Service:
Urology

Sacral Neuromodulation

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Introduction

Sacral neuromodulation is a procedure funded by the National Health Service (NHS). It is used to help treat individuals with certain bladder and/or bowels conditions. This leaflet aims to provide you with information of how the procedure is performed, what you can expect before and after the procedure and the contact details of the individuals who can answer any further questions you may have.

Please read this leaflet carefully as it is important that you understand all aspects of it. Should you have any queries or concerns, there is a section at the back for you to write these down and ask the clinician at your next visit.

What is sacral neuromodulation (SNM)?

SNM is an implanted system (a medical device) which can help improve bladder function by sending electrical signals to the nerves that control your bladder and pelvic floor. The device is similar to a pacemaker (used for the heart) and it can help restore the normal function of your bladder.

The device is inserted into the lower part of your back and is made up of a wire and a battery. SNM comes in two stages: a basic evaluation (test phase) and a full system implant (permanent implant).

Who does SNM work for?

SNM is a treatment that is used to treat the following urological conditions:

- **Overactive bladder syndrome/Detrusor overactivity** - this is when you have a strong need to get to the toilet quickly (urgency), increased daytime frequency (needing to pass urine often), nocturia (passing urine at night), and/or being unable to get to the toilet in time and leaking urine (urgency incontinence) before you get to the toilet.
Non-obstructive urinary retention – Non obstructive urinary retention is the inability to empty the bladder with no physical obstruction to the urine flow.

However the device does not work for everyone which is why all patients have to undergo a test phase to see whether they will respond to the treatment. We are hoping the device will significantly improve your symptoms; it may not completely cure them. The success rate is in the order of 75%.

What other alternative treatment options are available?

Overactive bladder (NBT002734) there are other options that you may have already considered, or tried; such as reducing caffeine intake, better fluid management, bladder re-training (learning ways to hold on for longer), physiotherapy and pelvic floor exercises, drug treatment (tablets) such as anticholinergics and Mirabegron, or botulinum toxin injections (into the bladder). There are also major surgical treatments options such as bladder enlargement or bladder replacement using bowel, as well as urinary diversion into a stoma.

Urinary retention – some people may be happy using a catheter (small tube you pass up your water pipe into your bladder) in order to empty their bladder. These can be left in for long periods of time or used intermittently multiple times a day. Another option available is a Mitrofanoff procedure which allows you to insert a catheter into your bladder via a channel created from bowel and coming out to the skin on your tummy.
Who is suitable for SNM?
If you have already tried and failed the conservative and medical treatment or were unable to tolerate them, then you may be suitable for this treatment. Not all patients are suitable for this type of treatment and if this is the case for you, it will be discussed fully in your consultation.

What is the process of SNM?
Initially, you will need to attend the hospital for an outpatient visit in the Urology Department to assess your suitability for this type of treatment. At this visit you will meet a specialist in SNM and they will be able to answer any questions you may have before you consent to this treatment. It is important that you have time to talk about the treatment options available to you and please remember you can change your mind at any time. At this appointment you will be given a 3-day bladder diary, a quality of life questionnaire and urinary symptom questionnaire. This paperwork gives us important information about your bladder function and it is essential you complete it fully and bring it with you on the day of your procedure. Without this paperwork we may not be able to proceed with the procedure.

There are two stages to SNM – the basic evaluation (test phase) and the full system implant (permanent implant) phase.

We will arrange your admission to hospital for these procedures, usually as a day case, but in rare cases an overnight stay may be required. We usually perform the test phase with local anaesthesia in the urodynamics suite but for the implant phase you will need to attend to the operating room (theatre) so you will be seen in pre-operative assessment clinic by the anaesthetic team prior to this.
You will be seen by a small team of individuals with a specialist knowledge, interest, and expertise in bladder problems. We work together so that we can help with the management and treatment of your bladder symptoms.

**Professor Hashim Hashim**  
Consultant Urological Surgeon responsible for the SNM service

**Miss Laura Thomas**  
Clinical Scientist and contact for queries or concerns

**Basic Evaluation Phase**

You will receive your appointment letter and paperwork prior to attending the appointment. Please contact us if you are currently taking any blood thinning medications or have any allergies we need to be made aware of.

