Axium™ Neurostimulator System

Physician Implant Manual

Spinal Modulation, Inc.

1135 O'Brien Drive

Menlo Park, CA 94025

USA

LP0275 Rev B, September 2011

Contents

Explanation of Symbols on Product or Package Labeling

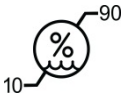
	Model Number
	Lot Number
	Consult Instructions for Use
	Read the Manual
	Do not resterilize
	Single Use Only
	Sterilized by Ethylene Oxide Gas
	Use By YYYY-MM
	Open sterile pouch by peeling pouch corner
	Open sterile tray by peeling tray corner
	Manufacturer
	Manufacturing Date
	Warning
	Standby
	Caution
	Not waterproof Applies to the Programmer when it is not in its carrying case

Limited waterproof. Applies to the TNS
Applies to the Programmer in its carrying case

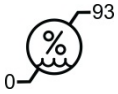
Contents of Package are Non-Sterile

Keep Dry

Storage temperature



Store between 10% and 90% humidity
Sterile Components



Store between 0% and 93% humidity
TNS and Programmers

The device is a radio transmitter

Magnet. Shows the location of the Programmer magnet.

Authorized European Representative

⚠ **RF Operating Frequencies.** Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS/MedRadio band: 402-405 MHz. The effective radiated power is below the limits as specified in

Europe: EN ETSI 301 839-2

USA FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219

FCC ID: Y8L-MN0200

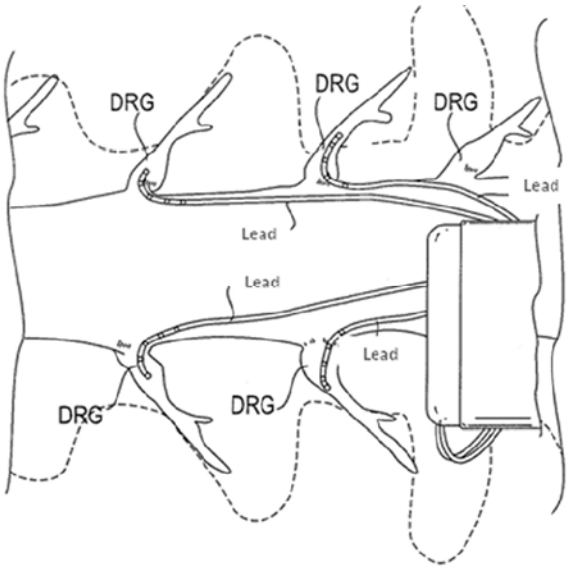
This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Introduction

This manual describes the Axium™ Neurostimulator System, including instructions for implantation. For detailed operation and clinical programming instructions, refer to the Clinical Programmer Manual.

System Overview

The Axium™ Neurostimulator System consists of an Implantable Neurostimulator (INS) device, Trial Neurostimulator (TNS) device, a Clinical Programmer, a Patient Programmer, one or more leads which may be used in combination with a lead extension and the accessories and tools used for implanting the system. The TNS or INS is connected to leads placed within the epidural space near the dorsal root ganglion (DRG). Up to four leads may be placed and connected to the neurostimulator to provide stimulation.



Patients who are indicated for the Axium™ Implantable Neurostimulator (INS) System will first undergo a temporary trial period using an external Trial Neurostimulator (TNS) System connected to implanted leads. If both the clinician and patient believe that sufficient pain relief was achieved, then the patient will be scheduled for an implant, in which the INS will be implanted.

NOTE: In this manual the general abbreviation "NS" is used for information which applies to both TNS and INS. In all other cases the specific abbreviations "TNS" or "INS" are used.

Indications for Use

The Axium™ Neurostimulator System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs.

Contraindications

Patients contraindicated for the Axium™ Neurostimulator System are those who:

- Have an active implantable medical device including but not limited to cardiac pacemakers and cardiac defibrillators
- Are unable to operate the system
- Are poor surgical risks
- Are pregnant
- Are under the age of 18

System Description

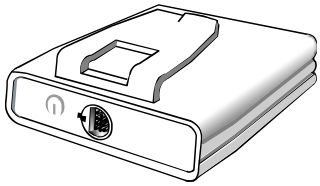
The Axium™ Neurostimulator System consists of the following components:

Component Name	Model Numbers	Package Content	Instructions for Use
Trial Neurostimulator	MN10100 MN20100	• Trial Neurostimulator	Trial Neurostimulator Manual
Implantable Neurostimulator	MN10200 MN20200	• Implantable Neurostimulator • Lead Port Plugs (3) • Torque Wrench • Sterile Magnet Sleeve • Medical Alert Card	Physician Implant Manual
Trial Lead Kit (length in cm specified by -XX)	MN10350-XX MN20350-XX	• Trial Lead • 22 cm Small Curve Delivery Sheath • 22 cm Big Curve Delivery Sheath • Guidewire • Complex Curved Stylet • 4.5” 14G Delivery Needle • Soft Tissue Anchor (2)	Physician Implant Manual

Component Name	Model Numbers	Package Content	Instructions for Use
Implant Lead Kit (length in cm specified by -XX)	MN10450-XX MN20450-XX	• Implant Lead • 22 cm Small Curve Delivery Sheath • 22 cm Big Curve Delivery Sheath • Guidewire • Complex Curved Stylet • 4.5” 14G Delivery Needle • Soft Tissue Anchor (2)	Physician Implant Manual
Connector Cable Kit	MN11350 MN21350	• Connector Cable • Lead Identifiers (3)	Physician Implant Manual
Tunneling Tool Kit 30 /51 cm	MN11900 MN21900 MN12200 MN22200	• Tunneling tool 30/51 cm • Straw • Trocar Tip • Pencil Tip • INS Sizer • Port Plugs (3) • Torque Wrench	Physician Implant Manual
Clinical Programmer	MN10700 MN20700	• Clinical Programmer • External Magnet • Programmer Charger • Carrying Case	Clinical Programmer Manual
Patient Programmer	MN10600 MN20600	• Patient Programmer • External Magnet • Programmer Charger • Carrying Case • Medical Alert Card	Patient Programmer Manual
Auxiliary Magnet Kit	MN13300 MN23300	• Auxiliary Magnet	Ancillary Items Manual
Programmer Charger Kit	MN13400 MN23400	• Programmer Charger	Ancillary Items Manual
Programmer Carrying Case	MN13500 MN23500	• Programmer Carrying Case	Ancillary Items Manual
Lead Accessories Kit	MN12050 MN22050	• 4.5” 14G Delivery Needle • 6.0” 14G Delivery Needle • Soft Tissue Anchor • Complex Curved Stylet • 30 cm Big Curve Delivery Sheath • 30 cm Small Curve Delivery Sheath	Physician Implant Manual

Component Name	Model Numbers	Package Content	Instructions for Use
22 cm Small Curve Delivery Sheath Kit	MN12150 MN22150	• 22 cm Small Curve Delivery Sheaths (2)	Physician Implant Manual
22 cm Big Curve Delivery Sheath Kit	MN13650 MN23650	• 22 cm Big Curve Delivery Sheaths (2)	Physician Implant Manual
4.5" Needle Kit	MN11700 MN21700	• 4.5" 14G Delivery Needle	Physician Implant Manual
Lead Extension Kit (length in cm specified by -XX)	MN10550-XX MN20550-XX	• Lead Extension 50 cm • Torque Wrench	Physician Implant Manual

Trial Neurostimulator (TNS)



The external TNS device connects to the Trial Lead(s) or Lead Extensions and is worn by the patient for up to 30 days during the trial period. The TNS device has a belt clip for the patient's convenience.

Implantable Neurostimulator (INS)

The Axium™ Implantable Neurostimulator (INS) is a non-rechargeable, 4 channel electronic device. It uses microelectronic circuitry, powered by a hermetically sealed battery, to generate a pulsed waveform to stimulate neural tissue. The electronic circuitry and battery are housed in a hermetically sealed titanium case.

Each neurostimulator has a unique internal identifier that allows the physician to identify the type of device through an X-ray. The radiopaque identifier inside the case allows identification of both the device manufacturer and model number using standard x-ray equipment. For the Axium™ Neurostimulator, the code is SM001 which identifies Spinal Modulation as the manufacturer and MN10200 / MN20200 as the model number.

The INS is packaged in a sealed inner tray within a sealed outer tray.

Implant Leads / Trial Leads / Lead Extension

The Lead Kits contain the Leads and the individual delivery devices that are required for their placement.

⚠ **CAUTION:** The temporarily placed Trial Leads are intended for use for up to 30 days.

- **Implant / Trial Leads:** The Leads are designed for percutaneous introduction into the body using a special needle and a set of custom delivery tools provided in their respective kits. Each Lead is fitted with four cylindrical electrodes spaced at equal intervals which are intended to provide stimulation at the target dorsal root ganglion (DRG). Each Lead is packaged with a Complex Curved Stylet inserted into the Lead and the Lead is pre-loaded into a 22 cm Small Curve Delivery Sheath for the physician's convenience.
- **Lead Extension:** The Lead Extension consists of a silicone port header that accepts the Spinal Modulation Trial Lead and Implant Lead. It is intended to extend the length of the lead and provide a connection between the lead and the Connector Cable or the lead and the Implantable Neurostimulator System. The Lead Extension is intended for chronic implantation as a component of the Axium™ Neurostimulator System.

Connector Cable Kit

The Connector Cable connects the Leads or Lead Extension to the external TNS.

