



# MEDTRONIC PAIN THERAPIES


Neurostimulation Patient Information



**Medtronic**

*Alleviating Pain · Restoring Health · Extending Life*





*Every 5 seconds—somewhere in the world—another person’s life is improved by a Medtronic product.*

At Medtronic, with over 30 years of collaboratively working with physicians and patients in neurostimulation and drug delivery technologies and more than 250,000 pain patients implanted—we set the standard for quality, safety, and reliability in pain management technologies.

If you are receiving neurostimulation therapy for pain management, you may be interested in our *Living Well* newsletter. *Living Well* is a periodic email newsletter designed for people who are using a Medtronic implantable device to treat chronic pain. To register for the newsletter, visit our website at [www.medtroniclivingwell.com](http://www.medtroniclivingwell.com).



## How to use this booklet

Please read each section carefully.

This booklet is not meant to cover all aspects of the product, your surgery, or therapy. Talk with your doctor before making any decisions about your treatment options.

## Who can I call with additional questions?

Consult your doctor with any questions you may have about your neurostimulation system. If you have additional questions, please contact Medtronic Patient Services at 1-800-510-6735.

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### What is neurostimulation?

Neurostimulation uses a system that is surgically placed under the skin to send mild electrical impulses to the epidural space near the spinal cord or to a peripheral nerve. The tiny electrical impulses are delivered through a lead (a special medical wire) and block the pain signal from reaching the brain.

### What are the benefits of neurostimulation?

Because neurostimulation works in the area where the pain signals travel, electrical impulses (which are felt as tingling) can be directed to specific sites where you are feeling pain. Neurostimulation can give effective pain relief and decrease the need for medications.<sup>1,3,5</sup> In addition, this therapy does not work by causing permanent changes to the spine or nerves.<sup>4</sup> The surgery to place the implant is reversible and minimally invasive. Typically, patients who have success with neurostimulation may experience a 50 percent or greater reduction in their pain and improved ability to perform daily activities. You have the opportunity to experience how neurostimulation will work for you during the screening test.

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*THE NEUROSTIMULATOR SENDS MILD ELECTRICAL IMPULSES DIRECTLY TO THE SPINAL AREA BLOCKING PAIN SIGNALS FROM REACHING THE BRAIN.*

## What does neurostimulation feel like?

The sensation felt with neurostimulation varies from person to person, but most report a tingling sensation in the area of their pain.

## Does neurostimulation completely eliminate pain?

Neurostimulation does not eliminate the source of the pain, so the amount of pain reduction varies from person to person. Typically, people who find the therapy helpful may experience greater than 50 percent pain relief.<sup>1-6</sup> Neurostimulation requires a strong patient commitment to effectively control pain. Learning to operate the neurostimulation equipment and participating in other prescribed therapies, such as physical therapy, help ensure success.

## Changes in sensation due to body positioning

Because neurostimulation is positional, some patients may feel more changes than others. However, in general the sensation of stimulation remains constant. Some people may feel changes in sensation with sudden abrupt movements or shifts in posture. For example, when lying down you may feel a stronger sensation because the lead is closer to the nerves of the spinal cord than when standing. Changes in stimulation are more common during the first several weeks after surgery.

## Types of neurostimulators

There are two types of Medtronic neurostimulation systems:

1. The rechargeable, neurostimulation system consists of the following:
  - Implantable neurostimulator
  - Implantable lead(s) and optional extension(s)
  - Clinician programmer
  - Patient programmer with an optional antenna
  - Recharger
  - Recharger belt/antenna
  - AC power supply and power cord
2. The non-rechargeable, neurostimulation system consists of the following:
  - Implantable neurostimulator
  - Implantable lead(s) and extension(s)
  - Clinician programmer
  - Patient programmer with an optional antenna
  - Optional external control magnet for the Itrel® 3 neurostimulator that turns the device ON and OFF

Your doctor will work with you to help you select the system that is most appropriate for your needs. Medtronic offers the greatest variety of neurostimulation systems to relieve your pain. Additional details on each of these systems will be reviewed in the following pages of this booklet.



