# 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 2010 Product Performance Report provides data on the devices followed in this registry. Additionally, Medtronic incorporates laboratory findings documented by the Returned Product Analysis (RPA) department for those ISPR devices with reported events that were returned to Medtronic.

### Implantable Systems Performance Registry (ISPR) Background

The Implantable Systems Performance Registry (ISPR) is a Web-based registry that was voluntarily created by Medtronic to monitor the performance of infusion and spinal cord stimulation systems commercially available in the United States. The dates of initiation of these systems into the ISPR were August 2003 and June 2004, respectively. Prior to the development of this registry, patient and product outcomes were typically measured by retrospectively analyzing data obtained from other data systems, including Returned Product Analysis (RPA), Enterprise Product Comment Reporting (EPCR), and the associated Medical Device Reporting (MDR) or MedWatch system. The ISPR allows for active surveillance of products through prospective data collection. This information is used to guide future product development efforts aimed at improving product reliability and quality. The data is 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). These infusion pumps deliver medications directly to the intrathecal space surrounding the spinal cord. This method of site-specific drug delivery may decrease the dose requirements and side effects that can occur with systemic administration of the same drugs.

Medtronic's spinal cord stimulation systems (spinal cord stimulators, leads, and extensions) for pain indications were later added to the registry. Spinal cord stimulation is the stimulation of the spinal cord or peripheral nerves by tiny electrical impulses. An implanted spinal cord stimulator sends electrical impulses through an implanted lead(s) to the nerves and these impulses block the pain messages to the brain for individuals with chronic pain.

Although some of our other therapies such as deep brain stimulation and sacral nerve stimulation involve neurostimulation, the performance of these products is not represented in our report at this time. We are committed to future updates which will include these new therapies.

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. The ISPR centers that satisfied selection criteria and were activated for the registry participated in data collection for intrathecal drug delivery systems and/or 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.

Patient and device information was collected for patients who were implanted prior to enrollment into the ISPR (existing patients) and prospectively for patients who were enrolled and followed since implant (new patients). After enrollment and initial data collection, all patients were followed prospectively for adverse events requiring surgical intervention or until the abandonment of therapy. Patient status updates were obtained every 6 months. Participating investigators reported one primary event reason for each ISPR event along with patient

symptoms and patient outcomes. Events were categorized as either product performance events or non–product performance events as described in the event classification section of this report. Any detection methods used to determine patient or device outcomes were also recorded (information not presented in this report). Adverse events that did not require a surgical intervention or did not result in therapy abandonment are not represented in the device survival analyses that are presented in this report.

## Medtronic 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 3rd 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 nonmalignant pain, malignant pain, and spasticity. These data are based on the tracking of over 6,100 patients in an ongoing surveillance study conducted in the United States called the Implantable Systems Performance Registry (ISPR). The registry now includes over 17,000 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. The 2010 Product Performance Report includes the addition of product data for the Synergy Versitrel neurostimulator.

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, Emerging Therapies, Clinical Research, and Reimbursement
Medtronic, Inc.

## Contact Information

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

MEDTRONIC
PHONE: (800) 328-0810

E-MAIL

**Written requests or suggestions can be mailed to:**

MEDTRONIC
ATTN: Todd Weaver, PhD, MPH or Michelle Wells, PhD
MAIL STOP: RCE 375
7000 CENTRAL AVENUE NE
MINNEAPOLIS, MN 55432

# Methodology

## Event Classification

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.

## Product Performance Events

Product performance events were defined as any change that prevented delivery of the therapy to the intended location, required surgical intervention to correct, and were related to a problem with the device itself. In order for an event to be considered a product performance event, one of the criteria listed under Condition One and one of the criteria listed under Condition Two must have been met:

| Condition One: | AND one of the following: | Condition Two: |
|---|---|---|
| • Pump-related<br>• Catheter-related<br>• Spinal cord stimulator-related<br>• Lead-related<br>• Extension-related | | • Device explanted/replaced<br>• Device explanted/not replaced<br>• Other surgical intervention<br>• Therapy abandoned<br>• Patient expired |

## Non–Product Performance Events

Non–product performance events were defined as any event that could not be classified as a product performance event and that resulted from therapy or a medical complication that caused death, therapy abandonment, or prevented optimal therapy delivery to the intended location and required surgical intervention to correct. In addition, non–product performance events were defined to include patient events (patient expired or lost to follow-up) and normal battery depletion events. For the purposes of analysis, when a device experiences a non–product performance event, it is no longer considered to be at risk of experiencing a product performance event and is excluded from the population of devices (censored) from that point forward.

### Surgical/Procedural and Therapy/Patient-Related Events

Surgical/procedural or therapy/patient-related events were any ISPR event where one of the criteria listed below under Condition One and one of the criteria listed under Condition Two were met.

| Condition One: | AND one of the following: | Condition Two: |
|---|---|---|
| • Lumbar site-related<br>• Pump pocket/access-related<br>• Spinal cord stimulator pocket-related<br>• Lead tract-related<br>• Extension tract-related<br>• Therapy/patient effects<br>• Elective action<br>• Intraspinal drug overdose/underdose | | • Device explanted/replaced<br>• Device explanted/not replaced<br>• Other surgical intervention<br>• Therapy abandoned<br>• Patient expired |

### Patient Events

Patient events were any ISPR event that resulted in discontinuation of therapy or follow-up that were not directly related to a device or therapy-related complication. These events would include patient expired or patient lost to follow-up (e.g., patient withdrawal, patient moved, or patient transferred care to another provider).

#### Normal Battery Depletion Events

Normal battery depletion events were any ISPR event that resulted from normal battery depletion.

## Consistency and Accuracy

Consistency and accuracy of ISPR event reporting is monitored at 4 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 Estimates

Throughout this report, cumulative device survival plots are presented. These figures show the percentage of implanted devices that remain free from product performance–related events at various time points. 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.

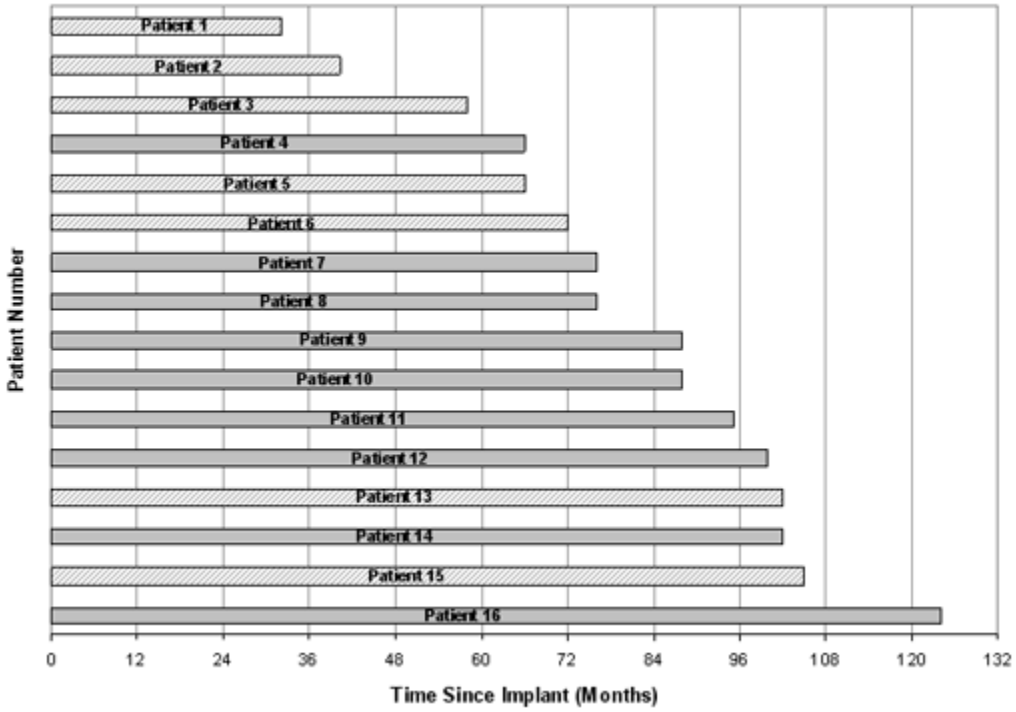
The Product Performance Report uses actuarial life table methods to estimate device performance over time.[1] The actuarial life table method includes experience for each device up until a product performance-related event occurs, or until the device is removed or therapy is abandoned for non–product 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. Discontinuation of follow-up for normal battery depletion, patient expired, and patient lost to follow-up is referred to as right censoring.

### 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 analysis. 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.

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.



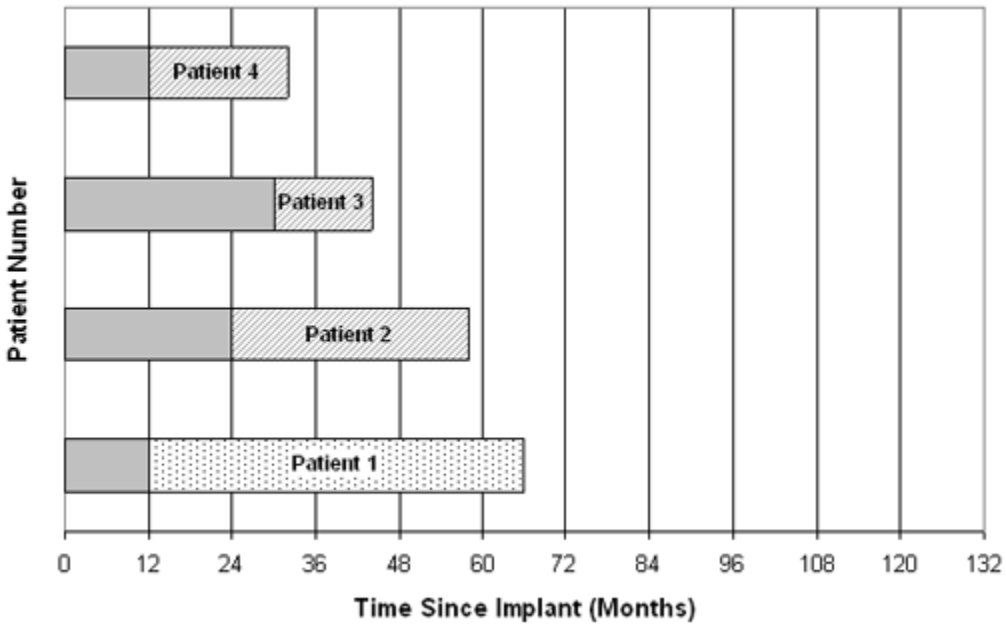

The first step in the life table method is to divide the time since implant into intervals of a specific length and determine how many devices entered each interval, how many were censored in each interval, and how many devices had events in each interval. This example will use 12-month intervals and 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 from the first 5 intervals (also known as the 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 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 overestimate the sample size because the censored devices do not complete the interval. Completely ignoring the censored devices in the interval would underestimate 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, 1 was right censored (patient 4), and 1 was removed for a product performance event (patient 5). 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 well 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.

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 is 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. Linear 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 (RPA)

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, physician reported event reason is used for analysis.

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 is believed to provide 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 devices are explanted and returned for analysis.



# 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 April 9, 2010. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

## Subjects

As the table below demonstrates, there were 4,384 total intrathecal drug delivery system patients enrolled in the ISPR through April 9, 2010. The table lists 3 primary indications with corresponding subindications as reported by the physician at implant. Fifty-two percent of patients were implanted with an intrathecal drug delivery system for treatment of nonmalignant pain (pain not related to cancer), followed by 29.3% for treatment of intractable spasticity, and 18.6% for treatment of malignant pain (pain related to cancer). The ISPR is slightly overrepresentative of malignant pain patients who comprise 9% of the total implanted population in the United States; however the subindications within each primary indication are representative of the total population implanted with an intrathecal drug delivery system in the United States.

**Primary Intrathecal Drug Delivery System Treatment Indications**

| Primary Treatment Indication* | Total Enrolled Patients (N=4,384) |
|---|---|
| **Nonmalignant Pain** | **2,285 (52.1%)** |
| Failed Back Syndrome | 1,114 |
| Joint Pain/Arthritis | 45 |
| Osteoporosis | 32 |
| Peripheral Neuropathy | 63 |
| Post-Herpetic Neuralgia | 10 |
| RSD/Causalgia (CRPS)† | 89 |
| Other and/or unspecified | 964 |
| **Intractable Spasticity** | **1,283 (29.3%)** |
| Brain Injury | 113 |
| Cerebral Palsy | 392 |
| Multiple Sclerosis | 341 |
| Spinal Cord Injury/Disease | 164 |
| Stroke | 43 |
| Other and/or unspecified | 259 |
| **Malignant Pain** | **816 (18.6%)** |
| Abdominal/Visceral | 89 |
| Extremity | 36 |

| | |
|---|---|
| Head/Neck | 33 |
| Pelvic | 71 |
| Spine/Back | 129 |
| Thoracic | 47 |
| Other and/or unspecified | 437 |
| **Total Patients** | **4,384** |

* Refer to product labeling for approved indications. Primary treatment indication information is obtained through the Medtronic Device and Registrant Tracking system.

†RSD is reflex sympathetic dystrophy. CRPS is complex regional pain syndrome.

## Event Summary

### Product Performance–Related Events

There were 2,726 events reported between August 2003 and April 9, 2010 in patients with intrathecal drug delivery systems. Fourteen percent of these events (389/2,726) were related to the pump or catheter, categorized as product performance-related events and are presented graphically within this report.

| EVENT | NO. | TIME TO EVENT IN MONTHS Mean (Median) ± SD |
|---|---|---|
| **Pump-Related Events:** | | |
| Drug-related cracked pump tube | 3 | 47.1 (46.2) ±8.0 |
| Hole in pump tube | 1 | 25.3 (25.3) ±NA |
| Motor gear corrosion | 14 | 47.6 (47.8) ±15.6 |
| Motor stall | 23 | 33.0 (29.9) ±19.0 |
| No infusion | 6 | 42.5 (48.3) ±16.7 |
| Premature battery depletion | 2 | 51.2 (51.2) ±2.2 |
| Unable to interrogate/program | 1 | 0.7 (0.7) ±NA |
| Underinfusion* | 11 | 43.1 (35.2) ±19.0 |
| **Pump-Related Events Subtotal** | **61** | **39.8 (40.8) ±18.5** |
| **Catheter-Related Events:** | | |
| Break/Cut | 62 | 30.3 (20.6) ±29.6 |
| Disconnection | 28 | 25.9 (15.2) ±27.0 |
| Dislodgement | 81 | 16.1 (6.3) ±21.5 |
| Inability to aspirate | 1 | 86.9 (86.9) ±NA |
| Kink/Occlusion | 122 | 36.5 (26.3) ±31.9 |

| | | |
|---|---|---|
| Loss of effect† | 8 | 26.8 (12.4) ±37.2 |
| Pump connector break/cut | 11 | 48.9 (60.1) ±20.1 |
| Puncture | 9 | 33.9 (23.4) ±35.9 |
| Sheared catheter tip | 3 | 73.3 (86.9) ±41.0 |
| Unknown | 3 | 24.4 (1.7) ±40.8 |
| **Catheter-Related Events Subtotal** | **328** | **29.9 (18.4) ±30.2** |
| **Product Performance–Related Events Subtotal** | **389** | **31.4 (24.2) ±28.9** |

* Patients experienced a worsening of symptoms, which physician attributed to underinfusion for various reasons.
† Physician reported worsening of symptoms and loss of therapeutic effect, due to an unspecified catheter-related etiology.

## Non-Product Performance–Related Events

Fifty-one percent of the events (1,382/2,726) were related to patient death (n=836) or becoming lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal, n=546). Of the 836 patient deaths, none were reported as a direct result of a device-related event or the infusion therapy. Nineteen percent of the total events (521/2,726) were related to the surgery or procedure (n=228), or attributed to the patient or delivery of the therapy (n=293). Sixteen percent of the events (434/2,726) were related to normal battery depletion.

| EVENT | NO. | TIME TO EVENT IN MONTHS Mean (Median) ± SD |
|---|---|---|
| **Surgical/Procedural–Related Events:** | | |
| **Lumbar Site–Related** | | |
| External CSF leak | 12 | 10.3 (2.0) ±19.9 |
| Fluid collection | 1 | 3.3 (3.3) ±NA |
| Infection | 18 | 16.4 (5.7) ±21.7 |
| Inflammation | 1 | 1.0 (1.0) ±NA |
| Pain/irritation | 1 | 67.8 (67.8) ±NA |
| Skin erosion | 1 | 26.0 (26.0) ±NA |
| Wound dehiscence | 3 | 5.0 (6.4) ±3.1 |
| **Lumbar Site–Related Subtotal** | **37** | **14.4 (3.3) ±21.2** |
| **Pump Pocket/Pump Access–Related** | | |
| Fluid collection | 4 | 39.8 (35.0) ±36.5 |
| Hematoma | 4 | 21.6 (13.1) ±28.1 |
| Infection | 76 | 6.7 (2.8) ±11.7 |
| Inflammation | 4 | 1.4 (0.9) ±1.7 |

| | | |
|---|---|---|
| Inversion | 34 | 10.1 (6.8) ±10.2 |
| Malpositioned | 1 | 9.5 (9.5) ±NA |
| Migration | 12 | 17.0 (11.3) ±12.2 |
| Pain at pump site | 11 | 19.8 (13.4) ±18.8 |
| Pump site incision not healing | 2 | 3.4 (3.4) ±1.1 |
| Seroma | 1 | 4.2 (4.2) ±NA |
| Skin erosion | 19 | 19.5 (14.1) ±21.1 |
| Trial catheter revision | 2 | 0.2 (0.2) ±NA* |
| Unable to enter catheter access port | 1 | 4.8 (4.8) ±NA |
| Unable to fill/refill reservoir | 2 | 5.1 (5.1) ±3.8 |
| Undesirable interaction with other equipment | 1 | 7.8 (7.8) ±NA |
| Wound dehiscence | 17 | 12.6 (7.2) ±19.2 |
| **Pump Pocket–Related Subtotal** | **191** | **11.3 (5.1) ±15.9** |
| **Surgical/Procedural–Related Events Subtotal** | **228** | **11.8 (4.9) ±16.9** |
| **Therapy/Patient–Related Events:** | | |
| **Elective Action** | | |
| Elective action† | 110 | 35.4 (32.5) ±25.0 |
| **Elective Action–Related Subtotal** | **110** | **35.4 (32.5) ±25.0** |
| **Intraspinal Drug Overdose or Underdose‡** | | |
| Drug side effects/toxicity | 1 | 9.2 (9.2) ±NA |
| **Intraspinal Drug Overdose– or Underdose–Related Subtotal** | **1** | **9.2 (9.2) ±NA** |
| **Therapy/Patient Effects** | | |
| Allergic reaction/sensitivity to drug | 5 | 9.5 (9.3) ±4.0 |
| Catheter tip fibrosis | 1 | 23.2 (23.2) ±NA |
| Catheter too short | 1 | 1.1 (1.1) ±NA |
| Corrective surgery§ | 3 | 35.6 (29.0) ±13.4 |
| Cosmetic issue | 1 | 8.0 (8.0) ±NA |
| Device damaged due to unrelated surgery | 5 | 27.1 (26.5) ±25.7 |
| Dissatisfaction with feeling of the pump | 1 | 1.9 (1.9) ±NA |
| Drug overdose | 1 | 28.6 (28.6) ±NA |

