Boston Scientific
Advancing science for life™

IMAGEREADY™ VERCISE™ DEEP BRAIN STIMULATION (DBS) SYSTEMS

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

Note: Procedures presented below are for Informational Purposes Only and not meant to replace the system guidelines. Please refer to the ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems for more information. The Instructions for Use must be reviewed prior to use.

RF EXPOSURE LIMITS

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR
Vercise Genus™ System (For a list of eligible components, see the ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems)	Full System or Mixed M8 System	Head	Head Coil	≤ 2.0μT	≤ 0.2W/kg
		At or Above C2	Body Coil	≤ 1.6μT	≤ 0.2W/kg
		C3 through T10		≤ 2.0μT	See table A
		T11 through Femur		≤ 3.2μT	≤ 1.5W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremity Coil	Normal Mode	Normal Mode

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR
Vercise Genus™ System (For a list of eligible components, see the ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems)	Mixed S8 System	Head	Head Coil	≤ 2.0μT	≤ 0.2W/kg
		At or Above C2	Body Coil	≤ 1.4μT	≤ 0.1W/kg
		C3 through T10		≤ 1.6μT	See table B
		T11 through Femur		≤ 3.2μT	≤ 0.2W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremity Coil	Normal Mode	Normal Mode

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR
All Boston Scientific 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	

RF EXPOSURE LIMITS

TABLE A: MAXIMUM SAR FOR C3 - T10
VERCISE GENUS™ DBS FULL SYSTEM OR VERCISE GENUS DBS MIXED M8 SYSTEM SCAN USING A BODY TRANSMIT COIL

Landmark Span	Large Adult[1]	Adult
Upper Chest	0.2W/kg	0.2W/kg
Heart	0.3W/kg	0.4W/kg
Lower Chest	0.5W/kg	0.7W/kg

TABLE B: MAXIMUM SAR FOR C3 - T10
VERCISE GENUS DBS MIXED S8 SYSTEM SCAN USING A BODY TRANSMIT COIL

Landmark Span	Large Adult[1]	Adult
Upper Chest	0.1W/kg	0.1W/kg
Heart	0.2W/kg	0.2W/kg
Lower Chest	0.5W/kg	0.4W/kg

1. A large adult is defined as body mass greater than 119 kg (262 lb) or body mass index (BMI) greater than 36 kg/m2 (lb/in2 x 703).

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 Genus Mixed System with M8 Adapter, Vercise Genus Mixed System with Adapter S8, 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.

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.

-Bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is 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 Boston Scientific Deep Brain Stimulation (DBS) Systems or any of its components, are 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 Boston Scientific 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 DBS System without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with Vercise Gevia or Vercise Genus or Vercise Genus Mixed System with M8 Adapter 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 DBS 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 Boston Scientific DBS Systems 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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