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 throughout the United States. This 2011 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.

Implantable Systems Performance Registry (ISPR) Background

The web-based Implantable Systems Performance Registry (ISPR) was created by Medtronic to monitor the performance of infusion and spinal cord stimulation systems commercially available in the United States. 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.

Although some of our other therapies such as deep brain stimulation and sacral nerve stimulation are tracked in the ISPR, the performance of these products is not represented in our report due to the small amount of data currently available.

The ISPR has collected data from 50 centers across the United States for intrathecal drug delivery systems and 43 centers for spinal cord stimulation systems. Each ISPR center received Institutional Review Board (IRB) approval of the registry protocol and associated Informed Consent Forms (ICF). Registry patients signed an ICF prior to enrollment. Each ISPR center followed its standard clinical practice for implanting infusion and spinal cord stimulation systems 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.

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 4th Annual Medtronic Spinal Cord Stimulation 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 and Intrathecal Drug Delivery Systems therapies, we believe that performance reporting is even more important. We strive for better performance with every new product we develop. This report shows the evolution of product performance over time and also reveals advances in therapies that come with this experience and knowledge. Through this sharing of information we can ensure that physicians are able to best leverage state of the art therapy delivery and also understand the performance of our devices to best manage patients. We also invite feedback to help drive continuous improvement.

Included in this report are product survival estimates for our commercially available implantable products used in the management of intractable non-malignant pain, malignant pain, and spasticity. These data are based on the tracking of over 6,800 patients in an ongoing surveillance study conducted in the United States called the Implantable Systems Performance Registry (ISPR). The Registry now includes over 19,000 pumps, catheters, spinal cord stimulators, 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 impact patient care management.

Although some of our other therapies such as deep brain stimulation, gastric stimulation, and sacral nerve stimulation, involve neurostimulation, the performance of these products is not represented in our report because these products were either not included in the ISPR during this time period or minimal data were available for reporting on these products at this time. We are committed to future updates and improvements in our reporting system.

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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Methodology

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

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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. These estimates are made in the absence of other risks, such as mortality or elective explants. For example, a device survival probability of 90% indicates that at the stated follow-up time, the device had a 10% risk of being removed for incurring a device failure 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.

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.

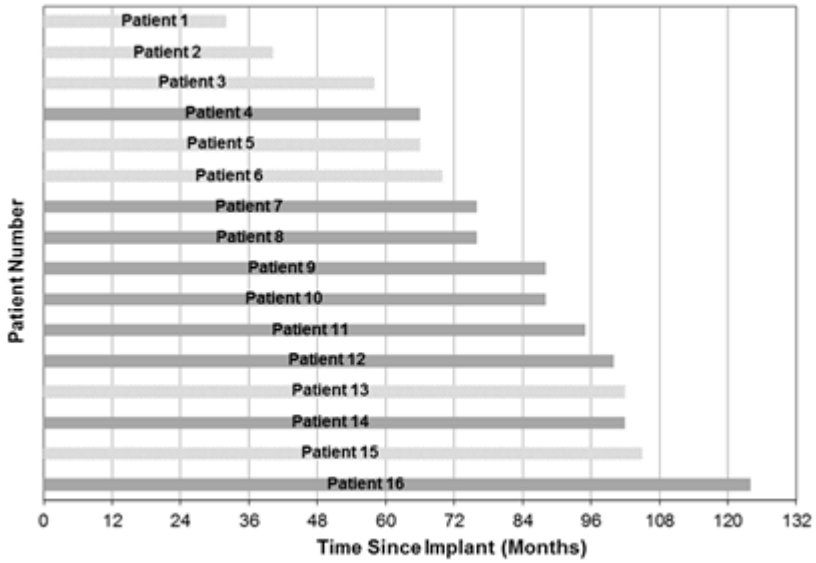

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Figure 1. Implant times for an individual device in 16 patients. Hashed bars indicate devices removed from service due to a product performance event. Solid bars indicate right censored devices.

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.

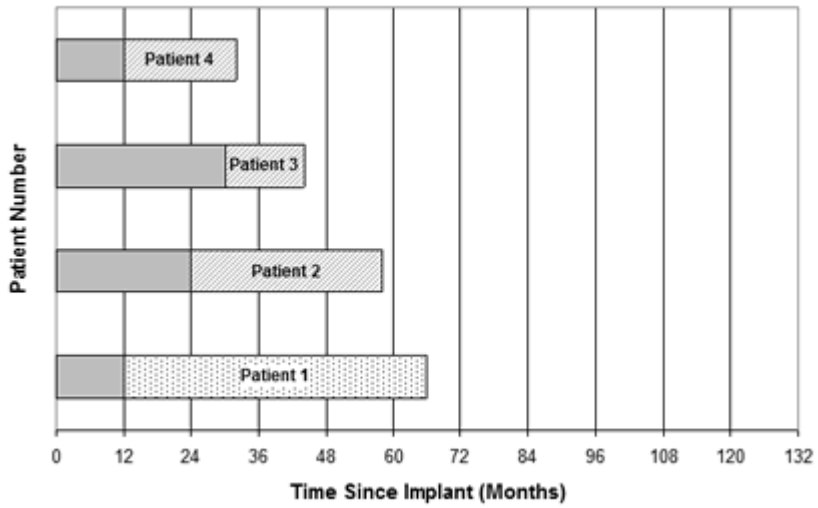

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Figure 2. Implant times for devices in 4 patients that were implanted prior to the device being enrolled in the ISPR. Solid bars represent the time from implant to enrollment in the ISPR, or the

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 spinal cord stimulators that are returned, and RPA establishes a root cause or finds no anomaly, results reported herein default to the RPA finding. 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.

Although returned product analyses are valuable for gaining insight into failure modes, Medtronic does not use these data for determining a device's survival probability because only a small fraction of explanted devices are returned for analysis.

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Intrathecal Drug Delivery Systems

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 29, 2011. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 4,891 total intrathecal drug delivery system patients enrolled in the ISPR through July 29, 2011. As indicated, 52.6% 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 27.1% 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 IndicationsPrimary IDD System Treatment Indications

Primary Treatment Indication[a]	N (Percent)
Pain	**3,535 (72.3%)**
Malignant pain	960 (19.6%)
Non-malignant pain	2,575 (52.6%)
Spasticity	**1,324 (27.1%)**

Combination	**6 (0.1%)**
Non-malignant pain & spasticity	6 (0.1%)
Not Specified	**26 (0.5%)**
Total Patients	**4,891**

[a] Refer to product labeling for approved indications

Malignant Pain Sub-Indications[a]	**N**
Location of Pain	
Spine/back	199
Abdominal/visceral	129
Pelvic	84
Extremity	72
Thoracic	70
Head/neck	40
Other	31
Unknown	440
Total Patients	**960**

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

Non-malignant Pain Sub-Indications	**N**
Back pain without leg pain	1,110
Back pain with leg pain	224
CRPS I[a]	84
Peripheral neuropathy	57
Joint pain/arthritis	35
A general neuropathic condition	21
Osteoporosis	19

CRPS II[a]	11
A general nociceptive condition	2
Other	42
Unknown	976
Total Patients	**2,581**

[a] CRPS is complex regional pain syndrome

Spasticity Sub-Indications	**N**
Cerebral palsy	389
Multiple sclerosis	334
Spinal cord injury	166
Brain injury	105
Stroke	40
Other	20
Unknown	276
Total Patients	**1,330**

Event Summary

There were 2,701 events reported between August 2003 and July 29, 2011 in patients with intrathecal drug delivery systems. Nineteen percent of these events (505/2,701) were categorized as product performance-related events and are presented graphically within this report. In addition, there were 1,164 non-product performance events and 1,032 deaths reported 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=4,891)**

Intrathecal Drug Delivery System Product Performance Events			
Catheter kink/occlusion	138	129	2.64%
Catheter dislodgment from intrathecal space	111	106	2.17%
Catheter break/cut	86	79	1.62%
Motor stall	36	36	0.74%
Medical device complication[c]	24	24	0.49%
Catheter related complication[d]	19	18	0.37%
Catheter disconnection at pump	16	16	0.33%
Catheter disconnection at distal connection	15	15	0.31%
Motor gear corrosion	14	14	0.29%
Pump underinfusion	11	11	0.22%
Catheter leakage	8	8	0.16%
Pump no infusion	4	4	0.08%
Reduced battery performance	4	4	0.08%
Unable to enter/withdraw from catheter access port	4	4	0.08%
Drug-related cracked pump tube	3	3	0.06%
Arachnoiditis[e]	1	1	0.02%
Gait disturbance[e]	1	1	0.02%
Hole in pump tube	1	1	0.02%

Intrathecal Drug Delivery System Product Performance Events			
Muscle spasticity[e]	1	1	0.02%
Pain[e]	1	1	0.02%
Pump migration	1	1	0.02%
Resonator cracked – alarm anomaly	1	1	0.02%
Therapeutic product ineffective[f]	1	1	0.02%
Unable to withdraw fluid from catheter access port	1	1	0.02%
Not coded	3	3	0.06%
Total	**505**	**431**	**8.81%**

[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 13 events reported as pump connector break/cut , 4 events reported as pump malfunction, 1 pump unable to interrogate/program, 1 possible corrosion of pump, 1 inconsistent pump reservoir volume, 1 telemetry stopped secondary to error code, 1 discrepancy in reservoir volume, 1 leak at pump connector, and 1 pump residual volume

[d] Includes 11 events reported as catheter malfunction, 2 coiled catheters, 1 suspected catheter failure, 1 difficulty aspirating catheter, 1 catheter wear, 1 patency issue with catheter, 1 catheter aneurysm, and 1 catheter arachnoid loculations caused by the 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 patient was under-medicated secondary to pump-related issue

A total of 415 (82.2%) of the 505 product performance events were related to the catheter, 83 (16.4%) were related to the pump, 1 (0.2%) was related to incisional site/device tract, 1 (0.2%) was related to medication, 3 (0.6%) were reported as "other" etiology, and 2 (0.4%) did not have a specified etiology.

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events and device events, deaths excluded)	
Event[a]	**Number of Non-Product Performance Events**
Pump end of service (EOS)	512

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events and device events, deaths excluded)	
Implant site infection	106
Therapeutic product ineffective	59
Pump inversion	53
Implant site pain	33
Pain	29
Wound dehiscence	24
Implant site erosion	23
Implant site effusion	21
Drug toxicity	20
Drug withdrawal syndrome	19
Cerebrospinal fluid leakage	18
Pump migration	17
No anomaly found by RPA[b]	11
Hypoaesthesia	10
Inflammatory mass (Confirmed)	10
Therapy non-responder	9
Medical device complication[c]	8
Implant site fibrosis	7
Infection	7
Muscle spasticity	7
Inflammatory mass (Possible)	6
Meningitis	6
Implant site inflammation	5

Intrathecal Drug Delivery System Non-Product Performance Events (including adverse events and device events, deaths excluded)	
Somnolence	5
Wound infection	5
Other[d]	134
Total Events	**1,164**

[a] MedDRA Preferred Term

[b] 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

[c] Includes 2 events reported as unable to fill/refill pump not caused by the pump, 1 pump dislodged from sutures, 1 protrusion of pump, 1 vascular runoff of intrathecal catheter, 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, and 1 suspected malfunction not yet related to a specific device

[d] Composed of 75 event codes that include less than 5 patients each and events that had not been MedDRA coded at the time of the report cut-off (n=15)

There were 1,032 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. As indicated, 68.4% of patient deaths occurred in patients receiving therapy for malignant pain, 22.8% for non-malignant pain, and 8.7% for intractable spasticity.

Deaths by Primary Indication	
Primary Indication	**Count (%)**
Malignant Pain	706 (68.4%)
Non-Malignant Pain	235 (22.8%)
Spasticity	90 (8.7%)
Not Specified	1 (0.1%)
Total	**1,032 (100.0%)**

Pumps

From August 2003 to the report cut-off date of July 29, 2011, 5,562 pumps were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=4,891) versus pumps is due to the fact that some patients were subsequently re-implanted with a pump multiple times.

Most of the pumps followed in the registry were either SynchroMed EL (21.5%) or SynchroMed II (78.4%), and a small number of pumps were SynchroMed Classic (0.1%). The aggregate total prospective follow-up time for all pumps was 138,494 months (11,541 years).

Pump Events

There were 83 product performance-related events with an underlying reported etiology related to pump function. Of these, 76 were the first event attributable to an enrolled pump. The current return rate of pumps to Medtronic Returned Product Analysis (RPA) was 443/2,009 (22%). 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. Forty-nine of the 83 pumps with malfunction events were analyzed by Medtronic RPA: 45 pumps failed due to non-battery-related issues (26 motor stalls, 14 motor gear corrosion, 3 cracked pump tubes, 1 hole in pump tube, and 1 cracked resonator), and 4 failed due to reduced battery performance. The remaining 34 pump events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 11 events due to underinfusion, 9 events due to a medical device complication, 8 events due to physician-reported motor stalls, 4 events due to no infusion, 1 event due to an ineffective pump, and 1 event was not coded. Of the 45 pumps with RPA-confirmed non-battery-related issues, as well as the 8 physician-reported motor stalls, 36 of 53 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 17 pumps, the complete drug history and exposure to admixtures could not be confirmed.

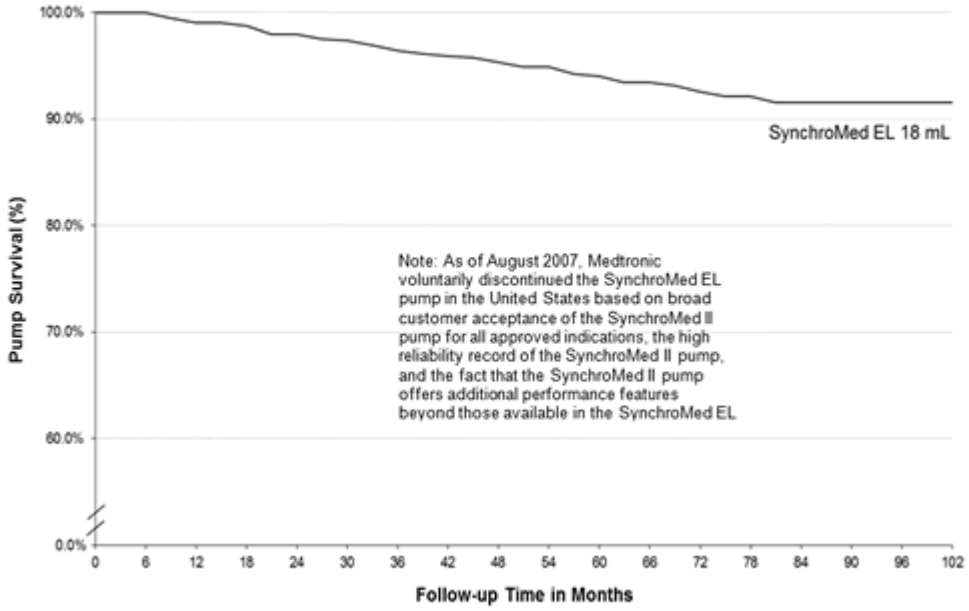
For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event, 2) the occurrence of a non-product performance-related or censoring event, or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. In addition to the 76 pumps which were cut-off due to product performance-related events, there were 3,512 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 1,974 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 Curves

The figures and tables below represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each 3-month interval. At 3 years of follow-up, the 95% confidence intervals for the SynchroMed EL and both SynchroMed II pumps do not overlap. In addition, 95% confidence intervals for the SynchroMed EL and SynchroMed II 40 ml pumps do not overlap at 4 years of follow-up indicating that survival from pump-related events is statistically significantly better for applicable SynchroMed II pumps than SynchroMed EL pumps at these 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.

