



Vercise™

Deep Brain Stimulation

Physician Manual

Guarantees

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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

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

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.

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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 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 Vercise DBS System 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.

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 $\mu\text{C}/\text{cm}^2$ per stimulation phase. To maintain safety limits, the software will display a warning when the level of stimulation exceeds 30 $\mu\text{C}/\text{cm}^2$ 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 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. Depression, suicidal ideation, and suicide are known risks of DBS. Consider adjustment of stimulation, discontinuing stimulation, adjusting medication, and/or psychiatric referral.

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.
- 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 5–40 °C (41–104 °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 cerebrospinal fluid infection or inflammation
- Cerebral spinal fluid (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
- Pain, headache or discomfort
- Pneumonia from difficulty with swallowing or from inhaling fluid
- Psychiatric disturbances such as anxiety, depression, lessened interest or emotion, hypersexuality, aggression, mania or hypomania, psychosis, emotional sensitivity, sleep problems, suicide, or suicidal thoughts or attempts
- Seizures
- Sensory changes
- Speech or language problems
- Swallowing difficulty
- Systemic effects such as rapid heart beat, sweating, fever, dizziness, changes in kidney function, difficulty passing urine, sexual effects, nausea, difficulty having bowel movements, bloating
- Weakness, muscle spasms, shaking, restlessness, or problems with movement,
- Undesirable sensations (e.g., tingling)
- Visual problems, eyelid or eye movement difficulties or other eye-related symptoms
- Weight changes

Device-related Risks

- Allergic or immune system response to implanted materials
- Failure or malfunction of any part of the device, including but not limited to: Battery leakage, battery failure, lead or extension breakage, hardware malfunctions, loose connections, electrical shorts or open circuits, and lead insulation breaches, whether or not these problems require device removal and/or replacement
- Implant site complications such as pain, poor healing, redness, warmth, swelling or wound reopening
- Implanted device components (stimulator, lead, or extension) may move from original implanted location or wear through the skin, which may lead to the need for additional surgery
- Infection
- Interference from external electromagnetic sources
- Loss of adequate stimulation
- Pain, headache or discomfort.
- Skin irritation or burns at the stimulator site
- Stiffness in muscles or joints
- Worsening of disease symptoms, potentially caused by loss of stimulation, medication changes, surgery, or illness. In rare cases worsening can become a life-threatening crisis associated with varied symptoms such as mental status changes, fever, and muscle rigidity
- Swelling, including fluid collecting around the device

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

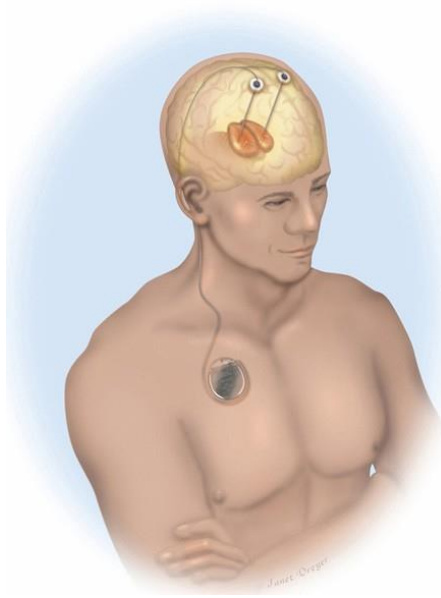
- Lead Boot
- Lead Stop – Screw and Ring
- Torque Wrench
- 1 cm Suture Sleeve
- 1 cm Split Suture Sleeve
- 2.3 cm Suture Sleeve
- 4 cm Suture Sleeve

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.

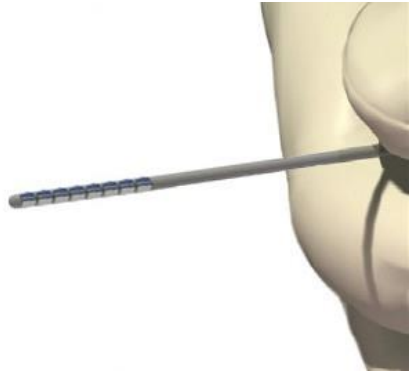
Note: Utilize meticulous care during implantation of the Vercise DBS System to prevent infection.

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



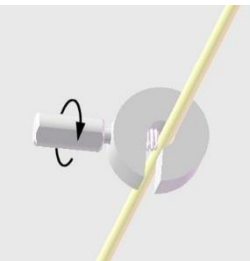
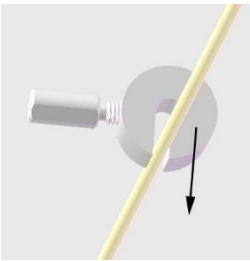
1. Prepare DBS Lead for implant. Visually inspect the DBS Lead and determine it to be acceptable for implantation.
2. Pass the DBS Lead through the cannula to ensure proper fit.
3. Insert the cannula (with stylet) into the brain to the desired depth.

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.



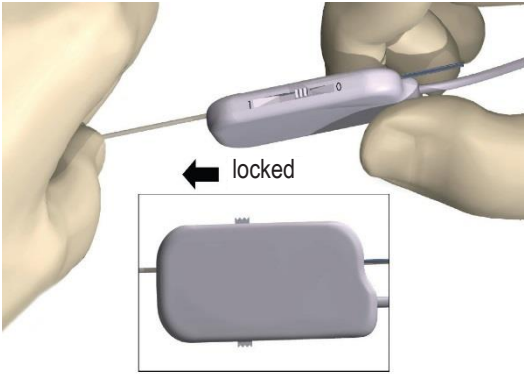
Note: *Make sure the Lead Stop will not slide on the DBS Lead when engaged.*

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.

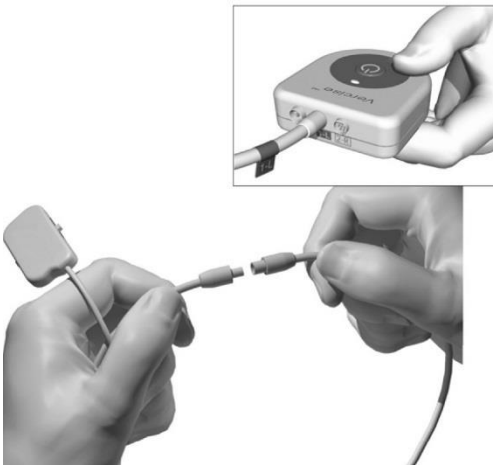


12. Secure the OR Cable connector to the microdrive.

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 $\mu\text{C}/\text{cm}^2$.*

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.

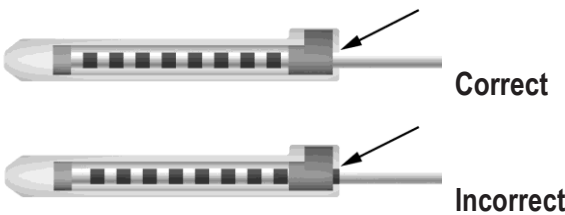
Note: Ensure that the adhesive is level with the superior surface of the skull.

4. Allow the adhesive to set according to the manufacturer's instructions.
5. Remove the Stylet.
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.

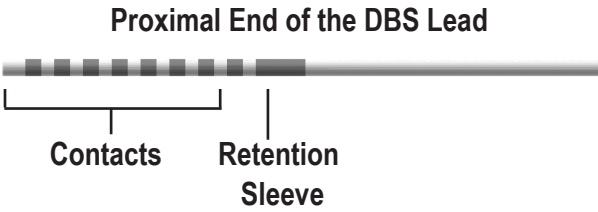
7. If the Stimulator will be implanted during a separate surgery, prepare the DBS Lead for the Stimulator Implantation procedure.
 - a. Place a Suture Sleeve on the left DBS Lead to differentiate the Leads.
 - b. Insert proximal end of the DBS Lead into the Lead Boot until it stops.

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.



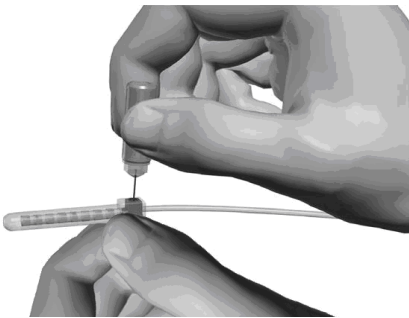
Note: The retention sleeve is easily distinguishable from the contacts by its length (see below).

* 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.



- c. Pass the Torque Wrench through the slit in the septum located on the top of the Lead Boot.
- 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.

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.*

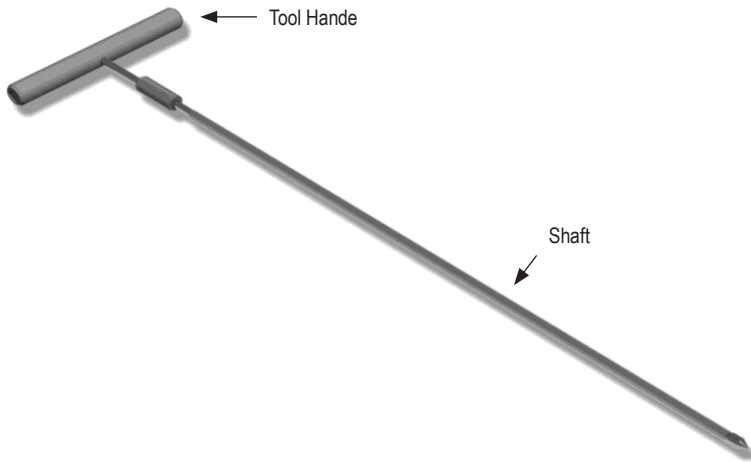
9. Plug the OR Cable into the ETS socket labeled “1-L.” If two DBS Leads are being used, connect the left DBS Lead to socket “1-L” and the right DBS Lead to socket “2-R.”
10. Verify impedances are acceptable by using the CP or Remote Control to measure monopolar impedances.

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.

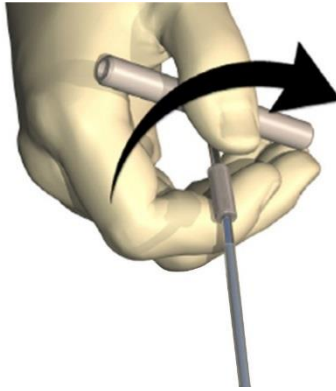
4. Create a subcutaneous tunnel from the incision above the ear, along the tunneling path to the Stimulator pocket.

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

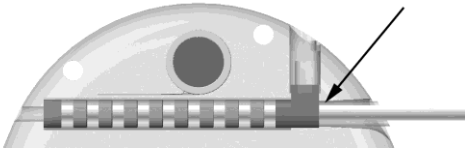


1. Fully insert the male end of the DBS Extension into the Stimulator until it stops.
 - a. Ensure the Stimulator is charged prior to implantation.
 - b. Insert the header plug to verify no Setscrews obstruct the socket.
 - c. Wipe the DBS Extension contacts before inserting.
 - d. Insert the DBS Extension 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.

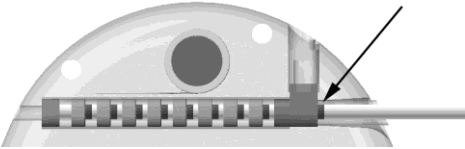


CAUTION: Verify proper DBS Extension insertion by checking impedances before tightening the Setscrew. Tightening the Setscrew down onto a contact can damage the DBS Extension.

2. Verify that the retention sleeve on the DBS Extension is located directly under the Setscrew in the Stimulator header.

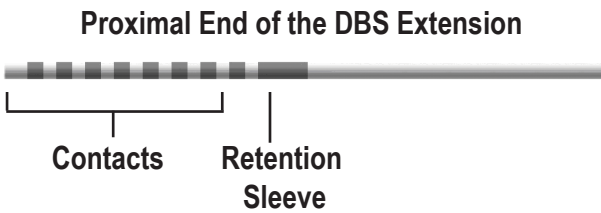


Correct



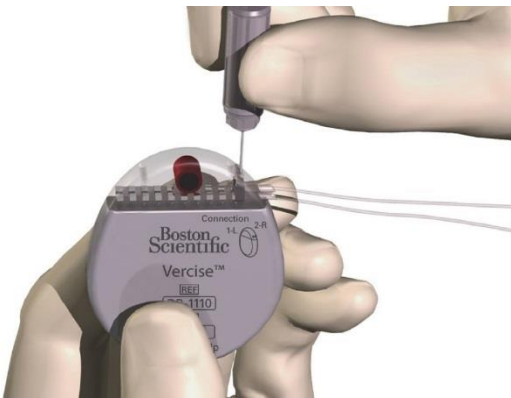
Incorrect

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



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.

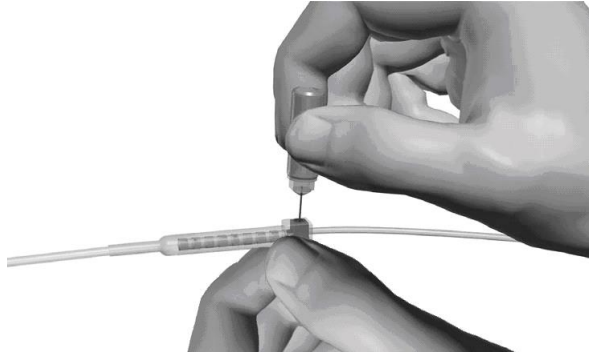


CAUTION: The wrench is torque limiting, such that the Setscrew cannot be over tightened. Use only the wrench provided, as other tools may over-tighten the Setscrew and damage the DBS Lead.

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 – 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 2-3 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.

14. Ship the explanted DBS Leads to Boston Scientific.

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.

6. Disconnect the DBS Extension connector. Return the DBS Extension connector to Boston Scientific.
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.

9. Ship the explanted DBS Extensions to Boston Scientific.

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. Patient's should expect a daily recharging time of 15 to 30 minutes or a periodic recharging time of 3 to 4 hours every 1 to 2 weeks, but their recharge routine may vary depending on their stimulation parameters. High power users will require more frequent charging. Boston Scientific recommends any recharge 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 recharge 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, patient 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*.

Battery Graphic	Description
	The Stimulator’s battery is <i>full</i> .
	The Stimulator’s battery is <i>ok</i> .
	The Stimulator’s battery is <i>low</i> .

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.



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.



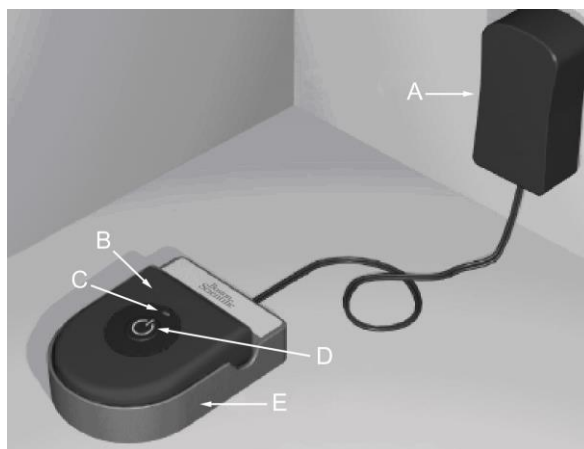
If the patient reports that stimulation has stopped, instruct the patient to check the Stimulator battery status with the Remote Control.

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.



- | | |
|--------------------|-----------------|
| A. Power Supply | D. Power Button |
| B. Charger | E. Base Station |
| C. Indicator Light | |

Charging the Charger

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

Indicator Light Status	Description
Green	The Charger is fully charged and ready to charge the Stimulator.
Yellow	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.
Off	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.

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

- 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.)*
- 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.*



- 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.
- If using the Charging Spacer, make sure it is between the Charger and the back of the pocket.
- Place the Counterweight in the pocket opposite of the Charger.
- Place the Charging Collar over the neck with the pockets facing out, as shown.

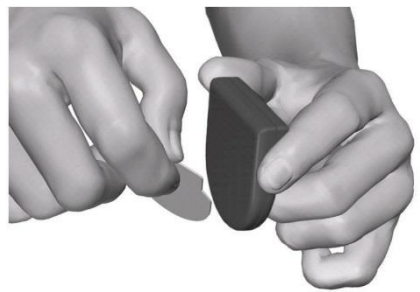
7. For best charging results, make sure the Charger is centered over the Stimulator. If the Charger is not centered, charging time may increase. See *Properly Aligning the Charger* to ensure you center the Charger over the Stimulator.
8. If the Charger is not centered over the Stimulator, you may need 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 | 4. Program Button |
| 2. Up/Activate | 5. Stimulation On/Off |
| 3. Down/Save | |

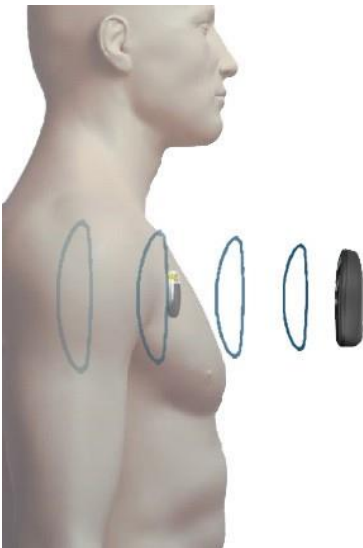
Some Remote Control functions (i.e., the Restore option and Clinician Mode) are accessed by pressing and holding a button (for approximately three seconds). These are identified in the appropriate sections following.

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 (60 cm or 2 ft).
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:

Signal Strength	Description
	The Remote Control is achieving <i>optimal</i> communication with your Stimulator.
	The Remote Control is achieving <i>good</i> communication with your Stimulator.
	The Remote Control is achieving <i>OK</i> communication with your Stimulator.
	The Remote Control is achieving <i>weak</i> communication with your Stimulator.
	The Remote Control is achieving either <i>very weak</i> or <i>no</i> communication with your Stimulator. 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.



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.








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*.

Battery Graphic	Description
	The Stimulator’s battery is <i>full</i> .
	The Stimulator’s battery is <i>ok</i> .
	The Stimulator’s battery is <i>low</i> .

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.

Graphic	Description
	A blank program slot.
	A full program slot
	The most recently activated or saved program.
	The currently selected program slot
	A reminder that the P button changes the selected program.

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 **⬆** 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

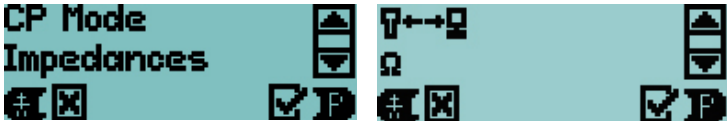
Clinicians and physicians can access additional options in the Remote Control to set up the Vercise™ DBS System. These options are not available to patients.

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 **I** and **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.

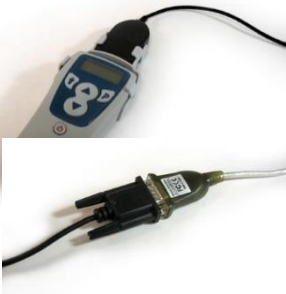
Selection #1 – Clinician Programmer (CP) Mode

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



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

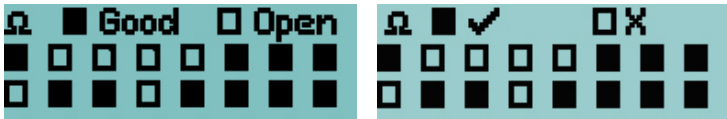
When the “Impedances” option is selected from the Enter Clinician Options menu, the Remote Control will take the measurements via telemetry; this will take a few seconds.



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

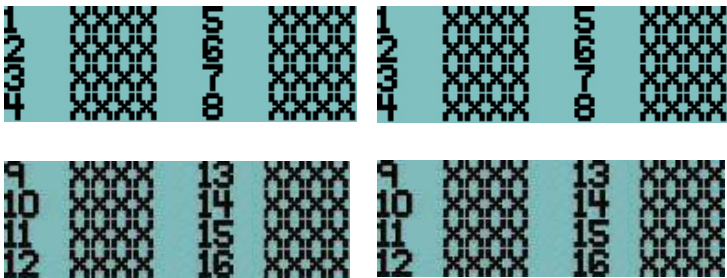
Eventually, the Remote Control will display the Contact Impedance Status screen.

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



Any key press other than the ►► 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.

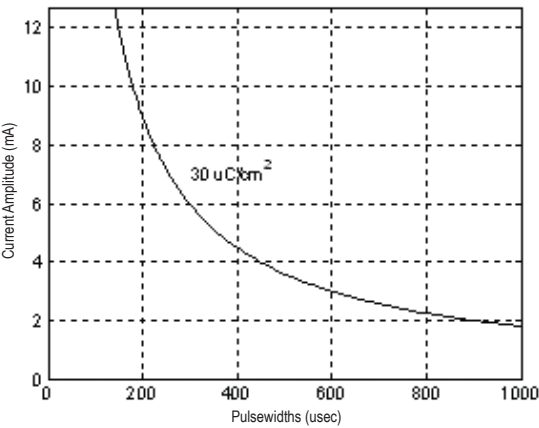
Then, press **P** on the next screen to confirm the selection. The Remote Control language will now change to your selected language.



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 $30\text{ }\mu\text{C}/\text{cm}^2$ per stimulation phase, as there is evidence of tissue damage above this level. However, the CP allows the stimulation to continue above this level.



This graph displays the recommended maximum charge density of $30\text{ }\mu\text{C}/\text{cm}^2$ 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 $30\text{ }\mu\text{C}/\text{cm}^2$.*

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 1: Stimulator Physical Properties	
Feature	Description
Case	Titanium
Header	Epoxy
Dimensions	55 mm x 45 mm x 11 mm
Volume	20.7 cm ³

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.

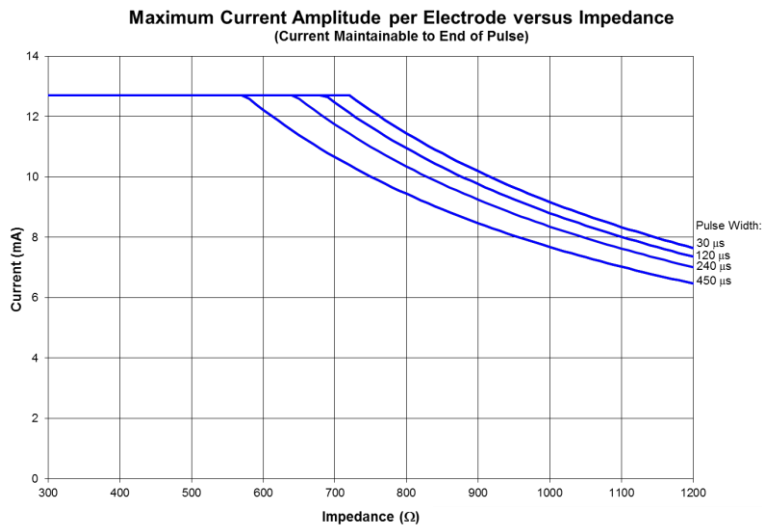
The programmable parameter ranges for the Stimulator are shown in Table 2.

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

Table 2: Stimulator Function	
Parameter	Range
Waveform	Charge balanced, asymmetric biphasic
Pulse Shape	Rectangular
Current or Voltage Regulated	Current
Amplitude ¹	0.1 – 20 mA
Rate	2 – 255 Hz
Pulse Width	10 – 450 µs
Cycle (On/Off)	1 s – 90 min
Stim Ramp On	1 – 10 s
Contact Connections	16
Independent Areas of Stim (4 Programs with 4 Areas per Program)	16
Current Path Options	Unipolar, Bipolar, or Multipolar

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.

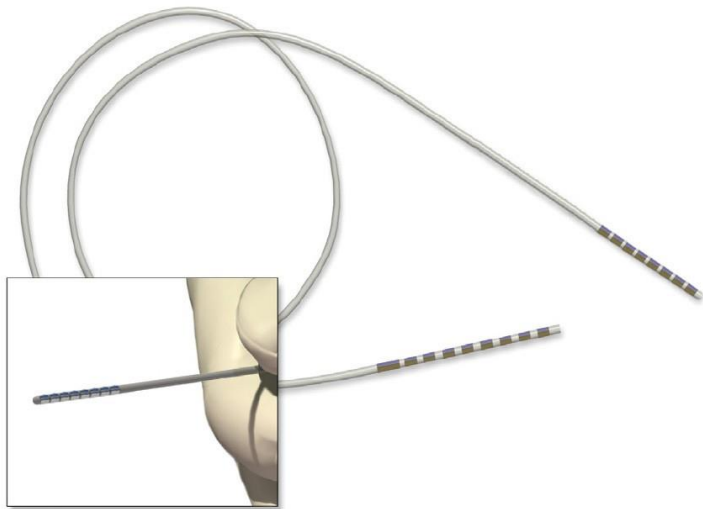


Table 3: DBS Lead	
Feature	Description
Number of Contacts	8
Contact Length	1.5 mm
Contact Surface Area	6.0 mm ²
Contact Spacing (Center-to-Center)	2.0 mm
Contact Span	15.5 mm
Distal Contact to Tip Length	< 1.3 mm
Diameter	1.3 mm
Overall Length	30 cm, 45 cm
Outer Jacket Tubing (Insulation)	Polyurethane
Contact Material	Platinum/Iridium
Impedance	≤ 90 Ω (measured from each connector to corresponding electrode contact)

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.

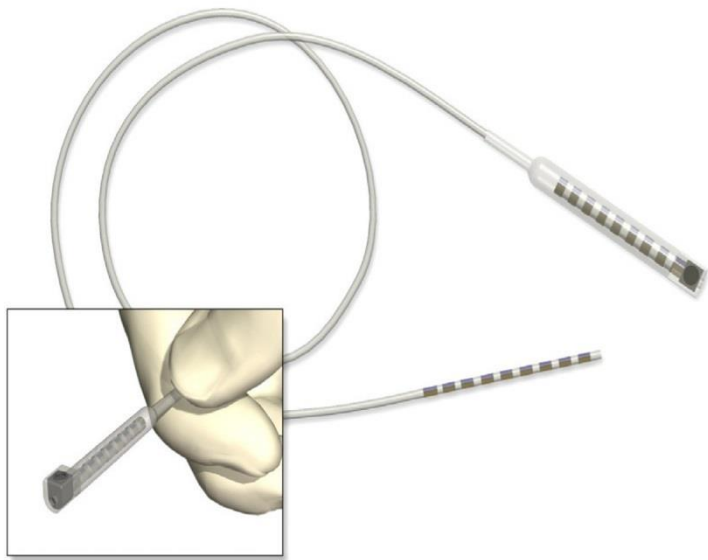


Table 4: DBS Extension	
Feature	Description
Overall Length	55 cm
Outer Diameter	1.35 mm
Number of Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone

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 5: DBS Lead Boot	
Feature	Description
Overall Length	3.3 cm
Setscrew	Titanium
Connector Block	Stainless Steel
End Stop	Stainless Steel
Insulation Material	Silicone

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.

