PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA FROM THE MEDTRONIC POST-MARKET REGISTRY

2022

v.1.0 06Mar2023

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Contents

6 Sacral Neuromodulation Systems

6.1 Study Participants

6.1.1 Centers

In this section, the sacral neuromodulation tables and graphs were generated based on data collected between April 2010 and the report cut-off date of October 31, 2022. Twenty-four centers in North America, South America, and Europe have enrolled and contributed patients to the sacral neuromodulation systems section of this report.

6.1.2 Patients

Of the 1,558 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 43.4% were implanted for the treatment of urinary urge incontinence, 27.1% were implanted for the treatment of urgency-frequency, 13.3% were implanted for the treatment of urinary retention, 9.4% were implanted for the treatment of fecal incontinence, 2.3% were implanted for the treatment of bladder pain syndrome, 3.3% were implanted for the treatment of some other indication, and 1.2% were implanted for indications that were not specified in the database at the time of data cut-off (see Figure 6.1 and Table 6.1).

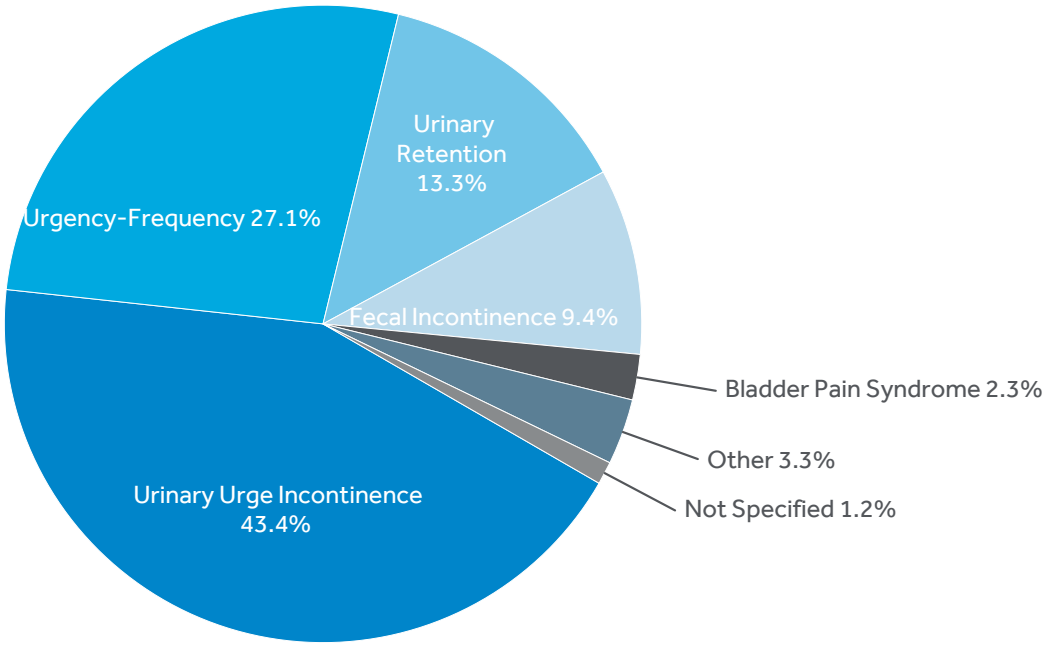


Figure 6.1: Sacral Neuromodulation Primary Treatment Indications

Table 6.1: Sacral Neuromodulation Primary Treatment Indications

Primary Treatment Indication[a]	Enrolled Patients (%)
Urinary Urge Incontinence	676 (43.4%)
Urgency-Frequency	422 (27.1%)
Urinary Retention	207 (13.3%)
Fecal Incontinence	147 (9.4%)
Bladder Pain Syndrome	36 (2.3%)
Other	52 (3.3%)
Not Specified	18 (1.2%)
Total Patients	**1,558 (100%)**

[a] For approved indications refer to product labeling for your geography.

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, which varies by geography. Please contact your local Medtronic representative for region-specific product labeling (http://www.medtronic.com/us-en/about/locations.html).

6.2 Event Summary

There were 238 product performance events reported between April 2010 and October 31, 2022, in patients with sacral neuromodulation systems. These events represent 19.3% of the total reported events (238/1,235), occurred in 168 (10.8%) of the 1,558 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 972 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the sacral neuromodulation 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=25).

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 6.2 differentiate 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 70 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.

6.2.1 Product Performance Events

Table 6.2: Sacral Neuromodulation System Product Performance Events

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=1,558[b]
RPA Determination	**0**	**0.00**	**0 (0.00%)**
Physician's Determination	**238**	**5.64**	**168 (10.78%)**
High Impedance	86	2.04	64 (4.11%)
Lead Migration/Dislodgement	47	1.11	38 (2.44%)
Device Lead Issue	29	0.69	19 (1.22%)
Lead Fracture	25	0.59	21 (1.35%)
Device Malfunction[c]	13	0.31	11 (0.71%)
Low Impedance	11	0.26	10 (0.64%)
Device Electrical Impedance Issue	6	0.14	4 (0.26%)
Premature Battery Depletion	4	0.09	3 (0.19%)
Device Issue	3	0.07	2 (0.13%)
Device Failure	2	0.05	1 (0.06%)
Device Overheating	2	0.05	2 (0.13%)
Neurostimulator Unable To Recharge	2	0.05	2 (0.13%)
Device Battery Issue	1	0.02	1 (0.06%)
Device Charging Issue	1	0.02	1 (0.06%)
Device Connection Issue	1	0.02	1 (0.06%)
Device Lead Damage	1	0.02	1 (0.06%)
Device Stimulation Issue	1	0.02	1 (0.06%)

...continued

Product Performance Events[a]	Event Counts	Events Per 100 Patient Years	Patients with Events (%) N=1,558[b]
Device Wireless Communication Issue	1	0.02	1 (0.06%)
Electromagnetic Interference	1	0.02	1 (0.06%)
Therapeutic Product Ineffective	1	0.02	1 (0.06%)
Total	**238**	**5.64**	**168 (10.78%)**

[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] See Neurostimulator Event Summary Tables for additional details on device malfunctions by model.

