Overview: Introduction

About Neuromodulation Product Performance

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 2009 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 date of initiation into the ISPR for these systems was 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 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 decreases the dose requirements and side effects that may occur with systemic administration of the same drugs.

Medtronic 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, gastric 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 and improvements in our reporting system.

The ISPR has collected data from 50 centers for intrathecal drug delivery systems and 42 centers for spinal cord stimulation systems across the United States. 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 agreed to sign 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. Any detection methods used to determine patient or device outcomes were also obtained. 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.

Overview: Commitment to Quality

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 2nd Annual Medtronic Spinal Cord Stimulation and Intrathecal Drug Delivery Systems Product Performance Report.

We are proud of our pioneering history at Medtronic and we realize the responsibility that comes with driving innovation in technology. As the first and only company to offer a full line of Spinal Cord Stimulation and Intrathecal Drug Delivery Systems therapies, we believe that performance reporting is even more important. We strive for better performance with every new product we develop. This report shows the evolution of product performance over time and also reveals advances in therapies that come with this experience and knowledge. Through this sharing of information we can ensure that physicians are able to best leverage state of the art therapy delivery and also understand the performance of our devices to best manage patients. We also invite feedback to help drive continuous improvement.

Included in this report are product survival estimates for our commercially available implantable products used in the management of intractable non-malignant pain, malignant pain and spasticity. These data are based on the tracking of over 5,100 patients in an ongoing surveillance study conducted in the United States called the Implantable Systems Performance Registry (ISPR). The Registry now includes nearly 13,000 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 2009 Product Performance Report includes the addition of product data for the 8709SC and 8731SC catheter models, RestoreUltra neurostimulator, and the 39565 lead model.

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 at this time because these products were not included in the ISPR during this time period. 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.

Overview: Contact Information

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 Christine Boes, BS
MAIL STOP: RCE 375
7000 CENTRAL AVENUE NE
MINNEAPOLIS, MN 55432

Editorial Staff

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Methodology: Event Classification

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:

- Pump related
- Catheter related
- Spinal cord stimulator related
- Lead related
- Extension related

AND one of the following:

Condition Two:

- Device explanted/replaced
- Device explanted/not replaced
- Other surgical intervention
- Therapy abandoned
- 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. These are not considered to be product performance events and are therefore censored in the analysis.

- **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:

- Lumbar site related
- Pump pocket/access related
- Spinal cord stimulator pocket related
- Lead tract related
- Extension tract related
- Therapy/patient effects
- Elective action
- Intraspinal drug overdose / underdose

AND one of the following:

Condition Two:

- Device explanted/replaced
- Device explanted/not replaced
- Other surgical intervention
- Therapy abandoned
- 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 (eg, 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

Methodology: **Device Survival Analyses**

Device Survival Estimates

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

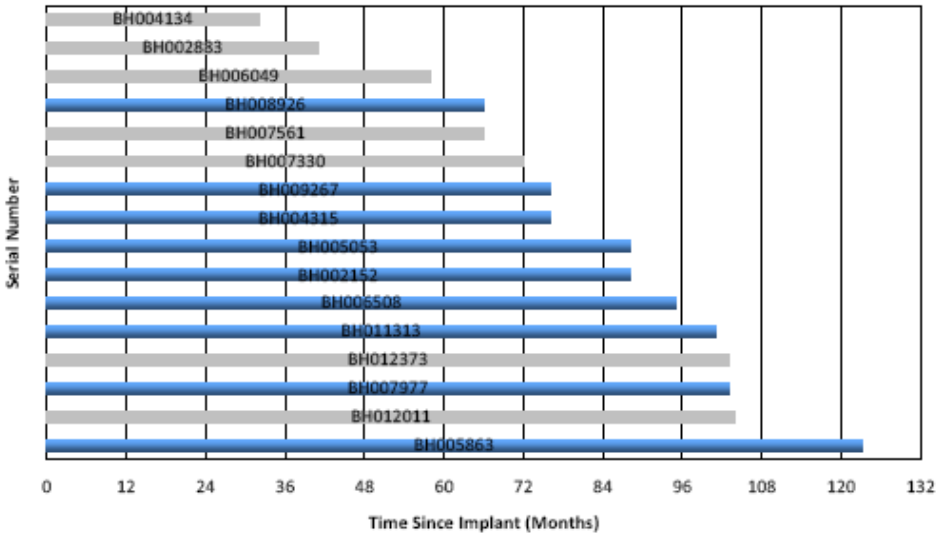
[1] Lee, Elisa T. (2003) Statistical Methods for Survival Data Analysis – 3rd Edition (Wiley Series in Probability and Statistics)

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 (serial number BH004134) operated for 32 months. At that time a product performance related event occurred. The fourth patient's device (serial number BH008926) 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 (gray bars), and 9 devices (blue bars) are censored.

Figure 1. *Implant times for an individual device in 16 patients. Gray bars indicate devices removed from service due to a product performance event. Blue 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, device BH004134 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 (device BH002883). For the 48-60 month interval, 14 devices entered the interval and 1 was removed for a product performance event (device BH006049). 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% =

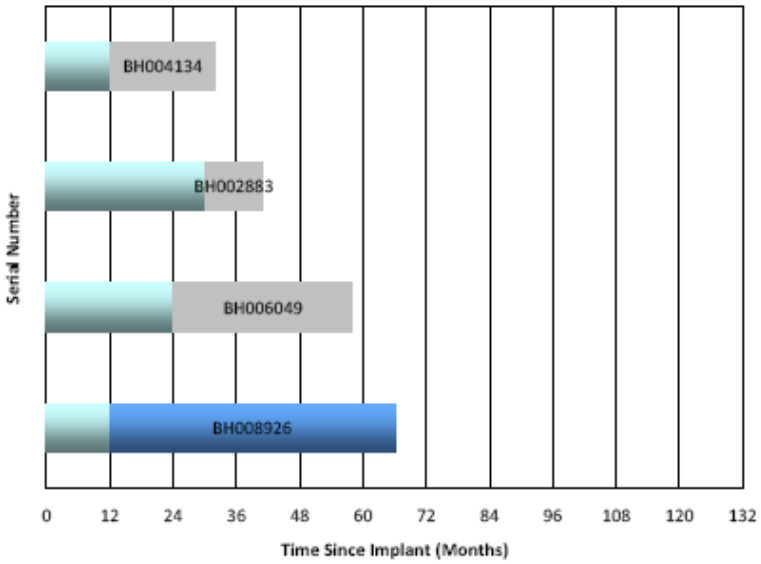
81% cumulative device survival at 5 years.

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 over-estimate the sample size because the censored devices do not complete the interval. Completely ignoring the censored devices in the interval would under-estimate the sample size because censored devices would not be credited with their full service time. Using one half the number of censored devices effectively splits the difference. Expanding the example above to determine a 72 month, or 6-year device survival estimate, involves a censored device and adjusting the effective sample size. For the 60-72 month interval, 13 devices entered the interval and 1 was right censored (device BH008926) and 1 was removed for a product performance event (device BH 007561). 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. Green bars represent the time from implant to enrollment in the ISPR, or the time interval that is left censored. Blue bars represent the time since enrollment into the ISPR, or the time interval when active surveillance occurred. Gray bars indicate devices removed from service due to a product performance event.*



For example, the first patient's device (serial number BH004134) 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.

[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.

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. Confidence intervals for 1-year device survival estimates 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.

Methodology: **Returned Product Analysis (RPA)**

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 identify 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

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 October 24, 2008. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

Subjects

As the table below demonstrates, there were 3,786 total intrathecal drug delivery system patients enrolled in the ISPR through October 24, 2008. The table lists 3 primary indications with corresponding sub-indications as reported by the physician at implant. Fifty-three percent of patients were implanted with an intrathecal drug delivery system for treatment of non-malignant pain, followed by 29.3% for treatment of intractable spasticity, and 17.7% for treatment of malignant pain.

Primary Intrathecal Drug Delivery System Treatment Indications

Primary Treatment Indication*	Total Enrolled Patients (N=3,786)
Nonmalignant Pain	**2,006 (53.0%)**
Failed Back Syndrome	1,052
Joint Pain/Arthritis	44
Osteoporosis	30
Peripheral Neuropathy	54
Post-Herpetic Neuralgia	8
RSD/Causalgia (CRPS)†	81
Other and/or Unspecified	767
Intractable Spasticity	**1,111 (29.3%)**
Brain Injury	96
Cerebral Palsy	326
Multiple Sclerosis	309
Spinal Cord Injury/Disease	146

Stroke	36
Other and/or Unspecified	223
Malignant Pain	**669 (17.7%)**
Abdominal/Visceral	79
Extremity	34
Head/Neck	27
Pelvic	62
Spine/Back	106
Thoracic	46
Other and/or Unspecified	338
Total Patients	**3,786**

*Refer to product labeling for approved indications. Primary treatment indication information is obtained through the Medtronic Device Registration System.
†RSD is reflex sympathetic dystrophy. CRPS is complex regional pain syndrome.

Intrathecal Drug Delivery Systems: Events Summary

Events Summary

Product Performance Related Events

There were 1,982 events reported between August 2003 and October 24, 2008 in patients with intrathecal drug delivery systems. Fourteen percent of these events (274/1,982) were related to the pump or catheter, categorized as product performance related events and are presented graphically within this report.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Pump Related Events:		
Drug Related Cracked Pump Tube	3	47.1 (46.2) ±8.0
Motor Stall	24	38.2 (36.6) ±16.0
No Infusion	2	37.6 (37.6) ±11.5
Unable to Interrogate/Program	1	0.7 (0.7) ±NA

Underinfusion*	8	37.0 (33.9) ±16.6
Pump Related Events Sub-Total	**38**	**37.6 (35.5) ±16.2**
Catheter Related Events:		
Break/Cut	45	28.5 (17.7) ±30.4
Disconnection	20	24.4 (23.2) ±21.8
Dislodgement	56	12.9 (4.8) ±19.6
Kink/Occlusion	89	32.9 (22.9) ±31.1
Loss of effect†	5	15.1 (11.9) ±14.3
Pump Connector Break/Cut	10	47.3 (54.8) ±20.5
Puncture	7	42.0 (40.3) ±36.0
Sheared Catheter Tip	3	73.3 (86.9) ±41.0
Unknown	1	1.7 (1.7) ±NA
Catheter Related Events Sub-Total	**236**	**27.6 (14.4) ±29.2**
Product Performance Related Events Total	**274**	**29.0 (22.7) ±27.9**

* Patient 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 (1,013/1,982) were due to the patient expiring or becoming lost to follow-up (eg, patient moved, transferred care to another provider, study withdrawal). No deaths were reported as a result of a device related event or the delivery of infusion therapy.Twenty percent of the total events (401/1,982) were related to the surgery or procedure (n=173), or attributed to the patient or delivery of the therapy (n=228). Fifteen percent of the events (294/1,982) were related to normal battery depletion.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Surgical/Procedural Related Events:		
Lumbar Site Related		
External CSF leak	7	11.7 (1.3) ±25.8
Fluid collection	1	3.3 (3.3) ±NA
Infection	11	8.9 (2.4) ±13.9
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	4.8 (6.4) ±3.4
Lumbar Site Related Sub-Total	**25**	**11.7 (2.9) ±20.1**
Pump Pocket / Pump Access Related		
Fluid collection	2	13.9 (13.9) ±18.0
Hematoma	3	28.7 (25.8) ±29.8
Infection	60	6.4 (2.9) ±11.6
Inflammation	3	1.8 (1.6) ±1.8
Inversion	28	8.6 (6.3) ±8.8
Migration	8	17.3 (11.3) ±13.7
Pain at pump site	7	23.8 (13.4) ±21.6
Pump pocket irregularity	1	32.7 (32.7) ±NA
Pump site incision not healing	3	5.2 (4.1) ±3.3
Seroma	1	4.2 (4.2) ±NA
Skin erosion	12	23.7 (13.3) ±25.0
Trial catheter revision	2	0.2 (0.2) ±NA*
Unable to fill/refill reservoir	2	19.7 (19.7) ±16.9
Undesirable interaction with other equipment	1	7.8 (7.8) ±NA
Wound dehiscence	15	13.0 (4.1) ±20.5
Pump Pocket Related Sub-Total	**148**	**11.1 (5.2) ±15.8**
Surgical/Procedural Related Events Sub-Total	**173**	**11.2 (4.9) ±16.4**
Therapy/Patient Related Events:		
Elective Action		
Elective action†	84	34.1 (30.2) ±25.3
Elective Action Related Sub-Total	**84**	**34.1 (30.2) ±25.3**
Intraspinal Drug Overdose or Underdose‡		
Catheter kink/occlusion	1	0.2 (0.2) ±NA
Pump underinfusion	1	41.8 (41.8) ±NA
Intraspinal Drug Related Sub-Total	**2**	**21.0 (21.0) ±29.4**
Therapy/Patient Effects		
Allergic reaction/sensitivity to drug	3	8.6 (9.3) ±1.3
Catheter tip fibrosis	1	23.2 (23.2) ±NA

Catheter too short	1	1.1 (1.1) ±NA
Corrective surgery[§]	2	27.9 (27.9) ±1.5
Device damaged due to unrelated surgery	4	26.5 (17.2) ±29.7
Dissatisfaction with feeling of the pump	1	1.9 (1.9) ±NA
Drug side effects/toxicity	13	18.6 (10.6) ±19.0
Drug withdrawal	3	31.2 (34.8) ±25.1
Frequent refill intervals[‖]	1	33.3 (33.3) ±NA
Inability to aspirate/painful aspiration	2	6.1 (6.1) ±1.6
Infection	9	15.9 (2.1) ±33.5
Inflammatory mass (definite or probable)[¶]	5	24.5 (25.1) ±14.3
Inflammatory mass (possible)**	5	47.0 (47.1) ±29.7
Loss of effect	37	20.7 (13.1) ±19.4
Malpositioned	4	4.0 (2.1) ±5.0
Myelitis	1	29.2 (29.2) ±NA
No anomaly found by RPA[††]	7	36.6 (44.3) ±20.3
Numbness/weakness in legs	2	32.1 (32.1) ±7.1
Pain/irritation	4	11.0 (2.5) ±17.8
Patient effects[‡‡]	1	49.9 (49.9) ±NA
Patient non-compliance[§§]	4	32.3 (28.7) ±18.8
Psychological issue	3	8.5 (7.0) ±4.4
Reservoir septum damage (user-related/ancillary damage)	1	28.5 (28.5) ±NA
Resolution of symptoms[‖ ‖]	13	32.7 (34.5) ±18.0
Therapy didn't meet patient's expectations	6	23.1 (22.0) ±7.7
Undesirable interaction with other equipment	6	8.2 (3.6) ±9.3
Unrelated surgery	1	16.7 (16.7) ±NA
Unspecified	1	44.3 (44.3) ±NA
Wound dehiscence[¶¶]	1	17.7 (17.7) ±NA
Therapy/Patient Effects Related Sub-Total	**142**	**22.5 (16.7) ±20.5**
Therapy/Patient Related Events Sub-Total	**228**	**26.7 (22.1) ±23.0**
Patient Related Events:* **		

Patient Expired†††	619	14.9 (6.4) ±18.6
Patient lost to follow-up	394	23.0 (17.6) ±20.1
Patient Related Events Sub-Total	**1,013**	**18.1 (10.3) ±19.6**
Normal Battery Depletion Events:		
Battery Depletion	294	63.9 (63.7) ±12.9
Battery Depletion Events Sub-Total	**294**	**63.9 (63.7) ±12.9**
Non-Product Performance Related Events Total	**1,708**	**26.4 (16.6) ±25.7**

* Trial catheter revision mean calculation excludes an extreme observation (ie, 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 (eg, 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.
** 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 non-compliant 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.
††† Seventy-one percent of patient deaths occurred in patients with a primary indication of malignant pain.

Pumps

From August 2003 to the report cut-off date of October 24, 2008, 4,214 pumps were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=3,786) versus pumps were due to the fact that some patients were subsequently re-implanted with a pump 1, 2, or more times.

Most of the pumps enrolled were either SynchroMed EL (30.7%) or SynchroMed II (69.2%), and a small number of pumps were SynchroMed Classic (0.2%). The majority of SynchroMed II pumps were new pumps (2,463/2,914, 84.5%), whereas the majority of SynchroMed EL pumps were existing pumps (1,112/1,293, 86.0%). Total prospective follow-up time for pumps was 93,304 pump months.

Pump Events

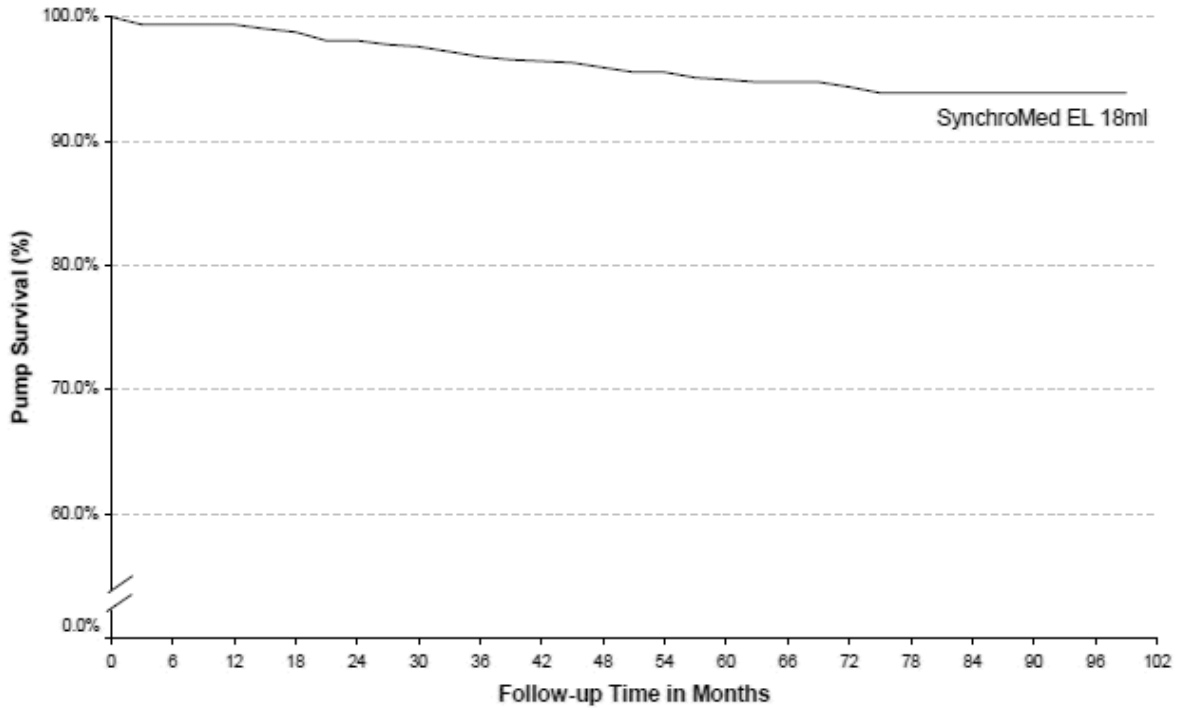
There were 38 pumps that experienced an event requiring surgical intervention with an underlying reported pump etiology related to pump function. For pumps enrolled in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 257/1,214 (21%). The proportion was based upon the number of pumps received by RPA, divided by the total number of explanted devices plus the total number of pumps in patients who have expired. Twenty-seven of the 38 pump events were analyzed by Medtronic RPA: 24 pumps failed related to motor stalls and 3 pumps had cracked pump tubes. The remaining 11 pump events were based upon physician report only (pumps were not returned to Medtronic) and included: 8 events related to pump underinfusion, 2 events related to no pump infusion, and 1 event related to the inability to interrogate the pump.

