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) System. Throughout this manual, the name “Boston Scientific DBS System” refers to the following: Vercise Genus™, Vercise Gevia™, and Vercise™ PC Deep Brain Stimulation Systems.

The products covered in this manual are components of a DBS System. Read all instructions carefully before using the DBS System. For indications for use, contraindications, warnings, precautions, adverse events, storage and handling, sterilization, device disposal, and post-procedure information, refer to the *DBS Information for Prescribers IFU*. For other device-specific information not included in this manual, refer to the appropriate Instructions for Use (IFU) for your Boston Scientific DBS System as listed in your *DBS Reference Guide*. Advise the patient that additional information may be available to them on the Boston Scientific website www.bostonscientific.com/patientlabeling.

Note: *Throughout this manual, the Vercise™ DBS Controller may be referred to as the Controller App.*

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

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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. To contact Boston Scientific for any other reason, use the contact information provided for your locality via www.bostonscientific.com, 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-2201-30DC	Lead Kit, 8 Contact, 30cm
DB-2201-45DC	Lead Kit, 8 Contact, 45cm
DB-2202-30	Vercise™ Cartesia™ Directional Lead Kit, 8 Contact, 30cm
DB-2202-45	Vercise™ Cartesia™ Directional Lead Kit, 8 Contact, 45cm
DB-2203-30	Vercise™ Cartesia™ X Directional Lead Kit, 16 Contact (5x3+1), 30cm
DB-2203-45	Vercise™ Cartesia™ X Directional Lead Kit, 16 Contact (5x3+1), 45cm
DB-2204-30	Vercise™ Cartesia™ HX Directional Lead Kit, 16 Contact (4x3+4), 30cm
DB-2204-45	Vercise™ Cartesia™ HX Directional Lead Kit, 16 Contact (4x3+4), 45cm
DB-4600-C	SureTek™ Burr Hole Cover Kit
DB-4605-C	SureTek™ Burr Hole Cover Spares Kit
DB-2500-C	Vercise™ Physician's Spare Kit, 8 Contact Lead
DB-2501	Vercise™ Physician's Spare Kit, 16 Contact Lead
NM-3138-55	Lead Extension Kit, 8 Contact, 55cm
DB-3128-55	Lead Extension Kit, 2x8 Contact, 55cm
DB-3128-95	Lead Extension Kit, 2x8 Contact, 95cm
DB-3128-55B	Lead Extension Kit, 2x8 Contact, 55cm
DB-3128-95B	Lead Extension Kit, 2x8 Contact, 95cm
DB-3216-55	Lead Extension Kit, 16 Contact, 55cm
DB-3216-95	Lead Extension Kit, 16 Contact, 95cm
DB-5170	Vercise™ External Trial Stimulator, ETS 3
DB-5132-S	Vercise™ DBS External Trial Stimulator 2
DB-4120-08	Push Button O.R. Cable, 8 Contact
DB-4120-16	Push Button O.R. Cable, 16 Contact
DB-4100A	O.R. Cable and Extension, 8 Contact
DB-9315	Vercise™ ETS Adapter
DB-1140-S	Vercise™ PC Implantable Pulse Generator Kit
DB-1200-S	Vercise Gevia™ 16 Contact Implantable Pulse Generator Kit
DB-1408	Vercise Genus™ P8 Implantable Pulse Generator Kit, 8 Contact
DB-1416	Vercise Genus™ P16 Implantable Pulse Generator Kit, 16 Contact
DB-1432	Vercise Genus™ P32 Implantable Pulse Generator Kit, 32 Contact

Model Number	Description
DB-1216	Vercise Genus™ R16 Implantable Pulse Generator Kit, 16 Contact
DB-1232	Vercise Genus™ R32 Implantable Pulse Generator Kit, 32 Contact
SC-4401	Precision Spectra™ IPG Port Plug
DB-4252	Straw Tunneling Tool, 28cm
DB-4254	Long Tunneling Tool, 35cm
SC-4275	Precision™ Hex Wrench

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Product Kits

Leads

Table 1: DB-2201-30DC and DB-2201-45DC Lead Kits, 8 Contact	
Description	**Quantity**
Lead	1
Lead Boot	1
Suture Sleeve	4
Stylet	1
Hex Wrench	1
Lead Stop - Ring and Screw	1
Note: *All contents of the inner package or tray are sterile.*	

Table 2: DB-2202-30 and DB-2202-45 Directional Lead Kits, 8 Contact	
Description	**Quantity**
Directional Lead	1
Lead Boot	1
Suture Sleeve	4
Stylet	1
Hex Wrench	1
Lead Stop - Ring and Screw	1
Note: *All contents of the inner package or tray are sterile.*	

Table 3: DB-2203-30, DB-2203-45, DB-2204-30, and DB-2204-45 Directional Lead Kits, 16 Contact	
Description	**Quantity**
Directional Lead	1
Lead Boot, Silver	1
Lead Boot, Gold	1
Suture Sleeve	4
Stylet	1
Hex Wrench	1
Lead Stop - Ring and Screw	1
Note: *All contents of the inner package or tray are sterile.*	

Table 4: DB-2500-C Physician's Spare Kit, 8 Contact	
Description	**Quantity**
Lead Boot	1
Suture Sleeve	4
Hex Wrench	1
Lead Stop - Ring and Screw	1
Note: *All contents of the inner package are sterile.*	

Table 5: DB-2501 Physician's Spare Kit, 16 Contact	
Description	**Quantity**
Lead Boot, Silver	1
Lead Boot, Gold	1
Suture Sleeve	4
Hex Wrench	1
Lead Stop - Ring and Screw	1
Note: *All contents of the inner package are sterile.*	

Lead Extensions

Table 6: NM-3138-55 Lead Extension Kit, 8 Contact	
Description	**Quantity**
Lead Extension	1
Hex Wrench	1
Note: *All contents of the inner package or tray are sterile.* ***Note:*** *Some product kits may include a Tunneling Tool.*	

Table 7: DB-3128-55, DB-3128-55B, DB-3128-95, and DB-3128-95B Lead Extension Kits, 2x8 Contact	
Description	**Quantity**
Lead Extension	1
Hex Wrench (also referred to as a Torque Wrench)	1
Port Plug	2
Note: *All contents of the inner package or tray are sterile.*	

Table 8: DB-3216-55 and DB-3216-95 Lead Extension Kits, 16 Contact	
Description	**Quantity**
Lead Extension	1
Hex Wrench	1
Port Plug	1
Note: *All contents of the inner package or tray are sterile.*	

ETS and O.R. Cables

Table 9: DB-5170 and DB-5132-S External Trial Stimulator Kits	
Description	**Quantity**
External Trial Stimulator	1
AA Battery	2

Table 10: DB-4120-08 Push Button O.R. Cable, 8 Contact	
Description	**Quantity**
O.R. Cable	1
Note: *All contents of the inner package are sterile.*	

Table 11: DB-4120-16 Push Button O.R. Cable, 16 Contact	
Description	**Quantity**
O.R. Cable	1
Note: *All contents of the inner package are sterile.*	

Table 12: DB-4100A O.R. Cable and Extension, 8 Contact	
Description	**Quantity**
O.R. Cable	1
Extension	1
Note: *All contents of the inner package are sterile.*	

Implantable Pulse Generators

Table 13: DB-1408 Implantable Pulse Generator Kit	
Description	**Quantity**
Implantable Pulse Generator	1
IPG Template	1
Hex Wrench	1
Port Plug	1
Note: *All contents of the inner package or tray are sterile.*	

Table 14: DB-1140-S, DB-1200-S, DB-1416, and DB-1216 Implantable Pulse Generator Kits	
Description	**Quantity**
Implantable Pulse Generator	1
IPG Template	1
Hex Wrench (also referred to as a Torque Wrench)	1
Port Plug	2
Note: *All contents of the inner package or tray are sterile.*	

Table 15: DB-1432 and DB-1232 Implantable Pulse Generator Kits	
Description	**Quantity**
Implantable Pulse Generator	1
IPG Template	1
Hex Wrench	1
Port Plug	4
Note: *All contents of the inner package or tray are sterile.*	

Surgical Accessories

Table 16: DB-4252 and DB-4254 Tunneling Tool	
Description	**Quantity**
Tunneling Tool	1
Note: *All contents of the inner package are sterile.*	

Table 17: SC-4275 Hex Wrench	
Description	**Quantity**
Hex Wrench	1
Note: *All contents of the inner package are sterile.*	

Table 18: SC-4401 IPG Port Plug	
Description	**Quantity**
Port Plug	2
Note: *All contents of the inner package are sterile.*	

Burr Hole Cover

Table 19: DB-4600-C Burr Hole Cover Kit	
Description	**Quantity**
Preassembled Base	1
Preassembled Bone Screw	2
Preassembled 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 20: DB-4605-C Burr Hole Cover Spares Kit	
Description	**Quantity**
Bone Screw	2
Retaining Clip	1
Cap	1
Note: *All contents of the inner package are sterile.*	

Safety Information

Intended Use

- The Leads are medical devices that are intended to deliver stimulation from the compatible Boston Scientific Stimulator to a brain target.
- The Lead Extensions are intended to connect the Lead to the compatible Boston Scientific Implantable Pulse Generator (IPG).
- The Burr Hole Cover is intended to anchor implanted compatible Leads to the skull.
- The Boston Scientific Implantable Pulse Generator (IPG) is an implanted medical device intended to generate stimulation that is delivered via Leads to a brain target.
- The Port Plug is intended to close an unused port of the compatible Boston Scientific Implantable Pulse Generator (IPG) or Lead Extension.
- The Boston Scientific External Trial Stimulator (ETS) is an external medical device intended to generate stimulation that is delivered via Leads to a brain target.
- The Tunneling Tool is intended to create a subcutaneous path for tunneling the Lead to the Lead Extension and/or the Lead Extension to the IPG pocket.
- The Physician's Spare Kit is intended to be an aid in implanting the Boston Scientific implantable medical devices.
    - The Lead Boot is intended to protect the proximal end of the implanted Lead/Lead Extension when it is not connected to an Implantable Pulse Generator (IPG).
    - The Lead Stop is intended to be temporarily fixed externally to the Lead to aid Lead placement at the desired depth.
    - The Hex Wrench is intended to be used to tighten or loosen a Setscrew (found in Adapters, Lead Extensions, Lead Boots, and IPGs).
    - Suture Sleeves are intended to anchor compatible Leads to appropriate tissue, or if a mini plate is used to secure the Lead, the Suture Sleeve is placed between the Lead and the mini plate to protect the Lead.
- The O.R. Cable is intended to connect the Lead to the ETS to facilitate stimulation testing.
- The External Trial Stimulator (ETS) Adapter is intended to connect the compatible O.R. Cable and Extension to the ETS during operating room test stimulation.

