Patient Therapy Guide

Enterra Ascent®

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 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 working properly and providing relief of your symptoms.

Be sure to inform your doctor if you change your address. If you must change doctors, your present doctor may recommend a new doctor. Confirm that your new doctor has your medical history.

Contact your doctor if any of the following events occur:

- You have pain, redness, or swelling at the incision site more than 6 weeks after the 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 an adjustment 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

Rx only Rx Only or prescription only

 Date of manufacture

 Use-by-date



Catalogue or reference number



Sterilized using ethylene oxide



Do not resterilize

 Do not use if package is damaged and consult instructions for use

 Double sterile barrier system with protective packaging inside

 Do not reuse/single use only

 Consult instructions for use or consult electronic instructions for use



Medical device



Country of origin

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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 Ascent - A therapy using an Enterra Ascent System to send mild electrical pulses to your stomach to reduce symptoms of nausea and vomiting associated with gastroparesis. The Enterra Ascent System includes an implantable neurostimulator, leads, and a Clinician Programmer for programming the system.

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

Gastroparesis - A stomach disorder in which food is emptied from the stomach more slowly than normal in the absence of obstruction; in some cases, this disorder causes 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 during Enterra Therapy.

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 Enterra Ascent System.

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.

About 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 will help you understand your Enterra Ascent System and the Clinician Programmer that controls your stimulator. You will learn about the system's parts and how they are implanted. For a list of questions that we recommend asking your doctor, refer to **Some common questions**. For definitions of medical terms that may be new to you, refer to the **Glossary**.

In **Living with your Enterra Ascent System**, we provide guidelines for your everyday use of the system.

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

In particular, you should ask about the potential complications, risks, and benefits of the therapy provided by the Enterra Ascent System. As with all surgical procedures, implanting your stimulation system involves some risks.

Indications (purpose of the neurostimulation system)

The Enterra Ascent 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 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.

Contraindications (medical procedures that are not allowed)

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

The Enterra Ascent 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 Enterra 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 lead wires can become entangled with your bowel or perforate your stomach and cause a 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 magnetic fields 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 10, 42
Defibrillation/ cardioversion, external	X	X		page 38
Diathermy, therapeutic	X	X		page 10
Electrocautery	X	X		page 39
Radio Frequency (RF)/ microwave ablation	X	X		page 40
Therapeutic ultrasound	X	X		page 10
Electrolysis		X		page 36
Hyperbaric chamber therapy		X		page 16
High-output ultrasonics		X		page 39

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 40
Radiation therapy		X		page 36
Bone growth stimulator			X	page 36
X-ray procedures requiring tight enclosure		X		page 37
Electromagnetic field devices: (such as arc welders and power stations)			X	page 32
Psychotherapeutic procedures		X	X	page 40
General household: CB or HAM radios, induction range, power tools			X	page 32
Externally applied stimulation (TENS unit, muscle stimulation)			X	page 37

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

Age Limitations - The safety and effectiveness of this therapy have 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 may require additional surgery.

Component failures - The neurostimulation system may cease to function due to battery depletion or other causes. These other 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 neurostimulation system components (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 (such as carotid scans or 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 precautions 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 lead fractures. Surgery may be required to repair or replace the lead(s).

Individualization of treatment

Patient management - Best results are achieved when you are fully informed of 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.

Patient detoxification (when applicable) - It is recommended that you undergo detoxification from narcotics prior to implant so that the effects of narcotics on your symptoms and gastric emptying can be properly assessed.

