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.
Drawings are for illustration purposes only.

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.

Product Model Numbers

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>DB-1110-C</td>
<td>Vercise Implantable Pulse Generator (IPG) Kit</td>
</tr>
<tr>
<td>DB-2201-30-DC</td>
<td>DBS Lead Kit, 30cm</td>
</tr>
<tr>
<td>DB-2201-45-DC</td>
<td>DBS Lead Kit, 45cm</td>
</tr>
<tr>
<td>NM-3138-55</td>
<td>55cm 8 Contact Extension Kit</td>
</tr>
<tr>
<td>DB-2500-C</td>
<td>Vercise Physician’s Spare Kit</td>
</tr>
<tr>
<td>DB-4252 and SC-4252</td>
<td>Tunneling Tool, 28cm Straw</td>
</tr>
<tr>
<td>DB-4254 and SC-4254</td>
<td>Tunneling Tool, 35cm Long</td>
</tr>
<tr>
<td>DB-4100-A and SC-4100-A</td>
<td>OR Cable &amp; Extension</td>
</tr>
<tr>
<td>DB-5110-C</td>
<td>Vercise External Trial Stimulator (ETS)</td>
</tr>
<tr>
<td>DB-5212-C</td>
<td>Vercise Remote Control</td>
</tr>
<tr>
<td>DB-5500-1</td>
<td>Vercise Remote Control Kit</td>
</tr>
<tr>
<td>NM-5312</td>
<td>Charger</td>
</tr>
<tr>
<td>NM-5305</td>
<td>Base Station</td>
</tr>
<tr>
<td>DB-64125-US</td>
<td>Vercise Charging System</td>
</tr>
<tr>
<td>DB-6200-C</td>
<td>Vercise Charger Collar, Small</td>
</tr>
<tr>
<td>DB-6100-C</td>
<td>Vercise Charger Collar, Medium</td>
</tr>
<tr>
<td>DB-6300-C</td>
<td>Charger Collar Accessories</td>
</tr>
<tr>
<td>NM-6350</td>
<td>Adhesive Kit</td>
</tr>
</tbody>
</table>

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

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.

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

**Introduction**
- Overview of Manual ................................................................. 1
- Intended Use / Indications for Use ........................................... 1
- System Description ..................................................................... 1

**Safety Information**
- Contraindications ...................................................................... 2
- Warnings ..................................................................................... 3
- Precautions .................................................................................. 5
- Adverse Events ............................................................................ 8

**Package Contents**
- Contents of the Implantable Pulse Generator Kit .................... 10
- Contents of the Lead Kit ............................................................ 10
- Contents of the Extension Kit .................................................... 10
- Contents of the Tunneling Tool Kit .......................................... 10
- Contents of the Spares Kit ......................................................... 11
- Other Components ..................................................................... 11

**DBS Lead Implantation**
- Pre-Conditions ......................................................................... 12
- Implanting the DBS Lead .......................................................... 13
- Intraoperative Stimulation Testing .......................................... 15
- Securing the DBS Lead ............................................................. 17

**Stimulator Implantation**
- Exposing the DBS Lead ............................................................ 19
- Connecting the DBS Lead to the DBS Extension .................... 19
- Assembling the Tunneling Tool ................................................ 21
- Tunneling the DBS Lead and Extension .................................. 22
- Connecting the Stimulator ....................................................... 23

**Vercise™ DBS System Revisions & Explantation**
- Explanting the DBS Lead .......................................................... 26
- Explanting the DBS Extensions ................................................. 27
- Explanting or Replacing the Stimulator .................................. 28

**The Vercise™ Stimulator**
- Stimulator Battery ................................................................. 29
- Stimulator Battery Messages ................................................... 30

**The Charging System**
- Charging the Charger .............................................................. 31
- Charging the Stimulator ......................................................... 32
- Using the Charging Collar ....................................................... 33
- Using the Adhesive Patch ........................................................ 34
- Properly Aligning the Charger ................................................. 35
The Remote Control ................................................................. 37
  Basic Operation ........................................................................ 37
  Remote Control Battery Life .................................................... 37
  Remote Control Position .......................................................... 38
  Stimulator Linking ...................................................................... 39
  Stimulation On/Off .................................................................... 40
  Signal Strength .......................................................................... 40
  Stimulation Amplitude .............................................................. 41
  Stimulator Battery ...................................................................... 41
  Program Selection ....................................................................... 42
  Modifying and Saving Programs ................................................. 43
  Individual Area Amplitude ......................................................... 43
  Restore Option ........................................................................... 43
  Searching .................................................................................... 44
  Clinician Options ....................................................................... 44

Stimulation Guidelines ................................................................. 47
  Charge Density .......................................................................... 47

Detailed Device Description ........................................................... 48
  General Component Description .................................................. 48
  Stimulator Physical Characteristics .............................................. 48
  Stimulator Programmable Characteristics .................................... 49
  DBS Lead .................................................................................. 51
  DBS Extension .......................................................................... 52
  DBS Lead Boot .......................................................................... 53
  Suture Sleeve ............................................................................. 54
  Tunneling Tool ........................................................................... 55
  Programmer Communication ....................................................... 56

Labeling Symbols ........................................................................ 57

Electromagnetic Compatibility ......................................................... 58
Introduction

Overview of Manual

This manual describes the implantation and usage of the Vercise™ Deep Brain Stimulation (DBS) System. The Vercise DBS System features a Stimulator coupled with DBS Leads and DBS Extensions. In this manual you will also find detailed descriptions of each system component. Additional information about programming the Vercise DBS System programming can be found in the DBS Programming Manual.

Intended Use / Indications for Use

The Vercise Deep Brain Stimulation (DBS) System is indicated for use in bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

System Description

The Vercise 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 rechargeable Vercise DBS System utilizes current steering across eight contacts per DBS Lead, which is intended to provide precise positioning of stimulation. The Stimulator is controlled by a handheld Remote Control, and can be interfaced with a Clinician’s Programmer using the Bionic Navigator™ Software. Periodically, the Stimulator battery must be replenished with a radiofrequency (RF) charging device provided in the Patient DBS Charging Kit.

Note: This product contains no detectable latex.
Safety Information

Contraindications

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

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™ 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 DBS System (Leads, Extensions, and Stimulator) should not be subjected to MRI. MRI exposure may result in:

- 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 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 and Charging System should not be implanted with the Vercise DBS System.

Poor Surgical Candidates. The Vercise 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. Whenever possible, the current amplitude and pulse width should be programmed such that the charge density is below 30 µC/cm² per stimulation phase. To maintain safety limits, the software will display a warning when the level of stimulation exceeds 30 µC/cm² per stimulation phase; however, the software allows the stimulation to be adjusted above this level by the physician.

Patients may have the ability to change the amplitude with the Remote Control. Set and verify the maximum and minimum amplitude levels allowed by the Remote Control to ensure that current levels remain safe.

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:

- 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. Stimulators, such as the Vercise™ Stimulator, may interfere with the operation of implanted devices such as pacemakers, cardioverter defibrillators, or medication delivery pumps. The effects of implanted stimulation devices on neurostimulators, such as the Vercise DBS System, are unknown.

Automobiles and Equipment. Patients should operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with caution after receiving the Vercise 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 hurt an unborn baby.
Precautions

Physician training is required for usage of the Vercise™ 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 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 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, Clinician Programmer, and Charger that were provided with the Boston Scientific Vercise™ DBS System should be used with the Vercise DBS System. Other models of these devices will not function with the Vercise 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/or a revision surgery.

Never attempt to change the orientation of or turn over the Stimulator. Patients should avoid touching the Stimulator site or incisions. 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.

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 DBS Leads’ insulation 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.
Patient Activities. 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 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.

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.
- Inspect the seal integrity and sterile indicator on the inner tray. The sterile indicator will be green with red stripes if sterile. Yellow stripes indicate the tray is not sterile. If the tray is not sterile, do not use the components and return to Boston Scientific.
- 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 and Remote Control is 5 to 40 °C (41 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 Stimulators, 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, ETS, 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, 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 pests, pets, 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 Charging System should not be disposed of in fire, as these components 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 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.

