Medtronic

ENTERRA™ THERAPY 4301

Unipolar Intramuscular Lead
for the Gastric Electrical Stimulation
System

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 restricts this device to sale by or on the order of a physician.

Technical Manual

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Device Description

The Model 4301 Lead is a component of the Enterra™ Therapy gastric electrical stimulation system. The Enterra Therapy system is comprised of a neurostimulator, Model 4301 lead, a programmer, and programmer software.

The Medtronic Model 4301 Lead (see Figure 1) is a unipolar, intramuscular lead with an adjustable electrode surface and a temporary testing wire. The lead comes with a 3.2 mm low profile Medtronic standard lead connector in a unipolar configuration. Only the pin is mechanically and electrically connected in the unipolar configuration.

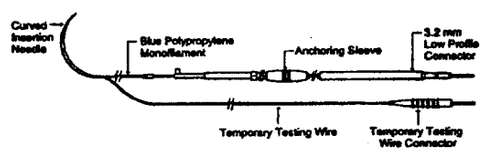

Figure 1. Lead Model 4301

The lead has a polyurethane insulation and a flexible electrode coil made of platinum and iridium contained in a movable polyurethane insulation sheath. Both ends of the movable sheath have a fixation mechanism (anchoring sleeve and fixation loop).

The platinum-iridium electrode tip is mechanically and electrically connected to the electrode coil. The lead holds a non-absorbable blue polypropylene monofilament and a curved needle for lead insertion, stimulation testing, and stable electrode positioning.

The Model 4301 Lead is intended to be used with the Medtronic® Model 7425G Neurostimulator, external programmer (Medtronic Model 7432) and programmer software (Medtronic MemoryMod Model 7457). The lead is designed for permanent intramuscular implantation to deliver electrical current to the stomach muscle.

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Device Description

Contents of the Package

The Medtronic Model 4301 Lead package contains the following:

Lead

- One Model 4301 (with anchoring sleeve attached to the movable insulation sheath)

Accessories

- 4 Fixation disks
- 1 Tunneling rod
- 2 Lead end caps
- 1 Operating room cable
- Product literature

Note: The contents of the inner package are sterile (ethylene-oxide sterilized).

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Device Description

Indications

The Enterra gastric lead is indicated for the treatment of patients with 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 is not a candidate for surgical procedures and/or anesthesia due to physical or mental conditions.

Physician Training

Prescribing physicians are encouraged to contact Medtronic and request a referral to a physician experienced in the surgical and/or implantation techniques, operational characteristics and functions of the Enterra Therapy system prior to prescribing the device for the first time. All programming should be by or under the supervision of a physician or other experienced medical personnel familiar with the use of the programming software.

Patient Counseling

The patient and family should be advised of the known risks of the surgical procedure and the therapy (as discussed in the other sections of this manual), as well as the potential benefits. The patient should be advised to read *The Enterra™ Therapy Gastric Electrical Stimulation System Patient Manual*, which is included in the Model 4301 package.

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Warnings

- **Age Limitations**—~~Safety and effectiveness of this system has not been established for patients under age 18 or over the age of 80.~~ This system has not been evaluated for patients under age 18 or over age 70.
- **Allergic Reaction**—There is a possibility of an allergic or immune system response to the implanted materials.
- **Anticoagulation Therapy**—Patients who are on anticoagulation therapy may be at a greater risk for postoperative complications, such as hematomas.
- **Cardiac Pacemakers**—Under certain conditions, the gastric stimulation system may adversely affect the operation of cardiac demand pacemakers.
- **Cardioverter Defibrillators**—Under certain conditions, the gastric stimulation system may affect the therapies programmed into cardioverter defibrillators.
- **Components**—The use of non-Medtronic components with this system may result in damage to Medtronic components, less than adequate stimulation, or increased risks to the patient.
- **Diathermy**—The effects of diathermy on patients with an implanted gastric stimulation system are unknown. Since internal components may be damaged, using diathermy over an implanted lead or neurostimulator is not recommended.
- **Electrocautery Devices, Radiation Therapy, and Ultrasonic Devices**—These devices may interfere with the operation of the neurostimulator and/or may cause some damage to the device.
- **External Defibrillators**—Safety for use of external defibrillatory discharges on patients with neurostimulators has not been established.

