Medtronic
Alleviating Pain · Restoring Health · Extending Life

INTERSTIM® THERAPY

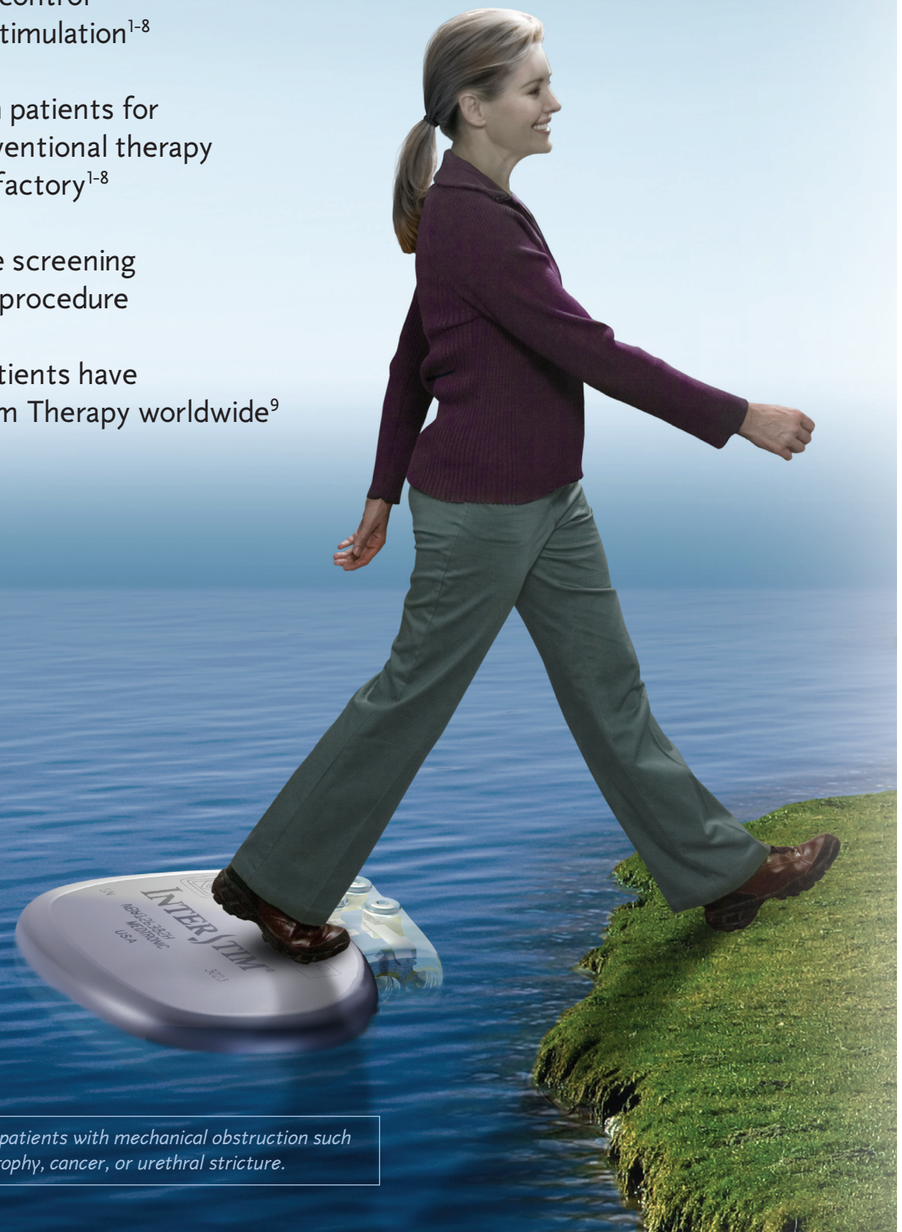
for Urinary Control

For patients with urinary control issues on drug therapy

Why wait until they have nowhere else to go?

