

# Paddle Lead Kit

Models 3214, 3219, 3228, 3240, 3244, 3245, 3286, 3288

## CLINICIAN'S MANUAL



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# Prescription and Safety Information

Read this section to gather important prescription and safety information.

## Intended Use

The leads covered in this manual are intended to be used with Abbott Medical neurostimulation systems by connecting to a compatible pulse generator, either directly or with a compatible lead extension.

## Indications for Use

Abbott Medical neurostimulation systems are indicated for spinal cord stimulation (SCS) in the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach.

## Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

## Warnings

The following warnings apply to these components.

**Preoperative imaging.** Preoperatively review imaging of the spine (e.g., MRI or computerized tomography [CT] with or without myelography) in the region where the paddle is intended to be implanted to ensure adequate space for the lead.

**Compressive lesions.** Systematically assess the presence of any compressive lesions in the region where the paddle is intended to be implanted.

**Poor surgical risks.** Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

**Magnetic resonance imaging (MRI).** Patients with implanted neurostimulation systems should not be subjected to MRI. MRI can cause a temperature rise in the electrodes leading to serious injury. Additionally, the electromagnetic field generated by an MRI may dislodge implanted components, 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. All patients are advised to inform their healthcare professional that they should not be exposed to diathermy treatment.

**Electrosurgery devices.** Electrosurgery devices should not be used in close proximity to an implanted IPG or lead. Contact between an active electrode and an implanted IPG or lead can cause severe injury to the patient. For additional electrosurgery information and guidance, refer to the IPG manual.

**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; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

**Theft detectors and metal screening devices.** Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may 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 has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

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

**Device modification.** To avoid damaging internal components or injuring a patient, do not modify the lead in any way, such as by cutting it or altering its shape.

## Precautions

The following precautions apply to these components.

### General Precautions

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

**Infection.** It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

**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. 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, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

**Implantation of multiple leads.** If multiple leads are implanted, the leads should be routed to the IPG adjacent to each other in the tunnel. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

### Sterilization and Storage

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

**Exposure to liquids.** System components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the seal integrity of the package materials.

## Handling and Implementation

**Expiration date.** An expiration date (or "use before" date) is printed on the packaging. Do not use a component if the use-before date has expired.

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

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

**Exposure to body fluids or saline.** Exposure of the internal metal (i.e., contacts on the lead, the IPG, or extension) to body fluids or saline can cause corrosion and affect stimulation. If this occurs, clean with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.

**System testing.** The operation of the system should always be tested after implantation and before the patient leaves the surgery suite to ensure correct operation.

**Component disposal.** Return all explanted components to Abbott Medical for safe disposal.

## Home and Occupational Environments

**Lead movement.** Patients should be instructed to avoid bending, twisting, stretching, or lifting objects over five pounds for six to eight weeks postimplantation. 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 ineffective or overstimulation.

## Adverse Effects

The use of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- 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 or local skin erosion
- Implant migration
- 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 site or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to implant materials

# Product Description

Abbott Medical leads are designed for spinal cord stimulation (SCS) to aid in the treatment of chronic, intractable pain. SCS is a method of pain control that uses low-intensity electrical impulses to stimulate nerve fibers within the spinal cord, often inhibiting chronic pain messages from reaching the brain. Paddle leads consist of plate-type electrodes embedded in a silicone paddle.

## Package Contents

In addition to the lead, the paddle lead kit may contain the following items:

- **Lead anchor.** Made of silicone and used to secure the lead for stability.
- **Tunneling tool.** Used to create a subcutaneous tunnel for routing the lead to the IPG site.
- **Torque wrench.** Used to tighten the setscrew on the connector assemblies of the IPG and extension.
- **Lead blank.** Used after preoperative assessment to confirm available space prior to paddle lead placement.

## Directions for Use

Carefully review the following suggested guidelines for implantation of a paddle lead. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

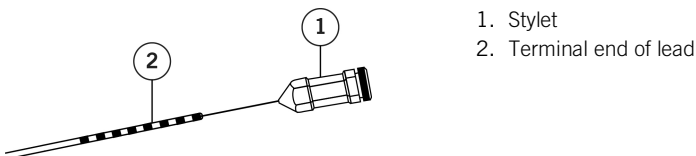
## Placing Paddle Leads

Paddle leads are designed for introduction into the dorsal epidural space through a laminotomy procedure. Each paddle lead is packaged with the accessories required for implantation. See Appendix A (page 12) for specifications.

