Medtronic

2017 PRODUCT PERFORMANCE REPORT

OVERVIEW

Introduction

Medtronic uses a prospective, long-term multi-center registry to monitor the performance of certain products at selected centers titled the Product Surveillance Registry (PSR). This 2017 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 Returned Product Analysis (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.

Medtronic's spinal cord stimulation systems (spinal cord neurostimulators, leads, and extensions) for pain indications were later added to the registry. Implanted spinal cord neurostimulators send 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 electrical stimulation to 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 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 64 centers that have contributed data for targeted drug delivery systems, 79 centers for spinal cord stimulation systems, 38 centers for deep brain stimulation, and 20 centers for sacral neuromodulation. There are 32, 38, 29, and 10 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.

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 10th 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 enable physicians 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 16,500 patients in our ongoing post-market registry. The registry has enrolled over 50,000 neuromodulation system components. Components include pumps, catheters, neurostimulators, leads, and extensions. Data on other events not directly attributed to product performance are also included 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.

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.

Todd Weaver, PhD, MPH
Senior Clinical Research Manager, Data Science
Medtronic

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® SureScan® MRI neurostimulator	Vectris® SureScan® leads

2017 Medtronic Product Performance Report: Data through October 31, 2017.

METHODOLOGY

Event Classification

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

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

Information on all deaths is 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 20.0 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.

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 requirement for 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 all continuous time points where there are at least 20 devices, and are cut off at the last 3-month time point where at least 20 total devices were still being followed. 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. Device survival estimates are presented at the device level, not at the system level which involves the combination of 2 or more devices.

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 a Returned Product Analysis (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.

TARGETED DRUG DELIVERY SYSTEMS

Study Participants

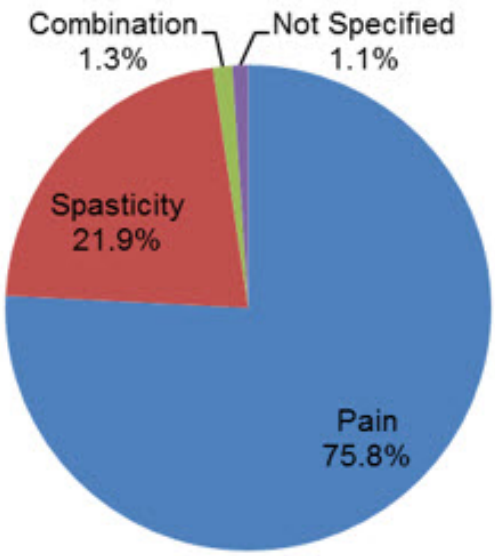
Centers

The following targeted drug delivery tables and graphs were generated based on data collected between August 7, 2003 and the report cut-off date of October 31, 2017. Sixty-four centers in America, Europe and South America enrolled and contributed patient data to the targeted drug delivery systems section of the report.

Patients

As the table below demonstrates, there were 7,975 total targeted drug delivery system patients enrolled through October 31, 2017. As indicated, 57.6% 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 21.9% for treatment of spasticity, and 18.2% for treatment of malignant pain (pain related to cancer). Primary treatment indication is provided by the physician.

Targeted Drug Delivery System Primary Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Pain	**6,045 (75.8%)**
Non-malignant pain	4,593 (57.6%)
Malignant pain	1,452 (18.2%)
Spasticity	**1,743 (21.9%)**
Combination	**103 (1.3%)**
Non-malignant pain & Spasticity	103 (1.3%)
Not Specified	**84 (1.1%)**
Total Patients	**7,975**

[a] Refer to product labeling for approved indications.

Malignant Pain Sub-indications	Total Enrolled Patients (Percent) [a]
Spine/Back	494 (34.0%)
Abdominal/Visceral	316 (21.8%)
Extremity	204 (14.0%)
Pelvic	195 (13.4%)
Thoracic	160 (11.0%)
Head/Neck	85 (5.9%)
Other	101 (7.0%)
Unknown	441 (30.4%)
Total Patients	**1,452**

[a] Percent is based on the number of total patients.

Non-Malignant Pain Sub-Indications	Total Enrolled Patients (Percent)
Back Pain without Leg Pain	1,422 (30.3%)
Back Pain with Leg Pain	1,396 (29.7%)
General Neuropathic Condition	180 (3.8%)
CRPS I [a]	146 (3.1%)
Peripheral Neuropathy	75 (1.6%)
Joint Pain/Arthritis	66 (1.4%)
CRPS II [a]	35 (0.7%)
General Nociceptive Condition	37 (0.8%)
Osteoporosis	20 (0.4%)
Other	358 (7.6%)
Not Specified	961 (20.5%)
Total Patients [b]	**4,696**

[a] CRPS is complex regional pain syndrome. CRPS I rarely includes detectable peripheral nerve injury. CRPS II includes detectable peripheral nerve or plexus injury.
[b] Includes patients with indications of non-malignant pain and a combination of non-malignant pain and spasticity.

Spasticity Sub-Indications	Total Enrolled Patients (Percent)
Cerebral Palsy	493 (26.7%)
Multiple Sclerosis	472 (25.6%)
Spinal Cord Injury	269 (14.6%)
Brain Injury	136 (7.4%)
Stroke	74 (4.0%)
Other	128 (6.9%)
Not Specified	274 (14.8%)
Total Patients [a]	**1,846**

[a] Includes patients with indications of spasticity and a combination of non-malignant pain and spasticity.

Event Summary

There were 1,758 product performance related events reported between August 7, 2003 and October 31, 2017 in patients with targeted drug delivery systems. These events represent approximately 25% of the total reported events (1,758/6,632). These events occurred in 1,160 of the 7,975 (14.5%) total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves).

In addition, there were 4,874 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the targeted drug delivery systems. There were also 1,972 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a product performance event. 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=7,975)**
Catheter occlusion [c]	323	289	3.62%
Catheter dislodgement from intrathecal space	304	260	3.26%

Targeted Drug Delivery System Product Performance Events			
Pump motor stall [d]	221	165	2.07%
Catheter break/cut	208	185	2.32%
Catheter kink	155	137	1.72%
Catheter related complication [e]	79	73	0.92%
Device malfunction [f]	77	72	0.90%
Catheter leakage	56	53	0.66%
Pump reservoir volume discrepancy	47	35	0.44%
Catheter disconnection at pump	43	43	0.54%
Pump unable to enter/withdraw from catheter access port	30	24	0.30%
Corrosion and/or gear wear	28	28	0.35%
Confirmed overinfusion [g*]	11	5	0.06%
Laboratory overinfusion finding [g**]	13	13	0.16%
Physician reported overinfusion [g***]	2	2	0.03%
Pump underinfusion	19	16	0.20%
Pump connector break/cut	17	16	0.20%
Medical device complication [h]	15	12	0.15%
Reduced battery performance	11	11	0.14%
Battery high resistance	9	9	0.12%
Device breakage	9	8	0.10%
Deformed pump tube	8	7	0.09%
Catheter disconnection between catheter segments	7	7	0.09%
Device difficult to use	6	6	0.08%
Reservoir access issues due to residue	6	5	0.06%
Catheter damage	5	5	0.06%
Device issue [i]	5	5	0.06%
Catheter access port issue	4	4	0.05%
Device alarm issue	4	4	0.05%
Motor feedthrough anomaly	3	3	0.04%
Pump not infusing	3	3	0.04%
Device damage	3	3	0.04%
Device end of life [j]	2	2	0.03%
Device connection issue	2	2	0.03%
Hole in pump tube	2	1	0.01%
Alarm and/or resonator anomaly	1	1	0.01%
Catheter blockage	1	1	0.01%

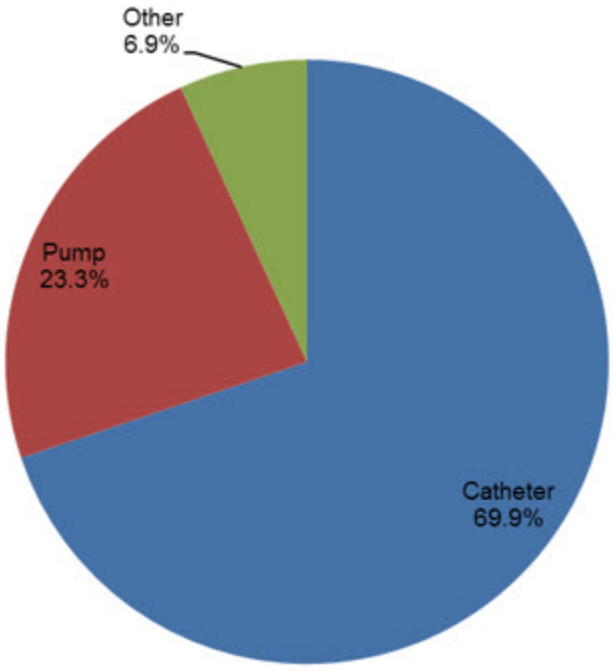
Targeted Drug Delivery System Product Performance Events			
Coil shorted to case	1	1	0.01%
Concave pump shield	1	1	0.01%
Connector block problem	1	1	0.01%
Cracked rotor magnet holder	1	1	0.01%
Device deployment issue	1	1	0.01%
Device infusion issue [k]	1	1	0.01%
Device leakage	1	1	0.01%
Device migration	1	1	0.01%
Device misdeployment (location)	1	1	0.01%
Device physical property issue	1	1	0.01%
Gear or bridging residue	1	1	0.01%
Hybrid Anomaly	1	1	0.01%
Leaky capacitor	1	1	0.01%
Manufacturing Issue Propellant Anomaly [l]	1	1	0.01%
Prescription table corruption	1	1	0.01%
Premature battery depletion	1	1	0.01%
Product sedimentation present	1	1	0.01%
Pump inversion	1	1	0.01%
Roller arm seized to ball bearing	1	1	0.01%
Totals	**1,758**	**1,160**	**14.55%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[b] The total number of patients with events 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] Of the 221 motor stalls, 215 had a pump etiology, and 6 motor stalls without pump etiology; 1 catheter etiology, 1 with other etiology, and 4 with MRI etiology. Of the 4 with MRI etiology 1 pump was replaced and 3 remain active in the patient. Motor stall count does not include temporary motor stalls that may be expected (e.g. due to MRI) and recovered within a 24-hour period. The SynchroMed II pump is designed to temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure for patient safety.
[e] Includes 20 inability to aspirate from catheter, 19 suspected catheter malfunctions, 18 catheter malfunctions, 4 coiled catheters, 2 difficulty aspirating catheter,1 catheter wrapped in coils and knots, 1 new catheter had a 'silicone gob',1 poor dye dispersion, 1 unable to access CAP during analysis, 1 catheter anchor malfunction, 1 evidence of catheter wear, 1 patency issues of catheter, 1 non-functioning catheter-failed spinal segment, 1 no free flow of CSF from spinal segment of catheter, 1 aneurysm in catheter, 1 poor CSF flow, 1 catheter wrapped around pump, 1 sluggish flow of CSF, 1 slight loop in catheter, 1 catheter failure, and 1 catheter occlusion.
[f] Includes 47 PTM malfunctions, 9 unexpectedly locked out of PTM, 4 pump malfunctions, 3 pump reset occurred, 2 PTM unable to sync with pump, 2 PTM displayed incorrect alarm date, 1 pump in stopped mode, 1 clinician programmer malfunction, 1 patient felt pump not working, 1 unspecific difficulties with PTM, 1 PTM bonding issue, 1 PTM issue, possibly due to antenna, 1 trouble connecting PTM to pump, 1 suspected pump and/or catheter malfunction, 1 suspected rotor problem, 1 possible pump malfunction.
[g] *Patient had clinical signs and symptoms consistent with pump overinfusion, pump returned, and positive laboratory test (n=5). ** Includes pumps where a physician reported a device related event not meeting the definition for confirmed overinfusion (n=13). *** Patient had clinical signs and symptoms, but pump not returned and analyzed n=2).
[h] Includes 2 worn pump connector and pump side catheter, 2 worn catheter connector, 2 possible corrosion of catheter due to concentration of drug, 1 metal clips on sutureless connector appear bent, 1 pump unable to interrogate/program, 1 pump in safe state, 1 prescription table corruption, 1 worn proximal connector, 1 telemetry was stopped secondary to error code, 1 worn

catheter, 1 sutureless connector failure, 1 pumped beeped.
[i] Includes 4 unable to activate PTM, and 1 de-coupled PTM.
[j] Includes 1 event reported as early battery depletion, and 1 pump reset.
[k] Includes 1 event reported as slow dosing at refills.
[l] Includes 1 event reported as manufacturing issue propellant anomaly found by Medtronic RPA.

There were 1238 (70.4%) product performance events reported to the registry that were related to the catheter. This includes 1128 (69.9%) events with a catheter etiology and 10 events with both a catheter and other etiology (including device and non-device etiologies). There were 416 (23.7%) events related to the pump. This includes 409 (23.3%) with a pump etiology and 7 events with both pump and other etiology (including device and non-device etiologies). There were 84 (4.8%) were reported as related to an external device, 19 (1.1%) were related to "multiple etiologies," which includes events where at least one device and one non-device etiology was indicated, 4 (0.2%) were related to MRI, 4 (0.2%) were related to incisional site/device tract, 3 (0.2%) were related to some "other" etiology, 3 (0.2%) were related to surgery/anesthesia, 2 (0.1%) were related to programming/refill, and 2 (0.1%) were related to medication. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a] Each event could have more than one etiology.

Events not-related to a product-performance issue are characterized below. Due to the differences in event collection between the ISPR and PSR protocols, events per patient years and other rates are not calculated.

Events are categorized by an event group term as noted in bold in the table below.

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**
Therapeutic and nontherapeutic effects (excluding toxicity)	**1492**
Adverse drug reaction	1193
Therapeutic product ineffective	141
Drug withdrawal syndrome	118
Therapeutic response decreased	28
Therapy non-responder	6
Other [c]	6
Complications associated with device	**883**
Medical device site pain	544
Medical device site extravasation	155
Medical device site erosion	38
Medical device discomfort	35
Medical device site erythema	22
Medical device site haematoma	22
Medical device site swelling	10
Medical device discomfort	8
Medical device site irritation	8
Complication associated with device	7
Medical device site inflammation	6
Drug-related pump anomaly	5
Other [c]	23
Device issues [d]	**392**
Pump inversion	184
Pump migration	86
Device malfunction	47
Pump reservoir volume discrepancy	25
Device issue	14
Device extrusion	6
Catheter break/cut	6

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Pump reservoir issue	6
Other [c]	18
Infections - pathogen unspecified	**351**
Medical device site infection	254
Wound infection	43
Meningitis	23
Infection	16
Other [c]	15
General system disorders NEC	**300**
Pain	178
No anomaly found by RPA [e]	57
Oedema peripheral	36
Oedema	8
Asthenia	6
Other [c]	15
Procedural related injuries and complications Not Elsewhere Classified (NEC)	**295**
Wound dehiscence	82
Inadequate analgesia	68
Seroma	42
Post lumbar puncture syndrome	33
Incision site erythema	10
Procedural headache	7
Suture related complication	5
Pseudomeningocele	5
Anaesthetic complication	5
Other [c]	38
Neurological disorders NEC	**278**
Cerebrospinal fluid leakage	110
Hypoaesthesia	60
Somnolence	27
Sedation	24
Paraesthesia	15
Hyperaesthesia	12
Lethargy	5
Other [c]	25
Administration site reactions	**164**

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Implant site extravasation	61
Inflammatory mass (Possible)	18
Catheter site fibrosis	17
Inflammatory mass (Confirmed)	14
Catheter site extravasation	7
Catheter site swelling	5
Other [c]	42
Psychiatric disorders NEC	**96**
Withdrawal syndrome	77
Mental status changes	19
Medication errors and other product use errors	**73**
Device difficult to use	66
Other [c]	7
Headaches	**53**
Headache	53
Overdoses and underdoses NEC	**52**
Overdose	50
Other [c]	2
Musculoskeletal and connective tissue disorders NEC	**45**
Back pain	27
Pain in extremity	7
Other [c]	11
Muscle disorders	**42**
Muscular weakness	33
Muscle spasms	9
Urinary tract signs and symptoms	**38**
Urinary retention	28
Dysuria	7
Other [c]	3
Neuromuscular disorders	**33**
Muscle spasticity	28
Other [c]	5
Gastrointestinal signs and symptoms	**32**
Nausea	16
Vomiting	9
Other [c]	7
Epidermal and dermal conditions	**28**

Targeted Drug Delivery System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Erythema	9
Pruritus	8
Other [c]	11
Tissue disorders NEC	**27**
Impaired healing	24
Other [c]	3
Bacterial infectious disorders	**23**
Medical device site cellulitis	18
Other [c]	5
Injuries NEC	**23**
Wound secretion	10
Other [c]	13
Exposures, chemical injuries and poisoning	**22**
Toxicity to various agents	22
Respiratory disorders NEC	**12**
Respiratory depression	5
Other [c]	7
Allergic conditions	**9**
Drug hypersensitivity	5
Other [c]	4
Gastrointestinal motility and defaecation conditions	**8**
Constipation	8
Mental impairment disorders	**8**
Memory impairment	6
Other [c]	2
Disturbances in thinking and perception	**7**
Hallucination	5
Other [c]	2
Skin and subcutaneous tissue disorders NEC	**7**
Skin erosion	7
Other [c]	**81**
Total	**4,874**

[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 or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Composed of event codes with fewer than 5 events each.
[d] Device issues count does not include temporary motor stalls that may be expected (e.g. due to MRI) and recovered within a 24-hour period. The SynchroMed II pump is designed to temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure for patient safety.

[e] 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).

There were 1,972 deaths reported for patients with targeted drug delivery systems, none of which were reported as a direct result of a product performance event. One death was reported by the physician as possibly related to the intrathecal medications in a patient who expired due to pulmonary embolism. A second death was reported by the physician as due to acute respiratory failure following a device procedure, and was assessed by Medical Safety as probably related to the device and implant procedure. A third death was reported by the physician as possibly related to the intrathecal medication in a patient who expired due to probable arteriosclerotic cardiovascular disease. Medical Safety assessed this event as unassessable due to incomplete information. The majority of deaths occurred in patients who were treated for malignant pain (58.8%), while a smaller fraction of deaths occurred in patients who were treated for non-malignant pain (31.6%), spasticity (9.0%), a combination of non-malignant pain and spasticity (0.3%) or unspecified primary indication (0.3%).

Number of Reports of Death by Primary Indication	
Primary Indication[a]	**N (%)**
Malignant pain	1,159 (58.8%)
Non-malignant pain	624 (31.6%)
Spasticity	178 (9.0%)
Non-Malignant Pain & Spasticity	6 (0.03%)
Not specified	5 (0.03%)
Total	**1,972**

[a] Refer to product labeling for approved indications.

Pumps

From August 7, 2003 to the report cut-off date of October 31, 2017, there were 9,713 pumps followed in the registry. The difference between the total number of patients (n=7,975) 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 283,715 months (23,643 years). The table below provides the number and percentage of pumps by model.

Pumps by Model

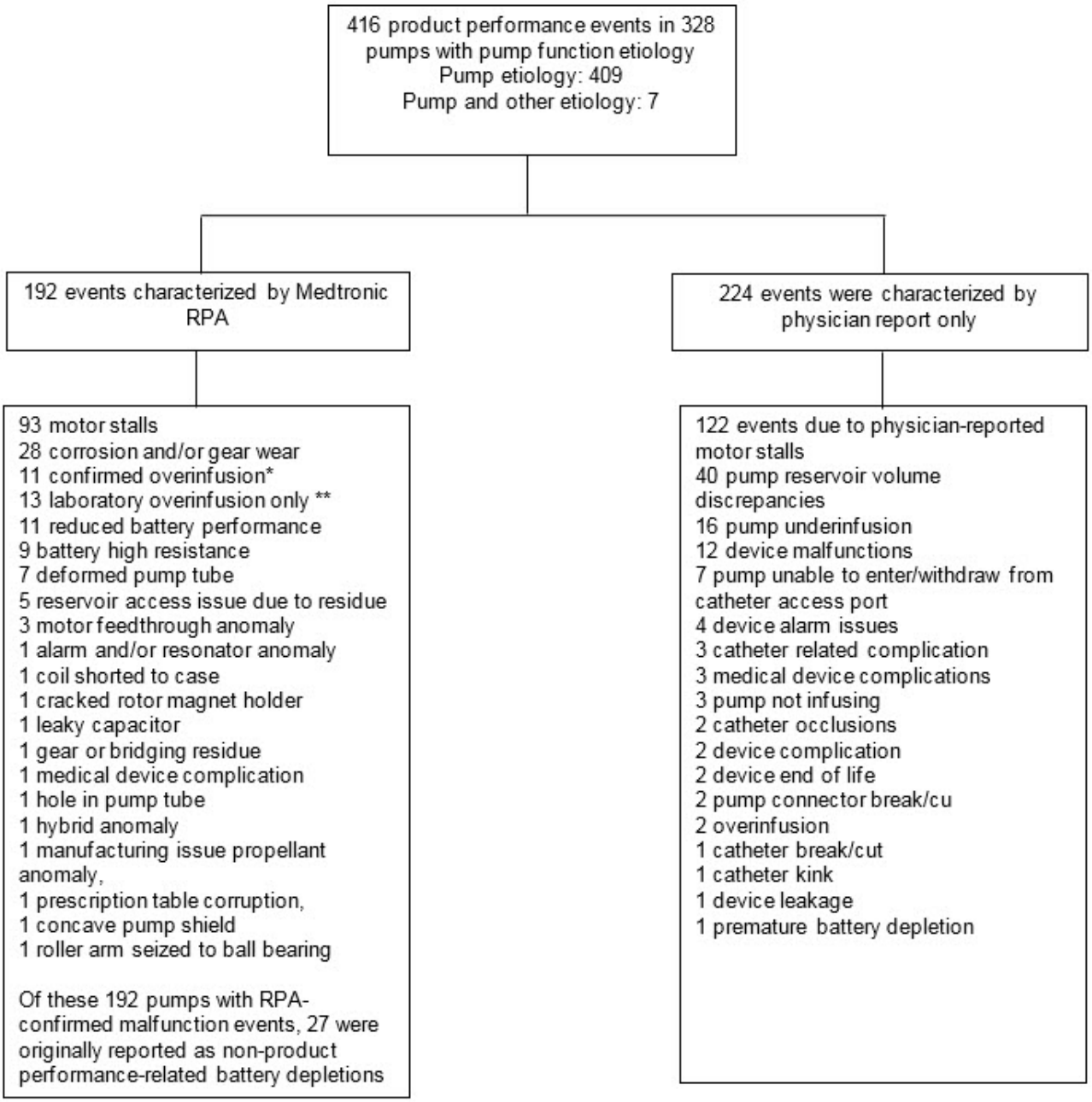
Model Name	**Number of Pumps (%)**
SynchroMed II	8,524 (87.8%)
Unspecified	2 (0.1%)
Pumps No Longer Manufactured	
SynchroMed EL	1,182 (12.2%)
SynchroMed	5 (0.1%)
Total	**9,713 (100%)**

Pump Events

There were 416 product performance-related events with an underlying reported etiology related to pump function. The current return rate of pumps to Medtronic RPA is (28.2%) (1259/4468). 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. The remaining 1,067 pumps returned to Medtronic were not determined to be product performance related events.

Of the 416 product performance related events with an underlying etiology of pump function, 328 events were the initial product performance event that affected pump survival estimates.

The flowchart below shows the distribution of these 416 product performance-related events by those characterized by RPA or by physician report only (pumps were not returned to Medtronic):



[*] There were 11 events reported in 5 patients.
[**] Includes 13 events in 13 pumps where a physician reported a device related event not meeting the definition for confirmed overinfusion.

In addition to the 416 product performance-related pump events, there were 16 pumps explanted due to 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 not considered failures because they represented normal implant duration ranging from 5.6-7.1 years with no associated physician or patient complaint. These other 5 pumps had an implant duration lower than 5.6 years, and we are working on them to code them.

Overinfusion

Medtronic executed a field action in March 2014 informing healthcare professionals of overinfusion associated with the SynchroMed II Infusion System. In September 2016, an updated customer letter was provided which stated an overinfusion occurrence rate for registry patients. This rate was based on pumps which had both laboratory overinfusion through returned product analysis and an in-vivo complaint of either clinical overinfusion symptoms or lower than expected residual volume. This definition was used because environmental factors during shipping may impact the results of returned product testing. As of October 5, 2017, there were 5 pumps in the registry that met this definition as stated in the customer letter. The 5 pumps with overinfusion provided 95% confidence that the occurrence rate is less than 0.0012 (0.12%). The use of non-indicated drug formulations (such as admixtures, compounded drugs and unapproved drug concentrations) increases the likelihood for overinfusion. Medtronic continues to monitor pump performance relative to overinfusion.

Overinfusion Rate

	In Vivo & Laboratory Overinfusion[a]
Number of Pumps	5
Occurrence Rate[b]	0.12%

[a] Based on definition of in-vivo and laboratory overinfusion in September 2016 Field Action letter.
[b] Upper one-sided exact 95% confidence interval.

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 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:

- 328 were cut-off due to product performance-related events.
- 6,871 were censored in the survival analysis for the following reasons: patient expired, pump explanted, site termination, patient discontinued, patient lost to follow-up, or therapy suspended.
- 2,514 free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

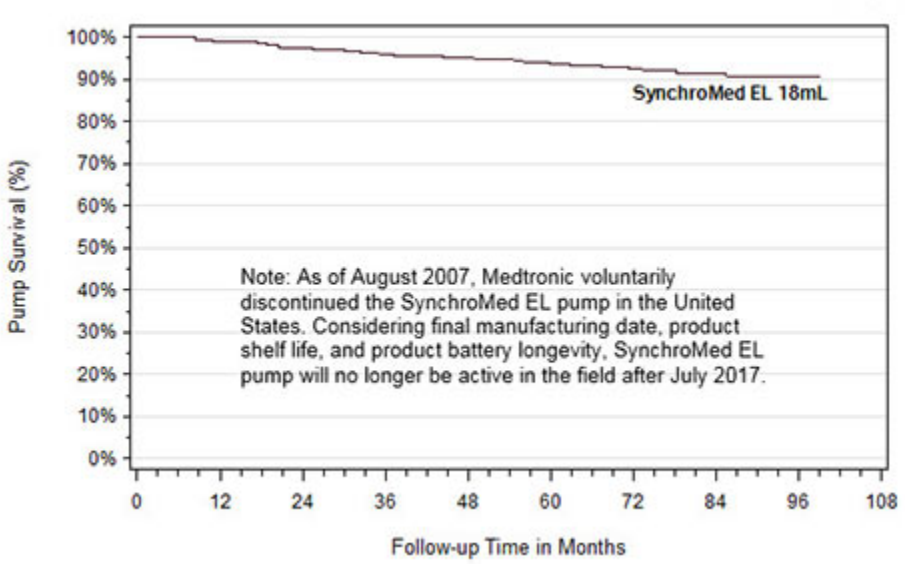
Pump Survival

The figures and tables below represent pump survival and 95% confidence intervals. Since the survival estimate may become very imprecise with sample sizes, the device survival curves below are truncated when the sample size is less than 20 active devices for each 3-month interval. Medtronic chose to voluntarily discontinue the SynchroMed EL pump in August 2007 in the United States.

Distribution of design changes to the SynchroMed II 20ml and 40ml pump models were initiated in January 2016 (Modified the Gear Wheel Material, Encapsulated Feedthroughs), July 2017 (Applied Diamond Like Coating, DLC) and September 2016 (Modified the Priming Bolus Software). Future Product Performance Reports will include analysis of survival of pumps with all four design updates.

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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Pump Characteristics	
Model Name	SynchroMed EL (18 mL)
FDA Approval Date	Mar 1999
Pumps Enrolled	1,148
Pumps Currently Active in Study	0
Device Events	34
Cumulative Months of Follow-up	31,275

SynchroMed EL 18mL Event Summary Table [a]	
Pump Event	**Total**

Corrosion and/or gear wear	17
Pump underinfusion	6
Pump motor stall	5
Device complication [b]	1
Cracked rotor magnet holder	1
Gear or bridging residue	1
Motor feedthrough anomaly	1
Reduced battery performance	1
Roller arm seized to ball bearing	1
Total Pump Events	**34**

[a] As of July 2017, there are no active commercially implanted SynchroMed EL pumps
[b] Includes 1 event for unable to interrogate/program pump

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**98.8%** (95.4%, 99.7%)	183
2 yrs	**97.4%** (94.2%, 98.9%)	375
3 yrs	**95.8%** (92.6%, 97.6%)	538
4 yrs	**95.0%** (91.8%, 96.9%)	594
5 yrs	**93.7%** (90.6%, 95.8%)	470
6 yrs	**92.4%** (89.0%, 94.7%)	248
7 yrs	**91.4%** (87.7%, 94.0%)	109
8 yrs	**90.4%** (86.2%, 93.4%)	36
at 99 mo	**90.4%** (86.2%, 93.4%)	24

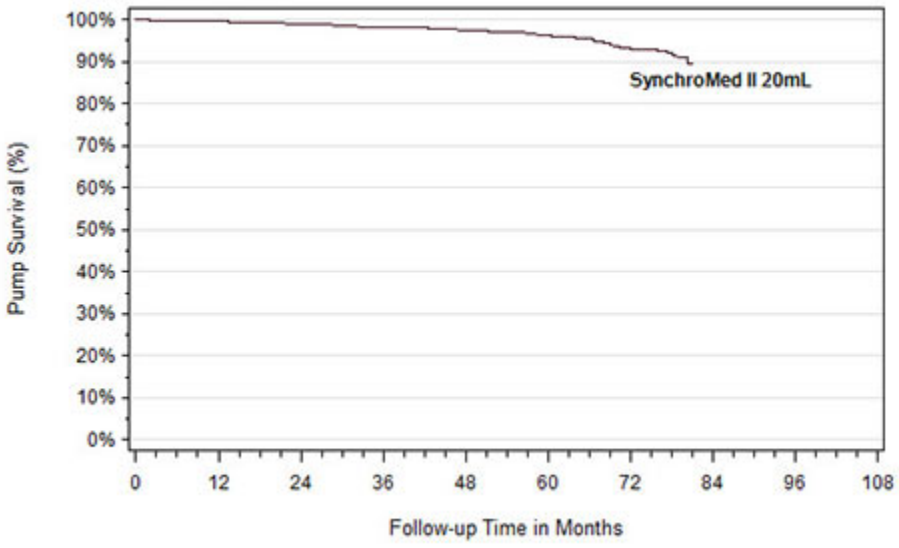
Model 8627-18 SynchroMed EL 18mL: Specifications

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

[a] Dependent on flow rate
[b] Actual limits depend on pump calibration constant and selected infusion mode.

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	3,350
Pumps Currently Active in Study	1,149
Device Events	93
Cumulative Months of Follow-up	116,339

SynchroMed II 20mL Event Summary Table	
Pump Event	**Total**
Pump motor stall	39
Pump reservoir volume discrepancy	9
Battery high resistance	6
Corrosion and/or gear wear	4
Device malfunction [a]	4
Pump unable to enter/withdraw from catheter access port	4
Confirmed overinfusion [b*]	1
Laboratory overinfusion finding [b**]	2
Physician reported overinfusion [b***]	1
Device alarm issue	3
Reduced battery performance	3
Medical device complication [c]	3
Motor feedthrough anomaly	2
Alarm and/or resonator anomaly	1
Catheter kink [d]	1
Catheter occlusion [e]	1
Catheter related complication [f]	1
Deformed pump tube	1
Hybrid Anomaly	1
Manufacturing Issue Propellant Anomaly	1
Prescription table Corruption	1
Premature battery depletion	1
Pump connector break/cut	1
Pump not infusing	1
Reservoir access issues due to residue	1
Total Pump Events	**93**

[a] Includes 2 events for pump malfunction, 1 suspected pump and/or catheter malfunction, and 1 event for suspected rotor problem.

[b] *Patient had clinical signs and symptoms consistent with pump overinfusion, pump returned, and positive laboratory test (n=1).
**Includes pumps where a physician reported a device related event not consistent with overinfusion (n=2), pump returned, and

positive laboratory test.
***Patient had clinical signs and symptoms, but pump not returned and analyzed (n=1).
[c] Includes 1 event for pump beeped, 1 event for pump in safe state, and 1 event for telemetry was stopped secondary to error code.
[d] Includes 1 event for catheter kink that was attributed to the pump and catheter.
[e] Includes 1 event for catheter occlusion that was attributed to the pump and catheter.
[f] Includes 1 event for catheter related complication that was attributed to the pump and catheter.

