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RestoreULTRA™ and Titan™ are trademarks of Medtronic, Inc.
Refer to the indications sheet for indications and related information.

Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

Refer to System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

Refer to the clinical summary booklet packaged with the neurostimulator for information on the clinical study results of the neurostimulation system and individualization of treatment.
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**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. Refer to Appendix A: Electromagnetic interference for further information.

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 effects:

- **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 neurostimulators 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.

Refer to Table 1, starting on page 4, and Appendix A: Electromagnetic interference for information on sources of EMI, the effect of EMI on the patient and the neurostimulation system, and instructions on how to reduce the risk from EMI.

For information about the effects of EMI on programming, refer to “Telemetry signal disruption from EMI” on page 9.
<table>
<thead>
<tr>
<th>Device or procedure</th>
<th>Serious patient injury</th>
<th>Device damage</th>
<th>Device turns OFF/ON</th>
<th>Momentary increase in stimulation</th>
<th>Intermittent stimulation</th>
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<td></td>
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</table>
MRI RF transmit body coil – Medtronic recommends that you do not conduct an MRI examination using an RF transmit body coil on a patient with any implanted neurostimulation system component because the interaction of the MRI with the neurostimulation system may lead to serious injury or death. See the section “Risks associated with MRI examination” on page 22.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body) can be conducted safely using an RF transmit/receive head coil when all instructions in Appendix B: MRI and neurostimulation therapy for chronic pain 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.

Neurostimulator interaction with implanted cardiac devices – When a patient’s medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, neurologist, neurosurgeon, cardiologist, 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 a cardiac device and could result in an inappropriate response of the cardiac device. 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 Hz. Program the cardiac device to bipolar sensing.

See also: “Programmer interaction with other active implanted devices” on page 8.

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

<table>
<thead>
<tr>
<th>Device or procedure</th>
<th>Serious patient injury</th>
<th>Device damage</th>
<th>Device turns OFF/ON</th>
<th>Momentary increase in stimulation</th>
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</tbody>
</table>

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Information for prescribers 2007-09 English 5
Precautions

Use in specific populations
The safety and effectiveness of this therapy has not been established for:
- pregnancy, unborn fetus, or delivery.
- pediatric use (patients under the age of 18).

Physician training
Implanting physicians – Implanting physicians should be experienced in spinal procedures and should review the procedures described in the implant manual before surgery.
Prescribing physicians – Prescribing physicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the neurostimulation system.

Storage and sterilization
Component packaging – Do not implant a component if the following circumstances have occurred:
- The storage package 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.

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.

Storage temperature: leads and extensions – Do not store or transport the leads or extensions 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.

System implant
Compatibility, all components – Follow these guidelines when selecting system components:
- Medtronic components: For proper therapy, use only Medtronic Neurological components that are compatible or specified in an intended use statement (if present). Components are compatible when the following conditions are met:
  - Components have the same indication.
For implanted components, the contact spacing and the number of electrode contacts at the connections for the lead and extension/neurostimulator or extension and neurostimulator are the same.

For each product, refer to the indication insert(s) and the shipping label artwork for this information.

- **Non-Medtronic components:** No claims of safety or efficacy are made with regard to the compatibility of using non-Medtronic components with Medtronic components. Refer to the non-Medtronic documentation for information.

**Compatibility, bifurcated extension** – When using a bifurcated extension with a different number of contacts than the neurostimulator, select leads of similar impedance. Using a low impedance lead with a standard impedance lead may result in perceived stimulation differences. The effect of dissimilar leads is unknown. (A low impedance lead [impedance below 2 ohms / 10 cm] is a Medtronic product name or model number designated by “Z,” or “LZ,” or “low impedance.”)

**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.

**Extension routing for multiple leads** – When multiple leads are implanted, route the lead-extensions so the area between them is minimized (Figure 1). If the lead-extensions are routed in a loop and the patient is exposed to some sources of electromagnetic interference (eg, theft detectors), the patient may perceive a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).

