Lead Implant Manual

Enterra® Therapy

Unipolar Lead Kit for Gastric Electrical Stimulation

4351-35

CE 0123

enterra medical™

Explanation of symbols on product or package labeling

Refer to the appropriate product to see symbols that apply.

Open here

Lead length

Do not use if package is damaged

Do not reuse

Do not resterilize

Sterilized using ethylene oxide

Consult instructions for use

Consult instructions for use at this website
https://www.enterramedical.com/hcp/manuals/

Date of manufacture

Manufacturer

Use by

Serial number

Caution for specific warnings or precautions associated with the medical device

CE 0123 Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.

Authorized representative in the European community

PIN number

Importer

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Information available for the system:

The information for prescribers manual provides information about indications, contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, and component disposal.

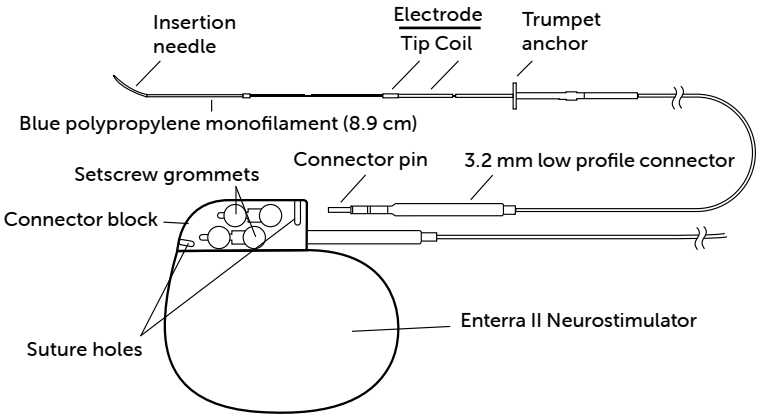
Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

Description

The Enterra® II System for gastric electrical stimulation is comprised of a neurostimulator, leads, programmer, and programmer software.

The Enterra Model 4351-35 Lead is a unipolar, intramuscular lead with a fixed 10 mm electrode. The lead features a non-absorbable monofilament suture ending in an insertion needle and a pre-attached trumpet shaped anchor. The lead comes with a 3.2 mm (0.13 in.) low profile Enterra Medical standard lead connector in a unipolar configuration. Only the pin is mechanically and electrically connected in the unipolar configuration. Refer to Figure 1.

Figure 1. Lead Model 4351-35 with neurostimulator



The lead has a polyurethane insulation and a flexible electrode coil made of platinum and iridium.

The platinum-iridium electrode tip is mechanically and electrically connected to the electrode coil. The lead has an attached, non-absorbable blue polypropylene monofilament and an insertion needle.

The Model 4351-35 Lead is intended to be used with the Model 37800 Neurostimulator.

The lead is designed for intramuscular implantation to deliver electrical current to the stomach muscle.

Intended purpose

The lead is an implanted component of a neurostimulator system intended to conduct electrical stimulation from a neurostimulator to the stomach muscle, as part of a neurostimulation system for gastric electrical stimulation therapy.

Package contents

- Lead with pre-attached trumpet anchor and blue polypropylene monofilament (with insertion needle)
- Fixation disks (four)
- Tunneling tool
- Lead end caps (two)
- Product literature

Note: The contents of the inner package are sterile (ethylene-oxide sterilized) and for single use only.

Device specifications

Table 1. Device specifications for the Model 4351-35 Lead[a]

Description	Value
Connector	3.2 mm low profile
Conductor resistance[b]	2.2 Ω per cm
Length	35 cm
Diameter (lead body)	1.0 mm
Surface area	
Lead	18.7 cm^2
Fixation disk	3.7cm^2
Materials and substances to which the patient can be exposed[c,d,e]	Silicone, polyurethane, platinum iridium alloy, polypropylene, stainless steel[f,g]
Distal (electrode) end Number of electrodes	
Number of electrodes	1
Electrode shape	Cylindrical
Electrode length	10 mm
Electrode tip diameter	0.9 mm
Electrode coil diameter	0.6 mm
Blue polypropylene monofilament	8.9 cm
Insertion needle length	32 mm
Proximal (connector) end	
Lead contact length	9 mm
Expected lifetime	5 years

[a] All measurements are approximate.
[b] Electrical resistance of this device only.
[c] Discuss any allergies or other intolerances related to the materials and substances with the patient before the procedure.
[d] Tested for category 1A or 1B carcinogenic, mutagenic, or toxic for reproduction (CMR) substances, or endocrine disrupting chemicals (EDC).
[e] Does not contain natural rubber latex.
[f] This material may contain a substance: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0 defined as CMR 1B, in a concentration above 0.1% weight by weight. This material is only tissue contacting during the implant procedure.
[g] Contains nickel. This material is only tissue contacting during the implant procedure.

Instructions for use

Implanting physicians should have experience in the surgical and/or implantation techniques for the Enterra II System, operational and functional characteristics of the Enterra II System, and experience in the continued management of patients by stimulation parameter adjustment.

