

Implanted neuromodulation system



Information for patients

Urology



PROUD TO MAKE A DIFFERENCE

SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST



Why do I need a neuromodulation implant (NMI)?

A neuromodulation implant (NMI) is used to improve bladder problems which may be in the form of frequency/urgency, including leakage of urine, or retention of urine (unable to pass urine).

What is NMI?

A NMI or neurostimulator generates mild electrical pulses. These pulses stimulate the nerves in your lower back which are associated with bladder and bowel control. The pulses are delivered to the nerves via an insulated wire called a tined lead.

This treatment will not cure your urinary symptoms, however it may reduce them to a more tolerable level.

The implantation of a neurostimulator is done in 2 stages. You initially have a test procedure which will indicate if you will benefit from this therapy. If the test period is successful you will be offered a permanent implant.

What does the test stage involve?

Before proceeding to the test stimulation phase, you will need to complete a 4 day bladder diary and a symptom questionnaire. You will also need to complete a further diary and questionnaire during the test stimulation period. These will help us decide if you should proceed to a permanent implant.

The test period can be carried out in 2 ways; either with a temporary wire known as a peripheral nerve evaluation (PNE) or a 1st stage procedure which involves the placement of the permanent tined lead in the lower part of your spine.

Peripheral nerve evaluation (PNE)

For a PNE a fine wire is put into the bottom of your back in an operating theatre. To do this you will have either a spinal or a general anaesthetic and you will be lying on your front. The wire is placed with x-ray guidance. There will be some wire visible on the outside and this is connected to a small box which contains a battery. The PNE test is temporary and reversible; there is no cutting involved. The test will last for 2 weeks and the wire is removed in outpatients. If successful you will require a further spinal or general anaesthetic, so that you can have a full implant which will involve the placement of the permanent tined lead and the NMI.

1st stage procedure

For a 1st stage test procedure a tined lead is put into the bottom of your back under either spinal or general anaesthetic. The wire is placed with x-ray guidance and, once it is in the correct place, the end is tunnelled across to the top of your buttock. It is then attached to another wire which is tunnelled under the skin. You will have two cuts; one across the top of your buttock which will be approximately 8cm long and one towards the middle of your back which will be 1cm long. The external wire is then attached to a small box which contains a battery. A 1st stage test procedure will last for 2-4 weeks. If the 1st stage procedure is successful you will have the NMI implanted under local anaesthetic.

The majority of test procedures are done as 1st stage procedures because:

- The tined lead is less likely to move than a temporary PNE wire.
- The test period can be extended beyond 2 weeks if necessary.
- The results of the test period should be reproducible with a permanent NMI.
- Only one spinal or general anaesthetic is required.

2nd stage procedure

A 2nd stage procedure only takes place if you have a successful trial. A decision to proceed to a permanent implant is based on your bladder diaries, symptom questionnaires and your thoughts. 50% improvement in your symptoms has to be shown for funding approval.

The 2nd stage involves the neurostimulator being implanted into your buttock. It is inserted under the skin (under the larger of the two wounds you had during the 1st stage procedure). To do this you will have local anaesthetic and you will be lying on your front. The wound is re-opened, the temporary external test wire is removed and the neurostimulator is then connected to your permanent tined lead.

If your 1st stage procedure is not successful you will return to theatre and the tined lead will be removed under a local anaesthetic. When removed there is risk that the lead can break, a small part may be left behind. Risk of this happening is approximately 1%. There is no evidence that a retained piece of lead will cause any future problems.

Will I need to take time off work?

You may need time off work, particularly if you have a manual job. For further advice on this please speak to your consultant or specialist nurse.

What are the risks?

- Swelling
- Bruising
- Infection
- Pain
- Failure of the implant

These risks will be explained further by your consultant and specialist nurse prior to the implant.

What are the benefits?

The aim of neuromodulation is to improve your bladder function.

What are the alternatives?

To stay as you are, using your current bladder management.

There may be alternative surgery you can undertake. If this is an option then your consultant will have already discussed this with you.

Living with a NMI

How long will my NMI last?

Your NMI is powered by a battery which is sealed within the unit. The battery cannot be replaced without replacing the whole neurostimulator. Eventually the battery will become too weak and the neurostimulator will have to be replaced surgically.

How long the battery lasts depends on your stimulation settings and like any battery the more it is used and the higher the settings the faster the battery will run out. The average life of the battery is approximately 4 years but may last as long as 7 years or as little as 2 years.

As the battery runs down the stimulation may feel less intense or feel different. When you feel this change, arrange an appointment with your clinical nurse specialist so that the battery can be checked and arrangements can be made for it to be replaced when necessary.

The NMI is changed under local anaesthetic as a day case procedure.

How is my NMI programmed?

1-2 weeks after you have had your neurostimulator implanted you will attend clinic for it to be activated and programmed. Your clinical nurse specialist will use a programmer to activate and programme your NMI and you will be taught how to use a patient hand-held programmer. You will be provided with written information on how to manage your implant and how to use the patient programmer.

