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Percutaneous Leads

Instructions for Use

Rx ONLY

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

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Guarantees

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Additional Information

The products covered in this manual are components of a Boston Scientific System. For System information (such as indications and contraindications) and other device-specific information not included in this manual, refer to the appropriate Instructions for Use (IFU) for your System, as listed in your *Reference Guide*.

 For clinical studies supporting the clinical use of the neurostimulation system, refer to the *Information for Prescribers IFU* or *Clinician Manual* for your spinal cord stimulator system.

Labeling Symbols

For an explanation of labeling symbols, refer to the Labeling Symbols document.

Warranty

For device warranty information, visit (www.bostonscientific.com/warranty).

Product Model Numbers

Model	Description
SC-2016-xx	Infinion™ 16 Lead and Splitter 2x8 Kit
SC-2016-xxE	Infinion 16 Lead and Splitter 2x8 Trial Kit
SC-2138-xx	Linear™ xxcm 8 Contact Lead
SC-2158-xx	Linear xxcm 8 Contact Lead
SC-2158-xxE	Linear xxcm 8 Contact Lead
SC-2208-xx	Linear ST xxcm 8 Contact Lead
SC-2218-xx	Linear ST xxcm 8 Contact Lead
SC-2218-xxE	Linear ST xxcm 8 Contact Lead
SC-2352-xx	Linear 3-4 xxcm 8 Contact Lead
SC-2352-xxE	Linear 3-4 xxcm 8 Contact Lead
SC-2366-xx	Linear 3-6 xxcm 8 Contact Lead
SC-2366-xxE	Linear 3-6 xxcm 8 Contact Lead
SC-3138-xx	xxcm 8 Contact Extension
SC-3304-xx	D4 Splitter 2x4
SC-3354-xx	W4 Splitter 2x4
SC-2316-xx	Infinion 16 xxcm 16 Contact Lead Kit
SC-2316-xxE	Infinion 16 xxcm 16 Contact Trial Lead Kit

Model	Description
SC-3400-xx	xxcm Splitter 2x8 Kit
SC-2317-xx	Infinion™ CX xxcm 16 Contact Lead Kit
SC-2317-xxE	Infinion CX xxcm 16 Contact Trial Lead Kit
SC-2318-xx	Infinion Pro Lead Kit, 16 Contact, xxcm

Note: xx = length (cm), xxE = length (cm) Trial Lead.

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Description

Leads function as a component of Boston Scientific's Spinal Cord Stimulation (SCS) systems by delivering electrical stimulation to the nerve structures in the dorsal aspect of the spinal cord, resulting in an inhibition of pain sensation.

The Entrada™ Needle (Model SC-4220-XX) functions as a component of Boston Scientific's Spinal Cord Stimulation (SCS) systems.

Percutaneous Leads

The eight-Contact Percutaneous Leads are available in lengths of 30 cm, 50 cm, and 70 cm. Each Linear Lead has eight Electrode Contacts located near the distal end. Each Contact is 3 mm in length and is spaced 1 mm, 4 mm, or 6 mm from the adjacent Contact.

Trial Leads

The Trial Lead Kit, containing the Linear Lead and the associated components, is intended to be used for the temporary trial phase.

Lead Extension

Lead Extensions are designed to connect the Percutaneous Leads to the 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 IPG.

Infinion™ 16 Lead

The Infinion 16 Percutaneous Lead is available in lengths of 50 cm and 70 cm. Each Lead has 16 Contacts located near the distal end. The Infinion 16 Lead can be connected directly to a 1x16 OR Cable when using the Trial Stimulator. When connecting to an IPG or a 1x8 or 2x8 OR Cable, a single Infinion 16 Lead must be inserted into a Splitter 2x8, which then connects to the IPG's 8 Contact Ports or the 1x8 or 2x8 OR Cable.

Infinion™ CX Lead

The Infinion CX Percutaneous Lead is available in lengths of 50 cm and 70 cm. Each Lead has 16 Contacts located near the distal end and two tails with 8 proximal Contacts. The Infinion CX Lead can be connected directly to a 2x8 OR Cable when using the Trial Stimulator. The Infinion CX Lead may be connected directly to the IPG's 8 Contact Ports.

