Overview

Introduction

Medtronic uses a prospective, long-term multi-center registry to monitor the performance of certain products at selected centers. The registry is currently conducted utilizing two protocols titled the Implantable Systems Performance Registry (ISPR) and the Product Surveillance Registry (PSR). Both protocols collect data on the performance of Medtronic products. In addition, PSR captures further information on select patient reported outcomes. This 2014 Product Performance Report provides data on the devices followed in the registry. Medtronic also incorporates the findings of Returned Product Analysis (RPA) for devices followed in the registry that are returned to Medtronic.

Depending upon geography, this report may contain information outside approved labeling for Medtronic's commercially available devices. It is recognized that healthcare providers prescribe approved therapies to meet specific patient needs; however, Medtronic only directs the use of its products according to geography-specific, approved labeling.

Registry Background

The registry was created by Medtronic to monitor the performance of commercially available infusion and spinal cord stimulation systems. These systems were initiated into the registry in August 2003 and June 2004, respectively. Prior to the development of the registry, Medtronic Neuromodulation typically evaluated patient and product outcomes by retrospectively analyzing data from RPA and complaints data. The registry allows Medtronic to prospectively capture valuable real-world information that can be used in conjunction with these retrospective and passive data sources. This information is used to guide future product development efforts aimed at improving product reliability and quality. The data are also used to measure progress toward improving product performance to fulfill regulatory requirements. In addition, data from the registry provide information about the treatment practices of physicians using these therapies.

This registry was initially designed to track performance of Medtronic's implantable targeted drug delivery systems (infusion pumps and catheters). These surgically-placed devices deliver prescribed medication directly to the fluid around the spinal cord for the treatment of chronic pain or severe spasticity, providing relief with a smaller fraction of the medication needed than if taken orally.[1]

Medtronic's spinal cord stimulation systems (spinal cord stimulators, leads, and extensions) for pain indications were later added to the registry. Implanted spinal cord stimulators send mild electrical impulses to the spinal cord.

In July 2009, Medtronic's deep brain stimulation systems (deep brain neurostimulators, leads, and extensions) were included in the registry. Deep brain stimulation (DBS) uses a surgically implanted neurostimulator to deliver carefully controlled electrical stimulation to precisely targeted areas in the brain.

In April 2010, Medtronic's sacral neuromodulation systems (neurostimulator, leads, and extensions) were added to the registry. This implantable system sends mild electrical pulses through a lead to the sacral nerves to modulate the neural activity that influences the behavior of the pelvic floor, lower urinary tract, urinary and anal sphincters, and colon.

The registry has collected data from centers across the United States, Europe, and South America. There have

been 55 centers that have contributed data for targeted drug delivery systems, 69 centers for spinal cord stimulation systems, 30 centers for deep brain stimulation, and 18 centers for sacral neuromodulation. There are 33, 49, 26, and 21 sites currently active for targeted drug delivery, spinal cord stimulation, deep brain stimulation, and sacral neuromodulation respectively. Each registry center received Institutional Review Board or Medical Ethics Committee approval of the registry protocol and associated Informed Consent Forms (ICF). Registry patients signed an ICF prior to enrollment. Each registry center followed its standard clinical practice for device system implantation including patient selection, implant methods, and post-implant therapy management. Centers were activated after receipt of the necessary documentation, completion of training, and approval to access the web-based registry system.

1. LIORESAL® intrathecal baclofen (manufactured by Novartis Pharma Stein AG) [Package Insert]. Minneapolis, MN: Medtronic Inc; 2013

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 7th Annual Medtronic Neurostimulation and Targeted Drug Delivery Systems Product Performance Report.

We are proud of our pioneering history at Medtronic and we realize the responsibility that comes with driving innovation in technology. As the first and only company to offer a full line of Spinal Cord Stimulation, Deep Brain Stimulation, Sacral Neuromodulation and Targeted 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 have tracked over 11,200 patients in our ongoing post-market registry. The registry now includes over 32,700 pumps, catheters, neurostimulators, leads, and extensions. Data on other events not directly attributed to product performance are also included in an effort to provide additional information that may be important for patient management. Although gastric stimulation also involves neurostimulation, the performance of these systems is not included in the registry at this time.

We welcome your suggestions on content, format, and any information you may have regarding the performance of Medtronic products. If you have questions or comments, please contact us through the information provided on the next page.

Thank you for your support.

Andrina Hougham
Vice President, Clinical Research, Reimbursement and Regulatory Affairs
Medtronic, Inc.

Contact Information

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

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RestoreAdvanced® neurostimulator	Soletra® neurostimulator
RestoreUltra® neurostimulator	Kinetra® neurostimulator
RestoreSensor® neurostimulator	Activa® neurostimulator
InterStim® neurostimulator	RestoreUltra® SureScan® MRI neurostimulator
RestoreSensor® SureScan® MRI neurostimulator	SynergyCompact® neurostimulator
PrimeAdvanced® SureScan® MRI neurostimulator	Vectris® SureScan® leads
RestoreAdvanced® SureScan® MRI neurostimulator	

2014 Medtronic Product Performance Report: Data through July 31, 2014

Therapies

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

Resources

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Methodology

- Event Classification
- Device Survival Analyses
- Returned Product Analysis

Event Classification

Events currently collected in the registry include all events that appear or worsen during the registry and are a result of:

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

All deaths are also collected regardless of their relatedness to the device, implant procedure, and/or therapy.

In early versions of the protocol for infusion and spinal cord stimulation systems, an event was reportable only if it required a surgical intervention, led to therapy abandonment, or resulted in death. This event threshold was expanded for infusion and spinal cord stimulation systems in April 2010 in order to capture additional adverse event data.

Additionally, since the protocol expansion, the seriousness (per ISO 14155-1) of adverse events has been assessed and reported by the registry investigators.

For centers participating in the PSR protocol of the registry, specific therapy relevant events are also collected and include:

- Urinary tract infection for sacral neuromodulation
- Negative changes in behavior from baseline for deep brain stimulation
- New or worsening depression from baseline for deep brain stimulation
- New or worsened suicidal ideation from baseline, attempted suicide or completed suicide for deep brain stimulation

By design, not all adverse events experienced by patients during participation were reported in the registry because the registry is primarily focused on understanding the long term reliability and performance of Medtronic implanted systems.

All events reported in the registry are coded using version 17.0 of the Medical Dictionary for Regulatory Activities (MedDRA). Medtronic's own coding system for events related to implanted neuromodulation systems, which do not exist in the MedDRA dictionary, was integrated with the MedDRA dictionary.

Registry Definitions

Adverse Event - any death or undesirable experience (associated with signs, symptoms, illnesses, or other medical events) occurring to the patient that appears or worsens during the clinical study and is possibly related to the device, implant procedure, and/or therapy.

Device Event - an issue with any of the implantable or external system components. An issue is defined as: the device is not functioning within specifications or programmed settings, whether or not it is associated with an adverse event.

Therapy Relevant Event- a specific event type for sacral neuromodulation and deep brain stimulation therapies which are collected regardless of relatedness to the device, procedure, or therapy.

Adverse Event/Device Event Flowchart

View Larger Image

Product-Performance or Non-Product Performance Categorization

For analysis purposes, events collected were collapsed into 2 categories: product performance events and non-product performance events. All events were reviewed by Medtronic to determine if they were product performance-related (product performance events are events that are possibly due to a device-related issue). A non-product performance related event was any undesirable experience (associated with signs, symptoms, illnesses, or other medical events) occurring to the patient, and that appears or worsens during the clinical study, that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as product performance-related.

Consistency and Accuracy

Consistency and accuracy of 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 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. Monitoring is accomplished through a risk-based approach that aligns with the current FDA guidance on monitoring. Through this approach not every data field is monitored but an emphasis is placed on data related to the primary objective (e.g., events). Clarification and subsequent adjudication of events may be required for, but is not limited to, the following reasons:

- Inconsistency with the protocols
- Inconsistency 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 Customer Support and Vigilance Complaint management requiring additional information
- Center personnel initiated corrections or additions

Device Survival Analyses

Device performance is expressed in terms of device survival estimates, where "survival" refers to freedom from a product performance event, not the survival of the patient. These survival probabilities are estimated using the Kaplan-Meier method[1]. The estimates are intended to illustrate the probability that a device will survive for a given number of years without a product performance related event.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases in the registry, active surveillance of a device starts after the device was implanted, which is called left truncation[1]. The survival probability of such a device is conditional on survival to the time when the device enters the registry. For the PPR analysis, a statistical method to incorporate data from these retrospectively enrolled devices was applied. Left truncation 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. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

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. This survival estimate is a good representation of the probability a device will survive a period of time without a product performance event. For example, a device survival probability of 90% indicates that through the stated follow-up time, the device had a 10% risk of incurring a product performance event since the time of implant.

The survival curves are statistical estimates. As performance experience accumulates, the accuracy of the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds[2]. 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, estimates of survival from product performance-related events are not different between models. When confidence intervals do not overlap, estimates of survival from product performance-related events are different between models.

The device survival curves are presented through the last 3-month time point where at least 20 total devices were still being followed, 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. Since the survival estimate can become very imprecise with small sample sizes, a minimum of 20 devices must have at least 12 months of follow-up as of the report cut-off date to present a survival curve in this report.

References

1. Klein, John P., Moeschberger, Melvin L. Survival Analysis Techniques for Censored and Truncated Data, New York: Springer-Verlag New York, Inc., 1997.
2. Lee, Elisa T. (2003) Statistical Methods for Survival Data Analysis – 3rd Edition (Wiley Series in Probability and Statistics)

Returned Product Analysis

Registry devices that are returned to Medtronic are analyzed via an RPA process following protocols to confirm proper functioning or identification of root cause for any failure or deficiency. For registry pumps and neurostimulators that are returned, and for which RPA establishes a root cause or finds no anomaly, results reported herein reflect the RPA finding unless otherwise indicated in this report. When available, RPA findings are also used as one of the sources to identify the root cause of failure or deficiency for catheters and leads. In cases where the center does not explant and/or return a device, the physician-reported event reason is used for classification and analysis purposes.

Medtronic uses data from RPA as well as complaint reports from non-returned product for ongoing quality monitoring and improvement efforts. This report presents data from the registry including the results of RPA for returned devices from registry centers and patients. Data from RPA outside the registry centers and patients are not presented in this report.

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Targeted Drug Delivery Systems

- Study Participants
- Event Summary
- Pumps
- Catheters

Study Participants

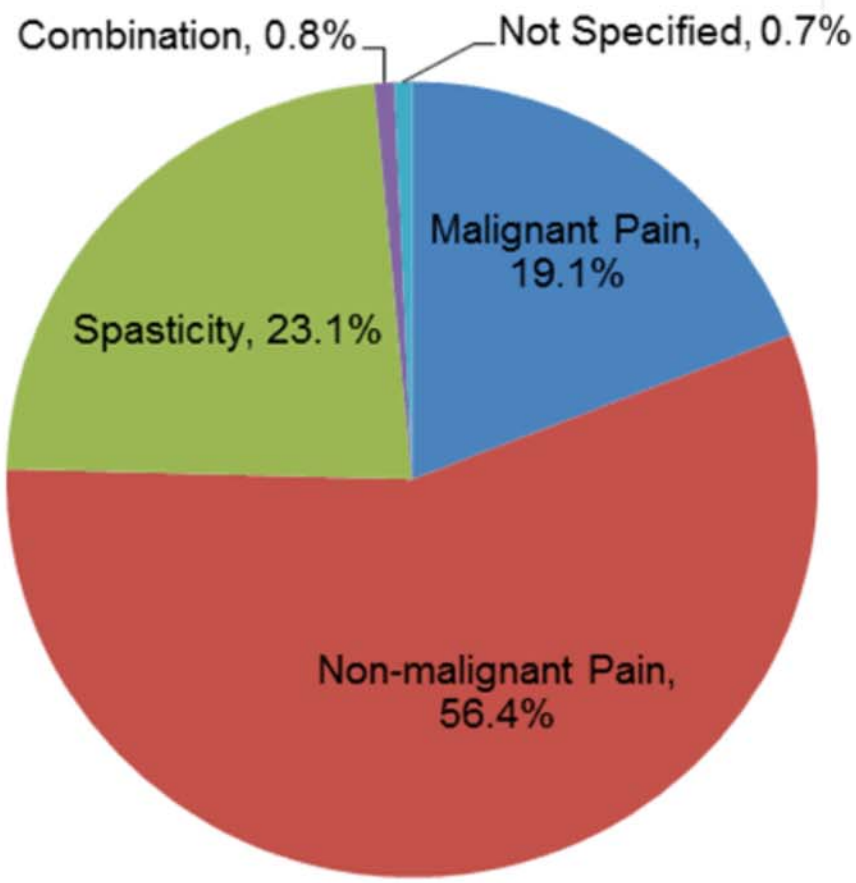
Centers

The following tables and graphs were generated based on data collected between August 7, 2003 and the report cut-off date of July 31, 2014. Fifty-five centers enrolled and contributed patients to the targeted drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 6,398 total targeted drug delivery system patients enrolled through July 31, 2014. As indicated, 56.4% of patients were implanted with a targeted drug delivery system for treatment of non-malignant pain (pain not related to cancer and its treatment), followed by 23.1% for treatment of spasticity, and 19.1% for treatment of malignant pain (pain related to cancer). Primary treatment indication is provided by the physician. The data are representative of the overall population of patients receiving new pump implants in the United States, with the minor exception of malignant pain, which is slightly over-represented (Registry = 19.1% versus U.S. population = 14.3% - data based on Device and Registration Tracking).

TDD System Primary Treatment Indications



Primary Treatment Indication[a]	N (Percent)
Pain	**4,825 (75.4%)**
Malignant pain	1,219 (19.1%)
Non-Malignant pain	3,606 (56.4%)
Spasticity	**1,477 (23.1%)**
Combination	**51 (0.8%)**
Non-Malignant pain & spasticity	51 (0.8%)
Not specified	**45 (0.7%)**
Total Patients	**6,398**

[a] Refer to product labeling for approved indications.

Malignant Pain Sub-Indications[a]	N (Percent) [b]

Location of Pain	
Spine/back	350 (28.7%)
Abdominal/visceral	244 (20.0%)
Pelvic	145 (11.9%)
Extremity	137 (11.2%)
Thoracic	117 (9.6%)
Head/neck	67 (5.5%)
Other	45 (3.7%)
Not specified	439 (36.0%)
Total Patients	**1,219**

[a] Patients may have more than one location of pain
[b] Percent is based on the number of total patients

Non-Malignant Pain Sub-Indications	**N (Percent)**
Back pain without leg pain	1,264 (34.6%)
Back pain with leg pain	832 (22.8%)
CRPS I[a]	115 (3.1%)
General neuropathic condition	103 (2.8%)
Peripheral neuropathy	63 (1.7%)
Joint pain/arthritis	50 (1.4%)
CRPS II[a]	24 (0.7%)
Osteoporosis	20 (0.5%)
General nociceptive condition	17 (0.5%)
Other	207 (5.7%)
Not specified	962 (26.3%)
Total Patients	**3,657**

[a] CRPS is complex regional pain syndrome. CRPS I rarely includes detectable peripheral nerve injury. CRPS II includes detectable

peripheral nerve or plexus injury.

Spasticity Sub-Indications	N (Percent)
Cerebral palsy	422 (27.6%)
Multiple sclerosis	387 (25.3%)
Spinal cord injury	202 (13.2%)
Brain injury	118 (7.7%)
Stroke	59 (3.9%)
Other	46 (4.3%)
Not specified	274 (17.9%)
Total Patients	**1,528**

Event Summary

There were 2,535 events reported between August 2003 and July 31, 2014 in patients with targeted drug delivery systems. Approximately forty percent of these events (1,008/2,535) were categorized as product performance-related events and are presented graphically within this report. The 1,008 product performance events occurred in 762 of the 6,398 total patients (11.91%) enrolled. In addition, there were 1,527 non-product performance events reported. There were also 1,511 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a device-related event or the infusion therapy. Early versions of the protocol required events to be reported only when the event required a surgical intervention, resulted in therapy abandonment, or resulted in death. The required event reporting definition was expanded in April 2010 to include all adverse events related to the device, implant procedure, and/or therapy. The event tables provided below include combined data from these versions of the protocol.

Targeted Drug Delivery System Product Performance Events			
Event[a]	**Number of Product Performance Events**	**Number of Patients with Event[b]**	**Percent of Patients with Event (n=6,398)**
Catheter dislodgment from intrathecal space	228	199	3.11%
Catheter occlusion[c]	200	186	2.91%

Targeted Drug Delivery System Product Performance Events			
Catheter break/cut	161	148	2.31%
Catheter kink	69	62	0.97%
Pump motor stall	62	62	0.97%
Catheter related complication[d]	51	47	0.73%
Catheter disconnection at pump	38	38	0.59%
Corrosion and/or gear wear[e]	27	27	0.42%
Catheter leakage	23	23	0.36%
Pump unable to enter/withdraw from catheter access port	23	21	0.33%
Pump underinfusion	18	15	0.23%
Pump reservoir volume discrepancy	16	14	0.22%
Device malfunction[f]	14	14	0.22%
Pump connector	13	13	0.20%

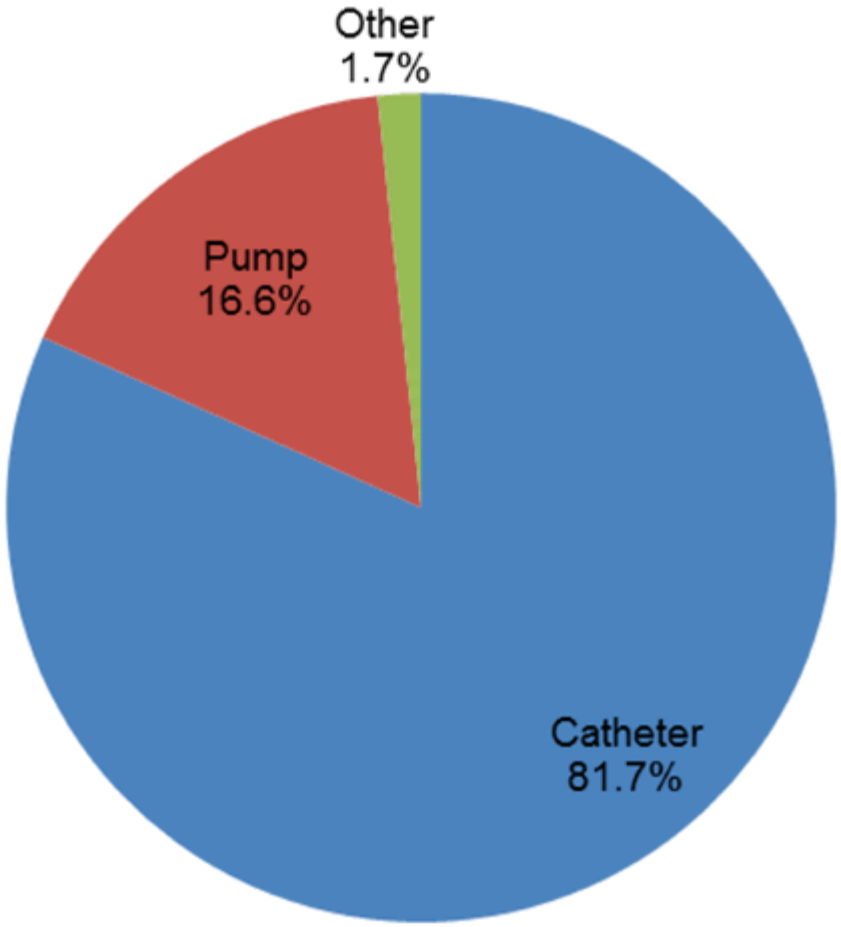
Targeted Drug Delivery System Product Performance Events			
break/cut			
Medical device complication[g]	9	8	0.13%
Pump overinfusion[h]	7	6	0.09%
Device infusion issue[i]	4	3	0.05%
Pump not infusing	4	4	0.06%
Reduced battery performance	4	4	0.06%
Deformed pump tube	3	3	0.05%
Device complication[j]	3	3	0.05%
Reservoir access issues due to residue	3	2	0.03%
Catheter breakage	2	2	0.03%
Catheter damage	2	2	0.03%
Device breakage	2	2	0.03%

Targeted Drug Delivery System Product Performance Events			
Device component issue[k]	2	2	0.03%
Motor feedthrough anomaly[l]	2	2	0.03%
Pump reservoir issue	2	1	0.02%
Alarm and/or resonator anomaly	1	1	0.02%
Catheter access port issue	1	1	0.02%
Catheter disconnection between catheter segments	1	1	0.02%
Catheter placement	1	1	0.02%
Cerebrospinal fluid abnormal[m]	1	1	0.02%
Coil shorted to case	1	1	0.02%
Concave pump shield	1	1	0.02%
Connector block problem	1	1	0.02%

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term
[b] The total number of patients with event may not represent the sum of all rows, as a patient may have experienced more than one type of event
[c] Includes events reported as catheter occlusion and catheter kink/occlusion
[d] Includes 14 inability to aspirate from catheter, 13 catheter malfunctions, 3 coiled catheters, 3 suspected catheter malfunctions, 3 inability to aspirate CSF, 2 difficulty aspirating catheter, 2 non-functioning distal catheter, 2 distal catheter malfunctions, 1 aneurysm in catheter, 1 catheter dysfunction, 1 catheter wrapped in coils and knots, 1 catheter wrapped around pump, 1 evidence of catheter wear, 1 catheter failure, 1 no free flow of CSF from spinal segment of catheter, 1 patency issues of catheter, and 1 slight loop in catheter
[e] Corrosion and/or gear wear is a returned product analysis finding without any report of motor stall
[f] Includes 8 PTM malfunctions, 3 pump malfunctions, 1 possible pump malfunction, 1 suspected rotor problem, and 1 possible pump and/or catheter malfunction
[g] Includes 1 pump connector appeared somewhat worn, 1 sutureless connector failure, 1 catheter malfunction, 1 pump beeped, 1 pump in safe state, 1 possible corrosion of pump due to concentration of drug, 1 worn catheter connector, 1 metal clips on sutureless connector bent, and 1 prescription table corruption
[h] There were a total of 14 pumps with overinfusion (physician reported or confirmed by return product analysis), 7 of these are reported in the table above. Of these 7 events, 4 were reported as pump overinfusion by the physician, but the pump was not returned for analysis. The remaining 3 pumps were returned for analysis and had a confirmed primary root cause finding of overinfusion. Two of these were initially reported by the physician as reservoir volume discrepancies, and 1 as pump malfunction. There were 7 additional pumps that were later confirmed to have overinfusion after returned product analysis but 3 were coded to a different primary root cause at the time of this report. Two were coded in the table above as pump motor stall, and 1 as corrosion and/or gear wear. The remaining 4 pumps had no reported events associated with explant (not reflected in the table above but included in the occurrence rate of overinfusion indicated in the Pump Events section of this report).
[i] Includes 2 events reported as fluctuating over and under medication distribution, 1 suspected pump connector malalignment, and 1 slow dosing at refills
[j] Includes 1 pump unable to interrogate/program, 1 telemetry stopped secondary to error code, 1 under-medicated event attributed to the pump
[k] Includes 2 broken anchors
[l] These events were initially reported by the physicians as battery depletion and pump underinfusion. The pumps were returned for analysis and had a confirmed primary root cause finding of motor feedthrough anomaly
[m] Poor CSF flow

A total of 824 (81.7%) of the 1,008 product performance events were related to the catheter, 167 (16.6%) were related to the pump, 10 (1.0%) were reported as related to "other device", 3 (0.3%) were reported as "other etiology", 2 (0.2%) were related to incisional site/device tract, 1 (0.1%) was related to surgery/anesthesia, and 1 (0.1%) was related to medication. Relatedness is determined by the physician.

Product Performance Events by Relatedness



Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Event[b]	**Number of Non-Product Performance Events**
Administration site reactions	**398**
Implant site infection	165
Implant site pain	84
Implant site extravasation	60
Implant site erosion	31
Implant site fibrosis	12
Implant site erythema	11

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Implant site haematoma	10
Implant site inflammation	5
Other[c]	20
Therapeutic and nontherapeutic effects (excluding toxicity)	**258**
Adverse drug reaction	154
Therapeutic product ineffective	60
Drug withdrawal syndrome	31
No therapeutic response	11
Other[c]	2
Device issues	**161**
Pump inversion	99
Pump migration	48
Other[c]	14
Procedural related injuries and complications not elsewhere classified (NEC)	**101**
Wound dehiscence	50
Seroma	22
Post lumbar puncture syndrome	7
Other[c]	22
General system disorders NEC	**98**
Pain	49
No anomaly found by RPA[d]	22

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Oedema peripheral	11
Other[c]	16
Infections - pathogen unspecified	**76**
Wound infection	22
Meningitis	17
Infection	15
Incision site infection	10
Other[c]	12
Injuries NEC	**72**
Cerebrospinal fluid leakage	65
Other[c]	7
Neurological disorders NEC	**68**
Hypoaesthesia	25
Sedation	13
Somnolence	9
Other[c]	21
Complications associated with device	**31**
Pump motor stall[e]	13
Medical device complication[f]	9
Drug-related pump anomaly	5
Other[c]	4
Psychiatric disorders NEC	**29**

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Withdrawal syndrome	17
Mental status changes	12
Catheter event	**22**
Inflammatory mass (Confirmed)	11
Inflammatory mass (Possible)	11
Medication errors	**22**
Overdose	21
Other[c]	1
Exposures, chemical injuries and poisoning	**18**
Toxicity to various agents	18
Muscle disorders	**18**
Muscular weakness	16
Other[c]	2
Neuromuscular disorders	**15**
Muscle spasticity	11
Other[c]	4
Epidermal and dermal conditions	**12**
Erythema	5
Other[c]	7
Gastrointestinal signs and symptoms	**12**
Nausea	7

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other [c]	5
Tissue disorders NEC	**12**
Impaired healing	10
Other[c]	2
Urinary tract signs and symptoms	**12**
Urinary retention	7
Other[c]	5
Vascular haemorrhagic disorders	**7**
Haematoma	6
Other[c]	1
Mental impairment disorders	**6**
Memory impairment	5
Other[c]	1
Skin and subcutaneous tissue disorders NEC	**5**
Skin erosion	5
Other[c]	**74**
Total	1,527

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms
[c] Composed of event codes with fewer than 5 events each and events that had not been MedDRA-coded at the time of the report cut-off (n=3).
[d] For products that are returned with a suspected device issue, and RPA establishes a root cause or finds no anomaly, results reported herein reflect the finding from Returned Product Analysis (RPA).
[e] 13 pump motor stalls occurred due to MRI and recovered in less than 24 hours with no pump issues.
[f] 1 pumps poorly positioned, 1 low drug pump alarm, 1 possible corrosion of the catheter due to drug concentration, 1 unable to remove catheter from scar tissue, 1 intraspinal infusate contamination, 1 inadvertent overfilling of the pump at refill, 1 mis-filling of pump into pocket, 1 difficulty locating pump port due to weight gain, and 1 increased

back pain.

In addition, there were 1,511 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a device-related event or the infusion therapy. A total of 974 (64.5%) of deaths occurred in patients receiving therapy for malignant pain, 400 (26.5%) for non-malignant pain, 133 (8.8%) for intractable spasticity, and 4 (0.3%) for patients whose primary indication was not specified.

Deaths by Primary Indication	
Primary Indication[a]	**Count (%)**
Malignant pain	974 (64.5%)
Non-malignant pain	400 (26.5%)
Spasticity	133 (8.8%)
Not specified	4 (0.3%)
Total	**1,511 (100.0%)**

[a] Refer to product labeling for approved indications.

Pumps

From August 2003 to the report cut-off date of July 31, 2014, there were 7,644 pumps followed in the registry. The difference between the total number of patients (n=6,398) versus pumps is due to the fact that some patients were subsequently re-implanted with a pump multiple times. The aggregate prospective follow-up time for all pumps was 189,754 months (15,813 years). The table below provides the number and percentage of pumps by model.

Pumps by Model	
Model Name	**Number of Pumps (%)**
SynchroMed II	6,456 (84.5%)
SynchroMed EL	1,183 (15.5%)
SynchroMed	5 (0.1%)
Total	**7,644**

Pump Events

There were 167 product performance-related events with an underlying reported etiology related to pump function. Of these, 150 were the first event attributable to an enrolled pump. The return rate of pumps to Medtronic Returned Product Analysis (RPA) was 796/3,237 (24.6%). The proportion was based upon the number of registry pumps received by RPA, divided by the total number of explanted pumps plus the total number of pumps in patients who expired.

Of the 167 product performance-related events related to the pump, 84 were analyzed by Medtronic RPA with the following analysis findings: 35 motor stalls, 27 corrosion and/or gear wear, 4 reduced battery performance, 3 with deformed pump tube, 3 overinfusion, 2 reservoir access issue due to residue, 2 motor feedthrough anomaly, 1 alarm and/or resonator anomaly, 1 with coil shorted to case, 1 concave pump shield, 1 cracked rotor magnet holder, 1 hole in pump tube, 1 leaky capacitor, 1 medical device complication, and 1 roller arm seized to ball bearing. Of these 84 pumps with RPA-confirmed malfunction events, 20 were originally reported as non-product performance-related battery depletions by the physician.

In addition to the 167 product performance-related events, there were 13 pump events reported as normal battery depletion by the physician, which were returned to Medtronic and had a RPA observation of high battery resistance. For this analysis, these pumps were categorized as having non-product performance-related battery depletion events, because they represented normal implant duration (ranging from 5.6-6.8 years) with no associated physician or patient complaint.

Within the 167 product performance-related events related to the pump, 83 events were characterized based upon physician report only (pumps were not returned to Medtronic) and included: 27 events due to physician-reported motor stalls, 14 pump underinfusion, 13 pump reservoir discrepancy, 6 device malfunction, 4 pump unable to enter/withdraw from catheter access port, 4 pump not infusing, 4 overinfusion, 3 medical device complication, 3 device complication, 2 pump reservoir issue, 1 device infusion issue, 1 catheter related complication, and 1 device alarm issue.

Of the 167 product performance-related events with an underlying reported etiology related to pump function, 123 had at least one confirmed exposure to drug admixtures over the course of therapy. Of the remaining 44 pumps, the complete drug history and exposure to admixtures could not be confirmed.

Medtronic executed a field action in March 2014 informing healthcare professionals of overinfusion associated with the SynchroMed II Infusion System. As of July 31, 2014, 10 pumps from registry patients were found to have confirmed overinfusion after returned product analysis. Two were initially reported by the physician as reservoir volume discrepancies, 2 as pump motor stalls, 1 as overinfusion, 1 as a pump battery end of life, and 4 had no reported events. The 10 reports of overinfusion occurred in 6,456 SynchroMed II pumps included in the registry at the time of analysis, providing 95% confidence that the occurrence rate is less than 0.0026 (0.26%).

In addition to the 10 pumps with confirmed overinfusion after returned product analysis, there were 4 pumps with physician reported overinfusion that were not returned for analysis. Combining the physician reported and confirmed pump overinfusion (n=14) provided 95% confidence that the occurrence rate is less than 0.0034 (0.34%). Medtronic continues to monitor pump performance relative to overinfusion.

For the purposes of survival analysis, a device's follow-up time is cut-off

for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For pumps:

- 150 were cut-off due to product performance-related events.
- 5,321 were censored in the survival analysis for the following reasons: patient expired, pump explanted, site termination, patient discontinued, patient lost to follow-up, other pump modification, therapy suspended, or non-product performance pump-related event with no associated intervention.
- 2,173 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

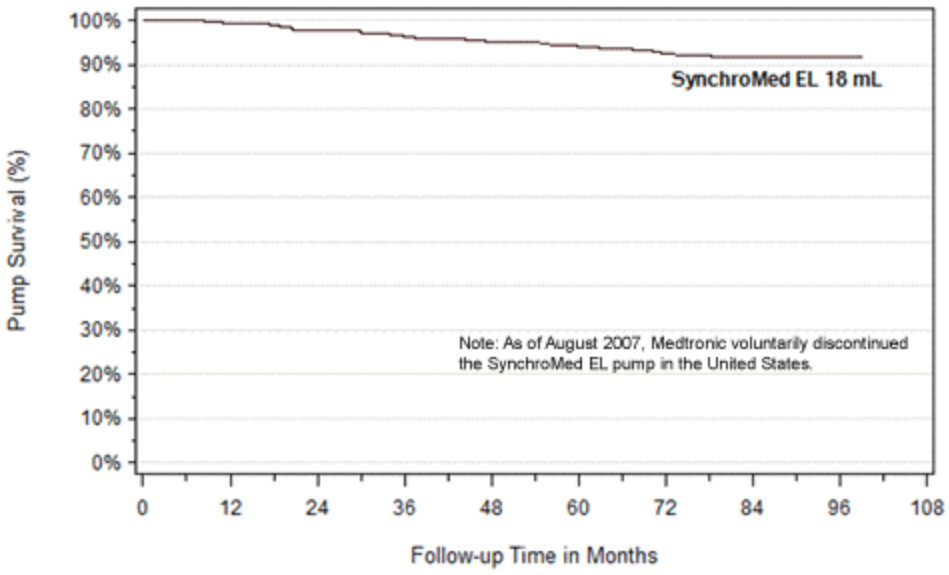
Pump Survival

The figures and tables below represent pump survival and 95% confidence intervals where at least 20 pumps contributed to each 3-month interval. Currently, estimates of device survival from pump-related events exceed 88% (confidence intervals are equal to or exceed 80%) for all pump models at the applicable follow-up time points that include at least 20 active devices. Medtronic chose to voluntarily discontinue the SynchroMed EL pump in August 2007 in the United States.