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.5%** (99.1%, 99.7%)	2,372
2 yrs	**99.0%** (98.5%, 99.3%)	1,975
3 yrs	**98.3%** (97.6%, 98.7%)	1,519
4 yrs	**97.5%** (96.6%, 98.1%)	1,135
5 yrs	**96.1%** (95.0%, 97.0%)	812
6 yrs	**93.1%** (91.3%, 94.5%)	542
at 81 mo	**89.3%** (85.8%, 92.0%)	69

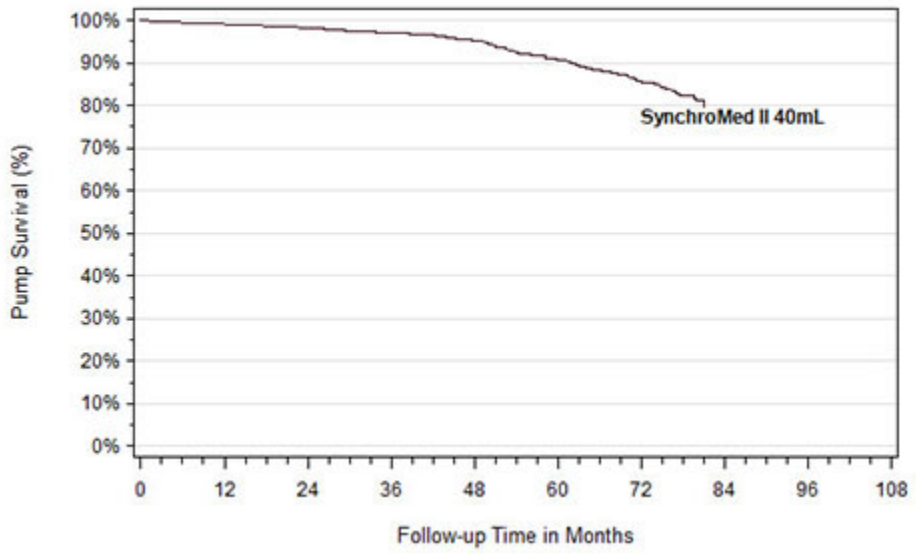
Model 8637-20 SynchroMed II 20mL: Specifications

Expected battery life[a]	6-7 years
Thickness	0.77 in (19.5 mm)
Diameter	3.4 in (87.5 mm)
Capacity	20.0 mL
Minimal Programmable Flow Rate[b]	0.048 mL/day
Maximum Programmable Flow Rate[b]	24 mL/day
Minimum Rate Infusion Mode[c]	0.006 mL/day

[a] Dependent on flow rate
[b] Actual limits depend on pump calibration constant and selected infusion mode.
[c] Nontherapeutic (if therapy is to be temporarily discontinued)

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	5,174
Pumps Currently Active in Study	1,415
Device Events	200
Cumulative Months of Follow-up	135,114

SynchroMed II 40mL Event Summary Table	
Pump Event	**Total**
Pump motor stall	111
Pump reservoir volume discrepancy	21
Confirmed overinfusion [a*]	4
Laboratory overinfusion finding [a**]	11
Physician reported overinfusion [a***]	1
Pump underinfusion	8
Reduced battery performance	7

Corrosion and/or gear wear	6
Device malfunction [b]	6
Deformed pump tube	5
Pump unable to enter/withdraw from catheter access port	3
Pump not infusing	2
Reservoir access issues due to residue	2
Battery high resistance	2
Catheter break/cut [c]	1
Catheter occlusion [d]	1
Catheter related complication [e]	1
Coil shorted to case	1
Concave pump shield	1
Device alarm issue	1
Device leakage	1
Hole in pump tube	1
Leaky capacitor	1
Medical device complication [f]	1
Pump connector break/cut	1
Total Pump Events	**200**

[a] *Patient had clinical signs and symptoms consistent with pump overinfusion, pump returned, and positive laboratory test (n=4). **Includes pumps where a physician reported a device related event not consistent with overinfusion (n=11), pump returned, and positive laboratory test. ***Patient had clinical signs and symptoms, but pump not returned and analyzed (n=1).
[b] Includes 2 events for pump reset occurred; pump in safe state, 1 event for pump malfunction, 1 event for possible pump malfunction, 1 pump in stopped mode, and 1 event for patient felt pump not working.
[c] Includes 1 event for catheter break/cut attributed to pump and catheter.
[d] Includes 1 event for catheter occlusion attributed to pump and catheter.
[e] Includes 1 event for suspected catheter malfunction attributed to pump and catheter.
[f] Includes 1 possible corrosion of pump due to concentration of drug.

Time Interval	Survival (95% Confidence Intervals)	Sample Size
1 yr	**99.1%** (98.8%, 99.4%)	3,071
2 yrs	**98.3%** (97.8%, 98.7%)	2,313
3 yrs	**97.1%** (96.4%, 97.7%)	1,631
4 yrs	**95.1%** (94.1%, 96.0%)	1,122
5 yrs	**90.7%** (89.0%, 92.2%)	726
6 yrs	**85.5%** (83.0%, 87.6%)	471

at 81 mo	**79.8%** (75.4%, 83.5%)	61

Model 8637-40 SynchroMed II 40mL: Specifications

Expected battery life[a]	6-7 years
Thickness	1.0 in (26 mm)
Diameter	3.4 in (87.5 mm)
Capacity	40.0 mL
Minimal Programmable Flow Rate[b]	0.048 mL/day
Maximum Programmable Flow Rate[b]	24 mL/day
Minimum Rate Infusion Mode[c]	0.006 mL/day

[a] Dependent on flow rate
[b] Actual limits depend on pump calibration constant and selected infusion mode.
[c] Nontherapeutic (if therapy is to be temporarily discontinued)

Pump Survival Summary

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	1,148	0	34	31,275
SynchroMed II (20 mL)	SynchroMed II	Sep 2003	3,350	1,149	93	116,339
SynchroMed II (40 mL)	SynchroMed II	Sep 2003	5,174	1,415	200	135,114

[a] There were a total of 416 pump-related events reported to the registry, but only 327 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 (i.e., SynchroMed EL 10 mL [n=1]) or were subsequent events (i.e. additional events that occurred after the initial device-related event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Intervals)								
Model Name	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**7 yrs**	**8 yrs**
SynchroMed EL (18 mL)	**98.8%** (95.4%, 99.7%)	**97.4%** (94.2%, 98.9%)	**95.8%** (92.6%. 97.6%)	**95.0%** (91.8%. 96.9%)	**93.7%** (90.6%. 95.8%)	**92.4%** (89.0%. 94.7%)	**91.4%** (87.7%, 94.0%)	**90.4%** (86.2%, 93.4%)
SynchroMed II (20 mL)	**99.5%** (99.1%, 99.7%)	**99.0%** (98.5%. 99.3%)	**98.3%** (97.6%. 98.7%)	**97.5%** (96.6%. 98.1%)	**96.1%** (95.0%. 97.0%)	**93.1%** (91.3%. 94.5%)	-	-
SynchroMed II (40 mL)	**99.1%** (98.8%, 99.4%)	**98.3%** (97.8%. 98.7%)	**97.1%** (96.4%. 97.7%)	**95.1%** (94.1%. 96.0%)	**90.7%** (89.0%. 92.2%)	**85.5%** (83.0%. 87.6%)	-	-

Product Performance 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 in the United States. Preservative-free morphine hydrochloride is also considered on-label outside of the United States.

Patient status updates were obtained every 6 months, until discontinuation of therapy, or until the patient was lost to follow-up. Medications within the pump were recorded at each 6-month follow-up. This provided a snapshot 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 study follow-up visits were not recorded.

Pump Groups – On/Off Label Categorization

There were 7,122 patients enrolled in the registry that had SynchroMed II pumps implanted. Of these patients, 56.1% were female and 44.0% were male with a mean age of 53.9 (SD = 17.6). Of the 8,524 SynchroMed II pumps enrolled through October 31, 2017, at least one drug record was available for 8,199 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 /hydrochloride 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, Lioresal® or Gablofen®, 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:

- All pumps: On-Label vs. Off-Label Drugs (including all indications)
- Pain: On-Label vs. Off-Label Drugs (including all pain)
- 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.

Results

Total Study Population: A total of 2,514 SynchroMed II pumps were classified as On-Label where there was no evidence of Off-Label drug/admixture exposure. A total of 5,685 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=2,514**	**Off-Label N=5,685**
Non-Malignant Pain	802 (16.5%)	4,047 (83.5%)
Malignant Pain	41 (3.1%)	1,299 (96.9%)
Spasticity	1,671 (89.0%)	206 (11.0%)
Multiple/Unknown	NA	133 (100%)

[a] Refer to product labeling for approved indications.

There were a total of 293 reported SynchroMed II pump product performance events (also referred to as failures in this section) during the study observation period. In addition to the 293 pump failures, there were 15 SynchroMed II pumps explanted due to 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 not considered failures, because they represented normal implant duration (ranging from 5.6-6.8 years) with no associated physician or patient complaint.

Two of the 293 pump failure events occurred in pumps with no drug records available. Of the remaining 291 SynchroMed II pump failures, 150 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 inconsistent pump reservoir volume, overinfusion, corrosion and/or gear wear, device malfunction, reduced battery performance, pump under infusion, and other non-conforming reasons. Overall, the rate of pump failures in this cohort was 3.5% (291/8,199) with a median follow-up of 24.8 months.

For the 150 pump failures due to motor stall, 67 of the events were associated with the patient presenting clinical signs and symptoms of possible drug withdrawal or increasing pain or spasticity. The other 83 events 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.

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

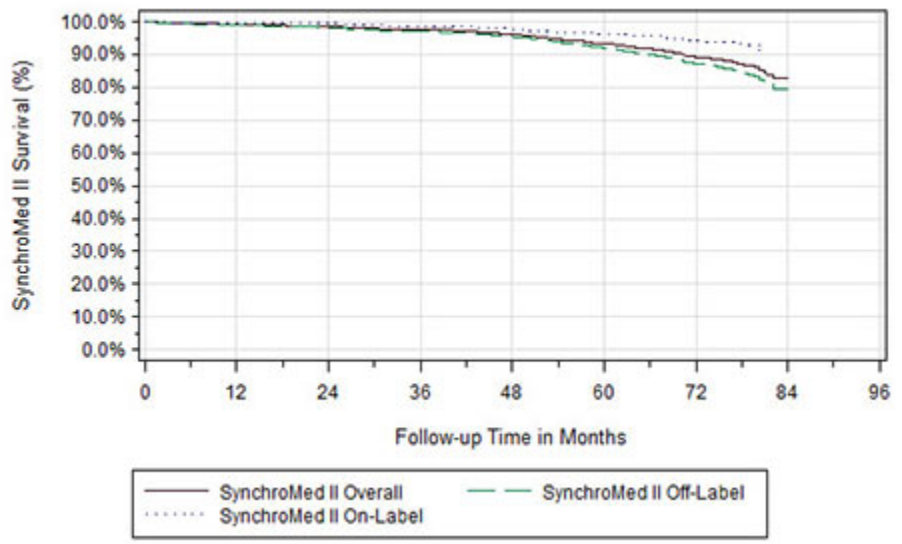
Total study population: Survival from product performance-related pump events for all indications, by On/Off-Label drug exposure for SynchroMed II pumps									
Category	**Time Interval**	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**at 81 months**	**7 yrs**
All Pumps	Survival	99.3%	98.6%	97.6%	96.2%	93.3%	89.2%	84.5%	82.7%
	Number of Pumps	5,355	4,233	3,119	2,231	1,525	1,007	129	34
On-Label Drugs	Survival	99.7%	99.4%	98.7%	97.8%	96.3%	94.1%	91.2%	[a]
	Number of Pumps	1,659	1,314	938	662	466	324	35	[a]
Off-Label Drugs	Survival	99.1%	98.2%	97.1%	95.5%	92.1%	87.1%	81.7%	79.3%
	Number of Pumps	3,696	2,919	2,181	1,569	1,059	683	94	21

[a] Sample size is less than 20 active devices at 7 years for On-Label pump group.

The cumulative survival curve of the SynchroMed II pump for the **entire population**, and stratified by the 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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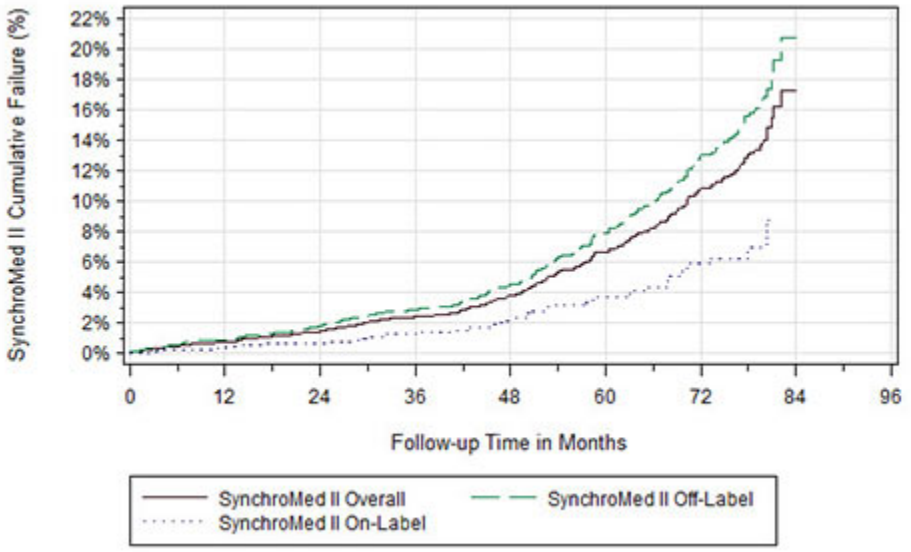
The table and figure below present the complementary cumulative failure rate estimates (Failure=100% - Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The table and graph depict the cumulative failure rate over time and estimate the risk of pump failure for specific implant durations (i.e. time period from pump implant). Overall, the pumps with known Off-Label drug exposure had a 2.3 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.0001).

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**	**at 81 months**	**7 yrs**
All Pumps	Failure	0.7%	1.4%	2.4%	3.8%	6.7%	10.8%	15.5%	17.3%
	Number of Pumps	5,355	4,233	3,119	2,231	1,525	1,007	129	34
On-Label Drugs	Failure	0.3%	0.6%	1.3%	2.2%	3.7%	5.9%	8.8%	[a]
	Number of Pumps	1,659	1,314	938	662	466	324	35	[a]
Off-Label Drugs	Failure	0.9%	1.8%	2.9%	4.5%	7.9%	12.9%	18.3%	20.7%
	Number of Pumps	3,696	2,919	2,181	1,569	1,059	683	94	21

[a] Sample size is less than 20 active devices at 7 years 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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Pain Study Population: A total of 843 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 5,346 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 the On-Label or Off-Label pump group.

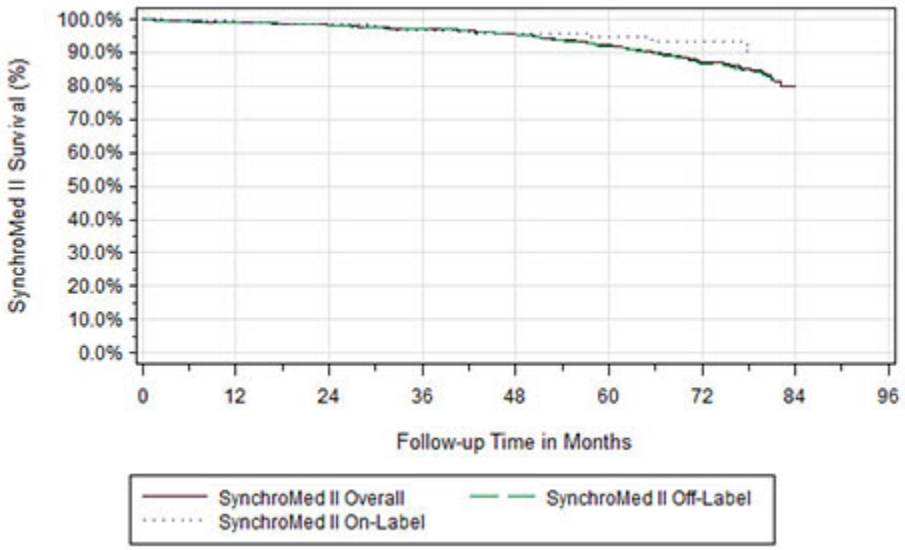
Pain study population: Survival from product performance-related pump events for Pain indications, by On/Off-Label drug exposure for SynchroMed II pumps									
Category[a]	**Time Interval**	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**at 81 months**	**7 yrs**
Pain Overall	Survival	99.2%	98.4%	97.2%	95.5%	92.2%	87.2%	82.3%	79.9%
	Number of pumps	3,972	3,082	2,257	1,594	1,066	686	91	21
Pain On-Label Drugs	Survival	99.5%	98.6%	96.8%	95.7%	94.6%	93.3%	[b]	[b]
	Number of pumps	508	347	217	130	82	51	[b]	[b]
Pain Off-Label Drugs	Survival	99.1%	98.3%	97.2%	95.5%	92.0%	86.8%	81.7%	[b]
	Number of pumps	3,464	2,735	2,040	1,464	984	635	84	[b]

[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, and for both On and Off-Label pump groups at 7 years.

The cumulative survival of the SynchroMed II pump for the **Pain** indications, and stratified by the 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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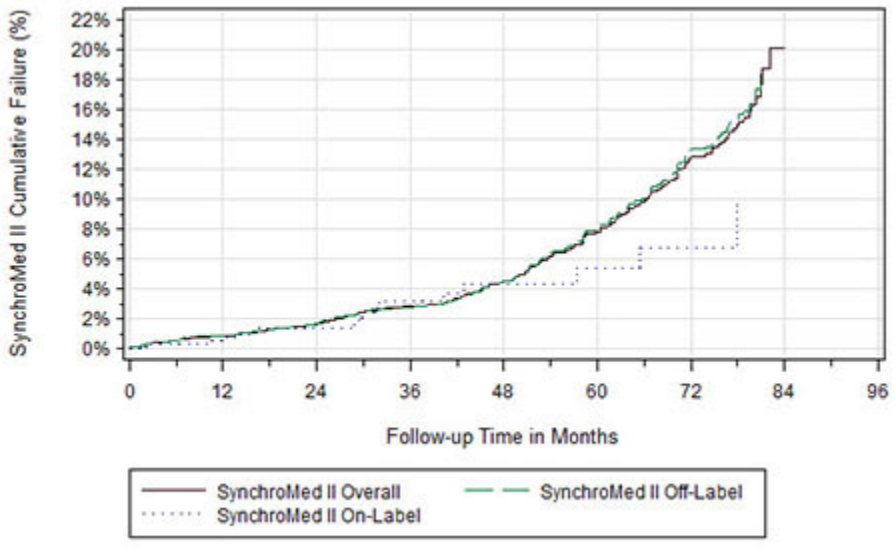
The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. The difference in survival between the On-Label and Off-Label groups for the pumps in the pain population was similar to what was observed for the entire population (all therapies). There was no statistically significant difference in the risk of failure between the On-Label and Off-Label pumps implanted for the treatment of pain (p= 0.17); however, the limited number of On-Label pumps may be insufficient to detect a difference.

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**	**at 81 months**	**7 yrs**
Pain Overall	Failure	0.8%	1.6%	2.8%	4.5%	7.8%	12.8%	17.7%	20.1%
	Number of pumps	3,972	3,082	2,257	1,594	1,066	686	91	21
Pain On-Label Drugs	Failure	0.5%	1.4%	3.2%	4.3%	5.4%	6.7%	[b]	[b]
	Number of pumps	508	347	217	130	82	51	[b]	[b]
Pain Off-Label Drugs	Failure	0.9%	1.7%	2.8%	4.5%	8.0%	13.2%	18.3%	[b]
	Number of pumps	3,464	2,735	2,040	1,464	984	635	84	[b]

[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, and for both On and Off-Label pump groups at 7 years.

SynchroMed II cumulative failure (Pain)

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



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Spasticity Study Population: A total of 1,671 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 206 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 the On-Label or Off-Label pump group.

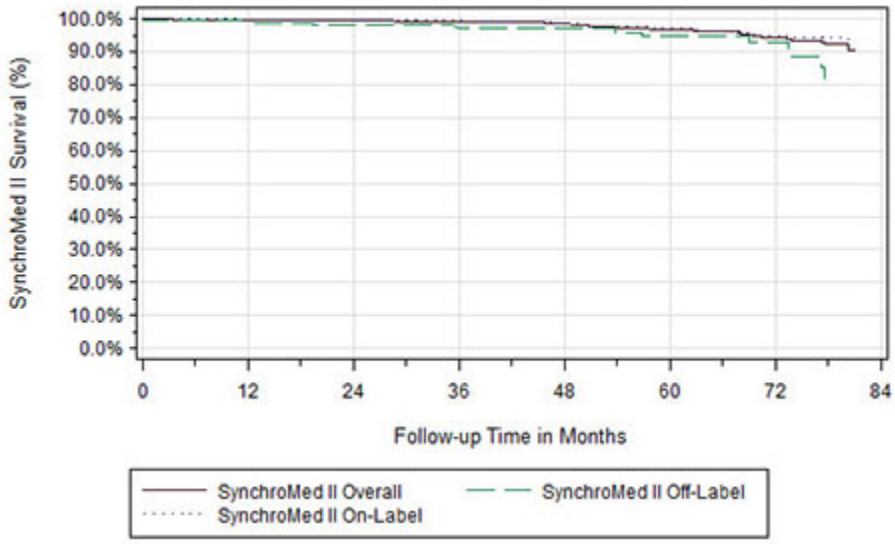
Spasticity study population: Survival from product performance-related pump events for Spasticity indication, by On/Off-Label drug exposure for SynchroMed II pumps									
Category [a]	**Time Interval**	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**at 78 months**	**at 81 months**
Spasticity Overall	Survival	99.7%	99.5%	99.2%	98.4%	96.6%	94.4%	92.2%	90.4%
	Number of pumps	1,309	1,105	829	620	450	320	118	38
Spasticity On-Label Drugs	Survival	99.8%	99.7%	99.4%	98.6%	97.0%	94.6%	94.2%	91.9%
	Number of pumps	1,151	967	721	532	384	273	98	28
Spasticity Off-Label Drugs	Survival	99.4%	98.1%	97.2%	97.2%	94.6%	92.9%	81.7%	[b]
	Number of pumps	158	138	108	88	66	47	20	[b]

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

The cumulative survival curve of the SynchroMed II pump for the **Spasticity** indication, and stratified by the 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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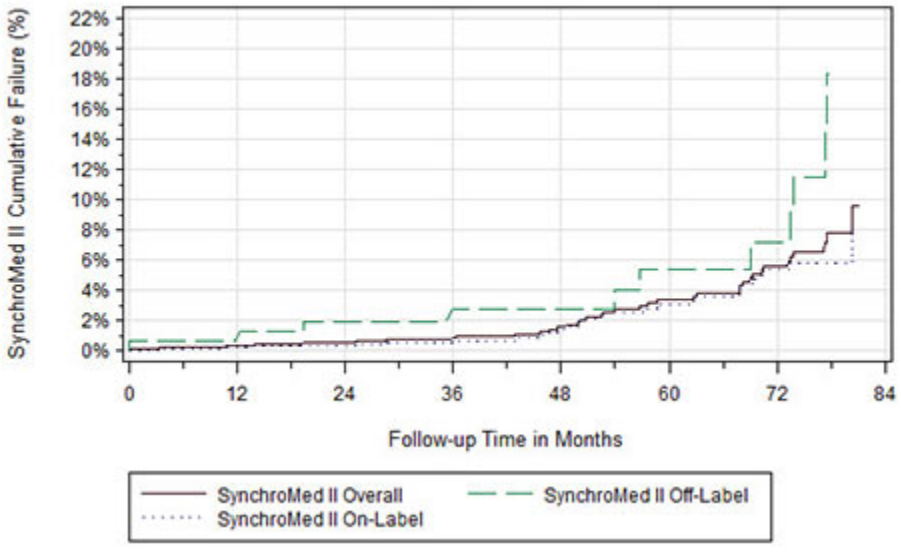
The table and figure below present the complementary cumulative failure rate estimates (Failure=100%-Survival), with the scale of the figure expanded to more clearly show the differences between the groups. Pumps with known Off-Label drug exposure had a 2.3 times greater risk of failure than pumps with no known Off-Label drug exposure (p=0.02).

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**	**at 78 months**	**at 81 months**
Spasticity Overall	Failure	0.3%	0.5%	0.8%	1.6%	3.4%	5.6%	7.8%	9.6%
	Number of pumps	1,309	1,105	829	620	450	320	118	38
Spasticity On-Label Drugs	Failure	0.2%	0.3%	0.6%	1.4%	3.0%	5.4%	5.8%	8.1%
	Number of pumps	1,151	967	721	532	384	273	98	28
Spasticity Off-Label Drugs	Failure	0.6%	1.9%	2.8%	2.8%	5.4%	7.1%	18.3%	[b]
	Number of pumps	158	138	108	88	66	47	20	[b]

[a] Refer to product labeling for approved Spasticity indication
[b] Sample size is less than 20 active devices at 81 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 2.3 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 48 months of follow-up. At 81 months of follow-up the survival from pump failure for On-Label pumps was 91.2% compared to a survival of 81.7% for Off-Label pumps.
- The data represent the reported registry experience with a median follow-up time of 24.8 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 was comprised of 66.5% of pumps with spasticity as the indication (1,671 vs. 843: Spasticity versus Pain pumps respectively). On the other hand, the Off-Label group consisted of 94% of pumps with pain indications (5,346 vs. 206: 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 period of time (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 7, 2003 to the report cut-off date of October 31, 2017, there were 8,992 catheters followed in the registry. The total number of catheters was not equal to the total number of pumps (n=9,713) 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 275,126 months (22,927 years). The table below provides the number and percentage of catheters by model.

Catheters by Model	
Model	**Number of Catheters (%)**
8709 (InDura)	2,859 (31.8%)
8709SC (InDura 1P)	1,063 (11.8%)
8780 (Ascenda)	914 (10.2%)
8711 (InDura)	655 (7.3%)
8781 (Ascenda)	741 (8.2%)

8731SC (w/ sutureless connector)	241 (2.7%)
Revised Not As Designed [a]	683 (7.6%)
Grafted Not As Designed [b]	464 (5.2%)
Other	271 (3.0%)
Revised As Designed [c]	222 (2.5%)
Ascenda RAD [d]	188 (2.1%)
Catheters No Longer Manufactured	
8731	507 (5.6%)
8703W	184 (2.0%)
Total	**8,992 (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 1,238 product performance events reported to the registry that were related to the catheter. This includes 1,228 events with a catheter etiology, and 10 events with both a catheter and other etiology (including device and non-device etiologies). The majority of the events were catheter occlusion (n=318), catheter dislodgement (n=302), break or cut in the catheter (n=209), or catheter kink (n=152). Of the 1,238 events, 1,071 were the initial product performance event that affected catheter survival estimates.

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 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:

- 1,071 had follow-up time cut-off due to product performance-related events.
- 5,530 were censored in the survival analysis for the following reasons: patient expired. catheter explanted/capped, site termination, patient discontinued, patient lost to follow-up, or therapy suspended.
- 2,391 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

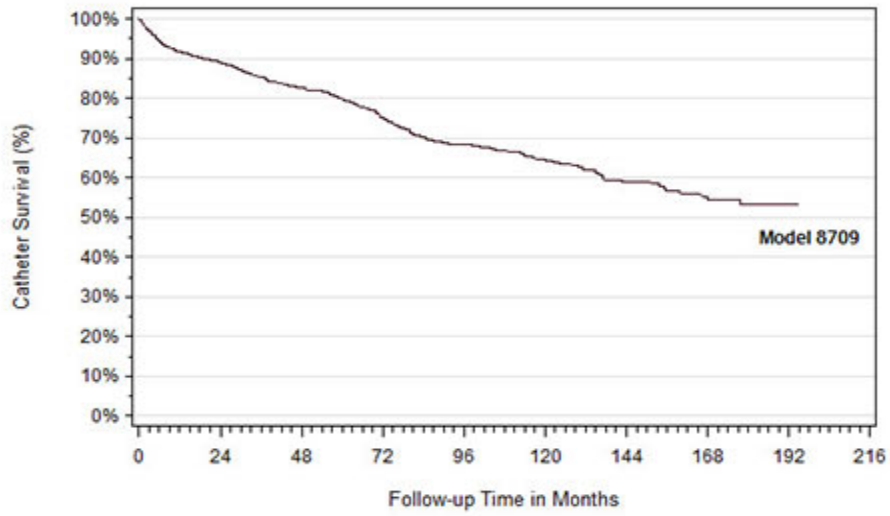
Catheter Survival

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.

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 catheter revision kits.

