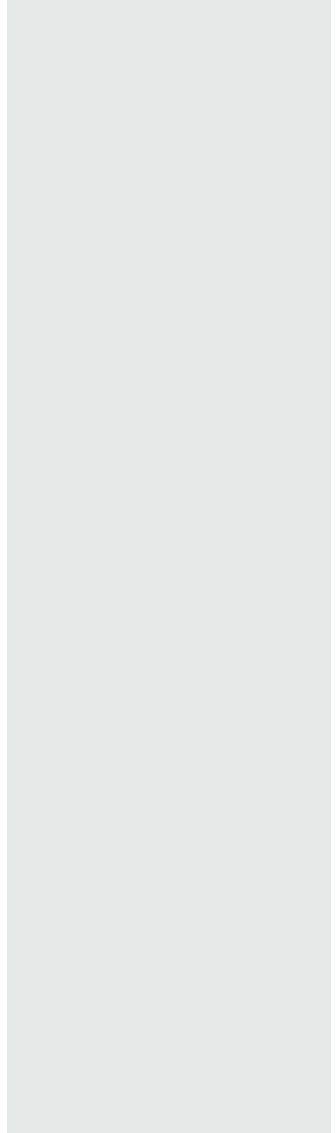


**Boston
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Nevro Lead Compatibility

Directions for Use



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

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.

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Additional Information

For contraindications, warnings, precautions, adverse events, storage and handling, sterilization, clinical studies supporting the use of the neurostimulation system, programming, labeling symbols, warranty, or other device-specific information not included in this manual, refer to the appropriate Directions for Use for your Boston Scientific SCS System as listed on your Boston Scientific *Reference Guide*.

Introduction

This manual outlines instructions for connecting Boston Scientific Spinal Cord Stimulator (SCS) devices to specific Nevro SCS Leads and Lead Extensions (see "Lead Compatibility") in a trial or permanent implant procedure. Boston Scientific recommends that physicians and healthcare providers read all applicable product labeling before implanting Boston Scientific devices.

Intended Use

The Boston Scientific SCS Implantable Pulse Generators, OR Cables, and Lead Extensions can be connected to compatible Nevro Leads and Lead Extensions as part of a spinal cord stimulation procedure.

Lead Compatibility

The Boston Scientific Implantable Pulse Generators, OR Cables, and Lead Extensions are compatible with the Nevro Leads and Lead Extensions listed in Table 1.

Table 1: Compatible Nevro Leads and Lead Extensions

Product Number	Product Description
LEAD2008-25B	Blue Lead Extension Kit, 25 cm
LEAD2008-35B	Blue Lead Extension Kit, 35 cm
LEAD2008-60B	Blue Lead Extension Kit, 60 cm
LEAD1058-30B	Blue Lead Kit, 30 cm with 5 mm spacing
LEAD1058-50B	Blue Lead Kit, 50 cm with 5 mm spacing
LEAD1058-70B	Blue Lead Kit, 70 cm with 5 mm spacing
LEAD1058-90B	Blue Lead Kit, 90 cm with 5 mm spacing
TLEAD1058-50B	Trial Lead Kit, 50 cm with 5 mm spacing
TLEAD1058-70B	Trial Lead Kit, 70 cm with 5 mm spacing
TLEAD1058-90B	Trial Lead Kit, 90 cm with 5 mm spacing

WARNING: The Nevro Leads and Lead Extensions have not been tested for compatibility with an MRI environment when used with the Boston Scientific SCS Systems. MRI scanning can result in severe patient injury.

Directions for Use

Section A: Connecting Boston Scientific Trial System Device after a Nevro Trial Procedure

This section outlines instructions for connecting the Boston Scientific SCS Trial Systems to the Nevro Trial or Perm Leads.

