Boston Scientific
Advancing science for life™

VERCISE GENUS™
Deep Brain Stimulation System

VERCISE DIRECTIONAL SYSTEMS* IMAGEREADY

MRI SAFETY INFORMATION

- Static magnetic field of 1.5T
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m)
- Maximum gradient slew rate per axis of less than or equal to 200 T/m/s)
  Cumulative active scan time (with RF On) should be limited to 30 minutes or less per imaging session.
- If 30 minutes of active scan time is reached, allow 60 minutes of non-active time before proceeding
- If B1 +rms is not available, the maximum MR system reported head or whole body averaged specific absorbtion rate (SAR) should be utilized

Note: Procedures presented below are not meant as replacement for the system guidelines. Please refer to the ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems for more information.

RF EXPOSURE LIMITS

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR (IF B1+RMS IS NOT AVAILABLE)
Vercise Genus™ System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Full System	Head	Head Coil	≤ 2.0µT	≤ 0.2W/kg
		At or Above C2	Body Coil	≤ 1.6µT	≤ 0.2W/kg
		C3 through C10		≤ 2.0µT	≤ 0.2W/kg
		T11 through Femur		≤ 3.2µT	≤ 1.5W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremilty Coil	Normal Mode	Normal Mode

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

RF EXPOSURE LIMITS

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR (IF B1+RMS IS NOT AVAILABLE)
All Leads	Fully Implanted or Externalized Leads-Only	Head	Head or Body Coil	≤ 2.0μT	≤ 0.1W/kg
Vercise Gevia™ System (Stimulator Model Number: DB-1200-S)	Full System with DB-2201 or DB-2202 Lead(s)	Head	Head Coil	≤ 2.0μT	≤ 0.1W/kg
	Full System with DB-2201 Lead(s)	Above T5	Body Coil	≤ 1.5μT	
		At or Below T5		≤ 2.0μT	
	Full System with DB-2202 Lead(s)	Above T12		≤ 1.2μT	
		At or Below T12		≤ 2.0μT	

ADDITIONAL INFORMATION

- MRI Mode must be enabled on the device prior to performing a scan.
- Rechargeable Stimulators must be fully charged prior to the MRI scan.
- Patients must be positioned in supine or prone position during the scan.
- If possible, patient should be in a psychological condition and mental state to be able to provide immediate feedback of any problem during the examination.

MR Conditional

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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