Instructions For Use
Part No.: PN-4790

MASIMO®

Bridge™

Rx Only

Items supplied in the kit: 1.BRIDGE stimulator with inserted but not activated batteries 2.Sterile Wire Harness for use with BRIDGE stimulator only 3.Round Bandages to fasten the appliance leads(8), Stimulator adhesive(2), Compound Benzoin Tincture, Alcohol swab (2), Sureprep®, Tegaderm™, Bio-Hazard Bag and Patient ID Card 4.Tweezers 5.Surgical Marker 6.Transilluminator • This instruction manual

Please check the contents when you open the package. The BRIDGE stimulator and its accessories are for single-use only, single patient only. Each device must be properly disposed of according to local health regulations.

Important: Before starting the application of BRIDGE stimulator, make sure that you read, understand and observe the warnings and safety instructions that follow. BRIDGE stimulator application should only be performed according to the certified training protocols provided by Innovative Health Solutions. Rx Only

Indications for Use
The BRIDGE is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.

About The BRIDGE Stimulator
BRIDGE stimulator is a battery-operated micro-stimulation appliance weighing 5 grams designed as a disposable product for a single use. BRIDGE stimulator is placed behind the patient's ear and connected to stimulation needles on the auricle. BRIDGE stimulator offers regular therapy over several days. The appliance transmits low-frequency electric pulses to exposed nerve endings.

Contraindications
·Use of cardiac pacemakers because no clinical data is available
·Hemophilia
·Psoriasis vulgaris
An intact skin surface is essential for the use of BRIDGE stimulator.
Contraindication Sureprep : On infected areas of skin.
Contraindication Steri-Strip: Steri-Strip compound benzoin tincture should not be used on patients with a previous history of sensitivity to compound benzoin tincture.

Warnings & Precautions
-The built-in microchip creates periods of stimulation and rest. After a time it could feel as if the intensity of the stimulation is decreasing. A decrease in the perceived intensity of stimulation may be subjective and have no bearing on the effectiveness of the therapy.
-The appliance is splash-proof but not watertight. If desired, hair should be washed before therapy. When showering the appliance must not be allowed to come into direct contact with water.
- Battery is automatically activated and therapy is administered by the device when the wire harness and generator are connected during installation. The device is programed to discontinue therapy 120 hours (5 days) after activation.
Steri-Strip Warnings:
1. Allergic contact dermatitis to compound benzoin tincture has been reported.
2. Flammable.
3. For external use only.
Steri-Strip Precaution: Spillage of compound benzoin tincture into the wound should be avoided, as it may impair the wound healing process.

Procedure For Placement of the BRIDGE Stimulator

(These instructions are to be used in conjunction with the training program designed to familiarize the clinician with the clinical features of the BRIDGE stimulator and how to use it in a safe and effective manner)


Fig. 1


Fig. 2

Clean off the anterior (ventral) and posterior (dorsal) of the outer ear with an alcohol pad to remove all surface oils, make up and disinfect the skin. Next use Sureprep® protective wipe on zones of ear where leads will be implanted. (Fig. 1, 2)


Fig. 3.1


Fig. 3.2

To activate the BRIDGE stimulator, the wire harness is inserted into the stimulator until firmly seated.(Fig. 3.1) Temporarily place the stimulator behind the patient's ear. Carefully observe that the stimulator is properly positioned extending the harness wires over the ear allowing enough length so the electrode needles can be placed at the desired location. (Fig. 3.2) Marking implantation site with the provided surgical marker is optional. After the proper position of the device is confirmed apply the supplied compound benzoin tincture to the skin surface where the BRIDGE stimulator is to be applied. This helps reduce the chances of component migration.


Fig. 4


Fig. 5

Remove the protective coating on the adhesive strip on the back of the BRIDGE stimulator. (Fig.4) Gently press the stimulator onto the skin posterior to the external ear. (Fig. 5)

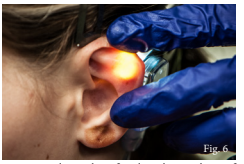
Fig. 6


Fig. 7

The correct location for implantation of the electrode needles is determined by cranial and occipital neurovascular bundles visualized by transillumination. (Fig. 6 , 7) **Detailed explanation of transillumination located on back of IFU.

