Sacral Neuromodulation for Bladder Problems

Why do I have Bladder Control Problems?
Nerves carry information to and from the brain. Some nerves control the bladder and muscles that relate to urination. When the communication system between these nerves and the brain is not working properly, a person may have bladder problems such as urinary retention and over active bladder including urgency and urge incontinence.

What is InterStim Therapy?
InterStim Therapy (also called sacral nerve stimulation or sacral neuromodulation) is a treatment which helps to restore normal bladder function by sending electrical signals to the nerves that control the bladder.

It can be used for a variety of bladder conditions including:
- urinary retention
- over active bladder including:
  - urgency and frequency
  - urge incontinence

The Interstim device consists of an electrode (thin wire) which is inserted through the back, and a stimulator which generates the electrical impulses.

How is the Interstim treatment performed?
InterStim Therapy is performed in 2 stages:
- Test phase
- Implant phase

The test phase is a simpler procedure which allows patients to find out whether or not they get relief from their symptoms. Those patients who get a beneficial response to the test phase can go on to have a permanent Interstim implant.

How well does this treatment work?
Studies have shown that most patients with urge incontinence (about 80%) who have Interstim treatment showed a good improvement in their symptoms, and around half are completely back to normal (that is, they have no more incontinence).

In patients with overactive bladders (urgency-frequency) but without incontinence, just over half have a good response to treatment (ie. a significant improvement in their symptoms).

Are there any side-effects?
Sometimes the electrodes (wires) can move or become broken. This happens in about 15% of patients. Other problems include infection around the device (5% of patients) or problems with the bowels (5%). Overall, about 1 in 3 patients need a further operation to deals with these sorts of problems.
**InterStim™ Therapy Testing Phase**

An electrode (a thin wire) is inserted near the nerves in your lower back that control the bladder. This electrode is then connected to a small box worn on your belt which delivers electrical pulses to the nerves. This procedure normally takes about an hour and can sometimes be done under local anaesthesia.

**What does the stimulation feel like?**

Stimulation sensations vary from person to person, but most people describe them as light “pulling”, “tingling” or “tapping” in their pelvic area (vagina, scrotum, or anus) or big toe. It should never be painful. People tend to notice these sensations less over time.

Most patients notice a change in their symptoms within a few days of starting treatment.

**What should I do once at home?**

The test period is usually about 2 weeks. During this period, you can continue to lead your everyday life but it is best to avoid intense physical activities during the test period in case the electrode becomes dislodged. Avoid bending, stretching, or lifting.

During the test phase you need to record your symptoms using a bladder diary or frequency-volume chart so that we can measure how your symptoms have changed.

**How to use the test stimulator**

The test stimulator has 2 large dials on top. The one labelled “R” sets the stimulation frequency. It is set by your doctor and you should not adjust it. The second dial, labelled “A”, sets the amplitude of the stimulation (how strong it is). It is initially set by your doctor, but you can adjust it to find the setting which is most comfortable.

To shut the stimulation off, simply turn the “A” dial to OFF. The top of the test stimulator also has two indicator lights: a green blinking light when the unit is on and a yellow light that shows when the battery needs to be changed.

**Your follow-up visit**

At the end of the test period, you will meet with your doctor to review your bladder diary (frequency-volume chart) to check if your symptoms have improved and decide if the therapy is appropriate for you. The test electrode will be removed. Be aware that your bladder symptoms will most likely return within a few hours after stopping the test stimulation.

**Frequently asked questions on the test:**

**May I work?**  
Yes you can, except if your work requires intense physical activities.

**May I use my mobile phone?**  
Yes you can, there is no problem.

**May I shower or take a bath?**  
Please avoid bathing. You may shower 48h after the procedure.

**Are sport activities limited?**  
Restrict your physical activities due to the risk of the electrode moving from its initial position.

**Do I have to fill in a bladder diary?**  
Yes, you have to fill it in during the test period and a few days after the end. Without the information provided by the diary it will not be possible to properly assess whether you are suitable for a permanent implant.

**May I have sexual intercourse?**  
We recommend that you avoid sexual intercourse during the test phase in case the electrode moves from the correct position.

**Is the test reversible?**  
Yes, the test stimulation is reversible and can be stopped at any moment.
**InterStim™ Therapy Implant Phase**

If the test stimulation was successful, your doctor will discuss having a permanent InterStim device implanted.

**What is an InterStim system?**

The InterStim System consists of:

- An implantable neurostimulator which is inserted under the skin.
- An electrode or thin wire that carries the electrical pulses to the bladder nerves.
- A hand-held patient programmer that enables you to adjust the level of the stimulation and allows you to turn your INS on or off.

