



**Medtronic**

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INFORMATION FOR  
PRESCRIBERS

Medtronic InterStim® Therapy

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Rx only

Medtronic and InterStim are registered trademarks and SoftStart/Stop is a trademark of Medtronic, Inc.

#### **Additional information available for the InterStim Therapy system**

##### **Documents packaged with this product:**

- For therapy-specific information, refer to the *Indications Insert*.
- For information regarding device compatibility, refer to the *System Overview and Compatibility Insert*.
- For information on the clinical study results for InterStim Therapy and for a complete summary of adverse events, refer to the *Clinical Summary*.
- For warranty information, refer to the *Limited Warranty and Special Notice Insert*.

##### **Documents packaged with the clinician programmer software application card:**

- For neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications refer to the *System Eligibility, Battery Longevity, Specifications Reference Manual*.

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# Contraindications

Implantation of an InterStim neurostimulation system is contraindicated for the following patients:

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the neurostimulator.

After implantation of any system component, the following contraindication applies:

**Diathermy** – Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. For more information about diathermy refer to Table 1 on page 6 and to "Appendix A: Electromagnetic interference" beginning on page 17.

## Warnings

### 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 electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong electromagnetic interference 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 surgical replacement.
- **Operational changes to the neurostimulator**, causing it to turn ON or OFF (particularly in Model 3023 Neurostimulators which are enabled for magnet use), or to reset to power-on-reset (POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of POR, requiring reprogramming by a clinician.
- **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 may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

For information on sources of EMI, the effect of EMI on the patient and the neurostimulation system, and instructions on how to reduce the risks from EMI, refer to Table 1 on page 6, and "Appendix A: Electromagnetic Interference" beginning on page 17.

For information about the effects of EMI on programming, refer to "Telemetry signal disruption from EMI" beginning on page 8.

**Table 1. Potential effects of EMI from devices or procedures**

Other possible effects

Medical procedure	Patient injury	Device damage	Momentary increase in stimulation	Turns device on or off	Intermittent stimulation	See guidelines
Bone growth stimulators		•	•		•	page 20
Defibrillation/cardioversion	•	•	•		•	page 17
Dental drills and probes		•				page 20
Diathermy, therapeutic <sup>a</sup>	•	•			•	page 5
Electrocautery	•	•				page 18
Electrolysis		•			•	page 21
Electromagnetic field devices: (eg, arc welding, power stations)			•	•	•	page 21
High-output ultrasonics/lithotripsy		•				page 18
Household items			•	•		page 22
Laser procedures		•				page 21
Magnetic resonance imaging (MRI)	•	•	•	•	•	page 19
Psychotherapeutic procedures	•	•	•	•	•	page 21
Radiation therapy		•				page 21
Radiofrequency (RF)/ microwave ablation	•	•			•	page 18
Theft detector	•		•	•	•	page 19
Therapeutic magnets				•		page 22
Therapeutic ultrasound <sup>a</sup>	•	•			•	page 17
Transcutaneous electrical nerve stimulation (TENS)			•	•		page 22

<sup>a</sup> Diathermy and therapeutic ultrasound procedures are contraindicated for patients who have an Interstim Therapy system. See page 5 for more information.

## Case Damage

If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

## Effects on other implanted devices

The neurostimulation system may affect the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps. Physical proximity may cause sensing problems and inappropriate device responses. Clinicians involved with both devices should evaluate any potential interference problems before surgery. Careful programming of each system may be necessary to optimize the patient's benefit from each device.

### Neurostimulator interaction with implanted cardiac devices

When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), clinicians involved with both devices (eg, neurologist, neurosurgeon, cardiologist, electrophysiologist, urologist, urogynecologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent the effects described below, implant the devices on opposite sides of the body and follow any additional instructions.

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from cardiac devices and could result in an inappropriate response of the cardiac devices. To minimize or prevent the cardiac device from sensing the neurostimulator output, program the neurostimulator to a bipolar configuration and to a minimum rate of 60 Hertz. Program the cardiac device to bipolar sensing.

See also: "Programmer interaction with other active implanted devices" beginning on page 8.

## Precautions

### Clinician programming

**Battery depletion** – Patients with very low stimulation thresholds may feel more intense stimulation as the neurostimulator battery nears total depletion. Patients should be told that as their neurostimulator battery approaches total depletion, they may need to adjust their stimulation amplitude more often to maintain the desired level of stimulation.