| | | |
|---|---|---|
| Drug side effects/toxicity | 16 | 21.2 (11.6) ±22.9 |
| Drug withdrawal | 4 | 36.0 (42.6) ±22.1 |
| Frequent refill intervals‖ | 1 | 33.3 (33.3) ±NA |
| Granuloma | 1 | 12.0 (12.0) ±NA |
| Inability to aspirate/painful aspiration | 2 | 6.1 (6.1) ±1.6 |
| Infection | 10 | 15.0 (3.2) ±31.8 |
| Inflammatory mass ¶ | 6 | 26.8 (29.6) ±12.8 |
| Inflammatory mass (possible)** | 6 | 40.4 (42.5) ±31.1 |
| Loss of effect | 48 | 23.7 (15.8) ±21.2 |
| Malpositioned | 6 | 28.6 (7.4) ±41.3 |
| Myelitis | 1 | 29.2 (29.2) ±NA |
| No anomaly found by RPA†† | 10 | 39.2 (43.9) ±19.9 |
| Numbness/weakness in legs | 2 | 32.1 (32.1) ±7.1 |
| Pain/irritation | 3 | 13.4 (1.4) ±21.0 |
| Patient effects‡‡ | 1 | 49.9 (49.9) ±NA |
| Patient noncompliance§§ | 4 | 31.6 (27.4) ±19.0 |
| Patient seeking pregnancy | 1 | 13.2 (13.2) ±NA |
| Poor circulation | 1 | 28.0 (28.0) ±NA |
| Pseudomeningocele | 2 | 13.1 (13.1) ±8.9 |
| Psychological issue | 5 | 13.9 (7.0) ±16.6 |
| Reservoir septum damage (user-related/ancillary damage) | 1 | 28.5 (28.5) ±NA |
| Resolution of symptoms‖ ‖ | 17 | 34.6 (32.2) ±17.1 |
| Therapy didn't meet patient's expectations | 9 | 23.0 (21.5) ±8.1 |
| Undesirable interaction with other equipment | 5 | 9.6 (5.3) ±9.7 |
| Unrelated surgery | 1 | 16.7 (16.7) ±NA |
| Wound dehiscence¶¶ | 1 | 17.7 (17.7) ±NA |
| **Therapy/Patient Effects Subtotal** | **182** | **24.7 (18.6) ±21.5** |
| **Therapy/Patient–Related Events Subtotal** | **293** | **28.6 (22.8) ±23.4** |
| **Patient–Related Events:*** ** | | |

| | | |
|---|---|---|
| Patient expired††† | 836 | 15.4 (6.8) ±18.9 |
| Patient lost to follow-up | 546 | 22.9 (18.3) ±20.1 |
| **Patient–Related Events Subtotal** | **1,382** | **18.4 (10.7) ±19.7** |
| **Normal Battery Depletion Events:** | | |
| Battery Depletion | 434 | 65.9 (65.3) ±14.7 |
| **Normal Battery Depletion Events Subtotal** | **434** | **65.9 (65.3) ±14.7** |
| **Non–Product Performance–Related Events Total** | **2,337** | **27.8 (18.2) ±26.7** |

* Trial catheter revision mean calculation excludes an extreme observation (i.e., 131 months to event).
† Elective action includes therapy abandoned or device explants primarily due to patient requests for device removal or changes in pump reservoir size with no device/therapy–related etiology.
‡ Refers to intraspinal drug overdoses or underdoses that required a hospital stay, but not a device surgical intervention.
§ Pump was removed due to corrective surgery (e.g., patient had lumbar fusion surgery and symptoms resolved).
‖ Pump replaced to increase reservoir volume due to frequent refill intervals.
¶ Includes definite or probable inflammatory mass. Definite classification required surgical and histological verification or clinical symptoms plus contrast enhanced MRI or CT myelogram and resolution of lesion following cessation of drug exposure. Probable classification required no surgical or histological verification, but clinical criteria and enhanced MRI or CT myelogram criteria were present. Inflammatory mass is defined as an intradural extramedullary enhancing lesion.
** Medical records reported inflammatory mass, but there was no surgical or histological verification, no clinical criteria, and no radiographic data available.
†† For products that are returned, and RPA establishes a root cause or finds no anomaly, results reported herein default to the RPA finding.
‡‡ Physician assigned the event etiology as patient effects. No additional information was available.
§§ Physician reported that patients were noncompliant with pump refill schedule and/or routine medical care.
‖‖ Device was no longer needed because patients' symptoms were attenuated through other medical therapies or resolution of the underlying disease.
¶¶ Physician reported event as therapy/patient effect and did not specify location of wound dehiscence.
*** Event summary frequencies are at the patient level, not device level.
††† Sixty-nine percent of patient deaths occurred in patients receiving therapy for malignant pain, 21% for nonmalignant pain, and 10% for intractable spasticity.

## Pumps

From August 2003 to the report cut-off date of April 9, 2010, 5,008 pumps were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=4,384) versus pumps were 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 (24.5%) or SynchroMed II (75.4%), and a small number of pumps were SynchroMed Classic (0.1%). The majority of SynchroMed II pumps were new pumps (3,322/3,776, 88.0%), whereas the majority of SynchroMed EL pumps were existing pumps (1,053/1,225, 86.0%). Total prospective follow-up time for all pumps was 128,647 months (10,721 years).

### Pump Events

A surgical intervention was required for 61 pumps with an underlying reported etiology related to pump function. The current return rate of pumps to Medtronic Returned Product Analysis (RPA) was 380/1,681 (23%). 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 subjects who expired. Forty of the 61 pumps with malfunction events were analyzed by Medtronic RPA: 38 pumps failed due to non–battery-related issues (20 motor stalls, 14 motor gear corrosion, 3 cracked pump tubes, and 1 hole in pump tube), and 2 failed due to

premature battery depletion. The remaining 21 pump events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 11 events due to underinfusion, 6 events due to no infusion, 3 events due to physician-reported motor stalls, and 1 event due to physician inability to interrogate the pump. Of the 38 pumps with RPA-confirmed non–battery-related issues, as well as the 3 physician-reported motor stalls, 26 of 41 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 15 pumps, the complete drug history and exposure to admixtures could not be confirmed.

There were an additional 2,266 pumps censored in the analysis as a result of patient expired, pump explanted, patient lost to follow-up, other surgical intervention, or therapy abandonment attributed to an event unrelated to the pump. Of the 186 explanted due to normal battery depletion that were subsequently returned to RPA, 9 were recoded as product performance events based on RPA findings. Of the 836 patient deaths, none were reported as a direct result of a device-related event or the infusion therapy.

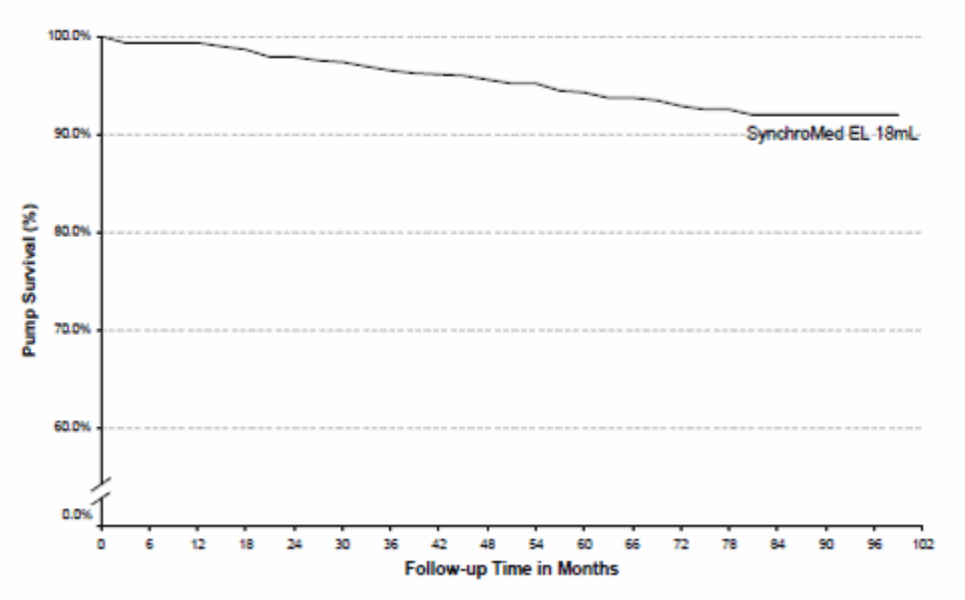
## Pump Survival Curves

The figures and tables below represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each 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.

Choose a model Go

- Data
- Model Info

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




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

| Pump Characteristics | |
|---|---|
| **Model Name** | SynchroMed EL (18 mL) |
| **FDA Approval Date** | Mar 1999 |
| **Pumps Enrolled** | 1,192 |
| **Pumps Active in Study** | 121 |
| **Device Events** | 39 |
| **Cumulative Months of Follow-up** | 38,805 |

| Pump Event | Total |
|---|---|
| **Drug-related cracked pump tube** | 3 |
| **Motor gear corrosion** | 14 |
| **Motor stall** | 13 |
| **No infusion** | 1 |
| **Unable to interrogate/program** | 1 |
| **Underinfusion** | 7 |
| **Total Pump Events** | **39** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.3% | 228 |
| 2 yrs | 97.9% | 461 |
| 3 yrs | 96.5% | 698 |
| 4 yrs | 95.6% | 730 |
| 5 yrs | 94.3% | 567 |
| 6 yrs | 92.9% | 321 |
| 7 yrs | 92.0% | 125 |
| 8 yrs | 92.0% | 38 |
| at 99 mo | 92.0% | 28 |

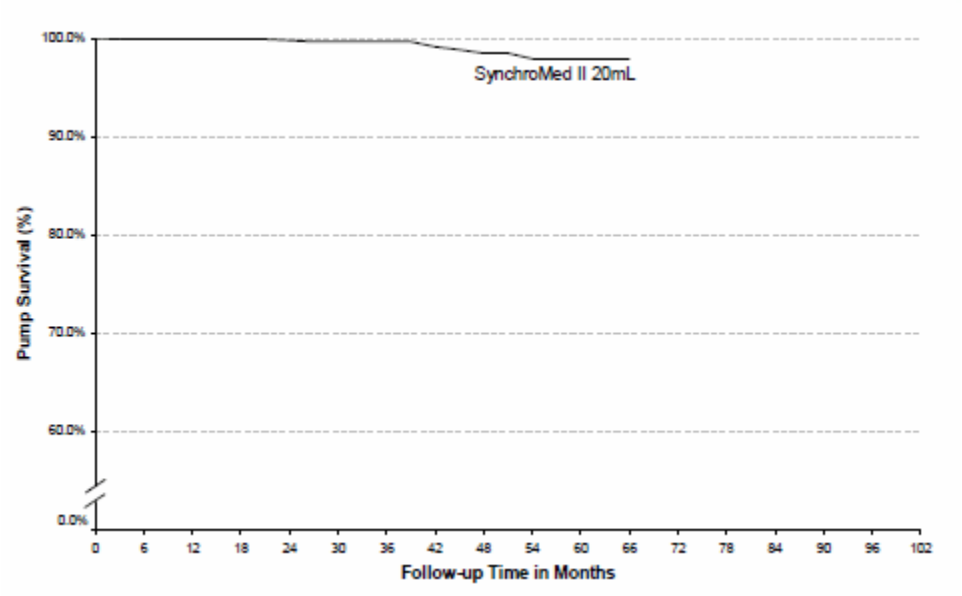
## Model 8627-18 SynchroMed EL 18mL: Specifications

| | |
|---|---|
| **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.

- Data
- Model Info

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




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

| Pump Characteristics | |
|---|---|
| **Model Name** | SynchroMed II (20 mL) |
| **FDA Approval Date** | Sep 2003 |
| **Pumps Enrolled** | 1,417 |
| **Pumps Active in Study** | 914 |
| **Device Events** | 8 |
| **Cumulative Months of Follow-up** | 38,760 |

| Pump Event | Total |
|---|---|
| **Hole in pump tube** | 1 |
| **Motor stall** | 5 |
| **No infusion** | 2 |
| **Total Pump Events** | **8** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.9% | 1,096 |
| 2 yrs | 99.8% | 809 |
| 3 yrs | 99.7% | 503 |
| 4 yrs | 98.5% | 270 |
| 5 yrs | 97.9% | 96 |
| at 66 mo | 97.9% | 35 |

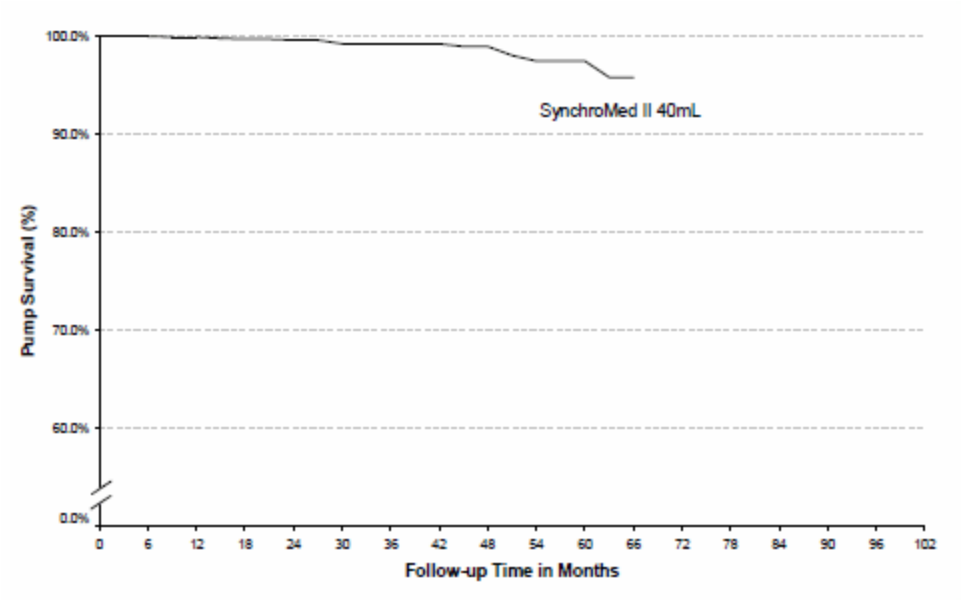
## Model 8637-20 SynchroMed II 20mL: Specifications

| | |
|---|---|
| **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.

- Data
- Model Info

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




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

| Pump Characteristics | |
|---|---|
| **Model Name** | SynchroMed II (40 mL) |
| **FDA Approval Date** | Sep 2003 |
| **Pumps Enrolled** | 2,359 |
| **Pumps Active in Study** | 1,179 |
| **Device Events** | 13 |
| **Cumulative Months of Follow-up** | 49,881 |

| Pump Event | Total |
|---|---|
| **Motor stall** | 5 |
| **No infusion** | 3 |
| **Premature battery depletion** | 2 |
| **Underinfusion** | 3 |
| **Total Pump Events** | **13** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.9% | 1,461 |
| 2 yrs | 99.6% | 1,016 |
| 3 yrs | 99.2% | 610 |

| | | |
|---|---|---|
| 4 yrs | 99.0% | 273 |
| 5 yrs | 97.5% | 90 |
| at 66 mo | 95.8% | 36 |

### 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 and 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 | Family | FDA Approval Date | Pumps Enrolled | Pumps Active in Study | Device Events* | Cumulative Months of Follow-up |
|---|---|---|---|---|---|---|
| **SynchroMed EL (18 mL)** | SynchroMed EL | Mar 1999 | 1,192 | 121 | 39 | 38,805 |
| **SynchroMed II (20 mL)** | SynchroMed II | Sep 2003 | 1,417 | 914 | 8 | 38,760 |
| **SynchroMed II (40 mL)** | SynchroMed II | Sep 2003 | 2,359 | 1,179 | 13 | 49,881 |

* There were a total of 61 pump-related events reported to the ISPR, but only 60 events included in this summary table. The remaining 1 pump-related event occurred in a SynchroMed EL 10 mL pump for which no device survival curves are presented due to an insufficient number of enrolled devices.

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

| Model Name | 1 yr | 2 yrs | 3 yrs | 4 yrs |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **SynchroMed EL (18 mL)** | **99.3%** (98.0%, 100.0%) | **97.9%** (96.1%, 99.7%) | **96.5%** (94.5%, 98.5%) | **95.6%** (93.5%, 97.7%) |
| **SynchroMed II (20 mL)** | **99.9%** (99.7%, 100.0%) | **99.8%** (99.5%, 100.0%) | **99.7%** (99.2%, 100.0%) | **98.5%** (97.2%, 99.7%) |
| **SynchroMed II (40 mL)** | **99.9%** (99.8%, 100.0%) | **99.6%** (99.3%, 100.0%) | **99.2%** (98.7%, 99.8%) | **99.0%** (98.2%, 99.7%) |

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

| Model Name | 5 yrs | 6 yrs | 7 yrs | 8 yrs |
|---|---|---|---|---|
| **SynchroMed EL (18 mL)** | **94.3%** (92.0%, 96.5%) | **92.9%** (90.4%, 95.4%) | **92.0%** (89.1%, 94.8%) | **92.0%** (89.1%, 94.8%) |
| **SynchroMed II (20 mL)** | **97.9%** (96.2%, 99.6%) | - | - | - |
| **SynchroMed II (40 mL)** | **97.5%** (95.6%, 99.3%) | - | - | - |

## Catheters

From August 2003 to the report cut-off date of April 9, 2010, 4,707 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=5,008) 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). Furthermore, the ISPR did not collect information for nonregistered catheters for existing patients. Total prospective follow-up time for all catheters was 129,750 months (10,812 years).

A total of 50.8% of the catheters were Model 8709 catheters, 12.0% were Model 8711 catheters, 10.7% were Model 8731 catheters, 10.1% were Model 8709SC catheters, 3.8% were Model 8703W catheters, 2.0% were Model 8731SC catheters, and 0.8% were other or unspecified catheters. An additional 2.4% were considered catheters Revised-As-Designed (8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); 4.4% 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 2.9% 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

A surgical intervention was required for 328 catheters with an underlying reported etiology related to the catheter. Of these events, 122 were related to a kink or occlusion, 81 were related to dislodgement, 62 were related to a break or cut in the catheter, 28 were related to catheter disconnection, 11 were related to pump connector break/cut, 9 were related to catheter puncture, 8 were related to loss of therapeutic effect, 3 were related to sheared catheter tip, 1 was related to an inability to aspirate, and 3 were unknown.

An additional 1,787 catheters were censored in the analysis due to patient expired, patient lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), catheter explanted, other surgical intervention, or therapy abandonment attributed to an event unrelated to the catheter.