A total of 158 (66.4%) of 238 product performance events were related to the lead only, 49 (20.6%) related to the neurostimulator only, 2 (0.8%) related to the extension only, 8 (3.4%) related to multiple etiologies (which includes events where at least one device and one non-device etiology was indicated), and 21 (8.8%) related to other etiologies . Relatedness is determined by the physician.

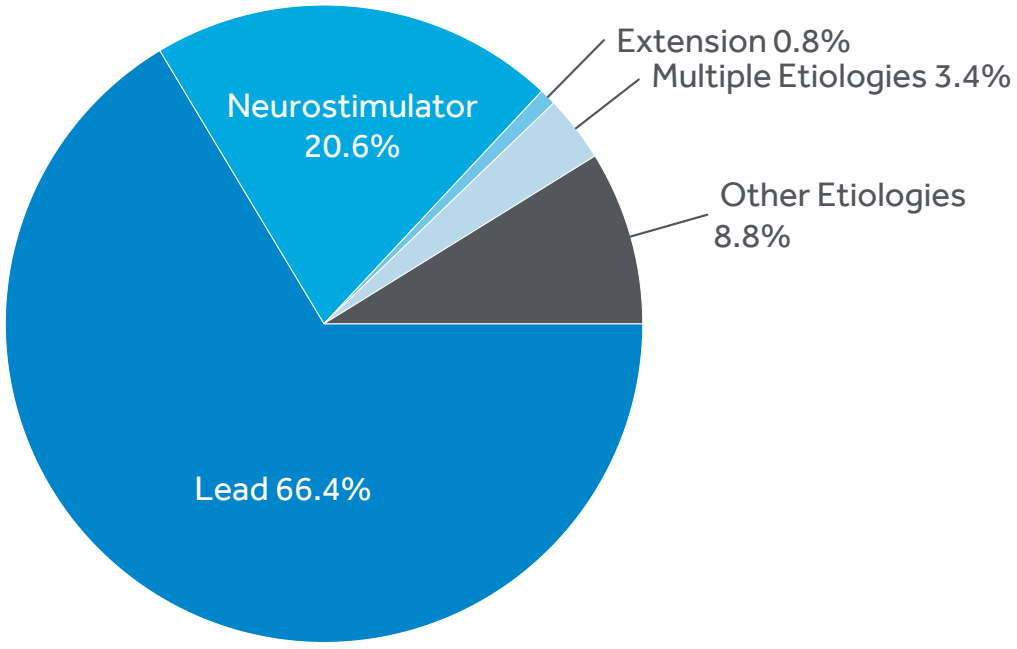


Figure 6.2: Sacral Neuromodulation System Product Performance Events by Relatedness

Table 6.3 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 PPEs, and all other reported PPEs are listed under Other. The subsequent columns represent the actions taken by the reporting physician.

Table 6.3: Sacral Neuromodulation System Product Performance Events by Intervention

Events by Intervention	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention [a]	No Action Taken	Total Events
High Impedance	45 (52.3%)	34 (39.5%)	0 (0.0%)	0 (0.0%)	7 (8.1%)	**86**
Lead Migration/Dislodgement	33 (70.2%)	6 (12.8%)	1 (2.1%)	1 (2.1%)	6 (12.8%)	**47**
Device Lead Issue	11 (37.9%)	9 (31.0%)	4 (13.8%)	0 (0.0%)	5 (17.2%)	**29**
Lead Fracture	17 (68.0%)	2 (8.0%)	1 (4.0%)	3 (12.0%)	2 (8.0%)	**25**
Device Malfunction	6 (46.2%)	4 (30.8%)	2 (15.4%)	0 (0.0%)	1 (7.7%)	**13**
Other [b]	24 (63.2%)	7 (18.4%)	1 (2.6%)	2 (5.3%)	4 (10.5%)	**38**
Total	**136**	**62**	**9**	**6**	**25**	**238**

[a] 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.
[b] Other represents all reported PPEs that were not in the top five of occurrence.

6.2.2 Clinical Events Not Related To Product Performance

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

- The patient was enrolled in the PSR at the time in which the clinical event collection was initiated (n=1,248)
- Categorized as serious adverse events (SAEs, n=11)
- Occurred with a System Organ Class (SOC) threshold $\geq$0.5% of patients
- Other Considerations
  - Some events are described in high level group terms (HLGT) to provide more specificity, if needed

Table 6.4: Sacral Neuromodulation System Clinical Events Not Related To Product Performance

Event Type	Number of SAE	Patients with SAE n (%) N=1,248	SAE Per 100 Patient Months	Patient with SAE Requiring Surgical Intervention n (%) N=1,248
Infections and infestations	**9**	**9 (0.72%)**	**0.024**	**7 (0.56%)**
Infections - pathogen unspecified	9	9 (0.72%)	0.024	7 (0.56%)
Other SOC Terms (<0.5% Threshold)[a]	**2**	**2 (0.16%)**	**0.005**	**1 (0.08%)**
Total	**11**	**11 (0.88%)**	**0.030**	**8 (0.64%)**

[a] Composed of high level group term event codes with fewer than 5 events each.

6.2.3 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 70 patients in the registry had expired. As with previous reports, no deaths were reported as a direct result of a product performance event.

The percentage is based upon the total patient death events and not based upon the rate of occurrence. **Tables depicted without a patient denominator should not be interpreted using other numbers within this report to calculate event rates**.

Table 6.5: Sacral Neuromodulation System Patient Deaths by Primary Indication

Number of Reports of Death by Primary Indication[a]	N (%) of Deaths
Urinary Urge Incontinence	28 (40.0%)
Urgency-Frequency	24 (34.3%)
Urinary Retention	9 (12.9%)
Fecal Incontinence	4 (5.7%)
Other	5 (7.1%)
Total	**70 (100%)**

[a] For approved indications refer to product labeling for your geography.