**Clinician programmer compatibility** – The clinician programmer can only be used to program Medtronic neurological devices that correspond with a Medtronic therapy application software such as the software on the InterStim Model 8870 Application Card.

**Magnet compatibility** – The Model 8529 Magnet is for use with Medtronic pumps only. If the clinician programmer has a Model 8529 Magnet attached, remove the magnet before approaching a patient who has an implanted neurostimulator or other implanted medical device (such as a pacemaker or defibrillator). If the magnet is too close to another implanted device, the therapy of the other device may change.

**Parameter adjustment** – Do the following to prevent an abrupt change in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation):

- Program parameter changes in small increments.
- Enable SoftStart/SoftStop mode whenever possible.
- Decrease the amplitude to 0.0 V before taking these actions:<sup>1</sup>
  - Connecting the screener cable to the screener.
  - Turning OFF the neurostimulator or screener.
  - Turning ON the neurostimulator or screener.

**Sensitivity to stimulation** – Patients with extremely high sensitivity to stimulation may sense the transmission of the programming signals from the programmer to the neurostimulator via radio-frequency (RF) telemetry.

**Programmer interaction with a cochlear implant** – When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming head as possible or by turning OFF the cochlear implant during programming.

**Programmer interaction with flammable atmospheres** – The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

**Programmer interaction with other active implanted devices** – When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator, neurostimulator) the following may occur:

- The radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.
- The magnet in a cardiac programmer may activate the magnetically controlled ON/OFF switch (**Model 3023 neurostimulator only**).

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times). Also, inform patients to contact their clinician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.

**Telemetry signal disruption from EMI** – Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). EMI may cause a disruption in programmer function. If EMI disrupts programming, move the programmer and the neurostimulator away from the likely source of EMI. Examples of sources of EMI are magnetic resonance imaging (MRI), lithotripsy, computer monitors, cellular telephones, x-ray equipment, and other electronic equipment (See Appendix A: Electromagnetic Interference).

**Sterile field** – When using the programmer in a sterile field, place the programmer, programming head, and extendable cord into a sterile bag. The programmer is not sterile and cannot be sterilized.

<sup>1</sup> The most recent software versions MMB and NNB automatically set the amplitude lower limit to zero.

**Amplitude lower limit** – If your programmer is using the previous version (MMA or NNA), program the amplitude lower limit to 0.0 V.<sup>1</sup> This will prevent the patient from experiencing unexpected or uncomfortable stimulation (eg, shocking, jolting) when turning the device ON, due to the abrupt change in stimulation.

## Clinician training

Refer to the *Indications Insert* for therapy-specific training precautions.

## Patient activities

**Activities requiring excessive twisting or stretching** – Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking and other sports or equipment that involve the movements described above. Ask your patients about the activities they are involved in and inform them of activity restrictions.

**Antenna attachment** – For antennas that attach to the skin, do not use the adhesive discs to attach the antenna over the neurostimulator incision until the incision heals. The adhesive discs may irritate or reopen the incision.

**Antenna use** – For antennas that attach to the skin, if swelling or redness occurs near the adhesive disc, advise the patient to contact the clinician before using the antenna again. Swelling or redness may indicate an infection or an allergic reaction to the adhesive disc or antenna.

**Component manipulation by patient (twiddler's syndrome)** – Patients should avoid manipulating or rubbing the neurostimulation system through the skin. Manipulation may cause component damage, lead dislodgement, skin erosion, or uncomfortable stimulation at the implant site.

**Scuba diving or hyperbaric chambers** – Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician.

**Skydiving, skiing, or hiking in the mountains** – High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to reposition or replace the lead.

**Unexpected changes in stimulation** – Electromagnetic interference, postural changes, and other activities may cause a perceived increase in stimulation, which some patients

<sup>1</sup> The most recent software versions MMB and NNB automatically set the amplitude lower limit to zero.

have described as uncomfortable stimulation (jolting or shocking sensation); therefore, patients should reduce the amplitude to the lowest setting and turn OFF the neurostimulator before engaging in activities that could be unsafe for themselves or others if they received an unexpected jolt or shock (eg, driving, operating power tools). Patients should discuss these activities with their clinician.