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
- A Port Plug that is used to close unused IPG or Lead Extension Ports

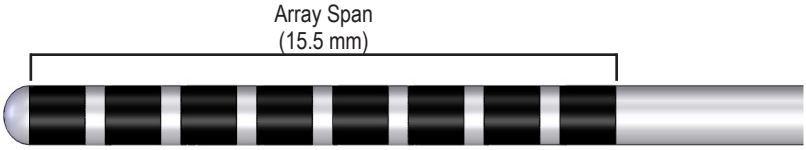
The non-implantable components of the Boston Scientific DBS System include the following:

- An External Trial Stimulator (ETS), an ETS Adapter, and O.R. 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 Stylet that is preloaded within the DBS Lead and maintains rigidity to help steer and stabilize the DBS Lead during Lead implantation
- A Lead Stop that is used to ensure that the DBS Lead is inserted to the proper depth
- An IPG Template that is used for guiding the IPG implant pocket sizing
- A Hex Wrench that is used to tighten or loosen a Setscrew
- A Clinician Programmer that is used to set and adjust stimulation parameters
- External devices, such as the Remote Control or mobile device with Controller App that are used to communicate with the IPG, and a Charging System (as applicable) to recharge the battery of rechargeable IPGs

Standard Lead

DBS Leads are thin, insulated wires that deliver electrical pulses to the brain. The Standard Lead consists of 8 cylindrical Contacts (Table 21). The diameter of the Lead is 1.3 mm. The Lead is compatible with existing commercially available DBS implantation tools.

Table 21: Technical Specifications Standard Lead (DB-2201)

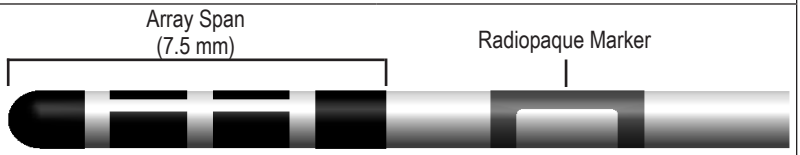


Feature	Specification
Contact Length	1.5 mm
Contact Surface Area	6.0 mm^2
Contact Spacing (axial)	0.5 mm
Array Span	15.5 mm
Distal Contact to Tip Length	< 1.3 mm
Lead Diameter	1.3 mm
Overall Length	30 cm or 45 cm
Outer Tubing Material	Polyurethane
Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured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

Directional Leads

DBS Leads are thin, insulated wires that deliver electrical pulses to the brain. The 8 Contact and 16 Contact Directional Leads have rows of Contacts that are segmented circumferentially to allow both axial and rotational stimulation selectivity (Table 22, Table 23, and Table 24). 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.

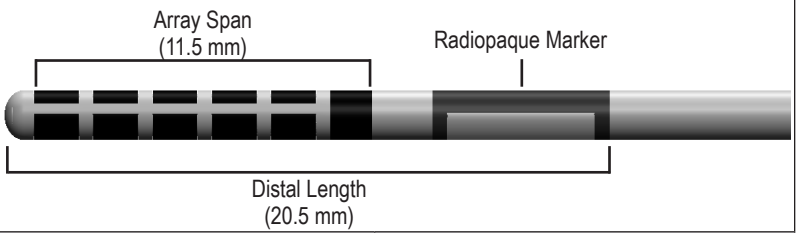
Table 22: Technical Specifications
8 Contact Directional Lead (DB-2202)



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.

Table 23: Technical Specifications
16 Contact Directional Lead (DB-2203)

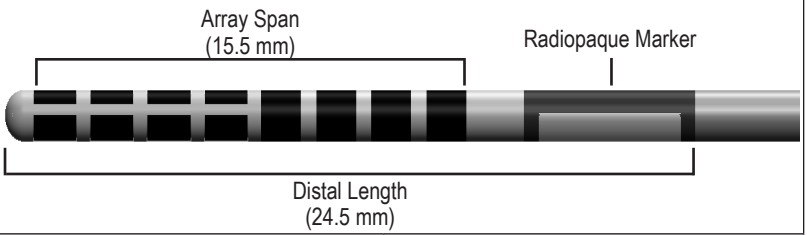


Feature	Specification
Configuration of Distal Contact Array[2]	(5 x 3) + 1
Contact Length	1.5 mm
Ring Contact Surface Area	6.0 mm^2
Segmented Contact Surface Area	1.5 mm^2
Contact Spacing (axial)	0.5 mm
Array Span	11.5 mm
Distal Length[3]	20.5 mm
Lead Diameter	1.3 mm
Overall Length	30 cm or 45 cm
Outer Tubing Material	Polyurethane
Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured from each connector to corresponding electrode Contact)

2 The specification (5x3) + 1 describes the configuration of the distal Contact array. From the distal tip to proximal: 5 rows of 3 segmented Contacts, 1 ring Contact. This Lead has a total of 15 segmented Contacts.

3 Do not apply fixation mechanism within this distal length.

Table 24: Technical Specifications
16 Contact Directional Lead (DB-2204)



Feature	Specification
Configuration of Distal Contact Array[4]	(4 x 3) + 4
Contact Length	1.5 mm
Ring Contact Surface Area	6.0 mm^2
Segmented Contact Surface Area	1.5 mm^2
Contact Spacing (axial)	0.5 mm
Array Span	15.5 mm
Distal Length[5]	24.5 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)

4 The specification (4x3) + 4 describes the configuration of the distal Contact array. From the distal tip to proximal: 4 rows of 3 segmented Contacts, 4 ring Contacts. This Lead has a total of 12 segmented Contacts.

5 Do not apply fixation mechanism within this distal length.

Lead Extensions

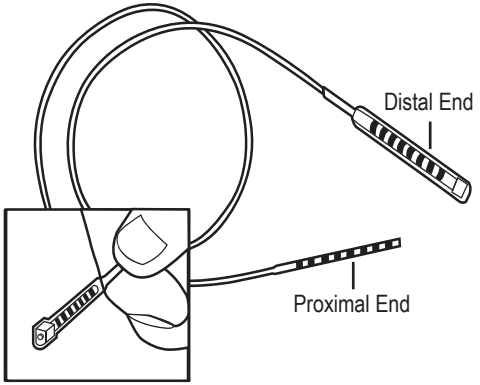
Lead Extensions are thin, insulated wires that connect the Leads to the Stimulator. The Lead Extension transfers the electrical stimulation from the Stimulator to the Lead. The Boston Scientific DBS System can include 8 or 16 Contact Leads implanted in the brain. The model of DBS Lead and position of 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 (Table 25). 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 25: Technical Specifications
8 Contact Lead Extension (NM-3138)

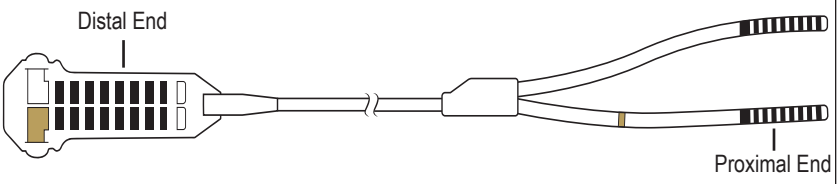


Feature	Specification
Overall Length	55 cm
Lead Extension Body Diameter	1.35 mm
Number of Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Setscrew Material	Titanium

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 (Table 26). 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. This model is intended to support IPGs implanted in the pectoral or abdominal region.

Table 26: Technical Specifications
2x8 Contact Lead Extension (DB-3128)



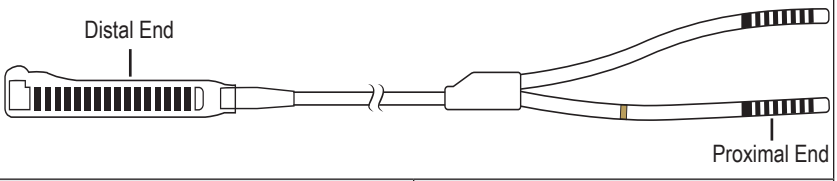
Feature	Specification
Overall Length	55 cm or 95 cm
Lead Extension Body Diameter	1.31 mm
Number of Contacts	2x8 (16 total Contacts)
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Connector Block Material	Stainless Steel and Gold
Marker Band Material[6]	Gold
Setscrew Material	Titanium

6 The 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.

16 Contact Lead Extension

The 16 Contact Lead Extension is used only with 16 Contact Leads (Table 27). Each of these Lead Extensions can connect with a 16 Contact Lead. The proximal end of the Lead Extension is bifurcated into two tails, each with 8 Contacts, which are inserted into the IPG. This model is intended to support IPGs implanted in the pectoral or abdominal region.

Table 27: Technical Specifications
16 Contact Lead Extension (DB-3216)



Feature	Specification
Overall Length	55 cm or 95 cm
Lead Extension Body Diameter	1.31 mm
Number of Contacts	16
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Connector Block Material	Stainless Steel
Marker Band Material[7]	Gold
Setscrew Material	Titanium

7 The 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.

Surgical Tools and Accessories

Lead Boot

The Lead Boot protects the proximal end of the implanted Lead until the IPG implant surgery (Table 28). 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 16 Contact Leads:

- A 16 Contact Lead Kit
- Vercise Physician's Spare Kit, 16 Contact Lead

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 Spare Kit, 8 Contact Lead

Table 28: Technical Specifications Lead Boot

Feature	Specification
Overall Length	3.3 cm or 3.95 cm
Setscrew Material	Titanium
Connector Block Material	Stainless Steel and/or Gold Plated 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 29).

