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**	**MRI ELIGIBLE**	**NOT MRI ELIGIBLE**
VERCISE GENUS™ DBS SYSTEMS — LEADS			
Vercise Cartesia™ 30 cm 8-Contact DBS Directional Lead	DB-2202-30	☐	☐
Vercise Cartesia 45 cm 8-Contact DBS Directional Lead	DB-2202-45	☐	☐
Vercise 30 cm 8-Contact DBS Lead	DB-2201-30-DC	☐	☐
Vercise 45 cm 8-Contact DBS Lead	DB-2201-45-DC	☐	☐
VERCISE GENUS DBS SYSTEM — EXTENSIONS			
55 cm 1x8 Contact Lead Extension	NM-3138-55	☐	☐
VERCISE GENUS DBS SYSTEM — STIMULATORS			
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 GENUS 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	☐	☐

*A System that includes the Vercise™ PC, Vercise Gevia™, or Vercise Genus™ IPG and Vercise Cartesia™ Directional Lead(s) forms the Vercise Directional System.

**MRI Conditional under specific conditions.

VERCISE GEVIA™ DBS SYSTEM — LEADS			
Vercise Cartesia™ 30 cm 8-Contact DBS Directional Lead	DB-2202-30	☐	☐
Vercise Cartesia 45 cm 8-Contact DBS Directional Lead	DB-2202-45	☐	☐
30 cm 8-Contact DBS Lead	DB-2201-30-DC	☐	☐
45 cm 8-Contact DBS Lead	DB-2201-45-DC	☐	☐
VERCISE GEVIA DBS SYSTEM — EXTENSION			
55 cm 1x8 Contact Lead Extension	NM-3138-55	☐	☐
VERCISE GEVIA DBS SYSTEM — STIMULATOR			
Vercise Gevia Implantable Pulse Generator	DB-1200	☐	☐
VERCISE GEVIA 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 Kit, DB-1200	☐	☐

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.

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

FULL SYSTEM**	
MRI ELIGIBLE	
☐ The stimulator must be implanted under the skin in a location 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 extensions 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: _____/_____/_____
☐ Extensions directly connected to stimulator. No adapters present.	☐ Single stimulator is implanted.
☐ For 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 Gevia Systems: The system does NOT have any unused lead extension ports (all lead extensions present have a lead inserted).	

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 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.

Indications for Use: The Boston Scientific 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.

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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NM-566609-AD