## **Patient programming and patient control devices**

**Neurostimulator battery depletion** – Patients with a very low perception threshold (the amplitude at which the patient first perceives stimulation) may feel the stimulation intensity fluctuate as the battery nears depletion. To compensate for this fluctuation, patients may need to decrease or increase the amplitude more often to maintain the desired level of symptom control.

**Patient access to a control device** – Patients must carry a patient control device at all times to have the capacity to adjust and/or turn OFF the neurostimulator.

**Patient control devices may affect other implanted devices** – Patients should not place a control device (patient programmer or control magnet) over another active implanted medical device (eg, pacemaker, defibrillator, another neurostimulator). The patient control devices could unintentionally change the operation of the other device.

**Patient magnet control feature disabled (Model 3023 Only)** – If the magnet control feature has been disabled, the patient must carry their patient programmer with them at all times so that they can turn the neurostimulator ON or OFF.

**Patient magnet may damage items (Model 3023 Only)** – Patients should not place the patient magnet on or near computers, computer monitors, magnetic storage disks or tapes, televisions, cellular phones, electronic personal information managers, credit cards, or other items affected by strong magnetic fields. If the patient magnet is too close, these items may be damaged.

**Patient programmer handling** – To avoid damaging the patient programmer, patients should not immerse it in liquid, clean it with bleach, nail polish remover, mineral oil, or similar substances; and should not drop it or mishandle it in a way that may damage it.

**Patient programmer use** – When operating a patient programmer, patients should use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the programmer could occur. The consequences of using a battery-powered programmer near flammable or explosive atmospheres are unknown.

## Storage

**Component packaging** – Do not implant a component if any of the following have occurred:

- The storage package or sterile pack has been pierced or altered, because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage, because the component may not function properly.
- The use-by date has expired, because component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

**Storage temperature: leads and extensions** – Do not store or transport the lead or extension above 57 °C (135 °F) or below -34 °C (-30 °F). Temperatures outside this range can damage components.

**Storage temperature: neurostimulators** – Do not store or transport the neurostimulator above 52 °C (125 °F) or below -18 °C (0 °F). Temperatures outside this range can damage components.

**Storage temperature: programmers and application card** – The recommended storage temperature range for the programmers and application card is -40 °C to 65 °C (-40 °F to 149 °F).

The recommended operating temperature range is 10 °C to 40 °C (48 °F to 105 °F). If the programmers or application card were stored at temperatures outside of the operating range, allow the equipment to stabilize to a temperature within the range before using it.

## System implant

**Compatibility, all components** – Follow these guidelines when selecting system components:

- **Medtronic components:** For proper therapy, use only components that are compatible with the applicable neurostimulator and indication. Compatible Medtronic components are listed in the *System Overview and Compatibility Insert*.
- **Non-Medtronic components** – The use of non-Medtronic components with the neurostimulation system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Use of non-Medtronic components may void Medtronic warranty coverage.

**Component failures** – A neurostimulation system may fail at any time due to random failure of the system components or the battery (prior to depletion). These events, which can include electrical shorts, open circuits and insulation breaches, cannot be predicted. In addition, all neurostimulators will ultimately cease to function.

**Component handling** – Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, which may result in intermittent or loss of stimulation, requiring surgical replacement.

Refer to the appropriate implant manual for additional instructions.

**Neurostimulator location** – Select a location that meets the following criteria:

- Is a minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
- Is on the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices.
- Is away from bony structures (eg, 3 – 4 cm [1.2 – 1.6 in]) to minimize discomfort at the neurostimulator site.
- Is away from areas of restriction or pressure to minimize the potential for skin erosion, patient discomfort, or damage to components.
- Is in an area accessible to the patient for proper operation of a patient control device (ie, patient programmer, control magnet, or with use of any optional remote antenna with a patient programmer).

## Use in specific populations

Refer to the *Indications Insert* for therapy-specific precautions related to specific populations.

## Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management.

**Patient selection** – Select patients carefully to ensure that they meet the following criteria:

- They are appropriate candidates for surgery.
- They can properly operate the system.
- They received satisfactory results from test stimulation.

## Adverse Events

In addition to the risks normally associated with surgery, implantation or use of a neurostimulation system includes, but is not limited to, the following risks. Certain adverse events may necessitate surgical intervention.

