Using neurostimulation for gastric electrical stimulation

Enterra® Therapy

Instructions for Use

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enterra medical™

Information available for the system:

Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

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Indications

The Enterra® Therapy System for Gastric Electrical Stimulation (GES) is indicated for the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis.

Patients should be carefully selected to assure that their symptoms are of physiological origin. Also, patients must be appropriate candidates for surgery.

Intended clinical benefit

The intended clinical benefit of Enterra Therapy is to reduce chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis.

Contraindications

The Enterra Therapy System is contraindicated in patients whose doctor determines are not candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

After implantation of any system component, the following contraindications apply:

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** on page 26 for more information.

The Enterra Therapy System is MR unsafe - Patients with an implanted Enterra or Enterra II Therapy System should not be exposed to the electromagnetic fields produced by Magnetic Resonance Imaging (MRI). The interaction of the MRI with the neurostimulation system may lead to serious injury or death. Use of MRI may also result in system failure, dislodgement, heating, or induced voltages in the neurostimulator and/or lead. An induced voltage through the neurostimulator or lead may cause uncomfortable "jolting" or "shocking" levels of stimulation.

Shelf Life - The Model 37800 IPG must be implanted within 18 months from date of manufacturer. The Model 4351-35 Lead must be implanted within 24 months from date of manufacturer.

Warnings

Use as indicated and instructed - Read all information available for the system. Contact

Enterra Medical for issues with device or package labels. Only use products for the indicated therapy and indicated populations. The consequences of using products for uses other than indicated and instructed are unknown. No claims of safety or efficacy are made with regard to the use of products for non-indicated or non-instructed uses.

Bowel obstruction/perforation - The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Either may lead to life threatening intra-abdominal infections and may require laparotomy, bowel resection, and system revision. Avoid excess lead slack in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms.

Gastric erosion/perforation - The lead(s) can erode through the stomach wall and result in gastric perforation with possible lead migration into the lumen of the intestine. Patients may experience high lead impedance measurements, decreased therapeutic

effect, increased nausea, vomiting, abdominal pain, life threatening intra-abdominal infections and gastrointestinal obstruction that may require laparotomy and/or system revision or removal. Post implant, consider gastric perforation as a possible etiology for patients exhibiting these symptoms.

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 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, potentially 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. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

Refer to **Table 1** (below) and **Appendix A: Electromagnetic interference** on page 26 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 18.

Table 1. Potential effects of EMI from devices or procedures

Device or procedure	Serious patient injury	Device damage	Momentary increase in stimulation	Intermittent stimulation	For guidelines
Bone growth stimulators		X	X	X	Page 34
CT scans			X		Page 29
Defibrillation/ cardioversion	X	X	X	X	Page 29
Dental drills and ultrasonic probes		X			Page 34
Diathermy, therapeutic	X	X		X	Page 27
Electrocautery	X	X			Page 30
Electrolysis		X		X	Page 34
Electromagnetic field devices: (e.g., arc welding, power stations)			X	X	Page 34
High-output ultrasonics		X			Page 31
Household items			X		Page 37
Laser procedures		X			Page 36
Lithotripsy		X			Page 31
Magnetic resonance imaging (MRI)	X	X	X	X	Page 5, Page 28
Psychotherapeutic procedures		X	X	X	Page 36
Radiation therapy		X			Page 36
Radio-frequency (RF) / microwave ablation	X	X		X	Page 31
Theft detector			X	X	Page 32
Therapeutic ultrasound	X	X		X	Page 27
Transcutaneous electrical nerve stimulation (TENS)			X		Page 36

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

Anticoagulation therapy - Patients on anticoagulation therapies may be at a greater risk for post-operative complications, such as hematomas.

Effects on other implanted devices

Neurostimulator interaction with implanted devices - When a patient's medical condition requires both a neurostimulator and an implanted device (e.g., pacemaker, defibrillator), clinicians involved with both devices (e.g., gastroenterologist, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. 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 device damage or device interactions, take the following steps:

- Implant the devices on opposite sides of the body.
- Program the neurostimulator therapy output to a bipolar configuration.

- Consider using bipolar sensing on the cardiac device.
- Check for interactions.

Careful programming and review of each system's performance is necessary to ensure safe cardiac system operation with effective gastric stimulation.

Programmer interaction with other implanted devices - When a patient has a neurostimulator and another active implanted device (e.g., pacemaker, defibrillator, neurostimulator), the Radio-Frequency (RF) signal used to program these devices may reset or reprogram the other device.

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.

Packaging and sterilization

Component packaging - Visually inspect the sterile packaging for damage that may invalidate device sterility before opening, and inspect the components before use. 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 - Enterra Medical, Inc. 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.

Single use - Do not reuse, reprocess, or resterilize single use products. Reusing, reprocessing, or resterilizing may compromise the functional integrity of the products and may create a risk of contamination, which could result in patient injury, illness, or death.

