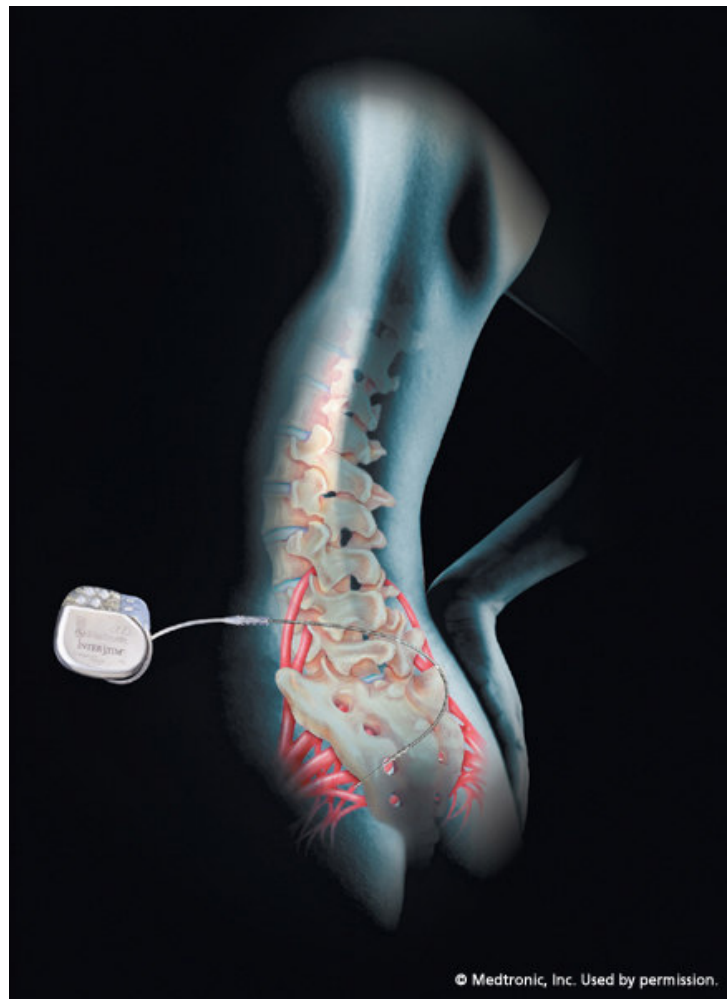


Sacral Nerve Stimulation

(Medtronic InterStim® Therapy for Urinary Control)



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A Therapy for Bladder Control Problems

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Introduction

Millions of people of all ages suffer from bladder control problems such as retention and overactive bladder. Effects of bladder control problems can be devastating. You have probably found that treatments such as drugs, behavior modification, diet changes, pelvic floor exercises or the use of a catheter to empty your bladder did not effectively treat your symptoms. Your doctor would like you to consider a therapy called sacral nerve stimulation (SNS). SNS involves the use of a device that can be thought of as a pacemaker for the bladder.

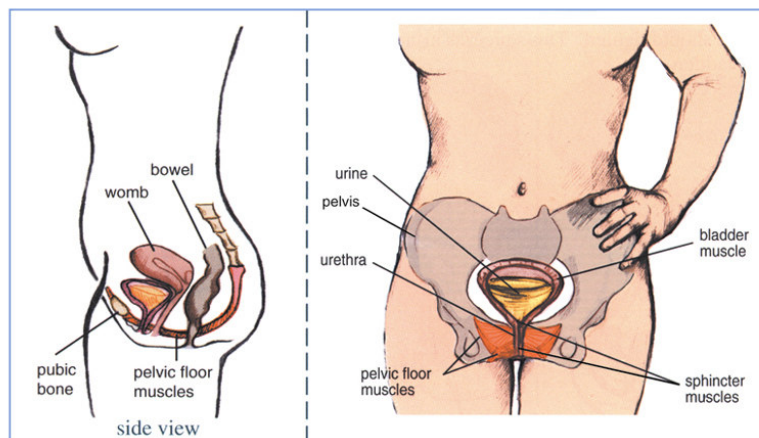
SNS therapy is not experimental. InterStim[®] Therapy (InterStim[®] is a registered trademark of Medtronic, Inc.), is a sacral nerve stimulation therapy made by Medtronic. It was approved by the U.S. Food and Drug Administration (FDA) in 1997 and has been used successfully to treat thousands of patients worldwide.

