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 2012 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 web-based 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 such as 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 to control symptoms.

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 track, 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, 15 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. Registry patients signed an ICF prior to enrollment. Each ISPR center followed its standard clinical practice for implanting including patient selection, implant methods, and post implant therapy management. Centers were considered 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 5th 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.

Included in this report for the first time are product survival estimates for our commercially available Deep Brain Stimulation and Sacral Neuromodulation systems. With the addition of this new data, we have tracked over 8,200 patients in our ongoing surveillance study: the Implantable Systems Performance Registry (ISPR). The Registry now includes over 23,000 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.

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Synergy Versitrel® neurostimulator	Pisces-Octad® lead
SynergyPlus+® neurostimulator	Pisces-Quad® lead
Restore® neurostimulator	Resume® TL lead
RestoreAdvanced® neurostimulator	Specify™ lead
RestoreUltra® neurostimulator	Soletra® neurostimulator
RestoreSensor® neurostimulator	Kinetra® neurostimulator
InterStim® neurostimulator	Activa® neurostimulator

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Therapies

- Deep Brain Stimulation for Movement Disorders
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Methodology

- Event Classification
- Device Survival Analyses
- Returned Product Analysis

Event Classification

In early versions of the protocol 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 recently expanded in order to capture additional adverse event data. Since April 2010, the protocol has required adverse event data collection as follows: adverse event information will be reported in the case of death or if the event is a result of:

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

Additionally since April 2010, the seriousness 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 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 the Medical Dictionary for Regulatory Activities (MedDRA).

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, i.e. 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. 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 Complaint Management requires additional information
- Center personnel initiated corrections or additions

Device Survival Analyses

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 at 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.

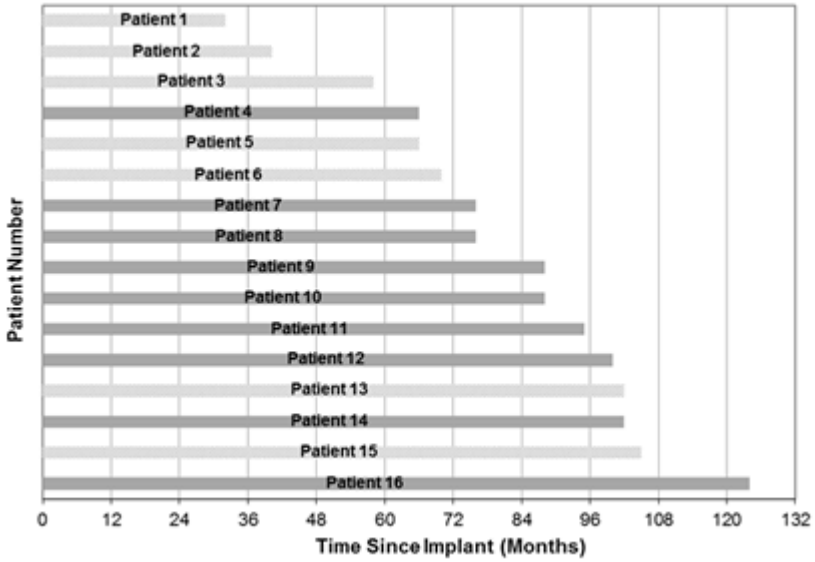

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Figure 1. Implant times for an individual device in 16 patients. Hashed bars indicate devices removed from service due to a product performance event. Solid bars indicate right censored devices.

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.

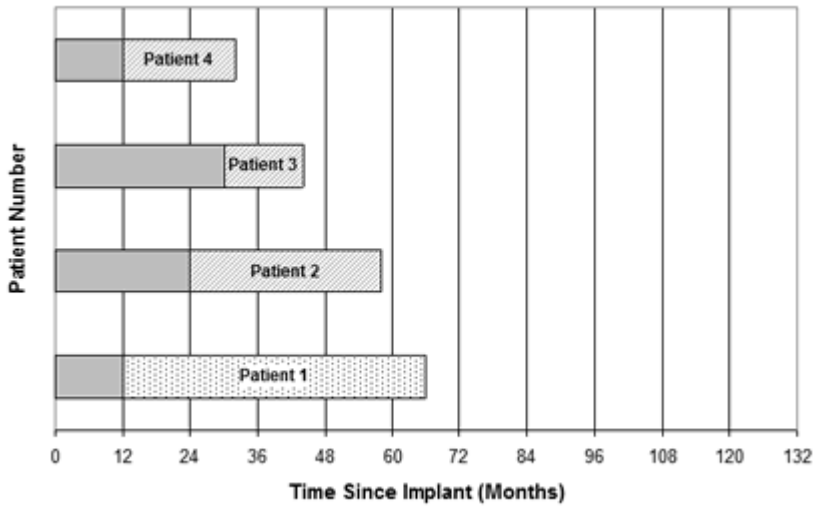

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Figure 2. Implant times for devices in 4 patients that were implanted prior to the device being enrolled in the ISPR. Solid bars represent the time from implant to enrollment in the ISPR, or the time interval that is left censored. Dotted bars represent 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 RPA establishes a root cause or finds no anomaly, results reported herein default to the RPA finding. The RPA finding is used even when there is no clinical complaint reported by the site in association with that device. 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 sites 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.

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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, 2012. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 5,362 total intrathecal drug delivery system patients enrolled in the ISPR through July 31, 2012. As indicated, 54.1% 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 25.8% for treatment of intractable spasticity, and 19.6% for treatment of malignant pain (pain related to cancer). For the most part, 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 = 19.6% versus U.S. population = 14.3%).

Primary IDD System Treatment Indications

Primary Treatment Indication[a]	N (Percent)
Pain	**3,951 (73.7%)**
Malignant pain	1,050 (19.6%)
Non-malignant pain	2,901 (54.1%)
Spasticity	**1,383 (25.8%)**
Combination	**17 (0.3%)**
Non-malignant pain & spasticity	17 (0.3%)
Not Specified	**11 (0.2%)**
Total Patients	**5,362**

[a] Refer to product labeling for approved indications

Malignant Pain Sub-Indications[a]	N
Location of Pain	
Spine/back	254
Abdominal/visceral	177
Pelvic	102
Thoracic	90
Extremity	87
Head/neck	46
Other	35
Unknown	439
Total Patients	**1,050**

[a] Patients may have more than one location of pain

Non-malignant Pain Sub-Indications	N
Back pain without leg pain	1,152
Back pain with leg pain	437
CRPS I[a]	96
Peripheral neuropathy	60
Joint pain/arthritis	40
A general neuropathic condition	30
Osteoporosis	19
CRPS II[a]	16
A general nociceptive condition	5
Other	100
Unknown	963
Total Patients	**2,918**

[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
Cerebral palsy	405
Multiple sclerosis	352
Spinal cord injury	174
Brain injury	110
Stroke	51
Other	34
Unknown	274

Total Patients	**1,400**

Event Summary

There were 3,492 events reported between August 2003 and July 31, 2012 in patients with intrathecal drug delivery systems. Twenty percent of these events (709/3,492) were categorized as product performance-related events and are presented graphically within this report. The 709 product performance events occurred in 566 of the 5,362 total patients (10.6%) enrolled. In addition, there were 1,587 non-product performance events and 1,196 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=5,362)
Catheter kink/occlusion	189	170	3.17%
Catheter dislodgment from intrathecal space	167	152	2.83%
Catheter break/cut	118	107	2.00%
Motor stall	52	52	0.97%
Medical device complication[c]	31	31	0.58%
Catheter related complication[d]	27	24	0.45%
Unable to enter/withdraw from catheter access port	20	20	0.37%

Intrathecal Drug Delivery System Product Performance Events			
Catheter disconnection at pump	17	17	0.32%
Catheter leakage	15	15	0.28%
Catheter disconnection at distal connection	14	14	0.26%
Motor gear corrosion	13	13	0.24%
Reduced battery performance	13	13	0.24%
Pump underinfusion	12	12	0.22%
Catheter blockage	3	2	0.04%
Drug-related cracked pump tube	3	3	0.06%
Pump no infusion	3	3	0.06%
Arachnoiditis[e]	1	1	0.02%
Device malfunction[f]	1	1	0.02%
Device protrusion[g]	1	1	0.02%
Gait disturbance[e]	1	1	0.02%
Hole in pump tube	1	1	0.02%
Implant site	1	1	0.02%

Intrathecal Drug Delivery System Product Performance Events			
fibrosis[h]			
Muscle spasticity[e]	1	1	0.02%
Pain[e]	1	1	0.02%
Pump inversion[i]	1	1	0.02%
Resonator cracked – alarm anomaly	1	1	0.02%
Unable to withdraw fluid from reservoir	1	1	0.02%
Not coded[j]	1	1	0.02%
Total	**709**	**566**	**10.56%**

[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 14 events reported as pump connector break or cut, 4 events reported as inconsistency in pump reservoir volume, 3 events reported as pump malfunction, 1 pump unable to interrogate/program, 1 possible corrosion of pump, 1 telemetry stopped secondary to error code, 1 leak at pump connector, 1 suspected catheter issue, 1 loop in catheter, 1 catheter wrapped around pump, 1 sutureless connector failure, 1 unable to completely fill pump, and 1 under medicated event attributed to the pump

[d] Includes 14 events reported as catheter malfunction, 4 difficulty aspirating catheter, 3 coiled catheters, 1 suspected catheter failure, 1 catheter wear, 1 patency issue with catheter, 1 catheter aneurysm, 1 torsion of the catheter preventing side port aspiration, and 1 failed catheter

[e] Event was reported by the physician as being caused by the catheter, but no device event was provided at the time of data cut-off

[f] Physician reported personal therapy manager (PTM) malfunctioning

[g] Catheter broke through the skin

[h] Unable to aspirate catheter, suspected catheter tip fibrosis

[i] Pump broke free from anchors

[j] Reported as inflammatory sheath, catheter

A total of 589 (83.1%) of the 709 product performance events were related to the catheter, 110 (15.5%) were related to the pump, 3 (0.4%) were related to medication, 3 (0.4%) were reported as “other” etiology, 2 (0.3%) were related to incisional site/device tract, 1 (0.1%) was related to both the pump and catheter, and 1 (0.1%) was related to a Personal Therapy Manager (myPTM).

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events and device events, excluding deaths)	
Event[a]	**Number of Non-Product Performance Events**
Pump end of service (EOS)	662
Implant site infection	133
Pump inversion	62
Therapeutic product ineffective	62
Implant site pain	60
Pain	48
Drug toxicity	39
Wound dehiscence	31
Implant site effusion	30
Drug withdrawal syndrome	27
Implant site erosion	25
Cerebrospinal fluid leakage	24
Pump migration	23
Hypoaesthesia	19
Muscle spasticity	15
Somnolence	15
Medical device complication[b]	13
No anomaly found by RPA[c]	13
Wound infection	12
Therapy non-responder	11

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events and device events, excluding deaths)	
Implant site fibrosis	10
Infection	10
Inflammatory mass (confirmed)	10
Overdose	10
Meningitis	9
Sedation	8
Inflammatory mass (possible)	7
Lumbar puncture headache	6
Mental status changes	6
Nausea	6
Asthenia	5
Impaired Healing	5
Implant site erythema	5
Implant site haematoma	5
Implant site inflammation	5
Oedema peripheral	5
Seroma	5
Other[d]	146
Total Events	**1,587**

[a] MedDRA Preferred Term

[b] Includes 3 malpositioned catheters, 3 events reported as pump dislodged from sutures, 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 patient unable to adequately dose with baclofen not caused by the pump, 1 scar tissue contorting the catheter, 1 possible corrosion of the catheter due to drug concentration, 1 intraspinal infusate contamination, and 1 elective replacement indicator occurrence.

[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] Composed of 101 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=3).

There were 1,196 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 67.0% of patient deaths occurred in patients receiving therapy for malignant pain, 24.4% for non-malignant pain, and 8.5% for intractable spasticity.

Deaths by Primary Indication

Primary Indication	Count (%)
Malignant pain	801 (67.0%)
Non-malignant pain	292 (24.4%)
Spasticity	102 (8.5%)
Not specified	1 (0.1%)
Total	**1,196 (100.0%)**

Pumps

From August 2003 to the report cut-off date of July 31, 2012, 6250 pumps were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=5,362) 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 r11egistry were either SynchroMed II (81.0%) or SynchroMed EL (18.9%), and a small number of pumps were SynchroMed Classic (0.1%). The aggregate prospective follow-up time for all pumps was 159,375 months (13,281 years).

Pump Events

There were 111 product performance-related events with an underlying reported etiology related to pump function. Of these, 106 were the first event attributable to an enrolled pump. The current return rate of pumps to Medtronic Returned Product Analysis (RPA) was 578/2,442 (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. Sixty-four of the 111 pumps with malfunction events were analyzed by Medtronic RPA: 51 pumps failed due to non-battery-related issues (33 motor stalls, 13 motor gear corrosion, 3 cracked pump tubes, 1 hole in pump tube, and 1 cracked resonator), and 13 failed due to reduced battery performance. The remaining 47 pump events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 18 events due to physician-reported motor stalls, 11 events due to

underinfusion, 11 events due to a medical device complication, 4 events due to an inability to enter/withdraw from the catheter access port, and 3 events due to no infusion. Of the 64 pumps with RPA-confirmed malfunction events, 21 were originally reported as non-product performance-related battery depletions by the site. A total of 69 (51 RPA confirmed and 18 physician reported motor stalls) pumps failed due to non-battery related issues. Of these, 49 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 20 pumps, the complete drug history and exposure to admixtures could not be confirmed.

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 106 pumps which were cut-off due to product performance-related events, there were 3,996 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 2,148 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.

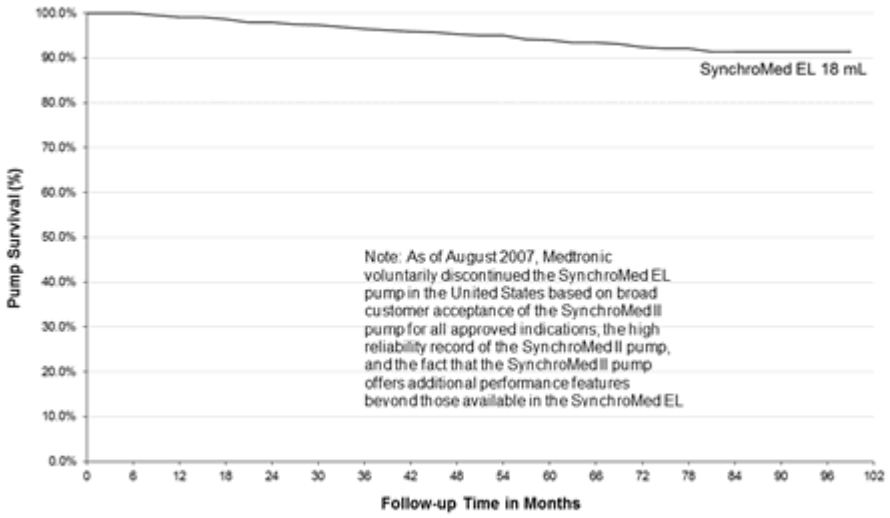
Pump Survival

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.



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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	1,150
Pumps Currently Active in Study	12
Device Events	39
Cumulative Months of Follow-up	36,115

Pump Event	**Total**
Motor stall	15
Motor gear corrosion	13
Pump underinfusion	7
Medical device complication[a]	1
Drug-related cracked pump tube	3

Total Pump Events	**39**

[a] Reported as unable to interrogate/program pump

Time Interval	Survival	Effective Sample Size
1 yr	99.0%	215
2 yrs	97.9%	444
3 yrs	96.4%	647
4 yrs	95.3%	663
5 yrs	94.0%	521
6 yrs	92.5%	286
7 yrs	91.4%	122
8 yrs	91.4%	41
at 99 mo	91.4%	30

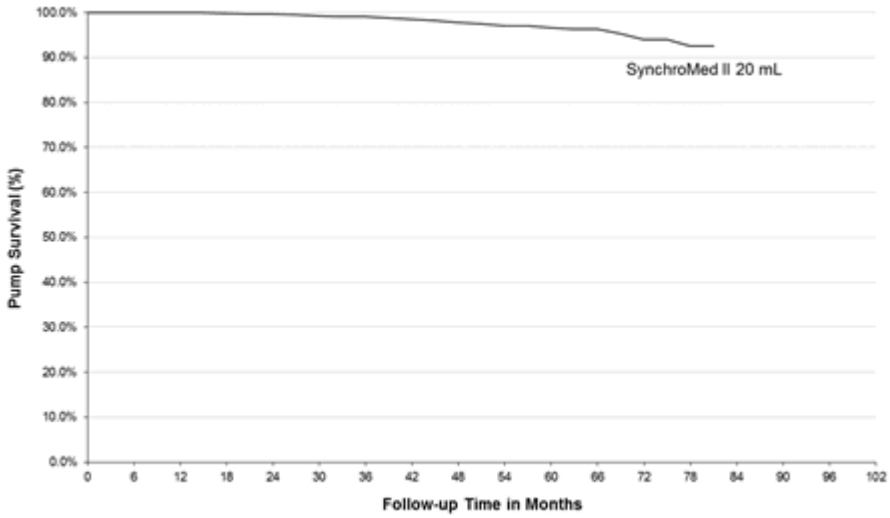
Model 8627-18 SynchroMed EL 18mL: Specifications

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.