Infinion™ Pro Lead

The Infinion Pro Percutaneous Lead is available in lengths of 50 cm and 70 cm. Each Lead has 16 Contacts located near the distal end and two tails with 8 proximal Contacts. The Infinion Pro Lead can be connected directly to a 2x8 OR Cable when using the Trial Stimulator. The Infinion Pro Lead may be connected directly to the IPG's 8 Contact Ports. The Infinion Pro Lead has a coiled Lead body between the Y-Junction Boot and the Distal Array.

Lead Splitters

The 2x4 Lead Splitters are designed to connect multiple Percutaneous Leads to the IPG. The Linear Leads may be inserted into a Splitter for a maximum of four Linear Leads per 2-Port IPG and a maximum of eight Leads per 4-Port IPG. Four of the eight Contacts of each Linear Lead will be activated. Two configurations of Splitter 2x4 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. Each Infinion 1x16 Lead requires a Splitter 2x8 to be used with two IPG Ports.

Package Contents

Percutaneous Permanent Lead Kits

- (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

Percutaneous Trial Lead Kit

- (1) Percutaneous Lead with pre-loaded Curved Stylet
- (1) Suture Sleeve
- (1) Insertion Needle with Stylet
- (1) Steering Cap

Lead Extension Kit

- (1) Lead Extension
- (1) Hex Wrench
- (1) Tunneling Tool Assembly

2x4 Splitter Kit

- (1) Splitter
- (1) Hex Wrench

Splitter 2x8 Kit

- (1) Splitter 2x8
- (1) Torque Wrench

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
- (1) Steering Cap

Infinion 16 Trial Lead Kit

- (1) 16 Contact Percutaneous Lead with pre-loaded Curved Stylet
- (1) Suture Sleeve
- (1) Insertion Needle
- (1) Steering Cap

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

Infinion CX Lead Kit

- (1) 16 Contact Percutaneous Infinion CX Lead with pre-loaded Curved Stylet
- (2) Suture Sleeves
- (1) Steering Cap

Infinion CX Trial Lead Kit

- (1) 16 Contact Percutaneous Infinion CX Lead with pre-loaded Curved Stylet
- (2) Suture Sleeves
- (1) Steering Cap

Infinion Pro Lead Kit

- (1) 16 Contact Percutaneous Infinion Pro Lead with pre-loaded Curved Stylet
- (2) Suture Sleeves
- (1) Steering Cap

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.

Specifications and Technical Data

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

Infinion Pro 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	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	Silicone, Polyurethane
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	Silicone, Polyurethane
Conductor Material	MP35N-DFT-28% Ag

Non-Pyrogenic

The devices covered by this IFU meet pyrogen limit specifications.

Instructions for Use

Physician training is required. Boston Scientific also recommends that implanting physicians read all product labeling prior to using our devices.

Preparation

Boston Scientific recommends that healthcare providers who are implanting the Boston Scientific System read all product labeling prior to using the Boston Scientific devices.

The Percutaneous Leads listed under “Product Model Numbers” on page ii, except for the Infinion CX Lead and Infinion Pro Lead, can be placed using the Insertion Needle or the Entrada Needle. The Infinion CX Lead and Infinion Pro Lead must only be placed using the Entrada Needle.

Entrada Needle

The Entrada Needle with peelable sheath is required to insert the Infinion CX Lead and Infinion Pro Lead into the epidural space. The Entrada Needle may also be used with all Percutaneous Leads listed under “Product Model Numbers” on page ii. Reusing the same Entrada Needle to insert a second Lead is not recommended.

Fully Assembled Entrada Needle



Components

Components are marked with dots to indicate use order, and the dots should be in the same direction when assembling the Needle.



Needle Stylet, •



Loss of Resistance (LOR) adaptor, ••

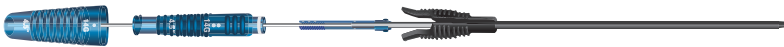


Slotted Needle, •••



Peelable Sheath

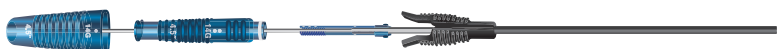
Note: Do not mix components between Entrada 4.5 in and 6.0 in Needles. Needles are clearly labeled with Needle lengths and are also color coded (as they appear on the product, green=6.0 in and blue=4.5 in).



