

# PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA  
FROM THE MEDTRONIC  
POST-MARKET  
REGISTRY

2022

v.1.0 07MAR2023

**Medtronic**  
Further, Together

# Contents

<b>4</b>	<b>Spinal Cord Stimulation Systems</b>	<b>4</b>
4.1	Study Participants	4
4.1.1	Centers	4
4.1.2	Patients	4
4.2	Event Summary	6
4.2.1	Product Performance Events	7
4.2.2	Clinical Events Not Related To Product Performance	11
4.2.3	Patient Deaths	12
4.3	Neurostimulators	13
4.3.1	Neurostimulator Events	14
4.3.2	Neurostimulator Models	16
4.3.2.1	Model Intellis with AdaptiveStim	17
4.3.2.2	Model Itrel 4	19
4.3.2.3	Model PrimeAdvanced	21
4.3.2.4	Model PrimeAdvanced SureScan MRI	23
4.3.2.5	Model RestoreAdvanced	25
4.3.2.6	Model RestoreAdvanced SureScan MRI	27
4.3.2.7	Model RestoreSensor	29
4.3.2.8	Model RestoreSensor SureScan MRI	31
4.3.2.9	Model RestoreUltra SureScan MRI	33
4.3.3	Neurostimulator Summary	34
4.4	Leads	37
4.4.1	Lead Events	38
4.4.2	Lead Models	38
4.4.2.1	Model 1x8 Compact	39
4.4.2.2	Model 1x8 SC	41
4.4.2.3	Model 1x8 Standard	43
4.4.2.4	Model AnkerStim	45
4.4.2.5	Model Pisces Compact	47
4.4.2.6	Model Pisces Plus	49
4.4.2.7	Model Pisces Standard	51
4.4.2.8	Model Specify 5-6-5	53
4.4.2.9	Model Specify SureScan MRI 2x8	55
4.4.2.10	Model Specify SureScan MRI 5-6-5	57

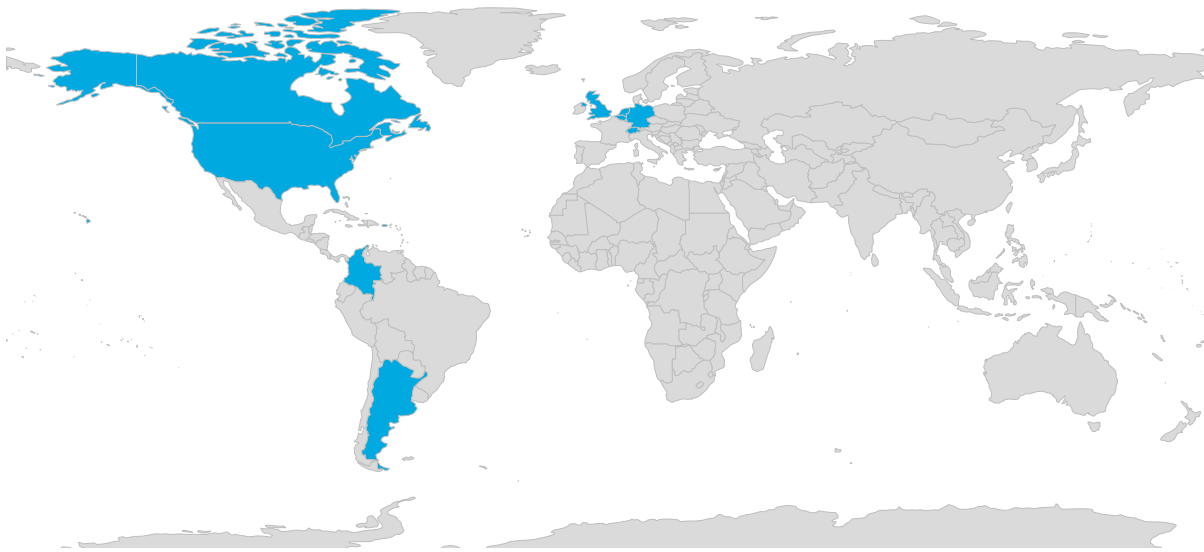
4.4.2.11	Model Vectris SureScan MRI 1x8 Compact . . . . .	59
4.4.2.12	Model Vectris SureScan MRI 1x8 Subcompact . . . . .	61
4.4.3	Lead Summary . . . . .	62
4.5	Extensions . . . . .	65
4.5.1	Extension Events . . . . .	66
4.5.2	Extension Models . . . . .	66
4.5.2.1	Model 1x8 Extension . . . . .	67
4.5.2.2	Model Bifurcated Stretch-Coil Extension . . . . .	69
4.5.2.3	Model Single Stretch-Coil Extension . . . . .	71
4.5.3	Extension Summary . . . . .	73

## 4 Spinal Cord Stimulation Systems

### 4.1 Study Participants

#### 4.1.1 Centers

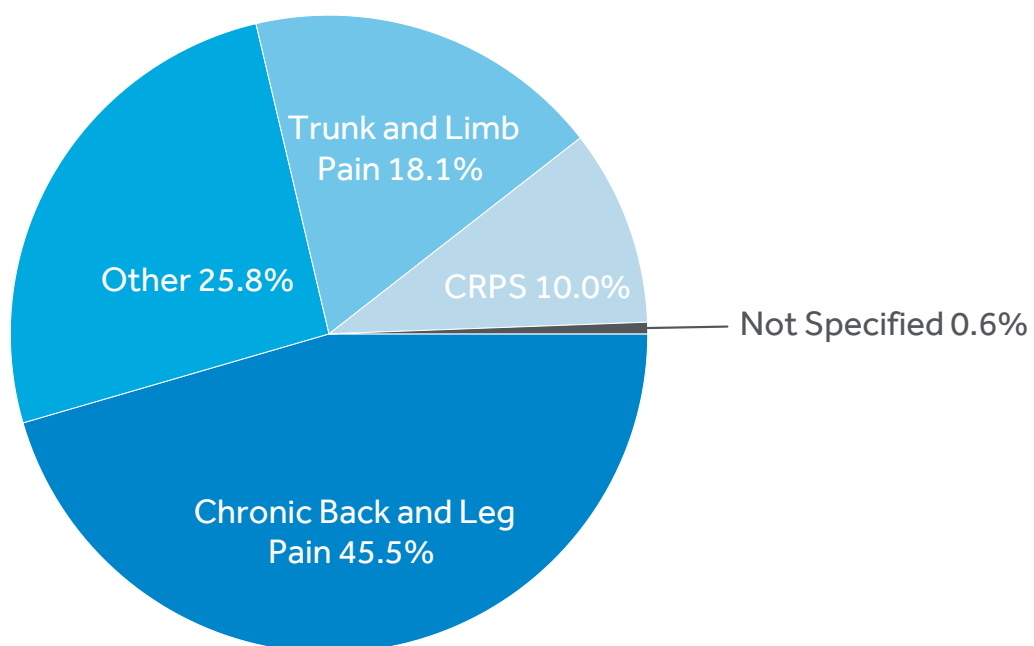
The spinal cord stimulation tables and graphs were generated based on data collected between June 2004 and the report cut-off date of October 31, 2022. Eighty-five centers, in North America, Europe and South America, enrolled patients and contributed patient data to the spinal cord stimulation systems section of this report. [Figure 4.1](#) shows a World Map and highlights the countries that enrolled spinal cord stimulation patients.



**Figure 4.1:** Countries with Spinal Cord Stimulation Patients in Registry (Highlighted)

#### 4.1.2 Patients

Of the 6,328 spinal cord stimulation patients enrolled, 45.5% were implanted for the treatment of chronic back and leg pain, 25.8% were implanted for the treatment of other primary indications, 18.1% were implanted for the treatment of trunk and limb pain, 10.0% were implanted for the treatment of complex regional pain syndrome (CRPS), and 0.6% were implanted for indications that were not specified in the database (see [Figure 4.2](#) and [Table 4.1](#)).



**Figure 4.2:** Spinal Cord Stimulation Primary Treatment Indications

**Table 4.1:** Spinal Cord Stimulation Primary Treatment Indications

<b>Primary Treatment Indication<sup>a</sup></b>	<b>Enrolled Patients (%)</b>
<b>Chronic Back and Leg Pain</b>	<b>2,879 (45.50%)</b>
Post Surgical Back and/or Leg Pain <sup>b</sup>	2,118 (33.47%)
Combination Back and Leg Pain	739 (11.68%)
Arachnoiditis	22 (0.35%)
<b>Other Primary Indication</b>	<b>1,634 (25.82%)</b>
Other Chronic Pain	862 (13.62%)
Cervical Pain	89 (1.41%)
Chronic Cluster Headache	70 (1.11%)
Traumatic Nerve Injury	56 (0.88%)
Diabetic Neuropathy	45 (0.71%)
Post Herpetic Neuralgia	18 (0.28%)
Angina	10 (0.16%)
Facial Pain	10 (0.16%)
Epidural Fibrosis	4 (0.06%)
Post Herniorrhaphy Pain	3 (0.05%)
Other	467 (7.38%)
<b>Trunk and Limb Pain</b>	<b>1,148 (18.14%)</b>
Radicular Pain Syndrome	860 (13.59%)
Degenerative Disc Disease	288 (4.55%)
<b>CRPS</b>	<b>630 (9.96%)</b>
CRPS I	489 (7.73%)
CRPS II	141 (2.23%)
<b>Not Specified</b>	<b>37 (0.58%)</b>
<b>Total Patients</b>	<b>6,328 (100%)</b>

<sup>a</sup> For approved indications refer to product labeling for your geography.

<sup>b</sup> Contains Failed Back Surgery Syndrome (FBSS), Post Laminectomy Pain, Multiple Back Operations and Unsuccessful Disc Surgery.

It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved labeling. Product labeling varies by geography. Contact a local Medtronic representative (<http://www.medtronic.com/us-en/about/locations.html>) for region-specific product labeling.

## 4.2 Event Summary

There were 1,970 product performance events reported between June 2004 and October 31, 2022, in patients with spinal cord stimulation systems. These events represent 35.5% of the

total reported events (1,970/5,549), occurred in 956 (15.1%) of the 6,328 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 3,521 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the spinal cord stimulation systems. As an ongoing registry, events not coded at the time of the data snapshot (waiting on further information) will be included in future reports (n=58).

Any registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings assist in the classification of the events. Within this report, [Table 4.2](#) differentiates the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 266 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.

#### 4.2.1 Product Performance Events

**Table 4.2:** Spinal Cord Stimulation System Product Performance Events

Product Performance Events <sup>a</sup>	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=6,328 <sup>b</sup>
<b>RPA Determination</b>	<b>4</b>	<b>0.02</b>	<b>4 (0.06%)</b>
Broken Bond Wire	1	0.01	1 (0.02%)
Grommet Loose	1	0.01	1 (0.02%)
Medical Device Complication <sup>c</sup>	1	0.01	1 (0.02%)
No Anomaly Found By RPA	1	0.01	1 (0.02%)
<b>Physician's Determination</b>	<b>1,966</b>	<b>11.93</b>	<b>953 (15.06%)</b>
Lead Migration/Dislodgement	820	4.98	433 (6.84%)
High Impedance	497	3.02	226 (3.57%)
Device Malfunction <sup>d</sup>	105	0.64	92 (1.45%)
Neurostimulator Unable To Recharge <sup>e</sup>	104	0.63	96 (1.52%)
Lead Fracture	99	0.60	65 (1.03%)
Low Impedance	56	0.34	26 (0.41%)
Device Stimulation Issue <sup>f</sup>	53	0.32	31 (0.49%)
Device Breakage <sup>g</sup>	42	0.25	38 (0.60%)
Device Charging Issue	27	0.16	22 (0.35%)
Extension Fracture	18	0.11	12 (0.19%)
Device Electrical Impedance Issue	17	0.10	11 (0.17%)
Therapeutic Product Ineffective	13	0.08	12 (0.19%)
Extension Migration	12	0.07	8 (0.13%)
Device Connection Issue	8	0.05	6 (0.09%)
Device Lead Damage	7	0.04	5 (0.08%)
Antenna Cable Breakage	6	0.04	6 (0.09%)
Device Overheating	6	0.04	6 (0.09%)

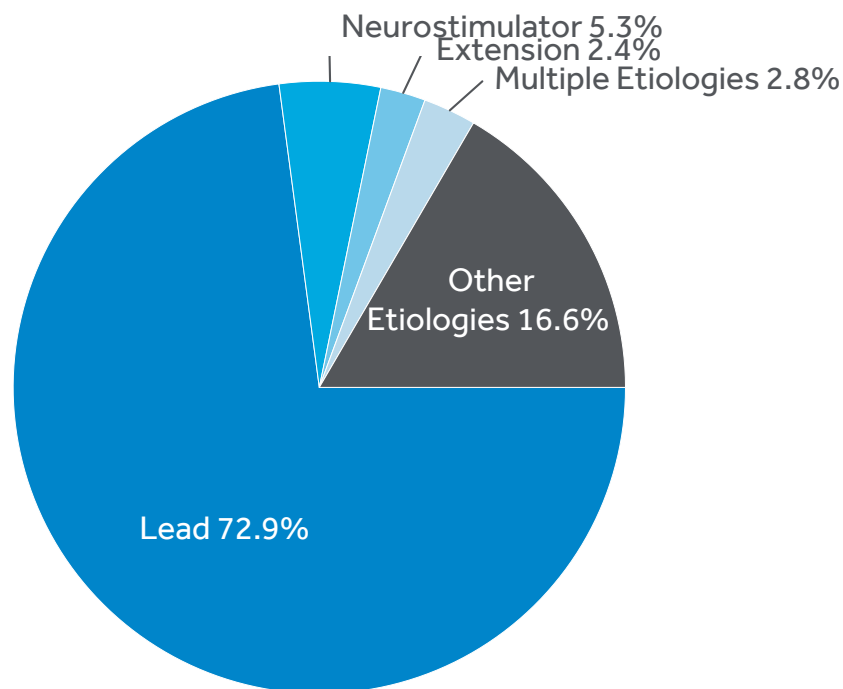
...continued

<b>Product Performance Events<sup>a</sup></b>	<b>Event Counts</b>	<b>Events Per 100 Patient Years</b>	<b>Patients with Events (%) N=6,328<sup>b</sup></b>
Medical Device Complication <sup>h</sup>	6	0.04	2 (0.03%)
Medical Device Site Pain	5	0.03	4 (0.06%)
Neurostimulator Migration	5	0.03	5 (0.08%)
Device Difficult To Program	4	0.02	4 (0.06%)
Device Failure <sup>i</sup>	4	0.02	3 (0.05%)
Inadequate Lead Connection	4	0.02	2 (0.03%)
Device Battery Issue	3	0.02	2 (0.03%)
Device Computer Software Issue	3	0.02	3 (0.05%)
Device Damage	3	0.02	3 (0.05%)
Device Telemetry Issue	3	0.02	3 (0.05%)
Device Use Issue	3	0.02	2 (0.03%)
Electric Shock Sensation	3	0.02	2 (0.03%)
Premature Battery Depletion	3	0.02	3 (0.05%)
Back Pain	2	0.01	2 (0.03%)
Device Loosening	2	0.01	2 (0.03%)
Medical Device Site Erosion	2	0.01	1 (0.02%)
Medical Device Site Warmth	2	0.01	2 (0.03%)
Device Difficult To Use	1	0.01	1 (0.02%)
Device End Of Service	1	0.01	1 (0.02%)
Device Image Display Error	1	0.01	1 (0.02%)
Device Issue	1	0.01	1 (0.02%)
Device Kink	1	0.01	1 (0.02%)
Device Material Deterioration	1	0.01	1 (0.02%)
Device Reset Issue	1	0.01	1 (0.02%)
Device Temperature Issue	1	0.01	1 (0.02%)
Device Wireless Communication Issue	1	0.01	1 (0.02%)
Eschar	1	0.01	1 (0.02%)
Extradural Abscess	1	0.01	1 (0.02%)
Headache	1	0.01	1 (0.02%)
Inappropriate Device Programming	1	0.01	1 (0.02%)
Lead Insulation Failure	1	0.01	1 (0.02%)
Medical Device Site Erythema	1	0.01	1 (0.02%)
Pain	1	0.01	1 (0.02%)
Pain In Extremity	1	0.01	1 (0.02%)
Scar Pain	1	0.01	1 (0.02%)
Sensory Disturbance	1	0.01	1 (0.02%)
<b>Total</b>	<b>1,970</b>	<b>11.95</b>	<b>956 (15.11%)</b>

<sup>a</sup> 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.

- <sup>b</sup> 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.
- <sup>c</sup> One event without a device diagnosis but has RPA finding. RPA finding is described as a problem with the functionality of the INS that appears to be related to the hybrid; however, the exact cause of the problem could not be determined.
- <sup>d</sup> There were 4307 patients that used rechargeable SCS neurostimulators in the registry. A total of 2.2% (96/4307) of patients with a rechargeable SCS neurostimulator experienced a neurostimulator unable to recharge event.
- <sup>e</sup> Includes recharging components, charging and other technical related issues.
- <sup>f</sup> Device stimulation issue reported by physician as being caused by neurostimulator (n=3), lead (n=47) or programming (n=3).
- <sup>g</sup> Includes external components.
- <sup>h</sup> Includes a combination of mechanical and electrical observations.
- <sup>i</sup> Device failure includes 3 events for lead failure, and 1 extension failure.

A total of 1,436 (72.9%) of the 1,970 product performance events were related to the Lead, 105 (5.3%) were related to the Neurostimulator, 47 (2.4%) were related to the Extension, 55 (2.8%) were related to Multiple Etiologies (which includes events where at least one device and one non-device etiology was indicated), and 327 (16.6%) were related to Other Etiologies, including: 218 (11.1%) were related to other component, 53 (2.7%) were related to recharging process, 26 (1.3%) were related to programming/stimulation, 16 (0.8%) were related to incisional site/device tract, 8 (0.4%) were related to surgery/anesthesia, 1 (0.1%) was related to MRI, and 5 (0.3%) were related to other etiology. Relatedness is determined by the physician.