## Surgically implanted components of the neurostimulation systems

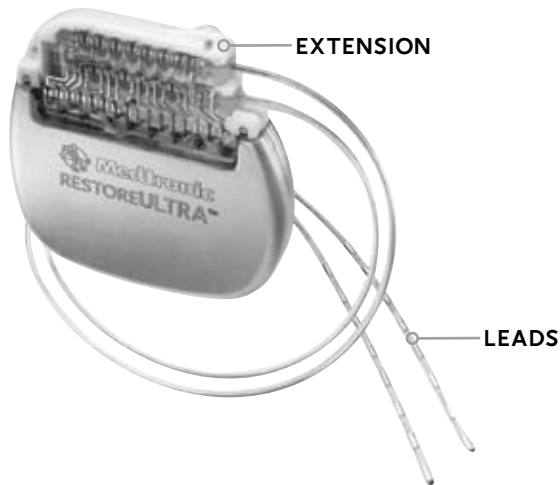
**Implantable Neurostimulator:** The implantable neurostimulator is the device that generates the electrical impulses that are sent to your spinal cord to control your pain. The neurostimulator contains a special battery and electronics to create these impulses. The device is often placed under the skin in your abdomen. Discuss placement of the device with your doctor prior to surgery.

- Rechargeable: This model has a rechargeable battery enclosed in the neurostimulator and has the potential to last up to nine years.
- Non-rechargeable: This model uses a battery enclosed in the neurostimulator that will need to be replaced when the battery is depleted.



**Lead:** Neurostimulation leads are special medical wires designed to deliver mild impulses to the spinal cord. A neurostimulation system may use one lead or more. The lead is placed under the skin near your spine. It contains a set of electrodes through which the neurostimulation is delivered to the spinal cord.

**Extension:** The extension is an insulated wire that is placed under the skin and connects the lead to the neurostimulator. (The extension is an optional item if you have a rechargeable neurostimulator.)



### External components of the implantable neurostimulation systems

**Clinician Programmer:** This programmer lets your clinician adjust your neurostimulation system to the appropriate level for your pain needs.\* The programming head is placed over the area where the neurostimulator is implanted to program the settings by use of radio waves. This procedure is done through the skin.

When you visit the doctor's office, your neurostimulation system can be reprogrammed to more effectively deal with your pain. For example, the multiple electrodes on leads can be readjusted to provide therapy for differing needs of pain coverage. The strength of the stimulation can be altered to accommodate lesser or greater pain.

**Patient Programmer:** The hand-held patient programmer allows you to program or to adjust your own stimulation (within the settings your clinician has selected). Depending on your need for pain control, you can use the patient programmer to turn your system off and back on. You may also direct your system to provide greater or lesser pain relief (by increasing or decreasing the tingling), within limits set by your doctor. You will not be able to change those limits on your own, but you may discuss the need for possible changes with your clinician.

*\*A clinician can be your doctor or other healthcare providers.*



*Clinician Programmer*

#### PATIENT PROGRAMMERS



*myStim®*



*Synergy® EZ*



*Itrel® EZ*

*There are three different hand-held patient programmers. You will receive either the myStim®, Synergy® EZ, or the Itrel® EZ depending on the type of neurostimulation system you and your physician determine is right for you.*

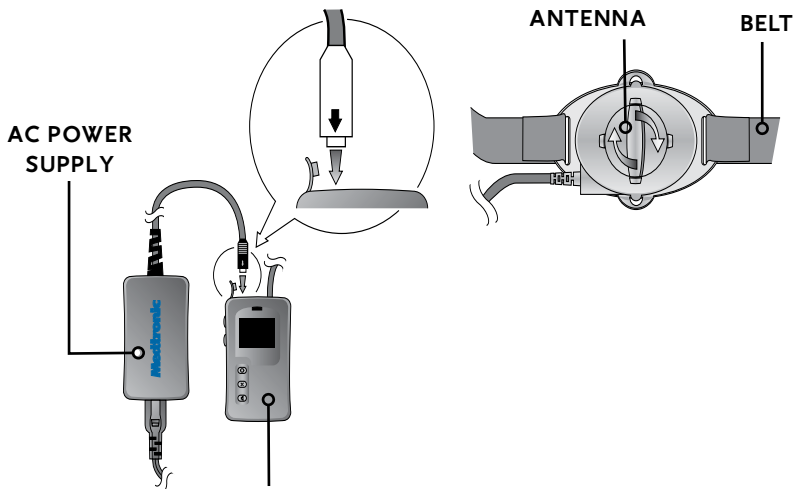
## Additional external components for the rechargeable neurostimulator

**Recharger:** The recharger is a hand-held device for recharging the battery in your neurostimulator. It can also turn your neurostimulator ON or OFF. The display on the recharger provides information on your recharging system.

**Antenna:** The antenna connects to the recharger to establish communications with your neurostimulator. It fits into the antenna belt and helps secure the placement of the recharging coil. The dial on the antenna may be adjusted as appropriate.

**Recharger Belt:** The belt allows you to keep the antenna directly over your neurostimulator during a recharging session.

