Guidelines for Implantation of a Percutaneous Spinal Cord Stimulator

C.M. Schade, M.D., Ph.D., P.E.
Diplomate, American Board of Anesthesiology

Jay D. Law, M.D.
Diplomate, American Board of Neurological Surgery

Allen J. Meril, M.D.
Fellow, American Academy of Orthopedic Surgeons
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>Patient Selection Criteria and Indications for Use</td>
<td>4</td>
</tr>
<tr>
<td>Approximate Stimulation Patterns</td>
<td>5</td>
</tr>
<tr>
<td>Preoperative Considerations</td>
<td>6</td>
</tr>
<tr>
<td>Safe and Efficient Use of the C-Arm Fluoroscope</td>
<td>9</td>
</tr>
<tr>
<td>Percutaneous Octrode Lead Placement</td>
<td>12</td>
</tr>
<tr>
<td>Test Stimulation</td>
<td>15</td>
</tr>
<tr>
<td>Octrode Receiver Implantation</td>
<td>17</td>
</tr>
<tr>
<td>Postoperative Considerations</td>
<td>21</td>
</tr>
<tr>
<td>References</td>
<td>22</td>
</tr>
<tr>
<td>Selected Articles</td>
<td>Inside Back Cover</td>
</tr>
</tbody>
</table>

Additional copies of this monograph are available from

**Neuromed, Inc.**  
Continuing Education Department  
5000-A Oakes Road  
Ft. Lauderdale, FL 33314  
(305) 584-3600 • FAX (305) 581-9580  
(800) SCS-STIM (727-7846)

© Neuromed, Inc. 1993
**Introduction**

The purpose of this monograph is to provide a “cookbook” for the novice or beginning implanter and possibly a “pearl or two” for the experienced implanter. In the interest of brevity, only the percutaneous placement of the Neuromed Octrode® lead for failed back surgery syndrome will be discussed. However, be aware that in some cases (i.e., spinal stenosis, epidural scarring, repeat procedures) the percutaneous technique may not be successful and a mini-laminotomy will be needed to place a Lamitrode®, Peritrode™, Quattrode™, or Octrode® lead.

The physiological basis for the clinical effects of spinal cord stimulation is still unclear. A popular hypothesis is that the mechanism of action of a spinal cord stimulator involves the Melzack-Wall gate control theory of pain.(1) Spinal cord stimulation may work by stimulating the axons in the dorsal column of the spinal cord. The objective in electrode placement is to activate these nerves at a convenient anatomical location. At the periphery, you can obviously stimulate only a single nerve, while at the level of the second cervical vertebral body you can stimulate many different nerve tracts and fibers.

It has been shown by exhaustive mapping and analysis of data that the average location for the so called “Sweet Spot” for low back stimulation is located at a point about half way between the inferior border of the pedicals of T9 and T10.(2)

Locating the “Sweet Spot” is made easier if you conceptually visualize the nerve fibers entering the dorsal column and becoming smaller, moving medially and ventrally as they ascend the spinal cord (see Figure 1).

The “Sweet Spot” for low back stimulation is typically at a point half-way between the pedicals of T9 and T10.

Dorsal Cord Fibers enter laterally and move medially and ventrally as they ascend the spinal cord.

**Figure 1**
Patient Selection Criteria and Indications For Use

Spinal cord stimulation is effective in treating chronic pain in carefully selected patients. Proper patient selection will improve any clinical results – short and long term.(3)

General Indications

1. There is an objective basis for the pain complaint (e.g., myelographically demonstrated arachnoiditis).
2. Alternative therapy has been exhausted or is not appropriate (e.g., ablation, microsurgical lysis of arachnoid adhesions).
3. Psychiatric clearance has been obtained (demonstrating motivation and long term commitment without major issues of secondary gain or a serious drug habituation problem).
4. The underlying pathology and topography are amenable to stimulation coverage (e.g., spinal stimulation for deafferentation, or central pain, rather than mechanical; and radicular rather than entirely axial pain).

Not all pain topographies can be treated by spinal cord stimulation. Those that can be treated by stimulation can be easy or difficult to treat. Thus, it has been recommended that some clinical problems be tackled by less experienced implanters, while more difficult cases should be referred to specialized centers (at least initially).(4)

Indications Ranked by Increasing Technical Complexity

1. Sympathetically maintained pain of one extremity.
   A. Reflex sympathetic dystrophy.
   B. Causalgia
2. Peripheral deafferentation pain.
   A. Post amputation neuralgia (stump pain).
   B. Intractable neuralgia, unilateral cervical or lumbosacral radiculitis (a small subset of failed back surgery syndrome, having very little or no back pain).
3. Pain associated with lesions of spinal cord and peripheral roots.
   A. Phantom limb.
   B. Post herpetic neuralgia.
4. Vasculopathic (peripheral ischemic) pain.
5. Pain of both upper or both lower extremities.
   A. Cervical or lumbosacral radiculitis (e.g., lumbar arachnoiditis – a small subset of failed back surgery syndrome).
   B. Sympathetically maintained pain of both arms or both legs.
6. Sympathetically maintained pain involving both upper and lower extremities, trunk, face, etc.
7. Low back pain, usually failed back surgery syndrome with major leg pain component.
8. Failed back surgery syndrome without significant leg pain.
Approximate Stimulation Patterns

When a patient meets the general and specific indications outlined previously, you will need to select the appropriate stimulator and electrode system to cover the patient's pain distribution (see Table I).

