A Treatment for Urinary Retention and Symptoms of Overactive Bladder
Bladder Control Problems
You may be one of millions of people who suffer from frustrating and embarrassing bladder control problems. These conditions, which prevent you from controlling when and how much you urinate, can make simple, everyday activities a challenge and social lives very difficult. You may have to cut back on your hobbies or stop working. You may feel trapped by a fear of leaking accidents, the need to be close to a bathroom at all times, and an overall preoccupation with your bladder.

You can be any age to have bladder control problems. You may try treatments such as diet changes, exercises, medications, and biofeedback. These treatments, however, do not always ease symptoms. In such cases, you must manage your bladder control problems with external collection devices such as catheters or absorbent undergarments. Or, you may consider surgery.

Now, for those in whom more conservative treatments do not work well, there is a therapy that may help. Medtronic InterStim® Therapy for Urinary Control may provide relief from symptoms and allow you to return to a more normal life.
Different Types of Bladder Control Problems

**RETENTION**
If you have retention you may:

- need a catheter to pass urine
- spend a long time at the toilet, but produce only a weak, dribbling stream of urine
- leak urine (sometimes called overflow incontinence)
- not have a sensation of when your bladder is full

With retention, you may store increasingly larger volumes of urine.

**SYMPTOMS OF OVERACTIVE BLADDER**
including:

**Urge Incontinence**
If you have urge incontinence, you may:

- lose urine as soon as you feel a strong need to go to the bathroom
- leak urine when you drink even a small amount of liquid, or when you hear or touch running water
- have frequent leaking episodes

**Urgency Frequency**
If you have urgency-frequency, you may:

- have frequent, uncontrollable urges to urinate
- go to the bathroom more often than normal (more than seven times a day)
- feel that your bladder is never completely empty
What Is InterStim Therapy?

InterStim Therapy is indicated for people with urinary retention and the symptoms of overactive bladder including urinary urge incontinence and significant symptoms of urgency-frequency in selected individuals.* The therapy uses a small implanted medical device to send mild electrical pulses to a nerve located just above the tailbone. This nerve, called the sacral nerve, controls the bladder and surrounding muscles that manage urinary function. The electrical stimulation may eliminate or reduce certain bladder control symptoms in some people.

How Will I Know If InterStim Therapy Will Work for Me?

A physician’s examination and evaluation can determine whether you are a candidate for InterStim Therapy. If your bladder control problems are not effectively managed by more conservative treatments and you have otherwise normally functioning urinary systems, you are a potential candidate.

A test (the temporary test stimulation) is used before implantation of the therapy to see what the effect of stimulation is on your symptoms. A test lead is surgically placed through a small incision near the appropriate sacral nerve, and mild stimulation with an external device is provided for several days. During the test stimulation, you will record your symptoms in a special diary. If symptoms improve or disappear during the test period, long-term use of InterStim Therapy may be appropriate for you.

What Does the Therapy Involve?

A lead (a thin wire with small electrodes at its tip) is surgically placed near the appropriate sacral nerve that controls urinary function. The lead is passed under the skin to a small neurostimulator (approximately the size of a stopwatch) that is placed in a “pocket” just beneath the skin.

The neurostimulator, which contains a special battery and electronics to control the stimulation to the sacral nerve, is usually placed by the physician in the upper buttock or lower abdomen.

The stimulator typically runs for 7-9 years and then can be replaced during an outpatient procedure.

* InterStim Therapy does not treat symptoms of stress incontinence. InterStim Therapy has not been studied in pregnant patients, pediatric patients, patients with diabetes, or patients with multiple sclerosis. It is not intended for patients with mechanical obstructions such as benign prostatic hypertrophy, cancer or urethral strictures.
Adjustments to the stimulation can be made in a physician’s office with a hand-held programmer. InterStim Therapy is reversible — it can be programmed off at any time.

What Are the Potential Benefits of InterStim Therapy?
InterStim Therapy may eliminate or reduce symptoms caused by bladder control problems.

In a Medtronic multicenter clinical study,* many patients who received InterStim Therapy experienced significant improvements in their symptoms.