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Pump Characteristics	
Model Name	SynchroMed II (20 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	1,918
Pumps Currently Active in Study	965
Device Events	28
Cumulative Months of Follow-up	53,078

Pump Event	Total
Motor stall	13
Reduced battery performance	6
Medical device complication[a]	3
Unable to enter/withdraw from catheter access port	3
Pump no infusion	1
Hole in pump tube	1
Resonator cracked – alarm anomaly	1

Total Pump Events	**28**

[a] Includes 1 event reported as pump malfunction, 1 inconsistent pump reservoir volume, and 1 discrepancy in reservoir volume

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	1,276
2 yrs	99.6%	965
3 yrs	99.0%	701
4 yrs	97.8%	486
5 yrs	96.7%	291
6 yrs	94.0%	145
at 81 mo	92.6%	25

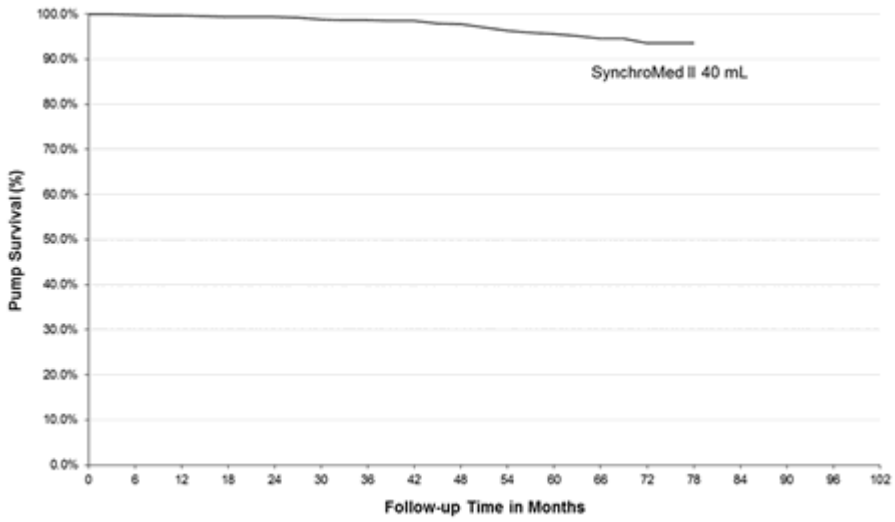
Model 8637-20 SynchroMed II 20mL: Specifications

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.



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Pump Characteristics	
Model Name	SynchroMed II (40 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	3,144
Pumps Currently Active in Study	1,112
Device Events	38
Cumulative Months of Follow-up	65,524

Pump Event	Total
Motor stall	20
Reduced battery performance	6
Medical device complication[a]	6
Pump underinfusion	3
Pump no infusion	2
Unable to enter/withdraw from catheter access port	1
Total Pump Events	**38**

[a] Includes 2 events reported as pump malfunction, 1 possible corrosion of the pump due to drug concentration,

1 reservoir volume discrepancy,1 unable to completely fill pump, and 1 under medicated event attributed to the pump

Time Interval	Survival	Effective Sample Size
1 yr	99.7%	1,709
2 yrs	99.3%	1,205
3 yrs	98.6%	810
4 yrs	97.7%	489
5 yrs	95.6%	257
6 yrs	93.5%	98
at 78 mo	93.5%	43

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	1,150	12	39	36,115
SynchroMed II (20 mL)	Sep 2003	1,918	965	28	53,078
SynchroMed II (40 mL)	Sep 2003	3,144	1,112	38	65,524

[a] There were a total of 111 pump-related events reported to the ISPR, but only 105 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), were subsequent events that did not affect the device survival estimates, or were events that were not able to be associated with a specific pump (eg, the event had a pump etiology, but no pump serial number was specified).

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%)	**96.4%** (94.4%, 98.4%)	**95.3%** (93.2%, 97.4%)
SynchroMed II (20 mL)	**100.0%** N/A	**99.6%** (99.2%, 100.0%)	**99.0%** (98.3%, 99.7%)	**97.8%** (96.6%, 98.9%)
SynchroMed II (40 mL)	**99.7%** (99.5%, 99.9%)	**99.3%** (98.9%, 99.7%)	**98.6%** (97.9%, 99.3%)	**97.7%** (96.7%, 98.8%)

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

Model Name	5 yrs	6 yrs	7 yrs	8 yrs
SynchroMed EL (18 mL)	**94.0%** (91.7%, 96.3%)	**92.5%** (89.9%, 95.0%)	**91.4%** (88.5%, 94.4%)	**91.4%** (88.5%, 94.4%)
SynchroMed II (20 mL)	**96.7%** (95.1%, 98.2%)	**94.0%** (91.1%, 96.8%)	-	-
SynchroMed II (40 mL)	**95.6%** (93.7%, 97.4%)	**93.5%** (90.5%, 96.6%)	-	-

Catheters

From August 2003 to the report cut-off date of July 31, 2012, 5922 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=6,250) 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 167,593 months (13,966 years).

A total of 46.0% of the catheters were Model 8709 catheters, 15.2% were Model 8709SC catheters, 10.3% were Model 8711 catheters, 8.2% were Model 8731 catheters, 3.1% were Model 8703W catheters, 2.3% were Model 8731SC catheters, and 0.7% were other or unspecified catheters. An additional 2.2% were considered catheters revised as designed, (8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); 6.9% 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 5.1% 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 590 product performance events reported related to the catheter. Of these events, the majority were catheter kink or occlusion (n=188), catheter dislodgement (n=164), or break or cut in the catheter (n=117). Of the 590 events, 536 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. In addition to the 536 catheters which were cut-off due to product performance-related events, there were 3,268 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 2,118 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. Currently at 2 and 3 years of follow-up, the 95% confidence interval for grafted not as designed catheters does not overlap with Models 8709, 8731, 8731SC, and revised as designed catheters. These differences continue to be observed at 4 years of follow-up between grafted not as designed catheters and 8709 and 8731 catheters. In addition, at 3 and 4 years of follow-up, the 95% confidence interval for revised not as designed catheters does not overlap with Model 8731.

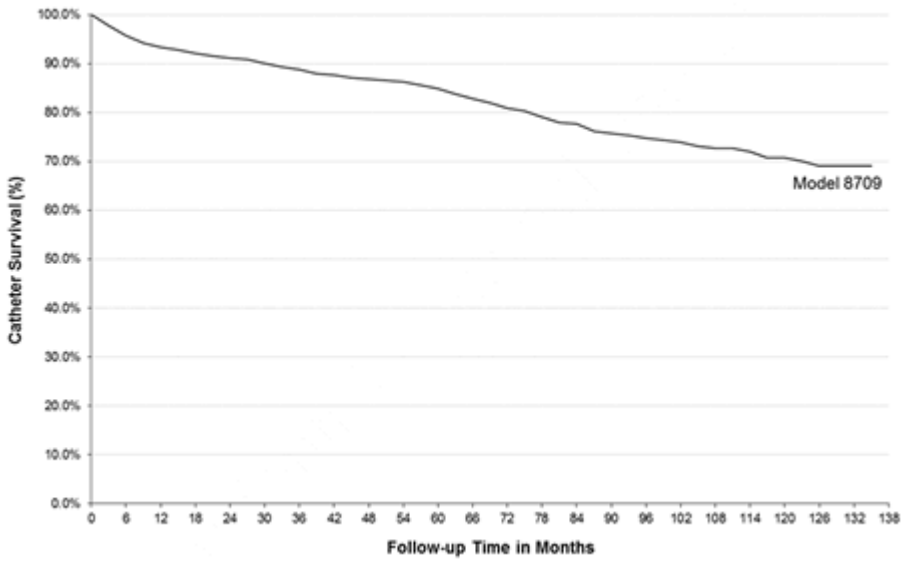
The survival estimates suggest that the survival of catheters revised not as designed (Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit) and catheters grafted not as designed (those catheters repaired or spliced using non-Medtronic components, or Medtronic 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, including catheters revised as designed. 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. Explanations for this finding remain speculative, and include small sample size and a relatively brief observation period compared to other catheter models. Other non-statistical explanations may include device-related causes and/or system troubleshooting errors. Another possible explanation is that intrathecal drug and cerebrospinal fluid mixing or flow anomaly existed that was not corrected by assembly of a grafted not as designed catheter system. Medtronic will continue to monitor and review the performance and survival of catheters revised not as designed and catheters grafted not as designed. 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	2,727
Catheters Currently Active in Study	663
Device Events	228

Cumulative Months of Follow-up	73,179

Catheter Events	Total
Catheter dislodgment from intrathecal space	69
Catheter kink/occlusion	65
Catheter break/cut	52
Medical device complication[a]	11
Catheter disconnection at pump	9
Catheter disconnection at distal connection	6
Catheter leakage	5
Unable to enter/withdraw from catheter access port	5
Catheter related complication[b]	3
Arachnoiditis[c]	1
Catheter blockage	1
Pain[c]	1
Total Catheter Events	**228**

[a] Includes 10 events reported as pump connector break/cut and 1 event reported as reservoir volume discrepancy

[b] Includes 1 event reported as difficulty aspirating catheter, 1 catheter aneurysm, and 1 coiled catheter

[c] Event was reported by the physician as being caused by the catheter, but no device event was provided at the time of data cut-off

Time Interval	Survival	Effective Sample Size
1 yr	93.3%	1,041
2 yrs	91.1%	930
3 yrs	88.8%	878
4 yrs	86.8%	756

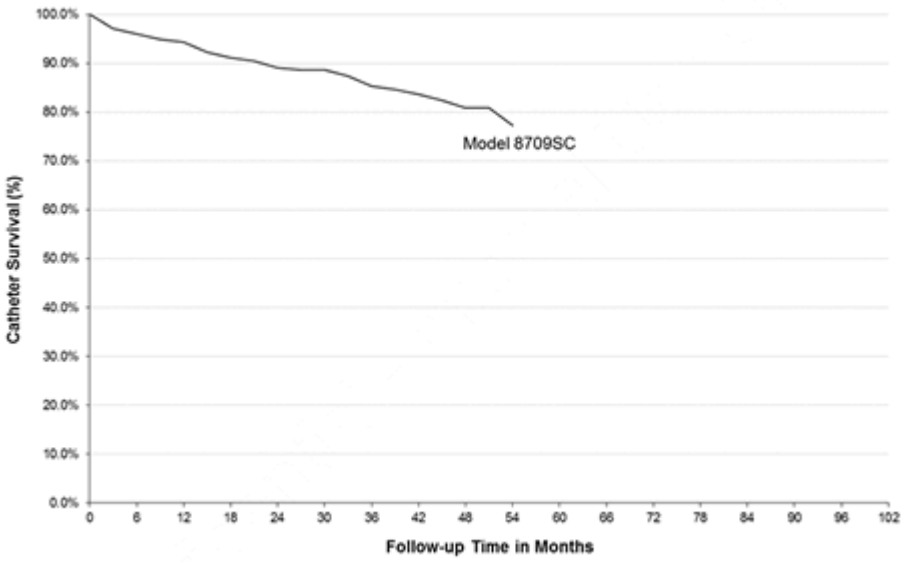
5 yrs	84.9%	610
6 yrs	80.9%	452
7 yrs	77.8%	322
8 yrs	74.7%	233
9 yrs	72.6%	148
10 yrs	70.8%	103
11 yrs	69.1%	54
at 135 mo	69.1%	44

Model 8709: Specifications

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

Model 8709SC: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8709SC
FDA Approval Date	Mar 2006
Catheters Enrolled	898
Catheters Currently Active in Study	501
Device Events	68
Cumulative Months of Follow-up	13,691

Catheter Events	Total
Catheter dislodgment from intrathecal space	22
Catheter kink/occlusion	15
Catheter break/cut	15
Catheter related complication[a]	4
Medical device complication[b]	4
Catheter disconnection at distal connection	2
Catheter leakage	2

Unable to enter/withdraw from catheter access port	2
Catheter disconnection at pump	1
Unable to withdraw fluid from reservoir	1
Total Catheter Events	**68**

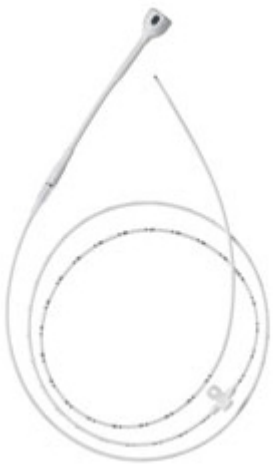
[a] Includes 3 events reported as catheter malfunction and 1 coiled catheter

[b] Includes 1 event reported as leak at pump connector, 1 catheter wrapped around pump, 1 loop in catheter, and 1 sutureless connector failure

Time Interval	Survival	Effective Sample Size
1 yr	94.3%	464
2 yrs	89.1%	246
3 yrs	85.4%	127
4 yrs	80.9%	54
at 54 mo	77.3%	22

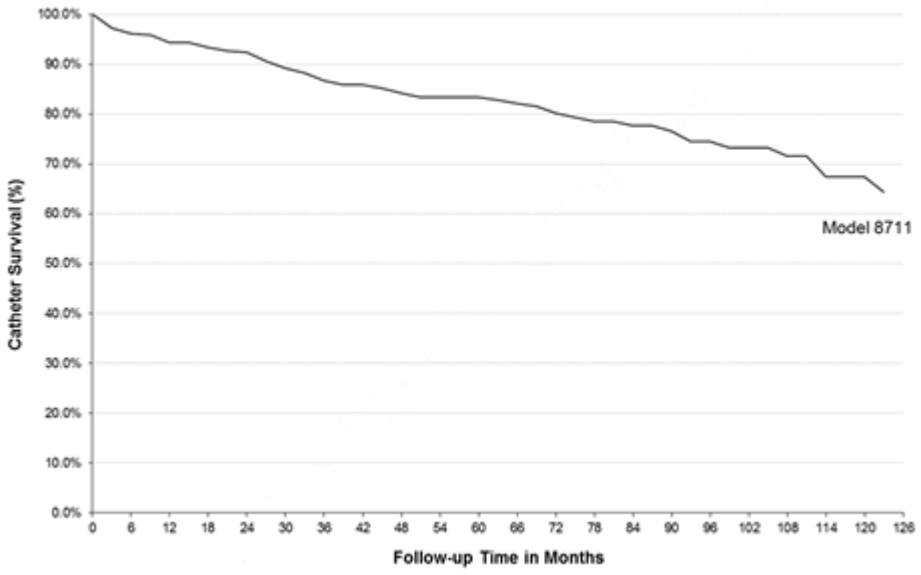
Model 8709SC: Specifications

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



Model 8711: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8711
FDA Approval Date	Oct 1999
Catheters Enrolled	610
Catheters Currently Active in Study	218
Device Events	68
Cumulative Months of Follow-up	19,896

Catheter Events	Total
Catheter kink/occlusion	26
Catheter break/cut	13
Catheter dislodgment from intrathecal space	12
Catheter related complication[a]	6
Unable to enter/withdraw from catheter access port	5
Catheter disconnection at pump	2
Catheter blockage	1

Medical device complication[b]	1
Gait disturbance[c]	1
Muscle spasticity[c]	1
Total Catheter Events	**68**

[a] Includes 5 events reported as catheter malfunction and 1 difficulty aspirating catheter

[b] Reported as pump connector break/cut

[c] Event was reported by the physician as being caused by the catheter, but no device event was provided at the time of data cut-off

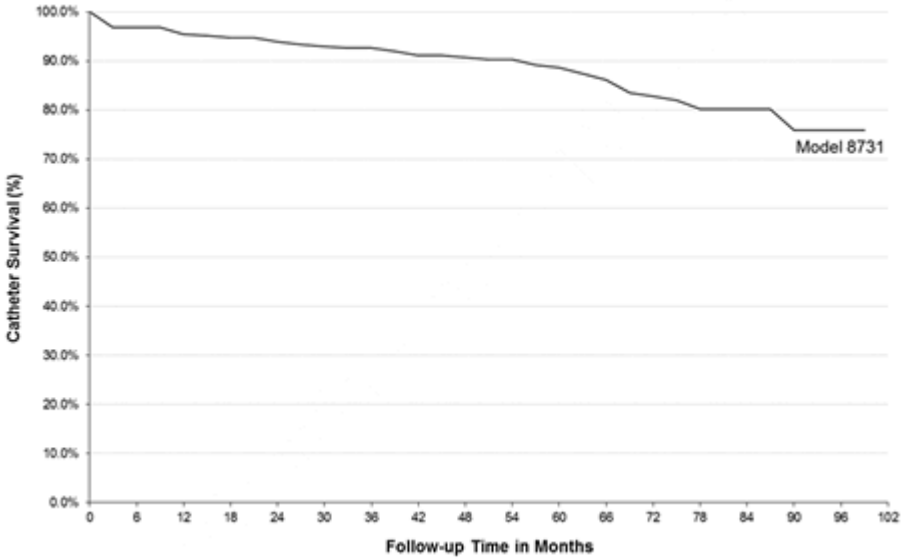
Time Interval	Survival	Effective Sample Size
1 yr	94.3%	312
2 yrs	92.4%	276
3 yrs	86.7%	238
4 yrs	84.3%	197
5 yrs	83.3%	162
6 yrs	80.1%	115
7 yrs	77.7%	86
8 yrs	74.5%	67
9 yrs	71.6%	43
10 yrs	67.4%	25
at 123 mo	64.3%	21

