Overview: Introduction

About Neuromodulation Product Performance

Medtronic utilizes 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 2008 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 that are used to guide future product development efforts aimed at improving product reliability and quality, measure progress toward improving product performance and to fulfill regulatory requirements. In addition, data from the ISPR provides information about the treatment practices of physicians using these therapies.

Intrathecal Drug Delivery Systems

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.

Spinal Cord Stimulation Systems

Medtronic spinal cord stimulation systems (spinal cord stimulators, leads, and extensions) for pain indications were added to the registry later. 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.

Centers

The ISPR is collecting data at 50 centers for intrathecal drug delivery systems and 41 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 intrathecal drug delivery

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.

Study Participants

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 six months. Event descriptions were provided by participating investigators 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. In the past, this has taken the form of utilizing passive surveillance data. This year, we are pleased to share the first 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. 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 4,300 patients in an ongoing surveillance study conducted in the United States called the Implantable Systems Performance Registry (ISPR). The Registry includes nearly 12,000 pumps, catheters, spinal cord stimulators, leads, and extensions. Data on other events not directly attributed to product performance is also included in an effort to provide additional information that may impact patient care management. By the end of 2007, the number of devices being followed in the ISPR reached a level where statistical analyses and the average length of follow-up time are informative and provide relatively stable estimates of device survivability.

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.

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.

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.

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PHONE: (800) 328-0810

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Written requests or suggestions can be mailed to:

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ATTN: Todd Weaver, PhD, MPH or Christine Boes, BS
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MINNEAPOLIS, MN 55432

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SynergyPlus+® neurostimulator	Pices-Quad®
Restore® implantable neurostimulator	Resume® TL lead
RestoreAdvanced® neurostimulator	Specify™ lead

Methodology: Event Classification

Event Classification

For analysis purposes, events collected through the Implantable Systems Performance Registry (ISPR) were collapsed into four categories: product performance events, non-product performance events, censoring patient events, and censoring normal battery depletion 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

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. These are not considered to be product performance events and are therefore censored in the analysis. In order for an event to be considered a non-product performance event one of the criteria listed below under Condition One and one of the criteria listed under Condition Two must have been 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

Condition Two (one of the following):

- Device explanted/replaced
- Device explanted/not replaced
- Other surgical intervention
- Therapy abandoned
- Patient expired

Censoring Patient Events

Censoring 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).

Condition One:

- Patient expired
- Patient lost to follow-up

Censoring Normal Battery Depletion Events

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

Condition One:

- Normal battery depletion

Consistency and Accuracy

Consistency and accuracy of ISPR event reporting is monitored at four levels: through logic checks built into the study database as center personnel enter information; through review of each event by the ISPR study team as it is received by Medtronic; review by the Medical Advisor when necessary; and through routine monitoring at each center per 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,

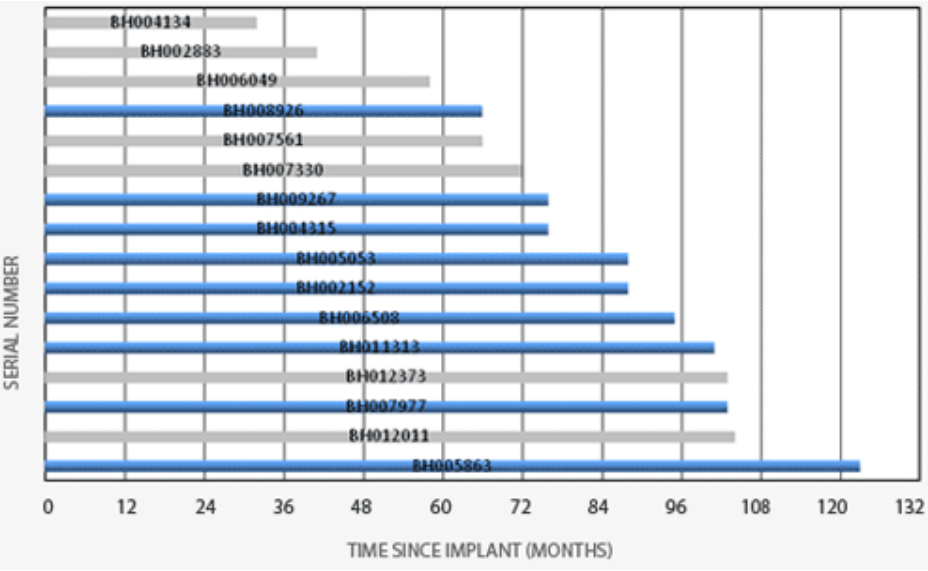
a device survival probability of 90% indicates that at the stated follow-up time, the device had a 10% risk of being removed for incurring a device failure since the time of implant.

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.

Right Censoring

For each right censored event, the device has performed for a period of time, after which its product 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.

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 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.

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 five-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 one was removed due to a product performance event. For the 36-48 month interval, only 15 devices entered the interval and one was removed for a product product performance event (device BH002883). For the 48-60 month interval, 14 devices entered the interval and one 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 five 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%

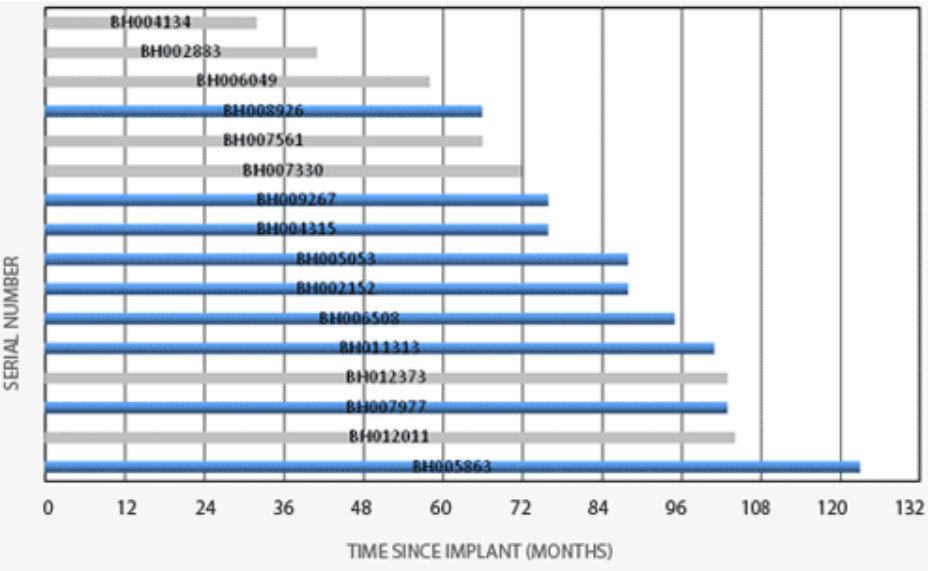
= 81% cumulative device survival at five years.

Effective sample size or devices at risk for each interval is defined as the number of devices with full opportunity to experience a qualifying 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 qualifying 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 six-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 one was right censored (device BH008926) and one 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 six-year cumulative device survival would be the five-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 existing 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 utilizes data from existing devices while appropriately adjusting the device survival curves for the time the device was not actually actively followed in the registry.

Figure 2. Implant times for devices in four 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.

Device Survival

Device survival for this report is evaluated over discrete three-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 together 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 a system level which involves the combination of two 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 one-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. In cases where the center does not explant and/or return a device, physician reported event reason is used for analysis.

Medtronic utilizes 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 utilizes 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 ISPR.

Although returned product analyses are valuable for gaining insight into failure modes, Medtronic Neuromodulation does not utilize this data by itself 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 tables and graphs in this section 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 December 31, 2007. Fifty centers enrolled and contributed patients to the intrathecal drug delivery systems section of the report.

Subjects

As the table below demonstrates, there were 3,256 total intrathecal drug delivery system patients enrolled in the ISPR through December 31, 2007. The table lists three primary indications with corresponding subindications as reported by the physician at implant. Fifty-four percent of patients were implanted with an intrathecal drug delivery system for treatment of nonmalignant pain, followed by 29% for treatment of severe spasticity, and 17% for treatment of malignant pain.

Primary Intrathecal Drug Delivery System Treatment Indications by Patient Type

Primary Treatment Indication*	Total Enrolled Patients (N=3,256)
Nonmalignant Pain	**1,767 (54.3%)**
Failed Back Syndrome	915
Joint Pain/Arthritis	42
Osteoporosis	28
Peripheral Neuropathy	53
Post-Herpetic Neuralgia	7
RSD/Causalgia (CRPS)†	74
Other and/or Unspecified	672
Severe Spasticity	**948 (29.1%)**
Brain Injury	73
Cerebral Palsy	259
Multiple Sclerosis	272
Spinal Cord Injury/Disease	129
Stroke	30
Other and/or Unspecified	208
Malignant Pain	**541 (16.6%)**
Abdominal/Visceral	70
Extremity	31
Head/Neck	21
Pelvic	56
Spine/Back	96
Thoracic	41
Other and/or Unspecified	248
Total Patients	**3,256**

*Refer to product labeling for approved indications.
†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 1506 Implantable Systems Performance Registry (ISPR) intrathecal drug delivery system related events reported between August 2003 and December 31, 2007. Fourteen percent of these events (210/1506) 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 Mean (Median) ±Standard Deviation
Pump Related Events:		
Alarm Anomaly	1	1.3 (1.3) ±NA
Drug Related Cracked Pump Tube	3	47.1 (46.2) ±8.0
Loss of effect	1	35.2 (35.2) ±NA
Motor Stall	21	37.7 (35.9) ±16.8
No Infusion	1	29.5 (29.5) ±NA
Pump Ran Dry	1	61.2 (61.2) ±NA
Unable to Interrogate/Program	1	0.7 (0.7) ±NA
Underinfusion	7	37.3 (33.8) ±17.9
Pump Related Events Sub-Total	36	36.7 (34.6) ±17.9
Catheter Related Events:		
Break/Cut	37	30.5 (17.7) ±32.3
Disconnection	13	25.6 (23.4) ±23.8
Dislodgement	45	13.2 (4.8) ±20.3
Kink/Occlusion	58	32.7 (18.2) ±32.4
Loss of effect	4	12.5 (7.2) ±15.0
Pump Connector Break/Cut	7	42.4 (34.7) ±22.6
Puncture	7	42.0 (40.3) ±36.0
Sheared Catheter Tip	2	77.6 (77.6) ±13.1
Unknown	1	1.7 (1.7) ±NA
Catheter Related Events Sub-Total	174	27.3 (12.4) ±29.9
Product Performance Related Events Total	**210**	**28.9 (20.5) ±28.4**

Non-Product Performance-Related Events

Twenty percent of the ISPR intrathecal drug delivery system events (295/1506) were related to the surgery or procedure, or attributed to the patient or delivery of the therapy, and categorized as non-product performance related events.

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	9	6.6 (1.0) ±11.9
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	1	7.1 (7.1) ±NA
Lumbar Site Related Sub-Total	21	11.7 (2.4) ±21.1
Pump Pocket / Pump Access Related:		
Fluid collection	1	1.1 (1.1) ±NA

Hematoma	1	25.8 (25.8) ±NA
Infection	46	4.4 (2.8) ±5.3
Inflammation	3	1.8 (1.6) ±1.8
Inversion/pump flipping	21	8.2 (5.8) ±9.6
Migration	6	12.0 (9.2) ±9.7
Pain at pump site	6	26.1 (19.3) ±22.6
Pump pocket irregularity	1	32.7 (32.7) ±NA
Pump site incision not healing	2	3.4 (3.4) ±1.1
Seroma	1	4.2 (4.2) ±NA
Skin erosion	10	24.6 (11.4) ±27.5
Trial catheter revision	1	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	9	9.0 (5.1) ±10.4
Pump Pocket Related Sub-Total	111	9.5 (4.4) ±13.8
Surgical/Procedural Related Events Sub-Total	132	9.8 (4.2) ±15.1
Therapy/Patient Related Events:		
Elective Action		
Elective action*	59	36.0 (33.3) ±25.3
Elective Action Related Sub-Total	59	36.0 (33.3) ±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
Device damaged due to unrelated surgery	2	5.5 (5.5) ±3.3
Dissatisfaction with feeling of the pump	1	1.9 (1.9) ±NA
Drug side effects/toxicity	7	25.4 (10.6) ±28.8
Drug withdrawal	2	29.4 (29.4) ±35.3
Frequent refill intervals	1	33.3 (33.3) ±NA
Inability to aspirate/painful aspiration	2	6.1 (6.1) ±1.6
Infection	1	0.5 (0.5) ±NA
Infection (possible)	1	16.8 (16.8) ±NA
Infection (site unknown)	4	5.7 (3.9) ±5.5
Inflammatory mass‡	5	27.8 (34.1) ±13.2
Inflammatory mass (possible)§	5	47.0 (47.1) ±29.7
Loss of effect	23	22.2 (14.9) ±21.6
Malpositioned	3	5.2 (3.6) ±5.4
Myelitis	1	29.2 (29.2) ±NA
No anomaly found by RPA	5	39.4 (45.1) ±21.8
Numbness/weakness in legs	2	32.1 (32.1) ±7.1
Pain/irritation	4	11.0 (2.5) ±17.8
Patient choice	1	23.8 (23.8) ±NA
Patient effects‖	1	49.9 (49.9) ±NA
Patient non-compliance	3	33.2 (27.9) ±22.9
Psychological issue	2	6.0 (6.0) ±1.4
Pump not refilled	1	13.5 (13.5) ±NA
Resolution of symptoms¶	8	32.1 (30.6) ±18.3
Therapy didn't meet patient's expectations	6	23.1 (22.0) ±7.7
Undesirable interaction with other equipment	4	11.8 (11.5) ±9.7
Unrelated surgery	1	16.7 (16.7) ±NA
Wound dehiscence	1	17.7 (17.7) ±NA
Therapy/Patient Effects Related Sub-Total	102	22.5 (17.2) ±20.3
Therapy/Patient Related Events Sub-Total	163	27.3 (22.6) ±23.0
Non-Product Performance Related Events Total	**295**	**19.4 (9.3) ±21.6**

*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.

‡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 documented inflammatory mass, but there was no surgical or histological verification, no clinical criteria, and

no radiographic data available.
‖Physician assigned the event etiology as patient effects. No additional information was available.
¶Patients symptoms were attenuated through other medical therapies or resolution of the underlying disease.

Patient Related Events

Fifty-three percent of the ISPR intrathecal drug delivery system events (806/1506) were due to the patient expiring or becoming lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), and classified as patient related events. No deaths were reported as a result of a device related event or the delivery of infusion therapy.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Patient Related Events*		
Patient Expired†	498	14.2 (6.1) ±17.9
Patient lost to follow-up	308	24.1 (19.1) ±20.6
Patient Related Events Total	**806**	**18.0 (10.0) ±19.5**

*Event summary frequencies are at the patient level, not device level.
†Seventy-three percent of patient deaths occurred in patients with a primary indication of malignant pain.

Battery Depletion Events

Thirteen percent of the ISPR intrathecal drug delivery system events (195/1506) were related to normal battery depletion, and categorized as censoring battery depletion events.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Battery Depletion Events		
Battery Depletion	195	62.1 (61.6) ±13.9
Battery Depletion Events Total	**195**	**62.1 (61.6) ±13.9**

Intrathecal Drug Delivery Systems: Pumps

Pumps

By the report cut-off date, 3,564 pumps were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=3,256) versus pumps were due to the fact that some patients were subsequently re-implanted with a pump one, two, or more times.

Most of the pumps enrolled were either SynchroMed EL (36%) or SynchroMed II (64%), and a small number of pumps were SynchroMed Classic (0.2%). The majority of SynchroMed II pumps were new pumps (pump implanted at the time of enrollment) (1,840/2,274), whereas the majority of SynchroMed EL pumps were existing pumps (retrospective enrollments) (1,106/1,284). Total prospective follow-up time for pumps was 69,577 pump months.

Pump Events

There were 42 pumps that experienced one or more events requiring surgical intervention with an underlying reported pump etiology related to pump function. For pumps enrolled in the ISPR, the current return

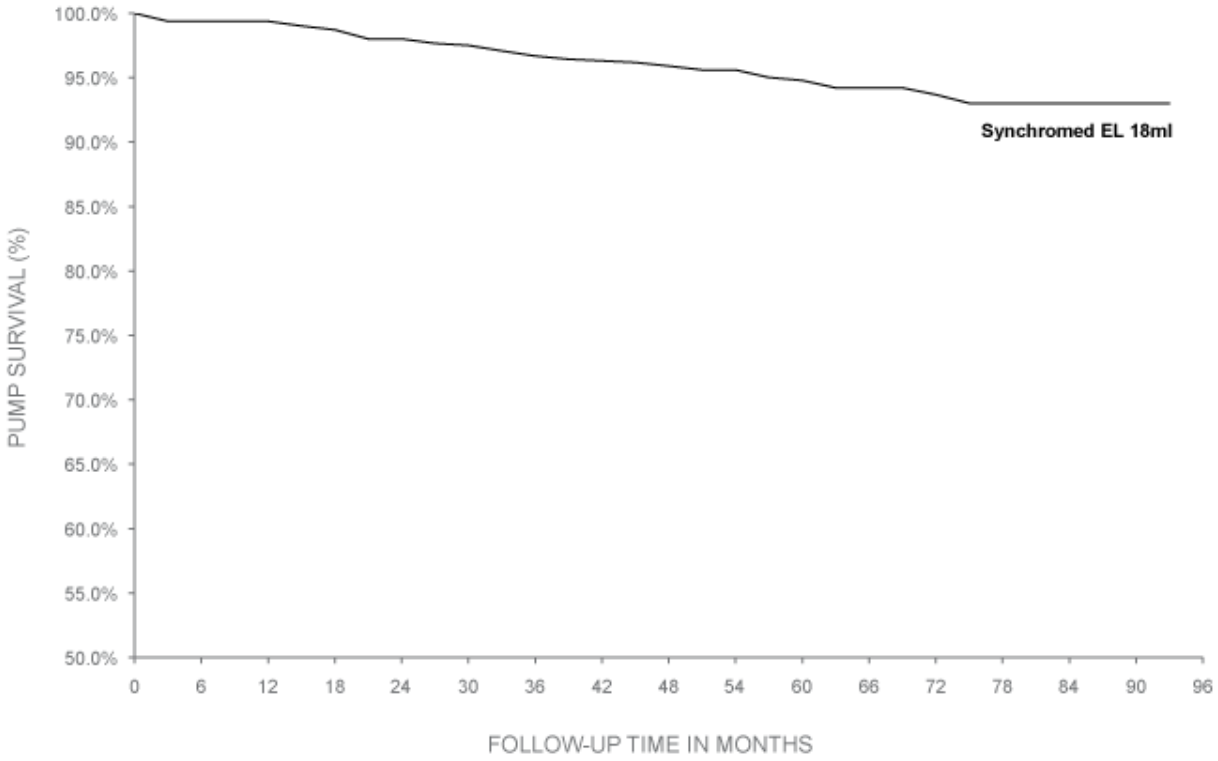
rate to Medtronic RPA was 159/930 (17%). The proportion was based upon the number of pumps received by RPA, divided by the total number of explanted devices plus the total number of pumps in patients who have expired. Thirty-two of the 42 pump events were analyzed by Medtronic RPA: 21 pumps failed related to motor stalls, three pumps had cracked pump tubes, one pump was allowed to run dry, one pump had an alarm anomaly, and six pumps had no anomaly found. The remaining 10 pump events were based upon physician report only (pumps were not returned to Medtronic) and included: 7 events related to pump underinfusion, one event related to no pump infusion, one event related to the inability to interrogate the pump, and one event related to pump therapy loss of effect.