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![Figure 1. Routing for multiple lead-extensions.](image)
Neurostimulator location — Select a location that is:
\- a minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
\- on the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices.
\- away from bony structures (eg, 3 – 4 cm [1.2 – 1.6 in]) to minimize discomfort at the neurostimulator site.
\- away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.
\- in an area accessible to the patient for proper operation of a patient control device (ie, patient programmer, control magnet, radio-frequency transmitter).

Patient detoxification — Before placing leads for test stimulation, patients should be detoxified from narcotics. If patients are not detoxified, test stimulation may not be properly assessed.

Clinician programming
Amplitude lower limit — Program the lower limit for amplitude to 0.0 V. If the patient cannot set the amplitude to 0.0 V before turning OFF the neurostimulator, the patient may experience unexpected or uncomfortable stimulation.

Parameter adjustment — To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation):
\- program parameter changes in small increments above the perception threshold (the amplitude value(s) at which the patient first perceives paresthesia).
\- decrease the amplitude(s) to 0.0 V before:
  \- changing groups.
  \- changing electrode polarities.
  \- connecting or disconnecting the cable to the screener or external neurostimulator.
  \- replacing the external neurostimulator or screener batteries.
  \- turning ON the neurostimulator or screener.

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 radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.
• the magnet in a cardiac programmer may activate magnetically controlled functions of
  the neurostimulator.

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 physician immediately if they experience symptoms that
could be related to either device or to the medical condition treated by either device.

**Screening with two screeners or external neurostimulators** – When screening a
patient who has two leads implanted, do not operate two screeners or external
neurostimulators simultaneously. The signals from simultaneously operated screeners and
external neurostimulators can interfere with each other and result in incorrect results.

**Telemetry signal disruption from EMI** – Do not attempt telemetry near equipment that
may generate electromagnetic interference (EMI). If EMI disrupts programming, move the
programmer 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 monitoring equipment.

**Patient programming and patient control devices**

**Group selection** – Patients should select the group recommended by the clinician for the
current activity or posture. Use of another group may result in uncomfortable or unexpected
stimulation (jolting or shocking) when stimulation is turned ON.

**Neurostimulator battery depletion** – For the Itrel 3 neurostimulator, patients with a very
low perception threshold (the amplitude at which the patient first perceives paresthesia) 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 control devices may affect other implanted devices** – Do not place the patient
control device (ie, patient programmer, control magnet, radio-frequency transmitter) over
another active implanted medical device (eg, pacemaker, defibrillator, another
neurostimulator). The patient control device could unintentionally change the operation of
the other device.

**Patient magnet disable** – If the neurostimulator magnet control has been programmed to
OFF, the patient must have a patient programmer to turn the neurostimulator ON or OFF.

**Patient magnet may damage items** – Do not place the patient magnet on or near
computer monitors, magnetic storage disks or tapes, televisions, credit cards, or other items
affected by strong magnetic fields. If the patient magnet is too close, these items may be
damaged.

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

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

**Screener or radio-frequency (RF) transmitter** – Advise the patient not to adjust the physician controls. If the patient adjusts these controls, stimulation could be changed, resulting in uncomfortable or loss of stimulation.

**Charging system (for rechargeable neurostimulators)**

**Wound contact** – DO NOT use the recharger on an unhealed wound. The recharger, antenna, and belt are not sterile, and contact with the wound may cause an infection.

**Low battery charge level** – Advise patients to charge the neurostimulator when a low battery screen is displayed on the patient programmer or recharger; this prevents the battery from overdischarging. If the neurostimulator battery is allowed to overdischarge, the patient cannot charge the neurostimulator; however, the clinician may be able to restore the battery function using the Physician Recharge Mode on the recharger (refer to the troubleshooting section of the software manual).

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced.
  - Battery function is not restored when:
    - the neurostimulator battery is permanently damaged.
    - the neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

**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. Spinal cord stimulation patients, in particular, should avoid excessive bending of the torso.

**Antenna attachment** – 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** – 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 stimulation at the implant.
site. Manipulation may also cause device inversion, making a rechargeable neurostimulator impossible to charge.

**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 physician.

**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 repair 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 (e.g., driving, operating power tools). Patients should discuss these activities with their physician.
Component disposal
When explanting a device (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

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

⚠️ Cautions:
- 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 functionality of the component cannot be guaranteed.