- **Connector Cable:** The Connector Cable is packaged separately from the Lead and Lead Extension Kit. The Connector Cable includes a connector and 2 extension cables for use as needed.
- **Lead Identifiers:** The Lead Identifiers are small bent wires that can be inserted into the proximal stylet lumen in the leads and are individually colored to identify the leads.

Lead Accessories

- **Small / Big Curve Delivery Sheath:** The Delivery Sheaths are intended to allow passage of the lead percutaneously into the epidural space. The labeled length of the sheath is the distance from the hub to the pre-shaped tip and the length of the curve at the tip is approximately 2 mm for the Small Curve and approximately 8mm for the Big Curve.
- **Complex Curved Stylet:** The Complex Curved Stylet is intended to assist in steering and positioning the lead within the epidural space. The Complex Curved Stylet has been pre-inserted into the Lead for the physician's convenience.
- **14G Delivery Needles:** The Delivery Needle is intended to access the epidural space, providing a conduit for lead, guidewire and delivery sheath placement.
- **Guidewire:** The Guidewire is intended to verify that the needle is in the epidural space after using a loss of resistance technique.

- **Soft Tissue Anchor:** The Soft Tissue Anchors are intended to anchor the Lead in the soft tissue or on the skin surface proximal to the distal contacts of the Lead.

Implantation Tools

- **Tunneling Tool:** The tunneling tool is used to provide a conduit for the Trial Lead, Implant Lead, or Lead Extension to the INS or away from the midline of the spine. It is packaged with 2 exchangeable tips: a blunt pencil tip and a sharp trocar tip. A straw is slid over the tunneling tool and when the steel handle is removed, the straw provides the conduit for tunneling.
- **INS Sizer:** The INS Sizer is approximately the same size as the INS and allows the physician to properly size the INS pocket.
- **Port Plugs:** The port plugs are used to fill unused ports in the INS. They are packaged with the INS, but spare port plugs are also packaged with the Tunneling Tool Kits for the convenience of the physician

Additional Accessories

- **Sterile Magnet Sleeve:** The magnet is placed in the sterile sleeve to allow it to be used during the implantation of the INS.
- **Medical Alert Card:** Identifies the patient as a user of the Neurostimulation System.
- **Programmer Charger:** To be used with the Clinical or Patient Programmers to charge the battery or allow use of the Programmers while plugged into standard electrical outlets.
- **Programmer Carrying Case:** Protects the Programmers from water.
- **Auxiliary Magnet**: Allows the user to the turn the NS off or activates RF to allow the user to communicate with the NS.

Clinical Programmer and Patient Programmer

Two programmers are available to interact with the NS device.

1. The Clinical Programmer is used to program the stimulation parameters for both the TNS and the INS. The instructions for programming the TNS and INS devices are the same. The Clinical Programmer is used by the physician or clinical staff.
2. The Patient Programmer allows the patient to adjust the stimulation settings of the TNS and INS devices within limits preset by the clinician. The Patient Programmer also allows the patient to turn stimulation off, if necessary.

Note: For detailed information and instructions related to the Clinical and Patient Programmer and the Trial Neurostimulator, refer to the respective user manuals.

Sterilization Information

Single-use, sterile device - The sterile components of the Axium™ Neurostimulator System are provided sterile in a double pouch or tray assembly and are intended for single use only. An expiration date (or "use-before" date) is marked on the label of each package. Use proper sterile techniques to open the packaging.

⚠ **WARNING: Do not resterilize or reuse any devices for any reason because of risk of infection to the subject and malfunction of the devices.**

Sterilization – The Spinal Modulation INS, Trial Lead Kit, Implant Lead Kit, Lead Extension Kit, Lead Accessories Kit and Tunneling Tool Kits have been sterilized using ethylene oxide (EO) gas.

Storage Conditions

Store all sterile product including the INS, Leads, and Lead Accessories Kits as follows:

Storage Temperature – Store components between 14°F (-10°C) and 122°F (50°C). Temperatures outside this range may damage the components. If a temperature deviation has occurred, do not use the product.

Storage Humidity –Store components between 10% and 90% humidity.

Storage Environment – Store components and their packaging where they will not come in contact with liquids of any kind.

Product Materials

Portions of the Axium™ Neurostimulator System will come in contact with bodily tissues.

⚠ **WARNING: Neurostimulation systems have materials that come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.**

The following materials are implanted and come in contact with tissue:

- Platinum iridium
- Polyurethane
- Titanium
- Epotek
- Silicone rubber
- Stainless Steel
- MP35N (nickel-cobalt-chromium-molybdenum alloy)
- PEEK (polyether ether ketone)
- PFA (perfluoroalkoxy copolymer resin)
- PMMA [poly(methyl methacrylate)]

Safety Information

⚠ General Warnings

The following warnings apply to the use of the Axium™ Neurostimulator System:

- **External Defibrillators** – Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established.
- **Magnetic Resonance Imaging** – The patient should be advised to not undergo any elective magnetic resonance imaging (MRI) with the system in place. Use of MRI in the vicinity of the lead(s) may result in forceful dislodgment of the lead(s), or damage to the Neurostimulator. If a voltage is induced through the lead, it may cause uncomfortable ("jolting" or "shocking") levels of stimulation or injury to the patient.
- **Ultrasonic Scanning** – Ultrasonic equipment may cause mechanical damage to the lead if used directly over the site.
- **Electrosurgery Devices** – Electrosurgery devices should not be used in close proximity to implanted lead(s). Contact between an active lead and the electrosurgical pencil can cause direct stimulation of the contacted nerve and can cause severe injury to the patient. Electrosurgery devices may also damage the lead and cause a loss of stimulation.
- **Pediatric Use** – Use of neurostimulation has not been approved specifically for children less than 18 years of age.
- **Pregnancy** – Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.
- **Non-Emergency Procedures** –The patient must be advised that they must not have non-emergency procedures while they are undergoing trial stimulation.
- **Emergency Procedures** – The patient should be instructed to designate a representative (family member or close friend) to notify any emergency medical personnel of their neurostimulator implant, if emergency care is required. Each patient also will be provided with a Medical Alert Card to carry with them that will inform emergency medical personnel of the patient's implant. The patient should be advised to use caution when undergoing any procedure that could include RF or microwave ablation, defibrillation or cardio version.
- **Routine Medical Procedures** – The patient should be instructed to not to undergo dental procedures, diathermy, electrolysis, diagnostic ultrasound, static field therapeutic magnets, diagnostic X-ray, and high output ultrasonic lithotripsy. These procedures may provide interference that can affect TNS or INS device operation or use or damage components of the system that may cause patient harm.

If the patient with an INS or TNS device is subsequently given any medical treatment in which an electrical current is passed through his/her body from an external source, either the device should first be deactivated, or care should be taken to monitor the functioning of the neurostimulator during the initial stages of treatment.

- **Diathermy Therapy** – Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. All patients are advised to inform their health care professionals that they should not be exposed to diathermy treatment.
- **Cardiac Pacemakers and Implantable Cardiac Defibrillators (ICD)** – It is possible that the device may affect the operation of other implantable devices such as pacemakers or implantable cardiac defibrillators. The physician should be aware of any other implantable devices the patient may have or is scheduled to receive.
- **Explosive or Flammable Gases** – Do not use the patient programmer or clinical programmer to communicate with the INS or TNS in an environment where explosive or flammable gas fumes or vapors are present. The operation of the programmer could cause them to ignite, causing severe burns, injury, or death.
- **Case Damage** – If the INS case is pierced or ruptured, an explosion can occur from the battery chemicals, which can lead to severe burns or even death.
- **Device Components** – The use of non Spinal Modulation components with the system may result in damage to the system and increased risk of harm to the patient.
- **Component Disposal** – Return all explanted Neurostimulators to Spinal Modulation for safe disposal. Do not crush, puncture, or burn the Neurostimulator because explosion or fire may result.
- **Exposure to Fluids** – Exposure of the external TNS or the Connector Cable to water, body fluids, saline, or cleaning agents can cause corrosion and affect stimulation. If this occurs, dry all components thoroughly prior to lead connection. Do not immerse the external TNS or Connector Cable in fluids.
- **Device Handling** - The patient must be instructed to not remove their Trial Lead(s) or Connector Cable. Manipulation of the components may result in an undesired outcome, such as the patient developing an infection, getting undesirable stimulation, or accidentally turning their stimulation off. The patient must be instructed to not rub or exert pressure on the implantable neurostimulator through the skin as this may cause: lead dislodgement leading to stimulation at the implant site, device inversion leading to the inability to communicate with the device, or skin erosion that can lead to another surgical procedure or possible infection.

⚠ Warnings – For Use in Home or Work Environments

- **Equipment Operation** – During stimulation, patients should be advised to not operate potentially dangerous equipment, such as power tools, automobiles, or other motor vehicles. They should not climb ladders or participate in other activities where postural change or an abrupt movement could alter the perception of stimulation intensity and cause patients to fall or lose control of equipment or vehicles or injure others.
- **Patient Activity** – Patients should be advised to limit their activities to low or moderate levels during their trial stimulation period and the first six weeks of implantation of the INS. Failure to do so may result in migration of the leads causing loss of stimulation therapy, muscle stimulation or painful stimulation thereby requiring reoperation to reposition.
- **Theft Detectors and Metal Screening Devices** – Certain types of antitheft devices, such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. It is possible that patients who are implanted with non-adjacent multiple leads and/or patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. It is recommended that patients use caution when approaching such a device and that they request assistance to bypass the device. If they must proceed through the device, patients should turn off the NS and proceed with caution, being sure to move through the detector quickly.
- **Restricted Areas** – The patient should be warned to seek medical guidance before entering environments which could adversely affect the operation of the implanted device, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.
- **Electromagnetic Interference (EMI)** – Certain commercial equipment such as resistance welders and induction furnaces, certain communication equipment such as microwave transmitters, linear power amplifiers, and high voltage power lines may generate sufficient EMI to interfere with the INS and TNS System resulting in understimulation, overstimulation, or difficulty in device communications. Certain medical devices may also cause EMI interference and make it difficult to communicate with the INS or TNS; such devices include bone growth stimulators, transcutaneous electrical nerve stimulation (TENS), and implanted cardiac devices.
- **Lead Movement** – The patient should be instructed to avoid excessive bending, twisting, and stretching, entering hyperbaric chambers above 2.0 atmosphere, and operating the neurostimulator while driving or lifting objects of over 2 Kg (5 lbs) for a minimum of 6 weeks after implantation. These activities may cause lead movement, which can result in understimulation or overstimulation for the patient. Excessive lead migration may lead to the need for reoperation to replace the leads.