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Warnings

- **Magnetic Resonance Imaging (MRI)**—Use of MRI may result in system failure, dislodgement or heating of the neurostimulator and/or the lead. The voltage induced through the lead and neurostimulator may cause uncomfortable "jolting" or "shocking" levels of stimulation. Patients should not be exposed to the electromagnetic fields that MRI produces.
- **Pregnancy**—Safety and effectiveness in pregnant women have not been established.
- **Pediatric Use**—Safety and effectiveness of this system have not been established for pediatric use.
- **Theft Detectors and Screening Devices**—It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. Higher levels have been described as uncomfortable, "jolting," or "shocking" by some patients as they pass through theft detectors and screening devices.

Special Notice

Medtronic lead kits consist of leads and tools to connect the lead to neurostimulators. Leads are implanted in the extremely hostile environment of the human body. Leads may fail to function for a variety of causes, including, but not limited to: medical complications, body rejection phenomena, fibrotic tissue, breakage, or breach of their insulation covering. In addition, leads and tools may easily be damaged by improper handling or use.

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Precautions

Inspecting the Package

Inspect the lead sterile package prior to opening. If the seal or package is damaged, contact your local Medtronic representative.

Handling the Lead

- Take care to avoid accidental bending of the electrode coil and the conductor coil; the angulation required to restore the electrode's original shape may weaken or fracture the electrode.
- Any severe bending, kinking, stretching, or handling with surgical instruments may cause permanent damage to the electrode coil, conductor coil, connector, or the lead body. If the lead is damaged, do not implant. Return the lead to your Medtronic representative.
- Do not implant a lead that was dropped; the lead may no longer be sterile.
- Do not tie a suture directly around the lead. Use the anchors, which are supplied with the lead kit.
- Do not pull the lead taut when implanted. Leave it as loose as possible to avoid unnecessary tension on the lead.
- When handling the lead with forceps, use only rubber-tipped bayonet forceps.
- Lead insulators attract small particles such as lint and dust; therefore, to minimize contamination, protect the lead from materials shedding these substances. Handle the lead with sterile surgical gloves that have been rinsed in sterile water or equivalent.
- Wipe off any body fluids on the lead contacts or connector before connecting the lead to the neurostimulator. Contamination of the connections can affect gastric stimulation.
- Do not immerse the lead in mineral oil, silicone oil, or any other equivalent.

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General Precautions

- The physician should be aware that gastric stimulation systems may unexpectedly cease to function. A system may fail at any time due to random failures of the system components or the battery (prior to depletion). These events, which can include electrical shorts or opens and insulation breaches, cannot be predicted.
- It is not recommended to use high output ultrasonic devices such as an electrohydraulic lithotriptor on patients with an implanted neurostimulator. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry.
- Ultrasonic scanning equipment, if used directly over the implant site, may cause mechanical damage to an implanted neurostimulator.
- Electrocautery can cause temporary suppression of the neurostimulator output and/or reprogramming of the device. Do not use an electrocautery tip in the vicinity of the Enterra Therapy system.
- The use of defibrillatory discharges in the vicinity of the neurostimulator or lead can cause permanent damage to the devices—including reprogramming of the neurostimulator. Such reprogramming may cause the stimulation mode, and all other programmable parameters, to reset to the nominal or preset state, with amplitude at zero and the output OFF.

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Precautions

Lead Repositioning

- Repositioning the lead is not recommended after implantation. If necessary, replace the lead. Removing the lead after long-term implant may be difficult due to fibrotic tissue development. If you cannot remove the lead safely, it is recommended that the lead be left in position. Place a lead end cap over the connector pin and secure the end cap with a suture. (See "Using a Lead End Cap.")

Patient Considerations

- Select patients carefully to assure that their symptoms are of physiological origin. Patients must be appropriate candidates for surgery.
- It is recommended that patients undergo detoxification from narcotics prior to implant.
- So that the benefit from the gastric stimulation system may be optimized, long-term, post-surgical management of the patient is strongly encouraged.