**AC Power Supply and Power Cord:** This device is used to charge the recharger using AC power. The power cord plugs into an electrical outlet and connects the AC power supply to the recharger. The recharger and the neurostimulator may be charged at the same time if necessary.



## Neurostimulation systems FAQ's

### ***HOW LONG WILL MY FULLY IMPLANTABLE NEUROSTIMULATION SYSTEM LAST?***

This time varies. The battery life of the neurostimulator depends on which kind of neurostimulator you receive, 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 rechargeable system is best for you based on your pain requirements.

### ***HOW CAN I EXTEND THE BATTERY LIFE?***

There are several ways to maximize the battery life. They include:

- Using cycling mode (if applicable and appropriate for the therapy) and programming the shortest ON time. (Your clinician can program this mode.)
- 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 needed electrodes. (Your clinician will determine the appropriate settings for your condition.)

### ***HOW WILL I KNOW WHEN THE BATTERY ON MY FULLY IMPLANTABLE NEUROSTIMULATION SYSTEM NEEDS TO BE REPLACED?***

Your clinician will be able to tell you the state of the battery in the neurostimulation system during regularly scheduled follow-up visits. Your patient programmer also has a battery indicator to show when your battery is low.

### ***WHAT HAPPENS WHEN MY BATTERY NEEDS TO BE REPLACED?***

With a fully implantable system, when it is time to have your battery replaced, your doctor will remove the device and replace it with a new device during a surgical procedure.

### ***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.

### ***WILL I BE ABLE TO ADJUST MY NEUROSTIMULATION SYSTEM?***

The neurostimulation system has a patient programmer (similar to a TV remote) that allows you to adjust the stimulation within the parameters set by your doctor.

***WILL I HEAR OR FEEL THE NEUROSTIMULATION SYSTEM INSIDE ME, AND WILL PEOPLE NOTICE IT?***

The neurostimulator does not make any noise. It may be felt as a small lump under your skin. It does not normally show through your clothes. It is often implanted in the lower abdomen, where it is most comfortable and least visible. Discuss placement of the device with your doctor prior to implant.



Before having a neurostimulation system implanted, you will be able to try the therapy during the neurostimulation screening test. This screening period gives you an opportunity to experience the system and enables the doctor to assess your battery requirements. The screening test procedure—or test stimulation—consists of a short test stimulation period in the operating room and an evaluation period of several days at home. During the evaluation period, your doctor determines your response to neurostimulation and your level of pain relief.

During the screening test, the doctor will place a lead in your back to deliver electrical stimulation to the spinal cord. The lead placement is one of the keys to successful results with a neurostimulation system. Your involvement is very important to determine proper placement, so be sure to follow your doctor's instructions carefully.

Typically, you will receive a local anesthetic and mild sedatives to keep you comfortable during the procedure. After that, your doctor will place the lead in your back.

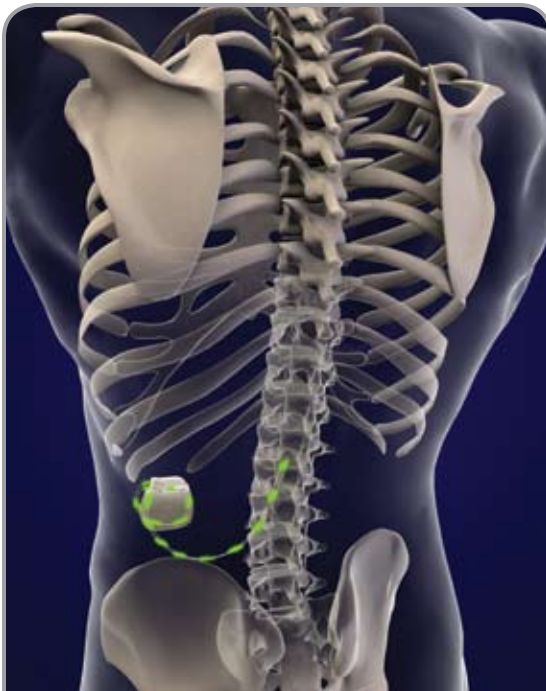
After the lead is placed, your doctor will connect the lead wires to an external screener or external neurostimulator that allows your clinician to adjust your stimulation. Both the external screener and the external neurostimulator are powered by external batteries that may need to be replaced.





If your neurostimulation screening test is successful, you may be a candidate for a permanent neurostimulation system. Medtronic offers the greatest variety of neurostimulation system options so your doctor can choose the system that is right for the pain you are experiencing.

