charge icon missing from patient programmer, and DBS system turned off by airport security
[e] Composed of 39 event codes that include fewer than 2 patients each

There were 19 deaths reported in the ISPR 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 79% of patient deaths occurred in patients receiving therapy for Parkinson's disease, and 21% for Essential Tremor.

Death by Primary Indication	
Primary Indication	**N (%)**
Essential Tremor	4 (21%)

Death by Primary Indication	
Parkinson's Disease	15 (79%)
Total	**19 (100%)**

Deep Brain Neurostimulators

From July 2009 to the report cut-off date of July 31, 2013, 774 deep brain neurostimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=760) versus neurostimulators is due to the fact that some patients have more than one neurostimulator implanted or were subsequently re-implanted.

Forty-seven percent (47.2%) of the neurostimulators were Activa PC, 28.4% were Activa SC, 14.3% were Activa RC, 8.7% were Soletra, and 1.4% were Kinetra. The aggregate prospective follow-up time for all neurostimulators was 7,430 months (619 years).

Deep Brain Neurostimulator Events

There was 1 product performance-related event with an underlying reported etiology related to deep brain neurostimulator function. For neurostimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 5/55 (9%). The proportion was based upon the number of ISPR 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 5 devices that were returned for analysis. The 1 deep brain stimulator with a performance-related event was not returned to Medtronic RPA but was assigned as device-related by the physician as medical device complication.

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. A total of 1 neurostimulator had follow-up time cut-off due to a product performance-related event. There were 100 neurostimulators censored in the survival analysis for the following reasons: patient expired, stimulator explanted, patient discontinued, patient lost to follow-up, other neurostimulator modification, or non-product performance neurostimulator-related event without an associated intervention. The remaining 673 neurostimulators, which were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

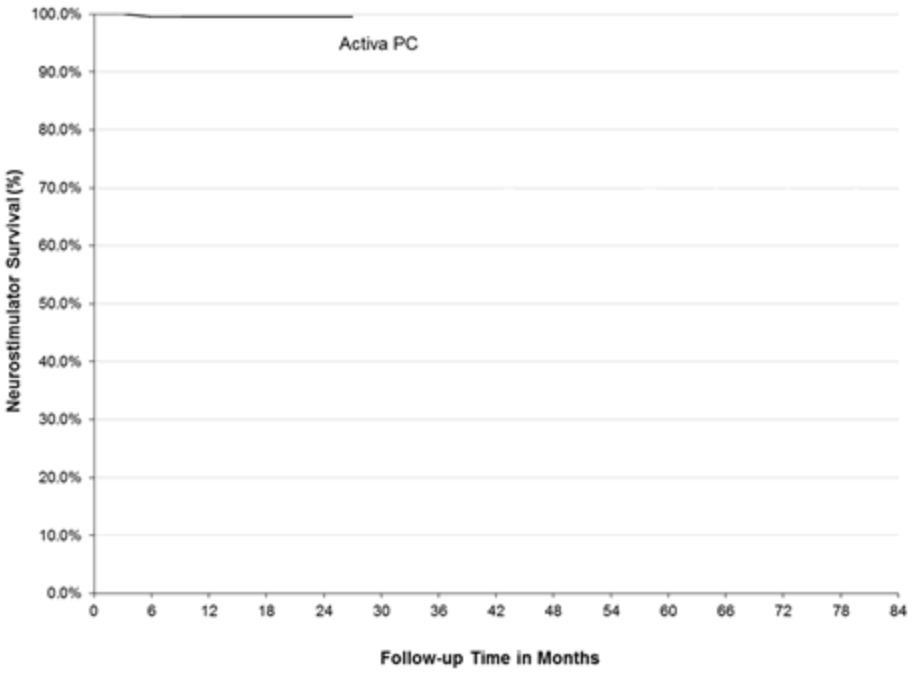
Deep Brain Neurostimulator Survival

The figures and tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. Currently, the 95% confidence intervals for all neurostimulator models overlap, indicating that survival from neurostimulator -related events is not significantly different between the neurostimulator models across various applicable follow-up time points.

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	365
Neurostimulators Currently Active in Study	316
Device Events	1
Cumulative Months of Follow-up	3,264

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

[a] Undesirable interaction with external electronic device

Time Interval	Survival	Effective Sample Size
1 yr	99.5%	140
2 yr	99.5%	37

at 27 mo	99.5%	21

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

Deep Brain Neurostimulator Characteristics	
Model Name	Activa SC
FDA Approval Date	Jan 2011
Neurostimulators Enrolled	220
Neurostimulators Currently Active in Study	163
Device Events	0

Cumulative Months of Follow-up	1,698

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	73
at 21 mo	100.0%	28

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

Deep Brain Neurostimulator Characteristics

Model Name	Activa RC
FDA Approval Date	Mar 2009
Neurostimulators Enrolled	111
Neurostimulators Currently Active in Study	92
Device Events	0
Cumulative Months of Follow-up	1,045