**Cleaning the Remote Control, External Trial Stimulator (ETS), Charger, Base Station, & Power Supply.** 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 the Charger, Base Station, or Power Supply 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 for treatment of Parkinson’s disease. 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 contact their 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 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
Safety Information

- 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
Package Contents

Contents of the Implantable Pulse Generator Kit

- Stimulator
- Stimulator Template
- Stimulator Header Plugs (2)
- Torque Wrench

*Note:* All contents of the inner package (or tray) are sterile.

Contents of the Lead Kit
(30 cm and 45 cm)

- DBS Lead with preloaded Straight Stylet
- Torque Wrench
- Lead Boot
- Lead Stop – Screw and Ring
- 1 cm Suture Sleeve
- 1 cm Split Suture Sleeve
- 2.3 cm Suture Sleeve
- 4 cm Suture Sleeve

*Note:* All contents of the inner package (or tray) are sterile and non-pyrogenic.

Contents of the Extension Kit
(55 cm)

- DBS Extension
- Torque Wrench
- Tunneling Tool Shaft (with Pre-Loaded Straw)
- Tunneling Tool Handle

*Note:* All contents of the inner package (or tray) are sterile.

Contents of the Tunneling Tool Kit
(28 cm, Straw and 35 cm, Long)

- Tunneling Tool Shaft (with Pre-Loaded Straw)
- Tunneling Tool Handle

*Note:* All contents of the inner package (or tray) are sterile.
Contents of the Spares Kit

- Lead Boot
- Lead Stop – Screw and Ring
- Torque Wrench
- 1 cm Suture Sleeve
- 1 cm Split Suture Sleeve
- 2.3 cm Suture Sleeve
- 4 cm Suture Sleeve

Note: All contents of the inner package (or tray) are sterile.

Other Components

- Remote Control with Batteries
- Remote Control Case
- Charger
- Base Station
- Power Supply
- Charging Collar (Small and Medium)
- Adhesive Patches
- Charging collar accessories (Charging Spacer and Counterweight)
- Clinician Programmer
  - Bionic Navigator™ 2.04 Installer
  - Keyboard
  - Tablet Pen
  - Power Cable for Tablet Computer
- External Trial Stimulator
- External Trial Stimulator Battery
- OR Cable and Extension
- IR Interface
- IR Interface Holder
- USB to Serial Cable
- Patient Travel Case
- Remote Control Kit (Remote Control, Batteries, Case)
- Charging Kit (Charger, Base Station, Power Supply, Charging Collar, and Accessories)
DBS Lead Implantation

This section describes the recommended procedures for implanting the Vercise™ DBS System. Procedures for DBS Lead insertion and intra-operative testing are outlined, followed by DBS Extension tunneling and Stimulator placement.

Note: Utilize meticulous care during implantation of the Vercise DBS System to prevent infection.

Pre-Conditions

The described implant procedures start with implanting the DBS Lead. It is assumed that the following procedures have been completed:

- The stereotactic frame and/or fiducials of a frameless system are attached to the patient.
- The desired trajectory of the DBS Lead insertion path has been determined.
- The incision in the scalp has been made and the burr hole drilled.
- If using the SureTek™ Burr Hole Cover, the Base of the Burr Hole Cover has been affixed over the burr hole. (See the manual provided with the Burr Hole Cover Kit for instructions for use.)
- The desired trajectory and DBS Lead depth may have been verified by microelectrode recording or an appropriate means.
### Implanting the DBS Lead

1. Prepare DBS Lead for implant. Visually inspect the DBS Lead and determine it to be acceptable for implantation.

2. Pass the DBS Lead through the cannula to ensure proper fit.

3. Insert the cannula (with stylet) into the brain to the desired depth.

   **Note:** Cannula depth depends on physician’s preference.

4. Assemble the Lead Stop by partially screwing the threaded portion of the Screw into the threaded hole in the Ring.

5. Measure the desired depth of DBS Lead with a gauge or ruler and apply the DBS Lead Stop at that length.

   To apply the DBS Lead Stop, push the DBS Lead to the center of the Lead Stop and then tighten the Screw. This will ensure that the DBS Lead will be inserted to the proper depth.

   **Note:** Make sure the Lead Stop will not slide on the DBS Lead when engaged.

6. Insert the DBS Lead, with the stylet in place, into the cannula.

7. Insert the DBS Lead and the cannula into the cannula guide on the microdrive.

8. Attach the DBS Lead to the microdrive.

9. Check that the locking lever on the OR Cable connector is in the open (0) position.

10. Slide the proximal end of the DBS Lead, with stylet, into the open port on the OR Cable connector.

   **Note:** The descriptors “proximal” and “distal” use the Stimulator as the reference throughout this manual.
11. Push the end of the DBS Lead into the port until it stops. Hold the DBS Lead in place while sliding the locking lever to the locked (1) position.

12. Secure the OR Cable connector to the microdrive.

Note: Make sure the stylet is inside the DBS Lead before advancing the Lead to the desired target.

13. Slowly advance the DBS Lead to the desired target using the microdrive.
Intraoperative Stimulation Testing

The ETS, OR Cable, OR Cable Extension, and Clinician Programmer (CP) may be used to conduct intraoperative stimulation testing during the procedure. The OR Cable Extension is designed for temporary connection to the OR Cable to facilitate stimulation testing outside of the sterile field.

Note: The following steps are for procedural reference only. Please refer to the DBS Programming Manual for instructions on setting and adjusting programming parameters.

CAUTION: Do not immerse the OR Cable connector or plug in water or other liquids. The OR Cable is intended for one-time use only; do not resterilize.

CAUTION: The External Trial Stimulator (ETS) may be damaged by electrostatic discharge. This can be mitigated by touching a large metal object before touching the ETS.

1. Attach the OR Cable Extension to the OR Cable.
2. Verify that the ETS is off.

WARNING: Always turn the ETS off before connecting or disconnecting the Cable Assemblies to prevent unexpected stimulation.

3. Plug the OR Cable into the ETS socket labeled “1-L.” If two DBS Leads are being used, connect the left DBS Lead to socket “1-L” and the right DBS Lead to socket “2-R.”

4. Verify impedances are acceptable by using the CP or Remote Control to measure monopolar impedances.

If using the CP, high impedance contacts will contain a red X. If using the Remote Control, high impedance contacts are represented by hollow rectangles.

Note: If using the Remote Control, press ▼ to view the impedance values.
5. Evaluate DBS Lead placement by appropriate means. Adjust the DBS Lead location or stimulation parameters if necessary.

**Note:** The stylet shall remain in place throughout DBS Lead insertion and adjustments.

**WARNING:** High charge density can cause permanent tissue damage. A warning will pop-up on the Clinician Programmer screen if the stimulation parameters will cause the charge density to exceed 30 µC/cm².

**WARNING:** Increasing the number of DBS Lead penetrations increases the probability of hemorrhage. The necessity for an acute DBS Lead revision should be minimized using techniques of target localization, such as microelectrode recordings and imaging, to correctly place the DBS Leads on the first attempt.

6. Turn off the ETS.

**WARNING:** A sudden increase in stimulation may occur if ETS is ON while disconnecting the OR Cables.

7. Disconnect the OR Cable and OR Cable Extension from the proximal end of the DBS Lead.

8. Verify that the DBS Lead has not moved from the desired location.
Securing the DBS Lead

Once a DBS Lead has been placed, it should be secured.

**CAUTION:** While securing the DBS Lead, use care not to move it.

1. Remove the Lead Stop by unscrewing the Screw and detaching the Lead Stop from the DBS Lead.
2. Slowly retract the cannula to just above the burr hole by sliding it over the proximal portion of the DBS Lead. Be careful not to move the DBS Lead.

**Note:** The descriptors “proximal” and “distal” use the Stimulator as the reference throughout this manual.

3. Fix the Lead in place. The SureTek™ Burr Hole Cover Kit is recommended for use with the Vercise™ System. (An appropriate commercially available filler may also be used.*) Fill the burr hole with an appropriate commercially available filler, such as hydroxyapatite (not provided), using the manufacturer's instructions.

**Note:** Remove any bone wax from the bone interface before applying the adhesive.

**Note:** Ensure that the adhesive is level with the superior surface of the skull.

4. Allow the adhesive to set according to the manufacturer’s instructions.
5. Remove the Stilet.
6. Remove the stereotactic frame and microdrive system.