- Adverse change in voiding function (bowel and/or bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation of stimulation which has been described as uncomfortable (jolting or shocking) by some patients
- Infection
- New pain
- Pain at neurostimulator and or lead site
- Seroma, hemorrhage, hematoma, and/or paralysis
- Suspected lead or neurostimulator migration or erosion
- Suspected nerve injury
- Suspected technical device problem
- Transient electric shock

For a comprehensive summary of adverse events, refer to the *Clinical Summary*.

## Patient Counseling Information

Clinicians should:

- Provide patients with the following:
  - Information about the components of the neurostimulation system.
  - Instructions for using the patient programmer and magnet (Model 3023 Neurostimulator only).
- Give the patient the *InterStim Therapy Patient Guide* and at a minimum, review these sections with the patient:
  - Living with your InterStim system
  - Information for your doctors
- Instruct patients to always do as follows:
  - Always inform health-care professionals, such as clinicians and dentists, that they have an implanted neurostimulation system. Patients should bring their InterStim Therapy Patient Guide to all medical and dental appointments to help them answer questions that the health-care professional may have regarding medical procedures and potential device interactions.
  - Always carry a patient control device to be able to adjust and/or turn OFF the neurostimulator.
  - Always bring their patient programmer to InterStim Therapy related appointments.
  - Contact their clinician if they notice any unusual symptoms or signs.

# Component Disposal

When explanting neurostimulation system components (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted component with completed paperwork to Medtronic for analysis and disposal.
- To allow for device analysis, do not autoclave the device or expose the device to ultrasonic cleaners.
- Dispose of any components not returned to Medtronic according to local environmental regulations; in some countries, explanting a battery-operated implantable device is mandatory.



## **Cautions:**

- Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Medtronic in the appropriate packaging supplied by Medtronic.
- Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.
- Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the sterility and functionality of the component cannot be guaranteed.

# Resterilization

Before shipment, the neurostimulation system's implantable components, accessories, and tools were sterilized by the process indicated on the package label. The only components that were shipped non-sterile were the clinician and patient programmers and patient magnet (if applicable).

**Note:** If contamination of sterile products is suspected because of a defective sterile package, the components should be returned to Medtronic. The components can be resterilized at the hospital using ethylene oxide or the appropriate procedure specified in Table 2. Resterilization does not change the use-by date specified for any component. Medtronic cannot accept responsibility for the resterilization and/or function of any component resterilized at the hospital.

Resterilizing a component voids the Medtronic Limited Warranty.



## Cautions:

- Do not resterilize any implantable device or implantable accessory after exposure to body tissues or fluids. Resterilizing does not guarantee component sterility.
- To prevent component damage, which may result in component failure, be aware of the following:
  - Do not use radiation to resterilize any component.
  - Do not expose any implantable device (ie, lead, percutaneous extension, extension, neurostimulator) to ultrasonic cleaners.
  - Do not use any resterilization method indicated as "No" in Table 2.

**Table 2. Resterilization options and restrictions**

Component	Resterilization methods <sup>a</sup>		
	Ethylene Oxide Maximum: 55 °C (130 °F) Aeration time: maximum	Autoclave <sup>121</sup> °C (250 °F) 103 kPa (15 psig) 30 minutes	Flash Autoclave 132 °C (270 °F) 186 kPa (27 psig) 5 minutes
Anchor, Grip-lock	No	No	No
Connector boots	Yes	No	No
Introducer (including sheath and guide)	Yes	No	No
Lead	Yes	No	No
Lead Extension	Yes	No	No
Neurostimulator	Yes	No	No
Plugs	Yes	No	No

**Table 2. Resterilization options and restrictions**

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Screws	Yes	No	No
Stylets	Yes	No	No
Silicone anchors (other than Grip-lock)	Yes	Yes	Yes
Extension set screw	Yes	Yes	Yes
Foramen needle	Yes	Yes	Yes
Guide wire	Yes	Yes	Yes
Torque wrench	Yes	Yes	Yes
Tunneling tools			
• Extender	Yes	Yes	Yes
• Extender wrench	Yes	Yes	Yes
• Tube (Passing straw)	Yes	Yes	Yes
• Tunneling rod	Yes	Yes	Yes
• Tunneling tips (including wedge tip)	Yes	Yes	Yes

<sup>a</sup> It is the responsibility of the clinician and hospital to ensure sterility with a validated process. Biological indicators or other acceptable methods should be used to validate the effectiveness of the hospital's sterilizer unit. The resterilization methods listed in this table are based on component integrity, not component sterility. Resterilization does not change the "Use By" date specified for any component. Medtronic cannot accept responsibility for the resterilization and/or function of any component resterilized at the hospital.

