Boston Scientific

Advancing science for life™

Vercise™ Deep Brain Stimulation Systems

Surgical Implant Manual

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

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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, and sterilization, 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.

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Warranty

For device warranty information, visit www.bostonscientific.com/warranty.

Technical Support

There are no user serviceable parts. If you have a specific question or issue, contact your sales representative, or call (833) DBS-INFO or (833) 327-4636.

Product Model Numbers

You will only receive products appropriate for your region.

Model Number	Description
DB-2201-XX-DC	DBS Lead Kit, 30 cm or 45 cm
DB-2202-XX	Vercise™ Cartesia™ 8 Contact DBS Directional Lead Kit, 30 cm or 45 cm
DB-4600-C	Burr Hole Cover
DB-4605-C	Burr Hole Cover Spares Kit
DB-2500-C	Vercise™ Physician's Spare Kit
NM-3138-55	8 Contact Lead Extension Kit, 55 cm
DB-3128-XX	2x8 Contact Lead Extension Kit, 55 cm or 95 cm
DB-5170	Vercise DBS External Trial Stimulator 3 (ETS 3)
DB-5132-S	Vercise DBS External Trial Stimulator 2 (ETS 2)
DB-4120-08	8 Contact Push-Button OR Cable
DB-4100-A; SC-4100-A	1x8 OR Cable and Extension
DB-9315	ETS Adapter
DB-1200-S	Vercise Gevia™ 16 Contact Implantable Pulse Generator Kit
DB-1140-S	Vercise PC™ Implantable Pulse Generator Kit
DB-1416	Vercise Genus™ P16 Implantable Pulse Generator Kit
DB-1432	Vercise Genus™ P32 Implantable Pulse Generator Kit
DB-1216	Vercise Genus™ R16 Implantable Pulse Generator Kit
DB-1232	Vercise Genus™ R32 Implantable Pulse Generator Kit
SC-4401	Port Plug, Spares
DB-4252; SC-4252	Straw Tunneling Tool, 28 cm
DB-4254; SC-4254	Long Tunneling Tool, 35 cm
SC-4275	Hex Wrench (Torque Wrench)
Note: *XX = length (cm) and/or configuration*	

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Product Kits

Leads

Table 1: 8 Contact Lead Kits	
Description	**Quantity**
Lead with preloaded Straight Stylet	1
Torque Wrench	1
Lead Boot	1
Lead Stop – Screw and Ring	1
1 cm Suture Sleeve	1
1 cm Split Suture Sleeve	1
2.3 cm Suture Sleeve	1
4 cm Suture Sleeve	1
Note: *All contents of the inner package or tray are sterile and non-pyrogenic.*	

Table 2: 8 Contact Directional Lead Kits	
Description	**Quantity**
Directional Lead with preloaded Straight Stylet	1
Torque Wrench	1
Lead Boot	1
Lead Stop – Screw and Ring	1
1 cm Suture Sleeve	1
1 cm Split Suture Sleeve	1
2.3 cm Suture Sleeve	1
4 cm Suture Sleeve	1
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	
Description	**Quantity**
Lead Boot	1
Lead Stop – Screw and Ring	1
Torque Wrench	1
1 cm Suture Sleeve	1
1 cm Split Suture Sleeve	1
2.3 cm Suture Sleeve	1
4 cm Suture Sleeve	1
Note: *All contents of the inner package are sterile.*	

Lead Extensions

Table 4: 8 Contact Lead Extension Kits	
Description	**Quantity**
Lead Extension	1
Torque Wrench	1
28 cm Tunneling Tool Shaft (with Pre-Loaded Straw)	1
Tunneling Tool Handle	1
Note: *All contents of the inner package or tray are sterile.*	

Table 5: 2x8 Contact Lead Extension Kits	
Description	**Quantity**
Lead Extension	1
Torque Wrench	1
Port Plugs	2
Note: *All contents of the inner package or tray are sterile.*	

ETS and OR Cables

Table 6: External Trial Stimulator Kit	
Description	**Quantity**
External Trial Stimulator	1
AA Batteries	2

Table 7: 8 Contact Push-Button OR Cable	
Description	**Quantity**
OR Cable	1
Note: *All contents of the inner package are sterile.*	

Table 8: 1x8 OR Cable	
Description	**Quantity**
OR Cable	1
OR Cable Extension	1
Note: *All contents of the inner package are sterile.*	

Implantable Pulse Generators

Table 9: 16 Contact Implantable Pulse Generator Kit	
Description	**Quantity**
Implantable Pulse Generator	1
Implantable Pulse Generator Template	1
Implantable Pulse Generator Port Plugs	2
Torque Wrench	1
Note: *All contents of the inner package or tray are sterile.*	

Table 10: 32 Contact Implantable Pulse Generator Kit	
Description	**Quantity**
Implantable Pulse Generator	1
Implantable Pulse Generator Template	1
Implantable Pulse Generator Port Plugs	4
Torque Wrench	1
Note: *All contents of the inner package or tray are sterile.*	

Table 11: Port Plug, Spares Kit	
Description	**Quantity**
Port Plugs	2
Note: *All contents of the inner package are sterile.*	

Surgical Accessories

Table 12: Tunneling Tool Kit	
Description	**Quantity**
Tunneling Tool Shaft (with Pre-Loaded Straw)	1
Tunneling Tool Handle	1
Note: *All contents of the inner package are sterile.*	

Table 13: Hex Wrench Kit	
Description	**Quantity**
Torque Wrench	1
Note: *All contents of the inner package are sterile.*	

Burr Hole Cover

Table 14: Burr Hole Cover Kit	
Description	**Quantity**
Base and Bone Screws preassembled to Butterfly Holding Tool	1
Retaining Clip	1
Cap	1
Placement/Removal Tool	1
Screwdriver	1
Note: *All contents of the inner package or tray are sterile.*	

Table 15: Burr Hole Cover Spares Kit	
Description	**Quantity**
Bone Screws	1
Retaining Clip	1
Cap	1
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 either rechargeable or 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

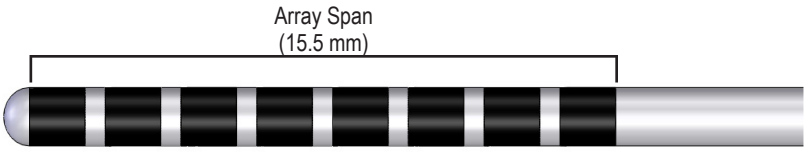
The non-implantable components of the Boston Scientific DBS System include the following:

