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Vercise™ PC Information for Prescribers

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

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.

Trademarks

All trademarks are the property of their respective holders.

Additional Information

For other device-specific information not included in this manual, or labeling symbols, refer to the appropriate DFU as listed on your DBS *Reference Guide.*

Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

Registration Information

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific Stimulator, DBS Lead, and DBS Extension. The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted DBS Lead, accessory, or device to gain quick access to pertinent data from the manufacturer.

Fill out the registration form included in the package contents. Return one copy to the Boston Scientific Customer Service Department, keep one copy for patient records, provide one copy to the patient, and save one copy for the physician.

Boston Scientific Neuromodulation Corporation
Attention: Customer Service Department
25155 Rye Canyon Loop
Valencia, CA 91355, USA

Patient Identification Card

Please ensure that the patient receives a completed temporary identification card following surgery. Permanent cards will be mailed directly to the patient following patient registration.

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Vercise™ PC DBS System Description

The Vercise PC DBS System includes a Stimulator with DBS Leads for bilateral stimulation. There are also DBS Extensions that allow the DBS Leads mounted in the skull to be extended to reach the Stimulator implanted near the clavicle. The Vercise PC DBS System utilizes current steering (also known as multiple independent current control or MICC) across eight contacts per DBS Lead to provide precise positioning of stimulation. The Stimulator is controlled by a hand-held Remote Control, and can be interfaced with a Clinician's Programmer.

The battery of the non-rechargeable Stimulator will become depleted. 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, refer to the appropriate programming manual as listed on your *DBS Reference Guide*.

Note: *The Vercise PC System was not made with natural latex.*

Intended Use / Indications for Use

The Vercise PC Deep Brain Stimulation (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.

Safety Information

Contraindications

The Boston Scientific Vercise PC DBS System, or any of its components, is contraindicated for the following:

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients implanted with the Vercise™ DBS System, or any of the system components. The energy generated by diathermy can be transferred to the Vercise PC DBS System, causing tissue damage at the contact site resulting in severe injury or death.

Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS). The safety of these therapies in patients implanted with the Vercise DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the Vercise DBS System, causing tissue damage that may result in severe patient injury or death.

Magnetic Resonance Imaging (MRI). Patients implanted with the full Vercise PC DBS System (Leads, Extensions, and Stimulator) should not be subjected to MRI. MRI exposure may result in the following:

- Dislodgement of implanted components
- Heating of the contacts, or other system components, causing permanent tissue lesioning
- Damage to the Stimulator's electronics
- Current induction through the DBS Leads and Vercise PC DBS System causing unpredictable levels of stimulation
- Distortion of the diagnostic image
- Personal injury or death

Note: *Vercise DBS Lead-Only System (before Stimulator is implanted) is MR Conditional. An MRI examination can be conducted safely when all the instructions in the supplemental manual MRI Guidelines for Boston Scientific DBS Systems are followed.*

For the latest version of the manual go to www.bostonscientific.com/manuals.

Patient Incapability. Patients who are unable to properly operate the Remote Control should not be implanted with the Vercise PC DBS System.

Poor Surgical Candidates. The Vercise PC DBS System is not recommended for patients who are poor surgical candidates.

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. Special precautions should be taken for patients who are prone to hemorrhage including patients with coagulopathy, with high blood pressure, or who are using prescribed anticoagulants. Microelectrode penetration and DBS Lead insertion can put patients who have a likelihood of intracranial hemorrhages at greater risk.

Charge Density. High levels of stimulation may damage brain tissue. To maintain safety limits, the software will display a message when the stimulation level would exceed the limit, and programming of these settings will be prevented.

Patients may be granted the ability to change stimulation amplitude with the Remote Control. The software prevents patient controlled amplitude from violating the limit.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication. Patients should be counseled to avoid or exercise care around the following:

- Theft detectors, tag deactivators and RFID devices, such as those used at department stores, libraries, and other public establishments. The patient 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. The patient should request assistance to bypass the device. If the patient must pass through the security screener, they should move quickly through the device staying as far from the physical device 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 systems 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.*

DBS Extension Connector and Stimulator Placement. Implanting the DBS Extension connector in the soft tissue of the neck may increase the chance of DBS Lead breakage. Boston Scientific recommends placing the DBS Extension connector behind the ear such that glasses or headgear do not interfere with the system. Boston Scientific recommends that the Stimulator be placed subclavicularly.

Stimulator Damage. Chemical burns may result if the Stimulator housing is ruptured or pierced, exposing the patient's tissue to battery chemicals. Do not implant the Stimulator if the housing is damaged.