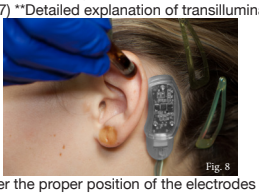
Fig. 8


Fig. 9

After the proper position of the electrodes is confirmed, apply the supplied compound benzoin tincture to the skin surface where the electrodes are to be applied. This helps reduce the chances of component migration.(Fig. 8 , 9)

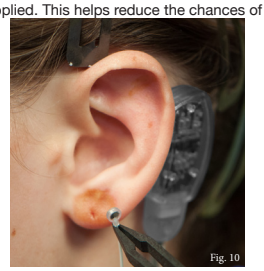
Fig. 10


Fig. 11

Stimulation can be accomplished by ventral (anterior) and/or dorsal (posterior) percutaneous implantation of the electrode needles. Once the desired neurovascular bundles are visualized by transillumination, the electrode needle is secured by the provided tweezers and implanted percutaneously with gentle pressure. The four needle electrode array, attached to the white wire, is placed on the ventral (outer) side of the ear lobe as determined by transillumination. (Fig.10,11)

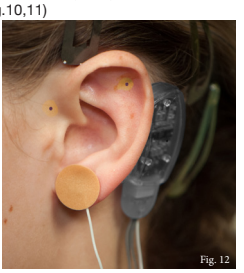
Fig. 12

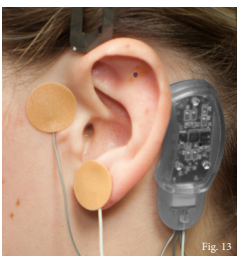
Fig. 13

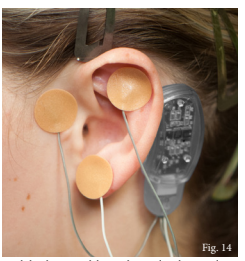
Fig. 14

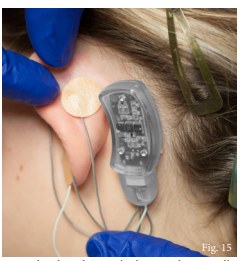
Fig. 15

A provided round bandage is then placed over the implanted electrode needle array and gently secured to prevent electrode needle array migration. The procedure is then repeated for implantation of the second electrode needle, the third electrode needle and the fourth and final electrode needle. (Fig.12, 13, 14, 15)

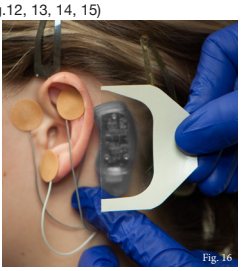
Fig. 16

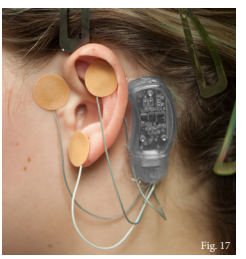
Fig. 17

The supplied Tegaderm™ strip is then placed over the stimulator to help avoid component migration. (Fig. 16) The application of the BRIDGE device is now complete. (Fig. 17). Have your patient return to the office in 5 days. Carefully and safely remove the device with appropriate instrumentation following blood hazard protocols. Place the device into the BioHazard Bag, contained in the surgical kit. Clean the patients ear area. Despose of the bag as medical waste, following your appropriate state regulations.

Transillumination

The correct location for implantation of the electrode needles is determined by cranial and occipital neurovascular bundles visualized by transillumination. Use of the transillumination technique will help ensure the BRIDGE stimulator will be implanted safely and effectively or all indicated patients.