There were an additional 1,250 pumps censored in the analysis as a result of patient expired, patient lost to follow-up, therapy abandoned, or the pump repositioned/explanted attributed to an event unrelated to the pump. In the pumps explanted due to normal battery depletion that were subsequently returned to RPA, none were considered premature battery depletion and were confirmed as reaching an acceptable longevity. 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 2008 Product Performance report included two device models: SynchroMed EL and SynchroMed II.

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.

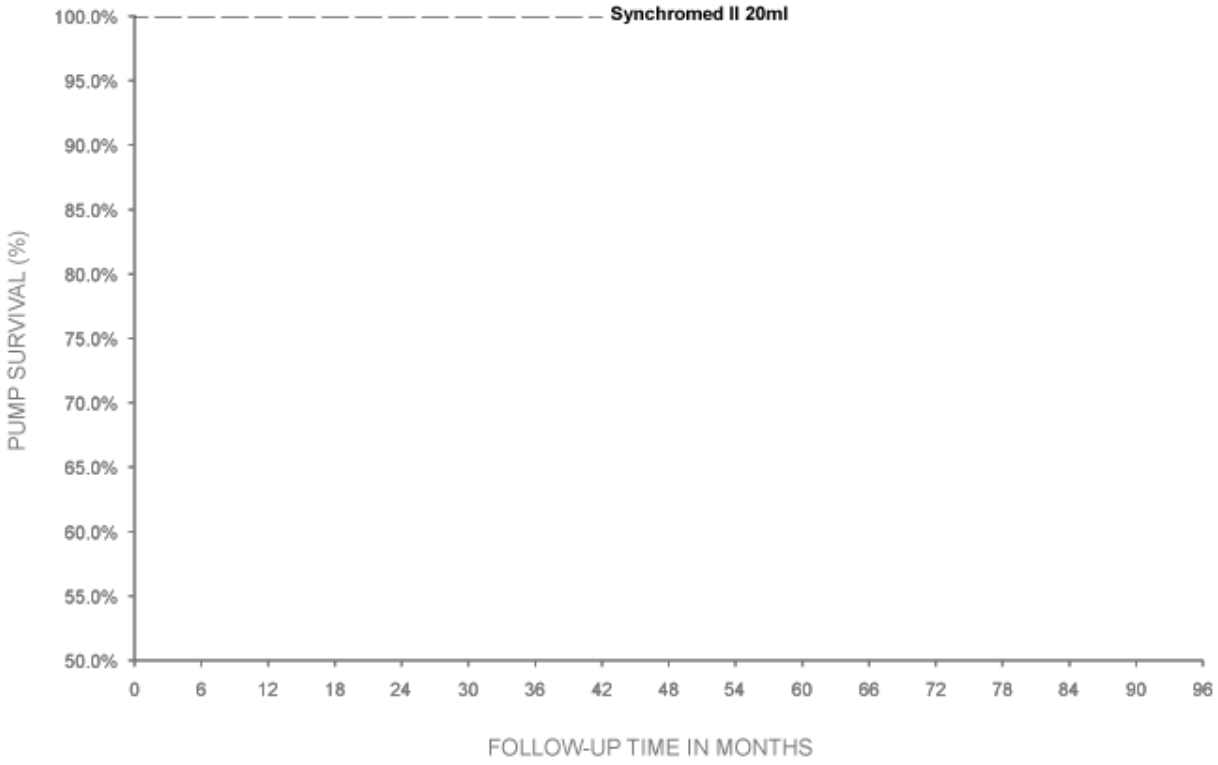
Note: As of August 2007, Medtronic voluntarily discontinued the SynchroMed EL pump in the United States based on broad customer acceptance of the SynchroMed II pump for all approved indications, the high reliability record of the SynchroMed II pump, and the fact that the SynchroMed II pump offers additional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

Pump Characteristics					
Model Name	**FDA Approval Date**	**Pumps Enrolled**	**Pumps Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
SynchroMed EL (18 mL)	Mar 99	1,251	622	31	34,611

Time Interval	1 year	2 years	3 years	4 years	5 years	6 years	7 years
Survival	99.4%	98.0%	96.7%	95.9%	94.8%	93.7%	93.0%

Effective Sample Size	240	488	732	694	404	178	65

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

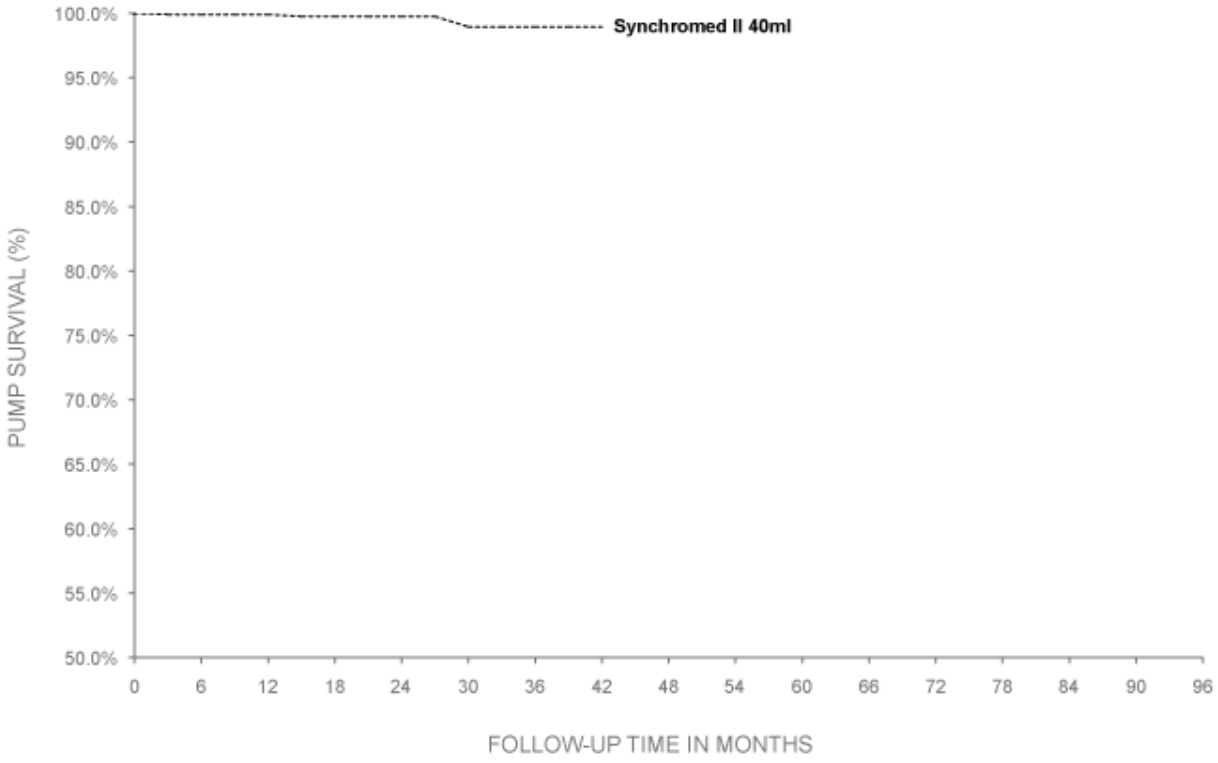


Data are shown if there are at least 20 devices in each 3 month interval.

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 03	871	740	0	14,490

Time Interval	1 year	2 years	3 years
Survival	100%	100%	100%
Effective Sample Size	560	316	90

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 03	1,402	934	4	19,640

Time Interval	1 yr	2 yrs	3 yrs
Survival	99.9%	99.8%	98.9%
Effective Sample Size	747	372	111

Pump Survival Summary

The figures and tables in this section represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each interval. Results at two years indicated 100% survival from pump related events for SynchroMed II 20 ml, 99.8% survival from pump related events for SynchroMed II 40 ml, and 98.0% survival for SynchroMed EL 18 ml pumps.

Longer term results at three years indicated 100% survival from pump related events for SynchroMed II 20 ml, 98.9% survival from pump related events for SynchroMed II 40 ml, and 96.7% survival for SynchroMed EL 18 ml pumps. Additional longer term follow-up data at five and seven years for the SynchroMed EL 18 ml pump demonstrated 94.8% and 93.0% survival, respectively.

Currently, at three years of follow-up, the 95% confidence intervals for the SynchroMed EL and SynchroMed II 40 ml pumps overlap, indicating that survival from pump related events is not statistically significantly different between these pump models. However, Medtronic voluntarily discontinued 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 product performance features beyond those available in the SynchroMed EL pump.

Pump Survival Summary Table

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 99	1,251	622	31	34,611
SynchroMed II (20 mL)	Sep 03	871	740	0	14,490
SynchroMed II (40 mL)	Sep 03	1,402	934	4	19,640

*There were a total of 36 pump related events reported to the ISPR, but only 35 events included in this summary table. The remaining one pump related event occurred in a SynchroMed EL 10 ml pump for which no device survival curve is presented due to there being less than 20 pumps followed at any given interval.

Device Survival Probability (%) and 95% Confidence Intervals							
Model Name	**1 year**	**2 years**	**3 years**	**4 years**	**5 years**	**6 years**	**7 years**
SynchroMed EL (18 mL)	99.4% (98.1%, 100%)	98.0% (96.3%, 99.7%)	96.7% (94.8%, 98.6%)	95.9% (93.9%, 97.9%)	94.8% (92.6%, 97.0%)	93.7% (91.1%, 96.2%)	93.0% (90.2%, 95.9%)
SynchroMed II (20 mL)	100% NA	100% NA	100% NA	-	-	-	-
SynchroMed II (40 mL)	99.9% (99.7%, 100%)	99.8% (99.4%, 100%)	98.9% (97.7%, 100%)	-	-	-	-

Intrathecal Drug Delivery Systems: Catheters

Catheters

By the report cut-off date, 3,409 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=3,564) because a patient may have undergone a pump replacement but utilized 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; therefore, the exact reason for the difference in pump and catheter numbers cannot be determined with certainty. Total prospective follow-up time for catheters was 69,055 catheter months.

A total of 43% of the catheters were Model 8709AA catheters, 15% were Model 8731 catheters, 13% were Model 8709 catheters, 12% were Model 8711 catheters, 5% were Model 8703W catheters, 2% were Model 8709SC catheters, 0.4% were Model 8731SC catheters, and 1% were other or unspecified catheters. An additional 3% were considered catheters revised as designed, (8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit); 4% were considered catheters revised not as designed (a Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit catheters); and 3% 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 174 catheters with events that required surgical intervention with an underlying reported etiology related to the catheter. Of these events, 58 were related to a kink or occlusion, 45 were related to dislodgement, and 37 were related to a break or cut in the catheter. The remaining 34 events include catheter disconnection (n= 13), pump connector break/cut (n=7), catheter puncture (n= 7), loss of therapeutic effect (n=4), sheared catheter tip (n=2), or unknown (n=1).

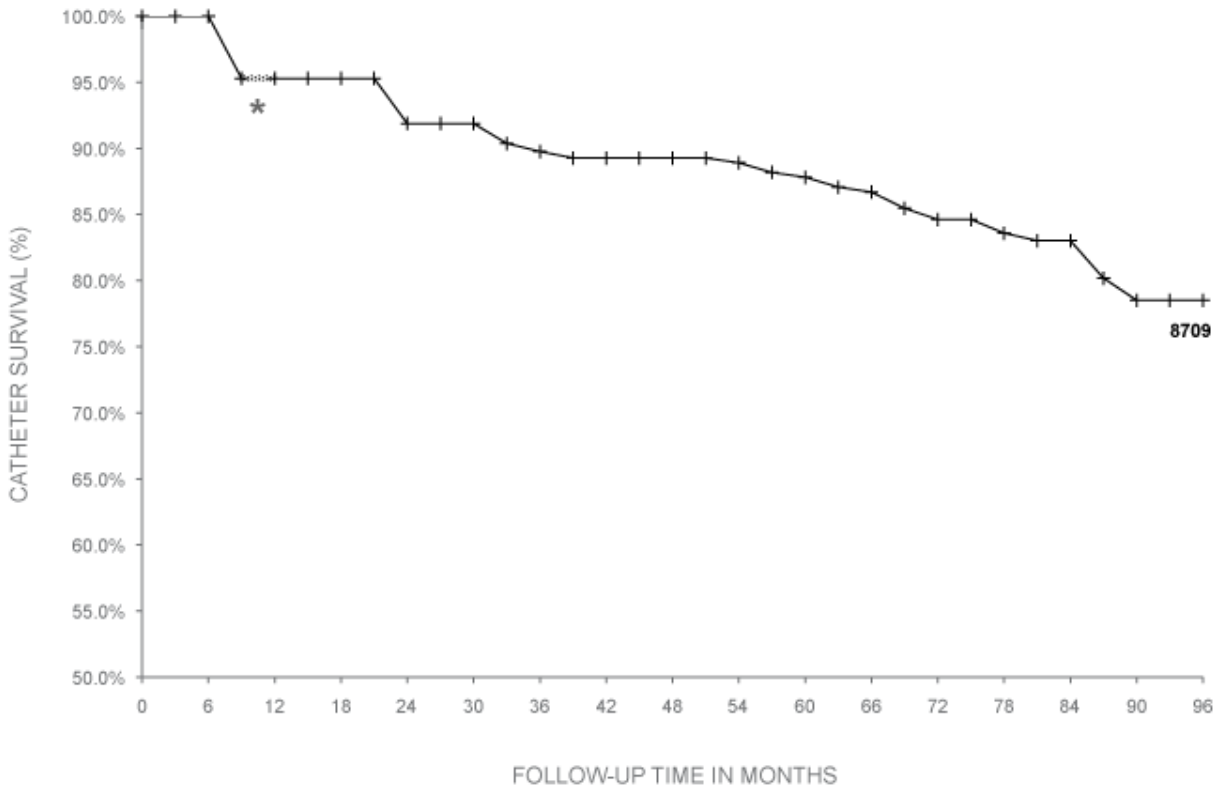
An additional 1,005 catheters were censored in the analysis due to patient expired, patient lost to follow-up (e.

g., patient moved, transferred care to another provider, study withdrawal), therapy abandoned, or catheter repaired/explanted attributed to an event unrelated to the catheter.

Catheter Survival Curves

The 2008 Product Performance report included several catheter models.

Model 8709: Survival from Catheter Events



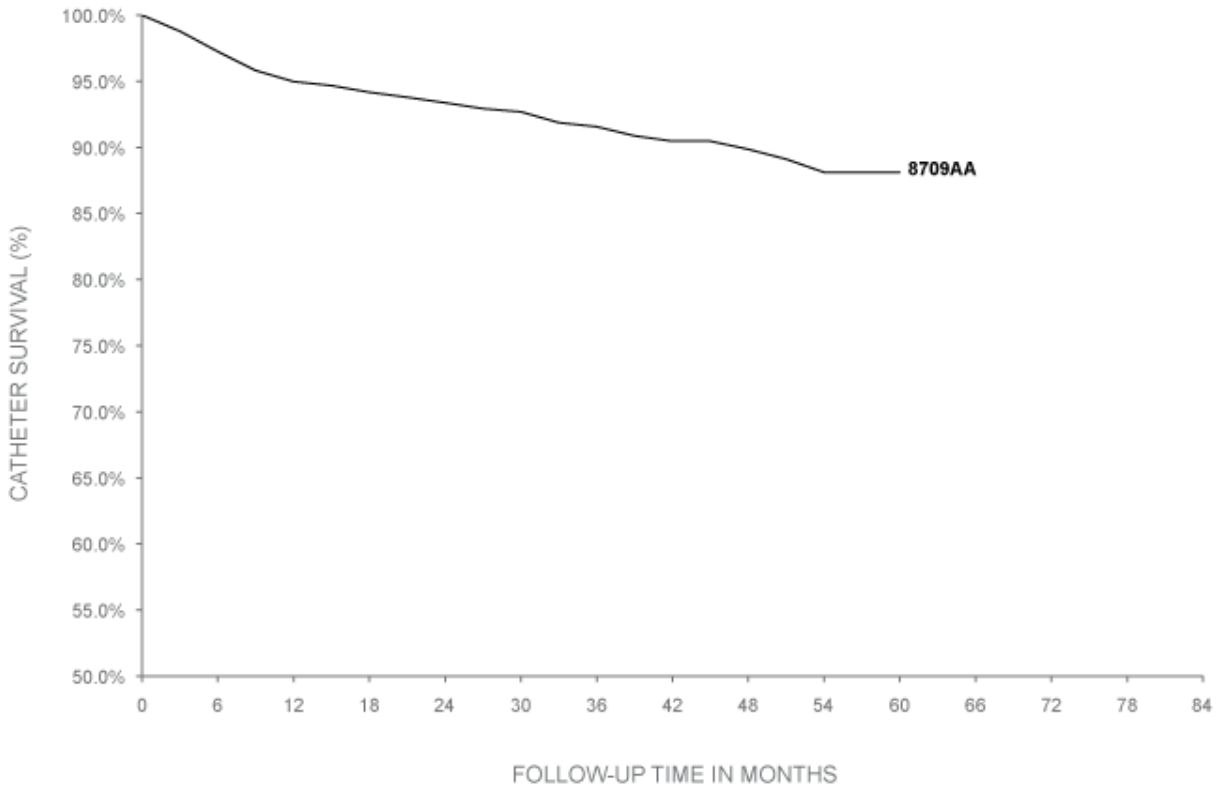
Data are shown if there are at least 20 devices in each 3 month interval.