Implantation of a paddle lead should be done with the aid of fluoroscopy. Care should be taken during handling and implantation of the lead. The lead can be damaged by mishandling, such as sharp bending, kinking, applying excessive traction, or contact with sharp instruments. Carefully examine each component upon removal from its sterile container. A lead exhibiting signs of damage should not be used.

Lamitrode™ S-Series™ leads (Model 3286, also called S-Series™ leads) have a slimline design for enhanced maneuverability. They also feature removable stylets (straight and curved) that provide added stiffness to facilitate steering and control during lead placement (see the following figure).

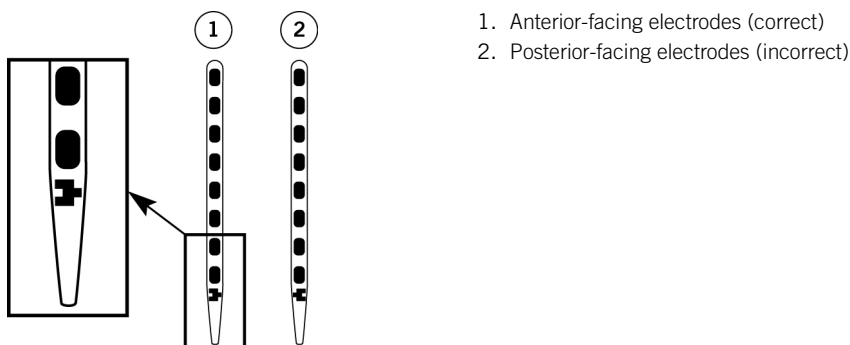
Figure 1. Stylets available in some model leads



S-Series leads also feature an indicator that shows which direction the electrodes are facing. An anterior-posterior (AP) fluoroscopic view will allow you to see the directional indicator (see the following figure). If the indicator is pointing to the right in the AP view, the electrodes are facing

anteriorly (toward the dura). If the indicator is pointing to the left, the electrodes are facing posteriorly (away from the dura).

Figure 2. Meaning of directional indicator of S-Series leads



**WARNING:** It is recommended that the physician assess the size of the spinal canal at the planned insertion and placement site. This should be compared with the dimensions of the lead and paddle to ensure adequate clearance and to avoid increased risk of spinal cord injury due to cord compression.

**WARNING:** When implanting for upper extremity pain, it is advisable to place the lead and paddle at C1-C2 to avoid increased risk of spinal cord injury due to cord compression.

**WARNING:** When selecting a placement location for a laminotomy-type lead in the thoracic spine, consideration should be given to existing spinal stenosis.

**Decompress the spinal canal prior to the paddle insertion if the level of the paddle insertion coincides with the level of spinal canal stenosis.**

1. Externally measure and determine the appropriate spinal level for placement of the paddle and the spinal level required for the laminotomy to expose the epidural space.

**CAUTION:** To prevent injury, avoid inserting the paddle at vertebral levels where:

- The thickness of the CSF layer is less than 3 mm along the width/length of the lead
- The thickness of the paddle allows less than approximately 1 mm of CSF clearance
- The spinal canal is narrowed by focal stenosis or degenerated discs and cannot be surgically corrected to allow for approximately 1 mm of clearance

**NOTE:** When placing a paddle in the cervical spine, you may need additional clearance to allow for flexion and extension of the head and neck.

2. Select the desired approach and perform the surgical procedure. Ensure that the dissection and resultant opening of the ligamentum flavum are adequate for the paddle to pass through.

3. Use standard operating technique to ensure that a clear pathway is established in the epidural space for placement of the lead.

**WARNING: To prevent patient injury, do not apply excessive force when using surgical instruments, such as an elevator, to clear a pathway in the spinal canal during paddle lead placement.**

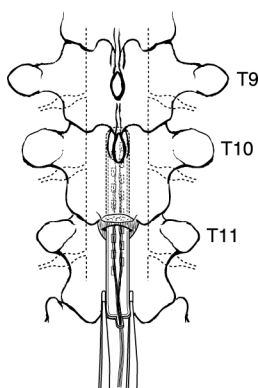
4. If desired, use the lead blank to help confirm that adequate space is available for placement of the paddle lead.

