



INTERSTIM® THERAPY FOR INCONTINENCE

Summary

InterStim® Therapy is a proven neuromodulation therapy targeting the communication problem between the brain and the nerves that control the bladder and bowel. If those nerves are not communicating properly, the bladder and bowel will not function properly. After talking with your doctor about the option of InterStim® Therapy, you may decide to try an InterStim® evaluation. Based on the outcome of the evaluation, you and your doctor will determine the next steps for your treatment.

InterStim® was created by Medtronic and over 100,000 people worldwide have received InterStim® Therapy. It has been FDA-approved since 1997 for urge incontinence and since 1999 for urinary retention and urgency/frequency. Recently, InterStim® was approved for the treatment of fecal (bowel) incontinence as well. InterStim® Therapy is NOT intended for patients with a urinary blockage.

Medicare and many other private insurance companies cover InterStim® Therapy.

How Does InterStim Therapy Work?

InterStim® Therapy works with the sacral nerves, located near the tailbone. The sacral nerves control the bladder, bowel, and muscles related to their function. It is believed that one possible cause of overactive bladder or fecal incontinence is a miscommunication between the brain and the sacral nerves; when the brain and sacral nerves don't communicate correctly, the nerves will not tell the organs to function correctly, which can cause control problems.

The theory behind InterStim® Therapy is that stimulation of the sacral nerves with mild electrical pulses reduces the signals to the nervous system which may be causing control symptoms such as leaks, the sudden urge to go, going too often, or getting up at night.

Typical Symptoms

- Frequent urges to urinate (urgency/frequency)
- Inability to hold urine (urgency)
- Inability to urinate (retention)
- Incomplete bladder emptying (partial retention)
- Involuntary leakage of stool (fecal incontinence)

Trial Procedure

The evaluation starts with a minimally invasive outpatient procedure usually done in the physician's office or ambulatory surgery center. There are two types of evaluations: the basic and the advanced. The basic evaluation uses a temporary 'lead'. Your doctor will numb a small area of your upper buttock and insert a thin wire near your sacral nerves, located by the tailbone. The advanced evaluation uses a long-term 'lead' that is fully implanted; one end of the lead is inserted near your sacral nerves. With both types of evaluations, the lead is connected to a small, external neurostimulator that you

wear on your waistband like a pager. The stimulator generates mild electrical pulses that are carried to the sacral nerve by the 'lead'.

The length of the evaluation may vary and depends on the type of evaluation you and your physician decide is appropriate to your particular complaints. Generally, if the short-term, temporary lead is used, the evaluation period lasts from 3-7 days; if the long-term lead is used, the evaluation period may last up to 14 days.

During the evaluation, you will use a bladder diary to document your urinary symptoms such as how many times you use the toilet, and if you experience any leaking. You should be able to work and continue your normal activities as long as you avoid lifting, bending or twisting movements. If you experience a significant reduction in your symptoms, you are most likely a candidate for long term therapy.

Permanent Implant

For long term InterStim® Therapy, the neurostimulator is placed under the skin of your upper buttock, above where you sit and below your waistline. This procedure is usually done in the ambulatory surgery center or hospital. One end of the lead (the thin wire) is placed near the sacral nerve, near the tailbone. The other end of the lead is attached to the neurostimulator. You control the neurostimulator with a hand-held programmer that works like a remote control; you turn the stimulation up or down, and on or off.

Risks

Implanting an InterStim® Therapy system has risks similar to any surgical procedure, including swelling, bruising, bleeding, and infection. Talk with your doctor about ways to minimize these risks.

Potential Side Effects of Neurostimulation

- Pain at the implant site
- Infection or skin irritation
- Lead (thin wire) movement/migration
- Device problems
- Interactions with certain other devices or diagnostic equipment, such as a MRI machine
- Undesirable changes in urinary or bowel function
- Uncomfortable stimulation (sometimes described as a jolting or shocking feeling)

Problems may be resolved with surgery, reprogramming, or medical therapy such as medication. These events may also resolve over time. There is a possibility some issues may not be resolved. Your physician will discuss alternative forms of treatment and management if InterStim® Therapy is not a practical option for you.