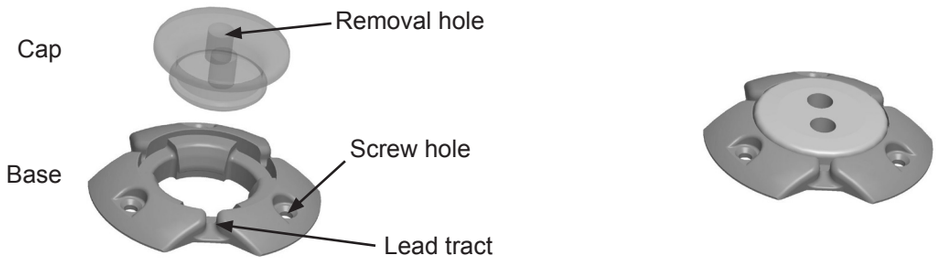
Burr Hole Cover Model 8110
Instructions for Use

Indications for Use / Intended Uses

The NeuroPace® Burr Hole Cover is intended for use following cranial surgery to cover a 14 mm burr hole. Secondarily, the NeuroPace Burr Hole Cover also can be used to support a 1.3 mm indwelling lead.

Device Description

The device consists of two pieces: a base and a cap. The base of the device is screwed to the cranium using bone screws. The cap is pressed into the base of the device to cover the opening in the base and secure the lead. Requires three bone screws (1.5 to 1.8 mm diameter). Screws and driver are not included.



The device is intended for SINGLE USE ONLY. Do Not resterilize. The contents of the unopened, undamaged package are sterile and nonpyrogenic.

Precautions

Requires three bone screws 1.5 to 1.8 mm diameter of appropriate length. (The base is approximately 1 mm thick at the screw hole.) Incorrect bone screw diameter or length may result in inadequate fixation of the Burr Hole Cover, lead migration, screw protrusion, damage to the Burr Hole Cover, or bone or scalp injury.

Do not attach the Burr Hole Cover over a cranial suture or to cranial bone that is damaged, diseased or too thin. Inadequate fixation of the Burr Hole Cover, lead migration, screw protrusion, or bone or scalp injury may result.

For use with leads of 1.3 mm diameter. Use with other lead diameters may result in inadequate lead retention, lead migration or lead damage.

The compatibility of the device with any lead to be anchored should be evaluated before use.

If the Burr Hole Cover is used to provide access for another device (e.g., a neurological lead), refer to the instructions for use for that device for all contraindications, warnings and precautions.

The Burr Hole Cover Model 8110 is single-use-only. Do not resterilize and/or re-use.

Do not implant or use the Burr Hole Cover Model 8110 after the “Use By” date.

Prior to opening the sterile packaging, inspect for any damage or breach in package seal integrity. If the packaging appears to be wet, punctured, or damaged, the contents may no longer be sterile and the product should not be used.

Specifications

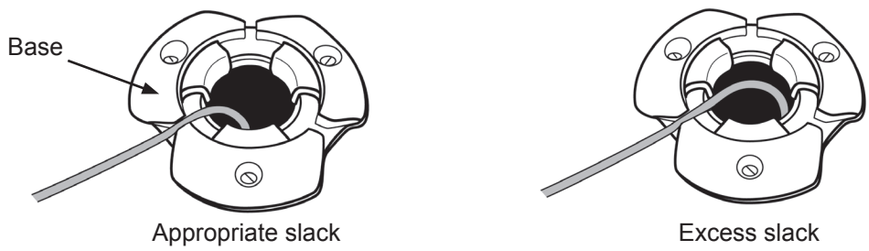
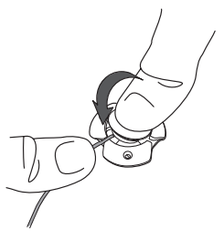
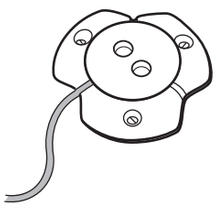
Materials	Polyaryletheretherketone (PEEK) and silicone
Burr Hole Compatibility	As produced by a 14 mm cranial burr. Minimum depth 2.7 mm
Lead Compatibility	1.3 mm diameter +/- 0.05 mm

Symbols

							
Caution	Prescription Only	MR Safe	Sterilized Using Ethylene Oxide	Pyrogen Free	Do Not Resterilize	Single Use	Temperature Limits

Caution: Federal law restricts this device to sale by or on the order of a physician.

Implant Procedure

STEP	ACTION
1	Drill a 14 mm burr hole in the appropriate location.
2	Seat the base of the device into the burr hole. Verify the base is secure and does not interfere with the edges of the bone or the tapered region within the burr hole.
3	Rotate the base of the device to orient one of the lead tracts in the direction intended for the lead to exit from the device.
4	Secure the base of the device to the cranium at three locations using three bone screws of appropriate length (not provided). Hold the base in place while inserting the first bone screw. Verify the outside edges of the base are against the skull and any sharp edges along the perimeter of the burr hole are covered. Caution: do not tighten screws excessively. Damage to the device or to the cranium may result.
5	Implant the lead in the desired location through the burr hole using appropriate neurosurgical techniques.
6	Hold the lead in place where it exits the burr hole and remove the lead stylet according to the instructions provided with the lead. Manage lead placement, lead positioning and lead stylet removal in accordance with the instructions for use provided with the lead.
7	Irrigate the cap, base and lead with sterile saline.
8	Determine the desired direction for the lead to exit the burr hole. Note which of the three lead tracts in the base is most closely aligned in this direction. Place the lead into the chosen lead tract. Gently press the lead body into the tract, leaving only a small amount of excess lead length (slack) within the burr hole to avoid stress on the lead or misalignment (see illustrations).  Appropriate slack Excess slack
9	With your thumb or forefinger, hold the lead in position where the lead exits the lead tract. With your other hand place the cap in the center of the base. Fully insert the cap by applying gentle pressure on the cap edge furthest from the lead with an even rolling motion towards the lead, inspecting that the lead remains in the lead tract. 
10	Direct the lead to its ultimate location, as recommended in the instructions for use for the lead. Avoid applying traction force to the lead. Leaving a small curve in the lead near where it exits the burr hole cover is recommended to avoid stress on the lead. 
11	Close the incision site while avoiding placing sutures near the lead body.

Burr Hole Cover Removal and Lead Management Procedure

STEP	ACTION
1	If no lead is present, remove the device by removing the three screws that secure the device to the cranium.
2	For access to the lead, insert sterile forceps into the two removal holes in the device cap and pull the cap gently until it separates from the device base.
3	Remove or adjust the lead using appropriate neurosurgical techniques.
4a	To replace the device cap, follow Implant Procedure steps 7-9 above, leaving appropriate slack in the lead as indicated to avoid stress on the lead.
4b	To remove the device base, remove the three screws that secure the device to the cranium.

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