Patient Therapy Guide

Enterra® Therapy

Gastric Electrical Stimulation System

Rx only
Humanitarian Device: Authorized by Federal (U.S.A.) Law for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

enterra medical™

Doctor visits and when to call your doctor

Always inform any health care personnel that you have an implanted neurostimulation system.

It is important that you keep all of your doctor appointments. Your doctor may send you to a special clinic for routine checkups. Generally, these visits will be brief but will help to determine if your neurostimulator is providing the desired therapy.

Be sure to inform your doctor if you change your address. If you must change doctors, your present doctor may recommend a new doctor. Also, your medical history must be sent to the new doctor.

Contact your doctor if any of the following events occur:

- You have pain, redness, or swelling at the incision later than 6 weeks after surgery.
- You have new or unusual abdominal pain, cramping, nausea, or vomiting at any time after surgery.
- You are experiencing an increase in your nausea or vomiting. The neurostimulator may simply require readjustment to a different therapy setting, or there could be a problem with the lead or neurostimulator. Your doctor should be able to determine the cause of the problem and correct it.

Label symbols

The following symbols appear within this manual or on the back cover.

 Manufacturer

MR Conditional

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Glossary

Contraindications - A medical term meaning that a procedure, device, or drug, etc. should always be avoided because the risk is greater than any possible benefit.

Diathermy - Therapy in which high-frequency currents (shortwave, microwave, ultrasound) produce heat in body tissues to treat certain conditions.

Electrocautery - A procedure using electrical current to stop bleeding of blood vessels. It is used during most surgeries.

Electrolysis - A procedure using electrical current to remove hair.

EMI (Electromagnetic Interference) - Electrical or magnetic energy that is strong enough to interfere with or disrupt your therapy.

Enterra Therapy - A therapy using an Enterra System to send mild electrical pulses to your stomach to manage symptoms of nausea and vomiting associated with gastroparesis.

Enterra Therapy System - A group of implantable devices and a programming device.

Gastric Electrical Stimulation (GES) - The delivery of mild electrical pulses to stimulate the stomach. This electrical stimulation helps control the symptoms associated with gastroparesis including nausea and vomiting.

Gastroparesis - A stomach disorder in which food moves through the stomach more slowly than normal, and in some cases results in severe, chronic nausea and vomiting.

Heart defibrillator - A medical device used to deliver a strong electrical shock to control a fast heart rhythm.

Implant - To insert into the body surgically.

Lead - An implantable thin wire with one or more electrodes at its tip. The lead delivers electrical stimulation to the stomach muscle.

Lithotripsy - A procedure using ultrasonic waves to break up blockages.

Mode - The manner in which stimulation is delivered.

MRI (Magnetic Resonance Imaging) - A type of scan using magnetic fields to provide detailed pictures of your anatomy.

Neurostimulator - An implantable device that produces electrical pulses to stimulate your stomach muscle.

Precaution - A statement that describes an action or situation which could harm you or damage the device.

Radiation therapy - A therapy which uses high energy rays to treat certain diseases, such as cancer.

Ultrasound - The use of high frequency sound waves for diagnostic or therapeutic purposes.

Voltage - The strength of stimulation for your specific therapy measured in volts. The voltage setting is one of several settings that can be adjusted by your doctor in the office or clinic using the clinician programmer.

Warning - A statement that describes an action or situation which could seriously harm you.

How to use this manual

Note: To obtain a paper copy of this manual, contact Enterra Medical at the phone number listed on the back cover of this manual.

This manual was written to help you understand your Enterra™ Therapy System and the device that controls it. It provides information about the system's parts and explains how they are implanted. It also suggests various questions you should discuss with your doctor.

General questions that you and your family may have about the system are answered in the **Some common questions** section. The manual also has a **Glossary** that defines medical terms that may be new for you.

Your system uses a battery and other electronic parts and this manual explains their special requirements. In the **Living with your Enterra System** section, we provide guidelines for your everyday use of the system.

Note: The terms *neurostimulator* and *implantable neurostimulator* (INS) are used interchangeably in this manual.