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

- Preoperatively, 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 for the condition being treated.
- Postoperatively, actively monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control.
- If a patient experiences new or worsening depression or suicidal ideation, manage these symptoms appropriately.
- Educate patients and caregivers about these potential risks prior to implantation, and be sure that they know about the importance of ongoing support and follow-up, including when to contact their health care provider.

Other Active Implantable Devices. Concurrent use of stimulators such as the Vercise PC Stimulator and other active implantable devices such as pacemakers, cardioverter defibrillators, or medication delivery pumps may result in interference with the operations of the devices. If the patient requires concomitant implantable active devices, careful programming of each system is necessary.

Automobiles and Equipment. Patients should operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the Vercise PC DBS System. Performing activities that would be dangerous if treated symptoms were to return, or instances in which stimulation changes occur, should be avoided.

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

Precautions

Physician training is required for usage of the Vercise PC DBS System. The implanting physician should be experienced in the subspecialty of Stereotactic and Functional Neurosurgery. The following is a list of precautions that should be taken when implanting or using the DBS Stimulator.

Connections. Before inserting any DBS Lead or DBS Extension into any connector or header ports, including the Stimulator header, DBS Extension connectors, and operating room cable assembly, always wipe the DBS Lead with a sterile, dry cotton sponge. Contamination inside the ports may be difficult to remove and can cause high impedances, preventing electrical connectivity which may compromise the integrity of the stimulation circuit.

Components. The use of components other than those supplied by Boston Scientific and intended for use with the Vercise PC DBS System may damage the system, diminish the effectiveness of therapy, and/or put the patient at unknown risk.

Excess DBS Extension. Coil excess DBS Extension around or below the Stimulator. Excess wire on top of the Stimulator may increase the potential for tissue erosion or damage during Stimulator replacement surgery.

Other Models of External Devices. Only the Remote Control and Clinician Programmer that were provided with the Boston Scientific Vercise PC DBS System should be used with the Vercise PC DBS System. Other models of these devices will not function with the Vercise PC DBS System.

Stimulator Orientation. Orient the Stimulator parallel to the skin surface. Suboptimal placement of the Stimulator may result in a revision surgery. Patients should avoid touching the Stimulator site or incisions. If patients notice a change in appearance of the skin at the Stimulator location, such as the skin becoming thin over time, they should contact their physician.

Setscrews. Before tightening Setscrews, always test impedance to confirm electrical connectivity. Tightening a Setscrew onto a contact may damage the contact and may result in the need to replace the DBS Lead or DBS Extension.

Sutures. Do not apply sutures tightly around the DBS Leads, as this may damage the insulation of the DBS Lead and may result in DBS Lead failure.

Surgical Tape. If tape is used to temporarily secure the DBS Lead during surgery, caution should be used to ensure the Lead is not cut or damaged when removing the tape.

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

Tissue Reaction. Temporarily, there may be some pain in the area of the Stimulator as the incisions heal. If there is excessive redness around the wound area, it should be checked for infection. 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. Patients should be instructed to avoid placing 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.

Patient Activities Requiring Coordination. Loss of coordination is a potential side effect of DBS therapy. Patients should exercise reasonable caution when participating in activities requiring coordination, including those that they were able to perform prior to receiving DBS therapy (e.g., swimming).

Bathing. Patients should exercise reasonable caution when bathing.

Patient Activity Following Surgery. During the two weeks following surgery, it is important for the patient to exercise extreme care so that appropriate healing will secure the implanted components. During this period, the patient should not attempt to move heavy objects. Instruct the patient to restrict head movements, including extension or flexion of the neck and rotation of the head, until healing is complete.

Massage Therapy. Patients should avoid receiving massage therapy near the implanted system components. If a patient does receive massage therapy, the patient should inform the masseuse that they have an implanted device and show him/her where the Stimulator, DBS Extension, and DBS Leads are located. The patient should have the masseuse avoid these areas and proceed with caution.

Environmental Precautions. Patients should avoid activities that could potentially involve large amounts of electromagnetic interference. Devices that contain permanent magnets, such as speakers, should not be placed near the Stimulator because they may cause the system to turn on or off.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off, cause permanent damage to the Stimulator, or may cause injury to the patient. 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 patient harm.

- Electrocautery – Electrocautery can transfer destructive current into the DBS Leads and/or Stimulator.
- External Defibrillation – Safe usage of external defibrillation has not been established.
- Lithotripsy – High frequency signals directed near the Stimulator may damage circuitry.
- MRI – Patients implanted with the full Vercise PC DBS System (Leads, Extensions, and Stimulator) should not be subjected to MRI to avoid damage to the device and patient harm.

