PainScience

Neuromodulation

Any surgical or invasive procedure carries risks. Before proceeding, you should seek a second opinion from an appropriately qualified health practitioner.

Neuromodulation

What is neuromodulation?

Neuromodulation is any technique that modifies nerve function. This includes electrical as well as pharmacological (drug) methods. In current pain medicine usage, this means any electrical technique that reduces pain.

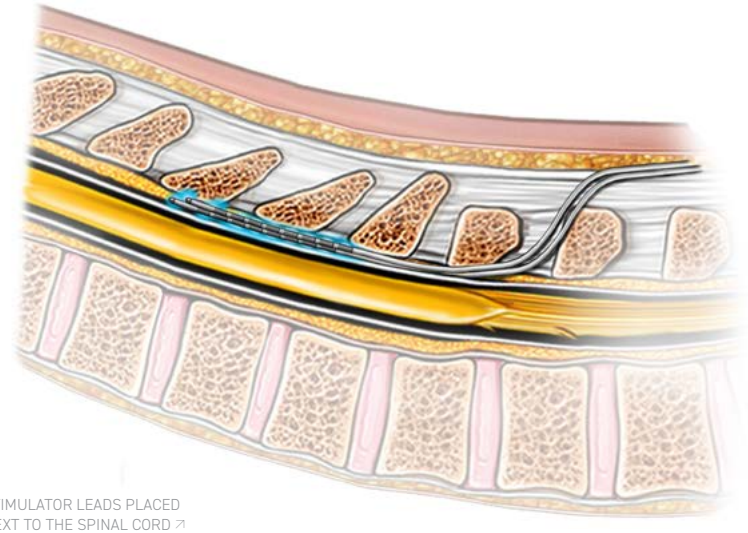
The most commonly used form of neuromodulation in Australia is Spinal Cord Stimulation, although this technique can be used on pain nerves in other parts of the body.

This involves inserting a "lead" which is a thin, flexible wire with electrical contacts into the space surrounding your spinal cord (see below), or sometimes other nerves in the body. This lead is connected to a small battery which is implanted inside your body, similar to a pacemaker (see page 7).

This battery then sends electrical signals to the nerves, which change how they receive and interpret pain signals. Depending on which battery is used, and other factors; they can have a lifespan between 5-25 years before needing to be replaced.

Other uses of this type of treatment (apart from treating pain) include deep brain stimulation (DBS) treatment for Parkinson's disease, and sacral nerve stimulation for pelvic disorders and incontinence.

Like all other available pain treatments, Neuromodulation is a tool to help better manage your pain, rather than a "cure" for your pain. In the right patient, used in the right way, it can lead to a significant improvement in your pain and function.



STIMULATOR LEADS PLACED NEXT TO THE SPINAL CORD ↗

Will I benefit from this?

This can depend on several factors, which your doctor can discuss further with you.

The types of pain that have the strongest evidence for neuromodulation include:

- Pain after spinal surgery.
  - » With appropriate selection, about 80% of people will get at least a 50% reduction in their pain level. This still means that not every person gets significant benefit, but many do.
- Pain from Complex Regional Pain Syndrome.
- Pain from poor blood supply that cannot be fixed with surgery (this is typically small vessel disease too small to stent).
- Painful Diabetic Neuropathy.

Neuromodulation can work for other types of pain not listed above, but the evidence base is less clear. This is mostly because it has not been well tested in clinical trials in other areas.

Even with the best evidence, it is not always clear who will benefit from this treatment. For this reason, we generally look at less invasive options for managing your pain, such as medications and rhizotomy, although this must be tailored to the specific pain you have.

PainScience also recommends that you are seen and have input from our specialised Allied Health team members, which typically includes Occupational Therapists, Physiotherapists, and sometimes Clinical Psychologists.

Some of these team members may be able to help your pain without relying on more medications or treatments. Other may be able to help get your body and mind into a better position, increasing your chances of having a good response to Neuromodulation.

If these treatments are not allowing enough improvement in your pain and function, the next step is to do a temporary trial of neuromodulation, and if this is successful, proceeding to a permanent implant. See below for more details about this process.

What are the risks?

Since Neuromodulation is a complex and invasive procedure, there are risks (both for the trial and the permanent implant). Generally speaking these are rare, and are mostly minor in nature. However there are some very rare, but serious complications which your Specialist will counsel you on specifically.