If you have questions not answered by this booklet, or if any unusual situations or problems arise, consult your doctor. He or she knows your personal medical history and can give you the detailed information you may need.

In particular, you should ask about the potential complications, risks, and benefits of this therapy. As with all surgical procedures, implanting your stimulation system involves some risks. The risks and related information are outlined in the Implant Manual that Enterra Medical provides to your physician.

Indications (purpose of the neurostimulation system)

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 of diabetic or idiopathic etiology in patients aged 18 to 70 years.

Humanitarian Device: Authorized by Federal (U.S.A.) Law for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The effectiveness of this device for this use has not been demonstrated.

Contraindications (medical procedures that are not allowed)

Always inform any health care personnel that you have an implanted neurostimulation system.

The Enterra Therapy System is contraindicated in patients whom the 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 contraindication applies:

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

Patients with the Enterra GES system can safely have MRI examinations of some body parts under certain conditions. Consult your doctor if you have any questions.

Warnings

Bowel Entanglement/Gastric Perforation - The Enterra wires can become entangled with your bowel or perforate your stomach and cause life-threatening blockage or infections that require immediate medical attention, and may require surgery. Contact your doctor if you have new or unusual abdominal pain, cramping, nausea, or vomiting at any time after surgery.

Electromagnetic Interference (EMI) - Electromagnetic Interference (EMI) is a field of energy (electric, magnetic, or a combination of both) 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, strong sources of electromagnetic interference can result in the following:

- Serious injury or death resulting from heating of the implanted neurostimulation system components, which can damage surrounding tissue.
- System damage, requiring surgical replacement or result in a loss of or change in symptom control.
- **Unexpected changes in stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting, shocking, or tingling sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the neurostimulator or cause injury.

Refer to Table 1 on pages 13 and 14 and **Appendix A: Information on electromagnetic interference** on page 31 for information on sources of electromagnetic interference, their effect on the patient and the neurostimulation system, and instructions on how to lessen the risk from electromagnetic interference.

Table 1. Potential Effects of Interactions from Devices or Procedures

Device / Procedure	Possible Serious Injury	Possible Device Damage	Temporary Stimulation Interruption	For Guidelines
Theft detector			X	page 33
Magnetic Resonance Imaging (MRI)	X	X	X	page 11
Defibrillation/ cardioversion, external	X	X		page 39
Diathermy, therapeutic	X	X		page 10
Electrocautery	X	X		page 40
Radio Frequency (RF)/ microwave ablation	X	X		page 41
Therapeutic ultrasound	X	X		page 10
Electrolysis		X		page 37
Hyperbaric chamber therapy		X		page 16
High-output ultrasonics		X		page 40

Warnings

Table 1. Potential Effects of Interactions from Devices or Procedures (continued)

Device / Procedure	Possible Serious Injury	Possible Device Damage	Temporary Stimulation Interruption	For Guidelines
Lithotripsy		X		page 41
Radiation therapy		X		page 37
Bone growth stimulator			X	page 37
X-ray procedures requiring tight enclosure		X		page 38
Electromagnetic field devices: (e.g., arc welding, power stations)			X	page 32
Psychotherapeutic procedures		X	X	page 41
General household: CB or HAM radios, induction range, power tools			X	page 32
Externally applied stimulation (TENS unit, muscle stimulation)			X	page 38

Interaction with other implantable devices - To minimize or prevent device damage or device interactions when a neurostimulator and an implanted device (e.g., pacemaker, defibrillator, cochlear implant) are required, the doctors involved with both devices (e.g., gastroenterologist, surgeon, cardiologist, cardiac surgeon) should discuss stimulator placement and possible interactions between the devices before implant. After implant, each system should be checked to ensure that it is working as intended.

Age Limitations - The safety and effectiveness of this therapy has not been established for patients under the age of 18 or over the age of 70.

Allergic Reaction - There is the possibility of an allergic or immune system response to the implanted materials.

Anticoagulation Therapy - If you are on anticoagulation therapies, you may be at a greater risk for post-operative complications, such as hematomas.

Pregnancy - Safety for use during pregnancy or delivery has not been established.

