



Urology Consultants, Ltd.

Center for Continence Care and Pelvic Medicine

INTERSTIM THERAPY FOR BLADDER CONTROL

This therapy, also known as neuromodulation or sacral nerve stimulation, involves the electrical stimulation of the sacral nerves, located in the lower area of your spinal cord and passing through your tailbone. The sacral nerves affect bowel and bladder function and electrically stimulating these nerves may change your symptoms. It is important to know that this therapy does not work for everyone. InterStim has been approved by the Food and Drug Administration (FDA) since the late 1990's for the treatment of urinary urgency/frequency, urge urinary incontinence, and some forms of urinary retention.

Medtronic, the makers of the InterStim device, have an ambassadors program. You can call **1-800-664-5111 ext 3017** and someone with similar symptoms who has experience with InterStim will call you back within a few days. A website is also available at: www.InterStimAmbassadors.com to view patient's personal stories and experiences.

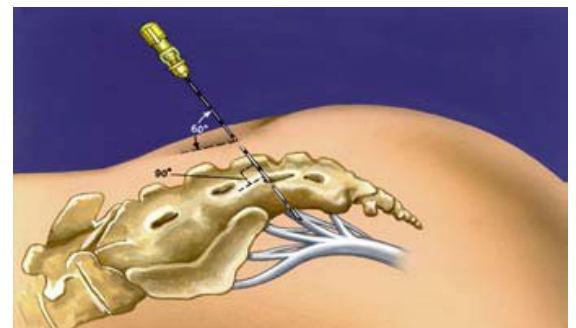
Since the therapy does not work for everyone it is performed in 2 stages. The first is a "test stage" where a special wire is placed through a natural opening (foramen) in the sacrum (tailbone) and in contact with one of the nerves that controls the bladder's reflexes. This wire is then connected to an external battery, which is worn on your belt, for the testing period, usually 1-3 weeks. If successful, in terms of improvement in urinary symptoms the second stage is performed where the permanent battery, similar to a pacemaker, is implanted in the upper part of the buttock. You will have no outside parts after the second stage.

You will not be able to have an MRI or therapeutic ultrasound (diathermy) after the device is placed. Regular ultrasound to evaluate the internal organs or for a pregnancy is safe. Because the effects of InterStim therapy on an unborn child are unknown if you become pregnant or are planning to become pregnant the device will need to be tuned off for the duration of your pregnancy.

Procedure

Stage 1: "test phase"

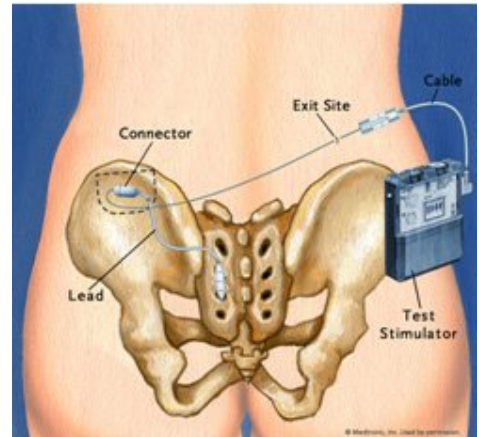
- The procedure is performed in the operating room under local anesthesia with sedation. You will be able to go home the same day. You will need a driver.
- In some cases an office based test is performed where only local anesthesia is needed.
- A special needle is inserted through a natural opening in your sacrum and placed next to the nerve going to your bladder. You may feel a needle stick of the right, left, or both sides.
- A small amount of electrical stimulation is given to the needle and we will be looking for specific physical responses.



- We may awaken you and ask you about the sensations you are feeling. You may feel and tingling, vibration, or pulsing area in the vagina, rectum, scrotum or penis. The sensation should be comfortable, if not we may need a adjust it.
- Once we have located the best placement a special wire, or lead, is placed through a small incision and a temporary testing wire will be brought out through the skin and attached to an external battery.
- X-rays will be used during the procedure and everything should be done in about one hour.

Stimulation Period: After the procedure you will be sent home with the lead connected to an external battery source. The device looks similar to a garage door opener and can be attached to your belt or put in your pocket.

