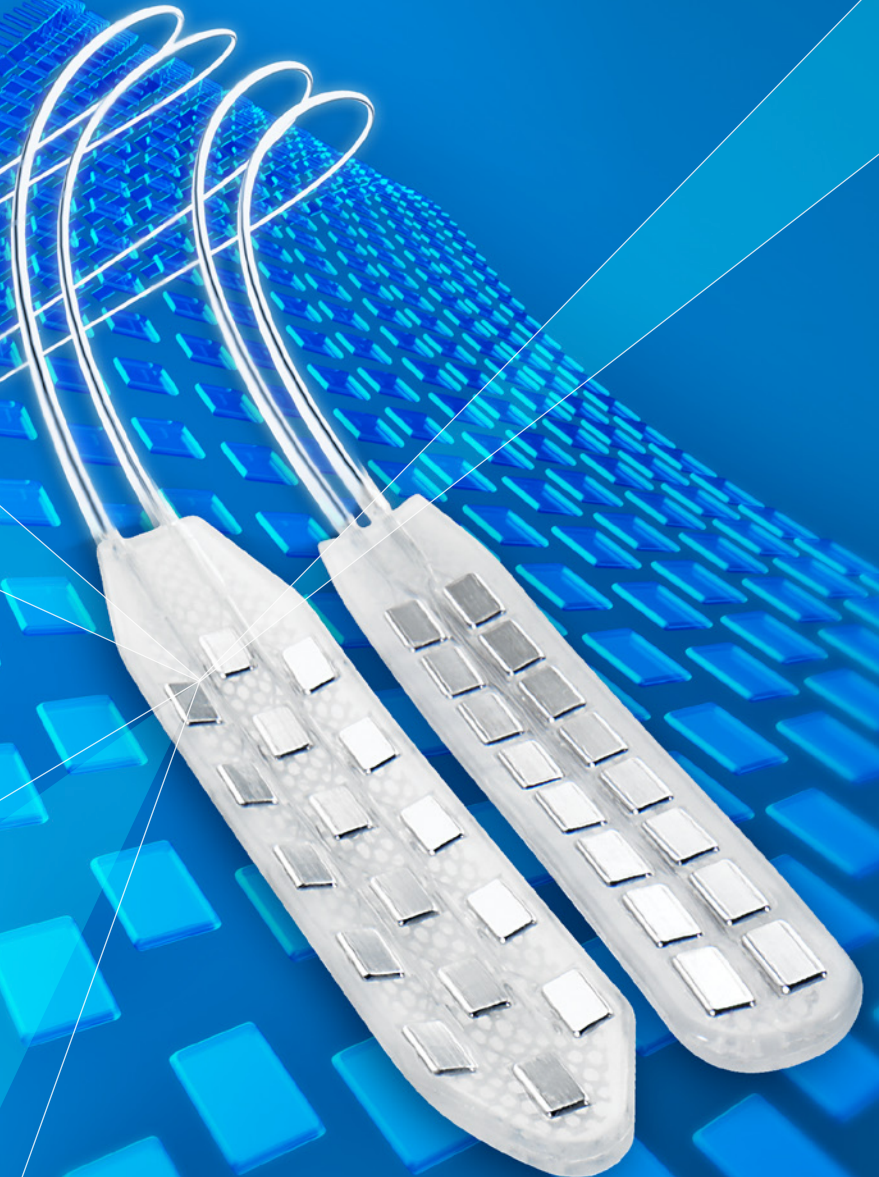




Surgical Lead Implantation Guide

NEUROSTIMULATION THERAPY FOR CHRONIC PAIN



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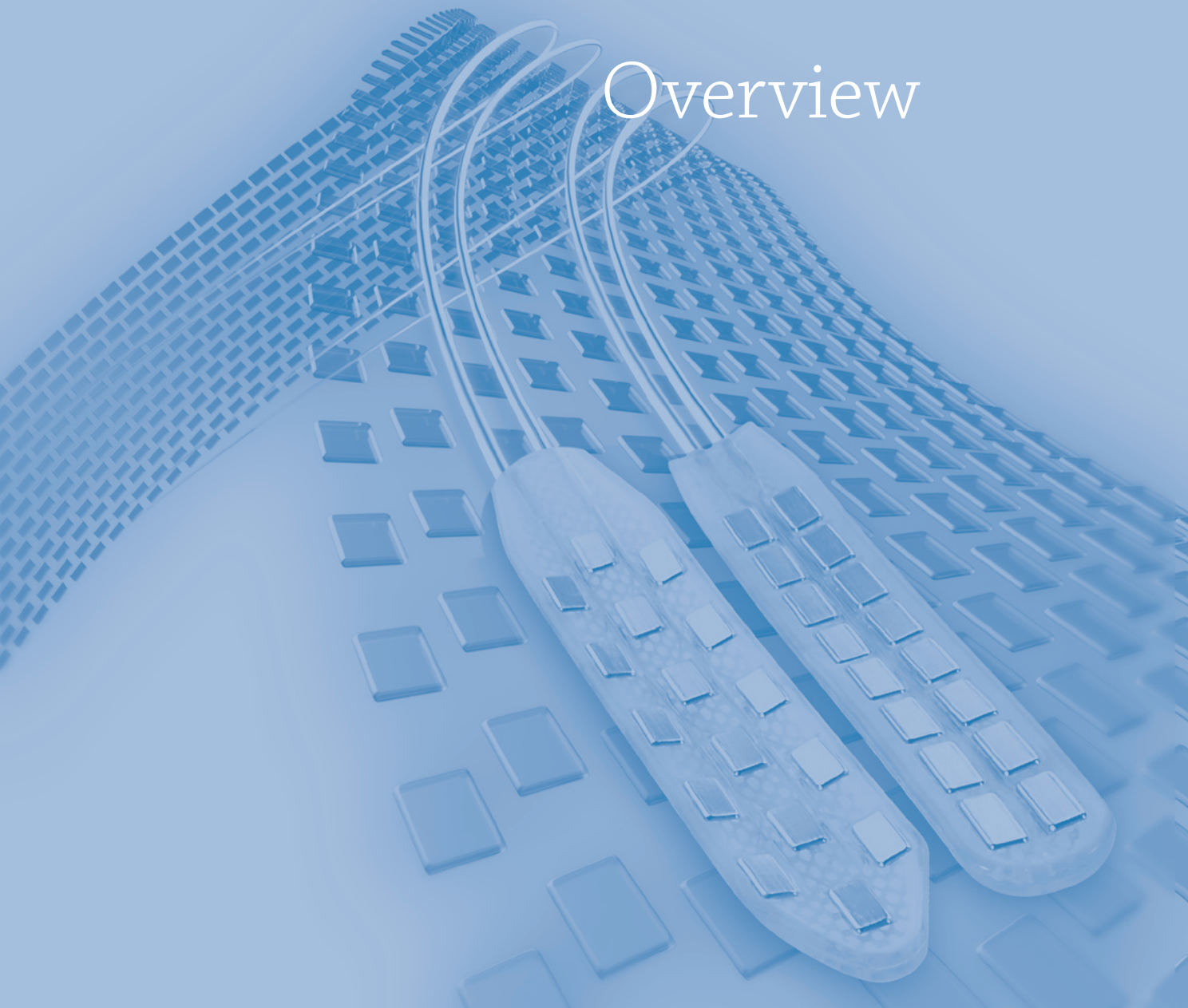
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1

Overview



Introduction

The Neurostimulation Therapy for Chronic Pain Surgical Lead Implantation Guide for 16-Electrode Leads is an educational guide to be used for physician education purposes only. See the product labeling for complete indications, contraindications, warnings, cautions, adverse events, and surgical procedures for specific components.

This guide presents one representative surgical procedure. The procedure starts with a neurostimulation trial using percutaneous leads and continues through a system implant using surgical leads. Although some physicians choose to use surgical leads for neurostimulation trials, a surgical lead trial procedure is not covered in this guide. Neurostimulation programming is also not covered.

The example procedure applies to the following components:

- Neurostimulation trial
 - » 1x8 percutaneous lead or 1x8 percutaneous trial stimulation lead
 - » External Neurostimulator (ENS) with snap-lid connector cable
- Neurostimulation system implant
 - » 65-cm Specify 5-6-5 or Specify 2x8 lead
 - » 30-cm Specify 5-6-5 or Specify 2x8 lead with two 1x8 extensions
 - » Restore, RestoreAdvanced, PrimeAdvanced, or RestoreUltra neurostimulator

Alternate leads, anchors, extensions, and neurostimulators are available through Medtronic.

Neurostimulation Therapy for Chronic Pain Overview

Neurostimulation for chronic pain is a therapy where low voltage electrical stimulation is delivered to targeted segments in the spinal cord area to inhibit the transmission of pain signals to the brain. The stimulation elicits a tingling sensation (paresthesia) in the corresponding dermatomes (FIGURE 1), with the goal of the stimulation paresthesia to fully cover the painful area.

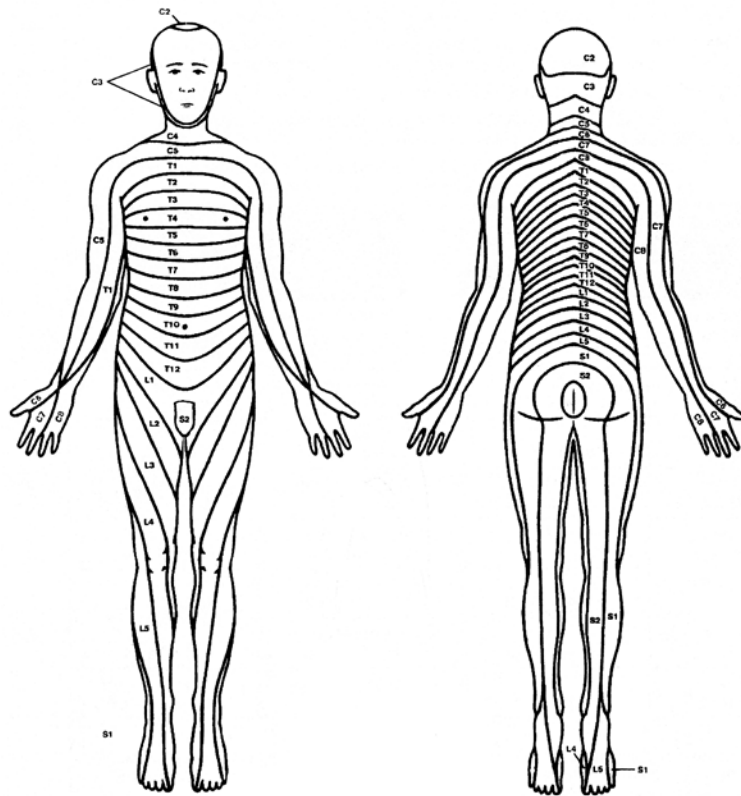


FIGURE 1

Dermatome map

Benefits

Benefits may include:

- Significant and sustained reduction in leg and back pain^{1,2,3}
- Improved ability to function^{1,2}
- Improved participation in activities of daily living^{2,3}
- Less oral pain medication⁴
- Safe and effective when used as directed
- Reversible—therapy can be turned off or, if desired, the neurostimulator can be surgically removed

Risks

Common adverse effects include:

- Lead movement resulting in a change in stimulation or loss of stimulation
- Intermittent stimulation
- Uncomfortable stimulation
- Pain at the neurostimulator site
- Programmer or data transmission problems

Serious adverse effects are possible, but occur less frequently and include:

- Postsurgical infection
- Hematoma or seroma developing in the area where the neurostimulator is implanted
- Spinal cord injury from incorrect surgical placement of the lead
- Device complications requiring surgery to relocate, revise, or replace system components

See [Important Safety Information](#) on page 83 and page 84 for more details.

1. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*. 2007;132:179-188.

2. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery*. 2008;63: 762-770.

3. Turner JA, Loseser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain*. 2004;108:137-147.

4. Ohnmeiss DD, Rashbaum RF, Bogdanffy GM. Prospective outcome evaluation of spinal cord stimulation in patients with intractable leg pain. *Spine*. 1996;21:1344-1350.

Indications for Neurostimulation for Chronic Pain

A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system 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 conditions:

- Failed back syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative disk disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex regional pain syndrome (CRPS), reflex sympathetic dystrophy (RSD), or causalgia

Patient Selection

Identifying appropriate candidates is critical for increased patient satisfaction and for therapy success. Following standard pain evaluation practices, relevant information regarding the patient's pain history is collected. The patient's pain history is then evaluated in combination with criteria that includes:

- Chronic, intractable pain for more than 3 months
- Lack of adequate relief from more conventional treatments
- Objective evidence of pathology
- Initial or further surgical intervention not indicated
- No contraindications to therapy or surgery exist
- Patient can properly operate system
- Patient understands therapy risks
- Therapy goals have been established
- Satisfactory results from neurostimulation trial
- No untreated substance abuse
- Psychological clearance obtained
- 18 years of age or older
- Patient is not pregnant

Neurostimulation Trial and Evaluation

A typical neurostimulation system implant with surgical leads is completed in two stages. The first stage is a 3- to 10-day neurostimulation trial. The neurostimulation trial system described in this guide uses percutaneous leads and an External Neurostimulator (ENS). Some physicians use surgical leads for the trial.

To prepare for a neurostimulation trial using percutaneous lead(s), one or more percutaneous lead(s) are placed into the epidural space. The clinician programs the portable ENS to generate the electrical pulses that produce the desired stimulation.

During the trial, the patient uses the neurostimulation trial system while completing daily activities. In some cases, the patient can use a patient control device to change some stimulation settings within physician-programmed limits.

Throughout the trial, the ENS collects patient use data. The patient also records activities, stimulation settings, and degree of pain relief in a trial log. After the trial, the results are evaluated to determine if the patient is a candidate for the second stage, a neurostimulation system implant.

Neurostimulation System Components

In a neurostimulation system, the following components are implanted:

- **Neurostimulator**—Rechargeable or nonrechargeable implanted power source that generates electrical pulses according to programmable stimulation parameters and features.
- **Lead**—A set of thin wires with a protective coating and electrodes near the tip (percutaneous lead) or on a paddle (surgical lead). The electrodes transmit the electrical pulses to the stimulation site.
- **Extension**—A set of thin wires with a protective coating that connects the neurostimulator to the lead (not required for all neurostimulation systems).

Additional components are used during a neurostimulation trial or to program, control, and maintain an implanted or trial neurostimulation system:

- External Neurostimulator (ENS)—External, programmable neurostimulator used during intraoperative lead placement and during the neurostimulation trial. The ENS produces comparable paresthesia to the Restore, RestoreAdvanced, PrimeAdvanced, and RestoreUltra neurostimulators when set to the same parameter settings.
- Clinician programmer—Handheld programmer used by the clinician to program all stimulation parameters and features.
- Patient programmer—Handheld programmer used by the patient to:
 - » Turn the neurostimulator on and off.
 - » Make adjustments to stimulation parameters within physician-prescribed limits.
- Battery Charger—Portable recharger used by the patient to charge the neurostimulator battery (applicable in rechargeable neurostimulation systems).

Multidisciplinary Treatment Team

Whether neurostimulation therapy is being prescribed and implanted in a comprehensive pain center or through a network of referrals, a multidisciplinary team should be established.

The team members include:

- Referring physician team
- Implanting physician team
- Psychologist—Before the trial evaluation, the psychologist can:
 - » Help patient specify clear goals
 - » Reinforce realistic pain relief expectations
 - » Administer and interpret a psychological assessment
- Patient Management Coordinator (PMC)—Preferably trained as a clinical nurse or nurse practitioner, the PMC coordinates:
 - » Patient evaluation and education
 - » Pain clinic support
 - » Ongoing patient management and outcome tracking
- Other team members may include:
 - » Physician assistants
 - » Physical therapists
 - » Psychiatrists
 - » Occupational therapists
 - » Vocational counselors

Patient Education

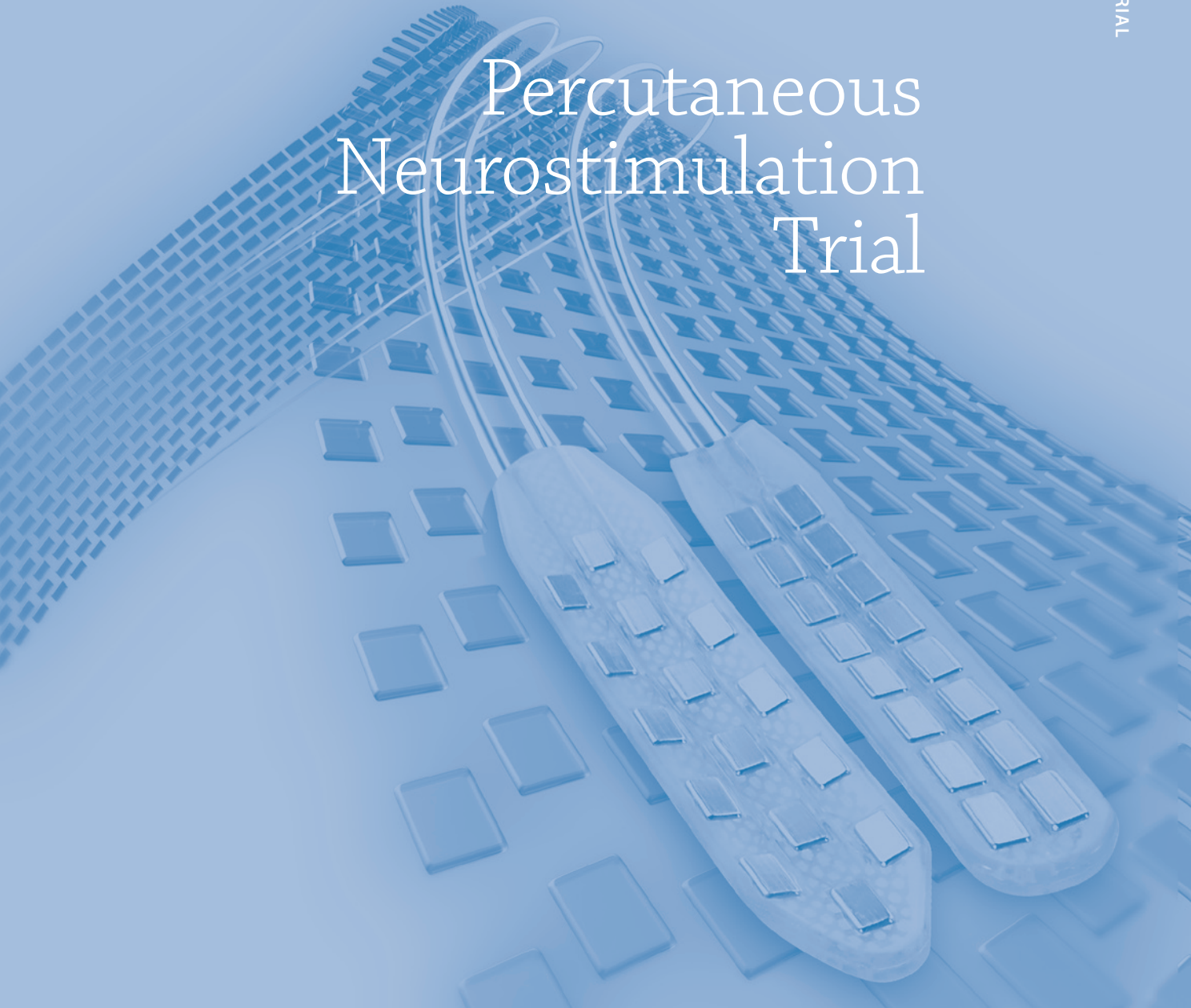
Thorough preoperative and postoperative patient education is crucial to the long-term success of neurostimulation therapy. In addition to standard preoperative and postoperative patient education topics, the patient, family, and caregiver should be educated on topics including the neurostimulation trial and neurostimulation system implant procedure, risks and benefits, device operation, device maintenance, and patient activity restrictions. Medtronic produces a number of materials such as brochures, DVDs, and patient manuals to use in patient education.

