Eterna™ Implantable Pulse Generator
Model 32400

Clinician's System Manual

Abbott

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The Eterna™ Spinal Cord Stimulation (SCS) System is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

Refer to the Indications for Use Data Sheet for Abbott Medical spinal cord stimulation systems.

Contraindications

The Eterna™ SCS System is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to this neurostimulation system.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical candidates. Neurostimulation should not be used for patients with comorbidities that could prevent successful implant or effective therapy.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave 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 cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. If use of electrocautery is necessary, place the neurostimulator in Surgery mode using the clinician programmer app or the patient controller app before using an electrosurgery device.

During the implant procedure, if an electrosurgery device must be used, take the following actions:

- Use bipolar electrosurgery only.
- Place the neurostimulator in Surgery mode before using an electrosurgery device.

- Set the electrosurgery device to the lowest possible energy setting. Output power below 80 W is recommended for all activations.
- Complete any electrosurgery before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Exit Surgery mode during intraoperative testing and after the procedure is completed.

  NOTE: During intraoperative testing, Surgery mode must be turned off for the neurostimulation system to function correctly.

- Confirm that the neurostimulation system is functioning correctly during the implant procedure, before closing the neurostimulator pocket, and after the implant procedure.

After any surgery, check the neurostimulation system for the following:

- Check the neurostimulator to ensure Surgery mode has been turned off, even if Surgery mode was not turned on at the beginning or during the procedure.
- Confirm the neurostimulation system is functioning.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems (minimum separation distance of approximately 8 cm (3 in.) between lead ends is recommended); (2) verify that the neurostimulation system is not interfering with the function of the implanted cardiac system; and (3) consider bipolar programming of both devices and use neurostimulation system settings that do not interfere with the function of the implantable cardiac system.

Other active implanted devices. The neurostimulation system may interfere with the normal operation of another active implanted device, such as a pacemaker, defibrillator, or another type of neurostimulator. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

Interference with other devices. Some of this system's electronic equipment, such as the programmer and controller, can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Operation of machines, equipment, and vehicles. Patients using therapy that generates paresthesia should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract them from properly operating it. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. For patients who do not feel paresthesia, sudden stimulation changes are less likely to occur and distract them while operating motorized vehicles, machinery, or equipment.

Explosive and flammable gases. Do not use a clinician programmer or patient controller around explosive or flammable gas fumes or vapors. This includes oxygen-enriched environments such as hyperbaric chambers. Operating the device near gas fumes or vapors could cause them to catch fire. If gas fumes or vapors catch fire, it could cause severe burns, injury, or death.

Keep dry to avoid damage. Clinician programmers, patient controllers, and chargers are not waterproof. Keep them dry to avoid damage. Advise patients to not use their devices when engaging in activities that might cause them to get wet, such as swimming or bathing.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) ≥8% (64 mmol/mol).

- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Device modification. This equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Application modification. To prevent unintended stimulation, do not modify the generator software in any way. Only apply software updates that are published directly by Abbott Medical.

Case damage. Do not handle the generator if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

Generator disposal. Return all explanted generators to Abbott Medical for safe disposal. Generators contain batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the generator because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to this neurostimulation system.

General Precautions

Clinician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Patients should avoid charging their generator over an incision that has not completely healed. Infections related to system implantation might require that the device be explanted.

Implantation of two systems. If two systems are implanted, ensure that at least 20 cm (8 in.) separates the implanted generators to minimize unintended interaction with other system components.

Implantation of multiple leads. If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

Implant heating. While charging the generator, patients may perceive an increase in temperature at the generator site. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or render the patient incapable of controlling the generator. If unpleasant sensations occur, turn off stimulation immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the

neurostimulation system to turn on or turn off or affect communication between the device and generator; however, it will not change the prescribed programmed parameters. Patients should be advised to keep their mobile phones and smart watches at least 15 cm (6 in.) away from the generator and avoid placing any smart device in a pocket near the generator. If a patient is concerned about a smart device interacting with their neurostimulation system, consider disabling magnet mode. For more information about setting the magnet mode, refer to the clinician programmer manual or contact Technical Support.