Assembling and Reassembling the Entrada Needle

CAUTION: Do not insert or reinsert the Needle Stylet, LOR adaptor, or Slotted Needle into the sheath while the sheath is inserted within the patient.

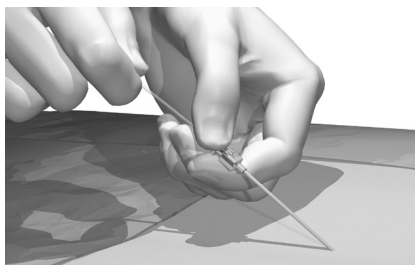
1. Insert the Slotted Needle into the sheath.
2. Insert the LOR adaptor into the Slotted Needle.
3. Insert the Needle Stylet into LOR adaptor and advance forward until fully seated into Needle assembly.



Percutaneous Lead Placement in the Epidural Space

Note: If using an Infinion CX Lead or Infinion Pro Lead, proceed to “Infinion CX Lead and Infinion Pro Lead Placement in the Epidural Space with Entrada Needle” on page 10.

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.

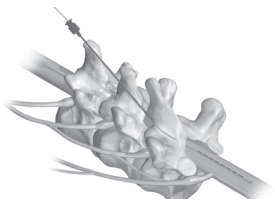
WARNING: The angle of the insertion Needle should be 45° or less. Steep angles increase the insertion force of the Stylet and also present more of an opportunity for the Stylet to pierce the Lead and cause tissue damage.

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 Lead 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 (for example, at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in Lead stabilization.
8. If using a Splitter, proceed to Lead Connection to Splitter in this manual.

—or—

If not using a Splitter, proceed to the instructions for connecting Leads or Extensions to the OR Cable assembly in the appropriate IFU for your SCS System, as listed in your *Reference Guide*.

Infinion CX Lead and Infinion Pro Lead Placement in the Epidural Space with Entrada Needle

Infinion CX Lead and Infinion Pro Lead



The Infinion CX Lead and Infinion Pro Lead have two tails to enable insertion into 8-Contact IPG Ports without the use of the 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 or Infinion Pro Lead. **Do not use a standard 14 gauge introducer or Epimed Needle to introduce the Infinion CX**

Lead or Infinion Pro Lead. Use only the Entrada Needle with peelable sheath to introduce the Infinion CX Lead or Infinion Pro Lead into the epidural space.

An Anchor must be pre-loaded on the distal end of the Infinion CX Lead or Infinion Pro Lead prior to inserting the Lead into the Entrada Needle. When using an Anchor or Suture Sleeve with the Infinion CX Lead or Infinion Pro Lead, the Stylet may be in place within the Lead when the Anchor is loaded on the Lead. Ensure that Stylet is removed from the Lead prior to securing the Anchor.

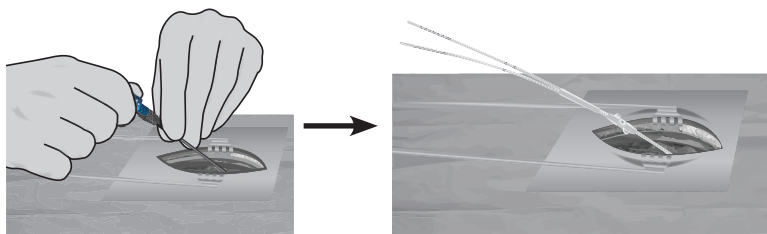
Infinion CX Lead and Infinion Pro Lead Placement in the Epidural Space with Entrada Needle

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 Entrada Needle is fully assembled by holding onto the sheath hub and applying forward pressure on the Stylet cap cover.

CAUTION: Do not bend the Entrada Needle. Bending the Entrada Needle may cause the Stylet or LOR Adapter to become jammed in the Needle assembly and difficult to remove.

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.

If cutting down after inserting the Entrada Needle, ensure that the sheath is in place and do not damage the sheath.