The surgical procedure to implant the neurostimulation system may require a brief hospital stay. Before the surgery, you and your doctor will decide where to position the neurostimulator for your comfort. During the surgical procedure, an incision is made over the spine so that your doctor can place the lead and connect it to the extension. The extension is tunneled under the skin and connected to the neurostimulator. Your doctor will then form a pocket under your skin (often in the abdominal area) that is large enough to hold the neurostimulator. Once the extension is connected to the neurostimulator, the incisions are closed and the surgery is complete.



## Implant procedure FAQ's

### ***CAN A PREVIOUS ABDOMINAL INCISION BE USED TO IMPLANT THE NEUROSTIMULATOR?***

Usually not. The incision needs to be made where the neurostimulator will be implanted to help properly anchor the neurostimulator. Proper anchoring helps keep the neurostimulator in place. This also will help minimize your discomfort and speed your recovery.

### ***HOW BIG ARE THE INCISIONS?***

The incision for the neurostimulator usually is about 2 inches long. There also is an incision made on your back that usually is about 2 inches long. This incision is used to place the lead in the spine. The other end of the lead and extension is tunneled under the skin and connected to the neurostimulator.

### ***ON AVERAGE, HOW LONG DOES THE SURGERY TAKE?***

Times vary depending on the technique of each individual doctor. On average, the procedure takes about one to two hours from start to finish. Talk with your doctor about the specifics and duration of your procedure.

### ***WHAT IS THE AVERAGE LENGTH OF THE HOSPITAL STAY?***

Depending on your doctor's preference and hospital policy, a one- or two-night hospital stay may be recommended. However, in some cases, the procedure may be performed on an outpatient basis, which means no overnight stay is required.

### **WHAT ARE THE RISKS ASSOCIATED WITH SURGERY?**

Implanting a neurostimulation system has risks similar to spinal procedures, including spinal fluid leaks, headaches, swelling, bruising, bleeding, infection, or paralysis. If you are on anticoagulation therapy, you might be at greater risk for postoperative complications such as hematomas that could result in paralysis. Please talk to your doctor for more information or if you have questions.

### Post-surgery care

After surgery, there will be some discomfort and tenderness where your neurostimulator and lead are placed. Your doctor may prescribe medication to relieve the pain from surgery and antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, notify your clinician.

After the implant, your doctor may recommend that you restrict your activity for six to eight weeks. Once your incision has healed, the site requires no special care. However, you should talk with your doctor before you perform any excessive or repetitive activities that may damage your neurostimulator or lead.

Following placement of your neurostimulation system, you will receive a permanent identification card from Medtronic and should carry this in your wallet.

## Post-surgery FAQs

### ***IS IT NORMAL TO FEEL PAIN FOR WEEKS AFTER THE PROCEDURE? WHAT CAN HELP?***

You may experience pain at the neurostimulator implant site up to six weeks after the surgery. This pain is part of the healing process and happens with any type of surgery. It is your body's natural response to the implant surgery. Once the scar tissue forms, the pain will begin to disappear. Your doctor may prescribe ice or medication to relieve the pain caused by surgery and antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, notify your doctor.

### ***AFTER THE IMPLANT, WHAT PRECAUTIONS SHOULD I FOLLOW?***

Your doctor may recommend that you restrict your activity for several weeks. During the first six to eight weeks following the surgery, you will need to avoid lifting, bending, and twisting movements. This allows time for scar tissue to form, which helps anchor the lead. Use normal caution with these types of movements after the initial six to eight weeks. Once your incision has healed, the neurostimulator site requires no special care. However, you should talk to your doctor before you perform any excessive or repetitive activities that may damage your neurostimulator or lead(s).

It is also important to keep all follow-up appointments as scheduled. Some patients build up a tolerance to neurostimulation, and the stimulation effect is reduced or lost. The reasons are not clearly understood. Contact your doctor if you experience changes in stimulation or pain.

### ***WHAT POSSIBLE SYSTEM COMPLICATIONS SHOULD I BE AWARE OF?***

As with any implanted device, infection can occur. The lead, extension, or neurostimulator could move within the body or push through the skin. There could be undesirable changes in stimulation. It is also possible that the implanted materials could cause an allergic or immune system response.

Your neurostimulation system might unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical shorts or open circuits, conductor (wire) fractures, and insulation breaches, cannot be predicted.

## Activities after your neurostimulation system implant

Your neurostimulation system generally will not limit normal daily activities, but you should always follow your doctor's instructions with regard to work, exercise, hobbies, and other activities.

In the weeks following your implant procedure, your awareness of the neurostimulator, or receiver, will lessen. Since there are no external parts to the fully implanted neurostimulation system, you may often forget it's there. You may find that wearing loose clothing over the implanted neurostimulator or receiver is most comfortable. Depending on your size and shape and where the device is placed, it may not show at all under regular clothes.

