Gastroparesis and Enterra Therapy® Video Script

This script is provided by Enterra Medical for informational and example purposes only. This does not constitute legal advice or recommendations regarding clinical practice. Enterra Medical is not responsible for edits made to the content provided. Enterra Medical makes no representations or warranties with respect to the contents of the video and disclaims any implied guarantee or warranty of fitness for any particular purpose. Enterra Medical specifically disclaims any liability or responsibility for the results or consequences of any actions taken in reliance on the content in this video.

Section 1: What is gastroparesis?

Gastroparesis is a medical condition that causes food to digest and move through the stomach more slowly than normal. In a healthy digestive system, strong muscular contractions move food through the stomach and the digestive tract. But with gastroparesis, the stomach does not work properly, and food moves through more slowly, causing symptoms such as nausea, vomiting, feelings of fullness and pain.

Gastroparesis has several causes, including diabetes, postsurgical complications, and other causes. But in many cases, the cause is unknown, or idiopathic.

Section 2: What are the symptoms of gastroparesis?

Typical symptoms can include chronic nausea, vomiting, and abdominal discomfort. Over time, the chronic nausea, vomiting and discomfort caused by gastroparesis can lead to low blood sugar, malnutrition, and a significant reduction in quality of life.

However, if you're already living with gastroparesis, you know that the chronic pain and discomfort from this disease is about more than just malnutrition or missing meals – it's about feeling like you're missing out on life.

Section 3: How is gastroparesis treated?

Diet modification and medications are common ways to treat gastroparesis. Diet changes may include increasing liquid intake, restricting fats and plant fiber, and eating smaller, more frequent meals to maintain adequate nutrition and minimize symptoms. Prescribed medications often consist

of prokinetic drugs to improve the rate of stomach emptying, and antiemetic drugs to control nausea and vomiting.

Unfortunately, many times diet changes and medication do not provide relief from the nausea and vomiting symptoms of gastroparesis. In fact, a recent study showed that only 4% of patients were satisfied with the current treatment options for gastroparesis, leaving many patients feeling frustrated and isolated.

If you have gastroparesis from diabetic or unknown origins and you've already tried diet changes and medications without success, gastric electrical stimulation with Enterra Therapy may be an option for you.

Section 4: What is Enterra Therapy?

The Enterra System is the first and only device designed specifically to relieve the nausea and vomiting symptoms associated with gastroparesis from diabetes or unknown origins by gently stimulating your stomach – a unique kind of therapy called gastric electrical stimulation (GES).

Section 5: How does Enterra Therapy work?

The Enterra System is made up of three parts:

1. A small neurostimulator that's implanted under the skin in the abdominal region
2. Two wires, called "leads", which connect the neurostimulator to the stomach muscles
3. And a handheld, external programming device

Once it's implanted, the neurostimulator sends mild electrical pulses through the leads to gently stimulate the smooth muscles of the lower stomach. These pulses are designed to relieve the chronic nausea and vomiting associated with gastroparesis.

Using the programming device, your doctor will adjust the neurostimulator to help ensure you receive the level of stimulation that's right for you. Adjusting your Enterra system's level of stimulation is non-invasive and does not require surgery.

Section 6: How is Enterra Therapy implanted?

Implanting the Enterra System typically takes 1-2 hours using minimally invasive techniques where special surgical instruments are used through tiny incisions.

Most people are able to go home within 1-2 days of the procedure, while some are even able to go home on the same day.

After you receive your Enterra System, your doctor will use the external clinician programmer to customize the level of stimulation that's right for you. Programming is non-invasive and can be done in your doctor's office.

Section 7: How do I know if Enterra Therapy is right for me?

If you have gastroparesis due to diabetes or an unknown (idiopathic) cause, have nausea and/or vomiting that is not helped with medications, and are 18-70 years old, then you may want to talk to your doctor about Enterra Therapy.

But like any medical procedure, Enterra Therapy comes with risks, so it isn't for everyone.

Section 8: How is Enterra Therapy different from other surgical treatments for gastroparesis?

Unlike some other surgical options, Enterra Therapy is minimally-invasive, customizable and reversible. Implanting the Enterra System typically takes 1 to 2 hours using minimally-invasive techniques where special surgical instruments are used through tiny incisions.

With Enterra Therapy, your doctor can non-invasively adjust your system to help find the level of stimulation that's right for you.

Lastly, unlike other surgical options, Enterra Therapy is reversible: if Enterra Therapy needs to be paused or isn't right for you, your physician can turn off or remove your system.

Section 9: Where can I go for more information on Enterra or other gastroparesis options?

[Include physician/hospital contact information, hospital website, etc.]

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.

The Enterra II Implantable 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.

The external components of the Enterra System, including the Model 8840 Clinician Programmer, are MR Unsafe. These devices must NOT be taken into the MR scanner room (ACR Zone IV).

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.

Enterra Medical, Inc., 5353 Wayzata Boulevard, Suite 400, St. Louis Park, MN 55416 | enterramedical.com | phone: 1-855-768-3772 | fax: 1-866-504-3214