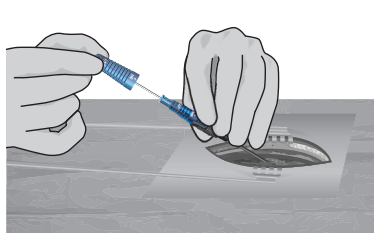
4. Under fluoroscopic guidance, place the Entrada Needle into the epidural space with the 14G marking facing up using an angle of 45° or less.

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.

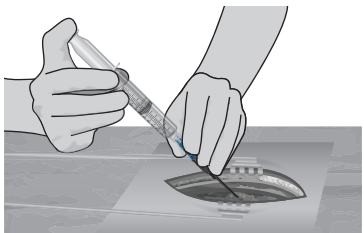
WARNING: The angle of the insertion Needle should be 45° or less. Steep angles increase the insertion force of the Stylet and also present more of an opportunity for the Stylet to pierce the Lead and cause tissue damage.

Note: If the Needle must be repositioned during this procedure, or if the sheath becomes damaged, reassemble the Needle outside of the body with a new sheath, see “Assembling and Reassembling the Entrada Needle” on page 9.

5. Remove the Needle Stylet from the insertion Needle and verify entry into the epidural space using the standard technique.

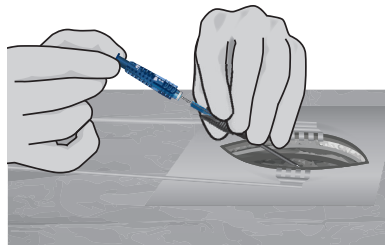


Remove Needle Stylet



Verify entry into the epidural space.

6. 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 the Lead. Pull the LOR adaptor straight out from the Slotted Needle without twisting or bending.
- Recommended: Hold the Slotted Needle in place while removing the LOR adaptor.



Note: An Anchor must be loaded over the distal end of the Infinion CX Lead or Infinion Pro 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 be fully inserted into the Lead. Slowly insert the Infinion CX Lead or Infinion Pro Lead into the Slotted Needle, directing the distal Lead tip into the Needle lumen.

OPTIONAL. Cover Slotted Needle with finger to aid in insertion of Infinion CX Lead or Infinion Pro Lead into Slotted Needle lumen.

OPTIONAL. If Needle steering within the Slotted Needle is not needed, remove Slotted Needle and insert Lead directly into sheath.



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 or Infinion Pro 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 or Infinion Pro 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 (at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in Lead stabilization.
11. Proceed to the instructions for connecting to the OR Cable assembly in the appropriate IFU for your SCS System, as listed in your *Reference Guide*.

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 Setscrews of the Splitter by using the Hex Wrench provided, turning counterclockwise.

Note: • *The Setscrew should only be loosened to an amount sufficient to insert a Lead.*
• *Do not excessively loosen the Setscrew. This may cause the Setscrew 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 Setscrew at this time.
6. Proceed to the instructions for connecting to the OR Cable assembly in appropriate IFU for your SCS System, as listed in your *Reference Guide*.
7. Check connections with an impedance measurement. If the impedance is satisfactory proceed to "Intraoperative Stimulation Testing" on page 15 to confirm proper Lead location.

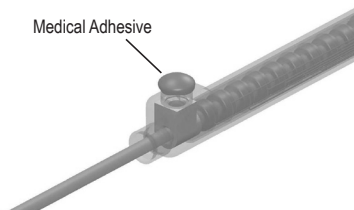
Note: *Do not tighten Setscrew mechanical lock before intraoperative stimulation testing.*

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 Setscrew 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. For intraoperative testing, proceed to the instructions for connecting to the Trial Stimulator in the appropriate IFU for your SCS System as listed in your *Reference Guide*.

—or—

To connect to an IPG, refer to the IPG instructions in the appropriate IFU for your SCS System, as listed on your *Reference Guide*.

Intraoperative Stimulation Testing

Note: The following steps are for procedural reference only. For detailed stimulation testing procedures and guidelines refer to the appropriate programming manual for your SCS system as listed in the *Reference Guide*.

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 Programming software. Refer to the appropriate programming manual for your SCS System as listed in your *Reference 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 Contacts. Impedances, indicated by an x or an orange circle in your Programming Software, are considered to be resultant from open or unconnected wires. Refer to your *Programming Manual* for additional information.
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 Setscrew counter clockwise to loosen.

