PADDLE LEAD KITS

Models 3214, 3219, 3224, 3228, 3240, 3243, 3244, 3245, 3246, 3262, 3266, 3268, 3283, 3286, 3288

Directions for Use

ST. JUDE MEDICAL™

⚠ **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

For a listing of patents for St. Jude Medical Neuromodulation Division products, visit http://patent.sjmneuro.com.

Description

St. Jude Medical Neuromodulation Division spinal cord stimulation leads are designed to aid in the treatment of chronic, intractable pain. Spinal cord stimulation (SCS) is a method of pain control that has benefited patients with certain types of chronic, intractable pain syndromes. SCS uses low-intensity electrical impulses to stimulate nerve fibers within the spinal cord that often inhibit chronic pain messages from reaching the brain.

Symbols and Definitions

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

Denotes that the user should pay special attention to avoid serious consequences. This document presents the symbol, the word WARNING or CAUTION, and a brief explanation of the seriousness of the situation.

A warning alerts the user to a situation which, if not avoided, could result in (1) death or serious injury, (2) serious or adverse reactions, or (3) safety hazards.

A caution alerts the user to a situation which, if not avoided, may result in (1) minor or moderate injury or (2) damage to the equipment or other property.

This symbol advises the reader to consult this document for important safety-related information.

Denotes single use only

Denotes expiration date

Denotes date of manufacture

Denotes temperature limits for storage conditions

Denotes humidity limits

Denotes pressure limits

Denotes do not use if the product sterilization barrier or its packaging is compromised

Denotes catalog number

Denotes manufacturer

Denotes content, the number of items contained in the package

Denotes code that uniquely identifies an inventory item

Denotes serial number

Denotes batch code

Rx only Denotes for prescription use only

STERILE EO Denotes ethylene oxide gas sterilization

EC REP Denotes authorized European representative

CE Denotes European conformity

0123 Denotes the EU notified body number for AIMD

Indications for Use

St. Jude Medical Neuromodulation Division 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 neurostimulation 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

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. Spinal cord stimulation (SCS) should not be used on patients who are poor surgical risks, such as those with multiple illnesses or active general infections.

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 can 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 health care professional that they should not be exposed to diathermy treatment.

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

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.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation receiver/IPG or lead. Contact between an active electrode and an implanted receiver/IPG or lead can cause direct stimulation of the spinal cord and cause severe injury to the patient.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are implanted with nonadjacent multiple leads and/or 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. It is recommended that patients use caution when approaching such a device and request assistance to bypass the device.

Device components. The use of non-St. Jude Medical Neuromodulation Division components with this system may result in damage to the system and increased risk to the patient.

Device modification. Do not modify the lead in any way, i.e., cutting or altering the shape of the lead. Modifying the lead may damage internal components that can cause injury to the patient.

⚠ Precautions

The following precautions are specific to St. Jude Medical Neuromodulation Division spinal cord stimulation leads. For detailed system information, refer to the appropriate device clinician's manual.

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.

Implantation of multiple leads. If multiple leads are implanted, the leads should be routed to the receiver/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 a St. Jude Medical Neuromodulation Division 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 because of risk of infection and device malfunction.

Storage temperature. Store system components between -10°C and 55°C (14°F and 131°F), because temperatures outside this range can damage components.

Storage humidity and pressure. Store system components between 10% and 90% humidity and between 70 kPa and 150 kPa (10.2 and 21.8 psi).

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, Implantation, and Explantation

Expiration date. Do not implant a device 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 to St. Jude Medical Neuromodulation Division for evaluation.

Exposure to body fluids or saline. Exposure of the internal metal (i.e., contacts on the lead, the receiver/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 assure correct operation.

