

Qualia Labs

A QUALIA Company

Peripheral Nerve Cuffs 2, 4, 5, 10, 12+ channels User Guide

www.qualia-labs.com

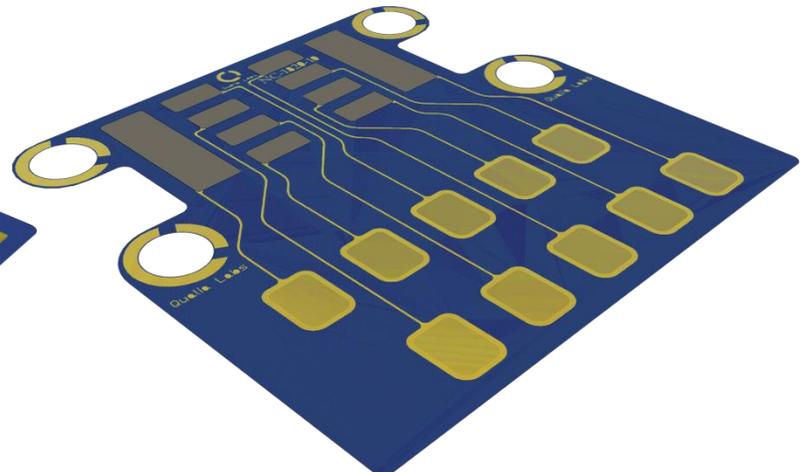
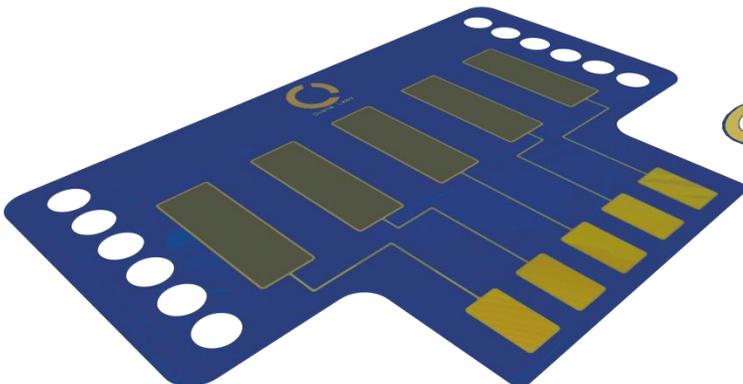
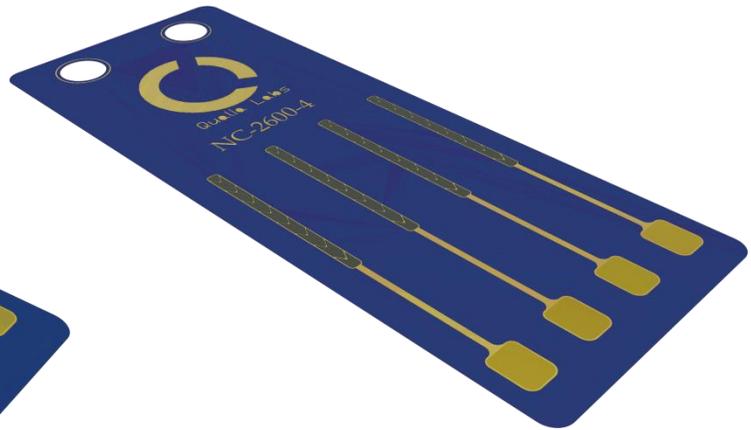
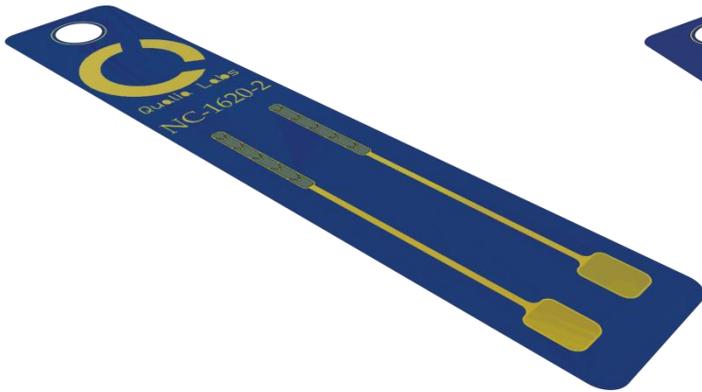




Table of Contents

<i>Introduction</i>	3
<i>Pre-Testing</i>	3
<i>Device Handling</i>	4
<i>Sterilization</i>	4
<i>Implantation</i>	5
<i>Additional Resources</i>	7
<i>Return Policy</i>	7
<i>Contact Information</i>	7