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:
- their symptoms are of physiological origin.
- they are appropriate candidates for surgery.
- they can properly operate the system.
- they received satisfactory results from test stimulation.

Use in specific populations
The safety and effectiveness of this therapy has not been established for:
- pregnancy, unborn fetus, or delivery.
- pediatric use (patients under the age of 18).

Long-term effectiveness of neurostimulation
The long-term effectiveness of neurostimulation has been documented. Long-term clinical data regarding the efficacy of Medtronic neurostimulation systems is not yet available. Not all patients realize long-term benefits from neurostimulation.
Adverse events summary

The implantation of a spinal cord stimulation system involves risks that are similar to other spinal procedures. In addition to those normally associated with surgery, implantation or use of a neurostimulation system includes, but is not limited to, the following risks:

- Allergic or immune system response to the implanted materials
- Infection
- Lead, extension, or neurostimulator erosion through the skin or migration
- Leakage of cerebrospinal fluid
- Loss of pain relief may return patients to their underlying pain condition
- Patients on anticoagulation therapies may be at greater risk for postoperative complications such as hematomas that can result in paralysis
- Persistent pain at the neurostimulator site
- Placement of the epidural lead-extension is a surgical procedure that may expose patients to risks of epidural hemorrhage, hematoma, or paralysis
- Radicular chest wall stimulation
- Seroma or hematoma at the neurostimulator site
- Change in stimulation, possibly related to cellular changes around the electrode(s), shifts in electrode position, loose electrical connections, lead or extension fractures, which has been described by some patients as uncomfortable stimulation (jolting or shocking sensation).

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

Patient counseling information

Physicians should provide patients with information about:

- the components of the neurostimulation system: lead, extension, and neurostimulator.
- the indications, contraindications, warnings, and precautions for a neurostimulation system.

Physicians should also instruct patients to:

- always inform any healthcare personnel that they have an implanted neurostimulation system before any procedure is begun.
- contact their physician if they notice any unusual symptoms or signs.
Appendix A: Electromagnetic interference

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

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.

Contraindications

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 when:

- 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 the following medical procedures or equipment may damage the device, interfere with device operation, or cause harm to the patient. If these procedures are required, follow the guidelines below:

CT scans – Prior to the patient undergoing a CT scan, program the neurostimulator to 0 V and turn the neurostimulator Off. If these guidelines are not followed, the patient may experience a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).

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 neurostimulation system by following these guidelines:

- Position defibrillation paddles as far from the neurostimulation system as possible.
- Position defibrillation paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy 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.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on-reset settings (e.g., output OFF, amplitude 0.0 V).

When electrocautery is necessary, follow these precautions:

- Before using electrocautery, turn OFF the neurostimulator.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- Use only bipolar cautery.
- If unipolar cautery is necessary:
  - 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. If lithotripsy must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

MRI RF transmit body coil – Medtronic recommends that you do not conduct an MRI examination using an RF transmit body coil on a patient with any implanted neurostimulation system component because the interaction of the MRI with the neurostimulation system may lead to serious injury or death. See the section “Risks associated with MRI examination” on page 22.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body) can be conducted safely using an RF transmit/receive head coil when all instructions in Appendix B: MRI and neurostimulation therapy for chronic pain are followed.

Radio-frequency or microwave ablation – Safety has not been established for radio-frequency (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.

Theft detectors and security screening devices – Advise patients to use care when approaching theft detector and security screening devices (such as those found in airports, libraries, and some department stores). 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 2).
   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 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 screening device, they should turn ON their neurostimulator.

**Figure 2.** Approaching security gates.
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 neurostimulation system 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 used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (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.
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 physician.

**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...
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** – Do not place transcutaneous electrical nerve stimulation (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, patients should discontinue using the TENS until they talk with their doctor.