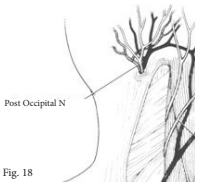

Fig. 18

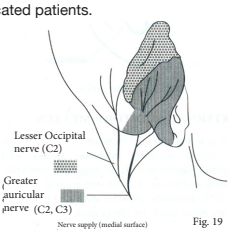

Fig. 19

The external ear contains peripheral branches of cranial nerves V,VII,IX,X as well as peripheral branches of the occipital nerves. (Fig. 18, 19)

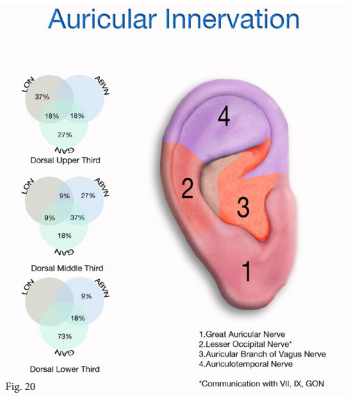

Fig. 20

These neurovascular bundles are located in predictable areas (referred to as zones) with predominant, predictable concentrations of cranial and occipital neurovascular bundles. (Fig. 20)

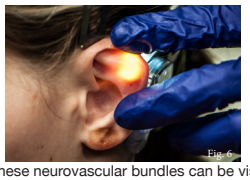

Fig. 6

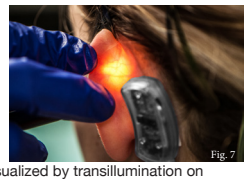

Fig. 7

These neurovascular bundles can be visualized by transillumination on the ventral (Fig. 6) and the dorsal (Fig. 7) aspect of the external ear. This is accomplished by placing the transilluminator tip against the skin and viewing the opposite side of the external ear as light passes through the tissue. The neurovascular bundles will be outlined due to anatomical variance and the difference in tissue density. Marking the desired implantation site with the provided surgical marker is optional. The location of the implantation site of the electrode needles must be within .5-2mm of a neurovascular bundle to avoid bleeding and discomfort. If bleeding and discomfort occurs, reevaluate placement location with transillumination and reposition the leads.

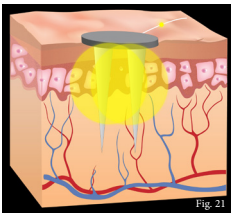

Fig. 21

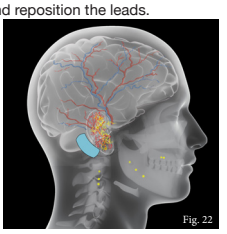

Fig. 22

Accurate percutaneous implantation of the electrode needles will create a zone of electrical stimulation which will encompass branches of the cranial and occipital nerves, arterial branches (both indirectly and transarterial), and the co-joined neurovascular bundles. (Fig. 21, 22)

MANUFACTURER LIABILITY

The manufacturer and supplier of the device will not accept any liability in the following cases: If the device is not used in accordance with the instructions for use. If the operator is inadequately qualified or is not sufficiently informed about the functioning of the device on the basis of the instructions for use and the safety instructions. If any defects are discovered when the contents of the package are examined, the complete unit including all components must be returned as described in section “Returned Devices” to the manufacturer or the manufacturer’s local representatives.

WARRANTY CONDITIONS

The manufacturer guarantees the product for the period up to the expiration date printed on the peel off label located on front of kit, or 12 months from date of purchase, whichever comes first. This guarantee applies to flaws of material and workmanship. Claims are only accepted under the following terms: The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made. The instructions of the manufacturer and/or supplier on storage or return of the device are within compliance. Presentation of a legible copy of the invoice for that particular device, showing the date of purchase. An exact description by the customer of the defect or fault identified. IMPORTANT: The manufacturer’s warranty will be void if it is found that the device was damaged by force, operator error, or that it was used in any way contrary to the instructions for use and the safety instructions. If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the cost and risk of transporting the device to and from the place of use. The manufacturer and/or supplier under no circumstances assumes liability for ordinary negligence. Claims for compensation for loss of earnings and profits will likewise not be accepted.

