

The Challenge of Gastroparesis

A GUIDE TO UNDERSTANDING AND MANAGEMENT



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This guide explains what causes gastroparesis, how to diagnose it, and ways to treat it.

Gastroparesis: A Serious Digestion Problem

Gastroparesis is a stomach disorder in which food moves through the stomach too slowly. In a healthy digestive system, strong muscular contractions move food through the digestive tract. With gastroparesis the stomach muscles work poorly, or not at all, preventing the stomach from emptying properly.

Gastroparesis can be devastating. It can cause chronic nausea and vomiting and lead to malnutrition. Constant discomfort can disrupt school, work, relationships and your social life.

The number of people with gastroparesis is unknown. There is no cure, but there are therapies that improve symptoms and offer hope for a better quality of life.



How the Stomach Works

The stomach stores food, mixes it with stomach secretions, grinds food into small particles, and moves these particles into the small intestine. Emptying is controlled by muscle contractions in different regions of the stomach. Ideally, these processes should occur at a rate that makes digestion easy and efficient.

If stomach muscle contractions stop working properly, the result can be delayed gastric emptying. Undigested food and fluids sit in the stomach, causing chronic nausea and vomiting.

Typical Symptoms

People with gastroparesis experience a number of gastrointestinal symptoms including:

Chronic nausea	Frequent vomiting	Abdominal bloating	Abdominal pain
Vomiting on an empty stomach	Dehydration	Heartburn or Gastroesophageal Reflux Disease (GERD)	Changes in blood sugar levels
Malnutrition	Electrolyte imbalances	Lack of appetite	Excessive weight loss
Feelings of fullness after only a few bites of food (early satiety)			

Nausea and vomiting have been reported as the most bothersome symptoms of gastroparesis¹

Common Causes

Damage to the vagus nerve may be a cause of gastroparesis. This nerve stretches from the brain stem to the colon and controls the functions of the esophagus, stomach, and intestines. Damage to stomach muscles is another cause. There are many ways the vagus nerve or stomach muscles can be damaged:^{1,2}

DIABETES, EITHER TYPE 1 OR TYPE 2

High blood sugar can damage the vagus nerve over time. Unfortunately, gastroparesis makes blood sugar levels harder to control.

POSTSURGICAL COMPLICATIONS

Surgery on the esophagus, stomach, or upper part of the small intestine can injure the vagus nerve. Symptoms may appear immediately or years later.*

OTHER CONDITIONS AND CAUSES

Parkinson’s disease, vascular disease, and pseudo-obstructions can all cause gastroparesis. Medications can also slow stomach emptying, resulting in symptoms that mimic gastroparesis.*

UNKNOWN

Frustratingly, the cause may not be known (idiopathic). Delayed gastric emptying without apparent cause or underlying abnormality is a common diagnosis.^{1,2} Rarely, gastroparesis develops after a person recovers from the flu or other viral illness.

* Enterra Therapy is not indicated for gastroparesis symptoms due to postsurgical complications, Parkinson’s disease, vascular disease or pseudo-obstructions.

When to Seek Treatment

Many people experience occasional nausea and vomiting. Warning signs of gastroparesis include:

- Nausea and/or vomiting occurring several times a day
- Nausea and/or vomiting episodes over 12 months or more
- Weight loss over the past year
- Excessive weight gain over the past year due to improper nutrition
- Supplemental nutrition needed
- Repeated hospitalizations
- Inadequate relief of symptoms from medications
- Diminished quality of life



Diagnostic Testing

Nausea and vomiting are symptoms of several other digestive disorders. After taking a complete medical history and performing a physical examination, your doctor will ask for some additional tests in order to determine a diagnosis.



PRIMARY TESTS (REQUIRED)

Upper Gastrointestinal Endoscopy

This test excludes other conditions (e.g., ulcers, physical abnormalities, or mechanical obstruction) that may be causing symptoms. A thin, flexible tube (endoscope) with a tiny camera at the tip is passed through the mouth and guided into the stomach while you are asleep. The endoscope allows the doctor to look into the stomach and at its lining.

