Medtronic

InterStim® Therapy

FOR URINARY CONTROL

Further

Take Treatment

تهران جراح نوین

Take Treatment **Further** with InterStim® Therapy

Bladder control problems are more common than you might think

1 in 6 adults in the US report experiencing overactive bladder (OAB)[1]

Many patients do not benefit from pharmacologic therapy for urinary control issues

25% of patients who responded to an online, nationwide survey* (n=1447) reported being somewhat or very dissatisfied with pharmacologic therapy.

45% of these respondents discontinued pharmacotherapy (n=651). The most common reasons for discontinuation reported were:[2]

- Lack of efficacy (41.3%)
- Side effects (22.4%)
- Cost (18.7%)

*An online 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.

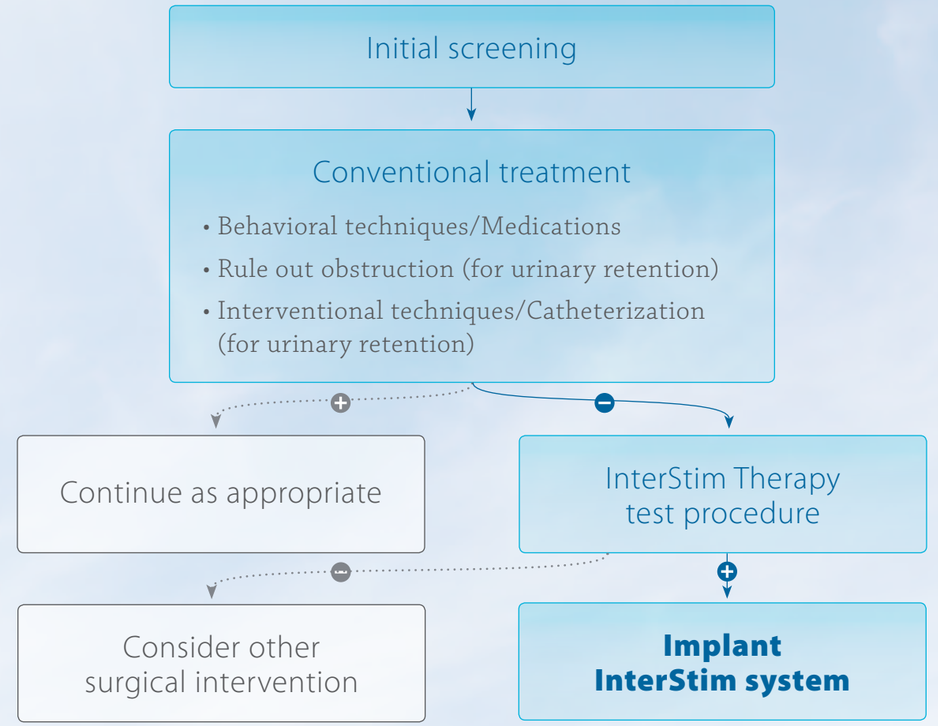
In a 2005 study evaluating adherence and persistence with medications for several chronic conditions:

Only 28% of patients on OAB medications remained persistent at 6 months—and only 18% were persistent at 1 year.[3]

Patients were less likely to remain on OAB medications than on any of the other drug classes assessed:[3]

- Statins (hyperlipidemia)
- ARBs (hypertension)
- Oral antidiabetic drugs (Type II)
- Bisphosphonates (osteoporosis)
- Prostaglandins analogs (indicated for glaucoma)

An established therapy that expands your treatment options for patients with urge incontinence, urgency-frequency, or urinary retention* who have failed or could not tolerate more conservative treatments



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

Why InterStim should be part of your treatment pathway

Proven efficacy for patients who are not satisfied with conventional therapy[4-11]

In-office Test—A simple test procedure, initiated in your office, gives you and your patients an opportunity to find out in as few as 3 days if InterStim Therapy will work for them.

Targeted Control—InterStim Therapy focuses on the nerves that control the pelvic floor and lower urinary tract. It offers control of symptoms through direct modulation of the nerve activity, making it different from oral medications.[12,13*]

Anticholinergic drugs target the muscular component of urinary control (muscarinic receptors of the bladder). These medications may also affect muscarinic receptors elsewhere in the body, causing bothersome side effects.[14]

Customizable—InterStim Therapy is externally programmable, enabling you and your patients to adjust the level of stimulation as needed to control symptoms.

Reversible—The implant can be surgically removed should you and your patient decide to pursue a different course of therapy.

*While the precise mechanism of action of InterStim Therapy has not been fully established, efficacy has been proven in clinical studies.

Test for potential success

Find out in as few as 3 days if InterStim Therapy will work for your patients

In-office Test

The Peripheral Nerve Evaluation (PNE) is a simple in-office test procedure that can help determine if long-term therapy will be beneficial.

A temporary lead is placed near the sacral nerves for 3-7 days and is removed after the test stimulation.

