PURSUING ADVANCED INDICATIONS: COMPLEX BACK AND LEG PAIN

The Art and Science of Neurostimulation

Not for Distribution Within the United States
Acknowledgements

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Contents

Pursuing Advanced Indications: Complex Back & Leg Pain
"The Art and Science of Neurostimulation"

Acknowledgements

Chapter 1: Overview.................................................................1
About this Guide ..................................................................1
Objectives .......................................................................1
Consultants ....................................................................2
Other Resources ............................................................3
Patient Education ..........................................................3

Chapter 2: The Science ..........................................................4
Introduction ........................................................................4
Patient Profile .................................................................5
Electrophysiologic Model of Neurostimulation .................6
Clinical Application .........................................................7

Chapter 3: Trial Screening ......................................................8
Introduction ........................................................................8
Protocol—Needle Insertion ..............................................9
Protocol—Lead Placement ..............................................11
Protocol—Usage Range Establishment .............................12
Protocol—Active Electrode Screening Technique Overview ...13
Protocol—Active Electrode Screening Technique Steps .........14
Protocol—Active Electrode Screening Technique Tips .........16

Chapter 4: Trial Screening Period ...........................................18
Patient Education ............................................................18
Pain Control Evaluation ..................................................18

Chapter 5: Concluding Remarks ............................................19
Commentary .................................................................19

Chapter 6: Disclosures ..........................................................20

Appendix ...........................................................................28

Glossary ...........................................................................30

References ........................................................................32
Chapter 1 Overview

In This Chapter

- About this Guide
- Objectives
- Consultants
- Other Resources
- Patient Education

About This Guide

This booklet is intended to serve as a companion to the video *Pursuing Advanced Indications: Complex Back & Leg Pain®*. It is designed to facilitate your exploration of therapeutic alternatives for your patients who experience this most challenging chronic pain condition.

The content is organized so that each two-page spread provides a visual reference keyed to the video; commentary which paraphrases the narration; selected details which provide a rationale for the procedure, technique, or methodology presented; and notes.

While the guide does contain information which supplements, expands, or documents the procedure in the video, it is no substitute for thorough training in, and successful experience with, the use of neurostimulation therapies. Physicians who view the video and refer to the additional information contained in this guide may gain useful insights into the therapy; patient selection criteria; trial screening and implantation; possible complications; and contraindications.

Objectives

Physicians who view the accompanying video and read this guide will be able to evaluate whether they want to offer this therapy to their patients who fit the selection criteria. They will also be able to judge their own needs for further information, training, and technical support.

While the procedures demonstrated in the video and described here are relatively straightforward, it is important that physicians who adopt these therapies have sufficient experience and knowledge of the patient's underlying chronic pain problem. The information Medtronic provides on the treatment of Complex Back and Leg Pain is intended to help minimize false negative results and avoid complications.
Consultants

This education and training material is the culmination of years of collective research, product development, and input from physicians and patients. Three individuals who have made invaluable contributions to this effort are Giancarlo Barolat M.D., Jan Holsheimer, Ph.D., and C. M. Schade, M.D., Ph.D., P.E.

Dr. Barolat is professor of neurosurgery and director of the Division of Functional Neurosurgery at Thomas Jefferson University; he is also chief of Neurosurgery at Thomas Jefferson University Hospital. Dr. Barolat is a Founding Member of the American Neuromodulation Society and President of the International Neuromodulation Society. He is a graduate of the University of Torino Medical School in Torino, Italy. He is board certified by the Italian and the American Boards of Neurosurgery. Dr. Barolat has more than 20 years of clinical and research experience with neurostimulation. He helped develop several neurostimulation leads and he has lectured and published extensively on neurostimulation and its use in the treatment of patients with chronic pain.

Dr. Holsheimer is an associate professor and researcher at the Institute of Biomedical Technology, Department of Electrical Engineering, University of Twente, Enschede, The Netherlands. He received the M.Sc. degree in biology and biophysics from the University of Groningen, The Netherlands, in 1965 and the Ph.D. degree in biomedical engineering from the University of Twente, Enschede, in 1982. He has developed an electrophysiologic model of spinal cord stimulation indicating that the effect of stimulating electrode size and spacing determine the depth and the breadth of the electrical field. This model provides part of the theoretical basis for the treatment of Complex Back and Leg Pain.

Dr. Schade is in private practice in Dallas, Texas. He is a graduate of the University of Miami School of Medicine, Miami, Florida. He is board certified by the American Board of Anesthesiology with additional qualifications in Pain Management. In addition to his medical degree, Dr. Schade holds Ph.D.'s in both electrical engineering and computer science from Stanford University. Dr. Schade has treated many patients with Complex Back and Leg Pain using dual-lead neurostimulation systems expanding on the pioneering work of Jay Law, M.D. (Law, 1982, 1987). He is the principal developer of the active electrode screening, or “trolling,” trial stimulation technique shown in the video and described in this guide.
Other Resources

Consult the following resources for additional information on the Synergy and Mattrix System for the treatment of Complex Back and Leg Pain. These five technical manuals are enclosed in the applicable device package.

- MemoryMod® Model 7459 Software Programming Guide for Synergy™ and Itrel® 3 Neurostimulation Systems
- Synergy™ Model 7427 Implantable Pulse Generator Physician and Hospital Staff Manual
- Synergy™ EZ Model 7435 Patient Programmer User Manual
- Mattrix® Dual-Channel Transmitter and Receiver System Physician and Hospital Staff Manual
- Mattrix® Dual-Channel Transmitter and Receiver System Patient Manual

Contact your Medtronic representative for more information on the Synergy™ System, Mattrix® System, Pisces-Quad Compact® leads, Specify™ surgical leads, and neurostimulation training availability.

Patient Education

The importance of patient education for the trial screening period and trial screening procedure cannot be over emphasized.

Tell the patient that very strong to uncomfortable stimulation may be needed temporarily to correctly position the electrodes. Stimulation is a new sensation for the patient, and the patient may have a tendency to stop the screening procedure before the therapy's efficacy can be assessed. However, sometimes very strong stimulation is needed to establish the screening algorithm.

