Neurostimulation

What is neurostimulation and how does it work?
Neurostimulation is a proven, effective, reversible treatment alternative when other pain treatments provide unsatisfactory relief. Results may vary from patient to patient. Neurostimulation uses a small system, surgically placed under the skin, to send mild electrical impulses to the spinal cord or to a peripheral nerve via a special medical wire. These impulses block the pain signals from reaching the brain. Because neurostimulation works in the area where pain signals travel, its electrical impulses (which are felt as tingling) can be directed to cover the specific sites where you are feeling pain. Neurostimulation can decrease the need for pain medications.

Will I hear or feel the neurostimulation system inside me, and will people notice it?
The neurostimulator is usually implanted in the lower abdomen or buttock, where it is most comfortable and least visible. The device does not make any noise. It may be felt as a small bulge under your skin but it does not normally show through your clothes.
The device ranges from 61 millimetres (mm) by 76 mm, to 56 mm by 61 mm or 49 mm by 65mm, depending on which system you receive. It is 15 mm to 10.16mm thick and weighs 42 grams (g) to 83 g.
If your doctor recommends a radio-frequency system, the transmitter will be visible and is usually worn on the belt like a pager. In addition, an antenna must be placed on your skin for the system to work.

Will I be able to adjust my neurostimulation system?
The totally implantable system has a patient programmer (similar to a computer mouse) that allows you to adjust the stimulation produced by the neurostimulation system. In the external system, a transmitter similar to a pager is used to adjust the system. This transmitter, with an antenna, needs to be worn at all times for the system to work.

Is it normal to feel pain for weeks after the procedure? What can help?
You may experience pain at the neurostimulator or receiver implant site for two to six weeks after the surgery. This pain, caused by developing scar tissue, happens with any type of implant surgery. It is your body’s natural response to the implant and the pain will begin to disappear once the scar tissue forms. Your doctor may prescribe ice or medication to relieve the pain caused by surgery, along with antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, you should notify your doctor.

Neurostimulation post-surgery care
Following your surgery, you will probably feel some discomfort at both the incision site in your back and the neurostimulator or receiver site in your abdomen/buttock. ‘Incisional pain’ feels like a bruise, but it heals quickly. You may also experience pain at the neurostimulator or receiver implant site for two to six weeks after the surgery. This pain, caused by developing scar tissue, happens with any type of implant surgery. It is your body’s natural response to the implant. Once the scar tissue forms, the pain will begin to disappear. With instructions from your doctor or nurse, you may use ice to reduce the swelling and pain for 24 hours after surgery. Your doctor may also prescribe medication to relieve the pain caused by surgery, along with antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, you should notify your doctor.
Your doctor may recommend that you restrict your activity for several weeks. During the first six to eight weeks following the implantation, you will need to avoid lifting, bending, and twisting movements. This allows time for scar tissue to form and anchor the lead. After the initial six to eight weeks you should continue to use some caution with these types of movements.
Once your incision has healed, the neurostimulator site requires no special care. However, you should talk to your doctor if you perform any excessive or repetitive activities that may damage your neurostimulator or its lead(s). After your implant procedure, it is important to follow your doctor’s instructions for post-surgery care and activities and keep all your scheduled follow-up appointments.
Some patients build up a tolerance to neurostimulation, and the effect is reduced or lost. The reasons are not clearly understood. You should contact your doctor if you experience changes in stimulation (tingling) or pain.

**What are the selection criteria for choosing either an external radio-frequency (RF) system or a totally implantable (Primary Cell) system or a Rechargeable Battery System?**

RF and implantable neurostimulators (Primary Cell and Rechargeable) each have their relative advantages and disadvantages.

**RF systems**
- May have a longer life span.
- are simpler to program and no special equipment is needed.
- are appropriate for patients who might find it difficult to return to a physician’s office for programming.

They are however considered less ‘user friendly’ in that the patient must apply an antenna to the skin at all times when therapy is required.

Some patients prefer the ease with which adjustments in some programming parameters can be made with an RF system without the need to carry a hand-held programmer.

**Implantable neurostimulators (implanted pulse generators or IPGs)**
- are appropriate for patients who do not want an external transmitter.
- are appropriate for patients who are sensitive to the adhesive patches required by the RF system.
- are appropriate for patients who are physically active, so that an external transmitter or antenna would be cumbersome to keep in place.

