

## Sacral nerve stimulation for bowel incontinence



Nerve stimulation by a treatment called sacral neuromodulation can help some people control their bowel and bladder problems. A Medtronic-sponsored, prospective, multicenter trial conducted under an FDA-approved investigational protocol with 120 implanted patients demonstrated a significant improvement in fecal incontinence symptoms and quality of life.

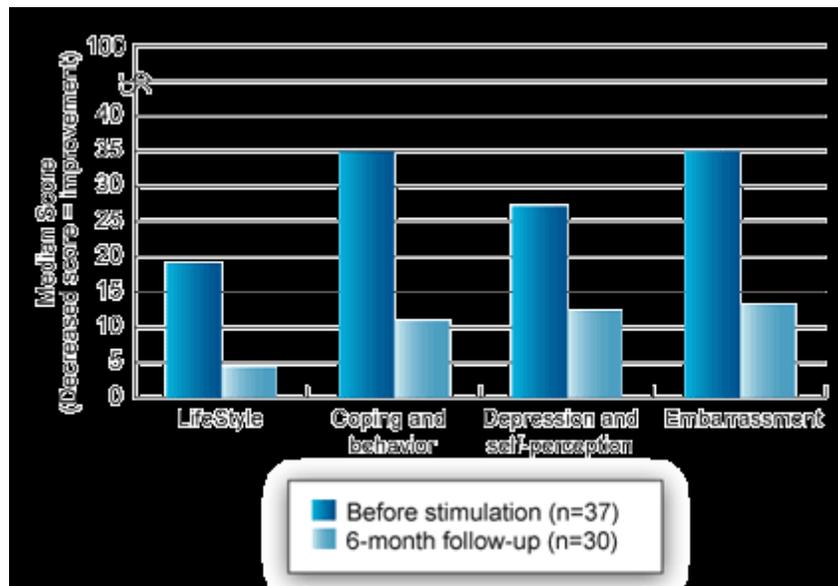
For the 106 implanted patients with complete follow-up diaries at 12 months:

41% achieved complete continence

83% achieved a 50% or greater reduction in incontinent episodes per week

Overall quality-of-life scores improved significantly from baseline, as measured by the four scales of the Fecal Incontinence Quality of Life instrument

Similar results were reported by Royal London Hospital QOL Questionnaire at 6-month follow-up ( $p < 0.05$ ). Score range 0-100.



### How is the device implanted?

A small device is surgically implanted in the buttocks. It's about the size of a stopwatch. This device stimulates the appropriate nerves by using mild or moderate electrical impulses. By doing this, it can help restore coordination between brain, pelvic floor, bladder or bowel, and sphincter muscles.

Sacral nerve stimulator therapy is an outpatient procedure that is performed in the operating room.

Your doctor will implant a thin, flexible wire (also known as a "lead," and pronounced "leed") near your tailbone. The wire is taped to your skin and connected to a small external device which you'll wear on your waistband.

The external device sends mild electrical pulses through the wire to nerves near your tailbone. The stimulation may get your bowel working the way it is supposed to. During the trial assessment, you'll wear an external neurostimulator on your waistband for several days. You can continue many of your low- to moderate-level daily activities with caution. You can usually continue to work throughout your trial assessment if your job doesn't require strenuous movement.

You'll be asked to document your symptoms. The trial assessment will help your doctor determine the next course of treatment for your bowel control problems. An authorized medtronic representative, your doctor or nurse will give you information about operating the test stimulator. He or she will also tell you about any precautions or activity restrictions related to the trial assessment.

If neurostimulation has worked for you in the trial period, a flexible wire (also known as a "lead" and pronounced "leed") and a neurostimulator are implanted under the skin permanently. This is done during a minimally invasive outpatient procedure.

### Benefits of Sacral neuromodulation

Sacral neuromodulation (also called sacral nerve stimulation) is reversible and can be discontinued at any time. People who have had Sacral neuromodulation for fecal incontinence have reported:

- Improved quality of life
- Complete freedom from incontinence episodes or a dramatic reduction
- Freedom to live without worry of leaks

### Risks of Therapy

As with any medical treatment, some people may experience some of the following side effects with sacral neuromodulation:

- Pain where the device is implanted
- The electrodes change position in the body
- Infection or skin irritation
- Technical problems
- Adverse changes in bowel or bladder function
- Numbness at the neurostimulator site
- Undesirable stimulation or sensations

The number of people with these side effects has been very low and in almost all cases they were solved.



### **Living With Sacral Nerve Stimulator**

After your sacral nerve stimulator has been implanted, and the surgical cuts are healed, you will be able to resume your regular activities. People with a neurostimulator have been able to do things they were not able to do before, such as go to restaurants, take long walks through the park, see films at the cinema or travel.

You will be given a hand-held patient programmer and an identification card after your short, minimally-invasive surgery. Although you will usually not use the patient programmer, it allows you to adjust the level of the stimulation and to turn your neurostimulator on or off.

### **Medical procedures and equipment**

It is a good idea to carry your identification card with you at all times and show it to medical staff before you undergo tests or treatments. Most procedures and equipment will not affect or be affected by your neurostimulator. But caution is needed with some equipment, such as magnetic resonance imaging, monitors and diathermy equipment.

### **Antitheft devices**

You should also let airport security staff, know about your device to avoid possible problems with airport screening systems. Airport screening systems or theft detectors in public department stores or banks can cause the neurostimulator to turn off or on. If this happens, don't worry. It does not change your stimulation settings. Simply use your patient programmer to switch your neurostimulator back on again. If you know you will need to pass through one of these devices, it's a good idea to switch off the neurostimulator before going through and turn it back on afterwards.

### **Getting a Replacement**

After several years, the neurostimulator battery will run down, causing the electrical stimulation to change and become less effective. Your symptoms may then reappear, but this is normal and there is no need to worry. You should consult your doctor as soon as you feel a change in the stimulation (less or more intense, or different). Your doctor will check the battery and may decide to replace the neurostimulator. Your patient programmer will also warn you if the neurostimulator battery is low.