Component disposal. Return all explanted components to St. Jude Medical Neuromodulation Division 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 implantation of a neurostimulation system involves some risk. In addition to those risks commonly associated with surgery, implantation, and/or use of a neurostimulation system, the following risks are possible:

- Undesirable changes in stimulation may occur over time. These changes in stimulation are possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, and/or lead failure.
- Placement of a lead in the epidural space is a surgical procedure that may expose the patient to risks of epidural hemorrhage, hematoma, infection, spinal cord compression, and/or paralysis.
- Radicular chest wall stimulation.
- Cerebrospinal fluid (CSF) leakage.
- Persistent pain at the electrode site or receiver/IPG site.
- Seroma at the incision site.
- Implant migration.
- Allergic or rejection response to implant materials.
- Lead migration and/or local skin erosion.
- Paralysis, weakness, clumsiness, numbness, or pain below the level of implantation.

Lead Material Composition

- **Electrode and terminal end contact material.** Platinum iridium
- **Paddle material.** Silicone
- **Insulation material.** Polycarbonate polyurethane
- **Lead blank paddle material.** Silicone with 20 percent barium sulfate

NOTE: The lead blank paddle for Model 3245 contains only silicone.

NOTE: Not all kits contain a lead blank. See Appendix A for a list of each kit's components.

Contents of Kits

St. Jude Medical Neuromodulation Division paddle leads consist of plate-type electrodes embedded in a silicone paddle. St. Jude Medical Neuromodulation Division paddle lead kits may also contain the following:

- **Lead anchor.** Made of silicone and used to secure the lead for stability.
- **Trial cable.** Used to connect the lead to a trial stimulator for intraoperative testing or an extended trial.
- **Tunneling tool.** Used to create a subcutaneous tunnel for routing the lead to the receiver/IPG site.
- **Torque wrench.** Used to tighten the setscrew on the connector assemblies of the receiver/IPG and extension.
- **Lead blank.** Used after preoperative assessment to confirm available space prior to paddle lead placement.

Paddle Lead Placement

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 for lead 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 (Models 3243, 3246, 3266, 3268, 3283, and 3286) 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 Figure 1).

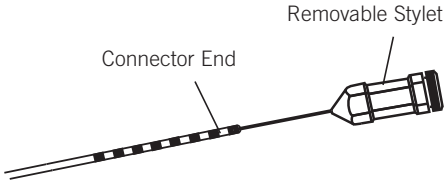


FIGURE 1

A directional indicator in the styleted leads designates the orientation of the stimulating electrodes. An anterior/posterior (A/P) fluoroscopic view will allow the visualization of the directional indicator (see Figure 2). If the indicator is pointing right in the A/P view, the electrodes are pointing down. If the indicator is pointing left, the electrodes are pointing up.

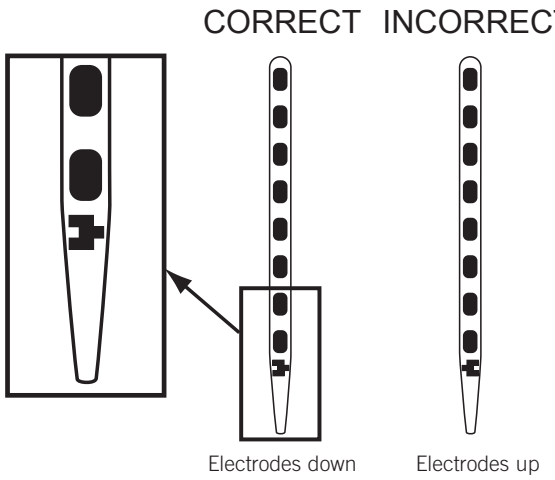


FIGURE 2

⚠ **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 patient 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 Figure 3).

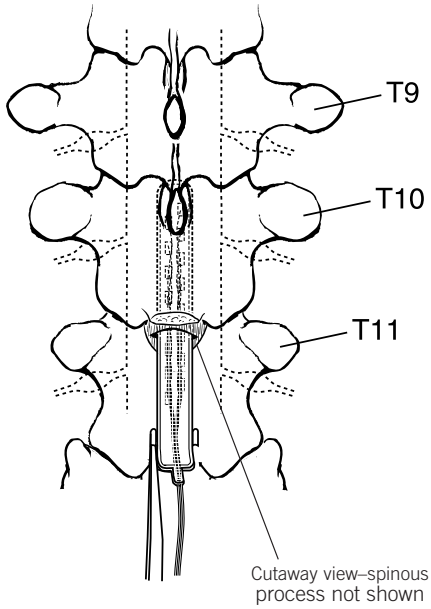


FIGURE 3

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 Figure 4).