With positive results, the patient can proceed directly to long-term therapy through an outpatient device implant.

If this test is inconclusive or unsuccessful, then the outpatient test is recommended.

Outpatient Test

The outpatient test procedure, referred to as the Staged Test, utilizes a tined lead to reduce migration. This lead is placed near the sacral nerves in the operating room during an outpatient procedure.

With conclusive test results, this lead can remain in place. The device and lead extension would then be implanted.

Complications can occur with the test procedure, including movement of the wire, technical problems with the device, and some temporary pain.

InterStim Therapy delivers significant improvements in quality of life

Help your patients re-engage in life with the lasting control provided by InterStim Therapy

In studies comparing patients who received InterStim Therapy with patients who delayed implant and continued standard management, those with InterStim experienced significant improvements in quality of life:[15]

Improved urgency-frequency measures:

- Physical function ($P<0.0001$)
- General health ($P=0.003$)
- Vitality ($P=0.01$)
- Social function ($P=0.002$)
- Mental health ($P=0.01$)

Improved urge incontinence measures:

- Physical function ($P=0.001$)
- General health ($P<0.0001$)
- Vitality ($P=0.018$)

Improved urinary retention measures:

- Bodily pain ($P=0.03$)

Patient satisfaction is reported with InterStim Therapy

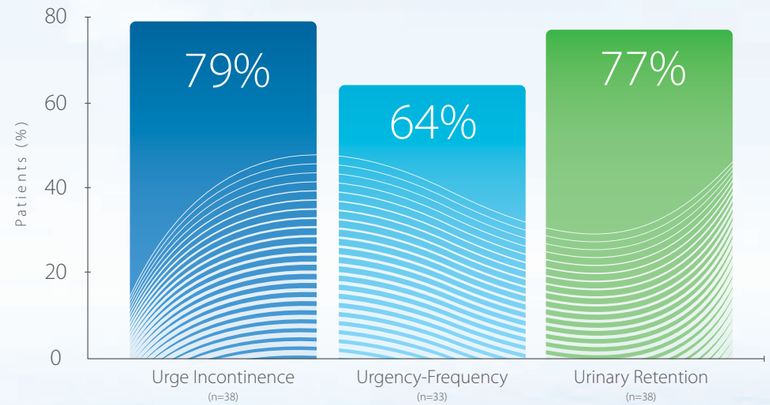
84% of InterStim patients who responded to a physician-initiated mailed questionnaire (n=49) reported being satisfied with the therapy, and 80% would "do it all over again."[16]

Safety Information

Patients should be advised to avoid activities that involve sudden, excessive, or repetitive bending, twisting, bouncing or stretching as they may cause discomfort or affect the implanted stimulator.

InterStim Therapy delivers clinical efficacy

Premarket approval study shows 12-month clinical success[15]



79% of patients with urge incontinence achieved clinical success[15]

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

64% of patients with urgency-frequency achieved clinical success[15]

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

77% of patients with urinary retention achieved clinical success[15]

- 61% eliminated use of catheters
- An additional 16% experienced ≥50% reduction in catherized urine volume

Efficacy that lasts, as proven in a 5-year clinical trial

Postmarket approval study shows 5-year clinical success[15]

Evaluable Patients—defined as the subset of subjects for whom both baseline and 5-year data were available

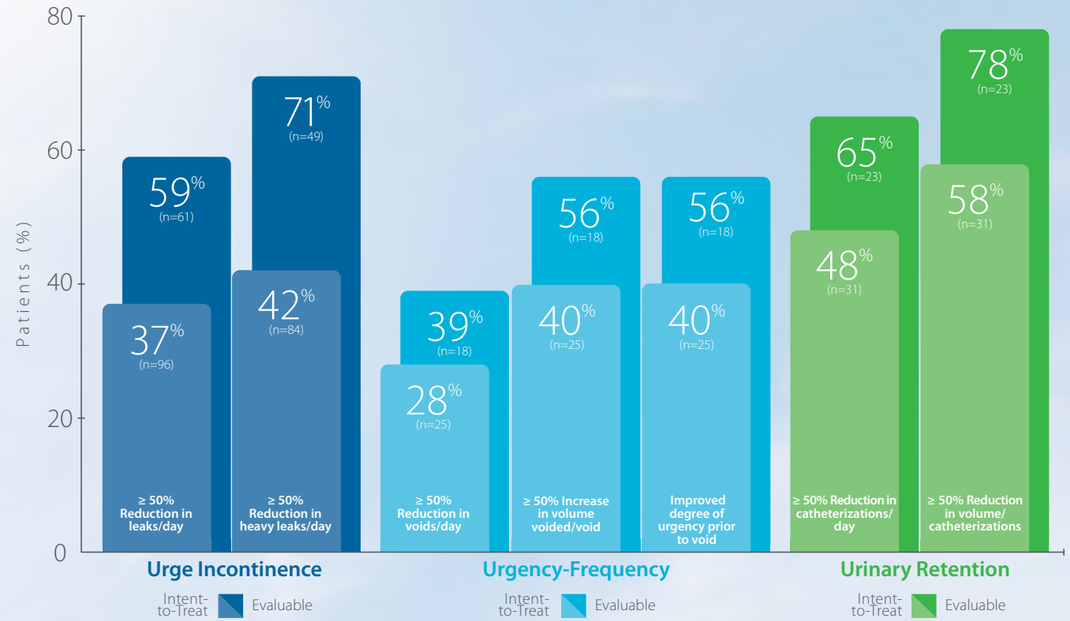
Intent-to-Treat Patients—defined as all implanted study subjects, including those who dropped out and were imputed as no change from baseline