Model 8709: Survival from Catheter Events

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



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Catheter Characteristics	
Model Number	8709
FDA Approval Date	May 1998
Catheters Enrolled	2,859
Catheters Currently Active in Study	238
Device Events	338
Cumulative Months of Follow-up	87,425

Model 8709: Event Summary Table	
Catheter Event	**Total**
Catheter dislodgement	92
Catheter occlusion	77
Catheter break/cut	75
Catheter kink	26
Catheter disconnection at pump	20
Catheter leakage	13
Catheter related complication [a]	13
Pump connector break/cut	10
Medical device complication [b]	2
Pump unable to enter/withdraw from catheter access port	2
Pump underinfusion	1
Catheter disconnection between catheter segments	1
Deformed pump tube	1
Device infusion issue [c]	1
Hole in pump tube	1
Motor stall [d]	1
Pump reservoir volume discrepancy	1
Reservoir access issues due to residue	1
Total Catheter Events	**338**

[a] Includes 3 events reported as unable to aspirate catheter, 3 catheter malfunctions/dysfunction, 2 suspected catheter malfunction/issue, 1 coiled catheter, 1 aneurysm in catheter,1 possible catheter malfunction, 1 unable to aspirate CSF; high pressure upon attempting to inject, and 1 difficulty aspirating catheter.
[b] Includes 1 event for pump connector appeared somewhat worn, and 1 for possible catheter corrosion due to concentration of drug.
[c] Reported as slow dosing at refills.
[d] Event reported as motor stall related to catheter and pump.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.8%** (90.0%, 93.2%)	977
2 yrs	**89.0%** (87.0%, 90.7%)	926
3 yrs	**85.4%** (83.2%, 87.4%)	863
4 yrs	**82.6%** (80.1% 84.7%)	771

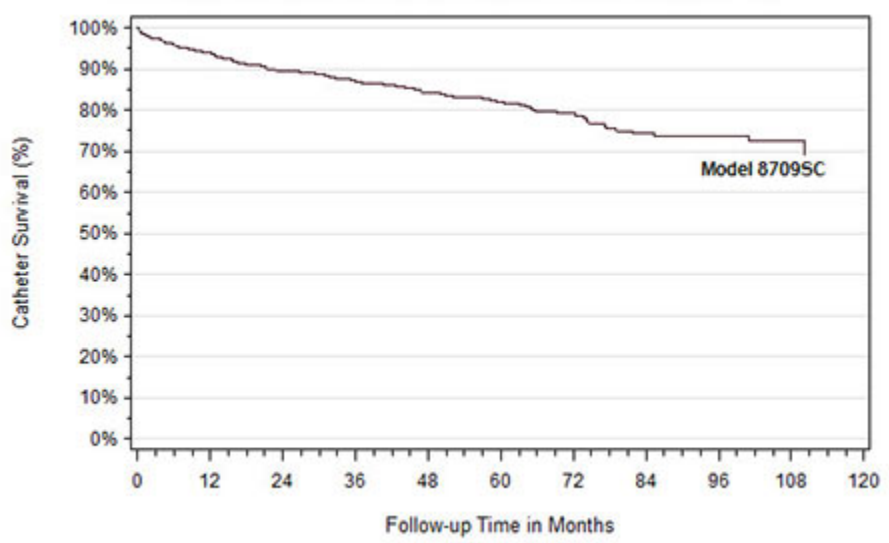
5 yrs	**79.9%** (77.3%, 82.2%)	659
6 yrs	**75.0%** (72.1%, 77.6%)	559
7 yrs	**70.4%** (67.3%, 73.3%)	483
8 yrs	**68.2%** (65.0%,71.2%)	390
9 yrs	**66.8%** (63.5%, 69.9%)	300
10 yrs	**64.2%** (60.7%, 67.5%)	244
11 yrs	**62.0%** (58.1%, 65.5%)	177
12 yrs	**59.0%** (54.8%, 63.0%)	118
13 yrs	**56.7%** (52.0%, 61.1%)	92
14 yrs	**54.5%** (49.3%, 59.3%)	69
15 yrs	**53.5%** (48.0%, 58.6%)	48
16 yrs	**53.5%** (48.0%, 58.6%)	28
at 195 mo	**53.5%** (48.0%,58.6%)	22

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	1,063
Catheters Currently Active in Study	268
Device Events	131
Cumulative Months of Follow-up	36,426

Model 8709SC: Event Summary Table	
Catheter Event	**Total**
Catheter dislodgement	34
Catheter break/cut	29
Catheter occlusion	28
Catheter related complication [a]	10
Catheter leakage	8
Catheter kink	6
Catheter disconnection at pump	4
Pump unable to enter/withdraw from catheter access port	3
Catheter damage	2
Medical device complication [b]	2

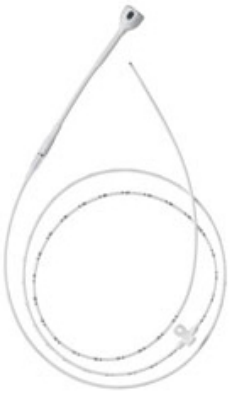
Catheter disconnection between catheter segments	1
Device connection issue	1
Product sedimentation present	1
Pump inversion [c]	1
Pump underinfusion	1
Total Catheter Events	**131**

[a] Includes 3 events reported as catheter malfunction, 1 suspected catheter malfunction, 1 coiled catheter, 1 catheter occlusion, 1 catheter unable to aspirate, 1 catheter wrapped around pump, 1 sluggish flow of CSF, and 1 slight loop in catheter.
[b] Includes 1 event reported as sutureless connector failure and 1 worn proximal connector.
[c] Includes 1 event reported as catheter failure to deliver medication due to pump inversion reported as related to the catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**93.9%** (92.0%, 95.4%)	663
2 yrs	**89.5%** (87.0%, 91.5%)	515
3 yrs	**87.0%** (84.2%, 89.3%)	433
4 yrs	**84.1%** (81.0%, 86.8%)	356
5 yrs	**82.0%** (78.5%, 84.9%)	264
6 yrs	**79.4%** (75.6%, 82.8%)	169
7 yrs	**74.4%** (69.5%, 78.6%)	125
8 yrs	**73.8%** (68.8%, 78.1%)	68
9 yrs	**72.4%** (66.6%, 77.3%)	31
at 111 mo	**69.3%** (60.7%, 76.3%)	22

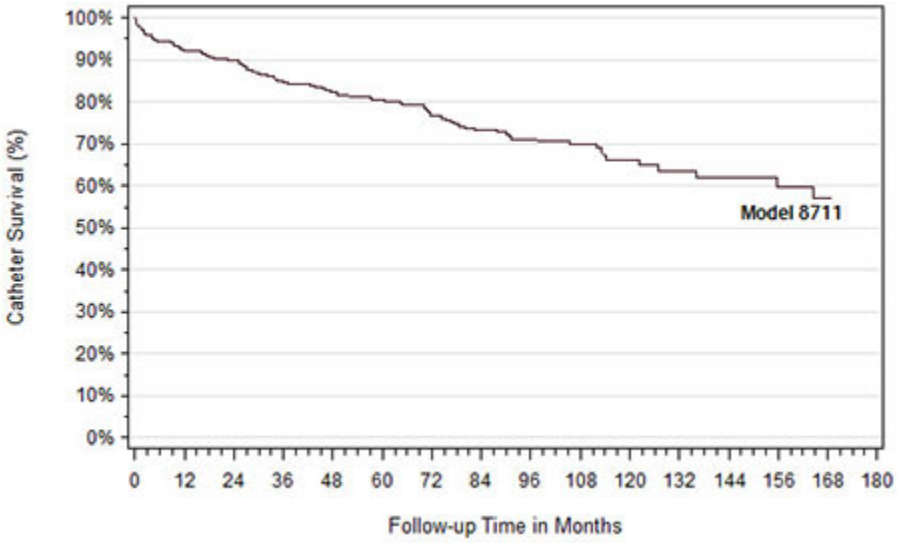
Model 8709SC: Specifications

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	655
Catheters Currently Active in Study	136
Device Events	93
Cumulative Months of Follow-up	26,531

Model 8711: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	27
Catheter break/cut	19
Catheter dislodgment	14
Catheter related complication [a]	14
Catheter kink	7
Pump unable to enter/withdraw from catheter access port	3
Catheter leakage	3
Catheter disconnection at pump	2
Catheter access port issue	1
Catheter disconnection between catheter segments	1
Medical device complication [b]	1
Pump connector break/cut	1
Total Catheter Events	**93**

[a] Includes 3 events reported as catheter malfunction, 3 unable to aspirate catheter, 2 cannot aspirate pump secondary to malfunction catheter, 1 non-functioning spinal catheters, 1 no free flow of CSF from spinal segment of catheter, 1 catheter malfunction at distal section, 1 non-functioning distal catheter, 1 suspected catheter malfunction, and 1 difficulty aspirating catheter.
[b] Includes 1 event reported as worn pump connector and pump side catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.2%** (88.6%, 94.7%)	310
2 yrs	**89.8%** (85.8%, 92.7%)	288
3 yrs	**84.7%** (80.2%, 88.2%)	259
4 yrs	**82.3%** (77.6%, 86.1%)	237
5 yrs	**80.6%** (75.7%, 84.6%)	224
6 yrs	**76.8%** (71.6%, 81.3%)	173
7 yrs	**73.3%** (67.6%, 78.1%)	158

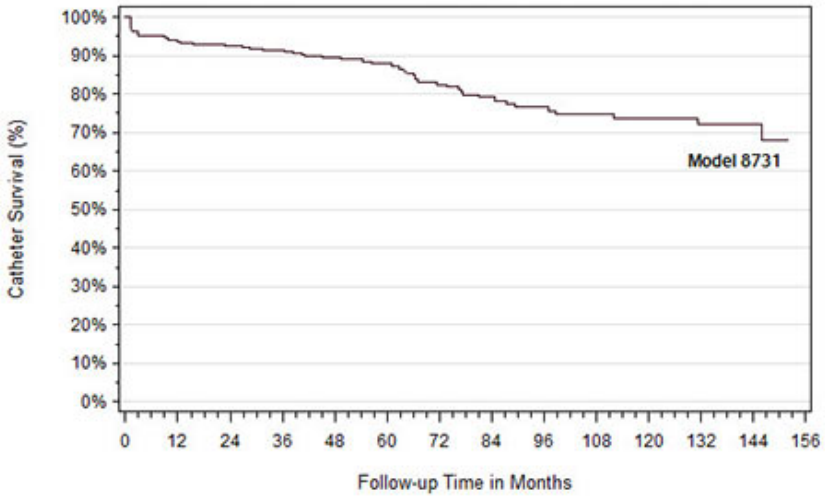
8 yrs	**71.2%** (65.3%, 76.2%)	123
9 yrs	**69.9%** (63.9%, 75.2%)	89
10 yrs	**66.3%** (59.5%, 72.2%)	54
11 yrs	**63.7%** (56.1%, 70.3%)	38
12 yrs	**61.9%** (53.7%, 69.1%)	33
13 yrs	**59.8%** (50.9%, 67.7%)	29
14 yrs	**57.2%** (47.1%, 66.0%)	21
at 171 mo	**57.2%** (47.1%, 66.0%)	20

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	507
Catheters Currently Active in Study	65
Device Events	53
Cumulative Months of Follow-up	21,422

Model 8731: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	21
Catheter dislodgement	19
Catheter related complication [a]	4
Catheter kink	3
Catheter break/cut	2
Catheter disconnection at pump	2
Medical device complication [b]	1
Pump connector break/cut	1
Total Catheter Events	**53**

[a] Includes 1 event reported as patency issue with catheter, 1 coiled spinal catheter, 1 suspected catheter malfunction, and 1 catheter malfunction.
[b] Includes 1 event reported as worn catheter connector.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**93.6%** (88.9%, 96.4%)	263
2 yrs	**92.3%** (87.6%, 95.3%)	304
3 yrs	**91.4%** (86.6%, 94.5%)	253
4 yrs	**89.4%** (84.5%, 92.9%)	196
5 yrs	**87.8%** (82.6%, 91.6%)	148
6 yrs	**82.5%** (76.3%, 87.2%)	134
7 yrs	**79.1%** (72.5%, 84.3%)	102
8 yrs	**76.6%** (69.5%, 82.3%)	79
9 yrs	**74.6%** (67.1%, 80.7%)	66
10 yrs	**73.5%** (65.7%, 79.8%)	62
11 yrs	**72.2%** (64.0%, 78.8%)	53
12 yrs	**72.2%** (64.0%, 78.8%)	39
at 153 mo	**68.2%** (58.5%, 76.1%)	23

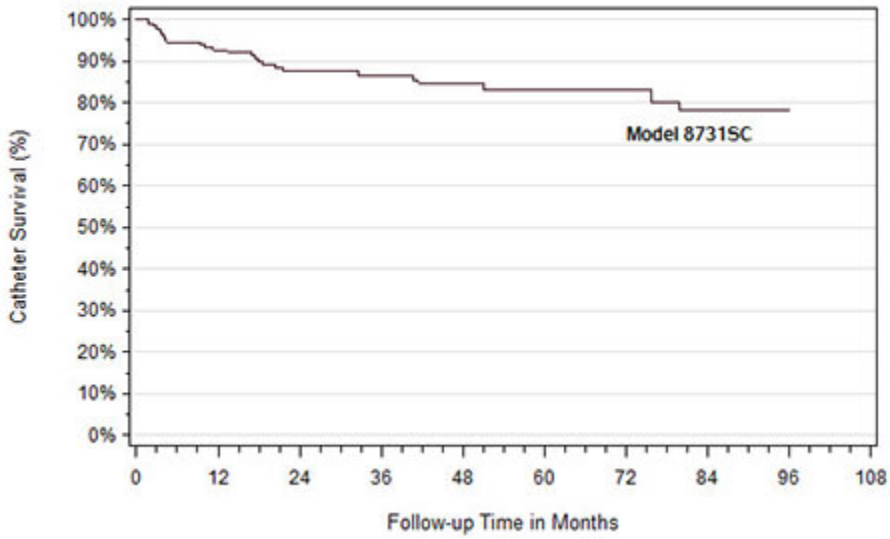
Model 8731: Specifications

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.



View Larger Image

Catheter Characteristics	
Model Number	8731SC
FDA Approval Date	Mar 2006
Catheters Enrolled	241
Catheters Currently Active in Study	101
Device Events	26
Cumulative Months of Follow-up	7,576

Model 8731SC: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	9
Catheter dislodgement	7
Catheter kink	3
Catheter related complication [a]	3
Pump unable to enter/withdraw from catheter access port	2
Catheter disconnection at pump	1
Catheter leakage	1
Total Catheter Events	**26**

[a] Includes 2 events reported as suspected catheter malfunction, and 1 event as catheter unable to aspirate.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.6%** (87.6%. 95.7%)	139
2 yrs	**87.5%** (81.2%, 91.8%)	105
3 yrs	**86.6%** (80.0%, 91.1%)	87
4 yrs	**84.4%** (77.2%, 89.5%)	67
5 yrs	**83.1%** (75.4%, 88.6%)	45
6 yrs	**83.1%** (75.4%, 88.6%)	30
7 yrs	**78.1%** (67.1%, 85.7%)	34
8 yrs	**78.1%** (67.1%, 85.7%)	21

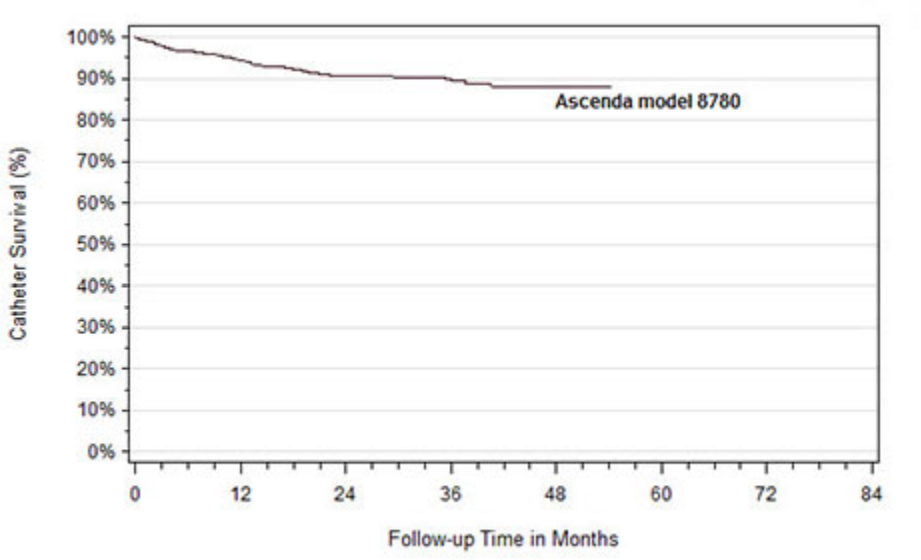
Model 8731SC: Specifications

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	914
Catheters Currently Active in Study	595
Device Events	62
Cumulative Months of Follow-up	17,477

Model 8780: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	26
Catheter dislodgement	13
Catheter kink	10
Catheter break/cut	6
Catheter disconnection at pump	2
Catheter leakage	2
Catheter damage	1
Catheter related complication [a]	1
Device migration	1
Total Catheter Events	**62**

[a] Includes 1 event reported as unable to aspirate catheter.

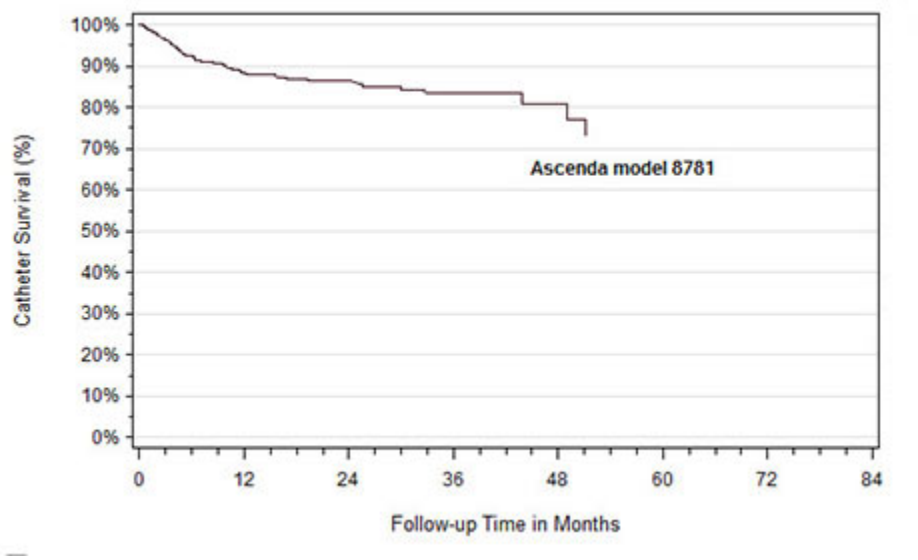
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.4%** (92.3%, 95.9%)	526
2 yrs	**90.7%** (88.0%, 92.8%)	317
3 yrs	**89.9%** (86.9%, 92.2%)	180
4 yrs	**88.2%** (84.5%, 91.0%)	63
at 54 mo	**88.2%** (84.5%, 91.0%)	20

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

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



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Catheter Characteristics	
Model Number	8781
FDA Approval Date	Sept 2012
Catheters Enrolled	741
Catheters Currently Active in Study	365
Device Events	75
Cumulative Months of Follow-up	10,303

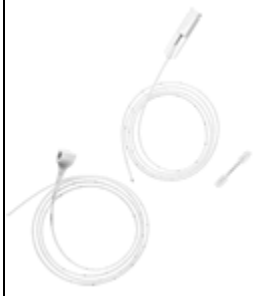
Model 8781: Event Summary Table	
Catheter Event	**Total**
Catheter kink	28
Catheter dislodgement	22
Catheter occlusion	13
Catheter leakage	3
Catheter related complication [a]	3
Catheter disconnection at pump	2
Catheter break/cut	2
Pump reservoir volume discrepancy	1
Pump underinfusion	1
Total Catheter Events	**75**

[a] Includes 1 event reported as possible catheter malfunction, 1 event as suspected catheter issue, and 1 event as poor dye dispersion.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**88.5%** (85.2%, 91.0%)	307
2 yrs	**86.5%** (82.9%, 89.4%)	187
3 yrs	**83.4%** (78.8%, 87.1%)	72
4 yrs	**80.8%** (73.3%, 86.4%)	23
at 51 mo	**77.2%** (66.3%, 85.0%)	20

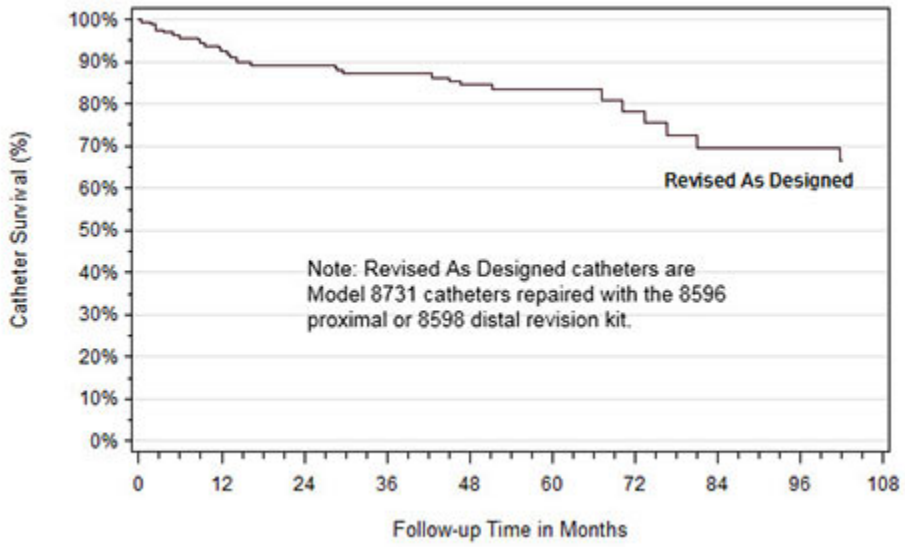
Model 8781: Specifications

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 Catheters: 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 Name	Revised As Designed
FDA Approval Date	Oct 2002
Catheters Enrolled	222
Catheters Currently Active in Study	71
Device Events	33
Cumulative Months of Follow-up	8,596

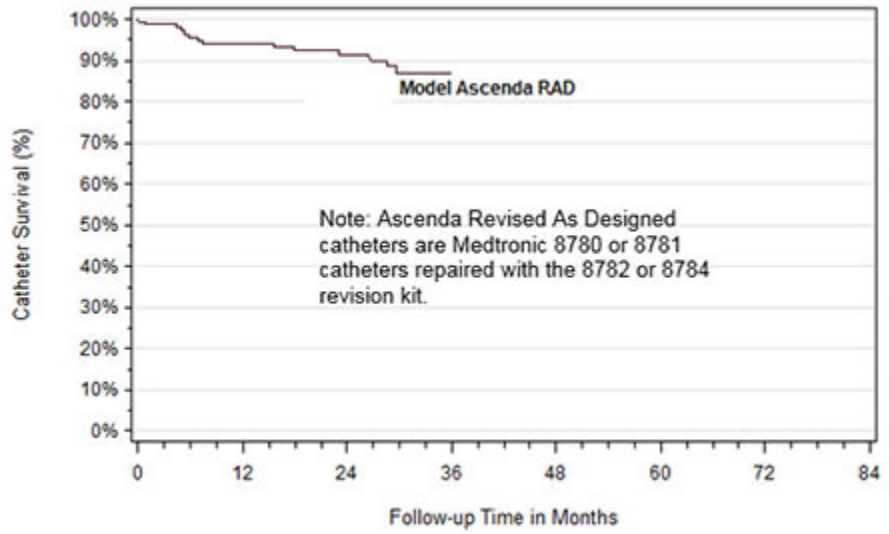
Revised As Designed Catheters: Event Summary Table [a]	
Catheter Event	**Total**
Catheter occlusion	14
Catheter dislodgement	8
Catheter kink	4
Catheter related complication [b]	3
Catheter break/cut	2
Device connection issue	1
Pump unable to enter/withdraw from catheter access port	1
Total Catheter Events	**33**

[a] Revised As Designed catheters are Model 8731 catheters repaired with the 8596 proximal or 8598 distal revision kit.
[b] Includes 1 event reported as catheter malfunction, 1 possible catheter malfunction, and 1 inability to aspirate catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.4%** (87.1%, 95.6%)	148
2 yrs	**89.3%** (83.3%, 93.2%)	127
3 yrs	**87.1%** (80.7%, 91.5%)	114
4 yrs	**84.5%** (77.6%, 89.5%)	86
5 yrs	**83.4%** (76.0%, 88.6%)	42
6 yrs	**78.3%** (67.6%, 85.8%)	27
7 yrs	**69.6%** (55.6%, 80.0%)	22
8 yrs	**69.6%** (55.6%, 80.0%)	21
at 102 mo	**66.4%** (51.4%, 77.7%)	20

Ascenda Revised As Designed Catheters: Survival from Catheter Events

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



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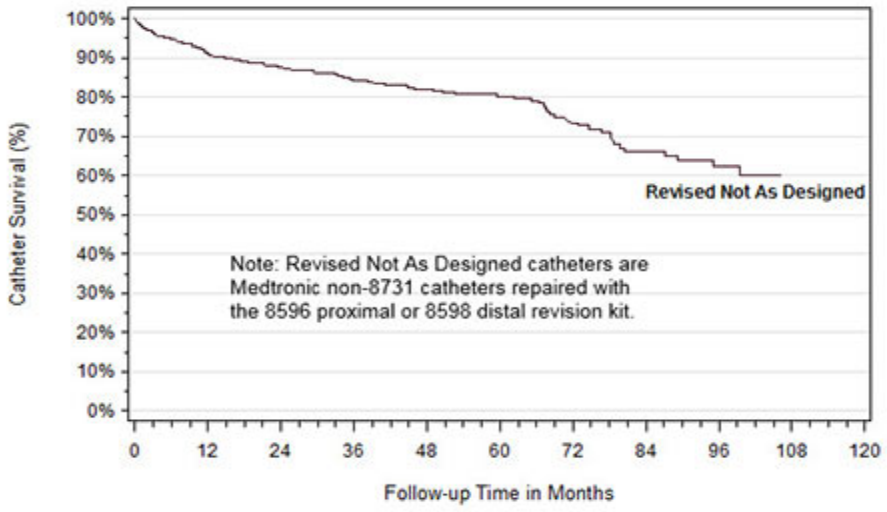
Catheter Characteristics	
Model Name	Ascenda Revised As Designed
FDA Approval Date	Sept 2012
Catheters Enrolled	188
Catheters Currently Active in Study	128
Device Events	15
Cumulative Months of Follow-up	3,591

Ascenda Revised As Designed Catheters: Event Summary Table	
Catheter Event	**Total**
Catheter occlusion	4
Catheter dislodgement	4
Catheter kink	2
Catheter break/cut	1
Catheter disconnection at pump	1
Catheter leakage	1
Pump connector break/cut	1
Pump reservoir volume discrepancy	1
Total Catheter Events	**15**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.2%** (89.0%, 96.9%)	119
2 yrs	**91.3%** (85.0%, 95.0%)	81
3 yrs	**87.0%** (78.6%, 92.3%)	26

Revised Not As Designed Catheters: Survival from Catheter Events

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



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Catheter Characteristics	
Model Name	Revised Not As Designed
FDA Approval Date	NA
Catheters Enrolled	683
Catheters Currently Active in Study	291
Device Events	114
Cumulative Months of Follow-up	24,617

Revised Not As Designed Catheters: Event Summary Table [a]	
Catheter Event	**Total**
Catheter occlusion	35
Catheter dislodgement	23
Catheter break/cut	16
Catheter kink	14
Catheter related complication [b]	5
Catheter leakage	5
Pump unable to enter/withdraw from catheter access port	5
Catheter disconnection at pump	4
Catheter access port issue	1
Connector block problem	1
Pump reservoir volume discrepancy	1

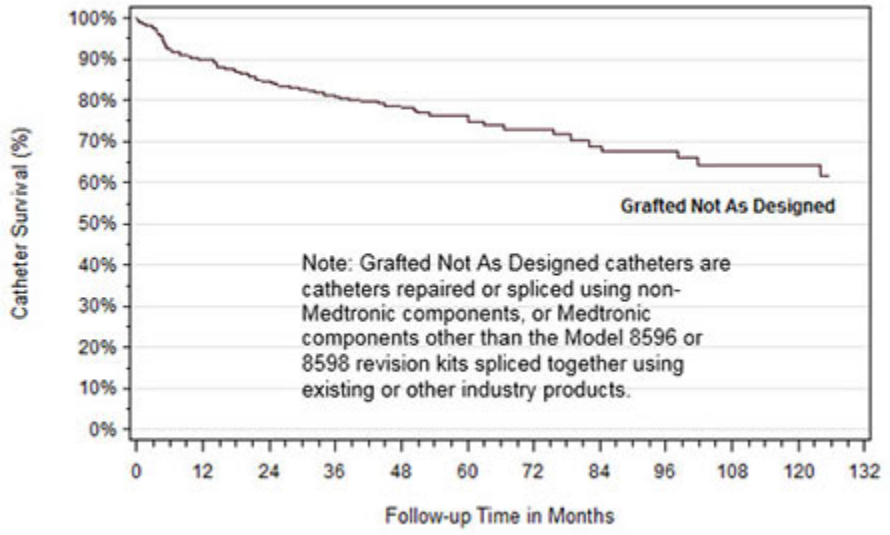
Catheter blockage	1
Catheter disconnection between catheter segments	1
Device misdeployment (location) [c]	1
Medical device complication [d]	1
Total Catheter Events	**114**

[a] Revised Not As Designed catheters are Medtronic non-8731 catheters repaired with the 8596 proximal or 8598 distal revision kit.
[b] Includes 2 events reported as catheter malfunction, 1 inability to aspirate catheter, 1 poor CSF flow, and 1 catheter wrapped in coils and knots.
[c] Includes 1 event on catheter previously placed at T12; should be at T8-9 for optimal coverage.
[d] Reported as worn catheter.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.2%** (88.4%, 93.3%)	470
2 yrs	**87.5%** (84.3%, 90.1%)	393
3 yrs	**84.2%** (80.6%, 87.2%)	304
4 yrs	**82.0%** (78.1%, 85.2%)	228
5 yrs	**80.2%** (76.0%, 83.8%)	152
6 yrs	**73.5%** (67.6%, 78.4%)	98
7 yrs	**66.2%** (59.2%, 72.4%)	68
8 yrs	**62.3%** (54.2%, 69.4%)	35
9 yrs	**60.2%** (51.4%, 68.0%)	20

Grafted Not As Designed Catheters: Survival from Catheter Events

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



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Catheter Characteristics	
Model Name	Grafted Not As Designed
FDA Approval Date	NA
Catheters Enrolled	464
Catheters Currently Active in Study	164
Device Events	83
Cumulative Months of Follow-up	16,851

Grafted Not As Designed Catheters: Event Summary Table [a]	
Catheter Event	**Total**
Catheter dislodgement	26
Catheter occlusion	22
Catheter break/cut	11
Catheter related complication [b]	6
Catheter leakage	5
Catheter kink	5
Pump unable to enter/withdraw from catheter access port	4
Catheter access port issue	1

Catheter disconnection at pump	1
Device breakage	1
Pump connector break/cut	1
Total Catheter Events	**83**

[a] 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.
[b] Includes 3 events reported as inability to aspirate catheter, 2 suspected catheter malfunction/issue, and 1 catheter malfunction.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**90.0%** (86.3%, 92.8%)	276
2 yrs	**84.5%** (80.0%, 88.0%)	229
3 yrs	**81.0%** (76.0%, 85.0%)	191
4 yrs	**78.1%** (72.8%, 82.5%)	146
5 yrs	**76.3%** (70.7%, 81.0%)	99
6 yrs	**73.0%** (66.7%, 78.4%)	62
7 yrs	**68.9%** (61.2%, 75.4%)	48
8 yrs	**67.5%** (59.4%, 74.4%)	43
9 yrs	**64.3%** (55.4%, 72.0%)	36
10 yrs	**64.3%** (55.4%, 72.0%)	27
at 126 mo	**61.7%** (51.5%, 70.4%)	22

[a] There were a total of 1238 catheter-related events reported to the registry, but only 1023 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=22), or in catheters for which no model information was provided (n=26). or were subsequent events (i.e. additional events that occurred after the initial device-related event) that did not affect the device survival estimates.
[b] Includes 8709 and 8709AA Models.

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	2,859	238	338	87,425
8709SC	8709	Mar 2006	1,063	268	131	36,426
8711	8711	Oct 1999	655	136	93	26,531
8731	8731	Oct 2002	507	65	53	21,422
8731SC	8731	Mar 2006	241	101	26	7,576
8780	Ascenda	Sept 2012	914	595	62	17,477
8781	Ascenda	Sept 2012	741	365	75	10,303
Revised As Designed	NA	Oct 2002	222	71	33	8,596
Ascenda Revised As Designed	NA	Sept 2012	188	128	15	3,591
Revised Not As Designed	NA	NA	683	291	114	24,617
Grafted Not As Designed	NA	NA	464	164	83	16,851

[a] There were a total of 1238 catheter-related events reported to the registry, but only 1023 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=22), or in catheters for which no model information was provided (n=26). or were subsequent events (i.e. additional events that occurred after the initial device-related event) 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	**91.8%** (90.0%, 93.2%)	**89.0%** (87.0%, 90.7%)	**85.4%** (83.2%, 87.4%)	**82.6%** (80.1%, 84.7%)	**79.9%** (77.3%, 82.2%)
8709SC	**93.9%** (92.0%, 95.4%)	**89.5%** (87.0%, 91.5%)	**87.0%** (84.2%, 89.3%)	**84.1%** (81.0%, 86.8%)	**82.0%** (78.5%, 84.9%)
8711	**92.2%** (88.6%, 94.7%)	**89.8%** (85.8%, 92.7%)	**84.7%** (80.2%, 88.2%)	**82.3%** (77.6%, 86.1%)	**80.6%** (75.7%, 84.6%)

8731	**93.6%** (88.9%, 96.4%)	**92.3%** (87.6%, 95.3%)	**91.4%** (86.6%, 94.5%)	**89.4%** (84.5%, 92.9%)	**87.8%** (82.6%, 91.6%)
8731SC	**92.6%** (87.6%. 95.7%)	**87.5%** (81.2%, 91.8%)	**86.6%** (80.0%, 91.1%)	**84.4%** (77.2%, 89.5%)	**83.1%** (75.4%, 88.6%)
8780	**94.4%** (92.3%, 95.9%)	**90.7%** (88.0%, 92.8%)	**89.9%** (86.9%, 92.2%)	**88.2%** (84.5%, 91.0%)	-
8781	**88.5%** (85.2%, 91.0%)	**86.5%** (82.9%, 89.4%)	**83.4%** (78.8%, 87.1%)	**80.8%** (73.3%, 86.4%)	-
Revised As Designed	**92.4%** (87.1%, 95.6%)	**89.3%** (83.3%, 93.2%)	**87.1%** (80.7%, 91.5%)	**84.5%** (77.6%, 89.5%)	**83.4%** (76.0%, 88.6%)
Ascenda Revised As Designed	**94.2%** (89.0%, 96.9%)	**91.3%** (85.0%, 95.0%)	**87.0%** (78.6%, 92.3%)	-	-
Revised Not As Designed	**91.2%** (88.4%, 93.3%)	**87.5%** (84.3%, 90.1%)	**84.2%** (80.6%, 87.2%)	**82.0%** (78.1%, 85.2%)	**80.2%** (76.0%, 83.8%)
Grafted Not As Designed	**90.0%** (86.3%, 92.8%)	**84.5%** (80.0%, 88.0%)	**81.0%** (76.0%, 85.0%)	**78.1%** (72.8%, 82.5%)	**76.3%** (70.7%, 81.0%)

Device Survival Probability (95% Confidence Intervals) – *Table 2 of 3*					
Model Number	**6 yrs**	**7 yrs**	**8 yrs**	**9 yrs**	**10 yrs**
8709	**75.0%** (72.1%, 77.6%)	**70.4%** (67.3%, 73.3%)	**68.2%** (65.0%, 71.2%)	**66.8%** (63.5%, 69.9%)	**64.2%** (60.7%, 67.5%)
8709SC	**79.4%** (75.6%, 82.8%)	**74.4%** (69.5%, 78.6%)	**73.8%** (68.8%, 78.1%)	**72.4%** (66.6%, 77.3%)	-
8711	**76.8%** (71.6%, 81.3%)	**73.3%** (67.6%, 78.1%)	**71.2%** (65.3%, 76.2%)	**69.9%** (63.9%, 75.2%)	**66.3%** (59.5%, 72.2%)
8731	**82.5%** (76.3%, 87.2%)	**79.1%** (72.5%, 84.3%)	**76.6%** (69.5%, 82.3%)	**74.6%** (67.1%, 80.7%)	**73.5%** (65.7%, 79.8%)
8731SC	**83.1%** (75.4%, 88.6%)	**78.1%** (67.1%, 85.7%)	**78.1%** (67.1%, 85.7%)	-	-
8780	-	-	-	-	-
8781	-	-	-	-	-

Revised As Designed	**78.3%** (67.6%, 85.8%)	**69.6%** (55.6%, 80.0%)	**69.6%** (55.6%, 80.0%)	-	-
Ascenda Revised As Designed	-	-	-	-	-
Revised Not As Designed	**73.5%** (67.6%, 78.4%)	**66.2%** (59.2%, 72.4%)	**62.3%** (54.2%, 69.4%)	**60.2%** (51.4%, 68.0%)	-
Grafted Not As Designed	**73.0%** (66.7%, 78.4%)	**68.9%** (61.2%, 75.4%)	**67.5%** (59.4%, 74.4%)	**64.3%** (55.4%, 72.0%)	**64.3%** (55.4%, 72.0%)

Device Survival Probability (95% Confidence Intervals) – *Table 3 of 3*						
Model Number	**11 yrs**	**12 yrs**	**13 yrs**	**14 yrs**	**15 yrs**	**16 yrs**
8709[a]	**62.0%** (58.1%, 65.5%)	**59.0%** (54.8%, 63.0%)	**56.7%** (52.0%, 61.1%)	**54.5%** (49.3%, 59.3%)	**53.5%** (48.0%, 58.6%)	**53.5%** (48.0%, 58.6%)
8709SC	-	-	-	-	-	-
8711	**63.7%** (56.1%, 70.3%)	**61.9%** (53.7%, 69.1%)	**59.8%** (50.9%, 67.7%)	**57.2%** (47.1%, 66.0%)	-	-
8731	**72.2%** (64.0%, 78.8%)	**72.2%** (64.0%, 78.8%)	-	-	-	-
8731SC	-	-	-	-	-	-
8780	-	-	-	-	-	-
8781	-	-	-	-	-	-
Revised As Designed	-	-	-	-	-	-
Ascenda Revised As Designed	-	-	-	-	-	-
Revised Not As Designed	-	-	-	-	-	-
Grafted Not As Designed	-	-	-	-	-	-

[a] Includes 8709 and 8709AA Models.