Risks

The risks of the Enterra Ascent System can include complications from and risks associated with surgery, side effects of neurostimulation, or complications associated with the neurostimulator or neurostimulation system. Any of these problems 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 surgeries. 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 associated with the neurostimulator or the neurostimulation system

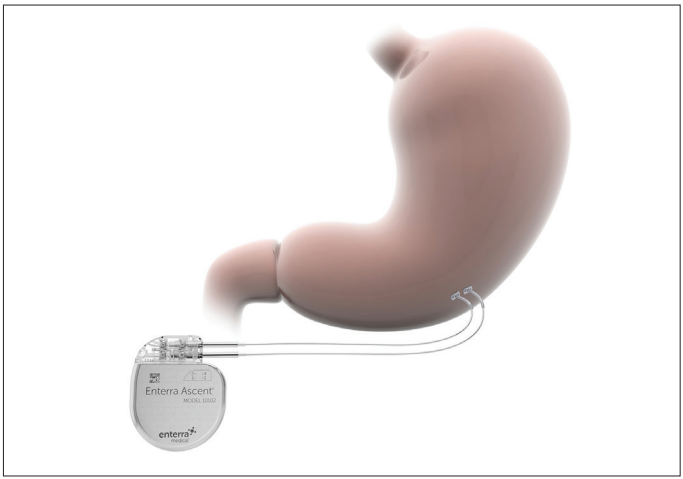
- There may be pain, lack of healing, or infection where the neurostimulation system parts are implanted.
- The neurostimulation system parts may wear through your skin which can cause an infection or scarring.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent 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 neurostimulator or cause injury to you.
- The Enterra Ascent 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 leads may perforate your stomach or may become entangled with or obstruct other internal organs, and you may require 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 Ascent System

Your neurostimulation system consists of a Clinician Programmer and three implantable components: a neurostimulator and two leads.

The implanted 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 two implanted leads, which are wires that carry the electrical pulses to the muscle layer of your stomach.

Figure 1. Enterra Ascent System



Your doctor uses the Clinician Programmer to program your neurostimulator and adjust your stimulation settings as necessary. The Clinician Programmer is kept at your doctor's office or the hospital.

What to expect from your implant procedure

How your Enterra Ascent System is implanted

Implanting your system involves three basic steps and usually is accomplished in one operation. The steps are as follows:

- Implanting the two leads in the stomach
- Implanting the neurostimulator beneath the skin
- Programming the neurostimulator to reduce nausea/vomiting

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.

Implanting the leads

While you are under general anesthesia, your doctor implants two leads into your stomach muscle.

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

Implanting the neurostimulator

After the leads are placed, your doctor makes an incision in your abdomen, where the neurostimulator is implanted.

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.

Programming the neurostimulator

After implanting the leads and neurostimulator, your doctor will use the Clinician Programmer to program the neurostimulator to the initial stimulation settings that are appropriate to your needs.

Living with your Enterra Ascent System

Healing from surgery

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

Activities following surgery

During your recovery (about 6 weeks), follow your doctor's advice regarding resuming daily activities and especially about food intake and your diet. As you begin to feel better, you may gradually be able to resume your normal lifestyle. Avoid activities where you must bend, stretch, or twist your body; these activities can move your leads and alter stimulation.

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

For particularly strenuous activities, such as lifting heavy objects, consult your doctor.

Battery information

Your neurostimulator operates on a sealed battery and, as with all batteries, it will not run indefinitely.

The battery life of the neurostimulator will vary depending on the stimulation settings for managing your condition. Like any battery-powered device, the more the neurostimulator is used and the higher the settings, the faster the battery will be depleted. Your doctor can 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 4 to 7 years. In rare situations with the highest settings, battery life could be less than 3 months.

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 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 them to the new neurostimulator. If the leads are not working as they should, your doctor may need to replace them also.

Your Enterra identification card

Your doctor will give you an identification card, which includes important information about your implant. You should carry your Enterra identification card at all times. In the event of an accident, this card will inform 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 +1-855-7-nterra (+1-855-768-3772). 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 the neurostimulator?

A neurostimulator is an implanted device that sends precise electrical pulses to your stomach muscle. The neurostimulator contains a special battery and electronics to generate these pulses, which induce gastric electrical stimulation.

What does stimulation feel like?

Most patients do not feel gastric electrical stimulation. Infrequently, you may experience unexpected stimulation from the neurostimulator, which may feel like a jolting, shocking or tingling sensation.

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 Ascent System eliminate my nausea and vomiting symptoms?

Most patients experience some relief of their symptoms. Contact your doctor to learn more about the Enterra Therapy clinical studies.