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

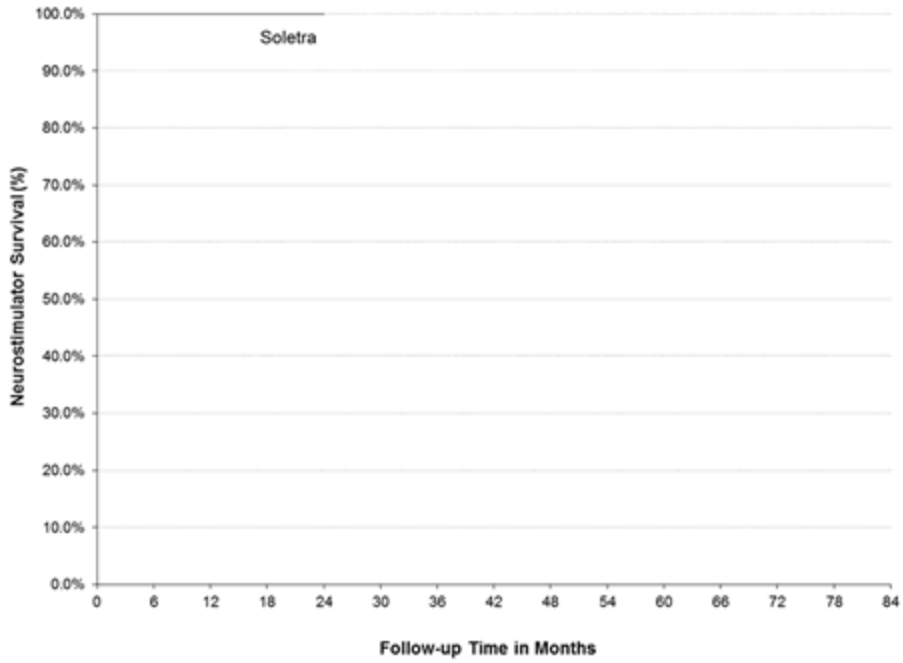
Time Interval	Survival	Effective Sample Size
1 yr	100.0%	37
at 18 mo	100.0%	20

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)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4

Programs	16 (up to 4 per group)
Implant Depth	≤ 1 cm

Model 7426 Soletra: Survival from Neurostimulator Events



View Larger Image

Deep Brain Neurostimulator Characteristics	
Model Name	Soletra
FDA Approval Date	Jan 2002
Neurostimulators Enrolled	67
Neurostimulators Currently Active in Study	26
Device Events	0
Cumulative Months of Follow-up	1,080

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	39
2 yrs	100.0%	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

Currently, survival from neurostimulator-related events is not statistically significantly different between the neurostimulator models across all applicable follow-up time points.

Deep Brain Neurostimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events	Cumulative Months of Follow-up
Activa PC	Activa	Apr 2009	365	316	1	3,264
Activa SC	Activa	Jan 2011	220	163	0	1,698

Activa RC	Activa	Mar 2009	111	92	0	1,045
Soletra	Soletra	Jan 2002	67	26	0	1,080

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs
Activa PC	**99.5%** (98.6%, 100.0%)	**99.5%** (98.6%, 100.0%)
Activa SC	**100.0%** NA	-
Activa RC	**100.0%** NA	-
Soletra	**100.0%** NA	**100.0%** NA

Leads

From July 2009 to the report cut-off date of July 31, 2013, there were 1,116 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus the total number of neurostimulators (n=774) were due to the fact that some patients were implanted with more than 1 lead or were subsequently re-implanted with a new lead.

A lead is a set of thin wires with a protective coating and electrodes near the tip. Over fifty-four percent (54.9%) were Model 3389, 44.4% were Model 3387 and 0.4% were Model 3391. The aggregate prospective follow-up time for all leads was 10,937 months (911 years).

Lead Events

There were 17 product performance-related events with an underlying reported etiology related to the lead. Six were lead fracture, 5 were high impedance, 2 were low impedance, 2 were medical device complication, 1 was device malfunction, and 1 lead migration/dislodgement. Of the 17 events, 9 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. A total of 9 leads had follow-up time cut-off due to product performance-related events. There were 142 leads censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, patient lost to follow-up, or other lead modification. The remaining 965 leads, which were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