Model 8711: Specifications

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

Model 8731: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8731
FDA Approval Date	Oct 2002
Catheters Enrolled	487
Catheters Currently Active in Study	120
Device Events	43
Cumulative Months of Follow-up	18,205

Catheter Events	Total
Catheter kink/occlusion	18
Catheter dislodgment from intrathecal space	17
Catheter related complication[a]	3
Catheter break/cut	2
Catheter disconnection at distal connection	2
Medical device complication[b]	1
Total Catheter Events	**43**

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

[b] Reported as pump connector break/cut

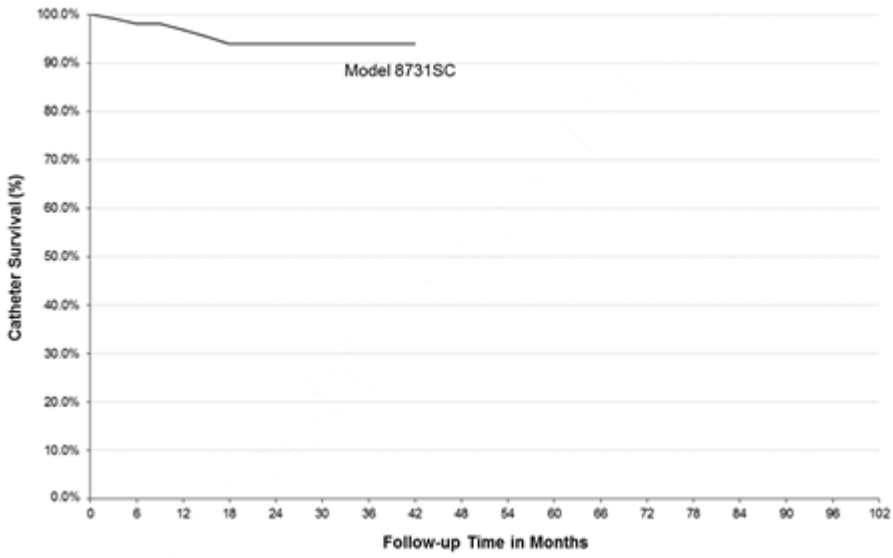
Time Interval	Survival	Effective Sample Size
1 yr	95.5%	290
2 yrs	93.9%	315
3 yrs	92.7%	273
4 yrs	90.8%	213
5 yrs	88.7%	155
6 yrs	82.8%	115
7 yrs	80.2%	59
8 yrs	75.8%	26
at 99 mo	75.8%	20

Model 8731: Specifications

Total Length	104.1 cm
Outer diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed tip, radiopaque, with 6 side holes
Catheter Volume	2.22µl/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.



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Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	136
Catheters Currently Active in Study	74

Device Events	5
Cumulative Months of Follow-up	2,558

Catheter Events	Total
Catheter kink/occlusion	2
Catheter dislodgment from intrathecal space	2
Catheter disconnection at distal connection	1
Total Catheter Events	**5**

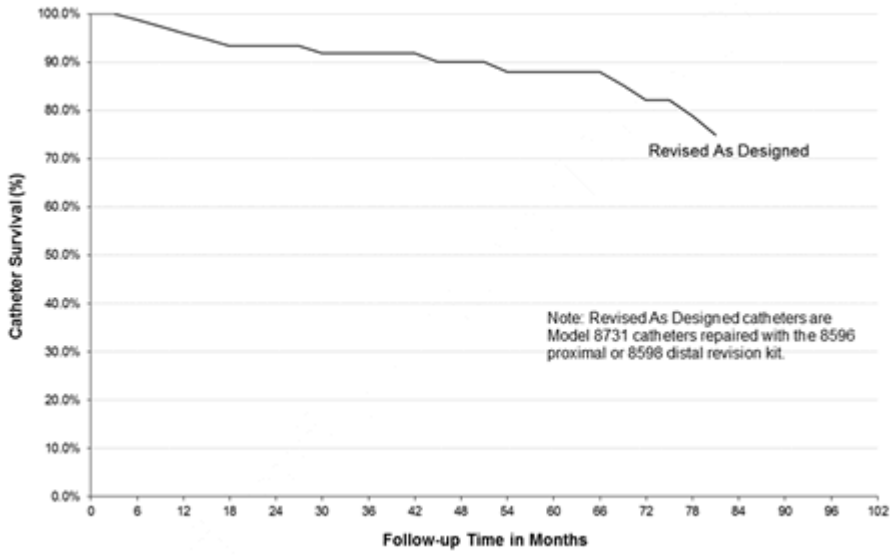
Time Interval	Survival	Effective Sample Size
1 yr	96.9%	77
2 yrs	94.0%	50
3 yrs	94.0%	31
at 42 mo	94.0%	21

Model 8731SC: Specifications

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

Revised As Designed: Survival from Catheter Events

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



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Note: Revised 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	129
Catheters Currently Active in Study	40
Device Events	13
Cumulative Months of Follow-up	4,329

Catheter Events	Total
Catheter kink/occlusion	9
Catheter dislodgment from intrathecal space	2
Catheter break/cut	1
Catheter related complication[a]	1
Total Catheter Events	**13**

[a] Reported as catheter malfunction

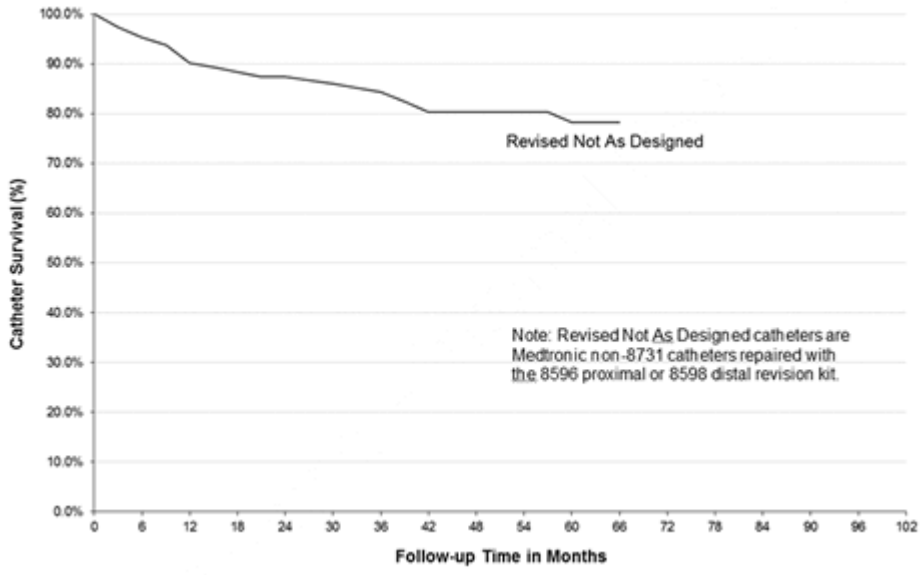
Time Interval	Survival	Effective Sample Size
1 yr	96.1%	74
2 yrs	93.4%	63
3 yrs	91.8%	55
4 yrs	90.1%	48
5 yrs	88.0%	38
6 yrs	82.2%	28
at 81 mo	74.9%	20

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.



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

Catheter Characteristics

Model Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	409
Catheters Currently Active in Study	233
Device Events	46
Cumulative Months of Follow-up	8,550

Catheter Events	**Total**
Catheter kink/occlusion	14
Catheter break/cut	11
Catheter dislodgment from intrathecal space	10
Catheter disconnection at distal connection	3
Catheter related complication[a]	2
Unable to enter/withdraw from catheter access port	2
Catheter leakage	1
Implant site fibrosis[b]	1
Pump inversion[c]	1
Pump underinfusion[d]	1
Total Catheter Events	**46**

[a] Includes 1 event reported as catheter malfunction and 1 inability to aspirate catheter
[b] Reported as unable to aspirate catheter, suspected catheter tip fibrosis
[c] Reported as flipping pump caused catheter to coil and knot
[d] Reported as reservoir volume discrepancy

Time Interval	**Survival**	**Effective Sample Size**
1 yr	90.2%	238

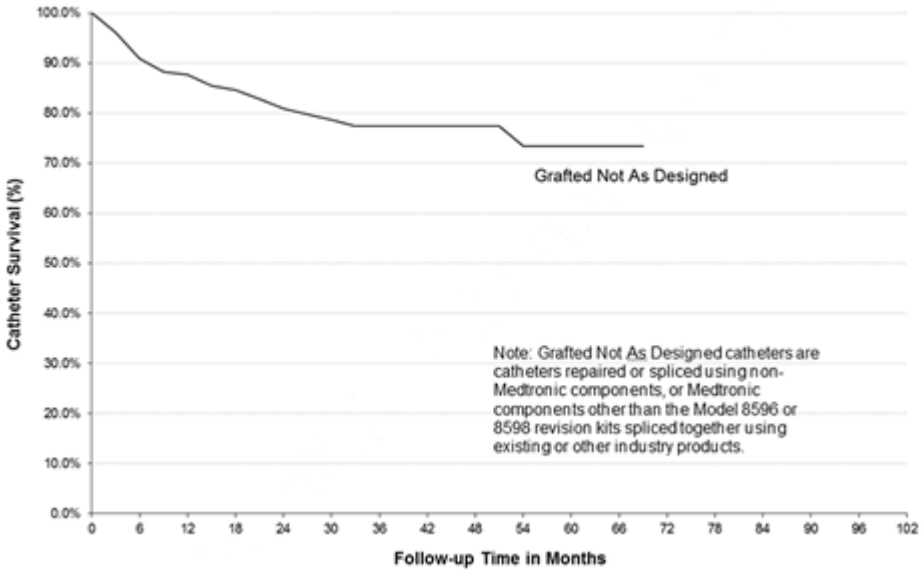
2 yrs	87.4%	152
3 yrs	84.4%	97
4 yrs	80.3%	59
5 yrs	78.3%	39
at 66 mo	78.3%	26

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 Catheters: Survival from Catheter Events

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



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Note: 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	301
Catheters Currently Active in Study	159
Device Events	44
Cumulative Months of Follow-up	6,065

Catheter Events	**Total**
Catheter dislodgment from intrathecal space	20
Catheter kink/occlusion	8
Catheter break/cut	6
Catheter leakage	4
Catheter related complication[a]	2
Unable to enter/withdraw from catheter access port	2
Catheter disconnection at pump	1
Medical device complication[b]	1
Total Catheter Events	**44**

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

[b] Reported as pump connector break/cut

Time Interval	**Survival**	**Effective Sample Size**
1 yr	87.7%	145
2 yrs	80.9%	84
3 yrs	77.4%	58
4 yrs	77.4%	43
5 yrs	73.4%	32
at 69 mo	73.4%	22

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 2 and 3 years of follow-up, the 95% confidence interval for grafted not as designed catheters does not overlap with Models 8709, 8731, 8731SC, and revised as designed catheters. These differences continue to be observed at 4 years of follow-up between grafted not as designed catheters and 8709 and 8731 catheters. In addition, at 3 and 4 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	2,727	663	228	73,179
8709SC	Mar 2006	898	501	68	13,691
8711	Oct 1999	610	218	68	19,896
8731	Oct 2002	487	120	43	18,205
8731SC	Mar 2006	136	74	5	2,558
Revised As Designed	Oct 2002	129	40	13	4,329
Revised Not As Designed	NA	409	233	46	8,550
Grafted Not As Designed	NA	301	159	44	6,065

[a] There were a total of 590 catheter-related events reported to the ISPR, but only 515 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=21) 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	**93.3%** (91.9%, 94.7%)	**91.1%** (89.5%, 92.7%)	**88.8%** (87.0%, 90.7%)	**86.8%** (84.8%, 88.9%)	**84.9%** (82.6%, 87.1%)
8709SC	**94.3%** (92.5%, 96.2%)	**89.1%** (86.1%, 92.0%)	**85.4%** (81.3%, 89.5%)	**80.9%** (75.0%, 86.9%	-
8711	**94.3%** (91.9%, 96.8%)	**92.4%** (89.5%, 95.2%)	**86.7%** (82.9%, 90.5%)	**84.3%** (80.1%, 88.5%)	**83.3%** (79.0%, 87.7%)
8731	**95.5%** (92.7%, 98.2%)	**93.9%** (90.9%, 96.9%)	**92.7%** (89.5%, 95.9%)	**90.8%** (87.2%, 94.3%)	**88.7%** (84.6%, 92.7%)
8731SC	**96.9%** (93.3%, 100.0%)	**94.0%** (88.6%, 99.3%)	**94.0%** (88.6%, 99.3%)	-	-
Revised As Designed	**96.1%** (91.6%, 100.0%)	**93.4%** (87.7%, 99.1%)	**91.8%** (85.4%, 98.2%)	**90.1%** (82.9%, 97.3%)	**88.0%** (79.9%, 96.1%)
Revised Not As Designed	**90.2%** (86.7%, 93.8%)	**87.4%** (83.2%, 91.5%)	**84.4%** (79.4%, 89.3%)	**80.3%** (74.2%, 86.5%)	**78.3%** (71.1%, 85.5%)
Grafted Not As Designed	**87.7%** (83.2%, 92.2%)	**80.9%** (74.6%, 87.1%)	**77.4%** (70.2%, 84.6%)	**77.4%** (70.2%, 84.6%)	-

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	**80.9%** (78.3%, 83.6%)	**77.8%** (74.7%, 80.8%)	**74.7%** (71.3%, 78.1%)	**72.6%** (68.8%, 76.4%)	**70.8%** (66.5%, 75.0%)	**69.1%** (64.3%, 73.9%)
8709SC	-	-	-	-	-	-
8711	**80.1%** (75.1%, 85.2%)	**77.7%** (72.0%, 83.3%)	**74.5%** (68.0%, 81.0%)	**71.6%** (64.1%, 79.1%)	**67.4%** (58.4%, 76.5%)	-
8731	**82.8%** (77.5%,	**80.2%** (74.2%,	**75.8%** (67.6%,	-	-	-

	88.2%)	86.2%)	84.1%)			
8731SC	-	-	-	-	-	-
Revised As Designed	**82.2%** (71.2%, 93.2%)	-	-	-	-	-
Revised Not As Designed	-	-	-	-	-	-
Grafted Not As Designed	-	-	-	-	-	-

2012 Medtronic Product Performance Report: Data through July 31, 2012

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Intrathecal 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, 2012. Forty-four centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Patients

Of the 2,210 total spinal cord stimulation patients enrolled in the ISPR, 44.8% were implanted for the treatment of other pain indications, 43.3% were implanted for the treatment of failed back surgery syndrome, 11.6% 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	**990 (44.8%)**
Radicular pain syndrome	231 (10.5%)
Degenerative disc disease	70 (3.2%)
Cervical pain	8 (0.4%)
Diabetic neuropathy	6 (0.3%)
Post herpetic neuralgia	4 (0.2%)
Epidural fibrosis	2 (0.1%)
Facial pain	2 (0.1%)
Post herniorrhaphy pain	1 (0%)
Other chronic pain	593 (26.8%)
Other	69 (3.1%)
Failed Back Surgery Syndrome	**956 (43.3%)**
Postlaminectomy pain	450 (20.4%)
Failed back syndrome (FBS)	343 (15.5%)
Combination back and leg pain	72 (3.3%)
Multiple back operations	64 (2.9%)

Arachnoiditis	21 (1%)
Unsuccessful disc surgery	6 (0.3%)
CRPS	**256 (11.6%)**
CRPS I	196 (8.9%)
CRPS II	60 (2.7%)
Not Specified	**8 (0.4%)**
Total Patients	**2,210**

[a] Refer to product labeling for approved indications.