Physician Training

Prescribing physicians should be experienced in the diagnosis and treatment of chronic intractable pain, and should be familiar with using the neurostimulation system. Implanting physicians should be experienced in epidural access procedures, trained in the use of neurostimulation devices, and thoroughly familiar with all product labeling.

2

Percutaneous Neurostimulation Trial



Percutaneous Neurostimulation Trial

The example procedure in this guide covers placing percutaneous lead(s) without an extension (percutaneous trial) and conducting intraoperative stimulation. A trial may also be completed using one or more percutaneous lead(s) with extension(s) or a surgical lead with extensions (buried lead trial).

Placing the Trial Stimulation Lead(s)

Lead placement is done under local anesthesia. Since the patient must interact during anesthesia, monitored anesthesia care (MAC) should be implemented according to physician judgment.

To place the lead(s), one or more percutaneous leads are introduced into the epidural space with the objective of positioning the electrodes near the spinal segment that innervates the targeted anatomical site. The proximal end of the lead(s) are externalized and temporarily anchored (e.g., with medical tape) at the skin exit site(s). The externalized end of the lead(s) are connected to a cable that is attached to an External Neurostimulator (ENS).

Intraoperative test stimulation is used to position the lead(s), select the electrodes, and select the initial parameter settings for stimulation. During intraoperative test stimulation, the patient responds to questions as to whether paresthesia covers the painful regions.

Conducting and Evaluating the Trial

During the 3- to 10-day neurostimulation trial, the patient uses the trial system while completing daily activities. In some cases, the patient can use a patient control device to change some stimulation settings within programmed limits.

The ENS collects patient use data. The patient also records activities, stimulation settings, and degree of pain relief in a trial log. The pain

management team uses the data collected by the ENS and the entries in the trial log to evaluate if the neurostimulation trial is successful and if the patient is a candidate for a neurostimulation system implant.

After the trial, the lead(s) from a percutaneous trial are removed.

The example procedure in this section uses the following components:

- One or more 1x8 percutaneous leads or 1x8 percutaneous trial leads

Alternate leads are available through Medtronic.

Preparing to Place the Trial Stimulation Leads

- 1 Place the patient in the prone position. For lumbar or thoracic lead placement, consider placing a pillow under the patient's abdomen in order to flex the spine.
- 2 Perform skin prep and drape the patient using standard sterile technique (FIGURE 2).

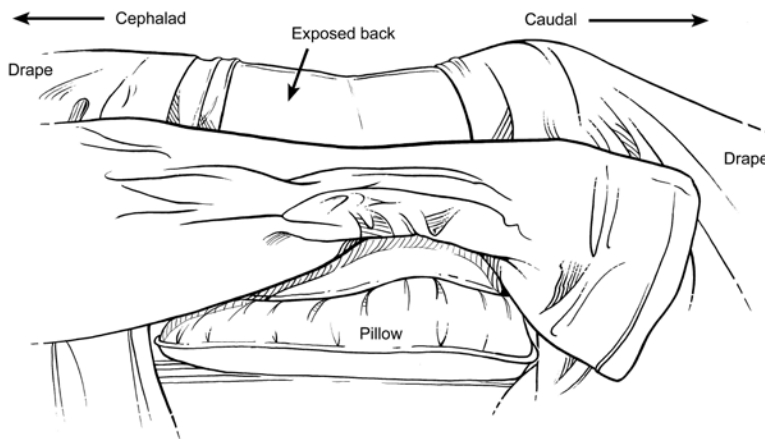


FIGURE 2

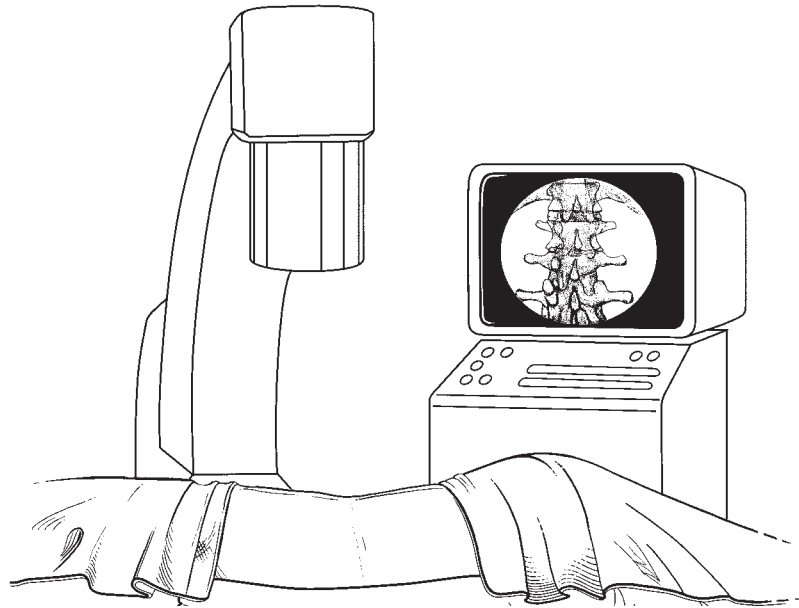
Positioning and draping the patient

- 3 Administer local anesthesia or conscious sedation for trial procedure. Monitor sedation closely to maintain comfort and to ensure that the patient can understand and respond during intraoperative test stimulation.
- 4 Administer prophylactic antibiotics according to standard medical practice or the standard protocol of the institution, as applicable.

- Using fluoroscopy, identify the appropriate spinal level and interlaminar access points for lead placement (FIGURE 3).

FIGURE 3

Identifying appropriate spinal level



NOTE:

Depending on the patient's pain pattern coverage requirements and anticipated changes in the patient's condition, it may be appropriate to implant multiple leads. Multiple leads may provide greater flexibility for covering the patient's pain pattern with paresthesia.

- 6 Mark the needle entry levels for the percutaneous trial on the skin (FIGURE 4).

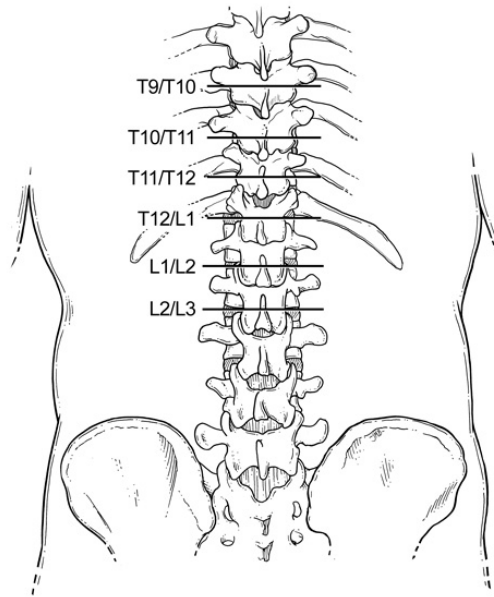


FIGURE 4

Marking the needle entry levels

- 7 Use an appropriate local anesthetic to anesthetize the skin and subcutaneous tissues at the needle entry site (FIGURE 5).

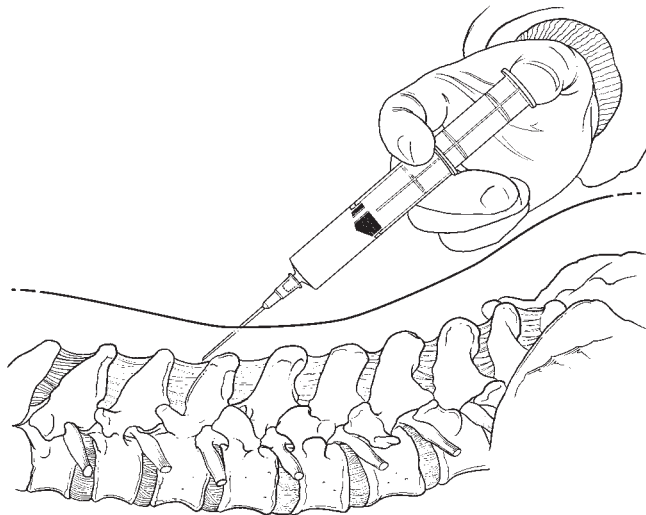


FIGURE 5

Anesthetizing the needle entry site

Placing the Trial Stimulation Leads

- 1 Using a paramedial approach and under fluoroscopy, insert the modified Tuohy needle (included in the lead package or from an accessory kit) into the epidural space at the appropriate angle (FIGURE 6).

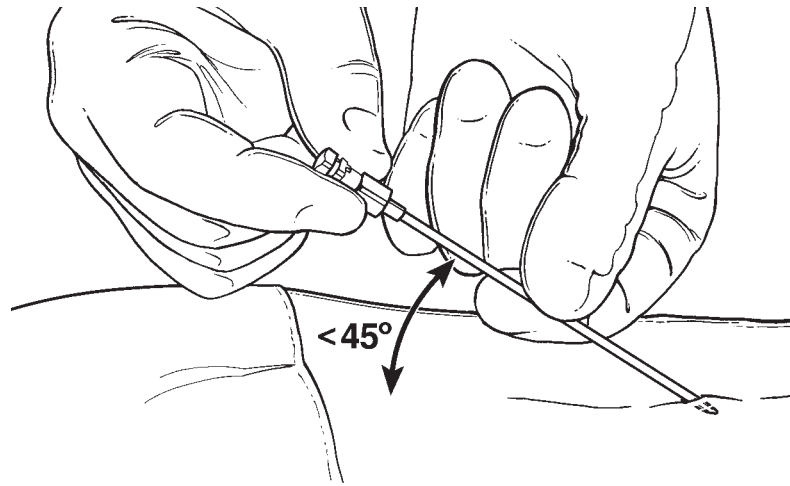


FIGURE 6

Inserting the modified Tuohy needle

⚠ WARNING:

As with any spinal procedure, the risk of serious injury to the patient (e.g., hemorrhage, hematoma, or paralysis) increases as location of the selected needle insertion site progresses up the vertebral column—from a lower risk at a lumbar location to a higher risk at a cervical location. Select a vertebral location that provides the widest and easiest access to the epidural space during needle insertion to reduce the risk of serious patient injury resulting from direct trauma to the spinal cord.

CAUTION:

To reduce the risk of lead damage that may result in intermittent stimulation or loss of stimulation, requiring additional surgery to replace the lead, use a shallow needle-insertion angle (45° or less) when inserting or withdrawing the needle into or out of the epidural space.

- 2 Confirm the needle location under fluoroscopy (FIGURE 7).

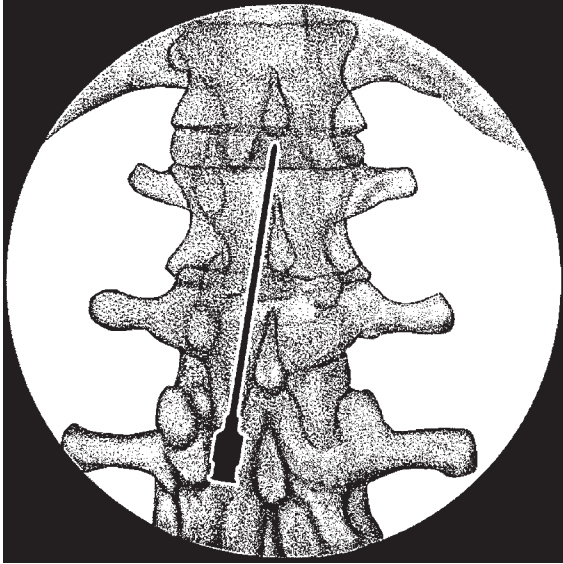


FIGURE 7

*Confirming the
needle location*

- 3 Rotate the needle so that the beveled edge faces cephalad.
- 4 Remove the needle stylet.
- 5 Advance the needle, confirming entry into the epidural space using a standard loss-of-resistance technique (FIGURE 8).

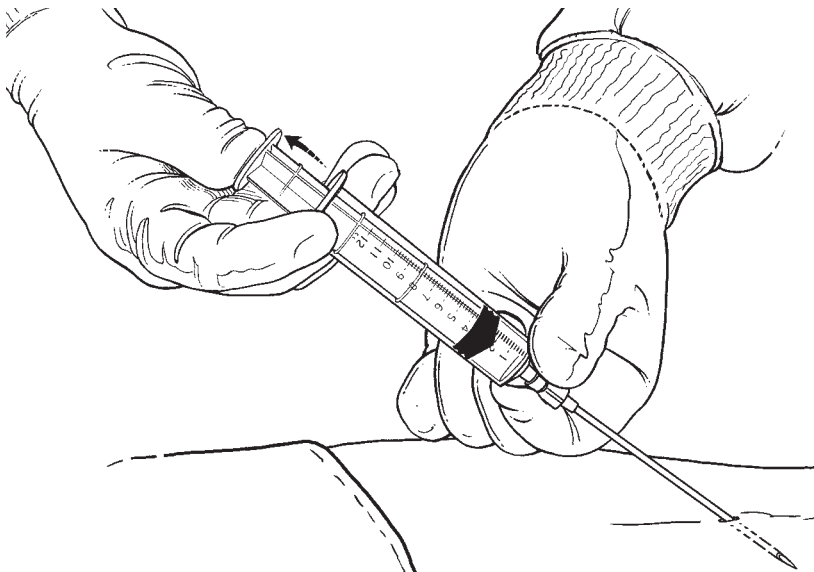


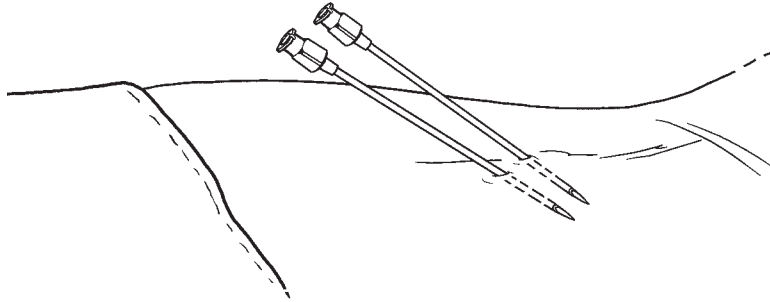
FIGURE 8

*Verifying entry into
the epidural space*

- 6 If you are placing two trial leads:
 - » Introduce the second needle one vertebral space below the first needle (FIGURE 9).

FIGURE 9

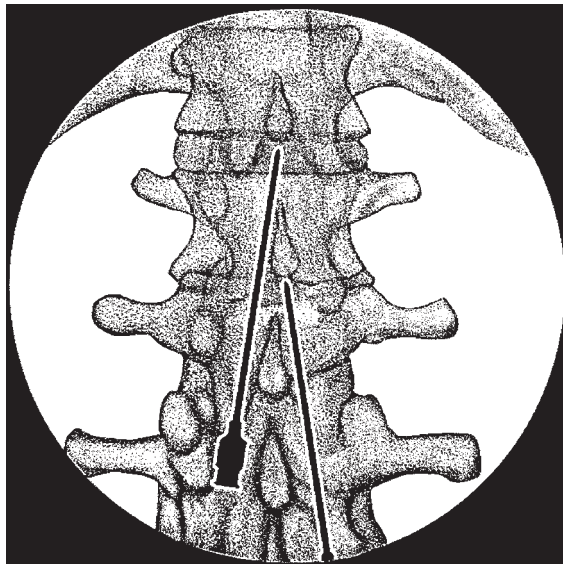
Inserting a second modified Tuohy needle for a dual lead implant



- » Stagger the needle tips or place them several vertebral spaces apart, depending on the position that produces the most effective paresthesia (FIGURE 10).

FIGURE 10

Confirming the location of the second needle



- 7 If desired, clear a path for the lead by inserting the guide wire through the needle, advancing the guide wire no farther than 1 to 3 cm past the needle tip (FIGURE 11).



FIGURE 11

*Introducing the
guide wire*

NOTE:

If the guide wire path deviates from the intended pathway, advancing the lead will be more difficult.

- 8 Remove the guide wire from the needle.
- 9 Using fluoroscopy, slowly insert the lead through the needle (FIGURE 12).

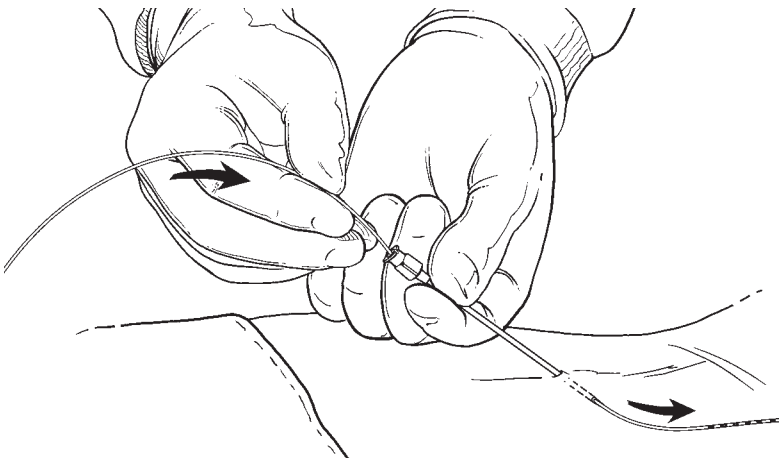


FIGURE 12

*Inserting the lead
through the needle*

- 10 Using the following technique, advance the lead to the initial target placement site. If needed, exchange the straight stylet for the curved stylet.
 - a. To control the lead, grasp the stylet handle or the lead (1 to 2 cm from the needle hub) and roll the lead between your thumb and forefinger (FIGURE 13), rotating the tip of the lead in the epidural space (FIGURE 14).