Will the Enterra Ascent System limit my activities?

Generally, no. However, the neurostimulator may hinder your ability to fully bend your torso. If you feel limited in your activities, consult your doctor.

Can stimulation be used during pregnancy?

The safety of Enterra Ascent 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 my doctor check the neurostimulator?

Generally, the neurostimulator battery should be checked once every 6 months.

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

How large is the neurostimulator?

The neurostimulator is oval shaped and approximately 62 mm (2.44 in) high, 50 mm (2.0 in) wide, and approximately 12.7 mm (0.5 in) thick. The neurostimulator weighs 45 grams (1.6 oz).

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.

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 using a microwave oven interfere with my neurostimulator operation?

No.

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

Theft detectors (found in places like public libraries and retail stores) and airport screening systems may cause the neurostimulator to turn on or off. Refer to safety information regarding theft detectors and screening devices 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.

Neurostimulator disposal

When your neurostimulator is explanted, we recommend that it be returned to Enterra Medical for analysis and disposal. Analyzing the condition of your neurostimulator will help us improve future products. Should you or your doctor have any questions, please contact Enterra Medical at the phone number listed on the back cover.

Appendix A: Information on electromagnetic interference

Please review the information on electromagnetic interference (EMI) 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.

Enterra System is generally safe if precautions are taken:

Induction range - Keep the neurostimulator away from the burners while the burners are turned on.

Power tools - Keep the tool away from the neurostimulator and lead.

Exercise care and 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

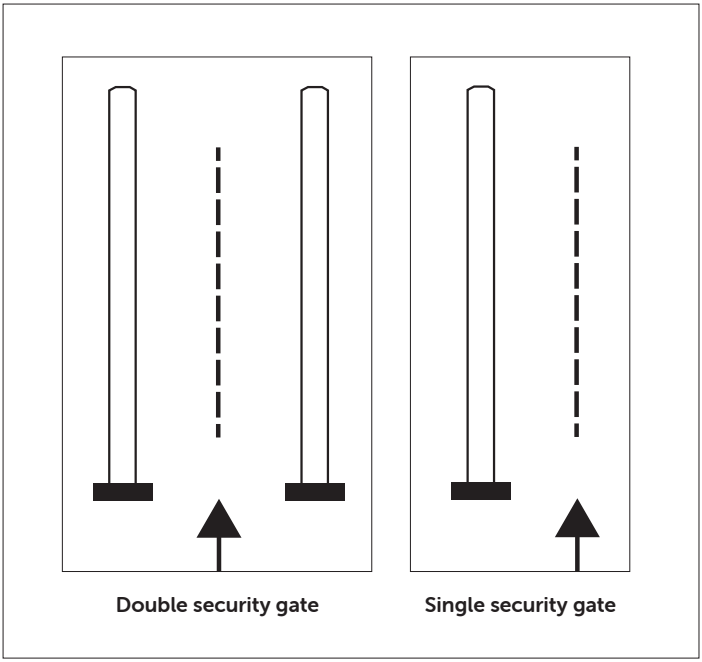
Use care when approaching theft detectors and security screening devices (such as those found in airports, libraries, and retail stores). When approaching these devices, do the following:

1. If possible, request to bypass these devices. Show your patient identification card to the security personnel 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 (such as carotid scans or 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: Strong 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. Adjust the X-ray equipment such that 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 precautions and 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 such 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 to your doctor.

X-rays Requiring Tight Enclosure - Pressing on the neurostimulator too strongly 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 - If you develop ventricular or atrial dysrhythmias, the first consideration is to get help and correct the cardiac dysrhythmia.

External defibrillation or cardioversion can damage the Enterra 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 away 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. The first priority is correction of the cardiac dysrhythmia.

Diathermy - See Diathermy on page 10.

Electrocautery - Electrocautery can damage the leads or the 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.

When using electrocautery, exercise the following precautions:

- The neurostimulator must 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 Enterra 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. Doing so may damage the neurostimulator.

Magnetic Resonance Imaging (MRI) - See page 10 for more information on MRI.

Psychotherapeutic Procedures - The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (such as electroconvulsive therapy or 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.

