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Precision™ Spinal Cord Stimulator System Clinician Manual

Directions for Use

Rx ONLY

CAUTION: Federal law restricts this device to sale,
distribution and use by or on the order of a physician.

91083273-01 REVA

Guarantees

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Additional Information

For device-specific information not included in this manual, see the appropriate *Directions for Use* as listed in the *Reference Guide*.

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Manual Overview

This manual provides basic information for the trial, implantation, and operation of the Boston Scientific Precision Spinal Cord Stimulator (SCS) system.

General surgical guidelines are presented in this manual for temporary and permanent implantation of Boston Scientific percutaneous leads, lead extensions, splitters, surgical paddle leads, and implantable pulse generator (IPG). These products are designed to aid in the management of chronic intractable pain.

This manual also provides an overview of accessories for programming and charging the IPG, clinical and surgical considerations, storage and handling requirements, and relevant precautions concerning an implanted neurostimulator. Additional information on system components and operation can be found in the Bionic Navigator™ Software Guide.

Device and Product Description

The Precision system consists of an implantable pulse generator, temporary and permanent percutaneous leads, surgical paddle leads, and lead extensions, each packaged as a separate kit. Single use accessories and disposable tools are also included in these kits.

Features of the Precision SCS System include:

- Stimulation electrode field navigation
- Sixteen independent current-controlled electrodes
- Four programmable stimulation areas per program; four possible programs
- Long-life operation
- High-range parameter capability
- Small size
- Two-foot programming range
- This product contains no detectable latex

Implantable Pulse Generator

The Precision Implantable Pulse Generator (IPG) system is intended to treat chronic pain by electrically stimulating the spinal cord. The multi-channel, multi-electrode device capability provides flexibility in conjunction with ease of programming. A rechargeable battery increases IPG longevity and output capability while reducing size and device replacement surgeries. The IPG is controlled by a handheld Remote Control, and can be engaged by a clinician computer using proprietary Bionic Navigator software. Periodically, the IPG battery requires replenishing with an RF charging device provided separately in the Patient Charging Kit.

Leads

The percutaneous and surgical paddle leads function as a component of the Precision SCS system by delivering electrical stimulation to the nerve structures in the dorsal aspect of the spinal cord, resulting in an inhibition of pain sensation.

Surgical Paddle Lead

The 2x8 Surgical Paddle Lead is available in lengths of 50 cm and 70 cm. The distal (paddle) end of the lead has two columns of eight evenly spaced planar electrodes. Each electrode is 3x2 mm² in area. On the proximal side, this lead employs 2 lead tails. The end of each tail has eight evenly spaced contacts, identical to the percutaneous leads. The right tail of the Paddle Lead is laser-etched to allow for ease of right and left identification. Each tail can be inserted into an IPG or into a lead extension.

Percutaneous Leads

The eight-contact percutaneous leads are available in lengths of 30 cm, 50 cm, and 70 cm. Each lead has eight electrode contacts located near the distal end. Each contact is 3 mm in length and is spaced 1, 4, or 6 mm from the adjacent contact. The 16 contact percutaneous lead (Infinion™ 16 Lead and Infinion CX Lead) is available in lengths of 50 cm and 70 cm. Each lead has 16 contacts located near the distal end. Each contact is 3 mm in length and is spaced 1 mm from the adjacent contact. The Infinion 16 lead must be inserted into a Splitter 2x8 which then connects to a Precision IPG's 8 contact ports or 8 contact OR Cables.

Lead Extension

Lead Extensions are designed to connect the percutaneous and paddle leads to the Precision IPG for spinal cord stimulation. The extension may be added to a lead to externalize the lead for a trial procedure or to extend the lead when a permanent IPG is implanted.

Lead extensions are available in lengths of 25 cm, 35 cm, and 55 cm. Each extension has eight electrode contacts located near the distal end. Each contact is 3 mm in length and is spaced 1 mm from the adjacent contact. The extension can be connected to either the Trial Stimulator (via an OR Cable Assembly included in the Leads Kit) or directly to the Precision IPG.

Lead Splitter

The 2x4 Splitters are designed to connect multiple percutaneous leads to the Precision IPG. The Linear leads may be inserted into a splitter for a maximum of four Linear leads per IPG. Four of the eight contacts of each Linear lead will be activated. Two configurations of 2x4 splitters are available: Distal 4 (D4) and Wide 4 (W4). The two versions offer different contact configurations.

The Lead Splitter 2x8 is required to connect the Infinion 16 contact lead to the IPG. Only one Infinion 16 lead through one Splitter 2x8 can be connected to a Precision IPG.

Indications for Use

The Boston Scientific PRECISION Spinal Cord Stimulator System (PRECISION System) is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Precision System Clinical Summary

Determination of the safety and effectiveness of the PRECISION System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The PRECISION System is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the PRECISION System for the treatment chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to support the effectiveness of the PRECISION System (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was depicted from the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, a totally implantable spinal cord stimulator was used in association with a percutaneous and/or surgical lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the PRECISION System.

The prospective study by Ohnmeiss et al. 1996, examined the long-term effectiveness of SCS in patients with intractable leg pain. Forty patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP (Sickness Impact Profile), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had greater than 50% improvement in pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study performed by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In this study, 27/41 patients, 66%, had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%), reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, one patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure.

Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis performed by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. Five patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were 4 (10%) patients who underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" 16/26 patients (62%) had greater than 50% pain relief with SCS. In this study, 2/16 (13%) had greater than 50% pain relief with opioids. Mean follow-up was 2.1 ± 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Eleven studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the PRECISION System. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. The table below depicts the number of patients, the number of events, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that citations cover both IPG and RF systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

Table 1: Summary of Risks Identified in the Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%
Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain Over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Clinical Experience-Safety

Clinical data has been collected during a clinical study of the PRECISION System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the PRECISION System. The follow-up period for the 26 implanted patients ranged from 2 weeks to 6 months. The following major adverse events were reported.

Table 2: Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced
Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

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Contraindications

Patients contraindicated for permanent SCS therapy are those who:

- are unable to operate the SCS system
- have failed trial stimulation by failing to receive effective pain relief
- are poor surgical risks
- are pregnant

Safety Information

Instructions for the Patient

Warnings

Heat Due to Charging. Do not charge while sleeping. This may result in a burn. While charging, the Charger may become warm. It should be handled with care. Failure to use the Charger with either the Charging Belt or an adhesive patch, as shown, may result in a burn. If you experience pain or discomfort, cease charging and contact Boston Scientific.

Magnetic Resonance Imaging (MRI). Patients implanted with the Precision SCS system should not be subjected to MRI. MRI exposure may result in dislodgement of implanted components, heating of the neurostimulator, damage to the device electronics and/or voltage induction through the leads and Stimulator causing an uncomfortable or “jolting” sensation.

Pediatric Use. The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on SCS patients. The energy generated by diathermy can be transferred through the Stimulator system, causing tissue damage at the lead site and resulting in severe injury or death. The IPG, whether it is turned on or off, may be damaged.

Implanted Stimulation Devices. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators. The effects of implanted stimulation devices on neurostimulators is unknown.

Stimulator Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals. Do not implant the device if the case is damaged.

Postural Changes. Patients should be advised that changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Patients should be advised to turn down the amplitude or turn off the IPG before making posture changes. If unpleasant sensations occur, the IPG should be turned off immediately.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, or cause uncomfortable or jolting stimulation. Patients should be counseled to avoid or exercise care around:

- Theft detectors or security screeners such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices. It is recommended that patients request assistance to bypass the device. If they must proceed through the device, the patient should turn off the Stimulator and proceed with caution, ensuring to move through the center of the screener as quickly as possible.
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers

Precautions

Physician training is required.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the Stimulator, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery: Do not use monopolar cautery. See “Instructions for the Physician” on page 11
- external defibrillation

- radiation therapy
- ultrasonic scanning
- high-output ultrasound

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 11 . Ultimately, however, the device may require explantation as a result of damage to the device.

Automobiles and Other Equipment. Patients should not operate automobiles, other motorized vehicles, or potentially dangerous machinery/ equipment with therapeutic stimulation switched on. Stimulation must be turned off first. Sudden stimulation changes, if they occur, may distract patients from attentive operation of the vehicle or equipment.

Post Operative. During the two weeks following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions:

- Do not lift objects of more than five pounds.
- Do not engage in rigorous physical activity such as twisting, bending, or climbing.
- If new leads were implanted, do not raise your arms above your head.

Temporarily, there may be some pain in the area of the implant as the incisions heal. If discomfort continues beyond two weeks, contact your physician.

If you notice excessive redness around the wound areas during this time, contact your physician to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Be sure to consult your physician before making lifestyle changes due to decreases in pain.

Stimulator Location. Never attempt to change the orientation or “flip” the Stimulator. Do not “finger” or play with the Stimulator. If the Stimulator flips over in your body, it cannot be charged. If you know that the device has turned, or if stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system. In some cases, the skin over your Stimulator may become very thin over time. If this occurs, contact your physician.

Lead Location. In some instances a lead can move from its original location, and stimulation at the intended pain site can be lost. If this occurs, consult your physician who may be able to restore stimulation by reprogramming the Stimulator in the clinic or repositioning the lead during another operation.

Device Failure. Stimulators can fail at any time due to random component failure, loss of battery functionality, or lead breakage. If the device stops working even after complete charging (up to four hours), turn off the Stimulator and contact your physician so that the system can be evaluated.

Storage, Handling and Transport. Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. **For proper operation, do not use the Charger if the ambient temperature is above 35 °C (95 °F).**

If the Remote Control or the Charging System is to be stored for a period of time without batteries, the storage temperature should not exceed -20 to 60 °C (-4 to 140 °F).

Handle the system components and accessories with care. Do not drop them or submerge them in water. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. (See “Limited Warranty - IPG” on page 65.)

Component Disposal. Do not dispose of the Remote Control or Charger in fire. The battery in these devices can explode in fire. Dispose of used batteries in accordance with local regulations. The IPG should be explanted in the case of cremation, and returned to Boston Scientific. External devices to be disposed of per local regulatory requirements. Please contact your healthcare professional.

Remote Control, Charging System Cleaning. The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning.

Cell Phones. While we do not anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time. If there is a concern or a problem is encountered, the physician should be contacted.

Adverse Effects

Potential risks are involved with any surgery. The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur. In some cases, the formation of reactive tissue around the lead in the epidural space can result in delayed onset of spinal cord compression and neurological/sensory deficit, including paralysis. Time to onset is variable, possibly ranging from weeks to years after implant.
- Skin erosion at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, lead dislodgement.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, the Stimulator may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

In any event, instruct the patient to contact their physician to inform him/her.

Instructions for the Physician

Implanted Stimulation Devices. If such implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies.

Postural Changes. Depending on the activity level of the patient, postural changes may affect stimulation intensity. Instruct patients to keep the Remote Control on hand at all times, and ensure that they understand how to adjust stimulation levels.

Medical Devices/Therapies. If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, or high-output ultrasound:

- Turn off stimulation at least five minutes before the procedure or application.

- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.
- Bipolar electrocautery is recommended. Do not use monopolar electrocautery.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.

