

PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA
FROM THE
MEDTRONIC POST-
MARKET REGISTRY

2025

v.1.0 09 July 2026

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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, 2025. Twenty-four centers in North America, South America, and Europe have enrolled and contributed patients to the sacral neuromodulation systems section of this report. [Figure 6.1](#) shows a World Map, in which the countries that enrolled SNM patients are highlighted in blue.

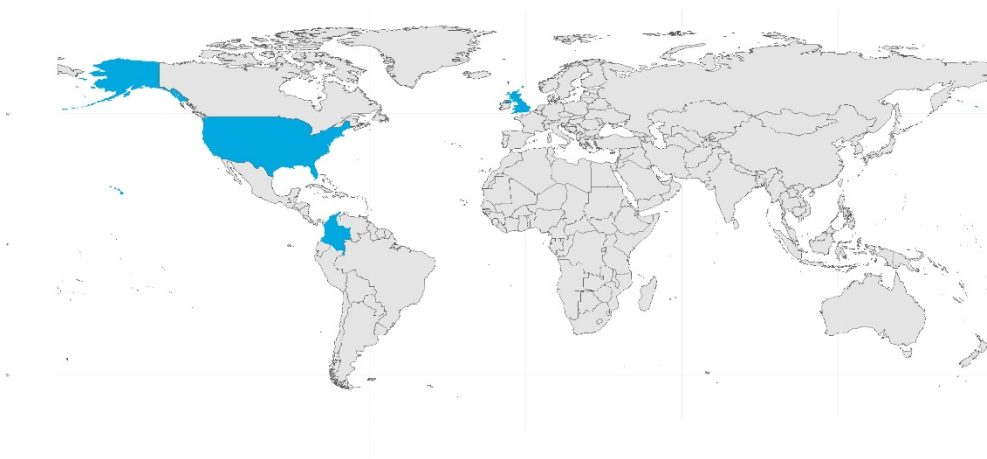


Figure 6.1: Countries with Sacral Neuromodulation Therapy Patients in Registry (Highlighted)

6.1.2 Patients

Of the 1,825 sacral neuromodulation patients enrolled, the primary indications for implant were as follows: 44.5% were implanted for the treatment of urinary urge incontinence, 25.8% were implanted for the treatment of urgency-frequency, 13.3% were implanted for the treatment of non-obstructive urinary retention, and 9.8% were implanted for the treatment of fecal incontinence. There were also 2.1% implanted for the treatment of bladder pain syndrome and 0.1% were implanted for the treatment of constipation, which are both considered off-label indications. There were 3.7% patients implanted for the treatment of some other indication, and 0.7% were implanted for indications that were not specified in the database at the time of data cut-off (see [Figure 6.2](#) and [Table 6.1](#)).

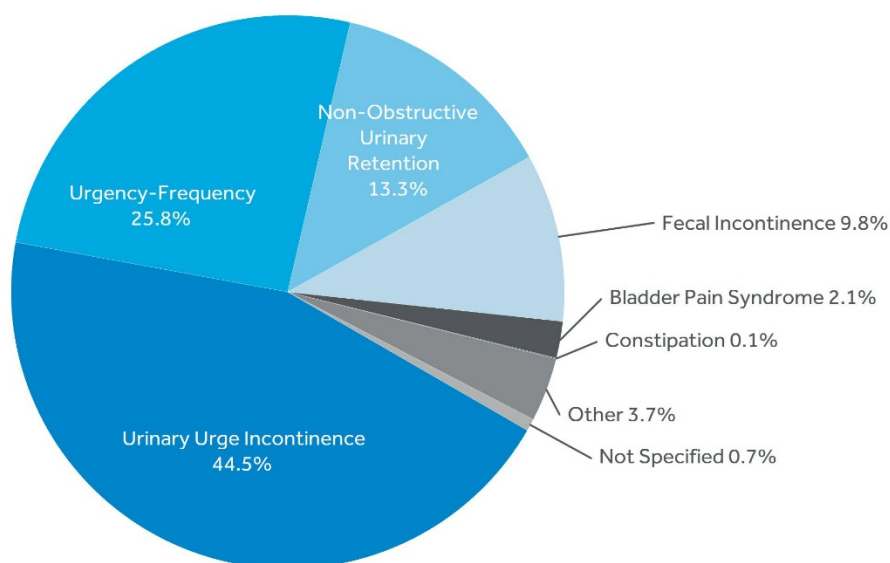


Figure 6.2: Sacral Neuromodulation Primary Treatment Indications

Table 6.1: Sacral Neuromodulation Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Urinary Urge Incontinence	813 (44.5%)
Urgency-Frequency	470 (25.8%)
Non-Obstructive Urinary Retention	242 (13.3%)
Fecal Incontinence	179 (9.8%)
Bladder Pain Syndrome	39 (2.1%)
Constipation	1 (0.1%)
Other	68 (3.7%)
Not Specified	13 (0.7%)
Total Patients	1825 (100.0%)

^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 (<https://www.medtronic.com/us-en/our-company/locations.html>).

6.2 Event Summary

Adverse and device events were reported by the investigational site, where the principal investigator determined the suspected etiology. For device-related events, etiology could be attributed to one or more system components (e.g., neurostimulator, lead, and/or extension). If multiple components were identified as contributing to a single event, a separate product performance event (PPE) was recorded for each implicated component. For example, an event attributed to both the neurostimulator and the lead would be counted as one PPE for the neurostimulator and an additional PPE for the lead. As a result, the total number of PPEs may exceed the number of unique PPEs.

