

# Sacral Neuromodulation Systems

## 2022 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, 2022, the registry had 3,292 implanted devices and 1,558 patients in the Sacral Neuromodulation therapy.

**Access the 2022 full report at:** <https://www.medtronic.com/us-en/healthcare-professionals/products/product-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 1,558 total Sacral Neuromodulation patients in the registry through October 31, 2022.
- 43.4% of patients were implanted for the treatment of urinary urge incontinence.
- 27.1% of patients were implanted for the treatment of urgency-frequency.
- 13.3% of patients were implanted for the treatment of urinary retention.
- 9.4% of patients were implanted for the treatment of fecal incontinence
- 3.3% of patients were implanted for the treatment of some other indication.
- 2.3% of patients were implanted for the treatment of bladder pain syndrome.
- 1.2% of patients were implanted for the treatment of indications not specified in the database at the time of the data cut-off.

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 (%) <sup>*</sup> |        |       |       |       |       |       |       |       |       |        |
|-------------------------------|------------------|--|-----------------------------------|--|--------|-------|-------|-------|-------|-------|-------|-------|-------|--------|
| Model Number/<br>Product Name | Devices Enrolled | Device Initial Product<br>Performance Events | Cumulative Months<br>of Follow-up |  | 1 yr   | 2 yrs | 3 yrs | 4 yrs | 5 yrs | 6 yrs | 7 yrs | 8 yrs | 9 yrs | 10 yrs |
| <b>Neurostimulators</b>       |                  |  |                                   |  |        |       |       |       |       |       |       |       |       |        |
| InterStim™                    | 101              | 2  | 3,944                             |  | 100%   | 100%  | 100%  | 97.7% | 97.7% | 97.7% | -     | -     | -     | -      |
| InterStim™ II                 | 1,378            | 41   | 44,664                            |  | 99.0%  | 98.4% | 96.9% | 95.5% | 94.2% | 92.9% | 92.9% | -     | -     | -      |
| InterStim™ Micro              | 60               | 0  | 619                               |  | 100%   | -     | -     | -     | -     | -     | -     | -     | -     | -      |
| <b>Leads</b>                  |                  |  |                                   |  |        |       |       |       |       |       |       |       |       |        |
| Model 3889                    | 1,175            | 108  | 43,364                            |  | 95.9%  | 92.9% | 90.5% | 88.9% | 87.3% | 83.8% | 82.3% | 82.3% | 76.4% | 76.4%  |
| Model 3093                    | 100              | 11   | 4,027                             |  | 98.4%  | 92.5% | 92.5% | 86.2% | 86.2% | 83.1% | 76.3% | 76.3% | -     | -      |
| Model 978A1                   | 55               | 0  | 619                               |  | 100.0% | -     | -     | -     | -     | -     | -     | -     | -     | -      |
| Model 978B1                   | 213              | 5  | 1,309                             |  | 95.4%  | -     | -     | -     | -     | -     | -     | -     | -     | -      |
| <b>Extension</b>              |                  |  |                                   |  |        |       |       |       |       |       |       |       |       |        |
| Model 3095                    | 102              | 1  | 4,096                             |  | 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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