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation of a neurostimulation system. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Patient training. Instruct patients to use their neurostimulation system only after an authorized clinician has programmed the generator and has trained the patient on how to safely control stimulation and to charge the system.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or "use-by" date) is printed on the packaging. Do not use the system if the use-by date has expired.

Recharge-by date. A recharge-by date is printed on the packaging. If this date has been reached or has been exceeded before the date of implantation, the generator should be charged prior to implantation.

Handle devices with care. The clinician programmer and patient controller are sensitive electronic devices that can be damaged by rough handling, such as dropping them on the ground.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package, the device, or any device components show signs of damage, tampering, or if the sterile seal is ruptured, or contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline prior to connection can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

System testing. To ensure correct operation, always test the system during the implant procedure, before closing the neurostimulator pocket, and before the patient leaves the surgery suite.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotriptor, may damage the electronic circuitry of an implanted generator. If lithotripsy must be used, do not focus the energy near the generator.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects

is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted generator should be shielded with lead. Damage to the system may not be immediately detectable.

Home and Occupational Environments

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Patients should cautiously approach such devices and should request help to bypass them. If they must go through a gate or doorway containing this type of device, patients should turn off their generator and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Before diving or using a hyperbaric chamber, patients should contact their physician to discuss the effects of high pressure on their implanted system. Implanted systems with non-Abbott Medical leads have not been evaluated for safety while scuba diving or in hyperbaric chambers. Patients with implanted Abbott Medical leads should avoid scuba diving in more than 30 m (100 ft) of water or entering hyperbaric chambers above 4.0 atmospheres absolute (ATA) for any length of time, as this may damage the neurostimulation system. For less than 30 m (100 ft) of water or pressures below 4.0 ATA, durations of less than 60 minutes are recommended.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your generator immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or generator site
- Seroma (mass or swelling) at the generator site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Safety and Effectiveness Studies

For information that supports the clinical use of this neurostimulation system, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems. This neurostimulation system is similar in technology and intended use to the systems reported in the literature and clinical studies. Therefore, the literature and clinical studies represent the safety and effectiveness of this neurostimulation system.

System Overview

This neurostimulation system is designed to deliver electrical stimulation to nerve structures. The neurostimulation system includes the following main components:

- Generator and accessories
- Charger and accessories
- Leads/Extensions/Adapters
- Clinician programmer application on clinician programmer device
- Patient controller application on patient controller device
- Patient magnet

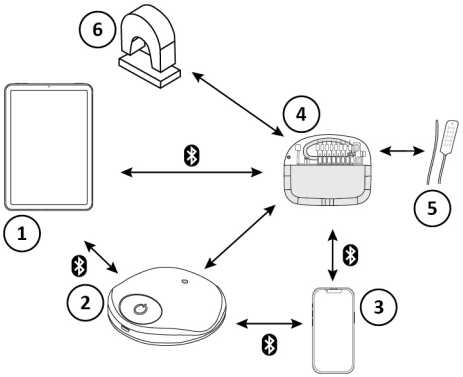
The implantable pulse generator (also referred to as an IPG or neurostimulator) delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The patient magnet can turn the generator on and off if the physician enables this functionality.

Physicians use the clinician programmer to create and modify programs for a patient, view and email program log files, and view generator and charger information. Patients use the patient controller to control their prescribed programs, monitor generator battery status to maintain stimulation, monitor charging status, and modify charger settings. Patients use the charger to charge their generator.

NOTE: In this document, the term “clinician programmer” refers to the NeuroSphere™ Clinician Programmer device, “patient controller” refers to the NeuroSphere™ Patient Controller device, “clinician programmer app” refers to the NeuroSphere™ Clinician Programmer app, and “patient controller app” refers to the NeuroSphere™ Patient Controller app.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction among main system components



1. Clinician programmer
2. Charger
3. Patient controller
4. Generator
5. Leads/Extensions/Adapters
6. Magnet

indicates devices communicate through Bluetooth® wireless technology

NOTE: This manual provides instructions for implanting the generator. For instructions for using other components or more information about the neurostimulation system, see the applicable manuals for those components.