This phase can be performed both in theatre and also in urology outpatients in the urodynamics suite and you will be informed of the location of your surgery prior to you attending. If your appointment is in urology outpatients then you can expect to be with us for approximately 2 hours and can leave straight after your procedure.

You will need to stop taking any anticholinergic medications, such as oxybutynin, vesicare, detrusitol, on the day of the test phase and then you can resume taking them after the wire is removed in 1-3 weeks.
The test stimulator kit

The test stimulator has 3 parts (see image)

- White verifier which is connected to you via a white cable and this delivers the stimulation.
- Handheld controller which is a touch screen and used to alter the intensity of the stimulation or to turn the device on/off.
- Thin wire which is inserted into the bottom of your back/spine in the sacrum.

How is the procedure performed?

Before the procedure

You will be contacted by the SNM team who will book your appointment and send out all relevant paperwork that you need to complete and bring with you on the day of your procedure.

If your procedure is being conducted in theatre (you will be advised of this when making your appointment), or we feel it is advised due to other medical conditions, you may receive an appointment for a pre-operative assessment before your admission date to assess your general fitness. You will be screened for a germ (bacteria) called MRSA (Methicillin-Resistant Staphylococcus Aureus) alongside some baseline investigations – blood pressure, heart rate, current medication or tablets prescribed to you by your doctor, and we will also record details of your medical history. Your urine will also be checked for any infection.
During the procedure

You will be seen by the SNM team to check you are still happy to progress with the procedure, answer any queries you may have and get you to sign a consent form. At this point we will also collect all completed paperwork (3-day bladder diary and quality of life questionnaires) from you.

Once this is done you will be asked to undress fully in private and change into a hospital gowns. You will then be asked to lie on your front (face down) on the couch and we will clean your lower back with a special cleaning solution (Iodine or Chlorhexidine). Please inform a member of the clinical team if you have an allergy to iodine or chlorhexidine. We will then use X-ray to mark/draw, with a pen on your back, where we need to insert the thin test wire and local anaesthetic will be injected in this region to numb it. If there is any chance you may be pregnant please inform a member of the team prior to the procedure. The wire will be placed close to your sacral nerves via a small needle. Once this is in the correct position we will use sticky dressings to hold it in place and connect it to a stimulator box (white box in image) which you will wear on a belt around your waist. You will go home with a controller (black handset in image) which will allow you to turn your stimulator on and off.

The device needs to stay in place for the whole test phase. Unfortunately, if the wire comes out there is no way to re-insert it without performing the whole procedure again. You therefore need to keep the dressing clean and dry. If it begins to peel off just add additional dressings or go to your practice nurse to add dressings to it. Please DO NOT remove the dressings that are on at any point as that will pull the wire out.
What happens immediately after the procedure?

On the day of your procedure, your temporary implant will be switched on and you will be taught how to use the controller so that you can obtain maximum benefit for your symptoms and maximum comfort for you. Once you are happy with these instructions and feel comfortable, you will be allowed to leave. When the implant is switched on, you will feel a tapping, pulling, or tingling sensation in the genital (vagina/scrotum) or rectal (anus) area. It should never be painful and the sensations are very mild. People tend to notice these sensations less over time as the body adjusts to the implant. If possible, it is advisable for someone to attend the appointment with you who can drive you home. If this is not possible please let a member of the team know.

Are there any risks or side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after this procedure. The most commonly reported side effects are wound infection, bruising, pain over the wound site, urinary tract infection, difficulty passing urine, change to bowel function or movement of the wire. Occasionally patients will report a slight discomfort in their leg or foot. Should this happen, we advise patients to turn the level of stimulation down and in cases where this isn’t sufficient we may ask you to switch the device off.

Please tell your SNM consultant or scientist if you have any of these side effects so they can decide whether any further treatment is needed.
What should I do once at home?

The test period with the temporary implant is usually about 2 weeks (1-3 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 wire becomes dislodged. Avoid over bending, stretching, or lifting heavy objects and please do not get the dressings wet. During the test phase you need to record your symptoms using a bladder diary so that we can measure how your symptoms have changed. This should be done for a minimum of three days. When you leave hospital, you will be given a discharge summary which holds important information about your temporary implant. If, in the first few days after your discharge, you need to call your GP or practice for any reason or to attend another hospital, please take this summary with you to allow the doctors to see details of your treatment. If you have any problems using your test stimulator, please contact your SNM scientist.