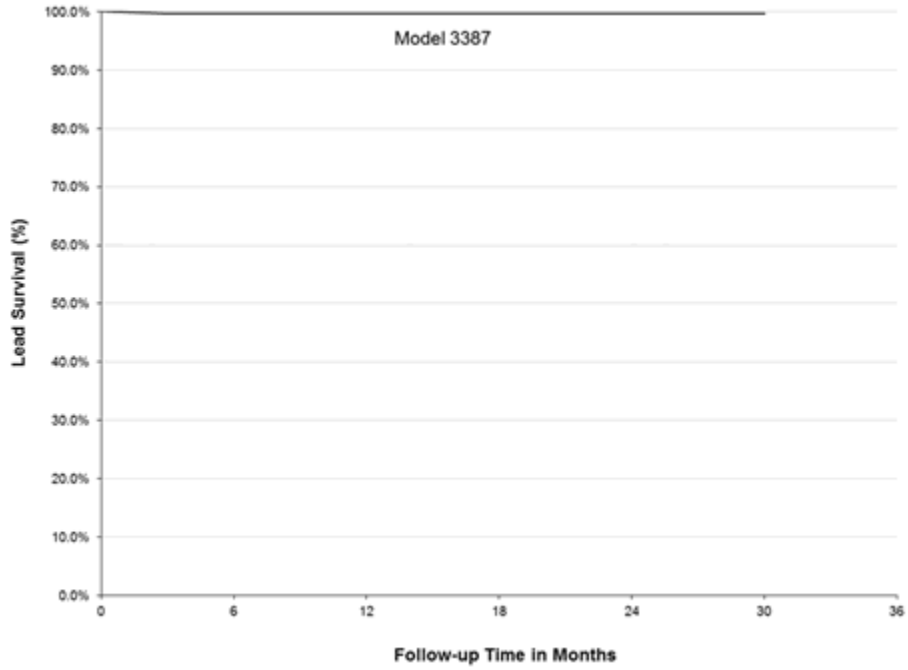
Lead Survival

The figure and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, the 95% confidence intervals for all lead models overlap, indicating that survival from lead-related events is not significantly different between the lead models across various applicable follow-up time points.

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.



View Larger Image

Lead Characteristics	
Model Number	3387
FDA Approval Date	Jan 2002
Leads Enrolled	495
Leads Currently Active in Study	386
Device Events	2[a]
Cumulative Months of Follow-up	4,487

[a] One event occurred at 114 months for a previously implanted lead when the effective sample size only included 1 device

Lead Event	Total
Lead migration/dislodgement	1

Low impedance	1
Total Lead Events	**2**

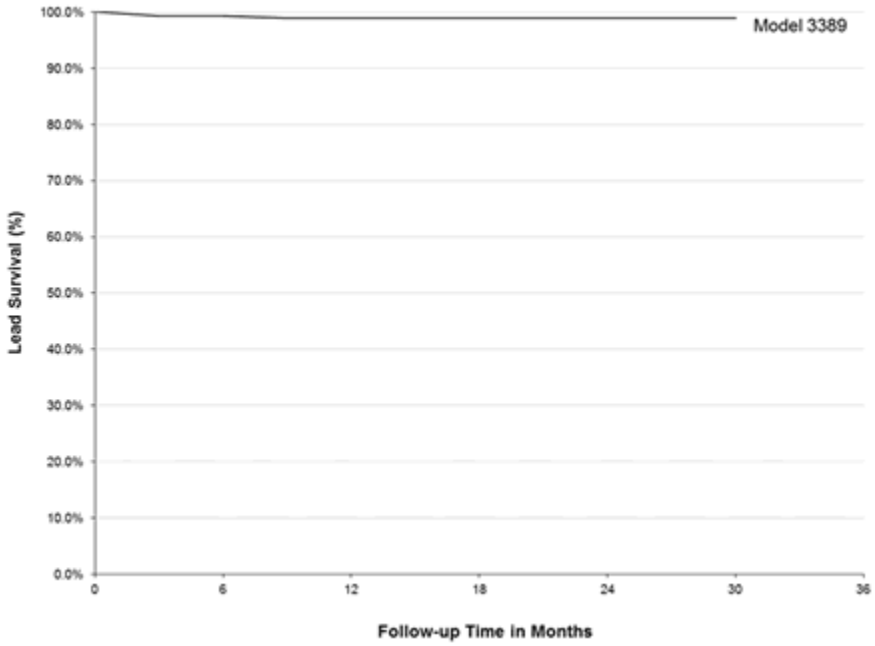
Time Interval	Survival	Effective Sample Size
1 yr	99.7%	145
2 yrs	99.7%	50
at 30 mo	99.7%	24

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.



View Larger Image

Lead Characteristics	
Model Number	3389
FDA Approval Date	Sep 1999
Leads Enrolled	613
Leads Currently Active in Study	530
Device Events	7[a]
Cumulative Months of Follow-up	6,250

[a] Three events occurred at 33, 63, and 149 months; the survival is not presented at these time points due to insufficient sample size (fewer than 20 leads).