There were an additional 1,646 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 121 explanted due to normal battery depletion that were subsequently returned to RPA, 5 were recoded as product performance events based on RPA findings. No deaths were reported among patients followed in the ISPR as a result of a product performance related event or the delivery of 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 4 years of follow-up, the 95% confidence intervals for the SynchroMed EL and SynchroMed II 40 ml pumps do not overlap, indicating that survival from pump related events is significantly different between these pump models. Medtronic chose to voluntarily discontinue the SynchroMed EL pump in August 2007 in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact that the SynchroMed II pump offers additional performance features beyond those available in the SynchroMed EL pump.

Model 8627-18 SynchroMed EL 18ml: Survival from Pump Events



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

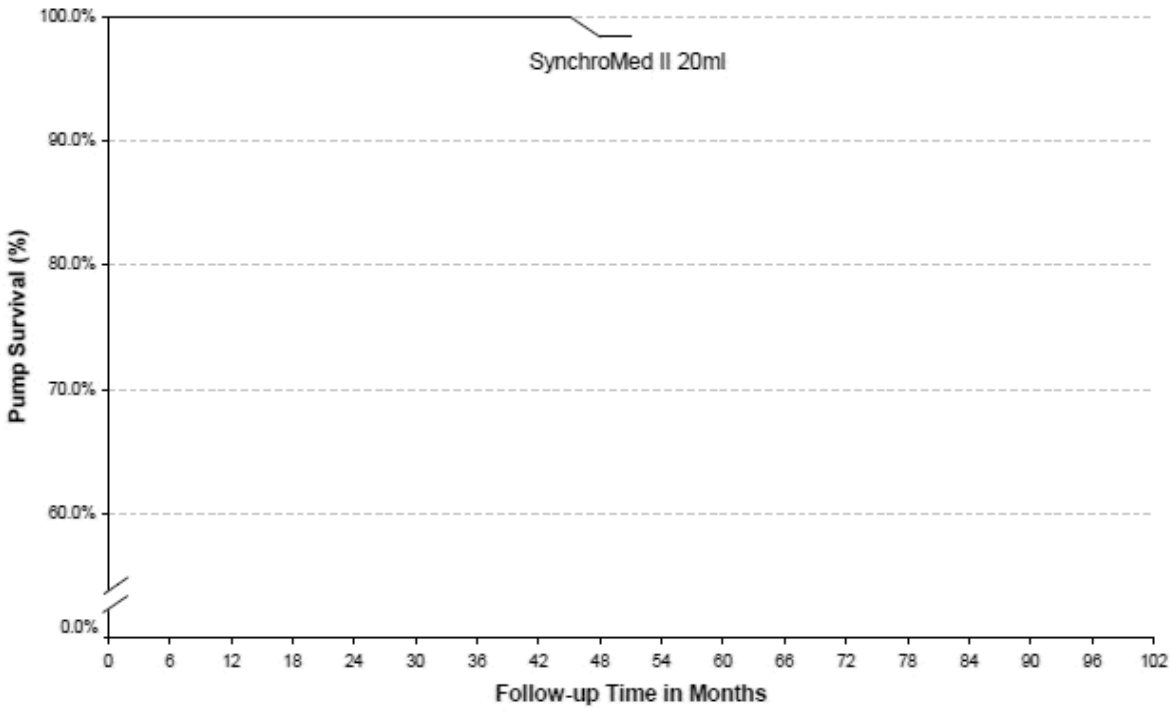
Note: As of August 2007, Medtronic voluntarily discontinued the SynchroMed EL pump in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact

that the SynchroMed II pump offers additional performance features beyond those available in the SynchroMed EL

Pump Characteristics					
Model Name	**FDA Approval Date**	**Pumps Enrolled**	**Pumps Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
SynchroMed EL (18 mL)	Mar 1999	1,260	499	32	39,340

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs	at 99 mo
Survival	99.4%	98.1%	96.8%	95.9%	94.9%	94.4%	93.9%	93.9%	93.9%
Effective Sample Size	259	508	740	767	568	247	90	32	24

Model 8637-20 SynchroMed II 20ml: Survival from Pump Events

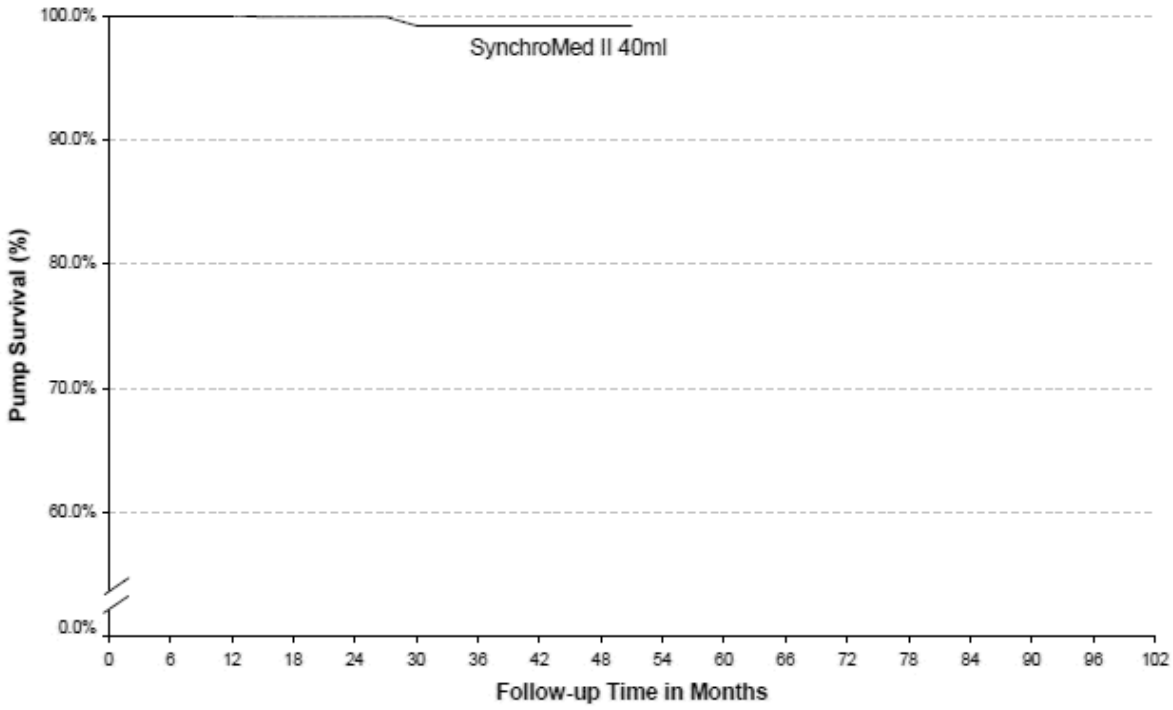


Data are shown if there are at least 20 devices in each 3 month interval.

Pump Characteristics					
Model Name	**FDA Approval Date**	**Pumps Enrolled**	**Pumps Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
SynchroMed II (20 mL)	Sep 2003	1,111	894	1	22,699

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	at 51 mo
Survival	100.0%	100.0%	100.0%	98.3%	98.3%
Effective Sample Size	768	516	229	60	29

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	**FDA Approval Date**	**Pumps Enrolled**	**Pumps Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
SynchroMed II (40 mL)	Sep 2003	1,803	1,174	4	30,120

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	at 51 mo
Survival	100.0%	99.9%	99.2%	99.2%	99.2%
Effective Sample Size	1,038	604	281	67	30

Pump Survival Summary

Pump Survival Summary Table

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	1,260	499	32	39,340
SynchroMed II (20 mL)	SynchroMed II	Sep 2003	1,111	894	1	22,699
SynchroMed II (40 mL)	SynchroMed II	Sep 2003	1,803	1,174	4	30,120

*There were a total of 38 pump related events reported to the ISPR, but only 37 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)								
Model Name	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**7 yrs**	**8 yrs**
SynchroMed EL (18 mL)	**99.4%** (98.2%, 100.0%)	**98.1%** (96.4%, 99.8%)	**96.8%** (94.9%, 98.7%)	**95.9%** (94.0%, 97.9%)	**94.9%** (92.9%, 97.0%)	**94.4%** (92.1%, 96.6%)	**93.9%** (91.5%, 96.3%)	**93.9%** (91.5%, 96.3%)
SynchroMed II (20 mL)	**100.0%** NA	**100.0%** NA	**100.0%** NA	**98.3%** (95.0%, 100.0%)	-	-	-	-
SynchroMed II (40 mL)	**100.0%** NA	**99.9%** (99.7%, 100.0%)	**99.2%** (98.3%, 100.0%)	**99.2%** (98.3%, 100.0%)	-	-	-	-

Intrathecal Drug Delivery Systems: Catheters

Catheters

From August 2003 to the report cut-off date of October 24, 2008, 3,991 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=4,214) 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 Registration System (DRS). Furthermore, the ISPR did not collect information for non-registered catheters for existing patients. Total prospective follow-up time for catheters was 93,374 catheter months.

A total of 37.5% of the catheters were Model 8709AA catheters, 16.4% were Model 8709 catheters, 13.0% were Model 8731 catheters, 12.0% were Model 8711 catheters, 5.4% were Model 8709SC catheters, 4.4% were Model 8703W catheters, 1.0% were Model 8731SC catheters, and 0.9% were other or unspecified catheters. An additional 2.7% were considered catheters revised as designed, (8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); 3.8% were considered catheters revised not as designed (Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit catheters); 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

There were 236 catheters with events that required surgical intervention with an underlying reported etiology related to the catheter. Of these events, 89 were related to a kink or occlusion, 56 were related to dislodgement, 45 were related to a break or cut in the catheter, 20 were related to catheter disconnection, 10 were related to pump connector break/cut, 7 were related to catheter puncture, 5 were related to loss of therapeutic effect, 3 were related to sheared catheter tip, and 1 was unknown.

An additional 1,300 catheters were censored in the analysis due to patient expired, patient lost to follow-up (eg, 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.

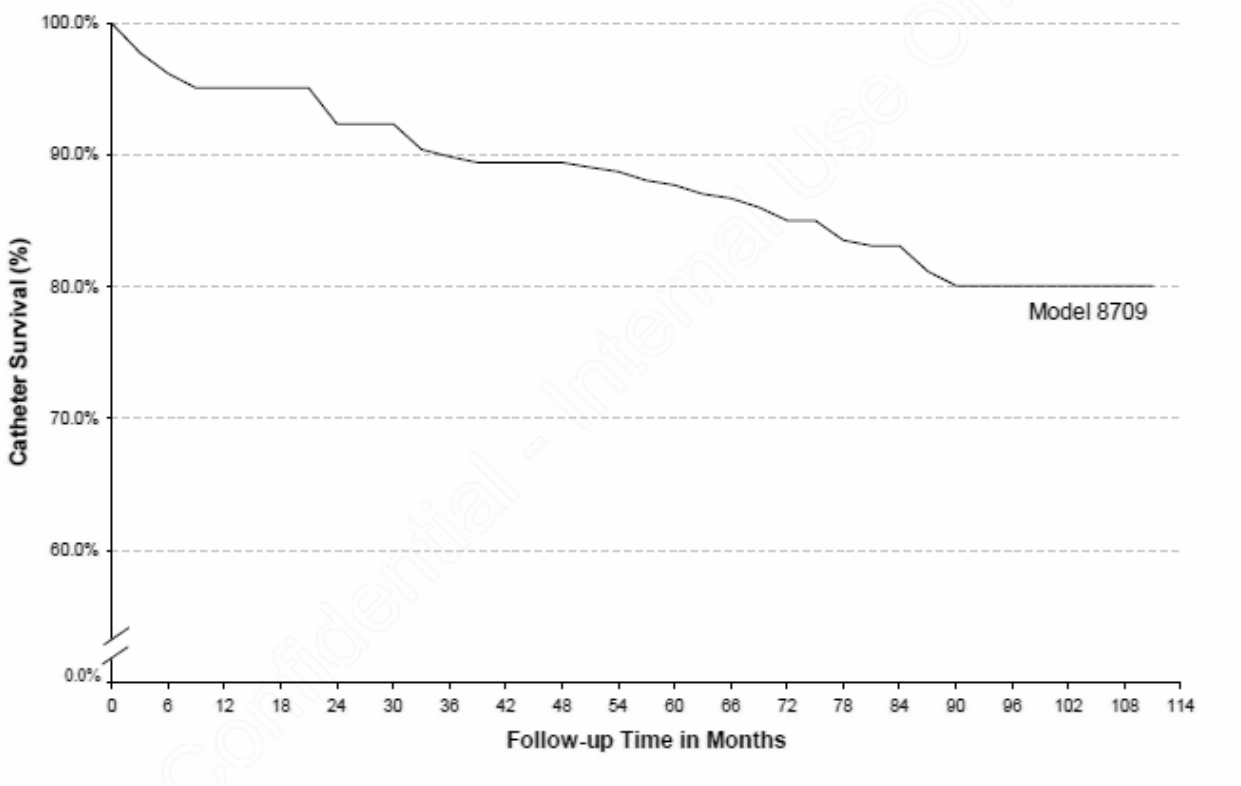
Catheter Survival Curves

The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each interval. At 2 and 3 years of follow-up, the 95% confidence intervals for models 8709, 8709AA, 8711, 8731, revised as designed, revised not as designed, and grafted not as designed catheters overlap, indicating that survival from catheter related events is not statistically significantly different between these catheter models. The sample size for Models 8709SC and 8731SC catheters is not sufficient to report survival at 2 or 3 years of follow-up.

Similarly, these data indicate at 4 years of follow-up, the 95% confidence intervals for Models 8709, 8709AA, 8711, 8731, and revised by design catheters overlap, indicating that survival from catheter related events are not statistically significantly different between these 4 catheter models. The sample size for Models 8709SC and 8731SC, revised not as designed, and grafted not as designed catheters is not sufficient to report survival at 4 years of follow-up.

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 catheters) 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 at 1 and 2 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 non-statistical explanations may include device-related causes and/or system troubleshooting errors. Medtronic catheter repair kits and 2-piece catheters include specially designed connector pins and strain relief sleeves to splice the catheter segments together. Catheters grafted not as designed, by definition, involve the ad-hoc assembly of components other than a Medtronic repair kit or brand new catheter. 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.