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

Precautions

Activities requiring excessive twisting or stretching - Avoid activities that may put undue stress on the implanted components of your neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause parts of your neurostimulation system to fracture or migrate. This can result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery.

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

Component Manipulation by Patient (Twiddler's Syndrome) - Avoid manipulating or rubbing the neurostimulator system components (e.g., neurostimulator or lead), which can cause component damage, skin erosion, or stimulation at the implant site.

Scuba diving or hyperbaric chambers - Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 202.65 kilopascals (kPa) or 2.0 atmospheres absolute (ATA). Pressures below 10 meters

(33 feet) of water or above 202.65 kilopascals (2.0 ATA) can damage your implanted neurostimulation system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Diagnostic Ultrasound (e.g., carotid scan, doppler studies) - An implanted neurostimulation system is unlikely to interfere with diagnostic ultrasound. To minimize potential image distortion, the neurostimulator should be turned off, and the transducer should be kept 15 cm (6 in) away from the neurostimulation system.

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.

Individualization of treatment

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

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

Risks

The risks of the Enterra Therapy System can include risks of surgery, side effects, or device complications. These may require programming changes, medical treatment or additional surgery.

Risks of Surgery

Implanting the neurostimulation system carries the same risks associated with any other gastric surgery. Risks may include:

- Infection
- Allergic response to implanted materials
- Temporary or permanent neurologic complications
- Pain at the surgery site
- Fever
- Bruising at the neurostimulator site

- Bleeding
- Stress incontinence
- Cardiovascular, renal-related events
- Tissue damage

Possible Side Effects

Side effects of neurostimulation of the stomach may include the following:

- Gastro-Intestinal (GI) symptoms or worsening of gastroparesis symptoms including nausea, bloating, vomiting, diarrhea and constipation, abdominal pain, and discomfort
- Feeding tube complications
- Difficulty swallowing
- Dehydration
- Acute diabetic complications
- Loss of therapeutic effect

Possible Device Complications

- There may be pain, lack of healing, or infection where the neurostimulation system parts are implanted.
- The neurostimulation system parts may wear through your skin which can cause an infection or scarring.

- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting, shocking or tingling sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or cause injury.
- The Enterra Therapy System could stop because of battery depletion or mechanical or electrical problems. These would require surgical replacement of the neurostimulator or other system components.
- Your body may have an allergic reaction to the neurostimulation system. Your body could also reject the system (as a foreign body).
- The lead may perforate your stomach, or device components may become entangled with or obstruct other internal organs, requiring surgery.
- There is the possibility of tissue damage resulting from the stimulation settings or a malfunction of one of the parts of the neurostimulation system.

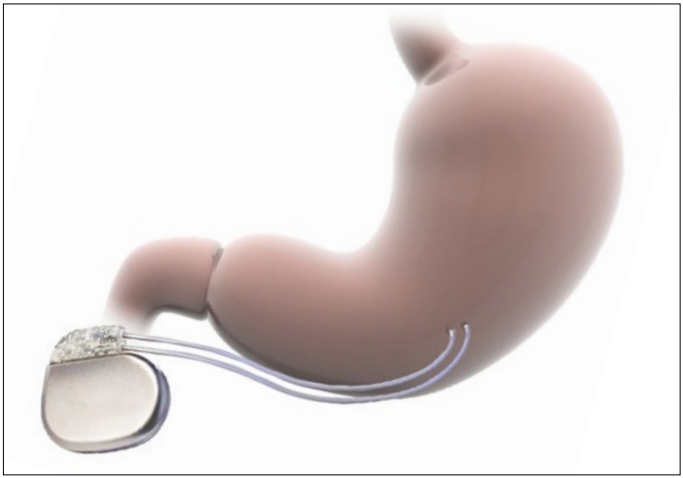
Your Enterra Therapy System

Your neurostimulation system consists of three implantable parts and a clinician programmer.

The implantable parts of your system are the neurostimulator and two leads.

The neurostimulator (Figure 1) produces the electrical pulse that stimulates your stomach muscle. A special battery and electronics inside the neurostimulator control the electrical stimulation. The neurostimulator connects to the leads to carry the electrical pulse to your stomach muscle.

