



Medtronic

Enterra® Therapy

Gastric Electrical Stimulation System

3116

Humanitarian Device: Authorized by Federal Law for use in 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.

Technical Manual

Rx Only

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System Description

The Medtronic Enterra Therapy Model 3116 Neurostimulator (implantable neurostimulator or INS) is a multiprogrammable device designed to deliver therapy through gastric electrical stimulation when connected to a lead system (Figure 1). These components comprise the implantable portion of the Medtronic Enterra Therapy system. The operation of the neurostimulator is supported by a clinician programmer.

The neurostimulator operates on a sealed battery and electronic circuitry to provide controlled electrical pulse stimulation, through the implanted lead system.

A wide range of noninvasively programmable parameters and stimulation modes are available. The neurostimulator provides current parameter information, via telemetry, when used with the clinician programmer.

For a complete list of model numbers and components compatible with the Enterra Therapy Model 3116 Neurostimulator, refer to the system components sheet.

Note: The terms *neurostimulator* and *INS (implantable neurostimulator)* are used interchangeably in this manual.

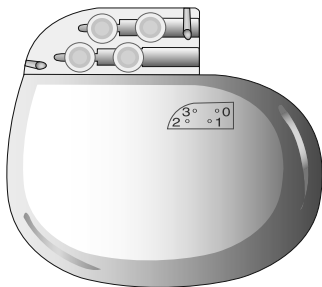


Figure 1. Neurostimulator.

Contents of Package

The Enterra Therapy Model 3116 Neurostimulator packaging contains the following:

- One Enterra Therapy Model 3116 Neurostimulator
- One hex wrench
- Product literature

Indications

The Medtronic Model 3116 Neurostimulator is part of an Enterra Therapy system for gastric electrical stimulation (GES). The system is indicated for 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.

Contraindications

The Enterra Therapy system is contraindicated in patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

After implantation of any system component, the following contraindication applies:

Diathermy – Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned “on” or “off.” Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.

Warnings

Electromagnetic Interference (EMI)

Electromagnetic interference is a field of energy (electric, magnetic, or a combination of both) generated by equipment found in the home, work, medical or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, strong sources of electromagnetic interference can result in the following:

- **Serious injury or death**, resulting from heating of the implanted neurostimulation system components, which can damage surrounding tissue.
- **System damage**, requiring surgical replacement or result in a loss of or change in symptom control.
- **Operational changes to the neurostimulator**, causing it to switch ON or OFF (particularly in neurostimulators enabled for magnet use), or to reset to

default factory settings which may result in loss of stimulation, return of symptoms, and require reprogramming by the physician.

Refer to Table 1 on page 7, and “Appendix A, Information on Electromagnetic Interference” on page 31, for information on sources of electromagnetic interference, their effect on the patient and the neurostimulation system, and instructions on how to lessen the risk from electromagnetic interference.

Table 1. Potential Effects of Interactions from Devices or Procedures

Risk^a	Device / Procedure	Serious Injury	Damage Device	Turn OFF/ ON	For Guidelines
High	Theft detector			X	page 32
	Magnetic resonance imaging (MRI)	X	X	X	page 35
	Defibrillation / cardioversion, external	X	X		page 34
	Diathermy, therapeutic	X	X		page 6
	Electrocautery	X	X		page 34
	Radio frequency (RF) / microwave ablation	X	X		page 35
	Therapeutic ultrasound	X	X		page 6
Medium	Electrolysis		X		page 34
	Hyperbaric chamber therapy		X		page 12
	High-output ultrasonics / lithotripsy		X		page 35
	Radiation therapy		X		page 34
	Bone growth stimulator			X	page 33
	X-ray procedures requiring tight enclosure		X		page 34
	Electromagnetic field devices: (e.g., arc welding, power stations)			X	page 31
	Psychotherapeutic procedures		X	X	page 35

Table 1. Potential Effects of Interactions from Devices or Procedures (continued)

Risk ^a	Device / Procedure	Serious Injury	Damage Device	Turn OFF/ ON	For Guidelines
Low	General household: freezer, refrigerator, storm door magnets, telephone handsets, cellular phones, CB or HAM radios, stereo speakers and radios for home or car, sewing machines, salon hair dryer, induction range, power tools			X	page 31
	Externally applied stimulation (TENS unit, muscle stimulation)			X	page 34
	Therapeutic magnets			X	page 33

^a **High:** the device and/or procedure a) may be encountered daily and could have significant effects on the patient, the system, and/or the therapy; or b) is seldom encountered but effects to the patient can be harmful. **Medium:** the device and/or procedure may be encountered occasionally and the effects could turn OFF the therapy, or damage the system, or both. **Low:** the device and/or procedure may be encountered daily (or is seldom encountered) and the effects to the patient are minimal.

Interaction with other Implantable Devices – When another implantable device (e.g., pacemakers, defibrillators, or cochlear implants) is required, the physicians involved in both therapies should discuss the possible interaction between the devices. Electrical impulses from the neurostimulation system may affect the sensing operation and cause inappropriate device response of other implanted devices. Careful programming of each system may optimize the benefit from each device. Follow these suggested guidelines:

- The neurostimulator should be placed on the opposite side of the body from the other implanted device.
- The neurostimulator should be reprogrammed to bipolar stimulation
- Each system should be checked to ensure that it is working as intended.

Case Damage – If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Component Compatibility – Use only Medtronic components that are compatible with this system. For a list of Medtronic compatible components refer to the system component sheet. The use of non-Medtronic components with this stimulation system can result in damage to Medtronic components, loss of therapy, or patient injury.

Age Limitations – The safety and effectiveness of this therapy has not been established for patients under the age of 18 or over the age of 70.

Allergic Reaction – There is the possibility of an allergic or immune system response to the implanted materials.

Anticoagulation Therapy – Patients on anticoagulation therapies may be at a greater risk for post-operative complications, such as hematomas.

Pregnancy – Safety for use during pregnancy or delivery has not been established.

Infection – It is recommended that the neurostimulator implant site be irrigated with antibiotic solution during surgery and that IV antibiotics be administered perioperatively. When possible, identify and treat any infections remote to the implant site prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system.

Bowel obstruction/perforation – The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Either may lead to life-threatening intra-abdominal infections and may require laparotomy, bowel resection, and system revision. Avoid excess lead slack in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms.

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. Post implant, consider gastric perforation as a possible etiology for patients exhibiting these symptoms.