Model 8709: Survival from Catheter Events

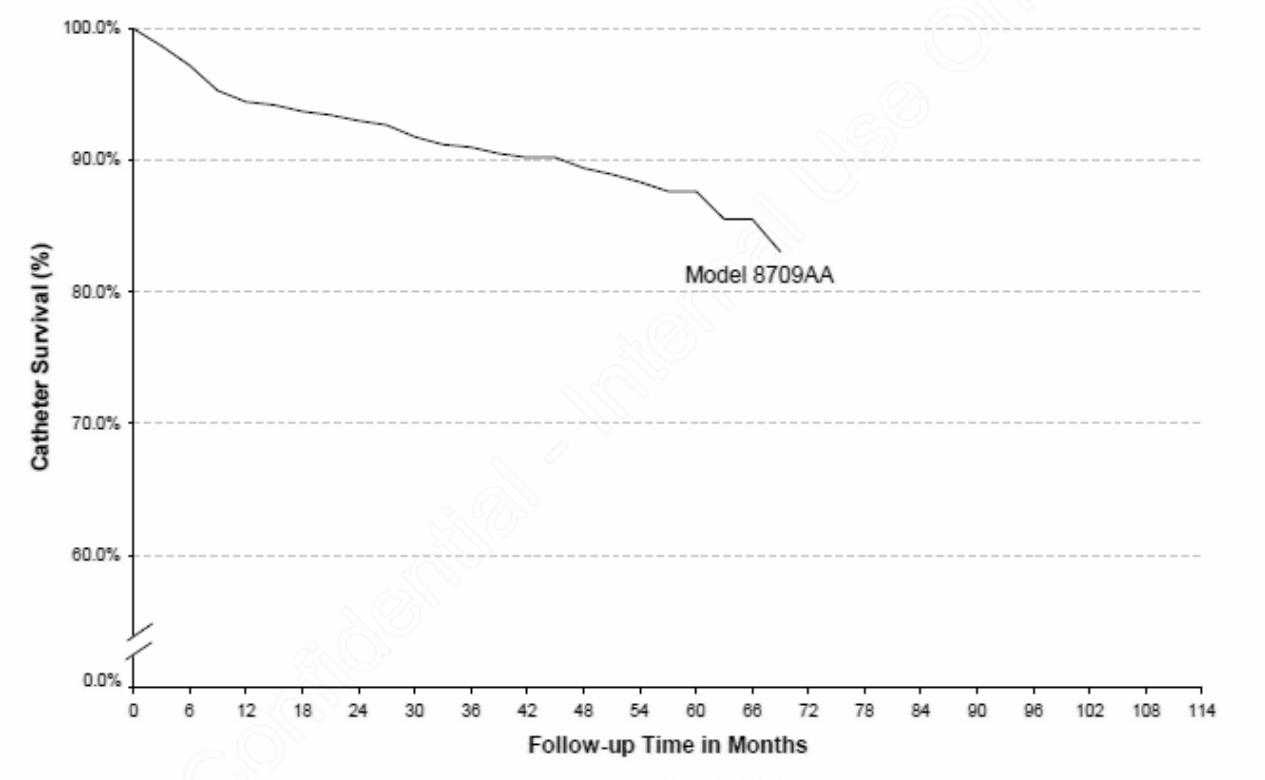


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8709	May 1998	655	498	39	17,862

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs	9 yrs	at 111 mo
Survival	95.1%	92.4%	89.9%	89.4%	87.7%	85.0%	83.1%	80.1%	80.1%	80.1%
Effective Sample Size	62	105	165	243	263	258	188	104	45	20

Model 8709AA: Survival from Catheter Events

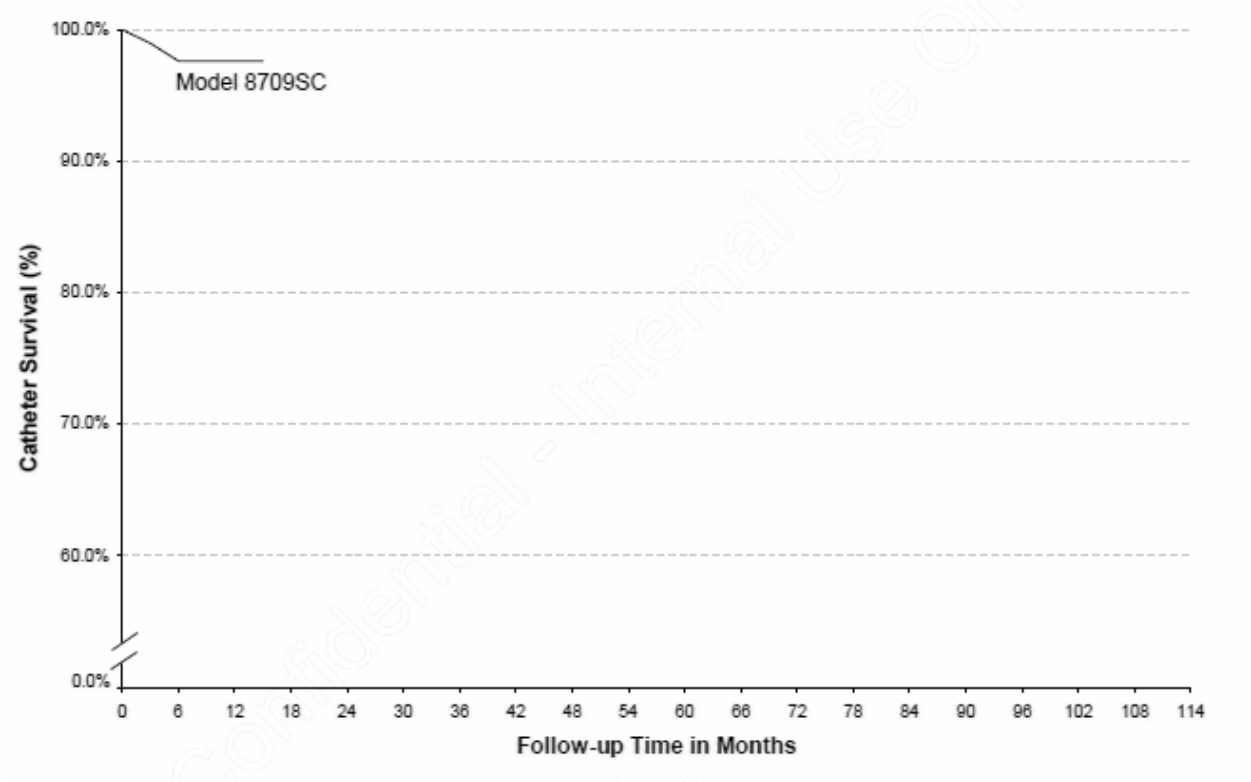


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8709AA	Jun 2001	1,496	870	81	30,566

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 69 mo
Survival	94.4%	93.0%	91.0%	89.4%	87.6%	83.1%
Effective Sample Size	794	637	428	223	103	34

Model 8709SC: Survival from Catheter Events

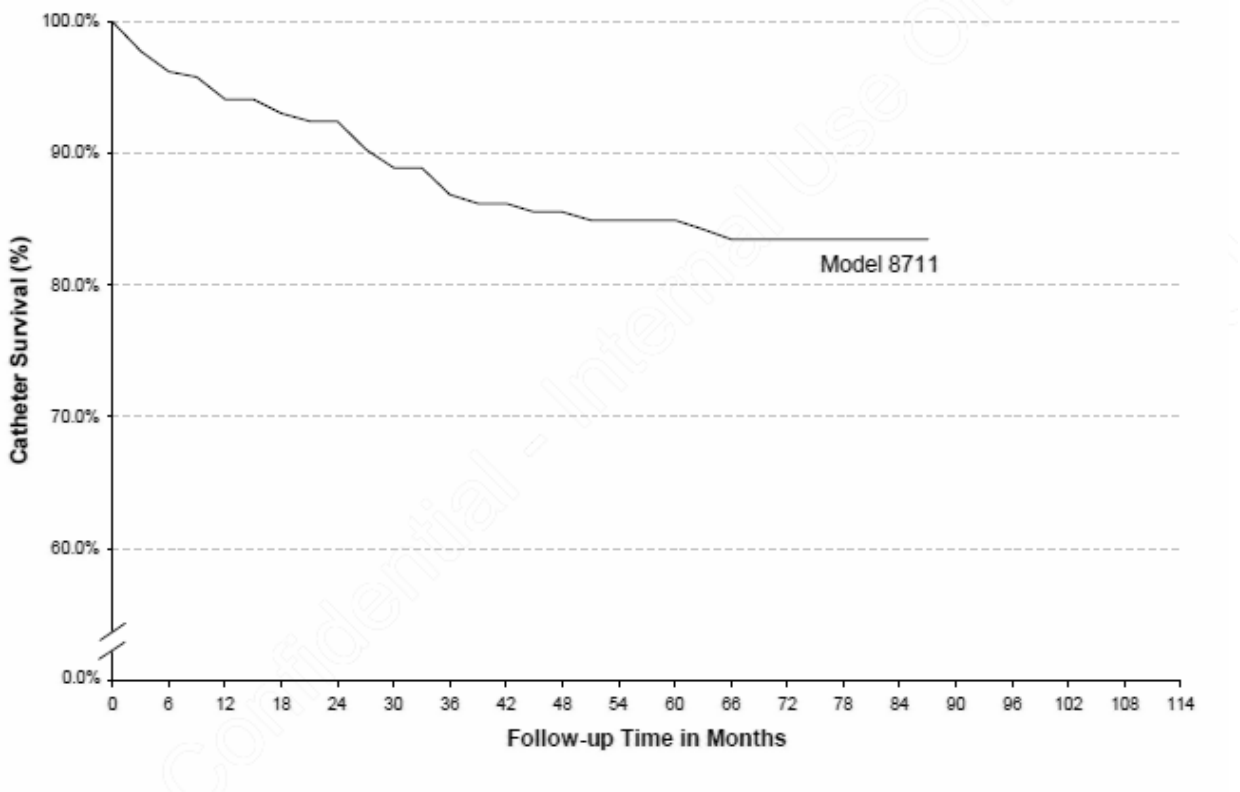


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8709SC	Mar 2006	217	179	4	1,589

Time Interval	1 yr	at 15 mo
Survival	97.6%	97.6%
Effective Sample Size	64	26

Model 8711: Survival from Catheter Events

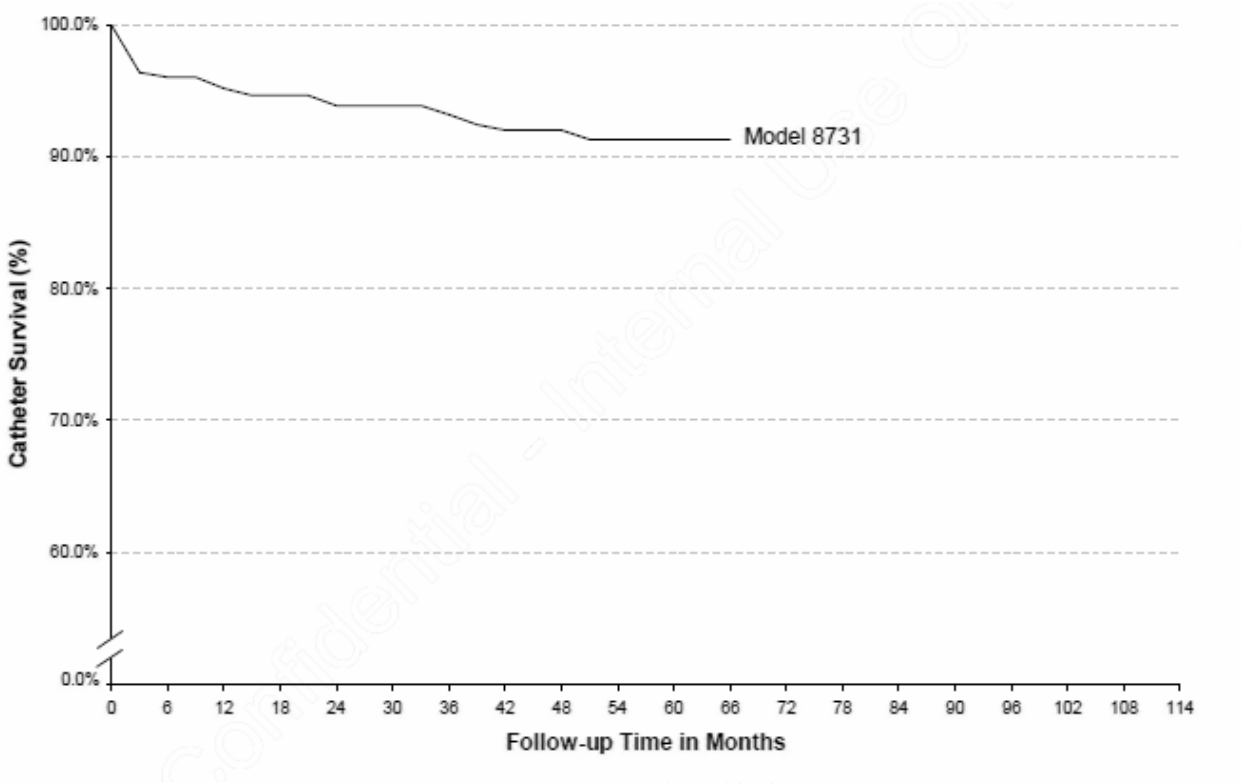


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8711	Oct 1999	478	397	32	11,680

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	at 87 mo
Survival	94.1%	92.5%	86.9%	85.6%	84.9%	83.5%	83.5%	83.5%
Effective Sample Size	227	149	131	132	133	77	34	24

Model 8731: Survival from Catheter Events

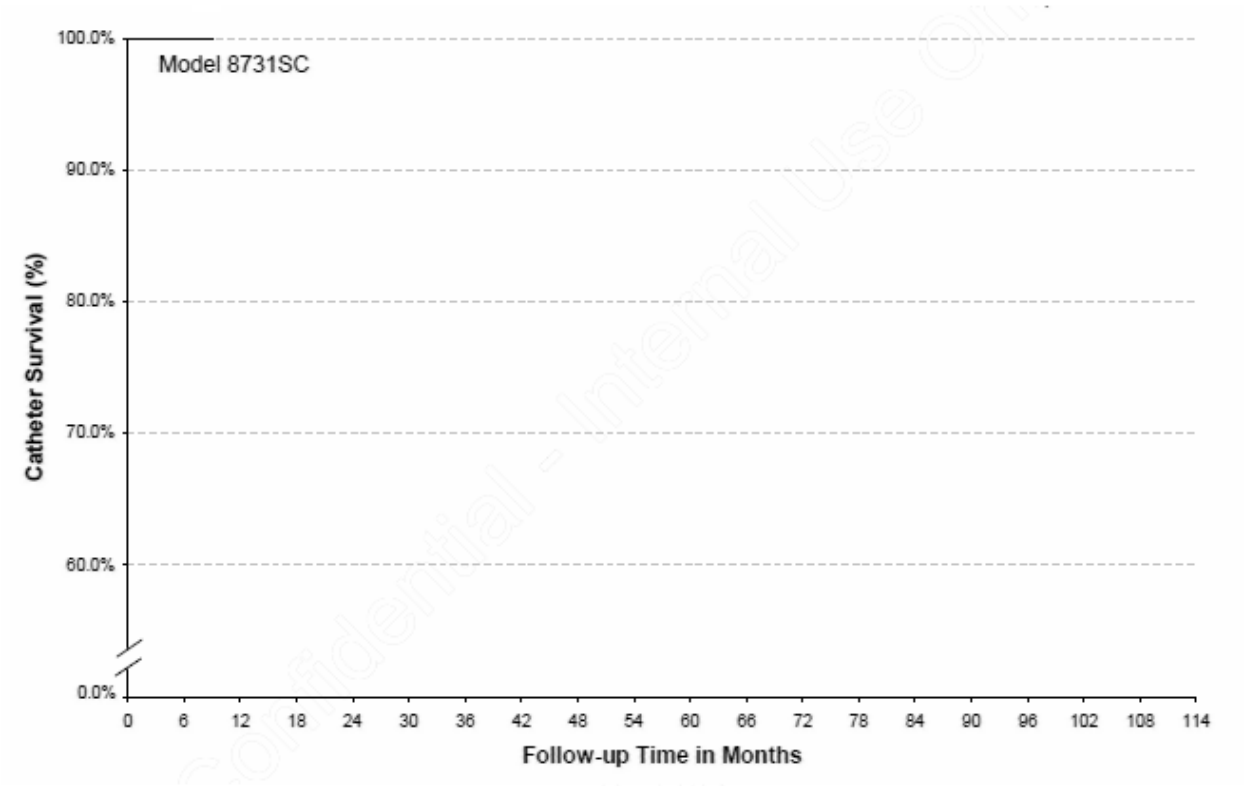


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8731	Oct 2002	517	400	24	15,374

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 66 mo
Survival	95.2%	93.9%	93.2%	92.0%	91.3%	91.3%
Effective Sample Size	341	363	281	158	62	21

