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Scientific**

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SureTek™ Burr Hole Cover

Directions for Use

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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Guarantees

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

Drawings are for illustration purposes only.

Trademarks

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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.

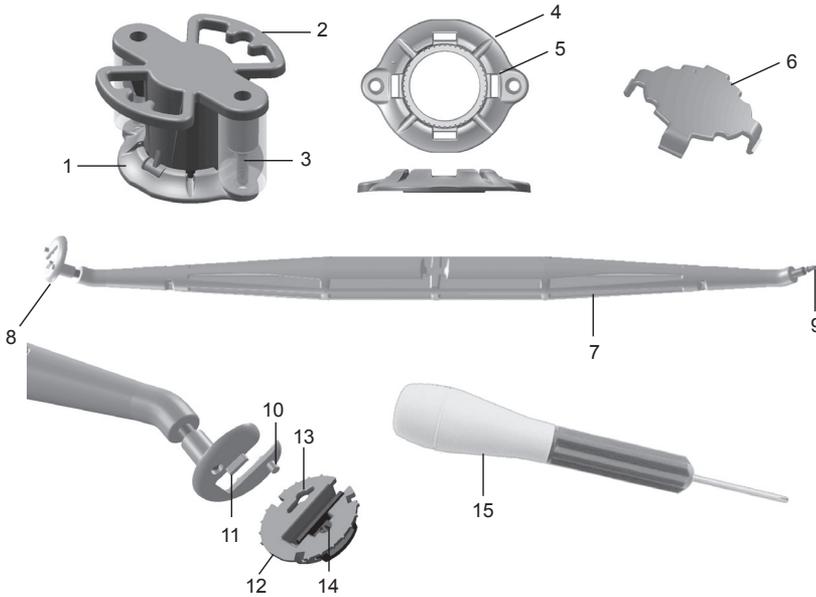
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Description

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.



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|-----|------------------------|------|--------------------------|
| 1 - | Base | 8 - | Horseshoe End |
| 2 - | Butterfly Holding Tool | 9 - | Tip End |
| 3 - | Bone Screw | 10 - | Post |
| 4 - | Lead Exit Slot | 11 - | Tab |
| 5 - | Cap Slot | 12 - | Retaining Clip |
| 6 - | Cap | 13 - | Clip Release Hole |
| 7 - | Placement/Removal Tool | 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.

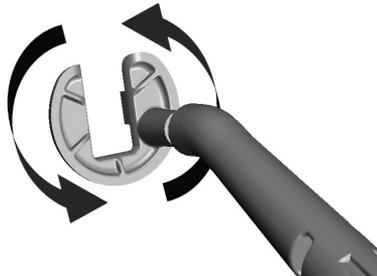
4. Grasp the handles of the Butterfly Holding Tool and remove it by pulling upward at an angle.

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.

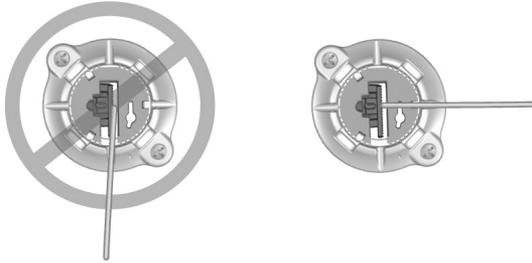
3. While stabilizing the lead, carefully position the Retaining Clip over the Base so that the lead is located in the Retaining Clip's open channel. Position the Retaining Clip so that the static side of the opening is against the lead.



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.

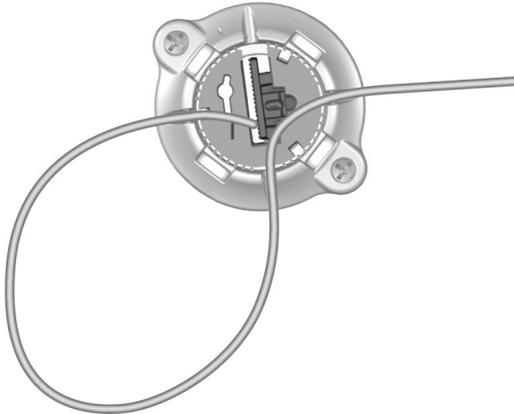


- Remove lead stylet prior to folding the lead for fixation.
- Gently fold the lead over and place it inside one of the four lead exit slots.



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

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



Cap Placement

- 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

- 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.
- Gently pry upward on the Cap until it releases from the Base.

Retaining Clip Removal

- 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.
- 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.

Boston Scientific

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