- Avoid using excessive force during surgery as this may damage the Lead Extension.
 - Do not sharply bend or kink the Lead Extension.
 - Do not tie suture(s) directly to the Lead Extension; use the provided suture sleeves or anchors.
 - Avoid handling the Lead Extension with sharp instruments; use only rubber-tipped forceps.
 - Take care when using sharp instruments such as hemostats or scalpels to prevent damaging the Lead Extension.
 - Remove body fluids from the end of the Lead connector before connecting it to any other component. Fluid contamination of these connections could compromise the integrity of the stimulation circuit.
1. Consult the Nevro product labeling for instructions on removing the Nevro OR Cables and Trial Stimulator.
 2. Ensure that stimulation is OFF and disconnect the Nevro OR Cables and Trial Stimulator.
 3. Ensure that the Nevro Lead (s) or Lead Extensions (s) are intact.
 4. If a Lead Extension is required, connect each Nevro Lead to each Boston Scientific Extension as follows:
 - a. Wipe the proximal end of the Lead to ensure that it is free of fluids.
 - b. Insert the proximal end of the Lead into the Lead Extension Connector until it stops and the retention ring is under the setscrew. Ensure that the Lead is fully inserted before proceeding to the next step to prevent Lead damage.

NOTE: *If there appears to be an obstruction when inserting the Nevro Lead into the Boston Scientific Lead Extension Connector, turn the hex wrench counterclockwise to loosen the setscrew, and/or gently rotate the lead to help advance the proximal end. When using the Hex Wrench, ensure that it is fully seated in the setscrew.*
 5. Connect each Lead or Lead Extension to the Boston Scientific OR Cables as detailed in the Trial Manual provided for your SCS system.
 6. Connect the Boston Scientific OR Cables to the Boston Scientific External Trial Stimulator as detailed in the Trial Manual for your SCS system.
 7. Link the Boston Scientific External Trial Stimulator to the Boston Scientific Clinician Programmer or Boston Scientific Remote Control to verify that components are properly connected. The Clinician Programmer and Remote Control displays impedances for each lead contact. Impedances may result from open or unconnected wires. For programming instructions, refer to the programming Directions for Use for your SCS system as listed in your *Reference Guide*.
 8. If a Boston Scientific Lead Extension was used in Step 4, use the Hex Wrench to turn the Extension Connector setscrew clockwise until it clicks, indicating that it is locked. Ensure that the Hex Wrench is fully seated in the setscrew before tightening. The Hex Wrench is torque-limiting and cannot be overtightened.
 9. If needed, create an appropriately-sized pocket using blunt dissection on either side of the midline for coiled excess Leads, Lead Extensions, or both.

10. Place a small loop at the lead for slack. If necessary, loosely tie a suture around the lead-loop. Do not tighten the suture onto the lead as this may cause Lead damage.
11. If necessary, carefully remove excess slack by gently pulling the extensions from the exit wound.
12. Place and tape a stress relief loop and dress the wound. Use standard aseptic dressing technique at the exit site and at the lead junction for the duration of the trial period.
13. To connect Nevro Perm Leads to a Boston Scientific Implantable Pulse Generator after the trial phase, consult the appropriate Directions for Use provided with your Boston Scientific Implantable Pulse Generator for detailed implant procedure.
14. To replace Trial or Perm leads with permanent Boston Scientific Leads and Implantable Pulse Generator, consult the appropriate Directions for Use provided with your Boston Scientific Leads and Implantable Pulse Generator.

Section B: Connecting Boston Scientific Devices after a Nevro Permanent Implant

This section outlines instructions for connecting permanently implanted Nevro Leads and Lead Extensions to a Boston Scientific Implantable Pulse Generator.

1. Consult the appropriate product labeling to explain the Nevro Implantable Pulse Generator.
2. If a Boston Scientific Trial procedure will be performed with a Boston Scientific Lead Extension, follow Steps 4-12 in Section A.
3. To connect the Nevro Lead or Lead Extension to the Boston Scientific Implantable Pulse Generator, consult the appropriate product labeling provided with your Boston Scientific Implantable Pulse Generator.

Customer Service - 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

Customer Service - Outside USA

If you have any other questions or need to contact Boston Scientific, choose your locality from the contact list.

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