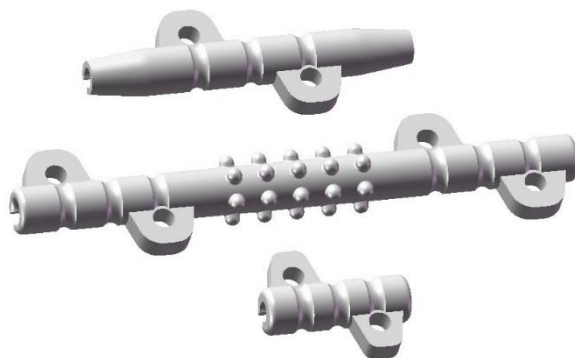


Table 6: Suture Sleeve	
Feature	Description
Overall Length	1 cm, 2.3 cm, 4 cm
Material	Silicone

Tunneling Tool

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



Table 7: Tunneling Tool	
Feature	Description
Length	28 cm (Straw), 35 cm (Long)
Shaft Material	Stainless Steel
Straw Material	PTFE
Handle Material	Stainless Steel, Ultem

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.

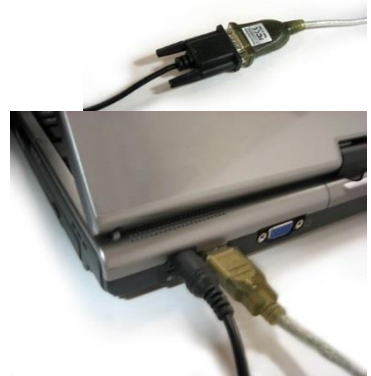
1. Turn on the CP and the Bionic Navigator™ Software will boot-up.
2. Enter the Clinician Options menu on the Remote Control by pressing the **I** and **P** buttons simultaneously.
3. Select CP Mode.
4. When the Remote Control displays “CP Ready,” put the IR Interface and Remote Control into the IR Interface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

 Rx ONLY Prescription only	 20XX-XX Use by YYYY-MM
REF Model Number	 X° C Y° C Temperature product should be stored at
SN Serial Number	 Consult the Instructions for Use
 20XX-XX Date of manufacture	 Fragile
STERILE EO Ethylene Oxide sterilized	 Single use only
 Non-Sterile	 Do not resterilize
 Type of Protection: BF	 Caution, consult accompanying documents.
 Double Insulation	 WEEE Directive
 Contents	LOT Batch code
 Do not use if package is damaged.	Refer to instruction manual/ booklet.
 Humidity Limitations	 Keep Dry
 MR Unsafe	

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.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	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. 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

The Vercise 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.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Air: ±2kV, ± 4kV, ± 8kV, ±15kV Contact:±8kV	Air: ±2kV, ± 4kV, ± 8kV, ±15kV Contact:±8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Note: Applies to external devices.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A – system is not connected to supply mains	N/A – system is not connected to supply mains
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A – system is not connected to supply mains	N/A – system is not connected to supply mains

Guidance and manufacturer's declaration – electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p><5 % U_T (>95 % dip in U_T) for 0,5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 s</p>	<p>N/A – system is not connected to supply mains</p> <p>T</p> <p>T</p> <p>T</p> <p>T</p>	<p>N/A – system is not connected to supply mains</p>
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Vercise 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.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - guidance
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	Professional healthcare facility environment and home healthcare environment
Radiated RF IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz	10 V/m, 80 MHz to 2.7 GHz	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: 
<p>Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>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.</p>			

<p>Recommended separation distances between portable and mobile RF communications equipment and the Vercise DBS System</p> <p>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.</p> <p>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>

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.

A Remote Control has to be linked with a stimulator to allow communication.

The Stimulator will not respond to any device that it is not linked to. There are additional mechanisms that ensure the integrity of the communicated data.

Telemetry Information

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

- Frequency Band: 119 – 131 kHz
- Modulation type: FSK
- Effective Radiated Power: 0.4 mW (-4 dBm) maximum
- Magnetic Field Strength (at 3 m distance): 94 μ A/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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Vercise™ Deep Brain Stimulation (DBS) System for Parkinson's disease (PD)

Clinical Summary

Rx ONLY

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

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Definition of Terms

Clinical Rating Scales

Global Impression of Change (1): The global impression of change (GIC) is a generic, single-item scale for quantifying one's overall impression of the patient's improvement following therapy. GIC can be patient-reported, clinician-reported or caregiver-reported.

Modified Schwab and England (2): The modified Schwab and England (SE) assessment is a disease-specific single-item scale for quantifying a PD (Parkinson's disease) patient's ability to perform activities of daily living.

Parkinson's Disease Diary (3) (PD diary): A patient-reported motor diary measuring the patient's state in 30 minute interval for 3 consecutive days at home. The patient reports his or her state in one of five categories:

"On without dyskinesia":	Good motor function resulting from therapeutic effects of anti-parkinsonian medication and stimulation but without the drug-induced side effect movements known as dyskinesia.
"On with non-troublesome dyskinesia":	Good motor function from the therapy but with involuntary movements of dyskinesia that are <u>not</u> disturbing to the patient
"On with troublesome dyskinesia":	Good motor function and relief from PD symptoms but with involuntary movements of dyskinesia that are disturbing to the patient
"Off":	When medication effect has worn off and the medication is no longer providing clinical benefits including improvement of mobility, lessening of slowness, and improved stiffness
"Asleep":	Asleep

39-item Parkinson's Disease Questionnaire (4): The 39-item Parkinson's Disease Questionnaire (PDQ-39) is a disease-specific patient-reported assessment for measuring the specific impact of PD on a patient's quality of life in the following domains: mobility, activities of daily living, emotional well-being, stigma, social support, cognitions, communication, and bodily discomfort.

Unified Parkinson's Disease Rating Scale (2) (UPDRS): A standard scale for assessing the current state and progression of Parkinson's Disease (PD). This assessment contains 4 sections: (I) Mentation, Behavior, and Mood, (II) Activities of Daily Living (ADL), (III) Motor Examination, and (IV) Complications of Therapy.

36-Item Short Form Survey (5) (SF-36) v2: A quality of life scale that measures functional health and well-being from patients' own point of view. It is comprised of 36 questions spanning eight health

domains that contribute to the scoring of two component summary measures: physical health and mental health.

Symptoms and Side Effects

Bradykinesia: Slowness of movement.

Dysarthria: Poorly articulated or slurred speech.

Dyskinesia: Abnormal involuntary movements, typically non-painful writhing that can be caused by dopaminergic drug therapy.

Dystonia: Abnormal, often painful involuntary muscle contractions of opposing muscles that twist a body part into an uncomfortable, position or posture.

Rigidity: Stiffness or inflexibility of the neck, limbs or joints.

Tremor: Involuntary, regular, sinusoidal, shaking of a limb or the head.

Clinical Study Terms

Meds OFF: A condition/period of assessment where patients have withheld their anti-parkinsonian medications or when they are not medicated as the medications have worn off.

Meds ON: A condition/period of assessment when the patient has taken their anti-parkinsonian medications and the medication has taken effect.

Levodopa equivalent: The conversion in milligrams (mg) to levodopa equivalent dose for non-levodopa medications. For example, 100 mg of standard levodopa = 125 mg of controlled-release levodopa; 10 mg of bromocriptine; 1 mg of pergolide; 1 mg of pramipexole; 3 mg of ropinirole; 4mg/24h of rotigotine; 60-90mg pirobedil.

Serious adverse event (SAE): Any adverse event that

- led to death or
- led to a serious deterioration in the health of the patient that either resulted in
 - a life-threatening illness or injury
 - a permanent impairment of a body structure or a body function
 - in-patient or prolonged hospitalization of existing hospitalization
 - medical/surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function.

Introduction

The Vercise Deep Brain Stimulation (DBS) System includes a Stimulator with DBS Leads for stimulation of the subthalamic nucleus (STN) in the brain. DBS Extensions are used to connect the DBS Leads to the Stimulator implanted near the clavicle. The Vercise DBS System is able to provide precise, independent current steering across each of the eight contacts per DBS Lead.

The Stimulator is controlled by a handheld Remote Control, and can be programmed by a Clinician Programmer using the Bionic Navigator™ Software. Periodically, the rechargeable Stimulator battery must be replenished with a radiofrequency (RF) charging device provided in the Charging Kit.

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.

This Clinical Summary document provides data from two studies: the INTREPID Study, and the VANTAGE Study. The INTREPID Study data has been collected per the pre-specified interim analysis of the ongoing U.S. Clinical Study sponsored by Boston Scientific (May 2013 through December 2016). Additional long-term data from INTREPID is anticipated upon study completion. Safety data from INTREPID includes all available data on 292 consented subjects while effectiveness data is presented for the cohort of 160 randomized subjects per the pre-specified interim analysis. Enrollment for the INTREPID Study is still ongoing. Supplemental safety data from the Boston Scientific VANTAGE Study that was conducted outside the U.S. (OUS) is also provided. This included 40 consented patients.

INTREPID Clinical Study

Study Design

INTREPID is a multi-center, prospective, double blind, randomized (3:1) controlled study. The study was designed to evaluate the safety and effectiveness of the Vercise™ Deep Brain Stimulation (DBS) System for 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.

Patients were treated starting in May 2013. The data used in consideration of this PMA reflected data collected through December 31, 2016, and included 292 patients from 23 investigational sites. Safety was evaluated based on all patients enrolled in the study within this timeframe (May 2013-December 2016) while effectiveness was analyzed using the 160 subjects who had been randomized, per the pre-specified interim analysis.

Subjects who passed screening criteria were implanted bilaterally with the Vercise DBS System in the subthalamic nucleus (STN) for the treatment of their Parkinson's disease.

The initial epoch of the study was a period of 12 weeks during which subjects remained blinded to their treatment assignment, and during which a blinded assessor (who was unaware of the subject assignment) completed all study assessments (ie, a double blind study design). The treating neurologist was responsible for subjects' programming and adjustment of their anti-parkinsonian medications. Subjects were randomized in a 3:1 ratio to either receive Active or Control settings. Subjects in the Active group received therapeutic settings titrated by the treating neurologist to best clinical effect. Subjects in the Control group received sham stimulation where the stimulation was not set to therapeutic levels. At the Week 12 post-randomization visit, all subjects began an open-label period, with a follow up period of up to 5 years. The study design is shown in Figure 1 below.

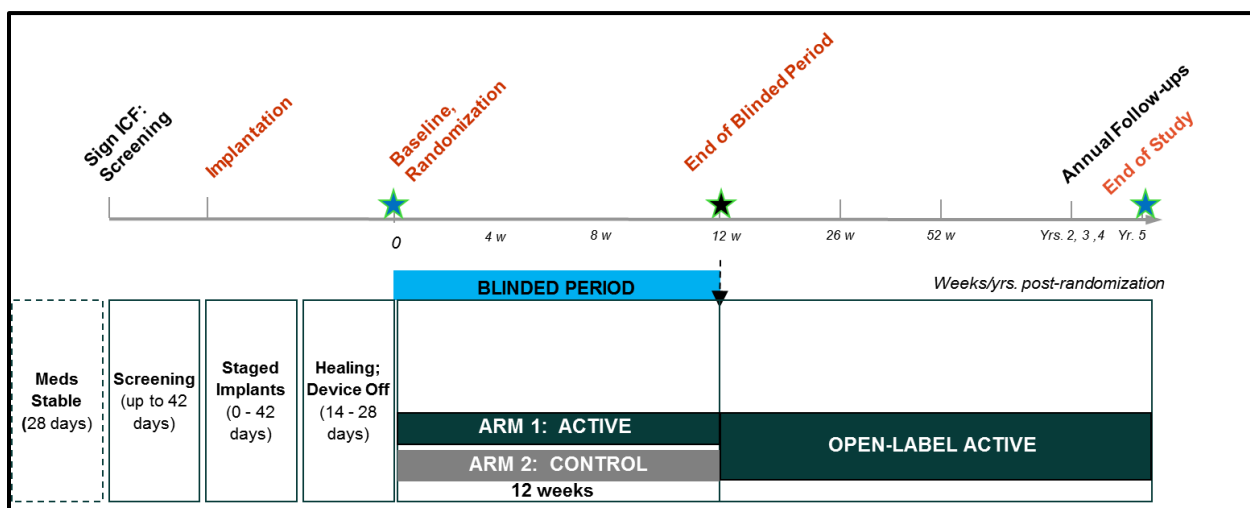


Figure 1: INTREPID Study Schematic

Subjects completed a 3-day Parkinson's Disease (3)(PD) diary to document their PD symptoms prior to each study visit. During specified in-office study visits, subjects completed study assessments in their *stim on/meds off* and *stim on/meds on* condition. A neuropsychological battery of tests was also completed during study screening, Week 12 and Week 52 visits, to evaluate the cognitive and behavioral aspects of the subject prior-to and after receiving their DBS implant.

To obtain a comprehensive overview of subjects' response to treatment in the study, additional assessments were administered including the Unified Parkinson's Disease Rating Scale (2) (UPDRS), 39-Item Parkinson's Disease Questionnaire (4) (PDQ-39), Modified Schwab and England (2) (SE), Treatment Satisfaction, Short Form Survey (5) (SF-36 v2), and Global Impression of Change (assessed by subject and assessor) (1).

During the study, subjects were evaluated without medication (*meds off condition*) and one-hour following intake of their anti-parkinsonian medications (*meds on condition*). The *meds off* and *meds on*

condition assessments were completed during screening, and at Baseline, Weeks 12, 26, and 52 visits post-randomization. These were also to be completed at Year 2, 3, 4 and 5 Visits post-randomization.

Safety event rates were monitored for the entire duration of the study by an independent Data and Safety monitoring board (DSMB) comprised of medical and statistical expert reviewers.

Study Inclusion and Exclusion Criteria

Key Inclusion Criteria

- Age at the time of enrollment: 22 - 75 years
- Duration of idiopathic Parkinson's disease (PD): ≥ 5 years of motor symptoms with persistent disabling PD symptoms or drug side effects despite optimal medical therapy; Severity of modified Hoehn and Yahr (6) (H&Y) stage ≥ 2 (*meds off* condition)
- Greater than or equal to 6 hours of poor motor function (OFF time plus ON time with troublesome dyskinesias) per day as assessed by Parkinson's Disease (3) (PD) diary
- Unified Parkinson's Disease Rating Scale – Section III (2) (UPDRS III) score of ≥ 30 in the *meds off* condition and improvement by $\geq 33\%$ following intake of anti-parkinsonian medications
- Dementia Rating Scale – 2 (7) (DRS-2) score ≥ 130 and Beck Depression Inventory II (8) (BDI-II) score < 17 in the *meds on* condition
- Be willing and able to comply with all visits and study related procedures (e.g., using the remote control, charging system and completing the PD Diary (3))
- Able to understand the study requirements and the treatment procedures and provides written informed consent before any study-specific tests or procedures are performed.

Key Exclusion Criteria:

- Any intracranial abnormality or medical condition that would contraindicate Deep Brain Stimulation (DBS) surgery
- Have untreated clinically significant depression per DSM-IV (9) (Diagnostics and Statistical Manual of Mental Disorders) criteria as determined by Beck Depression Inventory II (8) (BDI-II) score ≥ 17 . History of suicide attempt or current active suicidal ideation as determined by a positive response to Items 2 -5 of suicide ideation sub-scale of the Columbia Suicide Severity Rating Scale (10) (C-SSRS).
- Any current drug or alcohol abuse, per DSM-IV (9) (Diagnostics and Statistical Manual of Mental Disorders) criteria
- Any history of recurrent or unprovoked seizures or hemorrhagic stroke
- Any prior movement disorder treatments that involved intracranial surgery or device implantation.
- Any other active implanted devices including neurostimulators (e.g., cochlear implant, pacemaker) and /or drug delivery pumps, whether turned on or off. Passive implants (e.g., knee prostheses) allowed provided that they do not interfere with the functioning of the Vercise™ System.
- Have any significant medical condition that is likely to interfere with study procedures or likely to confound evaluation of study endpoints
- Any terminal illness with life expectancy of < 1 year

- A female who is breastfeeding or of child-bearing potential with a positive urine pregnancy test or not using adequate contraception
- Any impairment that would limit subject's ability to record PD Diary (3) entries or perform wound care, unless a caregiver is available to assist.

Clinical Endpoints

The primary safety endpoint included the rates of occurrence of the following adverse device effects (ADEs) at 52 weeks post-randomization:

- Cerebrovascular accident (CVA) and subdural hematomas
- Death
- Seizure
- Suicide or suicide attempt
- Pre-specified motor/sensory symptoms:
 - Dystonia;
 - Eye Deviation, Conjugate;
 - Eyelid Apraxia;
 - Muscle Spasm;
 - Postural/Gait Disturbances;
 - Speech Disorders;
 - Swallowing Disorders;
 - Undesired Sensations, Non-target Stimulation Area;
 - Visual Disturbances.
- Pre-specified psychiatric symptoms:
 - Anxiety;
 - Apathy without Mood Disorder;
 - Depression;
 - Emotional Reactivity;
 - Hallucinations;
 - Impulsive Behavior;
 - Mania;
 - Psychosis.

The primary efficacy endpoint for the study was the difference in the mean change from baseline to 12 weeks post-randomization between the Active and Control groups in the mean number of waking hours per day with good symptom control and no troublesome dyskinesia, as measured on the Parkinson's Disease (PD) Diary (3), with no increase in antiparkinsonian medications. The study met success criteria for the primary endpoint based on the pre-specified interim analysis.

The following secondary endpoints were analyzed at 12 weeks post-randomization between the Active and Control groups as compared with Baseline:

- Motor function as assessed by Unified Parkinson's Disease Rating Scale – Section III (2) (UPDRS III) scores in *stim on/meds off* condition and in *stim on/meds on* condition
- Activities of Daily Living (Unified Parkinson's Disease Rating Scale – Section II) (2) (UPDRS II) in *stim on/meds on* condition
- Quality of life as assessed by Parkinson's Disease Questionnaire (4) (PDQ-39), 36-Item Short Form Survey (5) (SF-36) v2 and Modified Schwab and England (2) (SE)
- Treatment Satisfaction
- Global impression of change (1) as assessed by subjects and clinicians.

Pre-Specified Statistical Analysis Plan

The study was designed such that there would be at least 160 randomized subjects, with a maximum of up to 310, at up to 30 US sites. These sample sizes would be based on the outcomes of four pre-specified interim analyses throughout the study. The four interim analyses would be performed as follows:

- For futility after 60 randomized subjects reached the 12 week post-randomization follow-up visit, and
- For effectiveness and futility after 160, 200, and 240 randomized subjects reached the 12 week post-randomization follow-up visit

The adaptive design used the Lan-DeMets group sequential method with the O'Brien-Flemming spending function and Pocock spending function.

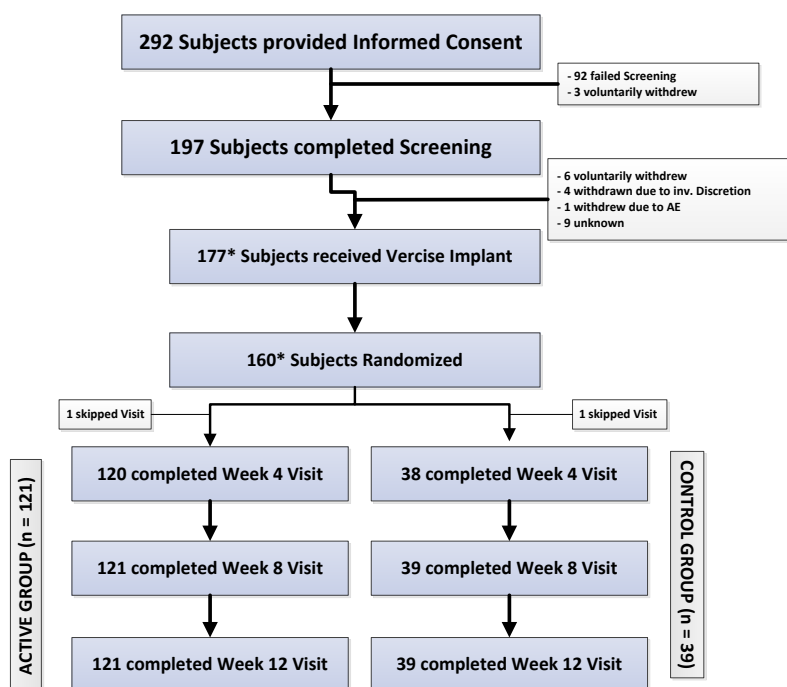
A two group t-test with a one-sided 0.025 significance level (adjusted for the interim analyses) was used to assess the primary endpoint. The Intent-To-Treat (ITT) analysis set was used for the primary analysis. Missing data at 12 week post-randomization were imputed appropriately. The 95% confidence interval (CI) of the treatment effect was reported.

Secondary endpoints were successively analyzed according to a parallel gatekeeping procedure (Benjamini and Hochberg) with five endpoint families using the aforementioned order.

Patient Accountability

Enrollment

A total of 292 subjects provided consent to participate in the study at 23 participating sites in U. S. One hundred and seventy-seven subjects received the Vercise™ Deep Brain Stimulation (DBS) System. The cohort of 160 randomized subjects was identified as the pre-specified interim analysis group. The following flowchart (Figure 2) shows the disposition of subjects in the study.



*As of Dec 31st 2016. Only those subjects included in the analysis are included

Figure 2: INTREPID Study Disposition

Study Population Demographics and Baseline Characteristics

One hundred sixteen of 160 subjects (72.5%) were male. The mean age of subjects at the time of consent was 59.9 ± 7.95 years. 43.1% (69/160) of subjects were younger than 60 years of age and 10.6% (17/160) of subjects were over the age of 70.

Subjects' medical history revealed that two subjects had a prior intracranial surgery - one had a temporal lobe biopsy and the other had surgical repair of a Chiari malformation. Four subjects had a history of major depressive disorder and two had a diagnosis of dopamine dysregulation syndrome. In the last four weeks prior to screening, 30% (48/160) reported anxiety and 17.5% (28/160) reported restless legs syndrome.

Subjects were diagnosed with bilateral idiopathic Parkinson's disease (3) (PD) with disease duration of 10.1 ± 3.61 years and mean severity of modified Hoehn and Yahr (6) (H&Y) score of 2.8 ± 0.73 . Subjects' mean Unified Parkinson's Disease Rating Scale – Section III (2) (UDPRS III) Scores in *meds off* condition was 43.4 ± 9.6 . Following intake of anti-parkinsonian medications, mean UPDRS III (2) scores improved by 57.5% (18.5 ± 8.26) in *meds on* condition.

Subjects completed a 3-day diary (3) in which they reported their PD symptoms in 30 minute increments. Subjects reported poor motor function with regard to the time spent ON with troublesome dyskinesias and OFF as summarized in Table 1 below. Subjects also demonstrated a poor quality of life as reported by scores in 39-Item Parkinson's Disease Questionnaire (4) (PDQ-39), Modified Schwab and England (2) (SE), Modified Hoehn and Yahr (6) (H&Y) and EuroQol-5D-5L (11) (EQ-5D-5L) scores.

Table 1: INTREPID Study Clinical Characteristics

All Randomized Subjects	
	Mean (SD) N
Parkinson's disease Duration	10.1 (3.61) 160
Parkinson's Disease Diary (hours/day)	
Asleep	7.20 (1.47) 158
OFF Time	6.92 (2.99) 158
ON without dyskinesia	4.65 (2.67) 150
ON with non-troublesome dyskinesia	3.65 (1.90) 120
ON with troublesome dyskinesia	4.35 (2.63) 105
UPDRS III Scores	
UPDRS-III score (<i>meds off</i> condition)	43.4 (9.60) 153
UPDRS-III score (<i>meds on</i> condition)	18.5 (8.26) 157

Safety Results

The analysis of the INTREPID safety data was based on a total of 292 consented (enrolled) subjects. Of these 292 subjects, 177 subjects received the Vercise System. Safety data for all the consented (enrolled) subjects (n = 292) is presented in this section (Table 2). Additionally, the safety data on the interim analysis cohort (n = 160) up to Week 12 post randomization (end of blinded period) is presented in Table 3. Please note that the VANTAGE Study (see below) also includes supplemental safety data on the 40 patients implanted with the Vercise System.

The primary safety endpoint of the study included the rates of occurrence of pre-specified adverse device effects (ADEs) at 52 weeks post-randomization. Additional safety parameters evaluated in the study included the rates of occurrence of all serious adverse events (SAEs) and all adverse device effects (ADEs), including serious adverse device effects (SADEs) and unanticipated adverse device effects (UADEs) at 5 years post-randomization (available upon study completion).

Safety event rates were monitored for the entire duration of the study by an independent Data and Safety monitoring board (DSMB) comprised of medical and statistical expert reviewers.

All Adverse Events

A total of 788 adverse events in 143 subjects were reported in the study for all consented (enrolled) subjects as of December 31, 2016. Of 788 events, 74 events were considered Serious Adverse Events (SAE) and 714 events were considered non-serious adverse events. There were no unanticipated adverse events.

All adverse events related to hardware, stimulation or procedure are summarized in Table 2 below. Of 788 events, a total of 65 events were reported as related to hardware, 157 related to stimulation and 128 related to procedure.