6.3 Neurostimulators

From April 2010 to the report cut-off date of October 31, 2022, there were 1,627 neurostimulators followed in the registry. The difference between the total number of patients (n=1,558) versus the total number of neurostimulators (n=1,627) is due to the fact that some

patients were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 49,272 months (4,106 years).

Table 6.6: Sacral Neuromodulation Neurostimulator Counts by Model

Model Name	N (%)
InterStim II	1378 (84.7%)
InterStim	101 (6.2%)
InterStim X	88 (5.4%)
InterStim Micro	60 (3.7%)
Total	**1,627 (100%)**

6.3.1 Neurostimulator Events

There were 53 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 49 events with a neurostimulator etiology and 4 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 44 were the initial product performance events that affected neurostimulator survival estimates. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 12.1% (57/471). The proportion was based upon the number of registry 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 53 neurostimulator events, 100.0% (53/53) were assigned as device related by the physician, not returned to Medtronic RPA (see Table 6.7).

Table 6.7: Sacral Neuromodulation Neurostimulator PPE by Determination

Product Performance Events	N (%)
Physician's Determination	**53 (100%)**
High Impedance	17 (32.1%)
Device Lead Issue	7 (13.2%)
Device Malfunction[a]	7 (13.2%)
Lead Migration/Dislodgement	5 (9.4%)
Premature Battery Depletion	3 (5.7%)
Device Electrical Impedance Issue	2 (3.8%)
Device Issue	2 (3.8%)
Device Overheating	2 (3.8%)
Lead Fracture	2 (3.8%)
Device Battery Issue	1 (1.9%)
Device Connection Issue	1 (1.9%)
Device Failure	1 (1.9%)
Device Stimulation Issue	1 (1.9%)
Neurostimulator Unable To Recharge	1 (1.9%)
Therapeutic Product Ineffective	1 (1.9%)

[a] See Neurostimulator Event Summary Tables for additional details on device malfunction model.

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:

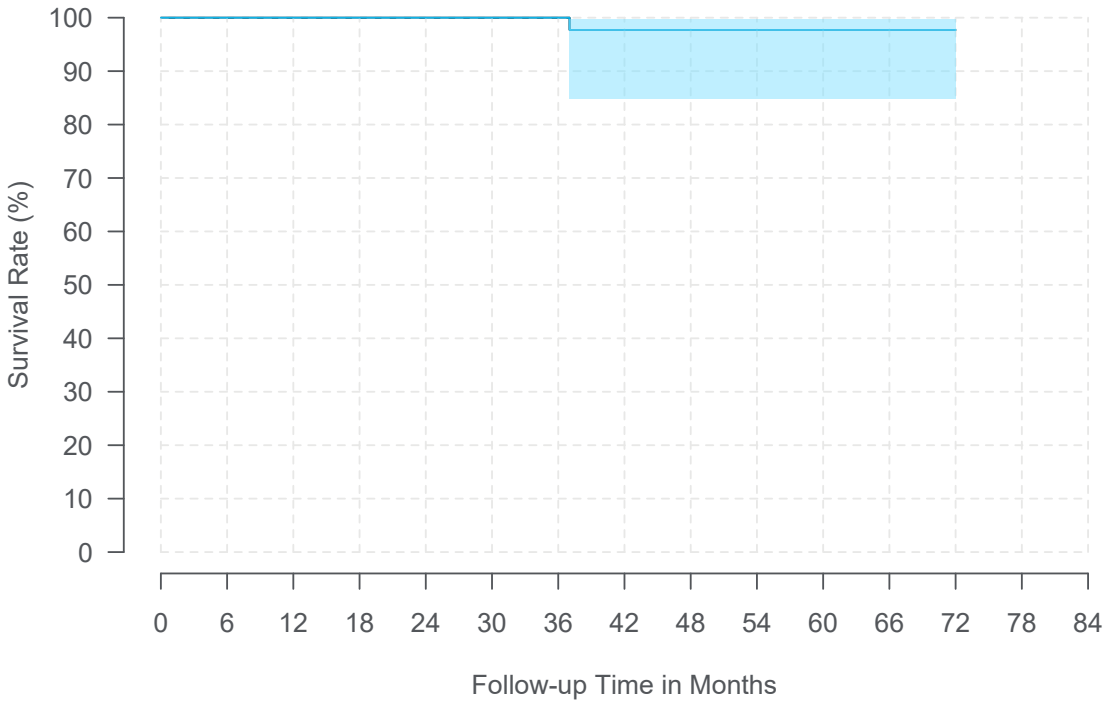
- 44 had follow-up time cut-off due to product performance-related events.
- 894 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 689 were free from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

6.3.2 Neurostimulator Models

The following figures and tables represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval. The InterStim X model is not shown due to the insufficient data.

6.3.2.1 Model 3023

Model Name	InterStim
FDA Approval Date	July 1998
Neurostimulators Enrolled	101
Neurostimulators Currently Active in Study	14
Initial Product Performance Events	2
Median Follow-up Time (Months)	30.4
Cumulative Follow-up Time (Months)	3,944



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)	97.7% (84.8%, 99.7%)	97.7% (84.8%, 99.7%)
Sample Size	70	60	43	33	25