Package Contents

IPG Kit

- (1) Precision Implantable Pulse Generator
- (1) Hex Wrench
- (1) Tunneling Tool Assembly
- (1) IPG Pocket Template
- (2) Port Plugs
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Manual

Percutaneous Permanent Lead Kit

- (1) Percutaneous Lead with pre-loaded Curved Stylet
- (1) Stylet Ring with a Curved and a Straight Stylet
- (4) Suture Sleeves
- (1) Insertion Needle with Stylet
- (1) Lead Blank
- (1) Steering Cap
- (1) OR Cable Assembly
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Manual

Percutaneous Trial Lead Kit

- (1) Percutaneous Lead with pre-loaded Curved Stylet
- (1) Suture Sleeve
- (1) Insertion Needle with Stylet
- (1) Steering Cap
- (1) OR Cable Assembly
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Manual
- (1) Device Registration Form/Temporary Patient Identification Card

Lead Extension Kit

- (1) Lead Extension
- (1) Hex Wrench
- (1) Tunneling Tool Assembly
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Manual

2x4 Splitter Kit

- (1) Splitter
- (1) Hex wrench
- (1) Manual and Insert
- (1) Device Registration Form/Temporary Patient Identification Card

Surgical Paddle Lead Kit

- (1) Paddle Lead
- (4) Suture Sleeves
- (2) OR Cable Assemblies
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Manual

Infinion 16 Lead Kit

- (1) 16 Contact Lead with pre-loaded Curved Stylet
- (1) Stylet Ring with a Curved and a Straight Stylet
- (1) Straight Stylet
- (4) Suture Sleeves
- (1) Insertion Needle
- (1) Lead blank
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Manual
- (1) Product Registration Form/Temporary Patient Identification Card
- (1) Steering Cap

Infinion 16 Trial Lead Kit

- (1) 16 Contact Percutaneous Lead with pre-loaded Curved Stylet
- (1) Suture Sleeve
- (1) Insertion Needle
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Manual
- (1) Product Registration Form/Temporary Patient Identification Card
- (1) Steering Cap

Infinion CX Lead Kit

- (1) 16 Contact Percutaneous Infinion CX Lead with pre-loaded Curved Stylet
- (2) Suture Sleeves
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Manual
- (1) Product Registration Form/Temporary Patient Identification Card
- (1) Steering Cap

Infinion CX Lead Trial Lead Kit

- (1) 16 Contact Percutaneous Infinion CX Lead with pre-loaded Curved Stylet
- (2) Suture Sleeves
- (2) Lead Position Labels—left and right (non-sterile)
- (1) Manual
- (1) Product Registration Form/Temporary Patient Identification Card
- (1) Steering Cap

Splitter 2x8 Kit

- (1) Splitter 2x8
- (1) Torque Wrench
- (1) Manual
- (1) Product Registration Form/Temporary Patient Identification Card

Infinion 16 Trial Configuration Kit

- (1) Infinion™ 16 Trial Lead Kit
- (1) 2x8 Splitter Kit

Infinion 16 Configuration Kit

- (1) Infinion™ 16 Lead Kit
- (1) 2x8 Splitter Kit

Sterilization, Handling, and Storage

Sterilization

All Precision system implantable and surgical components are sterilized with ethylene oxide.

Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.

- Do not use any component that shows signs of damage.
- Do not resterilize the package or the contents. Obtain a sterile package from Boston Scientific.
- Do not use the product if the labeled "Use By" date has passed.
- All components are for single use only. Do not reuse.
- Do not use if package is opened or damaged
- Do not use if labeling is incomplete or illegible.

WARNING: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.



For Single Use Only.
Do Not Reuse.



Do Not Resterilize.



Do not use if package is damaged.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

IPG Handling and Storage

- Handle the IPG and all components with care.
- Keep sharp instruments away from the components.
- Do not use the IPG if it has been dropped on a hard surface from a height of more than one foot.
- Do not incinerate an IPG. Improper disposal of the device could result in an explosion. Devices should be explanted in the case of cremation, and returned to Boston Scientific Neuromodulation. An explant kit is available.

Store the IPG between 0 °C and 45 °C (32 °F and 113 °F). Devices should always be kept in temperature regulated areas within the acceptable temperature range. IPG damage can occur at temperatures outside of this range.

Lead, Lead Extension, and Splitter Handling and Storage

- Avoid damaging the lead with sharp instruments or excessive force during surgery.
- Do not sharply bend or kink the lead, extension, or splitter.
- Do not tie suture(s) directly to the lead, extension, or splitter body; use the provided suture sleeves.
- For the Percutaneous Leads - avoid forcing the lead into the epidural space by carefully clearing a path using the lead blank.
- Avoid pulling an implanted lead taut; provide a stress relief loop at the insertion site to minimize tension on the lead.
- Avoid handling the lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments such as hemostats or scalpels to prevent damaging the lead.
- Wipe off any body fluids from the lead connector end before connecting it to any other component. Fluid contamination of these connections could compromise the integrity of the stimulation circuit.
- Wipe off any body fluids from the lead stylet before inserting or reinserting it into the lead.

Store components between 0 °C and 45 °C (32 °F and 113 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage.

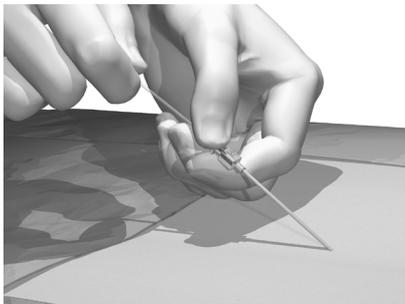
Pre-Op Instructions

1. Ensure that the IPG is fully charged prior to the permanent implant procedure. The approximate location of the IPG is marked on the IPG kit. Turn on the Charger and place it over the IPG to begin charging.
2. Check that the sterile package is intact. (See “Sterilization, Handling, and Storage” on page 16.)
3. Ensure that a Trial Stimulator is available for use. Install a new battery in the Trial Stimulator.
4. Be sure the Trial Stimulator and Remote Control stimulation settings have been reset. (See “Device Linking” on page 53.)
5. For trial procedures, ensure that a Patient Trial Kit is available, proceed to “Percutaneous Lead Placement in the Epidural Space” on page 19.
6. For permanent IPG implantation, proceed to “Removal of Trial Leads, Extensions, and Splitters” on page 40.

Percutaneous Lead Placement in the Epidural Space

Note: If using an Infinion™ CX Lead, proceed to “Infinion CX Lead Placement in the Epidural Space with Entrada™ Needle” on page 20

1. Position, prep and drape the patient in the usual accepted manner. Inject a local anesthetic at the needle insertion site.
2. Under fluoroscopic guidance, place the insertion needle into the epidural space with the bevel facing up using an angle of 45° or less.



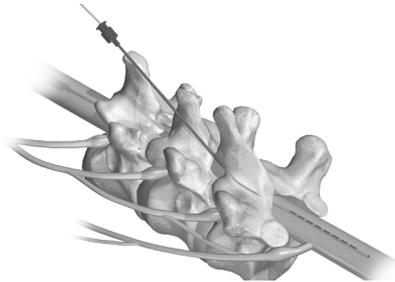
CAUTION: Use only an insertion needle provided by Boston Scientific. Other needles may damage the lead. The stamped number “14” on the needle hub (or the triangle on the hub of the curved Epimed needle, sold separately) corresponds to the orientation of the bevel, which must face up. Turning the bevel ventral (down) may result in lead damage. An angle of more than 45° increases the risk of lead damage.

WARNING: The angle of the insertion needle should be 45° or less. Steep angles increase the insertion force of the stylet and also present more of an opportunity for the stylet to pierce the lead and cause tissue damage.

3. Remove the needle stylet from the insertion needle and verify entry into the epidural space using the standard technique.
4. OPTIONAL. Under fluoroscopic guidance, insert the lead blank through the insertion needle and into the epidural space. Advance the lead blank to verify entry into the epidural space, then withdraw the blank.
5. While holding the lead stylet handle, place the steering cap over the proximal end of the stylet handle with moderate force until it is held in place. Then slowly insert the lead, with stylet, through the insertion needle. The lead stylet should extend to the tip of the lead.
6. OPTIONAL. If exchange of the lead stylet is desired, carefully pull out the existing stylet and insert the preferred stylet. While inserting the stylet into the lead, if resistance is encountered, withdraw the stylet approximately 3 cm, rotate the lead and/or stylet, and gently advance the stylet. If resistance is still encountered, repeat the above procedure until the stylet can be fully inserted.

WARNING: Do not exchange the lead stylet while the electrode array of the lead is in the bevel of the insertion needle. If the electrode array is in the bevel area, remove the lead from the insertion needle before exchanging the stylet. Inserting the lead stylet in the lead while the electrode array is in the bevel of the insertion needle increases the risk of lead and tissue damage.

WARNING: If the lead stylet is removed and reinserted, do not use excessive force when inserting the stylet into the lead. The use of instruments, such as forceps, to grasp the stylet during insertion is not recommended as this could result in applying excessive force and could increase the risk of lead and tissue damage.



7. Advance the lead to the appropriate vertebral level under fluoroscopic guidance. A sufficient length of lead (i.e., at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in lead stabilization.
8. If use of a splitter is desired or you are using the Infinion™ 16 lead, continue to “Lead Connection to Splitter” on page 25. Otherwise, continue to “Connecting the OR Cable Assembly” on page 29.

Infinion CX Lead Placement in the Epidural Space with Entrada™ Needle

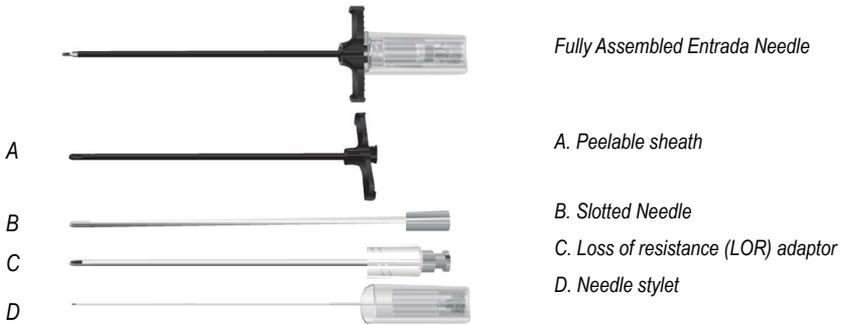
Infinion CX Lead



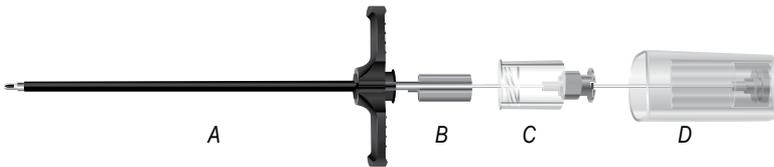
The Infinion CX Lead has two tails to enable insertion into 8-contact IPG ports without the use of a Splitter 2x8. The two tails will not fit through a standard 14 gauge insertion needle or Epimed needle, therefore these needles are not compatible with the Infinion CX Lead. **Do not use a standard 14 gauge introducer or Epimed needle to introduce the Infinion CX Lead.**

An Entrada Needle with peelable sheath is required to introduce the Infinion CX Lead into the epidural space and may be used with all percutaneous leads. Also, an anchor must be pre-loaded on the distal end of the Infinion CX Lead prior to inserting the lead into the Entrada Needle. For the Infinion CX Lead, the stylet may be in place within the lead when an anchor is loaded on the lead. Ensure that stylet is removed from the lead prior to locking the anchor.

Entrada™ Needle



Entrada Needle Assembly



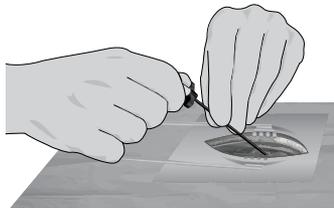
- A. Peelable Sheath
- B. Slotted needle inserts into sheath
- C. Insert LOR adaptor into slotted needle and lock on peelable sheath by turning clockwise
- D. Insert needle stylet into LOR adaptor and advance forward until fully seated into needle assembly.

1. Position, prep and drape the patient in the usual accepted manner. Inject a local anesthetic at the needle insertion site.