*A sample size of 19 catheters, rather than 20, was allowed for the 9-12 month interval for the Model 8709 catheter to enable generation of a continuous survival curve. Due to left censoring of existing devices, the sample size increases at two years.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8709	May 98	454	360	29	13,574

Time Interval	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
Survival	95.3%	91.9%	89.8%	89.3%	87.8%	84.6%	83.0%	78.5%
Effective Sample Size	19	83	146	221	245	203	134	63

Model 8709AA: Survival from Catheter Events

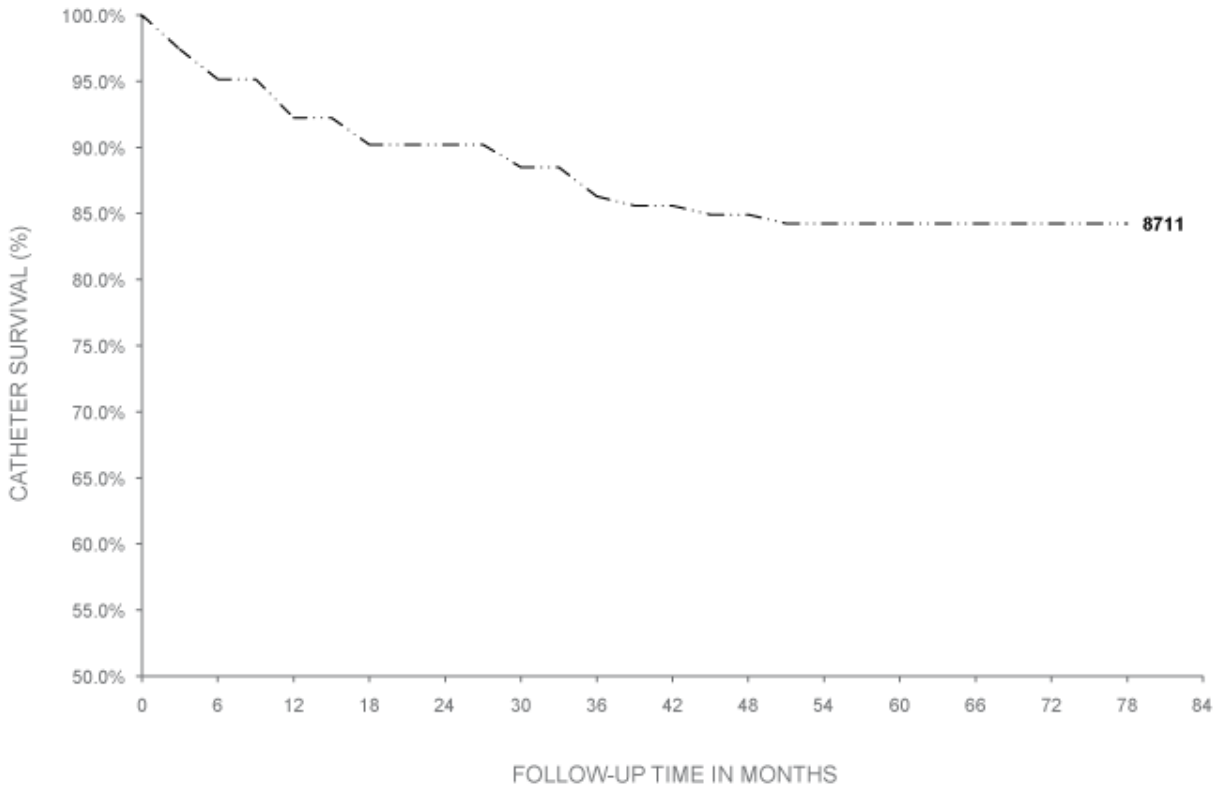


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8709AA	Jun 01	1,468	932	63	23,589

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
Survival	95.0%	93.4%	91.6%	89.9%	88.1%
Effective Sample Size	683	453	299	147	37

Model 8711: Survival from Catheter Events

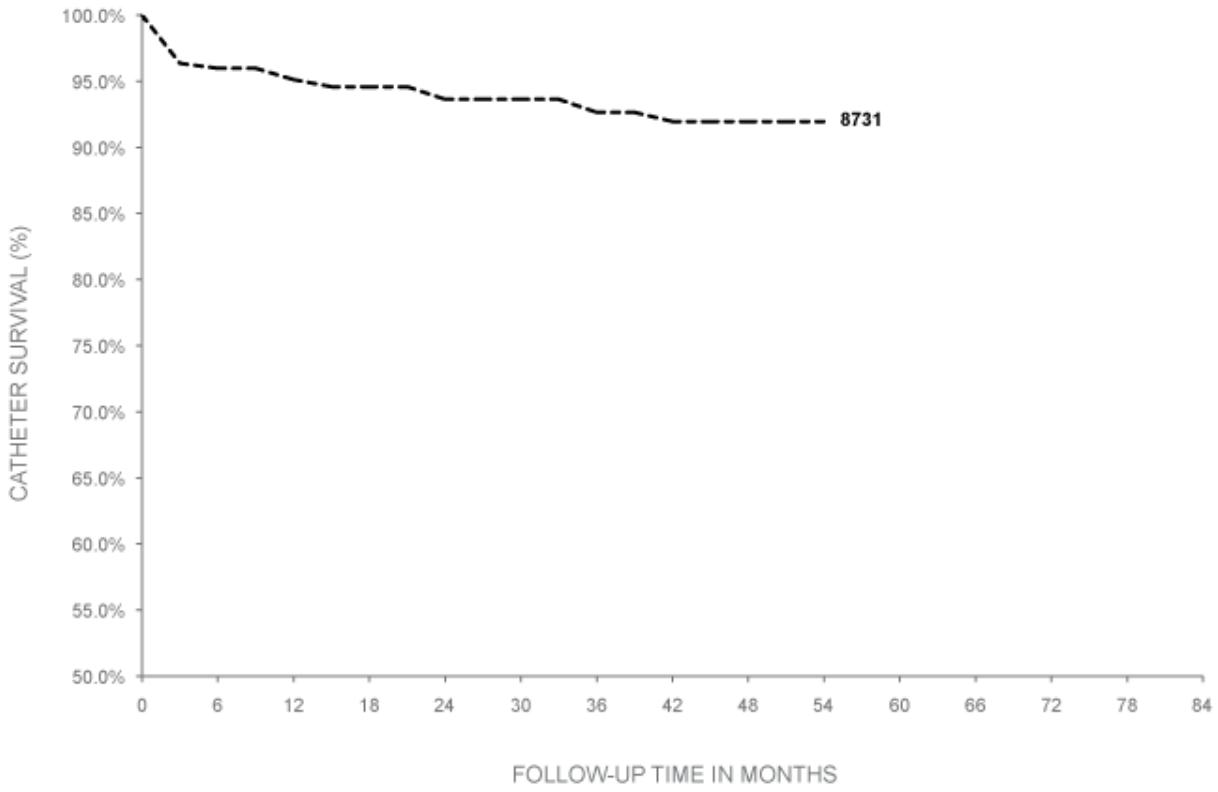


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8711	Oct 99	393	332	23	8,051

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs
Survival	92.2%	90.2%	86.3%	84.9%	84.2%	84.2%
Effective Sample Size	130	99	121	122	89	39

Model 8731: Survival from Catheter Events

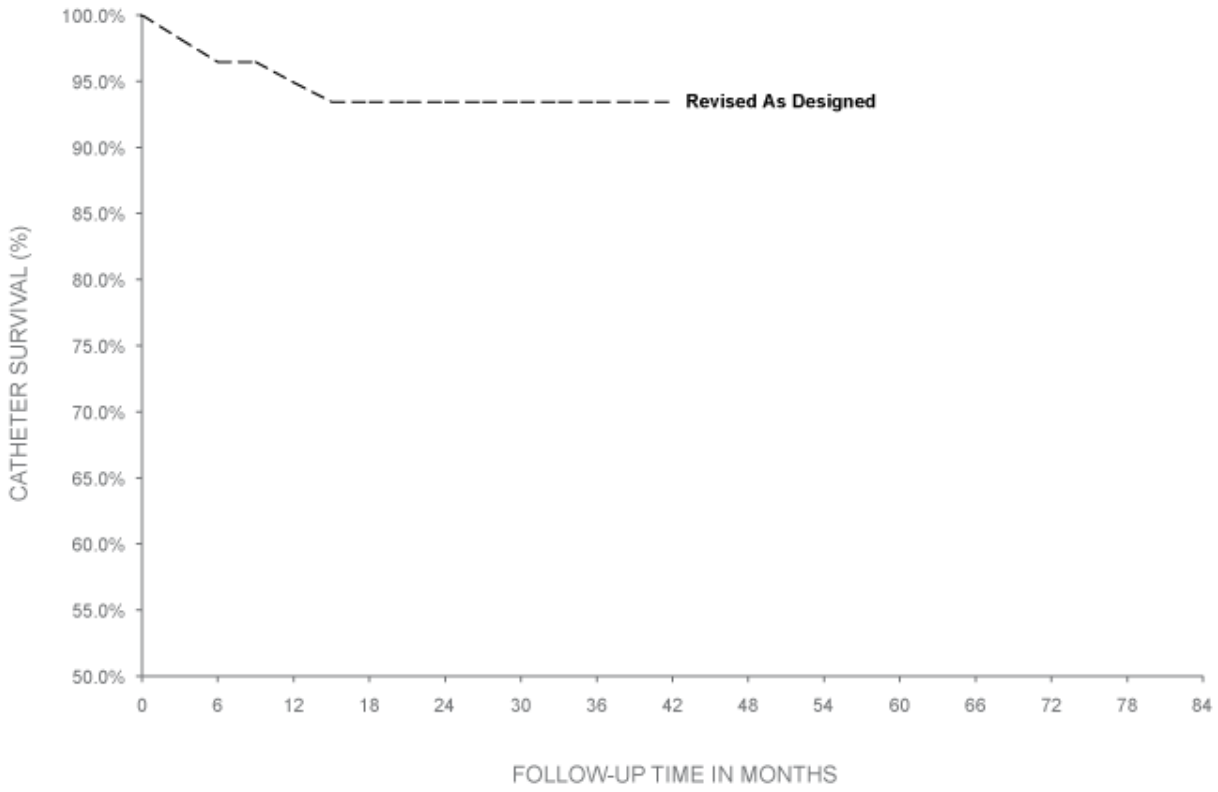


Data are shown if there are at least 20 devices in each 3 month interval.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
8731	Oct 02	509	403	20	11,874

Time Interval	1 yr	2 yrs	3 yrs	4 yrs
Survival	95.1%	93.6%	92.6%	92.0%
Effective Sample Size	334	299	189	86

Revised As Designed Catheter Survival Curve



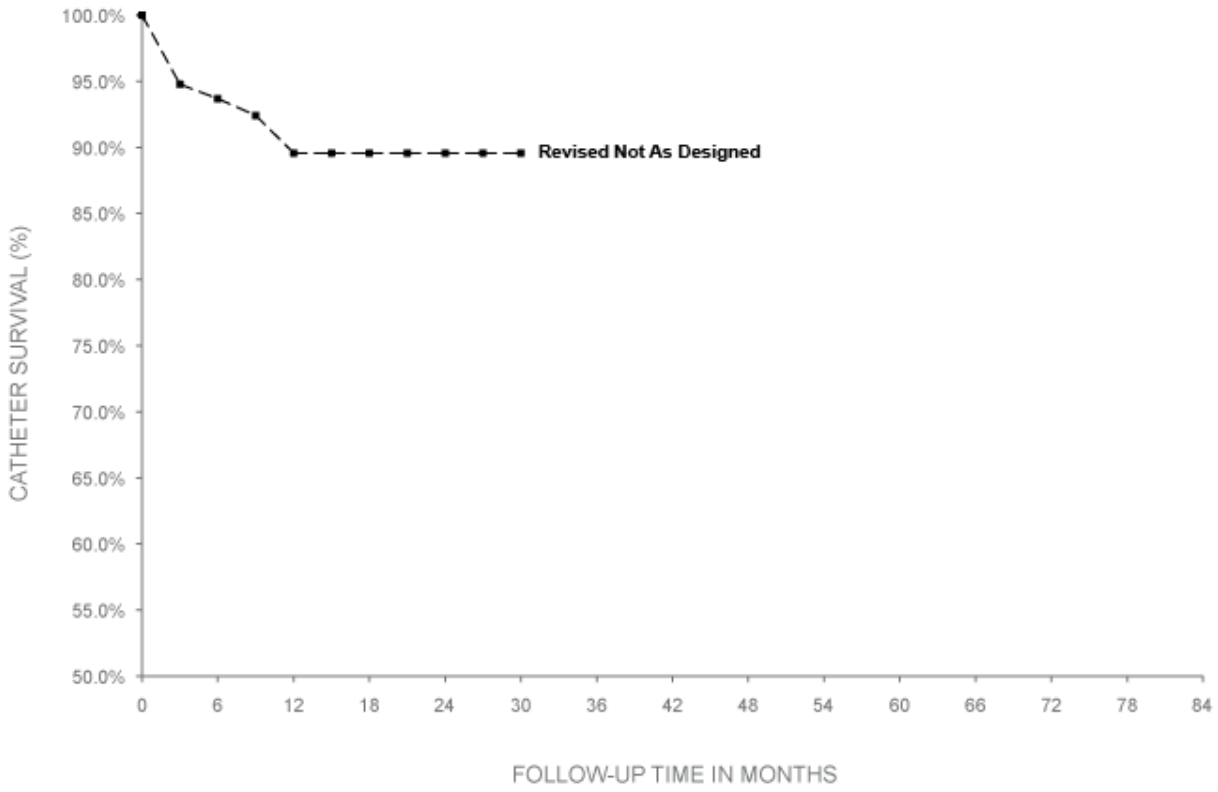
Data are shown if there are at least 20 devices in each 3 month interval.

Note: Catheters revised as designed were Model 8731 catheters that were repaired with an 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 02	93	80	4	2,149

Time Interval	1 yr	2 yr	3 yr
Survival	94.9%	93.4%	93.4%
Effective Sample Size	62	50	31

Revised Not As Designed Catheters: Survival from Catheter Events



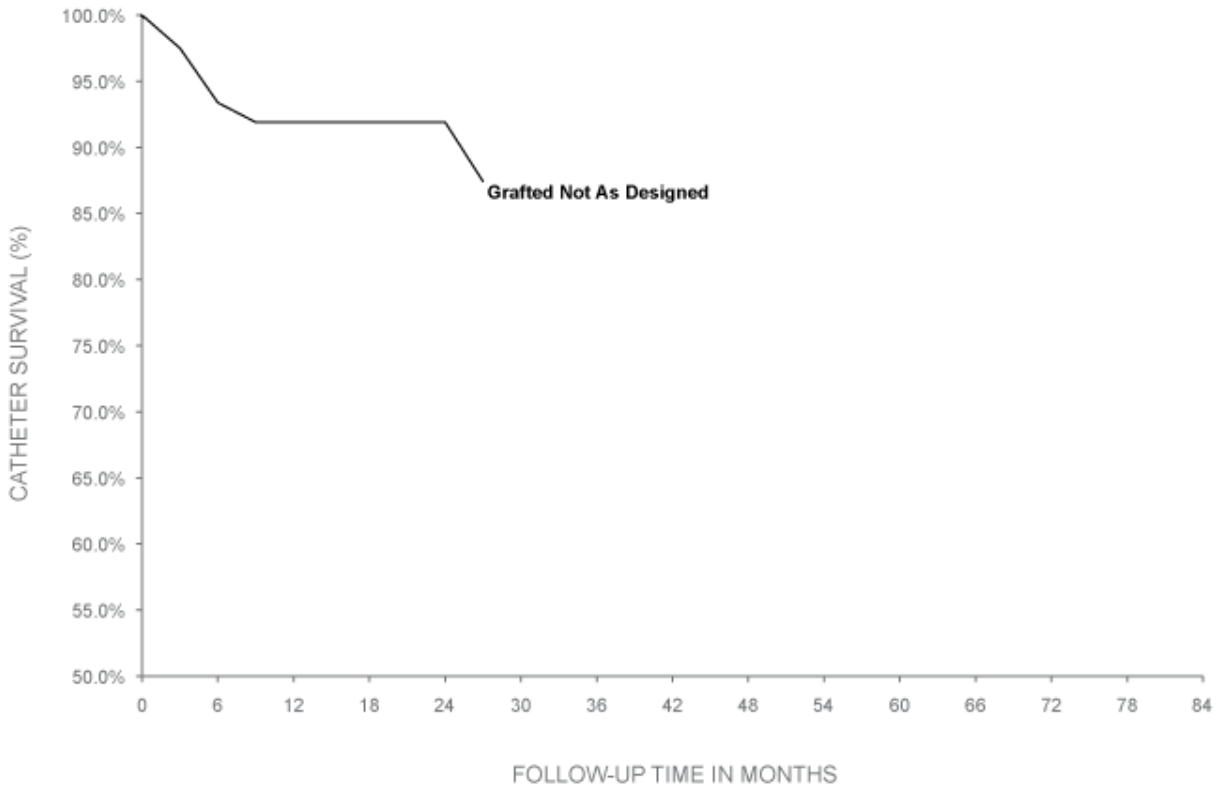
Data are shown if there are at least 20 devices in each 3 month interval.