Product Description

This implantable pulse generator is a rechargeable electronic device designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed rechargeable battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation.

The generator can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The generator communicates wirelessly with the clinician programmer and the patient controller and receives radio frequency energy from an external charger to charge the generator battery.

Additional functions supported:

- **Upgradeability**. Software upgrades after implantation provide patients with additional features as approved by the respective regulatory agencies. To upgrade features on the generator, a clinician programmer or patient controller is needed.
- **Compatibility**. The generator header is designed to allow the generator to connect to an Abbott adapter so compatible leads or extensions from another manufacturer can be used with the Eterna™ SCS system. Refer to the compatibility guidelines in this manual (see “Adapters and Extensions for Compatibility with Non-Abbott Leads” (page 13)).

Package Contents

In addition to the product documentation, the generator kit contains the following items:

- 1 generator (model 32400)
- 1 pocket sizer (model 12720)
- 1 torque wrench (model 1101)
- 2 port plugs (model 12710)

Identifying the Generator

You can identify the generator in the following ways:

- The model number and barcode are engraved on the generator.
- The generator has a radiopaque identification tag in the lower right corner that can be viewed with standard X-ray procedures. On the tag, ABT identifies Abbott Medical as the manufacturer, and the letter and a number combination A2 identifies the model family. Additionally, the header port plug is radiopaque and, if used, is visible with standard X-ray procedures (see the following figure).
- The clinician programmer app when connected to the generator indicates the model number and allows you to view other generator information. See the clinician programmer manual for instructions.

Figure 2. Location of the generator code on the Eterna™ implantable pulse generator

Directions for Use

Read this section carefully for suggested directions for use related to the Eterna™ implantable pulse generator. For directions for use for other system components such as the clinician programmer, see the clinician’s manual for the clinician programmer.

NOTE:

- Before the surgical procedure, set up communication between the clinician programmer and the generator while the generator is in its sterile packaging to ensure that it is functional and fully charged. If the generator has never established communication with a programmer, you must first activate the generator for communication by holding the magnet over the generator for 8 to 25 seconds.
- Ensure the generator is fully charged before implantation. The generator can be charged through its sterile packaging.

Creating a Generator Pocket

The following steps outline the suggested procedure to create a generator pocket:

1. Determine the site for the generator, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

   NOTE: Common sites for generator implantation are along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

   CAUTION:

   - **Do not place the generator deeper than 2.5 cm (0.98 in.) because the clinician programmer, generator charger, and patient magnet may not communicate effectively with the generator.**
   - **Ensure the generator is set to Surgery mode using the clinician programmer.**
2. Create the pocket so that the generator is parallel to the skin surface. Ensure the pocket is at least 0.5 cm (0.20 in.) below the surface of the skin but does not exceed a depth of 2.5 cm (0.98 in.).
3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the generator, allowing enough extra room for a strain relief loop for each lead or extension.

Connecting a Lead or Extension to the Generator

The following steps outline the suggested guidelines to connect a lead or extension to the generator:

WARNING: To avoid harming the patient or damaging the neurostimulation system, ensure that any electrosurgery procedures are completed before connecting the leads or extensions to the generator.

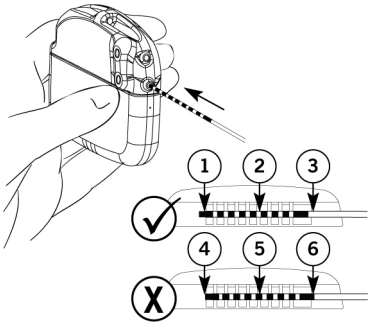
CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts are exposed to body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.
2. To help ensure that the lead or extension can be fully inserted into the generator header, insert the torque wrench through the septum on the generator header, turn the torque wrench clockwise to tighten the setscrew until the torque wrench clicks, and then loosen the setscrew again by turning the wrench counterclockwise about 2.5 times.

