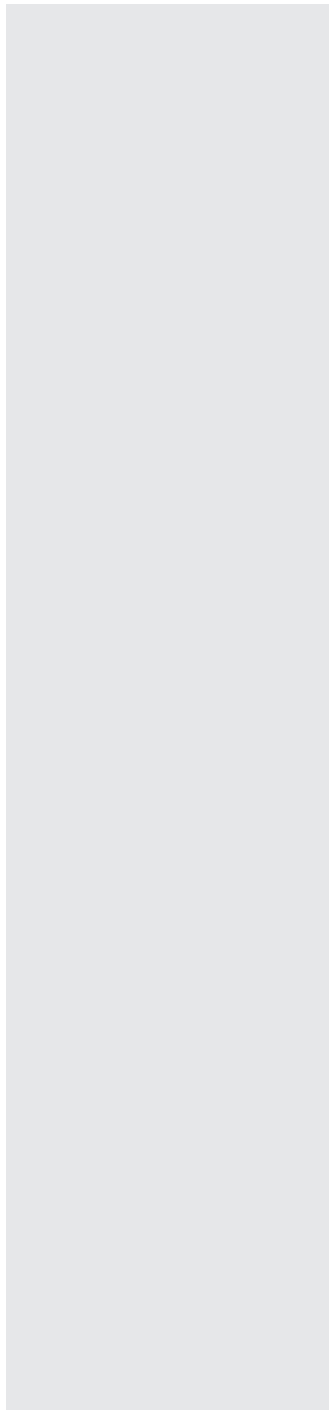




Advancing science for life™

Vercise™ DBS Leads

Directions for Use



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

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Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity. Drawings are for illustration purposes only.

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Additional Information

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

Product Model Numbers

Model Number	Description
DB-2201-30DC	DBS Lead Kit, 30 cm
DB-2201-45DC	DBS Lead Kit, 45 cm
DB-2202-30	Vercise™ Cartesia™ 30 cm 8 contact DBS Directional Lead Kit
DB-2202-45	Vercise Cartesia 45 cm 8 Contact DBS Directional Lead Kit
DB-2500-C	Vercise Physician's Spare Kit
DB-4100-A and SC-4100A	O.R. Cable 1x8 and Extension
DB-4108 and SC-4108	O.R. Cable 2x8, 61 cm and Extension
DB-5132-S	Vercise DBS External Trial Stimulator 2 (ETS 2)
DB-9315	Vercise ETS Adapter

Registration Information

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific Lead. The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory or device to gain quick access to pertinent data from the manufacturer. Fill out the registration form included in the package contents. Return one copy to Boston Scientific, keep one copy for patient records, provide one copy to the patient, and one copy to the physician.

Boston Scientific Neuromodulation Corporation
 25155 Rye Canyon Loop
 Valencia, California 91355 USA
 Attention: Customer Service Department

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Description

This manual outlines the implantation procedure for both the DBS Lead and DBS Directional Lead and intraoperative testing with the External Trial Stimulator 2 (ETS 2). The DBS lead consists of eight cylindrical contacts and is compatible with all Boston Scientific DBS Simulators. The DBS Directional lead consists of eight contacts with two rows of contacts that are separated circumferentially to allow both axial and rotational stimulation selectivity. The Directional Lead is compatible with all Boston Scientific DBS Simulators except the Vercise Stimulator, model number DB-1110.

Note: *The implantation procedure and intraoperative testing for the DBS leads with the External Trial Stimulator 1 (ETS 1) is provided in the Vercise Physician Manual.*

Package Contents

DBS Lead Kit

- (1) 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

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

DBS Directional Lead Kit

- (1) 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

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

Physician Spares Kit

- (1) 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

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

Instructions for Use

The DBS Lead and the DBS Directional Lead from any of the lead kits listed in the Product Model Numbers section of this manual are referred to as the “DBS Lead” in the following instructions.

Note: *Use meticulous care during implantation of the Boston Scientific DBS System to prevent infection.*

Pre-Conditions

The described implant procedures start with implanting 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 desired trajectory of the DBS Lead insertion path has been determined.
- The incision in the scalp has been made and the burr hole drilled.
- If using the SureTek™ Burr Hole Cover, the Base of the Burr Hole Cover has been affixed over the burr hole. (See the manual provided with the Burr Hole Cover Kit for instructions for use.)
- The desired trajectory and DBS Lead depth may have been verified by microelectrode recording or an appropriate means.