Precautions

Use in specific populations

Use in specific populations - The safety and effectiveness of this therapy have not been established for:

- Pregnancy, unborn fetus, or delivery.
- Pediatric use (patients under the age of 18).
- Patients over the age of 70.

Physician training

Implanting physicians - Implanting physicians should be experienced in laparoscopic 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 gastroparesis and should be familiar with using the neurostimulation system.

System implant

Compatibility, all components - Follow these guidelines when selecting system components:

- **Enterra Medical components:** For proper therapy, use only Enterra Medical Neuromodulation 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 neurostimulator are the same.

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

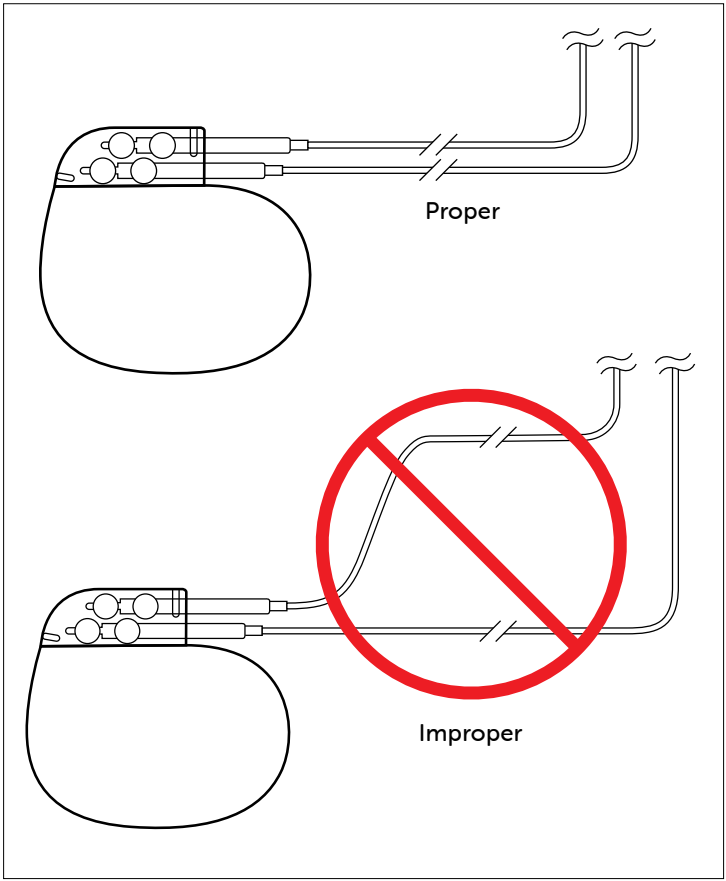
- **Non-Enterra Medical components:** No claims of safety or efficacy are made with regard to the compatibility of using non-Enterra Medical components with Enterra Medical components. Refer to the non-Enterra Medical documentation for information.

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.

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

Figure 1. Routing for multiple leads



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

Patient detoxification - It is recommended that patients undergo detoxification from narcotics prior to implant so that the effects of stimulation can be properly assessed.

Clinician programming

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 anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

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 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.

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.

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).

Hospital or medical environment

Effect on Electrocardiograms (ECGs) - Ensure that the neurostimulator is programmed off prior to initiating an ECG. If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Refer to **Appendix A: Electromagnetic interference** on page 26 for information about other medical procedures that may interact with the neurostimulation system.

Component Disposal

When explanting a device (e.g., replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted device with completed paperwork to Enterra Medical, Inc. for analysis and disposal. See the back cover for the mailing address.
- 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.
  - Do not incinerate or cremate the neurostimulator. It may explode if subjected to these temperatures.

    Note: The implanted neurostimulator must be removed before cremation.
  - 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.

⚠ **Caution:** Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Enterra Medical, Inc. in the appropriate packaging supplied by Enterra Medical, Inc.

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.

Adverse events summary

In addition to the risks associated with surgery, the following adverse events may occur with implantation or use of a neurostimulation system for Enterra Therapy, which may necessitate reprogramming, medical treatment, or additional surgery:

- Lead impedance out of range

- Undesirable change in stimulation (described as a shocking, jolting, or tingling sensation), possibly related to cellular charges around the electrodes, shifts in electrode position, loose electrical connections, or lead fractures
- Loss of therapeutic effect
- Neurostimulator system ceases to function due to battery depletion, telemetry issues, or other causes
- Lead or neurostimulator erosion or migration
- Bowel obstruction, perforation, ileus, or necrosis
- Infections, including device/implant site infections, intra-abdominal infections, abscess, peritonitis, sepsis, urinary tract infections
- Stomach wall perforation
- Upper gastro-intestinal (GI) symptoms including nausea, vomiting, abdominal pain, discomfort, distention, or increased severity of gastroparesis symptoms
- Lower gastrointestinal (GI) symptoms including diarrhea and constipation
- Hemorrhage, hematoma, and possible GI complications resulting from the surgical procedure to implant the neurostimulator and leads

- Persistent pain at the neurostimulator site
- Extra-abdominal pain, bone-and joint-related pain
- Seroma at the neurostimulator site
- Allergenic or immune system response to implanted materials
- Stress incontinence
- Fever
- Feeding tube complications
- Dehydration
- Dysphagia
- Acute diabetic complications
- Cardiovascular renal related events
- Tissue damage

If a serious incident related to a patient's therapy occurs, immediately report the incident to Enterra Medical and the applicable competent authority.