Model 8731SC: Survival from Catheter Events

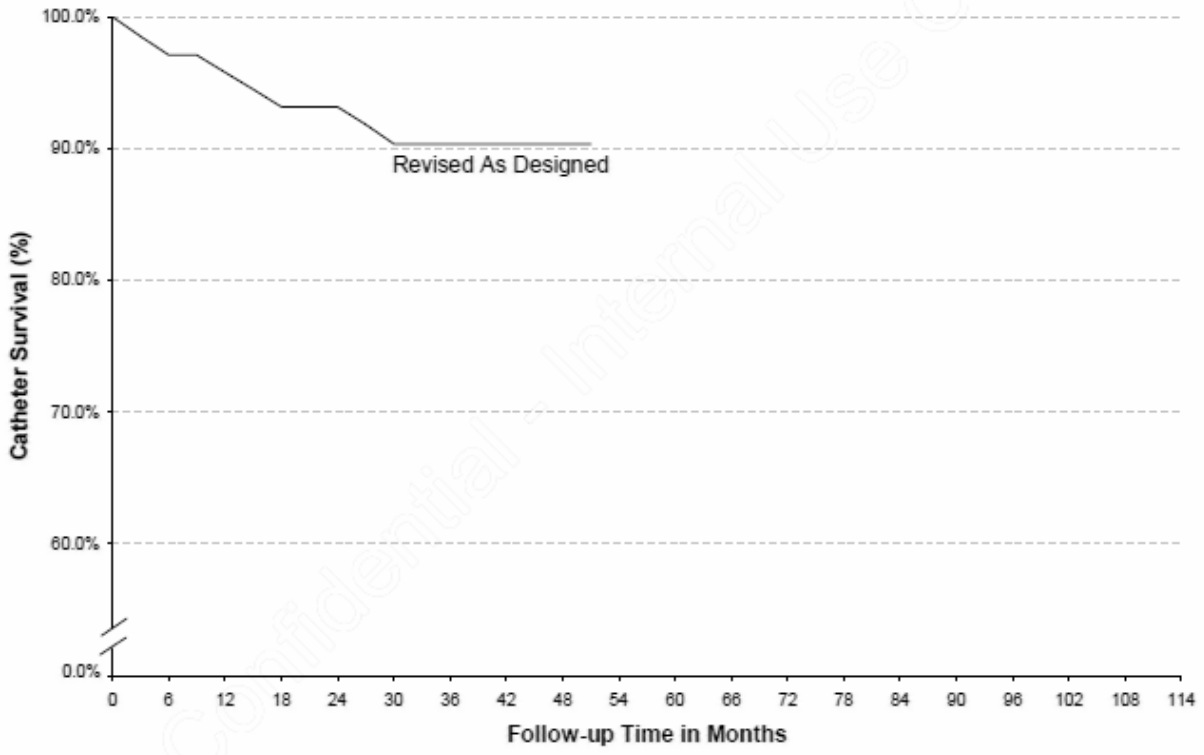


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8731SC	Mar 2006	41	39	0	336

Time Interval	at 9 mo
Survival	100.0%
Effective Sample Size	20

Revised As Designed Catheters: Survival from Catheter Events



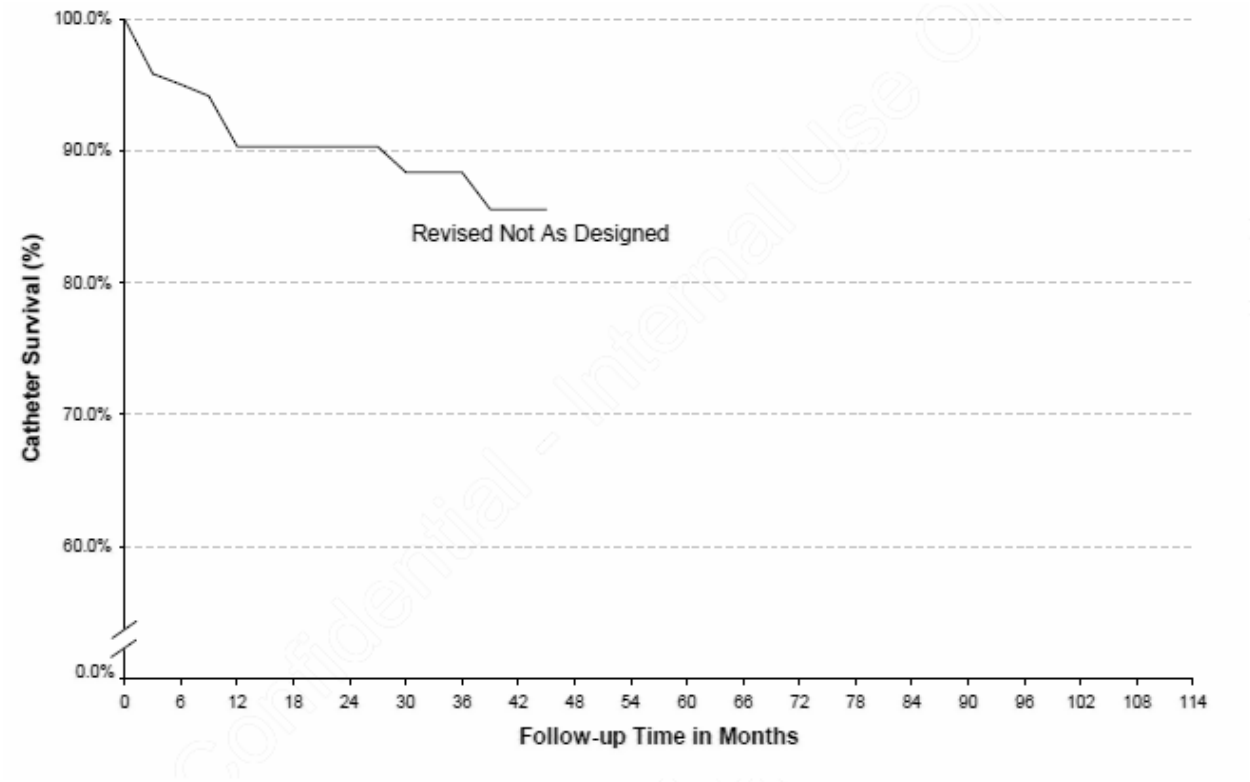
Data are shown if there are at least 20 devices in each 3 month interval.

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

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Revised As Designed	Oct 2002	107	88	7	3,000

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	at 51 mo
Survival	95.8%	93.2%	90.4%	90.4%	90.4%
Effective Sample Size	74	64	48	28	23

Revised Not As Designed Catheters: 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 Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Revised Not As Designed	NA	151	132	17	3,414

Time Interval	1 yr	2 yrs	3 yrs	at 45 mo
Survival	90.4%	90.4%	88.4%	85.6%
Effective Sample Size	98	58	36	20

Grafted Not As Designed Catheters: 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 Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Grafted Not As Designed	NA	116	79	15	2,351

Time Interval	1 yr	2 yrs	3 yrs
Survival	88.8%	87.4%	81.2%
Effective Sample Size	64	40	21

Catheter Survival Summary

Catheter Survival Summary Table

Catheter Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events***	**Cumulative Months of Follow-up**
8709	8709	May 1998	655	498	39	17,862

8709AA	8709	Jun 2001	1,496	870	81	30,566
8709SC	8709	Mar 2006	217	179	4	1,589
8711	8711	Oct 1999	478	397	32	11,680
8731	8731	Oct 2002	517	400	24	15,374
8731SC	8731	Mar 2006	41	39	0	336
Revised As Designed	NA	Oct 2002	107	88	7	3,000
Revised Not As Designed	NA	NA	151	132	17	3,414
Grafted Not As Designed	NA	NA	116	79	15	2,351

*There were a total of 236 catheter related events reported to the ISPR, but only 219 events included in this summary table. The remaining 17 catheter related events occurred in catheter models for which no device survival curves are presented due to an insufficient number of enrolled devices.

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Device Survival Probability (95% Confidence Intervals)

Model Number	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs	9 yrs
8709	**95.1%** (91.3%, 98.9%)	**92.4%** (87.6%, 97.2%)	**89.9%** (84.6%, 95.2%)	**89.4%** (84.1%, 94.8%)	**87.7%** (82.3%, 93.2%)	**85.0%** (79.5%, 90.6%)	**83.1%** (77.4%, 88.9%)	**80.1%** (74.1%, 86.1%)	**80.1%** (74.1%, 86.1%)
8709AA	**94.4%** (92.9%, 96.0%)	**93.0%** (91.2%, 94.8%)	**91.0%** (88.9%, 93.1%)	**89.4**% (86.9%, 91.9%)	**87.6%** (84.4%, 90.9%)	-	-	-	-
8709SC	**97.6%** (95.2%, 100.0%)	-	-	-	-	-	-	-	-
8711	**94.1%** (91.2%, 97.1%)	**92.5%** (89.0%, 95.9%)	**86.9%** (81.8%, 91.9%)	**85.6%** (80.3%, 90.9%)	**84.9%** (79.5%, 90.3%)	**83.5%** (77.8%, 89.2%)	**83.5%** (77.8%, 89.2%)	-	-
8731	**95.2%** (92.5%, 97.9%)	**93.9%** (91.0%, 96.8%)	**93.2%** (90.2%, 96.3%)	**92.0%** (88.7%, 95.4%)	**91.3%** (87.7%, 94.9%)	-	-	-	-
8731SC	Sample size at 1 year not large enough at this time; survival at 9 months is **100.0%**								
Revised As Designed	**95.8%** (91.0%, 100.0%)	**93.2%** (87.3%, 99.1%)	90.4% (83.4%, 97.3%)	**90.4%** (83.4%, 97.3%)	-	-	-	-	-
Revised Not As Designed	**90.4%** (84.8%, 95.9%)	**90.4%** (84.8%, 95.9%)	**88.4%** (81.7%, 95.1%)	-	-	-	-	-	-
Grafted Not As Designed	**88.8%** (82.1%, 95.5%)	**87.4%** (80.2%, 94.6%)	**81.2%** (70.3%, 92.0%)	-	-	-	-	-	-

Spinal Cord Stimulation: Study Participants

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 October 24, 2008. Forty-two centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Subjects

Of the 1,373 total spinal cord stimulation patients enrolled in the ISPR, 46.7% were implanted with a spinal cord stimulation system for the treatment of failed back, 40.6% for treatment of other indications, and 12.7% for treatment of complex regional pain syndrome (CRPS).

Primary Spinal Cord Stimulation Treatment Indications

Primary Treatment Indication*	Total Enrolled Patients (N=1,373)
Failed Back	**641 (46.7%)**
Arachnoiditis	23
Failed Back Syndrome	259
Multiple Back Operations	64
Post-laminectomy Pain	290
Unsuccessful Disc Surgery	5
Other	**557 (40.6%)**
Degenerative Disc Disease	37
Epidural Fibrosis	2
Radicular Pain Syndrome	140
Other Chronic Pain	378
CRPS	**175 (12.7%)**

Complex Regional Pain Syndrome Type I	149
Complex Regional Pain Syndrome Type II	26
Total Patients	**1,373**

* Refer to product labeling for approved indications. Primary treatment indication information is obtained through the Medtronic Device Registration System.

Spinal Cord Stimulation: Events Summary

Events Summary

Product Performance Related Events

There were 652 events reported between June 2004 and October 24, 2008 in patients with spinal cord stimulation systems. Twenty-seven percent of these events (173/652) 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.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Neurostimulator Related Events:		
Broken bond wire*	1	49.6 (49.6) ±NA
Loss of effect†	1	21.1 (21.1) ±NA
Recharging issue	1	1.8 (1.8) ±NA
Undesirable change in stimulation‡	2	22.1 (22.1) ±22.7
Neurostimulator Related Events Sub-Total	**5**	**23.3 (21.1) ±20.5**
Lead Related Events:		
Electrode contact damage	3	40.7 (25.1) ±27.0
Disconnection	1	0.9 (0.9) ±NA
Lead wire fracture	32	18.8 (17.7) ±10.5
Migration/dislodgement	77	11.7 (4.4) ±15.9
Undesirable change in stimulation	44	17.0 (4.6) ±23.5

Lead Related Events Sub-Total	**157**	**15.1 (7.1) ±18.2**
Extension Related Events:		
Extension failure[§]	3	4.0 (3.2) ±3.1
Fracture	8	20.2 (20.8) ±8.9
Extension Related Events Sub-Total	**11**	**15.8 (13.6) ±10.7**
Product Performance Related Events Total	**173**	**15.4 (7.4) ±17.8**

* 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-eight percent of total events (184/652) were related to the surgery or procedure (n=75), or attributed to the patient or delivery of the therapy (n=109). Twenty-four percent of events (155/652) were due to the patient expiring or becoming lost to follow-up (eg, patient moved, transferred care to another provider, study withdrawal). No deaths were reported as a result of a device related event or the delivery of neurostimulation therapy. Twenty-one percent of events (140/652) were related to normal battery depletion.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Surgical/Procedural Related Events:		
Neurostimulator Pocket/Access Related		
Hematoma	1	12.4 (12.4) ±NA
Infection	22	7.8 (4.3) ±9.2
Migration/inversion	11	19.9 (18.4) ±15.6
Pain at site	19	9.3 (8.7) ±5.4
Seroma	3	15.6 (13.2) ±7.6
Skin erosion	3	6.1 (3.9) ±4.3
Wound dehiscence	1	15.9 (15.9) ±NA
Neurostimulator Pocket Related Sub-Total	**60**	**11.0 (8.5) ±10.3**
Lead Tract Related		
Infection	5	10.9 (4.3) ±10.7
Pain at site	6	10.3 (9.8) ±4.1
Skin erosion	3	13.5 (6.7) ±14.6
Lead Tract Related Sub-Total	**14**	**11.2 (9.0) ±8.7**

Extension Tract Related		
Body fluids entry into connection	1	12.5 (12.5) ±NA
Extension Tract Related Sub-Total	**1**	**12.5 (12.5) ±NA**
Surgical/Procedural Related Events Sub-Total	**75**	**11.1 (8.9) ±9.9**
Therapy/Patient Related Events:		
Therapy/Patient Effects		
Allergic reaction	1	9.6 (9.6) ±NA
Corrective surgery*	6	16.4 (15.3) ±11.5
Cosmetic issue†	2	10.3 (10.3) ±11.3
Infection	4	9.7 (10.8) ±7.3
Leg pain/weakness	1	28.6 (28.6) ±NA
Loss of effect	13	17.4 (15.6) ±13.4
Needed expanded coverage‡	3	15.7 (10.6) ±10.2
No anomaly found by RPA§	1	19.5 (19.5) ±NA
Pain/irritation	1	9.3 (9.3) ±NA
Patient choice‖	1	0.9 (0.9) ±NA
Patient non-compliance¶	1	17.9 (17.9) ±NA
Psychological issue	3	15.6 (17.3) ±9.3
Resolution of symptoms**	3	20.2 (23.3) ±8.8
Therapy didn't meet patient's expectations	59	15.9 (12.2) ±11.9
Undesirable change in stimulation	2	14.6 (14.6) ±7.3
Undesirable interaction with other equipment	8	9.2 (7.7) ±6.2
Therapy/Patient Related Events Sub-Total	**109**	**15.3 (12.4) ±11.1**
Patient Related Events:††		
Patient Expired	23	16.8 (12.6) ±16.3
Patient lost to follow-up	132	16.1 (12.6) ±14.8
Patient Related Events Sub-Total	**155**	**16.2 (12.6) ±15.0**
Normal Battery Depletion Events:		
Battery Depletion	140	28.0 (26.5) ±14.2
Battery Depletion Events Sub-Total	**140**	**28.0 (26.5) ±14.2**

Non-Product Performance Related Events Total	**479**	**18.6 (14.9) ±14.6**

* Neurostimulator was removed due to corrective surgery (eg, patient had lumbar fusion surgery and symptoms resolved).
† Event was related to a cosmetic issue (eg, 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.

Spinal Cord Stimulation: Spinal Cord Stimulators

Spinal Cord Stimulators

From June 2004 to the report cut-off date of October 24, 2008, 1,562 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=1,373) versus spinal cord stimulators were due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted.

Thirty-one percent (31%) of the spinal cord stimulators were Synergy, 27.9% were Restore, 10.8% were PrimeAdvanced, 10.7% were RestoreAdvanced, 6.4% were RestoreUltra, 6.0% were Itrel 3, and a smaller number were RestorePrime (3.4%), Synergy Versitrel (2.2%), or SynergyPlus+ (1.6%). Total prospective follow-up time for spinal cord stimulators was 29,120 spinal cord stimulator months.

Spinal Cord Stimulator Events

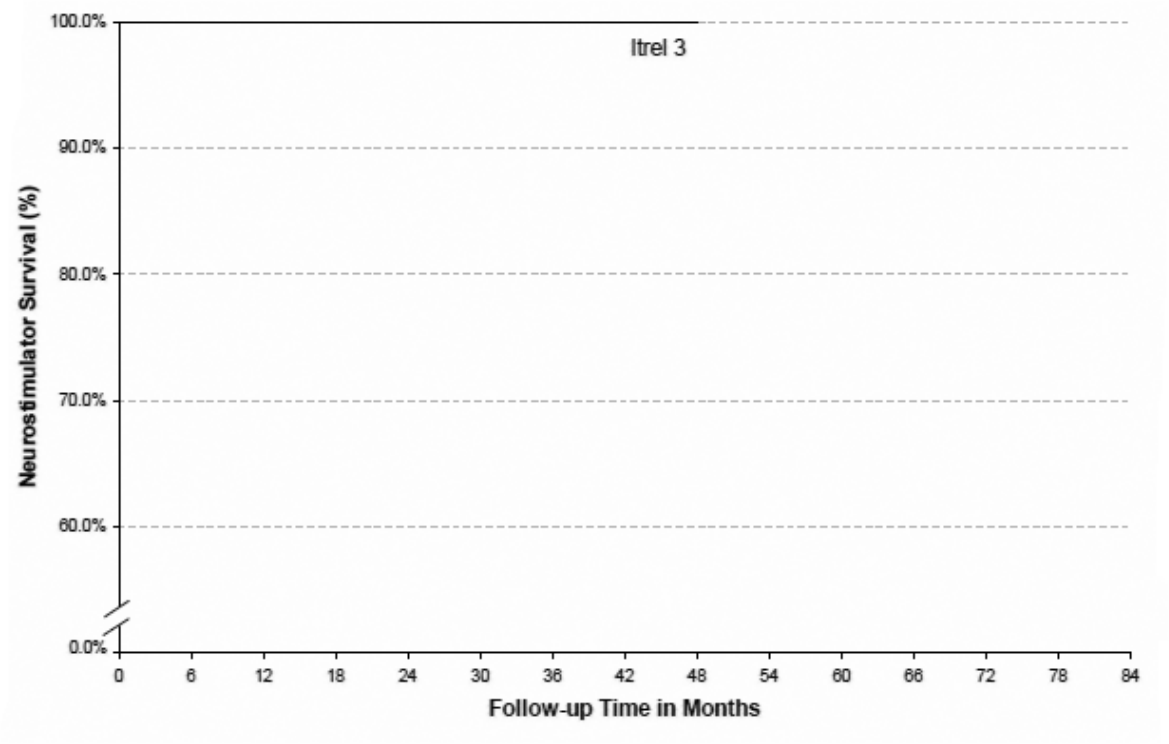
There were 5 spinal cord stimulator events requiring surgical intervention with an underlying etiology related to the spinal cord stimulator. For spinal cord stimulators enrolled in the ISPR, the current return rate to Medtronic Returned Product Analysis (RPA) was 41/304 (13%). The proportion was based 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 5 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 4 spinal cord stimulator events the physician assigned as device related and included 2 devices with an undesirable change in stimulation, 1 device with loss of therapeutic effect, and 1 device recharging issue.

There were an additional 473 spinal cord stimulators censored in the analysis due to spinal cord stimulator 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.

Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

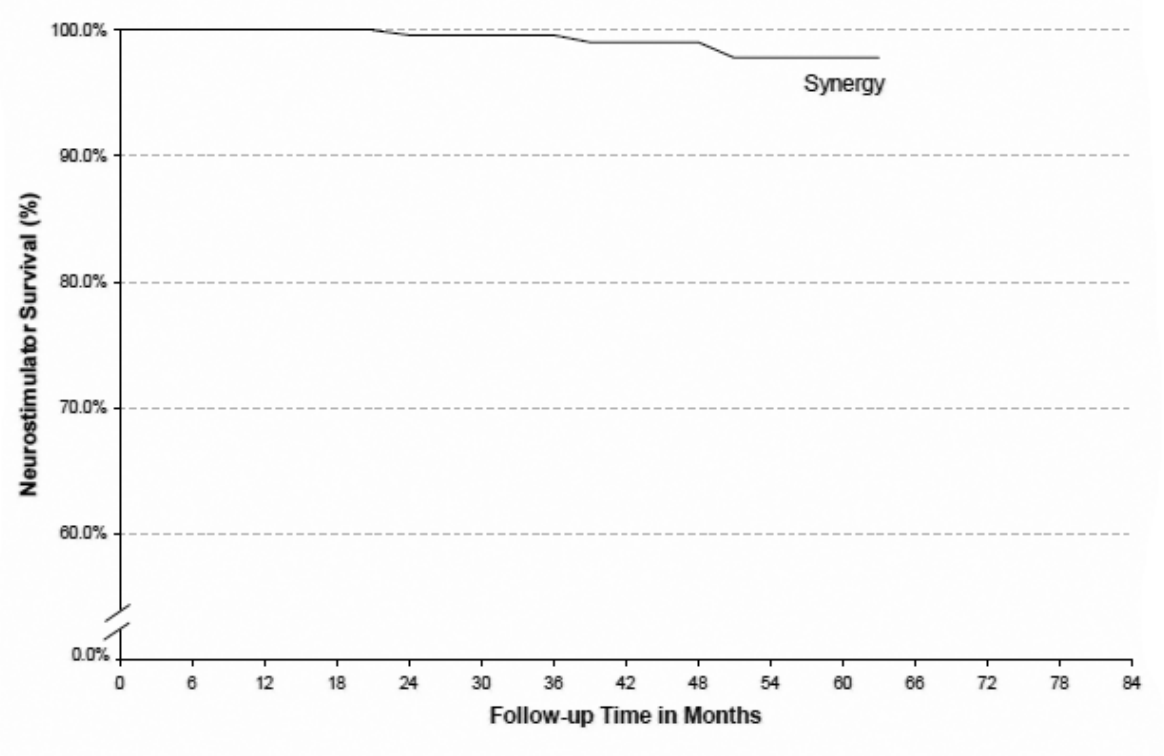


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Itrel 3	Aug 1995	94	53	0	2,235

Time Interval	1 yr	2 yrs	3 yrs	4 yrs
Survival	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	54	42	37	20

Model 7427 Synergy: Survival from Spinal Cord Stimulator Events

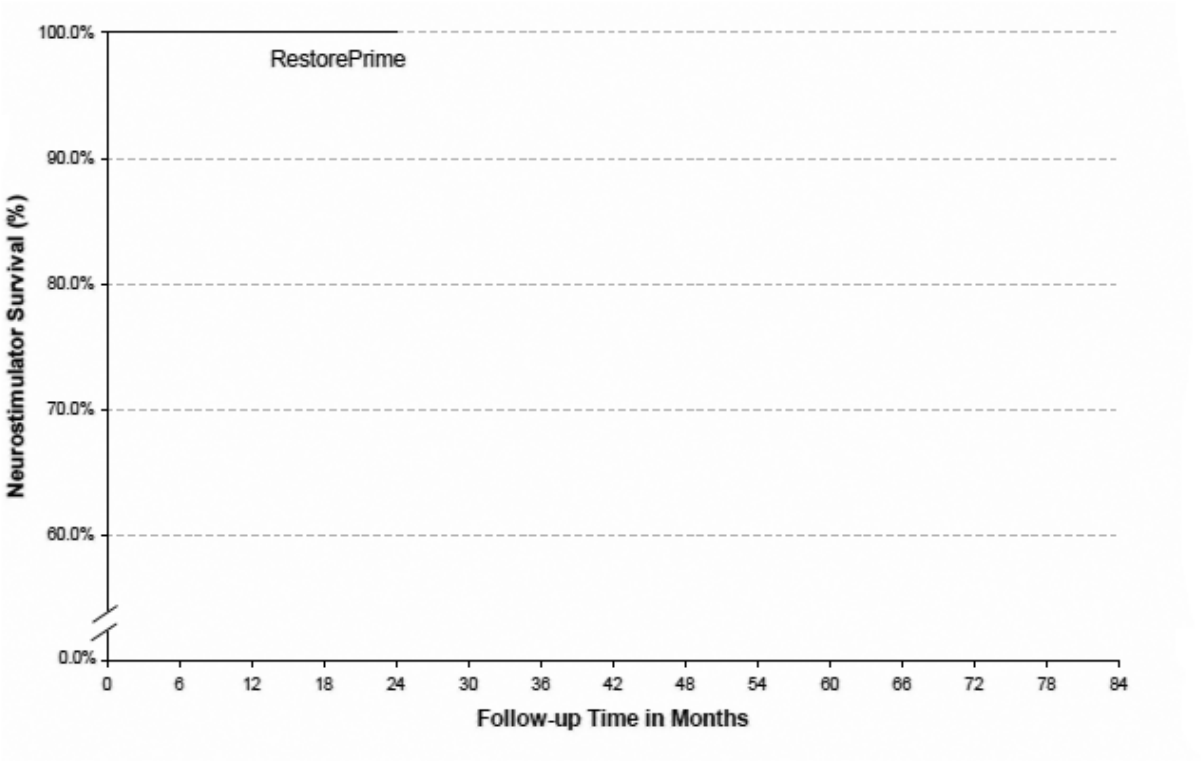


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Synergy	Nov 1999	484	273	3	11,558

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 63 mo
Survival	100.0%	99.6%	99.6%	99.0%	97.8%	97.8%
Effective Sample Size	292	263	194	100	35	26

Model 37701 RestorePrime: Survival from Spinal Cord Stimulator Events

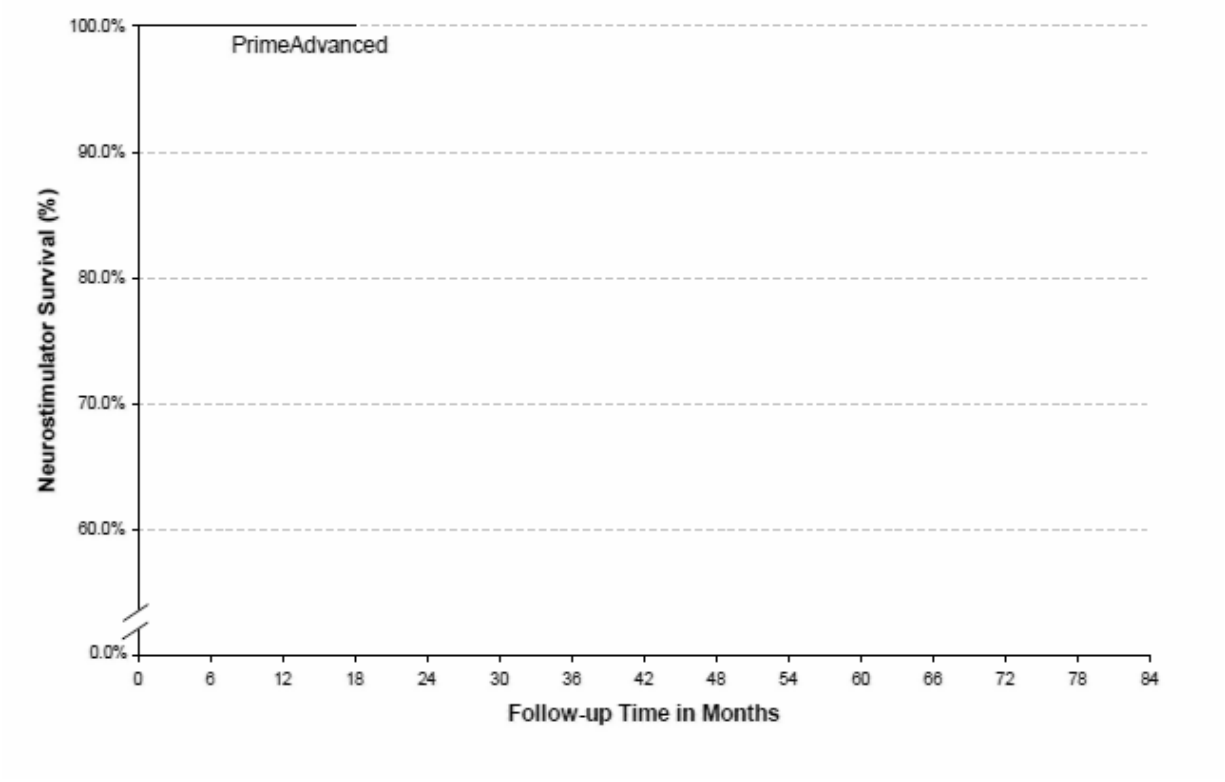


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
RestorePrime	Apr 2005	53	32	0	971

Time Interval	1 yr	2 yrs
Survival	100.0%	100.0%
Effective Sample Size	44	21

Model 37702 PrimeAdvanced: Survival from Spinal Cord Stimulator Events

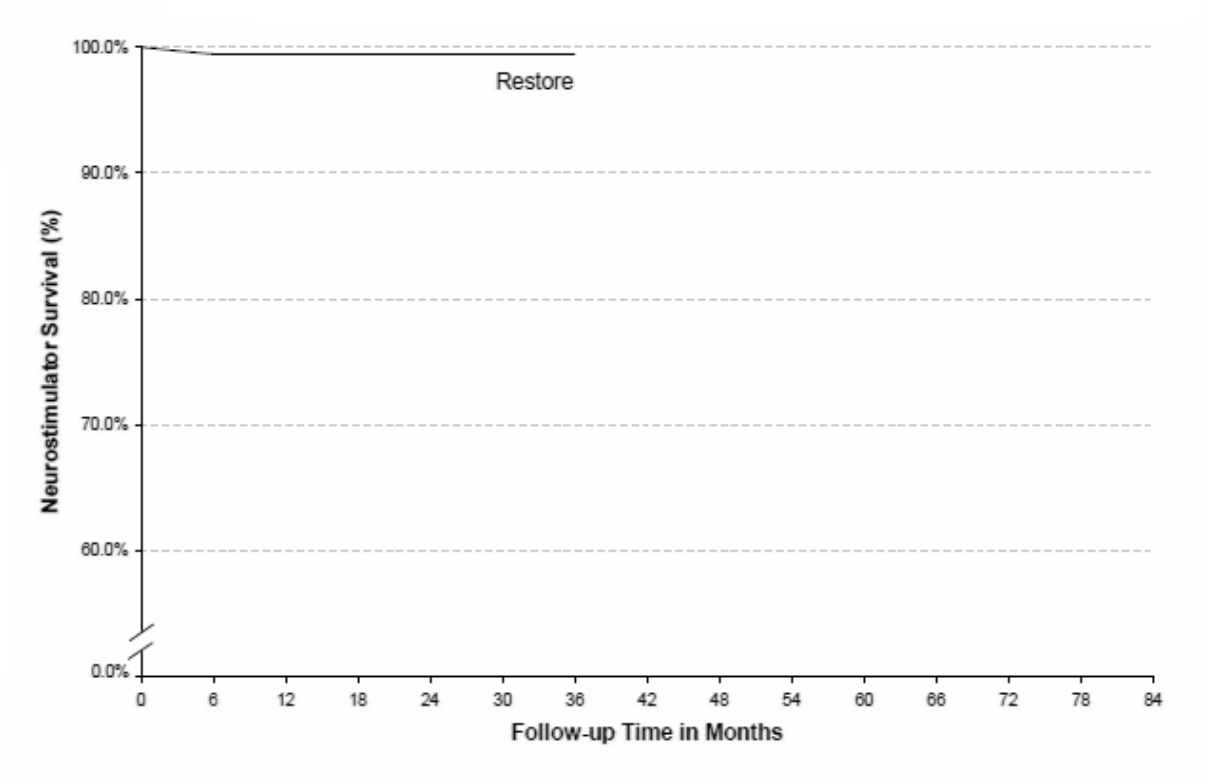


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
PrimeAdvanced	Jul 2006	168	142	0	1,888

Time Interval	1 yr	at 18 mo
Survival	100.0%	100.0%
Effective Sample Size	86	33

Model 37711 Restore: Survival from Spinal Cord Stimulator Events

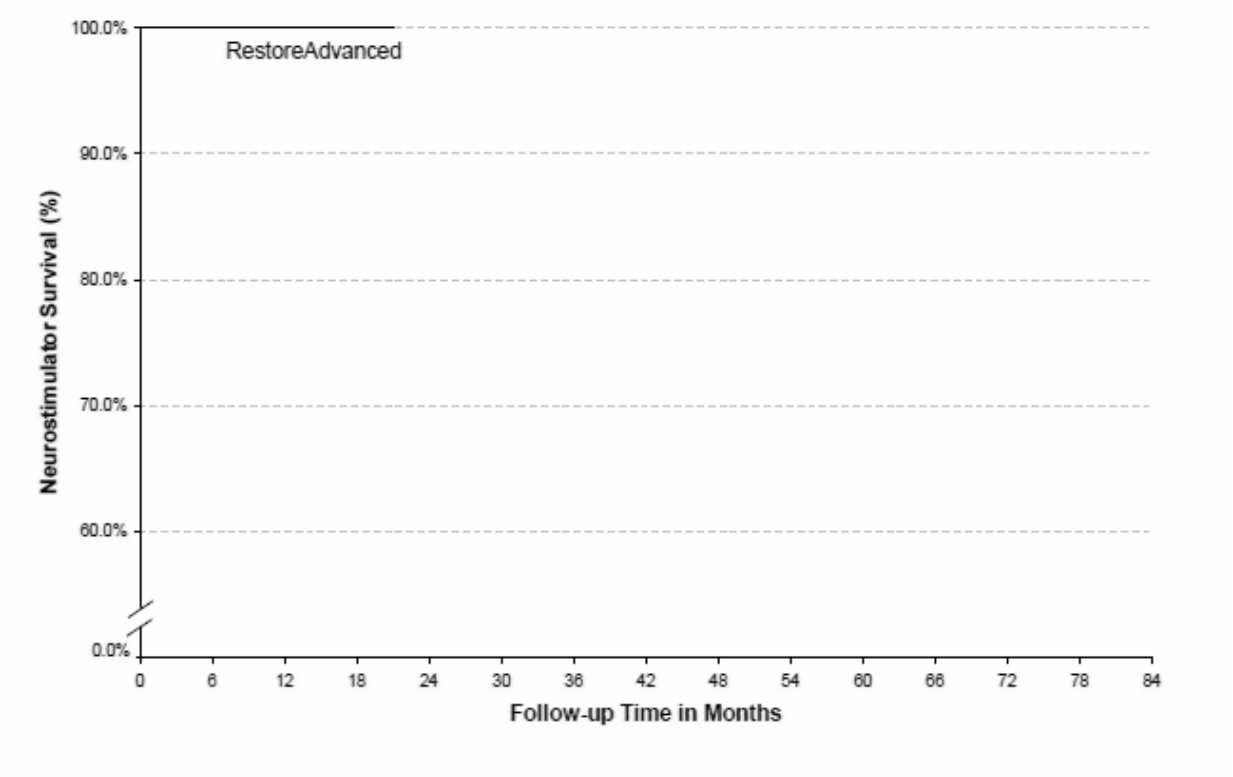


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Restore	Apr 2005	436	324	2	8,604

Time Interval	1 yr	2 yrs	3 yrs
Survival	99.5%	99.5%	99.5%
Effective Sample Size	340	211	35

Model 37713 RestoreAdvanced: Survival from Spinal Cord Stimulation Events

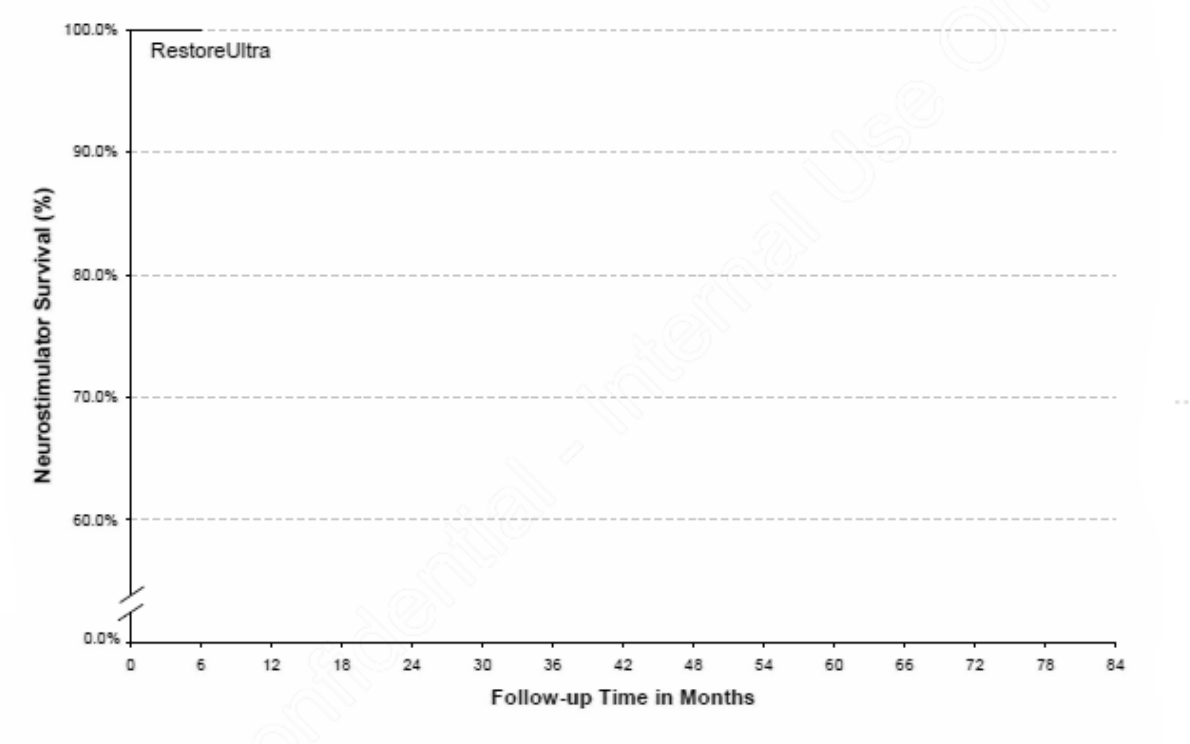


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
RestoreAdvanced	Jul 2006	167	143	0	2,124

Time Interval	1 yr	at 21 mo
Survival	100.0%	100.0%
Effective Sample Size	107	28

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	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
RestoreUltra	Jan 2008	100	98	0	460

Time Interval	at 6 mo
Survival	100.0%
Effective Sample Size	51

Spinal Cord Stimulator Survival Summary

Spinal Cord Stimulators Summary Table

Spinal Cord Stimulator Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Neurostimulators Enrolled**	**Neurostimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Itrel 3	Itrel 3	Aug 1995	94	53	0	2,235
Synergy	Synergy	Nov 1999	484	273	3	11,558

RestorePrime	RestorePrime	Apr 2005	53	32	0	971
PrimeAdvanced	PrimeAdvanced	Jul 2006	168	142	0	1,888
Restore	Restore	Apr 2005	436	324	2	8,604
RestoreAdvanced	Restore	Jul 2006	167	143	0	2,124
RestoreUltra	Restore	Jan 2008	100	98	0	460

Device Survival Probability (95% Confidence Intervals)

Model Number	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
Itrel 3	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA	-
Synergy	**100.0%** NA	**99.6%** (98.9%, 100.0%)	**99.6%** (98.9%, 100.0%)	**99.0%** (97.7%, 100.0%)	**97.8%** (95.0%, 100.0%)
RestorePrime	**100.0%** NA	**100.0%** NA	-	-	-
PrimeAdvanced	**100.0%** NA	-	-	-	-
Restore	**99.5%** (98.7%, 100.0%)	**99.5%** (98.7%, 100.0%)	**99.5%** (98.7%, 100.0%)	-	-
RestoreAdvanced	**100.0%** NA	-	-	-	-
RestoreUltra	Sample size at 1 year not large enough at this time; survival at 6 months is **100.0%**				

Spinal Cord Stimulation: Leads

Leads

From June 2004 to the report cut-off date of October 24, 2008, there were 2,545 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=1,562) were due to the fact that some patients were subsequently re-implanted with a new lead or were implanted with more than 1 lead.