59% of **urge incontinent** patients achieved ≥50% reduction in leaks per day*

71% of those **urge incontinent** patients who reported **heavy leaks** at baseline achieved ≥50% reduction in leaks per day†

56% of **urgency-frequency** patients achieved increased voided volume and improved degree of urgency‡

78% of **urinary retention** patients achieved ≥50% reduction in volume per catheterization§



*59% in evaluable patient population (n=61) and 37% in intent-to-treat population (n=96).

†71% in evaluable patient population (n=49) and 42% in intent-to-treat population (n=84).

‡56% in evaluable patient population (n=18) and 40% in intent-to-treat population (n=25).

§78% in evaluable patient population (n=23) and 58% in intent-to-treat population (n=31).

The most common adverse events experienced during clinical studies included 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. For additional safety information, please refer to the Important Safety Information on the back page of this brochure.

Medtronic has the experience you want

More than 85,000 patients worldwide have received InterStim Therapy

Training and Education

- Two ways to become a certified InterStim implanter:
  - 1-day courses offered at leading institutions
  - Online training available when combined with either an on-site visit for observation, a proctorship, or simulator training
- Tutorials to assist with practice efficiencies:
  - Guidelines for stacking multiple test procedures in a single day
  - Training for allied professionals on efficient patient follow-up

Reimbursement Resources

- Health economics managers
- Coverage and authorization services

Patient Awareness and Education Resources

- Comprehensive patient education materials
- Best practices on how and when to introduce InterStim Therapy to your patients
- Co-marketing patient outreach programs

References

1. Stewart WF, Van Rooyen JB, Cundiff GW et al. Prevalence and burden of overactive bladder in the United States. *World J Urol*. 2003;20:327-36.
2. Campbell UB, Stang P, Barron R. Survey assessment of continutation of and satisfaction with pharmacological treatment for urinary incontinence. *Value Health*. 2007;11:726-732.
3. Yeaw J, Benner JS, Walt JG, Sian S, Smith DB. Comparing adherence and persistence across 6 chronic medication classes. *J Manag Care Pharm*. 2009;15:724-736.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. Griebling TL. Neuromodulation: mechanisms of action. In: Kreder K, Dmochowski R, eds. *The Overactive Bladder: Evaluation and Management*. London, England: Informa UK Ltd; 2007:293-302.
13. Leng WW, Chancellor MB. How sacral nerve stimulation neuromodulation works. *Urol Clin N Am*. 2005;32:11-18.
14. Herbison P, Hay-Smith J, Ellis G, Moore K. Effectiveness of anticholinergic drugs compared with placebo in the treatment of overactive bladder: systematic review. *BMJ*. 2003;326:841-844.
15. Medtronic-sponsored research. InterStim Therapy Clinical Summary Insert, 2006.
16. Foster RT Sr, Anoia EJ, Webster GD, Amundsen CL. In patients undergoing neuromodulation for intractable urge incontinence a reduction in 24-hr pad weight after the initial test stimulation best predicts long-term patient satisfaction. *Neurourol Urodyn*. 2007;26:213-217.

Take treatment **further** with InterStim Therapy

- **Addresses a broad range of bladder symptoms: urge incontinence, urgency-frequency, and non-obstructive urinary retention**
- **Simple, in-office test procedure gives you and your patients an opportunity to find out in as few as 3 days if InterStim Therapy will work for them**
- **Reliable clinical efficacy proven up to 5 years for real and lasting control over the symptoms that restrict your patients' daily lives**

Important Safety Information

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:** Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

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; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins such as multiple sclerosis. 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. 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. USA Rx Only. Rev 0409

professional.medtronic.com/sns

United States of America
Medtronic Neuromodulation
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel. 763-505-5000
Toll-free 1-800-328-0810

Asia-Pacific
Medtronic International, Ltd.
Suite 1602 16/F
Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4456

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel. 1-905-826-6020

Europe
Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland
Tel. +41-21-802-7000

Australia
Medtronic Australasia Pty. Ltd.
97 Waterloo Road
North Ryde
NSW 2113
Australia
Tel. +61-2-9857-9000
www.medtronicneuro.com.au

Medtronic

UC200603196e EN **NI7132e** © 2010 Medtronic, Inc. Printed in USA.