How to Use this Manual

This manual describes the usage and implantation of the Boston Scientific Deep Brain Stimulation (DBS) Systems. Read all instructions carefully before using the DBS Systems.

For indications for use, contraindications, warnings, precautions, adverse events, storage and handling, sterilization, and warranty information refer to the DBS Information for Prescribers DFU. For other device-specific information not included in this manual, refer to the appropriate DFU for your Boston Scientific DBS System as listed in your DBS Reference Guide.

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. Note that not all drawings are to scale.

Trademarks

All trademarks are the property of their respective holders.

Contacting Boston Scientific

To contact Boston Scientific, see the “Technical Support” section of this manual.
**Product Model Numbers**

You will only receive products appropriate for your region.

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-2201-XX-DC</td>
<td>DBS Lead Kit, 30 cm or 45 cm</td>
</tr>
<tr>
<td>DB-2202-XX</td>
<td>Vercise™ Cartesia™ 8 Contact DBS Directional Lead Kit, 30 cm or 45 cm</td>
</tr>
<tr>
<td>DB-4600-C</td>
<td>Burr Hole Cover</td>
</tr>
<tr>
<td>DB-4605-C</td>
<td>Burr Hole Cover Spares Kit</td>
</tr>
<tr>
<td>DB-2500-C</td>
<td>Vercise™ Physician’s Spare Kit</td>
</tr>
<tr>
<td>NM-3138-55</td>
<td>8 Contact Lead Extension Kit, 55 cm</td>
</tr>
<tr>
<td>DB-5170</td>
<td>Vercise DBS External Trial Stimulator 3 (ETS 3)</td>
</tr>
<tr>
<td>DB-5132</td>
<td>Vercise DBS External Trial Stimulator 2 (ETS 2)</td>
</tr>
<tr>
<td>DB-5132-S</td>
<td>Vercise DBS External Trial Stimulator 2 (ETS 2)</td>
</tr>
<tr>
<td>DB-4120-08</td>
<td>8 Contact Push-Button OR Cable</td>
</tr>
<tr>
<td>DB-4100-A; SC-4100-A</td>
<td>1x8 OR Cable and Extension</td>
</tr>
<tr>
<td>DB-9315</td>
<td>ETS Adapter</td>
</tr>
<tr>
<td>DB-1408</td>
<td>Vercise Genus™ P8 Implantable Pulse Generator Kit</td>
</tr>
<tr>
<td>SC-4401</td>
<td>Port Plug, Spares</td>
</tr>
<tr>
<td>DB-4252; SC-4252</td>
<td>Straw Tunneling Tool, 28 cm</td>
</tr>
<tr>
<td>DB-4254; SC-4254</td>
<td>Long Tunneling Tool, 35 cm</td>
</tr>
<tr>
<td>SC-4275</td>
<td>Hex Wrench (Torque Wrench)</td>
</tr>
</tbody>
</table>

*Note: XX = length (cm)*
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Product Kits

Leads

Table 1: 8 Contact Lead Kits

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead with preloaded Straight Stylet</td>
<td>1</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
<tr>
<td>Lead Boot</td>
<td>1</td>
</tr>
<tr>
<td>Lead Stop – Screw and Ring</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Split Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>2.3 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>4 cm Suture Sleeve</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package or tray are sterile and non-pyrogenic.*

Table 2: 8 Contact Directional Lead Kits

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directional Lead with preloaded Straight Stylet</td>
<td>1</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
<tr>
<td>Lead Boot</td>
<td>1</td>
</tr>
<tr>
<td>Lead Stop – Screw and Ring</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Split Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>2.3 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>4 cm Suture Sleeve</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package or tray are sterile and non-pyrogenic.*
Table 3: Vercise Physician's Spares Kit for 8 Contact Leads

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Boot</td>
<td>1</td>
</tr>
<tr>
<td>Lead Stop – Screw and Ring</td>
<td>1</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>1 cm Split Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>2.3 cm Suture Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>4 cm Suture Sleeve</td>
<td>1</td>
</tr>
</tbody>
</table>

**Note:** All contents of the inner package are sterile.
# Lead Extensions

## Table 4: 8 Contact Lead Extension Kits

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Extension</td>
<td>1</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
<tr>
<td>28 cm Tunneling Tool Shaft (with Pre-Loaded Straw)</td>
<td>1</td>
</tr>
<tr>
<td>Tunneling Tool Handle</td>
<td>1</td>
</tr>
</tbody>
</table>

**Note:** All contents of the inner package or tray are sterile.
### ETS and OR Cables

#### Table 5: External Trial Stimulator Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Trial Stimulator</td>
<td>1</td>
</tr>
<tr>
<td>AA Batteries</td>
<td>2</td>
</tr>
</tbody>
</table>

#### Table 6: 8 Contact Push-Button OR Cable

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Cable</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*

#### Table 7: 1x8 OR Cable

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR Cable</td>
<td>1</td>
</tr>
<tr>
<td>OR Cable Extension</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*
### Implantable Pulse Generators

#### Table 8: 8 Contact Implantable Pulse Generator Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable Pulse Generator</td>
<td>1</td>
</tr>
<tr>
<td>Implantable Pulse Generator Template</td>
<td>1</td>
</tr>
<tr>
<td>Implantable Pulse Generator Port Plugs</td>
<td>1</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package or tray are sterile.*

#### Table 9: Port Plug, Spares Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Port Plugs</td>
<td>2</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*
## Surgical Accessories

### Table 10: Tunneling Tool Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tunneling Tool Shaft (with Pre-Loaded Straw)</td>
<td>1</td>
</tr>
<tr>
<td>Tunneling Tool Handle</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*

### Table 11: Hex Wrench Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torque Wrench</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*
Burr Hole Cover

Table 12: Burr Hole Cover Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base and Bone Screws preassembled to Butterfly Holding Tool</td>
<td>1</td>
</tr>
<tr>
<td>Retaining Clip</td>
<td>1</td>
</tr>
<tr>
<td>Cap</td>
<td>1</td>
</tr>
<tr>
<td>Placement/Removal Tool</td>
<td>1</td>
</tr>
<tr>
<td>Screwdriver</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package (or tray) are sterile.*

Table 13: Burr Hole Cover Spares Kit

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Screws</td>
<td>1</td>
</tr>
<tr>
<td>Retaining Clip</td>
<td>1</td>
</tr>
<tr>
<td>Cap</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note: All contents of the inner package are sterile.*
Product Descriptions

