

**Boston
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Boston Scientific Spinal Cord Stimulation (SCS) Systems

Reference Guide

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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Guarantees

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Introduction

The Reference Guide provides the list of *Directions for Use* (DFU) available for each Boston Scientific Spinal Cord Stimulator System. These manuals are designed for clinicians and other health care providers.

IMPORTANT: Please note that only the *Directions for Use* that are appropriate for your region will be provided with your SCS system.

Additional information may be provided in addendums to these DFUs.

How to Use this Reference Guide

In this Reference Guide, DFUs are listed for each Spinal Cord Stimulator System in a table format. Follow the instructions below to find information for your SCS system:

1. Find the appropriate table for your SCS system. For example, if you are using a Precision Spectra™ System, find the table labelled "Precision Spectra Directions for Use".
2. Use the highlighted rows to locate the information of interest to you (e.g. indications, implantable pulse generator, or programming). The DFU containing this information is listed below.

The Boston Scientific DFUs are provided either online (as directed in your product packaging) or with your SCS system.

Precision SCS System Directions for Use

Information	Directions for Use
Intended Use/Indications for Use	<ul style="list-style-type: none"> • <i>Precision Spinal Cord Stimulator System Clinician Manual</i>
<ul style="list-style-type: none"> • Indications for use 	
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Contraindications • Precautions • Warnings • Physician Instructions • Sterilization • Component Disposal • Information for contacting Boston Scientific 	
Precision Implantable Pulse Generator	
<ul style="list-style-type: none"> • Compatible Leads • Connecting to the IPG • IPG Battery Life • IPG Explant or Replacement • IPG Handling and Storage • IPG Implantation • Kit Contents • IPG Registration Information • IPG Specifications and Technical Data 	
OR Cables, OR Cable Extension, External Trial Stimulator	<ul style="list-style-type: none"> • <i>Precision Spinal Cord Stimulator System Clinician Manual</i>
<ul style="list-style-type: none"> • Connecting the Leads, Lead Extensions, or Splitter to the OR Cable • Connection to the External Trial Stimulator • Patient Trial Belt instructions for use 	
Percutaneous Leads, Extensions, and Splitters	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of percutaneous Leads for trial and permanent implant • Specifications and Technical data • Storage and handling for leads, extensions, and splitters 	<ul style="list-style-type: none"> • <i>Precision Spinal Cord Stimulator System Clinician Manual</i> <p>OR</p> <ul style="list-style-type: none"> • <i>Percutaneous Leads DFU</i>

Surgical Leads	
<ul style="list-style-type: none"> Intraoperative testing with OR Cable Assembly and External Trial Stimulator Kit contents Lead implantation List of surgical leads Specifications and Technical data Storage and handling for leads and extensions 	<ul style="list-style-type: none"> <i>Precision Spinal Cord Stimulator System Clinician Manual</i> <p>OR</p> <ul style="list-style-type: none"> <i>Surgical Leads Leads DFU</i>
Programming	
<ul style="list-style-type: none"> Clinician Programmer Programming with the Bionic Navigator™ software 	<ul style="list-style-type: none"> <i>Bionic Navigator Software Guide</i>
<ul style="list-style-type: none"> Remote Control Instructions for Use Connection of the External Trial Stimulator to the Clinician Programmer 	<ul style="list-style-type: none"> <i>Precision Spinal Cord Stimulator System Clinician Manual</i>
Adapters	
<ul style="list-style-type: none"> M1 Connector 	<ul style="list-style-type: none"> <i>M1 Connector DFU</i>
<ul style="list-style-type: none"> Precision M8 Adapter 	<ul style="list-style-type: none"> <i>Precision M8 Adapter DFU</i>
<ul style="list-style-type: none"> Precision S8 Adapter 	<ul style="list-style-type: none"> <i>Precision S8 Adapter DFU</i>
<ul style="list-style-type: none"> OMG Connector-A 	<ul style="list-style-type: none"> <i>OMG Connector-A DFU</i>
<ul style="list-style-type: none"> OMG Connector-M 	<ul style="list-style-type: none"> <i>OMG Connector-M DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> Clik™ Anchor 	<ul style="list-style-type: none"> <i>Clik Anchor DFU</i>
<ul style="list-style-type: none"> Clik X Anchor 	<ul style="list-style-type: none"> <i>Clik X Anchor DFU</i>
<ul style="list-style-type: none"> Introducer 	<ul style="list-style-type: none"> <i>Introducer DFU</i>
<ul style="list-style-type: none"> Med A 	<ul style="list-style-type: none"> <i>Med A DFU</i>
Warranty	
<ul style="list-style-type: none"> Warranty information 	<ul style="list-style-type: none"> <i>Limited Warranty</i>
Labeling Symbols	
<ul style="list-style-type: none"> Labeling Symbols 	<ul style="list-style-type: none"> <i>Labeling Symbols</i>