Event Summary

There were 1,317 events reported between June 2004 and July 31, 2012 in patients with spinal cord stimulation systems. Thirty-four percent of these events (447/1,317) were categorized as product performance-related and are presented graphically within this report. The 447 product performance events occurred in 219 of the 2,210 total patients (9.9%) enrolled. In addition, there were 805 non-product performance events and 65 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=2,210)**
Lead migration/dislodgment	241	134	6.06%
High impedance	48	21	0.95%
Undesirable change in stimulation[c]	46	26	1.18%
Lead fracture	43	29	1.31%

Neurostimulation System Product Performance Events			
Medical device complication[d]	23	12	0.54%
Extension fracture	13	8	0.36%
Recharging unable to recharge[e]	9	9	0.41%
Device malfunction[f]	6	5	0.23%
Low impedance	5	2	0.09%
Device failure[g]	3	3	0.14%
Impedance NOS	3	3	0.14%
Change in sensation of stimulation[h]	2	1	0.05%
Therapeutic productive ineffective[i]	2	1	0.05%
Back disorder[j]	1	1	0.05%
Broken bond wire	1	1	0.05%
Paraesthesia[k]	1	1	0.05%
Total	**447**	**219**	**9.90%**

[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=3) or lead (n=43)

[d] Includes 6 events reported as electrodes out of range, 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, 1 lead with pinched outer insulation, 1 separation of the material on the end of the neuroelectrode, 1 broken recharger strap, 1 broken recharge belt, 1 antenna was not working, 1 lead damaged contacts, and 1 unknown problem with an extension

[e] Patient was unable to recharge due to device related issue (includes 6 issues with external devices)

[f] Includes 2 events reported as impedance not measurable, 1 antenna malfunction, 1 increased lead impedance, 1 malfunction of the spinal cord stimulation system, 1 device malfunction: problems with reprogramming

[g] Includes 1 broken jack and antenna, 1 failure of lead electrodes, 1 extension failure

[h] Includes 2 events reported as lead lost all capability of stimulation

[i] Includes 2 events reported as loss of paraesthesia to bilateral lower extremities due to a lead related issue.

[j] Physician reported they were unable to program SCS leads due to pressure in back when device was on

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

A total of 406 (90.8%) of the 447 product performance events were related to the lead, 16 (3.6%) were related to the extension, 11 (2.5%) were related to an external device, 7 (1.6%) were related to the stimulator, 3 (0.7%) were related to programming/stimulation, 2 (0.4%) were related to recharging process, 1 (0.2%) was related to incisional site/device tract, and 1 (0.2%) was related to other etiology.

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

Events[a]	Number of Non-Product Performance Events
Neurostimulator expected battery depletion	270
Implant site pain	93
Therapy non-responder	61
Implant site infection	56
Undesirable change in stimulation[b]	40
Recharging unable to recharge[c]	35
Therapeutic product ineffective	34
Change in sensation of stimulation[b]	32
Pain	30
Neurostimulator migration	20
Implant site erosion	11
Implant site erythema	11
Implant site effusion	9
Medical device complication[d]	8

Neurostimulation System Non-Product Performance Events (including adverse events and device events, excluding deaths)	
Paraesthesia	6
Wound dehiscence	6
Infection	5
Lead migration/dislogment[e]	5
Other[f]	73
Total	**805**

[a] MedDRA Preferred Term

[b] Event reported by the physician with an etiology that was not device related

[c] Patient was unable to recharge due to an issue not related to the device

[d] Includes 2 events reported as inability to activate neurostimulation not due to neurostimulator, 1 'POR' alarm noted on patient's programmer that resolved with POR, 1 prominent protrusion of the neuroelectrodes and bifurcated connectors in the left flank, 1 ERI occurred, 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

[e] Etiology was reported as something other than lead related. Sites have been queried for clarification.

[f] Composed of 45 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 65 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, 55.4% of patient deaths occurred in patients receiving therapy for pain indications in the unspecified "other" category, 38.5% for failed back, and 6.2% for CRPS.

Death by Primary Indication	
Primary Indication N (%)	
CRPS	4 (6.2%)
Failed Back	25 (38.5%)
Other	36 (55.4%)
Total	**65 (100%)**

Spinal Cord Stimulators

From June 2004 to the report cut-off date of July 31, 2012, 2542 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=2,210) versus spinal cord stimulators is due to the fact that some patients had multiple spinal cord

stimulators or were subsequently re-implanted.

Over twenty percent (20.6%) of the spinal cord stimulators were RestoreUltra, 20.1% were PrimeAdvanced, 18.1% were Synergy, 17.6% were Restore, 12.0% were RestoreAdvanced, 4.1% were Itrel 3, 2.9% were RestoreSensor, and a smaller number were RestorePrime (2.2%), Synergy Versitrel (1.5%), SynergyPlus+ (0.9%), and there was 1 other unspecified model. The aggregate prospective follow-up time for all spinal cord stimulators was 48,368 months (4,031 years).

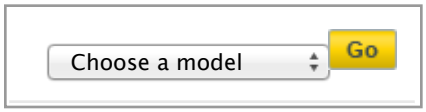
Spinal Cord Stimulator Events

There were 7 product performance-related events with an underlying reported etiology related to spinal cord stimulator function. For spinal cord stimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 132/632 (21%). 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 7 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 6 spinal cord stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device related by the physician as undesirable change in stimulation (n=3), device malfunction (n=2), 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. In addition to the 7 stimulators which were cut-off due to product performance-related events, there were 1,131 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 1,404 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.

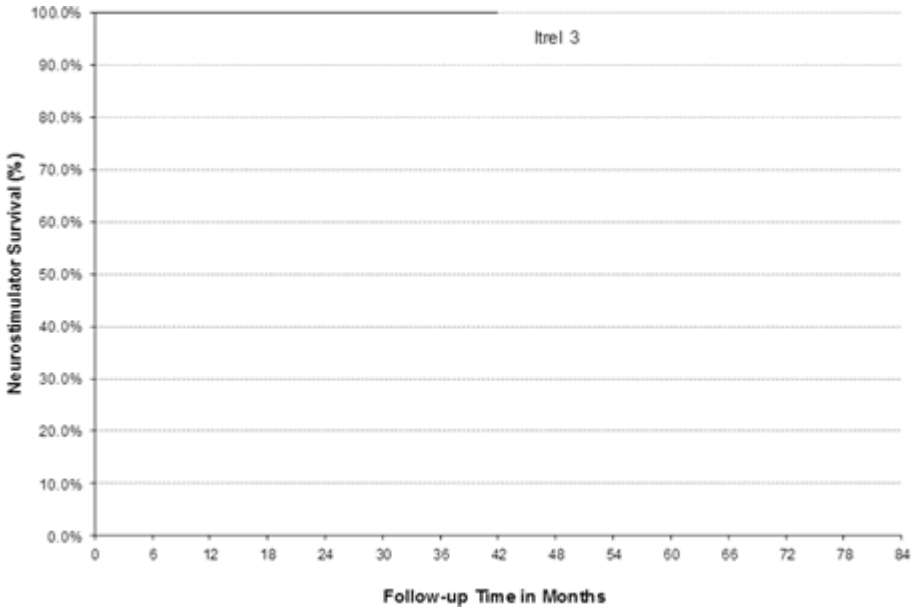
Spinal Cord Stimulator Survival

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. 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.



Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	103
Neurostimulators Currently Active in Study	5
Device Events	0
Cumulative Months of Follow-up	2,077

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

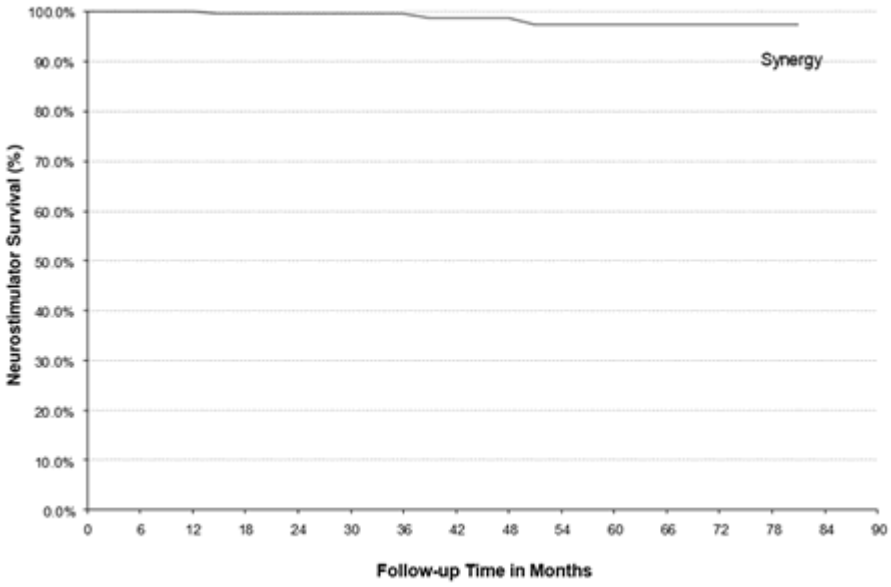
Time Interval Survival		Effective Sample Size
1 yr	100.0%	60
2 yrs	100.0%	45
3 yrs	100.0%	27
at 42 mo	100.0%	20

Model 7425 Itrel 3: Specifications

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

Model 7427 Synergy: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	460
Neurostimulators Currently Active in Study	35
Device Events	3
Cumulative Months of Follow-up	10,607

Neurostimulator Event	Total
Undesirable change in stimulation	2
Broken bond wire	1
Total Neurostimulator Events	**3**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	267
2 yrs	99.6%	212
3 yrs	99.6%	143

4 yrs	98.9%	83
5 yrs	97.5%	47
6 yrs	97.5%	31
at 81 mo	97.5%	22

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

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. See tables below for more information.

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

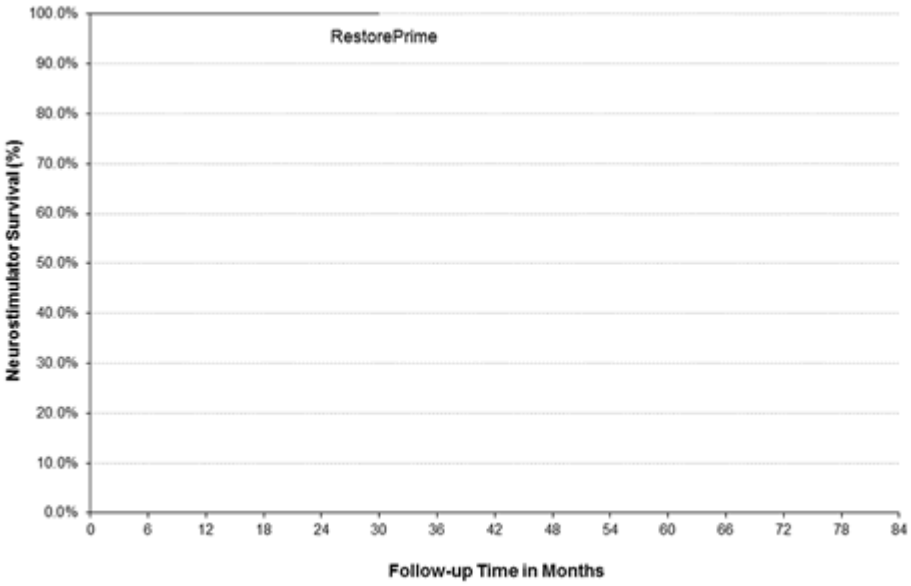
Model 7427V Synergy Versitrel: Specifications

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.



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Spinal Cord Stimulator Characteristics	
Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	56
Neurostimulators Currently Active in Study	8
Device Events	0
Cumulative Months of Follow-up	1,301

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval Survival	Effective Sample Size

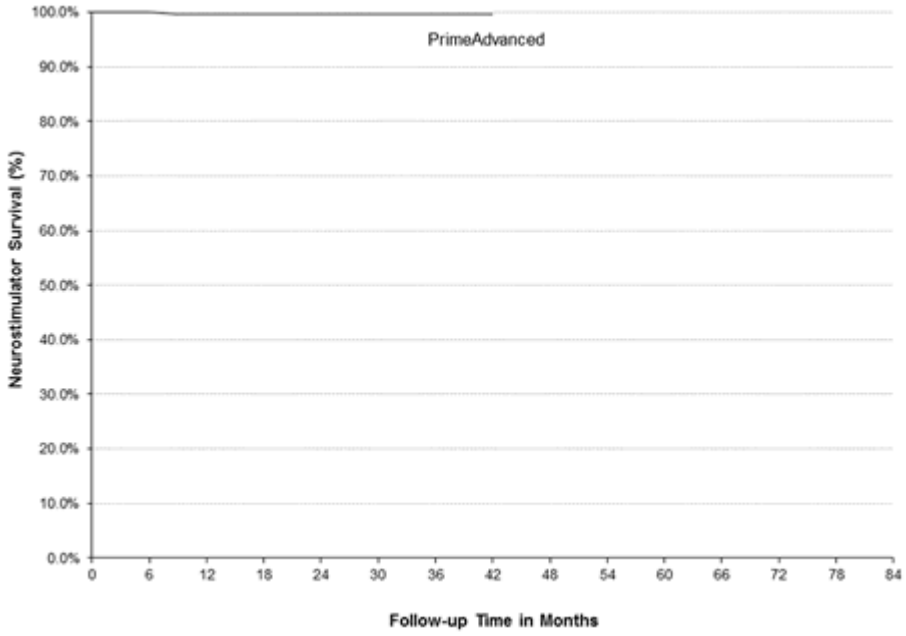
1 yr	100.0%	43
2 yrs	100.0%	23
at 30 mo	100.0%	20

Model 37701 RestorePrime: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	4
Implant Depth	≤ 4 cm

Model 37702 PrimeAdvanced: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	512
Neurostimulators Currently Active in Study	211
Device Events	1
Cumulative Months of Follow-up	6,309

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

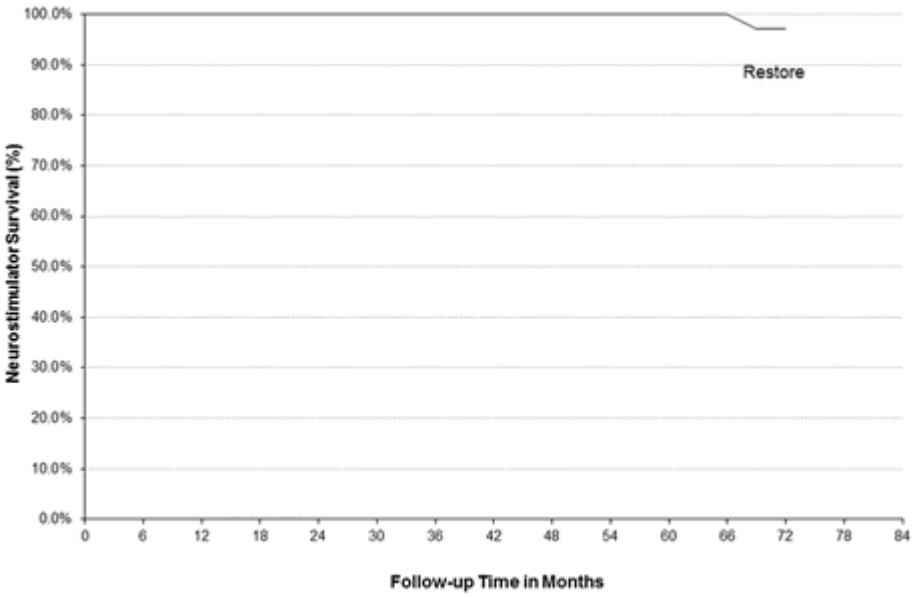
Time Interval Survival		Effective Sample Size
1 yr	99.7%	238
2 yrs	99.7%	96
3 yrs	99.7%	32
at 42 mo	99.7%	20

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.



