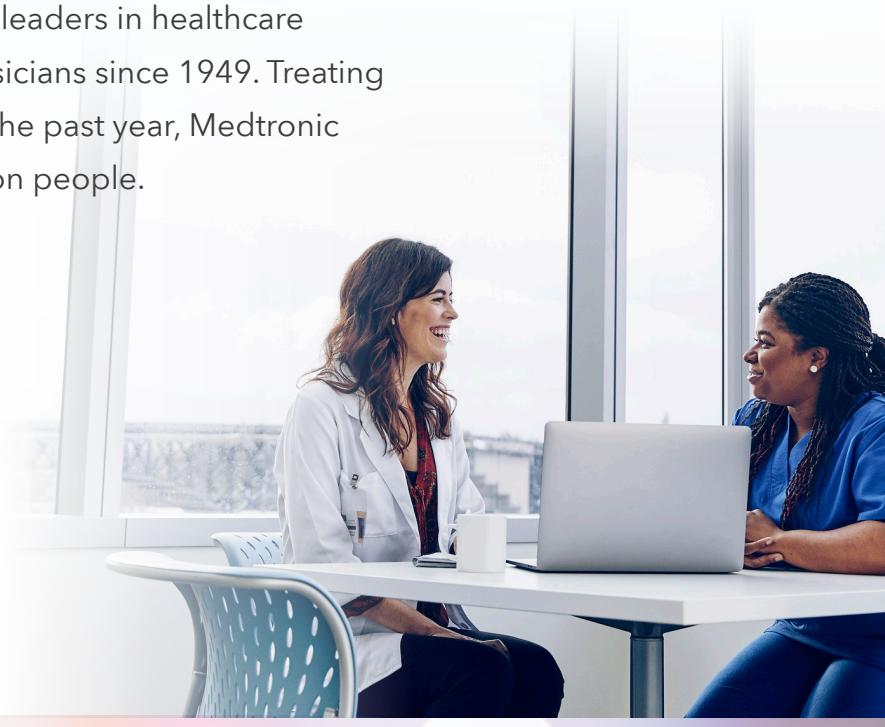
Medtronic

Introducing the InterStim X™ system

From the company that brought patients the first and most proven SNM therapy

Engineered by Medtronic

Medtronic, one of the most trusted global leaders in healthcare technology, has been partnering with physicians since 1949. Treating over 70 conditions in the human body, in the past year, Medtronic therapies transformed the lives of 72 million people.



That's two people every second of every hour of every day – and counting

Experience Matters. Trust Medtronic.

Meet InterStim X™

The next generation of the first and most proven SNM system

Powerful

- Recharge-free neurostimulator with over a decade of battery life* and up to 15 years under low energy settings**
- Proprietary 5th generation battery chemistry manufactured exclusively by Medtronic
- Detailed display on smart programmer with clearly visible information

Personalized

- 7 distinct programs and 4 custom options available on the smart programmer
- More features and flexibility to tailor patient therapy with the smart programmer†

Proven

- Only InterStim™ systems are backed by:

1,000+ Clinical articles

90+ Clinical studies

350K Patients treated

25yrs SNM experience

70+ FDA approvals

The most common adverse events experienced during clinical studies include pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms.

Most proven claim supported by:

1. Siegel S, Noblett K, Mangel J, et al. Five-year follow-up results of a prospective, multicenter study of patients with overactive bladder treated with sacral neuromodulation. *The Journal of Urology* 2018;Volume 199(1), 229–236.
2. Medtronic InterStim Therapy Clinical Summary (2018).
3. Hull T, Giese C, Wexner SD, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. *Dis Colon Rectum*. 2013;56(2):23.

* Under expected therapy settings and telemetry use.

** Please see System Eligibility, Battery Longevity, Specifications manual for battery longevity estimates.

† Compared to patient fob.

Indications for Use:

Sacral neuromodulation therapy provided by the InterStim™ system is indicated for the management of the following chronic intractable (functional) disorders of the pelvis and lower urinary or intestinal tract: overactive bladder, fecal incontinence, and nonobstructive urinary retention.

The following Warning applies only to Sacral Neuromodulation for Urinary Control:

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

Sacral Neuromodulation delivered by the InterStim™ system 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.

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. Product technical manual must be reviewed prior to use for detailed disclosure.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Medtronic

99 Hereford Street
Brampton, Ontario, L6Y 0R3
Toll-free: 800.268.5346
Tel: 905.460.3800

medtronic.ca

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