**Figure 4.3:** Spinal Cord Stimulation System Product Performance Events by Relatedness

Table 4.3 and Table 4.4 describe the interventions taken for reported impedance events. In 26.2% and 21.4% of the high and low impedance events, respectively, the action taken was a surgical intervention. However, impedance could be used as a diagnostic measurement and may not result in any intervention or clinical impact. The majority of events required no intervention or device reprogramming only (71.0% for high impedance and 76.8% for low impedance).

**Table 4.3:** Spinal Cord Stimulation System High Impedance Events by Intervention

<b>Intervention</b>	<b>N (%) of High Impedance Events</b>
Reprogramming	222 (44.7%)
Device Surgical Intervention	129 (26.0%)
Therapy Suspension	8 (1.6%)
Other Intervention	6 (1.2%)
Other Surgical Intervention	1 (0.2%)
No Action Taken	131 (26.4%)
<b>Total</b>	<b>497 (100%)</b>

**Table 4.4:** Spinal Cord Stimulation System Low Impedance Events by Intervention

<b>Intervention</b>	<b>N (%) of Low Impedance Events</b>
Reprogramming	26 (46.4%)
Device Surgical Intervention	11 (19.6%)
Other Intervention	1 (1.8%)
Other Surgical Intervention	1 (1.8%)
No Action Taken	17 (30.4%)
<b>Total</b>	<b>56 (100%)</b>

Table 4.5 describes the interventions taken for reported lead migration/dislodgement events; 76.7% of them led a surgical intervention, and 12.1% were reprogramming.

**Table 4.5:** Spinal Cord Stimulation System Lead Migration/Dislodgement Events by Intervention

Intervention	N (%) of Lead Migration/Dislodgement Events
Device Surgical Intervention	587 (71.6%)
Reprogramming	99 (12.1%)
Other Surgical Intervention	42 (5.1%)
Therapy Suspension	19 (2.3%)
Other Intervention	15 (1.8%)
Medical or Non-Surgical Therapy	3 (0.4%)
Medication	2 (0.2%)
No Action Taken	53 (6.5%)
<b>Total</b>	<b>820 (100%)</b>

Table 4.6 describes the interventions completed for product performance events that required action from the health care provider and thereby, may have resulted in an incremental impact to the patient. Survival estimates presented in previous product performance reports included events where no action was taken. To present survival estimates that may better correlate with patient impact, events where no action was taken have been removed from the device survival estimates presented in this 2022 report. The far-left column lists the top five reported product performance events (PPEs), and all other reported PPEs are listed under Other. The subsequent columns represent the actions taken by the reporting physician.

**Table 4.6:** Spinal Cord Stimulation System Product Performance Events by Intervention

Events by Intervention	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention <sup>a</sup>	No Action Taken	Total Events
Lead Migration/Dislodgement	629 (76.7%)	99 (12.1%)	19 (2.3%)	20 (2.4%)	53 (6.5%)	<b>820</b>
High Impedance	130 (26.2%)	222 (44.7%)	8 (1.6%)	6 (1.2%)	131 (26.4%)	<b>497</b>
Lead Fracture	95 (96.0%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	2 (2.0%)	<b>99</b>
Neurostimulator Unable To Recharge	36 (34.6%)	5 (4.8%)	4 (3.8%)	55 (52.9%)	4 (3.8%)	<b>104</b>
Device Malfunction	21 (20.0%)	9 (8.6%)	3 (2.9%)	62 (59.0%)	10 (9.5%)	<b>105</b>
Other <sup>b</sup>	170 (49.3%)	49 (14.2%)	9 (2.6%)	78 (22.6%)	39 (11.3%)	<b>345</b>
<b>Total</b>	<b>1,081</b>	<b>384</b>	<b>45</b>	<b>221</b>	<b>239</b>	<b>1,970</b>

<sup>a</sup> Medical or Non-Surgical Therapy contains but is not limited to the following actions: medication adjustment based on disease symptoms, imaging (e.g. MRI or X-ray), other specialist referral.

<sup>b</sup> Other represents all reported PPEs that were not in the top five of occurrence.

## 4.2.2 Clinical Events Not Related To Product Performance

The clinical events not related to product performance are summarized if:

- Enrolled in the PSR since 2013
- Categorized as serious adverse events (SAEs, N=127)
- Occurred with a System Organ Class (SOC) threshold  $\geq 1\%$  of patients

- Other Considerations

- Some events are described in high level group terms (HLGT) to provide more specificity, if needed
- Some therapies will provide therapy relevant events

**Table 4.7:** Spinal Cord Stimulation System Clinically Relevant Serious Adverse Events

Event Type	Number of SAE	Patients with SAE n (%) N=3,437	SAE Per 100 Patient Months	Patient with SAE Requiring Surgical Intervention n (%) N=3,437
<b>Infections and infestations</b>	<b>60</b>	<b>58 (1.69%)</b>	<b>0.06</b>	<b>42 (1.22%)</b>
Infections - pathogen unspecified	52	50 (1.45%)	0.05	39 (1.13%)
Bacterial infectious disorders	7	7 (0.20%)	0.01	3 (0.09%)
Other <sup>a</sup>	1	1 (0.03%)	0.00	0 (0.00%)
<b>Other SOC Terms (<math>\leq 1.0\%</math> Threshold)</b>	<b>67</b>	<b>58 (1.69%)</b>	<b>0.07</b>	<b>42 (1.22%)</b>
<b>Total</b>	<b>127</b>	<b>109 (3.17%)</b>	<b>0.13</b>	<b>78 (2.27%)</b>

<sup>a</sup> Composed of high level group term event codes with fewer than 5 events each.

### 4.2.3 Patient Deaths

In earlier versions of the protocol, deaths were only assessed for the relatedness to the device product performance. After 2010, death assessments were expanded to also include the relationship to the implant procedure and/or therapy. As of the report cut-off, a total of 266 patients in the registry had expired. As with previous reports, no deaths were reported as a direct result of a product performance event.

Since 2010, a total of 83 (31.2%) deaths have been reported in this patient registry study based upon patients receiving therapy for post surgical back and/or leg pain, 56 (21.1%) for other chronic pain, 37 (13.9%) for radicular pain syndrome, 30 (11.3%) for combination back and leg pain, 15 (5.6%) for CRPS I, 13 (4.9%) for degenerative disc disease, 3 (1.1%) for CRPS II, 2 (0.8%) for diabetic neuropathy, 2 (0.8%) for post herpetic neuralgia, 1 (0.4%) for angina, 1 (0.4%) for cervical pain, 1 (0.4%) for chronic cluster headache, 1 (0.4%) for traumatic nerve injury, and 21 (7.9%) for other indications. The percentage is based upon the total patient death events and not based upon the rate of occurrence. **All tables depicted without a patient denominator should not be interpreted using other numbers within this report to calculate event rates.**

**Table 4.8:** Spinal Cord Stimulation System Patient Deaths by Primary Indication

<b>Number of Reports of Death by Primary Indication<sup>a</sup></b>	<b>N (%) of Deaths</b>
Post Surgical Back and/or Leg Pain <sup>b</sup>	83 (31.2%)
Other Chronic Pain	56 (21.1%)
Radicular Pain Syndrome	37 (13.9%)
Combination Back and Leg Pain	30 (11.3%)
CRPS I	15 (5.6%)
Degenerative Disc Disease	13 (4.9%)
CRPS II	3 (1.1%)
Diabetic Neuropathy	2 (0.8%)
Post Herpetic Neuralgia	2 (0.8%)
Angina	1 (0.4%)
Cervical Pain	1 (0.4%)
Chronic Cluster Headache	1 (0.4%)
Traumatic Nerve Injury	1 (0.4%)
Other <sup>c</sup>	21 (7.9%)
<b>Total</b>	<b>266 (100%)</b>

<sup>a</sup> For approved indications refer to product labeling for your geography.

<sup>b</sup> Contains Failed Back Surgery Syndrome (FBSS), Post Laminectomy Pain and Multiple Back Operations.

<sup>c</sup> Includes specific free-text entries of the following nature: Radiculopathy, Lumbosacral Neuritis, Peripheral Neuropathy, Occipital Neuralgia, Raynaud's Disease, Bilateral Lower Legs and Feet, Post Hemangioma Surgery Complication, Headache, Arteriopathie, Vascular Pain, Leg Pain after Accident.

## 4.3 Neurostimulators

From June 2004 to the report cut-off date of October 31, 2022, there were 6,983 neurostimulators followed in the registry. The difference between the total number of patients (n=6,328) versus neurostimulators is due to the fact that some patients were subsequently re-implanted. The aggregate prospective follow-up time for all spinal cord neurostimulators was 192,005 months (16,000 years). [Table 4.9](#) provides the number and percentage of neurostimulators by model.

**Table 4.9:** Spinal Cord Stimulation Neurostimulator Counts by Model

Model Name	N (%)
<b>Currently manufactured</b>	<b>5,256 (75.27%)</b>
RestoreSensor SureScan MRI (97714)	1,382 (19.79%)
Intellis with AdaptiveStim (97715)	1,281 (18.34%)
PrimeAdvanced SureScan MRI (97702)	785 (11.24%)
PrimeAdvanced (37702)	668 (9.57%)
RestoreSensor (37714)	377 (5.40%)
RestoreAdvanced (37713)	357 (5.11%)
Itrel 4 (37703)	135 (1.93%)
RestoreAdvanced SureScan MRI (97713)	116 (1.66%)
RestoreUltra SureScan MRI (97712)	93 (1.33%)
Intellis LT (97716)	41 (0.59%)
Vanta	20 (0.29%)
Itrel 4 (37704)	1 (0.01%)
<b>No longer manufactured</b>	<b>1,718 (24.60%)</b>
RestoreULTRA (37712)	581 (8.32%)
Synergy (7427)	460 (6.59%)
Restore (37711)	448 (6.42%)
Itrel 3 (7425)	96 (1.37%)
RestorePrime (37701)	56 (0.80%)
Synergy Versitrel (7427V)	53 (0.76%)
SynergyPlus (7479)	17 (0.24%)
SynergyCompact (7479B)	7 (0.10%)
<b>Other/Unspecified</b>	<b>9 (0.13%)</b>
<b>Total</b>	<b>6,983 (100%)</b>

### 4.3.1 Neurostimulator Events

There were 118 product performance-related events with an underlying reported etiology related to spinal cord neurostimulator function. This includes 105 events with a neurostimulator etiology and 13 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 90 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 18.5% (396/2,135). The proportion was based upon the number of registry spinal cord neurostimulators received by RPA, divided by the sum of the total number of explanted devices and the total number of neurostimulators in patients who have expired. In the 118 spinal cord neurostimulator events, 96.6 % (114/118) were assigned as device related by the physician, not returned to Medtronic RPA (see [Table 4.10](#)).

**Table 4.10:** Spinal Cord Stimulation Neurostimulator Product Performance Events by Determination

<b>Product Performance Events</b>	<b>N (%)</b>
<b>RPA Determination</b>	<b>4 (3.4%)</b>
Broken Bond Wire	1 (0.8%)
Grommet Loose	1 (0.8%)
Medical Device Complication	1 (0.8%)
No Anomaly Found By RPA	1 (0.8%)
<b>Physician's Determination</b>	<b>114 (96.6%)</b>
High Impedance	28 (23.7%)
Device Malfunction	25 (21.2%)
Neurostimulator Unable To Recharge	24 (20.3%)
Lead Migration/Dislodgement	10 (8.5%)
Device Charging Issue	5 (4.2%)
Device Stimulation Issue	3 (2.5%)
Low Impedance	3 (2.5%)
Neurostimulator Migration	3 (2.5%)
Medical Device Site Warmth	2 (1.7%)
Premature Battery Depletion	2 (1.7%)
Therapeutic Product Ineffective	2 (1.7%)
Device Battery Issue	1 (0.8%)
Device Breakage	1 (0.8%)
Device Issue	1 (0.8%)
Device Overheating	1 (0.8%)
Device Telemetry Issue	1 (0.8%)
Extension Migration	1 (0.8%)
Pain	1 (0.8%)
<b>Total</b>	<b>118 (100%)</b>

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:

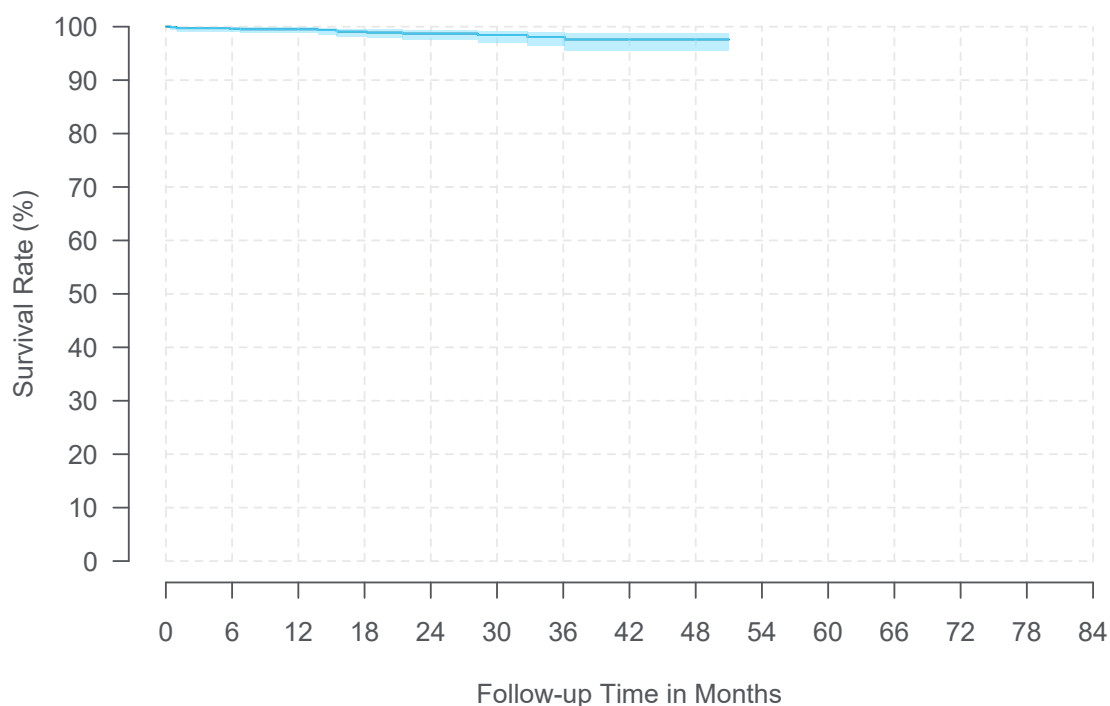
- 90 had follow-up time cut-off due to product performance-related events.
- 5,328 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 1,565 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

### 4.3.2 Neurostimulator Models

The following figures and tables represent spinal cord neurostimulator survival and 95% confidence intervals where at least 20 spinal cord neurostimulators contributed to each 3-month interval. The survival of Itrel 4 (model 37704) and Vanta are not shown due to insufficient follow-up data.

#### 4.3.2.1 Model Intellis with AdaptiveStim

<b>Model Name</b>	Intellis with AdaptiveStim (model 97715)
<b>FDA Approval Date</b>	September 2017
<b>Neurostimulators Enrolled</b>	1,281
<b>Neurostimulators Currently Active in Study</b>	887
<b>Initial Product Performance Events</b>	13
<b>Median Follow-up Time (Months)</b>	17.0
<b>Cumulative Follow-up Time (Months)</b>	24,254



<b>Time Interval</b>	<b>1 Year</b>	<b>2 Years</b>	<b>3 Years</b>	<b>4 Years</b>	<b>At 51 Months</b>
Survival (95% CI)	99.5% (98.8%, 99.8%)	98.7% (97.6%, 99.3%)	98.1% (96.4%, 99.0%)	97.6% (95.5%, 98.7%)	97.6% (95.5%, 98.7%)
Sample Size	744	454	214	52	35

**Specification: Intellis with AdaptiveStim**

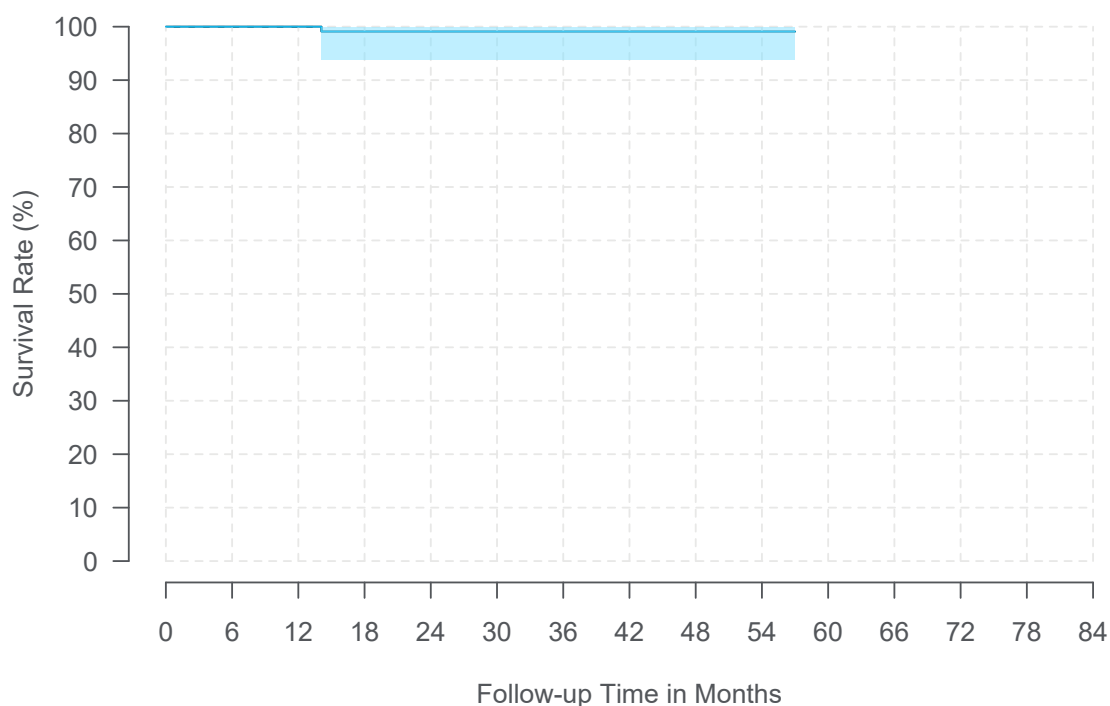
<b>Height</b>	57.1mm (2.2in)
<b>Width</b>	47.2mm (1.9in)
<b>Thickness Case</b>	6.3 mm (0.2 in)
<b>Thickness Connector</b>	9.1 mm (0.4 in)
<b>Volume</b>	13.9 cc
<b>Battery Type</b>	Rechargeable
<b>Expected Battery Life</b>	9 years before ERI
<b>Maximum Electrodes</b>	16
<b>Amplitude</b>	0 - 100 mA
<b>Rate Range</b>	40 - 1200 Hz
<b>Pulse Width</b>	60 - 1000 µsec
<b>Groups</b>	1 - 3
<b>Programs</b>	12
<b>Implant Depth</b>	≤ 3 cm