Quadrapolar leads are indicated in unilateral, single-extremity pain involving 1-3 dermatomes.

Dual quadrapolar leads are sometimes useful in axial pain patterns but most useful in bilateral pain, and often useful in multi-focal pain involving upper or lower extremities.

Octapolar leads are indicated for pain covering 4-7 dermatomes or axial pain with predominantly unilateral leg pain.

Dual octapolar leads are indicated for pain equally involving axial and bilateral leg patterns.

<table>
<thead>
<tr>
<th>Dermatomal Stimulation Distribution</th>
<th>Single Quad @ T9</th>
<th>Dual Quad @ T9</th>
<th>Single Octode @ T9</th>
<th>Dual Octrodes @ T9</th>
<th>Dermatomal Stimulation Distribution</th>
<th>Single Quad @ C4</th>
</tr>
</thead>
<tbody>
<tr>
<td>T9 Proximal</td>
<td>50</td>
<td>50</td>
<td>75</td>
<td>75</td>
<td>C4 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>75</td>
<td>75</td>
<td>75</td>
<td>75</td>
<td>Distal</td>
<td>25</td>
</tr>
<tr>
<td>T11 Proximal</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>C5 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>Distal</td>
<td>50</td>
</tr>
<tr>
<td>L1 Proximal</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>C6 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>50</td>
<td>50</td>
<td>75</td>
<td>90</td>
<td>Distal</td>
<td>90</td>
</tr>
<tr>
<td>L2 Proximal</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td>C7 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>Distal</td>
<td>75</td>
</tr>
<tr>
<td>L3 Proximal</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>50</td>
<td>C8 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>Distal</td>
<td>50</td>
</tr>
<tr>
<td>L4 Proximal</td>
<td>25</td>
<td>50</td>
<td>50</td>
<td>75</td>
<td>T1 Proximal</td>
<td>&lt;25</td>
</tr>
<tr>
<td>Distal</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>90</td>
<td>Distal</td>
<td>25</td>
</tr>
<tr>
<td>L5 Proximal</td>
<td>25</td>
<td>50</td>
<td>75</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>50</td>
<td>50</td>
<td>75</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1 Proximal</td>
<td>25</td>
<td>75</td>
<td>90</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>75</td>
<td>50</td>
<td>75</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S2 Proximal</td>
<td>50</td>
<td>75</td>
<td>90</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>25</td>
<td>50</td>
<td>90</td>
<td>90</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table I
Preoperative Considerations

It is recommended that patients be seen in the office 2 to 3 days before the date of their operation for a complete history and physical examination along with preoperative laboratory work. Particular attention must be paid to any signs of chronic or acute infection such as sinusitis, periodontal or dental infection and any skin problems, such as acne, rashes, or recent trauma in the area of the planned surgery. This is also a good time to determine the patient’s preference for the location of the receiver, which must be inserted parallel to, and no more than 1/4" below, the skin (see Figure 22B). In an obese patient, it is helpful to determine this location with the patient in a sitting posture since any fat rolls should be revealed in this position. Failure to determine this location beforehand may result in a sub-optimal placement of the receiver. Improper placement of the receiver is a common reason for surgical revision. The location should be marked before the patient is prepared and draped for surgery.

The consent forms are signed and the patient is given final preoperative instructions at that time. Typically, patients are not to take any pain medications after midnight on the day of surgery, so that they will be in their usual pain state, thus facilitating accurate placement of the Octrode lead. This is also an appropriate time to review with the patient once more where their pain usually is, in order to direct the test stimulation intraoperatively. Neuromed’s Pain Patient Prescreening Form is a convenient way to collect the data. Tables II, III, and IV are sample consent forms, preoperative orders, and patient instructions.

Having an implant assistant is extremely helpful during all phases of spinal cord stimulation. The implant assistant’s primary responsibilities include patient preoperative and postoperative education, insurance approval for the procedure (Neuromed also helps with reimbursement issues), intraoperative trial stimulation, postoperative programming, and patient/family counseling. Neuromed sponsors training courses for implant assistants and these are available several times during the year. When appropriate, on-site training and in-service for other departments can be arranged when starting a new spinal cord stimulation program.

It is very important to train your implant assistant and to conduct in-services for the operating room, post-anesthesia care unit, and floor nurses before your first case. This will ensure that the nurses know how to monitor the patient for complications, i.e., expanding epidural hematoma causing ascending paralysis which requires immediate surgical intervention.
Disclosure and Consent Medical and Surgical Procedures

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I (we) voluntarily request Dr. ____________________ as my physician, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my condition which has been explained to me by my physician as:


and I hereby release my physicians and any other participating health care providers from any and all liability for any adverse effects that may result from these procedures.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent and authorize these procedures: implantation of spinal cord stimulator to reduce pain. Alternatives include: live with pain; stronger medication; brain stimulator.

I (we) understand that my physician may discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and any associates, technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgements.