Appendix B: Enterra Ascent Neurostimulator model 10102 communications regulations

The following communications regulations apply to the model 10102.

United States Compliance

FCC ID: 2BH4M-10102

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Enterra Medical, Inc., could void the FCC Certification and negate your authority to operate this product.

Appendix C: MRI Guidelines

Glossary



MR Conditional - An item with demonstrated safety in the MR environment within defined conditions, including conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields. Additional conditions, including specific configurations of the item, may be required.



MR Unsafe - An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

ACR Zone - Zones of an MR site that denote areas with various MR safety levels, as defined by the American College of Radiology.

MRI - Magnetic Resonance Imaging.

1. What is magnetic resonance imaging (MRI)?

Magnetic Resonance Imaging (MRI) is a technique that is used for creating pictures of the internal structures of the body. Unlike an X-ray exam, MRI does not use radiation. Instead, it uses a large magnet, radio waves, and a computer to create pictures of body structures and organs.

2. Can I have an MRI?

Patients with an implanted Enterra Ascent® System may have an MRI scan of some body parts under certain conditions. Consult your doctor to determine if you are eligible for MRI examination.

If you have any other implanted device(s), you are required to tell your doctor. Possible implanted devices include:

- Pacemaker or Implantable Cardioverter-Defibrillator (ICD)
- Some aneurysm clips
- Cochlear implants
- Orthopedic prostheses (such as a hip implant)

- Other neurostimulators
- Stents
- Metal plates, pins, or screws
- Dental implants

An MRI requires that you to lie still during the exam. Before the MRI procedure, inform the MRI technologist if:

- You are pregnant or suspect you are pregnant
- You are breast feeding at the time of the scheduled procedure
- You have a fever

3. MRI safety information 

The Enterra System is **MR Conditional**. This means that patients with the Enterra System can safely have MRI examinations of some body parts under certain conditions. The conditions for MRI scans will vary with the type of MRI coil.

Always obtain the latest MRI guidelines. Refer to the contact information on the last page of this manual or go to www.enterramedical.com/intl-hcp/manuals.

3.1. MR Conditional Devices 

Non-clinical testing has demonstrated that the Enterra Ascent Neurostimulator with two Enterra unipolar leads are **MR Conditional**.

Patients with these devices can be safely scanned in an MR system meeting the conditions described in the following section.

3.2. For MRI examinations using a detachable head, upper extremity, or lower extremity RF transmit/receive volume coil

A patient implanted with the Enterra Therapy System may be safely scanned at the head or upper/lower extremity at 1.5T or 3.0T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.

MRI Safety Information

A person with the Enterra Ascent System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Enterra Ascent
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (Bo)	1.5 T or 3.0T
MR Scanner Type	Cylindrical
Bo Field Orientation	Horizontal
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head or Extremity Coils Only
RF Receive Coil Type	Head or Extremity Coils Only
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg
Maximum Head SAR	3.2 W/kg
Scan Duration	Scan for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Only head or extremity scanning allowed.
MR Image Artifact	The presence of this implant may produce an image artifact.

Please consult your doctor and the MRI technologist to make sure that the specific conditions above are met before MRI examination.

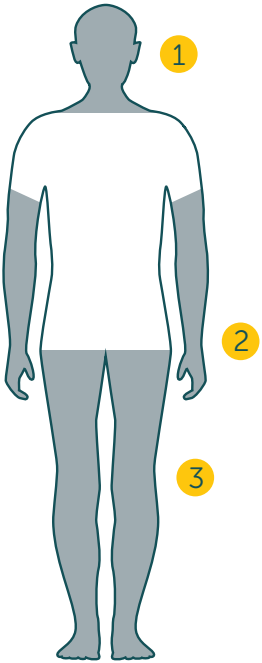


Figure 1: MRI scan* using detachable 1 head, 2 upper extremity, or 3 lower extremity RF transmit coil.