- Explain the screening procedure to the anesthesiologist to ensure that the patient will be awake enough to actively participate.
- Minimize the operating room suite noise so that the patient can focus on the screening and his or her responses can be heard.
- Explain the terms that will be used during the screening procedure to the patient so they can accurately respond.
- Don't prompt the patient's replies, but do verify their responses.
- Prior to lead placement and after surgery, educate the patient on what they should do during postoperative screening.
Introduction

A considerable number of patients with Complex Back and Leg Pain find no relief with conventional approaches. Today, physicians are discovering it is sometimes possible to treat patients with Complex Back and Leg Pain by innovative therapeutic application of neurostimulation.

Accumulating experience now suggests that the Medtronic Pisces-Quad Compact® leads, when optimally positioned and programmed, can provide effective pain relief in properly selected patients.

You may now be able to successfully treat low back pain for patients you were previously unable to help.

When treating a Complex Back and Leg Pain patient (Figure 2-1), the goal of neurostimulation is to establish paresthesias in regions ranging from the mid lumbar region to the foot. One of the challenges to treating these patients is achieving effective stimulation of the low back without causing pain, cramping, or other discomfort in the abdomen or the flank.

Discomfort can occur when dorsal root fibers (Figure 2-2) are preferentially stimulated before dorsal column fibers have had a chance to generate paresthesias in the low back. According to Dr. Barolat:

A segmentary distribution of paresthesia with a low electrical threshold and early motor recruitment is indicative of stimulation of a dorsal root in the lateral gutter of the spinal canal. A widespread distribution of paresthesias... and a slightly higher threshold is more indicative of activation of the dorsal columns (Medtronic, 1993: Barolat interview).

By activating dorsal column fibers to a greater degree, and dorsal root fibers to a lesser degree, it is possible to deliver more stimulation to the most appropriate sites and optimize pain relief.

Many physicians have used dual leads, positioned parallel to the dorsal column, to achieve this outcome.

In the clinical application of neurostimulation therapy, the ideal system would enable selective, deep stimulation of dorsal column fibers (Figure 2-3), reduce inadvertent recruitment of dorsal root fibers, and permit periodic adjustment of stimulation parameters in cases of disease progression.
Chapter 2 The Science

The Pisces-Quad Compact® lead (Figure 2-4) incorporates small, closely-spaced electrodes intended to improve the performance of neurostimulation systems used to treat Complex Back and Leg Pain. This relationship—among electrode spacing, size, and therapeutic effectiveness—has been investigated by Drs. Barolat, Holsheimer, Law, Schade, and others.

As electrode contacts move further apart, the electrical field becomes increasingly monopolar, spreading out in all directions (Figure 2-5a). As the anode and cathode are brought closer together, the electrical field becomes more longitudinally oriented (Figure 2-5b).

The Pisces-Quad Compact's electrode spacing makes it well suited to the efficacious delivery of neurostimulation in patients suffering from otherwise intractable Complex Back and Leg Pain.

**Patient Profile**

Candidates for this therapy are patients who experience what may be chronic neuropathic pain in the lower back and the lower extremities. Medications may not be able to provide these individuals adequate relief. Also, other forms of conservative treatment may not be effective for these patients.

The patients that I feel are the best candidates among this group are patients who have neuropathic pain in the lower extremity and back pain (Medtronic, 1999: Barolat interview).

*Stimulation works real well on sharp stabbing burning type pain, what I would call neuropathic pain. The aching low back or mechanical pain, it doesn't work on. So, if a patient has a mix of pains, which most failed back surgery syndrome patients do, they're going to have an improved quality of life because you're able to control both components [using neurostimulation and pain medications] (Medtronic, 1999: Schade interview).*

Patients should be carefully selected to ensure that there is an objective basis for their pain complaint. They must also be medically stable for surgery. And they should have a psychological evaluation to ensure that they are appropriate candidates for spinal cord stimulation.
However, no decision to implant a complete neurostimulation system should ever be made without first determining that the patient is an acceptable candidate by conducting a trial screening. This is the only way to determine if the patient's pain pattern can be covered, if it relieves the pain, and if the patient "likes" the paresthesia evoked by the electrical stimulation. While predicting successful outcomes is very difficult, it has been observed during trial screening that patients who have primarily neuropathic pain, and who can demonstrate a tolerance for stronger stimulation, may have a better overall result.

**Electrophysiologic Model of Neurostimulation**

Jan Holsheimer, Ph.D., is a pioneering researcher in the modeling of neurostimulation to treat pain. He postulates that stimulation works best when the electrical field is oriented so that it parallels the nerve fibers to be recruited. In the case of dorsal column fibers, the ideal electrical field should be longitudinal. And it should have just enough breadth and depth to stimulate these fibers without significantly affecting dorsal root fibers. Root fiber stimulation is problematic because it causes unwanted and painful radicular stimulation and can cause unwanted muscle contractions, which may be painful.

*In vivo*, the exact shape of the electrical field established by neurostimulation is always influenced by patient factors such as amount and location of scar tissue, fatty tissue, bone, and cerebrospinal fluid. Therefore, it may be irregular.

The orientation, depth, and breadth of the electrical field is also a function of electrode size and spacing. Therefore, lead selection becomes a critical factor in any situation where the creation of an electrical field possessing specific characteristics is desired.

The farther apart electrodes are spaced, the more diffuse and spherical (or basketball-shaped) the resulting electrical field will be (Figure 2-5c). The closer the electrodes are, the more focused and oblong (or American football-shaped) the resulting electrical field will be (Figure 2-5d). Small, closely-spaced electrodes can selectively deliver deep stimulation to the dorsal column fibers.
Chapter 2 The Science

Clinical Application

The clinical application of the modeling of neurostimulation electrical fields has also been examined by physicians interested in the treatment of Complex Back and Leg Pain.

Jay D. Law, M.D. of the Rocky Mountain Neurosurgical Alliance has conducted research that demonstrated that you can stimulate the low back with closely spaced dipoles (Law, 1983, 1986, 1987).

Richard North, M.D. of Johns Hopkins University has noted that: Achieving stimulation . . . of the lower back is recognized as technically difficult and may require complex electrode geometries and extensive psychophysical testing (North, 1993). Barolat adds that: New electrode configurations are being developed that might allow a more exclusive activation in the low-back fibers (Barolat, 1993). Barolat now reports that: . . . over the years, the systems have improved and we have been able to implant more complex systems that increase our ability to direct the stimulation where the pain is (Medtronic, 1999: Barolat interview).