The intent of this handout is to help you understand the therapy. After you have read about the therapy, your doctor will help you make an informed decision about whether to proceed with a test to see if sacral nerve stimulation will work for you. If you want more information and/or plan to move forward with the therapy ask your doctor for a more detailed manual available from Medtronic.

The Urinary System

How Does the Urinary System Work?

To understand how sacral nerve stimulation works, it is helpful to understand how the urinary system works. The urinary system includes two kidneys, two ureters, the bladder and the urethra (see Figure 1). The kidneys remove excess fluid and waste products from the blood and continuously produce urine. The ureters carry the urine to the bladder where the urine is stored. A muscle called a sphincter controls the opening and closing of the urethra (urine flows through the urethra during urination).



Parts of the bladder control system

Image produced by The National Kidney And Urologic Diseases Information Clearinghouse (NIUDIC).

Figure 1. Anatomy of the Bladder Control System

When the bladder begins to fill with urine, a message is sent along the sacral nerves to the brain telling the brain that the bladder is getting full (see Figure 2). As the bladder fills, this message to the brain becomes stronger. When the message becomes strong enough, and you decide to urinate, your brain sends a message back to the bladder along the sacral nerves telling the bladder muscle to contract and the pelvic muscles to relax to allow urine to empty from the bladder (urination). Urination is usually under voluntary control. This means that you decide when and where you want to urinate.

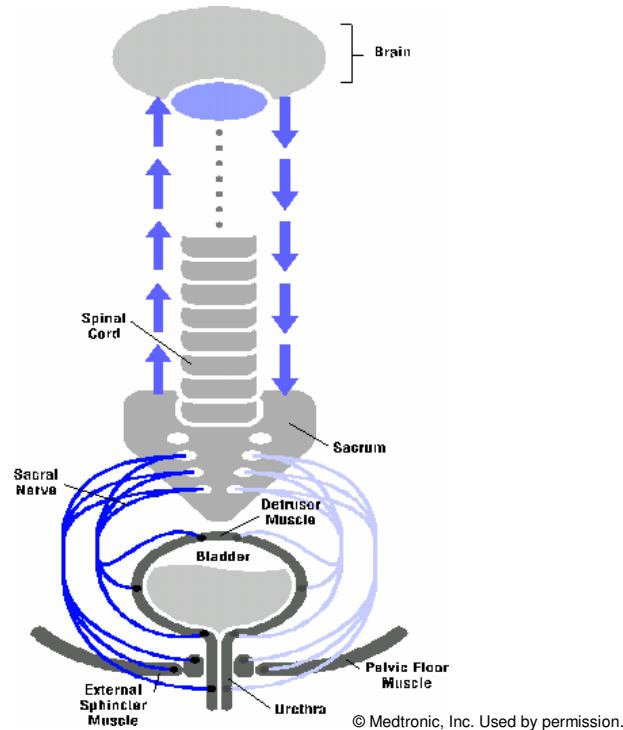


Figure 2. Communication Between the Brain and the Bladder

Why Do Some People Have Bladder Control Problems?

Sometimes, the two-way communication between the brain and bladder is disrupted. When this happens, patients may experience symptoms of bladder control problems. For many patients, sacral nerve stimulation may restore the communication between the brain and the bladder therefore reducing the symptoms associated with bladder control problems.

Sacral Nerve Stimulation (SNS)

What is Sacral Nerve Stimulation Therapy?

Sacral nerve stimulation therapy involves delivering an electrical pulse to the sacral nerves (located just above your tailbone). This stimulation may facilitate the communication between the brain and bladder, and may relieve the symptoms of urinary retention or symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in some patients.

SNS Therapy: Test Stimulation and Implant

SNS therapy is delivered in two procedures. The first is the test to see if the therapy will work for you. The next procedure, an implant of a SNS system, may be done if the test stimulation procedure was successful.

One of the biggest advantages of SNS is the test that allows you to try sacral nerve stimulation for several days. Once you have experienced the therapy, your doctor will discuss the results of the test with you. If the test was successful, you along with your doctor will decide whether to have the complete system placed. The test involves placement of a lead (thin wire) that is placed near the sacral nerves. There will be a thin wire that exits your skin. This wire is connected to a small cable and test stimulator that is worn on a belt for the duration of the test at home. The test stimulator provides stimulation similar to that felt with the implant.

The next step, the implant of the SNS system, may be done after a successful test stimulation. It involves placement of a neurostimulator (electronics and battery). The implanted system is entirely under the skin

How is the Test for SNS Therapy Done?

