InterStim Implant

This information is provided to help you make an informed decision about using neurostimulation (InterStim) to treat your bladder dysfunction. This therapy involves the electrical stimulation of the sacral nerves, located in the lower area of the spinal column above the tailbone. The sacral nerves affect the bladder and bowel functions. Electrically stimulating these nerves may change your symptoms, however, neurostimulation does not work for everyone.

Medtronic has an ambassador program. Call 1-800-664-5111 extension 3017 and an ambassador with similar symptoms who has experience with InterStim therapy will call you back within seven days. They also have a website at www.interstimambassadors.com to view the ambassadors and read their personal stories.

There are two stages to this therapy. The first stage is an "evaluation stage". This can be completed in either of two ways:

1. The Percutaneous Nerve Evaluation or PNE. Two temporary leads (special wires) are placed into the opening (foramen) in the sacral bone and connected to an external stimulator. The leads do not go near the spinal cord. The wires are tested for a week and then removed. This procedure is done at a hospital or an outpatient surgery center. IV sedation and local anesthetic are used. You will need a driver to take you home.
2. The Staged Implant. The chronic lead (another special wire) is placed into the opening (foramen) of the sacral bone in a surgical procedure, connected to an externalizing wire and then to the external stimulator. Again, the lead does not go near the spinal cord. This lead is tested over a period of 3-4 weeks. This procedure is done at a hospital or an outpatient surgery center. IV sedation and local anesthetic are used. You will need a driver to take you home.

If successful, the stimulation may improve your bladder symptoms. Success in the "evaluation stage" moves you into the "completion stage" where an IPG (the permanent battery/pulse generator) is implanted surgically in the upper part of the buttock area and connected to the lead. If your evaluation stage was the PNE, the permanent lead and the IPG would be implanted in a single surgical procedure. You will have no parts outside your body after this surgery.

You will not be able to have Therapeutic Ultrasound (diathermy). Also you will be unable to receive certain MRIs. You need to consider this if you decide to try neurostimulation.

You will need to complete a **4-consecutive day baseline bladder diary** before your Stage 1 or PNE procedure.

The following is a description of the procedures that will be done during the Staged Implant procedure. If your successful evaluation phase was the PNE, both Stage 1 and Stage 2 will be completed in one surgical procedure.

Stage 1:

This "evaluation phase" is a surgical procedure performed at a local hospital or outpatient surgery center. **You will go home the same day. You will need a driver. It is preferable to have someone with you when you receive your stimulator operation and discharge instructions because your memory will be affected by the medications you have received.**

- You will be given IV sedation and a local anesthetic will be used to numb the surgical area.
- A special needle is inserted into one of the sacral bone openings (foramen); this needle will be tested with the stimulator. We may use either the right or left side of the sacrum for stimulation. There may be needle sticks on both sides for testing, though usually only one side is used for the placement of the lead.
- A small amount of electrical stimulation is applied to the needle. We will be looking for specific physical responses to the stimulation.
- We may awaken you briefly during the procedure to ask you about the sensations you are feeling. Please be specific about the area and the type of sensation you are feeling. The sensations are typically a tingling, vibrating, pulsing or pulling/tightening in the area of the vagina, rectum, scrotum or penis. If the sensations are uncomfortable, please inform us so we can adjust them.
- When we have located the best placement, the permanent lead (special wire with electrodes) is placed through a small incision in the sacral area. The lead will then be tested in the same manner as the needle.
- Special X-rays (fluoroscopy) will also be used to help with the placement.
- The lead is tunneled under the skin and attached to a temporary test wire at a small incision in your right or left upper buttock. The test wire is then tunneled under the skin to the opposite side and brought out through a small hole in the skin.
- The incisions are closed with sutures and skin glue (Dermabond).
- The surgery takes approximately one hour.

Stimulation Period:

After surgery, when you are fully awake, the test lead will be connected to the external stimulator and a site for stimulation chosen.