According to Holsheimer, leads with smaller, more closely spaced electrodes produce the type of longitudinal electrical field which appears to be most effective in recruiting dorsal column fibers (Holsheimer, 1997). When this recruitment results in adequate paresthesia over the patient’s painful areas, it provides better outcomes for patients who experience Complex Back and Leg Pain.

C. M. Schade has developed an algorithm for trial screening patients with Complex Back and Leg Pain. His technique for locating a “sweet spot” that stimulates the low back is described in Chapter 3.

The Medtronic Pisces-Quad Compact lead with its closely-spaced electrodes provides the desired configuration for therapeutic application when used with the Synergy or Matrixx Systems (Figure 2-6a & b).
Introduction

The trial screening not only helps determine the patient’s suitability for neurostimulation—it’s also an opportunity to ascertain the optimal lead position relative to vertebral level and lateral distance from the electrophysiologic midline (Figure 3-1) of the spinal cord. Some physicians suggest the existence of a low back “sweet spot” (Figure 3-2) which, when sufficiently stimulated, produces back and leg paresthesias. This region is reported to be approximately 6 millimeters long (Law, 1992). The low back sweet spot is usually found to be between T8 and T10. Dual leads placed on both sides and within 1 to 3 millimeters of the electrophysiologic midline may capture the sweet spot.

When stimulation induces abdominal cramping or a “grabbing” sensation, it may be the result of the leads being placed above the sweet spot, or too far from it laterally. While every implanting physician’s experiences and preferences vary, the trial screening procedure depicted here represents one approach, based on Medtronic’s dual-channel systems used with Pisces-Quad Compact leads.

These neurostimulation systems permit the physician to set the voltage on each channel independently, enabling “steering” of the electrical field in order to center or balance it over the electrophysiological midline.

In This Chapter

- Introduction
- Protocol—Needle Insertion
- Protocol—Lead Placement
- Protocol—Usage Range Establishment
- Protocol—Active Electrode Technique Overview
- Protocol—Active Electrode Technique Steps
- Protocol—Active Electrode Technique Tips

Figure 3-1 Electrophysiologic midline

Figure 3-2 Theoretical “sweet spot”
Chapter 3 Trial Screening

Protocol—Needle Insertion

Prepare and drape the patient in the normal manner for a neurostimulation percutaneous lead trial stimulation. Prophylactic antibiotics should be administered intravenously for protection from infection.

Use a medical marker to identify the patient's anatomic midline and the applicable vertebral levels (Figure 3-3). The patient's last rib is normally at T12.

Identify and mark the T10 pedicals (Figure 3-4) to provide a landmark for the trial screening area between T8 and T10.

Administer local anesthesia at T10 (Figure 3-5a) and place a 22 gauge spinal needle under the skin (Figure 3-5b) to provide a fluoroscopic reference marker for the trial screening.

Administer local anesthesia at the scs needle entry site and make a small stab wound.

Using a paramedian approach, under fluoroscopic guidance, place the first introducer needle so that it enters the epidural space at L1,2 or L2,3. Be sure to insert the needle at the shallowest angle possible to reduce the risk of dural puncture and to allow atraumatic passage of the lead cephalad. For a patient of average weight, the skin needle puncture should be over the lateral and caudal corner of L3 (Figure 3-6) for a L1,2 epidural target. For a thinner patient, move it slightly cephalad, and for an obese patient, move it slightly caudad. The angle of the needle should not exceed 45°.

The epidural needle entry (Figure 3-7) should be approximately two vertebral levels below the most caudal target lead electrode destination, which in this example is assumed to be the inferior vertebral endplate of T10.

Some physicians trial with 56 cm leads to allow placement of the screening cable connectors off the midline. This may enhance patient comfort and allows the patient to lay on his or her back without laying on the connectors.
Verify entry into the epidural space by using the loss of resistance technique (Figures 3-8a & 3-8b). Use a contrast epiduragram to guarantee entry into the epidural space and to warn of the presence of any significant epidural scarring or obstruction.

Make a second stab wound lateral to the first one. Then, under fluoroscopic guidance (AP and lateral views), place the second introducer needle parallel to the first (Figure 3-9). Be sure to insert the needle at the shallowest angle possible; the angle of the needle should not exceed 45°. Adjacent needles facilitate grasping both leads simultaneously, with one hand, as you'll see later. (The adjacent needles also simplify anchoring the leads when this technique is later used when implanting a complete system.)
Protocol—Lead Placement

Under fluoroscopic guidance, slowly insert the Pisces-Quad Compact leads into the introducer needle (Figure 3-10) and guide them into the epidural space.

Grasp the stylet handle (Figure 3-11), rolling it between the thumb and forefinger. This steers the tip of the lead and helps advance it in the desired direction. Do not force the lead into the epidural space.

The distal electrode contacts should be positioned at the superior endplate of T8.

In the initial lead placement step, place the leads parallel to the spinal cord, on each side of the spinous process, 1 to 3 mm from the anatomic midline, with the distal electrode at the endplate of T8. Placing the introducer needles side-by-side facilitates single-handed control of the leads and electrode alignment.

Each lead should generate paresthesia primarily ipsilateral to its placement over the spinal cord. The patient may report feeling paresthesia in the ribs or abdomen if the leads are too far cephalad. A significant degree of paresthesia experienced on the side of the back ipsilateral to the lead without leg stimulation is indicative of a lead located too far from the midline—repositioning will be necessary in that case.
Seen under fluoroscopy, the leads should bracket the lateral margins of the spinous processes, as a starting point. The leads should be approximately 1.5 mm lateral of the spinal cord midline (Figure 3-12).

Mark the right screening cable to avoid any possible confusion during the trial screening.

Select the center bipole of each lead to set up the initial electrode combination (1+ & 2-/ 5+ & 6-), and the configuration used to establish lead position (Figure 3-13).

Set up the screener for the test stimulation (Figure 3-14). For optimal pain relief with dual-lead implants, first screen each lead individually; then fine-tune both leads as a system.

Start by stimulating through the right lead only, on channel one. Properly delivered stimulation should produce paresthesia predominantly ipsilateral to the lead. Stimulation of the abdominal or rib areas is likely in this initial lead position.

If paresthesia is not primarily ipsilateral, reposition the lead relative to the midline and re-stimulate.

Once the desired balance of ipsilateral paresthesia is obtained with the first lead, proceed with establishing the usage range.