Model 8627-18 SynchroMed EL 18mL: Device Survival Probability

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	1,162
Pumps Currently Active in Study	38
Device Events	39
Cumulative Months of Follow-up	36,444

Pump Event	**Total**
Motor stall	14
Motor gear corrosion	14
Pump underinfusion	7
Drug-related cracked pump tube	3

Medical device complication[a]	1
Total Pump Events	**39**

[a] Reported as unable to interrogate/program pump

Time Interval	Survival	Effective Sample Size
1 yr	99.0%	216
2 yrs	97.9%	444
3 yrs	96.4%	652
4 yrs	95.3%	668
5 yrs	94.0%	527
6 yrs	92.5%	294
7 yrs	91.5%	122
8 yrs	91.5%	42
at 102 mo	91.5%	20

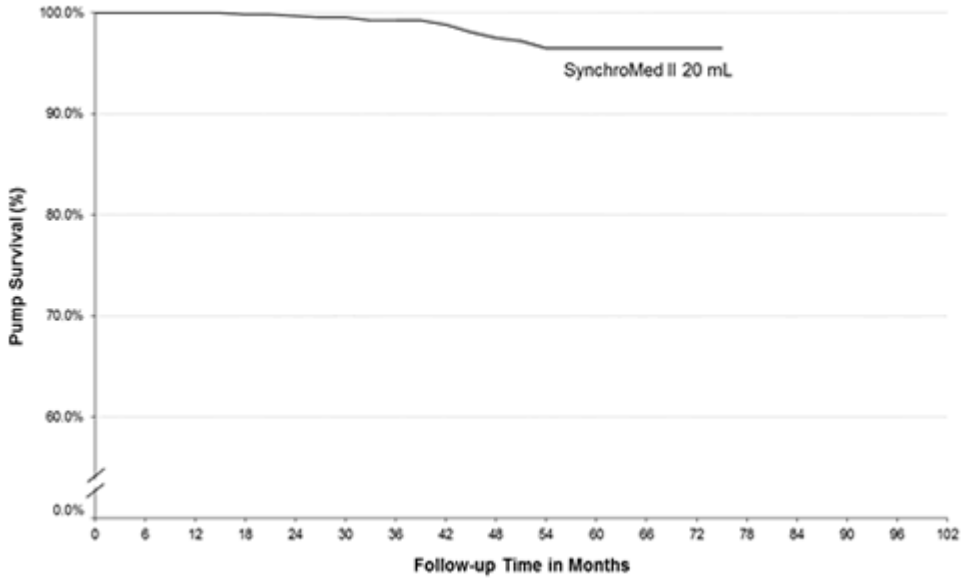
Model 8627-18 SynchroMed EL 18mL: Specifications

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

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

Model 8637-20 SynchroMed II 20mL: Device Survival Probability

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



View Larger Image

Pump Characteristics	
Model Name	SynchroMed II (20 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	1,615
Pumps Currently Active in Study	899
Device Events	16
Cumulative Months of Follow-up	43,446

Pump Event	Total
Motor stall	8
Medical device complication[a]	3
Pump no infusion	2
Hole in pump tube	1
Resonator cracked – alarm anomaly	1
Not coded	1
Total Pump Events	**16**

[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%	1,117
2 yrs	99.7%	865
3 yrs	99.3%	576
4 yrs	97.5%	356
5 yrs	96.5%	170
6 yrs	96.5%	59
at 75 mo	96.5%	36

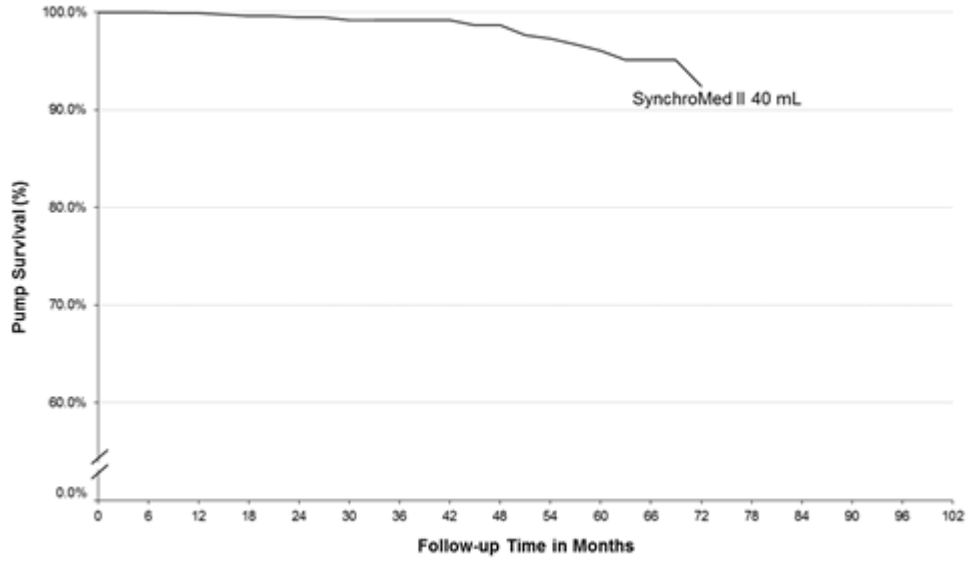
Model 8637-20 SynchroMed II 20mL: Specifications

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: Device Survival Probability

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	2,747
Pumps Currently Active in Study	1,050
Device Events	20
Cumulative Months of Follow-up	54,670

Pump Event	Total
Motor stall	10
Pump underinfusion	3
Reduced battery performance	3
Pump no infusion	2
Medical device complication[a]	1
Therapeutic product ineffective	1
Total Pump Events	**20**

[a] Reported as pump malfunction

Time Interval	Survival	Effective Sample Size
1 yr	99.9%	1,523
2 yrs	99.5%	1,057
3 yrs	99.2%	657
4 yrs	98.7%	359
5 yrs	96.0%	138
6 yrs	92.4%	35

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, at 3 years of follow-up the data indicate that survival from pump-related events is statistically significantly better for both SynchroMed II 20 mL & 40 mL pumps than SynchroMed EL pumps. At 4 years of follow-up, survival from pump-related events is statistically significantly better for SynchroMed II 40 mL pumps than SynchroMed EL pumps. 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	1,162	38	39	36,444
SynchroMed II (20 mL)	Sep 2003	1,615	899	16	43,446
SynchroMed II (40 mL)	Sep 2003	2,747	1,050	20	54,670

[a] There were a total of 83 pump-related events reported to the ISPR, but only 75 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%** (94.5%, 98.4%)	**95.3%** (93.2%, 97.4%)
SynchroMed II (20 mL)	**100.0%** N/A	**99.7%** (99.3%, 100.0%)	**99.3%** (98.6%, 99.9%)	**97.5%** (96.1%, 99.0%)
SynchroMed II (40 mL)	**99.9%** (99.7%, 100.0%)	**99.5%** (99.1%, 99.9%)	**99.2%** (98.6%, 99.7%)	**98.7%** (97.8%, 99.5%)

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

Model Name	5 yrs	6 yrs	7 yrs	8 yrs
SynchroMed EL (18 mL)	**94.0%** (91.8%, 96.3%)	**92.5%** (90.0%, 95.1%)	**91.5%** (88.6%, 94.5%)	**91.5%** (88.6%, 94.5%)
SynchroMed II (20 mL)	**96.5%** (94.6%, 98.3%)	**96.5%** (94.6%, 98.3%)	-	-
SynchroMed II (40 mL)	**96.0%** (93.6%, 98.4%)	**92.4%** (86.4%, 98.5%)	-	-

Catheters

From August 2003 to the report cut-off date of July 29, 2011, 5,283 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=5,562) 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 total prospective follow-up time for all catheters was 145,282 months (12,107 years).

A total of 48.8% of the catheters were Model 8709 catheters, 13.1% were Model 8709SC catheters, 10.8%

were Model 8711 catheters, 9.0% were Model 8731 catheters, 3.5% were Model 8703W catheters, 1.9% were Model 8731SC catheters, and 0.8% 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); 5.6% 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 4.2% 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 415 product performance events reported related to the catheter. Of these events, the majority were catheter kink or occlusion (n=138), catheter dislodgement (n=111), or break or cut in the catheter (n=86). Of the 415 events, 382 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 382 catheters which were cut-off due to product performance-related events, there were 2,961 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 1,940 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.

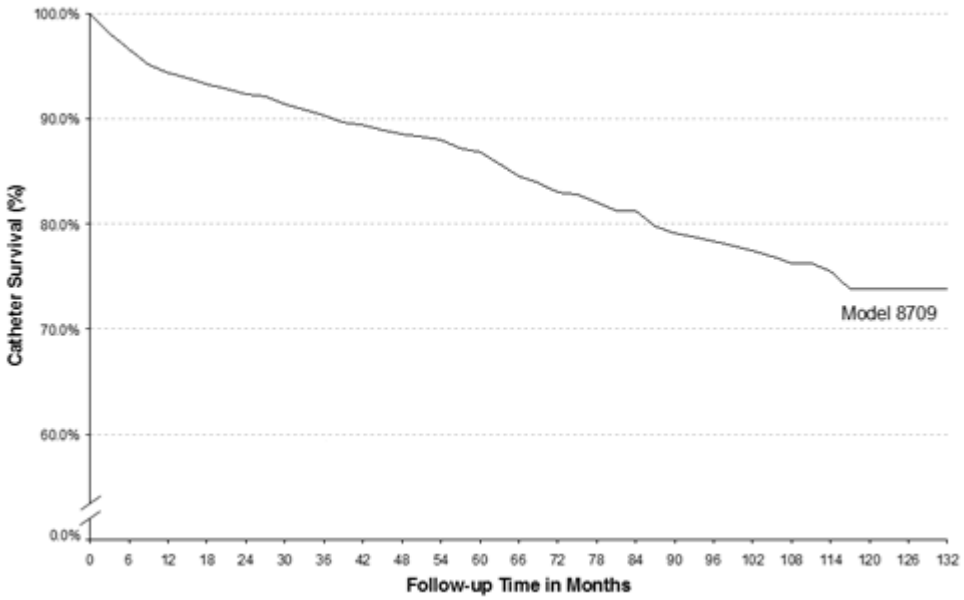
Catheter Survival Curves

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

Although not statistically significantly different, the survival estimates indicate 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 during the first 4 years of follow-up than any other catheter model, 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.

Model 8709: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8709
FDA Approval Date	May 1998
Catheters Enrolled	2,578
Catheters Currently Active in Study	755
Device Events	176
Cumulative Months of Follow-up	66,361

Catheter Events	Total
Catheter kink/occlusion	53
Catheter dislodgment from intrathecal space	44
Catheter break/cut	43
Medical device complication[a]	10
Catheter disconnection at pump	9
Catheter disconnection at distal connection	7

Catheter related complication[b]	3
Catheter leakage	3
Arachnoiditis[c]	1
Pain[c]	1
Unable to enter/withdraw from catheter access port	1
Not coded	1
Total Catheter Events	**176**

[a] Reported as pump connector break/cut

[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

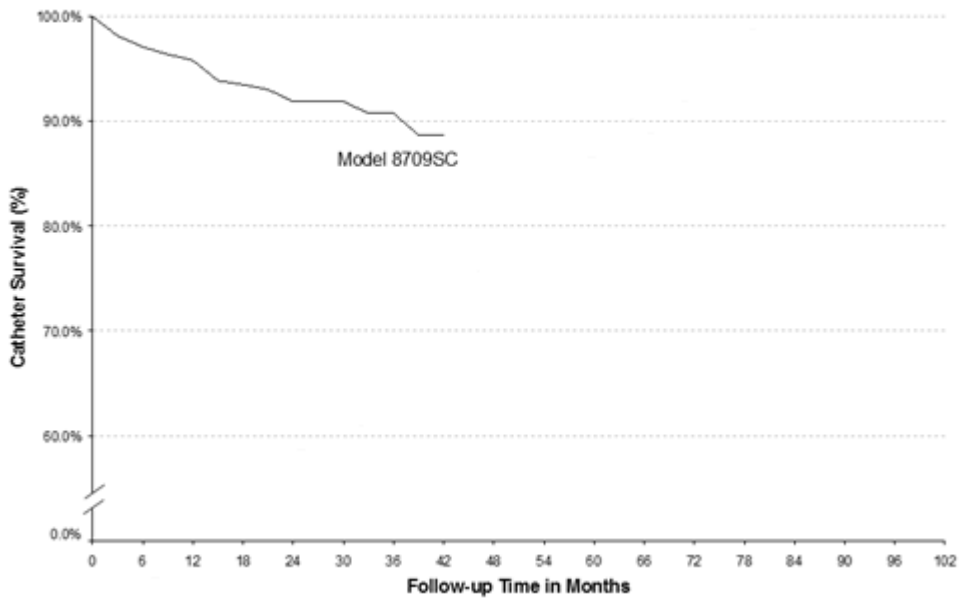
Time Interval	Survival	Effective Sample Size
1 yr	94.4%	986
2 yrs	92.4%	894
3 yrs	90.3%	838
4 yrs	88.6%	701
5 yrs	86.9%	498
6 yrs	83.0%	380
7 yrs	81.3%	289
8 yrs	78.4%	201
9 yrs	76.3%	122
10 yrs	73.8%	77
11 yrs	73.8%	32
at 135 mo	73.8%	24

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	692
Catheters Currently Active in Study	408
Device Events	33

Cumulative Months of Follow-up	9,308

Catheter Events	Total
Catheter dislodgment from intrathecal space	10
Catheter kink/occlusion	8
Catheter break/cut	7
Catheter related complication[a]	2
Catheter disconnection at distal connection	2
Catheter disconnection at pump	1
Catheter leakage	1
Unable to enter/withdraw from catheter access port	1
Medical device complication[b]	1
Total Catheter Events	**33**

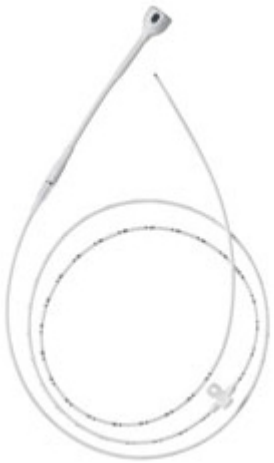
[a] Includes 1 event reported as catheter arachnoid loculations caused by the catheter and 1 catheter malfunction

[b] Reported as leak at pump connector

Time Interval	Survival	Effective Sample Size
1 yr	95.8%	347
2 yrs	91.9%	163
3 yrs	90.8%	60
at 42 mo	88.7%	25