Placing the Test Stimulation Lead

There are two types of leads used for test stimulation, a temporary lead or a long-term lead. Your doctor will explain the test stimulation procedure you will be undergoing.

The test stimulation lead is inserted in the doctor's office or hospital, depending upon the type of lead placed and/or your physician's preference. Your doctor will explain the type of anesthesia that will be used for your procedure. The medical team will make you as comfortable as possible during the procedure. You may be given pain medication and a sedative that will make you feel relaxed and drowsy, but able to cooperate during the procedure. Or, you may be given general anesthesia.

While you are lying on your stomach, your doctor will insert a lead and position it near a sacral nerve. The sacral nerves are located near the tailbone. During the procedure you may be asked to describe what you feel when the sacral nerve is stimulated. You may feel a "pulling", "tingling" or "tapping" sensation in your pelvic muscles and movement of your big toe. Women may feel a sensation in the vaginal area and men in the scrotum. Most likely you will go home the same day the lead is placed.

- If a temporary lead was used, it will exit your skin in your lower back. It will be taped to your skin and attached to the external test stimulator that you wear when you go home (see figure 3).
- If a long-term lead is used, a small wire is attached to the lead. The wire exits a small incision in your lower back or upper buttock. This wire is connected to the external test stimulator that you wear when you go home (see figure 4).

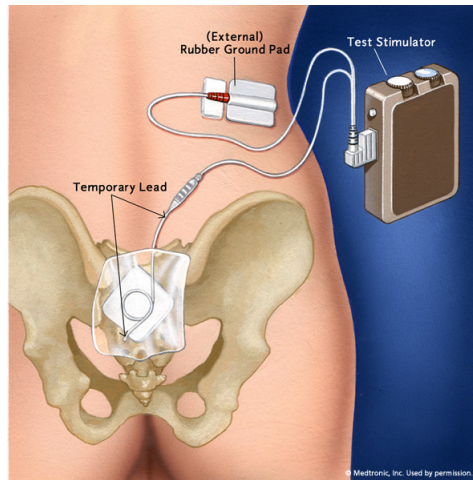


Figure 3. Test Stimulation Using the Temporary Lead

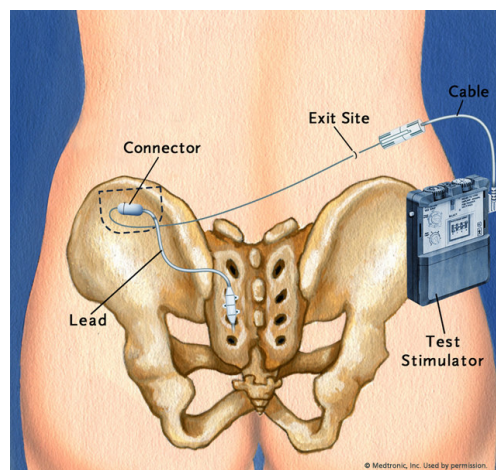


Figure 4. Test Stimulation Using the Long-term Lead

At Home

You will go home with a temporary system to “test” how the therapy works for you. The test stimulator generates mild, carefully controlled electrical pulses that are carried to the sacral nerve. These pulses cause the sensations of “pulling” or “tingling” or “tapping” in your pelvic area like you felt during the placement of the lead. Stimulation sensations vary from person to person, but should be comfortable. You will be shown how to control the intensity of stimulation and how to turn the system ON or OFF.

While undergoing the test, you will document your symptoms in a voiding diary. In the diary you will record how much and how often you urinate, any leaking episodes and any symptoms of urgency and frequency. If you have urinary retention and catheterize to empty your bladder, you will record the volume and time you catheterized. During the test you will know how stimulation feels and if it improves your symptoms. If your

bladder control symptoms improved during the test stimulation, you and your doctor will decide if you want to continue with the therapy.

Your Follow-up Office Visit

After the test, you will meet with your doctor to review your voiding diary and discuss whether your symptoms improved. Be aware that your bladder control symptoms will most likely return within a few hours after stopping the test stimulation.

If your symptoms improved – You and your doctor will decide if the SNS therapy is appropriate for you. Generally, if you have no problems and your symptoms improved during the test stimulation, you may be a potential candidate for SNS therapy.

If your symptoms did NOT improve – The test stimulation may be repeated. Or, you and your doctor may decide to try another procedure or different therapy.