Resterilizing a component voids the Medtronic Limited Warranty.

## Appendix A: Electromagnetic Interference

Please review Electromagnetic interference (EMI) under "Warnings" beginning on page 5 and Table 1 "Potential effects of EMI from devices or procedures" beginning on page 6.

Before any medical procedure is begun, patients should always inform any health care personnel that they have an implanted neurostimulation system. The potential for the following effects results from an interaction of the neurostimulation system and equipment—even when both are working properly.

### Contraindication

**Diathermy** – Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their health care professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment in the following instances:

- The neurostimulation system is turned ON or OFF.
- Diathermy is used anywhere on the body—not just at the location of the neurostimulation system.
- Diathermy delivers heat or no heat.
- Any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

### Warnings

EMI from various sources may damage the device, interfere with device operation, or cause harm to the patient. Please consider the following:

**Defibrillation or cardioversion** – When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage a neurostimulation system and cause induced currents in the lead-extension portion of the neurostimulation system that can injure the patient. Minimize the current flowing through the neurostimulator system by following these guidelines:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy (joules) output (watt seconds).

After defibrillation, confirm the neurostimulation system is functioning as intended.

**Electrocautery** – If electrocautery is used near an implantable device or contacts a device or insertion-needle, the following effects may occur:

- The tissue surrounding the insertion-needle (during placement of a percutaneous lead) may be damaged.
- The insulation on the lead or extension may be damaged, resulting in component failure or induced currents into the patient that may damage tissue or stimulate or shock the patient. If this occurs, do not use the damaged component. Obtain a new component from Medtronic for use.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on-reset (POR) settings (ie, output OFF, amplitude 0.0 V). If this occurs check the neurostimulator using the clinician programmer and reprogram all parameters to their intended settings. See the neurostimulator technical manual for POR settings and remedial actions.

When electrocautery is necessary, follow these precautions:

- Before using electrocautery, turn OFF the neurostimulator.
- Use only bipolar cautery.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- If unipolar cautery is necessary, follow these guidelines:
  - Use only a low-voltage mode.
  - Use the lowest possible power setting.
  - Keep the current path (ground plate) as far from the neurostimulator, extension, and lead as possible.
  - Do not use full-length operating room table grounding pads.
- After using electrocautery, confirm that the neurostimulator is functioning as intended.

**High-output ultrasonics or lithotripsy** – Use of high-output ultrasonic devices, such as electrohydraulic lithotriptors, is not recommended for patients who have an implanted neurostimulation system. While there is no danger to the patient, exposure to high-output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

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

**Magnetic resonance imaging (MRI)** – MRI is not recommended for a patient who has any implanted component of a neurostimulation system. Exposing a patient with an implanted neurostimulation system or component to MRI may potentially injure the patient or damage the neurostimulator. Clinicians should carefully weigh the decision to use MRI in patients with an implanted neurostimulation system, and note the following:

- Induced electrical currents from the MRI to the neurostimulation system or component may cause heating, especially at the lead electrode site, resulting in tissue damage. Induced electrical currents may also stimulate or shock the patient.

**Note:** This warning applies even if only a lead or extension is implanted.

Factors that increase the risks of heating and patient injury include, but are not limited to, the following:

- High MRI Specific Absorption Rate (SAR) Radio Frequency (RF) power levels.
- 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 may permanently damage the neurostimulator, requiring it be removed or replaced.
- An MRI may affect the normal operation of the neurostimulator. An MRI can also reset the neurostimulator to power-on-reset values requiring reprogramming by a trained InterStim clinician.
- 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 image details from MRI may be degraded, distorted, or blocked from view by the implanted neurostimulation system.

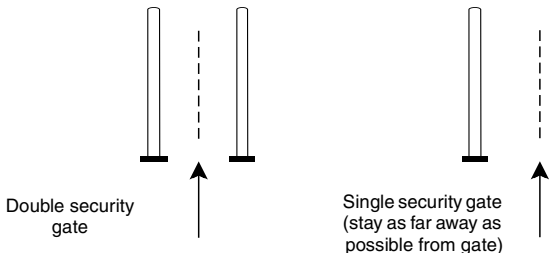
Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

**Effects of monitoring devices** – When using diagnostic monitoring devices such as an electrocardiogram (ECG), Holter Monitor, electroencephalogram (EEG), or implantable heart monitor, pulses from the neurostimulation system may be detected as an electrical signal. When evaluating the diagnostic information, be sure to identify the neurostimulator pulses as intrinsic.