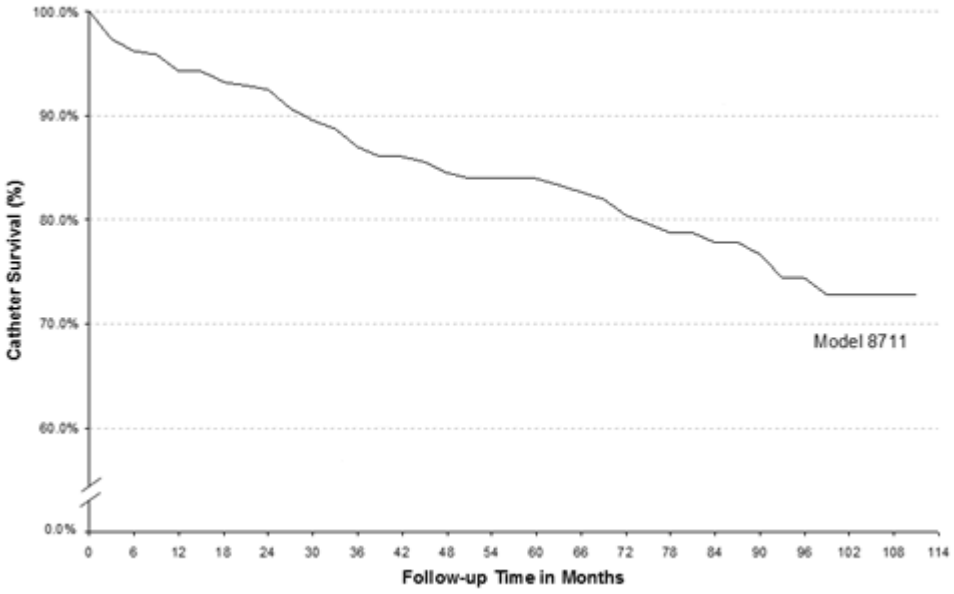
Model 8709SC: Specifications

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	573
Catheters Currently Active in Study	220

Device Events	58
Cumulative Months of Follow-up	17,640

Catheter Events	Total
Catheter kink/occlusion	22
Catheter dislodgment from intrathecal space	12
Catheter break/cut	11
Catheter related complication[a]	4
Catheter disconnection at pump	2
Unable to enter/withdraw from catheter access port	2
Medical device complication[b]	1
Gait disturbance[c]	1
Muscle spasticity[c]	1
Unable to withdraw fluid from catheter access port	1
Not coded	1
Total Catheter Events	**58**

[a] Reported as catheter malfunction

[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%	296
2 yrs	92.5%	258
3 yrs	87.0%	203
4 yrs	84.5%	164
5 yrs	84.0%	140
6 yrs	80.4%	107

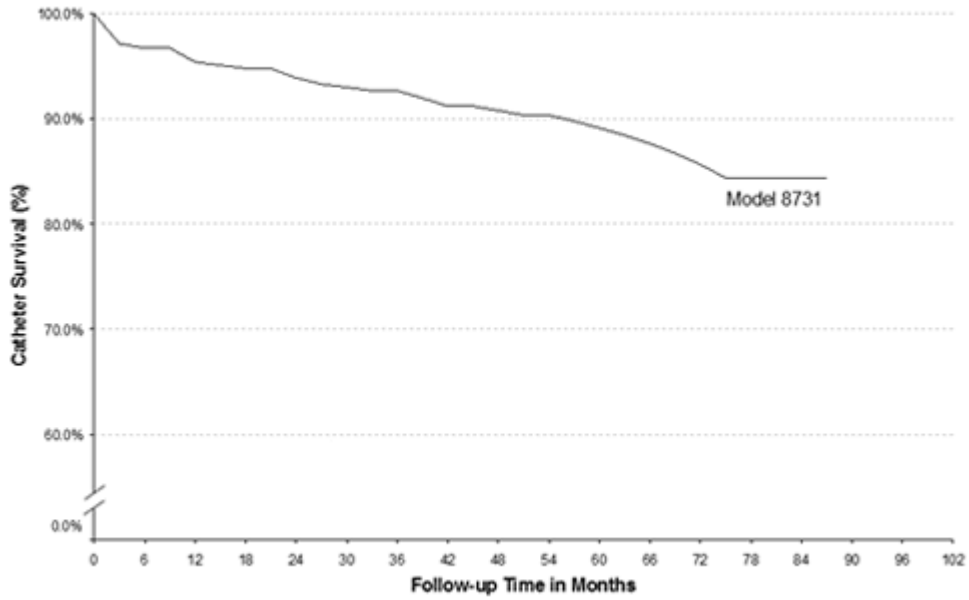
7 yrs	77.8%	82
8 yrs	74.4%	54
9 yrs	72.8%	31
at 111 mo	72.8%	24

Model 8711: Specifications

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

Model 8731: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8731
FDA Approval Date	Oct 2002
Catheters Enrolled	478
Catheters Currently Active in Study	128
Device Events	35
Cumulative Months of Follow-up	17,172

Catheter Events	Total
Catheter dislodgment from intrathecal space	16
Catheter kink/occlusion	12
Catheter related complication[a]	3
Catheter disconnection at distal connection	2
Catheter break/cut	1
Medical device complication[b]	1
Total Catheter Events	**35**

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

[b] Reported as pump connector break/cut

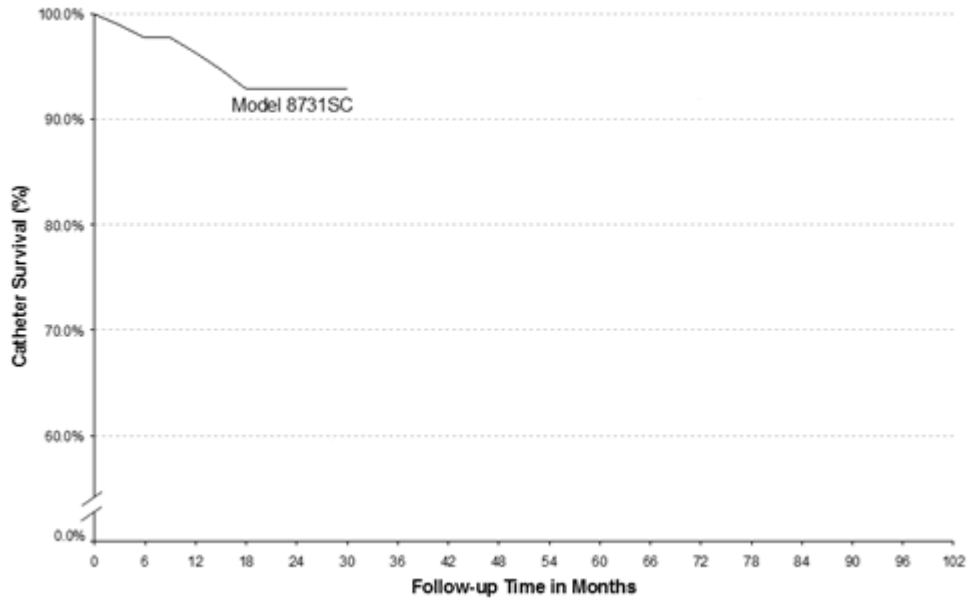
Time Interval	Survival	Effective Sample Size
1 yr	95.4%	291
2 yrs	93.9%	318
3 yrs	92.7%	276
4 yrs	90.8%	216
5 yrs	89.2%	141
6 yrs	85.7%	80
7 yrs	84.4%	33
at 87 mo	84.4%	24

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	103
Catheters Currently Active in Study	55
Device Events	5
Cumulative Months of Follow-up	1,807

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

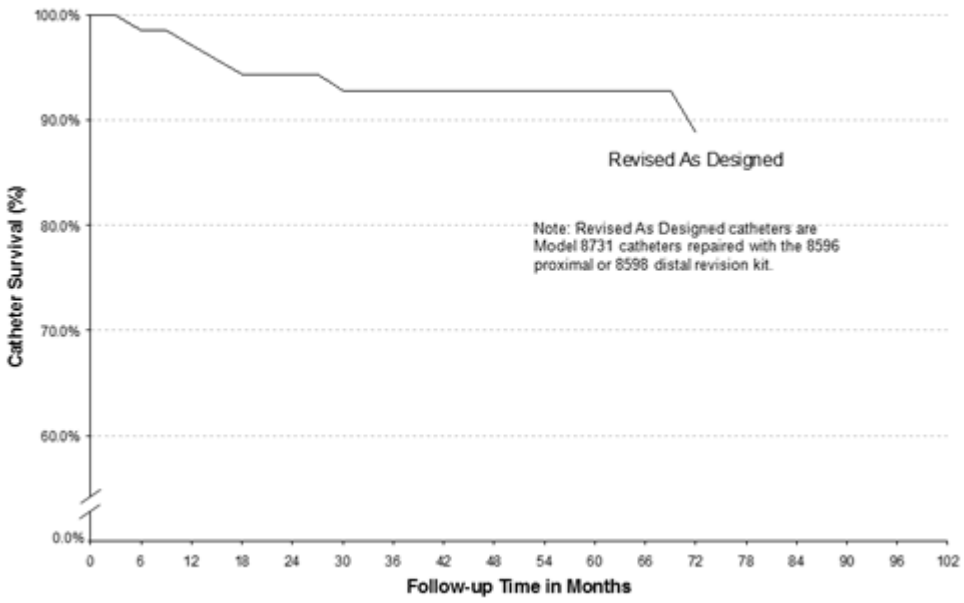
Time Interval	Survival	Effective Sample Size
1 yr	96.3%	67
2 yrs	92.9%	34
at 30 mo	92.9%	22

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	118
Catheters Currently Active in Study	41
Device Events	7
Cumulative Months of Follow-up	4,034

Catheter Events	Total
Catheter kink/occlusion	5
Catheter dislodgment from intrathecal space	1
Catheter related complication[a]	1
Total Catheter Events	**7**

[a] Reported as catheter malfunction

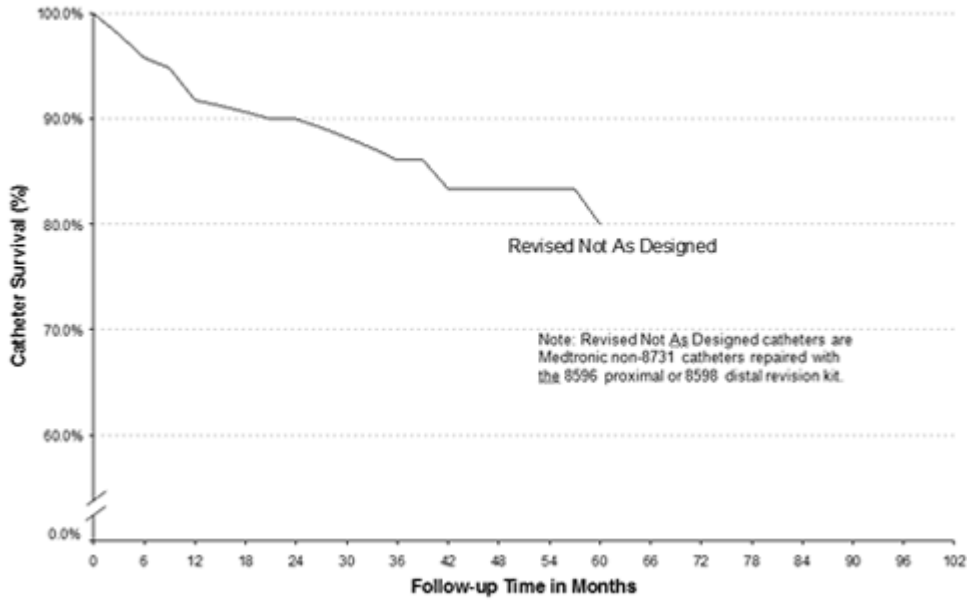
Time Interval	Survival	Effective Sample Size
1 yr	97.2%	69
2 yrs	94.4%	63
3 yrs	92.9%	55
4 yrs	92.9%	49
5 yrs	92.9%	38
6 yrs	88.9%	23

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	294
Catheters Currently Active in Study	153
Device Events	28
Cumulative Months of Follow-up	6,587

Catheter Events	Total
Catheter kink/occlusion	9
Catheter break/cut	8
Catheter dislodgment from intrathecal space	6
Catheter disconnection at distal connection	3
Catheter related complication[a]	1
Catheter leakage	1
Total Catheter Events	**28**

[a] Reported as catheter malfunction

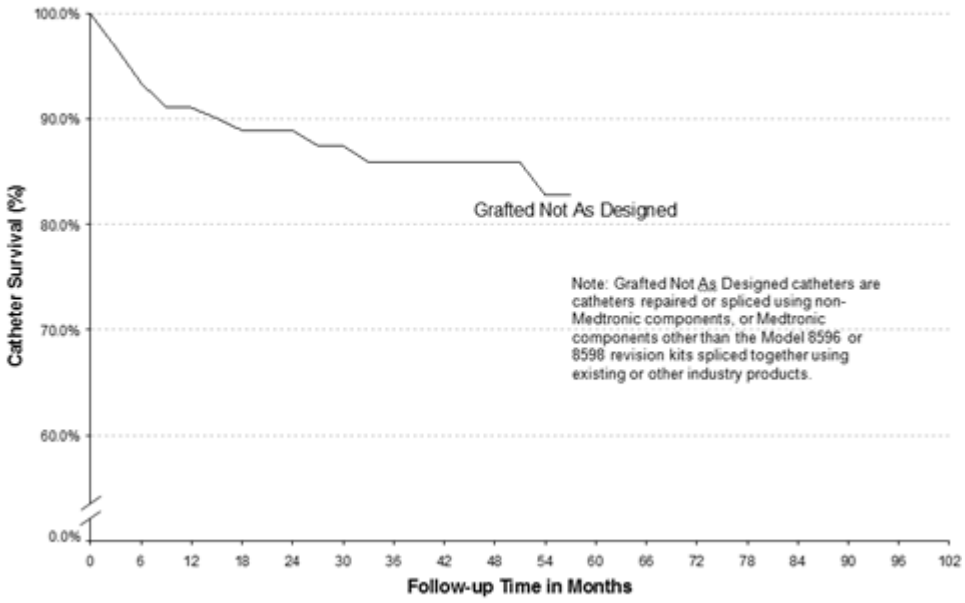
Time Interval	Survival	Effective Sample Size
1 yr	91.8%	187
2 yrs	90.0%	122
3 yrs	86.1%	77
4 yrs	83.4%	44
5 yrs	80.0%	25

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	224
Catheters Currently Active in Study	126
Device Events	21
Cumulative Months of Follow-up	4,427

Catheter Events	Total
Catheter dislodgment from intrathecal space	9
Catheter kink/occlusion	5
Catheter break/cut	3
Catheter related complication[a]	1

Catheter disconnection at pump	1
Medical device complication[b]	1
Catheter leakage	1
Total Catheter Events	**21**

[a] Reported as catheter malfunction
[b] Reported as pump connector break/cut

Time Interval	Survival	Effective Sample Size
1 yr	91.1%	102
2 yrs	88.9%	65
3 yrs	85.9%	50
4 yrs	85.9%	34
at 57 mo	82.8%	21

