

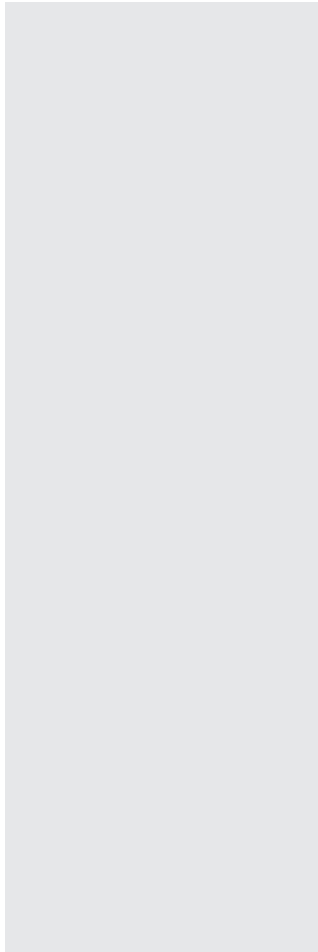
**Boston
Scientific**

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Clinician Trial Manual

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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Content: 91171768 REV AB

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Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only.

Additional Information

For Indications and related information, see the *Indications DFU*. For contraindications, warnings, precautions, adverse events summary, physician instructions, sterilization, storage and handling, component disposal, and contact information for Boston Scientific, refer to the *Information for Prescribers DFU* for your spinal cord stimulator system. For other device-specific information not included in this manual, labeling symbols, and warranty information, refer to the appropriate DFU for your SCS System as listed on your *Reference Guide*.

USA For FCC rules and for clinical studies supporting the clinical use of the neurostimulation system, refer to the *Information for Prescribers* manual.

Product Model Numbers

Model Number	Description
SC-4108	OR Cable 2x8, 213 cm and Extension
SC-4116	OR Cable 1x16, 213 cm and Extension
SC-5132	Trial Stimulator
SC-5160	Trial Stimulator
SC-5160R	Trial Stimulator (Refurbished)
SC-6360-32	Patient Trial Belt

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OR Cable Description

CAUTION: Do not immerse the OR Cable or extension in water or other liquids. The OR Cable and extension are intended for one-time only use; do not resterilize.

The OR Cable is designed for two purposes:

- Connect the lead to the Trial Stimulator (see: "Trial Stimulator Description" on page 7) to facilitate intraoperative stimulation testing from outside of the sterile field.
- Connect the lead to the Trial Stimulator during the trial phase.

The 2x8 OR Cable connects to (2) 8-contact leads. (When referring to the use of the OR Cable, a lead refers to the proximal end of a lead, splitter, or extension.) The 2x8 OR Cable is compatible with any Boston Scientific lead with an 8-contact proximal end.

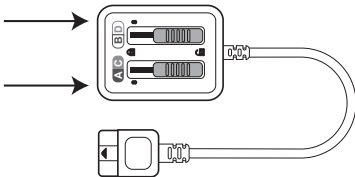


Figure 1: 2x8 OR Cable

The 1x16 OR Cable connects to a 1x16 contact lead.

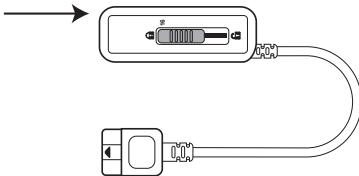


Figure 2: 1x16 OR Cable

The OR Cable extension may be used when desired to connect the OR Cable to the Trial Stimulator.

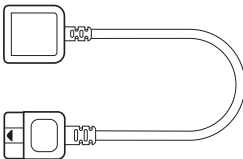


Figure 3: OR Cable Extension

Package Contents

OR Cable Kit (2x8)

(1) OR Cable (2x8)

(1) Extension

(1) Manual

OR Cable Kit (1x16)

(1) OR Cable (1x16)

(1) Extension

(1) Manual

Instructions for Use

Boston Scientific recommends that implanting physicians read all product labeling prior to using our devices.

