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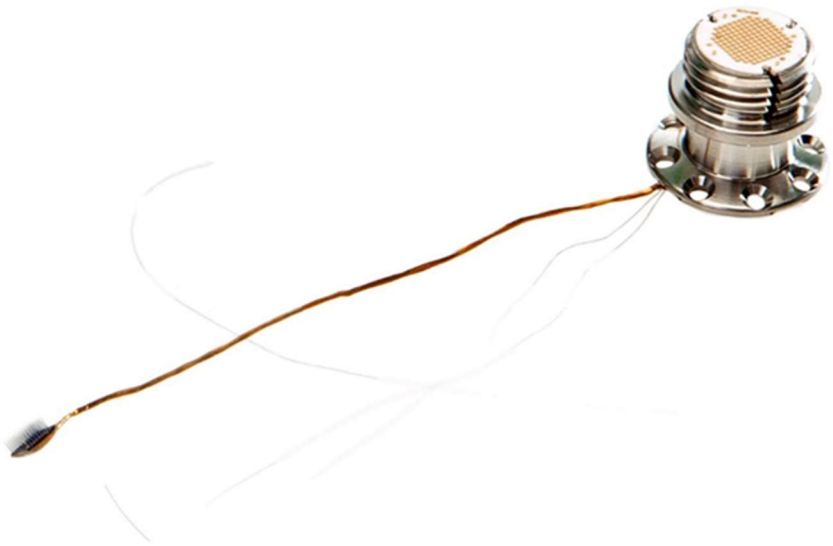
NeuroPort Electrode

PN 4312, 4382, 4383, 6248, and 6249
Instructions for Use



Revision 3.00 / LB-0612 – NeuroPort Electrode IFU – 2022/04

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What This Manual Covers

This manual is intended as an informational tool for use of the Blackrock NeuroPort Electrode. This manual is not intended to teach general surgical skills, techniques, or principles. It is expected that surgeons using this manual are trained and licensed neurosurgeons who have successfully completed the Blackrock Microsystems training program in which they learn how to implant the NeuroPort Electrode prior to attempting surgery. While this manual provides a detailed description of the Electrode, it is not intended to be an instructional tool for surgeons who have not been trained to implant the device.

This manual covers the use of the NeuroPort Electrode and can be used to identify pieces of parts of the device. This manual does not cover surgical procedure. For an overview of the surgical procedure, please refer to the Blackrock NeuroPort Surgical Manual.

Intended Use and Indications for Use

The intended use of the NeuroPort Electrode is for temporary (<30 days) recording and monitoring of brain electrical activity.

The NeuroPort Electrode senses neural signal from the cerebral cortex. It can detect single-neuron and multi-neuron signals as well as local field potentials. It is designed to be inserted with the Blackrock NeuroPort Electrode Inserter. Instructions for that device are covered in the Blackrock Surgical Training Manual and the Instructions for Use for the NeuroPort Electrode Inserter.

Contraindications, Warnings, and Precautions

Contraindications

- The NeuroPort Electrode should not be used on any patient whom the physician/surgeon considers at elevated risk of infection.
- The NeuroPort Electrode is a recording device and should not be used in applications involving stimulation.
- The NeuroPort Electrode is designed for a single patient use and should not be reused.

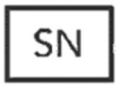
Warnings

- A thorough understanding of the technical principles, clinical applications and risks associated with neurosurgery is necessary before using this product.
- The NeuroPort Electrode is intended for use only by a trained and licensed neurosurgeon with expertise in stereotactically guided and functional neurosurgery procedures.
- Read this entire manual prior to using the device.
- Completion of the Blackrock Microsystems user training program is required prior to the use of the NeuroPort System.
- Once the NeuroPort Electrode has been implanted, the patient should not be exposed to electrocautery, therapeutic ultrasound, or diathermy.
- Once the NeuroPort Electrode has been implanted, peripheral nerve stimulation should not be used.
- The patient should not attempt to detach themselves from the recording system on their own.
- The cables between the recording system and the NeuroPort Electrode should not be bundled with or run parallel to other cables.
- The NeuroPort Biopotential Signal Processing System should be disconnected from the NeuroPort Electrode during cardiac defibrillation.
- Always touch the patient's skin before touching the electrode contacts during cleaning. Failure to do so may result in an increased risk of electric shock being delivered to the patient through the electrodes.
- Always keep a Pedestal Cap with Viton O-ring attached to the NeuroPort Electrode when the recording system is not attached, otherwise the patient may be subject to an increased risk of electrical shock being delivered through the electrodes.