I (we) (do) (do not) consent to the use of blood and blood products as deemed necessary.

I (we) understand that no warranty or guarantee has been made to me as to result or cure.

Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical, and/or diagnostic procedures planned for me. I (we) realize that common to surgical, medical, and/or diagnostic procedures is the potential for infection, blood clots in veins and lungs, hemorrhage, allergic reactions, and even death. I (we) also realize that the following risks and hazards may occur in connection with this particular procedure:

- 2-10% risk of infection resulting in removal of all parts; 10-30% risk of future malfunction of internal parts; 4% risk of a new increased pain; 1/2% risk of death, permanent or temporary paralysis or loss of feeling and/or coordination of bowel, bladder and/or sexual organs; failure of stimulator to relieve pain; undesirable changes in stimulation may occur in time; radicular chest wall stimulation; cerebrospinal fluid leakage; persistent pain at the electrode or receiver site; seroma at receiver site; receiver migration; allergic or rejection response to implanted materials; paralysis, weakness, clumsiness, numbness, or pain below the level of implantation.

I (we) understand that anesthesia involves additional risks and hazards but I (we) request the use of anesthetics for the relief and protection from pain during the planned and additional procedures. I (we) realize the anesthesia may have to be changed possibly without explanation to me (us).

I (we) understand that certain complications may result from the use of any anesthetic including respiratory problems, drug reaction, paralysis, brain damage, or even death. Other risks and hazards which may result from the use of general anesthetics range from minor discomfort to injury of vocal cords, teeth, or eyes. I (we) understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and chronic pain.

I (we) have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of nontreatment, the procedures to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give this informed consent.

I (we) certify this form has been fully explained to me, that I (we) have read it or have had it read to me, that the blank spaces have been filled in, that I (we) understand its contents, and that a copy of this form has been made available to me.

DATE: ____________________ TIME: _______ am/pm ____________________________________
Patient/other legally responsible person sign

WITNESS: Name ____________________ Address ____________________

Table II
Pre-Op Orders: Spinal Cord Stimulator

1. Admit.
2. NPO after midnight.
3. No medications after midnight on day of surgery.
4. CBC, UA, SMA 25, PT, PTT, Bleeding Time.
5. VDRL, HIV.
7. EKG if over 40 years.
8. Betadine scrub to surgical area for 10 min. the evening before surgery. Betadine scrub shower the evening before surgery.
9. Anesthesiologist to write pre-op orders.
10. Place routine post-op orders on chart prior to surgery.
12. Ancef 1 Gm IM with pre-op medication on all surgeries; if allergic to penicillin, use Cleocin 600mg IVPB.
13. Routine Surgex prep of the back, T4 to S1 to anterior axillary line bilaterally.
14. Lab work on chart and listed.

Table III

Patient SCS Pre-Op Instruction Sheet

You are scheduled to have your spinal cord stimulator implanted on _____________. You need to come to Dr. _______________ office for your History and Physical and your lab work on _________________.

Please do the following things for surgery:

1. You need to notify Dr. _______________ of any changes in your physical condition such as a bad cold, the flu, sore throat, fever, etc.
2. Shower with Betadine Scrub for 10 minutes, the evening before your surgery.
3. Do not have ANYTHING to eat or drink after midnight.
4. Do not take any pain medication or muscle relaxants after midnight. It is okay to take your other medications with a sip of water, unless you are instructed to do otherwise by your doctor.

The Admitting Nurse, at the hospital, will tell you what time you need to report to the hospital on the morning of surgery.

Table IV
Safe and Efficient Use of the C-Arm Fluoroscope

We cannot overemphasize how important it is to take the time to properly position the patient and the C-Arm with respect to the patient, in order to minimize radiation exposure and to correct for parallax error (see Figures 2 and 6B). For example, did you know that nine (9) minutes of high level control fluoroscopy (fluoro boost, high contrast enhancement, low noise) is equivalent to a single fraction therapy dose used to treat patients with basal cell carcinoma? Also, proper positioning of the C-Arm and patient can make the difference between a long, difficult, and perhaps unsuccessful procedure and a very simple, short, and successful procedure. For example, if you don’t take into account parallax error the procedure is often times doomed even before you start.

The patient should be placed prone on a radiolucent table. Place a pillow under the abdomen to make the back level. The C-Arm should be brought in with the arm perpendicular to the table and with the caudal/cephalad motion of the C-Arm parallel to the table (see Figure 2).

Positioning of the patient and C-Arm Fluoroscope

Shielding to reduce scattered radiation

Figure 2

Figure 3
Safe and Efficient Use of the C-Arm Fluoroscope (continued)

Portable fluoroscopy units, such as the C-Arm used in surgery, are notorious for very high levels of radiation both to the patient and also to the physician and assistants. We are all aware that we need to avoid the direct x-ray beam in order to avoid excessive radiation exposure. However, some physicians may be unaware of the risk of the scattered radiation. Over-exposure has occurred when the physician was unaware of the source of scattered radiation.\(^5\) When an x-ray source strikes a target such as depicted in Figure 4, scatter radiation is initiated. This is called Compton Scatter and it occurs at every interface and radiates in all directions. The two major sources of scatter radiation are the x-ray source and the patient.