Why do I need to keep a bladder diary?

We will ask you to keep a bladder diary before and during the test phase. It is prudent that you fill this out as it gives us some of the most important information which helps us to understand how your bladder is working on a day to day basis. It will also help to tell us how well the stimulator has worked, or is working, on your bladder during the test phase. You will come back to hospital after about 1-3 weeks to see us in clinic and we will ask you to bring your diary to this visit. The bladder diary can usually be filled out after 48 hours of having the test wire implanted.
Why do I need to fill in questionnaires?
For the same reasons that you are keeping a bladder diary, we will ask you to complete a bladder symptom, and quality of life questionnaire. These questionnaires gives us more information about your bladder symptoms and how much they bother you on a day to day basis, and also how well you think the treatment has worked for you. The questionnaires take about 5 – 10 minutes to complete.

What happens next?
Your follow-up appointment will be made for you to return to the hospital, usually within 1-3 weeks. You will receive this appointment in the post. The information you give us at this time is very important, as it will help decide whether you are suitable for the full system implant. We will check how much your symptoms have improved during the test phase (this will be done by your consultant or clinical scientist). At this stage, if the test phase has been successful you will be offered a permanent implant and the temporary wire is removed in the clinic. You also need to return the handheld controller to us.

Frequently asked questions on the test phase:

Can I work?
Yes you can, except if your work requires intense physical activities. If your job involves driving you can still do so but will need to switch your device off to drive.

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

Can I shower or take a bath?
No – please avoid showering or bathing during the test phase. You need to avoid getting the dressing wet but can wash around this using a wet towel.
Do I need to have my dressing changed?
No. The wire is temporary and held in place by the dressing. There are no stitches to hold it in place so it is important that you do no take the dressing off or allow anyone else to take it off.

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. Without the information provided by the diary it will not be possible to properly assess whether you are suitable for a permanent implant.

Can 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 time.

Will you tell my GP?
Yes, we will keep them up to date with your progress and whether this treatment is suitable for you.

What is a usual level of stimulation?
There is no set level of stimulation that gives the best results, with every patient being different. Please leave the stimulation at a level which is comfortable for you and whereby you can just feel the sensation. There is no benefit on having it on a high level – it is not an endurance test!
Advanced Evaluation (tined lead test)

In some cases where you have not had an optimal test phase, maybe because your wire moved out of position early in the trial, your doctor may decide you would benefit from an advanced evaluation with a tined lead.

An advanced evaluation involves having the permanent tined lead/wire inserted in theatre with you asleep, but once again connected up to an external battery pack as described in the basic evaluation section. The benefit of this is that the permanent wire has small fixation points on it, called tines, which make it less likely to migrate out of position during the trial phase.

The disadvantage of an advanced evaluation is that the wire needs to be put in in the operating room/theatre initially and you will then require a second surgical appointment 2-4 weeks after the insertion to either remove the wire if it has not worked, or attach the neurostimulator (battery) to the wire if you have had a significant improvement in symptoms.

The process of lead insertion and subsequent neurostimulator attachment are outlined in the full system implant section below.

Full System Implant – Permanent Implant

Implant Phase (InterStim™)

If the test stimulation was successful, your doctor and/or clinical scientist will talk to you about having a permanent device implanted and at this stage you will be placed on the waiting list. Once this has been confirmed, you will receive another appointment for your pre-operative assessment before your admission date.
What is an InterStim system?

The InterStim System consists of:

- An implantable nerve stimulator (battery) which is inserted under the skin (just larger than a £2 coin). Usually in the buttock area.

- An electrode or thin wire with barbs/tines 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 implant on or off.

You can ask the SNM team to show you a dummy of the whole device system in clinic.
What happens during the implant?

You will be asked to attend theatre on the day of the implant and most patients will be allowed to go home the same day. The procedure will take approximately an hour and will be performed using local anaesthetic and sedation with you asleep on your front. Rarely will you need to have a full general anaesthetic. The surgeon will also be taking x-rays during the procedure to ensure that the wire is place in the correct position. If you are pregnant or think you pregnant then you need to tell your surgeon as you would not be able to have the procedure done.