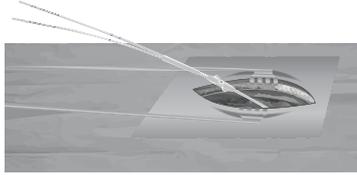
2. Verify that the Luer lock collar of the LOR adaptor is locked on the peelable sheath and that the needle stylet is fully inserted into the LOR adaptor hub before inserting the needle. To do so:
 - A. Pull back the stylet cap to expose the clear LOR adaptor hub.
 - B. Apply forward force to the LOR adaptor hub and rotate clockwise to fully engage onto the sheath luer connection.
 - C. Straighten metal hub of LOR adaptor so that notch is facing up.
 - D. Straighten the stylet cap with flat side facing up and advance forward to fully seat into the needle assembly.



3. Recommended for permanent or permanent-trial procedures: Cut down prior to inserting the Entrada Needle and insert needle into incision. Creating the incision before inserting the Entrada Needle provides a clear path for sliding the anchor into the incision.



Insert Entrada Needle using an angle of 45 degrees or less



- Under fluoroscopic guidance, place the Entrada™ Needle into the epidural space with the stylet cap flat side facing up using an angle of 45° or less.

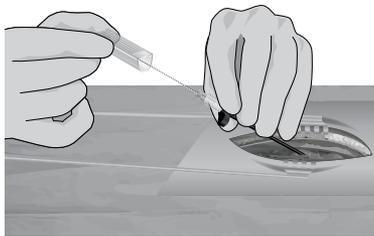
CAUTION: Use only an Entrada Needle provided by Boston Scientific. Other needles may damage the lead. Turning the bevel ventral (down) may result in lead damage. An angle of more than 45° increases the risk of lead damage.

WARNING: The angle of the insertion needle should be 45° or less. Steep angles increase the insertion force of the stylet and also present more of an opportunity for the stylet to pierce the lead and cause tissue damage.

- Remove the needle stylet from the insertion needle and verify entry into the epidural space using the standard technique.

Note: Hold onto sheath wings when attaching syringe to LOR needle.

Note: Maintain positive pressure on the needle while performing LOR.



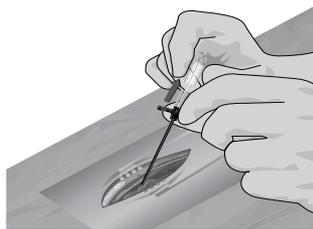
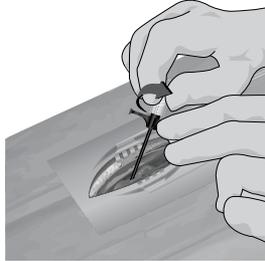
Remove needle stylet



Verify entry into the epidural space

- OPTIONAL. Under fluoroscopic guidance, insert the lead blank through the LOR adaptor and into the epidural space. Advance the lead blank to verify entry into the epidural space, then withdraw the blank

7. The LOR adaptor must be removed prior to inserting lead. Unscrew Luer lock collar and remove LOR adaptor assembly from sheath while holding slotted needle in place.



Note: An anchor must be loaded over the distal end of the Infinion™ CX Lead prior to inserting the lead into the Entrada™ Needle



8. While holding the lead stylet handle, place the steering cap over the proximal end of the stylet handle with moderate force until it is held in place. The lead stylet should extend to the tip of the lead. Slowly insert the Infinion CX Lead into the slotted needle, directing the distal lead tip into the needle lumen.



9. OPTIONAL. If exchange of the lead stylet is desired, carefully pull out the existing stylet and insert the

preferred stylet. The stylet must be inserted into the Infinion CX Lead tail with one marker band. While inserting the stylet into the lead, if resistance is encountered, withdraw the stylet approximately 3 cm, rotate the lead and/or stylet, and gently advance the stylet. If resistance is still encountered, repeat the above procedure until the stylet can be fully inserted.



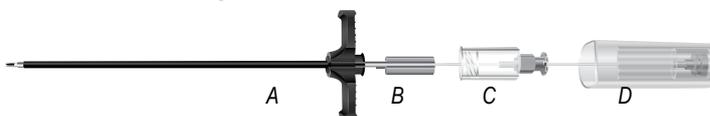
The stylet must be inserted into the Infinion CX Lead tail with one marker band

WARNING: Do not exchange the lead stylet while the electrode array of the lead is in the bevel of the insertion needle. If the electrode array is in the bevel area, remove the lead from the insertion needle before exchanging the stylet. Inserting the lead stylet in the lead while the electrode array is in the bevel of the insertion needle increases the risk of lead and tissue damage.

WARNING: If the lead stylet is removed and reinserted, do not use excessive force when inserting the stylet into the lead. The use of instruments, such as forceps, to grasp the stylet during insertion is not recommended as this could result in applying excessive force and could increase the risk of lead and tissue damage.

10. Advance the lead to the appropriate vertebral level under fluoroscopic guidance. A sufficient length of lead (i.e., at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in lead stabilization.
11. If the needle must be repositioned during the procedure, or if inserting a second Infinion™ CX Lead through the same Entrada™ Needle with a new sheath, re-assemble needle outside of the body.

Reassemble Entrada Needle using new sheath



- A. Sheath
- B. Insert slotted needle into new sheath
- C. Insert LOR adaptor into slotted needle and lock on peelable sheath by turning clockwise
- D. Insert needle stylet into LOR adaptor and advance forward until fully seated into needle assembly.

CAUTION: Do not reinsert the needle stylet, LOR adaptor, or slotted needle into the sheath while the sheath is inserted within the patient.

12. Proceed with needle insertion and lead placement
13. Continue to “Connecting the OR Cable Assembly” on page 29

Lead Connection to Splitter

1. Carefully withdraw the stylets from the leads to be inserted into the splitter.

2. Wipe clean the proximal connector ends of the leads.
3. Select the desired splitter model.

Note: A Splitter 2x8 must be used when implanting the Infinion™ 16 lead.

4. Check that the lead connector end can be easily inserted into the splitter without obstruction. If obstruction is encountered, loosen the set screws of the splitter by using the hex wrench provided, turning counterclockwise.

Note: • The set screw should only be loosened to an amount sufficient to insert a lead.

- Do not excessively loosen the set screw. This may cause the set screw to dislodge rendering the splitter unusable.

5. Insert proximal connector ends of desired leads into splitter receptacles until they are fully seated – each lead bottoms out in receptacles and retention sleeves (long ring) are under the setscrew blocks of the splitter receptacles. Do not tighten set screw at this time.
6. Continue to “Connecting the OR Cable Assembly” on page 29, then proceed to step 7 below.
7. Check connections with an impedance measurement. If the impedance is satisfactory, proceed to “Intraoperative Stimulation Testing” on page 30 to confirm proper lead location.

Note: Do not tighten set screw mechanical lock before intra-operative stimulation testing.

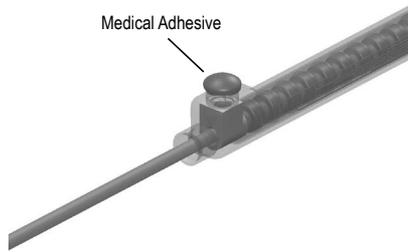
Note: On the 2x4 Splitter, the shorter splitter receptacle corresponds to contacts 1-4, while the longer receptacle corresponds to contacts 5-8. Make note of which lead is connected to each splitter receptacle.

Note: On the Splitter 2x8, one tail is laser-marked with bands, and corresponds to contacts 1-8 on the Infinion 16 percutaneous lead; the unmarked tail corresponds to contacts 9-16.



8. If lead repositioning is required, disconnect the splitter and reinsert the stylet before advancing the lead. Repeat steps 5 to 7 until satisfactory lead position is achieved.

9. Use the hex wrench supplied to tighten down the setscrews until the wrench clicks.



10. If using the Splitter 2x8, prior to closing the wound, clean the top of the splitter set-screw seal plug and use silicone medical adhesive (e.g. Dow Corning Silastic® Medical Adhesive Silicone, Type A - Sterile, as available from Boston Scientific, part number SC-4320) to coat and seal the top of the seal plug that has been penetrated by the hex wrench.

Note: *Inadvertent damage to the septum seal may lead to unintended stimulation at the Splitter 2x8 if the Medical Adhesive is not used as intended.*

11. Proceed to “Connecting to the Trial Stimulator” on page 39 or “Connecting to the IPG” on page 42.

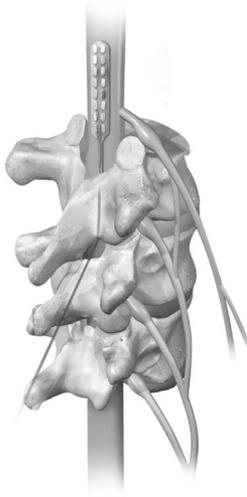
Surgical Paddle Lead Placement in the Epidural Space

1. Determine the appropriate vertebral level for lead placement using fluoroscopic guidance.
2. Position, prep and drape the patient in the usual accepted manner.
3. OPTIONAL Prior to introduction of the Paddle Lead into the epidural space, a Passing Elevator may be used. Passing Elevators are designed to help verify that the epidural space is cleared for placement of the Paddle Lead.

Grasp the curved area of the Passing Elevator with your fingertips. While avoiding pressure on the thecal sac and spinal cord, carefully and gently introduce the Passing Elevator at a shallow angle into the epidural space along the midline. When the Passing Elevator reaches the target site for the lead, gently remove the elevator.

CAUTION: Do not use the Passing Elevator to clear scar tissue or open up a narrow spinal canal. Exerting excessive force may cause patient injury or breakage of the Passing Elevator.

4. Use the standard technique to introduce the Paddle Lead into the epidural space, visually ensuring that the contacts are facing down towards the dura.
5. Advance the lead to the desired location.



Once the Paddle Lead is at the appropriate vertebral level, proceed to the instructions for “Connecting the OR Cable Assembly” on page 29.

Connecting the OR Cable Assembly

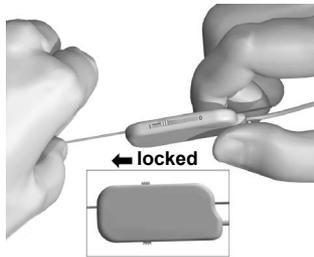
The OR cable assembly is designed for temporary connection of a lead to the Trial Stimulator. A cable extension is provided. When using a Splitter 2x8 prepare two OR Cable Assemblies.

CAUTION: Do not immerse the OR cable connector or plug in water or other liquids. The OR Cable Assembly is intended for one-time only use; do not resterilize.

1. If two leads are being implanted, wrap the non-sterile “1-L” and “2-R” labels around the cables at the Trial Stimulator to identify lead connections.
2. Verify that the Trial Stimulator is off.

CAUTION: Always turn the Trial Stimulator off before connecting or disconnecting the cable assemblies.

3. Check that the locking lever on the OR cable connector is in the open position, marked “0”.
4. For Percutaneous Leads, remove the steering cap from the stylet and slide the proximal end of the lead with stylet, or splitter, into the open port on the OR cable connector.
5. Push the end of the lead or splitter into the port until it stops. Hold the lead in place while sliding the lever to the locked position, marked “1”.



6. Plug the OR Cable Assembly into the corresponding Trial Stimulator port(s) labeled “1-L” (left) and “2-R” (right).



Superior (upper or left) leads connect to port “1-L”. Inferior (lower or right) leads connect to port “2-R”. If only a single lead is being used, connect it to “1-L”.

Note: If using a Splitter 2x8, connect the cable labeled “1-L” to the laser-marked tail, and the cable labeled “2-R” to the unmarked tail. If using an Infinion CX lead, connect the cable labeled “1-L” to the tail with one marker band, and the cable labeled “2-R” to tails with two marker bands.

7. Proceed to the instructions for “Intraoperative Stimulation Testing” on page 30.

Intraoperative Stimulation Testing

Note: *The following steps are for procedural reference only. Please refer to the BionicNavigator Software Guide for detailed stimulation testing procedures and guidelines.*

1. If using a splitter:
 - Visually check splitter to leads connection
 - Check impedance

Note: *If using the 2x4 Splitter, make note of splitter configuration in the BionicNavigator™ software per Splitter Programming Guide.*

2. After linking the Clinician Programmer to the Trial Stimulator, check impedances to verify that components are properly connected. Lead impedance is measured and displayed for each of the IPG's 16 electrode contacts. Impedances over 4500 Ohms are considered to be resultant from open or unconnected wires, displayed with an X.
3. Using test stimulation, enlist patient feedback to verify lead placement and pain coverage.