Precautions

Physician Training

Implanting Physician – Implanting physicians should have experience in the surgical and/or implantation techniques for the Enterra Therapy system, operational and functional characteristics of the Enterra Therapy system, and experience in the continued management of patients by stimulation parameter adjustment. Physicians may contact Medtronic before prescribing or implanting an Enterra Therapy System for the first time and request a referral to a physician experienced in the use of Enterra Therapy.

Prescribing Physician – Prescribing physicians should have expertise in the medical treatment of patients with gastric disorders. All system programming should be done by or under the supervision of a physician or other experienced medical personnel familiar with the use of the programming software and equipment. Physicians should be thoroughly familiar with appropriate supporting material, including, all product labeling and education and training materials.

Storage and Sterilization

Component Disposal – Follow these guidelines for proper component disposal:

- Do not incinerate the neurostimulator because it can explode if subjected to cremation or incineration temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal. Do not autoclave an explanted neurostimulator prior to returning.

Component Packaging – Do not implant a component under the following circumstances:

- When the storage package has been pierced or altered;
- The component shows signs of damage;
- The Use By date has expired (because this can adversely affect storage package sterility and battery longevity); or
- In the case of a neurostimulator only, it is dropped more than 12 in (30 cm).

Single Use Only – All components and accessories of this system are intended for Single Use Only. DO NOT REUSE.

Sterilization – Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Storage Temperature – Do not store or transport the neurostimulator above 125° F (52° C) or below 0° F (-18° C). Temperatures outside of this range can damage components.

System Implant

Component Handling – Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by mishandling, excessive traction, or sharp instruments, which may result in loss of stimulation, component failure, and/or require surgical replacement. The following practices will help ensure component life:

- Do not implant a neurostimulator if it has been dropped onto a hard surface from a height of 12 in (30 cm) or more.
- Do not immerse the lead in mineral oil, silicone oil, or any other equivalent.
- 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.
- Do not implant a lead that was dropped; the lead may no longer be sterile.
- 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 tie a suture directly to the lead body, because the suture could cut through the lead insulation. Use the anchor on the lead and the fixation disks, which are supplied with the lead kit. Do not overtighten sutures to avoid damage to the anchor or fixation disk.
 - Do not use a hemostat on the lead body.

- If handling the lead with forceps, use only rubber-tipped bayonet forceps.
- 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.
- 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.

Refer to the appropriate technical manual for additional instructions.

Component Failures – The neurostimulation system may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical shorts or open circuits, conductor (wire) fractures, and insulation breaches, cannot be predicted.

Connection Contamination – Wipe off any body fluids from the connector pins, connector block, or lead contacts of the component before making connections. Contamination of connections can adversely affect neurostimulation.

Excess Wire – Do not place any excess wire on top of the neurostimulator's front side. Wrap any excess wire around the perimeter of the neurostimulator (Figure 2). This action avoids any increase in the subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the wire.

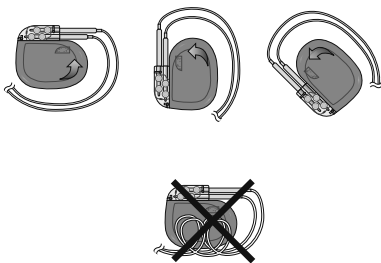


Figure 2. Wrap excess wire around the perimeter of the neurostimulator.

Tunneling – When approaching the neurostimulator pocket, proceed slowly to avoid additional trauma to the patient when resistance to tunneling suddenly ceases.

Neurostimulator Implant Location – Follow these guidelines when implanting the neurostimulator:

- Place the neurostimulator away from bony structures to minimize pain at the neurostimulator site.

- Place the neurostimulator with the etched identification side facing outward, away from muscle tissue to minimize the possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.
- It is advisable to minimize the length of the implanted lead. Long leads increase the susceptibility of the system to effects from electromagnetic interference.
- Place the neurostimulator in a location that is cosmetically acceptable to the patient and away from areas of friction from clothing.

Inadvertent Programming – To prevent inadvertent programming or interference with other implanted devices, follow these guidelines:

- If more than one neurostimulator is implanted, then the potential for unintentional programming changes to the other neurostimulator exists. If two neurostimulators are implanted, they must be implanted at least 20 cm (8 in) apart to minimize interference. Verify final programmed parameters by reviewing both devices at the conclusion of any programming session.

Diagnostic Ultrasound (e.g., carotid scan, doppler studies) – An implanted neurostimulation system is unlikely to interfere with diagnostic ultrasound. To minimize potential image distortion, turn OFF the neurostimulator and keep the transducer 15 cm (6 in) away from the neurostimulation system.

Patient Activities

Activities Requiring Excessive Twisting or Stretching – Patients should avoid activities that may put undue stress on the implanted components of the system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement can result in a cessation of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition a component.

Component Manipulation by Patient (Twiddler's Syndrome) – Patients should avoid manipulating or rubbing the neurostimulator system components (e.g., neurostimulator or lead), which can cause component damage, skin erosion, or stimulation at the implant site.

Scuba Diving or Hyperbaric Chambers – Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) or 202.8 kPa (29.4 pounds per square inch absolute). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

Individualization of Treatment

Patient Detoxification – It is recommended that patients undergo detoxification from narcotics prior to implant so that the effects of stimulation can be properly assessed.

Patient Management – Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedures, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management of patients.

Patient Selection – Select patients carefully to assure that their symptoms are of physiological origin and they are appropriate candidates for surgery.

Adverse Events Summary

In addition to those risks associated with surgery, implantation or use of a neurostimulation system includes, but is not limited to, the following risks, which may necessitate reprogramming, medical treatment, or additional surgery.

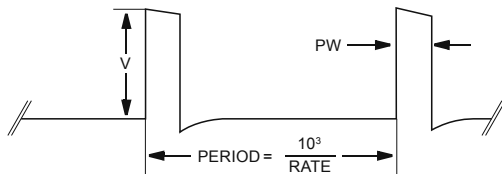
- Lead impedance out of range
- Undesirable change in stimulation (described as a shocking, jolting, or tingling sensation), possibly related to cellular charges around the electrodes, shifts in electrode position, loose electrical connections, or lead fractures
- Loss of therapeutic effect
- Neurostimulator system ceases to function due to battery depletion, telemetry issues, or other causes
- Lead or neurostimulator erosion or migration
- Bowel obstruction, perforation, ileus, or necrosis
- Infections, including device/implant site infections, intra-abdominal infections, abscess, peritonitis, sepsis, urinary tract infections
- Stomach wall perforation
- Upper gastro-intestinal (GI) symptoms including nausea, vomiting, abdominal pain, discomfort, distention, or increased severity of gastroparesis symptoms
- Lower gastrointestinal (GI) symptoms including diarrhea and constipation
- Hemorrhage, hematoma, and possible GI complications resulting from the surgical procedure to implant the neurostimulator and leads
- Persistent pain at the neurostimulator site
- Extra-abdominal pain, bone- and joint-related pain
- Seroma at the neurostimulator site
- Allergic or immune system response to implanted materials
- Stress incontinence
- Fever
- Feeding tube complications
- Dehydration
- Dysphagia
- Acute diabetic complications

- Cardiovascular renal related events

Refer to the lead implant manual for information about the clinical studies of the Enterra Therapy System and the adverse events observed during the clinical studies.