- **Therapeutic Radiation** – Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been performed and no definite information on radiation effects is available. Sources of therapeutic radiation include x-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted INS should be shielded with lead.

⚠ Precautions

The following precautions apply to the use of the Axium™Neurostimulator System:

- **Physician Training** – Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.
- **Patient Selection** – It is extremely important to select patients appropriately for neurostimulation and that thorough psychiatric screening be performed. Patients should not be dependent on drugs and should be able to operate the spinal cord stimulator system.
- **Infection** – It is important to follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.
- **Implantation of Two Systems** – If two systems are implanted, ensure that at least 15 cm (6 in) separates the implanted INSs to minimize the possibility of interference during programming.
- **Implantation of Multiple Leads** – If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.
- **High Stimulation Outputs** – Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.
- **Stimulation Parameters** – Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs unless ordered to do so by a physician.
- **Cellular Phones** – The effect of cellular phones on neurostimulation systems is unknown; patients should avoid placing cellular phones directly over the system.
- **Trial Leads** – Trial Leads are intended for use for up to 30 days. Use of these devices must be performed in accordance with the instructions provided in this manual.
- **Overprogramming –** Excessive communication with the device can shorten the life of the INS. The patient should be warned to communicate with the device only when necessary.

- **TNS Device Care –** The patient must be instructed to not spill fluids on, to wash or otherwise get their TNS device wet. The patient must not shower or bathe with it (sponge baths are acceptable as long as the TNS device does not get wet). The patient must be instructed not to drop or mishandle their TNS device. Physical damage to the unit may impair its function. The patient must be instructed to not open the TNS case.
- **Lead and Cable Care –** The patient must be instructed to not remove their lead(s) or Connector Cable during the trial period. Manipulation of the components may result in the patient developing an infection, getting undesirable stimulation, or accidentally turning their stimulation off.
- **TNS Device Failure –** Device failure, although unlikely, is possible due to random component failure. If the TNS device stops working, the patient should contact their physician.
- **TNS Device Disposal –** The patient is to be instructed that they must return their TNS device and Patient Programmer to their physician after the trial period. The patient must be instructed to not discard or burn their TNS device. Fire may cause the internal battery to explode.
- **TNS Battery Replacement –** It is unlikely that the battery will need replacement in the short time that the patient has their TNS device. However, if the TNS device does not function the patient must not try to open the TNS case. The internal battery must be replaced by Spinal Modulation personnel only. The patient should be advised to contact their physician during regular business hours.
- **Material Sensitivity –** Hypersensitivity (redness in the area of skin contact) can happen if the patient has an allergic reaction to the materials. If this occurs, the patient should be instructed to contact their physician during regulator business hours.

Adverse Events

The implantation of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with implantation and use of the Axium™ Neurostimulator System:

- Pain (where the needle has been inserted)
- Pain (caused by understimulation due to lead migration)
- Pain over the implantable neurostimulator site
- Escalating pain
- Bleeding (where the needle has been inserted)
- Headache
- Infection
- Localized collection of serous (clear) fluid at injection site
- Discomfort during the treatment
- Allergic or rejection response to implant materials
- Constant pain at the lead site
- Stimulation of the chest wall
- Lead migration (movement) and/or local skin breakage

- Weakness
- Clumsiness
- Numbness
- Temporary muscle activation

Very rare risks and side effects include:

- Cerebral Spinal Fluid (CSF) leakage
- Tissue damage
- Nerve damage
- Spinal cord compression
- Paralysis
- Hematoma
- Swelling
- Seroma
- Sensory loss
- Skin erosion around the INS or leads
- Battery failure and/or battery leakage
- Lead breakage requiring replacement of the lead
- Hardware malfunction requiring replacement of the neurostimulator
- Pain from a non-injurious stimulus to the skin (allodynia)
- An exaggerated sense of pain (hyperesthesia)

Additional risks to the subjects, as a result of the placement and stimulation of the lead in the area of the DRG, include potential tissue damage or pain due to setting the stimulation parameters too high. This may occur once the lead is in place and is connected to the neurostimulator and activated. The neurostimulator is controlled by a trained operator and the starting point for the stimulation will be set to the lowest available settings. Additionally, all subjects will be awake and conversant during the procedure to minimize the likelihood of any nerve damage.

Implanting the Neurostimulator System

⚠ Precautions for the Implant Procedure

- All implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.
- Do not bend, kink, or stretch the lead body, sheaths, or other components as this may result in damage to the component and poor function.
- Do not insert the sheath into the epidural space without the lead inserted, as this may cause injury to the dura. The lead cannot be inserted into the sheath with the sheath in the epidural space.

- When inserting the lead/sheath assembly through the needle into the epidural space, tighten the lead stabilizer to prevent lead migration out of the sheath. Failure to do so may cause harm to the patient such as damage to the dura.
- Do not bend the sheath without the lead inside the sheath, as this will permanently kink it and make it difficult to deploy the lead.
- Do not use surgical instruments to handle the lead. The force of the instruments may damage the lead or lead stylet.
- Do not bend, kink or use surgical instruments on the stylet, as this may damage it. Use care when reinserting a stylet. Too much pressure on the stylet could damage the lead, resulting in intermittent or loss of stimulation.
- Do not over manipulate the sheath and lead system as this may result in trauma within the epidural space.
- Do not use saline or other ionic fluids at or near any of the electrical connections, as this could result in short circuits.
- Do not place sutures directly around the lead body since the sutures may damage the lead.
- Before opening any sterile package, verify the kit model number, that the kit is within its expiration (use-by) date and that the packaging has not been damaged or compromised in any way. If the packaging has been compromised or the device is beyond its expiration date, do not use the device as it may be compromised and could cause harm to the patient.
- Carefully inspect the lead (in the sterile field) for damage after removing it from the sterile package. Damage to the lead body can cause improper function and stimulation or stimulation to areas other than the intended target.
- If the operating field is bloody, wipe gloves, lead, stylet, and sheath, before handling the lead. Failure to do so may result in difficulty delivering the lead.
- The leads, accessories, and neurostimulator are only compatible with the Spinal Modulation components. Use of other manufacturer's components may result in unexpected device performance and increased risk of injury to the patient.

Selection of Neurostimulator Trial Approach

There are two suggested approaches for a neurostimulation trial:

A. **Percutaneous Lead Trial** - A trial is done using a Trial Lead which exits the skin at the needle entry site and which is completely removed after the trial period. In a second procedure, the system is implanted, including the Implant Leads.

B. **Implanted Lead + Percutaneous Extension Trial** – A trial is done with an Implant Lead sutured to the soft tissue just above the spinous process, using the soft tissue anchor to protect the lead. An extension is tunneled away from the needle insertion site where it exits the skin. In a second procedure only the Lead Extension is removed and the Lead or a new Lead Extension is tunneled to a pocket, the INS is implanted in the pocket, and the Lead or Lead Extension is connected to the INS.

Preparing the Patient and Devices for Use

Leads are designed for placement in the epidural space. Each Lead is accompanied by accessories designed to aid the clinician in positioning the tip of the Lead near the target DRG.

- To perform a Percutaneous Lead trial, use the temporary Trial Lead Kit.
- To perform an Implant Lead trial**,** use the Implant Lead Kit.

⚠ **CAUTION:** The temporarily placed Trial Leads are intended for use for up to 30 days. Use of these devices must be performed in accordance with the instructions provided in this manual.

Using standard sterile technique, perform the appropriate skin prepping, draping, and injection of local anesthetic to perform the epidural approaches for percutaneous lead placement.

⚠ **WARNING: The placement of the leads involves some risk, as with any surgical procedure. Conscious sedation can cause side effects such as systemic toxicity, or cardiovascular or pulmonary problems. Use caution when sedating the patient. The patient must be awake and conversant during portions of the procedure to minimize the likelihood of nerve damage.**

Placing the Lead

Lead placement should always be done under fluoroscopic guidance. The appropriate vertebral level for needle entry should be identified and marked.