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed by referencing the following UDI/DI's:

- 37800 IPG - 085004596537800EH
- 4351-35 Lead - 08500459654351M9

Patient Counseling Information

Physicians should provide patients with information about:

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

Physicians should also instruct patients as follows:

- Always inform any health care personnel that they have an implanted neurostimulation system before any test or procedure is begun.
- Contact their physician if they notice any unusual symptoms or signs.

Patient implant card

A patient implant card, which contains identifying information about the implanted device, is included in the device package. After device implant, complete the patient implant card and provide it to the patient before they are discharged.

Network and data security:

The 8840 Clinician Programmer and 37800 Enterra implant are not Wi-Fi, Bluetooth, or network connectable. The 8840 Clinician Programmer may contain patient information. To protect against a security incident, Enterra Medical recommends that the 8840 Clinician Programmer not be accessed by any unauthorized person. If the 8840 Clinician Programmer is lost or stolen, contact Enterra Medical. If you suspect a security incident has occurred, contact Enterra Medical to document and respond to the suspected incident. If a security incident affects the operation of the 8840 Clinician Programmer, the programmer can be replaced. Contact information for Enterra Medical can be found at the end of this manual.

Appendix A: Electromagnetic interference

Please review **Electromagnetic Interference (EMI)** under **Warnings** on page 7 and **Table 1. Potential effects of EMI from devices or procedures** on page 9.

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

The Enterra Therapy System is contraindicated in patients whose doctor determines are not candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

After implantation of any system component, the following contraindications apply:

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 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 or neurostimulator) remains in the body.

The Enterra Therapy System is MR Unsafe — Patients with an implanted Enterra or Enterra II Therapy System should not be exposed to the electromagnetic fields produced by Magnetic Resonance Imaging (MRI). The interaction of the MRI with the neurostimulation system may lead to serious injury or death. Use of MRI may also result in **system failure,** dislodgement, heating, or induced voltages in the neurostimulator and/or lead. An induced voltage through the neurostimulator or lead may cause uncomfortable, "jolting," or "shocking" levels of stimulation.

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 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 neurostimulator 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 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 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 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 - Use of high-output ultrasonic devices is not recommended for patients who have an implanted neurostimulation system. If high-output ultrasonics must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

Lithotripsy - Safety has not been established. Lithotripsy is not recommended for patients with an implanted neurostimulation system. If lithotripsy must be used, do not focus the beam on the neurostimulator, which may damage the device.

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.

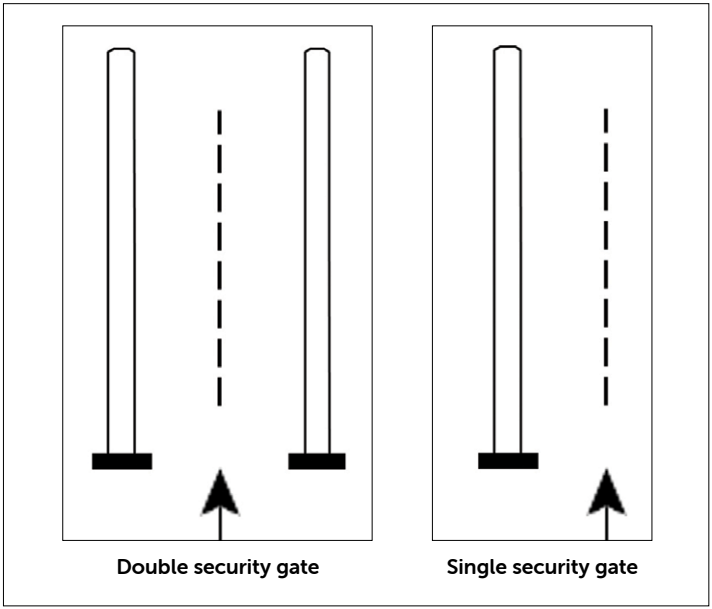
Theft detectors and security screening devices - Advise patients to use care when approaching theft detector and security screening devices (such as those found in airports, libraries, and some department stores). When approaching these devices, patients should do the following:

1. If possible, patients should 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 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. Patients should proceed through the security screening device. They should not linger near or lean on the security screening device.

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 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 - Keep the drill or probe 15 cm (6 in) away from the neurostimulator.

Electrolysis - Turn off the neurostimulator. Keep the electrolysis wand 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 to return the neurostimulator to the desired on and 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 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 transcutaneous electrical nerve stimulation 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:

- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned on.
- **Power tools:** Keep the motor away from the neurostimulator and lead.

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

- Diagnostic ultrasound (e.g., 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 that 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.

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