Note: *Vercise DBS Lead-Only System (before Stimulator is implanted) is MR Conditional. An MRI examination can be conducted safely when all the instructions in the supplemental manual MRI Guidelines for Boston Scientific DBS Systems are followed.*

For the latest version of the manual go to www.bostonscientific.com/manuals.

- Radiation Therapy – Lead shielding should be used over the Stimulator to prevent damage from high radiation. Any damage to the device by radiation may not be immediately detectable.
- 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.

If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, X-Ray or CT Scan:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away from the Stimulator as possible.
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the Stimulator.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm Stimulator functionality following treatment by turning on the Stimulator and gradually increasing stimulation to the desired level.

Sterilization. Contents of the surgical kits are supplied sterile using an ethylene oxide process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative and return the damaged part to Boston Scientific.

Single Use Only. **Do Not Resterilize.** For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Inspect Packaging Before Use. Check the expiration date on the package before opening the sterile package and using the contents. Do not use the contents if the current date is past the expiration date, if the package is opened or damaged, or if contamination is suspected because of a defective sterile package seal.

- Inspect the seal integrity of the outer tray before use.
- Open the inner tray in the sterile field.
- If the Stimulator was dropped, do not implant it in a patient. The dropped Stimulator may have lost sterility, experienced a loss of hermeticity, or been otherwise damaged. Replace the dropped Stimulator with a new, sterile Stimulator prior to implantation. Return the damaged Stimulator to Boston Scientific.
- Do not use any component that shows signs of damage.
- Do not use if “Use By” date has expired.

Operating Temperature. The operating temperature of the ETS, Remote Control, and Programming Wand is 5 °C to 40 °C (41 °F to 104 °F).

Storage, Handling and Transport. Store components implanted components like the Stimulator, Leads, and Extensions, between 0 °C to 45 °C (32 °F to 113 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage. If stored in conditions beyond the required storage temperature, do not use the components and return to Boston Scientific.

The non-rechargeable Stimulator will enter storage mode if its temperature falls below 8 °C. When the Stimulator is in storage mode, it will not connect to a Remote Control or Clinician Programmer. To exit storage mode, increase the Stimulator temperature above 8 °C.

Store external components like the Remote Control, External Trial Stimulator, ETS Adapter, OR Cable and Extension between -20 °C to 60 °C (-4 °F to 140 °F). Do not expose them 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.

Handle the system components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water that can come into contact with the devices. 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 away from pets, pests and children to avoid damage to the device.

Care must be taken to avoid damaging the DBS Lead with sharp instruments or excessive force during surgery. The following guidelines will help to ensure the longevity of components:

- Do not sharply bend or kink the DBS Lead or Extension.
- Do not tie suture(s) directly to the DBS Lead or Extension body.
- Avoid pulling an implanted DBS Lead taut; stress relief loops may help to minimize tension on the DBS Lead.
- Avoid handling the DBS Lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments, such as hemostats or scalpels, to prevent damaging the DBS Lead.

Component Removal, Disposal and Return. 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 should not be disposed of in fire, as this device contains batteries which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

Dispose of non-implantable components and packaging in accordance with hospital, administrative and/or local government policy.

Cleaning the Remote Control, External Trial Stimulator and Programming Wand. The 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. Do not use abrasive cleansers for cleaning. Do not clean any of the accessories while they are directly or indirectly connected to a power outlet.

Adverse Events

The following is a list of known risks with the use of deep brain stimulation. There may be 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 Lead during surgery.

If any of these events occur, patients should inform their physician as soon as possible.

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 IPG implant

Possible Side-Effects of Stimulation

- Confusion or problems with attention, thinking, or memory
- Gait difficulty (trouble walking) and falls

- New onset or worsening depression, which may be temporary or permanent, and suicidal ideations, suicide attempts, and suicide
- 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

External Trial Stimulator 2 (ETS 2) Maintenance

The ETS 2 is used to conduct intraoperative stimulation testing during the Lead implantation procedure. Refer to the DFU listed on your DBS Reference Guide for detailed procedure and guidelines for intraoperative testing.