Lead Event	Total
High impedance	5
Lead fracture	1
Medical device complication[a]	1
Total Lead Events	**7**

[a] Open circuits to right lead

Time Interval	Survival	Effective Sample Size
1 yr	98.9%	194
2 yrs	98.9%	56
at 30 mo	98.9%	23

Model 3389: Specifications

Model Number	3389
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm^2)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	0.5
Array Length (mm)	7.5

Lead Survival Summary

Currently, survival from lead-related events is not statistically significantly different between the lead models across all applicable follow-up time points.

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	495	386	2[b]	4,487
3389	**3389**	Sep 1999	613	530	7[c]	6,250

[a] There were a total of 17 lead-related events reported to the ISPR, but only 9 events included in this summary table. The remaining events were either subsequent events that did not affect the device survival

estimates or were not attributable to an enrolled lead.
[b] One event occurred at 114 months for a previously implanted lead when the effective sample size only included 1 device
[c] Three events occurred at 33, 63, and 149 months; the survival is not presented at these time points due to insufficient sample size (fewer than 20 leads).

Device Survival Probability (95% Confidence Interval)			
Model Number	**Family**	**1 yr**	**2 yrs**
3387	**3387**	**99.7%** (99.1%, 100.0%)	**99.7%** (99.1%, 100.0%)
3389	**3389**	**98.9%** (97.7%, 100.0%)	**98.9%** (97.7%, 100.0%)

Extensions

From July 2009 to the report cut-off date of July 31, 2013, there were 1,072 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus the total number of neurostimulators (n=774) 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=1,116) because patients were re-implanted with a new lead using existing extensions.

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). Over eighty-three percent (83.1%) of the extensions were Model 37086 extensions, 16% were Model 7482 extensions and 0.8% were Other model extensions. The aggregate prospective follow-up time for all extensions was 10,077 months (840 years).

Extension Events

There were 3 product performance-related events with an underlying reported etiology related to the extension. Two events were migration of implant attributed to the extensions and 1 was extension fracture.

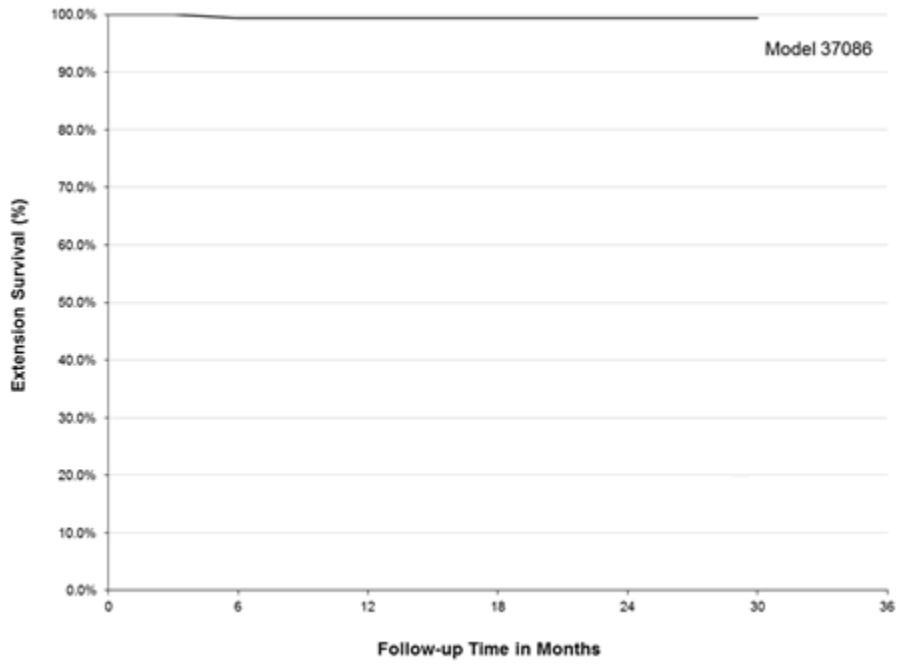
For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event, 2) the occurrence of a non-product performance-related or censoring event, or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. A total of 3 extensions had follow-up time cut-off due to product performance-related events. There were 147 extensions censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, patient lost to follow-up, or other extension modification. The remaining 922 extensions, which 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. Survival curves are only shown if more than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. Currently, the 95% confidence intervals for all extension models overlap at all-time intervals, indicating that survival from extension-related events is not significantly different between the extension models across various applicable follow-up time points.