Note: • *The Setscrew should only be loosened to an amount sufficient to insert a Lead.*
• *Do not excessively loosen the Setscrew. This may cause the Setscrew to dislodge, rendering the Splitter unusable.*

Option A: For a Temporary Trial, proceed to “Securing the Trial Lead” on page 16.

Option B: For a Permanent Trial, proceed to “Permanent Lead Anchoring and Tunneling” on page 17.

Option C: For a Permanent IPG Implantation using Percutaneous Leads, proceed to “Permanent Lead Anchoring and Tunneling” on page 17.

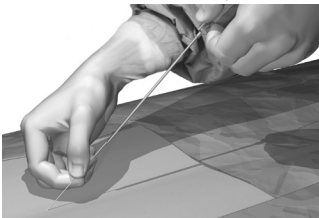
Option D: For a Permanent IPG Implantation using paddle Leads, proceed to “Permanent Lead Anchoring and Tunneling” in the *Surgical Leads IFU*.

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 Trial Lead, proceed to “Securing the Trial Infinion CX Lead”.*

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, refer to “Lead Connection to Splitter” on page 14.
6. For temporary Lead trials, refer to the instructions for connecting to the OR Cable assembly and External Trial Stimulator in the appropriate IFU for your SCS System as listed in your *Reference Guide*.

Securing the Trial Infinion CX 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.

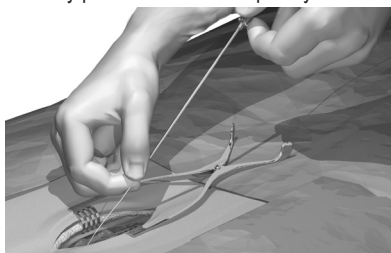
2. Snap sheath wings apart and peel sheath out of insertion site.
3. Remove the Stylet from the Lead.
4. If desired, a suture may be used to close the wound and stabilize the Lead.
5. Place and tape a stress relief loop and dress the wound.
6. For temporary Lead trials, refer to the instructions for connecting to the OR Cable assembly and External Trial Stimulator in the appropriate IFU for your SCS System as listed in your *Reference Guide*.

Permanent Lead Anchoring and Tunneling

Removing the Insertion Needle

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

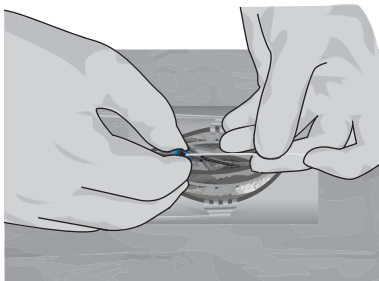
1. Cut down around the insertion Needle to provide access for anchoring the Lead.
2. Carefully withdraw the insertion Needle from the epidural space by slowly pulling the Needle up towards the proximal end of the Lead while holding the Lead in place.
3. Once the insertion Needle tip is exposed, hold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



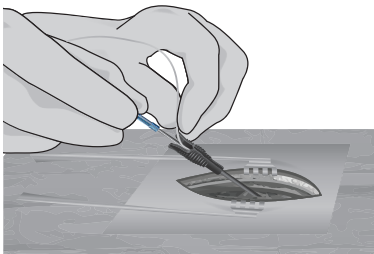
Removing the Entrada Needle

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.

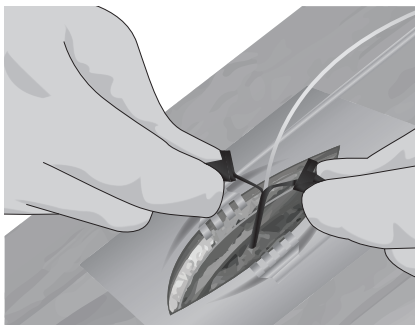


Stabilize Lead in line with the slot.



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 or Infinion Pro Lead, the Anchor or Suture Sleeve must be loaded over the distal end of the Lead prior to inserting the Infinion CX Lead or Infinion Pro Lead into the Entrada Needle. For the Infinion CX Lead and Infinion Pro Lead, the Stylet may be in place within the Lead when the Anchor is loaded on the Lead, however, the Stylet must be removed before the Anchor is locked down.