**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 motor away from the neurostimulator, lead, and extension.

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

- **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.
- **Diagnostic x-rays or fluoroscopy**
  - **Notes:**
    - To minimize potential image distortion, turn OFF the neurostimulator.
    - Tight pressure such as used during mammography 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.
Appendix B: MRI and neurostimulation therapy for chronic pain

Introduction

Medtronic recommends that you do not conduct an MRI examination of any part of the body on a patient using a radio-frequency (RF) transmit body coil. If all of the instructions stated in this Appendix B are followed, MRI examinations of the head only using an RF transmit/receive head coil may be safely performed.

It is important to read this information in its entirety before conducting an MRI examination on a patient with any implanted component of a Medtronic neurostimulation system for chronic pain. These instructions do not apply to other implantable products or other devices, products, or items. Contact Medtronic at the appropriate address or phone number listed at the back of this manual if you have any questions.

Due to the number and variability of parameters that affect MRI compatibility, the safety of patients or continued functioning of neurostimulation systems exposed to MRI cannot be absolutely ensured. MRI systems generate powerful electromagnetic fields that can produce a number of interactions with implanted components of the neurostimulation system. Some of these interactions, especially heating, are potentially hazardous and can lead to serious injury or death. However, when all instructions stated in this Appendix B are followed, MRI examinations of the head only may be safely performed. In addition, neurostimulation system components can affect the MRI image, potentially impacting the diagnostic use of this modality. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions.

The instructions in this Appendix B describe how to conduct a head-only MRI examination of a patient with a neurostimulation system implanted for chronic pain, using a transmit/receive head coil of a 1.5-Tesla horizontal bore MRI. MRI examinations of any other part of the body are not recommended, as these require the use of the MRI RF transmit body coil, which may produce hazardous temperatures at the location of the implanted lead electrodes.
Warnings

MRI RF transmit body coil – Medtronic recommends that you do not conduct an MRI examination using an RF transmit body coil on a patient with any implanted neurostimulation system component because the interaction of the MRI with the neurostimulation system may lead to serious injury or death. See the section “Risks associated with MRI examination” on page 22.

MRI transmit/receive head coil – An MRI examination of the head only (no other part of the body) can be conducted safely using an RF transmit/receive head coil when all instructions in Appendix B: MRI and neurostimulation therapy for chronic pain are followed.

Limitations –

- MRI should not be considered for patients with neurostimulation systems if other potentially safer diagnostic methods such as CT, x-ray, ultrasound, or others will provide adequate diagnostic information.
- These instructions apply only to Medtronic neurostimulation therapies for chronic pain for approved indications.
- The instructions in this Appendix B apply to all Medtronic fully implantable neurostimulators, leads, and extensions used for chronic pain therapy.

Note: The instructions contained in this Appendix B are not applicable to MRI examinations of patients with radiofrequency (RF) neurostimulators. Medtronic recommends physicians not prescribe MRI for a patient who has an implanted Itrel 3 Model 7425 Neurostimulator. The Itrel 3 Neurostimulator is highly susceptible to reset or damage when subjected to an MRI examination. If reset, the neurostimulator must be reprogrammed. If damaged, the neurostimulator must be replaced. The Itrel 3 Neurostimulator has an increased risk of induced electrical current, which may stimulate or shock the patient.

Contact Medtronic at the appropriate telephone number or address listed at the back of this manual for information about newer models or any updates.

- The RF transmit/receive head coil must not cover any implanted system component.
- If the patient has any other implants or products that prohibit or contraindicate an MRI examination, follow the instructions from the manufacturer. The instructions in this Appendix B apply only to the Medtronic products listed above.
- Do not conduct an MRI examination if the patient's neurostimulation system has a broken lead wire, because higher than normal heating may occur at the break or lead electrodes. Excessive heating can cause tissue damage and result in severe injury or death.
- Physicians should not prescribe MRI for patients undergoing trial neurostimulation and having systems that are not fully implanted.
- If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator to obtain an image, or use alternate imaging techniques. MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted neurostimulation system components, especially near the neurostimulator.
Do not remove the neurostimulator and leave the lead system implanted as this can result in higher than expected lead heating. Excessive heating can cause tissue damage and result in severe injury or death.