Figure 1. Enterra Therapy System



The leads are wires that carry the electrical pulse from your neurostimulator to the stomach muscle.

Your doctor uses the clinician programmer to program your neurostimulator and adjust your stimulation settings. The clinician programmer is kept at your doctor's office or the hospital.

What to expect from your implant procedure

How your Enterra Therapy System is implanted

Implantation of your system has three basic steps and usually is done in one operation. The steps are as follows:

- Lead implant
- Neurostimulator implant
- Neurostimulator programming

Your doctor will discuss the surgery with you in detail and determine the best locations for the incisions and implants based on your medical history and individual anatomy.

Lead implant

The doctor places two leads in the muscle of your stomach while you are under general anesthesia.

Then the doctor places the main part of the leads under your skin and routes them to a location where they will be connected to the neurostimulator.

Neurostimulator implant

The neurostimulator is implanted after the leads are placed. The doctor makes an incision in the abdomen.

The neurostimulator is placed below the skin in a "pocket." The leads are then connected to the neurostimulator. Your doctor will try to place the neurostimulator in an area that is most comfortable and cosmetically acceptable.

Neurostimulator programming

After the implantation, your doctor will use the clinician programmer to program the neurostimulator to the stimulation settings that are appropriate to your needs.

Living with your Enterra System

Healing

It takes several weeks to heal from surgery. You may feel some discomfort from the incision(s). You may also have some pain at the neurostimulator site up to 6 weeks. This pain is normal.

Activities

During your recovery (about 6 weeks), follow your doctor's advice. Avoid activities where you must bend, stretch, or twist your body; this can move your leads and alter your stimulation.

On the advice of your doctor and as you begin to feel better, you may gradually be able to resume your normal (before your implant) lifestyle. Such activities may include the following:

- Traveling
- Bathing or showering
- Sexual activity
- Working at home or at your business
- Hobbies or recreation, such as walking, hiking, gardening, bowling, golfing, fishing, or hunting

It is important, however, that you follow your doctor's advice. Ask your doctor about any particularly strenuous activities, such as lifting heavy objects.

Battery information

Your neurostimulator operates on a sealed battery and, as with all batteries, it will not run indefinitely. Ask your doctor to estimate the battery life for you based on your device settings.

Replacement surgery

Because the neurostimulator battery is sealed inside the neurostimulator, the battery cannot be replaced separately. Therefore, when it is time to replace the battery, your doctor will remove the entire neurostimulator and replace it with a new one. This requires a surgical procedure. During replacement surgery, your doctor will also check your implanted leads. If the leads are working properly, your doctor will connect the new neurostimulator. If the leads are not working as they should, your doctor may need to replace them also.

Your identification card

Your doctor will give you an identification card, which has important information about your implant. You should carry your identification card at all times. In the event of an accident, this card will tell those attending you that you have an implanted medical device. This card supplies basic information about your neurostimulator and identifies your doctor.

Also, if you need to bypass certain strong magnetic fields, such as a theft detector, present your identification card. It can help validate the reason for your request to bypass the detector.

Your card is especially important if you travel by air because airport security devices may interfere with your neurostimulator and detect the metal in your neurostimulator. **Show your identification card at the security checkpoint.** If you need a new identification card, or if you need to update the information on your card, contact Enterra Medical at +855-7-nterra (+855-768-3772). For additional information, please see **Theft detectors and security screening devices** on page 33.

Some common questions

What is gastric electrical stimulation?

Gastric electrical stimulation is the application of a small electrical current to the stomach muscle.

What is a neurostimulator?

A neurostimulator is the device that sends precise electrical pulses to the stomach muscle. The neurostimulator contains a special battery and electronics to create these pulses.

What does stimulation feel like?

Most patients do not feel gastric electrical stimulation.

Will I be able to turn the neurostimulator on and off?

No. Only your doctor can turn the neurostimulator on and off with the use of the clinician programmer.

Will the Enterra Therapy System eliminate my nausea and vomiting symptoms?

Most, but not all, patients have some relief of their symptoms. Contact your doctor to learn more about the Enterra Therapy clinical study.

Will the Enterra Therapy System limit my activities?