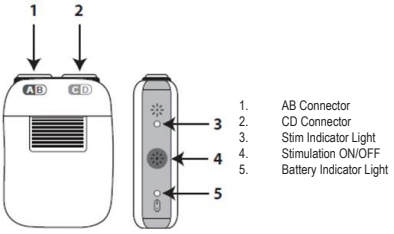

Figure 1: External Trial Stimulator 2

To turn stimulation on and off on the ETS, press the ON/OFF button on the ETS 2 (Figure 1). When the stimulation is on, the Stim Indicator Light will blink green. The ETS 2 runs on two AA batteries that are provided with every ETS 2 kit. When the batteries need replacement, the Battery Indicator Light will change from a flashing green to a flashing yellow.

Be sure that stimulation is off (the indicator light is not blinking) before opening the Trial Stimulator's battery compartment.

To install new batteries:

1. Confirm that stimulation is OFF by confirming that the stimulation indicator light is not blinking.
2. On the rear of the ETS 2, push in slightly and slide down the battery compartment cover.
3. Remove the old batteries.
4. Place two new AA batteries in the slots matching the positive (+) and negative (-) markings in the compartment.
5. Align the battery compartment cover on the case and slide the cover into position until is snaps closed.
6. Both the Battery Indicator light and the Stim On indicator lights will emit an amber glow for 15 seconds after which the Battery indicator light blinks green.

Vercise PC Stimulator Battery

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, refer to the appropriate programming manual as listed on your DBS Reference Guide.

Elective Replacement

When the implanted non-rechargeable Stimulator is nearing end of its battery life, the Stimulator will enter the Elective Replacement mode. The Elective Replacement Indicator (ERI) will appear on the Remote Control and Clinician Programmer. Changes made to the stimulation will not be saved, and stimulation will not be available soon. Patients should be advised to contact their physician to report this message screen. The Stimulator must be replaced to continue receiving stimulation. Batteries that have lasted 12 months or more without entering ERI mode will have a minimum of 4 weeks between entering ERI mode and reaching End of Battery Life. Surgery is required to replace the implanted non-rechargeable Stimulator, although Leads may stay in place while the Stimulator is exchanged.

End of Service

End of Battery Life

When the Stimulator battery is fully depleted, the End of Service (EOS) indicator will be displayed on the Remote Control and Clinician Programmer. Stimulation will not be available. Surgery is required to replace the implanted non-rechargeable Stimulator to continue providing stimulation.

End of Programmed Service

The Vercise PC Stimulator software has been programmed to end service after a defined period. When the Stimulator is within approximately 180 days of the end of its programmed period, the Remote Control and Clinician Programmer will display a message indicating the number of service days available.

Refer to the Programming Manual and the Remote Control DFU listed on your DBS Reference Guide for description of the End of Service messages displayed.

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 DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Vercise PC DBS System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Vercise PC DBS 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.
RF emissions CISPR 11	Class B	The Vercise PC DBS 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.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Vercise PC DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise PC 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: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: Remote Control: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV ETS and Wand: ± 2 kV, ± 4 kV, ± 8 kV Contact: Remote Control: ± 8 kV ETS and Wand: ± 6 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.
Electrical fast transient/ burst IEC 61000-4-4 (Programming Wand only)	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 (Programming Wand only)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 (Programming Wand only)	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vercise PC DBS System requires continued operation during power mains interruptions, it is recommended that the Vercise PC DBS System be powered from an uninterruptible power supply or a battery.
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.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Vercise PC DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise PC DBS System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	Professional healthcare facility environment and home healthcare environment.
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 Vercise PC DBS System is used exceeds the applicable RF compliance level above, the Vercise PC 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 Vercise PC DBS System.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Vercise PC DBS System
The Vercise PC DBS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vercise PC 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 Vercise PC 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

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.
- 18 inches (45.7 cm) between Wand and Stimulator 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.

Telemetry failures (Programming Wand):

- The signal to noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Signal to noise measurement is retried up to three times in case of insufficient range or in the presence of electromagnetic disturbances. User is notified of the communication failure after 3 failed attempts.
- Packet and message errors are verified for accuracy. Any erroneous packets/ messages are rejected and resent up to 3 times. User is notified of the communication failure after 3 failed attempts.
- User may re-try the command or follow on-screen instructions for telemetry help.

Wireless Security

The Vercise PC System has a short range inductively coupled telemetry system. A Remote Control (or Wand) 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 µA/m

FCC Compliance

The following is federal government communications regulation information about the Vercise™ PC 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 Vercise 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.

Boston Scientific

Advancing science for life™

Legal Manufacturer

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Boston Scientific

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Vercise Gevia™ Information for Prescribers

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Content: MP92152385-05 REV A

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

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.

Trademarks

All trademarks are the property of their respective holders.