![Compton Scatter](image)

Scattered radiation contained by Lead Shielding

**Figure 4**

Radiation protection philosophy is best summarized in the acronym ALARA, i.e., the radiation dose should be kept As Low As Reasonably Achievable (Table V). The three variables that can be manipulated to reduce radiation exposure are shielding, time, and distance (Table VI). The mnemonic STD (not a Sexually Transmitted Disease) will help you remember to practice SAFE RADIATION! The best way to limit the time is for the physician, and not the x-ray technician, to use the C-Arm foot switch. Proper positioning of the C-Arm also eliminates parallax error, thus making placement of the needle and centering of the spinal cord stimulator lead much less difficult, which in turn minimizes the total fluoroscopy time.

<table>
<thead>
<tr>
<th>Table V</th>
<th>Table VI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALARA</strong> Radiation Doses Should Be Kept AS LOW AS REASONABLY ACHIEVABLE**</td>
<td><strong>To Achieve ALARA</strong></td>
</tr>
<tr>
<td>1. Increase Shielding</td>
<td>1. Increase Shielding</td>
</tr>
<tr>
<td>2. Decrease Time</td>
<td>2. Decrease Time</td>
</tr>
<tr>
<td>3. Increase Distance</td>
<td>3. Increase Distance</td>
</tr>
</tbody>
</table>

Radiation exposure to the physician and his staff may be further reduced by using 1/16 inch thick lead shielding on the patient (see Figures 3 and 4). Ten-fold reductions of radiation are not uncommon when placing the shielding on the patient.\(^5\)

Significant protection can be afforded by positioning the radiation source under the patient for two reasons. First, it moves the x-ray tube (one of the primary sources of scattered radiation) away from your radiation sensitive organs, i.e., eye lenses, thyroid, lungs, breasts, and stomach. Secondly, the radiation exposure decreases as the reciprocal of the distance squared. Thus, every time you double the distance between you and the x-ray source, you will decrease your radiation exposure by a factor of four! Consequently, the only safe way to position the C-Arm is with the x-ray source under the table (see Figure 4). This not only maximizes the distance between your eyes and the x-ray source, but it also allows for a simple way to shield the radiation.

The two primary sources of Compton Scatter can now be easily shielded by using sheets of sterile lead draping on the surgical field and by placing a lead drape on the edge of the table extending to the floor (you may use a standard x-ray apron and tape it to the sides of the operating room table). In addition to wearing lead aprons, those individuals that are often close to the x-ray source should wear x-ray attenuating gloves and a full face protective mask or a combination of a thyroid shield and x-ray attenuating glasses.

In summary, it has been shown that individual shielding may be augmented to provide lower levels of radiation exposure when implanting spinal cord stimulators by placing the x-ray source under the patient and utilizing shielding from the patient to the floor.
Parallax Error

The purpose of using fluoroscopy is to direct the epidural needle and then the lead to a specific anatomical target. For the purposes of this discussion, x-rays behave similar to rays of light. Think of the fluoroscopy unit as a scope on a hunting rifle. It must be aimed at the target in order to get a proper hit. The first step is to make sure that the x-ray beam is perpendicular to your target, the spine (see Figure 5). The x-ray beam should be perpendicular in all planes. The movement of the C-Arm, up and down the spine, should be parallel to the table (see Figure 2). When the x-ray beam is properly aligned, the center of the beam will pass through the desired target (see Figure 6A).

Imagine a set of cross hairs at the center of your image intensifier screen and place the target at the center of the X. A laser aiming accessory makes this step simple. If the desired target is off axis, as illustrated in Figure 6B, parallax error occurs. Thus, when you advance the needle you will be striking a phantom target instead of the desired target. Parallax error is easy to demonstrate in the operating room by holding a metal pointer above your target and then moving the C-Arm from side to side. The distance between the x-ray source and the target will determine the amount of magnification (see Figure 7). The closer the source is to the target the more magnification you will get.

In order to reduce your exposure time and to double-check positioning landmarks, have your surgical assistant align the C-Arm and then do the marking on the skin of the patient to show the location of the pedicles from L5 to T6 (see Figure 8). Accurately marking the level of the pedicles from L5 to T6 is quite helpful in positioning the lead. This allows you to verify the markings and correlate them with the preoperative x-ray of the spine.
Percutaneous Octrode Lead Placement

The patient should receive no or minimal amounts of narcotics and sedatives. There are two reasons for this.

You do not want to alter the perception thresholds of stimulation during the test stimulation. Elevated perception thresholds will give you a false sense of security when performing the test stimulation. When the thresholds are altered by narcotics or sedatives, high levels of stimulation may be tolerated and may exhibit excellent spread of paresthesias and recruitment of the desired nerves and you will be lulled into believing that you have a good lead position. However, when the patient wakes up and these drugs have worn off, he/she will not be able to tolerate that level of stimulation. When stimulation is reduced to a tolerable level it may no longer recruit the nerve fibers needed to provide paresthesias over the entire painful area.