Precautions

- The NeuroPort Electrode is intended for use only with the NeuroPort Biopotential Signal Processing System. Refer to the NeuroPort System User Manual regarding use of the NeuroPort Electrode with the NeuroPort System.
- Do not use the NeuroPort Electrode if the sterile barrier packaging is damaged. Otherwise, the patient may experience an increased risk of infection.
- Do not use the Pedestal Cap with Viton O-ring accessory (Pedestal Cap) if the sterile barrier packaging is damaged or compromised. Failure to do so may lead to an increased risk of infection.
- The Pedestal Cap should be replaced every 24 hours or after every detachment of the recording system, failure to do so may lead to an increased risk of infection.
- Do not use if “Use-By” date has expired.
- Do not overtighten the Pedestal Cap, otherwise the cap may be more difficult to remove or cause the cap to detach from the NeuroPort Electrode more easily.

Symbols

ISO 15223-1:2021 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
Reference	**Symbol**	**Title**	**Meaning**
5.1.1		**Manufacturer**	Indicates the medical device manufacturer.
5.1.4		**Use-by Date**	Indicates the date after which the medical device is not to be used.
5.1.6		**Catalog Number**	Indicates the manufacturer's catalog number so that the device may be identified. For Blackrock Microsystems it is called the Part Number (PN).
5.1.7		**Serial Number**	Indicates the manufacturer's serial number so that a specific medical device can be identified.
5.2.3		**Sterilized Using Ethylene Oxide**	Indicates that the device has been sterilized using ethylene oxide.
5.2.6		**Do Not Resterilize**	Indicates that the device should not be re-sterilized after it once has been sterilized.
5.2.8		**Do Not Use if Package is Damaged**	Indicates that a medical device should not be used if the package has been damaged or opened.
5.4.2		**Do Not Reuse**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3		**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use, which you are currently reading.

ISO 15223-1:2021 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
5.4.4		**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
ISO 7000/IEC 60417 Graphical Symbols for Use on Equipment			
2724		**Non-Pyrogenic**	To indicate that the product is non-pyrogenic.
21 CFR 801. 109 (b) (1), 81 FR 38911 2016-09-13, U.S.A. FDA Guidance: Alternative to Certain Prescription Device Labeling Requirements 2000-01-21			
Symbol		**Title**	**Meaning**
		**Prescription Only**	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Specifications

The NeuroPort Electrode is available in two different electrode lengths and two different metallization options for a total of four unique device configurations. These are shown in the table below:

	PN 4382	PN 4383	PN 6249	PN 6248
Electrode Length	1.0 mm	1.5 mm	1.0 mm	1.5 mm
Number of Electrodes	100 (96 connected to percutaneous connector)	100 (96 connected to percutaneous connector)	100 (96 connected to percutaneous connector)	100 (96 connected to percutaneous connector)
This Impedance Range	100 – 800 kOhms	100 – 800 kOhms	1 – 80 kOhms	1 – 80 kOhms
Wire Bundle Length	13 cm	13 cm	13 cm	13 cm
Metallization Type	Platinum	Platinum	Iridium Oxide (SIROF/IrOx)	Iridium Oxide (SIROF/IrOx)
Connector Type	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal
Patient Contacting Materials	Titanium NuSil MED-4211 Parylene C Platinum Platinum/Iridium	Titanium NuSil MED-4211 Parylene C Platinum Platinum/Iridium	Titanium NuSil MED-4211 Parylene C Platinum Iridium Oxide Platinum/Iridium	Titanium NuSil MED-4211 Parylene C Platinum Iridium Oxide Platinum/Iridium

Overview of the Device

A single unit, the NeuroPort Electrode has four sub-components: The Electrode, the wire bundle, the reference wires, and the pedestal connector. The NeuroPort Electrode is shipped sterile inside of a sterilization holder to protect the Electrode during sterilization.