**WARNING:** Do not reinsert the stylet into the DBS Lead while the DBS Lead is in the brain, as this may damage the DBS Lead and/or cause patient harm.

7. If the Stimulator will be implanted during a separate surgery, prepare the DBS Lead for the Stimulator Implantation procedure.
   a. Place a Suture Sleeve on the left DBS Lead to differentiate the Leads.
   b. Insert proximal end of the DBS Lead into the Lead Boot until it stops.

**Note:** Be sure to fully insert the proximal tip of the DBS Lead into the Lead Boot (see below) so that the retention sleeve is located under the Setscrew.

**Note:** The retention sleeve is easily distinguishable from the contacts by its length (see below).

*a* DBS Lead secured and tested utilizing Biomet Mimix QS bone void filler, a Stryker 12 mm titanium mini plate, Stryker titanium screws, and a Boston Scientific 1 cm split suture sleeve. Data on file.
d. Tighten the Setscrew until the Torque Wrench clicks, indicating the Setscrew is fully secured.

**Note:** To tighten the Setscrew, use one hand to grasp the Lead Boot at the base and the other to rotate the Torque Wrench clockwise until it clicks, indicating the Setscrew is fully secured. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

**CAUTION:** The wrench is torque limiting, such that the Setscrew cannot be over tightened. Use only the wrench provided, as other tools may over-tighten the Setscrew and damage the DBS Lead.

e. Create a tunnel, for the proximal end of the DBS Lead, to a place closer to the desired DBS Extension connector location.

**Note:** Boston Scientific recommends placing the DBS Extension connector behind the ear.

**CAUTION:** Placement of the DBS Extension connector in the neck region can increase the risk of device failure due to repetitive movement of the neck.

f. Create a pocket under the skin for the excess DBS Lead and Lead Boot.

g. Coil excess DBS Lead material under the scalp, in the pocket, until it is ready to be connected to the DBS Extension.

**Note:** The DBS Lead may be connected to the DBS Extension and Stimulator during a separate surgery at a later time. See Stimulator Implantation.

8. Repeat the *Implanting the DBS Lead* procedure for the second DBS Lead. Use the Tunneling Tool to tunnel the second DBS Lead to the same side as the first Lead.

9. Close the incisions.
**Stimulator Implantation**

The Stimulator may be implanted immediately following DBS Lead implantation and intra-operative testing or during a separate surgery.

**Exposing the DBS Lead**

1. Palpate the DBS Lead Boot and DBS Lead under the scalp.
2. Mark and create an incision in the scalp to expose the Lead Boot. Be careful not to damage or cut the DBS Lead.
3. Expose the DBS Lead and Lead Boot through the incision.
4. Using the Torque Wrench, remove and discard the Lead Boot.

*Note:* To loosen the Setscrew, rotate the Torque Wrench counterclockwise. To tighten the Setscrew, rotate the Torque Wrench clockwise.
5. Dry the proximal end of the DBS Lead.

**Connecting the DBS Lead to the DBS Extension**

1. Check to ensure that the Setscrew is not restricting the entry port on the DBS Extension connector by unscrewing the Setscrew one to two turns with the Torque Wrench. Grip the DBS Lead next to the Retention Sleeve.

*Note:* The retention sleeve is easily distinguishable from the contacts by its extended length.
2. Push the DBS Lead into the DBS Extension connector until the DBS Lead electrodes line up with the DBS Extension contacts. Some resistance may be felt as each electrode enters into the DBS Extension Connector. You should be able view the DBS Lead electrodes as they pass through the DBS Extension Connector. Some additional resistance may be felt as the last electrode aligns into place.
3. Visually check to ensure that the DBS Lead electrodes are aligned with the DBS Extension contacts. If they are not aligned, continue to grip the DBS Lead next to the Retention Sleeve and push to advance the electrodes into alignment with the DBS Extension contacts. If necessary, back out the Lead slightly and then advance the electrodes into alignment again, until proper alignment can be confirmed.

   **Note:** Be sure to fully insert the DBS Lead into the connector so that the retention sleeve is located under the Setscrew.

4. Do not tighten the Setscrew at this time.

5. Repeat steps 1 through 4 to connect the second DBS Lead to the second DBS Extension.

6. Test the impedance of the connection to ensure that you have properly aligned the DBS Lead within the DBS Extension connector. Use the ETS, OR Cable, OR Cable Extension, and Clinician Programmer (CP) to test the impedance. The OR Cable Extension is designed for temporary connection to the OR Cable to facilitate stimulation testing outside of the sterile field.

   **Note:** The following steps are for procedural reference only. Please refer to the DBS Programming Manual for detailed impedance testing procedures and guidelines.

   **CAUTION:** Do not immerse the OR Cable connector or plug in water or other liquids. The OR Cable is intended for one-time use only; do not resterilize.

7. Attach the OR Cable Extension to the OR Cable.

8. Verify that the ETS is off.

   **WARNING:** Always turn the ETS off before connecting or disconnecting the Cable Assemblies to prevent unexpected stimulation.

9. Plug the OR Cable into the ETS socket labeled “1-L.” If two DBS Leads are being used, connect the left DBS Lead to socket “1-L” and the right DBS Lead to socket “2-R.”

10. Verify impedances are acceptable by using the CP or Remote Control to measure monopolar impedances.

    If using the CP, high impedance contacts will contain a red X. If using the Remote Control, high impedance contacts are represented by hollow rectangles.

   **Note:** If using the Remote Control, press ▼ to view the impedance values.
Assembling the Tunneling Tool

A Tunneling Tool and Straw are provided to facilitate tunneling of the DBS Extension.

1. Attach the Tunneling Tool Handle to the Shaft by turning the locking mechanism clockwise.
   a. Push the locking mechanism at the base of the Tool Handle onto the Shaft.
   b. Grasping the Tool Handle and the Tip of the Tunneling Tool, rotate the Shaft back and forth until the handle seats onto the Shaft.
   c. While firmly grasping the Tip of the Tunneling Tool to hold the Shaft stationery, turn the locking mechanism clockwise until secure.
Tunneling the DBS Lead and Extension

1. Create a pocket for the Stimulator under the skin in a location inferior to the clavicle on the same side as the DBS Lead and Extensions.

   **Note:** *Boston Scientific recommends implanting the Stimulator subclavicularly.*

   a. Mark the location of the pocket.
   b. Use the template to outline the intended pocket to guide the optimal pocket sizing.
   c. Make the pocket no deeper than 2 cm; Stimulator charging could become ineffective at greater depths.

   **Note:** *It is important to keep the pocket small to prevent the Stimulator from turning over.*

2. Mark a tunneling route from the location of the subclavicular pocket to the incision superior to the ear.

3. Administer appropriate local anesthetic along the tunneling route.

   **CAUTION:** *Be sure not to puncture or damage the DBS Lead or other components when administering local anesthetic.*

4. Create a subcutaneous tunnel from the incision above the ear, along the tunneling path to the Stimulator pocket.

   **WARNING:** *Be careful not to puncture or damage important structures along the tunneling path, such as the brachial plexus and jugular, as this may cause patient harm.*

5. If desired, bend the Tunneling Tool to an appropriate shape.

   **CAUTION:** *Do not bend locking joints.*

6. Once the Tip of the Tunneling Tool is completely exposed, unscrew and remove the Tunneling Tool Handle.

7. Grasp the Tip firmly with one hand and, while holding the Straw in place with the other hand, pull the Shaft out of the Straw.

8. Push the proximal ends of the DBS Extensions through the Straw, and then withdraw the Straw.

9. Optionally secure the DBS Extension connector to the fascia using sutures and/or suture sleeves.

   **CAUTION:** *Do not use polypropylene sutures as they may damage the suture sleeve. Do not suture directly onto the DBS Extension or use a hemostat on the DBS Extension body. This may damage the DBS Extension insulation.*
Connecting the Stimulator

Dual DBS Lead Connection

| Connect Left DBS Extension to port 1-L | Connect Right DBS Extension to port 2-R |

1. Fully insert the male end of the DBS Extension into the Stimulator until it stops.
   a. Ensure the Stimulator is charged prior to implantation.
   b. Insert the header plug to verify no Setscrews obstruct the socket.
   c. Wipe the DBS Extension contacts before inserting.
   d. Insert the DBS Extension into the header. When fully inserted, the tip of the DBS Extension will slide into the back of the port and the retention sleeve on the DBS Extension will be located under the Setscrew.