Choose a model Go

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

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



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Note: As of August 2007, Medtronic voluntarily discontinued the SynchroMed EL pump in the United States.

Pump Characteristics	
Model Name	SynchroMed EL (18 mL)
FDA Approval Date	Mar 1999
Pumps Enrolled	1,150
Pumps Currently Active in Study	1
Device Events	34
Cumulative Months of Follow-up	32,366

SynchroMed EL 18mL Event Summary Table

Pump Event	**Total**
Corrosion and/or gear wear	17
Pump underinfusion	7
Pump motor stall	6
Cracked rotor magnet holder	1
Device complication [a]	1
Motor feedthrough anomaly	1
Roller arm seized to ball bearing	1
Total Pump Events	**34**

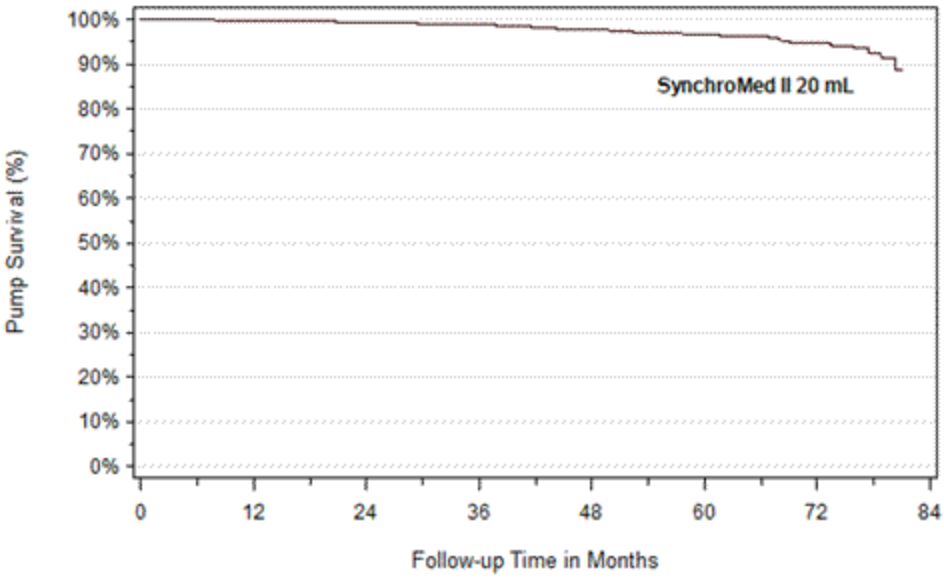
[a] Reported as unable to interrogate/program pump

Time Interval	**Survival (95% Confidence Intervals)**	**Sample Size**
1 yr	99.1% (96.5%, 99.8%)	241
2 yrs	97.9% (95.4%, 99.1%)	394
3 yrs	96.3% (93.7%, 97.8%)	533
4 yrs	95.3% (92.6%, 97.0%)	587
5 yrs	94.0% (91.3%, 95.9%)	467

6 yrs	92.6% (89.6%, 94.8%)	242
7 yrs	91.6% (88.2%, 94.1%)	105
8 yrs	91.6% (88.2%, 94.1%)	34
at 99 mo	91.6% (88.2%, 94.1%)	23

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

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



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Pump Characteristics	
Model Name	SynchroMed II (20 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	2,526
Pumps Currently Active in Study	1,122
Device Events	43
Cumulative Months of Follow-up	71,062

SynchroMed II 20mL Event Summary Table Pump Event	**Total**

Pump motor stall	17
Pump reservoir volume discrepancy	5
Corrosion and/or gear wear	4
Pump unable to enter/withdraw from catheter access port	3
Device malfunction [a]	2
Medical device complication [b]	2
Pump overinfusion	2
Alarm and/or resonator anomaly	1
Deformed pump tube	1
Device complication [c]	1
Device infusion issue	1
Hole in pump tube	1
Motor feedthrough anomaly	1
Pump not infusing	1
Reservoir access issues due to residue	1
Total Pump Events	**43**

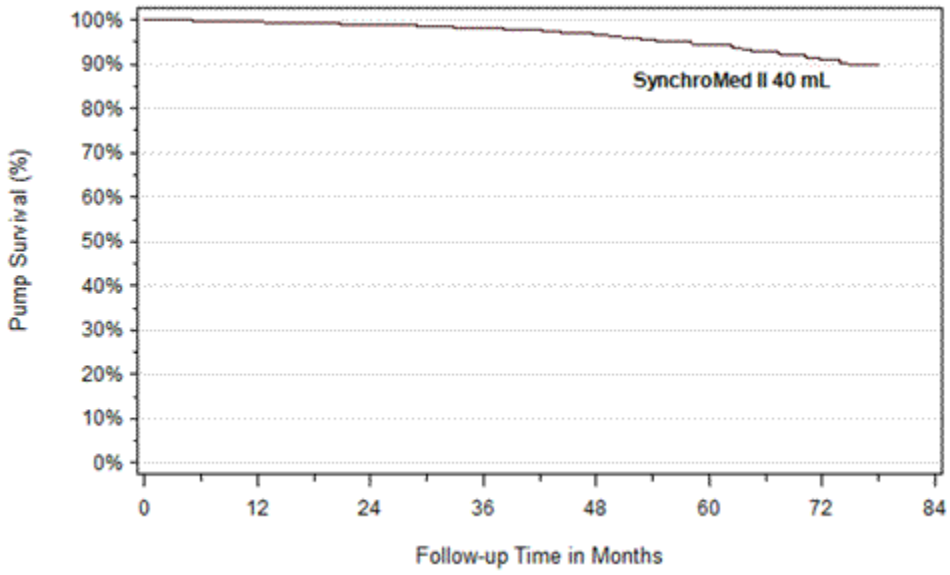
[a] Includes 1 event for suspected rotor problem, and 1 event for pump malfunction
[b] Includes 1 event for pump beeped and 1 event for pump in safe state
[c] Includes 1 event for telemetry stopped secondary to error code

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	99.8% (99.5%, 99.9%)	1,554
2 yrs	99.3% (98.7%, 99.6%)	1,197
3 yrs	98.7% (97.9%, 99.2%)	863
4 yrs	97.6% (96.4%, 98.4%)	633

5 yrs	96.6% (95.0%, 97.6%)	466
6 yrs	94.8% (92.6%, 96.3%)	275
at 81 mo	88.6% (80.4%, 93.5%)	23

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

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



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Pump Characteristics	
Model Name	SynchroMed II (40 mL)
FDA Approval Date	Sep 2003
Pumps Enrolled	3,930
Pumps Currently Active in Study	1,186
Device Events	72
Cumulative Months of Follow-up	85,432

SynchroMed II 40mL Event Summary Table Pump Event	Total
Pump motor stall	31

Corrosion and/or gear wear	6
Pump underinfusion	6
Pump reservoir volume discrepancy	5
Device malfunction [a]	4
Pump overinfusion	4
Pump not infusing	3
Reduced battery performance	3
Deformed pump tube	2
Coil shorted to case	1
Concave pump shield	1
Device alarm issue	1
Device complication [b]	1
Leaky capacitor	1
Medical device complication [c]	1
Pump unable to enter/withdraw from catheter access port	1
Reservoir access issues due to residue	1
Total Pump Events	**72**

[a] Includes 2 events reported as pump malfunction, 1 event for suspected pump malfunction, and 1 suspected pump and/or catheter malfunction
[b] Includes 1 event reported as under medicated event attributed to the pump
[c] Includes 1 event reported as possible corrosion of pump due to concentration of drug

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	99.5% (99.2%, 99.7%)	2,005
2 yrs	99.0% (98.4%, 99.3%)	1,438
3 yrs	98.1% (97.3%, 98.7%)	976

4 yrs	96.6% (95.4%, 97.6%)	672
5 yrs	94.3% (92.4%, 95.7%)	441
6 yrs	90.8% (88.0%, 93.0%)	228
at 78 mo	89.8% (86.5%, 92.3%)	74

Pump Survival Summary

Currently, estimates of device survival from pump-related events exceed 88% (confidence intervals are equal to or exceed 80%) for all pump models at the applicable follow-up time points that include at least 20 active devices.

Pump Characteristics

Model Name	Family	FDA Approval Date	Pumps Enrolled	Pumps Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
SynchroMed EL (18 mL)	SynchroMed EL	Mar 1999	1,150	1	34	32,366
SynchroMed II (20 mL)	SynchroMed II	Sep 2003	2,526	1,122	43	71,062
SynchroMed II (40 mL)	SynchroMed II	Sep 2003	3,930	1,186	72	85,432

[a] There were a total of 167 pump-related events reported to the registry, but only 149 events included in this summary table. The remaining events either occurred in pump models for which no device survival curves are presented due to an insufficient number of enrolled devices (ie, SynchroMed EL 10 mL[n=1]) or were subsequent events that did not affect the device survival estimates.

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

Model Name	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**
SynchroMed EL (18 mL)	**99.1%** (96.5%, 99.8%)	**97.9%** (95.4%, 99.1%)	**96.3%** (93.7%, 97.8%)	**95.3%** (92.6%, 97.0%)
SynchroMed II (20 mL)	**99.8%** (99.5%, 99.9%)	**99.3%** (98.7%, 99.6%)	**98.7%** (97.9%, 99.2%)	**97.6%** (96.4%, 98.4%)
SynchroMed II (40 mL)	**99.5%** (99.2%, 99.7%)	**99.0%** (98.4%, 99.3%)	**98.1%** (97.3%, 98.7%)	**96.6%** (95.4%, 97.6%)

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

Model Name	**5 yrs**	**6 yrs**	**7 yrs**	**8 yrs**

SynchroMed EL (18 mL)	**94.0%** (91.3%, 95.9%)	**92.6%** (89.6%, 94.8%)	**91.6%** (88.2%, 94.1%)	**91.6%** (88.2%, 94.1%)
SynchroMed II (20 mL)	**96.6%** (95.0%, 97.6%)	**94.8%** (92.6%, 96.3%)	-	-
SynchroMed II (40 mL)	**94.3%** (92.4%, 95.7%)	**90.8%** (88.0%, 93.0%)	-	-

Pump Survival by On/Off Label Medication Use

Product Peformance of SynchroMed II Pumps Exposed to On-Label and Off-Label Medications

The purpose of this section of the report is to provide additional information regarding the product performance of SynchroMed II pumps exposed to On-Label and Off-Label medications. This section contains information outside the FDA approved labeling for Medtronic's SynchroMed II Infusion System. It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products according to FDA approved labeling. Medtronic does not market its products for Off-Label indications and makes no representations regarding the efficacy for Off-Label uses. Infumorph®, Prialt®, Lioresal® and Gablofen® are the only intrathecal FDA approved formulations for the Medtronic SynchroMed II Infusion System. The long term drug stability/compatibility and safety and/or efficacy of drugs not FDA approved for use with the SynchroMed II Infusion System has not been established.

Patient status updates were obtained every 6 months or until discontinuation of therapy or the patient was lost to follow-up. Medications within the pump were recorded at each 6-month follow-up. This provided a snap shot of medication use at these points in time. The registry did not capture every medication or medication concentration used in the pump since any medication or concentration changes that occurred between follow-up visits were not recorded.

Pump Groups – On/Off Label Categorization

There were 5,674 patients enrolled in the registry that had SynchroMed II pumps implanted. Of these patients, 56% were female and 44% were male with a mean age of 52.7 (SD = 17.7). Of the 6,456 SynchroMed II pumps enrolled through July 31, 2014, at least one drug record was available for 6,129 pumps. If a pump had no drug records, the pump was not classified, and was excluded from analyses comparing On-Label to Off-Label. Pumps were categorized as being On- or Off-Label using the following criteria:

- On-Label: If a pump has at least one drug record in the registry, and none of the records show Off-Label drug exposure, that pump is considered On-Label even if the complete drug history of that pump is unknown.
    - For pumps used for pain patients, if the drug record has only one drug and it is morphine sulfate or ziconotide these pumps are considered On-Label.
    - For pumps used for spasticity patients, if the drug record has only one drug, and it is baclofen, that drug record is considered On-Label. Note: The classification was based on the name of the drug only, not the reported concentration of the drug.
    - Pumps with an On-Label drug history and currently containing preservative free water or preservative free saline, or if previously contained preservative free water/saline and currently containing on-label drug were considered On-Label.

- Off-Label: Any drugs not specified above within the approved indications are considered Off-Label. Additionally, any drug record with more than one drug at a time in the pump (admixture) is considered Off-Label.
    - If a pump had any known exposure to Off-Label drugs (i.e., the Off-Label data have been collected in the registry), that pump is considered Off-Label, regardless of the amount of exposure time.

- If a pump is filled with a medication that was reported as compounded, that pump is considered Off-Label.

Data Analysis

Survival estimates were calculated using the methods described in the Methodology section of this report. Statistical testing that compared survival curves was performed using a Cox proportional-hazards model. Since the survival estimate may become very imprecise with small sample sizes, Medtronic Neuromodulation's registry truncates device survival curves when the sample size is less than 20 active devices. At this threshold, one device failure yields a 5% decrease in cumulative survival. Additionally, the standard error for this survival estimate is approximately 5% (depending on previous conditional survival estimates), with 95% confidence intervals of approximately ± 10%. Overall, this large variability of 20% around the cumulative survival estimate would greatly reduce the precision for the point estimate.

Pump survival from product performance-related events was calculated and compared for the following groups:

1. All pumps: On-Label vs. Off-Label Drugs (including all indications)
2. Pain: On-Label vs. Off-Label Drugs (including all pain)
3. Spasticity: On-Label vs. Off-Label Drugs (including all spasticity)

Additionally, the cumulative failure rate (i.e. the estimated probability that a pump will have a product performance-related event by a given time point) is presented in table and graph formats for each of the sub-groups listed above.

Choose a result Go

Total Study Population: A total of 1,936 SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 4,193 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label drug/admixture.

Demographic table

Indication[a]: N (Row %)	On-Label N=1,936	Off-Label N=4,193
Non-Malignant Pain	650 (18.5%)	2,856 (81.5%)
Malignant Pain	37 (3.3%)	1,073 (96.7%)
Spasticity	1,249 (85.9%)	205 (14.1%)
Multiple/Unknown	NA	59 (100.0%)

[a] Refer to product labeling for approved indications.

There were a total of 115 reported SynchroMed II pump failures (i.e. had product performance event) during the study observation period. In addition to the 115 pump failures, there were 13 pump events reported as normal

battery depletion, but had a Returned Product Analysis (RPA) observation of high battery resistance. For this analysis, these pumps were not considered failures because they represented normal implant duration ranging from 5.6 – 6.8 years with no associated physician or patient complaint. Three of the 115 pump failure events occurred in pumps with no drug records available. Of the remaining 112 SynchroMed II pump failures, 48 pumps were classified as pump failure due to motor stall (with or without documented motor corrosion). The remaining pump failures were due to events such as corrosion and/or gear wear, inconsistent pump reservoir volume, pump under infusion, and other non-conforming reasons.

For the 48 pump failures due to motor stall, 32 of the pumps were associated with the patient presenting clinical signs and symptoms of possible drug withdrawal or increasing pain or spasticity. The other 16 pumps had no patient reported signs and symptoms associated with the event, but had a physician report of a motor stall occurrence. There were no issues reported when pumps were replaced and/or re-started, such as drug overdose. None of the pump failures resulted in patient death. Overall, the rate of pump failures in this cohort was 1.8% (112/6,129) at a median follow-up of 17.5 months.

The table below presents SynchroMed II pump survival for the **entire population** and is stratified by the On-Label or Off-Label pump group.

Total study population: Survival from product performance-related pump events for all indications, by On/Off-Label drug exposure for SynchroMed II pumps

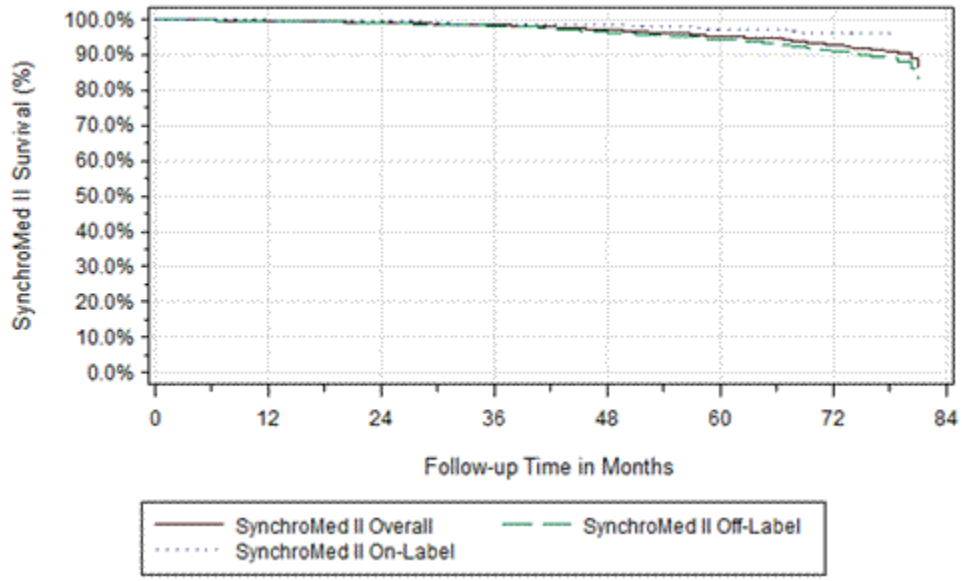
Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo	81 mo
All Pumps	Survival	99.7%	99.1%	98.4%	97.1%	95.4%	92.8%	91.1%	86.6%
	Number of pumps	3,559	2,635	1,839	1,305	907	503	170	39
On-Label Drugs	Survival	99.8%	99.6%	98.7%	98.4%	97.3%	96.4%	96.4%	-
	Number of pumps	1,176	903	622	428	286	150	35	- [a]
Off-Label Drugs	Survival	99.6%	98.9%	98.3%	96.4%	94.5%	91.2%	88.9%	83.2%
	Number of pumps	2,295	1,689	1,190	854	611	351	135	28

[a] Sample size is less than 20 active devices at 81 months for On-Label pump group

The cumulative survival curve of the SynchroMed II pump for the **entire population**, and stratified by On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (All therapies)

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



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The table and graph depict the cumulative failure rate over time and estimate the risk of pump failure for specific implant durations (i.e. time period from pump implant). Overall, the pumps with known Off-Label drug exposure had a 2.4 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.0006).

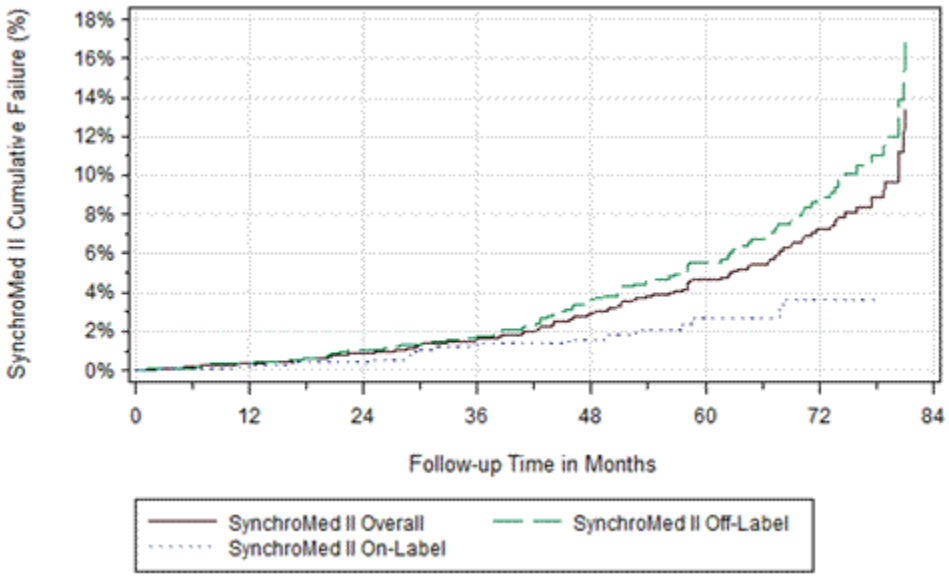
Total study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for all indications, by On/Off-Label drug exposure

Category	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	78 mo	81 mo
All Pumps	Failure	0.3%	0.9%	1.6%	2.9%	4.6%	7.2%	8.9%	13.4%
	Number of pumps	3,559	2,635	1,839	1,305	907	503	170	39
On-Label Drugs	Failure	0.2%	0.4%	1.3%	1.6%	2.7%	3.6%	3.6%	-
	Number of pumps	1,176	903	622	428	286	150	35	-[a]
Off-Label Drugs	Failure	0.4%	1.1%	1.7%	3.6%	5.5%	8.8%	11.1%	16.8%
	Number of pumps	2,295	1,689	1,190	854	611	352	135	28

[a] Sample size is less than 20 active devices at 81 months for On-Label pump group

SynchroMed II cumulative failure (All therapies)

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



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Overall Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medications used for all indications over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.4 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 78 months of follow-up, the survival from pump failure for On-Label pumps was 96.4%, compared to a survival of 88.9% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 17.5 months. The longer term data are based on a lower number of pumps and are subject to change as more follow-up data are obtained via the registry. Survival curve truncation or plateaus do not imply that the implanted devices will not be adversely impacted beyond the time points of the current data.
- The On-Label pump group consisted of 65% spasticity indication (1,249 vs. 687: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 95% pain indications (3,929 vs. 205: Pain versus Spasticity pumps respectively).
- Medication use was recorded as a snapshot at the time of follow-up. It is possible that some On-Label pumps received Off-Label medications in between 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) but was not designated as such in the registry database.
- The time a pump was exposed to an Off-Label medication was not assessed. It is possible that some Off-Label pumps were exposed only for a brief time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Pain Study Population: A total of 687 SynchroMed II pumps were classified as On-Label for pain therapy, where there was no evidence of Off-Label drug/admixture exposure. A total of 3,929 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label pain drug/admixture.

The table below presents SynchroMed II pump survival for the **Pain** indications and is stratified by On-Label pump group and Off-Label pump group.

Pain study population: Survival from product performance-related pump events for Pain indications, by

On/Off-Label drug exposure for SynchroMed II pumps

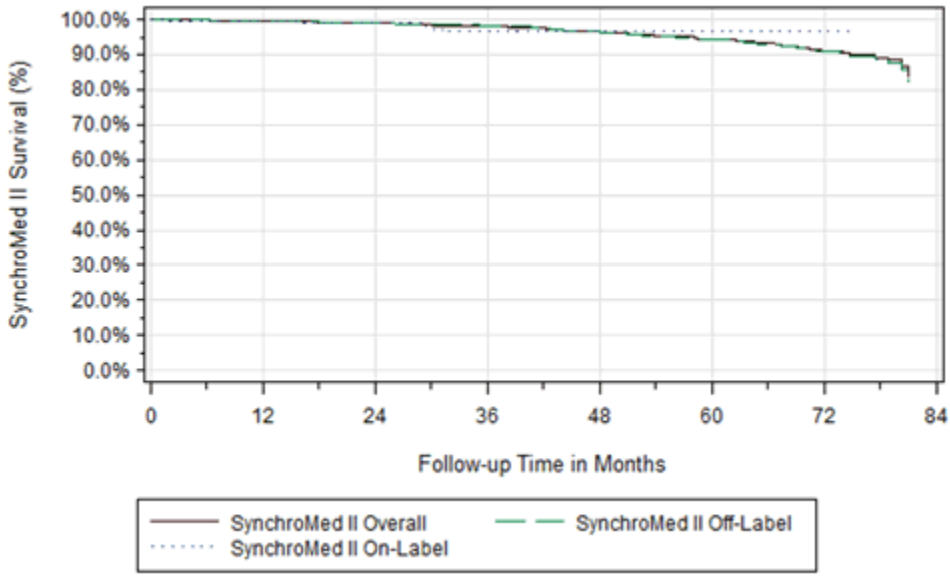
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Survival	99.6%	98.9%	98.1%	96.4%	94.5%	91.2%	90.2%	84.0%
	Number of pumps	2,543	1,806	1,227	844	603	350	261	32
Pain On-Label	Survival	99.8%	98.9%	96.8%	96.8%	96.8%	96.8%	96.8%	-
	Number of pumps	380	242	133	64	43	28	23	-[b]
Pain Off-Label	Survival	99.6%	98.9%	98.3%	96.4%	94.4%	90.7%	89.7%	82.6%
	Number of pumps	2,126	1,552	1,089	777	558	321	238	26

[a] Refer to product labeling for approved Pain indications.
[b] Sample size is less than 20 active devices at 81 months for Pain On-Label pump group .

The cumulative survival of the SynchroMed II pump for the **Pain** indications, and stratified by On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (Pain)

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



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The difference in survival between the On-Label and Off-Label groups for the pumps in the pain population was similar to what was observed for the entire population (all therapies). Statistical testing, however, was not performed due to low sample size in the On-Label group at the five-year (60-month) follow-up (n=43) and beyond.

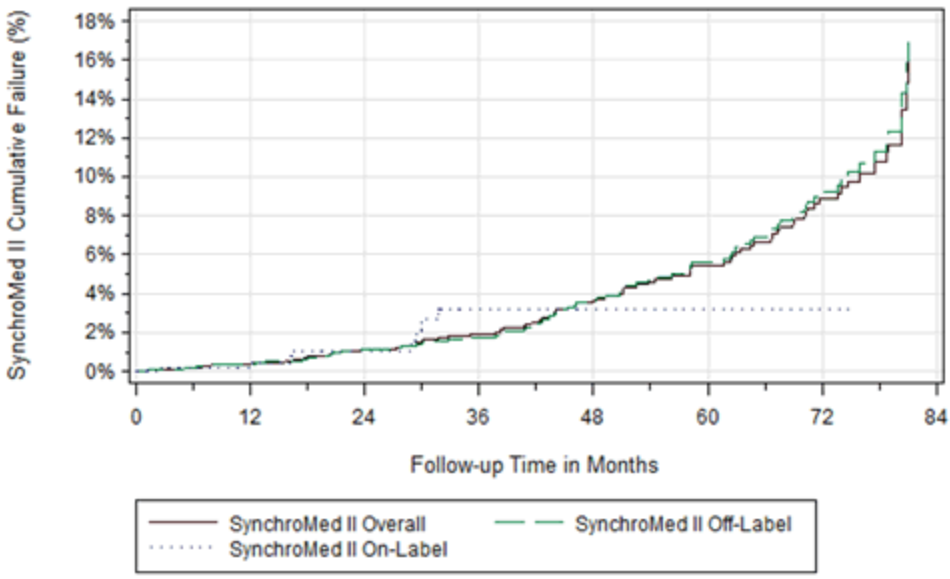
Pain study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Pain indications, by On/Off-Label drug exposure

Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	81 mo
Pain Overall	Failure	0.4%	1.1%	1.9%	3.6%	5.5%	8.8%	9.8%	16.0%
	Number of pumps	2,543	1,806	1,227	844	603	350	261	32
Pain On-Label	Failure	0.2%	1.1%	3.2%	3.2%	3.2%	3.2%	3.2%	-
	Number of pumps	380	242	133	64	43	28	23	- [b]
Pain Off-Label	Failure	0.4%	1.1%	1.7%	3.6%	5.6%	9.3%	10.3%	17.4%
	Number of pumps	2,126	1,552	1,089	777	558	321	238	26

[a] Refer to product labeling for approved Pain indications.
[b] Sample size is less than 20 active devices at 81 months for Pain On-Label pump group

SynchroMed II cumulative failure (Pain)

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



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Overall Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medications used for all indications over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.4 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 78 months of follow-up, the survival from pump failure for On-Label pumps was 96.4%, compared to a survival of 88.9% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 17.5 months. The longer term data are based on a lower number of pumps and are subject to change as more follow-up data are obtained via the registry. Survival curve truncation or plateaus do not imply that the implanted devices will not be adversely impacted beyond the time points of the current data.
- The On-Label pump group consisted of 65% spasticity indication (1,249 vs. 687: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 95% pain indications (3,929 vs. 205: Pain versus Spasticity pumps respectively).
- Medication use was recorded as a snapshot at the time of follow-up. It is possible that some On-Label pumps received Off-Label medications in between 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) but was not designated as such in the registry database.
- The time a pump was exposed to an Off-Label medication was not assessed. It is possible that some Off-Label pumps were exposed only for a brief time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Spasticity Study Population: A total of 1,249 SynchroMed II pumps were classified as On-Label for spasticity therapy, where there was no evidence of Off-Label drug/admixture exposure. A total of 205 pumps were classified as Off-Label where there was evidence of pump exposure to an Off-Label spasticity drug/admixture.

The table below presents SynchroMed II pump survival for the **Spasticity** indication and is stratified by On-Label pump group and Off-Label pump group.

Spasticity study population: Survival from product performance-related pump events for Spasticity indication, by On/Off-Label drug exposure for SynchroMed II pumps

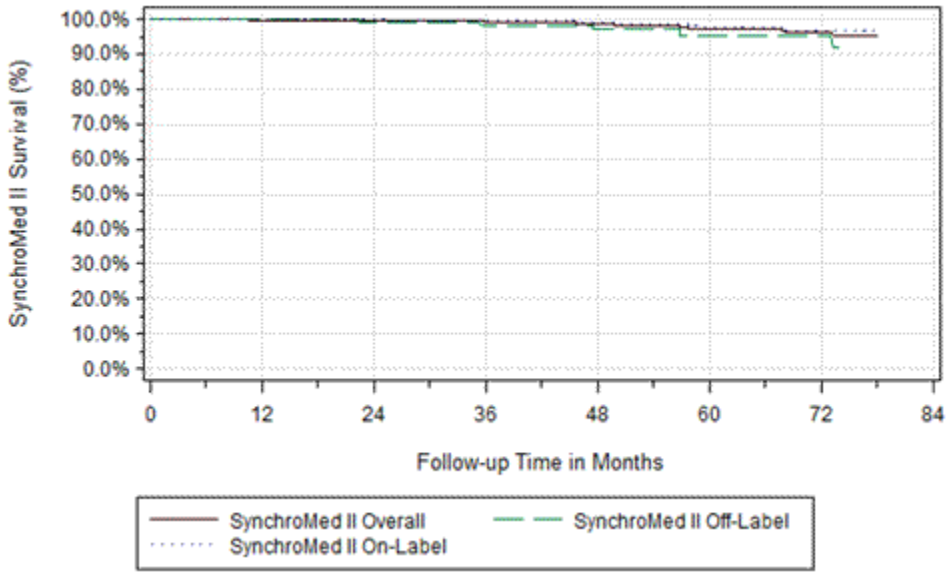
Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo
Spasticity Overall	Survival	99.7%	99.6%	99.0%	98.6%	97.1%	96.2%	95.5%	95.5%
	Number of pumps	995	822	611	461	304	153	97	33
Spasticity On-Label	Survival	99.9%	99.9%	99.4%	99.1%	97.8%	96.7%	96.7%	96.7%
	Number of pumps	796	661	489	364	243	122	76	24
Spasticity Off-Label	Survival	100.0%	99.2%	98.3%	97.1%	95.5%	95.5%	91.9%	-
	Number of pumps	149	130	100	77	53	30	21	-[b]

[a] Refer to product labeling for approved Spasticity indication.
[b] Sample size is less than 20 active devices at 78 months for Spasticity Off-Label pump group

The cumulative survival of the SynchroMed II pump for the **Spasticity** indication, and stratified by On-Label or Off-Label pump group, is shown below.

SynchroMed II cumulative survival (Spasticity)

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



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The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. Overall the survival for the On-Label pumps was similar to the entire pump population (all therapies). There were too few pumps in the Off-Label group to assess long term survival beyond five years (60 months). Statistical testing was not performed

due to low sample size in the Off-Label group at the 60-month follow-up (n=53) and beyond.

