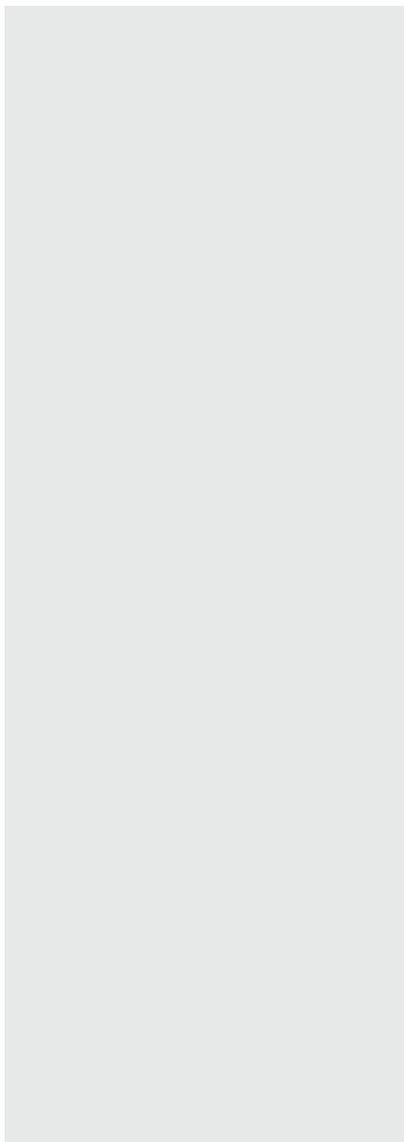


Boston Scientific

Advancing science for life™

Surgical Leads

Directions 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

For Indications and related information, see the *Indications DFU* or *Clinician Manual* for your spinal cord stimulator system. For contraindications, warnings, precautions, adverse events summary, physician instructions, sterilization, component disposal, and contact information for Boston Scientific, refer to the *Information for Prescribers DFU* or *Clinician Manual* for your spinal cord stimulator system.

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

For other device-specific information not included in this manual, labeling symbols, and warranty, refer to the appropriate DFU for your SCS system as listed on your *Reference Guide*.

Product Models Numbers

Model Numbers	Description
SC-3138-xx	xxcm 8 Contact Extension Kit
SC-8120-xx	Artisan™ xxcm 2x8 Surgical Lead Kit
SC-8216-xx	Artisan xxcm 2x8 Surgical Lead Kit
SC-8336-xx	CoverEdge™ 32 xxcm 4x8 Surgical Lead Kit
SC-8352-xx	CoverEdge X 32 xxcm 4x8 Surgical Lead Kit

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Description

The surgical paddle leads function as a component of Boston Scientific's Spinal Cord Stimulation systems 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

2x8 Surgical Paddle Lead

The 2x8 Surgical 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 mm in size. 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.

4x8 Surgical Paddle Lead

Two versions of the 4x8 Surgical Lead are available, the CoverEdge™ 32 Surgical Lead with tightly-spaced electrodes and the CoverEdge 32 X Surgical Lead with widely-spaced electrodes. Both versions of the 4x8 Surgical Lead are available in lengths of 50 cm and 70 cm. The distal (paddle) end of the lead has four columns of 8 evenly spaced planar electrodes. Each electrode is 1x3.4 mm in size. On the proximal side, the lead employs 4 tails. The end of each tail has 8 evenly spaced contacts; identical to the percutaneous leads. Each tail of the paddle lead is uniquely identified with marker bands. Reading from left to right with the electrodes faced down, the first tail has one marker band, the second has two, the third has three, and the fourth has four marker bands. Each tail corresponds to the respective column of contacts on the paddle. Each tail can be inserted into an IPG, or into a lead extension.

Note: *The 4x8 Surgical Lead is intended for use with the Precision Spectra™ or Spectra WaveWriter™ Systems only.*

Lead Extension

Lead Extensions are designed to connect the percutaneous and paddle 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. The extension can be connected to either the Trial Stimulator (via an OR Cable Assembly included in the Leads Kit) or directly to an IPG.

Package Contents

Lead Extension Kit

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

2x8 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

4x8 Surgical Paddle Lead Kit

- (1) Paddle Lead
- (6) Suture Sleeves
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Manual

Specifications and Technical Data

2x8 Surgical Lead

Part	Specification
Lead Lengths	50, 70 cm
Lead Shape	2 x 8 paddle
Lead Width	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

4x8 Surgical Lead

Part	Specification
Lead Lengths	50, 70 cm
Lead Shape	4 x 8 paddle
Lead Width	9 mm (tightly-spaced version), 10 mm (widely-spaced version)
Number of Electrode Contacts	32
Electrode Size - Width x Length	1 mm x 3.4 mm
Electrode Spacing (longitudinal)	1 mm (tightly-spaced version), 3.2 mm (widely-spaced version)
Contact Material	Platinum/Iridium
Insulation Material	Silicone, Polyurethane
Conductor Material	MP35N-DFT-28% Ag

Lead Extension

Part	Specification
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

Registering the Leads

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

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.

USA 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
25129 Rye Canyon Loop
Valencia, California 91355, USA
Attention: Customer Service Department

Instructions for Use

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

Lead and Lead Extension Handling and Storage

- Avoid damaging the lead with sharp instruments or excessive force during surgery.
- Do not sharply bend or kink the lead or extension.
- Do not tie suture(s) directly to the lead or extension; use the provided suture sleeves.
- 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.