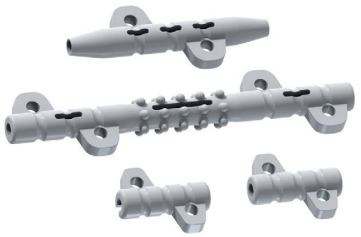
Table 29: Technical Specifications
Tunneling Tool (DB-4252 and DB-4254)

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 via sutures (Table 30). If a mini plate is used, the Suture Sleeve is placed between the Lead and the mini plate to protect the Lead.

Table 30: Technical Specifications
DBS Suture Sleeves

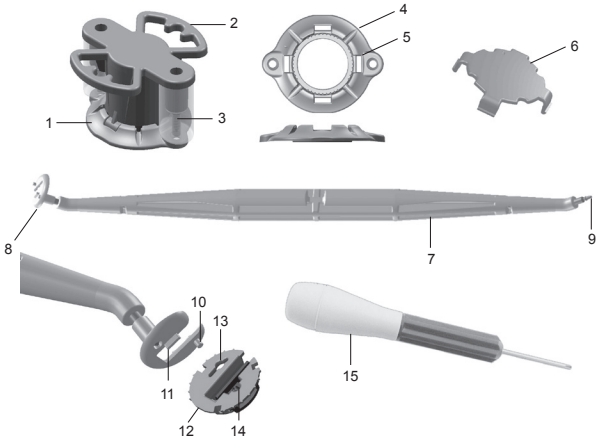


Feature	Specification
Overall Length	1 cm, 2.3 cm, 4 cm, 1 cm Split
Material	Silicone

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 31. The materials for the Burr Hole cover are listed in Table 32.

Table 31: 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 32: 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) and O.R. Cables

The External Trial Stimulator (ETS) sends small electrical pulses through the O.R. Cable to the end of the DBS Lead that is implanted in the brain. This produces stimulation in the brain. The ETS and O.R. Cable, along with Clinician Programmer (CP), Remote Control, or Controller App, 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. The physical characteristics of the ETS are outlined in Table 33. ETS Indicator light descriptions are outlined in Table 34.

Table 33: Physical Characteristics
ETS 2 (DB-5132-S) and ETS 3 (DB-5170)

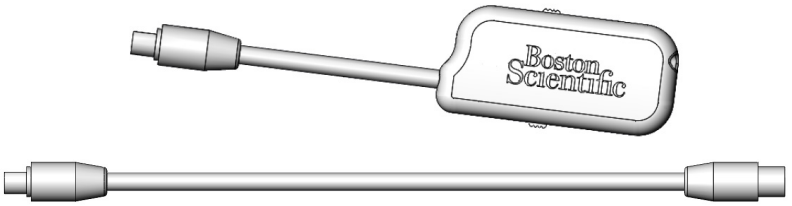
Feature	Specification
Dimensions	80 mm x 60 mm x 26 mm
Case Material	Silicone and Plastic
Number of Ports	2
Replacement Batteries	2 AA Batteries

Table 34: 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

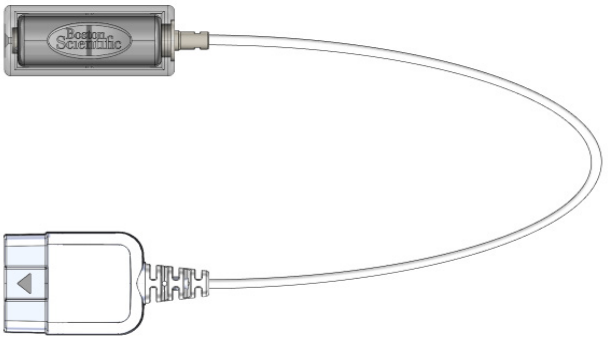
The O.R. Cable and Extension externally connects the Lead to the ETS to facilitate intraoperative testing. The O.R. Cable transfers electrical stimulation from the ETS to the DBS Lead. The physical characteristics of the O.R. Cable are outlined in Table 35, Table 36, and Table 37.

Table 35: Physical Characteristics
O.R. Cable and Extension (DB-4100A)



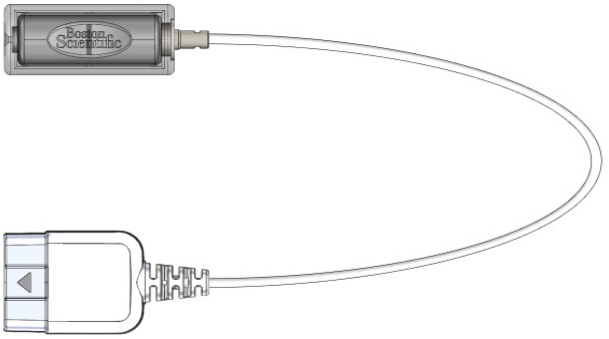
Feature	Specification
O.R. Cable Length	45 cm
Extension Length	152 cm
Number of Ports	1
Number of Contacts	8
Insulation Material	PVC

Table 36: Physical Characteristics
Push Button O.R. Cable (DB-4120-08)



Feature	Specification
Length	213 cm
Number of Ports	1
Number of Contacts	8
Insulation Material	Thermoplastic Polyurethane

Table 37: Physical Characteristics
Push Button O.R. Cable (DB-4120-16)



Feature	Specification
Length	213 cm
Number of Ports	1
Number of Contacts	16
Insulation Material	Thermoplastic Polyurethane

Implantable Pulse Generators (IPGs)

The IPG sends small electrical pulses to the end of the DBS Lead that is implanted in the brain. This produces stimulation in the brain. The IPG contains either a rechargeable or non-rechargeable battery. The battery supplies power to your DBS System.

Vercise Genus Non-Rechargeable Implantable Pulse Generators

The Vercise Genus DBS System features 8 Contact, 16 Contact, and 32 Contact non-rechargeable IPGs. For additional information on the Energy Use Index or the programmable characteristics of the Vercise Genus DBS System, refer to the appropriate *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 2, and Figure 3).

Figure 1. Vercise Genus P8 IPG Tag

Figure 2. Vercise Genus P16 IPG Tag

Figure 3. Vercise Genus P32 IPG Tag

The physical characteristics of the Vercise Genus P8, P16, and P32 non-rechargeable IPGs are outlined in Table 38, Table 39, and Table 40.

Table 38: Physical Characteristics Vercise Genus P8 IPG (DB-1408)

Feature	Specification
Number of Contacts	8 (1 Port)
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 39: 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 40: 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

The Vercise Genus DBS System 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 DBS System, refer to the appropriate *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 4 and Figure 5).

Figure 4. Vercise Genus R16 IPG Tag

Figure 5. Vercise Genus R32 IPG Tag

The physical characteristics of the Vercise Genus R16 and R32 rechargeable IPGs are outlined in Table 41 and Table 42.

Table 41: 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 42: 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

The Vercise Gevia DBS System 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 DBS System, refer to the appropriate *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 6).

Figure 6. Vercise Gevia IPG Tag

The physical characteristics of the Vercise Gevia IPG are outlined in Table 43.

Table 43: 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

The Vercise PC DBS System features a 16 Contact non-rechargeable IPG. For additional information on the Energy Use Index or the programmable characteristics of the Vercise PC DBS System, refer to the appropriate *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 7).

Figure 7. Vercise PC IPG Tag

The physical characteristics of the Vercise PC IPG are provided in Table 44.

Table 44: 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)

Materials List

Materials and substances that may contact the body during the DBS implant procedure are provided in Table 45.

Table 45: Materials	
Device Type	**Materials**
Stimulator	Titanium
	Epoxy
	Silicone
IPG Template	Stainless Steel
Port Plug	Thermoplastic
Lead	Thermoplastic
	Platinum - Iridium
	Epoxy
8 Contact Extension	Silicone
	Thermoplastic
	Epoxy
2x8 Contact Extension and 16 Contact Extension	Silicone
	Thermoplastic
	Gold
Suture Sleeve	Silicone
Lead Boot	Silicone
Burr Hole Base, Cap, and Lead Clip	Thermoplastic
Burr Hole Cover Screw	Titanium
Tunneling Tool Shaft	Stainless Steel
Tunneling Tool Straw	PTFE
The IPG Template and Tunneling Tool may contain cobalt: CAS No. 7440-48-4; EC No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight. ***Note:*** *The IPG Template and Tunneling Tool are made with stainless steel which may contain cobalt. Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.*	

DBS Product Compatibility

For compatibility of DBS Leads, Lead Extensions, IPGs, O.R. Cables, External Trial Stimulators, and Tunneling Tools, see Table 46, Table 47, Table 48, Table 49, and Table 50.