- 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, and a Charging System (as applicable) to recharge the battery of rechargeable IPGs

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 16: Technical Specifications
Standard Lead (DB-2201)



Feature	Specification
Contact Length	1.5 mm
Contact Surface Area	6.0 mm^2
Contact Spacing (axial)	0.5 mm
Array Span	15.5 mm
Distal Contact to Tip Length	< 1.3 mm
Lead Diameter	1.3 mm
Overall Length	30 cm or 45 cm
Outer Tubing Material	Polyurethane
Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured from each connector to corresponding electrode Contact)

Directional Leads

The 8 Contact Directional Leads (see Table 17) have 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 17: Technical Specifications
8 Contact Directional Lead (DB-2202, Cartesia™)

Feature	Specification
Contact Length[1]	1.5 mm
Ring Contact Surface Area	6.0 mm^2
Segmented Contact Surface Area	1.5 mm^2
Dome Tip Contact Surface Area	6.0 mm^2
Contact Spacing (axial)	0.5 mm
Array Span	7.5 mm
Lead Diameter	1.3 mm
Overall Length	30 cm or 45 cm
Outer Tubing Material	Polyurethane
Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured from each connector to corresponding electrode Contact)

1 Also applies to dome tip Contact.

Lead Extensions

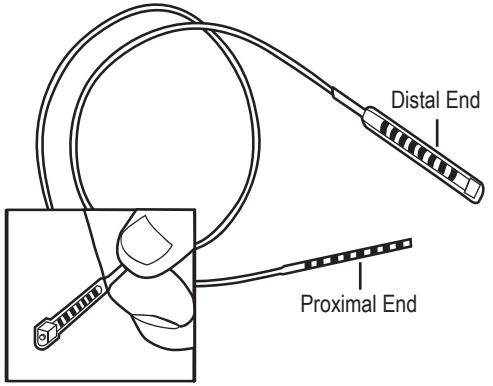
The model of DBS Lead and position of the DBS IPG being implanted will determine the compatible Lead Extension that should be used with that system. See the *"DBS Product Compatibility"* section of this manual.

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 Lead 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 18: Technical Specifications
8 Contact Lead Extension (NM-3138)

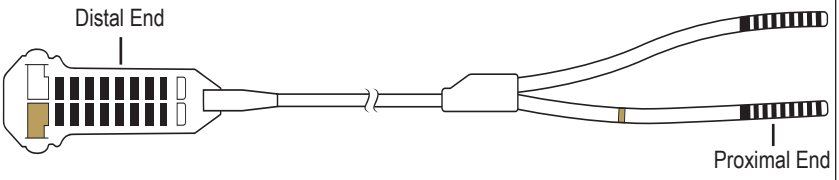


Feature	Specification
Overall Length	55 cm
Lead Extension Body Diameter	1.35 mm
Number of Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Setscrew Material	Titanium

2x8 Contact Lead Extension

The 2x8 Contact Lead Extension, also known as the Vercise™ Dual Extension, is a low profile Extension used with two 8 Contact Leads simultaneously. Each of these Lead Extensions can connect up to two Leads. The proximal end of the Lead Extension is bifurcated into two tails, each with 8 Contacts, which are inserted into the IPG. A gold marker band indicates the Lead Extension tail that contains Contacts 1 through 8. These same Contacts 1 through 8 are within the Lead Extension port with the gold connector block. This model is intended to support IPGs implanted in the pectoral or abdominal region.

Table 19: Technical Specifications
2x8 Contact Lead Extension (DB-3128)



Feature	Specification
Overall Length	55 cm or 95 cm
Lead Extension Body Diameter	1.31 mm
Number of Contacts	2x8 (16 total Contacts)
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Connector Block Material	Stainless Steel and Gold
Marker Band Material	Gold
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 compatible with 8 Contact Leads:

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

Table 20: Technical Specifications
Lead Boot

Feature	Specification
Overall Length	3.3 cm
Setscrew Material	Titanium
Connector Block Material	Stainless Steel
Endstop Material	Stainless Steel
Insulation Material	Silicone

Tunneling Tool

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

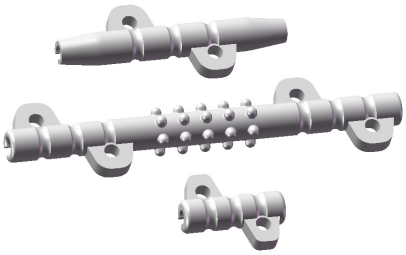
Table 21: Technical Specifications
Tunneling Tool (SC-4252, DB-4252, SC-4254, and DB-4254)

Feature	Specification
Length	28 cm (Straw), 35 cm (Long)
Shaft Material	Stainless Steel
Straw Material	PTFE
Handle Material	Stainless Steel, Ultem

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 22: Technical Specifications
DBS Suture Sleeves

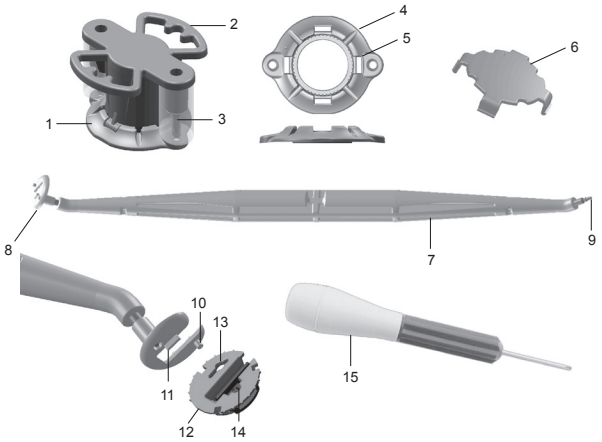


Feature	Specification
Overall Length	1 cm, 2.3 cm, 4 cm
Material	Silicone

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 23. The materials for the Burr Hole cover are listed in Table 24.