Prior to having the implant inserted the surgeon will see you to mark the ideal position of the nerve stimulator on your upper buttock. The mark should be just below your belt line but high enough up so that you do not sit on it when in the seated position. If you have a preference to one side or the other, please let your surgeon know. If you have a tattoo on your back, please be aware that this may get damaged or distorted.

The long-term electrode/wire will be inserted close to the nerves in your lower back (similar to the insertion of the test electrode). Once we are happy the electrode is in the correct position, it is then connected to the nerve stimulator which will be inserted under the skin in the upper buttock where it will be most comfortable and cosmetically acceptable for you. The scar you will get is about 5cm long and the sutures used will be dissolvable.
What happens after the implant?

You will likely feel sore and slightly uncomfortable at the site of your implant following surgery. This is completely normal and we will give you pain killers to reduce this. We also ask that you keep your dressings dry and clean for approximately 5 days after your procedure, which means no bathing or showering, and follow all dressing advice given by the surgical team. The sutures used are dissolvable and therefore do not need to be removed. It is important to keep the site clean and free of infection. You will be sent home on antibiotics for 5-7 days.

Your implantable nerve stimulator will run continuously and the battery will usually last for 5 years, on average. Once at home, you can gradually increase your activity level as your incision heals. You may be aware of the nerve stimulator at first, but this should gradually reduce over time.

The stimulator has many different settings and we will programme the implant for you. We may be able to do this for you on the day of implantation, or alternatively we may need to bring you back 1 - 2 weeks later. Normally your clinical scientist will plan a hospital visit 8 weeks after the implant to check everything is okay. The settings may need to be fine-tuned and sometimes several visits may be required during the first few months. After that we will stay in touch with you over the phone and via face to face follow ups. From time to time we will ask you to complete bladder diaries and symptom questionnaires so that we can monitor your progress. You can contact us at any time if you are having any problems or if you need any advice.

You will be given information on how to look after your permanent implant and how to use the patient programmer. You will also be given your personal ‘InterStim’ implant identification card which we advise you keep with you at all times, as it confirms you have a metal device implanted. You can contact Medtronic directly if you require a second, plastic, identification card.
What happens when the neurostimulator battery runs down?

After several years, the nerve stimulator 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 battery will need to be replaced, but the electrode does not usually need to be changed. This requires a minor surgical procedure to remove the old battery neurostimulator and implant a new one.

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 (InterStim Therapy Clinical Summary):
- Cardiac devices
- Heart defibrillators
- Lithotripsy (e.g. for kidney stones)
- Magnetic resonance imaging (MRI) – NB. some head MRI’s are compatible with the device however there are very strict guidelines from Medtronic regarding the type of MRI that can be used so please contact them prior to any MRI and they can send the details to your doctor who is performing the MRI scan.
- Radiation therapy over the neurostimulator
- Radiofrequency (RF)/microwave ablation
- Ultrasound scanning equipment
- Diathermy – Electrocautery used during surgery. If you are having surgery then you need to tell your surgeon as they may have to having using monopolar diathermy and have to use bipolar diathermy instead.

It is also important that you let your doctor know that you have an InterStim device before you have tests, such as electrocardiogram (ECG) or electroencephalogram (EEG), as the pulses from your nerve stimulation system may interfere with the test. The stimulator may need to be switched off during these kinds of tests. You can then switch it back on again when the test has been completed.
Contraindications and Complications

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.

There are also a few adverse events that have been reported as a result of the implant. These are outlined in the table below.