Figure 1–NeuroPort Electrode Removed from Sterile Packaging

The NeuroPort Electrode is used to detect signals from the cortex. It does not provide clinical benefit on its own but may be used to acquire signals that are useful in research.

Note that the device does not include the bone screws necessary for affixing the pedestal connector to the skull. The suggested screws are 6mm length, 2 mm diameter titanium Synthes self-tapping cranial cortex screws. Six to eight total screws are suggested (Johnson & Johnson Screw 401.356.97 as cleared in K980199 and K112583). The device also does not ship with the Pedestal Cap with Viton O-Ring attached (Part Number 4312), an accessory used to protect the surface of the pedestal connector and to help prevent electrostatic discharge into the electrodes through that connector.

Unpackaging the Device

The NeuroPort Electrode is shipped in a sterilization holder inside two Tyvek pouches as the sterile barrier, chipboard box, and overshipper. The device should not be removed from the sterile pouch unless it is intended to be used immediately.

To remove the NeuroPort Electrode from its packaging, follow the steps below.

1. Open Overshippper and remove Chipboard Box (**Figures 2 and 3**).
2. Open Chipboard Box, remove IFU and foam lid and ring (**Figures 4 through 6**).
3. Verify the serial number on the box and the assembly package inside the pouch (**Figure 7**).

Figure 2–Chipboard Box in Overshipper

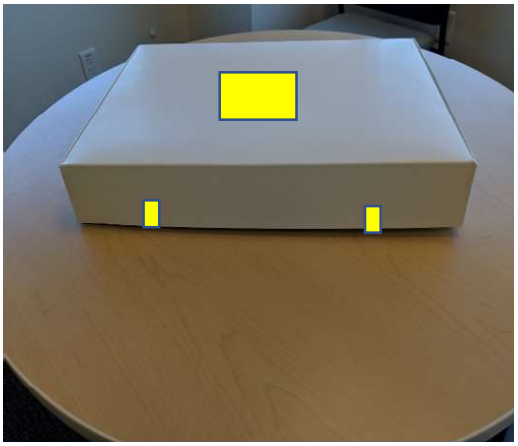


Figure 3–Chipboard Box with label and two closures.

Figure 4–IFU on foam lid

Figure 5–Lid placed inside foam ring

Figure 6–Foam ring on top of product

Figure 7–Double-pouched product with sterilization indicators inside each pouch. Product on foam base. Yellow indicates labels (one on inner pouch, one on outer pouch).

Figure 8–Foam base in Chipboard Box

4. Open the sealed pouches and remove the assembly from the inner pouch.

Testing Impedance

Impedance is the primary method of measuring electrode performance before it is placed into neural tissue, so it is important to take a measure of impedance of the electrodes before implantation. The electrode assembly holder is designed to allow one to take impedance readings while the electrode is held safely within the holder. The method of accessing the connector to measure impedance is below.

- The end cap must be removed from the assembly holder to access the pedestal. This can be done by unscrewing the thumb screw that is on the opposite side from the pedestal.

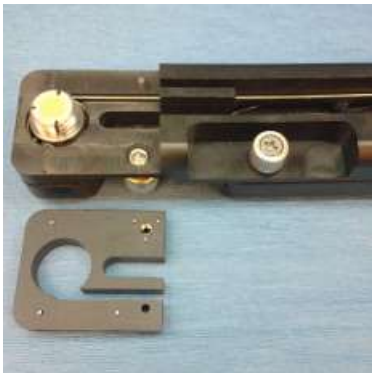


Figure 2–Remove the pedestal end cap.

- With the end cap removed, one can now attach an impedance testing device, such as the NeuroPlex E, to the pedestal to measure impedances in saline.
- The holder should be placed in 37 C saline with a pH of 7.0-7.2 (**Figure 10**). Let the electrodes sit in the saline for about 5 minutes before taking the impedance reading.
- When finished with the impedance reading, the assembly and the assembly holder should be rinsed with distilled water.