Table 23: Components of the SureTek Burr Hole Cover



Label	Description
1	Base
2	Butterfly Holding Tool
3	Bone Screw
4	Lead Exit Slot
5	Cap Slot
6	Cap
7	Placement/Removal Tool
8	Horseshoe End
9	Tip End
10	Post
11	Tab
12	Retaining Clip
13	Clip Release Hole
14	Closure Dimple on Slider
15	Screwdriver

Table 24: Burr Hole Cover Materials (DB-4600-C)	
Feature	**Specification**
Base	Polyether ether ketone (PEEK)
Retaining Clip	PEEK
Cap	PEEK
Bone Screws	Titanium
Butterfly Holding Tool	Polyetherimide, Silicone
Placement/Removal Tool	Polyetherimide, Titanium
Disposable Screwdriver	Polybutylene terephthalate (PBT) polycarbonate resin, stainless steel

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

Feature	Specification
Dimensions	80 mm x 60 mm x 26 mm
Case Material	Silicone and Plastic
Number of Ports	2
Replacement Batteries	2 AA Batteries

Table 26: ETS Indicator Lights	
Stimulator Light	**Description**
Solid Green	ETS is ON
Flashing Green	Stimulation is ON
Solid Yellow	Error
Battery Indicator Light	**Description**
Solid/Flashing Green	ETS is ON
Flashing Yellow	Replace the batteries in the ETS
Alternating Green and Yellow (ETS 3 Only)	The ETS is in Pairing Mode

Implantable Pulse Generators (IPGs)

Vercise Genus™ Non-Rechargeable Implantable Pulse Generators

Vercise Genus features 16 Contact and 32 Contact non-rechargeable IPGs. 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 and Figure 2).

Figure 1. Vercise Genus P16 Tag

Figure 2. Vercise Genus P32 Tag

The physical characteristics of the Vercise Genus P16 and P32 non-rechargeable IPGs are outlined in Table 27 and Table 28.

Table 27: Physical Characteristics
Vercise Genus P16 IPG (DB-1416)

Feature	Specification
Number of Contacts	16 (2 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	72 mm x 49.6 mm x 11.6 mm
Volume	34.9 cm^3 (including header)

Table 28: Physical Characteristics
Vercise Genus P32 IPG (DB-1432)

Feature	Specification
Number of Contacts	32 (4 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	75 mm x 49.6 mm x 11.6 mm
Volume	36.6 cm^3 (including header)

Vercise Genus™ Rechargeable Implantable Pulse Generators

Vercise Genus features 16 Contact and 32 Contact rechargeable IPGs. For instructions on charging the IPGs, refer to the *Charging Handbook* as listed in the *DBS Reference Guide*. For 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 3 and Figure 4).

Figure 3. Vercise Genus R16 Tag

Figure 4. Vercise Genus R32 Tag

The physical characteristics of the Vercise Genus R16 and R32 rechargeable IPGs are outlined in Table 29 and Table 30.

Table 29: Physical Characteristics
Vercise Genus R16 IPG (DB-1216)

Feature	Specification
Number of Contacts	16 (2 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	52.1 mm x 46 mm x 10.7 mm
Volume	20.1 cm^3 (including header)

Table 30: Physical Characteristics
Vercise Genus R32 IPG (DB-1232)

Feature	Specification
Number of Contacts	32 (4 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	55.6 mm x 46 mm x 10.7 mm
Volume	21.6 cm^3 (including header)

Vercise Gevia™ 16 Contact Implantable Pulse Generator

Vercise Gevia features a 16 Contact rechargeable IPG. For instructions on charging the IPG, refer to the *Charging Handbook* as listed in the *DBS Reference Guide*. For the programmable characteristics of the Vercise Gevia System, refer to the *Programming Manual* as listed in the *DBS Reference Guide.*

The Vercise Gevia IPG contains a radiopaque identification tag that is visible using standard x-ray procedures (Figure 5).

Figure 5. Vercise Gevia Tag

The physical characteristics of the Vercise Gevia IPG are outlined in Table 31.

Table 31: Physical Characteristics
Vercise Gevia IPG (DB-1200-S)

Feature	Specification
Number of Contacts	16 (2 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	51.3 mm x 46.0 mm x 10.8 mm
Volume	19.8 cm^3 (including header)

Vercise™ PC Implantable Pulse Generator

Vercise PC features a 16 Contact non-rechargeable IPG. For additional information on the Energy Use Index or the programmable characteristics of the Vercise PC System, refer to the *Programming Manual* as listed in the *DBS Reference Guide*.

The Vercise PC IPG contains a radiopaque identification tag that is visible using standard x-ray procedures (Figure 6).

Figure 6. Vercise PC Tag

The physical characteristics of the Vercise PC IPG are provided in Table 32.

Table 32: Physical Characteristics Vercise PC IPG (DB-1140-S)

Feature	Specification
Number of Contacts	16 (2 Ports)
Number of Contacts per Port	8
Case Material	Titanium
Header Material	Epoxy
Strain Relief Material	Silicone
Dimensions	70.9 mm x 49.5 mm x 11.3 mm
Volume	33 cm^3 (including header)

DBS Product Compatibility

For compatibility of DBS Leads, Lead Extensions, IPGs, OR Cables, External Trial Stimulators, and Tunneling Tools, see Table 33, Table 34, Table 35, Table 36, and Table 37.

Table 33: Compatibility
DBS Leads and Lead Extensions

Lead Model Number	Compatible Lead Extensions
DB-2201 (30 or 45 cm)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-2202 (30 or 45 cm)	NM-3138-55
	DB-3128[2] (55 or 95 cm)

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 34: Compatibility
IPGs and Lead Extensions

IPG Model Number	Compatible Lead Extensions
DB-1416 (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-1216 (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-1432 (4 Port, 32 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-1232 (4 Port, 32 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-1140-S (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)
DB-1200-S (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[2] (55 or 95 cm)

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.*

2 DB-3128 is a 2x8 Contact Lead Extension. A single DB-3128 Lead Extension can connect up to two (2) DB-2201 or DB-2202 8 Contact Leads.