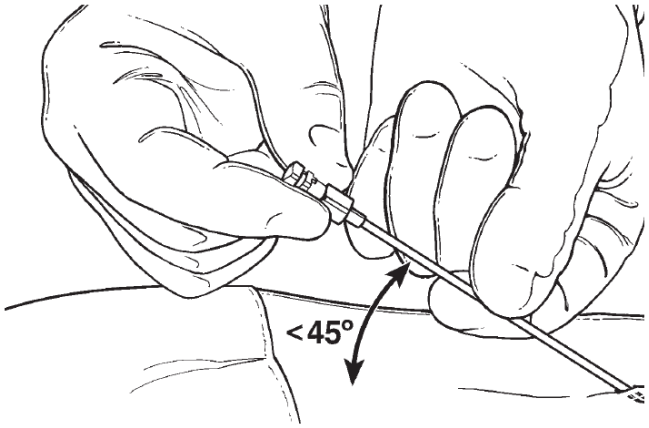
⚠ **WARNING: As with any spinal epidural procedure, potential risks of serious injury to the patient, although extremely rare, include epidural hemorrhage, hematoma, infection, spinal cord or nerve compression, and/or paralysis.**

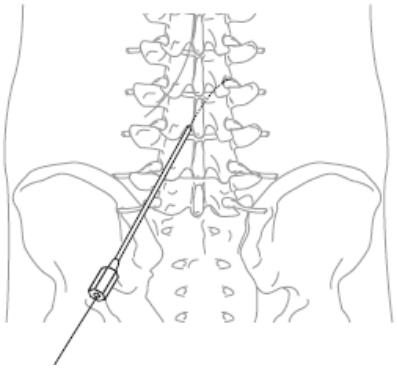
1. Determine the length of the lead required to extend from the target foraminal level to the Neurostimulator implantation site. Using a 90 cm lead in the lumbar region may cause difficulty in coiling the excess lead. A 50 cm lead used in the upper thoracic region may not be long enough to reach the Neurostimulator and a lead extension may be needed to bridge the additional length.

Choosing an Approach

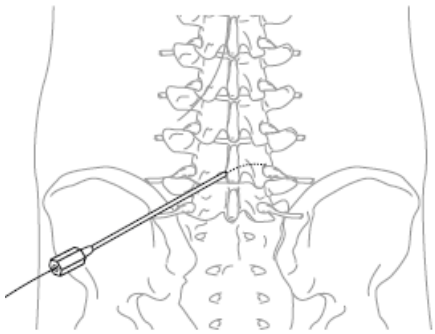
2. Antegrade Approach

Under fluoroscopic guidance, use a contralateral approach, with the bevel of the needle facing toward the target level, to insert the Delivery Needle into the epidural space at the appropriate angle until you encounter resistance from the ligamentum flavum. Start one or two levels below the target site. The needle angle should be no greater than 30 degrees to ensure smooth delivery of the delivery sheath and lead.





Single Level Delivery Approach



Two Level Delivery Approach

3. Contralateral Approach

Under fluoroscopic guidance, use a contralateral approach with the bevel of the needle facing toward the target level to insert the 14G delivery needle into the epidural space.

⚠ **WARNING: When using a contralateral approach, advance the needle slowly into the epidural space and take caution as it enters. The needle will be inserted at a steeper**

angle than in an antegrade approach and there is a greater chance of dural puncture that will lead to a cerebrospinal fluid leak.

4. Confirm entry into the epidural space using standard methods, such as a loss of resistance technique.

5. Once loss of resistance is achieved, the clinician may verify complete insertion into the epidural space using fluoroscopic guidance and/or inserting the guidewire through the needle. If resistance is discovered during guidewire insertion, either pull the needle out and repeat Steps 1-4 using a more acute angle or advance the needle further and reconfirm placement using the guidewire.

⚠ **WARNING: Use fluoroscopy and extreme care when inserting, advancing, or manipulating the guidewire or lead in the epidural space to minimize the risk of a dural tear.**

⚠ **WARNING: Dural puncture can occur if needle or guidewire is advanced aggressively once loss of resistance is achieved. Advance the needle and/or guidewire slowly.**

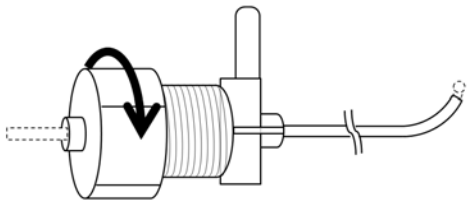
6. Remove the guidewire (if used) after confirmation of access to the epidural space.

   NOTE: The Complex Curved Stylet has been pre-inserted into the lead and the lead has been loaded into a 22 cm Small Curve Sheath to facilitate delivery by the clinician.

7. Before insertion into the needle, push the lead outside the sheath and verify that the stylet is pushed fully distal within the lead.

   NOTE: Failure to ensure the stylet is completely inserted may make delivery of the lead more difficult.

8. Before insertion into the needle, pull back on the lead so that the ball-tip end of the lead is flush against the Delivery Sheath and tighten down the lead stabilizer until the lead does not slide within the sheath.

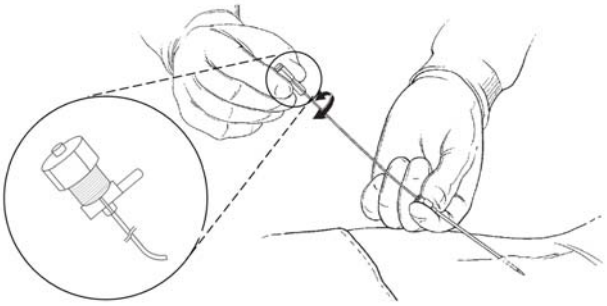


Tightening the Lead Stabilizer

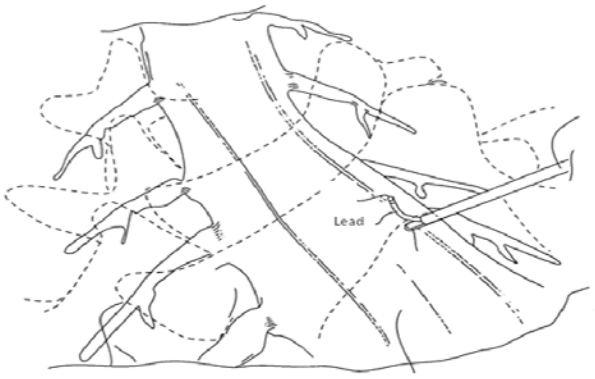
⚠ **WARNING: Insertion of a sheath without the lead may result in dural puncture. Securing the lead with the lead stabilizer will mitigate this risk.**

⚠ **WARNING: Use of the delivery sheath is necessary for successful placement of the Lead.**

9. Note that the steering wing on the sheath lines up with the bend in the sheath.

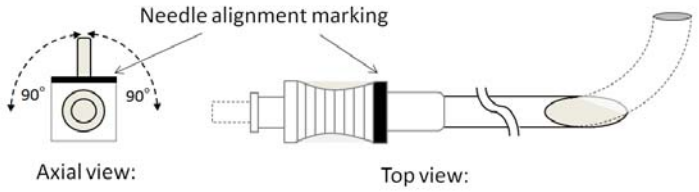


10. Before inserting the sheath into the needle, verify that the Lead is loaded. The Lead cannot be delivered through the sheath once the sheath is located within the epidural space.
11. Insert the sheath, lead, and stylet through the needle and advance through the epidural space to the target foraminal opening.



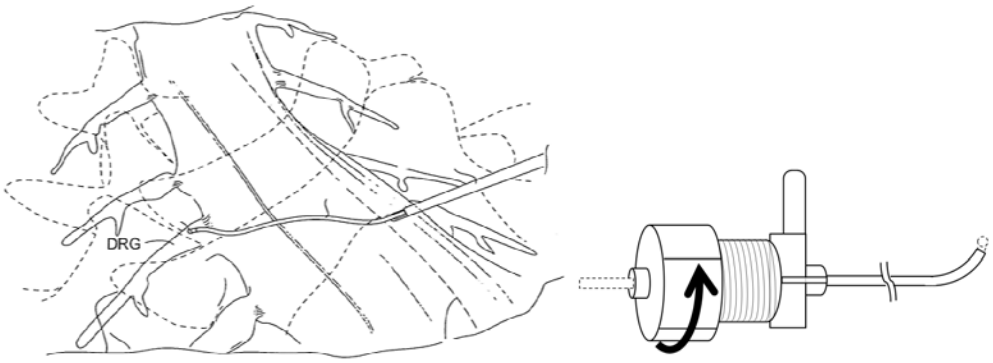
⚠ **WARNING: If the sheath needs to be retracted from the epidural space, verify that the steering wing is no more than 90 degrees misaligned with the mark on the needle. Failure**

to do so may result in damage to the sheath. Before reinserting sheath, verify there is no damage to the sheath.



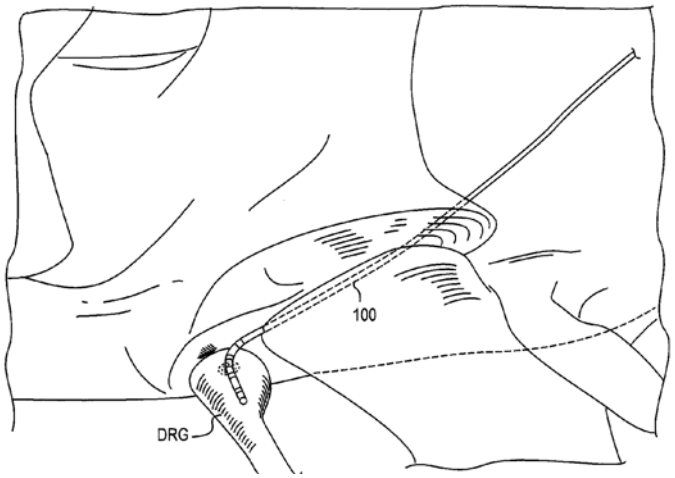
⚠ **WARNING: If the sheath is not responding to rotation, do not rotate the steering wing out of plane from the curve of the sheath more than 90 degrees. The tip of the sheath may whip around and could cause harm to the patient.**

12. With the distal end of the sheath in or at the target foramen, loosen the lead stabilizer, and advance the lead so that it moves into the foramen. Confirm placement of the lead on the dorsal side of the foramen using a lateral fluoroscopic view. Verify that the electrodes extend out of the sheath. If the electrodes remain within the sheath, stimulation will not be possible because of high impedance readings.