Continue following guidelines for good back care. As you become more active, you should discuss your level and type of activity with your doctor. Certain strenuous activities (for example, moving or lifting heavy objects) may break or move the lead. Consult your doctor before beginning any strenuous activity.

### Activities FAQs

#### **WHAT TYPES OF ACTIVITIES CAN DAMAGE OR MOVE THE LEAD?**

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 break the lead.

A lead can break or fracture due to action of nearby bones and ligaments. Although it is made of flexible and durable materials, it is still subject to wear. Therefore, seemingly harmless or repetitive movements can cause unseen damage over time, eventually causing the lead to fracture. This damage may require surgery to replace the lead.

#### **CAN I DRIVE A CAR WITH MY NEUROSTIMULATION SYSTEM?**

To help ensure safe operation of your vehicle, turn your neurostimulator OFF prior to driving. A change in stimulation could cause you to lose control of your vehicle.

#### **CAN I GO IN A HOT TUB, STEAM ROOM, OR SAUNA?**

Yes, but if you feel any localized heat sensation around your neurostimulator, get out of the hot tub, steam room, or sauna.

#### **SHOULD I BE CONCERNED ABOUT AIRPLANE FLIGHTS?**

Neurostimulators should not be affected by airplane flights.



***CAN I SCUBA DIVE OR ENTER HYPERBARIC CHAMBERS?***

Do not dive below 33 ft. (10 m) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 33 ft. (10 m) of water or above 2.0 ATA can damage the neurostimulation system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

***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?***

A: High altitudes should not affect the neurostimulator; however, you should consider the movements involved in any planned activity and take care to not put undue stress on your implanted neurostimulation system. For example, during skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the lead, requiring additional surgery to repair or replace the lead.



Once your neurostimulation system has been implanted (and during your neurostimulation screening test), you should avoid electrical or magnetic equipment (or other items) that generate high levels of electromagnetic interference. (See chart on page 28.)

You can safely use household appliances, such as microwaves, TVs, computers, cellular phones, and other items. See page 30 regarding minimizing interference with your neurostimulation system.

### Electromagnetic interference (EMI)

Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, strong sources of EMI can result in the following:

- Serious patient injury or death, resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue.
- System damage, resulting in a loss of or change in symptom control and requiring additional surgery.
- Operational changes to the neurostimulator that can cause it to turn ON or OFF (particularly in a neurostimulator enabled for magnet use) or to reset to the power-on-reset (POR) values, resulting in loss of stimulation, return of underlying symptoms, and in the case of POR, requiring your clinician to reprogram your neurostimulator.

- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or injure a patient directly. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured. Refer to the chart on page 28, for information on the sources of EMI, the effect of EMI on you and your neurostimulation system, and instructions on how to reduce the risk from EMI.



## Potential effects of EMI from devices or procedures

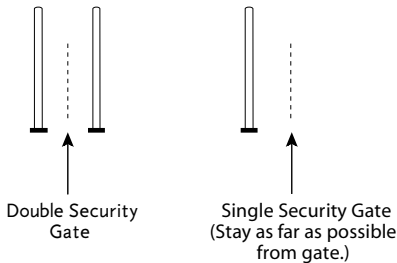
A discussion of these devices/procedures follows this chart.

Device/Procedure	Serious Patient Injury	Device Damage	Momentary Increase in Stimulation	Device Turns OFF or ON	Intermittent Stimulation
Bone Growth Stimulators		✓	✓		✓
Defibrillation/Cardioversion	✓	✓	✓		✓
Dental Drills and Probes		✓			
Diathermy, Therapeutic	✓	✓			✓
Electrocautery	✓	✓			
Electrolysis		✓			✓
Electromagnetic Field Devices (eg, Arc Welding, Power Stations)			✓	✓	✓
High-Output Ultrasonics/Lithotripsy		✓			
Household Items			✓	✓	
Laser Procedures		✓			
Magnetic Resonance Imaging (MRI)	✓	✓	✓	✓	✓
Psychotherapeutic Procedures		✓	✓	✓	✓
Radiation Therapy		✓			
Radiofrequency (RF)/Microwave Ablation	✓	✓			✓
Therapeutic Magnets				✓	
Theft Detectors/Security Devices			✓	✓	✓
Therapeutic Ultrasound	✓	✓			✓
Transcutaneous Electrical Nerve Stimulation (TENS)			✓	✓	

## Additional environmental information

**Theft detectors and security devices:** Use care when approaching theft detector, and security devices (such as those found in airports, libraries, and some department stores). When approaching these devices, do the following:

1. Show the security personnel your patient identification card for the neurostimulator and ask for a manual search. Security personnel may use a hand-held security wand, but ask them not to hold the security wand near the neurostimulator any longer than is needed.
2. If you must pass through the theft detector or security screening device, turn your neurostimulator OFF, approach the center of the device, and walk through normally.
  - a. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.
  - b. If one gate is present, walk as far away as possible from it.