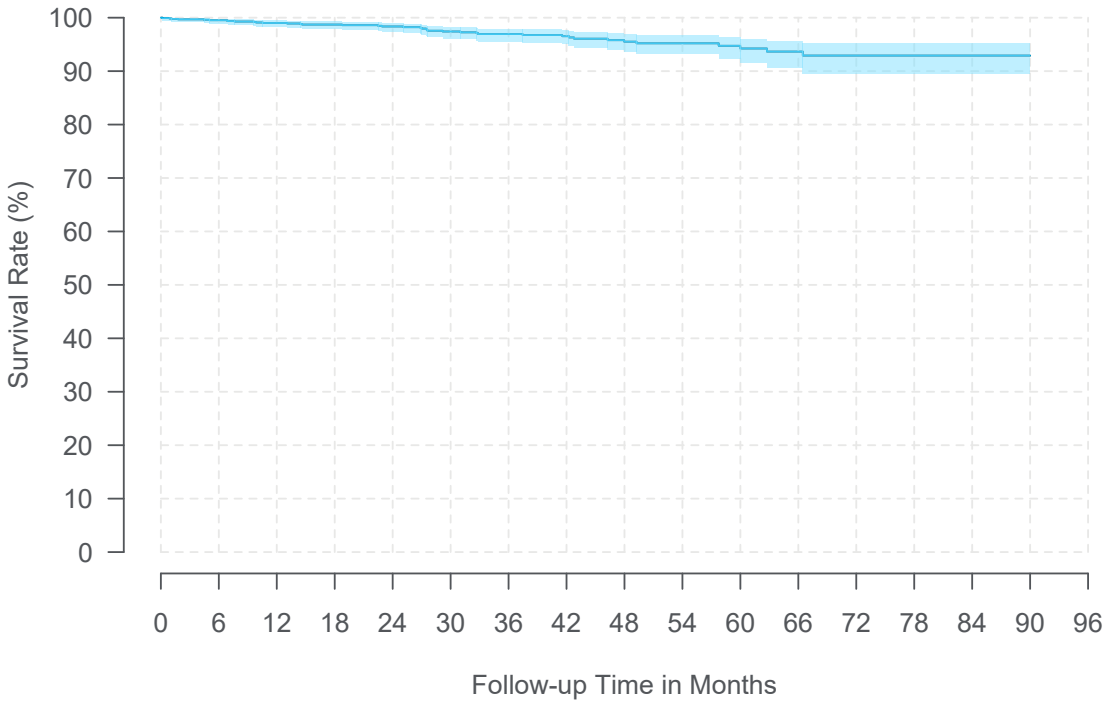
Time Interval	6 Years				
Survival (95% CI)	97.7% (84.8%, 99.7%)	—	—	—	—
Sample Size	20				

Specification: 3023	
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
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 µsec
Programs	4
Implant Depth	≤ 4 cm

Neurostimulator Event Summary: 3023	N
High Impedance	1
Premature Battery Depletion	1
Total	**2**

6.3.2.2 Model 3058

Model Name	InterStim II
FDA Approval Date	June 2006
Neurostimulators Enrolled	1,378
Neurostimulators Currently Active in Study	540
Initial Product Performance Events	41
Median Follow-up Time (Months)	29.2
Cumulative Follow-up Time (Months)	44,664



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.0% (98.3%, 99.4%)	98.4% (97.4%, 99.0%)	96.9% (95.5%, 97.9%)	95.5% (93.6%, 96.9%)	94.2% (91.6%, 96.0%)
Sample Size	1,058	781	552	336	186

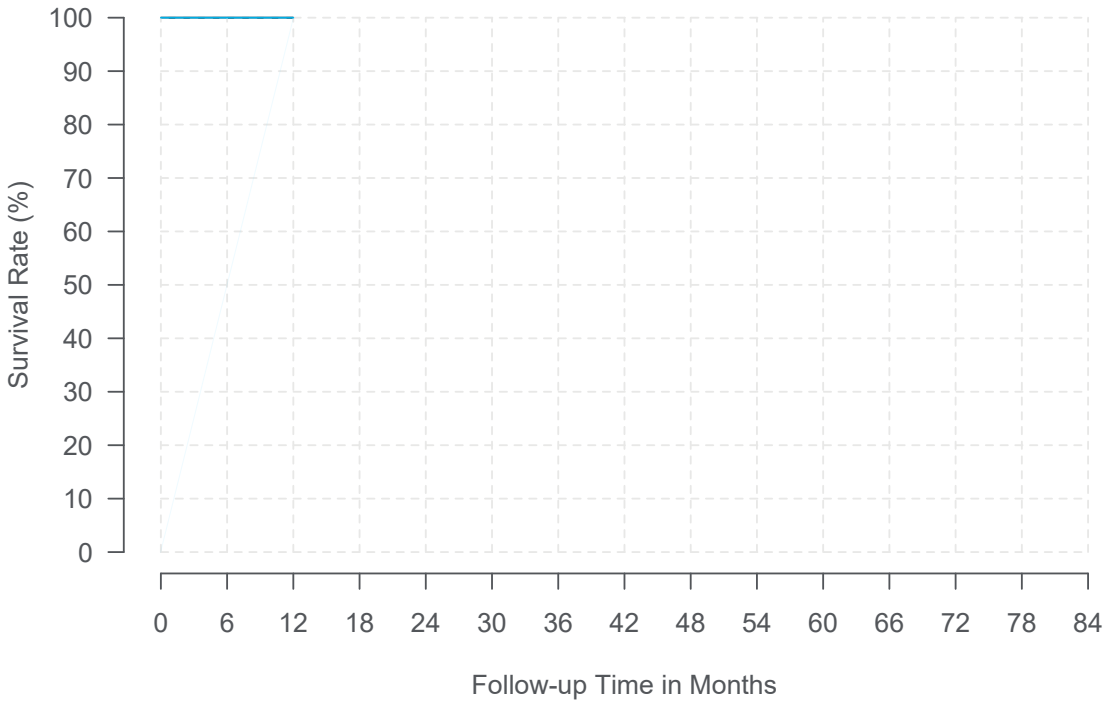
Time Interval	6 Years	7 Years	At 90 Months		
Survival (95% CI)	92.9% (89.5%, 95.2%)	92.9% (89.5%, 95.2%)	92.9% (89.5%, 95.2%)	—	—
Sample Size	98	47	25		