Implanting the DBS Lead

1. Prepare the DBS Lead for implant. Visually inspect the DBS Lead and determine it to be acceptable for implantation.
2. Pass the DBS Lead through the cannula to ensure proper fit. Then remove the DBS Lead from the cannula.
3. Insert the cannula (with cannula stylet) into the brain to the desired depth.

Note: *Cannula depth depends on physician's preference.*

-
- Assemble the Lead Stop (Figure 1) by partially screwing the threaded portion of the screw into the threaded hole in the Ring.



Figure 1: DBS Lead Stop

- Measure the desired depth of 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 and then tighten the Screw (Figure 2). This will ensure that the DBS Lead will be inserted to the proper depth.

Note: Make sure the Lead Stop will not slide on the DBS Lead when engaged.

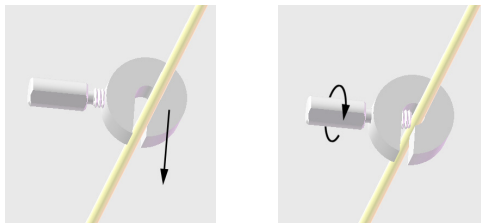


Figure 2: Applying the DBS Lead Stop

- Insert the DBS Lead, with the stylet in place, into the cannula.
- Insert the DBS Lead and the cannula into the cannula guide on the microdrive.
- Attach the DBS Lead to the microdrive.

For the DBS Directional Lead, you may orient the directional contacts by positioning the directional marker (see Figure 3) in a desired position when attaching the Lead to the microdrive. This directional marker is radiopaque. Boston Scientific recommends that the directional contacts be oriented such that contacts #2 and #5 and the directional marker are facing in an anterior direction within the brain.

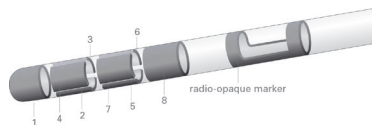


Figure 3: Directional Lead Marker

- Slowly advance the DBS Lead to the desired target using the microdrive.

Note: Ensure that the stylet is inside the Lead before advancing the Lead to the desired target.

Intraoperative Testing

The External Trial Stimulator (ETS), OR Cable, OR Cable Extension, ETS Adapter, and Clinician Programmer (CP) may be used to conduct intraoperative stimulation testing during the procedure. The OR Cable Extension is designed for temporary connection to the OR Cable to facilitate stimulation testing outside of the sterile field. The specific model of ETS, ETS Adapter, and OR Cables to be used depends on the Stimulator being implanted. See your DBS *Reference Guide* to determine the External Trial Stimulator, ETS Adapter, and OR cables compatible with the Stimulator being implanted.

Note: Refer to the *Vercise Physician Manual for Instructions for ETS 1*.

Intraoperative Testing using the External Trial Stimulator 2, the ETS Adapter, and 1x8 OR Cables and Extension

The following steps are for intraoperative testing using the ETS 2 (Model number DB-5132-S) and ETS Adapter (DB-9315) and 1x8 OR Cable and Extension (Model number DB-4100A or SC-4100A). Refer to your Programming Manual 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 one-time use only; do not resterilize.

1. Attach the OR Cable Extension to the OR Cable (Figure 4).

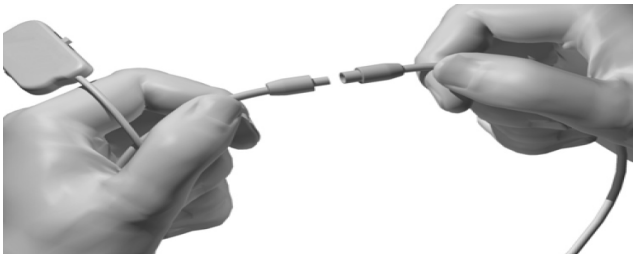


Figure 4: 1x8 OR Cables and Extension

2. Verify that the External Trial Stimulator 2 is off.

WARNING: Always turn the External Trial Stimulator 2 off before connecting or disconnecting the cable assemblies to prevent unexpected stimulation.