For SNM, there were 263 PPEs (224 unique PPEs) reported in 188 patients between April 2010 and October 31, 2025. These events represent 16.6% of the total reported events (263/1,581), occurring in 188 (10.3%) of the 1,825 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 1,318 non-product performance events that were collected to understand patient experience (clinical signs and symptoms) with the sacral neuromodulation systems.

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](#) 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 97 deaths reported for patients followed in the Product Surveillance Registry (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 (%) ^b N=1825
RPA Determination	0	0	0 (0.00%)
Physician's Determination	263	4.4	188 (10.30%)
High Impedance	101	1.7	76 (4.16%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=1825
Lead Migration/Dislodgement	48	0.8	39 (2.14%)
Device Lead Issue	30	0.5	20 (1.10%)
Lead Fracture	25	0.4	21 (1.15%)
Device Malfunction	15	0.3	13 (0.71%)
Low Impedance	11	0.2	10 (0.55%)
Device Electrical Impedance Issue	6	0.1	4 (0.22%)
Premature Battery Depletion	5	0.1	4 (0.22%)
Device Issue	4	0.1	3 (0.16%)
Unspecified	4	0.1	4 (0.22%)
Device Charging Issue	2	<0.1	2 (0.11%)
Device Failure	2	<0.1	1 (0.05%)
Device Overheating	2	<0.1	2 (0.11%)
Other ^c	8	0.1	8 (0.44%)
Total	263	4.4	188 (10.30%)

^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 Composed of event codes with 1 event each.

A total of 173 (65.8%) of 263 product performance events were related to the lead only, 53 (20.2%) related to the neurostimulator only, 2 (0.8%) related to the extension only, 8 (3.0%) related to multiple etiologies (which includes events where at least one device and one non-device etiology was indicated), and 27 (10.3%) related to other/not specified etiologies. Relatedness is determined by the physician.

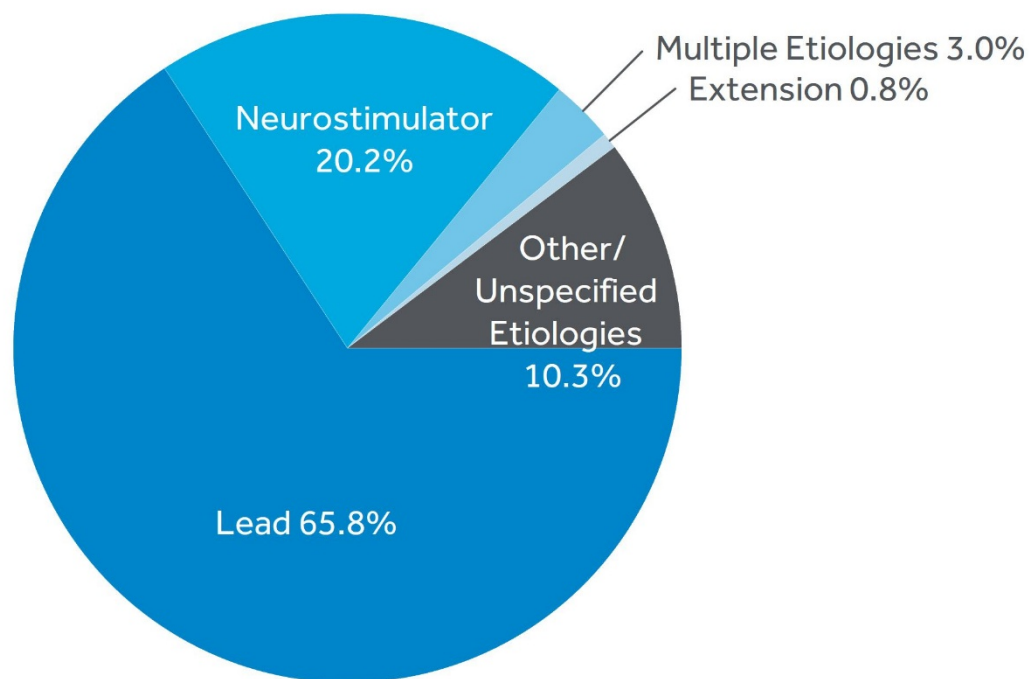


Figure 6.3: Sacral Neuromodulation System Product Performance Events by Relatedness

[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 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 ^a	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention	No Action Taken	Total Events
High Impedance	53 (52.5%)	37 (36.6%)	0 (0.0%)	0 (0.0%)	11 (10.9%)	101
Lead Migration/Dislodgement	34 (70.8%)	6 (12.5%)	1 (2.1%)	1 (2.1%)	6 (12.5%)	48
Device Lead Issue	12 (40%)	9 (30.0%)	4 (13.3%)	0 (0.0%)	5 (16.7%)	30

Events by Intervention ^a	Surgical Intervention	Reprogramming	Therapy Suspension	Medical or Non-Surgical Intervention	No Action Taken	Total Events
Lead Fracture	17 (68%)	2 (8.0%)	1 (4.0%)	3 (12%)	2 (8.0%)	25
Device Malfunction	8 (53.3%)	4 (26.7%)	2 (13.3%)	0 (0.0%)	1 (6.7%)	15
Other ^b	29 (65.9%)	6 (13.6%)	2 (4.5%)	3 (6.8%)	4 (9.1%)	44
Total	153 (58.2%)	64 (24.3%)	10 (3.8%)	7 (2.7%)	29 (11.0%)	263

^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 since 2013, the time in which clinical event collection was initiated (n=1,515)
- Categorized as serious adverse events (SAEs, n=23)
- 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=1515	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=1515
Infections and infestations	15	15 (0.99%)	0.026	13 (0.86%)
Infections - pathogen unspecified	15	15 (0.99%)	0.026	13 (0.86%)
Other SOC Terms (<0.5% Threshold)^a	8	8 (0.53%)	0.014	4 (0.26%)
Total	23	23 (1.52%)	0.040	17 (1.12%)

^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 97 patients in the registry had expired. 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	42 (43.3%)
Urgency-Frequency	31 (32.0%)
Non-Obstructive Urinary Retention	13 (13.4%)
Fecal Incontinence	6 (6.2%)
Other	5 (5.2%)
Total	97

^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, 2025, there were 1,981 neurostimulators followed in the registry. The difference between the total number of patients (n=1,825) versus the total number of neurostimulators (n=1,981) is due to the fact that some patients were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 69,523 months (5,794 years).

