Percutaneous Lead Kit

Models 3143, 3146, 3149, 3153, 3156, 3159, 3183, 3186, 3189

Clinician's Manual

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

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

Indications for Use

This neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

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.

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 St. Jude 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 in adjacent tunnels. 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 St. Jude 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 St. Jude 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

St. Jude 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. Percutaneous leads are designed for introduction into the epidural space using a special needle. The lead assembly consists of 4 or 8 cylindrical electrodes spaced at precise intervals. Percutaneous leads are supplied with a stylet to aid in positioning.

Package Contents

The percutaneous lead kits contain the following:

Guide wire. Used to establish an appropriate pathway for the lead in the epidural space. The guide wire is 50 cm (20 in) in length.

Lead anchor. Made of silicone and used to secure the lead to connective tissue for stability.

Tunneling tool. Used to create a subcutaneous tunnel to route the lead to the IPG site.

Epidural needle. Special 14-gauge needle designed for insertion of the percutaneous leads into the epidural space.

Introde-AK™ lead introducer. Radiopaque sheath designed to facilitate the insertion of the percutaneous lead into the epidural space and placement at the appropriate site.

Lead stylet. Inserted in the lead body to assist in steering and positioning.

Torque wrench. Used to tighten the setscrew on the connector assemblies of the IPG and extension.

Directions for Use

Carefully review the following suggested guidelines for implantation of percutaneous leads. If implanting multiple leads, repeat the appropriate steps for each lead. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

Placing Percutaneous Leads

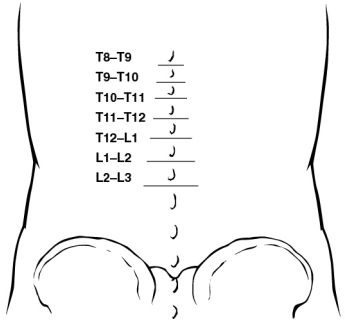
Percutaneous leads are designed for introduction into the dorsal epidural space using a special needle, a guide wire, and the optional Introde-AK™ lead introducer. Each percutaneous lead is packaged with the accessories required to place the lead percutaneously. See Appendix A (page 15) for specifications.

The following are suggested guidelines for placing percutaneous leads. For these instructions, use fluoroscopy as needed to assist in placing a device.

1. Externally measure and determine the length of lead required to extend from the appropriate spinal level to the predetermined location of the implanted IPG. The appropriate vertebral level for needle entry should be identified and marked (see the following figure) to allow approximately 20 cm (8 in) of the lead to lie in the epidural space. This will facilitate stabilization of the lead and electrodes following implantation. Typical entry levels for lead target sites include the following.

Figure 1. Suggested vertebral entry levels based on target sites

Lead Target Site	Entry Level
T8-T9	T11-T12
T9-T10	T12-L1
T10-T11	L1-L2
T11-T12	L2-L3
T1-T2	T4-T6
C3-C5	T1-T3
C1-C2	C6-C7



CAUTION: Handle the lead with care. 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.

2. After appropriate skin prepping, draping, and injection of local anesthetic, insert the epidural needle. A paramedian approach is recommended, and the needle angle should not be greater than 30° (see the following figures). Angles greater than 30° increase the risk of damage to the lead during insertion and manipulation.

Figure 2. Insert epidural needle using paramedian approach

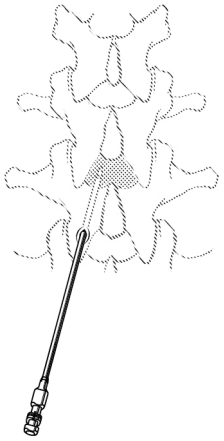
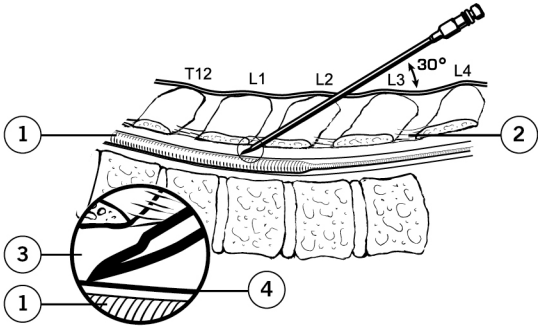