CAUTION: Verify proper DBS Extension insertion by checking impedances before tightening the Setscrew. Tightening the Setscrew down onto a contact can damage the DBS Extension.
2. Verify that the retention sleeve on the DBS Extension is located directly under the Setscrew in the Stimulator header.

![Correct](image1.png) ![Incorrect](image2.png)

**Note:** The retention sleeve is easily distinguishable from the contacts by its length (see below).

Proximal End of the DBS Extension

Contacts Retention Sleeve

3. Check impedances to verify connections before tightening the Setscrew.

4. Pass the Torque Wrench through the slit in the septum located on the top of the Stimulator header.

5. Tighten the Setscrew in the Stimulator until the Torque Wrench clicks, indicating the Setscrew is fully secured.

**Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

**CAUTION:** The wrench is torque limiting, such that the Setscrew cannot be over tightened. Use only the wrench provided, as other tools may over-tighten the Setscrew and damage the DBS Lead.

6. Check impedances to verify connections before tightening the Extension Setscrew.

**CAUTION:** Verify proper DBS Lead insertion by checking impedances before tightening the Setscrew. Tightening the Setscrew down onto a contact can damage the DBS Lead.

7. Pass the Torque Wrench through the slit in the septum located on the top of the DBS Extension connector.
8. Tighten the Setscrew in the DBS Extension connector until the Torque Wrench clicks, indicating the Setscrew is fully secured.

CAUTION:  The wrench is torque limiting, such that the Setscrew cannot be over tightened. Use only the wrench provided, as other tools may over-tighten the Setscrew and damage the DBS Lead.

Note:  To tighten the Setscrew, use one hand to grasp the Extension at the base and the other to rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

Note:  If a port plug is used, it is still necessary to tighten the Stimulator setscrew on the port plug as described above.

9. Repeat steps 1 through 8 to insert the second Extension into the Stimulator header, tighten the second Stimulator Setscrew on the second DBS Extension, and tighten the second Extension setscrew on the second DBS Lead.

10. Place the Stimulator in the subcutaneous pocket with the etched writing “This Side Up” facing the skin, and parallel to the skin surface.

WARNING:  Failure to orient the correct side of the Stimulator towards the skin may result in the inability to charge and/or a revision surgery.

   a. Coil the excess DBS Extension length around the Stimulator perimeter.

WARNING:  Avoid placing the excess DBS Extension length on the superficial surface of the Stimulator, as this may increase the potential for tissue erosion or damage during Stimulator replacement surgery and may interfere with charging.

   b. Optionally secure the Stimulator to the fascia by suturing through the holes in the Stimulator header.

11. Close the incisions.

CAUTION:  Be careful not to damage the DBS Lead, Stimulator, or other implanted components when closing the incisions.

Note:  When closing the incision over the Extension connector, orient the Extension connector to minimize the profile under the skin.
Vercise™ DBS System Revisions & Explantation

If the entire Vercise DBS System (Stimulator, DBS Extensions, and DBS Leads) is to be removed, then the DBS Leads should be removed first (as described below) followed by the DBS Extensions, and lastly the Stimulator. This order should reduce the potential spread of infection toward the skull opening.

Explanting the DBS Lead

**WARNING:** When explanting the Vercise DBS System, the DBS Lead should be pulled from the site above the ear and not the site near the burr hole to avoid a potential spread of infection toward the skull opening.

1. Turn off the Stimulator.
2. Palpate the scalp to locate the burr hole cover (BHC).
3. Make an incision near the BHC to expose the BHC and DBS Lead. Be careful not to damage or cut the DBS Lead or suture sleeve.
4. Cut the DBS Lead at a distance about 2 to 3 cm from the BHC, leaving enough length to grasp the Lead.
5. Unscrew the screws anchoring the BHC and gently remove the BHC.
6. If necessary, use appropriate methods to remove the DBS Lead from the adhesive.
7. Slowly and gently retract the DBS Lead from the neural tissue, pulling as close to perpendicular to the skull as possible. The DBS Lead should experience minimal resistance when retracted.
8. Palpate the region under the scalp to locate the DBS Extension connector.
9. Create an incision to expose the DBS Lead and DBS Extension connector. Be careful not to damage the implanted components to allow for proper analysis following explant.
10. Loosen the connector Setscrew on the DBS Extension using the Torque Wrench provided.

**Note:** Be sure to fully insert the Torque Wrench before loosening the Setscrew.

**Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

11. Remove the DBS Lead from the DBS Extension.
12. Gently pull the remainder of the DBS Lead through the incision behind the ear.

**WARNING:** The DBS Lead should be pulled from the site behind the ear and not the site near the burr hole to avoid a potential spread of infection toward the skull opening.

13. If you are replacing the DBS Lead, follow the instructions in the Implanting the DBS Lead section.

    If you are explanting the entire Vercise™ DBS System, continue on to the Explanting the DBS Extensions procedure.

    Otherwise, close the incisions.
Explanting the DBS Extensions

1. Turn off the Stimulator.
2. Palpate the region under the scalp to locate the DBS Extension connector.
3. Create an incision to expose the DBS Lead and DBS Extension connector. Be careful not to damage the implanted components to allow for proper analysis following explant.
4. Cut the DBS Extension(s) at the tapered (proximal) end of the connector.
5. Loosen the connector Setscrew using the Torque Wrench provided.

**CAUTION:** Loosen the Setscrew only as much as necessary to remove the DBS Lead. Loosening the Setscrew too much will cause it to fall out.

**Note:** To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

7. Expose and disconnect the DBS Extensions from the Stimulator by following the procedure in *Explanting or Replacing the Stimulator*.
8. Gently pull the DBS Extension through the tunnel from the Stimulator site.

**WARNING:** Avoid pulling towards the ear to reduce the potential for infection of the DBS Leads.


**Note:** If the DBS Extension has broken, then it may be necessary to make additional incisions or to pull one end of the DBS Extension out at the Stimulator site and the other end from the DBS Extension connector site.
Explanting or Replacing the Stimulator

1. Turn off the Stimulator.

2. Palpate the subclavicular area to locate the Stimulator.

3. Surgically open the pocket where the Stimulator is located. Be careful not to damage the implanted components to allow for proper analysis following explant.

CAUTION: Do not use electrocautery as it will damage the Stimulator.

Note: The incision should be large enough to remove the Stimulator from the pocket.

4. Withdraw the Stimulator from the pocket.

5. Using the Torque Wrench, unscrew the header Setscrews to release the DBS Extensions.

CAUTION: Loosen the Setscrew only as much as necessary to remove the DBS Extension. Loosening the Setscrew too much will cause it to fall out.

Note: To tighten the Setscrew, rotate the Torque Wrench clockwise. To loosen the Setscrew, rotate the Torque Wrench counterclockwise.

6. Remove the DBS Extensions from the Stimulator.

7. If the Stimulator is to be replaced, reconnect the new Stimulator by following the procedures in Connecting the Stimulator.

8. If the DBS Extensions will remain implanted, you may optionally clean the proximal ends of the DBS Extensions, attach Lead Boots (as described in the Securing the DBS Lead section), and coil the excess DBS Extension material in the pocket.

9. Close the incision.

10. Ship the explanted Stimulator to Boston Scientific.

CAUTION: Be careful not to damage any remaining implanted components when closing the incision.
The Vercise™ Stimulator

The Vercise 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 recharging routine may vary depending on their stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharging schedule that fits the patient’s schedule and lifestyle while maintaining sufficient charge to maintain stimulation.

Note: Variations in charging routine do not affect or diminish the battery life of the Stimulator.

Developing a patient’s recharging schedule involves finding the right balance between four factors:

- How much power is required for the patient to experience effective therapy.
- How often the patient wants to recharge.
- How long the patient wants to recharge.
- How the patient would like to manage their personal schedule.

The Clinician Programmer (CP) will estimate charging time based on 24 hours per day of stimulation at the programmed settings. Patients should be instructed to charge either a little every day (for 15 to 30 minutes) or fully charge once every 1 to 2 weeks (for 3 to 4 hours). If fully charging the Stimulator, patients should be instructed to charge until the Charger emits the end of charge double beep. The recharging process is simple, but important.