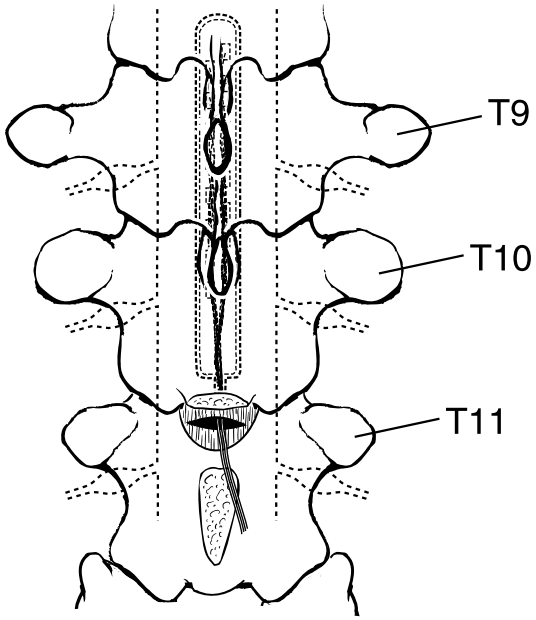


FIGURE 4

7. Select the trial cable and perform intraoperative testing (as described in the following section).

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

Intraoperative Testing

Intraoperative testing confirms proper electrode placement by allowing the patient to identify the location of the stimulation. To test intraoperatively:

1. Insert the end of the lead completely into the trial cable connector assembly (see Figure 5).

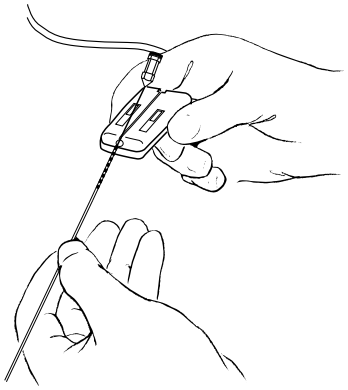


FIGURE 5

2. While maintaining forward pressure on the lead, push the sliding knob on top of the connector assembly toward the "I" until it clicks and locks the lead in place (see Figure 6).

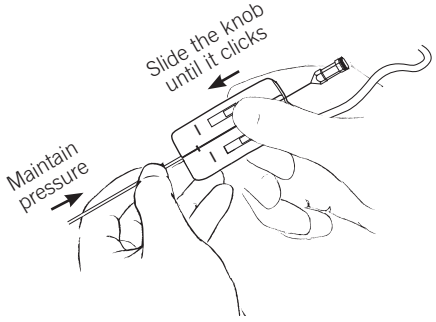


FIGURE 6

3. Attach the trial cable to the trial stimulator (see Figure 7).

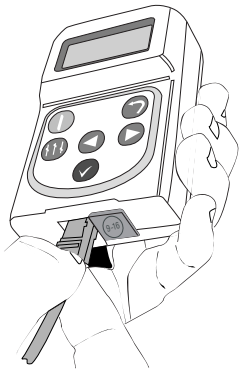


FIGURE 7

4. Conduct intraoperative testing. For detailed instructions, refer to the appropriate trial stimulator clinician's manual.

> ⚠ **CAUTION:** Turn the trial stimulator off before connecting or disconnecting the trial cable.

5. Upon completion of intraoperative testing, turn the trial stimulator off and disconnect the trial cable.
6. Record the lead position with fluoroscopy for comparison of position at time of closure to ensure that the lead has not moved.