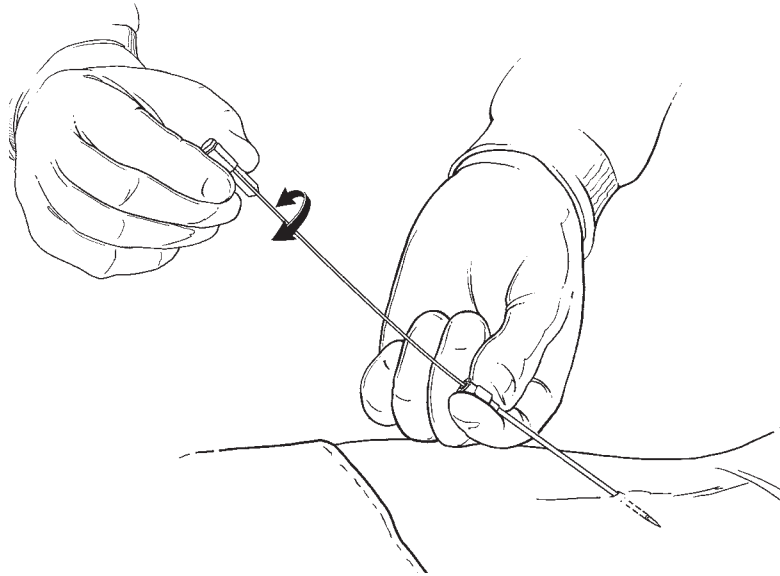


FIGURE 13

Rolling the stylet handle between the thumb and forefinger

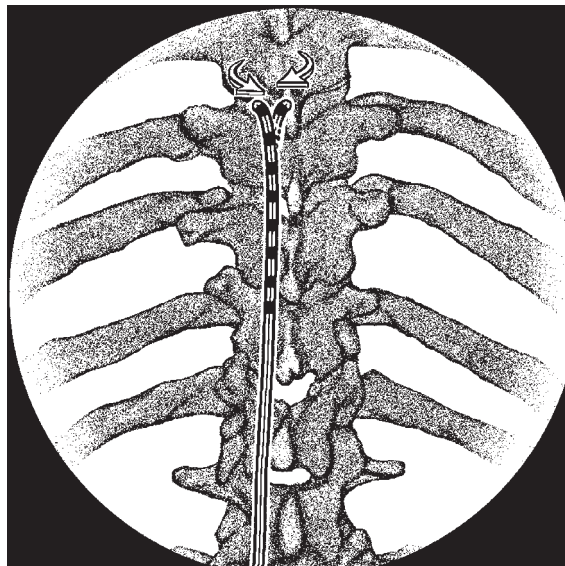


FIGURE 14

Rotating the lead tip in the epidural space

- b. Hold the needle hub and carefully advance the lead. Gently rotate the stylet handle to move the lead in the desired direction.
 - c. If you encounter resistance when using the curved stylet, exchange the curved stylet for the straight stylet and use short, firm movements to advance the lead.
- 11 Verify the lead position under fluoroscopy (anterior-posterior and lateral views) (FIGURE 15) and compare the lead tip location with the location that has the highest probability of paresthesia coverage.

NOTES:

- To increase lead stability, insert enough lead length to extend at least three vertebral bodies into the epidural space.
- Position the lead so that the center bipole electrodes (e.g., electrodes 3 and 4 on an octapolar lead) will be active. If axial lead migration occurs, effective stimulation may be regained through programming adjustments instead of surgical repositioning.

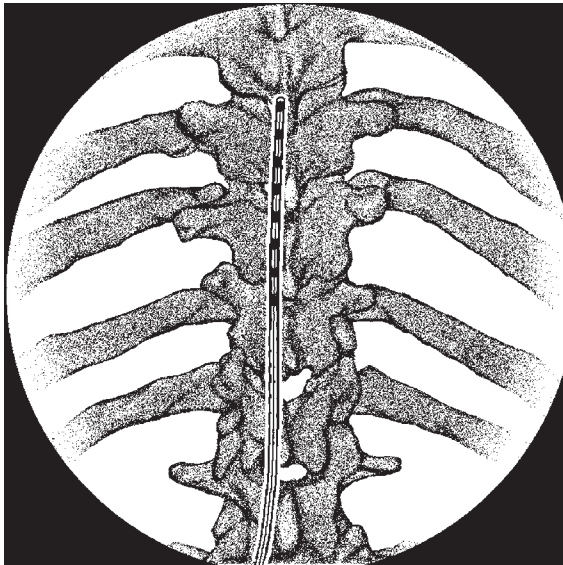


FIGURE 15

*Single lead in the epidural space**

* Single lead shown left of midline, but can be placed right of midline.

- 12 If you are using two trial leads, place the second lead in the desired location (FIGURE 16). The lead tips may be at the same vertebral level, or the tips may be staggered. Optimal lead positions will be determined during intraoperative test stimulation.

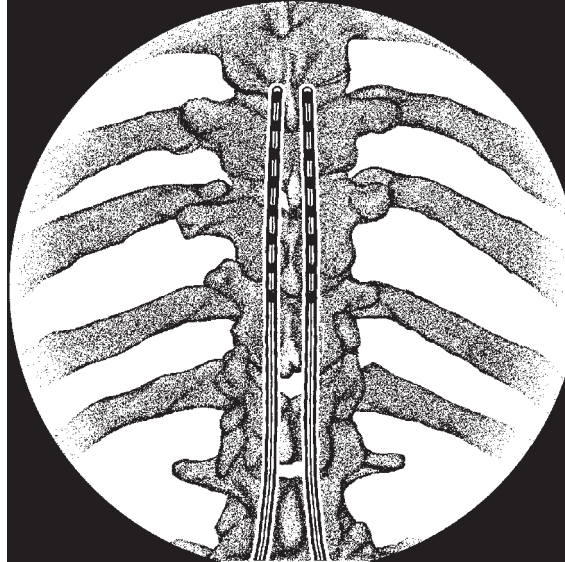


FIGURE 16

Dual leads in the epidural space

Preparing for Intraoperative Test Stimulation

To prepare for intraoperative test stimulation, the lead(s) are connected to an ENS using the snap-lid connector cable, then the ENS is attached to the clinician programmer.

Connecting the Snap-Lid Connector Cable

- 1 Open the snap-lid connector.
- 2 While holding the lead in place, disconnect the stylet handle from the lead (proximal end), and partially withdraw the stylet.
- 3 Align the proximal end of the lead against the inside end of an 8-contact lead groove (FIGURE 17), checking that the lead contacts line up with the electrical contacts inside the lead groove. If implanting a single lead, use the lead groove marked 0-7.

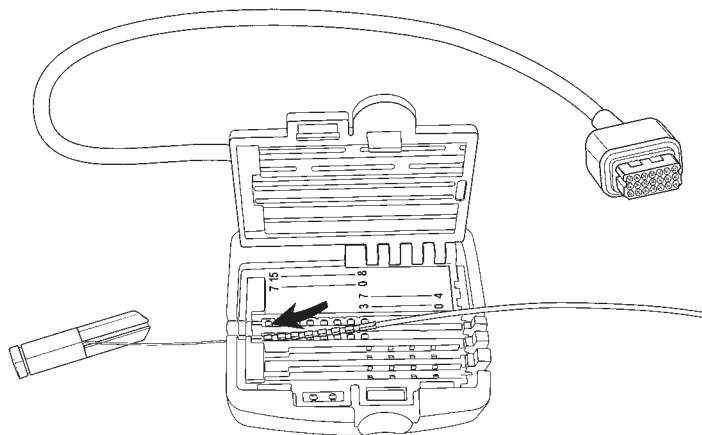


FIGURE 17

Aligning the lead in the snap-lid connector

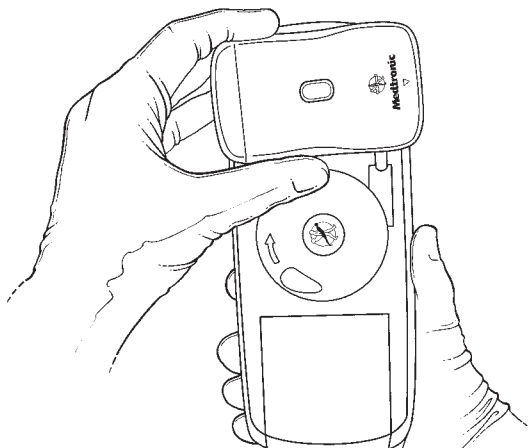
- 4 Press the lead gently into the lead groove.
- 5 If dual leads are implanted, position second lead in the groove marked 8-15.
- 6 Close the lid until the latch snaps shut in order to seat the lead(s) in the lead groove(s). Do not force the lid closed. If the lid does not close easily, disassemble the components and repeat the assembly steps.
- 7 Pass the end of the snap-lid connector cable that connects to the ENS out of the sterile field.

Attaching the External Neurostimulator (ENS)

- 1 Verify that the ENS is turned off.
- 2 Attaching the ENS to the clinician programmer properly aligns the two devices for communication and prevents the cable from resting on the programmer. To attach the ENS to the clinician programmer:
 - a. Place the ENS so it fits into the slot on the programming head (FIGURE 18).

FIGURE 18

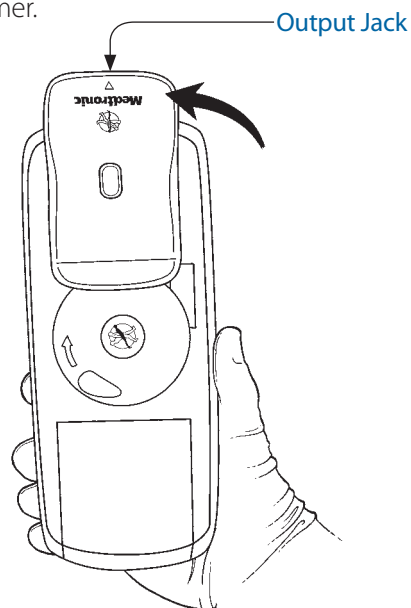
Attaching the ENS to the clinician programmer



- b. Turn the neurostimulator so the output jack is positioned as displayed in (FIGURE 19). Face the output jack away from the clinician programmer.

FIGURE 19

ENS attached to the clinician programmer



- 3 Connect the snap-lid connector cable to the ENS, aligning the arrows on the ENS and the cable plug (FIGURE 20).

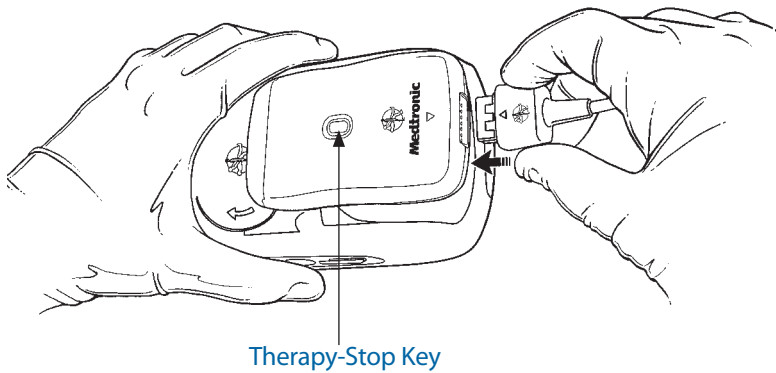


FIGURE 20

Connecting the snap-lid connector cable to the ENS

⚠ WARNING:

Maintain adequate slack in the cable. If there is not enough slack and the cable is pulled, the percutaneous components may be dislodged.

CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result in loss of stimulation.

NOTE:

The red Therapy-Stop key can be used if you need to immediately turn off the ENS (FIGURE 19). You must use either the patient or clinician programmer to turn the ENS on again. The Therapy-Stop key is not an on/off control.

Conducting Intraoperative Test Stimulation

The eight electrodes of the lead are numbered **0, 1, 2, 3, 4, 5, 6, 7** (FIGURE 21). If two trial leads are placed, the electrodes on the second lead are numbered **8, 9, 10, 11, 12, 13, 14, 15** (FIGURE 22).

FIGURE 21

Eight electrodes on a single lead

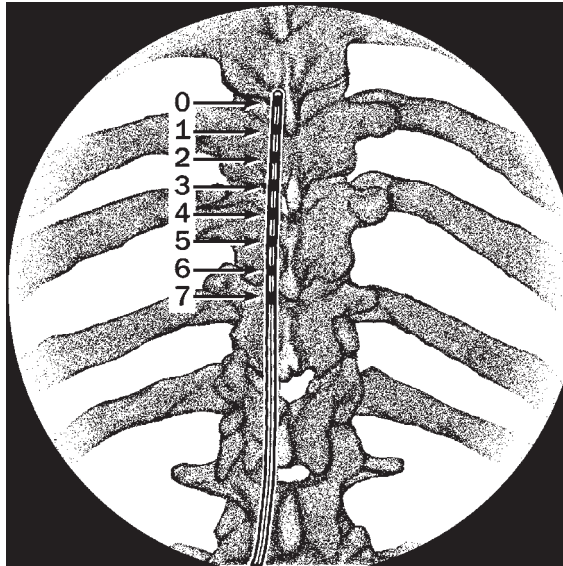
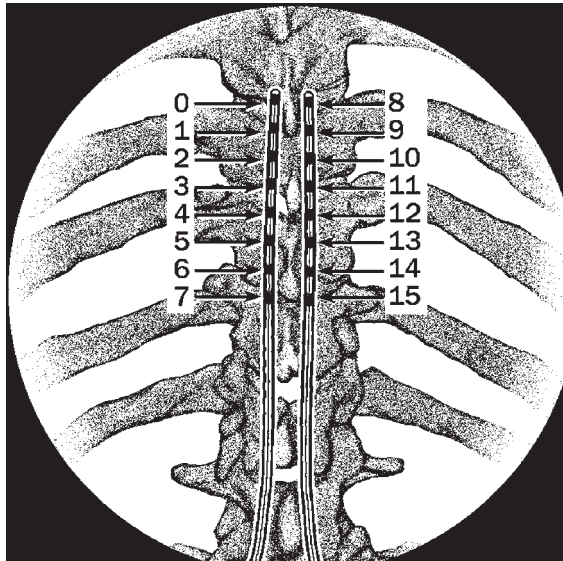


FIGURE 22

Eight electrodes on each of two leads



- 1 Ensure that the patient can provide immediate feedback.
- 2 Testing the stimulation for each lead separately, identify optimal electrode polarities and stimulation parameters, beginning with the following settings:
 - **Pulse width:** 210–240 μ s or higher
 - **Rate:** 30 Hz
 - **Amplitude:** 0.0 V
 - **Electrodes:** Use center bipoles for programming flexibility
- 3 While increasing the amplitude ask the patient closed ended questions to identify:
 - Perception threshold (the amplitude at which the patient first perceives paresthesia).
 - Discomfort threshold (the amplitude at which paresthesia is beyond the patient's tolerance or described as uncomfortable).

CAUTION:

To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation):

- **Program parameter changes in small increments above the perception threshold.**
- **Decrease the amplitude(s) to 0.0 V before:**
 - » **Connecting or disconnecting the cable to the External Neurostimulator**
 - » **Turning on the External Neurostimulator**

- 4 Adjust amplitude, pulse width, and rate until the pain area is covered and the patient has satisfactory paresthesia coverage.
- 5 If satisfactory paresthesia coverage is not attained, change electrode settings and retest thresholds before moving the leads.

- 6 If a lead has moved, retest for perception and discomfort thresholds before adjusting parameters for satisfactory paresthesia coverage.
- 7 If two leads were placed, repeat the process for the second lead, then optimize paresthesia coverage using both leads simultaneously.
- 8 When testing is complete, use the clinician programmer to turn the ENS off.

NOTE:

Decreasing the amplitude to 0.0 V before turning the ENS off may prevent possible uncomfortable or unexpected stimulation when the ENS is turned back on.

- 9 Record all settings and patient responses to stimulation in the patient's chart.
- 10 Obtain baseline fluoroscopy images to record the lead position(s) and place in patient's file.
- 11 Disconnect the snap-lid connector cable from the lead(s). Leave the cable in the sterile field for additional testing.

CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

Securing a Trial Stimulation Lead

- 1 Carefully, and without moving the lead, disconnect the stylet from the lead by gently bending the stylet handle from the lead.
- 2 Partially expose, but do not completely withdraw the stylet.
- 3 Secure the lead position by grasping the lead proximal to the needle hub.
- 4 While holding the lead secure, gently retract the needle from the epidural space and the ligamentum flavum while simultaneously indexing the lead to maintain lead position.
- 5 Carefully retract the needle through the tissue until the lead is visible at the distal end of the needle.
- 6 Hold the lead to maintain position and slowly withdraw the stylet.
- 7 Carefully grasp the exposed lead and slip the needle off the proximal end of the lead.

CAUTION:

Use minimal traction to remove the needle because quick or sudden removal may dislodge the lead.

- 8 If two leads were placed, repeat steps 1 through 7 for the second lead.
- 9 Verify that the lead location and pattern of stimulation have not changed:
 - a. Connect the snap-lid connector cable to the lead(s).
 - b. Connect the plug end of the snap-lid connector cable to the ENS.
 - c. Use the clinician programmer to verify that the pattern of stimulation has not changed.
 - d. Use fluoroscopy to verify that the lead location has not changed.
 - e. Disconnect the snap-lid connector cable from the lead(s).

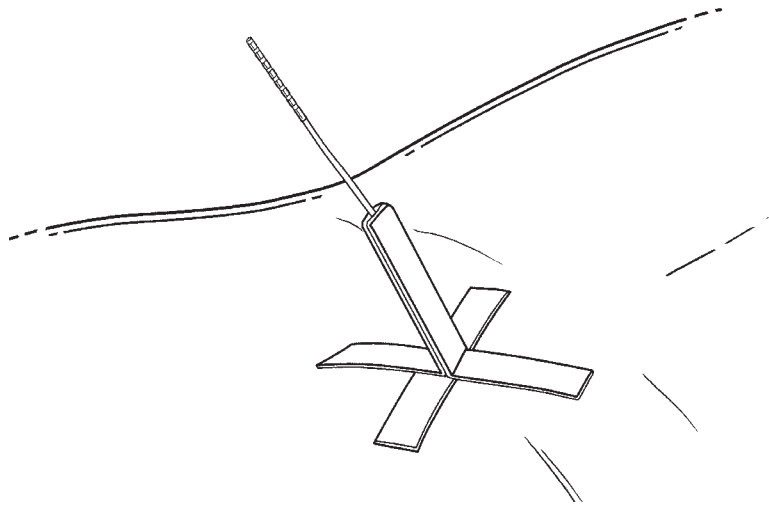
CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

- Secure the lead to the patient's skin using medical tape in a 4-point (FIGURE 23) or chevron configuration.

