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Additional information available for the InterStim system

- Refer to the Indications Insert for indications and related information.
- Refer to the System Overview and Compatibility Insert for information regarding device compatibility.
- Refer to the MRI Guidelines for the InterStim system manual for the MRI conditions and MRI-specific contraindications, warnings, and precautions for conducting an MRI scan.
- Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

[USA] Refer to the Clinical Summary for information on the clinical study results for sacral neuromodulation therapy delivered by the InterStim system and for a complete summary of adverse events.

[USA] Refer to the Limited Warranty and Special Notice Insert for warranty information.
- Refer to the System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications.
Contraindications

Implantation of an InterStim™ 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 4 and to "Appendix A: Electromagnetic Interference" beginning on page 13.

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 4, and "Appendix A: Electromagnetic Interference" beginning on page 13.

For information about the effects of EMI on programming, refer to "Telemetry signal disruption from EMI" beginning on page 7.
Table 1. Potential effects of EMI from devices or procedures

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Diathermy and therapeutic ultrasound procedures are contraindicated for patients who have an Interstim system. See page 5 for more information.
MRI during test stimulation – Explant all test stimulation components if an MRI scan is required. Physicians should not prescribe MRI for patients undergoing test stimulation or who have any neurostimulation system components that are not fully implanted. MRI has not been evaluated with test stimulation components. The external neurostimulator contains ferromagnetic material, which can be affected by the MRI magnet and is unsafe in the MRI environment.

**MR Conditional** – InterStim systems have been found to be MR Conditional. If this patient is implanted with an InterStim II Model 3058 Neurostimulator or an eligible serial number of an InterStim Model 3023 Neurostimulator (when implanted as a system including a neurostimulator, lead, and extension as applicable), MRI examinations of the head only may be safely performed under specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction.

MRI RF transmit body coil – Do not use an RF transmit body coil or a receive-only head coil. Serious patient injury could result.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body has been tested) can be conducted safely using an RF transmit/receive head coil when all instructions in the *MRI Guidelines for the InterStim system* manual are followed.

**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 (e.g., pacemaker, defibrillator), clinicians involved with both devices (e.g., 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. Minimize or prevent the cardiac device from sensing the neurostimulator output by:
– programming the neurostimulator therapy output to a bipolar configuration
– consider using bipolar sensing on the cardiac device
– checking for interactions

Careful programming and review of each system’s performance is necessary to ensure safe cardiac system operation with effective sacral neuromodulation.

See also: "Programmer interaction with other active implanted devices" beginning on page 7.

Surgery risk

**Bleeding risk** – Patients should be assessed preoperatively for the risk of increased or uncontrolled bleeding. Clinicians should consider all factors that may increase the risk for bleeding such as antithrombotic agents, vascular abnormalities, and coagulation disorders. Fatal retroperitoneal hematoma in the postoperative period has been reported following implant of the chronic lead in a patient who was on anticoagulation therapy.

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.

**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/Stop mode whenever possible.
- Decrease the amplitude to 0.0 V before taking these actions:\(^1\)
  - Connecting the screener cable to the screener.
  - Turning off the neurostimulator or screener.
  - Turning on the neurostimulator or screener.

\(^1\) The most recent software versions MMB and NNB automatically set the amplitude lower limit to zero.
**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 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 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 programming system components in a sterile field, place them in a sterile bag. Programming system components are not sterile and cannot be sterilized.

**Amplitude lower limit** – If your programmer is using software version MMA or NNA, program the amplitude lower limit to 0.0 V.¹ 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.

¹ Software versions other than MMA and NNA automatically set the amplitude lower limit to zero.
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 use – For antennas that contact the skin, if swelling or redness occurs near the contact site, 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 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 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 (or optional 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 control device handling – To avoid damaging the patient control device, 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 control device use – When operating a patient control device, patients should use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the control device could occur. The consequences of using a battery-powered control device 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 (for Model 8840 and Model 8870) – 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.

For storage and operating temperatures for other programming system components, see applicable manual.

**Sterilization**

Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

**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.

The 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 (or optional control magnet, or with use of any optional remote antenna with a patient control device).

**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, the following adverse events may occur with implantation or use of a neurostimulation system for sacral neuromodulation. 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, and/or hematoma
• 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 control device and optional magnet (Model 3023 Neurostimulator only).
- Give the patient the *InterStim System Patient Therapy 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 healthcare professionals, such as clinicians and dentists, that they have an implanted neurostimulation system. Patients should bring their *InterStim System Patient Therapy Guide* to all medical and dental appointments to help them answer questions that the healthcare 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 control device to InterStim system 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.
Appendix A: Electromagnetic Interference

Please review Electromagnetic interference (EMI) under "Warnings" beginning on page 3 and Table 1 "Potential effects of EMI from devices or procedures" beginning on page 4.

Before any medical procedure is begun, patients should always inform any healthcare 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 healthcare 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 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.

MRI during test stimulation – Explant all test stimulation components if an MRI scan is required. Physicians should not prescribe MRI for patients undergoing test stimulation or who have any neurostimulation system components that are not fully implanted. MRI has not been evaluated with test stimulation components. The external neurostimulator contains ferromagnetic material, which can be affected by the MRI magnet and is unsafe in the MRI environment.

MR Conditional – InterStim systems have been found to be MR Conditional. If this patient is implanted with an InterStim II Model 3058 Neurostimulator or an eligible serial number of an InterStim Model 3023 Neurostimulator (when implanted as a system including a neurostimulator, lead, and extension as applicable), MRI examinations of the head only may be safely performed under specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction.

MRI RF transmit body coil – Do not use an RF transmit body coil or a receive-only head coil. Serious patient injury could result.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body has been tested) can be conducted safely using an RF transmit/receive head coil when all instructions in the MRI Guidelines for the InterStim system manual are followed.

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.

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 optional control magnet or patient control device to return the neurostimulator to the desired on or off state. Use the patient control device 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 (eg, 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 should not be directed at the neurostimulator. High-radiation exposure may temporarily interfere with neurostimulator operation and may damage the neurostimulator. Damage may not be immediately apparent. To limit device exposure, use appropriate shielding or other measures, such as making beam angle adjustments to avoid the device.

**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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