

Reference: 97049464-FA

09 July 2025

Urgent Field Safety Notice SureTek™ Burr Hole Cover Kit, part of the Vercise™ Deep Brain Stimulation System, Retaining Clip Locking Difficulties – IFU Update

Dear «Users_Name»,

Boston Scientific is initiating a Product Correction (IFU update) to address difficulties while locking SureTek™ Burr Hole Covers (BHC) to secure Deep Brain Stimulation (DBS) Leads, part of the Vercise™ Deep Brain Stimulation System. In some cases, resistance has been encountered while closing the Retaining Clip locking mechanism to securely hold the lead in place.

This letter provides labelling updates to guide users if they encounter resistance or difficulties while closing the Retaining Clip locking mechanism. See **Appendix 1** for Surgical Implant Manual updates to be implemented.

The most common outcome is a limited procedural delay to exchange retaining clips or to withdraw the stylet before locking the Retaining Clip. If the lead is not properly secured during the initial procedure and there is resulting lead migration, the most serious outcome is the need for additional surgery to reposition a DBS lead.

Boston Scientific has received complaints describing prolonged procedures and/or the need for additional intervention due to difficulties using the SureTek Burr Hole Cover. Boston Scientific has received 46 complaints related to this issue, a rate of less than 0.2% over the past two-year period.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN). **This letter only affects the surgical implant manuals listed below.** No other Material Numbers (UPNs) are impacted and no product is being recalled.

Product Name	UPN
SureTek™ Burr Hole Cover Kit	M365DB4600C0
	M365DB4605C0

Surgical Implant Manual Document Number
92691261
92495783
92920693

Product Description

The SureTek BHC consists of four implantable components referred to as the Base, Bone Screws, Retaining Clip, and Cap. The Base is positioned over a burr hole and secured with Bone Screws. The Retaining Clip is placed over the Base once a DBS lead is implanted. The Retaining Clip anchors the DBS lead with a locking mechanism enabled using the included Placement Tool.

The Surgical Implant Manual includes instructions for use of these devices.

Recommendations and Instructions

1- Review the updates to the Surgical Implant Manual provided in **Appendix 1**. These updates will be found in the IFU once implemented.

2- If you are a facility that has sent products to another hospital or a facility within your network, ensure this notification is forwarded to them.

3- To provide awareness of this information, share this letter with any other clinicians in your hospital who use the Boston Scientific Burr Hole Cover Kit or Burr Hole Cover Spares Kit.

4- If users encounter resistance or difficulties while closing the Retaining Clip locking mechanism, refer to the Surgical Implant Manual updates provided in **Appendix 1**.

5- Maintain a copy of this letter in your facility's records.

6- Continue to report all device-related incidents or quality concerns experienced with the use of these devices to Boston Scientific at BSN.ComplaintCallCenter@bsci.com

7- **Please complete the attached Acknowledgement Form even if you do not have any affected product.**

8- **When completed, please return the Acknowledgement Form to your Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before 30 July 2025.**

Additional Information

Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific via email at BSN.ComplaintCallCenter@bsci.com.

Your Competent Authority is being notified of this Field Safety Notice.

Patient safety is Boston Scientific's highest priority. We are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant product information for managing your patients and their devices. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Yours sincerely,



John Donohue
Vice President, Quality Assurance
Boston Scientific

Appendix 1 – Vercise™ Deep Brain Stimulation Systems Surgical Implant Manual Updates

Table 1 below provides the planned updates to the Surgical Implant Manual, highlighted in blue pending review by relevant regulatory bodies.

Table 1: Updates to Instructions for Use

Surgical Implant Manual Section	Planned Updates
Securing the DBS Lead	<p>6. While stabilizing the DBS Lead, carefully position the Retaining Clip over the Base so that the DBS Lead is located in the open channel of the Retaining Clip. Position the Retaining Clip so that the static side of the opening is against the Lead (Figure 21).</p> <div style="text-align: center;">  </div> <p style="text-align: center;">Figure 21. Position the Retaining Clip Over the Base</p> <p>7. Push the Retaining Clip down into the Base. Ensure that the Retaining Clip is completely seated in the Base (Figure 22).</p> <div style="text-align: center;">  </div> <p style="text-align: center;">Figure 22. Push the Retaining Clip Into the Base</p> <p>8. 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 DBS 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 (Figure 23).</p>

Note: If you have difficulty locking the Slider, you may need to remove the Lead Stylet before locking the Slider in place, or replace the Retaining Clip using another Burr Hole Cover Kit or Burr Hole Cover Spares Kit.

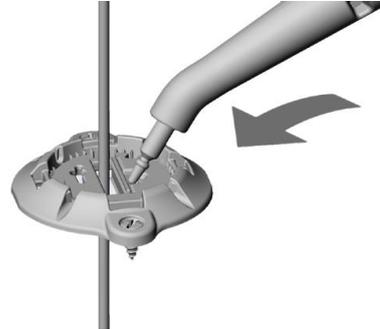


Figure 23. Lock the Slider

9. Remove the Lead Stylet. You may confirm the Slider is fully locked by repeating Step 8.

Caution: Do not reinsert the Lead 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.

10. Verify that the DBS Lead has not moved from the desired location (e.g. by intraoperative imaging).