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 Figures 8 and 9). Anchor selection should be based upon anatomical requirements and personal preference. The following steps outline the suggested lead anchoring procedure:

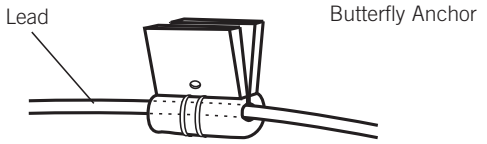


FIGURE 8

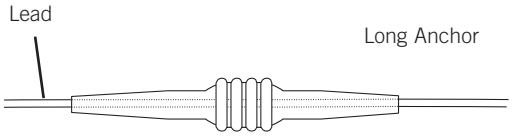


FIGURE 9

1. Check the lead position by fluoroscopic examination and reposition 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 Figure 10). Use sterile water (not saline) to lubricate the anchor and to 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.

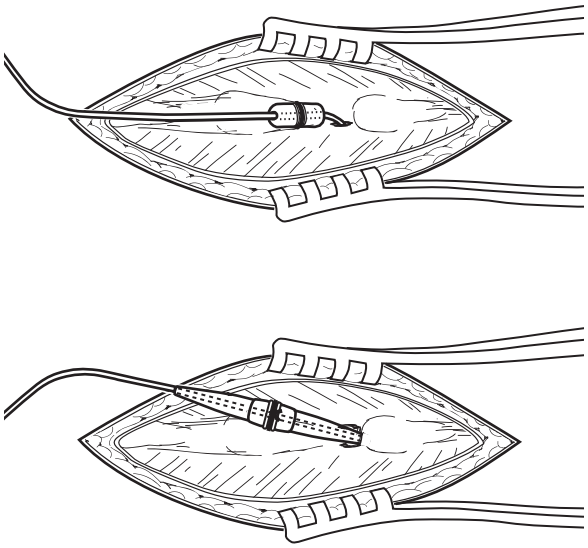


FIGURE 10

3. Secure the lead within the lead anchor using 2-0 nonabsorbable suture (see Figure 11.)

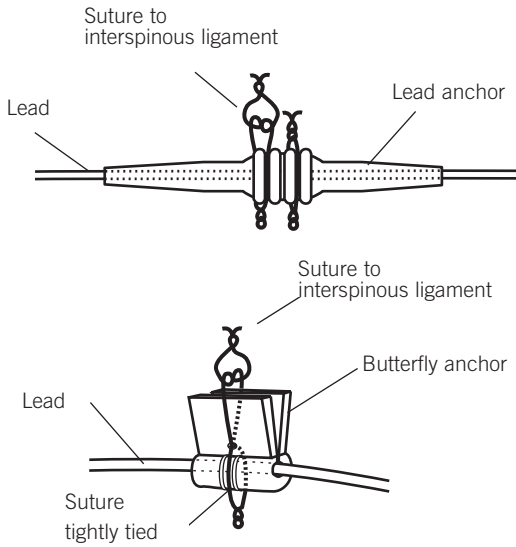


FIGURE 11

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

WARNING:

- 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 of 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 receiver/IPG site for system internalization.

Percutaneous Tunneling

Tunneling from the lead anchor site to the receiver/IPG pocket can be accomplished in one or two steps. For a lead that is connected directly to a receiver/IPG located at the back or side, tunneling is normally done in one step. If an extension is used, or if the receiver/IPG pocket is in the abdominal region, the tunneling procedure is performed in two steps. An incision with appropriate dissection is performed at the midpoint, and the lead is tunneled to that location. This step is then repeated for tunneling to the receiver/IPG pocket site.

1. With the outer sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the receiver/IPG pocket (see Figure 12). The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

WARNING: Use extreme care not to damage the lead with the sharp point of the tunneling tool.

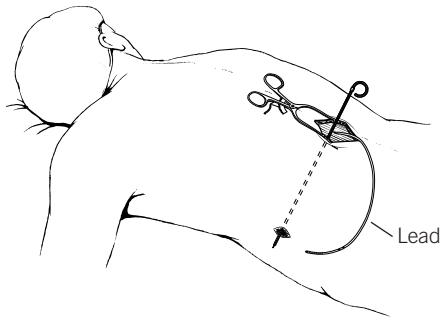


FIGURE 12

2. For multiple-lead systems, the leads and extensions must be routed adjacent to each other. Patients implanted with nonadjacent leads may experience changes in perceived stimulation levels caused by theft detectors and screening devices (see Figure 13).

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.