Adverse Events

The adverse effects observed during the clinical evaluation of the Enterra Therapy system include: lead impedance out of range, device infections, device erosion, device migration, stomach wall perforation, upper gastro-intestinal (GI) symptoms, extra-abdominal pain, feeding tube complications, lower GI symptoms, dehydration, bone- and joint-related pain, acute diabetic complications, dysphagia, cardiovascular/renal related events, urinary tract infections, stress incontinence, fever, and infections (sinus, pink eye, herpes zoster). These effects were related to the device, implant, underlying disease, other therapies, or other.

Other potential complications that were not seen during clinical evaluation include: undesirable change in stimulation, possibly related to cellular charges around the electrodes, shifts in electrode position,

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loose electrical connections, or lead fractures; hemorrhage, hematoma, and possible GI complications resulting from the surgical procedure to implant the neurostimulator and leads; migration of lead or generator, which may necessitate surgical revision; persistent pain at the neurostimulator site; seroma at the neurostimulator site; allergenic or immune system response to implanted materials; and loss of therapeutic effect.

Clinical Studies

Patients with drug-refractory gastroparesis of diabetic or idiopathic etiologies were evaluated in the following clinical studies conducted in the United States, Canada, and Europe: the World Wide Anti-Vomiting Electrical Stimulation Study (WAVESS) and a Compassionate Use Study.

WAVESS Study

The WAVESS Study was a double-blind, randomized cross-over study that enrolled a total of 33 subjects. The study was designed to collect both safety and effectiveness information.

Study Objective

The primary endpoint of the study was a reduction in vomiting frequency, as measured by patient diaries. The treatment was considered successful if a reduction in vomiting frequency by at least 80% was observed during the cross-over period of the study with the ON-mode stimulation, when compared to the OFF-mode stimulation.

The secondary endpoints in the study were quality of life (measured with the Medical Outcomes Study Short-Form 36 Health Survey), body mass index, hypoglycemic attacks (diabetic group only), subjective symptoms documented by a clinical status interview, glycosylated hemoglobin, and gastric emptying documented with a gastric emptying test.

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Clinical Studies

Entry Criteria

The inclusion criteria for the study included:

- Symptomatic gastroparesis ≥ 1 year, as documented by an initial gastric emptying test (GET)
- Refractory or intolerant to at least two anti-emetic and prokinetic drug classes
- On stable medical therapy, and, if applicable, stable nutritional support during the month prior to enrollment
- Frequency of vomiting > 7 vomiting episodes per week, as documented with a baseline patient diary
- Delayed gastric emptying, defined by greater than 60% retention at two hours and > 10% retention at four hours, as measured by standardized gastric emptying testing

The exclusion criteria included:

- Organ transplant
- Organic obstruction
- Pseudo obstruction
- Prior gastric surgery
- Scleroderma amyloidosis
- History of seizures
- Peritoneal or unstable dialysis
- Chemical dependency
- Pregnancy
- Primary eating or swallowing disorders
- Psychogenic vomiting
- Implanted electronic medical devices
- Age < 18 or > ~~80~~ 70 years.

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Study Enrollment

Enrollment and follow-up in the WAVESS study was as follows:

Table 1. Enrollment in WAVESS Study

Number of Subjects	at enrollment	Implanted > 30 days	Implanted > 60 days	Implanted > 6 Months	Implanted > 12 Months
(N)	33	33	33	25	15

Demographics

A total of 33 subjects were enrolled in the WAVESS study. The demographic information on these subjects is presented in the table below:

Table 2. Patient Demographics

	Diabetic (n=17)	Idiopathic (n=16)	Total (n=33)
gender (M/F)	9/8	0/16	9/24
age, mean	38.1	41.1	39.6
BMI, mean	24.7	22.9	23.7
gastric retention (mean/median) %			
@ 2 hours	79.7/80.0	73.1/76.5	76.5/78.0
@ 4 hours	53.2/51.0	34.3/28.0	44.0/34.0

Study Design

Subjects satisfying entry criteria received gastric stimulation systems that included an implanted neurostimulator connected to two unipolar leads that were implanted in the muscle wall of the stomach on the greater curvature at the limit of the corpus-antrum. All subjects received a Model 7425G implantable neurostimulator and a pair of Model 4301* leads. The stimulation parameters used in the study were: Intensity: 5 mA, Pulse Width: 330 µsec, Frequency: 14 Hz. The neurostimulator was set to deliver a pair of pulses at these parameters every five seconds continuously 24 hours per day.