Note: *If lead repositioning is necessary, turn stimulation off before proceeding.*

4. Reposition leads as necessary. If using a splitter, gently pull on lead attached to splitter to reposition caudad or disconnect splitter from leads, re-insert stylet, and advance leads to reposition cephalad.

CAUTION: *Do not force stylet into lead.*

5. Steer lead to new position.
6. Remove stylet, wipe proximal ends of leads and reconnect splitter.
7. Check impedances.
8. Repeat steps 1-3 if lead has been repositioned.
9. When the desired paresthesia is achieved:
 - A. Turn the Trial Stimulator off.
 - B. Unlock each OR cable connector and disconnect from the lead(s).
 - C. For percutaneous lead(s) - slowly withdraw the stylet(s).
10. Record the lead position by capturing a fluoroscopic image to be sure the leads have not moved. Retest if necessary.
11. If using a splitter, disconnect splitter from leads. Insert the hex wrench and turn the set screw counter clockwise to loosen.

Note: • *The set screw should only be loosened to an amount sufficient to insert a lead.*

- *Do not excessively loosen the set screw. This may cause the set screw to dislodge, rendering the splitter unusable.*

Option A: For a Temporary Trial, proceed to "Securing the Trial Lead" on page 31.

Option B: For a Permanent Trial, proceed to "Permanent Lead Anchoring and Tunneling" on page 33.

Option C: For a Permanent IPG Implantation using percutaneous leads, proceed to "Permanent Lead Anchoring and Tunneling" on page 33.

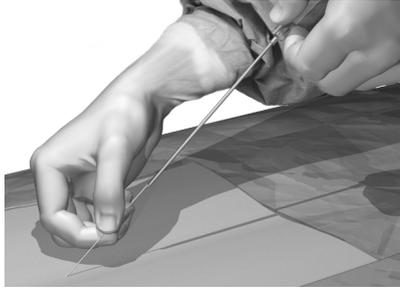
Option D: For a Permanent IPG Implantation using paddle leads, proceed to "Anchoring the Lead" on page 34.

Before receiving a permanent SCS system, it is recommended that patients undergo a trial procedure so that they can experience stimulation to evaluate if SCS is effective at treating their chronic pain.

Securing the Trial Lead

Note: If using an Infinion CX lead, proceed to “Securing the Infinion CX Trial Lead” on page 32.

1. Carefully withdraw the insertion needle from the epidural space by slowly pulling the needle up towards the proximal end of the lead while holding the lead in place.
2. Once the insertion needle tip is exposed, hold the lead as close to the percutaneous exit site as possible, then carefully pull the needle completely from the lead.



3. If desired, a suture may be used to close the wound and stabilize the lead.
4. Place and tape a stress relief loop and dress the wound.
5. If using a splitter continue to “Lead Connection to Splitter” on page 25.
6. Continue with “Connecting to the Trial Stimulator” on page 39.

Securing the Infinion CX Trial Lead

1. Carefully withdraw the slotted needle by slowly pulling the needle towards the proximal end of the lead while stabilizing lead in line with the slot to keep lead in place.

Note: *Do not reinsert the slotted needle into the sheath while the sheath is within the body.*

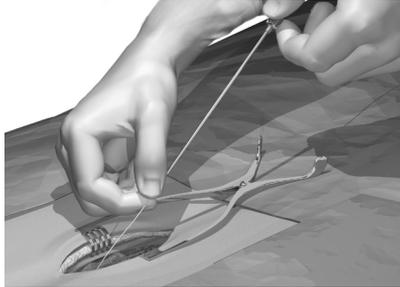
2. Snap sheath wings apart and peel sheath out of insertion site.
3. Remove the stylet from the lead
4. If desired, a suture may be used to close the wound and stabilize the lead.
5. Place and tape a stress relief loop and dress the wound.
6. Continue to “Connecting to the Trial Stimulator” on page 39.

Permanent Lead Anchoring and Tunneling

Removing the Insertion Needle

Note: *If using an Entrada Needle, proceed to “Removing the Entrada Needle”*

1. Cut down around the insertion needle to provide access for anchoring the lead.
2. Carefully withdraw the insertion needle from the epidural space by slowly pulling the needle up towards the proximal end of the lead while holding the lead in place.
3. Once the insertion needle tip is exposed, hold the lead as close to the exit site as possible, then carefully pull the needle completely from the lead.

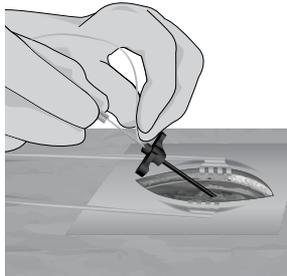


Removing the Entrada Needle

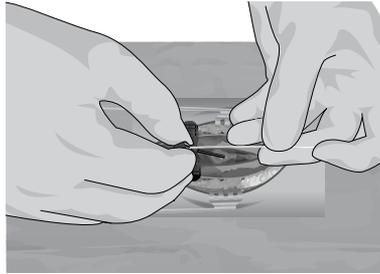
Note: *It is recommended to cut down prior to inserting the Entrada Needle. If cutting down after inserting the Entrada Needle, ensure that the sheath is in place and do not damage the sheath.*

1. Carefully withdraw the slotted needle by slowly pulling the needle towards the proximal end of the lead while stabilizing lead in line with the slot to keep lead in place.

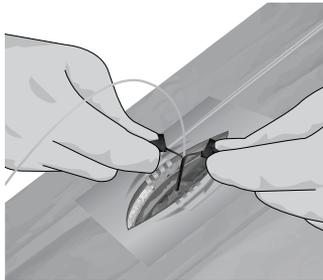
Note: *Do not reinsert the slotted needle into the sheath while the sheath is within the body.*



- A. Stabilize lead in line with the slot
- B. Slowly remove slotted needle



2. Snap sheath wings apart and peel sheath out of insertion site.



Snap sheath wings apart and peel sheath

3. Remove the stylet from the lead

Anchoring the Lead

Leads can be permanently anchored with a suture sleeve or with an anchor.

Note: *When using the Infinion CX Lead, the anchor or suture sleeve must be loaded over the distal end of the lead prior to inserting the Infinion CX Lead into the Entrada Needle. For the Infinion CX Lead, the stylet may be in place within the lead when the anchor is loaded on the lead.*

Refer to the *Directions for Use* for your Boston Scientific anchor as listed in your *Reference Guide*, or continue with the following steps to anchor using a suture sleeve.

1. For percutaneous leads, carefully remove the lead stylet using fluoroscopy to ensure the lead position does not change.
2. Place a suture sleeve over the lead and down to the supraspinous ligament or deep fascial tissue.
3. Ligate the suture sleeve onto the lead by tying a 2-0 silk or other nonabsorbable suture around the center groove of the sleeve to prevent sliding. Circumferential stitches may be tied at the compression slots.

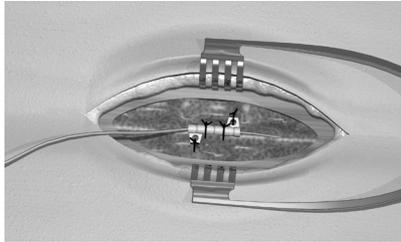
CAUTION: *Do not use polypropylene sutures as they may damage the suture sleeve. Do not suture directly onto the lead, splitter, or use a hemostat on the lead body. This may damage the lead insulation.*

Note: *The 4 cm and 2.3 cm suture sleeves each have three (3) compression slots, which are designed to reduce slippage.*

4. Suture the sleeve to the supraspinous ligament or deep fascia through the suture sleeve holes.
5. Tie multiple sutures as tightly as possible around the suture sleeve to secure it to the lead.

CAUTION: *Tightening sutures directly on the lead can damage the lead.*

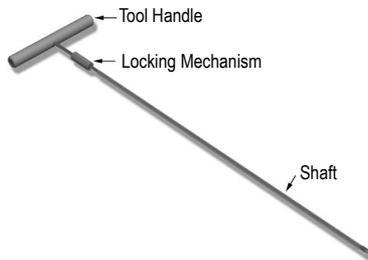
- For Permanent Trials, proceed to the instructions for "Tunneling the Lead or Lead Extension" on page 35.
- For Permanent IPG Implantation, proceed to the instructions for "IPG Implantation" on page 41.



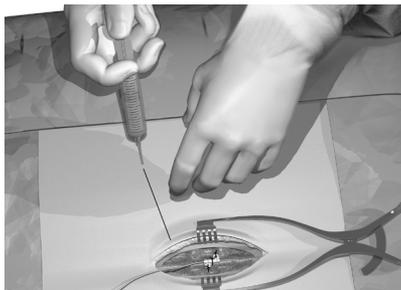
Tunneling the Lead or Lead Extension

Note: If tunneling an Infinion CX Lead, it is recommended to use the Long Tunneling Tool (35cm).

- Attach the tunneling tool handle to the shaft by turning the locking mechanism clockwise.

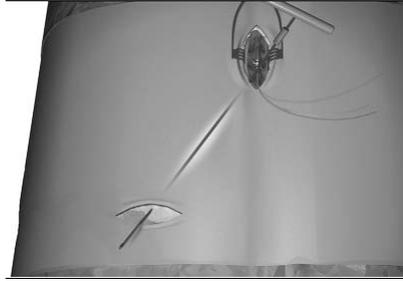


- Mark the desired route of the tunnel.

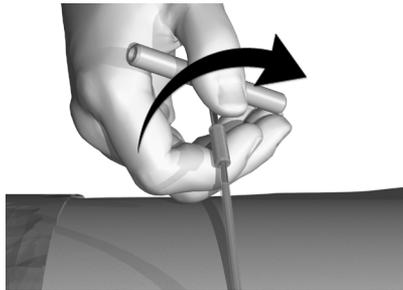


- Administer the appropriate local anesthetic along the tunneling path.
- OPTIONAL. If necessary, bend the tool shaft to conform to the patient's body.

5. Make a small incision at the desired exit site.



6. Create a subcutaneous tunnel between the midline incision and the exit site until the straw is visible and accessible at the exit point.



7. Unscrew and remove the tunneling tool handle.



8. Grasp the tip of the tool with one hand while holding the straw in place with the other hand. Pull the tunneling tool shaft out through the straw.
9. Push the lead or extension proximal ends through the straw, then withdraw the straw.

CAUTION: Do not tunnel splitter.

Note: If using the 2x8 Splitter and performing a permanent trial, the splitter tails may be tunneled to the exit site.

10. For Permanent Trials:

If using the Infinion 16 lead, proceed to “Lead Connection to Splitter” on page 25.

Otherwise, proceed to “Connecting the Lead Extension” on page 37.

11. For Permanent IPG Implantation, if extensions are used, proceed to the instructions for “Connecting the Lead Extension” on page 37.
12. For Permanent IPG Implantation, if splitters are used, proceed to the instructions for “Lead Connection to Splitter” on page 25.
13. For Permanent IPG Implantation, proceed to the instructions for “Connecting to the IPG” on page 42.

Note: *The following Codman Disposable Catheter Passers may be used in place of the Boston Scientific tunneling tool except for the Infinion CX Lead:*

REF 82-1515 (36 cm)

REF 82-1516 (55 cm)

REF 82-1517 (65 cm)

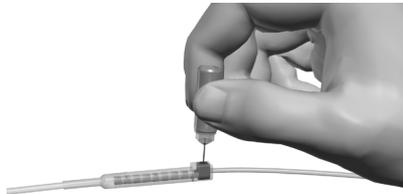
Note: *When using a Codman Disposable Catheter Passer, tunnel from the IPG pocket to the midline incision using the standard technique.*

Connecting the Lead Extension

1. Wipe clean the proximal end of the lead, then insert the proximal end into the lead extension connector or splitter until it stops and the retention ring (long ring) is under the setscrew.

