InterStim

CONSULTATION INFORMATION

UrologyAustin

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Making An Informed Decision

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. 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).

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. 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.

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 augment 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?

You may be one of millions of people who suffer from frustrating and embarrassing bladder control problems such as retention and overactive bladder. Effects of bladder control problems can be devastating. These conditions prevent you from controlling when and how much you urinate and 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 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. In the past there were few options for patients who did not respond to these therapies. Now, however, 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.

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.* At the heart of this therapy is an innovative and implantable neurostimulator about the size of a stop watch. The therapy uses a small implanted medical device to send mild electrical pulses to a nerve located just above the tail bone. These nerves are called sacral nerves. The sacral nerves [specifically S2, S3 and S4] activate or inhibited muscles and organs that contribute to urinary control-the bladder, sphincter and pelvic floor muscles. The electrical stimulation may eliminate or reduce certain bladder control functions in some people. 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.

InterStim therapy does not treat symptoms of stress incontinence. It 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 obstruction such as benign prostatic hypertrophy, cancer or urethral strictures.

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.

How is the Test for SNS Therapy Done?

Placing the Test Stimulation Lead

SNS therapy is delivered in two procedures. The first is the test to see if the therapy will work for you. A test [temporary test stimulation] is used before implantation of the InterStim Neurostimulator to see what the effect of the stimulation is on your symptoms. If this initial test is positive, you may proceed to the permanent implant.

The initial Percutaneous Nerve Evaluation is performed using a Medtronic "Verify" evaluating system. Based on certain factors, one of two methods will be used to install this system – Basic or Advanced. Most patients are approved for the basic installation.

Basic Test
This is an in-office procedure in which temporary leads are placed into the sacral nerve using a local anesthesia. After the leads are placed, a test will be performed to insure that the sacral nerve is being stimulated. This can be easily verified by the movement of the big toe. Regardless of overall test outcomes, these leads will be removed in the office after one week.

Advanced Test
This test is performed in the operating room on an out-patient basis. This is generally indicated for patients who have urinary retention, and in which a longer sacral nerve stimulation is necessary. Rather than placing temporary leads, this procedure uses one long-term lead that is left in the sacral nerve for a minimum of two weeks. If the patient is recommended for permanent placement of the InterStim device, this lead will remain in place and be connected to the InterStim after the test period is complete. If the patient is not recommended for the InterStim, they will still require a second surgery to remove the long-term lead.

Based on your specific health factors, your doctor will explain which test stimulation procedure you will be undergoing. As described above, depending on whether you are indicated for the basic or advanced test, the stimulation lead(s) will be inserted in the doctor's office, surgical center, or hospital. 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 your 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 the lead(s) 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(s) is placed.

- If temporary leads are used, they will exit your skin in your lower back. They will be taped to your skin and attached to the external test stimulator that you wear when you go home.
- 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.

Permanent Placement

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:

- 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 abddomen.

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%).

The 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.

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
- Fecal Incontinence – The inability to control your bowels

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 an MRI without MRI protocol, any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy - local heating of the body tissues with an electric current for medical or surgical purposes),) 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.

Preparing for Surgery

Predetermination For InterStim Placement & Patient Responsibility

Pre-determination must be submitted by mail to your insurance company for approval of the placement of the InterStim. In come cases it may take anywhere from 30 to 45 days for a decision to be made.

In order for insurance to approve and/or pay for the placement of the InterStim, the following must be present and documented in the patient's record.

- The patient has experienced urge continence for at least 12 months (the condition has resulted in significant disability; the frequency and/or severity of leakages are limiting the member's ability to participate in daily activities). Records from all other physicians (pcp, gyn, uro, etc.) will be needed to submit.
- The patient must have tried two pharmacotherapies that have either failed or are contraindicated.
- The patient must have tried pelvic floor exercises, behavior modification (timed voids and fluid management) or physical therapy.
- The patient must have a Bladder Diary (voiding times and fluid intake, etc.) **which includes one diary before the placement of the temporary InterStim and one diary after the temporary placement** to show at least 50% improvement. This must be delivered to the doctor's office for the pre-determination of the permanent placement of the InterStim.

Insurance plans have different benefits or exclusions on each policy but the companies are looking for all of these guidelines to be present before considering payment.

Pre-Op Instructions

10 Days Prior To Surgery

Stop taking Aspirin and any blood thinning products a full 10 days before your surgery. This includes Ibuprofen, Advil, Aleve, Coumadin, Plavix and any vitamin supplements (Vitamin E and Fish Oil). You may continue to take Tylenol for pain.

Two to Seven Days Prior To Surgery

Your physician may request that you have lab work and/or an EKG done prior to your surgery. Your physician will notify if this is required.

Night Before Surgery

You should **not eat or drink anything** after midnight the night before your surgery. This will insure that your surgery start time will not be delayed.

Night Before Surgery

Pack the InterStim booklet, supplied to you, to take to the hospital.

Post-Op Hospital Visit – Your Booklet

After surgery you will be visited by a Medtronic representative, while In recovery, to discuss your InterStim device. The rep will go over the sheets named:

InterStim Therapy Trial Assessment, InterStim Therapy Trial Assessment PNE ***Or*** InterStim Therapy Post Implant

You will also be instructed on the importance of the Voiding Diary.