Device Descriptions and Technical Specifications

The implantable components of the Boston Scientific DBS System include the following:

- An Implantable Pulse Generator (IPG) that is non-rechargeable (also referred to as a Stimulator throughout this manual).
- Leads
- Lead Extensions that extend the Leads to the IPG
- A Lead Boot to protect the proximal end of the Lead between surgeries
- Sutures Sleeves to protect the Lead and/or to anchor the Leads and Lead Extensions
- The Boston Scientific SureTek™ Burr Hole Cover that may be used to anchor the Leads

The non-implantable components of the Boston Scientific DBS System include the following:

- An External Trial Stimulator (ETS) and OR Cables that may be used for intraoperative testing
- A Tunneling Tool that is used to create a subcutaneous tunnel for the Leads and Lead Extensions
- A Clinician Programmer that is used to set and adjust stimulation parameters
- External patient devices, such as the Remote Control that is used to communicate with the IPG
**Standard Lead**

The Standard Lead consists of 8 cylindrical Contacts. The diameter of the Lead is 1.3 mm. The Lead is compatible with existing commercially available DBS implantation tools.

<table>
<thead>
<tr>
<th>Table 14: Technical Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Lead (DB-2201)</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Length</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>Contact Surface Area</td>
<td>6.0 mm²</td>
</tr>
<tr>
<td>Contact Spacing (axial)</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Array Span</td>
<td>15.5 mm</td>
</tr>
<tr>
<td>Distal Contact to Tip Length</td>
<td>&lt; 1.3 mm</td>
</tr>
<tr>
<td>Lead Diameter</td>
<td>1.3 mm</td>
</tr>
<tr>
<td>Overall Length</td>
<td>30 cm or 45 cm</td>
</tr>
<tr>
<td>Outer Tubing Material</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Contact Material</td>
<td>Platinum/Iridium</td>
</tr>
<tr>
<td>Impedance</td>
<td>≤ 90 Ω (measured from each connector to corresponding electrode Contact)</td>
</tr>
</tbody>
</table>
Directional Leads

The 8 Contact Directional Lead (see Table 15) has rows of Contacts that are segmented circumferentially to allow both axial and rotational stimulation selectivity. Each segmented Contact covers 90 degrees of the Lead circumference. Each Directional Lead has a radiopaque marker whose solid portion aligns with Contact 2. The outer diameter of each Directional Lead is 1.3 mm. The Directional Leads are compatible with existing commercially available DBS implantation tools.

### Table 15: Technical Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Length(^1)</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>Ring Contact Surface Area</td>
<td>6.0 mm(^2)</td>
</tr>
<tr>
<td>Segmented Contact Surface Area</td>
<td>1.5 mm(^2)</td>
</tr>
<tr>
<td>Dome Tip Contact Surface Area</td>
<td>6.0 mm(^2)</td>
</tr>
<tr>
<td>Contact Spacing (axial)</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Array Span</td>
<td>7.5 mm</td>
</tr>
<tr>
<td>Lead Diameter</td>
<td>1.3 mm</td>
</tr>
<tr>
<td>Overall Length</td>
<td>30 cm or 45 cm</td>
</tr>
<tr>
<td>Outer Tubing Material</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Contact Material</td>
<td>Platinum/Iridium</td>
</tr>
<tr>
<td>Impedance</td>
<td>(\leq 90 , \Omega) (measured from each connector to corresponding electrode Contact)</td>
</tr>
</tbody>
</table>

---

\(^1\) Also applies to dome tip Contact.
Lead Extensions

The Boston Scientific DBS System can include 8 Contact Leads implanted in the brain. The model of DBS Lead and position of the DBS IPG being implanted will determine the compatible Lead Extension that should be used with that system. See the “DBS Product Compatibility” section of this manual.

8 Contact Lead Extension

The 8 Contact Lead Extension consists of a Connector at the distal end and 8 cylindrical Contacts at the proximal end. The Lead is inserted and secured into the Connector on the distal end. The Connector also contains 8 Contacts that align with the Contacts on the Lead to form electrical connections. The proximal end of the extension is inserted into the IPG.

The 8 Contact Lead Extension may only be used with 8 Contact Leads. Each of these Lead Extensions connects to a single Lead. This 55 cm model is intended to support IPGs implanted in the pectoral region.

| Table 16: Technical Specifications        |     |
|------------------------------------------|--|--|
| 8 Contact Lead Extension (NM-3138)       |     |
| Feature                    | Specification      |
| Overall Length             | 55 cm              |
| Lead Extension Body Diameter | 1.35 mm            |
| Number of Contacts         | 8                  |
| Contact Material           | Platinum/Iridium   |
| Insulation Material        | Polyurethane, Silicone |
| Setscrew Material          | Titanium           |
Surgical Tools and Accessories

Lead Boot

The Lead Boot protects the proximal end of the implanted Lead until the IPG implant surgery. The Setscrew on the Lead Boot is used to secure the Lead in the Lead Boot when screwed onto the retention sleeve.

The Lead Boot provided in either of the kit types listed below is only compatible with 8 Contact Leads:

- An 8 Contact Lead Kit
- Vercise Physician's Spares Kit

<table>
<thead>
<tr>
<th>Table 17: Technical Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Feature</strong></td>
</tr>
<tr>
<td>Overall Length</td>
</tr>
<tr>
<td>Setscrew Material</td>
</tr>
<tr>
<td>Connector Block Material</td>
</tr>
<tr>
<td>Endstop Material</td>
</tr>
<tr>
<td>Insulation Material</td>
</tr>
</tbody>
</table>
**Tunneling Tool**

The Tunneling Tool is used to create a path for the Lead and Lead Extension in the subcutaneous tissue.

**Table 18: Technical Specifications**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>28 cm (Straw), 35 cm (Long)</td>
</tr>
<tr>
<td>Shaft Material</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Straw Material</td>
<td>PTFE</td>
</tr>
<tr>
<td>Handle Material</td>
<td>Stainless Steel, Ultem</td>
</tr>
</tbody>
</table>

**Suture Sleeves**

The Suture Sleeve may be used to anchor the Lead or Lead Extension to the fascia. If a mini-plate is used, the Suture Sleeve is placed between the Lead and the mini-plate to protect the Lead.