FIGURE 23

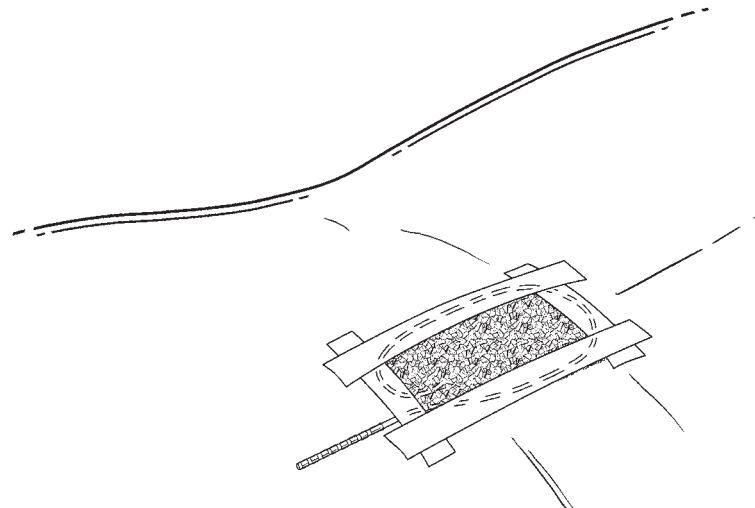
Securing the lead with medical tape



- Coil any excess lead under a sterile strip and dress the site (FIGURE 24).

FIGURE 24

Dressing the site



- Apply the sticker from the lead package to the patient's chart, and record the implanted lead information on the sticker.

Preparing for the Neurostimulation Trial

To prepare for the 3- to 10-day neurostimulation trial, the lead(s) are connected to the ENS, the ENS is programmed, and patient education topics are reviewed.

- 1 Making sure that the lead contacts are aligned with the connector electrical contacts, connect the snap-lid connector cable to the lead(s) (FIGURE 25) and the ENS.

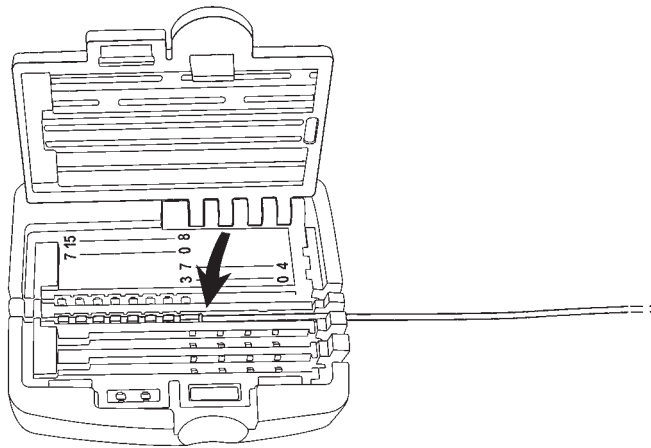


FIGURE 25

Connecting the snap-lid connector to the lead or extension

- 2 Using the clinician programmer, program the ENS with the neurostimulation trial parameters.
- 3 Review relevant patient education topics with the patient and family (or caregiver).

Evaluating Neurostimulation Trial Results

After the neurostimulation trial, review input from the pain management team, the patient, and the patient's family or caregivers. Evaluate if the goals of a neurostimulation trial have been met and determine if a full neurostimulation system will be implanted.

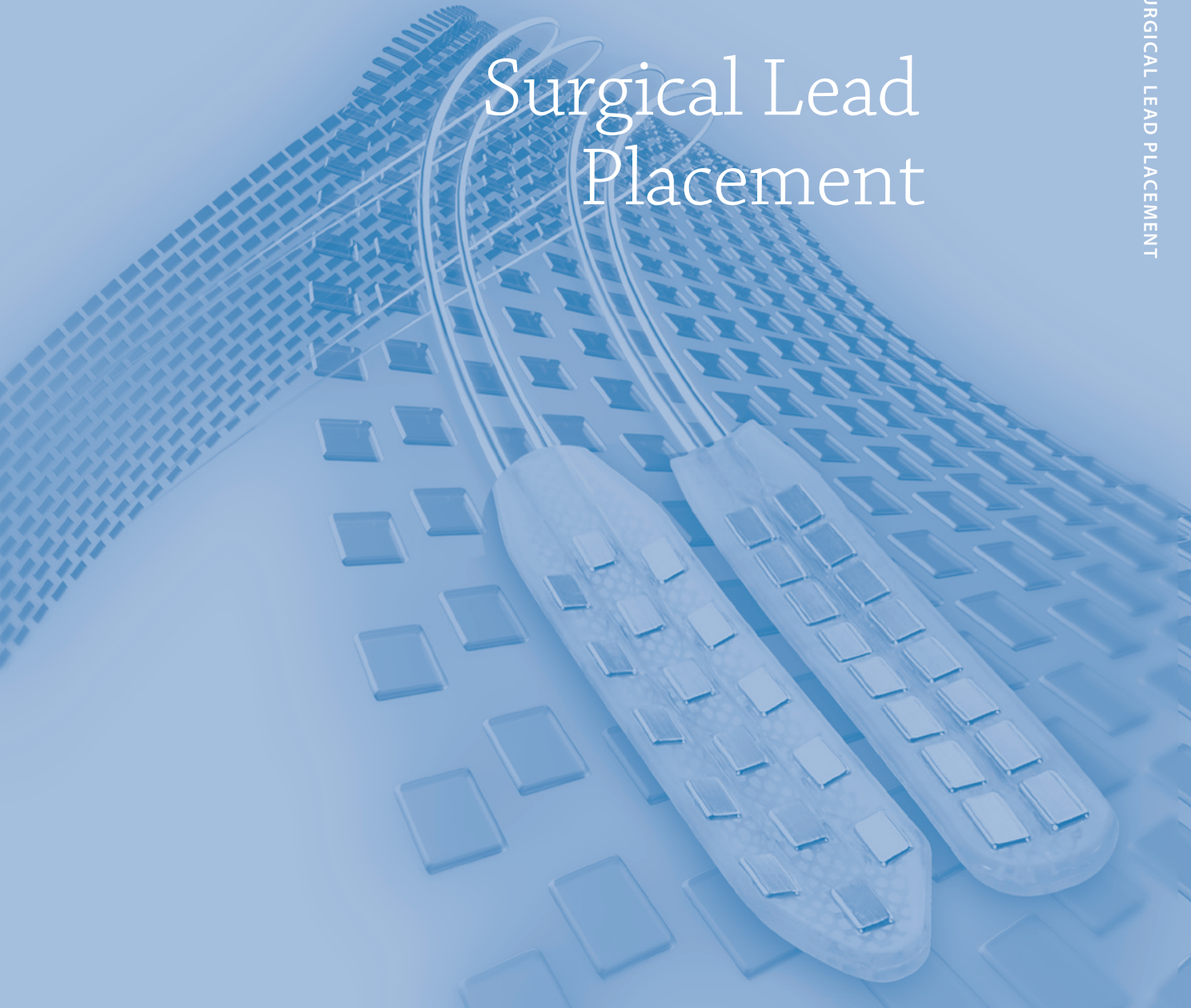
The goals of a neurostimulation trial are:

- Stimulation covers the patient's pain areas.
- Patient is comfortable with the sensation of stimulation.
- Patient experiences adequate pain relief.
- Patient experiences improved function.

After the trial, percutaneous trial lead(s) are removed.

3

Surgical Lead Placement



Surgical Lead Placement

Lead placement is the first step in a system implant. To place a surgical lead, a laminotomy is performed, then the lead paddle is positioned in the epidural space.

Lead placement is done under local anesthesia. Since the patient must interact during anesthesia, monitored anesthesia care (MAC) should be implemented according to physician judgment.

The example procedure applies to both of the following:

- 65-cm Specify 5-6-5 or Specify 2x8 lead
- 30-cm Specify 5-6-5 or Specify 2x8 lead with two 1x8 extensions

Alternate leads are available through Medtronic.

Preparing for System Implant

- 1 With patient participation, plan and mark the neurostimulator implant site based on patient preference, comfort, and ability to recharge the neurostimulator battery (if applicable).

CAUTION:

Select a location that is:

- A minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
- On the opposite side of the body from another active implanted device (e.g., pacemaker, defibrillator) to minimize possible interaction between the devices.
- Away from bony structures (e.g., 3–4 cm [1.2–1.6 in]) to minimize discomfort at the neurostimulator site.
- Away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.
- In an area accessible to the patient for proper operation of a patient control device (i.e., patient programmer).

- 2 **Verify neurostimulator operation:** Before opening the sterile neurostimulator package, verify that the neurostimulator is operable by using the clinician programmer to interrogate the neurostimulator and read the neurostimulator battery charge level (if applicable).
- 3 **Charge the neurostimulator battery:** If implanting a rechargeable neurostimulator, charge the neurostimulator battery before opening the package.

Preparing to Place a Surgical Lead

- 1 Place the patient in the prone position. For lumbar or thoracic lead placement, consider placing a pillow under the patient's abdomen in order to flex the spine.
- 2 Perform skin prep and drape the patient using standard sterile technique (FIGURE 26).

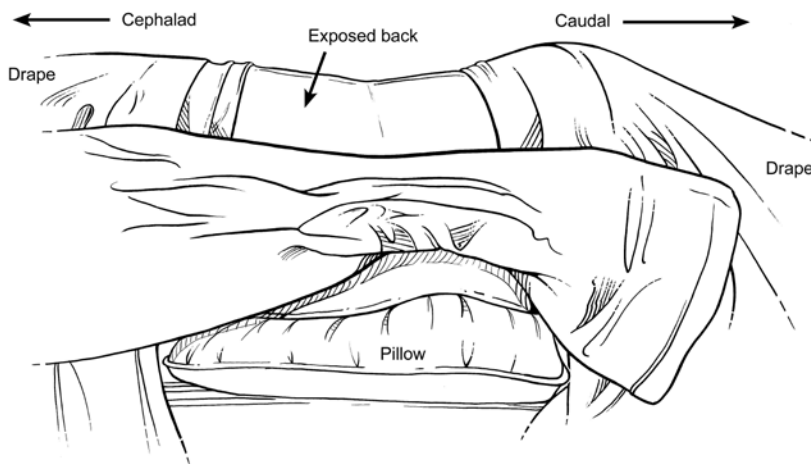


FIGURE 26

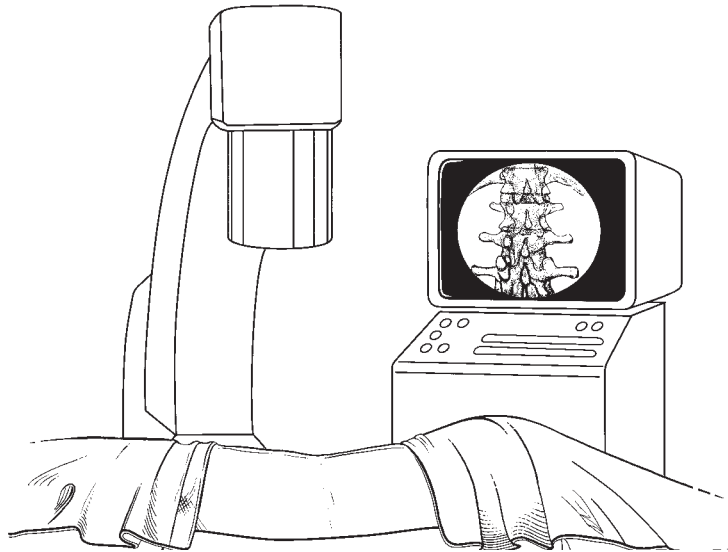
Positioning and draping the patient

- 3 Conduct the procedure under local anesthesia. Monitor sedation closely to maintain comfort and to ensure that the patient can understand and respond during intraoperative test stimulation.
- 4 Administer prophylactic antibiotics according to standard medical practice or the standard protocol of the institution, as applicable.

- 5 Using fluoroscopy, identify and mark the appropriate spinal level and interlaminar access points for lead placement (FIGURE 27).

FIGURE 27

Identifying appropriate spinal level



⚠ WARNING:

Evaluate the geometry and suitability of the spinal canal (by using an appropriate imaging method) to ensure that the spinal canal can safely accommodate insertion and permanent placement of the surgical lead paddle and body. The following factors should be considered during this evaluation:

- Adequate space within the spinal canal
- Pre-existing conditions or surgical procedures that may have altered the patient's epidural anatomy
- Potential for post-implant tissue changes around the lead
- Changes in epidural space associated with typical spinal movement

Inadequate space to accommodate the lead may result in localized compression of the spinal cord, increasing the risk of spinal cord injury.

CAUTION:

Implanting the surgical lead paddle in anatomical locations that have a high degree of mobility (such as the cervical spine) is not recommended. The stresses associated with these locations may reduce the functional survival time of the lead, requiring reprogramming and/or early replacement of the lead to restore effective therapy.

NOTE:

The laminotomy should be performed 1-2 vertebral spaces inferior to the desired final location of the surgical lead paddle.

- 6 Use an appropriate local anesthetic to anesthetize the skin and subcutaneous tissues at the planned incision site (FIGURE 28).

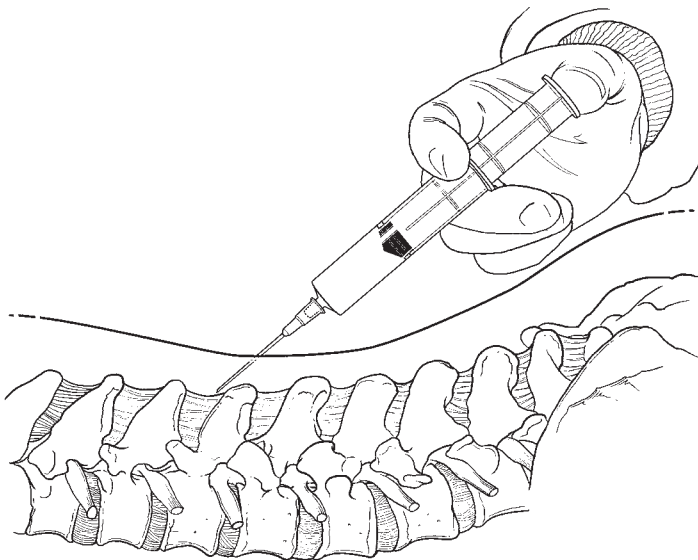


FIGURE 28

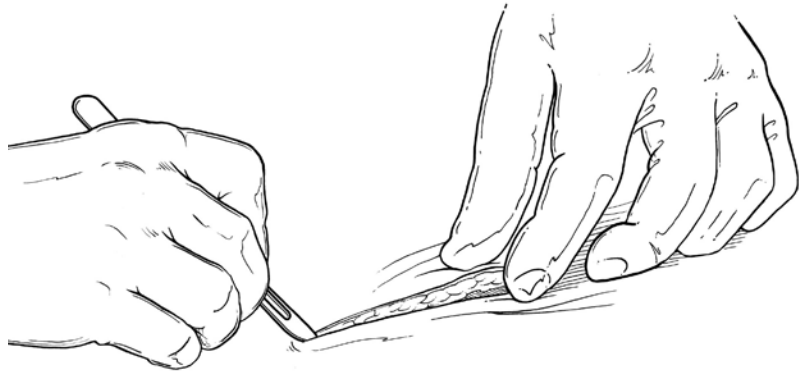
Anesthetizing the planned incision site

Placing a Surgical Lead

- 1 Perform a laminotomy 1-2 vertebral spaces inferior to the desired final location of the surgical lead paddle, while taking into account the following suggestions (FIGURE 29):

FIGURE 29

Making an incision at the laminotomy site



- Use electrocautery to dissect the site.
- Avoid subperiosteal stripping to maintain a clear operative field.
- Inject additional local anesthesia just prior to stripping the paraspinous muscles from the spine.
- Additional anesthesia should be liberally administered on patient demand.
- Make the laminotomy width consistent with the lead paddle width.

CAUTION:

Ensure that the laminotomy is wide enough to accommodate the surgical lead paddle. Failure to do so may result in forcing the lead into the epidural space, which may damage the lead.

- If the interlaminar space is narrow, use instruments to reflect the ligamentum flavum and remove enough bone for the lead blank insertion. (A rongeur may be required during this exposure.)

- Use bipolar forceps to grasp and coagulate the epidural fat so that the fat can be stripped away, exposing the dura mater.
- ② Slowly and with minimal force introduce the passing elevator into the epidural space along the midline (FIGURE 30), guiding the entry so that the approach angle is as shallow as possible.

⚠ WARNING:
Introduce the passing elevator, the lead blank, and the lead at a shallow angle. Using an angle that is too deep could cause contusion to the spinal cord.

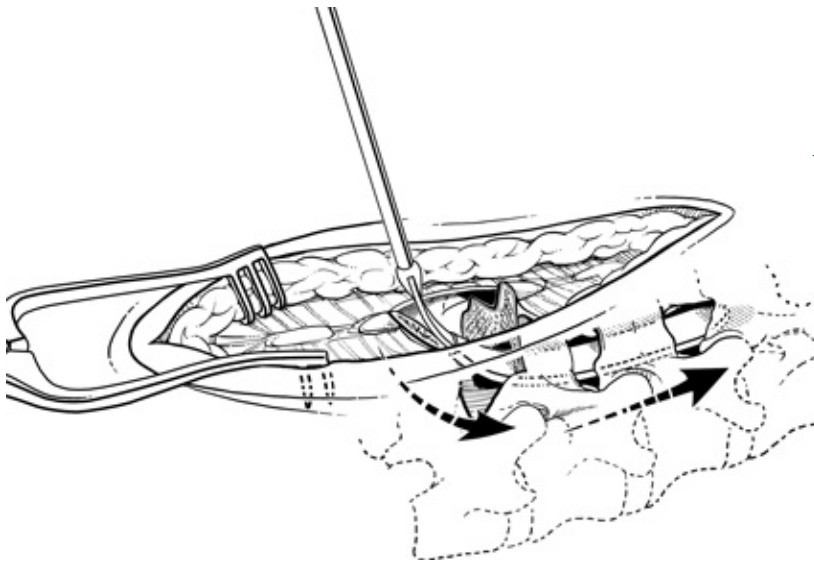


FIGURE 30

Introducing the passing elevator

- ③ Remove the passing elevator.
- ④ If desired, carefully introduce the lead blank into the epidural space to ensure proper size and location of the lead site.
- ⑤ If using the lead blank, remove and discard the lead blank.