PUT THEM ON THE PATH TO SUCCESS WITH INTERSTIM® THERAPY

- Effective urinary control via sacral nerve stimulation[1-8]
- Proven efficacy in patients for whom more conventional therapy has been unsatisfactory[1-8]
- Minimally invasive screening test and implant procedure
- Nearly 50,000 patients have received InterStim Therapy worldwide[9]



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

Not all patients benefit from drug therapy[12,14]

Standard pharmacological therapy for overactive bladder (OAB) consists of administering anti-cholinergic medications, which mainly treat the efferent limb of the micturition reflex (muscular activity).

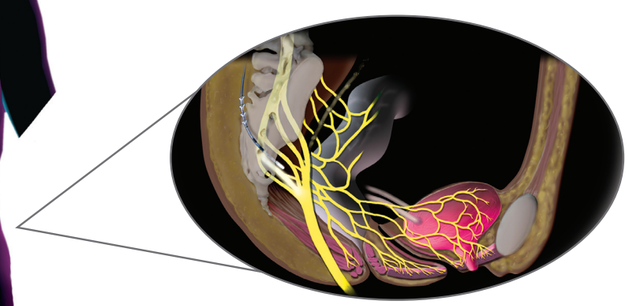
While anti-cholinergic drug therapy may alleviate OAB symptoms for some patients, they are not effective for everyone. Furthermore, some of these medications may cause intolerable side effects for patients.

For patients that don't benefit from drug therapy, InterStim Therapy may be an option

While anticholinergic drugs address the muscle component in urinary control, InterStim Therapy addresses the nerve component.[2,11,†]

Sacral nerve stimulation with InterStim Therapy

- Mild electrical pulses stimulate those nerves that provide the most distal common autonomic and somatic nerve supply to the pelvic floor and lower urinary tract[9,†]



URINARY CONTROL TREATMENT PATHWAY[9]

Initial Screening

↓

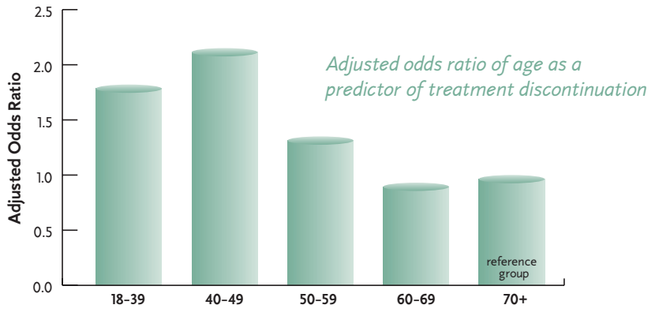
Conventional Treatment

Behavioral Techniques/Medications
Rule out obstruction (for urinary retention)
Interventional techniques/Catheterization (for urinary retention)

+	-
Continue as appropriate	**Screening Test: InterStim Therapy**
Implant InterStim System	Consider other surgical intervention

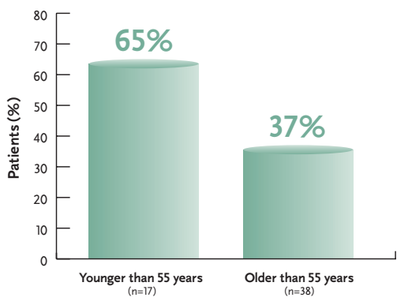
† The precise mechanism of action of InterStim has not been established.

Survey results show younger patients are more than twice as likely to discontinue anticholinergic drug therapy[12,†]



- Younger patients (ages 40 to 49) were more than twice as likely to discontinue their therapy when compared to 70-year-old respondents[12]

In a prospective clinical trial, patients under the age of 55 were statistically significantly more likely to remain completely dry than patients over 55[13]



P<.05
Patients with no daily leakage episodes after permanent implant

- Patients with fewer comorbid conditions were also found to have a statistically greater chance of remaining completely dry compared to those with multiple disease states[13]
- Adverse events included lead migration, pain at implant site and infection

† An on-line survey of 1,447 self-selected urinary incontinence patients receiving treatment for incontinence. Self-selected patients may not be representative of the general population. Survey included patients with stress incontinence, which is relatively resistant to pharmacotherapy.

