

IMAGEREADY™ MRI CHECKLIST FOR VERCISE™ DIRECTIONAL* SYSTEMS

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 MRI-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 8 Contact DBS Lead	DB-2201-30-DC	<input type="checkbox"/>	
45 cm 8 Contact DBS Lead	DB-2201-45-DC	<input type="checkbox"/>	
LEADS: DIRECTIONAL LEADS – DB-2202			
Vercise Cartesia™ 30 cm 8 Contact DBS Directional Lead	DB-2202-30	<input type="checkbox"/>	
Vercise Cartesia 45 cm 8 Contact DBS Directional Lead	DB-2202-45	<input type="checkbox"/>	
EXTENSION			
55 cm 1x8 contact Lead Extension	NM-3138-55	<input type="checkbox"/>	
95 cm 1x8 contact Lead Extension	NM-3138-95	<input type="checkbox"/>	<input type="checkbox"/> Not MRI eligible when used with a Vercise Gevia IPG
55 cm 2x8 contact "Dual" Lead Extension	DB-3128-55	<input type="checkbox"/>	
95 cm 2x8 contact "Dual" Lead Extension	DB-3128-95	<input type="checkbox"/>	<input type="checkbox"/> Not MRI eligible when used with a Vercise Gevia IPG
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)	<input type="checkbox"/>	
Lead Boot	Provided in the Vercise Physician Spares Kit DB-2500-C and with Leads (see above)	<input type="checkbox"/>	
Silicone Suture Sleeves	Provided in the Vercise Physician Spares Kit DB-2500-C and with Leads (see above)	<input type="checkbox"/>	

*A system that includes the Vercise Genus P16, Vercise™ Genus R16 or Vercise™ Gevia IPGs and Vercise Cartesia Directional Lead(s) form the Vercise Directional System.
**MRI Conditional under specific conditions.

STIMULATOR			
Vercise Gevia™ Implantable Pulse Generator	DB-1200	<input type="checkbox"/>	
Vercise Genus™ P16 Implantable Pulse Generator	DB-1416	<input type="checkbox"/>	
Vercise Genus R16 Implantable Pulse Generator	DB-1216	<input type="checkbox"/>	

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	
Fully Implanted Lead-Only System	Externalized Lead-Only System
MRI ELIGIBLE	MRI ELIGIBLE
<input type="checkbox"/> Stimulator NOT implanted.	<input type="checkbox"/> Stimulator NOT implanted.
<input type="checkbox"/> Lead extensions NOT implanted.	<input type="checkbox"/> Lead extensions NOT implanted.
<input type="checkbox"/> Leads capped with lead boot.	<input type="checkbox"/> Partially implanted Lead(s) extending out of the patient are straight with no loops.
<input type="checkbox"/> Lead(s) fully implanted under the scalp on the skull.	<input type="checkbox"/> The external portion of the partially implanted Lead(s) is NOT in contact with either the patient or any part of the scanner.
<input type="checkbox"/> Patient has up to two Leads implanted.	<input type="checkbox"/> Patient has up to two Leads implanted.
<input type="checkbox"/> NO evidence of fractured Leads.	<input type="checkbox"/> 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	MRI ELIGIBLE
<input type="checkbox"/> The Stimulator must be implanted under the skin in a location near the clavicle (pectoral region) or in the abdomen.**	<input type="checkbox"/> Unused Stimulator Ports have a Port Plug inserted.
<input type="checkbox"/> The Stimulator must be implanted on the same side of the body as the implanted Lead(s) and Lead Extension(s).	<input type="checkbox"/> Unused Lead Extension Ports when using the 2x8 Contact Lead Extensions, DB-3128, have a Port Plug inserted.
<input type="checkbox"/> Patient has up to two Leads implanted.	<input type="checkbox"/> If present, the 8 Contact Lead Extension, NM-3138-55, has a Lead inserted (does NOT have a Port Plug inserted).
<input type="checkbox"/> 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.	<input type="checkbox"/> No evidence of fractured Leads or compromised Stimulator-Lead system integrity.
<input type="checkbox"/> Extensions directly connected to Stimulator. No adapters present.	<input type="checkbox"/> Single Stimulator is implanted.

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

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.

**The Vercise Gevia DBS system is not MRI eligible when using the 95 cm extension.



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.

Product available in the European Economic Area (EEA) only.

Please check availability with your local sales representative or customer service.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

Material not intended for use in France.

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