Choose a model Go

Model 37086: Survival from Extension Events



View Larger Image

Extension Characteristics	
Model Number	37086
FDA Approval Date	Sep 2009
Extensions Enrolled	891
Extensions Currently Active in Study	740
Device Events	3
Cumulative Months of Follow-up	7,724

Extension Event	Total
Migration of implant	2
Extension fracture	1
Total Extension Events	**3**

Time Interval Survival Effective Sample Size

1 yr	99.4%	305
2 yrs	99.4%	86
at 30 mo	99.4%	32

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

Model 7482: Survival from Extension Events

Extension Characteristics	
Model Number	7482
FDA Approval Date	Jan 2002
Extensions Enrolled	172
Extensions Currently Active in Study	135
Device Events	0
Cumulative Months of Follow-up	2,256

Extension Event	Total
Total Extension Events	**0**

Time Interval	Survival	Effective Sample Size
at 3 mo	100.0%	22

Model 7482 Extension: Specifications

Device Name	Low-profile DBS Extension

Length (cm)	25, 40, 51, 66, 95
Distal End Compatibility	3387 or 3389 DBS lead
Distal End Set Screws	4
Proximal End INS Compatibility	Soletra, Kinetra, or Activa® SC Model 37602

Extension Survival Summary

Currently, survival from extension-related events is not statistically significantly different between the extension models across all applicable follow-up time points.

Extension Characteristics

Model Number	Family	FDA Approval Date	Extensions Enrolled	Extensions Currently Active in Study	Device Events	Cumulative Months of Follow-up
37086[a]	37086	Sep 2009	891	740	3	7,724
7482	7482	Jan 2002	172	135	0	2,256

Device Survival Probability (95% Confidence Interval)

Model Number	1 yr	2 yrs
37086[a]	**99.4%** (98.8%, 100.0%)	**99.4%** (98.8%, 100.0%)
7482	-[b]	-

[a] Includes Models 37085 and 37086
[b] Model 7482 device survival probability at 3 months of follow-up is 100.0%.

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

- Education and Training
- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines

- Clinical Trials Registry
- Clinical Research Investigator Guidance

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Sacral Neuromodulation Systems

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

Study Participants

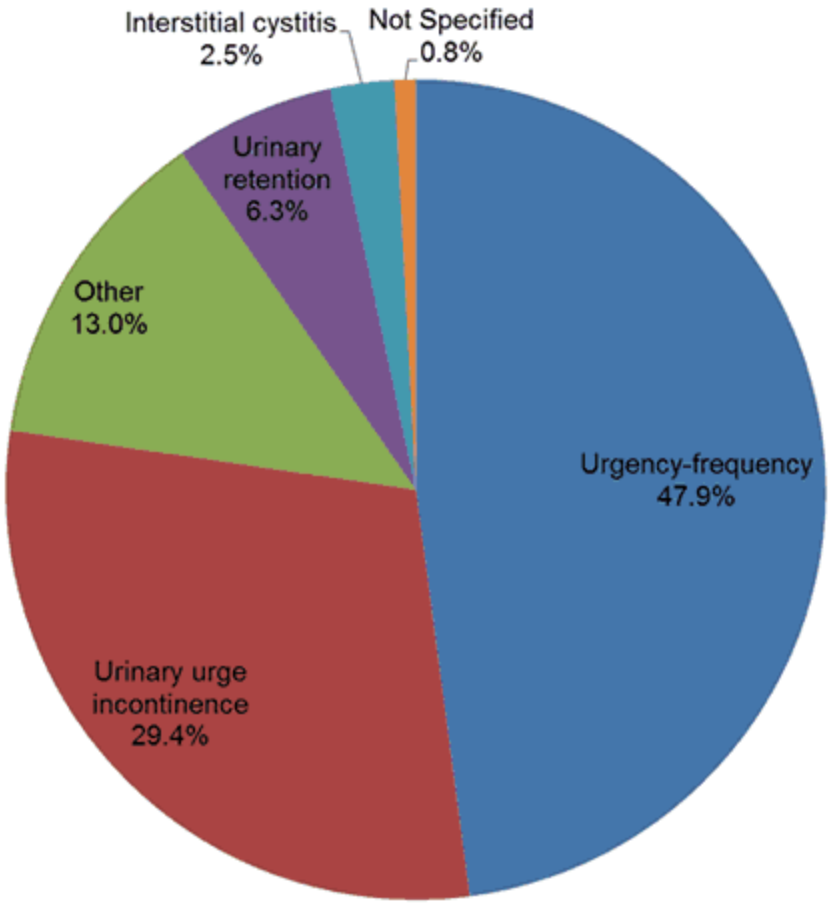
Centers

The following sacral neuromodulation tables and graphs were generated based on data collected between the date of initiation of the Implantable Systems Performance Registry (ISPR) for sacral neuromodulation systems in April 2010 and the report cut-off date of July 31, 2013. Five centers enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 238 sacral neuromodulation patients enrolled in the ISPR, the primary indication for implant were as follows: 47.9% were implanted for the treatment of urgency-frequency, 29.4% were implanted for the treatment of urinary urge incontinence, 6.3% were implanted for the treatment of urinary retention, 2.5% were implanted for the treatment of interstitial cystitis, 13.0% were treated for the treatment of some other indication, and 0.8% were treated for the indications that were not specified in the database. As of the report cut-off date, there have not been any patients enrolled with a primary indication of fecal incontinence, so the ISPR is under-representative of this population (~4% of U.S. implants - data based on Device and Registration Tracking).