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.

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. Ensure adequate space prior to introducing the paddle lead.

OPTIONAL: A Passing Elevator or Paddle Blank may be used prior to introducing the 2x8 Paddle lead or 4x8 Paddle lead into the epidural space (respectively). Select the appropriately sized Paddle Blank for use with the 4x8 Paddle. Passing elevators and Paddle Blanks 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. Grasp the tails of the Paddle Blank with your fingertips as you would hold the paddle lead. While avoiding pressure on the thecal sac and spinal cord, carefully and gently introduce the Passing Elevator or Paddle Blank at a shallow angle into the epidural space along the midline. When the Passing Elevator or Paddle Blank reaches the target site for the lead, gently remove the elevator or blank.

CAUTION: Do not use the *Passing Elevator* or *Paddle Blank* 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.



6. Once the Paddle lead is at the appropriate vertebral level, use standard technique to identify leads and proceed to the instructions for Connecting to the OR Cable in the appropriate DFU for your SCS system as listed in your *Reference Guide*.

Intraoperative Stimulation Testing

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

1. 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.

2. Using test stimulation, enlist patient feedback to verify lead placement and pain coverage.

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

3. Repeat steps 1 and 2 if the lead has been repositioned.
4. When the desired paresthesia is achieved:
 - a) Turn the Trial Stimulator off.
 - b) Unlock each OR cable connector and disconnect from the lead(s).
5. Record the lead position by capturing a fluoroscopic image to be sure the leads have not moved. Retest if necessary.

6. Proceed to “Anchoring the Lead.”

Note: 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.

Anchoring the Lead

Leads can be permanently anchored with a suture sleeve or with an anchor. 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. Place a suture sleeve over the lead and down to the supraspinous ligament or deep fascial tissue.
2. 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.

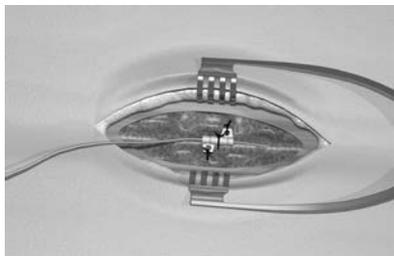
CAUTION: Do not use polypropylene sutures as they may damage the suture sleeve. Do not suture directly onto the lead or use a hemostat on the lead body. This may damage the lead insulation or result in lead fracture.

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

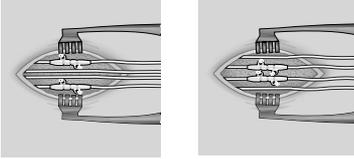
3. Suture the sleeve to the supraspinous ligament or deep fascia through the suture sleeve holes.
4. Tie multiple sutures as tightly as possible around the suture sleeve to secure it to the lead.

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

5. For Permanent Trials, proceed to the instructions for “Tunneling the Lead or Lead Extension” on page 7.
6. For Permanent IPG Implantation, proceed to the instructions for “IPG Implantation” in the appropriate DFU for your SCS system as listed in your *Reference Guide*.



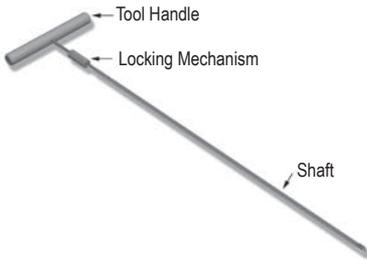
Example of 4x8 Surgical Lead secured by two anchors:



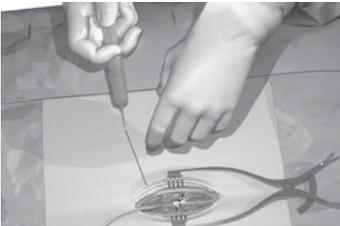
Tunneling the Lead or Lead Extension

Note: If using a 4x8 Surgical Lead, 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.



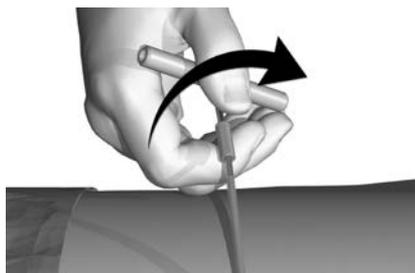
2. Mark the desired route of the tunnel.



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.
10. For Permanent Trials, proceed to “Connecting the Lead Extension” on page 8.
11. For Permanent IPG Implantation, if extensions are used, proceed to the instructions for “Connecting the Lead Extension” on page 8.
12. For Permanent IPG Implantation, refer to instructions for connecting to the IPG in the appropriate DFU 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 for the 2x8 Surgical Lead only:

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 until it stops and the retention ring (long ring) is under the set screw.

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 set screw and/or gently rotate the lead to help advance the proximal end.

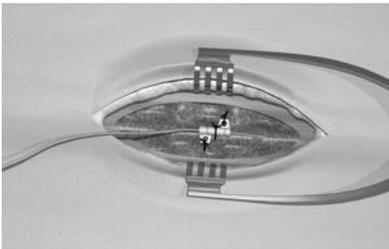
2. Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.
3. Using the hex wrench supplied, turn the extension connector set screw clockwise until it clicks, indicating lock.



- 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 instructions for connecting to the OR Cable Connector in the appropriate DFU for your SCS System as listed in your *Reference Guide*.



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

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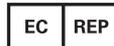
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