Table 35: Compatibility Leads with the OR Cables	
Lead Model Number	**Compatible OR Cables**
DB-2201 (30 or 45 cm)	DB-4120-08
	DB-4100-A
DB-2202 (30 or 45 cm)	DB-4120-08
	DB-4100-A

Table 36: Compatibility External Trial Stimulators with the OR Cables	
ETS Model Number	**Compatible OR Cables**
DB-5132-S	DB-4120-08
	DB-4100-A with ETS Adapter DB-9315
DB-5170	DB-4120-08
	DB-4100-A with ETS Adapter DB-9315

Table 37: Compatibility Lead Extensions and Tunneling Tools	
Lead Extension Model Number	**Compatible Tunneling Tools**
DB-3128 (55 or 95 cm)	DB-4254
NM-3138-55	DB-4254 or DB-4252

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.*

Implantable Pulse Generator (Rechargeable Stimulators Only)

The IPG should be fully charged before the implantation procedure if applicable. Follow the steps below to charge the IPG fully:

- Identify the grey dot or IPG outline marked on the IPG kit. This grey dot or IPG outline indicates the location of the IPG within the packaging.
- Place the IPG Kit on a flat surface with the grey dot or IPG outline facing up.
- Turn on the Charger and place it over the IPG to begin charging. Once powered on, the Charger will begin beeping until it is properly aligned with the IPG and charging. The Charger will emit a series of double beeps when the IPG is fully charged. For additional instructions on the Charger, refer to the appropriate *Charging Manual* as listed in the *DBS Reference Guide*.

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 7).

Figure 7. Base Attached to the Butterfly Holding Tool with Screwdriver Inserted

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 8) by partially screwing the threaded portion of the screw into the threaded hole in the ring.

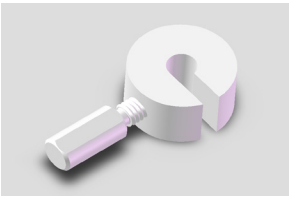


Figure 8. DBS Lead Stop

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 9). 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.*

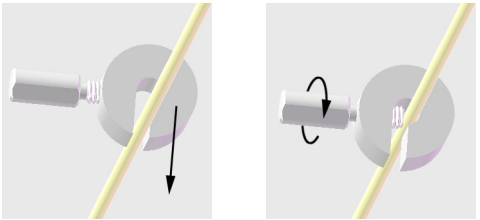


Figure 9. Applying the DBS Lead Stop

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 10) 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.

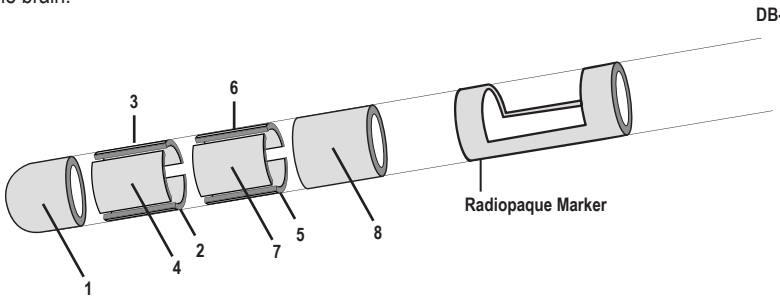


Figure 10. Directional Lead Marker

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 11).

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

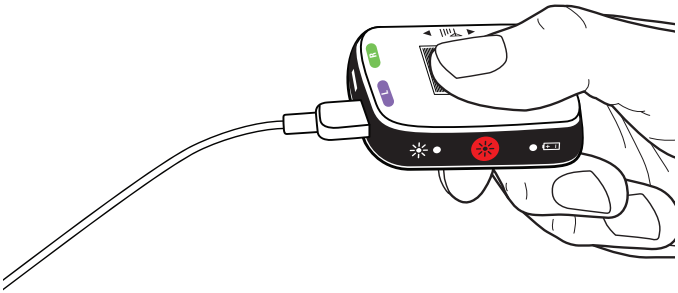


Figure 11. Connecting the OR Cable to ETS 3

3. Hold the OR Cable and DBS Lead as shown in Figure 12. 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 12). Make sure that the DBS Lead is fully inserted. The OR Cable Connector will stop when the DBS Lead is fully inserted.

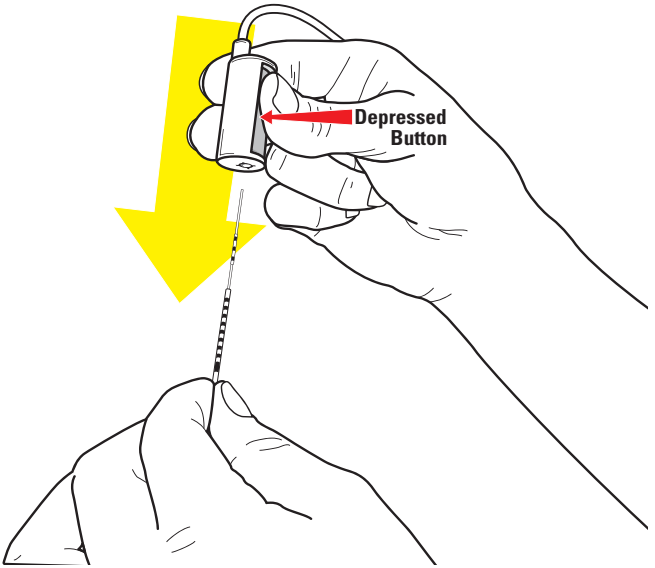


Figure 12. Depress Button on the OR Cable Connector to Connect OR Cable to DBS Lead

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 13.*

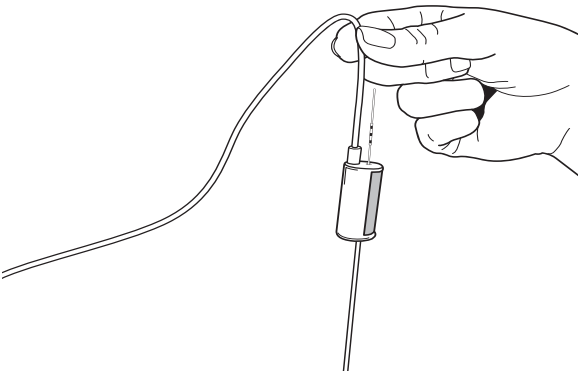


Figure 13. OR Cable Connected to DBS Lead

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 14).

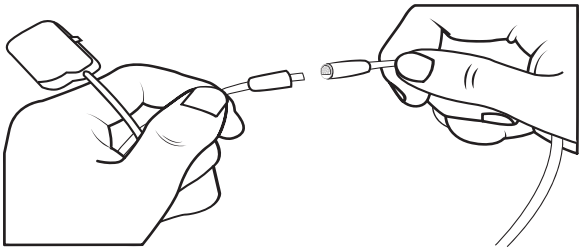


Figure 14. 1x8 OR Cables and Extension

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 15).