RETURNED DEVICES

Returned devices must be carefully cleaned and then returned in the original packaging. If the original packaging is no longer available the device must be suitably packaged for the method of shipping chosen.

OPERATION / TRANSPORT / STORAGE

Recommend no prolonged storage / exposure outside the recommended ranges for operation, transport and storage: Temperature: 22 °C +/- 5 °C Relative Humidity: 20 - 80 % The product has a limited shelf life. Details are printed on peel off label located on front of kit. Values higher or lower than the ranges specified above will shorten the useful life of the device or may cause certain components to be destroyed.

COMPANY CONTACT

Masimo Corporation
52 Discovery
Irvine, CA 92618
USA
www.masimo.com

CONTRACT MANUFACTURER

GMI Corporation
700 International Drive
Franklin, IN 46131

PRECLINICAL SUMMARY

The ability of the BRIDGE System to produce systemic effects by modulating branches of cranial nerves V, VII, IX and X has been demonstrated in preclinical animal models.

CLINICAL SUMMARY

The BRIDGE System (BRIDGE) has been evaluated in a clinical study to determine (1) the effects of the device on Clinical Opioid Withdrawal Scale (COWS) scores during the induction phase of opioid withdrawal therapy, and (2) the percentage of subjects who underwent successful withdrawal and transitioned to medication assisted therapy (MAT).

METHODS

Seventy-three (73) adult patients were treated with the BRIDGE stimulator during medically supervised withdrawal in outpatient clinics. The COWS scores were prospectively recorded during different intervals (20, 30 and 60 min) of treatment with the BRIDGE stimulator and analyzed retrospectively; a subset of patients had scores recorded 5 days after treatment with the device. Patients who returned to the clinic and received their first dose of maintenance medication were considered to be successfully transitioned.

RESULTS

In this group of patients (n=73), the mean COWS score prior to BRIDGE placement was 20.1 (±6.1). Twenty minutes after BRIDGE placement, the mean score was reduced 62.7% to 7.5 (±5.9) (62.7% reduction, p<0.001 vs baseline scores). The scores continued to decrease after 30 minutes to 4.0 (±4.4) and 60 minutes to 3.1 (±3.4) (84.6% reduction, p<0.001 vs baseline scores). No rescue medications were used during this period. The mean withdrawal score measured on a subset of thirty-three (33) patients on day 5 was 0.6 (97.1% reduction, p<0.001 vs baseline scores). Overall, 64/73 patients (88.8%) successfully transitioned to medically assisted therapy (MAT). All patients who transitioned to MAT at Day 5 had a negative urine toxicology screen for opioids prior to administering the MAT.

RISKS

No adverse events were noted in the study. Potential risks of percutaneous therapies, generally, would include bleeding or infection at the puncture site, pain at the application site, or skin irritation at the site of application.

SYMBOLS AND LABELS

Comply with recommended ambient conditions

LOT Batch designation

IEC 60601 Compliant

STERILE R Sterilization by irradiation (Needle packaging)

Caution: Comply with accompanying documents

01.XXXX 01 Year of manufacture XXXX Serial Number

For single use only

Use before ..,..,20..

The appliance and accessories must be disposed of in accordance with local regulations

MR

TECHNICAL DATA

Rx Only

Appliance: Percutaneous Nerve Field Stimulator (PNFS)
Type description: BRIDGE Stimulator
Power supply: 1 x 3V battery (Type CR1225 Lithium)
Output: Load impedance range 1k ohms-10k Ohms, max. 3.2V, Symmetrical, biphasic stimulation cycles occur at a frequency of 0.125Hz. Max possible total duration of treatment 5x 24 hours.
Protection level: IP20 Type: B
Classification: (in accordance with Directive 93/42 EEC)
Duty type: up to 120 hour duty/ with periodic rest.
Weight incl. battery: 5g Dimensions: 36 x 16 x 7 mm
Needle Dimensions: 0.5 mm width x 2 mm length
Patent Numbers: 9,662,269 9,839,577 10,010,479 10,322,062 10,413,719

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Rev. 01