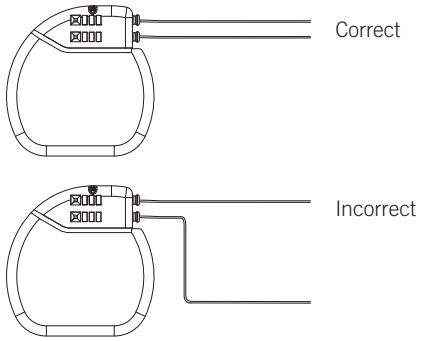


FIGURE 13

3. Withdraw the tunneling tool from the cannula sleeve. Leave the sleeve within the subcutaneous tunnel.
4. Carefully pass the end of the lead through the cannula sleeve from the anchor site to the receiver/ IPG pocket (see Figure 14). If a two-step tunneling procedure is used, pass the lead to the midway incision site and then to the receiver/IPG pocket. Multiple leads may be placed within the same tunnel.

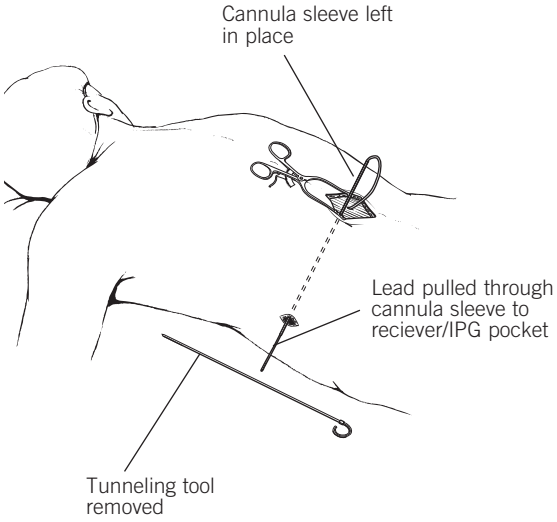


FIGURE 14

5. Withdraw the outer sleeve from the subcutaneous tunnel by passing it over the lead, taking care to avoid traction on the lead. Do not leave excessive lead anywhere but in large loops placed behind the receiver/IPG in its pocket.

Connecting the Leads

1. If needed, clean the end of the lead with sterile deionized water or sterile water for irrigation and dry completely. Use clean gloves and ensure that all body fluids and saline residue are cleaned from the end of the lead. This is important to prevent corrosion and potential failure of the system.

⚠ **WARNING:** Exposure of the internal receiver/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.

NOTE: All 16-electrode leads have two lead bodies exiting the paddle. The lead body exiting from the left side of the paddle (when the electrodes are face down) is connected to electrodes 1–8. This lead body (1-8) is distinguished by a "differentiation" band (see Figure 15) near the connector end of the lead (available only on the Lamitrode Tripole™ 16 and Penta™ leads).

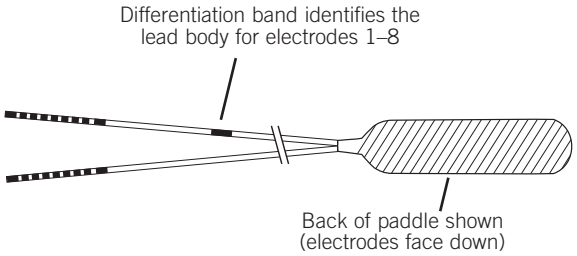


FIGURE 15

2. For lead connection instructions, consult the appropriate neurostimulation IPG/RF system clinician's manual.

Customer Service Information

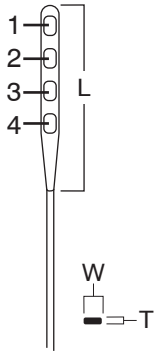
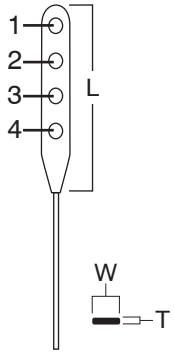
For help with a St. Jude Medical Neuromodulation Division product, including technical service or repairs, contact Customer Service using the following information.