Table 46: Compatibility
DBS Leads and Lead Extensions

Lead Model Number	Compatible Lead Extensions
DB-2201 (30 cm or 45 cm)	NM-3138-55
	DB-3128[8] (55 cm or 95 cm)
DB-2202 (30 cm or 45 cm)	NM-3138-55
	DB-3128[8] (55 cm or 95 cm)
DB-2203 (30 cm or 45 cm)	DB-3216 (55 cm or 95 cm)
DB-2204 (30 cm or 45 cm)	DB-3216 (55 cm 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.*

8 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 47: Compatibility IPGs and Lead Extensions	
IPG Model Number	**Compatible Lead Extensions**
DB-1408 (1 Port, 8 Contact IPG)	NM-3138-55
DB-1416 (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm or 95 cm)
DB-1216 (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm or 95 cm)
DB-1432 (4 Port, 32 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm or 95 cm)
DB-1232 (4 Port, 32 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm or 95 cm)
DB-1200-S (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm or 95 cm)
DB-1140-S (2 Port, 16 Contact IPG)	NM-3138-55
	DB-3128[9] (55 cm or 95 cm)
	DB-3216 (55 cm 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.*

9 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 48: Compatibility Leads with the O.R. Cables	
Lead Model Number	**Compatible O.R. Cables**
DB-2201 (30 cm or 45 cm)	DB-4120-08
	DB-4100A
DB-2202 (30 cm or 45 cm)	DB-4120-08
	DB-4100A
DB-2203 (30 cm or 45 cm)	DB-4120-16
DB-2204 (30 cm or 45 cm)	DB-4120-16

Table 49: Compatibility External Trial Stimulators with the O.R. Cables	
ETS Model Number	**Compatible O.R. Cables**
DB-5132-S	DB-4120-08
	DB-4120-16 (in Port C/D only)
	DB-4100A with ETS Adapter DB-9315
DB-5170	DB-4120-08
	DB-4120-16
	DB-4100A with ETS Adapter DB-9315

Table 50: Compatibility Lead Extensions and Tunneling Tools	
Lead Extension Model Number	**Compatible Tunneling Tools**
DB-3216 (55 cm or 95 cm)	DB-4254
DB-3128 (55 cm or 95 cm)	DB-4254
NM-3138-55	DB-4254
	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.

Caution: *Be careful when using sharp surgical tools around the DBS Lead to avoid nicking or damaging the DBS Lead. A damaged DBS Lead can result in intermittent or loss of stimulation, requiring surgical replacement or revision.*

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 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.*

- 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.
- A Microdrive System (with compatible Cannula) may be used to drive the DBS Lead to the desired target. If used, use in accordance with the IFU provided by the Microdrive System manufacturer.
- A Cannula may be used for insertion of the DBS Lead to the desired target. A Cannula Stylet should be in place during insertion of the Cannula into the brain.

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 Handbook* as listed in the *DBS Reference Guide*.

MRI Scan Eligibility

For full body MRI scan eligibility, confirm that the DBS System components are implanted according to the instructions contained in the *ImageReady™ MRI Guidelines for Boston Scientific DBS Systems*.

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 8).

Figure 8. 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 9) by partially screwing the threaded portion of the screw into the threaded hole in the ring.

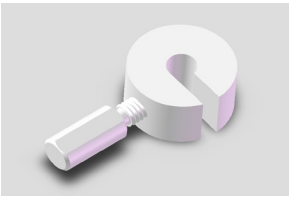


Figure 9. DBS Lead Stop

5. Measure the desired length of the DBS Lead with a gauge or ruler. Apply either the DBS Lead Stop or Microdrive Lead Holder to the DBS Lead at the appropriate length.

   To apply the DBS Lead Stop, push the DBS Lead to the center of the Lead Stop, then tighten the Screw (Figure 10). 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.*

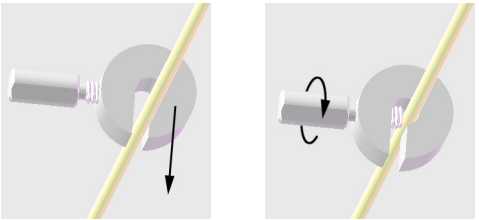


Figure 10. Applying the DBS Lead Stop

For a DBS Directional Lead, you may orient the Directional Contacts by positioning the Directional Marker (Figure 11) in a desired position when attaching the DBS Lead to the Microdrive Lead Holder. This Directional Marker is radiopaque. Boston Scientific recommends orienting the Directional Contacts so that the Directional Marker is facing an anterior direction within the brain. Contact labels (e.g., 3A, L6) as shown in the Clinician Programmer are provided in Figure 11. Contact numbering is also provided via the parentheticals within Figure 11.

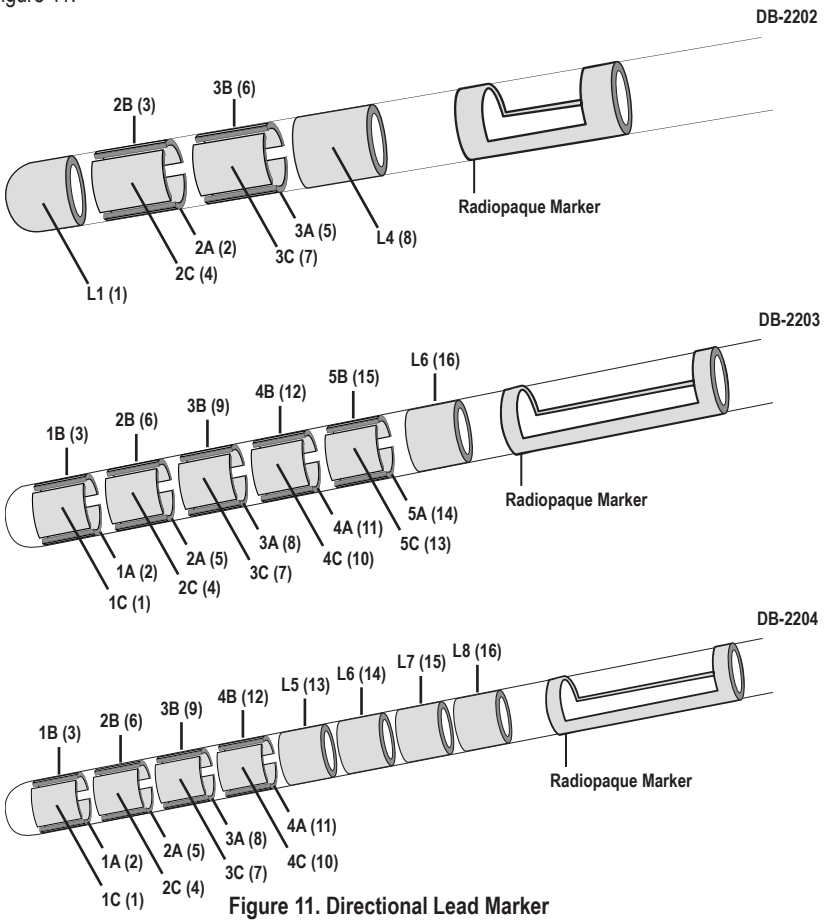


Figure 11. Directional Lead Marker

6. Remove the Cannula Stylet.
7. With the Lead Stylet in place, insert the DBS Lead into the Cannula. If using a Microdrive System, connect the Microdrive Lead Holder to the Microdrive System.
8. Slowly advance the DBS Lead to the desired target.

   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 O.R. 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 O.R. Cable Connector or plug in water or other liquids. The O.R. Cable is intended for single use only; do not resterilize.*

Intraoperative Testing Using ETS 3 and 8 Contact or 16 Contact Push Button O.R. Cable (DB-5170 with DB-4120-08 or DB-4120-16)

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 O.R. Cable assemblies to prevent unexpected stimulation.*

2. Connect the proximal end of the O.R. Cable Extension to the ETS 3 Port labeled "L" while keeping the distal end of the O.R. Cable within the sterile field (Figure 12).

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

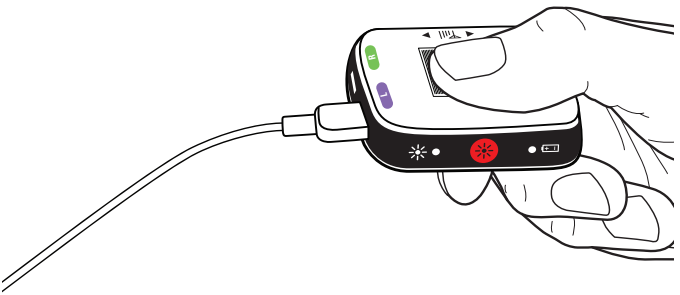


Figure 12. Connecting the O.R. Cable to ETS 3

3. Hold the O.R. Cable and DBS Lead as shown in Figure 13. Press down on the button to open the O.R. Cable Connector. Keep the button depressed.
4. With the Lead Stylet in place, slide the O.R. Cable Connector onto the proximal end of the DBS Lead (Figure 13). Make sure that the DBS Lead is fully inserted. The O.R. Cable Connector will stop when the DBS Lead is fully inserted.

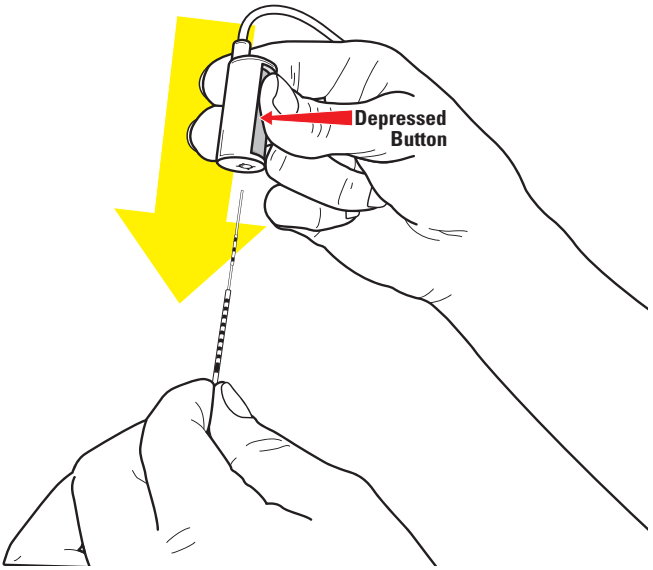


Figure 13. Depress Button on the O.R. Cable Connector to Connect O.R. Cable to DBS Lead

Note: *The Lead Stylet will extend through the back hole of the O.R. Cable Connector when the DBS Lead is fully inserted as shown in Figure 14.*