Clinician Programmer

The clinician programmer is used to program the stimulation parameters by means of telemetry (refer to the system components sheet for compatible programmers and neurostimulators). The clinician programmer controls various parameters and stimulation modes. Some of the parameters are graphically displayed in the pulse waveform (Figure 3). Special features of the clinician programmer include “nominal” parameter programming to quickly and automatically program a neurostimulator to a set of nominal values (Table 2). The display provides instruction “prompts” and show parameter data. A hard-copy printout can also be produced during a programming sequence. Neurostimulator internal counters automatically monitor items such as total therapy time and total number of output activations.



V = Voltage (V)

PW = Pulse Width (msec)

Period = Time between two successive pulses in ms

Rate = Pulses per second (Hz)

Figure 3. Pulse waveform.

Table 2. Model 3116 Neurostimulator Nominal Parameter Settings.^a

Parameter	Value
Voltage	Based on system impedance measurement and current setting of 5mA.
Rate	14 pps
Pulse width	330 μ sec

Table 2. Model 3116 Neurostimulator Nominal Parameter Settings.^a

Parameter	Value
Output on/off	Off
Mode	Cycling: On 0.1 sec Off 5.0 sec
Magnet function	Disabled
Electrode polarity	0 = Off 1 = Off 2 = Negative 3 = Positive Case = Off

^a Parameter settings for the neurostimulator are based on settings used in Medtronic-sponsored clinical studies. For more information, refer to the clinical studies section in the *Model 4351 Lead Implant Manual*.



Caution: Due to the potential for uncomfortable stimulation (which some patients have described as a jolting, shocking, or burning sensation), do the following:

- Take care when increasing the stimulation parameters to optimize or improve the therapeutic effect due to the potential for uncomfortable stimulation effects. Uncomfortable stimulation has been reported in neurostimulator settings at or above the typical settings.
- Following changes in stimulation parameters, direct patients to test various postural changes and movements that mimic daily activities to assess the potential for uncomfortable stimulation.
- If uncomfortable stimulation occurs, reduce the stimulation output to previously acceptable levels and adjust stimulation in smaller increments.
- Adverse effects related to stimulation parameter changes may not manifest immediately following parameter changes; direct patients to contact their clinician if they feel discomfort related to their stimulation.

For patients who live or work in electrically noisy environments, random on/off switching may be a problem. To avoid on/off switching, disable the magnet control circuitry with a command to the neurostimulator from the clinician programmer. Detailed instructions on disabling this feature are provided in the programming guide packaged with the application software.

Note: The Enterra Therapy Model 3116 Neurostimulator is shipped with the magnet function Disabled.

Telemetry Data

The Enterra Therapy Model 3116 Neurostimulator is capable of providing telemetered data transmissions when properly interrogated by the clinician programmer.

Upon interrogation, the neurostimulator transmits the following to the clinician programmer for display or printing, via a radio-frequency (RF) link:

- Model and serial number identification
- Programmed parameters and values
- Neurostimulator battery status
- Hours Used (since last reset)
- Last Reset
- Verification of program changes

Only the clinician programmer can receive and display or print complete telemetered data from the neurostimulator.

For a complete description of programming functions, refer to the programming guide packaged with the application software. Programmers made by other manufacturers are not compatible with the Enterra Therapy Model 3116 Neurostimulator.

Neurostimulator Counters

Hours Used – The total therapy time is the amount of time the neurostimulator output is enabled and the voltage is above zero volts, since last resetting the counter. It is a cumulative total with a counter capacity of 8,192 hours, or approximately one year. If cycling is programmed, the off cycle is included in the total therapy time.

Last Reset – The elapsed time is the amount of total time since last resetting the counters. The capacity of this counter is 8,192 hours, or approximately one year.

Counter Reset – All of the counters can be reset by using the clinician programmer.

Electrode Programming Configurations

The neurostimulation system offers two types of configurations: unipolar (neurostimulator case positive, lead electrode(s) negative) and bipolar (neurostimulator case off, one or more lead electrodes positive and one or more lead electrodes negative).

Four electrical connections are possible in the neurostimulator connector block which have corresponding parameters for electrode polarity in the software. Regardless of the device(s) that is connected, the software always displays four parameters.

Two leads are connected to the neurostimulator. The neurostimulator can be configured in the unipolar configuration (two leads connected, one used) or bipolar configuration (two leads connected, both used).

Each lead makes one electrical connection within the connector block and only one software parameter is programmed for each lead.

Some of the advantages and disadvantages of the configurations are discussed below. When selecting the configuration, check the impact on battery life. For more information on battery longevity, refer to “Battery Longevity Estimator” on page 29. For more information on the leads refer to the technical manual packaged with the product.



Warning: Use only leads that are compatible with the output capabilities of the neurostimulator. Refer to the technical manual packaged with the lead kits.

Unipolar Configurations – In a unipolar configuration, one or more lead electrodes are negative and the neurostimulator case is positive.

Bipolar Configurations – In a bipolar configuration, at least one lead electrode is positive and at least one lead electrode is negative, with the neurostimulator case Off. Bipolar configurations are better for use in an electrically noisy environment. Also, if one or more of the electrodes in a bipolar configuration is damaged, reprogramming the system to a unipolar configuration may allow continued stimulation.

Note: Activating multiple electrodes in either **unipolar or bipolar configurations** spreads the stimulation over a greater area, but may reduce the battery life. Activate multiple electrodes only after other electrode combinations have been tried. However, check the effect on battery life. For more information on battery longevity, refer to “Battery Longevity Estimator” on page 29.

Neurostimulator Implantation or Replacement

This section outlines the suggested procedure for implanting or replacing the neurostimulator. Detailed instructions for implanting the leads and programming the neurostimulator are contained in the lead implant manual.