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Spinal Cord Stimulator Characteristics	
Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	447
Neurostimulators Currently Active in Study	99
Device Events	1
Cumulative Months of Follow-up	12,034

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

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	315
2 yrs	100.0%	229
3 yrs	100.0%	145
4 yrs	100.0%	88

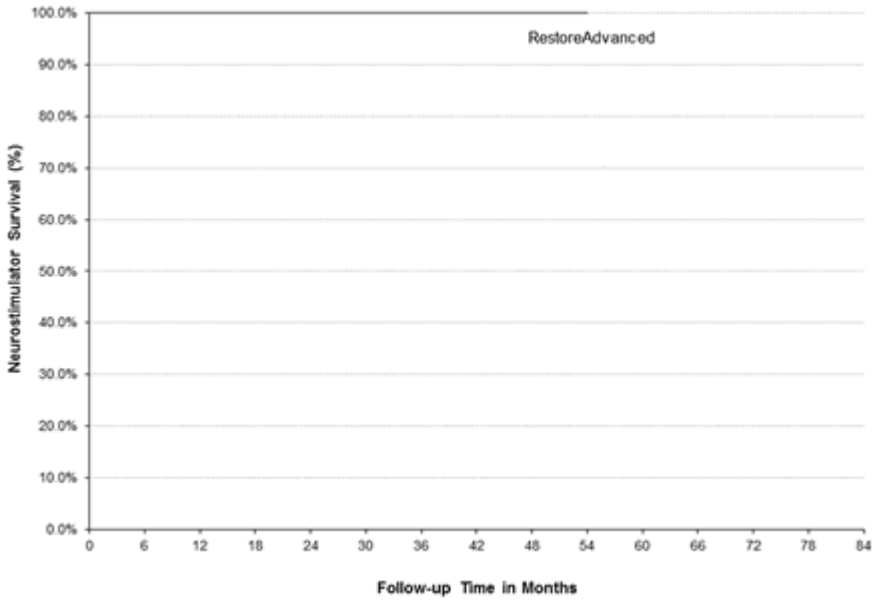
5 yrs	100.0%	60
6 yrs	97.1%	23

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 Stimulation Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	304
Neurostimulators Currently Active in Study	131
Device Events	0
Cumulative Months of Follow-up	5,865

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

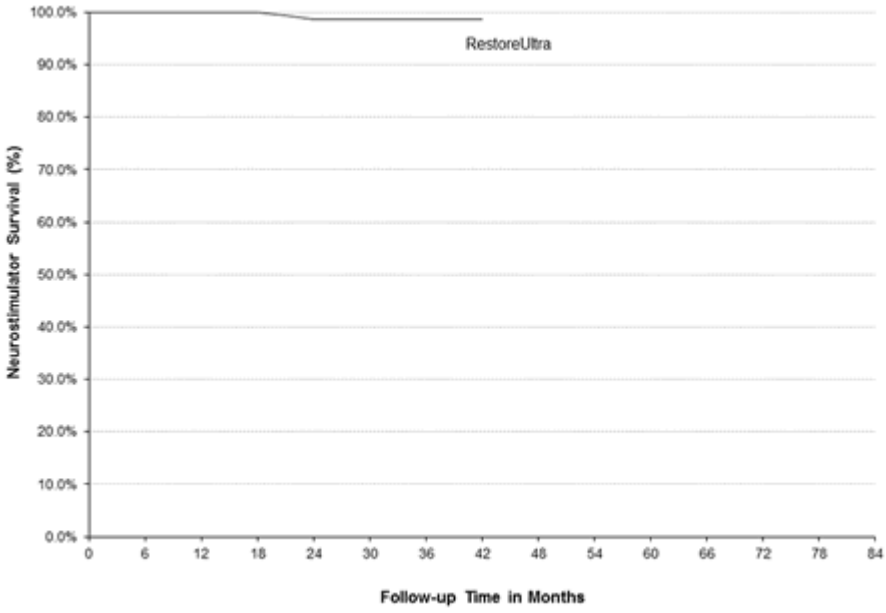
Time Interval	Survival	Effective Sample Size
1 yr	100.0%	175
2 yrs	100.0%	112
3 yrs	100.0%	63
4 yrs	100.0%	39
at 54 mo	100.0%	24

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 Stimulation Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	524
Neurostimulators Currently Active in Study	277
Device Events	2
Cumulative Months of Follow-up	7,454

Neurostimulator Event	Total
Device malfunction[a]	2
Total Neurostimulator Events	**2**

[a] One event reported as malfunction of the spinal cord stimulation system and 1 as problems with reprogramming

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	275
2 yrs	98.6%	129

3 yrs	98.6%	50
at 42 mo	98.6%	20

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 Stimulation Events

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. See tables below for more information.

Spinal Cord Stimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011
Neurostimulators Enrolled	73

Neurostimulators Currently Active in Study	70
Device Events	0
Cumulative Months of Follow-up	66

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
at 3 mo	100.0%	43

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	Cumulative Months of Follow-up
Primary Cell Neurostimulators						
Itrel 3	Itrel 3	Aug 1995	103	5	0	2,077
Synergy	Synergy	Nov 1999	460	35	3	10,607
Synergy Versitrel	Synergy	Dec 2001	38	1	0	737
Restore Prime	Restore	Mar 2006	56	8	0	1,301
Prime Advanced	Prime Advanced	Jul 2006	512	211	1	6,309
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	447	99	1	12,034
Restore Advanced	Restore	Jul 2006	304	131	0	5,865
Restore Ultra	Restore	Jan 2008	524	277	2	7,454
Restore Sensor	Restore	Nov 2011	73	70	0	66

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs
Primary Cell Neurostimulators						
Itrel 3	**100.0%** NA	**100.0%** NA	**100.0%** NA	-	-	-
Synergy	**100.0%** NA	**99.6%** (98.9%, 100.0%)	**99.6%** (98.9%, 100.0%)	**98.9%** (97.2%, 100.0%)	**97.5%** (94.3%, 100.0%)	**97.5%** (94.3%, 100.0%)

Synergy Versitrel	**100.0%** NA	-	-	-	-	-
RestorePrime	**100.0%** NA	**100.0%** NA	-	-	-	-
PrimeAdvanced	**99.7%** (99.0%, 100.0%)	**99.7%** (99.0%, 100.0%)	**99.7%** (99.0%, 100.0%)	-	-	-
Rechargeable Neurostimulators						
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	**97.1%** (91.4%, 100.0%)
RestoreAdvanced	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	-	-
RestoreUltra	**100.0%** NA	**98.6%** (96.6%, 100.0%)	**98.6%** (96.6%, 100.0%)	-	-	-
RestoreSensor	-	-	-	-	-	-

Leads

From June 2004 to the report cut-off date of July 31, 2012, there were 4,401 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=2,542) 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). More than eighty-nine percent (89.2%) of leads in the ISPR were percutaneous leads (3,927/4,401) including 55.1% (2,425/4,401) in the Pisces-Octad lead family, 28.3% (1,247/4,401) in the Pisces-Quad lead family, and 5.8% (255/4,401) in the Pisces-Quad LZ lead family. Ten percent (9.7%) of leads (426/4,401) were surgical leads. A small number of leads (48/4,401) were designated as Other (1.1%). The aggregate prospective follow-up time for all leads was 90,576 months (7,548 years).

Lead Events

There were 406 product performance-related events with an underlying reported etiology related to the lead. Of these events, the majority were lead migration/dislodgements (n=240), high impedance (n=46), undesirable change in stimulation (n=43), or lead fracture (n=41). Of the 406 events, 358 were the first event attributable to an enrolled lead. There were 340 events in 3,927 (8.7%) percutaneous leads and 18 events in 426 (4.2%) surgical leads.

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 358 leads which were cut-off due to product performance-related events there were 1,343 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 2,700 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

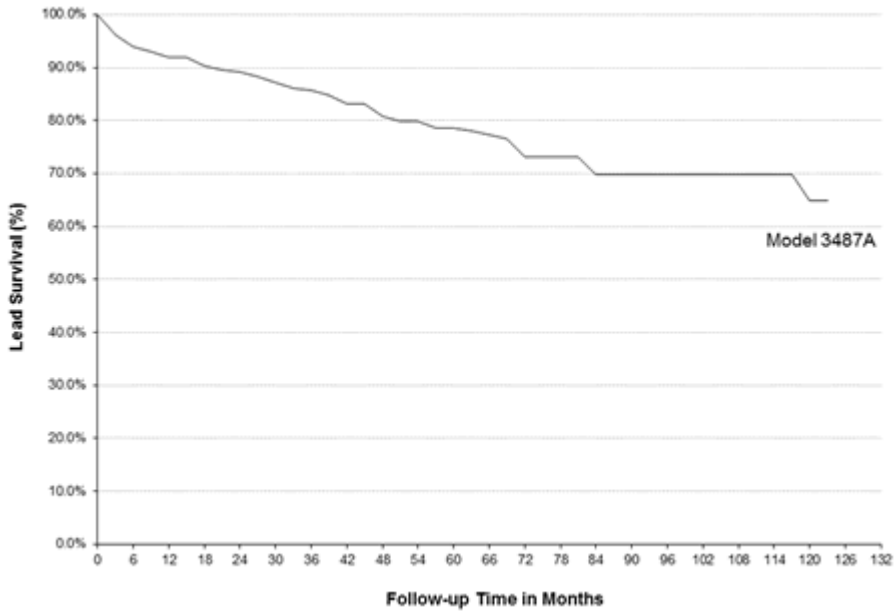
The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, the 95% confidence intervals for all surgical lead models overlap, indicating that survival from lead-related events is not significantly different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

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, indicating that Model 3891 may not perform as well as other percutaneous lead models. As of February 6, 2008, Medtronic has discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Choose a model Go

Model 3487A Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3487A

FDA Approval Date	May 1988
Leads Enrolled	774
Leads Currently Active in Study	342
Device Events	87
Cumulative Months of Follow-up	20,235

Lead Event	Total
High impedance	29
Lead migration/dislodgment	23
Undesirable change in stimulation	17
Lead fracture	8
Medical device complication[a]	5
Low impedance	3
Impedance NOS	2
Total Lead Events	**87**

[a] 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	91.9%	401
2 yrs	89.2%	304
3 yrs	85.7%	217
4 yrs	80.8%	172
5 yrs	78.6%	128
6 yrs	73.1%	91
7 yrs	69.9%	68

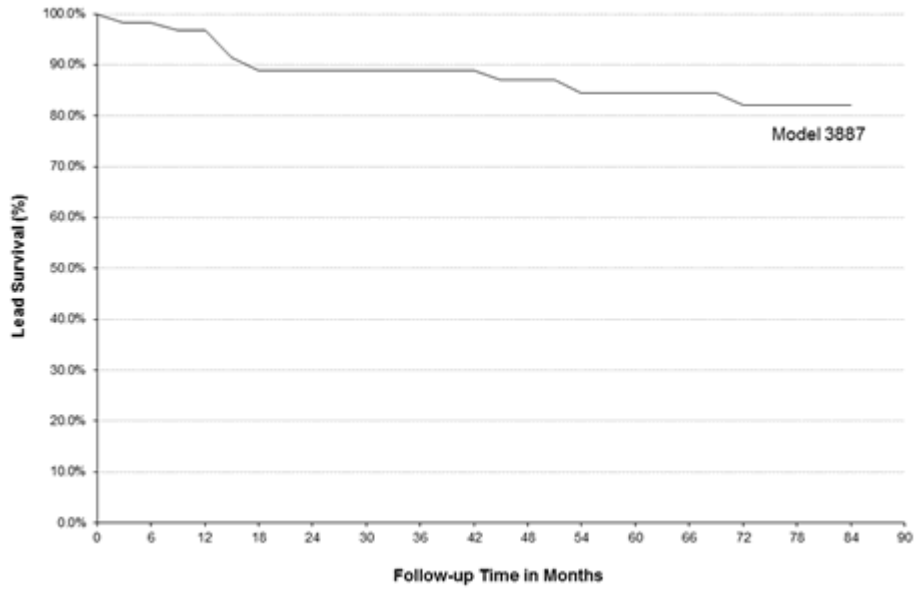
8 yrs	69.9%	43
9 yrs	69.9%	39
10 yrs	64.8%	28
at 123 mo	64.8%	24

Model 3487A Pisces-Quad: Specifications

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

Model 3887 Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3887
FDA Approval Date	Jan 1997
Leads Enrolled	145
Leads Currently Active in Study	32
Device Events	11
Cumulative Months of Follow-up	4,411

Lead Event	Total
Lead fracture	7
Undesirable change in stimulation	2
Lead migration/dislodgment	1
Medical device complication[a]	1
Total Lead Events	**11**

[a] Reported as lead damaged contacts

Time Interval Survival	Effective Sample Size

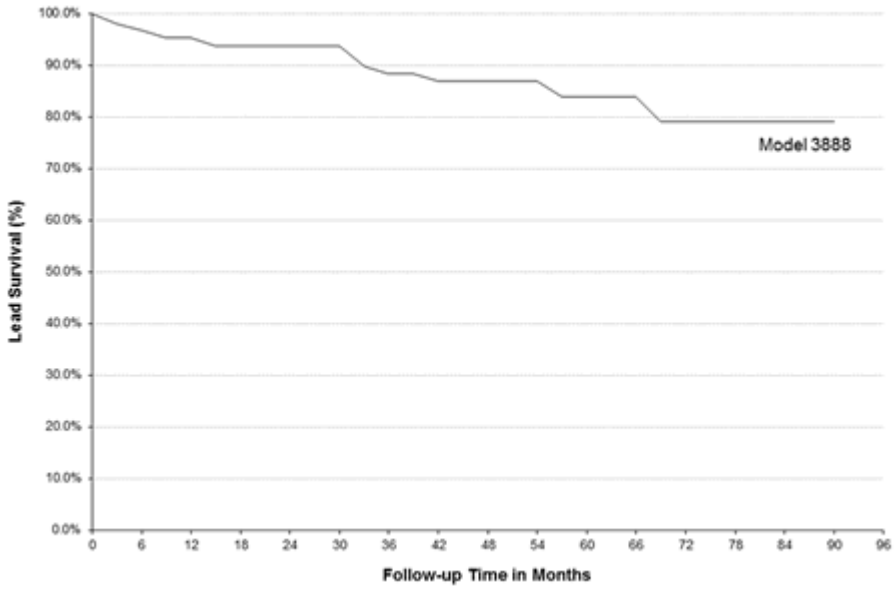
1 yr	96.8%	72
2 yrs	88.8%	58
3 yrs	88.8%	58
4 yrs	87.1%	43
5 yrs	84.5%	36
6 yrs	82.1%	36
7 yrs	82.1%	23

Model 3887 Pisces-Quad: Specifications

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

Model 3888 Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3888
FDA Approval Date	Nov 1992
Leads Enrolled	328
Leads Currently Active in Study	70
Device Events	19
Cumulative Months of Follow-up	6,723

Lead Event	Total
Lead migration/dislodgment	16
Undesirable change in stimulation	2
Lead fracture	1
Total Lead Events	**19**

Time Interval	Survival	Effective Sample Size
1 yr	95.4%	127
2 yrs	93.7%	76

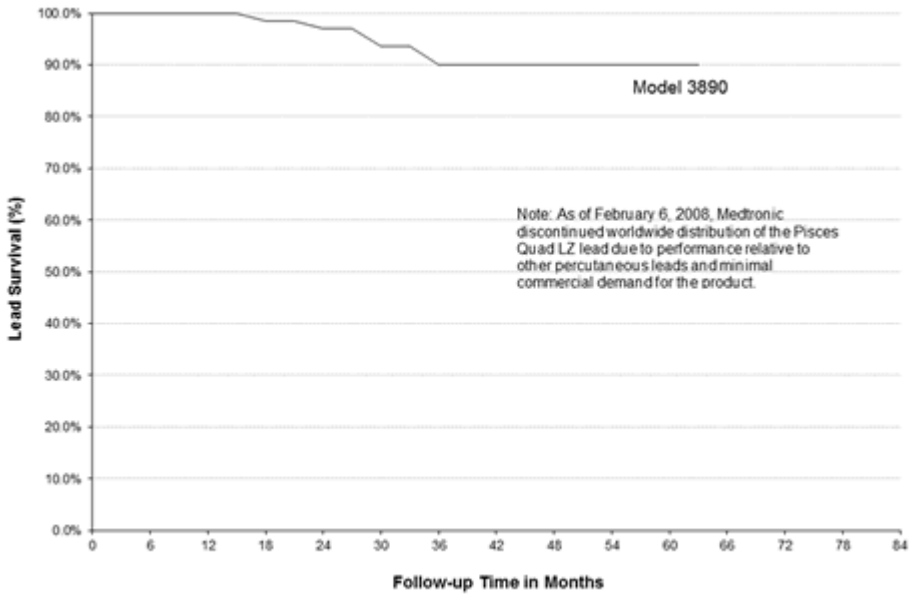
3 yrs	88.3%	67
4 yrs	87.0%	62
5 yrs	83.8%	50
6 yrs	79.1%	34
7 yrs	79.1%	23
at 90 mo	79.1%	21

Model 3888 Pisces-Quad: Specifications

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

Model 3890 Pisces-Quad LZ: Survival from Lead Events

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



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

Lead Characteristics	
Model Number	3890
FDA Approval Date	Sep 2002
Leads Enrolled	128
Leads Currently Active in Study	20
Device Events	6
Cumulative Months of Follow-up	3,124

Lead Event	Total
Lead fracture	2
Lead migration/dislodgment	2
Undesirable change in stimulation	2
Total Lead Events	**6**

Time Interval Survival	Effective Sample Size

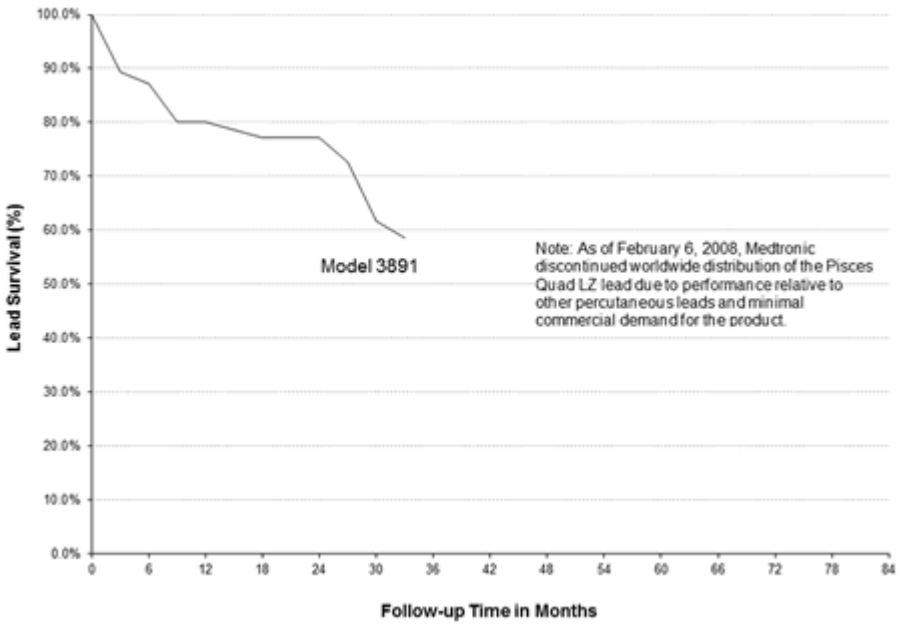
1 yr	100.0%	53
2 yrs	97.0%	67
3 yrs	90.0%	52
4 yrs	90.0%	35
5 yrs	90.0%	25
at 63 mo	90.0%	21

