Bridge™

Percutaneous Nerve Field Stimulator (PNFS)

DIRECTIONS FOR USE

Prior to using this product, the user should read and understand the warnings and safety instructions. Bridge stimulator application should only be performed according to the directions for use provided by the Manufacturer.

INDICATIONS

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.

CONTRAINDICATIONS

- Use of cardiac pacemakers because no clinical data is available
- Hemophilia
- Psoriasis vulgaris
- Do not use Sureprep on infected areas of skin.
- Steri-strip compound benzoin tincture should not be used on patients with previous history of sensitivity to compound benzoin tincture.

DESCRIPTION

Bridge ("Device") is a battery-operated micro-stimulation appliance designed as a disposable product for a single use. The device is placed behind the patient's ear and connected to stimulation needles on the auricle. The Device offers regular therapy over several days. The Device transmits low-frequency electric pulses to exposed nerve endings.

WARNINGS, CAUTIONS, AND NOTES

- An intact skin surface is essential for the use of the Bridge stimulator.
- 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 device is not MRI Compatible and must be removed before entering the MRI scanning room. Failure to remove may cause injury to patient, hospital personnel, or damage to the MRI machine.
- 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.

INSTRUCTIONS

A) Contents

- Refer to **Fig. 1.** 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.

B) Site Selection

- 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.
- Discuss if the patient wears glasses, hearing aids or uses a CPAP machine, to ensure Bridge is placed around them appropriately.
- If patient has long hair, pin the hair up and away from the ear.
- Remove all jewelry such as piercings and gauges from the application ear.

C) Preparation

1. Refer to **Fig. 2.** Use the alcohol pads to clean off the anterior (ventral and posterior (dorsal) of the outer ear to remove all surface oils, make up and disinfect the skin.
2. Use the Sureprep wipe on zones of ear where leads will be implanted.
3. Refer to **Fig. 3.** The correct location for implantation of the electrode needles is determined by visualizing the cranial and occipital neurovascular bundles through transillumination and anatomical landmarks.

   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 the 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.
   NOTE: Ensure that zones 3 and 4 are offset from each other.
4. Refer to **Figs. 4a. - 4d.** Mark zones 1-4 for lead placement:

   a.) Place the transilluminator 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 neurovasular bundle with provided surgical marker.
   NOTE: To avoid bleeding and discomfort, do not place zone location on the neurovascular bundle.

D) Applying Bridge to the patient

1. Refer to **Fig. 5.** Place the double-sided stimulator adhesive on the side of the stimulator that will make contact behind the patient's ear on the mastoid process. The correct location for implantation of the electrode needles is determined by visualizing the cranial and occipital neurovascular bundles through transillumination.
2. Refer to **Fig. 6.** Insert the wire harness into the stimulator until firmly seated to start therapy with the dimple side of harness and circuit chip facing up.
3. 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.
4. Refer to **Fig. 7.** 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 around the sites marked for lead placement.
5. Refer to **Fig. 8.** Gently press the stimulator with inserted the wire harness onto the skin at the desired application site for 3-5 seconds.
6. Refer to **Fig. 9.** Start with the placement of the ground lead (white color) on zone 1.
7. Refer to **Fig. 10.** Secure the electrode needle and place a round adhesive bandage on the flat side of the lead. Implant the lead percutaneously with gentle pressure.

   NOTE: Round adhesive can be applied to the electrode lead either before or after needle implantation.
8. Refer to **Fig. 11.** Repeat step 7 for the remaining zones with any of the grey leads.

   NOTE: If bleeding and discomfort occurs, reevaluate placement location with transillumination and reposition the leads.
9. Wait 5-10 mins to ensure that patient is able to feel the stimulation.

   NOTE: If the patient cannot feel or tolerate the stimulation after 5-10 min, reposition the leads.
10. Refer to **Fig. 12.** Gather any dangling wires and hold it close to the stimulator.
11. Refer to **Figs. 13a - 13c.** Place the Tegaderm™ strip over the stimulator to hold it in place.
12. If withdrawal symptoms begin to return within 5 days of starting therapy, 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.

E) Removal

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

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

ENVIRONMENTAL

Operating Temperature	22 °C +/- 5 °C
Storage/Transport Temperature	22 °C +/- 5 °C,
Operating and Storage/Transport Humidity	20 - 80 % Relative Humidity

TECHNICAL DATA

Appliance: Percutaneous Nerve Field Stimulator (PNFS)
Type description: Stimulator
Power supply: 1 x 3V battery (Type CR1225 Lithium)
Output: Load impedance range 1k ohms-10k Ohms, max. 3.2V,
Maximum possible total duration of treatment: 5 x 24 hours
Protection level: IP20 Type: B
Weight including battery: 5g
Dimensions: 36 x 16 x 7 mm
Needle Dimensions: 0.5 mm width x 2 mm length

GUIDANCE AND MANUFACTURER'S DECLARATION - Electromagnetic Emissions

The Bridge is intended for use in the electromagnetic environment specified below.
The customer or the user of the Bridge should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF Emissions CISPR 11	Group 1	Bridge uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Bridge is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A DC powered	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A DC powered	
RF Emissions CISPR 14-1	N/A Stand-alone sealed unit	Bridge is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	N/A Stand-alone sealed unit	Bridge is not suitable for interconnection with other equipment.