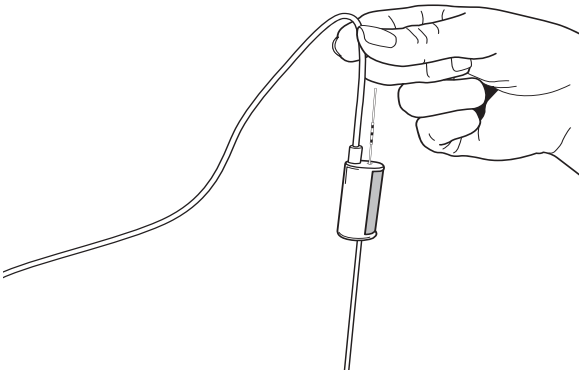


Figure 14. O.R. Cable Connected to DBS Lead

5. Support the O.R. Cable Connector to prevent unnecessary bending of the Lead during testing.
6. Verify that impedances are acceptable by using the Clinician Programmer, Remote Control, or Controller App.
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 O.R. Cables.*

9. Depress the button on the O.R. Cable Connector to release the Lead. Keep the button depressed until the O.R. Cable Connector has been fully removed from the Lead and Lead Stylet.
10. Disconnect the O.R. Cable from the proximal end of the DBS Lead by sliding the O.R. 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 ETS 2, 8 Contact O.R. Cable and Extension, and ETS Adapter (DB-5132-S with DB-4100A and DB-9315)

1. Attach the O.R. Cable Extension to the O.R. Cable (Figure 15).

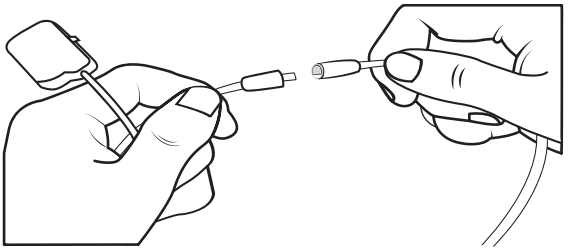


Figure 15. 8 Contact O.R. Cable and Extension

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 O.R. Cable assemblies to prevent unexpected stimulation.*

3. Plug the ETS Adapter into the ETS 2 Port labeled “CD” (Figure 16).

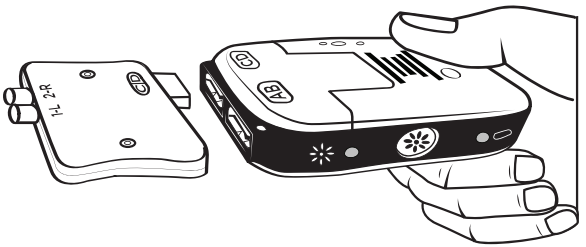


Figure 16. Connection of the ETS Adapter to the ETS 2

4. Plug the O.R. Cable with Extension into the ETS Adapter Port labeled “1-L” (Figure 17).

   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.

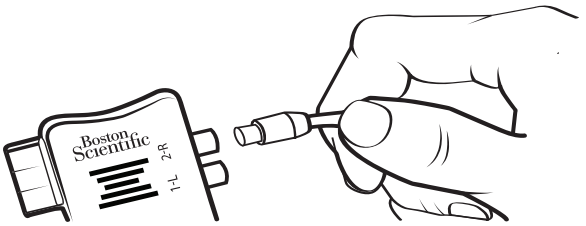


Figure 17. Connection of the 8 Contact O.R. Cable to ETS 2 and ETS Adapter

5. Check that the locking lever on the O.R. Cable Connector is in the open (0) position.

6. With the Lead Stylet in place, slide the O.R. Cable Connector onto the proximal end of the DBS Lead (Figure 18). Make sure that the DBS Lead is fully inserted.

   Note: *The Lead Stylet will extend through the back hole of the O.R. Cable Connector when the DBS Lead is inserted as shown in Figure 18.*

7. Hold the DBS Lead in place. Slide the locking lever to the locked (1) position (Figure 18).

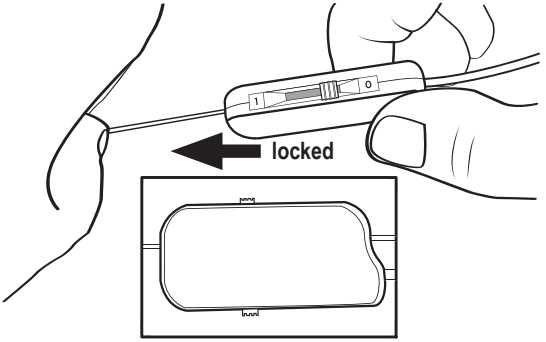


Figure 18. Securing the DBS Lead Into the 8 Contact O.R. Cable Connector

8. Support the O.R. Cable Connector to prevent unnecessary bending of the Lead during testing.
9. Verify that impedances are acceptable by using the Clinician Programmer, Remote Control, or Controller App.
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 O.R. Cables.*

12. Slide the locking lever to the open (0) position. Disconnect the O.R. 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 13.
   b. An appropriate commercially available filler and mini plate may also be used.[10] Ensure the Lead Stylet has been removed from the Lead prior to applying the mini plate. Ensure a Suture Sleeve is placed between the Lead and the mini plate to protect the Lead.

      Caution: *Securing the DBS Lead with a mini plate without a Suture Sleeve may damage the DBS Lead and require a surgical replacement or revision.*

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 19).

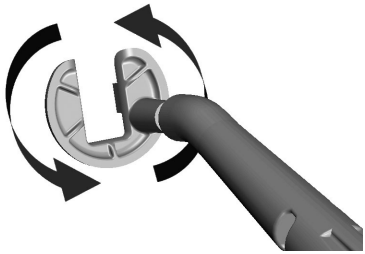


Figure 19. Rotational Direction for the Horseshoe End

10 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 20).

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

Figure 20. 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 21).

Figure 21. 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 22).

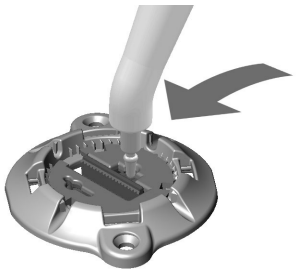


Figure 22. Lock the Slider

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. Remove or release the DBS Lead from the instrumentation such as the Cannula or Microdrive. If necessary, slowly further retract the instrumentation to allow clearance for the proximal array of the Lead without bending the proximal array.

    Caution: *While removing or releasing the DBS Lead from the instrumentation (e.g., Cannula, Microdrive), use care not to bend the proximal array of the DBS Lead. If the proximal array is bent during removal from the instrumentation, the DBS Lead may be damaged.*

11. 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 23).

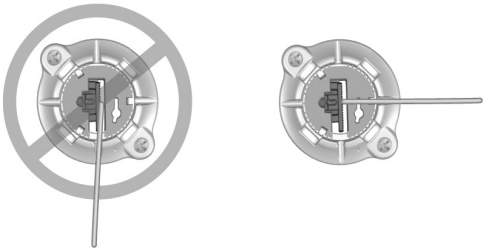


Figure 23. Placing the DBS Lead into the Lead Exit Slot

Caution: *Secure the DBS Lead using a Lead Exit Slot that is approximately perpendicular to the Retaining Clip channel.*

12. **Optional:** Secure the DBS Lead to additional Lead Exit Slots for added strain relief (Figure 24).

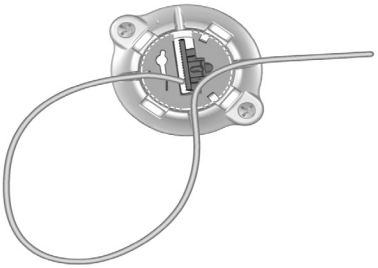


Figure 24. Placement of the DBS Lead into Additional Lead Exit Slots

13. 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.*

14. Remove the stereotactic frame and Microdrive system.

15. **If the IPG will be implanted during a separate surgery:**

a. Grip the Lead Boot at the Setscrew and begin insertion of the proximal end of the DBS Lead while holding the array. Continue gently inserting until it stops. It is recommended to place the Lead Boot with the gold marking, if available, or 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 25).*

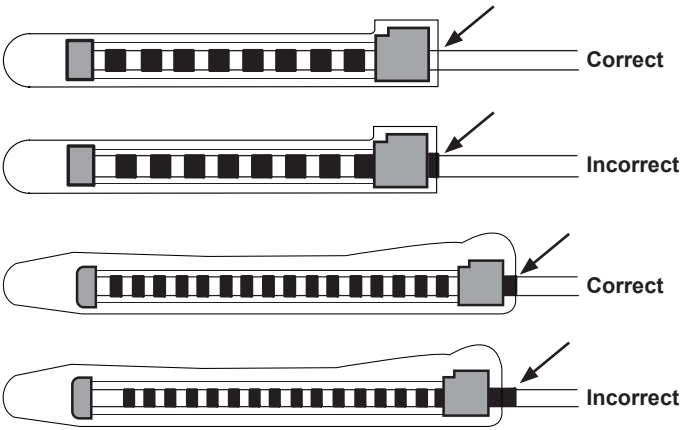


Figure 25. Securing the DBS Lead in the Lead Boot

Note: *The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 26).*

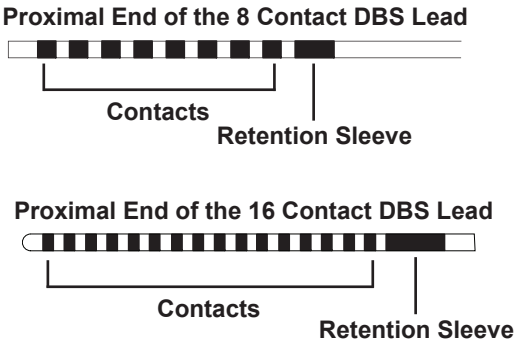


Figure 26. Retention Sleeve

b. Pass the Hex Wrench through the slit in the Septum located on the top of the Lead Boot.

c. Tighten the Setscrew until the Hex 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 Hex Wrench clockwise until it clicks, indicating that the Setscrew is fully secured (Figure 27). To loosen the Setscrew, rotate the Hex Wrench counterclockwise.*

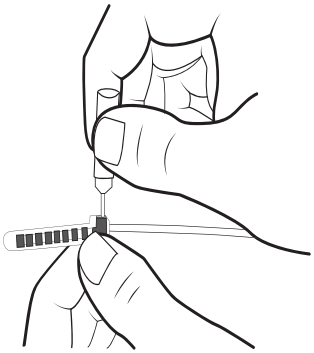


Figure 27. Tightening the Setscrew

Caution: *The Hex Wrench is torque-limiting to prevent overtightening of the Setscrew. Use only the Hex 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. Take care not to sharply bend the Lead near the Lead Boot exit.

