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FACT SHEET

Enterra™ Therapy

Overview
Enterra™ Therapy from Medtronic is being studied as a surgical option for the treatment of chronic nausea and vomiting associated with gastroparesis. Employed when conventional drug therapies are not effective, Enterra Therapy uses mild electrical pulses for gastric stimulation to help treat these debilitating symptoms.

What is gastroparesis?
Gastroparesis is a chronic disorder in which food passes through the stomach more slowly than normal. In some patients, this condition results in serious nausea and vomiting that cannot be adequately controlled with standard medications and can lead to dehydration and malnutrition. These patients have difficulty maintaining their nutritional status and sometimes require some form of intravenous or tube feeding to stay alive.

Diabetes is a major cause of gastroparesis; but in many cases, the cause is unknown.

Enterra Therapy
Enterra Therapy is a treatment option for people who suffer with chronic nausea and vomiting associated with gastroparesis of diabetic or idiopathic origin and for whom standard medications are ineffective. Enterra Therapy involves electrical stimulation of the lower stomach (antrum) with a fully implantable system that consists of two unipolar intramuscular leads (thin wires) and a neurostimulator. Because the neurostimulator can be turned off or removed, the physician can terminate Enterra Therapy.

With this therapy, patients are offered new hope for relief from this debilitating chronic condition.

Procedure and Follow-Up
A physician (in most cases a gastroenterologist — a specialist in disorders of the digestive system) prescribes Enterra Therapy if drug therapy is not effective. The treatment is performed under general anesthesia and involves two steps: implant and post-implant.
- **Implant:** The procedure involves the stimulation of the stomach wall. This stimulation is delivered with an implanted medical device comprising a neurostimulator, which is similar in size and function to a cardiac pacemaker; and two leads, with electrodes at one end.

The Enterra Therapy system implantation procedure is performed under general anesthesia and can range from one to three hours. Using laparoscopy or laparotomy, the implanting surgeon fixes two stimulation electrodes to the wall of the stomach. The connector end of each lead is attached to a neurostimulator, which is placed in the abdominal wall under the patient’s skin.

Following the surgery, most patients spend one to five nights in the hospital before returning home, depending on their medical condition.

- **Post-Implant:** Following implant, the neurostimulator is turned on. Adjustments to the stimulation to the stomach wall can be made non-invasively in an outpatient setting to optimize the therapy for each patient. Follow-up examinations vary depending on the physician, but can occur every six to 12 months to monitor the therapy’s effectiveness.

Patients should speak with their physician prior to undergoing surgery to ensure that they fully understand the procedure, including the risks, and what to expect afterward.

**Results and Risks of Enterra Therapy**

Results of a Medtronic-sponsored clinical trial show that Enterra Therapy may reduce symptoms of nausea and vomiting in patients with gastroparesis that could not be adequately controlled with standard medication. Comparing 12 months post-implant to baseline data:

- 93 percent of patients experienced a reduction of vomiting episodes greater than 50 percent at 12 month versus baseline;
- 53 percent of patients experienced a reduction of vomiting episodes greater than 80 percent at 12 month versus baseline.

Patients in the study also experienced improvements in other upper gastrointestinal symptoms, including better solid food intake, and among diabetic patients, a reduction in hypoglycemic attacks. In addition, they enjoyed improvements in health-related quality of life.

As with any surgical procedure, there are risks associated with Enterra Therapy. These include pain at the implant site, infection and the surgical procedure itself. However, for many patients, the potential benefits of having the procedure outweigh the possible risks, which are similar to those of other implanted neurostimulation systems.

Adverse effects that were observed in clinical studies of Enterra Therapy included infection, migration of the lead, lead perforation and erosion of the neurostimulator through the skin.
Enterra Therapy for Gastroparesis: Product technical manual must be reviewed prior to use for detailed disclosure.

**Indications:** The Medtronic Enterra Therapy System for gastric electrical stimulation (GES) is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

**Contraindications:** The Enterra Therapy System is contraindicated in patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a Neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it can also damage the Neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explanation and replacement. Injury or damage can occur during diathermy treatment whether the Neurostimulation system is turned “on” or “off.” Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.

**Warnings/Precautions/Adverse Events:** This system has not been evaluated for pregnancy, pediatric use, or patients under the age of 18 or over the age of 70. The system may be affected by or adversely affect anticoagulation therapy, cardiac pacemakers, cardioverters/defibrillators, external defibrillators, MRI, ultrasonic equipment, electrocautery, radiation therapy, and theft detectors. The use of non-Medtronic components with this system may result in damage. Adverse events related to the system include infection, stomach wall perforation, migration/erosion of the neurostimulator, undesirable change in stimulation, hemorrhage, hematoma, gastrointestinal complications, migration of the lead, persistent pain and/or seroma at the neurostimulator site, allergenic or immune system response to implanted materials, feeding tube complications, dehydration and loss of therapeutic effect.

**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. The effectiveness of this device for this use has not been demonstrated.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.