Specification: 3058	
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
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 Event Summary: 3058	N
High Impedance	14
Device Malfunction	6
Lead Migration/Dislodgement	5
Device Lead Issue	4
Device Electrical Impedance Issue	2
Device Issue	2
Premature Battery Depletion	2
Device Failure	1
Device Overheating	1
Device Stimulation Issue	1
Lead Fracture	1
Neurostimulator Unable To Recharge	1
Therapeutic Product Ineffective	1
Total	**41**

6.3.2.3 Model 97810

Model Name	InterStim Micro
FDA Approval Date	July 2020
Neurostimulators Enrolled	60
Neurostimulators Currently Active in Study	52
Initial Product Performance Events	0
Median Follow-up Time (Months)	11.1
Cumulative Follow-up Time (Months)	619



Time Interval	1 Year
Survival	100.0%
(95% CI)	(NA)
Sample Size	27

Specification: 97810	
Height	0.7 in (17 mm)
Length	1.9 in (47 mm)
Thickness	0.2 in (5 mm)
Volume	2.8 cc
Battery type	Rechargeable
Expected Battery life	15 years
Maximum Electrodes	1
Amplitude	0 to 12.5 mA (0.1 mA increment)
Rate	3 to 130 Hz
Pulse Width	40 to 450 µsec (10 µsec increment)
Programs	11
Implant Depth	$\leq$ 2.5 cm

6.3.3 Neurostimulator Summary

Table 6.8: Sacral Neuromodulation 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)
InterStim	July 1998	101	14	2	30.4	3,944
InterStim II	June 2006	1,378	540	41	29.2	44,664
InterStim Micro	July 2020	60	52	0	11.1	619

Table 6.9: Sacral Neuromodulation Neurostimulator Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	7 Years
InterStim	100.0%	100.0%	100.0%	97.7%	97.7%	97.7%	—
	(NA)	(NA)	(NA)	(84.8%, 99.7%)	(84.8%, 99.7%)	(84.8%, 99.7%)	
InterStim II	99.0%	98.4%	96.9%	95.5%	94.2%	92.9%	92.9%
	(98.3%, 99.4%)	(97.4%, 99.0%)	(95.5%, 97.9%)	(93.6%, 96.9%)	(91.6%, 96.0%)	(89.5%, 95.2%)	(89.5%, 95.2%)
InterStim Micro	100.0%	—	—	—	—	—	—
	(NA)						

6.4 Leads

From April 2010 to the report cut-off date of October 31, 2022, there were 1,555 leads followed in the registry. The difference between the total number of leads (n=1,555) versus the total number of neurostimulators (n=1,627) is 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 49,520 months (4,127 years). Table 6.10 provides the number and percentage of leads by model.

Table 6.10: Sacral Neuromodulation Lead Counts by Model

Model Name	N (%)
Currently manufactured	**1,443 (92.8%)**
InterStim Quad Lead Tined (3889)	1,175 (75.6%)
InterStim SureScan MRI Lead (978B1)	213 (13.7%)
InterStim SureScan MRI Lead (978A1)	55 (3.5%)
No longer manufactured	**105 (6.8%)**
InterStim Extended Electrode Quad Lead Tined (3093)	100 (6.4%)
InterStim Quad Lead (3080)	3 (0.2%)
InterStim Extended Electrode Quad Lead (3092)	2 (0.1%)
Other/Unspecified	**7 (0.5%)**
Total	**1,555 (100%)**

6.4.1 Lead Events

There were 162 product performance-related events with an underlying reported etiology related to lead function. This includes 158 events with a lead etiology and 4 events with both a lead and other etiology (including device and non-device etiologies). Of these, 126 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:

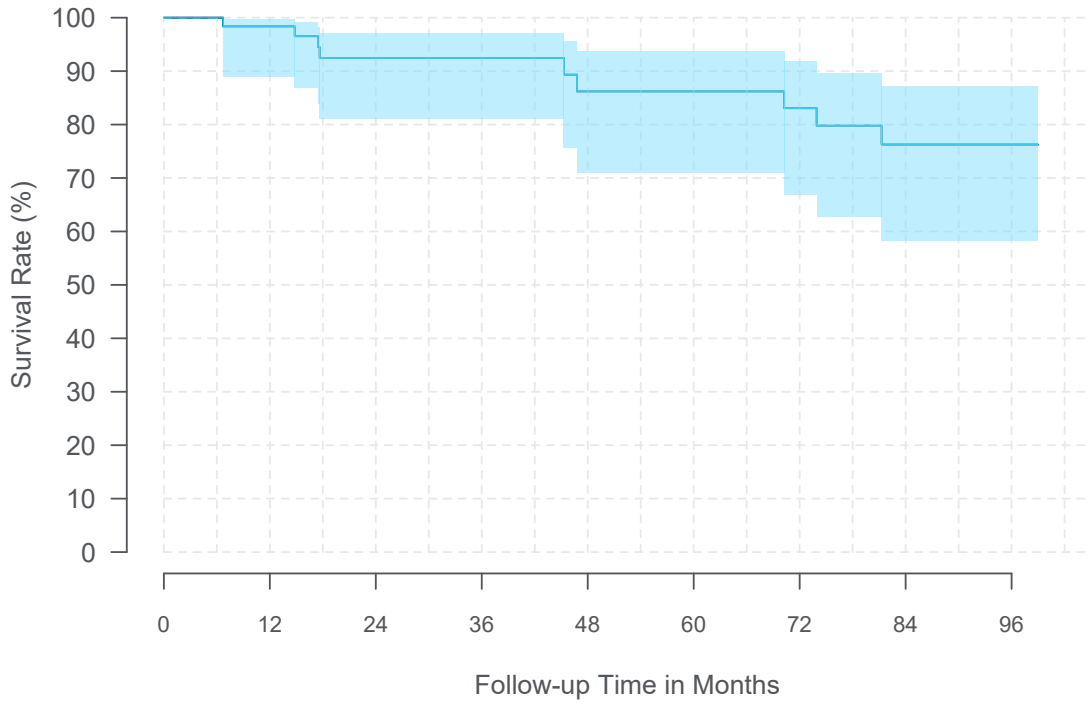
- 126 had follow-up time cut-off due to product performance-related events.
- 748 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 681 were free from product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