Minimally invasive, office-based screening test

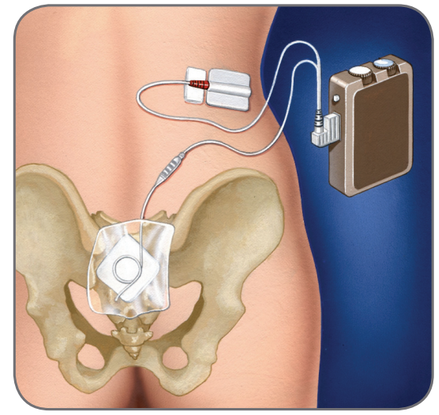
- Provides an easy way to assess the efficacy of InterStim Therapy
- Allows an opportunity to assess the viability of the therapy for a patient prior to the implant procedure

Two ways to test:

Test 1: Peripheral Nerve Evaluation

- In a simple, office-based procedure the thin wire lead is placed into the sacrum
- The lead is then secured to the outside of the patient's sacral area
- If good results are achieved from the test, the patient can proceed directly to long-term InterStim Therapy
- If the test is inconclusive or unsuccessful, proceed to Test 2

Test 1: Peripheral Nerve Evaluation

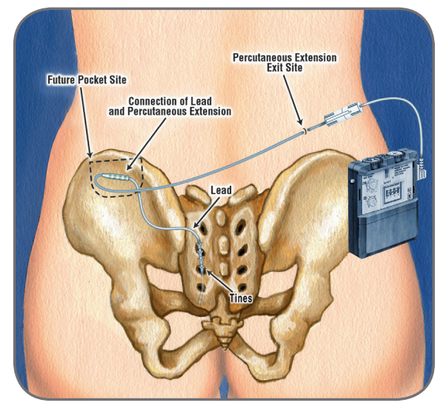


Test stimulation with temporary lead

Test 2: Chronic Lead

- The tined lead is typically placed in the S3 foramen
- The lead is connected—via tunneling—to a percutaneous extension through a small incision made at the prospective neurostimulator site which contralaterally exits the skin
- The chronic lead test, if successful, allows the patient to proceed directly to the second stage—the implant procedure for the InterStim neurostimulator[15]
- If the test is unsuccessful, the test may be repeated

Test 2: Chronic Lead



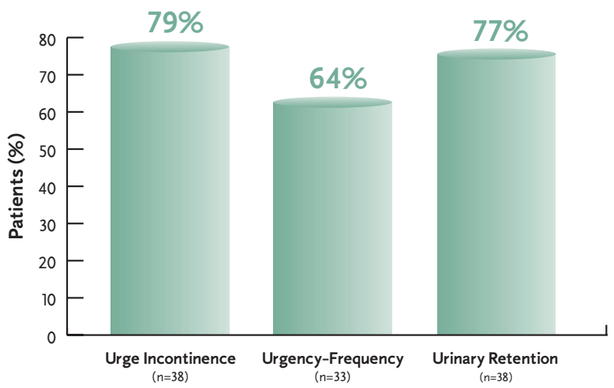
Test stimulation with chronic lead

Sacral nerve stimulation works for patients with urinary control issues*

In a clinical study, InterStim Therapy patients demonstrated significantly improved quality of life, as self reported on measures that included physical health status, physical functioning, physical and emotional role, pain, and mental health[10]

CLINICAL SUCCESS[9]

12-month results



79% success in urge-incontinence[9]

- 45% remained completely dry
- 34% experienced ≥50% reduction in leaking

64% success in urgency-frequency[9]

- 31% returned to normal voids (4 to 7 voids/day)
- 33% experienced ≥50% reduction in number of voids

77% success in urinary retention[9]

