Enterra® Therapy

Ordering Guide

enterra medical™

Effective November 2023

Ordering Information

OPTIONS TO PLACE AN ORDER

1) Email:

Send an e-mail with the information on the next page to: orders@enterramedical.com.

2) Phone:

Enterra Medical Customer Service: Toll-Free: 1-855-768-3772 **Fax:** 855-541-3367
Customer Service representatives are on duty to take your order between 8:00 a.m. and 5:00 p.m. Central Time. For faster service when calling, please have your account number available. An e-mail confirmation of the phone order will be required to complete the ordering process.

PAYMENT TERMS

Net 30 days from date of invoice. Prices are subject to change without notice. To gain more information on payment options, call **Enterra Medical Customer Service Toll Free:** 1-855-768-3772.

VENDOR MASTER SET-UP

Ensure Enterra Medical is the vendor for these products.

Order Distribution:	ACH/ACH Delivery: (Preferred payment method)	Remit to address:
Enterra Medical Inc. p/a HealthLink International Inc. 4049 Willow Lake Blvd, Suite 100 Memphis, TN 38118 Email: orders@enterramedical.com	J.P. Morgan AR Phone: 612-429-1787 AR Fax: 866-504-3214 Account# 950952520 Routing: 075000019 A/R Email: accounting@enterramedical.com Please reference invoice number	Enterra Medical 5353 Wayzata Blvd, Suite 400 St. Louis Park, MN 55416

SHIPPING

Implantable neurostimulation systems are shipped Freight on Board (FOB) shipping point. Freight will be billed with invoice unless customer shipping account is provided for charges. Please allow five (5) days for delivery. Vendor absorbs all freight costs for returns.

CREDIT AND RETURNS

Full credit will be given for unopened, undamaged, and unmarked packages returned within 90 days from date of invoice. No credit will be given for packages returned after 90 days from date of invoice or for packages that have been opened, damaged or marked. Please call Enterra Medical Customer Service for a Return Material Authorization (RMA) number prior to returning the product. Be sure the RMA# is visible on the outside of the package. Return instructions will be provided when the RMA# is assigned.

WARNING

The products described in this price list are intended for use only with Enterra components. The use of other components with these products may result in damage or risk to the patient.

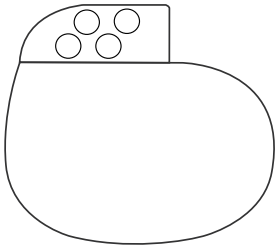
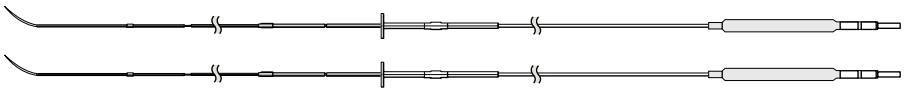
Enterra Therapy

PLEASE READ BEFORE ORDERING

When ordering, please consider all the components needed for a complete system for each patient procedure. Refer to specific model numbers in this catalog when placing your order.

Enterra Therapy for chronic nausea and vomiting due to gastroparesis

IMPLANTABLE SYSTEM

Enterra Therapy consists of a neurostimulator and two leads	
	
Model 37800 Enterra II Neurostimulator	**Model 4351-35** Two leads are required for implant

SYSTEM COMPONENTS

Neurostimulator

Model	Description	Price ($)
37800	**Enterra II Neurostimulator** Neurostimulator for use with lead Model 4351-35. *Sterile Content:* (1) INS (1) Torque Wrench *Nonsterile Content:* Literature	10,750

Lead

Model	Description	Price ($)
4351-35	**Lead Kit** *Sterile Content:* (1) Unipolar Intramuscular Lead Fixed 10 mm Electrode (4) Fixation Disks (1) Tunneling Rod (2) Lead End Caps *Nonsterile Content:* Literature	2,625

Order Form

Email orders: orders@enterramedical.com

PO#:

Date Submitted:

	Ship To:	Bill To: (if different)
Account ID		
Account Name		
Contact Name		
Address 1		
Address 2		
Address 3		
City, State, Zip		
Phone		
Fax		
Email		
Accounts Payable Email		
Tax Exempt? Y/N	☐ Yes ☐ No	
Ship Via	☐ Standard Overnight ☐ Priority Overnight ☐ 2Day ☐ 3Day ☐ Ground ☐ Other _____	
Sales rep:		

Product Code	Description	Price	QTY
37800	Neurostimulant IPG	$10,750	
4351-35	Unipolar Lead	$2,625	

Notes/Comments/Special Instructions

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

EXT-00091, Rev E

enterra medical™