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

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	2,578	755	176	66,361
8709SC	Mar 2006	692	408	33	9,308
8711	Oct 1999	573	220	58	17,640
8731	Oct 2002	478	128	35	17,172

8731SC	Mar 2006	103	55	5	1,807
Revised As Designed	Oct 2002	118	41	7	4,034
Revised Not As Designed	NA	294	153	28	6,587
Grafted Not As Designed	NA	224	126	21	4,427

[a] There were a total of 415 catheter-related events reported to the ISPR, but only 363 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=19) 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	**94.4%** (93.1%, 95.7%)	**92.4%** (90.8%, 93.9%)	**90.3%** (88.6%, 92.1%)	**88.6%** (86.6%, 90.6%)	**86.9%** (84.7%, 89.1%)
8709SC	**95.8%** (94.0%, 97.7%)	**91.9%** (88.8%, 95.0%)	**90.8%** (87.0%, 94.5%)	**-**	**-**
8711	**94.3%** (91.8%, 96.8%)	**92.5%** (89.6%, 95.4%)	**87.0%** (83.0%, 91.0%)	**84.5%** (80.1%, 88.9%)	**84.0%** (79.4%, 88.5%)
8731	**95.4%** (92.7%, 98.2%)	**93.9%** (90.9%, 96.9%)	**92.7%** (89.5%, 95.9%)	**90.8%** (87.3%, 94.4%)	**89.2%** (85.2%, 93.1%)
8731SC	**96.3%** (92.1%, 100.0%)	**92.9%** (86.6%, 99.2%)	**-**	**-**	**-**
Revised As Designed	**97.2%** (93.2%, 100.0%)	**94.4%** (89.0%, 99.8%)	**92.9%** (86.7%, 99.0%)	**92.9%** (86.7%, 99.0%)	**92.9%** (86.7%, 99.0%)
Revised Not As Designed	**91.8%** (88.1%, 95.5%)	**90.0%** (85.8%, 94.2%)	**86.1%** (80.5%, 91.7%)	**83.4%** (76.8%, 90.0%)	**80.0%** (70.9%, 89.1%)
Grafted Not As Designed	**91.1%** (86.5%, 95.7%)	**88.9%** (83.5%, 94.4%)	**85.9%** (79.2%, 92.6%)	**85.9%** (79.2%, 92.6%)	-

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	**83.0%** (80.3%, 85.8%)	**81.3%** (78.3%, 84.2%)	**78.4%** (74.9%, 81.8%)	**76.3%** (72.4%, 80.2%)	**73.8%** (69.1%, 78.6%)	**73.8%** (69.1%, 78.6%)
8709SC	-	-	-	-	-	-
8711	**80.4%** (75.1%, 85.8%)	**77.8%** (71.8%, 83.8%)	**74.4%** (67.5%, 81.3%)	**72.8%** (65.3%, 80.2%)	-	-
8731	**85.7%** (80.5%, 90.8%)	**84.4%** (78.7%, 90.1%)	-	-	-	-
8731SC	-	-	-	-	-	-
Revised As Designed	**88.9%** (79.2%, 98.6%)	-	-	-	-	-
Revised Not As Designed	-	-	-	-	-	-
Grafted Not As Designed	-	-	-	-	-	-

2011 Medtronic Product Performance Report: Data through July 29, 2011

Spinal Cord Stimulation Systems

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 29, 2011. Forty-three centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Patients

Of the 1,983 total spinal cord stimulation patients enrolled in the ISPR, 11.9% were implanted for the treatment of complex regional pain syndrome (CRPS), 42.9% were implanted for the treatment of failed back surgery syndrome, 43.9% were implanted for the treatment of other pain indications, and 1.3% were implanted for indications that were not specified in the database.

Primary SCS Treatment IndicationsPrimary SCS Treatment Indications

Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
CRPS	**236 (11.9%)**
CRPS I	189 (9.5%)
CRPS II	47 (2.4%)
Failed Back Surgery Syndrome	**851 (42.9%)**
Postlaminectomy pain	392 (19.8%)
Failed back syndrome (FBS)	342 (17.2%)
Multiple back operations	66 (3.3%)
Arachnoiditis	23 (1.2%)
Combination back and leg pain	22 (1.1%)
Unsuccessful disc surgery	6 (0.3%)
Other	**870 (43.9%)**
Radicular pain syndrome	195 (9.8%)
Degenerative disc disease	53 (2.7%)
Cervical pain	4 (0.2%)
Diabetic neuropathy	3 (0.2%)
Post herpetic neuralgia	3 (0.2%)
Epidural fibrosis	2 (0.1%)
Facial pain	2 (0.1%)
Post herniorrhaphy pain	1 (0.1%)
Other chronic pain	585 (29.5%)
Other	22 (1.1%)
Not Specified	**26 (1.3%)**
Total Patients	**1,983**

[a] Medtronic does not endorse use of our products that is contrary to the approved indications. Refer to product

labeling for approved indications.

Event Summary

There were 973 events reported between June 2004 and July 29, 2011 in patients with spinal cord stimulation systems. Thirty percent of these events (295/973) were categorized as product performance-related and are presented graphically within this report. In addition, there were 656 non-product performance events and 53 deaths reported 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=1,983)
Lead migration/dislodgment	157	97	4.89%
Undesirable change in stimulation[c]	48	27	1.36%
Lead fracture	40	26	1.31%
High impedance	15	9	0.45%
Extension fracture	11	6	0.3%
Medical device complication[d]	6	4	0.2%
Recharging unable to recharge[e]	4	4	0.2%
Device failure[f]	3	2	0.1%
Therapeutic productive ineffective[g]	2	1	0.05%
Back disorder[h]	1	1	0.05%
Broken bond wire	1	1	0.05%
Change in sensation of stimulation[i]	1	1	0.05%

Neurostimulation System Product Performance Events			
Device malfunction[j]	1	1	0.05%
Failure of implant[k]	1	1	0.05%
Impedance NOS	1	1	0.05%
Low impedance	1	1	0.05%
Paraesthesia[l]	1	1	0.05%
Not Coded	2	2	0.1%
Total	**295**	**163**	**8.22%**

[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=45)

[d] Includes 2 events reported as damaged leads, 2 lead malfunctions, 1 lead damaged contacts, and 1 unknown problem with an extension

[e] Patient was unable to recharge due to device related issue

[f] Includes 2 events reported as damaged electrodes and 1 extension failure

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

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

[i] Physicians reported effective stimulation coverage could not be obtained due to device issue

[j] Physician reported failure of lead electrodes

[k] Physicians reported extension and lead fracture

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

A total of 269 (91.2%) of the 295 product performance events were related to the lead, 15 (5.1%) were related to the extension, 4 (1.4%) were related to the stimulator, 3 (1.0%) were related to programming/stimulation, 2 (0.7%) were related to an external device, 1 (0.3%) was related to incisional site/device tract, and 1 (0.3%) was related to recharging process.

Neurostimulation System Non-Product Performance Events (including adverse events and device events, deaths excluded)	
Events[a]	**Number of Non-Product Performance Events**
Neurostimulator expected battery depletion	234
Therapeutic product ineffective	83

Neurostimulation System Non-Product Performance Events (including adverse events and device events, deaths excluded)	
Implant site pain	83
Implant site infection	46
Pain	26
Undesirable change in stimulation[b]	26
Change in sensation of stimulation	24
Neurostimulator migration	19
Recharging unable to recharge[c]	15
Implant site erosion	11
Implant site erythema	8
Implant site effusion	5
Infection	5
Medical device complication[d]	5
Wound dehiscence	5
Other[e]	61
Total	**656**

[a] MedDRA Preferred Term

[b] Undesirable change in stimulation 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 damaged leads, 2 lead malfunctions, 1 lead damaged contacts, and 1 unknown problem with an extension

[e] Composed of 41 event codes that include less than 5 patients each and events that had not been MedDRA coded at the time of the report cut-off (n=5)

There were 53 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, 52.8% of patient deaths occurred in patients receiving therapy for pain indications in the unspecified "other" category, 41.5% for failed back, and 5.7% for CRPS.

Death by Primary Indication
Primary Indication N (%)

Death by Primary Indication	
CRPS	3 (5.7%)
Failed Back	22 (41.5%)
Other	28 (52.8%)
Total	**53 (100%)**

Spinal Cord Stimulators

From June 2004 to the report cut-off date of July 29, 2011, 2,259 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). The difference between the total number of patients (n=1,983) versus spinal cord stimulators is due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted.

Twenty-one percent (21%) of the spinal cord stimulators were Synergy, 20.4% were RestoreUltra, 19.9% were Restore, 18.0% were PrimeAdvanced, 11.2% were RestoreAdvanced, 4.6% were Itrel 3, and a smaller number were RestorePrime (2.3%), Synergy Versitrel (1.7%), or SynergyPlus+ (1.1%). The aggregate total prospective follow-up time for all spinal cord stimulators was 53,606 months (4,467 years).

Spinal Cord Stimulator Events

There were 4 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 117/543 (21.5%). 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 4 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 3 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.

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 4 stimulators which were cut-off due to product performance-related events, there were 1,479 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 776 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.

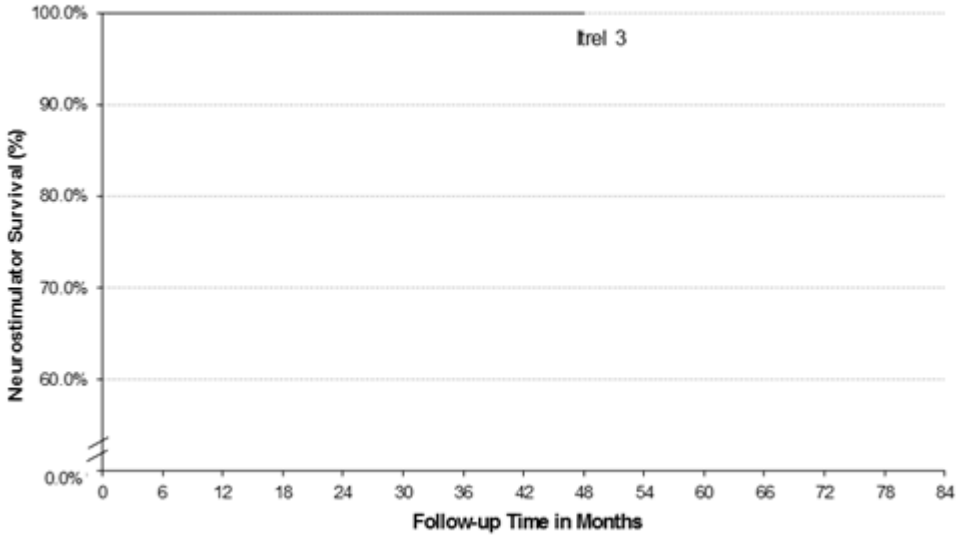
Spinal Cord Stimulator Survival

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.

Choose a model Go

Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	103
Neurostimulators Currently Active in Study	13
Device Events	0
Cumulative Months of Follow-up	3,506

Stimulator Event	Total
Total Stimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	67
2 yrs	100.0%	49
3 yrs	100.0%	38

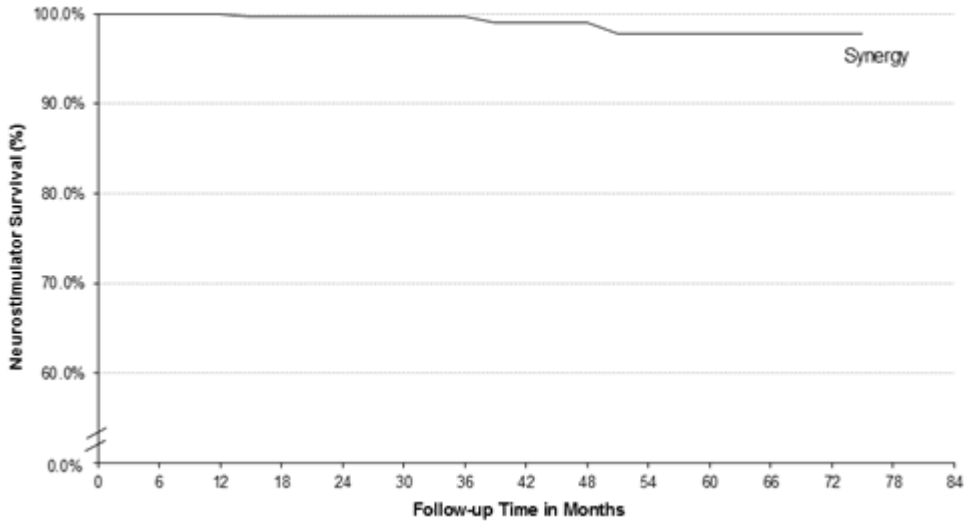
4 yrs	100.0%	23

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	470
Neurostimulators Currently Active in Study	60
Device Events	3
Cumulative Months of Follow-up	16,273

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

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	286
2 yrs	99.7%	251
3 yrs	99.7%	174
4 yrs	99.0%	102

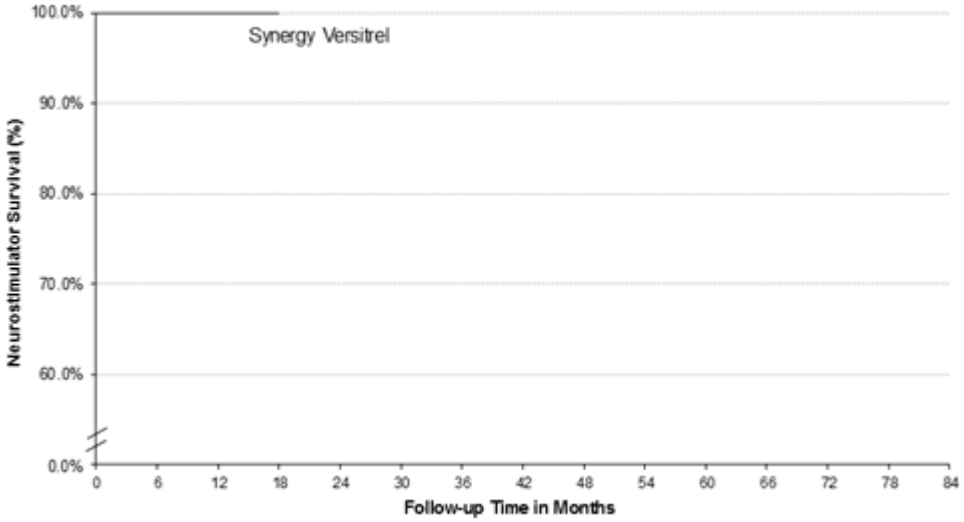
5 yrs	97.8%	50
6 yrs	97.8%	25
at 75 mo	97.8%	22

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

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 Versitrel
FDA Approval Date	Dec 2001
Neurostimulators Enrolled	39
Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	1,252

