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IMAGEREADY™ MRI CHECKLIST FOR VERCISE™ DIRECTIONAL* DBS SYSTEMS

This form provides information about the patient's implanted DBS system MRI scan eligibility. It may be provided to the radiologist to support the confirmation of the patient's MRI scan eligibility.

Refer to ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation 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
LEADS: STANDARD LEADS – DB-2201			
30 cm Lead	DB-2201-30-DC	☐	
45 cm Lead	DB-2201-45-DC	☐	
LEADS: DIRECTIONAL LEADS – DB-2202			
Vercise™ Cartesia™ 30 cm 8 contact DBS Directional Lead	DB-2202-30	☐	
Vercise Cartesia 45 cm 8 contact DBS Directional Lead	DB-2202-45	☐	
EXTENSION			
55 cm 8 Contact Extension	NM-3138-55	☐	
STIMULATOR			
Vercise Gevia™ 16 Contact Implantable Pulse Generator	DB-1200	☐	

*A System that includes the Vercise PC IPG or the Vercise Gevia IPG and Vercise Cartesia Directional Lead(s) form the Vercise Directional System.

**MRI Conditional under specific conditions.

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)	☐	
OTHER (LIST OTHER IMPLANTED COMPONENTS)			
		☐	☐
		☐	☐

Note: If the patient has medical implants from another manufacturer, also consult the instructions from the manufacturer before making a decision about MRI eligibility.

C. DBS IMPLANT CONFIGURATION AND SYSTEM INTEGRITY (Check all that apply for Lead-Only System or Full System)

LEAD-ONLY SYSTEM

MRI ELIGIBLE	NOT MRI ELIGIBLE
☐ Stimulator NOT impanted	☐ Stimulator impanted
☐ Lead extensions NOT impanted	☐ Lead extensions impanted
☐ Leads capped with lead boot	☐ Leads NOT capped with lead boot
☐ Leads fully implanted under the scalp of the skull	☐ Leads NOT fully implanted under the scalp of the skull
☐ NO evidence of fractured leads	☐ Evidence of fractured leads

FULL-SYSTEM**

MRI ELIGIBLE	NOT MRI ELIGIBLE
☐ Stimulator must be MRI compatible and be implanted under the skin in a location near the clavicle (pectoral region) on the same side of the body as the implanted lead-extension	☐ Stimulator implanted in locations other than under the skin in a location near the clavicle (pectoral region) on the same side of the body as the implanted lead-extension
☐ Extensions directly connected to Stimulator No adapters present	☐ Extensions not directly connected to Stimulator Adapters are present
☐ No evidence of fractured leads or compromised Stimulator-lead system integrity	☐ Evidence of fractured leads or compromised Stimulator-lead system integrity

Note: The patient is NOT MRI Eligible if any of the "Not MRI Eligible" boxes are checked.

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

1. Stimulator 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.

MR Conditional

The 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.

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 the Vercise Gevia 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. 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. All trademarks are the property of their respective owners.

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