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.*

Caution: *Performing blunt dissection with the Lead Boot may damage the Lead within the Lead Boot.*

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.*

16. 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.

17. If applicable, use the Tunneling Tool or appropriate means to tunnel the second DBS Lead to the same side as the first Lead.

18. Close the incisions.

Tunneling the Lead Extension

Assembling the Tunneling Tool

A Tunneling Tool (Figure 28) and Straw are provided to facilitate tunneling of the Lead Extension.

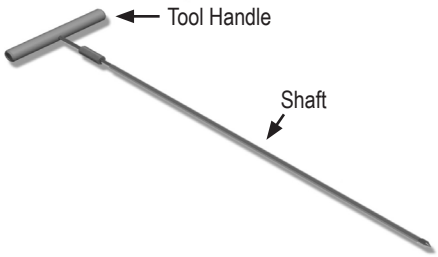


Figure 28. Tunneling Tool

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 either in the chest or in the abdomen 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.

      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.*

      Warning: *Submuscular implant in the pectoral region (i.e. subpectoral) may expose the Vercise Genus rechargeable IPG to frequent muscle tension forces which may cause component damage (feedthrough wire(s)) resulting in device malfunction that could lead to adverse events including explant of the IPG.*

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.[11]

   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.*

11 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.

6. Once the tip of the Tunneling Tool is completely exposed, unscrew and remove the handle of the Tunneling Tool (Figure 29).

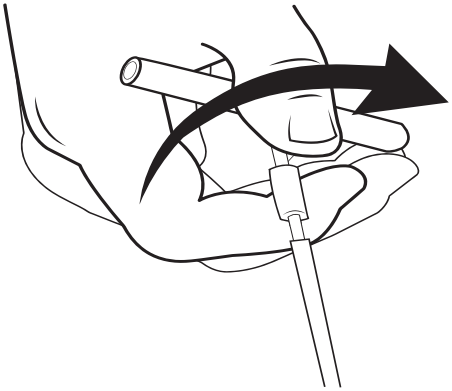


Figure 29. Removing the Handle of the Tunneling Tool

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. For cases with two bifurcated Lead Extensions, do either of the following:
   a. Stagger the points of bifurcation so that they are narrow enough to fit through the straw at the same time.
   b. Insert the Lead Extensions one at a time. Slide the first Lead Extension through the entire Straw. Repeat with the second Lead Extension.

   Note: *Some resistance may be felt when passing two bifurcated Lead Extensions. As needed, lubricate inside of the Straw and/or along the length of the bifurcated Lead Extensions with sterile saline, particularly at the points of bifurcation.*
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.*

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.

   Caution: *When planning the incisions necessary for connecting the Lead to the Lead Extension, ensure that there is enough length in the incision to expose the ends of the Lead and Lead Extension without excessive bending or kinking. Make an incision parallel to the path of the Lead and Lead Extension. Take care not to place an excessive bend in either Lead body adjacent to the Connector.*

3. Expose the DBS Lead and Lead Boot through the incision.
4. Using the Hex Wrench, remove and discard the Lead Boot.

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

5. Wipe dry the proximal end of the DBS Lead with sterile gauze.

Connecting the DBS Lead to the Lead Extension

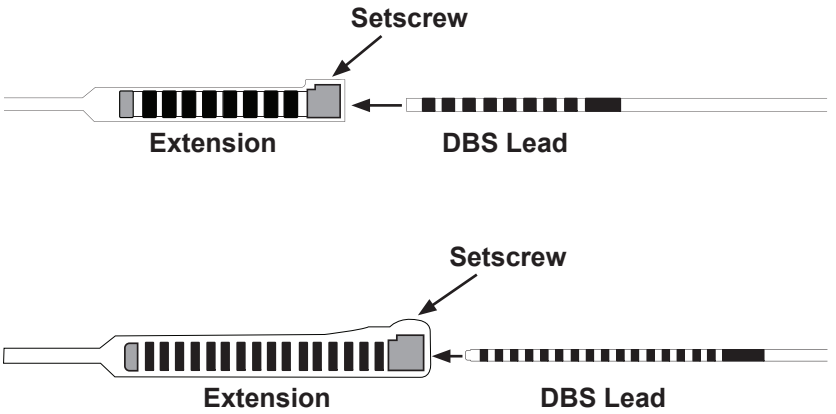


Figure 30. The DBS Lead and Lead Extension Connector (8 and 16 Contact Leads Shown)

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 Hex Wrench (Figure 30).

2. Grip the Lead Extension Connector at the Setscrew and begin insertion of the DBS Lead while holding the array (Figure 31).

   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.*

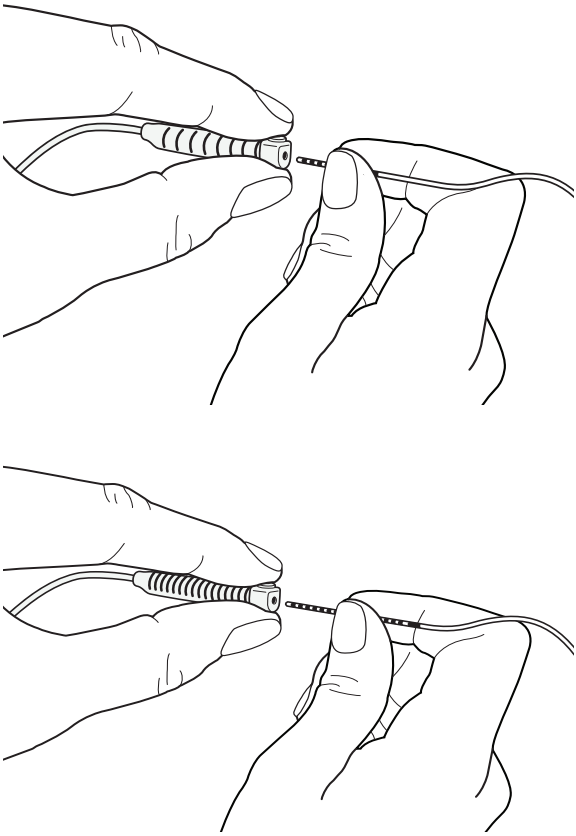


Figure 31. Grip the DBS Lead and the Setscrew of the Lead Extension Connector Prior to Insertion (8 and 16 Contact Leads Shown)

3. Gently guide the DBS Lead into the Lead Extension Connector until the DBS Lead Contacts align with the Lead Extension Contacts and the Retention Sleeve aligns with the Setscrew. Do not tighten the Setscrews at this time.

   Caution: *Take care not to bend or kink the DBS Lead or Lead Extension when inserting the proximal Lead array into the Lead Extension Connector. Take care not to over insert the Lead into the Lead Extension.*

   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 silver connector block within Lead Extension Connector. Ensure both DBS Leads are fully inserted such that the Retention Sleeves reside within the connector blocks, under the Setscrews. Do not tighten the Setscrews at this time.

   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 32).

   If they are not aligned, continue to grip the DBS Lead next to the Retention Sleeve and gently 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-2203 or DB-2204 16 Contact Directional Lead into a DB-3216 Lead Extension, the Retention Sleeve is a length such that, when no amount of the Retention Sleeve remains visible and is no longer protruding out of the Lead Extension Connector, then the DBS Lead is fully inserted.

   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.*

   Caution: *After connecting the DBS Lead to the Lead Extension, take care not to tug excessively on the Lead Extension.*

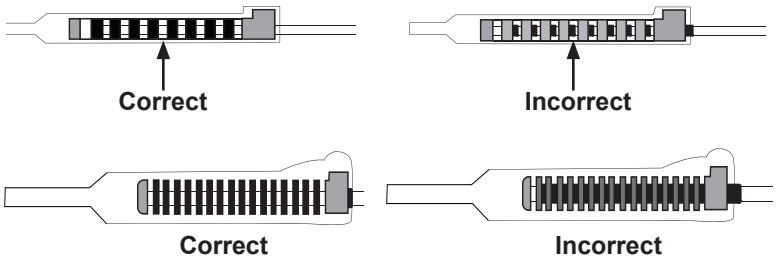


Figure 32. Alignment of the DBS Lead in the Lead Extension Connector (8 and 16 Contact Leads Shown)

5. If applicable, 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. Only use Port Plugs provided in the following Product Kits: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-3128-55, DB-3128-55B, DB-3128-95, DB-3128-95B, DB-3216-55, and DB-3216-95. 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 33).

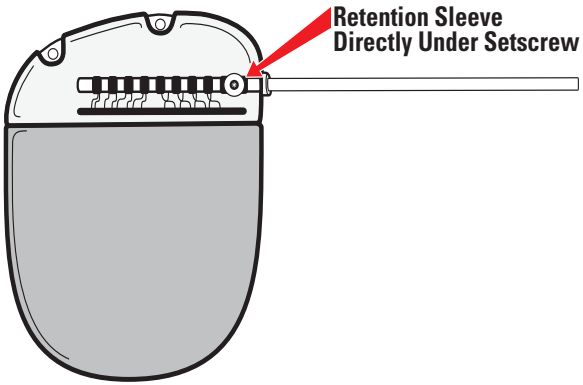


Figure 33. Alignment of Lead Extension Contacts in the DBS IPG Port

Note: *The Retention Sleeve is easily distinguished from the Contacts by its longer length (Figure 34).*

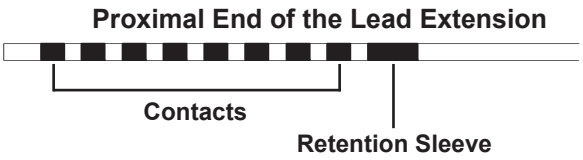


Figure 34. Retention Sleeve on the Lead Extension

6. If applicable, 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 Clinician Programmer, Remote Control, or Controller App.
8. Pass the Hex Wrench through the slit in the Septum located on the side of the IPG Header (Figure 35).
9. Tighten the Setscrew in the IPG Header until the Hex Wrench clicks, indicating that the Setscrew is fully secured.

