



The Enterra[®] II Gastric Electrical Stimulation System has received FDA approval for MR conditional use.

Patients with the Enterra II System can safely have MRI examinations of the head or extremities with a 1.5T MRI under certain conditions.

Component	Model Number
Enterra II IPG	37800
Enterra Unipolar Lead or Enterra ReliaStim [®]	4351-35 or 30101

MR Safety Information	
A person with the Enterra Medical Enterra II System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Enterra II
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (Bo)	1.5 T
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	Any
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.

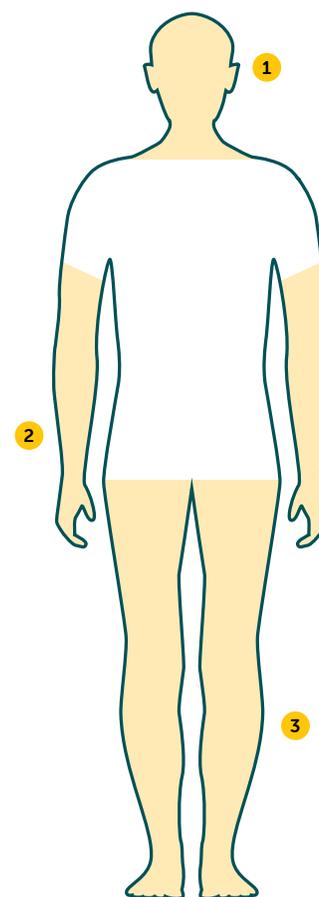


Figure: MRI scan* using detachable:

- 1 head,
- 2 upper extremity, or
- 3 lower extremity RF transmit coil.

At Enterra Medical, we continue to increase innovation in Enterra Therapy and are committed helping people living with gastroparesis find relief to take back their seat at the table.



Scan QR Code for
MRI Guideline Resources

*Illustrated in Figure are typical use scenarios of detachable RF transmit/receive volume coil. 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 given the aforementioned scan conditions are met.

Important Safety Information

Enterra® Therapy for treatment of chronic, resistant to medication nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years: patients should always discuss potential risks and benefits of the device with their physician.

Indications for Use: The Enterra Therapy System for gastric electrical stimulation is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years.

Contraindications: The Enterra Therapy System is not intended for patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an Enterra device.

Warnings/Precautions/Adverse Events: This system has not been evaluated for pregnant women, for use in patients under the age of 18, or patients over the age of 70. The system may be affected by or adversely affect cardiac devices. Strong sources of electromagnetic interference (EMI) such as from electrocautery, defibrillation/cardioversion, therapeutic ultrasound, radiofrequency (RF)/microwave ablation, or MRI, can result in serious injury, system damage, or operational changes to the system. EMI, postural changes, or other activities may cause shocking or jolting sensations.

 The Enterra II System is MR Conditional. This means that patients with the Enterra II 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. Obtain the latest MRI guidelines by referring to the manuals at www.enterramedical.com/hcp/manuals. Patients on anticoagulation therapy may be at a greater risk for post-operative complications. The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of therapy, or patient injury. There is the possibility of an allergic or immune system response to the implanted materials. When possible, a physician is to identify and treat any infections prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system. The lead can become entangled with the bowel or perforate your stomach and cause life-threatening blockage or infections that require immediate medical attention and may require surgery. Patients should avoid activities that may put undue stress on the implanted system components (activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching that can cause component fracture or dislodgement). Adverse events related to the therapy, device, or procedure can include: infection, pain at the surgery site, device components may wear through the skin, bruising at the neurostimulator site, bleeding, loss of therapeutic effect, undesirable change in stimulation (described as a jolting, shocking, or burning sensation), gastrointestinal symptoms and gastrointestinal complications (in that the lead may perforate your stomach or device components may become entangled with or obstruct other internal organs, requiring surgery). The system could stop because of battery depletion or mechanical or electrical problems. Any of these situations may require additional surgery or cause your symptoms to return.

Humanitarian Device: Authorized by Federal law for use in 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. The effectiveness of this device for this use has not been demonstrated.

For further information, please contact Enterra Medical at info@enterramedical.com.
USA Rx only.

www.enterramedical.com

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