6.4.2 Lead Models

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

6.4.2.1 Model 3093

Model Name	InterStim Extended Electrode Quad Lead Tined
FDA Approval Date	September 2002
Leads Enrolled	100
Leads Currently Active in Study	20
Initial Product Performance Events	11
Median Follow-up Time (Months)	30.1
Cumulative Follow-up Time (Months)	4,027



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.4% (89.0%, 99.8%)	92.5% (81.1%, 97.1%)	92.5% (81.1%, 97.1%)	86.2% (71.0%, 93.8%)	86.2% (71.0%, 93.8%)
Sample Size	53	37	28	27	26

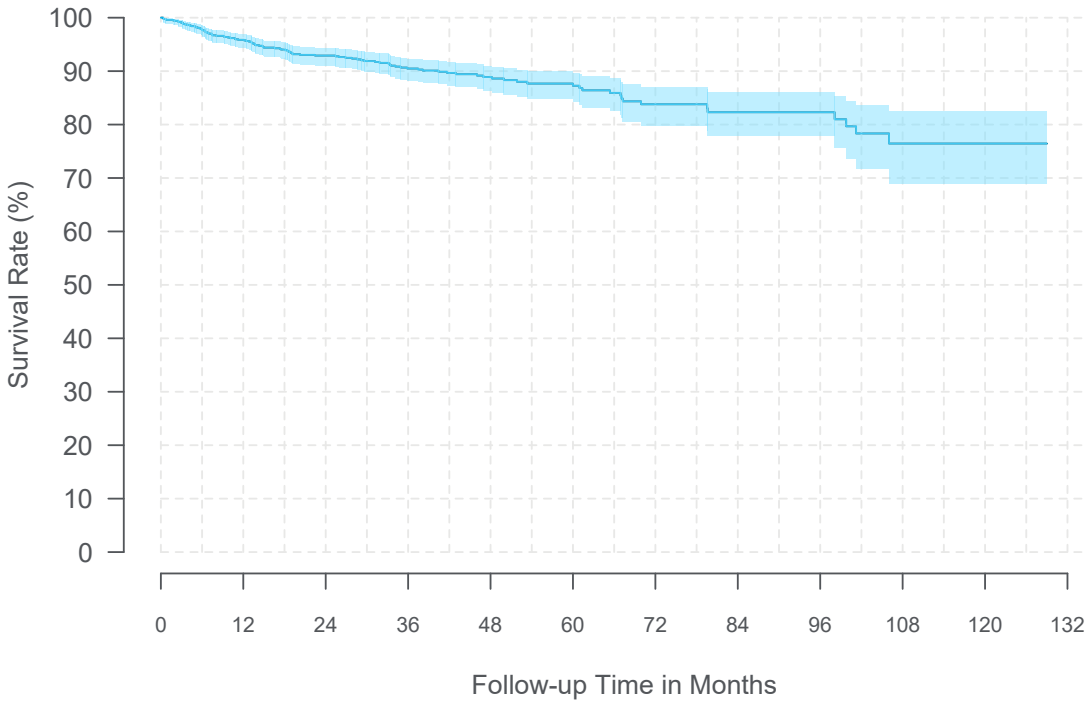
Time Interval	6 Years	7 Years	8 Years	At 99 Months	
Survival (95% CI)	83.1% (66.8%, 91.8%)	76.3% (58.3%, 87.3%)	76.3% (58.3%, 87.3%)	76.3% (58.3%, 87.3%)	—
Sample Size	26	22	24	22	

Specification: 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 Event Summary: 3093	N
High Impedance	5
Device Lead Issue	2
Device Electrical Impedance Issue	1
Device Lead Damage	1
Lead Fracture	1
Lead Migration/Dislodgement	1
Total	**11**

6.4.2.2 Model 3889

Model Name	InterStim Quad Lead Tined
FDA Approval Date	September 2002
Leads Enrolled	1,175
Leads Currently Active in Study	425
Initial Product Performance Events	108
Median Follow-up Time (Months)	32.6
Cumulative Follow-up Time (Months)	43,364



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	95.9% (94.4%, 96.9%)	92.9% (91.0%, 94.4%)	90.5% (88.2%, 92.3%)	88.9% (86.3%, 91.0%)	87.3% (84.3%, 89.7%)
Sample Size	877	680	487	322	212

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	83.8% (79.8%, 87.1%)	82.3% (77.8%, 86.0%)	82.3% (77.8%, 86.0%)	76.4% (68.8%, 82.5%)	76.4% (68.8%, 82.5%)
Sample Size	149	101	65	36	24