Additional Information

For other device-specific information not included in this manual, or labeling symbols, refer to the appropriate DFU as listed on your DBS *Reference Guide.*

Technical Support

There are no user serviceable parts. If you have a specific question or issue, please contact your sales representative or call (833) DBS-INFO or (833) 327-4636.

Registration Information

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific Stimulator, DBS Lead, and DBS Extension. The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted DBS Lead, accessory, or device to gain quick access to pertinent data from the manufacturer.

Fill out the registration form included in the package contents. Return one copy to the Boston Scientific Customer Service Department, keep one copy for patient records, provide one copy to the patient, and save one copy for the physician.

Boston Scientific Neuromodulation Corporation
Attention: Customer Service Department
25155 Rye Canyon Loop
Valencia, CA 91355, USA

Patient Identification Card

Please ensure that the patient receives a completed temporary identification card following surgery. Permanent cards will be mailed directly to the patient following patient registration.

Table of Contents

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Vercise Gevia™ DBS System Description

The Vercise Gevia™ Deep Brain Stimulation (DBS) System includes a rechargeable Stimulator with DBS Leads for bilateral stimulation. There are also DBS Extensions that allow the DBS Leads mounted in the skull to be extended to reach the Stimulator implanted near the clavicle. The Vercise Gevia DBS System utilizes current steering (also known as multiple independent current control or MICC) across eight contacts per DBS Lead to provide precise positioning of stimulation. The Stimulator is controlled by a hand-held Remote Control, and can be interfaced with a Clinician's Programmer using the Vercise Neural Navigator programming software. The battery must be replenished periodically with a charging device provided in the charging kit.

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

Intended Use / Indications for Use

The Vercise Gevia 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.

Safety Information

Contraindications

The Boston Scientific Vercise Gevia DBS System, or any of its components, is contraindicated for the following:

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients implanted with the Vercise Gevia DBS System, or any of the system components. The energy generated by diathermy can be transferred to the Vercise Gevia DBS System, causing tissue damage at the contact site resulting in severe injury or death.

Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS). The safety of these therapies in patients implanted with the Vercise Gevia DBS System has not been established. It is possible that the energy generated by these therapies can be transferred to the Vercise Gevia DBS System, causing tissue damage that may result in severe patient injury or death.

Patient Incapability. Patients who are unable to properly operate the Remote Control and Charging System should not be implanted with the Vercise Gevia DBS System.

Poor Surgical Candidates. The Vercise Gevia DBS System is not recommended for patients who are poor surgical candidates.

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. Special precautions should be taken for patients who are prone to hemorrhage including patients with coagulopathy, with high blood pressure, or who are using prescribed anticoagulants. Microelectrode penetration and DBS Lead insertion can put patients who have a likelihood of intracranial hemorrhages at greater risk.

Charge Density. High levels of stimulation may damage brain tissue. To maintain safety limits, the software will display a message when the stimulation level would exceed the limit, and programming of these settings will be prevented.

Patients may be granted the ability to change stimulation amplitude with the Remote Control. The software prevents patient controlled amplitude from violating the limit.

Magnetic Resonance Imaging (MRI). The Vercise Gevia DBS System is “MR Conditional.” An MRI examination can be conducted safely using a 1.5 Tesla horizontal closed bore MRI system when all instructions and safety information in the supplemental manual “ImageReady™ MRI Guidelines for Boston Scientific DBS Systems” are followed.

The ImageReady™ MRI Guidelines for Boston Scientific DBS Systems manual appears on the Boston Scientific website www.bostonscientific.com/manuals. It is important to read the information in this supplemental manual in its entirety before conducting or recommending an MRI examination on a patient with a Vercise Gevia DBS System.

External Devices: Boston Scientific external components (i.e., External Trial Stimulator, ETS Adapter, and OR Cables, Remote Control and accessories, Battery Charger, Clinician Programmer) are MR Unsafe. They must not be taken into any MR environment such as the MRI scanner.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication. Patients should be counseled to avoid or exercise care around the following:

- Theft detectors, tag deactivators and RFID devices, such as those used at department stores, libraries, and other public establishments. The patient 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. The patient should request assistance to bypass the device. If the patient must pass through the security screener, they should move quickly through the device staying as far from the physical device 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 systems 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.*

DBS Extension Connector and Stimulator Placement. Implanting the DBS Extension connector in the soft tissue of the neck may increase the chance of DBS Lead breakage. Boston Scientific recommends placing the DBS Extension connector behind the ear such that glasses or headgear do not interfere with the system. Boston Scientific recommends that the Stimulator be placed subclavicularly.