**Neurostimulator Event Summary: Intellis with AdaptiveStim**

	<b>N</b>
Device malfunction	4
High impedance	4
Device charging issue	1
Device overheating	1
Lead migration/dislodgement	1
Neurostimulator migration	1
Therapeutic product ineffective	1
<b>Total</b>	<b>13</b>

#### 4.3.2.2 Model Itrel 4

<b>Model Name</b>	Itrel 4 (model 37703)
<b>FDA Approval Date</b>	May 2012
<b>Neurostimulators Enrolled</b>	135
<b>Neurostimulators Currently Active in Study</b>	41
<b>Initial Product Performance Events</b>	1
<b>Median Follow-up Time (Months)</b>	30.2
<b>Cumulative Follow-up Time (Months)</b>	4,596



<b>Time Interval</b>	<b>1 Year</b>	<b>2 Years</b>	<b>3 Years</b>	<b>4 Years</b>	<b>At 57 Months</b>
Survival (95% CI)	100.0% (NA)	99.1% (93.8%, 99.9%)	99.1% (93.8%, 99.9%)	99.1% (93.8%, 99.9%)	99.1% (93.8%, 99.9%)
Sample Size	114	82	58	36	24

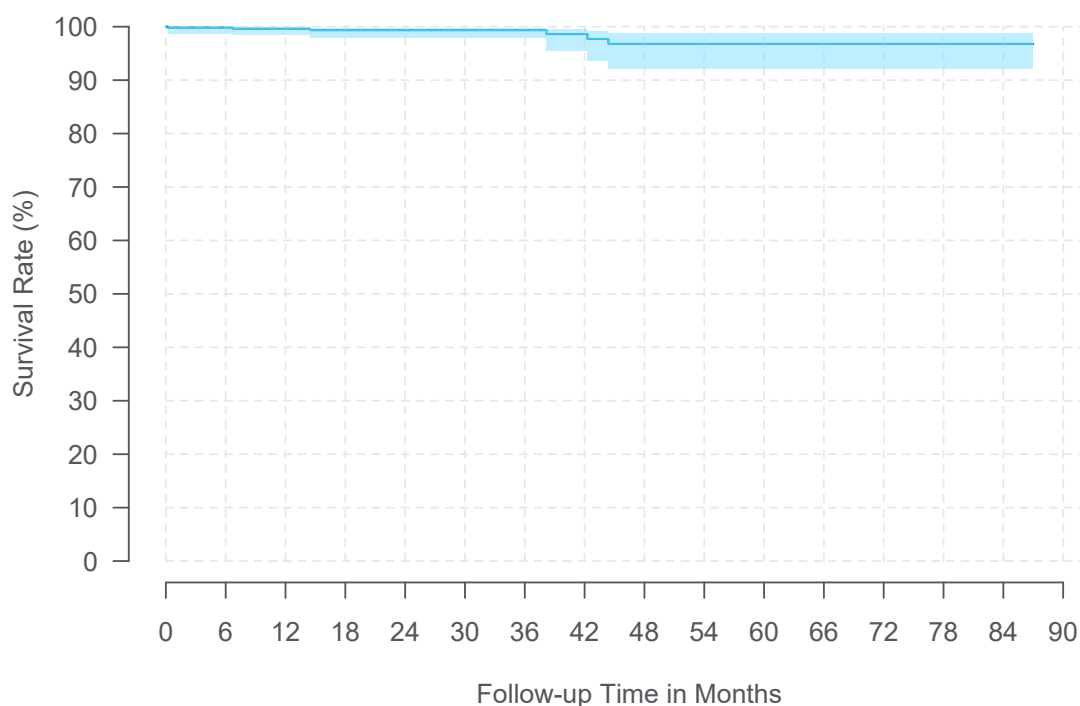
Specification: Itrel 4	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 $\mu$ sec
Groups	1
Programs	1
Implant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



Neurostimulator Event Summary: Itrel 4		N
High impedance		1
Total		1

#### 4.3.2.3 Model PrimeAdvanced

<b>Model Name</b>	PrimeAdvanced (model 37702)
<b>FDA Approval Date</b>	July 2006
<b>Neurostimulators Enrolled</b>	668
<b>Neurostimulators Currently Active in Study</b>	14
<b>Initial Product Performance Events</b>	6
<b>Median Follow-up Time (Months)</b>	16.0
<b>Cumulative Follow-up Time (Months)</b>	15,767



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	99.6%	99.3%	99.3%	96.8%	96.8%
(95% CI)	(98.5%, 99.9%)	(97.9%, 99.8%)	(97.9%, 99.8%)	(92.0%, 98.7%)	(92.0%, 98.7%)
Sample Size	393	238	143	95	66
Time Interval	6 Years	7 Years	At 87 Months		
Survival	96.8%	96.8%	96.8%	—	—
(95% CI)	(92.0%, 98.7%)	(92.0%, 98.7%)	(92.0%, 98.7%)	—	—
Sample Size	40	24	22		

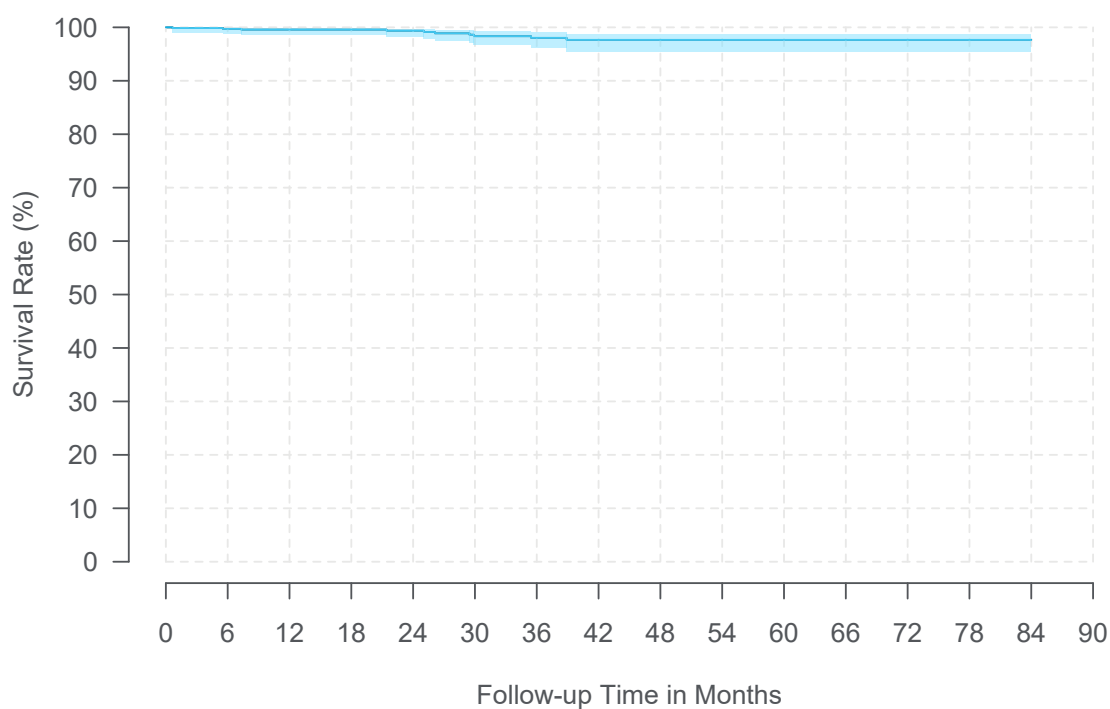
<b>Specification: PrimeAdvanced</b>	
<b>Height</b>	2.6 in (65 mm)
<b>Width</b>	1.9 in (49 mm)
<b>Thickness</b>	0.6 in (15 mm)
<b>Volume</b>	39 cc
<b>Battery type</b>	Non-Rechargeable
<b>Expected Battery life</b>	Depends on settings and use
<b>Maximum Electrodes</b>	16
<b>Amplitude</b>	0 - 10.5 V
<b>Rate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



<b>Neurostimulator Event Summary: PrimeAdvanced</b>	<b>N</b>
Device malfunction	2
High impedance	2
Device stimulation issue	1
Low impedance	1
<b>Total</b>	<b>6</b>

#### 4.3.2.4 Model PrimeAdvanced SureScan MRI

<b>Model Name</b>	PrimeAdvanced SureScan MRI (model 97702)
<b>FDA Approval Date</b>	March 2013
<b>Neurostimulators Enrolled</b>	785
<b>Neurostimulators Currently Active in Study</b>	223
<b>Initial Product Performance Events</b>	10
<b>Median Follow-up Time (Months)</b>	27.2
<b>Cumulative Follow-up Time (Months)</b>	24,884



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	99.6%	99.4%	98.0%	97.7%	97.7%
(95% CI)	(98.7%, 99.9%)	(98.3%, 99.8%)	(96.2%, 99.0%)	(95.5%, 98.8%)	(95.5%, 98.8%)
Sample Size	605	442	300	173	105
Time Interval	6 Years	7 Years			
Survival	97.7%	97.7%	—	—	—
(95% CI)	(95.5%, 98.8%)	(95.5%, 98.8%)	—	—	—
Sample Size	53	23			

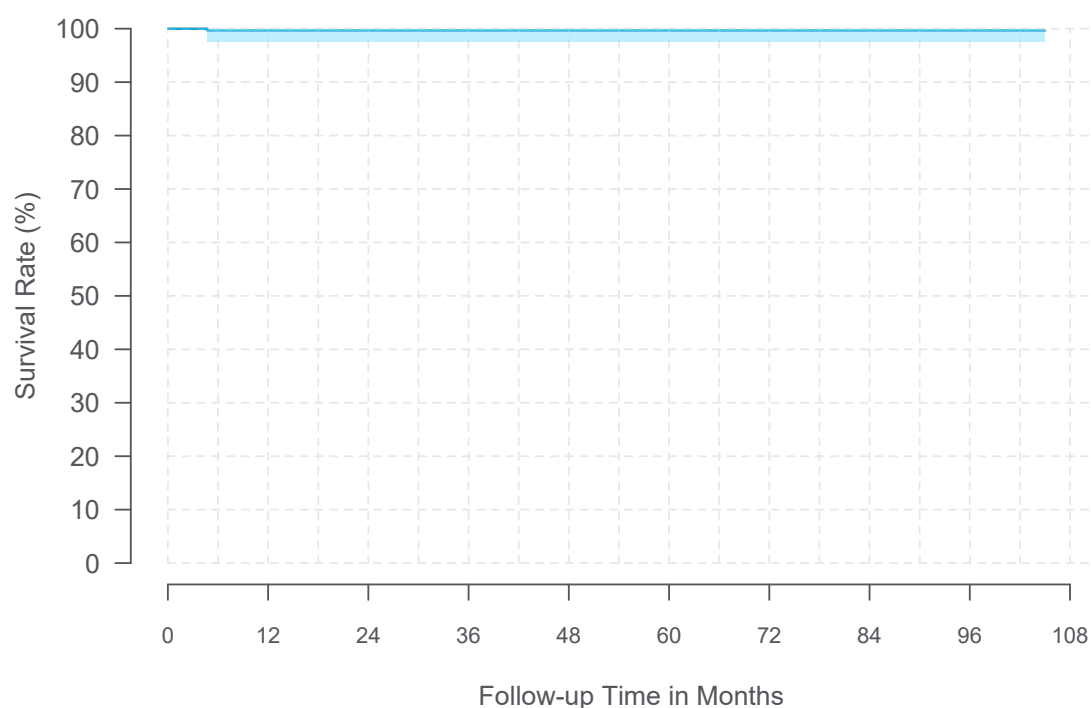
<b>Specification: PrimeAdvanced SureScan MRI</b>	
<b>Height</b>	2.6 in (65 mm)
<b>Width</b>	1.9 in (49 mm)
<b>Thickness</b>	0.6 in (15 mm)
<b>Volume</b>	39 cc
<b>Battery type</b>	Non-Rechargeable
<b>Expected Battery life</b>	Depends on settings and use
<b>Maximum Electrodes</b>	16
<b>Amplitude</b>	0 - 10.5 V
<b>Rate</b>	3 - 130 Hz
<b>Pulse Width</b>	60 - 450 $\mu$ sec
<b>Groups</b>	26
<b>Programs</b>	32
<b>Implant Depth</b>	$\leq$ 4 cm



<b>Neurostimulator Event Summary: PrimeAdvanced SureScan MRI</b>		<b>N</b>
High impedance		6
Premature battery depletion		2
Lead migration/dislodgement		1
Neurostimulator unable to recharge		1
<b>Total</b>		<b>10</b>

#### 4.3.2.5 Model RestoreAdvanced

<b>Model Name</b>	RestoreAdvanced (model 37713)
<b>FDA Approval Date</b>	July 2006
<b>Neurostimulators Enrolled</b>	357
<b>Neurostimulators Currently Active in Study</b>	2
<b>Initial Product Performance Events</b>	1
<b>Median Follow-up Time (Months)</b>	22.0
<b>Cumulative Follow-up Time (Months)</b>	11,327



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	99.7%	99.7%	99.7%	99.7%	99.7%
(95% CI)	(97.6%, 100%)	(97.6%, 100%)	(97.6%, 100%)	(97.6%, 100%)	(97.6%, 100%)
Sample Size	238	170	115	84	62

Time Interval	6 Years	7 Years	8 Years	At 105 Months	
Survival	99.7%	99.7%	99.7%	99.7%	
(95% CI)	(97.6%, 100%)	(97.6%, 100%)	(97.6%, 100%)	(97.6%, 100%)	—
Sample Size	49	35	29	20	

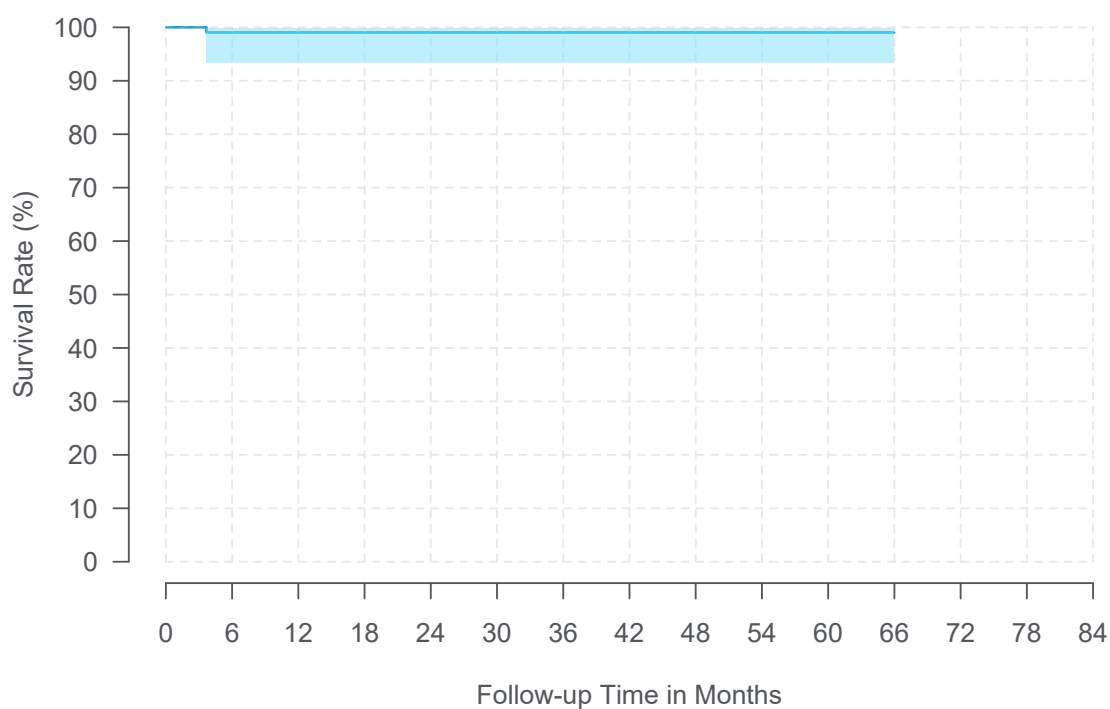
Specification: RestoreAdvanced	
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 $\mu$ sec
Groups	26
Programs	32
Implant Depth	$\leq 1$ cm



Neurostimulator Event Summary: RestoreAdvanced		N
Medical device complication		1
Total		1

#### 4.3.2.6 Model RestoreAdvanced SureScan MRI

<b>Model Name</b>	RestoreAdvanced SureScan MRI (model 97713)
<b>FDA Approval Date</b>	March 2013
<b>Neurostimulators Enrolled</b>	116
<b>Neurostimulators Currently Active in Study</b>	24
<b>Initial Product Performance Events</b>	2
<b>Median Follow-up Time (Months)</b>	33.6
<b>Cumulative Follow-up Time (Months)</b>	4,239



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	99.0%	99.0%	99.0%	99.0%	99.0%
(95% CI)	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)	(93.4%, 99.9%)
Sample Size	89	71	54	36	26

Time Interval	At 66 Months				
Survival	99.0%				
(95% CI)	(93.4%, 99.9%)	—	—	—	—
Sample Size	20				