Implanting a New Neurostimulator

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the abdomen.



Warnings:

- Do not implant the neurostimulator near other implanted devices. Place the neurostimulator on the opposite side of the body from other implanted devices. Electrical impulses from the neurostimulation system may affect the sensing operation and cause inappropriate device response of other implanted devices.
- It is recommended that the neurostimulator implant site be irrigated with antibiotic solution during surgery and that IV antibiotics be administered perioperatively. When possible, identify and treat any infections remote to the implant site prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system.

Notes:

- Placement below the ribs and above the hip bone provides a comfortable location for most patients.
 - To ensure proper programming, the neurostimulator should be located no more than 4 cm beneath the surface of the skin in subcutaneous tissue. The device must be placed parallel to the skin surface. The etched Medtronic logo and Enterra trademark side of the neurostimulator must face away from muscle tissue. If another neurostimulator is already implanted, ensure at least 20 cm between the two neurostimulators.
 - Do not presoak the neurostimulator. The neurostimulator is provided sterile and does not require any soaking in antibiotic solution, which can possibly affect lead connections.
2. Place the neurostimulator into the pocket to insure proper fit, and then remove it.
 3. If necessary (eg, during laparotomy), use the tunneling rod (provided in the lead package) to pass the leads subcutaneously to the pocket. Using the tunneling rod helps prevent sharp angle bends of the lead body.
 - a. Attach the connector end of each lead to the tunneling rod by inserting the connector pin into the small opening of the tunneler.
 - b. Pass the tunneling rod through the fascia to the pocket (create a separate tunnel for each lead).
 - c. Do not pull the lead taut; allow just enough slack to minimize component stress, tension, or migration, and allow for patient movement and for physiological movement of the stomach and other abdominal organs.



Warning: The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Either may lead to life-threatening intra-abdominal infections and may require laparotomy, bowel resection, and system revision. Avoid excess lead slack in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms

- d. To remove the lead from the tunneler, gently pull and twist off.
- e. Check that the lead connector pins and connector bodies are free of body fluids or tissue before connecting it to the neurostimulator.

Connecting to the Neurostimulator

1. Prepare the neurostimulator block for connection to the lead by temporarily inserting the lead connectors.
 - a. Wipe off any body fluids or tissue from the lead connector pins and the connector block before inserting the pins into the sockets.
 - b. Insert the connector pins into the neurostimulator sockets (Figure 4).
The connector pins must slide into the neurostimulator sockets until fully seated.

Note: If inserting the lead pins is still difficult, use sterile water as a lubricant.

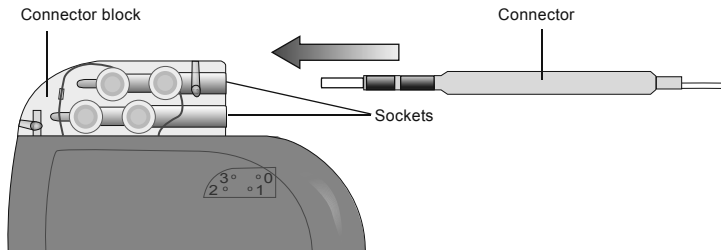


Figure 4. Insert connector pins into neurostimulator socket.

- c. If a setscrew obstructs the socket, back out the setscrew (Figure 5) only until the connector pin can slide in without force and then retighten.



Caution: Limit counterclockwise rotations of the setscrew. Rotate it enough to provide an unobstructed pathway for the connector pins. Too many rotations may disengage the setscrew from the neurostimulator connector block.

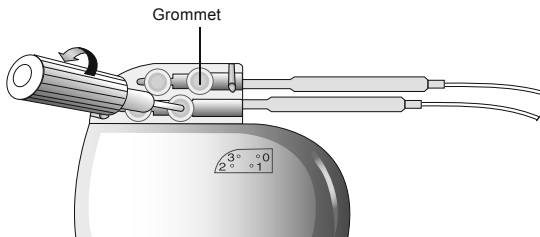


Figure 5. If needed, insert hex wrench in silicone rubber grommet and turn setscrew counterclockwise to back out setscrew.

2. When the lead connector pins are fully inserted in the neurostimulator sockets, do the following for each of the four setscrews:
 - a. Insert the hex wrench through the rubber grommet to engage the setscrew.
 - b. Tighten the setscrew by turning the hex wrench clockwise until resistance is felt (Figure 6).
 - c. Continue tightening for a **maximum of 1/4 turn**. The setscrews must touch the connector pins for proper electrical connection.

Note: Check the system impedance before placing the neurostimulator into the subcutaneous pocket.

Cautions:

- Discard the hex wrench after making all of the connections. The hex wrench is a single-use-only item. Its operation cannot be assured if it is used for multiple surgeries.
- Do not overtighten the setscrews or permanent damage to the setscrews and/or sockets could result.
- Verify that each leaf of the self-sealing grommet is closed after the hex wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.

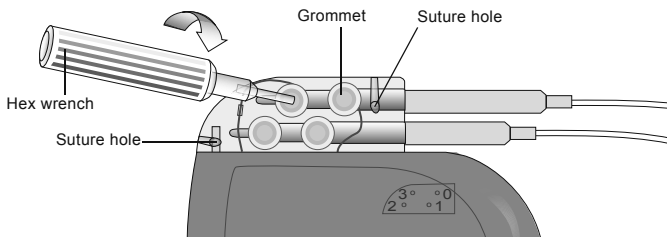


Figure 6. Insert hex wrench and tighten all four setscrews.

3. Place the neurostimulator into the subcutaneous pocket (Figure 7) with the etched Medtronic logo side facing away from muscle tissue. Position the neurostimulator so that no sharp bends occur along the lead (Figure 8).



Caution: Place the neurostimulator away from bony structures with the etched Medtronic logo and Enterra trademark side facing out toward the skin and away from the muscle tissue to minimize the possibility of skeletal muscle stimulation, which may be perceived as twitching or burning.

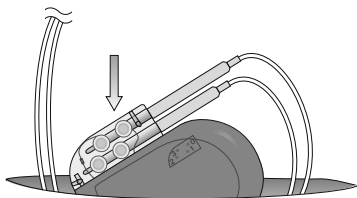


Figure 7. Place neurostimulator into subcutaneous pocket.



Caution: Do not loop or coil the wire on top of the neurostimulator's Medtronic logo side. Loosely wrap any excess wire around the perimeter of the neurostimulator (Figure 8). This avoids any increase in the subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of the wire.

