



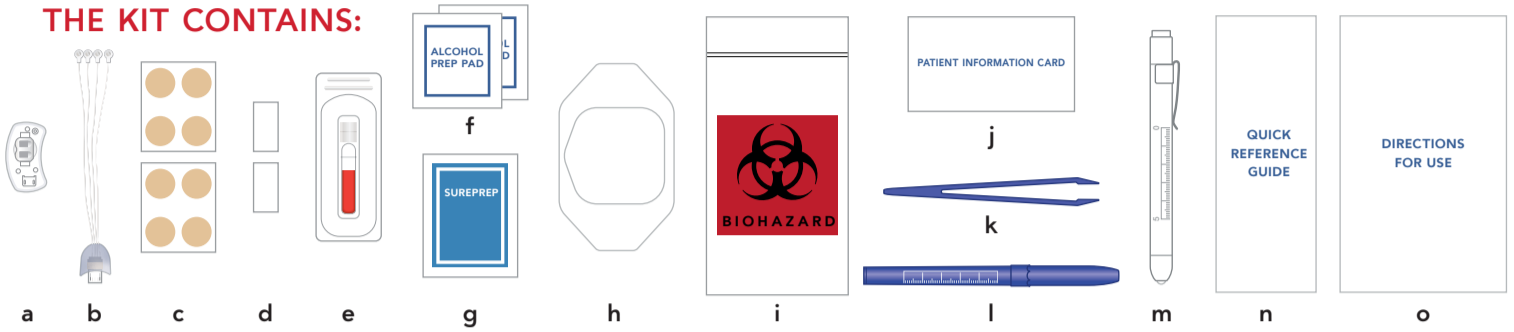
Rx only

Bridge™

Percutaneous Nerve Field Stimulator (PNFS)

Quick Reference Guide

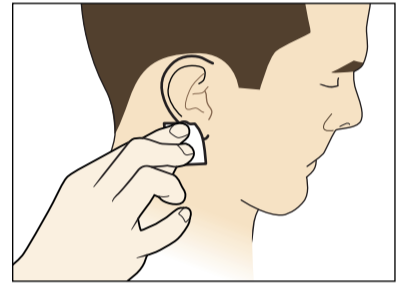
THE KIT CONTAINS:



- a** Bridge Stimulator with inserted but not activated batteries
- b** Sterile Wire Harness for use with Bridge Stimulator
- c** (8) Round Bandages to fasten the appliance leads
- d** (2) Stimulator Adhesive
- e** Compound Benzoin Tincture
- f** (2) Alcohol Swab
- g** Sureprep® Protective Wipe
- h** Tegaderm™
- i** Bio-Hazard Bag
- j** Patient Information Card
- k** Tweezers
- l** Surgical Marker
- m** Medical Light
- n** Quick Reference Guide
- o** Directions For Use

PUTTING ON BRIDGE

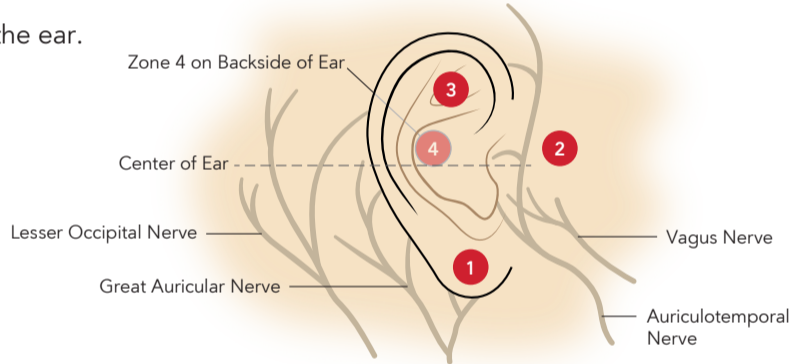
- 1** Ask the patient which side they generally sleep on and if they have a preference of which ear they would like the device applied to.
- 2** Discuss if the patient wears glasses, hearing aids or uses a CPAP machine, to ensure Bridge is placed around them appropriately.
- 3** If patient has long hair, pin the hair up and away from the ear.
- 4** Use the alcohol pad to clean off the anterior (ventral) and posterior (dorsal) of the outer ear to remove all surface oils, make up and disinfect the skin.
- 5** Additionally use the Sureprep wipe on zones of ear where leads will be implanted.
- 6** The correct location for implantation of the electrode needles is determined by visualizing the cranial and occipital neurovascular bundles through transillumination.