After you complete the first lead, repeat the procedure for the second lead.

Understanding the correlation between the electrodes' spinal location and the applicable areas of pain will be helpful in positioning the lead and directing the paresthesia appropriately. Also recognize that neurostimulation output levels are typically lower when a patient is in a recumbent position than in a standing position. This is because of the lead's proximity to the spinal cord.

**Protocol—Usage Range Establishment**

Once the leads have been positioned properly, determine the patient's Usage Range.
Chapter 3 Trial Screening

The Usage Range (UR) is the patient's Discomfort Threshold (DT) minus his or her Perception Threshold (PT) (Figure 3-15). The Comfort Level (CL) is the desired patient amplitude for the trial screening. Higher usage ranges are associated with higher success rates, according to some physicians.

Strong stimulation may be required to provide paresthesia in the low back. Therefore, patients need to be instructed to differentiate strong from uncomfortable stimulation.

The patient's Comfort Level (CL) voltages should be strong but comfortable—about half-way between the PT and the DT (Figure 3-15).

In this step, you establish the patient's sensitivity to neurostimulation. The patient's ability to perceive and tolerate stimulation establishes his or her Usage Range (UR). This involves the difference between strong paresthesia and uncomfortable paresthesia. A large UR—a range of 1.5 volts or greater—is believed to be one indication that you will be able to recruit the low back fibers.

The UR is established first for one lead, then the other, beginning with the Perception Threshold. Slowly increase the voltage on the selected channel of the screener until the patient begins to experience paresthesia. Expect a higher perception threshold on the side most affected by pain. Most patients report perceiving paresthesia at amplitude settings of less than 4.5 volts. A Perception Threshold (PT) greater than 5.0 volts and a high Discomfort Threshold (DT) are indicators that the lead may be in what is called a "dead zone," that is, an area of very high thresholds (refer to the technique tips on page 16).

With the PT established, continue increasing the amplitude. Ask the patient to distinguish between strong or "intense" paresthesia and intolerable or "extremely uncomfortable" paresthesia. The setting at which the patient reports paresthesia has become intolerable is the DT. Whenever the patient experiences discomfort, immediately lower the amplitude to the patient's comfort level. The UR for the lead can now be calculated. This process is repeated with the other lead. PT, DT, and UR can and will often differ between channels.

Protocol—Active Electrode Screening Technique Overview

Active electrode screening (or "trolling") involves very slowly moving the leads with the amplitude at the comfort level, at a rate of about one millimeter per second, and asking the patient if he or she prefers a particular lead position.

Screening with the "trolling" technique makes accurate lead positioning possible in a minimum amount of time. The goal is to find the sweet spot between T8 and T10 where spinal cord
stimulation produces paresthesias that cover the patient’s low back and leg pain, and to center the lead’s electrode array over it. By continuously stimulating the spinal cord as the leads are moved, every part of the spinal cord that the leads pass over is mapped and the target nerve fibers are precisely located. This is the stimulation target or “sweet spot” (Figure 3-16).

Optimally positioned, a pair of Pisces-Quad Compact leads can generate a longitudinal electrical field which will produce an area of paresthesia adequate to cover the lower back, leg, and foot.

**Protocol—Active Electrode Screening Technique Steps**

After establishing the patient’s Usage Range on each lead and with the leads in their starting positions (superior endplate of T8), reduce the amplitude on each channel to the Perception Threshold. Then, increase each channel, in about equal increments, until the patient reports perceiving strong, but comfortable, balanced paresthesia.

At this point, the voltage may be significantly different between channels. It is critical that the patient feels the same amount of paresthesia in each leg. This centers the electrical field over the electrophysiological midline, which is essential for locating the sweet spot.

Begin to move the leads to locate the precise target or “sweet spot” for stimulation (Figure 3-17a & 3-17b).

Take both leads between your thumb and forefinger and retract the leads at the same time using only slight movements, all while the electrodes are active (Figure 3-18a & 3-18b).

**WARNING:** The screener’s output can cause uncomfortable stimulation, which has been described as “jolting” or “shocking” by some patients. Always turn the screener off before connecting or disconnecting the screening cables, and reduce the amplitude to zero (0.0) volts before changing electrode polarities. Always keep the active electrode contacts clear of the introducer needle. Before adjusting the screener, properly connect the screener to the patient’s implanted leads and ensure that the patient can provide immediate feedback.

**WARNING:** During “trolling,” keep hands clear of introducer needle hub to avoid possible inadvertent needle contact; undesirable needle penetration could result from an unexpected patient movement due to unpleasant stimulation.

Fluoroscopic guidance and patient feedback are essential to ensure the optimal positioning of each lead. Less than optimal results may indicate an undesirable lead location. For example, if the patient experiences paresthesia or cramping at very low voltages, it is possible that the lead is near a dorsal root or in an intrathecal
location. Similarly, if the patient has paresthesia in the abdomen, radicular stimulation, or muscle contractions, it is possible that the lead is in an anterior location.

**Note:** Refer to the Appendix of this guide, Procedure to Determine Optimal Stimulation Settings, and the DualScreen Model 3628 Screener Kit Operator Manual for a description of the screener and detailed instructions on screener operation. Also refer to the Surgical Procedures section of the MemoryMod Model 7459 Software Programming Guide for Synergy and Itrel 3 Neurostimulation Systems. These reference documents will help you understand the differences between the screener system and the IPG system.

**Note:** Some Synergy Model 7427 IPG capabilities cannot be simulated with the screener. For example, although the Model 3628 Screener will simulate stimulation in an 8-electrode system with one channel, it does not have the capability to provide simultaneous delivery of two channels with 8 electrodes each.

**Note:** Synergy IPG output is not always identical to screener output at the same settings. Some adjustment to the Synergy IPG settings may be required to reproduce the stimulation results achieved during intraoperative screening.

Continue slowly retracting the leads simultaneously from cranial to caudal until the patient reports paresthesia covering the lower back, leg, and foot. Since the area of maximum sensitivity—the sweet spot—is believed to be approximately 6 mm in longitudinal length, the leads must be pulled very slowly from the starting position at T8.

An equal degree of leg paresthesia should be maintained throughout the trolling procedure, and may require periodic amplitude adjustments.