### Catheter Survival Curves

The figures and tables below represent catheter survival and 95% confidence intervals where at least 20

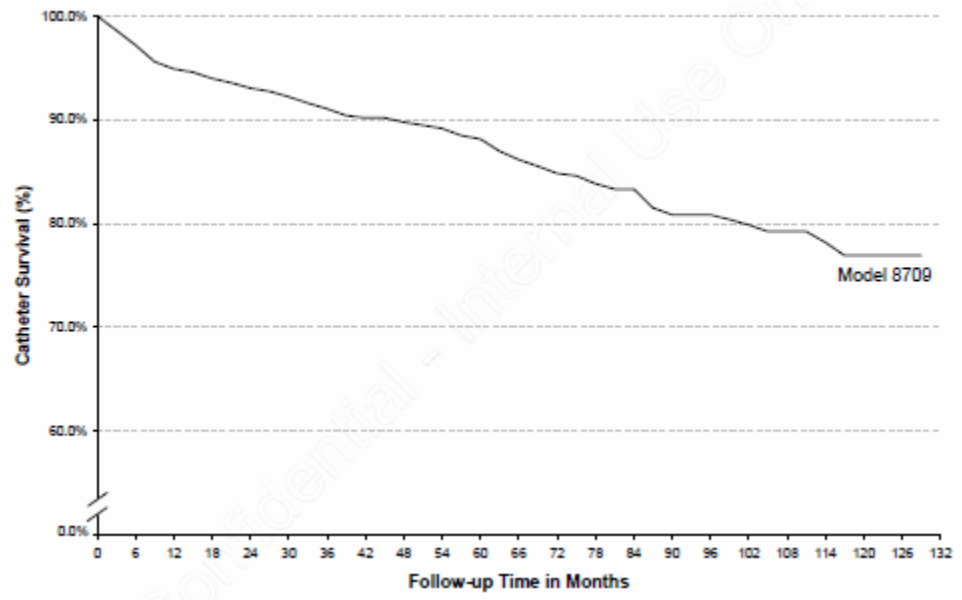
catheters contributed to each interval. Currently, the 95% confidence intervals for all catheter Models overlap at all time intervals, indicating that survival from catheter-related events is not significantly different between the catheter Models across various applicable follow-up time points.

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. Explanations for this finding remain speculative, and include small sample size and a relatively brief observation period compared to other catheter models. Other nonstatistical explanations may include device-related causes and/or system troubleshooting errors. Medtronic catheter repair kits and two-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. Another possible explanation is that a drug-delivery system or intrathecal drug and cerebrospinal fluid mixing or flow anomaly existed that was not corrected by assembly of a Grafted-Not-As-Designed catheter system. Medtronic will continue to monitor and review the performance and survival of catheters Revised-Not-As-Designed and catheters Grafted-Not-As-Designed. Medtronic recommends following the labeling for the Model 8596 and 8598 revision kits.

Choose a model Go

- Data
- Model Info

### Model 8709: Survival from Catheter Events




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

| Catheter Characteristics | |
|---|---|
| **Model Name** | 8709 |

| | |
|---|---|
| **FDA Approval Date** | May 1998 |
| **Catheters Enrolled** | 2,390 |
| **Catheters Active in Study** | 1,172 |
| **Device Events** | 151 |
| **Cumulative Months of Follow-up** | 64,766 |

| Catheter Event | Total |
|---|---|
| **Break/Cut** | 33 |
| **Disconnection** | 15 |
| **Dislodgement** | 32 |
| **Inability to aspirate** | 1 |
| **Kink/Occlusion** | 52 |
| **Loss of effect** | 2 |
| **Pump connector break/cut** | 8 |
| **Puncture** | 5 |
| **Sheared catheter tip** | 2 |
| **Unknown** | 1 |
| **Total Catheter Events** | **151** |

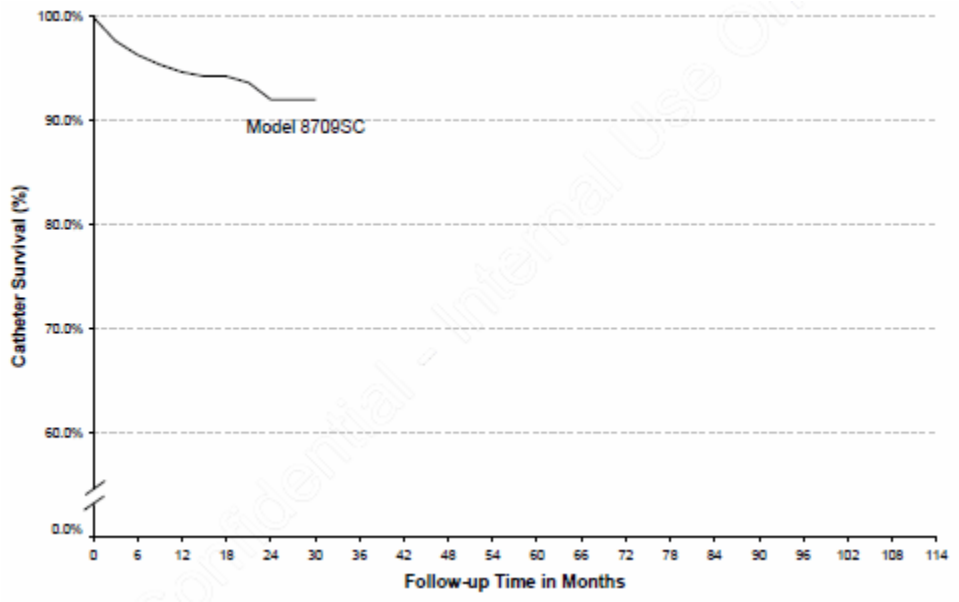
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 94.9% | 969 |
| 2 yrs | 93.0% | 904 |
| 3 yrs | 91.1% | 866 |
| 4 yrs | 89.8% | 654 |
| 5 yrs | 88.1% | 492 |
| 6 yrs | 84.8% | 379 |
| 7 yrs | 83.3% | 296 |
| 8 yrs | 80.9% | 197 |
| 9 yrs | 79.2% | 106 |
| 10 yrs | 76.9% | 51 |
| at 129 mo | 76.9% | 27 |

## 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 |

- Data
- Model Info

## Model 8709SC: Survival from Catheter Events




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

| Catheter Characteristics | |
|---|---|
| **Model Name** | 8709SC |
| **FDA Approval Date** | Mar 2006 |
| **Catheters Enrolled** | 474 |
| **Catheters Active in Study** | 348 |

| | |
|---|---|
| **Device Events** | 25 |
| **Cumulative Months of Follow-up** | 6,561 |

| Catheter Event | Total |
|---|---|
| **Break/Cut** | 5 |
| **Disconnection** | 2 |
| **Dislodgement** | 9 |
| **Kink/Occlusion** | 7 |
| **Puncture** | 1 |
| **Unknown** | 1 |
| **Total Catheter Events** | **25** |

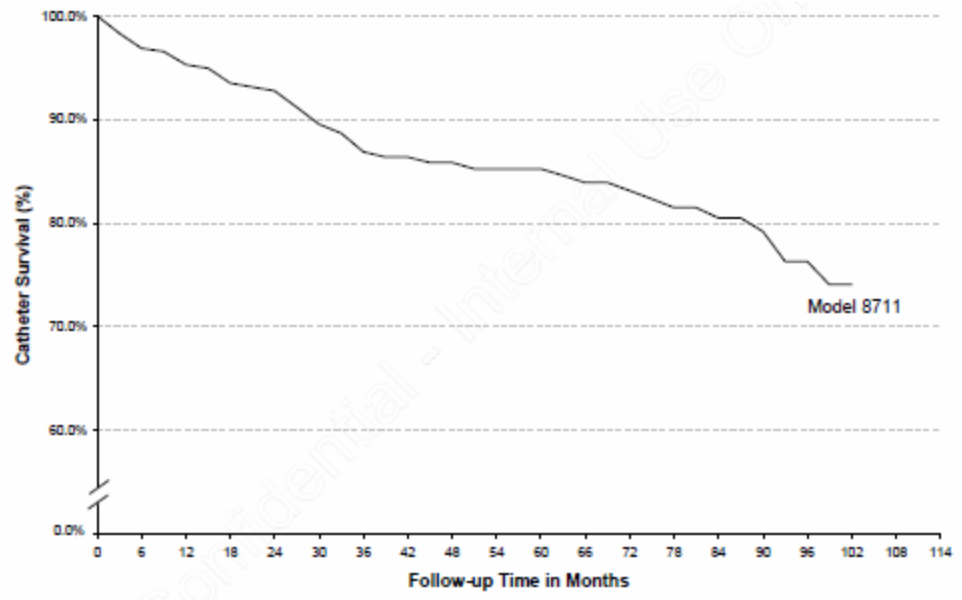
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 94.7% | 266 |
| 2 yrs | 92.1% | 115 |
| at 30 mo | 92.1% | 41 |

## 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 |

- Data
- Model Info

## Model 8711: Survival from Catheter Events




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

| Catheter Characteristics | |
|---|---|
| **Model Name** | 8711 |
| **FDA Approval Date** | Oct 1999 |
| **Catheters Enrolled** | 566 |
| **Catheters Active in Study** | 364 |
| **Device Events** | 50 |
| **Cumulative Months of Follow-up** | 16,796 |

| Catheter Event | Total |
|---|---|
| **Break/Cut** | 10 |
| **Disconnection** | 3 |
| **Dislodgement** | 10 |
| **Kink/Occlusion** | 25 |
| **Loss of effect** | 1 |
| **Pump connector break/cut** | 1 |
| **Total Catheter Events** | **50** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 95.3% | 300 |

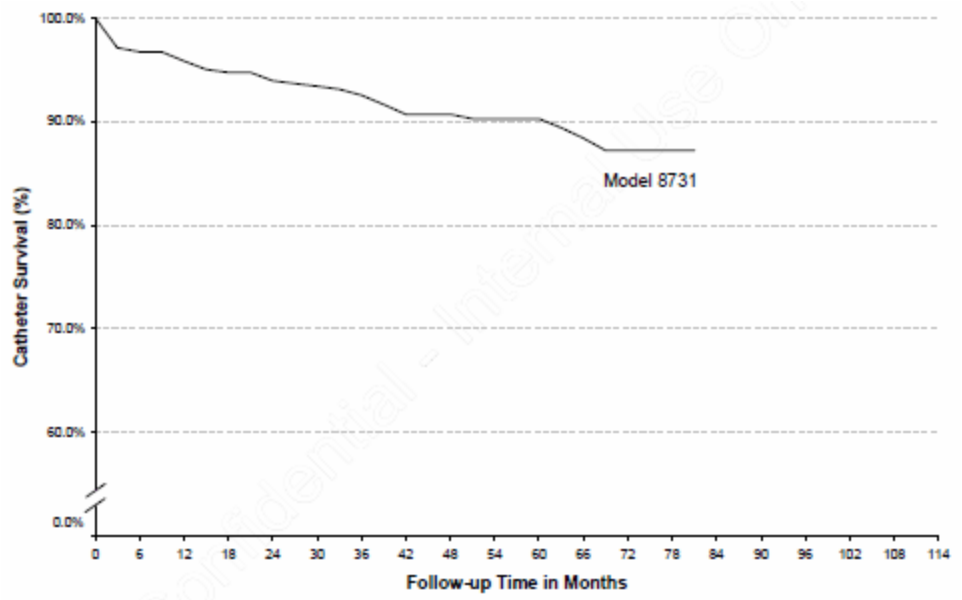
| | | |
|---|---|---|
| 2 yrs | 92.8% | 247 |
| 3 yrs | 86.9% | 197 |
| 4 yrs | 85.8% | 147 |
| 5 yrs | 85.2% | 139 |
| 6 yrs | 83.1% | 108 |
| 7 yrs | 80.5% | 82 |
| 8 yrs | 76.3% | 44 |
| at 102 mo | 74.1% | 25 |

## 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 |

- Data
- Model Info

## Model 8731: Survival from Catheter Events




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

| Catheter Characteristics | |
|---|---|
| **Model Name** | 8731 |
| **FDA Approval Date** | Oct 2002 |
| **Catheters Enrolled** | 503 |
| **Catheters Active in Study** | 232 |
| **Device Events** | 32 |
| **Cumulative Months of Follow-up** | 18,150 |

| Catheter Event | Total |
|---|---|
| **Break/Cut** | 1 |
| **Disconnection** | 2 |
| **Dislodgement** | 15 |
| **Kink/Occlusion** | 10 |
| **Loss of effect** | 2 |
| **Pump connector break/cut** | 1 |
| **Puncture** | 1 |
| **Total Catheter Events** | **32** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|

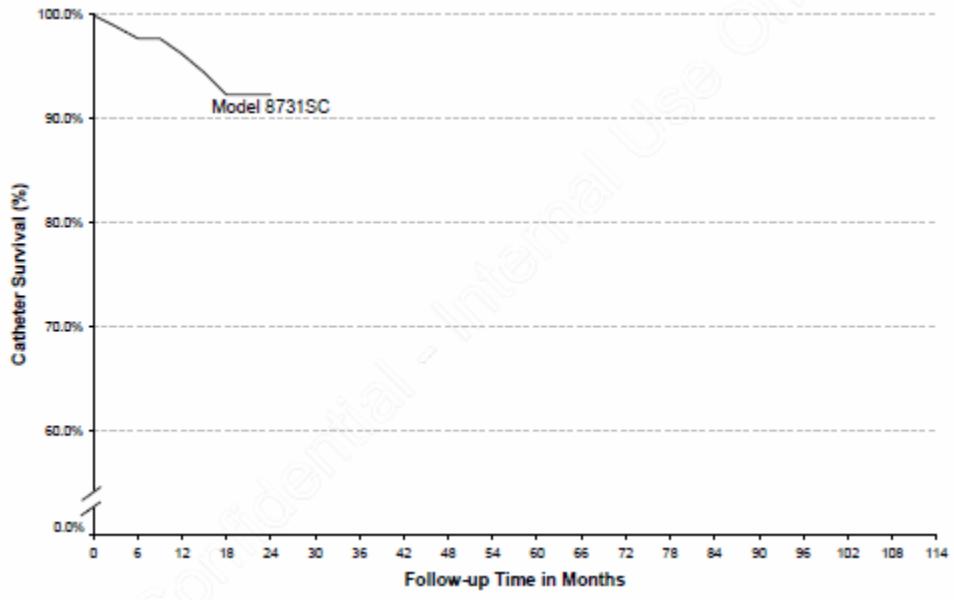
| | | |
|---|---|---|
| 1 yr | 95.8% | 327 |
| 2 yrs | 93.9% | 352 |
| 3 yrs | 92.5% | 323 |
| 4 yrs | 90.7% | 242 |
| 5 yrs | 90.3% | 120 |
| 6 yrs | 87.2% | 61 |
| at 81 mo | 87.2% | 25 |

## 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 |

- Data
- Model Info

## Model 8731SC: Survival from Catheter Events



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

| Catheter Characteristics | |
|---|---|
| **Model Name** | 8731SC |
| **FDA Approval Date** | Mar 2006 |
| **Catheters Enrolled** | 94 |
| **Catheters Active in Study** | 79 |
| **Device Events** | 5 |
| **Cumulative Months of Follow-up** | 1,504 |

| Catheter Event | Total |
|---|---|
| **Disconnection** | 1 |
| **Dislodgement** | 2 |
| **Kink/Occlusion** | 2 |
| **Total Catheter Events** | **5** |

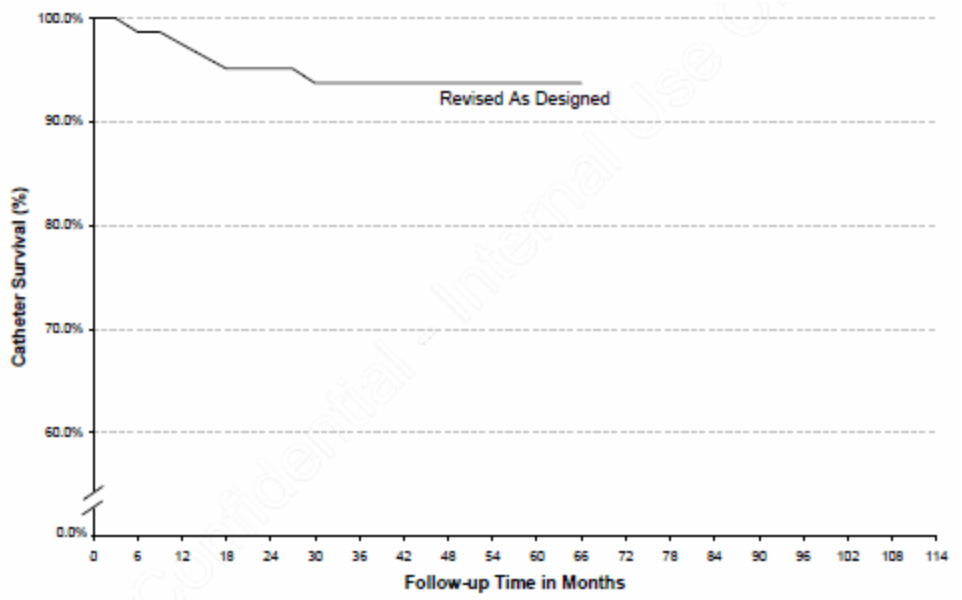
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 96.3% | 65 |
| 2 yrs | 92.3% | 25 |

## 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 |

- Data
- Model Info

## Revised-As-Designed: Survival from Catheter Events




Data are shown if there are at least 20 devices in each 3-month interval.
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** | 115 |
| **Catheters Active in Study** | 70 |
| **Device Events** | 5 |
| **Cumulative Months of Follow-up** | 4,092 |

| Catheter Event | Total |
|---|---|
| **Dislodgement** | 1 |
| **Kink/Occlusion** | 4 |
| **Total Catheter Events** | **5** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 97.5% | 81 |
| 2 yrs | 95.1% | 73 |
| 3 yrs | 93.7% | 57 |
| 4 yrs | 93.7% | 50 |

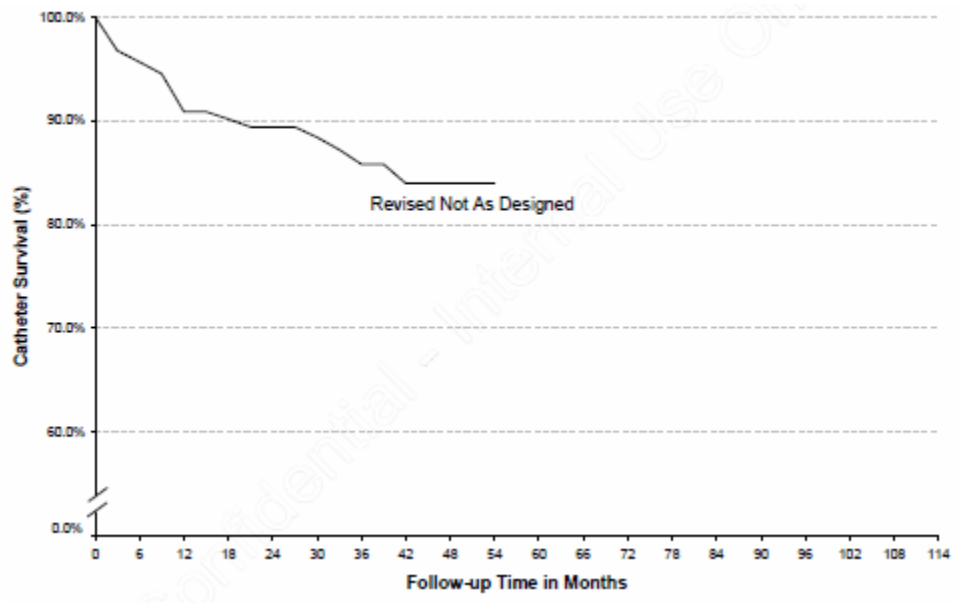
| | | |
|---|---|---|
| 5 yrs | 93.7% | 34 |
| at 66 mo | 93.7% | 23 |