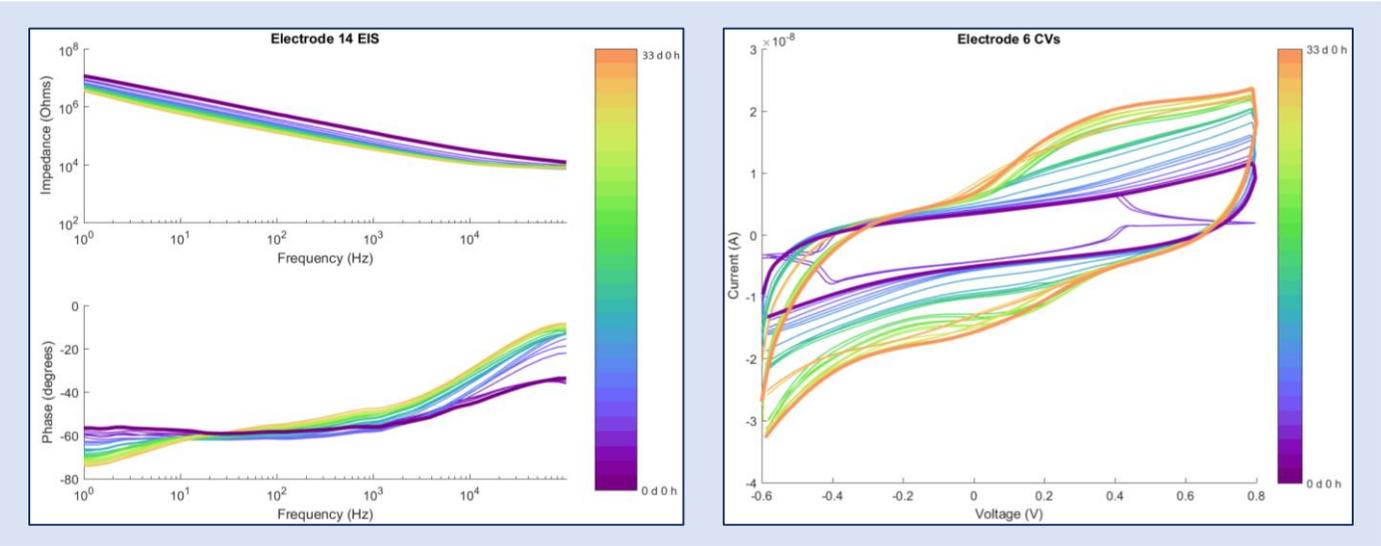
Introduction

Our peripheral nerve cuffs are fabricated on thiol-ene/acrylate shape memory polymer (SMP) substrates that are stiff at room temperature for surgical manipulation and insertion but decrease in elastic modulus by orders of magnitude at body temperature. This limits the foreign body response by significantly reducing the mechanical mismatch between the implant and surrounding tissue. This also allows the cuff to conform more closely to the nerve, increasing the efficacy of signal recording or stimulation.



Pre-Testing

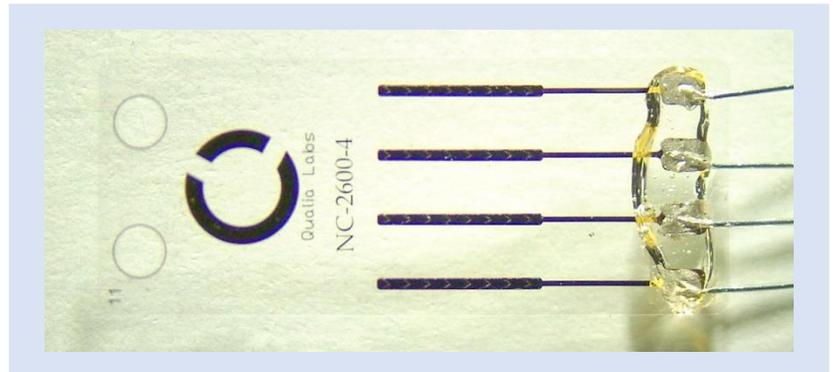
The impedance of a device from each batch is electrochemically evaluated to ensure device functionality and proper electrical characteristics. Electrical impedance spectroscopy is run at multiple frequencies in the 10 Hz to 100 kHz range for each device in addition to cyclic voltammetry testing. Accelerated aging tests are performed on select devices from each production wafer to ensure proper quality control.





Device Handling

The Qualia Labs nerve cuff consists of a flat, flexible panel of SMP with multiple electrodes placed on one side of the device. The nerve cuff device is individually packaged in a plastic box and held in place with soft foam. Although the shape memory polymer (SMP) substrate is not brittle like silicon-based devices, it can still be damaged by rough handling, primarily through tearing. Care must be taken not to sharply bend or pull on the device at any time.



