Boston Scientific
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IMAGEREADY™ MRI CHECKLIST FOR VERCISE™ DIRECTIONAL* DBS SYSTEMS

Refer to ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation (DBS) Systems on www.bostonscientific.com/manuals for labeling and safety conditions.

Patient Name: _____ Date: _____

Physician's Name: _____

Office Address: _____

Phone: _____

A. TYPE OF MR CONDITIONAL DBS SYSTEM
Lead-Only System (Leads, Lead Boots and/or Burr Hole Covers)
Full System** (Leads, Lead Extensions, Stimulator and/or Burr Hole Covers)

B. MR CONDITIONAL SYSTEM COMPONENTS	MODEL NUMBER		QUANTITY
VERCISE DBS SYSTEMS — LEADS			
Vercise Cartesia™ 8-Contact DBS Directional Lead	DB-2202-30, DB-2202-45		
Vercise 8-Contact DBS Lead	DB-2201-30-DC, DB-2201-45-DC		
VERCISE DBS SYSTEM — EXTENSIONS AND ADAPTERS			
55 cm 1x8 Contact Lead Extension	NM-3138-55		
2x8 Contact Lead Extension 55 cm	DB-3128-55		
2x8 Contact Lead Extension 95 cm	DB-3128-95		
Vercise M8 Adapter 15 cm	DB-9218-15		
Vercise M8 Adapter 55 cm	DB-9218-55		
MEDTRONIC DBS LEADS AND EXTENSIONS			
Medtronic 1.5mm spaced 4 contact standard lead	3387-28, 3387S-28, 3387-40, 3387S-40		
Medtronic 0.5mm spaced 4 contact standard lead	3389-28, 3389S-28, 3389-40, 3389S-40		
Medtronic Lead Extensions	37085-40, 37085-60, 37085-95, 37086-40, 37086-60, 37086-95		
VERCISE GENUS™ DBS SYSTEM — STIMULATORS			
Vercise Genus R32 Implantable Pulse Generator	DB-1232		
Vercise Genus P32 Implantable Pulse Generator	DB-1432		
Vercise Genus R16 Implantable Pulse Generator	DB-1216		
Vercise Genus P16 Implantable Pulse Generator	DB-1416		
Vercise Genus P8 Implantable Pulse Generator	DB-1408		
VERCISE GEVIA™ DBS SYSTEM — STIMULATOR			
Vercise Gevia Implantable Pulse Generator	DB-1200-S		

*A system that includes the Vercise™ PC, Vercise Gevia™, or the Vercise Genus™ IPG and Vercise Cartesia™ Directional Lead(s) forms the Vercise Directional System.
**MRI Conditional under specific conditions.

VERCISE™ DBS SYSTEM — FIXATION AND ACCESSORIES			
SureTek™ Burr Hole Cover	Provided in SureTek Burr Hole Cover Kit (DB-4600-C) and SureTek Burr Hole Cover Spares Kit (DB-4605-C)		
Lead Boot	Provided in the Vercise Physician Spares Kit DB-2500-C and with leads (see above)		
Silicone Suture Sleeves	Provided in the Vercise Physician Spares Kit DB-2500-C and with leads (see above)		
Port Plug	Provided in the Port Plug Spares Kit, SC-4401, IPG Kits, and Lead Extension Kits, DB-3128		

C. DBS IMPLANT CONFIGURATION AND SYSTEM INTEGRITY (Check all that apply for Lead-Only System or Full System)	
LEAD-ONLY SYSTEM	
Fully Implanted Lead-Only System	Externalized Lead-Only Sytem
MRI ELIGIBLE	MRI ELIGIBLE
Stimulator NOT implanted.	Stimulator NOT implanted.
Lead extensions NOT implanted.	Lead extensions NOT implanted.
Leads capped with lead boot.	Partially implanted lead(s) extending out of the patient are straight with no loops and stylet has been removed from externalized lead.
Lead(s) fully implanted under the scalp of the skull.	The external portion of the partially implanted lead(s) is NOT in contact with either the patient or any part of the scanner.
Patient has up to two leads implanted.	Patient has up to two leads implanted.
NO evidence of fractured leads.	NO evidence of fractured leads.
FULL SYSTEM**	
MRI ELIGIBLE	
The stimulator must be implanted: • For Genus under the skin near the clavicle (pectoral region) or in the abdomen • For Gevia under the skin near the clavicle (pectoral region)	Unused stimulator ports have a port plug inserted.
The stimulator must be implanted on the same side of the body as the implanted lead extension(s).	For a bilateral implant where two leads and lead extension(s) are connected to a single stimulator, both lead extensions are routed on the same side of the body as the stimulator.
Patient has up to two leads implanted.	No evidence of fractured leads or compromised stimulator-lead system integrity. as of: _____/_____/_____
Extension(s) directly connected to simulator or Vercise M8 adapter.	Single stimulator is implanted.

Note: All of the conditions above must be met for the paitent to be MRI eligible.

For Vercise Genus™ Systems: Any system with a single lead and unused lead extension port(s) have a port plug inserted into the unused lead extension port(s).

For Vercise Gevia™ Systems: The system does NOT have any unused lead extension ports (all lead extensions present have a lead inserted).

For Vercise Genus DBS Mixed System with M8 Adapter: The system does Not have any unsused lead extension ports (all lead extensions present have a lead inserted), and does NOT include both a 95cm Medtronic Lead Extension (37085-95 or 37086-95) and a 55cm M8 Adapter (DB-9218-55).

Note: All of the conditions above must be met for the paitent to be MRI eligible.

D. INSTRUCTIONS FOR THE PATIENT OR MRI CENTER PRIOR TO THE MRI SCAN (Full System only)

1. Rechargeable stimulators must be fully charged (stimulator battery level on the remote control must be at three bars) before the MRI scan. Patient must bring their charger to the MRI center in case additional charging is necessary.
2. MRI mode must be enabled on the stimulator using the patient remote control before performing an MRI scan. Patient must bring their remote control to the MRI center.

**MRI Conditional under specific conditions.

This information is not meant as a replacement for the ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems.

The Vercise Genus™ DBS System, Vercise Genus Mixed System with M8 Adapter, Vercise Gevia™ DBS System, and Vercise™ DBS Lead-only system (before Stimulator is implanted) provide safe access to full-body MRI scans when used with specific components and the patient is exposed to the MRI environment under specific conditions defined in the supplemental manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems.

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. The Boston Scientific Vercise 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, Model 3708560, Model 3708595 Extension

Indication for Use: The Boston Scientific Vercise™ PC, Vercise Gevia™, Vercise Genus™ Deep Brain Stimulation Systems are indicated for use in:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

The Boston Scientific Vercise Deep Brain Stimulation System is indicated for use in:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.

Contraindications, warnings, precautions, side effects: The Deep Brain Stimulation Systems or any of its components, is contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients implanted with the Vercise DBS System has not been established, patients who are unable to operate the system, patients who are poor surgical candidates or who experience unsuccessful test stimulation. Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with Vercise Gevia or Vercise Genus or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy. Monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control and manage appropriately. Refer to the Instructions for Use provided with the Vercise DBS System or BostonScientific.com for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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