

# Axium™ Neurostimulator System

## PHYSICIAN IMPLANT MANUAL

Proposition 65, a State of California voter initiative, requires the following notice:

**WARNING:** This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

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ST. JUDE MEDICAL™



**Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.**



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












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## Explanation of Symbols on Product or Package Labeling

	Model Number		Manufacturer
	Lot Number		Manufacturing Date
	Consult Instructions for Use		Warning
	Read the Manual		Contents of Package are Non-Sterile
	Do Not Resterilize		Keep Dry
	Single Use Only		Storage Temperature
	Sterilized by Ethylene Oxide Gas		Store between 10% and 90% humidity - Sterile Components
	Use by YYYY-MM-DD		Store between 0% and 93% humidity -TNS and Programmers
	Open Sterile Pouch by Peeling Pouch Corner		The device is a radio transmitter
	Open Sterile Tray by Peeling Tray Corner		Magnet - Shows the location of the Programmer Magnet
	Do not use if package is damaged		Not waterproof - Applies to the Programmer when it is not in its carrying case
	Turns the Programmer ON and OFF. Turns the stimulation OFF on the TNS.		Limited waterproof - Applies to the TNS. Applies to the Programmer in its carrying case
	Caution		Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Serial Number		Quantity

	MR Unsafe	ETL CLASSIFIED  Intertek 4009322	Electrical Safety Certification
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## Introduction

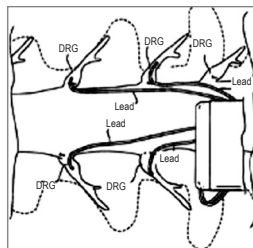
This manual describes the Axiom Neurostimulator System, including instructions for implantation. For detailed operation and clinical programming instructions, refer to the Clinical Programmer Manual.

## System Overview

The Axiom 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 Axiom Implantable Neurostimulator (INS) System will first undergo a temporary trial period using an external Trial Neurostimulator (TNS) 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.

## System Description

The Axiom Neurostimulator System consists of the following components:

Component Model Number	Package Contents	Associated Instructions for Use
Trial Neurostimulator MN10100	Trial Neurostimulator	Trial Neurostimulator Manual

Component Model Number	Package Contents	Associated Instructions for Use
Implantable Neurostimulator MN10200	Implantable Neurostimulator Lead Port Plugs (3) Torque Wrench Medical Alert Card	Physician Implant Manual
Trial Lead Kit (length in cm specified by -XX) MN10350-XX MN10350-XXA	Trial Lead / Trial Lead, SlimTip 22 cm Small Curve Delivery Sheath 22 cm Big Curve Delivery Sheath Guidewire Complex Curve Stylet 4.5" 14G Delivery Needle Soft Tissue Anchor (2) Straight Stylet (SlimTip lead kits only)	Physician Implant Manual
Implant Lead Kit (length in cm specified by -XX) MN10450-XX MN10450-XXA	Implant Lead / Implant Lead, SlimTip 22 cm Small Curve Delivery Sheath 22 cm Big Curve Delivery Sheath Guidewire Complex Curve Stylet 4.5" 14G Delivery Needle Soft Tissue Anchor (2) Straight Stylet (SlimTip lead kits only)	Physician Implant Manual
Connector Cable Kit MN11350	Connector Cable	Physician Implant Manual
Tunneling Tool Kit 30 cm / 51 cm MN11900 MN12200	Tunneling Tool 30 cm / 51 cm Straw Trocator Tip Pencil Tip INS Sizer Port Plugs (3) Torque Wrench Hex Key Sterile Magnet Sleeve	Physician Implant Manual

<b>Component Model Number</b>	<b>Package Contents</b>	<b>Associated Instructions for Use</b>
Clinical Programmer MN10700	Clinical Programmer External Magnet Programmer Charger Carrying Case	Clinical Programmer Manual
Patient Programmer MN10600-02	Patient Programmer External Magnet Programmer Charger Carrying Case Medical Alert Card	Patient Programmer Manual
Lead Accessories Kit MN12050	4.5" 14G Delivery Needle 6.0" 14G Delivery Needle Soft Tissue Anchor Complex Curve Stylet 30 cm Big Curve Delivery Sheath 30 cm Small Curve Delivery Sheath	Physician Implant Manual
22 cm Small Curve Delivery Sheath Kit MN12150	22 cm Small Curve Delivery Sheaths (2)	Physician Implant Manual
22 cm Big Curve Delivery Sheath Kit MN13650	22 cm Big Curve Delivery Sheaths (2)	Physician Implant Manual
22 cm Axium Small Curve Delivery Sheath MN13850	22 cm Axium Small Curve Delivery Sheath (1)	Physician Implant Manual
22 cm Axium Big Curve Delivery Sheath MN13950	22 cm Axium Big Curve Delivery Sheath (1)	Physician Implant Manual
Lead Extension Kit (length in cm specified by -XX) MN10550-XX	Lead Extension 50 cm Torque Wrench	Physician Implant Manual



Component Model Number	Package Contents	Associated Instructions for Use
Auxiliary Magnet Kit MN23300	Auxiliary Magnet	Ancillary Manual
Clinical Programmer Charger Kit MN23400	Clinical Programmer Charger	Ancillary Manual
Patient Programmer Charger Kit MN23400-U	Patient Programmer Charger	Ancillary Manual
Clinical Programmer Carrying Case MN13500	Clinical Programmer Carrying Case	Ancillary Manual
Patient Programmer Carrying Case MN13500-S	Patient Programmer Carrying Case	Ancillary Manual
Curved Needle MN14000	4.5" 14G Curved Delivery Needle	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.

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.

- **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. The Trial and Implant leads are designed with identical technical and performance characteristics in order to help ensure that the therapy experienced during the Trial phase is as close as possible to that experienced during the Implant phase. 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).
- **Lead Extension:** The Lead Extension consists of a silicone port header that accepts the Axiom 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. The Lead Extension is intended for chronic implantation as a component of the Axiom 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 two extension cables for use as needed.