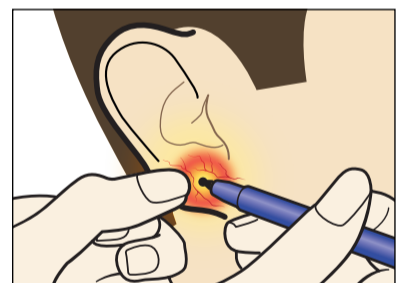
Steps 4 & 5

- 7** To mark zones 1-4 for lead placement:
 - a. Place the medical light tip against the skin on the opposite side of the zone identified and view the zone as light passes through the tissue. The neurovascular bundles will be visibly outlined.
 - b. Mark a location within 0.5-2mm of a neurovascular bundle with provided surgical marker.

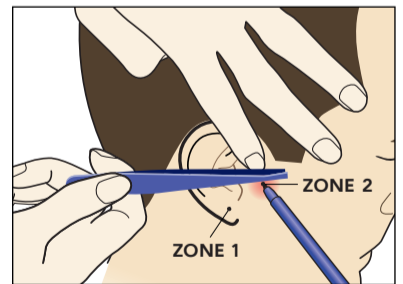
NOTE: to avoid bleeding and discomfort, do not place zone location on the neurovascular bundle.



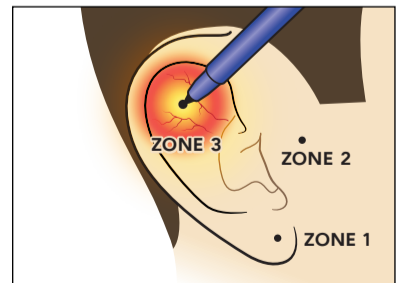
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- Zone 1 Great Auricular Nerve**
Center of the ear lobe.
 - Zone 2 Auricular Branch of the Vagus Nerve**
Anterior and superior to the tragus (lay the tweezers across center of ear horizontally to assist with marking the implantation site).
NOTE: Check for pulse in this area and mark zone **AWAY** from pulse.
 - Zone 3 Auriculotemporal Nerve**
At the triangular fossa.
 - Zone 4 Lesser Occipital Nerve**
Dorsal side of the triangular fossa.
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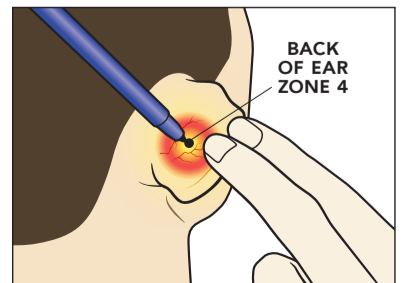
Zone 1



Zone 2

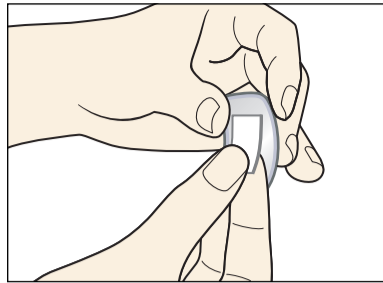


Zone 3



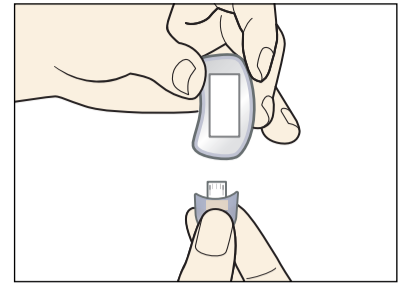
Zone 4

8 Place the double-sided stimulator adhesive on the side of the stimulator contacting the patient's ear.



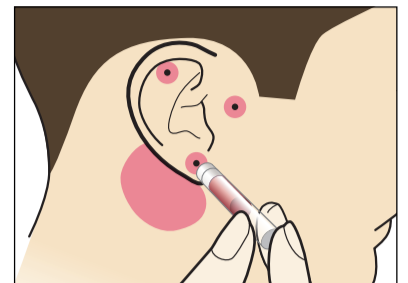
Step 8

9 Insert the wire harness into the stimulator until firmly seated to start therapy.



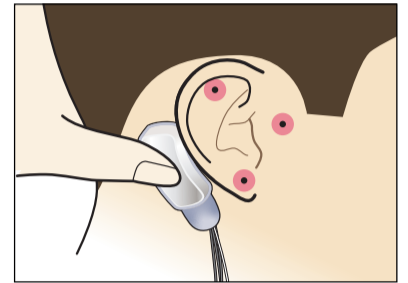
Step 9

10 Hold the stimulator with the inserted wire harness posterior to the patient's ear. Ensure that the stimulator is properly positioned extending the wires over the ear allowing enough length so the leads can be placed at the desired location.