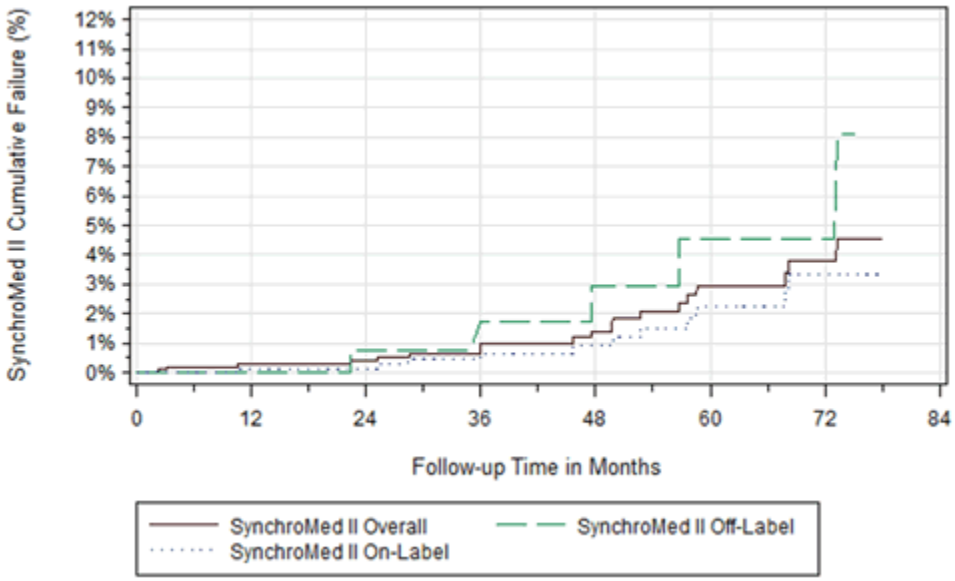
Spasticity study population: Cumulative failure of SynchroMed II pumps due to product performance-related pump events for Spasticity indication, by On/Off-Label drug exposure

Category[a]	Time Interval	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	75 mo	78 mo
Spasticity Overall	Failure	0.3%	0.4%	1.0%	1.4%	2.9%	3.8%	4.5%	4.5%
	Number of pumps	995	822	611	461	304	153	97	33
Spasticity On-Label	Failure	0.1%	0.1%	0.6%	0.9%	2.2%	3.3%	3.3%	3.3%
	Number of pumps	796	661	489	364	243	122	76	24
Spasticity Off-Label	Failure	0.0%	0.8%	1.7%	2.9%	4.5%	4.5%	8.1%	-
	Number of pumps	149	130	100	77	53	30	21	-[b]

[a] Refer to product labeling for approved Spasticity indication
[b] Sample size is less than 20 active devices at 78 months for Spasticity Off-Label pump group

SynchroMed II cumulative failure (Spasticity)

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



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Overall Summary and Limitations

- Pump failures have been observed in pumps with both On-Label and Off-Label medications used for all indications over the follow-up period.
- Off-Label medication exposure is associated with an overall 2.4 times greater risk of pump failure compared to On-Label medication exposure for the entire pump population. The rate of pump failure accelerates in the Off-Label group after 36 months of follow-up. At 78 months of follow-up, the survival from pump failure for On-Label pumps was 96.4%, compared to a survival of 88.9% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 17.5 months. The longer term data are based on a lower number of pumps and are subject to change as more follow-up data are obtained via the registry. Survival curve truncation or plateaus do not imply that the implanted devices will not be adversely impacted beyond the time points of the current data.
- The On-Label pump group consisted of 65% spasticity indication (1,249 vs. 687: Spasticity versus Pain pumps respectively). On the other hand, Off-Label group consisted of 95% pain indications (3,929 vs. 205: Pain versus Spasticity pumps respectively).
- Medication use was recorded as a snapshot at the time of follow-up. It is possible that some On-Label pumps received Off-Label medications in between 6-month follow-up periods. In addition, it is possible that some pumps designated as On-Label received compounded formulation of an On-Label equivalent (i.e. Lioresal) but was not designated as such in the registry database.
- The time a pump was exposed to an Off-Label medication was not assessed. It is possible that some Off-Label pumps were exposed only for a brief time period (e.g. < 6 months).
- The risk of pump failure by type of drug was not assessed. Many Off-Label pumps were exposed to multiple medications over the life span of the pump. This limits the ability to associate a specific drug, compounded drug, drug concentration, or drug combination with increased pump failure risk.

Catheters

From August 2003 to the report cut-off date of July 31, 2014, there were 7,154 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=7,644) because patients may have undergone pump replacements but used the same catheters, or patients may have been implanted with Medtronic pumps and non-Medtronic catheters which were not registered with Medtronic Device and Registrant Tracking system (DART). The aggregate prospective follow-up time for all catheters was 184,869 months (15,406 years). The table below provides the number and percentage of catheters by model.

Catheters by Model	
Model Number	**Number of Catheters (%)**
8709	2,782 (38.9%)
8709SC	1,000 (14.0%)
8711	633 (8.8%)
8731	495 (6.9%)
8780	355 (5.0%)
8781	247 (3.5%)
8703W	189 (2.6%)

8731SC	183 (2.6%)
Other/Unspecified	42 (0.6%)
Revised Not as Designed[a]	539 (7.5%)
Grafted Not As Designed[b]	387 (5.4%)
Revised as Designed (RAD)[c]	216 (3.0%)
Ascenda RAD[d]	86 (1.2%)
Total	**7,154 (100%)**

[a] Medtronic non-8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit
[b] Catheters that involve the ad-hoc assembly of components other than a Medtronic repair kit or brand new catheter
[c] 8731 catheters that had been repaired with an 8596 proximal or 8598 distal revision kit
[d] 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit

Catheter Events

There were 824 product performance events reported to the registry that were related to the catheter. Of these events, the majority were catheter dislodgement (n=225), catheter occlusion (n=199), or break or cut in the catheter (n=161). Of the 824 events, 727 were the first event attributable to an enrolled catheter.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For catheters:

- 727 had follow-up time cut-off due to product performance-related events.
- 4,280 were censored in the survival analysis for the following reasons: patient expired, catheter explanted/capped, site termination, patient discontinued, patient lost to follow-up, other catheter modification, therapy suspended, or non-product performance catheter-related event without an associated intervention.
- 2,147 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

Catheter Survival

The figures and tables below represent catheter survival and 95% confidence intervals where at least 20 catheters contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 12 months

of follow-up at the time of the report cut-off for each model.

Currently, the estimates of survival from catheter-related events exceed 80% (confidence intervals are equal to or exceed 70%) through 5 years of follow-up for applicable catheters with follow-up through that time point with the exception of revised not as designed and grafted not as designed catheters.

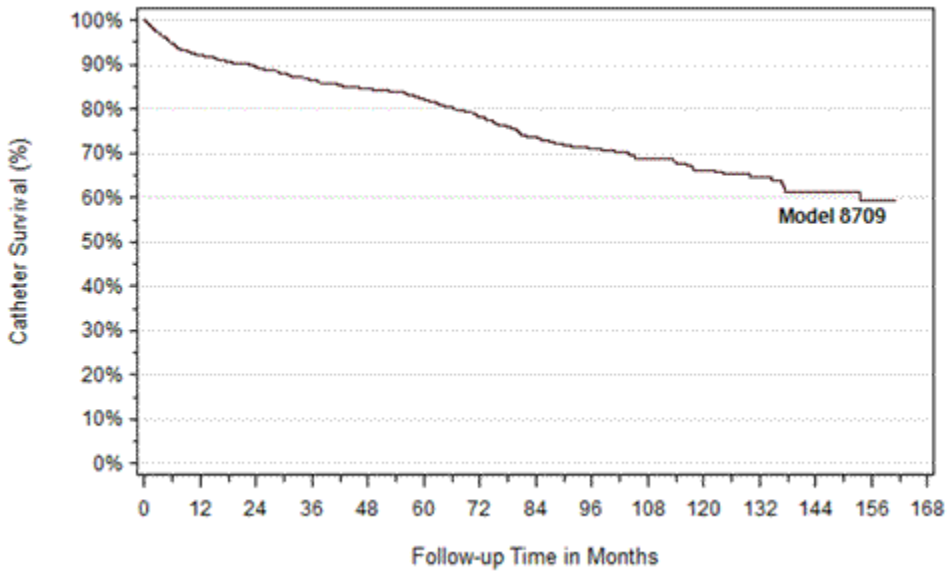
The survival estimates suggest that the survival of catheters grafted not as designed (those catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits) have a lower probability of survival across various applicable follow-up time points than some other catheter models. 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 those from a Medtronic repair kit or brand new catheter. Medtronic recommends that clinicians follow the labeling for the Model 8596 and 8598 revision kits.

In addition, although survival estimates for the Ascenda catheters may appear to demonstrate lower performance than the 8731SC predicate catheter at early follow-up time points, these results are reflective of limited cumulative follow-up months. The Ascenda catheters will continue to be monitored closely as we enroll more patients and follow devices for longer periods of time.

Choose a model Go

Model 8709: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8709
FDA Approval Date	May 1998
Catheters Enrolled	2,782

Catheters Currently Active in Study	366
Device Events	273
Cumulative Months of Follow-up	75,362

Model 8709: Event Summary Table

Catheter Event	**Total**
Catheter dislodgment from intrathecal space	80
Catheter break/cut	65
Catheter occlusion	63
Catheter disconnection at pump	18
Catheter kink	15
Catheter related complication[a]	9
Pump connector break/cut	9
Catheter leakage	7
Pump unable to enter/withdraw from catheter access port	2
Pump underinfusion	2
Device infusion issue[b]	1
Medical device complication[c]	1
Reservoir access issues due to residue	1
Total Catheter Events	**273**

[a] Includes 3 events reported as unable to aspirate catheter, 1 difficulty aspirating catheter, 1 coiled catheter, 1 unable to aspirate CSF, 1 aneurysm in catheter, 1 catheter dysfunction, 1 catheter malfunction
[b] Includes 1 event reported as slow dosing at refills
[c] Includes 1 event reported as pump connector appeared somewhat worn

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	92.1% (90.4%, 93.5%)	966
2 yrs	89.5% (87.5%, 91.2%)	899

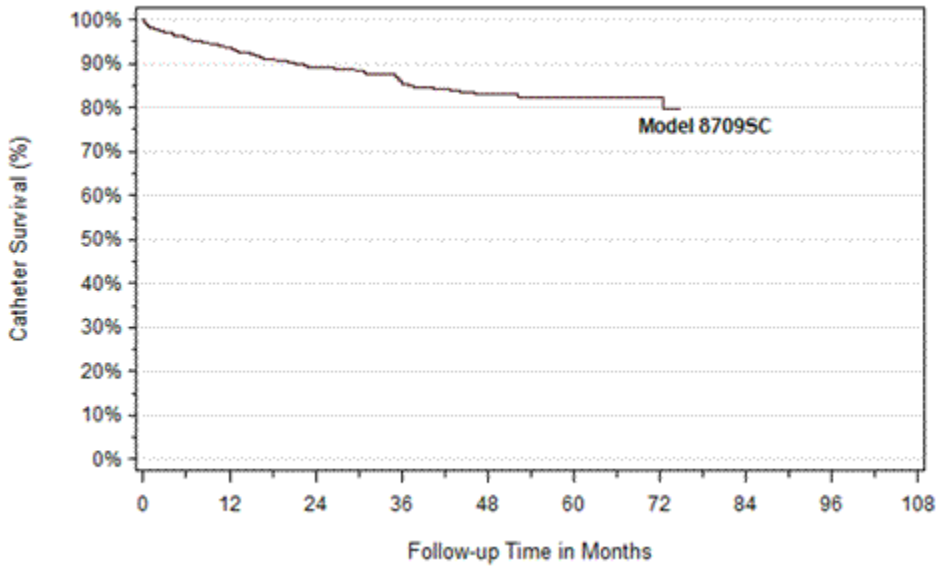
3 yrs	86.6% (84.4%, 88.5%)	821
4 yrs	84.5% (82.1%, 86.5%)	722
5 yrs	82.3% (79.7%, 84.5%)	594
6 yrs	78.2% (75.3%, 80.7%)	506
7 yrs	73.7% (70.5%, 76.6%)	399
8 yrs	71.0% (67.6%, 74.1%)	286
9 yrs	68.9% (65.2%, 72.3%)	178
10 yrs	66.3% (62.1%, 70.1%)	140
11 yrs	64.5% (60.0%, 68.7%)	92
12 yrs	61.3% (56.0%, 66.2%)	53
13 yrs	59.5% (53.1%, 65.3%)	28
at 162 mo	59.5% (53.1%, 65.3%)	20

Model 8709: Specifications

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

Model 8709SC: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8709SC
FDA Approval Date	Mar 2006
Catheters Enrolled	1,000
Catheters Currently Active in Study	408
Device Events	101
Cumulative Months of Follow-up	24,234

Model 8709SC: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	30
Catheter break/cut	22
Catheter occlusion	20
Catheter related complication[a]	7
Catheter kink	5
Catheter leakage	5
Catheter disconnection at pump	3
Medical device complication[b]	2
Pump unable to enter/withdraw from catheter access port	2
Catheter breakage	1
Catheter damage	1
Catheter disconnection between catheter segments	1
Product sedimentation present	1
Pump inversion	1
Total Catheter Events	**101**

[a] Includes 3 events reported as catheter malfunction, 1 coiled catheter, 1 catheter unable to aspirate, 1 catheter wrapped around pump, and 1 slight loop in catheter
[b] Includes 1 event reported as catheter occlusion and 1 sutureless connector failure

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	93.8% (91.9%, 95.3%)	650
2 yrs	89.1% (86.5%, 91.2%)	420
3 yrs	85.8% (82.6%, 88.5%)	252
4 yrs	83.0% (79.1%, 86.2%)	151

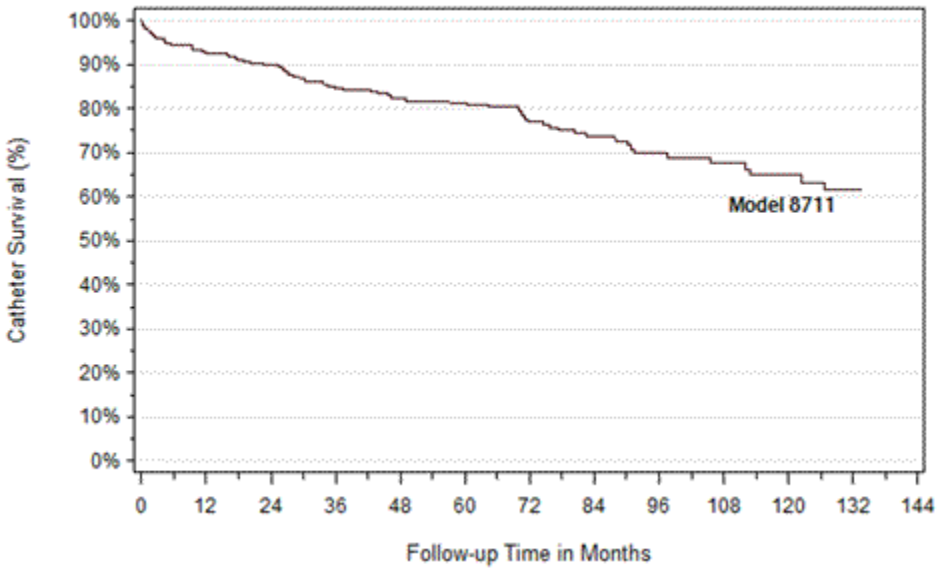
5 yrs	82.3% (78.2%, 85.7%)	84
6 yrs	82.3% (78.2%, 85.7%)	31
at 75 mo	79.5% (72.1%, 85.2%)	23

Model 8709SC: Specifications

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

Model 8711: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8711
FDA Approval Date	Oct 1999
Catheters Enrolled	633
Catheters Currently Active in Study	168
Device Events	80
Cumulative Months of Follow-up	21,460

Model 8711: Event Summary Table

Catheter Event	Total
Catheter occlusion	25
Catheter break/cut	17
Catheter dislodgment from intrathecal space	14
Catheter related complication[a]	12
Pump unable to enter/withdraw from catheter access port	5
Catheter kink	4
Catheter disconnection at pump	2
Pump connector break/cut	1
Total Catheter Events	**80**

[a] Includes 3 events reported as catheter malfunction, 3 unable to aspirate catheter, 2 non-functioning spinal catheters, 1 no free flow of CSF from spinal segment of catheter, 1 difficulty aspirating catheter, 1 distal catheter malfunction, 1 suspected catheter malfunction

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.5% (88.9%, 95.0%)	310
2 yrs	90.0% (86.1%, 92.9%)	272
3 yrs	84.5% (79.8%, 88.1%)	229

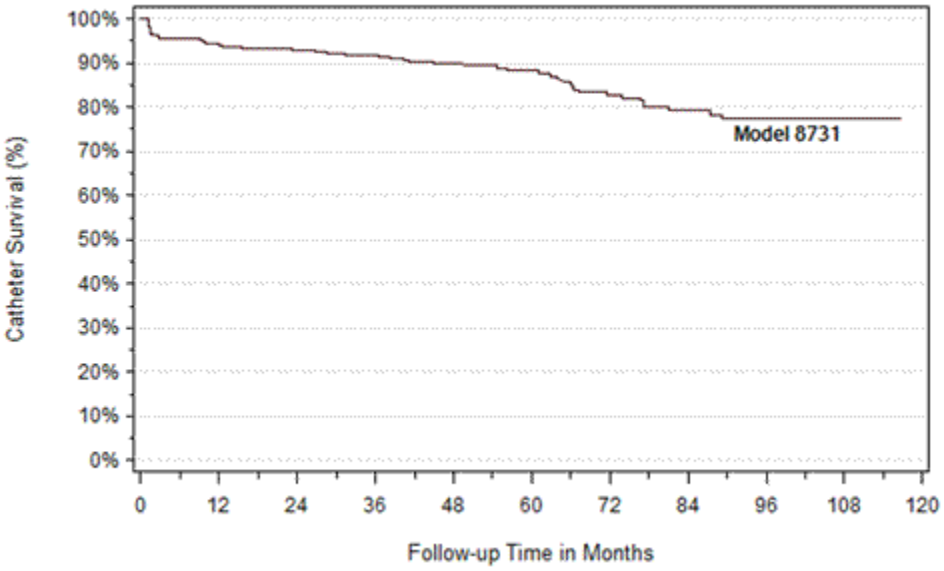
4 yrs	82.5% (77.6%, 86.4%)	202
5 yrs	81.3% (76.2%, 85.3%)	183
6 yrs	76.9% (71.2%, 81.6%)	125
7 yrs	73.5% (67.2%, 78.8%)	91
8 yrs	69.9% (62.9%, 75.9%)	69
9 yrs	67.7% (60.1%, 74.1%)	50
10 yrs	64.8% (56.6%, 71.9%)	42
11 yrs	61.5% (52.3%, 69.4%)	26
at 135 mo	61.5% (52.3%, 69.4%)	23

Model 8711: Specifications

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

Model 8731: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8731
FDA Approval Date	Oct 2002
Catheters Enrolled	495
Catheters Currently Active in Study	81
Device Events	44
Cumulative Months of Follow-up	18,812

Model 8731: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	18
Catheter occlusion	15
Catheter kink	3
Catheter related complication[a]	3
Catheter break/cut	2
Catheter disconnection at pump	2
Pump connector break/cut	1
Total Catheter Events	**44**

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

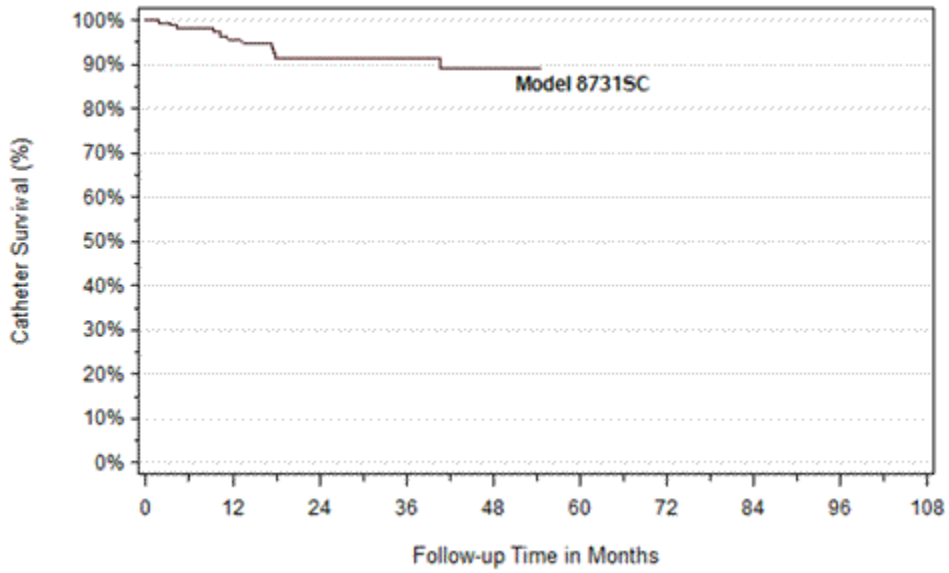
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	94.1% (89.5%, 96.7%)	260
2 yrs	92.8% (88.1%, 95.6%)	300
3 yrs	91.8% (87.1%, 94.8%)	251
4 yrs	89.8% (84.9%, 93.2%)	194
5 yrs	88.2% (83.0%, 91.9%)	147
6 yrs	82.8% (76.6%, 87.4%)	131
7 yrs	79.3% (72.5%, 84.5%)	94
8 yrs	77.3% (70.2%, 83.0%)	60
9 yrs	77.3% (70.2%, 83.0%)	42
at 117 mo	77.3% (70.2%, 83.0%)	23

Model 8731: Specifications

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

Model 8731SC: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	183
Catheters Currently Active in Study	98
Device Events	11
Cumulative Months of Follow-up	4,237

Model 8731SC: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	4
Catheter occlusion	4
Catheter disconnection at pump	1
Catheter kink	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**11**

Time Interval Survival	Sample Size

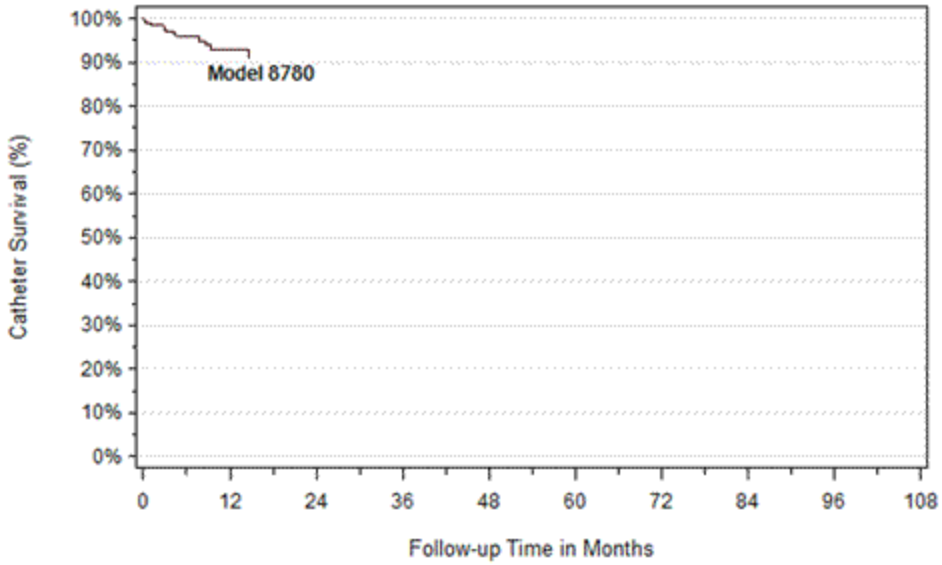
	(95% Confidence Interval)	
1 yr	95.5% (90.3%, 98.0%)	109
2 yrs	91.3% (84.2%, 95.3%)	59
3 yrs	91.3% (84.2%, 95.3%)	47
4 yrs	89.0% (79.9%, 94.1%)	32
at 57 mo	89.0% (79.9%, 94.1%)	23

Model 8731SC: Specifications

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

Model 8780: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8780
FDA Approval Date	Sept 2012
Catheters Enrolled	355
Catheters Currently Active in Study	298
Device Events	13
Cumulative Months of Follow-up	1,915

Model 8780: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	3
Catheter break/cut	2
Catheter disconnection at pump	2
Catheter kink	2
Catheter occlusion	2
Catheter related complication[a]	1
Device infusion issue[b]	1
Total Catheter Events	**13**

[a] Includes 1 event reported as unable to aspirate catheter
[b] Includes 1 event reported as suspected pump connector malalignment

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	93.0% (87.4%, 96.1%)	52
at 15 mo	91.0% (83.5%, 95.2%)	44

Model 8780: Specifications

Total Length	114 cm
Outer diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Connector end of the spinal segment

Model 8781: Survival from Catheter Events

Catheter Characteristics	
Model Number	8781
FDA Approval Date	Sept 2012
Catheters Enrolled	247
Catheters Currently Active in Study	145
Device Events	20
Cumulative Months of Follow-up	1,018

Model 8781: Event Summary Table

Catheter Event	Total
Catheter dislodgment from intrathecal space	9
Catheter kink	4

Catheter occlusion	3
Catheter break/cut	1
Catheter disconnection at pump	1
Catheter leakage	1
Pump underinfusion	1
Total Catheter Events	**20**

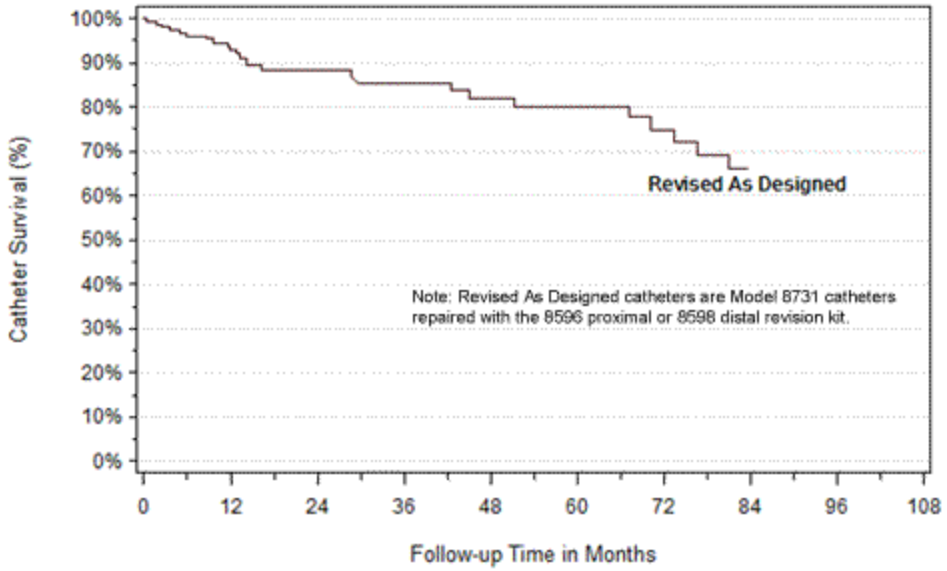
Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	88.3% (80.2%, 93.2%)	63
at 9 mo	83.8% (74.3%, 90.0%)	52

Model 8781: Specifications

Total Length	140 cm
Outer diameter (spinal segment)	1.2 mm (4.0 French)
Inner Diameter (spinal segment)	0.5 mm
Catheter Tip Description	Closed with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Catheter connector ends of the spinal and pump segments

Revised As Designed: Survival from Catheter Events

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



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

Catheter Characteristics	
Model Name	Revised As Designed
FDA Approval Date	Oct 2002
Catheters Enrolled	216
Catheters Currently Active in Study	93
Device Events	26
Cumulative Months of Follow-up	5,585

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.9% (87.1%, 96.1%)	111
2 yrs	88.4% (81.4%, 92.9%)	66
3 yrs	85.4% (77.0%, 90.9%)	53
4 yrs	82.1% (72.5%, 88.6%)	45

5 yrs	80.2% (70.0%, 87.3%)	37
6 yrs	74.9% (62.3%, 83.9%)	25
at 81 mo	66.0% (50.8%, 77.5%)	21

Revised As Designed: Specifications

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

Ascenda Revised As Designed Catheters: Survival from Catheter Events

Catheter Characteristics	
Model Name	Ascenda Revised As Designed[a]
FDA Approval Date	Sept 2012
Catheters Enrolled	86
Catheters Currently Active in Study	69
Device Events	2
Cumulative Months of Follow-up	354

[a] 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit

Ascenda Revised As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter dislodgment from intrathecal space	1
Catheter kink	1
Total Catheter Events	**2**

Revised As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter occlusion	11
Catheter dislodgment from intrathecal space	6
Catheter break/cut	2

Catheter kink	2
Catheter related complication[a]	2
Catheter placement[b]	1
Device connection issue	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**26**

[a] Includes 1 event reported as catheter malfunction and 1 inability to aspirate catheter
[b] Includes 1 event for catheter replacement with specific catheter problem not identified

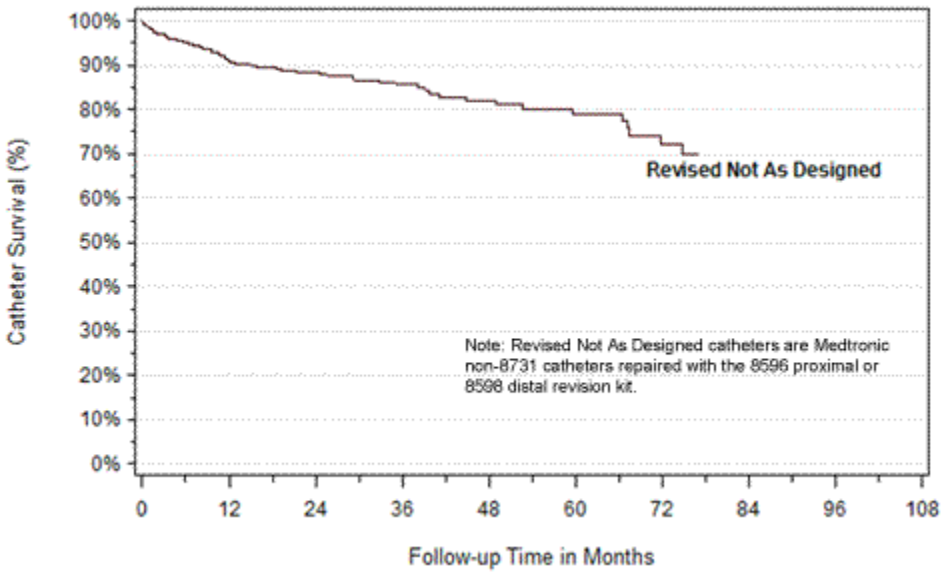
Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	98.2% (88.1%, 99.7%)	26

Ascenda Revised As Designed: Specifications

Ascenda Revised as Designed catheters are Model 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit

Revised Not As Designed: Survival from Catheter Events

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



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Note: Revised Not As Designed catheters are Medtronic non-8731 catheters repaired with the 8596

proximal or 8598 distal revision kit.

Catheter Characteristics	
Model Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	539
Catheters Currently Active in Study	291
Device Events	71
Cumulative Months of Follow-up	13,813

Revised Not As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter occlusion	18
Catheter dislodgment from intrathecal space	15
Catheter break/cut	14
Catheter kink	7
Catheter related complication[a]	4
Pump unable to enter/withdraw from catheter access port	4
Catheter disconnection at pump	3
Catheter access port issue	1
Catheter leakage	1
Cerebrospinal fluid abnormal[b]	1
Connector block problem	1
Device infusion issue[c]	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**71**

[a] Includes 2 events reported as catheter malfunction, 1 unable to aspirate catheter, and 1 catheter wrapped in coils and knots

[b] Reported as poor CSF flow

[c] Includes 1 event reported as fluctuating over and under medication distribution

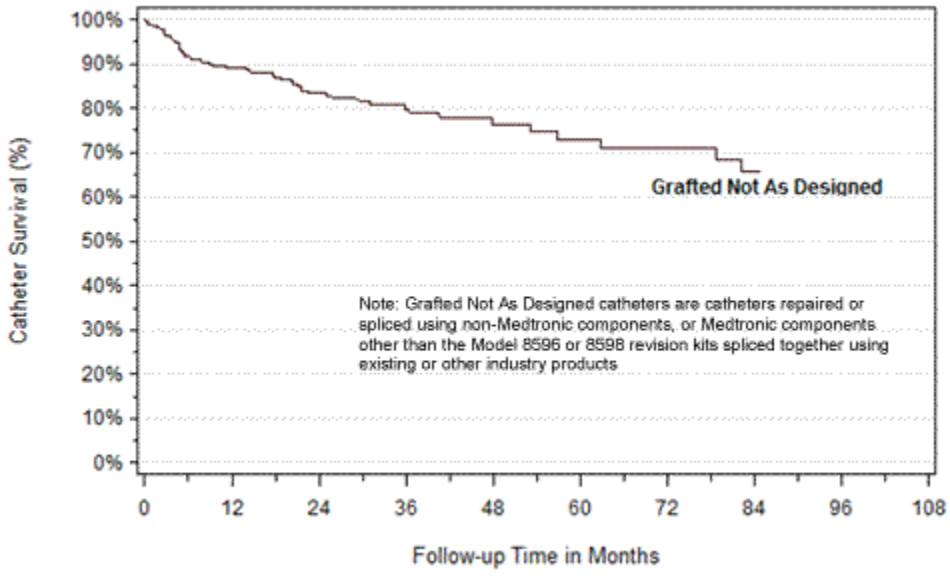
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	91.0% (87.7%, 93.4%)	349
2 yrs	88.4% (84.7%, 91.2%)	238
3 yrs	85.5% (81.3%, 88.9%)	143
4 yrs	82.1% (76.7%, 86.3%)	88
5 yrs	78.9% (72.5%, 84.0%)	65
6 yrs	72.1% (62.9%, 79.5%)	36
at 78 mo	70.0% (59.9%, 78.0%)	29

Revised Not As Designed: Specifications

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

Grafted Not As Designed: Survival from Catheter Events

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



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Note: Grafted Not As Designed catheters are catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits spliced together using existing or other industry products.