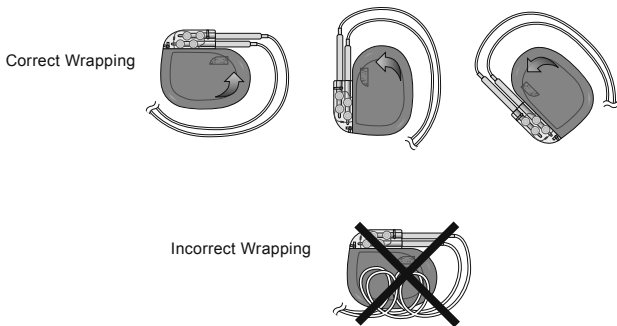


Figure 8. *Wrap excess length around perimeter of neurostimulator.*

4. Secure the neurostimulator in the subcutaneous pocket using both suture holes in the connector block.



Caution: Failure to secure the neurostimulator using both suture holes may increase the risk of device migration or rotation, which can cause component damage, skin erosion, unintended stimulation effects, or lead dislodgement.

5. Before closing the pocket, program the neurostimulator and check impedance according to the programming instructions in the lead implant manual.



Caution: A measured impedance outside the normal 200 to 800 ohm range may indicate that the electrical integrity of the Enterra Therapy System is compromised and should be investigated before closing the pocket.

6. Verify that the neurostimulator is secured in the subcutaneous pocket using both suture holes in the connector block.
7. Close and dress the incision.
8. Check the Enterra Therapy System impedance after the incision is closed, but before the patient leaves the operating room. This procedure is to verify electrical continuity between the leads and the neurostimulator.
9. Verify and document lead and neurostimulator locations by obtaining lateral and anterior-posterior x-rays of the abdominal region up to 48 hours after the implantation procedure.

Note: Based on your medical judgement, you may program the neurostimulator ON at this time, or wait until a later time.

10. Complete and mail the implant registration form to Medtronic (refer to “Patient Registration” on page 23).
11. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator battery and to confirm that the programmed parameter values are appropriate.

Replacing the Neurostimulator

1. Open the neurostimulator implant site using normal surgical procedure, and carefully remove the neurostimulator from the subcutaneous pocket.
2. Clean the neurostimulator and connector pins with sterile water; wipe both dry with surgical sponges.
3. Insert a hex wrench through the pre-pierced hole in the rubber sealing grommet, and loosen the setscrew by turning it counterclockwise.
4. Gently retract the connector pins from the neurostimulator connector block. If the connector pins show any signs of pitting or other corrosion, consider replacing the lead system. Clean and dry the pins and body — they must be free of fluids or tissue.
5. Set aside the explanted components for return to Medtronic.
6. Connect the lead system and replacement neurostimulator according to the steps in “Connecting to the Neurostimulator” on page 19.
7. Return the explanted neurostimulator to Medtronic for disposal (refer to “Explant and Disposal” on page 23).

Explant and Disposal

Please return explanted devices to Medtronic for analysis and disposal. When returning a product, please include an explanation for the explant on the *Returned Product Information Report*, packaged with the self-addressed mailer kits provided by Medtronic.

Return explanted products to:

Medtronic Inc.
Neurological Division
MSN600
PO Box 1250
Minneapolis, MN 55440-9087

Note: Self-addressed mailer kits are available from Medtronic sales representatives.

Patient Registration

Inside the shipping container for each neurostimulator is an implant registration form that is used to create a permanent record of your patient’s implant. It is important that you complete the form and promptly return the original to Medtronic. Two copies are provided for the patient’s medical records.

Medtronic transfers the information from the form to a wallet-sized, plastic-coated identification card, which is mailed directly to the patient. A temporary identification card is packaged with the neurostimulator for the patient's use until the permanent card arrives.

In addition to use in creating the patient identification card, the information on the form registers the device warranties and creates a record of the implant in Medtronic's implant data system.

Physician Instructions to Patient

It is suggested that you give the patient information concerning the Medtronic Enterra Therapy system. This should include information on the implanted neurostimulator, and the lead system. Patients should also be informed about the warnings, precautions, and adverse effects as described in this manual. Patients should be provided with a copy of the Enterra Therapy Patient Manual.

In general it is suggested that patients be instructed to:

- Avoid physical activities that may damage the implant site or implanted device.
- Consult his or her physician if they notice any unusual symptoms or signs.
- Inform health-care professionals, such as physicians and dentists, that they have an implanted neurostimulation system.

Note: Additional safety information about diathermy is located in "Contraindications" on page 6.

- Carry their Medtronic patient identification card at all times.

Specifications and Features

The Medtronic Model 3116 Neurostimulator is powered by a hermetically sealed lithium-thionyl chloride single-cell battery. To further protect the neurostimulator components from body fluids, the electronics and power source are hermetically sealed within an oval-shaped titanium shield.

The neurostimulator case has an external insulating coating to prevent skeletal muscle stimulation at the neurostimulator implant site. An uninsulated area on one side of the neurostimulator (etched identification side) forms the indifferent electrode. The uninsulated side should be positioned away from muscle tissue.

The neurostimulator has a self-sealing connector assembly with a corrosion-resistant titanium alloy body and titanium setscrews. Securing the lead system requires the use of a hex wrench which is packaged with the neurostimulator.

Other features of the Model 3116 Neurostimulator include an inherent rate limit circuit to protect against accidental high rate stimulation, two suture holes to allow you to secure the neurostimulator within the subcutaneous pocket, and a radiopaque identification symbol.

Refer to Table 3 for a list of neurostimulator parameter operating ranges. Table 4 provides the factory-set values when the neurostimulator is shipped. The neurostimulator physical description is provided in Table 5. Table 6 lists the implanted neurostimulator materials.

Table 3. Model 3116 Neurostimulator Operating Ranges.

Programmable Parameters	Values^a
Voltage (peak voltage)	0 to 10.5 V (0.1 V steps)
Pulse width	60 to 450 μ sec in 30 μ sec steps
Rate	49 values from 2.1 to 130 pps (Hz)
Cycle On time	0.1 to 0.9 sec in 0.1 sec steps 1 to 59 sec in 1 sec steps 1 to 29 min in 1 min steps 0.5 to 24 hr. in 0.5 hr. steps
Cycle Off time	0.1 to 0.9 sec in 0.1 sec steps 1 to 59 sec in 1 sec steps 1 to 29 min in 1 min steps 0.5 to 24 hr. in 0.5 hr. steps
Electrode polarity	0, 1, 2, 3 electrodes: off, negative, or positive; Case: off or positive
Magnet function	on or off

^a All values are approximate.