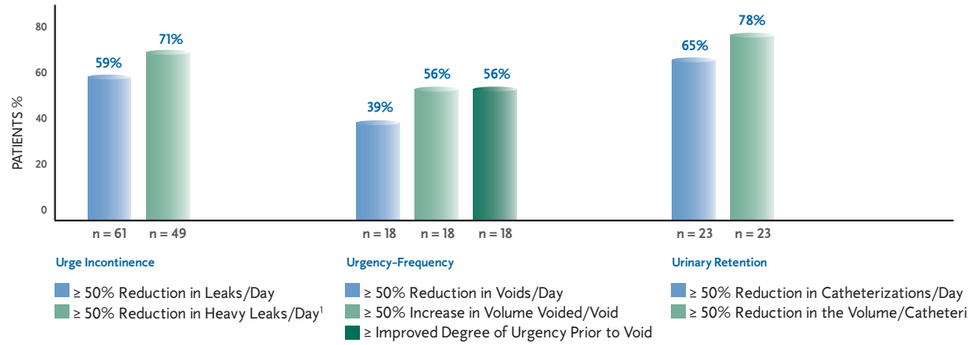
- 61% eliminated use of catheters
- 16% experienced ≥50% reduction in catheterized urine volume

* 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

Clinical study proves sustained efficacy over 5 years

EVALUABLE PATIENT POPULATION*

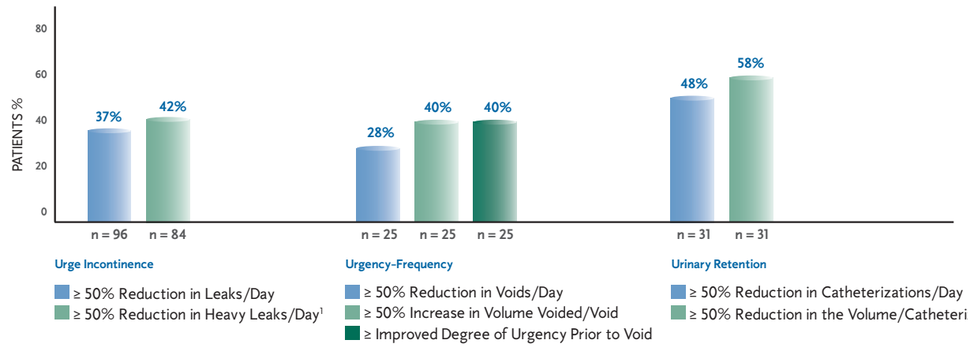
SIXTY MONTH POST-IMPLANT RESULTS (EVALUABLE PATIENT POPULATION)



[1] Excludes patients who reported no heavy leaks at baseline and at sixty months post implant.
* Referred to as the "evaluable patient population" in the Clinical Summary.

INTENT-TO-TREAT PATIENT POPULATION**

SIXTY MONTH POST-IMPLANT RESULTS (INTENT-TO-TREAT PATIENT POPULATION)



[1] Excludes patients who reported no heavy leaks at baseline and at sixty months post implant.
** Referred to as the "intent-to-treat" patient population in the Clinical Summary.

Purpose

This post-approval, non-randomized, multicenter study provided data on the long-term effects of sacral nerve stimulation for the treatment of urinary urge incontinence, urinary urgency-frequency, and urinary retention in patients who had failed or could not tolerate more conservative treatments. The study took place at 17 centers in the United States, Canada, and Europe.

Results

The study demonstrated that InterStim Therapy can be a long-term solution for patients with overactive bladder or non-obstructive urinary retention. Based on the subset of study subjects for whom both baseline and five-year data were available (i.e., the evaluable sample), improvement ranged from 39% to 78%, depending on the outcome assessed. If all implanted study subjects are considered (i.e., the intent-to-treat sample) and missing five-year data are imputed using baseline values (or, in the absence of baseline values, from the mean baseline of all subjects with baseline values), the results range from 28% to 58%, depending on the outcome assessed.

Why wait any longer?