Precision Montage™ MRI SCS System Directions for Use

Information	Directions for Use
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for use 	<ul style="list-style-type: none"> • <i>Indications for Use DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Battery Life • Component Disposal • Contraindications • Device Description • Electromagnetic Interference • End of Programmed Service • Information for contacting Boston Scientific • IPG Battery Life • MRI Information • Physician Instructions • Precautions • Sterilization • Storage and Handling • Telemetry Information • Warnings 	<ul style="list-style-type: none"> • <i>Precision Montage MRI Information for Prescribers DFU</i>
Precision Montage ImageReady™ MRI Guidelines	
<ul style="list-style-type: none"> • ImageReady MRI Full Body Guidelines for Precision Montage MRI SCS System 	<ul style="list-style-type: none"> • <i>ImageReady MRI Full Body Guidelines for Precision Montage MRI SCS System</i>
Precision Montage Implantable Pulse Generator (IPG)	
<ul style="list-style-type: none"> • Compatible Leads • Connecting to the IPG • IPG Battery Status • IPG Explant or Replacement • IPG Handling and Storage • IPG Implantation • IPG Registration Information • Kit contents • Specifications and Technical Data • SCS Implant Conditions for MRI Eligibility 	<ul style="list-style-type: none"> • <i>Precision Montage MRI Implantable Pulse Generator DFU</i>

OR Cable, OR Cable Extensions, External Trial Stimulator, Patient Trial Belt	
<ul style="list-style-type: none"> • Connection to the External Trial Stimulator • Inserting Leads, Lead Extensions, or Splitter into the OR Cable Connector <ul style="list-style-type: none"> - 1x16 OR Cable - 2x8 OR Cable • Patient Trial Belt instructions for use 	<ul style="list-style-type: none"> • <i>Clinician Trial Manual</i>
Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> • Clinician Programmer • Programming leads 	<ul style="list-style-type: none"> • <i>Bionic Navigator™ 3D Programming Manual (DFU)</i>
<ul style="list-style-type: none"> • Connection of the Clinician Programmer to the External Trial Stimulator by Programming Wand 	<ul style="list-style-type: none"> • <i>Programming Wand DFU</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5250) 	<ul style="list-style-type: none"> • <i>Freelink™ Remote Control DFU for SC-5250</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5260) 	<ul style="list-style-type: none"> • <i>Freelink™ Remote Control DFU for SC-5260</i>
Avista™ MRI Leads	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • Specifications and Technical data • Storage and handling for MRI leads • SCS Implant Conditions for MRI Eligibility 	<ul style="list-style-type: none"> • <i>Avista MRI Percutaneous Leads DFU</i>
Percutaneous Leads	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of percutaneous Leads for trial and permanent implant • Specifications and Technical data • Storage and handling for leads, extensions, and splitters 	<ul style="list-style-type: none"> • <i>Percutaneous Leads DFU</i>

Surgical Leads	
<ul style="list-style-type: none"> • Intraoperative testing with OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of surgical leads • Specifications and Technical data • Storage and handling for leads and extensions 	<ul style="list-style-type: none"> • <i>Surgical Leads DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> • Clik X MRI Anchor 	<ul style="list-style-type: none"> • <i>Clik X MRI Anchor DFU</i>
<ul style="list-style-type: none"> • Clik X Anchor 	<ul style="list-style-type: none"> • <i>Clik X Anchor DFU</i>
<ul style="list-style-type: none"> • Clik Anchor 	<ul style="list-style-type: none"> • <i>Clik Anchor DFU</i>
<ul style="list-style-type: none"> • Introducer 	<ul style="list-style-type: none"> • <i>Introducer DFU</i>
<ul style="list-style-type: none"> • Med A 	<ul style="list-style-type: none"> • <i>Med A DFU</i>
Warranty	
<ul style="list-style-type: none"> • Warranty information 	<ul style="list-style-type: none"> • <i>Limited Warranty</i>
Labeling Symbols	
<ul style="list-style-type: none"> • Labeling Symbols 	<ul style="list-style-type: none"> • <i>Labeling Symbols</i>