Will I need further surgery?

The battery will need replacing at some point but there are also other situations where further surgery is needed.

- The NMI may need moving if it is causing pain / discomfort. This is generally done under local anaesthetic and is a day case procedure. Moving the implant does not guarantee your symptoms will improve and disconnecting the tined lead can damage it requiring it to be changed also.
- The tined lead can move and it can sometimes stimulate another nerve. If this occurs you may experience pain or discomfort down the back of your leg and into your foot and in some cases you may notice your foot twitching or even curling. This can be uncomfortable and may require the tined lead removing and being replaced. The lead may also need replacing if it stops working either because it has moved or scar tissue has formed around it.
- There is a risk of erosion of either the NMI or the tined lead at the point it was inserted. If erosion occurs, both the NMI and the lead would need to be removed as they would be infected. If you're symptoms have been well controlled it would be possible to put a new implant in at a later date.
- Some patients will require the whole implant removing due to it no longer working for them, pain issues, or other medical problems.

Will I feel pain or discomfort?

After the surgery you will experience some pain or discomfort around the wounds. To help with this you can take some painkillers and you will be given some to take home with you if appropriate.

In the longer term some patients will develop pain / discomfort associated with the implant and this can lead to it being removed or changed. Pain can be experienced:

- Around the NMI site.
- Around the tined lead insertion site.
- Across your lower back.
- As a result of the stimulation, which may be around the NMI, in your lower back or down your leg and into your foot.

If you feel pain you should initially turn the level of stimulation down. If you continue to have problems then change the programme and if this doesn't help, turn the implant off.

Important information

Your InterStim system identification (ID) card

You will be given an ID card, which has important information about your implant.

You should try to carry your ID card at all times.

In case of an accident, this card will tell those looking after you that you have an implanted medical device. Some patients may also wish to use the medi-alert system.

Other medical treatment

When you are having any other medical treatment it is important that you let the key medical person know that you have an implant.

This includes doctors, dentists, nurses, physiotherapists and osteopaths. They may need to contact either Miss Reid or Sister Rachel Simmons for advice if a particular form of treatment is planned.

If your medical care is to involve an operation then your doctor must contact Miss Reid to confirm any special advice required during the operation. There is information in the handbook with special information for other health care professionals.

If you go for an ECG or EEG test, you must **turn off your implant** and inform the person carrying out the test, that you have an implant. Remember to turn the implant back on afterwards.

If you need physiotherapy or associated treatment you must inform your therapist that you have an implant. **You must not have 'deep heating' therapy known as 'physiotherapy diathermy'**. This uses shortwave, microwave radio and ultrasound therapy that can react with your implant and harm nearby tissues including nerves.

Any manipulation of joints around or near your implant may move the cable and cause it not to work.

Electrical stimulation treatments around or near the implant are not advised. Including TENS, muscle stimulators (e.g. Slendertone), etc.

Pregnancy

The device will not change your fertility status. If you do become pregnant, our advice is to **turn the implant off**.

Note: the device does not require removal prior to pregnancy.

Medical imaging

Magnetic Resonance Imaging scanners (MRI) use very strong magnetic fields. In certain circumstances an MRI may be possible of your head but you **must not** have an MRI anywhere else on the body below your neck. There are other imaging techniques, such as CT, which give similar information and which you can have.

Standard x-rays **do not** interfere with the implant.

Ultrasound imaging isn't usually a problem but remember to tell the radiographer about your implant and turn your implant off.

Non-essential lithotripsy (a treatment, typically using ultrasound shock waves, by which a kidney stone or other stones are broken into small particles) is not recommended. If lithotripsy is essential, physicians should not direct or focus lithotripsy within 6 inches (15cm) of the implant. Lithotripsy may damage the implant, which may require surgery to replace it.

Airport and security devices

You **must** avoid certain strong magnetic fields e.g. security detectors, you will need to show your ID card to explain this. Your card is especially important if you travel by air because airport security devices **will** interfere with your implant. You must **not** pass through the airport security detector or screening gate. Show your implant card to the security staff. **Do not allow security staff to pass hand screeners over the implant site.**

Note: these are also found at courts, so remember this if you are on jury service. Show your identity card to the security person and tell them where your implant is. It may be easier to tell them you have a 'pacemaker' but in a different place. Ask that a hand search be done to avoid the security device.

If you do have to go through these security gates, don't panic. Turn your implant off and go through as quickly as possible.

Shop theft security systems have not been shown to cause any problems for patients with this implanted system.

Interference from other electrical sources

In some places, there is a small chance that the implant may react to interference from other strong electrical sources. If this happens, you may notice that the stimulation either increases, decreases or stops. If you experience this, then simply move further away from the source of the interference. This interference will not break the implant, but may be uncomfortable.

Sources that may cause this include heavy industrial machinery motors and strong radio transmitters. In the home, power tools (e.g. drills, electric carving knife, mixer, etc) and mobile telephones may cause interference if held close over the implant.