**Theft detectors and security screening devices** – Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., occasionally may cause intermittent stimulation or a momentary increase in stimulation intensity. When they pass through these devices, some patients may perceive intermittent stimulation as switching their neurostimulation system on and off. It is also possible that patients, especially those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation when they pass through these devices. Higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients. In rare situations, such occurrences have caused patients to fall, potentially causing personal injury.

When approaching these devices, patients should do the following:

1. If possible, request to bypass these devices. Patients should show the security personnel their patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but patients should ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.
2. If patients must pass through the theft detector or security screening device, they should turn OFF their neurostimulator, approach the center of the device and walk through normally (Figure 1).
  - a. If two security gates are present, they should walk through the middle, keeping as far from each gate as possible.
  - b. If one gate is present, they should walk as far from it as possible.**Note:** Some theft detectors and screening devices may not be visible.
3. Proceed through the security device. Patients should not linger near or lean on the screening device.



**Figure 1.** Approaching security gates.

4. After patients pass through the security device, they should turn ON their neurostimulator.

## Precautions

EMI from the following equipment is unlikely to affect the neurostimulation system if the guidelines below are followed:

**Bone growth stimulators** – Keep external magnetic field bone growth stimulator coils 45 cm (18 in) away from the neurostimulation system. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and neurostimulator are working as intended.

**Dental drills and ultrasonic probes** – Turn OFF the neurostimulator. Keep the drill or probe 15 cm (6 in) away from the neurostimulator.

**Electrolysis** – Turn OFF the neurostimulator. Keep the electrolysis wand at least 15 cm (6 in) away from the neurostimulator.

**Electromagnetic field devices** – Patients should exercise care or avoid the following equipment or environments:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

If patients suspect that equipment is interfering with neurostimulator function, they should do the following:

1. Move away from the equipment or object.
2. If possible, turn OFF the equipment or object.
3. Then, if necessary, use the control magnet or patient programmer to return the neurostimulator to the desired ON or OFF state. Use the patient programmer to check or adjust output amplitude.
4. Inform the equipment owner or operator of the occurrence.

If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy is not effective after exposure to EMI, they should contact their clinician.

**Laser procedures** – Turn OFF the neurostimulator. Keep the laser directed away from the 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** – Do not direct high radiation sources such as cobalt 60 or gamma radiation at the neurostimulation system. If radiation therapy is required near the neurostimulation system, place lead shielding over the device to help prevent radiation damage.

**Transcutaneous electrical nerve stimulation (TENS)** – Do not place TENS electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the implanted neurostimulator, they should discontinue using the TENS until they talk with their clinician.

## Notes

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

- **Freezer, refrigerator, or storm door magnets that hold the door closed:** Do not lean against the magnetic strip of the door.
- **Radio-frequency sources** (AM/FM radios, analog and digital cellular telephones, cordless and conventional telephones): Keep these items at least 10 cm (4 in) away from the implanted neurostimulator.
- **Stereo speakers and radios for the home or car:** Do not lift or carry speakers or radios near the neurostimulator.
- **Sewing machines or salon hair dryer:** Keep the neurostimulator away from the motors.
- **Computer disk drives:** Keep the neurostimulator away from the disk drives.
- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned ON.
- **Power tools:** Keep the motors away from the neurostimulator, lead, and extension.

**Other medical procedures** – EMI from the following medical procedures is unlikely to affect the neurostimulation system:

- Computerized axial tomography (CT or CAT) scans.
- Diagnostic ultrasound (eg, carotid scan, Doppler studies).

**Note:** To minimize potential image distortion, turn OFF the neurostimulator and keep the transducer 15 cm (6 in) away from the neurostimulation system. Ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulator or implanted lead if used directly over the neurostimulator or lead implant site.

- Diagnostic x-rays or fluoroscopy

**Note:** External pressure used during some medical procedures may damage the neurostimulator or disconnect the neurostimulation system components, which may require surgery to reconnect or replace components. During x-ray procedures that require external compression around implanted components, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the neurostimulator.

- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans

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





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