enterra medical™

Gastroparesis Discussion Guide

This guide will provide an overview of gastroparesis, common tests used for diagnosis, treatment with Enterra® Therapy, as well as resources to help start a conversation with your provider.

What is gastroparesis?

Gastroparesis is a medical condition that causes food to digest more slowly than normal.

In a healthy digestive system, strong muscular contractions move food from the stomach through the digestive tract. But with gastroparesis, the stomach muscles work poorly or not at all—preventing the stomach from emptying properly.

Gastroparesis has several causes, including type 1 diabetes and type 2 diabetes, post surgical complications and other causes, but in many cases, the cause is unknown (idiopathic).

Are you unsure if you have gastroparesis?

Diagnosis is based on a complete medical history, physical examination, and tests that may include:

Upper Endoscopy is an endoscopic examination of the esophagus, stomach, and duodenum (the uppermost part of the small intestine). During the procedure, a specialist in the digestive system, uses an endoscope, a long flexible tube with a camera, to examine the area. Typically, in patients with suspected gastroparesis, this procedure is used to understand if there is an obstruction preventing food from emptying the stomach. The procedure is typically done under anesthesia in an outpatient or hospital setting.

A Gastric Emptying Test (GET) measures the rate at which food moves through the stomach. This test is the most widely used to diagnose gastroparesis and one of the ways to determine if you are a candidate for Enterra® Therapy.

The test takes around 4 ½ hours to complete.

1. Your doctor will typically give you a light meal that contains a small and safe amount of a substance that will appear on a medical scan.
2. A camera will then measure the movement of that food to monitor the rate at which food empties out of the stomach.
3. According to the Gastroenterology societies, the test is defined as "delayed" if there is > 60 % retention at 2 hours or > 10 % retention at 4 hours.[1]

Depending on how these tests are conducted results can vary.
It is important to go to a location that follows standard protocols.

It is important that you talk to your provider about your symptoms and determine if you should be tested for gastroparesis.

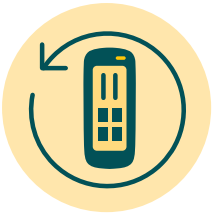
What is Enterra® Therapy?

Enterra Therapy is the first and only implantable device designed to help relieve the nausea and vomiting associated with gastroparesis through a unique kind of therapy called Gastric Electrical Stimulation (GES).

Unlike other surgical treatment options, Enterra Therapy is:

Implantable
The Enterra neurostimulator is placed just beneath the skin, usually in the lower abdominal region

Customizable
Your doctor will non-invasively adjust your system to help find the level of stimulation that's right for you



Reversible
If Enterra Therapy isn't right for you, your doctor can turn off or remove your system

Is Enterra Therapy right for you?

- ☑ I have gastroparesis due to diabetes or an unknown (idiopathic) cause
- ☑ I experience nausea and/or vomiting that is not helped with medications
- ☑ I am 18-70 years old

If the above statements are true, you may want to talk to your doctor about the risks and probable benefits of Enterra Therapy.

To see how Enterra Therapy works, scan the QR code or visit www.enterramedical.com/introduction-to-enterra-therapy

people have received
Enterra Therapy to help resume everyday activities, like taking their seat back at the table.

Preparing for your Appointment

My Next Appointment: _____/_____/_____

To give your provider examples of the issues you have experienced, track the number of hours you experience nausea and vomiting each day.

Track your symptoms in the diary below according to your provider's recommendations. If you had no episodes on a given day, record that as well. Please record the number of hours of nausea during each day, and the number of vomiting episodes each day. Talk with your provider if you have questions about completing this diary.

Nausea and Vomiting			
Date	Time	Severity of Nausea 0–4 (4 is high)	Vomiting Episode
Monday	10:10 (AM)/PM	4	✓
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		

Nausea and Vomiting			
Date	Time	Severity of Nausea 0–4 (4 is high)	Vomiting Episode
Monday	10:10 (AM)/PM	4	✓
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Total number of vomiting episodes							
Total number of nausea hours							

At the Appointment

Things to discuss with your provider.

I have been suffering from _____ symptoms.

My most bothersome symptom is _____.

My symptoms affect my life by: _____.

Potential causes for my gastroparesis could be _____.

Could it be gastroparesis?

What is gastroparesis?

What causes gastroparesis?

What tests do I need to understand if I have gastroparesis?

What is an upper endoscopy (EGD)?

What is a gastric emptying test (GET)?

What treatments exist for gastroparesis?

What advanced treatments exist for gastroparesis if diet and medications don't work?

Is Enterra Therapy right for me?