CAUTION:

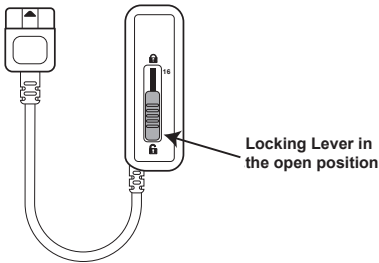
- Keep the Trial Stimulator dry. It should not be exposed to moisture.
- Do not connect the Trial Stimulator to any other device except to the OR Cables provided with it.
- Keep the Trial Stimulator away from pets, pests, and children to avoid damage to the device.

After the Trial, an applicable Boston Scientific SCS system may be used in the permanent implantation procedure:

- Spectra WaveWriter™ SCS System
- Precision Spectra™ SCS System
- Precision Novi™ SCS System
- Precision Montage™ MRI SCS System

CAUTION: Always turn the Trial Stimulator off and decrease the strength of stimulation to zero before connecting or disconnecting the OR Cable or extension.

1. Verify that the Trial Stimulator is off.
2. Check that the locking lever on the OR Cable connector is in the open position, marked with the unlocked symbol.



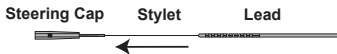
3. If necessary, wipe fluids from the proximal ends of the leads.
4. Insert the leads into the OR Cable Connector. See instructions on page 3.

Insert the Leads into the OR Cable Connector

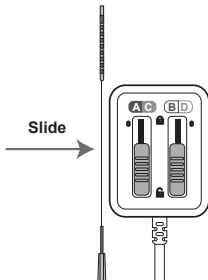
You can insert the leads into the OR Cable Connector with the steering cap on or off.

1. To insert the lead with the steering cap on:
 1. To insert the lead with the steering cap off, remove the steering cap from the stylet.

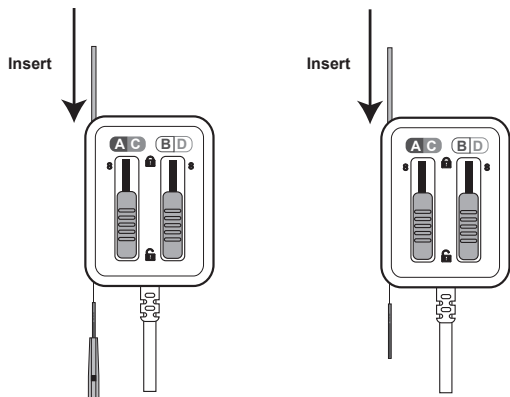
- a. Pull the stylet out slightly.



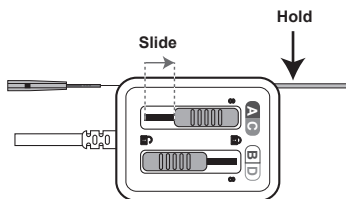
- b. Slide the stylet through the side slot in the OR Cable connector.



2. Insert the lead into the port of the OR Cable connector until it stops.



3. While continuing to hold the lead in place, slide the lever to the locked position.



4. Repeat this for additional leads (if applicable).

Note: Once the lead is secured in the connector, the stylet can be rotated in, but not removed from the lead.

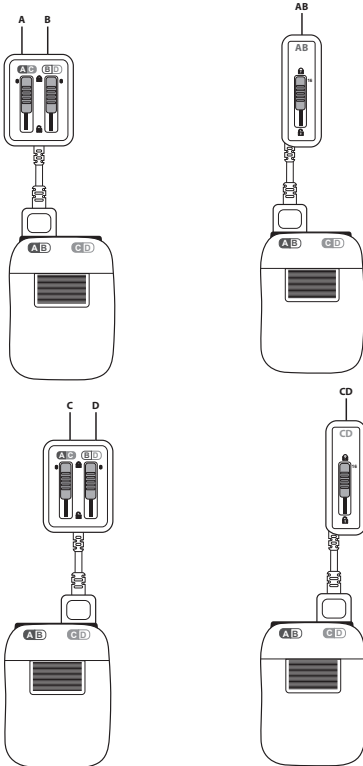
5. Connect to the Trial Stimulator. Refer to instructions on page 5.
6. For Intraoperative Testing instructions, proceed to the instructions for Intraoperative Testing in the appropriate Leads manual.