- 6 Making sure the stimulating electrodes face the dura mater and using a rubber-tipped forceps to handle the lead paddle, carefully position the lead paddle in the epidural space (FIGURE 31).

CAUTION:

Use bone wax or instrumentation to ensure that the bony edge of the laminotomy is smooth. Sharp edges may damage the lead, resulting in intermittent or loss of stimulation.

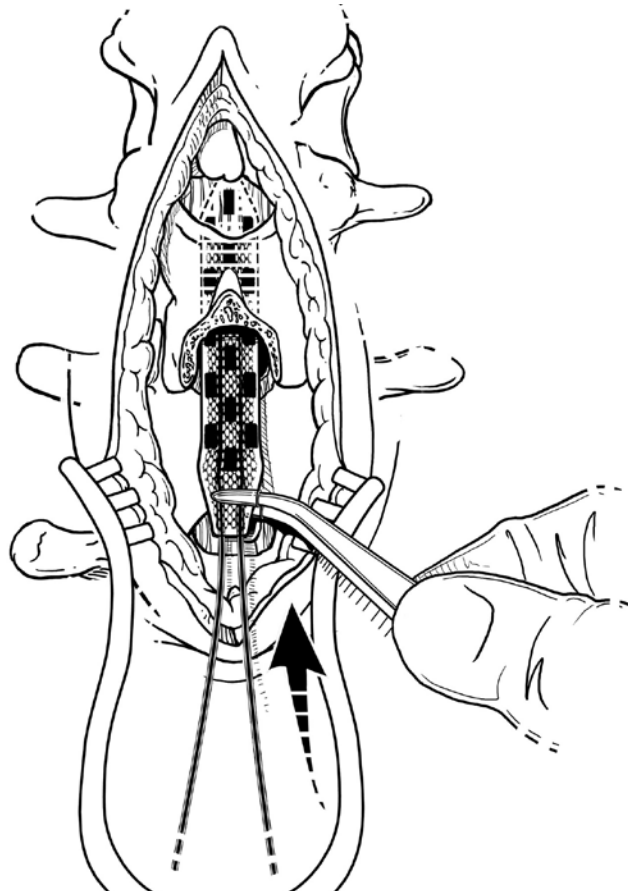


FIGURE 31

Positioning the lead paddle in the epidural space

- 7 Advance the lead paddle cephalad until the entire paddle is in the epidural space.

NOTE:

For bilateral pain, place the lead close to the midline.

- 8 Verify the lead position under fluoroscopy (AP and lateral views) (FIGURE 32).

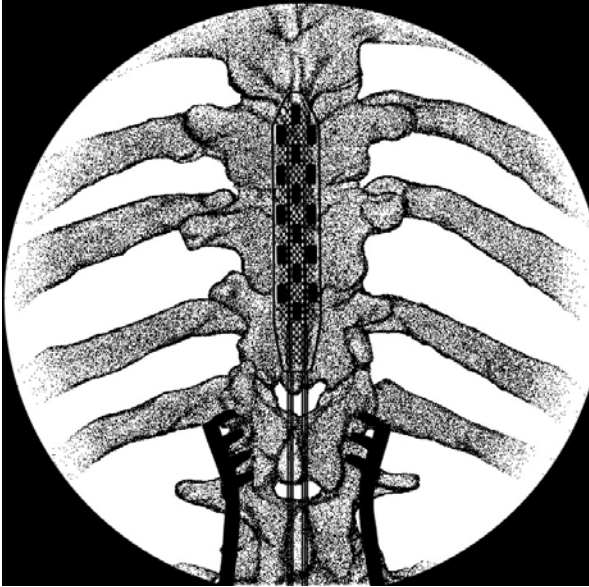


FIGURE 32

Verifying lead position

- 9 Prepare to conduct intraoperative test stimulation:
 - a. Connect the snap-lid connector cable to the lead. (Press the lead body with the marker band [e.g., white] into the groove marked 0-7. Press the other lead body into the groove marked 8-15.)
 - b. Pass the plug end of the snap-lid connector cable (end that connects to the ENS) out of the sterile field.
 - c. Verify that the ENS is turned off.
 - d. Connect the snap-lid connector cable to the ENS.

▲ WARNING:

Maintain adequate slack in the cable. If there is not enough slack and the cable is pulled, the percutaneous components may be dislodged.

- 10 Conduct intraoperative test stimulation:
- a. Identify optimal stimulation parameters, beginning with the following settings:
 - » **Pulse width:** 210–240 μ s or higher
 - » **Rate:** 30 Hz
 - » **Amplitude:** 0.0 V

NOTE:

Ensure that the patient can provide immediate feedback.

- b. While increasing the amplitude ask the patient closed-ended questions to identify:
 - » Perception threshold (the amplitude at which the patient first perceives paresthesia)
 - » Discomfort threshold (the amplitude at which paresthesia is beyond the patient's tolerance or described as uncomfortable)
 - » Paresthesia coverage

NOTE:

If good paresthesia coverage is not attained, change electrode settings before repositioning the lead to confirm the direction of lead movement.

- 11 In the patient's chart, document the lead position that provided appropriate stimulation coverage:
- » Record settings and patient responses
 - » Include a fluoroscopic image of the final lead position
- 12 Disconnect the snap-lid connector cable from the lead. Leave the cable in the sterile field for additional parameter testing before closing.

CAUTION:

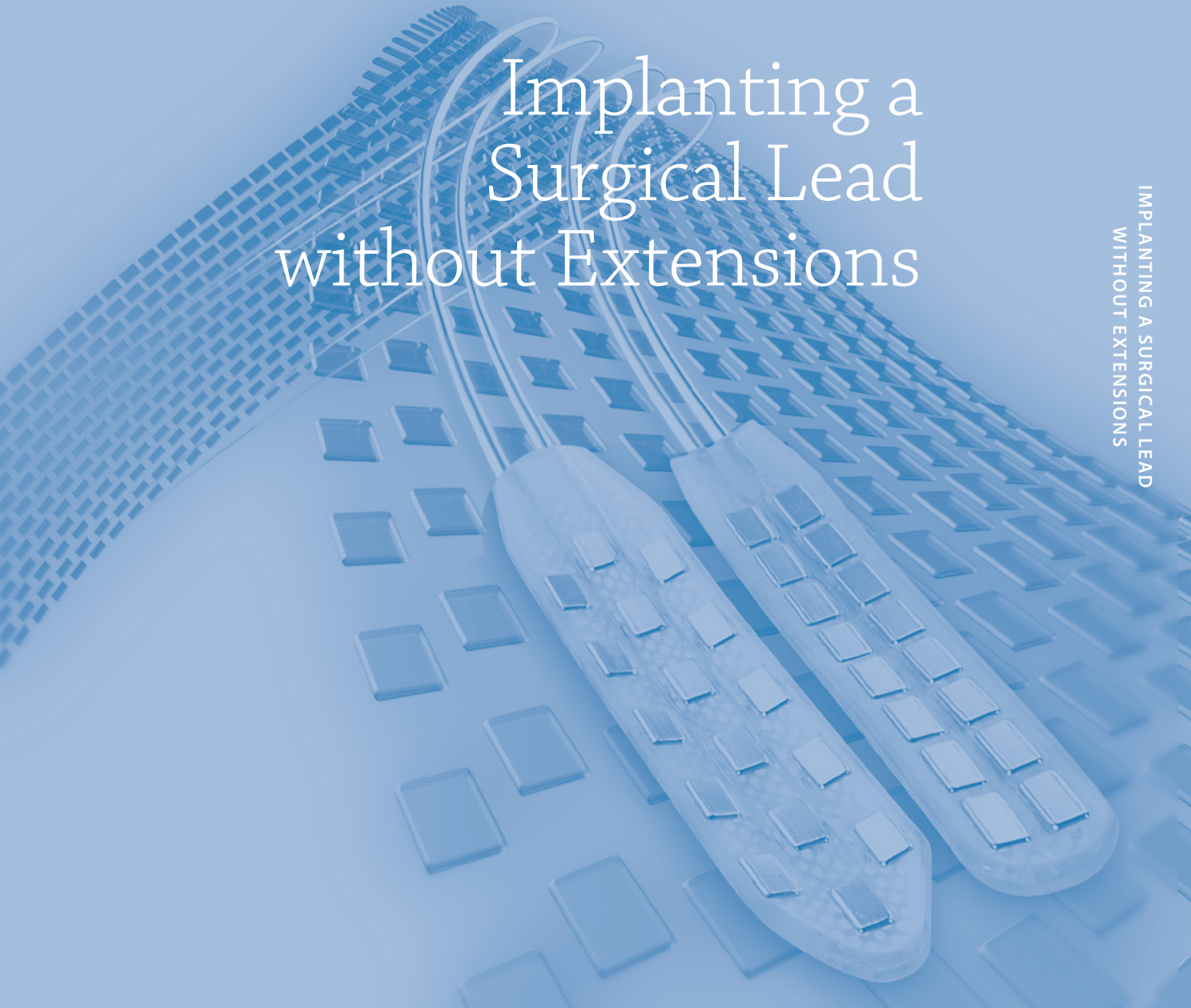
Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

- 13 If implanting a 65-cm Specify 5-6-5 or Specify 2x8 lead, go to:
- » **Implanting a Surgical Lead without Extensions** on page 47.
- 14 If implanting a 30-cm Specify 5-6-5 or Specify 2x8 lead, go to:
- » **Implanting a Surgical Lead with Extensions** on page 59.

4

Implanting a Surgical Lead without Extensions

IMPLANTING A SURGICAL LEAD
WITHOUT EXTENSIONS



Implanting a Surgical Lead without Extensions

If you are implanting a 65-cm Specify 5-6-5 or Specify 2x8 lead, the lead is optionally secured to the fascia with anchors supplied in the lead kit. The lead kit contains several kinds of anchors. The example procedure in this section uses the two-wing anchor.

After the lead is anchored, a neurostimulator pocket is created and the lead bodies are tunneled to the neurostimulator site.

Alternate leads are available through Medtronic.

Anchoring a Surgical Lead

- 1 Choose an anchor from the lead package (The example procedure in this section uses the two-wing anchor.)

NOTE:

Other anchor options are also packaged with the lead.

- Three-wing anchor—Same procedure as two-winged anchor.
- EZ anchor—Can be trimmed to a shorter length. See manufacturer labeling for procedure.

- 2 While maintaining lead position, slide an anchor onto the proximal end of each lead body (FIGURE 33).

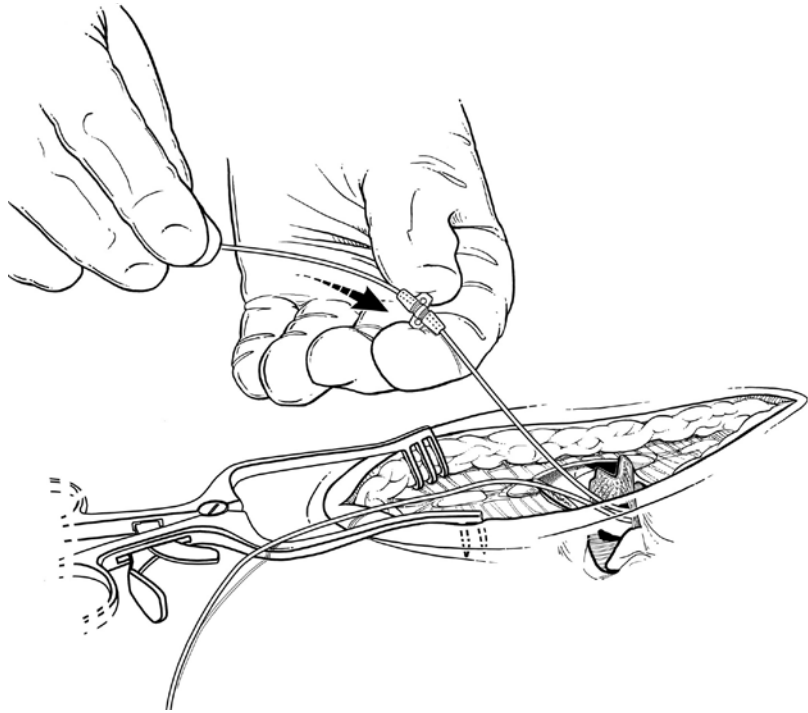


FIGURE 33

Sliding the anchors over the lead bodies

NOTE:

The anchor can be lubricated with sterile water.

- 3 Leaving enough slack in the lead body to create a strain relief loop between the lead paddle and the anchor, secure an anchor to each lead by tying ligatures (use 2-0 nonabsorbable suture) around the grooves in the middle of the anchor (FIGURE 34).

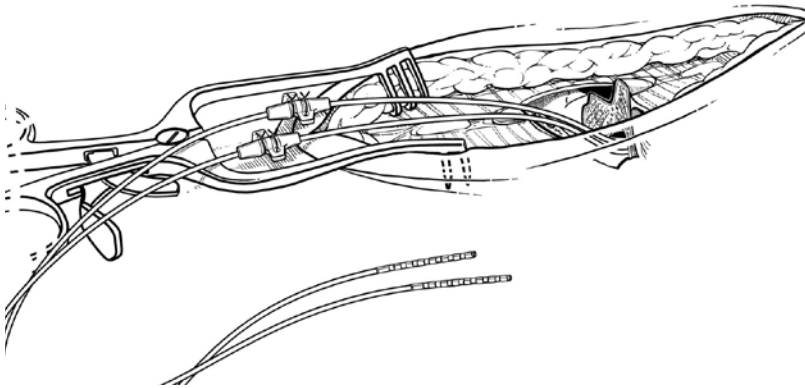


FIGURE 34

Securing anchors to the lead bodies

CAUTION:

- Do not tie ligatures around the lead body, which may damage the insulation.
- Do not overtighten ligatures on the anchor. Ligatures that are too tight may damage the lead.

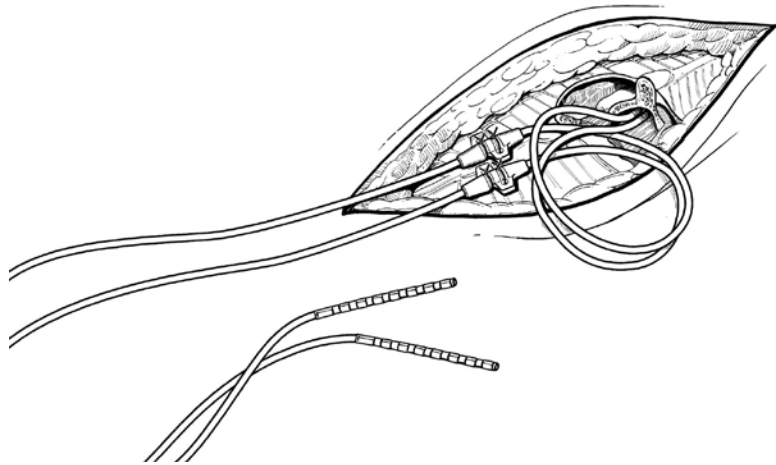
NOTE:

Laboratory testing has shown that injecting silicone medical adhesive between the anchor and lead after tying the ligatures increases the anchor-to-lead holding force.

- 4 While maintaining lead position, create a strain-relief loop with each of the lead bodies, by coiling the lead bodies near the lead paddle (FIGURE 35).

FIGURE 35

Creating strain relief loops



CAUTIONS:

- Use strain-relief loops as directed when implanting surgical leads. Implanting surgical leads without strain-relief loops may reduce the functional survival time of the lead, requiring reprogramming and/or early replacement of the lead to restore effective therapy.
- Do not pull the lead or extension taut. Allow enough slack in the lead to accommodate patient movement. Pulling the lead taut may result in a short or open circuit or migration of implanted components.
- Coil the excess lead into a circular loop greater than 2 cm (0.8 in) in diameter. Do not use a U-shaped loop or bend. A circular loop decreases the possibility of electromagnetic interference and its effects and prevents kinking or damaging the lead.



- 5 Secure the anchors in place by suturing the anchors to the supraspinous ligament or deep fascia (FIGURE 36).

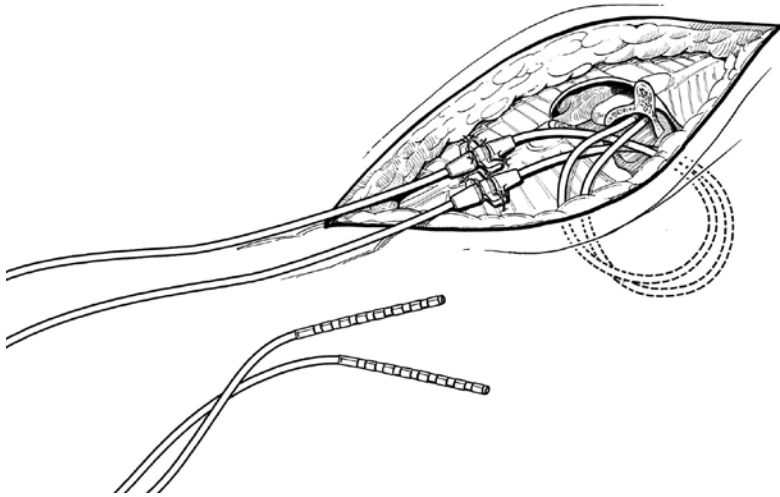


FIGURE 36

Suturing the anchors to the supraspinous ligament

- 6 If desired, verify that the lead paddle location and pattern of stimulation have not changed:
 - a. Connect the snap-lid connector cable to the lead. (Press the lead body with the marker band [e.g., white] into the groove marked 0–7. Press the other lead body into the groove marked 8–15.)
 - b. Connect the plug end of the snap-lid connector cable to the ENS.
 - c. Connect the ENS to the clinician programmer.
 - d. Use the clinician programmer to verify that the pattern of stimulation has not changed.
 - e. Disconnect the snap-lid connector cable from the lead.

CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

Creating a Neurostimulator Pocket

- 1 Administer local anesthetic at the neurostimulator pocket site.
- 2 Make an incision equal to the length of the neurostimulator (FIGURE 37).