Refer to the Instructions 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.

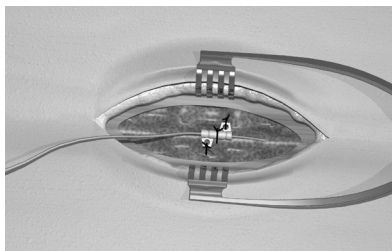
CAUTION: Do not use polypropylene sutures as they may damage the Suture Sleeve. Do not suture directly onto the Lead, Splitter, or use a hemostat on the Lead body. This may damage the Lead insulation.

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.

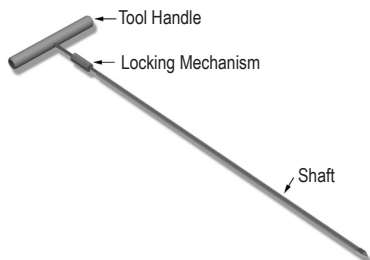
6. For Permanent Trials, proceed to “Tunneling the Lead or Lead Extension” on page 19.
7. For permanent IPG implantation, refer to IPG instructions in the appropriate IFU for your SCS system as listed in your *Reference Guide*.



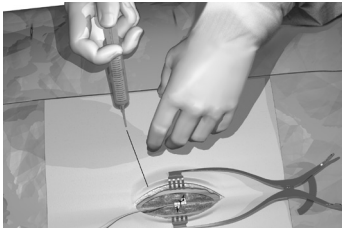
Tunneling the Lead or Lead Extension

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

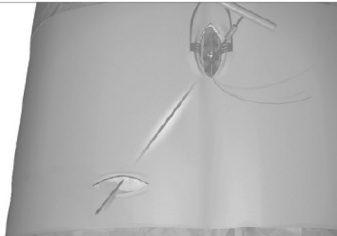
1. Attach the tunneling tool handle to the shaft by turning the locking mechanism clockwise.



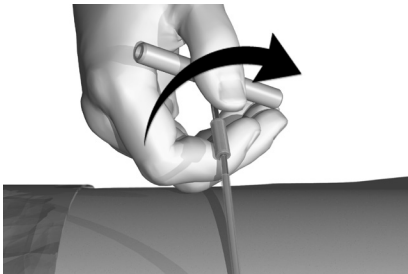
2. Mark the desired route of the tunnel.



3. Administer the appropriate local anesthetic along the tunneling path.
4. 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 14. Otherwise, proceed to “Connecting the Lead Extension” on page 21.
11. For Permanent IPG Implantation, if Extensions are used, proceed to the instructions for “Connecting the Lead Extension” on page 21.
12. For Permanent IPG Implantation, if Splitters are used, proceed to the instructions for “Lead Connection to Splitter” on page 14.
13. For Permanent IPG Implantation, refer to the IPG instructions in the appropriate IFU for your SCS system as listed in your *Reference Guide*.

Note: The following Codman Disposable Catheter Passers may be used in place of the Boston Scientific Tunneling Tool except for the Infinion CX Lead and Infinion Pro Lead:

REF 82-1515 (36 cm); REF 82-1516 (55 cm); REF 82-1517 (65 cm)

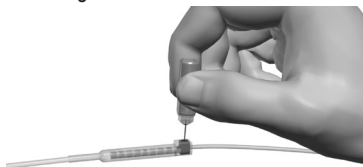
Note: When using a Codman Disposable Catheter Passer, tunnel from the IPG pocket to the midline incision using the standard technique.

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.



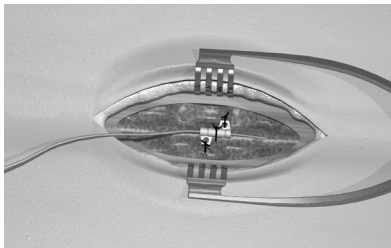
Note: Ensure that the Hex Wrench is fully seated in the Setscrew before tightening.

Note: 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 OR Cable Connector or External Trial Stimulator in the appropriate IFU for your SCS System, as listed in your *Reference Guide*.