3. Plug the ETS Adapter into the External Trial Stimulator 2 socket labeled “CD” (Figure 5).

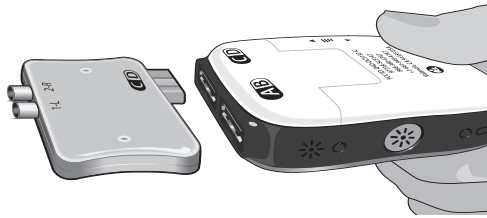


Figure 5: Connection of the ETS Adapter to the External Trial Stimulator 2

4. Plug the OR Cable with Extension into the ETS Adapter socket labeled “1-L” (Figure 6). If two DBS leads are being used, connect the left DBS Lead to socket “1-L” and the right DBS Lead to socket “2-R.”

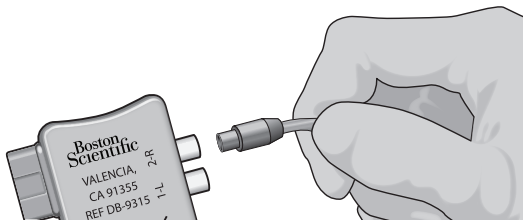


Figure 6: Connection of the 1x8 OR Cable to External Trial Stimulator 2 and ETS Adapter

5. Check that the locking lever on the OR Cable connector is in the open (0) position.
6. Slide the proximal end of the DBS Lead, with the stylet, into the open port on the OR Cable connector.

Note: The descriptors “proximal” and “distal” use the Stimulator as reference.

7. Push the end of the DBS Lead into the port until it stops. Hold the DBS Lead in place while sliding the locking lever to the locked (1) position (Figure 7).

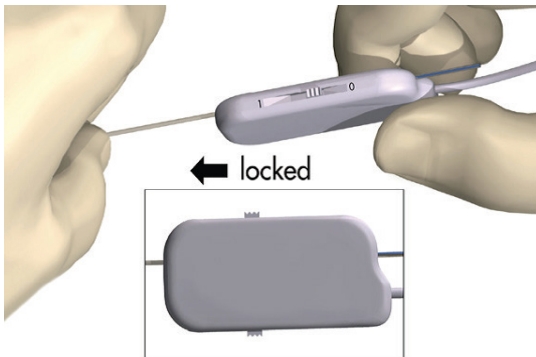


Figure 7: Securing the DBS Lead into the 1x8 OR Cable Connector

8. Secure the OR Cable with Extension to the microdrive or stereotactic frame.

- Verify impedances are acceptable by using the CP or Remote Control to measure impedances.
- Evaluate DBS Lead placement by appropriate means. Adjust the DBS Lead location or stimulation parameters if necessary.

Note: *The stylet should remain in place throughout DBS Lead insertion and adjustments.*

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 DBS Lead penetrations increases the probability of hemorrhage. The necessity for an acute DBS Lead revision should be minimized using techniques of target localization, such as microelectrode recordings and imaging, to correctly place the DBS Leads on the first attempt.

- Turn off the External Trial Stimulator 2.

WARNING: A sudden increase in stimulation may occur if External Trial Stimulator 2 is ON while disconnecting the OR Cables.

- Disconnect the OR Cable and Extension from the proximal end of the DBS Lead.

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

Intraoperative Testing with External Trial Stimulator 2 and 2x8 OR Cables and Extension

The following steps are for intraoperative testing using the ETS 2 (Model number DB-5132-S) and 2x8 OR Cable and Extension (Model number DB-4108 or SC-4108). Refer to the appropriate Programming Manual 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 one-time use only; do not resterilize.

- Attach the OR Cable Extension to the OR Cable (Figure 8).

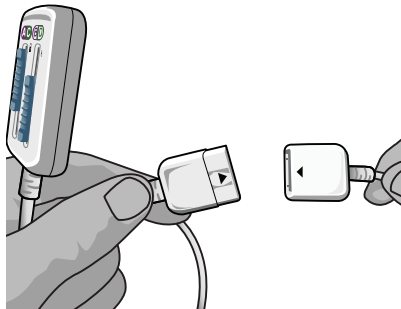


Figure 8: External Trial Stimulator 2 and 2x8 OR Cable and Extension

2. Ensure that the External Trial Stimulator 2 is off by checking the Stim Indicator light on the device.
3. Connect the OR Cable Extension to the External Trial Stimulator 2 socket labeled “CD” (Figure 9).