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

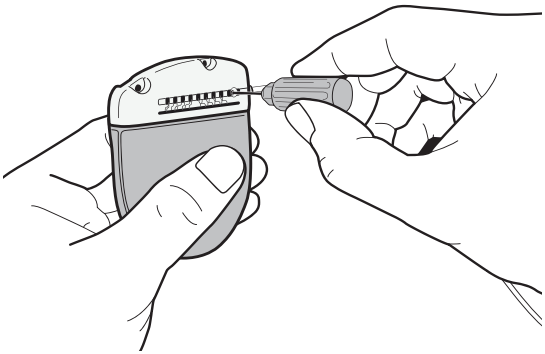


Figure 35. Inserting the Hex Wrench Into the IPG Header

Caution: *The Hex Wrench is torque-limiting so that the Setscrew cannot be overtightened. Use only the Hex 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 Hex 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 Hex 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 Hex Wrench clockwise. To loosen the Setscrew, rotate the Hex Wrench counterclockwise.*

14. Place the Lead Extension Connector in the desired location and orientation under the scalp. Gently tuck the exposed lengths of the DBS Lead and Lead Extension back under the scalp. Take care not to kink the Lead bodies or bend the Connector.

15. 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: *Submuscular implant in the pectoral region (i.e. subpectoral) may expose the Vercise Genus rechargeable IPG to frequent muscle tension forces which may cause component damage (feedthrough wire(s)) resulting in device malfunction that could lead to adverse events including explant of the IPG.*

    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.

    Caution: *Do not excessively bend the Lead bodies and Connectors while placing the DBS System under the skin and closing the incision.*

16. 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:

1. Connect the Lead Extension to Port C (Figure 36).

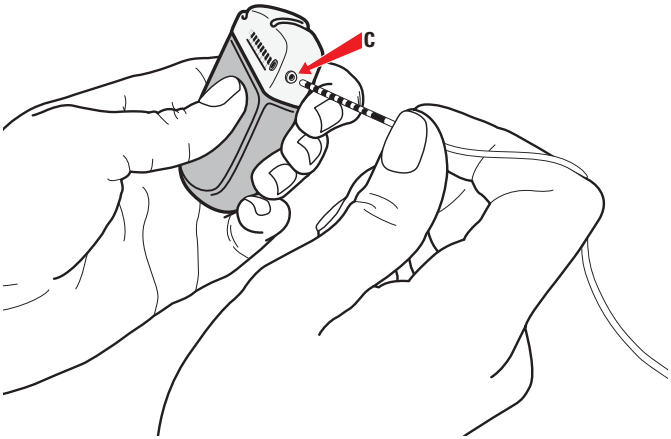


Figure 36. Connection to IPG Port C

2-Port (16 Contact) IPG

For single 16 Contact Lead connection with the bifurcated Lead Extension DB-3216 to the 2-Port IPG:[12]

1. Connect the Lead Extension tail with the gold marker band to Port L (or C) (Figure 37).

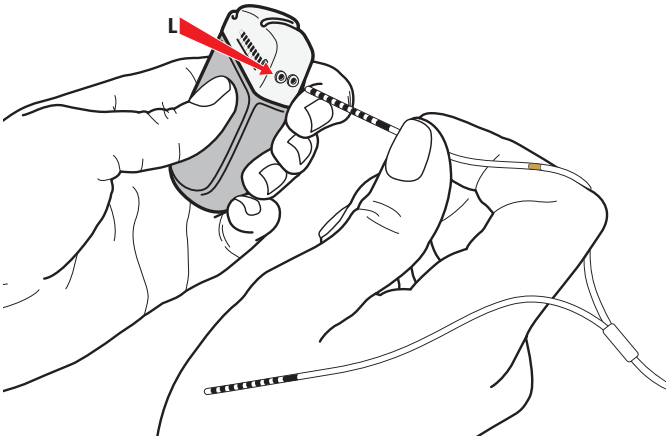


Figure 37. Connection to IPG Port L

2. Connect the Lead Extension tail with no marker band to Port R (or D) (Figure 38).

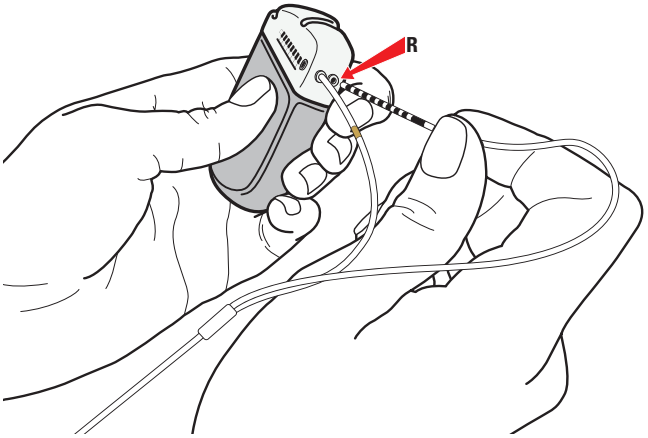


Figure 38. Connection to IPG Port R

12 DB-3216 Lead Extension can connect one (1) 16 Contact DBS Lead to an IPG.

For dual 8 Contact Lead connection with the bifurcated Lead Extension DB-3128 to the 2-Port IPG:[13]

1. Connect the left hemisphere Lead Extension tail with the gold marker band to Port L (or C) (Figure 39).

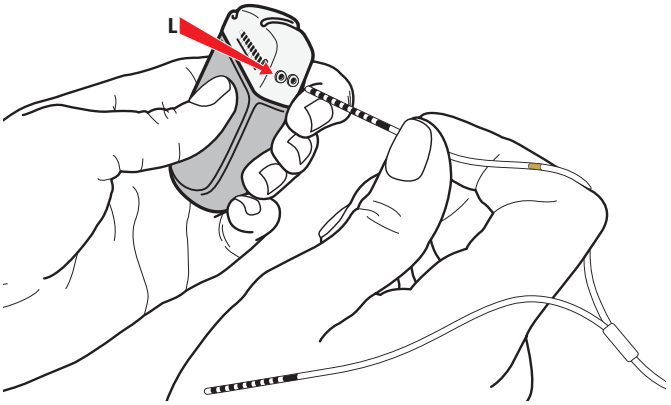


Figure 39. Connection to IPG Port L

2. Connect the right hemisphere Lead Extension tail with no marker band to Port R (or D) (Figure 40).

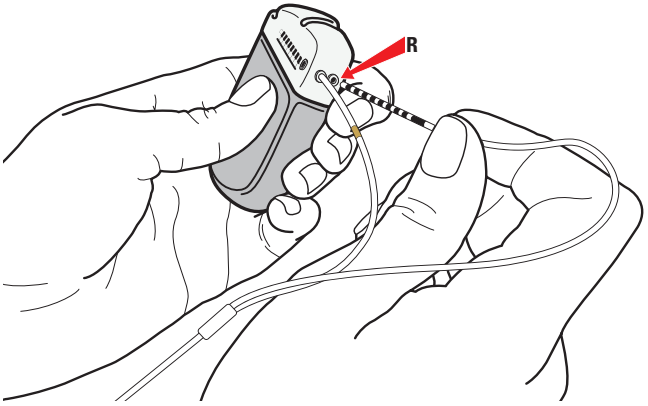


Figure 40. Connection to IPG Port R

13 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:[14]

1. Connect the left hemisphere Lead Extension to Port L (or C) (Figure 41).

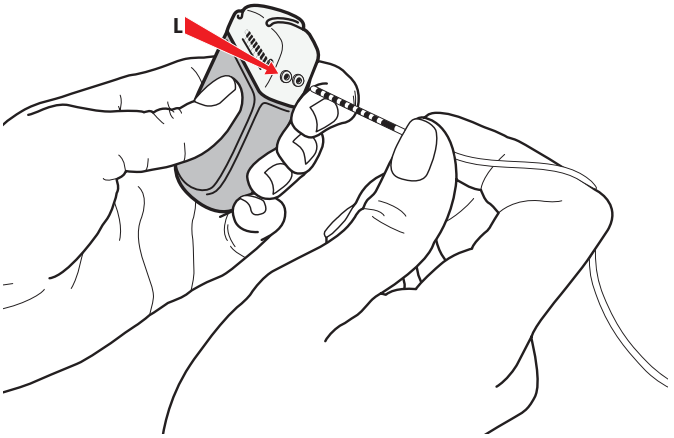


Figure 41. Connection to IPG Port L

2. Connect the right hemisphere Lead Extension to Port R (or D) (Figure 42).

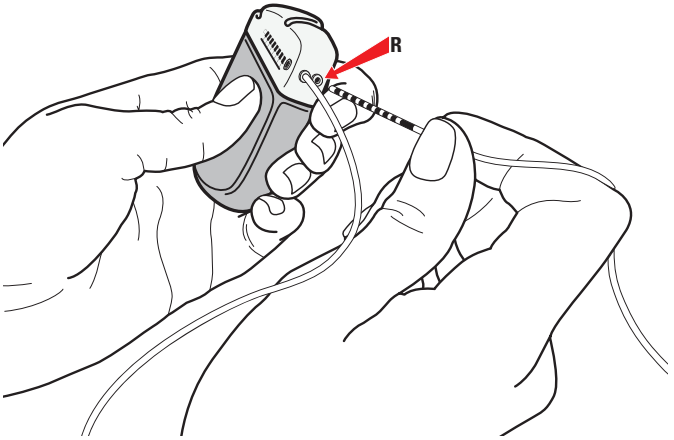


Figure 42. Connection to IPG Port R

14 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 16 Contact Lead connection with the bifurcated Lead Extension DB-3216 to the 4-Port IPG:

1. Connect the left hemisphere Lead Extension to Ports L1 and L2.
   a. Connect the tail with the gold marker band to the gold Port labeled L1 (Figure 43).