How is the Implant for SNS Therapy Done?

The InterStim[®] System for urinary control (made by Medtronic) is a sacral nerve stimulation system. The system includes a neurostimulator and lead that are surgically placed and programmers to adjust the stimulation settings.

Implanting the SNS Device

The implant procedure is performed in an operating room. As with the test stimulation procedure, the medical team will make you as comfortable as possible during the procedure. Your doctor will discuss the type of anesthesia to be used. You will either be given pain medication and a sedative or general anesthesia.

You will have one or two incisions. The incision made for the neurostimulator will be about 2 inches long; the other incision will be small, about ½ inch or less. The entire system will be under your skin.

- If a temporary lead was used for the test stimulation:
 - the lead will be removed
 - a long-term lead and neurostimulator will be implanted in the upper buttock or abdomen
- If a long-term lead was used for the test stimulation (see figure 5):
 - the long-term lead will remain in place
 - the external wire used for test stimulation will be removed, and
 - a neurostimulator will be connected to the long-term lead and placed under the skin in the upper buttock or abdomen.

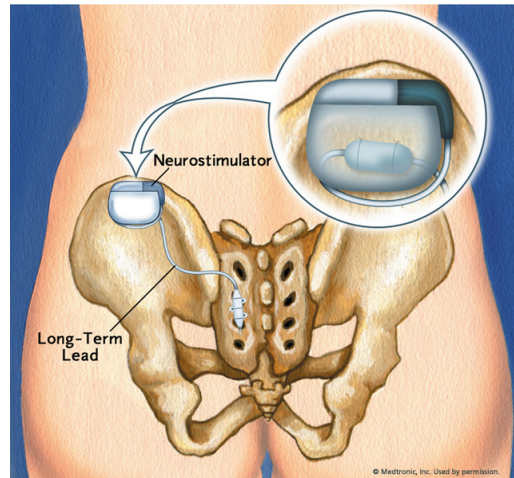


Figure 5. Implant of Lead and Neurostimulator (battery and electronics)

After Surgery

You should be able to go home the same day of the procedure. Your incisions may feel sore and somewhat painful, especially during the first two weeks. Your doctor may prescribe a medication to control your discomfort. As the incisions heal, you should become more comfortable and will be able to gradually increase your activity level. Your doctor or nurse will give you directions to follow after the surgery.

Your physician turns on the neurostimulator after surgery. When the system is turned ON, you will feel a slight tingling, tapping or pulling sensation similar to what you felt during the test stimulation. The sensation should not be painful. The level of stimulation will be increased or decreased to achieve the best control of your symptoms.

Adjusting the Level of Stimulation at Home

At home, you can control the level of stimulation and turn the SNS system ON and OFF with the patient programmer. The programmer is a hand-held device and is about the size of a cell phone (see Figure 6). When the programmer is held over the neurostimulator, the programmer “talks” to the neurostimulator to change the settings. (For more information, refer to technical manual or the Reference Card packaged with the InterStim System patient programmer.)