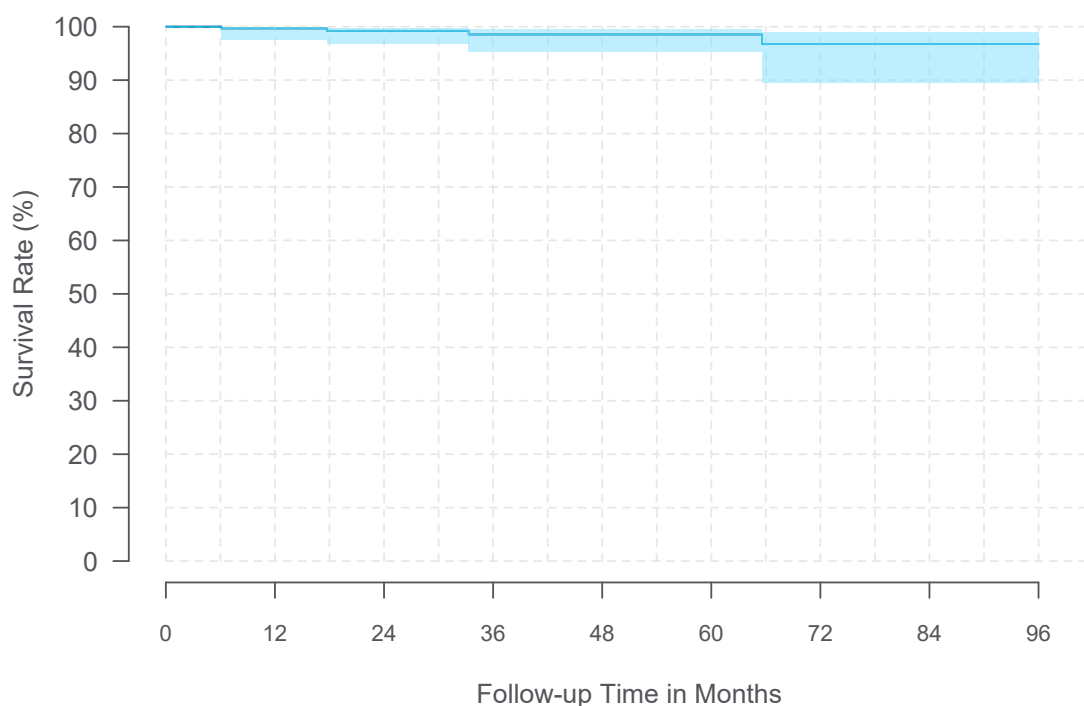
Specification:	
RestoreAdvanced MRI	SureScan
Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 $\mu$ sec
Groups	26
Programs	32
Implant Depth	$\leq$ 1 cm



Neurostimulator Event Summary: RestoreAdvanced SureScan MRI		N
Device malfunction		1
Neurostimulator unable to recharge		1
<b>Total</b>		<b>2</b>

#### 4.3.2.7 Model RestoreSensor

<b>Model Name</b>	RestoreSensor (model 37714)
<b>FDA Approval Date</b>	November 2011
<b>Neurostimulators Enrolled</b>	377
<b>Neurostimulators Currently Active in Study</b>	20
<b>Initial Product Performance Events</b>	5
<b>Median Follow-up Time (Months)</b>	23.2
<b>Cumulative Follow-up Time (Months)</b>	12,047



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	99.7%	99.2%	98.5%	98.5%	98.5%
(95% CI)	(97.7%, 100%)	(96.9%, 99.8%)	(95.3%, 99.6%)	(95.3%, 99.6%)	(95.3%, 99.6%)
Sample Size	258	185	135	92	65

Time Interval	6 Years	7 Years	8 Years		
Survival	96.8%	96.8%	96.8%	—	—
(95% CI)	(89.6%, 99.0%)	(89.6%, 99.0%)	(89.6%, 99.0%)	—	—
Sample Size	43	31	21		

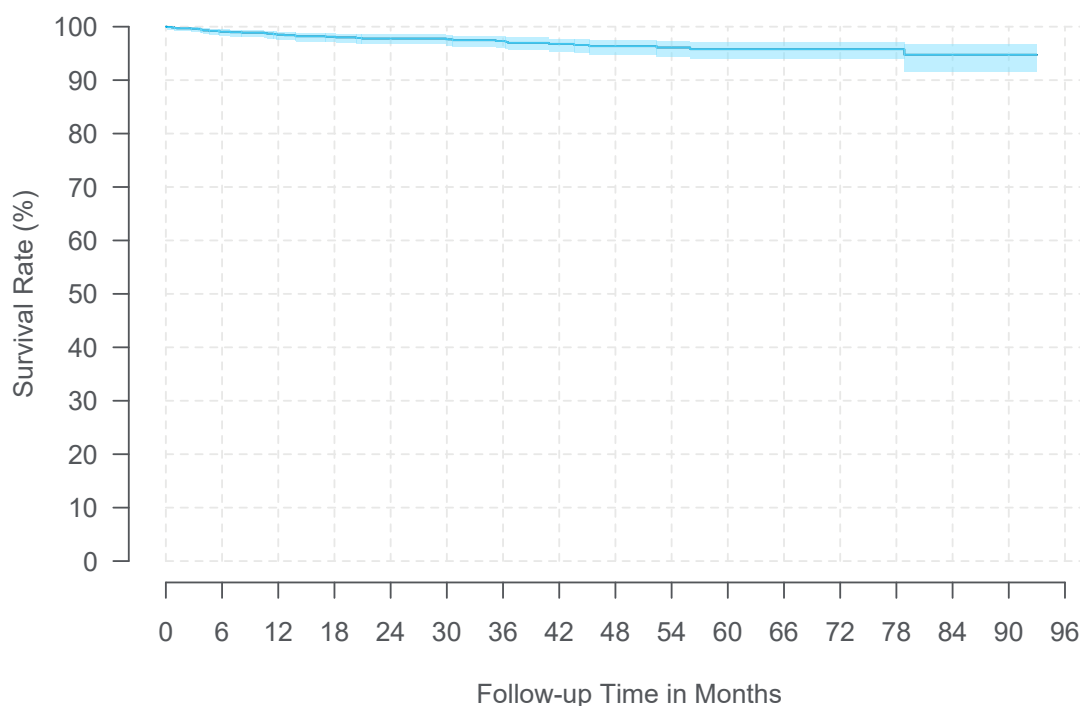
Specification: RestoreSensor	
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 1 cm



Neurostimulator Event Summary: RestoreSensor		N
Neurostimulator unable to recharge		3
Device issue		1
Device malfunction		1
Total		5

#### 4.3.2.8 Model RestoreSensor SureScan MRI

<b>Model Name</b>	RestoreSensor SureScan MRI (model 97714)
<b>FDA Approval Date</b>	March 2013
<b>Neurostimulators Enrolled</b>	1,382
<b>Neurostimulators Currently Active in Study</b>	278
<b>Initial Product Performance Events</b>	36
<b>Median Follow-up Time (Months)</b>	29.4
<b>Cumulative Follow-up Time (Months)</b>	48,075

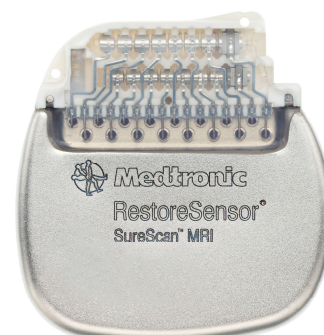


Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	98.5%	97.8%	97.3%	96.4%	95.8%
(95% CI)	(97.6%, 99.1%)	(96.7%, 98.5%)	(96.1%, 98.2%)	(94.8%, 97.5%)	(94.0%, 97.1%)
Sample Size	1,042	790	575	419	263

Time Interval	6 Years	7 Years	At 93 Months		
Survival	95.8%	94.7%	94.7%	—	—
(95% CI)	(94.0%, 97.1%)	(91.5%, 96.8%)	(91.5%, 96.8%)	—	—
Sample Size	142	63	23		

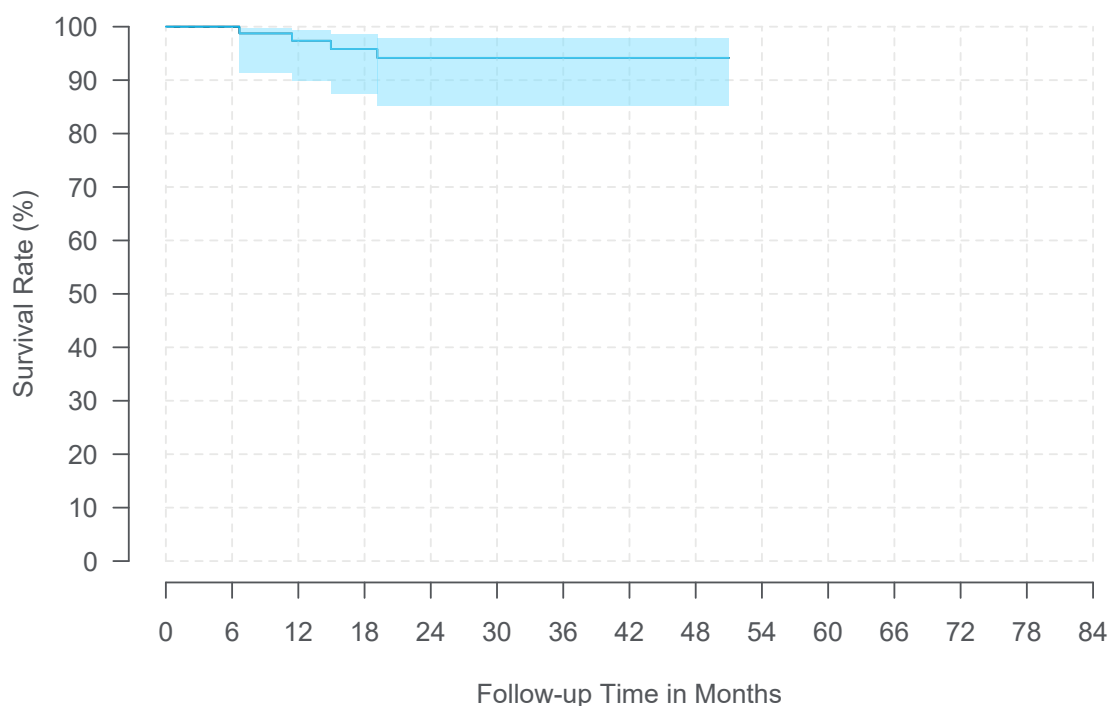
Specification: RestoreSensor SureScan MRI	
Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thickness	9 mm (0.4 in)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth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



Neurostimulator Event Summary: RestoreSensor SureScan MRI		N
Neurostimulator unable to recharge		11
Device malfunction		7
Lead migration/dislodgement		6
High impedance		2
Low impedance		2
Neurostimulator migration		2
Device battery issue		1
Device breakage		1
Device stimulation issue		1
Grommet loose		1
Medical device site warmth		1
Pain		1
<b>Total</b>		<b>36</b>

#### 4.3.2.9 Model RestoreUltra SureScan MRI

<b>Model Name</b>	RestoreUltra SureScan MRI (model 97712)
<b>FDA Approval Date</b>	March 2013
<b>Neurostimulators Enrolled</b>	93
<b>Neurostimulators Currently Active in Study</b>	34
<b>Initial Product Performance Events</b>	4
<b>Median Follow-up Time (Months)</b>	28.5
<b>Cumulative Follow-up Time (Months)</b>	2,917



<b>Time Interval</b>	<b>1 Year</b>	<b>2 Years</b>	<b>3 Years</b>	<b>4 Years</b>	<b>At 51 Months</b>
Survival	97.4%	94.2%	94.2%	94.2%	94.2%
(95% CI)	(89.8%, 99.3%)	(85.1%, 97.8%)	(85.1%, 97.8%)	(85.1%, 97.8%)	(85.1%, 97.8%)
Sample Size	68	51	38	22	22

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



<b>Neurostimulator Event Summary: RestoreUltra SureScan MRI</b>		<b>N</b>
Extension migration		1
Neurostimulator unable to recharge		1
No anomaly found by rpa		1
Therapeutic product ineffective		1
<b>Total</b>		<b>4</b>

### 4.3.3 Neurostimulator Summary

**Table 4.11:** Spinal Cord Stimulation Primary Cell Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Itrel 4 (model 37703)	May 2012	135	41	1	30.2	4,596
PrimeAdvanced (model 37702)	July 2006	668	14	6	16.0	15,767
PrimeAdvanced SureScan MRI (model 97702)	March 2013	785	223	10	27.2	24,884

**Table 4.12:** Spinal Cord Stimulation Primary Cell Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Itrel 4 (model 37703)	100.0% (NA)	99.1% (93.8%, 99.9%)	99.1% (93.8%, 99.9%)	99.1% (93.8%, 99.9%)	—
PrimeAdvanced (model 37702)	99.6% (98.5%, 99.9%)	99.3% (97.9%, 99.8%)	99.3% (97.9%, 99.8%)	96.8% (92.0%, 98.7%)	96.8% (92.0%, 98.7%)
PrimeAdvanced SureScan MRI (model 97702)	99.6% (98.7%, 99.9%)	99.4% (98.3%, 99.8%)	98.0% (96.2%, 99.0%)	97.7% (95.5%, 98.8%)	97.7% (95.5%, 98.8%)

Model Name	6 Years	7 Years			
Itrel 4 (model 37703)	—	—	—	—	—
PrimeAdvanced (model 37702)	96.8% (92.0%, 98.7%)	96.8% (92.0%, 98.7%)	—	—	—
PrimeAdvanced SureScan MRI (model 97702)	97.7% (95.5%, 98.8%)	97.7% (95.5%, 98.8%)	—	—	—

**Table 4.13: Spinal Cord Stimulation Rechargeable Neurostimulator Characteristics**

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Device Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Intellis with AdaptiveStim (model 97715)	September 2017	1,281	887	13	17.0	24,254
RestoreAdvanced (model 37713)	July 2006	357	2	1	22.0	11,327
RestoreAdvanced SureScan MRI (model 97713)	March 2013	116	24	2	33.6	4,239
RestoreSensor (model 37714)	November 2011	377	20	5	23.2	12,047
RestoreSensor SureScan MRI (model 97714)	March 2013	1,382	278	36	29.4	48,075
RestoreUltra SureScan MRI (model 97712)	March 2013	93	34	4	28.5	2,917

**Table 4.14: Spinal Cord Stimulation Rechargeable Neurostimulator Survival Probability (95% Confidence Intervals)**

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Intellis with AdaptiveStim (model 97715)	99.5% (98.8%, 99.8%)	98.7% (97.6%, 99.3%)	98.1% (96.4%, 99.0%)	97.6% (95.5%, 98.7%)	—
RestoreAdvanced (model 37713)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)
RestoreAdvanced SureScan MRI (model 97713)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)	99.0% (93.4%, 99.9%)
RestoreSensor (model 37714)	99.7% (97.7%, 100%)	99.2% (96.9%, 99.8%)	98.5% (95.3%, 99.6%)	98.5% (95.3%, 99.6%)	98.5% (95.3%, 99.6%)
RestoreSensor SureScan MRI (model 97714)	98.5% (97.6%, 99.1%)	97.8% (96.7%, 98.5%)	97.3% (96.1%, 98.2%)	96.4% (94.8%, 97.5%)	95.8% (94.0%, 97.1%)
RestoreUltra SureScan MRI (model 97712)	97.4% (89.8%, 99.3%)	94.2% (85.1%, 97.8%)	94.2% (85.1%, 97.8%)	94.2% (85.1%, 97.8%)	—

Model Name	6 Years	7 Years	8 Years		
Intellis with AdaptiveStim (model 97715)	—	—	—	—	—
RestoreAdvanced (model 37713)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)	99.7% (97.6%, 100%)	—	—
RestoreAdvanced SureScan MRI (model 97713)	—	—	—	—	—
RestoreSensor (model 37714)	96.8% (89.6%, 99.0%)	96.8% (89.6%, 99.0%)	96.8% (89.6%, 99.0%)	—	—
RestoreSensor SureScan MRI (model 97714)	95.8% (94.0%, 97.1%)	94.7% (91.5%, 96.8%)	—	—	—
RestoreUltra SureScan MRI (model 97712)	—	—	—	—	—

## 4.4 Leads

From June 2004 to the report cut-off date of October 31, 2022, there were 11,198 leads followed in the registry. The difference between the total number of leads (n=11,198) versus the number of neurostimulators (n=6,983) is due to the fact that some patients were subsequently re-implanted with a lead or were implanted with more than one lead. The aggregate prospective follow-up time for all leads was 344,437 months (28,703 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). [Table 4.15](#) provides the number and percentage of leads by model.

**Table 4.15:** Spinal Cord Stimulation Lead Counts by Model

Model Name	N (%)
<b>Currently manufactured</b>	<b>10,234 (91.4%)</b>
Vectris SureScan MRI 1x8 Compact (977A2)	4,602 (41.1%)
1x8 Compact (3778)	2,168 (19.4%)
Pisces Standard (3487A)	992 (8.9%)
1x8 Standard (3777)	838 (7.5%)
Pisces Plus (3888)	455 (4.1%)
Specify 5-6-5 (39565)	294 (2.6%)
AnkerStim Lead (Approved in Europe, 09100)	201 (1.8%)
Pisces Compact (3887)	200 (1.8%)
1x8 SC (3776)	188 (1.7%)
Vectris SureScan MRI 1x8 Subcompact (977A1)	144 (1.3%)
Specify SureScan MRI 5-6-5 (977C1)	77 (0.7%)
Specify SureScan MRI 2x8 (977C2)	43 (0.4%)
Specify 2x8 (39286)	32 (0.3%)
<b>No longer manufactured</b>	<b>686 (6.1%)</b>
Specify (3998)	157 (1.4%)
Pisces Z Standard (3890)	143 (1.3%)
Pisces Z Compact (3891)	130 (1.2%)
Resume TL (3986A)	108 (1.0%)
Resume II (3587A)	58 (0.5%)
2x4 Hinged Specify (3999)	54 (0.5%)
Pisces Z Plus (3892)	25 (0.2%)
On-Point (3987A)	9 (0.1%)
SymMix (3982A)	2 (0.0%)
<b>Other/Unspecified</b>	<b>278 (2.5%)</b>
<b>Total</b>	<b>11,198 (100%)</b>

Percutaneous leads composed 88.3% (9,885/11,198) of leads in the registry, including 42.4% (4,746/11,198) in the Vectris SureScan lead family, 28.5% (3,194/11,198) in the Pisces-Octad lead family, 14.7% (1,647/11,198) in the Pisces-Quad lead family, and 2.7% (298/11,198) in the Pisces-

Quad LZ lead family; 7.4% (834/11,198) of leads were surgical leads; and 4.3% (479/11,198) of leads were designated as "Other" or were unspecified in the database.

