



**Boston
Scientific**

Advancing science for life™

**Information
for Patients
Vercise™ PC and
Vercise Gevia™
Systems**

92104394-04

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Rx ONLY CAUTION: Federal law restricts this device to sale,
distribution and use by or on the order of a physician.



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Trademarks

All trademarks are the property of their respective holders.

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Additional Information

Refer to your *Remote Control Handbook* and *Vercise DBS Charging Handbook* for additional instructions and information about your Vercise Gevia DBS System. Refer to the *Labeling Symbols* document for an explanation of labeling symbols for your Vercise™ PC or Vercise Gevia™ System.

Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your healthcare professional. If you need to contact Boston Scientific for any other reason, please call (833) DBS-INFO or (833) 327-4636.

Patient Identification Card

Ensure you have received your Temporary Patient Identification Card. If not, please call your healthcare professional. Keep your Temporary Patient Identification Card with you until you receive your permanent card.

USER ASSISTANCE INFORMATION

Important Numbers

Physicians

Neurosurgeon _____

Neurologist _____

Caregiver _____

Patients, Family Members, and Caregivers

Please be aware of the following:

- We advise you to read this entire patient manual so that you understand its contents. It is unsafe to start using the device before reading the whole manual. If you have any questions, or need clarification of anything contained in this manual, please contact your physician.
- **Always inform any medical staff that you have been implanted with a brain stimulation device.** If medical personnel have any questions, they should contact Boston Scientific Technical Support at the number provided for your locality.
- If you have any questions or problems, please use the information on the previous page to contact your physician. In most cases, please contact your neurologist, as they are most likely to be able to resolve the issue. If any medical personnel have questions or concerns, please have them contact Boston Scientific Technical Support at the number provided for your locality. If there is an emergency, call 9-1-1 or local emergency services.

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Glossary

Adhesive Patch. Non-reactive skin patch designed to temporarily attach the Charger to the skin over the Stimulator site.

Adverse Event. Undesirable effect.

Amplitude. The measure of strength of delivered stimulation.

Base Station. A holder/power supply that supports the Charger and keeps it in a ready state for recharging the rechargeable Stimulator.

Battery. The power source for your Stimulator. The battery can be either rechargeable or non-rechargeable depending on your type of Stimulator.

Cardiac Pacemaker. A small implantable device used to control the rhythm of the heart.

Charger. A portable device used to recharge the rechargeable battery of the implanted Stimulator.

Charging Collar. A garment used to hold the Charger over the rechargeable Stimulator for proper charging.

Charging Spacer. A piece of material placed behind the Charger in the pocket of the Charging Collar, if directed by your physician.

Charging System. The Charging System consists of a Base Station, Charger, Power Supply, Charging Spacer, Counterweight, Charging Collar and Adhesive Patches. The Charging System is used for recharging the rechargeable Stimulator.

Computerized Axial Tomography (CT or CAT) Scans.
A procedure that creates a 3-D image of your brain or other parts of your body.

Contacts. Metal electrodes on the DBS Lead that deliver electrical stimulation pulses to the brain.

Contraindication. A condition under which the device should not be used because the risks outweigh any possible benefit.

Control Buttons. Buttons located on the Remote Control used for adjusting stimulation settings.

Counterweight. A device placed in the Charging Collar on the opposite side of the Charger to balance the garment.

DBS Lead. An insulated wire that allows electrical stimulation pulses to be delivered from the Stimulator to the brain.

Deep Brain Stimulation (DBS). A method of applying electrical pulses to the brain to deliver therapy for various disorders.

Diathermy. A therapeutic procedure used to heat body tissue by high-frequency electromagnetic currents or ultrasound.

Electrical Stimulation. Electrical pulses created by the Stimulator.

Elective Replacement Mode. The state of your nonrechargeable Stimulator when it is nearing depletion.

Electromagnetic Disturbance. Any electromagnetic phenomenon which can degrade the performance of a device or system.