**Note:** Some theft detectors might not be visible.

3. Proceed through the security device. Do not linger near or lean on the security device.

(continued on next page)

4. After you pass through the security device, turn your neurostimulator ON again to resume therapy.

**Household items:** Most household appliances and equipment that work properly and are properly grounded will not interfere with the neurostimulation system. The following equipment is safe if you follow these guidelines:

- Computer disk drives: Keep the neurostimulator away from disk drives.
- Induction range: Keep the neurostimulator away from the burners while the burners are turned on.
- Freezer, refrigerator, or storm doors: Do not lean against the magnetic strip that holds the door closed.
- Power tools: Keep the motor away from the neurostimulator, lead, and extension.
- Radio frequency sources: Keep AM/FM radios, and cellular, cordless, and conventional telephones at least 4 in. (10 cm) away from the implanted neurostimulator.
- Sewing machines or salon hair dryers: Keep the neurostimulator away from the motors.
- Stereo speakers and radios for the home or car: Do not lift or carry them close to or touching the part of your body where the neurostimulator is located.

### Specific medical procedures

Always consult your doctor about potential interactions with your neurostimulation system before undergoing any medical procedure. We recommend that you turn your device OFF before any medical procedure.

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 certain procedures. Contact your doctor for instructions on how to obtain a medical alert bracelet.

## This contraindication FOR DIATHERMY ONLY

**Diathermy:** Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, can cause tissue damage, and can result in severe injury or death.

Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and can require additional surgery to remove or replace parts of your implanted system. Personal injury or device damage can occur during diathermy treatment when:

- The neurostimulation system is turned ON or OFF.
  - Diathermy is used anywhere on your body (not just where your neurostimulation system is located).
  - Diathermy is used to deliver heat or no heat.
  - Any component of your neurostimulation system (lead, extension, neurostimulator) remains in your body.
-

## General warnings and precautions/ Medical procedures and equipment

**Bone growth stimulators:** The coils of an external magnetic field bone growth stimulator should be kept 18 in. (45 cm) away from the neurostimulation system. When a bone growth stimulator is used, your doctor should ensure that both the bone growth stimulator and neurostimulator are working as intended.

**Defibrillation/cardioversion:** When you are in ventricular or atrial fibrillation, the first consideration is your survival. External defibrillation or cardioversion can damage a neurostimulation system and cause induced electrical currents through the lead and extension. These induced electrical currents could injure you. The current flowing through the neurostimulation system should be minimized as follows:

- Paddles should be positioned as far from the neurostimulator as possible.
- Paddles should be positioned perpendicular to the neurostimulation system.
- The lowest clinically appropriate energy output (watt seconds) should be used.

After external defibrillation, your doctor should confirm that the neurostimulation system is working as intended.

**Dental drills and ultrasonic probes:** The neurostimulator should be turned OFF and the drill or probe should be kept at least 6 in. (15 cm) away from the neurostimulator.

**Electrocautery:** If electrocautery tools are used near an implanted device or contacts a device, the following effects can occur:



- The insulation on the lead or extension can be damaged, causing the lead or extension to fail and/or causing induced currents that can damage tissue or stimulate or shock you.
- The neurostimulator can be damaged, stimulation can be temporarily decreased or increased, or the neurostimulator can be turned OFF because the neurostimulator was reset to power-on-reset values (requiring your healthcare provider to reprogram your neurostimulator).

When electrocautery is necessary, these precautions must be followed:

- The neurostimulator should be turned OFF before using electrocautery.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
  - Only low-voltage modes should be used.
  - The lowest possible power setting should be used.
  - The current path (ground plate) should be kept as far away as possible from the neurostimulator, extension, and lead.
  - Full-length operating room table grounding pads should not be used.
- After electrocautery, your doctor should confirm that the neurostimulator is working as intended.

**Electrolysis:** The neurostimulator should be turned OFF, and the electrolysis wand should be kept at least 6 in. (15 cm) away from the neurostimulator.

**High-output ultrasonics/lithotripsy:** Use of high-output ultrasonics or lithotripsy is not recommended if you have an implanted neurostimulation system. If lithotripsy must be used, the beam should not be focused within 6 in. (15 cm) of the neurostimulator.

**Laser procedures:** The neurostimulator should be turned OFF, and the laser should be directed away from the neurostimulation system.