Gastric Emptying Test (GET)

This procedure measures the speed at which food empties from the stomach into the small intestine. The GET, considered the most accurate way to diagnose gastroparesis, requires that you eat a meal in which a solid food (usually eggs or oatmeal) contains a small and safe amount of a substance that will appear on a medical scan. A scanner is placed over the abdomen to monitor the food’s movement through the digestive tract.

SECONDARY TESTS (MAY NOT BE NECESSARY)

Gastroduodenal Manometry

In this test, the doctor passes a thin, pressure-sensitive tube through the mouth and into the stomach and small intestine. A computer connected to the tube monitors the strength and coordination of stomach muscle contractions and how well the stomach is emptying.

Electrogastrography (EGG)

This procedure records the electrical signals in the stomach before and after eating. An irregular electrical rhythm may indicate the presence of gastroparesis.

Treatment Options

There is no cure for gastroparesis. Several treatments are available that improve symptoms and offer a more comfortable lifestyle³:

NUTRITION EDUCATION AND DIET MODIFICATIONS

This can help reduce symptoms and maintain adequate fluids and nutrition. A modified diet typically consists of liquids, restricted fats and plant fiber, and frequent, small meals.

PROKINETIC DRUGS can improve the rate of stomach emptying and thereby reduce nausea and vomiting.

ANTIEMETIC DRUGS can control nausea and vomiting, but have no effect on stomach emptying.³

ENTERAL NUTRITION

This therapy involves the delivery of liquid nutrients via a tube placed directly into the stomach or small intestine. Feeding tubes are usually temporary and used only when gastroparesis is severe.

TOTAL PARENTERAL NUTRITION (TPN)

TPN supplies nutrients to your bloodstream through an intravenous (IV) infusion. TPN is used only if enteral feeding is not tolerated or is insufficient to meet caloric needs.

SURGERY

Surgery is considered a last resort. One surgery, called pyloroplasty, involves widening the muscle that separates the stomach from the upper region of the small intestine or duodenum. Another surgery, called gastrectomy, is a medical procedure where all or part of the stomach is surgically removed.

ENTERRA THERAPY*

This is a surgical option for patients with chronic, drug-refractory (resistant to medication) nausea and vomiting due to gastroparesis of diabetic or idiopathic (unknown) origin in patients aged 18 to 70 years. The Enterra Therapy System includes a battery-powered neurostimulator implanted beneath the skin. Your doctor can determine if you are a candidate for Enterra Therapy.

Any combination of diet modification, medication, nutritional support, surgery, and Enterra Therapy may be necessary to control symptoms of gastroparesis.

*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. Enterra Therapy received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) in 2000.

Enterra Therapy

Gastric Electrical Stimulation for Gastroparesis

Enterra Therapy* is designed to improve chronic, medication resistant nausea and vomiting associated with gastroparesis of diabetic or unknown (idiopathic) origin.

The Enterra Therapy System consists of a neurostimulator (about the size of a pocket watch) implanted beneath the skin, usually in the lower abdominal region. Two leads (insulated wires) are implanted in the muscle wall of the stomach and connected to the neurostimulator. The procedure is performed under general anesthesia.