Note: Catheters revised not as designed were Medtronic non-8731 catheters that were repaired with an 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	N/A	121	105	11	2,067

Time Interval	1 yr	2 yrs
Survival	89.6%	89.6%
Effective Sample Size	65	31

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: Catheters grafted not as designed were catheters involved the ad-hoc assembly of components other than a Medtronic repair kit or brand new catheter.

Catheter Characteristics					
Model Number	**FDA Approval Date**	**Catheters Enrolled**	**Catheters Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Grafted Not As Designed	N/A	97	78	9	1,734

Time Interval	1 yr	2 yr
Survival	91.9%	91.9%
Effective Sample Size	56	26

Catheter Survival Summary

The figures and tables in this section represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each interval, unless otherwise noted. Results at one year demonstrated 95.3% survival from catheter related events for Model 8709, 95.0% for Model 8709AA, 92.2% survival for Model 8711, 95.1% survival for Model 8731, 94.9% survival for catheters revised as designed, 89.6% survival for catheters revised not as designed, and 91.9% for catheters grafted not as designed.

Results at two years indicated 91.9% survival from catheter related events for Model 8709, 93.4% for Model 8709AA, 90.2% survival for Model 8711, 93.6% survival for Model 8731, 93.4% survival for catheters revised as designed, 89.6% survival for catheters revised not as designed, and 91.9% for catheters grafted not as designed.

Longer term follow-up data at three years demonstrated 89.8% survival for Model 8709, 91.6% survival for Model 8709AA, 86.3% survival for Model 8711, 92.6% for Model 8731, and 93.4% survival for catheters revised as designed. The follow-up data at four years further demonstrated 89.3% survival for Model 8709, 89.9% for Model 8709AA, 84.9% survival for Model 8711, and 92.0% survival for Model 8731. Longer term follow-up data at five years for Model 8709, 8709AA and Model 8711 catheters demonstrated 87.8%, 88.1% and 84.2% survival, respectively. Additional longer term follow-up data at six years for Model 8709 and Model 8711 catheters demonstrated 84.6% and 84.2% survival, respectively.

Currently, at 24 months of follow-up, the 95% confidence intervals for models 8709, 8709AA, 8711, 8731,

catheters revised as designed, catheters revised not as designed, and catheters grafted not as designed overlap, indicating that survival from catheter related events is not statistically significantly different between these catheter models.

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

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

Catheter Survival Summary Table

Catheter Characteristics

Model Number	FDA Approval Date	Catheters Enrolled	Catheters Active in Study	Device Events*	Cumulative Months of Follow-up
8709	May 98	454	360	29	13,574
8709AA	Jun 01	1,468	932	63	23,589
8711	Oct 99	393	332	23	8,051
8731	Oct 02	509	403	20	11,874
Revised As Designed	Oct 02	93	80	4	2,149
Revised Not As Designed	N/A	121	105	11	2,067
Grafted Not As Designed	N/A	97	78	9	1,734

*There were a total of 174 catheter related events reported to the ISPR, but only 159 events included in this summary table. The remaining 15 catheter related events occurred in catheter models for which no device survival curves are presented due to there being less than 20 catheters followed at any given interval.

Device Survival Probability (%) and 95% Confidence Intervals

Model Number	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs
8709	95.3% (86.1%, 100%)	91.9% (82.2%, 100%)	89.8% (80%, 99.5%)	89.3% (79.5%, 99%)	87.8% (78.1%, 97.5%)	84.6% (75%, 94.2%)	83% (73.4%, 92.6%)	78.5% (68.7%, 88.3%)
8709AA	95.0% (93.4%, 96.5%)	93.4% (91.5%, 95.2%)	91.6% (89.3%, 93.8%)	89.9% (87%, 92.7%)	88.1% (84.4%, 91.8%)			
8711	92.2% (88%, 96.4%)	90.2% (85.2%, 95.2%)	86.3% (80.4%, 92.2%)	84.9% (78.8%, 91%)	84.2% (78%, 90.4%)	84.2% (78%, 90.4%)		
8731	95.1% (92.3%, 97.9%)	93.6% (90.6%, 96.7%)	92.6% (89.3%, 96%)	92.0% (88.4%, 95.5%)				
Revised As Designed	94.9% (89.2%, 100%)	93.4% (87.1%, 99.8%)	93.4% (87.1%, 99.8%)					
Revised Not As Designed	89.6% (82.9%, 96.2%)	89.6% (82.9%, 96.2%)						

Grafted Not As Designed	91.9% (85.5%, 98.3%)	91.9% (85.5%, 98.3%)

Spinal Cord Stimulation: Study Participants

Study Participants

Centers

The tables and graphs in this section 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 December 31, 2007. Forty-one centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Subjects

Of the 1,096 total spinal cord stimulation patients enrolled in the ISPR, 48.6% were implanted with a spinal cord stimulation system for the treatment of failed back, 38.4% for treatment of other indications, and 13.0% for treatment of complex regional pain syndrome (CRPS).

Primary Spinal Cord Stimulation Treatment Indications by Patient Type

Primary Treatment Indication*	Total Enrolled Patients (N=1096)
Failed Back	**533 (48.6%)**
Arachnoiditis	23
Failed Back Syndrome	191
Multiple Back Operations	61
Post-laminectomy Pain	253
Unsuccessful Disc Surgery	5
Other	**421 (38.4%)**
Degenerative Disc Disease	27
Epidural Fibrosis	2
Radicular Pain Syndrome	118
Other Chronic Pain	274
CRPS	**142 (13.0%)**
Complex Regional Pain Syndrome Type I	122
Complex Regional Pain Syndrome Type II	20
Total Patients	1,096

*Refer to product labeling for approved indications.

Spinal Cord Stimulation: Events Summary

Events Summary

Product Performance Related Events

There were 466 spinal cord stimulation system events reported between June 2004 and December 31, 2007. Twenty-eight percent of these events (131/466) 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	1	38.1 (38.1) ±NA
Neurostimulator Related Events Sub-Total	4	27.7 (29.6) ±20.9
Lead Related Events		
Damaged electrodes	1	71.8 (71.8) ±NA
Disconnection	1	0.9 (0.9) ±NA
Fracture	26	18.9 (15.9) ±11.7
Migration/dislodgement	57	13.6 (4.4) ±17.6
Undesirable change in stimulation	39	9.8 (3.9) ±14.5
Lead Related Events Sub-Total	124	13.9 (6.6) ±16.5
Extension Related Events		
Extension failure	2	4.4 (4.4) ±4.3
Fracture	1	12.9 (12.9) ±NA
Extension Related Events Sub-Total	3	7.2 (7.4) ±5.8
Product Performance Related Events Total	**131**	**14.2 (7.1) ±16.6**

Non-Product Performance-Related Events

Twenty-five percent of the Implantable Systems Performance Registry (ISPR) neurostimulation events (117/466) were related to the surgery or procedure; or attributed to the patient or delivery of the therapy and categorized as non-product performance related events.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Surgical/Procedural Related Events		
Neurostimulator Pocket/Access Related		
Infection	14	4.4 (1.9) ±5.0
Migration/inversion	9	20.3 (18.4) ±17.3
Pain at site	7	7.5 (8.2) ±4.1
Seroma	2	16.8 (16.8) ±10.3
Skin erosion	1	3.2 (3.2) ±NA
Neurostimulator Pocket Related Sub-Total	33	10.1 (5.5) ±11.9
Lead Tract Related		
Infection	2	2.7 (2.7) ±2.3
Pain at site	5	10.6 (10.5) ±4.5
Lead Tract Related Sub-Total	7	8.3 (8.9) ±5.4
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	41	9.8 (6.1) ±10.8
Therapy/Patient Related Events		
Therapy/Patient Effects		
Corrective surgery	2	15.3 (15.3) ±9.6
Infection	2	10.8 (10.8) ±4.6
Leg pain/weakness	1	28.6 (28.6) ±NA
Loss of effect	6	14.5 (15.0) ±12.5
Needed expanded coverage	2	19.0 (19.0) ±11.8
Pain/irritation	1	17.6 (17.6) ±NA
Patient choice	1	20.9 (20.9) ±NA

Psychological issue	3	15.6 (17.3) ±9.3
Resolution of symptoms	2	16.8 (16.8) ±9.2
Seroma	1	13.2 (13.2) ±NA
Skin erosion	3	13.5 (6.7) ±14.6
Therapy didn't meet patient's expectations	50	15.1 (11.4) ±11.5
Undesirable interaction with other equipment	2	4.9 (4.9) ±4.1
Therapy/Patient Related Events Sub-Total	76	15.0 (12.3) ±10.8
Non-Product Performance Related Events Total	**117**	**13.2 (9.8) ±11.1**

Patient Related Events

Twenty-five percent of the ISPR neurostimulation events (115/466) were due to the patient expiring or becoming lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), and classified as patient related events. No deaths were reported as a result of a device related event or the delivery of neurostimulation therapy.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Patient Related Events*		
Patient Expired	16	16.3 (13.2) ±14.9
Patient lost to follow-up	99	15.3 (11.4) ±14.0
Patient Related Events Total	**115**	**15.4 (11.8) ±14.0**

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

Battery Depletion Events

Twenty-two percent of the ISPR neurostimulation events (103/466) were related to normal battery depletion, and categorized as censoring battery depletion events.

EVENTS	NO.	TIME TO EVENT IN MONTHS Mean (Median) ±Standard Deviation
Battery Depletion Events Total		
Battery Depletion	103	26.6 (24.2) ±13.2
Battery Depletion Events Total	**103**	**26.6 (24.2) ±13.2**

Spinal Cord Stimulation: Spinal Cord Stimulators

Spinal Cord Stimulators

By the report cut-off date, 1218 spinal cord stimulators were followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of patients (n=1096) versus spinal cord stimulators were due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted.

Thirty-seven (37%) percent of the spinal cord stimulators were Synergy, 32% were Restore, 8% were RestoreAdvanced, 7% were PrimeAdvanced, 7% were Itrel 3, and a smaller number were RestorePrime (4%), Synergy Versitrel (2%), or SynergyPlus+ (2%). Total prospective follow-up time for spinal cord stimulators was 19,502 spinal cord stimulator months.

Spinal Cord Stimulator Events

There were four spinal cord stimulator events requiring surgical intervention with an underlying etiology related

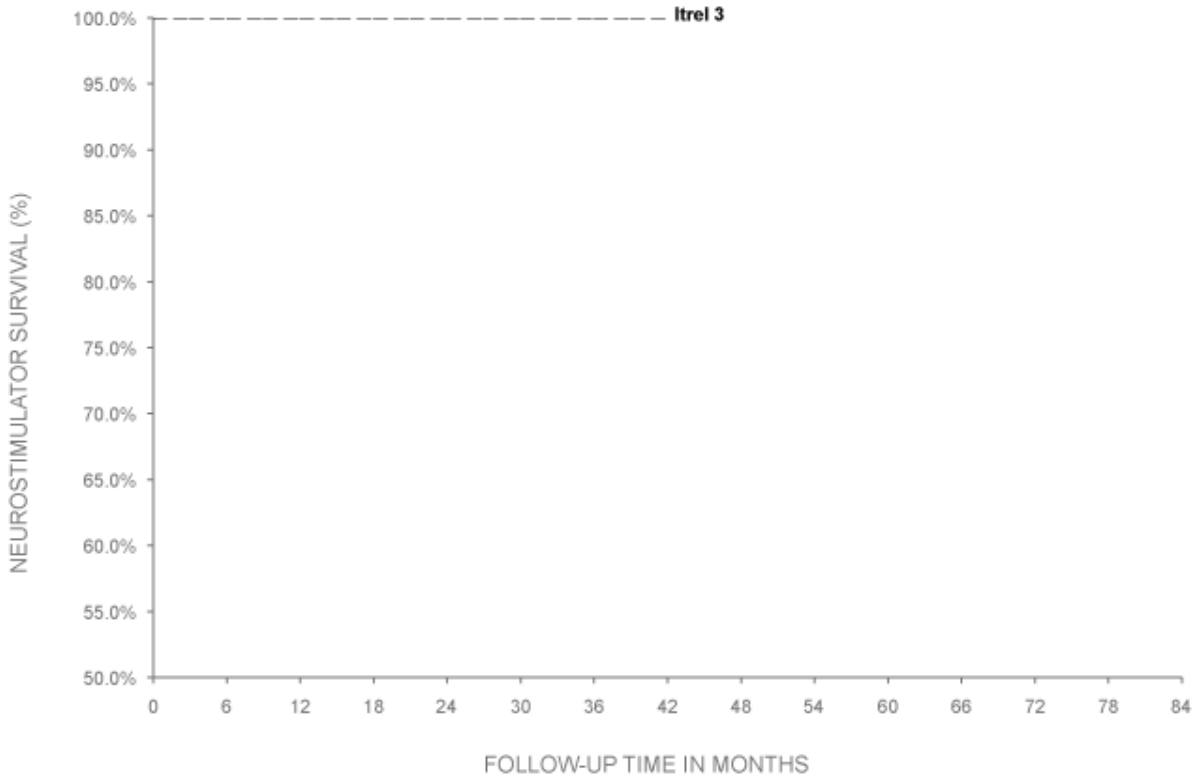
to the spinal cord stimulator. For spinal cord stimulators enrolled in the ISPR, the current return rate to Medtronic RPA was 25/223 (11%). The proportion was based upon the number of ISPR spinal cord stimulators received by RPA, divided by the total number of explanted devices plus the total number of spinal cord stimulation devices in patients who have expired. One of the four spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining three spinal cord stimulator events the physician assigned as device related and included one device with loss of therapeutic effect, one device recharging issue, and one device with an undesirable change in stimulation.

There were an additional 337 spinal cord stimulators censored in the analysis due to patient lost to follow-up, patient expired, therapy abandoned, or spinal cord stimulator repositioned/explanted attributed to an event unrelated to the spinal cord stimulator.

Spinal Cord Stimulator Survival Curves

The 2008 Product Performance Report included six device models: Itrel, Synergy, RestorePrime, PrimeAdvanced, Restore and RestoreAdvanced.

Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

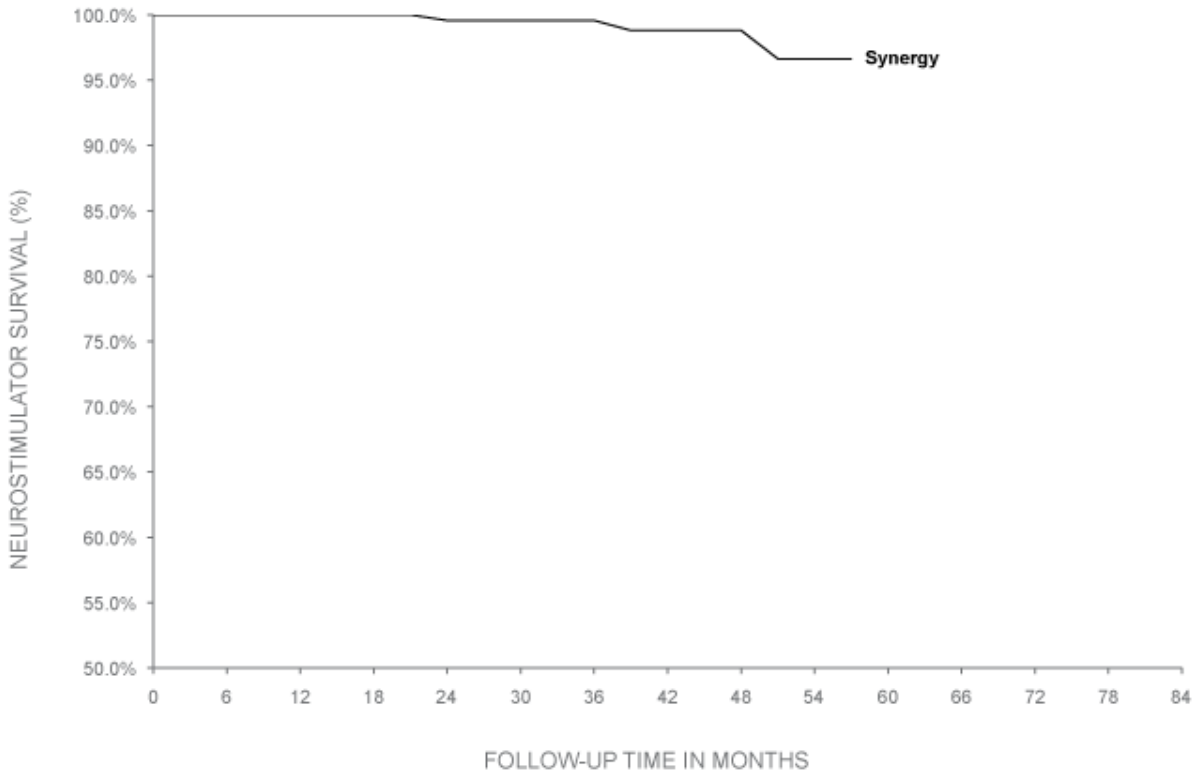


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Itrel 3	Aug 95	85	51	0	1,814