Before coming across these sources for the first time make sure you are not at risk of injury e.g. dropping hand tools.

Check you are not bothered by interference by getting someone else to turn on the power tool and slowly bring it close to your implant. If you feel interference then try turning your implant **off** and repeat the last interference test. **Remember power tools can be dangerous so you must check that you will not be surprised by any interference before you attempt to use them.**

Should you feel any interference from these or other sources, simply walk away from the source of the interference. This sometimes happens with mobile phones.

You should avoid or approach with care some heavy duty industrial machinery including:

- Electric welding
- Car scrap yard magnets
- Electric trucks

Rarely, your implant may turn on or off if exposed to the high levels of electromagnetic interference often found in industrial equipment. The implant could reset to factory settings if the interference is too high.

Rarely, your implant may be turned off from exposure to high radio frequency signals, you will be unable to switch it back on.

Magnetic bracelets and back support corsets which have magnetic properties (often sold to ease rheumatic pains) have been found to switch off the implant. This has often been unnoticed by the patient until the bladder symptoms start coming back. These should be avoided.

Employment, hobbies and general activities

It is important to discuss your employment and leisure activities during your consultation prior to having an implant. Some activities for example;- arc welding and sub-aqua diving, can cause problems. It is important to limit your risk of falling on your device; so you will need to avoid activities such as horse riding, ice skating, rock climbing etc.

Accidents where the implant has been knocked, bumped, etc

Ideally the implant area should not be knocked, but accidents do occasionally happen. If you experience a bump or a knock to the implant area, e.g. a door handle is opened over the implant area, or you suffer a fall, follow the advice in this leaflet.

The shock of the event may mean you do not feel the implant stimulation normally, e.g. if you fall on a hard surface after slipping on ice. If in any doubt switch the implant off, wait a few minutes and switch it back on.

If the sensation is in the same location and feels similar then there is likely to be no damage.

If the sensation is in a different place, this may be due to bruising or nerve damage from a fall.

If the sensation is in a very different location and feels sharp, then the implant may have been damaged: turn the device off.

The implant is quite well protected inside your body and a significant amount of force is required to cause damage.

Some common questions:

What does stimulation feel like?

Patients normally describe it as a bubbling or tapping sensation in the back passage. It is a similar sensation to the test phase.

Will I be able to increase or decrease the strength of stimulation?

Yes, each patient has a hand held controller to alter the strength within a range of stimulation pre-set by your Clinical Nurse Specialist.

Will I be able to turn the NMI on and off?

Yes, this can be done using the iCON hand controller.

Will the implant show through my clothes?

This is very unlikely due to its implant site (usually the top of the buttock), but you will be able to feel it under the skin.

What happens if the implant stops working?

The sensation of stimulation will stop and you will lose the therapeutic benefit.

What happens if the stimulation sensation changes or becomes painful?

Try turning down the level of stimulation using the hand held controller. If this does not stop the discomfort, turn the implant off.

What does it mean when I can't always feel the stimulation?

Your body and brain can filter out the sensation. You will get used to the stimulation and not always notice it. Remember 'listen to the bladder' and if it is working well, don't panic. Approximately 30% of patients don't feel the sensation.

Is it normal for the stimulation feeling to increase or decrease when I change position?

Generally, stimulation will feel constant. However, due to nerve movement, abrupt movements or changes in posture can make it feel like it is decreasing or increasing.

What if I feel a sharp, jolting stimulation?

Firstly check that you are not picking up some electrical interference. If not, turn down, or off, the level of stimulation to confirm that it is your implant that is causing it. If the pain eases or stops then it is possible that the stimulator is triggering some other nerves.

Does the implant make any noise?

No.

Will a microwave oven interfere with the implant?

No.

How often should you have the implant checked?

After the first programming session, the generator will be checked in 4 to 6 weeks. Then the implant will be checked at 6 months, should no problems occur in the interim period, and then yearly. If, however you encounter any problems contact your Clinical Nurse Specialist or your Consultant.

Who do I contact if I have any technical questions?

Medtronic, the company that makes the implants have a technical support helpline and they can be contacted on:

- **01923 205 101**

Between the hours of 09.00 – 16.00 (Monday to Friday)

Contact information

Royal Hallamshire
Hospital Glossop
Road Sheffield
S10 2JF

- **0114 271 1900**

For **immediate post-operative problems or out of hours emergencies**

please contact the Urology Assessment Unit at the Royal Hallamshire Hospital on:

- **0114 226 5149**

If there are issues you wish to discuss or non- emergency problems please contact the neuromodulation team on the following numbers.

Please remember if your device is causing you a problem, it is sensible just to switch it off (you will have been shown how to do this) until the problem can be dealt with.

Miss Reid, Consultant Urological Surgeon

Mr Mangera, Consultant Urological Surgeon

- **0114 271 2097** (secretary)

Sister Rachel Simmons, Clinical Nurse Specialist

- **0114 271 1774**

Urology Assessment Unit

- **0114 226 5149**



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