Eighty-seven percent (87%) of leads in ISPR were percutaneous leads (2,211/2,545) including 42% (1,077/2,545) in the Pisces-Octad lead family, 33% (832/2,545) in the Pisces-Quad lead family, and 12% (302/2,545) in the Pisces-Quad LZ lead family. Thirteen percent (13%) of leads (318/2,545) were surgical leads. A small number of leads

(16/2,545) were designated as Other (1%). Total prospective follow-up time for leads was 49,556 lead months.

Lead Events

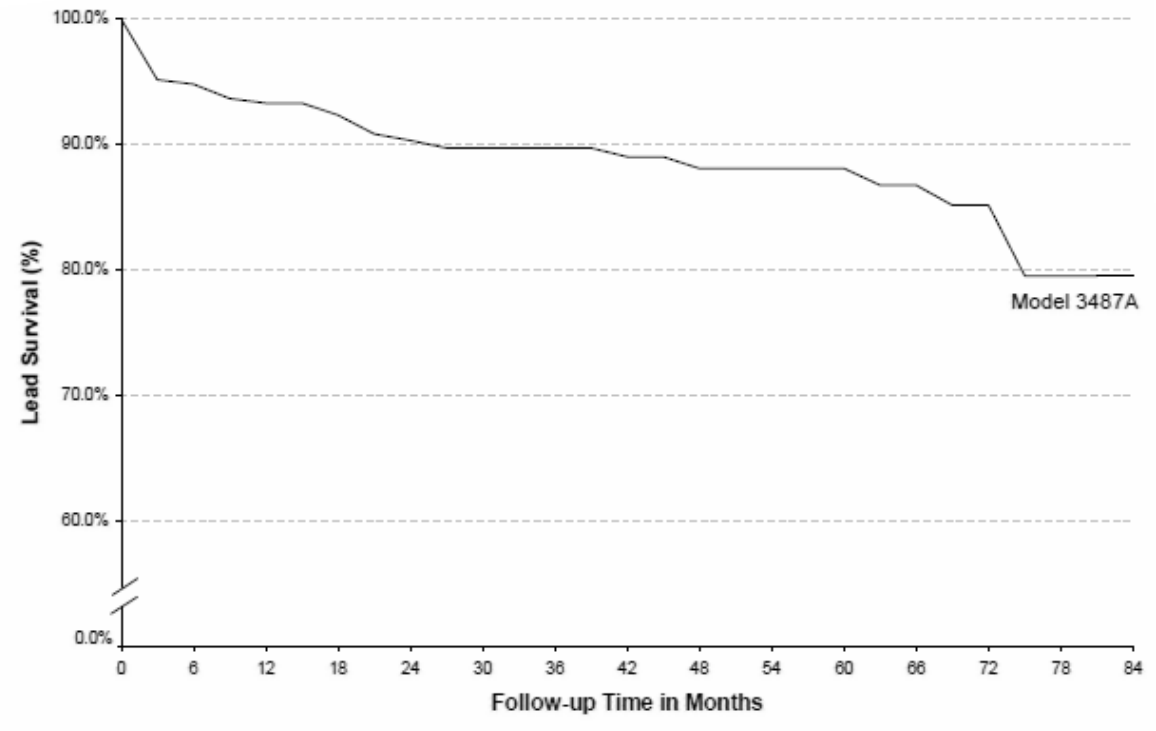
There were 157 lead events requiring surgical intervention with an underlying etiology related to the lead. Of these 157 events, 77 were due to lead migration or dislodgement, 44 were due to an undesirable change in stimulation, 32 were due to lead fractures, 3 were due to damaged electrodes, and 1 was due to disconnection. Eleven of the 157 events (7%) occurred in surgical leads including 4 due to lead fractures, 4 due to lead migration or dislodgement, and 3 due to undesirable change in stimulation. There were 145 events in 2,211 (7%) percutaneous leads, 11 events in 318 (3%) surgical leads, and 1 event in 16 (6%) leads designated as Other.

There were an additional 519 leads censored in the analysis due to patient lost to follow-up (eg, 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 all of the applicable lead Models except Pisces-Quad LZ Model 3891 overlap, indicating that survival from lead related events is not significantly different between these lead Models at 2 years. The 95% confidence interval for Pisces-Quad LZ Model 3891 leads does not overlap with any of the Pisces-Quad lead Models, Octad Models 3777 and 3778, Pisces-Quad LZ Model 3890, or surgical Model 3999 indicating a significant difference in performance at 2 years. The difference in performance is also observed at 3 years when compared to all applicable lead Models, with the exception of Pisces-Quad Model 3887. As of February 6, 2008, Medtronic has discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Model 3487A Pisces-Quad: Survival from Lead Events

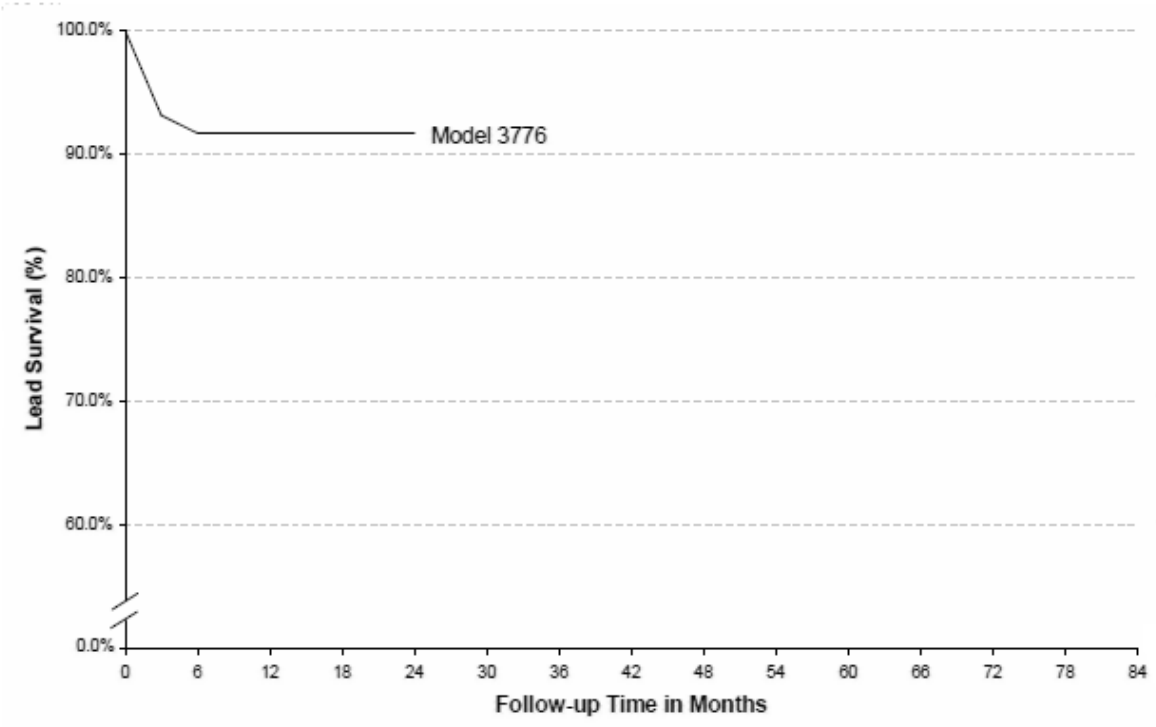


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3487A	Aug 1983	489	377	31	10,862

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs
Survival	93.3%	90.3%	89.7%	88.1%	88.1%	85.1%	79.5%
Effective Sample Size	254	175	127	95	67	50	21

Model 3776 Pisces-Octad: Survival from Lead Events

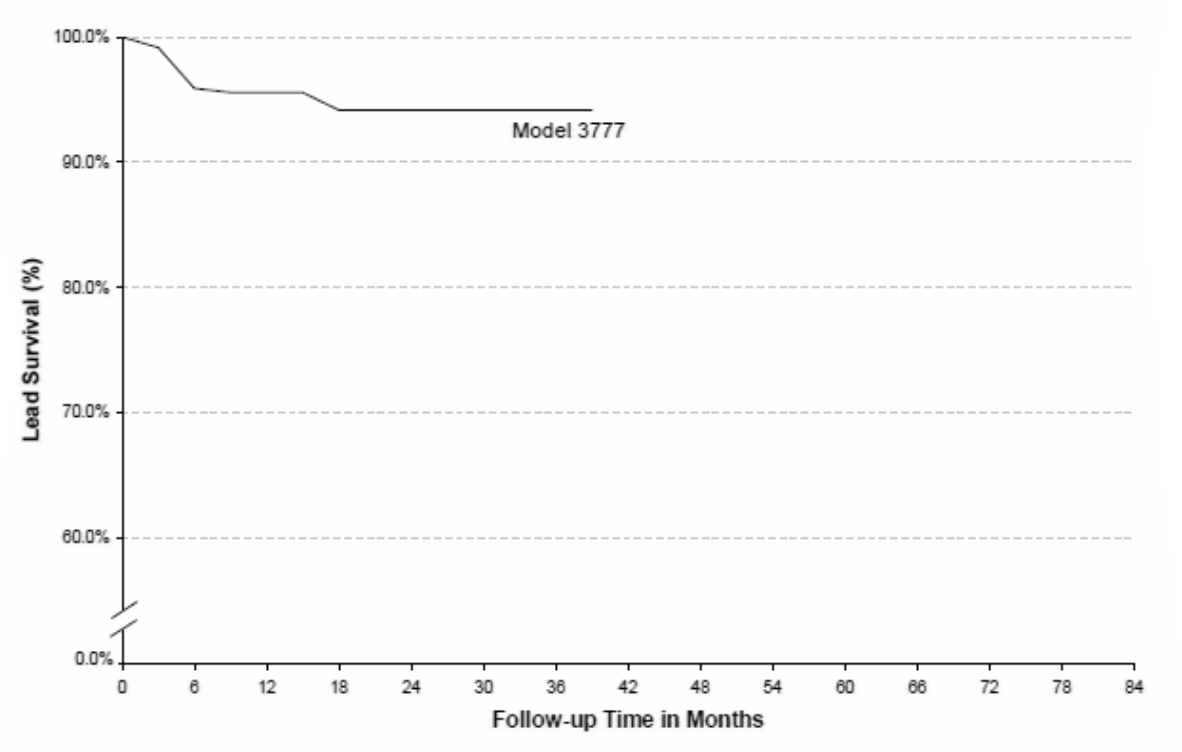


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3776	Nov 2005	81	63	6	1,276

Time Interval	1 yr	2 yrs
Survival	91.7%	91.7%
Effective Sample Size	61	23

Model 3777 Pisces Octad: Survival from Lead Events

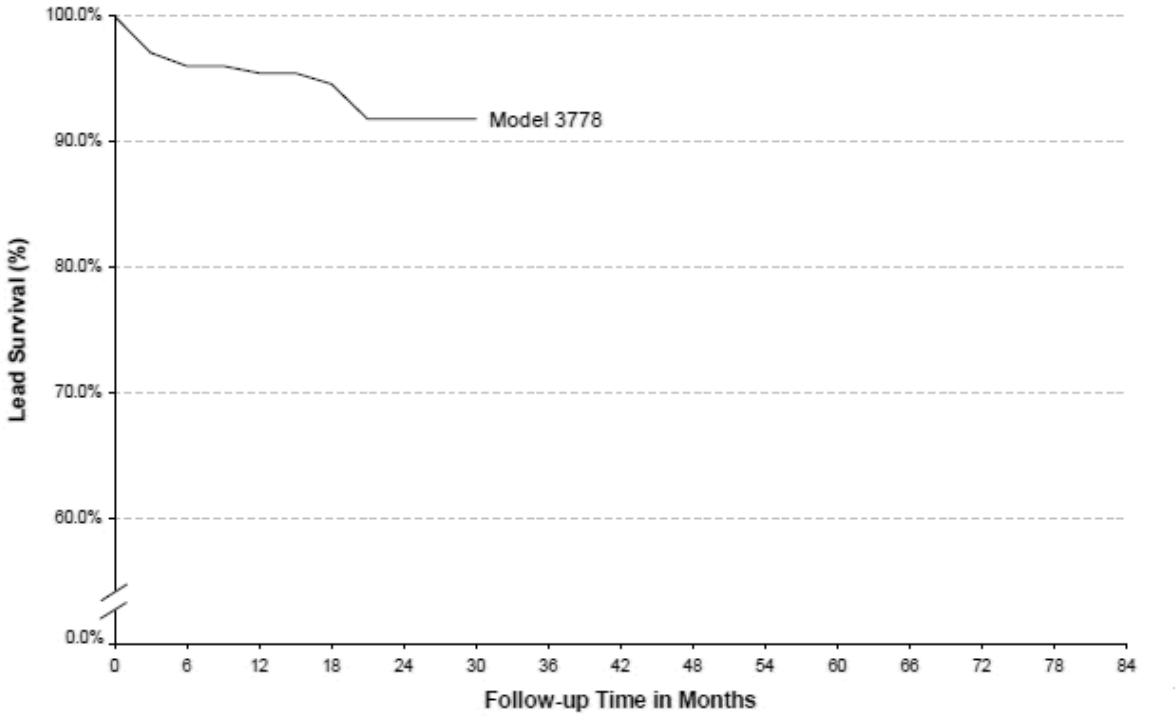


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3777	Apr 2005	436	334	19	7,180

Time Interval	1 yr	2 yrs	3 yrs	at 39 mo
Survival	95.6%	94.2%	94.2%	94.2%
Effective Sample Size	257	155	42	23

Model 3778 Pisces-Octad: Survival from Lead Events

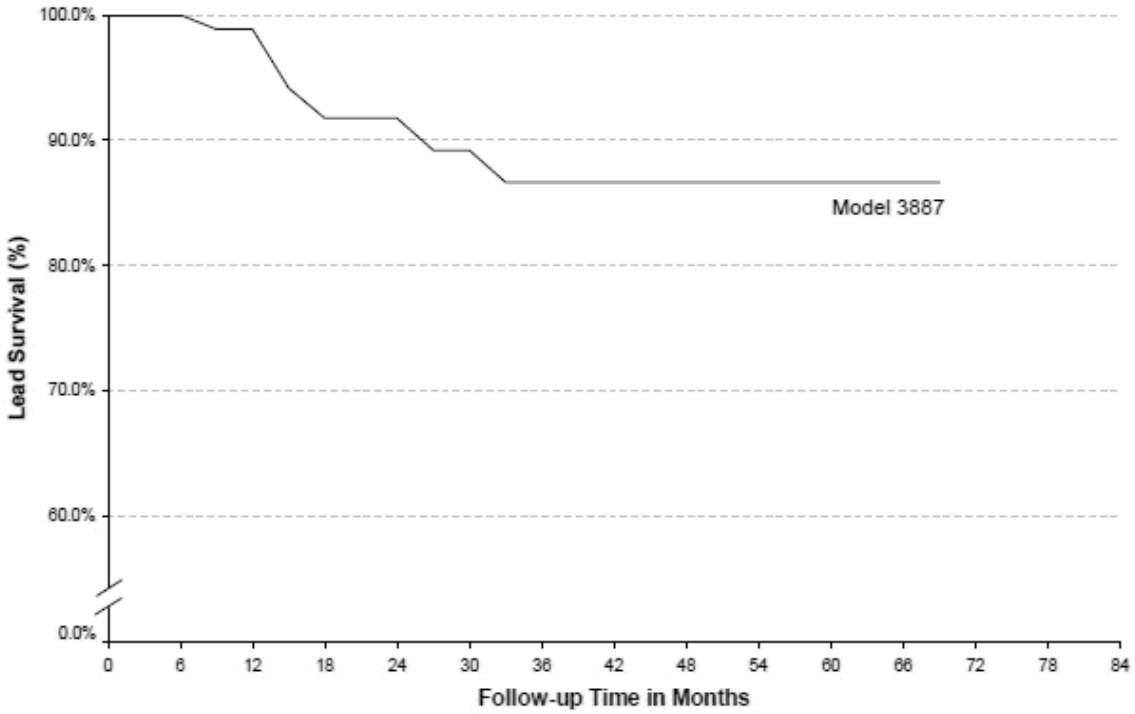


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3778	Apr 2005	560	462	29	7,869

Time Interval	1 yr	2 yrs	at 30 mo
Survival	95.5%	91.8%	91.8%
Effective Sample Size	336	118	41