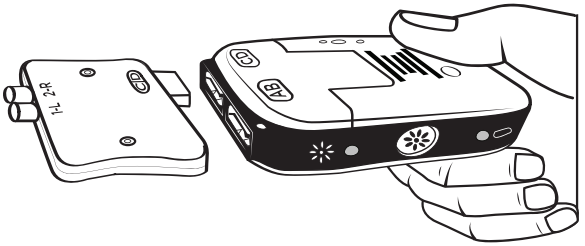


Figure 15. Connection of the ETS Adapter to the ETS 2

4. Plug the OR Cable with Extension into the ETS Adapter Port labeled “1-L” (Figure 16).

   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.

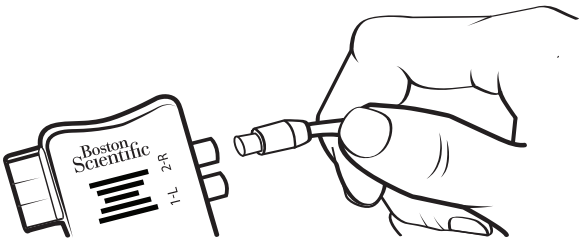


Figure 16. Connection of the 1x8 OR Cable to ETS 2 and ETS Adapter

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 17). 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 17.*

7. Hold the DBS Lead in place. Slide the locking lever to the locked (1) position (Figure 17).

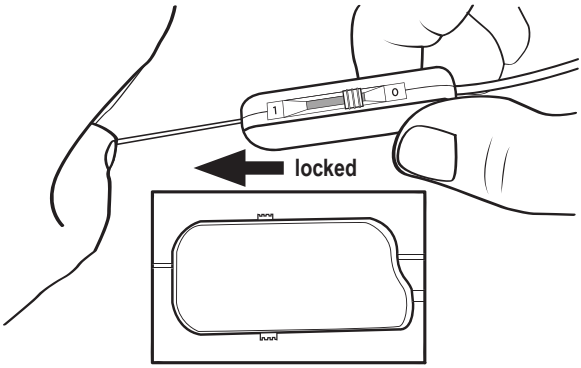


Figure 17. Securing the DBS Lead Into the 1x8 OR Cable Connector

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.[3] 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 18).

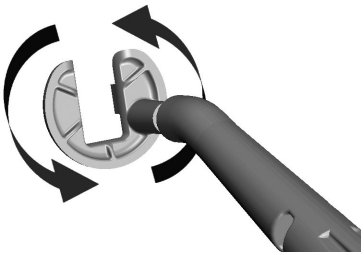


Figure 18. Rotational Direction for the Horseshoe End

3 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 19).

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

Figure 19. Attach Retaining Clip to Horseshoe End of Tool

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 20).

Figure 20. Position the Retaining Clip Over the Base

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 21).

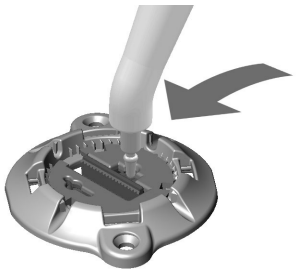


Figure 21. Lock the Slider

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 22).

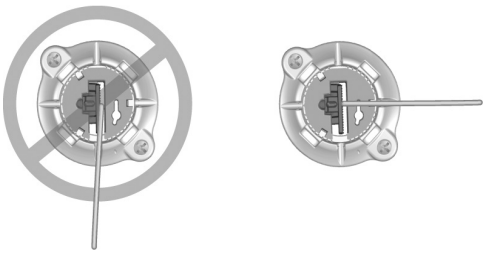


Figure 22. Placing the DBS Lead into the Lead Exit Slot

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 23).

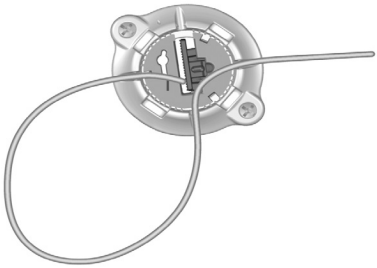


Figure 23. Placement of the DBS Lead into Additional Lead Exit Slots

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.

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 24).*

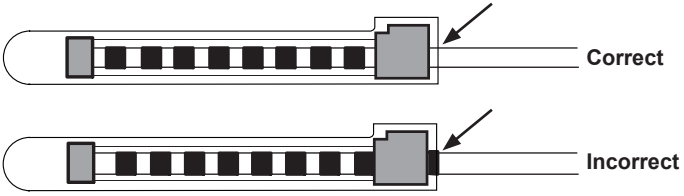


Figure 24. Securing the DBS Lead in the Lead Boot

Note: *The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 25).*

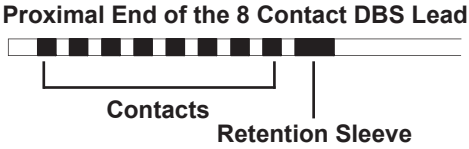


Figure 25. Retention Sleeve

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 26). To loosen the Setscrew, rotate the Torque Wrench counterclockwise.*

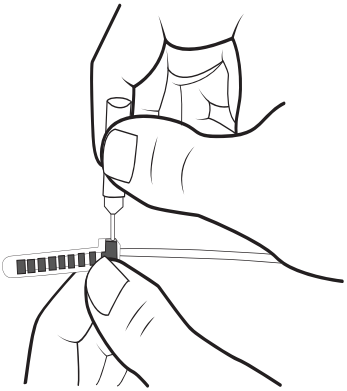


Figure 26. Tightening the Setscrew

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 Lead 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. If applicable, see the *"Implanting the DBS System"* section of this manual and repeat all subsections (as applicable) up to this point of the manual to implant the second DBS Lead.

16. Use the Tunneling Tool or appropriate means to tunnel the second DBS Lead to the same side as the first Lead.

17. Close the incisions.

Tunneling the Lead Extension

Assembling the Tunneling Tool

A Tunneling Tool (Figure 27) and Straw are provided to facilitate tunneling of the Lead Extension.

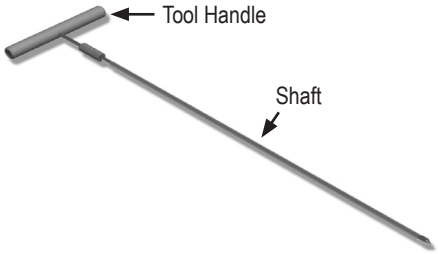


Figure 27. Tunneling Tool

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 or in the abdomen on the same side of the patient as the 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.