Figure 10–Assembly holder in saline.

Removing the Assembly from the Assembly Holder

To remove the assembly from the sterilization holder in preparation for implantation, follow the directions below.

1. The pedestal end cap of the assembly holder should be removed during the impedance reading step. If the end cap has not been removed or was restored, remove the pedestal end cap first.
2. After removing the pedestal end cap, unscrew the top center thumb screw to remove the top plate.
3. With the top plate removed, the assembly can now be carefully removed (**Figure 11**).

Figure 11–PN 8536 Assembly holder disassembled.

Using the Pedestal Cap with the NeuroPort Electrode

The Pedestal Cap with Viton O-Ring (PN 4312) is an accessory to the NeuroPort Electrode that is sold separately. It is used to protect the percutaneous connector when the NeuroPort Electrode is not attached to a recording system. The Pedestal Cap is sold sterilized by ethylene oxide (EtO) and is single-use only.

Figure 12–Pedestal Cap and O-Ring

Before attaching the pedestal cap, the included O-Ring should be placed over the pedestal threads onto the pedestal shelf. The Pedestal Cap should be attached by hand and screwed down to ‘two finger tightness’, that is, to a tightness achievable with just two fingers.

The cap may also be removed by hand, or a tool, such as a wrench, may be used to remove it.

Interpreting the Datasheet Sent with Your Electrode

Blackrock provides data sheets with every NeuroPort Electrode. These data sheets include information about the electrode layout, connector pinout, and impedance readings at the time of manufacture. It is important to note that the impedance readings are taken at room temperature and the values are recording in kOhms. When taking your own impedance readings, keep in mind that the temperature of the testing medium can influence the impedance value. The figure below shows an example layout, but individual NeuroPort Electrode mappings may differ from this example.