The goal is to move paresthesia from the ribs and stomach and into the low back and leg (Figure 3-19a). Typically when the paresthesia leaves the ribs it is in the low back. Continue until the patient feels back and leg paresthesia (Figure 3-19b).

Continue the active electrode screening process until the paresthesia is optimum, based on the patient's perceptions.

The “low back” region is very poorly defined by patients—thus, it is crucial that you and the patient clearly communicate about the pain, the paresthesia, and their locations throughout the procedure. Use gentle pressure on the back to help your patient confirm the paresthesia coverage of the areas in which the patient reports pain (Figure 3-20).
Chapter 3 Trial Screening

Protocol—Active Electrode Screening Technique Tips

Sometimes it may be difficult or impossible to establish paresthesia even at very high amplitudes—this can be the result of placing electrodes over a less sensitive area of the spinal cord, usually T8 or higher. These areas are referred to by some physicians as “dead zones.” It is thought that the increased depth of cerebrospinal fluid accounts for this phenomenon. Loose connections, electrode faults, screener faults, and leads shorting together may also account for an inability to establish paresthesia at high voltage settings.

⚠️ WARNING: Because there is a risk that moving active leads set at high amplitudes out of a dead zone to an area of normal sensitivity can painfully jolt the patient, the screener operator should always be ready to reduce lead voltage to zero immediately, if necessary.

To move leads out of a dead zone, the screener operator should turn both leads off and the leads should be retracted about half a vertebra length. Once the leads have been re-positioned, establishing the Usage Range (UR) may proceed.

As described earlier, paresthesia that the patient perceives to be comfortable and strong results from a voltage which is usually midway between the Perception Threshold (PT) and the Discomfort Threshold (DT). This setting is referred to as the Comfort Level (CL).

A number of physicians have reported locating an area of the spinal cord where relatively little electrical energy results in maximum pain relief. It is possible to establish a paresthesia which will control a patient’s pain, but at settings above the CL, the paresthesia may be too uncomfortable to tolerate long-term. If the voltage is set at the CL, the chances of locating the “sweet spot” are improved.

Retract the leads to move paresthesia out of the ribs and abdomen and into the lower back, leg, and foot. When this happens, the sweet spot has been located.

By further retracting the leads, you will discover a point where the patient reports less back paresthesia coverage. Returning to the last, best position should prove to be the optimum location. When returning to the last best position, care should be taken to ensure that you return through the previous path. Excessive resistance indicates that you may be off track. Periodic voltage adjustments may be needed to maintain equal sensation on both channels.

The “ophthalmologist’s method” involves asking the patient to compare the paresthesias resulting from different lead positions until the best coverage is found (Figure 3-21). Proceed by asking the patient, “Which position do you like better for low back paresthesia? Number 1 or Number 2... Number 1 or Number 3...?” Do this while simultaneously moving the leads cephalad and caudad until the leads are centered over the sweet spot.

Figure 3-21 Bipole position
The location of the sweet spot is represented by a bell-shaped curve with the center at approximately T9.2. According to Law, the position of the sweet spot may vary by approximately 1.5 cm and correlates with the level of the conus medularis (Law, 1992).

Once the leads have been positioned optimally, anchoring them and closing may be performed in standard fashion. Apply gauze and the appropriate outer wound dressing.

**CAUTION:** Exercise care to avoid nicking or kinking the lead during anchoring.

During the trial period, you will have ample opportunity to evaluate—and modify—all pertinent therapeutic parameters.

While in most cases, a bipole will be adequate, there are instances where increasing amplitude or activating a guarded cathode or a transverse electrode array may provide a more efficacious electrical field.

In cases where paresthesia does not reach all the way to the toes, a slight amplitude increase or activation of additional electrodes may produce the desired effect.

If successful, the trial provides the final indication for implantation of the Synergy System (Figure 3-22).

The Synergy System’s transverse stimulation (between leads) (Figure 3-23a & 3-23b) features broaden your range of options for generating paresthesias into the desired regions.

Using the trolling technique, you can optimize positioning of the Pisces-Quad Compact leads. And, with programming post-implantation, the Synergy System can be fine-tuned to provide precise generation of paresthesia, taking advantage of the flexibility afforded by transverse stimulation when needed.

The Medtronic Matrix System with either percutaneous leads or with a surgical lead such as the Specify lead (Figure 3-24), may be more appropriate for patients with higher power requirements.
After the leads have been properly positioned, teach the patient how to use the screener. Then, the patient is observed for a period of time to evaluate the effectiveness of neurostimulation, and to see if any complications develop.

**Patient Education**

During postoperative screening, the patient experiences neurostimulation during normal daily activities. The goal of postoperative screening is to evaluate the effect of spinal cord stimulation on the patient's pain, narcotic use, and quality of life, and also to determine the patient’s electrical energy requirements and optimal parameter settings. During this period, the patient should be taught and encouraged to try different parameters to optimize and fully “test” the spinal cord stimulation therapy. They should be shown how to maintain the trial screening log. At the conclusion of postoperative screening, you should be able to decide if the patient is a good candidate for therapy and, if so, what type of system is most appropriate.

**Pain Control Evaluation**

Your evaluation of your patient's trial screening period should include an assessment of the patient's:

- Trial screening log
- Visual Analog Scale of their pain
- Activities of daily living
- Quality of their sleep
- Use of pain medications
- Ability to operate the system
- Paresthesia comfort level
- Neurostimulation system parameters
- Frequency and duration of system use

The trial stimulation period is intended to enhance the predictive value for efficacy in individual patients (Kumar, et al., 1998). So based on these factors, you and your patient can determine if long-term neurostimulation is an appropriate choice for pain management of their Complex Back and Leg Pain.
Commentary

Neurostimulation may improve the quality of life for patients with Complex Back and Leg Pain. But it's just one option in the entire spectrum of care—rehabilitation or other modifications to the patient's medical management (especially when combined with neurostimulation) may offer added benefits.

You now possess the power and flexibility to control Complex Back and Leg Pain as never before. To find out more about the totally implantable Synergy System, Mattrix System, Pisces-Quad Compact leads, Specify leads, and the therapeutic alternatives they make possible for your patients, contact your Medtronic representative.
In addition to the various precautions provided in the text of this guide, you should read and understand the Product Technical Manual. Indications, contraindications, warnings, precautions, and adverse events are also provided here. This will help ensure that you safely and effectively use Medtronic's products in the treatment of your patients.

