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Vercise™ M8 Adapter

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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Drawings are for illustration purposes only.

Product Model Numbers

Model Numbers	Description
DB-9218-15	Vercise M8 Adapter, 15 cm
DB-9218-55	Vercise M8 Adapter, 55 cm

Additional Information

For indications for use, contraindications, warnings, precautions, adverse events, storage and handling, sterilization, labeling symbols, limited warranty, or other device-specific information not included in this manual, refer to the *Vercise Deep Brain Stimulation System Physician Manual* or the appropriate DFU for your DBS System as listed on your *DBS Reference Guide*.

Intended Use

The Vercise™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® lead extensions to the Boston Scientific DBS System Stimulator, as part of a deep brain stimulation procedure.

Lead Compatibility

The Boston Scientific M8 Adapter is compatible with the following Medtronic Leads:

- Model 3387 Lead
- Model 3389 Lead

The Boston Scientific Vercise M8 Adapter is compatible with the following Medtronic lead extensions:

- Model 3708640 Extension
- Model 3708660 Extension
- Model 3708695 Extension
- Model 3708540 Extension
- Model 3708560 Extension
- Model 3708595 Extension

Package Contents

Sterile

- (1) Vercise M8 Adapter
- (1) Torque Wrench

Non-sterile

- (1 set) Product identification stickers
- (1) Device registration form

Med A is sold separately.

The *Directions for Use* (DFU) is provided separately.

Cautions

- Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal. Do not reuse, reprocess, or resterilize.
- Do not use if the product is past the labeled expiration date.
- Do not use if labeling is incomplete or illegible.

- Do not bend, kink, or stretch the extension or Adapter; this may break its wires or connections. Broken wires or connections may create an open circuit, resulting in component failure, loss of stimulation, and potential surgical intervention.
- Do not handle the Vercise M8 Adapter with instruments that were not supplied with the Adapter. Other instruments may cause damage to the device, including broken wires or connections.
- The setscrew in the Vercise M8 Adapter must be retracted to insert the lead extension. There is no stop feature to prevent excessive retraction of the setscrew and disassembly of the Adapter. To avoid damage to the sealing grommet, do not retract the setscrew assembly more than is needed to insert the lead extension.
- Minimize the number of torque-wrench insertions into the Vercise M8 Adapter to prevent damage to the septum seal plug.

Directions for Use

1. Explant the Medtronic Stimulator, referring to the appropriate Medtronic product labeling for explant instructions.
2. Carefully open the Vercise M8 Adapter package and transfer the contents of the inner tray to the sterile field.
3. Ensure that the Medtronic lead extension is clean and not damaged.
4. Retract the setscrews in all Adapters: insert the torque wrench into the septum containing the setscrew and turn the torque wrench counter-clockwise (Figure 1).

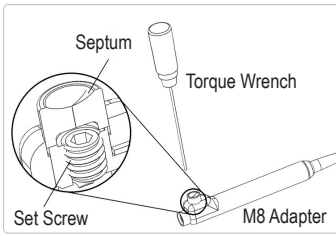


Figure 1: The setscrew assembly in the Vercise M8 Adapter

5. Ensure that stimulation is OFF before connecting to the Vercise M8 Adapter.
6. Ensure that the lead extension is clean before inserting into the Vercise M8 Adapter.
7. Insert the proximal end of the Medtronic lead extension into the Vercise M8 Adapter until the extension reaches the end stop of the Adapter; use one Vercise M8 Adapter for each Medtronic lead extension (Figure 2).

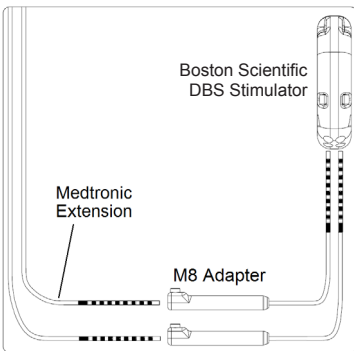


Figure 2: Connection of Vercise M8 Adapters to Medtronic lead extensions and Boston Scientific DBS Stimulator.

8. Ensure that the proximal end of the Vercise M8 Adapter is clean then insert the proximal end of the Adapter into the Boston Scientific DBS Stimulator. For further instructions on connecting to the stimulator, refer to the appropriate DFU for your Boston Scientific DBS System as listed on your Reference Guide.

9. Perform the permanent Stimulator implantation procedure. For instructions on implanting the stimulator, refer to the appropriate DFU for your Boston Scientific DBS System as listed on your Reference Guide.

NOTE: Do not place the distal segment of the Vercise M8 Adapter between its proximal end and the Boston Scientific DBS Stimulator. Placement of wires between these two devices could result in damage to the wire insulation resulting in loss of stimulation.

NOTE: Do not wrap or coil the excess extension wires or the distal Adapter segment around the perimeter or in front of the stimulator. Wrapping around the stimulator may cause wires to slip in front of the stimulator. Placing wires in front of the stimulator may cause kinking of the extension and Adapter wires, potential interference with telemetry and/or recharge operation, and damage during future stimulator replacement surgery.

10. Tighten the setscrew in the Vercise M8 Adapter until the Torque Wrench clicks, indicating the setscrew is fully secured
11. Apply a medical adhesive (e.g. Dow Corning Silastic® Medical Adhesive Silicone, Type-A Sterile, as available from Boston Scientific, part no. DB-4320) to coat and seal the top of the set screw port (Figure 3).

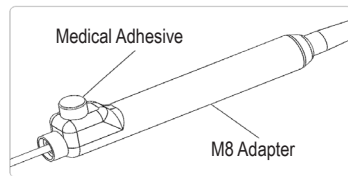


Figure 3: Medical adhesive covering the septum seal plug.

NOTE: Damage to the septum seal may lead to unintended stimulation at the implantation site if medical adhesive is not used as intended.

12. To program leads, refer to the contact-mapping diagram (Figure 4) and instructions provided in the programming manual provided for your Boston Scientific DBS System. The most distal contact, Contact 1, on the Medtronic DBS Lead maps to Contact 1 on the Boston Scientific programming software and so forth, as shown in Figure 4. Please note that Medtronic DBS Leads only have 4 contacts per lead while the Boston Scientific programming software interface displays 8 contacts per lead and therefore contacts 5-8 on the programming interface will display out of range impedance values indicating that there are no electrodes connected.



Figure 4: Contact mapping with the Vercise M8 Adapter

13. Complete the device registration form included in the Vercise M8 Adapter package. Use the product identification stickers, where necessary.

Specification and Technical Data

Part	Specification
Adapter Lengths	15, 55 cm
Adapter Diameter	1.3 mm
Number of Electrode Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N

WARNING: The Medtronic Leads have not been tested for electromagnetic compatibility or for safety in an MRI environment when used with Boston Scientific DBS Systems. Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication. MRI scanning can result in severe patient injury.

Technical Support

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

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92093578-01 2018-06