## 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 8 mm for the Big Curve.
- **Axiom Small / Big Curve Delivery Sheath:** Axiom Delivery Sheaths are also intended to allow passage of leads percutaneously into the epidural space. Axiom sheaths are internally reinforced with thin stainless steel braiding.
- **Complex Curve / Straight Stylet:** The Complex Curve and Straight stylets assist in steering and positioning the lead within the epidural space.
- **14G Delivery Needles:** The Delivery Needle is intended to access the epidural space, providing a conduit for lead, guidewire and delivery sheath placement. It is available as a straight needle or a curved needle. The Axiom Curved Needle is available in a separate package and is uniquely identified by the colored hub. The 14 Ga Delivery Needle is only available in the Implant Lead, Trial Lead, and Lead Accessories Kits.

- **Guidewire:** The Guidewire is intended to verify that the needle is in the epidural space after using a loss of resistance technique. It also provides stability to the sheath before front-loading the SlimTip lead.
- **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 Neurostimulator 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 turn the NS off or activates RF to allow the user to communicate with the NS.
- **Hex Key:** Allows the user to release a set screw in the INS header or Lead Extension header that has been unscrewed too far. The Hex Key is not to be used to tighten the set screw against the lead.

## Clinical Programmer and Patient Programmer

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. 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 Programmers and the Trial Neurostimulator, refer to the respective user manuals.*

## Indications for Use

The Axiom Neurostimulator System is indicated for spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable\* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.\*\*

\*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

\*\*Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively.

## Contraindications

Patients contraindicated for the Axiom Neurostimulator System are those who:

- Are unable to operate the system
- Are poor surgical risks

Patients who failed to receive effective pain relief during trial stimulation are contraindicated to proceed to the INS procedure.

# Safety Information

## General Warnings

The following warnings apply to the use of the Axiom Neurostimulator System:

- **Other Active Implantable Devices** - The Axiom system may interfere with other implanted stimulators, such as cardiac pacemakers and defibrillators which have sensing features, and may result in sensing problems or inappropriate responses. The effect of other implanted devices, including deep brain stimulators, peripheral nerve stimulators, implanted drug delivery pumps, and cochlear implants on the Axiom system are unknown.
- **External Defibrillators** – Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation confirm the neurostimulation system is still working.
- **Magnetic Resonance Imaging** – The Axiom System is MRI unsafe. The patient should be advised to not undergo any elective magnetic resonance imaging (MRI) with the entire system, or (in the case of removal of the implanted generator) leads or lead fragments 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. MRI may cause heating at the lead tip and unintended stimulation could result in tissue damage.
- **Computed Tomography (CT)** – If the patient requires a CT scan, all stimulation should be turned OFF prior to the procedure. If stimulation is not turned off, the patient may experience a momentary increase in stimulation, which may be uncomfortable. Before beginning a CT scan, the operator should use CT scout views to determine if implanted or externally worn electronic medical devices are present and if so, their location relative to the programmed scan range.

For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the operator should:

- Determine the device type;
- If practical, try to move external devices out of the scan range;
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed.
- Minimize x-ray exposure to the implanted or externally worn electronic medical device by:
  - Using the lowest possible x-ray tube current consistent with obtaining the required image quality; and
  - Making sure that the x-ray beam does not dwell over the device for more than a few seconds;

Important note: For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning directly over the implanted or externally worn electronic medical device:

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, even if the device was turned off. Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.
- Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.
- **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. Do not apply electrocautery directly to the INS as this can damage the INS or cause interference while communicating with the INS. The INS may be damaged, the output may be temporarily changed or suppressed, or stimulation may stop if exposed to electrosurgical devices.
- **Electrocautery** - If electrocautery is used, follow these steps:
  - Turn off the INS before the procedure.
  - Use the equipment as far away from the INS as possible.
  - Keep fields, such as current, radiation, or high-output ultrasonic beams, away from the INS.
  - Equipment should be set to the lowest energy setting possible.
  - After the therapy or procedure, check to see that the INS is functioning properly by gradually increasing stimulation to the desired level.
  - If the patient suspects that the device is not functioning properly after the use of these therapies or procedures, advise the patient to contact his or her healthcare provider.
- **Radiofrequency or microwave ablation** – Safety has not been established for radiofrequency (RF) or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.
- **Pediatric Use** – The safety and effectiveness of the Axiom Neurostimulator System has not been established for pediatric use.
- **Pregnancy** – The safety and effectiveness of this therapy has not been established for pregnancy, nursing, the unborn fetus, or delivery.
- **Implantation at Vertebral Levels above T10** – The safety and efficacy of implantation of leads implanted above the T10 vertebral level has not been evaluated.

- **Number of Leads Implanted** – The safety and efficacy of the implantation of greater than 4 leads has not been evaluated.
- **Back Pain** - The safety and efficacy for the treatment of patients who have back pain as the greatest region of pain has not been evaluated.
- **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 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 not to undergo dental procedures, diathermy, electrolysis, diagnostic ultrasound, static field therapeutic magnets, diagnostic X-ray, or 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 removal 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.
- **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** – Dispose of leads and neurostimulators per local requirements. 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.
- **Manipulation of the Trial Lead/Extension and the INS** –
  - 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.
- The patient must be instructed to always wear the TNS on the outside of clothing to avoid skin irritation.
- **Physician Training** – Physicians must be experienced in the diagnosis and treatment of chronic pain syndromes and have completed the Axium Implantable Neurostimulator training program.