Stimulator Event	Total
Total Stimulator Events	**0**

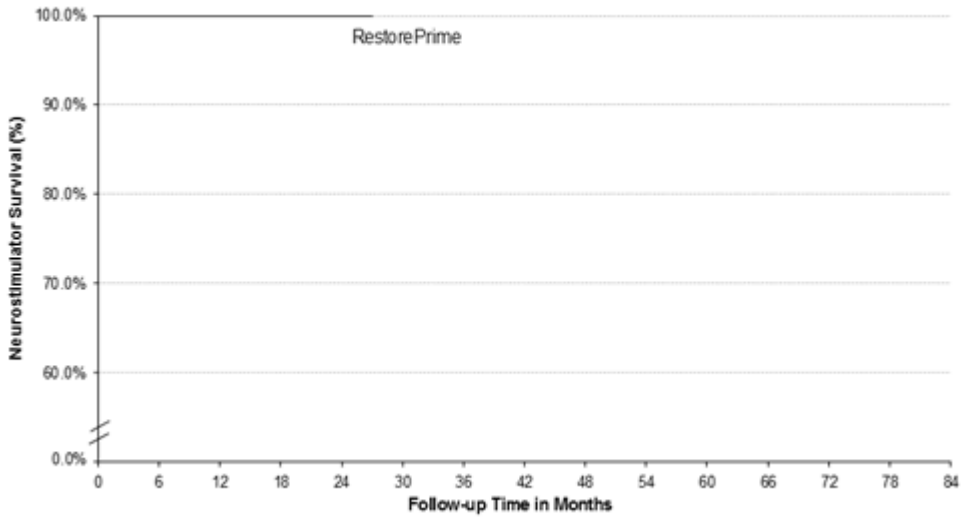
Time Interval Survival		Effective Sample Size
1 yr	100.0%	23
at 18 mo	100.0%	20

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	53
Neurostimulators Currently Active in Study	11
Device Events	0
Cumulative Months of Follow-up	1,301

Stimulator Event	Total
Total Stimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	40
2 yrs	100.0%	22
at 27 mo	100.0%	20

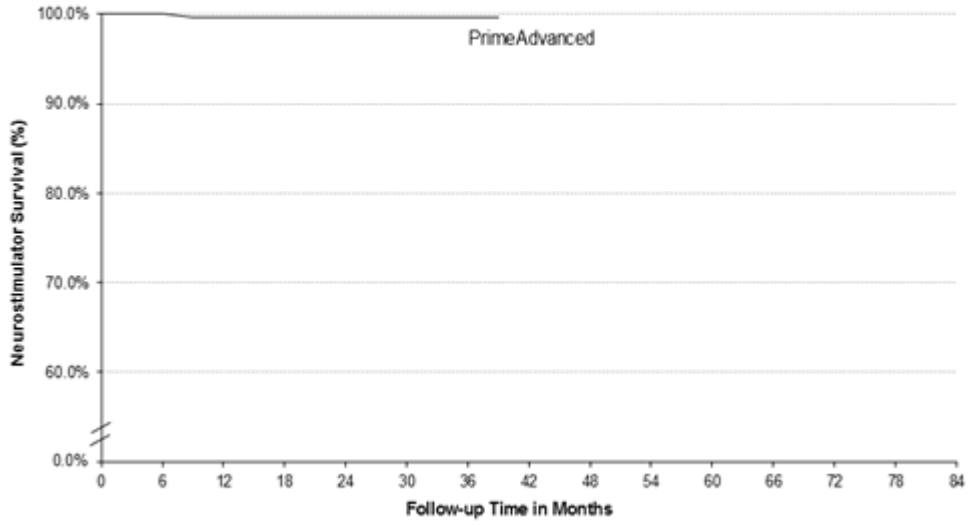
Model 37701 RestorePrime: Specifications

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	406
Neurostimulators Currently Active in Study	177
Device Events	1
Cumulative Months of Follow-up	5,866

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

Time Interval Survival	Effective Sample Size

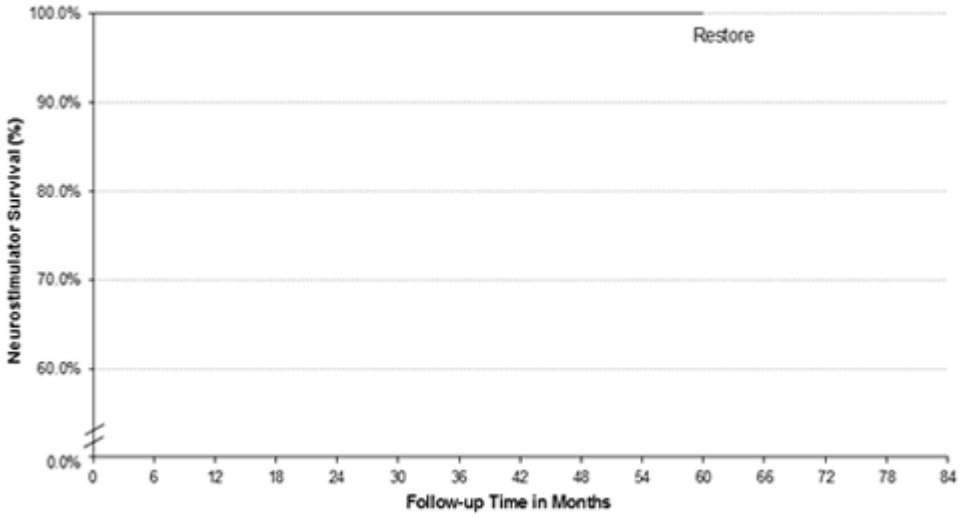
1 yr	99.6%	215
2 yrs	99.6%	88
3 yrs	99.6%	27
at 39 mo	99.6%	20

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	450
Neurostimulators Currently Active in Study	124
Device Events	0
Cumulative Months of Follow-up	13,236

Stimulator Event	Total
Total Stimulator Events	**0**

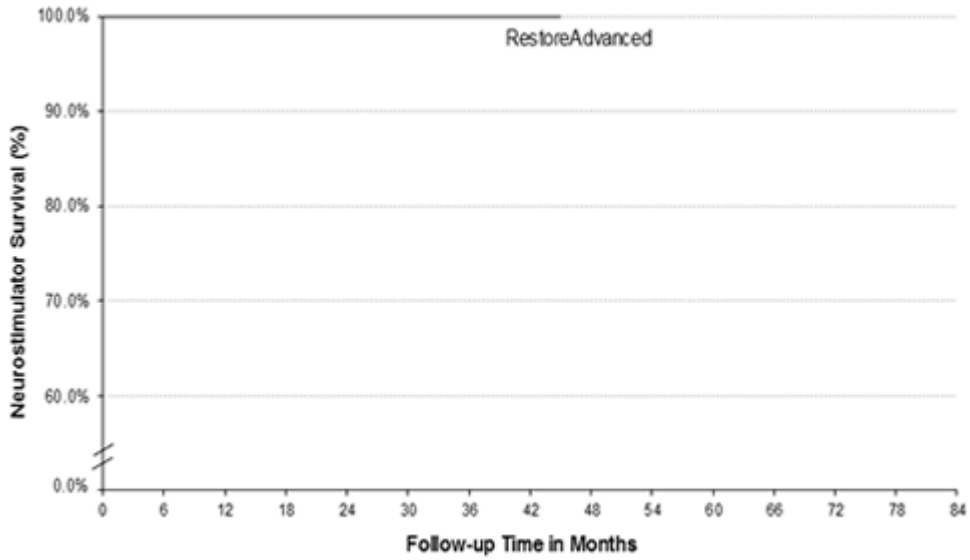
Time Interval Survival		Effective Sample Size
1 yr	100.0%	347
2 yrs	100.0%	252
3 yrs	100.0%	158
4 yrs	100.0%	81
5 yrs	100.0%	28

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	253
Neurostimulators Currently Active in Study	123
Device Events	0
Cumulative Months of Follow-up	5,437

Stimulator Event	Total
Total Stimulator Events	**0**

Time Interval	Survival	Effective Sample Size
1 yr	100.0%	165
2 yrs	100.0%	103
3 yrs	100.0%	57
at 45 mo	100.0%	28

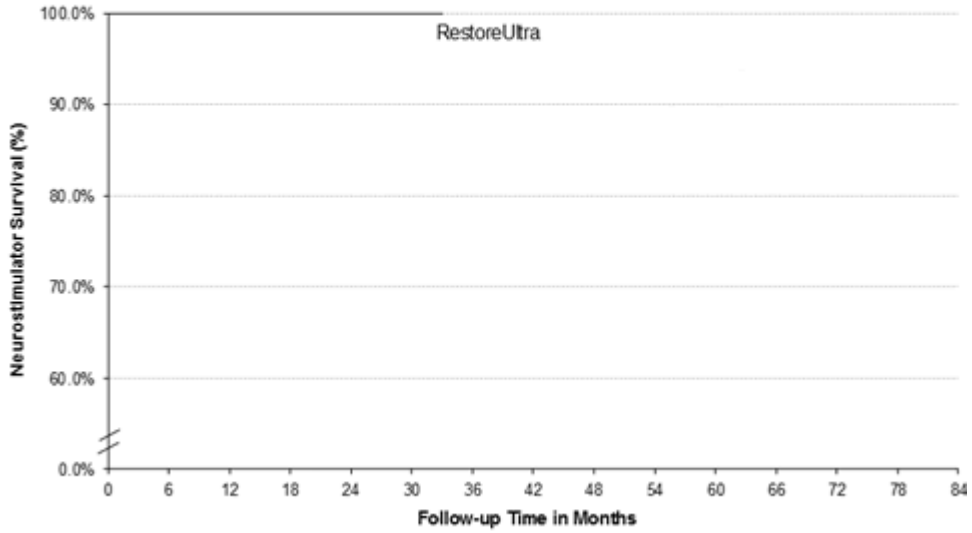
Model 37713 RestoreAdvanced: Specifications

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	461
Neurostimulators Currently Active in Study	295
Device Events	0
Cumulative Months of Follow-up	5,870

Stimulator Event	Total
Total Stimulator Events	**0**

Time Interval Survival	Effective Sample Size

1 yr	100.0%	250
2 yrs	100.0%	71
at 33 mo	100.0%	22

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

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

Itrel3	Itrel3	Aug 1995	103	13	0	3,506
Synergy	Synergy	Nov 1999	470	60	3	16,273
Synergy Versitrel	Synergy	Dec 2001	39	1	0	1,252
Restore	Restore	Apr 2005	450	124	0	13,236
Restore Prime	Restore Prime	Mar 2006	53	11	0	1,301
Restore Advanced	Restore	Jul 2006	253	123	0	5,437
Prime Advanced	Prime Advanced	Jul 2006	406	177	1	5,866
RestoreUltra	Restore	Jan 2008	461	295	0	5,870

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs
Itrel3	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	-	-
Synergy	**100.0%** NA	**99.7%** (99.0%, 100.0%)	**99.7%** (99.0%, 100.0%)	**99.0%** (97.6%, 100.0%)	**97.8%** (95.1%, 100.0%)	**97.8%** (95.1%, 100.0%)
Synergy Versitrel	**100.0%** NA	-	-	-	-	-
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	-
RestorePrime	**100.0%** NA	**100.0%** NA	-	-	-	-
RestoreAdvanced	**100.0%** NA	**100.0%** NA	**100.0%** NA	-	-	-
PrimeAdvanced	**99.6%** (98.8%, 100.0%)	**99.6%** (98.8%, 100.0%)	**99.6%** (98.8%, 100.0%)	-	-	-
RestoreUltra	**100.0%** NA	**100.0%** NA	-	-	-	-

Leads

From June 2004 to the report cut-off date of July 29, 2011, there were 3,816 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=1,983) 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). Eighty-eight percent (88%) of leads in ISPR were percutaneous leads (3,367/3,816) including 51% (1,960/3,816) in the Pisces-Octad lead family, 30% (1,147/3,816) in the Pisces-Quad lead family, and 7% (260/3,816) in the Pisces-Quad LZ lead family. Ten percent (10%) of leads (396/3,816) were surgical leads. A small number of leads (53/3,816) were designated as Other (1%). The aggregate total prospective follow-up time for all leads was 106,121 months (8,843 years).

Lead Events

There were 269 product performance-related events with an underlying reported etiology related to the lead. Of these events, the majority were lead migration/dislodgements (n=156), undesirable change in stimulation (n=45), or lead fracture (n=40). Of the 269 events, 239 were the first event attributable to an enrolled lead. There were 228 events in 3,367 (6.7%) percutaneous leads and 11 events in 396 (2.7%) 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 239 leads which were cut-off due to product performance-related events there were 2,105 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 1,472 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.

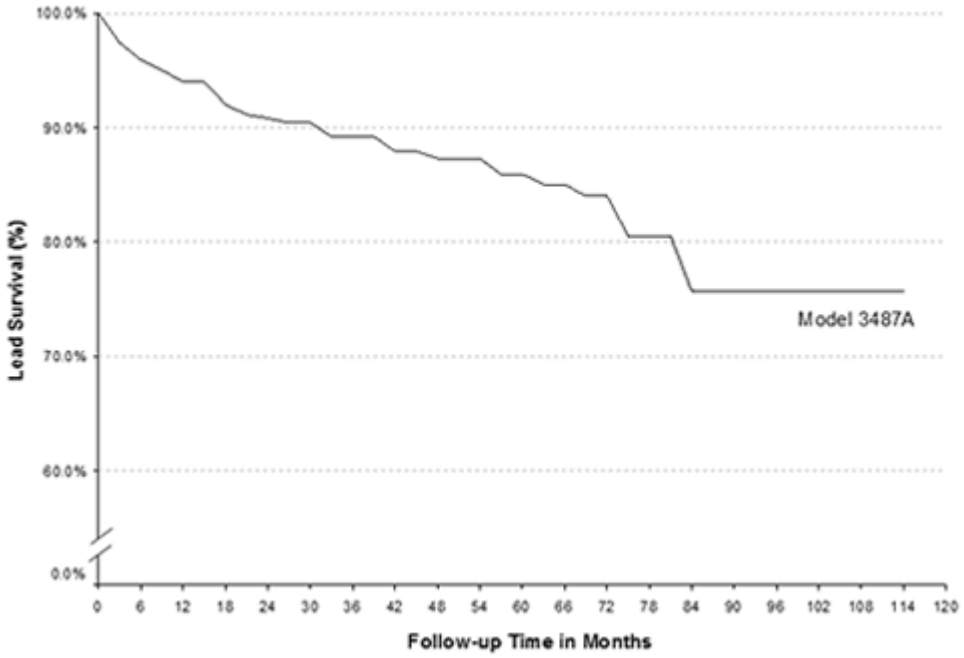
Lead Survival

The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, at 2 years of follow-up, the 95% confidence interval for Specify Model 39565 (surgical lead) does not overlap with percutaneous lead Pisces-Quad Model 3487A, Pisces-Octad Model 3777, Pisces-Octad Model 3778, and Pisces-Quad LZ Model 3891 suggesting that Model 39565 has statistically significantly better performance than Models 3487A, 3777, 3778, and 3891 at this time point.

At 3 years, the 95% confidence interval for Pisces-Quad LZ Model 3891 leads does not overlap with any other applicable lead models, indicating that Model 3891 may not perform as well as other lead models at 3 years. 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.