Sterilization

Qualia Labs recommends that ethylene oxide (EtO) gas sterilization be used with our nerve cuffs. Autoclave and UV sterilization will decrease the softening capabilities of the device and should not be used¹. Devices can be sterilized within their boxes with the lid closed to limit direct air flow.

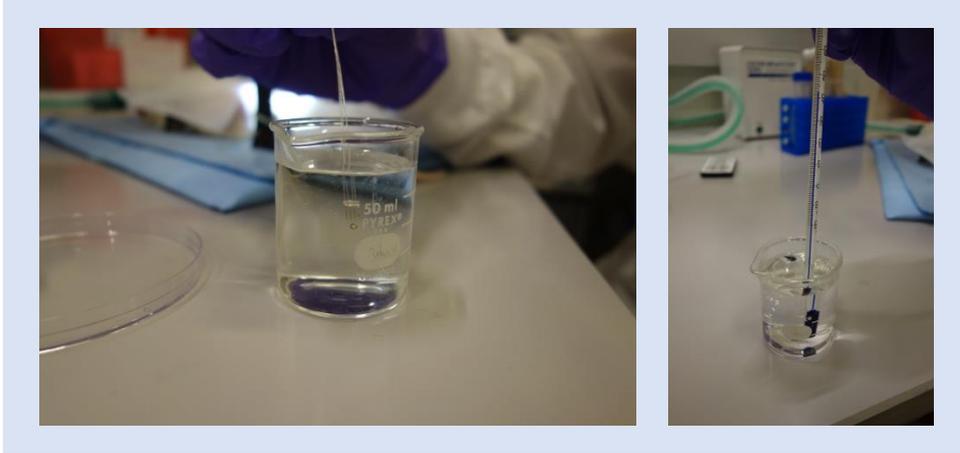
The sterilization cycle should last at least 24 hours, followed by outgassing for at least 72 hours at 37°C in a vacuum oven. Qualia is not responsible for device damage due to sterilization using other methods or procedures. Upon request, cuffs can also be shipped pre-sterilized and degassed.



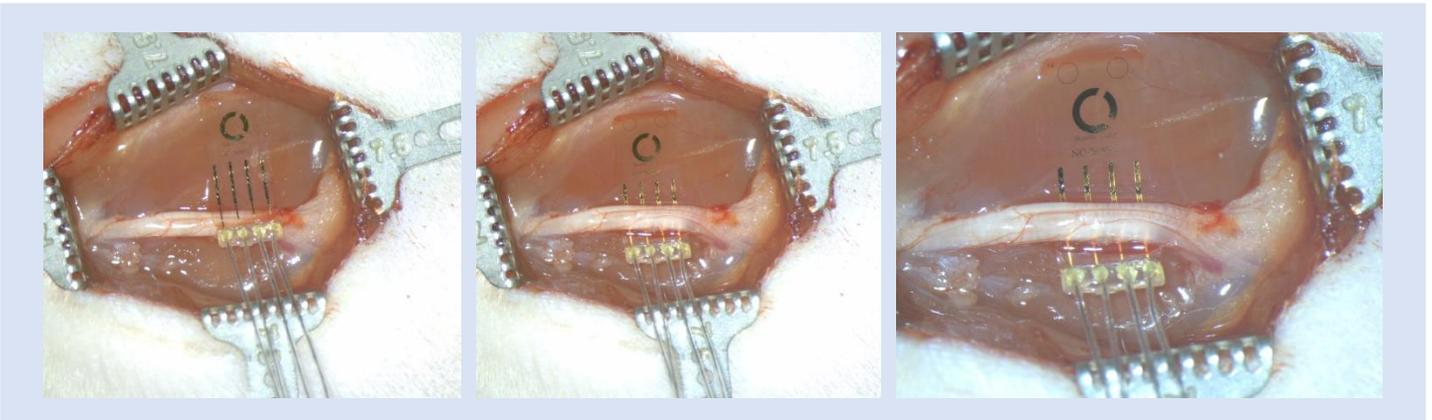


Implantation

- Soften the device in saline solution at 45-50°C.