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. For example, a Stimulator with settings requiring charging every 22 days during the first year, is expected to require charging every 20 days after five years of continuous use (amplitude = 3 mA, pulse width = 60 μsec, rate = 185 Hz, impedance = 1500 Ohms). The Stimulator will need replacement when stimulation can no longer be maintained with routine charging.

Stimulator Battery

When the Remote Control communicates with the Stimulator, the battery status is sent to the Remote Control.

The Remote Control displays a battery graphic near the top center of the screen to indicate the battery level of the Stimulator. The graphic is easy to understand: three filled-in bars means that the Stimulator has a fully-charged battery.

Note: The battery graphic indicates the battery level of the Stimulator, not the Remote Control.

As the battery strength wears down, depending on the stimulation parameters and usage, the bars will empty, as shown in the chart below. For complete information on maintaining the Stimulator’s battery, see Charging the Stimulator.

<table>
<thead>
<tr>
<th>Battery Graphic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🟢🟢🟢</td>
<td>The Stimulator’s battery is full.</td>
</tr>
<tr>
<td>🟢🟢</td>
<td>The Stimulator’s battery is ok.</td>
</tr>
<tr>
<td>🟢</td>
<td>The Stimulator’s battery is low.</td>
</tr>
</tbody>
</table>
Stimulator Battery Messages

When the Stimulator’s battery is low, the Remote Control will display a “Recharge Stimulator Soon” message. The Stimulator should be recharged as soon as possible.

![Recharge Stimulator Soon](image1)

If the Stimulator is not recharged and the Stimulator’s battery becomes very low, the Remote Control will display a “Recharge Stimulator Now” message. The Stimulator should be recharged immediately. Failure to recharge the Stimulator will lead to loss of stimulation within less than 24 hours. If the Stimulator turns off due to a very low battery, it will need to be charged for approximately two hours (with the Charger properly aligned) before it can be turned on again.

![Recharge Stimulator Now](image2)

If the patient reports that stimulation has stopped, instruct the patient to check the Stimulator battery status with the Remote Control.
The Charging System

WARNINGS:

- Do not charge while sleeping. This may result in a burn.
- Do not connect the Charger to any other device except to the Base Station provided with it.
- While charging, the Charger may become warm. It should be handled with care.
- Failure to use either the Charging Collar or an Adhesive Patch while charging, as shown in the Charging the Stimulator section, may result in a burn. If pain or discomfort is felt, the patient should cease charging and contact their physician.

The Charging System for the Stimulator consists of the Charger unit, a Base Station, and a Power Supply. The Base Station is designed to remain connected to a power outlet at all times. When it is not being used, keep the Charger on the Base Station so that it is always ready to deliver a charge.
Charging the Charger

1. Find a convenient electrical outlet, one that will not expose the Charging System components to water or direct heat.


3. Connect the Power Supply to the Base Station.

4. Place the Base Station on a flat surface.

5. Finally, place the Charger in the Base Station with the power button facing up until the indicator light turns green.

<table>
<thead>
<tr>
<th>Indicator Light Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>The Charger is fully charged and ready to charge the Stimulator.</td>
</tr>
<tr>
<td>Yellow</td>
<td>The Charger is partially charged. The Charger may still be used, but it may not be able to fully charge the Stimulator. To fully charge the Charger, place it in the Base Station.</td>
</tr>
<tr>
<td>Off</td>
<td>The Charger is off—or—the Charger battery is empty. If pressing the Power Button does not turn on the Charger, place the Charger in the Base Station to charge.</td>
</tr>
</tbody>
</table>

Charger Battery Service Life

The Charger battery has a typical service life of 500 charging cycles.

Charging the Stimulator

When charging the Stimulator, the patient must use the Charger with either the Charging Collar or an Adhesive Patch to hold the Charger over the Stimulator. The Adhesive Patches are made of non-reactive and Latex-free material suitable for most sensitive skin types.
Using the Charging Collar

1. When the indicator light is green, remove the Charger from the Base Station. *(The indicator light will go off, regardless of the ready status of the Charger.)*

2. If the patient’s Stimulator is in a shallow location or the patient has thin skin, instruct the patient to place the Charging Spacer at the back of the pocket in the Charging Collar. Patients with shallow Stimulators or thin skin will be able to charge faster with the Charging Spacer.

   **Note:** *Patients with Stimulators in a deep location should not use the Charging Spacer, as it may slow the speed of charging.*

3. Place the Charger into the appropriate pocket on the Charging Collar with the power button facing out. If the Stimulator is on the right side of the chest, place the Charger in the right pocket. If the Stimulator is on the left side of the body, place the Charger in the left pocket.

4. If using the Charging Spacer, make sure it is between the Charger and the back of the pocket.

5. Place the Counterweight in the pocket opposite of the Charger.

6. Place the Charging Collar over the neck with the pockets facing out, as shown.

7. For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See *Properly Aligning the Charger* to ensure you center the Charger over the Stimulator.

8. If the Charger is not centered over the Stimulator, you may need to adjust the length of the Charging Collar using the straps. Occasionally checking that the Charger is aligned over the Stimulator during your charging session is recommended.

   **Note:** *The Charging Collar can be placed under or over clothing. You should not wear tight fitting or heavy clothing over the Charger while charging to allow air flow around the Charger.*
Using the Adhesive Patch

1. When the indicator light is green, remove the Charger from the Base Station. *(The indicator light will go off, regardless of the ready status of the Charger.)*

2. Apply the Adhesive Patch to the backside of the Charger by peeling the clear liner from the patch and applying the white side with the blue stripe to the rear of the Charger, as shown to the right.

3. Remove the skin side beige liner from the adhesive (only good for one fixation).

4. For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See Properly Aligning the Charger to ensure you center the Charger over the Stimulator.

**WARNING:** *Do not put the Charger directly on the skin (e.g., without an Adhesive Patch). This may result in uncomfortable heating of the skin or a burn.*
Properly Aligning the Charger

1. Press the power button. The indicator light will come on again, and the Charger will begin beeping steadily to signal that it is searching for the Stimulator.

2. Place the Charger on the chest in the area of the Stimulator.

3. Position the Charger over the Stimulator.

   The beeping will stop when the Charger is partially aligned with the Stimulator, but the Charger should be fully aligned with the Stimulator for optimal charging. Charging time may increase if the Charger is not fully aligned with the Stimulator. To fully align the Charger over the Stimulator, position the bottom curve of the Charger approximately 1 cm lower than the bottom curve of the Stimulator, as shown below.

   You may use the tips of your index and middle fingers to help locate the Stimulator under the skin. Lay your fingers gently on the skin without applying pressure or gripping. You may use this method to locate the center of the Stimulator.

4. Secure the Charger over the Stimulator either by pressing the adhesive to the skin over the Stimulator, or letting go of the Charging Collar.

   **Note:** If the Adhesive Patch is accidentally located in the wrong place, or if the Charging Collar moves out of alignment, the Charger will start beeping again. Use a new Adhesive Patch or readjust the Charging Collar to place the Charger back into the fully aligned position.

   **Note:** Moving around while charging is acceptable, but be aware that the Charger must stay centered over the Stimulator for proper charging. Excessive movement may cause the Charger and Stimulator to become misaligned.
5. When the Charger emits a distinct double beep, press the power button to turn off the Charger and check the Stimulator’s battery with the Remote Control.

6. If the Stimulator is fully charged, remove the Charging Collar or Adhesive Patch from your body.

7. Separate the Charger from the Charging Collar or Adhesive Patch. Set aside the Charging Collar or discard the Adhesive Patch.

8. Return the Charger to the Base Station.

Do not confuse the end of charge signal (a distinct double beep) with the steady, continuous misalignment signal.

**Note:** 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.

**Note:** The end of a charge signal is a distinct double beep, and the alignment indicator light is a steady, continuous signal.
The Remote Control

Basic Operation

The Remote Control communicates with the Stimulator through a radio frequency (RF) telemetry link from a distance of 18 inches (45 cm). When it is not being used, the Remote Control is in sleep mode from which it can be reactivated by any button press. During normal patient use, the Remote Control will transition to sleep mode automatically after 60 seconds of non-use.