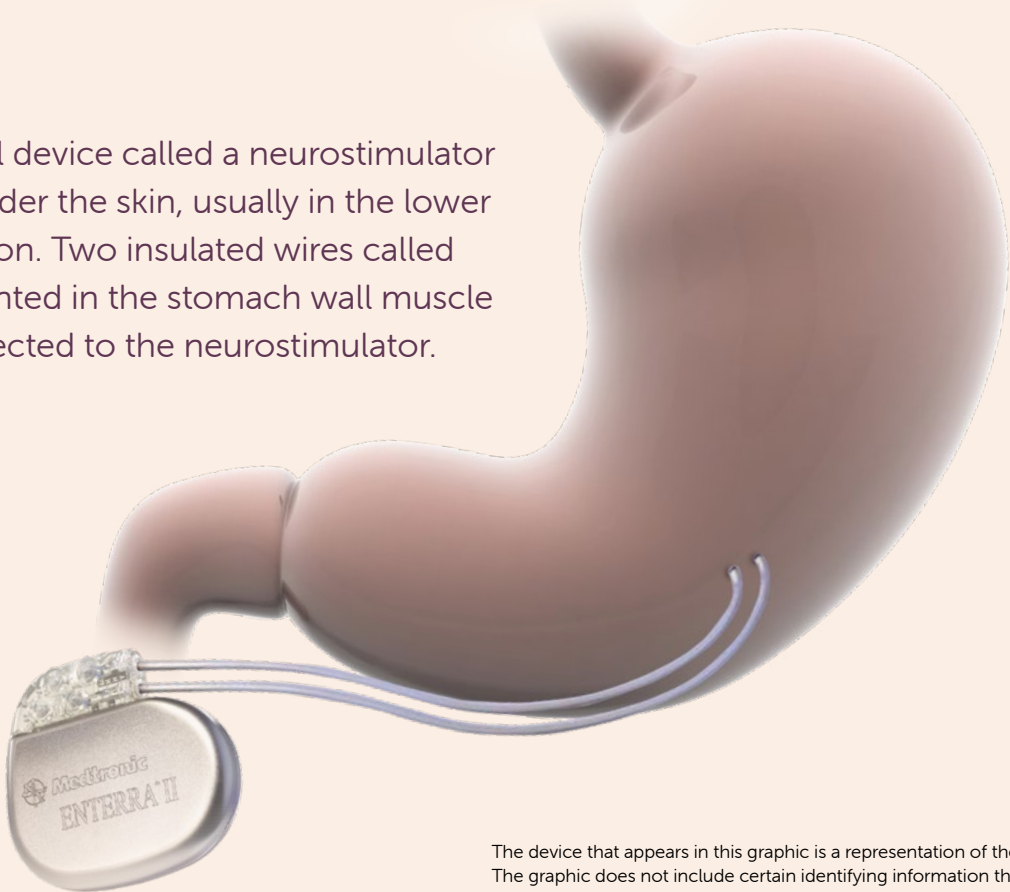
The neurostimulator sends mild pulses through the leads to stimulate the nerves and smooth muscles of the lower stomach. This may help control chronic nausea and vomiting.

During an office visit, the doctor adjusts the neurostimulator to customize therapy for you. The therapy can be turned off by the doctor at any time.

* 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. Enterra Therapy received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) in 2000.

Over 15,000 people have received Enterra Therapy to help resume everyday activities, like taking their seat back at the table.

A small medical device called a neurostimulator is implanted under the skin, usually in the lower abdominal region. Two insulated wires called leads are implanted in the stomach wall muscle and then connected to the neurostimulator.



The device that appears in this graphic is a representation of the device. The graphic does not include certain identifying information that may appear on actual devices such as model number or serial number.

Things to Consider Before You Decide

If your doctor determines that you are a candidate please consider the following:

- The therapy is intended to reduce symptoms of chronic nausea and vomiting associated with gastroparesis. But, it is not a cure.
- Improvements in symptoms may be gradual or immediate. Results vary from person to person.
- Implanting an Enterra Therapy System has risks and side effects. Surgical complications are possible and may include infection, bleeding, bruising, and pain at the implant site. Once implanted, the system may become infected, devices may move or wear through the skin, the lead may entangle with or obstruct the bowel, lead may perforate your stomach, irritation/inflammation over the implant site may occur. The system could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause return of symptoms, and some can be life threatening.
- Most often, a combination of Enterra Therapy, diet modification, and medication is necessary to effectively control symptoms of gastroparesis.
- If you have an Enterra Therapy System implanted, some precautions are necessary around certain electrical and medical equipment and when going through theft detection and security screening gates.
- Enterra Therapy is not appropriate for patients who are not candidates for surgical procedures and/or anesthesia because of physical or mental conditions.
- Enterra Therapy should not be used for patients who will be exposed to diathermy (deep heat treatment).
- Patients with Enterra Therapy should not have Magnetic Resonance Imaging (MRI).
- Enterra Therapy has not been evaluated in pregnant women, or in patients younger than age 18 or older than age 70.