* The Model 7425 Neurostimulator and Model 4300 Lead were used in the clinical study, and they are identical to the Model 7425G and Model 4301.

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Clinical Studies

The study was conducted in two phases:

1. Phase I was a double blind crossover study with evaluations prior to implant and at 30 days and 60 days. Subjects were randomly assigned to stimulation ON and OFF for the first month after implant and were crossed to OFF and ON for the second month. Subjects were blinded as to which stimulation sequence they received.
2. Phase II was an unblinded open label study with follow-up at six and twelve months. After the cross-over period was complete, the subjects were asked which month of the cross-over stimulation they preferred. After the selection was made, the study blind was broken. The subjects then received stimulation consistent with their preference.

The primary and all of the secondary endpoints, except gastric emptying, were measured at baseline, 30 days, 60 days, six months, and twelve months post-randomization. Gastric emptying was measured at baseline, and six and twelve months post-randomization.

Primary endpoint evaluations included weekly vomiting frequency and patient preference within Phase I of the study (see Study Design section on page 13). Secondary endpoint evaluations included gastric retention, hypoglycemic attacks, upper GI symptoms, and quality of life using the Medical Outcomes Study Short-Form 36 Health Survey.

Compassionate Use Study

The Compassionate Use study was an open label, non-randomized study that included a total of 18 subjects. This study was designed to provide safety information on gastric stimulation.

Study Objective

The purpose of the compassionate use study was to treat patients with drug-refractory gastroparesis who did not meet the entry criteria of the WAVESS study.

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Study Enrollment

Enrollment and follow-up in the compassionate use study was as follows:

Table 3. Enrollment in Compassionate Use Study

Number of Subjects	at enrollment	Implanted > 30 days	Implanted > 60 days	Implanted > 6 Months	Implanted > 12 Months
(N)	18	15	7	6	4

Entry Criteria

Candidates eligible for the compassionate use study consisted of those subjects who did not meet the complete entry criteria for the WAVESS study, but who had some documentation of drug-refractory gastroparesis. The entry criteria were:

- Patient had delayed gastric emptying, defined as greater than 60% retention at two hours and > 10% retention at four hours, as measured by a standardized gastric emptying test;
- Patient did not meet the complete entry criteria of the WAVESS study;
- Patient was considered high risk and needed (as determined by their physician) gastric stimulation therapy;
- Patient was able to provide informed consent

Study Design

Subjects satisfying entry criteria received gastric stimulation systems which included an implanted neurostimulator connected to two unipolar leads which were implanted in the muscle wall of the stomach on the greater curvature at the limit of the corpus-antrum. All subjects received a Model 7425G implantable neurostimulator and a pair of Model 4301 leads. The stimulation parameters used in the study were: Intensity: 5 mA, Pulse Width: 330 µsec, Frequency: 14 Hz. The neurostimulator was set to deliver a pair of pulses at these parameters every five seconds continuously 24 hours per day. The stimulation parameters could be adjusted at any time by the physician to optimize treatment therapy.

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Clinical Studies

In contrast to the WAVESS study design, the compassionate use study consisted solely of an unblinded open label study. Upon implantation of the device within each patient, the stimulation therapy was immediately initiated without a randomized ON/OFF cross-over period.

Results

The effectiveness results described below were obtained from the WAVESS study.

Primary Endpoint Evaluations:

There was no difference in the vomiting frequency with stimulation ON or OFF during the two month double blind cross over study (see Table 4). However, 21 subjects preferred the device ON while seven preferred the device OFF. Five had no preference. At the end of Phase I, subjects were unblinded and given the option of having the device programmed ON or OFF. At the six month follow-up, all subjects had the device programmed ON.