Electromagnetic Interference. Degradation of the performance of a transmission channel or system caused by an electromagnetic disturbance.

Hibernation Mode. A state your rechargeable Stimulator reaches when the battery level is too low to apply stimulation.

Idle Mode. A time-out period when the Remote Control is not being used. Also known as Sleep Mode.

Implantable Cardioverter Defibrillator (ICD). A small implantable device used to treat sudden cardiac arrest and to restore a normal heartbeat.

Incision. Small surgical cut or opening in the skin.

Indicator Light. A signal light on the Charger used to show the status of the Charger.

Level. Term used on the Remote Control screen to identify the amplitude or strength of stimulation.

Magnetic Resonance Imaging (MRI). A technique that uses magnetic fields and radio waves linked to a computer to create pictures of areas inside the body.

Non-Rechargeable Stimulator. A Stimulator with a battery that cannot be recharged. When the battery is depleted, it must be replaced for stimulation to continue.

Patient Identification Card. A wallet size card that lists the patient and physician names, and the Stimulator model and serial number.

Precaution. Generally, situations that you should be aware of in order to avoid potentially undesirable stimulation effects and/or damage to your DBS System.

Program. A set of parameters that define the pattern of your stimulation.

Rechargeable Stimulator. A Stimulator with a battery that can be recharged. When the battery is depleted, it must be recharged for stimulation to continue.

Remote Control. A battery-powered hand-held programmer used to adjust stimulation.

Stimulation. Low level electrical pulses applied to the brain.

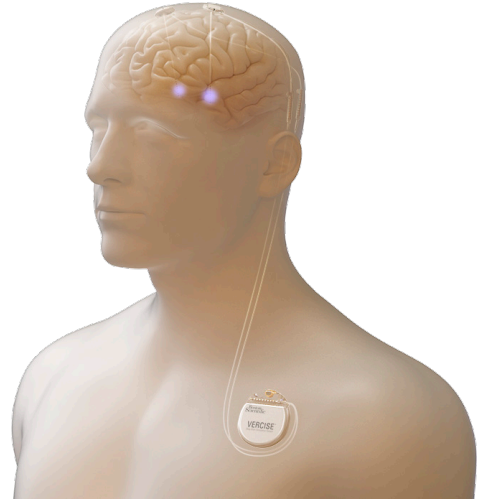
Stimulator. A device used to send electrical pulses to the brain. (Also referred to as the “Battery” or “Implantable Pulse Generator”).

Ultrasound. The use of high frequency sound waves to visualize structures inside your body.

Warning. Potential hazards that you must be aware of to avoid serious situations that may cause injury or death.

Introduction

The Boston Scientific DBS System is used for deep brain stimulation (DBS), a reversible therapy where structures in the brain are stimulated with small electrical pulses. The Vercise Gevia DBS System includes a rechargeable Stimulator. The Vercise PC DBS System includes a non-rechargeable Stimulator.



Descriptive Information

Intended Use / Indications for Use

The DBS System is indicated for use in bilateral stimulation of the subthalamic nucleus (STN) or globus pallidus internus (GPi) 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.

Description of the System

The DBS System includes both implantable and external components. The implanted portion of your DBS System has three main components:

- **DBS Leads:** the DBS Leads are thin, insulated wires that can carry electrical signals to any of eight contacts implanted within the brain and deliver stimulation to the brain tissue. The rest of the DBS Leads lie underneath the scalp and connect to the DBS Extension connector, typically behind the ear.
- **DBS Extensions** are thin, insulated wires that connect the DBS Leads to the Stimulator. The DBS Lead is inserted into one end of the DBS Extension. The connection between the DBS Lead and DBS Extension will typically be placed behind your ear. The other end of the DBS Extension lies beneath the skin and is inserted into the Stimulator. The DBS Extension transfers the electrical stimulation from the Stimulator to the DBS Lead.