**Table 19: Technical Specifications**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Length</td>
<td>1 cm, 2.3 cm, 4 cm</td>
</tr>
<tr>
<td>Material</td>
<td>Silicone</td>
</tr>
</tbody>
</table>
**SureTek Burr Hole Cover**

The SureTek Burr Hole Cover is a Lead-anchoring device for use with the Boston Scientific DBS System. The Burr Hole Cover is compatible with a burr hole created by a 14 mm perforator. The components of the Burr Hole Cover are listed in Table 20. The materials for the Burr Hole cover are listed in Table 21.

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Base</td>
</tr>
<tr>
<td>2</td>
<td>Butterfly Holding Tool</td>
</tr>
<tr>
<td>3</td>
<td>Bone Screw</td>
</tr>
<tr>
<td>4</td>
<td>Lead Exit Slot</td>
</tr>
<tr>
<td>5</td>
<td>Cap Slot</td>
</tr>
<tr>
<td>6</td>
<td>Cap</td>
</tr>
<tr>
<td>7</td>
<td>Placement/Removal Tool</td>
</tr>
<tr>
<td>8</td>
<td>Horseshoe End</td>
</tr>
<tr>
<td>9</td>
<td>Tip End</td>
</tr>
<tr>
<td>10</td>
<td>Post</td>
</tr>
<tr>
<td>11</td>
<td>Tab</td>
</tr>
<tr>
<td>12</td>
<td>Retaining Clip</td>
</tr>
<tr>
<td>13</td>
<td>Clip Release Hole</td>
</tr>
<tr>
<td>14</td>
<td>Closure Dimple on Slider</td>
</tr>
<tr>
<td>15</td>
<td>Screwdriver</td>
</tr>
<tr>
<td>Feature</td>
<td>Specification</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------------------------</td>
</tr>
<tr>
<td>Base</td>
<td>Polyether ether ketone (PEEK)</td>
</tr>
<tr>
<td>Retaining Clip</td>
<td>PEEK</td>
</tr>
<tr>
<td>Cap</td>
<td>PEEK</td>
</tr>
<tr>
<td>Bone Screws</td>
<td>Titanium</td>
</tr>
<tr>
<td>Butterfly Holding Tool</td>
<td>Polyetherimide, Silicone</td>
</tr>
<tr>
<td>Placement/Removal Tool</td>
<td>Polyetherimide, Titanium</td>
</tr>
<tr>
<td>Disposable Screwdriver</td>
<td>Polybutylene terephthalate (PBT) polycarbonate resin, stainless steel</td>
</tr>
</tbody>
</table>
External Trial Stimulators (ETS 2 and ETS 3)

The ETS, OR Cable, along with Clinician Programmer (CP) or Remote Control are used to conduct intraoperative test stimulation and/or intraoperative impedance measurements during the DBS surgical procedure. See the “DBS Product Compatibility” section of this manual.

Table 22: Physical Characteristics
ETS 2 (DB-5132 and DB-5132-S) and ETS 3 (DB-5170)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>80 mm x 60 mm x 26 mm</td>
</tr>
<tr>
<td>Case Material</td>
<td>Silicone and Plastic</td>
</tr>
<tr>
<td>Number of Ports</td>
<td>2</td>
</tr>
<tr>
<td>Replacement Batteries</td>
<td>2 AA Batteries</td>
</tr>
</tbody>
</table>

Table 23: ETS Indicator Lights

<table>
<thead>
<tr>
<th>Stimulator Light</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Green</td>
<td>ETS is ON</td>
</tr>
<tr>
<td>Flashing Green</td>
<td>Stimulation is ON</td>
</tr>
<tr>
<td>Solid Yellow</td>
<td>Error</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Battery Indicator Light</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid/Flashing Green</td>
<td>ETS is ON</td>
</tr>
<tr>
<td>Flashing Yellow</td>
<td>Replace the batteries in the ETS</td>
</tr>
<tr>
<td>Alternating Green and Yellow (ETS 3 Only)</td>
<td>The ETS is in Pairing Mode</td>
</tr>
</tbody>
</table>
Implantable Pulse Generators (IPGs)

Vercise Genus™ Non-Rechargeable Implantable Pulse Generator

Vercise Genus P8 is an 8 Contact non-rechargeable IPG, also known as a “single channel” device. Two Vercise Genus P8 IPGs may be implanted to support a bilateral configuration. For full body MRI scan eligibility, confirm that the IPG is implanted according to the instructions contained in the ImageReady™ MRI Guidelines for Boston Scientific DBS Systems. For additional information on the Energy Use Index or the programmable characteristics of the Vercise Genus System, refer to the Programming Manual as listed in the DBS Reference Guide.

Each Vercise Genus IPG contains a radiopaque identification tag that is visible using standard x-ray procedures (Figure 1).

Figure 1. Vercise Genus P8 Tag

The physical characteristics of the Vercise Genus P8 non-rechargeable IPG are outlined in Table 24.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Contacts</td>
<td>8 (1 Port)</td>
</tr>
<tr>
<td>Number of Contacts per Port</td>
<td>8</td>
</tr>
<tr>
<td>Case Material</td>
<td>Titanium</td>
</tr>
<tr>
<td>Header Material</td>
<td>Epoxy</td>
</tr>
<tr>
<td>Strain Relief Material</td>
<td>Silicone</td>
</tr>
<tr>
<td>Dimensions</td>
<td>72 mm x 49.6 mm x 11.6 mm</td>
</tr>
<tr>
<td>Volume</td>
<td>34.9 cm³ (including header)</td>
</tr>
</tbody>
</table>
DBS Product Compatibility

For compatibility of DBS Leads, Lead Extensions, IPGs, OR Cables, and External Trial Stimulators, see Table 25, Table 26, Table 27, and Table 28.