Primary SNM Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Urgency-frequency	114 (47.9%)
Urinary urge incontinence	70 (29.4%)
Urinary retention	15 (6.3%)
Interstitial cystitis	6 (2.5%)
Other	31 (13%)
Not specified	2 (0.8%)
Total Patients	**238**

[a] Refer to product labeling for approved indications.

Event Summary

There were 61 events reported between April 2010 and July 31, 2013 in patients with sacral neuromodulation systems. Of these events, 24.6% (15/61) were categorized as product performance-related and are presented graphically within this report. The 15 product performance events occurred in 15 of the 238 total patients (6.3%) enrolled. In addition, there were 43 non-product performance events and 3 deaths,

none of which were reported as a direct result of a device-related event or the stimulation therapy during this timeframe.

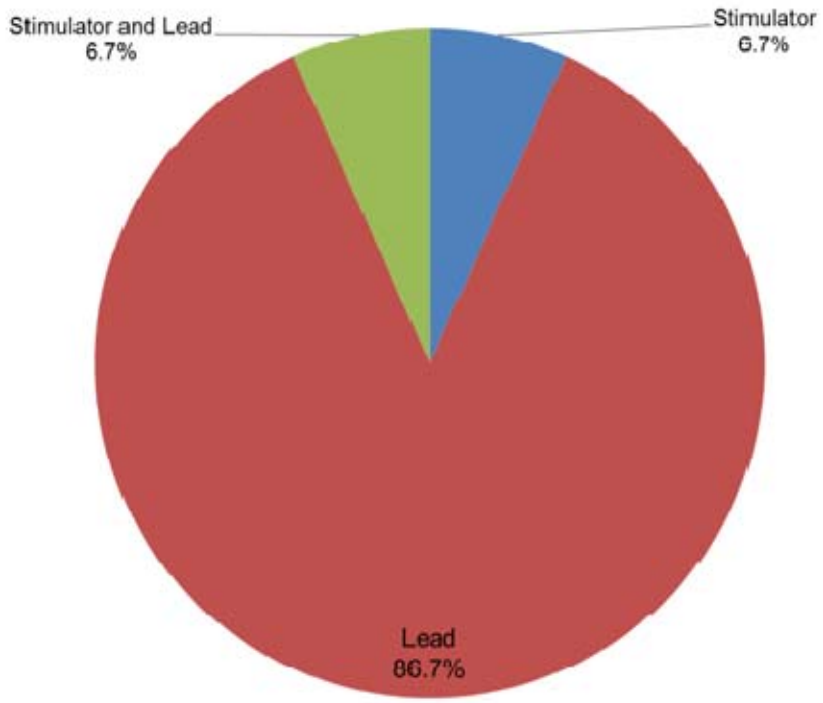
Sacral Neuromodulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event	Percent of Patients with Event (n=238)
High impedance	9	9	3.77%
Lead fracture	3	3	1.26%
Low impedance	2	2	0.84%
Medical device complication[b]	1	1	0.42%
Total	**15**	**15**	**6.28%**

[a] MedDRA Preferred Term
[b] Device function could not be recovered after a fall

A total of 13 (86.7%) of the 15 product performance events were related to the lead, 1 (6.7%) was related to the stimulator, and 1 (6.7%) was related to both the stimulator and the lead. Relatedness is determined by the physician.

Product Performance Events by Etiology



Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)	
Events[b]	**Number of Non-Product Performance Events**
Implant site pain	6
Therapeutic product ineffective	5
Pain	4
Incisional drainage	3
Neurostimulator battery depletion	3
Paraesthesia	3
Urinary incontinence	3
Undesirable change in stimulation	2
Arthralgia	1
Back pain	1
Bladder pain	1
Implant site erythema	1
Infection	1
Medical device complication	1
Migration of implant	1
Pain in extremity	1
Pelvic pain	1
Restless legs syndrome	1
Sensory disturbance	1
Skin reaction	1
Urinary tract disorder	1
Vaginal burning sensation	1

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths)	
Total	**43**

[a] Adverse events associated with product performance events are not included in this table
[b] MedDRA Preferred Term

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

Death by Primary Indication	
Primary Indication	**N (%)**
Urinary urge incontinence	2 (66.7%)
Urgency-frequency	1 (33.3%)
Total	**3 (100%)**

Neurostimulators

From April 2010 to the report cut-off date of July 31, 2013, 238 neurostimulators were followed in the Implantable Systems Performance Registry (ISPR).