**Risks associated with MRI examination** – Exposing a patient with an implanted neurostimulation system or component to MRI may potentially injure the patient or damage the neurostimulator. The known potential risks are as follows:

- 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) RF power levels
- Low impedance leads or extensions (Medtronic product names or model numbers designated by a “Z,” an “LZ,” or “low impedance”)
- MRI RF transmit/receive coil that is near or extends over the implanted lead system
- Implanted lead systems with small surface area electrodes
- Short distances between lead electrodes and heat-sensitive tissue

**Exposure to gradients exceeding a dB/dt limit of 20 Tesla per second may result in overstimulation or shocking, particularly for unipolar-capable devices.**

**MRI may permanently damage the neurostimulator, requiring explant or replacement.**

**MRI may affect the operation of the neurostimulator.** The MRI may also reset the parameters to power-on-reset settings, requiring reprogramming with the clinician programmer.

The Itrel 3 Model 7425 Neurostimulator is highly susceptible to reset or damage when subjected to an MRI examination. If reset, the neurostimulator must be reprogrammed. If damaged, the neurostimulator must be replaced. An Itrel 3 Neurostimulator also might exhibit unpredictable behavior if subjected to an MRI examination.

The neurostimulator may move within the implant pocket and align itself with the MRI field, which may cause patient discomfort or a recent neurostimulator implant incision to open.

**Precautions**

**Patient interaction during MRI** – If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination. Monitor the patient during the MRI examination. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations/uncomfortable stimulation, or unusual sensations.
MRI procedure using an RF transmit/receive head coil

Supervision

If all of the instructions stated in this Appendix B are followed, MRI examinations of the head using an RF transmit/receive head coil may be safely performed.

Prior to the MRI examination, an individual with the proper knowledge of MRI equipment such as an MRI radiologist or MRI physicist must ensure the MRI examination will be conducted according to the information outlined in this Appendix B.

Note: Due to the additional requirements in these instructions, MRI examination time may be significantly extended.

MRI exposure requirements

Prior to an MRI examination, determine whether the patient has multiple active medical device implants (such as deep-brain stimulation systems, implantable cardiac defibrillators, and others). The most restrictive MRI exposure requirements must be used if the patient has multiple active medical device implants. Contact the appropriate device manufacturers if you have questions.

If the following requirements cannot be met, do not proceed with the MRI examination.

- Use only an RF transmit/receive head coil.*
- Use only a 1.5-Tesla horizontal bore MRI (do not use open-sided or other field strength MRI systems).
- Enter the correct patient weight into the MRI console to ensure the head SAR is estimated correctly.

The MRI scan sequences must meet the following requirements. If they do not, the pulse parameters must be adjusted so that they comply with these requirements.

- Use MRI examination parameters that limit the head SAR to 1.5 W/kg or less for all RF pulse sequences.
- Limit the gradient dB/dt field to 20 Tesla per second or less.

*Important: If you are unsure if your MRI has RF transmit/receive head coil capability or if it displays "head SAR", check with your MRI manufacturer.

Note: The requirements provided are based on in-vitro testing and should result in a safe MRI examination of a patient with an implanted Medtronic neurostimulation system when all instructions in this appendix are followed. However, due to the many variables that affect safety, the safety of patients or continued functionality of neurostimulation systems exposed to MRI cannot be absolutely ensured. The user of this information assumes full responsibility for the consequences of conducting an MRI examination on a patient with an implanted neurostimulation system.