Table 25: Compatibility
DBS Leads and Lead Extensions

<table>
<thead>
<tr>
<th>Lead Model Number</th>
<th>Compatible Lead Extensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-2201 (30 or 45 cm)</td>
<td>NM-3138-55</td>
</tr>
<tr>
<td>DB-2202 (30 or 45 cm)</td>
<td>NM-3138-55</td>
</tr>
</tbody>
</table>

*Note: Leads and Lead Extensions of the same model are provided in different lengths. The length of the Lead and/or Lead Extension does not affect their compatibility with the listed component.*

Table 26: Compatibility
IPGs and Lead Extensions

<table>
<thead>
<tr>
<th>IPG Model Number</th>
<th>Compatible Lead Extensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-1408 (1 Port, 8 Contact IPG)</td>
<td>NM-3138-55</td>
</tr>
</tbody>
</table>

*Note: Leads and Lead Extensions of the same model are provided in different lengths. The length of the Lead and/or Lead Extension does not affect their compatibility with the listed component.*

Table 27: Compatibility
Leads with the OR Cables

<table>
<thead>
<tr>
<th>Lead Model Number</th>
<th>Compatible OR Cables</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-2201 (30 or 45 cm)</td>
<td>DB-4120-08</td>
</tr>
<tr>
<td></td>
<td>DB-4100-A</td>
</tr>
<tr>
<td>DB-2202 (30 or 45 cm)</td>
<td>DB-4120-08</td>
</tr>
<tr>
<td></td>
<td>DB-4100-A</td>
</tr>
</tbody>
</table>

Table 28: Compatibility
External Trial Stimulators with the OR Cables

<table>
<thead>
<tr>
<th>ETS Model Number</th>
<th>Compatible OR Cables</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-5132 and DB-5132-S</td>
<td>DB-4120-08</td>
</tr>
<tr>
<td></td>
<td>DB-4100-A with ETS Adapter DB-9315</td>
</tr>
<tr>
<td>DB-5170</td>
<td>DB-4120-08</td>
</tr>
<tr>
<td></td>
<td>DB-4100-A with ETS Adapter DB-9315</td>
</tr>
</tbody>
</table>
Implanting the DBS System

In the following instructions, the Standard Lead and the Directional Leads are collectively referred to as the “DBS Lead,” unless otherwise indicated. The SureTek Burr Hole Cover Kit is recommended for use with the Boston Scientific DBS System. The DBS Lead implantation procedure described in this manual includes the use of the Burr Hole Cover to anchor the DBS Lead.

Use meticulous care during implantation of the Boston Scientific DBS System to prevent infection. For additional information regarding recommended practices for the DBS procedure, see the “References” section of this manual.

Note: Throughout this manual, the descriptors “proximal” and “distal” use the position of the ETS or IPG as the reference point.

Pre-Conditions

Leads

The DBS surgical procedures described in this manual begin with implantation of the DBS Lead. It is assumed that the following procedures have been completed:

- The stereotactic frame and/or fiducials of a frameless system are attached to the patient.
- The incision in the scalp has been made and the burr hole drilled. The SureTek™ Burr Hole Cover is compatible with a 14 mm diameter burr hole.
- The desired trajectory and DBS Lead depth has been determined and verified by appropriate means.

Note: Review the Technical Specifications for the DBS Leads, included in this manual, when considering trajectory and target depth. Do not apply fixation mechanism within array regions including the distal length.
Securing the Base of the SureTek Burr Hole Cover

Visually inspect the Burr Hole Cover components to ensure that they are acceptable for implant. Before securing the base of the Burr Hole Cover, ensure that the 14 mm burr hole is free of obstructions, such as bone, that will prevent proper insertion of the Burr Hole Cover.

**Warning:** Before securing the Base of the Burr Hole Cover, examine the cranial bone and structure to ensure that disease or damage is not present and that the thickness of the cranial bone is 5 mm or greater. Failure to adhere to this warning may affect the following:

- **Lead Anchoring**: Lead migration due to an improperly anchored DBS Lead may diminish the effectiveness of therapy.
- **Burr Hole Closure**: An unstable burr hole closure may increase the risk of infection and place the patient at risk for damage to brain tissue, leakage of cerebrospinal fluid, and/or damage to the dura.

1. Place the Base of the Burr Hole Cover that is attached to the Butterfly Holding Tool over the burr hole (Figure 2).

![Figure 2. Base Attached to the Butterfly Holding Tool with Screwdriver Inserted](image)

2. Using the Screwdriver, gently push the Bone Screws through the Silicone Sleeve.

   **Note:** **Optional.** To fully visualize and access the screw head position while covering the burr hole, rotate the Butterfly Holding Tool 90 degrees. Return the Butterfly Holding Tool to the original position to continue with the procedure.

3. Tighten the two Bone Screws into the skull.

   **Note:** Continue tightening the Bone Screws until the Base of the Burr Hole Cover is flush to the skull and the screws are flush to the Base. The Base should not move or rock once secured. Do not use excessive force or overtighten the Screws.

4. Grasp the handles of the Butterfly Holding Tool and remove it by pulling upward at an angle.
Implanting the DBS Lead

**Note:** Throughout this manual, the descriptors “proximal” and “distal” use the position of the ETS or IPG as the reference point.

1. Visually inspect the DBS Lead and ensure that it is acceptable for implantation.
2. Pass the DBS Lead through the Cannula to ensure that it is a proper fit, then remove the DBS Lead from the Cannula.
3. With the Cannula Stylet in place, insert the Cannula into the brain to the desired depth.
   
   **Note:** Cannula depth depends on the physician’s preference.

4. Assemble the Lead Stop (Figure 3) by partially screwing the threaded portion of the screw into the threaded hole in the ring.

![Figure 3. DBS Lead Stop](image)

5. Measure the desired depth of the DBS Lead with a gauge or ruler and apply the DBS Lead Stop at that length.

   To apply the DBS Lead Stop, push the DBS Lead to the center of the Lead Stop, then tighten the Screw (Figure 4). This will ensure that the DBS Lead will be inserted to the proper depth. Take care not to overtighten the Lead Stop onto the Lead Body.

   **Note:** Ensure that the Lead Stop does not slide on the DBS Lead when engaged.

![Figure 4. Applying the DBS Lead Stop](image)

6. Remove the Cannula Stylet.
7. With the Lead Stylet in place, insert the DBS Lead into the Cannula.
8. Insert the Cannula with the DBS Lead into the Cannula guide on the Microdrive.

For a DBS Directional Lead, you may orient the Directional Contacts by positioning the Directional Marker (Figure 5) in a desired position when attaching the Lead to the Microdrive. This Directional Marker is radiopaque. Boston Scientific recommends orienting the Directional Contacts so that Contact #2 and the Directional Marker are facing an anterior direction within the brain.

![DB-2202](image)

Figure 5. Directional Lead Marker

9. Slowly advance the DBS Lead to the desired target using the Microdrive.

*Note:* Ensure that the Lead Stylet is inside the Lead before advancing the Lead to the desired target.
Intraoperative Testing

Intraoperative testing may be performed using the External Trial Stimulator (ETS) and the appropriate OR Cable. See the “DBS Product Compatibility” section of this manual. Refer to the appropriate Programming Manual as listed in the DBS Reference Guide for detailed stimulation procedures and guidelines.