The Synergy™ and Mattrix® Neurostimulation Systems are designed to aid in the management of pain via pulsed electrical stimulation through nerve structures in the dorsal aspect of the spinal cord. Activation of these structures produces nerve impulses that can inhibit the transmission of pain.

**Indications**

The Synergy Model 7427 Implantable Pulse Generator (IPG) and the Mattrix DualStim™ System are each part of a dual-channel system for spinal cord stimulation and peripheral nerve stimulation. The systems are indicated as an aid in the management of chronic, intractable pain of the trunk or limbs.

The Mattrix Receiver Model 3272 system is also indicated for peripheral nerve stimulation. Peripheral nerve stimulators are used to electrically stimulate peripheral nerves to relieve chronic intractable pain.

Patients should be carefully selected to assure that their pain is of physiological origin. Also, patients must be appropriate candidates for surgery.

**Contraindications**

Patients are contraindicated for internalization if they are clearly unsuccessful in receiving pain relief during trial stimulation, or if they are unable to properly operate the system.

The Mattrix system also is contraindicated for patients with an implantable cardiac pacemaker or cardioverter/defibrillator, or for those patients who will be exposed to magnetic resonance imaging (MRI).

**Warnings**

Case Damage—If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Equipment Operation—Patients should not operate potentially dangerous equipment such as power tools or automobiles during stimulation.

Pediatric Use—Safety and effectiveness of this system has not been established for pediatric use.

Postural Changes—Postural changes or abrupt movements may cause an increase or decrease in the perceived level of stimulation.
Higher levels of stimulation have been described as uncomfortable, "jolting," or "shocking" by some patients.

Pregnancy—Safety for use during pregnancy or delivery have not been established.

Telemetry—Do not send a patient home with "????" displayed on the physician programmer screen for any programmable value. This indicates that the parameter or mode is invalid and must be reprogrammed.

Antenna Use—Do not place the Mattrix transmitter directly over or adjacent to the antenna during stimulation as this may reduce the stimulating amplitude or affect other stimulation characteristics. Warn the patient to wear the transmitter several inches away from the implanted receiver to avoid this type of interference.

Mattrix Push Buttons—Accidental bumping of the transmitter buttons when in the SET position could cause a change in stimulation, which could result in unpleasant or less effective stimulation. Warn the patient to leave the OFF/SET/LOCK switch in the LOCK position at all times except when adjusting the controls.

Other Transmitters—Instruct your patients not to use the transmitter of another patient, or loan their transmitter to another patient. Explain that the therapy programmed into a patient's transmitter is a prescription only for that patient.

Aircraft—Do not use the transmitter while flying in an aircraft. Airlines recommend that electronic devices, especially those generating radio frequency signals, not be used while inflight to assure no interference occurs to aircraft communication systems.

Precautions

Physician Training

Implanting Physicians—Implanting physicians should be experienced in spinal procedures.

Prescribing Physicians—Prescribing physicians should be experienced in the diagnosis and treatment of chronic intractable pain of the trunk or limbs and should be familiar with the use of the Synergy or Mattrix Neurostimulation System.

Storage and Sterilization

Resterilization Considerations—All implantable components are supplied sterile. If resterilization is necessary, refer to "Resterilization" (Model 7427 IPG and Model 3271/72 Receiver Phys & Hosp Staff Manual) for further information.
Sterilization Method—The IPG and receiver were sterilized with ethylene oxide before shipment.

Storage Temperature—Store the IPG between 0°F (-18°C) and 125°F (52°C). Store the Matrix receiver between -40°F (-40°C) and 150°F (65°C). Temperatures outside this range can damage components.

**System and Therapy**

Component Failures—The physician should be aware that all neurostimulation systems may unexpectedly cease to function. A system may fail at any time due to random failures of the system components or the battery (prior to depletion). These events, which can include electrical short or open circuits and insulation breaches, cannot be predicted.

Components—The use of non-Medtronic components with this system may result in damage to Medtronic components, less than adequate stimulation, or increased risks to the patient.

Patient Detoxification—It is recommended that patients undergo detoxification from narcotics prior to implant.

Patient Management—To help ensure maximum benefits from the neurostimulation system, long-term postsurgical management of patients is recommended.

**Implantation/Explantation**

Component Disposal—if explanting a Synergy Neurostimulation System component, please remember the following guidelines:

- Do not incinerate the IPG; explosion can result if an IPG is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

Component Handling—Handle the implanted components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments. Any component showing signs of damage should not be used. The following practices will help ensure the component’s life:

- Do not bend or kink the lead.
- Do not tie a suture directly to the lead. Use one of the anchors (where applicable) supplied with the lead kit.
- Do not pull the lead taut when implanted. Leave it as loose as possible to avoid unnecessary tension on the lead.
- When handling the lead with forceps, use only rubber-tipped bayonet forceps.
Chapter 6 Disclosures

- Be extremely careful when using sharp instruments around the lead to avoid damaging the lead.

Etched Identification—Place the IPG with the etched identification side facing outward, away from the muscle layer of the body.

Extension-IPG Connection—Wipe off any body fluids from the extension connector pins or connector block before connecting them. Contamination of connections can affect neurostimulation. Do not tighten setscrews without the extension inserted. This can damage the connector block. Do not insert an extension into the IPG connector block without visual verification that the setscrews are sufficiently retracted to allow insertion.

Implant Considerations—Do not implant a device when the storage package has been pierced or altered, potentially rendering it non-sterile; the component shows signs of damage; or the Use Before Date has expired, because this can adversely affect storage package sterility and battery longevity.

IPG Handling—Be extremely careful when using sharp instruments around the IPG to avoid nicking or damaging the IPG case, the IPG insulation coating, or the connector block module.

The IPG can be damaged if dropped from a height of 12 inches (31 cm) or more onto a hard surface (i.e., a concrete floor). If this happens, do not implant the IPG.

Lead-Extension Connection—Wipe off any body fluids from the lead or extension contacts before connecting. Contamination of connections can affect neurostimulation. Do not overtighten setscrews.

Lead-Extension Routing—It is recommended that the implanted lead-extensions in dual lead-extension systems be routed so they do not form a "loop." When exposed to some theft detectors, looped lead-extensions increase the potential for patients to experience a momentary increase in their perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable, "jolting," or "shocking" by some patients as they pass through these devices.