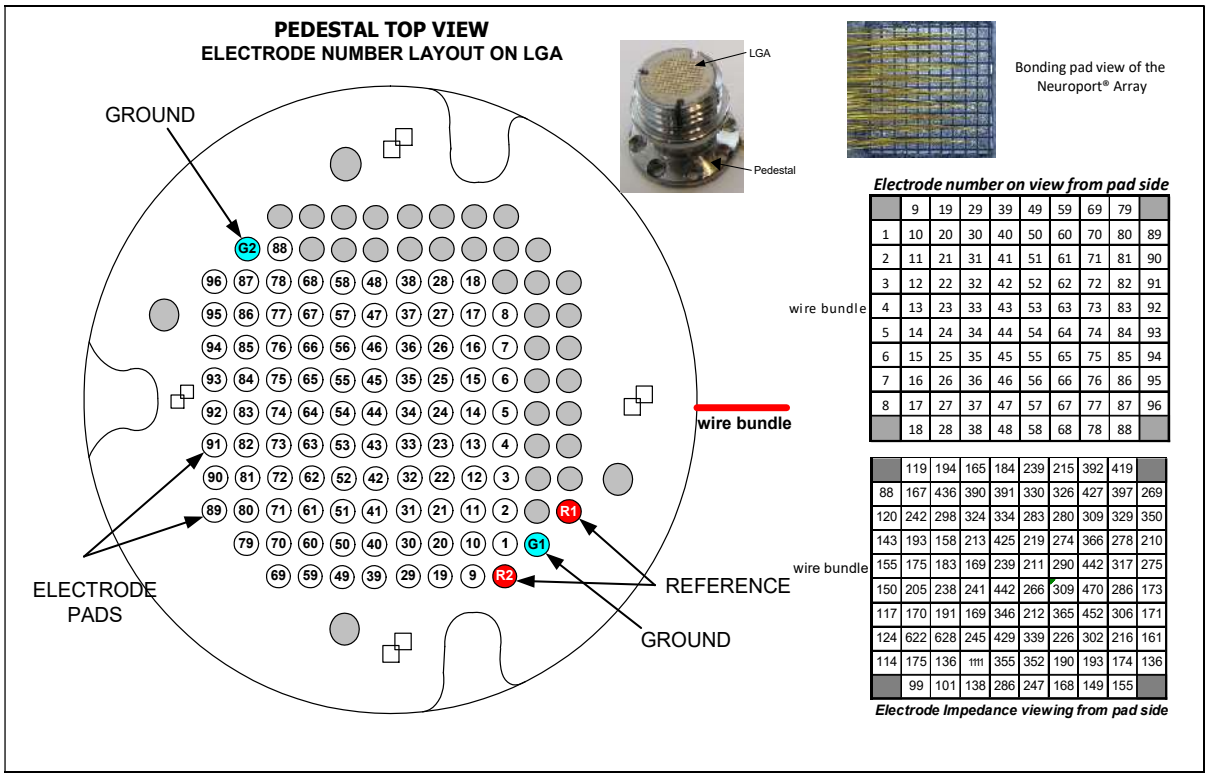


Figure 13–Example Electrode Layout in Datasheet

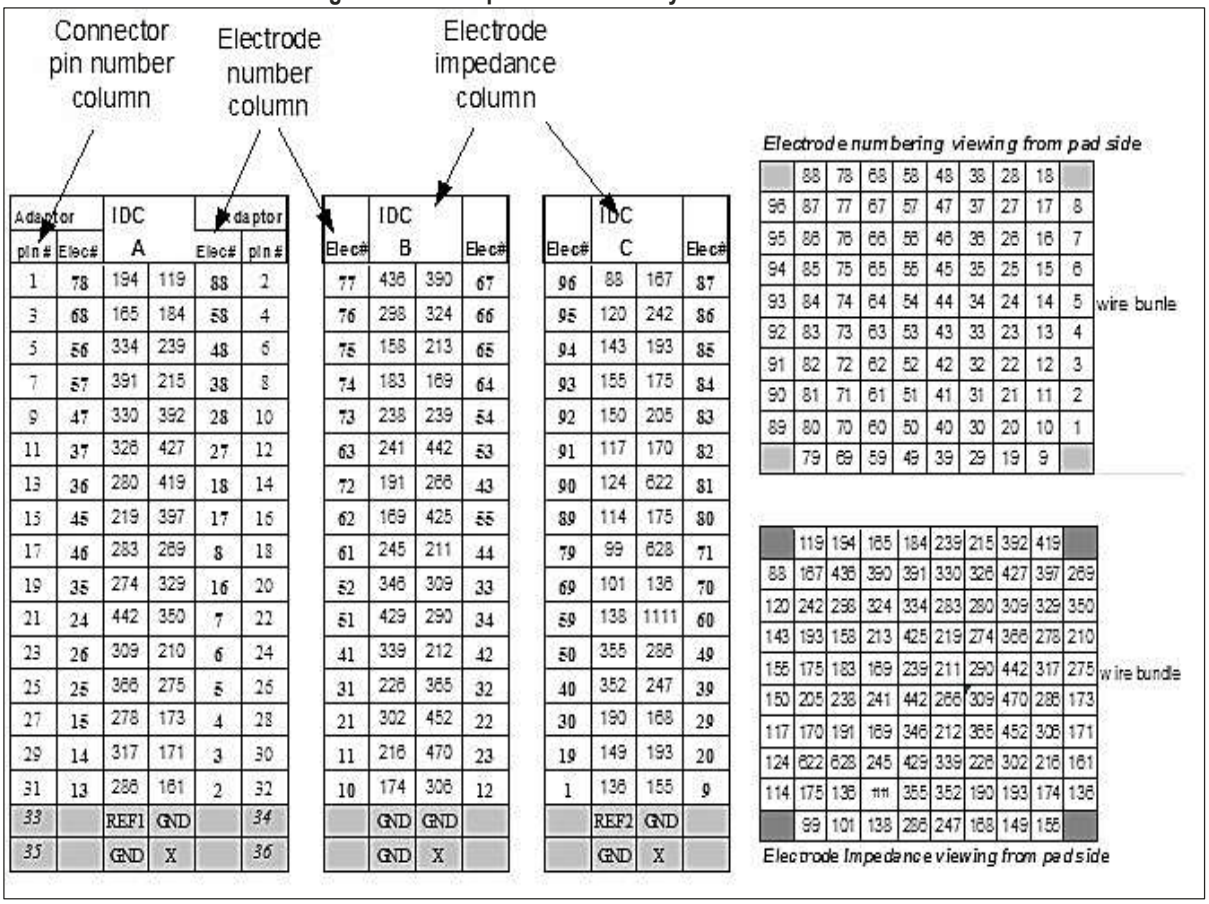


Figure 14–Electrode numbers in datasheet

Maintenance

The NeuroPort Electrode is shipped ethylene oxide (EtO) sterilized and is designated as single use. The NeuroPort Electrode contains no serviceable parts and requires no regular maintenance either before or after implantation.

Disposal

The NeuroPort Electrode is an implantable electrode for cerebral cortex. Follow institutional procedures for disposing potentially infectious or biohazardous implantable devices when disposing the NeuroPort Electrode.

Magnetic Resonance

The NeuroPort Electrode has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The NeuroPort Electrode has not been tested for heating, migration, nor image artifact in the MR environment.

Troubleshooting

Problem	Symptom	Failure	Potential fix
Bad impedance reading	Impedance reading will not occur or has bad values.	The most likely cause is that the electrodes, ground, or reference wires are not making good contact with saline.	Check to make sure that the reference wires are in contact with the saline. If the components all appear to be making good contact with the saline, visually inspect the electrode for damage. If no damage can be seen, contact Blackrock support
No signal	No neural signal is detected	Sometimes implantation can cause fluid ingress that can prevent detection of neural signal for a short time.	Wait 24 hours; if signal is still not detected, contact Blackrock support

Return Merchandise Authorization

In the event of a returned material authorization (RMA) or complaint, please provide the product description, product number, lot number, person requesting the RMA or complaint and address, and the nature of the RMA and complaint.

In the unlikely event that your device needs to be returned to Blackrock for repair or maintenance, do not send any equipment back without a Return Merchandise Authorization Number (RMA). An RMA number will be issued to you by a Blackrock representative. If you need to obtain an RMA number, you may contact a product support representative at +1 (801) 582-5533 or by emailing support@blackrockneuro.com.