Table 6.6: Sacral Neuromodulation Neurostimulator Counts by Model

Model Name	N (%)
InterStim II (model 3058)	1420 (71.7%)
InterStim X (model 97800)	399 (20.1%)
InterStim (model 3023)	102 (5.1%)
InterStim Micro (model 97810)	60 (3.0%)
Total	1981

6.3.1 Neurostimulator Events

There were 57 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 53 events with a neurostimulator etiology and 4 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 48 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 9.03% (58/642). 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 57 neurostimulator events, 100.00% (57/57) 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	57 (100%)
High Impedance	21 (36.8%)
Device Lead Issue	7 (12.3%)
Device Malfunction	7 (12.3%)
Lead Migration/Dislodgement	5 (8.8%)
Premature Battery Depletion	4 (7.0%)
Device Electrical Impedance Issue	2 (3.5%)
Device Issue	2 (3.5%)
Device Overheating	2 (3.5%)

Product Performance Events	N (%)
Lead Fracture	2 (3.5%)
Device Battery Issue	1 (1.8%)
Device Breakage	1 (1.8%)
Device Connection Issue	1 (1.8%)
Device Failure	1 (1.8%)
Unspecified	1 (1.8%)

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:

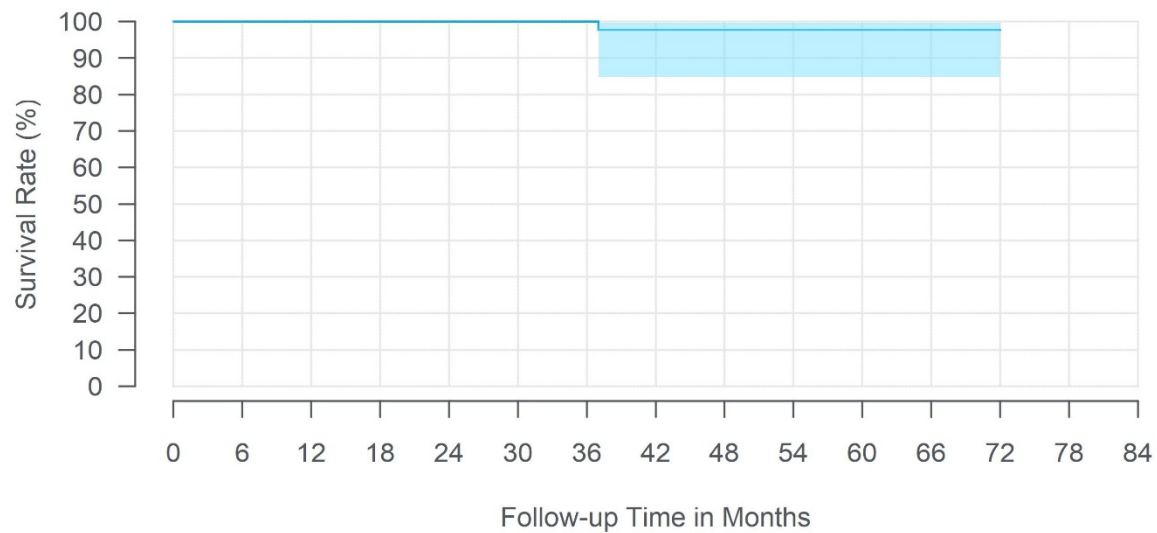
- 48 had follow-up time cut-off due to product performance related-events.
- 1,361 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 572 were free 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 (CIs) where at least 20 neurostimulators contributed to each 3-month interval.

6.3.2.1 Model 3023

Model Name	InterStim
FDA Approval Date	July 1998
Neurostimulators Enrolled	102
Neurostimulators Currently Active in Study	1
Initial Product Performance Events	2
Median Follow-up Time (Months)	28.8
Cumulative Follow-up Time (Months)	4,118