Table 4. Vomiting Frequency, WAVESS Phase I, all Subjects (N=33)

Vomiting Episodes per Week	Baseline	ON	OFF	Difference (OFF-ON)	% Difference
Mean (N±SD)	47.6 ± 52.6	23.0 ± 35.5	29.0 ± 38.2	6.0 ± 22.4	21
Median (N)	26.3	12.0	14.0	2.0	14.3

As noted above, at the end of the Phase I study period, each subject was asked which month of stimulation that was preferred (this applied only to those subjects enrolled in the WAVESS study). Twenty one preferred the ON mode, seven preferred the OFF mode, and five had no preference. Each of these patients had the option of requesting that stimulation be turned OFF or ON at any time during the Phase II period.

Although 33 patients completed the two-month cross-over period of the study (through Phase I), data at six months is provided for only 25 patients. Of these 25 patients, some patients had the device turned to the ON mode immediately at the end of the Phase I

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period, while others had the device turned ON later. By the end of the fourth month post-randomization, all 25 patients had the device turned ON. As a result, the vomiting frequency at 6 months documented in Table 5 was obtained from patients who received stimulation for at least 3 months (including the Phase II cross-over period). At the time at which the data set was locked, 6 month follow-up data were only available for 25 of the 33 patients.

Vomiting frequency results at six and 12 months post-implantation are shown in Tables 5-7. Table 5 includes data for all subjects, while Tables 6 and 7 include data for the idiopathic and diabetic gastroparesis groups, respectively. There was no statistical difference in vomiting frequency as compared to baseline for either group.

Table 5. Vomiting Frequency, WAVESS Phase II, All Subjects

All Patients Combined	Base-Line	6 Months	% Difference	Base-line	12 Months	% Difference
N	25	25	—	15	15	—
Mean Number of Episodes, ± SD	44.6 ± 50.7	19.2 ± 43.7	-57	42.7 ± 53.9	10.1 ± 19.8	-76
Median Number of Episodes	26.5	5.0	-81	18.5	4.5	-76
Patients with > 50% vomiting reduction vs baseline, N(%)	—	17 (68)	—	—	14 (93)	—
Patients with > 80% vomiting reduction vs baseline, N(%)	—	14 (56)	—	—	8 (53)	—

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Clinical Studies

Table 6. Vomiting Frequency, WAVESS Phase II, Idiopathic Gastroparesis Subjects

	Base-Line	6 Months	% Difference	Base-line	12 Months	% Difference
N	14	14	—	10	10	—
Mean Number of Episodes	32.7 ± 44.4	12.1 ± 25.1	-63	41.3 ± 53.3	13.8 ± 23.7	-67
Median Number of Episodes	22.5	3.0	-87	23.0	5.3	-77
Patients with > 50% vomiting reduction vs baseline	—	9 (64)	—	—	9 (90)	—
Patients with > 80% vomiting reduction vs baseline	—	8 (57)	—	—	5 (50)	—

Table 7. Vomiting Frequency, WAVESS Phase II, Diabetic Gastroparesis Subjects

	Base-Line	6 Months	% Difference	Base-line	12 Months	% Difference
N	11	11	—	5	5	—
Mean Number of Episodes	59.8 ± 56.1	28.2 ± 60.1	-53	45.5 ± 61.5	2.8 ± 4.2	-94
Median Number of Episodes	28.0	6.0	-79	18.0	1.0	-94
Patients with > 50% vomiting reduction vs baseline	—	8 (73)	—	—	5 (100)	—
Patients with > 80% vomiting reduction vs baseline	—	6 (55)	—	—	3 (60)	—

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Secondary Endpoint Evaluations:

The results of secondary endpoint evaluations indicate that many patients experienced improvements in quality of life (73%) and ability to tolerate solid meals (73%). Additionally, there was a trend in improvement for gastric retention, subjective symptoms, and hypoglycemic

Adverse Events

The adverse event information (Table 8) was obtained from both the WAVESS study (n=33) and compassionate use study (n=18). Adverse events were reported at each follow up visit or at interim periods as appropriated in both studies. The table below summarizes those adverse events reported through September 30, 1999.