Finding an Enterra Therapy Doctor

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



Next Steps

- 1. Get Evaluated**
Your doctor will determine the appropriate screening tools and diagnostic tests for you.
- 2. Review the Results**
Review the results from screening and testing with your doctor.
- 3. Discuss Treatment Options**
Ask your doctor for a treatment recommendation. Ask questions and review possible side effects of each therapy. Share any concerns you may have with your doctor.
- 4. Take Action**
With your doctor's help, choose the treatment option that is best for you. Follow the therapy plan, including diet modification, regular follow-up visits, and other instructions.
- 5. Seek Prior Authorization**
If your doctor determines Enterra Therapy is right for you, please ask them to obtain prior authorization from your health insurance company.



For more information

PUBLICATIONS

The Official Patient's Sourcebook on Gastroparesis: A Revised and Updated Directory for the Internet Age.
Icon Health Publications, 2002

Gastroparesis – A Medical Dictionary, Bibliography, and Annotated Research Guide to Internet References
Icon Health Publications, 2004

WEBSITES FOR EDUCATION, INFORMATION AND SUPPORT

American College of Gastroenterology
www.gi.org/topics/gastroparesis/
301-263-9000

**Association of Gastrointestinal
Motility Disorders, Inc.**
www.agmdhope.org
781-275-1300

Cyclic Vomiting Syndrome Association
www.cvsaonline.org
414-342-7880

**Gastroparesis Patient Association for
Cures & Treatments, Inc.**
www.g-pact.org
1-888-874-7228

**International Foundation for Functional
Gastrointestinal Disorders**
www.iffgd.org
414-964-1799

**National Institute of Diabetes & Digestive
& Kidney Diseases**
www.niddk.nih.gov/health-information/digestive-
diseases/gastroparesis
1-800-860-8747

National Pancreas Foundation
www.pancreasfoundation.org
866-726-2737

Oley Foundation (Nutritional Support)
www.oley.org
518-262-5079

QUESTIONS TO ASK

I have some warning signs that indicate gastroparesis. What testing do you recommend for further evaluation?

What medical conditions or medications cause symptoms of gastroparesis?

What are the potential side effects of each treatment option for gastroparesis?

What are the potential risks, complications, and side effects of the Enterra Therapy System?

What additional information can you give me about Enterra Therapy?

I have other questions and concerns (please list):

This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across its entire width, providing a guide for handwriting or typing. The background is a solid off-white color.

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 should not be considered medical advice. Always talk to your doctor about the best treatment options for your individual situation.

References

1. Soykan I, Sivri B, Sarosiek I, et al. Demography, clinical characteristics, psychological and abuse profile, treatment and long-term follow-up of patients with gastroparesis. *Dig Dis Sci*. 1998;43:2398-2404.
2. Ye Y, Yin Y, Huh SY, Almansa C, Bennett D, Camilleri M. Epidemiology, Etiology, and Treatment of Gastroparesis: Real-World Evidence From a Large US National Claims Database. *Gastroenterology*. 2022;162(1):109-121.e5. doi:10.1053/j.gastro.2021.09.064.
3. American Gastroenterology Association. Technical review on the diagnosis and treatment of gastroparesis. *Gastroenterology*. 2004;127:1592-1622.

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. Patients should not have magnetic resonance imaging (MRI).

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. 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

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