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	71	60	43	33	25

Time Interval	6 Years
Survival (95% CI)	97.7% (84.8%, 99.7%)
Sample Size	22

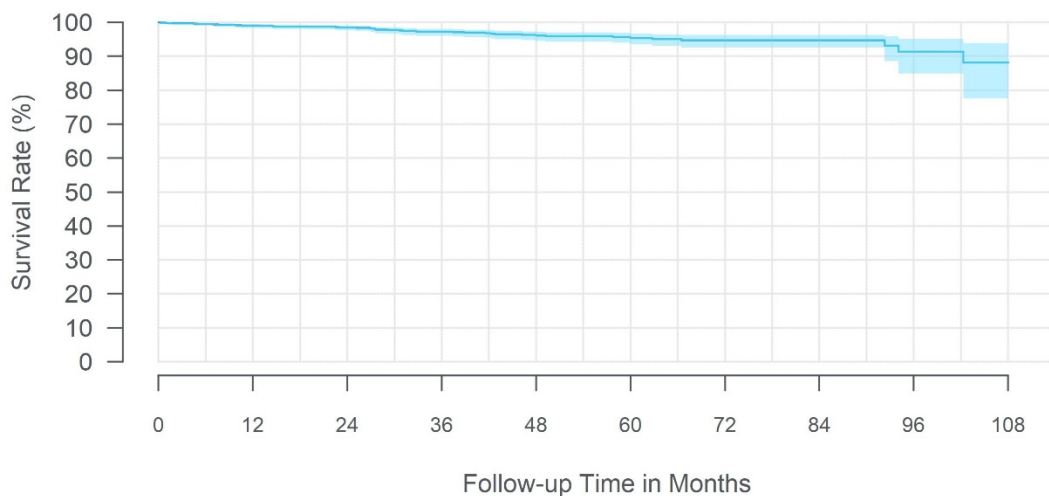
Specification: 3023	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (10 mm)
Volume	25 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 μ sec
Programs	4
Implant Depth	$\leq$ 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	1,420
Neurostimulators Currently Active in Study	206
Initial Product Performance Events	44
Median Follow-up Time (Months)	37.2
Cumulative Follow-up Time (Months)	57,547



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.1% (98.4%, 99.5%)	98.5% (97.6%, 99.1%)	97.3% (96.0%, 98.1%)	96.1% (94.6%, 97.2%)	95.4% (93.6%, 96.7%)
Sample Size	1174	938	729	516	342

Time Interval	6 Years	7 Years	8 Years	9 Years
Survival (95% CI)	94.7% (92.6%, 96.2%)	94.7% (92.6%, 96.2%)	91.4% (85.0%, 95.1%)	88.2% (77.6%, 93.9%)
Sample Size	200	113	47	21

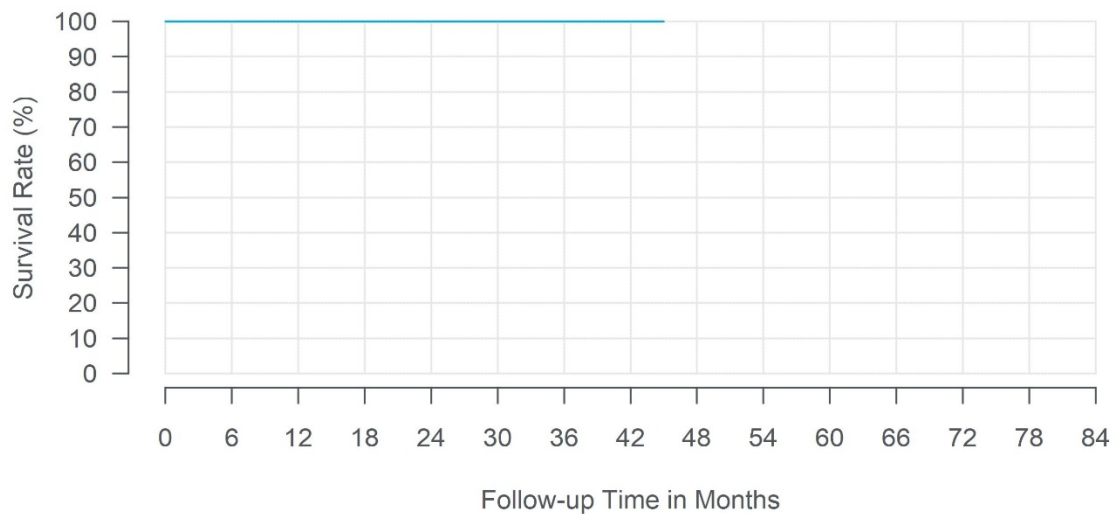
Specification: 3058	
Height	1.7 in (44 mm)
Width	2.0 in (51 mm)
Thickness	0.3 in (7.7 mm)
Volume	14 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 8.5 V
Rate	2.1 - 130 Hz
Pulse Width	60 - 450 μ sec
Programs	4
Implant Depth	≤ 2.5 cm



Neurostimulator Event Summary: 3058	N
High Impedance	17
Device Malfunction	6
Lead Migration/Dislodgement	5
Device Lead Issue	4
Premature Battery Depletion	3
Device Electrical Impedance Issue	2
Device Issue	2
Device Breakage	1
Device Failure	1
Device Overheating	1
Lead Fracture	1
Unspecified	1
Total	44

6.3.2.3 Model 97810

Model Name	InterStim Micro
FDA Approval Date	July 2020
Neurostimulators Enrolled	60
Neurostimulators Currently Active in Study	24
Initial Product Performance Events	0
Median Follow-up Time (Months)	34.4
Cumulative Follow-up Time (Months)	1,998



Time Interval	1 Year	2 Years	3 Years	At 45 Months
Survival (95% CI)	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	54	39	30	20