Catheter Characteristics	
Model Name	Grafted Not As Designed
FDA Approval Date	NA
Catheters Enrolled	387
Catheters Currently Active in Study	176
Device Events	61
Cumulative Months of Follow-up	9,546

Grafted Not As Designed Catheters: Event Summary Table

Catheter Event	**Total**
Catheter dislodgment from intrathecal space	23
Catheter occlusion	12
Catheter break/cut	7
Catheter kink	4
Catheter leakage	4
Catheter related complication[a]	4
Catheter disconnection at pump	2
Pump unable to enter/withdraw from catheter access port	2
Catheter breakage	1
Device component issue[b]	1
Pump connector break/cut	1
Total Catheter Events	**61**

[a] Includes 3 inability to aspirate catheter, 1 event reported as catheter malfunction
[b] Reported as broken anchor attributed to the catheter

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**

1 yr	89.1% (85.0%, 92.2%)	218
2 yrs	83.4% (78.2%, 87.4%)	144
3 yrs	79.8% (73.8%, 84.6%)	86
4 yrs	76.3% (69.0%, 82.1%)	51
5 yrs	72.9% (64.2%, 79.8%)	40
6 yrs	71.0% (61.7%, 78.5%)	33
7 yrs	65.7% (54.0%, 75.0%)	23
at 87 mo	65.7% (54.0%, 75.0%)	21

Grafted Not As Designed: Specifications

Grafted Not As Designed catheters are catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits spliced together using existing or other industry products.

Catheter Survival Summary

Currently, the estimates of survival from catheter-related events exceed 80% (confidence intervals are equal to or exceed 70%) through 5 years of follow-up for applicable catheters with follow-up through that time point with the exception of revised not as designed and grafted not as designed catheters.

The survival estimates suggest that catheters grafted not as designed (i.e, those catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 revision kits) have a lower probability of survival across various applicable follow-up time points compared to other catheter models.

In addition, although survival estimates for the Ascenda catheters may appear to demonstrate lower performance than the 8731SC predicate catheter at early follow-up time points, these results are reflective of limited cumulative follow-up months. The Ascenda catheters will continue to be monitored closely as we enroll more patients and follow devices for longer periods of time.

Catheter Characteristics						
Model Number	Family	FDA Approval Date	Catheters Enrolled	Catheters Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up

8709[b]	8709	May 1998	2,782	366	273	75,362
8709SC	8709	Mar 2006	1,000	408	101	24,234
8711	8711	Oct 1999	633	168	80	21,460
8731	8731	Oct 2002	495	81	44	18,812
8731SC	8731	Mar 2006	183	98	11	4,237
8780	Ascenda	Sept 2012	355	298	13	1,915
8781	Ascenda	Sept 2012	247	145	20	1,018
Revised As Designed	NA	Oct 2002	216	93	26	5,585
Ascenda Revised As Designed	NA	Sept 2012	86	69	2	354
Revised Not As Designed	NA	NA	539	291	71	13,813
Grafted Not As Designed	NA	NA	387	176	61	9,546

[a] There were a total of 824 catheter-related events reported to the registry, but only 700 events included in this summary table. The remaining catheter-related events either occurred in catheter models for which no device survival curves are presented due to an insufficient number of enrolled devices (n=27) or were subsequent events that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models

Device Survival Probability (95% Confidence Intervals) – *Table 1 of 3*					
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**
8709[a]	**92.1%** (90.4%, 93.5%)	**89.5%** (87.5%, 91.2%)	**86.6%** (84.4%, 88.5%)	**84.5%** (82.1%, 86.5%)	**82.3%** (79.7%, 84.5%)
8709SC	**93.8%** (91.9%, 95.3%)	**89.1%** (86.5%, 91.2%)	**85.8%** (82.6%, 88.5%)	**83.0%** (79.1%, 86.2%)	**82.3%** (78.2%, 85.7%)

8711	**92.5%** (88.9%, 95.0%)	**90.0%** (86.1%, 92.9%)	**84.5%** (79.8%, 88.1%)	**82.5%** (77.6%, 86.4%)	**81.3%** (76.2%, 85.3%)
8731	**94.1%** (89.5%, 96.7%)	**92.8%** (88.1%, 95.6%)	**91.8%** (87.1%, 94.8%)	**89.8%** (84.9%, 93.2%)	**88.2%** (83.0%, 91.9%)
8731SC	**95.5%** (90.3%, 98.0%)	**91.3%** (84.2%, 95.3%)	**91.3%** (84.2%, 95.3%)	**89.0%** (79.9%, 94.1%)	-
8780	**93.0%** (87.4%, 96.1%)	-	-	-	-
8781	[b]	-	-	-	-
Revised As Designed	**92.9%** (87.1%, 96.1%)	**88.4%** (81.4%, 92.9%)	**85.4%** (77.0%, 90.9%)	**82.1%** (72.5%, 88.6%)	**80.2%** (70.0%, 87.3%)
Ascenda Revised As Designed	[c]	-	-	-	-
Revised Not As Designed	**91.0%** (87.7%, 93.4%)	**88.4%** (84.7%, 91.2%)	**85.5%** (81.3%, 88.9%)	**82.1%** (76.7%, 86.3%)	**78.9%** (72.5%, 84.0%)
Grafted Not As Designed	**89.1%** (85.0%, 92.2%)	**83.4%** (78.2%, 87.4%)	**79.8%** (73.8%, 84.6%)	**76.3%** (69.0%, 82.1%)	**72.9%** (64.2%, 79.8%)

[a] Includes 8709 and 8709AA Models
[b] Model 8781 had a device survival probability of 83.8% (74.3%, 90.0%) at 9 months of follow-up
[c] Ascenda Revised As Designed had a device survival probability of 98.2% (88.1%, 99.7%) at 6 months of follow-up

Device Survival Probability (95% Confidence Intervals) – *Table 2 of 3*

Model Number	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs
8709[a]	**78.2%** (75.3%, 80.7%)	**73.7%** (70.5%, 76.6%)	**71.0%** (67.6%, 74.1%)	**68.9%** (65.2%, 72.3%)	**66.3%** (62.1%, 70.1%)
8709SC	**82.3%** (78.2%, 85.7%)	-	-	-	-
8711	**76.9%** (71.2%, 81.6%)	**73.5%** (67.2%, 78.8%)	**69.9%** (62.9%, 75.9%)	**67.7%** (60.1%, 74.1%)	**64.8%** (56.6%, 71.9%)

8731	**82.8%** (76.6%, 87.4%)	**79.3%** (72.5%, 84.5%)	**77.3%** (70.2%, 83.0%)	**77.3%** (70.2%, 83.0%)	-
8731SC	-	-	-	-	-
8780	-	-	-	-	-
8781	-	-	-	-	-
Revised As Designed	**74.9%** (62.3%, 83.9%)	-	-	-	-
Ascenda Revised As Designed	-	-	-	-	-
Revised Not As Designed	**72.1%** (62.9%, 79.5%)	-	-	-	-
Grafted Not As Designed	**71.0%** (61.7%, 78.5%)	**65.7%** (54.0%, 75.0%)	-	-	-

[a] Includes 8709 and 8709AA Models

Device Survival Probability (95% Confidence Intervals) – *Table 3 of 3*

Model Number	11 yrs	12 yrs	13 yrs
8709[a]	**64.5%** (60.0%, 68.7%)	**61.3%** (56.0%, 66.2%)	**59.5%** (53.1%, 65.3%)
8709SC	-	-	-
8711	**61.5%** (52.3%, 69.4%)	-	-
8731	-	-	-
8731SC	-	-	-
8780	-	-	-
8781	-	-	-
Revised As Designed	-	-	-
Ascenda Revised As Designed	-	-	-

Revised Not As Designed	-	-	-
Grafted Not As Designed	-	-	-

[a] Includes 8709 and 8709AA Models

2014 Medtronic Product Performance Report: Data through July 31, 2014

Therapies

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

Resources

- Education and Training
- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines
- Clinical Trials Registry
- Clinical Research Investigator Guidance

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Spinal Cord Stimulation Systems

- Study Participants
- Event Summary
- Spinal Cord Stimulators
- Leads
- Extensions

Study Participants

Centers

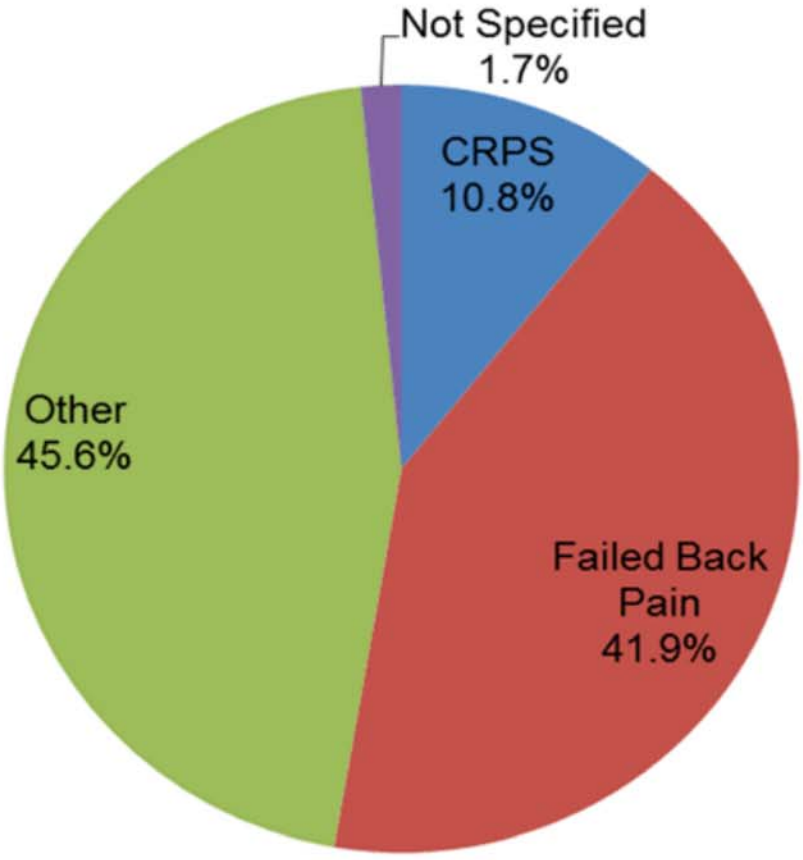
The following spinal cord stimulation tables and graphs were generated based on data collected between June 2004 and the report cut-off date of July 31, 2014. Sixty-nine centers enrolled and contributed patients to the spinal cord stimulation section of the report.

Patients

Of the 3,204 total spinal cord stimulation patients enrolled, 45.6% were implanted for the treatment of other pain indications, 41.9% were implanted for the treatment of failed back pain, 10.8% were implanted for the treatment of

complex regional pain syndrome (CRPS), and 1.7% were implanted for indications that were not specified in the database.

Primary SCS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Other	**1,462 (45.6%)**
Radicular pain syndrome	420 (13.1%)
Degenerative disc disease	121 (3.8%)
Cervical pain	22 (0.7%)
Diabetic neuropathy	15 (0.5%)
Traumatic nerve injury	11 (0.3%)
Post Herpetic Neuralgia	7 (0.2%)
Facial pain	5 (0.2%)
Epidural Fibrosis	2 (<0.1%)

Post herniorrhaphy pain	1 (<0.1%)
Other chronic pain	635 (19.8%)
Other	223 (7.0%)
Failed Back Pain	**1,343 (41.9%)**
Postlaminectomy pain	584 (18.2%)
Failed Back Syndrome (FBS)	456 (14.2%)
Combination back and leg pain	208 (6.5%)
Multiple Back Operations	68 (2.1%)
Arachnoiditis	21 (0.7%)
Unsuccessful Disc Surgery	6 (0.2%)
CRPS	**346 (10.8%)**
CRPS I	262 (8.2%)
CRPS II	84 (2.6%)
Not Specified	**53 (1.7%)**
Total Patients	**3,204**

[a] Refer to product labeling for approved indications.

Event Summary

There were 1,728 events reported between June 2004 and July 31, 2014 in patients with spinal cord stimulation systems. Over forty-two percent of these events (730/1,728) were categorized as product performance-related and are presented graphically within this report. The 730 product performance events occurred in 331 of the 3,204 total patients (10.33%) enrolled. In addition, there were 998 non-product performance events. There were also 86 deaths reported for patients with neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. Early versions of the protocol required events to be reported only when the event required a surgical intervention, resulted in therapy abandonment, or resulted in death. The required event reporting definition was expanded in April 2010 to include all adverse events related to the device, implant procedure, and/or therapy. The event tables provided below include combined data from these versions of the protocol.

Neurostimulation System Product Performance Events

Event[a]	Number of	Number of	Percent of

Neurostimulation System Product Performance Events

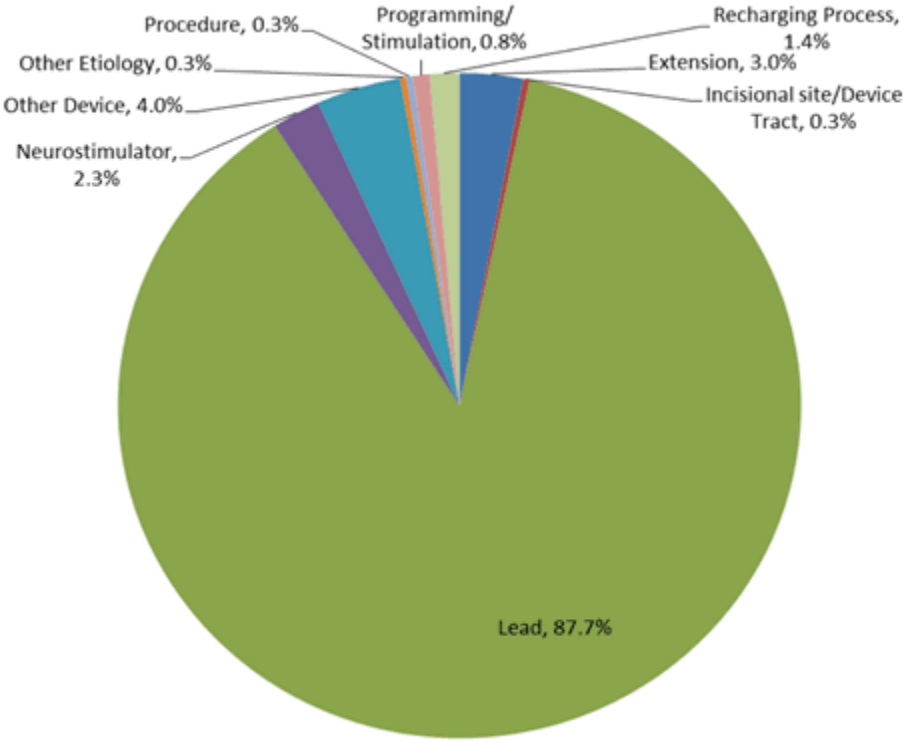
	Product Performance Events	Patients with Event[b]	Patients with Event (n=3,204)
Lead migration/dislodgment	377	192	5.99%
Lead high impedance	129	53	1.65%
Lead fracture	50	34	1.06%
Device stimulation issue[c]	45	25	0.78%
Lead low impedance	26	7	0.22%
Neurostimulator unable to recharge[d]	20	18	0.56%
Medical device complication[e]	15	10	0.31%
Extension fracture	13	8	0.25%
Device breakage[f]	12	12	0.37%
Device malfunction[g]	12	10	0.31%
Device connection issue	7	1	0.03%
Device lead damage	7	5	0.16%
Device failure[h]	4	3	0.09%
Device component issue[i]	3	2	0.06%
Not Coded[j]	2	1	0.03%
Paraesthesia[k]	2	2	0.06%
Therapeutic product ineffective	2	1	0.03%
Antenna cable breakage	1	1	0.03%

Neurostimulation System Product Performance Events			
Battery recharge issue	1	1	0.03%
Broken bond wire	1	1	0.03%
Device battery issue	1	1	0.03%
Total	**730**	**331**	**10.33%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term
[b] The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[c] Device stimulation issue reported by physician as being caused by neurostimulator (n=2) or lead (n=43).
[d] There were a total of 1,914 patients that used rechargeable SCS neurostimulators in the registry. A total of 1.0% (20/1,914) of patients with a rechargeable SCS neurostimulator experienced a recharging unable to recharge event.
[e] Includes 4 leads no longer providing stimulation, 3 error messages on patient programmer, 2 events reported as unable to pass stylet into lead, 2 leads with open circuits, 1 unknown problem with extension, 1 defective patient programmer, 1 excessive heating of charging unit, and 1 hybrid anomaly.
[f] Includes 6 broken recharger belts, 1 broken antenna, 1 broken antenna and jack, 1 broken charger, 1 broken patient programmer, 1 frayed cord to recharge antenna, and 1 frayed wire to recharger.
[g] Includes 3 neurostimulator malfunctions, 2 events for impedance not measurable, 2 events for non-functional lead electrodes , 1 antenna malfunction, 1 malfunctioning programmer, 1 event for lead impedance changes, 1 event for error messages on programmer, and 1 event for neurostimulator stopped working abruptly.
[h] Includes 2 events for lead failure, 1 event for failure of lead electrodes, and 1 extension failure.
[i] Includes 2 events for lead fractures and migration and 1 faulty antenna.
[j] Includes 2 events for malfunction in leads.
[k] Includes 1 event for shocking sensation at battery site and 1 shocking sensation at battery/extension connection.

A total of 640 (87.7%) of the 730 product performance events were related to the lead, 29 (4.0%) were related to "other device", 22 (3.0%) were related to the extension, 17 (2.3%) were related to the neurostimulator, 10 (1.4%) were related to recharging process, 6 (0.8%) were related to programming/stimulation, 2 (0.3%) was related to incisional site/device tract, 2 (0.3%) were related to other etiology, and 2 (0.3%) were related to the procedure. Relatedness is determined by the physician.

Product Performance Events by Relatedness



Neurostimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Device issues	**301**
Device stimulation issue[c]	150
Neurostimulator unable to recharge[d]	78
Neurostimulator migration	31
Device battery issue[e]	6
Device use error	5
Other[f]	31
Administration site reactions	**242**

Neurostimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Implant site pain	115
Implant site infection	70
Implant site erythema	15
Implant site erosion	13
Implant site extravasation	11
Other[f]	18
Therapeutic and nontherapeutic effects (excluding toxicity)	**234**
Therapeutic product ineffective	112
Therapeutic response decreased	60
No therapeutic response	58
Other[f]	4
General system disorders not elsewhere classified (NEC)	**52**
Pain	47
Other[f]	5
Procedural related injuries and complications NEC	**35**
Wound dehiscence	7
Incision site pain	5
Other[f]	23
Musculoskeletal and connective tissue disorders NEC	**27**
Pain in extremity	15
Back pain	8

Neurostimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other[f]	4
Complications associated with device	**19**
Medical device discomfort	14
Other[f]	5
Infections - pathogen unspecified	**19**
Infection	9
Wound infection	7
Other[f]	3
Neurological disorders NEC	**19**
Paraesthesia	11
Other[f]	8
Not Coded[g]	**6**
Other[f]	**44**
Total	**998**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms
[c] Event reported by the physician with an etiology that was not device related.
[d] Patient was unable to recharge due to an issue not related to the device.
[e] Includes 4 events reported as difficulty recharging neurostimulator, 1 unable to fully charge neurostimulator, and 1 unable to charge neurostimulator not due to the neurostimulator.
[f] Composed of event codes with fewer than 5 events each.
[g] Events were not coded at the time of data cut-off. Reported as1 unsatisfactory SCS analgesia secondary to lead migration, 1 malpositioned generator, 1 inadequate coverage, 1 possible connection issues, 1 abnormal system continuity check, and 1 not specified.

There were 86 deaths reported for patients with neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. As indicated, 46 (53.5%) of deaths occurred in patients receiving therapy for pain indications in the "other" category, 35 (40.7%) for failed back, and 5 (5.8%) for CRPS.

Death by Primary Indication
Primary Indication[a] N (%)

Death by Primary Indication	
CRPS	5 (5.8%)
Failed Back	35 (40.7%)
Other	46 (53.5%)
Total	**86 (100%)**

[a] Refer to product labeling for approved indications

Spinal Cord Stimulators

From June 2004 to the report cut-off date of July 31, 2014, 3,521 spinal cord stimulators were followed in the registry. The difference between the total number of patients (N=3,204) versus spinal cord stimulators is due to the fact that some patients had multiple spinal cord stimulators or were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord stimulators was 56,203 months (4,684 years). The table below provides the number and percentage of spinal cord stimulators by model.

Spinal Cord Stimulators by Model	
Model Name	**Number of Spinal Cord Stimulators (%)**
PrimeAdvanced	633 (18.0%)
RestoreUltra	579 (16.4%)
Synergy	461 (13.1%)
Restore	447 (12.7%)
RestoreAdvanced	360 (10.2%)
RestoreSensor	309 (8.8%)
RestoreSensor SureScan MRI	293 (8.3%)
PrimeAdvanced SureScan MRI	128 (3.6%)
Itrel 3	96 (2.7%)
RestorePrime	58 (1.6%)
Synergy Versitrel	42 (1.2%)
Itrel 4	32 (0.9%)
RestoreAdvanced SureScan MRI	29 (0.8%)
Other/Unspecified	18 (0.5%)

SynergyPlus+	16 (0.5%)
RestoreUltra SureScan MRI	12 (0.3%)
SynergyCompact	8 (0.2%)
Total	**3,521 (100%)**

Spinal Cord Stimulator Events

There were 17 product performance-related events with an underlying reported etiology related to spinal cord stimulator function. Of these, 13 were the first event attributable to an enrolled stimulator. For spinal cord stimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 213/809 (26.3%). The proportion was based upon the number of registry 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 17 spinal cord stimulator events was confirmed by Medtronic RPA as a broken bond wire. The remaining 16 spinal cord stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device related by the physician due to medical device complication (n=3), neurostimulator unable to recharge (n=3), lead high impedance (n=3), device malfunction (n=3), device stimulation issue (n=2), device battery issue (n=1), or device connection issue (n=1).

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For spinal cord stimulators:

- 13 had follow-up time cut-off due to product performance-related events.
- 1,960 were censored in the survival analysis for the following reasons: patient expired, stimulator explanted, site termination, patient discontinued, other stimulator modification, therapy suspended, or non-product performance stimulator-related event without an associated intervention.
- 1,548 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

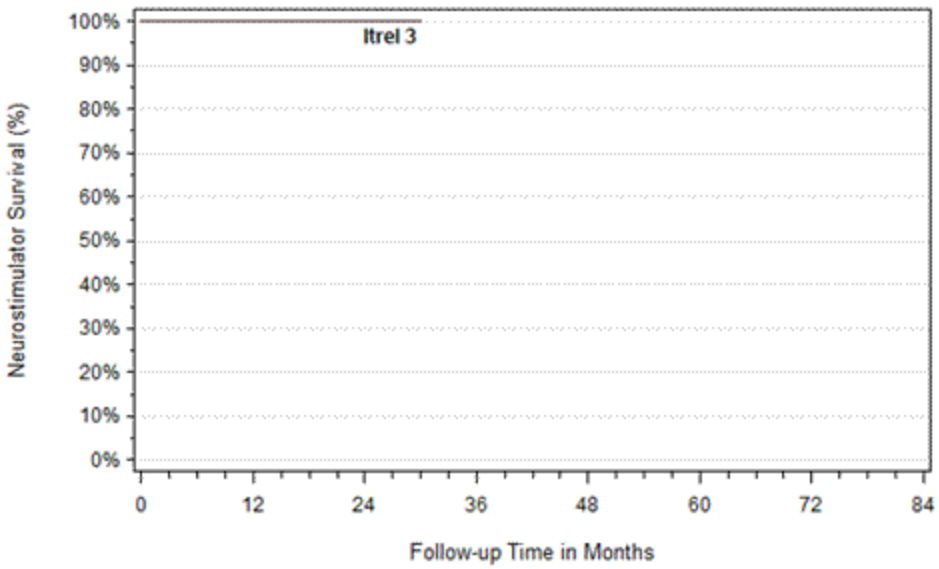
Spinal Cord Stimulator Survival

The figures and tables below represent spinal cord stimulator survival and 95% confidence intervals where at least 20 spinal cord stimulators contributed to each 3-month interval. Currently, estimates of device survival from neurostimulator-related events exceed 97% (confidence intervals exceed 87%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 7425 Itrel 3: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Itrel 3
FDA Approval Date	Aug 1995
Neurostimulators Enrolled	96
Neurostimulators Currently Active in Study	0
Device Events	0
Cumulative Months of Follow-up	1,360

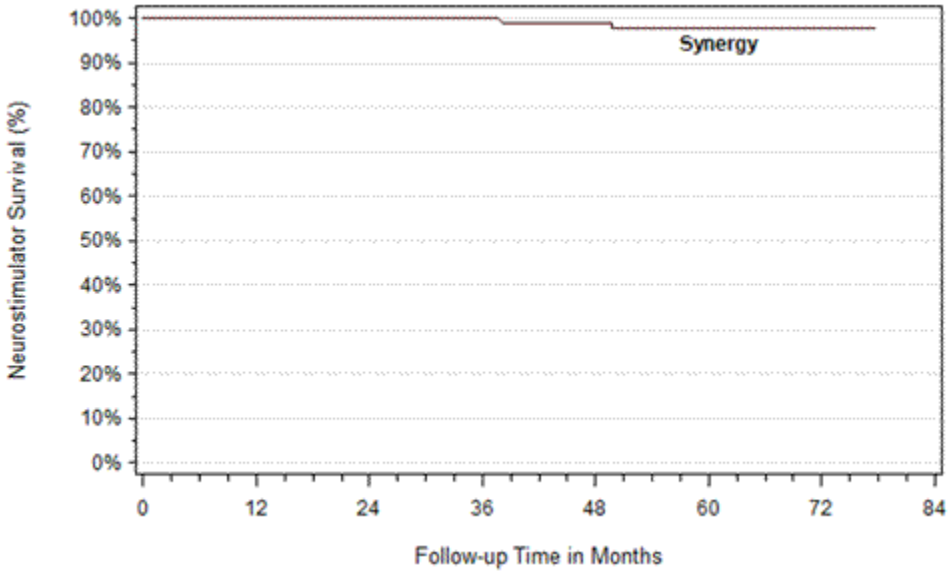
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	35
2 yrs	100.0% (NA)	23
at 30 mo	100.0% (NA)	21

Model 7425 Itrel 3: Specifications

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

Model 7427 Synergy: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics

Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	461
Neurostimulators Currently Active in Study	16
Device Events	2
Cumulative Months of Follow-up	8,778

Model 7427 Synergy: Event Summary Table

Neurostimulator Event	Total
Device stimulation issue	1
Broken bond wire	1
Total Neurostimulator Events	**2**

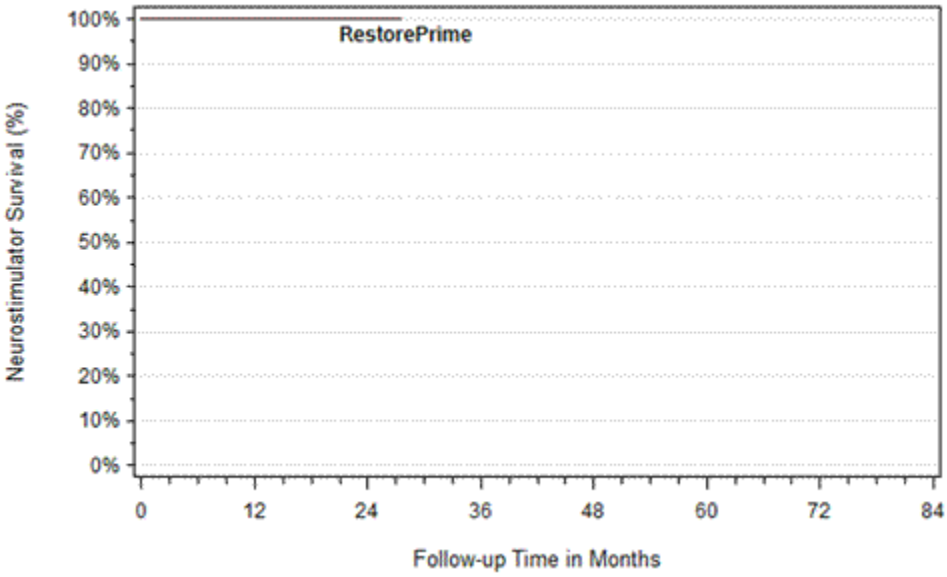
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	202
2 yrs	100.0% (NA)	166
3 yrs	100.0% (NA)	112
4 yrs	99.1% (93.6%, 99.9%)	73
5 yrs	97.6% (90.6%, 99.4%)	43
6 yrs	97.6% (90.6%, 99.4%)	28
at 81 mo	97.6% (90.6%, 99.4%)	20

Model 7427 Synergy: Specifications

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

Model 37701 RestorePrime: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics

Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	58
Neurostimulators Currently Active in Study	3
Device Events	0
Cumulative Months of Follow-up	1,237

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	35
2 yrs	100.0% (NA)	24
at 27 mo	100.0% (NA)	22

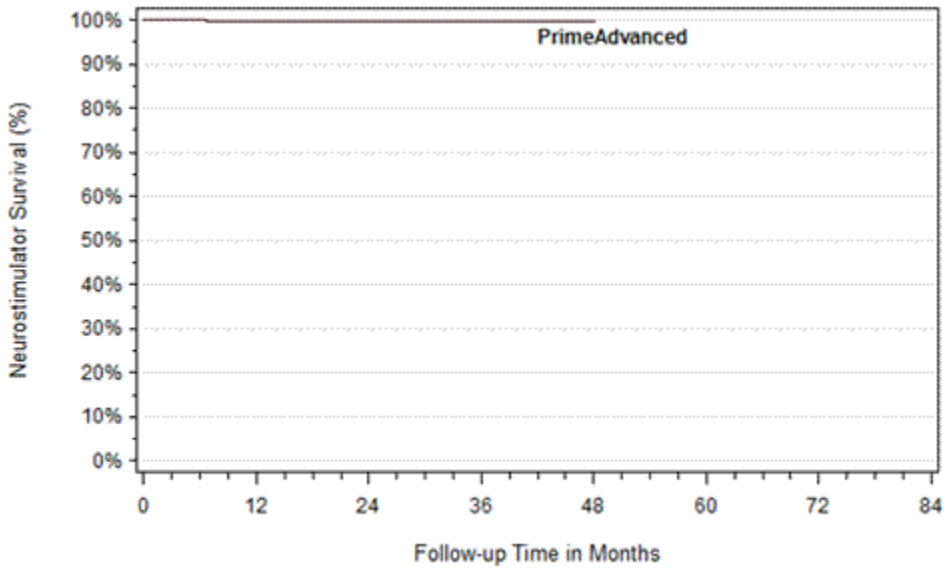
Model 37701 RestorePrime: Specifications

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

Implant Depth	≤ 4 cm

Model 37702 PrimeAdvanced: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	633
Neurostimulators Currently Active in Study	168
Device Events	1
Cumulative Months of Follow-up	9,329

Model 37702 PrimeAdvanced: Event Summary Table

Neurostimulator Event	Total
Device stimulation issue	1
Total Neurostimulator Events	**1**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.8% (98.2%,100.0%)	293

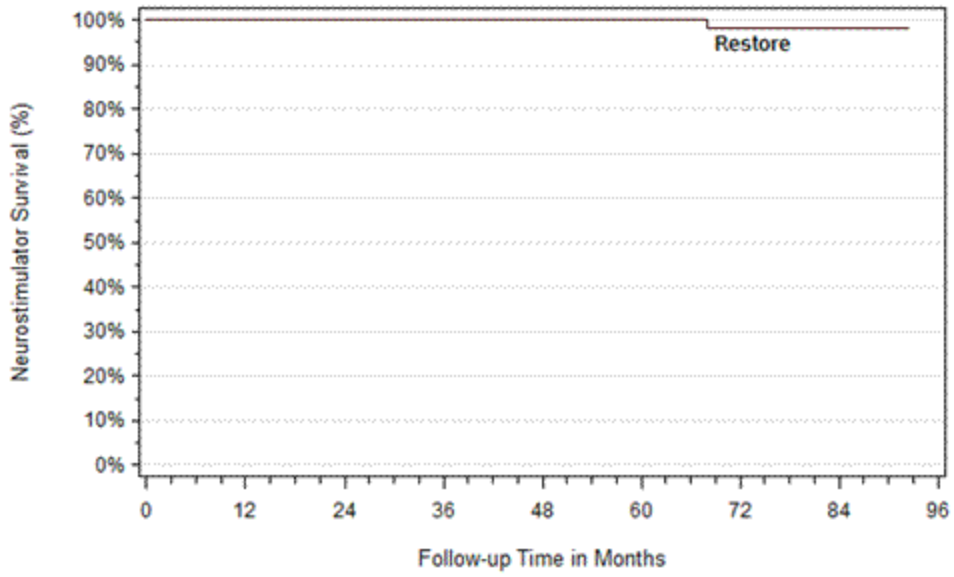
2 yrs	99.8% (98.2%,100.0%)	140
3 yrs	99.8% (98.2%,100.0%)	64
4 yrs	99.8% (98.2%,100.0%)	21