Minor risks:

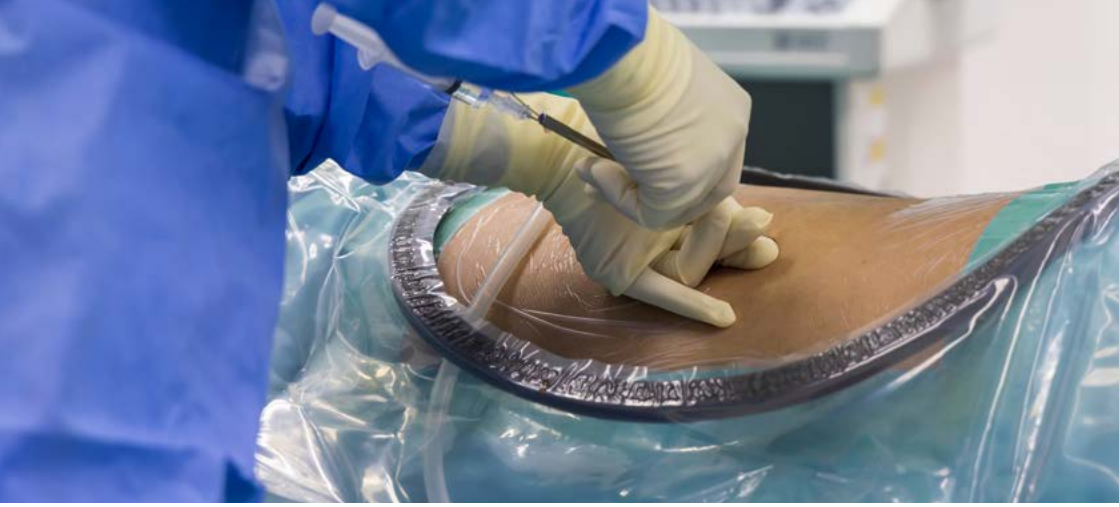
- Transient pain and bruising around the site of the procedure and the battery.
- Irritation to the skin from dressings/sutures/adhesives.
- Minor infection that usually settles with antibiotics.
- The treatment may not work (which is why we have a fully reversible trial).
- Lead migration that requires minor repositioning.
- Lead faults that could require replacing the leads.

More serious (but rare) risks:

- Bleeding or infection around the leads or battery – this might lead to removal of the system, and may require further imaging or input from other specialists.
- Significant damage to the nerves or spinal cord – this is an extremely rare complication.

Before the trial

Your doctor will usually put you in touch with a Representative/technician from one of the companies that manufacture and support the devices (there are several companies and devices, and we will choose which is appropriate for your specific type of pain). This Representative will contact you to discuss the treatment, and its potential use in your situation. You will meet this Representative several times during this process, as they will be responsible for programming the device during the trial and implantation periods.



The Trial

The trial itself requires placement of trial leads, which is done under sedation, in an operating theatre, and may require your feedback during the procedure. This is often similar to how epidural catheters are used for childbirth, although the specifics of this depend on the location of the trial leads specific to your pain area. You will usually have an overnight stay in hospital following this.

A small external device is worn during the trial phase to deliver the treatment. It is generally taped to you.

Some of the restrictions during the trial period may include:

- You will be wearing an electrical device, and it cannot be immersed or exposed to water.
- Avoiding excessive bending/stretching/lifting/twisting (these movements may cause your leads to move, reducing the efficacy of the trial).

You will need to wear the trial leads for a period of weeks, and the device programming may need to be adjusted during this period (in the clinic).

The aims of the trial phase are to:

- Establish if this type of device can help reduce your pain.
- Determine what sort of therapy will work for you.

During this trial phase, you will see the Practice Nurse at least once a week, to check the procedure site for infection, as well as possibly adjusting your device settings with the company technician. We may ask you at regular intervals about your pain and function, as well as asking you to fill out some questionnaires to measure these things.

At the end of the trial, the leads are removed (in the clinic) to allow recovery and healing.

You will then have an appointment with your Specialist (and sometimes other members of the Multidisciplinary Team) to look back over your trial and see if it was successful. If you have a successful trial, we may then proceed to the permanent device implantation if your Specialist is happy to proceed.