Step 11

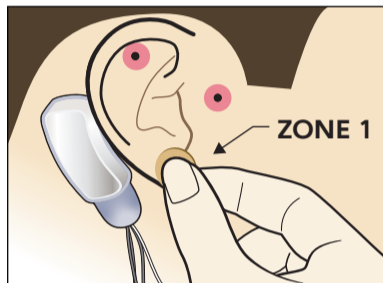
11 After the proper position of the device is confirmed apply the compound benzoin tincture to the skin where the stimulator is to be applied. Also apply the tincture at the sites marked for lead placement.



Step 12

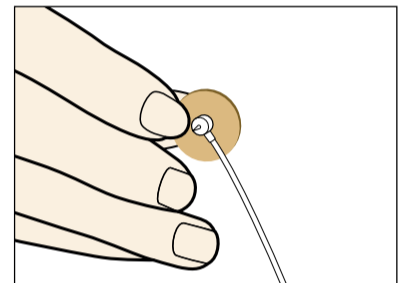
12 Gently press the stimulator with inserted wire harness onto the skin at the desired application site for 3-5 seconds.

13 Start with the placement of the ground lead (white color) on zone 1. Secure the electrode needle and place a round adhesive bandage on the flat side of the lead. Implant the lead percutaneously with gentle pressure.



Step 13a

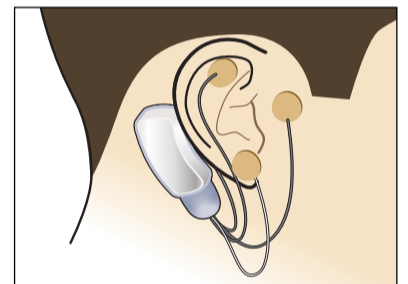
NOTE: Round adhesive can be applied to the electrode lead either before or after needle implantation.



Step 13b

14 Repeat step 13 for the remaining zones with any of the grey leads.

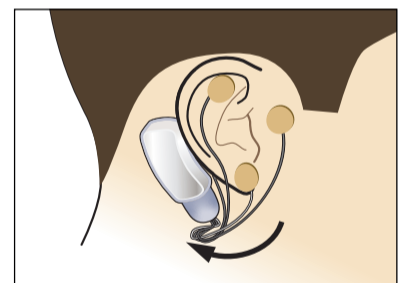
15 If bleeding and discomfort occurs, reevaluate placement location with transillumination and reposition the leads.



Step 14

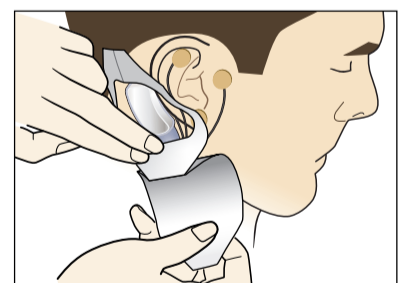
16 Wait 5-10 mins to ensure that patient is able to feel the stimulation.

17 If the patient cannot feel or tolerate the stimulation after 5-10 min, reposition the leads.



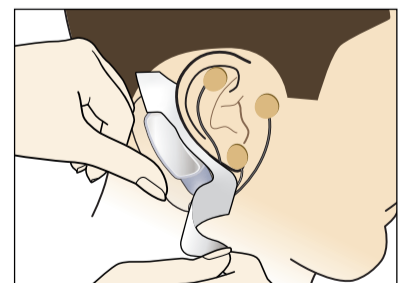
Step 18a

18 Gather any dangling wires and hold it close to the stimulator. Place the Tegaderm™ strip over the stimulator to hold it in place.



Step 18b

19 If withdrawal symptoms begin to return within 5 days of therapy starting, direct the patient to perform a pinch test to make sure the leads are in good contact with the ear. For the pinch test, simply pinch down on the lead.

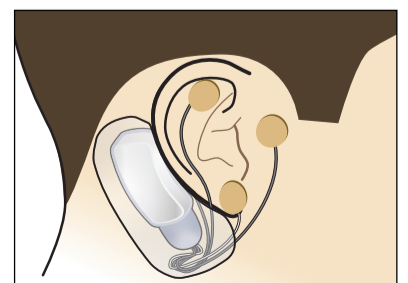


Step 18c

REMOVAL OF BRIDGE

Have patient return to the office after five days for removal.

- Gently remove each of the electrodes one at a time by slowly lifting off the round adhesive patch, then pulling the electrode needle out.
- After the electrodes have been removed, carefully pull off the stimulator from behind the ear.
- Once removal is complete, clean the areas of the ear where the electrodes were placed with an alcohol wipe.
- Place the used device into the biohazard waste bag provided and dispose of the bag as medical waste, following your appropriate state regulations.



Step 18d