Voiding Diary

After your surgery, you will be required to complete a 7-day Voiding Diary. The Voiding Diary has been included as part of your patient package. This dairy records your voiding cycles and amounts during a 24-hour period over 7 days. The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** If you have disgarded the cup you were given prior to the transplant, please take the one provided by the hospital.

This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Ongoing Support & Care After Your Surgery

Sacral Nerve Stimulation is delivered in two procedures: **TEST (PERCUTANEOUS STAGE) to STAGE 1 & 2** or **STAGE 1 to STAGE 2**. Your follow-up care will depend on which process was used.

TEST (PERCUTANEOUS STAGE) to STAGE 1 & 2

TEST (PERCUTANEOUS STAGE): Surgery Scheduling will schedule your follow-up appointments at the same time you are scheduled for surgery. In 3-10 days following surgery, your physician will access the wound site and review your diary results. At that time, the leads will be removed. If everything has been successful, you will be scheduled to proceed to Stage 1 & 2.

STAGE 1 & 2:

Your second visit will occur 1-3 weeks after your surgery to assess your wound and identify other programming needs. You should bring your voiding diary to this appointment to have it reviewed by the physician.

STAGE 1 to STAGE 2

STAGE 1:

The first visit with your physician will occur 3-5 days following surgery , at which the doctor will assess your wound site. **It is vital that you bring your a completed voiding diary to this visit so that it can be reviewed by your doctor.**

STAGE 2:

Your second visit will occur 1-3 weeks after your surgery to allow the doctor to assess your wound and to identify other programming needs. **You will need to bring your voiding diary to this visit to be reviewed.**

MANAGEMENT AND ASSESSMENT OF YOUR INTERSTIM:

If you have a problem, you can call at anytime for an appointment. You will be scheduled for a return appointment in six months, and then each year thereafter.

BATTERY CHANGES

A 5 year battery life is normal. A low battery symbol on the programmer will indicate when it is time to change the battery. But if it is getting close to the 5 year time period, your health care provider will have the remaining battery life tested.

Troubleshooting – Q & A

Is InterStim Therapy FDA approved?

Yes. InterStim Therapy was approved by the FDA in 1997 for urge incontinence and in 1999 for urinary retention and significant symptoms of urgency-frequency. It has been available in the US for over a decade.

Has InterStim Therapy been studied?

Yes. InterStim Therapy has been shown to be safe and effective for people who have not had success with other treatments. It has been used to treat thousands of people worldwide. In a clinical study, doctors found that nearly half of patients with urge incontinence who received InterStim Therapy were completely dry after 6 months, and many others have experienced greatly reduced symptoms.

Is InterStim Therapy for both men and women?

Yes. InterStim Therapy can be used to treat urinary control symptoms in both men and women.

Will my insurance cover the costs?

Medicare and many other private insurance companies cover InterStim Therapy. Your out-of-pocket costs will vary according to your insurance plan. Check with you insurance provider about the details of your coverage.

How will I know if it will work for me?

A trial assessment period lets you test InterStim Therapy to see if it will work for you before making a long-term commitment. The trial assessment is considered a success if you experience a significant reduction in your symptoms.
For example, your trial may be considered a success if you went to the bathroom 20 times per day before the trial and went 10 or fewer times during the trial.

How will InterStim Therapy impact my daily life?

InterStim Therapy can eliminate or greatly reduce bladder control symptoms for people suffering from overactive bladder (urge incontinence, urgency-frequency) or urinary retention problems. InterStim Therapy may allow you to regain your everyday freedom, so you can stop worrying about your bladder control problems and return to the life you once enjoyed. Your doctor will inform you of precautions and activity restrictions related to InterStim Therapy. You cannot have diathermy while you are receiving InterStim Therapy.

Will InterStim Therapy cure my condition?

No. InterStim Therapy is a treatment for bladder control problems, not a cure. If the neurostimulator were turned off or removed, your symptoms would return.

How will I know my model number?

The day of your surgery you will receive a temporary device card. A permanent one will be supplied to you by a Medtronic representative.

Under what circumstances should I turn off the device?

Your neurostimulator should be turned OFF when having a major medical or major dental procedure. However, check with your provider prior to any major procedures for their recommendation.

Information obtained from http://www.everyday-freedom.com/women/about/questions/index.htm now directed to http://www.medtronic.com/us-en/patients/treatments-therapies/bladder-control.html

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 1** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 2** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 3** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 4** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 5** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 6** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments

Voiding Diary

The Voiding Diary should be started while you're in the hospital with your first urination **with each implant stage.** This diary is very important as it will give your physician important information as to your voiding cycles post-surgery. At the same time, this diary will be submitted to your insurance company as verification of your symptom improvement. **Please be sure to bring this diary to your post-surgery follow-up visit with your physician.**

Name: _____ **Day 7** Date: _____

Time of Day	Amount Voided	Catheter Amount	Did you feel empty?	Fluid Intake	# of pads used per day	Additional Comments