IPGs are generally considered more patient friendly, however the life span of the battery is determined by the amount it is used and the programmed settings.

Some systems may be appropriate for patients with single-lead systems, or patients with dual-lead systems who achieve good pain relief with low parameter settings and identical settings for each lead (in which case the IPG is used with a bifurcated extension). Other systems may be appropriate for patients with dual-lead systems who achieve good pain relief with low parameter settings and individually programmed settings for each lead.

**Rechargeable battery systems** are the latest technology available. The power source (battery) is rechargeable in much the same way as one recharges the battery on a mobile phone. Commonly, patients will recharge the implanted battery every month or two, recharging takes approx 4 - 8 hours and patients can use the system whilst recharging. The life span of the implanted battery is 9 years irrespective of how much it used or how it is programmed.

**Rechargeable battery systems** offer the following benefits:
- Life span is not influenced by usage or programmed settings
- The device can support leads with up to 16 electrodes (previous systems offered a maximum of 8). This means that it is easier for the doctor to achieve coverage of a patient’s pain with parasthesia (the tingling sensation which is designed to replace pain).
- More programs can be enlisted. This allows the doctor to customise the system to individual patient needs whilst again ensuring that parasthesia coverage is optimal.

**How long will my totally implantable neurostimulation system last?**

This time varies depending on the model of neurostimulator, how many hours a day the system is used, the intensity of the stimulation, and individual patient differences. The screening trial process will help you and your doctor decide whether an internally powered or externally powered system is best for your battery requirements.
What can cause a lead kink, fracture, or dislodgement?
You should know where your lead is placed and keep in mind which movements may put strain on the lead or on the stitches that hold the neurostimulator in place.

• Leads become dislodged primarily because of certain motions or sudden or repetitive movements.
• Exercise and other activities should be approached with caution.
• Excessive or repetitive bending, twisting, bouncing, or stretching can move or kink the lead.
• A lead can kink or fracture by rubbing on your bones.
• Although it is made of flexible and durable materials, your lead is still subject to wear. Therefore, seemingly harmless or repetitive movements can cause unseen damage over time, eventually causing dislodgement. This damage may then require surgery to repair or replace the lead.

What is Complex Regional Pain Syndrome?
Complex Regional Pain Syndrome (CRPS) is the term used to describe the painful syndromes formerly known as Reflex Sympathetic Dystrophy (RSD) and Causalgia. CRPS usually develops in the foot or hand after an injury (such as a broken bone) or surgery that may involve nerve damage. The overriding symptom is extreme pain—frequently described as burning. Other symptoms can include sensitivity to touch, skin changes, swelling, weakness, and decreased function of the hand/foot.

Can I have diathermy?
No. Diathermy is a treatment that promotes the healing of tissue and reduces pain through heating tissues to reduce swelling and stiffness of joints and muscles. Diathermy (deep heat treatment and non deep heat treatment) should not be used with any implanted neurostimulation systems because the risks outweigh any possible benefit.

At least three forms of diathermy are in use in the medical community: radio-frequency or shortwave diathermy, ultrasound diathermy, and microwave diathermy.

Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death. The exact nature of the tissue or nerve damage depends on the location of the stimulation implanted electrodes and the extent of the exposure to diathermy treatment. Diathermy is further prohibited because it can damage the neurostimulator’s system components. This could lead to a loss of therapeutic effect or the need for surgery to revise or replace components. Injury or damage could occur whether the neurostimulation system is turned on or off.

This warning applies to any use of diathermy, regardless of where the diathermy treatment is targeted on the body. This warning also applies regardless of whether the neurostimulation system is turned on or off during diathermy treatment, and if any individual component (lead, extension, neurostimulator) of the neurostimulation system remains in the body.

You may want to consider obtaining a medical alert bracelet that lets emergency medical personnel know you have a neurostimulation system and therefore should not have diathermy. Contact your doctor for instructions on how to obtain a medical alert bracelet.

Can I have an MRI?
If you have a fully implantable neurostimulation system, you should not have magnetic resonance imaging (MRI) because of the potential effects of exposure to the strong electromagnetic fields produced by MRI. If possible, a CT scan should be used instead.