**Caution:** Do not immerse the OR Cable Connector or plug in water or other liquids. The OR Cable is intended for single use only; do not resterilize.

Intraoperative Testing Using ETS 3 and 8 Contact Push-Button OR Cables (DB-5170 with DB-4120-08)

1. Ensure that ETS 3 is off by checking the Stim Indicator light on the ETS.
   
   **Warning:** Always turn the ETS 3 off before connecting or disconnecting the OR Cable assemblies to prevent unexpected stimulation.

2. Connect the proximal end of the OR Cable Extension to the ETS 3 Port labeled “L” while keeping the distal end of the OR cable within the sterile field (Figure 6).
   
   If two DBS Leads are being tested simultaneously, connect the left DBS Lead to Port L and the right DBS Lead to Port R.

Figure 6. Connecting the OR Cable to ETS 3
3. Hold the OR Cable and DBS Lead as shown in Figure 7. Press down on the button to open the OR Cable Connector. Keep the button depressed.

4. With the Lead Stylet in place, slide the OR Cable Connector onto the proximal end of the DBS Lead (Figure 7). Make sure that the DBS Lead is fully inserted. The OR Cable Connector will stop when the DBS Lead is fully inserted.

**Figure 7. Depress Button on the OR Cable Connector to Connect OR Cable to DBS Lead**

*Note: The Lead Stylet will extend through the back hole of the OR Cable Connector when the DBS Lead is fully inserted as shown in Figure 8.*

**Figure 8. OR Cable Connected to DBS Lead**
5. Support the OR Cable Connector to prevent unnecessary bending of the Lead during testing.

6. Verify that impedances are acceptable by using the Clinician Programmer or Remote Control.

7. Evaluate Lead placement by appropriate methods. If necessary, adjust the Lead location or stimulation parameters.

   **Note:** The Lead Stylet should remain in place throughout insertions or adjustments of the DBS Lead.

   **Warning:** High charge density can cause permanent tissue damage. The Clinician Programmer will limit stimulation parameters to safe values.

   **Warning:** Increasing the number of Lead penetrations increases the probability of hemorrhage. To minimize acute Lead revisions, use techniques of target localization, such as microelectrode recordings and/or imaging.

8. Turn off ETS 3.

   **Warning:** A sudden increase in stimulation may occur if ETS 3 is ON while disconnecting the OR Cables.

9. Depress the button on the OR Cable Connector to release the Lead. Keep the button depressed until the OR Cable Connector has been fully removed from the Lead and Lead Stylet.

10. Disconnect the OR Cable from the proximal end of the DBS Lead by sliding the OR Cable Connector straight up and off the DBS Lead and Lead Stylet. Use caution to avoid disturbing the Lead Stylet within the DBS Lead.

11. Verify that the DBS Lead has not moved from the desired location.
Intraoperative Testing Using the ETS 2, the ETS Adapter, and 1x8 OR Cables and Extension

1. Attach the OR Cable Extension to the OR Cable (Figure 9).

![Figure 9. 1x8 OR Cables and Extension](image)

2. Ensure that ETS 2 is off by checking the Stim Indicator light on the ETS.

   **Warning:** Always turn the ETS 2 off before connecting or disconnecting the OR Cable assemblies to prevent unexpected stimulation.

3. Plug the ETS Adapter into the ETS 2 Port labeled “CD” (Figure 10).

![Figure 10. Connection of the ETS Adapter to the ETS 2](image)

4. Plug the OR Cable with Extension into the ETS Adapter Port labeled “1-L” (Figure 11).

   If two DBS Leads are being tested simultaneously, connect the left DBS Lead to Port 1-L and the right DBS Lead to Port 2-R.

![Figure 11. Connection of the 1x8 OR Cable to ETS 2 and ETS Adapter](image)

5. Check that the locking lever on the OR Cable Connector is in the open (0) position.
6. With the Lead Stylet in place, slide the OR Cable Connector onto the proximal end of the DBS Lead (Figure 12). Make sure that the DBS Lead is fully inserted.

   **Note:** The Lead Stylet will extend through the back hole of the OR Cable Connector when the DBS Lead is inserted as shown in Figure 12.

7. Hold the DBS Lead in place. Slide the locking lever to the locked (1) position (Figure 12).

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**Figure 12. Securing the DBS Lead Into the 1x8 OR Cable Connector**

8. Support the OR Cable Connector to prevent unnecessary bending of the Lead during testing.

9. Verify that impedances are acceptable by using the Clinician Programmer or Remote Control.

10. Evaluate Lead placement by the appropriate methods. If necessary, adjust the Lead location or stimulation parameters.

   **Note:** The stylet should remain in place throughout insertion or adjustments of the DBS Lead.

   **Warning:** High charge density can cause permanent tissue damage. The Clinician Programmer will limit the stimulation parameters to safe values.

   **Warning:** Increasing the number of Lead penetrations increases the probability of hemorrhage. To minimize acute Lead revisions, use techniques of target localization, such as microelectrode recordings and/or imaging.

11. Turn off ETS 2.

   **Warning:** A sudden increase in stimulation may occur if ETS 2 is ON while disconnecting the OR Cables.

12. Slide the locking lever to the open (0) position. Disconnect the OR Cable Connector and Extension from the proximal end of the DBS Lead.

13. Verify that the DBS Lead has not moved from the desired location.
Securing the DBS Lead

Once a DBS Lead has been placed, it should be secured.

**Caution:** While securing the DBS Lead, use care not to impact its implanted location.

1. Remove the Lead Stop by unscrewing the screw and detaching the Lead Stop from the DBS Lead.
2. Slowly retract the Cannula to just above the burr hole by sliding it over the proximal portion of the DBS Lead. Use care not to impact the location of the implanted Lead.
3. Fix the DBS Lead in place. Take care not to bend or clip on to any array regions, including the distal length, of the Lead during fixation.
   a. To use the Burr Hole Cover, see the “Securing the DBS Lead with the Burr Hole Cover” section of this manual and follow Steps 4 through 12.
   b. An appropriate commercially available filler and mini plate may also be used. Ensure the Lead Stylet has been removed from the Lead prior to applying the mini plate.

Securing the DBS Lead with the Burr Hole Cover

4. Rotate the horseshoe end of the Placement/Removal Tool so that the tool is oriented as desired (Figure 13).

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2 Securing of the DBS Lead has been tested utilizing Biomet Mimix QS bone filler, a Stryker 12 mm titanium mini plate, Stryker titanium screws, and a Boston Scientific 1 cm split suture sleeve. Data on file.
5. Attach the retaining clip to the horseshoe end of the Placement/Removal Tool. The post and the tab on the horseshoe end of this Tool should line up with the clip release hole and closure dimple (Figure 14).

