Boston Scientific
Advancing science for life™

VERCISE GENUS™
Deep Brain Stimulation System

VERCISE™ M8 Adapter

Connect to Meaningful Innovation

Why only replace when you can upgrade?

Designed to connect specific Medtronic lead extensions to the Boston Scientific DBS System

Precise Control:

- The VERCISE DBS system, powered by Multiple Independent Current Control (MICC) technology, allows for refinements in the size and shape of the stimulation field to customise therapy for individual patients.
- Both adaptors, B26 and M8, have been used since 2016. All patients whose hybrid system meets the new MR Conditional labelling with the VERCISE M8 Adaptor can now benefit from MRI access.

Patient Focus:

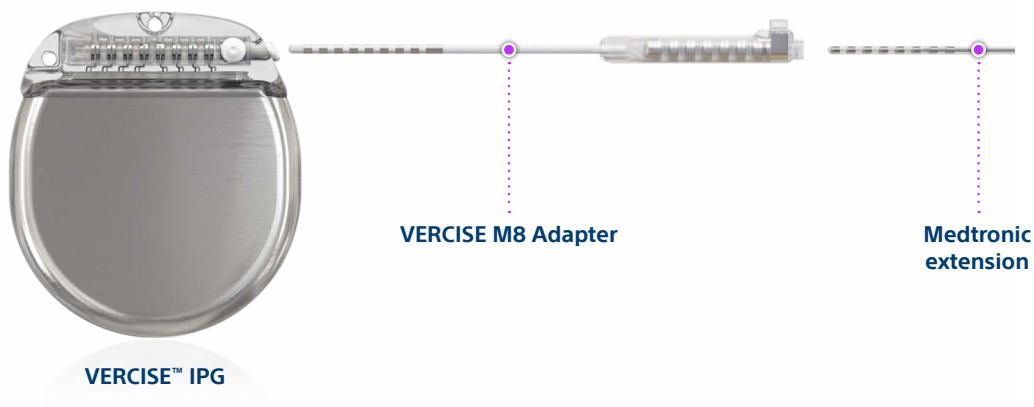
- With the VERCISE Genus™ DBS system patients can benefit from small, contoured rechargeable and non-rechargeable options.
- At least a 25 year* battery life with the VERCISE Genus rechargeable IPGs reducing the need for future replacements.
- Updating to a VERCISE Genus IPG with the VERCISE M8 Adaptor is now MR Conditional, maintaining your patient's access to this important diagnostic imaging tool should they need it in the future.

*The battery life is dependent on the stimulation settings and conditions.

VERCISE M8 Adapter Product Specifications

FEATURE	SPECIFICATION
Adapter Lengths	15cm, 55cm
Adapter Diameter	1.3mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N

For further information please consult the ImageReady™ guidelines for the Boston Scientific Deep Brain Stimulation systems.



VERCISE™ M8 ADAPTER IMAGE-READY* UPGRADE-READY

VERCISE Genus™ DBS Mixed System with M8 Adapter

MR Scanning conditions for Mixed-System

SYSTEM COMPONENTS	SYSTEM TYPE	ISOCENTER	TRANSMIT COIL TYPE	B1+RMS	SAR (IF B1+RMS IS NOT AVAILABLE)
VERCISE Genus DBS System (Stimulator Model Numbers: DB-1408, DB-1416, DB-1432, DB-1216, and DB-1232)	Full System or Mixed System with M8 Adapter	Head	Head Coil	< 2.0 µT	< 0.2 W/kg
		At or Above C2	Body Coil	< 1.6 µT	< 0.2 W/kg
		C3 through T10		< 2.0 µT	< 0.2 W/kg
		T11 through Femur		< 3.2 µT	< 1.7 W/kg
		Lower Extremities (knee and below)		Normal Mode	Normal Mode
		Lower Extremities (knee and below)	Lower Extremity Coil	Normal Mode	Normal Mode

Scan Eligible Components

Medtronic Lead(s)	• Model 3387-xx Lead (xx: 28 & 40) • Model 3387S-xx Lead (xx: 28 & 40) • Model 3389-xx Lead (xx: 28 & 40) • Model 3389S-xx Lead (xx: 28 & 40)
Medtronic Extension(s)	• Model 37085-xx Extension (xx: 40, 60 & 95) • Model 37086-xx Extension (xx: 40, 60 & 95)
Adapter(s)	• DB-9218-15, VERCISE Genus™ M8 Adapter 15cm • DB-9218-15, VERCISE Genus™ M8 Adapter 55cm
Stimulator	• DB-1416, VERCISE Genus™ P16 Implantable Pulse Generator • DB-1216, VERCISE Genus™ R16 Implantable Pulse Generator
Accessories	• Boston Scientific Port Plugs – Provided in the Port Plug Spares Kit, SC-4401, and IPG Kits, DB-1408, DB-1416, DB-1432, DB-1216, DB-1232 • Medtronic Stimloc Burr Hole Cover – 924256

VERCISE™ M8 Adapter Ordering Information

MODEL NUMBER	UPN NUMBER	DESCRIPTION
VERCISE M8 Adapter (15cm)	M365DB9218150	DB-9218-15
VERCISE M8 Adapter (55cm)	M365DB9218550	DB-9218-55
Medical Adhesive	M365DB43200	DB-4320
VERCISE Genus™ R16 IPG Kit	M365DB12160	DB-1216
VERCISE Genus P16 IPG Kit	M365DB14160	DB-1416

The VERCISE™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® lead extensions to the Boston Scientific DBS System Stimulator, as part of a deep brain stimulation procedure. The Boston Scientific VERCISE M8 Adapter is compatible with the following Medtronic Leads: Model 3387 Lead, Model 3389 Lead. The Boston Scientific VERCISE M8 Adapter is compatible with the following Medtronic lead extensions Model 3708640 Extension, Model 3708660 Extension, Model 3708695 Extension, Model 3708540, Model 3708560, Model 3708595 Extension.

The VERCISE Genus™ DBS System, VERCISE Genus Mixed System with M8 Adapter, 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.

MRI Safety Information

- Static magnetic field of 1.5 T
- 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 absorption rate (SAR) should be utilised

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 labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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