

Track your Symptoms



Patient Name _____ Date _____

Please 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."

SEVERITY

FREQUENCY

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."

Learn more about Enterra Therapy at 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.
Rx Only.

www.enterramedical.com

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