Model 3890 Pisces-Quad LZ: Specifications

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

Model 3891 Pisces-Quad LZ: Survival from Lead Events

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



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

Lead Characteristics	
Model Number	3891
FDA Approval Date	Sep 2002
Leads Enrolled	110
Leads Currently Active in Study	7
Device Events	28
Cumulative Months of Follow-up	2,086

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] Reported as damaged electrodes

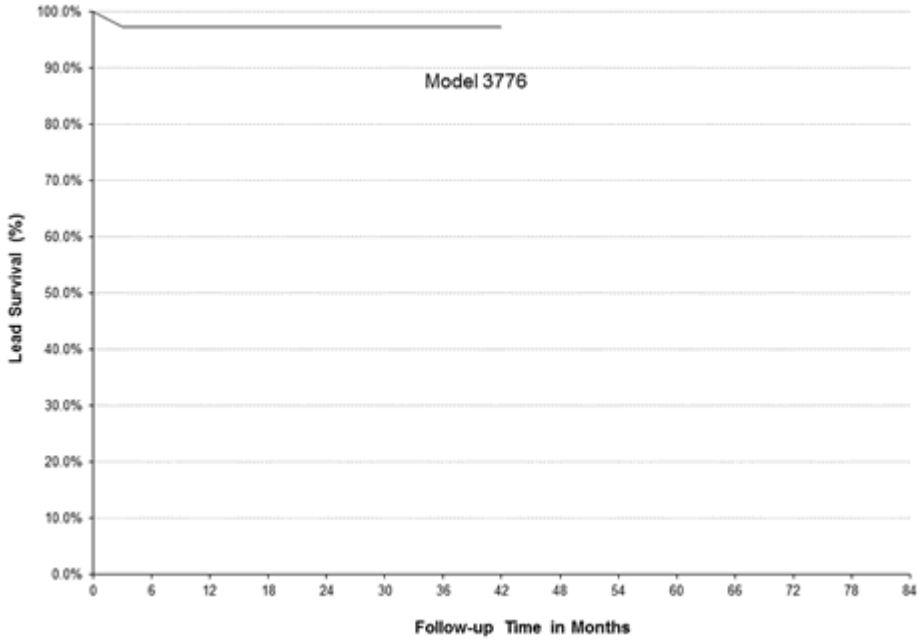
Time Interval	Survival	Effective Sample Size
1 yr	80.1%	66
2 yrs	77.2%	39
at 33 mo	58.6%	20

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.



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Lead Characteristics	
Model Number	3776
FDA Approval Date	Nov 2005
Leads Enrolled	138
Leads Currently Active in Study	55
Device Events	3
Cumulative Months of Follow-up	2,182

Lead Event	Total
Lead migration/dislodgement	2
Undesirable change in stimulation	1
Total Lead Events	**3**

Time Interval	Survival	Effective Sample Size
1 yr	97.3%	58
2 yrs	97.3%	38
3 yrs	97.3%	29

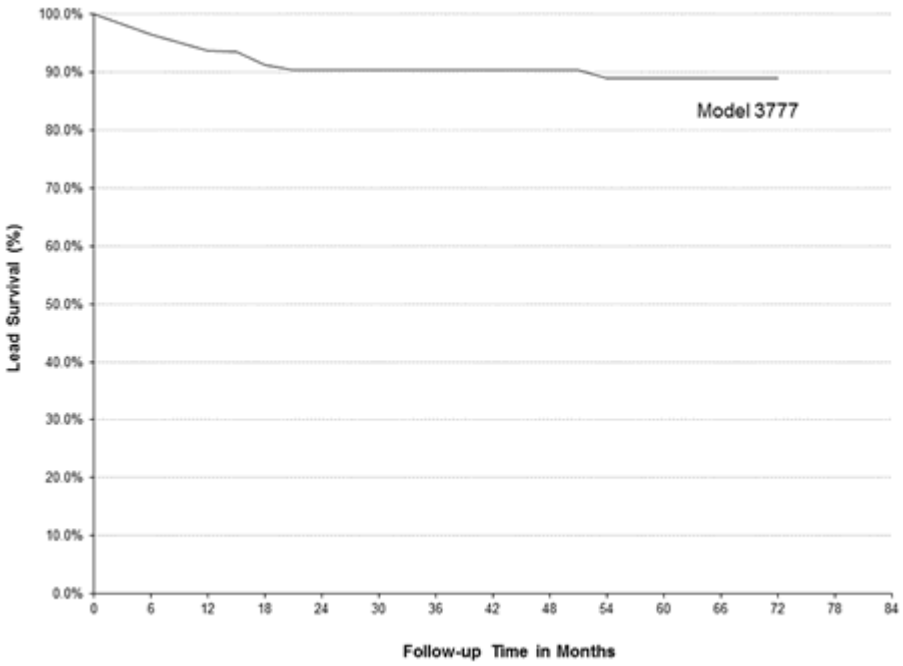
at 42 mo	97.3%	20

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.



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Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	638
Leads Currently Active in Study	190
Device Events	39
Cumulative Months of Follow-up	12,291

Lead Event	Total
Lead migration/dislodgment	28
Undesirable change in stimulation	7
Medical device complication[a]	2
High impedance	1
Lead fracture	1
Total Lead Events	**39**

[a] Reported as damaged leads

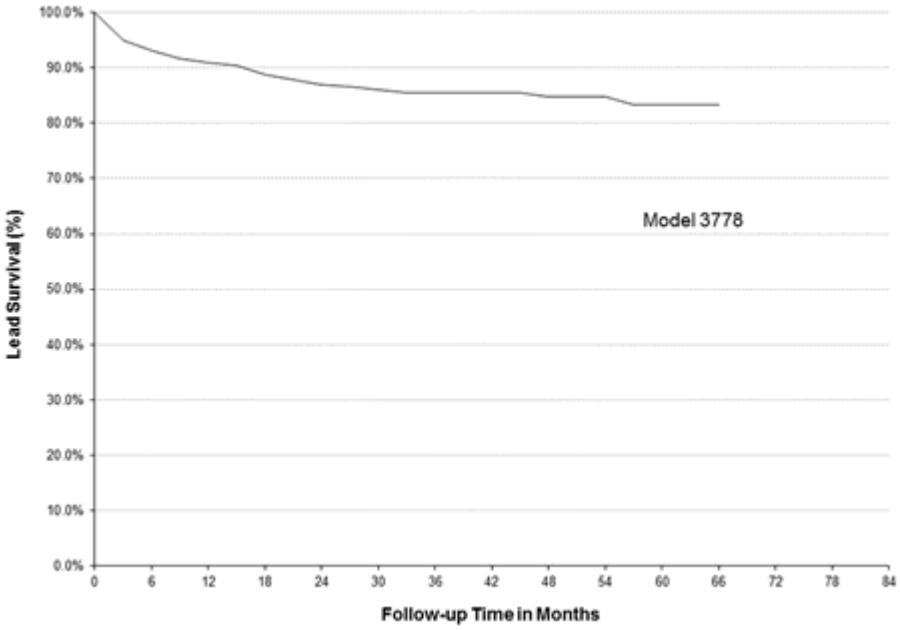
Time Interval	Survival	Effective Sample Size
1 yr	93.8%	367
2 yrs	90.4%	215
3 yrs	90.4%	126
4 yrs	90.4%	70
5 yrs	88.9%	46
6 yrs	88.9%	23

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.



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Lead Characteristics	
Model Number	3778
FDA Approval Date	Apr 2005
Leads Enrolled	1,649
Leads Currently Active in Study	828
Device Events	146
Cumulative Months of Follow-up	25,345

Lead Event	Total
Lead migration/dislodgment	123
Lead fracture	7
Medical device complication[a]	4
Undesirable change in stimulation	4
Change in sensation of stimulation	2
High impedance	2

Back disorder	1
Device malfunction[b]	1
Impedance NOS	1
Low impedance	1
Total Lead Events	**146**

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

Time Interval	Survival	Effective Sample Size
1 yr	90.9%	797
2 yrs	87.0%	436
3 yrs	85.5%	254
4 yrs	84.8%	121
5 yrs	83.4%	52
at 66 mo	83.4%	27

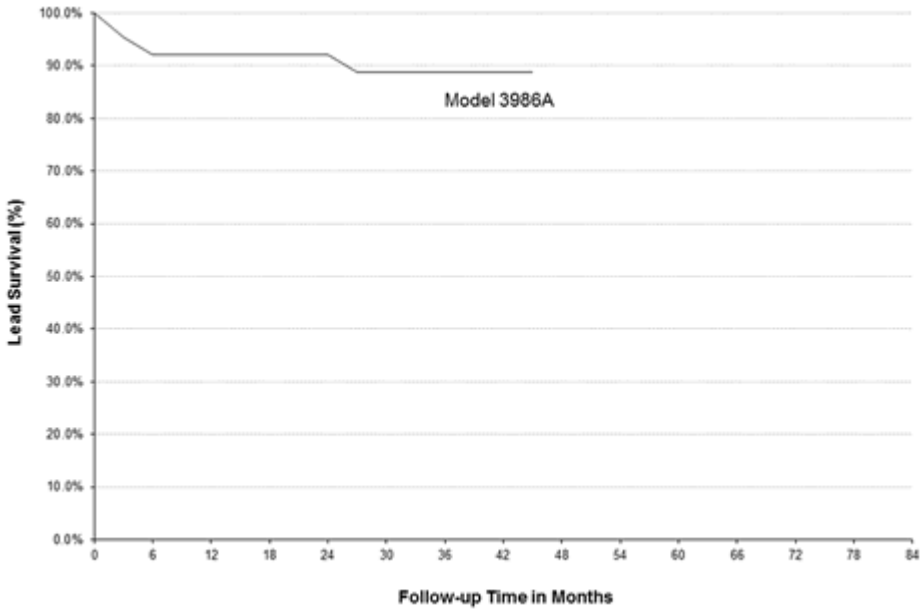
Model 3778 Pisces-Octad: Specifications

Device Name	**1x8 Compact**
Lead Type	**Percutaneous**
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8

Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

Model 3986A Resume TL: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3986A
FDA Approval Date	Apr 1995
Leads Enrolled	84
Leads Currently Active in Study	36
Device Events	6
Cumulative Months of Follow-up	1,954

Lead Event	Total
High impedance	4
Undesirable change in stimulation	2
Total Lead Events	**6**

Time Interval	Survival	Effective Sample Size
1 yr	92.1%	46
2 yrs	92.1%	30
3 yrs	88.7%	22
at 45 mo	88.7%	20

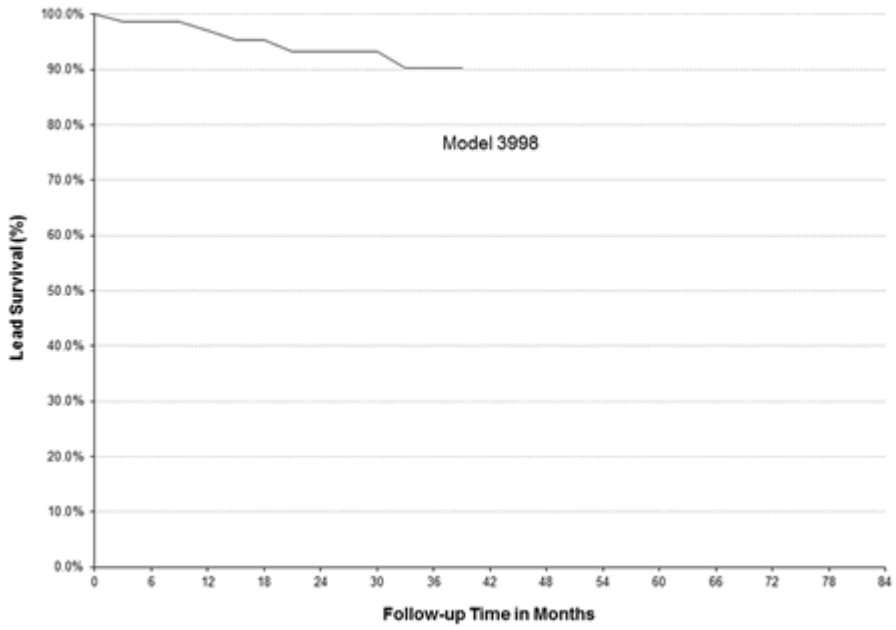
Model 3986A Resume TL: Specifications

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

Array Width (mm)	4.0
Paddle	
Length (mm)	44.0
Width (mm)	6.6
Thickness (mm)	1.4

Model 3998 Specify: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	126
Leads Currently Active in Study	22
Device Events	8
Cumulative Months of Follow-up	2,737

Lead Event	Total
Lead fracture	3
High impedance	2
Device failure[a]	1
Lead migration/dislodgment	1
Undesirable change in stimulation	1
Total Lead Events	**8**

[a] Reported as failure of lead electrodes

Time Interval	Survival	Effective Sample Size
1 yr	97.0%	60
2 yrs	93.3%	43
3 yrs	90.3%	26
at 39 mo	90.3%	22

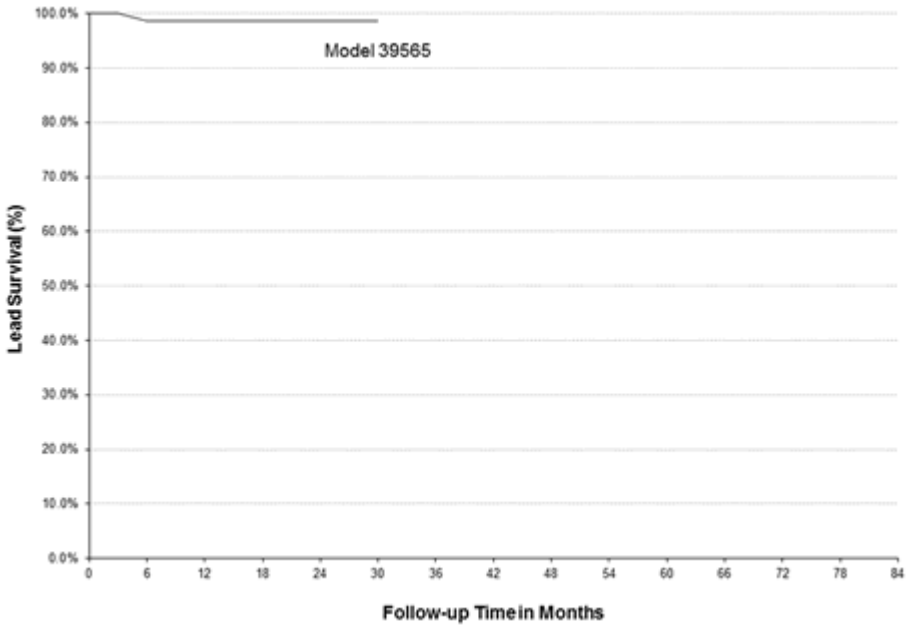
Model 3998 Specify: Specifications

Device Name	Specify
Lead Type	**Surgical**
Lead	
Length (cm)	20
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Rectangular
Length (mm)	3.0

Width (mm)	2.0
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	6.0
Lateral Spacing: Edge to Edge (mm)	2.0
Array Length (mm)	30.0
Array Width (mm)	6.0
Paddle	
Length (mm)	45.0
Width (mm)	7.9
Thickness (mm)	1.8

Model 39565 Specify: Survival from Lead Events

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



View Larger Image

Lead Characteristics

Model Number	39565
FDA Approval Date	Jun 2007
Leads Enrolled	103
Leads Currently Active in Study	56
Device Events	1
Cumulative Months of Follow-up	1,588

Lead Event	Total
Lead migration/dislodgment	1
Total Lead Events	**1**

Time Interval	Survival	Effective Sample Size
1 yr	98.6%	58
2 yrs	98.6%	32
at 30 mo	98.6%	20