### Revised-As-Designed: Specifications

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

- Data
- Model Info

### Revised-Not-As-Designed: Survival from Catheter Events




Data are shown if there are at least 20 devices in each 3-month interval.
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** | 208 |
| **Catheters Active in Study** | 154 |
| **Device Events** | 23 |
| **Cumulative Months of Follow-up** | 5,293 |

| Catheter Event | Total |
|---|---|

| | |
|---|---|
| **Break/Cut** | 6 |
| **Disconnection** | 3 |
| **Dislodgement** | 5 |
| **Kink/Occlusion** | 6 |
| **Loss of effect** | 1 |
| **Puncture** | 2 |
| **Total Catheter Events** | **23** |

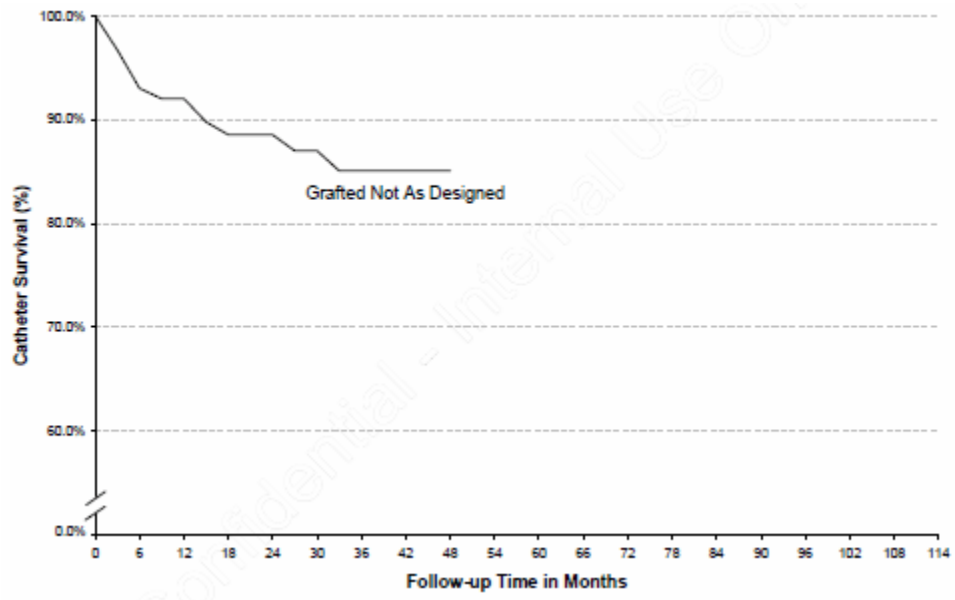
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 90.9% | 155 |
| 2 yrs | 89.4% | 108 |
| 3 yrs | 85.8% | 62 |
| 4 yrs | 84.0% | 31 |
| at 54 mo | 84.0% | 21 |

### 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.

- Data
- Model Info

### Grafted-Not-As-Designed: Survival from Catheter Events




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

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** | 138 |
| **Catheters Active in Study** | 87 |
| **Device Events** | 16 |
| **Cumulative Months of Follow-up** | 3,452 |

| Catheter Event | Total |
|---|---|
| **Break/Cut** | 1 |
| **Disconnection** | 1 |
| **Dislodgement** | 6 |
| **Kink/Occlusion** | 5 |
| **Loss of effect** | 1 |
| **Pump connector break/cut** | 1 |
| **Unknown** | 1 |
| **Total Catheter Events** | **16** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 92.0% | 88 |
| 2 yrs | 88.6% | 63 |
| 3 yrs | 85.1% | 44 |
| 4 yrs | 85.1% | 20 |

## 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 Name | Family | FDA Approval Date | Catheters Enrolled | Catheters Active in Study | Device Events* | Cumulative Months of Follow-up |
| **8709**† | 8709 | May 1998 | 2,390 | 1,172 | 151 | 64,766 |
| **8709SC** | 8709 | Mar 2006 | 474 | 348 | 25 | 6,561 |
| **8711** | 8711 | Oct 1999 | 566 | 364 | 50 | 16,796 |
| **8731** | 8731 | Oct 2002 | 503 | 232 | 32 | 18,150 |
| **8731SC** | 8731 | Mar 2006 | 94 | 79 | 5 | 1,504 |
| **Revised-As-Designed** | NA | Oct 2002 | 115 | 70 | 5 | 4,092 |
| **Revised-Not-As-Designed** | NA | NA | 208 | 154 | 23 | 5,293 |
| **Grafted-Not-As-Designed** | NA | NA | 138 | 87 | 16 | 3,452 |

*There were a total of 328 catheter-related events reported to the ISPR, but only 307 events included in this summary table. The remaining 21 catheter-related events occurred in catheter Models for which no device survival curves are presented due to an insufficient number of enrolled devices.

† Includes 8709 and 8709AA Models

| Device Survival Probability (95% Confidence Intervals) *Table 1 of 2* | | | | | |
|---|---|---|---|---|---|
| Model Name | 1 yr | 2 yrs | 3 yrs | 4 yrs | 5 yrs |
| **8709** | **94.9%** (93.6%, 96.2%) | **93.0%** (91.5%, 94.6%) | **91.1%** (89.3%, 92.8%) | **89.8%** (87.9%, 91.7%) | **88.1%** (86.0%, 90.3%) |
| **8709SC** | **94.7%** (92.4%, 97.0%) | **92.1%** (88.5%, 95.6%) | - | - | - |
| **8711** | **95.3%** (93.0%, 97.6%) | **92.8%** (89.8%, 95.7%) | **86.9%** (82.8%, 91.0%) | **85.8%** (81.5%, 90.2%) | **85.2%** (80.8%, 89.7%) |
| **8731** | **95.8%** (93.2%, 98.5%) | **93.9%** (91.0%, 96.9%) | **92.5%** (89.4%, 95.7%) | **90.7%** (87.3%, 94.1%) | **90.3%** (86.8%, 93.8%) |
| **8731SC** | **96.3%** (92.0%, 100.0%) | **92.3%** (85.5%, 99.2%) | - | - | - |
| **Revised-As-Designed** | **97.5%** (93.9%, 100.0%) | **95.1%** (90.3%, 99.9%) | **93.7%** (88.3%, 99.2%) | **93.7%** (88.3%, 99.2%) | **93.7%** (88.3%, 99.2%) |

| | | | | | |
|---|---|---|---|---|---|
| **Revised-Not-As-Designed** | **90.9%** (86.5%, 95.2%) | **89.4%** (84.6%, 94.2%) | **85.8%** (79.7%, 92.0%) | **84.0%** (76.9%, 91.0%) | - |
| **Grafted-Not-As-Designed** | **92.0%** (86.9%, 97.1%) | **88.6%** (82.2%, 94.9%) | **85.1%** (77.4%, 92.8%) | **85.1%** (77.4%, 92.8%) | - |

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

| Model Name | 6 yrs | 7 yrs | 8 yrs | 9 yrs | 10 yrs |
|---|---|---|---|---|---|
| **8709** | **84.8%** (82.2%, 87.5%) | **83.3%** (80.5%, 86.2%) | **80.9%** (77.6%, 84.1%) | **79.2%** (75.6%, 82.9%) | **76.9%** (72.1%, 81.8%) |
| **8709SC** | - | - | - | - | - |
| **8711** | **83.1%** (78.2%, 88.1%) | **80.5%** (74.8%, 86.2%) | **76.3%** (69.2%, 83.5%) | - | - |
| **8731** | **87.2%** (82.3%, 92.1%) | - | - | - | - |
| **8731SC** | - | - | - | - | - |
| **Revised-As-Designed** | - | - | - | - | - |
| **Revised-Not-As-Designed** | - | - | - | - | - |
| **Grafted-Not-As-Designed** | - | - | - | - | - |

2010 Medtronic Product Performance Report: Data through April 9, 2010

# 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 April 9, 2010. Forty-three centers enrolled and contributed patients to the spinal cord stimulation section of the report.

### Subjects

Of the 1,783 total spinal cord stimulation patients enrolled in the ISPR, 43.7% were implanted with a spinal cord stimulation system for the treatment of failed back, 44.0% for treatment of other indications, and 12.3% for treatment of complex regional pain syndrome (CRPS).

**Primary Spinal Cord Stimulation Treatment Indications**

| Primary Treatment Indication* | Total Enrolled Patients (N=1,783) |
|---|---|
| **Failed Back** | **780 (43.7%)** |
| Arachnoiditis | 22 |
| Failed Back Syndrome | 345 |
| Multiple Back Operations | 66 |
| Post-laminectomy Pain | 342 |
| Unsuccessful Disc Surgery | 5 |
| **Other** | **784 (44.0%)** |
| Degenerative Disc Disease | 50 |
| Epidural Fibrosis | 2 |
| Radicular Pain Syndrome | 170 |
| Other Chronic Pain | 562 |
| **CRPS** | **219 (12.3%)** |
| Complex Regional Pain Syndrome Type I | 180 |
| Complex Regional Pain Syndrome Type II | 39 |
| **Total Patients** | **1,783** |

* Refer to product labeling for approved indications. Primary treatment indication information is obtained through the Medtronic Device and Registrant Tracking system.

## Event Summary

**Product Performance–Related Events**

There were 1,078 events reported between June 2004 and April 9, 2010 in patients with spinal cord stimulation systems. Twenty-three percent of these events (252/1,078) were related to the spinal cord stimulator, lead, or extension, and categorized as product performance–related events and are presented graphically in depth within this report.

| EVENT | NO. | TIME TO EVENT IN MONTHS Mean (Median) ± SD |
|---|---|---|
| **Neurostimulator-Related Events:** | | |
| Broken bond wire* | 1 | 49.6 (49.6) ±NA |
| Device programming error | 3 | 20.0 (21.6) ±14.8 |

| | | |
|---|---|---|
| Loss of effect† | 3 | 14.3 (18.6) ±9.7 |
| Recharging issue | 2 | 6.1 (6.1) ±6.2 |
| Undesirable change in stimulation‡ | 3 | 19.7 (14.3) ±16.4 |
| **Neurostimulator–Related Events Subtotal** | **12** | **18.7 (16.4) ±15.2** |
| **Lead–Related Events:** | | |
| Disconnection | 1 | 0.9 (0.9) ±NA |
| Electrode contact damage | 5 | 32.0 (25.1) ±22.5 |
| Lead wire fracture | 38 | 24.2 (18.3) ±23.0 |
| Migration/dislodgement | 113 | 13.3 (5.7) ±20.2 |
| Undesirable change in stimulation | 70 | 15.7 (6.7) ±19.9 |
| **Lead–Related Events Subtotal** | **227** | **16.2 (8.0) ±21.0** |
| **Extension–Related Events:** | | |
| Extension failure§ | 3 | 4.0 (3.2) ±3.1 |
| Fracture | 10 | 20.1 (19.5) ±7.9 |
| **Extension–Related Events Subtotal** | **13** | **16.4 (16.1) ±9.9** |
| **Product Performance–Related Events Total** | **252** | **16.4 (8.2) ±20.3** |

*Broken bond wire was identified through returned product analysis.

† Physician reported worsening of symptoms and loss of therapeutic effect, due to an unspecified neurostimulator-related etiology.

‡ Physician reported neurostimulator-related undesirable change in stimulation and no lead-related issues were observed.

§ Physician attributed event to an unspecified failure of the extension.

## Non-Product Performance-Related Events

Twenty-seven percent of total events (294/1,078) were related to the surgery or procedure (n=118), or attributed to the patient or delivery of the therapy (n=176). Thirty percent of events (325/1,078) were related to patient death (n=36) or becoming lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal, n=289). Of the 36 patient deaths, none were reported as a direct result of a device-related event or neurostimulation therapy. Nineteen percent of events (207/1,078) were related to normal battery depletion.

| EVENT | NO. | TIME TO EVENT IN MONTHS Mean (Median) ± SD |
|---|---|---|
| **Surgical/Procedural–Related Events:** | | |
| **Neurostimulator Pocket/Access–Related** | | |
| Device damaged due to surgery | 1 | 1.1 (1.1) ±NA |
| Hematoma | 1 | 12.4 (12.4) ±NA |
| Infection | 26 | 7.7 (3.2) ±9.1 |

| | | |
|---|---|---|
| Malpositioned | 1 | 0.7 (0.7) ±NA |
| Migration/inversion | 14 | 16.2 (16.0) ±15.6 |
| Pain at site | 45 | 13.9 (9.9) ±12.1 |
| Seroma | 3 | 15.6 (13.2) ±7.6 |
| Skin erosion | 5 | 12.4 (11.0) ±9.6 |
| Wound dehiscence | 1 | 15.9 (15.9) ±NA |
| **Neurostimulator Pocket/Access–Related Subtotal** | **97** | **12.3 (8.7) ±11.8** |
| **Lead Tract–Related** | | |
| Infection | 7 | 19.1 (16.4) ±18.3 |
| Inflamation | 2 | 4.6 (4.6) ±5.2 |
| Pain at site | 5 | 10.6 (10.5) ±4.5 |
| Skin erosion | 3 | 13.5 (6.7) ±14.6 |
| Wound dehiscence | 3 | 3.5 (2.7) ±3.3 |
| **Lead Tract–Related Subtotal** | **20** | **12.3 (7.7) ±13.1** |
| **Extension Tract–Related** | | |
| Body fluids entry into connection | 1 | 12.5 (12.5) ±NA |
| **Extension Tract–Related Subtotal** | **1** | **12.5 (12.5) ±NA** |
| **Surgical/Procedural–Related Events Subtotal** | **118** | **12.3 (8.5) ±11.9** |
| **Therapy/Patient–Related Events:** | | |
| **Therapy/Patient Effects** | | |
| Allergic reaction | 1 | 9.6 (9.6) ±NA |
| Corrective surgery* | 11 | 16.5 (19.3) ±9.7 |
| Cosmetic issue† | 4 | 19.3 (18.9) ±14.3 |
| Infection | 4 | 17.7 (10.8) ±21.4 |
| Leg pain/weakness | 1 | 28.6 (28.6) ±NA |
| Loss of effect | 22 | 18.7 (17.9) ±12.3 |
| Needed expanded coverage‡ | 7 | 18.7 (13.8) ±11.0 |
| No anomaly found by RPA§ | 1 | 19.5 (19.5) ±NA |
| Pain/irritation | 4 | 10.5 (7.4) ±8.3 |
| Patient choice‖ | 1 | 0.9 (0.9) ±NA |

| | | |
|---|---|---|
| Patient noncompliance¶ | 2 | 27.5 (27.5) ±13.5 |
| Psychological issue | 3 | 15.6 (17.3) ±9.3 |
| Recharging issue | 1 | 5.7 (5.7) ±NA |
| Resolution of symptoms** | 5 | 22.1 (23.3) ±11.4 |
| Therapy didn't meet patient's expectations | 93 | 18.2 (12.9) ±14.0 |
| Undesirable change in stimulation | 5 | 11.4 (9.4) ±8.9 |
| Undesirable interaction with other equipment | 10 | 17.3 (15.6) ±12.3 |
| Unrelated health issues | 1 | 36.0 (36.0) ±NA |
| **Therapy/Patient–Related Events Subtotal** | **176** | **17.9 (14.5) ±12.9** |
| **Patient–Related Events:††** | | |
| Patient expired ‡‡ | 36 | 20.9 (15.2) ±18.0 |
| Patient lost to follow-up | 289 | 17.0 (13.4) ±15.3 |
| **Patient–Related Events Subtotal** | **325** | **17.5 (13.6) ±15.7** |
| **Normal Battery Depletion Events:** | | |
| Battery depletion | 207 | 29.3 (26.3) ±16.6 |
| **Normal Battery Depletion Events Subtotal** | **207** | **29.3 (26.3) ±16.6** |
| **Non-Product Performance–Related Events Total** | **826** | **19.8 (15.9) ±15.9** |

* Neurostimulator was removed due to corrective surgery (e.g., patient had lumbar fusion surgery and symptoms resolved).

† Event was related to a cosmetic issue (e.g., patient experienced weight loss and neurostimulator was removed because it was too superficial).

‡ New area of pain developed and required modification of the device to provide expanded coverage.

§ For products that are returned, and RPA establishes a root cause or finds no anomaly, results reported herein default to the RPA finding.

‖Patient chose to have the device replaced/repositioned due to personal reasons.

¶ Physician reported that patient was not compliant with recharging schedule.

**Device was no longer needed because patients' symptoms were attenuated through other medical therapies or resolution of the underlying disease.

†† Event summary frequencies are at the patient level, not device level.

‡‡Thirty-six percent of patient deaths occurred in patients receiving therapy for failed back (n=13), 6% for complex regional pain syndrome (n=2), and 58% for other indications (e.g., radicular pain syndrome and other chronic pain, n=21).

## Spinal Cord Stimulators

From June 2004 to the report cut-off date of April 9, 2010, 2,071 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=1,783) versus spinal cord stimulators were due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted.

Twenty-four percent (24%) of the spinal cord stimulators were Synergy, 22.1% were Restore, 16.6% were RestoreUltra, 15.2% were PrimeAdvanced, 11.3% were RestoreAdvanced, 5.1% were Itrel 3, and a smaller

number were RestorePrime (2.5%), Synergy Versitrel (1.9%), or SynergyPlus+ (1.2%). Total prospective follow-up time for all spinal cord stimulators was 44,267 months (3,689 years).

## Spinal Cord Stimulator Events

A surgical intervention was required for 12 spinal cord stimulators with an underlying reported etiology related to the spinal cord stimulator. For spinal cord stimulators in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 87/486 (18%). 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 12 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 11 spinal cord stimulators were not returned to Medtronic RPA but were assigned as device related by the physician, including 3 devices with an undesirable change in stimulation, 3 devices with a programming error, 3 devices with loss of therapeutic effect, and 2 device recharging issues.

There were an additional 820 spinal cord stimulators censored in the analysis due to spinal cord stimulator having been explanted, patient lost to follow-up, patient expired, therapy abandoned, or other surgical intervention attributed to an event unrelated to the spinal cord stimulator.