Secondly, if you are going to perform test stimulation in the operating room, the patient must be able to recall the results of the trial stimulation (i.e., the fact that the stimulation relieved his/her pain, and that he/she wanted the spinal cord stimulator implanted). Many anesthetics cause retrograde amnesia. It is a real problem to have an implanted stimulator that doesn’t work and a patient that doesn’t remember anything about his/her test stimulation!

Before you begin, check and make sure that all the equipment is on the table and ready to go. Check your lead to make sure that there are no defects. In addition, get out the epidural needle(s) you are going to use, and make sure that the lead passes freely through the needle. Note the feel of the lead when passing it through the needle.

Once the patient has been appropriately positioned, i.e., prone with the spine slightly flexed, it is recommended that the C-Arm be used to identify, localize, and mark the desired vertebral levels as discussed previously. An adequate surgical prep can then be performed and sterile drapes applied to expose the ENTIRE implant area including the receiver site.

The patient can now be given a short acting anesthetic, such as propofol or ketamine. The patient will be unconscious for 3 or 4 minutes and during that time you should inject local anesthesia in the desired areas as needed for the case. In this way the patient won’t remember the unpleasant experience of the numerous needle sticks.

The local anesthetic of choice is 0.25% Marcaine with 1-200,000 epinephrine. (Do not use more than 2 mg per kg per hour – see the package insert for complete information.) In addition, you can usually place one or more epidural needles in the epidural space before the patient regains consciousness.

The use of epidural anesthetics is difficult because they can alter the patient’s responses during trial stimulation and make it difficult or impossible to achieve proper lead position.

When placing the epidural needle, it is extremely important that the needle be introduced at the shallowest angle possible. It is also important that the tip of the needle be as close to the epidural anatomical midline as physically possible. A good epidural entry point for failed back surgery syndrome is at the L1-2 interspace. For a patient who is of average weight with respect to his height (i.e., the patient is neither skinny nor obese), the point of the needle puncture in the skin should be over the lateral and caudal corner of the vertebral body of L3 (see Figure 9).
Percutaneous Octrode Lead Placement (continued)

If the patient is skinny, you will move cephalad from this position. If the patient is obese, you will move caudad. This typically results in a needle angle of 30 to 40 degrees (see Figure 10). You should not exceed 40 degrees because the larger you make the angle, the more difficult it will be to introduce the lead blank and lead.

![Correct Needle Angle](image)

*Figure 10*

Use a number 11 blade to make a stab wound in the skin where you are going to insert the epidural needle. This avoids introduction of dermal matter into the epidural space and prevents excess pressure on the tip of the needle. The special needle is introduced through this incision at an angle of 30-40 degrees, at a vertebral level to ensure that roughly 20cm (one third of the lead) will be within the epidural space. This is especially critical with the Octrode lead to ensure that ALL ELECTRODES make contact with the dura and to provide additional lead stability. I recommend using a glass syringe with this technique. Avoid injecting air into the epidural space because air can interfere with the trial stimulation. An alternate technique is to use the lead blank to feel for the epidural space. Using a liquid to identify the epidural space is not generally advised because this makes it more difficult to recognize an inadvertent dural puncture. It is safest to advance the lead blank with the patient awake since you do not want to put undue pressure on the dura or the nerve roots. An awake patient will complain of pain and you will know to stop. If the patient is asleep, obviously you can do damage without knowing it.

When advancing the lead blank beyond the tip of the needle, it is very important that the stylet be withdrawn slightly. This provides maximum flexibility of the tip and minimizes the chance of a dural tear (see Figure 11). When advancing the lead blank, it is also very important to watch under fluoroscopy and to keep the tip on the midline at all times. If you are able to create only one pathway down the anatomic midline, then you have a better chance that the electrode will follow this path as opposed to multiple errant paths that have been created by the lead blank. You should also have two stylets ready, the first stylet being straight and another stylet with a 30 degree bend, approximately 5 millimeters from the tip. Using the curved stylet, you can steer the tip of the lead blank left or right by rotating the stylet appropriately (see Figure 12A).

![Correct Stylette Withdrawn](image)

*Figure 11*
Another helpful maneuver is withdrawing the curved stylet. This allows you to get an offset to place the tip in the midline (see Figure 12B). By careful use of the appropriate stylet (straight or curved) and the maneuvers outlined in Figures 12A and 12B, you can keep the lead blank in the midline. Unless the first lead blank is extremely easy to place, it may be advisable to place a second lead blank alongside the first lead blank. This lead blank can then act as a guide or “rail” to direct the Octrode lead. The lead blank should be advanced up to the target position. It is a good idea to attach a large hemostat to the pointer and place the pointer over your target (i.e., the pedicles of T10).

At this point it is highly suggested that the needle be removed carefully while leaving the lead blank in the epidural space. This will allow Neuromed's Introde™ lead introducer to be placed into the epidural space over the lead blank. The blank can then be removed leaving an excellent introducer which will allow the lead to be passed all the way to the target. If withdrawal of the lead is necessary, the Introde eliminates any possibility of shearing the insulation on the lead. If this step is omitted, it is possible that the needle will shear the lead if it is drawn back through the needle and create a condition for failure or undesirable stimulation post-implant. Since the Introde Lead Introducer may usually be advanced up to the top of the lead blank, special manipulation of the Octrode lead itself is usually unnecessary. However, when the Introde does not pass the ligamentum flavum, or if it is not used, there are certain techniques that will aid in lead placement.