Single Use—The IPG and other implanted components are intended for Single Use Only. DO NOT REUSE.

Implanting Two Receivers—If there is a need to implant two Matrixx receivers in a patient, they must be implanted at least 12 inches apart from each other to minimize interference.
Internal Switches—Reduce amplitude to zero (0) volts before making any changes in the internal physician switch settings. In addition, patients should be warned not to adjust the internal physician switches. While failure to abide by this warning may not be dangerous, per se, it could lead to less effective or unpleasant stimulation.

Cross Talk—Low amplitude cross talk from the radio frequency (RF) signal that programs the electrodes, typically 0.75 volts or less, may be perceived by some patients. Patients should be tested prior to internalization at 0 volts amplitude to determine sensitivity to this signal.

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, the following precautions should be noted.

Diathermy—The effects of diathermy on patients with an implanted neurostimulation system are unknown. Use of diathermy directly over an implanted lead-extension or neurostimulator is not recommended since internal components may be damaged.

Effects on Other Medical Devices—The neurostimulation system may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient’s benefit from each device.

Electrocautery—Electrocautery can cause reprogramming of the Synergy neurostimulator. If a Model 3888 lead is implanted, certain conditions during electrocautery may result in damage to the neurostimulator; neurostimulator replacement may be necessary. If use of electrocautery is necessary:

- Turn off the neurostimulator before performing electrocautery.
- Avoid using spray coagulation. If spray coagulation is necessary, keep the power setting less than 50 watts.
- Keep the current path (ground plate) as far away from the neurostimulator and lead as possible.
Bipolar cautery is recommended.

External Defibrillators—Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a neurostimulator. If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead-extension system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

Lithotripsy—Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Magnetic Resonance Imaging—Patients with an implanted device should not be exposed to the electromagnetic fields produced by magnetic resonance imaging (MRI). Use of MRI may potentially result in dislodgment, heating, or induced voltages in the neurostimulator and/or lead-extension. An induced voltage through the neurostimulator or lead-extension may cause uncomfortable “jolting” or “shocking” levels of stimulation. Clinicians should carefully weigh the decision to use MRI in patients with an implanted neurostimulation system, and note the following:

- Magnetic and radio-frequency (RF) fields produced by MRI may change the neurostimulator settings and injure the patient.
- Patients treated with MRI should be closely monitored and programmed parameters verified upon cessation of MRI.

Radiation Therapy—Radiation therapy can cause damage to the electronic components of a neurostimulator. It is not recommended to use radiation therapy directly over a neurostimulation device.
Home or Occupational Environment

Cellular Phones—Based on tests to date, cellular phones appear to have no effect on the Synergy Neurostimulation System. However, the effect of all cellular phones on neurostimulation systems is unknown and patients should avoid placing cellular phones directly over the device.

Electromagnetic Interference—Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to unexpectedly cease to function or cause sensitive patients to experience a momentary increase in their perceived level of stimulation. Also, severe EMI can permanently erase the IPG serial number, causing “???” to be displayed in place of the serial number.

High/Low Pressure Effects—The effects of high/low pressure on patients with an implanted neurostimulation system are unknown.

Home Appliances—Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation.

Occupational Environments—Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough EMI to interfere with neurostimulator operation if approached too closely.

Theft Detectors and Screening Devices—Theft detectors found in public libraries, department stores, etc., and airport/security screening devices may cause sensitive patients, or those with low stimulation thresholds, to experience a momentary increase in their perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable, "jolting," or "shocking" by some patients as they pass through these devices.

Instruct patients to do the following when approaching or passing through a theft detector or screening device:

1. Show the Medtronic patient identification card to security personnel. Ask to have the theft detector/screening device turned off or ask to bypass the theft detector/screening device.

2. If Step 1 is not possible and passing through the theft detector/screening device is unavoidable, reduce the amplitude of the IPG to the minimum and turn the IPG Off.
3. Approach the theft detector/screening device slowly. If any stimulation is felt, back out of the theft detector/screening device immediately without changing body position. If no stimulation is felt as the center of the theft detector/screening device is reached, move quickly through to the other side.

**Adverse Events**

As with all surgical procedures, the implantation of a spinal cord or peripheral nerve stimulation system involves some risks. In addition to those normally associated with surgery, implantation or use of a Synergy or Matrix Neurostimulation System carries the following risks:

- Allergic or immune system response to the implanted materials
- Infection
- Lead, extension and/or receiver/IPG erosion or migration
- Leakage of cerebrospinal fluid
- Loss of pain relief may return patient to his or her underlying pain condition
- Patients on anticoagulation therapies may be at greater risk for post-operative complications such as hematomas that can result in paralysis
- Persistent pain at the receiver/IPG site
- Placement of the epidural lead-extension is a surgical procedure which may expose patient to risks of epidural hemorrhage, hematoma, and/or paralysis
- Radicular chest wall stimulation
- Seroma or hematoma at the receiver/IPG site
- Undesirable change in stimulation, possibly related to cellular changes around the electrode(s), shifts in electrode position, loose electrical connections, lead or extension fractures, which have been described as uncomfortable, "jolting," or "shocking" by some patients.
- Nerve damage or degeneration
Model 3628 Screener Quick Reference

1. Set the amplitude (AMP2) for Channel 2 to 0.0 volts; this assures no output to electrodes 4, 5, 6, and 7.
   Note: If CH2 OFF is displayed on the LCD, you have scrolled AMP2 down too far. Use the AMP2 INCREASE key to set amplitude for Channel 2 to 0.0 volts.
   Note: If you want to access all 8 electrodes on one channel only, press the AMP2 DECREASE key until CH2 OFF is displayed on the LCD; this activates the screener’s Single Stim operation. In Single Stim operation, all eight electrodes are accessible on Channel 1. When the screener is in Dual Stim mode, however, Channel 1 can only access Electrodes 0, 1, 2, 3 and Channel 2 can only access Electrodes 4, 5, 6, 7.

2. Set the pulse width (PW) and rate (RATE) for Channel 1 as desired. Suggested values are:
   a. Pulse width = 450 µsec (500 µsec is the maximum DualScreen Model 3628 Screener and Matrixx 3210 transmitter value; 450 µsec is the maximum Synergy Model 7427 lPG value).
   Note: Dr. Schade uses 500 µsecs as the starting pulse width.
   b. Rate = 20 Hz (240 Hz is the maximum DualScreen Model 3628 Screener and Matrixx 3210 transmitter value; 130 Hz is the maximum Synergy Model 7427 lPG value).