## Warnings - For Use in Home or Work Environments

- **Equipment Operation** – Advise all patients who feel uncomfortable paresthesia during postural changes that they should not operate potentially dangerous equipment, such as power tools, automobiles, or other motor vehicles. These patients should not climb ladders or participate in activities where postural change or 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. The patient may be advised to turn off their device if stimulation becomes uncomfortable.
- **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.
- **Patient Activities Related to Lead Movement** – The patient should be instructed to avoid excessive bending, twisting, and stretching, and operating the neurostimulator while lifting objects 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. Excessive lead migration may require reoperation to replace the leads.
- **Scuba Diving and Hyperbaric Chambers** – The patient should be instructed to avoid scuba diving and entering hyperbaric chambers above 150 kPa. These activities may damage the Axiom System.
- **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.
- **Electromagnetic Interference (EMI)** – Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical or public environments that is strong enough to interfere with neurostimulator function. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. Patients should keep away from areas of EMI and turn off the stimulator if they are in such an area. Sources of strong electromagnetic interference can result in the following:
  - Operational changes to the neurostimulator, causing it to turn on or off (particularly in neurostimulators enabled for magnet use), or to reset to power-on- reset (POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of POR, requiring reprogramming by a clinician.
  - Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

Sources of potentially strong EMI include the following:

- Microwave transmitters
- Communication equipment such as microwave transmitters, linear power amplifiers, and high voltage power lines and power generators
- Electric arc welding equipment
- Large, magnetized stereo speakers
- Radio frequency identification devices (RFID)
- Antenna of citizens band (CB) or ham radio

- Electric steel furnaces
- Dental drills and ultrasonic probes
- Electrolysis

## Warnings for the Lead Implant Procedure

- 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.
- 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.
- Always be aware of the needle tip position. Use caution when positioning the needle to avoid unintended injury to surrounding anatomical structures.
- 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.
- 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.
- Dural puncture can occur if needle or guidewire is advanced aggressively once loss of resistance is achieved. Advance the needle and/or guidewire slowly.
- Insertion of a sheath without the lead may result in dural puncture. Securing the lead with the lead stabilizer will mitigate this risk.
- If the sheath needs to be retracted from the epidural space, verify that the steering wing is no more than 90 degrees rotated away from the mark on the needle. Failure to do so may result in damage to the sheath. Before reinserting the sheath, verify there is no damage to the sheath.
- Do not pull the standard Implant Lead through the sheath as this can cause separation of the ball-tip from the lead. With the SlimTip Implant Lead, it may be removed through the sheath as the ball-tip is small enough to allow passage back and forth through the sheath.
- 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.
- 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.

- 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.
- Failure to provide strain relief may result in lead migration requiring a revision procedure.
- 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.
- 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.
- Failure to appropriately anchor may result in lead migration and/or motor activation or painful stimulation.
- Use extreme care when using sharp instruments or electrocautery around the lead to avoid damaging the lead.
- 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.

### Warnings During Intraoperative Testing

- 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.
- As described in the Clinical Programmer User Manual, always turn the external TNS amplitude to 0  $\mu$ A 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.
- Once the clinical programmer ENABLE function is ON for a specific therapy target, any parameter change will be immediately active.

### Warnings While Removing the Lead

- 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.
- 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 the implantable neurostimulator.
- Do not remove a lead quickly, as this may result in lead breakage and unintentional lead fragments being left in the patient. Spinal Modulation recommends pulling slowly at a rate of approximately 1cm/second while holding the lead between the thumb and forefinger.

- Take proper precautions when handling removed Trial Lead components. Treat all used Trial Leads and delivery components as a “biohazard.”

## Warning While Removing the INS

- Do not crush, puncture, or burn the INS because it may explode or catch on fire.

## Warnings for Your Patient

- Do not use your Programmer or the Stimulator until your doctor has trained you.
- The safety and effectiveness of this therapy has not been established for pregnancy, nursing, the unborn fetus, or delivery.
- The safety and effectiveness of the Axiom Neurostimulator System has not been established for pediatric use.
- Do not use your Programmer until your doctor has set up your Stimulator.
- Before having a CT scan, tell your doctor that you have an implanted device. All stimulation for your device should be turned OFF before the procedure. After the scan, your doctor should turn it back on and make sure the system is working properly.
- Do not remove your leads or Connector Cable by yourself. This may cause serious injury and could cause an infection.
- Do not open or modify the Programmer or TNS. Keep them closed to protect them. Modifications to the device may cause improper operation.
- Do not transport the Programmer outside of its carrying case. Operate it only in a moisture-free environment. The Programmer may malfunction if it becomes wet.
- Power generators, arc welders and large magnetized speakers may cause interference. Do not stand near these or similar devices.
- Be aware of where you place your Charger. Pets, children or you can become entangled in the cord, which could cause a fall or strangulation.
- If contact with the Stimulator System causes a rash, report this to your doctor. If your throat or tongue starts to swell, get emergency aid immediately.
- Please contact your doctor if you experience unusual pain or discomfort during stimulation, the implant site is swollen, reddened, tender, or painful.

## Precautions

The following precautions apply to the use of the Axiom Neurostimulator System:

- **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.
- **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.
- **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 regular business hours.
- **Transcranial Magnetic Stimulation (TMS) and Electroconvulsive Therapy (ECT)** – Safety has not been established for TMS or ECT in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.
- **Transcutaneous Electrical Nerve Stimulation** – Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the implanted neurostimulator, patients should discontinue using the TENS until they talk with their doctor.
- **Long-Term Effectiveness of DRG Stimulation** – The long-term effectiveness of DRG stimulation has been documented. Not all patients realize long-term benefits from DRG stimulation. Stimulation effectiveness has been established for one year.
- **Cell Phones** - While interference with cell phones is not anticipated, cell phone technology continues to change, and interaction with a neurostimulation system is possible. Advise patients to contact your office if they have a concern about cell phone interaction with their neurostimulator system.