Heat Due to Charging. 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. The Patient should not charge while sleeping. This may result in a burn. If the patient experiences pain or discomfort, they should cease charging and contact their physician.

Stimulator Damage. Chemical burns may result if the Stimulator housing is ruptured or pierced, exposing the patient's tissue to battery chemicals. Do not implant the Stimulator if the housing is damaged.

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

- Preoperatively, 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 for the condition being treated.
- Postoperatively, actively monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control.
- If a patient experiences new or worsening depression or suicidal ideation, manage these symptoms appropriately.
- Educate patients and caregivers about these potential risks prior to implantation, and be sure that they know about the importance of ongoing support and follow-up, including when to contact their health care provider.

Other Active Implantable Devices. Concurrent use of stimulators such as the Vercise Gevia Stimulator and other active implantable devices such as pacemaker, cardioverter defibrillators, or medication delivery pumps may result in interference with the operations of the devices. If the patient requires concomitant implantable active devices, careful programming of each system is necessary.

Automobiles and Equipment. Patients should operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the Vercise Gevia DBS System. Performing activities that would be dangerous if treated symptoms were to return, or instances in which stimulation changes occur, should be avoided.

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

Precautions

Physician training is required for usage of the Vercise Gevia DBS System. The implanting physician should be experienced in the subspecialty of Stereotactic and Functional Neurosurgery. The following is a list of precautions that should be taken when implanting or using the DBS Stimulator.

Connections. Before inserting any DBS Lead or DBS Extension into any connector or header ports, including the Stimulator header, DBS Extension connectors, and operating room cable assembly, always wipe the DBS Lead with a sterile, dry cotton sponge. Contamination inside the ports may be difficult to remove and can cause high impedances, preventing electrical connectivity which may compromise the integrity of the stimulation circuit.

Components. The use of components other than those supplied by Boston Scientific and intended for use with the Vercise Gevia DBS System may damage the system, diminish the effectiveness of therapy, and/or put the patient at unknown risk.

Excess DBS Extension. Coil excess DBS Extension around or below the Stimulator. Excess wire on top of the Stimulator may increase the potential for tissue erosion or damage during Stimulator replacement surgery and may interfere with charging.

Other Models of External Devices. Only the Remote Control, Charging System and Clinician Programmer (CP) that were provided with the Boston Scientific Vercise Gevia DBS System should be used with the Vercise Gevia DBS System. Other models of these devices will not function with the Vercise Gevia DBS System.

Stimulator Orientation. To ensure proper charging, orient the Stimulator parallel to the skin surface and at a depth less than 2 cm below the skin. The etched writing “This Side Up” must be facing out of the pocket towards the patients skin. Suboptimal placement of the Stimulator may result in the inability to recharge and may require a revision surgery.

Patients should be instructed not to change the orientation of or turn over the Stimulator. If the Stimulator flips over in the body, then it cannot be charged. If stimulation cannot be turned on after charging, the Stimulator may have changed orientation or rotated; patients should contact their physician to arrange an evaluation of the system.

Patients should avoid touching the Stimulator site or incisions. If a patient notices a change in appearance of the skin at the Stimulator location, such as the skin becoming thin over time, they should contact their physician.

Setscrews. Before tightening Setscrews, always test impedance to confirm electrical connectivity. Tightening a Setscrew onto a contact may damage the contact and may result in the need to replace the DBS Lead or DBS Extension.

Sutures. Do not apply sutures tightly around the DBS Leads, as this may damage the insulation of the DBS Lead and may result in DBS Lead failure.

Surgical Tape. If tape is used to temporarily secure the DBS Lead during surgery, caution should be used to ensure the Lead is not cut or damaged when removing the tape.

Device Failure. Implants can fail at any time due to random component failure, loss of battery functionality, or DBS Lead breakage. Suddenly stopping brain stimulation can cause serious reactions to develop. If the Stimulator stops working even after complete charging (up to four hours when properly aligned), patients should be instructed to turn off the Stimulator and contact their physician immediately so that the system can be evaluated and appropriate medical care given to manage the return of symptoms.

Tissue Reaction. Temporarily, there may be some pain in the area of the Stimulator as the incisions heal. If there is excessive redness around the wound area, it should be checked for infection. 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. Patients should be instructed to avoid placing 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.

Patient Activities Requiring Coordination. Loss of coordination is a potential side effect of DBS therapy. Patients should exercise reasonable caution when participating in activities requiring coordination, including those that they were able to perform prior to receiving DBS therapy (e.g., swimming).