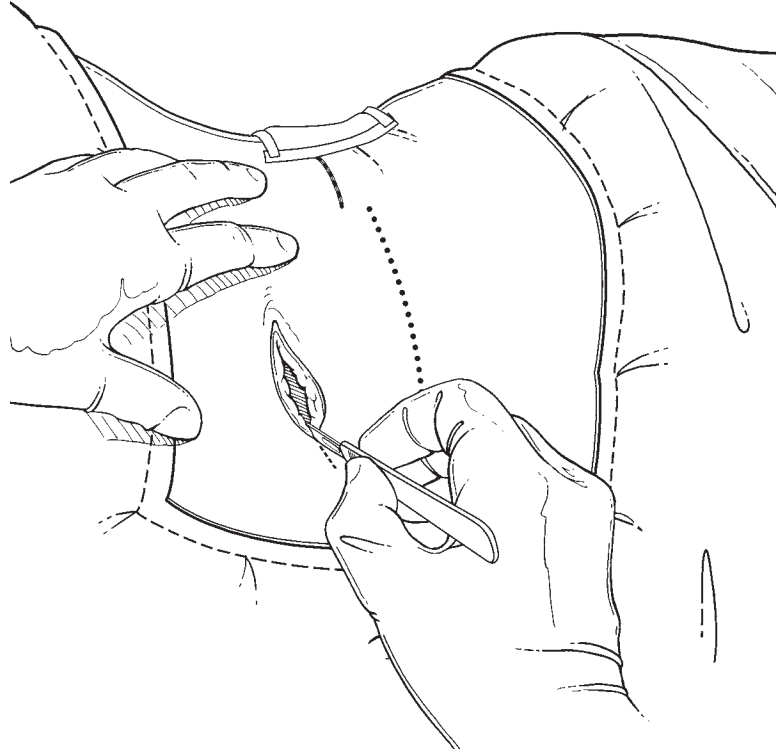


FIGURE 37

Making an incision at the neurostimulator pocket site

- 3 Use blunt dissection and/or electrocautery to create a subcutaneous pocket and to maintain hemostasis (FIGURE 38).

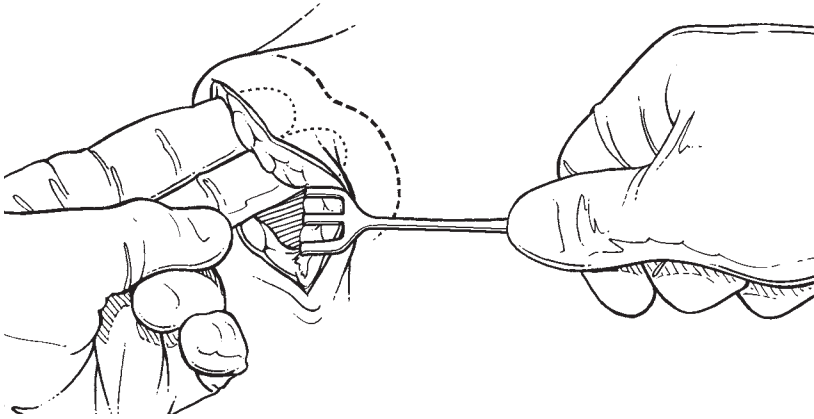


FIGURE 38

Creating a subcutaneous pocket

NOTE:

Ensure that the pocket is created so the neurostimulator will be placed parallel to the skin and at a depth that allows for efficient and successful telemetry and recharging (if applicable):

For rechargeable neurostimulators:

Place no deeper than 1 cm below the skin.

For nonrechargeable neurostimulators:

Place no deeper than 4 cm below the skin.

- 4 Making sure not to allow fluid into the connector block, verify the pocket size (FIGURE 39).

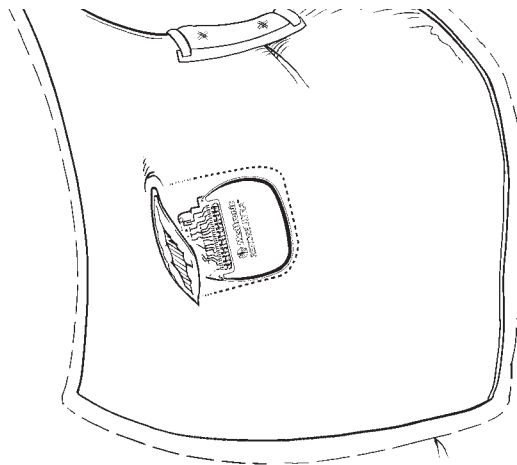


FIGURE 39

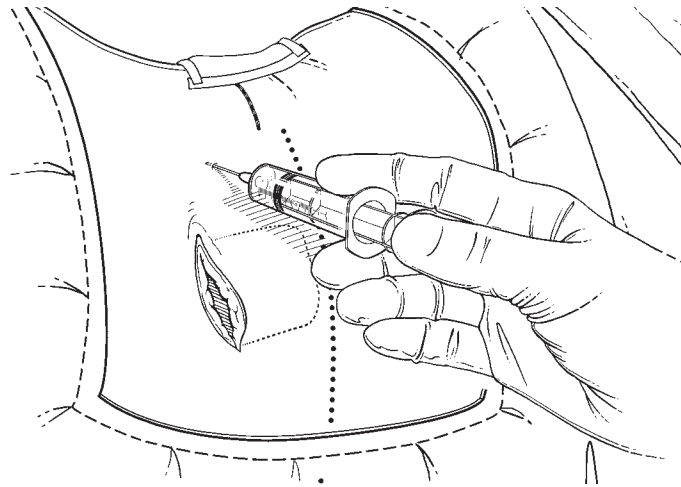
Verify neurostimulator pocket size

Tunneling the Lead Bodies

- 1 Identify the tunneling route between the lead incision and the neurostimulator pocket.
- 2 Administer local anesthetic to the tunneling route (FIGURE 40). Additional sedation may be administered at the discretion of the physician.

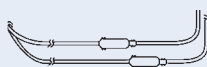
FIGURE 40

Administering local anesthetic to the tunneling route

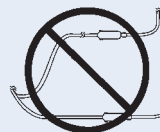


CAUTIONS:

- When routing the lead, avoid sharp bends or kinks, which may break the wires. Broken wires may create an open circuit, resulting in loss of stimulation or component failure and requiring surgical replacement.
- When routing two lead bodies, assure that the area between them is minimized. If the lead bodies are routed in a loop and the patient is exposed to some sources of electromagnetic interference (e.g., theft detectors), the patient may perceive a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).



CORRECT



INCORRECT

- Using the tunneling tool from the surgical lead package, the Model 3550 accessory kit (shown in [FIGURE 41](#) and in rest of procedure), or other appropriate accessory kit, bend the tunneling tool as necessary to conform to the patient's contour along the tunneling route.

NOTES:

- Models 3555 and 3655 tunneling tools can also be used.
- Models 3550, 3555, and 3655 tunneling tools are available in 38 -cm and 60-cm lengths.

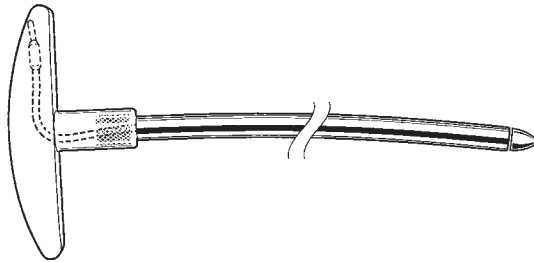


FIGURE 41

Bending the tunneling tool

- Introduce the obturator tip subcutaneously at the neurostimulator pocket site, then guide the tunneling tool by pushing the skin over the advancing obturator ([FIGURE 42](#)).

NOTE:

Model 3655 tunneling tool allows tunneling from either direction.

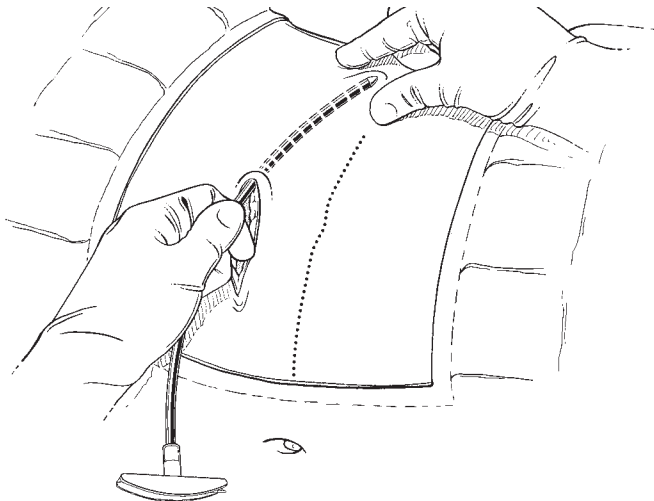


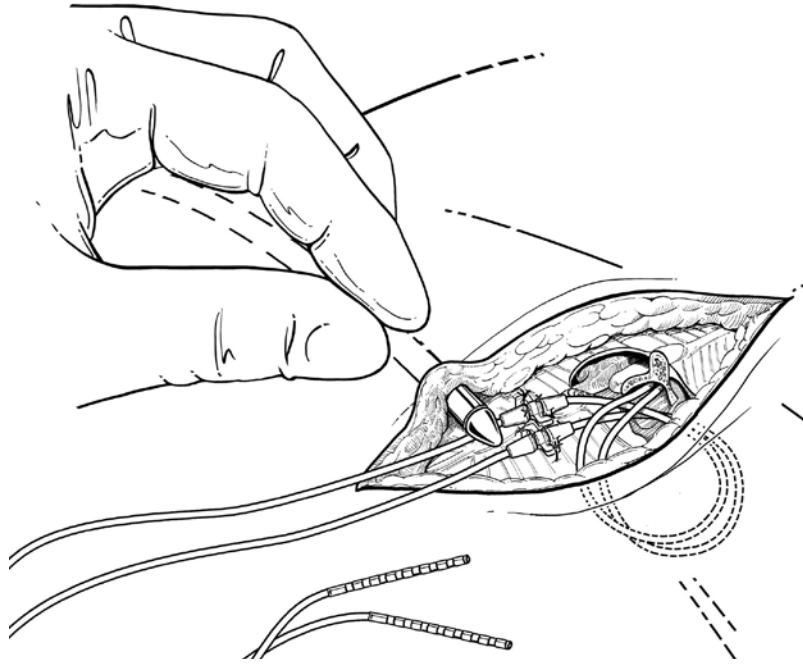
FIGURE 42

Guiding the tunneling tool

- 5 Tunnel subcutaneously from the neurostimulator pocket until the tip of the obturator is exposed at the lead site (FIGURE 43).

FIGURE 43

Advancing the obturator tip out of the lead site



NOTES:

- Deep tunneling is not desirable.
- Avoid the lower thoracic ribs.
- If the tunneling tool does not extend to the lead site, make an intermediate incision.

- 6 Remove the obturator from the tunneling tool.
- 7 Gently insert the proximal (neurostimulator) end of both lead bodies through the passer until they exit at the handle or until fully encompassed by the extension passer (FIGURE 44).

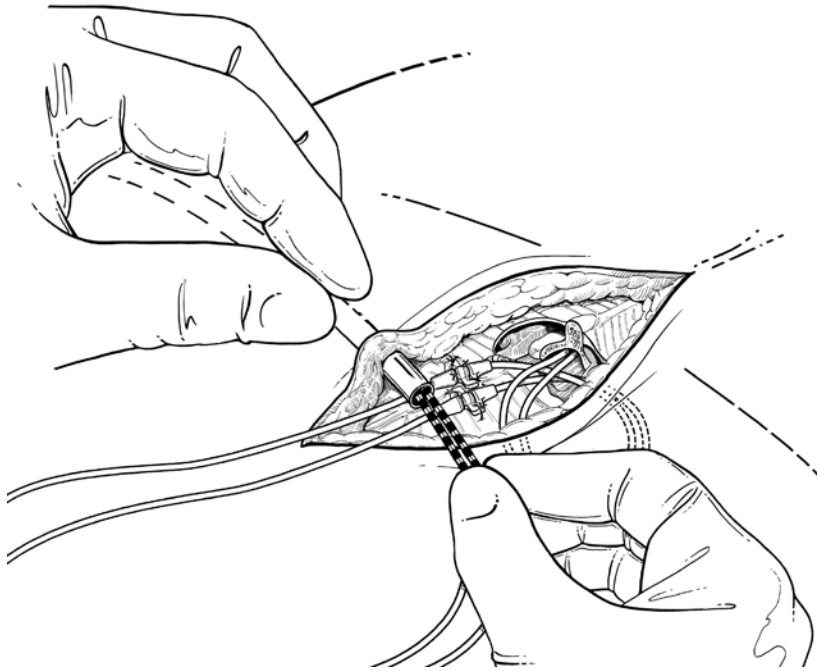


FIGURE 44

Inserting the lead bodies through the tunneling tool

- 8 Remove the tunneling tool (FIGURE 45).

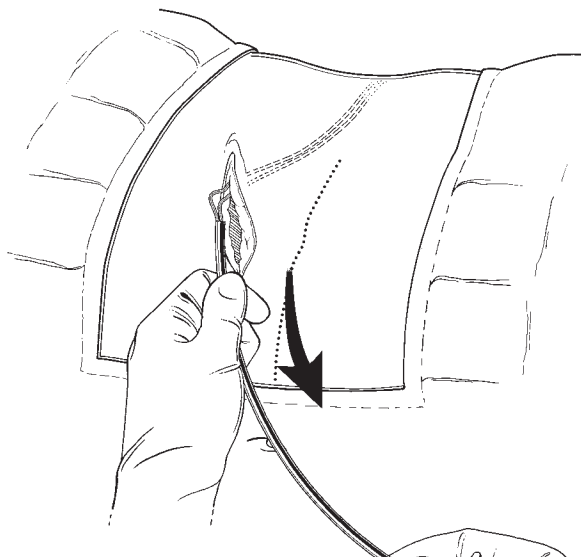


FIGURE 45

Removing the tunneling tool

- 9 Discard the tunneling tool.
- 10 Verify that the lead paddle location and pattern of stimulation have not changed:
 - a. Connect the snap-lid connector cable to the lead. (Press the lead body with the marker band [e.g., white] into the lead groove marked 0–7. Press the other lead body into the groove marked 8–15.)
 - b. Connect the plug end of the snap-lid connector cable to the ENS.
 - c. Connect the ENS to the clinician programmer.
 - d. Use the clinician programmer to verify that the pattern of stimulation has not changed.
 - e. Disconnect the snap-lid connector cable from the lead.

CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

- 11 Go to **Completing the Neurostimulation System Implant** on page 73.

5

Implanting a Surgical Lead with Extensions

IMPLANTING A SURGICAL
LEAD WITH EXTENSIONS



Implanting a Surgical Lead with Extensions

If you are implanting a 30-cm Specify 5-6-5 or Specify 2x8 lead, the neurostimulator pocket is created and two 1x8 extensions are tunneled to the neurostimulator site. The extensions are connected to the two lead bodies, and the lead-extension connector is sutured to the fascia.

Alternate leads and extensions are available through Medtronic.

Creating a Neurostimulator Pocket

- 1 Administer local anesthetic at the neurostimulator pocket site.
- 2 Make an incision equal to the length of the neurostimulator (FIGURE 46.)

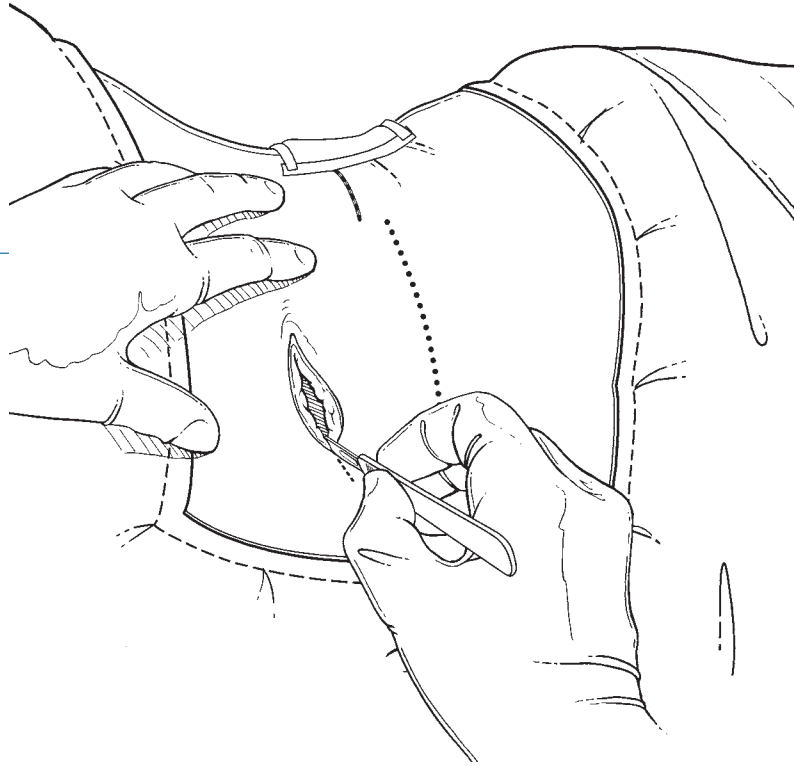


FIGURE 46

Making an incision at the neurostimulator pocket site

- 3 Use blunt dissection and/or electrocautery to create a subcutaneous pocket and to maintain hemostasis (FIGURE 47).

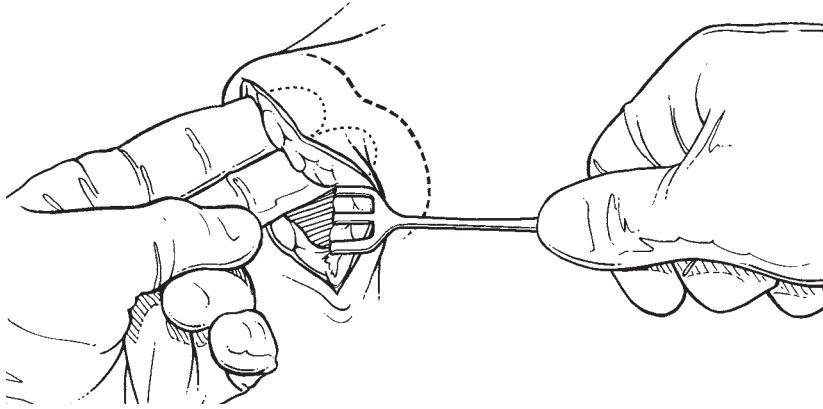


FIGURE 47

Creating a subcutaneous pocket

NOTE:

Ensure that the pocket is created so the neurostimulator will be placed parallel to the skin and at a depth that allows for efficient and successful telemetry and recharging (if applicable):

For rechargeable neurostimulators:

Place no deeper than 1 cm below the skin.

For nonrechargeable neurostimulators:

Place no deeper than 4 cm below the skin.

- 4 Making sure not to allow fluid into the connector block, verify the pocket size (FIGURE 48).