Preparation for the MRI examination

Do the following prior to performing an MRI examination on a patient who has an implanted neurostimulation component.
1. Inform the patient of all of the risks of undergoing an MRI examination as stated in this Appendix B.
2. If possible, do not use sedation so the patient can inform the MRI operator of any heating, discomfort, or other problems.
3. Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating occurs during the examination.
4. Determine if the patient has any other implants or conditions that would prohibit or contraindicate an MRI examination. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI examination if any conditions or implants that would prohibit or contraindicate an MRI are present.
5. Verify that all proposed MRI examination parameters comply with the MRI exposure requirements in this Appendix B. If not, the parameters must be modified to meet these requirements. If the parameters cannot be modified, do not perform an MRI.
6. If the patient has implanted leads but does not have an implanted neurostimulator, perform the following steps:
   a. Wrap the external portion of the leads/percutaneous extensions with insulating material, such as dry gauze.
   b. Keep the external portion of the leads/percutaneous extensions out of contact with the patient.
   c. Keep the external leads/percutaneous extensions straight, with no loops, and running down the center of the head coil.
7. If the patient has an implanted neurostimulator, perform the following steps:
   a. Review the neurostimulator with a clinician programmer and print out a copy of the programmed parameters for reference.
   b. Test for possible open circuits by measuring impedance on all electrodes. An impedance measurement greater than 4000 Ω for the RestoreULTRA, SynergyPlus+, SynergyCompact+, Synergy Versitrel, Synergy, or Itrel 3 Neurostimulator indicates a possible open circuit. An impedance measurement greater than 3600 Ω for the RestoreADVANCED, PrimeADVANCED, RestorePRIME, or Restore Neurostimulator indicates a possible open circuit.
   c. If an open circuit is suspected, obtain an x-ray to identify whether the open circuit is caused by a broken lead wire. If a broken lead wire is found, do not perform an MRI examination.
   ▲ Warning: Do not conduct an MRI examination if the patient’s neurostimulation system has a broken lead wire, because higher than normal heating may occur at the break or lead electrodes. Excessive heating can cause thermal lesions and result in severe injury or death.
8. If the system is functioning properly and no broken lead wires are found, program the neurostimulator to the settings provided in Table 2.
During the MRI examination

■ Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient is unable to respond to questions or reports any problems.

■ Conduct the examination using only the MRI pulse sequence that the MRI radiologist or physicist has confirmed meets the MRI examination requirements in this Appendix B.

Post-MRI examination review

■ Verify that the patient feels normal.

■ Verify that the neurostimulator is functional.

■ Reprogram the neurostimulator to pre-MRI settings.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation output</td>
<td>OFF (all programs)</td>
</tr>
<tr>
<td>Stimulation mode</td>
<td>Bipolar (all programs)</td>
</tr>
<tr>
<td>Amplitude</td>
<td>0 Volts (all programs)</td>
</tr>
<tr>
<td>Magnetic (reed) switch</td>
<td>Disabled (Itrel 3 Model 7425 only)</td>
</tr>
<tr>
<td>Other parameters</td>
<td>Do not change</td>
</tr>
</tbody>
</table>

Table 2. Recommended neurostimulator settings for MRI examinations
Contacts:

Asia: Medtronic International Ltd.
Tel. 02891-4068
Fax 2591-0313
Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia: Medtronic Australasia Pty. Ltd.
Tel. 02-9879-5999
Fax 02-9879-5100

Austria: Medtronic Österreich GmbH
Tel. 01-24044
Fax 01-24044-100

Belgium: Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada: Medtronic of Canada Ltd.
Tel. (1905)-826-6020
Fax (1905)-826-6820

Czech Republic: Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark: Medtronic-Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland: Medtronic Finland OY/LTD
Tel. (09)-755-2500
Fax (09)-755-25018

France: Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany: Medtronic GmbH
Tel. (0211)-52530
Fax (0211)-5293100

Greece: Medtronic Hellas S.A.
Tel. 02-10-677-95-99
Fax 02-10-677-93-99

Hungary: Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland: Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy: Medtronic Italia SpA,
Tel. 02-241371
Fax 02-241381

Japan: Medtronic Japan
Tel. 3-6430-2001
Fax 3-6430-7140

Latin America: Medtronic, Inc.
Tel. (1350)-500-9328
Fax (1786)-709-4244

The Netherlands: Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

Norway: Medtronic Vingmed AS
Tel. 67 58 06 80
Fax 67 10 12 12

Poland: Medtronic Poland Sp. z o.o.
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal: Medtronic Portugal, Lda.
Tel. 21-724-5100
Fax 21-724-5199

Spain: Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden: Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland: Medtronic (Schweiz) AG
Tel. 021-803-8000
Fax 021-803-8099

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Fax 01923-241004

USA: Medtronic, Inc.
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Contacts for specific countries are listed inside this cover.