Urge Incontinence (12 month results):
45% of patients remained completely dry
34% of patients had > 50% reduction in number of wetting episodes
79% clinical success
70% of patients eliminated heavy leaking episodes

Urgency-Frequency (12 month results):
33% of patients reduced the number of voids by 50% or more
31% of patients reduced the number to normal (4-7 per day)**
64% clinical success
82% of patients improved degree of urgency before a void***

Retention (12 month results):
61% of patients eliminated the use of catheters

* The multicenter study included 23 centers worldwide. A total of 581 patients were studied with 219 of them receiving InterStim Therapy.
** In patients with a baseline degree of > 7 voids per day.
*** Success is defined as increased voided volume with the same or reduced degree of urgency.
What Are the Risks of InterStim Therapy?
52% of clinical study patients implanted experienced therapy-related adverse events. 54% of these required hospitalization or surgery to resolve. No adverse events resulted in permanent injury. 9% were unresolved at database closure. The most common adverse events included pain at implant site, lead migration, and infection.

The surgical revision rate was 33% with the neurostimulator placed in the abdomen. In a later study the surgical revision rate was 15%, with the neurostimulator placed in the upper buttock.

How Do I Qualify for InterStim Therapy?
If you meet the following requirements, determined by a doctor’s testing and evaluation, you may be eligible for InterStim Therapy:

- Poor results from more conservative therapies such as diet modification, medication, and biofeedback
- Positive results from the diagnostic test (the temporary test stimulation)

Only your physician can determine if InterStim Therapy is right for you.

Where Can I Get More Information About InterStim Therapy?
If you would like more information about InterStim Therapy, or if you think you might be a candidate for this therapy, talk to your urologist or urogynecologist. You may also receive additional information about InterStim Therapy directly from Medtronic.

Call: 1-800-664-5111, extension 3000.
Also, visit us at: www.interstim.com.
Patient Stories
The following profiles recount the experiences of several patients who have received InterStim Therapy for the treatment of their problems. As you read them, please bear in mind that the experiences are specific to these particular people. Results vary; not every response is the same.

**Urinary Retention**

ROBIN

Around 1996, Robin began to experience urinary retention and as a result, had one to two bladder infections a month, and then yeast infections because of all the antibiotics for the bladder infections. “Initially, I had some urge to go and I could void about 250cc, but my post-void residuals (after self-catheterization) were about 350cc.”

“I catheterized myself every three hours around the clock. Medications were not working.”

Robin’s doctor told her about InterStim Therapy and suggested trying a test stimulation. “I jumped at the chance, because there wasn’t any other treatment for me and I hated living that way. You tend to take things for granted until you lose the function of a vital organ.”

“The test stimulation took place in January 1999. Within two hours after the placement of the leads, I voided. Dr. Page suggested that I cath myself to see how much I had as residual urine, and it was only a tiny amount of urine — 25 ccs — so I stopped cathing.”

“The implant surgery was on February 15, 1999. The surgery went fine and I was discharged the next day. I had quite a bit of pain after the surgery, especially at the incision site, so it took me about three weeks to heal completely and get back to work.”

“I feel like I’ve gotten my life back. I now sense the urge to go and can urinate on my own. I can get on with my life and I don’t have to think about cathing all the time. I’m sleeping through the night, I feel more positive and my family is happier. It feels like a gift.”
Urge Incontinence

Ever since he was a small boy, Lee of Indianapolis, Indiana, had difficulty with bladder control. He experienced this problem around the clock, always needing to be close to a bathroom and requiring special bedding in case he had leaking accidents during the night.

His urge incontinence problem remained serious into adulthood. “At work, I’d have to leave meetings to go to the bathroom. I couldn’t sit through movies. If I went out to dinner, I was always on the edge of my seat, ready to hop up and go. I couldn’t go to the bank because of the wait in line.”

Lee had seen numerous doctors and undergone many tests and treatments before his current urologist suggested InterStim Therapy. At first he was reluctant to have something implanted in his body, but other treatments had been unsuccessful and he was motivated to try this option. In July, 1998, Lee underwent a test (the test stimulation) under a local anesthetic. The results were immediately positive and in October he was scheduled for an implant.

Now 48 years old, Lee is pleased with the results of InterStim Therapy. He can watch movies, take airplane trips more comfortably, and work with greater ease. He also reports that the implant does not interfere with sexual function.

“I don’t have to go to the bathroom constantly anymore,” said Lee. “I have no more leaks and I’m not taking any medication. It’s also easy to use. I have a remote control to turn it on and off, and I can also increase and decrease the stimulation. I would recommend this therapy to anybody with bladder control problems like mine,” he said.
Urge Incontinence

Jane, of Las Vegas, Nevada, began having bladder control problems when she was only four years old and they continued throughout her life. A member of her high school marching band, Jane could not eat or drink for eight hours before a parade so she could get through it without a trip to the bathroom. In college, her friends always knew where she was—in the bathroom!