### Precautions During Lead Implant

- When handling the lead, do not bend the lead sharply as this may cause lead damage.
- Use caution when attaching the soft tissue anchor because damage to the anchor or lead can occur and result in failure of the system.
- 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.
- Use extreme care to not damage the lead with the sharp point of the tunneling tool.
- Leads or Extensions should be routed adjacent to one another to prevent changes in perceived stimulation from theft detectors and metal screening detectors.

### Precautions During INS Implant

- Before implantation, do not use chemicals or any cleaning agents to wipe the INS. This may cause irritation or inflammation at the implant site.
- 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.
- Do not implant the INS deeper than 2.0 cm, as the programmer will not be able to communicate with the INS.

- Do not connect a lead to the INS with body fluid on its contacts because corrosion can occur and cause failure of the system.
- 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.
- Insert the lead slowly into the header to prevent damage to the INS. If the lead needs to be retracted, retract the lead slowly.
- 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.
- 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.
- Do not bring the suture needle in contact with the INS or lead while sewing the INS into the pocket or closing the pocket. The components may be damaged if this occurs.

### Precaution During Intraoperative Testing

- 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.

### Precautions During the Implant Procedure

- 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 or guidewire inserted, as this may cause injury to the dura. The standard Implant Lead cannot be loaded into the sheath after the sheath is in the body. The SlimTip Lead, however, can be loaded after the sheath has been initially placed in the body.
- 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. Remove the stylet from the lead only when satisfied with lead placement. If the stylet is removed from the lead, it may be difficult to reinsert it.
- 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.
- 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.

## Precautions When using the Clinical and Patient Programmers

- Do not drop or mishandle the programmer. Physical damage may impair its function.
- Do not spill fluids on or wash the programmers. Excessive moisture may impair function. If cleaning is necessary, remove soil with a soft damp cloth.
- Do not use abrasive or caustic cleaning products on the programmers.
- Do not attempt to open the case for the programmers. Attempts to open a case may expose the programmer to elements that alter its function.
- The programmers have an internal magnet. Keep the programmers away from any credit cards, hard drives, or magnetic storage devices as it may demagnetize them.
- Do not operate the programmers outside the specified temperature range of 5°C to 40°C (41°F to 104°F). Rapid temperature changes may affect proper device operation.
- Do not store the programmers outside the specified temperature range of -10°C to 50°C (14°F to 122°F).
- Do not leave the programmers in a car or other places where temperatures can exceed 50°C (122°F).



- Do not burn or otherwise dispose of the programmers. Fire may cause the internal battery to explode.
- Do not allow unauthorized use of the programmers to avoid injury to patients.
- The NS device can only be programmed using Spinal Modulation's Clinical or Patient Programmer. Do not try to use any other manufacturer's device to program them.
- Do not use the programmers or NS in the presence of explosive or flammable gases as this may cause serious injury.
- Do not use the Programmer Charger if the power cord is damaged, excessively worn or frayed. This may cause injury or damage the Programmer.
- Frequent programming of the implanted device will cause the battery to deplete faster. Avoid unnecessary programming.

### Precautions While Removing Lead

- Always perform removal with the patient conscious and able to give feedback.
- If resistance is met while removing leads from the epidural space, do not use excessive force to extract. If the lead cannot be easily removed, seek surgical advice regarding lead removal.

## Sterilization Information

**Single-use, sterile device** – The sterile components of the Axiom 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 patient and malfunction of the devices.

**Sterilization** – The sterile components of the Axiom Neurostimulator System 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 Axiom 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	Stainless Steel
Polyurethane	MP35N (nickel-cobalt-chromium-molybdenum alloy)
Titanium	PEEK (polyether ether ketone)
Epotek	PFA (perfluoroalkoxy copolymer resin)
Silicone rubber	PMMA [poly(methyl methacrylate)]

## 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 Axiom 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
- 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)
- Change in stimulation, possibly related to tissue changes around the electrodes, shifts in electrode position, loose electrical connections, lead or extension fractures, which has been described by some patients as uncomfortable stimulation (jolting or shocking sensation).
- Formation of reactive tissue in the epidural space around the lead can result in delayed spinal cord compression and paralysis, requiring surgical intervention. Time to onset can range from weeks to many years after implant.

Additional risks to the patients, as a result of the placement and stimulation of the lead in the area of the DRG, include 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 patients will be awake and conversant during the procedure to minimize the impact.

# Implanting the Neurostimulator System

## 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.

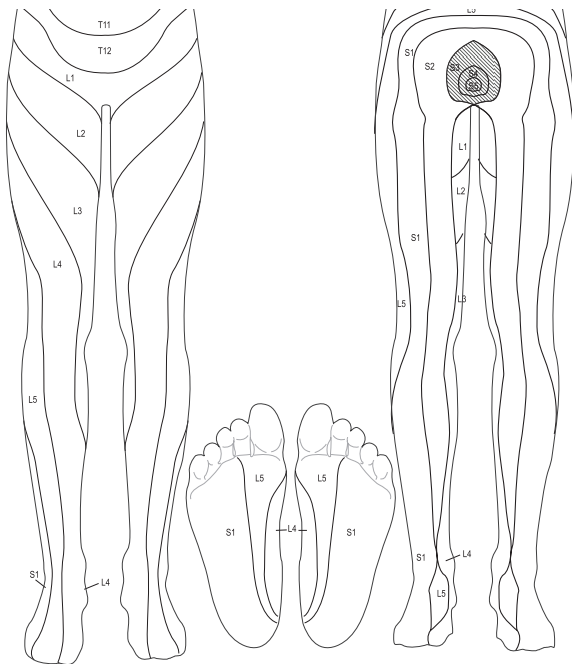
 **WARNING:** The temporarily placed Trial Leads are intended for use up to 30 days. Use of these devices must be performed in accordance with the instructions provided in this manual.

