

# Enterra<sup>®</sup> Therapy Discussion Guide

This guide will help you start a conversation with your provider about your experiences with chronic nausea and vomiting due to gastroparesis and treatment options, including Enterra Therapy.\*

## Questions?

Contact a Patient Educator at

1-855-374-3382

Monday to Friday,

8 a.m. to 5 p.m. ET



**"I have my life back...  
even more so than  
I could have ever  
imagined."**

Mary, Enterra Therapy Recipient

Mary's experience is unique to her  
and individual results may vary.

\*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.

# 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 does not empty properly.

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

## What is Enterra<sup>®</sup> 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:**



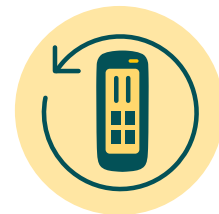
### **Minimally invasive**

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 needs to be paused or 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 these statements are true, you may want to talk to your provider about the risks and probable benefits of Enterra Therapy.

To see how Enterra Therapy works, visit

[www.enterramedical.com/introduction-to-enterra-therapy](http://www.enterramedical.com/introduction-to-enterra-therapy)

## Next Steps

Fill out this discussion guide and bring it to your next appointment.

1

**Schedule an appointment with your gastroenterologist** to discuss Enterra Therapy and your concerns with chronic nausea and vomiting due to gastroparesis. They will determine appropriate screening tools and diagnostic tests for you.

2

**Connect with a provider who implants and/or manages Enterra Therapy patients** to discuss treatment options and associated risks. If you are unsure of providers near you, visit [www.enterramedical.com/find-a-provider](http://www.enterramedical.com/find-a-provider).



**Not sure where to start or which type of provider to see?**

Call us at **1-855-374-3382**. Enterra Medical Patient Liaisons are here to answer your questions and help you find a provider near you.

3

**Prepare for your appointments by filling out this discussion guide** to track your symptoms and capture any questions you have for your provider.

# Preparing for your Appointment

## Nausea and vomiting symptom diary

**My Next Appointment:** \_\_\_\_/\_\_\_\_/\_\_\_\_

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		
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	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		
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	AM/PM		
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	AM/PM		

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

# At the Appointment

What questions might you have for your provider?

Write them down and keep track of how your provider answers.

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

Q: \_\_\_\_\_  
\_\_\_\_\_

A: \_\_\_\_\_  
\_\_\_\_\_

If you and your provider decide that Enterra Therapy is right for you, you may be referred to a center in your area.

Visit [www.enterramedical.com/find-a-provider](http://www.enterramedical.com/find-a-provider) to find a provider who specializes in Enterra Therapy.



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

To see how Enterra Therapy works, visit

[www.enterramedical.com/introduction-to-enterra-therapy](http://www.enterramedical.com/introduction-to-enterra-therapy)



# 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 System gastric electrical stimulation therapy consultation

Physician Name: \_\_\_\_\_ Date: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Learn more about Enterra Therapy at [www.enterramedical.com](http://www.enterramedical.com)

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 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.

#### 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](mailto:info@enterramedical.com).

Rx Only.

[www.enterramedical.com](http://www.enterramedical.com)

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