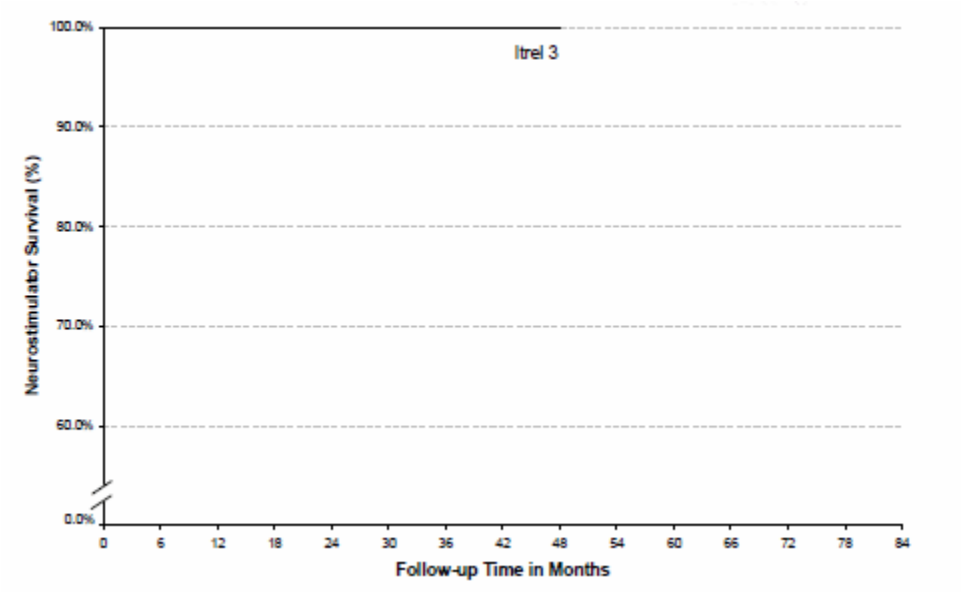
## Spinal Cord Stimulator Survival Curves

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

- Data
- Model Info

### 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.

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | Itrel 3 |
| **FDA Approval Date** | Aug 1995 |
| **Neurostimulators Enrolled** | 105 |
| **Neurostimulators Active in Study** | 23 |
| **Device Events** | 0 |
| **Cumulative Months of Follow-up** | 2,596 |

| Stimulator Event | Total |
|---|---|
| **Total Stimulator Events** | **0** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 66 |
| 2 yrs | 100.0% | 48 |
| 3 yrs | 100.0% | 40 |
| 4 yrs | 100.0% | 24 |

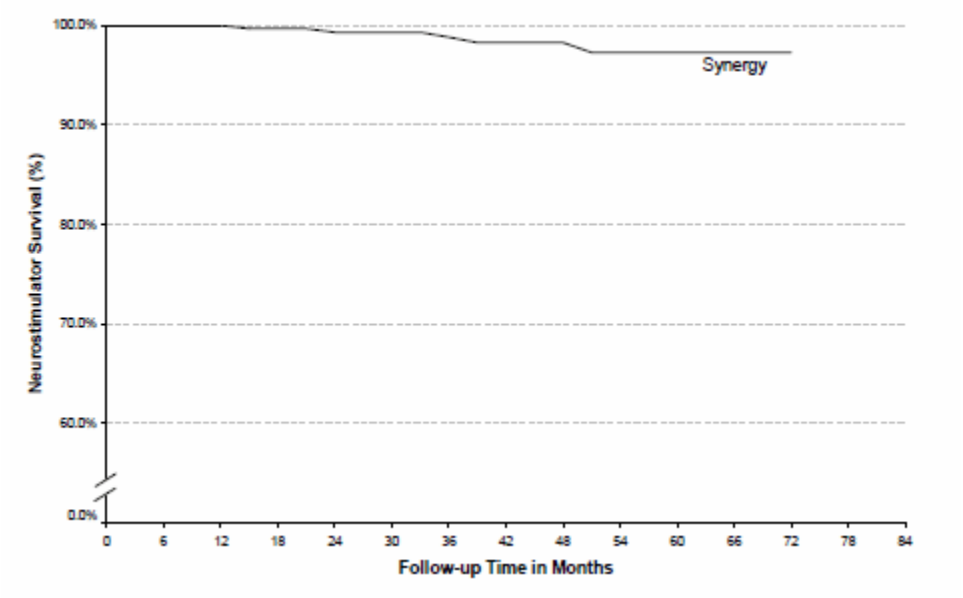
## Model 7425 Itrel 3: Specifications

| | |
|---|---|
| **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 |

- Data
- Model Info

### Model 7427 Synergy: Survival from Spinal Cord Stimulator Events




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

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | Synergy |
| **FDA Approval Date** | Nov 1999 |
| **Neurostimulators Enrolled** | 501 |
| **Neurostimulators Active in Study** | 93 |
| **Device Events** | 5 |
| **Cumulative Months of Follow-up** | 12,757 |

| Stimulator Event | Total |
|---|---|
| **Broken bond wire** | 1 |
| **Device programming error** | 1 |
| **Loss of effect** | 1 |

| | |
|---|---|
| **Undesirable change in stimulation** | 2 |
| **Total Stimulator Events** | **5** |

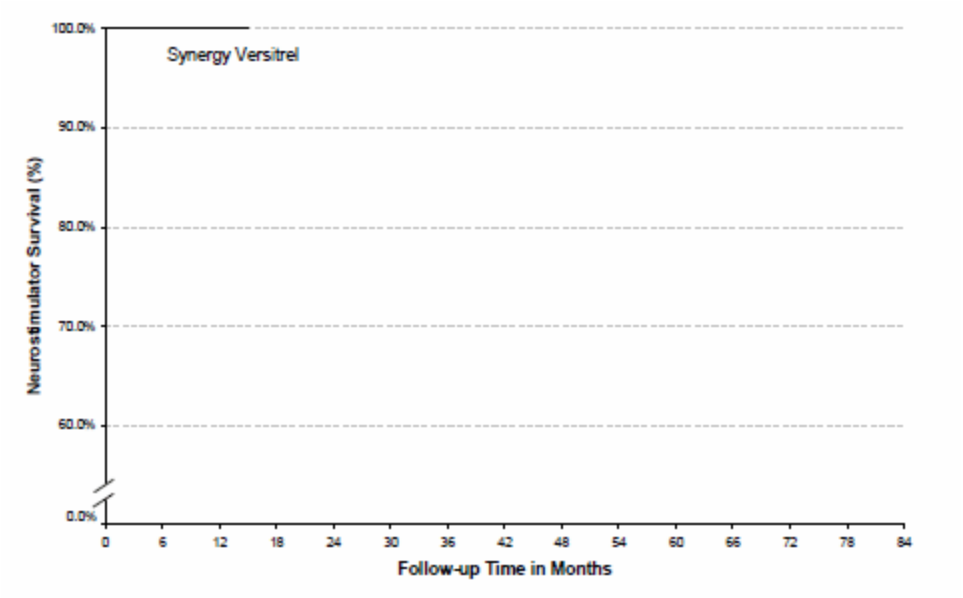
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 314 |
| 2 yrs | 99.3% | 267 |
| 3 yrs | 98.8% | 201 |
| 4 yrs | 98.3% | 123 |
| 5 yrs | 97.3% | 52 |
| 6 yrs | 97.3% | 20 |

## Model 7427 Synergy: Specifications

| | |
|---|---|
| **Height** | 2.4 in (61 mm) |
| **Width** | 3.0 in (76 mm) |
| **Thinness** | 0.6 in (15 mm) |
| **Volume** | 51 cc |
| **Battery type** | Non-Rechargeable |
| **Expected Battery life** | Depends on settings and use (additional Information) |
| **Maximum Electrodes** | 8 |
| **Amplitude** | 0 - 10.5 V |
| **Rate** | 3 - 130 Hz |
| **Pulse Width** | 60 - 450 µsec |
| **Groups** | 1 |
| **Programs** | 2 |
| **Implant Depth** | ≤ 4 cm |


- Data
- Model Info

## 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.

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | Synergy Versitrel |
| **FDA Approval Date** | Dec 2001 |
| **Neurostimulators Enrolled** | 40 |
| **Neurostimulators Active in Study** | 5 |
| **Device Events** | 0 |
| **Cumulative Months of Follow-up** | 827 |

| Stimulator Event | Total |
|---|---|
| **Total Stimulator Events** | **0** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 23 |
| at 15 mo | 100.0% | 25 |

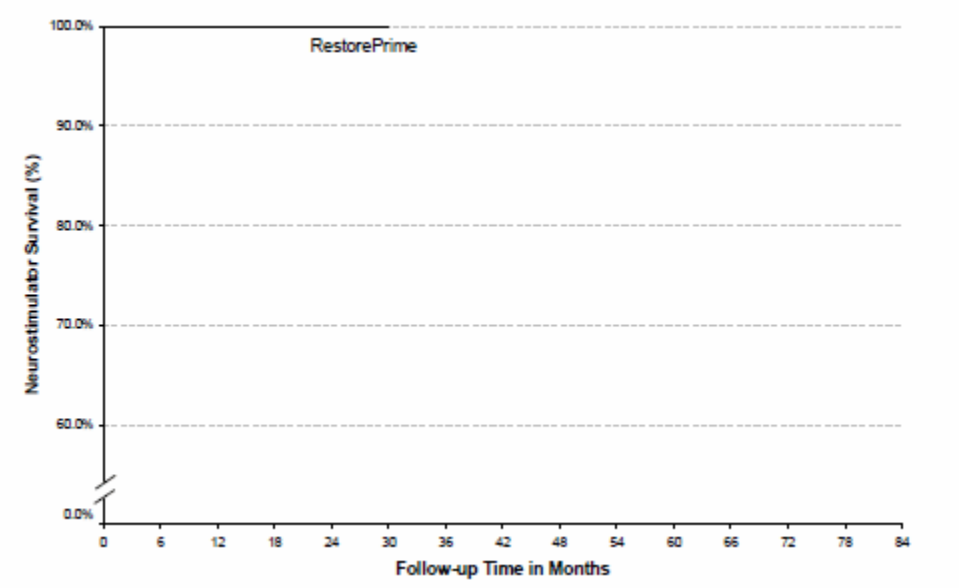
## Model 7427V Synergy Versitrel: Specifications

| | |
|---|---|
| **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 |


- Data
- Model Info

### Model 37701 RestorePrime: Survival from Spinal Cord Stimulator Events




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

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | RestorePrime |
| **FDA Approval Date** | Apr 2005 |
| **Neurostimulators Enrolled** | 51 |

| | |
|---|---|
| **Neurostimulators Active in Study** | 17 |
| **Device Events** | 0 |
| **Cumulative Months of Follow-up** | 1,187 |

| Stimulator Event | Total |
|---|---|
| **Total Stimulator Events** | **0** |

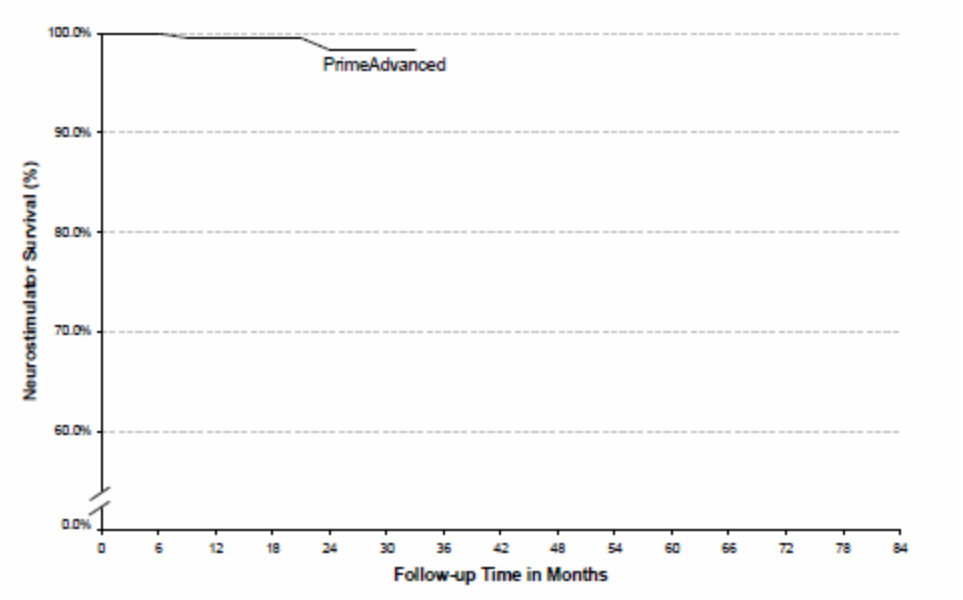
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 39 |
| 2 yrs | 100.0% | 22 |
| at 30 mo | 100.0% | 20 |

## Model 37701 RestorePrime: Specifications

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


- Data
- Model Info

## Model 37702 PrimeAdvanced: Survival from Spinal Cord Stimulator Events




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

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | PrimeAdvanced |
| **FDA Approval Date** | Jul 2006 |
| **Neurostimulators Enrolled** | 314 |
| **Neurostimulators Active in Study** | 196 |
| **Device Events** | 2 |
| **Cumulative Months of Follow-up** | 4,870 |

| Stimulator Event | Total |
|---|---|
| **Device programming error** | 1 |
| **Undesirable change in stimulation** | 1 |
| **Total Stimulator Events** | **2** |

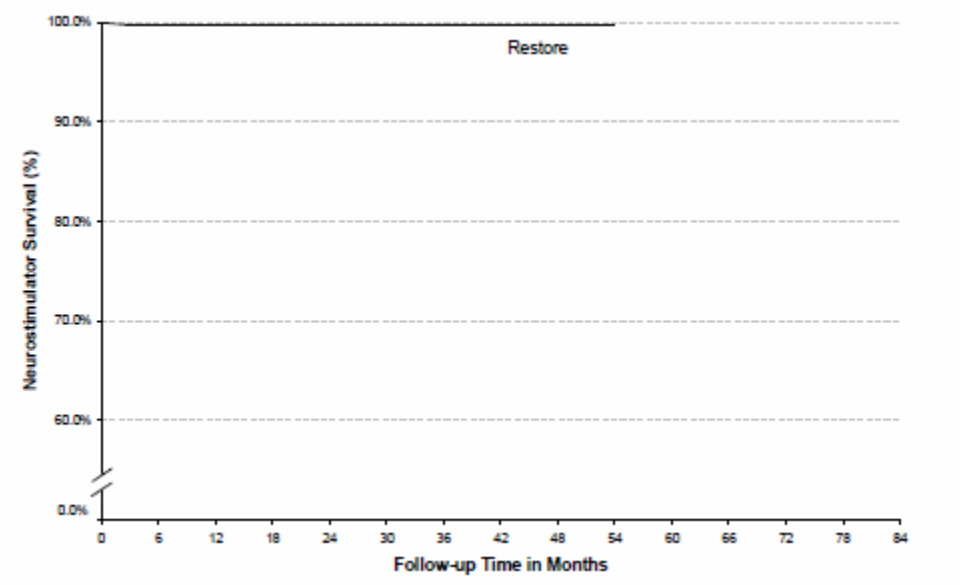
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.6% | 185 |
| 2 yrs | 98.3% | 82 |
| at 33 mo | 98.3% | 30 |

## 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 |

- Data
- Model Info

### Model 37711 Restore: Survival from Spinal Cord Stimulator Events




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

## Spinal Cord Stimulator Characteristics

| | |
|---|---|
| **Model Name** | Restore |
| **FDA Approval Date** | Apr 2005 |
| **Neurostimulators Enrolled** | 458 |
| **Neurostimulators Active in Study** | 182 |
| **Device Events** | 1 |
| **Cumulative Months of Follow-up** | 12,262 |

| Stimulator Event | Total |
|---|---|
| **Recharging issue** | 1 |
| **Total Stimulator Events** | **1** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.7% | 358 |
| 2 yrs | 99.7% | 268 |
| 3 yrs | 99.7% | 170 |
| 4 yrs | 99.7% | 67 |
| at 54 mo | 99.7% | 22 |

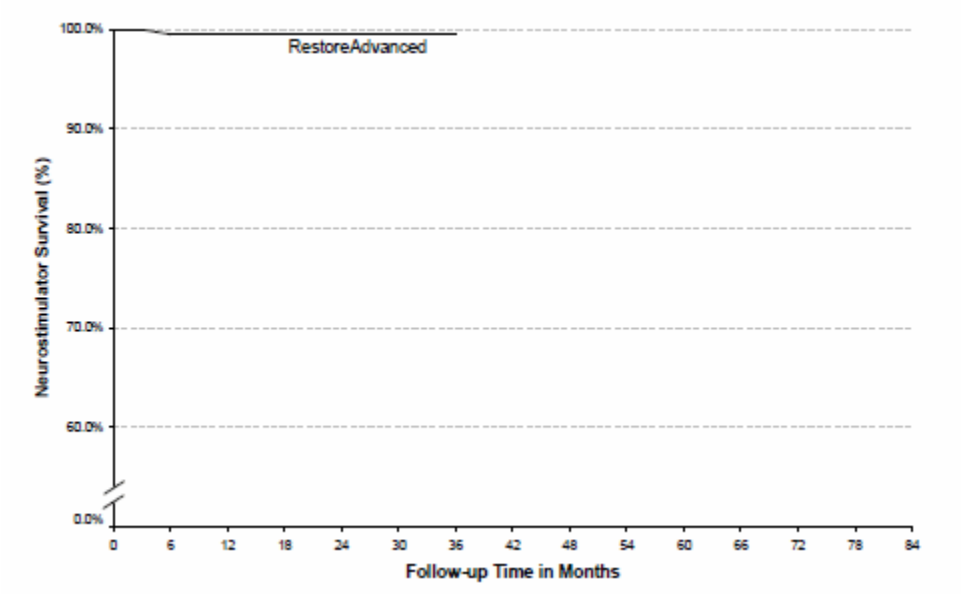
## Model 37711 Restore: Specifications

| | |
|---|---|
| **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 |

- Data
- Model Info

### Model 37713 RestoreAdvanced: Survival from Spinal Cord Stimulation Events




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

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | RestoreAdvanced |
| **FDA Approval Date** | Jul 2006 |
| **Neurostimulators Enrolled** | 234 |
| **Neurostimulators Active in Study** | 156 |
| **Device Events** | 1 |
| **Cumulative Months of Follow-up** | 4,897 |

| Stimulator Event | Total |
|---|---|
| **Loss of effect** | 1 |
| **Total Stimulator Events** | **1** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.5% | 169 |
| 2 yrs | 99.5% | 119 |

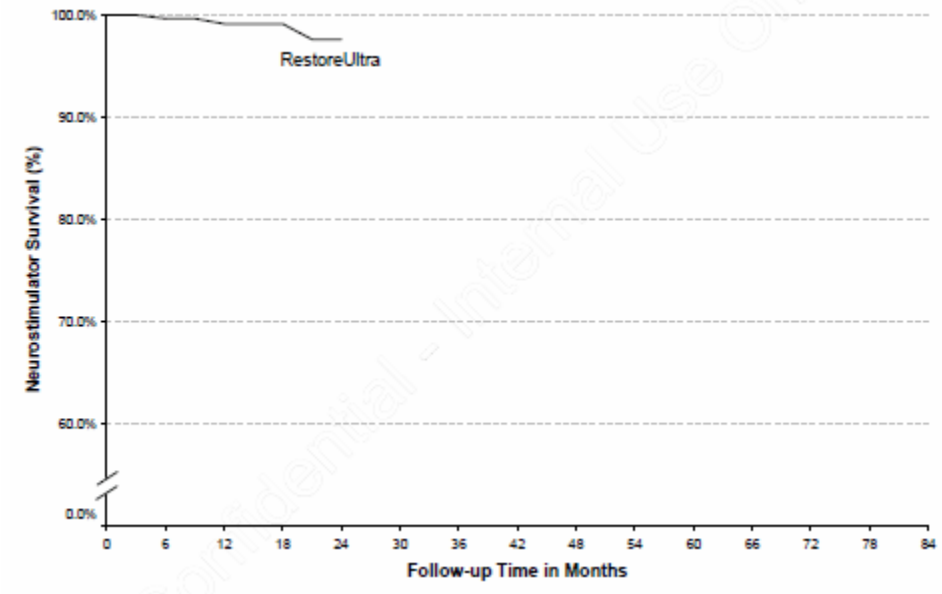
| | | |
|---|---|---|
| 3 yrs | 99.5% | 35 |