Using standard sterile technique, perform the appropriate skin prepping, draping and injection of local anesthetic to prepare 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. Use a dermatomal map to identify the correct level to place the leads. One example is the following:

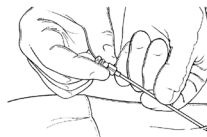


**WARNING:** As with any spinal epidural procedure, potential risks of serious injury to the patient, although extremely rare, include epidural hemorrhage, hematoma, infection, spinal cord or nerve compression, and/or paralysis.

**WARNING:** Always be aware of the needle tip position. Use caution when positioning the needle to avoid unintended injury to surrounding anatomical structures.

1. Determine the length of the lead required to extend from the target foraminal level to the Neurostimulator implantation site.
2. Choose an approach:

- **Antegrade Approach:** Under fluoroscopic guidance, use a contralateral or ipsilateral 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 by inserting the needle into the interlaminar space at the appropriate level, based on the patient's anatomy. The needle angle should be shallow to ensure a smoother delivery.



Example of Needle Angle

- **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.

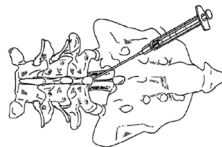


Examples of Angles of Approach

3. Confirm entry into the epidural space using standard methods, such as a loss of resistance technique.
4. 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 1-3 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.



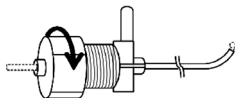
5. Remove the guidewire (if used) after confirmation of access to the epidural space.
6. Before insertion into the needle, push the lead outside the sheath and verify that the stylet is pushed fully distal within the lead.

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

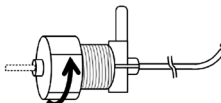
7. Before insertion into the needle, pull back on the lead so that the ball-tip end is protruding slightly from the Delivery Sheath tip and tighten down the lead stabilizer until the lead does not slide within the sheath. One way to ensure this placement is to line up the marker band of the sheath with the distal electrode.

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

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

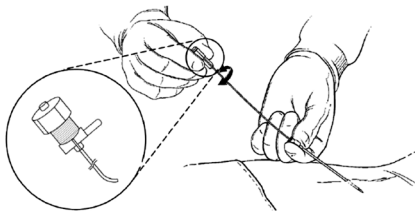


Tightening the Lead Stabilizer



Loosening the Lead Stabilizer

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

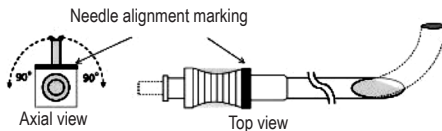


9. Before inserting the sheath into the needle, verify that the lead is loaded. The Implant Lead cannot be loaded into the sheath after the sheath is in the body. The SlimTip Lead, however, can be loaded after the sheath has been initially placed in the body.
10. Insert the sheath, lead, and stylet through 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 rotated away from the mark on the needle. Failure to do so may result in damage to the sheath. Before reinserting the sheath, verify there is no damage to the sheath.

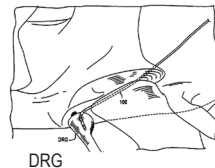
**WARNING:** Do not pull the standard Implant Lead through the sheath as this can cause separation of the ball-tip from the lead. With the SlimTip Implant Lead, it may be removed through the sheath as the ball-tip is small enough to allow passage back and forth through the sheath.

**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.





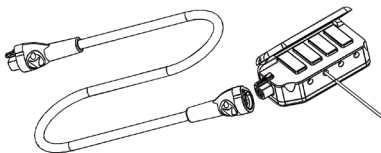
11. With the distal end of the sheath in or at the target foramen, loosen the lead stabilizer, and advance the lead so that it moves into the foramen. Confirm placement of the lead on the dorsal side of the foramen using a lateral fluoroscopic view. Verify that the electrodes extend out of the sheath.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



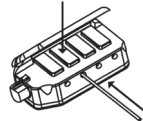
- WARNING:** If the lead is unable to deploy out of the sheath, inject sterile water or saline slowly to release tissue that may have entered between the sheath and the lead. Do not use excessive pressure when injecting through the sheath.
- WARNING:** Do not use excessive force to push the lead or sheath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



Push cable  
button down




Insert lead

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.

**NOTE:** *Up to four leads may be placed in one patient. Refer to “Placing the Lead” to position subsequent leads.*

 **PRECAUTION:** As described in the Clinical Programmer User Manual, always turn the external TNS amplitude to 0  $\mu$ A 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 movement.
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. To provide strain relief, create an S-curve with the lead in the epidural space.

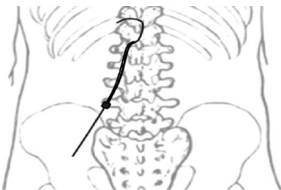


**WARNING:** Failure to provide strain relief may result in lead migration requiring a revision procedure.

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 rotated away from 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 $\mu$ A, 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 breakage.

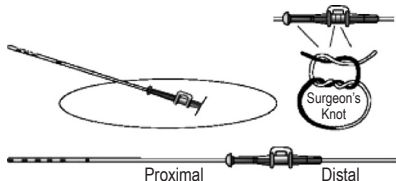
7. Record the lead position with both an A/P and lateral fluoroscopic view for comparison of the position at time of closure to ensure that the lead has not moved. Remove the stylet by holding forward pressure on the lead while retracting the stylet.



**WARNING:** Use extreme care when removing the lead stylet, the delivery sheath, and the needle, to 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 - Percutaneous Lead Trial

1. After placing a Trial Lead in its final position, it should be secured using a lead anchor on the skin.



Depiction of Anchoring Technique

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. One option would be to apply at least two ties to the main body and one tie to the leg. Physicians may apply their own technique based on patient anatomy, physical activity and other factors.

**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 appropriately anchor 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

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 the 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.


 **WARNING:** Do not remove a Trial Lead quickly, as this may result in lead breakage and unintentional lead fragments being left in the patient. Spinal Modulation recommends pulling slowly at a rate of approximately 1cm/second while holding the lead between the thumb and forefinger.