Table 4. Model 3116 Neurostimulator Values When Shipped.

Parameter	Value
Voltage	0 V
Pulse Width	330 μ sec
Rate	14 pps (Hz)
Output On/Off	Off ^a
Mode	Cycling: On 0.1 sec Off 5.0 sec
Magnet Function	Disabled
Electrode Polarity	0 = Off 1 = Off 2 = Negative 3 = Positive Case = Off
Battery Characteristics	
Initial voltage	3.7 V
Stoichiometric capacity	3.275 Ah
Maximum available capacity	3.0 Ah
Deliverable capacity ^b	2.7 Ah
Remaining battery capacity at low battery status	0.1 Ah

^a **Note:** Exposure to a strong source of electromagnetic interference (EMI) can cause the output switch to toggle to the on position. However, since the Voltage setting is 0.0 V, there is no neurostimulator output.

^b Deliverable capacity is projected to be 90% of the maximum available capacity.

Table 5. Model 3116 Neurostimulator Physical Description.

Description	Value
Height	2.2 in. (55 mm)
Length	2.4 in. (60 mm)
Thickness	0.4 in. (10 mm)
Weight	1.5 oz. (42 g)
Volume	1.5 in³ (25 cm³)
External shield	Titanium
Power source	3.7-V, Lithium-thionyl chloride cell
Storage temperature	-0° F to 125° F (-18° C to 52° C)

Table 6. Model 3116 Neurostimulator Materials.

Structure	Materials
Case	Titanium
Connector	Urethane
Grommets, seals	Silicone rubber
Setscrews	Titanium^a
Insulation coating	Polymeric insulating film
Adhesive	Silicone adhesive

^a **Note:** The Medtronic Model 3116 Neurostimulator has an insulation coating to prevent undesirable muscle stimulation. The uninsulated side with the etched identification should be positioned away from the muscle.

Measurement Functions

The measurement features of the neurostimulator include the neurostimulator battery status, capacity, longevity estimate, current drain, and load impedance check. These measurements are intended to aid your clinical observations. If, however, you obtain a reading that is not consistent with your other observations, it is recommended that you repeat the measurement. It is also recommended you use clinical judgment when interpreting any measurement.

As with any electronic system, internal and external factors can influence the neurostimulator measurements. For example, changes in the lead's position can affect the current or the load impedance measurement. And under some conditions, such as low voltages or narrow pulse widths, the circuit accuracy may be less than optimal. For example, at lower parameter settings, the neurostimulator accuracy for longevity, current, and load impedance may vary by $\pm 30\%$. Similarly, the repeatability of a measurement can vary by the same percentage. In general, better accuracies can be obtained at higher voltage and/or pulse width settings.

Battery Status Indicators

The Medtronic clinician programmer allows you to monitor your patient's neurostimulator battery status. The clinician programmer provides voltage and current measurements. For example, as the neurostimulator battery depletes, the telemetry readout will show **LOW** on the programmer display. When this occurs, the remaining battery life ranges from a few days to a few months, depending on the patient's therapy. The higher the battery current drain, the shorter the remaining battery life. As the battery voltage further decreases, the programmer shows the battery status as **EOL** (End-of-Life) on the display. After the neurostimulator battery has been depleted, telemetry is no longer possible.

In addition to the neurostimulator battery status, the clinician programmer can measure the battery current drain (μA).

The battery current drain measurement and its complementary load impedance measurement should be checked periodically. For example, battery longevity can be optimized by comparing battery current drains from your patient's various therapy combinations — the lowest setting can then be selected.

Also, it is recommended that battery current drain and load impedance measurements be taken after every programming session with your patient. This historical information can be valuable at a later time if a malfunction develops. The measurements can be used to troubleshoot and isolate the problem.

For example, measurements that show a significant reduction in battery current drain (or increase in load impedance) can indicate a fractured lead conductor, a loose setscrew, and so forth.

Conversely, a significant increase in battery current drain (or decrease in load impedance) can indicate shorted conductors, a break in lead insulation, and so forth. In either case, it is useful to know what the measured values were when the system was operating properly.

Battery Longevity Estimator

Use the battery longevity estimator to compare the effects on battery life for similarly efficacious stimulation settings for each patient at the time of implant. This feature is part of the software used with your clinician programmer. Instructions on using the battery longevity feature are contained in the programming guide packaged with the application software.

Use the battery life estimates from the clinician programmer as a general reference. The estimates cannot predict precise battery longevity for a particular patient because the actual usage and therapy settings (and thus battery life) are affected by the following:

- The reprogramming of therapy settings.
- Differences in tissue impedance from patient to patient or possibly over time.
- The battery life estimates are based on a new battery (i.e. a new implant). If the battery longevity estimator is used on a neurostimulator that has been on for some time, the estimator does not account for the usage.

The battery longevity estimator uses the currently programmed parameter values for your patient and then calculates how long the battery will last at those settings and with the specific patient's load impedance measurement. The estimation provides estimates in terms of months. You can try various parameter combinations to determine which settings are efficacious in treating your patient and optimizing battery life.

Use the battery longevity estimator on the clinician programmer or contact a therapy consultant for more information on the battery life.

Some general tips to increase battery life are listed below, however always use settings appropriate for effective stimulation:

- Use the lowest effective settings for voltage, rate, and pulse width.
- Use cycling mode instead of continuous and program with the shortest on time and longest off time that still provides effective stimulation.

Cautery Protection

Cautery protection is incorporated into the Enterra Therapy Model 3116 Neurostimulator. It enables the neurostimulator to return to normal function following electrosurgery. It is recommended that the electrical current path between the cautery tip electrode and the indifferent electrode be kept as far away from the neurostimulator/lead system as possible. The use of bipolar cautery is recommended.

Caution: Do not use an electrosurgical tip in close proximity (closer than 2 inches) to the neurostimulator or lead.

Power ON Reset

As a safety feature, if the neurostimulator is subjected to extreme electromagnetic stress (such as from cautery or defibrillation procedures), its parameters will automatically be reset. This is called power on reset (POR). It could be caused by use of an electrocautery tip near the neurostimulator, or by defibrillation. POR also can occur as the neurostimulator battery nears depletion. When the neurostimulator is removed from the interference source, the device must be reprogrammed to the desired settings. In addition, the serial number is lost and must be reprogrammed.