- The **Stimulator** sends small electrical pulses to the contacts at the end of the DBS Lead, producing stimulation in the brain. The Stimulator is commonly placed underneath the skin in the chest area, below the clavicle. The parameters of the Stimulator will be adjusted by your health care professional after your implantation surgery. The Vercise Gevia DBS System includes a rechargeable Stimulator. The Vercise PC DBS System includes a non-rechargeable Stimulator.

There are also two external parts to your Vercise Gevia DBS System:

- The **Remote Control** is a hand-held programmer used to control the Stimulator.
- The **Charging System** is used to periodically recharge the Stimulator.

There is also one external part to your Vercise PC DBS System:

- The **Remote Control** is a hand-held programmer used to control the Stimulator.

To make the most of your DBS System, it is important to learn:

- How to live safely with the Vercise PC or Vercise Gevia DBS System.
- How to use the Remote Control.
- How to use the Charging System to recharge the Stimulator (for Vercise Gevia DBS System only).

Note: The DBS System was not made with natural latex.

Stimulator Battery Information

For information regarding how to check the status of your Stimulator battery and Battery Messages please refer to your Remote Control Handbook.

Vercise Gevia Stimulator (rechargeable)

The Vercise Gevia Stimulator is rechargeable. You should expect a daily recharging time of 15 to 30 minutes or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks, but your recharge routine may vary depending on your stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharge routine that fits your schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

Note: Do not worry that variations in your charging routine will affect or diminish the battery life of the Stimulator.

Developing a recharge routine involves finding the right balance between four factors:

- How much power is required to experience effective therapy.
- How often you want to recharge.
- How long you want to recharge.
- How you would like to manage your personal schedule.

The Vercise Gevia DBS System's programming software gives your physician a conservative recommendation for how often to charge. This estimate assumes stimulation is on 24 hours per day, 7 days a week at the default stimulation level. While you may want to follow these recommendations, you and your physician can also develop an appropriate charge routine that best fits your schedule.

Keep in mind, if you do not charge your Stimulator before it enters Hibernation Mode, stimulation will stop until you charge the Stimulator again. Developing a charging routine you are comfortable with will help prevent you from losing stimulation due to a low battery.

The rechargeable Stimulator battery should provide at least five years of service. In many cases, the Stimulator battery should provide at least 15 years of service. Battery life is dependent on the stimulation settings and conditions.

After years of service, the Stimulator may require shorter intervals between charges. The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.

Vercise PC Stimulator (non-rechargeable)

The Vercise PC Stimulator has a non-rechargeable battery. The longevity of the Stimulator battery depends on the following factors:


- Programmed parameters.
- System impedance.
- Hours per day of stimulation.
- Changes to stimulation made by the patient.

For additional information on estimating the longevity of the non-rechargeable battery consult with your physician.

Safety Information

When the Device Should Not be Used (Contraindications)

The DBS System should not be used in cases where patients have the following conditions or will be exposed to the following procedures:

- **Diathermy.** You should not have any form of diathermy either as treatment for a medical condition or as part of a surgical procedure. The energy generated by diathermy can be transferred to the DBS System, causing tissue damage in the brain, which can result in severe injury or death. The use of shortwave, microwave, and/or therapeutic ultrasound diathermy with the DBS System implanted may result in severe injury or death.
- **Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS).** The safety of these therapies in patients implanted with the DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the DBS System, causing tissue damage that may result in severe injury or death.
- **Magnetic Resonance Imaging (MRI).**  Patients implanted with the Vercise PC DBS System should not have an MRI. Patient exposure to MRI can cause (1) dislodgement of implanted components, (2) heating of the contacts or other system components, causing permanent tissue damage, including damage to brain tissue, (3) damage to the device electronics, (4) changes in current flow, causing unpredictable levels of stimulation, (5) distortion of the MRI image, and/ or (6) personal injury or death.

