

# NeuroPort Array

*PN 4382, 4383, 6248,  
and 6249*

*Instructions for Use*



# Table of Contents

Table of Contents .....	2
Warnings and Cautions.....	3
Contraindications .....	3
Warnings.....	3
Cautions.....	3
What This Manual Covers.....	5
Intended Use and Indications for Use .....	5
Specifications.....	5
Overview of the Device .....	7
Unpackaging the Device .....	7
Testing Impedance .....	9
Impedance with PN 4109 (Single Thumb Screw).....	9
Impedance with PN 8536 (Two Thumb Screws) .....	11
Cleaning Assembly Holder Following Impedance Reading.....	11
Removing the Assembly from the Assembly Holder .....	12
Removing from PN 4109 (Single Thumb Screw) .....	12
Removing from PN 8356 (Two Thumb Screws) .....	12
Using the Pedestal Cap with the NeuroPort Array .....	13
Interpreting the Datasheet Sent with Your Array.....	13
Cleaning and Maintenance .....	15
Cleaning.....	15
Maintenance.....	16
Disposal .....	16
Magnetic Resonance .....	16
Troubleshooting .....	16
Warranty .....	17
Support.....	17
Complaints.....	17

# Warnings and Cautions

## *Contraindications*

- The NeuroPort Array should not be used on any patient whom the physician/surgeon considers at elevated risk of infection.
- The NeuroPort Array is a recording device and should not be used in applications involving stimulation.
- The NeuroPort Array 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 Array 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 Array has been implanted, the patient should not be exposed to electrocautery, therapeutic ultrasound or diathermy.
- Once the NeuroPort Array has been implanted, peripheral nerve stimulation should not be used.
- The Patient Cable End Cover should be applied while the patient cable is disconnected from the amplifier.
- While the Patient Cable is disconnected from the amplifier, care should be taken to prevent excess force on the cable.
- The patient should not attempt to detach themselves from the recording system on their own.
- The cables between the recording system and the NeuroPort Array should not be bundled with or run parallel to other cables.
- The NeuroPort Biopotential Signal Processing System should be disconnected from the NeuroPort Array during cardiac defibrillation.
- Always touch the patient's skin before touching the electrode contacts during cleaning. Failure to do so will 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 Array when the recording system is not attached, otherwise the patient will be subject to an increased risk of electrical shock being delivered through the electrodes.

## *Cautions*

- The NeuroPort Array is intended for use only with the NeuroPort System. Refer to the NeuroPort System User Manual with regard to use of the NeuroPort Array with the NeuroPort System.
- Do not use the NeuroPort Array 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 overtighten the Pedestal Cap, otherwise the cap may be more difficult to remove or cause the cap to more easily detach from the NeuroPort Array.

# What This Manual Covers

This manual is intended as an informational tool for use of the Blackrock NeuroPort Array. 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 Array prior to attempting surgery. While this manual provides a detailed description of the electrode array, 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 Array 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 NeuroPort Array's intended use is sensing neural signal from the cerebral cortex. It is designed for short term implantations of less than 30 days. It is capable of detecting single-neuron and multi-neuron signals as well as local field potentials. It is designed to be inserted with the Blackrock NeuroPort Electrode Array Inserter. Instructions for that device are covered in the Blackrock Surgical Training manual and the Instructions for Use for the NeuroPort Electrode Array Inserter.

## Specifications

The NeuroPort Array 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
<b>Electrode Length</b>	1.0 mm	1.5 mm	1.0 mm	1.5 mm
<b>Number of Electrodes</b>	100 (96 connected to percutaneous connector)			
<b>Impedance Range</b>	100 – 800 kOhms	100 – 800 kOhms	1 – 80 kOhms	1 – 80 kOhms
<b>Wire Bundle Length</b>	13 cm	13 cm	13 cm	13 cm
<b>Metallization Type</b>	Platinum	Platinum	Iridium Oxide (SIROF/IrOx)	Iridium Oxide (SIROF/IrOx)
<b>Connector Type</b>	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal	Blackrock NeuroPort Pedestal
<b>Patient Contact Materials</b>	Titanium NuSil MED-2174 Parylene C			

Platinum

Platinum

Platinum  
Iridium Oxide

Platinum  
Iridium Oxide

# Overview of the Device

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



*Figure 1 - NeuroPort Array Removed from Sterile Packaging*

The NeuroPort Array 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. The device also does not ship with the Pedestal Cap with Viton O-Ring (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 Array is shipped in a sterilization holder inside of a sterile pouch inside of a chipboard box. The device should not be removed from the sterile pouch unless it is intended to be used immediately.