SPINAL CORD STIMULATION SYSTEMS

Study Participants

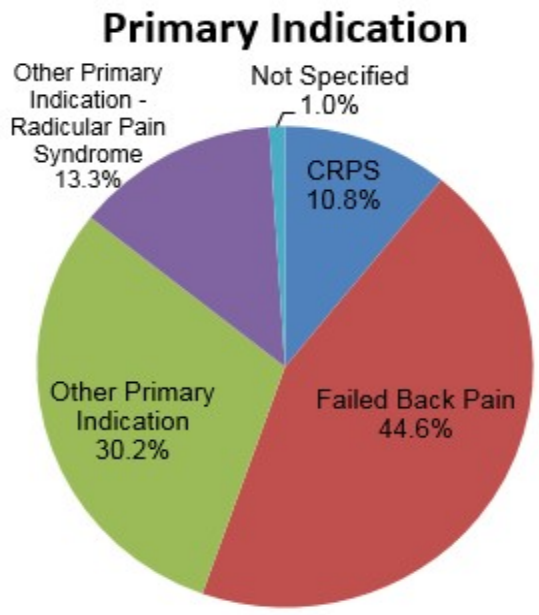
Centers

The following spinal cord stimulation tables and graphs were generated based on data collected between June 2004 and the report cut-off date of October 31, 2017. Seventy-nine centers in North America, Europe and South America, have enrolled and contributed patient data to the spinal cord stimulation section of the report.

Patients

Of the 4,867 total spinal cord stimulation patients enrolled, 44.6% were implanted for the treatment of failed back pain, 30.2% were implanted for the treatment of other primary indications, 13.3% were implanted for the treatment of other primary indication/Radicular Pain Syndrome, 10.8% were implanted for the treatment of complex regional pain syndrome (CRPS), and 1.0% were implanted for indications that were not specified in the database.

Primary Spinal Cord Stimulation Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Failed Back Pain	**2,169 (44.6%)**
Post Laminectomy pain	814 (16.7%)
Failed Back Surgery Syndrome (FBSS)	728 (15.0%)
Combination back and leg pain	511 (10.5%)
Multiple back operations	84 (1.7%)
Arachnoiditis	22 (0.5%)
Unsuccessful disc surgery	10 (0.2%)
Other Primary Indication	**2,120 (43.6%)**
Other chronic pain	799 (16.4%)
Radicular pain syndrome	648 (13.3%)
Other Secondary Indications	313 (6.4%)
Degenerative disc disease	205 (4.2%)
Cervical pain	50 (1.0%)
Traumatic nerve injury	37 (0.8%)
Diabetic neuropathy	29 (0.6%)
Post herpetic neuralgia	16 (0.3%)
Facial pain	7 (0.1%)
Angina	5 (0.1%)
Chronic cluster headache	4 (0.1%)
Epidural fibrosis	4 (0.1%)
Post herniorrhaphy pain	3 (0.1%)
CRPS	**528 (10.8%)**
CRPS I	406 (8.3%)
CRPS II	122 (2.5%)
Not Specified	**50 (1.0%)**
Total Patients	**4,867**

[a] Refer to product labeling for approved indications.

Event Summary

There were 1,253 product-performance events reported between June 2004 and October 31, 2017 in patients with spinal cord stimulation systems. These events represent over thirty-six percent of the total reported events (1,253/3,450). These events occurred in 589 of the 4,867 total patients (12.10%) enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves).

In addition, there were 2,197 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the spinal cord stimulation systems. There

were also 148 deaths reported for patients followed in the PSR with spinal cord stimulation systems, none of which were reported as a direct result of a product performance event. 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.

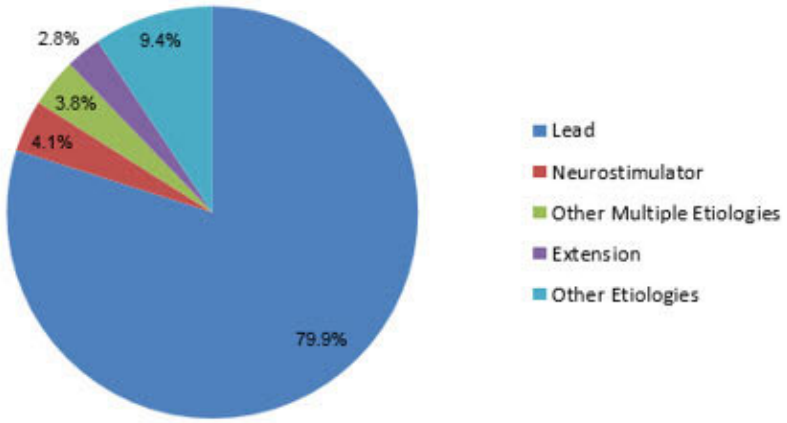
Spinal Cord Stimulation System Product Performance Events			
Event [a]	**Number of Product Performance Events**	**Number of Patients with Event [b]**	**Percent of Patients with Event (N=4,867)**
Lead migration/dislodgement	573	300	6.2%
High impedance	317	136	2.8%
Lead fracture	81	51	1.1%
Battery recharge issue [c]	57	55	1.1%
Device stimulation issue [d]	49	28	0.6%
Low impedance	38	14	0.3%
Device malfunction [e]	30	29	0.6%
Extension fracture	17	11	0.2%
Device breakage [f]	16	16	0.3%
Medical device complication [g]	15	10	0.2%
Device connection issue	6	4	0.1%
Device telemetry issue	5	5	0.1%
Extension migration	5	4	0.1%
Device failure [h]	4	3	0.1%
Impedance increased	4	3	0.1%
Antenna cable breakage	4	4	0.1%
Device battery issue	4	3	0.1%
Device defective	4	4	0.1%
Device component issue [i]	3	3	0.1%
Device difficult to use	3	3	0.1%
Device electrical impedance issue	2	2	0.04%
Impedance decreased	2	1	0.02%
Inadequate lead connection	2	1	0.02%
Paraesthesia [j]	2	2	0.04%
Therapeutic product ineffective	2	1	0.02%
Device electrical impedance issue	2	2	0.04%
Broken bond wire	1	1	0.02%

Spinal Cord Stimulation System Product Performance Events			
Device kink	1	1	0.02%
Device loosening	1	1	0.02%
Grommet loose	1	1	0.02%
Lead insulation failure	1	1	0.02%
Medical device site pain [k]	1	1	0.02%
Totals	**1,253**	**589**	**12.10%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Lower-LevelTerm or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[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] There were a total of 3,248 patients that used rechargeable SCS neurostimulators in the registry. A total of 1.8% (57/3,248) of patients with a rechargeable SCS neurostimulator experienced a neurostimulator unable to recharge or battery recharge issue product performance event.
[d] Device stimulation issue reported by physician as being caused by neurostimulator (n=2) or lead (n=45) or programming (2).
[e] Includes 6 charger malfunctions, 5 neurostimulator malfunctions, 3 patient recharger not working, 3 antenna malfunctions, 2 inability to turn neurostimulator on, 2 events for non-functional lead electrodes, 2 contacts not working, 3 malfunctioning programmer, 1 programmer reporting error message, 1 stimulator turning off and on, 1 SCS stopped abruptly, and 1 recharging cable malfunction.
[f] Includes 6 broken charger belts, 1 broken recharger strap, 3 broken chargers, 2 broken patient programmer, 1 frayed cord to charger antenna, 1 broken charger cord, 1 broken component of patient programmer and 1 frayed wire to charger.
[g] Includes 4 leads no longer providing stimulation, 4 error messages on patient programmer, 2 unable to pass stylet into lead, 2 leads with open circuits, 1 unknown problem with extension, 1 excessive heating of charging unit and 1 unknown programmer error message
[h] Includes 2 events for lead failure, 1 event for failure of lead electrodes, and 1 extension failure.
[i] Includes 1 event for damaged antenna cord, I extension stuck in IPG, and 1 faulty antenna.
[j] Includes 1 event for shocking sensation at battery site and 1 shocking sensation at battery/extension connection.
[k] Event reported by site has been queried.

A total of 1,001(79.9%) of the 1,253 product performance events were related to the lead, 68 (5.4%) were related to "other device", 51 (4.1%) were related to the neurostimulator, 48 (3.8%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 35 (2.8%) were related to the extension, 31 (2.5%) were related to the recharging process, 7 (0.6%) were related to programming/stimulation, 5 (0.4%) were related to "other" etiology, 4 (0.3%) were related to the incisional site/device tract, and 3 (0.2%) were related to surgery/anesthesia. Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a] Each event could have more than one etiology.

Events not-related to a product-performance issue are characterized below. Due to the differences in event collection between the ISPR and PSR protocols, events per patient years and other rates are not calculated for non-product performance events.

Events are categorized by an event group term as noted in bold in the table below.

Spinal Cord 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**
Device issues	**654**
Device stimulation issue [c]	310
Battery recharge issue [d]	187
Device battery issue [e]	47
Neurostimulator migration	31
Neurostimulator inversion	21
Device malfunction [f]	15
Device extrusion	5
Other [g]	30
Therapeutic and nontherapeutic effects (excluding toxicity)	**476**
Therapeutic product ineffective	272
Therapeutic response decreased	143
Therapy non-responder	56
Other [g]	5
Complications associated with device	**327**

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Medical device site pain	200
Medical device discomfort	21
Medical device site erythema	19
Medical device site extravasation	16
Medical device site erosion	13
Medical device site discomfort	9
Medical device site burn	7
Medical device site irritation	6
Medical device complication	5
Other [g]	31
Infections - pathogen unspecified	**154**
Medical device site infection	117
Wound infection	18
Infection	13
Other [g]	6
General system disorders Not Elsewhere Classified (NEC)	**135**
Pain	116
No anomaly found by RPA [h]	19
Other [g]	8
Procedural related injuries and complications NEC	**102**
Inadequate analgesia	29
Incision site pain	16
Incision site erythema	13
Wound dehiscence	12
Seroma	7
Suture related complication	6
Other [g]	19
Musculoskeletal and connective tissue disorders NEC	**82**
Pain in extremity	34
Back pain	31
Musculoskeletal pain	7
Musculoskeletal chest pain	6
Other [g]	4
Neurological disorders NEC	**68**
Paraesthesia	41
Sensory disturbance	7

Spinal Cord Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Cerebrospinal fluid leakage	5
Other [g]	15
Medication errors and other product use errors and issues	**47**
Device difficult to use	35
Device use error	8
Other [g]	4
Muscle disorders	**17**
Muscle spasms	13
Other [g]	4
Injuries NEC	**16**
Wound secretion	6
Other [g]	10
Spinal cord and nerve root disorders	**16**
Radiculopathy	14
Other [g]	2
Headaches	**15**
Headache	13
Other [g]	2
Epidermal and dermal conditions	**14**
Other [g]	14
Administration site reactions	**11**
Other [g]	**11**
Bacterial infectious disorders	**10**
Other [g]	10
Tissue disorders NEC	**10**
Impaired healing	10
Allergic conditions	**7**
Hypersensitivity	6
Other [g]	1
Anxiety disorders and symptoms	**6**
Other [g]	6
Gastrointestinal signs and symptoms	**6**
Other [g]	6
Other	**24**
Total	**2197**

[a] Adverse events associated with product performance events are not included in this table. Related adverse and device events reported on a single event form are represented individually 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 either not device related or had no associated device event.
[d] Events reported as recharge issues not due to a device malfunction.
[e] Events reported as battery discharge or depletion not due to a device malfunction.
[f] Events were device issues due to patient use or other non-device defect etiology.
[g] Comprised of event codes with fewer than 5 events each.
[h] 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).

There were 148 deaths reported for patients with spinal cord stimulation systems, none of which were reported as a direct result of a product performance event. As indicated, 75 (50.68%) of the deaths occurred in patients receiving therapy for pain indications in the "other" category, 62 (41.89%) for failed back, and 11 (7.43%) for CRPS.

Number of Reports of Death by Primary Indication	
Primary Indication[a]	**N (% of deaths)**
Other	75 (50.68%)
Failed Back	62 (41.89%)
CRPS	11 (7.43%)
Total	**148 (100%)**

[a] Refer to product labeling for approved indications

Neurostimulators

From June 2004 to the report cut-off date of October 31, 2017, 5,305 spinal cord neurostimulators were followed in the registry. The difference between the total number of patients (N=4,867) versus neurostimulators is due to the fact that some patients had multiple neurostimulators or were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord neurostimulators was 105,174 months (8,765 years). The table below provides the number and percentage of spinal cord neurostimulators by model.

Spinal Cord Neurostimulators by Model	
Model	**Number of Neurostimulators (%)**
RestoreSensor SureScan MRI (97714)	1,291 (24.3%)
PrimeAdvanced (37702)	671 (12.6%)
PrimeAdvanced SureScan MRI (97702)	579 (10.9%)
RestoreSensor (37714)	378 (7.1%)
RestoreAdvanced (37713)	357 (6.7%)

RestoreAdvanced SureScan MRI (97713)	113 (2.1%)
Itrel 4 (37703)	88 (1.7%)
RestoreUltra SureScan MRI (97712)	80 (1.5%)
Other/Unspecified	19 (0.4%)
Intellis with AdaptiveStim (97715)	9 (0.2%)
Neurostimulators No Longer Manufactured	
RestoreUltra (37712)	581 (11.0%)
Synergy (7427)	461 (8.7%)
Restore (37711)	448 (8.4%)
Itrel 3 (7425)	96 (1.8%)
RestorePrime (37701)	57 (1.1%)
Synergy Versitrel (7427V)	53 (1.0%)
Synergy Plus (7479)	16 (0.3%)
Synergy Compact (7479B)	8 (0.2%)
Total	**5,305 (100%)**

Neurostimulator Events

There were 61 product performance-related events with an underlying reported etiology related to spinal cord neurostimulator function. This includes 51 events with a neurostimulator etiology and 10 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 56 were the initial product performance event that affected neurostimulator survival estimates. For spinal cord neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 316/1,337 (24%). The proportion was based upon the number of registry spinal cord neurostimulators received by RPA, divided by the total number of explanted devices plus the total number of neurostimulators in patients who have expired. Two of the 61 spinal cord neurostimulator events was confirmed by Medtronic RPA as a broken bond wire and a loose grommet. The neurostimulators with the remaining 59 performance-related events were not returned to Medtronic RPA and the events were assigned as device related by the physician. These events included: neurostimulator unable to recharge (n=16), high impedance (n=16), device malfunction (n=7), lead migration/dislodgement (n=4), battery recharge issue (n=4), medical device complication (n=3), device stimulation issue (n=2), low impedance (n=2), device difficult to use (n=1), neurostimulator migration (n=1), device connection issue (n=1), device battery issue (n=1), and device telemetry 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 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 neurostimulators:

- 56 had follow-up time cut-off due to product performance-related events.
- 3,542 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.

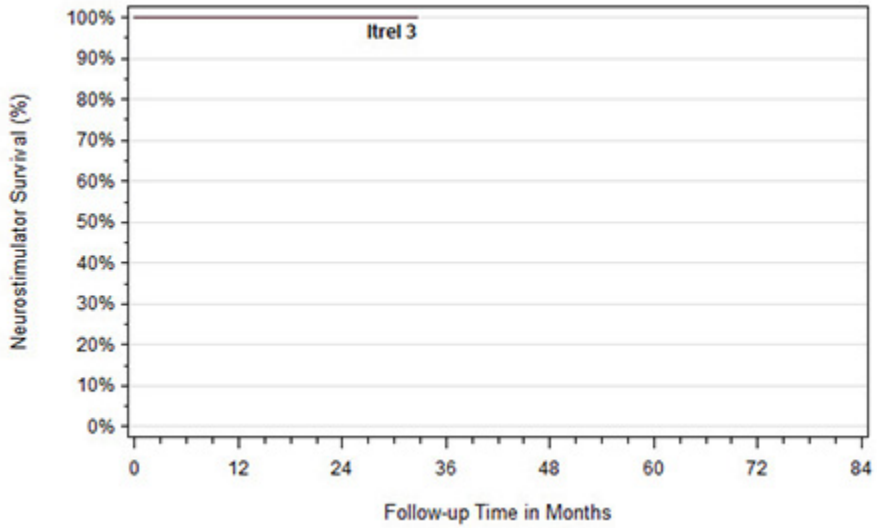
- 1,707 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

Neurostimulator Survival

The figures and tables below represent spinal cord neurostimulator survival and 95% confidence intervals where at least 20 spinal cord neurostimulators contributed to each 3-month interval.

Model 7425 Itrel 3: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator 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	1,457

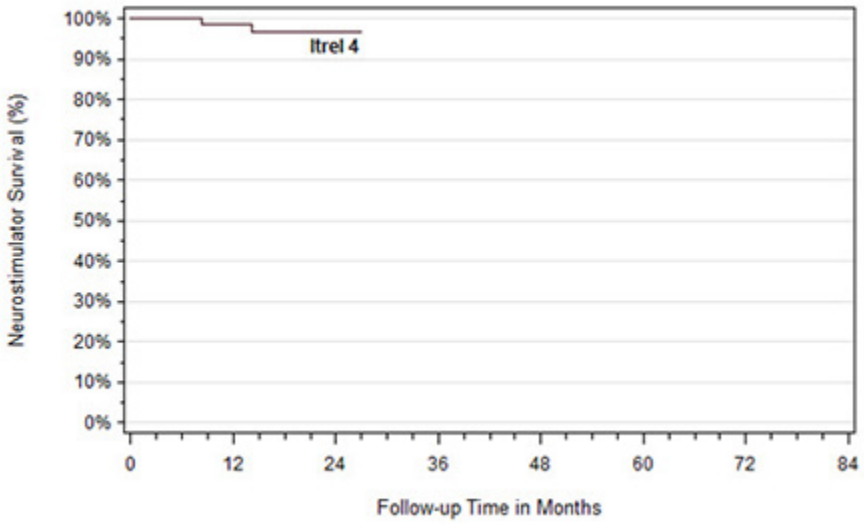
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	35
2 yrs	**100.0%** (NA)	26
at 33 mo	**100.0%** (NA)	20

Model 7425 Itrel 3: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
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 37703 Itrel 4: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	Itrel 4
FDA Approval Date	May 2012
Neurostimulators Enrolled	88
Neurostimulators Currently Active in Study	67
Device Events	2
Cumulative Months of Follow-up	1609

Model 37703 Itrel 4: Event Summary Table	
Neurostimulator Event	**Total**
High impedance	1
Device malfunction	1
Total Neurostimulator Events	**2**

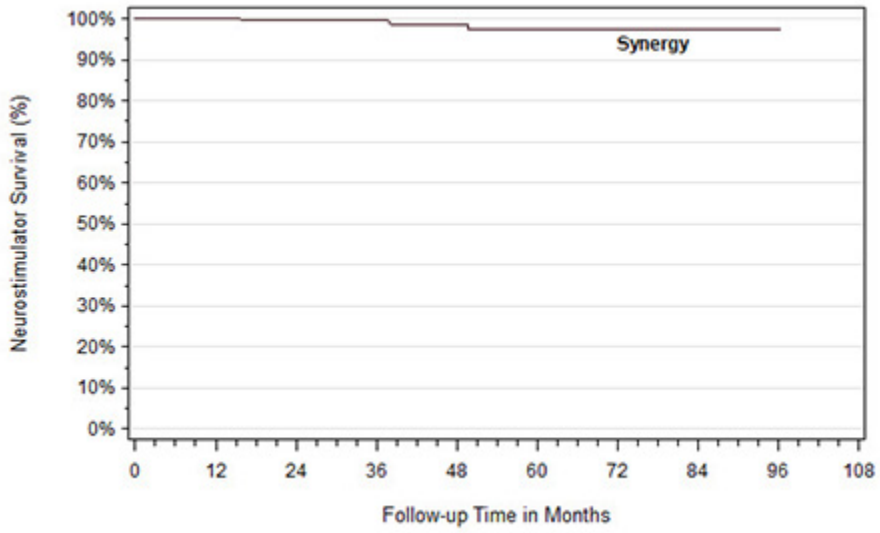
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.6%** (90.2%, 99.8%)	59
at 27 mo	**96.7%** (87.2%, 99.2%)	30

Model 37703 Itrel 4: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

Model 7427 Synergy: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	Synergy
FDA Approval Date	Nov 1999
Neurostimulators Enrolled	461
Neurostimulators Currently Active in Study	3
Device Events	3
Cumulative Months of Follow-up	9,820

Model 7427 Synergy: Event Summary Table	
Neurostimulator Event	**Total**
Broken bond wire	1
Device connection issue	1
Device stimulation issue	1
Total Neurostimulator Events	**3**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	210
2 yrs	**99.5%** (96.6%, 99.9%)	178
3 yrs	**99.5%** (96.6%, 99.9%)	123
4 yrs	**98.7%** (94.5%, 99.7%)	81
5 yrs	**97.4%** (91.5%, 99.2%)	48
6 yrs	**97.4%** (91.5%, 99.2%)	34
7 yrs	**97.4%** (91.5%, 99.2%)	23
8 yrs	**97.4%** (91.5%, 99.2%)	21

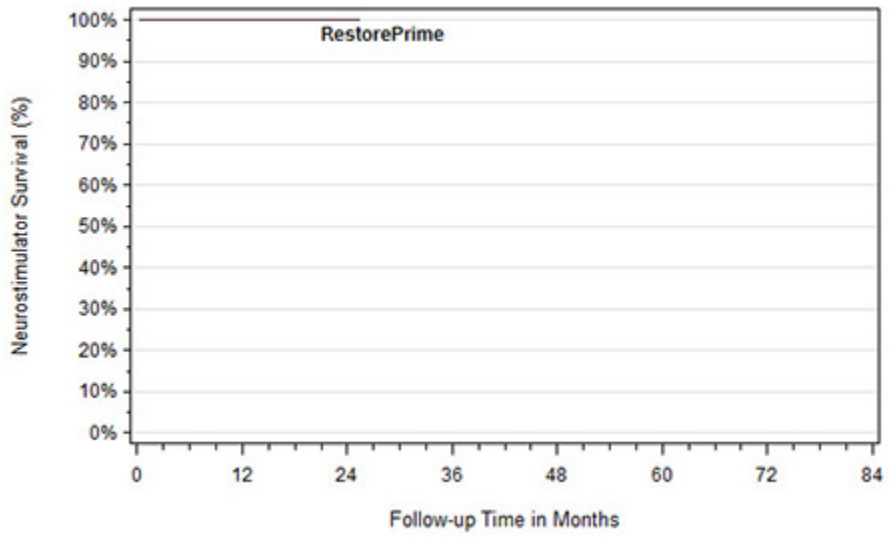
Model 7427 Synergy: Specifications

Height	2.4 in (61 mm)
Width	3.0 in (76 mm)
Thickness	0.6 in (15 mm)
Volume	51 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
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 Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestorePrime
FDA Approval Date	Mar 2006
Neurostimulators Enrolled	57
Neurostimulators Currently Active in Study	1
Device Events	0
Cumulative Months of Follow-up	1,305

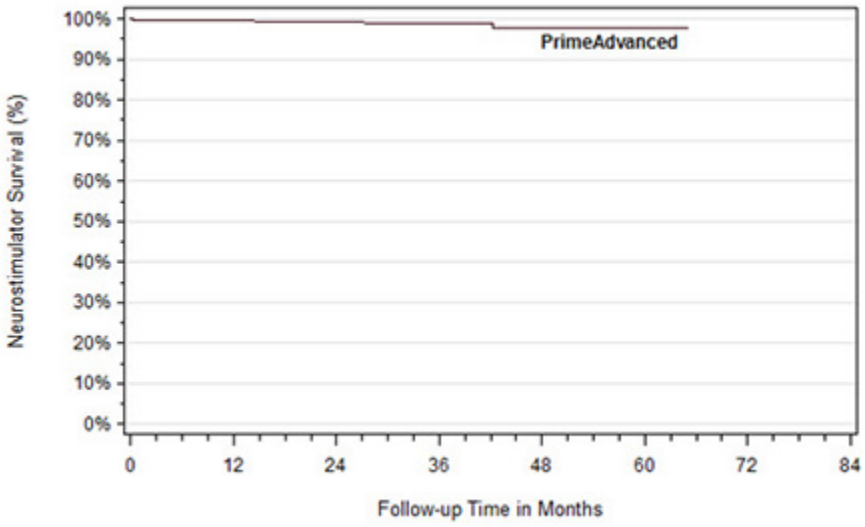
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	38
2 yrs	**100.0%** (NA)	24
at 27 mo	**100.0%** (NA)	22

Model 37701 RestorePrime: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
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 Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	PrimeAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	671
Neurostimulators Currently Active in Study	67
Device Events	6
Cumulative Months of Follow-up	13,760

Model 37702 PrimeAdvanced: Event Summary Table	
Neurostimulator Event	**Total**
High impedance	2
Battery recharge issue	1
Device malfunction [a]	1
Device stimulation issue	1
Low impedance	1
Total Neurostimulator Events	**6**

[a] Reported as suspected device malfunction.

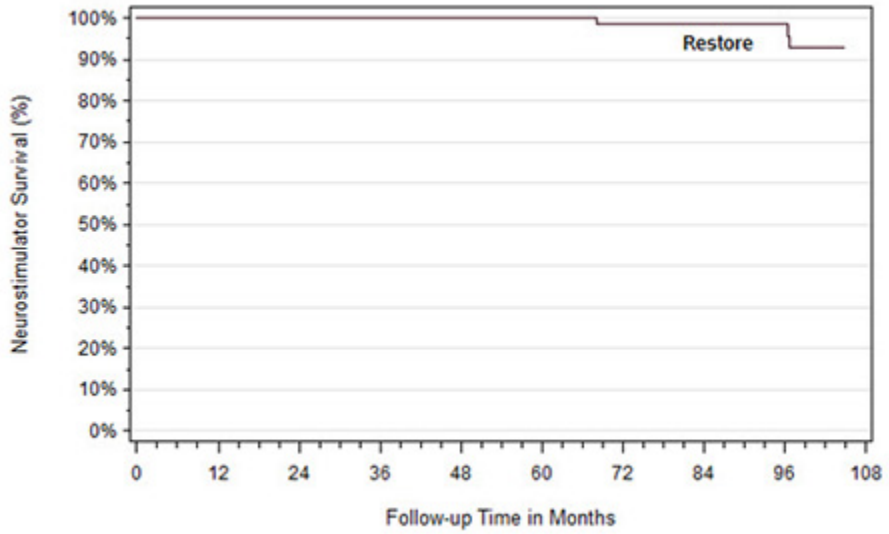
Model 37702 PrimeAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
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

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.5%, 99.9%)	390
2 yrs	**99.3%** (97.9%, 99.8%)	230
3 yrs	**98.8%** (96.5%, 99.6%)	123
4 yrs	**97.7%** (93.4%, 99.2%)	68
5 yrs	**97.7%** (93.4%, 99.2%)	32
at 66 mo	**97.7%** (93.4%, 99.2%)	27

Model 37711 Restore: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	Restore
FDA Approval Date	Apr 2005
Neurostimulators Enrolled	448
Neurostimulators Currently Active in Study	4
Device Events	5
Cumulative Months of Follow-up	13,902

Model 37711 Restore: Event Summary Table	
Neurostimulator Event	**Total**
Battery recharge issue	4
Device malfunction [a]	1
Total Neurostimulator Events	**5**

[a] Reported as suspected device malfunction.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	289
2 yrs	**100.0%** (NA)	234
3 yrs	**100.0%** (NA)	155
4 yrs	**100.0%** (NA)	99
5 yrs	**100.0%** (NA)	79
6 yrs	**98.5%** (89.7%, 99.8%)	59
7 yrs	**98.5%** (89.7%, 99.8%)	47
8 yrs	**98.5%** (89.7%, 99.8%)	35
at 105 mo	**92.9%** (78.9%, 97.7%)	23

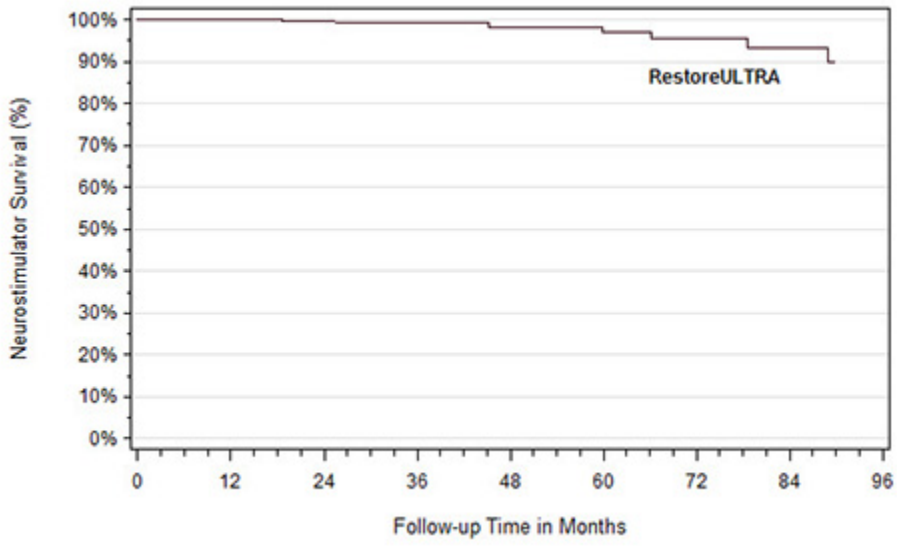
Model 37711 Restore: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	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 Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreUltra
FDA Approval Date	Jan 2008
Neurostimulators Enrolled	581
Neurostimulators Currently Active in Study	24
Device Events	8
Cumulative Months of Follow-up	14,599

Model 37712 RestoreUltra: Event Summary Table	
Neurostimulator Event	**Total**
Battery recharge issue	5
Device malfunction [a]	2
Medical device complication [b]	1
Total Neurostimulator Events	**8**

[a] Reported as malfunction of the spinal cord stimulation system.
[b] Reported as inadequate stimulation paresthesia coverage

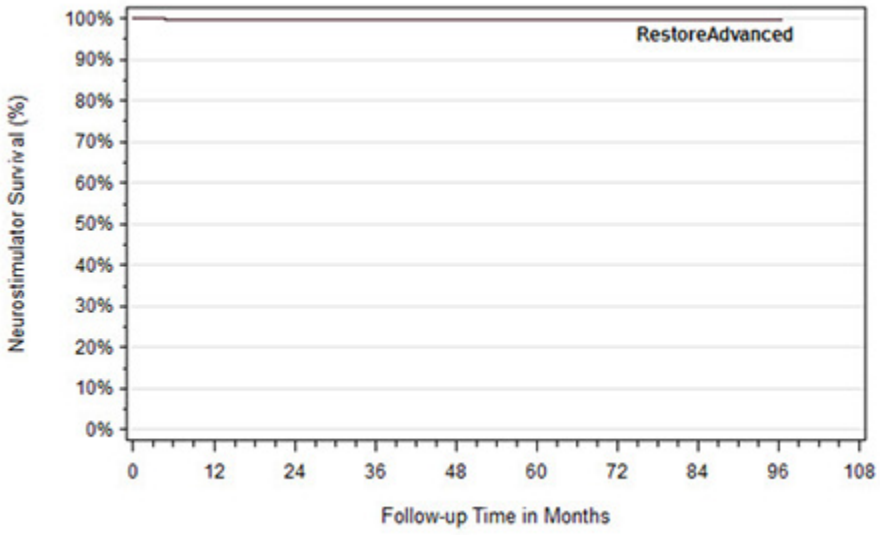
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100%** (NA)	342
2 yrs	**99.6%** (97.3%, 99.9%)	206
3 yrs	**99.1%** (96.5%, 99.8%)	143
4 yrs	**98.2%** (94.1%, 99.5%)	98
5 yrs	**97.0%** (91.3%, 99.0%)	77
6 yrs	**95.5%** (88.6%, 98.3%)	53
7 yrs	**93.2%** (83.8%, 97.3%)	33
at 90 mo	**89.7%** (76.3%, 95.8%)	24