Table 2: All Adverse Events related to hardware, stimulation or procedure

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Abnormal behavior	0 (0.0%)	2 (0.7%)	0 (0.0%)
Adverse drug reaction	0 (0.0%)	0 (0.0%)	1 (0.3%)
Affect lability	0 (0.0%)	2 (0.7%)	1 (0.3%)
Aggression	0 (0.0%)	1 (0.3%)	0 (0.0%)
Agitation	1 (0.3%)	3 (1.0%)	0 (0.0%)
Agitation postoperative	0 (0.0%)	0 (0.0%)	1 (0.3%)
Amnesia	1 (0.3%)	0 (0.0%)	2 (0.7%)
Anxiety	0 (0.0%)	1 (0.3%)	1 (0.3%)
Apathy	1 (0.3%)	2 (0.7%)	1 (0.3%)

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Aphasia	0 (0.0%)	1 (0.3%)	1 (0.3%)
Apraxia	0 (0.0%)	4 (1.4%)	0 (0.0%)
Arthralgia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Asthenia	0 (0.0%)	1 (0.3%)	0 (0.0%)
Balance disorder	1 (0.3%)	12 (3.4%)	1 (0.3%)
Blepharospasm	0 (0.0%)	1 (0.3%)	1 (0.3%)
Burning sensation	1 (0.3%)	0 (0.0%)	0 (0.0%)
Cerebral hemorrhage	1 (0.3%)	0 (0.0%)	3 (1.0%)
Cervicobrachial syndrome	0 (0.0%)	1 (0.3%)	0 (0.0%)
Chest discomfort	0 (0.0%)	1 (0.3%)	0 (0.0%)
Cognitive disorder	3 (1.0%)	2 (0.7%)	3 (1.0%)
Complex partial seizures	1 (0.3%)	0 (0.0%)	1 (0.3%)
Confusion postoperative	2 (0.7%)	0 (0.0%)	3 (1.0%)
Confusional state	0 (0.0%)	0 (0.0%)	6 (2.1%)
Convulsion	1 (0.3%)	0 (0.0%)	2 (0.7%)
Depressed mood	0 (0.0%)	1 (0.3%)	0 (0.0%)
Depression	2 (0.7%)	2 (0.7%)	4 (1.4%)
Device related infection	4 (1.4%)	0 (0.0%)	4 (1.4%)
Diplopia	0 (0.0%)	2 (0.7%)	0 (0.0%)
Dizziness	0 (0.0%)	2 (0.7%)	0 (0.0%)
Dysarthria	0 (0.0%)	7 (1.7%)	1 (0.3%)
Dysgeusia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Dyskinesia	0 (0.0%)	33 (10.3%)	1 (0.3%)
Dysphagia	0 (0.0%)	6 (1.7%)	1 (0.3%)
Dysphonia	0 (0.0%)	2 (0.7%)	0 (0.0%)
Dyspnoea	0 (0.0%)	1 (0.3%)	0 (0.0%)
Dystonia	0 (0.0%)	4 (1.4%)	0 (0.0%)
Ecchymosis	1 (0.3%)	0 (0.0%)	1 (0.3%)
Electrocardiogram change	0 (0.0%)	0 (0.0%)	1 (0.3%)
Emotional disorder	0 (0.0%)	1 (0.3%)	0 (0.0%)
Encephalitic infection	1 (0.3%)	0 (0.0%)	1 (0.3%)
Epicondylitis	0 (0.0%)	1 (0.3%)	0 (0.0%)
Fall	0 (0.0%)	9 (2.7%)	4 (0.3%)
Fatigue	0 (0.0%)	1 (0.3%)	0 (0.0%)
Freezing phenomenon	0 (0.0%)	0 (0.0%)	1 (0.3%)

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Gait disturbance	0 (0.0%)	4 (1.4%)	1 (0.3%)
Hematoma	0 (0.0%)	0 (0.0%)	1 (0.3%)
Hallucination, auditory	0 (0.0%)	0 (0.0%)	1 (0.3%)
Hallucination, visual	0 (0.0%)	0 (0.0%)	1 (0.3%)
Headache	1 (0.3%)	1 (0.3%)	4 (1.0%)
Hiccups	0 (0.0%)	1 (0.3%)	1 (0.3%)
Hypersensitivity	0 (0.0%)	0 (0.0%)	1 (0.3%)
Hypoaesthesia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Hypomania	0 (0.0%)	3 (1.0%)	0 (0.0%)
Hypotension	0 (0.0%)	0 (0.0%)	1 (0.3%)
Hypoventilation	0 (0.0%)	0 (0.0%)	1 (0.3%)
Impaired healing	1 (0.3%)	0 (0.0%)	1 (0.3%)
Implant site cellulitis	0 (0.0%)	0 (0.0%)	1 (0.3%)
Implant site erythema	2 (0.7%)	0 (0.0%)	1 (0.3%)
Implant site hemorrhage	1 (0.3%)	0 (0.0%)	1 (0.3%)
Implant site hypersensitivity	1 (0.3%)	0 (0.0%)	0 (0.0%)
Implant site infection	4 (1.4%)	0 (0.0%)	3 (1.0%)
Implant site edema	15 (4.8%)	0 (0.0%)	13 (4.1%)
Implant site pain	3 (1.0%)	0 (0.0%)	1 (0.3%)
Implant site paresthesia	1 (0.3%)	0 (0.0%)	1 (0.3%)
Implant site reaction	1 (0.3%)	0 (0.0%)	2 (0.7%)
Impulsive behavior	0 (0.0%)	4 (1.4%)	2 (0.7%)
Insomnia	0 (0.0%)	1 (0.3%)	0 (0.0%)
Intracranial hypotension	1 (0.3%)	0 (0.0%)	1 (0.3%)
Irritability	1 (0.3%)	0 (0.0%)	1 (0.3%)
Mania	0 (0.0%)	2 (0.7%)	0 (0.0%)
Medical device pain	1 (0.3%)	0 (0.0%)	1 (0.3%)
Memory impairment	0 (0.0%)	0 (0.0%)	1 (0.3%)
Mental status changes	1 (0.3%)	0 (0.0%)	2 (0.7%)
Musculoskeletal pain	0 (0.0%)	2 (0.7%)	0 (0.0%)
Musculoskeletal stiffness	0 (0.0%)	1 (0.3%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	1 (0.3%)
Nausea	0 (0.0%)	0 (0.0%)	1 (0.3%)
Neck pain	1 (0.3%)	1 (0.3%)	1 (0.3%)
Oesophageal obstruction	0 (0.0%)	1 (0.3%)	0 (0.0%)

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Oropharyngeal discomfort	0 (0.0%)	1 (0.3%)	0 (0.0%)
Pain in extremity	0 (0.0%)	1 (0.3%)	0 (0.0%)
Paresthesia	0 (0.0%)	1 (0.3%)	0 (0.0%)
Paranoia	0 (0.0%)	2 (0.7%)	0 (0.0%)
Parkinson's disease	1 (0.3%)	2 (0.7%)	1 (0.3%)
Parosmia	0 (0.0%)	1 (0.3%)	0 (0.0%)
Photophobia	0 (0.0%)	1 (0.3%)	0 (0.0%)
Photosensitivity reaction	0 (0.0%)	1 (0.3%)	0 (0.0%)
Pneumocephalus	3 (0.7%)	0 (0.0%)	5 (1.4%)
Postoperative fever	0 (0.0%)	0 (0.0%)	2 (0.7%)
Procedural vomiting	0 (0.0%)	0 (0.0%)	1 (0.3%)
Psychotic disorder	0 (0.0%)	1 (0.3%)	0 (0.0%)
Pyrexia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Respiratory disorder	0 (0.0%)	1 (0.3%)	0 (0.0%)
Road traffic accident	0 (0.0%)	1 (0.3%)	0 (0.0%)
Salivary hypersecretion	0 (0.0%)	2 (0.7%)	0 (0.0%)
Sleep disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)
Somnolence	0 (0.0%)	0 (0.0%)	2 (0.7%)
Speech disorder	0 (0.0%)	1 (0.3%)	0 (0.0%)
Staphylococcal skin infection	1 (0.3%)	0 (0.0%)	1 (0.3%)
Stitch abscess	0 (0.0%)	0 (0.0%)	1 (0.3%)
Subdural hemorrhage	0 (0.0%)	0 (0.0%)	1 (0.3%)
Suicidal ideation	0 (0.0%)	2 (0.7%)	0 (0.0%)
Suicide attempt	0 (0.0%)	1 (0.3%)	1 (0.3%)
Supraventricular tachycardia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Suture related complication	0 (0.0%)	0 (0.0%)	2 (0.3%)
Thrombophlebitis superficial	0 (0.0%)	0 (0.0%)	1 (0.3%)
Tremor	2 (0.7%)	5 (1.0%)	3 (1.0%)
Urinary tract infection	0 (0.0%)	0 (0.0%)	1 (0.3%)
Venous injury	0 (0.0%)	0 (0.0%)	1 (0.3%)
Vomiting	0 (0.0%)	0 (0.0%)	1 (0.3%)
Weight decreased	0 (0.0%)	1 (0.3%)	0 (0.0%)
Weight increased	0 (0.0%)	5 (1.7%)	0 (0.0%)
Wound dehiscence	2 (0.7%)	0 (0.0%)	3 (1.0%)
Wound hemorrhage	0 (0.0%)	0 (0.0%)	1 (0.3%)

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Wound infection	0 (0.0%)	0 (0.0%)	1 (0.3%)
TOTALS	65 (20.70%)	157 (48.80%)	128 (39.10%)

Incidence = Number of subjects with events divided by all consented subjects (n = 292)

Adverse Events up to 12 Weeks Post Randomization

In the cohort of 160 randomized subjects, a total of 362 events in 111 subjects were reported from time of consent to 12 weeks post randomization.

Of 362 adverse events, 283 events occurred in 86 subjects in the Active Group and 79 events occurred in 25 subjects in the Control Group. Table 3 summarizes only those events related to procedure, stimulation, or hardware, based on their treatment assignment.

Table 3: Adverse Events related to hardware, stimulation or procedure up to 12 weeks post randomization based on treatment assignment

	Related to Hardware		Related to Stimulation		Related to Procedure	
	Number of Events (Incidence)		Number of Events (Incidence)		Number of Events (Incidence)	
Event	Active	Control	Active	Control	Active	Control
Abnormal behavior	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Adverse drug reaction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Aggression	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Agitation	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Agitation postoperative	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Amnesia	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Anxiety	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Aphasia	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Apraxia	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Arthralgia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Asthenia	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Balance disorder	1 (0.8%)	0 (0.0%)	6 (5.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Blepharospasm	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Burning sensation	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cerebral hemorrhage	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Chest discomfort	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cognitive disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Confusion postoperative	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.5%)	0 (0.0%)

	Related to Hardware		Related to Stimulation		Related to Procedure	
	Number of Events (Incidence)		Number of Events (Incidence)		Number of Events (Incidence)	
Event	Active	Control	Active	Control	Active	Control
Confusional state	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (4.1%)	1 (2.6%)
Convulsion	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Depressed mood	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)
Depression	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	1 (2.6%)
Device related infection	3 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.5%)	0 (0.0%)
Diplopia	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dysarthria	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Dyskinesia	0 (0.0%)	0 (0.0%)	22 (16.5%)	1 (2.6%)	0 (0.0%)	0 (0.0%)
Dysphagia	0 (0.0%)	0 (0.0%)	4 (3.3%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Dysphonia	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dyspnoea	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dystonia	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Electrocardiogram change	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Fall	0 (0.0%)	0 (0.0%)	3 (2.5%)	0 (0.0%)	4 (0.8%)	0 (0.0%)
Freezing phenomenon	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Gait disturbance	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Hematoma	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Hallucination, auditory	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Hallucination, visual	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Headache	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	2 (2.6%)
Hiccups	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Hypersensitivity	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Hypoaesthesia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Hypomania	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypotension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Hypoventilation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Impaired healing	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Implant site erythema	1 (0.8%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Implant site infection	2 (1.7%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	1 (2.6%)
Implant site edema	8 (5.8%)	2 (5.1%)	0 (0.0%)	0 (0.0%)	5 (3.3%)	3 (7.7%)
Implant site pain	1 (0.8%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Implant site paresthesia	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Implant site reaction	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Impulsive behavior	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Insomnia	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Related to Hardware		Related to Stimulation		Related to Procedure	
	Number of Events (Incidence)		Number of Events (Incidence)		Number of Events (Incidence)	
Event	Active	Control	Active	Control	Active	Control
Intracranial hypotension	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Mania	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Memory impairment	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Mental status changes	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.1%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Nausea	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Neck pain	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Oropharyngeal discomfort	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Paranoia	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Parkinson's disease	0 (0.0%)	1 (2.6%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pneumocephalus	3 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (3.3%)	0 (0.0%)
Postoperative fever	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Procedural vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Pyrexia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Somnolence	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (2.6%)
Staphylococcal skin infection	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Stitch abscess	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Supraventricular tachycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Tremor	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	1 (2.6%)
Urinary tract infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Venous injury	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Weight increased	0 (0.0%)	0 (0.0%)	3 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Wound dehiscence	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (2.6%)
Wound haemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
TOTALS	29 (22.20%)	11 (28.50%)	67 (53.60%)	2 (5.20%)	76 (58.20%)	22 (54.40%)

Incidence = Number of subjects with events divided by number of subjects in each group (Active = 121 subjects, Control = 39 subjects)

Serious Adverse Events

Among all the consented (enrolled) subjects (n=292), a total of 74 Serious Adverse Events (SAE) were reported in 46 subjects. All serious adverse events related to hardware, stimulation or procedure are summarized in Table 4 below. Of 74 Serious Adverse Events, 19 were related to hardware, 2 related to stimulation, and 31 related to procedure.

Infection has been the most commonly reported serious adverse event associated with device-hardware/procedure (8 events, representing 2.7% of subjects). There were three events (each) of device-hardware/procedure-related serious adverse events of peri-operative intracranial hemorrhage (representing 1% of subjects) and seizure (representing 1% of subjects). Stimulation-related serious adverse events include one event of mania and one event of a failed suicide attempt.

Table 4: Serious Adverse Events related to hardware, stimulation or procedure

	Related to Hardware	Related to Stimulation	Related to Procedure
Event	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Aphasia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Cerebral hemorrhage	0 (0.0%)	0 (0.0%)	1 (0.3%)
Complex partial seizures	1 (0.3%)	0 (0.0%)	1 (0.3%)
Confusion postoperative	1 (0.3%)	0 (0.0%)	2 (0.7%)
Confusional state	0 (0.0%)	0 (0.0%)	1 (0.3%)
Convulsion	1 (0.3%)	0 (0.0%)	2 (0.7%)
Device related infection	4 (1.4%)	0 (0.0%)	4 (1.4%)
Encephalitic infection	1 (0.3%)	0 (0.0%)	1 (0.3%)
Hypoventilation	0 (0.0%)	0 (0.0%)	1 (0.3%)
Implant site hemorrhage	1 (0.3%)	0 (0.0%)	1 (0.3%)
Implant site infection	1 (0.3%)	0 (0.0%)	1 (0.3%)
Implant site edema	5 (1.7%)	0 (0.0%)	5 (1.7%)
Intracranial hypotension	1 (0.3%)	0 (0.0%)	1 (0.3%)
Mania	0 (0.0%)	1 (0.3%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	1 (0.3%)
Pneumocephalus	1 (0.3%)	0 (0.0%)	1 (0.3%)
Pyrexia	0 (0.0%)	0 (0.0%)	1 (0.3%)
Staphylococcal skin infection	1 (0.3%)	0 (0.0%)	1 (0.3%)
Subdural hemorrhage	0 (0.0%)	0 (0.0%)	1 (0.3%)
Suicide attempt	0 (0.0%)	1 (0.3%)	1 (0.3%)
Wound dehiscence	1 (0.3%)	0 (0.0%)	1 (0.3%)
Wound hemorrhage	0 (0.0%)	0 (0.0%)	1 (0.3%)
Wound infection	0 (0.0%)	0 (0.0%)	1 (0.3%)
TOTALS	19 (6.10%)	2 (0.60%)	31 (9.90%)

Incidence = Number of subjects with events divided by all consented subjects (n = 292)

In the cohort of 160 randomized subjects, a total of 26 serious adverse events in 20 subjects were reported. Of those, 21 serious adverse events in 16 subjects were in the active group and 5 serious adverse events in 4 subjects were in the control group was reported.

Table 5 summarizes only those serious adverse events related to hardware, stimulation or procedure up to Week 12 post randomization based on treatment assignment.

Table 5: Serious Adverse Events related to hardware, stimulation or procedure up to 12 weeks post randomization based on treatment assignment

Event	Related to Hardware		Related to Stimulation		Related to Procedure	
	Number of Events (Incidence)		Number of Events (Incidence)		Number of Events (Incidence)	
	Active	Control	Active	Control	Active	Control
Aphasia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Confusion postoperative	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.7%)	0 (0.0%)
Confusional state	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Convulsion	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Device related infection	3 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.5%)	0 (0.0%)
Hypoventilation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Implant site edema	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Implant site infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Intracranial hypotension	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Pneumocephalus	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Pyrexia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
Staphylococcal skin infection	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
Wound hemorrhage	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)	0 (0.0%)
TOTALS	5 (4.10%)	4 (10.40%)	0 (0.00%)	0 (0.00%)	13 (10.60%)	4 (10.40%)

Incidence = Number of subjects with events divided by number of subjects in each group (Active = 121 subjects, Control = 39 subjects)

Deaths

Two deaths were reported. One subject died as a result of accidental physical trauma which was determined to be unrelated to the study device and/or implant procedure. The other cause of death is unknown; additional information is not available, and the relationship of the death to the device or stimulation is not known

Efficacy Results

Primary Endpoint

The study efficacy results are based on a cohort of 160 randomized subjects who completed their Week 12 post randomization. Please note that though the total number of randomized subjects is 160, the total number of subjects available for analysis is 156 (118 active and 38 control). This is because four subjects (3 in treatment group and 1 in the control group) did not have baseline scores.

Based on the results of a pre-specified interim analysis, the study successfully met its primary endpoint with statistically significant improvement ($p < 0.001$) in mean change in waking hours per day with good symptom control and no troublesome dyskinesia, with no increase in antiparkinsonian medications (i.e., Levodopa Equivalent Dosage (LED)), from baseline to 12 weeks post-randomization in the Active (3.74 ± 4.79 hours) compared to the Control group (0.72 ± 3.56 hours) as shown in Table 6.

Table 6: Mean change in waking hours per day with good symptom control and no troublesome dyskinesia, with no increase in antiparkinsonian medications (LED), from baseline to 12 weeks post-randomization

	Active Group	Control Group
	Mean (SD) N [95% CI]	Mean (SD) N [95% CI]
Baseline	7.78 (3.65) 118 [7.1 - 8.4]	8.08 (2.92) 38 [7.1 - 9.0]
12 weeks post-randomization	12.37 (3.56) 118 [11.7 - 13.0]	8.96 (3.94) 38 [7.7 - 10.3]
Change from baseline to 12 weeks post-randomization	3.74 (4.79) 118 [2.9 - 4.6]	0.72 (3.56) 38 [-0.5 - 1.9]
Difference in change from baseline to 12 weeks post-randomization between Active and Control groups	3.03 (4.52) [1.4 - 4.7]	
p-value	<0.001	

Post-hoc analysis was performed to report the improvement in mean change in waking hours per day with good symptom control and no troublesome dyskinesias from Baseline to 12 weeks post-randomization, without requirement in the anti-parkinsonian medication (as included in the primary endpoint). An improvement of 4.6 ± 4.81 hours in the Active group compared to 0.88 ± 3.57 hours in the Control group was noted.

Secondary Endpoints

For the following secondary endpoints the sample size is reported as a single “n” out of the 160 (active and control) pre-specified interim analysis cohort. These analyses are reported using the available data only; this is acceptable because the missing data rate for this study is sufficiently low (~5%).

Unified Parkinson’s disease Rating Scale – Section III (UPDRS III)

UPDRS III is the motor sub-section of the Unified Parkinson’s disease Rating Scale (2) (UPDRS) and is used to evaluate overall motor disability, including the classic symptoms of Parkinson’s Disease (PD).

This questionnaire was administered in the *meds off* and *meds on* condition.

Meds off condition

This section summarizes the results in the *meds off* condition. Subjects withheld their anti-parkinsonian medications for at least 12 hours (or overnight) prior to study visit.

A 12.0 ± 11.4 (n = 115) point improvement in the UPDRS III scores in the *stim on/meds off* condition was reported in the Active group compared to a 1.19 ± 8.96 (n = 37) in the Control group as illustrated in Figure 3 below. A difference of 10.83 ± 10.88 ($p < 0.001$)¹ points between both the group was found.

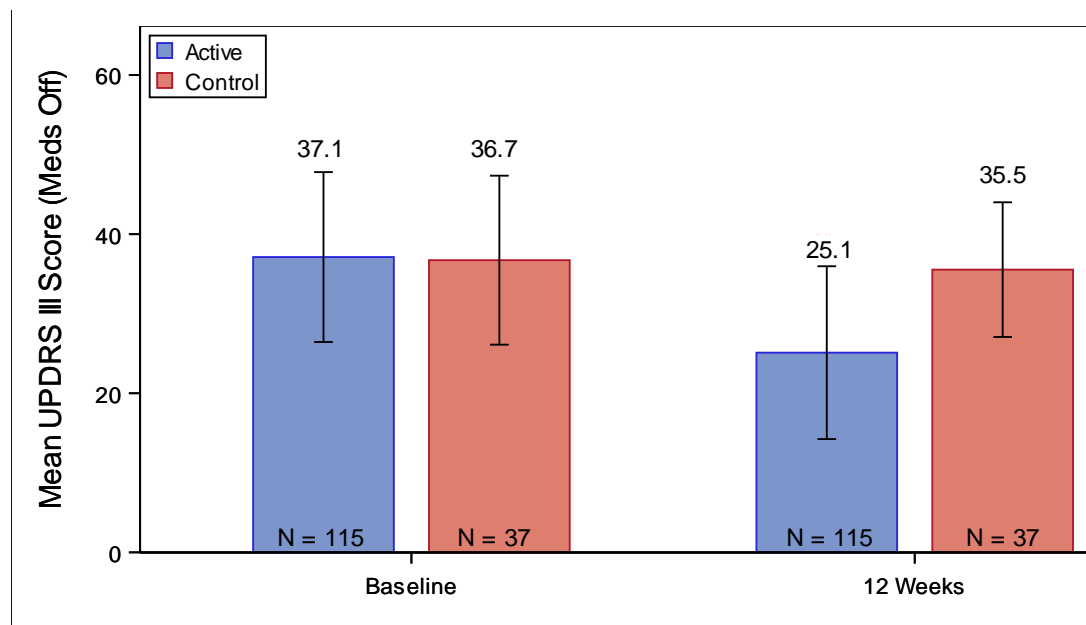


Figure 3: Difference between the Active and Control groups in the mean change in UPDRS-III Score from baseline meds off to 12 weeks post-randomization stim on/meds off.

At 12 weeks post-randomization, subjects in the Active group demonstrated over twice the improvement for clinical significance. Subjects in the Control group showed almost no change.

¹ Not adjusted for multiplicity

Meds on Condition

In the *meds on* condition subjects took their usual anti-parkinsonian medications and assessments were performed at 1 hour (± 10 minutes) post-dosing. (Note that it is possible that subjects may not have reached their Best *meds on* condition but instead be at a partial *meds on* condition at 1 hour post-dosing.) All *meds on* assessments were completed without any additional intervention (i.e. additional medication given or longer wait to get to Best *meds on* condition).

A larger improvement in UPDRS III scores in *stim on/meds on* condition at Week 12 post-randomization was noted in the Active group (5.06 ± 8.72 , $n = 114$) compared to the Control group (2.84 ± 11.20 , $n = 37$) as shown in Figure 4. However, this difference between the two groups was not statistically significant.

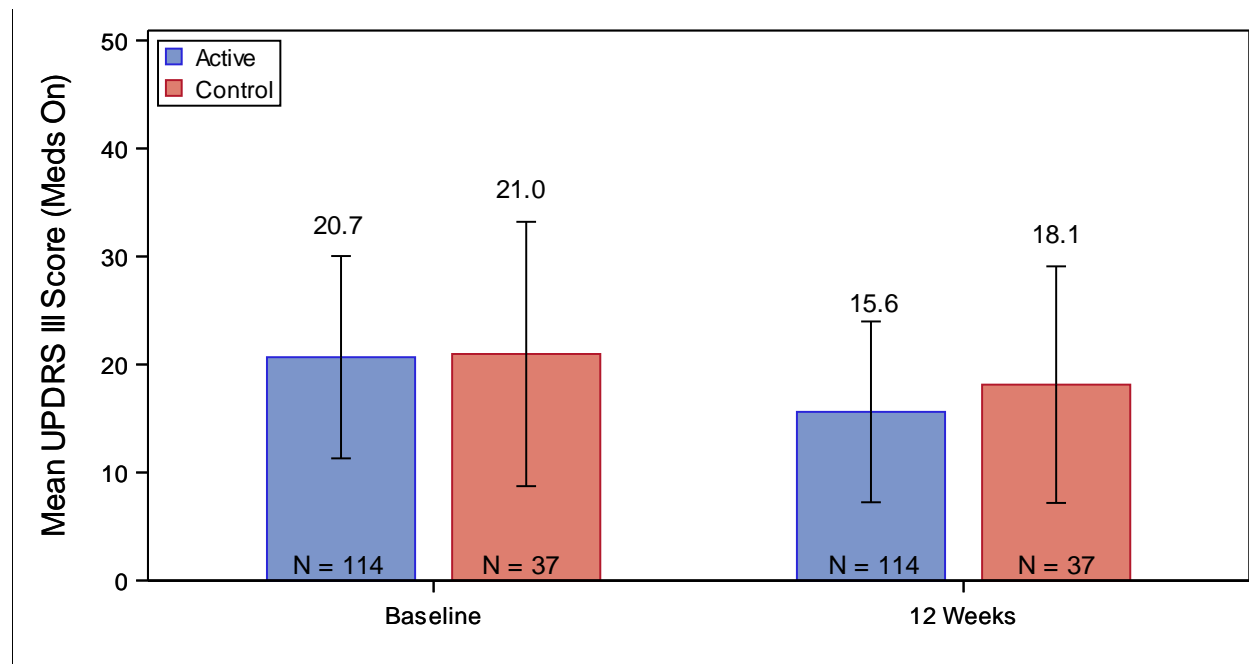


Figure 4: Difference between the Active and Control groups in the mean change in UPDRS-III scores from baseline *meds on* to 12 weeks *stim on/meds on* post-randomization.

39-item Parkinson's Disease Questionnaire (PDQ-39)

The impact of treatment on subjects' quality of life was evaluated using 39-item Parkinson's Disease Questionnaire (4) (PDQ-39), a 39-item questionnaire designed to measure the specific impact of Parkinson's disease on quality of life. The questionnaire measures the impact on health-related quality of life along 8 dimensions including mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication and bodily discomfort (higher scores indicate worsening of quality of life).

This questionnaire was administered in the *meds on* condition.

A 7.79 ± 12.55 (n = 115) point improvement (22%) in the Active group and a 2.56 ± 13.81 (n = 37) worsening (23%) in Control group was noted in the PDQ-39 summary index score as illustrated in Figure 5 below.