Precision Novi™ SCS System Directions for Use

Information	Directions for Use
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for use 	<ul style="list-style-type: none"> • <i>Indications for Use DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Contraindications • Component Disposal • Device Description • Elective Replacement • End of Service • Estimating Battery Longevity • Information for contacting Boston Scientific • IPG Battery Life • MRI Information • Physician Instructions • Precautions • Sterilization • Storage and Handling • Telemetry • Warnings 	<ul style="list-style-type: none"> • <i>Precision Novi Information for Prescribers DFU</i>
Precision Novi Implantable Pulse Generator (IPG)	
<ul style="list-style-type: none"> • Compatible Leads • Connecting to the IPG • IPG Battery Life • IPG Explant or Replacement • IPG Handling and Storage • IPG Implantation • IPG Registration Information • Kit contents • Specifications and Technical Data 	<ul style="list-style-type: none"> • <i>Precision Novi Implantable Pulse Generator DFU</i>
OR Cable, OR Cable Extensions, External Trial Stimulator, Patient Trial Belt	
<ul style="list-style-type: none"> • Connection to the External Trial Stimulator • Inserting Leads, Lead Extensions, or Splitter into the OR Cable Connector <ul style="list-style-type: none"> - 1x16 OR Cable - 2x8 OR Cable • Patient Trial Belt instructions for use 	<ul style="list-style-type: none"> • <i>Clinician Trial Manual</i>

Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> Clinician Programmer Programming Leads 	<ul style="list-style-type: none"> <i>Bionic Navigator 3D Programming Manual DFU</i>
<ul style="list-style-type: none"> Connection of the Clinician Programmer to the External Trial Stimulator by Programming Wand 	<ul style="list-style-type: none"> <i>Programming Wand DFU</i>
<ul style="list-style-type: none"> Instructions for using the remote control (SC-5240) 	<ul style="list-style-type: none"> <i>Freelink Remote Control DFU for SC-5240</i>
<ul style="list-style-type: none"> Instructions for using the remote control (SC-5250) 	<ul style="list-style-type: none"> <i>Freelink Remote Control DFU for SC-5250</i>
<ul style="list-style-type: none"> Instructions for using the remote control (SC-5260) 	<ul style="list-style-type: none"> <i>Freelink Remote Control DFU for SC-5260</i>
Percutaneous Leads, Extensions, and Splitters	
<ul style="list-style-type: none"> Intraoperative testing using the OR Cable Assembly and External Trial Stimulator Kit contents Lead implantation List of percutaneous Leads for trial and permanent implant Specifications and Technical data Storage and handling for leads, extensions, and splitters 	<ul style="list-style-type: none"> <i>Percutaneous Leads DFU</i>
Surgical Leads	
<ul style="list-style-type: none"> Intraoperative testing with OR Cable Assembly and External Trial Stimulator Kit contents Lead implantation List of surgical leads Specifications and Technical data Storage and handling for leads and extensions 	<ul style="list-style-type: none"> <i>Surgical Leads DFU</i>
Adapters	
<ul style="list-style-type: none"> M1 Connector 	<ul style="list-style-type: none"> <i>M1 Connector DFU</i>
<ul style="list-style-type: none"> Precision M8 Adapter 	<ul style="list-style-type: none"> <i>Precision M8 Adapter DFU</i>
<ul style="list-style-type: none"> Precision S8 Adapter 	<ul style="list-style-type: none"> <i>Precision S8 Adapter DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> Clik Anchor 	<ul style="list-style-type: none"> <i>Clik Anchor DFU</i>
<ul style="list-style-type: none"> Clik X Anchor 	<ul style="list-style-type: none"> <i>Clik X Anchor DFU</i>
<ul style="list-style-type: none"> Introducer 	<ul style="list-style-type: none"> <i>Introducer DFU</i>
<ul style="list-style-type: none"> Med A 	<ul style="list-style-type: none"> <i>Med A DFU</i>
Warranty	
<ul style="list-style-type: none"> Warranty information 	<ul style="list-style-type: none"> <i>Limited Warranty</i>
Labeling Symbols	
<ul style="list-style-type: none"> Labeling Symbols 	<ul style="list-style-type: none"> <i>Labeling Symbols</i>