**WARNING: Do not use the lead blank to clear scar tissue or open up a narrow spinal canal.**

5. Grasp the lead with rubber-tipped forceps, and pass it through the opening in the ligament, ensuring that the electrodes face the dura (see the following figure).

Figure 3. Use forceps to pass the lead through the ligament opening (cross-section view, spinous process is not shown)

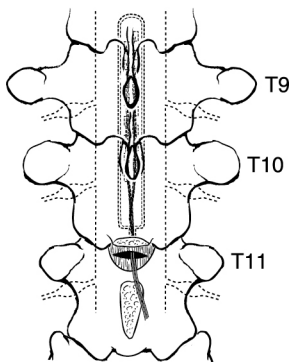
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6. Using fluoroscopic guidance, place the lead into the intended position. Ensure all electrodes are within the epidural space and that the lead paddle will be stabilized following implantation (see the following figure).

Figure 4. Ensure all electrodes are in the epidural space

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7. Perform intraoperative testing. See the clinician's manual for the appropriate trial stimulator for instructions.

**CAUTION:** Exercise extreme caution when using sharp instruments around the lead to avoid damage to the lead body.

## Final Lead Placement and Anchoring

Once final lead placement has been achieved, the lead should be secured with a lead anchor. Lead kits contain two styles of anchors: butterfly and long (see the following figures). Anchor selection should be based upon anatomical requirements and personal preference. The following steps outline the suggested lead anchoring procedure.

Figure 5. Butterfly anchor

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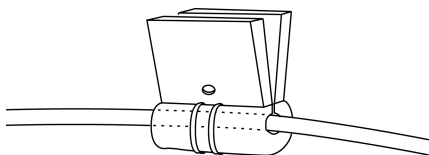
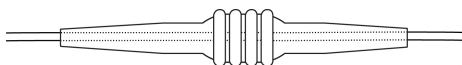


Figure 6. Long anchor

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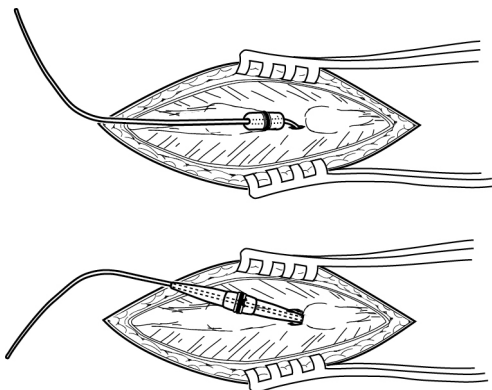


- 
1. Check the lead position by fluoroscopic examination, and reposition the lead if necessary.

2. Select the appropriate anchor and place it on the lead as closely as possible to where it emerges from the vertebral column (see the following figure). Use sterile water (not saline) to lubricate the anchor and facilitate sliding it down the lead. If using the long anchor, slide it down the lead until the anchor's distal strain relief is at least 1 cm (0.4 in) into the fascia. If implanting multiple leads, tag the leads with ligature so that their position can be identified later.

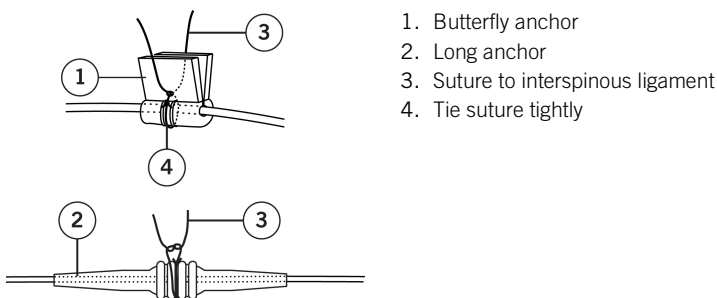
**WARNING:** Care should be taken not to bend the connector end of the lead when passing the long anchor over it.

Figure 7. Insert the anchor on the lead



3. Secure the lead within the lead anchor using 2-0 nonabsorbable suture (see the following figure).

Figure 8. Secure the anchor and the lead



**NOTE:** To ensure optimal holding force, use a surgeon's knot. A surgeon's knot is a form the square knot; the first loop of the knot has two throws, and the second loop has one.