*Illustrated are typical use scenarios of detachable RF transmit/receive volume coils. Other scanning scenarios are also permissible according to MR scanner/coil manuals. For example, an MRI scan of the ankle with a detachable lower extremity RF transmit/receive volume coil or an MRI scan of the upper arm with a detachable lower extremity RF transmit/receive volume coil in the superman posture is permissible provided that the aforementioned scan conditions are met.

3.3. MR unsafe devices

The external components of the Enterra Ascent System, including the Enterra Entrust Model 40100 Clinician Programmer, are **MR Unsafe**. These devices must NOT be taken into the MR scanner room (ACR Zone IV).

4. Possible risks of MRI with the Enterra Ascent System

Non-clinical testing has shown that patients with the Enterra Ascent System can safely have MRI when the conditions for safe MRI described in this document are met. However, there may be some risks of performing MRI when you have an implanted Enterra Ascent System. Possible risks include:

- Heating of the implant
- Unintended stimulation
- Image distortion and artifacts
- Magnetic field interactions
- Device malfunction or damage

4.1. Heating of the implant

MRI may cause the implant to become hot. However, if the conditions for safe MRI are met, this heating is minimal. If the specific MRI conditions are not followed, heating of the implant could damage surrounding tissue. If the site of your implant feels hot during MRI, inform the MRI technologist immediately and then contact your doctor.

4.2. Unintended stimulation

MRI may cause unintended stimulation from the implant. This unintended stimulation may be uncomfortable (you may feel a tingling, shocking, or jolting sensation). However, if the conditions for safe MRI are met, such stimulations may not occur. If you feel any uncomfortable stimulation during MRI, inform your MRI technologist immediately and then contact your doctor.

4.3. Image distortion and artifacts

No image distortion or artifacts should be visible in MRI head and extremity scans.

4.4. Magnetic field interactions

The magnets used in MRI may cause the neurostimulator to shift or move slightly within the implant pocket. This may cause stress to tissues and/or the lead. As a result, you may feel a slight tugging sensation at the site of your implant. If you feel uncomfortable while in the MRI, inform your MRI technologist immediately.

4.5. Device malfunction or damage

Non-clinical tests in various MRI systems were conducted. These tests did not cause any damage to, or malfunction of, the implant. If the implant malfunctions or becomes damaged, the result may be nerve damage and other associated problems. If you feel any stimulation or discomfort during MRI, inform your MRI technologist immediately and then contact your doctor.

5. MRI guidelines

The guidelines for MRI scans are based on non-clinical tests conducted on the Enterra Ascent System. Precautions are to be taken before, during, and after MRI scan. Talk to your MRI technologist or your doctor should you have any questions or concerns.

5.1. Before the MRI scan

- Consult your doctor and MRI technologist to determine if you are eligible for an MRI scan.
- Inform your doctor and MRI technologist if you have other implanted medical device(s), such as a pacemaker, drug pump, hip prosthesis, stent, etc.

- Inform your doctor and MRI technologist if you think that there is a problem with your device: a broken lead fragment, lead disconnection from the neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, a neurostimulator implanted at an area other than abdomen, or a system with open or low impedances (indicating a short circuit) on any electrodes. Consult your doctor to determine your eligibility for MRI if any of these conditions apply.
- Your MRI technologist may also provide MRI Patient Guides and Instructions. Be sure to comply fully with the guidelines and instructions. Discuss any concerns with your MRI technologist or your doctor.
- Bring the most up-to-date patient ID card to all MRI appointments.
- For MRI using detachable head, upper extremity, or lower extremity RF transmit/receive volume coils, make sure that the neurostimulator stimulation is turned off.
- Make sure you remove any external metallic objects before entering the MRI scanner room.

5.2. During MRI scan

- You may feel slight tugging, vibration, warming, and/or tapping in the area where the neurostimulator is located during the MRI scan. If these sensations cause discomfort, inform your MRI technologist immediately.
- If you are not feeling well for any other reason prior to or at the time of MRI scanning, please inform your MRI technologist.

5.3. After the MRI scan

- After the MRI scan, make sure the stimulation on your neurostimulator back on.
- If you feel any changes in stimulation or are uncomfortable after the MRI, contact your doctor.

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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