### 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 |

- Data
- Model Info

### Model 37712 RestoreUltra: Survival from Spinal Cord Stimulation Events




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

| Spinal Cord Stimulator Characteristics | |
|---|---|
| **Model Name** | RestoreUltra |
| **FDA Approval Date** | Jan 2008 |
| **Neurostimulators Enrolled** | 343 |
| **Leads Active in Study** | 274 |
| **Device Events** | 3 |
| **Cumulative Months of Follow-up** | 4,219 |

| Stimulator Event | Total |
|---|---|
| **Device programming error** | 1 |
| **Loss of effect** | 1 |
| **Recharging issue** | 1 |
| **Total Stimulator Events** | **3** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.1% | 195 |
| 2 yrs | 97.6% | 33 |

## 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 Active in Study | Device Events | Cumulative Months of Follow-up |
|---|---|---|---|---|---|---|
| **Itrel3** | Itrel3 | Aug 1995 | 105 | 23 | 0 | 2,596 |
| **Synergy** | Synergy | Nov 1999 | 501 | 93 | 5 | 12,757 |
| **Synergy Versitrel** | Synergy | Dec 2001 | 40 | 5 | 0 | 827 |
| **Restore Prime** | Restore Prime | Apr 2005 | 51 | 17 | 0 | 1,187 |
| **Prime Advanced** | Prime Advanced | Jul 2006 | 314 | 196 | 2 | 4,780 |
| **Restore** | Restore | Apr 2005 | 458 | 182 | 1 | 12,262 |
| **Restore Advanced** | Restore | Jul 2006 | 234 | 156 | 1 | 4,897 |
| **RestoreUltra** | Restore | Jan 2008 | 343 | 274 | 3 | 4,219 |

**Device Survival Probability (95% Confidence Intervals)**

| 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 | **99.3%** (98.3%, 100.0%) | **98.8%** (97.4%, 100.0%) | **98.3%** (96.5%, 100.0%) | **97.3%** (94.7%, 99.9%) | **97.3%** (94.7%, 99.9%) |
| **Synergy Versitrel** | **100.0%** NA | - | - | - | - | - |
| **RestorePrime** | **100.0%** NA | **100.0%** NA | - | - | - | - |
| | **99.6%** | **98.3%** | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **PrimeAdvanced** | (98.7%, 100.0%) | (95.8%, 100.0%) | - | - | - | - |
| **Restore** | **99.7%** (99.2%, 100.0%) | **99.7%** (99.2%, 100.0%) | **99.7%** (99.2%, 100.0%) | **99.7%** (99.2%, 100.0%) | - | - |
| **RestoreAdvanced** | **99.5%** (98.6%, 100.0%) | **99.5%** (98.6%, 100.0%) | **99.5%** (98.6%, 100.0%) | - | - | - |
| **RestoreUltra** | **99.1%** (97.9%, 100.0%) | **97.6%** (94.4%, 100.0%) | - | - | - | - |

## Leads

From June 2004 to the report cut-off date of April 9, 2010, there were 3,448 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=2,071) 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-nine percent (89%) of leads in ISPR were percutaneous leads (3,061/3,448) including 49% (1,680/3,448) in the Pisces-Octad lead family, 31% (1,077/3,448) in the Pisces-Quad lead family, and 9% (304/3,448) in the Pisces-Quad LZ lead family. Eleven percent (11%) of leads (369/3,448) were surgical leads. A small number of leads (18/3,448) were designated as Other (<1%). Total prospective follow-up time for all leads was 78,517 months (6,543 years).

### Lead Events

A surgical intervention was required for 227 leads with an underlying reported etiology related to the lead. Of these 227 events, 113 were due to lead migration or dislodgement, 70 were due to an undesirable change in stimulation, 38 were due to lead fractures, 5 were due to damaged electrodes, and 1 was due to disconnection. Two-hundred and eleven of the 227 events (93%) occurred in percutaneous leads including 107 due to lead migration or dislodgement, 64 due to undesirable change in stimulation, 34 due to fracture, 5 due to damaged electrodes, and 1 disconnection. Fifteen of the 227 events (7%) occurred in surgical leads including 6 due to undesirable change in stimulation, 5 due to lead migration or dislodgement, and 4 due to lead fractures. One event (lead migration or dislodgement) of the 227 events (<1%) occurred in leads designated as Other. There were 211 events in 3,061 (7%) percutaneous leads, 15 events in 367 (4%) surgical leads, and 1 event in 20 (5%) leads designated as Other.

There were an additional 1,029 leads censored in the analysis due to patient lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), lead explanted, therapy abandoned, patient expired, or other surgical intervention attributed to an event unrelated to the lead.

### Lead Survival Curves

The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each interval. Currently, at 2 years of follow-up, the 95% confidence intervals for the Pisces-Quad Model 3487A and Pisces-Octad Model 3777 do not overlap with the Pisces-Quad Model 3888, Pisces-Quad LZ Model 3890, and the Specify Model 39565 suggesting that Models 3888, 3890, and 39565 have statistically significantly better performance than Models 3487A and 3777 at this time point. However, this statistically significant difference is not sustained at 3 and 4 years of follow-up when compared to all applicable lead Models.

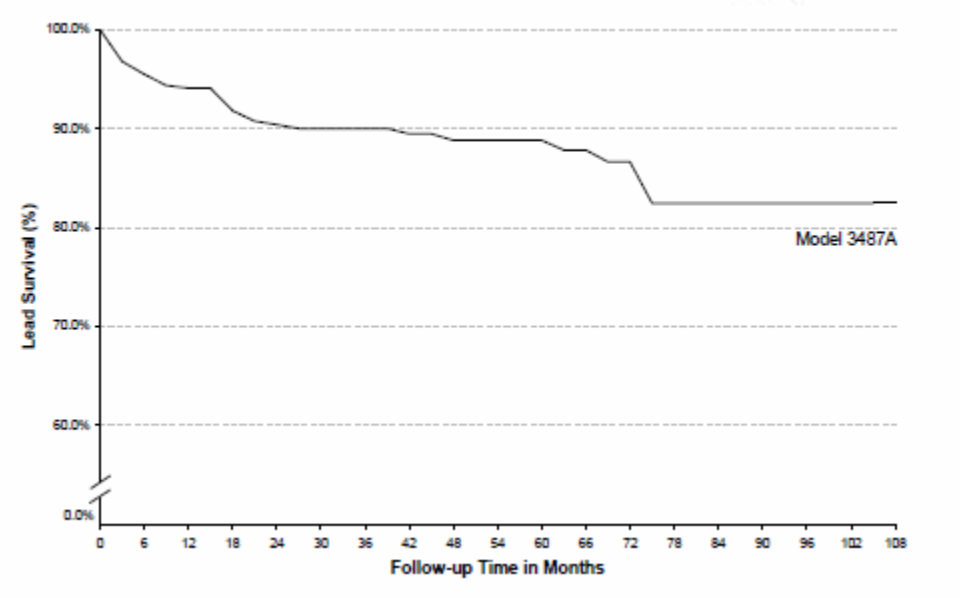
At 2 years, the 95% confidence interval for Pisces-Quad LZ Model 3891 leads does not overlap with any other lead Models, indicating that Model 3891 may not perform as well as other lead Models at 2 years. This

significant difference in performance continues at 3 and 4 years when compared to all applicable lead Models. As of February 6, 2008, Medtronic has discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Choose a model Go

- Data
- Model Info

### Model 3487A Pisces-Quad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3487A |
| **FDA Approval Date** | Aug 1983 |
| **Leads Enrolled** | 645 |
| **Leads Active in Study** | 322 |
| **Device Events** | 43 |
| **Cumulative Months of Follow-up** | 16,298 |

| Lead Event | Total |
|---|---|
| **Fracture** | 2 |
| **Migration/dislodgement** | 14 |

| | |
|---|---|
| **Undesirable change in stimulation** | 27 |
| **Total Lead Events** | **43** |

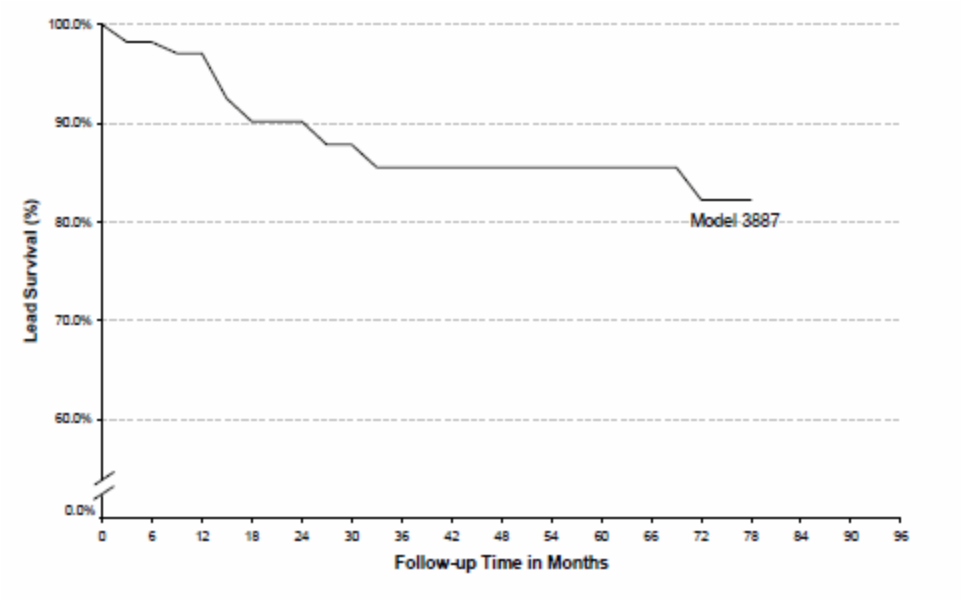
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 94.1% | 341 |
| 2 yrs | 90.4% | 250 |
| 3 yrs | 90.0% | 183 |
| 4 yrs | 88.8% | 137 |
| 5 yrs | 88.8% | 95 |
| 6 yrs | 86.6% | 66 |
| 7 yrs | 82.5% | 48 |
| 8 yrs | 82.5% | 39 |
| 9 yrs | 82.5% | 21 |

## 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 |

- Data
- Model Info

## Model 3887 Pisces-Quad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3887 |
| **FDA Approval Date** | Mar 2004 |
| **Leads Enrolled** | 163 |
| **Leads Active in Study** | 58 |
| **Device Events** | 13 |
| **Cumulative Months of Follow-up** | 5,211 |

| Lead Event | Total |
|---|---|
| **Damaged electrodes** | 1 |
| **Fracture** | 7 |
| **Migration/dislodgement** | 3 |
| **Undesirable change in stimulation** | 2 |
| **Total Lead Events** | **13** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 97.1% | 89 |
| 2 yrs | 90.2% | 75 |
| 3 yrs | 85.6% | 79 |

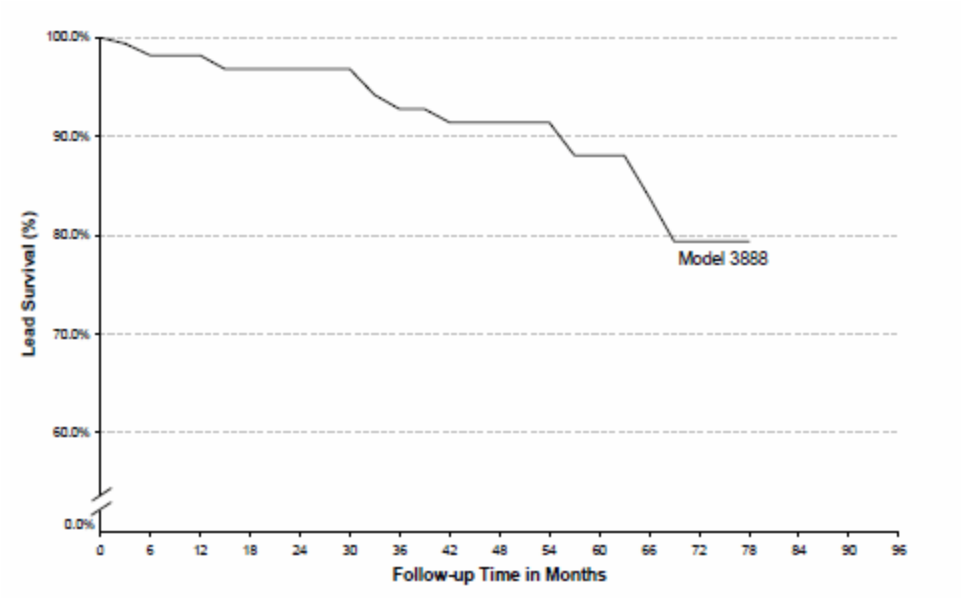
| | | |
|---|---|---|
| 4 yrs | 85.6% | 58 |
| 5 yrs | 85.6% | 47 |
| 6 yrs | 82.3% | 26 |
| at 78 mo | 82.3% | 21 |

### 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 |

- Data
- Model Info

### Model 3888 Pisces-Quad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3888 |
| **FDA Approval Date** | Nov 1992 |
| **Leads Enrolled** | 269 |
| **Leads Active in Study** | 186 |
| **Device Events** | 17 |
| **Cumulative Months of Follow-up** | 7,028 |

| Lead Event | Total |
|---|---|
| **Fracture** | 3 |
| **Migration/dislodgement** | 9 |
| **Undesirable change in stimulation** | 5 |
| **Total Lead Events** | **17** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 98.2% | 149 |
| 2 yrs | 96.8% | 93 |
| 3 yrs | 92.8% | 66 |
| 4 yrs | 91.4% | 64 |

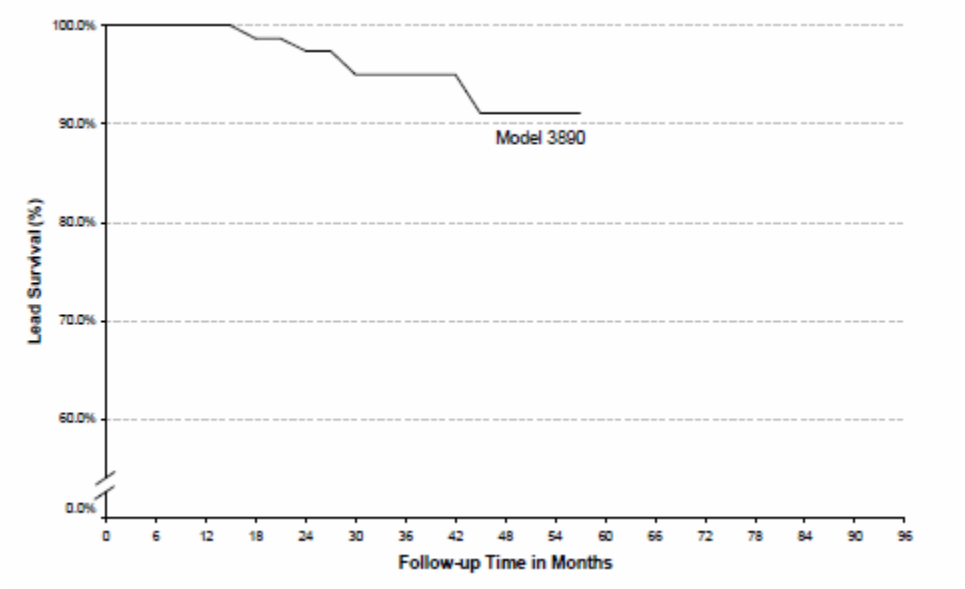
| | | |
|---|---|---|
| 5 yrs | 88.1% | 53 |
| 6 yrs | 79.4% | 28 |
| at 78 mo | 79.4% | 21 |

## Model 3888 Pisces-Quad: Specifications

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

- Data
- Model Info

## Model 3890 Pisces-Quad LZ: Survival from Lead Events



Data are shown if there are at least 20 devices in each 3-month interval.
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 Name** | 3890 |
| **FDA Approval Date** | Sep 2002 |
| **Leads Enrolled** | 136 |
| **Leads Active in Study** | 36 |
| **Device Events** | 6 |
| **Cumulative Months of Follow-up** | 3,518 |

| Lead Event | Total |
|---|---|
| **Fracture** | 2 |
| **Migration/dislodgement** | 2 |
| **Undesirable change in stimulation** | 2 |
| **Total Lead Events** | **6** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 61 |
| 2 yrs | 97.4% | 79 |
| 3 yrs | 95.0% | 72 |
| 4 yrs | 91.1% | 40 |
| at 57 mo | 91.1% | 21 |

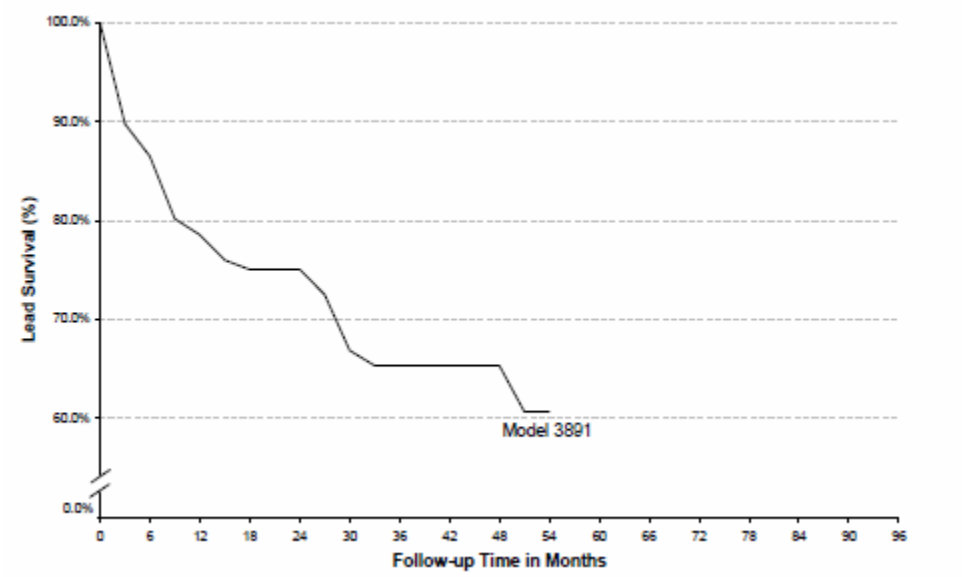
## Model 3890 Pisces-Quad LZ: Specifications

| 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 |

- Data
- Model Info

### Model 3891 Pisces-Quad LZ: Survival from Lead Events




Data are shown if there are at least 20 devices in each 3-month interval.
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 Name** | 3891 |
| **FDA Approval Date** | Sep 2002 |
| **Leads Enrolled** | 151 |
| **Leads Active in Study** | 19 |
| **Device Events** | 38 |
| **Cumulative Months of Follow-up** | 3,477 |

| Lead Event | Total |
|---|---|
| **Damaged electrodes** | 2 |
| **Fracture** | 10 |
| **Migration/dislodgement** | 16 |
| **Undesirable change in stimulation** | 10 |
| **Total Lead Events** | **38** |