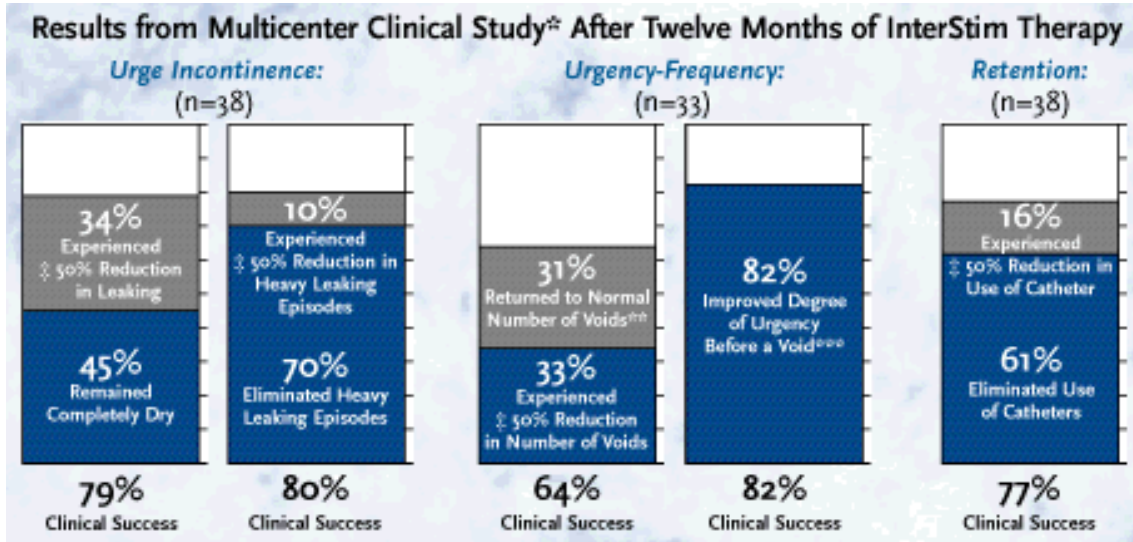


Figure 6. Patient Programmer

Clinical Study Results

Medtronic conducted an international, multi-center clinical study using Medtronic InterStim Therapy. Patients included in the study had symptoms of urge incontinence, urgency-frequency or retention.

The study showed that the InterStim Therapy successfully treated the symptoms of urge incontinence, urgency-frequency or retention. The results of the study are summarized in Figure 7.



*The multi-center 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.

Figure 7. Clinical Study Results

Problems or Complications

As with any surgical procedure, problems can occur. These problems may be resolved with reprogramming of the system, medications or surgery. The InterStim System can always be removed, if necessary.

The following events and approximate rate of occurrence occurred during the InterStim Therapy clinical study: pain where the neurostimulator is placed (15%), new pain (9%), movement of the lead (8%), infection (6%), sudden and brief increase in stimulation - sometimes described as shocking or jolting - (6%), pain at lead site (5%), significant change in bowel function (3%) and other¹ (16%).

¹The following problems each occurred less than 2% of the time: technical problems, suspected device problem, change in menstrual cycle, adverse change in voiding function, persistent skin irritation, suspected nerve injury, and device rejection. The following problems each occurred less than 0.5% of the time: change in sensation of stimulation, grand mal seizure, hematoma or seroma, urinary hesitancy, neurostimulator turns on or off, lack of orgasm, lack of efficacy, numbness and tingling, foot/leg movement, strong anal sensation, unable to perceive stimulation, stress urinary incontinence, swollen feeling in abdomen, vaginal cramps, superficial connection, and possible skin perforation at neurostimulator.

You should be aware that none of these problems in the clinical study resulted in permanent injury to patients. Additional information on clinical studies can be found at www.interstim.com

It is important to note that since this clinical study was conducted, changes in InterStim Therapy and surgical techniques have been made. For instance, the neurostimulator is now commonly placed in the upper buttock, rather than in the abdomen as in the original study. In addition, a new lead was developed which made the procedure much less invasive.

Candidates for SNS Therapy

Who Are Candidates for SNS Therapy?

SNS is intended for patients who have failed or could not tolerate more conservative treatments. Bladder control problems that may improve with SNS therapy include: Overactive bladder (includes urge incontinence and urgency frequency-alone or in combination)

- Urge incontinence – The involuntary loss of urine associated with a sudden, strong desire to void (urgency).
- Urgency-frequency– Frequent, uncontrollable urges to urinate (urgency) and voiding often in very small amounts (frequency).

Urinary retention – The inability to empty the bladder

Who Are Not Candidates for SNS Therapy?

InterStim Therapy is not intended to treat:

- symptoms of stress incontinence. People with stress incontinence lose urine when they exercise, sneeze, cough, or laugh.
- mechanical obstructions such as enlarged prostate (benign prostatic hypertrophy/BPH), cancer or narrowing of the urethra (urethral strictures).

Safety and effectiveness of InterStim Therapy has not been studied for stimulation with two leads, or for patients who are pregnant, have diabetes, neurological diseases or multiple sclerosis, or are under 16 years old.

What Other Limitations Apply to SNS Therapy?

Some known limitations for this therapy include: a failed test stimulation, or inability to use the patient programmer. Patients with other stimulation devices such as a pacemaker may also not be candidates for SNS.

Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, and can cause tissue damage, resulting in severe injury or death.

Is SNS a Cure for Bladder Control Problems?

As with any therapy, your own individual results may vary. While many patients implanted with InterStim Therapy experienced relief of many of their symptoms, the therapy will not result in complete improvement or a cure.

You should know that many patients have experienced positive results and experienced an improved quality of life after having the InterStim Therapy implanted. To learn more about the therapy, visit www.interstim.com or ask your doctor for the Medtronic patient manual and a brochure to read stories from patients who decided to have the InterStim System implanted.