Loosening the Lead Stabilizer

⚠ **WARNING: If the lead is unable to deploy out of the sheath, inject sterile water or saline slowly to release tissue that may have entered between the sheath and the lead. Do not use excessive pressure when injecting through the sheath.**

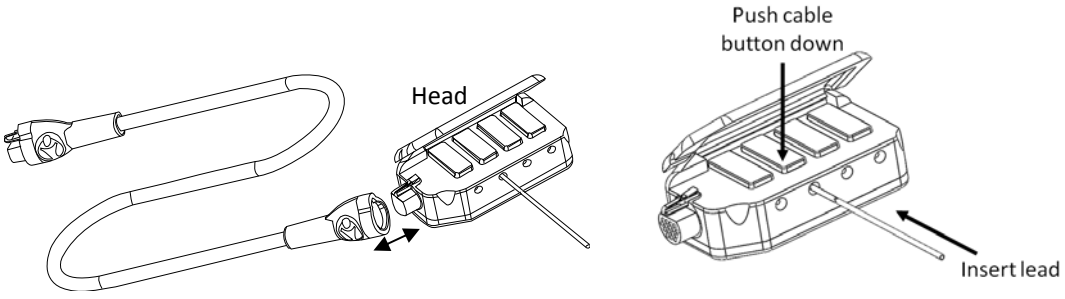


Lead Advanced Along Dorsal Aspect of DRG

⚠ **WARNING: Do not use excessive force to push the lead or sheath into the neural foramen as this may result in permanent or transient nerve damage. The patient should be awake and conversant during this part of the procedure so they can provide feedback to the physician.**

Intraoperative Testing

1. Connect the head to the cable. Press and hold the cable button down to release the locking mechanism and slide the proximal end of the leads into the head. Release the cable button to lock the lead into place. Verify that the lead comes to a stop before releasing the button. This will ensure that the electrical contacts are in the appropriate position.



2. Put the TNS in standby mode or turn the amplitude of each lead set to zero.

⚠ **PRECAUTION**: Put the trial stimulator in standby mode or reduce amplitude of leads to zero before plugging in the cable. Failure to do so may result in delivering an uncomfortable stimulation to the patient.

3. Pass the proximal end of the Connector Cable off the sterile field and connect to the TNS.

NOTE: Refer to the Trial Neurostimulator User Manual and Clinical Programmer User Manual for specific instructions on the operation of these devices.

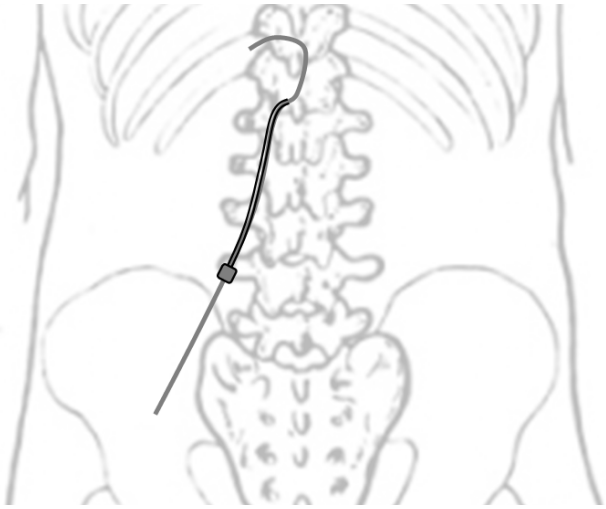
⚠ **WARNING: Maintain adequate slack in the cable. If there is not enough slack and the cable is pulled, the lead may be dislodged and will need to be replaced. This will extend the procedure.**

4. Using the TNS, test the various electrode configurations used to obtain appropriate paresthesia or pain relief.
5. Turn off the Trial Neurostimulator and disconnect the lead from the connector cable.
6. Up to four leads may be placed in one patient. Refer to "Placing the Lead" to position subsequent leads.

⚠ **WARNING: As described in the Clinical Programmer User Manual, always turn the external TNS amplitude to 0 µA when repositioning a lead, changing the selected electrode combination, or attaching the Connector Cable to the external TNS. When restarting stimulation, increase the amplitude SLOWLY until the desired paresthesia is achieved. Failure to do so may result in uncomfortable motor activation or painful stimulation.**

Removing the Delivery System Components – *Percutaneous Lead Trial*

1. Before removing the delivery system components, advance the lead further into the epidural space to create a strain relief.
2. Slowly remove the delivery sheath by first pulling back the sheath near the needle. Always hold forward pressure on the Lead while retracting the delivery sheath to prevent lead migration.
3. Retract the stylet into the needle so that it is retracted beyond the tip of the sheath.
4. Turn the sheath away from the opening of the foramen and push out the lead so that a loop is created in the epidural space.



⚠ **WARNING: Failure to put a loop in the epidural space may result in lead migration and may lead to a procedure to revise the position.**

5. Remove the sheath completely while holding forward pressure on the lead.

⚠ **WARNING: When removing the sheath, verify that the steering wing is no more than 90 degrees misaligned with the mark on the needle. Failure to do so may result in damage to the sheath. Before reinserting sheath, verify there is no damage to the bend of the sheath.**

6. Remove the needle following the same procedure. It is recommended that the desired paresthesia be re-tested after the removal of the delivery system components but before the complete removal of the stylet. With the external TNS amplitude set to 0 µA, reconnect the Connector Cable as described before.

⚠ **WARNING: If the sheath has been kinked during delivery, slowly retract through the needle with the curve facing the same direction as the bevel. Failure to do so can damage or cut the lead or sheath. If resistance is encountered, pull the needle out of the epidural space and then remove the sheath.**

⚠ **WARNING: Do not use excessive force if the lead needs to be removed. Excessive force may cause lead fracture.**

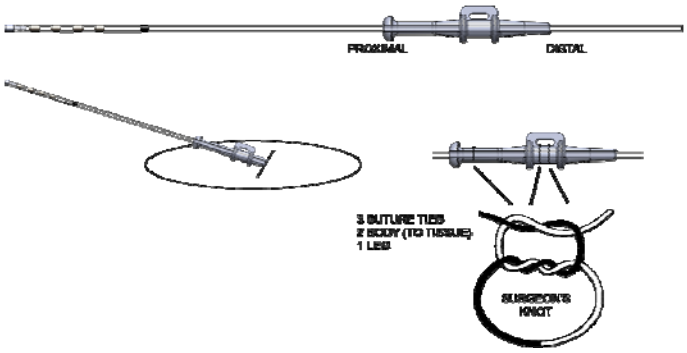
7. Record the lead position with both an A/P and lateral fluoroscopic view for comparison of the position at time of closure to ensure that the lead has not moved. Remove the stylet by holding forward pressure on the lead while retracting the stylet.

⚠ **WARNING: Use extreme care when removing the lead stylet, the delivery sheath, and the needle, to insure that the distal tip of the lead remains in the desired location. Removing each item in slow movements, while holding the remaining components in**

place, will assist this process.

Lead Anchoring – *Percutaneous Lead Trial*

1. After placing a Trial lead in its final position, it should be secured using a lead anchor on the skin.
2. Carefully slide the lead anchor over the proximal end of the Trial Lead and advance it to the puncture site. The short end of the suture anchor must be facing towards the incision.
3. Apply sutures around the anchor and cinch onto the Trial Lead as shown below. Apply at least two ties to the main body and one tie to the leg.



⚠ **WARNING: Do not suture directly onto the lead, as there is a risk of damaging the lead. Failure to secure the lead to the skin, or other tissue, may result in lead migration and/or motor activation or painful stimulation.**

⚠ **WARNING: Failure to comply to the anchoring technique may result in lead migration and/or motor activation or painful stimulation.**

4. Apply an antibacterial agent to the puncture site, if desired
5. Reconnect the connector cable to the leads and coil any excess Trial Lead length around the distal end of the Connector Cable, fold a gauze pad around the block, and apply a large adhesive patch over the area containing the Trial Lead(s), puncture site and Connector Cable.
6. Verify the connection of the Connector Cable to the Trial Leads and the external TNS prior to discharge of the patient.

Neurostimulation Trial –*Percutaneous Lead Trial*

1. Using the Clinical Programmer, program the TNS with the neurostimulation trial

parameters.

NOTE: Refer to the Trial Neurostimulator User Manual and Clinical Programmer User Manual for specific instructions on the programming of these devices.

Removing Trial Lead –*Percutaneous Lead Trial*

⚠ **WARNING: Always remove the Trial Leads before implanting the Implant Leads, as there is a risk of infection that may cause death if the leads are not removed. Always practice proper sterile practices when implanting leads and implantable neurostimulator.**

To remove the Trial Lead(s) from a patient:

1. Disconnect the Connector Cable connection for each Trial Lead.
2. Remove any sutures or anchor securing each Trial Lead to the patient's skin.
3. Slowly apply light tension to each Trial Lead and verify that the lead is retracting from the patient.
4. Place the used Trial Lead(s) into a designated "Biohazard" package clearly labeled with the patient's ID number and the removal date.
5. Send Trial Lead(s) back to Spinal Modulation for evaluation as instructed by clinical personnel.