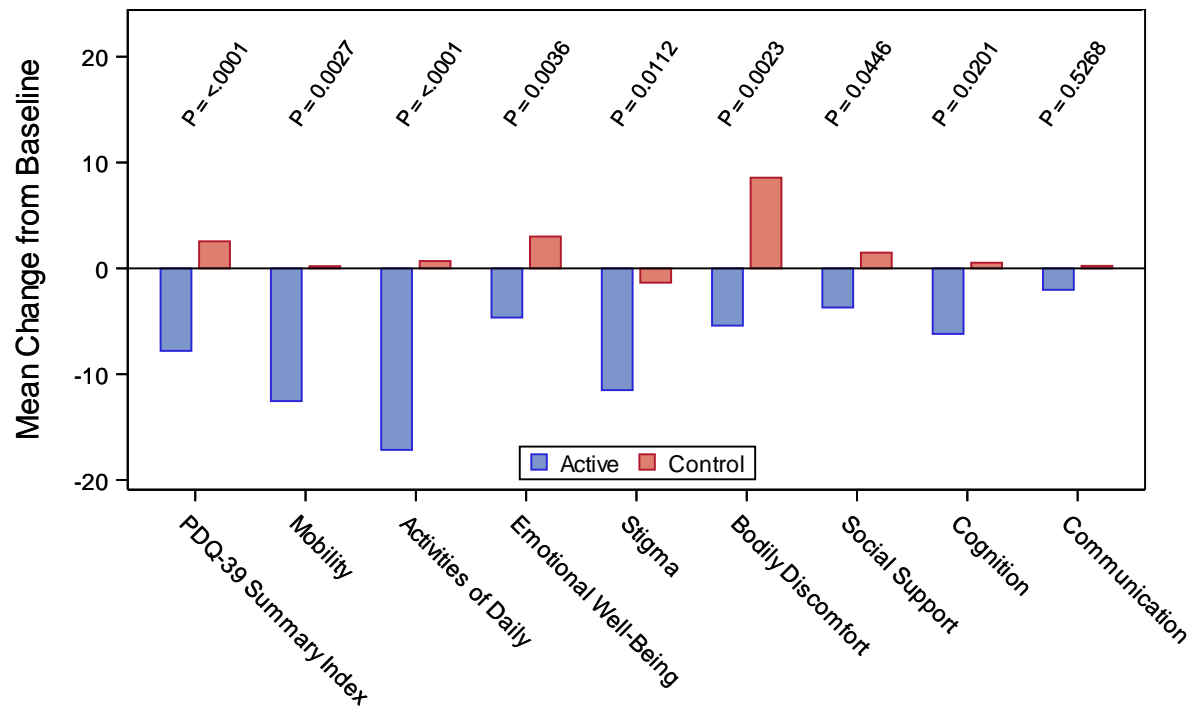


Figure 5: Difference between the Active and Control groups in mean change in PDQ-39 score from baseline to 12 weeks post-randomization. P value from two sample test (Not adjusted for multiplicity).

As illustrated in Figure 5 several sub-domains of the PDQ Questionnaire - mobility, ADL, stigma and cognition showed improvement in the Active group at Week 12 post-randomization.

Modified Schwab and England (SE)

Modified Schwab and England (2) (SE) is a single-item scale to quantify a PD patients' ability to perform activities of daily living. Scores range from 0% (completely bed-ridden) to 100% (completely independent) with higher scores indicating better function.

This questionnaire was administered in the *meds on* condition.

As shown in Figure 6, a 5.70 ± 14.26 (n = 114) point improvement in SE scores in the Active group as compared to a 1.89 ± 7.76 (n = 37) point worsening in SE scores in the Control group was reported.

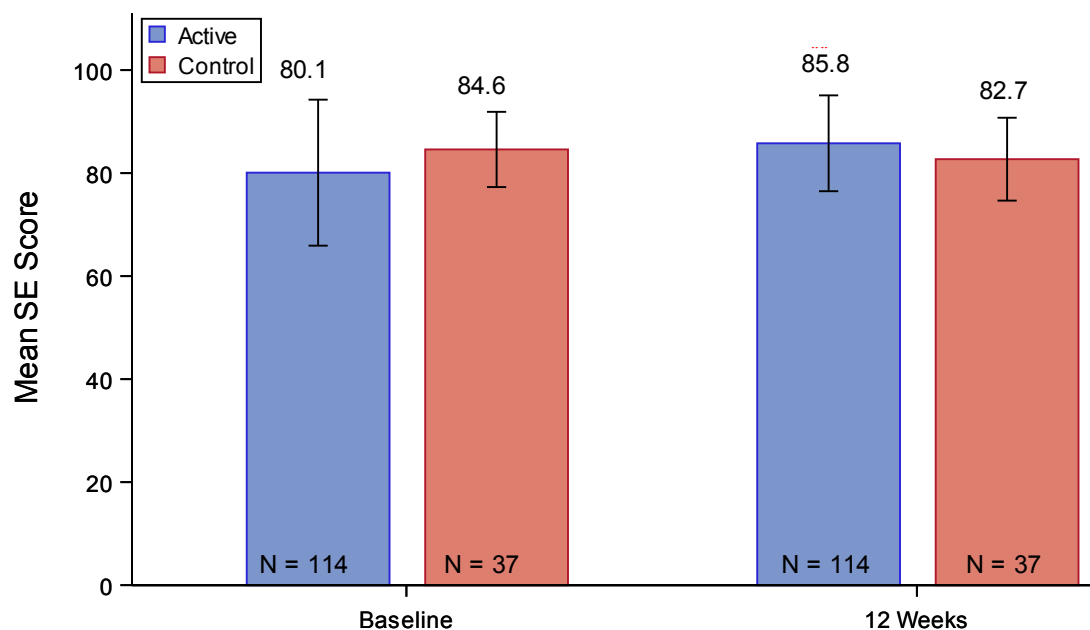


Figure 6: Difference between the Active and Control groups in the mean change in SE scores from baseline to 12 weeks post-randomization.

This difference in quality of life as measured by SE scores between Active and Control groups was statistically significant ($p < 0.01$)².

Clinical Global Impression of Change (CGI-C) as assessed by physician

Physicians (blinded assessor) were asked to report their impression of change (1) in subjects' symptoms in a manner similar to what was done by subjects' themselves at Week 12 post-randomization. The responses are illustrated in Figure 7 below.

² Not adjusted for multiplicity

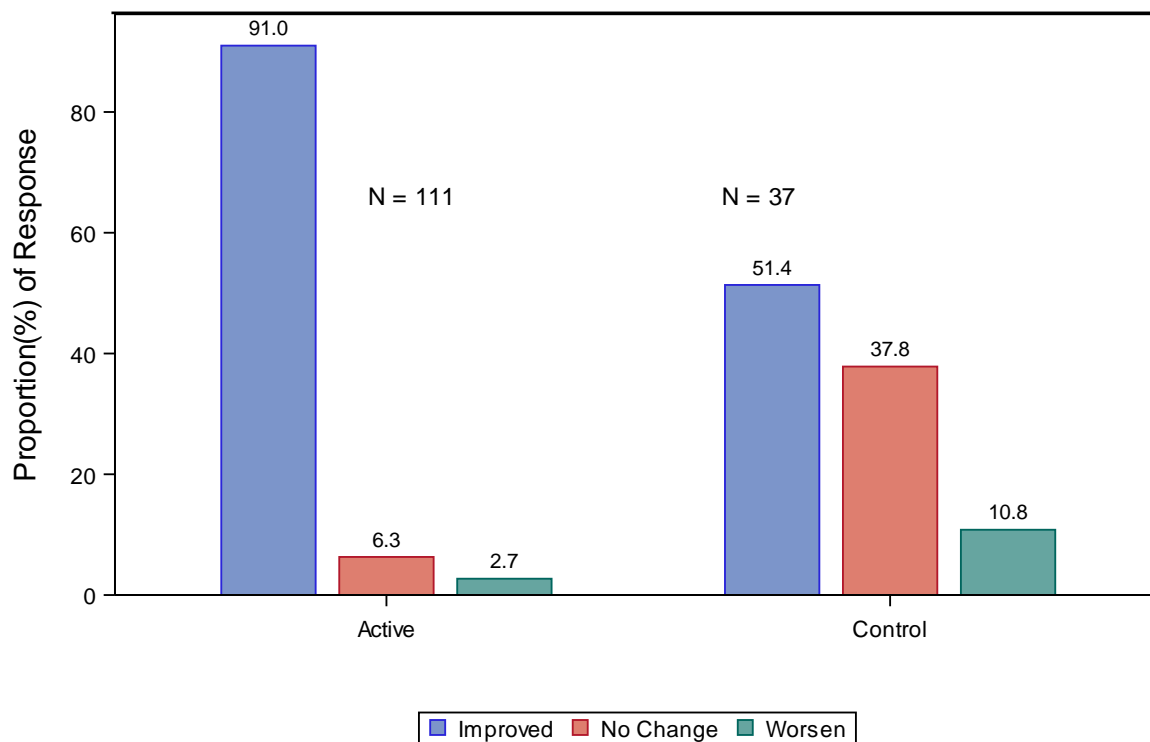


Figure 7: Difference between the Active and Control groups in the mean CGI-C, as assessed by the physician, at Week 12 post-randomization.

At Week 12 post-randomization, in the opinion of the blinded assessor (clinician), 91.0% of subjects in the Active group improved following DBS. A significant percentage of these subjects were in the “very much improved” and “much improved” category.

For those subjects in the Control group, the assessor reported 37.8% of subjects had no change in their PD symptoms. It was also interesting to note that they reported 51.4% of subjects showed improvement at 12 weeks as well.

A statistically significant ($p < 0.0001$)³ difference between the Active and Control groups was observed.

Clinical Global Impression of change as assessed by subjects

Subjects were asked to report their impression of change in their symptoms at Week 12 post-randomization as compared with Baseline using a questionnaire with a seven-point scale (ranging from “marked worsening” to “very much improved”). This questionnaire was administered in the *meds on* condition.

The results are illustrated in the graph below.

³ Not adjusted for multiplicity

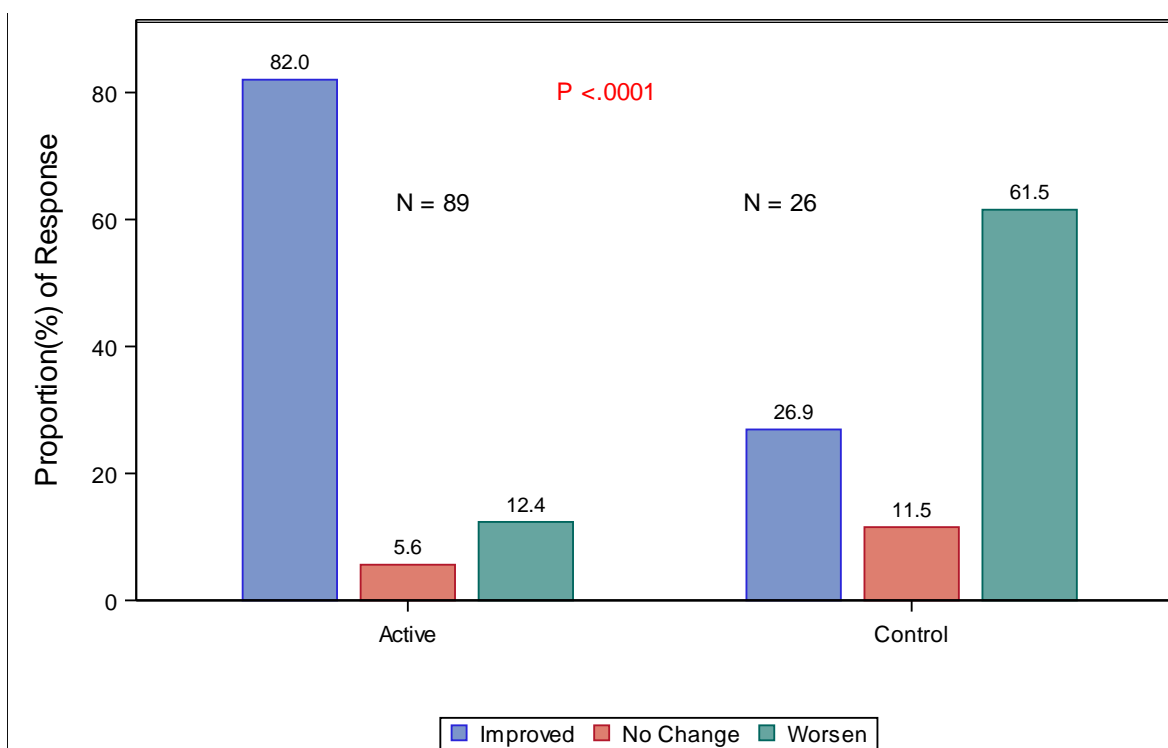


Figure 8: Difference between the Active and Control groups in the mean CGI-C, as assessed by the subject, at Week 12 post-randomization. P value from Fisher's Exact test.

At Week 12 post-randomization, 82.0% of Active subjects reported an improvement in their PD symptoms compared to 26.9% in the Control group. In the Control group, while 26.9% reported improved, a majority (61.5%) reported worsened disease state at 12 weeks.

A statistically significant ($p < 0.0001$)⁴ difference between the Active and Control groups was reported.

Treatment Satisfaction score

Subjects' satisfaction with treatment was assessed where they rated their overall satisfaction with the device and their willingness to recommend the therapy. They were also asked if they would be willing to repeat the treatment process again.

The responses of subjects in the Active and Control groups are summarized in the Table 7 below.

Table 7: Treatment Satisfaction Score at 12 weeks post-randomization

	Active Group	Control Group
Overall Satisfaction	%(n/N)	%(n/N)
Extremely Dissatisfied	3.4% (4 / 116)	11.1% (4 / 36)
Very Dissatisfied	3.4% (4 / 116)	13.9% (5 / 36)

⁴ Not adjusted for multiplicity

	Active Group	Control Group
Dissatisfied	1.7% (2 / 116)	16.7% (6 / 36)
Somewhat Satisfied	5.2% (6 / 116)	13.9% (5 / 36)
Satisfied	16.4% (19 / 116)	16.7% (6 / 36)
Very Satisfied	28.4% (33 / 116)	22.2% (8 / 36)
Extremely Satisfied	41.4% (48 / 116)	5.6% (2 / 36)
Willingness to go through treatment process again		
Yes	90.5% (105 / 116)	80.6% (29 / 36)
No	9.5% (11 / 116)	19.4% (7 / 36)
Would recommend therapy to a friend with Parkinson's disease		
Yes	91.4% (106 / 116)	83.3% (30 / 36)
No	8.6% (10 / 116)	16.7% (6 / 36)

91.4% of subjects in the Active group and 58.4% in the Control group reported being overall satisfied (varying degrees) with their treatment.

Over 90% of subjects in the Active group were willing to go through the treatment process again and would also recommend the therapy to a friend with Parkinson's disease. A similar trend was observed in the Control group as well.

A statistically significant ($p < 0.0001$)⁵ difference in treatment satisfaction score for both the groups was reported.

Unified Parkinson's Disease Rating Scale – Section II (UPDRS II) (Activities of Daily Living)

Unified Parkinson's Disease Rating Scale – Section II (2) (UPDRS II) is a sub-section of the UPDRS Scale and focuses on subjects' activities of daily living such as speech, salivation, swallowing, handwriting, cutting food and handling utensils, dressing, etc. UPDRS II was administered in the *meds off* and *meds on* condition during the study.

This section describes the results in the *meds on* condition. Details on how the *meds on* condition was achieved are summarized earlier in this section. A 1.74 ± 5.90 ($n = 115$) in the Active group versus a 0.06 ± 5.25 ($n = 36$) point improvement in the Control group in UPDRS II scores in the *stim on/meds on* condition was reported at Week 12 post-randomization as shown in Figure 9 below.

⁵ Not adjusted for multiplicity

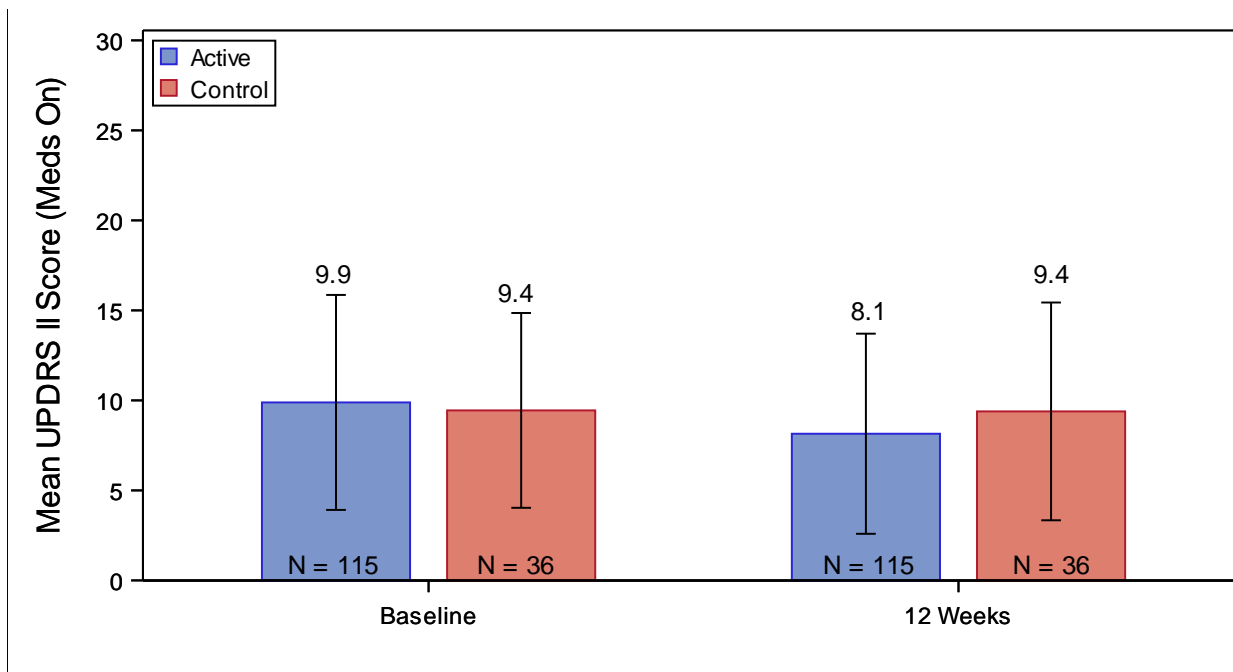


Figure 9: Difference between the Active and Control groups in the mean change in UPDRS-II scores from baseline *meds on* to 12 weeks *stim on/meds on* post-randomization.

The change in UPDRS II scores in *meds on* condition was not statistically significant.

36-Item Short Form Survey (SF-36 v2) (Quality of Life)

36-Item Short Form Survey (5) (SF-36v2) is a quality of life scale that measures subjects' functional health and well-being from their own point of view. It is comprised of several questions spanning eight health domains which contribute to the scoring of two component summary measures: physical health and mental health.

Subjects in the Active group noted an improvement of 3.35 ± 7.90 points compared to a slight worsening (-0.23 ± 6.79) in the Control group in the physical health domain. In the mental health domain, both groups showed small improvements as shown in Table 8 below. The difference between the two groups is not statistically significant.

Table 8: Mean change in the SF-36v2 score from baseline to 12 weeks post-randomization for Active and Control groups

SF-36v2 Physical (PCS)			SF-36v2 Mental (MCS)	
	Mean (SD) N [95% CI]		Mean (SD) N [95% CI]	
	Active Group	Control Group	Active Group	Control Group
Baseline	39.77 (7.64) 114 [38.3 - 41.2]	39.55 (6.52) 36 [37.3 - 41.8]	49.97 (8.23) 113 [48.4 - 51.5]	50.33 (8.44) 36 [47.5 - 53.2]
12 weeks post-randomization	43.12 (7.95) 114 [41.6 - 44.6]	39.32 (8.37) 36 [36.5 - 42.1]	51.18 (9.04) 113 [49.5 - 52.9]	52.01 (9.82) 36 [48.7 - 55.3]
Change from baseline to 12 weeks post-randomization	3.35 (7.90) 114 [1.9 - 4.8]	-0.23 (6.79) 36 [-2.5 - 2.1]	1.21 (9.53) 113 [-0.6 - 3.0]	1.68 (8.16) 36 [-1.1 - 4.4]
Difference in change between Active and Control groups	3.58 (7.65) [0.7 - 6.5]		-0.47 (9.22) [-4.0 - 3.0]	
p-value	0.0591			
PCS = Physical Component Summary score. MCS = Mental Component Summary score. p-value is from a two-sided two-group paired Hotelling's T-square test using the 2x1 vector of PCS and MCS differences in change between Active and Control groups. Not adjusted for multiplicity.				

Conclusions from INTREPID Clinical Study

The INTREPID Study was designed to evaluate the safety and effectiveness of the Boston Scientific Vercise™ Deep Brain Stimulation (DBS) System for bilateral stimulation of the subthalamic nucleus (STN) in the treatment of patients with advanced, levodopa-responsive bilateral Parkinson's disease (PD), which is not adequately controlled with medication.

Of the 292 subjects who provided consent to participate in the study, 177 subjects were implanted bilaterally in the STN with the Vercise DBS System. This document provides the effectiveness data for 160 randomized subjects that completed their Week 12 post-randomization visit as of December 31, 2016 and safety data for 292 enrolled subjects.

The primary endpoint of the study was the difference in change from Baseline to Week 12 post-randomization visit between the Active and Control groups in subjects' ON time with no increase in antiparkinsonian medications. ON time included "ON time" as well as "ON time with non-troublesome dyskinesias" as measured on the Parkinson's Disease (PD) diary (3). This validated measure was utilized for the primary endpoint as the PD diary allowed for subjects' to assess their own health status without any bias from study investigators or their interpretation. The PD diary collects subjects' PD symptoms/health status in 30 minute increments during their awake hours – this allows for a deeper understanding of their disease state including fluctuations and impact to their daily routine. In addition to ON time, the primary endpoint also included a requirement that subjects must have no increase in

their antiparkinsonian medications during the blinded period as calculated via levodopa equivalents. This was included to isolate the benefits of DBS for the treatment of PD. This additional criterion is stringent and further added to the scientific rigor of the INTREPID Study. Other randomized controlled trials including Okun 2012 (12), Weaver 2009 (13), Deuschl 2006 (14) did not have this additional criterion.

Though the study is still ongoing, per the scheduled interim analysis, the study successfully met its primary endpoint with statistically significant improvement ($p < 0.001$) in mean change in waking hours per day with good symptom control and no troublesome dyskinesia, with no increase in antiparkinsonian medications (LED), from baseline to 12 weeks post-randomization in the Active (3.74 ± 4.79 hours) compared to the Control group (0.72 ± 3.56 hours). Post-hoc analysis showed that this improvement increased when the analysis was performed with no requirement in medication (as included in the primary endpoint). An improvement of 4.6 ± 4.81 hours in the Active group compared to 0.88 ± 3.57 hours in the Control group was noted.

In addition to their ON time (good symptom control and no troublesome dyskinesia), subjects in the Active group also noted a significant improvement in their OFF time when the medication is no longer effective and subjects' symptoms return.

The primary endpoint result was also supported by several secondary endpoints including improvement in Unified Parkinson's Disease Rating Scale – Section III (2) (UPDRS III) scores, quality of life such as 39-Item Parkinson's Disease Questionnaire (4) (PDQ-39), Modified Schwab and England (2) (SE) scores. The overall change in subjects' disease state during the study follow-up as compare to Baseline was evaluated by the subjects and physicians to provide different perspectives. In the Active group, 82.0% of subjects reported varying degrees of improvement as compared to Baseline, which was supported by physician response of 91.0%, who similarly reported varying degrees of improvement in their subjects.

91.4% of subjects in the Active group reported being overall satisfied with their treatment. A similar trend was observed when subjects were asked if they would recommend the therapy or be willing to repeat the treatment again. This is indicative of the overall impact that DBS with the Vercise System had on subjects' PD state and their overall quality of life.

There were no unanticipated adverse events and the overall incidence of device/procedure-related serious adverse events (SAEs) was comparable to published reports. The adverse event and safety profiles were similar to those seen in other recent studies of DBS Systems.

Results of this prospective, multi-center, double-blinded randomized controlled trial designed to evaluate the Vercise DBS System for bilateral stimulation of the subthalamic nucleus in the treatment of Parkinson's disease demonstrated that its benefits outweigh the associated risks. Furthermore, the safety and effectiveness of the Vercise System were established.

VANTAGE Clinical Study

Study Design

VANTAGE is a multi-center, prospective, open-label, single-arm study of the safety and efficacy of the Vercise DBS System for bilateral stimulation of the subthalamic nucleus (STN) in the treatment of moderate to severe idiopathic Parkinson's Disease (PD). Six (6) sites participated in this study from Austria, France, Germany, Italy, Spain and the U.K. Enrollment was completed between November 2010 and December 2012. The study population included male and female patients, ages 21 to 75, diagnosed with idiopathic PD as determined by clinical presence of at least 2 of the 3 cardinal features (resting tremor, rigidity, and bradykinesia) and good levodopa response. Subjects were required to have a PD symptom severity level based on the following criteria:

- Modified Hoehn and Yahr (6) stage ≥ 2
- Unified Parkinson's Disease Rating Scale (2) (UPDRS) motor exam of ≥ 30 in the "Meds Off" condition
- Motor complications that cannot be controlled with pharmacologic therapy.

During the first 52 weeks post-implant, there were 2 pre-implant visits and 3 evaluation follow-up visits at 12, 26, and 52 weeks post-implant. Following DBS implant, clinicians monitored anti-parkinsonian medication dosages.

To obtain a comprehensive picture of patients improvement in the study, data collected at study visits (baseline and follow-up) included a 3-day motor diary recorded at home prior to the visit, the Unified Parkinson's Disease Rating Scale (2) (UPDRS), 39-Item Parkinson's Disease Questionnaire (4) (PDQ-39), 36-Item Short Form Survey (5) (SF-36 v2), and Global Impression of Change (1). At each visit, patients were evaluated without medication (Meds Off) and with medication (Meds ON). At follow-up visits post-implant, patients were evaluated with the DBS device turned on (Stim On).

Patient Accountability

A total of 40 patients were implanted in the study with the Vercise Deep Brain Stimulation (DBS) System. The majority of study patients were male (27/40; 67.5%). The mean age of study patients was 60.2 years (± 7.82) and the mean duration of Parkinson's Disease (PD) symptoms was 11.7 years (± 4.57).

Of the 40 patients implanted with the Vercise DBS System, 39 completed the 52 weeks of follow-up. 1 patient (2.5%) terminated prior to the 26 Week Visit due to death following pneumonia, not related to the study device or procedure.

Safety Results

All Adverse Events

During the 52 weeks post-implant period, a total of 125 adverse events (AEs) were reported in 37 implanted patients. Out of 125 adverse events, 107 were non-serious and 18 were serious adverse events. All adverse event relationships were assessed and reported by the investigators. Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA).

All adverse events reported by study site personnel as related to hardware, stimulation or procedure is summarized in Table 9 below. Of the 125 events, 6 events were considered related to hardware, 17 events were related to stimulation and 12 events were related to procedure.