Time Interval	1 yr	2 yrs	3 yrs
Survival	100%	100%	100%
Effective Sample Size	45	38	30

Model 7427 Synergy: Survival from Spinal Cord Stimulator Events

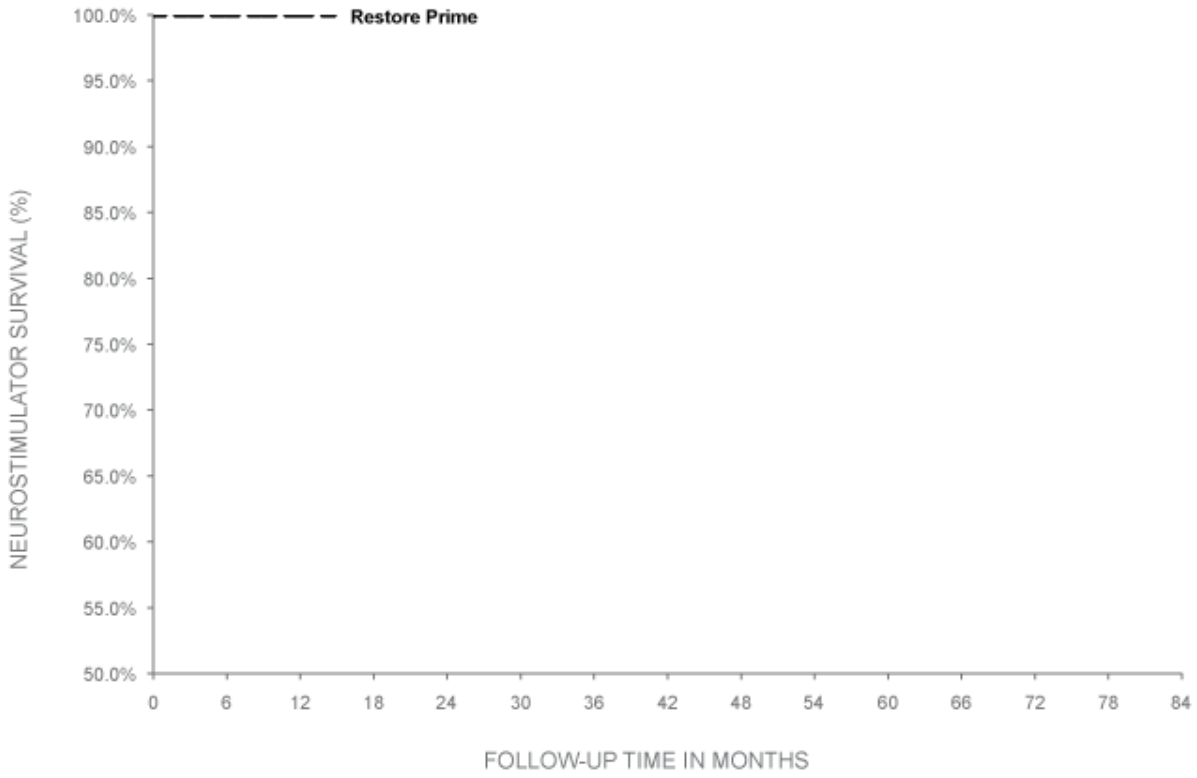


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Synergy	Nov 99	454	282	3	9,460

Time Interval	1 yr	2 yr	3 yr	4 yr
Survival	100%	99.6	99.6	98.8
Effective Sample Size	269	233	145	58

Model 37701 RestorePrime: Survival from Spinal Cord Stimulator Events

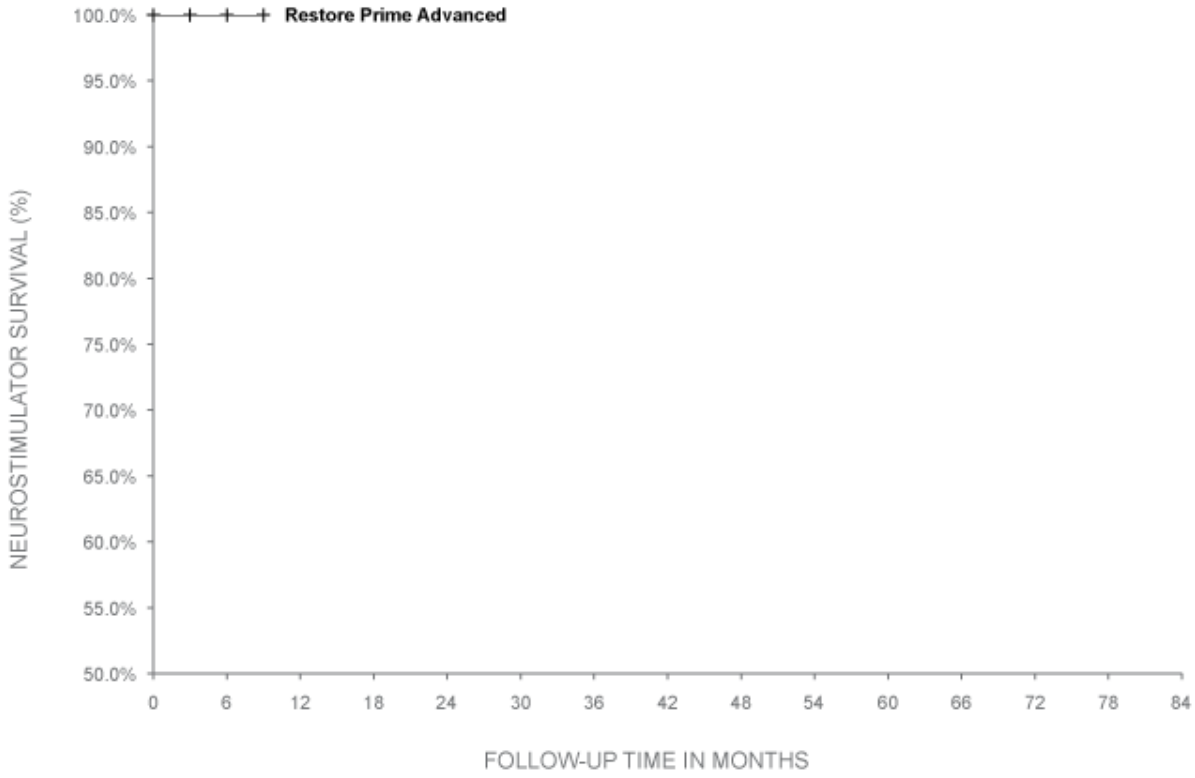


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
RestorePrime	Apr 05	44	32	0	565

Time Interval	1 yr
Survival	100%
Effective Sample Size	33

Model 37702 PrimeAdvanced: Survival from Spinal Cord Stimulator Events

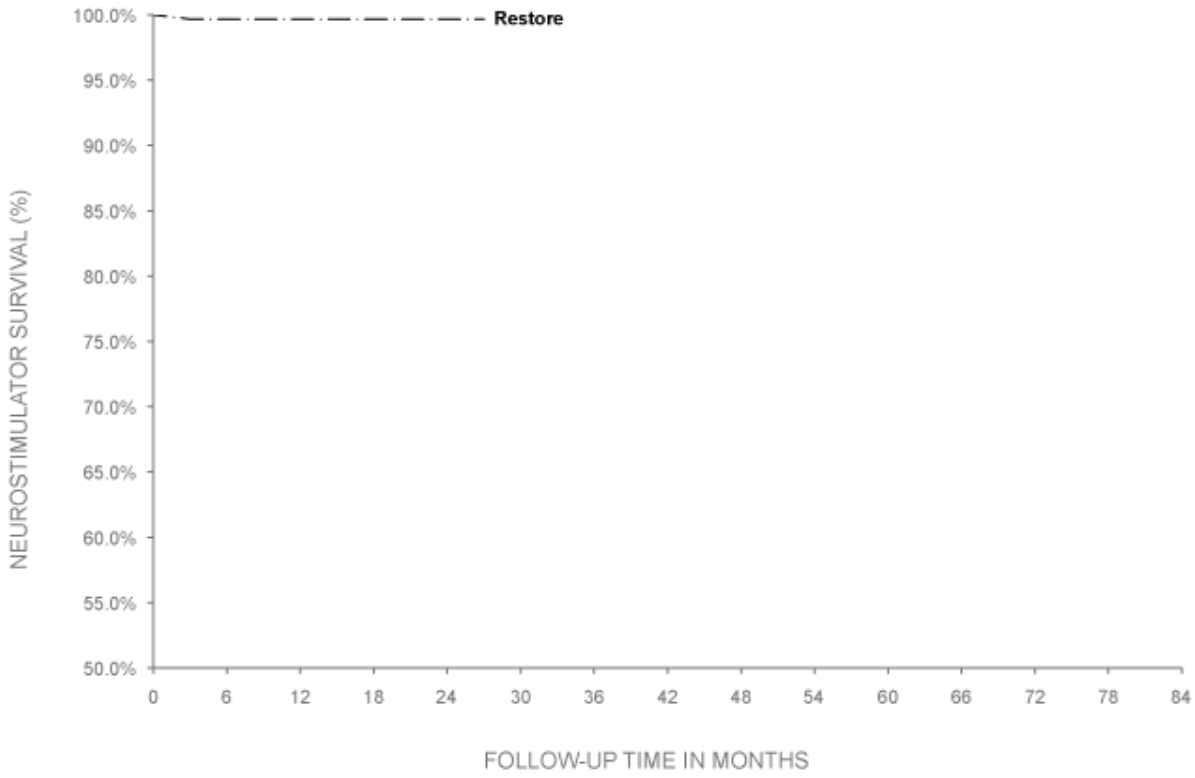


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
PrimeAdvanced	Jul 06	89	83	0	581

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs
Survival	Sample size not large enough at this time						
Effective Sample Size							

Model 37711 Restore: Survival from Spinal Cord Stimulator Events

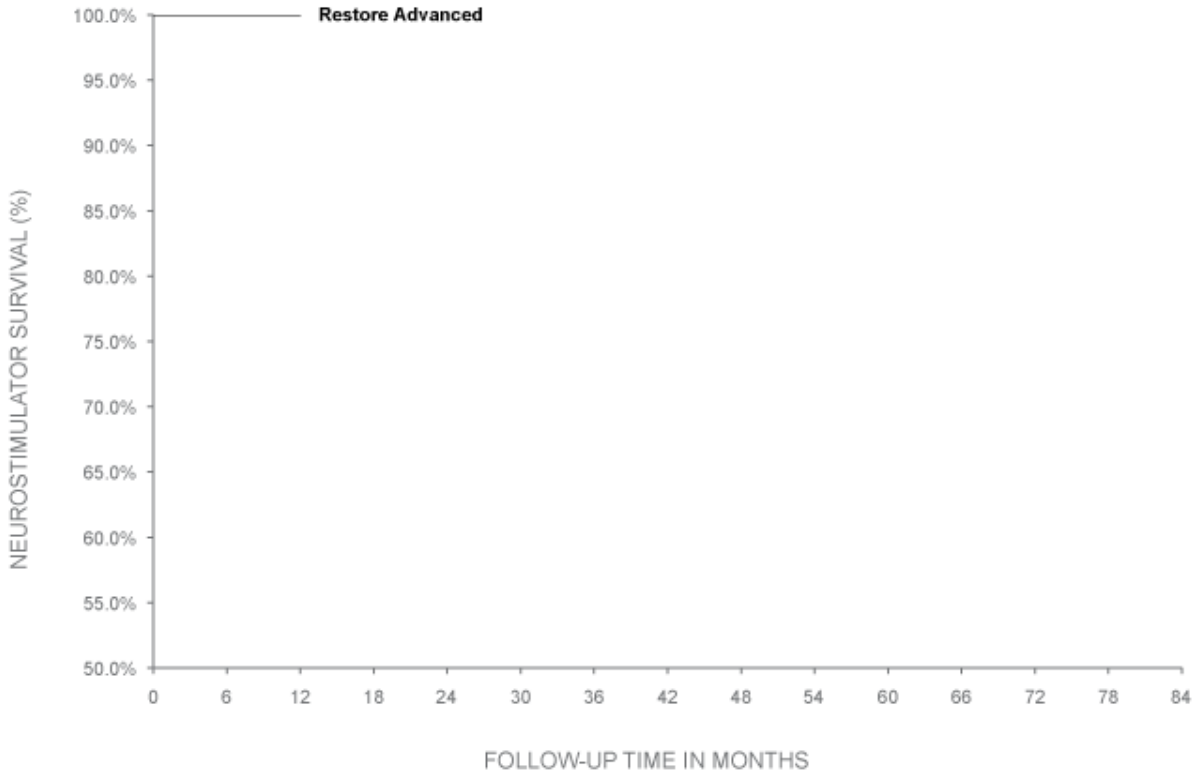


Data are shown if there are at least 20 devices in each 3 month interval.

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Restore	Apr 05	392	319	1	5,478

Time Interval	1 yr	2 yrs
Survival	99.7%	99.7%
Effective Sample Size	263	66

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**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
RestoreAdvanced	Jul 06	103	93	0	748

Time Interval	1 yr
Survival	100%
Effective Sample Size	29

Spinal Cord Stimulator Survival Summary

The figures and tables in this section represent spinal cord stimulator survival and 95% confidence intervals where at least 20 spinal cord stimulators contributed to each interval. Results at one year indicated 100% survival from spinal cord stimulator related events for Itrel 3, 100% survival for Synergy, 99.7% survival for Restore, 100% survival for RestoreAdvanced, and 100% survival for RestorePrime spinal cord stimulators.

Results at two years indicated 100% survival from spinal cord stimulator related events for Itrel 3, 99.6% survival for Synergy, and 99.7% survival for Restore.

Results at three years demonstrated 100% and 99.6% survival from spinal cord stimulator related events for the Itrel 3 and Synergy, respectively. Longer term follow-up data available for the Synergy demonstrated 98.8% survival at four years.

Spinal Cord Stimulators Summary Table

Spinal Cord Stimulator Characteristics					
Model Name	**FDA Approval Date**	**Spinal Cord Stimulators Enrolled**	**Spinal Cord Stimulators Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
Itrel 3	Aug 95	85	51	0	1,814
Synergy	Nov 99	454	282	3	9,460
RestorePrime	Apr 05	44	32	0	565
PrimeAdvanced	Jul 06	89	83	0	581
Restore	Apr 05	392	319	1	5,478
RestoreAdvanced	Jul 06	103	93	0	748

Device Survival Probability (%) and 95% Confidence Intervals				
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**
Itrel 3	100% (NA)	100% (NA)	100% (NA)	
Synergy	100% (NA)	99.6% (98.7%, 100%)	99.6% (98.7%, 100%)	98.8% (97.1%, 100%)
RestorePrime	100% (NA)			
PrimeAdvanced	Sample size not large enough at this time			
Restore	99.7% (99.0%, 100%)	99.7% (99.0%, 100%)		
RestoreAdvanced	100% (NA)			

Spinal Cord Stimulation: Leads

Leads

By the report cut-off date, there were 1982 leads followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of leads versus spinal cord stimulators (n=1218) were due to the fact that some patients were subsequently re-implanted with a new lead or were implanted with more than one lead.

Thirty-six percent (36%) of leads were in the Pisces-Octad lead family, 35% were in the Pisces-Quad lead family, 15% were in the Pisces-Quad LZ lead family, 13% were in the surgical lead family, and a small number were designated as Other (1%). Total prospective follow-up time for leads was 32,724 lead months.

Lead Events

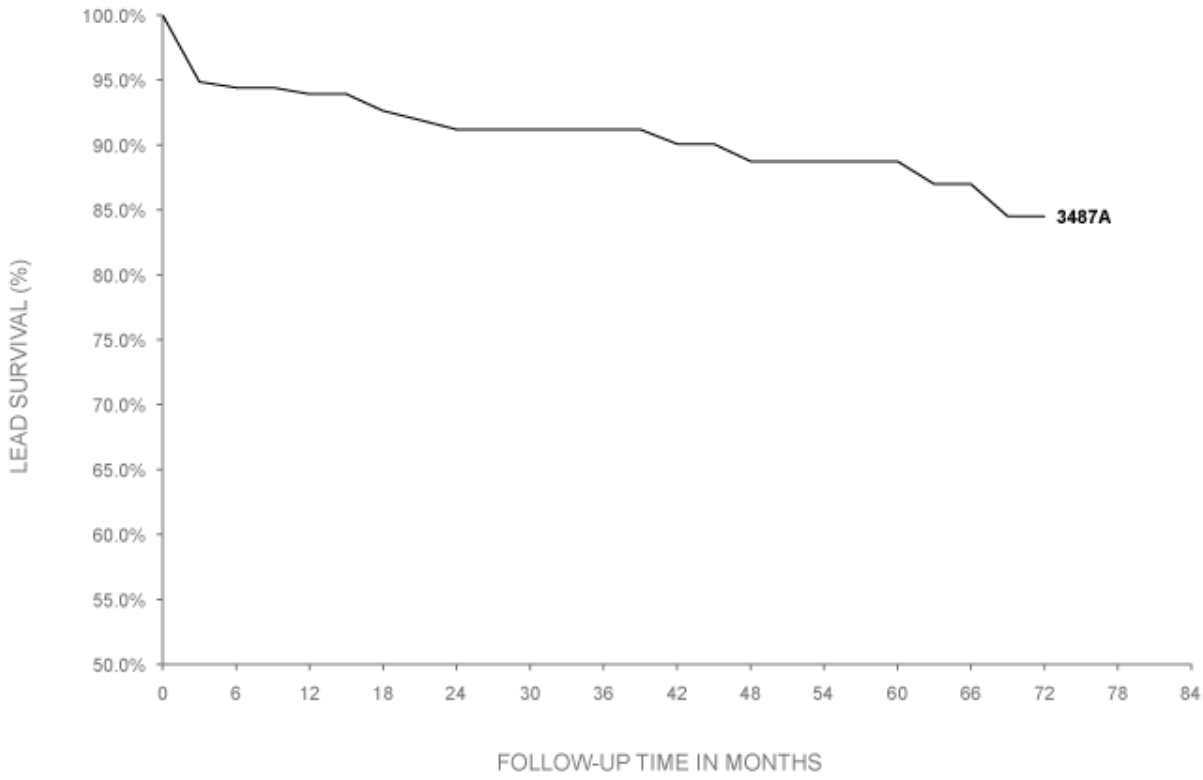
There were 124 lead events requiring surgical intervention with an underlying etiology related to the lead. Of these 124 events, 57 were due to lead migration or dislodgement, 39 were due to an undesirable change in stimulation, and 26 were lead fractures. The remaining lead events were either due to damaged electrodes (n=1) or disconnection (n=1).