<table>
<thead>
<tr>
<th>Therapy Related Events</th>
<th>Risk (%)</th>
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<tbody>
<tr>
<td>Failure to improve symptoms</td>
<td>20%</td>
</tr>
<tr>
<td>Need for a replacement/relocation or removal of implant</td>
<td>20%</td>
</tr>
<tr>
<td>Pain at neurostimulator/battery site</td>
<td>15.3%</td>
</tr>
<tr>
<td>New pain, including leg or foot</td>
<td>9.0%</td>
</tr>
<tr>
<td>Lead migration – movement inwards or outwards</td>
<td>8.4%</td>
</tr>
<tr>
<td>Infection</td>
<td>6.1%</td>
</tr>
<tr>
<td>Transient electric shock</td>
<td>5.5%</td>
</tr>
<tr>
<td>Pain at lead site</td>
<td>5.4%</td>
</tr>
<tr>
<td>Adverse change in bowel function</td>
<td>3.0%</td>
</tr>
<tr>
<td>Technical problem</td>
<td>1.7%</td>
</tr>
<tr>
<td>Change in menstrual cycle</td>
<td>1.0%</td>
</tr>
<tr>
<td>Adverse change in voiding function</td>
<td>0.6%</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>0.5%</td>
</tr>
<tr>
<td>Suspected nerve injury</td>
<td>0.5%</td>
</tr>
<tr>
<td>Device rejection</td>
<td>0.5%</td>
</tr>
<tr>
<td>Other</td>
<td>9.5%</td>
</tr>
</tbody>
</table>
If any of these complications happen then you may need the device removed, or the wire or battery resited as it may stop working or it can cause you pain.

**Frequently asked questions on long-term InterStim™ therapy:**

**What is the size of the InterStim neurostimulator?**

Height x length x thickness and weight:

- 4.4 cm x 5.1 cm x 0.8 cm, 22 g

**Will people be able to see it?**

No. The system is placed completely under your skin, in your buttock area, so others will not see it. They may see the scar you have depending on what swimsuit you wear or underwear you have on.

**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 as required
- to show whether the programmer batteries are 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. If it is still uncomfortable please switch it off and contact your SNM team.

**Will the stimulation keep me awake at night?**

No, it should not. If it does, contact your SNM team.
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 SNM team.

Can I have sex after my InterStim system is implanted?
Yes. Sexual activity is not restricted but we would recommend not having sex for about 2-4 weeks until the system is embedded in scar tissue to reduce the risk of it moving.

Will a microwave oven interfere with the nerve stimulator?
Generally not. Most home appliances do not affect the way your nerve stimulator operates.

Can the nerve stimulator battery be recharged?
No. The battery is sealed inside the nerve stimulator. It cannot be recharged without replacing the entire nerve stimulator. Future systems may be rechargeable.

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 nerve stimulator 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. The main concern is that the high pressure may cause the battery to blow up.
Are the sensations felt during the test different than with the permanent implant?
The sensations should be the same or at least similar.

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

Referral Pathway
> Referred to Professor Hashim Hashim
> Discussed and approved at Multidisciplinary Team Meeting
> Contacted by Sacral Neuromodulation (SNM) Team
> Outpatient Appointment in Urology Clinic - Consultant/ Clinical Scientist
> Assessed for suitability - Eligible Yes/No
> If Yes, Test Phase (Stage 1 arranged) - Consent taken
> If No, referred back to original Consultant

Basic Evaluation
> Pre-operative assessment arranged for some patients
> Operation date confirmed
> Day case Admission - Southmead Hospital Bristol
> Test electrode (wire) inserted and started (programmed)
> Test phase starts
> Outpatient Appointment with SNM team - Follow-up approximately 1-3 weeks
> Test phase stops and wire removed, results reviewed
> (Consultant/Clinical Scientist)
Full System Implant

> Pre-operative assessment arranged
> Operation date confirmed
> Day case Admission - Southmead Hospital, Bristol
> Implant (InterStimTM)
> Implant programmed and stimulator started
> Outpatient Appointment with SNM team - Follow-up approximately 8 weeks
> Follow-up visits arranged as required with SNM Team
> Telephone follow-up by SNM Team

References


Space for questions, queries or thoughts
What should I do with this form?

Thank you for taking the time to read this information sheet. If you wish to sign it and retain a copy for your own records, please do so below. If you would like a copy of this form to be filed in your hospital records for future reference, please let your Urologist or Clinical Scientist/Specialist Nurse know. If you do, decide to proceed with the scheduled procedure, you will be asked to sign a separate consent form which will be filed in your hospital notes and you will, in addition, be provided with a copy of the form if you wish.

I have read this information sheet and I accept the information it provides.

Signature  ........................................................................................................

Date  ........................................................................................................

If you or the individual you are caring for need support reading this leaflet please ask a member of staff for advice.