**Caution:** Do not adjust the horseshoe end of the Placement/Removal Tool after the Retaining Clip has been attached.

![Figure 14. Attach Retaining Clip to Horseshoe End of Tool](image)

6. While stabilizing the DBS Lead, carefully position the Retaining Clip over the Base so that the DBS Lead is located in the open channel of the Retaining Clip. Position the Retaining Clip so that the static side of the opening is against the Lead (Figure 15).

![Figure 15. Position the Retaining Clip Over the Base](image)

7. Push the Retaining Clip down into the Base. Ensure that the Retaining Clip is completely seated in the Base.
8. Place the tip end of the Placement/Removal Tool into the closure dimple or anywhere along the length of the Slider on the Retaining Clip to push the Slider towards the DBS Lead until it locks into place. Use the tip end of the Placement/Removal Tool to apply pressure on the Slider face in the opposite direction to ensure that the Slider is fully locked (Figure 16).

![Figure 16. Lock the Slider](image)

9. Remove the Lead Stylet.

**Caution:** Do not reinsert the Lead Stylet into the DBS Lead while the DBS Lead is in the brain, as this may damage the DBS Lead and/or cause patient harm.

10. Gently fold the DBS Lead over and place it inside one of the four Lead Exit Slots in the Base of the Burr Hole Cover (Figure 17).

![Figure 17. Placing the DBS Lead into the Lead Exit Slot](image)

**Caution:** Secure the DBS Lead using a Lead Exit Slot that is approximately perpendicular to the Retaining Clip channel.
11. **Optional:** Secure the DBS Lead to additional Lead Exit Slots for added strain relief (Figure 18).

![Figure 18. Placement of the DBS Lead into Additional Lead Exit Slots](image)

12. Insert the Burr Hole Cover Cap into the Base by aligning the arms of the Cap with the Cap Slots in the Base.

   *Note:* You may need to push inward on a Cap arm to complete Cap insertion.

13. Remove the stereotactic frame and Microdrive system.
14. If the IPG will be implanted during a separate surgery:

a. Insert proximal end of the DBS Lead into the Lead Boot until it stops. It is recommended to place a Suture Sleeve on the Lead placed in the left hemisphere of the brain to assist with later differentiation between Leads.

**Caution:** Do not use the 8 Contact Lead Boot on a 16 Contact Lead. Do not use the 16 Contact Lead Boot on an 8 Contact Lead. Make sure to use the Lead Boot provided in the Lead Kit or appropriate Physician’s Spare Kit. The Lead Boot length is different for 8 and 16 Contact Leads.

**Note:** Be sure to fully insert the proximal tip of the DBS Lead into the Lead Boot so that the Retention Sleeve is located under the Setscrew (Figure 19).

![Correct and Incorrect insertion of DBS Lead in Lead Boot]

**Figure 19. Securing the DBS Lead in the Lead Boot**

**Note:** The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 20).

![Proximal End of the 8 Contact DBS Lead]

**Figure 20. Retention Sleeve**

b. Pass the Torque Wrench through the slit in the Septum located on the top of the Lead Boot.
c. Tighten the Setscrew until the Torque Wrench clicks, indicating that the Setscrew is fully secured.

**Note:** To tighten the Setscrew, use one hand to grasp the base of the Lead Boot and the other hand to rotate the Torque Wrench clockwise until it clicks, indicating that the Setscrew is fully secured (Figure 21). To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

![Figure 21. Tightening the Setscrew](image)

**Caution:** The Torque Wrench is torque-limiting to prevent overtightening of the Setscrew. Use only the Wrench provided, as other tools may overtighten the Setscrew and damage the DBS Lead.

d. Create a tunnel to transfer the proximal end of the DBS Lead closer to the desired location for the Lead Extension Connector.

**Caution:** Placement of the Extension Connector in the neck region can increase the risk of device failure due to repetitive movement of the neck.

e. Create a pocket under the skin for the excess DBS Lead and Lead Boot.

f. Coil excess DBS Lead material under the scalp, in the pocket, until it is ready to be connected to the Lead Extension.

**Note:** The DBS Lead may be connected to the Lead Extension and IPG in a separate surgery.

15. Close the incisions.
Tunneling the Lead Extension

Assembling the Tunneling Tool

A Tunneling Tool (Figure 22) and Straw are provided to facilitate tunneling of the Lead Extension.

![Tunneling Tool](image)

**Figure 22. Tunneling Tool**

1. Attach the Tunneling Tool Handle to the Shaft by turning the locking mechanism clockwise:
   a. Push the locking mechanism at the base of the Tool Handle onto the Shaft.
   b. Grasping the Tool Handle and the tip of the Tunneling Tool, rotate the Shaft back and forth until the Tool Handle seats onto the Shaft.
   c. While firmly grasping the tip of the Tunneling Tool to hold the shaft stationery, turn the locking mechanism clockwise until it is secure.

Create the IPG Pocket and Tunnel the Lead Extension

1. Create a pocket for the IPG under the skin in a location that is in the chest on the same side of the patient as the DBS Lead(s) and Lead Extension(s) connection:
   a. Mark the location of the IPG pocket.
   b. Use the IPG template provided to outline the intended pocket to guide the optimal pocket sizing.
      **Note:** It is important to keep the pocket small to prevent the IPG from turning over.
   c. Non-rechargeable IPGs should be implanted no deeper than 2.5 cm. Communication, including device programming, could become ineffective at depths greater than 2.5 cm.
      **Note:** For full body MRI scan eligibility, confirm that the IPG is implanted according to the instructions contained in the ImageReady™ MRI Guidelines for Boston Scientific DBS Systems.

2. Mark a tunneling route from the location of the IPG pocket to the incision superior to the ear near the Lead Boots.
3. Administer appropriate local anesthetic along the tunneling route.
   **Caution:** Be careful not to puncture or damage the DBS Lead or other components when administering the local anesthetic.
4. If desired, bend the Tunneling Tool to an appropriate shape.

**Caution:** Do not bend locking joints.

5. Create a subcutaneous tunnel from the incision above the ear, along the tunneling path to the IPG pocket.³

**Warning:** Be careful not to puncture or damage important structures along the tunneling path, such as the brachial plexus and jugular vein, as this may cause patient harm.

