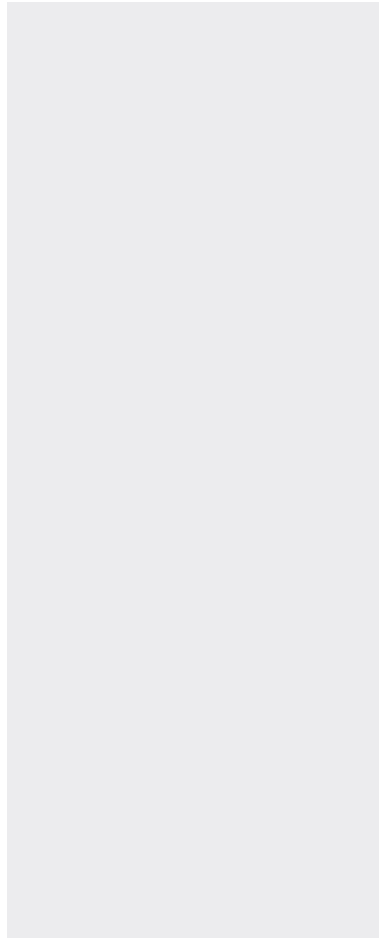


Boston Scientific

Advancing science for life™

Precision Spectra™ OMG

Model SC-9315



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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Precision Spectra™ OMG

Model SC-9315

Intended Use

The Precision Spectra Observational Mechanical Gateway (OMG) is used to connect the Precision Spectra External Trial Stimulator (ETS) or Spectra WaveWriter ETS to an OMG Connector-M (Model # SC-9310) or an OMG Connector-A (Model #SC-9305). It is intended to provide the physician with the capability to gain acute feedback from the patients to assess for any pain relief difference between the Medtronic and the St. Jude (formerly Advanced Neuromodulation Systems (ANS)) Systems and the Boston Scientific Precision Spectra System or Spectra WaveWriter System.

The Precision Spectra OMG is for evaluation purposes only. It is an adjunct to, but not part of, the Precision Spectra System or the Spectra WaveWriter System. Full trial of the Precision Spectra System or the Spectra WaveWriter System should precede permanent implant.

CAUTION



Precision Spectra OMG is for use only under the direct supervision of a healthcare professional. The Precision Spectra OMG may not be sent home with the patient..

Note: Throughout this document, the term “OMG Connector” is used to signify either the OMG Connector-M or the OMG Connector-A.

Note: Throughout this document, the “Boston Scientific ETS” is used to signify either the Precision Spectra ETS or Spectra WaveWriter ETS.

OMG Connector-M Compatibility

The Precision Spectra OMG and OMG Connector-M shall be compatible with the following Medtronic leads and OR Cable Assembly available prior to September 2013.

Medtronic OR Cable Assembly	Model Number
Twist-Lock Screening Cable	3550-03
Snap-Lid Connector Cable	355031
Multi-lead Trialing Cable	355531

Medtronic Lead	Model Number
Pisces Quad™	3487A**, 3887**, 3888**
Pisces Z-Quad™	3890**, 3891**, 3892**
1×8 percutaneous lead	3776, 3777, 3778
8 contact trial lead	3873, 3874, 3875
Resume™ II & TL	3587A**, 3986A**
On-Point PNS™	3987A**
SymMix™	3982A**
Specify™ 2×4	3998
Specify™ 2×8	39286
Hinged Specify™	3999**
Vectris™ SureScan® MRI 1x8 Subcompact	977A160, 977A175, 977A190
Vectris™ SureScan® MRI 1x8 Compact	977A260, 977A275, 977A290
Vectris™ SureScan® MRI Trial Leads	977D160, 977D260
Specify™ 5-6-5	39565*

Pisces Quad, Pisces Z-Quad, Resume II, Resume TL, On-Point PNS, SymMix, Specify, Hinged Specify, and Vectris are trademarks of Medtronic, Inc.

* These models numbers should be programmed in manual mode

** Program only the mapped contacts on the representative Boston Scientific lead

OMG Connector-A Compatibility

The Precision Spectra OMG and OMG Connector-A shall be compatible with the following St. Jude leads and OR Cable Assembly available prior to September 2013.