Seventy-nine percent (79.0%) of neurostimulators were InterStim II, and 21.0% were InterStim. The aggregate prospective follow-up time for all neurostimulators was 2,880 months (240 years).

Neurostimulator Events

There were 2 product performance-related events with an underlying reported etiology related to neurostimulator function. For neurostimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 5/16 (31%). The proportion was based upon the number of ISPR 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 5 devices that were returned for analysis. The 2 neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as a medical device complication (device function could not be recovered after a fall) and high impedance (both lead and stimulator).

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. A total of 2 stimulators had follow-up cut-off due to product performance-related events. There were 55 neurostimulators censored in the survival analysis for the following reasons: patient expired, stimulator explanted, patient discontinued, patient lost to follow-up, other stimulator modification, or non-product performance stimulator-related event with no associated intervention. The remaining 181 neurostimulators, which 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. Survival curves are only shown if more than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. Currently, the 95% confidence intervals for all neurostimulator models overlap, indicating that survival from neurostimulator

-related events is not significantly different between the neurostimulator models across various applicable follow-up time points.

Choose a model Go

Model 3023 InterStim: Survival from Neurostimulator Events

Neurostimulator Characteristics	
Model Name	InterStim
FDA Approval Date	Jul 1998
Neurostimulators Enrolled	50
Neurostimulators Currently Active in Study	40
Device Events	0
Cumulative Months of Follow-up	712

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	30
at 18 mo	100.0%	22

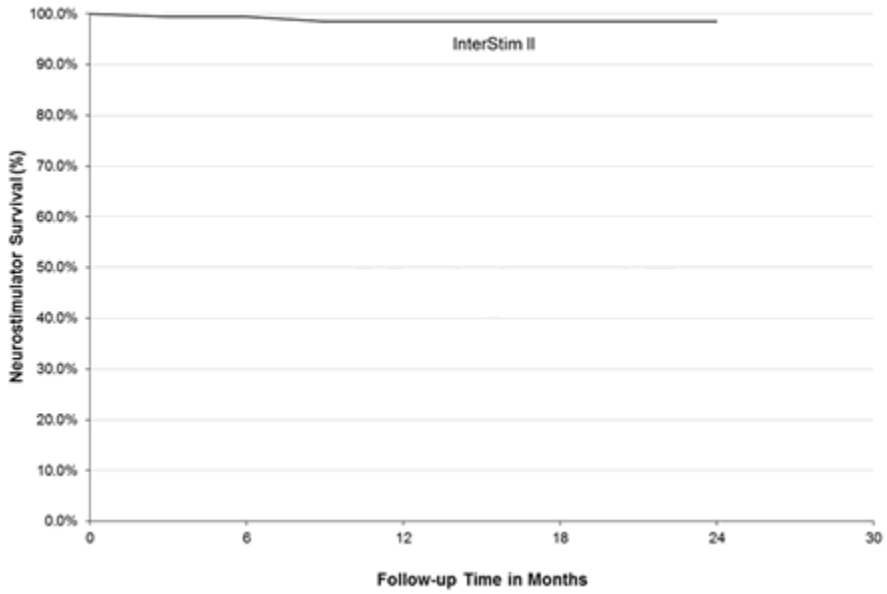
Model 3023 InterStim: Specifications

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.



View Larger Image

Neurostimulator Characteristics	
Model Name	InterStim II
FDA Approval Date	Jun 2006
Neurostimulators Enrolled	188
Neurostimulators Currently Active in Study	145
Device Events	2
Cumulative Months of Follow-up	2,130

Neurostimulator Event	Total

High impedance	1
Medical device complication[a]	1
Total Neurostimulator Events	**2**

[a] Device function could not be recovered after a fall

Time Interval	Survival	Effective Sample Size
1 yr	98.5%	90
2 yrs	98.5%	27

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

Currently, survival from neurostimulator-related events is not statistically significantly different between the neurostimulator models across all applicable follow-up time points.

Neurostimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events	Cumulative Months of Follow-up
InterStim	InterStim	Jul 1998	50	40	0	712
InterStim II	InterStim	Jun 2006	188	145	2	2,130

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs
InterStim	**100.0%** NA	-
InterStim II	**98.5%** (96.3%, 100.0%)	**98.5%** (96.3%, 100.0%)

Leads

From April 2010 to the report cut-off date of July 31, 2013, there were 238 leads followed in the Implantable Systems Performance Registry (ISPR).

A lead is a set of thin wires with a protective coating and electrodes near the tip. Almost eighty-three percent (82.8%) were Model 3889, 16.4% were Model 3093, and 0.8% were Model 3080. The aggregate prospective follow-up time for all leads was 2,880 months (240 years).