Physicians may contact Enterra Medical before prescribing or implanting an Enterra II System for the first time, and request a referral to a physician experienced in the use of the Enterra II System. Implanting physicians should be thoroughly familiar with all product labeling.

Preparing for surgery

⚠ **Warning:** To guard against the possibility of infection, it is recommended that the following guidelines be used. Infections at the implant site almost always require the surgical removal of the neurostimulator and leads.

- When possible, identify and treat any infections remote to the implant site prior to surgery.
- Administer IV antibiotics during surgery and post-surgery.
- Irrigate the neurostimulator pocket with antibiotic solution during surgery.

Before opening the lead package, verify the model number, use-by date, lead length, and connector type.

Implanting the lead

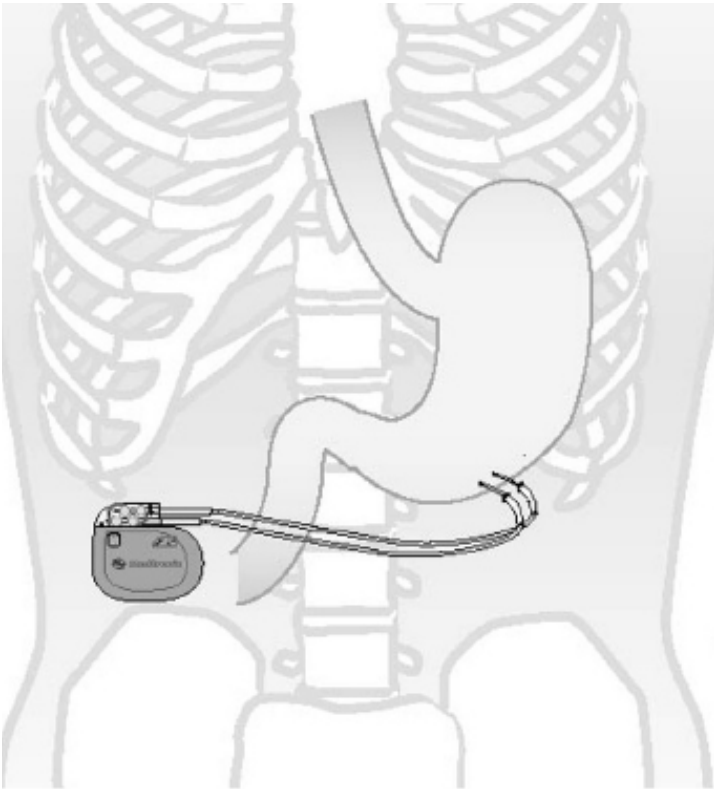
Note: Enterra Medical recognizes that a variety of approaches may be used to accomplish lead implantation; therefore, the following implant procedure is presented as one possible approach for the physician to consider.

Note: To help facilitate implantation, you may prepare the system by tying sutures onto the trumpet anchor, fixation disk, and neurostimulator connector block. Do not use absorbable suture material.

1. Using either a laparotomy or laparoscopic surgical procedure, expose and visualize the antrum of the stomach.
   Note: If using the laparoscopic approach, ensure that the port is sufficient in diameter to accommodate the lead.
2. Locate the limit of the corpus antrum.
3. Use the needle to insert the lead into the circular muscle layer of the stomach at the corpus antrum limit. Place the leads 1.0 cm apart and parallel to each other for optimal stimulation (Figure 2).

   Note: Position the lead into the stomach wall from the direction of the neurostimulator. Ensure that the lead placement angle avoids sharp bends or kinks.

Figure 2. Place leads in the stomach wall at the corpus antrum limit.



a. Under endoscopic observation, insert the needle into a 2 cm length of tissue to ensure that the electrode will lie completely within the stomach wall muscle.

b. Carefully pass the needle through the muscle. Stay clear of nerves and blood vessels to avoid possible injury to these structures.

c. When passing the needle, make sure the entire length of the 1.0 cm electrode will be positioned **completely** within the stomach muscle layer.

d. Use endoscopy to ensure that the needle is not exposed on the mucosal surface of the stomach.

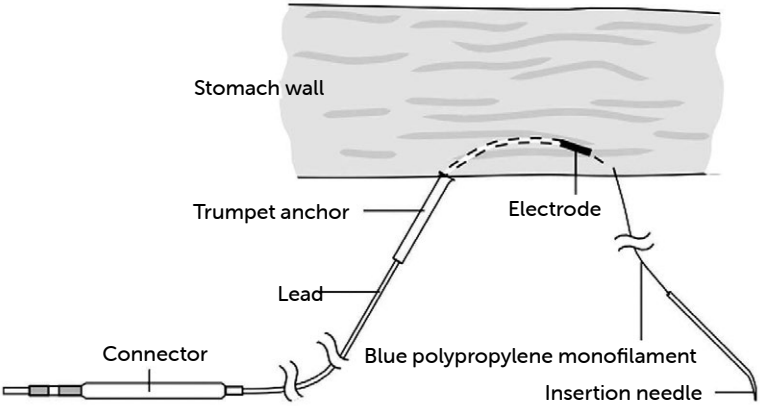
4. Insert electrode into the muscle wall.

a. Gently pull the blue polypropylene monofilament to insert the electrode into the muscle wall, making sure that the electrode lies within the stomach wall muscle (Figure 3).