Model 3887 Pisces-Quad: Survival from Lead Events

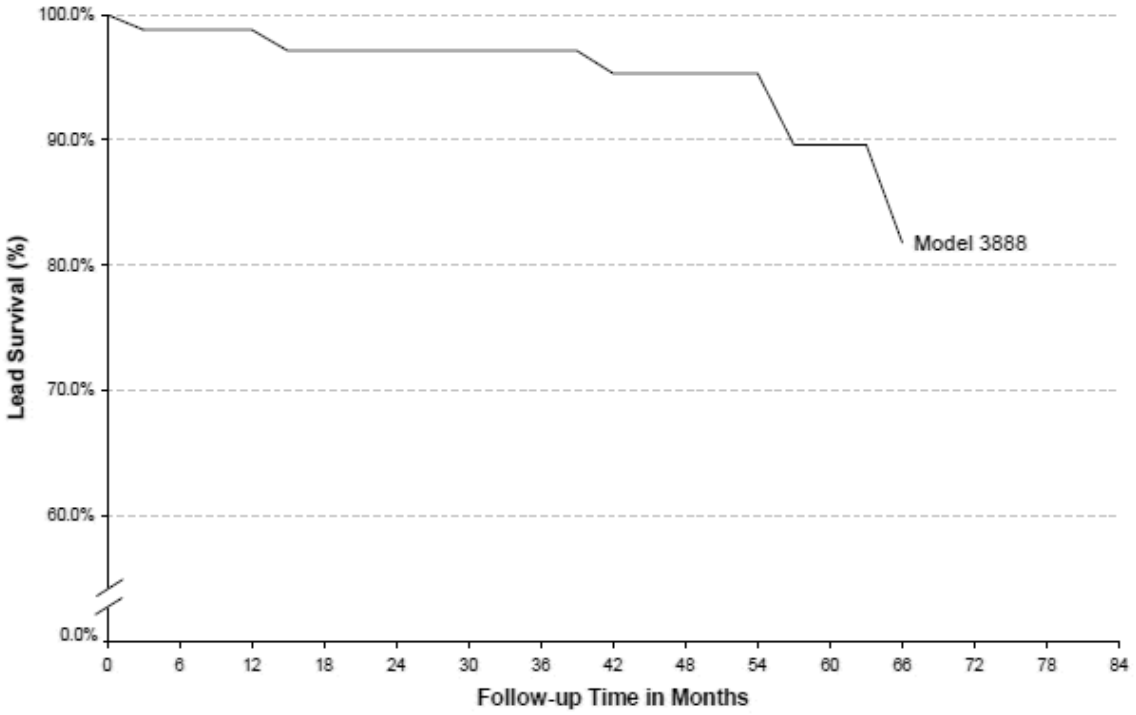


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3887	Mar 2004	155	93	12	4,295

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 69 mo
Survival	98.9%	91.8%	86.7%	86.7%	86.7%	86.7%
Effective Sample Size	88	70	74	47	24	21

Model 3888 Pisces-Quad: Survival from Lead Events

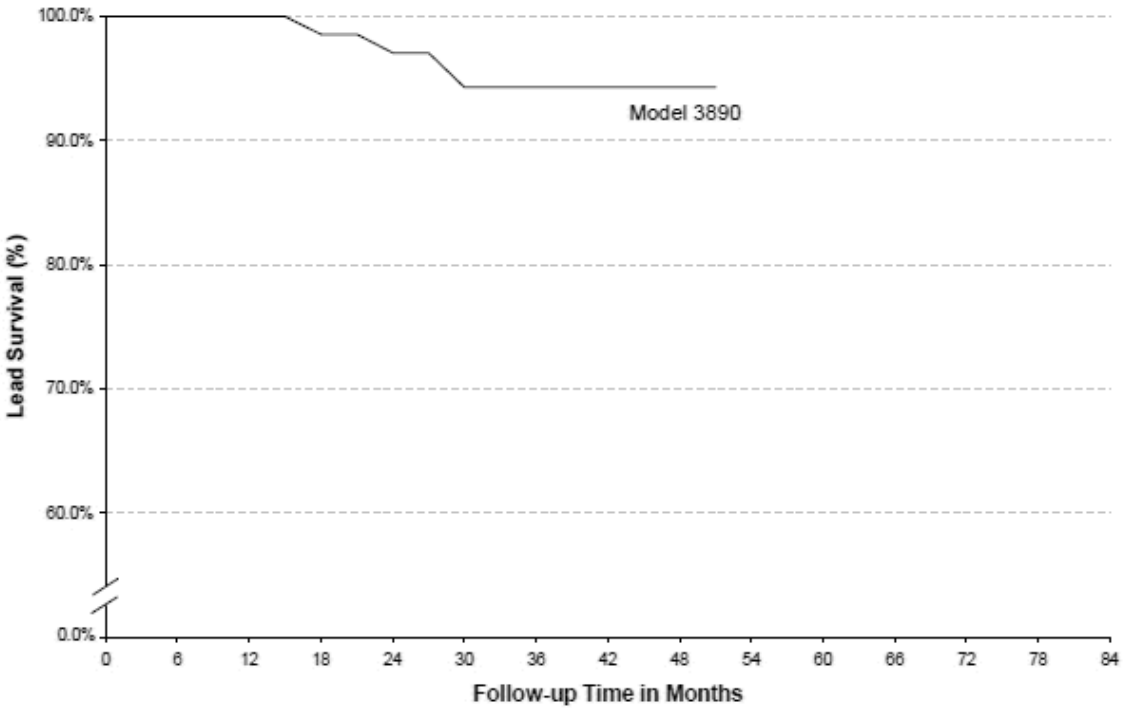


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3888	Nov 1992	183	138	9	4,014

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 66 mo
Survival	98.8%	97.1%	97.1%	95.3%	89.6%	81.8%
Effective Sample Size	64	56	54	53	30	23

Model 3890 Pisces-Quad LZ: Survival from Lead Events

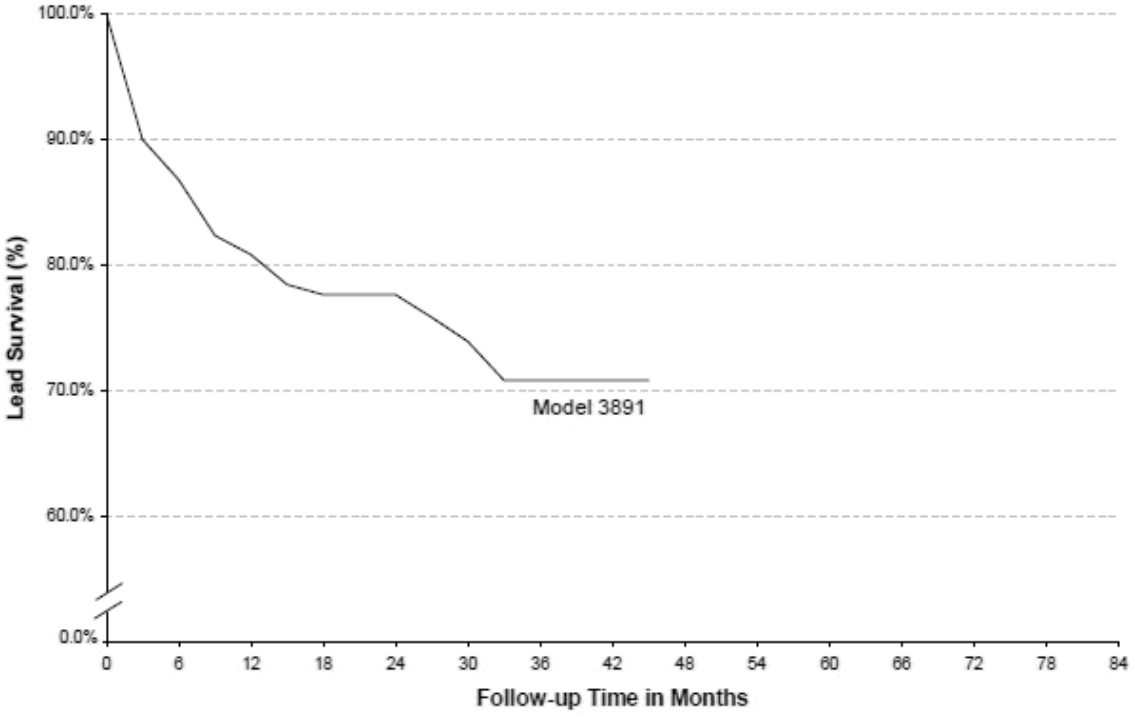


*Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3890	Sep 2002	130	92	4	2,900

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	at 51 mo
Survival	100.0%	97.1%	94.3%	94.3%	94.3%
Effective Sample Size	63	66	61	26	21

Model 3891 Pisces-Quad LZ: Survival from Lead Events

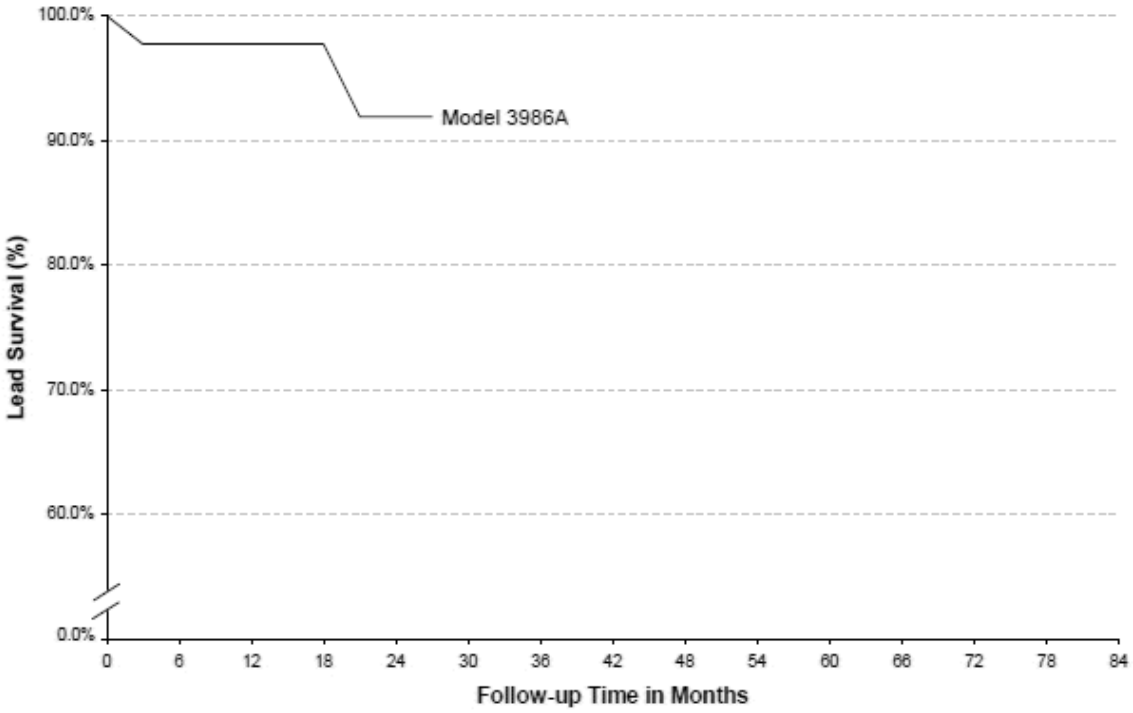


*Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3891	Sep 2002	157	82	34	3,911

Time Interval	1 yr	2 yrs	3 yrs	at 45 mo
Survival	80.8%	77.6%	70.8%	70.8%
Effective Sample Size	107	90	59	27

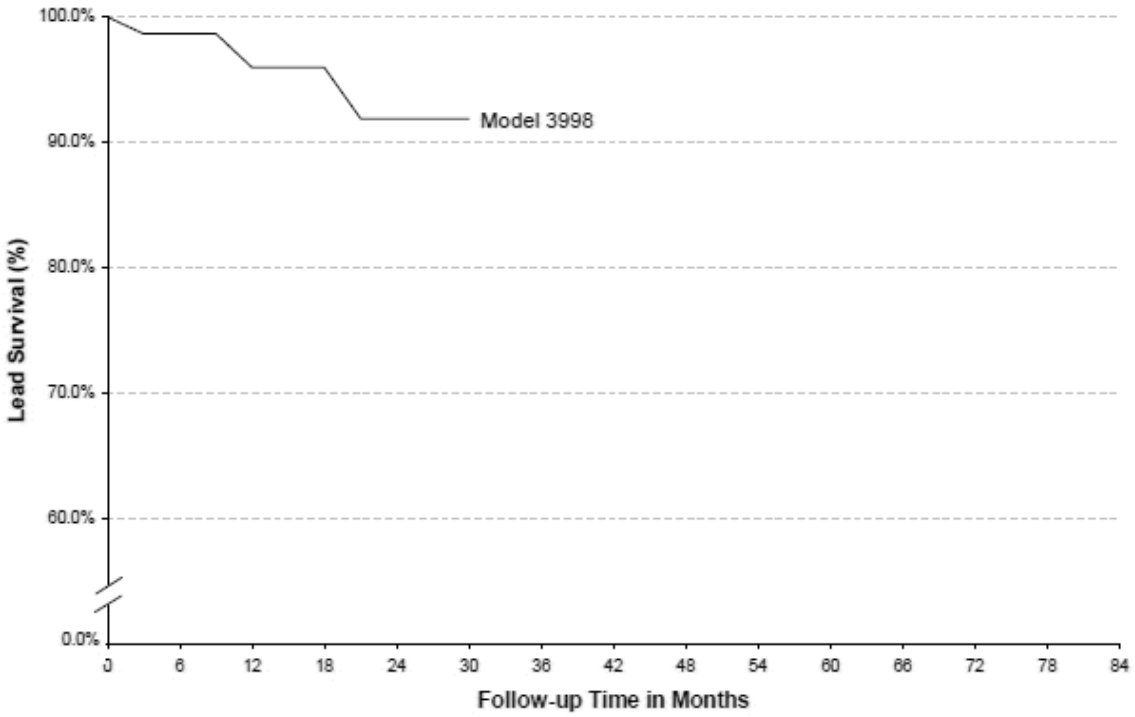
Model 3986A Resume TL: Survival from Lead Events



Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3986A	Mar 2004	59	46	4	1,230

Time Interval	1 yr	2 yrs	at 27 mo
Survival	97.7%	91.9%	91.9%
Effective Sample Size	41	30	24

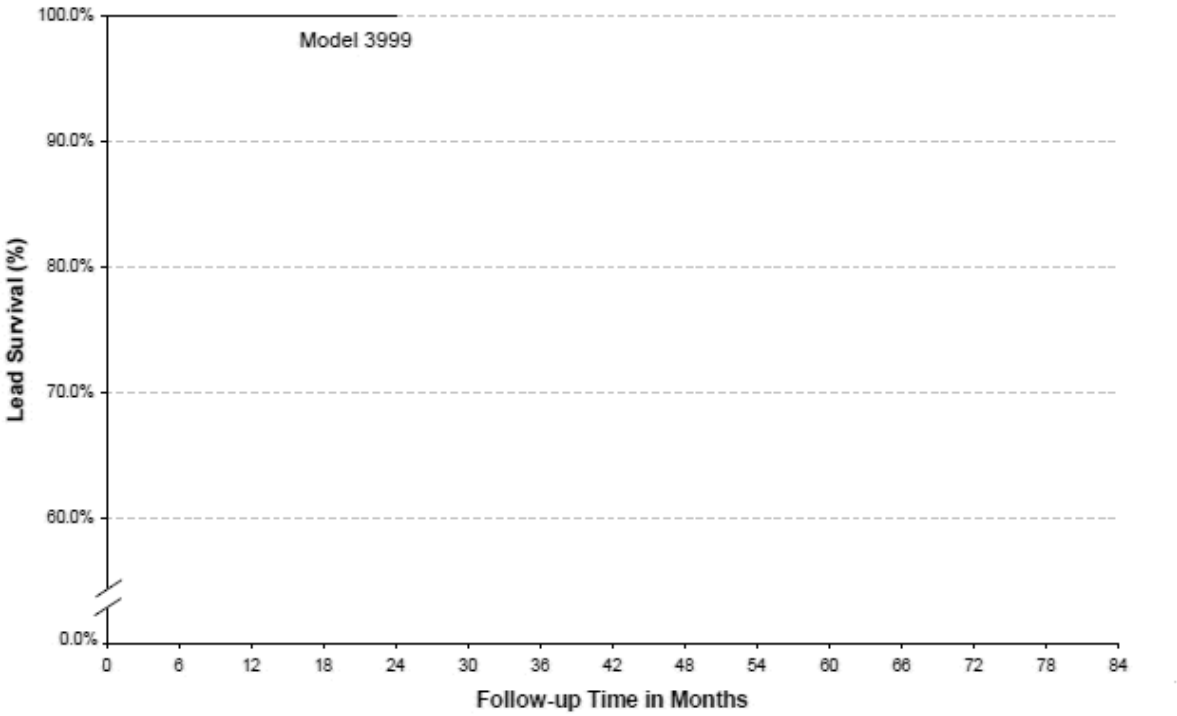
Model 3998 Specify: Survival from Lead Events



Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3998	Feb 1998	115	82	6	2,169

Time Interval	1 yr	2 yrs	at 30 mo
Survival	96.0%	91.9%	91.9%
Effective Sample Size	73	37	25