Note: *If there appears to be an obstruction when inserting the lead into the lead extension connector, use the hex wrench to loosen (counterclockwise) the setscrew and/or gently rotate the lead to help advance the proximal end.*

2. Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.
3. Using the hex wrench supplied, turn the extension connector setscrew clockwise until it clicks, indicating lock.

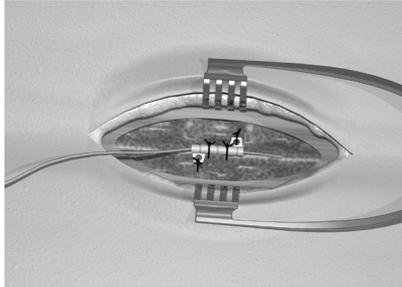


Note: • *Ensure that the hex wrench is fully seated in the setscrew before tightening.*

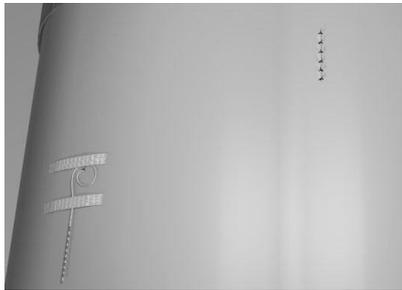
• *The hex wrench is torque-limited and cannot be overtightened.*

4. Form an appropriately-sized pocket using blunt dissection on either side of midline for coiled excess lead and extension connectors.
5. Place a small loop at the lead for slack. If necessary, loosely tie a suture around the lead-loop, but do not tighten onto the lead.

CAUTION: *Tightening sutures directly on the lead can damage the lead.*



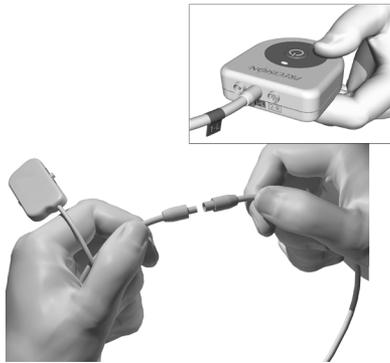
6. Carefully remove excess slack by gently pulling the extensions from the exit wound.
7. For Permanent Trials, if desired, a small suture may be used to close the exit wound of the extension. Place and tape a stress relief loop and dress the wound. Proceed to the instructions for “Connecting to the Trial Stimulator” on page 39.



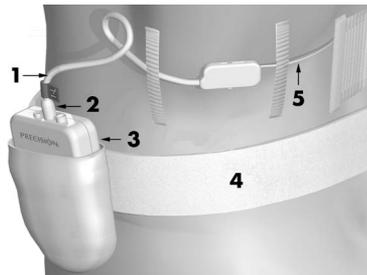
8. For Permanent Implant, close the midline incision, and proceed to the instructions for “Connecting to the IPG” on page 42.

Connecting to the Trial Stimulator

1. If two leads are used, connect the cable labeled "1-L" to the upper or left lead, and the cable labeled "2-R" to the lower or right lead. Labels are provided. If two 2x4 splitters are used, connect the cable labeled "1-L" to the proximal connector of one of the 2x4 splitters and connect the cable "2-R" to the proximal connector of the other splitter. If using a Splitter 2x8 connect the cable labeled "1-L" to the laser-marked tail and the cable labeled "2-R" to the unmarked tail. If an Infinium™ CX lead is used, connect the cable labeled "1-L" to the tail with one marker band and the cable labeled "2-R" to the tail with two marker bands.
2. Connect the OR cables to the Trial Stimulator.
If only one lead is used, connect the OR cable to "1-L" on the Trial Stimulator.



3. Fit the Trial Belt to the patient, cut off the excess length, and place the Trial Stimulator in the belt pocket.



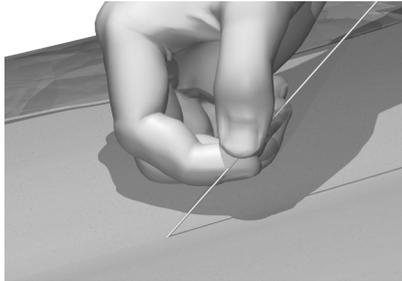
- | | |
|------------------------------------|----------------------|
| 1. OR Cable | 4. Trial Belt |
| 2. OR Cable Connector | 5. Lead or Extension |
| 3. External Trial Stimulator (ETS) | |

Removal of Trial Leads, Extensions, and Splitters

Remove bandages and properly cleanse the exit site. The method of removal depends upon whether a temporary trial or permanent trial was performed.

Option A: Percutaneous Lead Removal after Temporary Trial

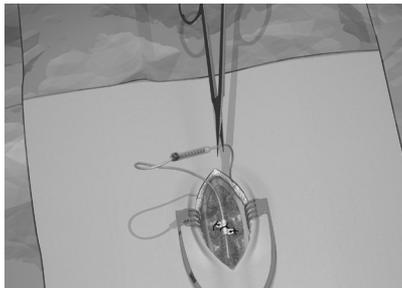
1. Clip sutures if used to secure the trial lead(s) in place.
2. Remove the lead(s) and discard.



3. To replace the trial lead(s) with permanent percutaneous lead(s), proceed to the instructions for “Percutaneous Lead Placement in the Epidural Space” on page 19.
4. To replace the trial lead(s) with a paddle lead proceed to the instructions for “Surgical Paddle Lead Placement in the Epidural Space” on page 28.

Option B: Lead Extension Removal after Permanent Trial

1. Open the midline incision to expose the lead extension and connector.
2. Cut the lead extension at the connector. Do not cut the implanted lead.



3. Remove the extension, being careful not to contact non-sterile portions to the patient's body.
4. Loosen the extension connector setscrew using the hex wrench. Disconnect and remove the connector without moving the implanted lead.
5. Proceed to the instructions for “IPG Implantation” on page 41.

Option C: Splitter Removal after Trial

1. If the splitter has been implanted, open the incision to expose the lead and splitter junction.
2. Loosen the connector set screw on the splitter receptacles using the hex wrench provided.
3. Disconnect and discard the splitter components.

IPG Implantation

1. Ensure that the area surrounding the lead entry site is incised to a dimension that will accommodate the tunneling tool. Check that the lead is securely anchored with the suture sleeve.
2. Select and mark the intended IPG site using the IPG template and create an incision at the top of the site.
3. Create a subcutaneous pocket no larger than the IPG outline at a depth of up to 2.0 cm from the surface. Implant charging could become ineffective at depths greater than 2.0 cm.

Note: *Using the IPG template will help guide the correct pocket sizing. It is important to keep the pocket small to reduce the chances of patient manipulation and IPG flipping.*



4. To tunnel to the IPG site, proceed to the instructions for “Tunneling the Lead or Lead Extension” on page 35.

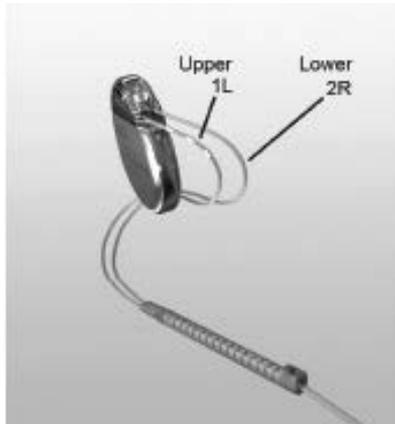
Connecting to the IPG

For Percutaneous Lead - Dual Lead Connection

- Superior (upper or left) leads, extensions, or 2x4 Splitters connect to IPG port “1-L”.
- Inferior (lower or right) leads, extensions, or 2x4 Splitters connect to IPG port “2-R”.

For Infinion™ 16 Lead Connection

- Laser-marked tail of Splitter 2x8 connects to IPG port “1-L”.
- Unmarked tail of Splitter 2x8 connects to IPG port “2-R”



For Infinion CX Lead Connection

- Proximal tail with one marker band connects to IPG port “1-L”.
- Proximal tail with two marker bands connects to IPG port “2-R”.

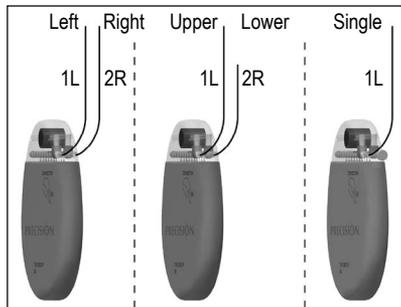
For Percutaneous Lead - Single Lead Connection

- Connect a single lead, extension, or 2x4 Splitter to IPG port “1-L”.
- Insert port plug into unused port.

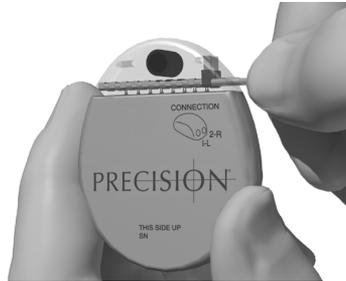
For Surgical Paddle Lead Connection

- Left side of lead connects to IPG port “1-L”.
- Right side of lead connects to IPG port “2-R”.

Note: The right tail of the Paddle Lead is laser-etched to allow for easy identification of right and left.



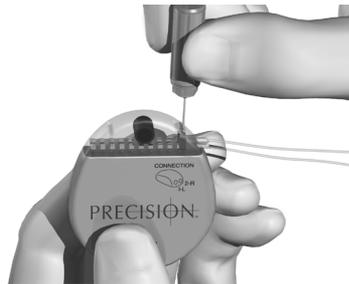
1. Fully insert the lead(s), extension(s), or splitters into the IPG port(s), being careful not to stress or bend the proximal end of the lead or extension. When the lead is properly inserted, the lead will stop and the retention ring will be located under the setscrew.



Note: If you experience difficulty when inserting the lead, lead extension, or port plug, use the hex wrench to loosen (counterclockwise) the setscrew and/or gently rotate the lead to help advance the proximal end.

Note: To confirm good connections, check impedances before tightening the setscrew.

2. Pass the hex wrench through the hole in the septum located on the top of the IPG header and tighten each set screw until the hex wrench “clicks,” indicating lock.



CAUTION: Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.

Note: • If a port plug is used, it is still necessary to tighten the setscrew on the port plug, as described above.

• The hex wrench is torque-limited and cannot be overtightened.

3. Place the IPG in the subcutaneous pocket with label facing towards the skin.
4. Coil excess lead, extension, or splitter under the IPG.

CAUTION: Do not excessively bend the Splitter 2x8 receptacle. Bending the receptacle at a radius tighter than 2" (5 cm) may result in loss of stimulation via one or more contacts. Ensure the correct lengths of leads are selected to prevent excessive coiling.

5. Secure the IPG in the pocket by suturing through the holes in the IPG header.

CAUTION: Do not suture through leads or splitter.

6. Close and dress the wound(s).

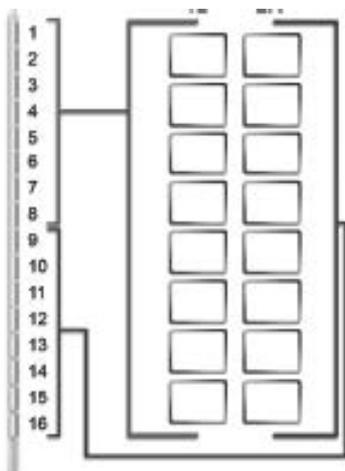
Programming with the Infinion 16 Lead and Infinion CX Lead

For detailed programming instructions, refer to the appropriate Bionic Navigator Software Guide. When the Infinion 16 lead is used with the Splitter 2x8 and placed properly into the Precision IPG ports (laser-marked tail of Splitter 2x8 connecting to IPG port "1-L"), the distal 8 contacts of the Infinion 16 lead (contacts 1-8) will correspond with contacts 1-8 on the left side of the Bionic Navigator software display. Likewise, the proximal 8 contacts of the Infinion™ 16 lead (contacts 9-16) will correspond with contact 9-16 on the right side of the Bionic Navigator software display.