Note: You may feel a slight resistance as the electrode passes into the muscle layer.

b. Continue using endoscopy to ensure that the blue polypropylene monofilament, lead, or electrode are not exposed on the mucosal surface of the stomach.

Figure 3. Insert electrode into muscle wall.



⚠ **Caution:** To ensure that the lead does not perforate the stomach wall during lead insertion, it is recommended that the lumen of the stomach be observed endoscopically during the implant procedure. If penetration of the stomach wall by the lead, the needle, or the blue polypropylene monofilament is observed, it should be immediately withdrawn and reinserted without perforating the stomach wall.

5. When the lead is properly positioned, secure the lead to the serosal surface of the stomach, according to the instructions in **Anchoring the lead** on page 14.

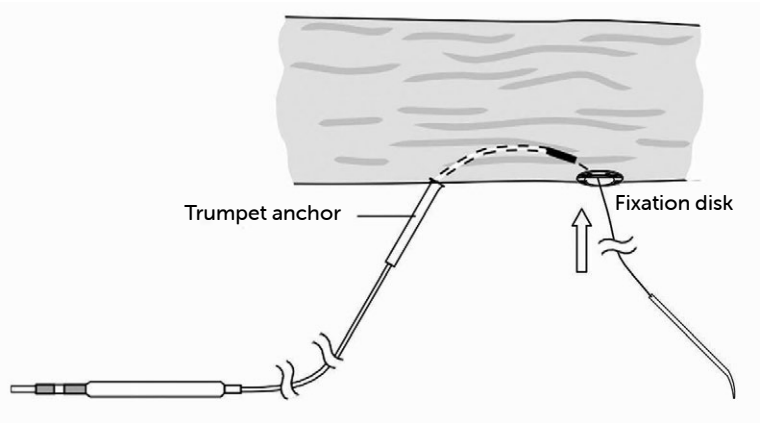
Anchoring the lead

1. To anchor the distal portion of the lead (electrode), insert the needle through the center of the fixation disk.

Note: Use one fixation disk per lead to adequately anchor the lead.

2. Slide the fixation disk down the blue polypropylene monofilament until it is directly on the serosal surface (Figure 4).

Figure 4. Slide fixation disk to serosal surface.



Note: Ensure that the fixation disk and the adjacent anterior serosal surface of the gastric antrum are flat and in the same plane.

3. Use a minimum of two surgical clips to anchor the fixation disk onto the blue polypropylene monofilament. Consult the manufacturer's literature for information on selection and instructions for use.

4. Secure the fixation disk to the serosal surface with non-absorbable suture material through a minimum of two suture holes (ideally across from each other for stability).

⚠ **Caution:** Ensure that the fixation disk is sutured to the serosal surface. Failure to suture the fixation disk may result in lead migration. Additional surgery may be required to restore therapy.

⚠ **Caution:** Keep the suture needles clear of the lead. The lead can be damaged by a suture needle. A damaged lead must be removed and replaced.

5. Suture both holes on the lead's trumpet anchor to the serosal surface of the stomach. Ensure that the electrode is not exposed outside the muscle.

⚠ **Caution:** Ensure that the trumpet anchor is sutured to the serosal surface. Failure to suture the trumpet anchor may result in lead migration. Additional surgery may be required to restore therapy.

6. Cut the blue polypropylene monofilament, leaving approximately a 2.5 cm "tail" from the end of the electrode.

7. Repeat the procedure to implant the second lead, placing it 1.0 cm from the first lead. Refer to **Implanting the lead** on page 10 and **Anchoring the lead** on page 14.

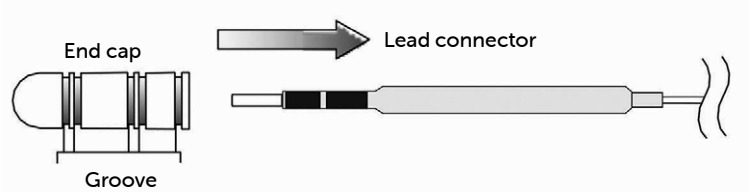
Using the lead end cap

Use a lead end cap to seal off the connector pin if a lead is being reserved for connection to a neurostimulator at a future date.

The end cap can be removed at a later date without damaging the lead. After the end cap is removed, the lead can be reconnected to a neurostimulator.

1. Insert the end cap securely over the lead connector pin (Figure 5). Only sterile water may be used to facilitate this application; no adhesives are necessary.

Figure 5. Insert end cap over lead.



2. Tie a non-absorbable, synthetic ligature in each end cap groove.

⚠ **Caution:** Do not secure the ligature so tightly that it damages the end cap and the lead. If the end cap or lead is damaged it may require the surgical removal of the lead.

Refer to the neurostimulator implant manual for instructions on creating a pocket for the neurostimulator, connecting the lead to the neurostimulator, checking system integrity, and completing the implant procedure.

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