**WARNINGS:**

- Do not use polypropylene or monofilament suture because of possible damage to the anchor and lead.
  - If the lead is not properly anchored, migration may occur.
  - Sutures placed directly on the lead without an anchor can cause permanent damage to the insulation and eventual failure of the lead.
  - Avoid sharp bends or kinking of the lead, or permanent damage may occur.
4. Suture the anchor to the interspinous ligament with 2-0 nonabsorbable suture. A strain relief for the lead should be created by coiling excess lead proximal to the lead anchor in loops no smaller than 2.5 cm (1 in) in diameter.
  5. Once anchored, the lead can be connected to an extension for trial screening or tunneled to the IPG site for system internalization.

## Tunneling to the Pocket

Tunneling is usually done from the lead anchor site directly to the IPG pocket. However, when an extension is used or the IPG pocket is in the abdominal region, tunneling is done from the lead anchor site to a midpoint (where an incision and appropriate dissection have been performed) and then continued to the IPG pocket site.

The following steps outline the suggested procedure to tunnel from the lead anchor site to the IPG pocket:

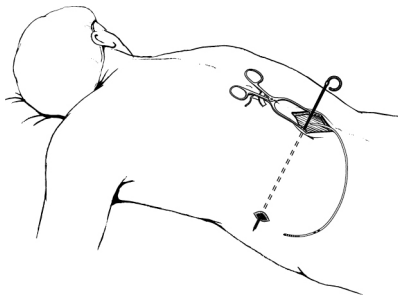
**CAUTION:** Use extreme care so as not to damage a lead with the sharp point of the tunneling tool.

**NOTE:** The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

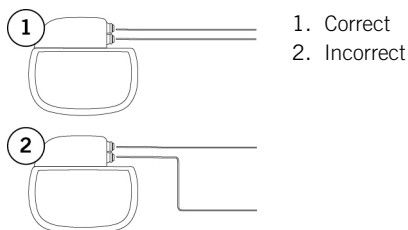
Figure 9. Suggested tunnel to the IPG pocket

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2. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve in the subcutaneous tunnel.

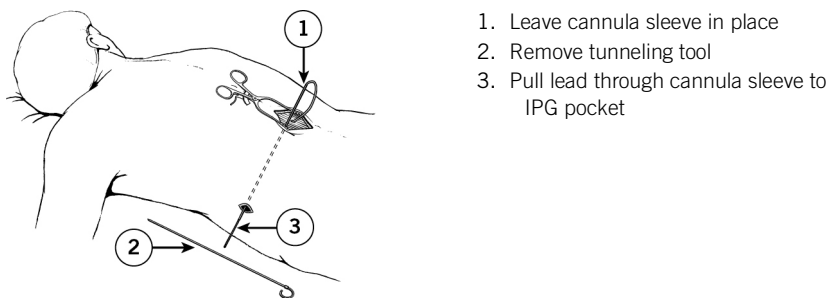
**CAUTION:** Multiple leads must be routed adjacent to one another. Patients with nonadjacent leads may experience changes in perceived stimulation from theft detectors and metal screening devices. The correct way to route multiple leads is as follows:



**WARNING:** It is possible that patients who are implanted with nonadjacent multiple leads may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting, when passing through antitheft devices or airport screening devices.

3. Carefully pass the end of the lead or leads through the cannula sleeve from the anchor site to the IPG pocket; or, if a two-step tunneling procedure is used, pass the lead or leads from the anchor site to the midway incision site and then to the IPG pocket. Multiple leads may be placed in the same tunnel.

Figure 10. Sequence of tunneling steps



4. Withdraw the cannula sleeve from the subcutaneous tunnel by passing it over the lead or leads, taking care not to cause traction on them.

## Connecting the Leads

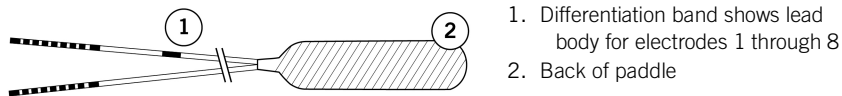
For instructions about connecting a paddle lead to an IPG or RF system, see the applicable neurostimulator clinician's manual.

**WARNING: Exposure of the internal IPG contacts to body fluids or saline can cause corrosion and affect stimulation. If exposure occurs, clean the contacts with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.**

Additionally, consider the following notes:

- Use clean gloves and ensure that all body fluids and saline residue are cleaned from the end of the lead.
- Use the differentiation band on 16-electrode leads (when available) to identify the correct lead body. All 16-electrode leads have two lead bodies exiting the paddle. When the paddle is facing anteriorly (toward the dura), the lead body that exits from the left side of the paddle is connected to electrodes 1 through 8. Additionally, the Lamitrode™ Tripole™ 16 and Penta™ leads contain a differentiation band near the terminal end of the lead that identifies the lead body for electrodes 1 through 8. (see the following figure).