- **Patient Incapability.** If you are unable to properly operate the Remote Control and/or Charging System, then you should not be implanted with the DBS System.
- **Poor Surgical Candidates.** The DBS System is not recommended for patients who are poor surgical candidates. Please consult with your doctor to determine your surgical risk.
- **Unsuccessful Test Stimulation.** The Vercise DBS System should not be used in patients who experience unsuccessful test stimulation.

Warnings

Unauthorized Modification

Unauthorized modification to the medical devices is prohibited. System integrity could be compromised and harm or injury to the patient could occur if the medical devices are subjected to unauthorized modification.

Intracranial Hemorrhage

Placement of the DBS Leads in the brain may increase the risk of intracranial hemorrhages (i.e., bleeding in the brain). If you are more prone to hemorrhage, have trouble forming blood clots (i.e., coagulopathy), or take medication to make your blood thinner, such as aspirin or prescribed anticoagulants, please notify your physician as these may increase your risk of intracranial hemorrhage.

High Stimulation Levels

High levels of stimulation may damage brain tissue. Your physician will set the maximum and minimum stimulation levels allowed by the Remote Control to ensure that stimulation levels remain safe.

Magnetic Resonance Imaging

For patients implanted with a Vercise Gevia DBS System Only: As a patient implanted with the Vercise Gevia DBS System, you will be able to have an MRI examination when specific conditions are met. These conditions are specified in the supplemental physician manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems available on the website www.bostonscientific.com/manuals.

It is important that your Physician read this information in its entirety and determine all conditions are met before conducting and recommending an MRI examination.

External Devices: Boston Scientific external components (i.e. Charger and Remote Control and accessories) are MR Unsafe. They must not be taken into any MR environment such as the MRI scanner room.

Electromagnetic Interference

Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication.

You should avoid or exercise care around:

- Theft detectors, tag deactivators and RFID devices, such as those used at department stores, libraries, and other public establishments. If you must proceed through the detector, you should proceed with caution, ensuring to move through the center of the detector as quickly as possible.
- Security screeners, such as those used in Airport Security or at entrances to government buildings, including hand-held scanners. It is recommended that you request assistance to bypass the screener. If you must proceed through the security screener, proceed with caution, ensuring to move quickly through the security screener and staying as far from the screener as allowable.
- Power lines or power generators.
- Electric steel furnaces and arc welders.
- Large magnetized stereo speakers.

- Strong magnets.
- Automobiles or other motorized vehicles using a LoJack system or other anti-theft system that can broadcast a radio frequency (RF) signal. The high energy fields produced by these systems may interfere with the operation of the Remote Control and its ability to control stimulation.
- Other sources of electromagnetic disturbance, such as RF transmitters at television or radio broadcast stations, Amateur Radio or Citizens Band radio transceivers, or Family Radio Service band transceivers.

Note: When in close proximity, equipment that generates strong electromagnetic fields might cause unintended stimulation or interfere with wireless communication even if they comply with International Special Committee on Radio Interference (CISPR) requirements.

Heat Due to Charging (Vercise Gevia DBS System only)

The Charger may become warm while charging the Stimulator. The Charger should be handled with care. Failure to use either the Charging Collar or an Adhesive Patch while charging, as directed, may result in a burn. You should not charge while sleeping. This may result in a burn. If you experience pain or discomfort, stop charging and contact your physician.

Suicide

New onset or worsening depression which may be temporary or permanent is a risk that has been reported with DBS therapy. Suicidal thoughts, suicide attempts, and suicide are events that have also been reported. Patients and caregivers should consider the following:

- Before the procedure, be sure you talk to your treating physician(s) if you have a history of depression, suicidal thoughts, or have attempted suicide. Be sure you understand the possible risks of new onset or worsening depression (including suicidal thoughts) as well as the potential clinical benefits of DBS therapy.
- After the procedure, if you notice unusual changes in mood or behavior (such as increased anxiety, sleeping problems, loss of interest in activities, feeling of hopelessness, mood swings, weight loss or weight gain), or impulse control, contact your physician. If you are having thoughts of suicide, contact your physician or emergency services immediately.
- It is important to attend on-going follow-up visits with your physician to manage your therapy.