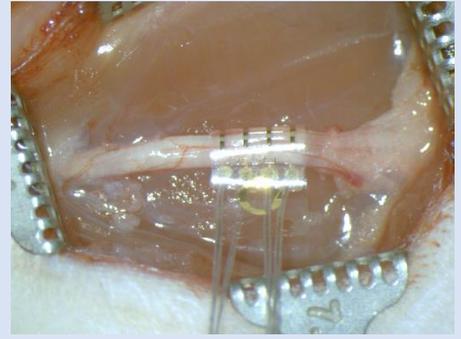
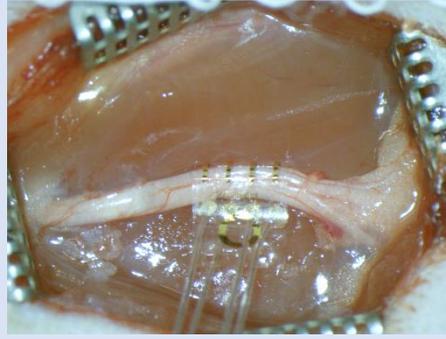
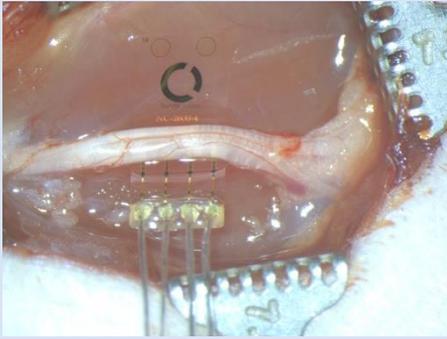
- Optional tip:
 - Gently wrap the device around a curvature (e.g. a glass rod) similar in size to that of the nerve and press each end of the device together.
 - Hold the two ends of the device together in this curved state outside of saline for at least 30 seconds to lock the shape. The device is now ready for implantation.
- Carefully slip the device under the nerve, ensuring that the side of the device with the Qualia logo and device name is the side contacting the nerve.



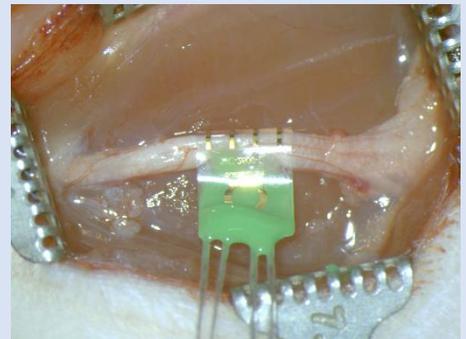
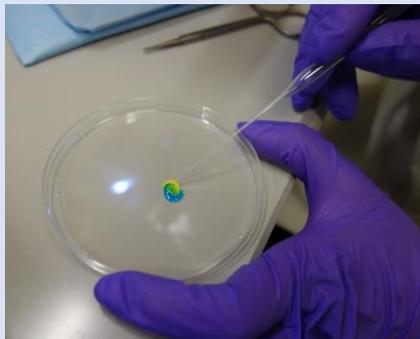


Implantation (continued)

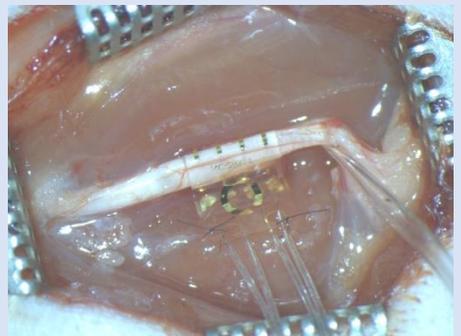
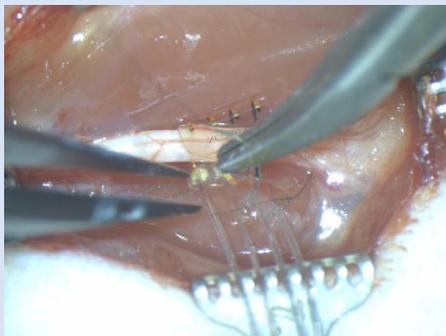
- Bring each end of the device together and hold.



- Dry the device of any biological fluid using a sponge.
- While holding the two ends of the device together, apply a drop of Kwik-Cast. Hold the ends together for at least 30 seconds while the Kwik-Cast sets.



- To limit device migration, there are two suture holes on the device that can be used to anchor the device to surrounding tissue or used to hold the device against the nerve.





Additional Resources

1. M. Ecker et al. Macromol. Mater. Eng. 2017, 302, 1600331.

Return Policy

Upon arrival, please inspect device packaging. If devices appear to have been damaged in shipment, please email us at sales@qualiamedical.com within 7 days of receipt to request a replacement.

All sales are final, no exceptions. Unused items may be exchanged with permission from Qualia Labs within 30 days of delivery. Custom-designed orders may not be exchanged.

If you have any other concerns regarding your order, please feel free to reach out to us at sales@qualiamedical.com.

Contact Information

Qualia Labs, Inc.
17217 Waterview Parkway, Suite 1.202
Dallas, TX 75252
Phone: (972) 861-2420
Email: sales@qualiamedical.com