   CAUTION:

   - **Use only the torque wrench included in the extension, generator, or torque wrench kit. If you need to loosen the setscrew, turn the setscrew (in quarter turns counterclockwise) just enough to insert or remove the lead or extension from the generator header. Retracting the setscrew too far may cause it to come loose and fail to secure the lead or extension to the generator.**
   - **To avoid sharply bending and damaging the lead or extension when performing the following step, insert the lead or extension parallel with the header port. Additionally, try grasping the lead or extension about 5 mm at a time from the opening of the header port while inserting.**
3. Using clean gloves, carefully slide the proximal end of the lead or extension into the generator header until it stops. Confirm that the lead or extension is correctly inserted by following these visual indicators and referring to the following figure:
   - The first contact band (at the tip) of the lead or extension extends slightly past the first header contact and is visible, the windows between each of the header contacts are clear, and the ninth contact band of the lead or extension is not visible.

Figure 3. Correct versus incorrect insertion of the lead or extension



Fully inserted

1. First contact band (tip) is visible past the first header contact
2. Window between each header contact is clear
3. Ninth contact band is not visible

Not fully inserted

4. First contact band (tip) is not visible past the first header contact
5. Window between each header contact is partially blocked by contact band
6. Ninth contact band is visible

4. Use the clinician programmer app to communicate with the generator and test the impedance to ensure that the lead or extension is fully inserted. See the clinician's manual for the clinician programmer app for instructions.

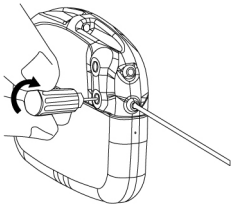
   NOTE:

   - To test the system integrity turn off Surgery mode. After system integrity has been verified, set the generator back into Surgery mode before closing the pocket.
   - If the system integrity check fails, disconnect the lead or extension and reconnect to the generator. Repeat the system integrity check.

5. Insert the torque wrench through the septum and tighten the setscrew, turning it clockwise until the torque wrench clicks.

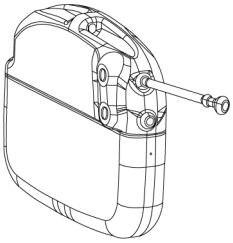
   NOTE: After removing the torque wrench, check the septum to ensure it has closed. If the septum did not close, gently reseat the septum flaps.

Figure 4. Tighten the setscrew clockwise



6. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until the torque wrench clicks.

Figure 5. Insert the port plug



Implanting the Generator

The following steps outline the suggested procedure to implant the generator:

CAUTION: Do not implant the IPG face down. Implant it with the label facing toward the skin, or it may not communicate or recharge.

1. Place the generator into the generator pocket. The depth of the generator pocket from the surface of the generator to the surface of the skin should be at least 0.5 cm (0.20 in.) and not exceeding 2.5 cm (0.98 in.).
2. Carefully coil any excess lead or extension behind the generator in loops no smaller than 2.5 cm (0.98 in.) in diameter to provide strain relief for the lead or extension and generator connection.

   CAUTION: Do not bring the suture needle in contact with a generator, lead, or extension, or the component may be damaged.
3. To stabilize the generator within the pocket, pass suture through the hole at the top of the generator header and through the hole on the side of the generator header, and secure these to connective tissue.
4. Check the entire system by fluoroscopy before closing to ensure proper positioning of the lead or leads and that the lead or leads are straight, with no sharp bends or kinks.
5. Use the clinician programmer app to communicate with the generator and perform intraoperative testing to confirm that the system is operational. See the clinician's manual of the clinician programmer app for instructions.

   NOTE:

   - Generator output may not be identical to that of the trial stimulator at the same settings.
   - Ensure the generator is set to Surgery mode.
6. Ensure that the generator is away from the pocket incision suture line, close the pocket incision, and apply the appropriate dressings.

   NOTE: When the surgical procedure is completed, ensure Surgery mode has been turned off.

Replacing the Generator

The following steps outline the suggested procedure to replace a generator:

1. Turn off stimulation or verify that it is turned off.

   CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.
2. Open the generator implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the generator header and loosen the setscrew by turning it counterclockwise.

   CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.
4. Gently remove the lead or extension from the generator header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the generator replacement procedure, see the following sections: “Connecting a Lead or Extension to the Generator” (page 8) and “Implanting the Generator” (page 10).

Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Checking the Status of the Generator Battery

The generator contains a rechargeable battery. The amount of time that the battery will provide active stimulation depends on the patient's stimulation settings and daily usage time. To check the status of the generator battery, use the clinician programmer app or patient controller app.

NOTE: Generator battery status is available upon initial connection to the clinician programmer app and the patient controller app.

The following list provides additional information about the battery status:

- Stimulation will automatically stop when the battery cannot support stimulation.
- Alert messages will appear on the clinician programmer app and the patient controller app when the generator battery is low or depleted and when charging is required to maintain uninterrupted stimulation therapy.
- All rechargeable batteries experience reduced capacity with repeated use and recharging cycles. As the generator battery ages, more frequent charging may be needed. If the charging frequency becomes inconvenient or interferes with therapy, consider replacing the generator.
- When the generator reaches 10 years of life, a Battery Reminder message will display on the clinician programmer and patient controller as a reminder to consider replacing the generator if the charging frequency becomes inconvenient.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

Storage and Excursion Temperature Specifications

Store the components in this kit according to the following recommended conditions.

Table 1. Recommended storage and excursion conditions for components

Long Term Storage Temperature	Store at 23°C or 73°F
Temperature Excursions	Excursions below 15°C (59°F) or above 30°C (86°F) should be <24 hours in duration
Excursion Temperature Limits	-20°C (-4°F) to 60°C to (140°F)

Product Materials

The following materials are intended to come into contact with tissue.

Table 2. Product materials for generator kit

Component	**Material**
Generator	Titanium, silicone rubber, epoxy resin
Pocket sizer	Polybutylene terephthalate
Port plug	Polyether ether ketone (PEEK) with barium sulfate

NOTE: These components are not made with natural rubber latex.

Generator Specifications

The Eterna™ implantable pulse generator has the following physical specifications.

Table 3. Generator specifications

Specifications	**Model 32400**
MR Conditional	Yes
Upgradeable features	Yes
BurstDR™ stimulation capable	Yes
Height	3.87 cm (1.52 in.)
Length	4.81 cm (1.89 in.)
Thickness	0.90 cm (0.36 in.)
Weight	26.4 g (0.93 oz)
Volume	13.79 cm^3 (0.84 $in.^3$)
Power source	Rechargeable lithium ion cell battery
Connector specifications	Two 8-channel connectors In-line, 2.54 mm (0.1 in.) spacing Connector strength: 5N
Program storage capacity	16 programs with 8 stim sets each

The generator has the following operating parameters.

Table 4. Operating parameters for the generator

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Pulse width	20–1000 µs	10 µs (20–500 µs range) 50 µs (500–1000 µs range)	50–1000 µs	50 µs
Frequency	2–200 Hz	2 Hz	—	—
	200–500 Hz	10 Hz	—	—
	500–1200 Hz	20 Hz	—	—
Burst frequency	—	—	10–60 Hz	10 Hz
Intra-burst rate	—	—	250–500 Hz	10 Hz
			500–1000 Hz	20 Hz
Amplitude	0–25.5 mA	0.1–1.0 mA	0–12.75 mA	0.05–0.50 mA
	0–12.75 mA	0.05–0.50 mA		

NOTE:

- Columns with * represent operating parameters for BurstDR™ stimulation programs on generators capable of BurstDR stimulation mode.
- For each tonic program, you have the option to select the amplitude range. For information on setting the amplitude range, see the clinician's programming manual for this system.
- The number of stim sets in use for a tonic program governs the maximum frequency (1200/number of stim sets).
- The maximum current depends on the impedance, frequency, and pulse width settings.

Adapters and Extensions for Compatibility with Non-Abbott Leads

The Eterna™ implantable pulse generator is compatible with select Medtronic leads and extensions. However, a compatible adapter or extension must be used to connect the Eterna™ implantable pulse generator to Medtronic leads. Compatible adapter and extension models are listed in the following table. Refer to the clinician manuals of the A127™ extension and the 8-channel adapter for the list of compatible Medtronic leads and extensions.