Table 9: All Adverse Events related to Hardware, Stimulation or Procedure

	Related to Hardware	Related to Stimulation	Related to Procedure
Preferred Term	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Anxiety	0 (0.0%)	1 (2.5%)	0 (0.0%)
Apathy	0 (0.0%)	3 (7.5%)	2 (5.0%)
Confusional state	0 (0.0%)	1 (2.5%)	0 (0.0%)
Device migration	0 (0.0%)	0 (0.0%)	1 (2.5%)
Diplopia	0 (0.0%)	1 (2.5%)	0 (0.0%)
Dysarthria	0 (0.0%)	1 (2.5%)	1 (2.5%)
Dystonia	0 (0.0%)	2 (2.5%)	0 (0.0%)
Fall	0 (0.0%)	1 (2.5%)	0 (0.0%)
Gait disturbance	0 (0.0%)	1 (2.5%)	0 (0.0%)
Hallucination, auditory	0 (0.0%)	0 (0.0%)	1 (2.5%)
Hypoaesthesia	0 (0.0%)	1 (2.5%)	0 (0.0%)
Implant site haematoma	0 (0.0%)	0 (0.0%)	1 (2.5%)
Implant site infection	0 (0.0%)	0 (0.0%)	1 (2.5%)
Incision site infection	1 (2.5%)	0 (0.0%)	1 (2.5%)
Laboratory test abnormal	0 (0.0%)	0 (0.0%)	1 (2.5%)
Localised infection	1 (2.5%)	0 (0.0%)	0 (0.0%)
Movement disorder	0 (0.0%)	1 (2.5%)	0 (0.0%)
Neck pain	1 (2.5%)	0 (0.0%)	0 (0.0%)
Parkinson's disease	1 (2.5%)	1 (2.5%)	0 (0.0%)
Postoperative wound infection	0 (0.0%)	0 (0.0%)	1 (2.5%)
Respiratory depression	0 (0.0%)	0 (0.0%)	1 (2.5%)
Speech disorder	0 (0.0%)	2 (5.0%)	1 (2.5%)

	Related to Hardware	Related to Stimulation	Related to Procedure
Preferred Term	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Staphylococcal infection	1 (2.5%)	0 (0.0%)	0 (0.0%)
Tremor	1 (2.5%)	0 (0.0%)	0 (0.0%)
Weight increased	0 (0.0%)	1 (2.5%)	0 (0.0%)
TOTALS	6 (12.5%)	17 (40.0%)	12 (30.0%)

Incidence = Number of subjects with events divided by all implanted subjects (n = 40)

Serious Adverse Events

A total of 18 Serious Adverse Events (SAE) were reported in 10 subjects. All serious adverse events related to hardware, stimulation or procedure is summarized in Table 10 below. Of 18 Serious Adverse Events, 2 were related to hardware and 3 were related to procedure. There were no serious adverse events related to stimulation.

Table 10: Serious Adverse Events related to hardware, stimulation or procedure

	Related to Hardware	Related to Stimulation	Related to Procedure
Preferred term	Number of Events (Incidence)	Number of Events (Incidence)	Number of Events (Incidence)
Device migration	0 (0.0%)	0 (0.0%)	1 (2.5%)
Implant site infection	0 (0.0%)	0 (0.0%)	1 (2.5%)
Localised infection	1 (2.5%)	0 (0.0%)	0 (0.0%)
Respiratory depression	0 (0.0%)	0 (0.0%)	1 (2.5%)
Staphylococcal infection	1 (2.5%)	0 (0.0%)	0 (0.0%)
TOTALS	2 (5.0%)	0 (0.0%)	3 (7.5%)

Incidence = Number of subjects with events divided by all implanted subjects (n = 40)

Two serious adverse events of infection reported as related to the study device occurred in 1 patient. These events included an initial infection of the patient's scalp treated with antibiotics and recurrent scalp infection (due to staphylococcus), also treated with antibiotics. Both infections have resolved without residual effects. In addition, there were 3 SAEs which were considered related to the study-procedure. The procedure related events include one event of implant site infection in the vicinity of the Implantable Pulse Generator (IPG) pocket (treated with antibiotics and surgical revision of the pocket area); one event of IPG migration (treated with surgical repositioning of the IPG); and one event of respiratory depression occurring during the implant procedure as a result of poor body positioning (treated with repositioning of the patient). All 3 procedure-related SAEs resolved without residual effects.

Of the 16 serious adverse events which were not device or hardware-related, 14 have resolved with/without residual effects; 2 are presently not resolved. These include individual reports of lumbago and neoplasm. One SAE of pneumonia resulted in death.

Conclusion from VANTAGE Clinical Study

The safety profile in VANTAGE Study was similar to those seen in the INTREPID Study and other recent studies of Deep Brain Stimulation (DBS). The most frequent device and/or procedure-related adverse events included infection, device migration and respiratory depression. All serious adverse events (SAEs) related to either a device or procedure resolved without residual effects. There were no unanticipated adverse events and the overall incidence of device and procedure-related SAEs is comparable to published reports. The VANTAGE Study data further supports the results from the INTREPID Study in demonstrating the safety of the Vercise DBS System.

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Vercise™ DBS Programming Manual

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Additional Information

For indications, contraindications, warnings, precautions, adverse events summary, sterilization, component disposal, storage and handling, labeling symbols, warranty information and other device specific information not included in this manual, refer to the Vercise Physician Manual.

Product Model Numbers

Model Number	Description
DB-1110-C	Vercise IPG Kit
DB-5110-C	Vercise ETS
DB-5212-C	Vercise Remote Control
DB-5500-1	Vercise Remote Control Kit
*DB-7161	Clinician Programmer
*DB-7161-R	Clinician Programmer (Refurbished)
*NM-7161	Clinician Programmer
*NM-7161-R	Clinician Programmer (Refurbished)
NM-4500	IR Interface
NM-4502	IR Interface Holder
NM-4512	USB Splitter
DB-7162 and NM-7162	Keyboard
DB-4511 and NM-4511	Cable, USB Serial

*Applicable after installation of Bionic Navigator 2.04 (Software version 9028287-204)

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.

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Glossary

Amplitude

The assigned current during the stimulation pulse, measured in milliamperes (mA).

Anode

Electrode that is positively charged during the stimulation pulse (in the context of neurostimulation).

Area

A set of stimulation parameters and contact assignments pertaining to a lead; a program may consist of up to 4 areas.

Battery

The component of the Stimulator that stores and delivers energy to the implanted system.

Cathode

Electrode that is negatively charged during the stimulation pulse (in the context of neurostimulation).

Charger

An external device that is used to charge the battery of the implanted Stimulator.

Contact

An electrically conductive component on the lead; a lead typically has multiple contacts (sometimes used interchangeably with the term “electrode”).

Charging

The act of recharging the implanted battery of the Stimulator.

Clinician Programmer

The device that runs the Bionic Navigator™ software, used for configuring stimulation parameters.

Frequency

See Pulse Rate.

Lead

Made up of insulated wires and contacts; conducts electricity from the Stimulator to the contacts in the tissue.

Patient Options

The default parameter settings for a specific patient, as opposed to system default settings.

Program

The stimulation settings that may be active at a given time; a program may be comprised of up to 4 areas (see also Area).

Program Database

A list of programs that were once saved in the Stimulator (i.e., program history).

Pulse Rate

The number of pulses of electric current in one second, measured in Hertz (Hz) or pulses per second (pps).

Pulse Width

The duration of the pulse of electric current, measured in microseconds (μ s).

Ramp Up Time or Ramp Time

The amount of time the Stimulator will take to increase stimulation from 0 mA to the programmed amplitude.

Introduction



Welcome to Bionic Navigator™ by Boston Scientific.

Bionic Navigator is a software program that is used to set and adjust stimulation parameters for the Vercise™ DBS System. The goal of this Programming Guide is to maximize patient benefits by providing useful information and instruction to persons using Bionic Navigator on the Clinician Programmer.

In the following pages, you will learn basic concepts, such as how to enter patient information, program a patient, and save patient programs to the Remote Control. You will also learn about additional features, such as creating reports and syncing data.

If you have any issues with Bionic Navigator, please refer to the Troubleshooting section.

Intended Use

Bionic Navigator is a software program that is used to set and adjust stimulation parameters for the Vercise DBS System.

Setting Up

Connecting the Remote Control to the Clinician Programmer

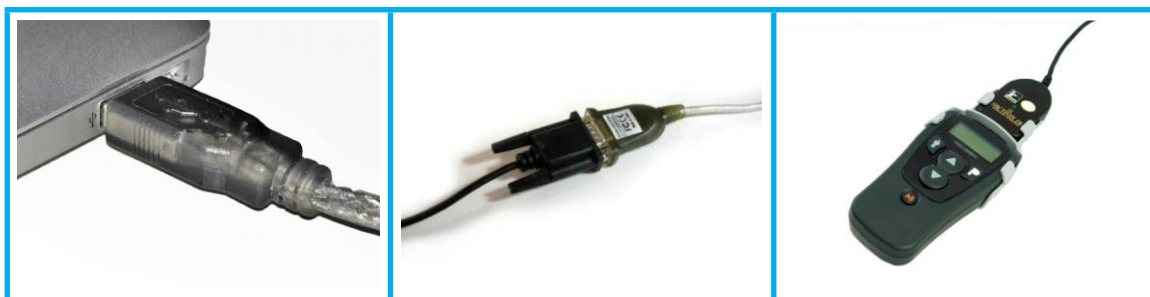
The Clinician Programmer (CP) communicates with the Stimulator via the Remote Control. The Clinician Programmer is connected to the Remote Control using an infrared (IR) link. The Remote Control uses a radio frequency (RF) link to communicate with the Stimulator. Programs can be loaded to the Clinician Programmer for previewing, activating, and changing stimulation parameters. Stimulation programs can also be saved to the Remote Control.

CAUTION: Use only Vercise™ DBS System components with the Clinician Programmer. Failure to do so can result in inappropriate stimulation.

CAUTION: The CP is not equipment for the patient environment as defined by IEC60601-1. The CP and the person using the CP should not be in contact with the patient while programming.

To connect the remote Control to the Clinician Programmer:

- 1 Plug the USB to Serial Cable into the USB port on the Clinician Programmer.
- 2 Plug the serial end of the USB to Serial Cable into the matching end of the IR Interface.
- 3 Insert the IR Interface and Remote Control into the plastic holder to keep the IR windows aligned, as shown below.




1



2

3

- 4 Position the patient within 18 inches (45 cm) of the Remote Control and orient the large surface of the Remote Control parallel to large surface of the Stimulator. Proper orientation will ensure a reliable communication link between the Clinician Programmer and the Stimulator.

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

- 5 Turn on the Clinician Programmer and log in.
- 6 If only Bionic Navigator is installed on the Clinician Programmer (CP), click on the Bionic Navigator icon  to launch Bionic Navigator.

If more than one DBS software is installed on the CP, click the Vercise Launcher icon  and select the Vercise DBS System icon  to start Bionic Navigator.

***Note:** Multiple programming softwares should not be run simultaneously on the same CP.*

- 7 Press and hold the **P** button to unlock the Remote Control.

***Note:** The Remote Control should be linked to the Stimulator (see Linking a Remote Control to a Stimulator on page 4).*

- 8 Enter the Clinician's screen on the Remote Control by pressing and holding both the **I** and **P** buttons simultaneously.
- 9 Press the **P** button to select "CP Mode."

The Remote Control will inform you that it is ready to communicate with the Clinician Programmer.

Once the Remote Control is within range of the Stimulator, the Clinician Programmer will detect the Stimulator and begin communication.

Linking a Remote Control to a Stimulator

Linking is defined as the process of configuring the Remote Control to communicate with a specific Stimulator.

To link a Remote Control that has been previously linked to a different Stimulator, you must first de-link the Remote Control from the original Stimulator (see *De-linking a Remote Control from a Stimulator* on page 6) and then link the Remote Control to the new Stimulator.

To link a Remote Control to a Stimulator:

- 1 Press and hold the **P** button to unlock the Remote Control.
The Remote Control will ask if you want to link it to a Stimulator.
- 2 Position the Remote Control within 18 inches (45 cm) of the Stimulator and orient the large surface of the Remote Control parallel to large surface of the Stimulator.
- 3 Press the **P** button to link the Remote Control with the Stimulator or cancel by pressing the **⏏** button.
- 4 Confirm the link by pressing the **P** button or cancel by pressing the **⏏** button.

If programs are stored in the...	Then...
<input checked="" type="checkbox"/> Remote Control <input checked="" type="checkbox"/> Stimulator	The Remote Control will automatically download the programs from the Stimulator.
<input type="checkbox"/> Remote Control <input checked="" type="checkbox"/> Stimulator	The Remote Control will automatically download the programs from the Stimulator.
<input checked="" type="checkbox"/> Remote Control <input type="checkbox"/> Stimulator	<p>The Remote Control will ask if you want to download the Remote Control programs to the Stimulator.</p> <p>Enter the password A-B-C to download the Remote Control programs to the Stimulator.</p>
<input type="checkbox"/> Remote Control <input type="checkbox"/> Stimulator	The Remote Control will be linked to the Stimulator immediately.

If programs are stored in the...	Then...
<input checked="" type="checkbox"/> Remote Control <input checked="" type="checkbox"/> External Trial Stimulator	<p>The Remote Control will prompt you to clear the programs on the External Trial Stimulator.</p> <p>Then, the Remote Control will ask if you want to download the Remote Control programs to the External Trial Stimulator.</p> <p>Enter the password A-B-C to download the Remote Control programs to the External Trial Stimulator.</p>
<input type="checkbox"/> Remote Control <input checked="" type="checkbox"/> External Trial Stimulator	<p>The Remote Control will prompt you to clear the programs on the External Trial Stimulator.</p>
<input checked="" type="checkbox"/> Remote Control <input type="checkbox"/> External Trial Stimulator	<p>The Remote Control will ask if you want to download the Remote Control programs to the External Trial Stimulator.</p> <p>Enter the password A-B-C to download the Remote Control programs to the External Trial Stimulator.</p>
<input type="checkbox"/> Remote Control <input type="checkbox"/> External Trial Stimulator	<p>The Remote Control will be linked to the External Trial Stimulator immediately.</p>

De-linking a Remote Control from a Stimulator

To de-link a Remote Control from a Stimulator:

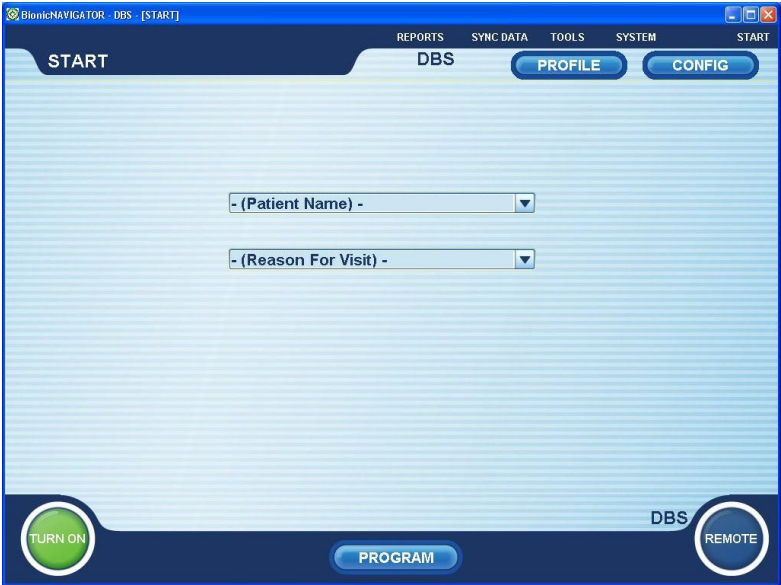
- 1 Press and hold the **P** button to unlock the Remote Control.
- 2 Enter the Clinician's screen on the Remote Control by pressing and holding both the **I** and **P** buttons simultaneously.
- 3 Scroll down to "Clear Link" and select "Clear Link" by pressing the **P** button.
- 4 Confirm that you want to clear the link by pressing the **P** button or cancel by pressing the **I** button.
- 5 Enter the password A-B-C.

***Note:** To re-link the Remote Control, see Linking a Remote Control to a Stimulator on page 4.*

Starting a Session

Getting to the Start Screen

The Start Screen will open when the Bionic Navigator Software launches. To access the Start Screen at any other time, click **START** from the top right corner of any screen.



If patient’s Remote Control is connected and positioned to communicate with the Stimulator, the system will automatically detect the DBS Stimulator.







Understanding the Toolbar

The toolbar is present at the top of every screen in the Bionic Navigator software. The toolbar allows you to access various features defined in the table below and further described in several sections of this guide.

Click...	to...
REPORTS	Create reports, including patient information reports, generic reports, patient list reports, clinical outcomes reports, and clinic activity reports.
SYNC DATA	Synchronize data between the Clinician Programmer and a Patient Card (for data transfer).
TOOLS	To access various tools, including system information, backing up data, enabling auto-impedance measurements, EGL-Scan, and viewing information about Bionic Navigator.
SYSTEM	View and edit default system settings.
START	To end your current session and restart Bionic Navigator.

Understanding the Common Buttons

Common buttons are dispersed around the perimeter of each screen in the Bionic Navigator software. These buttons allow you to quickly and conveniently access common screens or perform common actions. The function of these buttons are defined in the table below and further described in several sections of this guide.

Click...	to...
	Access the Profile screen.
	Access the Configuration screen.
	Turn stimulation on (applies to all areas with Amplitude set at a value greater than zero).
	Turn stimulation off.
	Access the Programming screen.
	Access the Remote Control screen.


Starting a New Patient Session

The Bionic Navigator software automatically starts a new session when it is opened. When the software is already open, you may start a new session or restart the Bionic Navigator software using the Start function.

To use the Start function, click **START** on the toolbar of any screen.

Creating a New Patient

To create a new patient:

- 1 Click the down arrow on the right side of the Patient drop-down menu.
- 2 Select New Patient.
The Profile Screen will automatically be displayed.
- 3 Fill in the patient's information.
For more information on the Profile Screen, see Managing a Patient's Profile on page 13.
- 4 Click  to save the information.
The Start Screen will automatically be displayed.
- 5 Click the down arrow on the right side of the Reason for Visit drop-down menu.
- 6 Select the appropriate reason for the visit.

Selecting an Existing Patient

The Clinician Programmer will automatically recognize a patient if you have previously link the Clinician Programmer to the patient's hardware.

To select an existing patient:


- 1 Click the down arrow on the right side of the Patient pull-down menu.
- 2 Select an appropriate patient from the alphabetized list.
- 3 Click the down arrow on the right side of the Reason for Visit pull-down menu.
- 4 Select the reason for the patient visit.

The patient session has now begun. You may now proceed to other screens by clicking the appropriate buttons on the screen.

Managing a Patient's Profile

Entering and Editing Patient Information

To create or edit a patient's profile:



- 1 Click  in the upper right corner of any screen.
If a patient is currently selected, the patient's information will show up on the Profile Screen.


Note: *If no patient was selected, it is assumed that you wish to create a new patient and the fields on the Profile Screen will be empty. To select or create a patient, see Starting a Session on page 7.*

- 2 Enter the following information.
Required fields are denoted by bold text.

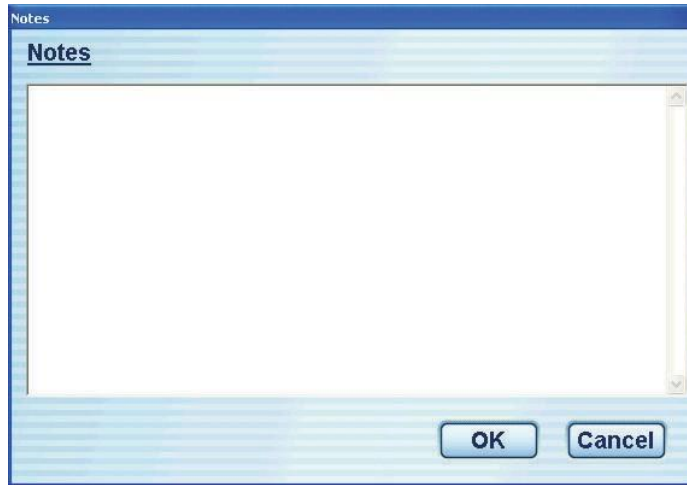
- **First Name**
- **Last Name**
- **Birth Date**
- Patient ID
- Gender: Male or Female
- Physician
- Diagnosis
- Patient Address
- Patient Phone Number

Note: *Though not required, it is preferred that you also enter information in the Patient ID and Physician fields.*

- 3 Click  to save the information.
You may click  to reverse any unsaved changes or entries.

Note: *In the event that any button other than  is selected, the patient information entered will automatically be saved.*

Entering Patient Notes



The **Notes** screen is used to enter information relevant to the patient and/or the programming session. The information entered is stored and can be chronologically viewed in the patient's case history.

To enter notes:

- 1 If you are not currently in the Profile Screen, click **PROFILE** in the upper right corner of any screen.
- 2 Click **Notes** towards the bottom of the Profile Screen.
- 3 Click the main entry field of the Notes window.
Current notes are editable, but past notes are read-only and can be viewed in the case history.
- 4 Enter text.
- 5 Click **OK** to save the information or **Cancel** to cancel the changes and return to the Profile Screen.

Viewing a Patient's Case History



Case History displays chronologically dated patient file information, including the visit history and notes. Each visit is time stamped and displayed along with the Reason for Visit and Notes.

***Note:** Patient visits are recorded and time stamped only when the user exits or saves the Profile Screen.*

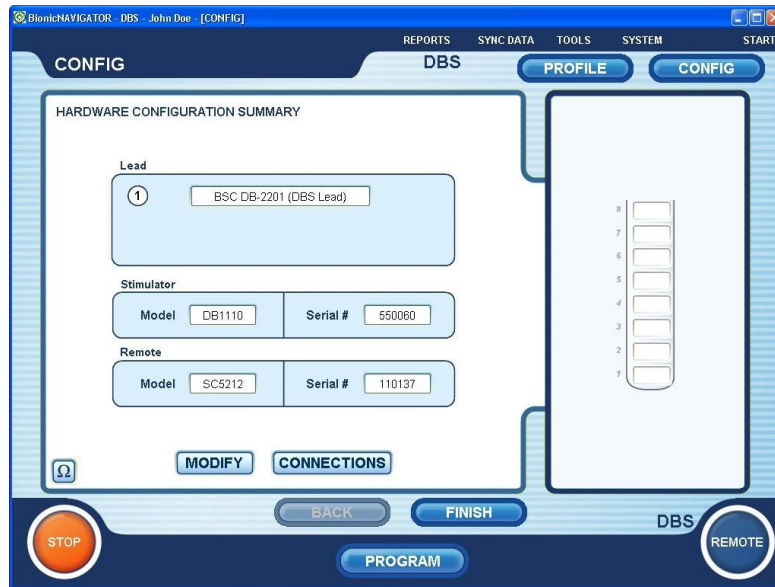
To view a patient's Case History:

- 1 If you are not currently in the Profile Screen, click **PROFILE** in the upper right corner of any screen.
- 2 Click **Case History** towards the bottom of the Profile Screen.
- 3 To exit, click **OK**.

Case History is read-only. To enter new Notes, see Entering Patient Notes on page 14. To print a patient's Case History, see Creating Reports on page 52.

Configuring the Vercise DBS System

Verifying the Vercise DBS System Configuration



The Configuration (or Config) screen displays information about the system components. The Stimulator and Remote Control product and serial numbers are automatically detected and recorded. The Lead information is also displayed.





Note: The Configuration screen may only be accessed once a patient is selected.

To verify the Vercise DBS System configuration:

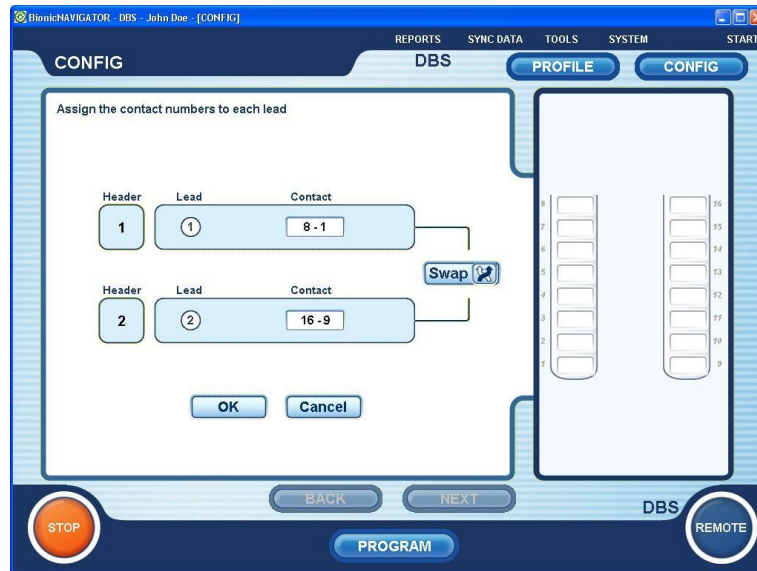
- 1 Click **CONFIG** in the upper right-hand corner of any screen.
If Lead information has not been entered, the information will be requested before the Configuration screen is displayed.
- 2 Verify that the Lead information is correct.
- 3 Verify that the Stimulator model and serial number are correct.
- 4 Verify that the Remote Control model and serial number are correct.
- 5 Verify that the electrode labels correctly correspond to the left and right Leads (in the image of the Leads to the right of the screen).
By default, Bionic Navigator assigns contacts 1-8 to the left Lead and contacts 9-16 to the right Lead. If the contacts do not correspond correctly, see Swapping the Leads on page 18.

Modifying the Lead Information

To modify the Lead information:

- 1 Click  from the Start Screen.
- 2 Click  to modify the lead information.
- 3 Choose the appropriate Lead model from the Lead 1 drop-down menu.
- 4 Choose the appropriate Lead model from the Lead 2 drop-down menu. If using only 1 Lead, select None from the Lead 2 drop-down menu.
- 5 Click  to save your changes or  to exit without your changes.

Swapping the Leads



By default, Bionic Navigator assigns contacts 1-8 (1-L port) to the Lead that appears on the left and contacts 9-16 (2-R port) to the Lead that appears on the right.

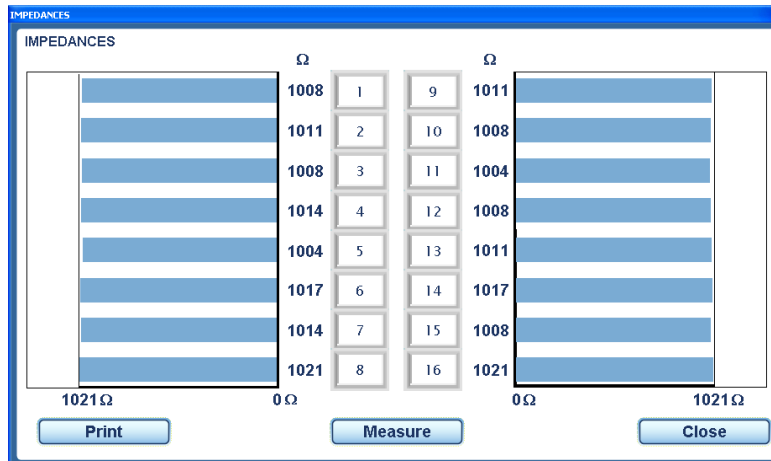
To aid in programming the Stimulator, you may wish to rearrange the display so that the Lead connected to port 1-L (contacts 1-8) appears on the right, and the Lead connected to port 2-R (contacts 9-16) appears on the left.