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


## Removing the Delivery System Components - Implant Lead Trial Only

These instructions pertain only after placing Implant Leads 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.


 **WARNING:** 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 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. To provide strain relief, create an S-curve with the lead in the epidural space.


 **WARNING:** Failure to provide strain relief may result in lead migration requiring a revision procedure.

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 rotated away from 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 TNS amplitude set to 0  $\mu$ A, 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 breakage.


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.


-  **WARNING:** 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. Apply sutures around the anchor and cinch onto the Lead as shown. One option would be to apply at least two ties to the main body and one tie to the leg. Physicians may apply their own technique based on patient anatomy, physical activity and other factors.

-  **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  $\mu$ A, reconnect the Connector Cable as described before.

## Percutaneous Extension Tunneling - Implant Trial Lead 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 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.



**NOTE:** *If it is difficult to insert the lead, the set screw may be unscrewed with the Torque Wrench just enough to allow the lead to pass. If the set screw is fully unscrewed, the Torque Wrench may not be able to tighten it again.*

- If this occurs, use the Hex Key included in the Tunneling Tool Kit to release the set screw. Insert the Hex Key into the set screw and release it by turning the key only part of a turn clockwise.*
- Once the set screw is released, remove the Hex Key. Do not use the Hex Key to tighten the screw against the lead as it may be overtightened and may damage the lead or the screw head.*

16. Use the torque wrench supplied in the package to tighten the set screw. 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.



**PRECAUTION:** Use only the Torque Wrench provided by Spinal Modulation or the device or lead may be damaged and unusable.

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 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 Trial Lead 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.

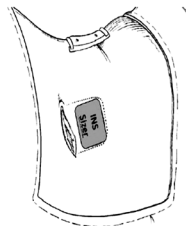
3. Expose the lead-extension to lead connection.
4. While maintaining lead position, carefully remove the lead-extension connections from the incision.
5. Disconnect the lead from the extension.
6. Cut the extension near the lead-extension connector.
7. Discard the lead-extension connector.
8. Preserving 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 leads have 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 belt line)*
  - *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 with 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.



**WARNING:** 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, tunnel to a midpoint and then continue to INS site.

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



**WARNING:** 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 to prevent changes in perceived stimulation from theft detectors and metal screening detectors.

6. Pass the end of the Leads or Extensions 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 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:

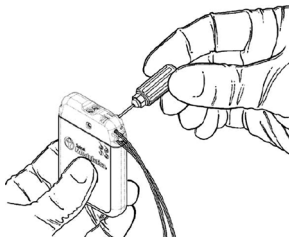
**⚠ PRECAUTION:** Do not connect a lead with body fluid on its contacts because corrosion can occur and cause failure of the system.

**⚠ 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.


**NOTE:** *If it is difficult to insert the lead, the set screw may be unscrewed with the Torque Wrench just enough to allow the lead to pass. If the set screw is fully unscrewed, the Torque Wrench may not be able to tighten it again.*

- *If this occurs, use the Hex Key included in the Tunneling Tool Kit to release the set screw. Insert the Hex Key into the set screw and release it by turning the key only part of a turn clockwise.*
- *Once the set screw is released, remove the Hex Key. Do not use the Hex Key to tighten the screw against the lead as it may be overtightened and may damage the lead or the screw head.*




**⚠ 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.

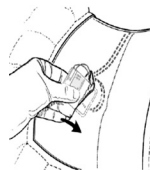
3. Insert the torque wrench through the seal plug and tighten the set screw by turning it clockwise, until the wrench clicks.
4. Carefully remove the torque wrench and verify that the septum over the set screw is closed. Reseat the flaps if it is not closed.
5. If implanting less than 4 leads, insert the port plugs in each of the vacant header ports. Use the torque wrench to tighten the set screw 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 one 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 the 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 while sewing the INS into the pocket or closing the pocket. The components may be damaged 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.

#### Magnet Activation Target

Magnet must be within 3.5 cm of INS surface to activate communication.



**NOTE:** *The INS output may not be identical to the Trial Neurostimulator output. When restarting stimulation, increase amplitude SLOWLY until the desired paresthesia is achieved. Failure to do so may result in uncomfortable motor activation or painful stimulation. Always start stimulating from a setting lower than that used to stimulate with the Trial Neurostimulator.*

7. Ensure that the INS is away from the pocket incision suture line, close the pocket incision, and apply appropriate dressings.

### 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

Follow standard procedure for wound closure and bandaging.

## 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.



**WARNING:** 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 set screw by turning it counterclockwise.



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

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, see "Revising or Removing a Lead".
8. To complete the INS replacement procedure, see "Connecting the INS".
9. To complete lead placement, see "Placing The Lead".

## Disposing of an Explanted Device

Dispose of INS per local waste disposal requirements.

1. Decontaminate the explanted device.
2. Place it in a container with a biohazard label.
3. If you wish to return it to Spinal Modulation, contact your Spinal Modulation representative for device return.

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

## Revising or Removing a Lead

1. Place the patient in a flexed position–

Put the patient in the prone position by bolstering with pillows or bend the table into an inverted “V”. This will put the patient in flexion and may help release tension on the lead.

**PRECAUTION:** Always perform removal with the patient conscious and able to give feedback.

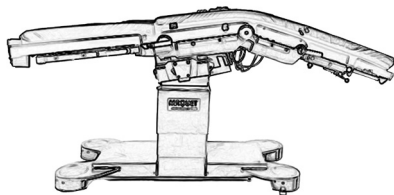


Table in “inverted V” position.



2. Disconnect the lead from the extension or INS.

**WARNING:** Exercise care when using sharp instruments or electrocautery around leads, or they may be damaged.



### Lead Extension – If the lead is connected to an extension and not directly to the INS:

- a. Using standard surgical technique, make an incision above the location of the suture anchor.
- b. Carefully cut the sutures from the suture anchor.