Generally, no. However, the neurostimulator may hinder sharp bending of the body trunk. If you feel limited in your activities, consult your doctor.

Can stimulation be used during pregnancy?

The safety of Enterra Therapy for use during pregnancy or delivery has not been established. If you learn, or suspect, that you are pregnant, consult your doctor.

How often should the doctor check the neurostimulator?

Generally, the neurostimulator battery should be checked about once every six months.

However, your doctor may want to see you more or less often, depending on your situation.

How large is the neurostimulator?

The neurostimulator is oval shaped and approximately 55 mm (2.2 inches) long, 60 mm (2.4 inches) wide, and about 12 mm (0.5 inches) thick. The neurostimulator weighs 45 grams (1.6 ounces).

Will the neurostimulator show through my clothes?

Your doctor will try to place the neurostimulator in a place that is most comfortable and cosmetically acceptable. However, depending on your body build, the neurostimulator may be noticeable as a small bulge under the skin.

Does the neurostimulator make noise?

No.

What happens if the neurostimulator stops working?

If for some reason the neurostimulator stops working, your symptoms may return. If this happens, contact your doctor. He or she will use the clinician programmer to verify the function of the neurostimulator.

How long will the neurostimulator battery last?

The battery life of the neurostimulator will vary depending on the stimulation settings for managing your condition. Like any battery-powered device, the more it is used and the higher the settings, the faster the battery will be depleted. Your doctor is able to accurately estimate the battery life of your neurostimulator based on the settings your doctor will choose to manage your condition. Ask your doctor to estimate the battery life of your neurostimulator. With typical stimulation settings, the battery will last between 4 to 7 years. In rare situations with the highest settings, battery life could be less than 3 months.

Can the battery be recharged?

No.

How is the battery replaced?

Because the neurostimulator battery is sealed inside the neurostimulator case, the battery cannot be replaced separately. To replace the battery, your doctor must replace the entire neurostimulator. A surgical procedure is required to replace the neurostimulator.

Will a microwave oven interfere with a neurostimulator?

No.

Will there be any problems when I pass through theft detectors and screening devices?

Theft detectors (found in places like public libraries and stores) and airport screening systems may cause the neurostimulator to turn on or off. Refer to safety information about theft detectors and screening devices located in the **Warnings** section of this manual.

Also, the security devices may detect metal in your neurostimulator.

Whom should I contact in case I have a problem?

Your first call should be to your doctor. If you are unable to contact your doctor, please contact Enterra Medical at the phone number listed on the back cover of this manual.

Neurostimulator disposal

We suggest that you request that your explanted device be returned to Enterra Medical for analysis and disposal. Analyzing the condition of your device will help us improve future devices. Refer to the back cover of this manual for contact information if you or your doctor have any questions.

Appendix A: Information on electromagnetic interference

Please review the information on electromagnetic interference under **Warnings** on page 11. Refer to **Table 1** on pages 13 and 14 for the effects of electromagnetic interference on patients and neurostimulation system components.

Home, public, and occupational environment

Most household appliances and equipment that are in good working order and properly grounded will not interfere with the neurostimulation system. Refer to **Table 1** on pages 13 and 14 for a list of items and the effects of electromagnetic interference.

If you suspect that equipment is interfering with neurostimulator function, do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Inform the equipment owner / operator of the occurrence.

If the above actions do not resolve the effects of the interference, or you suspect that your therapy is not effective after exposure to EMI, contact your doctor.

Generally safe if precautions are followed:

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.

Exercise care or avoid the following equipment or environments:

- Antenna of Citizen Band (CB) radio or ham radio
- Electric arc welding equipment
- Resistance welders
- Electric induction heaters used in industry to bend plastic
- Electric steel furnaces
- High voltage (safe if outside the fenced area)

- Television and radio transmitting towers (safe if outside the fenced area)
- Microwave communication transmitters (safe if outside the fenced area)
- Linear power amplifiers
- High power amateur transmitters
- Perfusion systems
- Magnets or other equipment that generates strong magnetic fields
- Magnetic degaussers

Theft detectors and security screening devices

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, do the following:

1. If possible, request to bypass these devices. Show the security personnel your patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. You may wish to ask for another form of personal search.