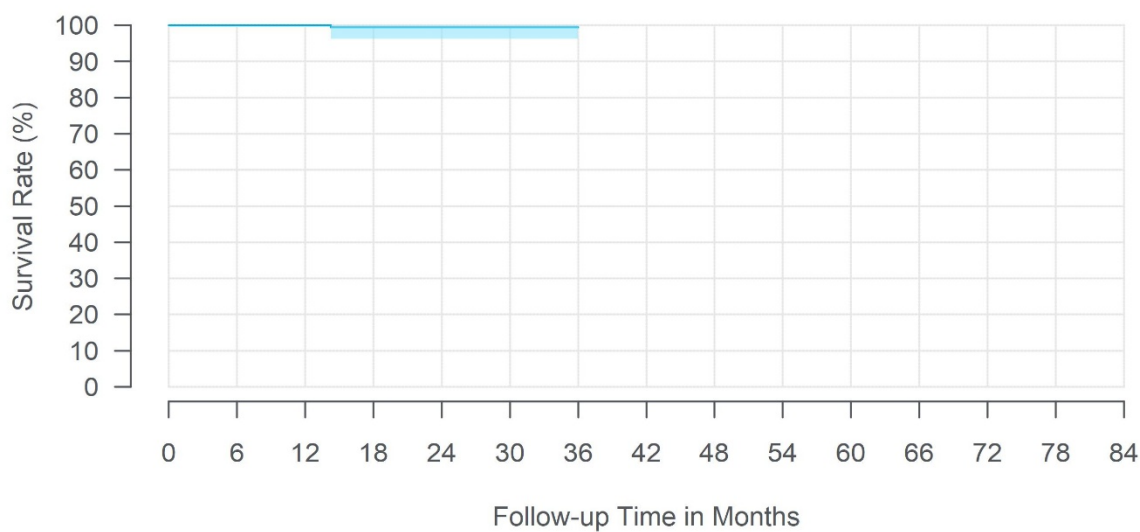
Specification: 97810	
Height	0.7 in (17 mm)
Length	1.9 in (47 mm)
Thickness	0.2 in (5 mm)
Volume	2.8 cc
Battery type	Rechargeable
Expected Battery life	15 years
Maximum Electrodes	1
Amplitude	0 to 12.5 mA (0.1 mA increment)
Rate	3 to 130 Hz
Pulse Width	40 to 450 µsec (10 µsec increment)
Programs	11
Implant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



Neurostimulator Event Summary: 97810	Total
N	0

6.3.2.4 Model 97800

Model Name	InterStim X
FDA Approval Date	February 2022
Neurostimulators Enrolled	399
Neurostimulators Currently Active in Study	341
Initial Product Performance Events	2
Median Follow-up Time (Months)	13.2
Cumulative Follow-up Time (Months)	5,859



Time Interval	1 Year	2 Years	3 Years
Survival (95% CI)	100.0% (NA)	99.5% (96.3%, 99.9%)	99.5% (96.3%, 99.9%)
Sample Size	209	99	22

Specification: 97800	
Height	1.7 in (44 mm)
Length	2.0 in (51 mm)
Thickness	0.3 in (7.7 mm)
Volume	12.5 cc
Battery type	Recharge-free
Expected Battery life	10.2 years ^a
Maximum Electrodes	4
Amplitude	0 - 12.5 mA (0.1 mA increment)
Rate	3 - 130 Hz
Pulse Width	40 - 450 µsec (10 µsec increment)
Programs	Up to 7 standard programs (Programs 1-7) and up to 4 custom programs (Programs A-D)
Implant Depth	No deeper than 2.5 cm (1 in) below the skin



^aService life may be up to 15 years depending on device settings and patient impedance. See System Eligibility, Battery Longevity, Specifications (available at manuals.medtronic.com) for details about the impact of programming parameters and patient impedance on battery longevity.

Neurostimulator Event Summary: 97800	N
Device Connection Issue	1
High Impedance	1
Total	2

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 (model 3023)	July 1998	102	1	2	28.8	4,118
InterStim II (model 3058)	June 2006	1,420	206	44	37.2	57,547
InterStim Micro (model 97810)	July 2020	60	24	0	34.4	1,998

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
InterStim X (model 97800)	February 2022	399	341	2	13.2	5,859

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

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
InterStim (model 3023)	100.0%	100.0%	100.0%	97.7%	97.7%
	(NA)	(NA)	(NA)	(84.8%, 99.7%)	(84.8%, 99.7%)
InterStim II (model 3058)	99.1%	98.5%	97.3%	96.1%	95.4%
	(98.4%, 99.5%)	(97.6%, 99.1%)	(96.0%, 98.1%)	(94.6%, 97.2%)	(93.6%, 96.7%)
InterStim Micro (model 97810)	100.0%	100.0%	100.0%		
	(NA)	(NA)	(NA)		
InterStim X (model 97800)	100.0%	99.5%	99.5%		
	(NA)	(96.3%, 99.9%)	(96.3%, 99.9%)		

Model Name	6 Years	7 Years	8 Years	9 Years
InterStim (model 3023)	97.7%			
	(84.8%, 99.7%)			
InterStim II (model 3058)	94.7%	94.7%	91.4%	88.2%
	(92.6%, 96.2%)	(92.6%, 96.2%)	(85.0%, 95.1%)	(77.6%, 93.9%)
InterStim Micro (model 97810)				
InterStim X (model 97800)				

6.4 Leads

From April 2010 to the report cut-off date of October 31, 2025, there were 1,884 leads followed in the registry. The difference between the total number of leads (n=1,884) versus the total number of neurostimulators (n=1,981) 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 69,988 months (5,832 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	551 (29.2%)
InterStim SureScan MRI (model 978B1)	479 (25.4%)
InterStim SureScan MRI (model 978A1)	72 (3.8%)
No longer manufactured	1321 (70.2%)
InterStim Quad Tined (model 3889)	1230 (65.3%)
InterStim Extended Electrode Quad Tined (model 3093)	87 (4.6%)
InterStim Quad (model 3080)	3 (0.2%)
InterStim Extended Electrode Quad (model 3092)	1 (0.1%)
Other/Unspecified	12 (0.6%)
Total	1884 (100.0%)

6.4.1 Lead Events

There were 177 product performance-related events with an underlying reported etiology related to lead function. This includes 173 events with a lead etiology and 4 events with both a lead and other etiology (including device and non-device etiologies). Of these, 137 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:

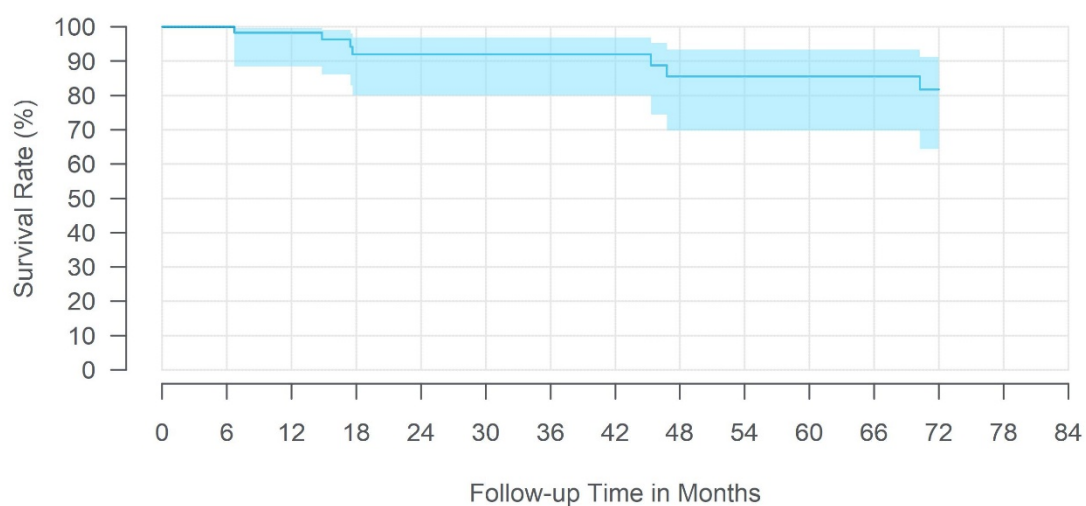
- 137 had follow-up time cut-off due to product performance-related events.
- 1,179 were censored in the survival analysis for the following reasons: patient expired, lead explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 568 were free from product 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
FDA Approval Date	Lead Tined September 2002
Leads Enrolled	87
Leads Currently Active in Study	2
Initial Product Performance Events	11
Median Follow-up Time (Months)	27.3
Cumulative Follow-up Time (Months)	3,626



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.3% (88.5%, 99.8%)	92.0% (80.0%, 96.9%)	92.0% (80.0%, 96.9%)	85.6% (69.8%, 93.4%)	85.6% (69.8%, 93.4%)
Sample Size	50	36	27	26	24

Time Interval	6 Years
Survival (95% CI)	81.8% (64.4%, 91.2%)
Sample Size	20

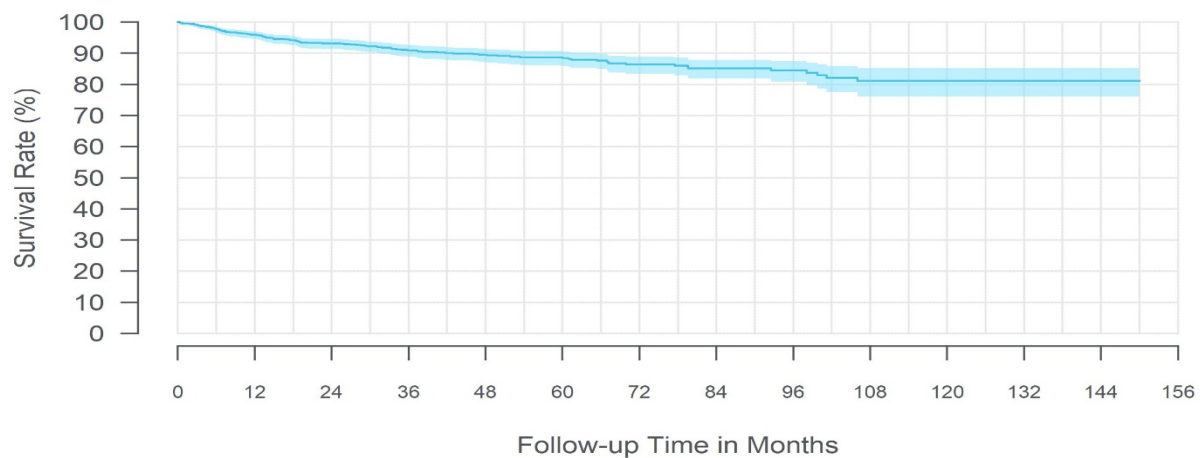
Specification: 3093	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical/coiled
Length (mm)	3.0 (3x) and 10.2 (1x)
Individual Surface Area (mm ²)	12.0 and 40.7
Inter-Electrode Spacing: Edge to Edge (mm)	1.5
Array Length (mm)	23.7



Lead Event Summary: 3093	N
High Impedance	4
Device Lead Issue	3
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	1,230
Leads Currently Active in Study	190
Initial Product Performance Events	112
Median Follow-up Time (Months)	38.8
Cumulative Follow-up Time (Months)	53,529



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	96.0% (94.6%, 97.0%)	93.2% (91.4%, 94.6%)	90.9% (88.8%, 92.6%)	89.5% (87.2%, 91.5%)	88.5% (86.0%, 90.5%)
Sample Size	907	726	588	462	352

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	86.4% (83.5%, 88.9%)	85.2% (81.9%, 87.9%)	84.5% (81.0%, 87.5%)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)
Sample Size	251	177	116	73	49

Time Interval	11 Years	12 Years	At 150 Months
Survival (95% CI)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)	81.1% (76.1%, 85.2%)
Sample Size	34	21	22