### INS – If the lead is connected directly to the INS without an extension:

- a. Open the INS implant site using standard surgical procedure.
- b. Remove the suture from the INS header, without damaging the lead, and carefully remove the INS from the pocket.



**PRECAUTION:** Do not bend the lead sharply as this may cause lead damage.

- c. Clean the INS header and the lead with sterile water, and then wipe with a surgical sponge.
  - d. Insert the torque wrench through the septum of the INS header, and loosen the set screw by turning it counterclockwise.
  - e. Gently remove the lead from the INS header.
  - f. Make an incision above the location of the suture anchor.
  - g. Carefully cut the sutures from the suture anchor.
3. Slowly slide the lead out of the epidural space.  
When removing the lead, use live fluoroscopy to monitor the position of the lead during extraction.

**NOTE:** *Spinal Modulation recommends pulling slowly at a rate of approximately 1cm/second while holding the lead between the thumb and forefinger.*



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



**PRECAUTION:** If resistance is met while removing leads from the epidural space, do not use excessive force to extract. If the lead cannot be easily removed, seek surgical advice regarding lead removal.



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

4. To complete the procedure, see Implanting an INS.

## Appendix A: Trial Lead Kit / Implant Lead Kit

### How Supplied

The components of the Axiom Lead Kits are provided sterile in a double pouch assembly and are intended for single use only.

**WARNING:** 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 Lead Kits 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.

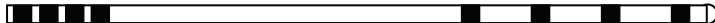
**Sterilization** - The Lead Kits, Lead Extension Kit, and all Lead Kit Accessories have been sterilized using ethylene oxide (EO) gas.

### Package Contents

- |  |  |
|--|--|
| (1) Trial / Implant Lead 50 cm / 90 cm | (1) Complex Curve Stylet                     |
| (1) 22 cm Small Curve Delivery Sheath  | (1) Straight Stylet (SlimTip lead kits only) |
| (1) 22 cm Big Curve Delivery Sheath    | (1) 4.5" 14 Gauge Needle                     |
| (1) Guidewire                          | (2) Soft Tissue Anchors                      |

### Device Specifications

The Lead has four electrodes on the distal end and the proximal end fits into a four conductor connector on the Connector Cable, Lead Extension or into the INS ports.



Lead showing four proximal electrical connectors and four radiopaque electrodes

The approximate measurements for a Lead are presented below:

Proximal Electrical Connector .....	Quadrupolar, 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.....	1.0 - 1.5 mm (0.040" - 0.060")
Stylet Wire Diameter .....	0.25 mm (0.010")
DC Lead Impedance (50cm / 90cm / Extension) .....	<20Ω / <35Ω / <60Ω

## 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 patient for up to 30 days during the study period. The device is intended to be connected to the Axiom 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 patient 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

### Device Specifications


Specifications	Range	Step Size	Default Value
Pulse Amplitude - PA ( $\mu\text{A}$ ) (Depending on measured impedance)	0 – 6000 $\mu\text{A}$	25 $\mu\text{A}$ @ 0-2000 $\mu\text{A}$ 50 $\mu\text{A}$ @ 2000-6000 $\mu\text{A}$	0 $\mu\text{A}$
Maximum Pulse Amplitude - Max ( $\mu\text{A}$ ) Programmable by Patient	Same as PA	Same as PA	0 $\mu\text{A}$
Pulse Width – PW ( $\mu\text{s}$ )	40 – 1000 $\mu\text{s}$	10 $\mu\text{s}$	300 $\mu\text{s}$
Pulse Frequency - PF (Hz)	4 – 80 Hz	2 Hz	20 Hz

## Handling

Storage Conditions: -10°C - 50°C

Humidity Range: 0 – 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 to avoid 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.

 **WARNING:** 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 Axium Leads and Lead Extensions. Four ports allow for simultaneous stimulation of up to four leads. An antenna in the header allows wireless communication with the Axium Clinical Programmer or Patient Programmer.

### Package Contents

- |                                 |                        |
|---------------------------------|------------------------|
| (1) Implantable Neurostimulator | (3) Lead Port Plugs    |
| (1) Torque Wrench               | (1) Medical Alert Card |

## 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 ( $\mu\text{A}$ ) (Depending on measured impedance)	0 – 6000 $\mu\text{A}$	25 $\mu\text{A}$ @ 0-2000 $\mu\text{A}$ 50 $\mu\text{A}$ @ 2000-6000 $\mu\text{A}$	0 $\mu\text{A}$
Maximum Pulse Amplitude - Max ( $\mu\text{A}$ ) Programmable by Patient	Same as PA	Same as PA	0 $\mu\text{A}$
Pulse Width – PW ( $\mu\text{s}$ )	40 – 1000 $\mu\text{s}$	10 $\mu\text{s}$	300 $\mu\text{s}$
Pulse Frequency - PF (Hz)	4 – 80 Hz	2 Hz	20 Hz


Therapy Accuracy .....	10% over the range of 1000 to 6000 $\mu\text{A}$
Impedance Measurement Accuracy.....	10% over the range of 400 to 2500 Ohms
Height.....	6.52 cm (2.57 in)
Width.....	4.77 cm (1.88 in)
Thickness.....	1.10 cm (0.43 in)
Volume .....	31 $\text{cm}^3$ (1.89 $\text{in}^3$ )
Maximum Connector Strength .....	10N
Number of Channels .....	4
Power Source.....	CFx, lithium - carbon monofluoride

## Handling

Storage Conditions: -10°C - 50°C (14°F - 122°F)

Storage 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

Programmed settings impact the longevity of the implanted device. With 2 leads at 1600 ohms impedance programmed at nominal stimulation settings of 800  $\mu$ A amplitude, 300  $\mu$ sec pulse width, 20 Hz frequency, the battery may be expected to last 3.3 years. These nominal settings represent average settings seen in world-wide use of the Axium system. Higher stimulation settings, especially pulse amplitude and frequency, result in greater energy usage and therefore reduce the estimated battery longevity.