Before inserting the Octrode lead, you may gently bend the distal tip. Make a 30 to 45 degree angle by gently bending the lead between the second and fourth electrode contacts. You can more easily steer an Octrode lead with a slight bend since it allows you to rotate and steer it in the direction you want it to go. It often takes several attempts to get that curve “just right” and to develop enough “memory” in the lead so it will hold the shape you want.

**CAUTION:** When withdrawing the lead through a needle, be very, very careful that it does not snag on the end of the needle or that the needle does not cut into the lead (refer back to your initial testing where you were passing the lead through the needle). If there is any excessive drag or snagging, the entire needle will need to be withdrawn with the lead in it. Alternatively, the needle may be withdrawn and the Introde slipped over the lead into the epidural space. However, we recommend that the Introde be placed over the lead blank before lead placement. It is very easy to nick or cut the lead and removal of the lead through the needle is not recommended. However, with practice and by using a very low angle of the needle, the lead can be inserted and withdrawn carefully without damage. If you encounter difficulty steering the lead, you can use the other lead blank, which you previously placed, to push it over to the appropriate position or to block it from advancing to the incorrect position. Position the Octrode lead with the fourth and fifth contacts under the pointer at the pedicals of T10 (see Figure 13). It has been shown that this is the best point to start your trial stimulation for failed back surgery syndrome.
Test Stimulation

There are three main objectives of Test Stimulation.

1. To get the electrode in the optimum position for covering all, or at least a significant portion, of the areas where the patient has pain.

2. To see if stimulation in the area of pain provides pain relief.

3. To verify that the sensation of electrical stimulation is acceptable to the patient.

Secure the external Test Stimulation cable to the surgical drape with a clamp as illustrated in Figure 14 (be careful not to break the insulation on the cable). The lead can then be inserted and the screws tightened. The other end of the cable should be passed off the sterile field to the person conducting the Test Stimulation. At this point it is imperative that the patient be awake and not sedated. (Refer to the TS-8 Test Stimulator Physician Information booklet for operation of the test stimulator.)

1. To begin test stimulation, set the controls as follows:
   A. Pulse width: 200 microseconds
   B. Physician amplitude control: minimum
   C. Frequency: 20–50 Hz
   D. Electrodes: 4+, 5–(a)

2. Slowly increase the patient amplitude control up to maximum or until proper stimulation is achieved. If the patient reports no sensation, reduce the setting to six (6) on the patient amplitude control and then slowly increase the physician amplitude until appropriate stimulation is achieved.

3. When the patient reports a comfortable stimulation level, ask the patient to describe where the stimulation is perceived and if it is covering his/her usual painful area. If the test stimulation is too low (caudad), try 1+, 2– and conversely, if the stimulation is too high (cephalad), try 7+, 8–. Note that the stimulator threshold may be quite different, so increase the amplitude level slowly. (Recall that electrode #1 is the most cephalad electrode and electrode #8 is the most caudad electrode.) (See Figure 15.)

(a) Alternatively, the electrodes may be programmed with electrode #1 as a cathode and electrode #2 as an anode as the initial step in defining the most cephalad level of stimulation.
4. Ultimately position the Octrode lead so that the fourth and fifth electrodes are over the “sweet spot.” The “sweet spot” is the area that provides the best coverage and pain relief for that patient. The “sweet spot” can vary over approximately a 1½ centimeter distance, along the long axis of the spinal cord, probably related to the anatomical location of the conus(2).

CAUTION: In order to avoid any unpleasant stimulation to the patient, which can be very painful, observe the following:

1. Always turn the test stimulator off and disconnect the test cable from the test stimulator when moving the Octrode lead.

2. Always turn the test stimulator off when changing settings.

3. After you have obtained an Octrode lead position and an electrode combination that cover the patient’s pain topography, set the patient amplitude to a comfortable setting and let the patient experience the effects of spinal cord stimulation. This is the time to ask the patient if the spinal cord stimulator is relieving his pain and, if it is, does he want the stimulator implanted? Another question to ask is whether the relief provided by stimulation is as good or better than any prior therapy. The patient, and not the physician, should make the decision to proceed with a permanent implant. Allow enough time for the patient to feel comfortable and secure with the sensation of spinal cord stimulation. Taking an extra few minutes here will be invaluable.
Octrode Receiver Implantation

When the decision is made to implant the receiver, the patient may be given I.V. sedation. It is important to use agents that do not cause retrograde amnesia. You want the patient to remember the test stimulation and the fact that he/she made the decision to have the system implanted.

There are two popular sites for Octrode receiver placement. On most patients, except those that are very skinny, a position along the left mid-axillary line is preferred (assuming that the patient is right handed) (see Figure 16). A good alternate position is the upper buttock in the posterior axillary line (be careful to avoid the patient’s belt line). The mid-axillary line is preferable for most patients because the chance of electrode fracture is less likely. The mid-axillary line also offers the advantage that the arm protects the receiver, thus reducing the risk of things bumping into the receiver. Some women prefer the mid-axillary line because the receiver can be placed under their bra strap and they may not have to use adhesive tape to hold the antenna in place. Others strongly dislike the mid-axillary line because they do not want any scars above their waist. When the upper buttock position is used, it is important to position the receiver along the posterior axillary line, so that when a patient is sitting in a chair, the receiver does not hit either the back or the side arm of the chair.