#### 4.4.1 Lead Events

There were 1,464 product performance-related events with an underlying reported etiology related to lead function. This includes 1,436 events with a lead etiology and 28 events with both a lead and other etiology (including device and non-device etiologies). Of these, 1,072 were the initial product performance event that affected lead survival estimates; the majority were lead migration/dislodgement (n=647), high impedance (n=238), lead fracture (n=84), device stimulation issue (n=42), and low impedance (n=29). There were 984 events in 9,885 (10.0%) percutaneous leads, 47 events in 834 (5.6%) surgical leads, and 41 events occurred in leads with unknown/other model numbers.

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:

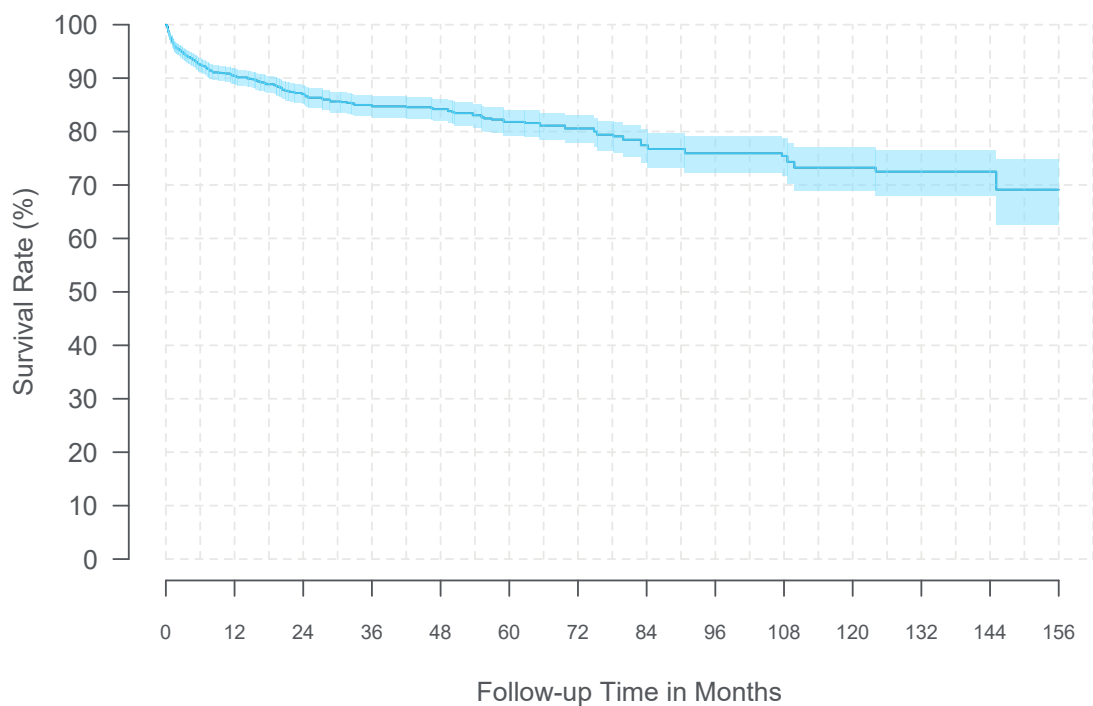
- 1,072 had follow-up time cut-off due to product performance-related events.
- 7,600 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,526 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

#### 4.4.2 Lead Models

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

#### 4.4.2.1 Model 1x8 Compact

<b>Model Name</b>	1x8 Compact (model 3778)
<b>FDA Approval Date</b>	April 2005
<b>Leads Enrolled</b>	2,168
<b>Leads Currently Active in Study</b>	101
<b>Initial Product Performance Events</b>	265
<b>Median Follow-up Time (Months)</b>	17.9
<b>Cumulative Follow-up Time (Months)</b>	68,373



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	90.4% (88.9%, 91.8%)	87.0% (85.1%, 88.6%)	84.7% (82.6%, 86.6%)	84.2% (82.0%, 86.1%)	81.8% (79.3%, 84.1%)
Sample Size	1,210	801	601	455	378
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	80.6% (77.8%, 83.0%)	77.4% (74.1%, 80.4%)	75.9% (72.3%, 79.1%)	75.4% (71.7%, 78.7%)	73.2% (69.0%, 77.0%)
Sample Size	291	218	177	146	110
Time Interval	11 Years	12 Years	13 Years		
Survival (95% CI)	72.5% (68.0%, 76.5%)	72.5% (68.0%, 76.5%)	69.1% (62.6%, 74.8%)	—	—
Sample Size	71	44	21		

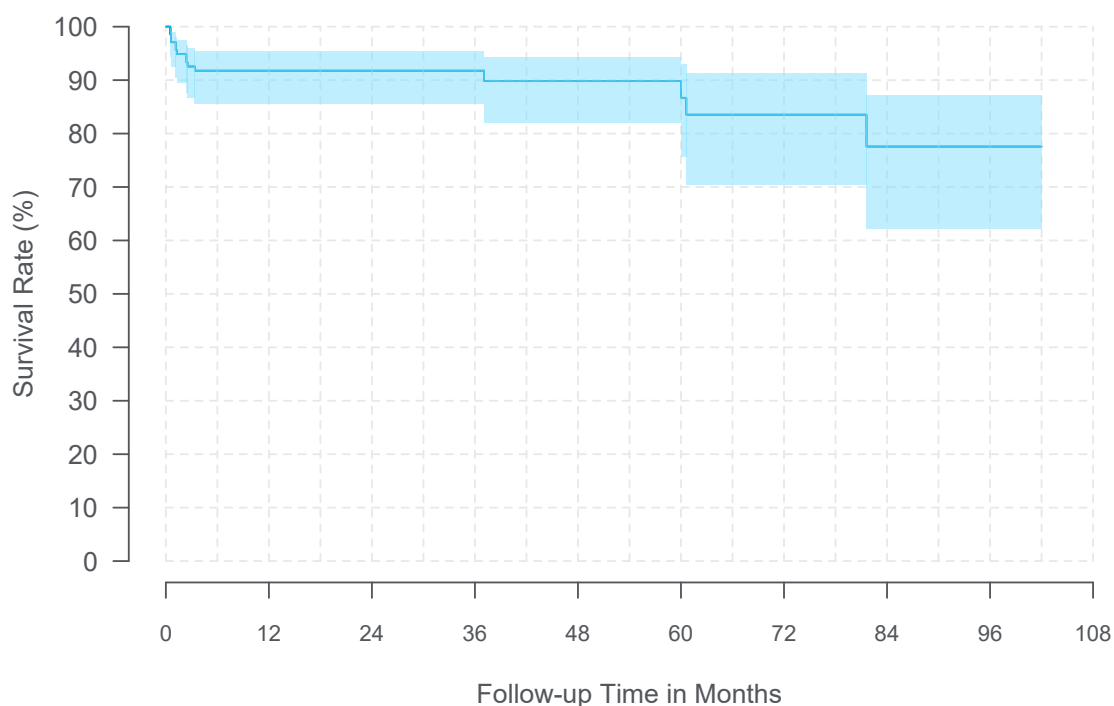
Specification: 1x8 Compact	
Lead Type	Percutaneous
Lead	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0



Lead Event Summary: 1x8 Compact	N
Lead migration/dislodgement	205
High impedance	27
Lead fracture	19
Device stimulation issue	6
Device malfunction	2
Low impedance	2
Medical device complication	2
Medical device site erosion	2
<b>Total</b>	<b>265</b>

#### 4.4.2.2 Model 1x8 SC

<b>Model Name</b>	1x8 SC (model 3776)
<b>FDA Approval Date</b>	November 2005
<b>Leads Enrolled</b>	188
<b>Leads Currently Active in Study</b>	13
<b>Initial Product Performance Events</b>	17
<b>Median Follow-up Time (Months)</b>	15.0
<b>Cumulative Follow-up Time (Months)</b>	5,565



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	91.8%	91.8%	91.8%	89.8%	86.7%
(95% CI)	(85.6%, 95.4%)	(85.6%, 95.4%)	(85.6%, 95.4%)	(82.0%, 94.4%)	(75.6%, 93.0%)
Sample Size	86	64	49	37	27

Time Interval	6 Years	7 Years	8 Years	At 102 Months	
Survival	83.5%	77.6%	77.6%	77.6%	
(95% CI)	(70.4%, 91.2%)	(62.3%, 87.3%)	(62.3%, 87.3%)	(62.3%, 87.3%)	—
Sample Size	22	23	24	21	

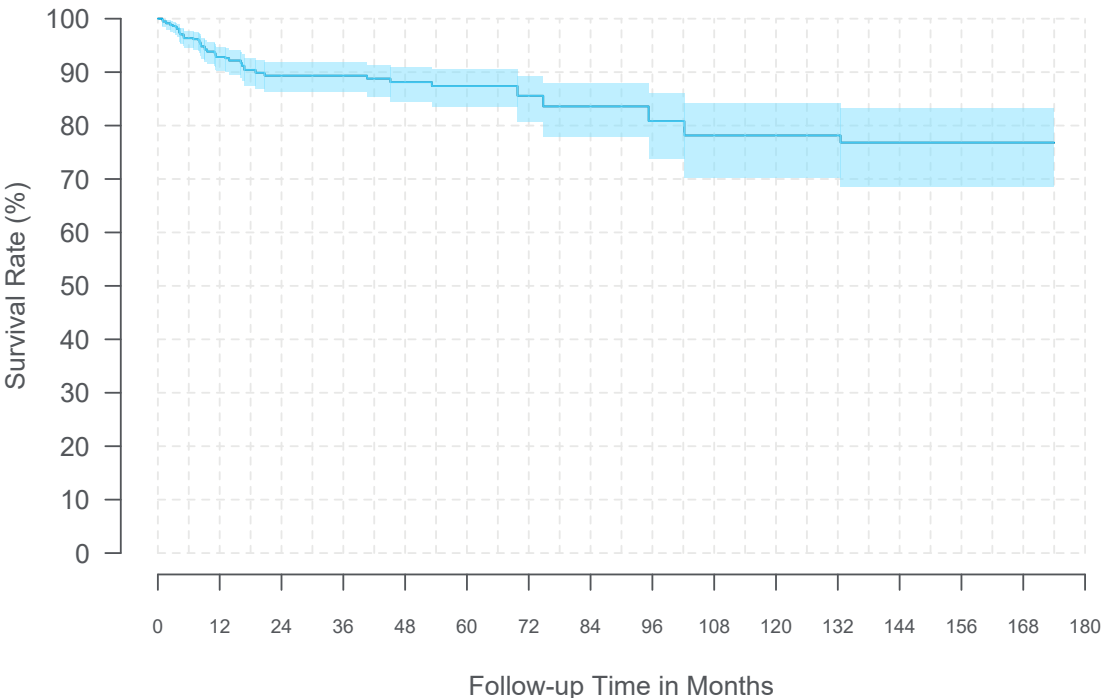
<b>Specification: 1x8 SC</b>	
<b>Lead Type</b>	Percutaneous
<b>Lead</b>	
Length (cm)	45, 60, 75
Diameter (mm)	1.3
<b>Electrode</b>	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	35.0



<b>Lead Event Summary: 1x8 SC</b>	<b>N</b>
Lead migration/dislodgement	12
High impedance	3
Device stimulation issue	1
Lead fracture	1
<b>Total</b>	<b>17</b>

4.4.2.3 Model 1x8 Standard

Model Name	1x8 Standard (model 3777)
FDA Approval Date	April 2005
Leads Enrolled	838
Leads Currently Active in Study	57
Initial Product Performance Events	71
Median Follow-up Time (Months)	16.4
Cumulative Follow-up Time (Months)	24,810



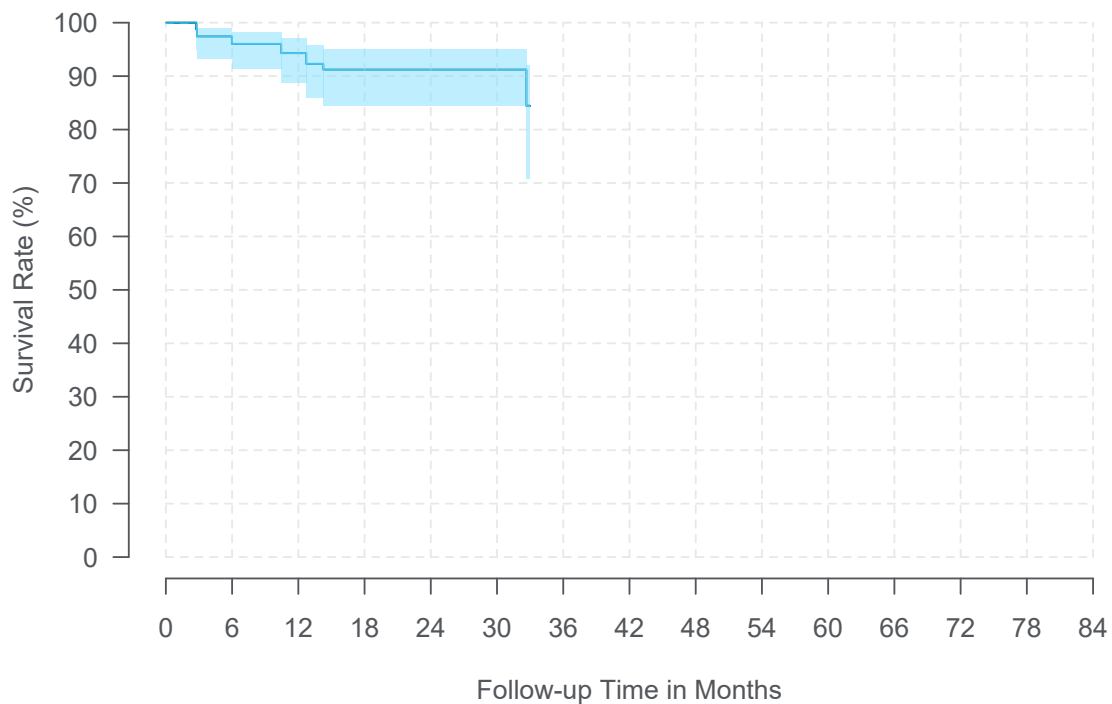
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.8% (90.3%, 94.7%)	89.3% (86.2%, 91.8%)	89.3% (86.2%, 91.8%)	88.1% (84.5%, 91.0%)	87.4% (83.4%, 90.5%)
Sample Size	443	287	186	129	105
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	85.6% (80.7%, 89.3%)	83.6% (77.9%, 87.9%)	80.8% (73.9%, 86.1%)	78.1% (70.3%, 84.2%)	78.1% (70.3%, 84.2%)
Sample Size	89	72	58	72	66
Time Interval	11 Years	12 Years	13 Years	14 Years	At 174 Months
Survival (95% CI)	78.1% (70.3%, 84.2%)	76.8% (68.5%, 83.2%)	76.8% (68.5%, 83.2%)	76.8% (68.5%, 83.2%)	76.8% (68.5%, 83.2%)
Sample Size	58	49	40	27	23

Specification: 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 <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	66.0

Lead Event Summary: 1x8 Standard	N
Lead migration/dislodgement	41
High impedance	14
Device stimulation issue	7
Lead fracture	3
Device lead damage	2
Device malfunction	2
Low impedance	2
<b>Total</b>	<b>71</b>

#### 4.4.2.4 Model AnkerStim

<b>Model Name</b>	AnkerStim (model 09100)
<b>FDA Approval Date</b>	NA
<b>Leads Enrolled</b>	201
<b>Leads Currently Active in Study</b>	142
<b>Initial Product Performance Events</b>	13
<b>Median Follow-up Time (Months)</b>	12.6
<b>Cumulative Follow-up Time (Months)</b>	3,165



<b>Time Interval</b>	<b>1 Year</b>	<b>2 Years</b>	<b>At 33 Months</b>
Survival	94.3%	91.2%	84.5%
(95% CI)	(88.9%, 97.1%)	(84.5%, 95.1%)	(70.9%, 92.1%)
Sample Size	101	54	22

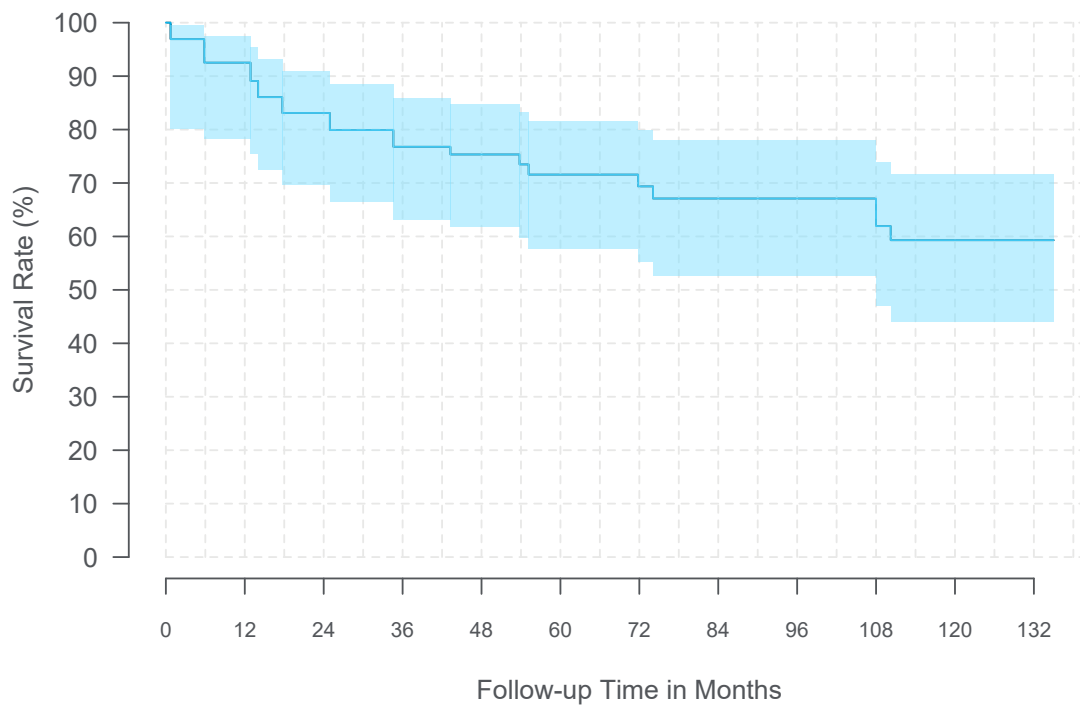
Specification: AnkerStim	
<b>Lead Type</b>	Percutaneous
<b>Lead</b>	
Length (cm)	60
Diameter (mm)	1.3
<b>Electrode</b>	
Number	4
Shape	Cylindrical
Length (mm)	6.0
Individual Surface Area (mm)	24.5
Inter-Electrode Spacing: Edge to Edge (mm)	12.0
Array Length (mm)	60.0



