Precision™ M8 Adapter
Directions for Use
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.

Additional Information
For contraindications, labeling symbols, warranty, or other device-specific information not included in this manual, refer to the appropriate DFU for your SCS System as listed on your Reference Guide.

Product Model Numbers

<table>
<thead>
<tr>
<th>Model Numbers</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SC-9218-15</td>
<td>Precision M8 Adapter, 15 cm</td>
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<tr>
<td>SC-9218-55</td>
<td>Precision M8 Adapter, 55 cm</td>
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<tr>
<td>SC-9218-15E</td>
<td>Precision M8 Adapter, 15 cm Trial</td>
</tr>
<tr>
<td>SC-9218-55E</td>
<td>Precision M8 Adapter, 55 cm Trial</td>
</tr>
</tbody>
</table>
Intended Use

The Precision™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® leads to the Boston Scientific SCS implantable pulse generators, OR Cables, leads, and lead extensions, as part of a spinal cord stimulation procedure.

Lead Compatibility

The Boston Scientific Precision M8 Adapter is compatible with the following Medtronic leads and lead extensions:

- Specify™ 2x8 Model 39286
- Specify 5-6-5 Model 39565
- 1x8 Compact Model 3778, 3878
- 1x8 Standard Model 3777, 3877
- 1x8 Sub-Compact Model 3776, 3876
- Test: 1x8 Compact Model 3874
- Test: 1x8 Standard Model 3873
- Test: 1x8 Sub-Compact Model 3875
- Model 37081 Extension
- Model 37083 Extension
- Model 37082 Extension
- Vectris™ SureScan® MRI 1x8 Subcompact Model 977A160, 977A175, 977A190
- Vectris SureScan MRI 1x8 Compact Model 977A260, 977A275, 977A290
- Vectris SureScan MRI Trial Leads Model 977D160, 977D260

**WARNING:** The Vectris Lead has not been tested for compatibility with an MRI environment when used with the Boston Scientific SCS Systems via the Precision M8 adapter. MRI scanning under conditions different than those in the labeling can result in severe patient injury.

Package Contents

- (1) Precision M8 Adapter
- (1) Torque wrench
- (1) Clinician eDFU card or DFU
- (1 set) Product identification stickers
- (1) Device registration form

Med A is sold separately.

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 M8 Adapter to prevent damage to the septum seal plug.
1. Refer to the appropriate Medtronic product labeling for instructions on opening the midline incision and explanting Medtronic lead extensions or IPG.

2. Carefully open the Precision M8 Adapter package and transfer the contents of the inner tray to the sterile field.

3. Ensure that the Medtronic 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 counterclockwise (Figure 1).

5. Ensure that stimulation is OFF before connecting to the Precision M8 Adapter.

6. Ensure that the leads are clean before inserting them into the Precision M8 Adapter.

7. Insert the proximal end of the lead into the Precision M8 Adapter until the lead reaches the end stop of the Adapter; use one Precision M8 Adapter for each 8-contact Medtronic lead tail (Figure 2).

8. Ensure that the proximal end of the Precision M8 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 M8 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.

9. Tighten the setscrew in the Precision M8 Adapter until the Torque wrench clicks, indicating the setscrew is fully secured.

10. If the Precision M8 Adapter will be implanted, apply a medical adhesive (e.g. Dow Corning Silastic® Medical Adhesive Silicone, Type-A Sterile, as available from Boston Scientific, part no. SC 4320) to coat and seal the top of the setscrew port (Figure 3).

**NOTE:** Damage to the septum seal may lead to unintended stimulation at the implantation site if medical adhesive is not used as intended.
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 M8 Adapter](image)

12. Complete the device registration included in the Precision M8 Adapter package. Use the product identification stickers, where necessary.

### Specifications and Technical Data

<table>
<thead>
<tr>
<th>Part</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapter Lengths</td>
<td>15, 55 cm</td>
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<tr>
<td>Adapter Diameter</td>
<td>1.3 mm</td>
</tr>
<tr>
<td>Number of Electrode Contacts</td>
<td>8</td>
</tr>
<tr>
<td>Contact Material</td>
<td>Platinum/Iridium</td>
</tr>
<tr>
<td>Insulation Material</td>
<td>Polyurethane, Silicone</td>
</tr>
<tr>
<td>Conductor Material</td>
<td>MP35N</td>
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</table>

### 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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