Note: This function only visually changes the order of the Leads on the Configuration and Programming screens. It does not change the order of the Leads displayed in reports or programs, which list contacts 1-8 followed by contacts 9-16.

To rearrange the display of the Lead(s) (left to right):



- 1 Click **CONNECTIONS** from the Configuration screen.
- 2 Click **Swap** to change the connection of the Leads to the Stimulator ports.
- 3 Click **OK** to save your changes or **Cancel** to exit without saving your changes.

Testing Impedances





The Impedance button is used to verify electrical integrity. Lead impedance is measured and displayed for each of the Stimulator's 16 contacts. Impedances over 4500 Ω are considered to be resultant from open or unconnected wires and are displayed with an orange bar on the Impedance screen (or an "X" on the Program screen).

To check the Lead impedances:

- 1 Click  while in the Configuration screen or the Program screen. *The impedances will be measured and displayed. To re-measure the impedances, click .*

Note: All measured impedances are saved into the Clinician Programmer database.

- 2 To print the impedance report, click .
- 3 To exit, click .

Programming the Patient

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.

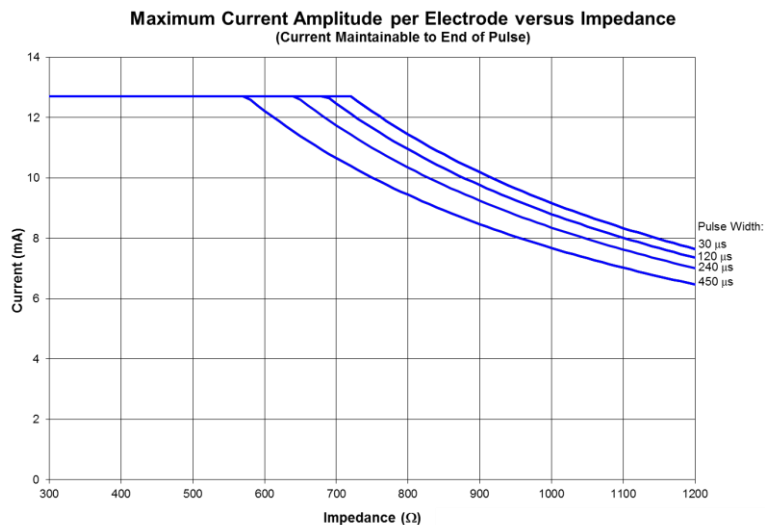
It is possible to configure one lead as monopolar, and one as multipolar. It is also possible to configure a single lead with both monopolar and multipolar areas, as long as the same contacts are not used in both.

The programmable parameter ranges for the Stimulator are shown below.

Stimulator Function	
Parameter	Range
Amplitude ¹	0.1 – 20 mA
Rate ²	2 – 255 Hz
Pulse Width	10 – 450 µs
Cycle (On/Off)	1 s – 90 min
Stim Ramp On	1 – 10 s
Contact Connections	16
Independent Areas of Stim (4 Programs with 4 Areas per Program)	16

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.

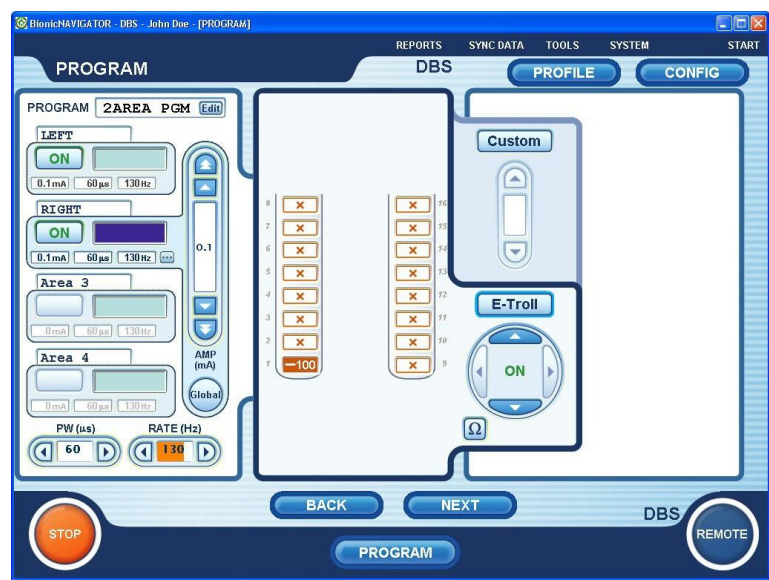
² The rate is limited to 255 Hz for a given area. The global rate limit for each lead is also 255 Hz.



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 (i.e., a warning displays when the charge density $\geq 30\mu\text{C}/\text{cm}^2/\text{phase}$), 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.

Getting to the Programming Screen



Vercise™ DBS Programming Manual

The Programming screen displays the active stimulation settings and allows programming of stimulation parameters.

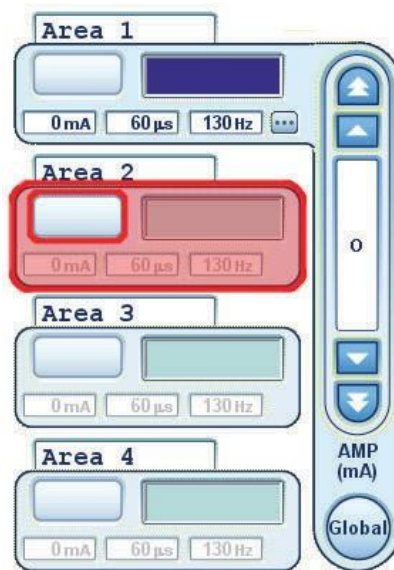
To get to the Programming screen, select  at the bottom center of any screen.

Selecting an Area

Stimulation settings can be programmed for up to four different stimulation fields or Areas. For example, one Area may correspond to a right brain target, while another Area may correspond to a left brain target. These Areas run in an interleaved fashion, and multiple Areas (up to four) constitute a program. Stimulation parameters and the contact configuration are displayed for one selected Area at a time.

To select an Area:

- 1 Click the on the desired Area control box on the left of the Programming screen, as highlighted in the image below.



Selecting Contacts




You may program the patient either by manually selecting anodes and cathodes in Custom Mode or automatically trolling the stimulation field along the lead in E-Troll Mode. Both monopolar and multipolar configurations are permitted in Custom Mode. A monopolar configuration uses only cathode(s) on the contacts, with the stimulator case acting as the anode. A multipolar configuration has anode(s) and cathode(s) assigned to the contacts.

Note: *Prior to measuring impedances for the first time, all contacts will display an “X”. After an impedance measurement, only contacts with an Impedance over 4500 Ω will display an “X”. Impedances over 4500 Ω are considered to be resultant from open or unconnected wires. Although an “X” inside a contact indicates higher than normal impedances, contacts may still be included in a stimulation configuration.*

E-Troll Mode

E-Troll Mode is an enhanced way of conducting a monopolar review. E-Trolling allows you to steer a monopolar cathode along the selected Lead with a single button – eliminating the need to manually select each contact. E-Troll gradually shifts a percentage of the monopolar cathode to the next contact using current steering technology to create smooth transitions between contacts.

To E-Troll along a lead:

- 1 Switch to E-Troll mode by clicking  in the middle of the screen.
- 2 Select a contact to assign it as a cathode and adjust the amplitude.
- 3 Use the  and  buttons in the E-Troll panel to incrementally steer the stimulation focus.


To choose another starting point or to E-Troll on the other lead, click another contact.

Note: *The amplitude for the selected Area will drop to 0.1 mA when another contact is selected.*

Note: *Contacts assigned in a multipolar configuration in one Area cannot be assigned to a monopolar configuration in another Area, so E-Trolling is interrupted in such cases.*

Custom Mode





Custom Mode allows you to manually select contacts to be anodes or cathodes. You may create both monopolar and multipolar configurations of contacts in Custom Mode.

- 1 If necessary (i.e., to switch to Custom Mode from E-Troll Mode), press the  button at the top of the middle panel on the Programming screen.
- 2 Click on a contact to select that contact.
- 3 Click on the selected contact to turn the contact into an anode.

Click on the selected contact again to turn the contact into a cathode. Click on the selected contact again to turn the contact OFF (blank). *Contact polarity options include anode (+), cathode (-), and OFF (blank). **Note:***

Changing the contact polarities will reset the amplitude to zero.

- 4 Repeat steps 3-4 until all desired contacts are selected.

Click...	to...
	Increase the percentage of total cathodic or anodic current on the selected contact.
	Decrease the percentage of total cathodic or anodic current on the selected contact.
	Equalize the percentages of current on all contacts of the selected contact type (anode or cathode).
	Measure the impedances of the contacts.

Note: When using the External Trial Stimulator, if a monopolar configuration is programmed, then all unassigned contacts will contribute as anodes.

Note: Contacts assigned to a monopolar configuration in one Area cannot be assigned to a multipolar configuration in another Area and vice versa.

Note: Although an “X” inside a contact indicates higher than normal impedances, contacts may still be included in a stimulation configuration.

Turning Stimulation On and Off for Individual Areas


To turn ON stimulation for an Area:

- 1 Make sure the Area you wish to turn on is selected.
To select an Area, see Selecting an Area on page 22.

Note: *To initially turn on stimulation for an area, that area must first be configured with at least one cathode.*

- 2 Click the  button of the selected area to turn stimulation ON.

To turn OFF stimulation for an Area:





- 1 Make sure the Area you wish to turn off is selected.
To select an Area, see Selecting an Area on page 22.
- 2 Click the  button of the selected Area to turn stimulation OFF.

Increasing and Decreasing the Amplitude



The amplitude of stimulation is the peak value of a stimulation pulse and is measured in milliamps (mA).

To increase or decrease the amplitude of the selected area:

- 1 To increase the amplitude, click or click and hold one of the up arrows above the AMP label on the Programming screen.
- 2 To decrease the amplitude, click or click and hold one of the down arrows above the AMP label..

Click...	to...
	Increase the amplitude quickly.
	Increase the amplitude slowly.
	Decrease the amplitude slowly.
	Decrease the amplitude quickly.

To increase or decrease the amplitude for all areas that have stimulation turned on:

- 1 On the Programming screen, click the  button.
If the Global button is selected (the button will have a bright blue circle around it), only the amplitude can be adjusted.
- 2 Increase or decrease the amplitude as described above.
- 3 Click the  button again to discontinue Global amplitude adjustment.

Increasing and Decreasing the Pulse Width

The pulse width of the stimulation describes the length of time a burst of energy is applied to the desired area. The pulse width is measured in microseconds (μS).

- 1 To increase the pulse width, click or click and hold the  button below the PW label on the Programming Screen.

Note: *If you attempt to adjust the pulse width above the $30\mu\text{C}/\text{cm}^2/\text{phase}$ charge density limit, then you will see a caution message.*

- 2 To decrease the pulse width, click or click and hold the  button below the PW label.

Increasing and Decreasing the Rate

The pulse rate of the stimulation, often called just the rate or the frequency, dictates how many stimulation pulses are delivered in a second, measured in Hertz (Hz) or pulses per second (pps).

- 1 To increase the rate, click or click and hold the  button below the RATE label on the Programming Screen.

Note: *If you attempt to adjust the rate above the $30\mu\text{C}/\text{cm}^2/\text{phase}$ charge density limit, then you will see a caution message.*

- 2 To decrease the rate, click or click and hold the  button below the RATE label.

Note: *Areas that are assigned to the same lead port cannot have rates that sum up to greater than 255 Hz.*

Programming Multiple Areas

Programming Multiple Areas with the Same Rate

The Vercise™ DBS System allows two Areas to be programmed with the same rate (or frequency). If more than two Areas are turned on, then all Areas must have the same rate.

***Note:** The rates for the first and second Areas must be equal to one another before a third Area may be turned on.*

Programming Two Areas with Different Rates

The Vercise DBS System allows two Areas to be programmed with different rates (or frequencies). This feature allows you to simultaneously stimulate two areas of the brain with different rates.

To program two Areas with different rates:

- 1** Turn on one Area and turn off all the other Areas.
- 2** Select the desired rate for the first Area.
- 3** Turn on a second Area.
- 4** Select the desired rate for the second Area.

***Note:** You will have a limited number of rates available for programming when selecting the rate for the second Area.*

***Note:** Modifying the rate of either Area will alter the available rates for the other Area.*

***Note:** When establishing two areas with different rates, the first area must be on while the rate for second area is programmed.*

The two rates are dependent on one another in that only certain combinations of rates are permitted. The table below indicates which frequencies are available for the second Area at commonly used frequencies for the first Area.

First Area Rate (Hz)	Subset of Available Second Area Rates (Hz)*
99	89†, 99, 112†, 113†, 116†, 119, 128†, 132, 139†, 149, 154‡, 159†**, 170‡**, 174†**, 179†**, 198**, 223†**, 231†**, 238‡**
132	99, 113†, 116‡, 119‡, 132**, 149‡**, 154‡**, 159†**, 170‡**, 176**, 185‡**, 198**, 231‡**, 238‡*
179	89**, 99†**, 104‡**, 112†**, 119**, 128†**, 139‡**, 143†**, 149†**, 179**, 208‡**, 223†**, 238†**
238	89†**, 95**, 99‡**, 119**, 132‡**, 136‡**, 143†**, 149‡**, 159**, 170‡**, 179†**, 190‡**, 198‡**, 238**

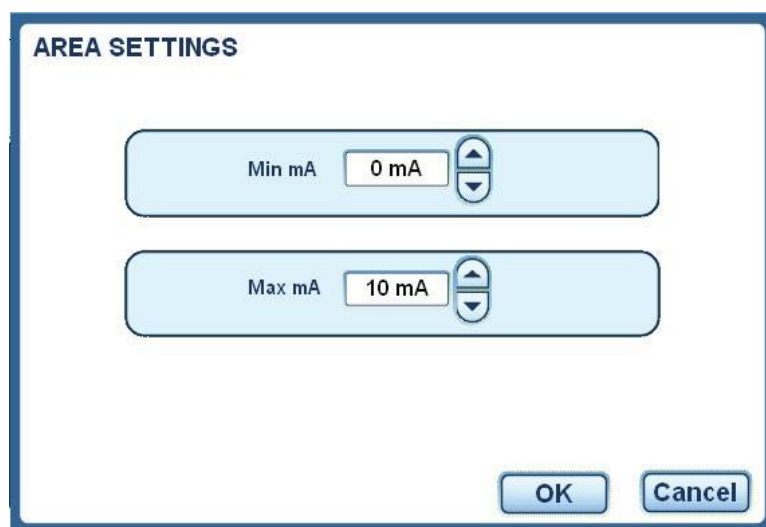
*Subset includes only frequencies in typical DBS range (89-255 Hz) using typical pulse widths (30-90 μ s).

†Available when both pulse widths are less than or equal to 60 μ s.

‡Available when both pulse widths are less than or equal to 30 μ s.

**Available when areas are on different ports.

Defining the Amplitude Range





By default, patients will not have the ability to adjust the amplitude of their stimulation. However, in some cases, you may want to give a patient the ability to adjust the amplitude of their stimulation using the remote Control. In these cases, you must unlock Remote Control amplitude adjustments and define an amplitude range.


The Area Settings screen allows you to view and edit the amplitude range allowed by the patient's Remote Control. The amplitude range is defined by the minimum and maximum stimulation amplitude. The patient may only adjust his or her stimulation amplitude within this range.


Note: *The patient cannot adjust the pulse width and rate of stimulation with the Remote Control.*


To unlock the ability for patients to adjust stimulation amplitude with the Remote Control:

- 1 Click  from any screen.
- 2 Click  on the left of the screen.
- 3 Uncheck the Lockout Remote Amplitude option.

To define the amplitude range for an Area:

- 1 Ensure “Lockout Remote Amplitude” is disabled (see above).
- 2 From the Program screen, click  in the desired Area tab.
Each Area may have a different amplitude range.

- 3 Set the minimum amplitude using the  buttons in the top box.
The minimum amplitude allowed is 0 mA.

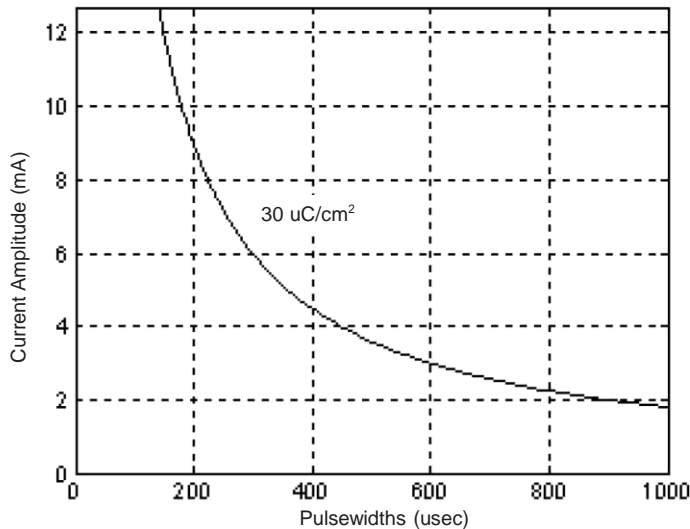
- 4 Set the maximum amplitude using the  buttons in the bottom box.
The maximum amplitude allowed is 20 mA.

- 5 Click  to save your changes or  to exit without saving.

Note: A charge density limit warning will be displayed on the Programming screen when the maximum amplitude setting for any area is above the charge density limit, $30\mu\text{C}/\text{cm}^2/\text{phase}$, and will clear when the maximum amplitude settings for all areas are below it.

Understanding the Charge Density Warnings

The Clinician Programmer software provides several warnings when the charge density at a contact may exceed 30 microcoulombs/cm² per stimulation phase, as there is evidence of tissue damage above this level. The graph below displays the recommended maximum charge density of 30 microCoulombs/cm² for different combinations of current amplitude (mA) and pulse width (μs) for Boston Scientific DBS Leads.



The Clinician Programmer software provides a warning when the charge density at a contact is about to be programmed to exceed 30 microcoulombs/cm² per stimulation phase. However, the Clinician Programmer allows the stimulation to continue above this level. The warning reads:

“CAUTION: Charge density limit reached. Continue programming at your discretion.”

Note: A charge density limit warning will be displayed on the Programming screen while any area is above the 30μC/cm²/phase charge density limit and will clear when all areas are below it.

A warning is also displayed when the amplitude range of a program exceeds charge density limits. The warning reads:

“Caution: With present settings, the patient could exceed the charge density limit with the remote control. Continue programming at your discretion.”

Another warning is displayed when a program that is capable of exceeding the charge density limit is saved to a program slot in the patient’s Remote Control. The warning reads:



“Caution: Charge density limit may be reached with the current Max mA set. Do you want to continue?”

Naming the Areas

You are able to name each Area so that you, and the patient, are reminded of the anatomical location of each stimulation Area. For example, you may name one Area “Left” for a stimulation Area located on the left side of the brain and another Area “Right” for a stimulation Area located on the right side of the brain.

Note: *The Area names are displayed on the Clinician Programmer.*

To name an Area:




- 1 Make sure the Area you wish to name is selected.
To select an Area, see [Selecting an Area](#) on page 22.
- 2 Click on the Area’s name.
The default Area names are Area 1, Area 2, Area 3, and Area 4.
- 3 Edit the text.
Area names may not exceed eight characters in length.
- 4 Click  to save the changes or  to exit without saving your changes.

Naming the Program

You can name each program so that you and the patient are reminded of the purpose of each program. For example, you may name one program “Sleeping” and another program “Walking.”

***Note:** The program names are displayed on the Clinician Programmer and the patient’s Remote Control.*


To name a program:

- 1 From the Programming screen, click  next to the Program field near the top of the screen.
- 2 Edit the text.
Program names may not exceed nine characters in length.
- 3 Click  to save the changes or  to exit without saving your changes.


Globally Turning Stimulation Off and On

The Stimulation Power button will stop and start stimulation for those Areas that are active (turned on). The Stimulation Power button will only apply to active Areas.

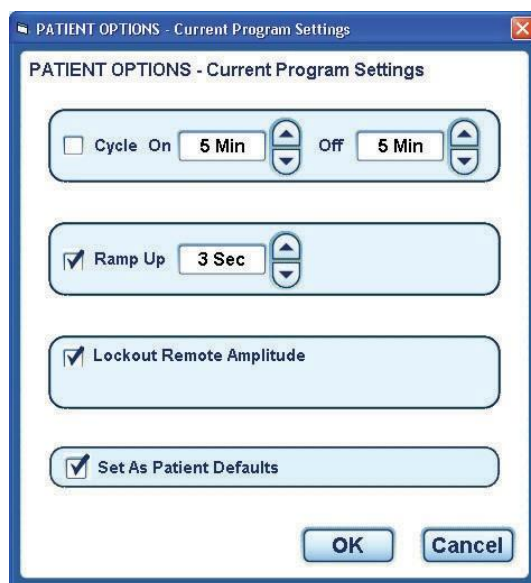
To turn stimulation OFF for all active Areas:

- 1 Click the red  button in the lower left-hand corner of any screen.
Stimulation will stop for those Areas that are turned on.

To turn stimulation ON for all previously active Areas:




- 1 Click the green  button in the lower left-hand corner of any screen.
Stimulation will ramp up to the stored amplitude levels for the active program settings.
Stimulation will turn on for those Areas that were last turned off by clicking the “STOP” button.

Adjusting Patient Options



The Patient Options window allows you to view and edit additional program settings, including stimulation cycling, ramp up time, and Remote Control amplitude lockout. Program settings are only applied to the currently active program (which appears on the left side of the Remote screen). After making changes to Patient Options, save the currently active program to a slot to preserve the changes.

To access Patient Options:

- 1 Click  from any screen or  from the Programming screen.
- 2 Click  on the left side of the Remote screen.

Changing the Stimulation Cycle


The Cycle option determines the on and off duration of stimulation delivery.


For continuous stimulation, the Cycle option should be unchecked.

The option is unchecked by default, resulting in continuous stimulation.

For intermittent stimulation:

- 1 Check the box next to the Cycle option.

- 2 Set the stimulation on time using the  buttons next to the On field.
The range for stimulation on time is 1 second to 90 minutes.

- 3 Set the stimulation off time using the  buttons next to the Off field.

The range for stimulation off time is 1 second to 90 minutes.

- 4 If desired, check Set as Patient Defaults to save these settings to the Remote Control as defaults.

Note: *If the Set as Patient Defaults is checked, these program settings will be used for all future programs created for the current patient.*

- 5 Click  to save your changes or  to exit without saving.

Defining the Stimulation Ramp Up Time

The stimulation Ramp Up time is the amount of time the Stimulator will take to increase stimulation from 0 mA to the programmed amplitude when stimulation is turned on.

To define the Ramp Up time:

- 1 Check the box next to the Ramp Up option.

- 2 Set the Ramp Up time using the  buttons next to the Ramp Up field.
The default setting is 3 seconds. The range for Ramp Up time is 1 to 10 seconds.

- 3 If desired, check Set as Patient Defaults to save settings to the Remote Control as defaults.

Note: *If the Set as Patient Defaults is checked, these program settings will be used for all future programs created for the current patient.*

- 4 Click  to save your changes or  to exit without saving.

Activating or Deactivating Patient Amplitude Control

The Lockout Remote Amplitude option controls the patient's ability to change stimulation amplitude using the Remote Control.

Note: *The patient will be able to adjust their own amplitude level using the Remote Control if the Lockout Remote Amplitude option is unchecked.*

To activate or deactivate the Lockout Remote Amplitude option:

- 1 Check or uncheck the box next to the Lockout Remote Amplitude option.



The Lockout Remote Amplitude option is activated.
The patient cannot change the stimulation amplitude using the Remote Control.



The Lockout Remote Amplitude option is deactivated. The patient is able to change the stimulation amplitude using the Remote Control.

- 2 If desired, check Set as Patient Defaults to save settings to the Remote Control as defaults.

***Note:** If the Set as Patient Defaults is checked, these program settings will be used for all future programs created for the current patient.*

- 3 Click  to save your changes or  to exit without saving.

Setting Program Options as Patient Defaults

The Set as Patient Defaults option allows you to use the current program settings (Cycle, Ramp Up, and Lockout Remote Amplitude) for all new programs created for the current patient.

- 1 Check or uncheck the box next to the Set as Program Defaults option.



The current program options will be used for all future programs created for the current patient.

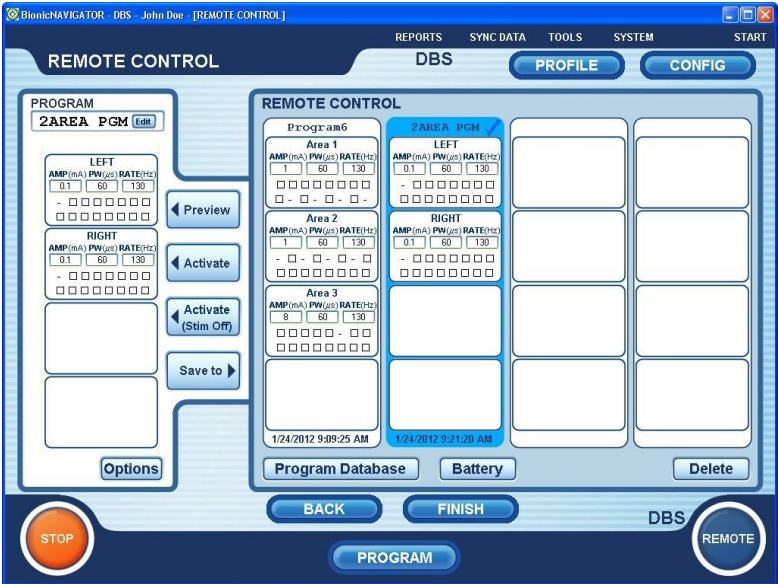


The default program options will be used for all future programs created for the current patient.

- 2 Click  to save your changes or  to exit without saving.