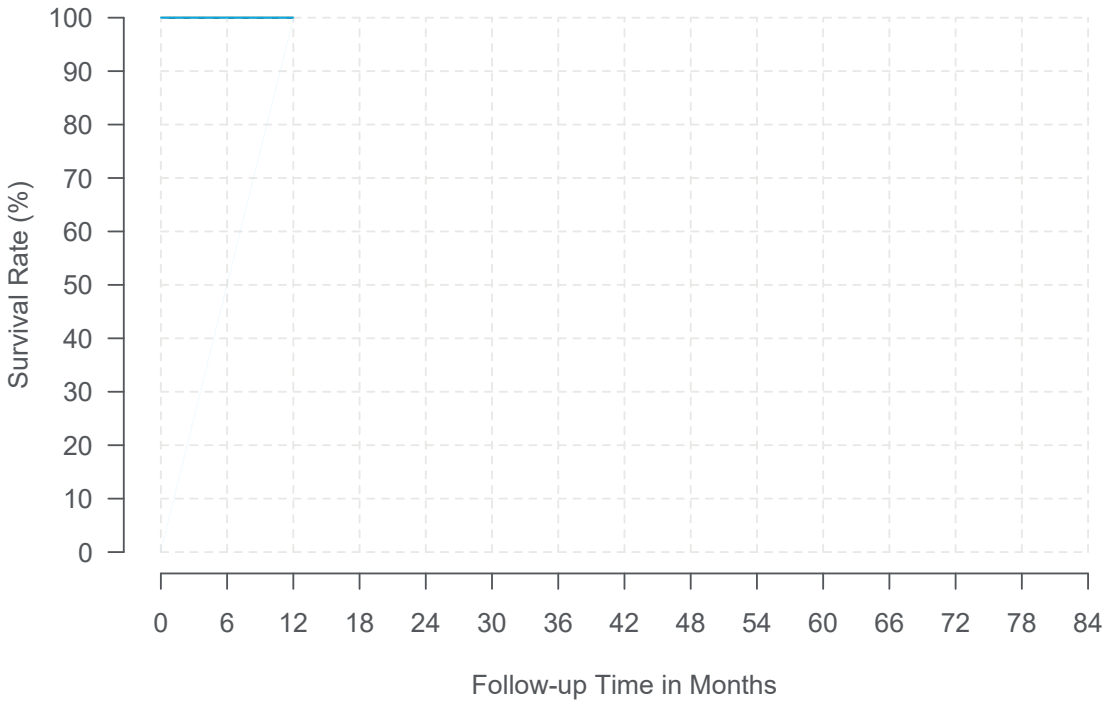
Time Interval	At 129 Months				
Survival (95% CI)	76.4% (68.8%, 82.5%)	—	—	—	—
Sample Size	21				

Specification: 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

Lead Event Summary: 3889	N
High Impedance	44
Lead Migration/Dislodgement	28
Lead Fracture	14
Device Lead Issue	10
Low Impedance	6
Device Electrical Impedance Issue	2
Device Failure	1
Device Issue	1
Device Malfunction	1
Premature Battery Depletion	1
Total	**108**

6.4.2.3 Model 978A1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	55
Leads Currently Active in Study	47
Initial Product Performance Events	0
Median Follow-up Time (Months)	12.9
Cumulative Follow-up Time (Months)	619

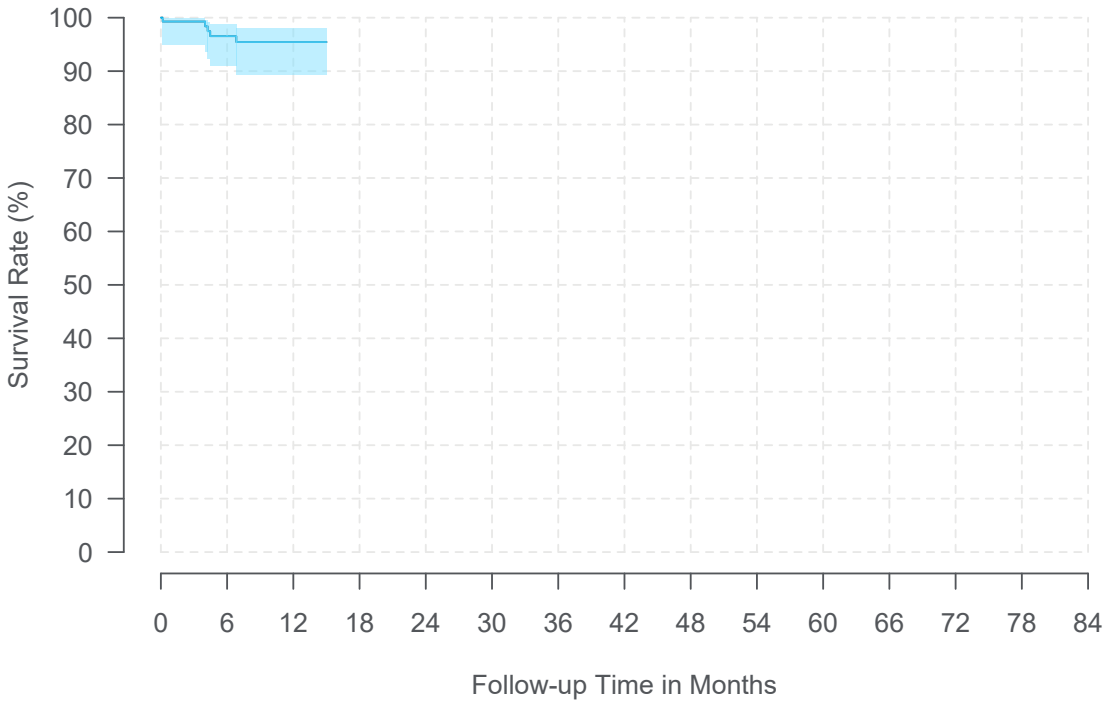


Time Interval	1 Year
Survival	100.0%
(95% CI)	(NA)
Sample Size	28

Specification: 978A1	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3 (4x)
Individual Surface Area (mm^2)	11.61
Inter-Electrode Spacing: Edge to Edge (mm)	3
Array Length (mm)	21

6.4.2.4 Model 978B1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	213
Leads Currently Active in Study	194
Initial Product Performance Events	5
Median Follow-up Time (Months)	4.5
Cumulative Follow-up Time (Months)	1,309



Time Interval	1 Year	At 15 Months
Survival (95% CI)	95.4% (89.3%, 98.1%)	95.4% (89.3%, 98.1%)
Sample Size	43	26

Specification: 978B1	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3 (4x)
Individual Surface Area (mm^2)	11.61
Inter-Electrode Spacing: Edge to Edge (mm)	3
Array Length (mm)	21

Lead Event Summary: 978B1	N
Device Lead Issue	2
Device Electrical Impedance Issue	1
High Impedance	1
Lead Migration/Dislodgement	1
Total	**5**

6.4.3 Lead Summary

Table 6.11: Sacral Neuromodulation 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)
InterStim Extended Electrode Quad Lead Tined (model 3093)	September 2002	100	20	11	30.1	4,027
InterStim Quad Lead Tined (model 3889)	September 2002	1,175	425	108	32.6	43,364
InterStim SureScan MRI Lead (978A1)	July 2020	55	47	0	12.9	619
InterStim SureScan MRI Lead (978B1)	July 2020	213	194	5	4.5	1,309

