Enterra Ascent®
MR Conditional Approved

enterra® medical

Patients with the Enterra Ascent® Gastric Electrical Stimulation System can safely have MRI examinations of the head or extremities with a 1.5T or 3.0T MRI under certain conditions.

Enterra Ascent® has not been approved by the U.S. Food and Drug Administration (FDA). FDA has notified Enterra Medical that Enterra Ascent® and Enterra Entrust® may be distributed for implant under an FDA enforcement policy. This document is not a substitute for labeling. Always refer to the full Instructions for Use and Implant Manual.

Component	Model Number
Enterra Ascent IPG	10102
Enterra ReliaStim® Unipolar Lead	30101
Enterra® Unipolar Lead	4351-35

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.

† The device stimulation must be turned Off using an Enterra Entrust Clinician Programmer.

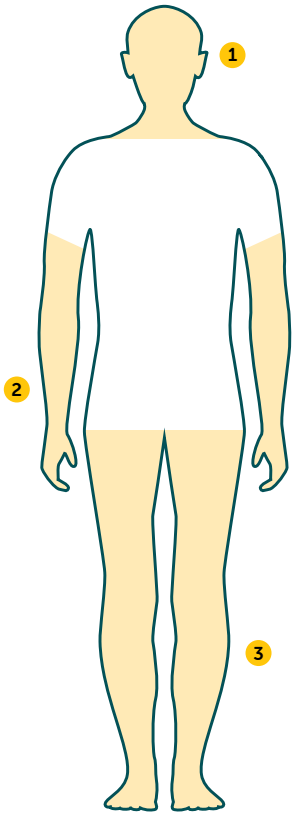


Figure: MRI scan* using detachable:

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

MR unsafe devices

The external components of the Enterra 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).

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

Scan QR Code for MRI Guideline Resources

Enterra Ascent® has not been approved by the U.S. Food and Drug Administration (FDA). Because of a shortage of the Enterra® II device, FDA has notified Enterra Medical that Enterra Ascent may be distributed under an FDA enforcement policy for medical device supply shortages while FDA's review of the Enterra Ascent submission continues. This does not mean that FDA has approved Enterra Ascent or made any determination about its safety or probable benefit. Enterra Ascent is intended to provide the same therapy as Enterra II, but it has design changes that FDA has not yet fully reviewed. Before implanting Enterra Ascent, review the Enterra Ascent instructions for use, including all warnings, precautions, and potential adverse events.

*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.

Important Safety Information
Enterra® Therapy, with Enterra Ascent®, is 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. Patients cannot have diathermy (deep heat treatment from electromagnetic energy) if they have an Enterra device.

Warnings/Precautions/Adverse Events: This system has not been evaluated for pregnant women, or for use in patients under the age of 18 or 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 and Enterra Ascent Implantable Systems are MR Conditional. This means that patients with the Enterra II System and Enterra Ascent 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.



The Enterra I System and the external components of the Enterra System, including the N'Vision® Clinician Programmer and the Enterra Entrust® Clinician Programmer, are MR Unsafe. These devices must NOT be taken into the MR scanner room (ACR Zone IV).

Patients on anticoagulation therapy may be at a greater risk for post-operative complications. The use of non-Enterra Medical components with this system may result in damage to Enterra Medical 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 the 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 the 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 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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