X-Ray Identification

Radiopaque identification permits the determination of manufacturer and neurostimulator model number (Figure 9). With standard x-ray procedures, the code appears as black characters on white background. The Medtronic symbol identifies Medtronic as the manufacturer. For the Enterra Therapy Model 3116 Neurostimulator, the designated letters are NHV.

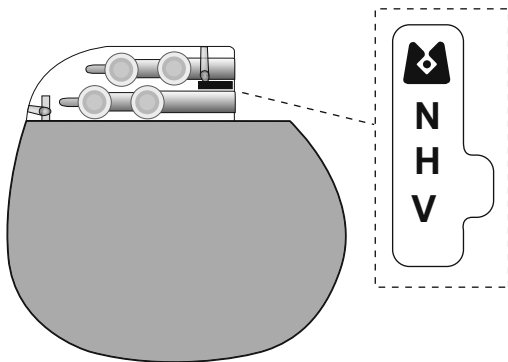


Figure 9. Radiopaque code block.

Appendix A, Information on Electromagnetic Interference

Please review the information on electromagnetic interference under “Warnings” on page 6. Refer to Table 1 on page 7 for the effects of electromagnetic interference on patients and neurostimulation system components.

Home, Public, and Occupational Environment

Most household appliances and equipment that are in good working order and properly grounded will not interfere with the neurostimulation system. Refer to Table 1 on page 7 for a list of items and the effects of electromagnetic interference. If patients suspect that equipment is interfering with neurostimulator function, they should do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Inform the equipment owner / operator of the occurrence.

If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy is not effective after exposure to EMI, they should contact their physician.

Generally Safe if precautions are followed:

- **Freezer, refrigerator, or storm door magnets that hold the door closed:** Do not lean against the magnetic strip of the door.
- **Radio Frequency Sources:** Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones, etc., should be kept at least 4 in (10 cm) away from the implanted neurostimulator.
- **Stereo speakers and radios for the home or car:** Do not lift or carry them so that they are close to or touching the part of your body where the neurostimulator is located.
- **Sewing machines or salon hair dryer:** Keep the neurostimulator away from the motors.
- **Computer disk drives:** If repairing or adding additional components to a computer, keep the neurostimulator away from the disk drives.
- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned on.
- **Power tools:** Keep the motor away from the neurostimulator and lead.

Exercise care or avoid the following equipment or environments:

- Antenna of citizen band (CB) radio or ham radio
- Electric arc welding equipment
- Resistance welders
- Electric induction heaters used in industry to bend plastic

- Electric steel furnaces
- High voltage (safe if outside the fenced area)
- Television and radio transmitting towers (safe if outside the fenced area)
- Microwave communication transmitters (safe if outside the fenced area)
- Linear power amplifiers
- High power amateur transmitters
- Perfusion systems
- Magnets or other equipment that generates strong magnetic fields
- Magnetic degaussers

Theft Detectors and Security Screening Devices

Patients should be advised to use care when approaching theft detector and security screening devices (such as those found in airports, libraries, and some department stores). When approaching these devices, patients should do the following:

1. If possible, request to bypass these devices. The patient should show the security personnel their patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but the patient should ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. The patient may wish to ask for another form of personal search.
2. If patients must pass through the theft detector or security screening device, they should approach the center of the device and walk through normally (Figure 10).
 - a. If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
 - b. If one gate is present, they should walk as far away as possible from it.

Note: Some theft detectors may not be visible.
3. Proceed through the security device. Do not linger near or lean on the screening device.

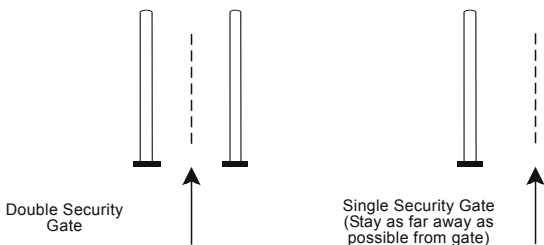


Figure 10. Approaching security gates.

Therapeutic Magnets – If a neurostimulator is enabled for magnet use, therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps, etc.), can inadvertently turn the neurostimulator ON or OFF. Advise patients to keep their therapeutic magnets at least 10 in (25 cm) away from their neurostimulator. Magnetic fields of 10 gauss or less will generally not affect the neurostimulator.

Medical and Hospital Environment

Patients should always inform any health care personnel that they have an implanted neurostimulation system.

Refer to Table 1 on page 7 for a list of items and the effects of electromagnetic interference.

Safe from Electromagnetic Interference

The following medical procedures are not likely to affect the implanted system:

- Computerized Axial Tomography (CT or CAT) Scans
- Diagnostic X-rays / Fluoroscopy
- **Note:** Tight pressure can affect the system. Refer to “X-rays Requiring Tight Enclosure” on page 34.
- Magnetoencephalography (MEG)
- Positron Emission Tomography (PET) Scans

Precautions Required

The following medical procedures are unlikely to affect the implanted system if the guidelines provided below are followed:

Bone Growth Stimulators – Keep external magnetic field bone growth stimulator coils 18 in (45 cm) away from the neurostimulator / lead system. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and neurostimulator are working as intended.

Dental Drills and Ultrasonic Probes – Turn OFF the neurostimulator. Keep the drill or probe 6 in (15 cm) away from the neurostimulator.

Electrolysis – Turn OFF the neurostimulator, and keep the electrolysis wand at least 6 in (15 cm) away from the neurostimulator.

Laser Procedures – Turn off the neurostimulator, and keep the laser directed away from the neurostimulation system.

Radiation Therapy – Do not direct high radiation sources such as cobalt 60 or gamma radiation at the neurostimulation system. If radiation therapy is required in the vicinity of the neurostimulation system, place lead shielding over the device to prevent radiation damage.

TENS (Transcutaneous External Neurostimulator) – Do not place TENS electrodes so that the TENS current passes over any part of the neurostimulator / lead system. If the patient feels that the TENS unit may be interfering with the implantable neurostimulator, the patient should talk with their doctor.

X-rays Requiring Tight Enclosure – Pressing the neurostimulator too tightly during X-ray procedures that require enclosure of the implant area may damage the neurostimulator or disconnect the neurostimulation system components, which may require surgery to fix the system or replace components. Adjust the X-ray equipment to limit the amount of pressure exerted on the neurostimulator during procedures that require enclosure of the implant area.