During MRI, the following effects may happen:
• The system may move, twist, or dislodge.
• Tissue surrounding the lead or neurostimulator may be damaged because the system was heated.
• A temporary increase in stimulation may feel like a jolt or shock.
• The neurostimulator may be reset to factory settings so stimulation is off (zero amplitude, stimulation off). This would need to be reprogrammed by your physician.
- Neurostimulators with reed switches, (which turn the device ON or OFF) may be activated. A magnet or patient programmer could return the neurostimulator to its original state.
- The implanted neurostimulator may cause distortion that may make the MRI image unusable, especially for areas near the implanted system.

How will I know when the battery on my implantable neurostimulation system needs to be replaced?
Your doctor will be able to check the state of the battery in your neurostimulation system during regularly scheduled follow-up visits.

### How can I extend the battery life?

The battery life varies by patient and depends on the model of neurostimulator, how many hours a day the system is used, the intensity of the stimulation, and individual patient differences. After the battery is depleted, you will need surgery to replace the implanted neurostimulator. There are several ways to maximise the battery life of a non-rechargeable neurostimulator. They include:

- Using cycling mode (if applicable and appropriate for the therapy) and programming the shortest ‘ON’ time.
- Turning off the neurostimulator when therapy is not needed, such as when sleeping.
- Using the lowest effective settings, especially the rate setting.
- Using the minimum number of active electrodes (your doctor can help you determine this).

### When should I call my doctor about my neurostimulation system?

Consult your doctor when:

- You experience additional/unusual pain.
- You notice unusual changes in the quality of your stimulation or when you experience no sensation.
- You are increasing stimulation more often than normal.
- The stimulation pattern changes.

Otherwise, visit your doctor according to your follow-up schedule. A typical follow-up schedule is once every six months, although initially equipment may require more frequent adjustments. Your doctor may want to see you more or less frequently, depending on your situation.

### Should I be concerned about long-duration airplane flights?

Neurostimulators should not be affected by long-duration airplane flights.

### Can I sky dive? What about other high altitude activities such as skiing or hiking in the mountains or flying in a non-commercial airplane?

High altitudes should not affect the neurostimulator. However, it is recommended that you consider what movements are involved in the planned activity and take precautions to avoid putting undue stress on the implanted system. You should be aware that skydiving may cause lead dislodgment and/or fractures from sudden jerking (such as when the parachute opens) which may require surgery to repair or replace the lead.

### Can I scuba dive?

Scuba diving BELOW 10 metres (33 feet) of seawater (2.0 atmospheres absolute or 29.4 pounds per square inch absolute) is NOT recommended. Neurostimulators operate normally down to 10m of sea water, however, they may begin to deform at greater depths. Damage to the neurostimulator may require surgery for replacement. You and your physician should discuss the safety concerns with diving, as there may be health issues other than possible device damage.

### Can I go in a hot tub, steam room or sauna?

Yes, but if you feel any localised heat sensation around your neurostimulator, you should get out of the hot tub, steam room or sauna. Elevated temperatures may cause a very slight reduction in battery life.
### Can I work on an automobile?

If you experience any discomfort or problems in the area of your implanted device while working on an automobile, you should discontinue the activity immediately and call your doctor. Your device may require reprogramming. Experience indicates that automobiles do not produce strong enough EMI fields to affect these devices.

Please note that if you are working on an automobile, excessive or repetitive bending, twisting, or stretching, can cause the lead to dislodge or fracture. This may also change or increase the intensity of stimulation which can cause a potentially dangerous reaction resulting in contact with moving parts of the automobile. Overextension of the torso may cause dislodgment.

It is recommended that you talk to your doctor to find out what type of movements would put strain on the implanted system. Certain movements can cause the electrode to move off the target and you could lose stimulation all together, or lose optimal stimulation.

### Can I use power tools?

You are advised against using potentially dangerous equipment unless your neurostimulator amplitude is programmed to ‘0’ and turned off. Most power tool motors create a weak electrical field, so some neurostimulators with the magnetic switch enabled may turn on and off. Some power tools that operate from DC electrical power or batteries, or have permanent magnets, may activate the reed switch if brought close enough to the neurostimulator. Other neurostimulators will not turn on and off because of an electrical field.