When the Infinion CX Lead is placed properly into the Precision IPG ports (tail with one marker band connecting to IPG port "1-L"), the distal 8 contacts of the Infinion CX Lead (contacts 1-8) will correspond with contacts 1-8 on the left side of the Bionic Navigator software display. Likewise, the proximal 8 contacts of the Infinion CX Lead (contacts 9-16) will correspond with contact 9-16 on the right side of the Bionic Navigator software display.

The following diagram depicts this wiring.

Using test stimulation, enlist patient feedback to verify lead placement and pain coverage. The user may program with the Infinion 16 Lead and Infinion CX Lead using all the functions available in Bionic Navigator for the Linear family of leads (E-Troll, Navigator, etc.). For complete instructions on programming, see the Bionic Navigator Software Guide.



IPG Explant or Replacement

1. Turn off the IPG.
2. Surgically open the IPG pocket and withdraw the device. Do not use monopolar electrocautery. Please try to preserve the integrity of all components so that complete device assessment can be performed.
3. Loosen the connector setscrews to release and remove the leads, extensions, or splitters.
4. For replacement, connect the new IPG following the instructions for "Connecting to the IPG" 39. Or, to terminate therapy, surgically remove the implanted lead system.
5. Notify Boston Scientific to document the reason for explant or replacement and to arrange for return of IPG and components.

Rechargeable Stimulator System

The Precision Stimulator is rechargeable. Depending on stimulation power usage and programming, the majority of patients will need to recharge the Stimulator between once per week and once per month. High power users will require more frequent charging. Boston Scientific recommends any recharge routine that fits the patient's schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

Developing a patient's recharge routine involves finding the right balance among the following:

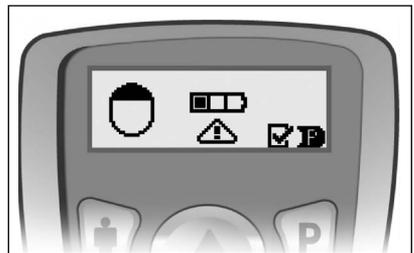
- How much power is required for the patient to experience effective therapy.
- How often the patient wants to recharge.
- How long the patient wants to recharge.
- How the patient would like to manage their personal schedule.

The Bionic Navigator software will estimate charging time based on 24 hours per day of stimulation at the programmed settings. Recharge time can range from ten minutes to four hours. To charge fully, wait until the Charger emits an end of charge beep signal or the Remote Control displays three battery bars. The recharging process is simple, but important.

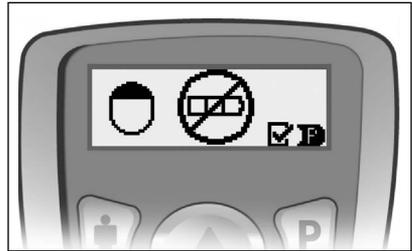
The rechargeable Stimulator battery should provide at least five years of service. Over time and with repeated charging, the battery in the Stimulator will lose its ability to recover its full capacity. As a result, the Stimulator may need to be recharged more often. The Stimulator may need replacement when stimulation can no longer be maintained with regular charging.

IPG Battery Status

The patient Remote Control displays the Stimulator battery status when communicating with the Stimulator. When the Remote Control indicates a low battery (message: Recharge Stimulator Soon), the Stimulator should be recharged as soon as possible.



Failure to recharge may lead to loss of stimulation in less than 24 hours and the following message will appear on the Remote Control: "Recharge Stimulator Now." After stimulation stops, communication with the Stimulator will also cease and multiple recharge sessions may be required. Until a sufficient level of charge has been attained, the Stimulator may not communicate with the Remote Control.



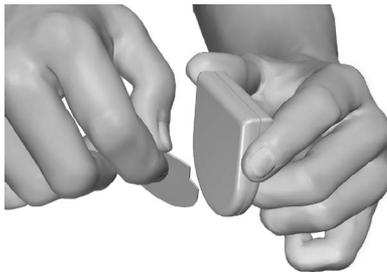
Charging Steps

WARNINGS:

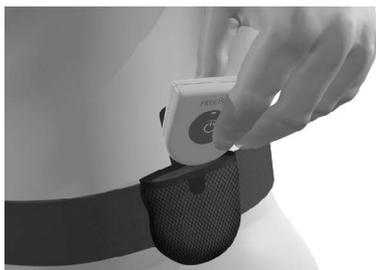
- Do not charge while sleeping. This may result in a burn.
- While charging, the Charger may become warm. It should be handled with care.
- Failure to use the Charger with either the Charging Belt or an adhesive patch, as shown, may result in a burn. If pain or discomfort is felt, cease charging and contact Boston Scientific.

The Charger Base Station should be plugged in and the Charger placed in the Base Station when not in use. When the indicator light is green, the Charger is fully charged. When the indicator is amber, the Charger is partially charged, but is still able to deliver a charge to the Stimulator.

1. When the indicator light is green, remove the Charger from the Base Station. The indicator light will then turn off.
2. Press the power button. The indicator light will come on again, and the Charger will begin beeping as it searches for the Stimulator.
3. Place the Charger over the Stimulator. When the Charger is aligned with the Stimulator, the beeping will stop.
 - Centering the Charger over the Stimulator will ensure the shortest charging time.
 - Many patients are able to feel the implanted Stimulator and can place the Charger directly on top of it.
 - Alternatively, centering the Charger within the alignment area (i.e., the area where the Charger does not beep) will also ensure that the Charger is centered.
4. Secure the Charger over the Stimulator by using either an adhesive patch or the Charging Belt.
 - Adhesive Patch: Remove the clear liner from the patch. Apply the white side with the blue stripe to the back of the Charger. Then remove the beige liner from the patch. Secure the Charger over the Stimulator by pressing the adhesive to the skin over the Stimulator (see diagram below).



- Charging Belt: Place the Charger into the pocket on the Charging Belt with the power button facing out. Secure the Charger over the Stimulator by adjusting the Charging Belt (see diagram below).



Note: If you accidentally locate the patch in the wrong place, or if the Charging Belt moves out of alignment, the Charger will start beeping again. Use a new adhesive patch or readjust the belt to place the Charger back into position.

5. When the Charger emits a series of double beeps, the Stimulator is fully charged. Turn off the Charger, remove the Charging Belt or adhesive patch, and return the Charger to the Base Station. Do not confuse the end of charge signal (a series of double beeps) with the continuous beeps that indicate that the Charger is searching for the Stimulator.

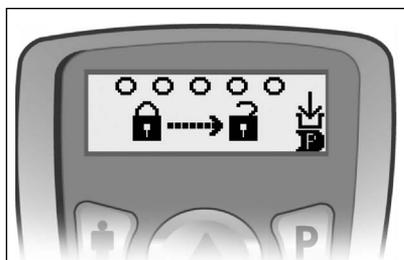
- Note:**
- Depending on your program parameters, you may expect daily recharging times from as low as 10 minutes up to four hours, or weekly recharging times from as low as one hour up to four hours. Charging times may be longer than 4 hours when not properly aligned.
 - The end of a charge signal is a distinct double beep, and the alignment indicator is a steady continuous signal.
 - Remote will not be able to communicate with the IPG when charging.

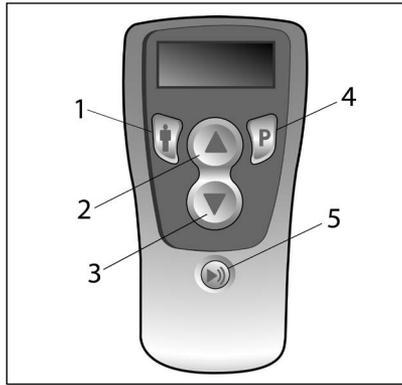
Patient Remote Control

Basic Operation

The Remote Control communicates with the Stimulator through a radio frequency (RF) telemetry link from a distance of up to 60 cm (2 feet).

The Remote Control goes into idle (or sleep) mode when not in use. It can be reactivated by pressing any button. To unlock the Remote Control, hold down **P**, until “Release P To Unlock” appears.





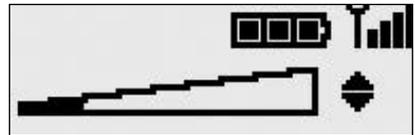
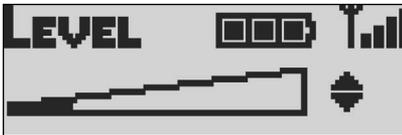
- | | |
|----------------|-----------------------|
| 1. Area Button | 4. Program Button |
| 2. Up/Activate | 5. Stimulation On/Off |
| 3. Down/Save | |

Stimulation On/Off

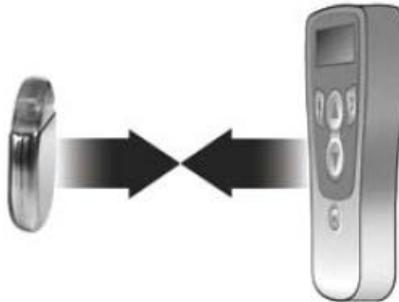
Press the stimulation on/off button ►) at any time to turn the Stimulator on or off.

Signal Strength

The Remote Control indicates the communication signal strength between itself and the Stimulator in the upper right corner of the display.



For BEST communication, your Remote Control should face the Stimulator.



- If there are no signal bars, communication may still be achieved at a very weak level. Move the Remote Control closer to the Stimulator and/or reorient its position to improve communication.
- If there are 1 or 2 signal bars, there is adequate communication between the Remote Control and the Stimulator.
- If there are 3 or 4 signal bars, the Remote Control is achieving optimal communication with the Stimulator.

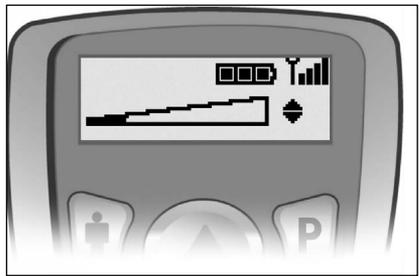
- If communication is unsuccessful, the Remote Control will display the “Searching” message. The Remote Control will then start continuously looking for a signal. Either reorient the Remote Control so that it faces the Stimulator (see picture above), move the Remote Control closer to the Stimulator, or move away from potential sources of interference. To cancel searching press and hold the Area Button .

Note: Avoid common sources of communication interference such as televisions and computer monitors.

Note: Communication between the Remote Control and the Stimulator is not possible while charging. Temporarily discontinue charging in order to use the Remote Control.

Stimulation Amplitude

The Level screen is the Remote Control’s “default” screen.



Press the  or  button from the Level screen to increase or decrease stimulation strength.

Stimulator Battery Status

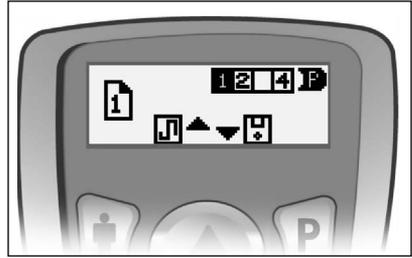
The Level screen also displays the Stimulator battery status in the top center of the screen. Three solid bars represent a fully charged Stimulator. As the Stimulator battery depletes, depending on the patient’s stimulation settings and usage, the bars will “empty” accordingly. For their convenience, patients are encouraged to recharge the Stimulator at the first “Recharge Battery Soon” message displayed by the Remote Control. Due to Zero Volt™ Technology, the Stimulator can be completely and repeatedly discharged without causing battery failure.