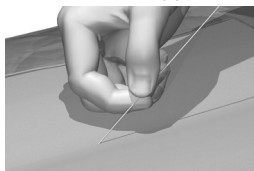
8. For Permanent Implant, close the midline incision, and proceed to instructions for connecting to the IPG in the appropriate IFU for your SCS System, as listed in your *Reference Guide*.

Lead/Extension/Splitter Removal

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

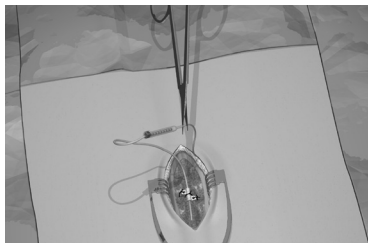
1. Clip sutures if used to secure the trial Lead(s) in place.
2. Remove the Lead(s) and discard.



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 9 or "Infinion CX Lead and Infinion Pro Lead Placement in the Epidural Space with Entrada Needle" on page 10.
4. To replace the trial Lead(s) with a paddle Lead proceed to instructions for "Surgical Paddle Lead Placement in the Epidural Space" in the *Surgical Leads IFU*.

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 IPG Implantation instructions in the appropriate IFU for your SCS system as listed in your *Reference Guide*.

Option C: Splitter Removal

1. If the Splitter has been implanted, open the incision to expose the Lead and Splitter junction.
2. Loosen the connector Setscrew on the Splitter receptacles using the Hex Wrench provided.
3. Disconnect and discard the Splitter components.

Device Disposal

After use or in the case of explantation, devices may contain biohazardous substances. Devices that contain biohazardous substances are considered biohazardous waste and should be stored in a biohazard container that is labeled with the biological hazard symbol until disposed of in accordance with hospital, administrative and/or local government policy. Untreated biohazardous waste should not be disposed of in the municipal waste system. Alternatively, biohazardous waste may be disposed of utilizing a certified facility for biohazardous waste for proper treatment in accordance with hospital, administrative, and/or local government policy. Alternatively, if you would like to return this device to Boston Scientific Corporation, contact your sales representative for return instructions.

Post-Procedure

Any serious incident that occurs in relation to these devices should be reported to Boston Scientific and relevant local regulatory authority.

Programming with the Infinion 16 Lead, Infinion CX Lead, and Infinion Pro Lead

For detailed programming instructions, refer to the appropriate *Bionic Navigator™ Software Guide* or the *Bionic Navigator™ 3D System Programming Manual*.

If using the Bionic Navigator 3D Software:

When the Infinion 16 Lead is used with the Splitter 2x8 and placed properly into the Ports of the 4-Port IPG (the Splitter tail with laser etched bands to the left Ports A or C and the unmarked Splitter tail to the right Ports B or D) the laser marked Splitter tail corresponds to Contacts 1-8 on the distal end of the Infinion 16 Lead and the unmarked Splitter tail corresponds to Contacts 9-16 of the Infinion 16 Lead.

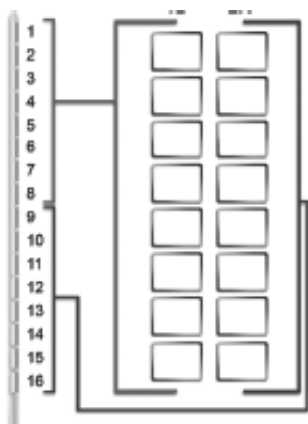
When the Infinion CX Lead or Infinion Pro Lead is placed properly in the Ports of the 4-Port IPG (tail with one marker band to the left Ports A or C and tail with two marker bands to the right Ports B or D) the tail with one marker band corresponds to Contacts 1-8 on the distal end of the Infinion CX Lead or Infinion Pro Lead and the tail with two marker bands corresponds to Contacts 9-16 of the Infinion CX Lead or Infinion Pro Lead.

If using Bionic Navigator Software:

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 or Infinion Pro 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 or Infinion Pro 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 or Infinion Pro Lead (Contacts 9-16) will correspond with Contact 9-16 on the right side of the Bionic Navigator software display.

The diagram below 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, Infinion CX Lead, or Infinion Pro 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*.



Boston Scientific

Advancing science for life™



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