**What happens during the implant?**

The long-term electrode will be inserted close to the nerves in your lower back (similar to the insertion of the test electrode). The electrode is then connected to the neurostimulator which will be inserted under the skin in the upper buttock where it will be the most comfortable and cosmetically acceptable for you. The stimulator is about the size of a two pound coin.

This procedure may take an hour and can sometimes be done under local anaesthesia.

![The implanted stimulator](image1)

![The stimulator, electrode and programmer](image2)

**What happens after the implant?**

Your implantable neurostimulator will run continuously and the battery will usually last for many years. Once at home, you can gradually increase your activity level as your incision heals. You may be aware of the neurostimulator at first, but this should gradually diminish.

Normally your doctor will schedule a visit after 1 month after the implant to check everything is OK. The settings may need to be fine-tuned and sometimes, several visits are necessary during the first 3 months.

**What happens when the neurostimulator battery runs down?**

After several years, the neurostimulator battery runs down and you may notice your symptoms starting to return. You should consult your doctor when you feel a change in the stimulation so that the battery can be checked.

If the battery has run down, the stimulator will need to be replaced, but the electrode usually will not need to be changed.
What precautions do I need to know about?

Medical procedures and equipment

Before you undergo medical tests or treatments, always tell your doctor or dentist that you have an implanted InterStim system.

Most medical procedures and routine tests such as X-ray should not affect your InterStim system. However, the following medical equipment and treatments may adversely affect you and your InterStim system:

- Heart defibrillators
- Lithotripsy (e.g. for kidney stones)
- Magnetic resonance imaging (MRI)
- Radiation therapy over the neurostimulator
- Radiofrequency (RF)/microwave ablation
- Ultrasound scanning equipment

It is also important that you let your doctor know that you have an InterStim device before you get have tests such as electrocardiogram (ECG) or electroencephalogram (EEG) as the pulses from your neurostimulation system may interfere with the test. The stimulator may need to be switched off during these kinds of tests.

Commercial equipment

Commercial electrical equipment (for example arc welders, induction furnaces) as well as high voltage power lines may interfere with your neurostimulator system if you get too close to them.

You should tell your doctor if you work in such an environment.

Theft detectors and screening devices.

Airport screening systems or theft detectors found in public department stores or banks can cause the neurostimulator to turn OFF or ON. Do not worry. It does not change your stimulation settings.

Use your patient programmer to switch your neurostimulator to what it was before. To avoid possible problems with airport screening systems, you may want to show your InterStim identification card and ask those in charge to let you bypass the screening device. If you must pass through the theft detector or security screening device, turn your neurostimulator OFF and walk through normally.

Contraindications

Anyone who has an implanted InterStim™ Therapy system (even if it is turned OFF) CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy anywhere on their body.
Frequently asked questions on long-term InterStim™ Therapy:

**What is the size of the InterStim neurostimulator?**
There are 2 possible sizes and weights (height x length x thickness):
- 4.4 cm x 5.1 cm x 0.8 cm, 22 g
- 5.5 cm x 6.0 cm x 1.0 cm, 42 g.

**Will people be able to see it?**
Since your system is placed completely under your skin, others will not see it.

**What am I supposed to do with the patient programmer?**
The patient programmer is used for the following things:
- to show whether the stimulation is ON or OFF
- to turn it ON or OFF
- to show the level of stimulation and adjust it
- to show whether the battery is low
- in some cases to change the stimulation settings

**What do I do if the stimulation becomes uncomfortable?**
If the stimulation becomes uncomfortable, use your patient programmer to decrease the stimulation level.

**Will the stimulation keep me awake at night?**
No, it should not. If it does, contact your doctor.

**Can InterStim therapy be used during pregnancy?**
The safety of this therapy for use during pregnancy has not been established. If you think you are or might be pregnant, turn OFF your InterStim system and inform your doctor.

**Can I have sex after my InterStim system is implanted?**
Yes. Sexual activity is not restricted.

**Will a microwave oven interfere with the neurostimulator?**
Generally no. Most home appliances do not affect the way your neurostimulator operates.

**Can the neurostimulator battery be recharged?**
No. The battery is sealed inside the neurostimulator. It cannot be replaced without replacing the entire neurostimulator.

**Will the InterStim system limit my activities?**
Normally there are no restrictions to physical activities. You should avoid activities that involve sudden, excessive or repetitive bending, twisting, bouncing or stretching soon after the surgery. These movements could damage or move the electrode wire making it less effective.

**May I dive after my InterStim neurostimulator is implanted?**
Yes, but do not dive below 10 meters of water or enter hyperbaric chambers above 202.65 kilopascals (kPa), (2.0 ATA ). Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

**Are the sensations felt during the test different than with the permanent implant?**
No, the sensations should be the same.

**Should I turn the neurostimulator OFF to urinate or defecate?**
This is not usually necessary.