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. Together, we can further patient safety and improve lives.


The registry is currently tracking more than 43,900 implanted devices and more than 14,600 patients in these therapies.

Access the 2016 full report at: professional.medtronic.com/performance
METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers. The registry is currently conducted utilizing two protocols, titled the Implantable Systems Performance Registry (ISPR) and 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** — 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.

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 being followed for at least 6 months.

PATIENT ENROLLMENT

- 19 centers enrolled 756 total sacral neuromodulation patients in the registry through July 31, 2016.
- 39.9% of patients were implanted for the treatment of urinary urge incontinence.
- 33.2% of patients were implanted for the treatment of urgency-frequency.
- 9.7% of patients were implanted for the treatment of urinary retention.
- 5.3% of patients were implanted for the treatment of fecal incontinence.
- 9.7% of patients were implanted for the treatment of some other indication.
- 2.2% of patients were implanted for the treatment of indications not specified in the database at the time of the data cut-off.
# Medtronic Sacral Neuromodulation Systems Device Survival Summary Table

<table>
<thead>
<tr>
<th>Device Summary Information</th>
<th></th>
<th>Device Survival Probability (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Number/Product Name</td>
<td>Devices Enrolled</td>
<td>Device Events</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>Neurostimulators†</strong></td>
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<tr>
<td>InterStim™</td>
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<td>InterStim™ II</td>
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<td><strong>Leads§</strong></td>
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<td>Model 3093</td>
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<tr>
<td>Model 3095</td>
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<td>1</td>
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</tbody>
</table>

* Table shows the percentage of implanted devices that remain free from product performance-related events at various time points.
† There were a total of 6 neurostimulator-related product performance events reported to the registry.
‡ One event occurred at 37 months of follow-up, a point beyond which the survival estimates are provided due to a low number of active devices (less than 20).
§ There were a total of 57 lead-related product performance events reported to the registry, but only 48 events included in this summary table. The remaining 9 events occurred in a lead model for which no device survival curve is presented due to an insufficient number of enrolled devices (i.e., Model 3080) (n = 1) or were subsequent events that did not affect the device survival estimates.

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

Medtronic
U.S. Technical Services Department
Phone: (800) 707-0933
Fax: (763) 367-1406
Indications for Use:

**InterStim® Therapy for Urinary Control** is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to InterStim Therapy for Urinary Control:

**Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

**InterStim® Therapy for Bowel Control** is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

**Contraindications for Urinary Control and for Bowel Control:** Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

**Warnings/Precautions/Adverse Events:**

**For Urinary Control:** Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins such as multiple sclerosis.

**For Bowel Control:** Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

**For Urinary Control and for Bowel Control:** The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at [www.medtronic.com](http://www.medtronic.com). Product technical manual must be reviewed prior to use for detailed disclosure.

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