Lead Events

There were 14 product performance-related events with an underlying reported etiology related to the lead. Of these, 9 were high impedance, 3 were lead fracture, and 2 were low impedance. Of the 14 events, 13 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. A total of 13 leads had follow-up time cut-off due to product performance-related events. There were 46 leads censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, or patient lost to follow-up. The remaining 179 leads, which were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

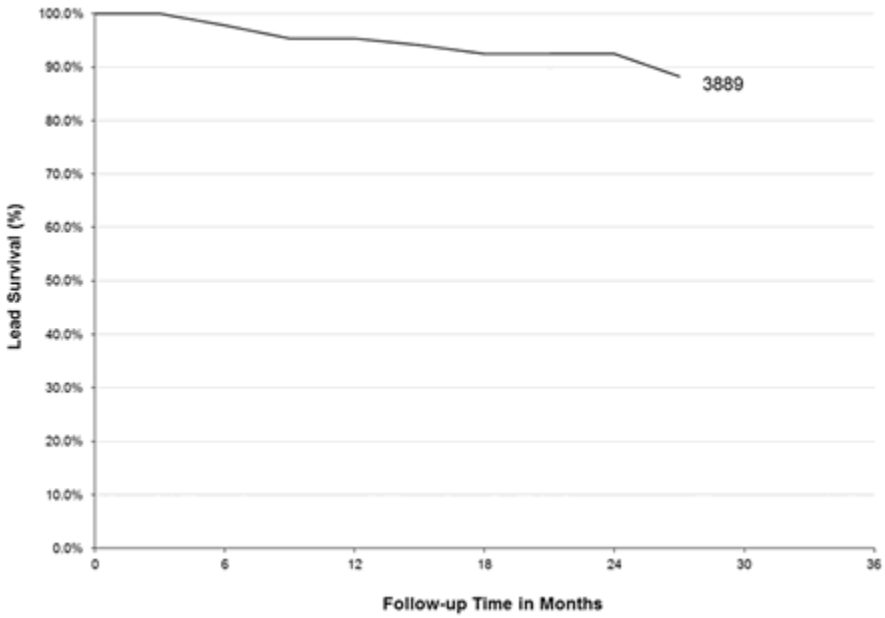
Lead Survival

The figure and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, the number of leads enrolled is insufficient to evaluate statistical differences between the lead models. Survival from lead-related events will continue to be monitored as more devices are enrolled.

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.



View Larger Image

Lead Characteristics	
Model Number	3889
FDA Approval Date	Sep 2002
Leads Enrolled	197
Leads Currently Active in Study	151
Device Events	12
Cumulative Months of Follow-up	2,410

Lead Event	Total
High impedance	8
Lead fracture	3
Low impedance	1
Total Lead Events	**12**

Time Interval	Survival	Effective Sample Size
1 yr	95.3%	96

2 yrs	92.5%	31
at 27 mo	88.2%	22

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

[Lead Survival Summary]

Currently, the number of leads enrolled is insufficient to evaluate statistical differences between the lead models. Survival from lead-related events will continue to be monitored as more devices are enrolled.

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	197	151	12	2,410

Device Survival Probability (95% Confidence Interval)			
Model Number	**Family**	**1 yr**	**2 yrs**
3889	**3889**	**95.3%** (91.5%, 99.1%)	**92.5%** (87.2%, 97.9%)

[a] There were 14 lead-related events reported to the ISPR, but only 12 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 was a subsequent event that did not affect the device survival estimates.

Extensions

From April 2010 to the report cut-off date of July 31, 2013, there were 52 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus the total neurostimulators (n=238) were due to the fact that not all patients required 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 733 months (61 years).

Extension Events

There were no product performance-related events with an underlying reported etiology related to the extension as of the cut-off date of July 31, 2013.

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. Twelve extensions were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, or patient lost to follow-up. The remaining 40 extensions that 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 tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval unless otherwise noted. A survival curve is not shown because fewer than 20 devices had at least 24 months of follow-up at the time of the report cut-off. As of the report cut-off date, Model 3095 extension had 100% survival from product performance-related events at 18 months of follow-up.

Choose a model Go

Model 3095: Survival from Extension Events

Extension Characteristics	
Model Number	3095
FDA Approval Date	Jul 1998
Extensions Enrolled	52
Extensions Currently Active in Study	40
Device Events	0
Cumulative Months of Follow-up	735

Extension Event	Total
Total Extension Events	0

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	28
at 18 mo	100.0%	21

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]

Currently, Model 3095 extension had 100% survival from product performance-related events at 18 months of follow-up.

Extension Characteristics						
Model Number	Family	FDA Approval Date	Extensions Enrolled	Extensions Currently Active in Study	Device Events	Cumulative Months of Follow-up
3095	3095	Jul 1998	52	40	0	735

Device Survival Probability (95% Confidence Interval)	
Model Number	1 yr
3095	**100.0%** NA

2013 Medtronic Product Performance Report: Data through July 31, 2013

Therapies

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

Resources

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

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services