Model 37702 PrimeAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 4 cm

Model 37711 Restore: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	447
Neurostimulators Currently Active in Study	40
Device Events	3
Cumulative Months of Follow-up	11,958

Model 37711 Restore: Event Summary Table

Neurostimulator Event	Total
Neurostimulator unable to recharge	2
Device battery issue	1
Total Neurostimulator Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	267
2 yrs	100.0% (NA)	216
3 yrs	100.0% (NA)	139
4 yrs	100.0% (NA)	80

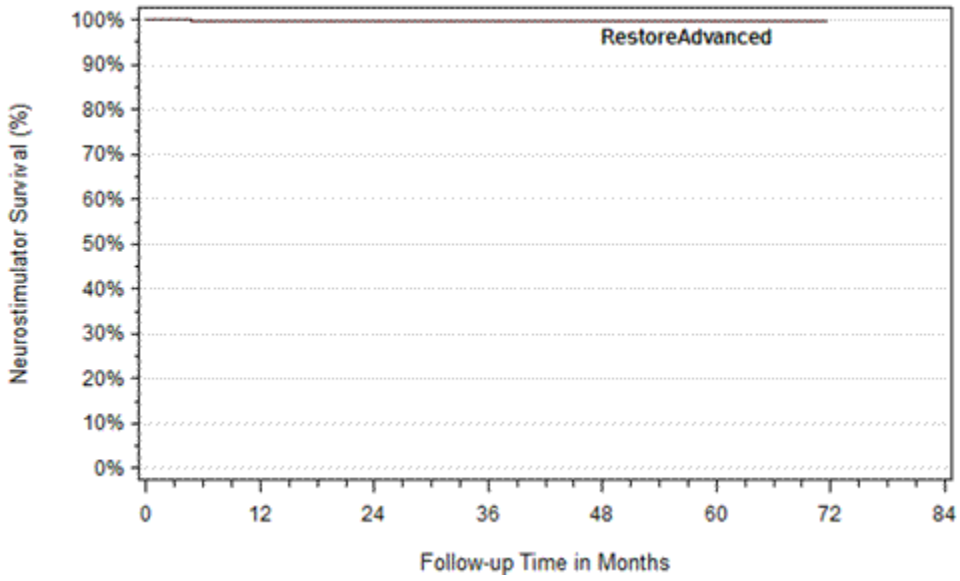
5 yrs	100.0% (NA)	63
6 yrs	98.1% (87.2%, 99.7%)	47
7 yrs	98.1% (87.2%, 99.7%)	32
at 93 mo	98.1% (87.2%, 99.7%)	20

Model 37711 Restore: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 1 cm

Model 37713 RestoreAdvanced: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	360
Neurostimulators Currently Active in Study	123
Device Events	1
Cumulative Months of Follow-up	8,012

Model 37713 RestoreAdvanced: Event Summary Table

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

[a] One event reported as hybrid anomaly

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.6% (97.4%, 99.9%)	203
2 yrs	99.6% (97.4%, 99.9%)	129

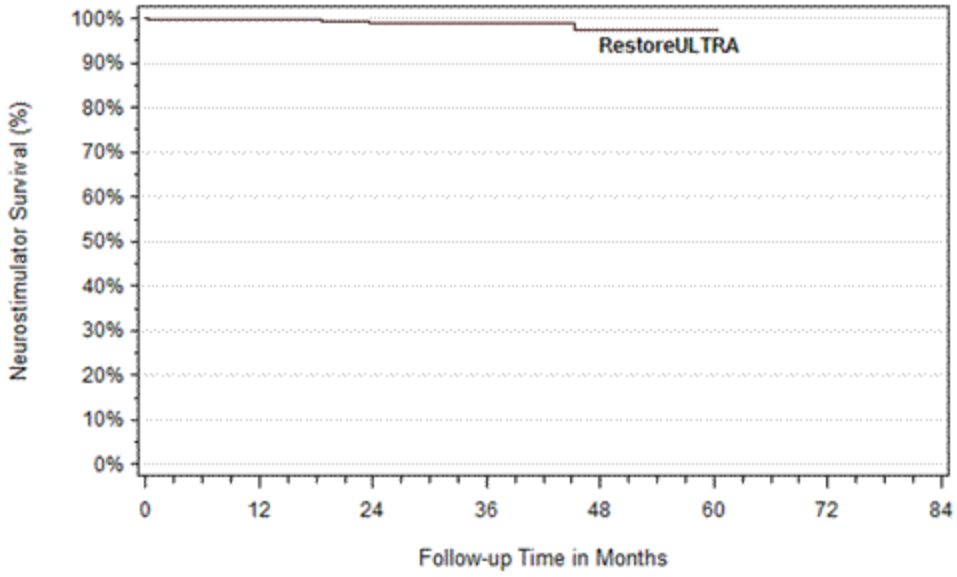
3 yrs	99.6% (97.4%, 99.9%)	75
4 yrs	99.6% (97.4%, 99.9%)	54
5 yrs	99.6% (97.4%, 99.9%)	32
6 yrs	99.6% (97.4%, 99.9%)	20

Model 37713 RestoreAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 1 cm

Model 37712 RestoreUltra: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	579
Neurostimulators Currently Active in Study	146
Device Events	4
Cumulative Months of Follow-up	10,802

Model 37712 RestoreUltra: Event Summary Table

Neurostimulator Event	Total
Device malfunction[a]	2
Lead high impedance	1
Medical device complication[b]	1
Total Neurostimulator Events	**4**

[a] One event reported as malfunction of the spinal cord stimulation system and 1 as problems with reprogramming
[b] Error message on patient programmer

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.8%	291

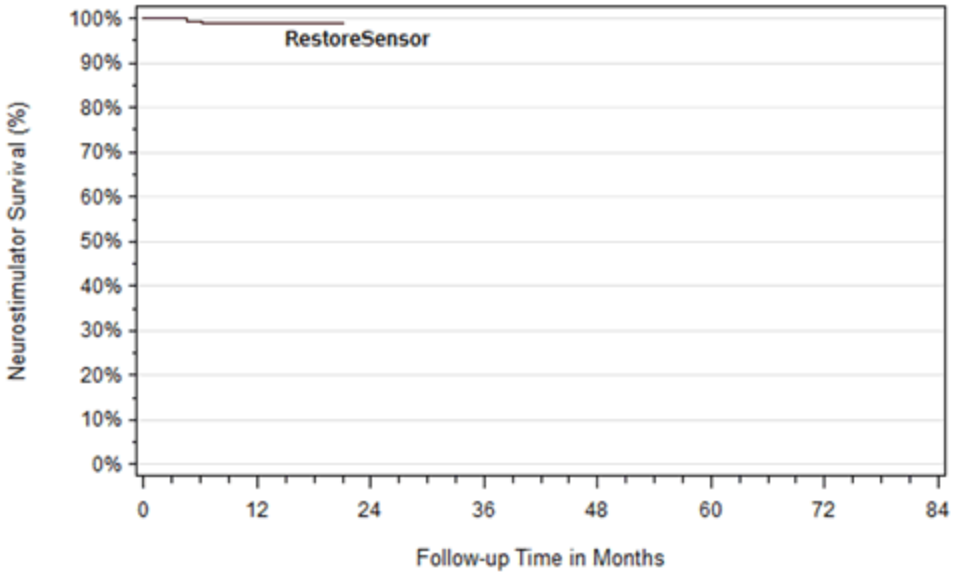
	(98.5%, 100.0%)	
2 yrs	98.7% (95.9%, 99.6%)	168
3 yrs	98.7% (95.9%, 99.6%)	112
4 yrs	97.5% (92.1%, 99.2%)	66
5 yrs	97.5% (92.1%, 99.2%)	23

Model 37712 RestoreUltra: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	0.4 in (10 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 1 cm

Model 37714 RestoreSensor: Survival from Spinal Cord Stimulator Events

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



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Spinal Cord Stimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011
Neurostimulators Enrolled	309
Neurostimulators Currently Active in Study	239
Device Events	2
Cumulative Months of Follow-up	2,632

Model 37714 RestoreSensor: Event Summary Table

Neurostimulator Event	Total
Device malfunction[a]	1
Neurostimulator unable to recharge	1
Total Neurostimulator Events	**2**

[a] One event reported as neurostimulator malfunction

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	98.9% (95.5%, 99.7%)	94
at 21 mo	98.9% (95.5%, 99.7%)	31

Model 37714 RestoreSensor: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 1 cm

Spinal Cord Stimulator Survival Summary

Currently, estimates of device survival from neurostimulator-related events exceed 97% (confidence intervals exceed 87%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Spinal Cord Stimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
Primary Cell Neurostimulators						
Itrel 3	Itrel 3	Aug 1995	96	0	0	1,360
Synergy	Synergy	Nov 1999	461	16	2	8,778

Restore Prime	Restore	Mar 2006	58	3	0	1,237
Prime Advanced	Prime Advanced	Jul 2006	633	168	1	9,329
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	447	40	3	11,958
Restore Advanced	Restore	Jul 2006	360	123	1	8,012
Restore Ultra	Restore	Jan 2008	579	146	4	10,802
Restore Sensor	Restore	Nov 2011	309	239	2	2,632

[a] There were 17 neurostimulator-related events reported to the registry, but only 13 events included in this summary table. The remaining neurostimulator-related events were subsequent events that did not affect the device survival estimates.

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

Model Name	1 yr	2 yrs	3 yrs	4 yrs
Primary Cell Neurostimulators				
Itrel 3	**100.0%** NA	**100.0%** NA	-	-
Synergy	**100.0%** NA	**100.0%** NA	**100.0%** NA	**99.1%** (93.6%, 99.9%)
RestorePrime	**100.0%** NA	**100.0%** NA	-	-
PrimeAdvanced	**99.8%** (98.2%, 100.0%)	**99.8%** (98.2%, 100.0%)	**99.8%** (98.2%, 100.0%)	**99.8%** (98.2%, 100.0%)
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA
RestoreAdvanced	**99.6%** (97.4%, 99.9%)	**99.6%** (97.4%, 99.9%)	**99.6%** (97.4%, 99.9%)	**99.6%** (97.4%, 99.9%)

RestoreUltra	**99.8%** (98.5%, 100.0%)	**98.7%** (95.9%, 99.6%)	**98.7%** (95.9%, 99.6%)	**97.5%** (92.1%, 99.2%)
RestoreSensor	**98.9%** (95.5%, 99.7%)	-	-	-

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

Model Name	5 yrs	6 yrs	7 yrs
Primary Cell Neurostimulators			
Itrel 3	-	-	-
Synergy	**97.6%** (90.6%, 99.4%)	**97.6%** (90.6%, 99.4%)	-
RestorePrime	-	-	-
PrimeAdvanced	-	-	-
Rechargeable Neurostimulators			
Restore	**100.0%** NA	**98.1%** (87.2%, 99.7%)	**98.1%** (87.2%, 99.7%)
RestoreAdvanced	**99.6%** (97.4%, 99.9%)	**99.6%** (97.4%, 99.9%)	-
RestoreUltra	**97.5%** (92.1%, 99.2%)	-	-
RestoreSensor	-	-	-

Leads

From June 2004 to the report cut-off date of July 31, 2014, there were 5,998 leads followed in the registry. Differences between the total number of leads versus spinal cord stimulators (N=3,521) were due to the fact that some patients were subsequently re-implanted with a new lead or were implanted with more than 1 lead. The aggregate prospective follow-up time for all leads was 103,974 months (8,665 years).

A lead is a set of thin wires with a protective coating and electrodes near the tip (percutaneous lead) or on a paddle (surgical lead). The table below provides the number and percentage of leads by model.

Leads by Model

Model Number	Number of Leads (%)
3778	2,095 (34.9%)
3487A	880 (14.7%)
3777	764 (12.7%)

977A2	608 (10.1%)
3888	383 (6.4%)
39565	178 (3.0%)
3776	172 (2.9%)
3887	164 (2.7%)
3998	142 (2.4%)
3890	128 (2.1%)
3891	117 (2.0%)
3986A	94 (1.6%)
3999	52 (0.9%)
3587A	48 (0.8%)
977A1	36 (0.6%)
3892	17 (0.3%)
39286	17 (0.3%)
3987A	7 (0.1%)
3982A	1 (<0.1%)
Other/Unspecified	95 (1.6%)
Total	**5,998 (100%)**

Over ninety percent (90.4%) of leads in the registry were percutaneous leads (5,423/5,998) including 50.5% (3,031/5,998) in the Pisces-Octad lead family, 23.8% (1,427/5,998) in the Pisces-Quad lead family, 10.7% (644/5,998) in the Vectris SureScan MRI lead family, and 4.4% (262/5,998) in the Pisces-Quad LZ lead family. Almost eight percent (8.0%) of leads (479/5,998) were surgical leads. A small number of leads (96/5,998) were designated as Other (1.6%).

Lead Events

There were 640 product performance-related events with an underlying reported etiology related to the lead. Of these events, the majority were lead migration/dislodgements (n=373), high impedance (n=119), and lead fracture (n=50). Of the 640 events, 547 were the first event attributable to an enrolled lead: 519 events in 5,423 (9.6%) percutaneous leads, 27 events in 479 (5.6%) surgical leads, and 1 event occurred in a lead with an unknown model number.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence

of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

- 547 had follow-up time cut-off due to product performance-related events.
- 2,683 were censored in the survival analysis for the following reasons: patient expired, lead explanted, site termination, patient discontinued, other lead modification, therapy suspended, or non-product performance lead-related event without an associated intervention.
- 2,768 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

Lead Survival

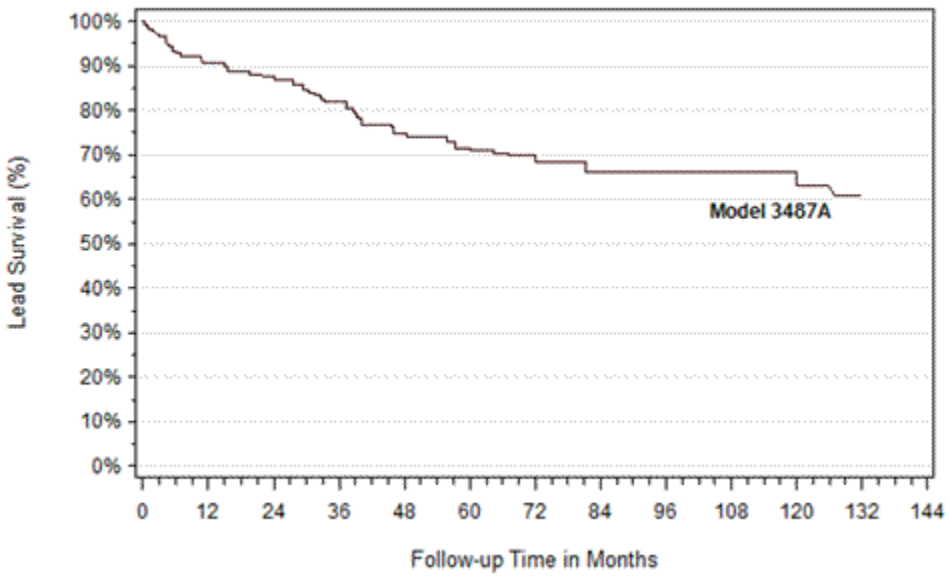
The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Survival curves are only shown if more than 20 devices had at least 12 months of follow-up at the time of the report cut-off for each model. For surgical leads, currently the estimates of device survival from lead-related events exceed 87% (confidence intervals exceed 72%) at the applicable follow-up time points that include at least 20 active devices with the exception of model 3986A.

For percutaneous leads, currently the estimates of survival from lead-related events exceed 71% (confidence intervals exceed 61%) through 5 years of follow-up for applicable leads with follow-up through that time point. At 2 years of follow-up, model 3891 estimates of device survival are less than 76% compared to other models which exceed 83% (confidence intervals exceed 68%). As of February 6, 2008, Medtronic has discontinued worldwide distribution of the Pisces-Quad LZ lead (Models 3890, 3891, and 3892) due to performance relative to other percutaneous leads and minimal commercial demand for the product.

Choose a model Go

Model 3487A Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics

Model Number	3487A
FDA Approval Date	May 1988
Leads Enrolled	880
Leads Currently Active in Study	319
Device Events	133
Cumulative Months of Follow-up	22,440

Model 3487A Pisces-Quad: Event Summary Table

Lead Event	**Total**
Lead high impedance	50
Lead migration/dislodgment	35
Lead low impedance	21
Device stimulation issue	17
Lead fracture	10
Total Lead Events	**133**

Time Interval	**Survival (95% Confidence Interval)**	**Sample Size**
1 yr	90.5% (87.5%, 92.8%)	404
2 yrs	87.6% (84.2%, 90.3%)	314
3 yrs	81.8% (77.7%, 85.2%)	254
4 yrs	74.9% (70.0%, 79.1%)	187
5 yrs	71.5% (66.2%, 76.1%)	133
6 yrs	68.5% (62.7%, 73.5%)	105
7 yrs	66.2% (60.1%, 71.7%)	75

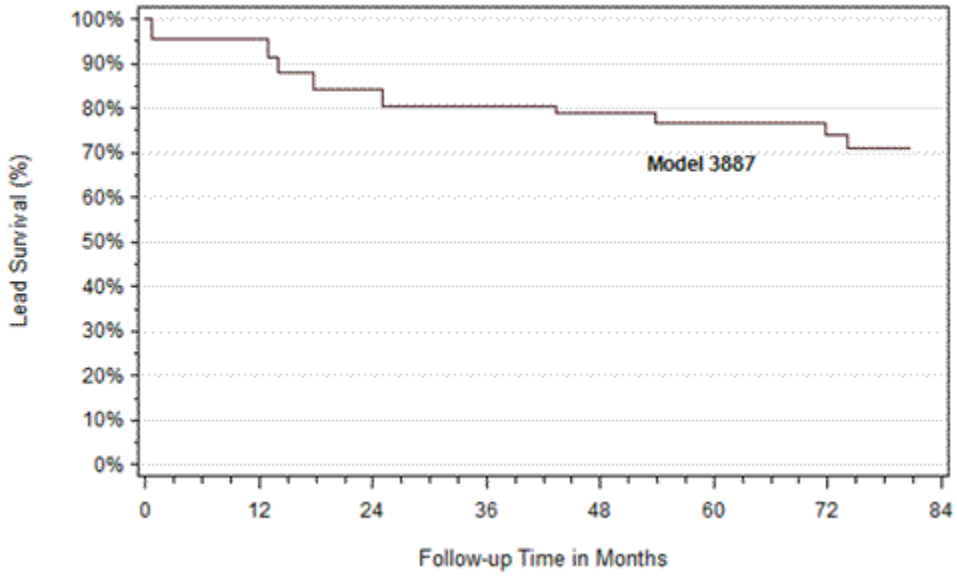
8 yrs	66.2% (60.1%, 71.7%)	48
9 yrs	66.2% (60.1%, 71.7%)	40
10 yrs	62.9% (55.4%, 69.6%)	37
11 yrs	60.9% (52.4%, 68.3%)	25

Model 3487A Pisces-Quad: Specifications

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

Model 3887 Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3887
FDA Approval Date	Jan 1997
Leads Enrolled	164
Leads Currently Active in Study	39
Device Events	15
Cumulative Months of Follow-up	3,765

Model 3887 Pisces-Quad: Event Summary Table

Lead Event	Total
Lead fracture	7
Lead migration/dislodgment	3
Device stimulation issue	2
Lead high impedance	2
Device lead damage	1
Total Lead Events	**15**

Time Interval	Survival (95% Confidence Interval)	Sample Size

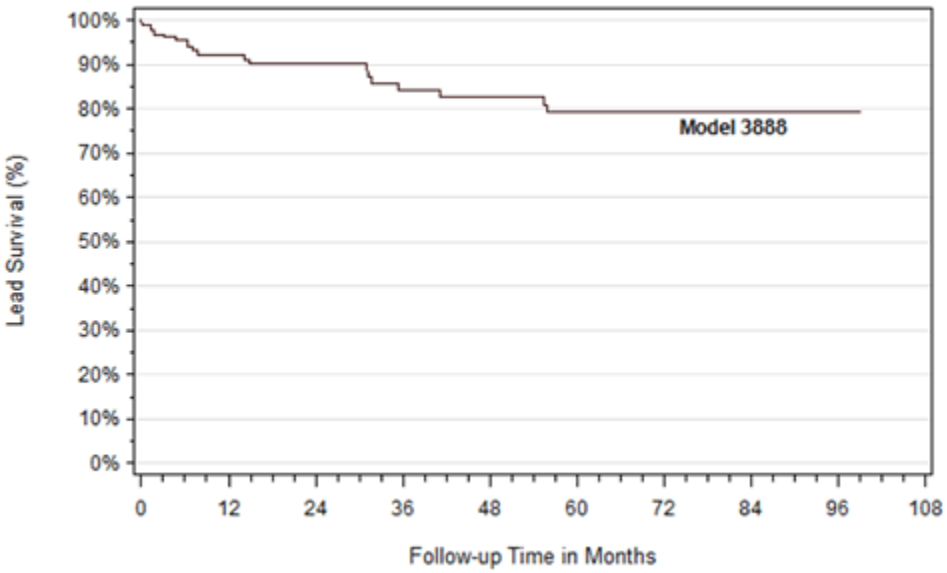
1 yr	95.6% (72.4%, 99.4%)	43
2 yrs	84.4% (68.9%, 92.6%)	47
3 yrs	80.6% (65.2%, 89.7%)	43
4 yrs	78.9% (63.5%, 88.3%)	41
5 yrs	76.7% (61.2%, 86.6%)	34
6 yrs	73.9% (57.9%, 84.6%)	26
at 81 mo	71.1% (54.8%, 82.5%)	21

Model 3887 Pisces-Quad: Specifications

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

Model 3888 Pisces-Quad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3888
FDA Approval Date	Nov 1992
Leads Enrolled	383
Leads Currently Active in Study	61
Device Events	24
Cumulative Months of Follow-up	6,608

Model 3888 Pisces-Quad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	21
Device stimulation issue	2
Lead fracture	1
Total Lead Events	**24**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	92.0% (87.0%, 95.1%)	116

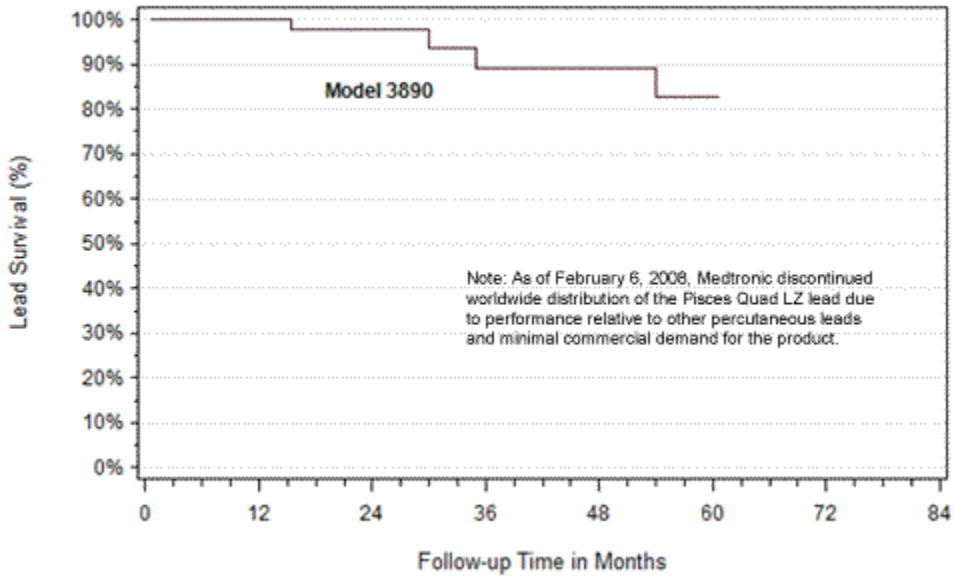
2 yrs	90.2% (84.6%, 93.9%)	65
3 yrs	84.1% (75.3%, 90.0%)	58
4 yrs	82.6% (73.3%, 88.9%)	49
5 yrs	79.2% (68.9%, 86.4%)	43
6 yrs	79.2% (68.9%, 86.4%)	26
7 yrs	79.2% (68.9%, 86.4%)	22
8 yrs	79.2% (68.9%, 86.4%)	21
at 102 mo	79.2% (68.9%, 86.4%)	20

Model 3888 Pisces-Quad: Specifications

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

Model 3890 Pisces-Quad LZ: Survival from Lead Events

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



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

Lead Characteristics	
Model Number	3890
FDA Approval Date	Sep 2002
Leads Enrolled	128
Leads Currently Active in Study	8
Device Events	10
Cumulative Months of Follow-up	2,561

Model 3890 Pisces-Quad LZ: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	4
Device malfunction[a]	2
Lead fracture	2
Lead high impedance	2

Total Lead Events	**10**

[a] Two events reported as impedance not measurable

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	38
2 yrs	97.7% (84.8%, 99.7%)	48
3 yrs	89.0% (75.6%, 95.3%)	38
4 yrs	89.0% (75.6%, 95.3%)	31
5 yrs	82.7% (66.5% ,91.5%)	22
at 63 mo	82.7% (66.5%, 91.5%)	20

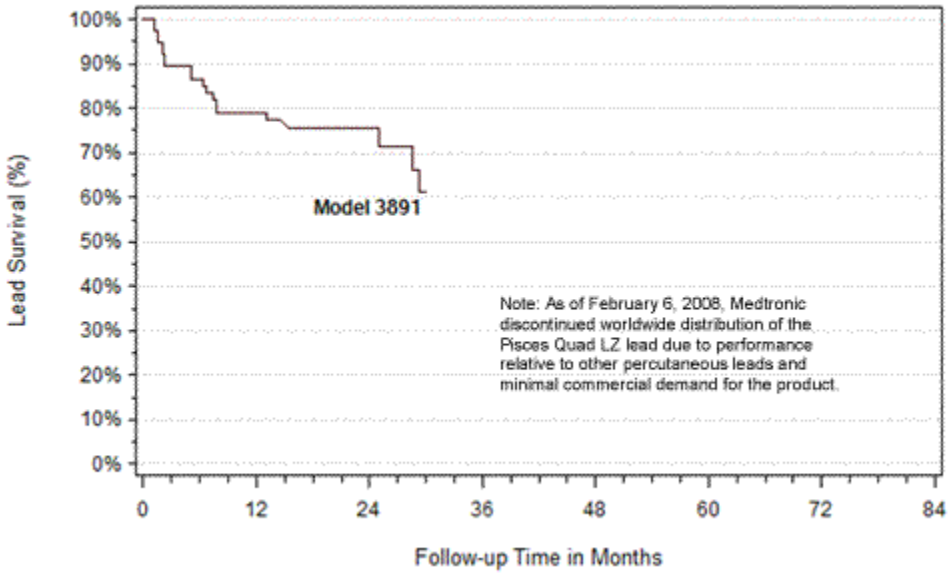
Model 3890 Pisces-Quad LZ: Specifications

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

Array Length (mm)	30.0

Model 3891 Pisces-Quad LZ: Survival from Lead Events

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



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

Lead Characteristics	
Model Number	3891
FDA Approval Date	Sep 2002
Leads Enrolled	117
Leads Currently Active in Study	6
Device Events	30
Cumulative Months of Follow-up	1,860

Model 3891 Pisces-Quad LZ: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgment	18
Lead fracture	6
Device stimulation issue	4

Device lead damage	2
Total Lead Events	**30**

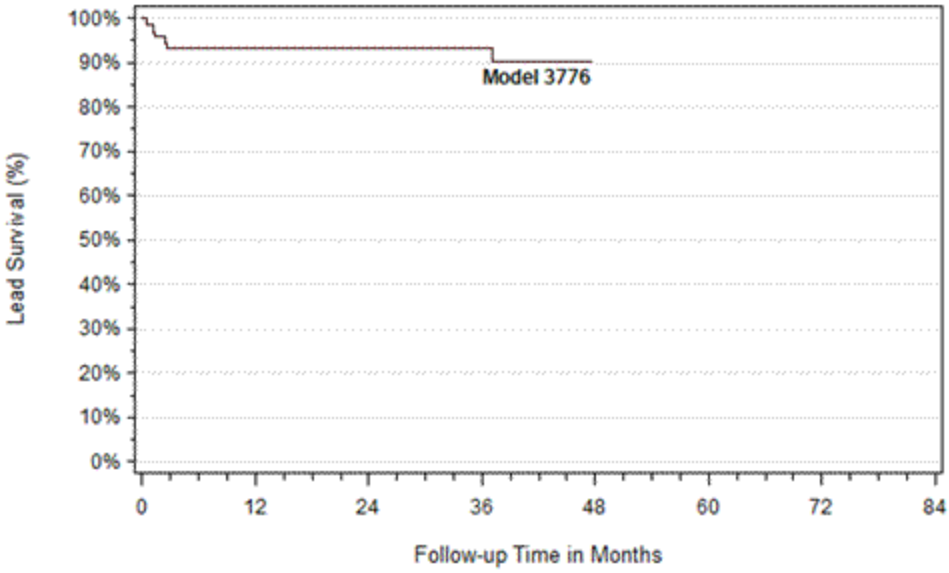
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	78.9% (67.5%, 86.8%)	47
2 yrs	75.5% (63.4%, 84.1%)	35
at 30 mo	61.1% (46.5%, 72.9%)	21

Model 3891 Pisces-Quad LZ: Specifications

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

Model 3776 Pisces-Octad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3776
FDA Approval Date	Nov 2005
Leads Enrolled	172
Leads Currently Active in Study	49
Device Events	4
Cumulative Months of Follow-up	2,941

Model 3776 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	7
Device stimulation issue	1
Lead fracture	1
Total Lead Events	**9**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	93.4% (87.2%, 96.6%)	71
2 yrs	93.4% (87.2%, 96.6%)	42

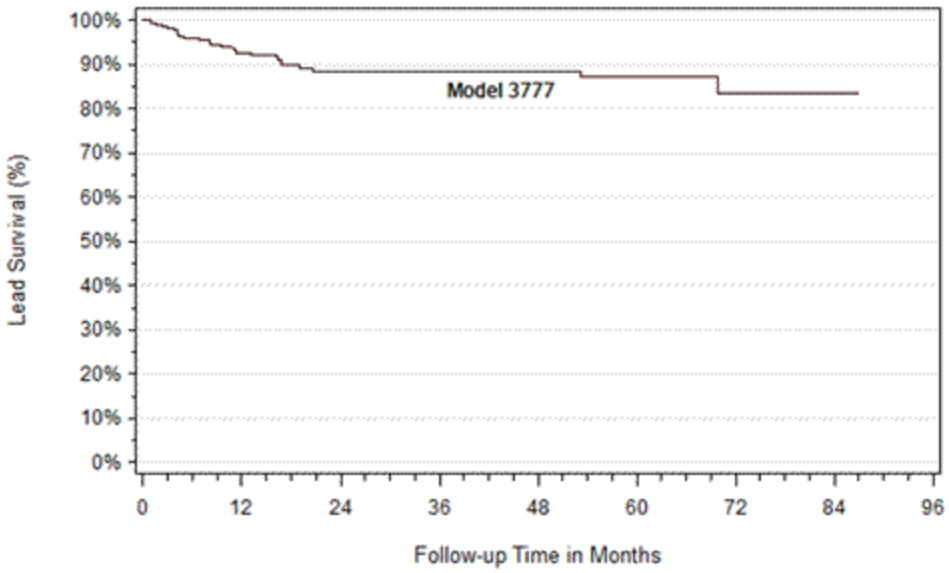
3 yrs	93.4% (87.2%, 96.6%)	30
4 yrs	90.2% (79.5%, 95.5%)	21

Model 3776 Pisces-Octad: Specifications

Device Name	**1x8 Sub-compact**
Lead Type	**Percutaneous**
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	35.0

Model 3777 Pisces-Octad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	764
Leads Currently Active in Study	188
Device Events	48
Cumulative Months of Follow-up	13,361

Model 3777 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	35
Device stimulation issue	7
Lead high impedance	3
Device lead damage	2
Lead fracture	1
Total Lead Events	**48**