Managing Programs

Getting to the Remote Screen



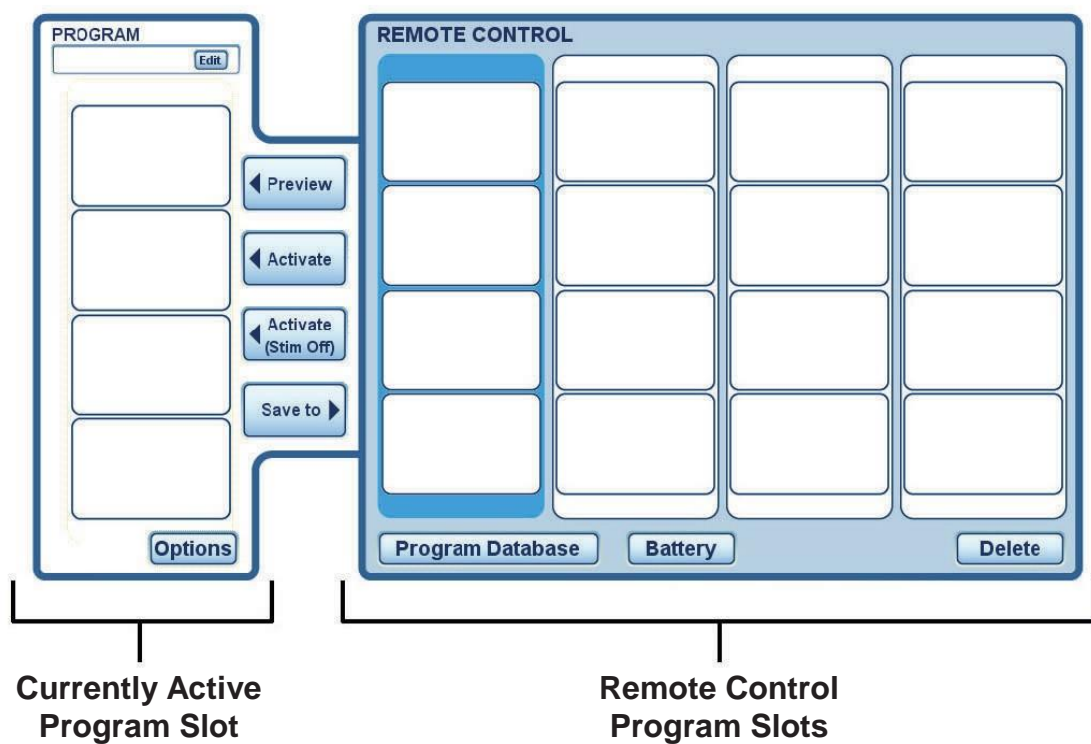
The Remote Control screen displays programs stored on the patient’s Remote Control, as well as the currently active program.

To get to the Remote Control screen:

- 1 Click  from the Programming screen or  in the lower right-hand corner of any screen.

Understanding the Program Slots

The program currently running on the stimulator is displayed on the left panel. On the right side of the screen, the four program slots are displayed.



Saving a Program

The currently active program can be saved to one of the four program slots. Programs are stored in the Stimulator and accessed/controlled by the Remote Control. The Remote Control also stores a copy of the programs.

To save a program to the Stimulator:

- 1 Name the program by clicking “Edit” at the top of the left panel, typing a program name, and selecting the “check mark”. The program name will be displayed on the Remote Control.
- 2 Click a program slot on the right of the screen to which you want to save the program.
You can select a blank slot to save a program to, or you can select a slot that already has a program to overwrite it.

- 3 Click .

The currently active program will be saved to the selected program slot.

Note: The ✓ symbol in the Remote Control panel indicates last activated or saved program.


Activating a Program from the Remote Control Panel


A program that has been stored to one of the four program slots may be activated to become the current stimulation program. The activated program may then be modified in the Programming screen. Depending on the steps you take below, you may activate a program with stimulation on or stimulation off.



To activate a program:

- 1 Click the program on the right of the screen that you want to activate.

Note: The ✓ symbol indicates last activated or saved program.

- 2 To activate the program with stimulation on, click . If stimulation is off, stimulation will turn on. If stimulation is already on, stimulation will remain on.

- 3 To activate the program with stimulation off, click . If stimulation is on, stimulation will turn off. If stimulation is already off, stimulation will remain off.

Note: If the current program has not been saved, then a pop-up window will ask if you want to continue. If you do not want to save the current program, click  to continue and activate the selected program. If you do want to save the current program, click  and save the current program.


Previewing a Program from the Remote Control Panel




The Preview feature allows you to compare and contrast programs. Before overwriting the currently active program, a program in the Remote Control may be previewed.

Note: *The preview feature may be used to determine which program on the Remote Control you wish to overwrite if all program slots are filled.*

To preview a program:




- 1 Click the desired program on the right side of the Remote screen.

- 2 Click  to preview the program.
The currently active program will be stopped and the selected program will be temporarily activated.

- 3 Click  or  to keep the program active, or  to return to the previously active program.

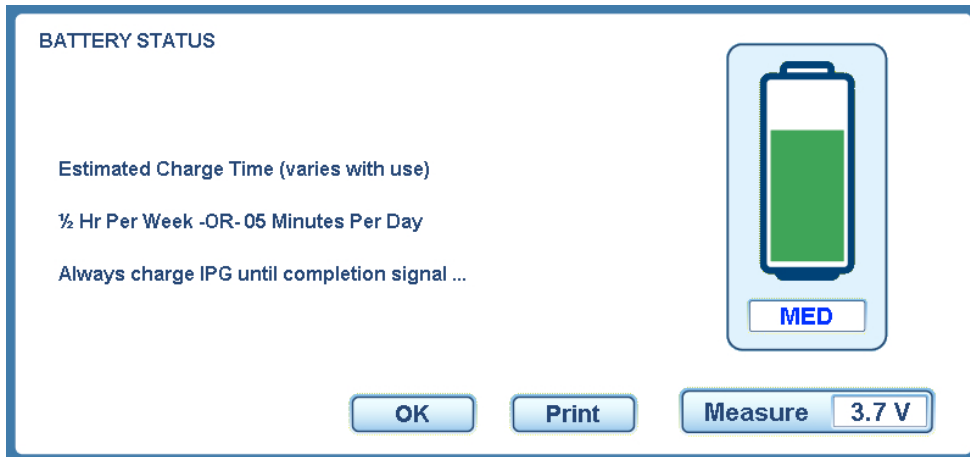
Deleting a Program

When a program is deleted, it is removed from the stimulator and will no longer be displayed on the remote control. To delete a program:

- 1 Click the desired program on the right side of the Remote screen.
- 2 Click  to erase the program from the Stimulator and Remote Control. *Upon deleting the program, the program slot will become empty.*
- 3 A pop-up will ask you if you want to delete the program. Click  to confirm the deletion or  to exit without deleting.

Note: *If you accidentally delete a program from the Remote Control, you can find the program in the Program Database.*

Checking the Stimulator Battery Status and Viewing the Estimated Charging Time



The Battery Status screen displays the battery level of the Stimulator and gives an estimate of the time required to charge which will help you to determine a charging routine. Battery level options include full, medium, and low. The voltage of the Stimulator battery is also displayed.

To check the status of the Stimulator battery:



- 1 From the Remote screen, click **Battery**.
*To re-measure the battery status, click **Measure** .*
- 2 If necessary, click **Print** to print the battery status.
- 3 Click **OK** to exit.

Managing Programs in the Program Database

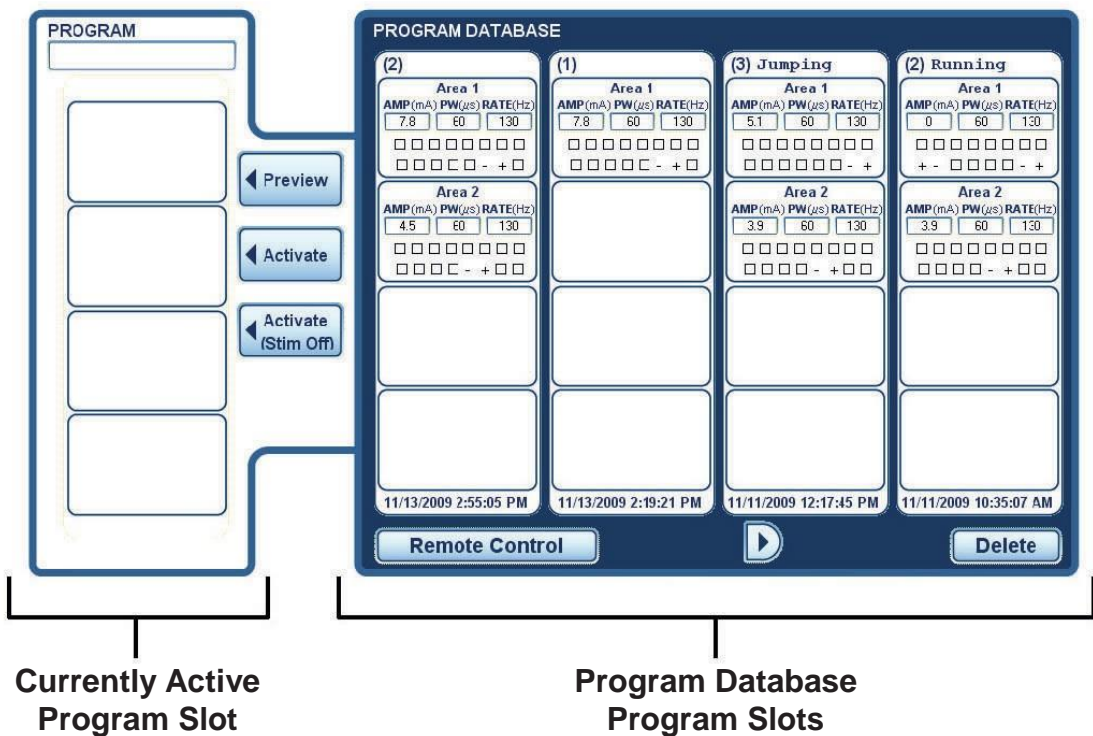
Viewing Programs in the Program Database

The Program Database screen displays a list of all stimulation programs that have previously been saved using the current CP (Clinician Programmer).

To view the programs in the Program Database:

- 1 From the Remote screen, click **Program Database**.
- 2 Use the  and  buttons to navigate within the Program Database.

The currently active program slot is displayed in the left panel and database programs are displayed in the right panel. Four programs in the Program Database are displayed at a time.



Activating a Program from the Program Database

A program located in the Program Database may be activated to become the current stimulation program. The activated program may then be modified in the Program screen. Depending on the steps you take below, you may activate a program with stimulation on or stimulation off.

To activate a program:



- 1 Click the program on the right of the screen that you want to activate.

- 2 To activate the program with stimulation on, click .

If stimulation was off, stimulation will turn on. If stimulation was already on, stimulation will remain on.

To activate the program with stimulation off, click .

If stimulation was on, stimulation will turn off. If stimulation was already off, stimulation will remain off.

Note: *If the current program has not been saved, then a pop-up window will ask if you want to continue. If you do not want to save the current program, click  to continue and activate the selected program. If you do want to save the current program, click  and save the current program.*

Previewing a Program from the Program Database




Before overwriting the currently active program, a program in the Program Database may be previewed.

To preview a program:

- 1 Click the desired program on the right side of the Program Database screen.

- 2 Click  to preview the program.

The currently active program will be stopped and the selected program will be temporarily activated.

- 3 Click  or  to permanently activate the program, or  to return to the previously active program.



Deleting a Program from the Program Database

To delete a program from the Program Database:

1 Click the desired program on the right side of the Program Database screen.

2 Click  to erase the program from the Program Database.

***Note:** If you delete a program from the Program Database, you cannot recover the program at a future date.*

3 A pop-up will ask you if you want to delete the program. Click  to confirm the deletion or  to exit without deleting.

Creating Reports

Choosing a Report

The Reports screen is used to create a patient or clinic report based on data from stimulators used with the CP. The CP does not need to be connected to any IPG to create or view reports. By selecting various options for individual patients or groups, the user can create, view, print, or export database information. Reports can be customized through sorting filters.

The five report types and the information they may include are described in the following sections. Choose the report that includes the information you require.

PATIENT INFORMATION

Patient information, clinical information, hardware information, stimulation settings, profile information, battery use information, case history, and patient notes.

GENERIC REPORT

Programs, threshold measurements, impedances, battery charge profile, stimulation use profile, and patient history.

PATIENT LIST

Last visit, serial number, implant date, and physician.

CLINICAL OUTCOMES

Implant, last visit, physician, diagnosis, percentages and means, implant duration, mean age, replacements, explants, and revisions.

CLINIC ACTIVITY

Last visit, physician and patient follow-ups. May include reprogramming, trials, Lead implants, total patients, average durations, and total durations.

Patient Information Report

To create a Patient Information report:

- 1 Click **REPORTS** on the toolbar of any screen.



- 2 Click the button.

- 3 Select what information to include in the report by checking the box in front of the option. Choose from any or all of the following categories:

- Patient Information: name, address, and date of birth
- Clinical Information: physician name, first and last programming sessions, and reason for last visit
- Hardware Information: model and serial numbers of the stimulator and remote control, and model numbers of the lead(s)
- Stimulation Settings: program options, program details for each saved program
- Use Profile Information: 4 week history of what program numbers were used, in hours per day
- Battery Use Information: 4 week history of battery charge, in Volts. Also referred to as a 4 week “battery charge profile”
- Case History: date, reason, and notes for each programming visit
- Patient Notes: notes from the last programming session saved in the profile page for each patient

- 4 Select one or more patients from the list on the right side of the screen.

To filter the patients that are shown in the list by the date of their last visit, click the button next to Today, 2 Days, Week, or All to view patients whose last visit occurred within that time frame.

- 5 Click **Create Report** to create the report.

- 6 To export the report as an electronic file, click **Export Report**.

- 7 To print the report, click **Print**.

- 8 Click **FINISH** to exit from the report.

Generic Report

Generic Report provides different reporting options for one patient based on data acquired within a specified range of dates. To create a Generic Report:

- 1 Click **REPORTS** on the toolbar of any screen.



- 2 Click the button.

- 3 Select the type of report to generate by clicking on the corresponding button. Choose from:

- Programs: all programs created with the CP, including date/time it was saved, slot number, graphical display of electrode configuration, stimulation parameters, and options for each program
- Threshold Measurements: not applicable
- Impedances: history of all impedance measurements made with the CP
- Battery Charge Profile: history of battery charge, in Volts, measured at 4 hour intervals
- Stimulation Use Profile: history of program usage
- Patient History: date, reason, and notes for each visit

- 4 Select a patient from the Patient drop-down list on the right side of the screen.

- 5 Limit the results in the report by selecting two dates from the drop-down menus, such that only information on the selected patient collected during visits that occurred between these two dates will be included in the report.

- 6 Select the order the information will be displayed.
Check the box next under the Order option to display the information in an ascending order (by date). Uncheck the box to display the information in descending order (by date).

- 7 Click **Create Report** to create the report.






- 8 To export the report as an electronic file, click **Export Report**.

- 9 To print the report, click **Print**.

- 10 Click **FINISH** to exit from the report.

Patient List Report

Patient List Report lists all patients in the CP's database, or only those who match the specified parameters. Report includes patient name, patient ID, IPG serial number, and date of first programming session. To create a Patient List report:

- 1 Click **REPORTS** on the toolbar of any screen.
- 2 Click the  button.
- 3 Select the range of the report by checking the boxes next to one or more options. Options include:
 - Implant Date
Only information on patients who were implanted between the two selected dates will be included in the report.
Note: "Implant Date" is the date that a stimulator was first used with this CP.
 - Last Visit
Only information on patients whose last visit occurred between the two selected dates will be included in the report.
 - Serial Number
Only information on patients with Stimulator serial numbers between the two selected numbers will be included in the report
 - Physician
Only information on patients with the selected physician will be included in the report.
- 4 Click  to create the report.
- 5 To export the report as an electronic file, click .
- 6 To print the report, click .
- 7 Click  to exit from the report.






Clinical Outcomes Report

Clinical Outcomes Report summarizes patient statistics, for one or all physicians. Reported statistics include number of patients, mean implant duration, mean patient age, and gender (percentage male/female). To create a Clinical Outcomes report:

- 1 Click **REPORTS** on the toolbar of any screen.
- 2 Click the **CLINICAL OUTCOMES** button.
- 3 Select the range of the report by checking the boxes next to the options. Options include:
 - Implant Date
Only information on patients who were implanted between the two selected two dates will be included in the report.
 - Last Visit
Only information on patients whose last visit occurred between the two selected two dates will be included in the report.
 - Physician
Only information on patients with the selected physician will be included in the report.
 - Diagnosis
Only information on patients with the selected diagnoses will be included in the report.
- 4 Click **Create Report** to create the report.
- 5 To export the report as an electronic file, click **Export Report**.
- 6 To print the report, click **Print**.
- 7 Click **FINISH** to exit from the report.

Clinical Activity Report

The Clinical Activity Report lists and groups patient visits based on “reason for visit” for one or all physicians. To create a Clinical Activity report:

- 1 Click **REPORTS** on the toolbar of any screen.
- 2 Click the  button.
- 3 Select the range of the report by checking the boxes next to one or both options.
Options include:
 - Last Visit
Only information on patients whose last visit occurred between the two selected dates will be included in the report.
 - Physician
Only information on patients with the selected physician will be included in the report.
- 4 Click  to create the report.
- 5 To export the report as an electronic file, click .
- 6 To print the report, click .
- 7 Click  to exit from the report.

Synchronizing Data

Understanding the Synchronizing Data function



The Synchronize Data function provides a convenient way to manage patient files between clinic users and multiple Clinician Programmers. Using the Sync Data function, patient data can be transferred between the database on the Clinician Programmer and an external memory storage device (referred to as “Patient Card”).

The “Backup Card” located in the compact flash card slot should never be removed except by a Boston Scientific Representative. For more information regarding this card, contact Technical Services. Refer to the Troubleshooting section for contact numbers.

Installing a New Patient Card

To install a new Patient Card:

- 1 Insert the Patient Card into any unused USB port. The Patient Card may be any external storage device (for example, a USB flash drive).

Synchronizing Data

To synchronize data between the database on the Clinician Programmer and the Patient Card:

- 1 Insert the Patient Card into any unused USB port. The Patient Card may be any external storage device (for example, a USB flash drive).
- 2 Click **SYNC DATA** on the toolbar of any screen.
- 3 Check the box in front of a specific patient's name or click **Select All** to select all the patients.

***Note:** If a discrepancy is found between a patient's information on the Clinician Programmer and the Patient Card, a window will pop-up displaying both sets of information. Click **USE THIS** under the correct set of information or click **SKIP** to cancel data synchronization for this patient.*

- 4 Click **Sync Selected**. When synchronization is complete, the synchronized patients' names will appear in the right side of the screen, and no names will be selected.
- 5 Click **Done**.

Deleting Patient Records

To delete patient records in the database on the Patient Card:

- 1 Click **SYNC DATA** on the toolbar of any screen.
- 2 Check the box in front of a specific patient's name or click **Select All** to select all the patients. To delete patient records from the Patient Card select names from the right side of the screen.
- 3 Click **Delete Selected**.
- 4 Click **Done**.

Using Additional Tools

Viewing System Information



A screenshot of a software window titled "SYSTEM INFORMATION". The window contains a list of system parameters, each with a label and a corresponding text box displaying its value. The parameters are: Stimulator Telemetry ID (550060 (0x864AC)), Stimulator Serial Number (550060), Stimulator Type (5), Stimulator Battery Voltage (3.701 V), Stimulator Battery Status (OK), Stimulator Firmware Version (9028343-303-02), Remote Telemetry ID (110137), and Remote Firmware Version (9028323-101-03). At the bottom center of the window is a blue button labeled "OK".

Parameter	Value
Stimulator Telemetry ID	550060 (0x864AC)
Stimulator Serial Number	550060
Stimulator Type	5
Stimulator Battery Voltage	3.701 V
Stimulator Battery Status	OK
Stimulator Firmware Version	9028343-303-02
Remote Telemetry ID	110137
Remote Firmware Version	9028323-101-03

System Information provides the following information about the Vercise™ DBS System:

- Stimulator Telemetry ID
- Stimulator Serial Number
- Stimulator Type
- Stimulator Battery Voltage
- Stimulator Battery Status
- Stimulator Firmware Version
- Remote Telemetry ID
- Remote Firmware Version

***Note:** System Information can only be accessed when a Stimulator is connected to the Clinician Programmer.*

To view System Information:

- 1 Click **TOOLS** from the toolbar on any screen.
- 2 Select System Information from the drop-down menu.
- 3 Click **OK** to exit.

Backing Up Data and Logs

The Backup Data/Logs menu may be used to create a compressed backup file of the system database and logs.

To backup data and logs:

- 1 Insert the removable media to copy database and logs.

***Note:** The removable media should not be named “CLINIC”.*

- 2 Click **TOOLS** from the toolbar on any screen.
- 3 Select Backup Data/Logs from the drop-down menu.
- 4 Select a drive from the drop-down menu to which the file is to be saved.
- 5 Click **OK** to save or click **Cancel** to exit without saving.
- 6 Read the agreement and click **OK** to accept.
- 7 A message will appear to confirm that a back up zip file was created successfully. A zip file will be saved to a folder named BN_Backup on the selected drive. Click **OK** to exit.

Measuring Field Potentials

The EGL Scan™ function in DBS mode measures field potentials using an impedance-like measurement. The EGL Scan function is not required for DBS therapy. These measurements may be taken for data analysis purposes and stored in the system, but they will not appear on the screen. If you wish to view this data, contact Boston Scientific.

To measure field potentials with EGL Scan:

- 1 Click **TOOLS** from the toolbar on any screen.
- 2 Select EGL Scan from the drop-down menu. A message will appear to indicate when measurements are complete.
- 3 Click **Cancel** to exit.

Adding a Lead

This custom feature is not supported.

Enabling and Disabling Auto Impedance

The Auto Impedance feature automatically measures the impedances of the Vercise™ DBS System when you enter the Programming screen. The Auto Impedance feature will be disabled whenever the Bionic Navigator software is exited.

If the Auto Impedance feature is disabled, the contacts on the Programming screen will display an [X] until you measure impedances. If the Auto Impedance feature is enabled, no [X]'s will appear on the Programming screen (unless impedances are over 4500 Ω for a specific contact).

To enable the Auto Impedance feature:



- 1 Click **TOOLS** from the toolbar on any screen.
- 2 Select Enable Auto Impedance from the drop-down menu.

To disable the Auto Impedance feature:

- 1 Click **TOOLS** from the toolbar on any screen.
- 2 Select Disable Auto Impedance from the drop-down menu.

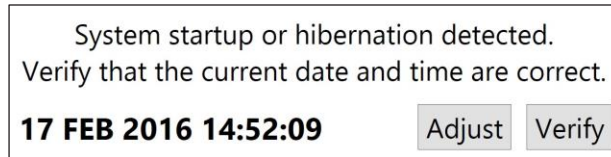
Viewing Information about Bionic Navigator

To view information about the Bionic Navigator™ software, including the software version, part number, confirmation key, and last upgrade date:

- 1 Click  from the toolbar on any screen.
- 2 Select About Bionic Navigator from the drop-down menu.
- 3 Click  to exit.

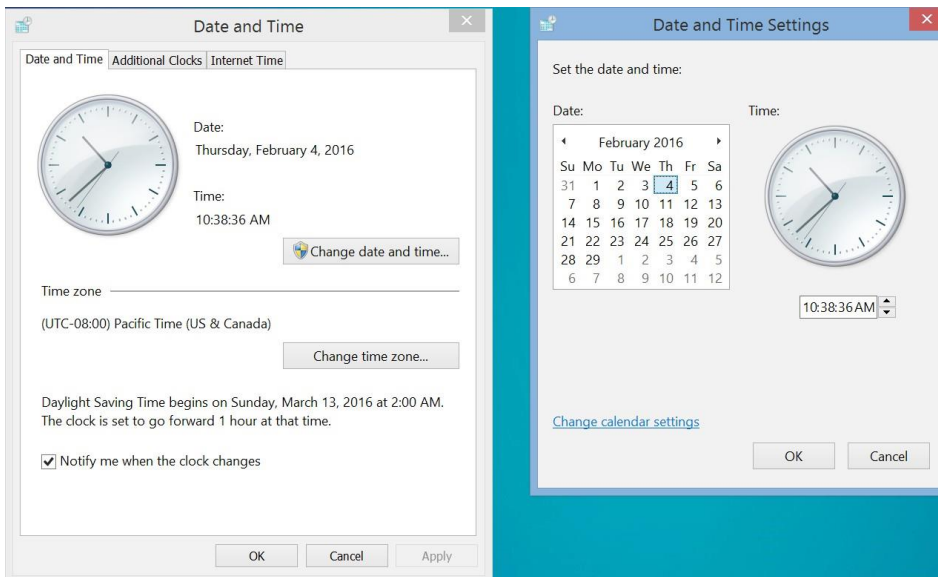
Adjusting CP Time and Date


If system startup or hibernation is detected, the CP provides a notification to verify that the system time and date is correct.



If the Time and Date are correct, select **Verify** to dismiss the notification bar.

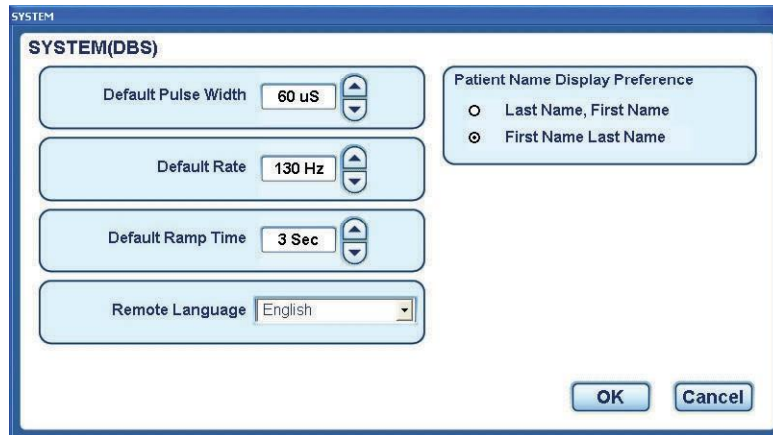
If the Time and Date are incorrect select **Adjust** to modify the time and date and click **Ok** to confirm changes.



Note: You can also click the Time and Date icon  on the Desktop to launch the time and date adjustment window.

Managing System Settings

Viewing the System Settings



The System screen is used to view and adjust system-wide default program settings, including pulse width, rate, ramp time, Remote Control language, and the preference for how patients' names are displayed. Defaults will be used as a starting point for programming a patient for the first time.

To view the System settings:

- 1 Click **SYSTEM** in the toolbar on any screen.
- 2 To exit, click **OK** to save your changes or **Cancel** to exit without saving.

Adjusting the Default Pulse Width

To adjust the default pulse width:

- 1 Click **SYSTEM** in the toolbar on any screen.



- 2 Click the buttons next to the Default Pulse Width field to achieve the desired pulse width.

The range of available pulse widths is 10 μ s to 450 μ s.


- 3 Click **OK** to save your changes or **Cancel** to exit without saving.

Adjusting the Default Rate

To adjust the default rate:

- 1 Click **SYSTEM** in the toolbar on any screen.



- 2 Click the  buttons next to the Default Rate field to achieve the desired rate.
The range of available rates is 2 Hz to 255 Hz.
- 3 Click **OK** to save your changes or **Cancel** to exit without saving.