Model 37712 RestoreUltra: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	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 37713 RestoreAdvanced: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreAdvanced
FDA Approval Date	Jul 2006
Neurostimulators Enrolled	357
Neurostimulators Currently Active in Study	30
Device Events	1
Cumulative Months of Follow-up	10,593

Model 37713 RestoreAdvanced: Event Summary Table	
Neurostimulator Event	**Total**
Medical device complication[a]	1
Total Neurostimulator Events	**1**

[a] Reported as simulation therapy did not meet patient's expectations.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.7%** (97.6%, 100.0%)	236
2 yrs	**99.7%** (97.6%, 100.0%)	168
3 yrs	**99.7%** (97.6%, 100.0%)	110
4 yrs	**99.7%** (97.6%, 100.0%)	73
5 yrs	**99.7%** (97.6%, 100.0%)	52
6 yrs	**99.7%** (97.6%, 100.0%)	41

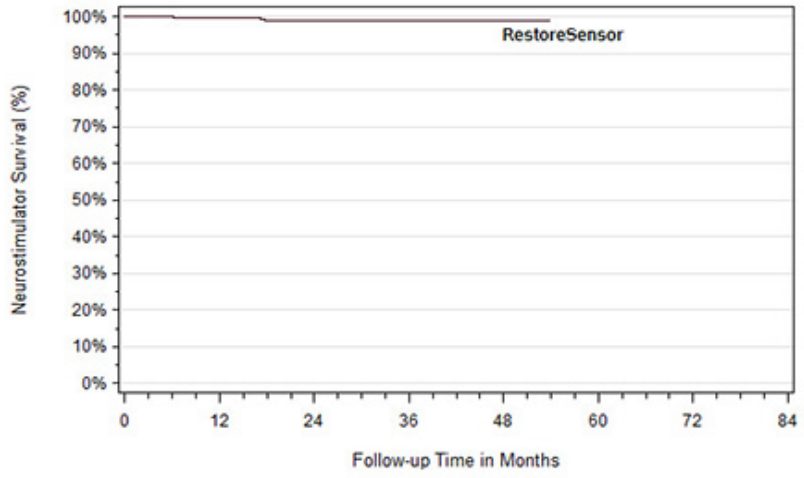
7 yrs	**99.7%** (97.6%, 100.0%)	29
8 yrs	**99.7%** (97.6%, 100.0%)	21
at 99 mo	**99.7%** (97.6%, 100.0%)	20

Model 37713 RestoreAdvanced: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	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 37714 RestoreSensor: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreSensor
FDA Approval Date	Nov 2011
Neurostimulators Enrolled	378
Neurostimulators Currently Active in Study	116
Device Events	3
Cumulative Months of Follow-up	9,012

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.7%** (97.6%, 100.0%)	252
2 yrs	**98.7%** (96.1%, 99.6%)	171
3 yrs	**98.7%** (96.1%, 99.6%)	109
4 yrs	**98.7%** (96.1%, 99.6%)	47

at 54 mo	**98.7%** (96.1%, 99.6%)	26

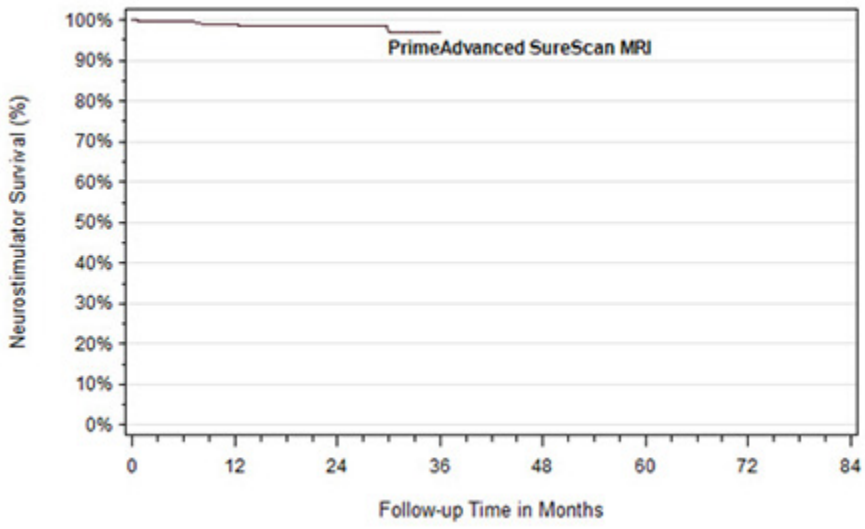
Model 37714 RestoreSensor: Event Summary Table	
Neurostimulator Event	**Total**
Battery recharge issue	2
Device difficult to use	1
Total Neurostimulator Events	**3**

Model 37714 RestoreSensor: Specifications

Height	2.1 in (54 mm)	
Width	2.1 in (54 mm)	
Thickness	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	

Model 97702 PrimeAdvanced SureScan MRI: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	PrimeAdvanced SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	579
Neurostimulators Currently Active in Study	392
Device Events	6
Cumulative Months of Follow-up	7,776

Model 97702 PrimeAdvanced SureScan MRI: Event Summary Table	
Neurostimulator Event	**Total**
High impedance	3
Device battery issue	1
Lead migration/dislodgement [a]	1
Battery recharge issue	1
Total Neurostimulator Events	**6**

[a] Reported as related to both lead and neurostimulator.

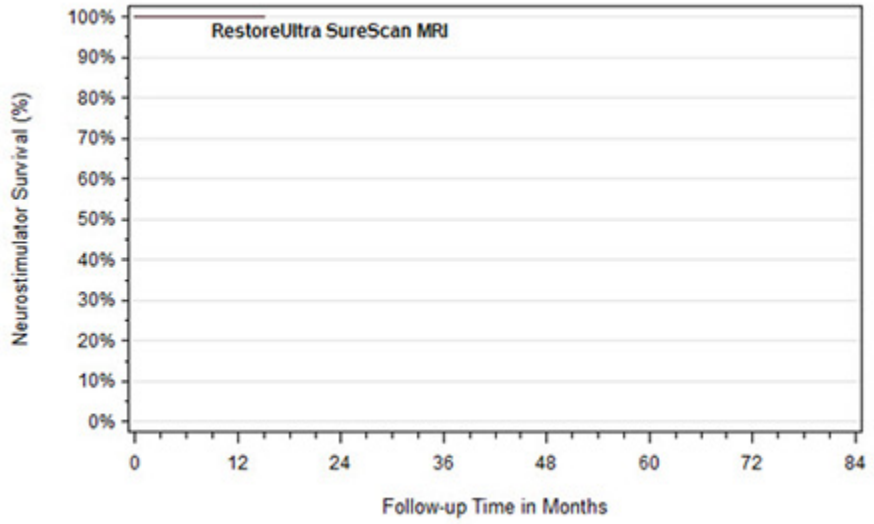
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.0%** (97.4%, 99.6%)	289
2 yrs	**98.6%** (96.7%, 99.4%)	118
3 yrs	**96.9%** (90.1%, 99.0%)	22

Model 97702 PrimeAdvanced SureScan MRI: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	3 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 4 cm

Model 97712 RestoreUltra SureScan MRI: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreUltra SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	80
Neurostimulators Currently Active in Study	48
Device Events	0
Cumulative Months of Follow-up	928

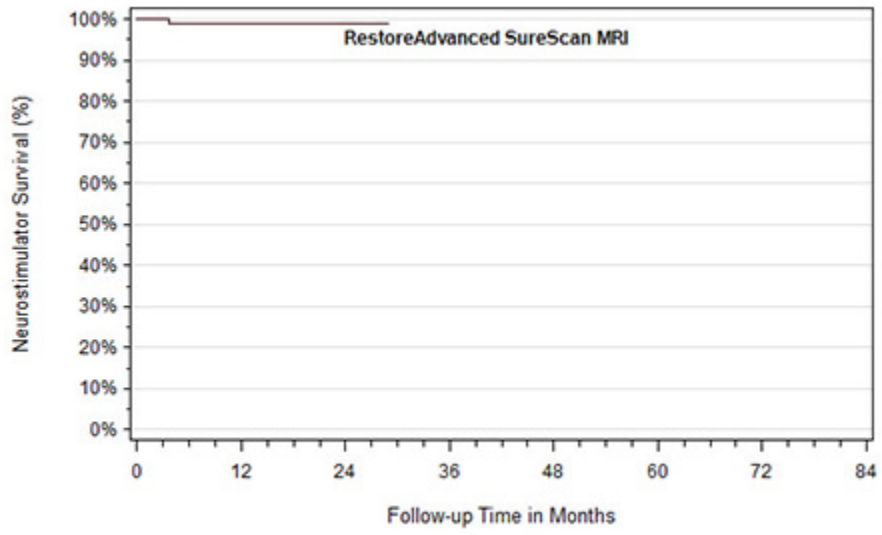
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100%** (NA)	34
at 15 mo	**100%** (NA)	26

Model 97712 RESTOREULTRA SURESCAN MRI: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	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 97713 RestoreAdvanced SureScan MRI: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreAdvanced SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	113
Neurostimulators Currently Active in Study	68
Device Events	1
Cumulative Months of Follow-up	1,842

Model 97713 RestoreAdvanced SureScan MRI: Event Summary Table	
Neurostimulator Event	**Total**
Device malfunction[a]	1
Total Neurostimulator Events	**1**

[a] Reported as malfunction of spinal cord neurostimulator.

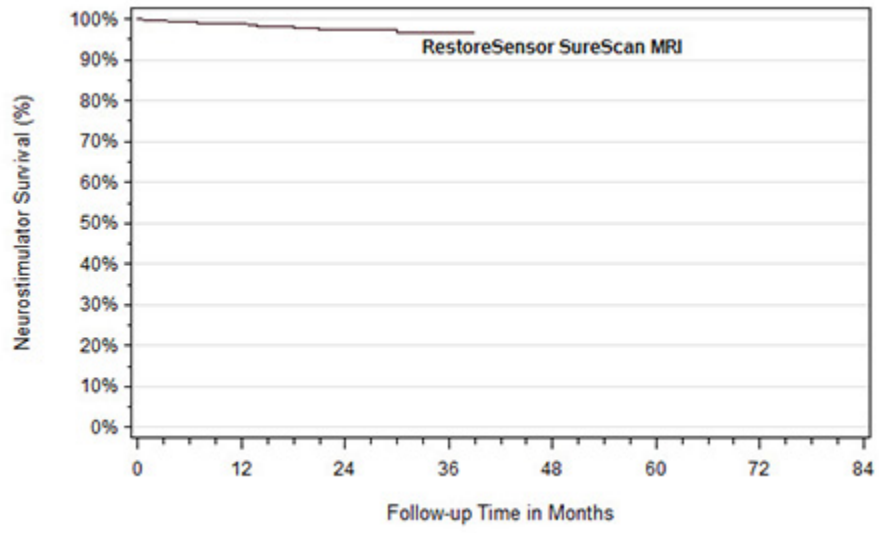
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.9%** (92.2%, 99.8%)	63
2 yrs	**98.9%** (92.2%, 99.8%)	31
at 30 mo	**98.9%** (92.2%, 99.8%)	22

Model 97713 RestoreAdvanced SureScan MRI: Specifications

Height	2.6 in (65 mm)	
Width	1.9 in (49 mm)	
Thickness	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 97714 RestoreSensor SureScan MRI: Survival from Spinal Cord Neurostimulator Events

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



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Spinal Cord Neurostimulator Characteristics	
Model Name	RestoreSensor SureScan MRI
FDA Approval Date	Mar 2013
Neurostimulators Enrolled	1,291
Neurostimulators Currently Active in Study	875
Device Events	19
Cumulative Months of Follow-up	16,795

Model 97714 RestoreSensor SureScan MRI: Event Summary Table	
Neurostimulator Event	**Total**
Battery recharge issue	7
High impedance	4
Lead migration/dislodgement [a]	3
Device telemetry issue	1
Low impedance	1
Neurostimulator migration	1
Device malfunction [b]	1
Grommet loose	1
Total Neurostimulator Events	**19**

[a] Reported as related to both lead and neurostimulator.
[b] Reported as stimulator "turning off and on" on its own.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.8%** (97.8%, 99.3%)	598
2 yrs	**97.5%** (95.9%, 98.5%)	241
3 yrs	**96.8%** (94.3%, 98.2%)	60
at 39 mo	**96.8%** (94.3%, 98.2%)	41

Model 97714 RestoreSensor SureScan MRI: Specifications

Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thickness	9 mm (0.4 in)
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 msec
Groups	8
Programs	16
Implant Depth	≤ 1 cm

Spinal Cord Neurostimulator Survival Summary Table						
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	1,457
Itrel 4	Itrel 4	May 2012	88	67	2	1,609
Synergy	Synergy	Nov 1999	461	3	3	9,820
Restore Prime	Restore	Mar 2006	57	1	0	1,305

Prime Advanced	Prime Advanced	Jul 2006	671	67	6	13,760
Prime Advanced SureScan MRI	Prime Advanced	Mar 2013	579	392	6	7,776
Rechargeable Neurostimulators						
Restore	Restore	Apr 2005	448	4	5	13,902
Restore Ultra	Restore	Jan 2008	581	24	8	14,599
Restore Advanced	Restore	Jul 2006	357	30	1	10,593
Restore Sensor	Restore	Nov 2011	378	116	3	9,012
Restore Ultra SureScan MRI	Restore	Mar 2013	80	48	0	928
Restore Advanced SureScan MRI	Restore	Mar 2013	113	68	1	1,842
Restore Sensor SureScan MRI	Restore	Mar 2013	1,291	875	19	16,795

[a] There were 61 neurostimulator-related events reported to the registry, but only 54 events included in this summary table. The remaining neurostimulator related events occurred in a model for which no device survival data are presented due to an insufficient number of enrolled devices (n=2), or were subsequent events (i.e. additional events that occurred after the initial device event) 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)	-	-
Itrel 4	**98.6%** (90.2%, 99.8%)	**96.7%** (87.2%, 99.2%)	-	-
Synergy	**100.0%** (NA)	**99.5%** (96.6%, 99.9%)	**99.5%** (96.6%, 99.9%)	**98.7%** (94.5%, 99.7%)

RestorePrime	**100.0%** (NA)	**100.0%** (NA)	**-**	**-**
PrimeAdvanced	**99.6%** (98.5%, 99.9%)	**99.3%** (97.9%, 99.8%)	**98.8%** (96.5%, 99.7%)	**97.7%** (93.4%, 99.2%)
PrimeAdvanced SureScan MRI	**99.0%** (97.4%, 99.6%)	**98.6%** (96.7%, 99.4%)	**96.9%** (90.1%, 99.0%)	**-**
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**100.0%** NA	**100.0%** NA	**100.0%** NA
RestoreUltra	**100.0%** (NA)	**99.6%** (97.3%, 99.9%)	**99.1%** (96.5%, 99.8%)	**98.2%** (94.1%, 99.5%)
RestoreAdvanced	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)
RestoreSensor	**99.7%** (97.6%, 100.0%)	**98.7%** (96.1%, 99.6%)	**98.7%** (96.1%, 99.6%)	**98.7%** (96.1%, 99.6%)
RestoreUltra SureScan MRI	**100.0%** (NA)	**-**	**-**	**-**
RestoreAdvanced SureScan MRI	**98.9%** (92.2%, 99.8%)	**98.9%** (92.2%, 99.8%)	**-**	**-**
Restore Sensor SureScan MRI	**98.8%** (97.8%, 99.3%)	**97.5%** (95.9%, 98.5%)	**96.8%** (94.3%, 98.2%)	**-**

Device Survival Probability (95% Confidence Interval)– *Table 2 of 2*				
Model Name	**5 yrs**	**6 yrs**	**7 yrs**	**8 yrs**
Primary Cell Neurostimulators				
Itrel 3	**-**	**-**	**-**	**-**
Itrel 4	**-**	**-**	**-**	**-**
Synergy	**97.4%** (91.5%, 99.2%)	**97.4%** (91.5%, 99.2%)	**97.4%** (91.5%, 99.2%)	**97.4%** (91.5%, 99.2%)
RestorePrime	-	**-**	**-**	**-**

PrimeAdvanced	**97.7%** (93.4%, 99.2%)	-	-	-
PrimeAdvanced SureScan MRI	-	-	-	-
Rechargeable Neurostimulators				
Restore	**100.0%** NA	**98.5%** (89.7%, 99.8%)	**98.5%** (89.7%, 99.8%)	**98.5%** (89.7%, 99.8%)
RestoreUltra	**97.0%** (91.3%, 99.0%)	**95.5%** (88.6%, 98.3%)	**93.2%** (83.8%, 97.3%)	-
RestoreAdvanced	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)	**99.7%** (97.6%, 100.0%)
RestoreSensor	-	-	-	-
RestoreAdvanced SureScan MRI	-	-	-	-
Restore Sensor SureScan MRI	-	-	-	-
RestoreUltra SureScan MRI	-	-	-	-

Leads

From June 2004 to the report cut-off date of October 31, 2017, there were 8,765 leads followed in the registry. Differences between the total number of leads versus spinal cord neurostimulators (N=5,305) 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 185,444 months (15,454 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.

Model	Number of Leads (%)
Vectris SureScan MRI Compact (977A2) [a]	2,602 (29.7%)
Pisces Octad Compact (3778) [a]	2,163 (24.7%)
Pisces Standard (3487A) [a]	980 (11.2%)
Pisces Octad Standard (3777) [a]	834 (9.5%)
Pisces Plus (3888) [a]	443 (5.1%)
Specify 5-6-5 (39565) [b]	282 (3.2%)
Pisces Compact (3887) [a]	196 (2.2%)
Pisces Octad Subcompact (3776) [a]	185 (2.1%)
Vectris SureScan MRI Subcompact (977A1) [a]	117 (1.3%)
Specify 2x8 (39286) [b]	32 (0.4%)
Specify SureScan MRI 5-6-5 (977C1) [b]	30 (0.3%)
Specify SureScan MRI 2x8 (977C2) [b]	10 (0.1%)
Other/Unspecified	215 (2.5%)
Leads No Longer Manufactured	
Specify (3998) [b]	155 (1.8%)
Pisces Z Standard (3890) [a]	141 (1.6%)
Pisces Z Compact (3891) [a]	130 (1.5%)
Resume TL (3986A) [b]	108 (1.2%)
Hinged Specify (3999) [b]	54 (0.6%)
Resume II (3587A) [b]	52 (0.6%)
Pisces Z Plus (3892) [a]	25 (0.3%)
On-Point (3987A) [b]	9 (0.1%)
SymMix (3982A) [b]	2 (<0.1%)
Total	**8,765 (100%)**

[a] Percutaneous lead
[b] Surgical lead

Percutaneous leads composed over eighty-nine percent (89.2%%) of leads in the registry (7,816/8,765), including 36.3% (3,182/8,765) in the Pisces-Octad lead family, 31.0% (2,719/8,765) in the Vectris SureScan MRI lead family, 18.5% (1,619/8,765) in the Pisces-Quad lead family, and 3.4% (296/8,765) in the Pisces-Quad Z lead family. Over eight percent (8.4%) of leads (734/8,765) were surgical leads. A small percent (2.5%) of leads (215/8,765) were designated as "Other" or were unspecified in the database.

Lead Events

There were 1,025 product performance-related events with an underlying reported etiology related to the lead. This includes 1,001 events with a lead etiology and 24 events with both a lead and other etiology (including device and non-device etiologies). Of these events, the majority were lead migration/dislodgements (n=562), high impedance (n=275), and lead fracture (n=69). Of the 1,025 lead events, 889 were the initial product performance event that affected lead survival

estimates. There were 820 events in the 7816 (10.5%) percutaneous leads, 50 events in the 734 (6.8%) surgical leads, and 19 events occurred in a lead with an unknown/other 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 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:

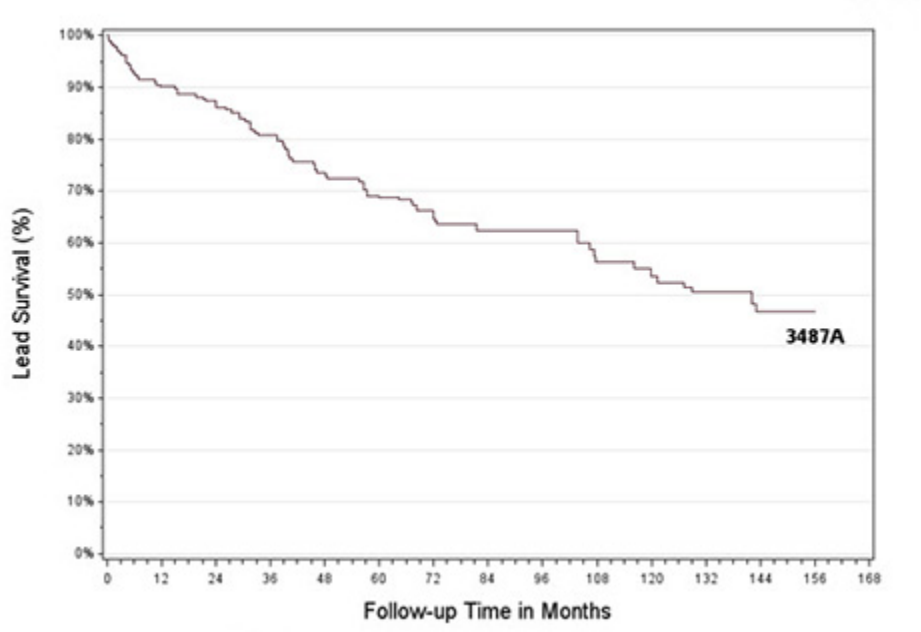
- 889 had follow-up time cut-off due to product performance-related events.
- 5,091 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,785 were free from product performance-related events and censoring events, were censored at the last follow-up prior to the report cut-off.

Lead Survival

The tables below represent annual lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval.

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	980
Leads Currently Active in Study	112
Device Events	199
Cumulative Months of Follow-up	32,353

Model 3487A Pisces-Quad: Event Summary Table	
Lead Event	**Total**
High impedance	87
Lead migration/dislodgement	55
Low impedance	25
Device stimulation issue	17
Lead fracture	13
Inadequate lead connection	2
Total Lead Events	**199**

Time Interval	Survival (95% Confidence Interval)	Sample Sie
1 yr	**90.2%** (87.4%, 92.4%)	497
2 yrs	**87.4%** (84.3%, 89.9%)	406
3 yrs	**80.7%** (76.9%, 83.9%)	331
4 yrs	**73.6%** (69.2%, 77.4%)	244
5 yrs	**69.0%** (64.3%, 73.3%)	205
6 yrs	**64.7%** (59.6%, 69.3%)	172
7 yrs	**62.3%** (57.1%, 67.1%)	143
8 yrs	**62.3%** (57.1%, 67.1%)	107
9 yrs	**56.3%** (50.3%, 61.8%)	93
10 yrs	**53.7%** (47.5%, 59.5%)	77
11 yrs	**50.6%** (44.0%, 56.8%)	55
12 yrs	**46.8%** (39.5%, 53.8%)	35
at 156 mo	**46.8%** (39.5%, 53.8%)	22

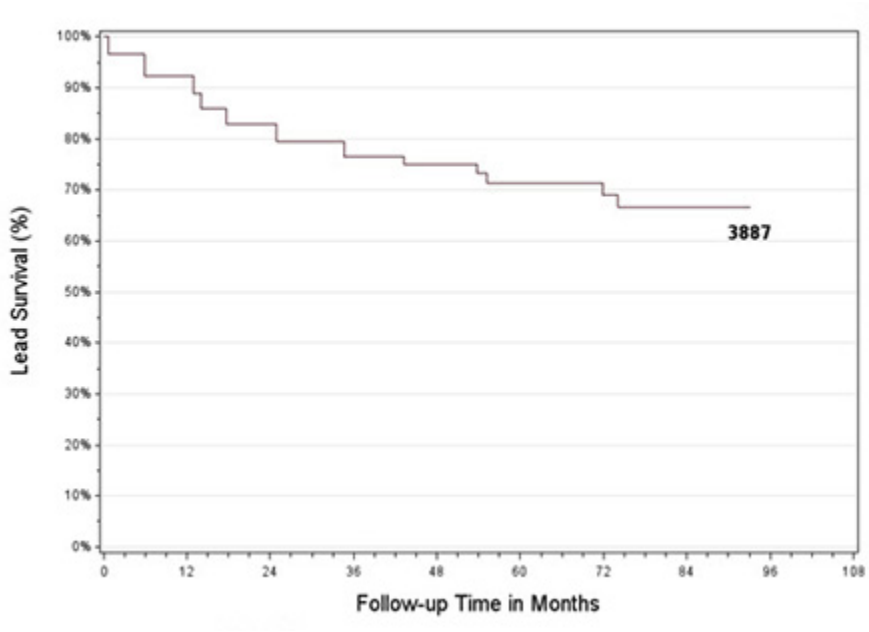
Model 3487A Pisces-Quad: Specifications

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	196
Leads Currently Active in Study	53
Device Events	29
Cumulative Months of Follow-up	5,202

Model 3887 Pisces-Quad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	14
Lead fracture	8
High impedance	4
Device stimulation issue	2
Device lead damage	1
Total Lead Events	**29**

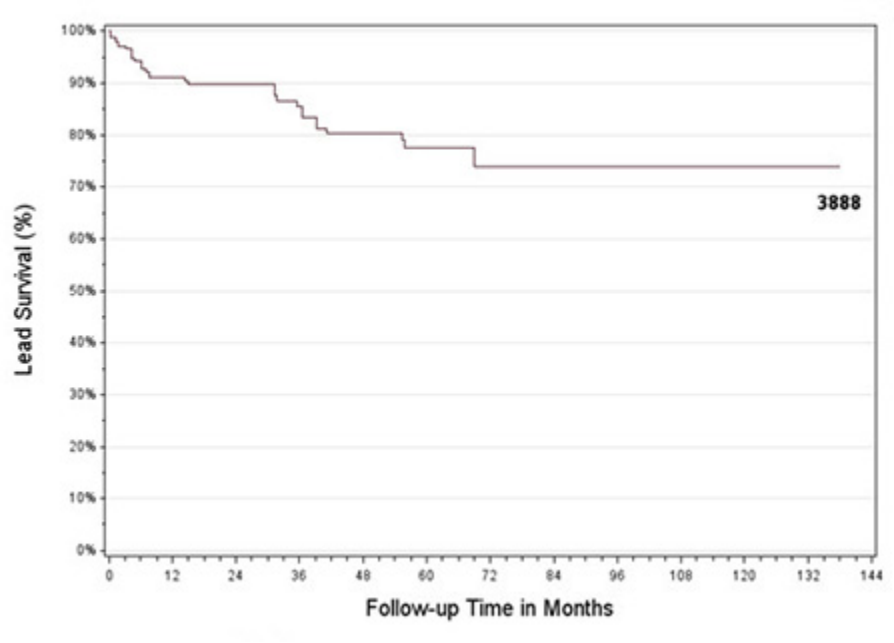
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.3%** (77.7%, 97.5%)	51
2 yrs	**82.9%** (69.3%, 90.9%)	52
3 yrs	**76.5%** (62.7%, 85.7%)	49
4 yrs	**75.1%** (61.3%, 84.5%)	43
5 yrs	**71.3%** (57.3%, 83.4%)	36
6 yrs	**69.0%** (54.6%, 79.6%)	29
7 yrs	**66.6%** (51.9%, 77.7%)	22
at 93 mo	**66.6%** (51.9%, 77.7%)	20

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	443
Leads Currently Active in Study	78
Device Events	42
Cumulative Months of Follow-up	8,835

Model 3888 Pisces-Quad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	28
High impedance	11
Device stimulation issue	2
Lead fracture	1
Total Lead Events	**42**

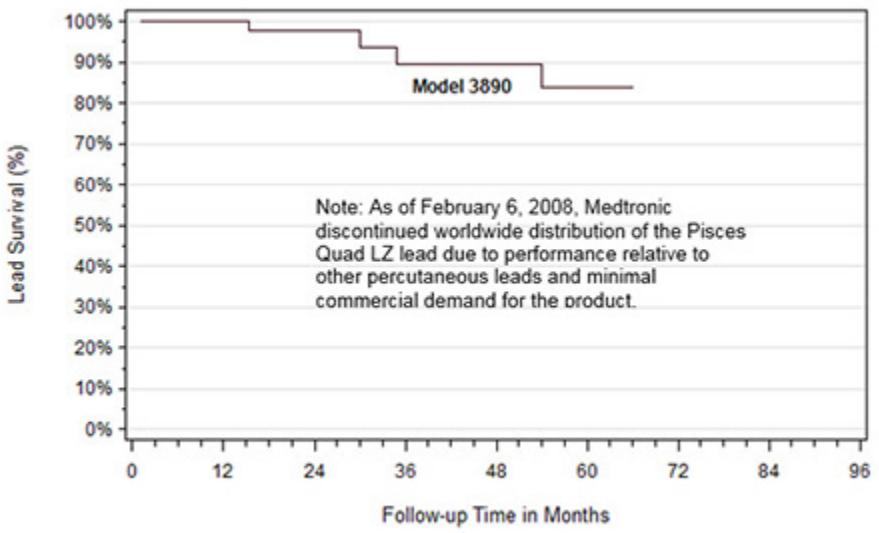
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.1%** (86.3%, 94.3%)	149
2 yrs	**89.7%** (84.5%, 93.2%)	97
3 yrs	**85.6%** (78.8%, 90.3%)	80
4 yrs	**80.3%** (72.2%, 86.2%)	64
5 yrs	**77.7%** (68.9%, 84.3%)	51
6 yrs	**73.9%** (63.8%, 81.6%)	36
7 yrs	**73.9%** (63.8%, 81.6%)	31
8 yrs	**73.9%** (63.8%, 81.6%)	29
9 yrs	**73.9%** (63.8%, 81.6%)	23
10 yrs	**73.9%** (63.8%, 81.6%)	22
11 yrs	**73.9%** (63.8%, 81.6%)	20
at 135 mo	**73.9%** (63.8%, 81.6%)	20

Model 3888 Pisces-Quad: Specifications

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

Model 3890 Pisces-Quad LZ: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3890
FDA Approval Date	Sep 2002
Leads Enrolled	141
Leads Currently Active in Study	16
Device Events	10
Cumulative Months of Follow-up	3,158

Model 3890 Pisces-Quad LZ: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	4
Impedance decreased	2
Lead fracture	2
High impedance	2
Total Lead Events	**10**

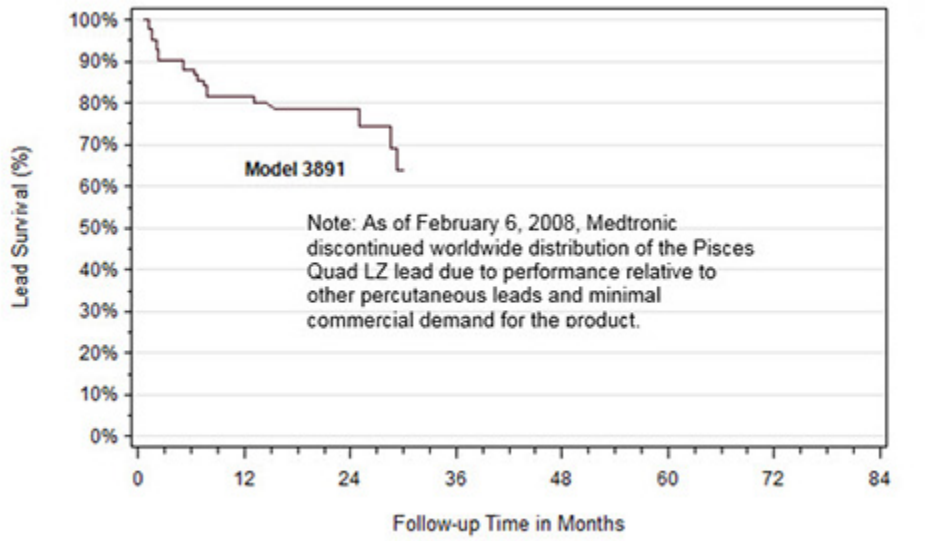
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	38
2 yrs	**97.8%** (85.1%, 99.7%)	51
3 yrs	**89.4%** (76.4%, 95.5%)	40
4 yrs	**89.4%** (76.4%, 95.5%)	33
5 yrs	**83.8%** (68.8%, 92.0%)	22
at 66 mo	**83.8%** (68.8%, 92.0%)	20

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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Lead Characteristics	
Model Number	3891
FDA Approval Date	Sep 2002
Leads Enrolled	130
Leads Currently Active in Study	17
Device Events	32
Cumulative Months of Follow-up	2,414

Model 3891 Pisces-Quad LZ: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	18
Lead fracture	6
Device stimulation issue	4
Device lead damage	2
High impedance	2
Total Lead Events	**32**