Bridge™

Percutaneous Nerve Field Stimulator (PNFS)

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Distributed By:
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www.masimo.com

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GUIDANCE AND MANUFACTURER'S DECLARATION - Electromagnetic Immunity

The Bridge is intended for use in the electromagnetic environment specified below.
The customer or the user of the Bridge should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLI-ANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	N/A	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an interruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V_3] V	Portable and mobile RF communications equipment should be used no closer to any part of the Bridge, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	[E_3] V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Bridge is used exceeds the applicable RF compliance level above, the Bridge should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Bridge.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

WARRANTY

Masimo warrants to the initial buyer only that these products, when used in accordance with the directions provided with the Products by Masimo, will be free of defects in materials and workmanship for a period of twelve (12) months. Single use products are warranted for single patient use only.

THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended device or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS), EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER (UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM) EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCT(S) INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED WITH A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

NO IMPLIED LICENSE

PURCHASE OR POSSESSION OF THIS PRODUCT DOES NOT CARRY ANY EXPRESS OR IMPLIED LICENSE TO USE THIS PRODUCT WITH ANY DEVICE THAT IS NOT AN AUTHORIZED DEVICE OR SEPARATELY AUTHORIZED TO USE MASIMO PRODUCTS.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

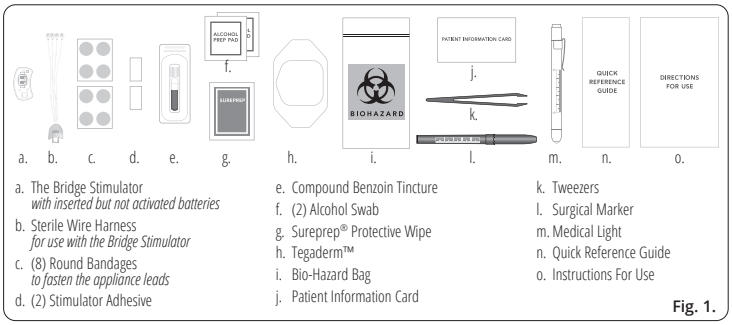
For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer of the device or monitoring system connected to this product.

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION	SYMBOL	DEFINITION
(blue background)	Follow instructions for use		Separate collection for electrical and electronic equipment (WEEE).	Rx ONLY	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use	LOT	Lot code	CE 0123	European Union Conformity Mark
	Manufacturer	REF	Catalogue number (model number)	EC REP	Authorized representative in the European community
	Date of manufacture YYYY-MM-DD	####	Masimo reference number		Body weight
SN	Serial Number	>	Greater than		Storage temperature range
1	Single patient - multiple use	<	Less than		Keep dry
NON STERILE	Non-Sterile	%	Storage humidity limitation		Do not use if package is damaged
	Not made with natural rubber latex		Fragile, handle with care		Atmospheric pressure limitation
	Caution	IP20	Protection against solid foreign objects 12.5mm and greater		Importer
MD	Medical device	UDI	Unique device identifier		Distributor
MR	MR Unsafe. Not appropriate for use in MR environment *(i.e.: inside the MR magnet room)*	eIFU Indicator	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs **Note: eIFU is not available in all countries.**		

Patents: http://www.masimo.com/patents.htm



a. The Bridge Stimulator
with inserted but not activated batteries
b. Sterile Wire Harness
for use with the 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. Instructions For Use

Fig. 1.

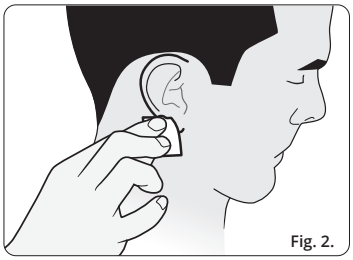


Fig. 2.

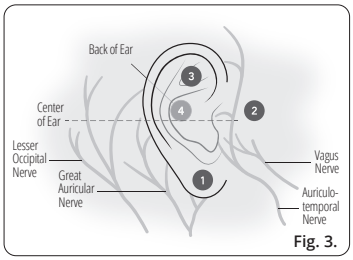


Fig. 3.

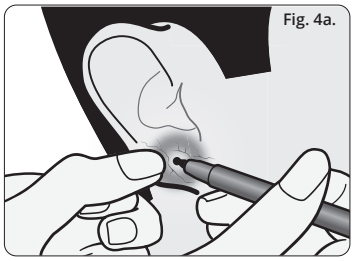


Fig. 4a.

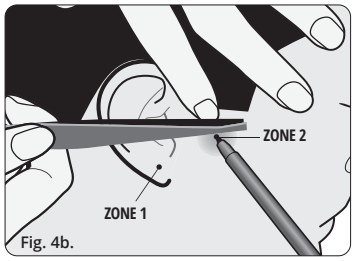


Fig. 4b.