In either location, it is important that the receiver be located in a flat area that the patient can easily reach for placing the antenna. The abdomen should be avoided in most patients, as there is a greater chance that the receiver will turn over or “float,” which will make it difficult for the patient to properly place the antenna.

The patient should still have satisfactory local anesthesia from the earlier Marcaine injection. However, if the block is not satisfactory, 1% Lidocaine with 1-200,000 epinephrine should be used to supplement the local block.

Many physicians prefer to make the pocket incision before tunneling the lead (see Figure 17). Hematomas are more likely to form at the receiver site and this allows more time for hemostasis. The pocket should be made so that the suture line is slightly removed from the receiver (see Figure 23) and the receiver lies not more than 1/4 of an inch below the skin surface (see Figure 22B). The receiver and antenna must be parallel to each other to ensure proper data reception and maximum power transfer. After completing the pocket and obtaining hemostasis, pack it with raytex gauze soaked in antibiotic solution.

![Typical Receiver Placement](image)

![Figure 16](image)

![Figure 17](image)
Octrode Receiver Implantation (continued)

Leave the needle or Introde in place, make an incision next to the needle (or Introde) and proceed cephalad. Follow the needle down to a strong fascial plane to find a secure place to tie the anchor. Always secure the anchor sutures to the deep fascia or to the interspinous ligament. Movement of the skin over this area should not result in any movement of the anchor. Place a 2-0 nonabsorbable suture at this time.

Next make a 2-4 centimeter incision midway along the line between the receiver pocket and the epidural needle (see Figures 17 & 18A). This makes it easier to pass the tunnelling tool around the chest wall (see Figure 18A). Pass the tunnelling tool from the midpoint incision to the midline incision (see Figure 18B). Remove the trocar.

**NOTE:** Protect the lead in order to avoid inadvertent damage with the tunnelling tool.

Carefully remove the epidural needle or Introde from the tissue using the PUSH and HOLD technique (see Figure 19). The “Push and Hold” Technique is used to minimize electrode migration.

---

**Tunnelling Technique**

*Figure 18A*

Place tunnelling trocar with needle in place to protect the electrode.

*Figure 18B*

**Needle Removal**

*Figure 19*

**PUSH AND HOLD TECHNIQUE**

Grasp the lead with two fingers, approximately 1 inch away from the hub of the epidural needle. With the other hand, gently push the needle or Introde® up over the lead body until the hub and fingers meet. Repeat this “Push and Hold” procedure until the needle clears the tissue. At this point, have your assistant grasp the Octrode lead where emerges from the tissues with a pair of rubber shod diamond tip forceps (the assistant should hold the lead...
Octrode Receiver Implantation (continued)

until the anchoring is completed). Now, carefully remove the needle or Introde from the Octrode lead, taking care that the connector bands are not snagged causing the lead to move.

Next, ligate the lead anchor to the lead with 2-0 nonabsorbable sutures. One good method is to have an assistant hold the anchor around the lead, out of the wound, while you pass the suture around it and lock but not tie the suture. The anchor can easily be slid down the lead until it meets with the tissue and then securely knotted at that location. The previously placed suture should now be threaded through the hole completely around the lead anchor and tied securely (see Figure 20). Gently tug on the lead to make sure that it is secure. When it is secure, recheck lead placement by fluoroscopic examination and adjust if necessary.

NOTE: Even with a very tight ligature around the anchor, the lead will still move. This is a design characteristic of the anchor as the stimulating end of the Octrode lead is designed for tissue ingrowth and eventual anchoring at that site.

Slide the terminal end of the Octrode lead through the opening of the connector boot (see Figure 21), being careful not to bend the terminal end. Verify that the screws in the connector are loosened and not blocking the lead insertion hole of the connector. Carefully slide the terminal end of the Octrode lead into the connector and tighten the eight set screws, taking care not to over-tighten and strip them, making them impossible to remove. Carefully slide the connector boot over the connector and ligate 2-0 nonabsorbable sutures at each end.

After the system has been completely assembled, you may use a sterile antenna to test the system (the antenna can be autoclaved or put in a sterile bag). You should make sure that you have good receiver placement and that the antenna locator tone changes when the antenna is placed into proper position over the receiver. It is advisable to flush all incisions with an antibiotic solution.
Octrode Receiver Implantation (continued)

Place the receiver in the pocket with the antenna coil (writing side) facing outward (see Figure 22A & B). If the antenna coil is facing inward, the receiver will not be able to link with the transmitter. When the receiver is lying in the pocket, the suture line should not cross over the receiver (see Figure 23). If the suture line crosses over the receiver, the suture line will be more likely to break down and become infected. Infections almost always require explanation of the entire system.

At this point it is good practice to inspect the system under fluoroscopy to ensure that no kinks are visible in the lead over its entire length and that the lead has not been inadvertently moved. Have the x-ray technician save the spot films showing the final location of the Octrode lead with the pointer at the pedicles of T10. In addition, have a full sized AP x-ray taken immediately postoperatively, preferably in the O.R. before transferring the patient, to document the position of the Octrode lead.