      Rechargeable IPGs should be implanted no deeper than 2 cm.

      Communication, including device programming, could become ineffective at depths greater than 2.5 cm.

      IPG charging could become ineffective at depths shallower than 0.5 cm or greater than 2 cm (rechargeable IPG only).

      Note: *The 2.5 cm depth restriction does not apply to Vercise PC IPG (DB-1140-S). The depth restriction does apply to all other non-rechargeable Boston Scientific IPGs.*

      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.[4]

   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 28).

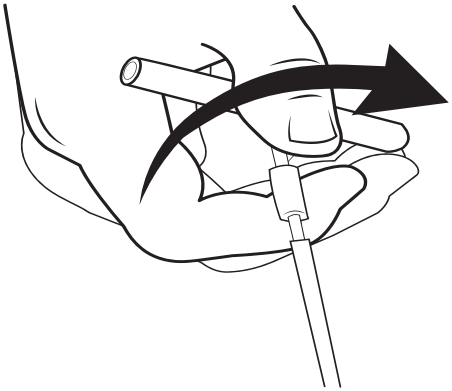


Figure 28. Removing the Handle of the Tunneling Tool

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 ends of the Lead Extension(s) through the Straw, then withdraw 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.*

4 Tunneling has been tested utilizing 46 cm, 61 cm, and 70 cm Integra Reusable Peritoneal Shunt Introducers (models 901218, 901224, 9MD270) with Replacement Peritoneal Shunt Sheaths (models 901118, 901124, 9MN170). 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.

   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

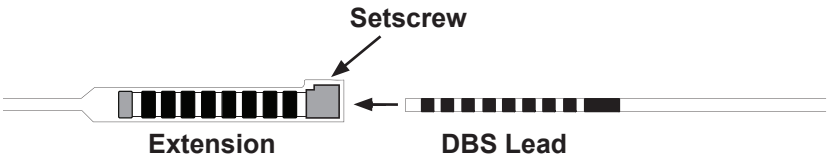


Figure 29. The DBS Lead and Lead Extension Connector

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 29).

2. Grip the DBS Lead next to the Retention Sleeve. Grip the Lead Extension in the center of the Lead Extension Connector (Figure 30).

   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.*

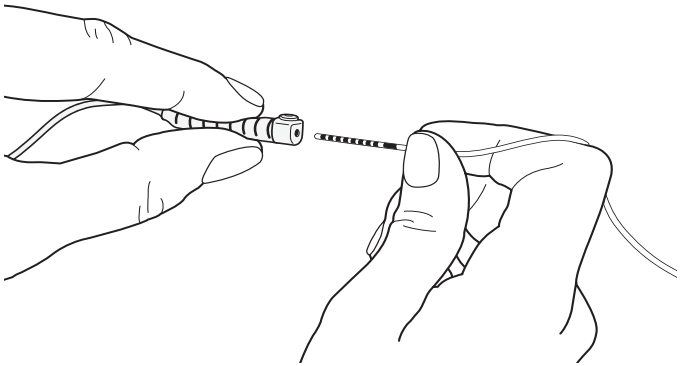


Figure 30. Grip the DBS Lead and the Center of the Lead Extension Connector Prior to Insertion

3. Push the DBS Lead into the Lead Extension Connector until the DBS Lead Contacts align with the Lead 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.*

   If using a 2x8 Lead Extension, it is recommended that the left hemisphere DBS Lead be inserted into the port with the gold connector block and the right hemisphere DBS Lead into the port with the silver connector block within the Lead Extension Connector.

   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.

4. Visually check that the DBS Lead electrodes are aligned with the Lead Extension Contacts (Figure 31).

   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 Lead 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.*

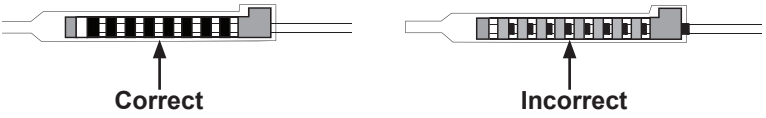


Figure 31. Alignment of the DBS Lead in the Lead Extension Connector

5. To connect the second DBS Lead to the second Lead Extension, see the *"Exposing the DBS Lead"* section of this manual and repeat Steps 1 through 5 to expose the DBS Lead. Then see the *"Connecting the DBS Lead to the Lead Extension"* section of this manual and repeat Steps 1 through 4 to connect to the Lead Extension.
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. Ensure that the IPG is charged before implantation (rechargeable Stimulators only). See the *"Pre-Conditions"* section of this manual.
2. Insert and then remove the Port Plug from the IPG Ports to verify that no Setscrews are obstructing the socket.
3. Wipe the Lead Extension Contacts.
4. 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.*
5. 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 32).

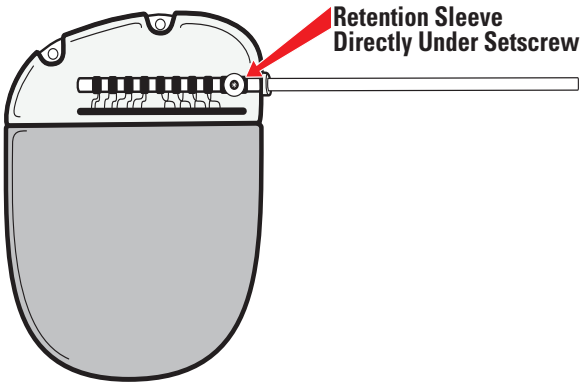


Figure 32. Alignment of Lead Extension Contacts in the DBS IPG Port

Note: *The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 33).*

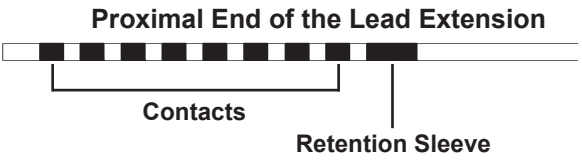


Figure 33. Retention Sleeve on the Lead Extension

6. Repeat Steps 1 through 5 (*"Implanting the IPG"* section of this manual) to insert the remaining Lead Extensions into the IPG Ports. For any unused IPG Ports, insert the IPG Port Plug into the open IPG Port.
7. 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.
8. Pass the Torque Wrench through the slit in the Septum located on the side of the IPG Header (Figure 34).
9. 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.*