Model 3487A Pisces-Quad: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3487A
FDA Approval Date	May 1988
Leads Enrolled	712
Leads Currently Active in Study	321
Device Events	58
Cumulative Months of Follow-up	26,958

Lead Event	Total
Lead migration/dislodgment	21
Undesirable change in stimulation	17
Lead fracture	11
High impedance	8
Low impedance	1
Total Lead Events	**58**

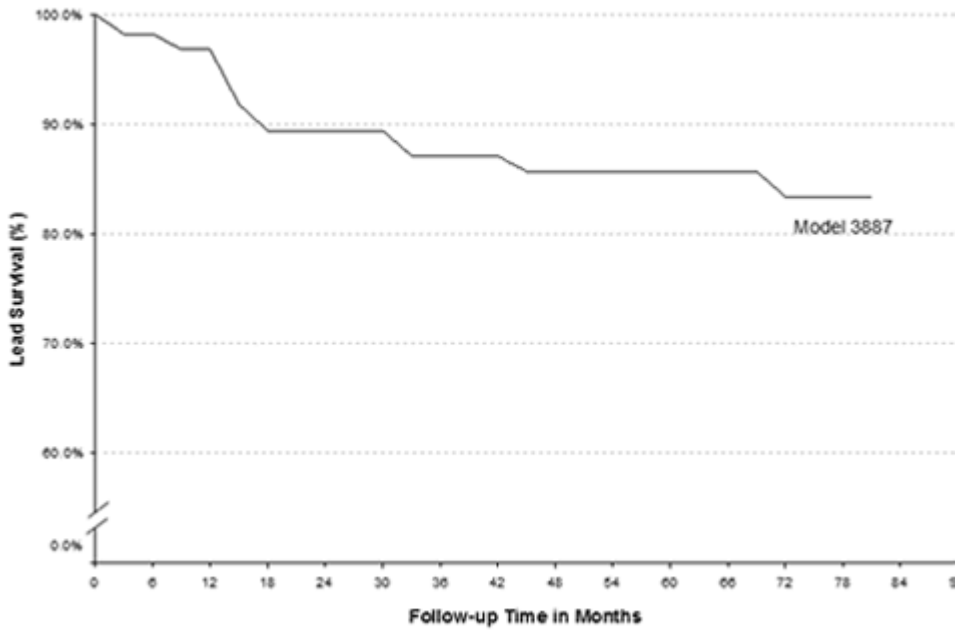
Time Interval	Survival	Effective Sample Size
1 yr	94.0%	397
2 yrs	90.8%	278
3 yrs	89.2%	209
4 yrs	87.3%	171
5 yrs	85.9%	109
6 yrs	84.0%	74
7 yrs	75.7%	51
8 yrs	75.7%	37
9 yrs	75.7%	25
at 114 mo	75.7%	20

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	151
Leads Currently Active in Study	34
Device Events	12
Cumulative Months of Follow-up	7,645

Lead Event	Total
Lead fracture	5
Lead migration/dislodgment	3
Undesirable change in stimulaiton	2
Medical device complication[a]	1
Not Coded	1
Total Lead Events	**12**

[a] Reported as lead damaged contacts

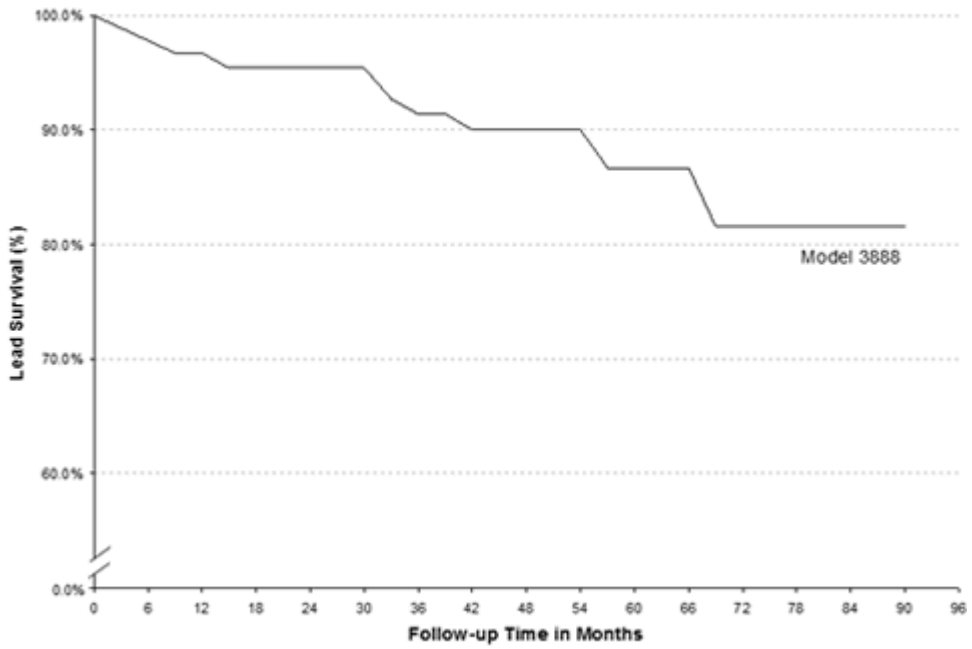
Time Interval	Survival	Effective Sample Size
1 yr	96.8%	76
2 yrs	89.4%	71
3 yrs	87.1%	77
4 yrs	85.7%	57
5 yrs	85.7%	42
6 yrs	83.4%	38
at 81 mo	83.4%	21

Model 3887 Pisces-Quad: Specifications

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

Model 3888 Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3888
FDA Approval Date	Nov 1992
Leads Enrolled	284
Leads Currently Active in Study	73
Device Events	16
Cumulative Months of Follow-up	10,489

Lead Event	Total
Lead migration/dislodgment	13
Undesirable change in stimulation	2
Lead fracture	1
Total Lead Events	**16**

Time Interval	Survival	Effective Sample Size
1 yr	96.7%	161
2 yrs	95.4%	99

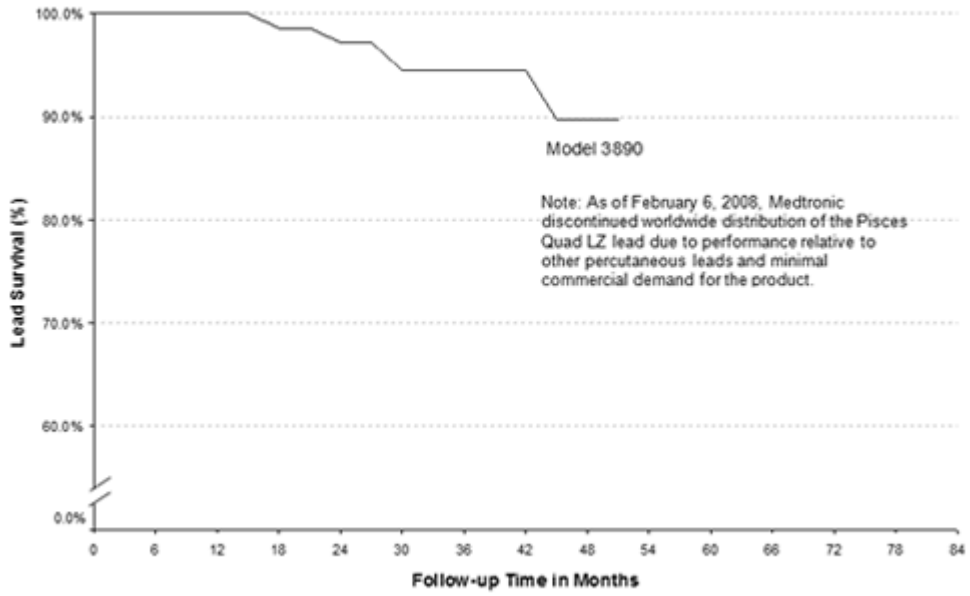
3 yrs	91.4%	68
4 yrs	90.0%	62
5 yrs	86.7%	48
6 yrs	81.6%	31
at 90 mo	81.6%	20

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	133
Leads Currently Active in Study	32
Device Events	6
Cumulative Months of Follow-up	4,598

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

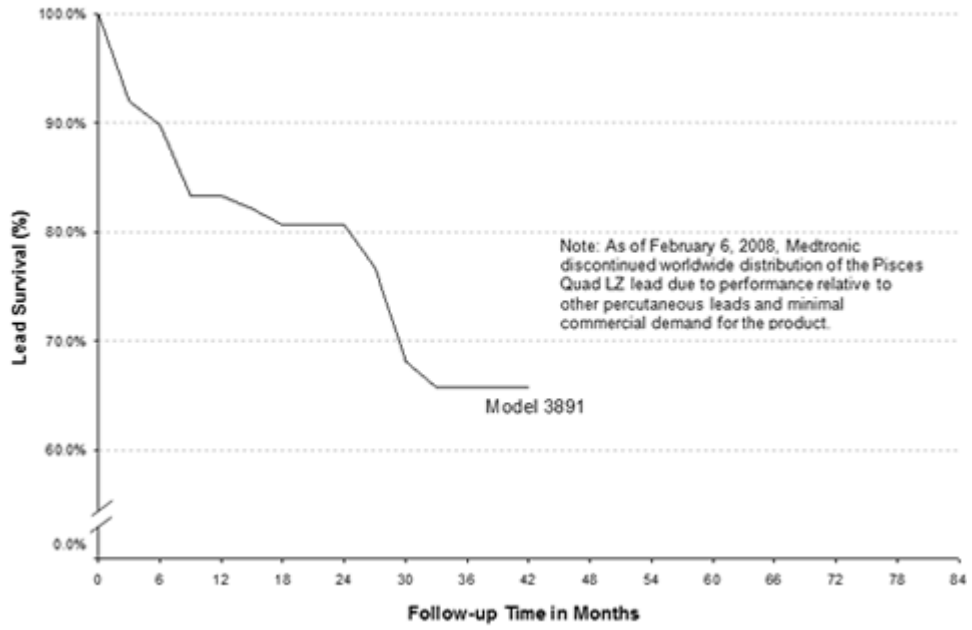
1 yr	100.0%	57
2 yrs	97.2%	71
3 yrs	94.5%	68
4 yrs	89.7%	29
at 51 mo	89.7%	21

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	112
Leads Currently Active in Study	18
Device Events	26
Cumulative Months of Follow-up	3,026

Lead Event	Total
Lead migration/dislodgment	14
Lead fracture	6
Undesirable change in stimulation	4
Device failure[a]	2
Total Lead Events	**26**

[a] Reported as damaged electrodes

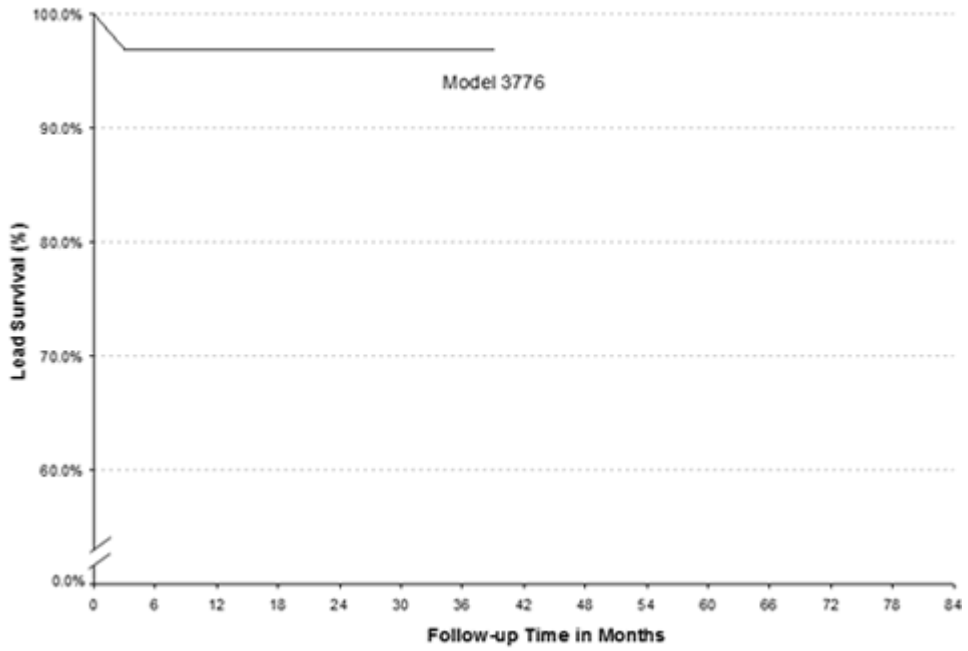
Time Interval	Survival	Effective Sample Size
1 yr	83.3%	73
2 yrs	80.6%	45
3 yrs	65.7%	25
at 42 mo	65.7%	21

Model 3891 Pisces-Quad LZ: Specifications

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

Model 3776 Pisces-Octad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3776
FDA Approval Date	Nov 2005
Leads Enrolled	109
Leads Currently Active in Study	30
Device Events	3
Cumulative Months of Follow-up	2,079

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

Time Interval	Survival	Effective Sample Size
1 yr	96.9%	67
2 yrs	96.9%	31
3 yrs	96.9%	21

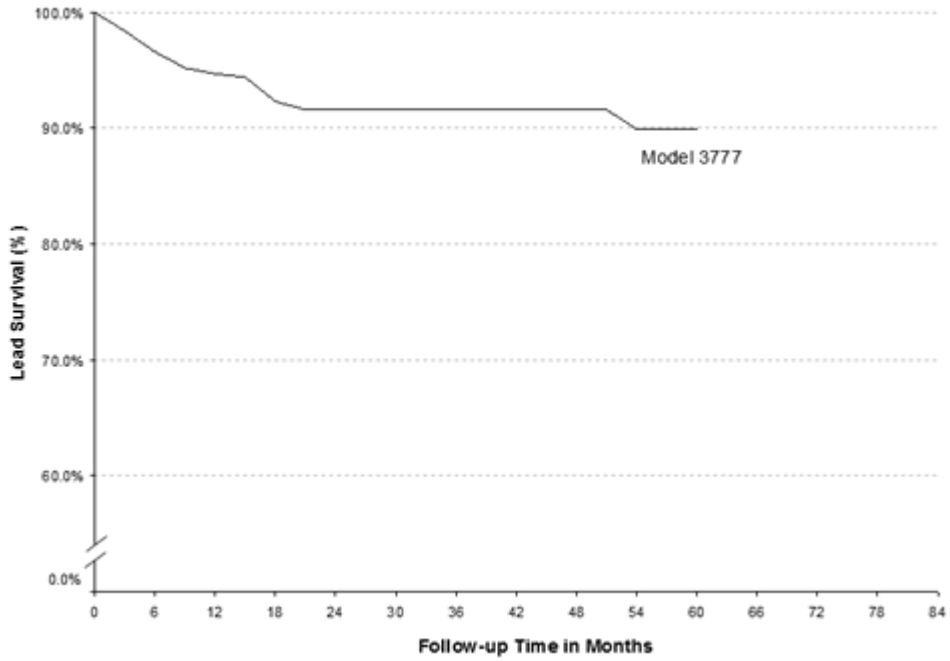
at 39 mo	96.9%	20

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	Mar 2005
Leads Enrolled	586
Leads Currently Active in Study	178
Device Events	35
Cumulative Months of Follow-up	13,536