“I’ve done Kegel exercises, tried biofeedback, had biometrics and bladder surgeries, and tried every pad and medication that was out there,” said Jane. “Nothing worked to relieve my symptoms.”

Because of her bladder control problems, Jane was extremely limited in her daily living activities. “During the 23 years I worked as an elementary school guidance counselor, I took along extra clothing every day in case I had a leaking accident. I couldn’t spend a night at anyone’s home or take long plane or car trips, so I didn’t visit my family on the East Coast. I couldn’t see movies from beginning to end.”

Jane finally met a urologist who diagnosed her symptoms as urge incontinence and suggested InterStim Therapy for Urinary Control. He prescribed a diagnostic test (the test stimulation) to see if the therapy would work for her before an implant. She responded positively to the test and received an InterStim Therapy system a month later.

Now 58 years old, Jane has returned to a fuller life with her InterStim Therapy. “My leaking episodes have decreased by about 90%,” said Jane. “I can eat and drink normally—no more fasting to avoid leaking. I’m not afraid of cross-country air travel any more. I can now visit my children and grandchildren and stay with them without worrying about embarrassing accidents at night,” said Jane. “Overall, it feels like a miracle.”
Urgency-Frequency

JEANETTE

For years, 57-year-old Jeanette of Waterbury, Connecticut, struggled with urinary urgency-frequency, a condition with symptoms that turned her life “upside down.” Jeanette spent most of her day in the bathroom. “I had to go 50 to 75 times a day, and most of the time it felt as if I had gone only a few drops. If I didn’t get to the bathroom fast enough, I’d leak,” she said.

Jeanette finally had to quit her job where she answered telephones for four hours a day. “I couldn’t answer the phones when I was in the bathroom all the time. I tried every type of therapy including drugs, surgery, exercises, but nothing really worked,” said Jeanette. “During the five years before I received InterStim Therapy, I spent most of my time in bed or in my bathroom.”

When Jeanette had almost lost all hope for recovery, she met a urologist who suggested InterStim Therapy for Urinary Control. A diagnostic test (the test stimulation) was performed in May, 1998, with positive results. “For the first time in years, my urinary frequency was cut in half. I felt as if I was getting my life back again,” she said.

In September, Jeanette received a permanent InterStim Therapy system. “Now I go to the bathroom 10 to 12 times a day instead of the 50 to 75 times before my implant. Some nights, I don’t have to get up at all,” said Jeanette. “InterStim has enabled me to have a life. I can again do things that other people take for granted—shopping, laundry, going to church. I now have a much better quality of life.”
Urinary Retention

Kerri of central California has had urinary retention, urinary tract infections, and bladder spasms most of her life. At five years old, she had her urethra dilated to help relieve her chronic bladder infections. Subsequently she began to experience urinary retention.

“I was put on oxybutinin and even doxazosin mesylate which is a blood pressure medication, but none of those medications helped.”

“My doctor suggested InterStim Therapy for Urinary Control. I’d never heard of it, but I was willing to try it if it could make me feel better. I thought, ‘If this doesn’t work, I don’t know what I’m going do.’”

In October 1999, Kerri had the test stimulation in the outpatient clinic. Test stimulation lasted for five days and she kept a voiding diary during that time. During the day she urinated every hour or two - approximately 175 - 200 ccs. Her doctor had her catheterize herself several times, but her bladder was empty.

“My implant surgery took place in December 1999. I stayed in the hospital overnight. While I was recovering, I got respiratory flu, so it took me longer to recover than it takes most people - about six weeks. But by mid-January, I felt fantastic. I’d healed up, I was over the flu and I’d figured out where the stimulation levels should be.”

However, in mid-March 2000, Kerri bumped into a brick ledge pretty hard and several days later fell hard on her rear end while she was at work. “Those two injuries did something to the system. I had the stimulation turned all the way up and still couldn’t feel it.” Kerri’s InterStim system was replaced in July 2000.

“After the second implant surgery, it took me only 3 days to recover. I feel great now. I feel very fortunate to have 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.

**Precautions/Adverse Events**:

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

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.

For more information, call:
1-800-664-5111, extension 3000,
or visit us at:  www.interstim.com

If you would like to join a support group for incontinence, call 1-800-BLADDER or visit www.nafc.org.