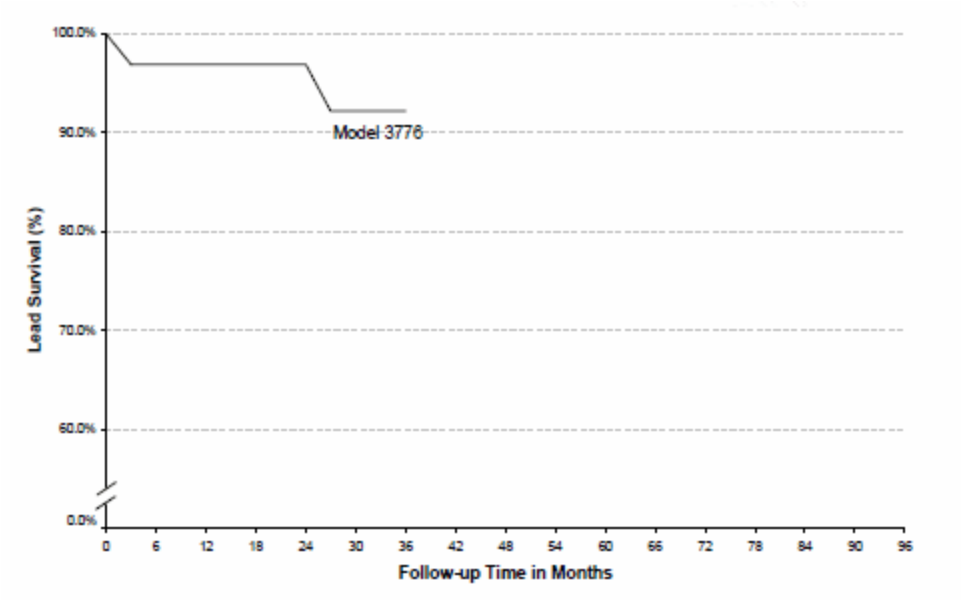
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 78.5% | 99 |
| 2 yrs | 75.0% | 65 |
| 3 yrs | 65.3% | 42 |
| 4 yrs | 65.3% | 30 |
| at 54 mo | 60.7% | 22 |

### Model 3891 Pisces-Quad LZ: Specifications

| Device Name | Pisces Z<br>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 |

- Data
- Model Info

### Model 3776 Pisces-Octad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3776 |
| **FDA Approval Date** | Nov 2005 |
| **Leads Enrolled** | 109 |
| **Leads Active in Study** | 48 |
| **Device Events** | 5 |
| **Cumulative Months of Follow-up** | 2,179 |

| Lead Event | Total |
|---|---|
| **Migration/dislodgement** | 4 |
| **Undesirable change in stimulation** | 1 |
| **Total Lead Events** | **5** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 96.9% | 75 |
| 2 yrs | 96.9% | 44 |
| 3 yrs | 92.2% | 23 |

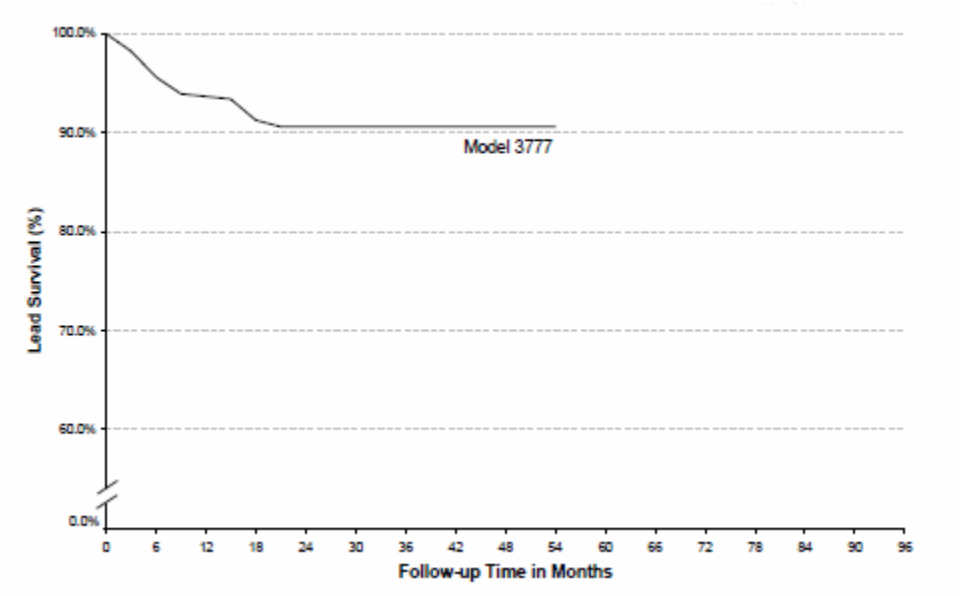
## Model 3776 Pisces-Octad: Specifications

| Device Name | 1x8<br>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 |



- Data
- Model Info

### Model 3777 Pisces-Octad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3777 |

| | |
|---|---|
| **FDA Approval Date** | Apr 2005 |
| **Leads Enrolled** | 529 |
| **Leads Active in Study** | 235 |
| **Device Events** | 38 |
| **Cumulative Months of Follow-up** | 11,789 |

| Lead Event | Total |
|---|---|
| **Damaged electrodes** | 2 |
| **Disconnection** | 1 |
| **Fracture** | 1 |
| **Migration/dislodgement** | 24 |
| **Undesirable change in stimulation** | 10 |
| **Total Lead Events** | **38** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 93.7% | 361 |
| 2 yrs | 90.6% | 241 |
| 3 yrs | 90.6% | 131 |
| 4 yrs | 90.6% | 59 |
| at 54 mo | 90.6% | 31 |

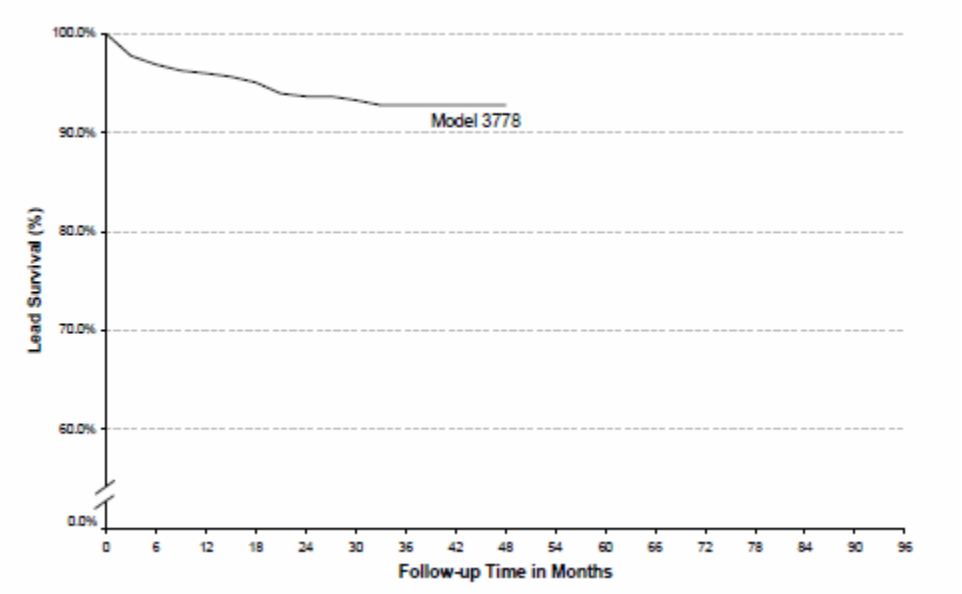
## Model 3777 Pisces-Octad: Specifications

| 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 |

- Data
- Model Info

### Model 3778 Pisces-Octad: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3778 |
| **FDA Approval Date** | Apr 2005 |
| **Leads Enrolled** | 1,034 |
| **Leads Active in Study** | 731 |
| **Device Events** | 50 |
| **Cumulative Months of Follow-up** | 18,792 |

| Lead Event | Total |
|---|---|
| **Fracture** | 8 |
| **Migration/dislodgement** | 35 |
| **Undesirable change in stimulation** | 7 |

| | |
|---|---|
| **Total Lead Events** | **50** |

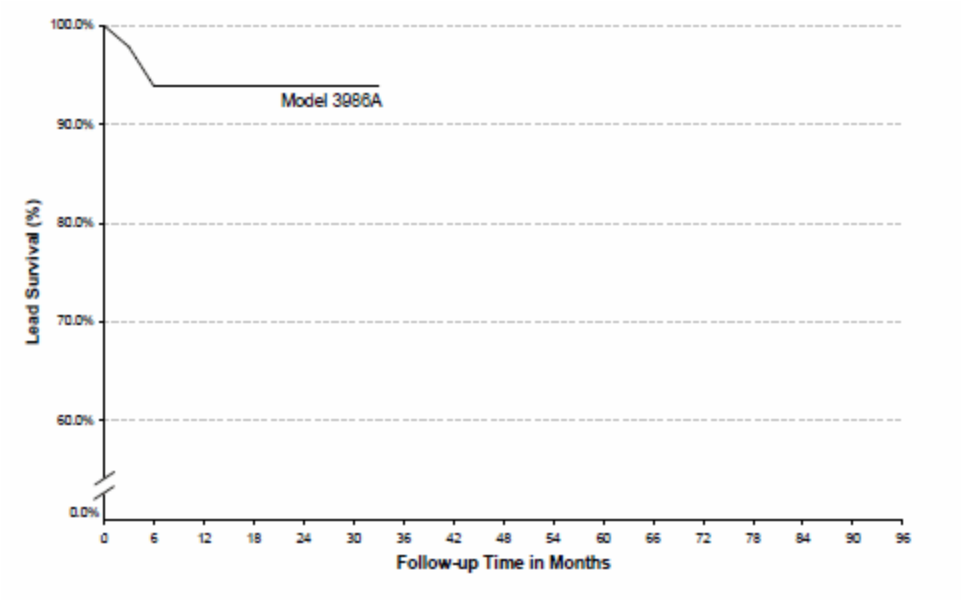
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 96.0% | 678 |
| 2 yrs | 93.7% | 348 |
| 3 yrs | 92.8% | 141 |
| 4 yrs | 92.8% | 24 |

## Model 3778 Pisces-Octad: Specifications

| Device Name | 1x8 Compact |
|---|---|
| **Lead Type** | **Percutaneous** |
| **Lead** | |
| Length (cm) | 45, 60, 75 |
| Diameter (mm) | 1.3 |
| **Electrode** | |
| Number | 8 |
| Shape | Cylindrical |
| Length (mm) | 3.0 |
| Individual Surface Area (mm) | 12.0 |
| Inter-Electrode Spacing: Edge to Edge (mm) | 4.0 |
| Array Length (mm) | 52.0 |

- Data
- Model Info

## Model 3986A Resume TL: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3986A |
| **FDA Approval Date** | Mar 2004 |
| **Leads Enrolled** | 67 |
| **Leads Active in Study** | 26 |
| **Device Events** | 4 |
| **Cumulative Months of Follow-up** | 1,491 |

| Lead Event | Total |
|---|---|
| **Fracture** | 1 |
| **Undesirable change in stimulation** | 3 |
| **Total Lead Events** | **4** |

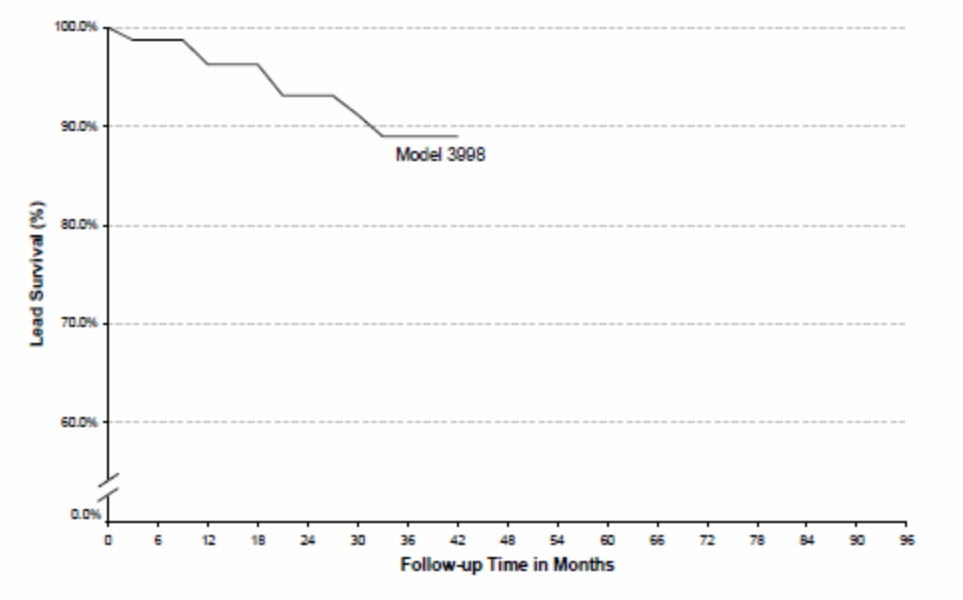
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 93.9% | 35 |
| 2 yrs | 93.9% | 30 |
| at 33 mo | 93.9% | 23 |

## 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 |

- Data
- Model Info

### Model 3998 Specify: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3998 |
| **FDA Approval Date** | Feb 1998 |
| **Leads Enrolled** | 124 |
| **Leads Active in Study** | 30 |
| **Device Events** | 7 |
| **Cumulative Months of Follow-up** | 3,050 |

| Lead Event | Total |
|---|---|
| **Fracture** | 3 |
| **Migration/dislodgement** | 2 |
| **Undesirable change in stimulation** | 2 |
| **Total Lead Events** | **7** |

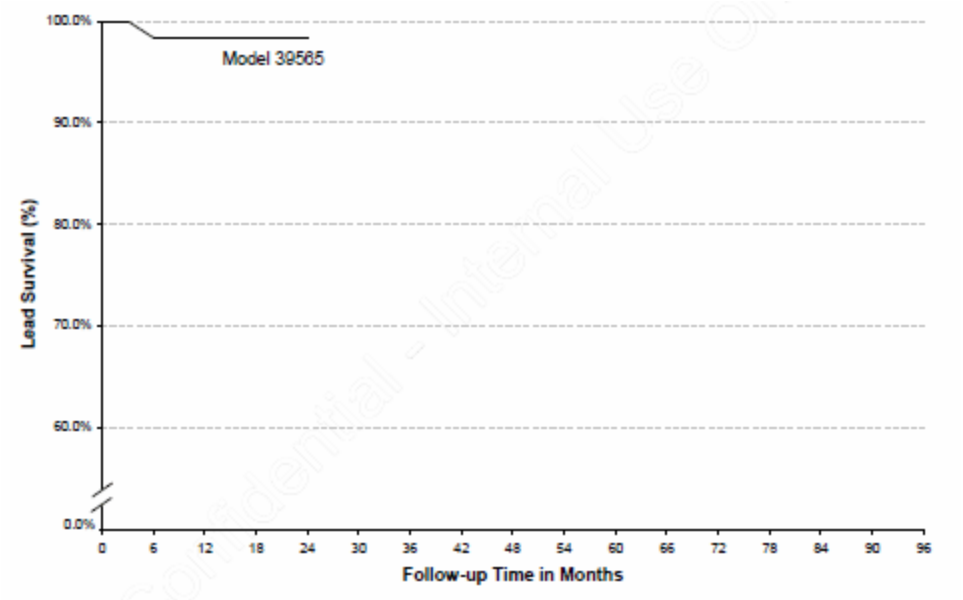
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 96.3% | 80 |
| 2 yrs | 93.1% | 51 |
| 3 yrs | 89.0% | 33 |
| at 42 mo | 89.0% | 22 |

## Model 3998 Specify: Specifications

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

- Data
- Model Info

## Model 39565 Specify: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 39565 |
| **FDA Approval Date** | Jun 2007 |
| **Leads Enrolled** | 70 |
| **Leads Active in Study** | 48 |
| **Device Events** | 1 |
| **Cumulative Months of Follow-up** | 1,155 |

| Lead Event | Total |
|---|---|
| **Migration/dislodgement** | 1 |
| **Total Lead Events** | **1** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 98.4% | 46 |
| 2 yrs | 98.4% | 22 |

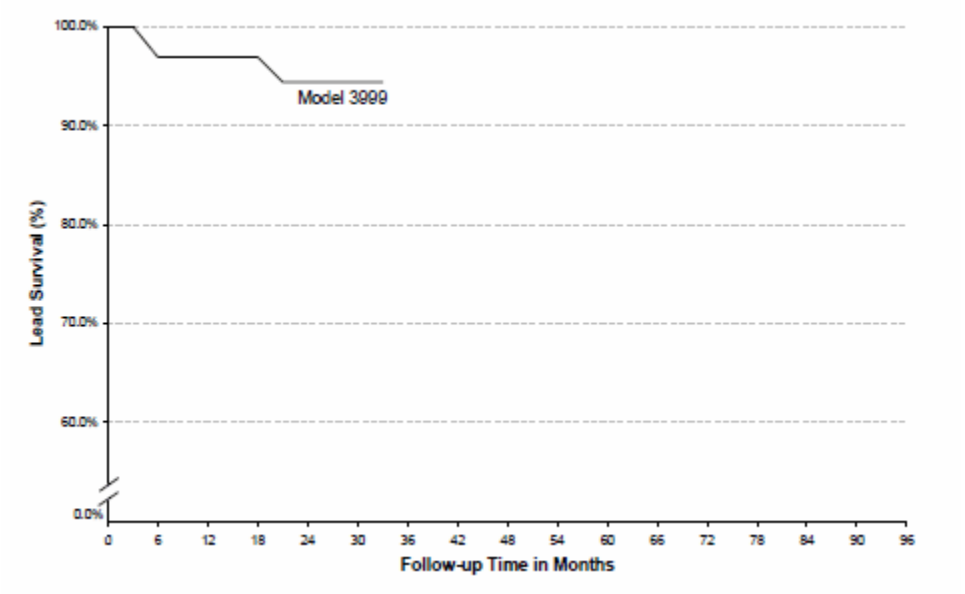
### Model 39565 Specify: Specifications

| 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 |

- Data
- Model Info

### Model 3999 2x4 Hinged: Survival from Lead Events




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

| Lead Characteristics | |
|---|---|
| **Model Name** | 3999 |
| **FDA Approval Date** | Jun 2004 |
| **Leads Enrolled** | 50 |
| **Leads Active in Study** | 6 |
| **Device Events** | 2 |
| **Cumulative Months of Follow-up** | 1,225 |

| Lead Event | Total |
|---|---|
| **Migration/dislodgement** | 2 |
| **Total Lead Events** | **2** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 96.9% | 41 |
| 2 yrs | 94.4% | 34 |
| at 33 mo | 94.4% | 20 |

## 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, lead Models 3888, 3890, and 39565 have statistically significantly better performance than lead Models 3487A and 3777. However, this statistically significant difference is not sustained at 3 years and 4 years of follow-up when compared to all applicable lead Models. Also at 2 years of follow-up, the data indicate that Model 3891 does not perform as well as other lead Models. This significant difference in performance continues at 3 and 4 years when compared to all applicable lead Models. As of February 6, 2008, Medtronic has 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 Name** | **Family** | **FDA Approval Date** | **Leads Enrolled** | **Leads Active in Study** | **Device Events*** | **Cumulative Months of Follow-up** |
| **Percutaneous Leads** | | | | | | |
| **3487A** | **Pisces-Quad** | Aug 1983 | 645 | 322 | 43 | 16,298 |
| **3776** | **Pisces-Octad** | Nov 2005 | 109 | 48 | 5 | 2,179 |
| **3777** | **Pisces-Octad** | Nov 2005 | 529 | 235 | 38 | 11,789 |
| **3778** | **Pisces-Octad** | Nov 2005 | 1,034 | 731 | 50 | 18,792 |
| **3887** | **Pisces-Quad** | Mar 2004 | 163 | 58 | 13 | 5,211 |
| **3888** | **Pisces-Quad** | Nov 1992 | 269 | 186 | 17 | 7,028 |
| **3890** | **Pisces-Quad LZ** | Sep 2002 | 136 | 36 | 6 | 3,518 |
| **3891** | **Pisces-Quad LZ** | Sep 2002 | 151 | 19 | 38 | 3,477 |
| **Surgical Leads** | | | | | | |
| **3986A** | **Resume TL** | Mar 2004 | 67 | 26 | 4 | 1,491 |
| **3998** | **Specify** | Feb 1998 | 124 | 30 | 7 | 3,050 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **3999** | **2 x 4 Hinged Specify** | Jun 2004 | 50 | 6 | 2 | 1,225 |
| **39565** | **Specify** | Jun 2007 | 70 | 48 | 1 | 1,155 |

*There were a total of 227 lead-related events reported to the ISPR, but only 224 events included in this summary table. The remaining 3 lead-related events occurred in lead Models for which no device survival curves are presented due to an insufficient number of enrolled devices.