6. Once the tip of the Tunneling Tool is completely exposed, unscrew and remove the handle of the Tunneling Tool (Figure 23).

![Figure 23. Removing the Handle of the Tunneling Tool](image)

7. Grasp the tip of the Tunneling Tool firmly with one hand and, while holding the Straw in place with the other hand, pull the Shaft out of the Straw.

8. Push the proximal end of the Lead Extension through the Straw.

9. Withdraw the Tunneling Tool Straw.

10. **Optional:** Secure the Lead Extension Connector to the fascia using Sutures and/or Suture Sleeves.

**Caution:** Do not use polypropylene Sutures as they may damage the Suture Sleeve. Do not suture directly onto the Lead Extension or use a hemostat on the body of the Lead Extension. This may damage the insulation of the Lead Extension.

³ Tunneling has been tested utilizing 46 cm Integra Reusable Peritoneal Shunt Introducers (model 901218) with Replacement Peritoneal Shunt Sheaths (model 901118). Data on file.
Connecting the DBS Lead to the Lead Extension

Exposing the DBS Lead
1. Palpate the Lead Boot and DBS Lead under the scalp.
2. Mark and create an incision in the scalp to expose the Lead Boot. Be careful not to damage or cut the DBS Lead.
3. Expose the DBS Lead and Lead Boot through the incision.
4. Using the Torque Wrench, remove and discard the Lead Boot.
   \textbf{Note:} To loosen the Setscrew, rotate the Torque Wrench counterclockwise. To tighten the Setscrew, rotate the Torque Wrench clockwise.
5. Dry the proximal end of the DBS Lead.

Connecting the DBS Lead to the Lead Extension

![Diagram of DBS Lead and Lead Extension Connector](image)

\textbf{Figure 24. The DBS Lead and Lead Extension Connector}

1. Ensure that the Setscrew is not restricting the entry port on the Lead Extension Connector by unscrewing the Setscrew 1 to 2 turns with the Torque Wrench (Figure 24).
2. Grip the DBS Lead next to the Retention Sleeve. Grip the Extension in the center of the Extension Connector (Figure 25).

   **Note:** Grip the stiff portion of the Lead to avoid accidentally bending or kinking the Lead and potentially damaging the Lead during insertion into the Lead Extension Connector.

![Figure 25. Grip the DBS Lead and the Center of the Lead Extension Connector Prior to Insertion](image)

3. Push the DBS Lead into the Lead Extension Connector until the DBS Lead Contacts align with the Extension Contacts. Do not tighten the Setscrews at this time.

   **Caution:** Take care not to bend or kink the proximal Lead array, the stiff portion of the Lead body adjacent to the array, or the Lead Extension Connector during insertion.

   Some resistance may be felt as each Contact enters the Lead Extension Connector. You should be able to view the Lead Contacts as they pass through the Lead Extension Connector. Some additional resistance may be felt as the last Contact aligns.
5. Visually check that the DBS Lead electrodes are aligned with the Lead Extension Contacts (Figure 26).

If they are not aligned, continue to grip the DBS Lead next to the Retention Sleeve and push to advance the Contacts into alignment with the Lead Extension Contacts. If necessary, slightly retract the Lead, then advance the Contacts again until proper alignment is confirmed. Do not tighten the Setscrew in the Lead Extension Connector at this time.

When inserting either a DB-2201 or DB-2202 8 Contact Lead into an 8 Contact Extension, the retention sleeve will no longer be visible when the lead is fully inserted. Full insertion and alignment should be confirmed by visually checking that all contacts are aligned.

**Note:** Ensure that the DBS Lead is fully inserted into the Lead Extension Connector so that the Retention Sleeve is located under the Setscrew.

![Correct](Correct.png) ![Incorrect](Incorrect.png)

Figure 26. Alignment of the DBS Lead in the Lead Extension Connector

6. Do not tighten Setscrews at this time.

**Note:** Any unused Lead Extension ports should be filled with a port plug. Tighten the Setscrew on any Port Plugs.
Implanting the IPG

1. Insert and then remove the Port Plug from the IPG Ports to verify that no Setscrews are obstructing the socket.

2. Wipe the Lead Extension Contacts.

3. Insert the Lead Extensions into the IPG Port. See the “Connecting to the IPG” section of this manual for model specific details. Do not tighten the Setscrews at this time.

When fully inserted, the tip of the Lead Extension will slide to the back of the IPG Port and the Retention Sleeve on the Lead Extension will be located under the Setscrew.

**Caution:** Verify that the Lead Extension was properly inserted into the IPG Port by checking impedances before tightening the Setscrew. Tightening the Setscrew on a Contact can damage the Lead Extension.

4. Visually confirm that the Contacts on the Lead Extension are aligned with the Contacts within the IPG Header. Verify that the Retention Sleeve on the Lead Extension is located directly under the Setscrew in the IPG Port (Figure 27).

![Retention Sleeve Directly Under Setscrew](image)

**Figure 27. Alignment of Lead Extension Contacts in the DBS IPG Port**

**Note:** The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 28).

![Proximal End of the Lead Extension](image)

**Figure 28. Retention Sleeve on the Lead Extension**
5. Check impedances to verify connections before tightening the Setscrew:
   a. Place the IPG partially in the subcutaneous pocket.
   b. Test impedances using the Remote Control or Clinician Programmer.

6. Pass the Torque Wrench through the slit in the Septum located on the side of the IPG Header (Figure 29).

7. Tighten the Setscrew in the IPG Header until the Torque Wrench clicks, indicating that the Setscrew is fully secured.
   
   **Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

8. Pass the Torque Wrench through the slit in the septum located on the side of the Lead Extension Connector. Ensure the Retention Sleeve on the DBS Lead is still located under the Extension Setscrew.

9. Tighten the Setscrew in the Lead Extension until the Torque Wrench clicks, indicating the Setscrew is fully secured.

   **Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.
10. Place the IPG in the subcutaneous pocket with the etched writing “This Side Up” facing the skin and parallel to the skin surface.

**Note:** Make the pocket no deeper than 2.5 cm for Vercise Genus non-rechargeable IPGs. Communication, including device programming could become ineffective at depths greater than 2.5 cm.

**Warning:** Incorrect placement of the IPG in the pocket could require a revision surgery.

a. Coil the excess Lead Extension length under or around the IPG perimeter.