Figure 11. Use the differentiation band (when available) to identify the lead body for electrodes 1 through 8



## 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.

## 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

NOTE: Not all models are available in all countries. Contact your local representative for more information.

### Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

|                    |                            |
|--------------------|----------------------------|
| <b>Temperature</b> | -10°C–55°C (14°F–131°F)    |
| <b>Humidity</b>    | 10%–90% (noncondensing)    |
| <b>Pressure</b>    | 70–150 kPa (10.2–21.8 psi) |

### Product Materials

Table 2. Product materials for paddle leads

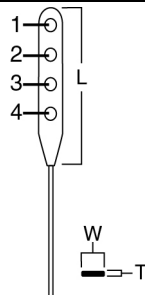
| <b>Component</b>                     | <b>Material</b>                               |
|--------------------------------------|-----------------------------------------------|
| Electrodes and terminal end contacts | Platinum iridium                              |
| Paddle                               | Silicone                                      |
| Insulation                           | Polycarbonate polyurethane                    |
| Lead blank <sup>1</sup>              | Silicone with 20% barium sulfate <sup>2</sup> |

<sup>1</sup> Not all kits contain a lead blank; see the lead specifications for a list of each kit's components.

<sup>2</sup> The lead blank paddle for Model 3245 contains only silicone.

# Lead Specifications (4 Channel)

Table 3. Specifications for Lamitrode™ S-4 and 4 leads

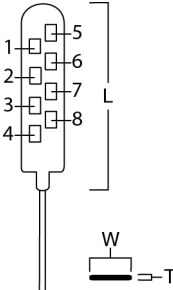
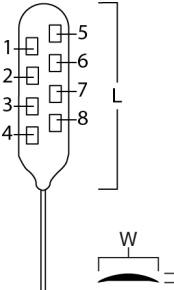
| Description                       |  | Lamitrode 4                                                                       |               |
|-----------------------------------|--|-----------------------------------------------------------------------------------|---------------|
|                                   |  |  |               |
| Lead length and model             |  | 60 cm                                                                             | 3240          |
| Lead diameter                     |  |                                                                                   | 1.4 mm        |
| Electrodes                        |  |                                                                                   |               |
| Number                            |  |                                                                                   | 4             |
| Configuration                     |  |                                                                                   | 1 column of 4 |
| Length                            |  |                                                                                   | 4 mm          |
| Width                             |  |                                                                                   | 4 mm          |
| Longitudinal spacing              |  |                                                                                   | 6 mm          |
| Array length                      |  |                                                                                   | 35 mm         |
| Array width                       |  |                                                                                   | 4 mm          |
| Paddles                           |  |                                                                                   |               |
| Length (L, includes taper)        |  |                                                                                   | 51 mm         |
| Width (W)                         |  |                                                                                   | 8 mm          |
| Thickness (T)                     |  |                                                                                   | 1.7 mm        |
| Lead resistance (for all lengths) |  |                                                                                   | < 10 ohms     |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)

# Lead Specifications (8 Channel)

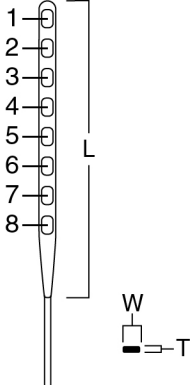
Table 4. Specifications for Lamitrode™ 44 and 44C leads

