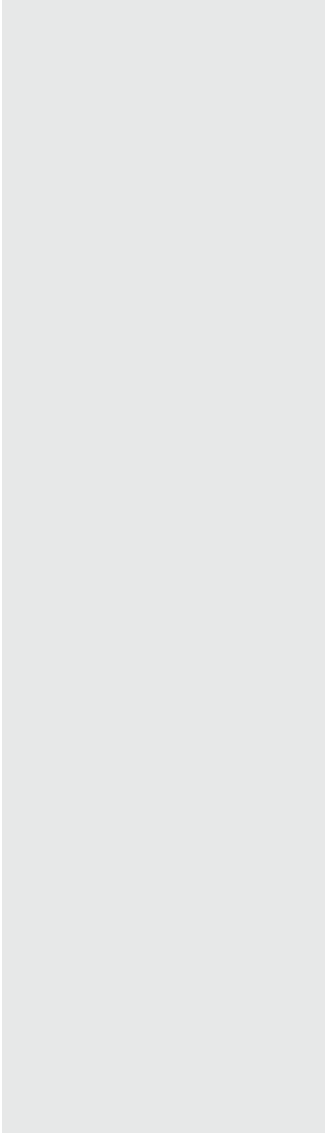


Precision™ S8 Adapter

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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Trademarks

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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.

Product Model Numbers

Model Numbers	Description
SC-9208-15	Precision™ S8 Adapter, 15 cm
SC-9208-55	Precision S8 Adapter, 55 cm
SC-9208-15E	Precision S8 Adapter, 15 cm Trial
SC-9208-55E	Precision S8 Adapter, 55 cm Trial

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

[USA] 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.

Intended Use

The Precision™ S8 Adapter is a 1 x 8 in-line connector that is designed to connect specific St. Jude (Abbott) leads to the Boston Scientific SCS implantable pulse generators, OR Cables, and lead extensions, as part of a spinal cord stimulation procedure.

Lead Compatibility

The Boston Scientific Precision S8 Adapter is compatible with the following St. Jude (Abbott) leads and lead extensions:

- 3283/3286/3268/3269 Lamitrode S8
- 3280 Lamitrode 8
- 3244/3262/3263 Lamitrode 44
- 3245/3264/3265 Lamitrode 44C
- 3208 Lamitrode Tripole 8
- 3210 Lamitrode Tripole 8C
- 3288 Lamitrode 88
- 3289 Lamitrode 88C
- 3214 Lamitrode Tripole 16C
- 3219 Lamitrode Tripole 16
- 3228 Penta
- 3183/3186/3189/3191 Octrode
- 3086 Octrode Trial Lead Kit
- 2283 8-channel Adapter
- 3341 / 3342 / 3343 / 3346 Dual 4 Extension
- 3382 / 3383 / 3386 Single 8 Extension

Package Contents

- (1) Precision S8 Adapter
- (1) Torque wrench
- (1) Clinician eDFU card or DFU
- (1 set) Product identification stickers
- (1) Device registration form

Warning

- The Precision S8 Adapter has not been tested for electromagnetic compatibility or for safety in an MRI environment.

Cautions

- 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 reuse, reprocess, or resterilize.
- Do not use if the product is past the labeled expiration date.
- Do not use if labeling is incomplete or illegible.
- Do not bend, kink, or stretch the extension or Adapter; this may break its wires or connections. Broken wires or connections may create an open circuit, resulting in component failure, loss of stimulation, and potential surgical intervention.
- Do not retract the setscrew completely as the setscrew may fall out.
- Minimize the number of torque-wrench insertions into the Precision S8 Adapter to prevent damage to the septum seal plug.

Directions for Use

1. Refer to the appropriate St. Jude (Abbott) product labeling for instructions on opening the midline incision and explanting St. Jude (Abbott) lead extensions or IPG.
2. Carefully open the Precision S8 Adapter package and transfer the contents of the inner tray to the sterile field.
3. Ensure that the St. Jude (Abbott) lead is clean and not damaged.
4. Retract the setscrews in all Adapters: Insert the torque wrench into the septum containing the setscrew and turn the torque wrench counter-clockwise (Figure 1).

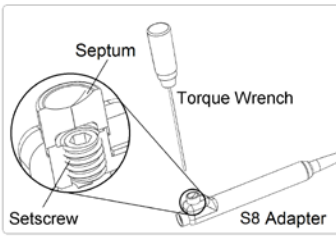


Figure 1: Location of setscrew in the Precision S8 Adapter.

5. Ensure that stimulation is OFF before connecting to the Precision S8 Adapter.
6. Ensure that the leads are clean before inserting them into the Precision S8 Adapter.
7. To insert the lead into the adapter, grip the adapter at the distal end near the setscrew and grip the lead on the proximal contact array (Figure 2). Without bending, gently push the lead into the adapter, one contact at a time. Do not grip the lead above the contact array during insertion.

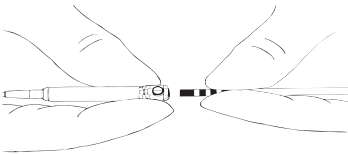


Figure 2: Connecting a Precision S8 Adapter to a St. Jude (Abbott) lead.

8. Use one Precision S8 Adapter for each 8-contact St. Jude (Abbott) lead tail (Figure 3).

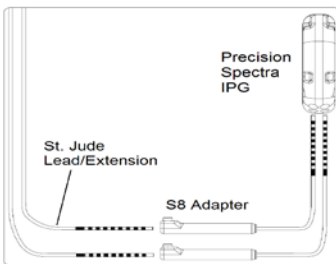


Figure 3: Connection of Precision S8 Adapters to leads and IPG.

9. Ensure that the proximal end of the Precision S8 Adapter is clean then:

- For permanent implant procedures, insert the proximal end into a BSN Extension or BSN IPG, referring to the section “Connecting the Lead, Extension, Splitter or Connector to the IPG” found in the IPG Directions for Use or “Connecting to the IPG” in the Clinician Manual for your spinal cord stimulator system.
 - For trial procedures, insert the proximal end into a BSN Extension or BSN OR Cable, referring to instructions for connecting the External Trial Stimulator (ETS) in the Trial Manual for your spinal cord stimulator system. The Precision S8 Adapter can be connected to a Boston Scientific ETS in the same manner as a Boston Scientific lead or extension. Use standard aseptic dressing technique at the exit site and at the Adapter / lead junction for the duration of the trial period.
10. Tighten the setscrew in the Precision S8 Adapter until the torque wrench clicks, indicating the setscrew is fully secured.
 11. To program leads, refer to the contact-mapping diagram (Figure 4) and instructions provided in the *Programming Manual* or *Bionic Navigator™ Software Guide* provided for your spinal cord stimulator system.



Figure 4: Contact mapping with the Precision S8 Adapter.

12. Complete the device registration form included in the Precision S8 Adapter package. Use the product identification stickers, where necessary.

Specification and Technical Data

Part	Specification
Adapter Lengths	15, 55 cm
Adapter Diameter	1.3 mm
Number of Electrode Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N-DFT-28% Ag

Customer Service - USA

In USA, to order replacement parts, or for answers to any questions you might have, please contact the Customer Service Department:

- Phone: (866) 360-4747, +1 (661) 949-4747
- Fax: +1 (661) 949-4022
- Boston Scientific Neuromodulation
25155 Rye Canyon Loop
Valencia, CA 91355, USA

Outside USA, if you have a specific question or issue, please contact your healthcare professional.

Customer Service - Outside USA

If you have any other questions or need to contact Boston Scientific, choose your locality from the contact list at the end of this document.

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Boston Scientific

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