⚠ **WARNING: Do not remove a Trial Lead quickly, as this may result in lead breakage and unintentional lead fragments being left in the patient.**

⚠ **WARNING: Take proper precautions when handling removed Trial Lead components. Treat all used Trial Leads and delivery components as a "biohazard".**

⚠ **WARNING: Do not reuse any device from the Trial Lead Kit or Trial Accessories Kit.**

Removing the Delivery System Components – Implant Lead Trial Only

These instructions pertain only after placing Implant Lead during the trial procedure. After placing a lead in its final position, using the techniques described above, it should be secured using a lead anchor to the supraspinous ligament or fascia and then connected to the externalized lead extensions.

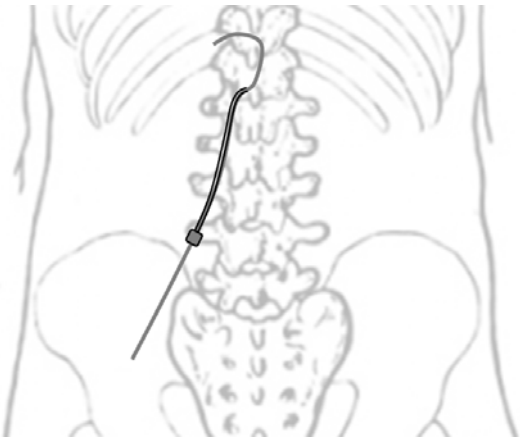
⚠ **WARNING: Do not suture directly onto the lead, as there is a risk of damaging the lead. Failure to secure the lead may result in lead migration and uncomfortable motor stimulation or painful stimulation.**

⚠ **PRECAUTION:** Use extreme care when using sharp instruments or electrocautery around the lead to avoid damaging the lead.

1. Leaving the needle in place, prepare the anchor site by making an approximately a 3 - 7 cm

longitudinal incision, centered on the needle to the depth of the supraspinous ligament.

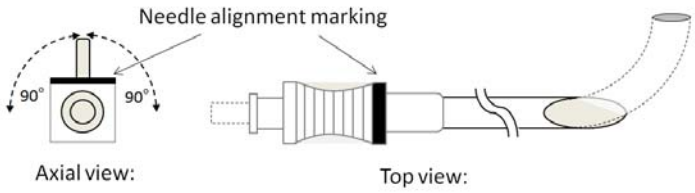
2. Establish hemostasis and use retractors for good visualization.
3. Slowly remove the delivery sheath by first pulling back the sheath near the needle. Always hold forward pressure on the Lead while retracting the delivery sheath to prevent movement.
4. Retract the stylet into the needle so that it is retracted beyond the tip of the sheath.
5. Turn the sheath away from the opening of the foramen and push out the lead so that a loop is created in the epidural space.



⚠ **WARNING: Failure to put a loop in the epidural space may result in lead migration and may lead to a procedure to revise the position.**

6. Remove the sheath completely while holding forward pressure on the lead.

⚠ **WARNING: When removing the sheath, verify that the steering wing is no more than 90 degrees misaligned with the mark on the needle. Failure to do so may result in damage to the sheath.**



⚠ **WARNING: If the sheath has been kinked during delivery, slowly retract through the needle with the curve facing the same direction as the bevel. If resistance is encountered, pull out the needle and then proceed to remove the sheath. Failure to do so can damage or cut the lead or sheath.**

7. Remove the needle following the same procedure.
8. It is recommended that the desired paresthesia be re-tested after the removal of the delivery system components but before the complete removal of the stylet. With the external TNS amplitude set to 0 µA, reconnect the Connector Cable as described before.

⚠ **WARNING: Do not use excessive force if the lead needs to be removed. Excessive force may cause lead fracture.**

9. Record the lead position with both an A/P and lateral fluoroscopic view for comparison of the position at time of closure to ensure that the lead has not moved. Remove the stylet by holding forward pressure on the lead while retracting the stylet.

⚠ **WARNING: Use extreme care when removing the lead stylet, the delivery sheath, and the needle, to ensure that the distal tip of the lead remains in the desired location. Removing each item in slow movements, while holding the remaining components in place, will assist this process.**

Lead Anchoring

After placing a lead in its final position, it should be secured using a soft tissue anchor and then connected to externalized extensions.

⚠ **WARNING: Do not suture directly onto the lead, as there is a risk of damaging the lead. Failure to secure the lead to the skin, or other tissue, may result in lead migration and uncomfortable muscle stimulation.**

⚠ **PRECAUTION:** Use extreme care when using sharp instruments or electrocautery around the lead to avoid damaging the lead.

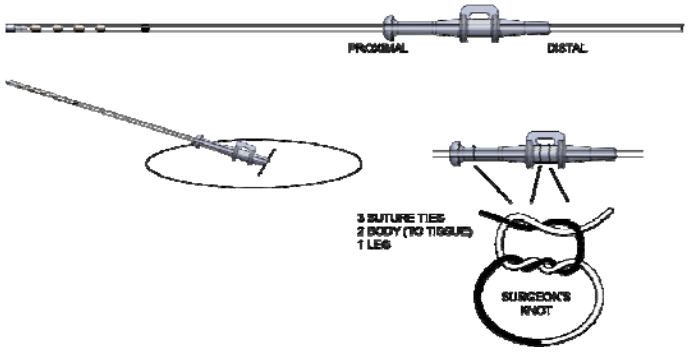
1. Soak the anchor in sterile water (not saline) to lubricate it.
2. Place the anchor on the lead and slide it down as close as possible to where the lead emerges from the vertebral column. Be careful not to move the lead.

NOTE: If implanting multiple leads, tag the leads with suture (ligature) so that their position can be identified later.

⚠ **PRECAUTION:** Observe these cautions when attaching the soft tissue anchor because damage to the anchor or lead can occur and result in failure of the system:

- Do not use polypropylene or monofilament suture
- Do not place sutures directly on the lead.
- Avoid sharp bends or kinking on the lead.

3. Using the 2-0 silk non-absorbable suture, tie two ligatures around the center of the anchor to secure the anchor to the lead. If needed, make minor adjustments to the lead position. Tie one ligature around the leg and do not tie to the soft tissue. Verify that the short end of the anchor enters into the ligament.



⚠ **PRECAUTION:** Failure to push the short end of the soft tissue anchor into the ligament or fascia may result in lead migration and a procedure to revise the lead location.

4. It is recommended that the lead position is verified under fluoroscopy and desired paresthesia be re-tested after fixation. With the external TNS amplitude set to 0 µA, reconnect the Connector Cable as described before.

Percutaneous Extension Tunneling – *Implant Lead Trial Only*

1. Identify the tunneling route between the lead incision and the extension exit site.
2. Administer anesthetic at the exit site and along the tunneling route.
3. Assemble the tunneling tool packaged with the lead by slipping the passing straw over the tunneling rod, then attaching the tunneling tip.
4. Bend the tunneling tool as necessary to conform to the patient's contour along the tunneling route.
5. Make a stab wound at the exit site.
6. Begin at the exit site and tunnel subcutaneously to the lead incision
7. Guide the tunneling tool subcutaneously along the tunneling route by pushing the skin over the advancing tool tip until the tip and approximately 1 cm of the passing straw are exposed at the lead incision.
8. Withdraw the tunneling tool leaving the passing straw in place in the tunnel.
9. Gently insert the proximal end of the extension through the passing straw to the exit site.

10. Slide the passing straw over the extension and out of the skin exit site, leaving the extension in place.
11. If not done previously, use blunt dissection to a form a subcutaneous pocket off the lead incision for the lead-extension connection.
12. Wipe the lead and extension connector junction with sterile gauze. If necessary, moisten the gauze with sterile water or a nonionic antibiotic solution.
13. Dry all connections. Fluid in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.
14. Hold the extension connector straight while firmly, but gently, inserting the lead into the connector one or two contacts at a time until each lead contact is aligned under each extension connector contact. During insertion, some resistance is typical because the internal seals provide electrical isolation.
15. Verify that the mark on the lead aligns with the end of the extension connector. This will verify that the lead is fully inserted.
16. Use the torque wrench supplied in the package to tighten the setscrew. Tighten until a click is heard. Using minimal force, and while securely holding the lead to prevent dislodgement, pull on the connection to ensure that it is secure.
17. Using minimal force, pull the extension from the skin exit site, feeding the lead-extension connection into the lead-extension connection pocket.
18. In order to aid in identification of each lead after the trial period, tie a suture lightly to the lead and another one to the lead extension. Use different color suture and numbers of suture to identify the leads. This will aid in identification during the implant procedure.
19. Create strain relief loops by coiling excess lead proximal to the soft tissue anchor in loops. Insert the coiled lead into the pocket, under the connection, leaving as much slack as possible in the lead between the anchor and the lead-extension connection.
20. Close the incision and dress the incision site.
21. At the exit site, coil any excess extension around the distal end of the Connector Cable, fold a gauze pad around the block, and apply a large adhesive patch over the area containing exit puncture, excess extension, and Connector Cable.

Removing Lead Extension – *Implant Lead Trial Only*

1. Remove the bandage near the exit point of the lead extension.
2. Pull the lead extension lightly out of the incision and cut the lead extension.
3. Expose the lead-extension to lead connection.
4. While maintaining lead position, carefully remove the lead-extension connections from the incision.
5. Disconnect the lead from the extension.

6. Cut the extension near the lead-extension connector.
7. Discard the lead-extension connector.
8. Preserving sterility, pull the extension out through the skin exit site.
9. Discard the extension.
10. If multiple extensions are implanted, repeat the removal steps for the other extensions.

Creating the INS Pocket – Implant

Once the lead(s) has been anchored, a Neurostimulator pocket should be created and the lead tunneled for connection to the INS.