| Description                                   | Lamitrode 44                                                                      |                       | Lamitrode 44C                                                                     |  |
|-----------------------------------------------|-----------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------|--|
| Electrodes are shown facing down (anteriorly) |  |                       |  |  |
| Lead length and model                         | 60 cm                                                                             | 3244                  | 3245                                                                              |  |
| Lead diameter                                 |                                                                                   | 1.4 mm                | 1.4 mm                                                                            |  |
| Electrodes                                    |                                                                                   |                       |                                                                                   |  |
| Number                                        |                                                                                   | 8                     | 8                                                                                 |  |
| Configuration                                 |                                                                                   | 2 offset columns of 4 | 2 offset columns of 4                                                             |  |
| Length                                        |                                                                                   | 4 mm                  | 4 mm                                                                              |  |
| Width                                         |                                                                                   | 2.5 mm                | 2.5 mm                                                                            |  |
| Longitudinal spacing                          |                                                                                   | 3 mm                  | 3 mm                                                                              |  |
| Lateral spacing                               |                                                                                   | 1 mm                  | 2 mm                                                                              |  |
| Array length                                  |                                                                                   | 28 mm                 | 28 mm                                                                             |  |
| Array width                                   |                                                                                   | 6 mm                  | 7 mm                                                                              |  |
| Paddles                                       |                                                                                   |                       |                                                                                   |  |
| Length (L, includes taper)                    |                                                                                   | 51 mm                 | 51 mm                                                                             |  |
| Width (W)                                     |                                                                                   | 10 mm                 | 13 mm                                                                             |  |
| Thickness (T)                                 |                                                                                   | 1.7 mm                | 2 mm tapering to 0.4 mm                                                           |  |
| Lead resistance (for all lengths)             |                                                                                   | < 10 ohms             | < 10 ohms                                                                         |  |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank, 44C only
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)

Table 5. Specifications for Lamitrode™ S-8 leads

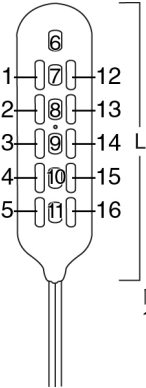
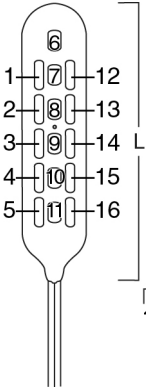
| Description                       |       | Lamitrode S-8                                                                     |
|-----------------------------------|-------|-----------------------------------------------------------------------------------|
|                                   |       |  |
| Lead length and model             | 60 cm | 3286                                                                              |
| Lead diameter                     |       | 1.4 mm                                                                            |
| Electrodes                        |       |                                                                                   |
| Number                            |       | 8                                                                                 |
| Configuration                     |       | 1 column of 8                                                                     |
| Length                            |       | 4 mm                                                                              |
| Width                             |       | 2.5 mm                                                                            |
| Longitudinal spacing              |       | 3 mm                                                                              |
| Array length                      |       | 53 mm                                                                             |
| Array width                       |       | 2.5 mm                                                                            |
| Paddles                           |       |                                                                                   |
| Length (L, includes taper)        |       | 67 mm                                                                             |
| Width (W)                         |       | 4 mm                                                                              |
| Thickness (T)                     |       | 1.8 mm                                                                            |
| Lead resistance (for all lengths) |       | < 10 ohms                                                                         |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)
- 1 stylet, straight (Model 1121, 1123, or 1125)
- 1 stylet, curved (Model 1122, 1124, or 1126)

# Lead Specifications (16 Channel)

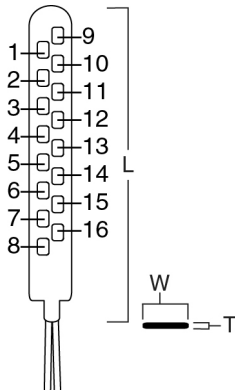
Table 6. Specifications for Lamitrode™ Tripole™ 16C and 16 leads