**Warning:** Avoid placing the excess length of the Lead Extensions on the superficial surface of the IPG as this may result in tissue erosion, ineffective communication, or charging difficulty.

b. **Optional:** Secure the IPG to the fascia by suturing through the holes in the IPG Header.

11. Close the incisions.

**Caution:** Be careful not to damage the DBS Lead, IPG, or other implanted components when closing the incisions.

**Note:** When closing the incision over the Lead Extension Connector, orient the Lead Extension Connector to minimize the profile under the skin.
Connecting to the IPG

When connecting the Lead Extension to the IPG, it is recommended that the following connection configurations are utilized.

1-Port (8 Contact) IPG

For single 8 Contact Lead connection with the Lead Extension NM-3138-55 to the 1-Port IPG:

a. Connect the Extension to port C (Figure 30).

Figure 30. Connection to IPG Port C
Explanting or Replacing the DBS System

Explanting the DBS System

If the entire DBS System (Stimulator, Extensions, and DBS Leads) will be explanted, then the DBS Leads should be removed first (as described below) followed by the Lead Extensions, then the IPG. This order will reduce the potential spread of infection toward the incision on the skull. However, if only a single component will be replaced, follow the instructions below for that specific component.

Removing the DBS Leads

Warning: When explanting the Boston Scientific DBS System, the DBS Lead should be pulled from the site above the ear and not the site near the burr hole, to avoid a potential spread of infection toward the incision on the skull.

1. Turn off the IPG.
2. Palpate the scalp to locate the Burr Hole Cover.
3. Make an incision near the Burr Hole Cover to expose it and the DBS Lead. While making the incision, be careful not to damage or cut the DBS Lead or Suture Sleeve.
4. Cut the DBS Lead approximately 2 to 3 cm from the Burr Hole Cover, leaving enough length to grasp the DBS Lead.
5. If applicable, see the “Removing the Burr Hole Cover” section of this manual to remove the Burr Hole Cover.
6. Slowly and gently retract the distal portion of the DBS Lead from the neural tissue, pulling as perpendicular to the skull as possible. Resistance should be minimal when retracting the DBS Lead.
7. Palpate the region under the scalp to locate the Lead Extension Connector.
8. Create an incision to expose the DBS Lead and Lead Extension Connector. Be careful not to damage the implanted components to allow for proper analysis after explant.
9. Loosen the Setscrew on the Lead Extension Connector using the Torque Wrench provided.
   Note: Ensure that the Torque Wrench is fully inserted before loosening the Setscrew. To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.
10. Remove the DBS Lead from the Lead Extension.
11. Gently pull the remainder of the DBS Lead through the incision behind the ear.
   Warning: The DBS Lead should be pulled from the site behind the ear and not the site near the burr hole to avoid a potential spread of infection toward the incision on the skull.
12. To replace the DBS Lead, see the “Implanting the DBS System” section of this manual and repeat all subsections (as applicable).
13. To explant other components of the DBS System, see the “Removing the Burr Hole Cover”, “Removing the Lead Extensions”, and “Removing or Replacing the DBS IPG” sections of this manual.

14. To continue with this procedure, close the incisions.

15. Ship the explanted DBS Leads to Boston Scientific.

Removing the Burr Hole Cover

1. While supporting the top of the Cap to control the release, insert the tip end of the Placement/Removal Tool into an open Lead Exit Slot.

2. Gently pry upward on the Cap until it releases from the Base.

3. To open the Slider and release the DBS Lead, use the tip end of the Placement/Removal Tool to gently push down and back on the closure dimple on the Slider.

4. If desired, remove the DBS Lead using appropriate surgical techniques. See the “Removing the DBS Leads” section of this manual.

5. Insert the tip end of the Placement/Removal Tool into the Clip Release Hole on the Retaining Clip (Figure 31). The tip of the Placement/Removal Tool should snap into place.

![Figure 31. Inserting the Placement/Removal Tool](image)

6. Gently push the Placement/Removal Tool partially toward the Slider and pull upward until the Retaining Clip releases from the Base.

7. Unscrew the two screws from the Base using the Screwdriver included in the kit or another compatible screwdriver.

Removing the Lead Extensions

1. Turn off the IPG.

2. Palpate the region under the scalp to locate the Lead Extension Connector.

3. Create an incision to expose the DBS Lead and Lead Extension Connector. Be careful not to damage the implanted components to allow for proper analysis following explant.

4. Cut the Lead Extension at the tapered (proximal) end of the Connector.

5. Loosen the Connector Setscrew using the Torque Wrench provided.

   **Caution:** Loosen the Setscrew only as much as is necessary to remove the DBS Lead. Loosening the Setscrew too much will cause it to fall out.

   **Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

7. Expose and disconnect the Lead Extensions from the IPG by following the procedure in the "Removing or Replacing the DBS IPG" section of this manual.

8. Gently pull the Lead Extension through the tunnel from the IPG site.

   **Note:** If the Lead Extension is broken, then it may be necessary to make additional incisions or to pull one end of the Lead Extension out at the IPG site and the other end from the Lead Extension Connector site.

   **Warning:** Avoid pulling towards the ear to reduce the potential for infection of the DBS Leads.


**Removing or Replacing the DBS IPG**

1. Turn off the IPG.

2. Palpate the pectoral area to locate the IPG.

3. Surgically open the pocket where the IPG is located. The incision should be large enough to remove the IPG from the pocket. Be careful not to damage the implanted components to allow for proper analysis following explant.

4. Remove the IPG from the IPG pocket.

5. Using the Torque Wrench, unscrew the IPG Header Setscrews to release the Lead Extensions.

   **Caution:** Loosen the Setscrew only as much as is necessary to remove the Lead Extension. Loosening the Setscrew too much will cause it to fall out.

   **Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

6. Remove the Lead Extensions from the IPG.

7. **If the Lead Extension will remain implanted:**
   a. **Optional:** Clean the proximal ends of the Lead Extension.
   b. Attach the Lead Boots from the Physician’s Spares Kit.
   c. Coil the excess Lead Extension in the IPG pocket.

8. **To replace the IPG,** see the “Implanting the DBS System” section of this manual and repeat all subsections (as applicable).

9. Close the incision.

   **Caution:** Be careful not to damage any remaining implanted components when closing the incision.

10. Ship the explanted IPG to Boston Scientific.
References


Technical Support

Boston Scientific Corporation has highly trained service professionals to assist you. The Technical Support Department is available to provide technical consultation 24 hours a day.

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