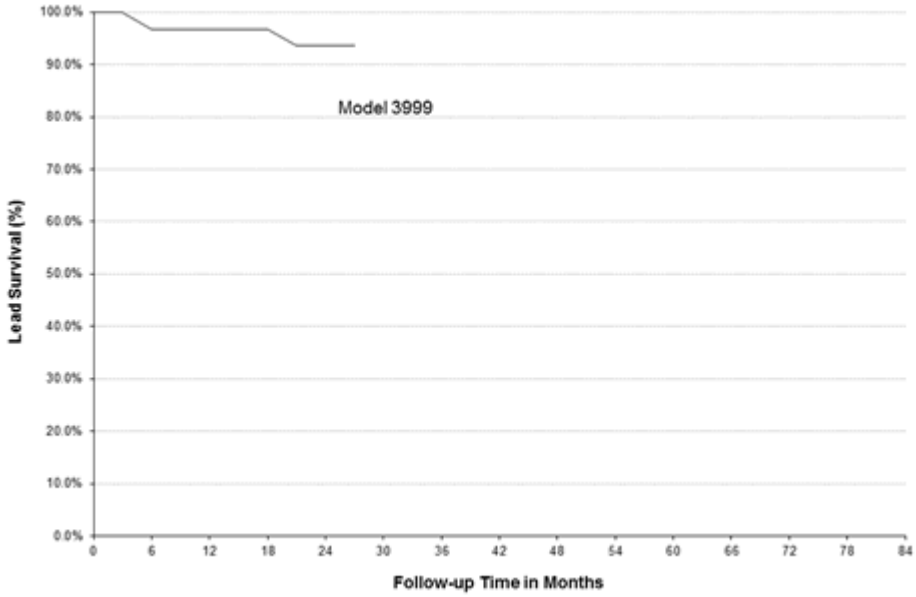
Model 39565 Specify: Specifications

Device Name	**Specify 5-6-5**
Lead Type	**Surgical**
Lead	
Length (cm)	30, 65
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Length (mm)	4.0

Width (mm)	1.5
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	4.5
Lateral Spacing: Edge to Edge (mm)	1.0
Array Length (mm)	49.0
Array Width (mm)	7.5
Paddle	
Length (mm)	64.2
Width (mm)	10.0
Thickness (mm)	7.5

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	3
Device Events	2
Cumulative Months of Follow-up	1,011

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	**2x4 Hinged Specify**
Lead Type	**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

Currently, survival from lead-related events is not statistically significantly different between surgical lead models across all applicable follow-up time points. The data indicate that Model 3891 does not perform as well as several other percutaneous lead models at 1 and 2 years of follow-up. As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces-Quad LZ lead (which includes the 3890 and 3891 leads) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

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	774	342	87	20,235
3887	**Pisces-Quad**	Jan 1997	145	32	11	4,411
3888	**Pisces-Quad**	Nov 1992	328	70	19	6,723
3890	**Pisces-Quad LZ**	Sep 2002	128	20	6	3,124
3891	**Pisces-Quad LZ**	Sep 2002	110	7	28	2,806

3776	**Pisces-Octad**	Nov 2005	138	55	3	2,182
3777	**Pisces-Octad**	Apr 2005	638	190	39	12,291
3778	**Pisces-Octad**	Apr 2005	1,649	828	146	25,345
Surgical Leads						
3986A	**Resume TL**	Apr 1995	84	36	6	1,954
3998	**Specify**	Feb 1998	126	22	8	2,737
3999	**2 x 4 Hinged Specify**	Jun 2004	51	3	2	1,011
39565	**Specify**	Jun 2007	103	56	1	1,588

[a] There were a total of 406 lead-related events reported to the ISPR, but only 356 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=2) or were subsequent or unlinked device events that did not affect the survival estimates.

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

Model Name	Family	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
Percutaneous Leads						
3487A	**Pisces-Quad**	**91.9%** (89.4%, 94.4%)	**89.2%** (86.2%, 92.1%)	**85.7%** (82.1%, 89.3%)	**80.8%** (76.4%, 85.2%)	**78.6%** (73.8%, 83.5%)
3887	**Pisces-Quad**	**96.8%** (92.2%, 100.0%)	**88.8%** (81.4%, 96.3%)	**88.8%** (81.4%, 96.3%)	**87.1%** (78.9%, 95.2%)	**84.5%** (75.2%, 93.9%)
3888	**Pisces-Quad**	**95.4%** (92.2%, 98.6%)	**93.7%** (89.7%, 97.7%)	**88.3%** (81.9%, 94.7%)	**87.0%** (80.2%, 93.8%)	**83.8%** (75.8%, 91.7%)

3890	**Pisces-Quad LZ**	**100.0%** NA	**97.0%** (92.8%, 100.0%)	**90.0%** (82.2%, 97.8%)	**90.0%** (82.2%, 97.8%)	**90.0%** (82.2%, 97.8%)
3891	**Pisces-Quad LZ**	**80.1%** (71.5%, 88.7%)	**77.2%** (68.0%, 86.5%)	-	-	-
3776	**Pisces-Octad**	**97.3%** (94.3%, 100.0%)	**97.3%** (94.3%, 100.0%)	**97.3%** (94.3%, 100.0%)	-	-
3777	**Pisces-Octad**	**93.8%** (91.6%, 96.1%)	**90.4%** (87.4%, 93.5%)	**90.4%** (87.4%, 93.5%)	**90.4%** (87.4%, 93.5%)	**88.9%** (84.6%, 93.2%)
3778	**Pisces-Octad**	**90.9%** (89.3%, 92.6%)	**87.0%** (84.8%, 89.2%)	**85.5%** (82.9%, 88.0%)	**84.8%** (81.9%, 87.6%)	**83.4%** (79.4%, 87.3%)
Surgical Leads						
3986A	**Resume TL**	**92.1%** (85.3%, 98.9%)	**92.1%** (85.3%, 98.9%)	**88.7%** (79.3%, 98.0%)	-	-
3998	**Specify**	**97.0%** (92.8%, 100.0%)	**93.3%** (86.8%, 99.8%)	**90.3%** (81.6%, 99.0%)	-	-
3999	**2 x 4 Hinged Specify**	**96.7%** (90.3%, 100.0%)	**93.6%** (84.7%, 100.0%)	-	-	-
39565	**Specify**	**98.6%** (95.9%, 100.0%)	**98.6%** (95.9%, 100.0%)	-	-	-

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

Model Name	Family	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs
Percutaneous Leads						
3487A	**Pisces-Quad**	**73.1%** (67.1%,	**69.9%** (63.1%,	**69.9%** (63.1%,	**69.9%** (63.1%,	**64.8%** (55.4%,

		79.2%)	76.7%)	76.7%)	76.7%)	74.2%)
3887	**Pisces-Quad**	**82.1%** (71.9%, 92.4%)	**82.1%** (71.9%, 92.4%)	-	-	-
3888	**Pisces-Quad**	**79.1%** (69.2%, 89.0%)	**79.1%** (69.2%, 89.0%)	-	-	-
3890	**Pisces-Quad LZ**	-	-	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-	-
3776	**Pisces-Octad**	-	-	-	-	-
3777	**Pisces-Octad**	**88.9%** (84.6%, 93.2%)	-	-	-	-
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, 2012, there were 2,486 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=2,542) 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-five percent (35.8%) of the extensions were Model 37081 extensions, 27.3% were Model 7489 extensions, 20.0% were Model 37082 extensions, 8.0% were Model 7495 extensions, 7.4% 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 51,058 months (4,255 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. In addition to the 15 extensions which were cut-off due to product performance-related events there, were 1,026 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 1,445 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.

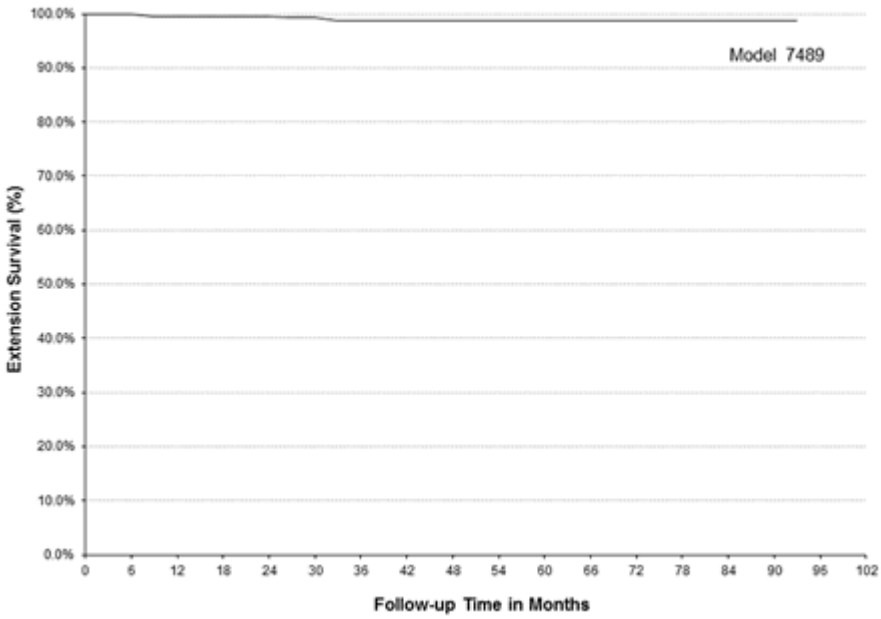
Extension Survival

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 Extension Family: 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	678
Extensions Currently Active in Study	77
Device Events	3
Cumulative Months of Follow-up	15,099

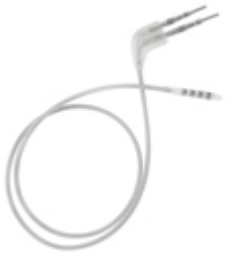
Extension Event	Total
Extension fracture	2
Medical device complication[a]	1
Total Extension Events	**3**

[a] Reported as unknown problem with extension

Time Interval	Survival	Effective Sample Size
1 yr	99.6%	284
2 yrs	99.6%	292
3 yrs	98.8%	217
4 yrs	98.8%	143
5 yrs	98.8%	104
6 yrs	98.8%	76
7 yrs	98.8%	51
at 93 mo	98.8%	25

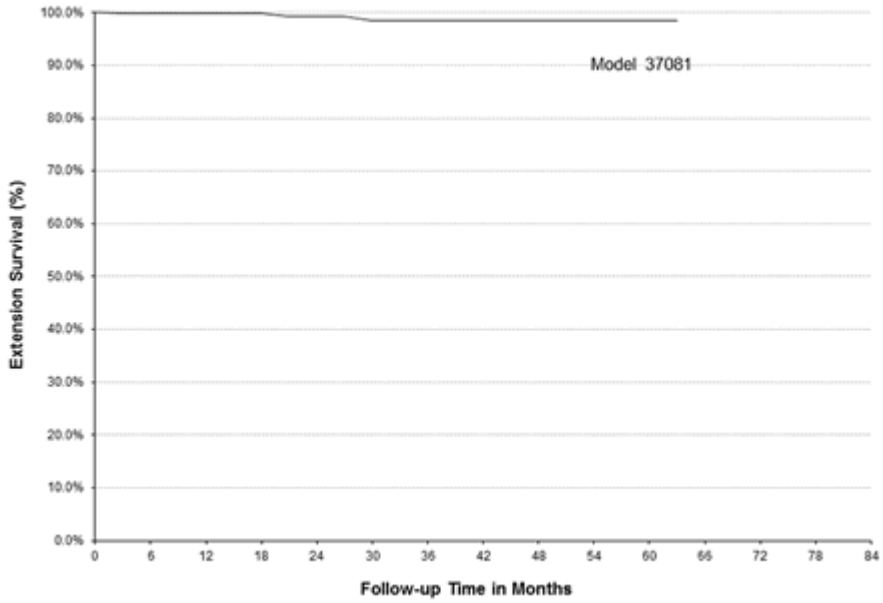
Model 7489 Extension Family: Specifications

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 Extension Family: 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	889
Extensions Currently Active in Study	318
Device Events	5
Cumulative Months of Follow-up	15,423

Extension Event	Total

Extension fracture	5
Total Extension Events	**5**

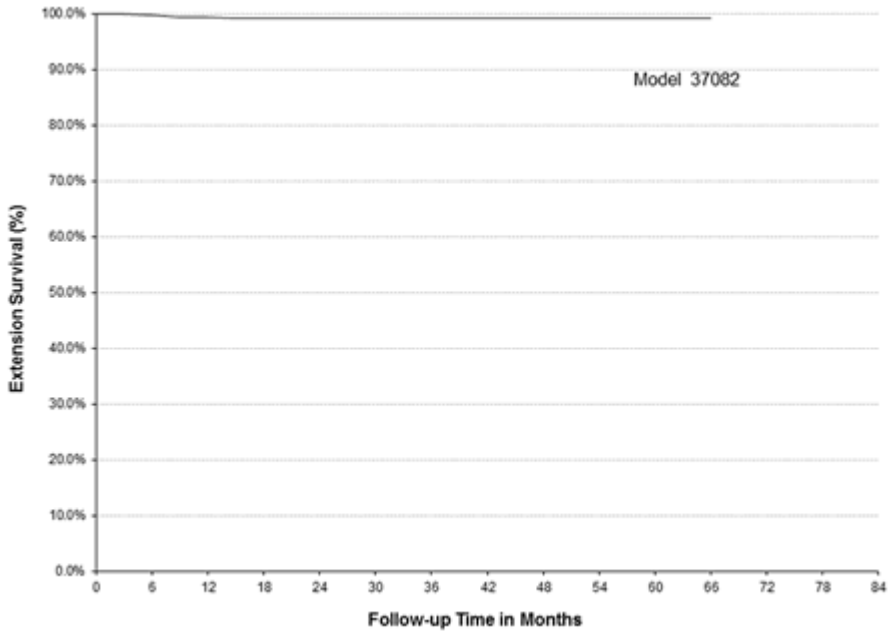
Time Interval	Survival	Effective Sample Size
1 yr	99.8%	494
2 yrs	99.3%	301
3 yrs	98.4%	157
4 yrs	98.4%	66
5 yrs	98.4%	28
at 63 mo	98.4%	24

Model 37081 Extension Family: 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 Extension Family: 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	498
Extensions Currently Active in Study	207
Device Events	3
Cumulative Months of Follow-up	9,986

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	99.4%	309

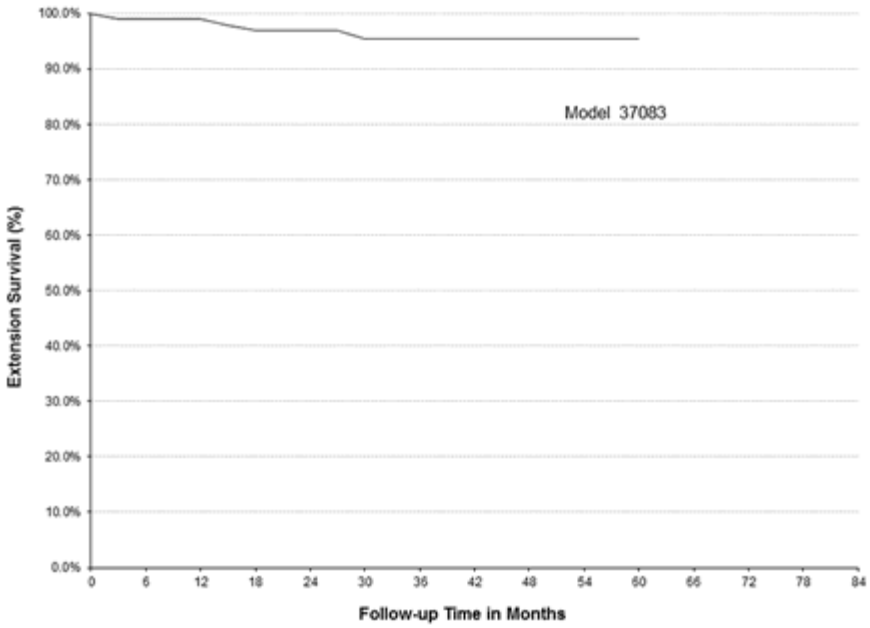
2 yrs	99.1%	190
3 yrs	99.1%	92
4 yrs	99.1%	56
5 yrs	99.1%	34
at 66 mo	99.1%	21

37082 Extension Family: 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 Extension Family: 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	183
Extensions Currently Active in Study	53
Device Events	4
Cumulative Months of Follow-up	3,925

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%	100
2 yrs	96.9%	84
3 yrs	95.5%	48
4 yrs	95.5%	34
5 yrs	95.5%	20

Model 37083 Extension Family: 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	889	318	5	15,423
37082	37082	Mar 2006	498	207	3	9,986
37083	37083	Sep 2005	183	53	4	3,925
7489	7489	Oct 2002	678	77	3	15,099

[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	**99.8%** (99.5%, 100.0%)	**99.3%** (98.4%, 100.0%)	**98.4%** (96.9%, 99.9%)	**98.4%** (96.9%, 99.9%)	**98.4%** (96.9%, 99.9%)
37082	**99.4%** (98.6%, 100.0%)	**99.1%** (98.0%, 100.0%)	**99.1%** (98.0%, 100.0%)	**99.1%** (98.0%, 100.0%)	**99.1%** (98.0%, 100.0%)
37083	**99.0%** (96.9%,	**96.9%** (93.4%,	**95.5%** (91.1%,	**95.5%** (91.1%,	**95.5%** (91.1%,

	100.0%)	100.0%)	100.0%)	100.0%)	100.0%)
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	9 yrs	10 yrs
37081	-	-	-	-	-
37082	-	-	-	-	-
37083	-	-	-	-	-
7489	**98.8%** (97.5%, 100.0%)	**98.8%** (97.5%, 100.0%)	-	-	-

2012 Medtronic Product Performance Report: Data through July 31, 2012

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Intrathecal 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, 2012. Fifteen centers enrolled and contributed patients to the deep brain stimulation section of the report.