Stimulator Damage

Chemical burns may result if the Stimulator housing is ruptured or pierced and your tissue is exposed to battery chemicals.

Other Implanted Stimulation Devices

Concurrent use of the Stimulator and other implantable stimulation devices such as pacemakers, cardioverter defibrillators, or medication delivery pumps may result in interference with the operations of the devices. If you require concomitant implantable stimulation devices, careful programming of each system is necessary. If there is a concern or a problem is encountered, please contact your physician.

Automobiles and Equipment

Operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the DBS System. Avoid performing activities that would be dangerous if treated symptoms were to return. Actions that cause stimulation changes to occur should be avoided. Impaired driving performance and an increased accident risk have been previously reported for patients with Parkinson's disease.

If your DBS System ceases treatment for any reason while operating a car, any other motorized vehicle, or potentially dangerous machinery/equipment, you are at an increased risk of causing injury or death to yourself and others.

Pregnancy

It is unknown whether this device may cause complications with pregnancy and/or hurt an unborn baby.

Precautions

Other Models of External Devices

Only the Remote Control and Charger provided with the Boston Scientific Vercise Gevia DBS System should be used with the Vercise Gevia DBS System. Other similar models of these devices will not function with the Vercise Gevia DBS System.

Only the Remote Control provided with the Boston Scientific Vercise PC DBS System should be used with the Vercise PC DBS System. Other similar models of these devices will not function with the Vercise PC DBS System.

Stimulator Orientation

Never attempt to change the orientation of or turn over the Stimulator. Avoid touching the Stimulator site or incisions. If you notice a change in appearance of the skin at the Stimulator location, such as the skin becoming thin over time, contact your physician.

If the Vercise Gevia Stimulator flips over in your body, then it cannot be charged. If stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system.

Device Failure

Implants can fail at any time due to random component failure, loss of battery functionality, DBS Lead breakage, or DBS Lead migration. Suddenly stopping brain stimulation can cause serious reactions to develop. If the Stimulator stops working even after complete charging, turn off stimulation and contact your physician immediately so that the system can be evaluated and appropriate medical care given to manage the return of symptoms.

Post-Operative

Following your surgery, the medical staff will ensure that you will receive standard medical care:

- A CT Scan may be taken to record the position of the DBS Leads and Stimulator.
- You and a family member will be educated on the system operations, including instructions on how to turn stimulation on and off, how to charge the Stimulator's battery, and realistic expectations of stimulation in the treatment of your disease.
- Antibiotics may be prescribed to prevent infection.
- Post-operative pain concerns will be addressed by your physician prior to discharge from the hospital.
- A responsible adult companion who is able to fully understand the post-operative care instructions will be required to drive you home after the surgery.

During the period following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incision:

- You should restrict head movements, as instructed by your physician, including extension or flexion of the neck and rotation of the head, until healing is complete.
- Do not attempt to move heavy objects.
- Do not shower until cleared by your physician. Surgical sutures and staples will need to be removed by your physician in a follow-up visit after surgery.
- Follow your physician's instructions regarding how to care for the dressing covering the area where the Stimulator has been implanted.

Initiating your stimulation therapy may be delayed up to 2 months until swelling (edema) is resolved. The timing will depend on your physician's judgment. Post-surgical swelling is expected to subside. If you experience continued swelling, contact your physician. If swelling is still present at the Stimulator site (typically in the chest area) once stimulation therapy has begun, swelling may lead to longer charging times or the inability to charge the Stimulator.

Temporarily, there may be some pain in the area of the Stimulator until healing is complete. If discomfort continues beyond two weeks, contact your physician.

If you notice excessive redness or drainage around the wound areas, contact your physician. In rare cases, adverse tissue reaction to implanted materials can occur.