STEP UP TO INTERSTIM THERAPY

The effective option for your patients with urinary control issues

- Effective urinary control via sacral nerve stimulation[1-8]
- Proven efficacy in patients for whom more conventional therapy has been unsatisfactory[1-8]
- Minimally invasive screening test and implant procedure
- Nearly 50,000 patients have received InterStim Therapy worldwide[9]
- For technical support call **1-800-707-0933**

Brief Summary Disclosure for InterStim® Therapy for Urinary Control
InterStim® Therapy for Urinary Control: Product technical manual must be reviewed prior to use for detailed disclosure. Indications: 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. **Contraindications:** Patients are contraindicated for implant of the InterStim System if they have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system.

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

Precautions/Adverse Events: Safety and effectiveness have not been established for: bilateral stimulation, patients with neurological disease origins such as multiple sclerosis, pregnancy and delivery, or for pediatric use under the age of 16. System may be affected by or adversely affect cardiac pacemakers or therapies, cardioverter defibrillators, electrocautery, external defibrillators, ultrasonic equipment, radiation therapy, magnetic resonance imaging (MRI), theft detectors and screening devices. Adverse events related to the therapy, device, or procedure can include: pain at the implant sites, lead migration, infection, or skin irritation, technical or device problems, transient electric shock, adverse change in bowel or voiding function, numbness, nerve injury, seroma at the neurostimulator site, change in menstrual cycle, and undesirable stimulation or sensations.
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

References: 1. Schmidt RA, Jonas U, Oleson KA, et al, for the Sacral Nerve Stimulation Study Group. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. J Urol. 1999;162:352-357. 2. Siegel SW, Catanzaro F, Dijkema HE, et al. Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. Urology. 2000;56(suppl 6A):87-91. 3. Janknegt RA, Hassouna MM, Siegel SW, et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. Eur Urol. 2001;39:101-106. 4. Weil EHJ, Ruiz-Cerdá JL, Eerdmans PHA, Janknegt RA, Bemelmans BLH, van Kerrebroeck PhEV. Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. Eur Urol. 2000;37:161-171. 5. Hassouna MM, Siegel SW, Lycklama à Nÿeholt AAB, et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety. J Urol. 2000;163:1849-1854. 6. Jonas U, Fowler CJ, Chancellor MB, et al. Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation. J Urol. 2001;165:15-19. 7. Aboseif S, Tamaddon K, Chalfin S, et al. Sacral neuromodulation in functional urinary retention: an effective way to restore voiding. BJU Int. 2002;90:662-665. 8. Spinelli M, Bertapelle P, Cappellano F, et al, for the GINS Group. Chronic sacral neuromodulation in patients with lower urinary tract symptoms: results from a national register. J Urol. 2001;166:541-545. 9. Data on file. Medtronic, Inc. 2008 10. Cappellano F, Bertapelle P, Spinelli M, et al, for the Italian Group of Sacral Neuromodulation (GINS). Quality of life assessment in patients who undergo sacral neuromodulation implantation for urge incontinence: an additional tool for evaluating outcome. J Urol. 2001;166:2277-2280. 11. Hashim H, Abrams P. Drug treatment of overactive bladder: efficacy, cost and quality-of-life considerations. Drugs. 2004;64:1643-1656. 12. Campbell UB, Stang P, Barron R. Survey assessment of continuation of and satisfaction with pharmacological treatment for urinary incontinence. *Value in Health* 2007. 13. Amundsen CL, Romero AA, Jamison MG, Webster GD. Sacral neuromodulation for intractable urge incontinence: are there factors associated with cure? Urology. 2005;66:746-750. 14. Yu YF, Nichol MB, Yu AP, Ahn J. Persistence and adherence of medications for chronic overactive bladder/urinary incontinence in the California Medicaid program. *Value in Health* 2005;8(4):495-505. 15. Janknegt RA, Weil EHJ, Eerdmans PHA. Improving neuromodulation technique for refractory voiding dysfunctions: two-stage implant. *Urology*. 1997;49:358-362.

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