St. Jude Medical Neuromodulation Division
6901 Preston Road
Plano, TX 75024
USA

800 727 7846
972 309 8000
972 309 8150 Fax

Appendix A: Paddle Lead Specifications

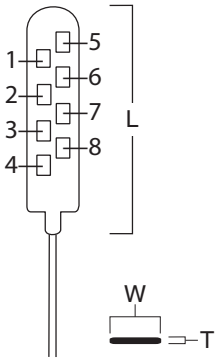
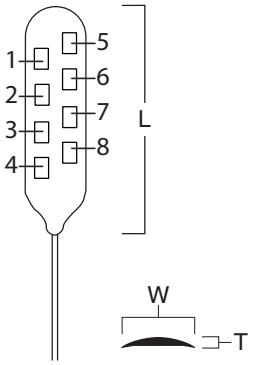
Four-Channel Leads

Description		Lamitrode™ S-4	Lamitrode 4
			
Lead Length and Model	30 cm	3243	—
	60 cm	3246	3240
	90 cm	3266	—
Lead Diameter		1.4 mm	1.4 mm
Electrodes			
Number		4	4
Configuration		1 column of 4	1 column of 4
Length		4 mm	4 mm
Width		2.5 mm	4 mm
Longitudinal Spacing		3 mm	6 mm
Array Length		25 mm	35 mm
Array Width		2.5 mm	4 mm
Paddles			
Length (L, includes taper)		39 mm	51 mm
Width (W)		4 mm	8 mm
Thickness (T)		1.8 mm	1.7 mm
Lead Resistance (for all lengths)		< 10 ohms	< 10 ohms

Each kit listed above includes the following:

- 1 directions for use
- 1 lead
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool (Model 1112)
- 1 stylet, straight (Model 1121, 1123, or 1125), S-4 only
- 1 stylet, curved (Model 1122, 1124, or 1126), S-4 only
- 1 trial cable (Model 3009)

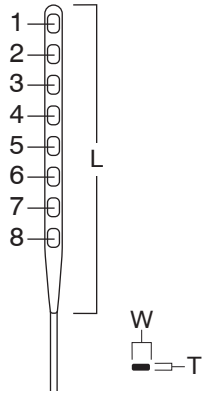
Eight-Channel Leads

Description		Lamitrode 44	Lamitrode 44C
Electrodes are shown facing down (anteriorly).			
Lead Length and Model	60 cm	3244	3245
	90 cm	3262	—
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 above includes the following:

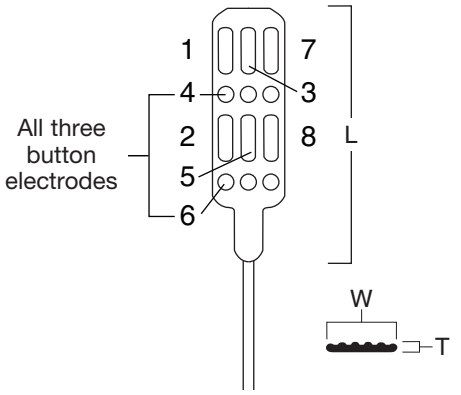
- 1 directions for use
- 1 lead
- 1 lead blank*
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool (Model 1112)
- 1 trial cable (Model 3009)

** The lead blank is not included with the Lamitrode 44 lead (Models 3244 and 3262).*

Description		Lamitrode S-8
		
Lead Length and Model	30 cm	3283
	60 cm	3286
	90 cm	3268
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 above includes the following:

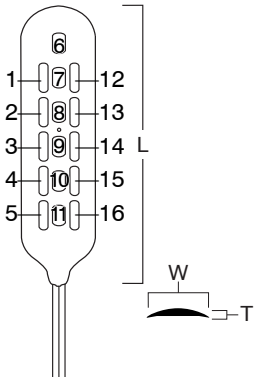
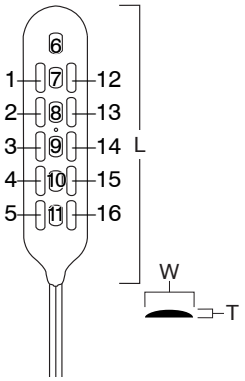
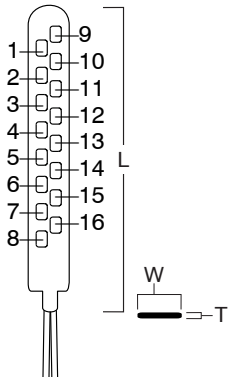
- 1 directions for use
- 1 lead
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool (Model 1112)
- 1 stylet, straight (Model 1121, 1123, or 1125)
- 1 stylet, curved (Model 1122, 1124, or 1126)
- 1 trial cable (Model 3009)