Unsafe or Special Precautions

The following medical procedures can damage the device, interfere with device operation, or cause harm to the patient. If these procedures are required, follow the guidelines below:

Defibrillation / Cardioversion – When a patient is in ventricular or atrial fibrillation, the first consideration should be patient survival. External defibrillation or cardioversion can damage a neurostimulation system. It is recommended not to use defibrillation or cardioversion paddles near the neurostimulator. When external defibrillation or cardioversion is necessary, minimize the current flowing through the neurostimulator and lead system as follows:

- Position paddles as far from the neurostimulator as possible.
- Position paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Neurostimulation system function should be confirmed after external defibrillation.

Defibrillation or cardioversion may also cause induced currents in the lead portion of the neurostimulation system that could be hazardous or cause further injury.

Diathermy – See “Contraindications” on page 6 of this manual.

Electrocautery – Electrocautery can damage the lead or neurostimulator. It can also cause temporary suppression of neurostimulator output and/or reprogram the neurostimulator to Power ON Reset parameters (output off, amplitude = 0V), which requires neurostimulator reprogramming. Electrocautery may also cause induced

currents in the lead portion of the neurostimulation system that could be hazardous or cause further injury.

Follow these precautions when using electrocautery:

- Turn off the neurostimulator before performing electrocautery.
- Do not contact the lead with the electrocautery device.
- Only bipolar cautery is recommended.
- If unipolar cautery is necessary:
 - Do not use high voltage modes.
 - Keep the power setting as low as possible.
 - Keep the current path (ground plate) as far away from the neurostimulator and lead as possible.
- Confirm the neurostimulator function after electrocauterization.

High-Output Ultrasonics / Lithotripsy – Use of high-output ultrasonic devices, such as electrohydraulic lithotripter, is not recommended for patients with an implanted neurostimulation system. If lithotripsy must be used, do not focus the beam within 6 inches (15 cm) of the neurostimulator.

Magnetic Resonance Imaging (MRI) – Patients with an implanted device should not be exposed to the electromagnetic fields produced by magnetic resonance imaging (MRI). Use of MRI may potentially result in **system failure**, dislodgement, heating, or induced voltages in the neurostimulator and/or lead. An induced voltage through the neurostimulator or lead may cause uncomfortable, “jolting,” or “shocking” levels of stimulation. Clinicians should carefully weigh the decision to use MRI in patients with an implanted neurostimulation system, and note the following:

- Magnetic and radio-frequency (RF) fields produced by MRI may change the neurostimulator settings and injure the patient.
- Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

Psychotherapeutic Procedures – The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) has not been established in patients with an implanted neurostimulation system.

Radiofrequency (RF) / Microwave Ablation – Safety has not been established for radiofrequency (RF) or microwave ablation in patients with an implanted neurostimulation system. Induced electrical currents from these procedures to the neurostimulation system may cause heating, especially at the lead electrode site, resulting in tissue damage.

Glossary

Cycle Time Off – In a cycling mode, the length of time between stimulation periods, that is, the time of the resting period.

Cycle Time On – In a cycling mode, the length of time that stimulation is delivered.

Interference – Anything that reduces the effectiveness of the neurostimulator, a programming transmission, or telemetry reception.

INS – Implantable neurostimulator. See neurostimulator.

Load Impedance – The combined load impedance of the leads and body tissue for an implanted neurostimulator system.

Mode – The type of stimulation delivery, either continuous or cycling on and off.

Neurostimulator – Implantable neurostimulator or INS. The device that generates the electrical impulses for the neurostimulation system.

Nominal Command Parameters – The settings programmed when the Nominal key on the clinician programmer is pressed.

Parameter – The output waveform conditions that can be varied to affect the type of stimulation for the patient (for example, voltage, pulse width, and rate).

Pulse Width – A measure, in microseconds (μsec), of the duration of each stimulating pulse.

Rate – A measure, in pulses-per-second (pps or Hz), that provides the number of times stimulating pulses are delivered each second.

Telemetry – A radio-frequency type of communication.

Voltage – A measure of the electrical intensity delivered in a stimulating pulse, measured in volts.

Special Notice

Medtronic Neurostimulator kits consist of a neurostimulator and tools to connect the neurostimulator to an implantable lead system. Neurostimulators are used with a lead system, which are implanted in the extremely hostile environment of the human body. Neurostimulators may fail to function for a variety of causes, including but not limited to, medical complications, body rejection phenomena, or component failure. In addition, neurostimulators and tools may be easily damaged by improper handling or use. For tools, Medtronic disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct incidental or consequential damages caused by any defect, failure or malfunction of any tool, whether a claim for such damage is based upon warranty, contract, tort or otherwise. No person has any authority to bind Medtronic to any representation or warranty with respect to tools.

Limited Warranty

Medtronic Neurological Neurostimulator Limited Warranty¹ (U.S. Customers Only)

- A. This Limited Warranty provides the following assurance to the patient who receives a Medtronic Enterra Therapy Model 3116 Neurological Neurostimulator hereafter referred to as neurostimulator:
- (1) Should the neurostimulator fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the date of implantation of the neurostimulator, Medtronic will at its option: (a) issue a credit to the purchaser of the replacement neurostimulator equal to the Purchase Price, as defined in Subsection A(3), against the purchase of any neurostimulator requested as its replacement, or, (b) provide a functionally comparable replacement neurostimulator at no charge.
 - (2) Battery cell depletion will occur with time and is not considered to be a defect in materials or workmanship. The batteries have a specified capacity which may deplete at different rates depending on settings and requirements for neurostimulation functions. Therefore, no representation is made that the neurostimulator will last the entire term of this Limited Warranty.
 - (3) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement neurostimulator.
- B. To qualify for this Limited Warranty, these conditions must be met:
- (1) The neurostimulator must be implanted prior to its "USE BY" date in conjunction with Medtronic leads or leads of equal quality and comparable electrical characteristics.
 - (2) All device registration materials must be completed and returned to Medtronic within thirty (30) days of implantation of the neurostimulator.
 - (3) Replaced neurostimulators must be returned to Medtronic within thirty (30) days of explantation and shall be the property of Medtronic.
- C. This Limited Warranty is limited to its express terms. In particular:
- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE NEUROSTIMULATOR TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

¹ This Limited Warranty is provided by Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432-5604 USA. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

- (2) This Limited Warranty is made only to the patient in whom the neurostimulator was implanted. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.



Medtronic

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

www.medtronic.com

Tel. 1-763-505-5000

Toll-free 1-800-328-0810

Fax 1-763-505-1000



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