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

| Model Name | Family | 1 yr | 2 yrs | 3 yrs | 4 yrs | 5 yrs |
|---|---|---|---|---|---|---|
| **Percutaneous Leads** | | | | | | |
| **3487A** | **Pisces-Quad** | **94.1%** (91.6%, 96.5%) | **90.4%** (87.2%, 93.6%) | **90.0%** (86.7%, 93.3%) | **88.8%** (85.2%, 92.5%) | **88.8%** (85.2%, 92.5%) |
| **3776** | **Pisces-Octad** | **96.9%** (93.4%, 100.0%) | **96.9%** (93.4%, 100.0%) | **92.2%** (84.9%, 99.5%) | - | - |
| **3777** | **Pisces-Octad** | **93.7%** (91.3%, 96.0%) | **90.6%** (87.6%, 93.5%) | **90.6%** (87.6%, 93.5%) | **90.6%** (87.6%, 93.5%) | - |
| **3778** | **Pisces-Octad** | **96.0%** (94.7%, 97.3%) | **93.7%** (91.8%, 95.6%) | **92.8%** (90.5%, 95.0%) | **92.8%** (90.5%, 95.0%) | - |
| **3887** | **Pisces-Quad** | **97.1%** (92.9%, 100.0%) | **90.2%** (83.5%, 96.8%) | **85.6%** (77.8%, 93.3%) | **85.6%** (77.8%, 93.3%) | **85.6%** (77.8%, 93.3%) |
| **3888** | **Pisces-Quad** | **98.2%** (96.2%, 100.0%) | **96.8%** (94.0%, 99.6%) | **92.8%** (87.5%, 98.1%) | **91.4%** (85.5%, 97.3%) | **88.1%** (80.8%, 95.4%) |
| **3890** | **Pisces-Quad LZ** | **100.0%** NA | **97.4%** (93.8%, 100.0%) | **95.0%** (90.1%, 99.9%) | **91.1%** (83.9%, 98.2%) | - |
| **3891** | **Pisces-Quad LZ** | **78.5%** (71.0%, 86.1%) | **75.0%** (67.0%, 83.1%) | **65.3%** (55.5%, 75.1%) | **65.3%** (55.5%, 75.1%) | - |
| **Surgical Leads** | | | | | | |
| **3986A** | **Resume TL** | **93.9%** (87.0%, 100.0%) | **93.9%** (87.0%, 100.0%) | - | - | - |
| **3998** | **Specify** | **96.3%** (92.0%, 100.0%) | **93.1%** (87.1%, 99.1%) | **89.0%** (80.9%, 97.1%) | - | - |
| **3999** | **2 x 4 Hinged Specify** | **96.9%** (90.9%, 100.0%) | **94.4%** (86.7%, 100.0%) | - | - | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| **39565** | **Specify** | **98.4%** (95.1%, 100.0%) | **98.4%** (95.1%, 100.0%) | - | - | - |

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

| Model Name | Family | 6 yrs | 7 yrs | 8 yrs | 9 yrs |
|---|---|---|---|---|---|
| **Percutaneous Leads** | | | | | |
| **3487A** | **Pisces-Quad** | **86.6%** (81.9%, 91.3%) | **82.5%** (76.0%, 89.0%) | **82.5%** (76.0%, 89.0%) | **82.5%** (76.0%, 89.0%) |
| **3776** | **Pisces-Octad** | - | - | - | - |
| **3777** | **Pisces-Octad** | - | - | - | - |
| **3778** | **Pisces-Octad** | - | - | - | - |
| **3887** | **Pisces-Quad** | **82.3%** (72.4%, 92.1%) | - | - | - |
| **3888** | **Pisces-Quad** | **79.4%** (68.7%, 90.0%) | - | - | - |
| **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 April 9, 2010, there were 2,277 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=2,071) 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-two percent (32%) of the extensions were Model 7489 extensions, 32% were Model 37081 extensions, 17% were Model 37082 extensions, 8% were Model 37083 extensions, 6% were Model 7495 extensions, 4% were Model 7495LZ extensions, 1% were Model 7471 extensions, and <1% were Model 7496 and other extensions. Total prospective follow-up time for all extensions was 56,281 months (4,690 years).

## Extension Events

A surgical intervention was required for 13 extensions with an underlying reported extension etiology. These 13 events included 10 related to an extension fracture and 3 related to extension failure that the physician assigned as extension-related.

There were an additional 929 extensions censored in the analysis due to patient lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), extensions explanted, patient expired, therapy abandoned, or other surgical intervention attributed to an event unrelated to the extension.

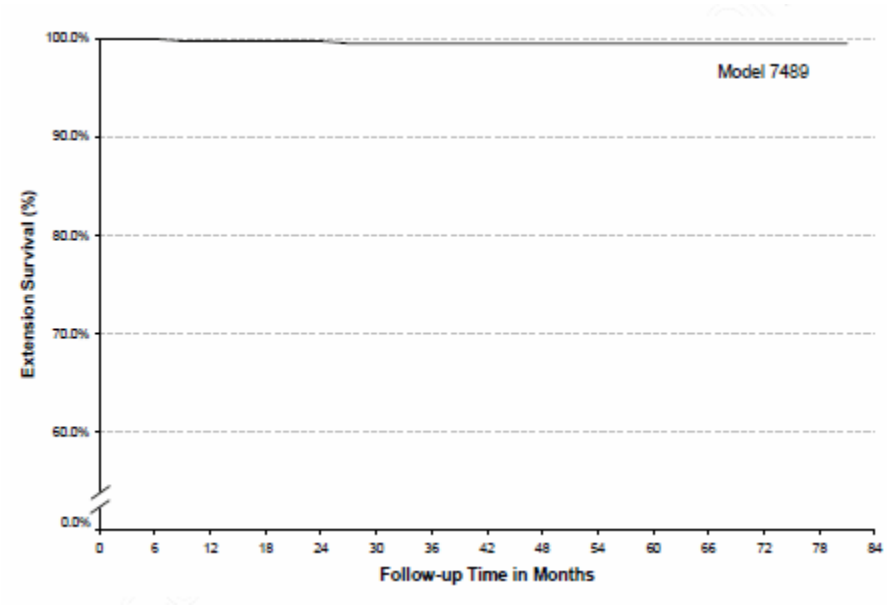
## Extension Survival Curves

The figures and tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each interval. Currently, at 3 years of follow-up, the 95% confidence intervals for the 7489, 37081, 37082, and 37083 extensions overlap, indicating that survival from extension-related events is not significantly different between these extension Models at 3 years.

Choose a model Go

- Data
- Model Info

### Model 7489 Extension Family: Survival from Extension Events




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

| Extension Characteristics | |
|---|---|
| **Model Number** | 7489 |
| **FDA Approval Date** | Oct 2002 |
| **Extensions Enrolled** | 734 |

| | |
|---|---|
| **Extensions Active in Study** | 151 |
| **Device Events** | 2 |
| **Cumulative Months of Follow-up** | 20,900 |

| Extension Event | Total |
|---|---|
| **Extension failure** | 1 |
| **Fracture** | 1 |
| **Total Extension Events** | **2** |

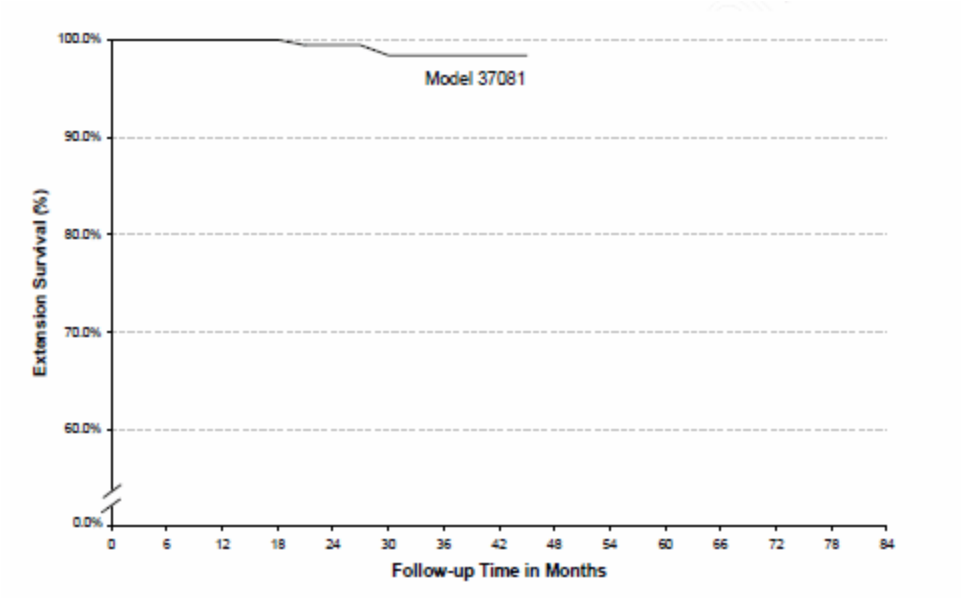
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.8% | 483 |
| 2 yrs | 99.8% | 446 |
| 3 yrs | 99.5% | 331 |
| 4 yrs | 99.5% | 218 |
| 5 yrs | 99.5% | 105 |
| 6 yrs | 99.5% | 34 |
| at 81 mo | 99.5% | 21 |

## 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 |

- Data
- Model Info

## Model 37081 Extension Family: Survival from Extension Events




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

| Extension Characteristics | |
|---|---|
| **Model Number** | 37081 |
| **FDA Approval Date** | Apr 2005 |
| **Extensions Enrolled** | 730 |
| **Extensions Active in Study** | 426 |
| **Device Events** | 4 |
| **Cumulative Months of Follow-up** | 14,626 |

| Extension Event | Total |
|---|---|
| **Fracture** | 4 |
| **Total Exension Events** | **4** |

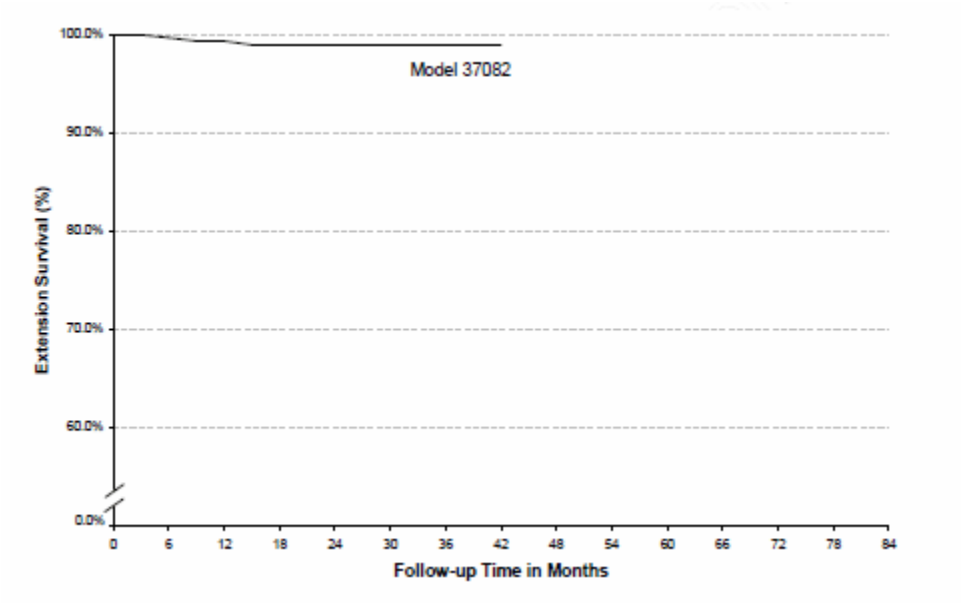
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 100.0% | 523 |
| 2 yrs | 99.4% | 291 |
| 3 yrs | 98.4% | 116 |
| at 45 mo | 98.4% | 35 |

## 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 |

- Data
- Model Info

### Model 37082 Extension Family: Survival from Extension Events




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

| Extension Characteristics | |
|---|---|
| **Model Number** | 37082 |
| **FDA Approval Date** | Mar 2006 |
| **Extensions Enrolled** | 397 |
| **Extensions Active in Study** | 226 |
| **Device Events** | 3 |
| **Cumulative Months of Follow-up** | 7,761 |

| Extension Event | Total |
|---|---|
| **Extension failure** | 1 |

| | |
|---|---|
| **Fracture** | 2 |
| **Total Extension Events** | **3** |

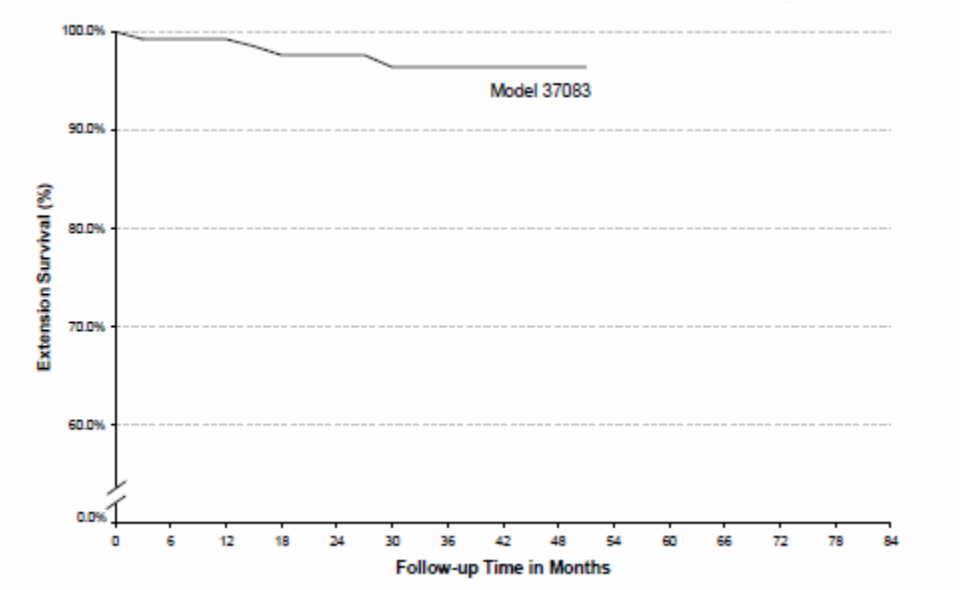
| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.4% | 279 |
| 2 yrs | 99.0% | 162 |
| 3 yrs | 99.0% | 65 |
| at 42 mo | 99.0% | 27 |

### 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 |

- Data
- Model Info

### Model 37083 Extension Family: Survival from Extension Events




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

| Extension Characteristics | |
|---|---|
| **Model Number** | 37083 |
| **FDA Approval Date** | Sep 2005 |
| **Extensions Enrolled** | 178 |
| **Extensions Active in Study** | 93 |
| **Device Events** | 4 |
| **Cumulative Months of Follow-up** | 4,521 |

| Extension Event | Total |
|---|---|
| **Extension failure** | 1 |
| **Fracture** | 3 |
| **Total Extension Events** | **4** |

| Time Interval | Survival | Effective Sample Size |
|---|---|---|
| 1 yr | 99.3% | 138 |
| 2 yrs | 97.6% | 88 |
| 3 yrs | 96.4% | 66 |
| 4 yrs | 96.4% | 30 |
| at 51 mo | 96.4% | 21 |

## 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** | **Family** | **FDA Approval** | **Extensions** | **Extensions Active in** | **Device** | **Cumulative Months of** |

| Number | | Date | Enrolled | Study | Events | Follow-up |
|---|---|---|---|---|---|---|
| **7489** | 7489 | Oct 2002 | 734 | 151 | 2 | 20,900 |
| **37081** | 37081 | Apr 2005 | 730 | 426 | 4 | 14,626 |
| **37082** | 37082 | Mar 2006 | 397 | 226 | 3 | 7,761 |
| **37083** | 37083 | Sep 2005 | 178 | 93 | 4 | 4,521 |

| Device Survival Probability (95% Confidence Intervals) | | | | | | |
|---|---|---|---|---|---|---|
| **Model Number** | **1 yr** | **2 yrs** | **3 yrs** | **4 yrs** | **5 yrs** | **6 yrs** |
| **7489** | **99.8%** (99.3%, 100.0%) | **99.8%** (99.3%, 100.0%) | **99.5%** (98.9%, 100.0%) | **99.5%** (98.9%, 100.0%) | **99.5%** (98.9%, 100.0%) | **99.5%** (98.9%, 100.0%) |
| **37081** | **100.0%** NA | **99.4%** (98.7%, 100.0%) | **98.4%** (96.8%, 100.0%) | **-** | - | - |
| **37082** | **99.4%** (98.5%, 100.0%) | **99.0%** (97.8%, 100.0%) | **99.0%** (97.8%, 100.0%) | **-** | - | - |
| **37083** | **99.3%** (97.8%, 100.0%) | **97.6%** (94.9%, 100.0%) | **96.4%** (92.8%, 100.0%) | **96.4%** (92.8%, 100.0%) | - | - |

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