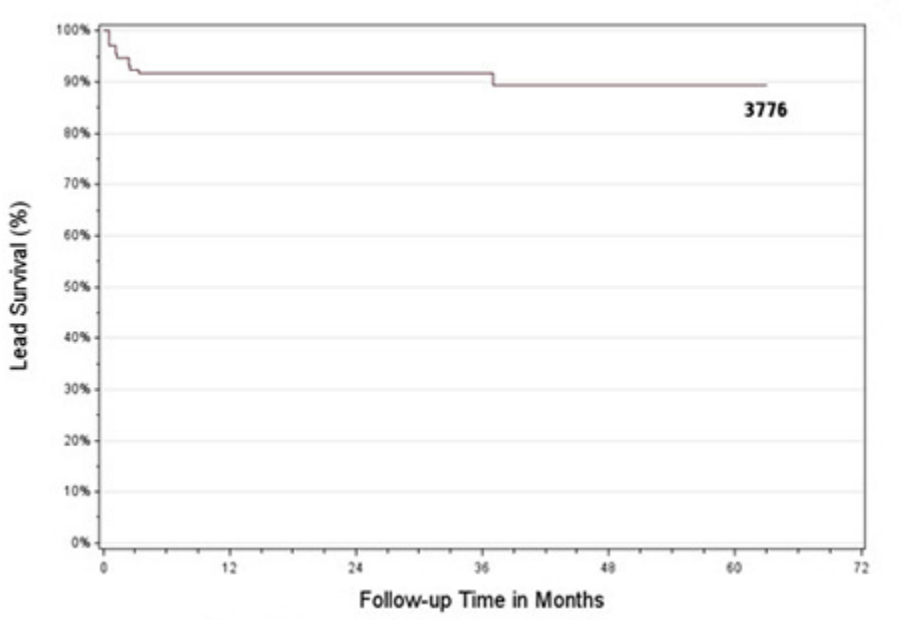
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**81.7%** (71.4%, 88.5%)	56
2 yrs	**78.7%** (67.9%, 86.2%)	37
at 30 mo	**63.9%** (49.3%, 75.3%)	21

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	185
Leads Currently Active in Study	36
Device Events	14
Cumulative Months of Follow-up	4,208

Model 3776 Pisces-Octad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	10
High impedance	2
Device stimulation issue	1
Lead fracture	1
Total Lead Events	**14**

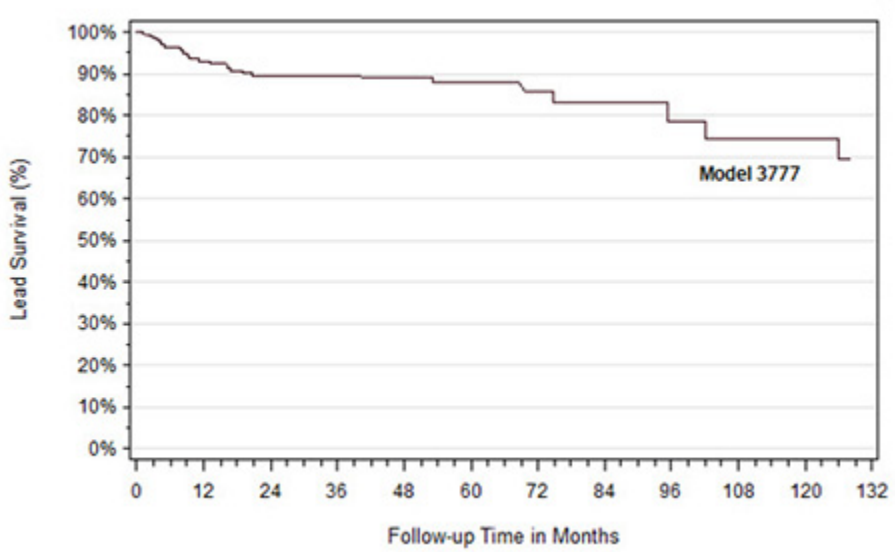
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**91.6%** (85.4%, 95.3%)	84
2 yrs	**91.6%** (85.4%, 95.3%)	61
3 yrs	**91.6%** (85.4%, 95.3%)	43
4 yrs	**89.4%** (81.1%, 94.2%)	29
5 yrs	**89.4%** (81.1%, 94.2%)	20
at 63 mo	**89.4%** (81.1%, 94.2%)	20

Model 3776 Pisces-Octad: Specifications

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

Model 3777 Pisces-Octad: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3777
FDA Approval Date	Apr 2005
Leads Enrolled	834
Leads Currently Active in Study	120
Device Events	68
Cumulative Months of Follow-up	19,221

Model 3777 Pisces-Octad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	40
High impedance	15
Device stimulation issue	7
Device lead damage	2
Lead fracture	2
Low impedance	2
Total Lead Events	**68**

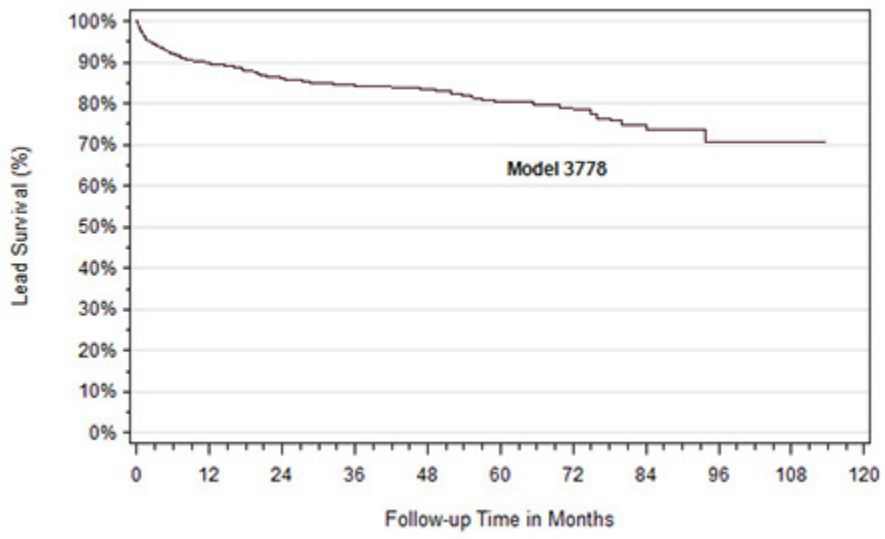
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**92.8%** (90.2%, 94.7%)	435
2 yrs	**89.6%** (86.4%, 92.0%)	274
3 yrs	**89.6%** (86.4%, 92.0%)	173
4 yrs	**89.0%** (85.6%, 91.6%)	111
5 yrs	**88.1%** (84.2%, 91.1%)	85
6 yrs	**85.8%** (80.5%, 89.7%)	68
7 yrs	**83.0%** (76.3%, 88.0%)	45
8 yrs	**78.7%** (69.2%, 85.5%)	34
9 yrs	**74.4%** (63.4%, 82.6%)	44
10 yrs	**74.4%** (63.4%, 82.6%)	33
at 129 mo	**69.6%** (57.1%, 79.1%)	21

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	2,163
Leads Currently Active in Study	333
Device Events	274
Cumulative Months of Follow-up	54,152

Model 3778 Pisces-Octad: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	204
High impedance	36
Lead fracture	18
Device stimulation issue	6
Medical device complication[a]	4
Device lead damage	2
Device malfunction[b]	2
Impedance increased	1
Low impedance	1
Total Lead Events	**274**

[a] Includes 2 events reported as lead lost capability of stimulation and 2 events of open circuit on lead.
[b] Includes 2 events reported as lead electrodes not functional.

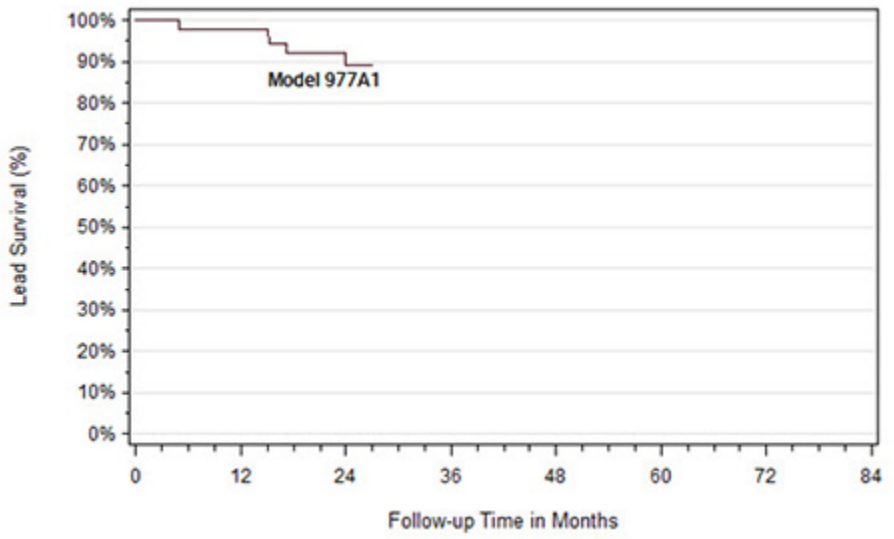
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**89.8%** (88.2%, 91.2%)	1,209
2 yrs	**86.1%** (84.2%, 87.8%)	799
3 yrs	**84.2%** (82.0%, 86.0%)	582
4 yrs	**83.6%** (81.4%, 85.6%)	406
5 yrs	**80.4%** (77.6%, 82.9%)	263
6 yrs	**78.4%** (75.1%, 81.3%)	177
7 yrs	**74.9%** (70.7%, 78.6%)	113
8 yrs	**70.7%** (65.2%, 75.5%)	74
9 yrs	**70.7%** (65.2%, 75.5%)	36
at 114 mo	**70.7%** (65.2%, 75.5%)	23

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 977A1 Vectris SureScan MRI 1x8 Subcompact: 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	977A1
FDA Approval Date	Mar 2013
Leads Enrolled	117
Leads Currently Active in Study	67
Device Events	6
Cumulative Months of Follow-up	1,804

Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	3
Device lead fracture	2
High impedance	1
Total Lead Events	**6**

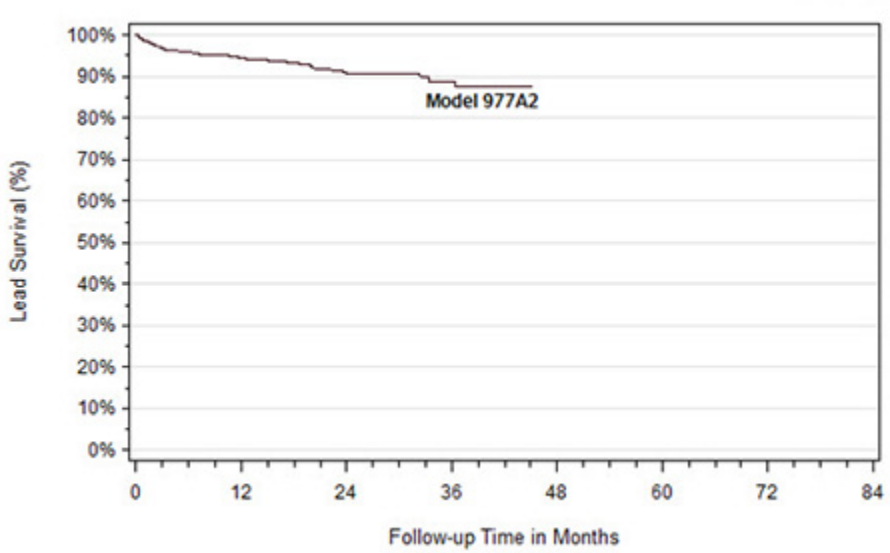
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**97.7%** (91.1%, 99.4%)	65
2 yrs	**89.1%** (75.9%, 95.3%)	27
at 27 mo	**89.1%** (75.9%, 95.3%)	22

Model 977A1 Vectris SureScan MRI 1x8 Subcompact: Specifications

Device Name	Vectris SureScan MRI 1x8 Subcompact	
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)	1.5	
Array Length (mm)	34.5	

Model 977A2 Vectris SureScan MRI 1x8 Compact: 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	977A2
FDA Approval Date	Mar 2013
Leads Enrolled	2,602
Leads Currently Active in Study	1,774
Device Events	145
Cumulative Months of Follow-up	33,287

Model 977A2 Vectris SureScan MRI 1x8 Compact: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	108
High impedance	28
Lead fracture	7
Impedance increased	1
Low impedance	1
Total Lead Events	**145**

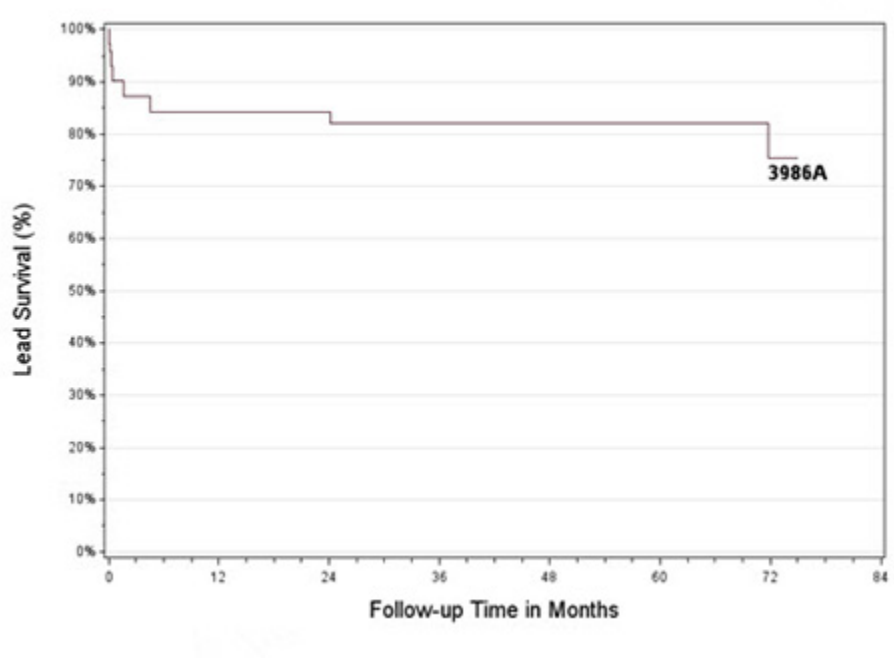
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**94.3%** (93.1%, 95.3%)	1,161
2 yrs	**90.7%** (88.8%, 92.2%)	501
3 yrs	**88.8%** (86.1%, 91.0%)	144
at 45 mo	**87.5%** (84.2%, 90.2%)	30

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	

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	108
Leads Currently Active in Study	14
Device Events	19
Cumulative Months of Follow-up	3,528

Model 3986A Resume TL: Event Summary Table	
Lead Event	**Total**
High impedance	10
Device connection issue	2
Device stimulation issue	2
Low impedance	2
Lead migration/dislodgement	2
Lead fracture	1
Total Lead Events	**19**

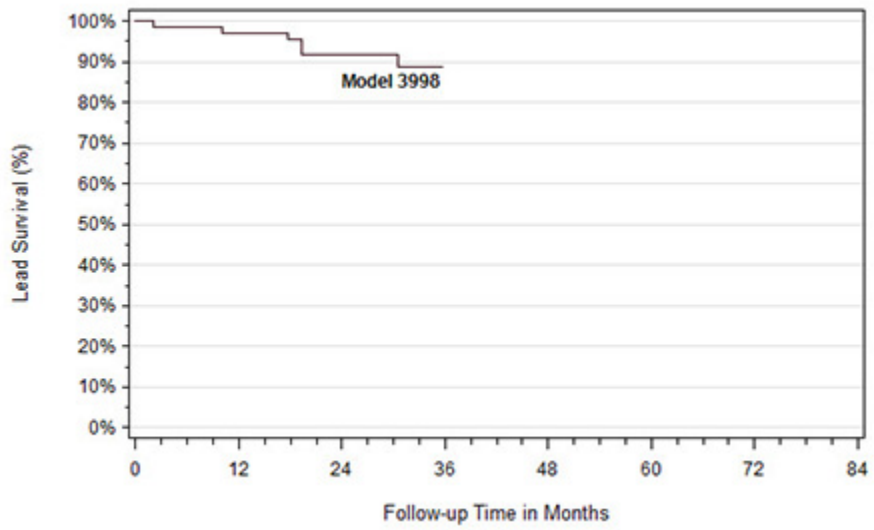
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**84.2%** (73.3%, 91.0%)	48
2 yrs	**84.2%** (73.3%, 91.0%)	38
3 yrs	**82.0%** (70.3%, 89.5%)	30
4 yrs	**82.0%** (70.3%, 89.5%)	33
5 yrs	**82.0%** (70.3%, 89.5%)	29
6 yrs	**75.5%** (60.6%, 85.4%)	22
at 75 mo	**75.5%** (60.6%, 85.4%)	20

Model 3986A Resume TL: Specifications

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

Model 3998 Specify: Survival from Lead Events

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



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Lead Characteristics	
Model Number	3998
FDA Approval Date	Feb 1998
Leads Enrolled	155
Leads Currently Active in Study	24
Device Events	10
Cumulative Months of Follow-up	3,352

Model 3998 Specify: Event Summary Table	
Lead Event	**Total**
High impedance	4
Lead fracture	3
Lead migration/dislodgement	2
Device stimulation issue	1
Total Lead Events	**10**

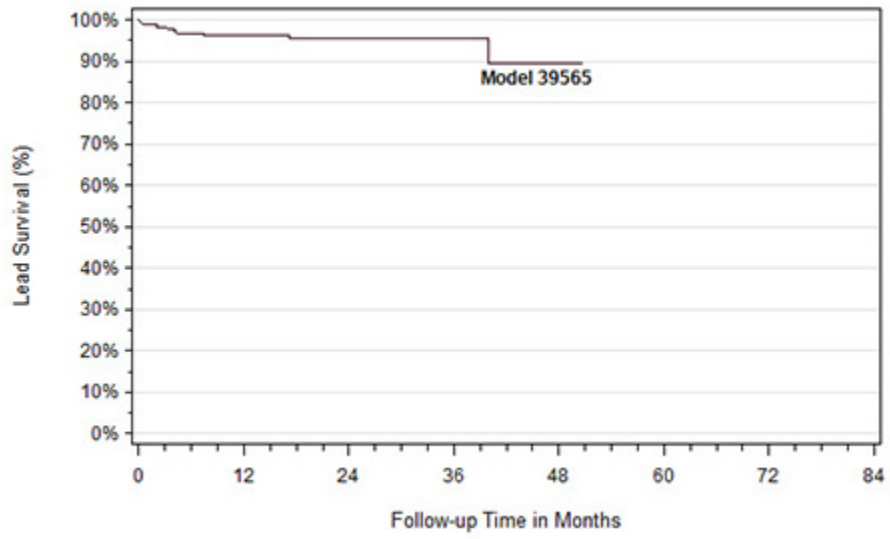
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**97.1%** (88.7%, 99.3%)	60
2 yrs	**91.7%** (81.1%, 96.5%)	41
3 yrs	**88.7%** (75.8%, 94.9%)	20

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	282
Leads Currently Active in Study	75
Device Events	13
Cumulative Months of Follow-up	5,507

Model 39565 Specify: Event Summary Table	
Lead Event	**Total**
Lead migration/dislodgement	10
High impedance	1
Lead fracture	1
Lead insulation failure	1
Total Lead Events	**13**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**96.3%** (92.7%, 98.1%)	153
2 yrs	**95.6%** (91.6%, 97.7%)	94
3 yrs	**95.6%** (91.6%, 97.7%)	43
4 yrs	**89.6%** (77.2%, 95.4%)	23
at 51 mo	**89.6%** (77.2%, 95.4%)	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	

Lead Survival Summary

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	980	112	199	32,353
3887	**Pisces-Quad**	Jan 1997	196	53	29	5,202
3888	**Pisces-Quad**	Nov 1992	443	78	42	8,835
3890	**Pisces-Quad LZ**	Sep 2002	141	16	10	3,158
3891	**Pisces-Quad LZ**	Sep 2002	130	17	32	2,414
3776	**Pisces-Octad**	Nov 2005	185	36	14	4,208
3777	**Pisces-Octad**	Apr 2005	834	120	68	19,221
3778	**Pisces-Octad**	Apr 2005	2,163	333	274	54,152
977A1	**Vectris SureScan**	Mar 2013	117	67	6	1,804
977A2	**Vectris SureScan**	Mar 2013	2,602	1,774	145	33,287
Surgical Leads						
3986A	**Resume TL**	Apr 1995[b]	108	14	19	3,528
3998	**Specify**	Feb 1998	155	24	10	3,352
39565	**Specify**	Jun 2007	282	75	13	5,507

[a] There were a total of 1025 lead-related events reported to the registry, but only 861 events included in this summary table. The remaining lead-related events occurred in lead models for which no device survival data are presented due to an insufficient number of enrolled devices (n=9), leads with an unknown model numbers (n=19), or were subsequent device events (i.e. additional events that occurred after the survival censoring event) 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**	**90.2%** (87.4%, 92.4%)	**87.4%** (84.3%, 89.9%)	**80.7%** (76.9%, 83.9%)	**73.6%** (69.2%, 77.4%)
3887	**Pisces-Quad**	**92.3%** (77.7%, 97.5%)	**82.9%** (69.3%, 90.9%)	**76.5%** (62.7%, 85.7%)	**75.1%** (61.3%, 84.5%)
3888	**Pisces-Quad**	**91.1%** (86.3%, 94.3%)	**89.7%** (84.5%, 93.2%)	**85.6%** (78.8%, 90.3%)	**80.3%** (72.2%, 86.2%)
3890	**Pisces-Quad LZ**	**100.0%** (NA)	**97.8%** (85.1%, 99.7%)	**89.4%** (76.4%, 95.5%)	**89.4%** (76.4%, 95.5%)
3891	**Pisces-Quad LZ**	**81.7%** (71.4%, 88.5%)	**78.7%** (67.9%, 86.2%)	-	-
3776	**Pisces-Octad**	**91.6%** (85.4%, 95.3%)	**91.6%** (85.4%, 95.3%)	**91.6%** (85.4%, 95.3%)	**89.4%** (91.1%, 94.2%)
3777	**Pisces-Octad**	**92.8%** (90.2%, 94.7%)	**89.6%** (86.4%, 92.0%)	**89.6%** (86.4%, 92.0%)	**89.0%** (85.6%, 91.6%)
3778	**Pisces-Octad**	**89.9%** (88.2%, 91.2%)	**86.1%** (84.2%, 87.8%)	**84.2%** (82.0%, 86.0%)	**83.6%** (81.4%, 85.6%)
977A1	**Vectris SureScan**	**97.7%** (91.1%, 99.4%)	**89.1%** (75.9%, 95.3%)	-	-
977A2	**Vectris SureScan**	**94.3%** (93.1%, 95.3%)	**90.7%** (88.8%, 92.2%)	**88.8%** (86.1% 91.0%)	-
Surgical Leads					
3986A	**Resume TL**	**84.2%** (73.3%, 91.0%)	**84.2%** (73.3%, 91.0%)	**82.0%** (70.3%, 89.5%)	**82.0%** (70.3%, 89.5%)
3998	**Specify**	**97.1%** (88.7%, 99.3%)	**91.7%** (81.1%, 96.5%)	**88.7%** (75.8% 94.9%)	-
39565	**Specify**	**96.3%** (92.7%, 98.1%)	**95.6%** (91.6%, 97.7%)	**95.6%** (91.6%, 97.7%)	**89.6%** (77.2%, 95.4%)

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**	**69.0%** (64.3%, 73.3%)	**64.7%** (59.6%, 69.3%)	**62.3%** (57.1%, 67.1%)	**62.3%** (57.1%, 67.1%)
3887	**Pisces-Quad**	**71.3%** (57.3%, 81.4%)	**69.0%** (54.6%, 79.6%)	**66.6%** (51.9%, 77.7%)	-
3888	**Pisces-Quad**	**77.7%** (68.9%, 84.3%)	**73.9%** (63.8%, 81.6%)	**73.9%** (63.8%, 81.6%)	**73.9%** (63.8%, 81.6%)
3890	**Pisces-Quad LZ**	**83.8%** (68.8%, 92.0%)	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-
3776	**Pisces-Octad**	**89.4%** (81.1%, 94.2%)	-	-	-
3777	**Pisces-Octad**	**88.1%** (84.2%, 91.1%)	**85.8%** (80.5%, 89.7%)	**83.0%** (76.3%, 88.0%)	**78.7%** (69.2%, 85.5%)
3778	**Pisces-Octad**	**80.4%** (77.6%, 82.9%)	**78.4%** (75.1%, 81.3%)	**74.9%** (70.7%, 78.6%)	**70.7%** (65.2%, 75.5%)
977A1	**Vectris SureScan**	-	-	-	-
977A2	**Vectris SureScan**	-	-	-	-
Surgical Leads					
3986A	**Resume TL**	**82.0%** (70.3%, 89.5%)	**75.5%** (60.6%, 85.4%)	-	-
3998	**Specify**	-	-	-	-
39565	**Specify**	-	-	-	-

Device Survival Probability (95% Confidence Interval) – *Table 3 of 3*						
Model Number	**Family**	**9 yrs**	**10 yrs**	**11 yrs**	**12 yrs**	**13 yrs**
Percutaneous Leads						
3487A	**Pisces-Quad**	**56.3%** (50.3%, 61.8%)	**53.7%** (47.5%, 59.5%)	**50.6%** (44.0%, 56.8%)	**46.8%** (39.5%, 53.8%)	**46.8%** (39.5%, 53.8%)
3887	**Pisces-Quad**	-	-	-	-	-
3888	**Pisces-Quad**	**73.9%** (63.8%, 81.6%)	**73.9%** (63.8%, 81.6%)	**73.9%** (63.8%, 81.6%)	-	-
3890	**Pisces-Quad LZ**	-	-	-	-	-
3891	**Pisces-Quad LZ**	-	-	-	-	-
3776	**Pisces-Octad**	-	-	-	-	-
3777	**Pisces-Octad**	**74.4%** (63.4%, 82.6%)	**74.4%** (63.4%, 82.6%)	-	-	-
3778	**Pisces-Octad**	**70.7%** (65.2%, 75.5%)	-	-	-	-
977A1	**Vectris SureScan**	-	-	-	-	-
977A2	**Vectris SureScan**	-	-	-	-	-
Surgical Leads						
3986A	**Resume TL**	-	-	-	-	-
3998	**Specify**	-	-	-	-	-
39565	**Specify**	-	-	-	-	-

Extensions

From June 2004 to the report cut-off date of October 31, 2017, there were 3,364 extensions followed in the registry. Differences between the total number of extensions versus spinal cord neurostimulators (N=5,305) were due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 88,699 months (7,392 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	**Number of Extensions (%)**
37081 (1x8)	1,427 (42.4%)
37082 (bifurcated stretch coil)	628 (18.7%)
37083 (single stretch coil)	228 (6.8%)
Other/Unspecified	17 (0.5%)
Extensions No Longer Manufactured	
7489 (Low profile quadripolar)	752 (22.4%)
7495 (quadripolar in-line)	270 (8.0%)
7472 (bifurcated 1x8)	24 (0.7%)
7496 (quadripolar)	9 (0.3%)
7471 (1x8)	9 (0.3%)
Total	**3,364 (100%)**

Extension Events

There were 45 product performance-related events with an underlying reported etiology related to the extension. This includes 35 events with an extension etiology and 10 events with both an extension and other etiology (including device and non-device etiologies). Of these events, the majority were extension fractures (n=17). Of the 45 events, 36 were the initial product performance event that affected extension survival estimates.

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 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:

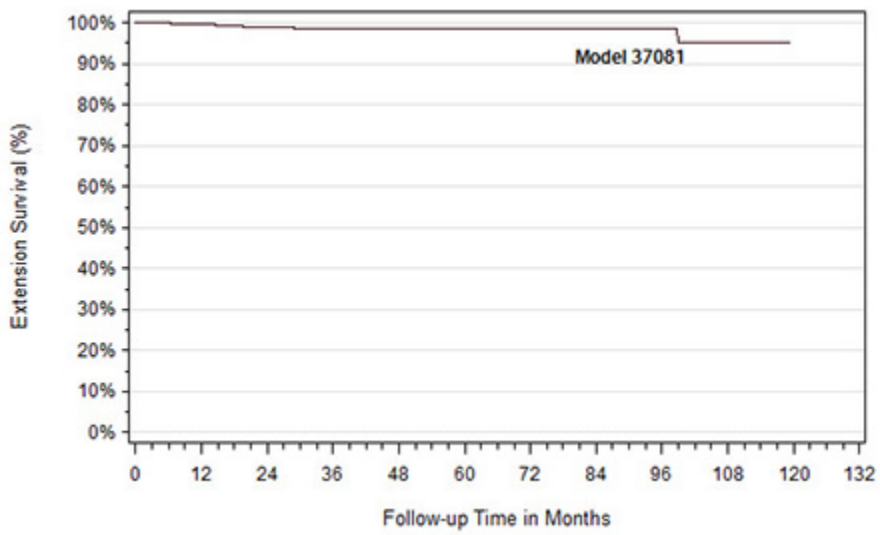
- 36 had follow-up time cut-off due to product performance-related events.
- 2,659 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, or therapy suspended.
- 669 were free from product performance-related events 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.

Model 37081: Survival from Extension Events

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



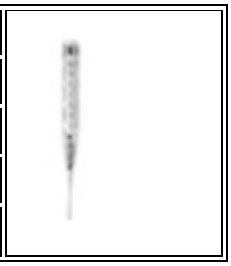
View Larger Image

Extension Characteristics	
Model Number	37081
FDA Approval Date	Apr 2005
Extensions Enrolled	1,427
Extensions Currently Active in Study	401
Device Events	14
Cumulative Months of Follow-up	33,949

Model 37081 Extension: Event Summary Table	
Extension Event	**Total**
Extension fracture	6
High impedance	6
Extension migration	1
Low impedance	1
Total Extension Events	**14**

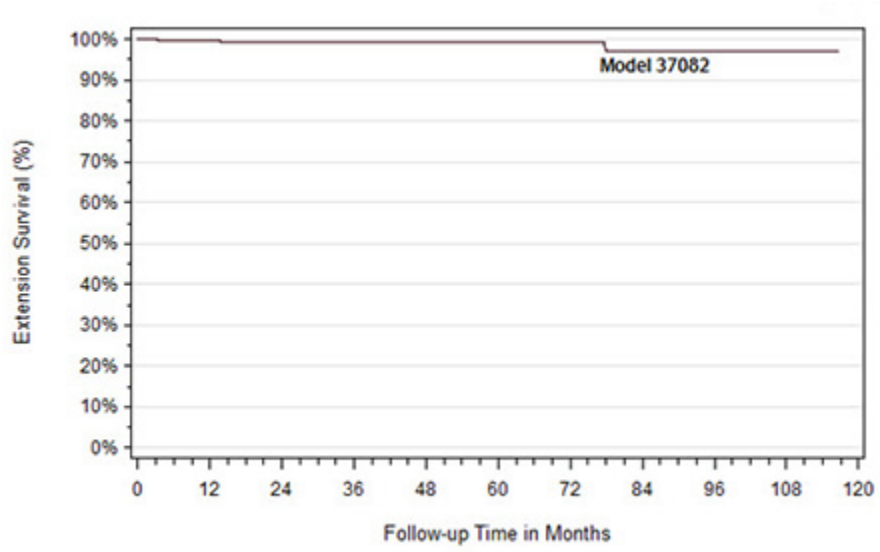
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.8%** (99.2%, 99.9%)	780
2 yrs	**98.9%** (97.8%, 99.5%)	484
3 yrs	**98.4%** (97.0%, 99.2%)	301
4 yrs	**98.4%** (97.0%, 99.2%)	226
5 yrs	**98.4%** (97.0%, 99.2%)	154
6 yrs	**98.4%** (97.0%, 99.2%)	124
7 yrs	**98.4%** (97.0%, 99.2%)	85
8 yrs	**98.4%** (97.0%, 99.2%)	71
9 yrs	**95.1%** (87.7%, 98.1%)	44
10 yrs	**95.1%** (87.7%, 98.1%)	26

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.



View Larger Image

Extension Characteristics	
Model Number	37082
FDA Approval Date	Mar 2006
Extensions Enrolled	628
Extensions Currently Active in Study	67
Device Events	5
Cumulative Months of Follow-up	20,484

Model 37082 Extension: Event Summary Table	
Extension Event	**Total**
Device connection issue	2
Extension fracture	2
Paraesthesia[a]	1
Total Extension Events	**5**

[a] Reported as shocking sensation at battery/extension connection.

