Patient Referral Form for Enterra® Therapy

Patient name: _____

DOB: _____/_____/_____

Phone: _____

General Practitioner: _____

General Practitioner address: _____

_____

_____

Patient between 18-70 years of age:

☐ **Drug refractory nausea and vomiting secondary to gastroparesis**

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:_____/_____

Hospitalisations

How many hospitalisations has the patient had in the past year due to gastroparesis?

Episodes of admission/# of days:_____/_____

☐ **Difficulty managing symptoms after failed first line therapies (diet and medications)**

Failed Diet and First Line Therapy History

Dietary Modification:_____

Supplemental Nutrition: ☐ Oral Supplement ☐ NJ Tube ☐ J Tube (GJ Tube or PEG-J) ☐ TPN

Medications:

Medication Tried and Failed:

☐ Metoclopramide ☐ 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 gastric electrical stimulation therapy consultation

Physician Name: _____ Date: _____

Phone: _____ Email: _____

enterra medical®

Indications: The Enterra® Therapy System for Gastric Electrical Stimulation (GES) is indicated for the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis. Patients should be carefully selected to assure that their symptoms are of physiological origin. Also, patients must be appropriate candidates for surgery. **Intended clinical benefit:** The intended clinical benefit of Enterra Therapy is to reduce chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis. **Patient selection:** Select patients carefully to ensure that: • Their symptoms are of physiological origin. • They are appropriate candidates for surgery. **Contraindications:** The Enterra Therapy System is contraindicated in patients whose doctor determines are not candidates for surgical procedures and/or anesthesia due to physical or mental conditions. After implantation of any system component, the following contraindications apply: • Diathermy - Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy on patients implanted with a neurostimulation system.

- The Enterra Therapy System is MR unsafe - Patients with an implanted Enterra or Enterra II Therapy System should not be exposed to the electromagnetic fields produced by Magnetic Resonance Imaging (MRI).
- Shelf Life - The Model 37800 IPG must be implanted within 18 months from date of manufacturer. The Model 4351-35 Lead must be implanted within 24 months from date of manufacturer.

Warnings: Use as indicated and instructed - Read all information available for the system. Only use products for the indicated therapy and indicated populations. Bowel obstruction/perforation - The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Gastric erosion/perforation - The lead(s) can erode through the stomach wall and result in gastric perforation with possible lead migration into the lumen of the intestine. Patients may experience high lead impedance measurements, decreased therapeutic effect, increased nausea, vomiting, abdominal pain, life threatening intra-abdominal infections and gastrointestinal obstruction that may require laparotomy and/or system revision or removal. Electromagnetic Interference (EMI) – Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical or public environments that is strong enough to interfere with gastric stimulator function. **Precautions:** The safety and effectiveness of this therapy have not been established for: • Pregnancy, unborn fetus, or delivery. • Pediatric use (patients under the age of 18). • Patients over the age of 70. **Adverse events:** 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). The system could stop because of mechanical or electrical problems. Any of these situations may require additional surgery or cause your symptoms to return. For full instructions for use please consult the IFU at https://www.enterramedical.com/intl-hcp/manuals/. For use by healthcare professionals only.

EC REP **Authorized Representative**
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