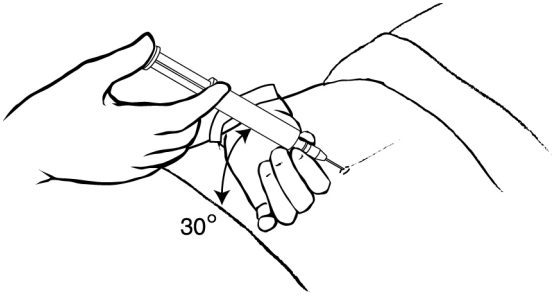
Figure 3. Insert needle at an angle of 30° or less



1. Spinal cord
2. Ligamentum flavum
3. Epidural space
4. Dural sac

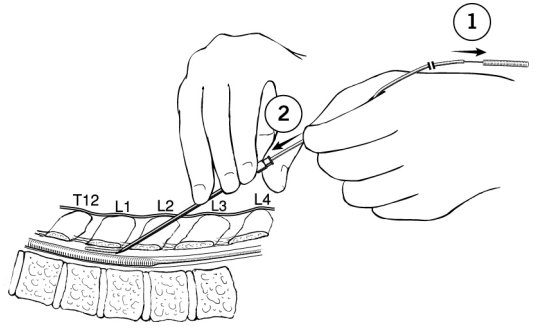
3. Confirm entry into the epidural space using standard methods such as the loss-of-resistance technique (see the following figure).

Figure 4. Use loss-of-resistance technique to confirm entry



4. Under fluoroscopic guidance, insert the guide wire, with the stylet slightly withdrawn, through the needle into the epidural space (see the following figure). Withdrawing the stylet slightly increases the flexibility of the guide wire tip and minimizes the risk of a dural tear.

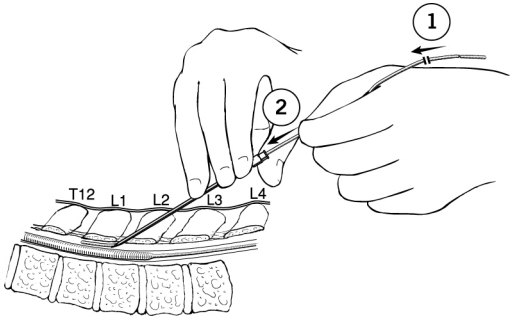
Figure 5. Insert the guide wire



1. Slightly withdraw the stylet
2. Insert the guide wire

5. Once the tip of the guide wire is within the epidural space and slightly beyond the distal tip of the needle, fully reinsert the stylet and advance the guide wire to the desired target (see the following figure). When advancing the guide wire, it is very important to do so under fluoroscopic guidance and to manipulate the guide wire carefully to minimize the risk of dural tear.

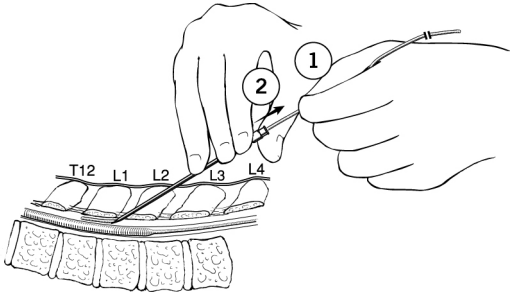
Figure 6. Advance the guide wire to the target



1. Fully insert the stylet
2. Advance the guide wire

6. If using the lead introducer to place the lead (optional), remove the needle using the hold-and-push technique, leaving the guide wire in the epidural space (see the following figure).

Figure 7. If using the lead introducer (optional), remove the needle

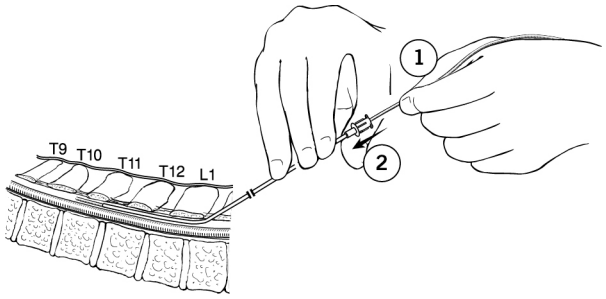


1. Hold the guide wire
2. Remove the needle

7. If using the lead introducer (optional), insert the lead introducer over the proximal end of the guide wire at the same angle (no more than 30°) as the previously placed needle (see the following figure). Advance the lead introducer into the epidural space under fluoroscopy to the target position.