**Magnetic resonance imaging (MRI):** Medtronic conducted testing to determine procedures for performing head-only MRI scans on Spinal Cord Stimulation patients.

There are restrictions and there are risks associated with the procedure that are outlined on the next page.

Medtronic does not recommend any MRI scans if you have or have had either of the following neurostimulators: Matrix® or X-trel®.

For other Medtronic neurostimulation systems, an MRI examination of the head only may be safely performed under certain specific conditions.\* However, Medtronic recommends that an MRI using a radiofrequency (RF) transmit body coil should **not** be prescribed for you if you have any part of an implanted neurostimulation system. Exposing you to an MRI using a radiofrequency (RF) transmit body coil, or not following the specific conditions indicated above, can cause tissue damage and can result in severe injury or death.

*\*Please have your doctor contact Medtronic for specific MRI guidelines for head-only MRI scans. Contact information is found on the last page of this booklet.*

The known potential risks are as follows:

- Induced electrical currents during an MRI using an RF transmit body coil can cause heating of the neurostimulation system, especially at the lead electrode site, which can cause tissue damage and can result in severe injury or death. Induced electrical currents can also stimulate or shock you.

**Note:** This warning applies even if only a lead or an extension is implanted in your body. Factors that increase the risks of heating and injury include, but are not limited to, the following:

- High MRI Specific Absorption Rate (SAR) RF power levels
  - Lower impedance leads or extensions (Medtronic product names or model numbers designated with a “Z,” an “LZ,” or “Low Impedance”)
  - MRI RF transmit coil that is near or extends over the implanted lead
  - Implanted leads with small surface area electrodes
  - Short distances between lead electrodes and tissue that is sensitive to heat
- An MRI can permanently damage the neurostimulator, requiring it to be removed or replaced.
  - An MRI can affect neurostimulator operation. The MRI can also reset the neurostimulator to power-on-reset values requiring your clinician to reprogram your neurostimulator.
  - The neurostimulator can move within the implant pocket and align with the MRI field, resulting in discomfort or reopening of a recent implant incision.

In addition, the MRI image can be degraded, distorted, or blocked from view by your implanted neurostimulation system.

**Psychotherapeutic procedures:** Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

**Radiation therapy:** High-radiation sources such as cobalt 60 or gamma radiation should not be directed at the neurostimulation system. If radiation therapy is required near the neurostimulation system, lead shielding should be placed over the device to help prevent damage.

**Radiofrequency (RF)/microwave ablation:** Safety has not been established for RF or microwave ablation in patients with an implanted neurostimulation system. Induced electrical currents can cause heating, especially at the lead electrode site, resulting in tissue damage.

**Therapeutic ultrasound:** Refer to Diathermy on Page 31 of this booklet.

**Therapeutic magnets:** (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) Keep the magnet at least 10 in. (25 cm) away from your neurostimulator. Magnetic fields of 10 gauss or less will generally not affect the neurostimulator.

**Transcutaneous electrical nerve stimulation (TENS):** TENS electrodes should not be placed so that current passes over any part of the neurostimulation system. If you feel that the TENS unit might be interfering with your neurostimulator, discontinue using the TENS until you talk with your doctor.

## Other medical procedures

EMI from the following medical procedures is unlikely to affect your neurostimulation system:

- **Computerized axial tomography (CT or CAT) scans**
- **Diagnostic ultrasound (e.g., carotid scan, doppler studies)**

***Note:** To minimize potential image distortion, the neurostimulator should be turned OFF and the transducer kept 6 in. (15 cm) away from the neurostimulation system.*

- **Diagnostic x-rays or fluoroscopy**

***Note:** Tight pressure in the area of your neurostimulator, such as that used during mammography, can damage the neurostimulator or disconnect components of your neurostimulation system. This will require surgery to replace or repair the neurostimulation system. X-ray equipment should be adjusted so it does not squeeze the neurostimulator too tightly.*

- **Magnetoencephalography (MEG)**
- **Positron Emission Tomography (PET) scans**

**Acute** — Sharp or severe, for a short time.

**Amplitude** — The strength or intensity of an electrical pulse.

**Antenna** — Sends a signal from the transmitter to the receiver when placed on the skin over the receiver.

**Battery** — Provides power for neurostimulation.

**Caution** — A statement describing actions that could result in damage to or improper functioning of a device.

**Charging system** — Equipment used to charge the battery inside an implanted neurostimulator.

**Chronic pain** — Pain that persists over a long period of time.

**Clinician** — A health care professional such as a doctor or nurse.

**Clinician programmer** — A device used by a clinician to send instructions to a neurostimulator.

**Contraindication** — A condition or circumstance when a person should not have a procedure with a neurostimulation system.