Model 3999 2x4 Hinged: Survival from Lead Events

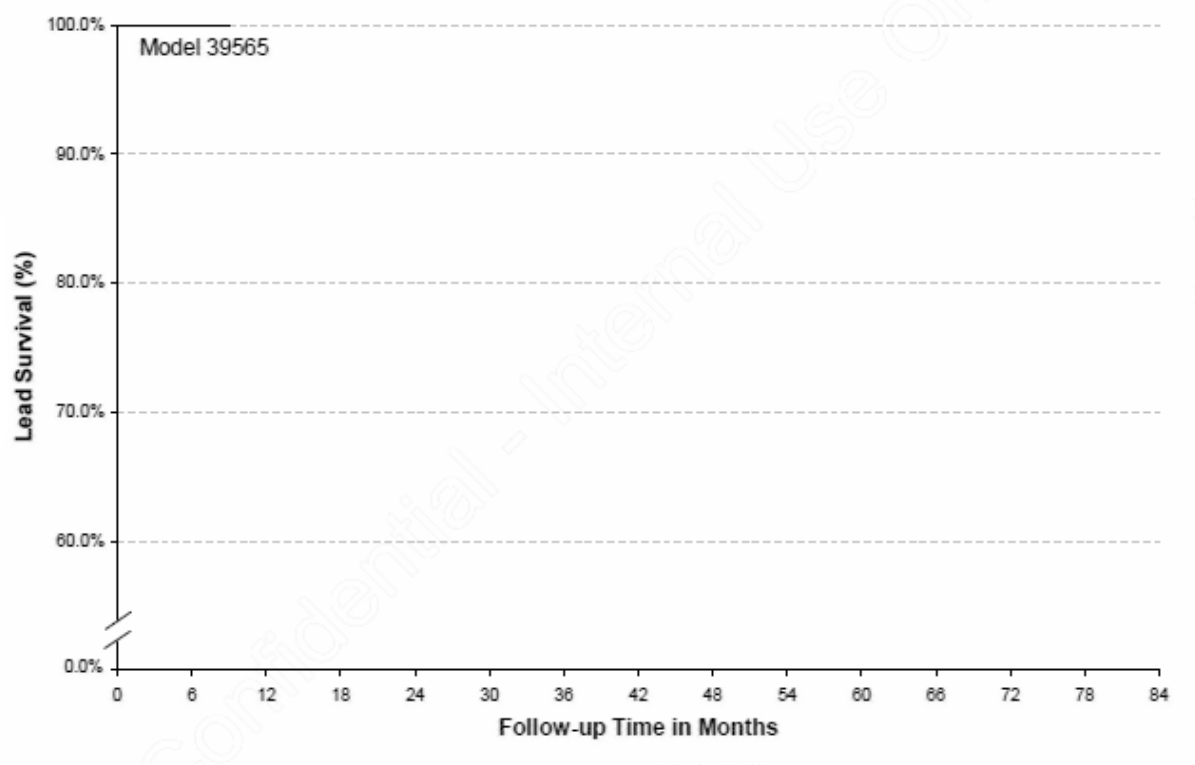


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics					
Model Name	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3999	Jun 2004	48	33	0	947

Time Interval	1 yr	2 yrs
Survival	100.0%	100.0%
Effective Sample Size	39	23

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	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
39565	Jun 2007	46	42	0	387

Time Interval	at 9 mo
Survival	100.0%
Effective Sample Size	27

Lead Survival Summary

Lead Survival Summary Table

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	489	377	31	10,862
3776	Pisces-Octad	Nov 2005	81	63	6	1,276

3777	Pisces-Octad	Nov 2005	436	334	19	7,180
3778	Pisces-Octad	Nov 2005	560	462	29	7,869
3887	Pisces-Quad	Mar 2004	155	93	12	4,295
3888	Pisces-Quad	Nov 1992	183	138	9	4,014
3890	Pisces-Quad LZ	Sep 2002	130	92	4	2,900
3891	Pisces-Quad LZ	Sep 2002	157	82	34	3,911
Surgical Leads						
3986A	Resume TL	Mar 2004	59	46	4	1,230
3998	Specify	Feb 1998	115	82	6	2,169
3999	2 x 4 Hinged Specify	Jun 2004	48	33	0	947
39565	Specify	Jun 2007	46	42	0	387

*There were a total of 157 lead related events reported to the ISPR, but only 154 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)

Model Name	Family	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs
Percutaneous Leads								
3487A	Pisces-Quad	**93.3%** (90.1%, 96.4%)	**90.3%** (86.4%, 94.2%)	**89.7%** (85.7%, 93.7%)	**88.1%** (83.5%, 92.7%)	**88.1%** (83.5%, 92.7%)	**85.1%** (79.1%, 91.2%)	**79.5%** (71.1%, 88.0%)
3776	Pisces-Octad	**91.7%** (85.2%, 98.2%)	**91.7%** (85.2%, 98.2%)	-	-	-	-	-
3777	Pisces-Octad	**95.6%** (93.4%, 97.7%)	**94.2%** (91.5%, 96.8%)	**94.2%** (91.5%, 96.8%)	-	-	-	-
3778	Pisces-Octad	**95.5%** (93.5%, 97.4%)	**91.8%** (88.5%, 95.1%)	-	-	-	-	-
3887	Pisces-Quad	**98.9%** (96.6%, 100.0%)	**91.8%** (85.8%, 97.7%)	**86.7%** (79.1%, 94.2%)	**86.7%** (79.1%, 94.2%)	**86.7%** (79.1%, 94.2%)	-	-
3888	Pisces-Quad	**98.8%** (96.4%, 100.0%)	**97.1%** (93.1%, 100.0%)	**97.1%** (93.1%, 100.0%)	**95.3%** (90.0%, 100.0%)	**89.6%** (80.3%, 98.9%)	-	-
3890	Pisces-Quad LZ	**100.0%** NA	**97.1%** (93.0%,	**94.3%** (88.7%,	**94.3%** (88.7%,	-	-	-

			100.0%)	99.8%)	99.8%)			
3891	Pisces-Quad LZ	**80.8%** (73.6%, 88.0%)	**77.6%** (70.1%, 85.2%)	**70.8%** (62.3%, 79.3%)	-	-	-	-
Surgical Leads								
3986A	Resume TL	**97.7%** (93.2%, 100.0%)	**91.9%** (82.8%, 100.0%)	-	-	-	-	-
3998	Specify	**96.0%** (91.4%, 100.0%)	**91.9%** (84.7%, 99.0%)	-	-	-	-	-
3999	2x4 Hinged Specify	**100.0%** NA	**100.0%** NA	-	-	-	-	-
39565	Specify	Sample size at 1 year not large enough at this time; survival at 9 months is **100.0%**						

Spinal Cord Stimulation: Extensions

Extensions

From June 2004 to the report cut-off date of October 24, 2008, there were 1,928 extensions were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=1,562) were due to the fact that some patients were subsequently re-implanted with an extension or implanted with 2 or more extensions.

Thirty-eight percent (38%) of the extensions were Model 7489 extensions, 29% were Model 37081 extensions, 15% were Model 37082 extensions, 7% 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 extensions was 39,530 extension months.

Extension Events

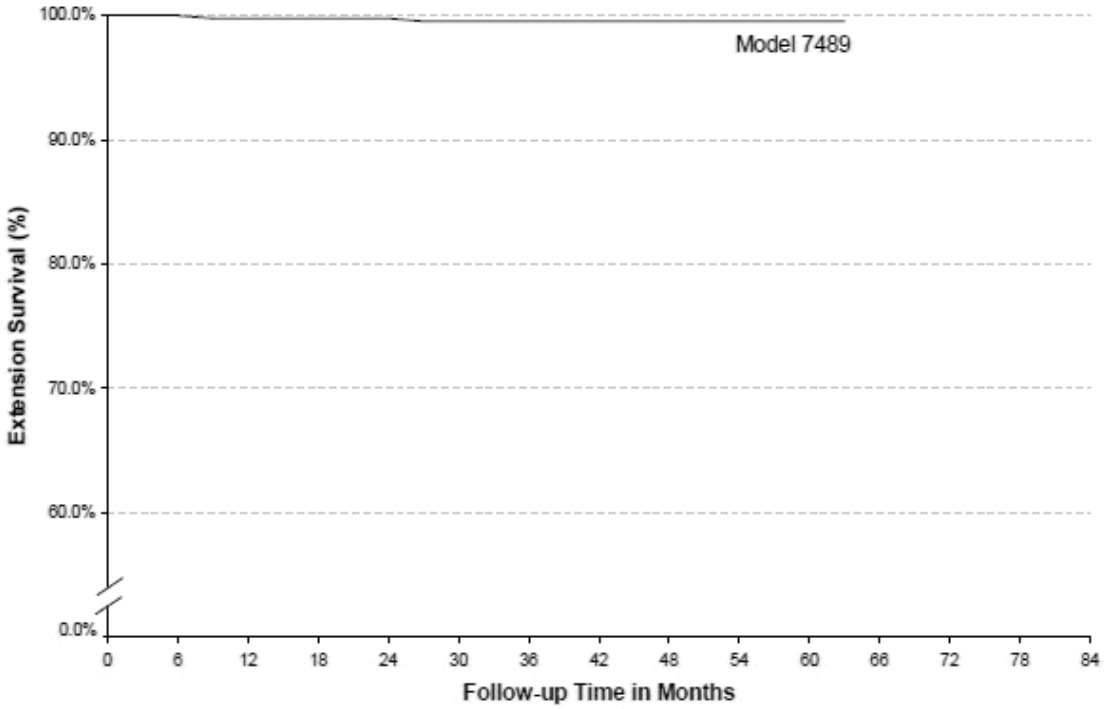
There were 11 extension events requiring surgical intervention with an underlying reported extension etiology. These 11 events included 8 related to an extension fracture and 3 related to extension failure that the physician assigned as extension related.

There were an additional 564 extensions censored in the analysis due to patient lost to follow-up (eg, 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 2 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 2 years.

7489 Extension Family: Survival from Extension Events

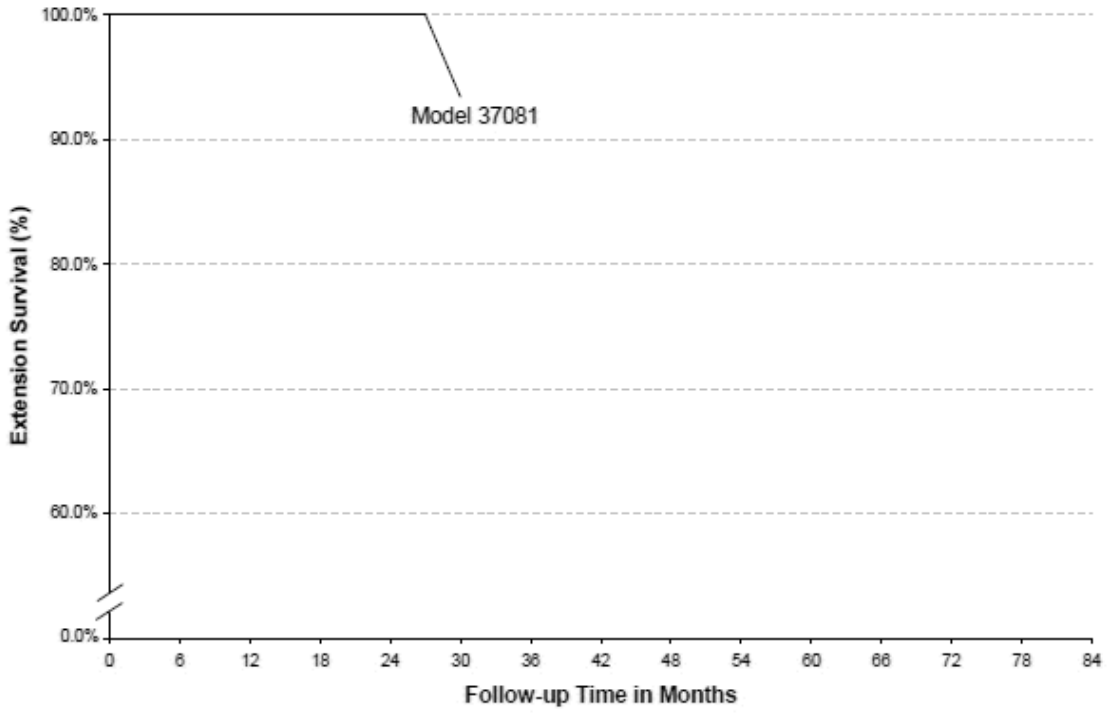


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
7489	Oct 2002	730	440	2	18,885

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	at 63 mo
Survival	99.8%	99.8%	99.5%	99.5%	99.5%	99.5%
Effective Sample Size	486	463	325	150	50	35

37081 Extension Family: Survival from Extension Events

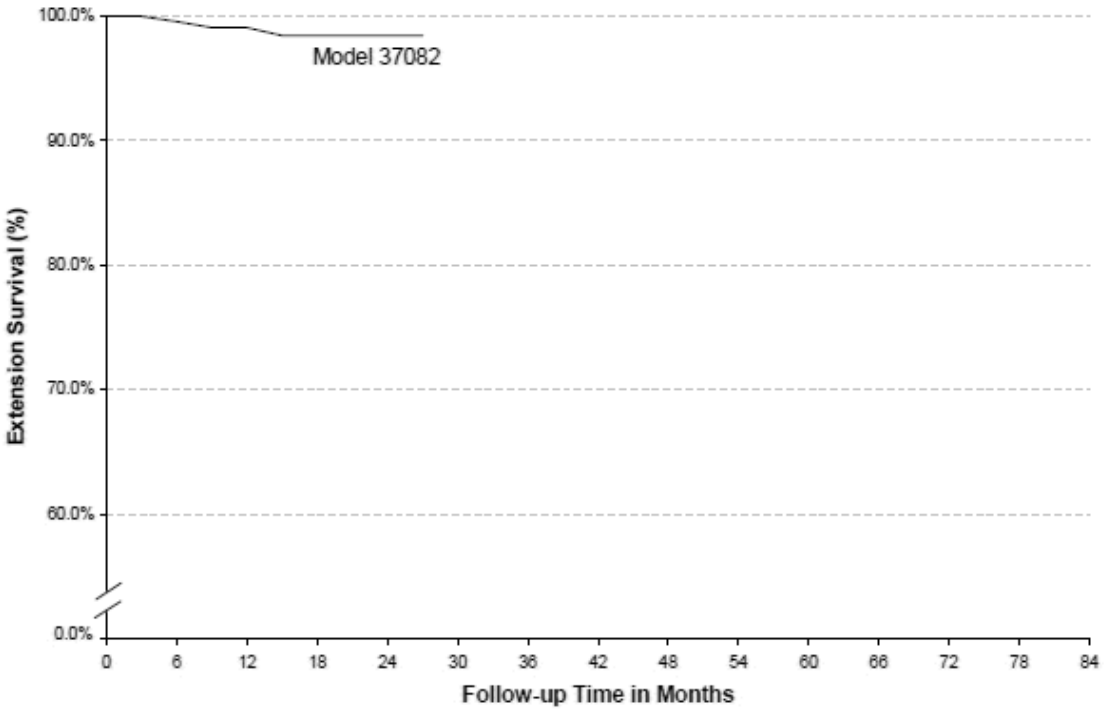


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
37081	Apr 2005	565	448	2	7,433

Time Interval	1 yr	2 yrs	at 30 mo
Survival	100.0%	100.0%	93.4%
Effective Sample Size	317	91	30

37082 Extension Family: Survival from Extension Events

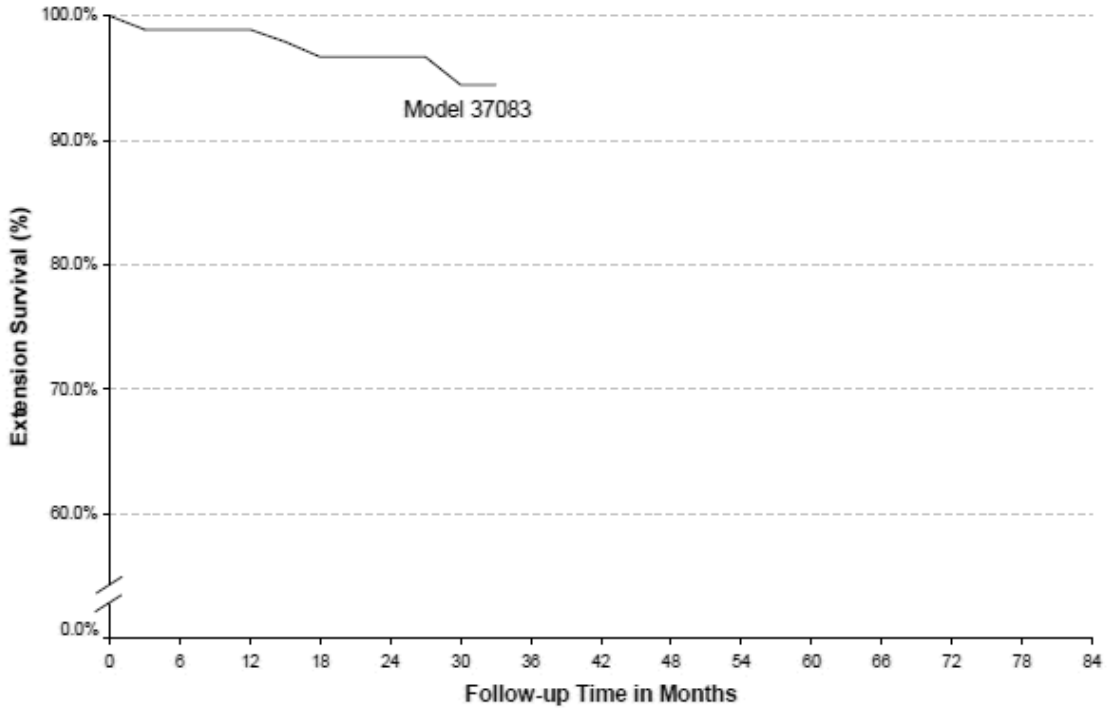


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
37082	Mar 2006	279	223	3	4,063

Time Interval	1 yr	2 yrs	at 27 mo
Survival	99.1%	98.4%	98.4%
Effective Sample Size	184	67	40

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	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
37083	Sep 2005	129	99	4	2,488

Time Interval	1 yr	2 yrs	at 33 mo
Survival	98.9%	96.7%	94.5%
Effective Sample Size	104	57	29

Extension Survival Summary

Extension Survival Summary Table

Extension Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
7489	7489	Oct 2002	730	440	2	18,885
37081	37081	Apr 2005	565	448	2	7,433
37082	37082	Mar 2006	279	223	3	4,063

37083	37083	Sep 2005	129	99	4	2,488

Device Survival Probability (95% Confidence Intervals)

Model Number	Family	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
7489	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%)
37081	37081	**100.0%** NA	**100.0%** NA	-	-	-
37082	37082	**99.1%** (97.8%, 100.0%)	**98.4%** (96.6%, 100.0%)	-	-	-
37083	37083	**98.9%** (96.7%, 100.0%)	**96.7%** (93.0%, 100.0%)	-	-	-