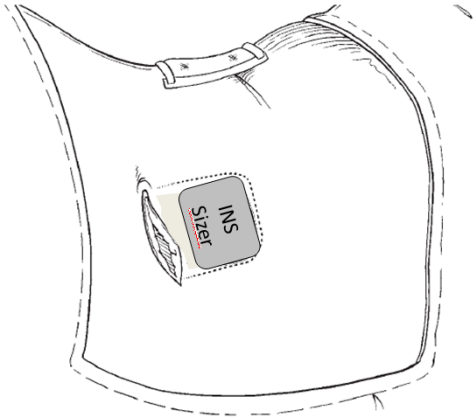
The following steps outline the suggested procedure to create an INS pocket:

1. Determine the site for the INS. This should be done before implanting the lead to verify there is enough length to reach the INS pocket and provide strain relief in the pocket, near the anchor, and in the epidural space.

   NOTE: The INS should be located in an area that the patient can easily reach with the magnet and/or programmer:

   - *In the upper buttocks along the posterior axillary line (avoiding the beltline)*
   - *Just over the abdomen below the lowest rib*

2. Administer local anesthetic at the neurostimulator pocket site.
3. Use blunt dissection to create a pocket so that the INS is parallel to the skin surface and no deeper than 2.0 cm below the skin surface. Use electrocautery to maintain hemostasis.
4. (Optional) Insert the INS sizer to ensure the pocket is large enough to accommodate the INS, allowing extra room for a strain relief loop for each lead.



⚠ **PRECAUTION:** Do not implant the INS deeper than 2.0 cm, as the programmer will not be able to communicate with the INS.

⚠ **PRECAUTION:** Do not apply electrocautery directly to the INS as this can damage the INS or cause interference while communicating with the INS.

Lead or Extension Tunneling

Tunnel the leads from the anchor site to the INS pocket. When tunneling to the abdomen, the clinician has two options:

- Tunnel to a midpoint and then continue to INS site.
- Use the 51 cm tunneling tool and curve the conduit around the side of the patient.

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

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

1. Identify the tunneling route between the lead incision and the neurostimulator pocket.
2. Administer local anesthetic along the tunneling route. Additional sedation may be administered at the discretion of the physician.
3. Bend the tunneling tool as necessary to conform to the patient's contour along the tunneling route
4. With the straw in place on the tunneling tool, tunnel from the INS pocket to the lead anchor site.
5. Withdraw the tunneling tool from the straw, leaving the straw in the subcutaneous tunnel.

⚠ **PRECAUTION:** Leads or Extensions should be routed adjacent to one another as to prevent changes in perceived stimulation from theft detectors and metal screening detectors.

6. Pass the end of the Lead(s) or Extension(s) through the straw from the anchor site to the INS pocket or to the midpoint if tunneling to the abdomen. At each incision point, leave a strain relief loop in place as to minimize the chances of lead migration.
7. Remove the straw from the tunnel by passing it over the leads, taking care not to cause traction on them and disturb the lead position.

Connecting Lead to Extension

If an extension is used to connect the Lead to the INS, refer to the section "Percutaneous Extension Tunneling" for instructions on how to connect the Extension to the Lead.

Connecting the INS

The following steps outline the guidelines to connecting a Lead or Extension to the INS:

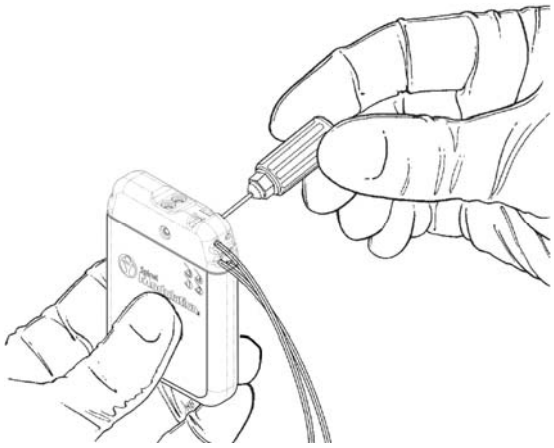
⚠ **PRECAUTION:** Do not connect a lead with body fluid on its contacts because corrosion can occur and cause failure of the system.

⚠ **PRECAUTION:** If there is a need to communicate with the INS prior to implantation, do not put the INS on a stainless steel table, as communication may be difficult. This may prolong the procedure.

1. If the lead contacts came in contact with body fluids or saline, thoroughly clean with sterile deionized water or sterile water for irrigation and then dry them completely.
2. Using clean gloves, carefully slide the lead or extension into the INS header until the depth marker aligns with the edge of the header.

⚠ **PRECAUTION:** Use only the torque wrench provided by Spinal Modulation or the device or lead may be damaged and unusable. Tighten until a click is heard or the lead may make intermittent contact with the stimulator.

3. Insert the torque wrench through the seal plug and tighten the setscrew by turning it clockwise, until the wrench clicks.



4. Carefully remove the torque wrench and verify that the septum over the set screw is closed. Reseat the flaps if it is not closed.
5. If implanting less than 4 leads, insert the port plugs in each of the vacant header ports. Use the torque wrench to tighten the setscrew on the port plug until it clicks.

⚠ **PRECAUTION:** Insert the lead slowly into the header to prevent damage to the INS. If the lead needs to be retracted, retract the lead slowly.

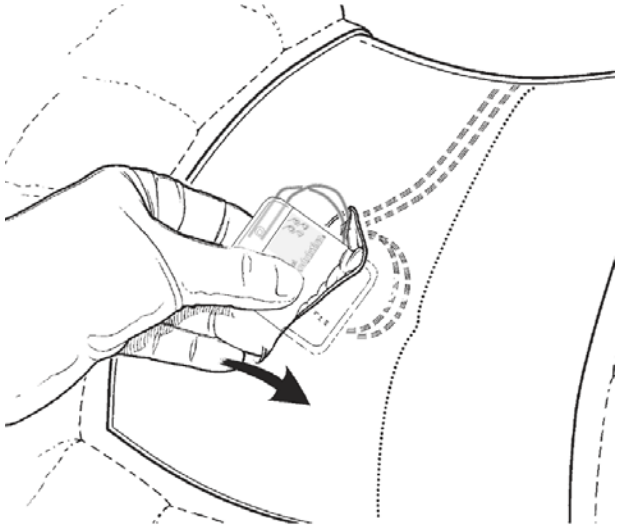
Implanting the INS

The following steps outline the procedure for implanting the INS:

⚠ **PRECAUTION:** Do not implant the INS face down. Always implant with the label facing up. Failure to do so will prevent communication with the programmer and/or magnet.

⚠ **PRECAUTION:** If using more than INS, implant them at least 15 cm apart. Putting them too close together may interfere with the programmer's ability to communicate with each one separately.

1. Place the INS into the pocket at a depth no greater than 2 cm from the skin surface, with the label facing the skin surface.
2. Carefully coil excess lead behind the INS or around the INS in loops to provide strain relief for the lead and INS connection.



⚠ **PRECAUTION:** Coiling the lead on the top surface of the INS (closest to the skin) will interfere with the ability of the programmer to communicate with the device.

⚠ **PRECAUTION:** Do not bring the suture needle in contact with the INS, or lead during sewing the INS into the pocket or closing the pocket. The components may be damage if this occurs.

3. To stabilize the INS within the pocket, pass a suture through the two suture holes in the INS and secure it to connective tissue.
4. Check the entire system by fluoroscopy prior to closing to ensure proper positioning of the leads. Verify that the leads have no sharp bends or kinks.
5. Place the magnet into a sterile bag and wave over the INS.

6. Slowly awaken the patient and test for stimulation perception and thereby verifying the system is operational.

NOTE: The INS output may not be identical to the trial neurostimulator output. Always start stimulating from a setting lower than that used to stimulate with the trial neurostimulator.

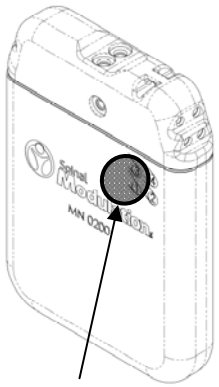
7. Ensure that that the INS is away from the pocket incision suture line, close the pocket incision, and apply appropriate dressings.
8. Fill out the patient registration information form and return it to Spinal Modulation.

Checking System Integrity

1. Place the magnet in a sterile pouch and wave it over the device to start programmer communication.
2. Using the clinical programmer in the non-sterile field, program the basic stimulation parameters, check the battery status, and check the electrode impedances to ensure there is no short or open circuit.
3. Once the system's function is verified, turn the neurostimulator off.

Completing the Procedure

1. Follow standard procedure for wound closure and bandaging.



Magnet Activation Target
Magnet must be within 3.5 cm of INS surface for activation of communication.

Replacing an INS

The following steps outline the suggested procedure to replace an INS:

1. Turn off the INS and verify that it has been turned off.

⚠ **PRECAUTION:** Exercise care when using sharp instruments or electrocautery around leads or they might be damaged.

2. Open the INS implant site per normal surgical procedures.
3. Remove the suture from the INS header, without damaging the lead, and carefully remove the INS from the pocket.
4. Clean the INS header and the lead with sterile water and then wipe with a surgical sponge.
5. Insert the torque wrench through the septum of the INS header and loosen the setscrew by turning it counterclockwise.

⚠ **PRECAUTION:** When performing the following steps, do not bend the lead sharply as this may cause lead breakage.

6. Gently remove the lead from the INS header; then clean and dry all connections on the lead, ensuring they are free from fluid and tissue.

⚠ **PRECAUTION:** If resistance is met while removing leads from the epidural space, do not use excessive force to extract. Always perform removal with the patient conscious and able to give feedback.