- Your representative from Medtronic will assist you in using the device.
- The stimulation may be felt in the vagina, rectum, scrotum, penis or gluteus muscle. It may feel like tingling, vibrating, pulsing, tightening or pressure. <u>The stimulation should always be comfortable.</u> Each site of stimulation may be a different sensation, felt in a different place.
- There are several different stimulation sites we can test. We may need to test more than one before we find the site that is best for you.
- You will be given medication for your incisional discomfort and an antibiotic to prevent infection after surgery.
- **You will need to reduce your activity for approximately one week.** You will have additional activity restrictions <u>until you are released by the physician.</u>

Restrictions

- ✓ Do not bend at the waist to touch the floor. You may squat or kneel if you keep your back straight.
- ✓ No twisting at the waist to reach behind you. Move your feet to turn around. You may turn from side to side.
- ✓ No lifting, pulling or pushing more than 15lbs.
- ✓ No reaching high above your head.
- ✓ No aerobics, running, stretches or strenuous exercises. Walking is good, but go at an easy pace.
- ✓ No vacuuming or scrubbing floors.

- You will not be able to shower/bathe after your surgery. You will need to "bird bath."
- During the time between the two surgeries, we will be checking with you frequently to monitor your progress. You may be asked to complete more than one diary if your symptoms improve. These diaries will be compared to the baseline diary to measure the degree of improvement.
- If your symptoms improve significantly, a letter will be written to your insurance company asking for their approval to proceed with Stage 2.
- If your symptoms do not improve, the lead will be removed at the second surgery.

Stage 2:

This "completion phase" is the implanting of the internal stimulator if your symptoms have improved significantly, or the removal of the lead if there is no change. You and the physician will make this decision with the information provided by the diaries.

Like the first stage: **You will go home the same day. You will need a driver. It is preferable to have someone with you when you receive your patient programmer and discharge instructions because your memory will be affected by the medications you have received.**

- The implantation of the internal stimulator (IPG, battery pack, generator) is done under IV sedation with local anesthetic to numb the surgical area.
- The incision in the right or left buttock area from the first surgery is reopened and a pocket made in the fatty tissue. The stimulator is placed inside this pocket.
- The outside test wire is removed and the permanent lead is connected to the stimulator.
- After the surgery, when you are fully awake, the stimulation will be initiated and you will be instructed on the use of the patient programmer.
- **You will need to be off work and limit your activities for approximately one week.** The activity restrictions from the Stage 1 surgery will continue until your last visit with the physician. (If your test phase was unsuccessful and the lead was removed, you will no longer have the activity restrictions.)
- You will be given medication for your incisional discomfort and an antibiotic to prevent infection after surgery.

- The incisions are closed with sutures and skin glue (Dermabond). You may shower 48 hours after your surgery.
- You will have an appointment in the clinic approximately two to three weeks after your surgery with a provider for a wound check and to monitor your progress. You will have an appointment approximately 6 weeks after your surgery to follow-up with the physician.

After Stage 2:

- As you heal and increase your activity, the stimulation may need to be changed.
- There are many settings on your stimulator that can be changed to give you the best results. Some of these changes will need to be done in our office.
- You will have a patient programmer at home that enables you to turn the stimulator on and off, as well as increase or decrease the strength of the stimulation. Your programmer will also allow you to change between up to 7 different stimulation sites without having to come into the office.
- You will need to moderate some activities for several months following this surgery. After a period of time, you should be able to resume your usual activities.
- **Reminder: You will not be able to have certain MRIs or therapeutic ultrasound (diathermy)** as long as you have this device/implanted.

Possible Risks or Discomforts: Risks are rare, but may occur during or after these surgeries.

- Any time the skin is opened you could develop an infection. Every care is taken to prevent this. The procedures are done under sterile technique. You will receive antibiotics during and after both surgeries. If you do develop an infection, there is a chance the entire Implant may need to be removed.
- Some swelling, bleeding or bruising at the incision sites is normal, however there is a risk of excessive bleeding from the incision sites, the formation of a seroma (fluid under the incisional area) or hematoma (blood collection under the incision). These conditions are very treatable by your physician.
- You will have some pain or discomfort in the incisional areas. Please take your pain medication as needed. It is better to take the medication early in the onset of pain rather than waiting until the pain becomes intense. If you have pain caused by the stimulation, the settings on the stimulator can be adjusted to reduce/eliminate the pain.
- **There is a risk of the lead moving or lead fracture after placement.** This can be caused by too much activity during the healing process, a fall, or a traumatic injury to the surgical area. The site of stimulation may need to be changed or the lead may need to be replaced.
- There is a risk of skin irritation at incision sites due to tape or dressings.
- **The risk of damage to an unborn child is unknown. If you plan to become pregnant, the stimulation must be turned off.**
- There may be other risks that are unknown at this time.