Note: The descriptors “proximal” and “distal” use the Stimulator as reference.

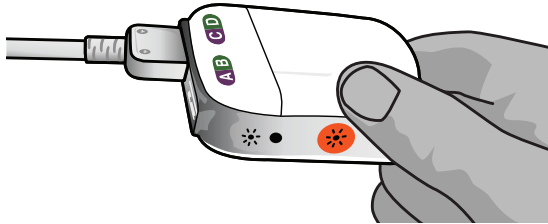




Figure 9: Connection of the 2x8 OR Cable to the External Trial Stimulator 2

4. Ensure that the locking lever on the OR Cable connector is in the open () position.
5. Slide the proximal end of the DBS Lead, with stylet, into the open port labeled “C” on the OR Cable connector. If two DBS leads are being used, connect the left DBS lead to Port C and the right DBS lead to Port D.
6. Push the end of the DBS Lead into the port until it stops. Hold the DBS Lead in place while sliding the locking lever to the locked () position (Figure 10).

WARNING: Always turn the External Trial Stimulator 2 off before connecting or disconnecting the cable assemblies to prevent unexpected stimulation.

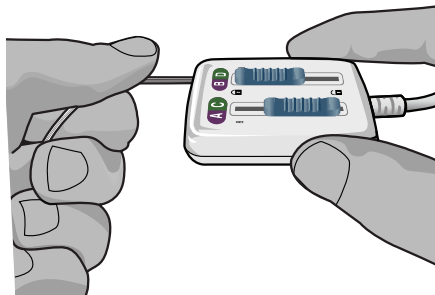


Figure 10: Securing the DBS Lead into the 2x8 OR Cable Connector

7. Secure the OR Cable to the microdrive or stereotactic frame.
8. Verify impedances are acceptable by using the CP or Remote Control to measure impedances.
9. Evaluate Lead placement by appropriate means. Adjust the Lead location or stimulation parameters if necessary.

Note: *The stylet should remain in place throughout Lead insertion and adjustments.*

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. The necessity for an acute Lead revision should be minimized using techniques of target localization, such as microelectrode recordings and imaging, to correctly place the Leads on the first attempt.

10. Turn off the External Trial Stimulator 2.

WARNING: A sudden increase in stimulation may occur if External Trial Stimulator 2 is ON while disconnecting the OR Cables.

11. Disconnect the OR Cable and OR Cable Extension from the proximal end of the Lead.

12. Verify that the 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 move it.

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. Be careful not to move the DBS Lead.

Note: *The descriptors “proximal” and “distal” use the Stimulator as the reference throughout this manual.*

3. Fix the Lead in place. The SureTek™ Burr Hole Cover Kit is recommended for use with the Boston Scientific DBS System. (An appropriate commercially available filler may also be used.¹)
4. Remove the stylet.

CAUTION: Do not reinsert the 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.

5. Remove the stereotactic frame and microdrive system.
6. If the Stimulator will be implanted during a separate surgery, prepare the DBS Lead for the Stimulator implantation procedure.
 - (a). Insert proximal end of the DBS Lead into the Lead Boot until it stops.
 - (b). Place a Suture Sleeve on the left DBS Lead to differentiate the 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 11).*

¹ DBS Lead secured and 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.

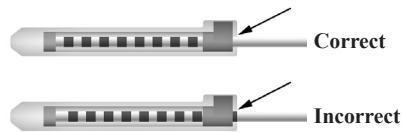


Figure 11: Securing the DBS Lead in the Lead Boot

Note: The retention sleeve is easily distinguishable from the contacts by its length (Figure 12).

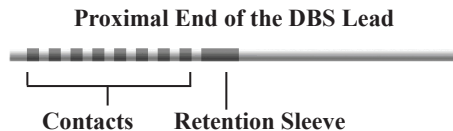


Figure 12: Retention Sleeve

- (c). Pass the Torque Wrench through the slit in the septum located on the top of the Lead Boot.
- (d). Tighten the Setscrew until the Torque Wrench clicks, indicating the Setscrew is fully secured.