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	92.5% (89.5%, 94.6%)	330
2 yrs	88.5% (84.8%, 91.4%)	211
3 yrs	88.5% (84.8%, 91.4%)	129
4 yrs	88.5% (84.8%, 91.4%)	72
5 yrs	87.2% (82.4%, 90.7%)	51
6 yrs	83.5% (75.9%, 88.9%)	41
7 yrs	83.5% (75.9%, 88.9%)	24
at 90 mo	83.5% (75.9%, 88.9%)	24

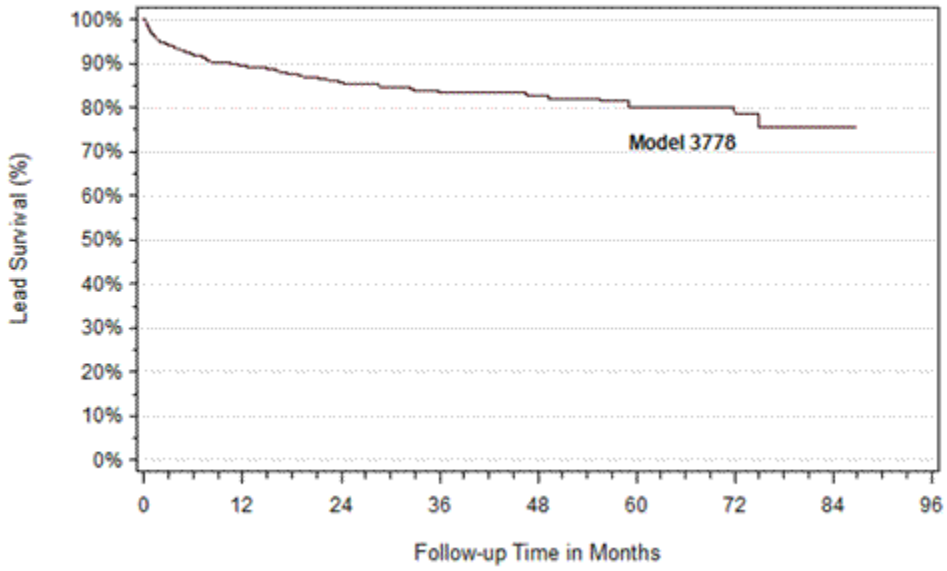
Model 3777 Pisces-Octad: Specifications

Device Name	**1x8 Standard**
Lead Type	**Percutaneous**
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0

Array Length (mm)	66.0

Model 3778 Pisces-Octad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3778
FDA Approval Date	Apr 2005
Leads Enrolled	2,095
Leads Currently Active in Study	713
Device Events	230
Cumulative Months of Follow-up	38,226

Model 3778 Pisces-Octad: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	183
Lead high impedance	22
Lead fracture	12
Device stimulation issue	4
Medical device complication[a]	4

Device malfunction[b]	2
Not Coded[c]	2
Lead low impedance	1
Total Lead Events	**230**

[a] Two events were reported as lead lost capability of stimulation and 2 as open circuit on lead
[b] Reported as lead electrodes not functional
[c] Two events reported as lead malfunction

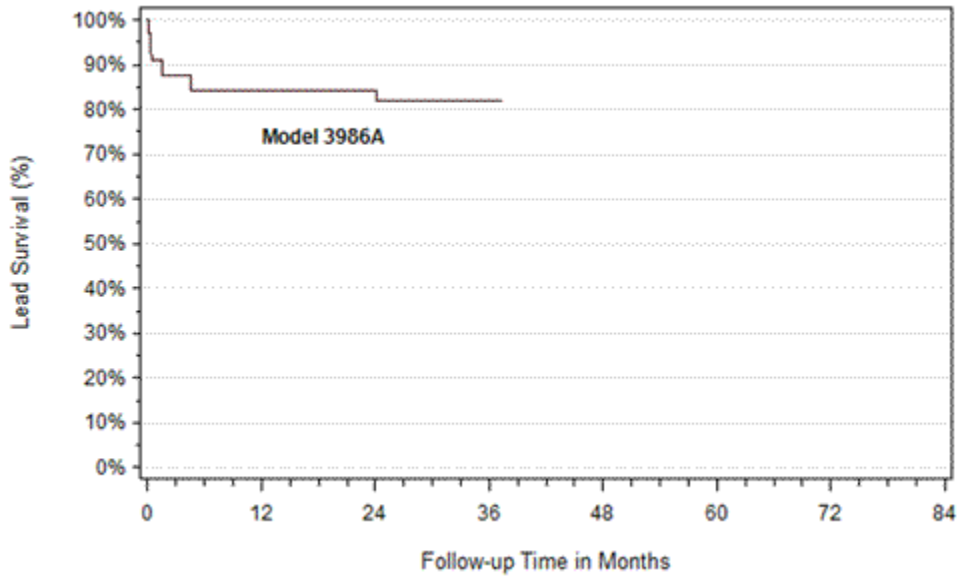
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	89.5% (87.9%, 91.0%)	1,020
2 yrs	85.8% (83.8%, 87.6%)	566
3 yrs	83.4% (81.0%, 85.6%)	363
4 yrs	82.7% (80.1%, 85.0%)	212
5 yrs	80.1% (76.6%, 83.2%)	121
6 yrs	78.7% (73.9%, 82.6%)	52
7 yrs	75.4% (68.8%, 80.9%)	22
at 87 mo	75.4% (68.8%, 80.9%)	21

Model 3778 Pisces-Octad: Specifications

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

Model 3986A Resume TL: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3986A

FDA Clearance Date	Apr 1995
Leads Enrolled	94
Leads Currently Active in Study	37
Device Events	14
Cumulative Months of Follow-up	2,244

Model 3986A Resume TL: Event Summary Table

Lead Event	Total
Lead high impedance	8
Device stimulation issue	2
Lead low impedance	2
Lead migration/dislodgment	2
Total Lead Events	**14**

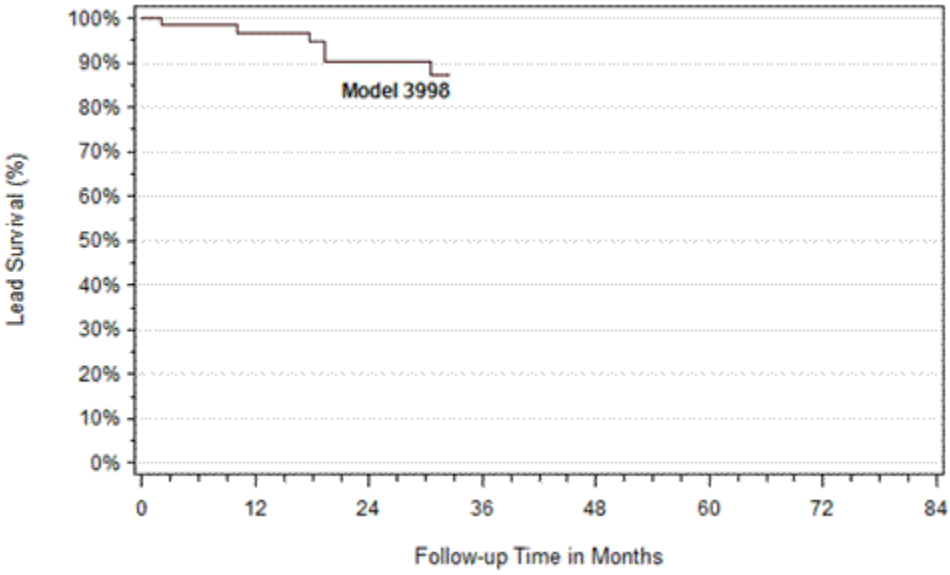
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	84.3% (72.7%, 91.2%)	43
2 yrs	84.3% (72.7%, 91.2%)	35
3 yrs	81.9% (69.5%, 89.7%)	23
at 39 mo	81.9% (69.5%, 89.7%)	21

Model 3986A Resume TL: Specifications

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

Model 3998 Specify: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	142
Leads Currently Active in Study	21
Device Events	9
Cumulative Months of Follow-up	2,512

Model 3998 Specify: Event Summary Table

Lead Event	Total
Lead fracture	3
Lead high impedance	3
Lead migration/dislodgment	2
Device stimulation issue	1
Total Lead Events	**9**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	96.7% (87.6%, 99.2%)	52

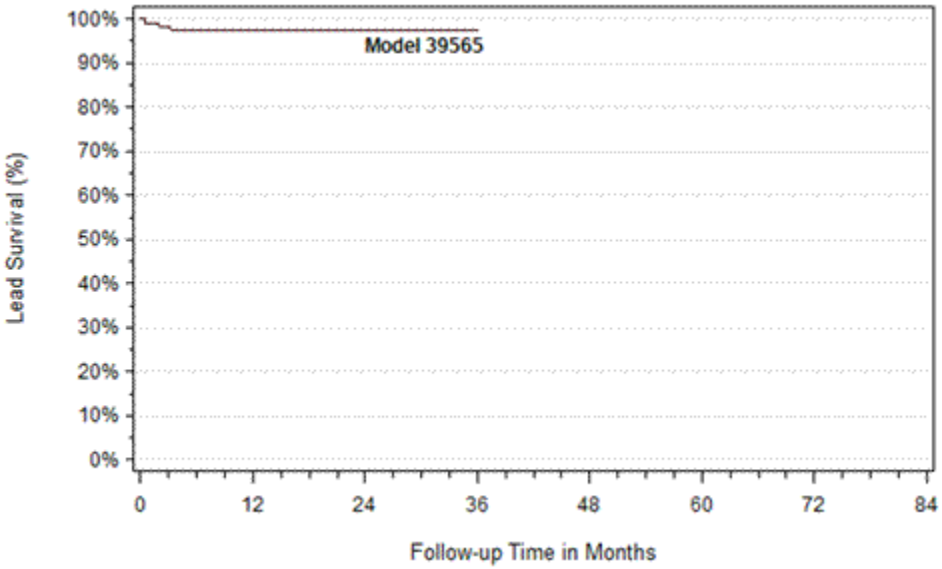
2 yrs	90.4% (78.3%, 95.9%)	36
at 33 mo	87.1% (72.8%, 94.2%)	25

Model 3998 Specify: Specifications

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

Model 39565 Specify: Survival from Lead Events

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



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Lead Characteristics	
Model Number	39565
FDA Approval Date	Jun 2007
Leads Enrolled	178
Leads Currently Active in Study	98
Device Events	3
Cumulative Months of Follow-up	2,106

Model 39565 Specify: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	3
Total Lead Events	**3**

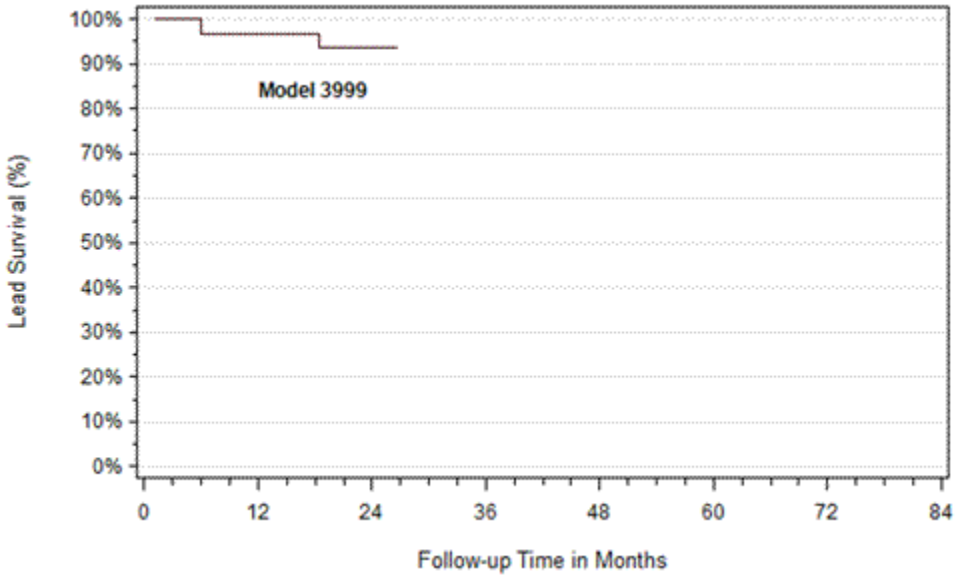
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	97.4% (92.1%, 99.1%)	66
2 yrs	97.4% (92.1%, 99.1%)	40
3 yrs	97.4% (92.1%, 99.1%)	21

Model 39565 Specify: Specifications

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

Model 3999 2x4 Hinged: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3999
FDA Approval Date	Jun 2004
Leads Enrolled	52
Leads Currently Active in Study	2
Device Events	3
Cumulative Months of Follow-up	985

Model 3999 2x4 Hinged: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	2
Lead high impedance	1
Total Lead Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	96.5% (77.6%, 99.5%)	32
2 yrs	93.6% (76.7%, 98.4%)	24

at 27 mo	93.6% (76.7%, 98.4%)	20

Model 3999 2x4 Hinged: Specifications

Device Name	**2x4 Hinged Specify**
Lead Type	**Surgical**
Lead	
Length (cm)	30, 45, 60
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Rectangular
Length (mm)	3.0
Width (mm)	2.0
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	3.3
Lateral Spacing: Edge to Edge (mm)	3.5
Array Length (mm)	28.2
Array Width (mm)	7.5
Paddle	
Length (mm)	41.0
Width (mm)	9.9
Thickness (mm)	1.8

Model 977A2 Vectris SureScan MRI 1x8 Compact: Survival from Lead Events

Lead Characteristics	
Model Number	977A2

FDA Approval Date	Mar 2013
Leads Enrolled	608
Leads Currently Active in Study	581
Device Events	14
Cumulative Months of Follow-up	973

Model 977A2 Vectris SureScan MRI 1x8 Compact: Event Summary Table

Lead Event	Total
Lead migration/dislodgment	10
Lead high impedance	3
Lead fracture	1
Total Lead Events	**14**

Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	93.8% (89.5%, 96.5%)	36

Model 977A2 Vectris SureScan MRI 1x8 Compact: Specifications

Device Name	**Vectris SureScan MRI 1x8 Compact**
Lead Type	**Percutaneous**
Lead	
Length (cm)	60, 75, 90
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm)	12.0

Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

Lead Survival Summary

For surgical leads, currently the estimates of device survival from lead-related events exceed 87% (confidence intervals exceed 72%) at the applicable follow-up time points that include at least 20 active devices with the exception of model 3986A.

For percutaneous leads, currently the estimates of survival from lead-related events exceed 71% (confidence intervals exceed 61%) through 5 years of follow-up for applicable leads with follow-up through that time point. At 2 years of follow-up, model 3891 estimates of device survival are less than 76% compared to other models which exceed 84% (confidence intervals exceed 68%). 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.

Lead Characteristics

Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
Percutaneous Leads						
3487A	**Pisces-Quad**	May 1988	880	319	133	22,440
3887	**Pisces-Quad**	Jan 1997	164	39	15	3,765
3888	**Pisces-Quad**	Nov 1992	383	61	24	6,608
3890	**Pisces-Quad LZ**	Sep 2002	128	8	10	2,561
3891	**Pisces-Quad LZ**	Sep 2002	117	6	30	1,860
3776	**Pisces-Octad**	Nov 2005	172	49	9	2,941
3777	**Pisces-Octad**	Apr 2005	764	188	48	13,361
3778	**Pisces-Octad**	Apr 2005	2,095	713	230	38,226
977A2	**Vectris SureScan**	Mar 2013	608	581	14	973
Surgical Leads						
3986A	**Resume TL**	Apr 1995[b]	94	37	14	2,244
3998	**Specify**	Feb 1998	142	21	9	2,512

3999	**2 x 4 Hinged Specify**	Jun 2004	52	2	3	985
39565	**Specify**	Jun 2007	178	98	3	2,446

[a] There were a total of 640 lead-related events reported to the registry, but only 542 events included in this summary table. The remaining lead-related events occurred in lead models for which no device survival curves are presented due to an insufficient number of enrolled devices (n=4), a lead with an unknown model number (n=1), or were subsequent or unlinked device events that did not affect the survival estimates.
[b] FDA clearance date

Device Survival Probability (95% Confidence Interval) – *Table 1 of 3*

Model Number	Family	1 yr	2 yrs	3 yrs	4 yrs
Percutaneous Leads					
3487A	**Pisces-Quad**	**90.5%** (87.5%, 92.8%)	**87.6%** (84.2%, 90.3%)	**81.8%** (77.7%, 85.2%)	**74.9%** (70.0%, 79.1%)
3887	**Pisces-Quad**	**95.6%** (72.4%, 99.4%)	**84.4%** (68.9%, 92.6%)	**80.6%** (65.2%, 89.7%)	**78.9%** (63.5%, 88.3%)
3888	**Pisces-Quad**	**92.0%** (87.0%, 95.1%)	**90.2%** (84.6%, 93.9%)	**84.1%** (75.3%, 90.0%)	**82.6%** (73.3%, 88.9%)
3890	**Pisces-Quad LZ**	**100.0%** NA	**97.7%** (84.8%, 99.7%)	**89.0%** (75.6%, 95.3%)	**89.0%** (75.6%, 95.3%)
3891	**Pisces-Quad LZ**	**78.9%** (67.5%, 86.8%)	**75.5%** (63.4%, 84.1%)	-	-
3776	**Pisces-Octad**	**93.4%** (87.2%, 96.6%)	**93.4%** (87.2%, 96.6%)	**93.4%** (87.2%, 96.6%)	**90.2%** (79.5%, 95.5%)
3777	**Pisces-Octad**	**92.5%** (89.5%, 94.6%)	**88.5%** (84.8%, 91.4%)	**88.5%** (84.8%, 91.4%)	**88.5%** (84.8%, 91.4%)
3778	**Pisces-Octad**	**89.5%** (87.9%, 91.0%)	**85.8%** (83.8%, 87.6%)	**83.4%** (81.0%, 85.0%)	**82.7%** (80.1%, 85.0%)
977A2	**Vectris SureScan**	[a]	-	-	-
Surgical Leads					
3986A	**Resume TL**	**84.3%** (72.7%, 91.2%)	**84.3%** (72.7%, 91.2%)	**81.9%** (69.5%, 89.7%)	-
3998	**Specify**	**96.7%** (87.6%, 99.2%)	**90.4%** (78.3%, 95.9%)	-	-

3999	**2 x 4 Hinged Specify**	**96.5%** (77.6%, 99.5%)	**93.6%** (76.7%, 98.4%)	-	-
39565	**Specify**	**97.4%** (92.1%, 99.1%)	**97.4%** (92.1%, 99.1%)	**97.4%** (92.1%, 99.1%)	-

[a] Model 977A2 had a device survival probability of 93.9% (89.5% , 96.5%) at 6 months of follow-up

Device Survival Probability (95% Confidence Interval) – *Table 2 of 3*

Model Number	Family	5 yrs	6 yrs	7 yrs	8 yrs
Percutaneous Leads					
3487A	**Pisces-Quad**	**71.5%** (66.2%, 76.1%)	**68.5%** (62.7%, 73.5%)	**66.2%** (60.1%, 71.7%)	**66.2%** (60.1%, 71.7%)
3887	**Pisces-Quad**	**76.7%** (66.2%, 76.1%)	**73.9%** (57.9%, 84.6%)	-	-
3888	**Pisces-Quad**	**79.2%** (68.9%, 86.4%)	**79.2%** (68.9%, 86.4%)	**79.2%** (68.9%, 86.4%)	**79.2%** (68.9%, 86.4%)
3890	**Pisces-Quad LZ**	**82.7%** (66.5%, 91.5%)	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
3776	**Pisces-Octad**	-	-	-	-
3777	**Pisces-Octad**	**87.2%** (82.4%, 90.7%)	**83.5%** (75.9%, 88.9%)	**83.5%** (75.9%, 88.9%)	-
3778	**Pisces-Octad**	**80.1%** (76.6%, 83.2%)	**78.7%** (73.9%, 82.6%)	**75.4%** (68.8%, 80.9%)	-
977A2	**Vectris SureScan**	-	-	-	-
Surgical Leads					
3986A	**Resume TL**	-	-	-	-
3998	**Specify**	-	-	-	-
3999	**2 x 4 Hinged Specify**	-	-	-	-
39565	**Specify**	-	-	-	-

Device Survival Probability (95% Confidence Interval) – *Table 3 of 3*

Model Number	Family	9 yrs	10 yrs	11 yrs
Percutaneous Leads				
3487A	**Pisces-Quad**	**66.2%** (60.1%, 71.7%)	**62.9%** (55.4%, 69.6%)	**60.9%** (52.4%, 68.3%)
3887	**Pisces-Quad**	-	-	-
3888	**Pisces-Quad**	-	-	-
3890	**Pisces-Quad LZ**	-	-	-
3891	**Pisces-Quad LZ**	-	-	-
3776	**Pisces-Octad**	-	-	-
3777	**Pisces-Octad**	-	-	-
3778	**Pisces-Octad**	-	-	-
977A2	**Vectris SureScan**	-	-	-
Surgical Leads				
3986A	**Resume TL**	-	-	-
3998	**Specify**	-	-	-
3999	**2 x 4 Hinged Specify**	-	-	-
39565	**Specify**	-	-	-

Extensions

From June 2004 to the report cut-off date of July 31, 2014, there were 2,898 extensions followed in the registry. Differences between the total number of extensions versus spinal cord stimulators (N=3,521) was due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 60,684 months (5,057 years).

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. The table below provides the number and percentage of extensions by model.

Extensions by Mode

Model Number	Number of Extensions (%)
37081	1,155 (39.9%)
7489	707 (24.4%)

37082	573 (19.8%)
7495	229 (7.9%)
37083	198 (6.8%)
7472	12 (0.4%)
7496	9 (0.3%)
7471	8 (0.3%)
Other/Unspecified	7 (0.2%)
Total	**2,898 (100%)**

Extension Events

There were 22 product performance-related events with an underlying reported etiology related to the extension. Of these events, the majority were extension fractures (n=13). Of the 22 events, 15 were the first event attributable to an enrolled extension.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

- 15 had follow-up time cut-off due to product performance-related events.
- 1,790 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, other extension modification, therapy suspended, or non-product performance extension-related event without an associated intervention.
- 1,093 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

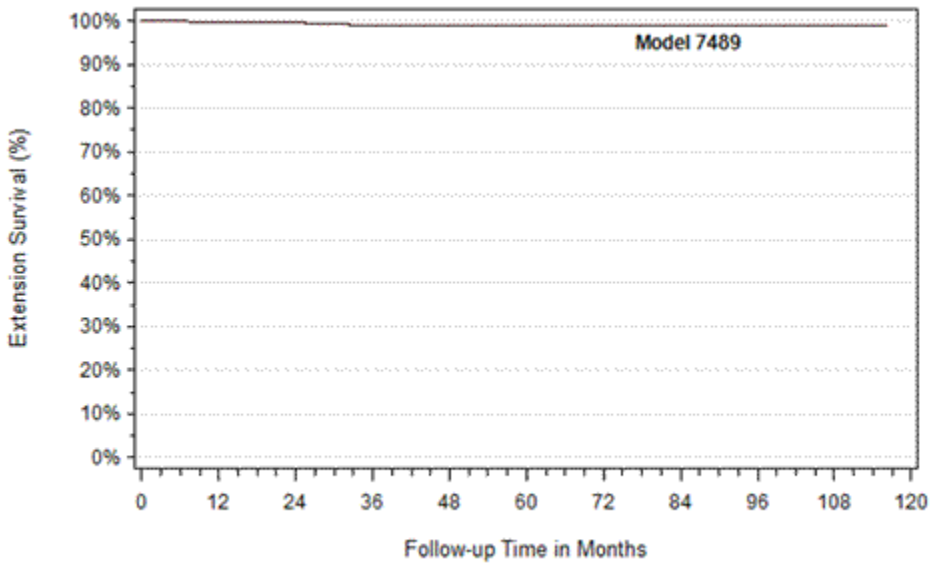
Extension Survival

The figures and tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval. Currently, estimates of device survival from extension-related events exceed 95% (confidence intervals exceed 89%) for all extension models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 7489: Survival from Extension Events

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



View Larger Image

Extension Characteristics	
Model Number	7489
FDA Approval Date	Oct 2002
Extensions Enrolled	707
Extensions Currently Active in Study	71
Device Events	3
Cumulative Months of Follow-up	15,379

Model 7489 Extension: Event Summary Table

Extension Event	Total
Extension fracture	2
Medical device complication[a]	1
Total Extension Events	**4**

[a] Reported as unknown problem with extension

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.6% (97.2%, 99.9%)	285
2 yrs	99.6% (97.2%, 99.9%)	274

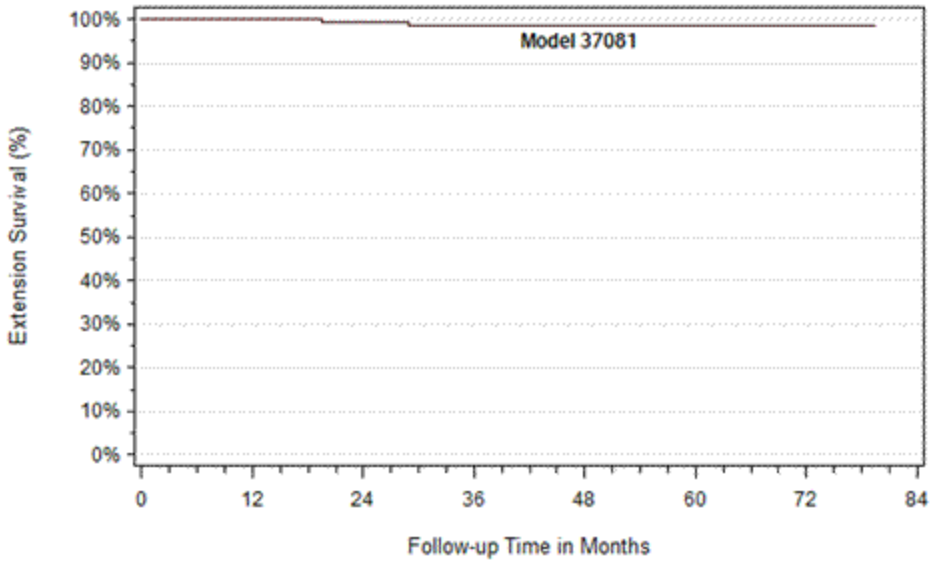
3 yrs	98.8% (96.2%, 99.6%)	193
4 yrs	98.8% (96.2%, 99.6%)	130
5 yrs	98.8% (96.2%, 99.6%)	97
6 yrs	98.8% (96.2%, 99.6%)	69
7 yrs	98.8% (96.2%, 99.6%)	57
8 yrs	98.8% (96.2%, 99.6%)	53
9 yrs	98.8% (96.2%, 99.6%)	35
at 117 mo	98.8% (96.2%, 99.6%)	23

Model 7489: Specifications

Device Name	Low Profile Quad Extension
Length (cm)	10, 25, 40, 51, 66
Distal End Compatibility	1 Quad Lead
Distal End Set Screws	4
Proximal End INS Compatibility	Itrel 3, Synergy, Versitrel

Model 37081: Survival from Extension Events

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



View Larger Image

Extension Characteristics	
Model Number	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	1,155
Extensions Currently Active in Study	395
Device Events	5
Cumulative Months of Follow-up	20,541

Model 37081 Extension: Event Summary Table

Extension Event	Total
Extension fracture	5
Total Extension Events	**5**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.9% (99.1%, 100.0%)	562
2 yrs	99.4% (98.0%, 99.8%)	309
3 yrs	98.6% (96.6%, 99.5%)	177

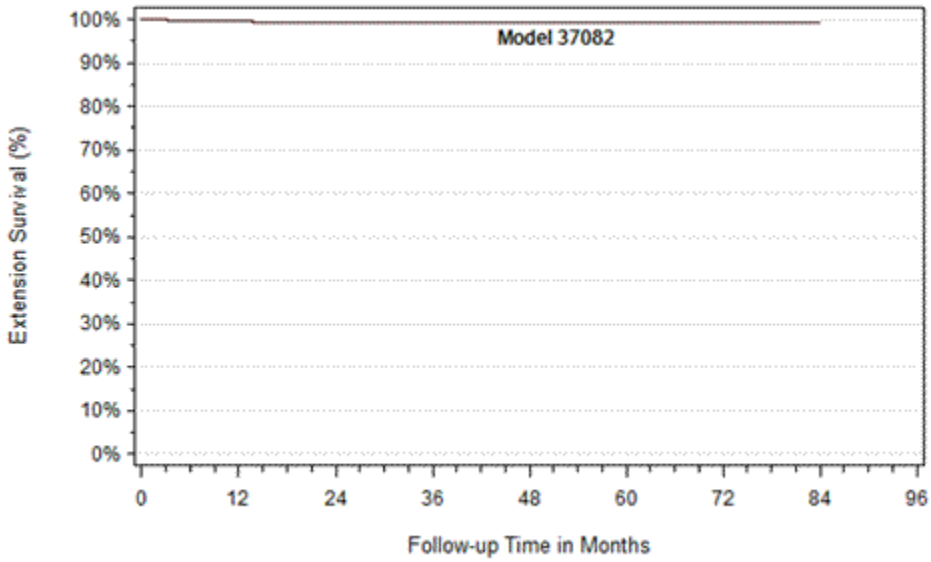
4 yrs	98.6% (96.6%, 99.5%)	104
5 yrs	98.6% (96.6%, 99.5%)	64
6 yrs	98.6% (96.6%, 99.5%)	32
at 81 mo	98.6% (96.6%, 99.5%)	22

Model 37081: Specifications

Device Name	1x8 Extension
Length (cm)	20, 40, 60
Distal End Compatibility	1 Octad Lead
Distal End Set Screws	1
Proximal End INS Compatibility	Restore Family

Model 37082: Survival from Extension Events

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



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Extension Characteristics

Model Number	37082
FDA Approval Date	Mar 2006
Extensions Enrolled	573
Extensions Currently Active in Study	182
Device Events	3
Cumulative Months of Follow-up	13,786

Model 37082 Extension: Event Summary Table

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

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

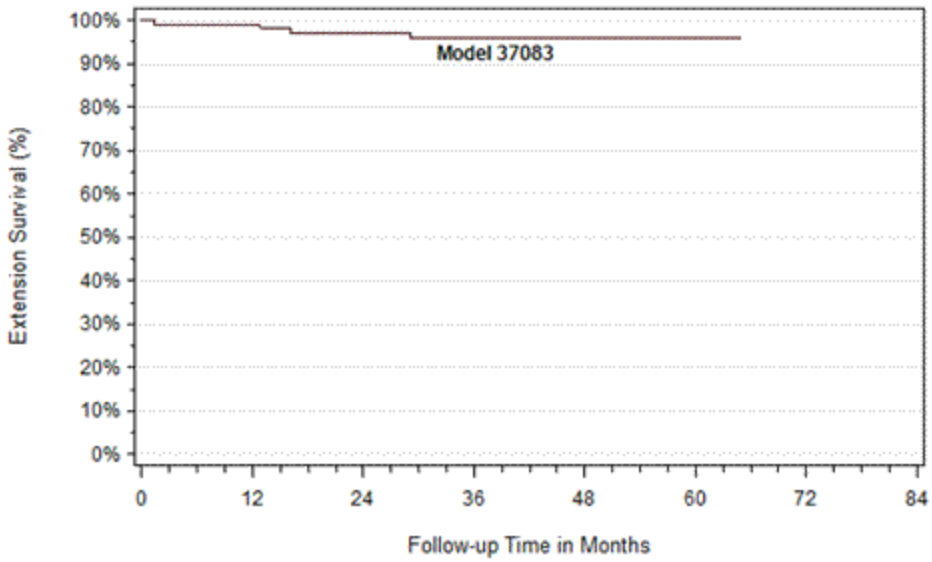
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.5% (98.2%, 99.9%)	341
2 yrs	99.2% (97.6%, 99.8%)	219
3 yrs	99.2% (97.6%, 99.8%)	132
4 yrs	99.2% (97.6%, 99.8%)	100
5 yrs	99.2% (97.6%, 99.8%)	64
6 yrs	99.2% (97.6%, 99.8%)	40
at 75 mo	99.2% (97.6%, 99.8%)	20

Model 37082: Specifications

Device Name	Bifurcated Stretch-Coil Extension
Length (cm)	20, 40, 60
Distal End Compatibility	2 Quad Leads
Distal End Set Screws	8 (4 per Lead)
Proximal End INS Compatibility	Restore Family

Model 37083: Survival from Extension Events

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



View Larger Image

Extension Characteristics	
Model Number	37083
FDA Approval Date	Sep 2005
Extensions Enrolled	198
Extensions Currently Active in Study	37
Device Events	4
Cumulative Months of Follow-up	4,798

Model 37083 Extension: Event Summary Table

Extension Event	Total
Extension fracture	3

Device failure[a]	1
Total Extension Events	**4**

[a] Reported as extension failure

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.1% (93.5%, 99.9%)	118
2 yrs	97.2% (91.6%, 99.1%)	92
3 yrs	95.9% (89.3%, 98.5%)	55
4 yrs	95.9% (89.3%, 98.5%)	43
5 yrs	95.9% (89.3%, 98.5%)	24
at 66 mo	95.9% (89.3%, 98.5%)	21

Model 37083: Specifications

Device Name	Single Stretch-Coil Extension
Length (cm)	20, 40, 60
Distal End Compatibility	1 Quad Lead
Distal End Set Screws	4
Proximal End INS Compatibility	Restore Family

Extension Survival Summary

Currently, estimates of device survival from extension-related events exceed 95% (confidence intervals exceed 89%) for all extension models at the applicable follow-up time points that include at least 20 active devices.