Table 5. Compatible Abbott Adapters

Device	Model
A127™ Extension	2341, 2342, 2343, 2346
8-Channel Adapter	2311, 2316

WARNING: Always use a compatible adapter to connect the Eterna™ implantable pulse generator to compatible Medtronic leads and extensions. Do not insert a Medtronic lead or extension directly into the Eterna generator header as this may damage the header.

Appendix B: System Components and Accessories

The Eterna™ SCS system includes the following components.

NOTE:

- Not all models are available in all countries. Contact your local representative for more information.
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Generator

Model	Description
32400	Eterna™ implantable pulse generator

Generator Accessories

Model	Description
1101	Torque wrench
12710	Port plug

Charging System

Model	Description
16000	Charger

Charging System Accessories

Model	Description
16730	Travel case
16740	Charging cable and power adapter kit
16750	Charging apparel kit – lumbar
16760	Charging apparel kit – pectoral
36000	Charger kit – lumbar

Programmers and Controllers

Model	Description
55500	Patient controller app
55600	Clinician programmer app

Programmer and Controller Accessories

Model	Description
1210	Magnet kit
35500	SCS patient controller kit

Leads and Extensions

Model	Description
3100-series	Percutaneous leads
3200-series	Paddle leads

Model	Description
3300-series	Extensions

Leads and Extensions Accessories

Model	Description
1100-series	Stylets
1102	Guidewire for percutaneous leads
1103	Introde-AK™ lead introducer
1105	Lead anchor, butterfly
1106	Lead anchor, long
1109	Strain relief
1112	Tunneling tool, 12 in.
1114	Epidural needle, 14 gauge, 4 in. (10 cm)
1116	Epidural needle, 14 gauge, 6 in. (15 cm)
1120	Tunneling tool, 20 in.
1192	Swift-Lock™ anchor
1194	Cinch™ anchor
1701	SCS accessory kit

Adapters and Extensions

Model	Description
2311	8-channel adapter, M, 10 cm
2316	8-channel adapter, M, 60 cm
2341	A127™ extension, 15 cm
2342	A127™ extension, 40 cm
2343	A127™ extension, 60 cm
2346	A127™ extension, 90 cm

Appendix C: Generator Battery Information

The Eterna™ implantable pulse generator contains a rechargeable lithium ion battery. This battery should provide at least 10 years of service before replacement is recommended. If the patient does not charge the generator battery, stimulation will eventually stop. When programmed with nominal stimulation settings for BurstDR™ programs (listed below), a newly implanted battery can support 69 to 74 days of stimulation therapy on a full charge. A full charge would be needed 5 times per year. If the patient prefers shorter and more frequent charging sessions, a newly implanted battery can support one month of stimulation therapy with 1 hour and 8 minutes of charging.

When the generator reaches 10 years of life, a Battery Reminder message will display on the clinician programmer and patient controller as a reminder to consider replacing the generator if the charging frequency becomes inconvenient.

Battery longevity and the time it takes to recharge a battery depend on multiple factors, including but not limited to the following:

- Program stimulation settings, such as frequency, pulse width, amplitude, and number of active electrodes
- Program dosage
- Program impedance
- Daily usage time
- Age of the generator battery
- Length of time since the last charge
- Shelf life of the device between the dates of manufacture and implant
- Duration of communication sessions between the generator and the patient controller or clinician programmer
- If the generator was stored outside of recommended storage temperatures

Nominal stimulation settings for BurstDR™ programs are as follows:

- 2 leads
- 1 area
- BurstDR™ stimulation
- 5 pulses per Burst
- Amplitude: 0.6 mA
- Pulse width: 1000 µs
- Burst frequency: 40 Hz
- Intra-burst rate: 500 Hz
- Intermittent dosage with 30 seconds On Time and 90 seconds Off Time
- Therapy on 24 hours a day
- Program impedance: 525 Ω

Appendix D: Regulatory Statements

This section contains regulatory statements about your product.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful

interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 6. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMIPG1

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® wireless technology as it is implemented in the device.