There were an additional 363 leads censored in the analysis due to patient expired, patient lost to follow-up (e. g., patient moved, transferred care to another provider, study withdrawal), therapy abandoned, or lead repositioned/explanted attributed to an event unrelated to the lead.

Lead Survival Curves

The 2008 Product Performance Report included leads from several families including: Pisces-Quad leads, Pisces-Octad leads and Pisces-Surgical leads.

Model 3487A: Survival from Lead Events

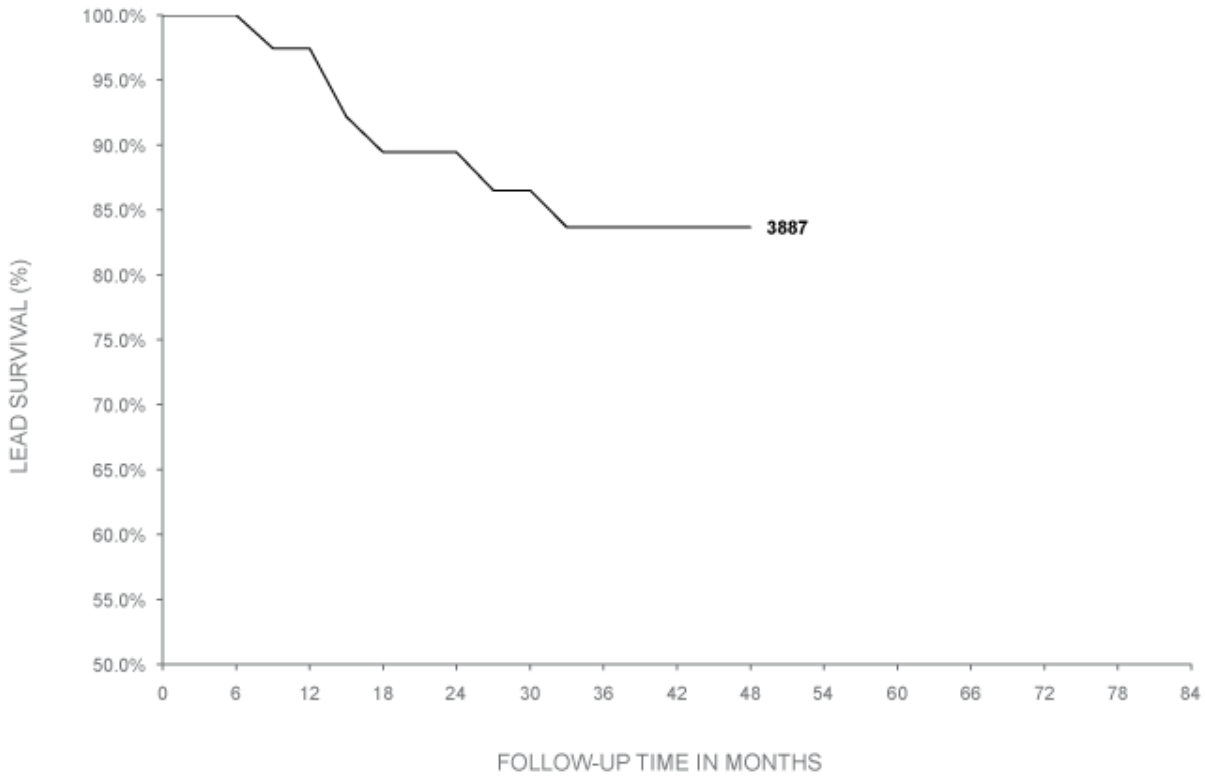


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3487A	Pisces-Quad	Aug 83	429	347	20	7,874

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs
Survival	93.9%	91.2%	91.2%	88.7%	88.7%	84.5%
Effective Sample Size	189	125	101	67	50	26

Model 3887: Survival from Lead Events

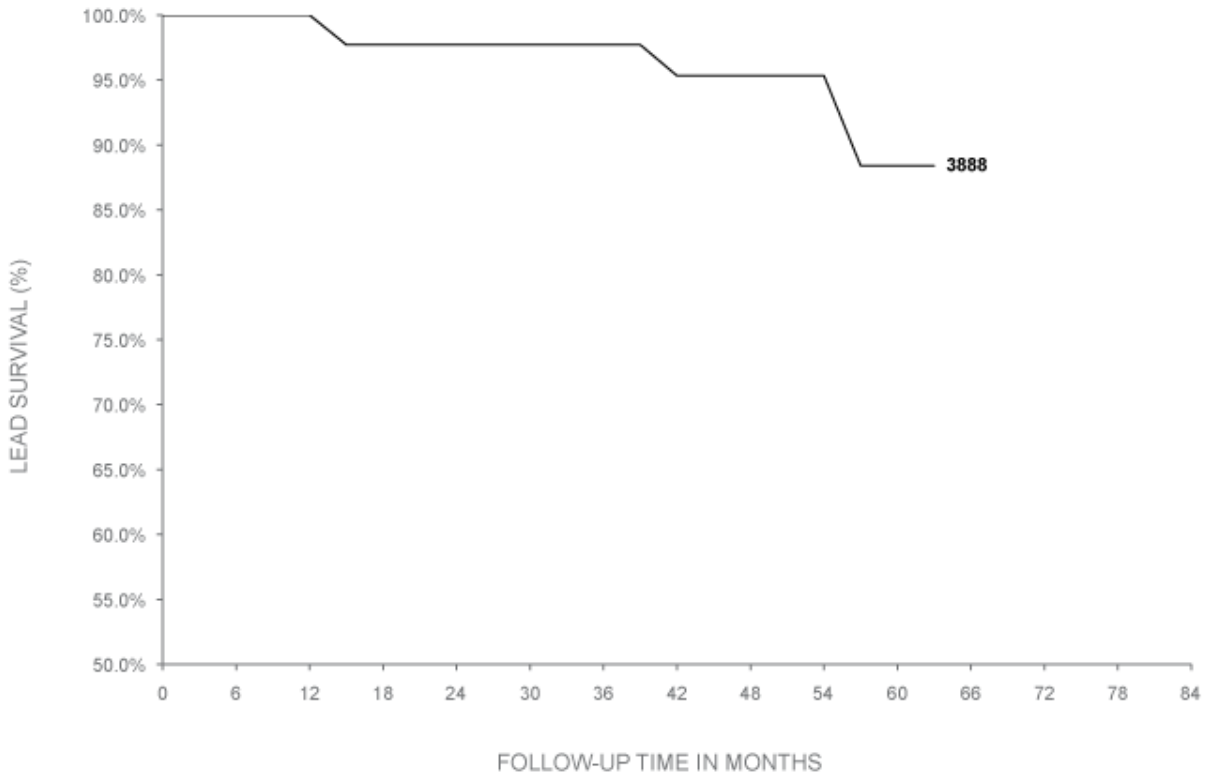


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3887	Pisces-Quad	Mar 04	149	91	13	3,373

Time Interval	1 yr	2 yrs	3 yrs	4 yrs
Survival	97.4%	89.4%	83.7%	83.7%
Effective Sample Size	78	60	57	22

Model 3888: Survival from Lead Events

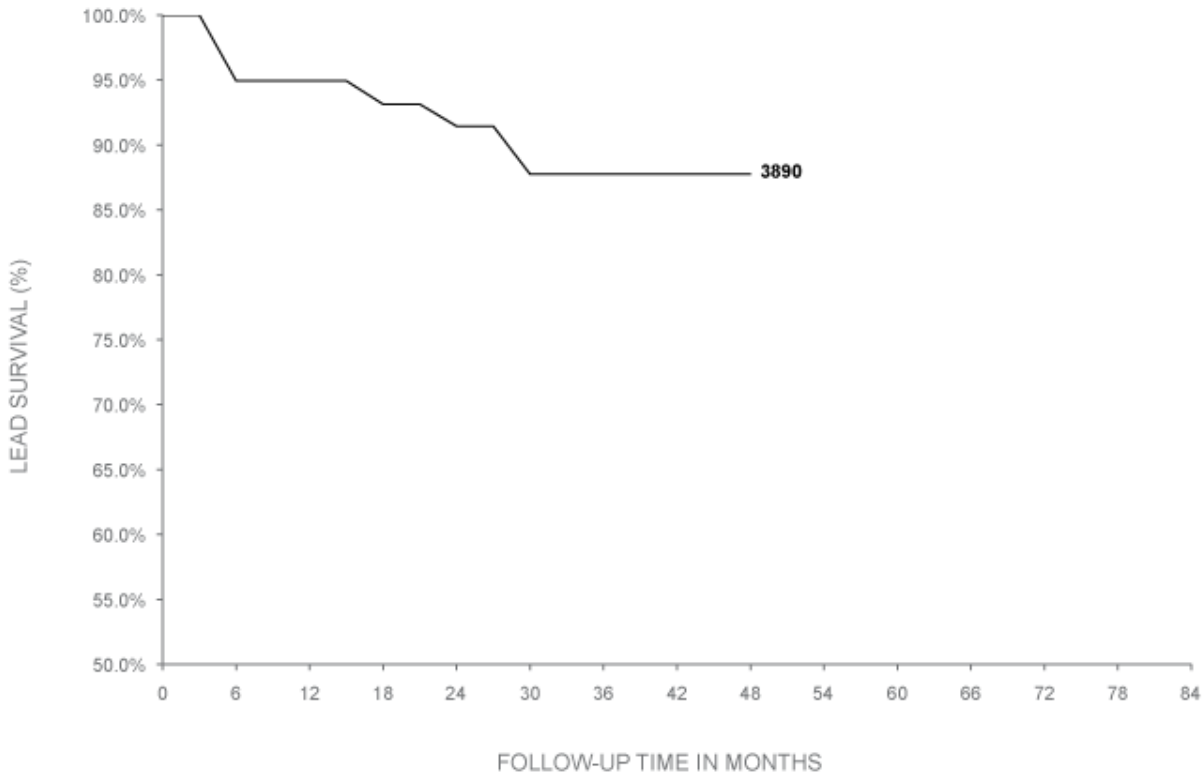


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3888	Pisces-Quad	Nov 92	125	89	6	2,736

Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
Survival	100%	97.7%	97.7%	95.3%	88.4%
Effective Sample Size	37	44	46	31	25

Model 3890: Survival from Lead Events

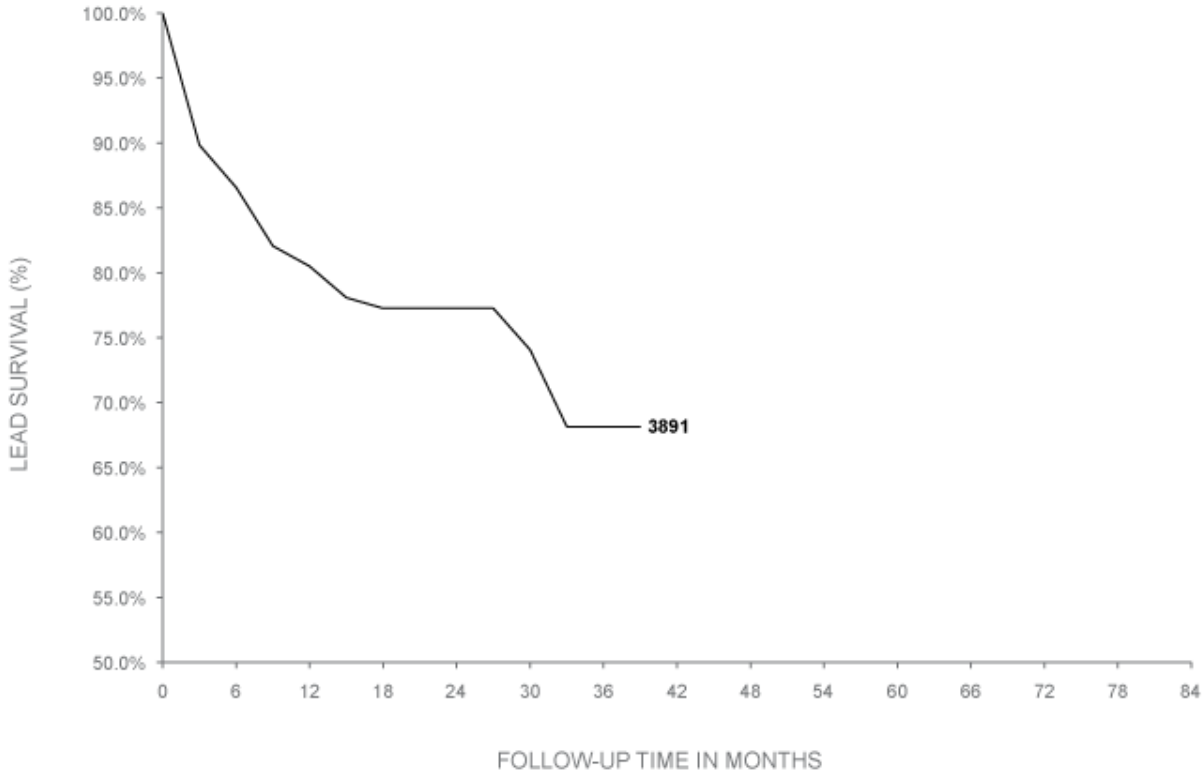


*Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3890	Pisces-Quad LZ	Sep 02	124	90	6	2,187

Time Interval	1 yr	2 yrs	3 yrs	4 yrs
Survival				
Effective Sample Size	94.9%	91.4%	87.7%	87.7%

Model 3891: Survival from Lead Events

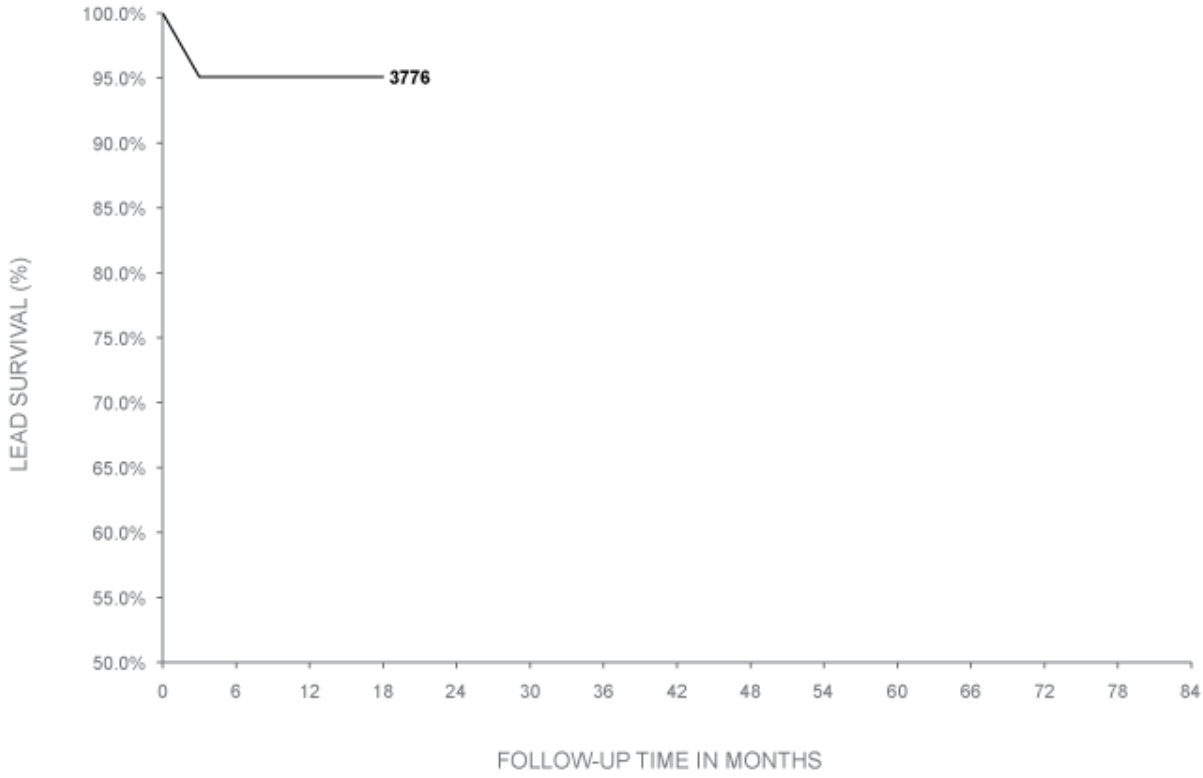


*Note: As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces Quad LZ lead due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3891	Pisces-Quad LZ	Sep 02	155	84	32	3,105

Time Interval	1 yr	2 yrs	3 yrs
Survival	80.5%	77.3%	68.2%
Effective Sample Size	105	77	29