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

1. Open one end of the box and remove the pouch package.
2. Verify the serial number on the box and the assembly package inside the pouch (Figure 2).



*Figure 2 - Box and pouch package.*

3. Open the sealed pouch, and remove the wrapped assembly from the pouch (Figure 3).



*Figure 3 - Wrapped assembly.*

4. Pull the tape by the end to remove the first sterilization wrap (Figures 4 and 5).



*Figure 4 - Grasp tape end and pull.*



*Figure 5 - Remove first sterilization wrap.*

5. Grasp the second piece of tape by the end and pull up again to open the second wrap and remove the sterilization holder (figure 6).



Figure 6 - Remove second sterilization wrap.

6. Note: There are two different designs of the assembly holder (Figure 7).



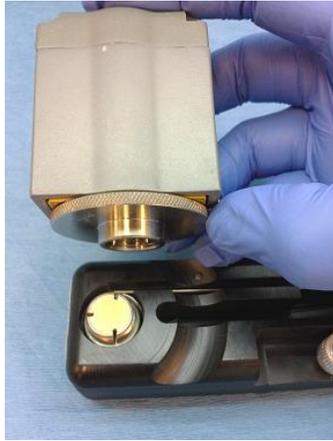
Figure 7 - Assembly holder PN 4109 and Assembly Holder PN 8536

## 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 different between the two assembly holder models.

### *Impedance with PN 4109 (Single Thumb Screw)*

In this model, the impedance testing device should access the connector directly without any disassembly of the assembly holder required. This means that this assembly holder may only work with certain models of Blackrock headstages and cables (Figure 8).



*Figure 8 - Matching the Blackrock Patient Cable to the pedestal.*

The holder should be placed in 37 C saline with a pH of 7.0-7.2 (Figure 9). Let the electrodes sit in the saline for about 5 minutes before taking the impedance reading.



*Figure 9 - Assembly holder in saline.*

## *Impedance with PN 8536 (Two Thumb Screws)*

In this model, an 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 10 - Remove the pedestal end cap.*

With the end cap removed, one can now attach an impedance testing device, such as the Blackrock Patient Cable, 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 11). Let the electrodes sit in the saline for about 5 minutes before taking the impedance reading.



*Figure 11 - Assembly holder in saline.*

## *Cleaning Assembly Holder Following Impedance Reading*

When finished with the impedance reading, the assembly and the assembly holder should be rinsed with distilled water.

# Removing the Assembly from the Assembly Holder

To remove the assembly from the sterilization holder in preparation for implantation, follow the directions below. These instructions are different for each of the two assembly holder models.

## *Removing from PN 4109 (Single Thumb Screw)*

Unscrew the single thumb screw to allow the top portion of the assembly holder to be removed. After the top plate is removed, the assembly can be carefully removed from the bottom half of the assembly holder (Figure 12).



*Figure 12 -PN 4109 Assembly holder disassembled.*

## *Removing from PN 8356 (Two Thumb Screws)*

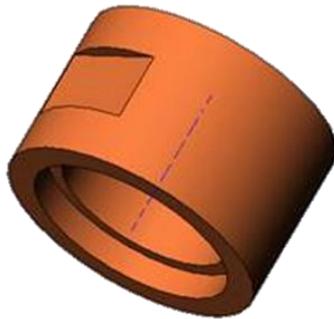
The pedestal end cap of the assembly holder should be removed during the impedance reading step. If the end cap has not been removed or was restored, remove the pedestal end cap first. After removing the pedestal end cap, unscrew the top center thumb screw to remove the top plate. With the top plate removed, the assembly can now be carefully removed (Figure 13).