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Adverse Events

Table 8. Summary Study of Adverse Events

Event	# Events	# Patients	% of Patients
Device or Implant Related:			
Lead Impedance Out of Range	7	6	12%
Device Infections[A]	2	2	4%
Device Erosion[B]	1	1	2%
Neurostimulator Migration[C]	2	1	2%
Stomach Wall Perforation[D]	1	1	2%
Underlying Disease (Diabetes or Gastroparesis) Related:			
Upper GI Symptoms	81	23	45%
Extra Abdominal Pain	33	14	27%
Feeding Tube Complications	23	14	27%
Lower GI Symptoms	17	9	20%
Dehydration	15	8	16%
Bone and Joint Related	11	8	16%
Acute Diabetic Complications	9	6	12%
Dysphagia	5	1	2%
Cardiovascular/Renal Related	2	2	4%
Other Therapy Complications:			
Feeding Tube or IV Complications	23	14	27%
Miscellaneous:			
Urinary Tract Infections	4	4	8%
Stress Incontinence	2	2	4%
Fever	6	4	8%
Other Infections (sinus, pink eye, herpes zoster)	3	3	6%

Notes

A: Implant system removed in both patients; new system implanted in one patient later on.

B: Implant system removed; new system implanted later.

C: System was surgically revised, but not removed, twice in the same patient.

D: System was removed and not re-implanted.

There were three types of device related adverse events that required surgical intervention, including device infection (N = 3), stomach wall perforation (N = 1) and migration of the neurostimulator (N = 1).

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ENTERRA THERAPY

Gastric Electrical Stimulation System

Patient Manual

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 restricts this device to sale by or on the order of a physician.

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INTRODUCTION

This booklet was written to help you understand your Enterra™ Therapy gastric electrical stimulation system. If you have questions and cannot find the answers in this booklet, or if any unusual situations or problems arise, consult your physician. He or she knows your personal medical history and can give you the detailed information that you may need.

Gastric Electrical Stimulation for Nausea and Vomiting

Several diseases, such as gastroparesis, may lead to frequent vomiting and nausea. Despite drug treatment, your vomiting persists.

Your Enterra Therapy System

A physician has prescribed the Enterra Therapy system to treat your frequent vomiting. If you should experience any inflammation or irritation from the device, immediately contact your physician.

The Enterra Therapy system comprises:

- A Model 7425G Neurostimulator, which is surgically placed in the region of the abdomen.
- Two intramuscular leads, also called electrodes, Enterra Model 4301, with electrodes placed so they can be sutured into the muscle of your stomach.
- A Physician Programmer Model 7432 that the physician uses to the control and adjust the settings of your implanted neurostimulator.

See Figure 1 to identify the implanted components that make up part of the Enterra Therapy system.

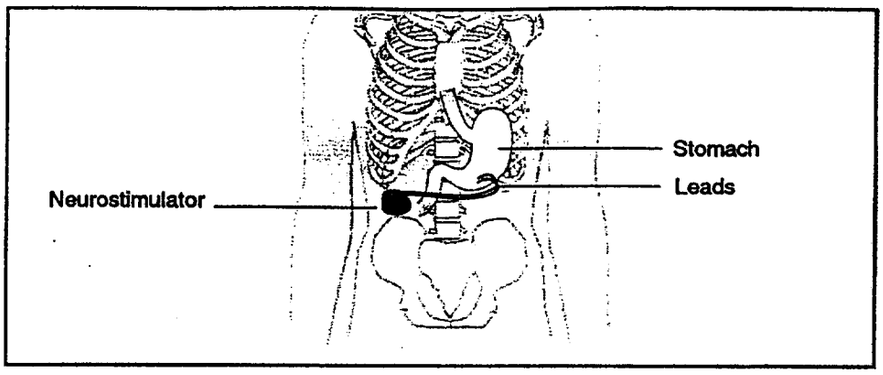

Figure 1. Implanted components: Leads and neurostimulator

The neurostimulator is the source of stimulation. It contains a battery and electronics to control stimulation. The neurostimulator and the leads are implanted during surgery. Your physician keeps the Physician Programmer in the hospital so he or she can adjust the neurostimulator settings during your hospital visits.