Trial Stimulator Description

The Trial Stimulator is a temporary external spinal cord stimulator that is connected via the OR cable(s) to the lead(s) placed along the spinal cord. This external system is used to test how effective stimulation is in relieving a patient's pain.

Connect to the Trial Stimulator

1. Plug the OR Cable or extension into the desired Trial Stimulator port(s).
2. Note connections from lead to OR Cable to Trial Stimulator to facilitate testing and programming. See the example below. Note: Stickers may be used to label OR Cables.



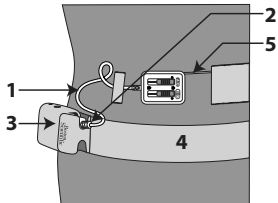
3. Refer to “Securing the Trial Lead” in the appropriate Leads Directions for Use.

If desired, secure the OR Cable to the skin using standard dressing technique.

- OR Cables may be placed side by side and gauze may be used as padding. The area may be covered with an adhesive and secured with a bandage or dressing.

Fitting the Trial Belt to the Patient

1. Determine which side of the patient is best for placement of the Trial Stimulator.
2. Fit the trial belt to the patient with the pocket opening facing the patient's back.
3. Fasten the belt to the patient.
4. If desired, cut off excess length of the trial belt.
5. Place the Trial Stimulator in the belt pocket with the stimulation ON/OFF button facing up.
6. If OR Cable extension(s) were used, ensure that they are no longer connected to the OR Cable(s).
7. Connect the OR Cable(s) to the Trial Stimulator.
8. Fasten the belt pocket to secure the Trial Stimulator.

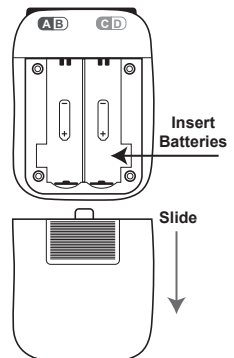


- 1– OR Cable
- 2– OR Cable Connection to Trial Stimulator
- 3– Trial Stimulator
- 4– Trial Belt
- 5– Lead or Extension


Replacing the Trial Stimulator Battery

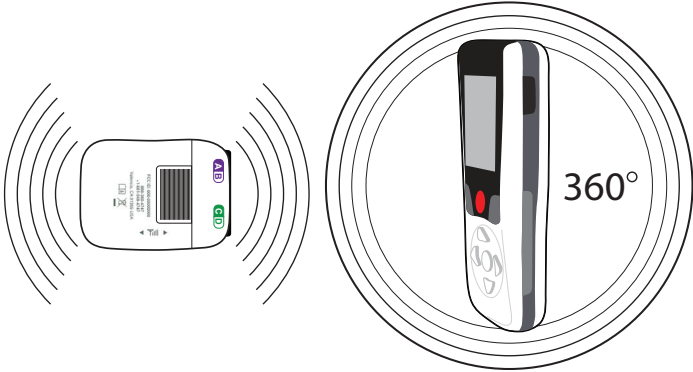
The Trial Stimulator battery has a typical service life of 7 days.

1. Be sure that stimulation is off (the indicator light is not blinking) before opening the Trial Stimulator's battery compartment.
2. On the rear of the Trial Stimulator, push in slightly and slide down the battery compartment cover.
3. Place the two new AA batteries in the slots, matching the positive (+) and (-) markings in the compartment.
4. Align the battery compartment cover on the case and slide the cover into position until it snaps closed.



Telemetry Symbol for Optimal Device Orientation

A Telemetry Symbol ◀  ▶ on the back of the Trial Stimulator indicates the best orientation of the Trial Stimulator, with relationship to the Remote Control and Programming Wand, for optimal telemetry (communication between the devices).



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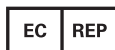
Legal Manufacturer

Boston Scientific Neuromodulation
Corporation
25155 Rye Canyon Loop
Valencia, CA 91355 USA
(866) 789-5899 in US and Canada
(661) 949-4000, (661) 949-4022 Fax
(866) 789-6364 TTY
www.bostonscientific.com
Email: neuro.info@bsci.com



Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666



EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway, Ireland
T: +33 (0) 1 39 30 97 00
F: +33 (0) 1 39 30 97 99

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