Cell Phones

While interference caused by cell phones is not anticipated, the full effects of interaction with cell phones are unknown at this time. Do not place the cell phone directly over the Implanted Stimulator. If interference does occur, move the cell phone away from the Implanted Stimulator or turn off the phone. If there is a concern or problem please contact your physician.

Massage Therapy

You should avoid receiving massage therapy near the implanted system components. If you do receive massage therapy, inform the masseuse that you have an implanted device and show him/her where the Stimulator, DBS Extension, and DBS Leads are located. Have the masseuse avoid these areas and proceed with caution.

Medical Devices/Therapies

The following medical therapies or procedures may turn stimulation off, cause permanent damage to the Stimulator, and/or may cause you injury, particularly if used in close proximity to the device. If any of the procedures below is required by medical necessity, the procedure(s) should be performed as far from the implanted components as possible. Stimulator function should be confirmed after the procedure. Ultimately, however, the Stimulator may require explantation as a result of damage to the device or severe injury.

- Electrocautery – The use of a heated electric probe to stop bleeding during surgery.
- External Defibrillation – The use of electrically charged paddles to restart the heart in an emergency.
- Lithotripsy – High-output sound or shock waves often used to treat gall stones and kidney stones.
- Radiation Therapy – Ionizing energy commonly used to treat cancer. Any damage to the device by radiation may not be immediately detectable.
- MRI – A technique that uses magnetic fields and radio waves linked to a computer to create pictures of areas inside the body. If you have the Vercise Gevia DBS System you will be able to have an MRI examination when specific conditions are met. These conditions are specified in the supplemental physician manual ImageReady™ MRI Guidelines for Boston Scientific DBS Systems available on the website www.bostonscientific.com/manuals.
- If you have the Vercise PC DBS System you should not be subjected to MRI to avoid damage to the device and personal injury or even death.
- X-ray and CT scans may damage the Stimulator if stimulation is on. X-Ray and CT Scans are unlikely to damage the Stimulator if stimulation is turned off.

Diagnostic ultrasonic scanning is unlikely to damage the Stimulator if stimulation is turned off.

Before having these procedures, medical therapies, or diagnostics, have your healthcare professional call the Boston Scientific Technical Support department for proper instructions. Please refer to the contact list.

Component Disposal

Any explanted components should be returned to Boston Scientific. The Stimulator should be explanted in the case of cremation and returned to Boston Scientific. Cremation may cause the Stimulator battery to explode.

The Remote Control and Charging System should not be disposed of in fire, as this component contains batteries which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

Operating Temperature

The operating temperature of the Remote Control is 5 °C to 40 °C (41 °F to 104 °F). For proper operation, do not use the Charging System if the ambient temperature is above 35 °C (95 °F).

Storage, Handling and Transport

Do not expose the Remote Control or Charging System to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. If the Remote Control or the Charging System are to be stored for a period of time, be careful that the storage temperature does not exceed -20 °C to 60 °C (-4 °F to 140 °F).

Handle the system components and accessories with care. Do not drop them or submerge them in water. Accessories, including the Remote Control, Charger, and charging components, must be kept dry and not be exposed to moisture. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. Keep the Remote Control, Charger, and charging components away from pets, pests and children to avoid damage to the devices.

Remote Control and Charging System Cleaning

The external components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth and then wiped dry. Do not clean the Charger, Base Station or Power Supply while they are directly or indirectly connected to a power outlet.

Do not use abrasive cleansers for cleaning. Remove the Charger and Counterweight from the Charging Collar before washing the Charging Collar. Wash the Charging Collar with mild soap and warm water. Do not machine wash the Charging Collar. Let the Charging Collar air dry. Do not use the Charging Collar when it is damp or wet.

As an operator of the external devices, you should perform only the following service and maintenance tasks on the external devices:

- Charging the battery
- Cleaning

Ensure that the devices are not in use while performing service and maintenance tasks.

Activities Requiring Coordination

Loss of coordination is a possible side effect of DBS therapy. You should use caution when doing activities that require coordination, even if you were able to do them before receiving therapy (for example, swimming).