| Description                                   | Tripole 16C                                                                       |                                                      | Tripole 16                                                                        |                                                      |
|-----------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------|
| Electrodes are shown facing down (anteriorly) |  |                                                      |  |                                                      |
| Lead length and model                         | 60 cm                                                                             | 3214                                                 |                                                                                   | 3219                                                 |
| Lead diameter                                 |                                                                                   | 1.4 mm                                               |                                                                                   | 1.4 mm                                               |
| Electrodes                                    |                                                                                   |                                                      |                                                                                   |                                                      |
| Number                                        |                                                                                   | 16                                                   |                                                                                   | 16                                                   |
| Configuration                                 |                                                                                   | 1 center column with 2 offset columns on either side |                                                                                   | 1 center column with 2 offset columns on either side |
| Length                                        |                                                                                   | Center column: 4 mm<br>Outer column: 6 mm            |                                                                                   | Center column: 4 mm<br>Outer column: 6 mm            |
| Width                                         |                                                                                   | Center column: 2.5 mm<br>Outer column: 1.8 mm        |                                                                                   | Center column: 2.5 mm<br>Outer column: 1.8 mm        |
| Longitudinal spacing                          |                                                                                   | Center column: 3 mm<br>Outer column: 1 mm            |                                                                                   | Center column: 3 mm<br>Outer column: 1 mm            |
| Lateral spacing                               |                                                                                   | 1 mm                                                 |                                                                                   | 1 mm                                                 |
| Array length                                  |                                                                                   | 40 mm                                                |                                                                                   | 40 mm                                                |
| Array width                                   |                                                                                   | 8 mm                                                 |                                                                                   | 8 mm                                                 |
| Paddles                                       |                                                                                   |                                                      |                                                                                   |                                                      |
| Length (L, includes taper)                    |                                                                                   | 57 mm                                                |                                                                                   | 57 mm                                                |
| Width (W)                                     |                                                                                   | 13 mm                                                |                                                                                   | 10 mm                                                |
| Thickness (T)                                 |                                                                                   | 2 mm tapering to 0.4 mm                              |                                                                                   | 2 mm tapering to 0.4 mm                              |
| Lead resistance (for all lengths)             |                                                                                   | < 10 ohms                                            |                                                                                   | < 10 ohms                                            |
| Differentiation band signifies                |                                                                                   | Not available                                        |                                                                                   | Electrodes 1–8                                       |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (Model 1101)
- 2 lead anchors, butterfly (Model 1105)
- 2 lead anchors, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)

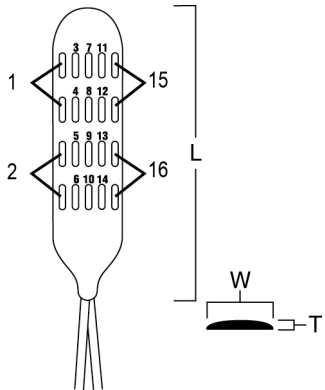
Table 7. Specifications for Lamitrode™ 88 leads

| Description                                   |       | Lamitrode 88                                                                      |
|-----------------------------------------------|-------|-----------------------------------------------------------------------------------|
| Electrodes are shown facing down (anteriorly) |       |  |
| Lead length and model                         | 60 cm | 3288                                                                              |
| Lead diameter                                 |       | 1.4 mm                                                                            |
| Electrodes                                    |       |                                                                                   |
| Number                                        |       | 16                                                                                |
| Configuration                                 |       | 2 offset columns of 8                                                             |
| Length                                        |       | 4 mm                                                                              |
| Width                                         |       | 2.5 mm                                                                            |
| Longitudinal spacing                          |       | 3 mm                                                                              |
| Lateral spacing                               |       | 1 mm                                                                              |
| Array length                                  |       | 56 mm                                                                             |
| Array width                                   |       | 6 mm                                                                              |
| Paddles                                       |       |                                                                                   |
| Length (L, includes taper)                    |       | 79 mm                                                                             |
| Width (W)                                     |       | 10 mm                                                                             |
| Thickness (T)                                 |       | 1.7 mm                                                                            |
| Lead resistance (for all lengths)             |       | < 5 ohms                                                                          |
| Differentiation band signifies                |       | Not available                                                                     |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (Model 1101)
- 2 lead anchors, butterfly (Model 1105)
- 2 lead anchors, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)

Table 8. Specifications for Penta™ leads

| Description                                   |       | Penta, 3 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrodes are shown facing down (anteriorly) |       |  The diagram illustrates the Penta 3 mm lead. It features a central shaft with two sets of electrodes, labeled 1 through 16. Electrodes 1-8 are on the upper set, and 9-16 are on the lower set. The electrodes are arranged in five columns of four. Brackets indicate the length (L) of the electrode array and the width (W) of the lead body. A cross-section view shows the lead body with width W and thickness T. |
| Lead length and model                         | 60 cm | 3228                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Lead diameter                                 |       | 1.4 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Electrodes                                    |       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Number                                        |       | 16                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Configuration                                 |       | 5 columns of 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Length                                        |       | 4 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Width                                         |       | 1 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Longitudinal spacing                          |       | 3 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Lateral spacing                               |       | 1 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Array length                                  |       | 25 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Array width                                   |       | 9 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Paddles                                       |       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Length (L, includes taper)                    |       | 46 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Width (W)                                     |       | 11 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Thickness (T)                                 |       | 2 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Lead resistance (for all lengths)             |       | < 10 ohms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Differentiation band signifies                |       | Electrodes 1–8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (Model 1101)
- 2 lead anchors, butterfly (Model 1105)
- 2 lead anchors, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)