Precision Spectra™ SCS System Directions for Use

Information	Directions for Use
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for use 	<ul style="list-style-type: none"> • <i>Indications for Use DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Electromagnetic Interference • End of Programmed Service • Information for contacting Boston Scientific • MRI Information • IPG Battery Life • Physician Instructions • Precautions • Sterilization • Storage and Handling • Warnings 	<ul style="list-style-type: none"> • <i>Precision Spectra Information for Prescribers DFU</i>
Precision Spectra Implantable Pulse Generator (IPG)	
<ul style="list-style-type: none"> • Compatible Leads • Connecting to the IPG • IPG Battery Status • IPG Explant or Replacement • IPG Handling and Storage • IPG Implantation • IPG Registration Information • Kit contents • Specifications and Technical Data 	<ul style="list-style-type: none"> • <i>Precision Spectra Implantable Pulse Generator DFU</i>
Precision Spectra ImageReady™ MRI Guidelines	
<ul style="list-style-type: none"> • ImageReady MRI Guidelines 	<ul style="list-style-type: none"> • <i>ImageReady MRI Head Only Guidelines for Precision Spectra Spinal Cord Stimulator System</i>

OR Cable, OR Cable Extensions, External Trial Stimulator, Patient Trial Belt	
<ul style="list-style-type: none"> • Connection to the External Trial Stimulator • Inserting Leads, Lead Extensions, or Splitter into the OR Cable Connector <ul style="list-style-type: none"> - 1x 16 OR Cable - 2x8 OR Cable • Patient Trial Belt instructions for use 	<ul style="list-style-type: none"> • <i>Clinician Trial Manual</i>
Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> • Clinician Programmer • Programming leads 	<ul style="list-style-type: none"> • <i>Bionic Navigator™ 3D Programming Manual (DFU)</i>
<ul style="list-style-type: none"> • Connection of the Clinician Programmer to the External Trial Stimulator by Programming Wand 	<ul style="list-style-type: none"> • <i>Programming Wand DFU</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5240) 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU for SCS-5240</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5250) 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU for SC-5250</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5232) 	<ul style="list-style-type: none"> • <i>Precision Spectra System Clinician Remote Control DFU</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5260) 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU for SCS-5260</i>
Percutaneous Leads, Extensions, and Splitters	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of percutaneous Leads for trial and permanent implant • Specifications and Technical data • Storage and handling for leads, extensions, and splitters 	<ul style="list-style-type: none"> • <i>Percutaneous Leads DFU</i>
Surgical Leads	
<ul style="list-style-type: none"> • Intraoperative testing with OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of surgical leads • Specifications and Technical data • Storage and handling for leads and extensions 	<ul style="list-style-type: none"> • <i>Surgical Leads DFU</i>

Adapters	
• M1 Connector	• <i>M1 Connector DFU</i>
• Precision Spectra OMG™ Adapter	• <i>Precision Spectra OMG Adapter DFU</i>
• Precision M8 Adapter	• <i>Precision M8 Adapter DFU</i>
• Precision S8 Adapter	• <i>Precision S8 Adapter DFU</i>
Surgical Tools and Accessories	
• Klik Anchor	• <i>Klik Anchor DFU</i>
• Klik X Anchor	• <i>Klik X Anchor DFU</i>
• Introducer	• <i>Introducer DFU</i>
• Med A	• <i>Med A DFU</i>
Warranty	
• Warranty information	• <i>Limited Warranty</i>
Labeling Symbols	
• Labeling Symbols	• <i>Labeling Symbol</i>

Spectra WaveWriter™ SCS System Directions for Use

Information	Directions for Use
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for use 	<ul style="list-style-type: none"> • <i>Indications for Use DFU</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Electromagnetic Interference • End of Programmed Service • Information for contacting Boston Scientific • MRI Information • IPG Battery Life • Physician Instructions • Precautions • Sterilization • Storage and Handling • Warnings 	<ul style="list-style-type: none"> • <i>Spectra WaveWriter Information for Prescribers DFU</i>
Spectra WaveWriter Implantable Pulse Generator (IPG)	
<ul style="list-style-type: none"> • Compatible Leads • Connecting to the IPG • IPG Battery Status • IPG Explant or Replacement • IPG Handling and Storage • IPG Implantation • IPG Registration Information • Kit contents • Specifications and Technical Data 	<ul style="list-style-type: none"> • <i>Spectra WaveWriter Implantable Pulse Generator DFU</i>
Spectra WaveWriter ImageReady™ MRI Guidelines	
<ul style="list-style-type: none"> • ImageReady MRI Guidelines 	<ul style="list-style-type: none"> • <i>ImageReady MRI Head Only Guidelines for Spectra WaveWriter Spinal Cord Stimulator Systems</i>