Description		Exclaim™
Electrodes are shown facing down (anteriorly).		
Lead Length and Model	60 cm	3224
Lead Diameter		1.4 mm
Electrodes		
Number of Channels		8
Configuration		3 columns with rows that alternate between rectangular and button electrodes
Length		Rectangular: 5.8 mm Button: 2.2 mm (diameter)
Width		Rectangular: 1.8 mm
Longitudinal Spacing		1.6 mm
Lateral Spacing		1 mm
Array Length		21 mm
Array Width		8 mm
Paddles		
Length (L, includes taper)		33 mm
Width (W)		9.5 mm
Thickness (T)		2 mm
Lead Resistance (for all lengths)		< 10 ohms

Each kit listed above includes the following:

- 1 directions for use
- 1 lead
- 1 lead blank
- 1 torque wrench (Model 1101)
- 1 lead anchor, butterfly (Model 1105)
- 1 lead anchor, long (Model 1106)
- 1 tunneling tool (Model 1112)
- 1 trial cable (Model 3009)

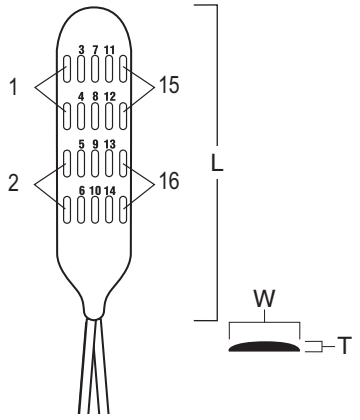
Sixteen-Channel Leads

Description		Tripole™ 16C	Tripole 16	Lamitrode 88
Electrodes are shown facing down (anteriorly).				
Lead Length and Model	60 cm	3214	3219	3288
Lead Diameter		1.4 mm	1.4 mm	1.4 mm
Electrodes				
Number		16	16	16
Configuration		1 center column with 2 offset columns on either side	1 center column with 2 offset columns on either side	2 offset columns of 8
Length		Center column: 4 mm Outer column: 6 mm	Center column: 4 mm Outer column: 6 mm	4 mm
Width		Center column: 2.5 mm Outer column: 1.8 mm	Center column: 2.5 mm Outer column: 1.8 mm	2.5 mm
Longitudinal Spacing		Center column: 3 mm Outer column: 1 mm	Center column: 3 mm Outer column: 1 mm	3 mm
Lateral Spacing		1 mm	1 mm	1 mm
Array Length		40 mm	40 mm	56 mm
Array Width		8 mm	8 mm	6 mm
Paddles				
Length (L, includes taper)		57 mm	57 mm	79 mm
Width (W)		13 mm	10 mm	10 mm
Thickness (T)		2 mm tapering to 0.4 mm	2 mm tapering to 0.4 mm	1.7 mm
Lead Resistance (for all lengths)		< 10 ohms	< 10 ohms	< 5 ohms
Differentiation Band Signifies		Not available	Electrodes 1-8	Not available

Each kit listed above includes the following:

- 1 directions for use
- 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 (Model 1112)
- 2 trial cables (Model 3009)

* *The lead blank is not included with the Lamitrode 88 lead (Model 3288)*

Description		Penta, 3 mm
Electrodes are shown facing down (anteriorly).		
Lead Length and Model	60 cm	3228
Lead Diameter		1.4 mm
Electrodes		
Number of Channels		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 above includes the following:

- 1 directions for use
- 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 (Model 1112)
- 2 trial cables (Model 3009)

Notes

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