Program Selection and Activation

Note: The program that is currently or was most recently running will be underlined (). Empty program slots are denoted by an empty box [] with no program number.

1. Press the **P** button from the Level screen to go to the Program selection screen. Program 1 will be highlighted.
2. From the Program selection screen, press the **P** button to highlight the next program number. Press the  button to select the previous program number. Pressing the **P** button from program 4 or the  button from

program 1 returns to the Level screen.



3. Highlight the desired program and press ▲ to activate the program.

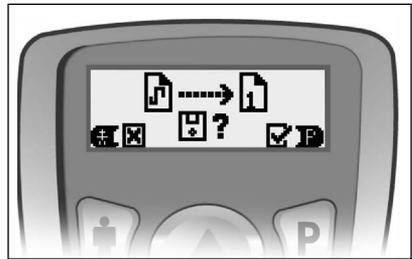
Modifying and Saving Programs

If the stimulation amplitude, pulse width, or rate (see “Additional Area Options” on page 52) have been changed, the new settings can be saved by following the instructions below.

1. Press **P** once to access the Program selection screen, and then press **P** as needed to highlight the desired program.

Note: Typically, patients will want to highlight the currently running program. This program is underlined (). Highlighting the underlined program will save the new settings to the currently running program.

2. To save/store changes, select the appropriate program number and press ▼. A confirmation screen will appear.

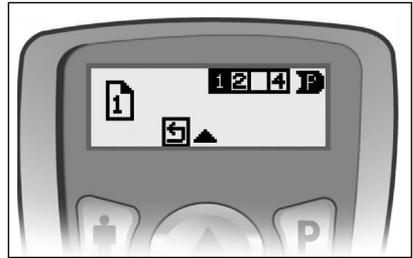


3. Press **P** to confirm and overwrite, or press the **⏏** button to cancel the operation.

Restoring Programs:

The original clinic programs can be restored by following the instructions below.

1. Press and hold **P** for approximately 3 seconds to access the Restore screen. Program 1 will be highlighted.
2. Press the **P** button to cycle through the programs and select the program to be restored.
3. Press ▲ to restore the clinic-programmed settings.



Coverage Area Selection

Each program can consist of up to 4 different coverage areas (Areas). The stimulation strength and other settings for each Area can be adjusted.

1. Press the **1** button to access the Area level screen. This controls the stimulation strength for each Area individually. Press the **1** button as needed to highlight a specific stimulation coverage area.
2. Press the **▲** or **▼** button to adjust the stimulation strength (amplitude) of the selected Area.

Additional Area Options

The Pulse Width and Rate parameters are available as programming options to allow patients greater control of their therapy. By default, access to Pulse Width and Rate are disabled in the patient Remote Control. Access to these parameters can be enabled through the BionicNavigator software.

To Access the Pulse Width and Rate Options (if enabled through Bionic Navigator):

1. Press and hold the **1** button on the Remote Control for three seconds until the Pulse Width screen appears. This is indicated by "Width" in the bottom left corner of the screen.

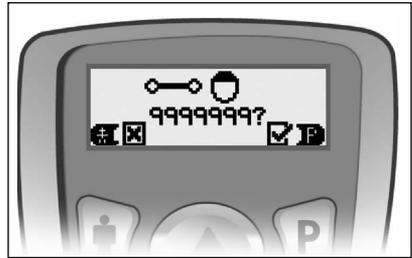
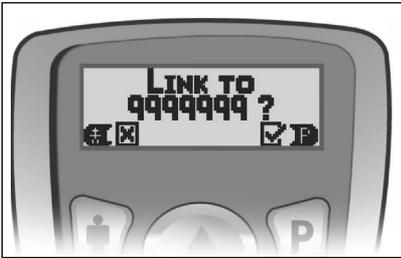


2. Area 1 will initially be highlighted. Press the **1** button to cycle to the Area you wish to adjust.
3. When the desired Area is highlighted, press **▲** or **▼** to increase or decrease the Pulse Width.
4. To continue to Rate adjustment, press and hold the **1** button for three seconds from any Pulse Width Area screen. The Rate screen is indicated by "Rate" in the bottom left corner of the screen.
5. Area 1 will initially be highlighted. Press the **1** button to cycle to the Area you wish to adjust.
6. When the desired area screen is highlighted, press **▲** or **▼** to increase or decrease the Rate.
7. To return to the main Level screen, press and hold the **1** button for three seconds until the Level screen appears.

Device Linking

A Remote Control can communicate with only one Stimulator at a time. This prevents the Remote Control from accidentally controlling an unintended device. In the linking process, the Remote Control will identify, by telemetry, the intended Stimulator for communication.

1. Press and hold the **P** button to unlock the Remote Control and initiate communication between the Remote Control and the Stimulator.
2. If the Remote Control is not linked to a Stimulator, it will display a "Link?" screen. Press **P** to link. The Remote Control will search for the nearest Stimulator.



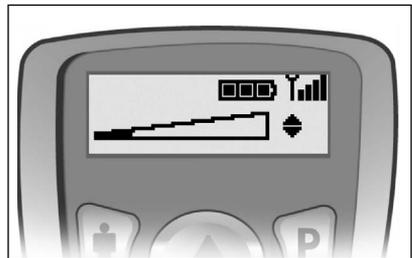
If the Remote Control is already linked to a Stimulator, it may continuously search for it. This link must be cleared before a new link can be established. (See "Clinician Options" on page 54).

3. The Remote Control will identify the Stimulator by serial number. Verify before proceeding.
4. Press **P** to confirm and continue. Press **↓** to cancel.

When linking with a Trial Stimulator, the Remote Control will ask whether existing programs on the Trial Stimulator should be cleared. If the programs on the Trial Stimulator are cleared and if the Remote Control contains existing programs, it will then ask if these should be used.

When linking with an IPG, the Remote Control will automatically use any programs stored in the IPG. If the IPG contains no programs and the Remote Control contains existing programs, it will ask whether to use the programs from the Remote Control.

When the link is established, you will see the main Level screen:



Searching

If there is a loss of communication, the Remote Control will automatically begin "searching" for the Stimulator. Move the Remote Control closer to the Stimulator and/or reorient its position to help it locate the Stimulator. To cancel searching, press and hold the **↓** button.

If, after searching, the Remote Control is unable to locate a Stimulator, it will display a message indicating no response. Press **P** to retry searching or press **⏏** to cancel.



Clinician Options

Additional clinician functions are available on the Remote Control. These functions include:

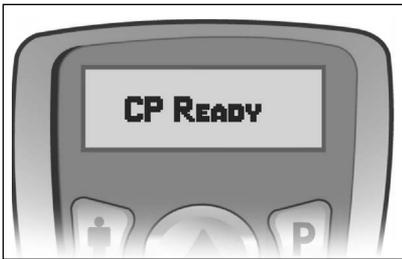
- Communication with the clinician programmer
- Electrode impedance monitoring
- Linking the Remote Control and Stimulator
- Language selection

To access the Clinician Options menu:

1. Press the **⏏** and **P** buttons simultaneously for three seconds. The Clinician Options menu will appear.
2. Press the **▲** or **▼** button to navigate the Clinician Options menu.
3. Each option is discussed below.

Selection #1 – CP Mode

1. From the Clinician Options menu, highlight "CP Mode" and press the **P** button to select this menu item. This will prepare the Remote Control for communication with the Clinician Programmer (CP). When in CP Mode, "CP Ready" will appear on the Remote Control screen.



2. Place the Remote Control and the IR dongle in the plastic IR Holder so that their communication ports are facing each other.
3. Plug the dongle's USB connector into the appropriate connector on the CP.
4. Launch the BionicNavigator software and wait for the "Communication Established" message.



- Note:**
- The Remote Control will remain CP Ready for up to 15 minutes with no activity.
 - All buttons are active during CP Ready and pressing any button returns the Remote Control to the Level screen.
 - Stimulation may be turned on or off in CP Ready state.
 - Whenever the Remote Control is re-activated from idle mode the display will default to the Level screen.

The Clinician Programmer can communicate with either an External Trial Stimulator or an IPG.

Arrange for the patient to be seated within two feet of the Remote Control to ensure an adequate communication link from the programmer to the Stimulator.

For instructions on how to use the Clinician Programmer with the BionicNavigator software to program the IPG and transfer programs to the Remote Control, see the BionicNavigator Software Guide.

Selection #2 – Impedances

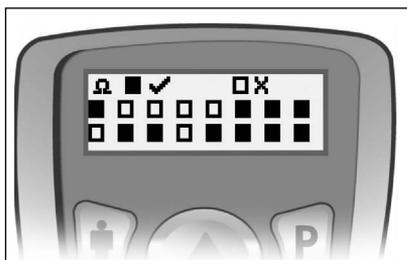
When the "Impedances" option is selected from the Clinician Options menu, the Remote Control will measure impedances at each contact on the lead(s). This will take about 10 seconds.



Note: During this measurement the serial number of the Stimulator will be displayed on the screen.

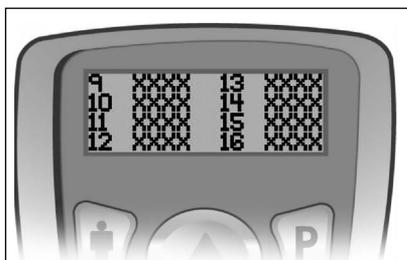
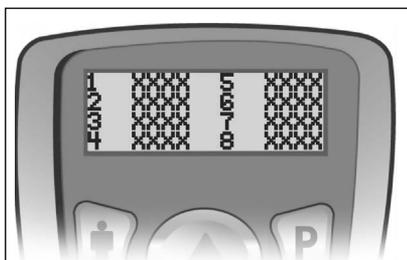
The Remote Control will display the contact impedance status screen.

Contacts 1 through 8 (lead position "1-L") are represented by the rectangles in the top row, starting with contact 1 on the left. Contacts 9 through 16 (lead position "2-R") are represented by the rectangles in the bottom row, starting with contact 9 on the left.



Contacts within the typical impedance range are displayed as solid rectangles. High impedance contacts (above 4500 ohms) are represented by hollow rectangles.

To display the impedance values press any key (other than the Stim On/Off button ►). Impedance values for contacts 1 - 8 will be shown first. Press the key again to show impedance values for contacts 9 - 16.

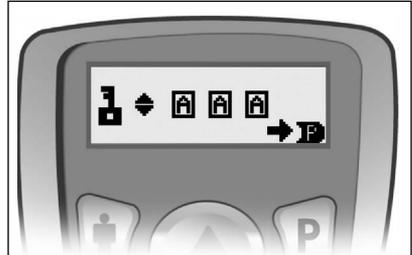


Pressing any key will show the "Measure Again?" screen. To measure impedances again, push the **P** button. To cancel and exit, push the **⏏** button.



Selection #3 – To Clear Link

When the “Clear Link” option is selected from the Clinician Options menu, the serial number of the Stimulator will be displayed and you will be asked to confirm clearing the link. To confirm and clear the link, press the **P** button. You will then be asked to enter a password. To cancel, press the **⏏** button.



To enter the password:

The first character is highlighted when the Enter Password screen opens. To scroll through possible characters, use **▲** or **▼**. To select/confirm any character and move to the next character position, press **P**. If the correct password is entered, the link between the Remote Control and the Stimulator is broken immediately. The Remote Control will display the “Link?” message. However, the programs in the Remote Control will remain intact.

If an incorrect password is entered, the process is aborted and the Remote Control will return to the Clinician Options menu.

Selection #4 – To Choose Language

When the “Language” option is chosen from the Clinician Options menu, you may scroll through the seven language options by pressing ▲ or ▼. Use the **P** button to select English, Spanish, French, Italian, German, Dutch, or Iconic Symbols when the language is highlighted.

After you select the desired language, the Remote Control will ask you to confirm the selection; press **P** to accept. To cancel, press the **⏏** button. The Remote Control language will now change to your selected language.