⚠ **WARNING: Do not remove a lead quickly, as this may result in lead breakage and unintentional lead fragments being left in the patient.**

⚠ **WARNING: Take proper precautions when handling removed lead components. Treat all used leads and delivery components as a "biohazard".**

7. If you need to replace a lead, perform the following actions:
    a. Make an incision above the location of the suture anchor.
    b. Carefully cut the sutures from the suture anchor.
    c. Slide the lead out of the epidural space slowly.
8. To complete the INS replacement procedure, see "Connecting the Lead to the INS".
9. To complete lead placement, see "Placing a Lead".

Disposing of an Explanted Device

All explanted INSs should be returned to Spinal Modulation for proper disposal. To dispose of an explanted device, follow these steps:

⚠ **WARNING: Do not crush, puncture, or burn the INS because it may explode or catch on fire.**

1. Decontaminate the explanted device.
2. Place it in a container with a biohazard label.
3. Include a completed "Returned Product Form." (One is packaged with each new INS)
4. Return the explanted device to:

    Spinal Modulation

    1135 O'Brien Drive

    Menlo Park, CA 94025

    U.S.A.

Appendix A: Trial Lead Kit / Implant Lead Kit

How Supplied

The components of the Spinal Modulation Trial Lead Kit and Implant Lead Kit are provided sterile in a double pouch assembly and are intended for single use only. Do not resterilize or reuse any devices from the Lead Kits, for any reason, because of risk of infection to the subject and malfunction of the devices.

⚠ **PRECAUTION:** Do not resterilize the Lead Kits or any other sterile components as it will create a risk of infection or malfunction of the device.

Storage Temperature - Store the Trial Lead Kit and Lead Accessories Kit between 14°F (-10°C) and 122°F (50°C). Temperatures outside this range may damage the components. If a temperature deviation has occurred, do not use the product.

Sterilization - The Trial Lead Kit, Connector Cable, and all Lead Kit Accessories have been sterilized using ethylene oxide (EO) gas.

Package Contents

(1) Trial / Implant Lead 50 cm / 90 cm

(1) 22 cm Small Curve Delivery Sheath

(1) 22 cm Big Curve Delivery Sheath

(1) Guidewire

(1) Complex Curve Stylet

(1) 4.5” 14 Gauge Needle

(2) Soft Tissue Anchors

(1) Physician Implant Manual

Device Specification

The Lead has four electrodes on the distal end and the proximal end fits into a four conductor connector on the Connector Cable or into the INS ports. The Complex Curved Stylet has been inserted into the proximal end of the lead and the lead has been pre-loaded into a 22 cm Small Curve Delivery Sheath for user convenience. An illustration of the Trial Lead is given in Figure 1.

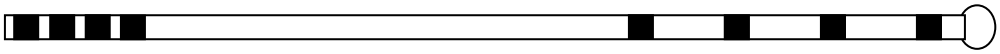


Figure 1: Lead showing four proximal electrical connectors and four radiopaque electrodes

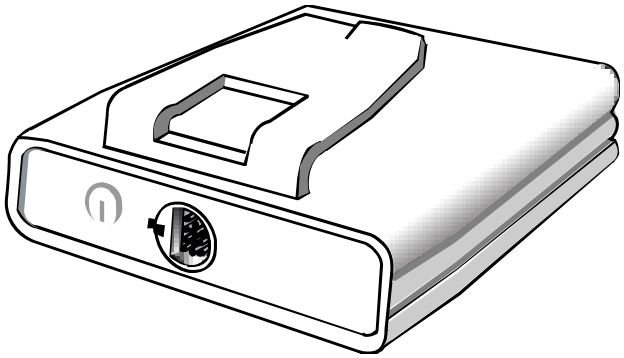
The approximate measurements for a Trial Lead are presented below:

Proximal Electrical Connector.....Quadrapolar, in-line
Center to Center Connector Spacing .....3.3 mm (0.130”)
Diameter .....1.0 mm (0.040”)
Length .....50 cm (20”) or 90 cm (35”)
Number of Electrodes.....4
Electrode Shape.....Cylindrical
Electrode Length .....1.25 mm (0.050”)
Edge to Edge Spacing .....5 mm (0.200”)
Center to Center Spacing.....6.25 mm (0.250”)
Array Length.....20 mm (0.790”)
Ball Tip Diameter.....1.5 mm (0.060”)
Stylet Wire Diameter.....0.25 mm (0.010”)
DC Lead Impedance (50cm / 90cm / Extension).... <20Ω / <35Ω / <60 Ω

Appendix B: Trial Neurostimulator

Device Description

See the Trial Neurostimulator Manual for the full description of the device. The external Trial Neurostimulator (TNS) provides energy and controls electrical signals delivered to the Leads. The TNS device is intended to be connected to the Leads and worn by the subject for up to 30 days during the study period. The device is intended to be connected to the Spinal Modulation Connector Cable. It is not compatible with other cables from other manufacturers. The external TNS device has a belt clip that can be used or the subject may choose to use a flexible, elastic bandage to secure their TNS device during the trial period. The patient should be advised not to allow the TNS to make direct contact with skin.



Package Contents

(1) Trial Neurostimulator

(1) TNS Manual

Device Specifications

Specifications	Range	Step Size	Default Value
Pulse Amplitude - PA (µA) (Depending on measured impedance)	0 – 6000 µA	25 µA: 0-2000 µA 50 µA: 2000-6000 µA	0 µA
Maximum Pulse Amplitude - Max (µA) Programmable by Patient	Same as PA	Same as PA	0 µA
Pulse Width – PW (µs)	40 – 720 µs	10 µs	40 µs
Pulse Frequency - PF (Hz)	4 – 100 Hz	2 Hz	60 Hz

Handling

Storage Conditions: -10°C - 50°C

Humidity Range: 10 – 93%

Cleaning Instructions for Healthcare Professional: For disinfecting the TNS surfaces after gross filth and heavy soil loads have been removed, spray Cavicide or equivalent onto a paper towel, and then wipe the surface of the TNS with the wet paper towel. Allow the surface to remain damp for 2 minutes. Dry the surface using a dry paper towel. Do not immerse the TNS in liquid. Advise the patient not to clean the TNS with excessive liquid. A damp cloth may be used to wipe the TNS, if necessary.

⚠ **WARNING: Always wear the TNS on the outside of clothing as the material may cause skin irritation.**

Appendix C: Implantable Neurostimulator

How Supplied

The Axium™ Implantable Neurostimulator is provided sterile in a double tray assembly and is intended for single use only. Do not resterilize or reuse, for any reason, because of risk of infection to the patient and malfunction of the devices.

⚠ **PRECAUTION:** Do not resterilize the INS as it will create a risk of infection or malfunction of the device.

Device Description

The Implantable Neurostimulator is a four channel neurostimulator that is only compatible with Spinal Modulation Implant Leads and Lead Extensions. It has four ports to allow for stimulation of up to four leads simultaneously. It has an antenna in the header that allows wireless communication with the device using the Spinal Modulation Clinical Programmer or Patient Programmer.

Package Contents

(1) Implantable Neurostimulator
(3) Lead Port Plugs
(1) Torque Wrench
(1) Sterile Magnet Sleeve
(1) Medical Alert Card
(1) Reference to Implant Manual

Device Specifications

Output of the INS is equivalent to the output of the TNS. The device is programmed in current, impedance is measured by the device, and the appropriate output voltage matches the impedance and current programmed.

Specifications	Range	Step Size	Default Value
Pulse Amplitude - PA (µA) (Depending on measured impedance)	0 – 6000 µA	25 µA: 0-2000 µA 50 µA: 2000-6000 µA	0 µA
Maximum Pulse Amplitude - Max (µA) Programmable by Patient	Same as PA	Same as PA	0 µA
Pulse Width – PW (µs)	40 – 720 µs	10 µs	40 µs
Pulse Frequency - PF (Hz)	4 – 100 Hz	2 Hz	60 Hz

Therapy Accuracy.....10% over the range of 300 to 6000 µA
Impedance Measurement Accuracy.....5% over the range of 400 to 2000 Ohms
Height.....6.52 cm (2.57 in)
Width .....4.77 cm (1.88 in)
Thickness.....1.10 cm (0.43 in)
Volume.....31 cm^3 (1.89 in^3)
Maximum Connector Strength 10N
Number of Channels 4
Power Source .....CFx, lithium - carbon monofluoride
Storage Temperature.....-10°C (14°F) to 50°C (122°F)
Storage Humidity .....10% to 90%

Handling

Storage Conditions: -10°C - 50°C

Humidity Range: 10 – 90%

Handling: Before implantation, only wipe with sterile water and do not use any cleaning agents.

⚠ **PRECAUTION:** Before implantation, do not use chemicals or any cleaning agents to wipe the INS. This may cause irritation or inflammation at the implant site.

Device Longevity

For information regarding device longevity, contact Spinal Modulation.

The Axium™ Neurostimulator System complies with the following International Standards:

- IEC 60601-1: 2005
- IEC 60601-1-11: 2010
- IEC 60601-1-2: 2007
- ISO 14708-1: 2000
- ISO 14708-3: 2008

Company and Authorized Representative Contact Information

Spinal Modulation, Inc.
1135 O'Brien Drive
Menlo Park, CA 94025
U.S.A.
Telephone: (650) 543-6800 (24-hour support line)
Fax: (650) 327-2336
Email: clinicalsupport@spinalmodulation.com

Healthlink Europe B.V.
De Tweeling 20-22
's Hertogenbosch 5215 MC
The Netherlands
Telephone: + 31 13 547 9300
Fax: + 31 13 547 9301

CE 0086 Authorization to affix the CE mark granted in 2011