Lead Event Summary: AnkerStim	N
Lead migration/dislodgement	5
High impedance	4
Lead fracture	2
Medical device complication	2
<b>Total</b>	<b>13</b>

#### 4.4.2.5 Model Pisces Compact

<b>Model Name</b>	Pisces Compact (model 3887)
<b>FDA Approval Date</b>	January 1997
<b>Leads Enrolled</b>	200
<b>Leads Currently Active in Study</b>	26
<b>Initial Product Performance Events</b>	25
<b>Median Follow-up Time (Months)</b>	22.5
<b>Cumulative Follow-up Time (Months)</b>	7,666



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (78.3%, 97.6%)	83.1% (69.7%, 90.9%)	76.8% (63.2%, 85.9%)	75.3% (61.8%, 84.7%)	71.6% (57.7%, 81.6%)
Sample Size	51	54	49	43	37
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	69.4% (55.2%, 79.8%)	67.1% (52.7%, 78.0%)	67.1% (52.7%, 78.0%)	61.9% (46.9%, 73.8%)	59.3% (44.1%, 71.7%)
Sample Size	31	26	24	23	24
Time Interval	11 Years	At 135 Months			
Survival (95% CI)	59.3% (44.1%, 71.7%)	59.3% (44.1%, 71.7%)	—	—	—
Sample Size	20	20			

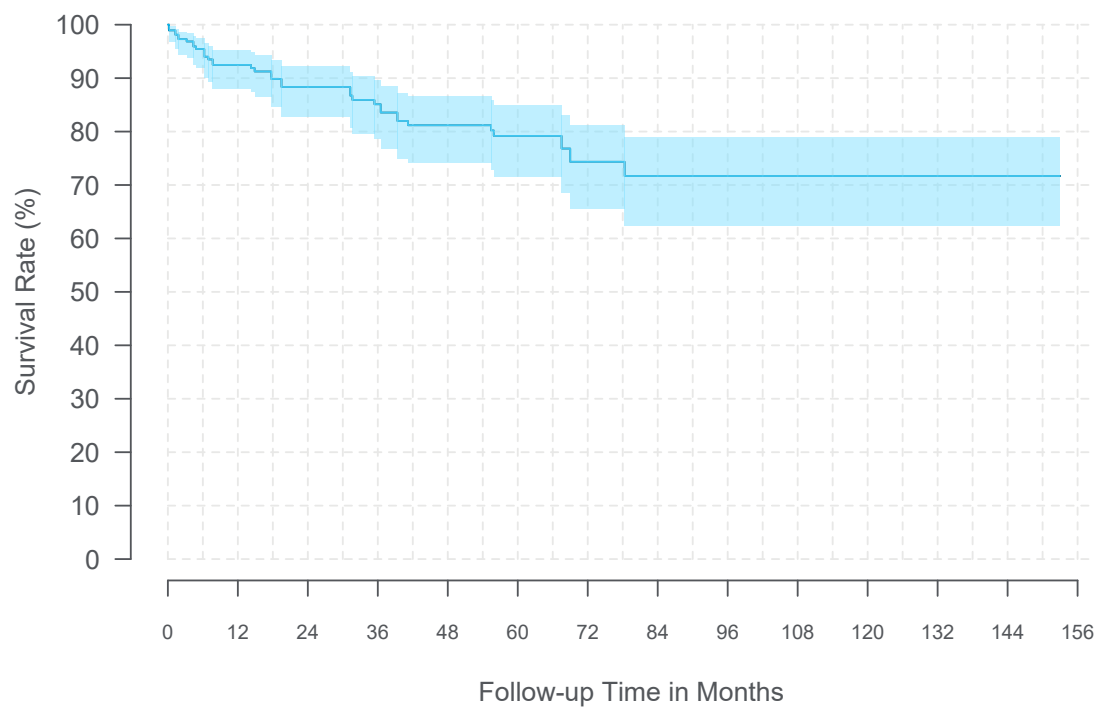
Specification: Pisces Compact	
Lead Type	Percutaneous
Lead	
Length (cm)	28, 33, 45, 56
Diameter (mm)	1.3
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	24.0



Lead Event Summary: Pisces Compact	N
Lead fracture	9
Lead migration/dislodgement	9
High impedance	4
Device stimulation issue	2
Device lead damage	1
<b>Total</b>	<b>25</b>

#### 4.4.2.6 Model Pisces Plus

<b>Model Name</b>	Pisces Plus (model 3888)
<b>FDA Approval Date</b>	November 1992
<b>Leads Enrolled</b>	455
<b>Leads Currently Active in Study</b>	44
<b>Initial Product Performance Events</b>	44
<b>Median Follow-up Time (Months)</b>	14.9
<b>Cumulative Follow-up Time (Months)</b>	12,490



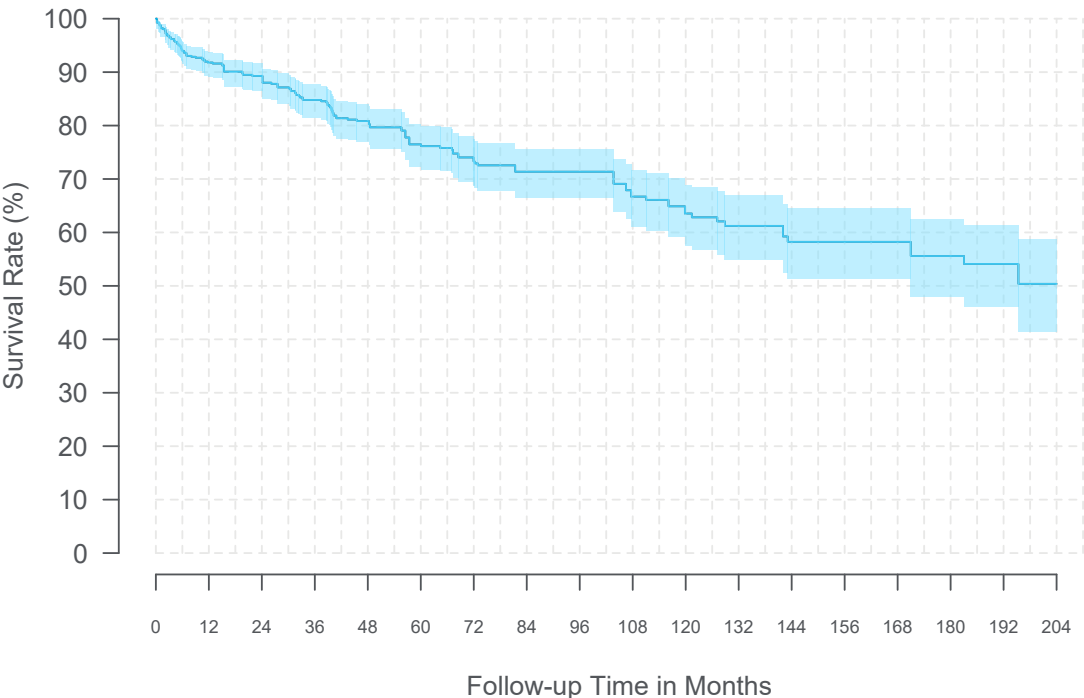
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	92.5% (88.1%, 95.3%)	88.3% (82.8%, 92.2%)	85.1% (78.7%, 89.7%)	81.2% (74.1%, 86.5%)	79.2% (71.6%, 85.0%)
Sample Size	163	115	108	89	72
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	74.3% (65.6%, 81.2%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)
Sample Size	55	46	43	35	35
Time Interval	11 Years	12 Years	At 153 Months		
Survival (95% CI)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	—	—
Sample Size	31	24	23		

Specification: 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 <sup>2</sup> )	24.0
Inter-Electrode Spacing: Edge to Edge (mm)	12.0
Array Length (mm)	60.0

Lead Event Summary: Pisces Plus	N
Lead migration/dislodgement	31
High impedance	10
Device stimulation issue	2
Lead fracture	1
<b>Total</b>	<b>44</b>

4.4.2.7 Model Pisces Standard

<b>Model Name</b>	Pisces Standard (model 3487A)
<b>FDA Approval Date</b>	May 1988
<b>Leads Enrolled</b>	992
<b>Leads Currently Active in Study</b>	55
<b>Initial Product Performance Events</b>	166
<b>Median Follow-up Time (Months)</b>	31.1
<b>Cumulative Follow-up Time (Months)</b>	42,088



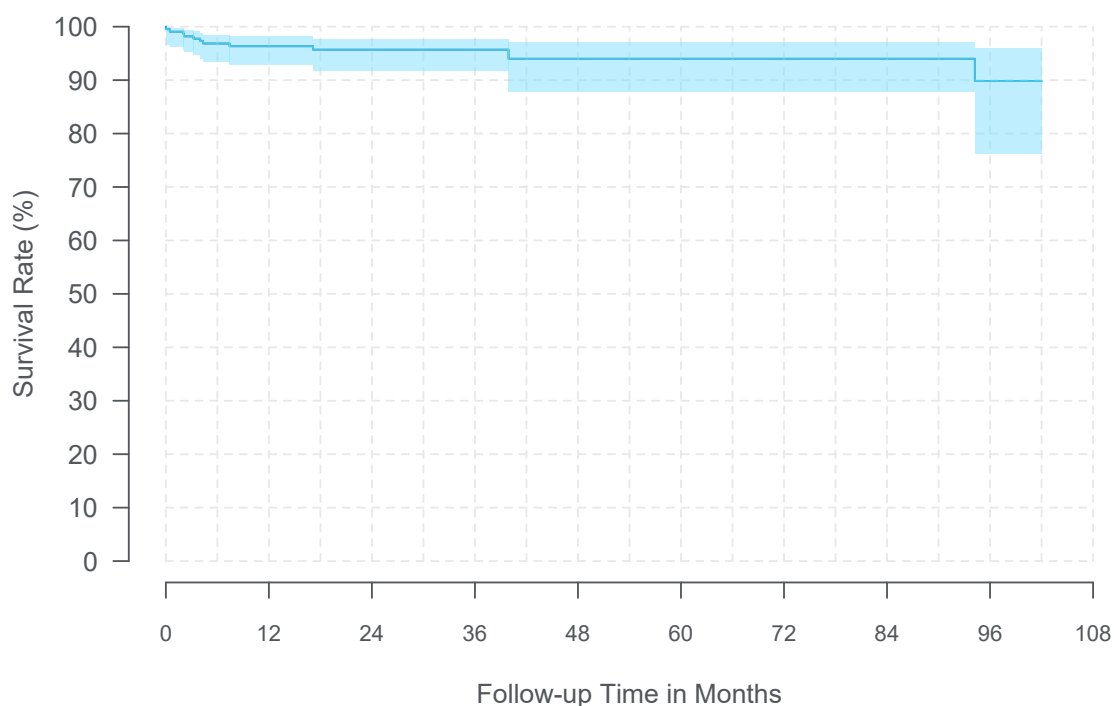
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	91.8% (89.2%, 93.8%)	89.3% (86.4%, 91.6%)	84.8% (81.4%, 87.6%)	80.8% (77.0%, 84.1%)	76.5% (72.2%, 80.2%)
Sample Size	511	422	358	281	231
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	73.3% (68.7%, 77.4%)	71.4% (66.5%, 75.6%)	71.4% (66.5%, 75.6%)	66.7% (61.1%, 71.7%)	63.5% (57.5%, 68.9%)
Sample Size	198	166	133	112	93
Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	61.2% (54.8%, 67.0%)	58.2% (51.3%, 64.6%)	58.2% (51.3%, 64.6%)	58.2% (51.3%, 64.6%)	55.6% (48.0%, 62.5%)
Sample Size	67	58	54	45	40
Time Interval	16 Years	17 Years			
Survival (95% CI)	54.1% (46.1%, 61.4%)	50.4% (41.4%, 58.7%)	—	—	—
Sample Size	31	21			

Specification: 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 <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	6.0
Array Length (mm)	30.0

Lead Event Summary: Pisces Standard	N
High impedance	69
Lead migration/dislodgement	53
Device stimulation issue	17
Low impedance	15
Lead fracture	9
Inadequate lead connection	2
Device lead damage	1
<b>Total</b>	<b>166</b>

#### 4.4.2.8 Model Specify 5-6-5

<b>Model Name</b>	Specify 5-6-5 (model 39565)
<b>FDA Approval Date</b>	June 2007
<b>Leads Enrolled</b>	294
<b>Leads Currently Active in Study</b>	32
<b>Initial Product Performance Events</b>	11
<b>Median Follow-up Time (Months)</b>	22.5
<b>Cumulative Follow-up Time (Months)</b>	8,507



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	96.3%	95.7%	95.7%	94.0%	94.0%
(95% CI)	(92.8%, 98.2%)	(91.8%, 97.8%)	(91.8%, 97.8%)	(87.9%, 97.1%)	(87.9%, 97.1%)
Sample Size	163	116	71	46	35

Time Interval	6 Years	7 Years	8 Years	At 102 Months	
Survival	94.0%	94.0%	89.8%	89.8%	
(95% CI)	(87.9%, 97.1%)	(87.9%, 97.1%)	(76.1%, 95.9%)	(76.1%, 95.9%)	—
Sample Size	30	22	21	20	

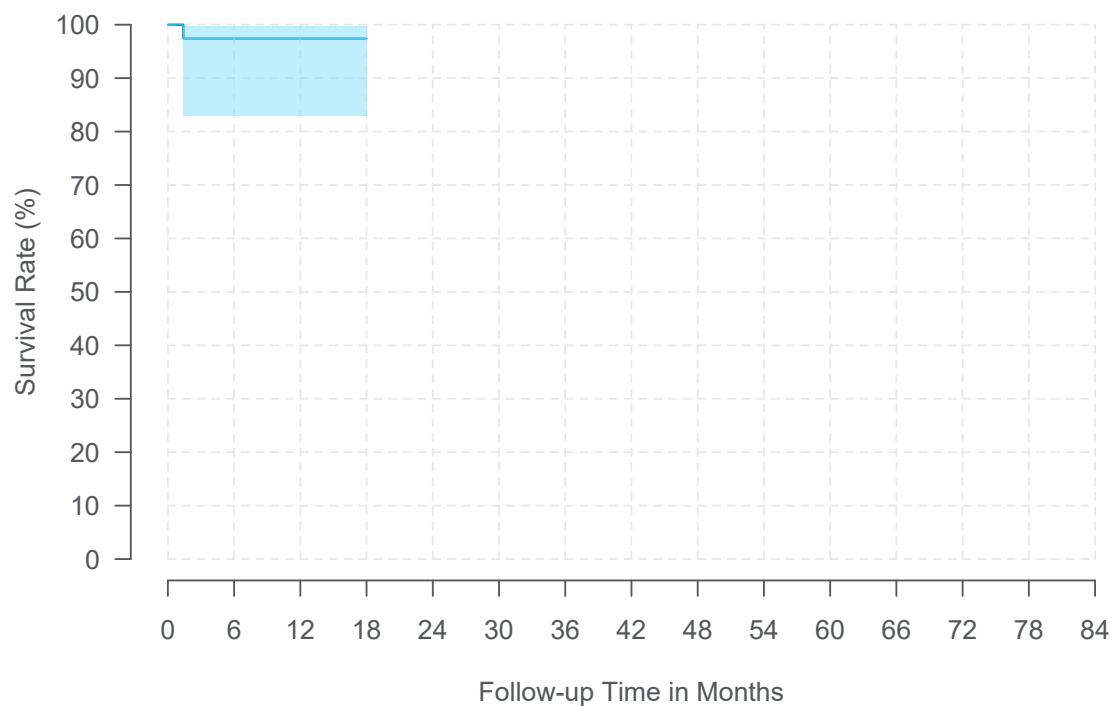
Specification: Specify 5-6-5	
<b>Lead Type</b>	Surgical
<b>Lead</b>	
Length (cm)	30, 65
Diameter (mm)	1.3
<b>Electrode</b>	
Number	16
Shape	Rectangular
Length (mm)	4.0
Width (mm)	1.5
Individual Surface Area (mm <sup>2</sup> )	6.0
Longitudinal Spacing: Edge to Edge (mm)	4.5
Lateral Spacing: Edge to Edge (mm)	1.0
Array Length (mm)	49.0
Array Width (mm)	7.5
<b>Paddle</b>	
Length (mm)	64.2
Width (mm)	10.0
Thickness (mm)	7.5



Lead Event Summary: Specify 5-6-5	N
Lead migration/dislodgement	9
Lead fracture	1
Lead insulation failure	1
<b>Total</b>	<b>11</b>

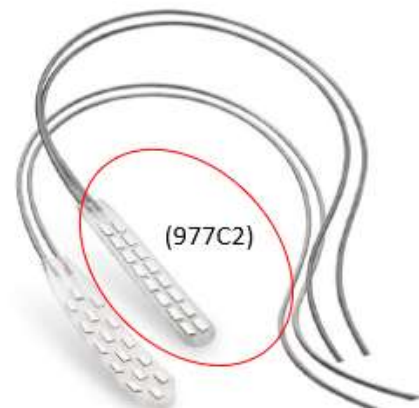
#### 4.4.2.9 Model Specify SureScan MRI 2x8