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How the Enterra Therapy System is Implanted

The surgeon will place two leads (also called electrodes) in the muscle of your stomach and then implant a neurostimulator in your abdomen. Sometimes the area where the neurostimulator is implanted is called a "pocket." The surgeon will connect the leads to the neurostimulator. Before you leave the operating room, the surgeon will determine the electrical settings and program those settings into the neurostimulator.

LIVING WITH YOUR ENTERRA THERAPY SYSTEM

Medications

Your doctor may prescribe medications that will work together with your Enterra Therapy system to manage your symptoms. It is important that you follow your doctor's orders for taking the prescribed medicine. You may want to keep a special calendar to record each time you take the medicine. You may also want to record any symptoms that you experience.

Activities and Exercise

The recovery time for each patient is different. At first, there will be some discomfort near the incision site. You may feel very aware of the neurostimulator implanted in your abdomen. After a period of time, your awareness of the neurostimulator will gradually diminish, and you may not even feel its presence. Follow your doctor's advice regarding any activities that require bending and twisting. The body tissue around the leads needs time to heal. It is very important to follow the advice of your doctor, and he or she will know when it is best for you to resume your normal lifestyle activities.

Environmental Problems

Your neurostimulator has built-in features that protect it from interference produced by other electrical devices. Many electrical items that you encounter in an ordinary day are safe, posing no

threat to your neurostimulator. You can use common household appliances, including:

- Microwave ovens
- Televisions, FM and AM radios, and stereos
- Toasters, blenders, and electric can openers
- Hair dryers, and electric shavers
- Washers, dryers, and electric stoves
- Electric blankets and heating pads

Note: Theft Detectors and Screening Devices–It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. Higher levels have been described as uncomfortable, "jolting" or "shocking" by some patients as they pass through theft detectors and screening devices.

Additional equipment that may affect a momentary increase in perceived stimulation:

- Electrical arc welding equipment
- Electric induction heaters used in industry to bend plastic
- Electric steel furnaces
- Power lines
- Electrical substations and power generators

Medical Procedures and Medical Devices

Some medical procedures and devices may interfere with your Enterra Therapy system. You must notify any medical personnel that you have an implanted system because he or she needs to be made aware of the possible risks and precautions associated with the procedures or devices.

Magnetic resonance imaging (MRI) procedures are not compatible with the neurostimulator and leads. If you have an MRI procedure, your neurostimulator and leads may be moved and you may experience pain.

The neurostimulator may also interfere with other devices, such as defibrillators and implanted pacemakers. Make sure to inform your doctor if you have any implanted devices.

External defibrillators, electrocautery devices, diathermy, radiation therapy, and ultrasonic devices may interfere with the proper operation of the neurostimulator. These external devices may cause some damage to the neurostimulator. In addition, the electrical signal from the implanted neurostimulator may interfere with the proper operation of the external defibrillator. The safety for the use of the external defibrillators on patients with this implanted Enterra Therapy system has not been established.

CHECKING YOUR ENTERRA THERAPY SYSTEM

Doctor and Clinic Visits

It is important that you keep all your scheduled doctor appointments. Your doctor may send you to a special clinic for routine checkups to determine if your Enterra Therapy system is providing the appropriate therapy.

Tell your other doctors and dentists that you have an implanted Enterra Therapy system. This information is necessary so that they can avoid prescribing treatments that may interfere with your system.

Signs to Watch For

When your neurostimulator is switched ON, you may or may not sense the stimulation. If your neurostimulator is switched OFF, symptoms will likely resume. Contact your physician, who will use the Physician Programmer to verify the function of the neurostimulator.

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Battery Information

Your neurostimulator contains a sealed battery. The batteries will not function indefinitely. The Enterra Therapy system output stimulation pattern will change slightly as the battery runs down. Ordinarily, the battery in your neurostimulator should last for several years.

REPLACEMENT SURGERY

Because the battery is sealed inside the stimulator case, it cannot be replaced separately. When it is time to replace the battery, the doctor will remove the old neurostimulator and implant a new device. Your doctor will also check the implanted leads at the same time. If the system is working properly, the doctor will connect the new neurostimulator to the same leads.