- Using the “A” button on the stimulator you will be able to control the amount of stimulation that you feel.
- The stimulation should be felt in the vagina, rectum, scrotum, penis, or gluteus muscle. It will feel like a pulsing, vibrating, tingling, tightening, or pressure. It should always be comfortable.
- We can change the settings on the stimulator if your current setting is not helpful.
- During the stimulation period, you will be asked again to complete bladder diaries. These will be compared to your baseline diaries to measure your degree of improvement.
- You will be given pain medication and antibiotics after the procedure



- **You will need to restrict or reduce your activities for 7-10 days after the procedure.**
- Restrictions
 - Do not bend from the waist to the floor. If you need to pick something up bend at the knees
 - No twisting at the waist
 - No lifting over 20 pounds
 - No reaching high above your head
 - No aerobics or back exercises until instructed
 - No vacuuming or scrubbing floors until instructed
 - It is alright to do normal walking and to go up and down stairs
- You will be able to shower 1-2 days after the procedure. You will need to cover all wires and disconnect the stimulator box.
- If your bladder symptoms are significantly improved you will be able to move onto Stage 2 where an internal battery, similar to a pacemaker, will be placed in your upper buttock. If InterStim therapy does not work for you the lead will be removed at your second procedure.

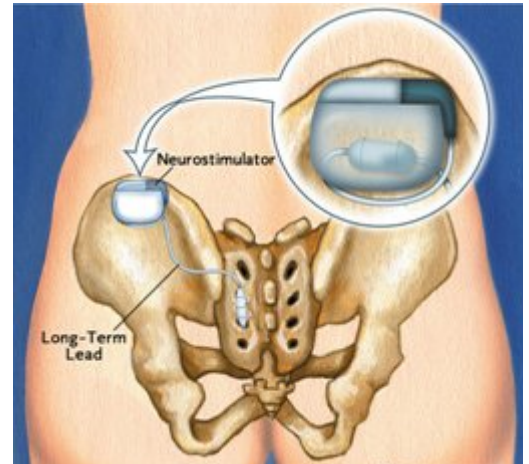
Stage 2: Stage 2 is the implantation of the internal stimulator if your symptoms are significantly improved or removal of the lead if there is no change. You and your doctor will make this decision with the information provided in your bladder diaries.

- This procedure is performed under local anesthesia with sedation

- The incision on the buttock area from the first surgery is reopened and a pocket is made in the fatty tissue and the generator placed inside.
- The outside wire is removed
- The procedure takes about 30 minutes and you can go home the same day.
- You should again limit for activities for 7-10 days.

After Stage 2:

- As you heal and increase your activity the stimulation may need to be adjusted.
- There are many settings that can be changed to give you the best results. **These changes need to be done in the office.**
- You will have a patient programmer at home that enables you to turn the generator off and on as well as increase or decrease the stimulation. **Please bring this with you to all your office visits.**
- **Remember you will not be able to have an MRI or therapeutic ultrasound (diathermy). If you become or are planning to become pregnant the device should be turned off for the duration of your pregnancy.**



Possible risks: Risks that may occur during or after the 2 stages are rare, but may occur.

- Anytime the skin is opened you may develop an infection. Every care is taken to avoid this and the procedure is performed under sterile technique. You will be placed on antibiotics after each procedure. If an infection does develop there is a chance that the equipment will need to be removed.
- There is risk of bleeding from the incision sites, the formation of a seroma (fluid under the incision area) or hematoma (blood collection under the incision). Some swelling, bleeding, and bruising is normal and very treatable.
- You will have some pain or discomfort at the incision site. Pain medicine will be prescribed.
- If you have pain with the stimulation the settings can be adjusted to reduce the pain.
- There is a risk of the lead moving after placement. This can be caused by too much activity too soon or a fall. The site of stimulation may need to be changed or the lead may need to be replaced.
- **The risks to an unborn child are unknown. If you become or are planning to become pregnant the device should be turned off for the duration of your pregnancy.**
- There may be other risks, which are unknown at the time.