Table 6.12: Sacral Neuromodulation Lead Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
InterStim Extended Electrode Quad Lead Tined (model 3093)	98.4% (89.0%, 99.8%)	92.5% (81.1%, 97.1%)	92.5% (81.1%, 97.1%)	86.2% (71.0%, 93.8%)	86.2% (71.0%, 93.8%)
InterStim Quad Lead Tined (model 3889)	95.9% (94.4%, 96.9%)	92.9% (91.0%, 94.4%)	90.5% (88.2%, 92.3%)	88.9% (86.3%, 91.0%)	87.3% (84.3%, 89.7%)
InterStim SureScan MRI Lead (978A1)	100.0% (NA)	__	__	__	__
InterStim SureScan MRI Lead (978B1)	95.4% (89.3%, 98.1%)	__	__	__	__

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Extended Electrode Quad Lead Tined (model 3093)	83.1% (66.8%, 91.8%)	76.3% (58.3%, 87.3%)	76.3% (58.3%, 87.3%)	__	__
InterStim Quad Lead Tined (model 3889)	83.8% (79.8%, 87.1%)	82.3% (77.8%, 86.0%)	82.3% (77.8%, 86.0%)	76.4% (68.8%, 82.5%)	76.4% (68.8%, 82.5%)
InterStim SureScan MRI Lead (978A1)	__	__	__	__	__
InterStim SureScan MRI Lead (978B1)	__	__	__	__	__

6.5 Extensions

From April 2010 to the report cut-off date of October 31, 2022, there were 110 extensions followed in the registry, in which 92.7% were Model 3095 (102/110). The difference between the total number of extensions (n=110) versus the total number of neurostimulators (n=1,627) is due to the fact that not all systems require an extension, or some patients were subsequently re-implanted with a new neurostimulator.

The aggregate prospective follow-up time for all extensions was 4,098 months (342 years).

6.5.1 Extension Events

There were 2 product performance-related events with an underlying reported etiology related to extension function. Of these, 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:

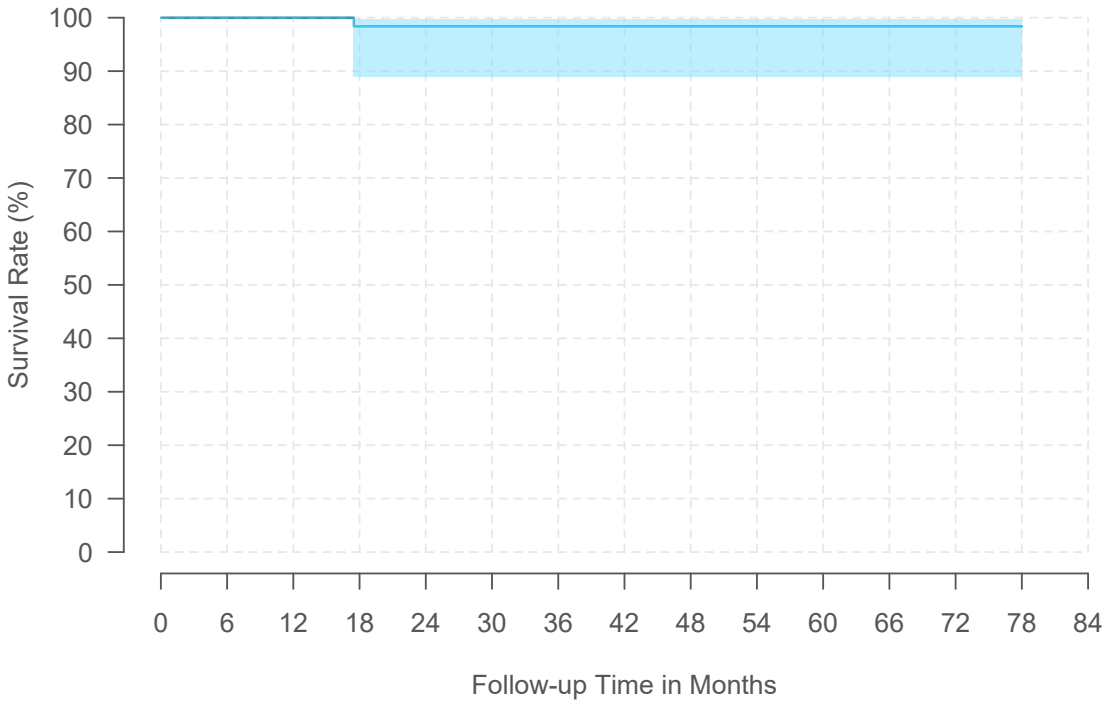
- 1 had follow-up time cut-off due to product performance-related events.
- 85 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 24 were free from product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

6.5.2 Extension Models

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

6.5.2.1 Model 3095

Model Name	Quadripolar extension
FDA Approval Date	July 1998
Extensions Enrolled	102
Extensions Currently Active in Study	16
Initial Product Performance Events	1
Median Follow-up Time (Months)	28.6
Cumulative Follow-up Time (Months)	4,096



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	100.0% (NA)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)
Sample Size	64	52	34	26	24

Time Interval	6 Years	At 78 Months			
Survival (95% CI)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)	—	—	—
Sample Size	22	20			

Specification: 3095	
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 Event Summary: 3095	N
Lead Fracture[a]	1
Total	**1**

[a] Site reported event related to multiple system components.

6.5.3 Extension Summary

Table 6.13: Sacral Neuromodulation 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)
Quadripolar extension (model 3095)	July 1998	102	16	1	28.6	4,096

Table 6.14: Sacral Neuromodulation Extension Survival Probability (95% Confidence Intervals)

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years
Quadripolar extension (model 3095)	100.0%	98.4%	98.4%	98.4%	98.4%	98.4%
	(NA)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)	(89.0%, 99.8%)