YOUR ENTERRA THERAPY SYSTEM IDENTIFICATION CARD

Your doctor will give you an identification card. Carry the identification card at all times. In the event of an accident or emergency, this card will provide information to those attending to you that you have an implanted medical device. The card carries basic information about your Enterra Therapy system and identifies your doctor.

The identification card is convenient to have if you travel by air. Although airport security screening devices are unlikely to interfere with your implanted neurostimulator, they may detect the metal in the neurostimulator. Therefore, to obtain clearance, it may be necessary to present the identification card to the airline clerk.

If you need a new identification card, list all the information from the current card, noting any changes, and send the information to the address listed on the card.

If your card is misplaced, contact your physician.

FREQUENTLY ASKED QUESTIONS

1. ***What is gastric electrical stimulation?***

   Gastric electrical stimulation is the application of a small electrical current to the stomach. As a result, the stomach muscle contracts.

2. ***What is a Neurostimulator?***

   A neurostimulator is the device that sends precise electrical pulses to the stomach.

3. ***Will the Enterra Therapy system get rid of my problem with vomiting?***

   The clinical study of the Enterra Therapy system used in treating nausea and vomiting has shown that most, but not all, patients have some relief of their symptoms.

4. Will I feel the stimulation?

Most patients do not feel continuous gastric electrical stimulation.

5. Will I be able to turn the neurostimulator on and off?

No. Only your physician can turn the neurostimulator on and off with the use of the Physician Programmer.

6. How long will the neurostimulator battery last?

The battery longevity of the neurostimulator will vary depending on how strong the stimulation must be for managing your condition. The battery life is estimated to be from 5-10 years. Generally, the neurostimulator battery should be checked about once every six months. However, your physician may want to see you more or less often, depending on your situation.

7. Can the battery be recharged?

No.

8. How is the battery replaced?

To replace the battery, your physician must replace the entire neurostimulator, which requires a surgical procedure. (See page 4, *How the Enterra Therapy System is implanted.*)

9. Will the Enterra Therapy system limit my activities?

Generally, no. However, the neurostimulator may hinder sharp bending of the body trunk. If you feel limited in your activities, consult your physician.

10. How large is the neurostimulator?

The neurostimulator is oval shaped and approximately 2.5 inches (60 mm) long, 2 inches (50 mm) wide, and about 0.5 inches (12 mm) thick.

11. Will the neurostimulator show through my clothes?

Your physician will try to place the neurostimulator in a place that is most comfortable and cosmetically acceptable. However, depending on your body build, the neurostimulator may be noticeable as a small bulge under the skin.

12. What happens if the neurostimulator stops working?

If for some reason the neurostimulator stops working, your symptoms may return. If this happens, contact your physician. He or she will use the Physician Programmer to verify the function of the neurostimulator.

If the neurostimulator is found to be nonfunctional, another surgical procedure will be necessary to replace the neurostimulator.

13. Does the neurostimulator make noise?

No.

14. Will a microwave oven interfere with the neurostimulator?

No.

15. How often should the physician be seen to check the neurostimulator?

Generally, the neurostimulator battery should be checked about once every six months. However, your physician may want to see you more or less often, depending on your situation.

GLOSSARY

Amplitude—A measure of the electrical intensity delivered in a stimulation pulse, which is measured in volts.

Electrocautery device—A device that stops bleeding of blood vessels. It is used during most surgeries.

Diathermy—Therapy in which high-frequency currents produce heat in body tissues to treat certain conditions.

External defibrillator—A medical device used to deliver a strong electrical shock that stops a fast heartbeat.

Gastroparesis—Paralysis of the stomach.

Mode—The manner in which stimulation is delivered.

Parameter—The conditions that can be varied to affect the type of stimulation for you.

Pulse Width—A measure, in microseconds, of the duration of each stimulating pulse.

Radiation therapy—A therapy used in cancer treatment. This may be done if the focus of the therapy is away from the neurostimulator.

Rate—A measure, in pulses per second, that provides the number of times stimulating pulses are delivered each second.

Telemetry—A radio-frequency method of communication. It is a technique used to verify and control the operations of your neurostimulator.

Ultrasonic device—Medical device that emits high-frequency sound waves used to diagnose certain conditions.

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When Life Depends on Medical Technology

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