Make sure the antenna and lettering are facing the skin.

Correct Receiver Placement

1/4 Inch Maximum Depth

Antenna Facing Out

Figure 22A

Figure 22B

Suture line to the side of the receiver.

Figure 23
Postoperative Considerations

The patient should be admitted for a minimum of 23 hours, of which the first eight-twelve hours should be spent at absolute bedrest in order to minimize the movement of the lead. The patient should be advised to avoid stretching, bending, pulling or sudden movements for at least a week. The probability of the Octrode lead moving decreases significantly after the first 24 to 48 hours. I.V. antibiotics should be continued for 24 hours. The patient may then be kept on P.O. antibiotics for another 3 days (Table VII).

A patient who has had test stimulation which was UNSUCCESSFUL should also be treated in the same manner. A rare, but potentially lethal complication is an expanding epidural hematoma causing ascending paralysis. The nursing staff needs to be aware of this complication. Furthermore, a surgical team should be readily available for an emergency decompression during the first 24 hours.

The patients are sent home with instructions (Table VIII) and seen after 5 days for postoperative wound check and dressing change.

The sutures are removed the following week. X-rays may be taken to verify lead position at any future visit. It is advisable to delay stimulation until the receiver wound is healed in order to avoid contamination of the wound.

COMPLICATIONS

Spinal cord stimulation is a safe, nondestructive, and reversible surgical procedure. However, as with all operations, complications can occur. The one complication that you need to pay special attention to is postoperative infection. Latent infection, often observed months after implant, may result if appropriate sterile techniques are not adhered to. You should use the same protocol for spinal cord stimulators that is used for total joint replacements. This includes a 10 minute prep BY THE CLOCK, double masking, traffic control (i.e., minimizing the number of personnel that enter the operating room), meticulous aseptic technique, preoperative and postoperative antibiotic coverage, and excellent wound care. The following complications have also been reported.(4, 6, 7) They are not listed in any particular order.

1. Infection.
2. Transient paraplegia, lasting about 3 months.
3. Postoperative allodynia (touch perceived as pain).
4. Seroma and tenderness over the receiver or anchor site.
5. CSF leakage.
6. Electrode migration.
7. Electrode failure.
8. Receiver failure.
9. Expanding epidural hematoma causing ascending paralysis.

See the Physician’s Manual for a complete listing of complications and contraindications.

Table VII

POST-OP ORDERS:
SPINAL CORD STIMULATOR

1. Neuro checks q15 min. in PACU, then q1 hr x 6 hrs. (watch for ascending paralysis).
2. Diet as tolerated.
4. Turn cough deep breathe q2 hr x 8 hrs. while awake.
5. Strict bed rest x 12 to 24 hours and then ambulate with assistance ad lib and BRP with assistance unless specifically ordered otherwise. May shower 2 days post-op.
6. Reinforce dressing PRN with sterile technique.
7. Straight cath x 2 PRN then Foley if necessary.
8. D/C IV (change to Heparin Lock) unless otherwise ordered. Notify MD if problems arise.
9. Dalmane 30mg PO HS PRN sleep, may repeat x 1.
10. Ancef 1 gram q6 hrs. IVPB via HL x 3 doses, with routine Heparin loc flushes. If allergic to Penicillin, give Cleocin 600mg q6 hrs. IVPB x 36 hrs.
11. Demerol 50mg and Vistaril 50mg IM q6 hrs. PRN pain.
12. Vicodin 1 or 2 tabs PO q3-4 hrs. PRN pain. If allergic to Vicodin, Talwin 1 or 2 tabs PO q3-4 hrs. PRN pain.
14. X-ray of SCS placement in PACU. Send films to doctor’s office (films not to be read by Radiologist).
Postoperative Considerations (cont’d)

SCS POST-OP INSTRUCTION SHEET

Congratulations on receiving the most advanced product available for the relief of pain!

For the first two weeks after surgery, you need to avoid stretching, pulling, and pushing. You need to avoid any sudden movements or activities that may dislodge or move your electrode.

Take special care of your wounds. Try to keep them clean and dry. You need to watch very closely for any signs of infection:

1. Increased pain at surgical site.
2. Increased redness.
3. Increased swelling.
4. Drainage.
5. Fever over 101 degrees F., or shaking chills with sweating when the fever breaks.
6. Opening of the wound.

If at any time you should have any problems with your incision, you are to call your doctor.

You need to make an appointment with your doctor’s office to be seen approximately five (5) days after surgery, for wound check and dressing change. You will also make another appointment for one (1) week later so that your doctor can remove the sutures. You will then make an appointment to see Dr. _______ for initial programming of the spinal cord stimulator. If Dr. _______ takes X-rays showing the placement of the electrode, you will need to bring those x-ray films with you to the doctor’s office.

Dr. _______ uses the films to program the spinal cord stimulator.

Dr. _______ will manage all of your medications until he/she removes the sutures.

After your sutures are out and Dr. _______ begins programming the spinal cord stimulator, Dr. _______ will be managing all of your medications.

Table VIII

References