Lead Event	Total
Lead migration/dislodgment	24
Undesirable change in stimulation	7
Medical device complication[a]	2
High impedance	1
Lead fracture	1
Total Lead Events	**35**

[a] Reported as damaged leads

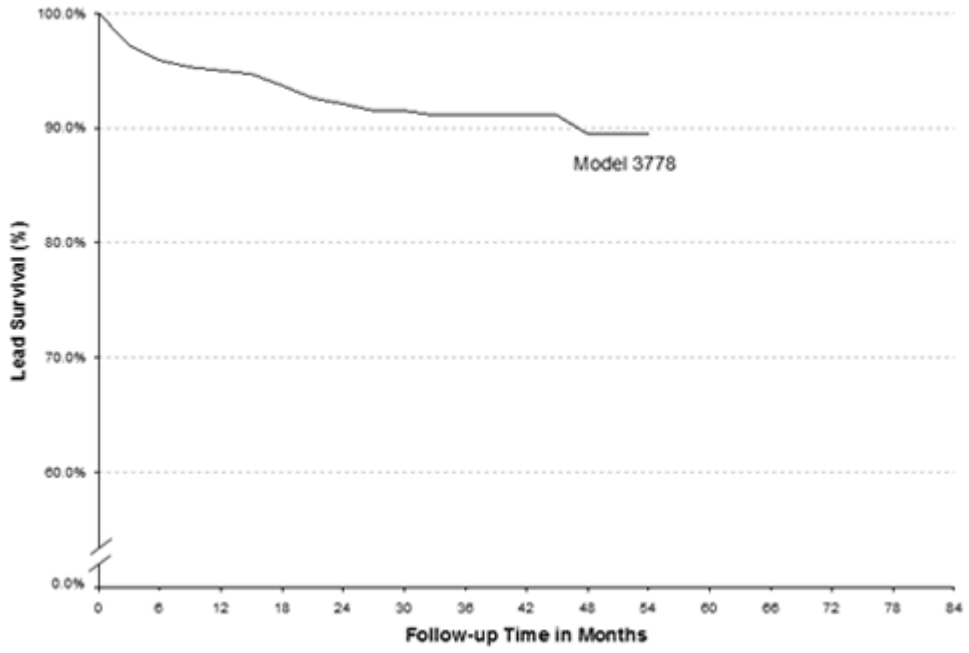
Time Interval	Survival	Effective Sample Size
1 yr	94.7%	377
2 yrs	91.6%	235
3 yrs	91.6%	132
4 yrs	91.6%	74
5 yrs	89.9%	32

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	Mar 2005
Leads Enrolled	1,265
Leads Currently Active in Study	726
Device Events	71
Cumulative Months of Follow-up	21,974

Lead Event	Total
Lead migration/dislodgment	57
Lead fracture	5
Undesirable change in stimulation	4
Medical device complication[a]	2
Back disorder[b]	1
High impedance	1

Impedance NOS	1
Total Lead Events	**71**

[a] Reported as lead malfunctions

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

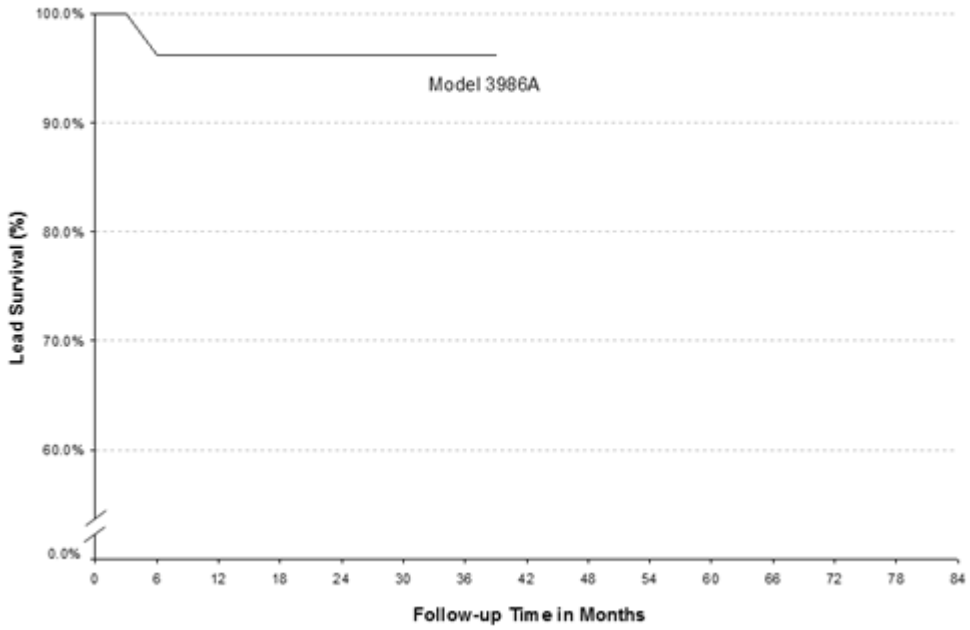
Time Interval	Survival	Effective Sample Size
1 yr	95.0%	726
2 yrs	92.1%	374
3 yrs	91.1%	188
4 yrs	89.5%	55
at 54 mos	89.5%	22

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	Jul 1997
Leads Enrolled	74
Leads Currently Active in Study	31
Device Events	2
Cumulative Months of Follow-up	1,758

Lead Event	Total
Undesirable change in stimulation	2
Total Lead Events	**2**

Time Interval	Survival	Effective Sample Size
1 yr	96.2%	39
2 yrs	96.2%	28
3 yrs	96.2%	23

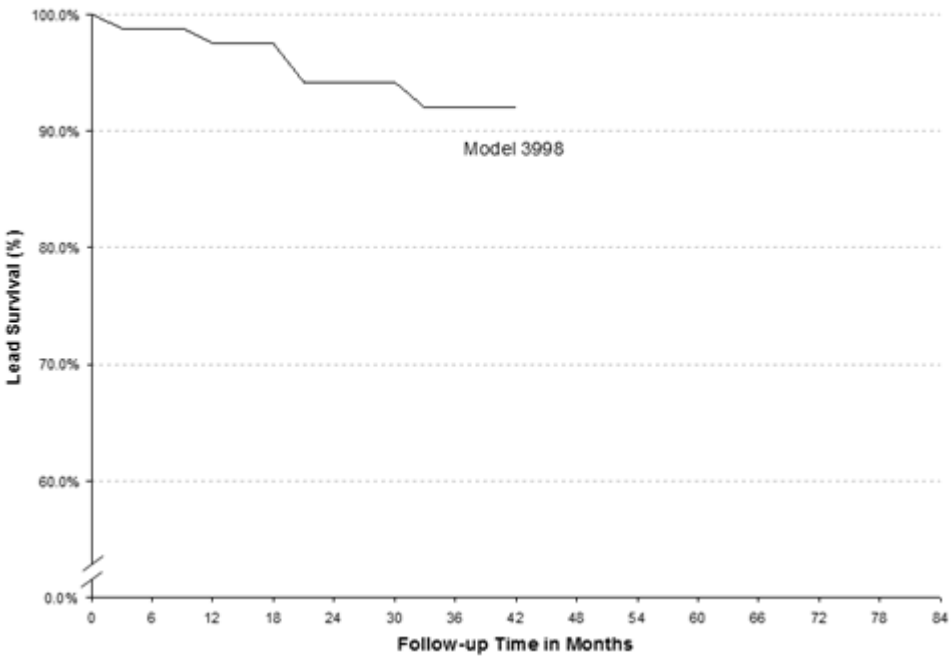
at 39 mo	96.2%	20

Model 3986A Resume TL: Specifications

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

Model 3998 Specify: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	126
Leads Currently Active in Study	22
Device Events	6
Cumulative Months of Follow-up	4,366

Lead Event	Total
Lead fracture	3
Device malfunction[a]	1
Lead migration/dislodgment	1
Undesirable change in stimulation	1
Total Lead Events	**6**

[a] Reported as failure of lead electrodes

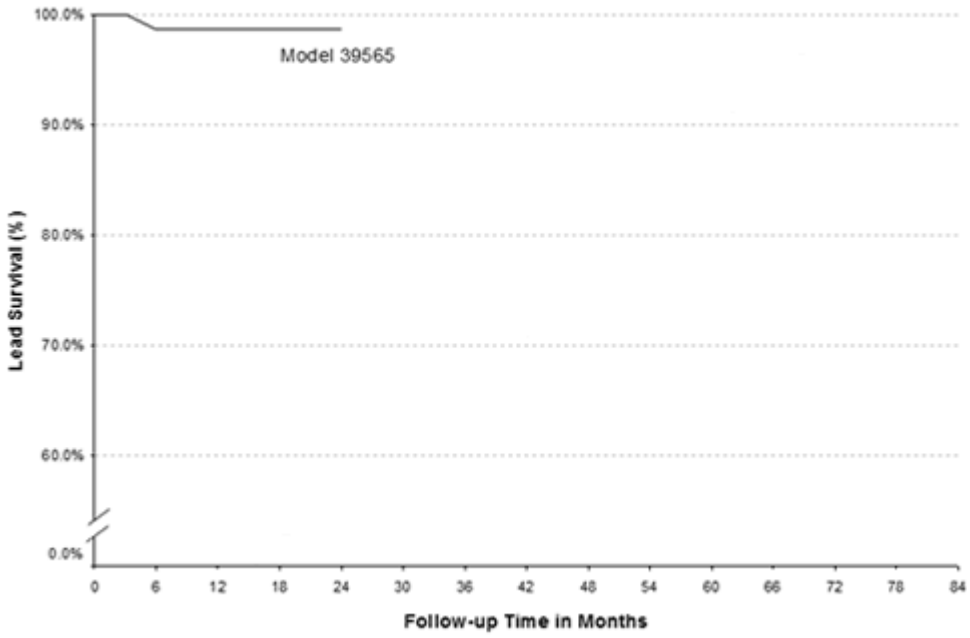
Time Interval	Survival	Effective Sample Size
1 yr	97.5%	76
2 yrs	94.2%	53
3 yrs	92.0%	32
at 42 mo	92.0%	23

Model 3998 Specify: Specifications

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

Model 39565 Specify: Survival from Lead Events

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



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Lead Characteristics	
Model Number	39565
FDA Approval Date	Jun 2007
Leads Enrolled	89
Leads Currently Active in Study	57
Device Events	1
Cumulative Months of Follow-up	1,466

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

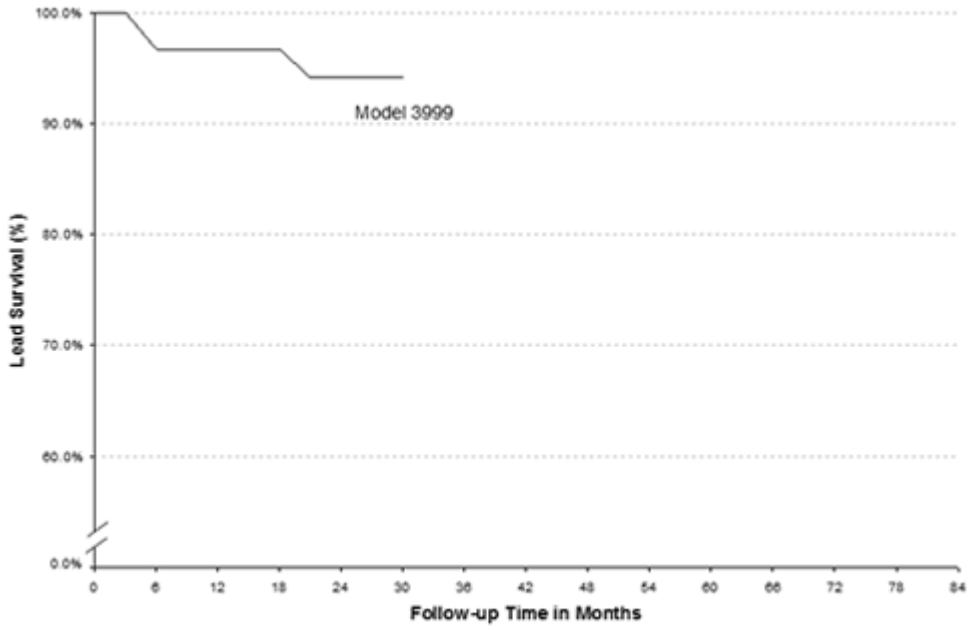
Time Interval	Survival	Effective Sample Size
1 yr	98.6%	57
2 yrs	98.6%	24

Model 39565 Specify: Specifications

Device Name	**Specify 5-6-5**
Lead Type	**Surgical**
Lead	
Length (cm)	30, 65
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Length (mm)	4.0
Width (mm)	1.5
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	4.5
Lateral Spacing: Edge to Edge (mm)	1.0
Array Length (mm)	49.0
Array Width (mm)	7.5
Paddle	
Length (mm)	64.2
Width (mm)	10.0
Thickness (mm)	7.5

Model 3999 2x4 Hinged: 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	3999
FDA Approval Date	Jun 2004
Leads Enrolled	50
Leads Currently Active in Study	5
Device Events	2
Cumulative Months of Follow-up	1,384

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

Time Interval	Survival	Effective Sample Size
1 yr	96.7%	39
2 yrs	94.1%	34
at 30 mo	94.1%	23

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]

At 2 years of follow-up, surgical lead Model 39565 has statistically significantly better performance than percutaneous lead Models 3487A, 3777, 3778, and 3891. At 3 years of follow-up, the data indicate that Model 3891 does not perform as well as other lead models. 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	712	321	58	26,958
3776	**Pisces-Octad**	Nov 2005	109	30	3	2,079
3777	**Pisces-Octad**	Mar 2005	586	178	35	13,536
3778	**Pisces-Octad**	Mar 2005	1,265	726	71	21,974
3887	**Pisces-Quad**	Jan 1997	151	34	12	7,645
3888	**Pisces-Quad**	Nov 1992	284	73	16	10,489
3890	**Pisces-Quad LZ**	Sep 2002	133	32	6	4,598
3891	**Pisces-Quad LZ**	Sep 2002	112	18	26	3,026
Surgical Leads						
3986A	**Resume TL**	Jul 1997	74	31	2	1,758
3998	**Specify**	Feb 1998	126	22	6	4,366
3999	**2 x 4 Hinged Specify**	Jun 2004	50	5	2	1,384
39565	**Specify**	Jun 2007	89	57	1	1,466

[a] There were a total of 269 lead-related events reported to the ISPR, but only 238 events included in this summary table. The remaining events either occurred in lead models for which no device survival curves are presented due to an insufficient number of enrolled devices (ie, Model 3892), were subsequent events that did not affect the device survival estimates, or were events that were not able to be associated with a specific lead (eg, the event had a lead etiology, but no lead serial number or lot number was specified).