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

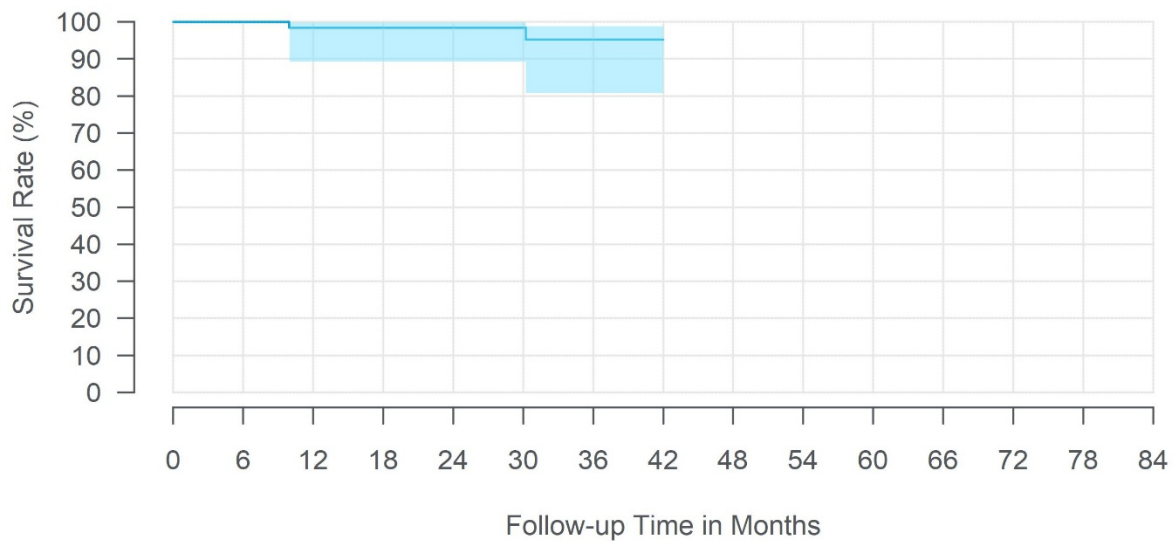


Lead Event Summary: 3889	N
High Impedance	47
Lead Migration/Dislodgement	28
Lead Fracture	14
Device Lead Issue	10
Low Impedance	6
Device Electrical Impedance Issue	2
Device Malfunction	2
Device Failure	1
Device Issue	1
Premature Battery Depletion ^a	1
Total	112

^aSite reported event related to multiple system components.

6.4.2.3 Model 978A1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	72
Leads Currently Active in Study	32
Initial Product Performance Events	2
Median Follow-up Time (Months)	28.2
Cumulative Follow-up Time (Months)	2,203



Time Interval	1 Year	2 Years	3 Years	At 42 Months
Survival (95% CI)	98.4% (89.3%, 99.8%)	98.4% (89.3%, 99.8%)	95.2% (80.7%, 98.9%)	95.2% (80.7%, 98.9%)
Sample Size	61	40	27	23

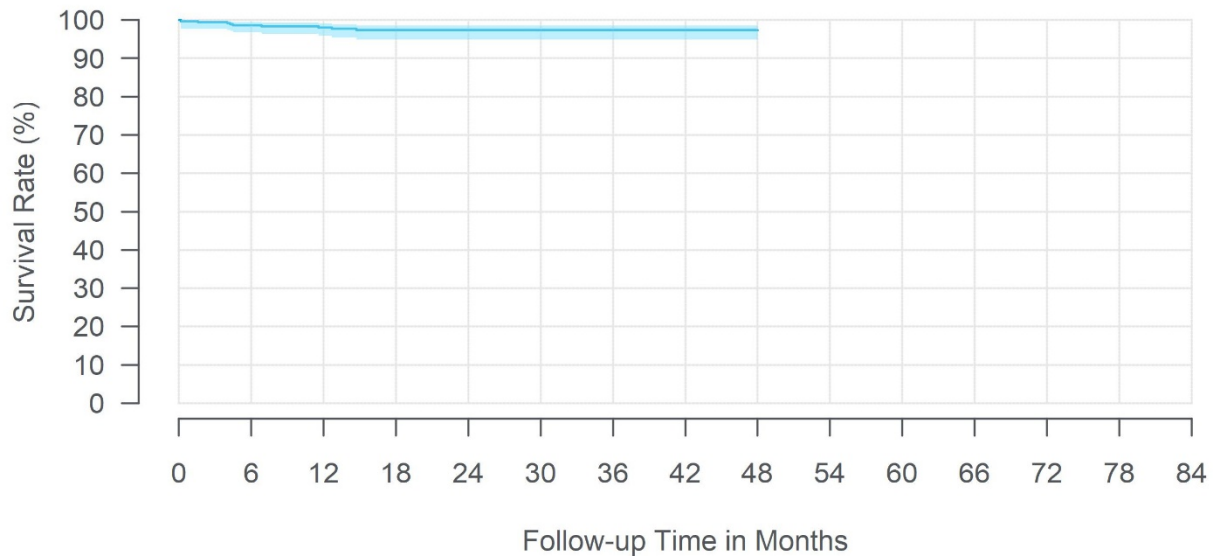
Specification: 978A1	
Lead	
Length (cm)	28, 33, 41
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3 (4x)
Individual Surface Area (mm ²)	11.61
Inter-Electrode Spacing: Edge to Edge (mm)	3
Array Length (mm)	21



Lead Event Summary: 978A1	N
High Impedance	1
Lead Migration/Dislodgement	1
Total	2

6.4.2.4 Model 978B1

Model Name	InterStim SureScan MRI Lead
FDA Approval Date	July 2020
Leads Enrolled	479
Leads Currently Active in Study	340
Initial Product Performance Events	10
Median Follow-up Time (Months)	18.2
Cumulative Follow-up Time (Months)	10,266