   NOTE: It may be necessary to rotate the lead introducer as it passes through the ligamentum flavum.

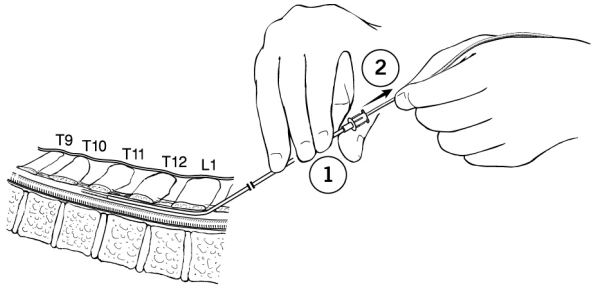
Figure 8. If using the lead introducer (optional), insert the lead introducer



1. Hold the guide wire
2. Insert the lead introducer

8. If using the lead introducer (optional), after the lead introducer reaches the desired spinal level for electrode placement, remove the guide wire (see the following figure).

Figure 9. If using the lead introducer (optional), remove the guide wire

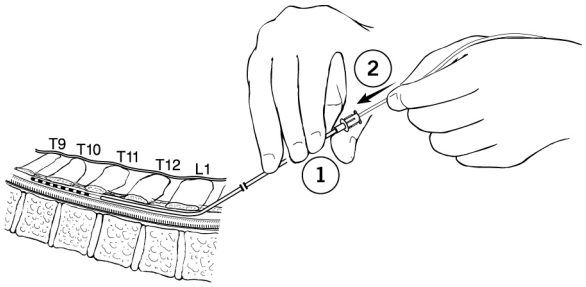


1. Hold the lead introducer
2. Remove the guide wire

9. Insert the lead through the lumen of the needle or the lead introducer (whichever is in place), and advance the lead to the target site under fluoroscopic control (see the following figure). To aid placement, percutaneous leads feature a removable stylet that provides added stiffness and facilitates control.

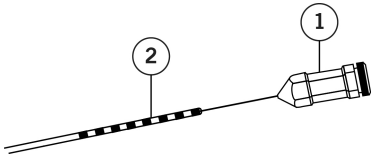
   WARNING: If pulling the lead back through the needle, use caution to avoid severe damage to the lead due to shearing from the needle's tip.

Figure 10. Insert and advance the lead to the target



1. Hold needle or lead introducer
2. Advance the lead

Figure 11. Use the stylet to help place the lead



1. Stylet
2. Terminal end of lead

10. Through fluoroscopic evaluation, confirm that the electrodes extend beyond the distal tip of the lead introducer or needle. If they do not, advance the lead or withdraw the lead introducer as necessary to expose the electrodes.
11. Perform intraoperative testing. See the clinician's manual for the appropriate trial stimulator for instructions.

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 12. Butterfly anchor

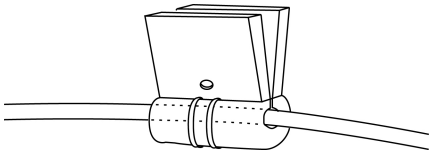
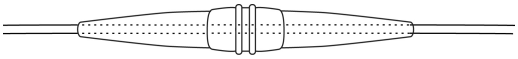


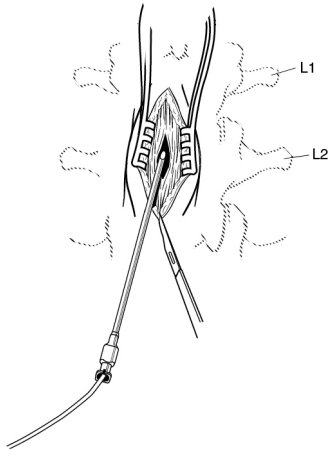
Figure 13. Long anchor



1. Centered on the needle or lead introducer, make a longitudinal incision approximately 3 to 7 cm (1.2 to 2.8 in) in length to the depth of the interspinous ligament. Use extreme care not to cut the lead introducer or the lead (see the following figure).

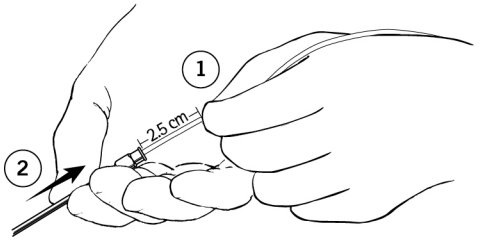
   WARNING: Use extreme caution when using sharp instruments around the lead to avoid damage to the lead body.