The permanent device

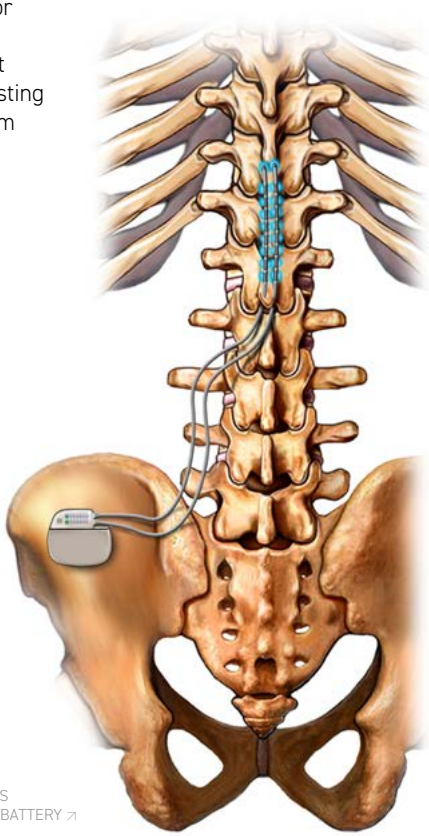
If you have a successful trial, then you may proceed to a permanent device implantation. This is generally done several weeks after the trial is finished to allow recovery from the trial.

The insertion is generally done under full anaesthesia, and it involves making surgical incisions to place the device in a pocket under the skin, as well as to secure the leads so they do not move.

Although the device can be turned on at any stage after insertion (typically once you have recovered from the anaesthetic), the leads are still at risk of moving for many weeks after the operation. You will need to avoid doing anything that involves heavy lifting, bending or twisting for this period whilst you recover from the surgery.

How much does this procedure cost?

Currently PainScience is only able to provide this service for patients with Private Health Insurance. We do not charge any out-of-pocket expenses for the inpatient procedure. However there may be an associated nursing and management fee to cover consumables, dressings, and the time our nurses will spend with you. This will be discussed further during your appointment.



STIMULATOR LEADS
ATTACHED TO THE BATTERY ↗

How to Prepare for your Trial

Our main focus during the trial is to give you a chance to try out the treatment in a fully reversible setting. Factors that can interfere with this include movement of the trial leads, and infection.

Any infection of the trial device would mean ending the trial early, so most of the following advice is about reducing the risk of infection.

- Our nurse will contact you prior to the trial to arrange for swabs of your nose, looking for bacteria that can cause serious infection.
- We will provide you with a body wash, to be used for 2 days before the trial.
- We will provide you with a cream, to be applied in your nose, to help eradicate certain bacteria.
- We ask that you pay particular attention to your hygiene in the days leading up to your procedure, including keeping fingernails trim and clean.
- Ensure that your dental hygiene is adequately maintained, as any signs of infection/caries could be a potential source of infection.
- If you are diabetic, good sugar control significantly reduces the risk of infection.
- Reducing/ceasing smoking will also significantly reduce the risk of infection.

There will be physical restrictions on what you can and can't do during the trial period. Please ensure that if this is a problem for you, that you have adequate support during this time.

Restrictions during the trial period (usually 2-3 weeks):

- No excessive bending/ stretching/twisting.
- No lifting anything heavier than 2.5kg.
- No lifting your arms overhead.
- No sudden sitting/lying down movements.
- No showering.

How to prepare for your Permanent Device

The same process as above will be followed. In addition to this, the period of physical restriction will be longer (see below).

After this procedure, you will be left with 2 surgical incisions (one for the leads, and one for the battery). You will also now have a permanent implanted device under your skin. This can be associated with a temporary amount of pain. You may require extra medication to manage this pain for a period of time.

You will need to be extra vigilant during the recovery from your implantation procedure, for any signs of infection. We will arrange regular review with our nurses to monitor your wounds. Usually this will coincide with seeing the representative from the company which manufactures your device.

The same physical restrictions that apply during the trial period, will also apply after your device is implanted. **This can be for up to 12 weeks**, and is to allow your body to heal, and for the device to naturally fix into place.

Living with a Neuromodulation system

The purpose of this treatment is to allow you to live as normal a life as possible. It is intended to help manage (not cure) your pain.

However, there are some factors that you must be aware of (your company Representative can answer these questions more specifically):

- Some devices require regular charging, and may become faulty if not properly charged.
- **Not all devices are compatible with MRI machines** (this is less of an issue with newer technology, but if this is a concern, please discuss carefully with your doctors).
- **Not all devices/therapies can be used while driving.**
- You may be required to declare the device when passing through security checkpoints (such as in an airport).
- If you require surgery in the future (for any reason), you will need to inform your surgeon and anaesthetist about the presence of the device.

IMPORTANT

Any new weakness or numbness in arms or legs, difficulty with bladder or bowel control, severe pain, shortness of breath, or fever, should be reported immediately to the PainScience clinic during office hours on **(08) 6205 7104** or **0480 152 255.**

If the pain clinic is not immediately contactable, please go to the nearest emergency department (if possible Joondalup Health Campus) as soon as possible.

Please call an ambulance on **000** if you are seriously concerned.

PainScience

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