Table 7. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Modified monopole
Antenna dimensions	10.7 mm x 4.3 mm x 3.0 mm
Modulation	GFSK
Output power (EIRP*)	2 mW (+3 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz
Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology
Semi-duplex capability	Yes

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator or charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator or charger, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 18).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator encrypts its wireless communication with the programming device using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the generator at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.
- Proprietary authentication for the patient controller or clinician programmer applications in addition to the pairing procedure specified in Bluetooth LE, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized application from communicating with the generator.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the generator to a legitimate patient controller or clinician programmer.

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the clinician programmer or patient controller app; then turn the clinician programmer or patient controller off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

  NOTE:

  - Equipment such as the following can interfere with the neurostimulation system: radiation-based imaging devices, electrosurgery devices, medical monitoring devices, radiofrequency identification devices (RFID), diathermy devices, wireless home network devices, and consumer electronic devices.

- For more information, refer to the clinician programmer manual to troubleshoot potential issues for wireless communication.

Appendix E: Electromagnetic Compatibility Guidelines

The implantable pulse generator (model 32400), hereafter the device, is part of the Eterna™ SCS system and should be used with the following guidance:

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has essential performance when operating as a system, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). The device complies with the limits for medical devices contained in IEC 60601-1-2:2014+AMD1:2020 (Ed 4.1) and CISPR11:2015+AMD1:2016+AMD2:2019 (BS EN 55011:2016+A2:2021). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

NOTE: The non-Abbott Medical accessories supporting the clinician programmer, such as charging cords, adapters, should not be used while running the clinician programmer app. The effect of use of such accessories while running the app has not been evaluated.

Table 8. Guidance and Manufacturer's Declaration — Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device, when operating as a system, produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device, when operating as a system, is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A*	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class 5 Full Compliance*	

*Only applicable to Power Adapter (model 16720) when operating with the charging system.

Table 9. Guidance and Manufacturer's Declaration — Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2**	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 10%.
Electrical fast transient/burst IEC 61000-4-4*	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the device which operates on internal battery.
Surge IEC 61000-4-5*	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the device which operates on internal battery.
Voltage dips, short interruptions IEC 61000-4-11*	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the

Table 9. Guidance and Manufacturer's Declaration — Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
	25 cycles <5% U_T (>95% dip in U_T) for 5 s	25 cycles <5% U_T (>95% dip in U_T) for 5 s	device which operates on internal battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.
Conducted RF IEC 61000-4-6*	3 Vrms 150 kHz to 80 MHz	3 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d}\sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).
	6 Vrms ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

*Only applicable to Power Adapter (model 16720) when operating with the charging system.

**Applicable to the Charging system (model 16000, 16740), Patient Controller (model 55500), and Clinician Programmer (model 55600) while operating with the IPG.

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 10. Guidance and Manufacturer's Declaration—Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance d = 0.3 m
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	2450 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	

Table 10. Guidance and Manufacturer's Declaration—Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 in.) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Table 11. Guidance and Manufacturer's Declaration—Enclosure Port Immunity to RF Wireless Communication Equipment

Immunity Test	Band (MHz)	Maximum Power (W)	Immunity Test Level (V/m)
IEC 61000-4-3	380 to 390	1.8	27
	430 to 470	2	28
	704 to 787	0.2	9
	800 to 960	2	28
	1700 to 1900	2	28
	2400 to 2570	2	28
	5100 to 5800	0.2	9

Table 12. Guidance and Manufacturer's Declaration—Enclosure Port Immunity to Proximity Magnetic Fields

Immunity Test	Test Frequency	Modulation	Immunity Test Level (A/m)
IEC 61000-4-39	30.0 kHz	Continuous wave	8
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

Appendix F: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 13. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.

Table 13. Symbols and definitions

Symbol	Definition
	Non-ionizing electromagnetic radiation
	Do not re-use
	Do not resterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Long term storage temperature
	Temperature limit
	Excursions permitted within this range
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Medical Device
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit

Table 13. Symbols and definitions

Symbol	Definition
	Implantable device
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	Sterilized using ethylene oxide
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

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