**Defibrillator** — A machine that restarts the heart in an emergency.

**Diathermy** — A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

**Electrode** — A metal piece near the tip of the lead. Electrodes deliver electrical pulses to the area where your pain signals will be blocked.

**Electromagnetic interference (EMI)** — A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly.

**Extension** — A thin wire covered with a protective coating that connects the neurostimulator to a lead.

**External neurostimulator** — See Neurostimulator.

**General anesthesia** — Anesthesia used for surgery, for which the patient is not awake.

**Group** — Combined programs that provide stimulation to one or more pain sites. Each group may be defined for a different activity, symptom, or time of day.

**Implanted neurostimulator** — See Neurostimulator.

**Indication** — The purpose of the neurostimulation system and the medical condition for which it may be implanted.

**Intractable pain** — Pain that is not responsive to conservative treatment.

**Lead** — A special medical wire with protective coating that has metal electrodes on one end and a connector on the other.

**Local anesthesia** — Anesthesia that numbs a particular area. The patient remains awake with local anesthesia.

**Magnetic resonance imaging (MRI)** — A special type of diagnostic imaging.

**Neuropathic pain** — Pain caused by damage to the nerve tissue itself.

**Neurostimulation** — A procedure in which a lead is placed near the spine or peripheral nerve that transmits electrical impulses to block pain messages being sent to the brain.

**Neurostimulation system** — Components that deliver electrical pulses to block pain signals as they move to the brain.

**Neurostimulator** — The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation you feel.

- An external neurostimulator is carried outside the body. During test stimulation, it is used to determine whether or not stimulation is effective.
- An implanted neurostimulator is placed inside the body. If stimulation is effective during test stimulation, the neurostimulator is implanted.

**Nociceptive pain** — Pain caused from external sources such as a burn or a broken bone.

**Pacemaker** — An implantable device used to manage slow heartbeat.

**Pain** — A process in which receptors in the skin and other tissues send impulses through the spinal cord to the brain.

**Parameter** — One of three stimulation settings that adjust the electrical pulse: amplitude; pulse width; and rate.

**Patient programmer** — A hand-held device that allows you to turn your neurostimulator ON and OFF. It is also used to adjust some stimulation settings.

**Program** — Stimulation directed to a specific pain site.

**Precaution** — See Caution.

**Pulse width** — The length or duration of an electrical pulse.

**Radio frequency waves** — The means by which the neurostimulation system is programmed through the skin.



**Rate** — The number of times per second that an electrical impulse is delivered to control pain (speed of stimulation).

**Receiver** — An implanted device that contains electronic circuits but no batteries. This is an externally powered system.

**Screener** — An external device that provides the power source for stimulation during the trial period; allows the patient to adjust rate and amplitude.

**Screening test** — A process by which patient and doctor determine if neurostimulation is effective in reducing the patient's pain.

**Settings** — See Stimulation settings.

**Spinal cord** — Nerve signals from the entire body travel to your spinal cord, and then to your brain.

**Stimulation** — The delivery of electrical pulses to the area where pain signals are blocked as they move to the brain. Stimulation blocks some pain signals from reaching the brain.

**Stimulation settings** — Refers to all the features assembled to define the stimulation you feel. The clinician programs all stimulation settings. You can adjust some stimulation settings.

**Synchronize** — The process of sending and receiving information between the patient programmer and neurostimulator.

**TENS** — An external device that is intended to reduce pain by applying low voltage electricity through electrodes placed over the skin.

**Test stimulation** — The period of time when an external screener or external neurostimulator is used to determine if stimulation blocks the pain signals effectively.

**Therapy** — Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to one or more pain sites.

**Tingling** — The sensation you feel when your neurostimulator is turned on. The neurostimulator changes the signal of pain to one of “tingling.”

**Trial screening** — A process by which patient and doctor determine if the patient is a candidate for a permanent neurostimulation system.

**Ultrasound** — A special test that uses sound waves to create a picture.

**Warning** — A statement describing an action or situation that could harm the patient.

**Warning screen** — A screen displayed on the patient programmer that alerts you to a problem with the programmer, antenna, or neurostimulator.

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## IMPORTANT SAFETY INFORMATION

### NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

**Brief Summary:** Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

**Indication for Use** - Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, & therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines & precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, & other activities may cause shocking/jolting. **Adverse Events:** Undesirable change in stimulation; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, & surgical risks.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at [www.medtronic.com](http://www.medtronic.com). Rx Only. November, 2007.



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UC200802857 EN NI8405

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