OR Cable, OR Cable Extensions, External Trial Stimulator, Patient Trial Belt	
<ul style="list-style-type: none"> • Connection to the External Trial Stimulator • Inserting Leads, Lead Extensions, or Splitter into the OR Cable Connector <ul style="list-style-type: none"> - 1x 16 OR Cable - 2x8 OR Cable • Patient Trial Belt instructions for use 	<ul style="list-style-type: none"> • <i>Clinician Trial Manual</i>
Programming: Clinician Programmer, Wand, and Remote Control	
<ul style="list-style-type: none"> • Clinician Programmer • Programming leads 	<ul style="list-style-type: none"> • <i>Bionic Navigator™ 3D Programming Manual (DFU)</i>
<ul style="list-style-type: none"> • Connection of the Clinician Programmer to the External Trial Stimulator by Programming Wand 	<ul style="list-style-type: none"> • <i>Programming Wand DFU</i>
<ul style="list-style-type: none"> • Instructions for using the remote control (SC-5260) 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU for SCS-5260</i>
Percutaneous Leads, Extensions, and Splitters	
<ul style="list-style-type: none"> • Intraoperative testing using the OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of percutaneous Leads for trial and permanent implant • Specifications and Technical data • Storage and handling for leads, extensions, and splitters 	<ul style="list-style-type: none"> • <i>Percutaneous Leads DFU</i>
Surgical Leads	
<ul style="list-style-type: none"> • Intraoperative testing with OR Cable Assembly and External Trial Stimulator • Kit contents • Lead implantation • List of surgical leads • Specifications and Technical data • Storage and handling for leads and extensions 	<ul style="list-style-type: none"> • <i>Surgical Leads DFU</i>
Adapters	
<ul style="list-style-type: none"> • M1 Connector 	<ul style="list-style-type: none"> • <i>M1 Connector DFU</i>
<ul style="list-style-type: none"> • Precision Spectra OMG™ Adapter 	<ul style="list-style-type: none"> • <i>Precision Spectra OMG Adapter DFU</i>
<ul style="list-style-type: none"> • Precision M8 Adapter 	<ul style="list-style-type: none"> • <i>Precision M8 Adapter DFU</i>
<ul style="list-style-type: none"> • Precision S8 Adapter 	<ul style="list-style-type: none"> • <i>Precision S8 Adapter DFU</i>

Surgical Tools and Accessories	
• Klik Anchor	• <i>Klik Anchor DFU</i>
• Klik X Anchor	• <i>Klik X Anchor DFU</i>
• Introducer	• <i>Introducer DFU</i>
• Med A	• <i>Med A DFU</i>
Warranty	
• Warranty information	• <i>Limited Warranty</i>
Labeling Symbols	
• Labeling Symbols	• <i>Labeling Symbol</i>

Argentina

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

Australia / New Zealand

T: +61 2 8063 8100, F: +61 2 9330 1444

Austria

T: +43 1 726 30 05 F: +43 1 726 30 05 1030

Balkans

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

Belgium

T: 080094 494 F: 080093 343

Brazil

T: +55 11 5502 8500 F: +55 11 5103 2212

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 1 612 4761

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

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: +30 602 5555 F: +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 1 381 25 401 F: +351 1 381 25 589

Singapore

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

South Africa

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

Spain

T: +34 934 447 200 F: +34 934 059 045

Sweden

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

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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 – Ankara

T: +90 312 447 98 50 F: +90 312 447 98 54

Turkey – Istanbul

T: +90 212 327 78 00 F: +90 212 327 74 27

Uruguay

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

UK & Eire

T: +44 1727 831666 F: +44 1727 865862

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

| | |-----| | AUS | |-----| 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

| | | |----|-----| | EC | REP | |----|-----| 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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