*Figure 13 - PN 8356 Assembly holder disassembled.*

# Using the Pedestal Cap with the NeuroPort Array

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



*Figure 14 - Pedestal Cap (shown without included 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 Array

Blackrock provides data sheets with every NeuroPort Array. 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 Array mappings may differ from this example.

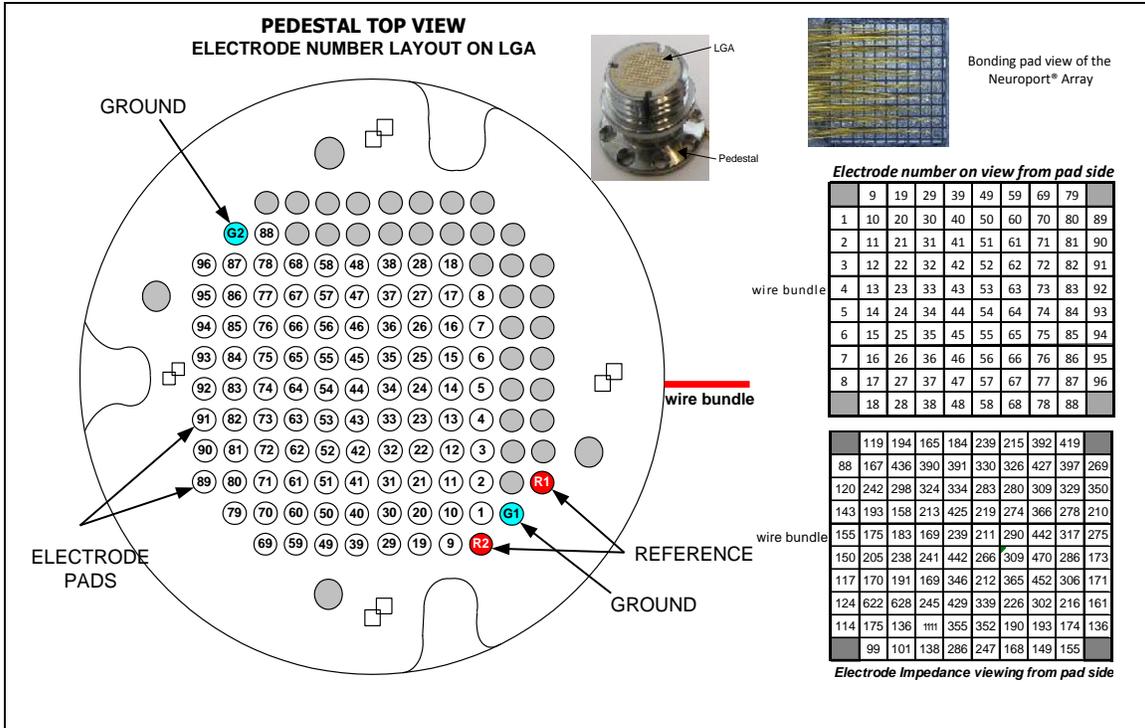


Figure 15 – Example Electrode Layout in Datasheet

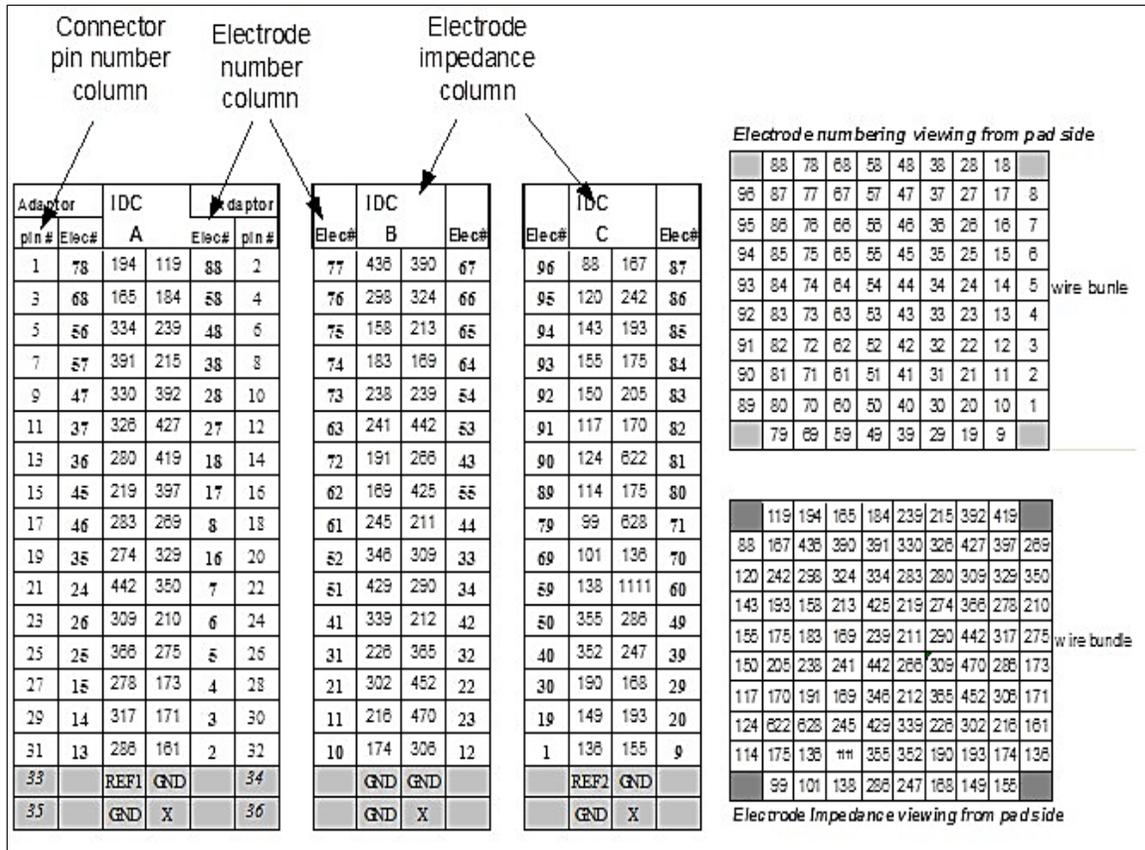


Figure 16 - Electrode numbers in datasheet

# Cleaning and Maintenance

## Cleaning

The NeuroPort Array is shipped ethylene oxide (EtO) sterilized and is designated as single use, so no cleaning or reprocessing should occur. That said, after implantation, it is possible that one would need to clean the pedestal surface. This requires no disassembly, but will require removal of the NeuroPort Pedestal Cap accessory. The procedure below has been validated to show no detrimental effect on the pedestal, but these steps cannot guarantee removal of any contaminants. Choose from the following options when cleaning the pedestal:

- Clean the pedestal using distilled water and a foam-tipped applicator.
  - Start on the LGA surface and scrub lightly for about five seconds using a foam tipped applicator dipped in water
  - Scrub the threads and guide pin slots for about 5 seconds with the same applicator.
  - Repeat twice more with a new foam tipped applicator each time.
  - Finish by drying with a new, fourth applicator and letting the pedestal air dry for a minimum of 5 minutes before use.
- Follow the above procedure, but use isopropyl alcohol (70%) instead of distilled water.
- Follow the first procedure, but use 3% hydrogen peroxide instead of distilled water.

## *Maintenance*

The NeuroPort Array contains no serviceable parts and requires no regular maintenance either before or after implantation.

### **Disposal**

The NeuroPort Array is an implantable electrode for the cerebral cortex. One should follow institutional procedures for discarding potentially infectious implanted devices when discarding the NeuroPort Array.

## **Magnetic Resonance**

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

## **Troubleshooting**

*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 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.

# 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

[www.blackrockmicro.com](http://www.blackrockmicro.com)

## Issues or Questions

[www.blackrockmicro.com/  
support@blackrockmicro.com](http://www.blackrockmicro.com/support@blackrockmicro.com)

U.S. - +1.801.839.1062

U.S. - +1.801.582.5533

Europe - +49 (0)511.132.211.10

## *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.

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 restricts this device to sale by or on the order of a physician.