St. Jude OR Cable Assembly	Model Number
OR Cable Assembly	3009

St. Jude Lead	Model Number
Trial lead, 4-Channel	3046**
Trial lead, 8-Channel	3086
Axxess® Trial Lead	4044**, 4054**
Octrode®	3183, 3186, 3189, 3181
Quattrode®	3143**, 3146**, 3149**, 3141**, 3153**, 3156**, 3159**, 3151**
Axxess®	4143**, 4146**, 4153**, 4156**
Lamitrode® 22	3222*
Lamitrode® 4	3240**, 3254**, 3255**
Lamitrode® 8	3280
Lamitrode® 44 and 44C	3244*, 3262*, 3263*, 3245*, 3264*, 3265*
Lamitrode® Tripole 8 & 8c	3208,* 3210*
Lamitrode® Tripole 16 & 16c	3214, 3219
Lamitrode® 88 & 88c	3288*, 3289*
Lamitrode S-8	3283, 3286, 3268, 3269

Axxess, Octrode Quattrode and Lamitrode are trademarks of Advanced Neuromodulation Systems

* These models numbers should be programmed in manual mode

** Program only the mapped contacts on the representative Boston Scientific lead

Directions for Use

Connecting the Precision Spectra OMG

1. Inspect the Precision Spectra OMG and OMG Connector-for damage. If damaged, do not proceed. Return the damaged component(s) to Boston Scientific Neuromodulation or your healthcare professional.
2. Turn off the non-Boston Scientific ETS.

CAUTION



Failure to turn off the non-Boston Scientific ETS before connecting the OMG Connector may result in excess stimulation.

3. Disconnect the proximal end(s) of the non-Precision Spectra OR Cable Assembly and insert into the corresponding port on the OMG Connector:
 - A. **OMG Connector-A**
Disconnect the proximal end(s) of the non-Precision Spectra OR Cable Assembly and insert it into the corresponding port on the OMG Connector-A. Plug the non-Boston Scientific OR Cable Assembly into the OMG Connector-A socket(s) labeled "1-L" (left) and "2-R" (right). If only a single lead is being used, connect it to "1-L".
 - B. **OMG Connector-M**
Medtronic Twist-Lock Screening Cables (Model # 3550-03)
 - If the trial is using the Twist-Lock Screening Cables, plug the non-Boston Scientific OR Cable Assembly into the OMG Connector socket(s) labeled "1-L" (left) for a single-lead trial. The lead shows up as contacts 1-4 in the Bionic Navigator™ 3D

software.

- For a two-lead trial, connect the non-Boston Scientific OR Cable Assemblies into “1-L” (left) and “2-R” (right). The lead shows up as contacts 1-4 and 9-12 in the Bionic Navigator 3D software.

Medtronic Snap-Lid Connector Cable (Model # 355031) or Medtronic Multi-lead Trialing Cable (Model # 355531)

- If the trial is using the Snap-Lid Connector Cable, plug the non-Boston Scientific connector into the OMG Connector-M socket labeled “Single Connector.” If 2 four contact-leads are placed in the Snap-Lid Connector Cable, the first and second leads show up as contacts 1-4 and 5-8, respectively, in the Bionic Navigator 3D software. The 4-contact leads should be programmed in Manual Mode.
 - If 2 eight-contact leads are used, the leads show up as contacts 1-8 and 9-16 in the Bionic Navigator 3D software.
- Place the OMG Connector in a secure location on a flat surface so that patient movement will not cause the connector to fall.
 - Align and connect the “1-L” and “2-R” ports on the Precision Spectra OMG and the respective OMG Connector.
 - Making sure that the Boston Scientific ETS is OFF, connect the Boston Scientific ETS to the port labeled “CD” on the Precision Spectra OMG.

CAUTION



Failure to turn off the Boston Scientific ETS before connecting the Precision Spectra OMG may result in excess stimulation.

Programming the Boston Scientific ETS

- Link the Boston Scientific Clinician Programmer (CP) to the Boston Scientific ETS per the standard procedure.
- Use the Bionic Navigator 3D Software to program the Boston Scientific ETS. *Refer to the list of competitor leads for guidance in selecting the programming mode to use with the lead.*

Disconnecting the Precision Spectra OMG

- Turn OFF stimulation.
- Disconnect the Boston Scientific ETS from the Precision Spectra OMG.
- Disconnect the Precision Spectra OMG from the OMG Connector.
- Disconnect the proximal end(s) of the non-Boston Scientific OR Cable Assembly(ies) from the OMG Connector.

CAUTION



Failure to turn off the Boston Scientific ETS before disconnecting the Precision Spectra OMG may result in excess stimulation.

Cleaning the Precision Spectra OMG

The Precision Spectra OMG can be cleaned using a mild detergent applied with a lightly dampened cloth or tissue. Residue from soapy detergents should be removed with a cloth lightly dampened with water. Do not use abrasive cleansers for cleaning.

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.

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.

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

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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
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 Authorised 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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