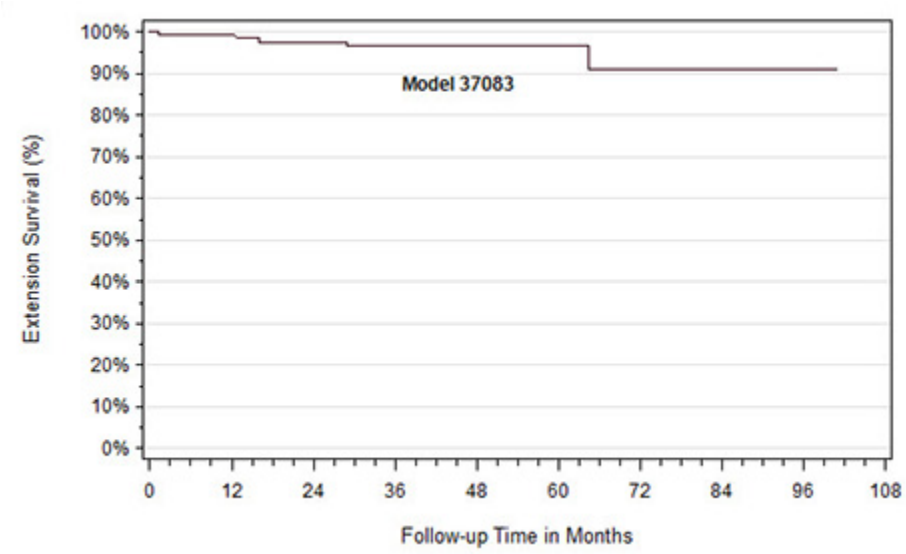
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.4%, 99.9%)	415
2 yrs	**99.3%** (98.0%, 99.8%)	293
3 yrs	**99.3%** (98.0%, 99.8%)	202
4 yrs	**99.3%** (98.0%, 99.8%)	143
5 yrs	**99.3%** (98.0%, 99.8%)	120
6 yrs	**99.3%** (98.0%, 99.8%)	99
7 yrs	**97.1%** (91.6%, 99.0%)	77
8 yrs	**97.1%** (91.6%, 99.0%)	50
9 yrs	**97.1%** (91.6%, 99.0%)	35
at 117 mo	**97.1%** (91.6%, 99.0%)	22

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.



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Extension Characteristics	
Model Number	37083
FDA Approval Date	Sep 2005
Extensions Enrolled	228
Extensions Currently Active in Study	44
Device Events	7
Cumulative Months of Follow-up	6,531

Model 37083 Extension: Event Summary Table	
Extension Event	**Total**
Extension fracture	5
Device failure[a]	1
Extension migration	1
Total Extension Events	**7**

[a] Reported as extension failure

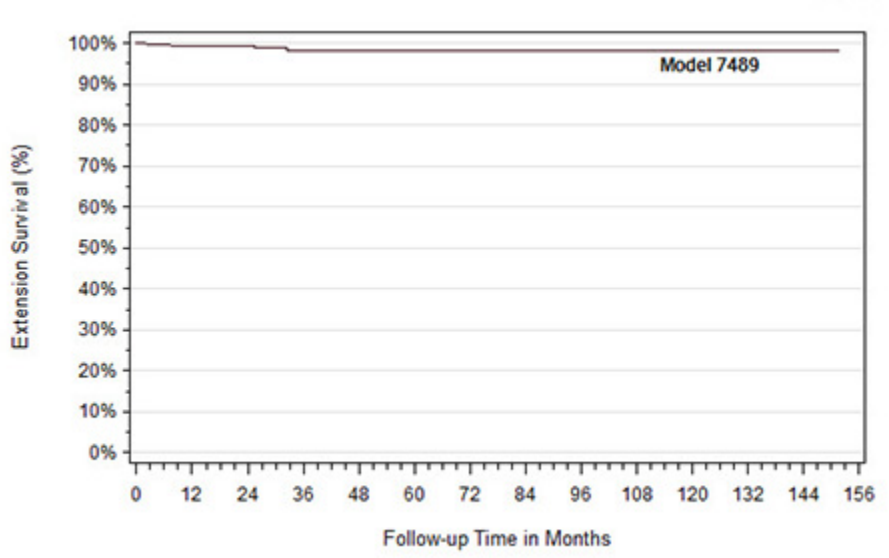
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.2%** (94.3%, 99.9%)	131
2 yrs	**97.5%** (92.6%, 99.2%)	108
3 yrs	**96.5%** (90.9%, 98.7%)	63
4 yrs	**96.5%** (90.9%, 98.7%)	46
5 yrs	**96.5%** (90.9%, 98.7%)	34
6 yrs	**91.0%** (78.5%, 96.4%)	29
7 yrs	**91.0%** (78.5%, 96.4%)	28
8 yrs	**91.0%** (78.5%, 96.4%)	24
at 102 mo	**91.0%** (78.5%, 96.4%)	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	

Model 7489: Survival from Extension Events

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



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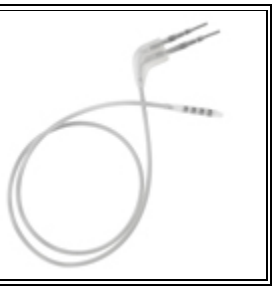
Extension Characteristics	
Model Number	7489
FDA Approval Date	Oct 2002
Extensions Enrolled	752
Extensions Currently Active in Study	87
Device Events	5
Cumulative Months of Follow-up	18,823

Model 7489 Extension: Event Summary Table	
Extension Event	**Total**
Extension fracture	2
Extension migration	2
Medical device complication[a]	1
Total Extension Events	**5**

[a] Reported as unknown problem with extension

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.1%** (96.5%, 99.8%)	294
2 yrs	**99.1%** (96.5%, 99.8%)	290
3 yrs	**98.3%** (95.6%, 99.4%)	205
4 yrs	**98.3%** (95.6%, 99.4%)	138
5 yrs	**98.3%** (95.6%, 99.4%)	103
6 yrs	**98.3%** (95.6%, 99.4%)	83
7 yrs	**98.3%** (95.6%, 99.4%)	64
8 yrs	**98.3%** (95.6%, 99.4%)	62
9 yrs	**98.3%** (95.6%, 99.4%)	61
10 yrs	**98.3%** (95.6%, 99.4%)	62
11 yrs	**98.3%** (95.6%, 99.4%)	64
12 yrs	**98.3%** (95.6%, 99.4%)	49
at 153 mo	**98.3%** (95.6%, 99.4%)	20

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	

Extension Survival Summary

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	1,427	401	14	33,949
37082	37082	Mar 2006	628	67	5	20,484
37083	37083	Sep 2005	228	44	7	6,531
7489	7489	Oct 2002	752	87	5	18,823

[a] There were a total of 45 extension-related events reported to the registry, but only 31 events are included in this summary table. The remaining extension-related events occurred in an extension model for which no device survival data is presented due to an insufficient number of enrolled devices (n=5), or were subsequent device events (i.e. additional events that occurred after the survival censoring event) 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**	**6 yrs**
37081	**99.8%** (99.2%, 99.9%)	**98.9%** (97.8%, 99.5%)	**98.4%** (97.0%, 99.2%)	**98.4%** (97.0%, 99.2%)	**98.4%** (97.0%, 99.2%)	**98.4%** (97.0%, 99.2%)
37082	**99.6%** (98.4%, 99.9%)	**99.3%** (98.0%, 99.8%)	**99.3%** (98.0%, 99.8%)	**99.3%** (98.0%, 99.8%)	**99.3%** (98.0%, 99.8%)	**99.3%** (98.0%, 99.8%)
37083	**99.2%** (94.3%, 99.9%)	**97.5%** (92.6%, 99.2%)	**96.5%** (90.9%, 98.7%)	**96.5%** (90.9%, 98.7%)	**96.5%** (90.9%, 98.7%)	**91.0%** (78.5%, 96.4%)
7489	**99.1%** (96.5%, 99.8%)	**99.1%** (96.5%, 99.8%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)

Device Survival Probability (95% Confidence Interval) – *Table 2 of 2*						
Model Number	**7 yrs**	**8 yrs**	**9 yrs**	**10 yrs**	**11 yrs**	**12 yrs**
37081	**98.4%** (97.0%, 99.2%)	**98.4%** (97.0%, 99.2%)	**95.1%** (87.7%, 98.1%)	**95.1%** (87.7%, 98.1%)	-	-
37082	**97.1%** (91.6%, 99.0%)	**97.1%** (91.6%, 99.0%)	**97.1%** (91.6%, 99.0%)	-	-	-
37083	**91.0%** (78.5%, 96.4%)	**91.0%** (78.5%, 96.4%)	-	-	-	-
7489	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)	**98.3%** (95.6%, 99.4%)

2017 Medtronic Product Performance Report: Data through October 31, 2017.

Deep Brain Stimulation Systems

Study Participants

Centers

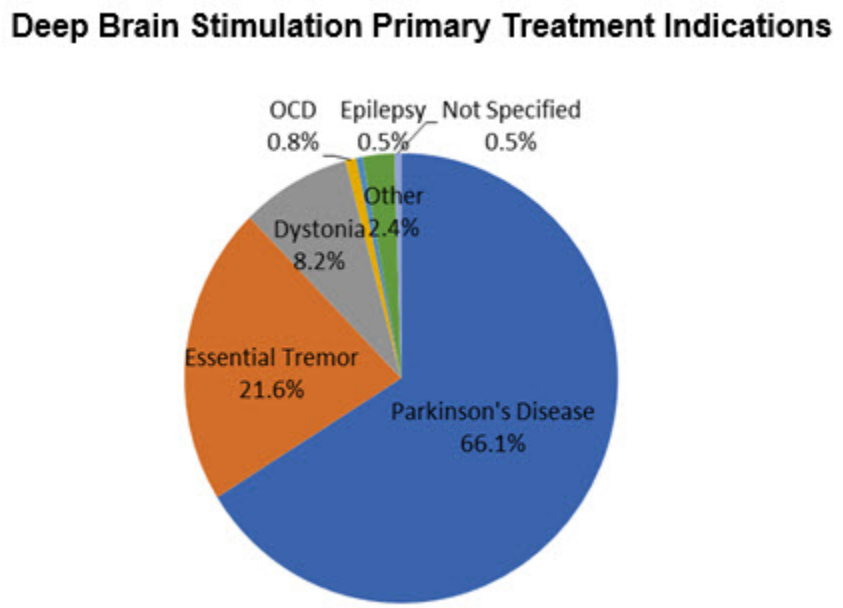
The following deep brain stimulation tables and graphs were generated based on data collected between July 2009 and the report cut-off date of October 31, 2017. Thirty-eight centers, including sites in North America, Europe and South America, have enrolled and contributed patient data to the deep brain stimulation section of the report.

Patients

Of the 2,459 deep brain stimulation patients enrolled, 66.1% were implanted for the treatment of Parkinson's Disease, 21.6% were implanted for the treatment of Essential Tremor, 8.2% were implanted for the treatment of Dystonia, 0.8% were implanted for the treatment of Obsessive Compulsive Disorder, 0.5% were implanted for the treatment of Epilepsy, 2.4% were implanted for the treatment of some other indication, and 0.5% were implanted for indications that were not specified in the database at the time of data cut-off.

As outlined in the PSR protocol, enrollment may be limited when the number of patients enrolled are sufficient to characterize product performance. As such an enrollment guide was implemented in the Fall of 2016, limiting future enrollment of Parkinson's disease patients. The enrollment guide was implemented using a staged approach across all sites. Therapy-naïve patients in other indications (e.g., essential tremor, dystonia) continue to be enrolled to generate evidence for those indications.

Primary DBS Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Parkinson's disease	1,626 (66.1%)
Essential Tremor	530 (21.6%)
Dystonia	201 (8.2%)
OCD	20 (0.8%)
Epilepsy	12 (0.5%)
Other	58 (2.4%)
Not specified	12 (0.5%)
Total Subjects	**2,459**

[a] Refer to product labeling for approved indications.

Event Summary

There were 205 product performance events reported between July 2009 and October 31, 2017, in patients with deep brain stimulation systems. These events represent 17.9% of the total reported events (205/1,166). These events occurred in 126 of the 2,459 total patients (5.1%) enrolled and are presented graphically within this report (e.g. events per patient years as well as survival curves).

In addition, there were 957 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the deep brain stimulation systems. There were also 128 deaths reported for patients with deep brain stimulation systems. None of these deaths were reported as a direct result of a product performance event. All deaths are adjudicated for relatedness by a clinical events committee (CEC) comprised of independent physicians who review events for seriousness and relatedness.

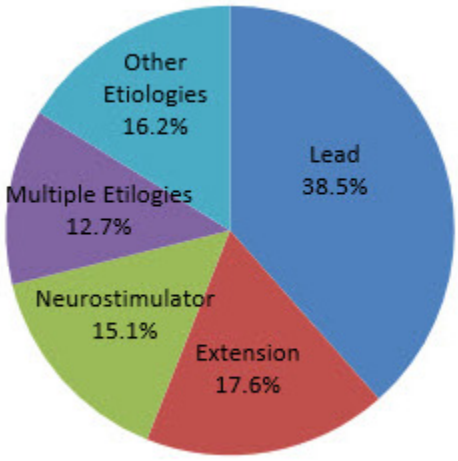
Deep Brain Stimulation System Product Performance Events				
Event[a]	**Number of Product Performance Events**	**Events per 100 Patient Years**	**Number of Patients with Event[b]**	**Percent of Patients with Event (N=2,459)**
High impedance	94	1.92	53	2.2%
Lead migration/dislodgement	24	0.49	18	0.7%
Device malfunction	16	0.33	10	0.4%
Lead fracture	14	0.29	14	0.6%
Medical device complication[c]	11	0.22	9	0.4%
Extension migration	9	0.18	6	0.2%
Low impedance	7	0.14	5	0.2%
Impedance increased	6	0.12	2	0.1%
Extension fracture	5	0.10	4	0.2%
Neurostimulator unable to recharge[d]	5	0.10	5	0.2%
Device breakage[e]	4	0.08	4	0.2%
Premature battery depletion	3	0.06	3	0.1%
Battery recharge issue	2	0.04	2	0.08%
Device connection issue	2	0.04	1	0.04%
Antenna cable breakage	1	0.02	1	0.04%
Device migration[f]	1	0.02	1	0.04%
Electromagnetic interference	1	0.02	1	0.04%
Totals	**205**	**4.18**	**126**	**5.12%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[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, 2 events for extension twisting, 1 event reported as lead open circuit, 1 antenna heating while recharging, 1 suspicion of heating of the antenna while recharging, 1 undesirable interaction with external electronic device, 1 short circuit, 1 open circuit, and 1 issue with controller not communicating.
[d] There were 360 patients that used rechargeable neurostimulators for DBS in the registry. A total of 1.39% (5/360) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.
[e] Related to the external recharger
[f] Related to the adaptor

A total of 79 (38.5%) of the 205 product performance events were related to the lead, 36 (17.6%) were related to the extension, 31 (15.1%) were related to the neurostimulator, 26 (12.7%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, 16 (7.8%) were related to external device components, 9 (4.4%) were related to surgery/anesthesia, 4 (2.0%) were related to the recharging process, 3 (1.5%) were related to programming/stimulation, and 1 (0.4%) was related to incisional site/device tract.

Relatedness is reported by the physician. In cases where the CEC has adjudicated relatedness differently from the site, the CEC adjudication is used in this report for analysis purposes. However, both the site's reporting and the CEC's adjudication remain in the database.

Product Performance Events by Relatedness[a]



[a] Each event could have more than one etiology.

Events not-related to a product-performance issue are characterized below. Due to the differences in event collection between the ISPR and PSR protocols, events per patient years and other rates are not calculated for non-product performance events.

Events are categorized by an event group term as noted in bold in the table below.

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**
Movement disorders (including parkinsonism)	**199**
Tremor	82
Dyskinesia	47
Dystonia	27
Freezing phenomenon	11
Parkinson's disease	9
Bradykinesia	7
Other[c]	16
Neurological disorders Not Elsewhere Classified (NEC)	**133**
Dysarthria	37
Speech disorder	31
Paraesthesia	26
Balance disorder	23
Sensory disturbance	7
Other[c]	9
Infections - pathogen unspecified	**100**
Medical device site infection	77
Wound infection	12
Other[c]	11
Complications associated with device	**54**
Medical device site pain	15
Medical device site erosion	13
Medical device site inflammation	6
Other[c]	20

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Depressed mood disorders and disturbances	**52**
Depression[d]	51
Other[c]	1
General system disorders NEC	**44**
Gait disturbance	31
Pain	5
Other[c]	8
Device issues	**43**
Neurostimulator migration	25
Other[c]	18
Procedural related injuries and complications NEC	**33**
Wound dehiscence	17
Other[c]	16
Injuries NEC	**26**
Fall	9
Subdural haematoma	7
Other[c]	10
Anxiety disorders and symptoms	**22**
Anxiety	17
Other[c]	5
Central nervous system vascular disorders	**22**
Cerebral haematoma	8
Other[c]	14
Mood disorders and disturbances NEC	**19**
Apathy	8

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Affect lability	6
Other[c]	5
Deliria (including confusion)	**14**
Confusional state	10
Other[c]	4
Psychiatric and behavioural symptoms NEC	**14**
Abnormal behaviour	14
Musculoskeletal and connective tissue disorders NEC	**12**
Other[c]	12
Physical examination and organ system status topics	**12**
Weight increased	12
Bacterial infectious disorders	**11**
Staphylococcal infection	8
Other[c]	3
Seizures (including subtypes)	**11**
Seizure	5
Other[c]	6
Mental impairment disorders	**10**
Cognitive disorder	6
Other[c]	4
Psychiatric disorders NEC	**10**
Mental disorder	6
Other[c]	4
Disturbances in thinking and perception	**9**
Hallucination	9

Deep Brain Stimulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Therapeutic and nontherapeutic effects	**9**
Other[c]	9
Muscle disorders	**8**
Other[c]	5
Suicidal and self-injurious behaviours NEC	**8**
Suicidal ideation	5
Administration site reactions	**7**
Other[c]	7
Medication errors and other product use errors and issues	**7**
Other[c]	7
Gastrointestinal signs and symptoms	**5**
Other[c]	5
Headaches	**5**
Headache / Migraine[e]	5
Other[c]	**58**
Total	**957**

[a]Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Composed of event codes with fewer than five events each.
[d] Includes depression (n=45), depression suicidal (n=4), and depressed mood (n=2).
[e] Includes headache (n=3) and migraine (n=2).

There were 128 deaths reported for patients with deep brain stimulation systems. None of these deaths were reported as a direct result of a product performance event. A total of 105 (82.0%) deaths occurred in patients receiving therapy for Parkinson's disease, 19 (14.8%) for Essential Tremor, and four (3.1%) for Dystonia.

Number of Reports of Death by Primary Indication	
Primary Indication[a]	**N (%) of deaths**
Parkinson's disease	105 (82.0%)

Number of Reports of Death by Primary Indication	
Essential Tremor	19 (14.8%)
Dystonia	4 (3.1%)
Total	**128**

[a] Refer to product labeling for approved indications

Neurostimulators

From July 2009 to the report cut-off date of October 31, 2017, 3,150 deep brain neurostimulators were followed in the registry. The difference between the total number of patients (N=2,459) 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 62,527 months (5,211 years). The table below provides the number and percentage of neurostimulators by model.

Neurostimulators by Model	
Model	**Number of Neurostimulators (%)**
Activa PC (37601)	1,865 (59.2%)
Activa SC (37602/37603)	814 (25.8%)
Activa RC (37612)	364 (11.6%)
Other/Unspecified [a]	28 (0.9%)
Neurostimulators No Longer Manufactured	
Soletra (7426)	67 (2.1%)
Kinetra (7428)	12 (0.4%)
Total	**3,150 (100%)**

[a] Other includes Activa PC+S (n=10) and non-Activa systems used for DBS (n=18).

Neurostimulator Events

Of the total of 205 product performance events, there were 34 product performance-related events with an underlying reported etiology related to deep brain neurostimulator function.

- Of these, 31 events had a neurostimulator etiology (13.7%), and 3 had both a neurostimulator and other etiology (including device and non-device etiologies).
- All 34 of these events were the initial product performance event that affected neurostimulator survival estimates.

For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) is 49/733 (6.7%). 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.

- Two of the 34 product performance-related events were confirmed by Medtronic RPA as premature battery depletion.
- The remaining 32 deep brain neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as high impedance (n=15), device malfunction (n=7), medical device complication (n=3), impedance increased (n=2), device connection issue (n=1), electromagnetic interference (n=1), low impedance (n=1) extension migration (n=1) and premature battery depletion (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 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:

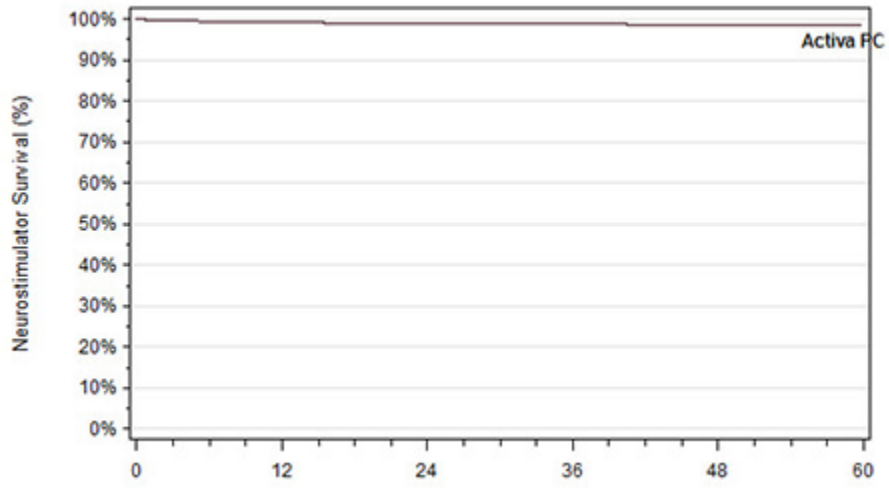
- 34 had follow-up time cut-off due to a product performance-related event.
- 1,258 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 1,858 were free 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.

Model 37601 Activa PC: 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 PC
FDA Approval Date	Apr 2009
Neurostimulators Enrolled	1,865
Neurostimulators Currently Active in Study	1,169
Device Events	21
Cumulative Months of Follow-up	37,204

Model Activa PC: Event Summary Table	
Neurostimulator Event	**Total**
High impedance [a]	8
Device malfunction	4
Impedance increased [b]	2
Medical device complication [c]	2
Premature battery depletion	2
Device connection issue	1
Electromagnetic interference	1
Low impedance	1
Total Neurostimulator Events	**21**

[a] Reported as high impedance attributed to neurostimulator, leads, extensions.
[b] Reported as increased impedance attributed to the neurostimulator and extension.
[c] Reported as undesirable interaction with external electronic device and open circuit.

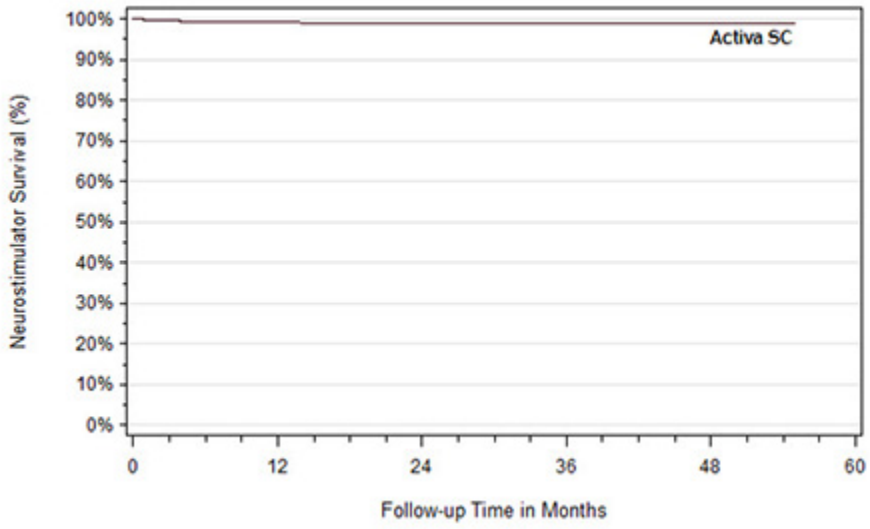
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.2%** (98.7%, 99.6%)	1,197
2 yrs	**98.8%** (98.1%, 99.3%)	647
3 yrs	**98.8%** (98.1%, 99.3%)	300
4 yrs	**98.4%** (96.8%, 99.2%)	107
5 yrs	**98.4%** (96.8%, 99.2%)	34

Model 37601 Activa PC: Specifications

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
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	814
Neurostimulators Currently Active in Study	426
Device Events	6
Cumulative Months of Follow-up	15,817

Model Activa SC: Event Summary Table	
Neurostimulator Event	**Total**
High impedance[a]	3
Device malfunction	1
Medical device complication[b]	1
Premature battery depletion	1
Total Neurostimulator Events	**6**

[a] Reported as high impedance attributed to neurostimulator, leads and extensions.
[b] Reported as short circuit.

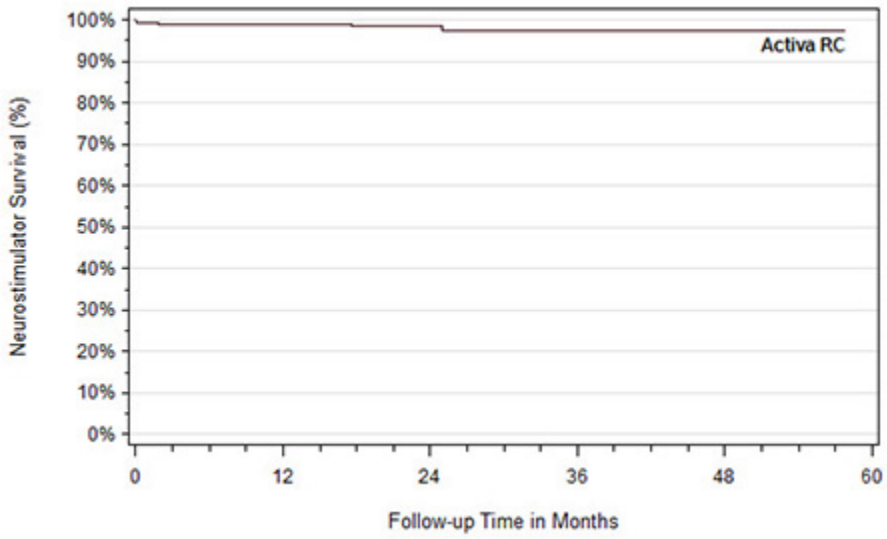
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.3%** (98.2%, 99.7%)	507
2 yrs	**99.0%** (97.9%, 99.6%)	287
3 yrs	**99.0%** (97.9%, 99.6%)	118
4 yrs	**99.0%** (97.9%, 99.6%)	46
at 54 mo	**99.0%** (97.9%, 99.6%)	29

Models 37602 & 37603 Activa SC: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	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
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.



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Deep Brain Neurostimulator Characteristics	
Model Name	Activa RC
FDA Approval Date	Mar 2009
Neurostimulators Enrolled	364
Neurostimulators Currently Active in Study	255
Device Events	5
Cumulative Months of Follow-up	7,249

Model Activa RC: Event Summary Table	
Neurostimulator Event	**Total**
High impedance[a]	3
Device malfunction	1
Extension migration	1
Total Neurostimulator Events	**5**

[a] Reported as high impedance attributed to neurostimulator, leads and extensions.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.1%** (97.1%, 99.7%)	202
2 yrs	**98.4%** (95.7%, 99.4%)	114
3 yrs	**97.5%** (93.6%, 99.1%)	68
4 yrs	**97.5%** (93.6%, 99.1%)	44
at 57 mo	**97.5%** (93.6%, 99.1%)	24

Model 37612 Activa RC: Specifications

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	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

Leads

From July 2009 to the report cut-off date of October 31, 2017, there were 4,045 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=3,150) were due to the fact that some patients were implanted with more than 1 lead or were subsequently re-implanted with a new lead or neurostimulator. The aggregate prospective follow-up time for all leads was 96,979 months (8,082 years). The table below provides the number and percentage of leads by model.

Leads by Model	
Model Number	**Number of Leads (%)**
3389 (compact electrode spacing)	2,310 (57.1%)
3387 (standard electrode spacing)	1,693 (41.9%)
3391 (large electrodes and wide spacing)	25 (0.6%)
Other/Unspecified [a]	17 (0.4%)
Total	**4,045 (100%)**

[a] Includes leads used in non-Activa systems

Lead Events

Of the 205 product performance events, there were 98 product performance-related events with an underlying reported etiology related to the lead.

- Of these, 82 events had a lead etiology (36.3%) and 16 events had both a lead and other etiology (including device and non-device etiologies).
- 72 were the first event attributable to that enrolled lead

Events were characterized as follows: Fifty-four events were high impedance, 17 were lead migration/dislodgment, 16 were lead fracture, 4 were lead low impedance, 2 were device malfunction, 2 were device defective, 2 were extension fractures, and 1 was medical device complication.

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 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:

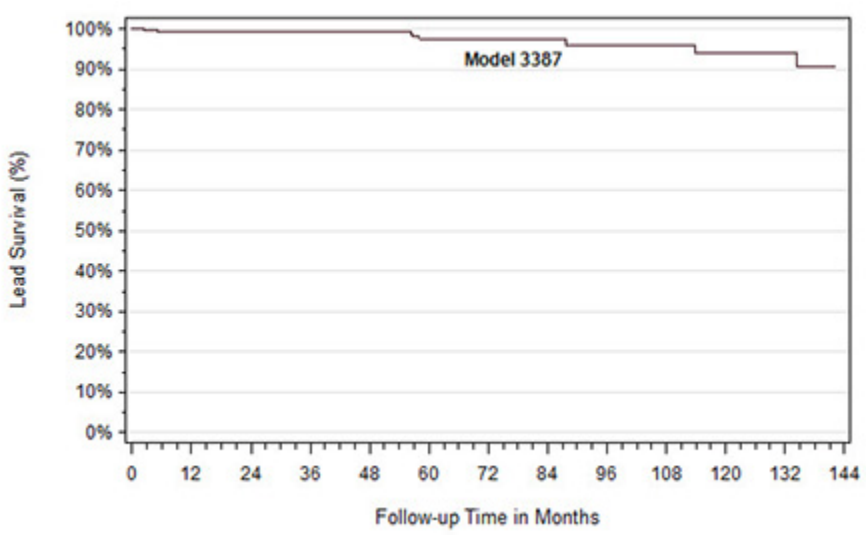
- 72 had follow-up time cut-off due to product performance-related events.
- 1,076 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,897 were free 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.

Model 3387: 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	3387
FDA Approval Date	Jan 2002
Leads Enrolled	1,693
Leads Currently Active in Study	1,156
Device Events	17
Cumulative Months of Follow-up	40,644

Model 3387: Event Summary Table	
Lead Event	**Total**
High impedance	7
Lead migration/dislodgement	4
Lead fracture	3
Low impedance	1
Extension fracture	1
Medical device complication[a]	1
Total Lead Events	**17**

[a] Reported as open circuit of lead.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.3%** (98.6%, 99.6%)	977
2 yrs	**99.1%** (98.4%, 99.5%)	592
3 yrs	**99.1%** (98.4%, 99.5%)	391
4 yrs	**99.1%** (98.4%, 99.5%)	226
5 yrs	**97.4%** (94.4%, 98.8%)	154
6 yrs	**97.4%** (94.4%, 98.8%)	81
7 yrs	**97.4%** (94.4%, 98.8%)	61
8 yrs	**96.0%** (90.6%, 98.3%)	63*
9 yrs	**96.0%** (90.6%, 98.3%)	52

10 yrs	**94.1%** (86.5%, 97.5%)	45
11 yrs	**94.1%** (86.5%, 97.5%)	32
at 138 mo	**90.7%** (78.3%, 96.2%)	20

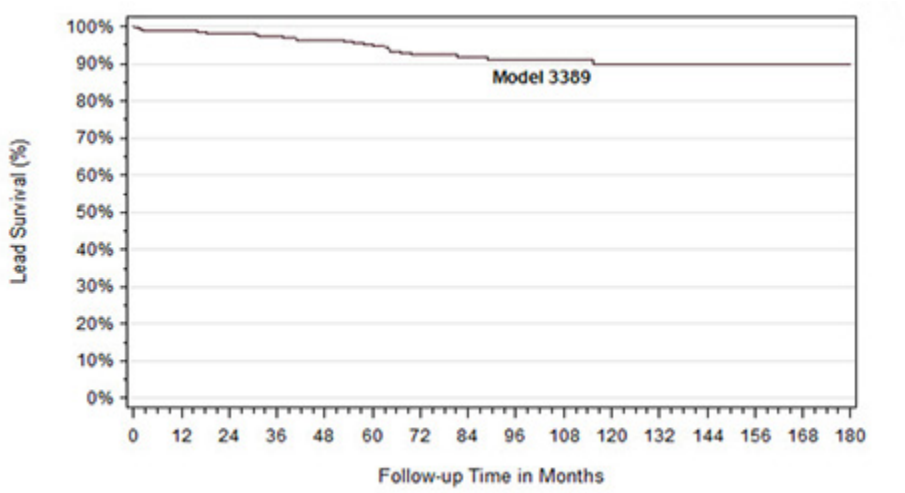
* Due to enrollment of replacement patients with previously implanted leads, sample size may increase at later timepoints.

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.