## Appendix B: Symbols and Definitions

The following symbols may be used in this document and on some of the products and packaging:

Table 9. Symbols and definitions

| Symbol                                                                              | Definition                                                                      |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
|    | Caution, consult accompanying documents                                         |
|    | Consult instructions for use                                                    |
|    | Follow instructions for use on this website                                     |
|    | Single use only                                                                 |
|    | Do not resterilize                                                              |
|    | Expiration date                                                                 |
|    | Date of manufacture                                                             |
|    | Manufacturing facility                                                          |
|    | Temperature limits for storage conditions                                       |
|   | Humidity limits                                                                 |
|  | Pressure limits                                                                 |
|  | Do not use if the product sterilization barrier or its packaging is compromised |
|  | Catalog number                                                                  |
|  | Manufacturer                                                                    |
|  | Contents quantity                                                               |
|  | One lead                                                                        |

Table 9. Symbols and definitions

| Symbol                                                                            | Definition                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Accessories                                                                                                                                                                                                                                              |
|  | Serial number                                                                                                                                                                                                                                            |
|  | Batch code                                                                                                                                                                                                                                               |
|  | Unique Device Identification                                                                                                                                                                                                                             |
|  | Prescription use only                                                                                                                                                                                                                                    |
|  | Ethylene oxide gas sterilization                                                                                                                                                                                                                         |
|  | Authorized European representative                                                                                                                                                                                                                       |
|  | European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive. |

### Additional Symbols for Product Labels

The following table shows additional symbols that may appear on the product labels for parts related to this kit.

Table 10. Additional symbols for product labels

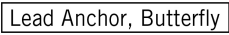
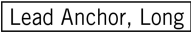
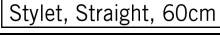
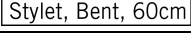
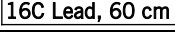
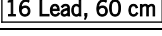
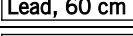
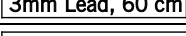
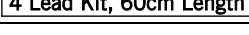
| Symbol                                                                              | Definition                    |
|-------------------------------------------------------------------------------------|-------------------------------|
|    | Torque wrench                 |
|   | Lead anchor, butterfly        |
|  | Lead anchor, long             |
|  | Tunneling tool, 12 in (30 cm) |
|  | Stylet, straight, 60 cm       |
|  | Stylet, bent, 60 cm           |
|  | 16C lead, 60 cm               |
|  | 16 lead, 60 cm                |
|  | Lead, 60 cm                   |
|  | 3-mm lead, 60 cm              |
|  | 4 lead kit, 60 cm length      |

Table 10. Additional symbols for product labels

| Symbol                           | Definition                 |
|----------------------------------|----------------------------|
| <b>44 Lead Kit, 60cm Length</b>  | 44 lead kit, 60 cm length  |
| <b>44C Lead Kit, 60cm Length</b> | 44C lead kit, 60 cm length |
| <b>S-8 Lead Kit, 60cm Length</b> | S-8 lead kit, 60 cm length |
| <b>88 Lead Kit, 60cm Length</b>  | 88 lead kit, 60 cm length  |

## Appendix C: CE Mark Date

Table 11. Year in which CE mark was awarded

| Model                                    | Year |
|------------------------------------------|------|
| 1101, 1105, 1106, 1112, 3240, 3244, 3288 | 1999 |
| 1121, 1122, 1123, 1124                   | 2001 |
| 3286                                     | 2002 |
| 3245                                     | 2004 |
| 1125, 1126                               | 2006 |
| 3214                                     | 2008 |
| 3219, 3228                               | 2009 |









Abbott Medical  
6901 Preston Road  
Plano, Texas 75024 USA  
+1 855 478 5833  
+1 651 756 5833



St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5  
Santana Industrial Park  
Arecibo, PR 00612  
USA



Abbott Medical  
The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem  
Belgium  
+32 2 774 68 11



St. Jude Medical Operations (M) Sdn. Bhd.  
Plot 102, Lebuhraya Kampung Jawa,  
Bayan Lepas Industrial Zone  
11900 Penang  
Malaysia



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