<b>Model Name</b>	Specify SureScan MRI 2x8 (model 977C2)
<b>FDA Approval Date</b>	February 2016
<b>Leads Enrolled</b>	43
<b>Leads Currently Active in Study</b>	21
<b>Initial Product Performance Events</b>	2
<b>Median Follow-up Time (Months)</b>	17.1
<b>Cumulative Follow-up Time (Months)</b>	902



<b>Time Interval</b>	<b>1 Year</b>	<b>At 18 Months</b>
Survival	97.4%	97.4%
(95% CI)	(83.0%, 99.6%)	(83.0%, 99.6%)
Sample Size	26	21

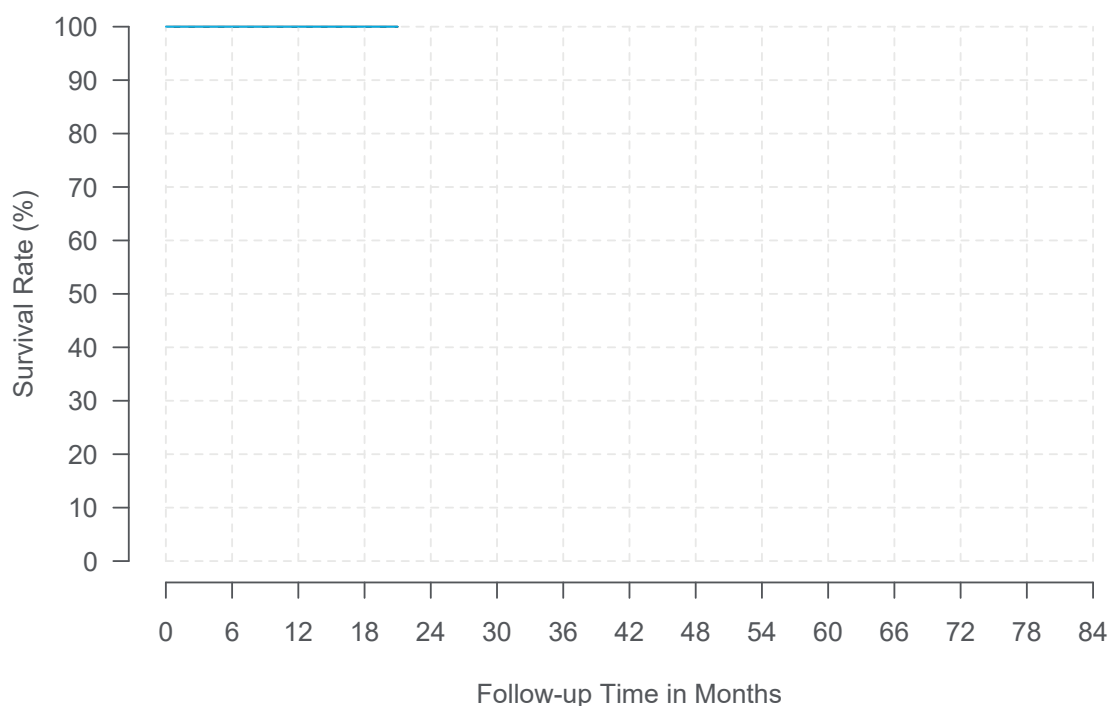
Specification: Specify SureScan MRI 2x8	
<b>Lead</b>	
Length (cm)	65, 90
Diameter (mm)	1.3
<b>Electrode</b>	
Number	16
Shape	Rectangular
Size (width x length)	1.5 mm x 4.0 mm
Stimulating area (mm <sup>2</sup> )	6.0
<b>Inter-Electrode Spacing: Edge to Edge</b>	
In-line spacing (mm)	1.0
Row spacing (mm)	1.0
Lead paddle length (mm)	56.4



Lead Event Summary: Specify SureScan MRI 2x8		N
High impedance		1
Lead migration/dislodgement		1
<b>Total</b>		<b>2</b>

#### 4.4.2.10 Model Specify SureScan MRI 5-6-5

<b>Model Name</b>	Specify SureScan MRI 5-6-5 (model 977C1)
<b>FDA Approval Date</b>	February 2016
<b>Leads Enrolled</b>	77
<b>Leads Currently Active in Study</b>	25
<b>Initial Product Performance Events</b>	2
<b>Median Follow-up Time (Months)</b>	12.5
<b>Cumulative Follow-up Time (Months)</b>	1,297



<b>Time Interval</b>	<b>1 Year</b>	<b>At 21 Months</b>
Survival	100.0%	100.0%
(95% CI)	(NA)	(NA)
Sample Size	40	23

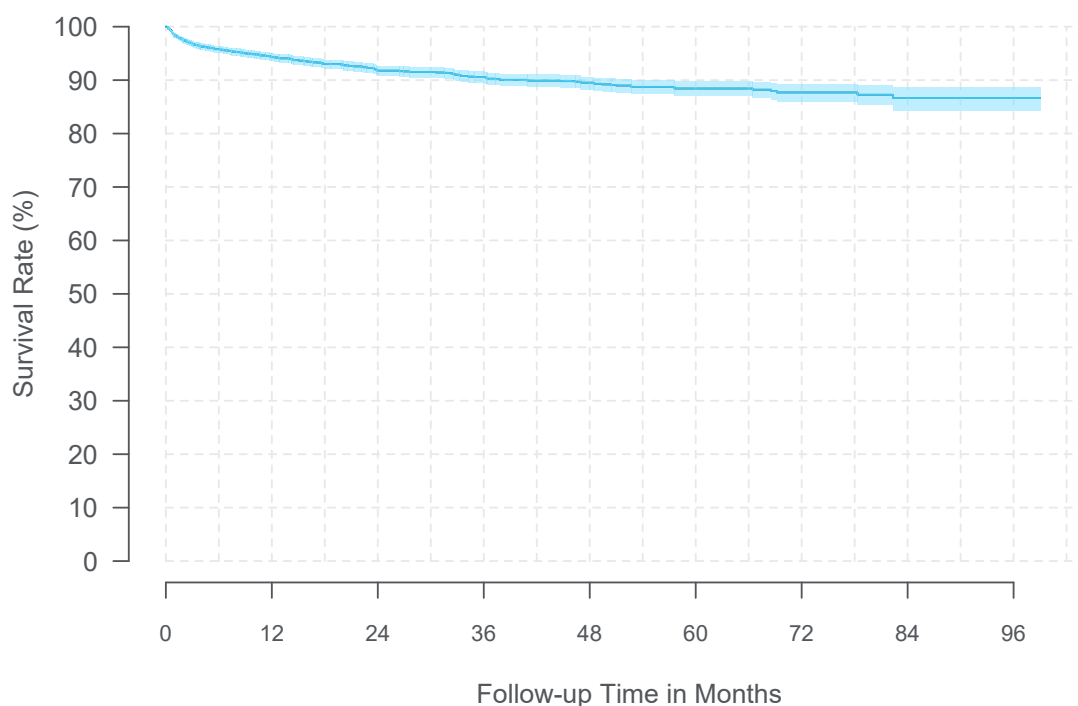
Specification: Specify SureScan MRI 5-6-5	
<b>Lead</b>	
Length (cm)	65, 90
Diameter (mm)	1.3
<b>Electrode</b>	
Number	16
Shape	Rectangular
Size (width x length)	1.5 mm x 4.0 mm
Stimulating area (mm <sup>2</sup> )	6.0
<b>Inter-Electrode Spacing: Edge to Edge</b>	
In-line spacing (mm)	4.5
Row spacing (mm)	1.0
Lead paddle length (mm)	64.2



Lead Event Summary: Specify SureScan MRI 5-6-5		N
High impedance		2
<b>Total</b>		<b>2</b>

#### 4.4.2.11 Model Vectris SureScan MRI 1x8 Compact

<b>Model Name</b>	Vectris SureScan MRI 1x8 Compact (model 977A2)
<b>FDA Approval Date</b>	March 2013
<b>Leads Enrolled</b>	4,602
<b>Leads Currently Active in Study</b>	1,876
<b>Initial Product Performance Events</b>	342
<b>Median Follow-up Time (Months)</b>	23.3
<b>Cumulative Follow-up Time (Months)</b>	130,139



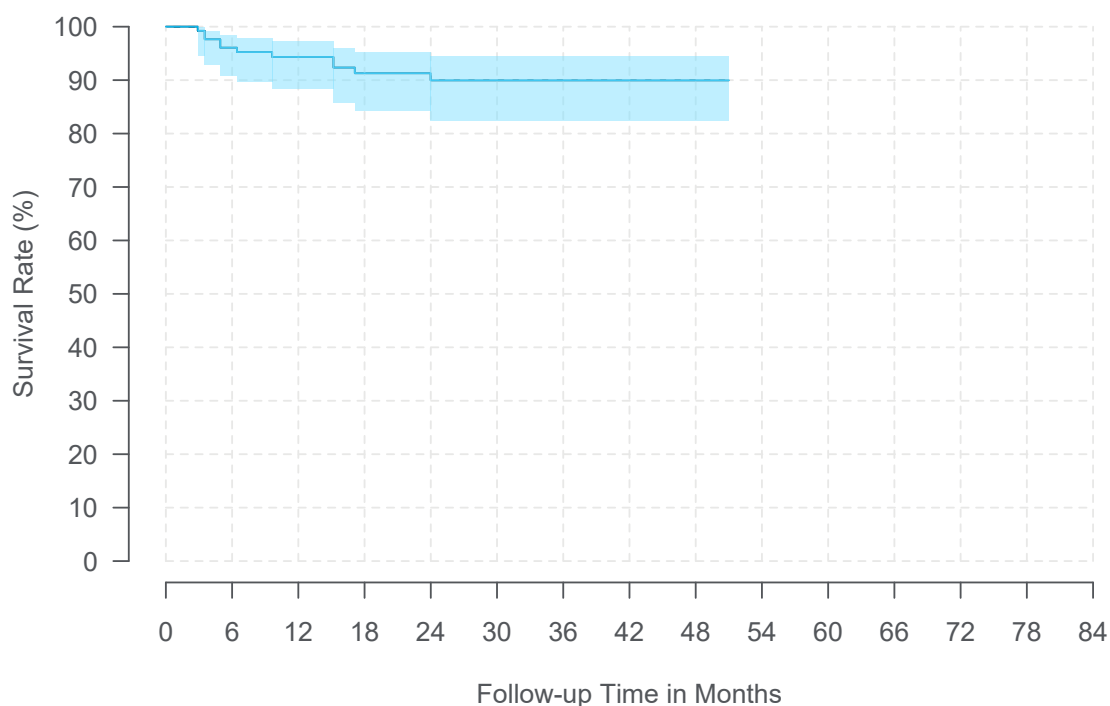
Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival	94.4%	91.8%	90.6%	89.5%	88.4%
(95% CI)	(93.6%, 95.0%)	(90.8%, 92.7%)	(89.5%, 91.6%)	(88.3%, 90.6%)	(87.0%, 89.7%)
Sample Size	2,986	2,109	1,390	865	535
Time Interval	6 Years	7 Years	8 Years	At 99 Months	
Survival	87.7%	86.6%	86.6%	86.6%	
(95% CI)	(86.0%, 89.2%)	(84.3%, 88.6%)	(84.3%, 88.6%)	(84.3%, 88.6%)	—
Sample Size	295	134	46	32	

<b>Specification: Vectris SureScan MRI 1x8 Compact</b>	
<b>Lead Type</b>	Percutaneous
<b>Lead</b>	
Length (cm)	60, 75, 90
Diameter (mm)	1.3
<b>Electrode</b>	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	52.0

<b>Lead Event Summary: Vectris SureScan MRI 1x8 Compact</b>	<b>N</b>
Lead migration/dislodgement	243
High impedance	62
Lead fracture	23
Device electrical impedance issue	6
Low impedance	3
Device charging issue	2
Device malfunction	1
Medical device site pain	1
Therapeutic product ineffective	1
<b>Total</b>	<b>342</b>

#### 4.4.2.12 Model Vectris SureScan MRI 1x8 Subcompact

<b>Model Name</b>	Vectris SureScan MRI 1x8 Subcompact (model 977A1)
<b>FDA Approval Date</b>	March 2013
<b>Leads Enrolled</b>	144
<b>Leads Currently Active in Study</b>	33
<b>Initial Product Performance Events</b>	11
<b>Median Follow-up Time (Months)</b>	23.3
<b>Cumulative Follow-up Time (Months)</b>	4,153



Time Interval	1 Year	2 Years	3 Years	4 Years	At 51 Months
Survival	94.3%	90.0%	90.0%	90.0%	90.0%
(95% CI)	(88.5%, 97.3%)	(82.4%, 94.4%)	(82.4%, 94.4%)	(82.4%, 94.4%)	(82.4%, 94.4%)
Sample Size	96	67	53	30	30

Specification: Vectris SureScan MRI 1x8 Subcompact	
<b>Lead Type</b>	Percutaneous
<b>Lead</b>	
Length (cm)	60, 75, 90
Diameter (mm)	1.3
<b>Electrode</b>	
Number	8
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm <sup>2</sup> )	12.0
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	34.5



Lead Event Summary: Vectris SureScan MRI 1x8 Subcompact	N
Lead migration/dislodgement	7
Lead fracture	3
High impedance	1
<b>Total</b>	<b>11</b>

#### 4.4.3 Lead Summary

**Table 4.16:** Spinal Cord Stimulation Percutaneous Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
1x8 Compact (model 3778)	April 2005	2,168	101	265	17.9	68,373
1x8 SC (model 3776)	November 2005	188	13	17	15.0	5,565
1x8 Standard (model 3777)	April 2005	838	57	71	16.4	24,810
AnkerStim Lead (Approved in Europe): 09100	NA	201	142	13	12.6	3,165
Pisces Compact (model 3887)	January 1997	200	26	25	22.5	7,666
Pisces Plus (model 3888)	November 1992	455	44	44	14.9	12,490
Pisces Standard (model 3487A)	May 1988	992	55	166	31.1	42,088
Vectris SureScan MRI 1x8 Compact (model 977A2)	March 2013	4,602	1,876	342	23.3	130,139
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	March 2013	144	33	11	23.3	4,153

**Table 4.17:** Spinal Cord Stimulation Percutaneous Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
1x8 Compact (model 3778)	90.4% (88.9%, 91.8%)	87.0% (85.1%, 88.6%)	84.7% (82.6%, 86.6%)	84.2% (82.0%, 86.1%)	81.8% (79.3%, 84.1%)
1x8 SC (model 3776)	91.8% (85.6%, 95.4%)	91.8% (85.6%, 95.4%)	91.8% (85.6%, 95.4%)	89.8% (82.0%, 94.4%)	86.7% (75.6%, 93.0%)
1x8 Standard (model 3777)	92.8% (90.3%, 94.7%)	89.3% (86.2%, 91.8%)	89.3% (86.2%, 91.8%)	88.1% (84.5%, 91.0%)	87.4% (83.4%, 90.5%)
AnkerStim Lead (Approved in Europe): 09100	94.3% (88.9%, 97.1%)	91.2% (84.5%, 95.1%)	—	—	—
Pisces Compact (model 3887)	92.5% (78.3%, 97.6%)	83.1% (69.7%, 90.9%)	76.8% (63.2%, 85.9%)	75.3% (61.8%, 84.7%)	71.6% (57.7%, 81.6%)
Pisces Plus (model 3888)	92.5% (88.1%, 95.3%)	88.3% (82.8%, 92.2%)	85.1% (78.7%, 89.7%)	81.2% (74.1%, 86.5%)	79.2% (71.6%, 85.0%)
Pisces Standard (model 3487A)	91.8% (89.2%, 93.8%)	89.3% (86.4%, 91.6%)	84.8% (81.4%, 87.6%)	80.8% (77.0%, 84.1%)	76.5% (72.2%, 80.2%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	94.4% (93.6%, 95.0%)	91.8% (90.8%, 92.7%)	90.6% (89.5%, 91.6%)	89.5% (88.3%, 90.6%)	88.4% (87.0%, 89.7%)
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	94.3% (88.5%, 97.3%)	90.0% (82.4%, 94.4%)	90.0% (82.4%, 94.4%)	90.0% (82.4%, 94.4%)	—

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 Compact (model 3778)	80.6% (77.8%, 83.0%)	77.4% (74.1%, 80.4%)	75.9% (72.3%, 79.1%)	75.4% (71.7%, 78.7%)	73.2% (69.0%, 77.0%)
1x8 SC (model 3776)	83.5% (70.4%, 91.2%)	77.6% (62.3%, 87.3%)	77.6% (62.3%, 87.3%)	—	—
1x8 Standard (model 3777)	85.6% (80.7%, 89.3%)	83.6% (77.9%, 87.9%)	80.8% (73.9%, 86.1%)	78.1% (70.3%, 84.2%)	78.1% (70.3%, 84.2%)
AnkerStim Lead (Approved in Europe): 09100	—	—	—	—	—
Pisces Compact (model 3887)	69.4% (55.2%, 79.8%)	67.1% (52.7%, 78.0%)	67.1% (52.7%, 78.0%)	61.9% (46.9%, 73.8%)	59.3% (44.1%, 71.7%)
Pisces Plus (model 3888)	74.3% (65.6%, 81.2%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)
Pisces Standard (model 3487A)	73.3% (68.7%, 77.4%)	71.4% (66.5%, 75.6%)	71.4% (66.5%, 75.6%)	66.7% (61.1%, 71.7%)	63.5% (57.5%, 68.9%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	87.7% (86.0%, 89.2%)	86.6% (84.3%, 88.6%)	86.6% (84.3%, 88.6%)	—	—
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	—	—	—	—	—

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
1x8 Compact (model 3778)	72.5% (68.0%, 76.5%)	72.5% (68.0%, 76.5%)	69.1% (62.6%, 74.8%)	—	—
1x8 SC (model 3776)	—	—	—	—	—
1x8 Standard (model 3777)	78.1% (70.3%, 84.2%)	76.8% (68.5%, 83.2%)	76.8% (68.5%, 83.2%)	76.8% (68.5%, 83.2%)	—
AnkerStim Lead (Approved in Europe): 09100	—	—	—	—	—
Pisces Compact (model 3887)	59.3% (44.1%, 71.7%)	—	—	—	—
Pisces Plus (model 3888)	71.7% (62.4%, 79.0%)	71.7% (62.4%, 79.0%)	—	—	—
Pisces Standard (model 3487A)	61.2% (54.8%, 67.0%)	58.2% (51.3%, 64.6%)	58.2% (51.3%, 64.6%)	58.2% (51.3%, 64.6%)	55.6% (48.0%, 62.5%)
Vectris SureScan MRI 1x8 Compact (model 977A2)	—	—	—	—	—
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	—	—	—	—	—