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**	**94.0%** (91.7%, 96.2%)	**90.8%** (87.9%, 93.7%)	**89.2%** (86.0%, 92.4%)	**87.3%** (83.7%, 91.0%)	**85.9%** (81.8%, 90.1%)
3776	**Pisces-Octad**	**96.9%** (93.4%,	**96.9%** (93.4%,	**96.9%** (93.4%,	-	-

		100.0%)	100.0%)	100.0%)		
3777	**Pisces-Octad**	**94.7%** (92.6%, 96.8%)	**91.6%** (88.8%, 94.4%)	**91.6%** (88.8%, 94.4%)	**91.6%** (88.8%, 94.4%)	**89.9%** (85.7%, 94.2%)
3778	**Pisces-Octad**	**95.0%** (93.6%, 96.4%)	**92.1%** (90.1%, 94.1%)	**91.1%** (88.8%, 93.4%)	**89.5%** (85.5%, 93.5%)	-
3887	**Pisces-Quad**	**96.8%** (92.4%, 100.0%)	**89.4%** (82.3%, 96.5%)	**87.1%** (79.4%, 94.7%)	**85.7%** (77.7%, 93.7%)	**85.7%** (77.7%, 93.7%)
3888	**Pisces-Quad**	**96.7%** (94.1%, 99.4%)	**95.4%** (92.2%, 98.6%)	**91.4%** (85.8%, 96.9%)	**90.0%** (83.9%, 96.1%)	**86.7%** (79.2%, 94.1%)
3890	**Pisces-Quad LZ**	**100.0%** NA	**97.2%** (93.2%, 100.0%)	**94.5%** (89.2%, 99.8%)	**89.7%** (81.4%, 98.0%)	-
3891	**Pisces-Quad LZ**	**83.3%** (75.5%, 91.2%)	**80.6%** (72.1%, 89.1%)	**65.7%** (53.3%, 78.1%)	-	-
Surgical Leads						
3986A	**Resume TL**	**96.2%** (91.0%, 100.0%)	**96.2%** (91.0%, 100.0%)	**96.2%** (91.0%, 100.0%)	-	-
3998	**Specify**	**97.5%** (93.9%, 100.0%)	**94.2%** (88.6%, 99.9%)	**92.0%** (84.9%, 99.1%)	-	-
3999	**2 x 4 Hinged Specify**	**96.7%** (90.3%, 100.0%)	**94.1%** (86.1%, 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
Percutaneous Leads					
3487A	**Pisces-Quad**	**84.0%** (79.1%, 88.8%)	**75.7%** (67.9%, 83.6%)	**75.7%** (67.9%, 83.6%)	**75.7%** (67.9%, 83.6%)

3776	**Pisces-Octad**	-	-	-	-
3777	**Pisces-Octad**	-	-	-	-
3778	**Pisces-Octad**	-	-	-	-
3887	**Pisces-Quad**	**83.4%** (74.4%, 92.4%)	-	-	-
3888	**Pisces-Quad**	**81.6%** (71.8%, 91.5%)	-	-	-
3890	**Pisces-Quad LZ**	-	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
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 29, 2011, there were 2,316 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=1,983) 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). Thirty-three percent (33%) of the extensions were Model 37081 extensions, 30.1% were Model 7489 extensions, 19.0% were Model 37082 extensions, 8.6% were Model 7495 extensions, 7.8% were Model 37083 extensions, and <1% were Model 7472, Model 7496 and other models. The aggregate total prospective follow-up time for all extensions was 75,616 months (6,301 years).

Extension Events

There were 15 product performance-related events with an underlying reported etiology related to the extension. Of these events, the majority were extension fractures (n=11). Of the 15 events, 14 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 14 extensions which were cut-off due to product performance-related events there, were 1,584 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 718 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.

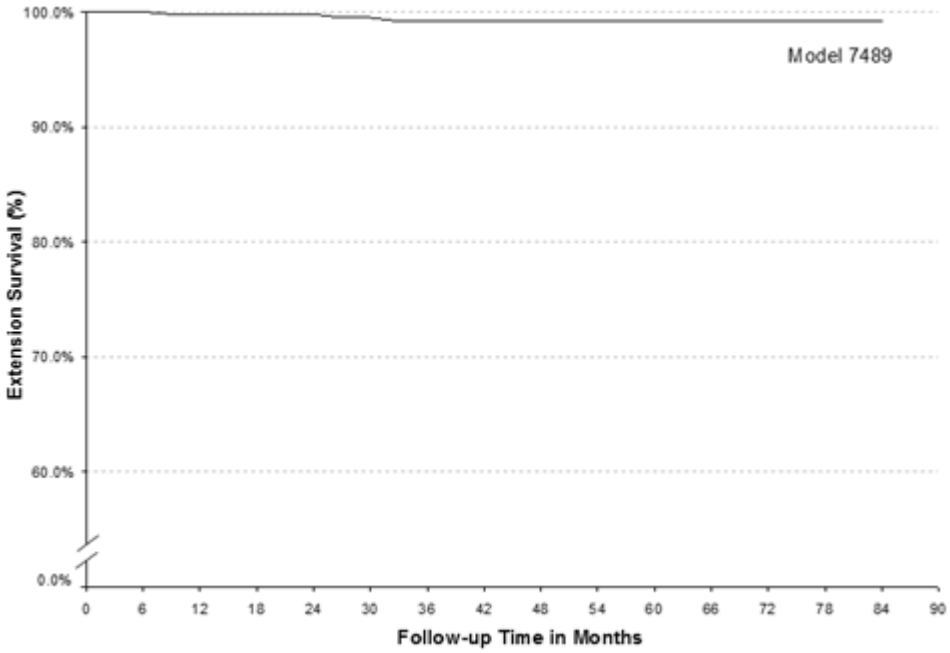
Extension Survival

The 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.



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Extension Characteristics	
Model Number	7489
FDA Approval Date	Oct 2002
Extensions Enrolled	696

Extensions Currently Active in Study	110
Device Events	3
Cumulative Months of Follow-up	26,496

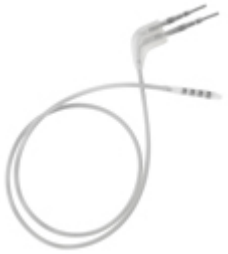
Extension Event	Total
Extension fracture	2
Medical device complication[a]	1
Total Extension Events	**3**

[a] Reported as unknown problem with extension

Time Interval	Survival	Effective Sample Size
1 yr	99.8%	446
2 yrs	99.8%	427
3 yrs	99.2%	313
4 yrs	99.2%	188
5 yrs	99.2%	112
6 yrs	99.2%	60
7 yrs	99.2%	21

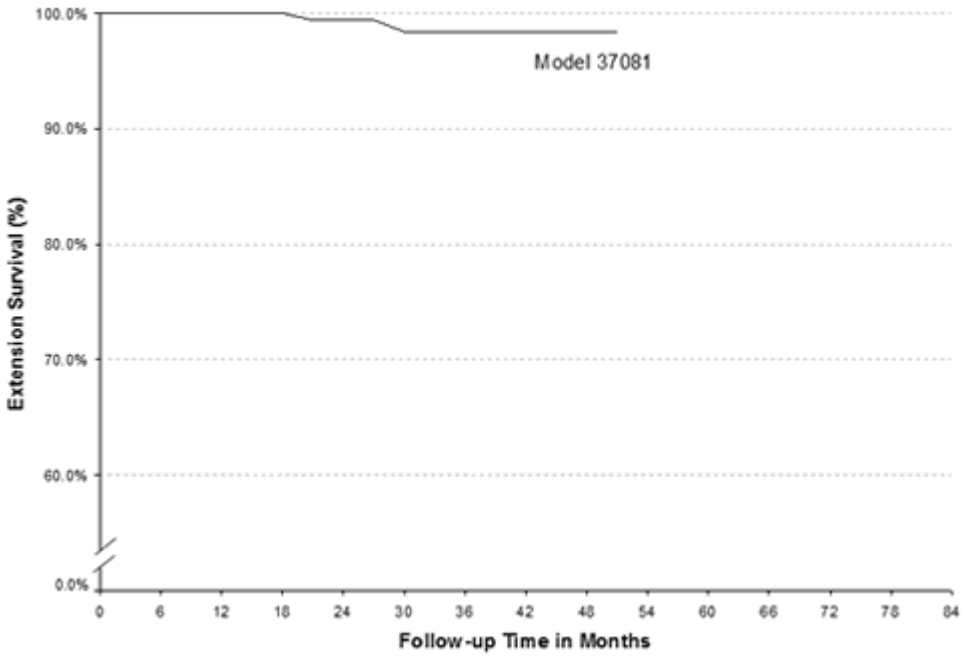
Model 7489 Extension Family: Specifications

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.



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Extension Characteristics	
Model Number	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	764
Extensions Currently Active in Study	302
Device Events	4
Cumulative Months of Follow-up	15,345

Extension Event	Total
Extension fracture	4
Total Extension Events	**4**

Time Interval Survival		Effective Sample Size
1 yr	100.0%	508
2 yrs	99.4%	276
3 yrs	98.4%	128
4 yrs	98.4%	31

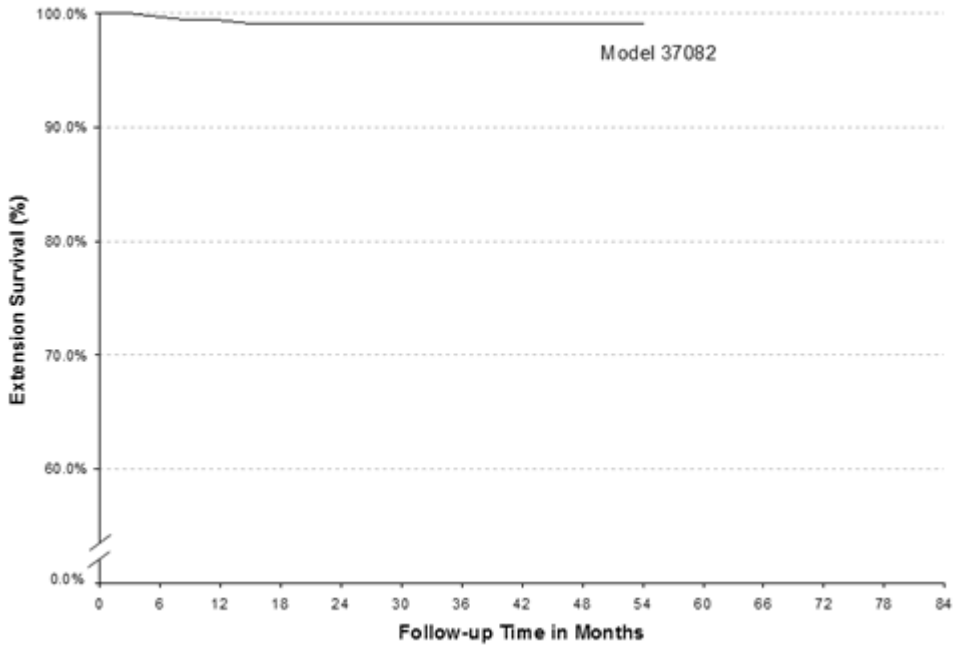
at 51 mo	98.4%	22

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.



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Extension Characteristics	
Model Number	37082
FDA Approval Date	Mar 2006
Extensions Enrolled	439

Extensions Currently Active in Study	182
Device Events	3
Cumulative Months of Follow-up	9,159

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

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

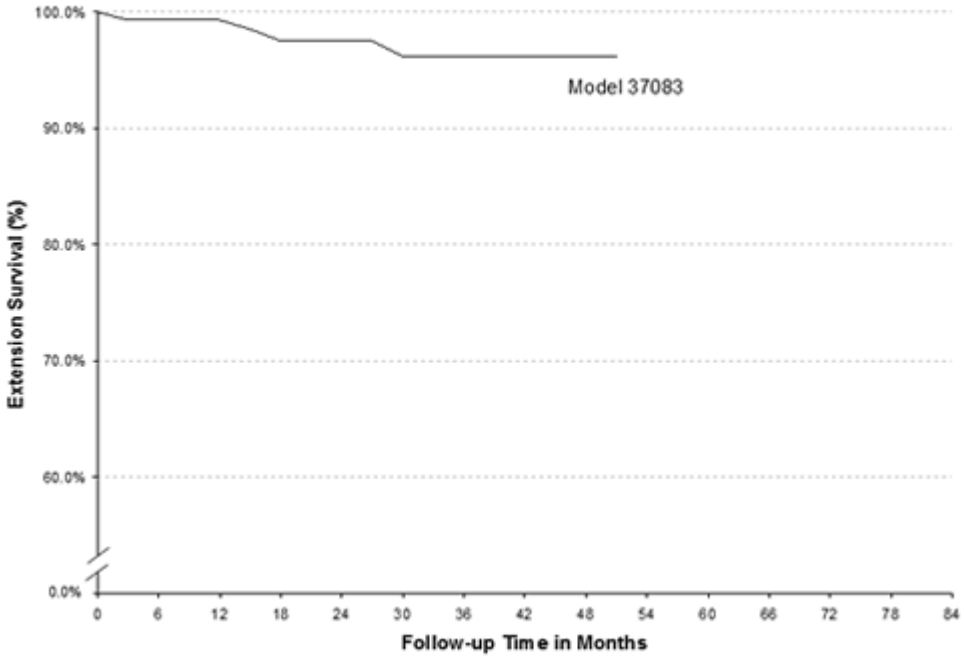
Time Interval	Survival	Effective Sample Size
1 yr	99.4%	311
2 yrs	99.1%	179
3 yrs	99.1%	75
4 yrs	99.1%	32
at 54 mo	99.1%	20

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.



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Extension Characteristics	
Model Number	37083
FDA Approval Date	Sep 2005
Extensions Enrolled	180
Extensions Currently Active in Study	64
Device Events	4
Cumulative Months of Follow-up	4,757

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	99.3%	134

2 yrs	97.5%	84
3 yrs	96.2%	56
4 yrs	96.2%	26
at 51 mo	96.2%	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
7489	7489	Oct 2002	696	110	3	26,496
37081	37081	Apr 2005	764	302	4	15,345
37082	37082	Mar 2006	439	182	3	9,159
37083	37083	Sep 2005	180	64	4	4,757

[a] There were a total of 15 extension-related events reported to the ISPR, but only 14 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

7489	**99.8%** (99.3%, 100.0%)	**99.8%** (99.3%, 100.0%)	**99.2%** (98.3%, 100.0%)	**99.2%** (98.3%, 100.0%)	**99.2%** (98.3%, 100.0%)
37081	**100.0%** NA	**99.4%** (98.6%, 100.0%)	**98.4%** (96.8%, 100.0%)	**98.4%** (96.8%, 100.0%)	-
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%)	-
37083	**99.3%** (97.8%, 100.0%)	**97.5%** (94.7%, 100.0%)	**96.2%** (92.3%, 100.0%)	**96.2%** (92.3%, 100.0%)	-

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

Model Number	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs
7489	**99.2%** (98.3%, 100.0%)	**99.2%** (98.3%, 100.0%)	-	-	-
37081	-	-	-	-	-
37082	-	-	-	-	-
37083	-	-	-	-	-

2011 Medtronic Product Performance Report: Data through July 29, 2011