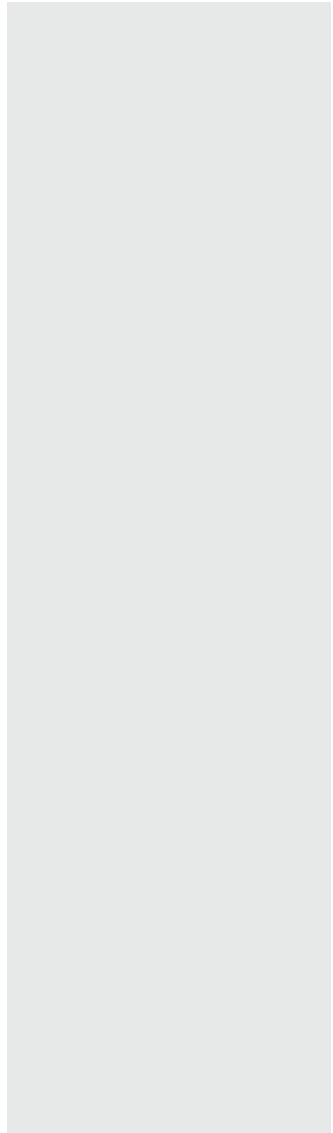


**Boston
Scientific**

Advancing science for life™

Precision™ M8 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.

90893429-09 REV A

Trademarks

All trademarks are the property of their respective owners.

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

Model Numbers	Description
SC-9218-15	Precision M8 Adapter, 15 cm
SC-9218-55	Precision M8 Adapter, 55 cm
SC-9218-15E	Precision M8 Adapter, 15 cm Trial
SC-9218-55E	Precision M8 Adapter, 55 cm Trial

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.

Directions for Use

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 counter-clockwise (Figure 1).

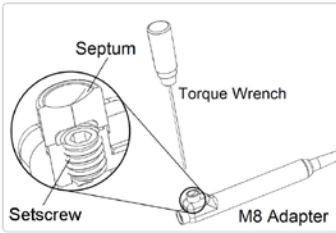


Figure 1: Location of setscrew in the Precision M8 Adapter.

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).

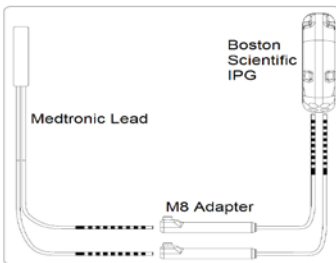


Figure 2: Connection of Precision M8 Adapters to leads and IPG.

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).

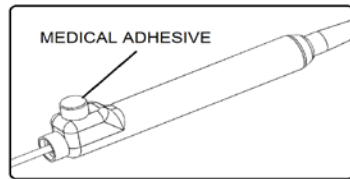


Figure 3: Medical Adhesive covering the septum seal plug

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

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

Specifications 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

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.

This page intentionally left blank.

Argentina

T: +5411 4896 8556 F: +5411 4896 8550

Australia / New Zealand

T: 1800 676 133 F: 1800 836 666

Austria

T: +43 1 60 810 F: +43 1 60 810 60

Balkans

T: 0030 210 95 37 890 F: 0030 210 95 79 836

Belgium

T: 080094 494 F: 080093 343

Brazil

T: +55 11 5853 2244 F: +55 11 5853 2663

Bulgaria

T: +359 2 986 50 48 F: +359 2 986 57 09

Canada

T: +1 888 359 9691 F: +1 888 575 7396

Chile

T: +562 445 4904 F: +562 445 4915

China – Beijing

T: +86 10 8525 1588 F: +86 10 8525 1566

China – Guangzhou

T: +86 20 8767 9791 F: +86 20 8767 9789

China – Shanghai

T: +86 21 6391 5600 F: +86 21 6391 5100

Colombia

T: +57 1 629 5045 F: +57 1 629 5082

Czech Republic

T: +420 2 3536 2911 F: +420 2 3536 4334

Denmark

T: 80 30 80 02 F: 80 30 80 05

Finland

T: 020 762 88 82 F: 020 762 88 83

France

T: +33 (0) 1 39 30 97 00 F: +33 (0) 1 39 30 97 99

Germany

T: 0800 072 3301 F: 0800 072 3319

Greece

T: +30 210 95 42401 F: +30 210 95 42420

Hong Kong

T: +852 2960 7100 F: +852 2563 5276

Hungary

T: +36 1 456 30 40 F: +36 1 456 30 41

India – Bangalore

T: +91 80 5112 1104/5 F: +91 80 5112 1106

India – Chennai

T: +91 44 2648 0318 F: +91 44 2641 4695

India – Delhi

T: +91 11 2618 0445/6 F: +91 11 2618 1024

India – Mumbai

T: +91 22 5677 8844 F: +91 22 2617 2783

Italy

T: +39 010 60 60 1 F: +39 010 60 60 200

Korea

T: +82 2 3476 2121 F: +82 2 3476 1776

Malaysia

T: +60 3 7957 4266 F: +60 3 7957 4866

Mexico

T: +52 55 5687 63 90 F: +52 55 5687 62 28

Middle East / Gulf / North Africa

T: +961 1 805 282 F: +961 1 805 445

The Netherlands

T: +31 30 602 5555 F: +31 30 602 5560

Norway

T: 800 104 04 F: 800 101 90

Philippines

T: +63 2 687 3239 F: +63 2 687 3047

Poland

T: +48 22 435 1414 F: +48 22 435 1410

Portugal

T: +351 21 3801243 F: +351 21 3801240

Singapore

T: +65 6418 8888 F: +65 6418 8899

South Africa

T: +27 11 840 8600 F: +27 11 463 6077

Spain

T: +34 901 111 215 F: +34 902 267 888

Sweden

T: 020 65 25 30 F: 020 55 25 35

Switzerland

T: 0800 826 786 F: 0800 826 787

Taiwan

T: +886 2 2747 7278 F: +886 2 2747 7270

Thailand

T: +66 2 2654 3810 F: +66 2 2654 3818

Turkey – Istanbul

T: +90 216 464 3666 F: +90 216 464 3677

Uruguay

T: +59 82 900 6212 F: +59 82 900 6212

UK & Eire

T: +44 844 800 4512 F: +44 844 800 4513

Venezuela

T: +58 212 959 8106 F: +58 212 959 5328

Boston Scientific

Advancing science for life™



Legal Manufacturer

Boston Scientific Neuromodulation
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

© 2015 Boston Scientific Corporation
or its affiliates. All rights reserved.

90893429-09 REV A 2015-07