With all neurostimulators, there is the potential for a change in position or certain movements to cause a change in stimulation, which could cause an unexpected reaction.

### Can I use a computer while my neurostimulation system is on?

Yes. Your neurostimulation system will not cause any damage to your personal computer and will not be affected by the computer.

### Can I go through theft/security detectors at stores, libraries, or airports?

Use care when approaching security detectors (such as those found in airports, libraries, and many retail stores) because these machines can cause inappropriate or additional stimulation if you pass through them. If the electrical stimulation is too strong (which may occur when passing through security devices) or if the stimulation is turned up too high, the tingling (paraesthesia) may feel like a shock.

Present your patient identification card to security personnel for clearance. It is advisable to approach the centre of the security device and walk slowly. If you feel uncomfortable stimulation, back out of the security device immediately without changing body position. Turn off the neurostimulator, move quickly through the security device, and turn it on again.

Many newer models of stimulator are not affected by such devices.

### Can I be around industrial equipment?

In general, you should be aware that working with potentially dangerous equipment, driving, or being in a potentially dangerous environment may always be hazardous. If your stimulation changes (increases or decreases), this may cause an unexpected physical reaction or a return of your symptoms.

Some neurostimulators with the magnetic switch enabled may turn on or off when magnets are encountered. This type of switch can be deactivated using the physician programmer to eliminate this potential. For other neurostimulators, turning the stimulator off and the amplitude to ‘0’ prior to driving or operating any other potentially dangerous equipment is recommended, because of the potential for positional changes in stimulation that could cause an unexpected reaction.

With all implantable battery-powered neurostimulators, there is a potential for the device to reset to factory settings if the interference is too high. If this occurs, the device will not deliver any stimulation even when turned on because the amplitude limit will be reset to ‘0’. If this occurs, the device will
Can I arc weld?
It is recommended that the stimulator be turned off and the amplitude set to ‘0’ (if appropriate for the therapy) prior to operating any potentially dangerous equipment. Caution is advised when using arc welders, as they emit large amounts of EMI (see What is EMI/RFI?). It is possible that the magnetic fields generated by arc welding could momentarily induce a voltage into the neurostimulator lead system - and you may feel this as a shock or jolt even when the neurostimulator is turned off.

Can I use magnetic pain products?
Some fully implantable neurostimulators have a magnetic reed switch in them, which is activated by magnetic fields of approximately 10 Gauss or stronger. Some of the magnets in pain products are of sufficient strength to activate this reed switch (turning the device ON or OFF) if they are placed close enough to the neurostimulator. Most magnets, if kept 25 or more centimetres from the neurostimulator, should not be strong enough to activate the reed switch. Because magnetic force cannot be seen, heard or felt, your neurostimulator could turn from ON to OFF (or vice versa) unexpectedly.

Magnetic mattresses, blankets and wrist magnets typically come into close contact with the neurostimulator. They are therefore more likely to cause this type of on/off activation. Some other neurostimulator models do not have a reed switch, so they will not be affected by magnetic pain products.

Can I use a TENS unit?
The neurostimulator should not be affected by the therapy pulses from the TENS unit. However, since there are many different types of TENS units, and since they have not all been tested with neurostimulators, you should use caution and notify your doctor if you feel that the TENS unit may be interfering with your neurostimulator.

Can I use a bone growth stimulator?
There are two basic types of bone growth stimulators, external and implantable, which may use several different types of fields (electric, magnetic and ultrasonic). There are no known risks from bone growth stimulators. However, with the implantable type, the programming head of the bone growth stimulator should be kept at least 10cm (4 inches) away from the neurostimulator to minimise any potential interference. Both types of bone growth stimulators create an electromagnetic field, which could cause activation of the magnetic switch in some models of neurostimulators with the magnetic switch enabled. This would cause your device to turn on or off. If this occurs and causes discomfort, consult your physician to see if any adjustment can be made to minimise this effect.

Can I have radiation therapy?
Using radiation therapy in the vicinity of the neurostimulation system is not recommended. Radiation therapy can cause damage - that can be cumulative after repeated exposures - to the electronic components of a neurostimulator. If you require radiation therapy, lead shielding should be placed over the neurostimulation system to help prevent damage to the neurostimulator. The neurostimulator function and programmed parameters should be checked after exposure to radiation therapy. Surgery may be required to replace neurostimulators that are damaged during radiation treatment.

