



# 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.\*

**"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.

# 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. Your provider 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. With their help, you can choose the treatment option that is most appropriate for 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.

## Enterra Therapy Eligibility

Enterra Therapy might be right for you if you:

- have gastroparesis due to diabetes or an idiopathic (unknown) cause
- are 18-70 years old
- have chronic, intractable (has not responded to medication) nausea and vomiting

# Preparing for your Appointment

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

To give your doctor examples of the issues you have experienced, mark the severity and frequency of gastroparesis symptoms by using the following scores:

## Severity:

- 0 = absent
- 1 = mild (not influencing normal activities)
- 2 = moderate (diverting from, but not urging modification of, usual activities)
- 3 = severe (influencing usual activities severely enough to urge modifications)
- 4 = extremely severe (requesting bed rest)

## Frequency:

- 0 = absent
- 1 = rare (1 time/week)
- 2 = occasional (2-4 times/week)
- 3 = Frequent (5-7 times/week)
- 4 = extremely frequent (> 7 times/week)

## SYMPTOM

### 1. Vomiting

**Definition:** Forceful expulsion of stomach content from the mouth. It should be distinguished from retching, which is defined as "heaving as if to vomit."

### 2. Nausea

**Definition:** Feeling sick to your stomach as if you were going to vomit.

### 3. Early satiety

**Definition:** A feeling that the stomach is over-filled soon after starting to eat so that you are not able to finish a normal-sized meal.

### 4. Bloating

**Definition:** Feeling like you need to loosen your clothes. Stomach or belly is visibly larger.

### 5. Postprandial fullness

**Definition:** Feeling excessively full after meals.

### 6. Epigastric pain

**Definition:** The epigastrium can be identified as an area approximately the size of one hand in the central part of the upper abdomen. The pain should be distinguished from discomfort, which is defined as a subjective, negative, and unpleasant feeling that "does not hurt."

### 7. Epigastric burning

**Definition:** Burning is a special type of pain that can be described as an "inside flame."

# Preparing for your appointment

Track your nausea and vomiting frequency and bring completed diary with you to your appointment.

Nausea and Vomiting			
Date	Time	Severity of Nausea 0-4 (4 is high)	Vomiting Episode
Monday	10:10 (AM/PM)	4	✓
	AM/PM		
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	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
	AM/PM		
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Nausea and Vomiting			
Date	Time	Severity of Nausea 0-4 (4 is high)	Vomiting Episode
Monday	10:10 (AM/PM)	4	✓
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Do you feel that your current therapy is providing you relief?  Yes  No

How would you characterize your improvement?  Slightly improved  Moderately improved  Greatly improved

	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.

Scan the QR code to find a provider who specializes in Enterra Therapy



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

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

**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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