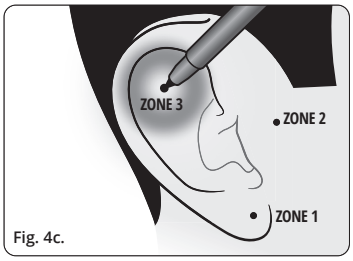


Fig. 4c.

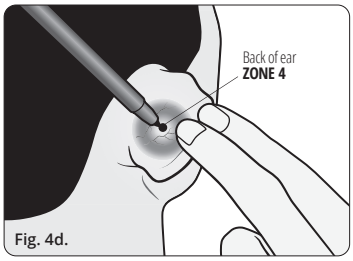


Fig. 4d.

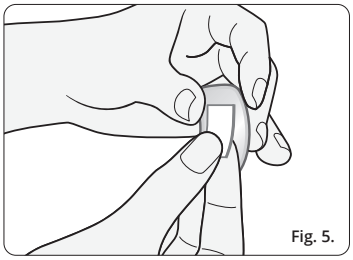


Fig. 5.

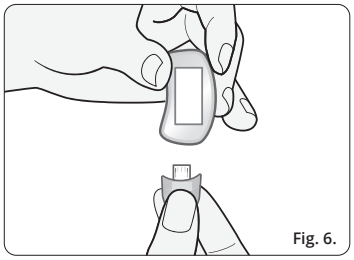
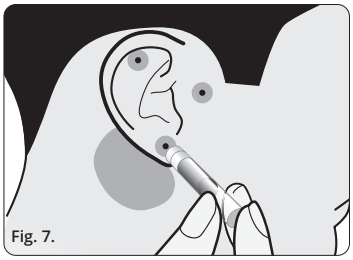


Fig. 6.



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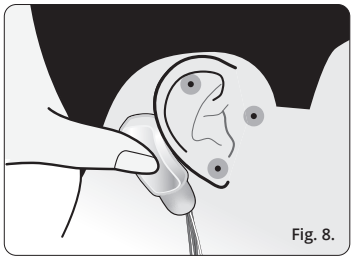

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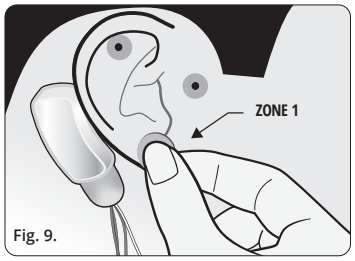

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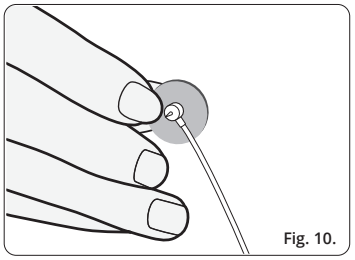


Fig. 10.

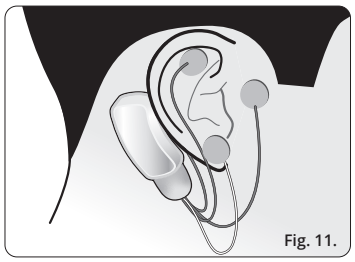
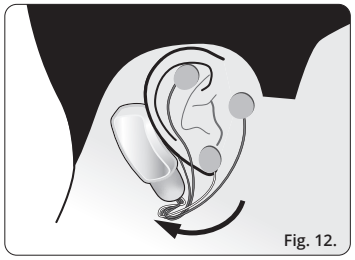


Fig. 11.



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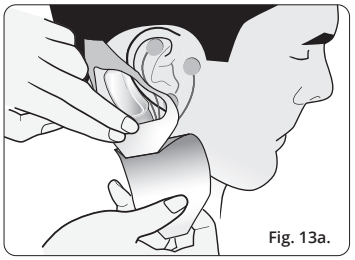

Fig. 13a.

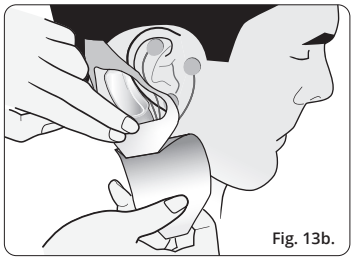

Fig. 13b.

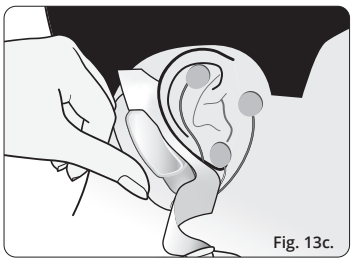

Fig. 13c.

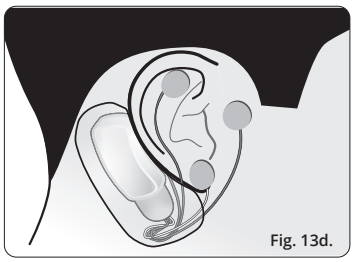

Fig. 13d.