Bathing

Patients should exercise reasonable caution when bathing.

Adverse Events

The following is a list of known risks with the use of deep brain stimulation. It is possible there are risks that are unknown. Note that some of these symptoms may be resolved or reduced by current steering, changing stimulation parameters, or by changing the position of the DBS Lead during surgery.

If any of these events occur, you should contact your physician as soon as possible to inform them.

Risks associated with Surgical Procedure and Post-operative period

- Allergic reaction to anesthesia or antibiotics including anaphylaxis
- Blood clot formation in the extremities (e.g., in the veins of the legs)
- Blood clot or air forming in or traveling through the blood stream, which can block blood flow to parts of the lungs or other tissue that could be life-threatening
- Brain contusion (bruising)
- Brain or cerebral spinal fluid (CSF) infection or inflammation
- CSF leaking outside the skull or collecting inside the skull abnormally
- Confusion or problems with attention, thinking, or memory (acute or chronic)
- Death
- Fibrosis (thickened skin and scarring) around the Lead Extension (including tightening, tethering, and bowstringing)
- Hemiparesis (muscular weakness or partial paralysis on one side of the body)

- Hemiballism (uncontrollable involuntary movements of a limb or limbs on one or both sides of the body)
- Intracranial hemorrhage (which can lead to stroke, paralysis, or death)
- Intraparenchymal cyst
- Infection
- Injury to areas next to the implant, such as blood vessels, nerves, the chest wall, and the brain
- Injury to the nerves in the armpit (brachial plexus) leading to pain or weakness of the arm or hand
- Neurosurgery/anesthesia risks, including unsuccessful implant and pneumonia
- Pain at the surgical site(s), headache or discomfort
- Seizures
- Speech or language difficulties
- Subcutaneous hemorrhage or seroma (blood or fluid collection under the skin, including the skin over the skull)
- Stroke resulting in temporary or permanent problems
- Swelling or bruising of the muscles or skin in the area of the Lead or of the Stimulator implant

Possible Side-Effects of Stimulation

- Confusion or problems with attention, thinking, or memory
- Gait difficulty (trouble walking) and falls
- Pain, headache or discomfort
- Pneumonia from difficulty with swallowing or from inhaling fluid

- Psychiatric disturbances such as anxiety, depression, lessened interest or emotion, hypersexuality, aggression, mania or hypomania, psychosis, emotional sensitivity, sleep problems, suicide, or suicidal thoughts or attempts
- Seizures
- Sensory changes
- Speech or language problems
- Swallowing difficulty
- Systemic effects such as rapid heart beat, sweating, fever, dizziness, changes in kidney function, difficulty passing urine, sexual effects, nausea, difficulty having bowel movements, bloating
- Weakness, muscle spasms, shaking, restlessness, or problems with movement
- Undesirable sensations (e.g., tingling)
- Visual problems, eyelid or eye movement difficulties or other eye-related symptoms
- Weight changes

Device-related Risks

- Allergic or immune system response to implanted materials
- Failure or malfunction of any part of the device, including but not limited to: Battery leakage, battery failure, Lead or Extension breakage, hardware malfunctions, loose connections, electrical shorts or open circuits, and Lead insulation breaches, whether or not these problems require device removal and/or replacement
- Implant site complications such as pain, poor healing, redness, warmth, swelling or wound reopening

- Implanted device components (Stimulator, Lead, or Extension) may move from original implanted location or wear through the skin, which may lead to the need for additional surgery
- Infection
- Interference from external electromagnetic sources
- Loss of adequate stimulation
- Pain, headache or discomfort
- Skin irritation or burns at the Stimulator site
- Stiffness in muscles or joints
- Worsening of disease symptoms, potentially caused by loss of stimulation, medication changes, surgery, or illness. In rare cases worsening can become a life-threatening crisis associated with varied symptoms such as mental status changes, fever, and muscle rigidity
- Swelling, including fluid collecting around the device

