Patient Management Worksheet
For Nausea and Vomiting Control

enterra medical™

Reminder: Programming decisions are the responsibility of the clinician and are based on the ability to establish settings that will provide optimal patient symptom relief, minimize patient discomfort, and maintain neurostimulator battery life to the best possible extent. Similarly, the clinician and patient together are responsible for the decision whether to proceed with an Enterra® Therapy implant. The Manage-by-Fact 5 standard programs provide a range of electrical stimulation fields. A systematic assessment of patient response to these programs may help facilitate optimum program settings.

For Provider Use Only

Patient Name: _____ DOB: _____ Date of Implant: _____

Managing Healthcare Provider: _____ Implanting Surgeon: _____ INS Location: _____

Pre-Implant Data		Post Implant Data								
Program Name										
Date										
Battery Status (EOL, LOW, OK)										
Therapy Measurement (Impedance)										
Amplitude/Voltage										
Cycle On/Off Time										
Rate										
Nausea Diary (Average)	**Baseline**									
#Nausea Hours in 24 hrs										
Severity of Nausea (0-4)										
Vomiting Diary (Average)	**Baseline**									
#Vomiting Episodes in 24 hrs										
Vomiting Severity (0-4)										

IF INADEQUATE SYMPTOM IMPROVEMENT:
1. Review troubleshooting questions with patient
2 .Fill out a Symptom Diary
3. Compare current diary information with baseline
4. Check impedance and battery life when appropriate

Standard Programs 1-5	PGRM 1	PGRM 2	PGRM 3	PGRM 4	PGRM 5
Electrode Configuration Pulse Width 330, Rate 14	2-/3+	2+/3-	2-/C+	3-/C+	2-,3-/C+

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.

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.

MR 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. The conditions for MRI scans will vary with the type of MRI coil. Obtain the latest MRI guidelines by referring to the manuals at www.enterramedical.com/hcp/manuals. 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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