1. Area Button
2. Up/Activate
3. Down/Save
4. Program Button
5. Stimulation On/Off

Some Remote Control functions (i.e., the Restore option and Clinician Mode) are accessed by pressing and holding a button (for approximately three seconds). These are identified in the appropriate sections following.

Remote Control Battery Life

The Remote Control uses three AAA batteries. Under typical usage, the Remote Control batteries will last 15 days before replacement is necessary.
Remote Control Position

You will achieve a strong communication link between the Remote Control and the implanted Stimulator if the Remote Control is positioned as shown in the picture below.

In some situations, you may need to bring the Remote Control closer to the Stimulator. The distance at which you will be able to achieve communication depends on your environment and the relative orientation of the Remote Control to the Stimulator.
Stimulator Linking

A Remote Control is restricted to communicating with one Stimulator at a time in order to prevent it from inadvertently controlling an unintended device. Therefore, the Remote Control must be linked with the Stimulator before use.

If the Remote Control is linked to a different Stimulator, you will need to clear the link before linking it to the new Stimulator. See Selection #3 – Clear Link in the Clinician Options section.

The initial step in the linking process involves the Remote Control identifying, by telemetry, the intended Stimulator for communication. The second step in establishing the link depends on whether:

- The Stimulator is an External Trial Stimulator or an implantable Stimulator.
- Programs are stored in either the Remote Control or Stimulator.
- The Remote Control and Stimulator contain different program sets (if so, one set will need to be cleared).

The Remote Control will display the following message upon first activation (when any button is pressed):

1. Ensure the Remote Control is within telemetry range of the Stimulator (45 cm or 18 in).
2. Press \( P \) to initiate communication between the Remote Control and the Stimulator. The Remote Control will identify the Stimulator by ID number.

3. Press \( P \) to confirm and continue.

The Remote Control will automatically detect available program sets in the Remote Control or Stimulator. If there are no available programs, the link will be completed immediately and you will see the screen below:

However, if programs are present in either device (Remote Control or Stimulator) during linking, you will be required to respond to one or more decision screens. Your decisions will guide the Remote Control to complete the linking with the desired program set saved to the desired device (Remote Control or Stimulator). You may also need to enter the clinician's password.

If an error occurs during the process or if the password is incorrect linking will be aborted. For further information, including information about the clinician's password, see Selection #3 – Clear Link in the Clinician Options section.
Stimulation On/Off

Stimulation is turned on and off via a dedicated power switch on the Remote Control keypad. Simply press the stimulation on/off button at any time – even when the Remote Control is in sleep mode – to change the stimulation status of the Stimulator.

Signal Strength

The Remote Control indicates the signal strength between itself and the Stimulator in the upper right corner of the display:

<table>
<thead>
<tr>
<th>Signal Strength</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚫⚫⚫</td>
<td>The Remote Control is achieving optimal communication with your Stimulator.</td>
</tr>
<tr>
<td>⚫⚫</td>
<td>The Remote Control is achieving good communication with your Stimulator.</td>
</tr>
<tr>
<td>⚫</td>
<td>The Remote Control is achieving OK communication with your Stimulator.</td>
</tr>
<tr>
<td>⚫</td>
<td>The Remote Control is achieving weak communication with your Stimulator.</td>
</tr>
<tr>
<td>⚫</td>
<td>The Remote Control is achieving either very weak or no communication with your Stimulator.</td>
</tr>
</tbody>
</table>

Communication between the Remote Control and the Stimulator may or may not be achieved. To improve the communication speed, move the Remote Control closer to the Stimulator and position it as shown in Remote Control Position above.

After missing a telemetry message, the Remote Control will display the “Searching” screen. The Remote Control will then start looking for signal strength every second. Move to a better spot and wait for the signal strength to display. To cancel searching press .

**Note:** Avoid common sources of interference, such as televisions and computer monitors when trying to use the Remote Control.
Stimulation Amplitude

Whenever stimulation is turned on, or after the Remote Control is awakened from sleep mode, the Remote Control display defaults to the Level screen.

Note: When there is no button activity for more than 60 seconds, the Remote Control will transition to sleep mode and the display screen will be blank.

![Level Screen Example]

Usually, changes to the amplitude of stimulation will not be permitted using the Remote Control. In these cases, the physician should determine the optimal amplitude for stimulation therapy. However, for certain patients, physicians may allow patients to change stimulation levels.

If the physician has allowed control of the stimulation amplitude, press the ▲ or ▼ button from the Level screen to increase or decrease the amplitude. The triangular ramp in the center of the screen will fill as the stimulation amplitude increases.

Stimulator Battery

The Level screen also displays a battery graphic near the top center of the screen to indicate the battery level of the Stimulator. The graphic is easy to understand: three filled-in bars means that the Stimulator has a fully-charged battery.

![Level Screen Example]

Note: The battery graphic indicates the battery level of the Stimulator, not the Remote Control.

As the battery strength wears down, depending on the stimulation parameters and usage, the bars will empty, as shown in the chart below. For complete information on maintaining the Stimulator’s battery, see Charging the Stimulator.

<table>
<thead>
<tr>
<th>Battery Graphic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Battery Full]</td>
<td>The Stimulator’s battery is full.</td>
</tr>
<tr>
<td>![Battery OK]</td>
<td>The Stimulator’s battery is ok.</td>
</tr>
<tr>
<td>![Battery Low]</td>
<td>The Stimulator’s battery is low.</td>
</tr>
</tbody>
</table>
Program Selection

A stimulation program is a set of stimulation parameters that determine the patient’s therapy. A program may apply stimulation to up to four independent stimulation fields or areas, depending on how the program is set up. For example, one area may correspond to a right brain target, while another area may correspond to a left brain target. The Remote Control can store up to four programs – numbered 1 through 4 – for the patient to select and activate at any time.

<table>
<thead>
<tr>
<th>Graphic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Blank Program Slot" /></td>
<td>A blank program slot.</td>
</tr>
<tr>
<td><img src="image2" alt="Full Program Slot" /></td>
<td>A full program slot.</td>
</tr>
<tr>
<td><img src="image3" alt="Recently Activated Program" /></td>
<td>The most recently activated or saved program.</td>
</tr>
<tr>
<td><img src="image4" alt="Currently Selected Program" /></td>
<td>The currently selected program slot.</td>
</tr>
<tr>
<td><img src="image5" alt="Program Reminder" /></td>
<td>A reminder that the P button changes the selected program.</td>
</tr>
</tbody>
</table>

**Note:** If a patient tries to activate an empty program, nothing will happen.

To select a program:

1. Press the P button from the Level screen to go to the Program screen.

   From the Program screen, each additional P button press selects the next program number. Press  to select the previous program number. The black highlighted box shows where you are in the cycle. Pressing P from program 4 returns you to the Level screen. Pressing P from program 1 also returns you to the Level screen.

2. Press P or  to move until the program you want is highlighted.

3. Press ▲ to activate the program.

Once you have selected and activated a program, the Remote Control will return to the Level screen.
Modifying and Saving Programs

1. Press P as needed from the Level screen to cycle to the desired program.

   **Note:** The most recently retrieved or saved program will be underlined(_). Empty program slots are denoted by a blank box with no program number []. If a patient tries to activate an empty program, nothing will happen.

2. Press ▲ to activate the selected program.

3. After the Remote Control times out to the Level screen, you may change the amplitude of all areas in the program.

4. To save/store changes, select the program again and press ▼. You will be required to confirm the adjustment first.

5. Press P to confirm, or press the button to cancel the operation.

   **Note:** To save the modifications as a new program, simply select an empty [] program slot and press ▼ instead of overwriting the existing program.

Individual Area Amplitude

A program may apply stimulation to one area, or up to four areas, depending on how the program it set up. To adjust the amplitude of each area independently:

1. Press the button as needed from the Level screen to cycle to a specific stimulation area.

2. Press the ▲ or ▼ button to adjust the amplitude of the selected area.

Restore Option

With the Vercise™ DBS System, the “Restore” is readily available to all patients. The Restore feature allows patients to return a program to the original settings you programmed for them at the initial fitting or at a follow-up.

To access the Restore option:

1. Press and hold P approximately 3 seconds to reach Restore Program 1.

2. If necessary, press the P button again (normal press) to cycle through the programs and select the program to be restored.