Electromagnetic Compatibility

EN 60601-1-2 Classification Information

- Internally Powered Equipment
- Continuous Operation
- Ordinary Equipment
- Class II

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The Vercise PC and Vercise Gevia DBS Systems are intended for use in electromagnetic environment specified below. The customer or the user of the Systems should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	<p>The Vercise Gevia System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p> <p>The Vercise PC System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p>
RF emissions CISPR 11	Class B	<p>The Vercise Gevia System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</p>
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	<p>The Vercise PC System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.</p>


Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Vercise PC and Vercise Gevia DBS Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the DBS System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Air: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}, \pm 15 \text{ kV}$ Contact: $\pm 8 \text{ kV}$	Air: Remote Control and Charger: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}, \pm 15 \text{ kV}$ Contact: Remote Control and Charger: $\pm 8 \text{ kV}$	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Note: Applies to external devices.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Vercise PC and Vercise Gevia DBS Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the DBS System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Professional healthcare facility environment and home healthcare environment. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol shown below: 

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DBS System is used exceeds the applicable RF compliance level above, the DBS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DBS System.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Vercise PC and Vercise Gevia DBS Systems

The Vercise PC and Vercise Gevia DBS Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DBS System can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the DBS System.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Essential Performance

Failure of the external electrical components will not result in an unacceptable risk to the user.

Quality of Wireless Service: Vercise PC

The Vercise PC System uses a Half-Duplex, direct point-to-point, primary-secondary communication system with the following characteristics:

- Typical range: 22 inches (55.8 cm) between Remote Control and Stimulator.
- Timing: Once a command is initiated by the user, the system will respond in less than 1.5 seconds.
- Telemetry failures (Remote Control)
 - The signal-to-noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Telemetry operations are retried for six seconds in case of insufficient range or in presence of interference. User is notified of the communication failure if the system has not been able to connect with the Stimulator within six seconds.
 - Packet and message errors are verified for accuracy. Any erroneous packets/messages are rejected and resent for up to six seconds. User is notified of the communication failure after six seconds of failed attempts.
 - User may re-try the command or follow on-screen instructions for telemetry help.

Quality of Wireless Service: Vercise Gevia

The Vercise Gevia System uses a Half-Duplex, direct point-to-point, primary-secondary communication system with the following characteristics:

- Typical range: 36 inches (91.4 cm) between Remote Control and Stimulator with 95% or higher communication success rate.
- Timing: Once a command is initiated by the user, the system will respond in less than 1.5 seconds.
- Telemetry failures (Remote Control):
 - The signal-to-noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Telemetry operations are retried for six seconds in case of insufficient range or in presence of interference. User is notified of the communication failure if the system has not been able to connect with the Stimulator within six seconds.
 - Packet and message errors are verified for accuracy. Any erroneous packets/messages are rejected and resent for up to six seconds. User is notified of the communication failure after six seconds of failed attempts.
 - User may re-try the command or follow on-screen instructions for telemetry help.

Wireless Security

The Vercise PC and Vercise Gevia Systems have a short range inductively coupled telemetry system. A Remote Control has to be linked with a Stimulator to allow communication. The Stimulator will not respond to any device that it is not linked to. There are additional mechanisms that ensure the integrity of the communicated data.

Telemetry Information

The following parameters describe the wireless communication link between the Stimulator and the Remote Control:

- Frequency Band: 119 kHz to 131 kHz
- Modulation type: FSK
- Effective Radiated Power: 0.05 mW (-13 dBm) maximum
- Magnetic Field Strength (at 3 m distance): 46 μ A/m

FCC Compliance

The following is federal government communications regulation information about the Vercise PC and Vercise Gevia DBS System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The DBS System components should only be serviced by Boston Scientific. Do not attempt to open or repair any of the components.

Changes or modifications to this product not authorized by Boston Scientific Corporation could void the FCC Certification and negate your authority to operate this product.

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Boston Scientific

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