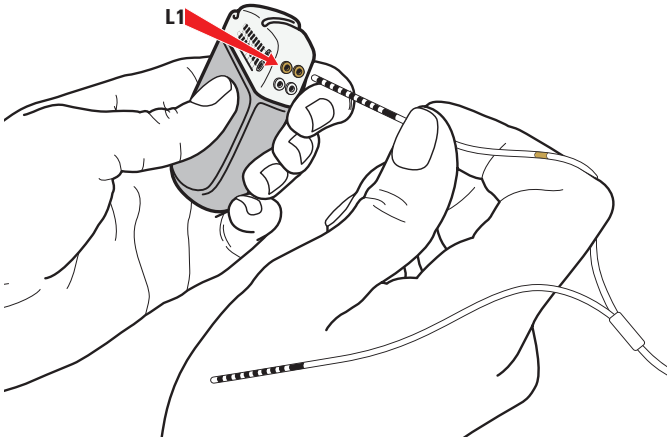


Figure 43. Connection to IPG Port L1

   b. Connect the tail with no marker band to the Port labeled L2 (Figure 44).

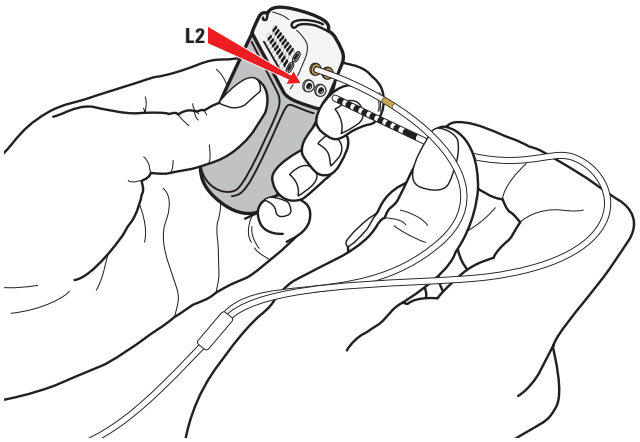


Figure 44. Connection to IPG Port L2

2. Connect the right hemisphere Lead Extension to Ports R1 and R2.
   a. Connect the tail with the gold marker band to the gold Port labeled R1 (Figure 45).

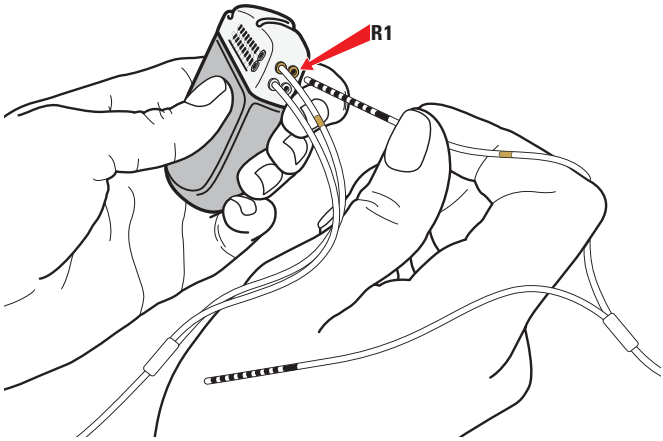


Figure 45. Connection to IPG Port R1

   b. Connect the tail with no marker band to the Port labeled R2 (Figure 46).

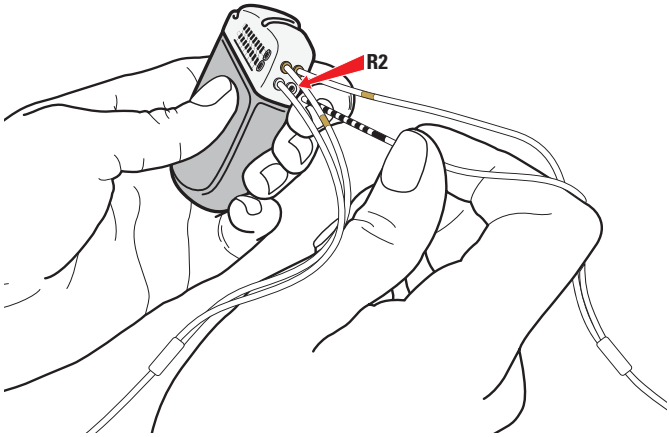


Figure 46. Connection to IPG Port R2

For dual 8 Contact Lead connection with the bifurcated Lead Extension DB-3128 to the 4-Port IPG:[15]

1. Connect the left hemisphere Lead Extension tail with the gold marker band to Port L2 (Figure 47).

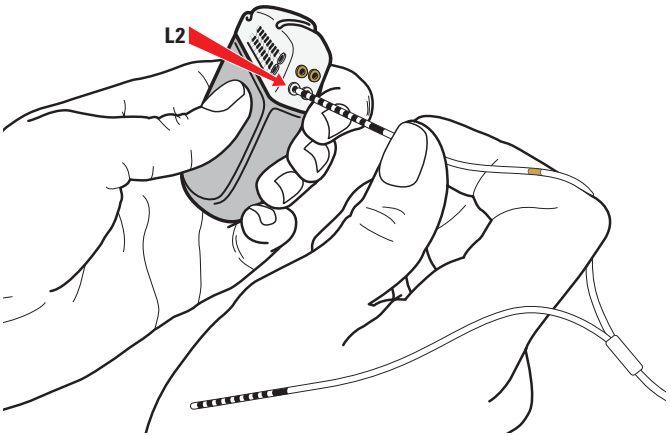


Figure 47. Connection to IPG Port L2

2. Connect the right hemisphere Lead Extension tail with no marker band to Port R2 (Figure 48).

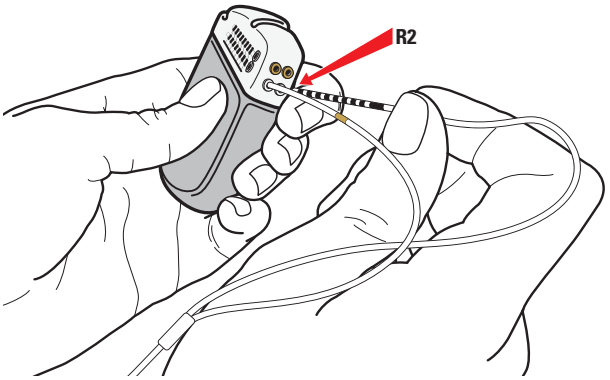


Figure 48. Connection to IPG Port R2

15 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:[16]

1. Connect the left hemisphere Lead Extension to Port L2 (Figure 49).

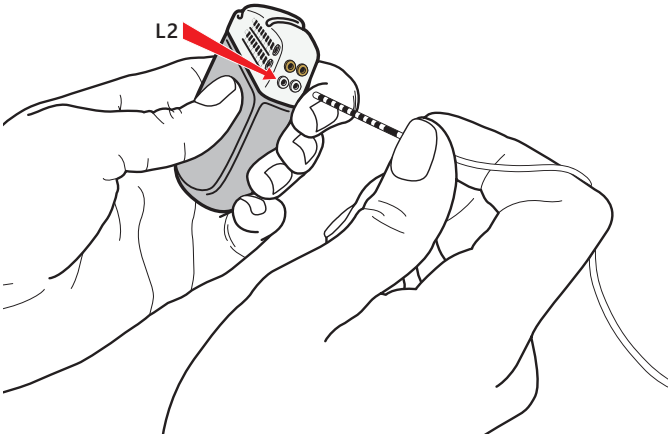


Figure 49. Connection to IPG Port L2

2. Connect the right hemisphere Lead Extension to Port R2 (Figure 50).

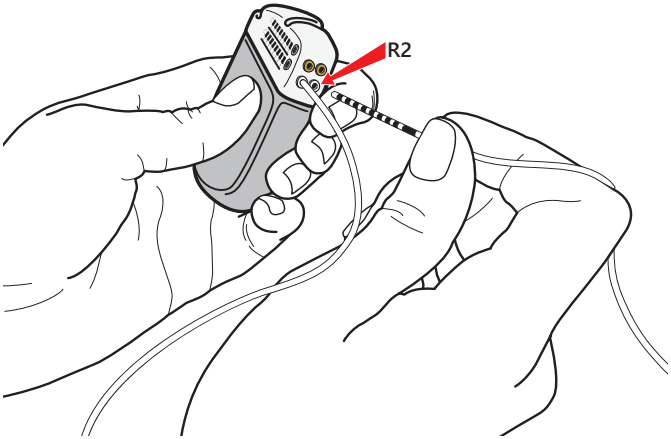


Figure 50. Connection to IPG Port R2

16 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 behind 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 cm 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 Hex Wrench provided.

   Note: *Ensure that the Hex Wrench is fully inserted before loosening the Setscrew. To tighten the Setscrew, rotate the Hex Wrench clockwise. To loosen the Setscrew, rotate the Hex 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 51). The tip of the Placement/Removal Tool should snap into place.

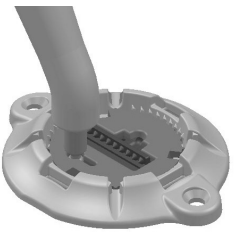


Figure 51. Inserting the Placement/Removal Tool

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 Lead Extension Connector.
5. Loosen the Lead Extension Connector Setscrew using the Hex 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 Hex Wrench clockwise. To loosen the Setscrew, rotate the Hex 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 Hex 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 Hex Wrench clockwise. To loosen the Setscrew, rotate the Hex 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 Spare 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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