3. Press ▲ to restore the last clinic-programmed settings.
Searching

In the event of communication interference, the Remote Control will automatically begin “searching” for the Stimulator. Try to reposition the Remote Control closer to the Stimulator to help it locate the Stimulator.

Clinician Options

Clinicians and physicians can access additional options in the Remote Control to set up the Vercise™ DBS System. These options are not available to patients.

Patient-restricted clinician screens provide access to:

- Remote Control and Stimulator clearing and relinking
- Communication with the clinician programmer
- Contact impedance monitoring

To access Clinician Options menu:

1. Press the \( \mathbf{1} \) and \( \mathbf{P} \) buttons simultaneously for approximately three seconds. The Enter Clinician Options menu will appear as shown below.

2. Press the ▲ or ▼ button to navigate the Clinician Options menu.

Each option is discussed in sequence below.

Selection #1 – Clinician Programmer (CP) Mode

1. From the Enter Clinician Mode menu, press the \( \mathbf{P} \) button to prepare the Remote Control for communication with the Clinician's Programmer (CP).

\[ \text{CP Ready} \]

\[ \text{CP Mode} \]

\[ \text{Impedances} \]

\[ \text{P} \]

\[ \text{P} \]

\[ \text{P} \]

\[ \text{P} \]

\[ \text{P} \]

Note:  The Remote Control will remain CP Ready for 15 minutes.

2. Place the Remote Control and the IR Interface in the IR Interface Holder with their communication ports facing.

3. Plug the serial end of the USB to Serial Adapter into Interface Holder.

4. Plug the USB to Serial Adapter into the USB port on the CP.

5. Power-on the CP.
6. Launch the Bionic Navigator™ Software and wait for the IR Communication Established display.

**Selection #2 – Impedances**

When the “Impedances” option is selected from the Enter Clinician Options menu, the Remote Control will take the measurements via telemetry; this will take a few seconds.

*Note: During this measurement the serial number of the Stimulator will be displayed on the screen.*

Eventually, the Remote Control will display the Contact Impedance Status screen.

Contacts 1 through 8 (Lead position 1-L) are represented by the rectangles in the top row; contacts 9 through 16 (Lead position 2-R) are represented by the rectangles in the bottom row.

Contacts within the acceptable impedance range are displayed as solid rectangles; high impedance contacts (above 4500 Ohms) are represented by hollow rectangles.

Pressing any key, except the δ Stim On/Off button, will display the value of the reading of contacts 1 through 8. Subsequent pressing of any key, except the δ Stim On/Off button, will show values for contacts 9 through 16.

Any key press other than the δ Stim On/Off button will show the Measure Again screen which allows for repeating the measurement or exiting this function.

*Note: The Remote Control will terminate the CP Ready state and transition to the sleep mode if there is no IR signal after 15 minutes.*

All buttons are active during CP Ready and pressing any button returns the Remote Control to the Level screen.

Stimulation may be turned on or off during CP Ready.

Once IR Communication is established, the Remote Control will terminate communication and transition to the sleep mode if there is no IR activity after 15 minutes.
All buttons are active during IR Communication and pressing any button returns the Remote Control to the Level screen.

Whenever the Remote Control is re-activated from sleep mode the display will default to the Level screen.

Selection #3 – Clear Link

When the “Clear Link” option is selected from the Enter Clinician Options menu, you will immediately be required to enter the clinician’s password in order to continue.

The password for the Clear Link option is A-B-C.

To enter the password:

The first character is highlighted when the Enter Password screen opens. To select/confirm any character and/or move to the next character position, press P. To scroll through possible characters, use ▲ or ▼.

Note: Do not share this password with patients, as they may unknowingly clear the link between their Remote Control and Stimulator.

When clearing a link:

If the password is entered correctly, the link between the Remote Control and the “previous” Stimulator is broken immediately, and the Remote Control displays the Not Linked screen. The Remote Control’s programs remain intact. If the password is entered incorrectly, the process is aborted and the Remote Control will return to the Enter Clinician Options screen.

Note: If the password is entered incorrectly during an attempt to link the Remote Control, the process is aborted and the Remote Control returns to the Sleep screen.

Selection #4 – Language

When the “Language” option is chosen from the Enter Clinician Options menu, you may scroll through the six language screens by pressing ▲ or ▼.

Use the P key to select English, Spanish, French, Italian, German, or Dutch when the language is highlighted.

Then, press P on the next screen to confirm the selection. The Remote Control language will now change to your selected language.
Stimulation Guidelines

Charge Density

The Clinician Programmer (CP) software provides a warning when the charge density at a contact is about to be programmed to exceed 30 µC/cm² per stimulation phase, as there is evidence of tissue damage above this level. However, the CP allows the stimulation to continue above this level.

![Graph displaying recommended maximum charge density of 30 µC/cm² for different combinations of current amplitude (mA) and pulse width (µs). These estimates of charge density are only for the Boston Scientific DBS Leads.

WARNING: Patients may have the ability to change the amplitude with the Remote Control. The physician should set and verify the maximum and minimum amplitude levels allowed by the Remote Control to ensure that current levels remain safe. Do not set the default amplitude outside of the minimum and maximum amplitude range.

Note: A warning will pop-up on the Clinician Programmer screen if the stimulation parameters will cause the charge density to exceed 30 µC/cm².
Detailed Device Description

General Component Description

The implantable portion of the Vercise™ DBS System includes a Stimulator and two DBS Leads. Other implantable components include the DBS Extensions that extend the DBS Leads to the Stimulator, a DBS Lead Boot to protect the proximal end of the DBS Lead between surgeries, and Sutures Sleeves to protect the DBS Lead and/or to anchor the DBS Leads and DBS Extensions.

The Tunneling Tool is a surgical instrument used to create a subcutaneous tunnel for the DBS Leads and DBS Extensions.

The patient will be provided with external devices including a Remote Control to communicate with the Stimulator and a Charger to recharge the battery of the Stimulator.

Stimulator Physical Characteristics

The physical characteristics of the Stimulator are outlined in Table 1. The Stimulator contains a radiopaque identification tag. The identification tag is visible using standard x-ray procedures.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>Titanium</td>
</tr>
<tr>
<td>Header</td>
<td>Epoxy</td>
</tr>
<tr>
<td>Dimensions</td>
<td>55 mm x 45 mm x 11 mm</td>
</tr>
<tr>
<td>Volume</td>
<td>20.7 cm³</td>
</tr>
</tbody>
</table>
Stimulator Programmable Characteristics

The stimulation parameters are independent for the two DBS Leads such that stimulation of two different brain targets can have different amplitudes, pulse widths, stimulation rates, and contact configurations. The two DBS Leads can also have differing monopolar and multipolar configurations; however, a given DBS Lead contact cannot be programmed as both monopolar and multipolar.

The programmable parameter ranges for the Stimulator are shown in Table 2.

Note: Some frequency combinations may not be used. See the DBS Programming Manual for specific frequency combinations.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waveform</td>
<td>Charge balanced, asymmetric biphasic</td>
</tr>
<tr>
<td>Pulse Shape</td>
<td>Rectangular</td>
</tr>
<tr>
<td>Current of Voltage Regulated</td>
<td>Current</td>
</tr>
<tr>
<td>Amplitude(^1)</td>
<td>0.1 to 20 mA</td>
</tr>
<tr>
<td>Rate(^2)</td>
<td>2 to 255 Hz</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>10 to 450 µs</td>
</tr>
<tr>
<td>Cycle (On/Off)</td>
<td>1 s to 90 min</td>
</tr>
<tr>
<td>Stim Ramp On</td>
<td>1 to 10 s</td>
</tr>
<tr>
<td>Contact Connections</td>
<td>16</td>
</tr>
<tr>
<td>Independent Areas of Stim (4 Programs with 4 Areas per Program)</td>
<td>16</td>
</tr>
<tr>
<td>Current Path Options</td>
<td>Unipolar, Bipolar, or Multipolar</td>
</tr>
</tbody>
</table>

\(^1\) The programmable coverage for each individual contact is limited to 12.7 mA. A programming interlock is enforced to limit the total output current to 20 mA or less per coverage area. For example, a maximum current output of 12.7 mA on one contact would limit the total summed current output on the remaining contacts to 7.3 mA within one coverage area.