GIVE THIS TO YOUR PROVIDER AT YOUR NEXT APPOINTMENT

Patient Referral Form for Enterra® Therapy

Patient Name: _____
DOB: _____/_____/_____
Phone: _____
Primary Care Provider: _____
Insurance (Primary): _____
(Secondary): _____
Plan ID: _____

Patient between 18-70 years of age:

☐ **Gastroparesis caused by diabetic or unknown origin with chronic, resistant to medication nausea and vomiting**

Etiology

☐ Is the patient Diabetic? ☐ Type 1 or ☐ Type 2 HbA1c:_____ Duration:_____

☐ Does the patient have gastroparesis of unknown origin? ☐ Other:_____

Symptoms

Symptoms (Start Date/Severity): Nausea:_____/_____ out of 10 Vomiting:_____/_____ times per week

Early Satiety:_____/_____ out of 10 Bloating:_____/_____ out of 10 Abdominal Pain:_____/_____ out of 10

Weight Gain/Loss History (Date/Weight):_____/_____ _____/_____

Quality of Life (date/score): ☐ GCSI:_____/_____ ☐ Other:_____/_____

Hospitalizations

How many hospitalizations has the patient had in the past year due to gastroparesis?

Episodes of admission/# of days:_____/_____

☐ **Difficulty managing symptoms after failed frontline therapies (diet and medications)**

Failed Diet and Frontline Therapy History

Dietary Modification:_____

Supplemental Nutrition: ☐ Oral Supplement ☐ NJ Tube ☐ GJ Tube ☐ J Tube ☐ TPN

Medications:

Medication Tried and Failed:

☐ Metoclopramide ☐ Erythromycin ☐ Domperidone ☐ Other:_____

Current Medical Regimen: _____

_____

☐ **Previous diagnostic studies such as gastric emptying study or endoscopy have been conducted and results attached**

Diagnostics

Gastric Emptying Study Results (Off Prokinetics for 3 Days): % Retention 2 hrs:_____ 4 hrs:_____

Date of Endoscopy: _____ Results: _____

☐ I recommend this patient for an Enterra gastric electrical stimulation therapy consultation

Physician Name: _____ Date: _____

Phone: _____ Email: _____

Enterra Medical is dedicated to helping more people with chronic gastroparesis live better lives through advancing technology, bolstering clinical science, and accelerating patient access to Enterra Therapy.

The FDA approved the Humanitarian Device Exemption for Enterra Therapy in 2000. In 2022, Enterra Medical assumed commercial responsibility of Enterra Therapy.

The information provided in this brochure is for general educational purposes only and is not a substitute for professional medical advice, diagnosis or treatment. Always talk to your doctor about the best treatment options for your individual situation.

1. Abell TL, Camilleri M, Donohoe K, et al. Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. *The American journal of gastroenterology.* 2008;103(3):753-763. doi:10.1111/j.1572-0241.2007.01636.

Important Safety Information

Intended Use: The Enterra® Therapy System is an implanted device that provides gastric stimulation to treat chronic, intractable, nausea and vomiting that is not well treated by drugs or other means in patients aged 18 to 70 years caused by diabetes or an unknown origin.

Contraindications: Enterra Therapy is only for patients who are healthy enough for surgical procedures and/or anesthesia. Once implanted, patients need to avoid diathermy, which is deep heat treatment from electromagnetic energy, as it may cause injury or device failure.

Warnings: Enterra Therapy has not been studied in pregnant women, patients under the age of 18, or over 70. Issues may occur if the system interacts with other implanted devices such as pacemakers. Patient injury or device failure may be caused by other medical treatments such as electrocautery, defibrillation/cardioversion, therapeutic ultrasound, or radiofrequency (RF)/microwave ablation. Patient 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. Consult your doctor to determine if you are eligible for MRI examination.

Risks: Potential risks include infection, pain at the surgery site, allergic or immune system response, lead and bowel twist together, device wearing through the skin, bruising, bleeding, loss of therapeutic effect, jolting, shocking, burning sensation, gastrointestinal or stomach issues, loss of therapy due to component failure or battery wear out, or perforated stomach which may cause life-threatening blockage or infections that require immediate medical attention including surgery. Risks can be minimized by avoiding activities such as sudden, excessive, or repetitive bending, twisting, bouncing, or stretching.

Humanitarian Device: Authorized by Federal law for the intended use described above. The effectiveness of this device has not been demonstrated.

Always discuss potential risks and benefits of the device with your physician.
For further information, please contact Enterra Medical at info@enterramedical.com.
Rx Only.

www.enterramedical.com

MKT-B-01274, Rev A

enterra medical™