Figure 14. Make a longitudinal incision



2. Grasp the lead with two fingers and carefully remove the stylet from the lead.
3. If needed, carefully remove the lead introducer or needle using the hold-and-push technique, leaving the lead in place as follows: Grasp the lead with two fingers, approximately 2.5 cm (1 in) away from the hub of the lead introducer or needle. With the other hand, gently push the lead introducer or needle up over the lead body until the hub and fingers meet. Repeat this procedure until it clears the tissue. Once clear, grasp the lead as close to the tissue as possible, and slowly remove the lead introducer or needle over the lead with the other hand (see the following figure).

Figure 15. Carefully remove the needle or lead introducer

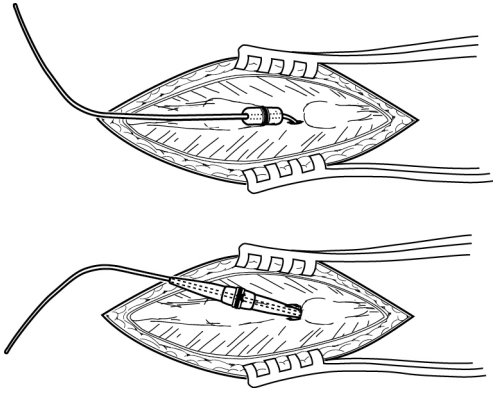


1. Hold lead 2.5 cm from needle or lead introducer
2. Remove needle or lead introducer

4. Check the lead position by fluoroscopic examination, and reposition the lead if necessary.
5. 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 implanting multiple leads, tag the leads with ligature so that their position can be identified later.

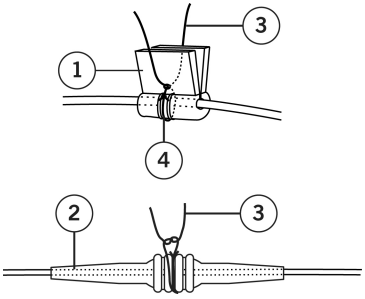
   WARNING: Care should be taken not to bend the connector end of the lead when passing the long anchor over it.

Figure 16. Insert the anchor on the lead



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

Figure 17. Secure the anchor and the lead



1. Butterfly anchor
2. Long anchor
3. Suture to interspinous ligament
4. Tie suture tightly

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.**
- **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.**

7. 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.

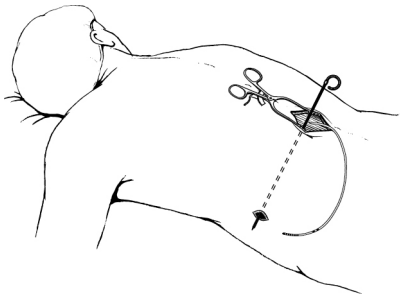
The following steps outline the suggested procedure to tunnel from the lead anchor site to the IPG pocket:

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.

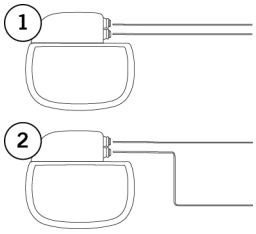
1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

Figure 18. Suggested tunnel to the IPG pocket



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:

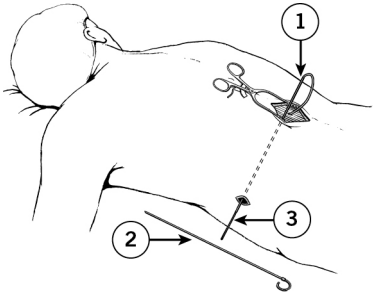


1. Correct
2. Incorrect

   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 19. Sequence of tunneling steps



1. Leave cannula sleeve in place
2. Remove tunneling tool
3. Pull lead through cannula sleeve to IPG pocket

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.

Disposing of Explanted Components

Explanted St. Jude Medical™ components should be returned to St. Jude 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 St. Jude Medical representative or Technical Support.

Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

For additional assistance, call your local St. Jude 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

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

Product Materials

Table 2. Product materials for percutaneous leads

Component	Material
Electrodes and terminal end contacts	Platinum iridium
Insulation	Polyurethane

Lead Specifications

Table 3. Percutaneous lead specifications

Description		Octrode™	Quattrode™ 3/4	Quattrode™ 3/6
				
Lead length and model	30 cm	3183	3143	3153
	60 cm	3186	3146	3156
	90 cm	3189	3149	3159
Lead diameter		1.4 mm	1.4 mm	1.4 mm
Electrodes				
Number		8	4	4
Length		3 mm	3 mm	3 mm
Longitudinal spacing		4 mm	4 mm	6 mm
Center-to-center spacing		7 mm	7 mm	9 mm
Array length		52 mm	24 mm	30 mm
Lead resistance (for all lengths)		< 10 ohms	< 10 ohms	< 10 ohms

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

- 1 lead
- 1 torque wrench (Model 1101)
- 1 guide wire for percutaneous leads (Model 1102)
- 1 Introde-AK™ lead introducer (Model 1103)
- 1 anchor, butterfly (Model 1105)
- 1 anchor, long (Model 1106)
- 1 tunneling tool, 12 in (Model 1112)
- 1 epidural needle, 14 gauge, 4 in (Model 1114)
- 1 stylet, straight (Model 1121, 1123, or 1125)
- 1 stylet, curved (Model 1122, 1124, or 1126)

Appendix B: Regulatory Statements

This section contains regulatory statements about your product.

Declaration of Conformity

Hereby, St. Jude Medical declares that this medical device is in compliance with the essential requirements and other relevant provisions of AIMD directive 90/385/EEC. For a copy of the declaration of conformity, please contact Technical Support.

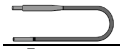
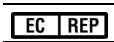
Appendix C: Symbols and Definitions

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

Table 4. Symbols and definitions

Symbol	Definition
	Caution, consult accompanying documents
	Consult instructions for use
	Follow instructions for use on this website
	Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	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

Table 4. Symbols and definitions

Symbol	Definition
	Manufacturer
	Contents quantity
	One lead
	Accessories
	Serial number
	Batch code
	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, St. Jude 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 5. Additional symbols for product labels

Symbol	Definition
Torque Wrench	Torque wrench
Guide Wire for Percutaneous Leads	Guide wire for percutaneous leads
Lead Introducer	Lead introducer
Lead Anchor, Butterfly	Lead anchor, butterfly
Lead Anchor, Long	Lead anchor, long
Tunneling Tool, 12"	Tunneling tool, 12 in (30 cm)
Epidural Needle, 14 gauge, 4" (10cm)	Epidural needle, 14 gauge, 4 in (10 cm)
Epidural Needle, 14 gauge, 6" (15cm)	Epidural needle, 14 gauge, 6 in (15 cm)
Tunneling Tool, 20"	Tunneling tool, 20 in
Stylet, Straight, 30 cm	Stylet, straight, 30 cm
Stylet, Bent, 30cm	Stylet, bent, 30 cm

Table 5. Additional symbols for product labels

Symbol	Definition
Stylet, Straight, 60cm	Stylet, straight, 60 cm
Stylet, Bent, 60cm	Stylet, bent, 60 cm
Stylet, Straight, 90cm	Stylet, straight, 90 cm
Stylet, Curved, 90cm	Stylet, curved, 90 cm
Lead 3/4 mm, 30 cm	Lead, 3/4 mm, 30 cm
Lead, 3/4 mm, 60 cm	Lead, 3/4 mm, 60 cm
Lead, 3/4 mm, 90 cm	Lead, 3/4 mm, 90 cm
Lead, 3/6 mm, 30 cm	Lead, 3/6 mm, 30 cm
Lead, 3/6 mm, 60 cm	Lead, 3/6 mm, 60 cm
Lead, 3/6 mm, 90 cm	Lead, 3/6 mm, 90 cm
Lead Kit, 30cm Length	Lead kit, 30 cm length
Lead Kit, 60cm Length	Lead kit, 60 cm length
Lead Kit, 90cm Length	Lead kit, 90 cm length

Appendix D: CE Mark Date

Table 6. Year in which CE mark was awarded

Model	Year
1101, 1102, 1103, 1105, 1106, 1112, 1114, 1116, 1120, 3143, 3146, 3153, 3156, 3183, 3186	1999
1121, 1122, 1123, 1124	2001
1125, 1126, 3149, 3159, 3189	2006

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Manufacturing Site:
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