2. If you must pass through the theft detector or security screening device, approach the center of the device and walk through normally (Figure 2).

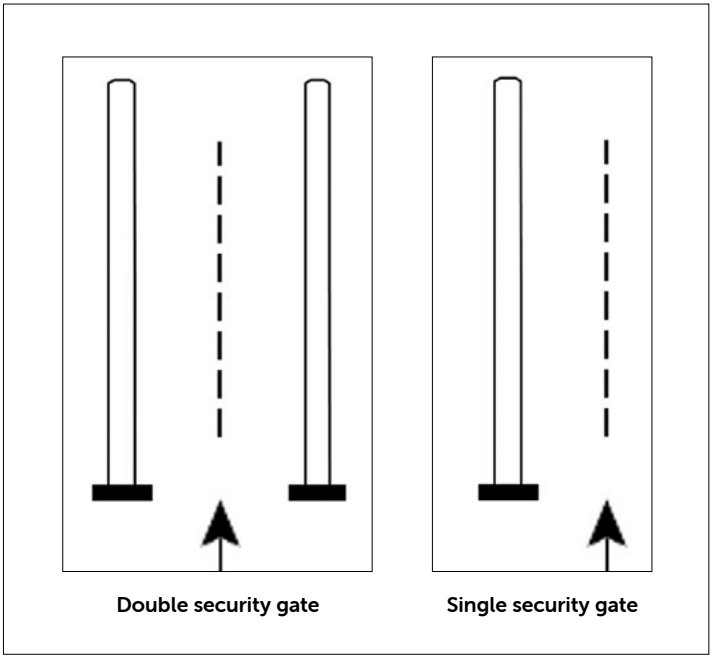
   a. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.

   b. If one gate is present, walk as far away as possible from it.

Note: Some theft detectors may not be visible.

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

Figure 2. Approaching security gates



Medical and hospital environment

Always inform any health care personnel that you have an implanted neurostimulation system. Refer to **Table 1** on pages 13 and 14 for a list of items and the effects of electromagnetic interference.

Safe from electromagnetic interference

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

- Diagnostic ultrasound (e.g., carotid scan, doppler studies)
  Note: To minimize potential image distortion, the neurostimulator should be turned off and the transducer kept 15 cm (6 in) away from the neurostimulation system.
- Diagnostic X-rays or fluoroscopy
  Note: Tight pressure in the area of your neurostimulator may damage or disconnect components of your neurostimulation system. This may require surgery to replace or repair the neurostimulation system. X-ray equipment should be adjusted so it does not squeeze the neurostimulator too tightly.
- Magnetoencephalography (MEG)
- Positron Emission Tomography (PET) scans

The following medical procedures are not likely to affect the implanted system:

- Computerized Axial Tomography (CT or CAT) Scans

Precautions required

The following medical procedures are unlikely to affect the implanted system if the guidelines provided below are followed:

Bone Growth Stimulators - External magnetic field bone growth stimulator coils should be kept away from the neurostimulator or lead system. When either an implantable or external bone growth stimulator is used, your doctor should ensure that both the bone stimulator and neurostimulator are working as intended.

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

Electrolysis - The neurostimulator should be turned off, and the electrolysis wand should be kept away from the neurostimulator.

Laser procedures - The neurostimulator should be turned off, and the laser should be directed away from the neurostimulation system.

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

X-rays Requiring Tight Enclosure - Pressing the neurostimulator too tightly during X-ray procedures that require enclosure of the implant area may damage the neurostimulator or disconnect the neurostimulation system components, which may require surgery to fix the system or replace components. X-ray equipment should be adjusted to limit the amount of pressure exerted on the neurostimulator during procedures that require enclosure of the implant area.

Unsafe or special precautions

The following medical procedures are unlikely to affect the implanted system if the guidelines provided below are followed:

Defibrillation / Cardioversion - When you are in ventricular or atrial fibrillation, the first consideration should be your survival.