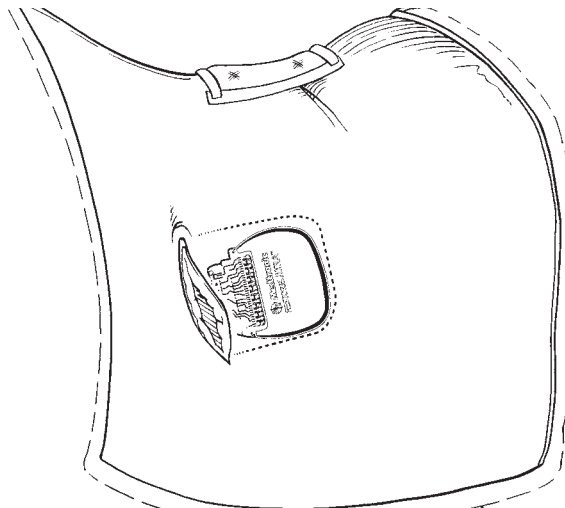


FIGURE 48

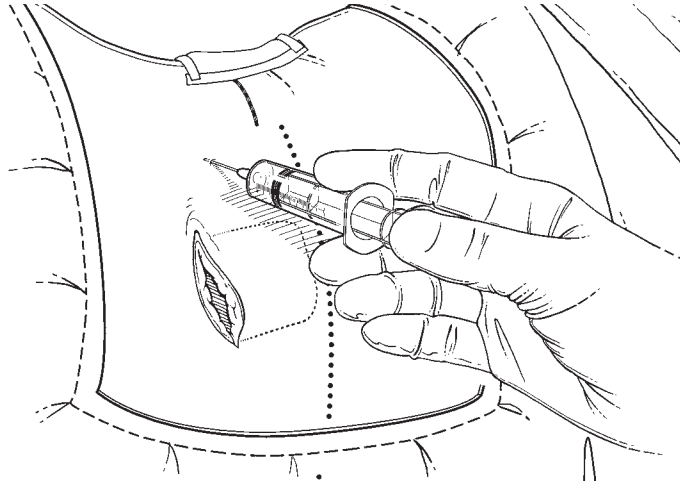
Verify neurostimulator pocket size

Tunneling the Extensions

- 1 Identify the tunneling route between the lead incision and the neurostimulator pocket.
- 2 Administer local anesthetic to the tunneling route (FIGURE 49). Additional sedation may be administered at the discretion of the physician.

FIGURE 49

Administering local anesthetic to the tunneling route



CAUTIONS:

- When routing the extension, avoid sharp bends or kinks, which may break the wires. Broken wires may create an open circuit, resulting in loss of stimulation or component failure and requiring surgical replacement.
- When routing two lead bodies, assure that the area between them is minimized. If the lead bodies are routed in a loop and the patient is exposed to some sources of electromagnetic interference (eg, theft detectors), the patient may perceive a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).



- Using the tunneling tool from the surgical lead package, the Model 3550 accessory kit (SHOWN IN FIGURE 50 AND IN REST OF PROCEDURE), or other appropriate accessory kit, bend the tunneling tool as necessary to conform to the patient's contour along the tunneling route.

NOTES:

- Models 3555 and 3655 tunneling tools can also be used.
- Models 3550, 3555, and 3655 tunneling tools are available in 38 -cm and 60-cm lengths.

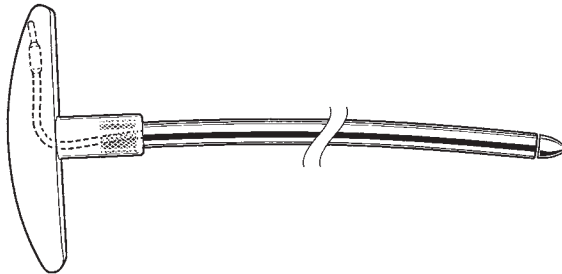


FIGURE 50

Bending the tunneling tool

- Introduce the obturator tip subcutaneously at the neurostimulator pocket site, then guide the tunneling tool by pushing the skin over the advancing obturator (FIGURE 51).

NOTE:

Model 3655 tunneling tool allows tunneling from either direction.

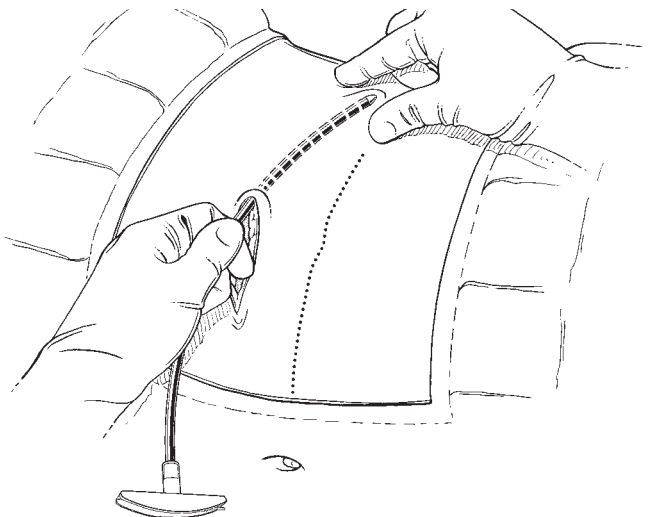


FIGURE 51

Guiding the tunneling tool

- 5 Tunnel subcutaneously from the neurostimulator pocket until the tip of the obturator is exposed at the lead site (FIGURE 52).

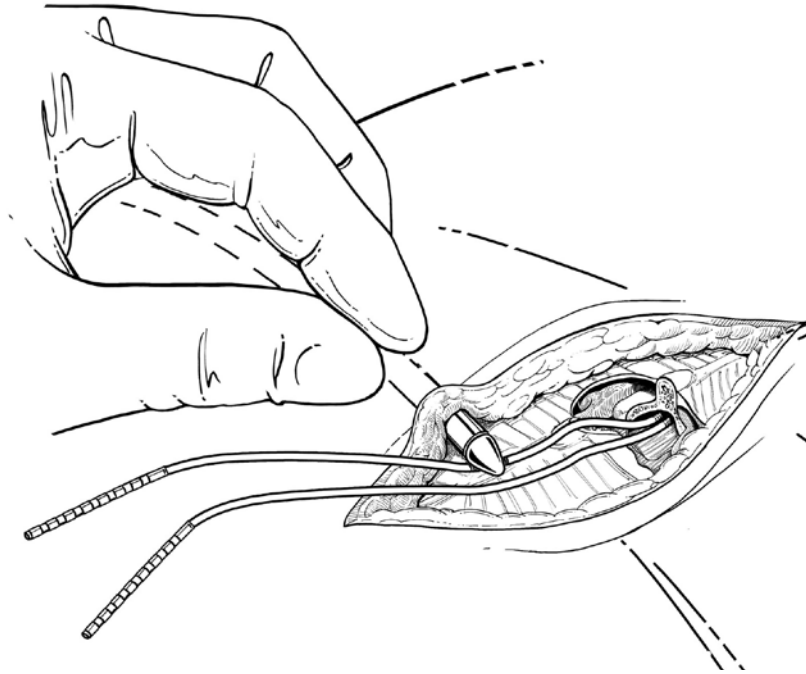


FIGURE 52

Advancing the obturator tip out of the lead site

NOTES:

- Deep tunneling is not desirable.
- Avoid the lower thoracic ribs.
- If the tunneling tool does not extend to the lead site, make an intermediate incision.

- 6 Remove the obturator from the tunneling tool.
- 7 Gently insert the proximal (neurostimulator) end of both extensions through the passer until they exit at the handle or until fully encompassed by the extension passer (FIGURE 53).

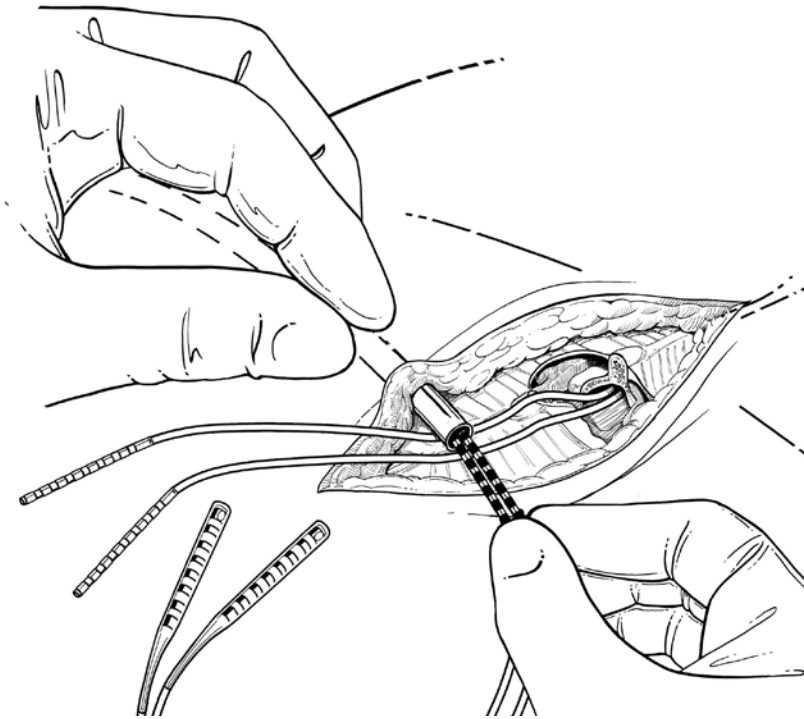


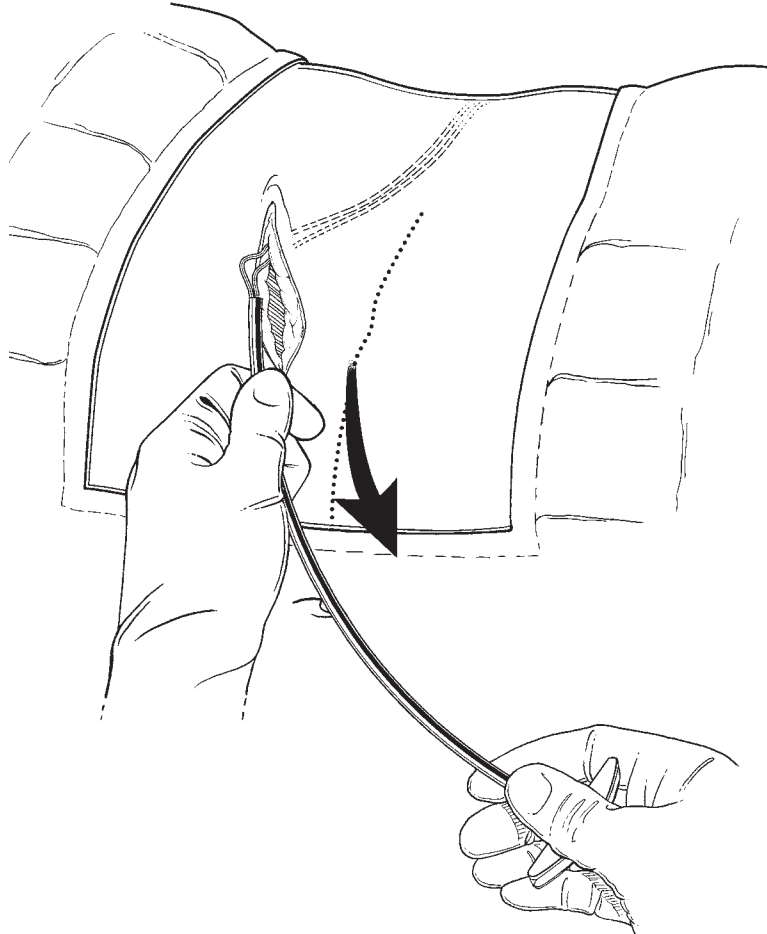
FIGURE 53

Inserting the extension through the tunneling tool

- 8 Remove the tunneling tool (FIGURE 54).

FIGURE 54

Removing the tunneling tool



- 9 Discard the tunneling tool.

Connecting the Lead Bodies to Two Extensions

- 1 Use blunt dissection to form a subcutaneous pocket off the lead incision for the lead-extension connection.

The pocket should be:

- Lateral to the lead incision
- Deep enough to minimize the potential for skin erosion or irritation
- Large enough to accommodate the lead-extension connection(s)

CAUTION:

Do not place the lead-extension connection on the paraspinal muscles or the spinous processes. The connection may erode through the skin, resulting in infection and requiring removal of the neurostimulation system.

- 2 Slide a connector boot onto each lead body with the open end facing outward, exposing the lead contacts (FIGURE 55).

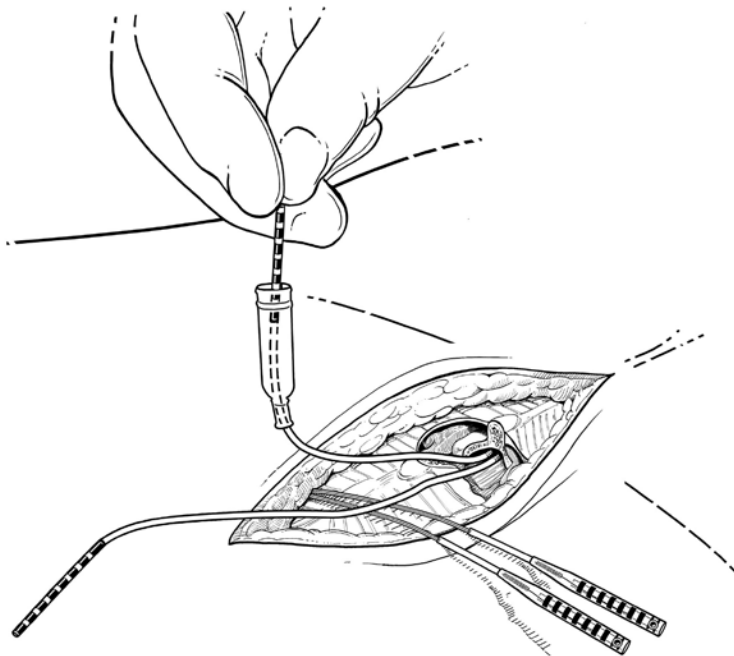


FIGURE 55

Sliding the connector boot onto the lead

- 3 Wipe the lead bodies and the extension connector junctions with sterile gauze. If necessary, moisten the gauze with sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
- 4 Dry all connections. Fluid in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.
- 5 For each lead body, hold the extension connector straight while firmly, but gently, inserting the lead into the connector one or two contacts at a time until each lead contact is aligned under each extension connector contact (FIGURE 56). During insertion, some resistance is typical because internal seals provide electrical isolation.

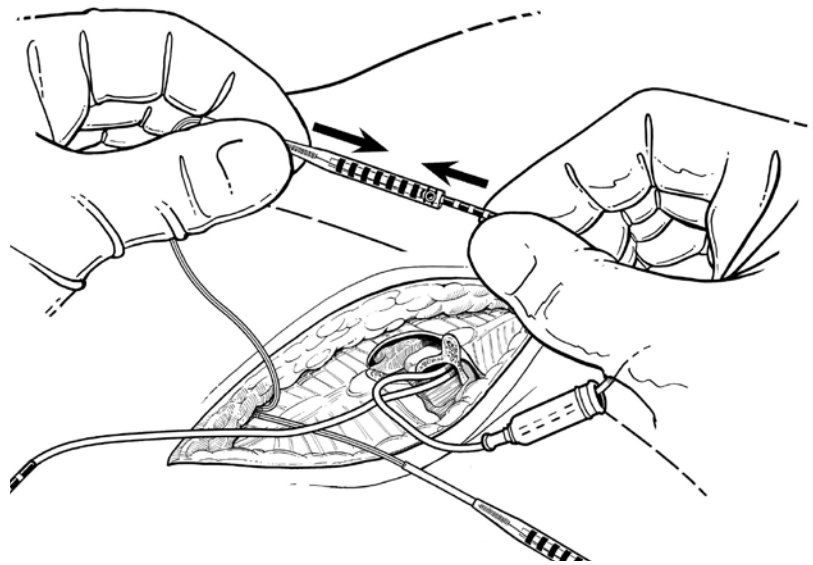


FIGURE 56

Inserting the lead into the extension connector

- 6 Use the torque wrench supplied in the extension package to tighten the setscrews, completing the electrical circuit (FIGURE 57).

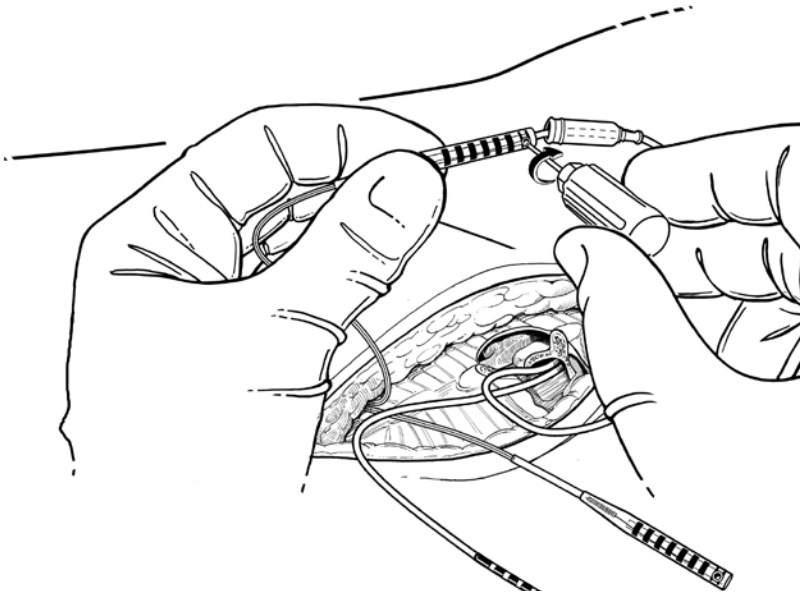


FIGURE 57

Tightening the setscrew on the extension connector

- 7 Using minimal force and while securely holding the lead to prevent dislodgement, pull on each connection to ensure that it is secure.
- 8 Confirm the integrity of the connections by rechecking the stimulation pattern.
 - a. Connect the snap-lid connector cable to the extensions. (Press the extension attached to the lead with the marker band [e.g., white] into the groove marked 0–7. Press the other extension into the groove marked 8–15.)
 - b. Connect the plug end of the snap-lid connector cable to the ENS.
 - c. Use the clinician programmer to verify that the pattern of stimulation has not changed.
 - d. Disconnect the snap-lid connector cable from the extensions.