Once an RMA number has been issued, it is important to safely pack the returned item for shipping back to Blackrock. It is preferred that you save the original boxes and packing materials that your system arrived in for return shipment. Please address the package as follows:

Blackrock Neurotech, LLC
ATTN: RMA#
630 S. Komas Dr., Suite 200
Salt Lake City, UT 84108 USA
Tel: +1 (801) 582-5533

Warranty

Blackrock Microsystems (“Blackrock”) warrants its products are free from defects in materials and manufacturing for a period of one year from the date of shipment. At its option, Blackrock will repair or replace any product that does not comply with this warranty. This warranty is voided by: (1) any modification or attempted modification to the product done by anyone other than an authorized Blackrock employee; (2) any abuse, negligent handling or misapplication of the product; or (3) any sale or other transfer of the product by the original purchaser.

Except for the warranty set forth in the preceding paragraph, Blackrock provides no warranties of any kind, either express or implied, by fact or law, and hereby disclaims all other warranties, including without limitation the implied warranties of merchantability, fitness for a particular purpose, and non-infringement of third-party patent or other intellectual property rights.

Blackrock shall not be liable for special, indirect, incidental, punitive, force majeure or consequential damages (including without limitation, damages resulting from loss of use, loss of profits, interruption or loss of business or other economic loss) arising out of non-compliance with any warranty. Blackrock’s entire liability shall be limited to providing the remedy set forth in the previous paragraph.

Support

Blackrock prides itself in its customer support. For additional information on this product or any of our products, you can contact our Support team through the contact information below:

Manuals, Software Downloads, and Application Notes
https://blackrockneurotech.com/research/support/

Complaints

When filing a complaint, please provide the product description, product number, software version, lot number, complainant’s name and address, and the nature of the complaint.

Issues or Questions
http://www.blackrockneurotech.com/
support@blackrockneuro.com
U.S.: +1 (801) 582-5533

Notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

CAUTION

Federal law (United States) restricts this device to sale by or on the order of a physician.