Time Interval	1 Year	2 Years	3 Years	4 Years
Survival (95% CI)	98.1% (95.9%, 99.1%)	97.4% (94.9%, 98.6%)	97.4% (94.9%, 98.6%)	97.4% (94.9%, 98.6%)
Sample Size	293	178	84	25

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
High Impedance	4
Device Lead Issue	2
Device Electrical Impedance Issue	1
Device Kink	1
Device Malfunction	1
Lead Migration/Dislodgement	1
Total	10

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 Tined (model 3093)	September 2002	87	2	11	27.3	3,626
InterStim Quad Tined (model 3889)	September 2002	1,230	190	112	38.8	53,529
InterStim SureScan MRI (model 978A1)	July 2020	72	32	2	28.2	2,203
InterStim SureScan MRI (model 978B1)	July 2020	479	340	10	18.2	10,266

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 Tined (model 3093)	98.3%	92.0%	92.0%	85.6%	85.6%
	(88.5%, 99.8%)	(80.0%, 96.9%)	(80.0%, 96.9%)	(69.8%, 93.4%)	(69.8%, 93.4%)
InterStim Quad Tined (model 3889)	96.0%	93.2%	90.9%	89.5%	88.5%
	(94.6%, 97.0%)	(91.4%, 94.6%)	(88.8%, 92.6%)	(87.2%, 91.5%)	(86.0%, 90.5%)
InterStim SureScan MRI (model 978A1)	98.4%	98.4%	95.2%		
	(89.3%, 99.8%)	(89.3%, 99.8%)	(80.7%, 98.9%)		
InterStim SureScan MRI (model 978B1)	98.1%	97.4%	97.4%	97.4%	
	(95.9%, 99.1%)	(94.9%, 98.6%)	(94.9%, 98.6%)	(94.9%, 98.6%)	

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Extended Electrode Quad Tined (model 3093)	81.8%				
	(64.4%, 91.2%)				

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
InterStim Quad Tined (model 3889)	86.4%	85.2%	84.5%	81.1%	81.1%
	(83.5%, 88.9%)	(81.9%, 87.9%)	(81.0%, 87.5%)	(76.1%, 85.2%)	(76.1%, 85.2%)
InterStim SureScan MRI (model 978A1)					
InterStim SureScan MRI (model 978B1)					

Model Name	11 Years	12 Years
InterStim Extended Electrode Quad Tined (model 3093)		
InterStim Quad Tined (model 3889)	81.1%	81.1%
	(76.1%, 85.2%)	(76.1%, 85.2%)
InterStim SureScan MRI (model 978A1)		
InterStim SureScan MRI (model 978B1)		

6.5 Extensions

From April 2010 to the report cut-off date of October 31, 2025, there were 165 extensions followed in the registry, of which 61.8% were Model 3095 102/165. The remaining 63 extensions were Percutaneous Extension Model 3560022 (n=61) or Model 3560030 (n=2) and are not shown in this report due to the sample size at 1 year follow-up not being equal to an n=20. The difference between the total number of extensions (n=165) versus the total number of neurostimulators (n=1,981) 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 5,392 months (449 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:

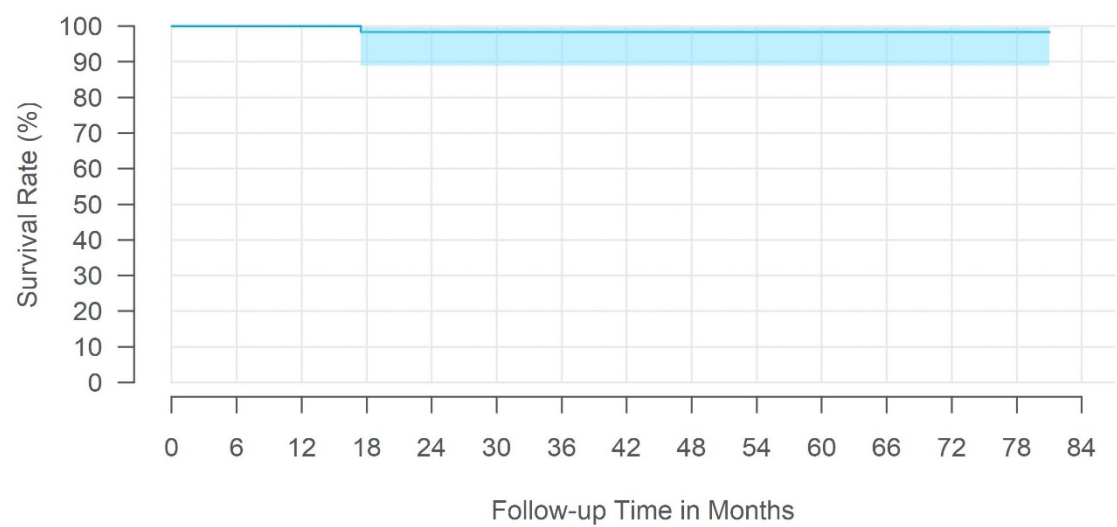
- 1 had follow-up time cut-off due to product performance-related events.
- 105 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 59 were free from product 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	Quadrupolar Extension
FDA Approval Date	July 1998
Extensions Enrolled	102
Extensions Currently Active in Study	7
Initial Product Performance Events	1
Median Follow-up Time (Months)	28.6
Cumulative Follow-up Time (Months)	4,484



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 81 Months
Survival (95% CI)	98.4% (89.0%, 99.8%)	98.4% (89.0%, 99.8%)
Sample Size	23	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 (model 3095)	July 1998	102	7	1	28.6	4,484

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 (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%)