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Lead Characteristics	
Model Number	3389
FDA Approval Date	Sep 1999
Leads Enrolled	2,310
Leads Currently Active in Study	1,745
Device Events	52
Cumulative Months of Follow-up	55,327

Model 3389: Event Summary Table	
Lead Event	**Total**
High impedance	34
Lead migration/dislodgement	7
Lead fracture	6
Low impedance	3
Device defective	1
Extension fracture	1

Total Lead Events	52

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.8%** (98.2%, 99.3%)	1243
2 yrs	**98.1%** (97.2%, 98.7%)	775
3 yrs	**97.3%** (96.1%, 98.2%)	494
4 yrs	**96.1%** (94.3%, 97.3%)	332
5 yrs	**95.0%** (92.8%, 96.6%)	240
6 yrs	**92.4%** (89.2%, 94.8%)	171
7 yrs	**91.8%** (88.2%, 94.3%)	136
8 yrs	**91.1%** (87.2%, 93.9%)	120
9 yrs	**91.1%** (87.2%, 93.9%)	89
10 yrs	**89.8%** (84.8%, 93.2%)	52
11 yrs	**89.8%** (84.8%, 93.2%)	46
12 yrs	**89.8%** (84.8%, 93.2%)	39
13 yrs	**89.8%** (84.8%, 93.2%)	36
14 yrs	**89.8%** (84.8%, 93.2%)	25

at 177 mo	**89.8%** (84.8%, 93.2%)	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

Lead Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Leads Enrolled**	**Leads Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**
3387	**3387**	Jan 2002	1,693	1,156	17	40,644
3389	**3389**	Sep 1999	2,310	1,745	52	55,327

[a] There were a total of 98 lead-related events reported to the registry, but only 69 events included in this summary table. The remaining lead-related events occurred in a lead model for which no device survival data are presented due to an insufficient number of enrolled devices (n=3) or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval) – *Table 1 of 3*						
Model Number	**Family**	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**
3387	**3387**	**99.3%** (98.6%, 99.6%)	**99.1%** (98.4%, 99.5%)	**99.1%** (98.4%, 99.5%)	**99.1%** (98.4%, 99.5%)	**97.4%** (94.4%, 98.8%)
3389	**3389**	**98.8%** (98.2%, 99.3%)	**98.1%** (97.2%, 98.7%)	**97.3%** (96.1%, 98.2%)	**96.1%** (94.3%, 97.3%)	**95.0%** (92.8%, 96.6%)

Device Survival Probability (95% Confidence Interval) – *Table 2 of 3*						
Model Number	**Family**	**6 yrs**	**7 yrs**	**8 yrs**	**9 yrs**	**10 yrs**
3387	**3387**	**97.4%** (94.4%, 98.8%)	**97.4%** (94.4%, 98.8%)	**96.0%** (90.6%, 98.3%)	**96.0%** (90.6%, 98.3%)	**94.1%** (86.5%, 97.5%)
3389	**3389**	**92.4%** (89.2%, 94.8%)	**91.8%** (88.2%, 94.3%)	**91.1%** (87.2%, 93.9%)	**91.1%** (87.2%, 93.9%)	**89.8%** (84.8%, 93.2%)

Device Survival Probability (95% Confidence Interval) – *Table 3 of 3*						
Model Number	**Family**	**11 yrs**	**12 yrs**	**13 yrs**	**14 yrs**	**at 177 mo**
3387	**3387**	**94.1%** (86.5%, 97.5%)	-	-	-	-
3389	**3389**	**89.8%** (84.8%, 93.2%)	**89.8%** (84.8%, 93.2%)	**89.8%** (84.8%, 93.2%)	**89.8%** (84.8%, 93.2%)	**89.8%** (84.8%, 93.2%)

Extensions

From July 2009 to the report cut-off date of October 31, 2017, there were 4,084 extensions followed in the registry. Differences between the total number of extensions versus the total number of neurostimulators (N=3,150) were due to the fact that some patients were implanted with more than 1 extension or subsequently re-implanted with an extension or neurostimulator replacement. In addition, the number of extensions does not equal the number of leads (N=4,045) because some patients were re-implanted with a new lead using existing extensions. The aggregate prospective follow-up time for all extensions was 96,076 months (8,006 years).The table below provides the number and percentage of extensions by model.

Extensions by Model	
Model Number	**Number of Extensions (%)**
37086 [a] (quadripolar stretch)	3,503 (85.8%)
Other/Unspecified [b]	113 (2.8%)
Extensions No Longer Manufactured	
7482 [c] (quadripolar)	468 (11.5%)
Total	**4,084 (100%)**

[a] Includes Models 37085 and 37086
[b] Includes extensions for other legacy stimulation systems
[c] Includes Models 7482 and 7482a

Extension Events

Of the total of 205 product performance events, there were 42 product performance-related events with an underlying reported etiology related to the extension.

- Of these, 36 events had an extension etiology (15.9%) and 6 events had both an extension and other etiology (including device and non-device etiologies).
- 39 were the first event attributable to that enrolled extension.

Events are characterized as follows: Twenty events were high impedance attributed to the extensions, 5 were extension migrations, 4 were medical device complications, 3 were extension fractures, 3 were increased impedance attributed to an extension, 2 were device malfunctions, 2 were device migrations attributed to the extensions, 2 were low impedance attributed to an extension, and 1 was a device connection issue.

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 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:

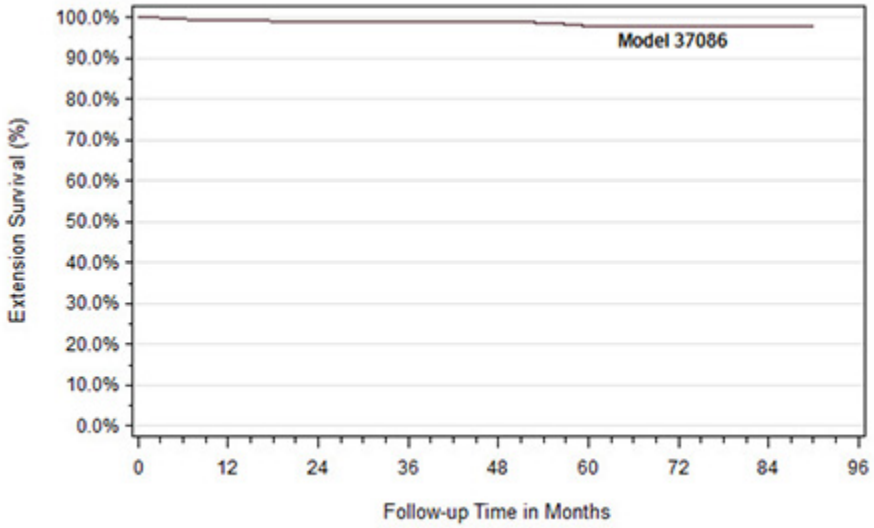
- 39 extensions had follow-up time cut-off due to product performance-related events.
- 1,137 were censored in the survival analysis for the following reasons: patient expired, extension explanted, site termination, patient discontinued, or therapy suspended.
- 2,908 were free from product performance-related 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.

Model 37086: 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	37086
FDA Approval Date	Sep 2009
Extensions Enrolled	3,503
Extensions Currently Active in Study	2,531
Device Events	32
Cumulative Months of Follow-up	80,005

Model 37086 Extension: Event Summary Table	
Extension Event	**Total**
High impedance	18
Extension migration	5
Medical device complication[a]	4
Extension fracture	2
Low impedance	2
Impedance increased[b]	1
Total Extension Events	**32**

[a] Includes 2 events for extension cable loop, and 2 events for twisting of extensions.
[b] Reported as increased impedance attributed to the neurostimulator and extension.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.5%** (99.1%, 99.7%)	2,180
2 yrs	**99.1%** (98.6%, 99.4%)	1,324
3 yrs	**98.9%** (98.4%, 99.3%)	832
4 yrs	**98.8%** (98.1%, 99.2%)	471
5 yrs	**97.8%** (96.2%, 98.8%)	257
6 yrs	**97.8%** (96.2%, 98.8%)	109
7 yrs	**97.8%** (96.2%, 98.8%)	36
at 90 mo	**97.8%** (96.2%, 98.8%)	21

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

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	3,503	2,531	32	80,005

Device Survival Probability (95% Confidence Interval)							
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**	**7 yrs**
37086[b]	**99.5%** (99.1%, 99.7%)	**99.1%** (98.6%, 99.4%)	**98.9%** (98.4%, 99.3%)	**98.8%** (98.1%, 99.2%)	**97.8%** (96.2%, 98.8%)	**97.8%** (96.2%, 98.8%)	**97.8%** (96.2%, 98.8%)

[a] There were a total of 42 extension-related events reported to the registry, but only 32 events included in this summary table. The remaining events occurred in an extension model for which no device data are presented due to an insufficient number of enrolled devices (n=7) or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates or attributable to other models not included on this table.
[b] Includes Models 37085 and 37086.

2017 Medtronic Product Performance Report: Data through October 31, 2017.

SACRAL NEUROMODULATION SYSTEMS

Study Participants

Centers

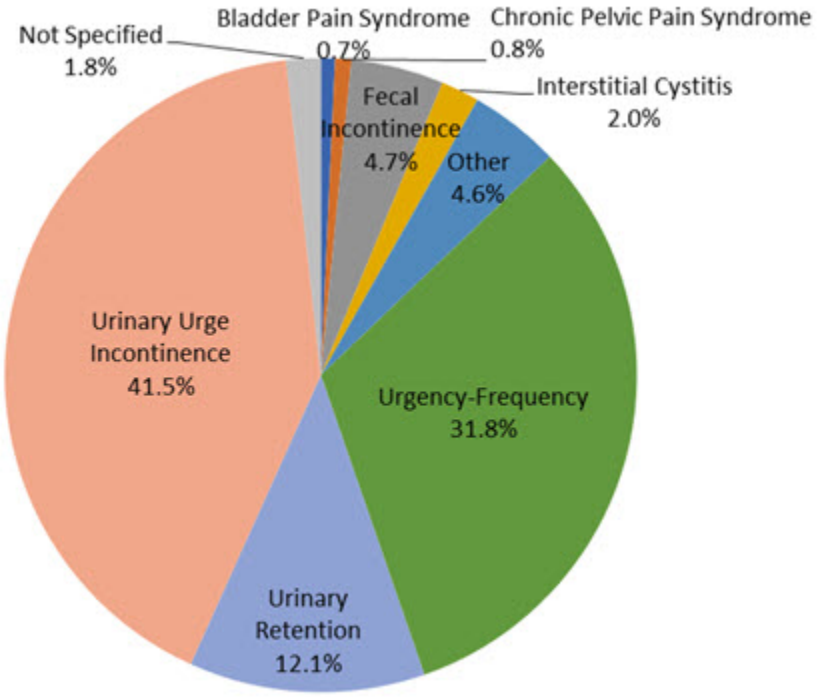
The following sacral neuromodulation tables and graphs were generated based on data collected between April 2010 and the report cut-off date of October 31, 2017. Twenty centers in North and South America enrolled and contributed patients to the sacral neuromodulation section of the report.

Patients

Of the 969 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 41.5% were implanted for the treatment of urinary urge incontinence, 31.8% were implanted for the treatment of urgency-frequency, 12.1% were implanted for the treatment of urinary retention, 4.7% were implanted for the treatment of fecal incontinence, 2.0% were implanted for the treatment of interstitial cystitis, 0.8% were implanted for the treatment of chronic pelvic pain syndrome, 0.7% were implanted for the treatment of bladder pain syndrome, 4.6% were implanted for the treatment of some other indication, and 1.8% were implanted for indications that were not specified in the database at the time of data cut-off.

Primary SNM Treatment Indications

Sacral Neuromodulation Primary Treatment Indications



Primary Treatment Indication[a]	Total Enrolled Patients (Percent)
Urinary Urge Incontinence	402 (41.5%)
Urgency-Frequency	308 (31.8%)
Urinary Retention	117 (12.1%)
Fecal Incontinence	46 (4.7%)
Interstitial Cystitis	19 (2.0%)
Chronic Pelvic Pain Syndrome	8 (0.8%)
Bladder Pain Syndrome	7 (0.7%)
Other	45 (4.6%)
Not Specified	17 (1.8%)
Total Patients	**969**

[a] Refer to product labeling for approved indications.

Event Summary

There were 90 product-performance events reported between April 2010 and October 31, 2017, in patients with sacral neuromodulation systems. These events represent 17.0% of the total reported events (90/530). These events occurred in 76 of the 969 total patients (7.8%) enrolled and are presented graphically within this report (e.g. events per patient years as well as survival curves).

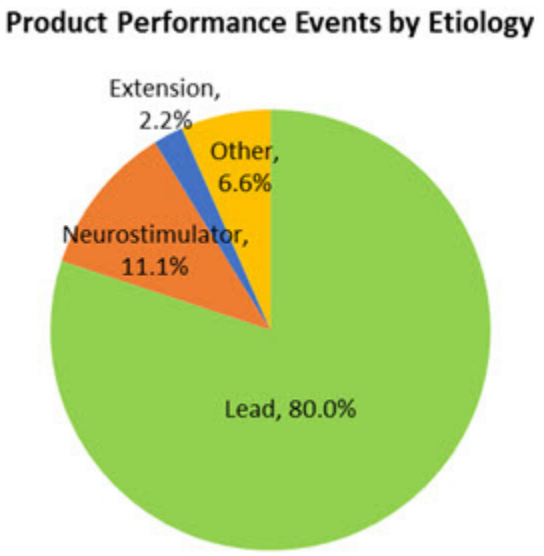
In addition, there were 440 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the sacral neuromodulation systems. There were also 18 deaths reported for patients followed in the PSR with sacral neuromodulation systems, none of which were reported as a direct result of a product performance event.

Sacral Neuromodulation System Product Performance Events				
Event [a]	**Number of Product Performance Events**	**Events per 100 Patient Years**	**Number of Patients with Event**	**Percent of Patients with Event (N=969)**
High impedance	38	2.59	32	3.3%
Lead migration/dislodgement	18	1.23	16	1.7%
Lead fracture	15	1.02	14	1.4%
Low impedance	7	0.48	7	0.7%
Device battery issue	4	0.27	3	0.3%
Device malfunction [b]	4	0.27	4	0.4%
Device electrical impedance issue	2	0.14	1	0.1%
Device lead issue	1	0.07	1	0.1%
Device telemetry issue	1	0.07	1	0.1%
Totals	**90**	6.13	76	**7.8%**

[a] Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.
[b] See Neurostimulator Event Summary Tables for additional details on device malfunctions by model.

A total of 72 (80.0%) of the 90 product performance events were related to the lead, 10 (11.1%) were related to the neurostimulator, 2 (2.2%) were related to the extension, 2 (2.2%) were related to programming/stimulation, 3 (3.3%) were related to "multiple etiologies", which includes events where at least one device and one non-device etiology was indicated, and 1(1.1%) was related to some "other etiology". Relatedness is determined by the physician.

Product Performance Events by Relatedness[a]



[a]Each event could have more than one etiology.

Events not-related to a product-performance issue are characterized below. Due to the differences in event collection between the ISPR and PSR protocols, events per patient years and other rates are not calculated.

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**
Infections - pathogen unspecified	**225**
Urinary tract infection [c]	201
Medical device site infection	16
Wound infection	6
Other [d]	2
Therapeutic and nontherapeutic effects (excluding toxicity)	**68**
Therapeutic product ineffective	53
Therapeutic response decreased	15
Complications associated with device	**46**
Medical device site pain	36
Medical device discomfort	5
Other [d]	5
Device issues	**19**
Device stimulation issue	9
Neurostimulator migration	5

Sacral Neuromodulation System Non-Product Performance Events (including adverse events[a] and device events, excluding deaths and normal battery depletions)	
Other [d]	5
Neurological disorders Not Elsewhere Classified (NEC)	**18**
Paraesthesia	14
Other [d]	4
Urinary tract signs and symptoms	**17**
Urinary incontinence	5
Other [d]	12
Musculoskeletal and connective tissue disorders NEC	**8**
Pain in extremity	5
Other [d]	3
Injuries NEC	**5**
Wound secretion	5
Other [d]	**34**
Total	**440**

[a] Adverse events associated with product performance events are not included in this table.
[b] Medical Dictionary for Regulatory Activities (MedDRA) or Medtronic's own coding system terms for events that do not exist in the MedDRA dictionary.
[c] Therapy relevant event collected per registry protocol but not device related.
[d] Comprised of event terms with fewer than five events each.

There were 18 deaths reported for patients in the registry, none of which were reported as being related to a product performance event. Ten deaths occurred in patients with a primary indication of urgency-frequency, three deaths in patients with a primary indication of urinary urge incontinence, two in patients with a primary indication of urinary retention and three deaths in patients for other indications.

Number of Reports of Death by Primary Indication	
Primary Indication[a]	**N (%) of deaths**
Urgency-frequency	10 (55.6%)
Urinary urge incontinence	3 (16.7%)
Urinary retention	2 (11.1%)
Other[b]	3 (16.7%)
Total	**18 (100%)**

[a] Refer to product labeling for approved indications.
[b] Includes 1 indication of atony of bladder, 1 of neurogenic bladder, and 1 of BPH without urinary obstruction.

Neurostimulators

From April 2010 to the report cut-off date of October 31, 2017, 910 neurostimulators were followed in the registry. The difference between the total number of patients (n=969) versus neurostimulators (n=910) is due to the fact that patients could enroll prior to implant but may not have received an implanted device, or patients were enrolled but not implanted, before the data cut-off.

Over eighty-eight percent (88.9%) of neurostimulators were InterStim II (n=809), and 11.1% (n=101) were InterStim I. The aggregate prospective follow-up time for all neurostimulators was 17,068 months (1422 years).

Neurostimulator Events

There were 11 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 10 events with a neurostimulator etiology, and 1 event with both a neurostimulator and programming/stimulation etiology. All 11 of these events were the initial product performance event that affected neurostimulator survival estimates. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 20/123 (16%). 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 20 devices that were returned for analysis. The 11 neurostimulators with performance-related events were not returned to Medtronic RPA but were assigned as device-related by the physician as device malfunction (n=4), high impedance (n=3), device battery issue (n=3), and device electrical impedance 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 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:

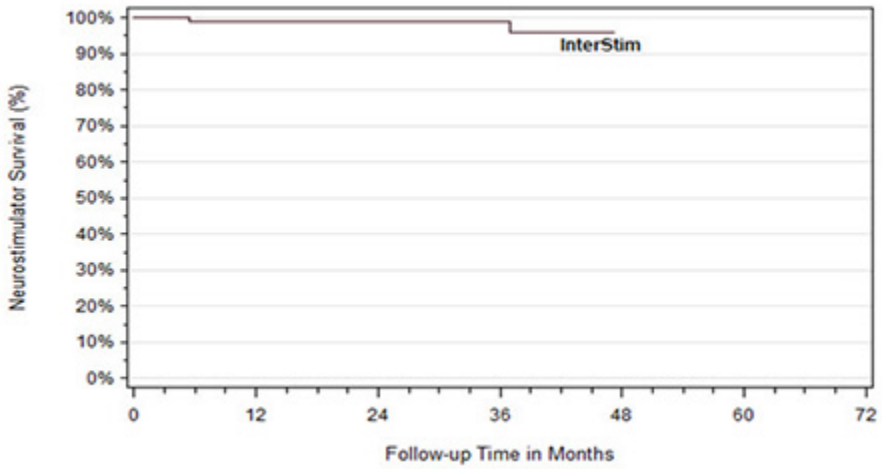
- 11 had follow-up cut-off due to product performance-related events.
- 373 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 526 were free from product performance-related events and censoring events, were censored at the last follow-up visit prior to the report cut-off.

Neurostimulator Survival

The figure and tables below represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval.

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	101
Neurostimulators Currently Active in Study	31
Device Events	2
Cumulative Months of Follow-up	2,816

Model 3023 InterStim: Event Summary Table	
Neurostimulator Event	**Total**
Device battery issue	1
Device malfunction [a]	1
Total Neurostimulator Events	**2**

[a] Device intermittently turning off.

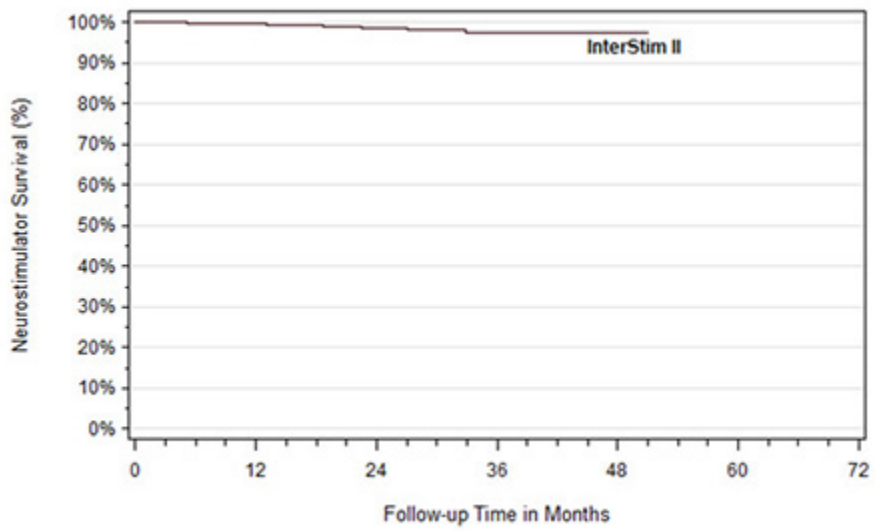
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.9%** (92.2, 99.8%)	67
2 yrs	**98.9%** (92.2, 99.8%)	50
3 yrs	**98.9%** (92.2, 99.8%)	34
4 yrs	**96.0%** (83.0, 99.1%)	21

Model 3023 InterStim: Specifications

Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	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.



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Neurostimulator Characteristics	
Model Name	InterStim II
FDA Approval Date	Jun 2006
Neurostimulators Enrolled	809
Neurostimulators Currently Active in Study	495
Device Events	9
Cumulative Months of Follow-up	14,252

Model 3058 InterStim II: Event Summary Table	
Neurostimulator Event	**Total**
High impedance[a]	3
Device malfunction[b]	3
Device battery issue	2
Device electrical impedance issue[c]	1
Total Neurostimulator Events	**9**

[a] Includes 3 events reported as high impedance attributed to both lead and neurostimulator.
[b] Includes 1 event reported as device function could not be restored after a fall, 1 event for battery heating up and 1 neurostimulator malfunction.
[c] Event reported as impedance out of range, physician did not specify whether high or low.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**99.6%** (98.5%, 99.9%)	456
2 yrs	**98.5%** (96.6%, 99.3%)	252
3 yrs	**97.4%** (94.5%, 98.8%)	124
4 yrs	**97.4%** (94.5%, 98.8%)	34
at 51 mo	**97.4%** (94.5%, 98.8%)	21

Model 3058 InterStim II: Specifications

Height	1.7 in (44 mm)
Width	2.0 in (51 mm)
Thickness	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

Neurostimulator Characteristics						
Model Name	**Family**	**FDA Approval Date**	**Neuro-stimulators Enrolled**	**Neuro-stimulators Currently Active in Study**	**Device Events**	**Cumulative Months of Follow-up**
InterStim	InterStim	Jul 1998	101	31	2	2,816
InterStim II	InterStim	Jun 2006	809	495	9	14,252

Device Survival Probability (95% Confidence Interval)				
Model Name	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**
InterStim	**98.9%** (92.2, 99.8%)	**98.9%** (92.2, 99.8%)	**98.9%** (92.2, 99.8%)	**96.0%** (83.0, 99.1%)
InterStim II	**99.6%** (98.5%, 99.9%)	**98.5%** (96.6%, 99.3%)	**97.4%** (94.5%, 98.8%)	**97.4%** (94.5%, 98.8%)

Leads

From April 2010 to the report cut-off date of October 31, 2017, there were 895 leads followed in the registry. Differences between the total number of leads versus the total number of neurostimulators (N=910) were due to the fact that some patients were subsequently re-implanted with a new neurostimulator. The aggregate prospective follow-up time for all leads was 16,392 months (1,366 years).

The table below provides the number and percentage of leads by model.

Leads by Model	
Model	**Number of Leads (%)**
3889 (tined)	795 (88.8%)
Other/Unknown	3 (0.3%)
Leads No Longer Manufactured	
3093 (tined)	91 (10.2%)
3080	4 (0.5%)
3092	2 (0.2%)
Total	**895 (100%)**

Lead Events

There were 74 product performance-related events with an underlying reported etiology related to the lead. This includes 72 events with a lead etiology and 2 events with both a lead and other etiology (including device and non-device etiologies). The majority of the events were high impedance (n=35). Of the 74 product performance-related lead events, 66 (89.1%) were the initial product performance event that affected lead survival estimates.

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 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:

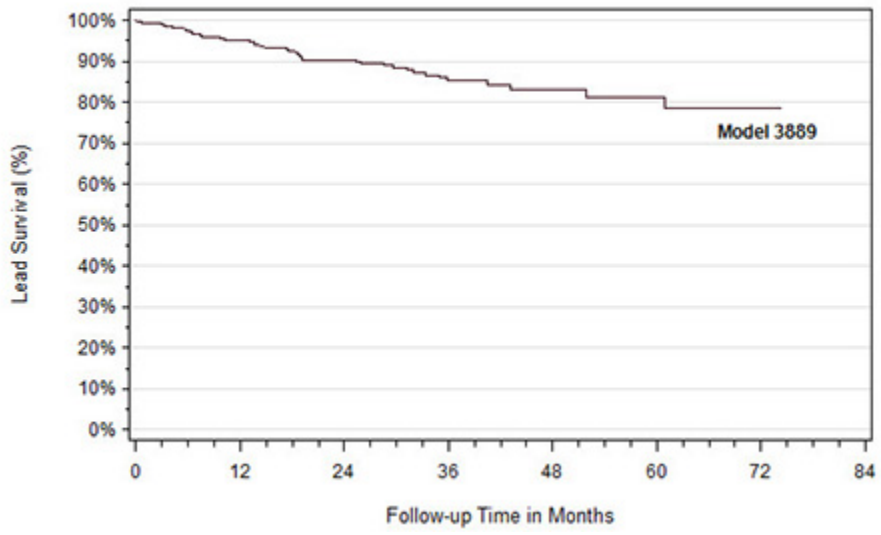
- 66 had follow-up time cut-off due to product performance-related events.
- 322 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participating in the registry.
- 507 were free from product 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.

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	795
Leads Currently Active in Study	474
Device Events	60
Cumulative Months of Follow-up	14,163

Model 3889: Event Summary Table	
Lead Event	**Total**
High impedance	28
Lead fracture	12
Lead migration/dislodgement	11
Low impedance	6
Device lead issue [a]	1
Device electrical impedance issue	1
Device battery issue [b]	1
Total Lead Events	**60**

[a] Lead coiled

[b] Battery depletion attributable to both neurostimulator and leads

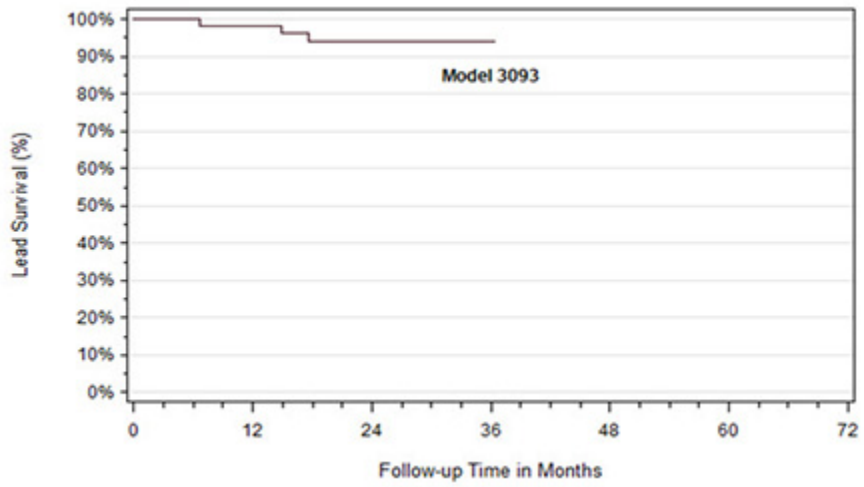
Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**95.3%** (93.1%, 96.8%)	410
2 yrs	**90.4%** (87.2%, 92.8%)	226
3 yrs	**85.2%** (80.3%, 89.0%)	113
4 yrs	**83.1%** (77.4%, 87.6%)	53
5 yrs	**81.2%** (74.0%, 86.6%)	33
6 yrs	**78.7%** (69.7%, 85.3%)	24
at 75 mo	**78.7%** (69.7%, 85.3%)	21

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	91
Leads Currently Active in Study	45
Device Events	4
Cumulative Months of Follow-up	2,125

Model 3093: Event Summary Table	
Lead Event	**Total**
Device lead damage	1
High impedance	1
Lead fracture	1
Lead migration/dislodgement	1
Total Lead Events	**4**

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**98.3%** (88.5%, 99.8%)	49
2 yrs	**94.0%** (82.4%, 98.0%)	34
3 yrs	**94.0%** (82.4%, 98.0%)	21
at 39 mo	**94.0%** (82.4%, 98.0%)	21

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

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	795	474	60	14,163
3093	**3093**	Sep 2002	91	45	4	2,125

[a] There were 74 lead-related events reported to the registry, but only 64 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 (i.e., Model 3080) (n=2) or were subsequent events (i.e. additional events that occurred after the survival censoring event) that did not affect the device survival estimates.

Device Survival Probability (95% Confidence Interval)						
Model Number	**1 yr**	**2 yrs**	**3 yrs**	**4 yrs**	**5 yrs**	**6 yrs**
3889	**95.3%** (93.1%, 96.8%)	**90.4%** (87.2%, 92.8%)	**85.2%** (80.3%, 89.0%)	**83.1%** (77.4%, 87.6%)	**81.2%** (74.0%, 86.6%)	**78.7%** (69.7%, 85.3%)
3093	**98.3%** (88.5%, 99.8%)	**94.0%** (82.4%, 98.0%)	**94.0%** (82.4%, 98.0%)	**-**	**-**	**-**

Extensions

From April 2010 to the report cut-off date of October 31, 2017, there were 101 extensions followed in the registry. Differences between the total number of extensions versus the total neurostimulators (N=910) were due to the fact that not all systems require an extension, or some patients were subsequently re-implanted with a new neurostimulator.

All the extensions were Model 3095. The aggregate prospective follow-up time for all extensions was 2,849 months (237 years).

Extension Events

There were 2 product performance-related events with an underlying reported etiology related to the extension. Of these 2 events, 1 was the initial product performance event that affected extension survival estimates.

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 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:

- 1 had follow-up time cut-off due to product performance-related events.
- 65 were censored in the survival analysis for the following reasons: patient expired, extension explanted, or patient discontinued.

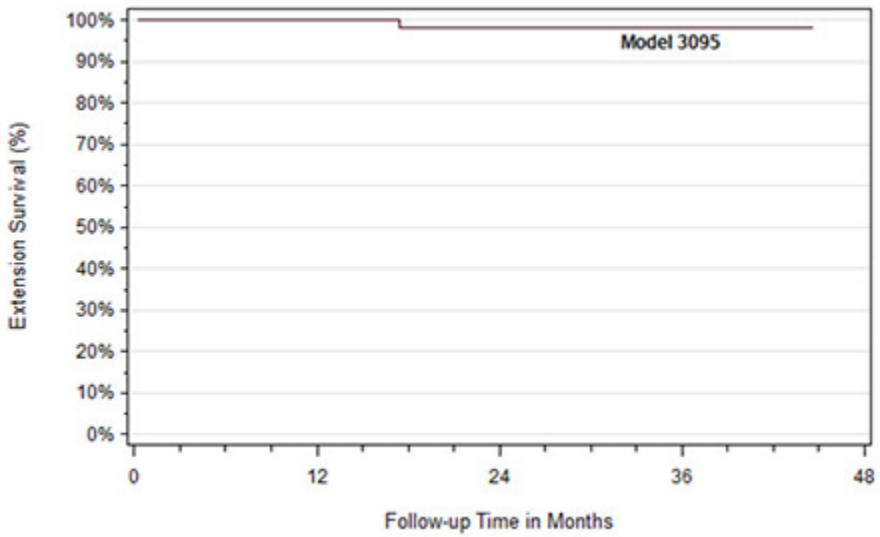
- 35 were free from product performance-related events and censoring events were censored at the last follow-up visit prior to the report cut-off.

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.

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	101
Extensions Currently Active in Study	35
Device Events	1
Cumulative Months of Follow-up	2,849

Model 3095: Event Summary Table	
Lead fracture[a]	1
Total Extension Events	**1**

[a] Lead fracture attributed to both the lead and extension.

Time Interval	Survival (95% Confidence Interval)	Sample Size
1 yr	**100.0%** (NA)	62
2 yrs	**98.3%** (88.3%, 99.8%)	45
3 yrs	**98.3%** (88.3%, 99.8%)	28
at 45 mo	**98.3%** (88.3%, 99.8%)	20

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

Extension Characteristics						
Model Number	**Family**	**FDA Approval Date**	**Extensions Enrolled**	**Extensions Currently Active in Study**	**Device Events[a]**	**Cumulative Months of Follow-up**
3095	3095	Jul 1998	101	35	1	2,849

Device Survival Probability (95% Confidence Interval)			
Model Number	**1 yr**	**2 yrs**	**3 yrs**

3095	**100.0%** NA	**98.3%** (88.3%, 99.8%)	**98.3%** (88.3%, 99.8%)

[a] There were a total of 2 extension-related events reported to the registry, but only 1 event included in this summary table. The remaining event was a subsequent event (i.e. additional event that occurred after the survival censoring event) that did not affect the device survival estimates.

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