Note: To tighten the Setscrew, use one hand to grasp the Lead Boot at the base and the other to rotate the Torque Wrench clockwise until it clicks, indicating the Setscrew is fully secured (Figure 13). To loosen the Setscrew, rotate the Torque Wrench counterclockwise.



Figure 13: Tightening the setscrew

CAUTION: The wrench is torque limiting, such that the Setscrew cannot be over tightened. Use only the wrench provided, as other tools may over-tighten the Setscrew and damage the DBS Lead.

- (e). Create a tunnel, for the proximal end of the DBS Lead, to a place closer to the desired DBS Extension connector location.

CAUTION: Placement of the DBS Extension connector in the neck region can increase the risk of device failure due to repetitive movement of the neck.

- (f). Create a pocket under the skin for the excess DBS Lead and Lead Boot.
- (g). Coil excess DBS Lead material under the scalp, in the pocket, until it is ready to be connected to the DBS Extension.

Note: *The DBS Lead may be connected to the DBS Extension and Stimulator during a separate surgery at a later time. See “Stimulator Implantation” in the appropriate IPG DFU as listed on your DBS Reference Guide.*

7. Repeat the “Implanting the DBS Lead” procedure for the second DBS Lead. Use the Tunneling Tool to tunnel the second DBS Lead to the same side as the first Lead.
8. Close the incisions.


Explanting the DBS Leads

For instructions on explanting the DBS leads, see the appropriate DFU for your Boston Scientific DBS System as listed on your DBS *Reference Guide*.

Technical Specifications


The DBS Lead consists of 8 cylindrical contacts. The outer diameter of the DBS Lead is 1.3 mm and is compatible with existing commercially available DBS implantation tools, such as stereotactic surgical equipment.

Table 1: DBS Lead

	Feature	Specification
	Number of Contacts	8
	Contact Length	1.5 mm
	Contact Surface Area	6.0 mm ²
	Contact Spacing (Center-to-Center)	2.0 mm
	Contact Span	15.5 mm
	Distal Contact to Tip Length	< 1.3 mm
	Diameter	1.3 mm
	Overall Length	30 cm, 45 cm
	Outer Jacket Tubing (Insulation)	Polyurethane
	Contact Material	Platinum/Iridium
	Impedance	≤ 90 Ω (measured from each connector to corresponding electrode contact)

The DBS Directional lead consists of 8 contacts with two rows of contacts that are separated circumferentially to allow both axial and rotational stimulation selectivity. It also has a radio opaque marker that aligns with contacts 2 and 5. The outer diameter of the directional lead is 1.3 mm and is compatible with existing commercially available DBS implantation tools.


Table 2: DBS Directional Lead

	Feature	Specification
	Number of Dome Tip Contacts	1
	Number of Segmented Contacts	6
	Number of Ring Contacts	1
	Contact Length	1.5 mm
	Ring Contact Surface Area	6.0 mm ²
	Segmented Contact Surface Area	1.5mm ²
	Dome Tip Contact Surface Area	6.0mm ²
	Contact Spacing (Center-to-Center)	2.0 mm
	Contact Span	7.5 mm
	Distal Contact to Tip Length	N/A
	Diameter	1.3 mm
	Overall Length	30 cm, 45 cm
	Outer Jacket Tubing (Insulation)	Polyurethane
	Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured from each connector to corresponding electrode contact)	

Lead Boot

The DBS Lead Boot protects the proximal end of the Lead prior to the Stimulator implant surgery. The setscrew, when engaged, secures the Lead in the Lead Boot.

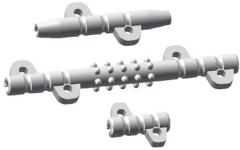
Table 3: DBS Lead Boot

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

Suture Sleeves

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

Table 4: DBS Suture Sleeves

	Part	Description
	Overall Length	1 cm, 2.3 cm, 4 cm
	Material	Silicone

Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your healthcare professional. If you need to contact Boston Scientific for any other reason, please call (833) DBS-INFO or (833) 327-4636.

Boston Scientific

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92104398-01 2018-07