Patients

Of the 474 deep brain stimulation patients enrolled in the ISPR, 67.1% were implanted for the treatment of Parkinson's Disease, 20.7% were implanted for the treatment of Essential Tremor, 9.1% were implanted for the treatment of Dystonia, 0.2% were implanted for the treatment of Obsessive Compulsive Disorder, 0.2% were implanted for the treatment of some other indications and 2.7% were implanted for indications that were not specified in the database.

Primary DBS Treatment Indications

Primary Treatment Indication[a]	Total Enrolled Patients (N=474)
Parkinson's Disease	318 (67.1%)
Essential Tremor	98 (20.7%)
Dystonia	43 (9.1%)
Obsessive Compulsive Disorder	1 (0.2%)
Other	1 (0.2%)
Not specified	13 (2.7%)
Total Patients	**474**

[a] Refer to product labeling for approved indications.

Event Summary

There were 91 events reported between July 2009 and July 31, 2012 in patients with deep brain stimulation systems. Sixteen percent of these events (15/91) were categorized as product performance-related and are presented graphically within this report. The 15 product performance events occurred in 10 of the 474 total patients (2.5%) enrolled. In addition, there were 64 non-product performance events and 12 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=474)
Medical device complication[c]	5	4	0.84%
Recharging unable to recharge	2	2	0.42%
Migration of implant	2	1	0.21%
Device malfunction[d]	1	1	0.21%
High impedance	1	1	0.21%
Low impedance	1	1	0.21%
Extension fracture	1	1	0.21%
Impedance NOS	1	1	0.21%
Lead fracture	1	1	0.21%
Total	**15**	**10**	**2.53%**

[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 lead dysfunction, 1 suspicion of heating of the antenna while recharging, 1 undesirable interaction with external electronic device, and 1 open circuit to lead

[d] Reported as increased impedance

A total of 6 (40.0%) of the 15 product performance events were related to the lead, 3 (20.0%) were related to the extension, 3 (20.0%) were related to the recharging process, 2 (13.3%) were related to both neurostimulator and lead, and 1 (6.7%) was related to neurostimulator.

Deep Brain Stimulation System Non-Product Performance Events (including adverse events and device events, excluding deaths)	
Events[a]	**Number of Non-Product Performance Events**
Implant site infection	6
Neurostimulator battery depletion	6
Fall	3
Speech Disorder	3
Dysarthria	2
Dyskinesia	2
Dysphonia	2
Muscle spasticity	2
Paraesthesia	2
Recharging unable to recharge[b]	2
Weight increased	2
Other[c]	32
Total	**64**

[a] MedDRA Preferred Term

[b] Patient was unable to recharge due to an issue not related to the device

[c] Composed of 30 event codes that include fewer than 2 patients each and events that had not been MedDRA coded at the time of the report cut-off (n=2)

There were 12 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 75% of patient deaths occurred in patients receiving therapy for Parkinson's disease, and 25% for Essential Tremor.

Death by Primary Indication

Death by Primary Indication	
Primary Indication	**N (%)**
Essential Tremor	3 (25%)
Parkinson's Disease	9 (75%)
Total	**12 (100%)**

Deep Brain Neurostimulators

From July 2009 to the report cut-off date of July 31, 2012, 430 deep brain neurostimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=474) versus neurostimulators is due to the fact that some patients were enrolled, but their implant information was not available in the database at the time of the report cut-off date.

Almost forty-two percent (41.9%) of the neurostimulators were Activa PC, 25.1% were Activa SC, 16.7% were Activa RC, 14.2% were Soletra, and 2.1% were Kinetra. The aggregate prospective follow-up time for all neurostimulators was 2,416 months (201 years).

Deep Brain Neurostimulator Events

There were 3 product performance-related events 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 2/21 (9.5%). 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 two devices that were returned for analysis. The 3 deep brain stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device related by the physician as medical device complication, high impedance, and low impedance.

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 3 neurostimulators which were cut-off due to product performance-related events, there were 46 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 381 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 tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. Survival curves are not shown because fewer 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 Neurotimulator Events

Deep Brain Neurostimulator Characteristics	
Model Name	Activa PC
FDA Approval Date	Apr 2009
Neurostimulators Enrolled	180
Neurostimulators Currently Active in Study	166
Device Events	1
Cumulative Months of Follow-up	970

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
6 mo	98.9%	92
1 yr	98.9%	37

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	108
Neurostimulators Currently Active in Study	107
Device Events	1
Cumulative Months of Follow-up	298

Neurostimulator Event	**Total**

High Impedance[a]	1
Total Neurostimulator Events	**1**

[a] Site currently attributed high impedance to the neurostimulator

Time Interval	Survival	Effective Sample Size
6 mo	96.8%	32

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	72
Neurostimulators Currently Active in Study	56
Device Events	0
Cumulative Months of Follow-up	350

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	36

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

Deep Brain Neurostimulator Characteristics	
Model Name	Soletra
FDA Approval Date	Jan 2002
Neurostimulators Enrolled	61
Neurostimulators Currently Active in Study	40
Device Events	1[a]
Cumulative Months of Follow-up	702

[a] One event occurred at 30 months when the effective sample size only included 4 devices

Neurostimulator Event	Total
Low Impedance[a]	1
Total Neurostimulator Events	**1**

[a] Site currently attributed low impedance to the neurostimulator

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	42
1 yr	100.0%	28
18 mo	100.0%	21

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	180	166	1	970
Activa SC	Activa	Jan 2011	108	107	1	298

Activa RC	Activa	Map 2009	72	56	0	350
Soletra	Soletra	Jan 2002	61	40	1[a]	702

[a] One event occurred at 30 months when the effective sample size only included 4 devices

Device Survival Probability (95% Confidence Interval)		
Model Name	**6 mo**	**1 yr**
Activa PC	**98.9%** (96.8%, 100.0%)	**98.9%** (96.8%, 100.0%)
Activa SC	**96.8%** (90.6%, 100.0%)	**-**
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, 2012, there were 593 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus the total number of neurostimulators (n=430) 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. Over fifty-four percent (54.6%) were Model 3389, 45.0% were Model 3387 and 0.3% were Model 3391S. The aggregate prospective follow-up time for all leads was 3,319 months (277 years).

Lead Events

There were 8 product performance-related events with an underlying reported etiology related to the lead. Three were medical device complication, 1 was device malfunction, 1 was impedance NOS, 1 was high impedance, 1 was low impedance, and 1 was lead 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. Although 8 product performance-related events with an underlying etiology related to the lead were reported, only 4 were included in the survival analysis. The remaining 4 were not currently able to be linked to the specific lead models in the database; therefore, they were excluded from survival analyses presented in this report. In addition to the 4 leads which were cut-off due to product performance-related events there were 55 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 534 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 tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Survival curves are not shown because fewer 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 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

Lead Characteristics	
Model Number	3387
FDA Approval Date	Jan 2002
Leads Enrolled	267
Leads Currently Active in Study	242
Device Events	1[a]
Cumulative Months of Follow-up	1,357

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

Lead Event	Total
Impedance NOS	1
Total Lead Events	**1**

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	109
1 yr	100.0%	48
at 15 mo	100.0%	21

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

Lead Characteristics	
Model Number	3389
FDA Approval Date	Sep 1999
Leads Enrolled	324
Leads Currently Active in Study	281
Device Events	3
Cumulative Months of Follow-up	1,916

Lead Event	Total
High impedance	1
Lead fracture	1
Medical device complication[a]	1

Total Lead Events	**3**

[a] Open circuits to right lead

Time Interval	Survival	Effective Sample Size
6 mo	99.5%	127
1 yr	99.5%	48
at 15 mo	99.5%	31

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	267	242	1[a]	1,357
3389	**3389**	Sep 1999	324	281	3	1,916

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

Device Survival Probability (95% Confidence Interval)			
Model Name	**Family**	**6 mo**	**1 yr**
3387	**3387**	**100.0%** NA	**100.0%** NA
3389	**3389**	**99.5%** (98.5%, 100.0%)	**99.5%** (98.5%, 100.0%)

Extensions

From July 2009 to the report cut-off date of July 31, 2012, there were 563 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus the total number of neurostimulators (n=430) were due to the fact that some patients were subsequently re-implanted with an extension or implanted with more than 1 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). Over eighty-four percent (84.7%) of the extensions were Model 37085 extensions, 14% were Model 7482 extensions and 1.2% were Other model extensions. The aggregate prospective follow-up time for all extensions was 3,034 months (253 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. In addition to the 3 extensions which were cut-off due to product performance-related events there, were 118 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 442 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 tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval. Survival curves are not shown because fewer 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 37085: Survival from Extension Events

Extension Characteristics	
Model Number	37085
FDA Approval Date	Sep 2009
Extensions Enrolled	477
Extensions Currently Active in Study	426
Device Events	3
Cumulative Months of Follow-up	2,391

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

Time Interval	Survival	Effective Sample Size
6 mo	98.7%	231
1 yr	98.7%	81
at 15 mo	98.7%	37

Model 37085 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	79
Extensions Currently Active in Study	66
Device Events	0
Cumulative Months of Follow-up	628

Extension Event	Total
Total Extension Events	**0**

Time Interval Survival		Effective Sample Size
at 3 mo	100.0%	21

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[a]	Cumulative Months of Follow-up
37085	37085	Sep 2009	477	426	3	2,391
7482	7482	Jan 2002	79	66	0	628

Device Survival Probability (95% Confidence Interval)

Model Number	6 mo	1 yr
37085	**98.7%** (97.2%, 100.0%)	**98.7%** (97.2%, 100.0%)
7482	-	-

2012 Medtronic Product Performance Report: Data through July 31, 2012

Therapies

- Deep Brain Stimulation for Movement Disorders
- Deep Brain Stimulation for Psychiatric Disorders
- Gastric Electrical Stimulation
- Intrathecal Baclofen Therapy for Severe Spasticity
- Intrathecal 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

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, 2012. Five centers enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 173 sacral neuromodulation patients enrolled in the ISPR, the primary indication for implant were as follows: 50.9% were implanted for the treatment of urgency-frequency, 27.2% were implanted for the treatment of urinary urge incontinence, 2.9% were implanted for the treatment of urinary retention, 1.2% were implanted for the treatment of interstitial cystitis, 14.5% were treated for the treatment of some other indication, and 3.5% 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).

Primary Sacral Neuromodulation Treatment Indications

Primary Treatment Indication[a]	Total Enrolled Patients (N=173)
Urgency-frequency	88 (50.9%)
Urinary urge incontinence	47 (27.2%)
Urinary retention	5 (2.9%)
Interstitial cystitis	2 (1.2%)
Other	25 (14.5%)
Not specified	6 (3.5%)
Total Patients	**173**

[a] Refer to product labeling for approved indications.

Event Summary

There were 33 events reported between April 2010 and July 31, 2012 in patients with sacral neuromodulation systems. Of these events, 21.2% (7/33) were categorized as product performance-related and are presented graphically within this report. The 7 product performance events occurred in 7 of the 173 total patients (4.0%) enrolled. In addition, there were 24 non-product performance events and 2 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=173)
Lead fracture	3	3	1.73%
Low impedance	2	2	1.16%
High impedance	1	1	0.58%
Medical device complication[b]	1	1	0.58%
Total	**7**	**7**	**4.05%**

[a] MedDRA Preferred Term

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

A total of 6 (85.7%) of the 7 product performance events were related to the lead, and 1 (14.3%) was related to the neurostimulator.

Sacral Neuromodulation System Non-Product Performance Events (including adverse events and device events, excluding deaths)

Events[a]	Number of Non-Product Performance Events
Pain	4
Urinary incontinence	3
Implant site pain	2
Therapeutic product ineffective	2
Urinary tract disorder	2
Arthralgia	1

Sacral Neuromodulation System Non-Product Performance Events (including adverse events and device events, excluding deaths)	
Back pain	1
Implant site erythema	1
Incisional drainage	1
Pain in extremity	1
Pelvic pain	1
Restless legs syndrome	1
Sensory disturbance	1
Skin reaction	1
Undesirable change in stimulation	1
Vaginal burning sensation	1
Total	**24**

[a] MedDRA Preferred Term

There were 2 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. One patient death occurred in a patient receiving therapy for urgency-frequency and 1 for an indication specified as Other.

Death by Primary Indication	
Primary Indication	**N (%)**
Urgency-frequency	1 (50%)
Other	1 (50%)
Total	**2 (100%)**

Neurostimulators

From April 2010 to the report cut-off date of July 31, 2012, 167 neurostimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=173) versus neurostimulators is due to the fact that some patients were enrolled, but their implant information was not available in the database at the time of the report cut-off date.

Almost seventy five percent (74.9%) of neurostimulators were InterStim II, and 25.1% were InterStim. The aggregate prospective follow-up time for all neurostimulators was 1,096 months (91 years).

Neurostimulator Events

There was 1 product performance-related event with an underlying reported etiology related to sacral nerve stimulator function. For neurostimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 0/6 (0%). 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. The one neurostimulator with a performance-related event was not returned to Medtronic RPA but was assigned as device related by the physician.

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 1 stimulator which was cut-off due to product performance-related events, there were 70 neurostimulators censored in the survival analysis for the following reasons: patient expired, stimulator explanted, patient discontinued, or patient lost to follow-up. The remaining 96 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 tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. Survival curves are not shown because fewer 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

Sacral Neurostimulator Characteristics	
Model Name	InterStim
FDA Approval Date	Jul 1998
Neurostimulators Enrolled	42
Neurostimulators Currently Active in Study	39
Device Events	0
Cumulative Months of Follow-up	361

Neurostimulator Event	Total
Total Neurostimulator Events	**0**

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	30
at 9 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

Neurostimulator Characteristics	
Model Name	InterStim II
FDA Approval Date	Jun 2006
Neurostimulators Enrolled	125
Neurostimulators Currently Active in Study	114

Device Events	1
Cumulative Months of Follow-up	735

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

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

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	63
1 yr	97.9%	31
at 15 mo	97.9%	20

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	42	39	0	361
InterStim II	InterStim	Jun 2006	125	114	1	735

Device Survival Probability (95% Confidence Interval)

Model Name	6 mo	1 yr
InterStim	**100.0%** NA	-
InterStim II	**100.0%** NA	**97.9%** (93.8%, 100.0%)

Leads

From April 2010 to the report cut-off date of July 31, 2012, there were 169 leads followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of neurostimulators (n=167) versus the total leads is due to the fact that some patients 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. Eighty four percent (84.0%) were Model 3889, 13.6% were Model 3093, 0.6% were Model 3080 and 1.8% were other models. The aggregate prospective follow-up time for all leads was 1,105 months (92 years).

Lead Events

There were 6 product performance-related events with an underlying reported etiology related to the lead. Of these, 3 were lead fracture, 2 were low impedance, and 1 was high impedance.

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 6 leads which were cut-off due to product performance-related events there were 15 leads censored in the survival analysis for the following reasons: patient expired, lead explanted, patient

discontinued, or patient lost to follow-up. The remaining 148 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 tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Survival curves are not shown because fewer than 20 devices had at least 24 months of follow-up at the time of the report cut-off for each model. 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

Lead Characteristics	
Model Number	3889
FDA Approval Date	Sep 2002
Leads Enrolled	142
Leads Currently Active in Study	130
Device Events	6
Cumulative Months of Follow-up	937

Lead Event	Total
Lead fracture	3
Low impedance	2
High impedance	1
Total Lead Events	**6**

Time Interval	Survival	Effective Sample Size
6 mo	95.9%	74
1 yr	91.8%	38
at 15 mo	91.8%	24

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	Cumulative Months of Follow-up
3889	**3889**	Sep 2002	142	130	6	937

Device Survival Probability (95% Confidence Interval)

Model Number	Family	6 mo	1 yr
3889	**3889**	**95.9%** (91.4%, 100.0%)	**91.8%** (84.4%, 99.1%)

Extensions

From April 2010 to the report cut-off date of July 31, 2012, there were 43 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus the total neurostimulators (n=167) 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 373 months (31 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, 2012.

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. Four 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 39 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 9-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	43
Extensions Currently Active in Study	39
Device Events	0
Cumulative Months of Follow-up	373

Extension Event	Total
Total Extension Events	**0**

Time Interval	Survival	Effective Sample Size
6 mo	100.0%	31
at 9 mo	100.0%	23

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 9-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	43	39	0	373

Device Survival Probability (95% Confidence Interval)

Model Number	6 mo	9 mo
3095	**100.0%** NA	**100.0%** NA

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Therapies

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

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- Research Proposal Contacts and Guidelines

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- Clinical Research Investigator Guidance

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