

INTERSTIM THERAPY

Neuromodulation Therapy for Faecal Incontinence

& Urinary Storage and Voiding Dysfunction

Introduction

The InterStim™ Therapy System is a form of Sacral nerve stimulation (SNS) that generates direct, chronic and low-voltage electrical stimulation of the sacral nerve roots. It is a surgically implanted device with 3 components:

1. Neurostimulator: delivers unilateral electrical pulse to sacral nerve.
2. Electrical lead: implanted on a sacral nerve.
3. Programmer: hand held device to control electrical pulse delivered by the neurostimulator.

The advent of sacral neuromodulation therapy for the treatment of faecal incontinence, urinary voiding and storage dysfunction has provided an effective alternative therapy for patients who have failed more conservative treatments. Evidence supports efficacy and safety of its use in the specified group of patients.

InterStim Therapy for urinary control is indicated for the treatment of non-obstructive urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

InterStim Therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

The procedure

There are 2 phases for the procedure.

In the first stage, the neuromodulator wire is inserted into the pelvic nerves through the anatomical foramina (small openings in the bone that the nerves pass through) on

the back of the sacrum (the lower part of the back). The correct placement of the wire is checked by x-ray and by the response achieved on stimulation during the procedure. The procedure takes between half an hour to an hour. The first stage requires two to eight weeks to assess your initial response with an external neuromodulator device in order to assess whether a permanent device will be a good option for you. A voiding diary needs to be filled in. Improvement of more than 50% is considered successful. The permanent device will be inserted under the skin on your buttocks under general anaesthetic and will take about half an hour. If however your tests have been unsuccessful, then you will still have surgery but the operation will involve removing the temporary wire.

The batteries last for approximately 5-7 years and then need to be replaced, which involves a minor procedure. This therapy is reversible at any time

Risk

Common (greater than 1 in 10)

- Replacement, relocation or removal of the implanted pulse generator device
- Replacement, relocation or removal of the lead
- Pain

Occasional (between 1 in 10 and 1 in 50)

- Wound infection
- Adverse effect on bowel function
- Urinary infection
- Implanted pulse generator device malfunction

Rare (less than 1 in 50)

- None

Preparation before the procedure

A voiding diary will need to be filled in prior to the procedure.

Care after the procedure

Moderate discomfort over the sacrum (lower back) might be experienced: you may also feel some pain over the metal implant site.

We ask that you NOT taking shower or bath (although body washing is fine) until you have been back to see us for review. Try to keep your dressings dry. During the time that you are at home, hygiene is of paramount importance – it is essential that the wound does not get infected. If it does, the lead will have to be removed and the first stage procedure will have to be done again.

Follow up

The wound should be covered with light dressing, and be kept clean. You will be arranged to attend SNM Follow up clinic for regular follow up, re-programming and battery power assessment.

Precautions after implantation

Always inform your doctors that you have a sacral neuromodulator if you are having any kind of surgery or imaging investigation (e.g. MRI scans).

At the airport it is advisable to avoid going through the security screening device. Show the security your sacral neuromodulation identification card and they may let you bypass the system although this is not always guaranteed. If you do have to pass through such devices it is essential you turn the neuromodulator off.

The effect of neuromodulation on pregnancy is largely unknown. Therefore, it is advised that you must have your device turned off by the hospital if you are planning to start a family or as soon as you know you are pregnant.

Remarks

This is general information only and the list of complications is not exhaustive. Other unforeseen complications may occasionally occur. In special patient groups, the actual risk may be different. For further information please contact your doctor.