Bathing. Patients should exercise reasonable caution when bathing.

Patient Activity Following Surgery. During the two weeks following surgery, it is important for the patient to exercise extreme care so that appropriate healing will secure the implanted components. During this period, the patient should not attempt to move heavy objects. Instruct the patient to restrict head movements, including extension or flexion of the neck and rotation of the head, until healing is complete.

Massage Therapy. Patients should avoid receiving massage therapy near the implanted system components. If a patient does receive massage therapy, the patient should inform the masseuse that they have an implanted device and show him/her where the Stimulator, DBS Extension, and DBS Leads are located. The patient should have the masseuse avoid these areas and proceed with caution.

Environmental Precautions. Patients should avoid activities that could potentially involve large amounts of electromagnetic interference. Devices that contain permanent magnets, such as speakers, should not be placed near the Stimulator because they may cause the system to turn on or off.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off, cause permanent damage to the Stimulator, or may cause injury to the patient. 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 patient harm.

- Electrocautery – Electrocautery can transfer destructive current into the DBS Leads and/or Stimulator.
- External Defibrillation – Safe usage of external defibrillation has not been established.
- Lithotripsy – High frequency signals directed near the Stimulator may damage circuitry.
- Radiation Therapy – Lead shielding should be used over the Stimulator to prevent damage from high radiation. Any damage to the device by radiation may not be immediately detectable.
- 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.

If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, X-Ray or CT Scan:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.

- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm Stimulator functionality following treatment by turning on the Stimulator and gradually increasing stimulation to the desired level.

Sterilization. Contents of the surgical kits are supplied sterile using an ethylene oxide process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative and return the damaged part to Boston Scientific.

Single Use Only. **Do Not Resterilize.** For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Inspect Packaging Before Use. Check the expiration date on the package before opening the sterile package and using the contents. Do not use the contents if the current date is past the expiration date, if the package is opened or damaged, or if contamination is suspected because of a defective sterile package seal.

- Inspect the seal integrity of the outer tray before use.
- Open the inner tray in the sterile field.
- If the Stimulator was dropped, do not implant it in a patient. The dropped Stimulator may have lost sterility, experienced a loss of hermeticity, or been otherwise damaged. Replace the dropped Stimulator with a new, sterile Stimulator prior to implantation. Return the damaged Stimulator to Boston Scientific.
- Do not use any component that shows signs of damage.
- Do not use if “Use By” date has expired.

Operating Temperature. The operating temperature of the ETS, Remote Control, and Programming Wand 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. Store implanted components like the Stimulator, Leads, and Extensions, between 0 °C to 45 °C (32 °F to 113 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage. If stored in conditions beyond the required storage temperature, do not use the components and return to Boston Scientific.

Store external components like the Remote Control, External Trial Stimulator, ETS Adapter, OR Cable and Extension, and Charging System between -20 °C to 60 °C (-4 °F to 140 °F). Do not expose them 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.

Handle the system components and accessories with care. Do not drop them or submerge them in water. Accessories, including the Remote Control and Charger, must be kept dry. They should 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 and Charger away from pets, pests and children to avoid damage to the devices.

Care must be taken to avoid damaging the DBS Lead with sharp instruments or excessive force during surgery. The following guidelines will help to ensure the longevity of components:

- Do not sharply bend or kink the DBS Lead or Extension.
- Do not tie suture(s) directly to the DBS Lead or Extension body.
- Avoid pulling an implanted DBS Lead taut; stress relief loops may help to minimize tension on the DBS Lead.
- Avoid handling the DBS Lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments, such as hemostats or scalpels, to prevent damaging the DBS Lead.

Component Removal, Disposal and Return. 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 or Charger should not be disposed of in fire, as these devices contain batteries which may explode causing injury when exposed to fire. Used batteries should be disposed of in accordance with local laws and regulations.

Dispose of non-implantable components and packaging in accordance with hospital, administrative and/or local government policy.

Cleaning the Remote Control, External Trial Stimulator, Charger, Base Station, Power Supply and Programming Wand. The 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. Do not use abrasive cleansers for cleaning. Do not clean any of the accessories while they are directly or indirectly connected to a power outlet.

Cleaning the Charging Collar. Hand wash the Charging Collar with mild soap and warm water. Do not machine wash the Charging Collar. Let the Charging Collar air dry. Be sure to remove the Charger and Counterweight from the Charging Collar before washing the Charging Collar.

Adverse Events

The following is a list of known risks with the use of deep brain stimulation. There may be 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 Lead during surgery.