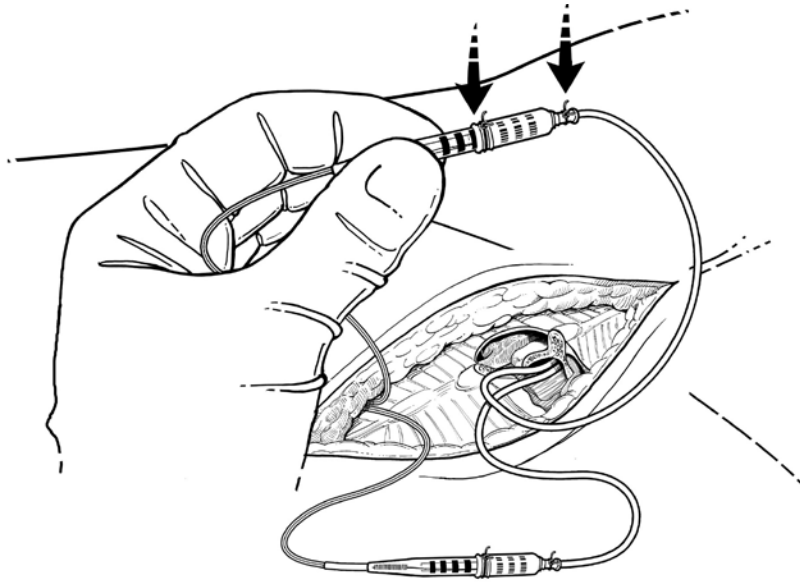
CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

- 9 Slide the connector boots over the lead-extension connections. When a connector boot is in place, the boot does not cover the entire lead-extension connection, but does cover the setscrew.
- 10 Tie a ligature (using nonabsorbable silk) between the pairs of rings at either end of each connector boot (FIGURE 58).

FIGURE 58

Suturing the ends of the connector boot



CAUTIONS:

- Do not tie ligatures around the lead or extension, which may damage the insulation.
- Do not overtighten ligatures on the connector boot. Ligatures that are too tight may damage the component.
- Ensure that the end of the connector boot is secure to prevent fluid in the lead-extension connection, which may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

- 11 While maintaining lead position, create a strain-relief loop with each of the lead bodies, by coiling the lead bodies near the connector boots (FIGURE 59).

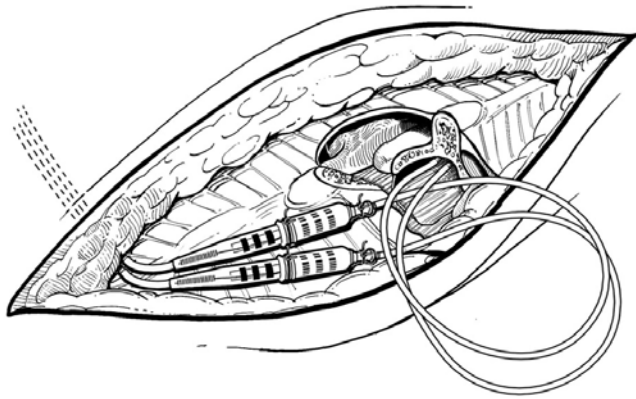


FIGURE 59

Creating strain relief loops

CAUTIONS:

- Do not pull the lead or extension taut. Allow enough slack in the lead or extension to accommodate patient movement. Pulling the lead or extension taut may result in a short or open circuit or migration of implanted components.
- Coil the excess lead into a circular loop greater than 2 cm (0.8 in) in diameter. Do not use a U-shaped loop or bend. A circular loop decreases the possibility of electromagnetic interference and its effects and prevents kinking or damaging the lead body.



- 12 Insert the strain-relief loops into the lead-extension connection pocket, under the connection, leaving as much slack as possible in the lead bodies between the lead paddle and the lead-extension connections.

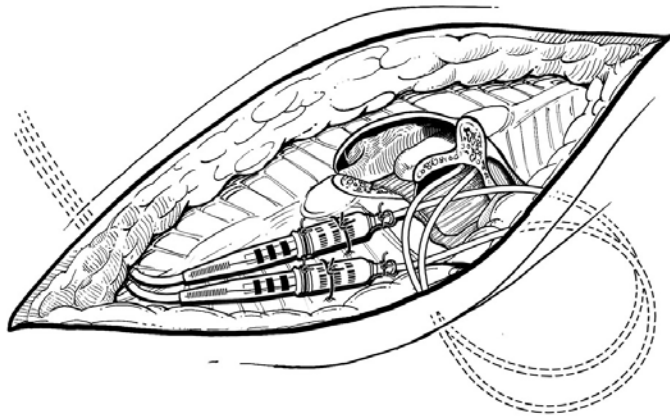
- 13 Suture each connector boot (using nonabsorbable silk) to the supraspinous ligament or to the deep fascia (FIGURE 60).

NOTES:

- Do not suture the narrow end of the connector boots or anywhere on the lead bodies.

FIGURE 60

Suturing the connector boot to the supraspinous ligament



- 14 If desired, verify that the lead paddle location and pattern of stimulation have not changed:
- a. Connect the snap-lid connector cable to the extensions. (Press the extension attached to the lead with the marker band [e.g., white] into the groove marked 0–7. Press the other extension into the groove marked 8–15.)
 - b. Connect the plug end of the snap-lid connector cable to the ENS.
 - c. Connect the ENS to the clinician programmer.
 - d. Use the clinician programmer to verify that the pattern of stimulation has not changed.
 - e. Disconnect the snap-lid connector cable from the extensions.

CAUTION:

Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result.

6

Completing the Neurostimulation System Implant

COMPLETING THE
NEUROSTIMULATION SYSTEM
IMPLANT

Completing the Neurostimulation System Implant

To complete the neurostimulation system implant, the lead bodies or extensions are connected to the neurostimulator. The neurostimulator is then sutured into the pocket, and a system integrity check is performed to verify that the components are properly connected.

In addition to standard postoperative considerations, activity restrictions and patient education specific to neurostimulation therapy are addressed. Neurostimulation therapy may be initiated during postoperative recovery or at a follow-up appointment.

The example procedure in this section uses a RestoreUltra neurostimulator.

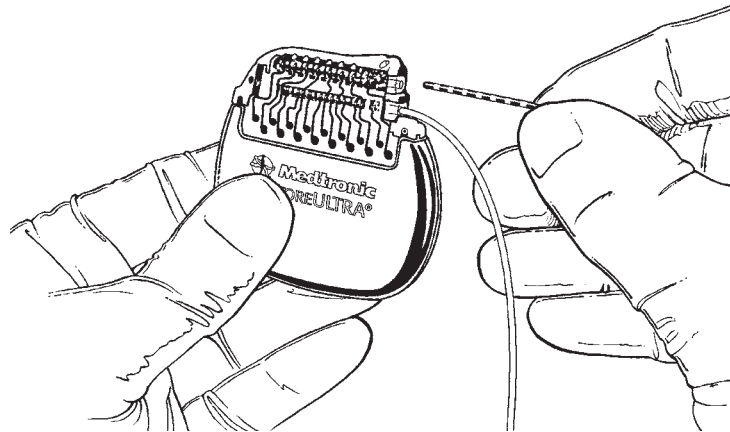
Alternate neurostimulators are available through Medtronic.

Connecting a Lead or Extension to a Neurostimulator

- 1 Wipe the extension or lead connector pins with sterile gauze. If necessary, moisten the gauze with sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
- 2 Make sure the connector block receptacles are dry and clean. Fluid in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.
- 3 Insert the appropriate extension or lead connector pins into the appropriate neurostimulator socket until they are fully seated in the connector block (FIGURE 61).
 - » Socket 1 (top)—Electrodes 0–7
 - » Socket 2 (bottom)—Electrodes 8–15

FIGURE 61

Inserting the lead or extension connector pins into the connector block



NOTES:

- During insertion, some resistance is typical.
- To retract the setscrews, insert the torque wrench from the neurostimulator package into the self-sealing grommet and rotate the setscrews counterclockwise; however, do not remove the setscrews from the connector block.

- 4 For each lead or extension, fully insert the torque wrench from the neurostimulator package into each self-sealing grommet of the connector block and tighten each setscrew (FIGURE 62).

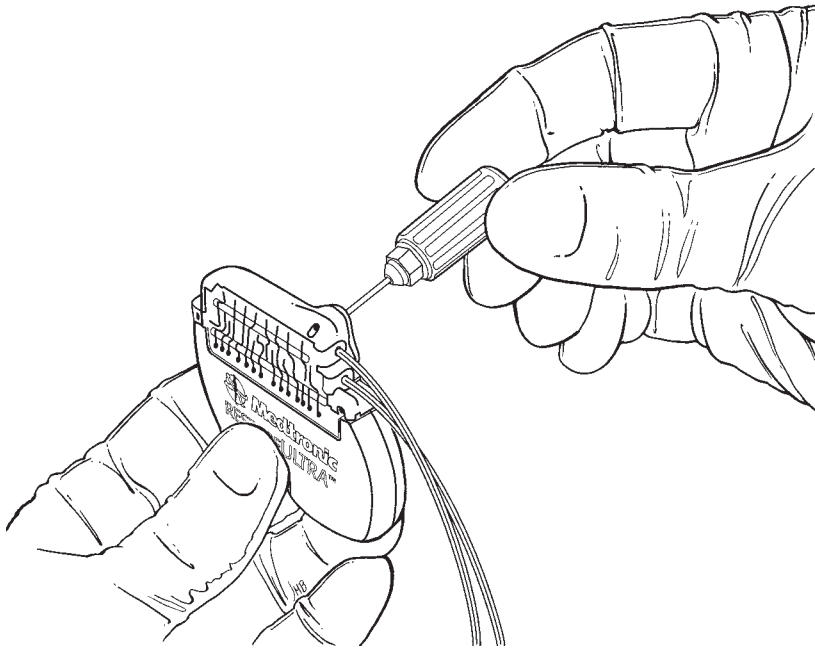


FIGURE 62

*Tightening each setscrew
in the connector block*

CAUTION:

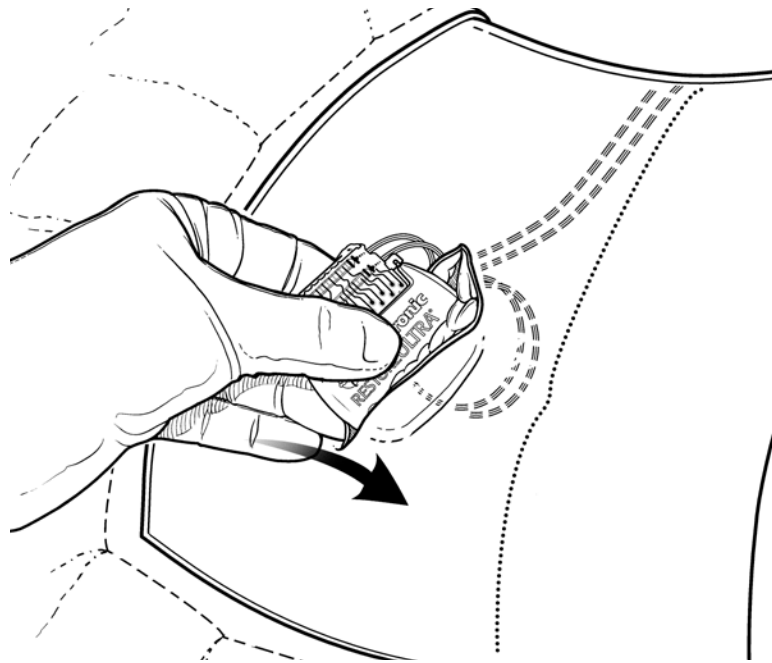
Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.

Implanting the Neurostimulator

- 1 Place the neurostimulator into the subcutaneous pocket (FIGURE 63) ensuring:
 - Medtronic logo is facing outward and parallel to the skin surface to allow for successful telemetry and recharging (if applicable).
 - Extension(s) or lead(s) are coiled around the perimeter and/or placed behind the neurostimulator and are not bent sharply.

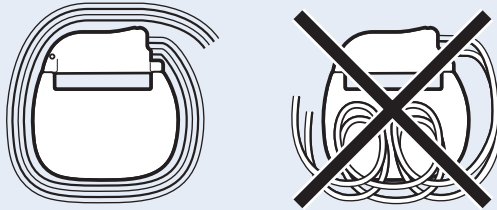
FIGURE 63

Orienting the neurostimulator



CAUTION:

Do not coil excess extensions or leads in front of the neurostimulator. Wrap excess extensions or leads around the perimeter or behind the neurostimulator to help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension or lead, and minimize interference with telemetry and recharge operation.



NOTE:

Ensure that the neurostimulator is placed parallel to the skin and at a depth that allows for efficient and successful telemetry and recharging (if applicable):

For rechargeable neurostimulators:

Place no deeper than 1 cm below the skin.

For nonrechargeable neurostimulators:

Place no deeper than 4 cm below the skin.

- 2 Use the suture holes in the connector block to secure the neurostimulator to the muscle fascia. Suture using nonabsorbable suture.

Checking System Integrity

A system integrity check ensures that each lead or extension is properly connected to the neurostimulator.

CAUTION:

To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

- 1 Using the clinician programmer, program the basic stimulation parameters, check the battery status, and check the electrode impedances to rule out a short or open circuit (FIGURE 64).

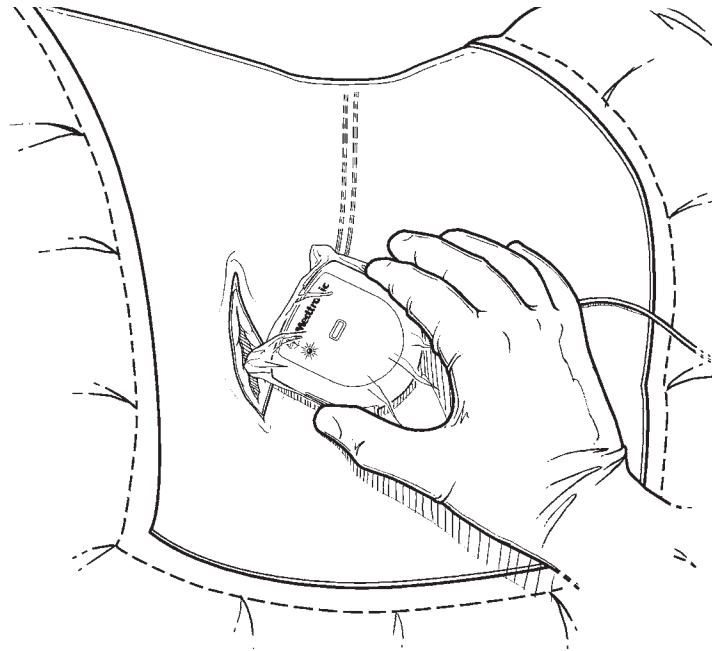


FIGURE 64

Positioning the clinician programmer over the neurostimulator

- 2 Once the system's function is verified, turn the neurostimulator off.

Completing the System Implant Procedure

- 1 Follow standard procedure for wound closure (FIGURE 65) and bandaging.

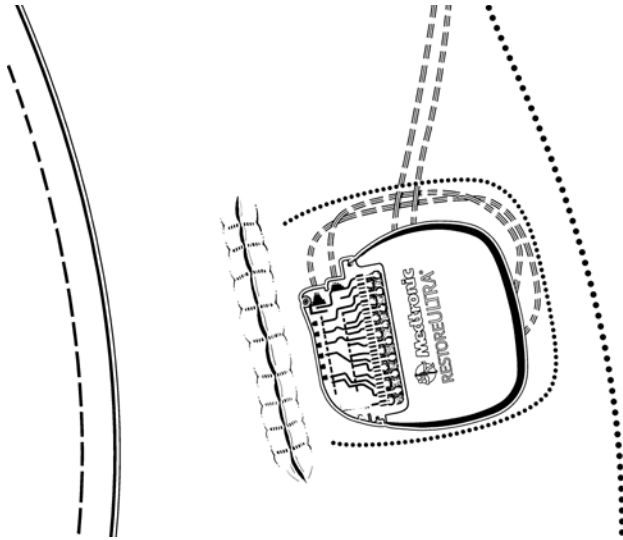


FIGURE 65

Closing incisions

- 2 Ensure that a patient programmer is given to the patient when the patient is sent to the recovery room.
- 3 Complete the registration paperwork in the component packages. Return the documents to Medtronic. The patient will receive a device registration card from Medtronic.

Postoperative Considerations

Operating Room

If desired, immediately postoperatively take anteroposterior (AP) and lateral images to establish baseline lead placement.

Recovery

Use routine procedures and standard practice for patient management in the recovery area.

If desired, you can initiate neurostimulation therapy in recovery. At this time, you can program the initial settings, but programming for maximum coverage may not be appropriate until a follow-up appointment.

Postoperative Activity Restrictions

Postoperative activity restrictions emphasize that maintaining lead position is critical. The patient should understand that abrupt movements may shift the implanted lead position, and small movements may produce significant changes in stimulation.

To maintain lead position, the patient should avoid:

- Lifting their arms overhead
- Lifting more than 5 lbs (2.3 kg), stretching, reaching, pulling, or twisting
- Electromagnetic interference (MRI, lithotripsy), postural changes or other activities (e.g., driving, operating power tools) that could cause an unexpected jolt or shock*

*For complete information on EMI warnings and cautions, see product labeling.

Before Discharging the Patient

Before the patient is discharged:

- Schedule the initial follow-up appointment.
- Ensure the patient is ambulatory and capable of appropriate range-of-motion exercises.
- Provide the patient with a temporary ID card and educational materials (brochures, manuals, DVDs).
- To expedite appropriate treatment during an emergency, recommend that patients wear a medical alert bracelet or necklace indicating that they have an implanted device.

Postoperative Patient Education

Thorough postoperative patient education is crucial to the long-term success of neurostimulation therapy. In addition to standard postoperative patient education topics, the patient, family, and caregiver should be educated on topics related to their neurostimulation system including:

- Neurostimulator and patient programmer operation
- Neurostimulation system maintenance
- Patient activity restrictions
- Applicable cautions and warnings including how MRI affects the neurostimulation system
- Instructions to carry patient identification card at all times in order to inform emergency or medical personnel of device information.

Medtronic produces a number of materials such as brochures, DVDs, and patient manuals to use in patient education related to the neurostimulation system.

7

Important Safety Information

Neurostimulation Systems For Pain Therapy

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications

Implantable neurostimulation systems—A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system 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 conditions:

- Failed back syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative disk disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex regional pain syndrome (CRPS), reflex sympathetic dystrophy (RSD), or causalgia

Contraindications

Diathermy—Do not use shortwave diathermy, microwave 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 locations of the implanted electrodes, resulting in severe injury or death.

Warnings

Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions

The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting.

Adverse Events

Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks.

For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

USA Rx Only Rev 0209

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