Can I have lithotripsy?
It is advised that lithotripsy not be directed towards or focused within 15cm (6 inches) of the neurostimulator. Surgery may be required to replace neurostimulators that are damaged during lithotripsy.

Can I have defibrillation?
When a patient is in ventricular fibrillation - a potentially fatal heart problem - the physician’s first consideration is patient survival. It is recommended to not place defibrillation paddles near the neurostimulator. When external defibrillation is necessary, the physician can minimise the current flowing through the neurostimulator and lead-extension system as follows:
Position defibrillation paddles as far from the neurostimulator as possible.

Use the lowest clinically appropriate energy output (watt seconds).

Confirm neurostimulation system function after external defibrillation.

Defibrillation may also cause induced currents in the lead/extension portion of the neurostimulation system that could be hazardous or cause further injury. You may want to consider obtaining a medical alert bracelet that lets emergency medical personnel know you have a neurostimulation system. Contact your doctor for instructions on how to obtain a medical alert bracelet.

**Can I have cardioversion?**

If you need cardioversion for atrial fibrillation, the physician can usually plan the best approach to limit potential damage to your neurostimulator. It is recommended to not place cardioversion paddles near the neurostimulator. When cardioversion is necessary, the physician can minimise the current flowing through the neurostimulator and lead-extension system as follows:

- Position paddles as far from the neurostimulator as possible.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function after cardioversion.

**Can I use a tanning bed?**

Yes, but if the area around your neurostimulator feels warm while you are in a tanning bed, you should get out.

**Can I drive a car with my neurostimulation system?**

If you have a neurostimulation system to treat chronic pain, turn your stimulator OFF to ensure safe operation of your vehicle. Do not drive or use equipment with your stimulator on. If you are driving a vehicle or operating power tools, a change in stimulation could cause you to lose control of your vehicle or equipment.

You should discuss your medical condition with your specialist clinician before driving.

**Can I have electrocautery?**

Special precautions need to be taken before using electrocautery. If the electrocautery currents enter the neurostimulation or lead system, one or more of the following effects are likely:

- Heating of the electrode contacts at the end of the lead may cause tissue injury surrounding the lead or neurostimulator.
- Damage to the neurostimulator causing a change in patient’s symptom control, or the need for surgery to replace the device.
- The neurostimulator may have its stimulation output reset to ‘Off’, causing a change in your symptom control. If this occurs, reprogramming will be required using the physician programmer.

Based on tests to date, if the doctor determines that electrocautery is necessary, follow these precautions:

- Turn off the neurostimulator before using electrocautery.
- Only bipolar cautery is recommended.
- Do not use high voltage modes if unipolar cautery is necessary.
- Keep the power setting as low as possible.
- Keep the current path (ground plate) as far from the neurostimulator, extension, and lead, as possible.
- Do not apply unipolar cautery if any part of the neurostimulation system or lead is between the active cautery probe and the return ground plate of the electrocautery device.
- Confirm neurostimulator function after surgery.
Can I have diagnostic ultrasound?
Do not place the ultrasound instrument head within 15cm (6 inches) of the neurostimulator, lead and/or extension. Several patients and physicians have reported that a neurostimulator did not work following an ultrasound, which required surgery to replace the device.
If possible, turn the amplitude to zero prior to the ultrasound and then turn the neurostimulator off. For externally powered neurostimulators, remove the transmitter and antenna. If you suspect your device has turned on or off during the ultrasound, check your therapy status with your patient programmer or contact your physician.

Can I have a pacemaker or an implantable cardioverter defibrillator (ICD)?
In many cases, both the pacemaker and the neurostimulator can be mutually compatible. Appropriate testing, placement and programming of the devices can help in achieving mutual compatibility. Under certain conditions, it is possible that the pacemaker or ICD could detect the output stimuli from a neurostimulator. This would cause inappropriate pacemaker or ICD operation during the time the stimuli are detected and possibly cause the delivery of an inadvertent shock. Since there are so many possible combinations of devices and individual patient considerations, your physician and your cardiologist should discuss your particular situation.