If any of these events occur, patients should inform their physician as soon as possible.

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) fluid 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 IPG implant

Possible Side-Effects of Stimulation

- Confusion or problems with attention, thinking, or memory
- Gait difficulty (trouble walking) and falls
- New onset or worsening depression, which may be temporary or permanent, and suicidal ideations, suicide attempts, and suicide
- 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

External Trial Stimulator 2 (ETS 2) Maintenance

The ETS 2 is used to conduct intraoperative stimulation testing during the Lead implantation procedure. Refer to the DFU listed on your DBS Reference Guide for detailed procedure and guidelines for intraoperative testing.

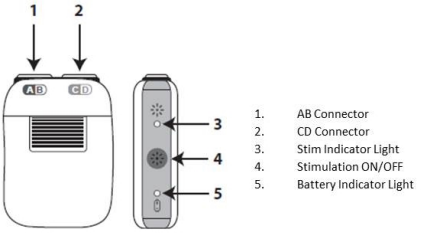

Figure 1: External Trial Stimulator 2

To turn stimulation on and off on the ETS, press the ON/OFF button on the ETS 2 (Figure 1). When the stimulation is on, the Stim Indicator Light will blink green. The ETS 2 runs on two AA batteries that are provided with every ETS 2 kit. When the batteries need replacement, the Battery Indicator Light will change from a flashing green to a flashing yellow.

Be sure that stimulation is off (the indicator light is not blinking) before opening the Trial Stimulator's battery compartment.

To install new batteries:

1. Confirm that stimulation is OFF by confirming that the stimulation indicator light is not blinking.
2. On the rear of the ETS 2, push in slightly and slide down the battery compartment cover.
3. Remove the old batteries.
4. Place two new AA batteries in the slots matching the positive (+) and negative (-) markings in the compartment.
5. Align the battery compartment cover on the case and slide the cover into position until is snaps closed.
6. Both the Battery Indicator light and the Stim On indicator lights will emit an amber glow for 15 seconds after which the battery indicator light blinks green.

Vercise Gevia Stimulator Battery

The Vercise Gevia Stimulator is rechargeable. Patients 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 their recharge routine may vary depending on their stimulation parameters. High power users will require more frequent charging. The Clinician Programmer will provide a recharging estimate based on 24 hours per day of stimulation at the programmed settings. Boston Scientific recommends any recharge schedule that fits the patient's schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

If fully charging the Stimulator, patients should be instructed to charge until the Charger emits the end of charge double beep.

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 no longer can be maintained with routine charging.

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 Gevia DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Vercise Gevia DBS System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Vercise Gevia DBS 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.
RF emissions CISPR 11	Class B	The Vercise Gevia DBS 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.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Vercise Gevia DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise Gevia 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: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: Remote Control and Charger: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV ETS and Wand: ± 2 kV, ± 4 kV, ± 8 kV Contact: Remote Control and Charger: ± 8 kV ETS and Wand: ± 6 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.
Electrical fast transient/ burst IEC 61000-4-4 (Programming Wand only)	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 (Programming Wand only)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 (Programming Wand only)	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vercise Gevia DBS System requires continued operation during power mains interruptions, it is recommended that the Vercise Gevia DBS System be powered from an uninterruptible power supply or a battery.
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.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	Professional healthcare facility environment and home healthcare environment.
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 Vercise Gevia DBS System is used exceeds the applicable RF compliance level above, the Vercise Gevia 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 Vercise Gevia DBS System.

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

The Vercise Gevia DBS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vercise Gevia 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 Vercise Gevia 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.

Telemetry Information

- 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 µA/m

Quality of Wireless Service

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.
- 33 inches (83.8 cm) between Wand 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.

Telemetry failures (Programming Wand)

- The signal to noise ratio is measured before initiating a communication. Telemetry failures can occur if signal-to-noise ratio is low. Signal to noise measurement is retried up to three times in case of insufficient range or in the presence of electromagnetic disturbances. User is notified of the communication failure after 3 failed attempts.
- Packet and message errors are verified for accuracy. Any erroneous packets/ messages are rejected and resent up to 3 times. User is notified of the communication failure after 3 failed attempts.
- User may re-try the command or follow on-screen instructions for telemetry help.

Wireless Security

The Vercise Gevia DBS System has a short range inductively coupled telemetry system. A Remote Control (or Wand) 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.

FCC Compliance

The following is federal government communications regulation information about the 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 Vercise Gevia 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.

Boston Scientific

Advancing science for life™

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