3. Verify that the amplitude (AMP) for Channel 1 is 0.0 volt and program the electrode polarity for Lead 1. (+1, -2)

4. Set the desired amplitude for Channel 1.

5. Make adjustments as needed to optimize pain relief. If necessary, carefully reposition the lead.

⚠️ WARNING: The screener’s output can cause uncomfortable stimulation, which has been described as ‘jolting’ or ‘shocking’ by some patients. Always turn the screener off before connecting or disconnecting screening cables, and reduce the amplitude to zero (0.0) volts before changing electrode polarities. Always keep the active electrode contacts clear of the introducer needle. Before adjusting the screener, properly connect the screener to the patient’s implanted leads and ensure that the patient can provide immediate feedback.

6. Set the amplitude for Channel 1 to 0.0 volt.
Appendix

7. Set the pulse width for Channel 2 and rate as desired. Suggested values are:
   a. Pulse width = 450 \mu\text{sec} (500 \mu\text{sec is the maximum Model 3628 Screener and Matrix 3210 transmitter value; 450 \mu\text{sec is the maximum Synergy Model 7427 IPG value}).
   
b. Rate = 20 Hz (240 Hz is the maximum Model 3628 Screener and Matrix 3210 transmitter value; 130 Hz is the maximum Synergy Model 7427 IPG value).

8. Verify that the amplitude for Channel 2 is 0.0 volt and program the electrode polarity for Lead 2. (5+, 6-)

9. Set the desired amplitude for Channel 2.

10. Make adjustments as needed to optimize pain relief. If necessary, carefully reposition the lead.

   \text{\textbf{WARNING:}} Please comply with Step 5 warning.

11. After pain relief has been optimized for both leads together, record the settings.

12. Unplug the screening cables from the screener and while still in PHY mode, do the following:
   a. Set the electrodes for both leads to the desired polarity.
   
b. Set the amplitude for Channels 1 and 2 to the desired maximum level, which the patient can select.

   \text{Note: It is recommended that the amplitude maximum be set at the patient's Discomfort Threshold recorded when optimal paresthesia was achieved.}

   c. Set the rate to the desired maximum level, which the patient can select.

13. Position the PHY/PT switch to PT to save the settings.

   \textbf{Note:} When switching to PT mode, all the parameter settings entered in PHY mode are saved. These saved values represent the maximum parameter settings for the patient. However, the screener output value for amplitude reverts to 0.0 and remains at 0.0 until the patient adjusts it.
Active Electrode Screening—This is a technique for stimulating the dorsal column of the spinal cord by very slowly moving two leads with active electrodes. This technique may save time and may eliminate "skipped spots" because it is not necessary to turn the system off and on every time the leads are moved. The purpose of this technique is to locate the "sweet spot" that results in the desired paresthesia for Complex Leg and Back Pain.

Amplitude—A measure of the electrical intensity delivered in a stimulating pulse, measured in volts.

Bipole—A single lead electrode configuration where one electrode is positive and one is negative. Typically in a neurostimulation trial, a center bipole configuration is used with electrode number 1 positive and electrode number 2 negative.

Channel—A group of selected electrodes and parameter values.

Cycle Time Off—In a cycling mode, the length of time between stimulation periods, that is, the "resting" period.

Cycle Time On—In a cycling mode, the length of time that stimulation is delivered.

DayCycling—A method of synchronizing a patient’s therapy schedule to the 24-hour clock.

DualStim™—An operation in which both channels are active. The DualStim mode, amplitude, pulse width, and electrode polarity are programmed independently for each channel.

Guarded Cathode—A single lead electrode configuration where a center electrode is set negative and the two adjacent electrodes are set positive. This is demonstrated with electrode number 1 as the negative center (cathode), and adjacent electrodes number 0 and 2 as the positive "guards" (anodes). This configuration helps to focus the electrical current into the dorsal column tissue.

Interference—Anything that reduces the effectiveness of the IPG, a programming transmission, or telemetry reception.

Mode—The type of stimulation (continuous, cycling). Continuous and cycling modes can be delivered with or without a SoftStart™/Stop.

Parameter—The output waveform conditions that can be varied to affect the type of stimulation for the patient. These are amplitude, pulse width, and rate.

Paresthesia—This is the sensation the patient feels as a result of stimulation. It is often described as "tingling," "numbness," or "pins and needles."
Pulse Width—A measure, in microseconds, of the duration of each stimulating pulse.

Rate—A measure of frequency, in pulses-per-second, that provides the number of times stimulating pulses are delivered each second.

SingleStim™—An operation in which only one channel is active; all electrodes are available on the single channel and have the same amplitude, pulse width and rate.

SoftStart™/Stop—The SoftStart/Stop feature allows stimulation to begin with a ramped output. It gradually increases the amplitude of the stimulation up to the programmed value. It also gradually decreases the amplitude of the stimulation back down to zero when the IPG output is turned off, or when the off Cycle begins.

Stimulation—This is the effect of the electrical current delivered through the lead electrodes to nervous system structures.

Sweet Spot—This is a theoretical physiological location on the spinal cord, not an exact anatomical structure. Its location is subjective—based on patient report. When electrical stimulation is applied to this spinal cord location, a patient with Complex Back and Leg Pain usually feels paresthesia coverage of the lower back, leg and foot.

Telemetry—A radio frequency type of communications.

Transverse electrode array—This is the electrode setting on two leads that is needed to generate transverse stimulation across the spinal cord. This can be demonstrated with electrode settings on Lead 1, where electrode 1 is negative, and on the parallel Lead 2, where electrode 5 is positive.

Transverse stimulation—This is neurostimulation that is produced by an electrical field that travels across two leads by having active electrodes on both leads at one time. It is typically generated by two leads placed on either side of the electrophysiologic midline of the spinal cord.

Trial screening period—This refers to the post-operative patient evaluation portion of the neurostimulation trial used to determine the effectiveness of the therapy for the patient.

Trial screening procedure—This refers to the intraoperative screening portion of the neurostimulation trial used to determine the effectiveness of the therapy for the patient and to position the leads so that the patient feels paresthesia where they usually hurt.

Trolling—See Active Electrode Screening.