Model 3776: Survival from Lead Events

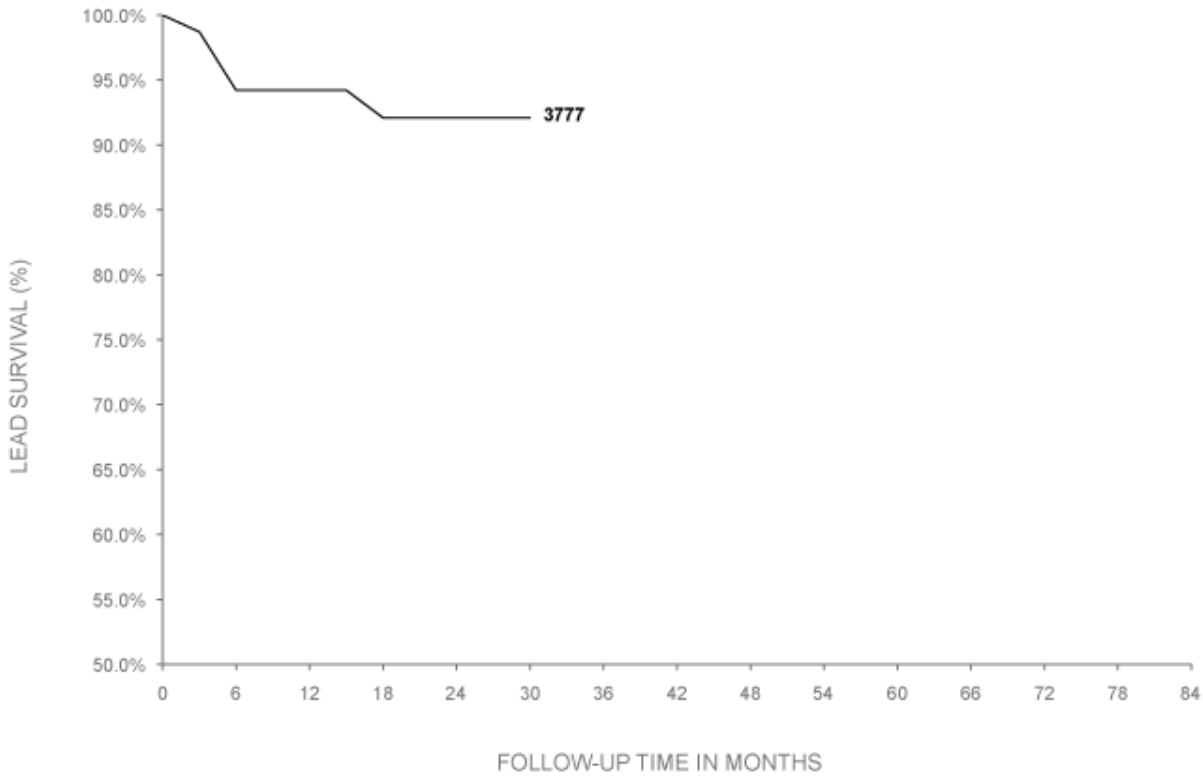


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3776	Pisces-Octad	Nov 05	67	58	3	843

Time Interval	1 yr
Survival	95.1%
Effective Sample Size	48

Model 3777: Survival from Lead Events

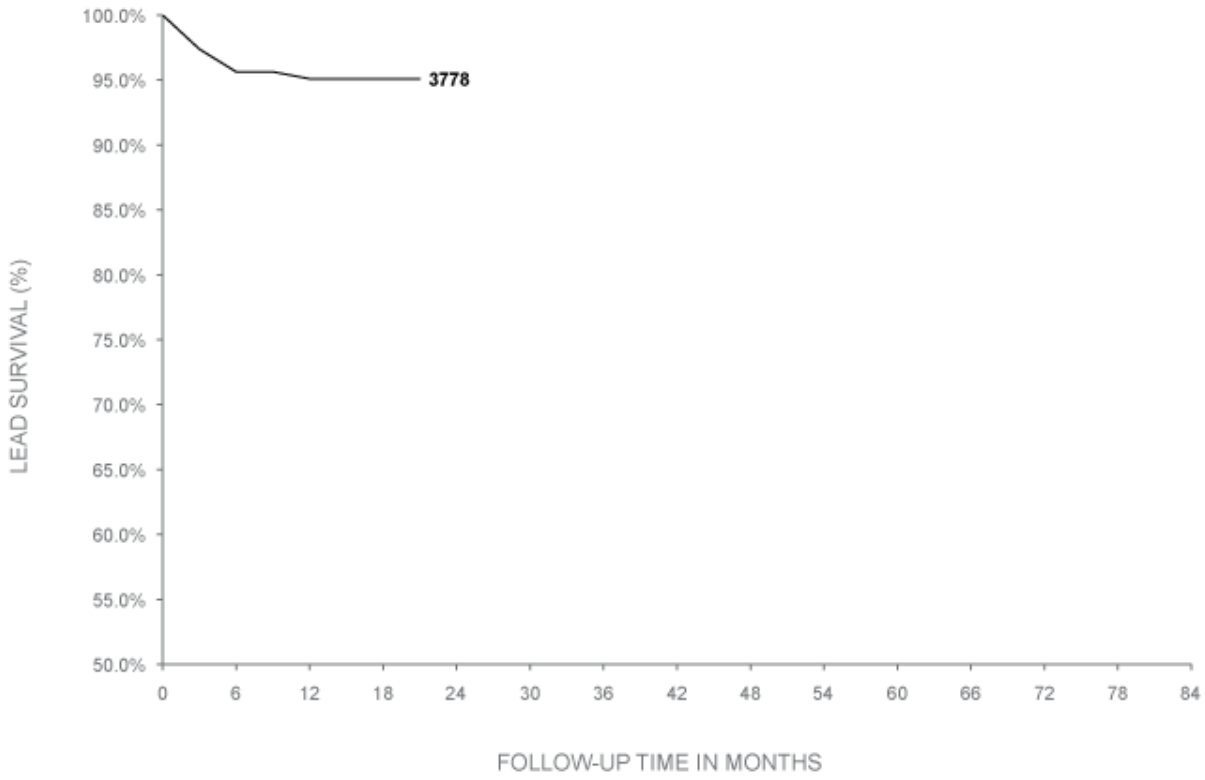


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3777	Pisces-Octad	Apr 05	298	240	17	4,187

Time Interval	1 yr	2 yrs
Survival	94.2%	92.1%
Effective Sample Size	182	73

Model 3778: Survival from Lead Events

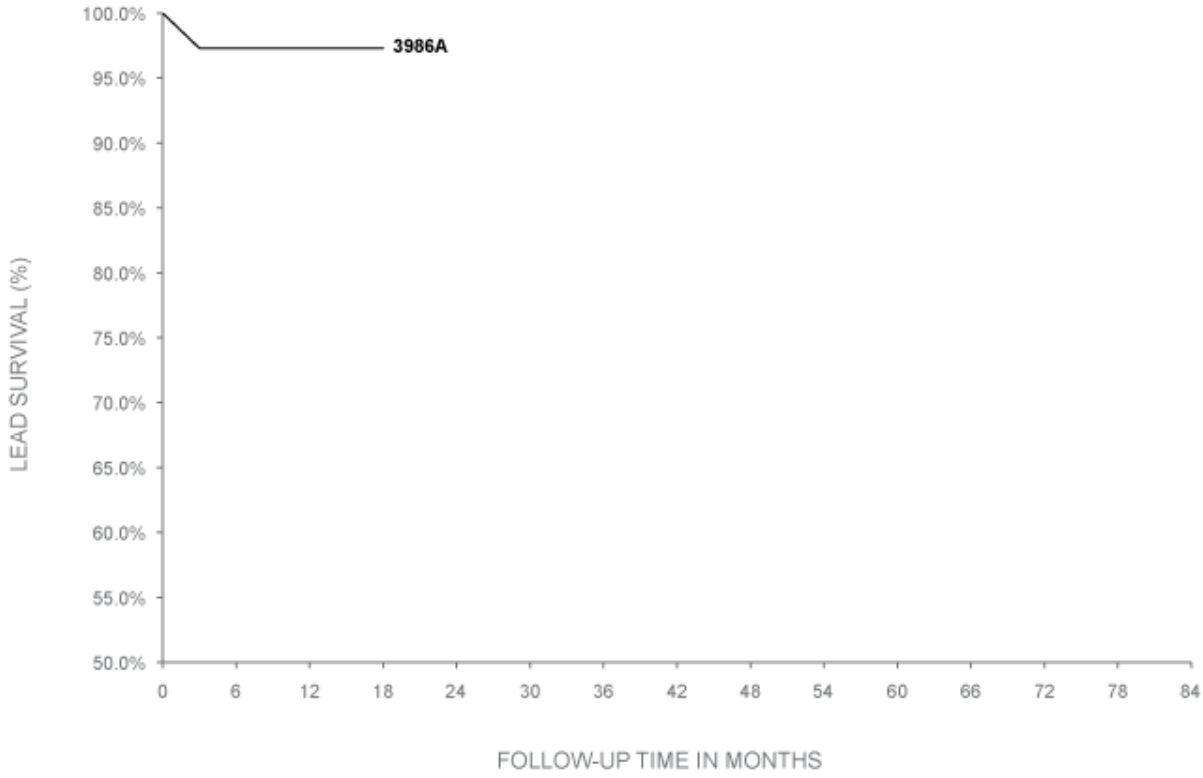


Data are shown if there are at least 20 devices in each 3 month interval.

Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3778	Pisces-Octad	Apr 05	346	299	14	3,651

Time Interval	1 yr
Survival	95.1%
Effective Sample Size	177

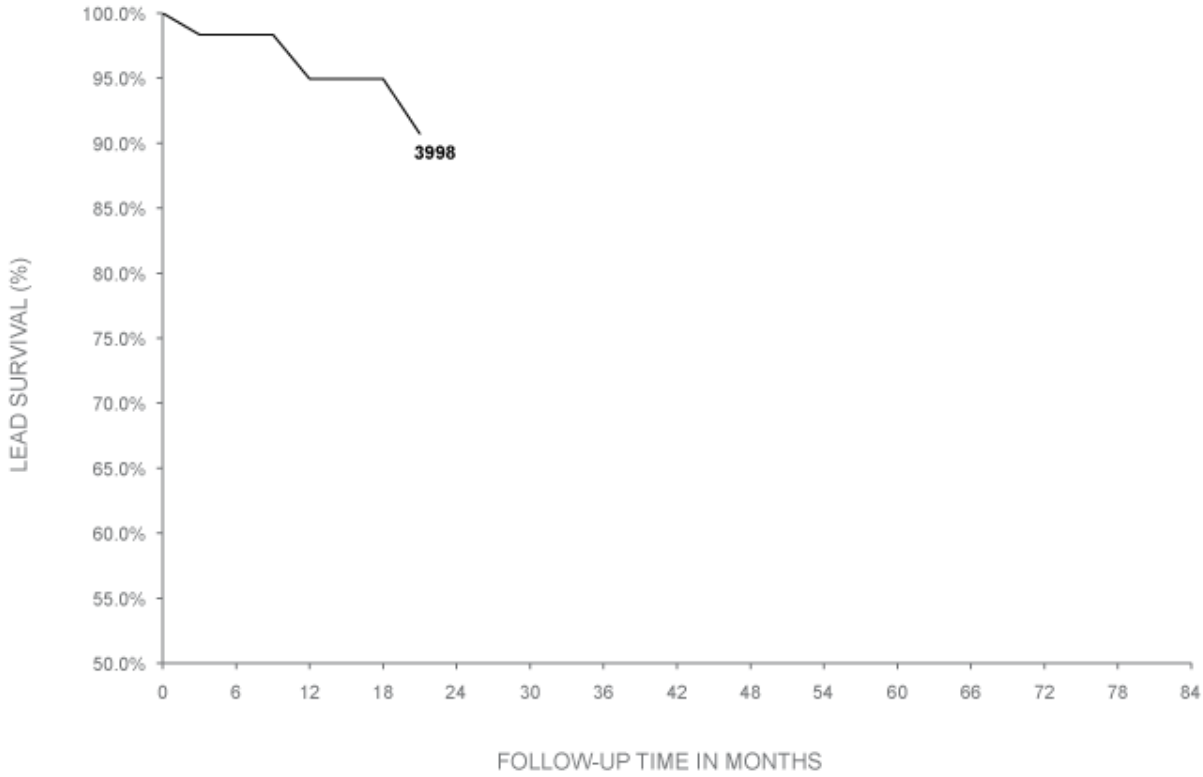
Model 3986A Resume TL: Survival from Lead Events



Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3986A	Resume TL	Mar 04	51	40	3	751

Time Interval	1 yr
Survival	97.3%
Effective Sample Size	29

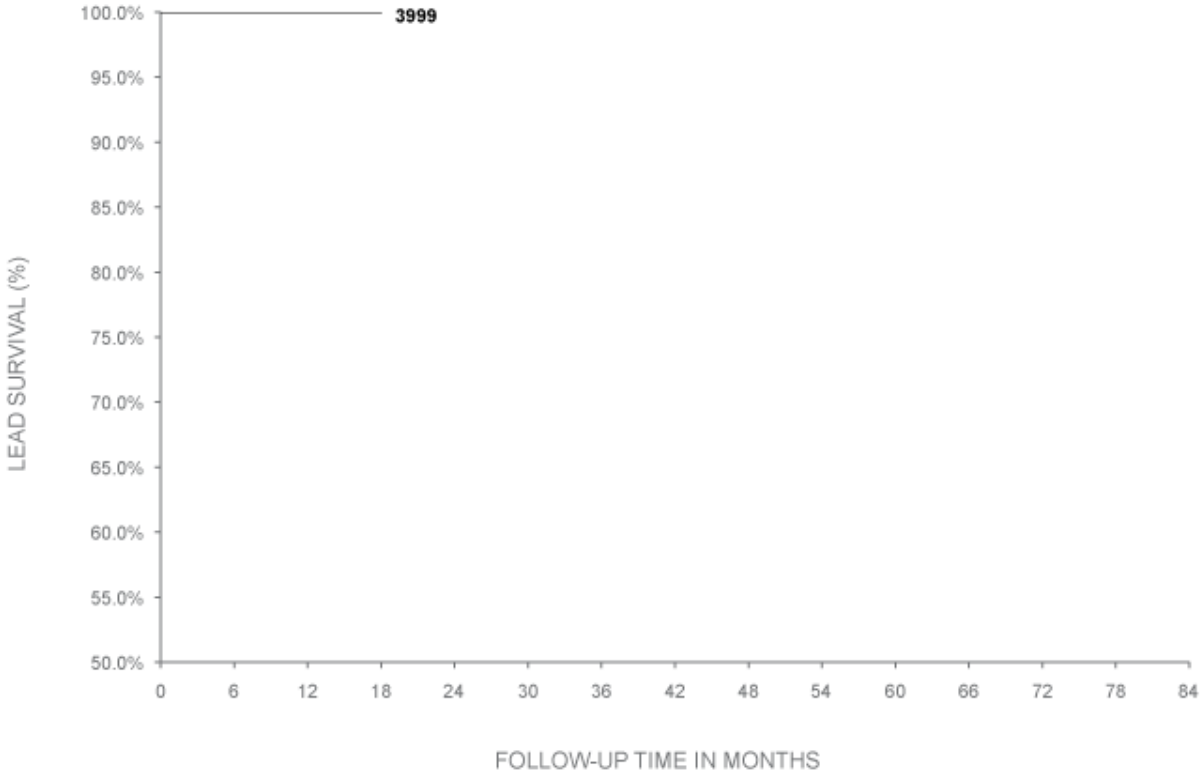
Model 3998 Specify: Survival from Lead Events



Lead Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3998	Specify	Feb 98	102	75	5	1,481

Time Interval	1 yr
Survival	94.9%
Effective Sample Size	57

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 04	44	39	0	586

Time Interval	1 yr
Survival	100%
Effective Sample Size	28

Lead Survival Summary

The figures and tables in this section represent lead survival and 95% confidence intervals where at least 20 leads contributed to each interval. Results at one year indicated 93.9% for the Model 3487A Pisces-Quad lead, 95.1% for the Model 3776 Pisces-Octad lead, 94.2% for the Model 3777 Pisces-Octad lead, 95.1% for the Model 3778 Pisces-Octad lead, 97.4% for the Model 3887 Pisces-Quad lead, 100% for the Model 3888 Pisces-Quad lead, 94.9% for the Model 3890 Pisces-Quad LZ lead, 80.5% for the Model 3891 Pisces-Quad LZ lead, 97.3% for the Model 3986A surgical lead, 94.9% for the Model 3998 surgical lead, and 100% for the Model 3999 surgical lead.

Results at two years indicated 91.2% for the Model 3487A Pisces-Quad lead, 92.1% for the Model 3777 Pisces-Octad lead, 89.4% for the Model 3887 Pisces-Quad lead, 97.7% for the Model 3888 Pisces-Quad lead, 91.4% for the Model 3890 Pisces-Quad LZ lead, and 77.3% for the Model 3891 Pisces-Quad LZ lead.

Results at three years indicated 91.2% for the Model 3487A Pisces-Quad lead, 83.7% for the Model 3887 Pisces-Quad lead, 97.7% for the Model 3888 Pisces-Quad lead, 87.7% for the Model 3890 Pisces-Quad LZ lead, and 68.2% for the Model 3891 Pisces-Quad LZ lead.

Results at four years indicated 88.7% for the Model 3487A Pisces-Quad lead, 83.7% for the Model 3887 Pisces-Quad lead, 95.3% for the Model 3888 Pisces-Quad lead, and 87.7% for the Model 3890 Pisces-Quad LZ lead.

Results at five years indicated 88.7% for the Model 3487A Pisces-Quad lead and 88.4% for the Model 3888 Pisces-Quad lead. Additional longer term follow-up data was available for the Model 3487A Pisces-Quad lead which demonstrated 84.5% at six years.

