Nevro Lead Compatibility

Directions for Use

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.
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.

Trademarks
All trademarks are the property of their respective owners.

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

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEAD2008-25B</td>
<td>Blue Lead Extension Kit, 25 cm</td>
</tr>
<tr>
<td>LEAD2008-35B</td>
<td>Blue Lead Extension Kit, 35 cm</td>
</tr>
<tr>
<td>LEAD2008-60B</td>
<td>Blue Lead Extension Kit, 60 cm</td>
</tr>
<tr>
<td>LEAD1058-30B</td>
<td>Blue Lead Kit, 30 cm with 5 mm spacing</td>
</tr>
<tr>
<td>LEAD1058-50B</td>
<td>Blue Lead Kit, 50 cm with 5 mm spacing</td>
</tr>
<tr>
<td>LEAD1058-70B</td>
<td>Blue Lead Kit, 70 cm with 5 mm spacing</td>
</tr>
<tr>
<td>LEAD1058-90B</td>
<td>Blue Lead Kit, 90 cm with 5 mm spacing</td>
</tr>
<tr>
<td>TLEAD1058-50B</td>
<td>Trial Lead Kit, 50 cm with 5 mm spacing</td>
</tr>
<tr>
<td>TLEAD1058-70B</td>
<td>Trial Lead Kit, 70 cm with 5 mm spacing</td>
</tr>
<tr>
<td>TLEAD1058-90B</td>
<td>Trial Lead Kit, 90 cm with 5 mm spacing</td>
</tr>
</tbody>
</table>

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 explant 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.

Argentina
T: +54 11 4896 8556 F: +54 11 4896 8550
Australia / New Zealand
T: 1800 676 153 F: 1800 836 666
Austria
T: +43 1 60 810 0 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: +56 2 449 4904 F: +56 2 449 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: 8 30 30 02 02 F: 8 30 30 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 4201 F: +30 210 95 4240
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