Specifications and Technical Data

Parameter	Range	Default
Areas (Channels)	4	—
Amplitude	0 – 20 mAa	0 mA
Rate	2 – 1200 pps ^b	40 pps
Width	0 – 1000 μ sec	210 μ sec
Cycle	0 – 90 min, OFF	OFF
Ramp ON	1 – 10 secs	3 secs
Contacts	1 – 16; +, -, OFF	1 – 16: OFF

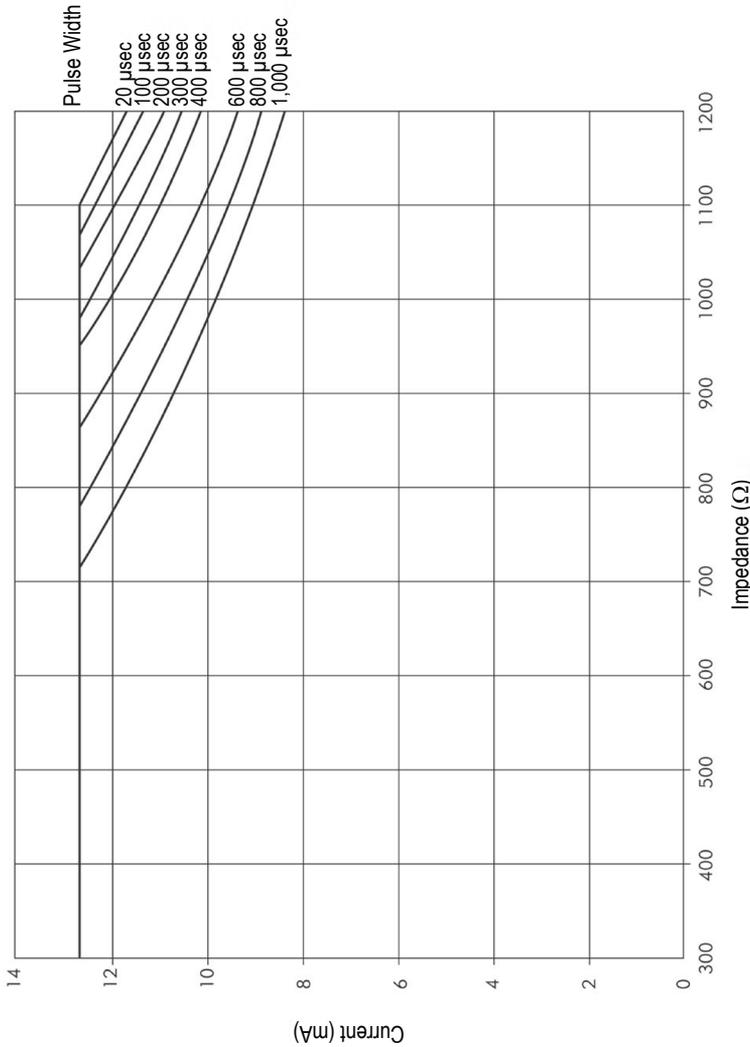
a. The Precision System includes programmable coverage areas with each individual electrode contact limited to 12.7 mA. A programming interlock is enforced to limit the coverage area output current to 20 mA or less. For example, a maximum current output of 12.7 mA on a first electrode would limit the total summed current output on remaining electrodes to 7.3 mA within one coverage area.

b. Only one Area is available if the rate is 130 pps.

Materials

Case	Titanium
Header	Epoxy
Strain Relief	Silicone
Size/Volume	55 mm x 45 mm x 11 mm / 20.7 cm ³ (including header)

Max Current Amp. per Electrode vs. Impedance



Note: Maximum output capability is frequency independent.

Linear Lead

Part	Specifications
Lead Lengths	30, 50, 70 cm
Lead Shape	In-line
Lead Diameter	1.3 mm
Number of Electrode Contacts	8
Electrode Length	3 mm
Electrode Spacing	1, 4 or 6 mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane
Conductor Material	MP35N-DFT-28% Ag

Infinion 16 Lead

Part	Specifications
Lead Lengths	50, 70 cm
Lead Shape	In-line
Lead Diameter	1.3 mm
Number of Contacts	16
Contact Length	3 mm
Contact Spacing	1 mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane
Conductor Material	35N LT – DFT- 28% Ag

Infinion CX Lead

Part	Specifications
Lead Lengths	50, 70 cm
Lead shape	In-line
Lead Diameter	1.3 mm (each segment)
Number of Contacts	16
Contact Length	3 mm
Contact Spacing	1 mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane
Conductor Material	35N LT-DFT-28% Ag

Lead Extension

Part	Specifications
Extension Lengths	25, 35, 55 cm
Extension Diameter	1.3 mm
Number of Electrode Contacts	8
Contact Material	Platinum/Iridium, Stainless Steel
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N-DFT-28% Ag

Surgical Lead

Part	Specifications
Lead Lengths	50, 70 cm
Lead Shape	2 x 8 paddle
Lead Diameter	8 mm
Number of Electrode Contacts	16
Electrode Length	3 mm
Electrode Spacing	1 mm
Contact Material	Platinum
Insulation Material	Silicone/Polyurethane
Conductor Material	MP35N-DFT-28% Ag

2x4 Splitter

Part	Specifications
Splitter Length	25 cm
Splitter Diameter	1.3 mm (each segment)
Number of Electrode Contacts	8 (4 per receptacle)
Contact Material	Platinum/Iridium, Stainless Steel
Insulation Material	Polyurethane, Silicon
Conductor Material	MP35N-DFT-28%Ag

Splitter 2x8

Part	Specifications
Splitter Length	30 cm
Splitter Diameter	1.3 mm (each segment)
Number of Electrode Contacts	16 (8 per tail)
Contact Material	Platinum/Iridium, Stainless Steel
Insulation Material	Polyurethane, Silicon
Conductor Material	MP35N-DFT-28%Ag

Registration Information

Registering the Stimulator and Leads

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific neurostimulator and lead/lead extension/splitter.

The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory or device to gain quick access to pertinent data from the manufacturer.

Fill out the registration form included in the package contents. Return one copy to Boston Scientific, keep one copy for patient records, provide one copy to the patient, and one copy to the physician.

Boston Scientific Neuromodulation
25155 Rye Canyon Loop
Valencia, California 91355
Attention: Customer Service Department

Technical Service

Boston Scientific has highly trained service professionals located worldwide to assist you. The Technical Service Department is available to provide technical consultation 24 hours a day.

In North America, please call **(866) 566-8913** to speak to a representative.

Limited Warranty - IPG

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient who receives a Precision Implantable Pulse Generator (referred to as the IPG) that the IPG will be free from defects in workmanship and materials for a period of (5) five years from the date of surgical implant of the IPG. This warranty applies only to the patient who has the IPG implanted and no other person or entity. This warranty does not apply to the leads, extensions, or surgical accessories used with the IPG.

If the IPG fails to function within normal ranges within (5) five years after the date it is implanted, Boston Scientific will replace the IPG with a functionally equivalent IPG made by Boston Scientific. No other relief whatsoever is available under this limited warranty. The limited warranty for a replacement IPG will last only for five years from the date of surgical implant of the original IPG. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of surgery.
2. The IPG must be purchased after January 1, 2005 and implanted before the “use by” date.
3. Failure of the IPG must be confirmed by Boston Scientific.
4. The IPG must be returned to Boston Scientific (or a Boston Scientific authorized agent) within 30 days after it fails to function within normal ranges. That IPG will be the property of Boston Scientific.
5. This limited warranty does not include failures to function within normal ranges caused by:
 - (a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as “Acts of God”;
 - (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the IPG in accordance with manufacturer’s instructions;
 - (c) unauthorized attempts to repair, maintain, or modify the IPG by the patient or any unauthorized third party; or
 - (d) attaching equipment to the IPG that is not supplied or expressly authorized by Boston Scientific.

This limited warranty is the only warranty that applies to the IPG, and Boston Scientific expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose. Under this limited warranty, Boston Scientific will be responsible only for replacement of the IPG with a functionally equivalent IPG made by Boston Scientific and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the IPG, whether the claim is based on warranty, contract, tort or any other theory.

Boston Scientific assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

Limited Warranty - Leads

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient that the Linear Lead Models, Infinion 16 Lead, Lead Extensions, Artisan Surgical Paddle Leads, and Splitters are free from defects in workman-ship and materials for a period of one (1) year from the date of implantation.

A Lead, Extension, or Splitter that fails to function within normal tolerances within (1) year from the date of surgery is covered under this Limited Warranty. The liability of Boston Scientific under this warranty shall be limited to: (a) replacement with a functionally equivalent Lead, Extension, or Splitter; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new Lead, Extension, or Splitter. Product claims under Boston Scientific Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of surgery in order to obtain warranty rights.
2. The Lead, Extension, or Splitter must be returned to Boston Scientific (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Boston Scientific.
3. The Lead, Extension, or Splitter must be implanted prior to the “use by” date.
4. Failure of the Lead, Extension, or Splitter must be confirmed by Boston Scientific. This warranty specifically excludes defects or malfunctions caused by: (a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as “Acts of God”; (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the Lead or Extension in accordance with manufacturer’s instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment by the customer or any unauthorized third party; or (d) attachment of any equipment not supplied by Boston Scientific without prior approval.
5. This warranty does not include surgical accessories used with the Linear Lead, Extension, or Splitter.
6. The decision as to product replacement or credit shall be made solely at the discretion of Boston Scientific. For a replacement Lead, Extension, or Splitter, the warranty will run only to the end of the warranty period for the original Lead, Extension, or Splitter that was replaced.

This warranty is in lieu of any other warranty, expressed or implied, including any warranty of merchantability or fitness for intended use. Except as expressly provided by this Limited Warranty, Boston Scientific shall not be responsible or liable for any direct, consequential or incidental damages caused by device malfunction, failure or defect, whether the claim is based on warranty, contract, tort or otherwise.

Boston Scientific assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

Limited Warranty - Externals

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient that the Remote Control device and Charging System (Charger and/or Charger Base Station) are free from defects in workmanship and materials for a period of one (1) year from the date of purchase.

If a Remote Control Device or Charging System component fails to function within normal ranges within one year after the date of purchase, Boston Scientific will replace the device or component with a functionally equivalent device or component made by Boston Scientific. No other relief whatsoever is available under this limited warranty. The limited warranty for a replacement device or component will last only for one year after the date of purchase. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of purchase.
2. Boston Scientific must confirm the device or component failure.
3. The device or component must be returned to Boston Scientific (or Boston Scientific's authorized agent) within 30 days after it fails to function within normal ranges. That device or component will be Boston Scientific's property.
4. This limited warranty does not include failures to function within normal ranges caused by:
 - (a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as "Acts of God";
 - (b) accident, misuse, abuse, negligence, or the customer's failure to operate the device or component in accordance with manufacturer's instructions;
 - (c) unauthorized attempts to repair, maintain, or modify the device or component by the patient or any unauthorized third party; or
 - (d) attaching equipment to the device or component that is not supplied or expressly authorized by Boston Scientific.

This limited warranty is the only warranty that applies to the device or component, and Boston Scientific expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose.

Under this limited warranty, Boston Scientific will be responsible only for replacement of the device or component with a functionally equivalent device or component made by Boston Scientific and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the device or component, whether the claim is based on warranty, contract, tort, or any other theory.

Patient Identification

Please ensure that the patient receives a completed temporary identification card following surgery. Permanent cards will be mailed directly to the patient following patient registration.

The following is federal government communications regulation information about the Precision System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The Precision System components should only be serviced by Boston Scientific. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair the components will void the warranty.

Changes of modifications to this product not authorized by Boston Scientific Corporation could void the FCC Certification and negate your authority to operate this product.

Boston Scientific

Advancing science for life™



Legal Manufacturer

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(661) 949-4000, (661) 949-4022 Fax
(866) 789-6364 TTY
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