\(^2\) The rate is limited to 255 Hz for a given area. The global rate limit for each Lead is also 255 Hz.
Stimulation Output at Maximum Parameters vs. Impedance. The above graph shows the maximum output current when stimulation settings are set to the maximum values on an electrode (Amplitude Max = 12.7 mA, PW = Various shown (450, 240, 120, 30 µs), Rate Max = 255 Hz). Please note that for typical parameters (PW = 60 µs, Rate = 130 Hz, Amplitude = 3 mA), these limits are not expected to be reached.

**WARNING:** Although the CP utilizes warnings to aid clinicians in their determination of safe charge density levels, the primary responsibility of keeping safe current levels resides with the clinician. Additionally, maximum and minimum amplitude levels allowed by the Remote Control should be set and verified by the physician to ensure that these levels are safe.
**DBS Lead**

The DBS Lead consists of 8 cylindrical contacts. The outer diameter of the DBS Lead and contacts is 1.3 mm and is compatible with existing commercially available DBS implantation tools, such as stereotactic surgical equipment. The DBS Lead can be implanted and attached to the Stimulator for bilateral stimulation.

Table 3: DBS Lead

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Contacts</td>
<td>8</td>
</tr>
<tr>
<td>Contact Length</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>Contact Surface Area</td>
<td>6.0 mm²</td>
</tr>
<tr>
<td>Contact Spacing (Center-to-Center)</td>
<td>2.0 mm</td>
</tr>
<tr>
<td>Contact Span</td>
<td>15.5 mm</td>
</tr>
<tr>
<td>Distal Contact to Tip Length</td>
<td>&lt; 1.3 mm</td>
</tr>
<tr>
<td>Diameter</td>
<td>1.3 mm</td>
</tr>
<tr>
<td>Overall Length</td>
<td>30 cm, 45 cm</td>
</tr>
<tr>
<td>Outer Jacket Tubing (Insulation)</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Contact Material</td>
<td>Platinum/Iridium</td>
</tr>
<tr>
<td>Impedance</td>
<td>≤ 90 Ω (measured from each connector to corresponding electrode contact)</td>
</tr>
</tbody>
</table>
DBS Extension

The DBS Extension consists of a connector at the distal end and 8 cylindrical contacts at the proximal end. The DBS Lead may be inserted and secured into the connector, which also contains 8 contacts that align with the contacts on the DBS Lead to form electrical connections. The DBS Extension can be implanted and attached to the Stimulator and the DBS Lead for bilateral stimulation.

Table 4: DBS Extension

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Length</td>
<td>55 cm</td>
</tr>
<tr>
<td>Outer Diameter</td>
<td>1.35 mm</td>
</tr>
<tr>
<td>Number of Contacts</td>
<td>8</td>
</tr>
<tr>
<td>Contact Material</td>
<td>Platinum/Iridium</td>
</tr>
<tr>
<td>Insulation Material</td>
<td>Polyurethane, Silicone</td>
</tr>
</tbody>
</table>
DBS Lead Boot

The DBS Lead Boot protects the proximal end of the DBS Lead prior to the Stimulator implant surgery. The Setscrew, when engaged, secures the DBS Lead in the Lead Boot.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Length</td>
<td>3.3 cm</td>
</tr>
<tr>
<td>Setscrew</td>
<td>Titanium</td>
</tr>
<tr>
<td>Connector Block</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>End Stop</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Insulation Material</td>
<td>Silicone</td>
</tr>
</tbody>
</table>
Suture Sleeve

The Suture Sleeve is placed between the DBS Lead and the mini plate to protect the DBS Lead. The Suture Sleeve may also be used to anchor the DBS Lead or DBS Extension to the fascia.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Length</td>
<td>1 cm, 2.3 cm, 4 cm</td>
</tr>
<tr>
<td>Material</td>
<td>Silicone</td>
</tr>
</tbody>
</table>
Tunneling Tool

The Tunneling Tool is used to create a path for the DBS Lead and DBS Extension in the subcutaneous tissue.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>28 cm (Straw), 35 cm (Long)</td>
</tr>
<tr>
<td>Shaft Material</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Straw Material</td>
<td>PTFE</td>
</tr>
<tr>
<td>Handle Material</td>
<td>Stainless Steel, Ultem</td>
</tr>
</tbody>
</table>
Programmer Communication

The Clinician Programmer (CP) can communicate with a Stimulator. In order to begin a programming session, the CP and the Remote Control Infrared (IR) windows must be aligned.

1. Turn on the CP and the Bionic Navigator™ Software will boot-up.
2. Enter the Clinician Options menu on the Remote Control by pressing the and buttons simultaneously.
3. Select CP Mode.
4. When the Remote Control displays “CP Ready,” put the IR Interface and Remote Control into the IR Interface Holder to keep the IR windows aligned.

**Note:** Orient the IR Interface with the yellow circle facing down to maximize communication.

5. Plug the serial end of the USB to Serial Adapter into the IR Interface.
6. Plug the USB to Serial Adapter into the USB port on the CP.
7. Position the patient within 60 cm (2 ft) of the Remote Control to ensure a complete communication link from the programmer to the Stimulator (see Remote Control Position).

**Note:** A message will be displayed on the Clinician Programmer if the communication range is not satisfactory.

For more detailed instructions on how to use the Clinician Programmer and Bionic Navigator Software with the Vercise™ DBS System, see the DBS Programming Manual.
Labeling Symbols

The symbols used in the labeling of the Vercise™ system internal and external components are as follows:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE 0123</td>
<td>European Community Mark of Conformity. Authorized to affix the CE Mark in 20xx.</td>
</tr>
<tr>
<td>Single use. Do not re-use.</td>
<td></td>
</tr>
<tr>
<td>Rx ONLY</td>
<td>Prescription Only</td>
</tr>
<tr>
<td>Do Not Resterilize</td>
<td></td>
</tr>
<tr>
<td>REF</td>
<td>Model Number</td>
</tr>
<tr>
<td>MR Unsafe</td>
<td></td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>MR Conditional</td>
<td></td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>Type BF Applied Part</td>
<td></td>
</tr>
<tr>
<td>Use By Date</td>
<td>Class II Equipment</td>
</tr>
<tr>
<td>Contents</td>
<td>Separate Collection</td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td>Keep Dry</td>
</tr>
<tr>
<td>XX-####-R</td>
<td>R stands for refurbished products.</td>
</tr>
<tr>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>Do not use if package is damaged.</td>
<td>Humidity Limitation</td>
</tr>
<tr>
<td>Caution. Attention: Consult accompanying documents.</td>
<td>Temperature Limitation</td>
</tr>
<tr>
<td>Consult Instructions for Use</td>
<td>Legal Manufacturer</td>
</tr>
<tr>
<td>Follow Instructions for Use</td>
<td>EU Authorized Representative</td>
</tr>
<tr>
<td>Sterile EO</td>
<td>Sterilized using ethylene oxide.</td>
</tr>
<tr>
<td>AUS</td>
<td>Australian Sponsor Address</td>
</tr>
<tr>
<td>Non-Sterile</td>
<td></td>
</tr>
</tbody>
</table>
## 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 DBS System is intended for use in electromagnetic environment specified below. The customer or the user of the Vercise DBS System should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Vercise 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The Vercise 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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV</td>
<td>Air: Remote Control and Charger: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV ETS: ± 2 kV, ± 4 kV, ± 8 kV Contact: Remote Control and Charger: ± 8 kV ETS: ± 6 kV</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Contact: ± 8 kV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>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.</td>
</tr>
</tbody>
</table>
The Vercise DBS System is intended for use in the electromagnetic environment specified below. The customer or the user of the Vercise DBS System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6 (ETS only)</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz to 80 MHz Professional healthcare facility environment and home healthcare environment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz</td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m 80 MHz to 2.7 GHz Professional healthcare facility environment and home healthcare environment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, 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:</td>
</tr>
</tbody>
</table>

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 DBS System is used exceeds the applicable RF compliance level above, the Vercise 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 DBS System.

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

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

- Typical range: 18 inches (45 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:
  - 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 re-sent 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 System has a short range inductively coupled telemetry system. 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 – 131 kHz
- Modulation type: FSK
- Effective Radiated Power: 0.4 mW (-4 dBm) maximum
- Magnetic Field Strength (at 3 m distance): 94 μA/m

FCC Compliance

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