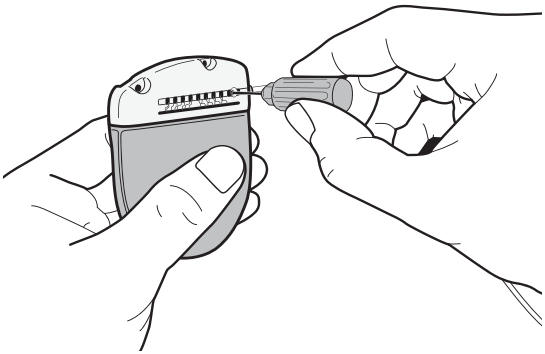


Figure 34. Inserting the Torque Wrench Into the IPG Header

Caution: *The Torque Wrench is torque-limiting so that the Setscrew cannot be overtightened. Use only the wrench provided, as other tools may overtighten the Setscrew and damage the Lead Extension.*

Note: *If an IPG Port Plug is used, it is still necessary to tighten the Setscrew on the Port Plug, as outlined in Steps 7 through 9 ("Implanting the IPG" section of this manual).*

10. Repeat Steps 8 through 9 (*"Implanting the IPG"* section of this manual) to tighten the IPG Setscrew onto the Retention Sleeve of each remaining Lead Extension.
11. 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 Lead Extension Setscrew.
12. Tighten the Setscrew in the Lead Extension until the Torque Wrench clicks, indicating the Setscrew is fully secured.

13. Repeat Steps 11 through 12 (*"Implanting the IPG"* section of this manual) for all Lead Extension Setscrews.

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

14. 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 cm for rechargeable IPGs and 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. For rechargeable IPGs, IPG charging could become ineffective at depths shallower than 0.5 cm or greater than 2 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.

15. 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.

2-Port (16 Contact) IPG

For dual 8 Contact Lead connection with the bifurcated Lead Extension DB-3128 to the 2-Port IPG:[5]

a. Connect the left hemisphere Lead Extension tail with the gold marker band to Port L (or C) (Figure 35).

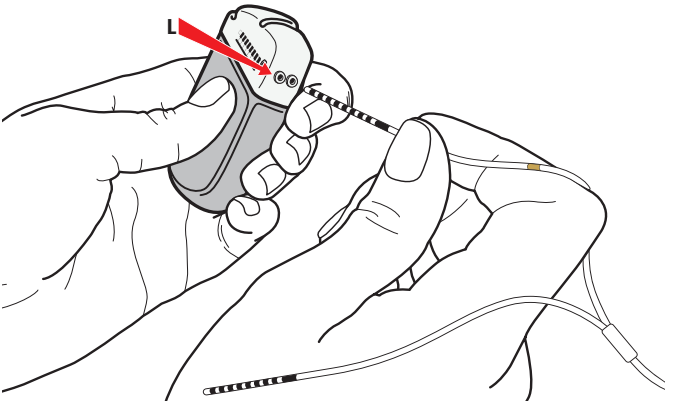


Figure 35. Connection to IPG Port L

b. Connect the right hemisphere Lead Extension tail with no marker band to Port R (or D) (Figure 36).

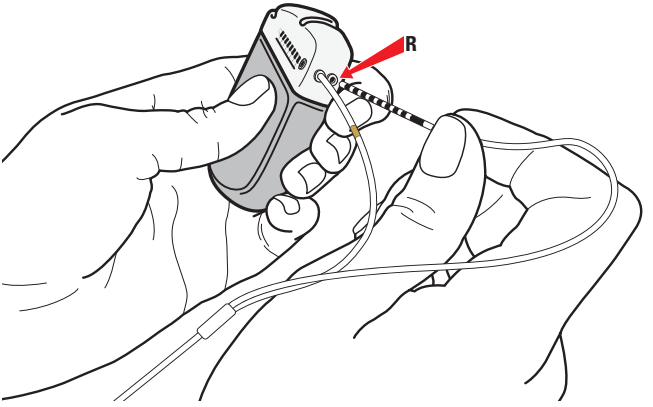


Figure 36. Connection to IPG Port R

5 DB-3128 is a 2x8 Lead Extension and can connect up to two (2) 8 Contact DBS Leads to an IPG.

For dual 8 Contact Lead connection with the Lead Extension NM-3138-55 to the 2-Port IPG:[6]

a. Connect the left hemisphere Lead Extension to Port L (or C) (Figure 37).

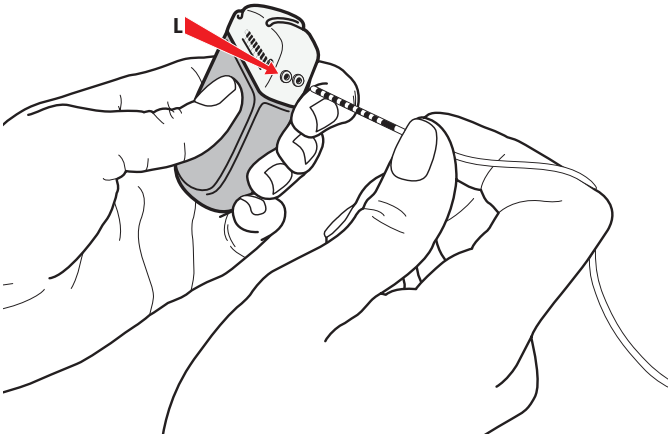


Figure 37. Connection to IPG Port L

b. Connect the right hemisphere Lead Extension to Port R (or D) (Figure 38).

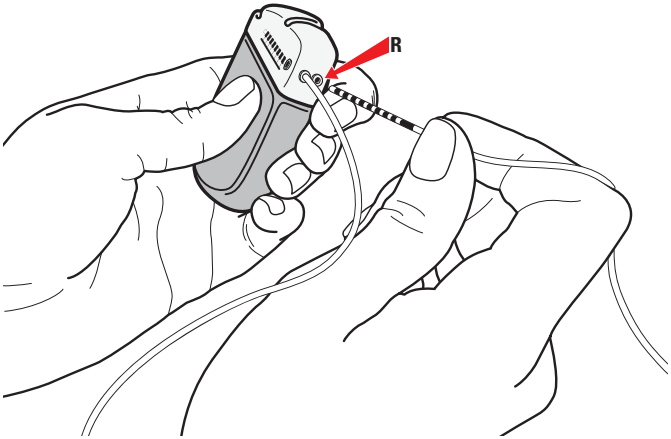


Figure 38. Connection to IPG Port R

6 NM-3138-55 Lead Extension can connect one (1) 8 Contact DBS Lead to one port of an IPG. Two NM-3138-55 Lead Extensions are required to connect two (2) 8 Contact DBS Leads to the IPG.