Adjusting the Default Ramp Time

To adjust the default ramp time:

- 1 Click **SYSTEM** in the toolbar on any screen.



- 2 Click the buttons next to the Default Ramp Time field to achieve the desired ramp time.

The range of available ramp times is 1 s to 10 s.

- 3 Click **OK** to save your changes or **Cancel** to exit without saving.

Selecting the Default Remote Control Language

To select the default Remote Control language:

- 1 Click **SYSTEM** in the toolbar on any screen.
- 2 Click the down arrow next to the Remote Language field.
- 3 Select the desired language from the drop-down menu.
Available languages include English, German, Dutch, French, Italian, Spanish, and Iconic.
- 4 Click **OK** to save your changes or **Cancel** to exit without saving.

Setting the Patient Name Display Preference

To set the default patient name display format preference:

- 1 Click **SYSTEM** in the toolbar on any screen.
- 2 Click the button next to the desired patient name display format.
(*Last Name, First Name or First Name Last Name*).
- 3 Click **OK** to save your changes or **Cancel** to exit without saving.

Addendum

Additional notes on the Clinician Programmer Software:

PROGRAMMING

After changing stimulation settings in PROGRAM, always navigate to the REMOTE screen and SAVE the latest changes to a program slot.

REPORTS

The patient report may display an incorrect ramp time value. The same ramp time is displayed for all programs in the report, when in the Patient Options menu, the “Set As Patient Defaults” is checked. This may not be the correct ramp time value for all individual programs on the report. The ramp time value in the “Patient Options” window always displays the correct ramp time value for all individual programs.

GENERAL NOTES

If “No Stimulator Detected” is displayed, do the following:

- Verify that everything is still connected and aligned.
- Check to see that the Remote Control is still in CP Mode.
- Press “START.”

SYNC DATA

When data is synced between two Clinician Programmer systems that have different system times set, there can be overlap of data in the reports. Check and update system clocks before syncing.

If no Clinic Patients are displayed when attempting to sync, exit by selecting the “Done” button and select “Sync Data” again.

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92161115-01 2017-09



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Vercise™ M8 Adapter

Directions for Use

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

92093578-01

Content ID: 92093651 REV A

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Product Model Numbers

Model Numbers	Description
DB-9218-15	Vercise M8 Adapter, 15 cm
DB-9218-55	Vercise M8 Adapter, 55 cm

Additional Information

For indications for use, contraindications, warnings, precautions, adverse events, storage and handling, sterilization, labeling symbols, limited warranty, or other device-specific information not included in this manual, refer to the *Vercise Deep Brain Stimulation System Physician Manual* or the appropriate DFU for your DBS System as listed on your *DBS Reference Guide*.

Intended Use

The Vercise™ M8 Adapter is a 1 x 8 in-line connector that is designed to connect specific Medtronic® lead extensions to the Boston Scientific DBS System Stimulator, as part of a deep brain stimulation procedure.

Lead Compatibility

The Boston Scientific M8 Adapter is compatible with the following Medtronic Leads:

- Model 3387 Lead
- Model 3389 Lead

The Boston Scientific Vercise M8 Adapter is compatible with the following Medtronic lead extensions:

- Model 3708640 Extension
- Model 3708660 Extension
- Model 3708695 Extension
- Model 3708540 Extension
- Model 3708560 Extension
- Model 3708595 Extension

Package Contents

Sterile

- (1) Vercise M8 Adapter
- (1) Torque Wrench

Non-sterile

- (1 set) Product identification stickers
- (1) Device registration form

Med A is sold separately.

The *Directions for Use* (DFU) is provided separately.

Cautions

- Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal. Do not reuse, reprocess, or resterilize.
- Do not use if the product is past the labeled expiration date.
- Do not use if labeling is incomplete or illegible.

- Do not bend, kink, or stretch the extension or Adapter; this may break its wires or connections. Broken wires or connections may create an open circuit, resulting in component failure, loss of stimulation, and potential surgical intervention.
- Do not handle the Vercise M8 Adapter with instruments that were not supplied with the Adapter. Other instruments may cause damage to the device, including broken wires or connections.
- The setscrew in the Vercise M8 Adapter must be retracted to insert the lead extension. There is no stop feature to prevent excessive retraction of the setscrew and disassembly of the Adapter. To avoid damage to the sealing grommet, do not retract the setscrew assembly more than is needed to insert the lead extension.
- Minimize the number of torque-wrench insertions into the Vercise M8 Adapter to prevent damage to the septum seal plug.

Directions for Use

1. Explant the Medtronic Stimulator, referring to the appropriate Medtronic product labeling for explant instructions.
2. Carefully open the Vercise M8 Adapter package and transfer the contents of the inner tray to the sterile field.
3. Ensure that the Medtronic lead extension is clean and not damaged.
4. Retract the setscrews in all Adapters: insert the torque wrench into the septum containing the setscrew and turn the torque wrench counter-clockwise (Figure 1).

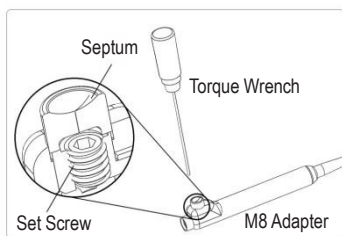


Figure 1: The setscrew assembly in the Vercise M8 Adapter

5. Ensure that stimulation is OFF before connecting to the Vercise M8 Adapter.
6. Ensure that the lead extension is clean before inserting into the Vercise M8 Adapter.
7. Insert the proximal end of the Medtronic lead extension into the Vercise M8 Adapter until the extension reaches the end stop of the Adapter; use one Vercise M8 Adapter for each Medtronic lead extension (Figure 2).

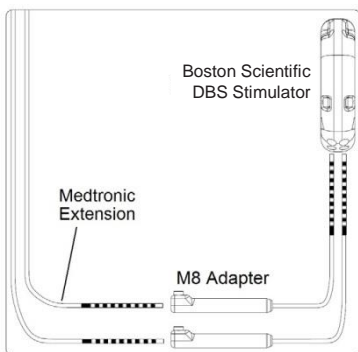


Figure 2: Connection of Vercise M8 Adapters to Medtronic lead extensions and Boston Scientific DBS Stimulator.

8. Ensure that the proximal end of the Vercise M8 Adapter is clean then insert the proximal end of the Adapter into the Boston Scientific DBS Stimulator. For further instructions on connecting to the stimulator, refer to the appropriate DFU for your Boston Scientific DBS System as listed on your Reference Guide.

9. Perform the permanent Stimulator implantation procedure. For instructions on implanting the stimulator, refer to the appropriate DFU for your Boston Scientific DBS System as listed on your Reference Guide.

NOTE: Do not place the distal segment of the Vercise M8 Adapter between its proximal end and the Boston Scientific DBS Stimulator. Placement of wires between these two devices could result in damage to the wire insulation resulting in loss of stimulation.

NOTE: Do not wrap or coil the excess extension wires or the distal Adapter segment around the perimeter or in front of the stimulator. Wrapping around the stimulator may cause wires to slip in front of the stimulator. Placing wires in front of the stimulator may cause kinking of the extension and Adapter wires, potential interference with telemetry and/or recharge operation, and damage during future stimulator replacement surgery.

10. Tighten the setscrew in the Vercise M8 Adapter until the Torque Wrench clicks, indicating the setscrew is fully secured
11. Apply a medical adhesive (e.g. Dow Corning Silastic® Medical Adhesive Silicone, Type-A Sterile, as available from Boston Scientific, part no. SC 4320) to coat and seal the top of the set screw port (Figure 3).

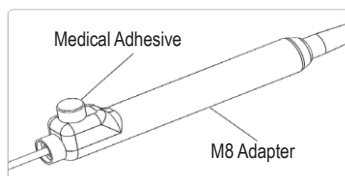


Figure 3: Medical adhesive covering the septum seal plug.

NOTE: Damage to the septum seal may lead to unintended stimulation at the implantation site if medical adhesive is not used as intended.

12. To program leads, refer to the contact- mapping diagram (Figure 4) and instructions provided in the programming manual provided for your Boston Scientific DBS System. The most distal contact, Contact 1, on the Medtronic DBS Lead maps to Contact 1 on the Boston Scientific programming software and so forth as shown in Figure 4. Please note that Medtronic DBS Leads only have 4 contacts per lead while the Boston Scientific programming software interface displays 8 contacts per lead and therefore contacts 5-8 on the programming interface will display out of range impedance values indicating that there are no electrodes connected.



Figure 4: Contact mapping with the Vercise M8 Adapter

13. Complete the device registration form included in the Vercise M8 Adapter package. Use the product identification stickers, where necessary.

Specification and Technical Data

Part	Specification
Adapter Lengths	15, 55 cm
Adapter Diameter	1.3 mm
Number of Electrode Contacts	8
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N

Warning: the Medtronic Leads have not been tested for electromagnetic compatibility or for safety in an MRI environment when used with Boston Scientific DBS Systems. Strong electromagnetic fields can potentially turn the Stimulator off, cause temporary unpredictable changes in stimulation, or interfere with the Remote Control communication. MRI scanning can result in severe patient injury.

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.

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92093578-01 2017-07



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Boston Scientific

Deep Brain Stimulation

Reference Guide

Rx ONLY

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

92094272-01
Content ID: 92094274 REV B

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Introduction

The Reference Guide provides the list of Directions for Use (DFU) available for the Boston Scientific Deep Brain Stimulation (DBS) System. These manuals are designed for clinicians and other health care providers. The Reference Guide also provides device-specific information, such as the list of compatible leads for the DBS system.

The Boston Scientific DFUs are provided either online (as directed in your product packaging) or with your DBS system.

How to Use this Reference Guide

This Reference Guide provides information for the DBS System in a table format. Use the highlighted rows to locate the information of interest to you (e.g. indications, implantable pulse generator, or programming).

Vercise™ DBS System

List of Directions for Use (DFU)

Information	DFU
Intended Use/Indications for Use	
<ul style="list-style-type: none"> • Indications for use 	<i>Vercise DBS Physician Manual</i>
Contraindications, Safety Information, General Device Information	
<ul style="list-style-type: none"> • Adverse Events Summary • Component Disposal • Contraindications • Device Description • Electromagnetic Compatibility • Information for contacting Boston Scientific • MRI Information • Package Contents • Precautions • Sterilization • Storage and Handling • Warnings 	<i>Vercise DBS Physician Manual</i>
Summary of Clinical Data	
<ul style="list-style-type: none"> • Summary of Clinical Data 	<i>Deep Brain Stimulation for Parkinson's Disease Clinical Summary</i>
Charging System	
<ul style="list-style-type: none"> • Charging System Instructions 	<i>Vercise DBS Physician Manual</i>
Vercise Implantable Pulse Generator (IPG) and Lead Extensions	
<ul style="list-style-type: none"> • Explant of Leads, Extensions, and IPG • IPG and Extension implantation • IPG Registration • Kit Contents • Specifications and Technical Data • Stimulator Battery Information • Stimulator Programmable Characteristics • Vercise System Revisions and Replacement 	<i>Vercise DBS Physician Manual</i>
OR Cable, OR Cable Extensions, External Trial Stimulator	
<ul style="list-style-type: none"> • Connection to 1x8 OR Cable • Connection to External Trial Stimulator 	<i>Vercise DBS Physician Manual</i>
Programming: Clinician Programmer and Remote Control	
<ul style="list-style-type: none"> • Clinician Programmer • Programming leads 	<i>Vercise DBS Programming Manual</i>
<ul style="list-style-type: none"> • Instructions for using the Remote Control 	<i>Vercise DBS Physician Manual</i>

Leads: Standard	
<ul style="list-style-type: none"> Intraoperative testing using the OR Cable Assembly and External Trial Stimulator Kit contents Lead implantation Specifications and Technical data 	<i>Vercise DBS Physician Manual</i>
Adapters	
<ul style="list-style-type: none"> Vercise M8 Adapter 	<i>Vercise M8 Adapter DFU</i>
Surgical Tools and Accessories	
<ul style="list-style-type: none"> SureTek™ Burr Hole Cover 	<i>Burr Hole Cover DFU</i>
<ul style="list-style-type: none"> Suture Sleeves Lead Boot Lead Stop 	<i>Vercise DBS Physician Manual</i>
<ul style="list-style-type: none"> Tunneling Tool 	<i>Vercise DBS Physician Manual</i>
Warranty: IPG, Leads, Extensions, Externals	
<ul style="list-style-type: none"> Limited Warranty 	<i>Vercise DBS Physician Manual</i>
Labeling Symbols	
<ul style="list-style-type: none"> Labeling Symbols 	<i>Vercise DBS Physician Manual</i>

Compatible Products

Model	Description
Implantable Products	
<ul style="list-style-type: none"> DB-1110-C DB-2201-30-DC and DB-2201-30-AC DB-2201-45-DC and DB-2201-45-BC NM-3138-55 DB-4600-C DB-9218-15 DB-9218-55 	<ul style="list-style-type: none"> Vercise Implantable Pulse Generator Kit 30cm Lead Kit 45cm Lead Kit 55cm 8 Contact Extension Kit Suretek Burr Hole Cover Kit 15 cm Vercise M8 Adapter 55 cm Vercise M8 Adapter
Accessories and Spares	
<ul style="list-style-type: none"> DB-5110-C DB-4100A and SC-4100A DB-2500-C DB-4605-C DB-4252 and SC-4252 DB-4254 and SC-4254 SC-4320 and DB-4320 NM-6105 	<ul style="list-style-type: none"> Vercise DBS External Trial Stimulator (ETS 1) O.R. Cable and Extension Vercise Physician's Spare Kit SureTek Burr Hole Cover Spares Kit 28cm Straw Tunneling Tool 35cm Long Tunneling Tool Medical Adhesive ETS Battery
Patient Products and Spares	
<ul style="list-style-type: none"> DB-5500-1 DB-64125-US DB-6300-C DB-6200-C DB-6100-C NM-6350 DB-5212-C NM-3100 NM-6600 NM-5312 NM-5305 NM-6300 and SC-6300 	<ul style="list-style-type: none"> Vercise Remote Control Kit Vercise Charging System Vercise Charger Collar Accessories Vercise Charger Collar, Small Vercise Charger Collar, Medium Adhesive Kit Vercise Remote Control Remote Control Case Patient Travel Case Charger Base Station Power Supply For Charger
Clinician Programming	
<ul style="list-style-type: none"> DB-7101-204 DB-7161 and NM-7161 DB-7161-R, NM-7161-R NM-4500 NM-4511 and DB-4511 NM-4512 NM-4502 DB-7162 and NM-7162 NM-7113 NM-6317 	<ul style="list-style-type: none"> Bionic Navigator 2.04 Installer Clinician Programmer Clinician Programmer (refurbished) IR Interface USB Serial Cable USB Splitter IR Interface Holder CP Keyboard Tablet Pen Tablet Power Supply

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92094272-01 2017-09



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SureTek™ Burr Hole Cover

Directions for Use

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92093581-01
Content ID: 92093654 REV A

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Additional Information

For indications for use, contraindications, warnings, precautions, adverse events, storage and handling, sterilization, labeling symbols, limited warranty, or other device-specific information not included in this manual, refer to the Vercise Deep Brain Stimulation Physician's Manual or the appropriate DFU for your DBS System as listed on your DBS *Reference Guide*.

Product Model Numbers

Model Numbers	Description
DB-4600-C	Burr Hole Cover
DB-4605-C	Burr Hole Cover Spares Kit

Registration Information

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific Burr Hole Cover.

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 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 Boston Scientific, keep one copy for patient records, provide one copy to the patient, and one copy to the physician.

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

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.

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 Cap Placement 5

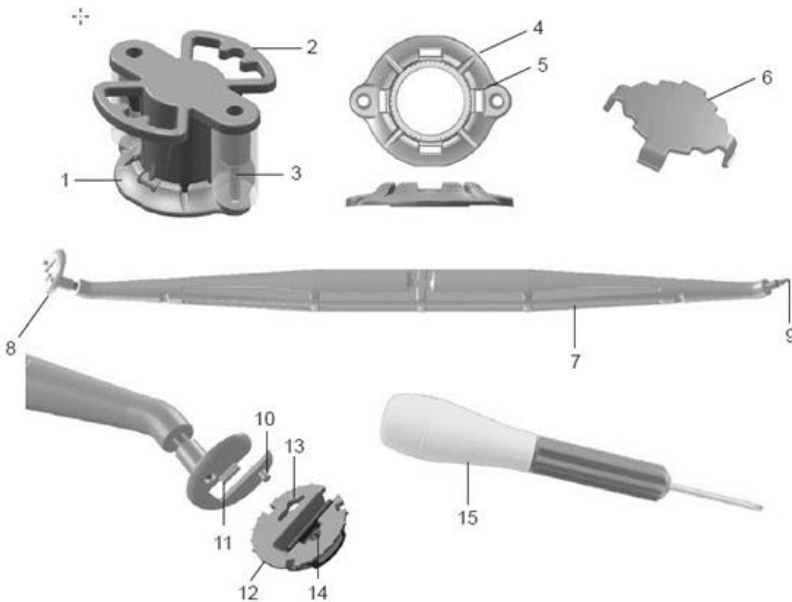
Materials 6

Limited Warranty - Burr Hole Cover 7

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Description

The SureTek™ Burr Hole Cover is a Lead anchoring device for use with the Boston Scientific Deep Brain Stimulation (DBS) system. The Burr Hole Cover is compatible with a burr hole created by a 14 mm perforator.



- 1 - Base
- 2 - Butterfly Holding Tool
- 3 - Bone Screw
- 4 - Lead Exit Slot
- 5 - Cap Slot
- 6 - Cap
- 7 - Placement/Removal Tool

- 8 - Horseshoe End
- 9 - Tip End
- 10 - Post
- 11 - Tab
- 12 - Retaining Clip
- 13 - Clip Release Hole
- 14 - Closure Dimple on Slider
- 15 - Screwdriver

Burr Hole Cover Kit Contents

- (1) **Base** and (2) **Bone Screws** preassembled to (1) **Butterfly Holding Tool**
- (1) **Retaining Clip**
- (1) **Cap**
- (1) **Placement/Removal Tool**
- (1) **Screwdriver**

Intended Use/Indications for Use

The SureTek™ Burr Hole Cover is a lead anchoring device for use with the Boston Scientific Deep Brain Stimulation (DBS) System.

Warnings

Prior to securing the base, examine the cranial bone and structure to ensure that disease or damage are not present and that the thickness of the bone is 5 mm or greater. Failure to adhere to this warning may negatively impact the following:

- **Lead Anchoring.** Lead migration due to an improperly anchored lead may diminish the effectiveness of therapy.
- **Burr Hole Closure.** An unstable closure may increase the risk of infection and place the patient at risk for damage to neural brain tissue, CSF leakage and/or damage to the dura.

Precautions

Components. The use of components other than those supplied by Boston Scientific and intended for use with the Boston Scientific DBS System may damage the system, diminish the effectiveness of therapy, and/or put the patient at unknown risk. A backup device should be available at the time of surgery.

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.

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. If you think the sterility of the device may be compromised, obtain a new sterile device for implantation.

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 "Use By" 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.
- Do not use any component that shows signs of damage.
- Do not use if "Use By" date has expired.

Storage, Handling and Transport. Store components 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.

Component Removal and Disposal. Dispose of the Burr Hole Cover kit components and packaging in accordance with hospital, administrative and/or local government policy.

Instructions for Use

Prior to securing the Base, a 14mm diameter burr hole should be prepared at the target site. Ensure that the burr hole is free of obstructions, such as bone, that will prevent proper insertion of the Burr Hole Cover. Visually inspect the Burr Hole Cover components to ensure that they are acceptable for implant.

Securing the Base

1. Place the Base attached to the Butterfly Holding Tool over the burr hole.



2. Using the Screwdriver gently push the Bone Screws through the Silicone Sleeve.
3. Tighten both Screws into the skull.

Note: Continue tightening the screws until the Base is flush to the skull and the screws are flush to the Base. The Base should not move or rock once secured. Do not over-tighten the Screws or use excessive force.

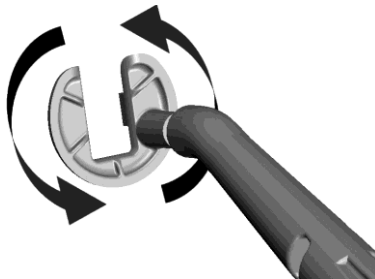
4. Grasp the handles of the Butterfly Holding Tool and remove it by pulling upward at an angle.

Note: The Butterfly Holding Tool can be replaced after rotating 90 degrees for full visibility of the screw head position. This will allow for screw access while still covering the Burr Hole.

Retaining Clip Placement

For lead placement and removal instructions, refer to the appropriate DFU as listed on your DBS Reference Guide.

1. Rotate the horseshoe end of the Placement/Removal Tool so that the tool is oriented as desired.



2. Attach the Retaining Clip to the horseshoe end of the Placement/Removal Tool.



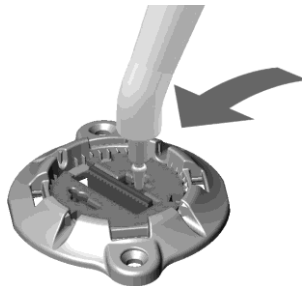
The post and the tab on the horseshoe end of the Placement/Removal tool line up with the clip release hole and closure dimple.

CAUTION: Do not adjust the horseshoe end of the Placement/Removal Tool after the Retaining Clip has been attached.

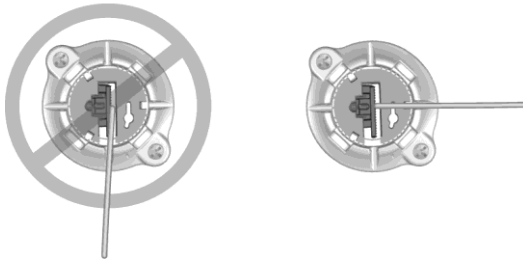
3. While stabilizing the lead, carefully position the Retaining Clip over the Base so that the lead is located in the Retaining Clip's open channel. Position the Retaining Clip so that the static side of the opening is against the lead.



4. Push the Retaining Clip down into the Base. Make sure that the Retaining Clip is completely seated in the Base.
5. Place the tip end of the Placement/Removal Tool into the closure dimple or anywhere along the length of the Slider on the Retaining Clip to push the Slider towards the Lead until it locks into place. Use the tip end of the Placement/Removal Tool to apply pressure on the Slider face in the opposite direction to ensure that the Slider is fully locked.

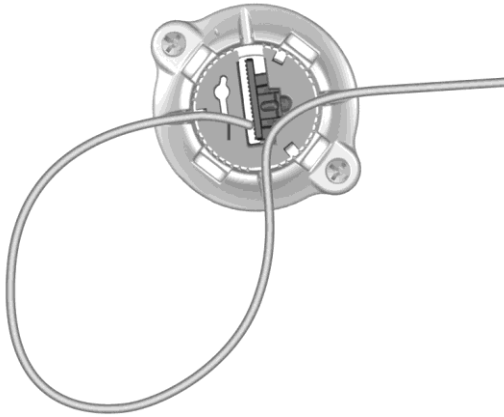


6. Remove lead stylet prior to folding the lead for fixation.
7. Gently fold the lead over and place it inside one of the four lead exit slots.



CAUTION: Secure the Lead using a lead exit slot that is approximately perpendicular to the Retaining Clip channel.

8. Optional: The Lead may be secured to additional Lead Exit Slots.



Cap Placement

1. Insert the Cap into the Base by aligning the arms of the Cap with the Cap Slots in the Base.

Note: You may need to push inward on a Cap arm in order to complete Cap insertion.

Removing the Burr Hole Cover

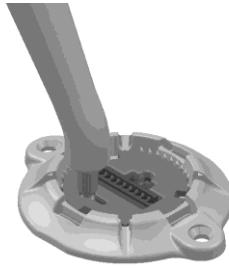
Cap Removal

1. While supporting the top of the Cap to control the release, insert the tip end of the Placement/Removal Tool into an open Lead Exit Slot.
2. Gently pry upward on the Cap until it releases from the Base.

Retaining Clip Removal

3. To open the Slider and release the lead, use the tip end of the Placement/Removal Tool to gently push down and back on the closure dimple on the Slider.
4. If desired, remove the lead using appropriate surgical techniques.

5. Insert the tip end of the Placement/Removal Tool into the Clip Release Hole on the Retaining Clip. The tip of the Placement/Removal Tool should snap into place.



6. Gently push the Placement/Removal Tool partially toward the Slider and upward until the Retaining Clip releases from the Base.

Base Removal

7. Unscrew the two screws from the base using the Screwdriver included in the kit or another compatible screwdriver.

Materials

Part	Description
Base	Polyether ether ketone (PEEK)
Retaining Clip	PEEK
Cap	PEEK
Bone Screws	Titanium
Butterfly Holding Tool	Polyetherimide, Silicone
Placement/Removal Tool	Polyetherimide, Titanium
Disposable Screwdriver	Polybutylene terephthalate (PBT) polycarbonate resin, stainless steel

Limited Warranty - Burr Hole Cover

Boston Scientific Corporation (referred to as Boston Scientific) warrants to the patient that the SureTek™ Burr Hole Cover is free from defects in workmanship and materials for a period of one (1) year from the date of implantation.

A Burr Hole Cover that fails to function within normal tolerances within one (1) year from the date of surgery is covered under this Limited Warranty. The liability of Boston Scientific under this warranty shall be limited to: (a) replacement with a functionally equivalent Burr Hole Cover; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new Burr Hole Cover. Product claims under Boston Scientific Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Boston Scientific within 30 days of surgery in order to obtain warranty rights.
2. The Burr Hole Cover must be returned to Boston Scientific (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Boston Scientific.
3. The Burr Hole Cover must be implanted prior to the “use by” date.
4. Failure of the Burr Hole Cover must be confirmed by Boston Scientific. This warranty specifically excludes defects or malfunctions caused by: (a) fire, floods, lightning, natural disasters, water damage, and other calamities commonly defined as “Acts of God”; (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the Burr Hole Cover in accordance with manufacturer’s instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment by the customer or any unauthorized third party; or (d) attachment of any equipment not supplied by Boston Scientific without prior approval.
 - a. This warranty does not include surgical accessories used with the Burr Hole Cover.
5. The decision as to product replacement or credit shall be made solely at the discretion of Boston Scientific. For a replacement Burr Hole Cover, the warranty will run only to the end of the warranty period for the original Burr Hole Cover that was replaced.

This warranty is in lieu of any other warranty, expressed or implied, including any warranty of merchantability or fitness for intended use. Except as expressly provided by this Limited Warranty, Boston Scientific shall not be responsible or liable for any direct, consequential or incidental damages caused by device malfunction, failure or defect, whether the claim is based on warranty, contract, tort, or otherwise.

Boston Scientific assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

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