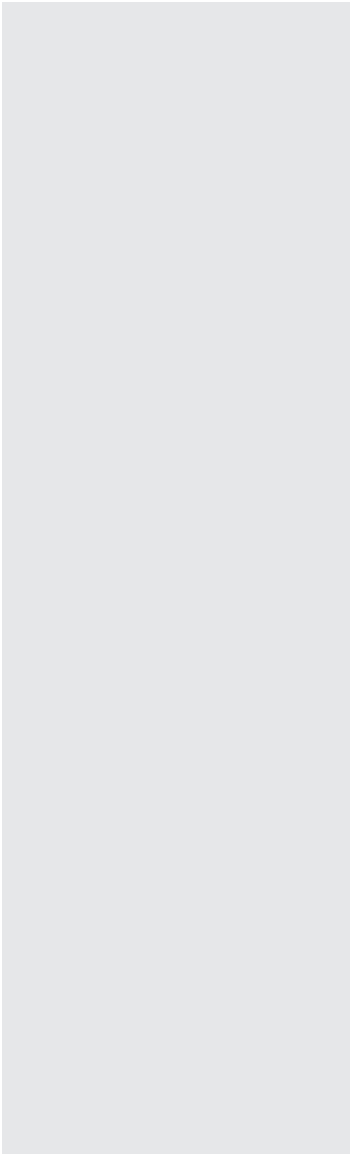


**Boston
Scientific**

Advancing science for life™

Boston Scientific Spinal Cord Stimulator (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"> • 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 	<ul style="list-style-type: none"> • <i>Precision Spinal Cord Stimulator System Clinician Manual</i>
OR Cables, OR Cable Extension, External Trial Stimulator	
<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 DFU</i>
Neuro Lead Compatibility	
<ul style="list-style-type: none"> Connecting to Neuro Leads and Extensions 	<ul style="list-style-type: none"> <i>Neuro Lead Compatibility Directions for Use</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</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 	<ul style="list-style-type: none"> • <i>Freelink™ Remote Control DFU</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>
Neuro Lead Compatibility	
<ul style="list-style-type: none"> Connecting to Neuro Leads and Extensions 	<ul style="list-style-type: none"> <i>Neuro Lead Compatibility Directions for Use</i>
Adapters	
<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 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</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 	<ul style="list-style-type: none"> <i>Freelink Remote Control DFU</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>
Nevro Lead Compatibility	
<ul style="list-style-type: none"> Connecting to Nevro Leads and Extensions 	<ul style="list-style-type: none"> <i>Nevro Lead Compatibility Directions for Use</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"> - 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</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 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU</i> • <i>Precision Spectra System Clinician Remote Control DFU</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>

Nevro Lead Compatibility	
• Connecting to Nevro Leads and Extensions	• <i>Nevro Lead Compatibility Directions for Use</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"> - 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</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 	<ul style="list-style-type: none"> • <i>Freelink Remote Control DFU</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>
Neuro Lead Compatibility	
<ul style="list-style-type: none"> • Connecting to Neuro Leads and Extensions 	<ul style="list-style-type: none"> • <i>Neuro Lead Compatibility Directions for Use</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>

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Mexico

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Middle East / Gulf / North Africa

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The Netherlands

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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

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Singapore

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South Africa

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