4-Port (32 Contact) IPG

For dual 8 Contact Lead connection with the bifurcated Lead Extension DB-3128 to the 4-Port IPG:[7]

a. Connect the left hemisphere Lead Extension tail with the gold marker band to Port L2 (Figure 39).

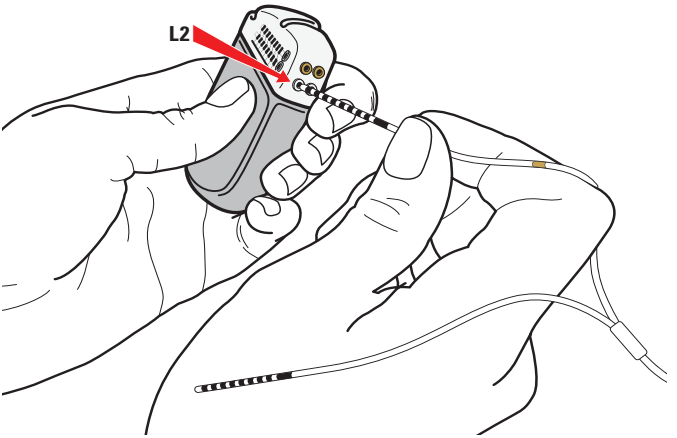


Figure 39. Connection to IPG Port L2

b. Connect the right hemisphere Lead Extension tail with no marker band to Port R2 (Figure 40).

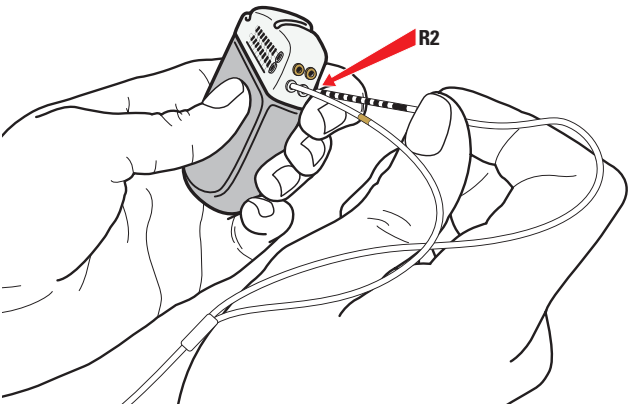


Figure 40. Connection to IPG Port R2

7 DB-3128 is a 2x8 Lead Extension and can connect up to two (2) 8 Contact DBS Leads to an IPG.

For dual 8 Contact Lead connection with the Lead Extension NM-3138-55 to the 4-Port IPG:[8]

a. Connect the left hemisphere Lead Extension to Port L2 (Figure 41).

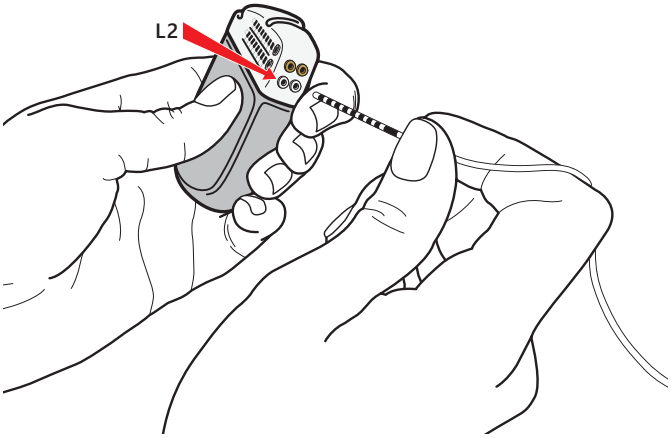


Figure 41. Connection to IPG Port L2

b. Connect the right hemisphere Lead Extension to Port R2 (Figure 42).

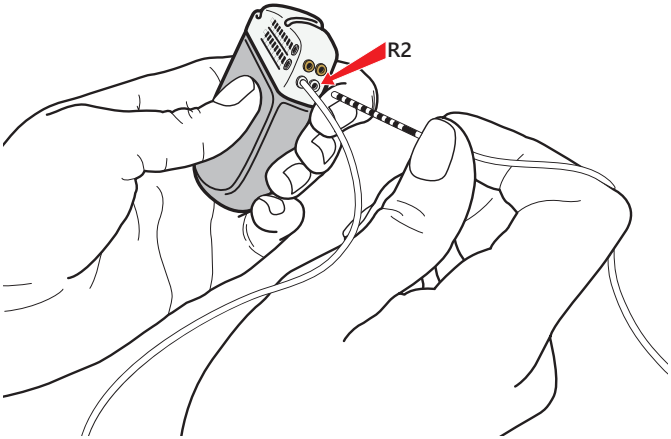


Figure 42. Connection to IPG Port R2

8 NM-3138-55 Lead Extension can connect one (1) 8 Contact DBS Lead to one port of an IPG.

Explanting or Replacing the DBS System

Explanting the DBS System

If the entire DBS System (Stimulator, Lead 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 43). The tip of the Placement/Removal Tool should snap into place.

Figure 43. Inserting the Placement/Removal Tool

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.*

6. Disconnect the Lead Extension Connector. Return the Lead Extension Connector to Boston Scientific.
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.*
9. Ship the explanted Lead Extensions to Boston Scientific.

Removing or Replacing the DBS IPG

1. Turn off the IPG.
2. Palpate the pectoral or abdominal 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

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2. Starr PA & Sillay K (2008). “Complication Avoidance and Management in Deep Brain Stimulation Surgery” In Tarsy, Vitek, Starr & Okun (eds.), Deep Brain Stimulation in Neurological and Psychiatric Disorders. (pp. 135-150). Totowa, NJ: Humana Press.
3. Umemura A (2007). “Complications and Avoidance” In Baltuch & Stern (eds.), Deep Brain Stimulation for Parkinson’s Disease. (pp. 103-112). New York, NY: Informa Healthcare.

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