External defibrillation or cardioversion can damage a neurostimulation system. It is recommended that defibrillation or cardioversion paddles not be used near the neurostimulator. When external defibrillation or cardioversion is necessary, the current flowing through the neurostimulator and lead system should be minimized as follows:

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

Defibrillation or cardioversion may also cause induced currents in the lead portion of the neurostimulation system that could be hazardous or cause further injury.

Diathermy - See Diathermy on page 10.

Electrocautery - Electrocautery can damage the lead or neurostimulator. It can also cause temporary suppression of neurostimulator output and/or reprogram the neurostimulator prior settings. Electrocautery may also cause induced currents in the lead portion of the neurostimulation system that could be hazardous or cause further injury.

These precautions should be followed when using electrocautery:

- The neurostimulator should be turned off before performing electrocautery.
- Only bipolar cautery is recommended.
- If unipolar cautery is necessary:
  – High voltage modes should not be used.
  – The power setting should be kept as low as possible.
  – The current path (ground plate) should be kept as far away from the neurostimulator and lead as possible.
- Neurostimulator function should be confirmed after electrocauterization.

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.

Magnetic Resonance Imaging (MRI) - See page 11 for more information on MRI.

Psychotherapeutic Procedures - The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) has not been established in patients with an implanted neurostimulation system.

Radiofrequency (RF) / Microwave Ablation - Safety has not been established for radiofrequency (RF) or microwave ablation in patients with an implanted neurostimulation system. Induced electrical currents from these procedures to the neurostimulation system may cause heating, especially at the lead electrode site, resulting in tissue damage.

Enterra Medical Neurostimulation System limited warranty[1] (U.S. customers only)

A. This limited warranty provides the following assurance to the patient who receives an Enterra Medical Neurostimulation System. The neurostimulation system includes neurostimulators, permanent leads, single-use accessories, and disposable tools, hereafter referred to as "components", unless specifically noted.

(1) Should the components fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the date of implantation or use of the components, Enterra Medical will at its option: (a) issue a credit to the purchaser of the replacement component equal to the Purchase Price, as defined in Subsection A(3), against the purchase of any same component requested as its replacement, or, (b) provide a functionally comparable replacement component at no charge.

[1] This limited warranty is provided by Enterra Medical, Inc., 5353 W. Wayzata Boulevard., Suite 400, St. Louis Park, MN 55416-9906. It applies only in the United States. Areas outside the United States should contact their local Enterra Medical representative for exact terms of the limited warranty.

(2) Neurostimulator battery cell depletion will occur with time and is not considered to be a defect in materials or workmanship. The batteries have a specified capacity that may deplete at different rates depending on settings and individual requirements for neurostimulation functions. Therefore, no representation is made that the neurostimulator will last the entire term of this limited warranty.

(3) As used herein, "purchase price" shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement component.

B. To qualify for this limited warranty, these conditions must be met:

(1) The components must be implanted prior to its "USE BY" date.

(2) The components must be used in conjunction with components compatible with the Enterra Medical Neurostimulation System.

(3) All device registration materials must be completed and returned to Enterra Medical within thirty (30) days of implantation of the neurostimulator.

(4) Replaced neurostimulators must be returned to Enterra Medical within thirty (30) days of explantation and shall be the property of Enterra

Medical. For all other components, the component, or portion thereof, must be returned to Enterra Medical within 30 (thirty) days after discovery of the defect and shall be the property of Enterra Medical, and if not explanted, the serial number or lot number must be provided to Enterra Medical instead.

(5) The components must be used in accordance with the labeling and instructions for use provided with the components.

C. This limited warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, ENTERRA MEDICAL IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION NEUROSTIMULATOR TO FUNCTION WITHIN NORMAL TOLERANCES, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT OR OTHERWISE.

(2) This limited warranty is made only to the patient in whom the Components were implanted. AS TO ALL OTHERS, ENTERRA MEDICAL MAKES NO WARRANTY, EXPRESS OR IMPLIED,

INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this limited warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the limited warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this limited warranty did not contain the particular part or term held to be invalid. This limited warranty gives the patient specific legal rights. The patient may also have other rights that vary from state to state.

(4) No person has any authority to bind Enterra Medical to any representation, condition, or warranty, except this limited warranty.

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