Extension Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**

37081	37081	Apr 2005	1,155	395	5	20,541
37082	37082	Mar 2006	573	182	3	13,786
37083	37083	Sep 2005	198	37	4	4,798
7489	7489	Oct 2002	707	71	3	15,379

[a] There were a total of 22 extension-related events reported to the registry, but only 15 events are included in this summary table. The remaining 7 events were unlinked device events that did not affect the survival estimates.

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

Model Number	1 yr	2 yrs	3 yrs	4 yrs	5 yrs
37081	**99.9%** (99.1%, 100.0%)	**99.4%** (98.0%, 99.8%)	**98.6%** (96.6%, 99.5%)	**98.6%** (96.6%, 99.5%)	**98.6%** (96.6%, 99.5%)
37082	**99.5%** (98.2%, 99.9%)	**99.2%** (97.6%, 99.8%)	**99.2%** (97.6%, 99.8%)	**99.2%** (97.6%, 99.8%)	**99.2%** (97.6%, 99.8%)
37083	**99.1%** (93.5%, 99.9%)	**97.2%** (91.6%, 99.1%)	**95.9%** (89.3%, 98.5%)	**95.9%** (89.3%, 98.5%)	**95.9%** (89.3%, 98.5%)
7489	**99.6%** (97.2%, 99.9%)	**99.6%** (97.2%, 99.9%)	**98.8%** (96.2%, 99.6%)	**98.8%** (96.2%, 99.6%)	**98.8%** (96.2%, 99.6%)

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

Model Number	6 yrs	7 yrs	8 yrs	9 yrs
37081	**98.6%** (96.6%, 99.5%)	-	-	-
37082	**99.2%** (97.6%, 99.8%)	**99.2%** (97.6%, 99.8%)	-	-
37083	-	-	-	-
7489	**98.8%** (96.2%, 99.6%)	**98.8%** (96.2%, 99.6%)	**98.8%** (96.2%, 99.6%)	**98.8%** (96.2%, 99.6%)

2014 Medtronic Product Performance Report: Data through July 31, 2014

Therapies

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

Resources

- Education and Training
- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines
- Clinical Trials Registry
- Clinical Research Investigator Guidance

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Deep Brain Stimulation Systems

- Study Participants
- Event Summary
- Deep Brain Neurostimulators
- Leads
- Extensions

Study Participants

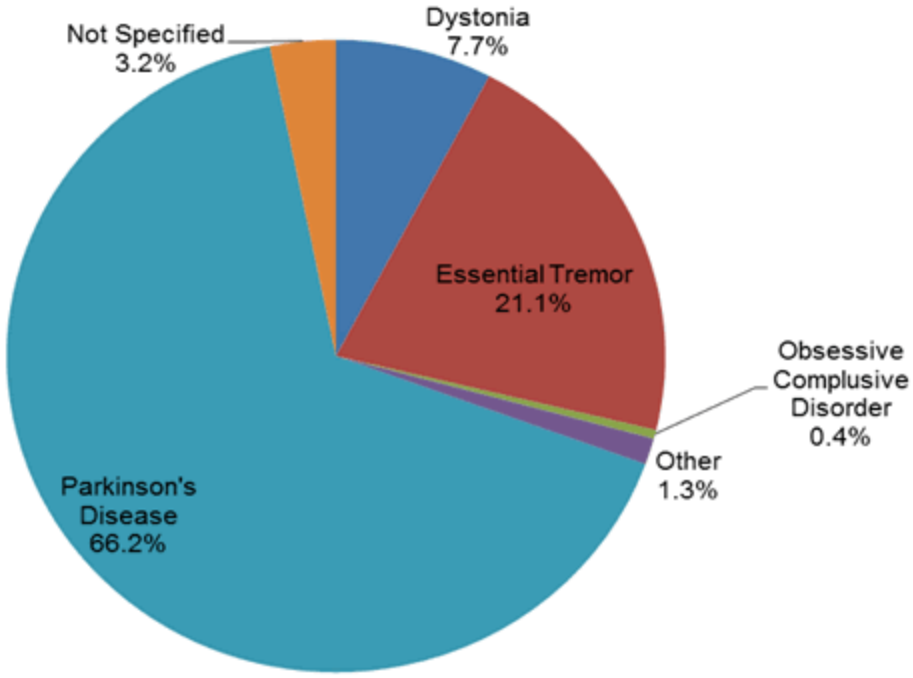
Centers

The following deep brain stimulation tables and graphs were generated based on data collected between July 2009 and the report cut-off date of July 31, 2014. Thirty centers enrolled and contributed patients to the deep brain stimulation section of the report.

Patients

Of the 1,116 deep brain stimulation patients enrolled, 66.2% were implanted for the treatment of Parkinson's Disease, 21.1% were implanted for the treatment of Essential Tremor, 7.7% were implanted for the treatment of Dystonia, 0.4% were implanted for the treatment of Obsessive Compulsive Disorder, 1.3% were implanted for the treatment of some other indication and 3.2% were implanted for indications that were not specified in the database.

Primary DBS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Parkinson's Disease	739 (66.2%)
Essential Tremor	235 (21.1%)
Dystonia	86 (7.7%)
Obsessive Compulsive Disorder	5 (0.4%)
Other	15 (1.3%)
Not specified	36 (3.2%)
Total Patients	**1,116**

[a] Refer to product labeling for approved indications.

Event Summary

There were 249 events reported between July 2009 and July 31, 2014 in patients with deep brain stimulation systems. Over seventeen percent of these events (43/249) were categorized as product performance-related and are presented graphically within this report. The 43 product performance events occurred in 28 of the 1,116 total patients (2.5%) enrolled. In addition, there were 206 non-product performance events reported. There were also 27 deaths reported for patients with deep brain neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy.

Deep Brain Stimulation System Product Performance Events

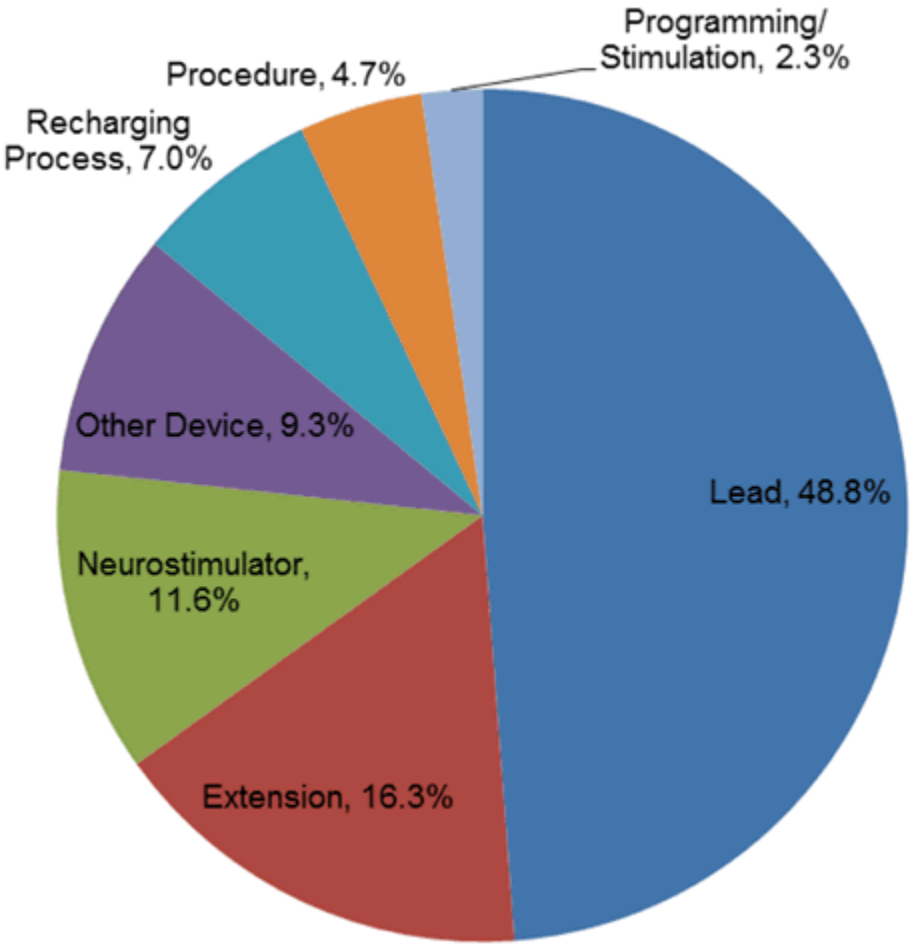
Deep Brain Stimulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event[b]	Percent of Patients with Event (n=1,116)
Lead high impedance	18	11	1.0%
Lead fracture	7	4	0.4%
Medical device complication[c]	7	6	0.5%
Lead low impedance	2	2	0.2%
Neurostimulator migration[d]	2	1	0.1%
Neurostimulator unable to recharge[e]	2	2	0.2%
Device connection issue	1	1	0.1%
Device migration	1	1	0.1%
Electromagnetic interference	1	1	0.1%
Extension fracture	1	1	0.1%
Lead migration/dislodgment	1	1	0.1%
Totals	**43**	**28**	**2.5%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term
[b] The total number of patients may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[c] Includes 2 events for extension cable loop, 1 event reported as open circuit to lead, 1 antenna heating while recharging, 1 suspicion of heating of the antenna while recharging, 1 undesirable interaction with external electronic device, and 1 issue with controller not communicating.
[d] Coiling of the two extension wires with appearance typical of Twiddler's syndrome.
[e] There were a total of 128 patients that used rechargeable neurostimulators for DBS in the registry. A total of 1.6% (2/128) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

A total of 21 (48.8%) of the 43 product performance events were related to the lead, 7 (16.3%) were related to the extension, 5 (11.6%) were related to neurostimulator, 4 (9.3%) were related to other devices, 3 (7.0%) were related to the recharging process, 2 (4.7%) were related to the procedure, and 1 (2.3%) was related to programming/stimulation. Relatedness is determined by the physician.

Product Performance Events by Relatedness



Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Administration site reactions	**41**
Implant site infection	24
Implant site erosion	6
Implant site pain	3
Implant site erythema	2
Other[c]	6
Device issues	**26**

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Neurostimulator migration	11
Neurostimulator unable to recharge[d]	5
Device stimulation issue	2
Other[c]	8
Neurological disorders not elsewhere classified (NEC)	**22**
Dysarthria	6
Speech disorder	6
Paraesthesia	5
Pneumocephalus	2
Sensory disturbance	2
Other[c]	1
Movement disorders (including parkinsonism)	**18**
Tremor	6
Dyskinesia	4
Dystonia	4
Parkinson's disease	2
Other[c]	2
Injuries NEC	**11**
Fall	5
Subdural haematoma	2
Other[c]	4
Procedural related injuries and complications NEC	**11**

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Wound dehiscence	5
Other[c]	6
Central nervous system vascular disorders	**7**
Haemorrhage intracranial	4
Other[c]	3
Complications associated with device	**7**
Medical device discomfort	3
Medical device complication[e]	2
Other[c]	2
Infections - pathogen unspecified	**5**
Wound infection	3
Infection	2
Physical examination and organ system status topics	**5**
Weight increased	5
Bacterial infectious disorders	**4**
Staphylococcal infection	2
Other[c]	2
General system disorders NEC	**4**
Gait disturbance	3
Other[c]	1
Mood disorders and disturbances NEC	**4**
Affect lability	2

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other[c]	2
Seizures (including subtypes)	**4**
Convulsion	3
Other[c]	1
Headaches	**3**
Migraine	2
Other[c]	1
Depressed mood disorders and disturbances	**2**
Depression	2
Gastrointestinal signs and symptoms	**2**
Dysphagia	2
Neuromuscular disorders	**2**
Muscle spasticity	2
Respiratory disorders NEC	**2**
Dysphonia	2
Other[c]	**26**
Total	**206**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms.
[c] Composed of event codes that included fewer than 2 events each.
[d] Patient was unable to recharge their neurostimulator due to an issue not related to the device.
[e] Includes 1 event reported as charge icon missing from patient programmer and 1 DBS system turned off by airport security.

There were 27 deaths reported for patients with deep brain neurostimulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. A total of 21 (77.8%) of deaths occurred in patients receiving therapy for Parkinson's disease and 6 (22.2%) for Essential Tremor.

Death by Primary Indication

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Essential Tremor	6 (22.2%)
Parkinson's Disease	21 (77.8%)
Total	**27 (100%)**

[a] Refer to product labeling for approved indications

Deep Brain Neurostimulators

From July 2009 to the report cut-off date of July 31, 2014, 1,176 deep brain neurostimulators were followed in the registry. The difference between the total number of patients (N=1,116) versus neurostimulators is due to the fact that some patients have more than one neurostimulator implanted or were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 13,471 months (1,123 years). The table below provides the number and percentage of neurostimulators by model.

Neurostimulators by Model	
Model Name	**Number of Neurostimulators (%)**
Activa PC	631 (53.7%)
Activa SC	328 (27.9%)
Activa RC	138 (11.7%)
Soletra	67 (5.7%)
Kinetra	11 (0.9%)
Other	1 (0.1%)
Total	**1,176 (100%)**

Deep Brain Neurostimulator Events

There were 5 product performance-related events with an underlying reported etiology related to deep brain neurostimulator function. Of these, 4 were the first event attributable to an enrolled stimulator. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 9/98 (9.2%). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of deep brain stimulation devices in patients who have expired. There were no anomalies found in the 9 devices that were returned for analysis. The 5 deep brain stimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as lead high impedance (n=3), electromagnetic interference (n=1), and medical device complication (n=1).

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

- 4 had follow-up time cut-off due to a product performance-related event.
- 272 were censored in the survival analysis for the following reasons: patient expired, neurostimulator

explanted, patient discontinued, therapy suspended, other neurostimulator modification, site termination, or non-product performance neurostimulator-related event without an associated intervention.
- 900 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

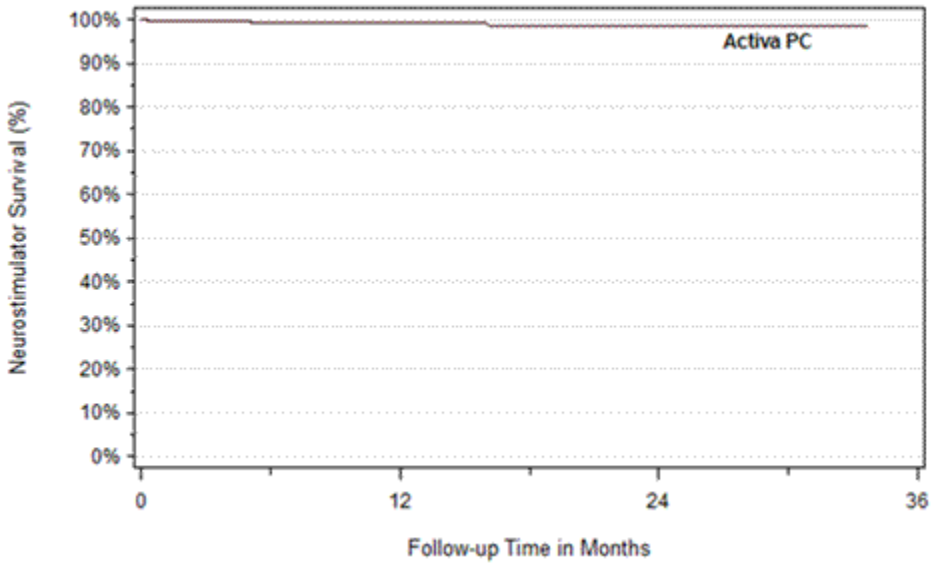
Deep Brain Neurostimulator Survival

The figures and tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. Currently, estimates of device survival from neurostimulator-related events exceed 98% (confidence intervals exceed 96%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 37601 Activa PC: Survival from Neurostimulator Events

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



View Larger Image

Deep Brain Neurostimulator Characteristics	
Model Name	Activa PC
FDA Approval Date	Apr 2009
Neurostimulators Enrolled	631
Neurostimulators Currently Active in Study	514
Device Events	4
Cumulative Months of Follow-up	6,603

Model Activa PC: Event Summary Table Neurostimulator Event	Total
Lead high impedance[a]	2
Electromagnetic interference	1
Medical device complication[b]	1
Total Neuromodulator Events	**4**

[a] Two events for high impedance >40000 attributed to the neurostimulator
[b] Undesirable interaction with external electronic device

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.3% (97.7%, 99.8%)	229
2 yr	98.7% (96.3%, 99.6%)	82
at 33 mo	98.7% (96.3%, 99.6%)	33

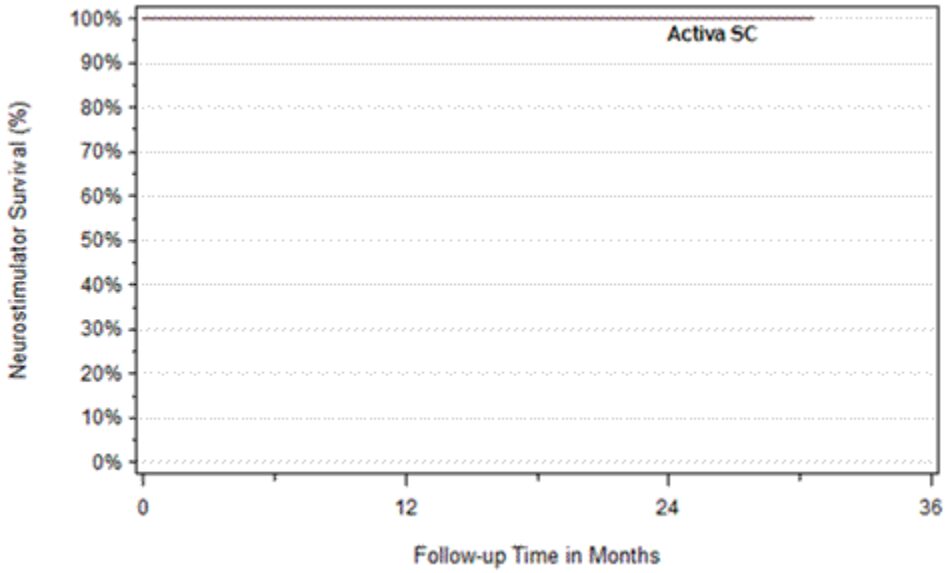
Model 37601 Activa PC: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thinness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)

Pulse Width	60 - 450 µsec
Groups	4
Programs	16 (up to 4 per group)
Implant Depth	≤ 4 cm

Models 37602 & 37603 Activa SC: Survival from Neurostimulator Events

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



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Deep Brain Neurostimulator Characteristics	
Model Name	Activa SC
FDA Approval Date	Jan 2011
Neurostimulators Enrolled	328
Neurostimulators Currently Active in Study	225
Device Events	0
Cumulative Months of Follow-up	3,581

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	125
2 yr	100.0% (NA)	50

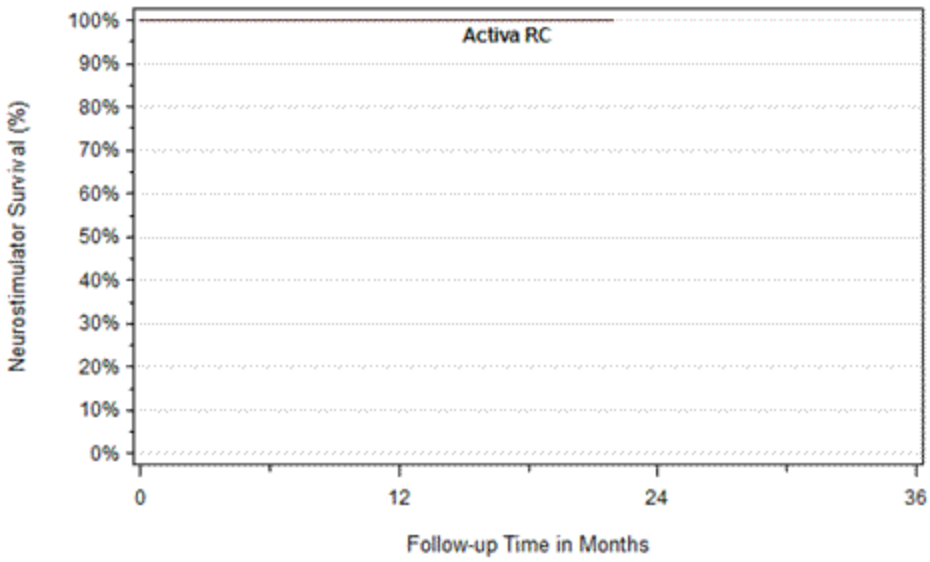
at 30 mo	100.0% (NA)	23

Models 37602 & 37603 Activa SC: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	0.4 in (11 mm)
Volume	28 cc (Model 37602) 27 cc (Model 37603)
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	8 (up to 2 per group)
Implant Depth	≤ 4 cm

Model 37612 Activa RC: Survival from Neurostimulator Events

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



View Larger Image

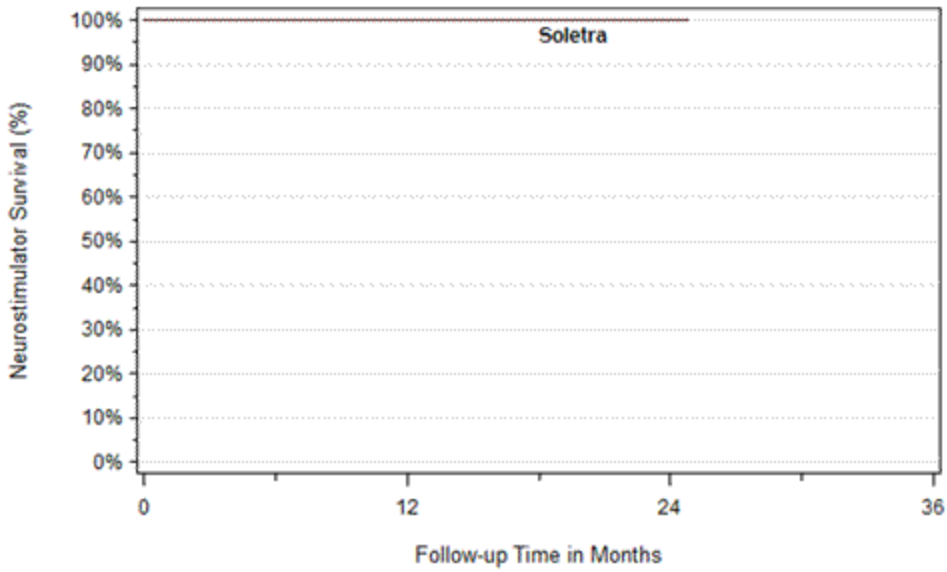
Deep Brain Neurostimulator Characteristics	
Model Name	Activa RC
FDA Approval Date	Mar 2009
Neurostimulators Enrolled	138
Neurostimulators Currently Active in Study	89
Device Events	0
Cumulative Months of Follow-up	1,874

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	75
at 21 mo	100.0% (NA)	36

Model 37612 Activa RC: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thinness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	16 (up to 4 per group)
Implant Depth	≤ 1 cm

Model 7426 Soletra: Survival from Neurostimulator Events



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Deep Brain Neurostimulator Characteristics

Model Name	Soletra
FDA Approval Date	Jan 2002
Neurostimulators Enrolled	67
Neurostimulators Currently Active in Study	12
Device Events	0
Cumulative Months of Follow-up	1,210

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	43
2 yrs	100.0% (NA)	23

Model 7426 Soletra: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	0.4 in (10 mm)
Volume	22 cc
Battery type	Non-rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	3 - 185 Hz
Pulse Width	30 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

Deep Brain Neurostimulator Survival Summary

Currently, estimates of device survival from neurostimulator-related events exceed 98% (confidence intervals exceed 96%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Deep Brain Neurostimulator Characteristics

Model Name	Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
Activa PC	Activa	Apr 2009	631	514	4	6,603
Activa SC	Activa	Jan 2011	328	225	0	3,581
Activa RC	Activa	Mar 2009	138	89	0	1,874
Soletra	Soletra	Jan 2002	67	12	0	1,210

[a] There were a total of 5 neurostimulator-related events reported to the registry, but only 4 events are included in this summary table. The remaining 1 event was a subsequent or unlinked device event that did not affect the survival estimates.

Device Survival Probability (95% Confidence Interval)

Model Name	1 yr	2 yrs
Activa PC	**99.3%** (97.7%, 99.8%)	**98.7%** (96.3%, 99.6%)
Activa SC	**100.0%** NA	**100.0%** NA
Activa RC	**100.0%** NA	**-**
Soletra	**100.0%** NA	**100.0%** NA

Leads

From July 2009 to the report cut-off date of July 31, 2014, there were 1,710 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=1,176) were due to the fact that some patients were implanted with more than 1 lead or were subsequently re-implanted with a new lead. The aggregate prospective follow-up time for all leads was 20,432 months (1,703 years).

A lead is a set of thin wires with a protective coating and electrodes near the tip. The table below provides the number and percentage of leads by model.

Leads by Model

Model Number	Number of Leads (%)
3389	912 (53.3%)
3387	782 (45.7%)
3391	12 (0.7%)
Other/Unspecified	4 (0.2%)
Total	**1,710 (100%)**

Lead Events

There were 21 product performance-related events with an underlying reported etiology related to the lead. Ten were lead high impedance, 7 were lead fracture, 2 were lead low impedance, 1 was medical device complication, and 1 was lead migration/dislodgement. Of the 21 events, 10 were the first event attributable to an enrolled lead.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

- 10 had follow-up time cut-off due to product performance-related events.
- 289 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, site termination, therapy suspended, or other lead modification, or non-product performance lead-related event without an associated intervention.
- 1,411 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

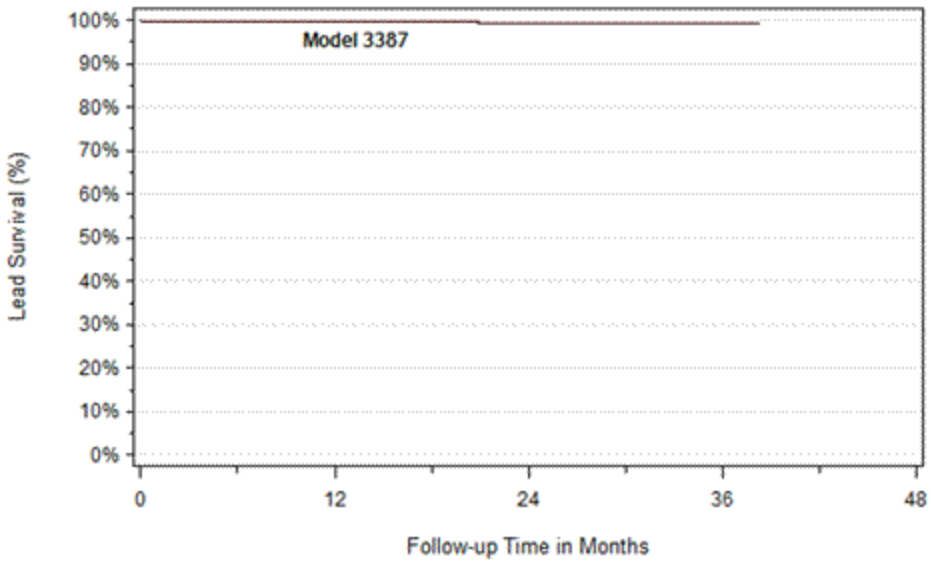
Lead Survival

The figure and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, estimates of device survival from lead-related events exceed 95% (confidence intervals exceed 86%) for all lead models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 3387: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3387
FDA Approval Date	Jan 2002
Leads Enrolled	782
Leads Currently Active in Study	590
Device Events	4[a]
Cumulative Months of Follow-up	8,799

[a] One event occurred at 114 months for a previously implanted lead when the sample size was below 20

Model 3387: Event Summary Table Lead Event	Total
Lead high impedance	2
Lead low impedance	1
Lead migration/dislodgment	1
Total Lead Events	**4**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.8% (98.9%, 100.0%)	240

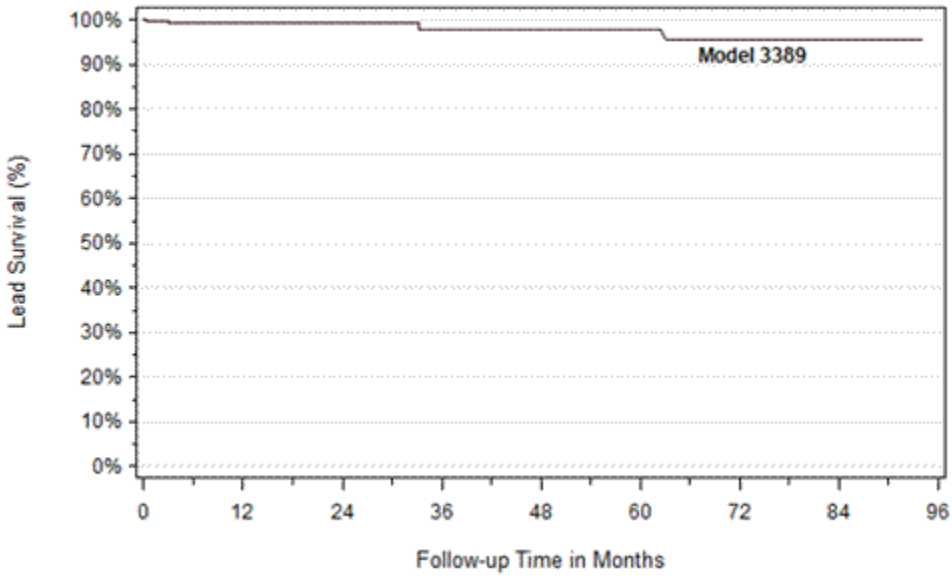
2 yrs	99.1% (95.3%, 99.8%)	94
3 yrs	99.1% (95.3%, 99.8%)	32
at 39 mo	99.1% (95.3%, 99.8%)	31

Model 3387: Specifications

Model Number	**3387**
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm^2)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	10.5

Model 3389: Survival from Lead Events

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



View Larger Image

Lead Characteristics	
Model Number	3389
FDA Approval Date	Sep 1999
Leads Enrolled	912
Leads Currently Active in Study	719
Device Events	6
Cumulative Months of Follow-up	11,497

Model 3389: Event Summary Table

Lead Event	Total
Lead high impedance	5
Lead fracture	1
Total Lead Events	**6**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.2% (97.9%, 99.7%)	316
2 yrs	99.2% (97.9%, 99.7%)	124

3 yrs	97.8% (92.0%, 99.4%)	48
4 yrs	97.8% (92.0%, 99.4%)	43
5 yrs	97.8% (92.0%, 99.4%)	54
6 yrs	95.7% (86.9%, 98.7%)	26
7 yrs	95.7% (86.9%, 98.7%)	29
at 93 mo	95.7% (86.9%, 98.7%)	22

Model 3389: Specifications

Model Number	**3389**
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm^2)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	0.5
Array Length (mm)	7.5

Lead Survival Summary

Currently, estimates of device survival from lead-related events exceed 95% (confidence intervals exceed 86%) for all lead models at the applicable follow-up time points that include at least 20 active devices.

Lead Characteristics

Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
Percutaneous Leads						
3387	**3387**	Jan 2002	782	590	4[b]	8,799
3389	**3389**	Sep 1999	912	719	6	11,497

[a] There were a total of 21 lead-related events reported to the registry, but only 10 events included in this summary table. The remaining events were either subsequent events that did not affect the device survival estimates or were not attributable to an enrolled lead.
[b] One event occurred at 114 months for a previously implanted lead when the sample size was less than 20.

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

Model Number	Family	1 yr	2 yrs	3 yrs	4 yrs
3387	**3387**	**99.8%** (98.9%, 100.0%)	**99.1%** (95.3%, 99.8%)	**99.1%** (95.3%, 99.8%)	-
3389	**3389**	**99.2%** (97.9%, 99.7%)	**99.2%** (97.9%, 99.7%)	**97.8%** (92.0%, 99.4%)	**97.8%** (92.0%, 99.4%)

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

Model Number	Family	5 yrs	6 yrs	7 yrs
3387	**3387**	-	-	-
3389	**3389**	**97.8%** (92.0%, 99.4%)	**95.7%** (86.9%, 98.7%)	**95.7%** (86.9%, 98.7%)

Extensions

From July 2009 to the report cut-off date of July 31, 2014, there were 1,701 extensions followed in the registry. Differences between the total number of extensions versus the total number of neurostimulators (N=1,176) were due to the fact that some patients were implanted with more than 1 extension or subsequently re-implanted with an extension. In addition, the number of extensions does not equal the number of leads (N=1,710) because patients were re-implanted with a new lead using existing extensions. The aggregate prospective follow-up time for all extensions was 19,920 months (1,660 years).

