

Sacral Neuromodulation Systems

2025 Medtronic Product Performance Report

Executive Summary

INTRODUCTION

Medtronic's commitment to quality has long been stated as part of the Medtronic Mission. We will **strive without reserve for the greatest possible reliability and quality**. The annual Medtronic Product Performance Report (PPR) reflects that commitment. Through this sharing of information, we can enable physicians to best leverage state-of-the-art therapy delivery and also understand the performance of our devices to best manage patients.

Medtronic published the industry's first Neuromodulation PPR in 2008. The report uses data gathered from a prospective, long-term, multi-center registry. It allows for active surveillance of our Spinal Cord Stimulation, Targeted Drug Delivery, Deep Brain Stimulation, and Sacral Neuromodulation devices.

As of October 31, 2025, the registry had 4,030 implanted devices and 1,825 patients in the Sacral Neuromodulation therapy.

Access the 2025 full report at: <https://www.medtronic.com/en-us/healthcare-professionals/product-resources/product-advisories-performance/neuromodulation-product-performance.html>

METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers titled the Product Surveillance Registry (PSR).
- Medtronic also incorporates the findings of Returned Product Analysis (RPA) for devices followed in the registry that are returned to Medtronic.
- Patients at each center who provide informed consent are enrolled in the registry. Patients are followed prospectively for events related to the device, procedure, and/or therapy.
- Participating investigators provide event descriptions, patient symptoms, and patient outcomes. Any detection methods used to determine patient or device outcomes are also obtained.

EVENT CATEGORIZATION

Events collected through the registry are collapsed into two categories:

- **Product performance** - event possibly due to a device-related issue.
- **Non-product performance** (or a clinical event not related to product performance) - any undesirable patient symptom, illness, or other medical event that appears or worsens during the clinical study that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as a product performance event. All clinical events not related to a product performance and reported as a serious adverse event were summarized by MedDRA System Organ Class (SOC) if the event met a patient threshold and are included in the full Product Performance Report.

DEVICE SURVIVAL ESTIMATES

Note that cumulative device survival-not patient survival- estimates are presented throughout this summary.

- Figures show the percentage of implanted devices that remain free from product performance-related events at various time points.
- Example: a device survival probability of 90% indicates that through the stated follow-up time period, the device had a 10% risk of incurring a product performance event since the time of implant.

- Estimates represent device survival where at least 20 total devices are still being followed for at least 6 months.

PATIENT ENROLLMENT

- 24 centers enrolled 1,825 total Sacral Neuromodulation patients in the registry through October 31, 2025.
- 44.5% of patients were implanted for the treatment of urinary urge incontinence.
- 25.8% of patients were implanted for the treatment of urgency-frequency.
- 13.3% of patients were implanted for the treatment of non-obstructive urinary retention.
- 9.8% of patients were implanted for the treatment of fecal incontinence.
- 3.7% of patients were implanted for the treatment of some other indication.
- 2.1% of patients were implanted for the treatment of bladder pain syndrome.
- 0.7% of patients were implanted for the treatment of indications not specified in the database at the time of the data cut-off.
- 0.1% of patients were implanted for the treatment of constipation.

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 regulatory 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>).

Medtronic Sacral Neuromodulation Systems Device Survival Summary Table

Device Summary Information				Device Survival Probability (%)*											
Model Number/ Product Name	Devices Enrolled	Device Initial Product Performance Events	Cumulative Months of Follow-up	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs	12 yrs
Neurostimulators															
InterStim™	102	2	4,118	100%	100%	100%	97.7%	97.7%	97.7%	-	-	-	-	-	
InterStim™ II	1,420	44	57,547	99.1%	98.5%	97.3%	96.1%	95.4%	94.7%	94.7%	91.4%	88.2%	-	-	
InterStim™ Micro	60	0	1,998	100%	100%	100%	-	-	-	-	-	-	-	-	
InterStim™ X	399	2	5,859	100%	99.5%	99.5%	-	-	-	-	-	-	-	-	
Leads															
Model 3889	1,230	112	53,529	96.0%	93.2%	90.9%	89.5%	88.5%	86.4%	85.2%	84.5%	81.1%	81.1%	81.1%	81.1%
Model 3093	87	11	3,626	98.3%	92.0%	92.0%	85.6%	85.6%	81.8%	-	-	-	-	-	
Model 978A1	72	2	2,203	98.4%	98.4%	95.2%	-	-	-	-	-	-	-	-	
Model 978B1	479	10	10,266	98.1%	97.4%	97.4%	97.4%	-	-	-	-	-	-	-	
Extension															
Model 3095	102	1	4,484	100.0%	98.4%	98.4%	98.4%	98.4%	98.4%	-	-	-	-	-	

* Table shows the percentage of implanted devices that remain free from product performance-related events at various time points.

If you have suggestions, inquiries, or specific problems related to our products or this information, contact:

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