Currently, at one year of follow-up, the 95% confidence intervals for the 3487A Pisces-Quad, 3776 Pisces-Octad, 3777 Pisces-Octad, 3778 Pisces-Octad, 3887 Pisces-Quad, 3888 Pisces-Quad, 3890 Pisces-Quad LZ, 3986A surgical, 3998 surgical, and 3999 surgical leads overlap, indicating that survival from lead related events is not significantly different between these lead models at 12 months. However, the 95% confidence interval for the 3891 Pisces-Quad LZ leads does not overlap with these lead models indicating a significant difference in product performance at 12 months. The difference in product performance is not maintained beyond one year, but this difference will likely reappear once a larger number of 3891 Pisces-Quad LZ leads are followed for longer periods of time. As of February 6, 2008, Medtronic discontinued worldwide distribution of the Pisces-Quad LZ lead family (which include the 3890 and 3891 leads) due to product performance relative to other percutaneous leads and minimal commercial demand for the product.

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
3487A	Pisces-Quad	Aug 83	429	347	20	7,874
3776	Pisces-Octad	Nov 05	67	58	3	843
3777	Pisces-Octad	Nov 05	298	240	17	4,187
3778	Pisces-Octad	Nov 05	346	299	14	3,651
3887	Pisces-Quad	Mar 04	149	91	13	3,373
3888	Pisces-Quad	Nov 92	125	89	6	2,736
3890	Pisces-Quad LZ	Sep 02	124	90	6	2,187
3891	Pisces-Quad LZ	Sep 02	155	84	32	3105
3986A	Resume TL	Mar 04	51	40	3	751
3998	Specify	Feb 98	102	75	5	1481
3999	2 x 4 Hinged Specify	Jun 04	44	39	0	586

*There were a total of 124 lead related events reported to the ISPR, but only 119 events included in this summary table. The remaining five lead related events occurred in lead models for which no device survival curves are presented due to there being less than 20 leads followed at any given interval.

Device Survival Probability (%) and 95% Confidence Intervals

Model Name	Family	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs
3487A	Pisces-Quad	93.9% (90.5%, 97.3%)	91.2% (86.9%, 95.5%)	91.2% (86.9%, 95.5%)	88.7% (83.4%, 94.1%)	88.7% (83.4%, 94.1%)	84.5% (76.6%, 92.4%)
3776	Pisces-Octad	95.1% (89.5%, 100%)					
3777	Pisces-Octad	94.2% (91.2%, 97.2%)	92.1% (88.3%, 95.9%)				
3778	Pisces-Octad	95.1% (92.5%, 97.7%)					
3887	Pisces-Quad	97.4% (93.9%, 100%)	89.4% (82.4%, 96.5%)	83.7% (75%, 92.3%)	83.7% (75%, 92.3%)		
3888	Pisces-Quad	100% (NA)	97.7% (93.2%, 100%)	97.7% (93.2%, 100%)	95.3% (88.9%, 100%)	88.4% (77.2%, 99.6%)	
3890	Pisces-Quad LZ	94.9% (88%, 100%)	91.4% (83.2%, 99.7%)	87.7% (78.3%, 97.2%)	87.7% (78.3%, 97.2%)		
3891	Pisces-Quad LZ	80.5% (73.2%, 87.8%)	77.3% (69.6%, 84.9%)	68.2% (57.9%, 78.4%)			
3986A	Resume TL	97.3% (92%, 100%)					

3998	Specify	94.9% (89.2%, 100%)
3999	Specify	100% (NA)

Spinal Cord Stimulation: Extensions

Extensions

By the report cut-off date, there were 1,552 extensions followed in the Implantable Systems Performance Registry (ISPR). Differences between the total number of extensions versus spinal cord stimulators (n=1,218) were due to the fact that some patients were subsequently re-implanted with an extension or implanted with two or more extensions.

Forty-five percent (45%) of the extensions were Model 7489 extensions, 21% were Model 37081 extensions, 13% were Model 37082 extensions, 7% were Model 37083 extensions, 7% were Model 7495 extensions, 5% were Model 7495LZ extensions, 1% were Model 7471 extensions, 0.4% were Model 7496 extensions, and 0.1% were other extensions. Total prospective follow-up time for extensions was 27,212 extension months.

Extensions Events

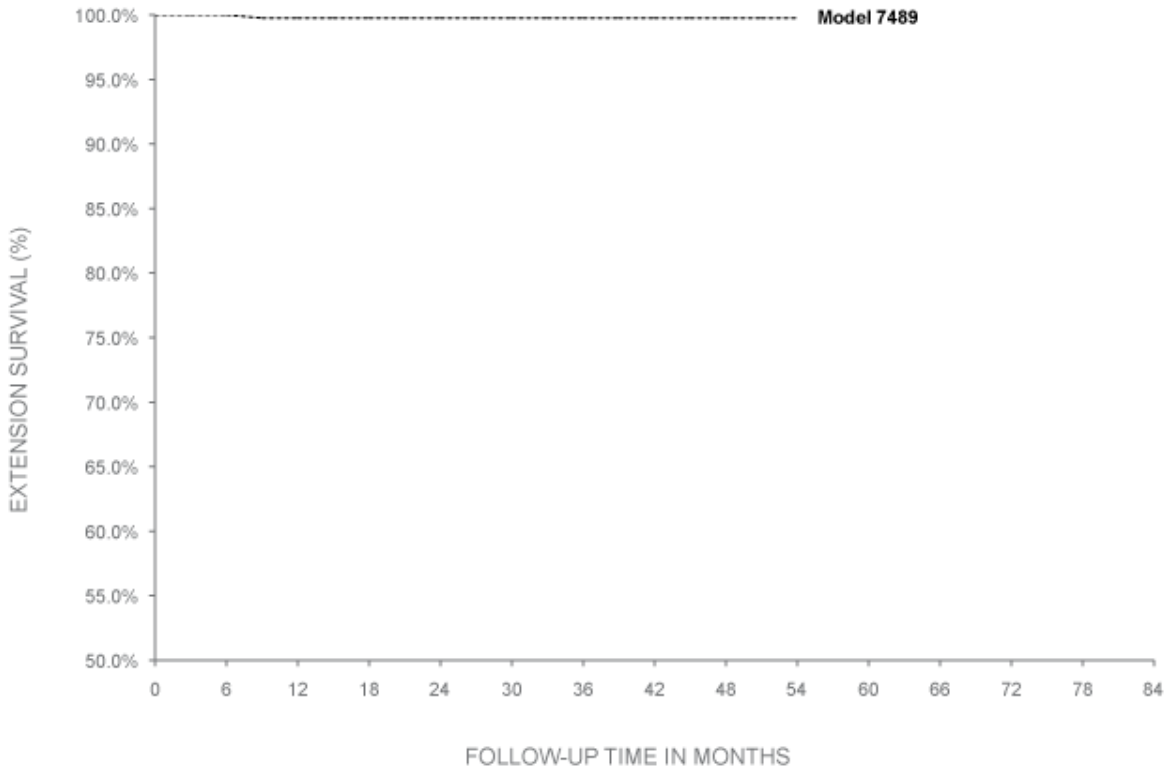
There were three extension events requiring surgical intervention with an underlying reported extension etiology. These three events included two related to extension failure that the physician assigned as extension related and one related to an extension fracture.

There were an additional 419 extensions censored in the analysis due to patient expired, patient lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal), therapy abandoned, or extensions repositioned/explanted attributed to an event unrelated to the extension.

Extensions Survival Curves

The 2008 Product Performance Report included several extension models.

7489 Extension Family: Survival from Extension Events

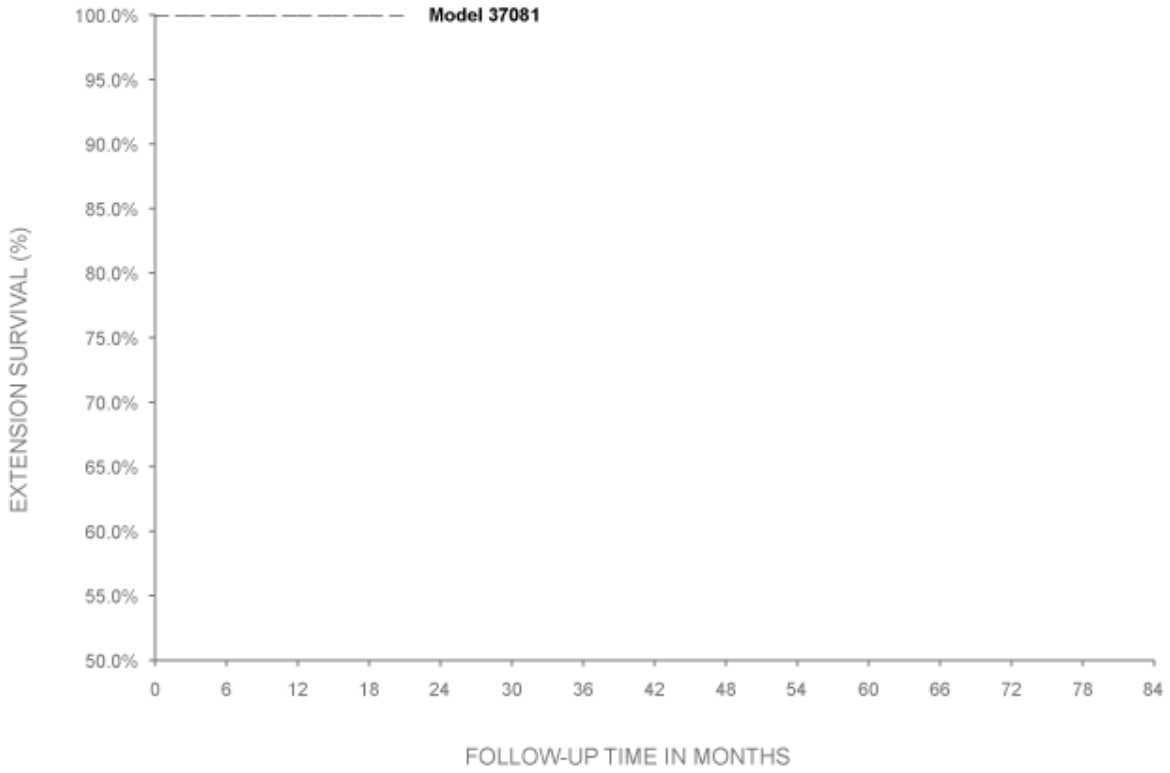


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
7489	Oct 02	693	448	1	14,986

Time Interval	1 yr	2 yrs	3 yrs	4 yrs
Survival	99.7%	99.7%	99.7%	99.7%
Effective Sample Size	459	411	210	71

37081 Extensions Family: Survival from Extensions Events

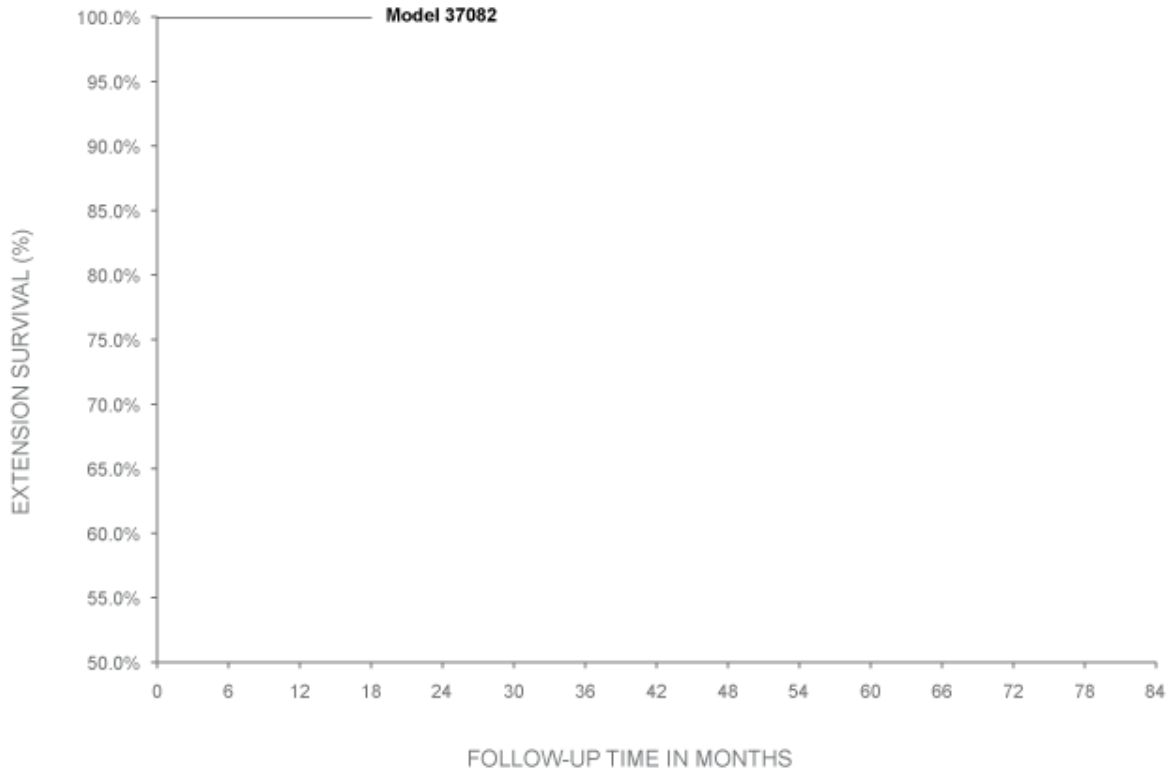


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
37081	Apr 05	319	268	0	3,086

Time Interval	1 yr
Survival	100%
Effective Sample Size	139

37082 Extensions Family: Survival from Extensions Events

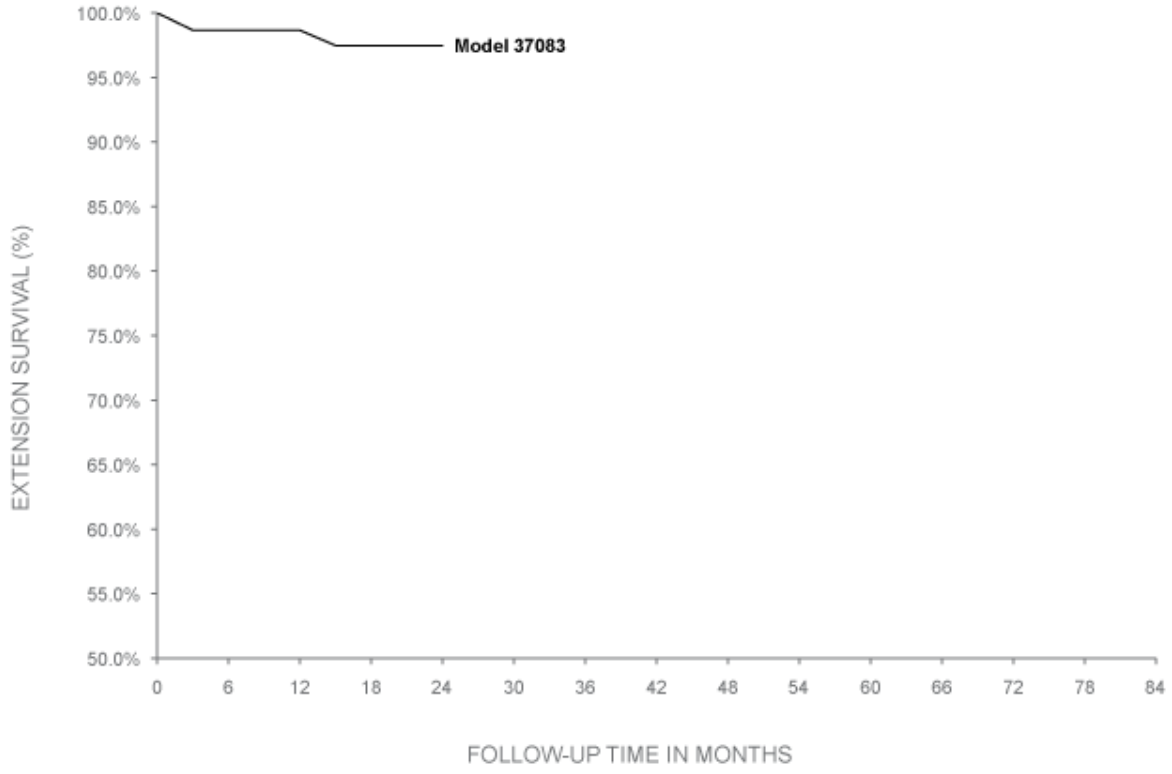


Data are shown if there are at least 20 devices in each 3 month interval.

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
37082	Mar 06	208	178	0	1,996

Time Interval	1 yr
Survival	100%
Effective Sample Size	92

37083 Extensions Family: Survival from Extensions 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 05	115	91	2	1,642

Time Interval	1 yr	2 yrs
Survival	98.7%	97.5%
Effective Sample Size	85	30

Extensions Survival Summary

The figures and tables in this section represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each interval. Results at 12 months indicated 99.7% survival from extension related events for model 7489, 100% survival from extension related events for 37081, 100% survival from extension related events for 37082, and 97.5% survival from extension related events for 37083 extensions.

Results at 24 months indicated 99.7% survival from extension related events for model 7489, and 97.5% survival from extension related events for 37083 extensions. Additional longer term follow-up data available for the 7489 extensions demonstrated 99.7% survival at 36 and 48 months, respectively.

Currently, at 12 months 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 12 months.

Extensions Survival Summary Table

Extension Characteristics					
Model Number	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
7489	Oct 02	693	448	1	14,986
37081	Apr 05	319	268	0	3,086
37082	Mar 06	208	178	0	1,996
37083	Sep 05	115	91	2	1,642

Device Survival Probability (%) and 95% Confidence Intervals				
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**
7489	99.7 (99.2%, 100%)	99.7 (99.2%, 100%)	99.7 (99.2%, 100%)	99.7 (99.2%, 100%)
37081	100% (NA)			
37082	100% (NA)			
37083	97.5% (93.9%, 100%)	97.5% (93.9%, 100%)		