Model Name	16 Years	17 Years			
1x8 Compact (model 3778)	—	—	—	—	—
1x8 SC (model 3776)	—	—	—	—	—
1x8 Standard (model 3777)	—	—	—	—	—
AnkerStim Lead (Approved in Europe): 09100	—	—	—	—	—
Pisces Compact (model 3887)	—	—	—	—	—
Pisces Plus (model 3888)	—	—	—	—	—
Pisces Standard (model 3487A)	54.1% (46.1%, 61.4%)	50.4% (41.4%, 58.7%)	—	—	—
Vectris SureScan MRI 1x8 Compact (model 977A2)	—	—	—	—	—
Vectris SureScan MRI 1x8 Subcompact (model 977A1)	—	—	—	—	—

**Table 4.18:** Spinal Cord Stimulation Surgical Lead Characteristics

Model Name	FDA Approval Date	Leads Enrolled	Leads Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Specify 5-6-5 (model 39565)	June 2007	294	32	11	22.5	8,507
Specify SureScan MRI 2x8 (model 977C2)	February 2016	43	21	2	17.1	902
Specify SureScan MRI 5-6-5 (model 977C1)	February 2016	77	25	2	12.5	1,297

**Table 4.19:** Spinal Cord Stimulation Surgical Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Specify 5-6-5 (model 39565)	96.3% (92.8%, 98.2%)	95.7% (91.8%, 97.8%)	95.7% (91.8%, 97.8%)	94.0% (87.9%, 97.1%)	94.0% (87.9%, 97.1%)
Specify SureScan MRI 2x8 (model 977C2)	97.4% (83.0%, 99.6%)	—	—	—	—
Specify SureScan MRI 5-6-5 (model 977C1)	100.0% (NA)	—	—	—	—

Model Name	6 Years	7 Years	8 Years		
Specify 5-6-5 (model 39565)	94.0% (87.9%, 97.1%)	94.0% (87.9%, 97.1%)	89.8% (76.1%, 95.9%)	—	—
Specify SureScan MRI 2x8 (model 977C2)	—	—	—	—	—
Specify SureScan MRI 5-6-5 (model 977C1)	—	—	—	—	—

## 4.5 Extensions

From June 2004 to the report cut-off date of October 31, 2022, there were 3,677 extensions followed in the registry. The difference between the total number of extensions (n=3,677) versus neurostimulators (n=6,983) is due to the fact that some systems did not use an extension. The aggregate prospective follow-up time for all extensions was 122,692 months (10,224 years). An extension is a set of thin wires with a protective coating that connects the neurostimulator to the lead. [Table 4.20](#) provides the number and percentage of extensions by model.

**Table 4.20:** Spinal Cord Stimulation Extension Counts by Model

Model Name	N (%)
<b>Currently manufactured</b>	<b>2,571 (69.9%)</b>
1x8 (37081)	1,533 (41.7%)
Bifurcated Stretch-Coil (37082)	647 (17.6%)
Single Stretch-Coil (37083)	391 (10.6%)
<b>No longer manufactured</b>	<b>1,082 (29.4%)</b>
Low Profile Quad (7489)	758 (20.6%)
Quadripolar in-line (7495)	280 (7.6%)
Synergy bifurcated 1x8 (7472)	26 (0.7%)
Quadripolar (7496)	9 (0.2%)
Synergy 1x8 (7471)	9 (0.2%)
<b>Other/Unspecified</b>	<b>24 (0.7%)</b>
<b>Total</b>	<b>3,677 (100%)</b>

### 4.5.1 Extension Events

There were 57 product performance-related events with an underlying reported etiology related to extension function. This includes 47 events with an extension etiology and 10 events with both an extension and other etiology (including device and non-device etiologies). Of these, 43 were the initial product performance event that affected extension survival estimates; the majority were extension fracture (n=17) and extension migration (n=10).

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:

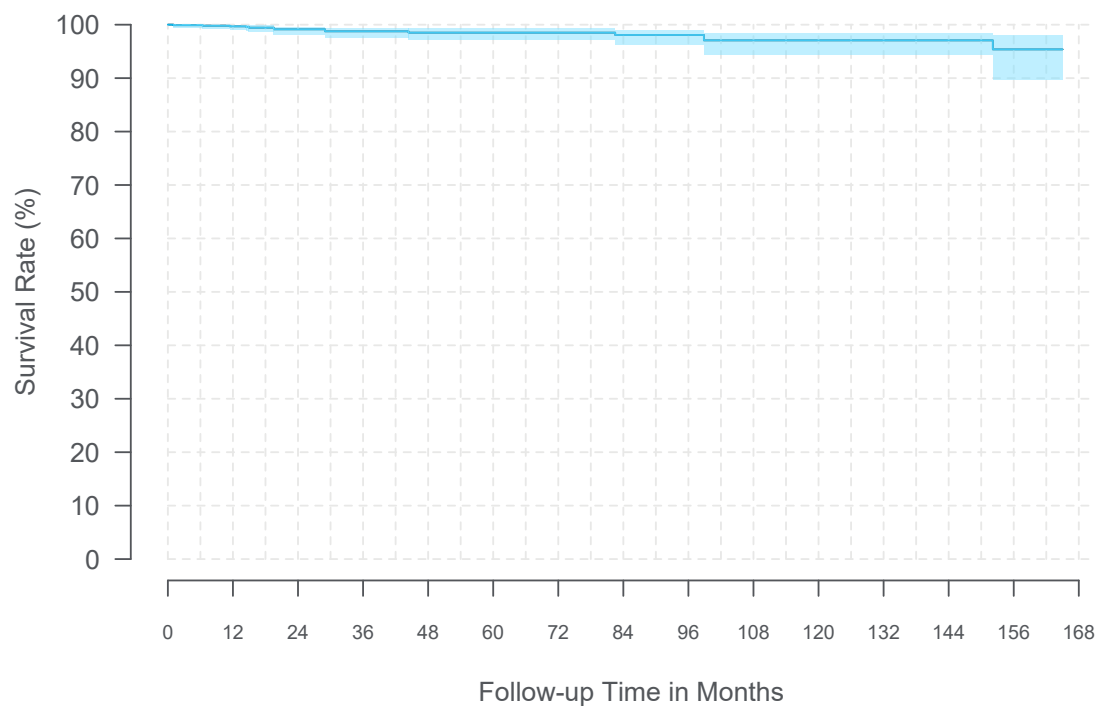
- 43 had follow-up time cut-off due to product performance-related events.
- 3,073 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 561 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

### 4.5.2 Extension Models

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

#### 4.5.2.1 Model 1x8 Extension

<b>Model Name</b>	1x8 Extension (model 37081)
<b>FDA Approval Date</b>	April 2005
<b>Extensions Enrolled</b>	1,533
<b>Extensions Currently Active in Study</b>	280
<b>Initial Product Performance Events</b>	15
<b>Median Follow-up Time (Months)</b>	21.8
<b>Cumulative Follow-up Time (Months)</b>	52,830



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (99.1%, 99.9%)	99.1% (98.2%, 99.6%)	98.8% (97.6%, 99.4%)	98.5% (97.2%, 99.2%)	98.5% (97.2%, 99.2%)
Sample Size	851	577	424	364	328
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.5% (97.2%, 99.2%)	98.1% (96.3%, 99.0%)	98.1% (96.3%, 99.0%)	97.1% (94.5%, 98.5%)	97.1% (94.5%, 98.5%)
Sample Size	278	217	201	177	137
Time Interval	11 Years	12 Years	13 Years	At 165 Months	
Survival (95% CI)	97.1% (94.5%, 98.5%)	97.1% (94.5%, 98.5%)	95.4% (89.7%, 98.0%)	95.4% (89.7%, 98.0%)	—
Sample Size	102	74	45	25	

#### Specification: 1x8 Extension

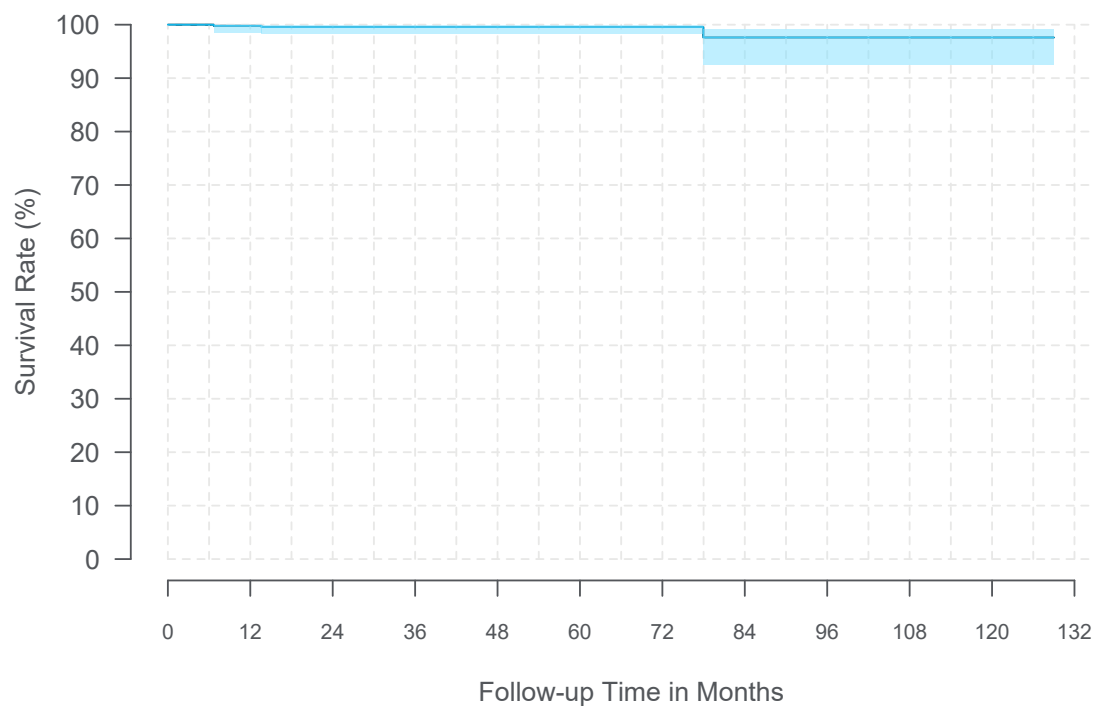
Length (cm)	20, 40, 60
Distal End Compatibility	1 Octad Lead
Distal End Set Screws	1
Proximal End INS Compatibility	Restore Family



Extension Event Summary: 1x8 Extension	N
Extension fracture	7
High impedance	5
Extension migration	2
Low impedance	1
<b>Total</b>	<b>15</b>

#### 4.5.2.2 Model Bifurcated Stretch-Coil Extension

<b>Model Name</b>	Bifurcated Stretch-Coil Extension (model 37082)
<b>FDA Approval Date</b>	March 2006
<b>Extensions Enrolled</b>	647
<b>Extensions Currently Active in Study</b>	40
<b>Initial Product Performance Events</b>	4
<b>Median Follow-up Time (Months)</b>	23.6
<b>Cumulative Follow-up Time (Months)</b>	23,353



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.8% (98.6%, 100%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)
Sample Size	436	314	227	173	140
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	99.6% (98.2%, 99.9%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)
Sample Size	111	88	66	50	36
Time Interval	At 129 Months				
Survival (95% CI)	97.6% (92.6%, 99.2%)	—	—	—	—
Sample Size	20				

#### Specification: 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

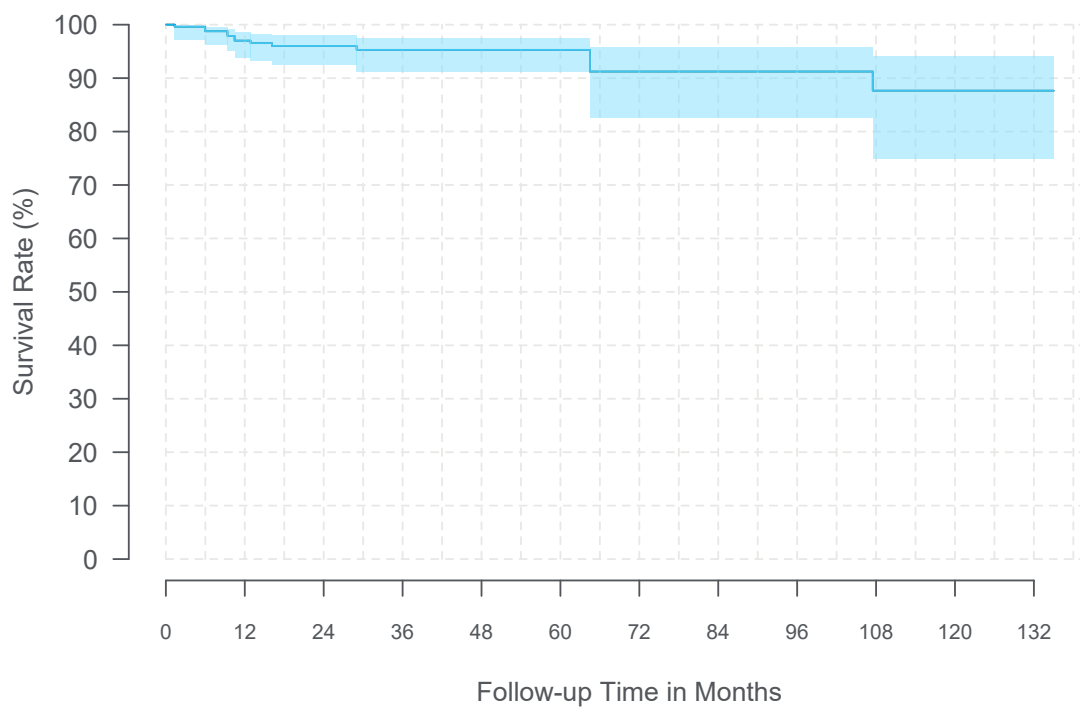


#### Extension Event Summary: Bifurcated Stretch-Coil Extension

	N
Device connection issue	2
Extension fracture	2
<b>Total</b>	<b>4</b>

#### 4.5.2.3 Model Single Stretch-Coil Extension

<b>Model Name</b>	Single Stretch-Coil Extension (model 37083)
<b>FDA Approval Date</b>	September 2005
<b>Extensions Enrolled</b>	391
<b>Extensions Currently Active in Study</b>	142
<b>Initial Product Performance Events</b>	16
<b>Median Follow-up Time (Months)</b>	16.1
<b>Cumulative Follow-up Time (Months)</b>	10,796



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	97.0% (93.8%, 98.6%)	96.0% (92.5%, 97.9%)	95.3% (91.3%, 97.5%)	95.3% (91.3%, 97.5%)	95.3% (91.3%, 97.5%)
Sample Size	221	157	84	61	46
Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	91.2% (82.6%, 95.7%)	91.2% (82.6%, 95.7%)	91.2% (82.6%, 95.7%)	87.7% (74.9%, 94.2%)	87.7% (74.9%, 94.2%)
Sample Size	38	38	30	24	22
Time Interval	11 Years	At 135 Months			
Survival (95% CI)	87.7% (74.9%, 94.2%)	87.7% (74.9%, 94.2%)	—	—	—
Sample Size	20	20			

#### Specification: Single Stretch-Coil Extension

Length (cm)	20, 40, 60
Distal End Compatibility	1 Quad Lead
Distal End Set Screws	4
Proximal End INS Compatibility	Restore Family



#### Extension Event Summary: Single Stretch-Coil Extension

	N
Extension migration	6
Extension fracture	5
Lead migration/dislodgement	2
Medical device complication	2
Device failure	1
<b>Total</b>	<b>16</b>

### 4.5.3 Extension Summary

**Table 4.21:** Spinal Cord Stimulation Extension Characteristics

Model Name	FDA Approval Date	Extensions Enrolled	Extensions Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
1x8 Extension (model 37081)	April 2005	1,533	280	15	21.8	52,830
Bifurcated Stretch-Coil Extension (model 37082)	March 2006	647	40	4	23.6	23,353
Single Stretch-Coil Extension (model 37083)	September 2005	391	142	16	16.1	10,796

**Table 4.22:** Spinal Cord Stimulation Extension Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
1x8 Extension (model 37081)	99.7% (99.1%, 99.9%)	99.1% (98.2%, 99.6%)	98.8% (97.6%, 99.4%)	98.5% (97.2%, 99.2%)	98.5% (97.2%, 99.2%)
Bifurcated Stretch-Coil Extension (model 37082)	99.8% (98.6%, 100%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)	99.6% (98.2%, 99.9%)
Single Stretch-Coil Extension (model 37083)	97.0% (93.8%, 98.6%)	96.0% (92.5%, 97.9%)	95.3% (91.3%, 97.5%)	95.3% (91.3%, 97.5%)	95.3% (91.3%, 97.5%)

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
1x8 Extension (model 37081)	98.5% (97.2%, 99.2%)	98.1% (96.3%, 99.0%)	98.1% (96.3%, 99.0%)	97.1% (94.5%, 98.5%)	97.1% (94.5%, 98.5%)
Bifurcated Stretch-Coil Extension (model 37082)	99.6% (98.2%, 99.9%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)	97.6% (92.6%, 99.2%)
Single Stretch-Coil Extension (model 37083)	91.2% (82.6%, 95.7%)	91.2% (82.6%, 95.7%)	91.2% (82.6%, 95.7%)	87.7% (74.9%, 94.2%)	87.7% (74.9%, 94.2%)

Model Name	11 Years	12 Years	13 Years		
1x8 Extension (model 37081)	97.1% (94.5%, 98.5%)	97.1% (94.5%, 98.5%)	95.4% (89.7%, 98.0%)	—	—
Bifurcated Stretch-Coil Extension (model 37082)	—	—	—	—	—
Single Stretch-Coil Extension (model 37083)	87.7% (74.9%, 94.2%)	—	—	—	—