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. The table below provides the number and percentage of extensions by model.

Extensions by Model

Model Name	Number of Extensions (%)
37086[a]	1,425 (83.8%)
7482	250 (14.7%)

Other/Unspecified	26 (1.5%)
Total	**1,701 (100%)**

[a] Includes Models 37085 and 37086

Extension Events

There were 7 product performance-related events with an underlying reported etiology related to the extension. Two events were migration of implant attributed to the extensions, 2 were medical device complications, 2 were lead high impedance attributed to the extensions, and 1 was extension fracture. Of the 7 events, 5 were the first event attributable to an enrolled extension.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

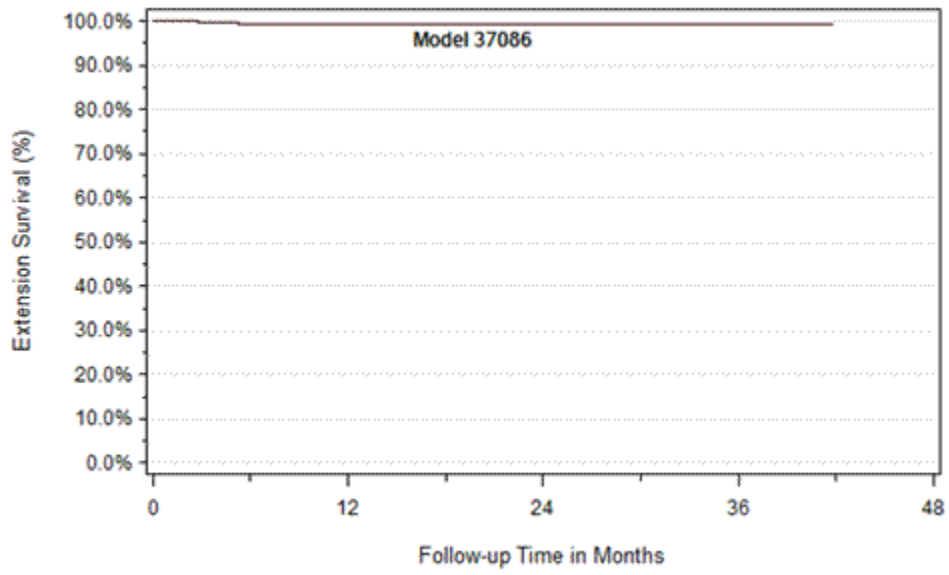
- 5 extensions had follow-up time cut-off due to product performance-related events.
- 294 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, therapy suspended, other extension modification, or non-product performance extension-related event without an associated intervention.
- 1,402 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

Extension Survival

The figure and tables below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval. Currently, survival from extension-related events is greater than 99% (confidence interval exceeds 98%) at 3 years of follow-up.

Choose a model Go

Model 37086: Survival from Extension Events



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Extension Characteristics	
Model Number	37086
FDA Approval Date	Sep 2009
Extensions Enrolled	1,425
Extensions Currently Active in Study	1,115
Device Events	5
Cumulative Months of Follow-up	15,835

Model 37086 Extension: Event Summary Table

Extension Event	Total
Medical device complication[a]	2
Neurostimulator migration[b]	2
Extension fracture	1
Total Extension Events	**5**

[a] Includes 2 events for extension cable loop

[b] Coiling of the two extension wires with appearance typical of Twiddler's syndrome

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	99.4% (98.7%, 99.8%)	519
2 yrs	99.4% (98.7%, 99.8%)	205
3 yrs	99.4% (98.7%, 99.8%)	59
at 42 mo	99.4% (98.7%, 99.8%)	27

Model 37086 Extension: Specifications

Device Name	Stretch-Coil® DBS Extension
Length (cm)	40, 40, 95
Distal End Compatibility	3387, 3389, or 3391 DBS lead
Distal End Set Screws	4
Proximal End INS Compatibility	Activa® RC, Activa PC, or Activa SC 37603

Extension Survival Summary

Currently, survival from extension-related events is greater than 99% (confidence interval exceeds 98%) at 3 years of follow-up.

Extension Characteristics

Model Number	Family	FDA Approval Date	Extensions Enrolled	Extensions Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
37086[b]	37086	Sep 2009	1,425	1,115	5	15,835

Device Survival Probability (95% Confidence Interval)

Model Number	1 yr	2 yrs	3 yrs
37086[b]	**99.4%** (98.7%, 99.8%)	**99.4%** (98.7%, 99.8%)	**99.4%** (98.7%, 99.8%)

[a] There were a total of 7 extension-related events reported to the registry, but only 5 events included in this summary table. The remaining events were either subsequent events that did not affect the device survival estimates or were not attributable to an enrolled extension.
[b] Includes Models 37085 and 37086

2014 Medtronic Product Performance Report: Data through July 31, 2014

Therapies

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

Resources

- Education and Training
- Reimbursement and Practice Management
- MRI Guidelines
- Research Proposal Contacts and Guidelines
- Clinical Trials Registry
- Clinical Research Investigator Guidance

Customer Support

- Contact Us
- Addresses and Phone Numbers
- Reimbursement and Support Services

Sacral Neuromodulation Systems

Study Participants

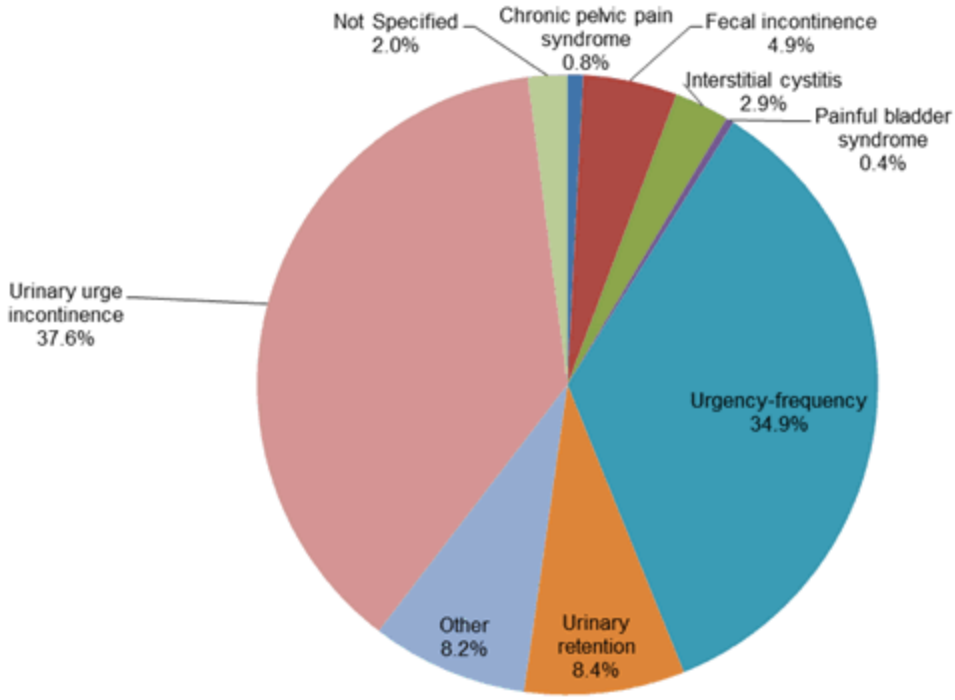
Centers

The following sacral neuromodulation tables and graphs were generated based on data collected between April 2010 and the report cut-off date of July 31, 2014. Eighteen centers enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 490 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 37.6% were implanted for the treatment of urinary urge incontinence, 34.9% were implanted for the treatment of urgency-frequency, 8.4% were implanted for the treatment of urinary retention, 4.9% were implanted for the treatment of fecal incontinence, 2.9% were implanted for the treatment of interstitial cystitis, 0.8% were implanted for the treatment of chronic pelvic pain syndrome, 0.4% were implanted for the treatment of painful bladder syndrome, 8.2% were implanted for the treatment of some other indication, and 2.0% were implanted for indications that were not specified in the database.

Primary SNM Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Urinary urge incontinence	184 (37.6%)
Urgency-frequency	171 (34.9%)
Urinary retention	41 (8.4%)
Fecal incontinence	24 (4.9%)
Interstitial cystitis	14 (2.9%)
Chronic pelvic pain syndrome	4 (0.8%)
Painful bladder syndrome	2 (0.4%)
Other	40 (8.2%)
Not specified	10 (2.0%)
Total Patients	**490**

[a] Refer to product labeling for approved indications.

Event Summary

There were 134 events reported between April 2010 and July 31, 2014 in patients with sacral neuromodulation systems. Of these events, 23.9% (32/134) were categorized as product performance-related and are presented

graphically within this report. The 32 product performance events occurred in 29 of the 490 total patients (5.92%) enrolled. In addition, there were 102 non-product performance events reported. There were also 7 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy.

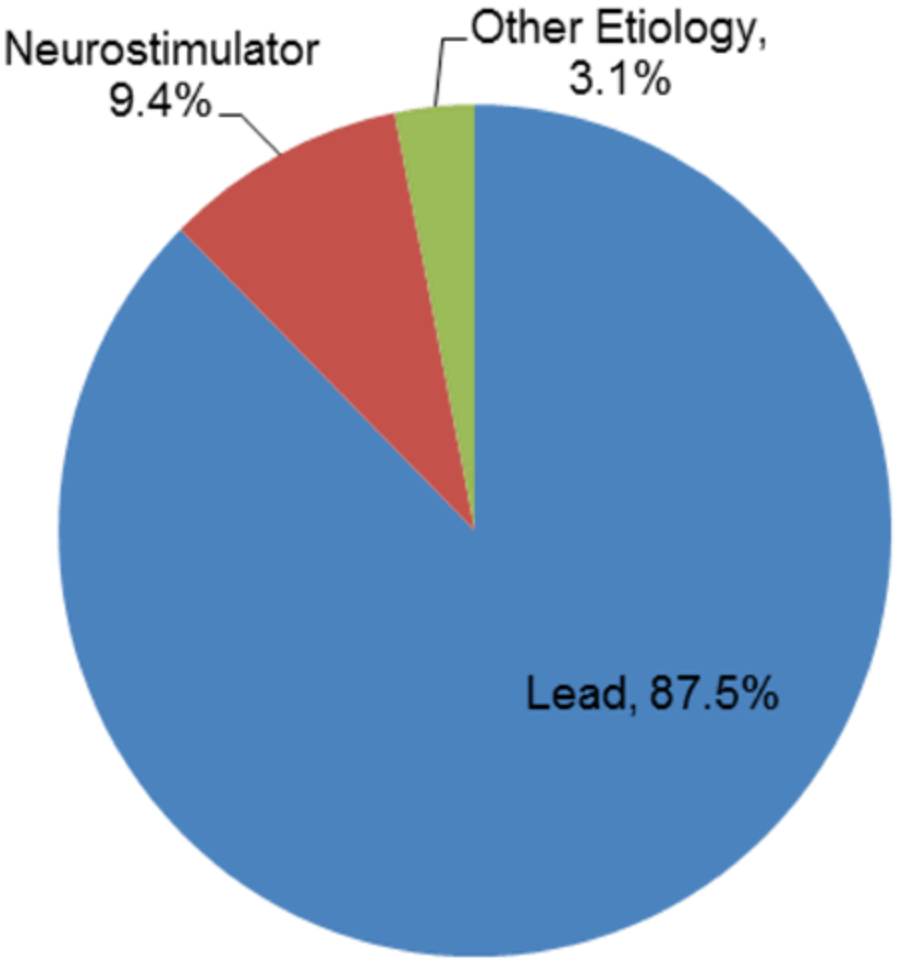
Sacral Neuromodulation System Product Performance Events

Event[a]	Number of Product Performance Events	Number of Patients with Event	Percent of Patients with Event (n=490)
Lead high impedance	18	16	3.27%
Lead fracture	4	4	0.82%
Lead migration/dislodgment	4	4	0.82%
Lead low impedance	3	3	0.61%
Paraesthesia[b]	2	1	0.20%
Device malfunction[c]	1	1	0.20%
Total	**32**	**29**	**5.92%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term
[b] Reported as multiple inappropriate shocks by neurostimulator.
[c] Device function could not be recovered after a fall.

A total of 28 (87.5%) of the 32 product performance events were related to the lead, 3 (9.4%) were related to the neurostimulator, and 1 (3.1%) was related to other etiology. Relatedness is determined by the physician.

Product Performance Events by Relatedness



Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Events[b]	**Number of Non-Product Performance Events**
Therapeutic and nontherapeutic effects (excluding toxicity)	**19**
Therapeutic product ineffective	19
Infections - pathogen unspecified	**19**
Urinary tract infection[c]	17
Infection	1
Wound infection	1
Administration site reactions	**18**

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Implant site pain	14
Implant site infection	3
Implant site erythema	1
Device issues	**10**
Device stimulation issue	6
Device extrusion	1
Device lead issue	1
Neurostimulator inversion	1
Neurostimulator migration	1
Neurological disorders not elsewhere classified (NEC)	**8**
Paraesthesia	6
Restless legs syndrome	1
Sensory disturbance	1
Urinary tract signs and symptoms	**5**
Urinary incontinence	3
Urge incontinence	1
Bladder pain	1
Bacterial infections disorders	**4**
Staphylococcal infection	2
Cellulitis	1
Implant site cellulitis	1
General system disorders NEC	**4**

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Pain	3
Sensation of pressure	1
Therapeutic procedures and supportive care NEC	**3**
Incisional drainage	3
Anal and rectal conditions NEC	**1**
Proctalgia	1
Bladder and bladder neck disorders (excluding calculi)	**1**
Cystitis	1
Bone disorders (excluding congenital and fractures)	**1**
Bone pain	1
Epidermal and dermal conditions	**1**
Skin reaction	1
Genitourinary tract disorders NEC	**1**
Urinary tract disorder	1
Joint disorders	**1**
Arthralgia	1
Musculoskeletal and connective tissue disorders NEC	**1**
Pain in extremity	1
Procedural related injuries and complications NEC	**1**
Wound dehiscence	1

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Reproductive tract disorders NEC	**1**
Pelvic pain	1
Vulvovaginal disorders (excluding infections and inflammations)	**1**
Vulvovaginal pain	1
Not Coded[d]	**2**
Totals	**102**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) High-Level Group Terms and Preferred Terms
[c] Therapy relevant event.
[d] Events were not coded at the time of data cut-off. Reported as fall with open wound at implant site and lead revision.

There were 7 deaths reported for patients with sacral neuromodulation systems, none of which were reported as a direct result of a device-related event or the stimulation therapy. Three deaths occurred in patients receiving therapy for urgency-frequency, 2 deaths for urinary urge incontinence and 2 for other indications.

Death by Primary Indication	
Primary Indication[a]	**N (%)**
Urgency-frequency	3 (42.9%)
Urinary urge incontinence	2 (28.6%)
Other[b]	2 (28.6%)
Total	**7 (100%)**

[a] Refer to product labeling for approved indications
[b] Includes 1 indication of atony of bladder and 1 of urinary tract infection

Neurostimulators

From April 2010 to the report cut-off date of July 31, 2014, 447 neurostimulators were followed in the registry.

Over eighty-one percent (81.7%) of neurostimulators were InterStim II (n=365), and 18.3% (n=82) were InterStim. The aggregate prospective follow-up time for all neurostimulators was 4,833 months (403 years).

Neurostimulator Events

There were 3 product performance-related events with an underlying reported etiology related to neurostimulator function. Of the 3 events, 2 were able to be included in the survival analysis. The remaining event was not included because data needed to link the event to the neurostimulator was missing at the time of data cut-off for this report.

For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 7/30 (23%). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of stimulation devices in patients who have expired. There were no anomalies found in the 7 devices that were returned for analysis. The 3 neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as device malfunction (device function could not be restored after a fall), high impedance (both lead and stimulator), and paraesthesia.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

- 2 had follow-up cut-off due to product performance-related events.
- 57 were censored in the survival analysis for the following reasons: patient expired, stimulator explanted, patient discontinued, therapy suspended, other stimulator modification, or non-product performance stimulator-related event with no associated intervention.
- 388 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

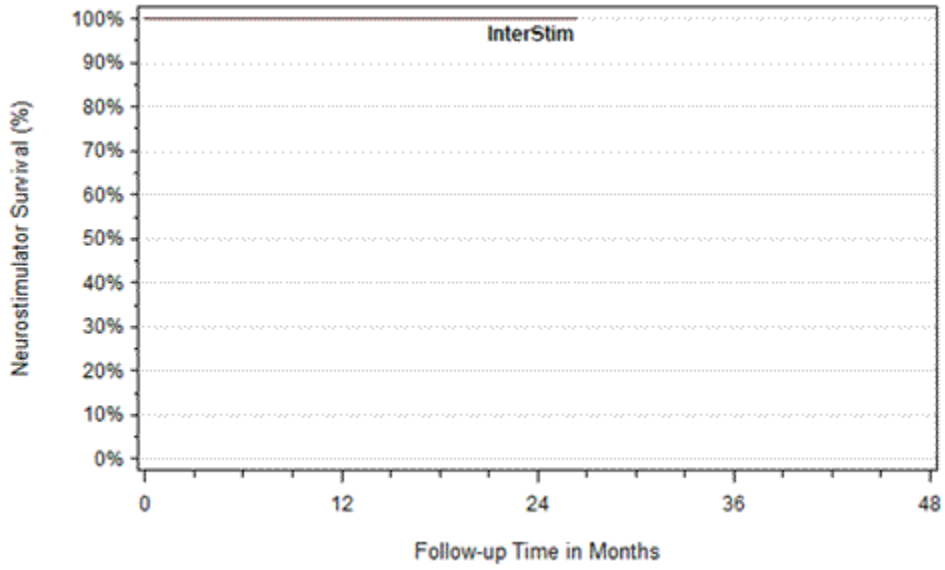
Neurostimulator Survival

The figures and tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. Currently estimates of device survival from neurostimulator-related events exceed 98% (confidence intervals exceed 91%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 3023 InterStim: Survival from Neurostimulator Events

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



View Larger Image

Neurostimulator Characteristics	
Model Name	InterStim
FDA Approval Date	Jul 1998
Neurostimulators Enrolled	82
Neurostimulators Currently Active in Study	56
Device Events	0
Cumulative Months of Follow-up	1,165

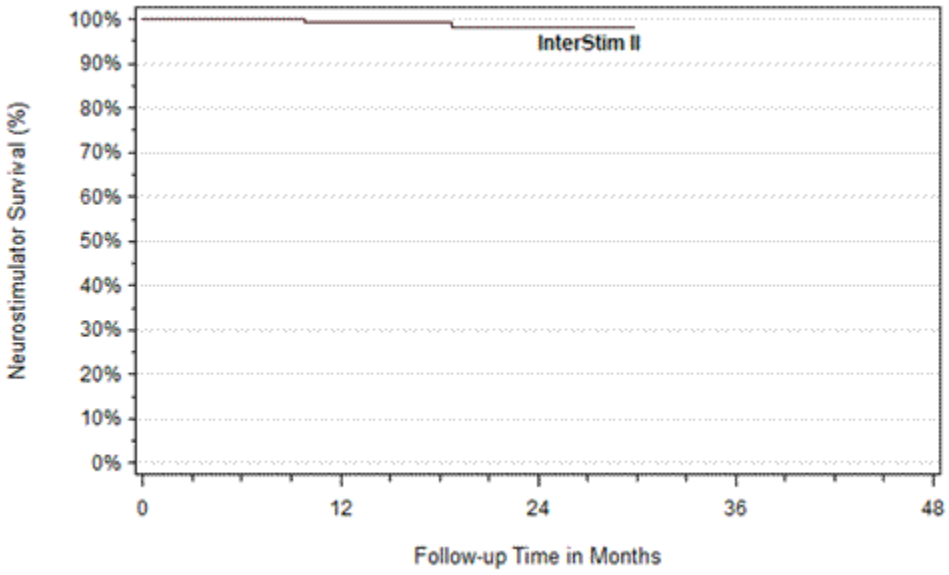
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	37
2 yrs	100.0% (NA)	23
at 27 mo	100.0% (NA)	20

Model 3023 InterStim: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thinness	0.4 in (10 mm)
Volume	25 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 µsec
Programs	4
Implant Depth	≤ 4 cm

Model 3058 InterStim II: Survival from Neurostimulator Events

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



View Larger Image

Neurostimulator Characteristics	
Model Name	InterStim II
FDA Approval Date	Jun 2006
Neurostimulators Enrolled	365
Neurostimulators Currently Active in Study	265
Device Events	2
Cumulative Months of Follow-up	3,668

Model 3058 InterStim II: Event Summary Table

Neurostimulator Event	Total
Lead high impedance[a]	1
Device malfunction[b]	1
Total Neurostimulator Events	**2**

[a] High impedance of both lead and neurostimulator
[b] Device function could not be restored after a fall

Time Interval	Survival (95% Confidence Interval)	Sample Size

1 yr	99.3% (95.3%, 99.9%)	129
2 yrs	98.0% (91.9%, 99.5%)	50
at 30 mo	98.0% (91.9%, 99.5%)	25

Model 3058 InterStim II: Specifications

Height	1.7 in (44 mm)
Width	2.0 in (51 mm)
Thinness	0.3 in (7.7 mm)
Volume	14 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use (additional Information)
Maximum Electrodes	4
Amplitude	0 - 8.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 µsec
Programs	4
Implant Depth	≤ 2.5 cm

Neurostimulator Survival Summary

Currently, estimates of device survival from neurostimulator-related events exceed 98% (confidence intervals exceed 91%) for all neurostimulator models at the applicable follow-up time points that include at least 20 active devices.

Neurostimulator Characteristics

Model Name Family	FDA Approval Date	Neuro-stimulators Enrolled	Neuro-stimulators Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up

InterStim	InterStim	Jul 1998	82	56	0	1,165
InterStim II	InterStim	Jun 2006	365	265	2	3,668

Device Survival Probability (95% Confidence Interval)		
Model Name	1 yr	2 yrs
InterStim	**100.0%** NA	**100.0%** NA
InterStim II	**99.3%** (95.3%, 99.9%)	**98.0%** (91.9%, 99.5%)

[a] There were a total of 3 neurostimulator-related events reported to the registry, but only 2 events included in this summary table. The remaining event was not included because data needed to link the event to the neurostimulator was missing at the time of data cut-off for this report.

Leads

From April 2010 to the report cut-off date of July 31, 2014, there were 449 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=447) were due to the fact that some patients were subsequently re-implanted with a new lead. The aggregate prospective follow-up time for all leads was 4,675 months (390 years).

A lead is a set of thin wires with a protective coating and electrodes near the tip. The table below provides the number and percentage of leads by model.

Leads by Model	
Model Number	**Number of Leads (%)**
3889	381 (84.9%)
3093	64 (14.3%)
3080	3 (0.7%)
Unspecified	1 (0.2%)
Total	**449 (100%)**

Lead Events

There were 28 product performance-related events with an underlying reported etiology related to the lead. Of these, 24 were included in the following survival curves. The remaining events occurred in a lead that already had an event included in the survival curves (n=3) or occurred in a lead model for which no device survival curve is presented due to an insufficient number of enrolled devices (i.e., Model 3080). The majority of the events were lead high impedance (n=17).

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

- 25 had follow-up time cut-off due to product performance-related events.
- 48 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, other lead modification, therapy suspended, or non-product performance lead-related event without an associated intervention.
- 376 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

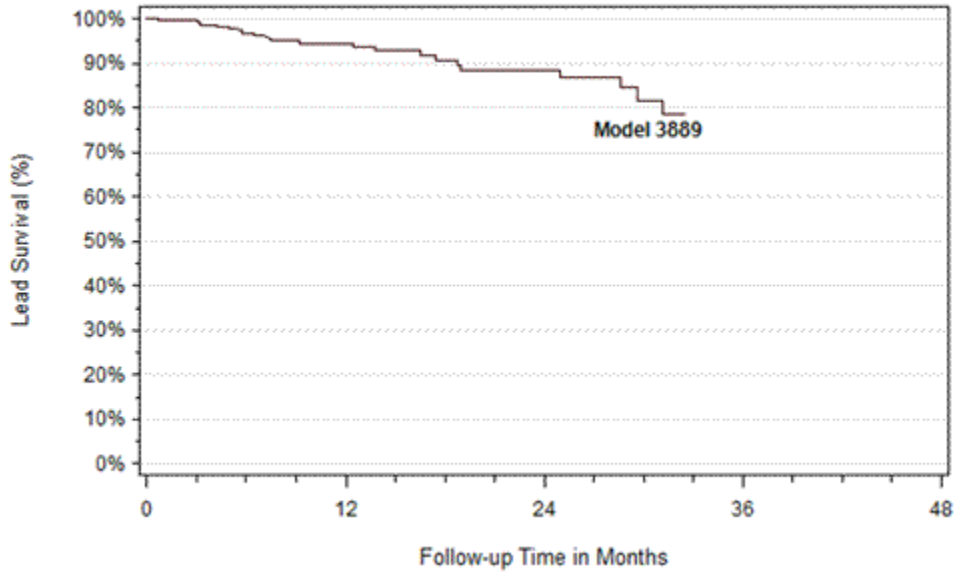
Lead Survival

The figures and tables below represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Currently, estimates of device survival from lead-related events exceed 78% (confidence intervals exceed 65%) for all lead models at the applicable follow-up time points that include at least 20 active devices.

Choose a model Go

Model 3889: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3889
FDA Approval Date	Sep 2002
Leads Enrolled	381
Leads Currently Active in Study	267
Device Events	24

Cumulative Months of Follow-up	3,893

Model 3889: Event Summary Table	
Lead Event	**Total**
Lead high impedance	14
Lead fracture	4
Lead low impedance	3
Lead migration/dislodgment	3
Total Lead Events	**24**

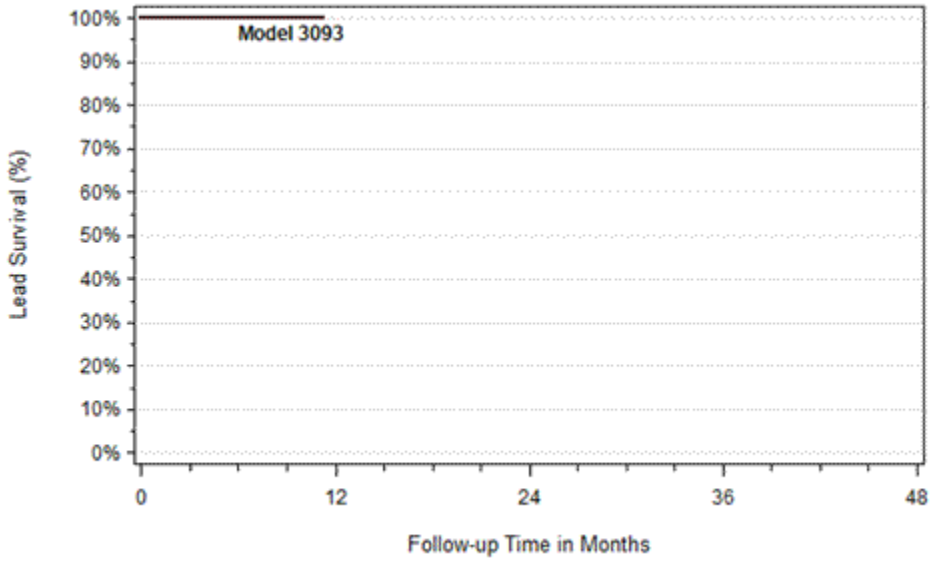
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	94.4% (90.0%, 96.9%)	124
2 yrs	88.4% (81.5%, 92.9%)	56
at 33 mo	78.7% (65.8%, 87.2%)	20

Model 3889 Tined Lead: Specifications

Model Number	**3889**
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0
Individual Surface Area (mm^2)	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	3.0
Array Length (mm)	21.0

Model 3093: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3093
FDA Approval Date	Sep 2002
Leads Enrolled	64
Leads Currently Active in Study	50
Device Events	0
Cumulative Months of Follow-up	752

Time Interval	Survival (95% Confidence Interval)	Sample Size
at 6 mo	100% (NA)	35
1 yr	100% (NA)	20

Model 3093 Tined Lead: Specifications

Model Number	**3093**
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0 (3x) and 10.2 (1x)
Individual Surface Area (mm^2)	12.0 and 40.7
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	23.7

Lead Survival Summary

Currently, estimates of device survival from lead-related events exceed 78% (confidence intervals exceed 65%) for all lead models at the applicable follow-up time points that include at least 20 active devices.

Lead Characteristics

Model Number	Family	FDA Approval Date	Leads Enrolled	Leads Currently Active in Study	Device Events[a]	Cumulative Months of Follow-up
3889	**3889**	Sep 2002	381	267	24	3,893
3093	**3093**	Sep 2002	64	50	0	752

[a] There were 28 lead-related events reported to the registry, but only 24 events included in this summary table. The remaining events occurred in a lead model for which no device survival curve is presented due to an insufficient number of enrolled devices (ie, Model 3080) (n=1) or was a subsequent event that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval)

Model Number	**Family**	**1 yr**	**2 yrs**
3889	**3889**	**94.4%** (90.0%, 96.9%)	**88.4%** (81.5%, 92.9%)
3093	**3093**	**100%** NA	**-**

Extensions

From April 2010 to the report cut-off date of July 31, 2014, there were 81 extensions followed in the registry. Differences between the total number of extensions versus the total neurostimulators (N=447) were due to the fact that not all systems require an extension.

An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead (not required for all neurostimulation systems). All the extensions were Model 3095. The aggregate prospective follow-up time for all extensions was 1,166 months (97 years).

Extension Events

There were no product performance-related events with an underlying reported etiology related to the extension as of the cut-off date of July 31, 2014.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a non-product performance-related or censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

- 13 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, or therapy suspended.
- 68 were free from product performance-related events and censoring events were censored at the last follow-up visit prior to the report cut-off.

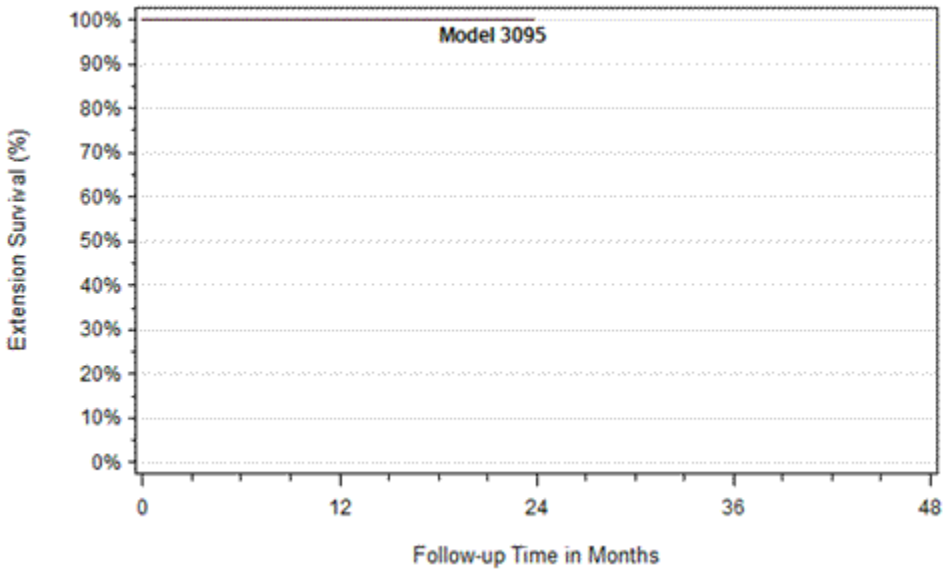
Extension Survival

The figure and table below represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval unless otherwise noted. As of the report cut-off date, Model 3095 extension had 100% survival from product performance-related events at 2 years of follow-up.

Choose a model Go

Model 3095: Survival from Extension Events

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



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Extension Characteristics	
Model Number	3095
FDA Approval Date	Jul 1998
Extensions Enrolled	81
Extensions Currently Active in Study	53
Device Events	0
Cumulative Months of Follow-up	1,166

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	100.0% (NA)	33
2 yrs	100.0% (NA)	21

Model 3095 Extension: Specifications

Device Name	Quadripolar Extension
Length (cm)	10, 25, 51
Distal End Compatibility	Tined lead models 3889 and 3093
Distal End Set Screws	4
Proximal End INS Compatibility	InterStim Model 3023

Extension Survival Summary

Currently, Model 3095 extension had 100% survival from product performance-related events at 2 years of follow-up.

Extension Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Currently Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
3095	3095	Jul 1998	81	53	0	1,166

Device Survival Probability (95% Confidence Interval)		
Model Number	**1 yr**	**2 yrs**
3095	**100.0%** NA	**100.0%** NA

2014 Medtronic Product Performance Report: Data through July 31, 2014

Therapies

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

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