The system has two warnings about battery life – ERI which is Elective Replacement Indication when the battery is low but stimulation is still available, and EOS which is End of Service when stimulation has been permanently turned off. At nominal settings, there is a 1 month period between ERI and EOS. Depending on specific settings, the duration may range between 20 and 35 days.

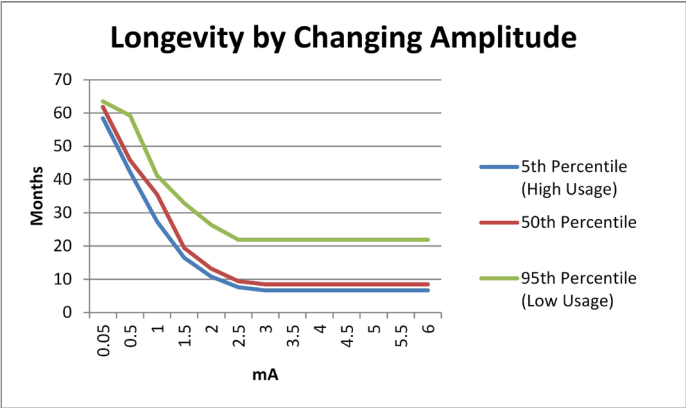
The table below includes patient settings used in the US ACCURATE Clinical Study. The 5th percentile, 50th percentile, and 95th percentile patients were selected based on estimated longevity. The Low Settings example shows the effect of reducing amplitude and frequency.

Patient Settings used in the US ACCURATE Clinical Study						
Patient	Amplitude ( $\mu$ A)	Pulse Width ( $\mu$ sec)	Frequency (Hz)	Impedance (ohms)	Leads	Estimated Longevity (Years)
5th Percentile	2750	410	20	1609	2	0.9
	1350	300	34	1796		
50th Percentile	675	1000	16	1727	1	3.5
95th Percentile	500	160	20	1886	1	4.9
Low Settings	650	110	10	1140	2	5.0
	350	230	10	1968		

The number of leads is not directly proportional to longevity, but on average the longevity decreases as multiple leads are added. The summation of energy delivered through the leads is the primary factor for longevity. Note that both the 0.9 year and the 5.0 year patients have two leads, but the 0.9 year patient is programmed with higher energy settings of 2.75 mA amplitude and 34 Hz frequency compared to the 5.0 year patient's lower energy settings of 350  $\mu$ A amplitude and 10 Hz frequency.

Impact of programmed amplitude on battery longevity

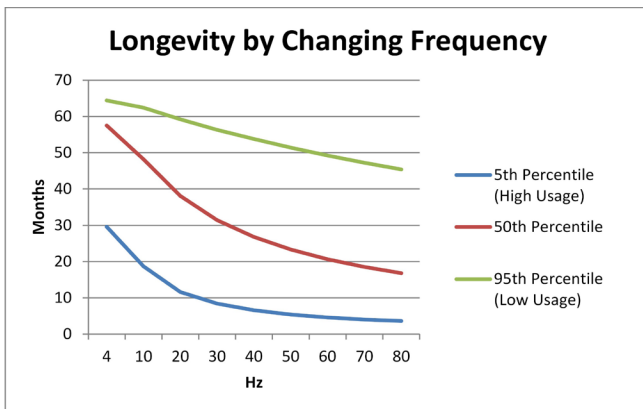
Modifying programmed amplitude can impact the longevity of an implanted device. The graph below depicts expected battery longevity for the percentile patients listed above. The patient's pulse width and frequency settings are kept fixed, and the Amplitude setting is varied across the X-axis for all leads. Longevity ranges from 5.3 years to 7 months, depending on the programmed amplitudes for the leads. Note: When the INS reaches maximum output, the expected longevity plateaus.





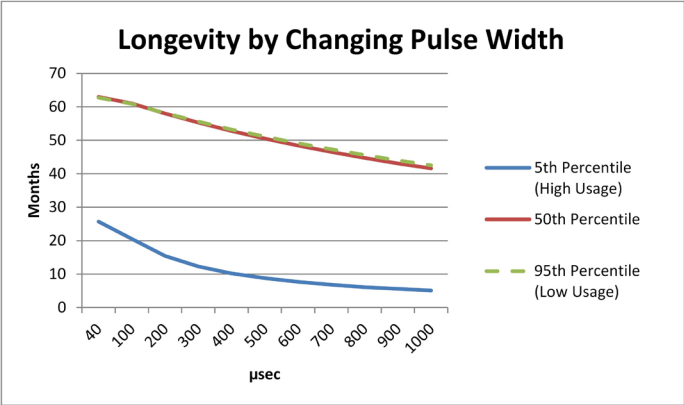
## Impact of programmed frequency on battery longevity

Modifying programmed frequency can also impact the longevity of an implanted device. The graph below depicts expected battery longevity for the chosen percentile patients above. The patient's pulse width and amplitude settings are kept fixed, and the Frequency setting is varied across the X-axis for all leads. Longevity ranges from 5.4 years to 4 months, depending on the programmed frequencies for the leads.



### Impact of programmed pulse width on battery longevity

Modifying programmed pulse width can impact the longevity of an implanted device. The graph below depicts expected battery longevity for the selected percentile patients. The patient's amplitude and frequency settings are kept fixed, and the Pulse Width setting is varied across the X-axis for all leads. Longevity ranges from 5.3 years to 5 months, depending on the programmed pulse widths for the leads. Note: The amplitude and frequency settings are very similar for the 50th and 95th percentile patients, so the lines overlap each other.



## Manufacturer Statements

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.



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